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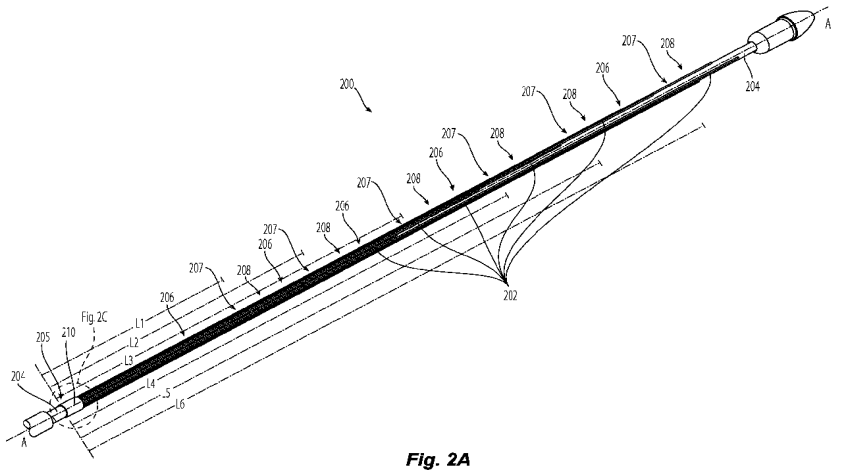

Fig. 2A

(57) **Abstract**: A device and method for intravascular treatment of an embolism is disclosed herein. One aspect of the present technology, for example, is directed toward a clot treatment device that includes a support member configured to extend through a delivery catheter and a plurality of clot engagement members positioned about the circumference of a distal portion of the support member. The clot engagement members can be configured to penetrate clot material along an arcuate path and mechanically macerate clot and release embolic particles when re-sheathed into the delivery catheter.

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METHODS AND APPARATUS FOR TREATING PULMONARY EMBOLISM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of U.S. Provisional Patent Application No. 61/845,796, filed July 12, 2013, entitled "DEVICES AND METHODS FOR TREATING OF VASCULAR OCCLUSION", U.S. Provisional Patent Application No. 61/864,356, filed August 9, 2013, entitled "DEVICES AND METHODS FOR TREATING OF VASCULAR OCCLUSION", U.S. Provisional Patent Application No. 61/949,953 filed March 7, 2014, entitled "METHODS AND APPARATUS FOR TREATING EMBOLISM," and U.S. Patent Application No. 14/299,933, filed June 9, 2014, entitled "METHODS AND APPARATUS FOR TREATING PULMONARY EMBOLISM", all of which are incorporated herein by reference in their entireties.

TECHNICAL FIELD

[0002] The present technology relates generally to devices and methods for intravascular treatment of emboli within a blood vessel of a human patient. Many embodiments of the technology relate to the intravascular treatment of a pulmonary embolism.

BACKGROUND

[0003] Thromboembolism occurs when a thrombus or blood clot trapped within a blood vessel breaks loose and travels through the blood stream to another location in the circulatory system, resulting in a clot or obstruction at the new location. As shown schematically in Figure 1, when a clot C forms in the venous circulation V, it often travels to the lungs L via the heart H and lodges within a pulmonary blood vessel PV causing a pulmonary embolism PE. A pulmonary embolism PE can decrease blood flow through the lungs L, which in turn causes decreased oxygenation of the lungs L, heart H and rest of the body. Moreover, pulmonary embolisms can cause the right ventricle RV of the heart H to pump harder to provide sufficient blood to the pulmonary blood vessels PV, which can cause right ventricle RV dysfunction (dilation), and heart failure in more extreme cases.

[0004] Conventional approaches to treating thromboembolism and/or pulmonary embolism include clot reduction and/or removal. For example, anticoagulants can be introduced to the affected vessel to prevent additional clots from forming, and thrombolytics can be introduced to the vessel to at least partially disintegrate the clot. However, such agents typically take a prolonged period of time (e.g., hours, days, etc.) before the treatment is effective and in some instances can cause hemorrhaging. Transcatheter clot removal devices also exist, however, such devices are typically highly complex, prone to cause trauma to the vessel, hard to navigate to the pulmonary embolism site, and/or expensive to manufacture. Conventional approaches also include surgical techniques that involve opening the chest cavity and dissecting the pulmonary vessel. Such surgical procedures, however, come with increased cost, procedure time, risk of infection, higher morbidity, higher mortality, and recovery time. Accordingly, there is a need for devices and methods that address one or more of these deficiencies.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] 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.

[0006] Figure 1 is a schematic illustration of an embolism traveling through the heart and forming an embolism in a pulmonary vessel.

[0007] Figure 2A is a perspective view of one embodiment of a clot treatment device in a collapsed or delivery state configured in accordance with an embodiment of the present technology.

[0008] Figure 2B is a perspective view of the clot treatment device of Figure 2A in a deployed state configured in accordance with an embodiment of the present technology.

[0009] Figure 2C is an enlarged view of a portion the clot treatment device shown in Figure 2A.

[0010] Figure 2D is an axial-perspective view of a portion of the clot treatment device shown in Figure 2A.

[0011] Figures 3A-3C are isolated, enlarged side views of clot engagement members in a deployed state configured in accordance with embodiments of the present technology.

[0012] Figure 4A is a perspective view of another embodiment of a clot treatment device in a collapsed or delivery state configured in accordance with an embodiment of the present technology.

[0013] Figure 4B is a perspective view of the clot treatment device of Figure 4A in a deployed state configured in accordance with an embodiment of the present technology.

[0014] Figure 5 is a perspective view of a clot treatment device configured in accordance with another embodiment of the present technology.

[0015] Figure 6 is a perspective view of a clot treatment device configured in accordance with another embodiment of the present technology.

[0016] Figure 7A is a perspective view of a clot treatment device configured in accordance with another embodiment of the present technology.

[0017] Figure 7B is a cross-sectional end view taken along line 7B-7B in Figure 7A.

[0018] Figure 8 is a perspective view of a clot treatment device configured in accordance with another embodiment of the present technology.

[0019] Figure 9A is a perspective view of a clot treatment device configured in accordance with another embodiment of the present technology.

[0020] Figure 9B is a cross-sectional end view of a portion of the clot treatment device shown in Figure 9A.

[0021] Figure 9C is a side view of a binding member configured in accordance with the present technology.

[0022] Figure 10 is a side partial cross-sectional view of a delivery system configured in accordance an embodiment of the present technology.

[0023] Figures 11A-11K illustrate a method for using a clot treatment device configured in accordance with the present technology to remove clot material from a vessel.

[0024] Figure 12 is a cross-sectional view of a preferred embodiment of a clot treatment device in accordance with the present invention in a compressed, undeployed state;

[0025] Figure 13 is a top view of a preferred embodiment of a clot treatment device in accordance with the present invention;

[0026] Figures 14A-14F are a series of cross-sectional views of a preferred embodiment of the method and device of the present invention;

[0027] Figures 15A-15B are a series of cross-sectional views of a preferred embodiment of the method and device of the present invention;

[0028] Figure 16 is a cross-sectional view of another preferred embodiment of the method and device of the present invention; and,

[0029] Figures 17A-17H show cross-sectional views of preferred embodiments of a clot treatment device in accordance with the present invention.

[0030] Figure 18 is a cross-sectional view of a clot treatment device in accordance with another embodiment of the present technology.

[0031] Figures 19 and 20 are detailed cross-sectional views of a distal portion and a proximal portion, respectively, of an expandable member of a clot treatment device in accordance with an embodiment of the present technology.

[0032] Figures 21 and 22 are detailed cross-sectional views of a proximal portion and a distal portion, respectively, of an expandable member of a clot treatment device in accordance with another embodiment of the technology.

[0033] Figures 23-26 are side views of guide members for use with clot treatment devices and methods in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0034] Specific details of several embodiments of clot treatment devices, systems and associated methods in accordance with the present technology are described below with reference to Figures 2A-26. 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. Additionally, several other embodiments of the technology can have different 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 2A-26 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 2A-26 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 2A-26.

[0035] 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 clot treatment device and/or an associated delivery device with reference to an operator and/or a location in the vasculature.

I. Selected Embodiments of Clot Treatment Devices

[0036] Figure 2A is a perspective view of one embodiment of a clot treatment device 200 ("the device 200") in a low-profile or delivery state, and Figure 2B is a perspective view of the device 200 in an unrestricted expanded or deployed state that is well suited for removing clot material from a blood vessel (e.g., a pulmonary blood vessel). Referring to Figures 2A and 2B together, the device 200 can include a support member 204 and a plurality of clot engagement members 202 positioned about the circumference of the support member 204. As best shown in Figure 2B, the individual clot engagement members 202 can include a first portion 206 having a proximal region 205 and a distal region 207, and a second portion 208 extending from the distal region 207 of the first portion 206. In the delivery state, as shown in Figure 2A, the clot

engagement members 202 can be generally linear and extend generally parallel to the support member 204. In the expanded state, as shown in Figure 2B, the second portions 208 can project radially outwardly relative to the support member 204 in a curved shape. The second portions 208 can have a proximally facing section 212 which defines a proximally facing concave portion, and, in some embodiments, the second portions 208 can further include an end section 214 that curves radially inwardly from the proximally facing section 212. When deployed within a blood vessel adjacent to clot material, the clot engagement members 202 are configured to penetrate the clot material along an arcuate path and hold clot material to the device 200, as discussed in greater detail below with reference to Figures 10-11K.

[0037] Figure 2C is an enlarged view of a portion of the device 200 of Figure 2A showing that the device 200 can include a hub 210 that couples the proximal regions 205 of the first portions 206 to the support member 204. The first portions 206 can extend distally from their proximal regions 205 in a longitudinal direction along the length of the support member 204 to their distal regions 207, and the distal regions 207 can be free to move relative to the support member 204. As such, the first portions 206 can be cantilevered portions of the clot engagement members 202 that enable the clot engagement members 202 to flex and move independently of the support member 204 in response to forces present within the blood vessel, such as blood flow, gravity, and/or the local anatomy. The first portions 206 can be sufficiently rigid to maintain a generally linear shape along their respective lengths, yet flexible enough to bend and/or flex about the hub 210. For example, in some instances, in response to local forces, one or more of the distal regions 207 of the first portions 206 can be spaced radially apart from the support member 204 such that one or more first portions 206 forms an angle with the support member 204.

[0038] Referring back to Figures 2A and 2B, the first portions 206 of different clot engagement members 202 can have different lengths such that the second portions 208 of at least two clot engagement members extend radially outwardly at different locations along the length of the support member 204. For example, as best shown in Figure 2B, the clot treatment device 200 can include a first group 202a of clot engagement members 202 having first portions 206 with a first length L1, a second group 202b of clot engagement members 202 having first portions 206 with a second length L2 greater than the first length L1, a third group of clot engagement members 202c having first portions 206 with a third length L3 greater than the second length L2,

a fourth group of clot engagement members 202d having first portions 206 with a fourth length L4 greater than the third length L3, a fifth group of clot engagement members 202e having first portions 206 with a fifth length L5 greater than the fourth length L4, and a sixth group of clot engagement members 202f having first portions 206 with a sixth length L6 greater than the fifth length L5. It will be appreciated that although six groups of clot engagement members are shown in Figures 2A and 2B, in other embodiments the clot treatment device can have more or fewer than six groups (e.g., one group, two groups, three groups, seven groups, ten groups, etc.) and/or the lengths of all or some of the first portions 206 can be the same or different.

[0039] Moreover, the second portions 208 of the first group 202a of clot engagement members 202 extend radially outward at a first area of the support member 204, the second portions 208 of the second group 202b of the clot engagement members 202 extend radially outward from a second area of the support member 204, the second portions 208 of the third group 202c of clot engagement members 202 extend radially outward from a third area of the support member 204, the second portions 208 of the fourth group 202d of clot engagement members 202 extend radially outward from a fourth area of the support member 204, the second portions 208 of the fifth group 202e of clot engagement members 202 extend radially outward from a fifth area of the support member 204, and the second portions 208 of the sixth group 202f of clot engagement members 202 extend radially outward from a sixth area of the support member 204. It will be appreciated that although six areas of clot engagement members are shown in Figures 2A and 2B, in other embodiments the clot treatment device can have more or fewer than six areas (e.g., one area, two areas, three areas, five areas, nine areas, etc.).

[0040] Figure 2D is an enlarged, axial-perspective view of a portion of the device 200 in which the groups of clot engagement members 202a-f (only the first, second and third groups 202a-c shown) are arranged about the circumference of the support member 204 such that the second portions (labeled 208a-c) of adjacent groups 202a-c are circumferentially offset from one another. As such, in the embodiment shown in Figure 2D, the second portions 208 of adjacent groups of clot engagement members 202a-f are not circumferentially aligned, and thus can engage the clot material at different circumferential positions along the length of the clot material.

[0041] Figure 3A is a side view of a clot engagement member 202 in the expanded state. Individual clot engagement members can be made from a shape memory material such that, when unconstrained, assume a preformed curved shape. As shown in Figure 3A, the second portion 208 can have an arcuate shape that includes an outwardly extending section 216, the proximally facing section 212 extending from the outwardly extending section 216, and the end section 214 extending from the proximally facing section 212. In one embodiment, the demarcation between the proximally facing section 212 and the end section 214 occurs at an apex 218 of the second portion 208. The proximally facing section 212 is configured to retain clot material with the clot engagement member 202 as the device 200 is pulled proximally through the vessel (arrow P), and the apex 218 provides a smooth curve that can atraumatically slide along the vessel wall as the device 200 is pulled proximally through the vessel. In the embodiment shown in Figure 3A, the second portion 208 of the clot treatment device 200 can have a single or constant radius of curvature R_1. In other embodiments, such as the clot engagement member 402 shown in Figure 3B, the second portions 208 can have a plurality of radii of curvature, such as a first region with a first radius of curvature R_1 and a second region with a second radius of curvature R_2. In the embodiment shown in Figures 2A-2D, the second portions 208 of the clot engagement members 202 have a single radius of curvature that is the same for all of the clot engagement members 202. In other embodiments, the device 200 can have a first group of second portions with a constant radius of curvature and a second group of second portions with a plurality of radii of curvature. Moreover, in additional embodiments the device 200 can include a first group of second portions having a first radius of curvature and a second group of second portions having a second radius of curvature different than the first radius of curvature. In some embodiments, the radius R_1 of the clot engagement members 202 can be between about 1.5 mm and about 12 mm, and in some embodiments, between about 2 mm and about 12 mm.

[0042] As shown in Figure 3C, the arc length a of the clot engagement members 202 may be substantially greater than 180 degrees to provide several benefits in performance of clot engagement and retrieval. In particular, a greater arc length a can provide improved clot engagement during retraction when resistance due to clot friction and interference with the vessel wall deflects the clot engagement member 202 distally (arrow D). A greater arc length a may provide more deflection and/or unravelling or straightening of the arcuate shape without loss of engagement with the clot. In some embodiments, the arc length a of the clot engagement

members 202 can be greater than about 200 degrees. In some embodiments the arc length a of the clot engagement members 202 may be between about 200 degrees and 340 degrees and between about 240 degrees and 300 degrees in other embodiments. It can be advantageous to keep the arc length a under about 360 degrees so as to avoid overlap of the clot engagement member 202. Greater arc length a can allow for the use of smaller clot engagement member filaments or wires that may be particularly beneficial for minimization of the collapsed profile of the device. Greater arc length a can also allow for a larger total number of clot engagement members 202 that also enhance the ability of the device to remove embolic material from a vessel. Moreover, in some embodiments, the distal end of the clot engagement members 202 may define an angle with respect to the axis of the support member and/or the straight portion of the engagement members (as shown in Figure 3C). This angle may be between about 30 degrees and about 90 degrees, and in some embodiments between about 40 degrees and about 80 degrees.

[0043] The clot engagement members 202 can be made from a variety of materials. In a particular embodiment, the clot engagement members 202 comprise a material with sufficient elasticity to allow for repeated collapse into an appropriately sized catheter and full deployment in a blood vessel. Such suitable metals can include nickel-titanium alloys (e.g., Nitinol), platinum, cobalt-chrome alloys, Elgiloy, stainless steel, tungsten, titanium and/or others. Polymers and metal/polymer composites can also be utilized in the construction of the clot engagement members. Polymer materials can include Dacron, polyester, polyethylene, polypropylene, nylon, Teflon, PTFE, ePTFE, TFE, PET, TPE, PLA silicone, polyurethane, polyethylene, ABS, polycarbonate, styrene, polyimide, PEBAX, Hytrel, polyvinyl chloride, HDPE, LDPE, PEEK, rubber, latex and the like. In some embodiments, the clot engagement members 202 may comprise an environmentally responsive material, also known as a smart material. Smart materials are designed materials that have one or more properties that can be significantly changed in a controlled fashion by external stimuli, such as stress, temperature, moisture, pH, electric or magnetic fields.

[0044] In some embodiments, portions of the exterior surfaces of the support member 204 and/or clot engagement members 202 may be textured, or the exterior surfaces can include microfeatures configured to facilitate engagement or adhesion of thrombus material (e.g., ridges, bumps, protrusions, grooves, cut-outs, recesses, serrations, etc.). In some embodiments, the clot engagement members 202 may be coated with one or more materials to promote platelet

activation or adhesion of thrombus material. Adhesion of thrombi to clot engagement members 202 may facilitate capture and/or removal.

[0045] In some embodiments, the clot treatment device 200 can include between about 8 and about 80 clot engagement members 202, and in some embodiments, between about 12 and about 60 clot engagement members 202. In a particular embodiment, the clot treatment device 200 can include between about 16 and about 40 clot engagement members 202. The clot engagement members 202 can individually have one consistent diameter or have a variety of diameters (among the members 202) along their lengths. In addition, an individual clot engagement member 202 may have a tapered or varying diameter along its length to provide desired mechanical characteristics. The average diameter of the clot engagement members 202 can be between about 0.1 mm to about 0.2 mm in some embodiments and in a particular embodiment, between about 0.12 mm and 0.16 mm.

[0046] In any of the embodiments described herein, the clot engagement members 202 can be formed from a filament or wire having a circular cross-section. Additionally, the clot engagement members 202 can be formed from a filament or wire having a non-circular cross-section. For example, filaments or wires having square, rectangular and oval cross-sections may be used. In some embodiments, a rectangular wire (also known as a "flat wire") may have a height or radial dimension of between about 0.05 mm to about 0.2 mm. In some embodiments, a rectangular wire may have a width or transverse dimension of between about 0.08 mm to about 0.3 mm. In some embodiments, a rectangular wire may have a height to width ratio of between about 0.3 to about 0.9 and between about 1 and about 1.8.

[0047] Figures 4A and 4B illustrate an embodiment in which clot engagement members having non-circular cross-sections are fabricated from a tube (e.g., a hypotube). The tube may be cut or machined by various means known in the art including conventional machining, laser cutting, electrical discharge machining (EDM) or photochemical machining (PCM). Referring to Figure 4A, a tube may be cut to form a plurality of clot engagement members 454 that are integral with a hub member 456. The cut tube may then be formed by heat treatment to move from a delivery state shown in Figure 4A to a deployed state shown in Figure 4B in which an array of arcuate clot engagement members 454 project radially outward. As is known in the art of heat setting, a fixture or mold may be used to hold the structure in its desired final

configuration and subjected to an appropriate heat treatment such that the clot engagement members assume or are otherwise shape-set to the desire arcuate shape. In some embodiments, the device or component may be held by a fixture and heated to about 475-525 °C for about 5-15 minutes to shape-set the structure. In some embodiments, the tubular clot engagement structure may be formed from various metals or alloys such as Nitinol, platinum, cobalt-chrome alloys, 35N LT, Elgiloy, stainless steel, tungsten or titanium.

[0048] Figure 5 is a perspective view of another embodiment of a clot treatment device 500 in a deployed state in accordance with the present technology. As shown in Figure 5, the clot treatment device 500 can include a plurality of clot engagement members 502 generally similar to the clot engagement members 202 and 402 described with reference to Figures 2A-4B, except the clot engagement members 502 of Figure 5 are arranged about the support member 204 such that the length of the first portions 506 increase in a clockwise or counterclockwise direction about 360 degrees of the support member 204. As such, the second portions 508 spiral around the length of the support member 204 and each successive second portion 508 extends from a location along the shaft that is circumferentially offset and distal to the location of the immediately adjacent second portion 508.

[0049] Figure 6 is a perspective view of another embodiment of a clot treatment device 600 in a deployed state in accordance with the present technology. The clot treatment device 600 can include a plurality of clot engagement members 602 generally similar to the clot engagement members 202 and 402 described with reference to Figures 2A-4B, except the second portions 608 of the clot engagement members 602 of Figure 6 are not arranged in groups, but instead extend at irregular intervals from support member 204.

[0050] Figure 7A is a perspective view of another embodiment of a clot treatment device 700 in a deployed state in accordance with the present technology, and Figure 7B is a cross-sectional end view taken along line 7B-7B in Figure 7A. Referring to Figures 7A and 7B together, the clot treatment device 700 can have groups of clot engagement members 702a-f spaced along the support member 204. The groups 702a-f can include a plurality of arcuate clot engagement members 702 generally similar to the clot engagement members 202 and 402 described with reference to Figures 2A-4B, except the second portions 708 of the clot engagement members 702 of Figure 7A extend at an angle from the support member 204 such that the distal

ends 713 of the second portions 708 are not circumferentially aligned with the corresponding proximal ends 711 of the second portions 708. For example, as shown in Figure 7B, the second portions 708 can extend at an angle θ from the first portions 706. In some embodiments, the angle θ can be between about 10 and about 80 degrees. In a particular embodiment, the angle θ can be between about 40 and about 60 degrees. Additionally, as shown in Figures 4B and 7B, the clot engagement members may form a substantially circular axial array about the axis of the support member. A circular array may engage clot more uniformly and securely than a non-circular array and thus may facilitate retrieval and removal of clot from the vessel.

[0051] Figure 8 is a perspective view of another embodiment of a clot treatment device 800 in a deployed state in accordance with the present technology. As shown in Figure 8, the clot treatment device 800 can have groups of clot engagement members 802a-f spaced along the support member 204. The groups 802a-f can include a plurality of arcuate clot engagement members 802 generally similar to the clot engagement members 202 and 402 described with reference to Figures 2A-4B, except the clot engagement members 802 of Figure 8 do not include a first or cantilevered portion. As such, the clot engagement members 802 include only a curved second portion 808 which is coupled to the support member 204 at one end (e.g., via hubs 810a-f). In a particular embodiment, the clot engagement members 802 can have a first portion; however, in such embodiments, the first portions of the clot engagement members 802 are relatively short (e.g., less than about 10 mm). In some embodiments, the groups 802a-f can be evenly spaced along the support member 204, and in other embodiments the groups 802a-f can have any spacing or state along the support member 204. Additionally, the arcuate clot engagement members 802 at one group 802 can have a different size than the arcuate clot engagement members 802 at a different group 802. The groups 802a-f can be deployed or expanded simultaneously (e.g., via a push-wire or other deployment methods) or consecutively (e.g., by retracting a sheath).

[0052] Figure 9A is a perspective view of another embodiment of a clot treatment device 950 in a deployed state configured in accordance with the present technology. In some embodiments, the device 950 can include a plurality of clot engagement members 952 arranged in closely-packed circular array. The clot engagement members 952 can be generally similar to the clot engagement members 202 and 402 described with reference to Figures 2A-4B. A proximal portion of the clot engagement members 952 can be bound together and surrounded by a tubular

binding member 960. The clot engagement members 952 can fill substantially all of a lumen of the binding member 960, as shown in the cross-sectional view of Figure 9B (other than the small gaps between the clot engagement members (that are too small for another clot engagement member)). In another embodiment (not shown), a lumen or tube may provide for passage of a guidewire or catheter through the bundle of clot engagement members. Referring to Figure 9A, the clot engagement members 952 can have first portions 956 with differing lengths so that the second portions 956 are spread out over a deployed engagement member length L. In some embodiments, the deployed engagement member length L may be between about 0.5 cm and about 8 cm, and in some embodiments, between about 1 cm and about 5 cm. As shown in Figure 9C, the binding member 960 can be a coil, spiral, tube, sleeve, braid and/or other generally suitable tubular configurations. The binding member 960 may be slotted, cut or otherwise fenestrated to enhance flexibility. The binding member 960 may be made of various metals, polymers and combinations thereof and may comprise materials visible under x-ray or fluoroscopy so as to function as a radiopaque marker to facilitate deployment, placement and retraction by the user.

[0053] Figure 10 is a side partial cross-sectional view of one embodiment of a delivery system 910 for delivering the clot treatment device 200 to a treatment site, such as a pulmonary embolism. The delivery system 910 can include a proximal portion 911, an elongated delivery catheter 920 extending from a distal region of the proximal portion 911, a delivery sheath 930 slidably received within a lumen of the delivery catheter 920, a tubular push member 940 slidably received within a lumen of the delivery sheath 930, and a guidewire 912 slidably received within a lumen of the push member 940. As shown in Figure 10, the clot treatment device 200 can be positioned within the delivery sheath 930 such that the delivery sheath 930 constrains the clot engagement members 202 in a low-profile delivery state that is generally parallel with the support member 204. In some embodiments, the delivery catheter 920 can have an outside diameter between about 0.8 mm and about 1.8 mm, and in some embodiments, between about 0.1 mm and about 0.16 mm. A proximal portion of the support member 204 can be coupled to a distal region of the push member 204 such that axial movement of the push member 204 causes axial movement of the support member 204 (and thus the clot treatment device 200).

[0054] The proximal portion 911 of the device can include a first hub 922 and a second hub 932 configured to be positioned external to the patient. The first and/or second hubs 922, 932 can include a hemostatic adaptor, a Tuohy Borst adaptor, and/or other suitable valves and/or sealing devices. A distal region 920a of the first hub 922 can be coupled to the delivery catheter 920, and a proximal region of the first hub 922 can include an opening 924 configured to slidably receive the delivery sheath 930 therethrough. In some embodiments, the first hub 922 can further include an aspiration line 926 coupled to a negative pressure-generating device 928 (shown schematically), such as a syringe or a vacuum pump. A distal region 932a of the second hub 932 can be fixed to a proximal region of the delivery sheath 930, and a proximal region of the second hub 932 can include an opening 934 configured to receive the push member 940 therethrough. Additionally, in some embodiments, the second hub 932 can include a port 936 configured to receive one or more fluids before, during and/or after the procedure (e.g., contrast, saline, etc.).

[0055] Figures 11A-11K illustrate one example for treating an embolism (e.g., a pulmonary embolism) with the clot treatment device 200 (and delivery system 910). Figure 11A is a side view of a delivery system 910 positioned adjacent to an embolism or clot material PE within a pulmonary blood vessel V. Access to the pulmonary vessels can be achieved through the patient's vasculature, for example, via the femoral vein. The delivery system 910 can be guided through the right atrium, through the tricuspid valve, into the right ventricle, through the pulmonary valve and into the main pulmonary artery. Depending on the location of the embolism, the delivery system 910 can be guided to one or more of the branches of the right pulmonary artery and/or the left pulmonary artery. 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.

[0056] As shown in Figure 11A, the delivery sheath 930 containing the collapsed clot treatment device 200 (not shown) can be advanced together with the delivery catheter 920 over the guidewire 912 to the treatment site. For example, the guidewire 912 can be inserted through

the target pulmonary embolism PE. Referring to Figure 11B, a distal portion of the delivery catheter 920 and/or delivery sheath 930 can then be advanced through the pulmonary embolism PE such that the distal ends 201 of at least one group of the clot engagement members 202 are aligned with or positioned distal to a distal edge of the pulmonary embolism PE. In other embodiments (not shown), a distal portion of the delivery catheter 920 and/or delivery sheath 930 can be positioned such that the distal ends 201 of at least one group of the clot engagement members 202 are positioned proximal to a distal edge of the pulmonary embolism PE.

[0057] Once the device is positioned, the guidewire 912 can then be removed proximally through a lumen of the delivery sheath 930 and/or delivery catheter 920, and the delivery sheath 930 can be pulled proximally to a position proximal of the pulmonary embolism PE (as shown in Figure 11B). As shown in Figures 11C-11G, the delivery sheath 930 can be retracted proximally to expose the distal portions of the second portions 208 of the clot engagement members such that the exposed portions radially expand and bend backwards in a proximal direction. As the second portions 208 expand, they extend into the pulmonary embolism PE around the device along an arcuate path P. The arcuate path P can extend radially outward and proximally with respect to the support member (not shown) and, as shown in Figure 11F, can eventually curve radially inwardly. The second portions 208 can thus form hook-like capture elements that penetrate into and hold clot material to the device 200 for subsequent removal. Moreover, should the second portions 208 extend radially outwardly enough to touch the vessel wall, the end sections 214 of the second portions 208 form an atraumatic surface that can abut or apply pressure to the vessel wall without damaging the vessel wall. In some embodiments, the device presents a plurality of arcuate members that may be substantially parallel with the axis of the device at the point of contact with the vessel wall when in the deployed state.

[0058] Still referring to Figure 11F, when the delivery sheath 930 is withdrawn proximally beyond the second portions 208 of the most distal group of clot engagement members 202f, the first portions 206 of the clot engagement members 202f are exposed. In some embodiments, the delivery sheath 930 can be withdrawn so as to expose only a portion of the clot engagement members. Additionally, in those embodiments having two or more groups of clot engagement members, the delivery sheath 930 can be withdrawn to expose all or some of the groups of clot engagement members. As shown in Figure 11G, the delivery sheath 930 can continue to be

withdrawn proximally to expose additional second portions 208 and/or groups of clot engagement members 202a-f. Clot engagement members 202a-f may just contact or be slightly deflected by the vessel wall. If the device is sized such that the diameter of the clot engagement members are larger than the vessel diameter (e.g., "over-sized"), the clot engagement members may be compressed by the vessel wall. Thus, while fully deployed, the device may be in state of a small amount of radial compression. In some embodiments, the device may be diametrically over-sized by between about 5% and 50% and in other embodiments between about 10% and 25%.

[0059] As shown in Figures 11H-11K, once at least a portion of the clot engagement members and/or second portions 208 have penetrated and engaged the targeted clot material PE, the clot treatment device 200 can be withdrawn proximally, thereby pulling at least a portion of the clot material PE in a proximal direction with the device 200. For example, the push member 940, second hub 932, and delivery sheath 930 (Figure 10) can be retracted proximally at the same time and rate. As such, the delivery catheter 920 can be held in place while the delivery sheath 930, clot material PE, and clot treatment device 200 are pulled proximally into the delivery catheter 920. The curved shape of the second portions 208 increases the surface area of the clot engagement members 202 in contact with the clot material PE, thus increasing the proximal forces exerted on the clot material. Withdrawal of the device 200 not only removes the clot but also can increase blood flow through the vessel.

[0060] As shown in Figure 11K, in some embodiments the delivery catheter 920 can include an aspiration lumen (not shown) configured to apply a negative pressure (indicated by arrows A) to facilitate removal of the clot material PE. For example, the delivery catheter 920, delivery sheath 930 and/or clot treatment device 200 of the present technology can be configured to be operably coupled to the retraction and aspiration apparatus disclosed in Attorney Docket No. 111552.8004.US00, titled "Retraction and Aspiration Apparatus and Associated Systems and Methods," filed concurrently herewith, which is incorporated herein by reference in its entirety. When coupled to the retraction and aspiration apparatus, a negative pressure is applied at or near the distal portion of the delivery catheter 920 (via the aspiration lumen) only while the clot treatment device 200 and/or delivery sheath 930 is being retracted. Therefore, when retraction pauses or stops altogether, aspiration also pauses or stops altogether. Accordingly, aspiration is non-continuous and dependent upon retraction of the delivery sheath 930 and/or clot treatment

device 200. Such non-continuous, synchronized aspiration and retraction can be advantageous because it reduces the amount of fluid withdrawn from the patient's body during treatment (and thus less fluid need be replaced, if necessary). In addition, it may be advantageous to consolidate the steps and motions required to both mechanically transport thrombus into the guide catheter (e.g. aspiration tube) and remove fluid from the tube into one motion, by one person.

II. Additional Selected Embodiments of Clot Treatment Devices

[0061] Figure 12 shows an enlarged, side view of one embodiment of a clot treatment device 1202 (also referred to as "the device 1202") configured in accordance with the present technology, shown in a low-profile or delivery state and constrained within a delivery catheter 1406. Figure 13 shows the device 1202 of Figure 12 in an expanded or deployed state after removal of the delivery catheter 1406. As described in greater detail below, the clot treatment device 1202 can be delivered to a clot at a treatment site to restore blood flow through the clot and remove at least a portion of the clot. Referring to Figures 12 and 13 together, the device 1202 can be made of a self-expanding mesh or braided material such as a wire lattice, wire braid and/or stent. The material can be superelastic (e.g., Nitinol) or an alternative material such as a cobalt chrome alloy. It is believed that that porous structure of the clot treatment device 1202 allows for the flow of blood through the device 1202 during treatment, thus creating a lumen through the clot material that restores significant blood flow across the clot.

[0062] The clot treatment device 1202 can have distal ends coupled to an atraumatic distal hub 1205 and proximal ends coupled to proximal hub 1203. The proximal hub 1203 can be coupled to an elongated pusher member 1201 (shown in Figure 13), such as an elongated rod, wire, or tubular coil. In some embodiments, the clot treatment device 1202 can be an "over the wire" device. In such embodiments, the pusher member 1201 can have a lumen, and the proximal hub 1203 and/or the distal hub 1205 can have a hollow, central lumen for receiving a guide wire. In these and other embodiments, the distal portion of the clot treatment device 1202 can have a flexible, atraumatic member (not shown) that extends distally from the device 1202. In yet further embodiments, the distal hub 1205 can be tapered to better penetrate the clot material in the vessel.

[0063] In some embodiments, the clot treatment device 1202 can have a generally cylindrical shape that, during use, provides a flow lumen for blood across a clot. The treatment device 1202

is not, however, limited to a generally cylindrical shape. For example, the shape can be generally conical, generally concave or generally convex along its axis, so long as such shapes provide the aforesaid lumen for blood flow.

[0064] Referring still to Figures 12 and 13, the clot treatment device 1202 is compressed to fit within the diameter D_L of a lumen 1407 of the delivery catheter 1406 in the undeployed state. In the deployed state shown in Fig. 13, the clot treatment device 1202 has a plurality of capture elements, such as a series of radially extending capture portions 1206 which are separated from each other by flow restoration portions 1212. The flow restoration portions 1212 are configured to expand outwardly from the low-profile undeployed state within the delivery catheter lumen 1407 to a first cross-sectional dimension D_1 (e.g., diameter) in the deployed state. For example, the flow restoration portions 1212 can be generally cylindrical braided sections that expand radially outward from the undeployed stated to the deployed state. In many applications, the first cross-sectional dimension D_1 is greater than the diameter D_L of the delivery catheter lumen 1407. The capture portions 1206 are configured to expand outwardly from the low-profile undeployed state to a second cross-sectional dimension D_2 greater than the first cross-sectional dimension D_1 in the deployed state. As explained in more detail below, the capture portions 1206 can project into the clot such that they extend transverse to a longitudinal axis L-L of the clot treatment device 1202, while the flow restoration portions 1212 expand radially outward into the clot to open a passage through which blood can quickly resume flow through the vessel. The clot treatment device 1202 can be porous so blood flows therethrough. In this regard, many embodiments of the clot treatment device 1202 are made from a mesh or braided material. The material can be a super-elastic material such as Nitinol or an alternative material such as cobalt chrome alloy. The device can be made from a wire lattice, wire braid or stent.

[0065] Referring again to Figure 13, the clot treatment device 1202 can comprise a single mesh structure that is generally cylindrical in the low-profile undeployed state (shown in Figure 12). The series of radially extending capture portions 1206 accordingly extend from the same mesh as the corresponding series of flow restoration portions 1212. The flow restoration portions 1212 can be generally cylindrical sections in the deployed state, or in other embodiments the flow restoration portions 1212 may taper in the distal direction individually and/or collectively to form a conical lumen (not shown). Each of the radially extending

portions 1206 can be a radial or otherwise transversely projecting disk that projects outward relative to the flow restoration portions 1212.

[0066] Figures 14A-14F illustrate a method in accordance with the present technology for restoring flow and removing/retrieving clot material in a body lumen L using the clot treatment device 1202. Access to a treatment site, such as a clot E in a pulmonary vessel, can be achieved as described with reference to Figures 11A-11K. Upon delivery of the device 1202 to the treatment site, a guidewire 1402 can be extended through the clot E in the body lumen L as shown in Figure 14A. As shown in Figure 14B, a guide catheter 1404 can then be placed over the guidewire 1402 and moved to a location where a distal end of the guide catheter 1404 is positioned proximal to the clot E. At this point, the guidewire 1402 can optionally be withdrawn. However, in the embodiment shown in Figure 14C, the guidewire 1402 can remain positioned through the clot and a delivery catheter 1406 can be moved through the guide catheter 1404 over the guidewire 1402 and pushed through the clot E. As shown in Figure 14D, the guidewire 1402 can then be withdrawn, and the clot treatment device 1202 can be advanced distally through the delivery catheter 1406 until it is positioned at a distal portion of the delivery catheter 1406. Alternatively, if an over-the-wire device configuration is used, the guidewire 1402 can be left in place while the treatment device 1202 is deployed and retracted.

[0067] Referring to Figure 14E, the delivery catheter 1406 can then be retracted in a proximal direction while maintaining forward pressure on the clot treatment device 1202 via the pusher member 1201 so that the clot treatment device 1202 becomes exposed and released from the delivery catheter 1406. The clot treatment device 1202 can radially expands into the clot E and, some embodiments, at least a portion of the clot treatment device 1202 expands distal of the clot E. For example, at least one of the radially extending capture portions 1206 of the clot treatment device 1202 is located distal to the clot E upon expansion of the device 1202. Additionally, the flow restoration portions 1212 between the capture portions 1206 also expand outwardly against a portion of the clot E to form a flow passage 1230 though the clot treatment device 1202.

[0068] The clot treatment device 1202 accordingly restores blood flow through the clot E immediately or at least quickly after expanding to the deployed state as shown by arrows 1207 in Figure 14E. More specifically, the blood freely moves through the mesh of the clot treatment

device 1202, travels through the device lumen and exits the clot treatment device 1202 distal to the clot E. As a result, the acute condition of blockage is mediated thus immediately improving the circulation of oxygenated blood in the patient.

[0069] The restoration of blood flow is anticipated to equate with restoration of a substantial portion of the normal blood flow rate for the patient. In less severe, e.g., "sub-massive" pulmonary embolism patients, the clot treatment device 1202 can increase blood flow rate by at least about 50 ml/min, at least about 150 ml/min or between about 100 to 250 ml/min. In severe, e.g., "massive" pulmonary embolism patients, a larger amount of the pulmonary artery flow is compromised. Hence, in some embodiments, at least about 500 ml/min of blood flow rate may be restored. Moreover, at least a portion of the flow restoration is expected to occur prior to the removal of the clot E, or any portion thereof.

[0070] The restoration of blood flow by the clot treatment device 1202 can be achieved in a low pressure environment. For example, the pressure in the target vessel can be less than 60 mmHg and the blood can be venous blood, substantially non-oxygenated blood or low oxygenated blood.

[0071] In addition to restoring blood flow, the expansion of the clot treatment device 1202 also impinges or cuts into the clot material. This enhances the subsequent removal of the clot E since portions of the clot E collect (1) between the capture portions 1206; (2) through the pores of the mesh forming the radially extending portions 1206; (3) along the longitudinal cylindrical sections 1212 between the capture portions 1206 of the treatment device 1202; and (4) within the clot treatment device 1202 itself.

[0072] As can be understood from the above description and the drawing figures, the deployment of the clot treatment device 1202 results in an outwardly expanding generally cylindrical force being urged against an inner surface of the clot E. This force pushes the clot material outwardly and creates a lumen through which blood flow is restored. As can also be appreciated, the presence of the radially extending portions 1206 on the clot treatment device 1202 causes the outwardly expanding generally cylindrical force to vary in magnitude along the axis of the clot treatment device 1202. The force on the clot material may be greater at the locations of the capture portions 1206.

[0073] In braided embodiments of the clot treatment device 1202, deployment of the device leads the filaments of the braid to change their angular orientation with respect to the axis of the device. This angular change may improve or enhance adherence of clot material to the clot treatment device 1202.

[0074] After the clot treatment device 1202 has been expanded and blood flow restored, the user then retracts the clot treatment device 1202 in a proximal direction as shown in Figure 14F. Since the capture portions 1206 extend transverse to the longitudinal dimension of the vessel, the capture portions 1206 form transverse surfaces relative to the force exerted against the clot E as the clot treatment device 1202 is pulled in the proximal direction. The capture portions 406 accordingly enhance the ability of the clot treatment device 1202 to securely dislodge and retain the clot E as the clot treatment device 1202 and the delivery catheter 1406 are pulled back simultaneously into the guide catheter 1404. This is followed by the entire apparatus (e.g., clot treatment device 1202, delivery catheter 1406 and guide catheter 1404) being withdrawn through the heart and the venous circulation and out of the body.

[0075] As further shown in Figure 14F, the clot treatment device 1202 may elongate as it is being withdrawn into the guide catheter 1404 due to the resistance it encounters from the presence of clot material of the clot E. The presence of the radially extending portions 1206 may allow elongation of the device 1202 that enhances the capability of the device 1202 to capture the maximum amount of clot material. This is further discussed below with respect to the surface area and expansion ratio of preferred embodiments of the clot treatment device 1202.

[0076] It will be appreciated that variations in the above-described method are contemplated. For example, in certain circumstances a guide catheter 1404 may not be necessary or desirable and the user may choose to use only the delivery catheter 1406 for placing and manipulation of the clot treatment device 1202. As a further example, the clot may be of such a nature that the user may desire repeat the above-described process, or at least portions of it, in order to more fully remove the clot E or clot material.

[0077] Referring next to Figures 15A-15B, it may be advantageous to include the use of a collection or funnel catheter 1412 to assist in the removal of the clot E. Such a funnel catheter 1412 has an expandable portion 1414 at its distal end and may be situated between the guide catheter 1404 and the delivery catheter 1406 or may be part of the guide catheter 1404. In

the presence of the collection catheter 1412, the clot treatment device 1202 is pulled proximally into the collection catheter 1412 such that the clot or portions of it are captured within the collection catheter 1412. In an alternative embodiment, the collection catheter 1412 can be pushed distally over the clot treatment device 1202 and capture the clot, or portions thereof, in that manner. If the collection catheter 1412 is separate from the guide catheter 1404, the collection catheter with the clot treatment device 1202 is then pulled into the guide catheter for ultimate removal of all devices (and the clot) from the patient.

[0078] In certain circumstances, it may be advisable to remove the clot E without capturing it in the guide catheter 1404 or the collection catheter 1412 (if used) and remove the clot E by withdrawing the entire system, e.g., guide catheter 1404, delivery catheter 1406, clot treatment device 1202 and collection catheter 1412 (if used) simultaneously.

[0079] In several embodiments, the expandable portion 1414 the collection catheter 1412 is a conical funnel or tapered member constructed from a mesh, braid or stent structure. Such structure assists in retrieving and containing the clot material in the withdrawal process. In yet further embodiments, the collection catheter 1412 contains structural features to assist in the expansion of the funnel portion 1414 and to hold the funnel portion 1414 open towards the wall of the blood vessel. Such features (not shown) include interwoven support struts, self-expanding material (e.g., Nitinol), longitudinal wire supports, stent supports, polymeric webbing, etc.

[0080] In another embodiment of the present invention, a vacuum apparatus can be used to aid in the removal of the clot material. Referring to Figure 16, a syringe 1602 is shown connected to a vacuum manifold 1606 that is in fluid communication with the proximal end of the guide catheter 1404. At the time the clot treatment device 1202 (and clot material) is being withdrawn into the guide catheter 1404 (or the collection catheter 1412), vacuum is applied by pulling on the syringe. Alternative sources of vacuum 1604 are also acceptable, e.g., a vacuum pump. A system is also contemplated whereby vacuum is actuated automatically when the clot treatment device 1202 (and the clot material) is being withdrawn. A representation of the effect of the use of vacuum can be seen with reference to Figure 15B which shows how vacuum causes flow 1501 into the catheter 1412.

[0081] Referring now to Figures 17A-17H, alternative preferred embodiments of the clot treatment device 1202 are disclosed.

[0082] Referring to Figure 17A, the capture portions 1206 between the generally cylindrical flow restoration portions 1212 of the clot treatment device 1202 are defined by a cylindrical disk shape with a rounded triangular cross-section.

[0083] Referring to Figure 17B, the radially extending portions 1206 between the generally cylindrical flow restoration portions 1212 of the clot treatment device 1202 are defined by a cylindrical disk shape with a rounded triangular cross-section wherein the diameter of the disk increases along the length of the device 1202 thus forming a conical exterior extent.

[0084] Referring to Figure 17C, the capture portions 1206 between the generally cylindrical flow restoration portions 1212 of the clot treatment device 1202 are defined by a cylindrical disk shape with a rectangular cross-section.

[0085] Referring to Figure 17D, the radially extending portions 1206 between the flow restoration portions 1212 of the clot treatment device 1202 are defined by a cylindrical disk shape with a linear (non-rounded) triangular cross-section.

[0086] Referring to Figure 17E, some of the capture portions 1206 between the generally cylindrical flow restoration portions 1212 of the clot treatment device 1202 are defined by a cylindrical disk shape with a rounded cross-section and others have a rectangular cross section.

[0087] Referring to Figure 17F, the radially extending portions 1206 between the generally cylindrical flow restoration portions 1212 of the clot treatment device 1202 alternate between cylindrical disk shape with a T-shaped cross-section and a flare-shaped cross-section.

[0088] Referring to Figure 17G, the radially extending portions 1206 between the generally cylindrical flow restoration portions 1212 of the clot treatment device 1202 are defined by a partial cylindrical disk shapes.

[0089] Referring to Figure 17H, the radially extending portions 1206 between the generally cylindrical flow restoration portions 1212 of the clot treatment device 1202 are defined by tabs and bumps or protuberances arising from the cylindrical surface of the device 1202.

[0090] Figure 18 is a cross-sectional view of another embodiment of the clot treatment device 1202 in accordance with the technology having an expandable member 1810, an

elongated inner member 1820, and an elongated outer member 1822. The expandable member 1810 is configured to have an undeployed state in which the expandable member 1810 is elongated axially to have a low profile that fits within a delivery catheter as shown in Figure 18. The expandable member 1810 is further configurable into a deployed state in which the expandable member 1810 forms a flow channel 1812 for restoring blood flow through the region obstructed by the clot. The expandable member 1810, for example, can be a mesh, braid, stent-type device, or other suitable member through which blood flows in the deployed state. In one embodiment, the expandable member 1810 is a continuous braid formed from a shape-memory material that has been heat set such that, in the deployed state, the expandable member 1810 has a plurality of flow restoration portions 1212 that expand to the first cross-sectional dimension D_1 to form the flow channel 1812 and a plurality of radially extending portions 1206 that expand to the second cross-section dimension D_2 greater than the first cross-sectional dimension D_1. The flow restoration portions 1212 accordingly exert an outward force (arrows 0) against clot material (not shown) to create the flow channel 1812, and the radially extending portions 1206 accordingly exert a longitudinal force L (arrows L) against the clot material as the clot treatment device 1202 is moved proximally.

[0091] The elongated inner member 1820 can be a tube or coil having inner lumen configured to receive the guidewire 1402 for over-the-wire or rapid exchange delivery of the expandable member 1810 to the clot. The elongated outer member 1822 can be a tube or coil having a lumen configured to receive the elongated inner member 1820 such that the elongated inner member 1820 and/or the elongated outer member 1822 can move relative to each other along the longitudinal dimension of the clot treatment device 1202.

[0092] Figures 19 and 20 are detailed views of a distal portion 1901a (Figure 19) and a proximal portion 1901b (Figure 20) of the expandable member 1010 of the clot treatment device 1202 shown in Figure 18. Referring to Figure 19, the distal portion 1901a is attached to a distal end of the elongated inner member 1820 by the distal hub 1205. The distal hub 1205 can be blunt as described above with reference to the embodiment of the clot treatment device 1202 shown in Figure 20, or the tip 405 can have a tapered distal portion 1840 configured to pass through the clot as shown in Figure 19. Additionally, the distal hub 1205 can have a proximal opening 1842 configured to receive the distal end of the elongated inner member 1820 and the distal end of the expandable member 1810. Referring to Figure 18, the proximal portion 1901b is

attached to the distal end of the elongated outer member 1822 by a proximal hub 1830. For example, the distal and proximal portions 1901a and 1901b can be attached to the elongated inner member 1820 and the elongated outer member 1822, respectively, using welds, adhesives, crimping or clamping forces, and/or other suitable attachment mechanisms.

[0093] In the operation of the clot treatment device 1202 shown in Figures 18-20, the expandable member 1810 can self-expand from the undeployed state to the deployed state without an actuator. For example, as a delivery catheter is drawn proximally to release the expandable member 1810, the elongated inner member 1820 can be held in place to hold the distal portion 1901a of the expandable member 1810 distally of the clot. As the distal end of the delivery catheter moves proximally, the elongated outer member 1822 will slide distally as the expandable member 1810 expands until the expandable member 1810 reaches its predetermined deployed size or otherwise reaches equilibrium with the clot. In other embodiments, the elongated inner member 1820 and/or the elongated outer member 1822 can be actuators that are moved proximally and/or distally to control the radial expansion and/or the radial contraction of the expandable member 1810.

[0094] Figures 21 and 22 are detailed views of the proximal and distal portions 1901b and 1901a, respectively, of an expandable member 1810 and other components of a clot treatment device 1202 in accordance with another embodiment of the technology. In this embodiment, the clot treatment device 1202 has a proximal tube 2110 (Figure 21) and an expansion element 2120 having one end attached to the proximal tube 2110 and another end attached to the distal portion 1901a (Figure 22) of the expandable member 1810. The expansion element 2120, for example, can be a coil or spring that is stretched from its normal state when the expandable member 1810 is the low-profile, undeployed state inside the delivery catheter. As the distal portion 1901a and then the proximal portion 1901b of the expandable member 1810 are released from the delivery catheter, the expansion element 2120 contracts axially under its own stored spring force causing the expandable member 1810 to contract axially and expand radially outward.

[0095] In the embodiments where the expandable member 1810 is self-expanding, the expansion element 2120 assists the expansion of the expandable member 1810. In other embodiments, the expandable member 1810 may not be self-expanding or may be inherently

spring-biased into the low-profile undeployed state, and the expansion element 2120 can have enough stored energy when it is stretched in the low-profile undeployed state to pull the distal portion 1901a and the proximal portion 1901b of the expandable member 1810 toward each other and thereby radially expand the expandable member 1810.

[0096] In the foregoing embodiments, the radially extending portions 1206 provide more surface area along the device than a device that is uniformly cylindrical. Moreover, the radially extending portions 1206 extend transversely to the longitudinal dimension of the device to more effectively transfer the axial force as the device is moved axially along the vessel after deployment. Such increased surface area facilitates the treatment and/or retrieval of a much larger portion of the clot E than is generally feasible with a uniformly cylindrical device. For example, in a preferred embodiment of the clot treatment device 1202, the device will have an external surface area between 1.5x and 6x the surface area of a uniformly cylindrical device of the same general diameter of the cylindrical flow restoration portions 1212. In other preferred embodiments the ratio can be 2x to 4x.

[0097] This can be advantageous particularly during retraction of the clot treatment device 1202 through the clot E. As shown in Fig. 14F, the clot treatment device 1202 may become elongated as it is being withdrawn through the clot E. Such elongation causes the clot material to encounter greater surface area of the clot treatment device 1202 than would otherwise occur with a device that was only generally cylindrical, e.g., that did not incorporate radially extending portions 1206. Accordingly the clot treatment device 1202 is particularly adept at capturing the maximum amount of clot material during withdrawal.

[0098] The clot treatment device 1202 is intended for use in large vessels, i.e., vessels with a diameter greater than 8 mm. For example, the diameter of the pulmonary arteries typically range from 15 to 30 mm whereas the first branches of the pulmonary arteries typically range from 10 to 15 mm and the secondary and tertiary branches typically range from 5 to 10 mm. At the same time, however, it is important to minimize the size of catheter providing access to the clot E. Accordingly, the clot treatment device 1202 has a large expansion ratio. In a preferred embodiment the expansion ratio from the diameter of the flow restoration portions 1212 in the collapsed state to the expanded state will be between 4 and 8. In another preferred embodiment

the ratio will be between 5 and 7. The large expansion ratio also enables the formation of a flow channel in the clot E that is large, e.g., on the order of 4-8 mm.

[0099] The radially extending portions 1206, in their fully expanded position are intended to have a size that matches the diameter of the target blood vessel. However, the diameters may be slightly larger than the vessel diameter so to apply greater radial force against the blood vessel (without causing trauma) in those circumstances when it is desirable to improve clot collection. Similarly, in those circumstances where there is a concern of creating trauma on delicate blood vessels, the radially extending portions 1206 may have a diameter that is smaller than the vessel diameter. It is contemplated that different sizes of the device 1202 will be available for selection by the user for a particular presentation of the patient.

[00100] As for the length of the clot treatment device 1202, it is known that a typical pulmonary embolism will have a length within the range between about 2 cm and 10 cm and sometimes between about 1 cm and 20 cm. Accordingly, in a preferred embodiment, the clot treatment device 1202 will have a length that exceeds the length of the embolism so that a portion of the clot treatment device is positioned distal of the clot E during expansion.

[00101] With regard to the delivery catheter 1406, in a preferred embodiment for use with a pulmonary embolism, the size will be around 1 F - 6 F. Smaller diameters will pass through the clot 100 more easily. In addition, the delivery catheter 1406 may have stiffness characteristics to assist in making sure the delivery catheter 1406 passes through the clot in a smooth manner. Such stiffness characteristics include self-expanding Nitinol wire braids or stent structures that are contained within the structure of the delivery catheter 1406. The delivery catheter 1406 also has sufficient flexibility so that it may carry the clot treatment device 1202 and still pass through a tortuous vessel path as described above starting with insertion of the delivery catheter 1406 in the femoral vein FV.

[00102] In some preferred embodiments, the method and device in accordance with the present invention may reduce the Mean Resting Pulmonary Artery Pressure (MRPAP). Upon at least partial relief from the clot 100, MRPAP may be reduced by about 20-50mmHg to a normal range of 8-20 mmHg. In some embodiments, the reduction in MRPAP may be about 25-50%. In some embodiments, the reduction in MRPAP may be about 15% to 40% and in other embodiments between about 30% and 75%.

[00103] Such a reduction in MRPAP can occur in two steps. A first step is when the clot treatment device 1202 is first deployed and blood flow is at least partially restored. A second step may be when the clot treatment device 1202 is retracted and at least some of the clot E is removed from the vessel. A third step may be after the clot treatment device 1202 has been removed and the effect of the body's own processes and/or thrombolytic drugs that may have been used before, during or after the procedure take effect upon clot that has been disrupted by the clot treatment device.

[00104] Figure 15 is a side view of an embodiment of a guide catheter 1500 for use with any of the foregoing embodiments of the clot treatment devices 1202 (not shown in Figure 23). The guide catheter 2300 can include a shaft 2302 having a sufficiently large lumen to accommodate the delivery catheter 1406 (Figures 12 and 14A). The guide catheter 2300 can further include an expandable guide member 2310 at the distal end of the shaft 2302 configured to expand radially outward to contact or nearly contact the vessel wall VW. The guide member can be formed from a permeable, radially expanding material, such as a mesh or other macroporous structure (e.g., a braid of wires or filaments). The guide member 2310, for example, may be formed from a tubular braid of elastic or super-elastic filaments such as Nitinol that has been heat set into the desired expanded shape. The permeable, radially expanding guide member 2310 may have advantages over an occlusive member such as a balloon or impermeable funnel. For example, the guide member 1510 allows a substantial amount of blood flow BF to continue flowing through the blood vessel where therapy is being directed. In addition, the guide member 2310 positions the shaft 2302 and delivery catheter 606 at or near the center of the vessel. The clot treatment device 1202 (not shown in Figure 23) may also be substantially self-centering upon deployment, and the guide member 2310 may further guide the clot material captured by the clot treatment device 1202 into the shaft 2302 as the clot treatment device 1202 moves into proximity of the distal end of the shaft 2302. This is expected to enhance aspiration of the clot material. For example, in the embodiment shown in Figure 23, the radially expanding guide member 2310 has a funnel shape adjacent the distal end of the shaft 2302 to guide thrombus material into the distal opening of the shaft 2302 where it can be more readily aspirated.

[00105] The radially expanding guide member 2310 may also be formed by conventional machining, laser cutting, electrical discharge machining (EDM) or other means known in the art to make a fenestrated, mesh or porous structure that can be affixed near the distal end of the

shaft 2302. In some embodiments the radially expanding guide member 2310 may self-expand, but in other embodiments it may be actuated by an operator using, for example, electrical or electromechanical means. By having a porous radially expanding guide member 2310, the guide catheter 2300 may be substantially centered within a vessel without blocking a large portion of the flow around the catheter. In some embodiments, the radially expanding guide member 2310 may block less than about 50% of the flow about the catheter and in other embodiments less than about 25% of the flow. When the guide member 2310 is made with a braid of filaments (e.g. wires), it may be formed from a tubular braid. In some embodiments, the tubular braid may be formed with approximately 12 to approximately 144 filaments, or in other embodiments from about 36 to about 96 filaments. The pores as measured by the largest circle that can be inscribed within an opening of the mesh may be between about 0.5 mm and 5 mm.

[00106] Figures 24 and 25 show additional embodiments of guide members 2410 and 2510, respectively, that can be used instead of or in addition to the guide member 2310. Referring to Figures 23 and 24, one or both ends of the tubular braid of the guide members 2310 and 2410 may be inverted and attached to the catheter body. Referring to Figure 25, neither end of the guide member 2510 is inverted. With the distal end inverted, it advantageously may form a funnel adjacent the distal opening of the catheter that may enhance clot capture and aspiration.

[00107] Figure 26 shows an embodiment of a guide catheter 2600 having a shaft 2602 and a guide member 2610 in accordance with another embodiment of the technology. In the embodiment shown in Figure 26, the guide member 2610 has a tapered or funnel shape, and includes a non-permeable portion 2612 and a permeable portion 2614. The permeable portion 2614 can comprise a flared radially expanding mesh that has, at least in part, a tapered or funnel shape, and the non-permeable portion 2612 may have a substantially non-porous or otherwise non-permeable material or coating over the mesh. Preferably, the non-permeable material is a highly elastic material such as polyurethane, silicone, latex rubber and the like so that it can flex with the expansion of the mesh. In some embodiments, the non-permeable material covers a proximal portion of the mesh as shown in Figure 26. The non-permeable portion 2612 may divert some flow away from the distal end of the catheter. The covering may cover a portion of the mesh to a diameter "d". In some embodiments, the diameter d of the covering is less than about 75% of the diameter "D" of the mesh funnel. In some embodiments, the diameter d may be less than about 50% of diameter D. The concept of a non-permeable

material can also be applied to the guide catheter 2300 shown above in Figure 23. For example, the expandable guide member 2310 of the guide catheter 2300 can have a non-permeable portion 2312 at the proximal portion of the expandable guide member 2310 similar to the non-permeable portion 2612 shown and described with reference to Figure 26.

[00108] In any of the above embodiments shown and/or described herein, the clot treatment device and/or delivery system can be configured to facilitate maceration, fragmentation and/or disruption of the clot material. For example, unsheathing and re-sheathing the clot treatment device via advancement and retraction of the delivery catheter and/or the guide catheter can macerate the clot material held by the clot treatment device. As the guide catheter and/or delivery catheter slide across the outer layer of the clot material, the guide catheter and/or delivery member causes a repeated shear stress on the outer layer of the clot material that can weaken and/or fragment the clot and/or slough off outer layers of the clot. Moreover, retracting a clot having a larger diameter than the guide catheter and/or delivery catheter (or at the very least, having a portion that extends beyond the diameter of the guide catheter and/or delivery catheter) shears the clot material as it enters the guide catheter and/or delivery catheter, thus fragmenting the clot and releasing embolic particles from the main clot mass. In those embodiments where the clot treatment device and/or delivery system do not include a distal filter or embolic protection device, the released embolic particles are allowed to freely flow in the direction of the blood flow without being captured by a downstream device. It is expected that such restored blood flow causes natural lysis of the embolic particles.

III. Examples

[00109] Several examples of the present technology are as follows:

1. A clot treatment device for treating a pulmonary embolism within a blood vessel, the clot treatment device being moveable between a low-profile undeployed state and a deployed state, the clot treatment device comprising:

a support member configured to extend through a delivery catheter, wherein the support member has a proximal portion and a distal portion;

a plurality of clot engagement members positioned circumferentially about at least an area of the distal portion of the support member, wherein individual clot engagement members have a curved portion;

wherein the clot engagement members are configured to penetrate clot material along an arcuate path and mechanically macerate clot material and release embolic particles when re-sheathed into the delivery catheter.

2. The clot treatment device of example 1 wherein, in the deployed state, individual curved portions of the clot engagement members project radially outwardly relative to the support member in a curve that has a proximally extending section which defines a proximally facing concave portion, and wherein the individual curved portions further include an end section that curves radially inwardly from the proximally extending section.

3. A method of treating a pulmonary embolism, comprising:

accessing a venous vessel of a patient;

inserting a catheter in the vessel and urging the catheter through the vessel, through chambers of the patient's heart and into a pulmonary artery until a distal end of the catheter is located at a region distal of a pulmonary embolism;

delivering a treatment device having a plurality of radially extending members through the catheter;

disturbing the embolus by mechanical maceration of the embolus to release embolic particles without capturing the embolic particles in an embolic protection device; and

establishing one or more blood flow channels through the embolus wherein the one or more blood flow channels facilitate natural lysis of the embolus.

4. A method of treating a pulmonary embolism comprising:

delivering an embolectomy device through the heart to a pulmonary embolism that at least partially restricts blood flow through a pulmonary vessel, wherein the embolectomy device comprises an expandable cylindrical section and a radial expansion member configured to expand outwardly from the cylindrical section;

deploying the embolectomy device within the pulmonary embolism so as to restore blood flow through said pulmonary embolism,

wherein deploying the embolectomy device comprises expanding the cylindrical section within the pulmonary embolism such that the cylindrical section forms an expanded flow channel through the pulmonary embolism and expanding the radial expansion member to a greater extent than the cylindrical section, and wherein at full expansion of the cylindrical member the radial expansion member projects outward from the cylindrical member;

fragmenting the pulmonary embolism while moving the embolectomy device and at least a portion of the pulmonary embolism along the pulmonary vessel; and

withdrawing the embolectomy device and at least a portion of the pulmonary embolism from the pulmonary vessel.

5. A device for treating a pulmonary embolism that at least partially restricts blood flow through a pulmonary vessel, the device comprising:

an elongated shaft having a proximal region and a distal region;

an expandable braid attached to the distal region of the elongated shaft, the braid having a plurality of radially extending portions and at least one cylindrical portion, and the radially extending portions and the cylindrical portion being configured to move from a compressed state sized to fit in a delivery catheter to an expanded state;

wherein the cylindrical portion is between a pair of the radially extending portions, and in the expanded state the cylindrical portion is configured to press radially outward against the pulmonary embolism;

wherein the radially extending portions extend radially outward from the cylindrical portion in the expanded state such that portions of the pulmonary embolism are retained between the radially extending portions; and

wherein the cylindrical portion has a first length along a longitudinal direction of the braid in the expanded state and the radially extending portions have a second length along the longitudinal direction of the braid in the expanded state that is less that the first length; and

wherein the radially extending portions and/or the cylindrical portions are configured to elongate and/or contract when re-sheathed into the delivery catheter to mechanically macerate clot and release embolic particles.

6. The device of example 1 wherein at least a portion of the individual radially extending portions is disk-shaped.

7. The device of example 1 wherein the individual radially extending portions include a curved portion and a linear portion.

[00110] 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 exampled 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.

CLAIMS

I/We claim:

1. A clot treatment device for treating a pulmonary embolism within a blood vessel, the clot treatment device being moveable between a low-profile undeployed state and a deployed state, the clot treatment device comprising:

a support member configured to extend through a delivery catheter, wherein the support member has a proximal portion and a distal portion;

a plurality of clot engagement members positioned circumferentially about at least an area of the distal portion of the support member, wherein individual clot engagement members have a curved portion;

wherein the clot engagement members are configured to penetrate clot material along an arcuate path and mechanically macerate clot material and release embolic particles when re-sheathed into the delivery catheter.

2. The clot treatment device of claim 1 wherein, in the deployed state, individual curved portions of the clot engagement members project radially outwardly relative to the support member in a curve that has a proximally extending section which defines a proximally facing concave portion, and wherein the individual curved portions further include an end section that curves radially inwardly from the proximally extending section.

3. A method of treating a pulmonary embolism, comprising:

accessing a venous vessel of a patient;

inserting a catheter in the vessel and urging the catheter through the vessel, through chambers of the patient's heart and into a pulmonary artery until a distal end of the catheter is located at a region distal of a pulmonary embolism;

delivering a treatment device having a plurality of radially extending members through the catheter;

disturbing the embolus by mechanical maceration of the embolus to release embolic particles without capturing the embolic particles in an embolic protection device; and

establishing one or more blood flow channels through the embolus wherein the one or more blood flow channels facilitate natural lysis of the embolus.

4. A method of treating a pulmonary embolism comprising:

delivering an embolectomy device through the heart to a pulmonary embolism that at least partially restricts blood flow through a pulmonary vessel, wherein the embolectomy device comprises an expandable cylindrical section and a radial expansion member configured to expand outwardly from the cylindrical section;

deploying the embolectomy device within the pulmonary embolism so as to restore blood flow through said pulmonary embolism,

wherein deploying the embolectomy device comprises expanding the cylindrical section within the pulmonary embolism such that the cylindrical section forms an expanded flow channel through the pulmonary embolism and expanding the radial expansion member to a greater extent than the cylindrical section, and wherein at full expansion of the cylindrical member the radial expansion member projects outward from the cylindrical member;

fragmenting the pulmonary embolism while moving the embolectomy device and at least a portion of the pulmonary embolism along the pulmonary vessel; and

withdrawing the embolectomy device and at least a portion of the pulmonary embolism from the pulmonary vessel.

5. A device for treating a pulmonary embolism that at least partially restricts blood flow through a pulmonary vessel, the device comprising:

an elongated shaft having a proximal region and a distal region;

an expandable braid attached to the distal region of the elongated shaft, the braid having a plurality of radially extending portions and at least one cylindrical portion, and the radially extending portions and the cylindrical portion being configured to move from a compressed state sized to fit in a delivery catheter to an expanded state;

wherein the cylindrical portion is between a pair of the radially extending portions, and in the expanded state the cylindrical portion is configured to press radially outward against the pulmonary embolism;

wherein the radially extending portions extend radially outward from the cylindrical portion in the expanded state such that portions of the pulmonary embolism are retained between the radially extending portions; and

wherein the cylindrical portion has a first length along a longitudinal direction of the braid in the expanded state and the radially extending portions have a second length along the longitudinal direction of the braid in the expanded state that is less that the first length; and

wherein the radially extending portions and/or the cylindrical portions are configured to elongate and/or contract when re-sheathed into the delivery catheter to mechanically macerate clot and release embolic particles.

6. The device of claim 1 wherein at least a portion of the individual radially extending portions is disk-shaped.

7. The device of claim 1 wherein the individual radially extending portions include a curved portion and a linear portion.

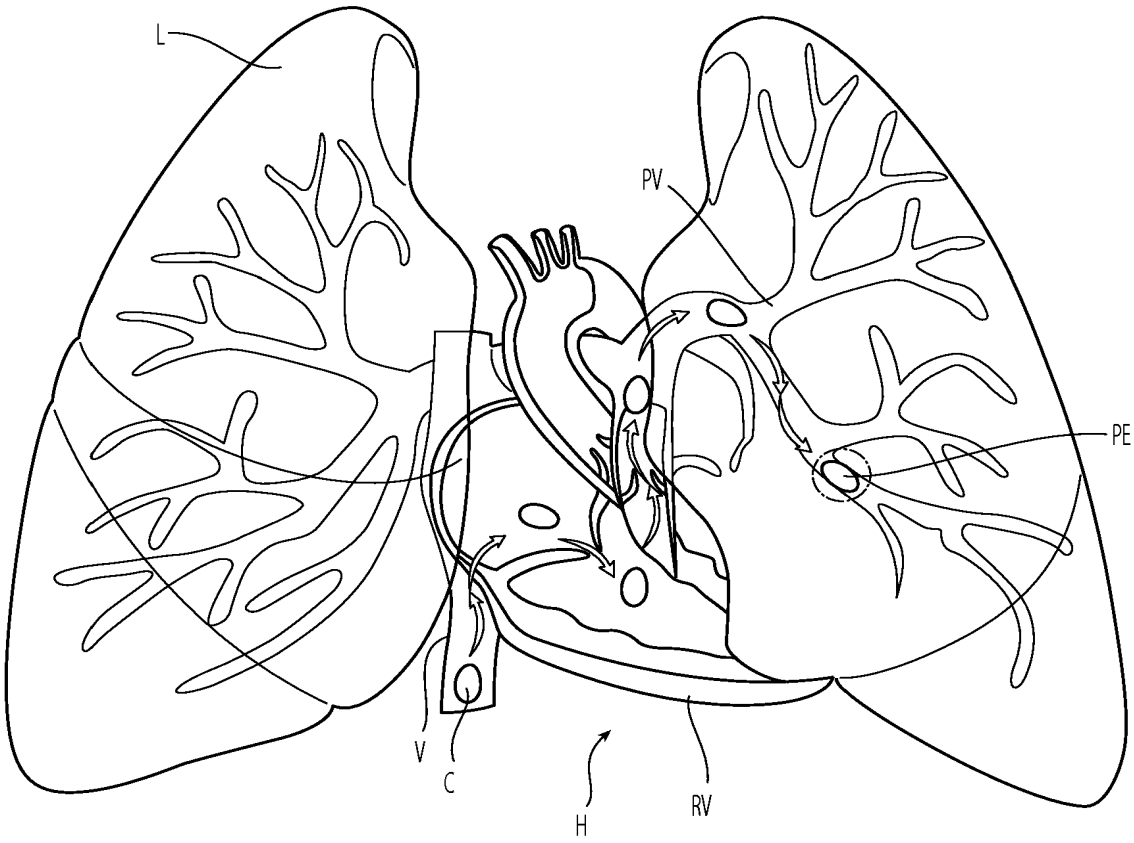

Fig. 1

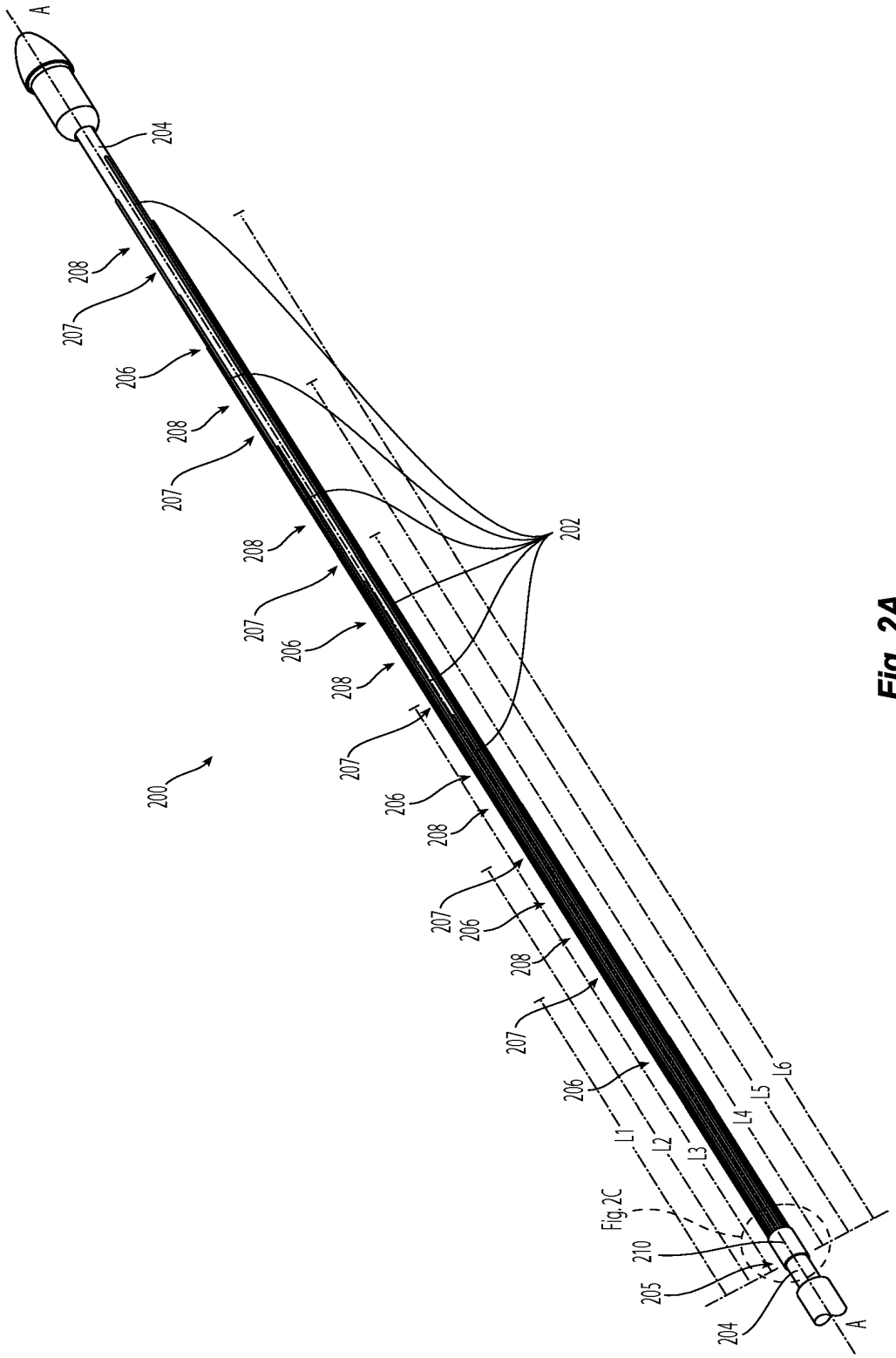
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Fig.2C
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Fig. 2A

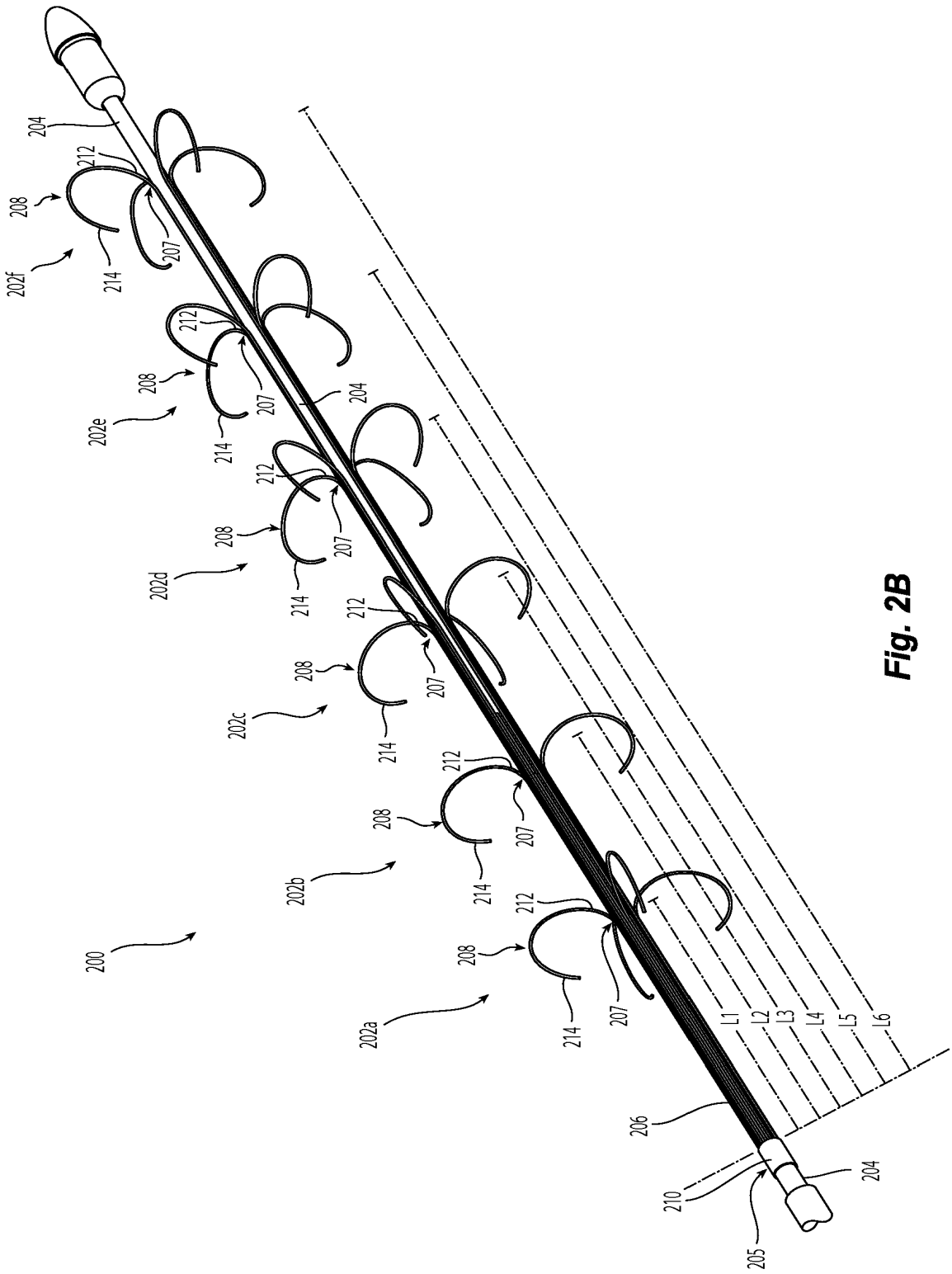
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Fig. 2B

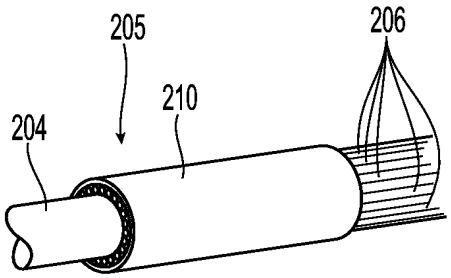

Fig. 2C

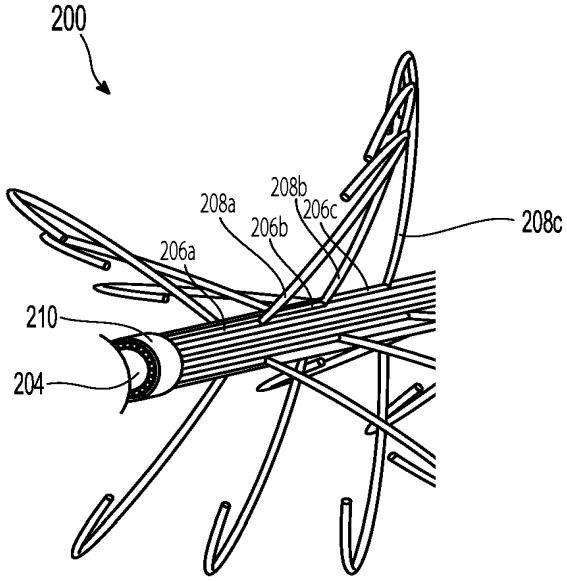

Fig. 2D

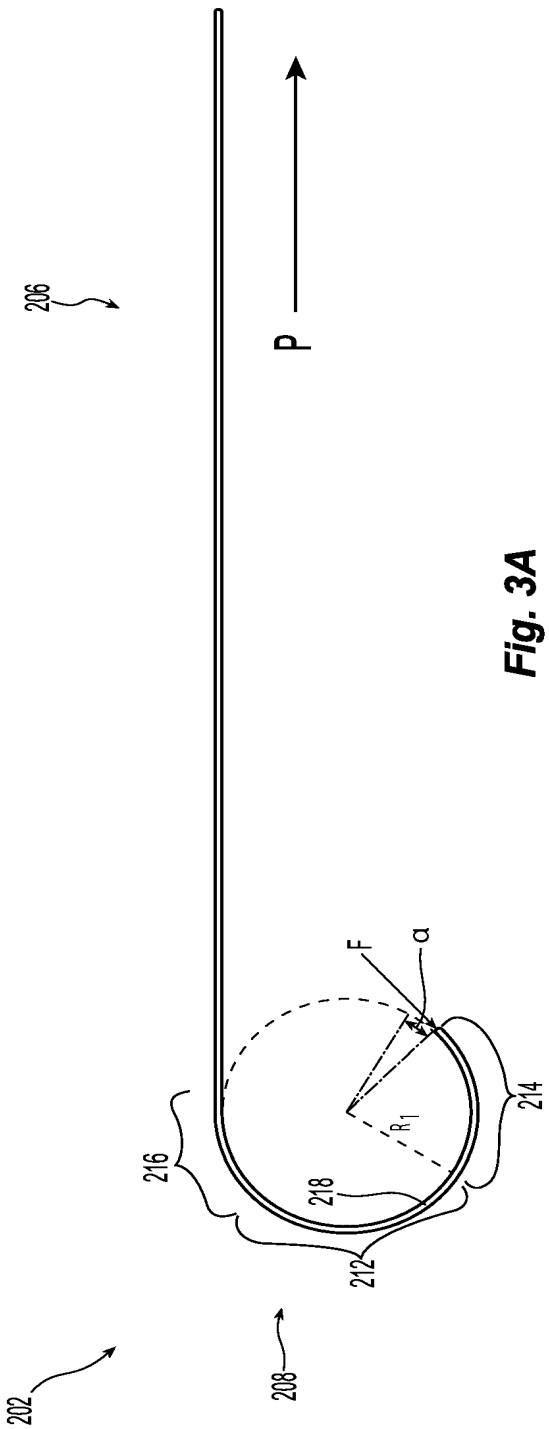

Fig. 3A

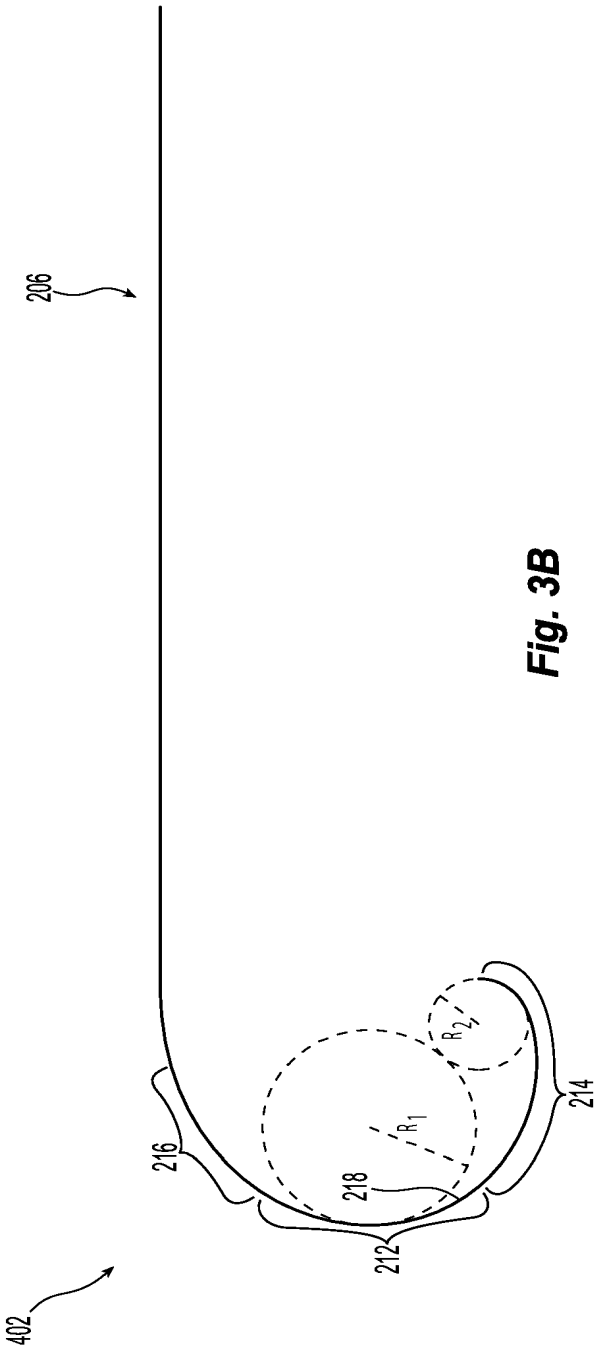

Fig. 3B

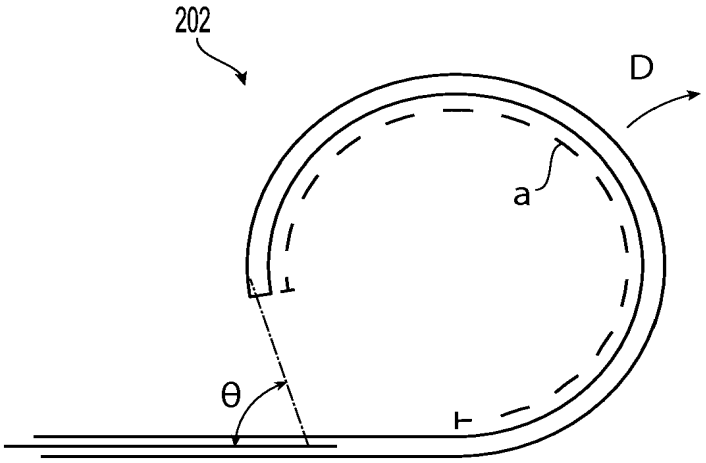

Fig. 3C

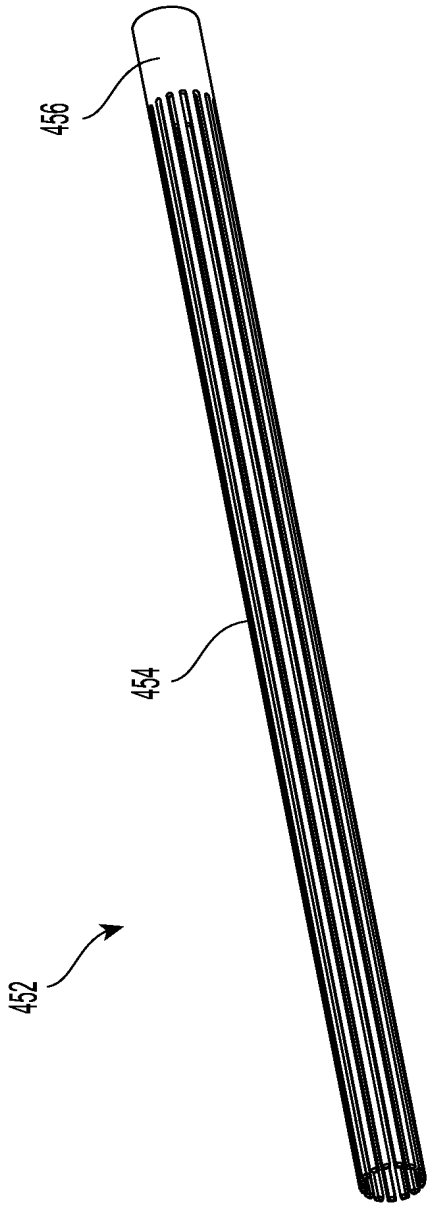

Fig. 4A

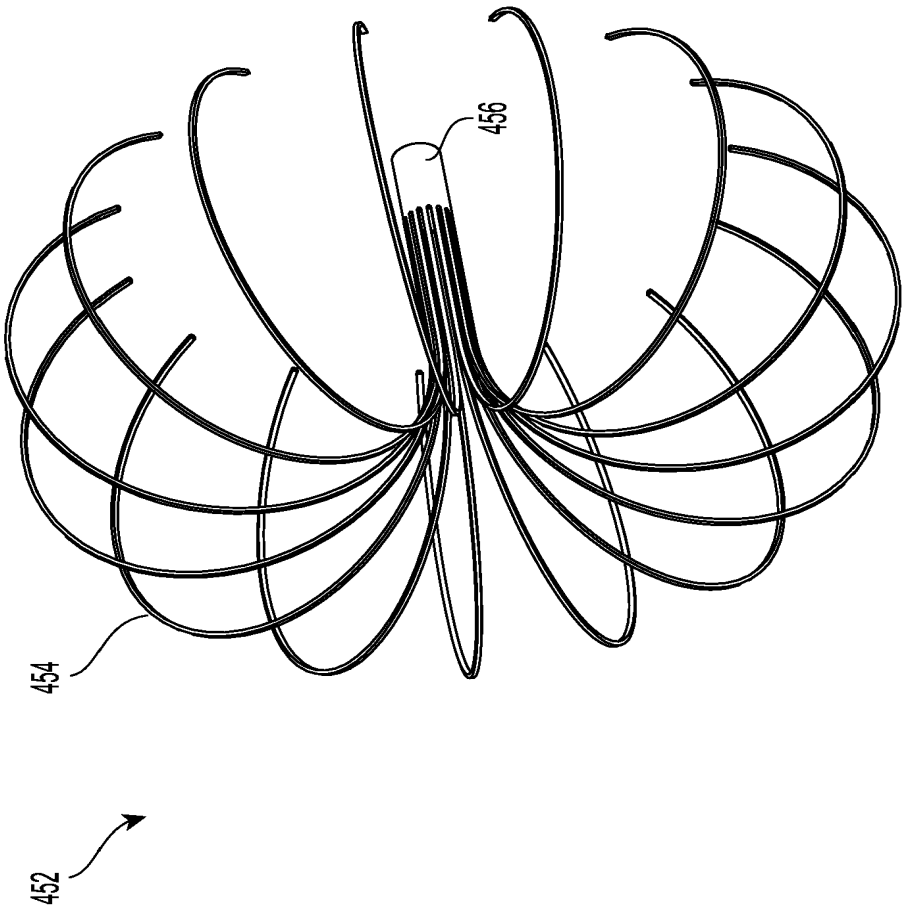

Fig. 4B

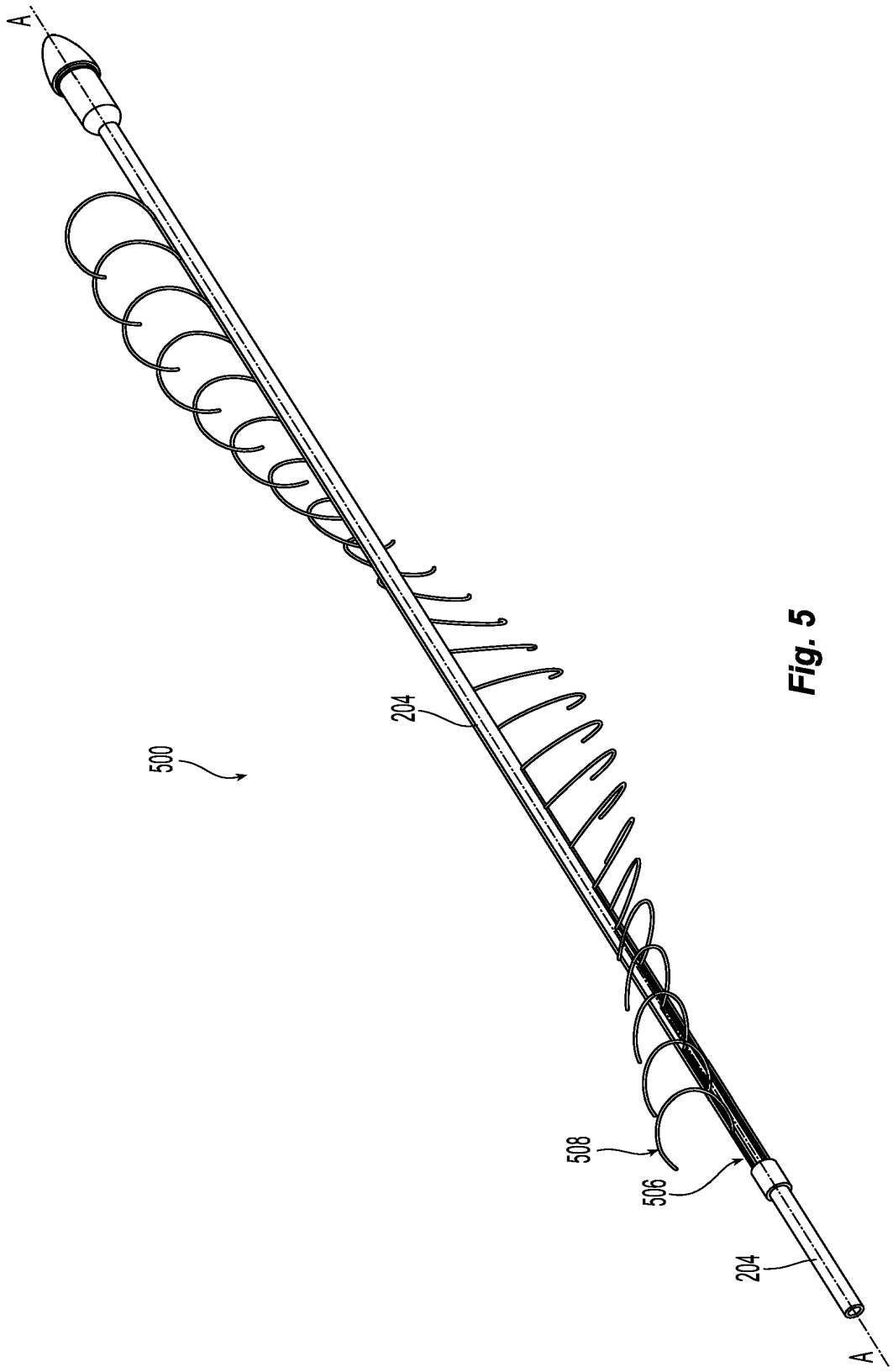

Fig. 5

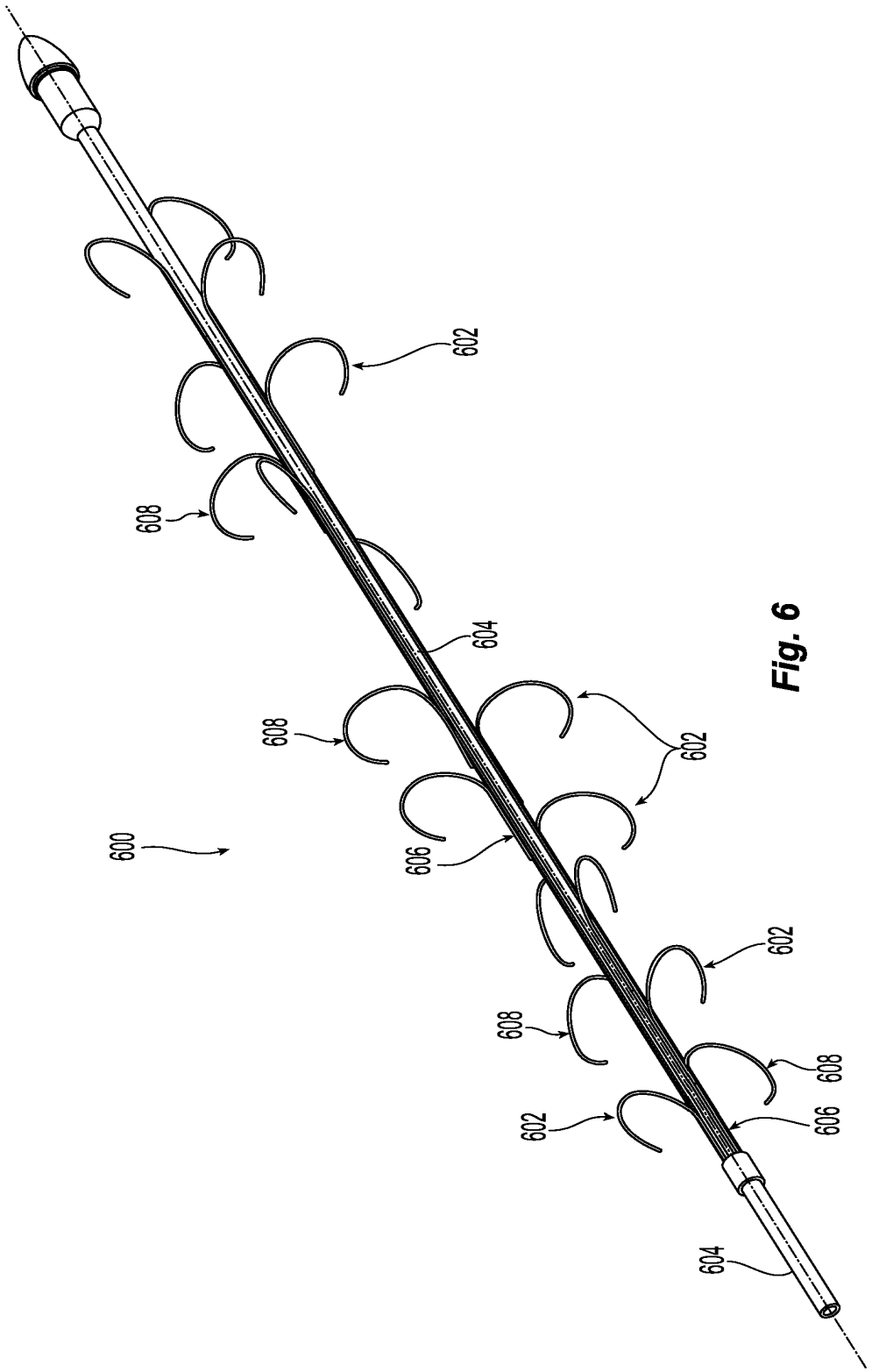

Fig. 6

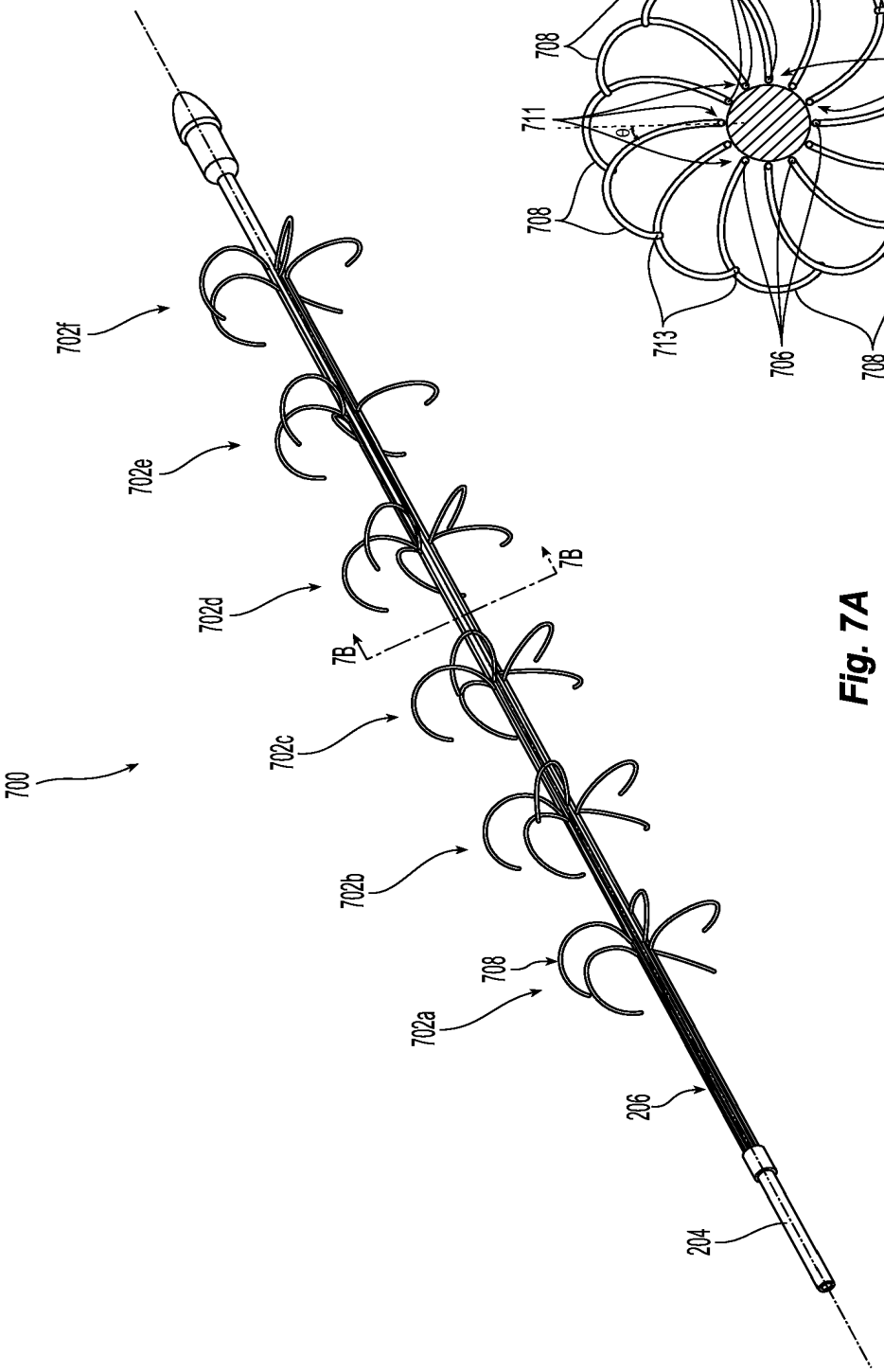
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Fig. 7A

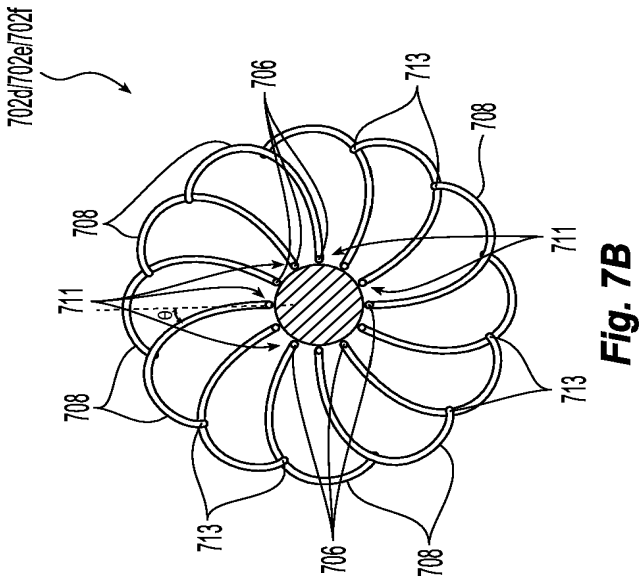
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Fig. 7B

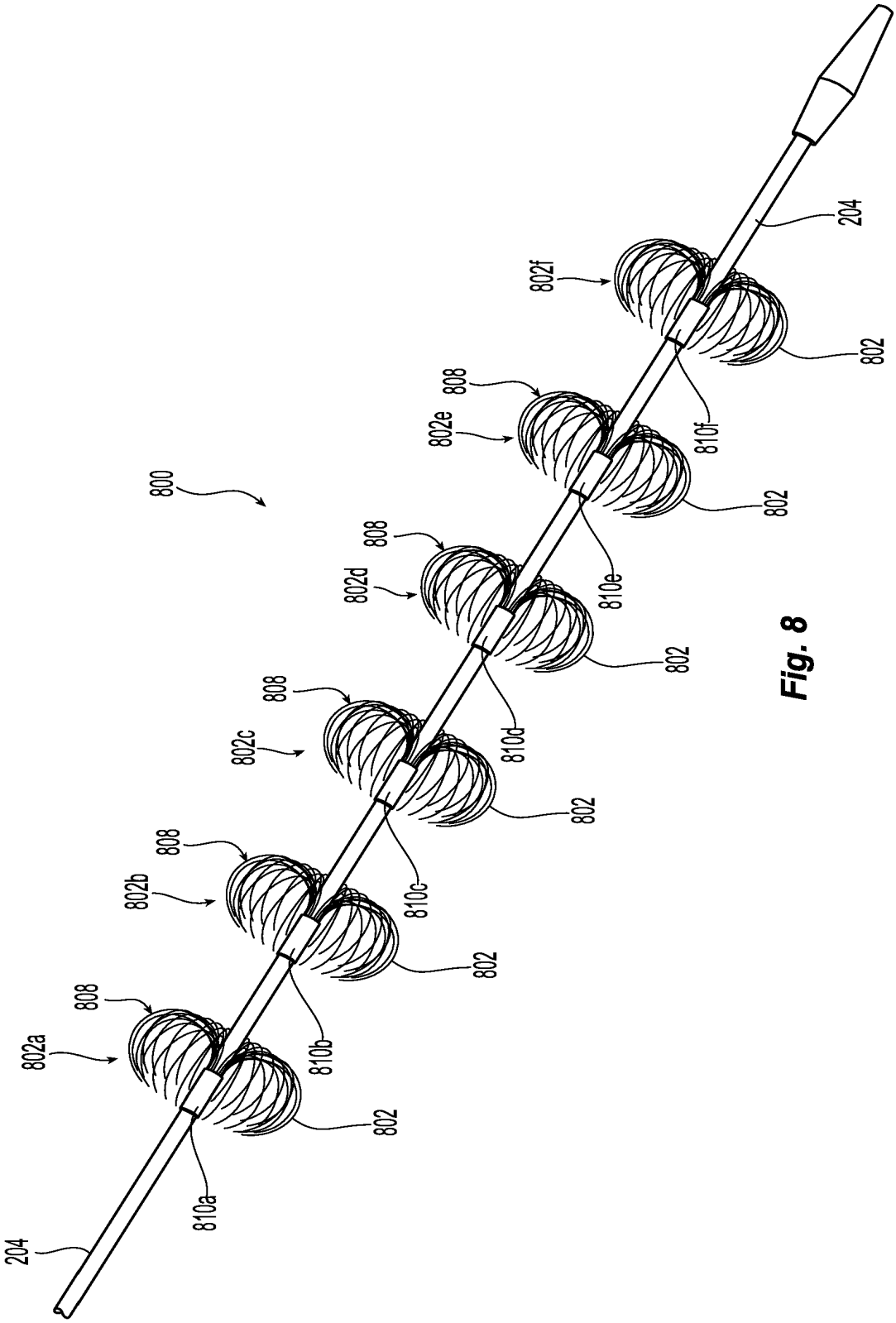
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Fig. 8

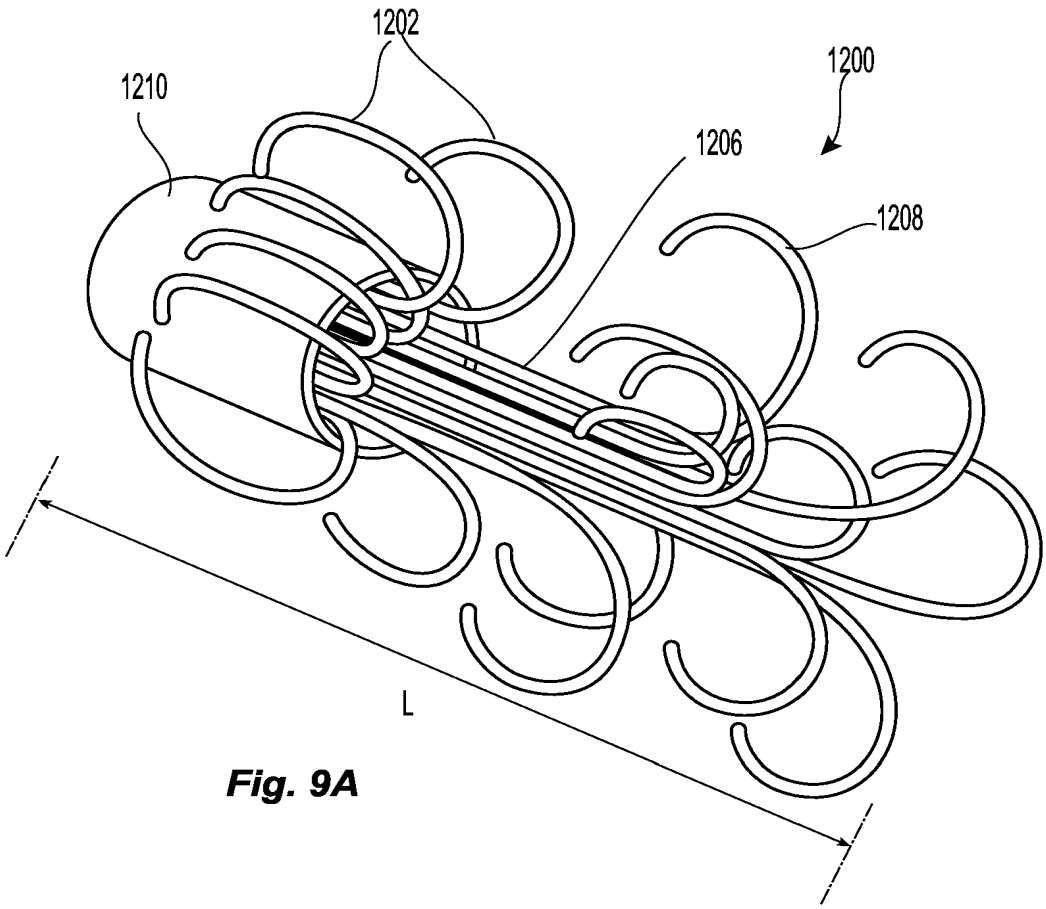

Fig. 9A

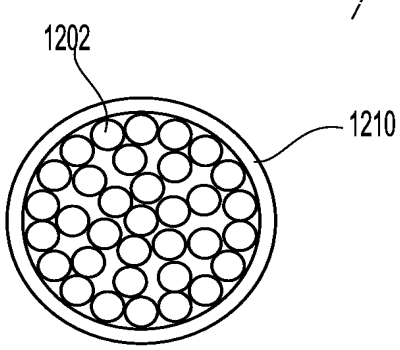

Fig. 9B

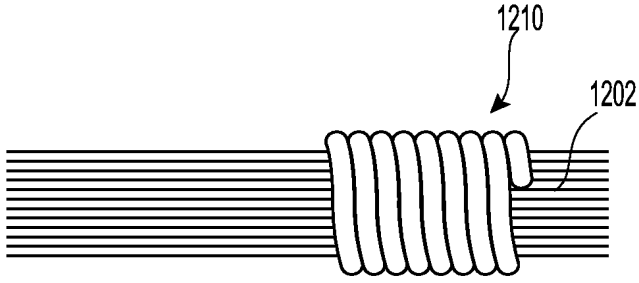

Fig. 9C

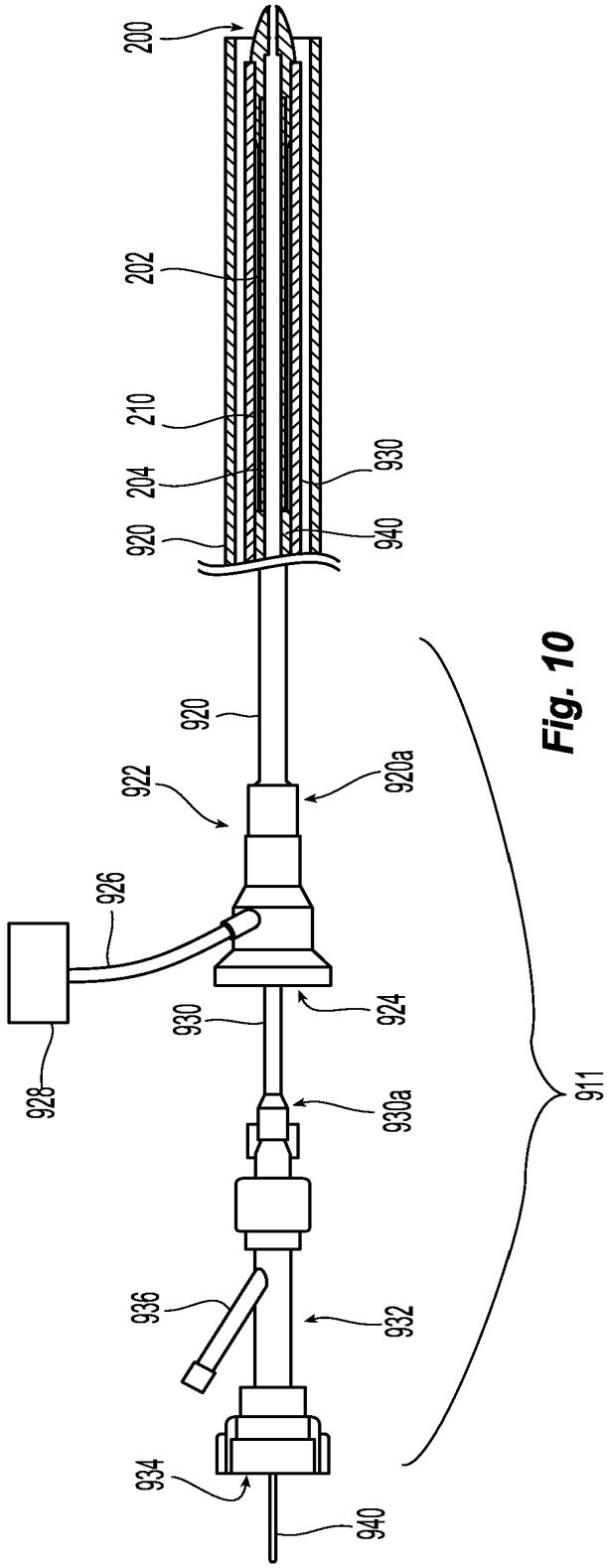
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Fig. 10

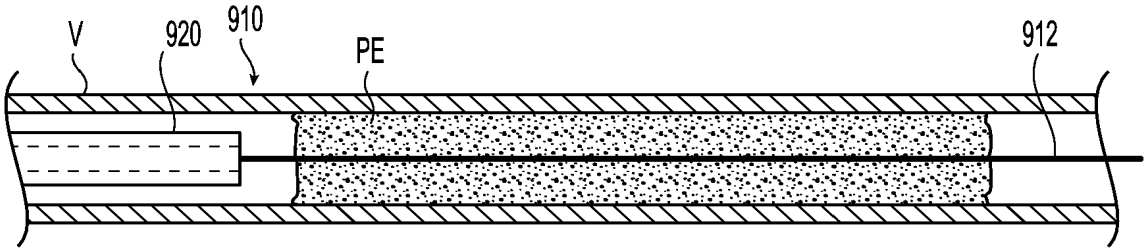

Fig. 11A

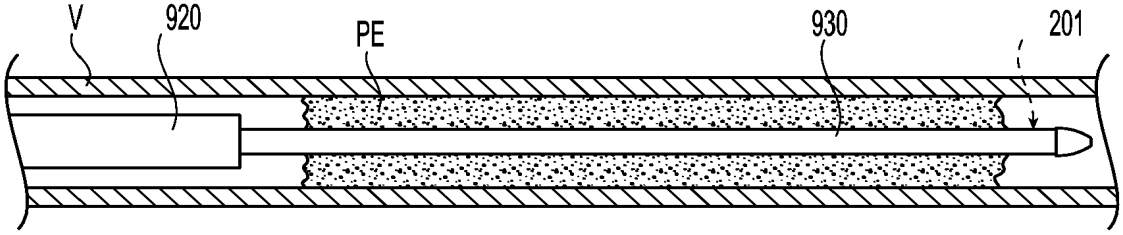

Fig. 11B

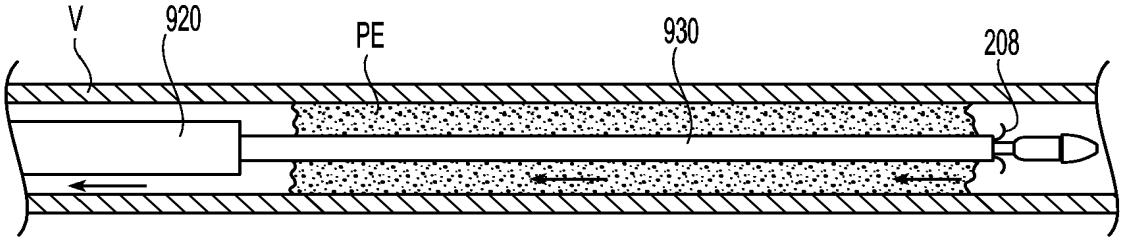

Fig. 11C

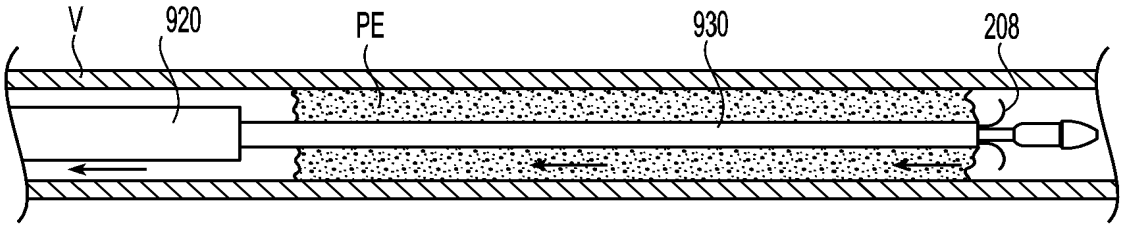

Fig. 11D

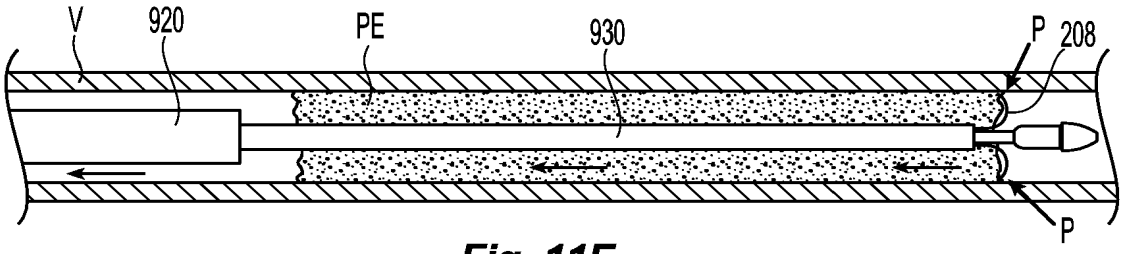

Fig. 11E

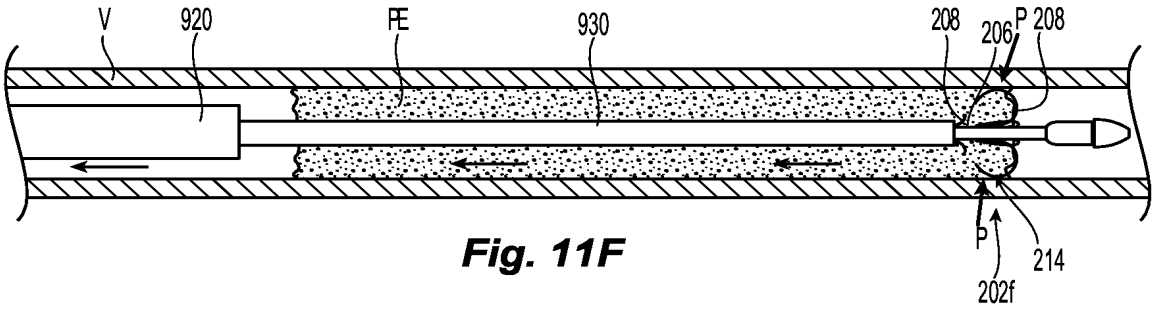

Fig. 11F

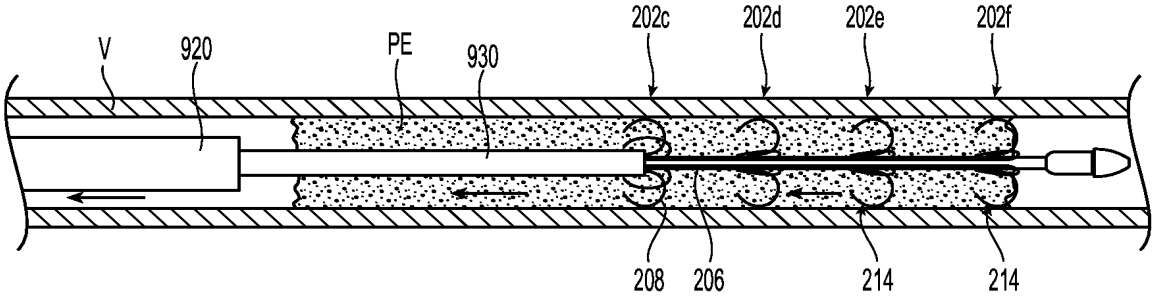

Fig. 11G

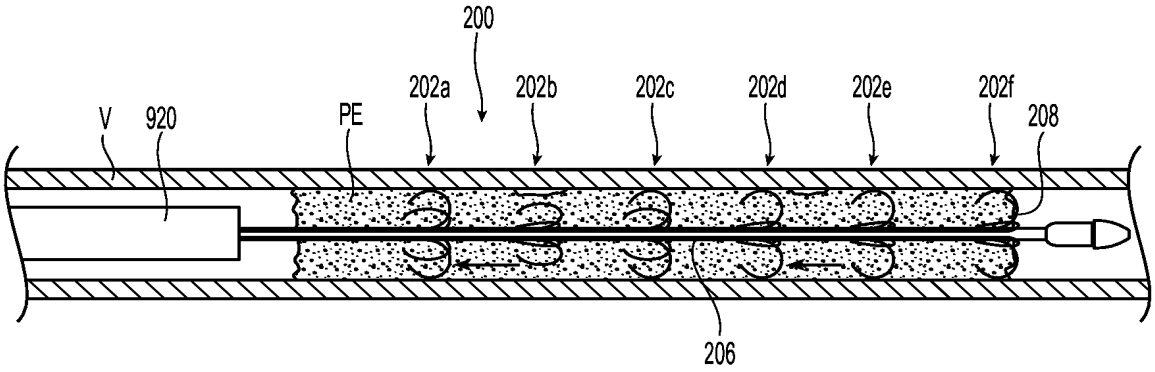

Fig. 11H

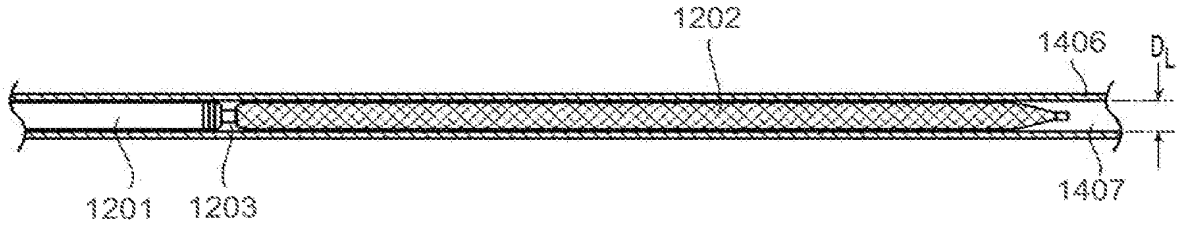
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Fig. 12

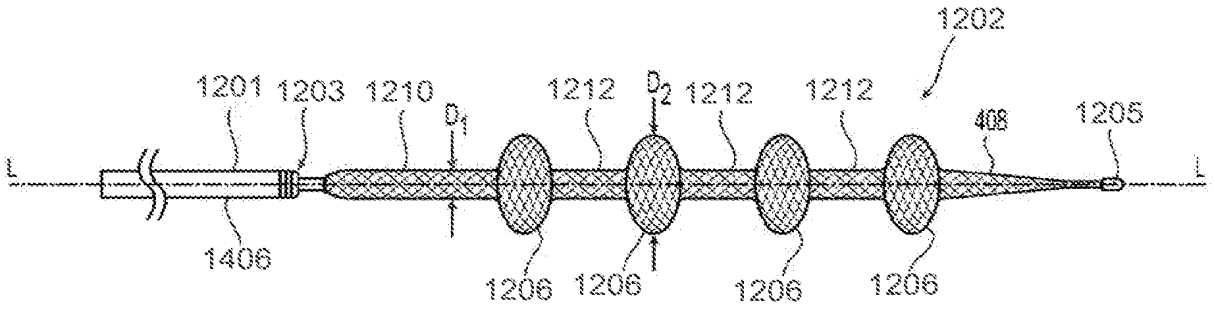
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Fig. 13

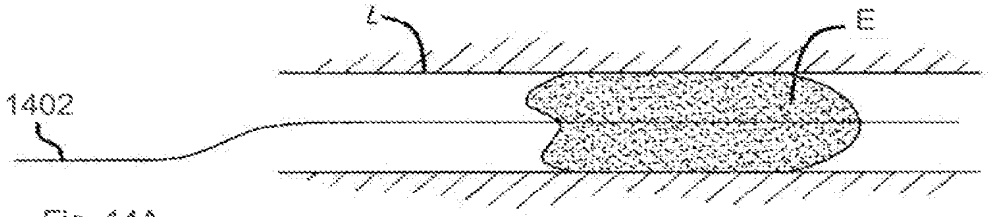

Fig. 14A

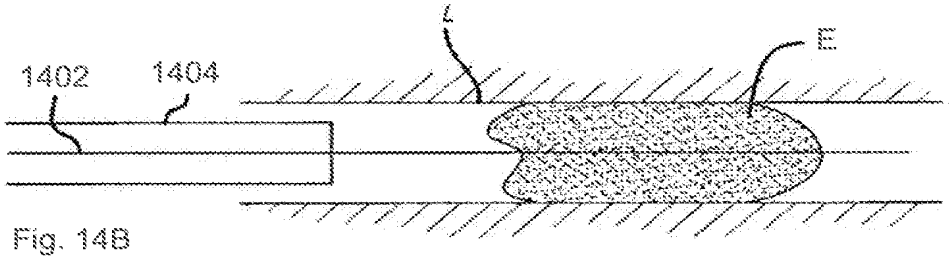

Fig. 14B

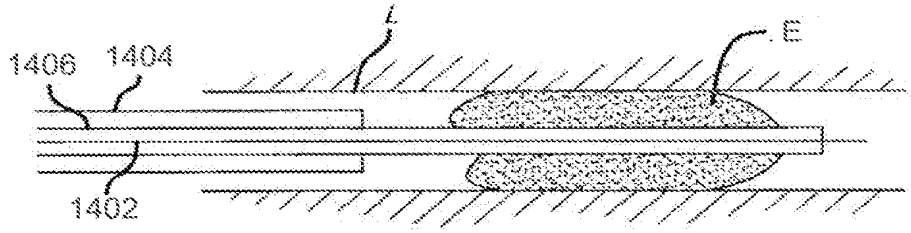

Fig. 14C

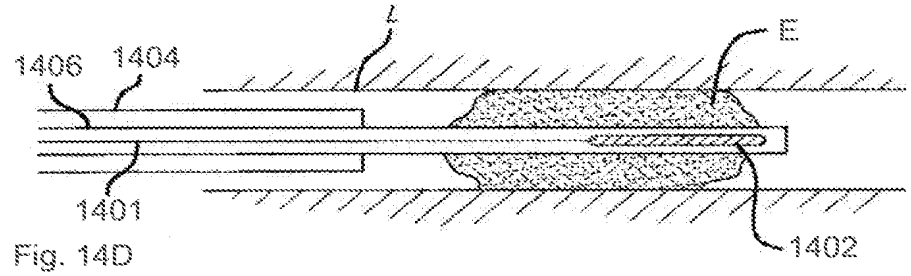

Fig. 14D

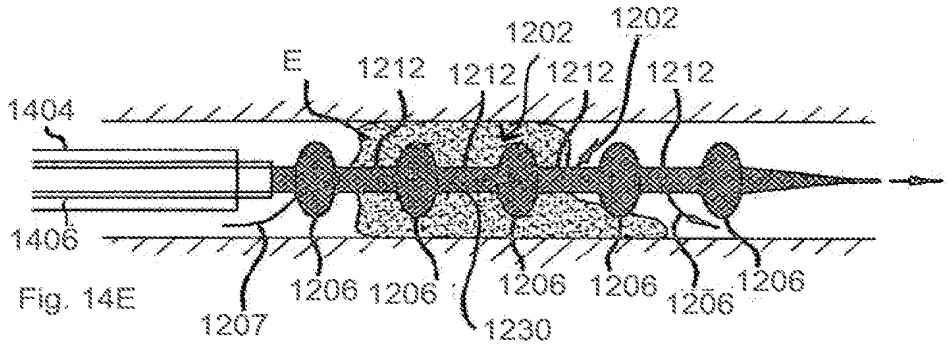

Fig. 14E

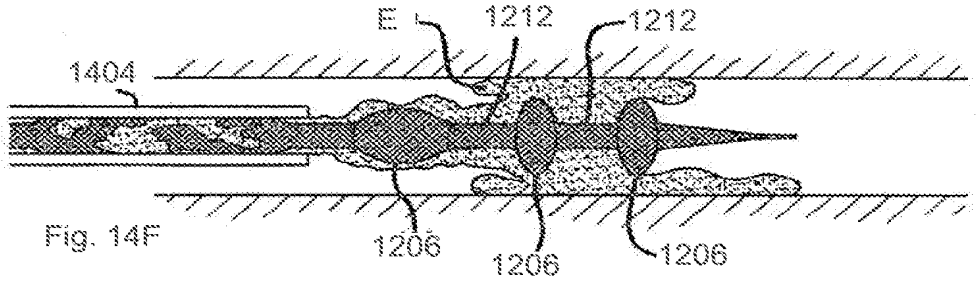

Fig. 14F

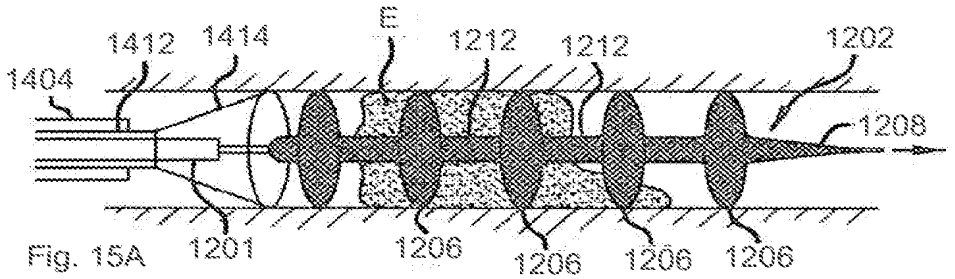

Fig. 15A

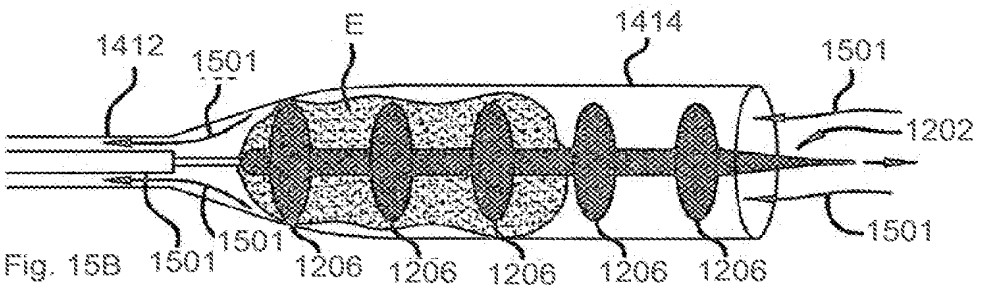

Fig. 15B

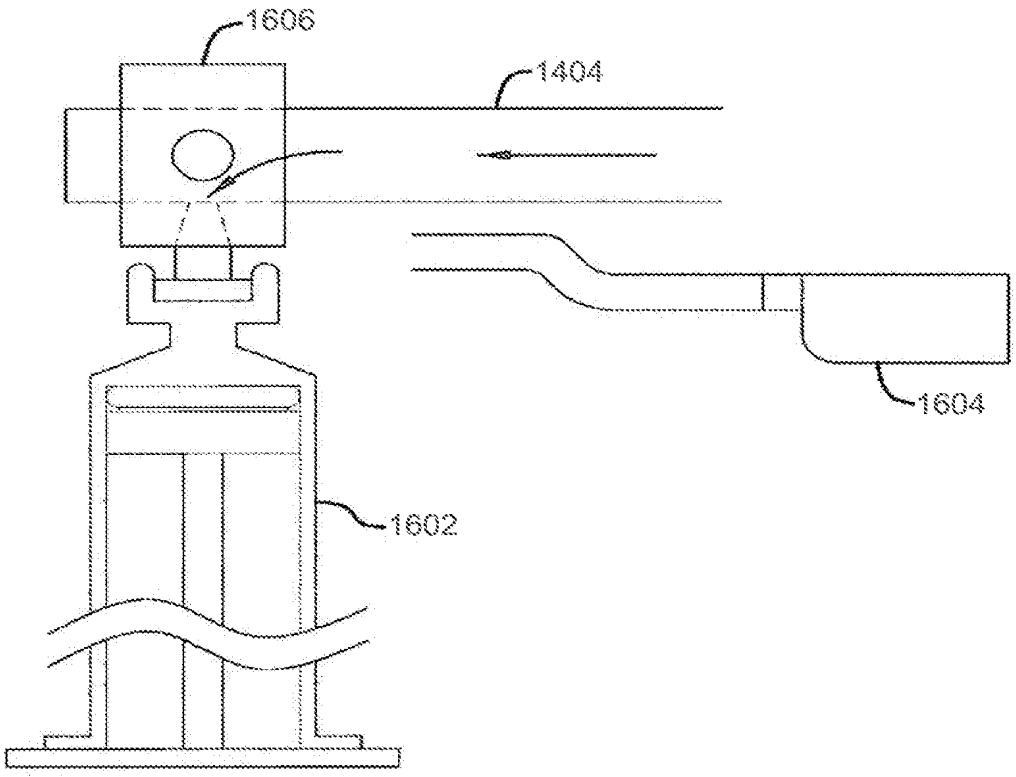

Fig. 16

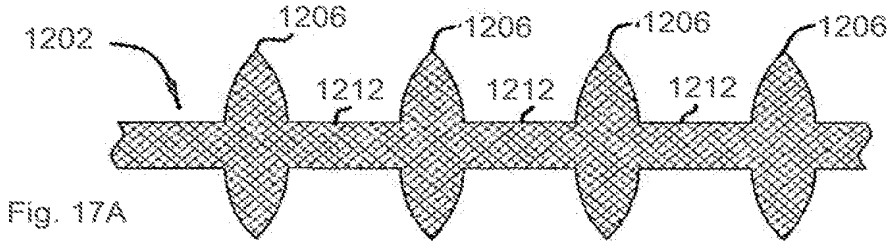

Fig. 17A

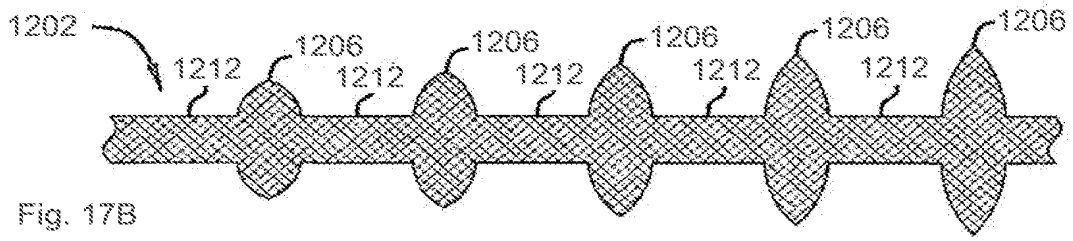

Fig. 17B

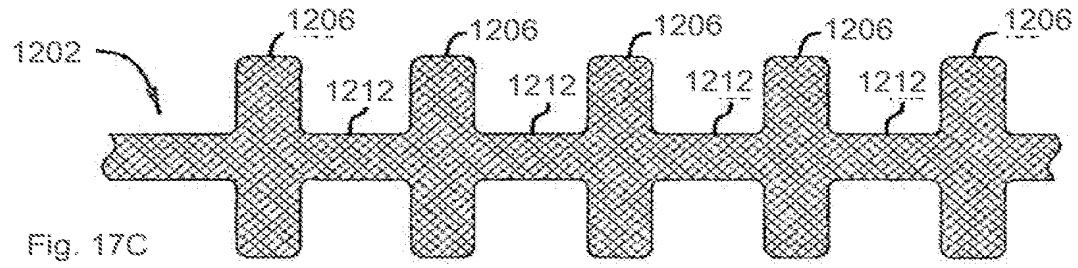

Fig. 17C

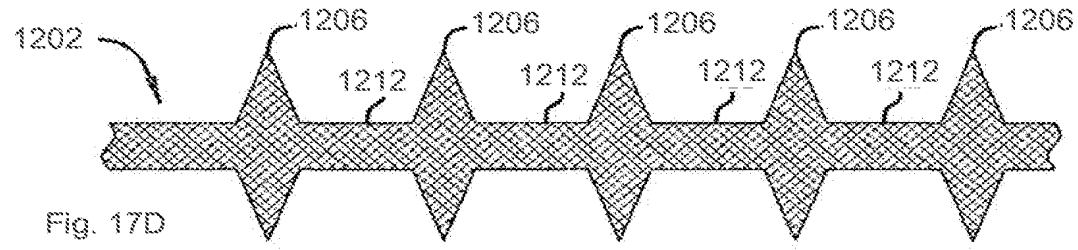

Fig. 17D

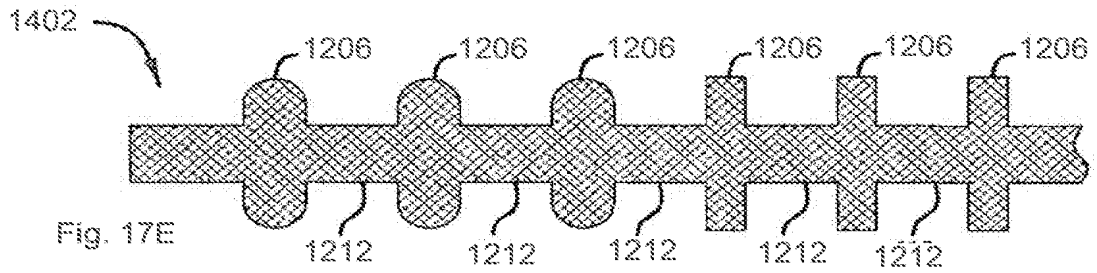

Fig. 17E

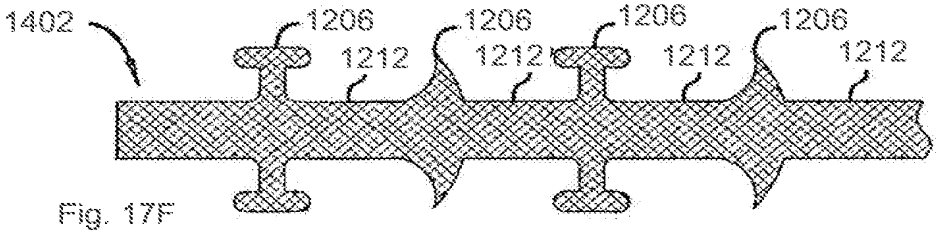

Fig. 17F

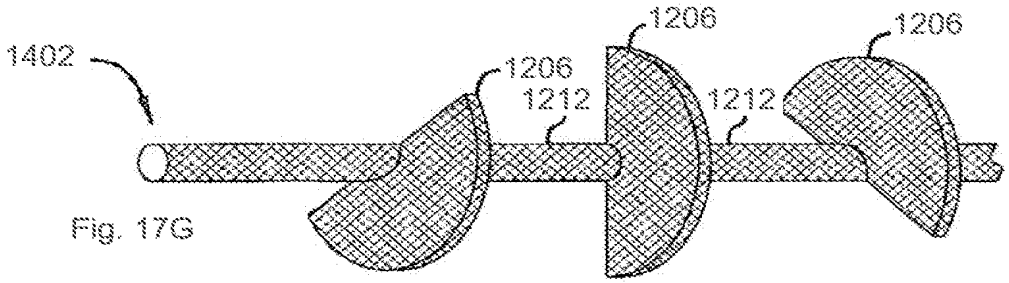

Fig. 17G

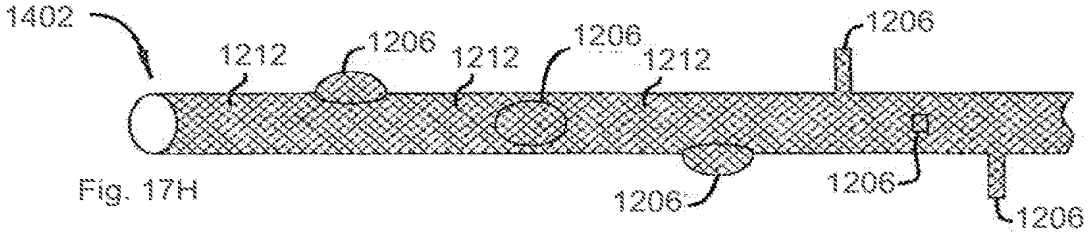

Fig. 17H

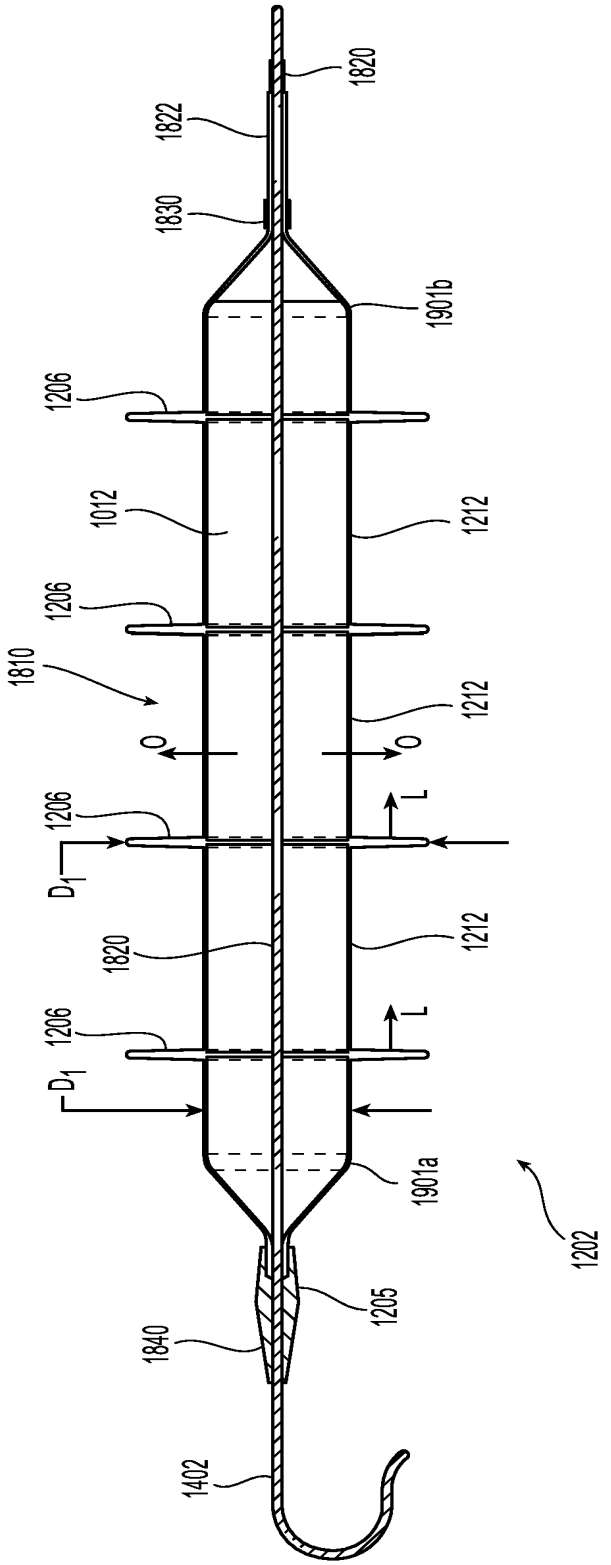
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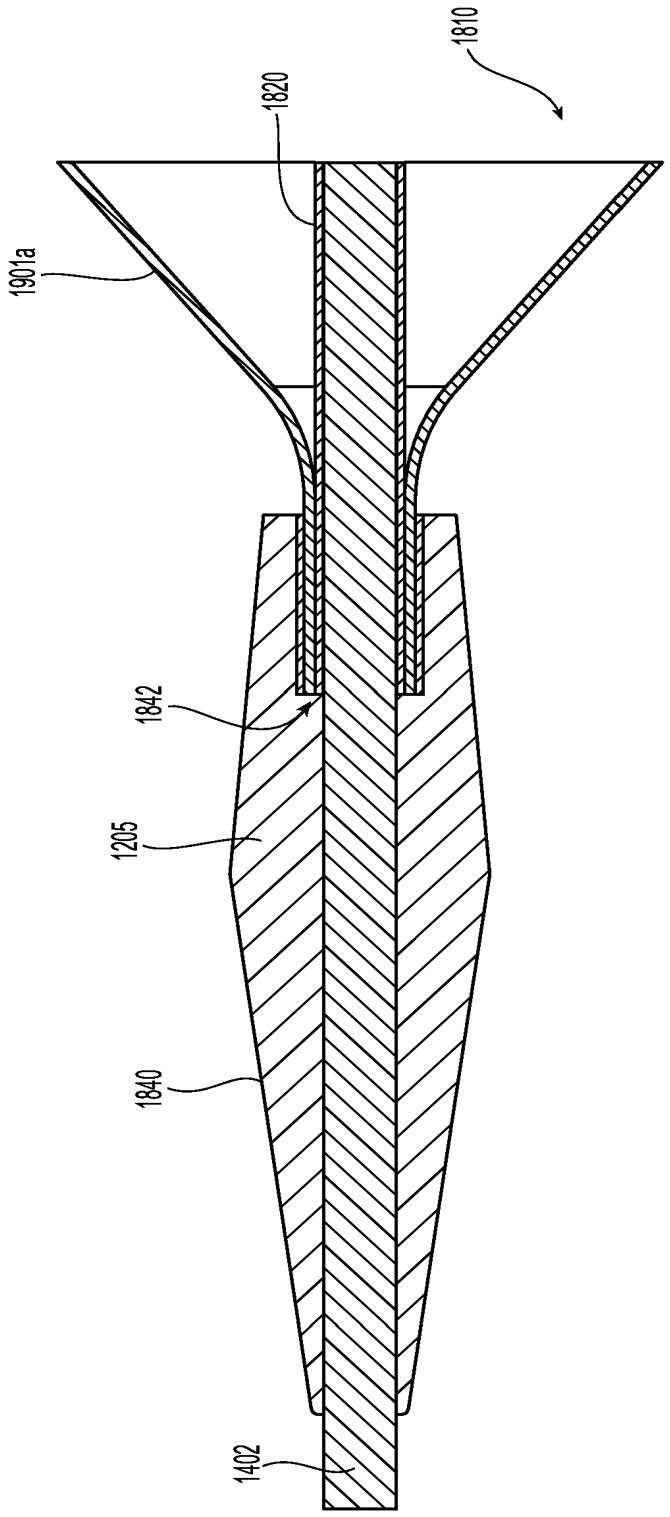
Fig. 18



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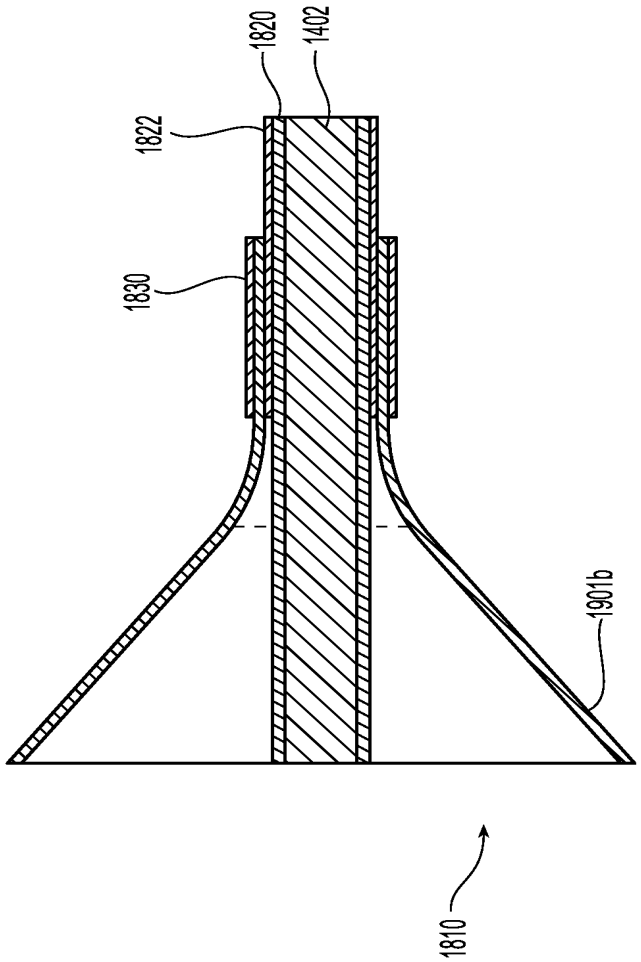

Fig. 20

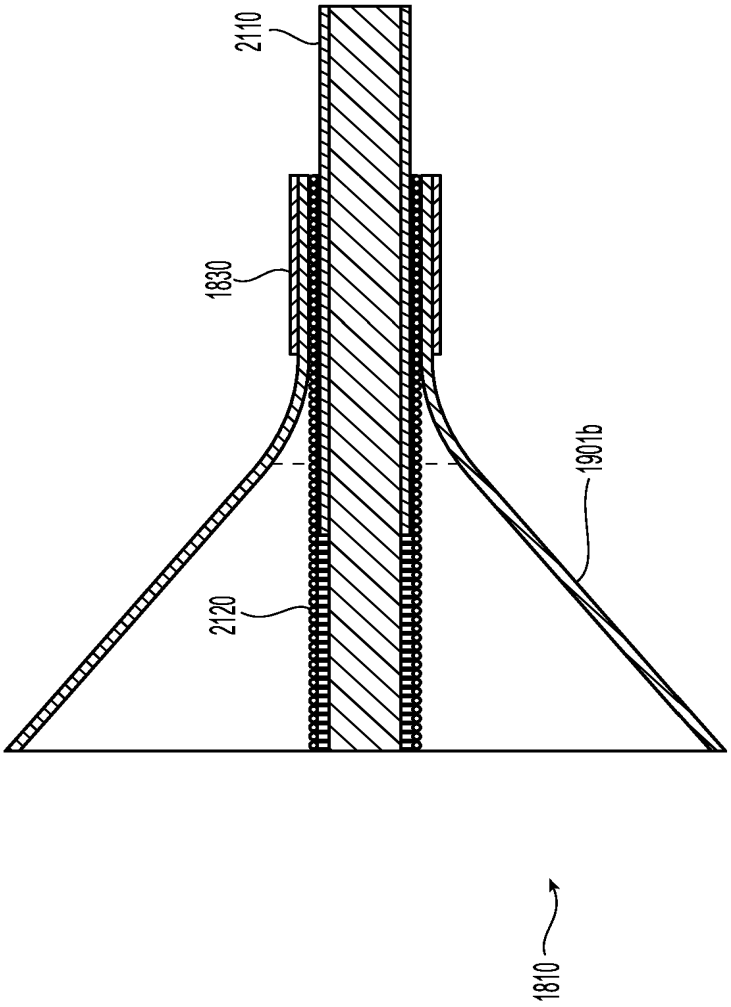

Fig. 21

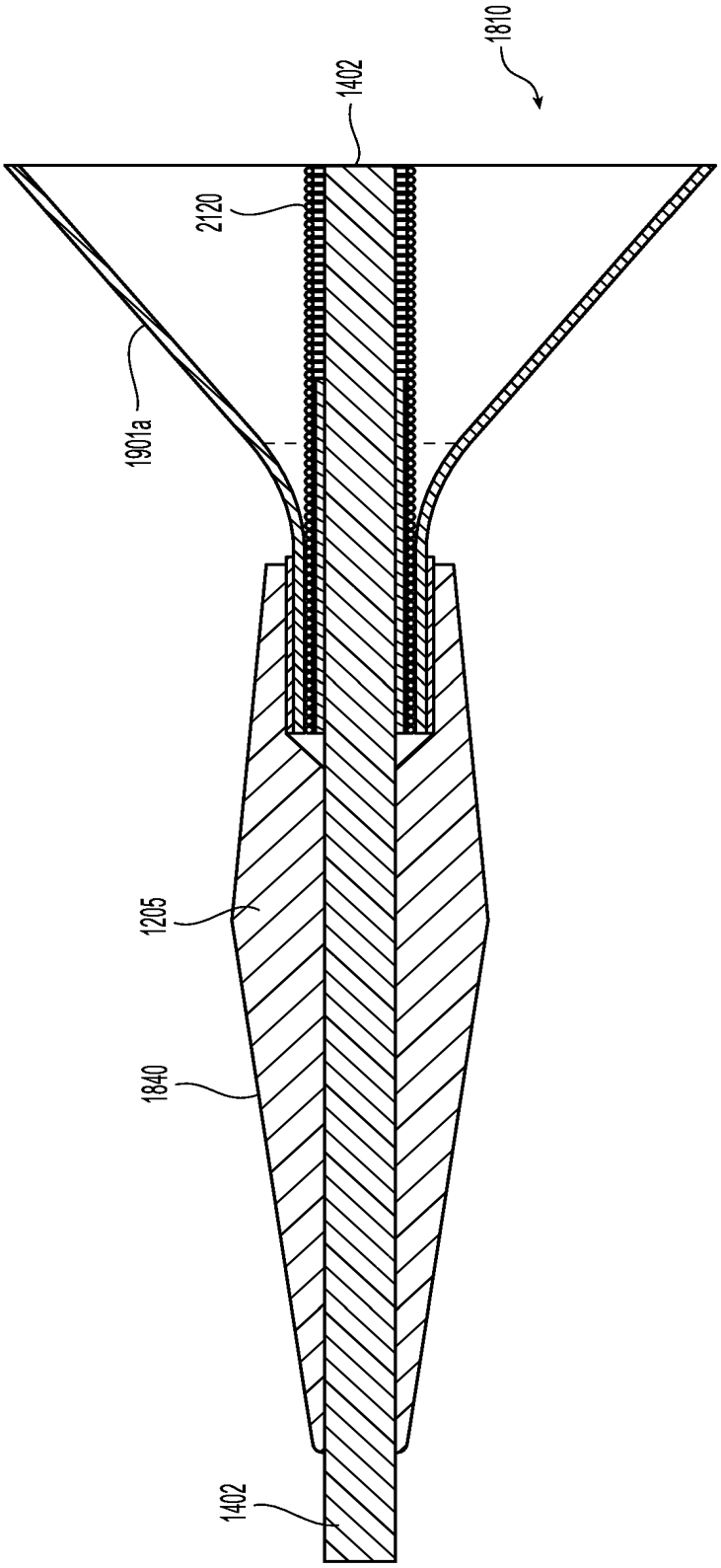

Fig. 22

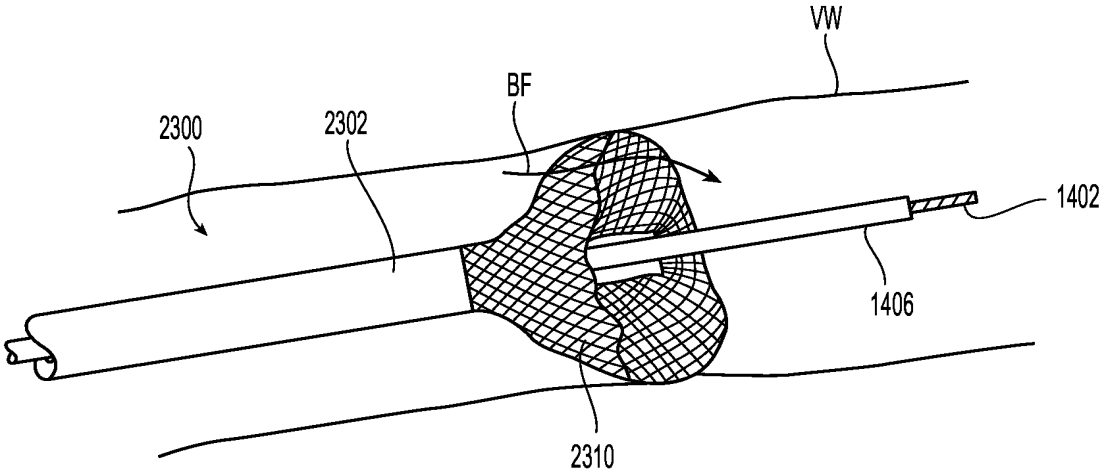

Fig. 23

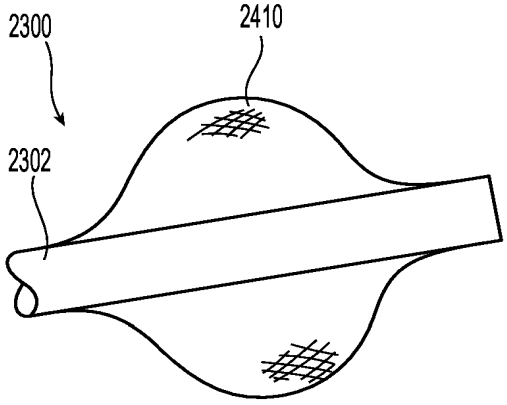

Fig. 24

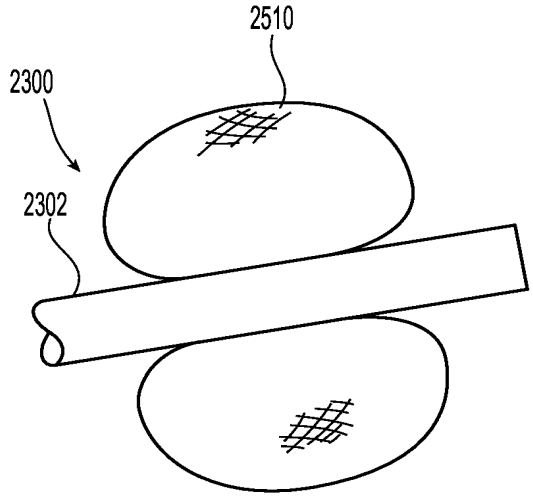

Fig. 25

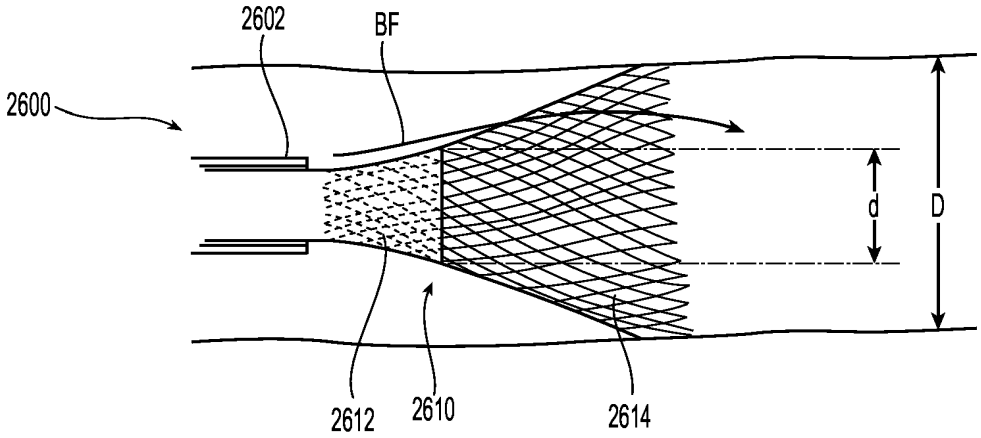

Fig. 26

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/046567

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/22(2006.01)i, A61B 17/3205(2006.01)i, A61M 25/01(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B 17/22; A61M 29/00; A61B 17/3205; A61M 25/01

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords:pulmonary embolism, support member, clot engagement members, curved portion

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008-0228209 A1 (DEMELLO et al.) 18 September 2008 See paragraphs [0070], [0073], [0075], [0076], [0087]-[0090]; claims 1, 2; and figures 7, 15-17.	1,2
A		5-7
X	US 2011-0213403 A1 (ABOYTES, MARIA) 1 September 2011 See abstract; paragraphs [0084]-[0089]; and figures 4A-4B.	5-7
A	US 6254571 B1 (HART, CHARLES C.) 3 July 2001 See column 4, line 30 - column 6, line 17; column 7, lines 7-31; and figures 1A-2B, 5A-5D.	1,2,5-7
A	US 2008-0167678 A1 (MORSI, HESHAM) 10 July 2008 See paragraphs [0031]-[0033], [0044]-[0052]; and figures 3, 6.	1,2,5-7
A	US 2011-0251629 A1 (GALDONIK et al.) 13 October 2011 See paragraphs [0075], [0076], [0092], [0093]; and figures 2, 11.	1,2,5-7
A	US 6066149 A (SAMSON et al.) 23 May 2000 See column 5, line 43-column 6, line 35; column 9, line 31-column 10, line 13; and figures 2A-2B, 6A-6D.	1,2,5-7

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"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 October 2014 (29.10.2014)	**03 November 2014 (03.11.2014)**

Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701,
Republic of Korea
Facsimile No. +82-42-472-7140

Authorized officer
CHANG, Bong Ho
Telephone No. +82-42-481-3353

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/046567

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.: 3 ,4
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 3 and 4 pertain to methods for treatment of the human body by surgery, and thus relate to a subject-matter which this International Searching Authority is not required, under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv), to search.

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 addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2014/046567

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2008-0228209 A1	18/09/2008	US 2005-0234474 A1	20/10/2005
		US 2007-0118165 A1	24/05/2007
		WO 2008-051431 A1	02/05/2008
US 2011-0213403 A1	01/09/2011	None	
US 6254571 B1	03/07/2001	WO 97-38631 A1	23/10/1997
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		WO 2008-086180 A1	17/07/2008
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		US 6383205 B1	07/05/2002
		US 7875050 B2	25/01/2011
		US 8486104 B2	16/07/2013
		WO 99-16362 A1	08/04/1999

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
7 January 2010 (07.01.2010)

PCT

(10) International Publication Number
WO 2010/003135 A2

(51) International Patent Classification:
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(21) International Application Number:
PCT/US2009/049639

(22) International Filing Date:
2 July 2009 (02.07.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

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61/153,620	18 February 2009 (18.02.2009)	US
61/214,667	27 April 2009 (27.04.2009)	US
61/215,732	8 May 2009 (08.05.2009)	US

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(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **KROLIK, Jeffrey, A.** [US/US]; 1198 Longfellow Avenue, Campbell, CA 95008 (US). **MIRZAE, Daryush** [US/US]; 629 Ashbourne Drive, Sunnyvale, CA 94087 (US). **WATANABE, Gwendolyn** [US/US]; 1134 Parkington Avenue, Sunnyvale, CA 94087 (US). **DOMINGO, Juan** [US/US]; 881 Trestle Point, Lathrop, CA 95330 (US). **DREHER, James, H.** [US/US]; 744 San Lorenzo Street, Santa Monica, CA 90402 (US).

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(54) **Title**: APPARATUS AND METHODS FOR TREATING OBSTRUCTIONS WITHIN BODY LUMENS

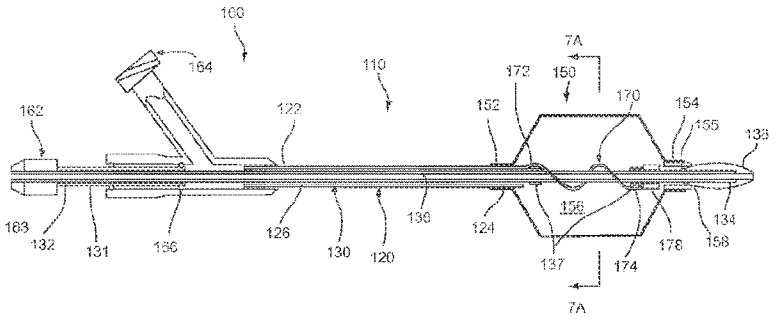

FIG. 7

(57) **Abstract**: An apparatus is provided that is operable in different modes to perform various functions for treating a body lumen. The apparatus includes a shaft including a proximal end, a distal end, a lumen extending therebetween, and a balloon on the distal end having an interior communicating with the lumen. The apparatus includes a valve on the distal end that selectively opens or closes an outlet communicating with the lumen. With the valve open, fluid introduced into the lumen exits the outlet into a body lumen. With the valve closed, fluid introduced into the lumen expands the balloon. The apparatus also includes an actuator for axially compressing the balloon, and a helical member extends between ends of the balloon interior that expands the balloon from a contracted condition to an expanded helical shape when the actuator is activated.

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APPARATUS AND METHODS FOR TREATING OBSTRUCTIONS WITHIN BODY LUMENS

FIELD OF THE INVENTION

The present invention relates generally to apparatus for treating obstructive material and/or other obstructions within a body lumen of a patient, e.g., within a tubular graft, aorto-venous fistula, blood vessel, and the like. More particularly, the present invention relates to apparatus, e.g., balloon catheters, for infusing fluids into a body lumen, for removing or otherwise capturing thrombus or other obstructive material within a body lumen, and/or for dilating a body lumen, and to methods for making and using such apparatus.

BACKGROUND

Flow within a blood vessel or other body lumen within a patient's vasculature may become constricted or ultimately interrupted for a variety of reasons. For example, a vessel may gradually narrow due to inflammation and/or cell proliferation. In addition, thrombus may form due to such narrowing or other flow problems within a vessel.

For example, an aorto-venous graft may be implanted in an arm of a patient experiencing kidney failure, e.g., to facilitate dialysis treatment. Such grafts may be a fistula formed directly in the patient's body, e.g., through tissue between an adjacent artery and vein or other vessels, may be a xenograft implanted between two vessels, or may be a synthetic graft. Such grafts only have a limited life cycle due to inflammation, thrombus formation, and the like. Once such a graft becomes sufficiently occluded or otherwise deteriorates, a new graft must be implanted at a new location for subsequent treatment.

Accordingly, apparatus and methods for removing material from aorto-venous grafts, blood vessels, or other body lumens and/or otherwise treating body lumens would be useful.

SUMMARY

The present invention is directed to apparatus for treating a body lumen of a patient, e.g., a tubular graft, aorto-venous fistula, blood vessel, and the like. More particularly, the present invention is directed to apparatus for infusing fluids into a body

lumen, for removing or otherwise capturing thrombus or other obstructive material within a body lumen, and/or for dilating a body lumen, and to methods for making and using such apparatus.

In accordance with a first embodiment, an apparatus is provided for treating a body lumen that is operable in different modes to perform various functions, e.g., possibly reducing the number of device exchanges during a procedure. For example, the apparatus may include a shaft including a proximal end, a distal end sized for introduction into a body lumen, a lumen extending therebetween, and a balloon on the distal end having an interior communicating with the lumen. The apparatus may also include a valve on the distal end of the shaft that selectively opens or closes an outlet communicating with the lumen. With the valve open, fluid introduced into the lumen may exit the outlet into a body lumen beyond the distal end. With the valve closed, fluid introduced into the lumen may expand the balloon from a contracted condition to an expanded condition, e.g., a cylindrical shape for dilating an obstruction within a body lumen or a bulbous shape for removing material within the body lumen. Optionally, the valve may include a stop that may be extended to push a distal end of the balloon, e.g., to stretch or otherwise reduce a profile of the balloon and/or otherwise facilitate introduction into a patient's body.

In addition or alternatively, the apparatus may include an actuator for axially compressing the balloon, and the balloon may be configured to expand from the contracted condition to an expanded helical shape when axially compressed. For example, the actuator may include an inner member within the shaft that is coupled to a distal end of the balloon, and a helical member may extend around the inner member within the balloon. When the inner member is directed proximally or otherwise actuated, the helical member may be compressed and consequently expand radially outwardly, thereby expanding the balloon to the expanded helical shape. The inner member may be extended distally to extend and return the balloon back towards the contracted condition, e.g., after using the balloon in the expanded helical shape to remove material within a body lumen.

In accordance with another embodiment, an apparatus is provided for treating a body lumen that includes an elongate tubular member including a proximal end, a distal end, and a first lumen extending between the proximal and distal ends; an expandable balloon including a proximal end secured to the tubular member distal end, and a distal end including an outlet, the balloon including an interior communicating with the first lumen and the balloon outlet; and an elongate member slidably disposed within the first

lumen. The elongate member may include a proximal end adjacent the tubular member proximal end, and a distal end extending from the balloon outlet. The balloon and elongate member may include cooperating features providing a valve for selectively opening and closing the balloon outlet. For example, a sealing member on the distal end of the elongate member sized to be engaged with the balloon distal end to substantially seal the outlet from fluid flow.

The elongate member may be movable between a first position wherein the sealing member is spaced part from the balloon outlet such that fluid introduced through the first lumen passes through the balloon interior and out the balloon outlet, and a second position wherein the sealing member substantially seals the balloon outlet such that fluid introduced through the first lumen enters the balloon interior to expand the balloon.

Optionally, the apparatus may include a helical member including a first end coupled to the tubular member distal end and a second end coupled to the elongate member distal end, the helical member extending helically around the elongate member within the balloon interior. The elongate member may be movable to a third position in which the elongate member distal end is directed towards the tubular member distal end to cause the helical member to compress axially and expand radially outwardly, thereby expanding the balloon to an expanded helical shape.

In accordance with yet another embodiment, an apparatus is provided for treating a body lumen that includes an outer tubular member including a proximal end, a distal end, and a first lumen extending between the proximal and distal ends; an inner member slidably disposed within the first lumen; and an expandable balloon including a proximal end secured to the outer member distal end, an interior communicating with the first lumen and a balloon outlet. The inner member includes a distal end extending from the balloon outlet, and carrying one or more sealing members. A helical member includes a first end coupled to the outer member distal end and a second end coupled to the inner member distal end, the helical member extending helically around the inner member within the balloon interior.

The inner member may be movable relative to the outer member for deploying the balloon in multiple modes. For example, the inner member may be movable from a first position wherein the sealing member is spaced from the balloon outlet such that fluid introduced through the first lumen passes through the balloon interior and out the balloon outlet, and a second position wherein the sealing member substantially seals the balloon

outlet such that fluid introduced through the first lumen enters the balloon interior to expand the balloon. In addition or alternatively, the inner member may be movable from the first position to a third position in which the inner member distal end is directed proximally towards the outer member distal end to cause the helical member to expand radially outwardly, thereby expanding the balloon to an expanded helical shape.

In accordance with still another embodiment, an apparatus is provided for treating a body lumen that includes an outer tubular member including a first lumen extending between proximal and distal ends thereof, an inner member slidably disposed within the first lumen, and an expandable balloon comprising a proximal end secured to the outer member distal end, and a distal end coupled to a distal end of the inner member. The balloon includes an interior communicating with the first lumen such that inflation media may be delivered through the first lumen into the balloon interior for expanding the balloon radially outwardly from a contracted condition to an expanded condition, e.g., defining a cylindrical or bulbous shape. The inner member may be movable axially relative to the outer member for causing the balloon to compress axially and expand radially from the contracted condition to an expanded helical shape.

For example, the apparatus may include a helical member extending helically around the inner member within the balloon interior, and including a first end coupled to the outer member distal end and a second end coupled to the inner member. When the inner member is moved axially, the helical member may be compressed axially and expanded radially outwardly, thereby directing the balloon to the expanded helical shape.

Optionally, the inner member may include a second lumen extending between the inner member proximal and distal ends, e.g., for receiving a guidewire or other rail. Thus, the apparatus may be advanced over a guidewire loaded through the second lumen. Once the balloon is disposed within a target body lumen, the inner member may be directed to one or more of the first, second, and/or third positions, as desired, to perform various functions using the apparatus, e.g., without having to remove the apparatus and/or introduce another device into the body lumen,

In accordance with another embodiment, a method is provided for treating a body lumen of a patient using a balloon apparatus that includes an elongate shaft including a first lumen extending between proximal and distal ends thereof, and a balloon carried on the distal end of the shaft that includes an outlet and an interior communicating with the first lumen and the outlet. The distal end of the shaft may be introduced into a body lumen

with the balloon in a contracted condition, and positioned relative to obstructive material within the body lumen that is to be removed. Once positioned adjacent the obstructive material, the balloon may be expanded from the contracted condition to an expanded helical shape, and the distal end of the apparatus may be directed along the body lumen with the balloon in the expanded helical shape to remove the material from the body lumen. For example, the helical shape of the balloon may enhance dislodging material adhered to a wall of the body lumen. Optionally, the balloon may include one or more features, e.g., edges, grooves, and the like, to facilitate separating adherent material from the wall of the body lumen. If desired, the balloon may be returned to the contracted condition, moved to a new location within the body lumen, and again expanded to the expanded helical shape to remove additional material within the body lumen. Once sufficient material is removed, the balloon may be returned to the contracted condition.

Before or after removing obstructive material from the body lumen, inflation media may be introduced through the first lumen into the balloon interior to expand the balloon from the contracted condition to an expanded condition, e.g., defining a substantially cylindrical shape. The balloon may be expanded to dilate an obstruction, lesion or otherwise treat a wall of the body lumen. After dilating the body lumen, the inflation media may be withdrawn from the balloon interior through the first lumen to collapse the balloon back towards the contracted condition.

If the apparatus includes a valve adjacent the balloon for opening or closing an outlet communicating with the first lumen and the balloon interior, the valve may be closed before inflating the balloon. Optionally, at any time during the procedure, the valve may be opened, e.g., to infuse fluid into the body lumen, e.g., for diagnostic and/or therapeutic purposes. After expanding the balloon one or more times, e.g., to the cylindrical shape and/or helical shape, the distal end of the apparatus may be removed from the body lumen and/or entirely from the patient's body with the balloon in the contracted condition.

Other aspects and features of the present invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

It will be appreciated that the exemplary apparatus shown in the drawings are not necessarily drawn to scale, with emphasis instead being placed on illustrating the various aspects and features of the illustrated embodiments.

FIG. 1 is a side view of a first exemplary embodiment of an apparatus including a balloon for treating a body lumen, the apparatus operable in a first mode for minimizing a profile of the apparatus for introduction into the body lumen, a second mode for infusing fluid into the body lumen, and a third mode for removing material within the body lumen.

FIG. 2 is a side view of the apparatus of FIG. 1 in the first mode for minimizing a profile of the apparatus for introduction into a body lumen.

FIG. 3 is a side view of the apparatus of FIG. 1 in the second mode for infusing fluid into a body lumen.

FIG. 4 is a side view of the apparatus of FIG. 1 in the third mode in which the balloon is expanded for removing material within a body lumen.

FIG. 5 is a side view of the apparatus of FIGS. 1 and 4 in the third mode, showing a size of the balloon being increased to facilitate removing material within a body lumen.

FIGS. 6A-6D are side view details of the apparatus of FIGS. 1-5, showing alternative configurations for the balloon.

FIG. 7 is a side view of a second exemplary embodiment of an apparatus including a balloon for treating a body lumen, the apparatus operable in a first mode for infusing fluid into the body lumen, a second mode for dilating an obstruction within the body lumen, and a third mode for removing material within the body lumen.

FIGS. 7A-7H are cross-sections of the balloon of the apparatus of FIG. 7, showing alternate constructions for integrally forming a helical member into the balloon.

FIG. 8 is a side view of a third exemplary embodiment of an apparatus including a balloon for treating a body lumen, the apparatus operable in a first mode for dilating an obstruction within the body lumen, and a second mode for removing material within the body lumen.

FIGS. 9A-9G are cross-sections of a body lumen showing exemplary methods for removing thrombus or other obstructive material from the body lumen and/or for dilating an obstruction within the body lumen using the apparatus of FIG. 7 or 8.

FIGS. 10A-10D are cross-sectional views of alternative embodiments of balloon structures that may be provided on the apparatus of FIG. 8 to enhance removal of adherent material within a body lumen.

FIG. 11 is a side view of an alternative embodiment of the apparatus of FIGS. 7 or 8, including an obstruction removal balloon having different size coils in different regions of the balloon.

FIGS. 12 and 13 are cross-sectional views of a patient's body, showing methods for treating an arterio-venous dialysis graft using the apparatus of FIG. 11.

FIG. 14 is a side view of another alternative embodiment of the apparatus of FIG. 11, including a dilation balloon adjacent the obstruction removal balloon.

FIGS. 15A and 15B are alternative embodiments of coil structures that may be provided within the balloon of any of the apparatus of FIGS. 8-14.

FIG. 16 is a side view of a fourth exemplary embodiment of an apparatus including a balloon for treating a body lumen, the apparatus operable in a first mode for removing material within the body lumen, and in a second mode for dilating an obstruction within the body lumen.

FIGS. 17A-17D are side views of the apparatus of FIG. 10, showing operation of the apparatus between an initial delivery configuration (FIG. 11A), the first mode for removing material within a body lumen (FIGS. 11B and 11C), and the second mode for dilating an obstruction within a body lumen (FIG. 11D).

FIG. 18 is a side view of a distal end of another embodiment of a balloon catheter including a plurality of difference size balloons and a valve member for selectively delivering inflation media to one of the balloons.

FIG. 19 is a side view of an exemplary embodiment of an apparatus for removing obstructive material within a body lumen.

FIG. 20 is a detail of a handle of the apparatus of FIG. 19.

FIGS. 21A and 21B are details of a distal end of the apparatus of FIG. 19, showing lumen clearing elements being actuated between a low profile and a large profile, respectively.

FIGS. 22A-22F are cross-sectional views of a body lumen, showing a method for removing obstructive material within the body lumen using the apparatus of FIGS. 18-21B.

FIG. 23A is a perspective view of an apparatus, similar to that shown in FIG. 7, including a first exemplary embodiment of a handle for actuating the apparatus.

FIG. 23B is a cross-sectional detail of components of a rotary knob control on the handle of FIG. 23A with a housing of the handle removed to show internal components.

FIG. 24A is a perspective view of another apparatus, similar to that shown in FIG. 7, including a second exemplary embodiment of a handle for actuating the apparatus.

FIG. 24B is a cross-sectional detail of components of a slider control on the handle of FIG. 24A with a housing of the handle removed to show internal components.

FIG. 24C is a detail of an alternate slider control, similar to that shown in FIGS. 24A and 24B, including visual indicators identifying actuatable positions of the apparatus.

FIG. 25A is a perspective view of yet another apparatus, similar to that shown in FIG. 7, including a third exemplary embodiment of a handle for actuating the apparatus.

FIG. 25B is a cross-sectional detail of components of a rotary wheel control on the handle of FIG. 25A with a housing of the handle removed to show internal components.

FIG. 26A is a perspective view of still another apparatus, similar to that shown in FIG. 7, including a fourth exemplary embodiment of a handle for actuating the apparatus.

FIG. 26B is a cross-sectional detail of components of a squeeze control on the handle of FIG. 26A with a housing of the handle removed to show internal components.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

Turning to the drawings, FIGS. 1-5 show a first exemplary embodiment of an apparatus 10 for treating a body lumen, e.g., for infusing fluid into a body lumen and/or for removing thrombus, objects, and/or obstructive material from within a body lumen, such as a blood vessel, aorto-venous fistula, tubular graft, and the like (not shown). Generally, the apparatus 10 includes a catheter, sheath, or other tubular outer member 20, a core wire, shaft, or other elongate inner member 30, and an expandable balloon 50 carried by the inner and/or outer members 20, 30. The apparatus 10 may be operable in multiple modes, for example, to perform various treatments or other functions within a body lumen, e.g., to reduce or eliminate the need to exchange multiple devices during a procedure within a body lumen. For example, the apparatus 10 may be operable in a first mode for minimizing a profile of the apparatus 10, e.g., to facilitate introduction into a patient's body (FIG. 2), a second mode for infusing fluid into a body lumen (FIG. 3), and a

third mode for removing material within a body lumen (FIGS. 4 and 5), as described further below.

As best seen in FIG. 1, the outer member 20 includes a proximal end 22, a distal end 24 sized for introduction into a body lumen, and a first lumen 26 extending therebetween. The outer member 20 may have a substantially uniform construction along its length, or alternatively, the construction may be varied. For example, a proximal portion of the outer member 20 may be substantially rigid or semi-rigid to facilitate advancement of the apparatus 10 from the proximal end 22 and/or a distal portion of the outer member 20 may be flexible, e.g., to facilitate bending and/or advancement through tortuous anatomy without substantial risk of kinking or buckling. In exemplary embodiments, the outer member 20 may be formed from materials such as metal, plastic, e.g., PEEK, Grilamed L25, and the like, or composite materials. The outer member 20 may have a length between about thirty and one hundred thirty centimeters (30-130 cm) and an outer diameter between about 1.2 to 2.0 millimeters, and the first lumen 26 may have a diameter between about 1.0 and 1.8 millimeters.

The inner member 30 also includes a proximal end 32, a distal end 34, and, optionally, may include a second lumen 36 extending between the proximal and distal ends 32, 34, which may be sized to slidably receive a guide wire, or other rail (not shown) therethrough, e.g., having a diameter between about 0.3 and 1.0 millimeter. The inner member 30 is sized to be slidably received within the first lumen 26 of the outer member 20, e.g., such that an annular space is defined between the outer and inner members 20, 30 for passing one or more fluids therethrough, as described further below. The inner member 30 may have a length relative to the outer member 20 such that the inner member proximal end 32 is received within or extends proximally beyond the outer member proximal end 22 and the inner member distal end 34 extends distally beyond the outer member distal end 24, e.g., through the balloon 50, as described further below.

The balloon 50 includes a proximal end 52 coupled to the outer member distal end 24, a distal end 54 defining an outlet 58, and an interior 56 communicating with the first lumen 26 and the outlet 58. The proximal end 52 of the balloon 50 may be attached or otherwise secured to the distal end 24 of the outer member 20 to provide a fluid-tight connection, e.g., by one or more of bonding with adhesive, interference fit, sonic welding, fusing, engagement with a surrounding sleeve or other connector (not shown), and the like.

The distal end 34 of the inner member 30 may extend through the distal end 54 of the balloon 50, e.g., such that the outlet 58 defines an annular passage between the distal end 54 of the balloon 50 and the distal end 34 of the inner member 30. The size of the outlet 58 may be substantially the same as the size of the first lumen 26, or alternatively, the outlet 58 may be larger or smaller than the first lumen 26, as desired, depending on the desired degree of friction or resistance to fluid flow through the outlet 58. For example, with the outlet 58 open to allow fluid flow, the resistance to fluid flowing through the outlet 58 may be substantially less than the resistance of the balloon 50 to expansion, such that the fluid preferentially flows through the outlet 58, rather than expanding the balloon 50, as described further below.

As shown in FIG. 1, the distal end 54 of the balloon 50 may be integrally formed with the main wall of the balloon 50 (defining the interior 56), and, optionally the proximal end 52 of the balloon 50. For example, the balloon 50 and its proximal and distal ends 52, 54 may be molded, blown, or otherwise formed from a single tubular section of material. Optionally, the main wall of the balloon 50 may be relatively thin compared to the distal end 54, e.g., such that the distal end 54 of the balloon 50 maintains its original size and/or shape as the balloon 50 is expanded.

For example, the distal end 54 of the balloon 50 may be sufficiently thick and/or rigid to provide a sealing ring on the distal end 54. Optionally, the distal end 54 of the balloon 50 may include one or more additional features, e.g., surrounding or otherwise defining the outlet 58 and/or reinforcing the distal end 54. For example, the distal end 54 may include a collar or sleeve (not shown, see, e.g., sleeve 155 shown in FIG. 7), within or around the distal end 54 e.g., attached or otherwise secured to the distal end 54, e.g., by bonding with adhesive, interference fit, sonic welding, fusing, and the like.

The balloon 50 may be formed from elastic material, e.g., to provide a compliant or semi-compliant balloon that may be expanded to a variety of sizes and/or shapes, e.g., based on the amount of fluid and/or pressure within the interior 54 of the balloon 50 and/or the relative position of the inner member 30, as described further below. Alternatively, the balloon 50 may be formed from substantially inelastic material, e.g., to provide a non-compliant balloon that expands to a predetermined size when inflated independent of pressure (once a minimum volume and/or pressure is introduced to achieve the predetermined size). Such a non-compliant balloon 50 may expand to the predetermined size even if inflated to relatively high pressures, e.g., until the balloon 50

bursts or otherwise ruptures, e.g., at pressures of at ten atmospheres, twenty atmospheres, thirty atmospheres, and the like.

One or more sealing members 38 may be carried on the inner member distal end 34, e.g., such that the sealing member(s) 38 are movable relative to the balloon 50 as the inner member 30 is moved, e.g., for selectively opening and closing the outlet 58 of the balloon 50 to provide a valve, as described further below. The sealing member(s) 38 may be formed from flexible materials, e.g., which may enhance engagement with the balloon distal end 54, such as elastomeric materials, e.g., silicone, or other plastics, e.g., PEBAX.

As best seen in FIG. 1, a first sealing member 38a may be provided on the inner member 30 proximal to or otherwise adjacent a second sealing member 38b. The sealing member(s) 38 may be disposed adjacent a distal tip 35 of the inner member 30 or may extend beyond the distal tip 35. The distal tip 35 (or the sealing member extending beyond the distal tip 35) may be substantially atraumatic, e.g., rounded, softened, provided with a "J" tip, and the like (not shown), to facilitate advancement of the apparatus 10 within a patient's body without substantial risk of the distal tip 35 puncturing or otherwise damaging walls of body lumens through which the distal tip 35 passes.

The sealing member(s) 38 may have a size, e.g., outer diameter, that is larger than the distal end 54 of the balloon 50, e.g., larger than the inner diameter of the outlet 58. As shown in FIG. 1, the sealing members 38 are spaced apart sufficiently from one another such that the distal end 54 of the balloon 50 is free floating between the sealing members 38. When the inner member 30 is directed axially, one of the sealing members 38 may engage or otherwise contact the distal end 54 of the balloon 50. The sealing member(s) 38 may have tapered shapes to facilitate seating or other engagement by the sealing member(s) 38 with the distal end 54.

For example, with additional reference to FIG. 2, the inner member 30 may be directed distally to a first or distal position wherein the first sealing member 38a pushes or otherwise contacts the distal end 54, and the second sealing member 38b is spaced from the balloon outlet 58. As shown, the inner member 30 may be advanced distally to cause the first sealing member 38a to push the distal end 54. Because the outer diameter of the first sealing member 38a is larger than inner diameter of the distal end 54, the first sealing member 38a pushes the distal end 54 of the balloon 50 away from the proximal end 52tie, thereby stretching the balloon 50. This configuration may minimize or otherwise reduce the profile of the balloon 50, e.g., to facilitate introduction into a patient's body. In this

first position, the first sealing member 38a may substantially seal the outlet 58, although alternatively, the first sealing member 38a may include one or more axial grooves or other features that allow at least some fluid to pass through the outlet 58 even when the first sealing member 38a is seated or pushing against the distal end 54.

Turning to FIG. 3, the inner member 30 may be directed axially to a second position, e.g., proximal to the first position, such that the distal end 54 of the balloon 50 is disposed between the sealing members 38a, 38b and the outlet 58 is substantially open. Thus, fluid introduced through the first lumen 26 of the outer member 20 may pass through the balloon interior 56 and exit through the outlet 58, e.g., between the balloon distal end 54 and inner member distal end 24 into the body lumen beyond the distal tip 35.

As shown in FIG. 4, the inner member 30 may also be directed proximally to a third position, e.g., proximal to the second position, in which the second sealing member 38b engages the distal end 54 of the balloon 50, thereby substantially sealing the outlet 58 from fluid flow therethrough. Thus, any fluid introduced through the first lumen 26 enters the balloon interior 56 and expands the balloon 50. Optionally, as shown in FIG. 5, once the balloon 50 is expanded, the inner member 30 may be directed further proximally, e.g., to an indefinite number of positions wherein the second sealing member 38b continues to seal the outlet 58, and the size and/or shape of the expanded balloon 50 may be changed. For example, as shown in FIG. 4, with the inner member 30 in the third position, the balloon 50 may be inflated to an elliptical or generally spherical shape, e.g., by delivering a predetermined volume of fluid into the interior 56 of the balloon 50. If the balloon 50 is compliant, one of a range of desired volumes may be delivered into the interior 56 to expand the balloon 50 to a desired diameter.

With further reference to FIG. 5, thereafter, as the inner member 30 is directed proximally further, the distal end 54 of the balloon 50 (captured between the sealing members 38) is also directed proximally, i.e., towards the proximal end 52 of the balloon 50, thereby compressing the balloon 50 axially and expanding the balloon 50 further.

As shown in FIG. 6A, the balloon 50 wall may have a substantially uniform wall thickness between the proximal and distal ends 52, 54. Thus, when the balloon is compressed, as shown in FIG. 5, the proximal and/or distal ends 52, 54 of the balloon 50 may at least partially evert into the interior 56 of the balloon 50. Thus, the wall of the balloon 50 may fold over onto the outside of the proximal and/or distal ends 52, 54 as the inner member 30 is directed proximally from the third position.

Alternatively, as shown in FIG. 6B, the thickness of the balloon 50' may be reduced along its length, e.g., thinning from the proximal and distal ends 52,' 54' towards a central region 55' of the balloon 50.' Thus, the regions of the balloon 50' immediately adjacent the proximal and distal ends 52,' 54' may be relatively rigid compared to the central region 55.' When the balloon 50' is compressed after expansion, the regions immediately adjacent the proximal and distal ends 52,' 54' may resist the balloon 50' everting and the thinner central region 55' may expand to a greater diameter compared to the balloon 50 of FIG. 6A.

In further alternatives, shown in FIGS. 6C and 6D, the regions of the balloon 50," 50"' immediately adjacent the proximal and/or distal ends 52," 54" or 52,"' 54"' may be reinforced further, e.g., including additional materials, to reinforce the base of the balloon 50," 50"' to reduce everting and/or otherwise preferentially control expansion of the balloon 50," 50."' For example, in FIG. 6C, composite materials 53" have been embedded or otherwise provided in the balloon material adjacent the proximal and distal ends 52," 54," while in FIG. 6D, an additional layer of material 53"' has been added, which may be the same material or different material than the rest of the balloon 50."' The layer may be attached to the balloon 50"' similar to the materials and methods described elsewhere herein for attaching the balloon 50"' to the outer member 20.

Returning to FIG. 1, a handle or hub 60 may be coupled to or otherwise provided on the proximal end 22 of the outer member 20, e.g., for manipulating the outer member 20 and/or the entire apparatus 10. The handle 60 may have an ergonomic shape, e.g., to facilitate holding and/or manipulating the handle 60, and including one or more controls or actuators for actuating the components of the apparatus 10. For example, as shown, a pull handle 62 may be provided adjacent the main handle 60 that is coupled to the inner member 30. Thus, to move the inner member 30 to the various positions described above, the pull handle 62 may be pushed or pulled, e.g., pushed distally to direct the inner member 30 to the first position shown in FIG. 2, and pulled proximally to direct the inner member 30 to the second and third (or further proximal) positions, shown in FIGS. 3-5. Alternatively, similar to the embodiments shown in FIGS. 11 and 14, a slider actuator (not shown) may be provided on the handle 60 that is coupled to the inner member 30 for directing the inner member 30 axially relative to the handle 60 and outer member 20. In a further alternative, a wheel or other actuator may be provided for directing the inner member 30 axially relative to the outer member 20.

The pull handle 62 and/or inner member 30 may be biased to one of the positions shown in FIGS. 2-5, e.g., by one or more springs or other biasing mechanisms (not shown) within the handle 60. For example, the inner member 30 may be biased to the second (infusion) position, but may be directed to the other positions by overcoming the bias. Alternatively, the handle 60 may include one or more features, e.g., pockets, notches, and the like (not shown), providing tactile feedback and/or for releasably securing the inner member 30 in one of the positions. In addition or alternatively, the handle 60 may include one or more visual markers (not shown), e.g., to inform the user when the various positions are achieved. In a further alternative, the first sealing member 38a may be eliminated and the first position eliminated, e.g., if there is less concern with profile of the apparatus 10 during introduction and/or to simplify operation of the apparatus 10.

With continued reference to FIG. 1, the handle 60 may also include one or more ports for coupling one or more fluid sources to the apparatus 10, such as a source of inflation media, a source of vacuum, and/or a source of diagnostic and/or therapeutic agents (not shown). For example, as shown, a side port 64 may communicate with the first lumen 26. The side port 64 may include one or more connectors (not shown) to facilitate coupling one or more sources of fluid to the side port 64, e.g., a Luer lock connector, and/or one or more seals, e.g., a hemostatic seal, to prevent fluid from leaking from the side port 64.

A syringe or other source of fluid (not shown) may be coupled to the side port 64 to allow delivery of the fluid through the first lumen 26 into the interior 56 of the balloon 50 and/or through the outlet 58, depending upon the position of the inner member. For example, if the inner member 30 is in the second (infusion) position, contrast material, e.g., radiopaque, echogenic, or other fluid that facilitates observation using fluoroscopy, ultrasound, or other external imaging, may be delivered through the first lumen 26 and outlet 58 into a body lumen. Such material may facilitate monitoring the apparatus 10 during advancement through a patient's body into a target body lumen and/or to identify the status of treatment of a body lumen, as described further below. With the inner member 30 in the third position, the same fluid may be delivered through the first lumen 26 to expand the balloon 50, or the source of contrast material may be replaced with a source of a different fluid, e.g., a syringe of saline, to facilitate expansion and/or collapse of the balloon 50.

Alternatively, multiple ports may be provided that communicate with the first lumen 26, e.g., such that various fluids may be delivered selectively through the first lumen 26 depending upon the desired function. For example, a source of contrast and a source of saline could be coupled to different ports such that each fluid may be delivered independently depending upon the position of the inner member 30 without having to change out the sources. Alternatively, a source of one or more therapeutic agents may be coupled to the side port 64 (or to a separate port), e.g., when desired, to deliver the agent(s) into the target body lumen.

Optionally, the handle 60 may include one or more seals, bushings, and the like to facilitate relative motion of the outer and inner members 20, 30 and/or to seal the first lumen 26. For example, as shown in FIG. 1, an o-ring 66 may be provided between the outer and inner members 20, 30, which may guide the inner member 30 as it moves axially relative to the outer member 30 and handle 60. The o-ring 66 may also be located proximal to the side port 64, thereby providing a substantially fluid-tight seal between the outer and inner members 20, 30 to prevent leakage of fluid introduced into the side port 64 from the handle 60.

As shown, the pull handle 162 includes a port 163 for receiving a guidewire or other rail (not shown) therethrough. For example, a guidewire may be introduced into the second lumen 136, e.g., from the port 163 or by backloading into the inner member distal end 134. The port 163 may include one or more seals, e.g., a hemostatic seal (not shown), to accommodate passage of a guidewire through without risk of substantial risk of leakage of blood or other body fluids from the second lumen 136.

Optionally, the outer member 20 may include one or more additional lumens (not shown) extending between the proximal and distal ends 22, 24, e.g., a guidewire lumen for receiving a guidewire or other rail (not shown), e.g., if the inner member 30 does not include the second lumen 36, an inflation lumen for delivering inflation media to another balloon (not shown) on the distal end 24, and the like.

In addition or alternatively, if desired, the apparatus 10 may include one or more markers to facilitate positioning and/or advancement of the apparatus 10 during use. For example, one or more radiopaque markers may be placed on the outer member distal end 24, on the inner member 30 within or adjacent the balloon 50 or distal tip 35, on the balloon 50, e.g., on the proximal and/or distal ends 52, 54, and/or on the sealing member(s) 38. Alternatively, one or more components of the apparatus 10 may be formed

from radiopaque or other materials that may facilitate imaging the apparatus 10 during use. For example, radiopaque markers and/or materials may facilitate positioning or otherwise imaging the apparatus 10 using fluoroscopy or other x-ray imaging, e.g., when positioning the balloon 50 (either before or after expansion) and/or when infusing fluid via the outlet 48. Alternatively, echogenic markers and/or materials may be provided to facilitate imaging using ultrasound or similar imaging techniques.

With continued reference to FIGS. 2-5, an exemplary method will now be described for treating a body lumen (not shown), e.g., using an apparatus 10, which may be any of the embodiments described herein, and not necessarily limited to the embodiment shown and described below with reference to FIG. 1. The target body lumen may be a blood vessel, e.g., a vein or artery, a graft, e.g., an aorto-venous fistula, tubular xenograft, or synthetic tubular graft, and the like. For example, the body lumen may be a passage communicating between an adjacent artery and vein (not shown), e.g., in an arm or other region of a dialysis patient. Alternatively, the body lumen may be a blood vessel within a patient's vasculature, e.g., a peripheral vessel in a patient's leg, a cerebral vessel, and the like. In a further alternative, the material may be a stone within a patient's urinary tract or other foreign object to be removed from the patient's body.

Optionally, the body lumen may be accessed using one or more additional instruments (not shown), which may be part of a system or kit including the apparatus 10. For example, an introducer sheath, guide catheter, or other tubular member (not shown) may be introduced adjacent the target site where the material is to be removed, or may be introduced elsewhere in the patient's body to provide access to the patient's vasculature or other passages communicating with the body lumen. If the body lumen is located in a peripheral vessel of the patient, a percutaneous puncture or cut-down may be created using a needle or other instrument (not shown) at a peripheral location, such as a femoral artery, carotid artery, or other entry site (also not shown), and an introducer sheath may be placed through the puncture at the peripheral location to provide access. The apparatus 10 may be advanced through the patient's vasculature from the entry site, e.g., alone or with the aid of a guide catheter, guidewire, and the like (not shown).

For example, to facilitate directing the apparatus 10 from an entry site to the target body lumen, a guide catheter, micro-catheter, or other tubular body may be placed from the entry site to the body lumen using conventional methods. In addition or alternatively, a guidewire (not shown) may be placed from the entry site to the body lumen if desired,

e.g., if the inner member 30 includes the second lumen 36. The tubular body may also be used for aspiration, e.g., coupled to a source of vacuum for capturing material removed by the apparatus 10.

Initially, with reference to FIG. 2, the apparatus 10 may be advanced into the body lumen with the inner member 30 in the second or distal position, e.g., such that the balloon 50 is stretched to reduce its profile. Optionally, if the first sealing member 38a does not seal the outlet 58, one or more fluids may be delivered into the body lumen, e.g., to facilitate imaging and/or positioning the apparatus 10. Alternatively, the inner member 30 may be directed to the first position, shown in FIG. 3, and fluid delivered to facilitate imaging.

For example, radiopaque contrast or other fluid may be delivered into the body lumen via the annular passage defined by the first lumen 26 between the outer and inner members 20, 30 to facilitate locating and/or measuring the size of the material 92 using fluoroscopy. Markers (not shown) on the apparatus 10 may facilitate positioning the balloon 50 relative to material intended to be removed before the balloon 50 is expanded, e.g., to facilitate verifying that the balloon 50 is positioned distal to or otherwise beyond the material. If desired, the inner member 30 may be directed back and forth between the first and second positions, e.g., to allow infusion of contrast and to reduce the profile of the apparatus 10 to facilitate further advancement, e.g., until the balloon 50 is located beyond obstructive material targeted for removal.

Optionally, the apparatus 10 may be introduced through a guide catheter or other tubular member (not shown), that includes a lumen communicating with a source of vacuum. With the balloon 50 disposed beyond the guide catheter but not yet expanded, the source of vacuum may be activated to aspirate material within the body lumen during the subsequent treatment.

Turning to FIG. 4, the inner member 30 may be directed to the third position, thereby sealing the outlet 58, and the balloon 50 may be inflated within the body lumen, e.g., such that the balloon 50 extends substantially entirely across the body lumen. The entire apparatus 10 may then be retracted to pull the occlusive material from the body lumen, e.g., to be aspirated into guide catheter, or otherwise removed from the body lumen. As shown in FIG. 5, if desired, the inner member 30 may be pulled to further expand the balloon 50, e.g., to substantially engage the wall of the body lumen. The

additional pressure from the balloon 50 may facilitate separating adherent material from the wall of the body lumen and allow its removal.

Once material is removed, the inner member 30 may be directed back towards the second position, and fluid introduced to observe the amount of material removed and/or remaining within the body lumen. If additional material is to be removed, the inner member back be directed to the first position, e.g., if desired to advance the apparatus 10 through additional material to be removed. Once the balloon 50 is located beyond the material, the process may be repeated as often as desired.

If desired, the obstructive material may be treated, e.g., at least partially dissolved, macerated, and the like before, during, or after withdrawal. For example, a therapeutic agent may be delivered into the body lumen via the first lumen 26 of the outer member 20, e.g., to at least partially dissolve or separate thrombus or other relatively soft material before being removed by the balloon 50 and/or otherwise to treat the wall of the body lumen.

Because a single lumen, i.e., the first lumen 26, is used for both inflation of the balloon 50 and delivering fluid into the body lumen, the profile of the outer member 20 and therefore of the overall apparatus 10 may be smaller than devices that include separate inflation and infusion lumens. Further, although the second lumen 36 of the inner member 30 could be used for infusion of fluids, this would generally require removing the guidewire over which the apparatus 10 is introduced since the guidewire may substantially fill the second lumen 36. Because the first lumen 26 may be used for infusion, the guidewire may remain within the second lumen 36 throughout the procedure, thereby potentially reducing the number of guidewire or other device exchanges. Further, the apparatus 10 may remain over the guidewire, which may facilitate advancing the apparatus 10 to other target body lumens intended for treatment.

In various alternatives, the valve created by the sealing member(s) 38 and the outlet 58 of the balloon 50 may be provided at other locations on the apparatus 10, if desired. For example, the configuration may be reversed such that the outlet 58 and sealing members 38 may be located proximal to the balloon 50. For example, a sealing member (not shown) may be provided on the distal end 24 of the outer member 20, and the proximal end 52 of the balloon 50 may float adjacent the sealing member(s), with the distal end 54 of the balloon 50 is secured to the distal end 34 of the inner member 30 (also not shown). Thus, movement of the inner member 30 relative to the outer member 20 may

cause the balloon proximal end to selectively engage or disengage the sealing member(s), allowing infusion from the first lumen 24 when the balloon proximal end is not engaged with the sealing member(s) and allowing balloon inflation when the balloon proximal end engages the sealing member(s).

In another alternative, a balloon (not shown) may be provided on the distal end 24 of the outer member 20 proximal to the balloon 50 and/or on the distal end 34 of the inner member 30 distal to the balloon 50, if desired, similar to other embodiments described herein. Such a balloon may be a non-compliant, high pressure balloon, e.g., for dilating the body lumen, or an elastic, compliant balloon for substantially sealing the body lumen to isolate one or more regions of the body lumen before infusion of fluid therein.

Turning to FIG. 7, another embodiment of an apparatus 110 is shown for treating a body lumen that generally includes an outer tubular member 120, an inner member 130, and an expandable balloon 150 carried by the inner and/or outer members 120, 130, similar to the previous embodiments. The apparatus 110 may be operable in a first mode for infusing fluid into a body lumen, a second mode for dilating an obstruction within a body lumen, and/or a third mode for removing obstructive material within a body lumen, as described further below.

As shown, the outer member 120 includes a proximal end 122, a distal end 124 sized for introduction into a body lumen, and a first lumen 126 extending therebetween, which may be constructed similar to the previous embodiments. The inner member 130 also includes a proximal end 132, a distal end 134, and, optionally, a second lumen 136 extending between the proximal and distal ends 132, 134, e.g., sized to slidably receive a guide wire, or other rail (not shown) therethrough. The inner member 130 is sized to be slidably received within the first lumen 126 of the outer member 120, e.g., such that an annular space is defined between the outer and inner members 120, 130 for passing one or more fluids therethrough, also similar to the previous embodiments.

The balloon 150 includes a proximal end 152 coupled to the outer member distal end 124, a distal end 154 defining an outlet 158, and an interior 156 communicating with the first lumen 126 and the outlet 158. The distal end 134 of the inner member 130 may extend through the distal end 154 of the balloon 150, e.g., such that the outlet 158 defines an annular passage between the distal end 154 of the balloon 150 and the distal end 134 of the inner member 130. As shown, the distal end 154 of the balloon 150 includes a collar or sleeve 155 attached or otherwise secured to the distal end 154, e.g., by bonding with

adhesive, interference fit, sonic welding, fusing, and the like. Optionally, the collar 155 may extend proximally into the interior 156 of the balloon 150 (not shown) and the interior section of the collar 155 may include one or more side ports or other openings (also not shown), e.g., to facilitate fluid passing from the balloon interior 156 through the outlet 158.

The balloon 150 may be formed from substantially inelastic material, e.g., to provide a non-compliant balloon that expands to a predetermined size when inflated independent of pressure (once a minimum volume is introduced to achieve the predetermined size). Such a non-compliant balloon 150 may expand to the predetermined size even if inflated to relatively high pressures, e.g., until the balloon 150 bursts or otherwise ruptures, e.g., at pressures of at ten atmospheres, twenty atmospheres, thirty atmospheres, and the like. Alternatively, the balloon 150 may be formed from elastic material, similar to other embodiments described elsewhere herein.

One or more sealing members 138 may be carried on the inner member distal end 134, e.g., such that the sealing member(s) 138 are movable relative to the balloon 150 as the inner member 130 is moved, e.g., to provide a valve for selectively opening and closing the outlet 158 of the balloon 150. As shown, a first sealing member 138 is provided on the inner member 130 distal to the balloon distal end 154 and collar 155. The sealing member 138 may have a size, e.g., outer diameter, that is larger than the collar 155 and distal end 154 of the balloon 150 such that the sealing member 138 may substantially engage the collar 155 and/or distal end 154 of the balloon 150 to substantially seal the outlet 158.

In the exemplary embodiment shown, the sealing member 138 may include a tapered shape, e.g., on one or both of its proximal and distal ends. For example, a tapered shape on the proximal end of the sealing member 138 may automatically guide the sealing member 138 into being seated in the outlet 158 of the balloon 150, e.g., to enhance a fluid-tight seal therebetween. A tapered shape on the distal end of the sealing member 138 may provide a rounded or otherwise substantially atraumatic tip for the apparatus 110. Alternatively, a substantially atraumatic distal tip (not shown) may be provided on the inner member 130 beyond the first sealing member 138, similar to the previous embodiments.

With continued reference to FIG. 7, a handle or hub 160 may be coupled to or otherwise provided on the proximal end 122 of the outer member 120, e.g., for

manipulating the outer member 120 and/or the entire apparatus 110, generally similar to the previous embodiments. The handle 160 may include a pull handle 162 or other actuator coupled to the inner member 130 for moving the inner member 130 to the various positions described below. The handle 160 may also include one or more ports, such as side port 164 for coupling one or more fluid sources to the apparatus 110, e.g., a syringe or other source of fluid for delivering fluid through the first lumen 126 into the interior 156 of the balloon 150 and/or through the outlet 158, depending upon the position of the inner member 130.

Optionally, the handle 160 may include one or more seals, bushings, and the like, such as o-ring 166, between the outer and inner members 120, 130, which may guide the inner member 130 as it moves axially relative to the outer member 130 and handle 160. In this embodiment, the inner member 130 includes a section of hypotube or other substantially rigid tubing 131 attached or otherwise coupled to the proximal end 132 of the inner member 130. The tubing 131 may provide axial support for the inner member 130, e.g., to prevent buckling or kinking when the inner member 130 is directed axially. The tubing 131 may also allow the inner member 130 to move axially more easily, e.g., if the tubing 131 has a substantially smooth or lubricated outer surface that slides easily through the o-ring 166 while maintaining a fluid-tight seal therebetween.

In addition or alternatively, if desired, the apparatus 110 may include one or more markers to facilitate positioning and/or advancement of the apparatus 110 during use. For example, as shown in FIG. 7, radiopaque marker bands 137 may be attached around the distal end 134 of the inner member 130, e.g., within the balloon interior 56. As shown, a marker 137 is attached adjacent both the proximal end 152 and the distal end 154 of the balloon 150, which may facilitate monitoring the location of the balloon 150 before dilating an obstruction within a body lumen. In addition or alternatively, a core wire of the helical member 170 may be formed from radiopaque material, and/or radiopaque filler material, BAS04, may be dispersed into plastic material used to form the helical member 170, if desired.

Unlike the previous embodiments, the apparatus 110 includes a helical member 170 coupled between the outer and inner members 120, 130 within the balloon interior 156. The helical member 170 may be movable from a relatively low profile, such as that shown in FIG. 7, to an expanded helical shape, as described further below. As shown, the helical member 170 is a wire, tube, or other filament including a first end 172 coupled to

the distal end 124 of the outer member 120 and a second end 174 coupled to the distal end 134 of the inner member 130. For example, the helical member 170 may be from a core wire having a tube or sleeve formed or attached around the wire (not shown). Between the first and second ends 172, 174, the helical member 170 may wrap helically around the inner member 130 one or more times. As shown, the helical member 170 extends around the inner member 130 about one and a half turns, although it will be appreciated that the helical member 170 may include more or fewer turns.

As shown, the first end 172 of the helical member 170 may be attached or otherwise secured directly to the distal end 124 of the outer member 120, e.g., by one or more of bonding with adhesive, sonic welding, soldering, interference fit (e.g., by wrapping the first end 172 one or more times around the distal end 124), inserting the first end 172 into an annular groove, hole, or pocket (not shown) in the distal end 124, fusing, and the like. The second end 174 of the helical member 170 may be similarly attached or otherwise secured to a sleeve 178 fixed to the distal end 134 of the inner member 130 or directly to the distal end 134.

The sleeve 178 may be a relatively short tube attached to the inner member distal end 134 adjacent the balloon distal end 154, e.g., by bonding with adhesive, sonic welding, interference fit, fusing, and the like. The sleeve 178 may have an outer diameter larger than the inner diameter of the collar 155 and/or distal end 154 of the balloon 150, thereby providing a stop that limits movement of the collar 155 and distal end 154 relative to the inner member 130. When the sleeve 178 contacts the collar 155 and/or distal end 154, the sleeve 178 may not substantially obstruct the annular passage communicating with the outlet 158, e.g., such that fluid may still flow through the outlet 158 when introduced into the balloon interior 156. Alternatively, the sleeve 178 may be shaped to substantially seal the outlet 158 when the sleeve 178 engages the collar 155 and/or distal end 154 of the balloon 150, similar to the other sealing members described elsewhere herein. Optionally, during manufacturing or assembly, the collar 155 may be positioned between the sealing member 138 and the sleeve 178 when the collar and sleeve 178 are attached to the inner member distal end 134, i.e., before attaching the collar 155 to the balloon distal end 154. The balloon distal end 154 may then be attached over the collar 155 when the balloon 154 is attached to the outer member distal end 124. If desired, the balloon distal end 154 may be attached to the collar 155 such that a proximal section of the collar 155 is disposed within the interior 156 of the balloon 150. If so, the proximal

section of the collar 155 may include one or more openings (not shown) to facilitate fluid passing from the balloon interior 156 through the collar 155 and out the outlet 158, i.e., when the outlet 158 is not sealed by the sealing member 138, as described further below.

The inner member 130 may be movable axially relative to the outer member 120, e.g., between a first or distal position, a second or intermediate position (shown in FIG. 7), and/or a third or proximal position (not shown), thereby allowing the apparatus 110 to provide different functions for treating a body lumen. For example, in the first position, the inner member 130 may direct the sealing member 138 distally such that the sealing member 138 is spaced apart from the balloon outlet 158. Thus, fluid introduced through the first lumen 126 of the outer member 120 may pass through the balloon interior 156 and out the outlet 158, e.g., into the body lumen beyond the distal tip 35, similar to the previous embodiments.

If desired, the inner member 130 may be directed proximally to a second position, such as that shown in FIG. 7, in which the sealing member 138 engages the collar 155 and/or distal end 154 of the balloon 150, thereby substantially sealing the outlet 158 from fluid flow therethrough. Thus, any fluid introduced through the first lumen 126 enters the balloon interior 156 and may expand the balloon 150. In this mode, the balloon 150 may be expanded to an elongate substantially cylindrical shape, e.g., having a substantially uniform diameter main portion between tapered end portions. In expanded condition, the main portion of the balloon 150 may have a length between about twenty and eighty millimeters (20-80 mm) and a diameter between about three and twelve millimeters (3-12 mm). The balloon 150 may be used to dilate or otherwise apply substantial pressure to a wall of a body lumen, e.g., for dilating a stenosis, lesion, or other obstruction, similar to the method shown in FIGS. 9E-9G and described further below.

In addition or alternatively, after inflating the balloon 150 to dilate the body lumen, a source of vacuum may be coupled to the side port 164 and the balloon 150 collapsed to a contracted condition around the helical member 170. Alternatively, if the balloon 150 has not been previously inflated, it may not be necessary to collapse the balloon 150 using vacuum since the balloon 150 may already be sufficiently collapsed or otherwise remain in the contracted condition.

The inner member 130 may then be directed proximally to the third position, thereby directing the ends of the helical member 170 towards one another. This causes the helical member 170 to expand radially outwardly as it is compressed axially, thereby

causing the balloon 150 also to compress axially and expand radially into an expanded helical shape around the helical member 170, e.g., as shown in FIG. 7A. Optionally, the inner member 130 and/or handle 150 may include one or more stops (not shown) that limit proximal movement of the inner member 130 when compressing and expanding the balloon 150 and helical member 170. For example, the stop(s) may allow the inner member 130 to be pulled until the balloon length is reduced to between about six and thirty millimeters (6-30 mm), thereby preventing overcompression of the balloon 150 and/or helical member 170.

In one embodiment, the helical member 170 may have sufficient rigidity that the helical member 170 may simply buckle elastically from the low profile towards the helical shape as it is compressed axially. Thus, the helical member 170 may expand without substantial plastic deformation such that the helical member 170 may be returned to its original low profile shape (and expanded and collapsed repeatedly, if desired). Alternatively, the helical member 170 may be biased to a predetermined expanded helical shape but may be constrained in the low profile, e.g., by providing axial tension on the ends 172, 174 of the helical member 170 when the inner member 130 is in the first or second positions. As the inner member 130 is directed towards the third position, the tension may be released, whereupon the helical member 170 may resiliently expand towards the expanded helical shape.

In another alternative, the helical member may be integrally formed or otherwise coupled directly to the balloon 150, e.g., attached to, embedded within, or otherwise secured to the balloon wall (not shown) between the proximal and distal ends 152, 154. For example, as shown in FIG. 7B and 7D, one or more helically shaped wires or fibers 157' (e.g., one shown in FIG. 7B, two shown in FIG. 7D) may be molded, embedded, or integrally formed in the wall of the balloon 150.' As the balloon 150' is compressed axially when the inner member 130 is moved towards the third position, the fiber(s) 157' may automatically bias the balloon 150' towards the expanded helical shape. Alternatively, as shown in FIG. 7C, a fiber 157" may be molded, embedded, or integrally formed in the wall of the balloon 150" that includes a core wire or member 159," e.g., a radiopaque material, a biased core wire, and the like. In further alternatives, FIGS. 7E-7H show alternate shapes and/or configurations for a fiber 157_e to 157_h or other stiffening features that may be molded, embedded, or otherwise integrally formed in the wall of the balloon 150_e to 150_h and extend helically between proximal and distal ends of the balloon

150_e to 150_h. The fiber(s) and/or stiffening features may include one or more turns between the proximal and distal ends of the balloon 150', 150", or 150_e to 150_h, e.g., one and a half, two, three, four, or more turns. In addition, any of the fibers and/or stiffening features included on a balloon may provide cutting edges or elements, e.g., that may be at least partially embedded into a wall of a body lumen when the balloon 150', 150", or 150_e to 150_h is inflated to dilate an obstruction in a body lumen.

Returning to FIG. 7, with the balloon 150 in the expanded helical shape, the entire apparatus 110 may be directed along a body lumen, e.g., to remove obstructive material including scraping, scrubbing, or otherwise separating adherent material from a wall of the body lumen, if desired, similar to the method shown in FIGS. 9A-9D and described further below. Thus, in this embodiment, a single balloon 150 may be used for both dilation, e.g., using relatively high pressures, and for scraping, scrubbing, or otherwise removing obstructive material within a body lumen.

Turning to FIGS. 23A and 23B, an apparatus 110' is shown that is generally similar to the apparatus 110 of FIG. 7, except that the apparatus 110' includes an alternative embodiment of a handle 760 on the proximal end 122' of the outer member 120.' Generally, the handle 760 includes an outer housing 761 (shown in FIG. 23A), an inner carriage 765 (shown in FIG. 23B) slidable axially within the housing 761, a rotary knob 762 carried by the housing 761 and coupled to the carriage 765, and a hub 763 extending from the housing 761.

The housing 761 may include one or more pieces, e.g., one or more sets of mating halves or clamshells (not shown) that may be connected together, e.g., along a longitudinal seam (also not shown) to provide the housing 761, e.g., secured together by mating connectors, bonding with adhesive, sonic welding, fusing, and the like. The housing 761 may include a slot, track or other features (not shown) that allow the carriage 765 to slide axially within the housing 761 without substantial lateral movement. The housing 761 and/or carriage 765 may include one or more cooperating features, e.g., stops (not shown) within the housing 761 that limit axial movement of the carriage 765 relative to the housing 761, for example, to limit movement of the inner member 130' between the first position (for infusion from the outlet 158') and the third position (where the balloon 150' is directed to an expanded helical shape, not shown).

The housing 761 may include a side port 764, e.g., including a Luer lock or other connector, for connecting a source of fluid to the apparatus 110.' The side port 764 may

communicate with a lumen extending through the outer member 120' for delivering fluid into the interior of the balloon 150,' similar to the previous embodiments.

The knob 762 may include an outer portion 762a surrounding or otherwise extending radially from the housing 761, e.g., including ridges or other features to facilitate rotation or other manipulation of the knob 762 during use, and an inner stem 762b that extends axially along a first passage 765a within the carriage 765. The inner stem 762b and the carriage 765 may include cooperating features, e.g., helical threads 762c, that translate rotation of the knob 762 into axial movement of the carriage 765. Thus, the knob 762 may be substantially fixed axially relative to the housing 761 and freely rotatable about a longitudinal axis of the apparatus 110.'

The proximal end 132' of the inner member 130' may pass freely through the inner stem 762b and be fixed relative to the carriage 765. For example, the inner member proximal end 132' may be secured to the carriage 765 by fixing the proximal end 132' in a second passage 765b adjacent to and/or communicating with the first passage 765a, e.g., bonding with adhesive, sonic welding, fusing, interference fit, mating connectors (not shown), and the like. Thus, axial movement of the inner member 130' may be coupled to movement of the carriage 765.

The hub 763 may include a hypotube or other tubular member 763a and a Luer lock or other connector 763b secured to one another and/or to the outer housing 761. For example, a proximal end of the tubular member 763a and/or the connector 763b may attached to a proximal end of the housing 761, e.g., by bonding with adhesive, sonic welding, fusing, interference fit, mating connectors (not shown), and the like.

The tubular member 763a may be slidably received in the second passage 765b such that the tubular member 763a and connector 763b remain substantially stationary relative to the housing 761 as the carriage 765 is directed axially. One or more seals, e.g., o-ring 766, may be provided within or around the second passage 765b that allow the tubular member 763a to slide therethrough while providing a fluid-tight seal that prevents fluid from leaking through the passages 765a, 765b and out of the housing 761.

During use, the knob 762 may be rotated in a first direction, thereby translating the inner member 130' distally to the first position to open the outlet 158.' Thus, fluid delivered through the outer member 120' may pass through the balloon 150' and exit the outlet 158,' as described above. The knob 762 may be rotated in a second opposite direction, thereby translating the inner member 130' proximally to the second position,

e.g., until the sealing member 138' seals the outlet 158' to allow balloon expansion, and/or further to the third position, e.g., to expand the balloon 150' to the expanded helical shape, also as described above. Optionally, the knob 762 and/or housing 761 may include visual, audible, or other indicators (not shown) that identify the direction to rotate the knob 762 to achieve the desired position(s) and/or that indicate when a particular position is achieved, e.g., by aligning an arrow (not shown) on the knob 762 with respective indicators (also not shown) that identify the first, second, and/or third positions. Otherwise, the apparatus 110' may operate similar to the previous embodiments.

Turning to FIGS. 24A-24C, another embodiment of a handle 860 is shown that includes an outer housing 861 with a side port 864 (shown in FIG. 24A), an inner carriage 865 (shown in FIG. 24B) slidable axially within the housing 861, and a hub 863 extending from the housing 861, generally similar to the handle 760. For example, the housing 861 may include one or more pieces, e.g., one or more sets of mating halves or clamshells (not shown) that may be connected together and may include a slot, track or other features (not shown) that allows the carriage 865 to slide axially within the housing 861, e.g., without substantial lateral movement. The housing 861 and/or carriage 865 may include one or more features that limit axial movement of the carriage 865 relative to the housing 861, e.g., to limit movement of the inner member 130' between the first position (for infusion from the outlet 158'), second position (for balloon inflation), and the third position (where the balloon 150' is directed to an expanded helical shape, not shown).

The proximal end 132' of the inner member 130' is substantially fixed relative to the carriage 865, e.g., by fixing the proximal end 132' in a passage 865a adjacent to a distal end of the carriage 865, for example, bonding with adhesive, sonic welding, fusing, interference fit, mating connectors (not shown), and the like. Thus, axial movement of the inner member 130' may be coupled to movement of the carriage 865.

The hub 863 may include a hypotube or other tubular member 863a and a Luer lock or other connector 863b secured to one another and/or to the outer housing 861. For example, a proximal end of the tubular member 863a and/or the connector 863b may attached to a proximal end of the housing 861, e.g., by bonding with adhesive, sonic welding, fusing, interference fit, mating connectors (not shown), and the like.

The tubular member 863a may be slidably received in the passage 865a, e.g., adjacent a proximal end of the carriage 865, such that the tubular member 863a and connector 863b remain stationary relative to the housing 861 (and inner member proximal

end 132') as the carriage 865 is directed axially. With both the tubular member 863a and inner member proximal end 1323' received in the passage 865a, a guidewire or other instrument, backloaded through the inner member 130' may pass freely through the passage 865a, tubular member 863a, and out the connector 863b (or inserted through the connector 863b into the inner member 130'). One or more seals, e.g., o-ring 866, may be provided within or around the passage 865a that allow the tubular member 863 to slide therethrough while providing a fluid-tight seal that prevents fluid from leaking through the passage 865a out of the housing 861.

Instead of a rotary knob 762, the handle 860 includes a push button 862 carried by the housing 861 and coupled to the carriage 865. For example, the housing 861 may include an elongate slot 861a and the push button 862 may be slidable axially within the slot 861a. Optionally, as shown, the slot 861a may include one or more pockets or detents 861b that may capture the push button 862, e.g., to releasably secure the push button 862, and consequently the carriage 865 and inner member 130,' in one or more positions.

Optionally, the housing 861 may include one or more visual indicators, e.g., for identifying the position of the inner member 132' when the push button 862 is received in a particular pocket 861b. For example, as shown in FIG. 24C, the housing 861 may include numbers or other symbols 861c aligned with respective pockets (not shown) such that when the push button, in this embodiment, lever 862 is aligned with a particular symbol 861c, the user can confirm that the inner member 130' is in a respective particular position.

As best seen in FIG. 24B, the push button 862 may include a base 862a substantially fixed relative to the carriage 865 and a cap 862b slidable laterally relative to the base 862a. For example, the base 862a may be integrally molded or otherwise formed with the carriage 865 and the cap 862b may be attached to the base 862a such that the cap 862b may be slid laterally, e.g., substantially perpendicular to the longitudinal axis of the handle 860. For example, the cap 862b may be biased such that the cap 862b may automatically slide into a pocket 861b with which the cap 862b is aligned, yet the bias may be overcome to move the cap 862b out of the respective pocket 861b into the slot 861a so that the cap 862b may be slid axially into another pocket 861b. For example, a spring or other biasing mechanism (not shown) may be provided within the cap 862b or housing 861 that may push the cap 862b laterally from the base 862a.

Alternatively, the entire push button 862 may be fixed relative to the carriage 865, e.g., integrally molded or formed together, and the push button 862 and carriage 865 may be pivoted about the longitudinal axis to allow the cap 862b to be directed out a particular pocket 861b, directed axially along the slot 861a, and released or otherwise placed in another pocket 861b. In this alternative, a spring or other biasing mechanism (not shown) may bias the push button 862 and carriage 865 to direct the cap 862b into any pocket 861b with which the cap 862b is aligned when the cap 862b is released.

In an exemplary embodiment, the handle 860 may include three pockets 861b, e.g., one corresponding to the first position of the inner member 130,' one corresponding to the second position, and one corresponding to the third position. Thus, to place the inner member 130' in any of the first, second, or third positions, the cap 862b may directed out of a pocket within which the cap 862b is received, the push button 862 may be slid axially along the slot 861a, and released or otherwise directed into the desired pocket 861b. Alternatively, the handle 860 may include only one or two pockets 861b, e.g., if the push button 862 is biased axially to one of the positions.

During use, the push button 862 may be directed axially in a first direction, e.g., distally to the indicator "R" in FIG. 24C, and released or captured in a corresponding pocket, thereby translating the inner member 130' distally to the first position to open the outlet 158.' Thus, fluid delivered through the outer member 120' may pass through the balloon 150' and exit the outlet 158,' as described above. The push button 862 may be directed out of the pocket and directed axially, e.g., proximally, to the indicator "N", thereby translating the inner member 130' proximally to the second position, e.g., until the sealing member 138' seals the outlet 158' to allow balloon expansion. In addition, if desired, the push member 872 may be directed out of the "N" pocket, axially within the slot 861a, and released in the third pocket, corresponding to indicator "D," thereby translating the inner member 130' to the third position, e.g., to expand the balloon 150' to the expanded helical shape, also as described above.

Turning to FIGS. 25A and 25B, still another embodiment of a handle 960 is shown that includes an outer housing 961 including a side port 964 (shown in FIG. 25A), a carriage (not shown) within the housing 961, and a hub 963 extending from the housing 961, generally similar to the previous embodiments. The carriage may include a rack 965 (shown in FIG. 25B) including a plurality of teeth 965a spaced apart axially along the rack 965.

The proximal end (not shown) of the inner member 130' may be substantially fixed relative to the carriage (not shown) such that axial movement of the inner member 130' is coupled to movement of the carriage and consequently to the rack 965, similar to the previous embodiments.

The hub 963 may include a hypotube or other tubular member (not shown) and a Luer lock or other connector 963b secured to one another and/or to the outer housing 961, similar to the previous embodiments. The tubular member may be slidably received in a passage in the carriage, e.g., such that the connector 963b remains substantially stationary relative to the housing 961 (and inner member 130') as the carriage is directed axially.

In this embodiment, the actuator is a rotary wheel 962 rotatably mounted to the housing 961, as shown in FIG. 25A. The rotary wheel 962 includes an outer wheel 962a including ridges or other features to facilitate engaging and/or rotating the rotary wheel 962, and a pinion 962b that extends into the housing 961. As best seen in FIG. 25B, teeth on the pinion 962b may interlock with the teeth 965a on the rack 965 such that rotation of the outer wheel 962a causes the rack 965, and consequently, the inner member 130,' to move axially relative to the housing 961 and outer member 120.' Optionally, the housing 961 may include one or more visual indicators, e.g., for identifying the position of the inner member 132' when the wheel 962a is rotated to one or more orientations, similar to the previous embodiments.

During use, the rotary wheel 962 may be rotated in a first direction, e.g., to translate the inner member 130' distally to the first position to open the outlet 158.' When desired, the rotary wheel 962 may be rotated in a second opposite direction to translate the inner member 130' proximally to the second position and/or third position, e.g., to allow inflation of the balloon 150' and/or expanding the balloon 150' to the expanded helical shape, similar to the previous embodiments. One advantage of the rotary wheel 962 is that the ratio of the outer wheel 962a, pinion 962b, and teeth 965 on the rack 965 may be designed to provide a desired mechanical advantage and/or precision of movement of the inner member 130.'

Another embodiment of a handle 1060 is shown in FIGS. 26A and 26B that may be included in any of the apparatus shown herein. Similar to the previous embodiments, the handle 1060 includes a housing 1061 including a hub 1063 and a side port 1064. In this embodiment, the actuator is a squeeze button 1062 that may be depressed to direct the inner member 130' axially. e.g., from a first position to a second position, similar to the

embodiments described elsewhere herein. Generally, when the squeeze button 1062 is pressed inwardly, links 1062a, 1062b defining the button 1062 are flattened out, thereby directing the proximal link 1062a proximally if the distal link 1062b is fixed axially relative to the housing 1061.

For example, a first end of the distal link 1062b may be pivotally coupled to the housing 1061 and a second end pivotally coupled to a first end of the proximal link 1062. A second end of the proximal link 1062a may be slidable axially along the housing 861, e.g., within a slot or track (not shown). With the second end of the proximal link 1062a coupled to the inner member 130,' e.g., by a cable or other linkage 1062c, as the squeeze button 1062 is pressed inwardly, the proximal link 1062 pulls the inner member 130,' e.g., from a first position (with the outlet 158' open) to a second position (allowing the balloon 158' to be inflated and/or expanded to the expanded helical shape).

Optionally a cover (not shown) may be placed over the squeeze button 1062 to protect the user from catching anything between the links 1062a, 1062b. In addition or alternatively, the squeeze button 1062 may be provided on the top of the housing 1061 (as shown), e.g., to allow a user to actuate the squeeze button 1062 with their thumb, or on the bottom of the housing 1061 (not shown), e.g., to allow a user to actuate the squeeze button 1062 with their index finger. Optionally, the handle 1060 may include one or more features (not shown) to allow the squeeze button 1062 to be releasably secured at one or more positions before the links 1062a, 1062b are completely flattened, e.g., to allow the inner member 130' to be translated and fixed in different positions, e.g., successively in the second and third positions, similar to the previous embodiments.

Turning to FIG. 8, still another embodiment of an apparatus 210 is shown for treating a body lumen that generally includes an outer tubular member 220, an inner member 230, and an expandable balloon 250, and helical member 270 carried by the inner and/or outer members 220, 230, similar to the previous embodiments, but does not include a valve for opening or closing an outlet in the balloon, unlike the embodiment of FIG. 7. The apparatus 110 may be operable in a first mode for dilating an obstruction within a body lumen, and/or a second mode for removing obstructive material within a body lumen, as described further below.

As shown, the outer member 220 includes proximal and distal ends 222, 224, and a first lumen 226 extending therebetween, and the inner member 230 also includes proximal and distal ends 232, 234, and a second lumen 236 extending therebetween. The inner

member 230 is sized to be slidably received within the first lumen 226 of the outer member 220, e.g., such that an annular space is defined between the outer and inner members 220, 230 for passing one or more fluids therethrough, also similar to the previous embodiments.

A handle or hub 260 may be coupled to or otherwise provided on the proximal end 222 of the outer member 220, e.g., including a pull handle or other actuator 262 for moving the inner member 230 relative to the outer member 220, a side port 264 for coupling one or more fluid sources to the apparatus 210, and an o-ring or other seal 166 between the outer and inner members 220, 230, which may also be similar to the previous embodiments.

The balloon 250 includes a proximal end 252 coupled to the outer member distal end 224, a distal end 254 coupled to the inner member distal end 234, e.g., attached by bonding with adhesive, interference fit, sonic welding, fusing, and the like, similar to the previous embodiments. The balloon 250 may be formed from substantially inelastic material, e.g., to provide a non-compliant balloon that expands to a predetermined size when inflated independent of pressure, or alternatively, the balloon 250 may be formed from elastic material, similar to the other embodiments described elsewhere herein.

Also similar to the embodiment of FIG. 7, the helical member 270 is coupled between the outer and inner members 220, 230. Thus, the helical member 270 may be movable from a relatively low profile, such as that shown in FIG. 8, to an expanded helical shape, as described further below with reference to FIGS. 9A-9D. As shown in FIG. 8, a first end 272 of the helical member 270 may be attached or otherwise secured directly to the distal end 224 of the outer member 220 and a second end 274 of the helical member 270 may be attached or otherwise secured to the distal end 234 of the inner member 230 adjacent the balloon distal end 252.

During use, in the exemplary methods shown in FIGS. 9A-9G, the apparatus 210 may used for treating a body lumen 90, e.g., for removing obstructive material 92 and/or dilating an obstruction 94 within a body lumen 90, e.g., as shown in FIG. 9A. Similar to the previous embodiments, the target body lumen 90 may be a blood vessel, e.g., a vein or artery, a graft, e.g., an aorto-venous fistula, tubular xenograft, or synthetic tubular graft, and the like.

Optionally, the body lumen may be accessed using one or more additional instruments (not shown), which may be part of a system or kit including the apparatus 210,

e.g., including one or more introducer sheaths, guide catheters, and/or guidewires (not shown). For example, to facilitate directing the apparatus 210 from an entry site to the target body lumen, a guide catheter, micro-catheter, introducer sheath, or other tubular body (not shown) may be placed from the entry site to the body lumen 90 using conventional methods. In addition or alternatively, a guidewire (not shown) may be placed from the entry site to the body lumen 90 if desired.

Initially, with reference to FIG. 9B, the apparatus 210 may be advanced into the body lumen 90 with the inner member 230 in the first or distal position, e.g., such that the balloon 250 is substantially collapsed. Optionally, contrast or other fluid may be delivered into the body lumen 90, e.g., via the second lumen 236 in the inner member 230 (not shown, see FIG. 8) or via a separate lumen (not shown) in the outer member 220. Markers (not shown) on the apparatus 10 may facilitate positioning the balloon 250 relative to the material 92 intended to be removed, e.g., to position the balloon 250 beyond or otherwise adjacent the material 92.

Optionally, the apparatus 210 may be introduced through a guide catheter or other tubular member (not shown), that includes a lumen communicating with a source of vacuum. With the balloon 250 disposed beyond the guide catheter, the source of vacuum may be activated to aspirate material within the body lumen 90, e.g., as the material 92 is dislodged or otherwise removed by the balloon 250, as described below.

Turning to FIG. 9C, the inner member 230 may be directed proximally relative to the outer member 220, thereby causing the helical member 270 and consequently the balloon 250 to expand towards the expanded helical shape, as described above. As shown in FIG. 9D, the entire apparatus 210 may then be retracted to remove the material 92, e.g., scraping, scrubbing, or otherwise separating material that may be adhered to a wall of the body lumen 90. For example, the apparatus 210 may be pulled to remove the material 92 from the body lumen and into the lumen of the guide catheter, where the material 92 may be aspirated from the patient's body. Alternatively, the material 92 may be released in a manner that the material 92 may be metabolized naturally by the patient's body.

If desired, the inner member 230 may be returned to the first position to collapse the balloon 250, and the apparatus 210 moved to another location within the body lumen 90. The inner member 230 may be directed between the first and second positions as often as desired to expand the balloon 250 and separate or otherwise remove sufficient material 92.

Turning to FIG. 9E, with sufficient material 92 removed, a stenosis, lesion, or other obstruction 94 is identified within the body lumen 90. The apparatus 210 may be reintroduced or repositioned in the body lumen 90 with the balloon 250 collapsed until the balloon 250 is positioned adjacent the obstruction 94, e.g., using fluoroscopy or other additional imaging. Once properly positioned, as shown in FIG. 9F, the balloon 250 may be inflated to dilate and/or otherwise treat the obstruction 94. Optionally, the balloon 250 may carry one or more diagnostic and/or therapeutic agents, which may be delivered against and/or into the obstruction 94 using the balloon 2500. After sufficient treatment, the balloon may be deflated, and the apparatus 10 removed from the body lumen 90, as shown in FIG. 9G.

Optionally, with any of the embodiments described herein, various balloon configurations may be provided. For example, turning to FIG. 10A, with additional reference to the apparatus 250 of FIG. 8, an exemplary cross-section of the apparatus 210, taken through the balloon 250, is shown. FIG. 10A shows the helical member 270 wound around the inner member 230 and surrounded by the expanded balloon 250. Thus, both the helical member 270 and the inner member 230 are disposed within the interior 256 of the balloon 250. One of the disadvantages of such a balloon 250 is that the wall must be relatively thick since it is difficult to predict which areas of the balloon wall are going to contact and scrape along a wall of a target body lumen.

FIGS. 10B-10D show alternative embodiments of balloon or tubular constructions that may be provided for any of the embodiments described herein. These constructions may be provided for a balloon capable of inflation or for a tubular member capable of expansion to an expanded helical shape without being inflated. Exemplary embodiments of such devices are disclosed in U.S. Patent No. 4,762,130.

For example, as shown in FIG. 10B, a balloon or tubular member 250' is shown that includes a first lumen 251' that receives the inner member 230 and a second lumen 253' that receives the helical member 270 therein. When the tubular member 250' and helical member 270 are compressed axially, the helical member 270 may expand radially outwardly away from the inner member 230, thereby directing surface region 280' radially outwardly away from the inner member 230 since the surface region 280' is furthest from the first lumen 251.' Thus, because the surface region 280' is likely to contact the wall of the body lumen when the tubular member 250' is expanded, the construction of the tubular wall may be varied to enhance scraping and/or other removal of obstructive material. For

example, features may be integrally molded or otherwise formed in the wall of the tubular member 250,' e.g., that extend helically around the tubular member 250' adjacent the second lumen 253.'

As shown in FIG. 10B, the surface region 280' may include a plurality of grooves that provide edges 282' that may facilitate scraping adherent material from the wall of the target body lumen, e.g., by concentrating contact forces with the wall of the body lumen.. In addition, the tubular wall opposite the surface region 280' may be relatively thin since this area of the wall is unlikely to contact the wall of the body lumen, which may allow an overall cross-section or profile of the tubular member 250' to be reduced. Alternatively, or in addition, if desired, different property materials may be used, e.g., harder elastomeric materials with relatively thinner wall thickness for the surface region 280' or elsewhere on the tubular member 250.'

Turning to FIG. 10C, another embodiment of a tubular member 250" is shown that includes ridges or protrusions 282" along surface region 280" that will contact the wall of the body lumen when the tubular member 250" is expanded. In a further alternative, shown in FIG. 10D, a tubular member 250"' may be provided that includes a first lumen 251"' having convolutions molded or otherwise formed into the tubular wall. The convolutions may increase the circumferential length of the tubular wall, and therefore allow the wall to stretch to a greater radial dimension, yet still direct the surface region 280"' towards the wall of a body lumen being treated.

Turning to FIG. 11, another embodiment of an apparatus 310 is shown that includes an outer member 320, an inner member 330, and an expandable member 350 carried on distal ends 324, 334 of the outer and inner members 320, 330, similar to the previous embodiments. Unlike the previous embodiments, the expandable member 350 may not include an interior coupled to a lumen extending through the outer member 320, i.e., the expandable member 350 may not be inflatable. However, alternatively, if desired, the apparatus 310 may include a lumen (not shown) extending through the outer member 320 and communicating with an interior of the expandable member 350 for selectively inflating or collapsing the expandable member 350. In addition, if desired, the apparatus 310 may include one or more sealing members or other valve (not shown) that may be opened or closed for selectively infusing fluid or inflating the expandable member 350, similar to the previous embodiments.

The expandable member 350 generally includes a proximal end 352 coupled to the outer member distal end 324 and a distal end 354 coupled to the inner member distal end 334, e.g., by bonding with adhesive, sonic welding, fusing, interference fit, one or more bands or other connectors (not shown), and the like. In addition, the apparatus 310 includes a helical member (not shown) that may also be coupled between the outer member and inner member distal ends 324, 334 and extend helically around the inner member 330 within the interior of the expandable member 350.

For example, the helical member may be loose within the interior of the expandable member 350. Alternatively, the helical member may be embedded in or otherwise attached to the wall of the expandable member 350, e.g., to an inner surface of the expandable member 350.

Unlike the previous embodiment, the helical member includes a first coil within a first region 350a of the expandable member 350 and a second coil within a second region 350b of the expandable member 350 having different properties. The first and second coils may be coupled to one another, e.g., integrally formed together as a single wire, filament, and the like, or may be formed as separate wires or filaments attached to one another. Each coil includes a plurality of turns that extend helically around the inner member 330, e.g., between the proximal and distal ends 352, 354 of the expandable member 350.

The coils may be provided in a relatively low profile around the inner member 330, e.g., when the inner member 330 is extended distally relative to the outer member 320 to a first position. When the inner member 330 is retracted proximally from the first position towards a second position, the coils may be compressed axially, thereby causing the coils to expand radially outwardly and expand the expandable member 350 radially outwardly to an expanded helical shape, similar to the previous embodiments.

The coils may have different mechanical properties from one another, thereby causing the first and second regions 350a, 350b of the expandable member 350 to expand to different sizes and/or shapes in the expanded helical shape. For example, as shown in FIG. 11, the first region 350a may be expanded to a smaller diameter than the second region 350b. This may be achieved by forming the first coil from thinner, narrower, or otherwise more flexible material than the second coil. In addition or alternatively, the coils may be biased to different diameters such that when the inner member 330 is in the distal or first position, the coils may be constrained in the low profile, and when the inner

member 330 is directed proximally towards the second position, the coils may resiliently expand radially outwardly to the diameters set into the coil material.

In addition or alternatively, the coils may be expandable sequentially, e.g., such that the first region 350a of the expandable member 350 may expand to the expanded helical shape before the second region 350b. For example, the first coil in the first region 350a may have less resistance to expansion than the second coil in the second region 350b, e.g., by forming the first coil from thinner, narrower, and/or otherwise more flexible material than the second coil. For example, the first coil may include a bare wire wound helically around the inner member 330, while the second coil may include the same or different wire wrapped in a section of tubing, a sleeve, and the like, which may increase resistance to expansion. Thus, when the inner member 330 is directed from the first position towards the second position, the compressive force may be applied initially to the first coil, thereby expanding the first coil and the first region 350a of the expandable member 350, until a predetermined threshold is achieved, whereupon the second coil may expand and expand the second region 350b of the expandable member 350.

In another alternative, a sleeve (not shown) attached to the inner member 330 may initial surround the second coil in the first position such that only the first coil is free to expand when initially compressed. When the inner member 330 is directed towards the second position, the second coil may become exposed from the sleeve, and then expand radially outwardly to the expanded helical shape.

Turning to FIGS. 12 and 13, an exemplary method is shown for treating a body lumen, e.g., a arterio-venous dialysis graft 190, using the apparatus 310 of FIG. 11. As shown, the graft 190 includes a first or venous anastomosis 192 attached to a vein 193 within a patient's body, e.g., within the patient's arm, and a second or arterial anastomosis 194 attached to an artery 195 adjacent the vein 193. As shown, the graft 190 includes obstructive material 92, e.g., thrombus, plaque, and the like at multiple locations in the graft 190 including within each anastomosis 192, 194.

Initially, an introducer or guide sheath 380 may be placed within the graft 190, e.g., percutaneously through the patient's skin into a central region of the graft 190, using similar methods to those described elsewhere herein. The sheath 380 may include a distal end 382 having a size and/or shape for introduction into the graft 190 and a balloon 382 on the distal end 384 for substantially engaging a wall of the graft 190, e.g., to stabilize the sheath 380 relative to the graft 190 and/or to substantially seal the graft 190 from fluid

flow between the ends 192, 194 of the graft 190. The sheath 380 may also include a reservoir 386 communicating with a lumen extending to an opening (not shown) in the distal end 382, and a source of vacuum 388, e.g., a syringe, for applying a vacuum to aspirate material from within the graft 190 during treatment.

The apparatus 310 may be introduced through the sheath 380 into the graft 190 with the expandable member 350 initially in a contracted condition. As shown in FIG. 12, the apparatus 310 may be advanced until the expandable member 350 is disposed distally beyond obstructive material 92 within the venous side of the graft 190, whereupon the inner member 330 (not shown) may directed proximally to expand the expandable member 350 to the expanded helical shape. As shown, both coils have been expanded, thereby expanding both the first and second regions 350a, 350b of the expandable member 350, e.g., such that the second region 350b may substantially engage or otherwise contact the wall of the graft 190.

The apparatus 310 may then be withdrawn to scrape or otherwise separate adherent material 92 from the wall of the graft 190 and pull the material 92 towards the sheath 380. The source of vacuum 388 may be activated, if not already, to aspirate the material 92 through the sheath 380 into the reservoir 386. If desired, the inner member 330 may be advanced to collapse the expandable member 350 back towards the contracted condition and advanced further into the graft 190, e.g., to repeat the process of expanding the expandable member 350 to scrape or otherwise remove material 92.

Optionally, the sheath 380 may be repositioned within the graft 190 towards the arterial anastomosis 194, and the apparatus 310 reintroduced with the expandable member 350 in the contracted condition, e.g., to remove material 92 within the arterial side of the graft 190. Turning to FIG. 13, although material has been removed from the graft 190, additional obstructive material 92 remains within the arterial anastomosis 194. Because the anastomosis 194 communicates with the artery 195, care should be taken to ensure that material is not released into the artery 195, where the material may flow into tissue beds, cause ischemia, or other damage to tissue downstream of the artery 195.

The apparatus 310 may be advanced until the distal end 334 of the inner member 330 passes through material 92 within the arterial anastomosis 194 with the expandable member 350 in the contracted condition. At this point, the inner member 330 may be directed proximally sufficient distance to expand the first region 350a of the expandable member 350 without substantially expanding the second region 350b. The apparatus 310

may then be withdrawn to pull the expandable member 350 back towards the sheath 380, where any material 92 removed from the anastomosis 194 may be aspirated out of the graft 190. Thus, the smaller first region 350b may allow greater care to remove material from sensitive regions, while the second region 350b may be expanded within relatively large body lumens or otherwise when it is desired to apply greater force and/or remove greater amounts of material.

Turning to FIG. 14, an alternative embodiment of the apparatus 310 shown in FIG. 11 is shown. The apparatus 310' is generally the same as apparatus 310, e.g., including an outer member 320,' an inner member 330,' an expandable member 350,' and first and second coils defining a helical member within the expandable member 350,' similar to the previous embodiments. Unlike the previous embodiment, the apparatus 310' includes a dilation balloon 359,' e.g., a substantially non-compliant, high pressure balloon, on the outer member distal end 324.' In addition the apparatus 310' includes a handle 360' that includes a side port 364' to which a source of inflation media and/or vacuum 368' may be connected.

The apparatus 310' may be used similar to the apparatus 310 shown in FIG. 11, e.g., using the methods of FIGS. 12 and 13. In addition, the dilation balloon 359' may be positioned within a stenosis, lesion, or other obstruction, e.g., in the graft 190 of FIGS. 12 and 13, or within other body lumens. The balloon 359' may then be inflated or otherwise expanded to dilate the body lumen, similar to other embodiments described above. Optionally, a stent or other prosthesis (not shown) may be carried by the balloon 359,' e.g., such that the prosthesis may implanted within a body lumen after using the balloon 350' to remove obstructive material from the body lumen. Alternatively, a stent or other prosthesis may be carried and delivered using any of the other embodiments described herein, e.g., on the balloon 150 or 250 of the apparatus 110 or 210, shown in FIGS. 7 or 8.

Turning to FIGS. 15A and 15B, exemplary embodiments of coils are shown that may be included in any of the apparatus described above including a helical member for expanding a balloon or other expandable member to an expanded helical shape. For example, FIG. 15A shows a coil 370 that includes substantially smooth, uniform turns 372 that may be incorporated as a helical member in any of the apparatus described above. Alternatively, as shown in FIG. 15B, a coil 370' may be provided that includes a plurality of turns 372' having alternating high points 374' and low points 376' that may increase contact force with a wall of a body lumen when the coil 370' is included within a balloon

or expandable member (not shown), such as those described above. The high and low points 374,' 376' may be staggered between adjacent turns, e.g., to ensure that at least some high points 374' contact and/or scrape along substantially the entire circumference of a wall of a target body lumen.

Turning to FIG. 16, still another embodiment of an apparatus 410 is shown that includes multiple expandable devices on a single shaft, e.g., such that the apparatus 410 may be operable in multiple modes, e.g., a first mode for removing material within a body lumen, and a second mode for dilating an obstruction within a body lumen.

Generally, the apparatus 410 generally includes an outer member 420, an inner member 430, a handle 460, and a first balloon or other expandable member 450 carried by the outer and inner members 420, 430, similar to the previous embodiments. The outer member 420 includes proximal and distal ends 422, 424, and a first lumen 426 extending therebetween, and the inner member 430 also includes proximal and distal ends 432, 434, and a second lumen 436 extending therebetween.

The first balloon 450 includes a proximal end 452 coupled to the outer member distal end 424 and a distal end coupled to the inner member distal end 434, and includes an interior communicating with the first lumen 426. The first balloon 450 may be formed from elastic material, e.g., such that the first balloon 450 may be expanded to a range of diameters and/or shapes, e.g., depending upon the volume of inflation media delivered into the interior of the first balloon 450 and/or the position of the inner member 430 relative to the outer member 420.

In addition, a second balloon 459 may be provided on the outer member 420, e.g., proximal to the first balloon 450. The second balloon 459 may be formed from substantially inelastic material, e.g., to provide a non-compliant, high pressure dilation balloon, similar to other embodiments described elsewhere herein. The outer member 420 includes a third inflation lumen 465 communicating with the interior of the second balloon 459.

As shown, the handle 460 includes a first side port 464a communicating with the first lumen 426 for delivering inflation media into the first balloon 450, and a second side port 464b communicating with the third inflation lumen 465 for delivering inflation media into the second balloon 459. In addition, the handle 460 may include a pull handle or other actuator 462 for directing the inner member 430 to one or more axial positions

relative to the outer member 420, and one or more seals, e.g., o-ring 466 for sealing the first lumen 426, similar to the previous embodiments.

Turning to FIGS. 17A-17D, the apparatus 410 is shown in different modes with the inner member 430 in respective positions. First, as shown in FIG. 17A, the inner member 430 is in a first or distal position with the first and second balloons 450, 459 in contracted conditions. In this configuration, the apparatus 410 may be introduced into a patient's body, into a target body lumen being treated, similar to the previous embodiments.

Turning to FIG. 17B, the first balloon 450 has been inflated to an expanded condition with the inner member remaining in the first position. Thus, the first balloon 450 may be expanded to one or more diameters, e.g., to engage or contact the wall of a body lumen being treated. The apparatus 410 may then be retracted or otherwise directed axially to scrape the first balloon 450 along the wall, e.g., to remove thrombus or other adherent material from the wall. Optionally, as shown in FIG. 17C, if greater pressure is desired, or a larger balloon is desired due to the size of the body lumen, the pull handle 462 may be directed proximally to pull the inner member 430 proximally relative to the outer member 420, thereby axially compressing and radially expanding the first balloon 450.

Finally, as shown in FIG. 17D, if it desired to dilate a stenosis, lesion, or other obstruction, the first balloon 450 may be collapsed to the contracted condition, and the second balloon 459 may be positioned adjacent the obstruction and inflated to expand and dilate the obstruction, similar to the previous embodiments. Thus, the apparatus 410 may be used to different treatments, e.g., embolectomy and/or angioplasty, without having to remove the apparatus 410, similar to the previous embodiments. The apparatus 410 may be tracked over a guidewire or other rail received through the second lumen 436 of the inner member 430, which may facilitate directing the apparatus 410 to various positions within a body lumen during treatment.

Turning to FIG. 18, another embodiment of a balloon apparatus 510 is shown that includes a catheter body or other tubular member 520 including a proximal end (not shown), a distal end 524 sized for introduction into a body lumen, and a plurality of lumens 526 extending between the proximal end and the distal end 524. For example, the catheter body 520 may include a guidewire lumen 526a, e.g., sized for slidably receiving a guidewire or other rail (not shown) therethrough, such that the apparatus 510 may be advanced over a guidewire into a patient's body.

In addition, the catheter body 520 may include an inflation lumen 526b that may communicate with a source of inflation media and/or source of vacuum (not shown) connected to the proximal end of the catheter body 520. A plurality of balloons or other expandable members 550 are spaced apart on the distal end 524 that may be independently expandable. For example, the balloons 550 may be formed from substantially inelastic material, such that the balloons 550 may be expanded to a predetermined diameter. Thus, the balloons 550 may be non-compliant, high pressure dilation balloons, similar to the other embodiments described elsewhere herein.

For example, the balloons 550 may be configured such that the inflated diameter and/or length of the balloons 550 vary along the distal end 524 of the catheter body 520. As shown, in an exemplary embodiment, the first balloon 550a may be expandable to a diameter of seven millimeters (7 mm), the second balloon 550b to a diameter of six millimeters (6 mm), the third balloon 550c to a diameter of five millimeters (5 mm), and the fourth balloon 550d to a diameter of four millimeters (4 mm). Thus, during use, the fourth balloon 550d may be initially positioned within an obstruction and inflated to dilate the obstruction. If further dilation is needed, the fourth balloon 550d may be deflated, the third balloon 550c may be positioned with the obstruction, and inflated to further dilate the obstruction. Thus, each successive balloon may be used, if desired, to provide increasing dilation of an obstruction.

The interior of each of the balloons 550 may communicate with the inflation lumen 526b, i.e., such that the catheter body 520 includes only a single inflation lumen 526, which may reduce the overall profile of the catheter body 520. In order to selectively inflate one of the balloons 550, a valve member 570 may be provided within the inflation lumen 526b that may be positioned such that the inflation lumen or a lumen 576 within the valve member 570 communicates with an interior of only one of the balloons 550.

For example, as shown, the valve member 570 may include an outlet port 574 on a distal end 572 of the valve member 570 that may communicate with the valve member lumen 576. The valve member 570 may slidably but sealingly engage the catheter body 520, such that the outlet port 574 may be aligned with an interior of a respective balloon 526. Thus, when inflation media is delivered through the valve member lumen 576, the inflation media may exit the outlet port 574 and inflate only the balloon 526 with which the outlet port 574 is aligned. It will be appreciated that other valve arrangements may be provided for delivering inflation media into the balloons individually. For example, a

valve member (not shown) may be rotatable within the inflation lumen 526b and may include one or more outlet ports that are aligned with passages (also not shown) into the interiors of respective balloons 550 when the valve member is in a predetermined angular orientation.

Turning to 19-21B, an exemplary embodiment of an apparatus 610 is shown for removing, retrieving, and/or otherwise capturing thrombus, objects, and/or obstructive material within a body lumen 90, such as a blood vessel, aorto-venous fistula, tubular graft, and the like. Generally, the apparatus 610 includes a catheter, sheath, or other tubular member 620, and an obstruction clearing or fragmentor device 640 including one or more fragmentor loops or elements 650 carried by a guidewire, shaft, or other elongate member 630.

As best seen in FIG. 19, the catheter 620 includes a proximal end 622, a distal end 624 sized for introduction into a body lumen, and a lumen 626 extending therebetween. The proximal end 622 is coupled to a handle 660 that includes an actuator for activating the fragmentor device 640 and/or other components of the apparatus 610. As shown, the handle 660 includes first and second handle portions 662, 664 that are movably coupled to one another, e.g., by pin, hinge, or other fulcrum 663, such that the second handle portion 662 may pivot or otherwise move relative to the first handle portion 662 to actuate the apparatus 610.

The first handle portion 662 includes a housing 666 (shown schematically in FIGS. 19 and 20) carrying various components of the apparatus 610 and to which the proximal end 622 of the catheter 620 is attached or otherwise coupled. For example, the housing 666 may include a piston assembly or other source of vacuum 668 including a piston 669 slidable within a chamber 670 and communicating with the lumen 626 of the catheter 620 via passage 671. The piston 669 may be coupled to the second handle portion 664 such that the piston 669 may be directed into and out of the chamber 670 during actuation of the second handle portion 664, e.g., to apply a vacuum to the catheter 620 lumen for aspirating material adjacent the catheter distal end 624. The housing 666 includes a reservoir 672 also communicating with the lumen 626 via passage 671. The piston assembly 668 may also provide positive pressure to expel fluid or other material within the passage 671 into the reservoir 672.

For example, as best seen in FIG. 20, a pair of one-way valves, e.g., duckbill or other check valves 673, 674, may be provided in the passage 671 for allowing flow of

fluid or other material through the valves 673, 674 in only one direction. For example, inlet valve 673 may allow material to enter the passage 671 from the catheter lumen 626 without allowing substantial flow of material back into the lumen 626 from the passage 671. Outlet valve 674 may allow material to flow from the passage 671 into reservoir 672 without allowing substantial flow of material back into the passage 671.

Thus, when the piston 669 is drawn partially from the chamber 670, e.g., by actuation of the second handle portion 664, a vacuum may be created, opening the inlet valve 673 and creating a vacuum within the catheter lumen 626, thereby aspirating material from beyond the catheter distal end 624 through the lumen 626 into the passage 671. When the piston 669 is advanced back into the chamber 670, e.g., when the second handle portion 664 is released or reset, a positive pressure is created in the passage 671, the inlet valve 673 is closed and the outlet valve 674 is opened, thereby forcing material within the passage 671 into the reservoir 672.

Returning to FIG. 19, the guidewire 630 generally includes a proximal end 632 extending into the handle 660, e.g., coupled to the second handle portion 664, and a distal end extending from the lumen 626 of the catheter 620 distally beyond the distal end 624 of the catheter 620. A seal 623 may be provided in the handle 660, e.g., to accommodate movement of the guidewire 630 into and out of the handle 660 and catheter 620 while preventing fluid from leaking from within the lumen 626.

As best seen in FIG. 20, the proximal end 632 of the guidewire 630 may be coupled to an adjustment control 636, e.g., to adjust a distance the guidewire 630 is pulled when the second handle portion 664 is actuated. For example, as shown, the proximal end 632 of the guidewire 630 may be slidably received in a slot 637 and coupled to a jack screw 638. The jack screw 638 may be coupled to a control knob 639 such that rotation of the know causes the jack screw 638 to move the proximal end 632 of the guidewire 630 up or down in the slot 637.

As the proximal end 632 of the guidewire 630 is directed upwardly in the slot 637, the proximal end 632 becomes further from the fulcrum 663, thereby increasing the distance the proximal end 632 of the guidewire 630 moves when the second handle portion 664 is actuated and released. As the proximal end 632 is directed downwardly in the slot 637, the distance the proximal end 632 moves decreases when the second handle portion 664 is actuated and released. Movement of the proximal end 632 causes the distal

end 634 of the guidewire 630 to move proximally and distally relative to the catheter distal end 624 for actuating the fragmentor device 640, as described further below.

Turning to FIGS. 20A and 20B, the fragmentor device 640 includes a pair of loops 650, although alternatively, the fragmentor device 640 may include additional loops, e.g., even numbers such that the loops may be coupled to the guidewire 630. As shown, a proximal edge of the first loop 650a is coupled to the catheter distal end 624 and an opposite distal edge is coupled to a proximal edge of the second loop 650 whose opposite distal edge is coupled to the guidewire 630, e.g., at hub 633. Each of these connections may be hinged, e.g., to allow the loops 650 to move proximally and distally during actuation. Optionally, the proximal edge of the first loop 650a may be hingedly coupled to the catheter distal end 624 at least partially within the lumen 626, e.g., to partially draw the first loop 650a into and out of the lumen 626 during actuation.

In addition, the fragmentor device 640 includes a fragmentor coil 642 including a first end 643 coupled to the catheter distal end 624, e.g., adjacent or within the lumen 626, and a second end 644 coupled to the guidewire 630, e.g., at hub 633. The fragmentor coil 642 may extend helically around the guidewire 630 between the first and second ends 632, 644, as best seen in FIG. 20B.

The fragmentor device 640 has two positions that it moves between during actuation. For example, FIG. 20A shows the fragmentor device 640 in a first or distal position in which the guidewire 630 is extended distally relative to the catheter distal end 624. Consequently, the fragmentor loops 650 and coil 644 are extended distally or longitudinally so that they adopt a low profile, e.g., with the coil 644 compressed around the guide wire 630 and the loops 650 lying substantially flat adjacent the guidewire 630. When the second handle portion 664 is actuated, the guidewire 630 is pulled proximally, thereby pulling the hub 633 on the distal end 634 and consequently compressing the fragmentor loops 650 and coil 644 proximally so that they adopt a larger profile, e.g., with the loops 650 adjacent one another and the coil 642 expanded away from the guidewire 630.

In the larger profile, the orientation of the loops 650 may approximate the diameter or other cross-section of a body lumen 90 within which the apparatus 610 is introduced, as best seen in FIG. 20B. To adjust the maximum diameter or cross-section of the loops 650 in the larger profile, the adjustment control 636 on the handle 660 may be adjusted, e.g., to

shorten the guidewire 630 travel distance and reduce the maximum diameter, or to extend the guidewire 630 travel distance and increase the maximum diameter, as desired.

The distal end 634 of the core wire 630 may be substantially atraumatic, e.g., rounded or otherwise shaped to minimize risk of perforation and/or catching during advancement relative to the catheter distal end 624 within a patient's body. Optionally, the distal end 634 may be covered by a coiled wire and/or a polymeric covering, and/or may include a "J" or other curved tip (not shown).

Optionally, the apparatus 610 may include one or more markers to facilitate positioning and/or advancement of the apparatus 610 during use. For example, one or more radiopaque markers may be placed on the catheter distal end 624, on the guidewire distal end 630, and/or on the fragmentor device 640. For example, one or more of the loops 650 and/or coil 642 may be formed from radiopaque or other materials that may facilitate imaging the apparatus 610 during use, similar to the previous embodiments.

Turning to FIGS. 21A-21F, an exemplary method for removing thrombus or other material 92 from within a body lumen 90 is shown. Initially, as shown in FIG.21A, the apparatus 610 may be introduced into a patient's body and directed into a target body lumen 90. Similar to previous embodiments, the body lumen 90 may be a blood vessel, e.g., a vein or artery, a graft, e.g., an aorto-venous fistula, tubular xenograft, or synthetic tubular graft, and the like. The apparatus 610 may introduced from a percutaneous puncture or other entry site and advanced through any intervening body passages into the body lumen 90. Optionally, the apparatus 610 may be introduced through an introduced sheath, guide catheter, and the like (not shown). In addition or alternatively, the apparatus 610 may be advanced over a guidewire or other rail (not shown), e.g., if the catheter 620 or guidewire 630 includes a guidewire lumen (not shown).

As shown in FIG. 21A, the distal end 634 of the guidewire 630 has been directed through a mass of thrombus 92 such that the catheter distal end 624 is adjacent the thrombus 92 and the fragmentor device 640 at least partially contacts the thrombus 92. The fragmentor device 640 may be advanced along the thrombus 92 in the low profile, e.g., to reduce the risk of breaking off pieces of the thrombus 92 prematurely and/or pushing the thrombus 92 away from the catheter distal end 624.

Turning to FIGS. 21B and 21C, the fragmentor device 640 is shown being actuated, e.g., such that the loops 650 expand from the low profile at least partially across the body lumen 90, and the coil 642 expands away from the guidewire 630, e.g., into the

thrombus 92. As described above with reference to FIG. 20, to actuate the fragmentor device 640, the first and second handle portions 662, 664 may be squeezed together, e.g., pivoting the second handle portion 664 relative to the first handle portion 662 and pulling the proximal end 632 of the guidewire 630 proximally. This pulls the distal end of the guidewire 630, and consequently, the hub 633, loops 650, and coil 642 proximally, e.g., until the larger profile shown in FIG. 21C is achieved. This motion of the loops 650 and coil 642 may engage and cut or otherwise separate one or more pieces of the thrombus 92 from the main mass, as shown in FIG. 21C.

In addition, as the second handle portion 664 is actuated, the piston 669 may be drawn out of the chamber 670, thereby creating a vacuum to aspirate pieces of the thrombus 92 into the catheter lumen 626 and into the reservoir 672 (see FIG. 20). Alternatively, a syringe, external continuous source of vacuum, and the like (not shown) may be connected to the handle 660 to aspirate material into the catheter lumen 626, if desired, rather than using a self-contained apparatus 610, as shown. The separated pieces of thrombus 92 may be sufficiently small to enter freely into the catheter lumen 626 and/or sufficient suction may be created to pull pieces of the thrombus 92 into the catheter lumen 626.

Turning to FIG. 21D, actuation of the apparatus 610 may be released, e.g., by releasing the second handle portion 664. The handle 660 may include one or more springs or other biasing mechanisms (not shown) for automatically returning the second handle portion 664 to its original position, and consequently returning the fragmentor device 640 to the distal, low profile. Because all of the desired thrombus 92 may not have been removed, the user may again actuate the fragmentor device 640, e.g., as shown in FIGS. 21E and 21F, by again squeezing the handle 660 and causing the loops 650 and coil 643 to compress axially and expand radially to separate additional pieces of the thrombus 92 for aspiration into the catheter lumen 626. The process may be monitored using external imaging, e.g., fluoroscopy, ultrasound imaging, and the like, until it is confirmed that sufficient, e.g., substantially all of the, thrombus 92 has been broken up and aspirated. Optionally, a source of contrast (not shown) may be connected to the apparatus 610, e.g., that communicates with the catheter lumen 626 or a lumen in the guidewire 630, to inject contrast to facilitate imaging the thrombus 92 within the body lumen 90, similar to the previous embodiments. Once the body lumen 90 is sufficiently cleared, the apparatus 610 be directed to another body lumen or removed entirely from the patient's body.

It will be appreciated that elements or components shown with any embodiment herein are exemplary for the specific embodiment and may be used on or in combination with other embodiments disclosed herein.

While the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents and alternatives falling within the scope of the appended claims.

We claim:

1. An apparatus for treating a body lumen, comprising:

an elongate tubular member including a proximal end, a distal end sized for introduction into a body lumen, and a first lumen extending between the proximal and distal ends;

an expandable balloon comprising a proximal end secured to the tubular member distal end, and a distal end comprising an outlet, the balloon comprising an interior communicating with the first lumen and the balloon outlet;

an elongate member slidably disposed within the first lumen, the elongate member comprising a proximal end adjacent the tubular member proximal end, and a distal end extending from the balloon outlet; and

a sealing member on the elongate member distal end, the elongate member being movable between a first position wherein the sealing member is spaced from the balloon outlet such that fluid introduced through the first lumen passes through the balloon interior and out the balloon outlet, and a second position wherein the sealing member substantially seals the balloon outlet such that fluid introduced through the first lumen enters the balloon interior to expand the balloon.

2. The apparatus of claim 1, wherein the sealing member has a cross-section larger than the balloon outlet.

3. The apparatus of claim 2, wherein the elongate member distal end has a cross-section smaller than the balloon outlet such that an annular lumen is defined between the elongate member and the balloon outlet for delivering fluid from the balloon interior through the balloon outlet when the elongate member is in the first position.

4. The apparatus of claim 1, wherein the elongate member has a cross-section smaller than the first lumen such that an annular lumen is defined between the elongate member and the tubular member for delivering fluid from the tubular member proximal end into the balloon interior.

5. The apparatus of claim 1, wherein the balloon comprises elastic material.

6. The apparatus of claim 1, wherein the balloon comprises substantially inelastic material.

7. The apparatus of claim 1, further comprising a handle on the tubular member proximal end, and an actuator on the handle for directing the elongate member between the first and second positions.

8. The apparatus of claim 1, wherein the elongate member is biased to one of the first and second positions.

9. The apparatus of claim 1, further comprising a helical member including a first end coupled to the tubular member distal end and a second end coupled to the elongate member distal end, the helical member extending helically around the elongate member within the balloon interior, the elongate member movable to a third position in which the elongate member distal end is directed towards the tubular member distal end to cause the helical member to expand radially outwardly to an expanded helical shape, thereby expanding the balloon to the expanded helical shape.

10. The apparatus of claim 9, wherein the helical member second end is coupled to a stop secured to the elongate member distal end, the stop having a cross-section larger than the balloon outlet such that the stop limits relative movement of the balloon distal end relative to the elongate member distal end as the elongate member is directed between the second and third positions.

11. The apparatus of claim 9, further comprising a source of vacuum communicating with the first lumen for collapsing the balloon before the elongate member is directed to the third position such that the balloon conforms substantially to the expanded helical shape of the helical member.

12. The apparatus of claim 9, wherein the balloon distal end is directed towards the balloon proximal end when the elongate member is moved to the third position, thereby axially compressing the balloon.

13. The apparatus of claim 12, further comprising a stop on the elongate member distal end proximal to the balloon distal end, the elongate member movable from the third position back towards the second position, thereby extending and collapsing the helical member, the stop engaging the balloon distal end and directing the balloon distal end distally as the elongate member is moved from the third position back towards the second position, thereby axially extending and collapsing the balloon.

14. An apparatus for treating a body lumen, comprising:

an outer tubular member including a proximal end, a distal end sized for introduction into a body lumen, and a first lumen extending between the proximal and distal ends;

an expandable balloon comprising a proximal end secured to the outer member distal end, and a distal end comprising an outlet, the balloon comprising an interior communicating with the first lumen and the balloon outlet;

an inner member slidably disposed within the first lumen and having a cross-section smaller than the first lumen such that an annular lumen is defined between the outer and inner members between the proximal and distal ends of the outer member, the inner member comprising a proximal end adjacent the outer member proximal end, and a distal end extending from the balloon outlet;

a sealing member on the inner member distal end, the inner member movable between a first position wherein the sealing member is spaced from the balloon outlet such that fluid introduced through the first lumen passes through the balloon interior and out the balloon outlet, and a second position wherein the sealing member substantially seals the balloon outlet such that fluid introduced through the first lumen enters the balloon interior to expand the balloon; and

a helical member comprising a first end coupled to the outer member distal end and a second end coupled to the inner member distal end, the helical member extending helically around the inner member within the balloon interior, the inner member movable to a third position in which the inner member distal end is directed towards the outer member distal end to cause the helical member to expand radially outwardly, thereby expanding the balloon to an expanded helical shape.

15. The apparatus of claim 14, wherein the balloon comprises substantially inelastic material.

16. The apparatus of claim 14, wherein the helical member second end is coupled to a stop secured to the inner member distal end, the stop having a cross-section larger than the balloon outlet such that the stop limits relative movement of the balloon distal end relative to the inner member distal end as the elongate member is directed between the second and third positions.

17. The apparatus of claim 14, further comprising a source of vacuum communicating with the first lumen for collapsing the balloon before the inner member is directed to the third position such that the balloon conforms substantially to the shape of the helical member as the balloon is expanded to the expanded helical shape.

18. An apparatus for treating a body lumen, comprising:

an outer tubular member including a proximal end, a distal end sized for introduction into a body lumen, and a first lumen extending between the proximal and distal ends;

an inner member slidably disposed within the first lumen and having a cross-section smaller than the first lumen such that an annular lumen is defined between the outer and inner members between the proximal and distal ends of the outer member, the inner member comprising a proximal end adjacent the outer member proximal end, and a distal end extending beyond the outer member distal end;

an expandable balloon comprising a proximal end secured to the outer member distal end, and a distal end coupled to the inner member distal end, the balloon comprising an interior communicating with the first lumen and the balloon outlet;

a source of inflation media communicating with the first lumen for delivering inflation media through the first lumen into the balloon interior for expanding the balloon radially outwardly from a contracted condition to a cylindrical expanded condition; and

a helical member comprising a first end coupled to the outer member distal end and a second end coupled to the inner member distal end, the helical member extending helically around the inner member within the balloon interior, the inner member movable from a first distal position in which the helical member is disposed adjacent the inner

member and the balloon is in the contracted condition to a second proximal position that causes the helical member to compress axially and expand radially outwardly, thereby compressing axially and expanding radially the balloon to an expanded helical shape.

19. The apparatus of claim 18, wherein the helical member comprises first and second regions between the first and second ends, the first region expandable to a diameter greater than the second region such that the balloon defines first and second helical regions in the expanded helical shape, the first helical region having a diameter greater than the second helical region.

20. The apparatus of claim 18, further comprising a source of vacuum communicating with the first lumen for collapsing the balloon towards the contracted condition before the inner member is directed to the second position such that the balloon conforms substantially to the shape of the helical member in the expanded helical shape.

21. An apparatus for treating a body lumen, comprising:

an outer tubular member including a proximal end, a distal end sized for introduction into a body lumen, and a first lumen extending between the proximal and distal ends;

an inner member slidably disposed within the first lumen and comprising a proximal end adjacent the outer member proximal end, and a distal end extending beyond the outer member distal end;

an expandable balloon comprising a proximal end secured to the outer member distal end, and a distal end coupled to the inner member distal end, the balloon comprising an interior communicating with the first lumen and the balloon outlet; and

a helical member comprising a first end coupled to the outer member distal end and a second end coupled to the inner member distal end, the helical member extending helically around the inner member within the balloon interior, the inner member movable from a first distal position in which the helical member is disposed adjacent the inner member and the balloon is in the contracted condition to a second proximal position that causes the helical member to compress axially and expand radially outwardly, thereby compressing axially and expanding radially the balloon to an expanded helical shape, the helical member comprising first and second regions between the first and second ends, the

first region expandable to a diameter greater than the second region such that the balloon defines first and second helical regions in the expanded helical shape, the first helical region having a diameter greater than the second helical region.

22. An apparatus for removing material within a body lumen, comprising:

an elongate tubular member including a proximal end, a distal end sized for introduction into a body lumen, and an aspiration lumen extending between the proximal and distal ends;

an elongate guide member extending from the distal end and terminating in a distal tip, the guide member being reciprocable relative to the tubular member such that the distal tip is moved towards and away from the tubular member distal end; and

a fragmentor device comprising a plurality of loops coupled sequentially to one another, a first loop being coupled to the tubular member distal end and a last loop being coupled to the guide member such that, as the guide member is reciprocated, the loops are directed between a low profile extending generally along the guide member and a large profile in which the loops extend transversely relative to the guide member.

23. The apparatus of claim 22, wherein the fragmentor device further comprises a fragmentor coil disposed helically around the guide member distal end, the fragmentor coil coupled to the guide member such that the fragmentor coil is extended and compressed radially when the loops are directed to the low profile and the fragmentor coil is compressed axially and expanded radially when the loops are directed to the large profile.

24. The apparatus of claim 22 or 23, wherein the loops are directed to the low profile when the guide member is directed distally relative to the tubular member distal end and the loops are directed to the large profile when the guide member is directed proximally relative to the tubular member distal end.

25. The apparatus of any one of claims 22-24, further comprising a handle on the tubular member proximal end, the handle comprising an actuator coupled to the guide member for reciprocating the guide member.

26. The apparatus of claim 25, further comprising a source of vacuum carried by the handle and configured to create a vacuum within the tubular member lumen to aspirate obstructive material engaged or separated by the fragmentor device.

27. A method for treating a body lumen of a patient using a balloon apparatus comprising an outer member including a first lumen extending between proximal and distal ends thereof, an inner member slidable within the first lumen, and a balloon carried by the outer and inner members, the balloon comprising an outlet and an interior communicating with the first lumen and the outlet, the method comprising:

introducing a distal end of the balloon apparatus into a body lumen with the balloon in a contracted condition;

directing proximal and distal ends of the balloon towards one another to expand the balloon from the contracted condition to an expanded helical shape;

directing the distal end of the apparatus along a wall of the body lumen with the balloon in the expanded helical shape to remove obstructive material from the wall of the body lumen;

introducing inflation media through the first lumen into the balloon interior to expand the balloon from the contracted condition to a substantially cylindrical shape to dilate a wall of the body lumen;

withdrawing the inflation media from the balloon interior through the first lumen to collapse the balloon back towards the contracted condition; and

removing the distal end of the apparatus from the body lumen with the balloon in the contracted condition.

28. A method for treating a body lumen of a patient, comprising:

introducing a distal end of an apparatus into a body lumen, the apparatus carrying an expandable member on the distal end in a contracted condition;

directing proximal and distal ends of the expandable member towards one another to expand the expandable member from the contracted condition to an expanded helical shape;

directing the distal end of the apparatus along a wall of the body lumen with the expandable member in the expanded helical shape to remove obstructive material from the wall of the body lumen; and

introducing inflation media through the shaft into an interior of the expandable member to expand the expandable member from the contracted condition to an expanded shape comprising one of a substantially cylindrical shape and a bulbous shape.

29. A method for treating a body lumen, comprising:

introducing a distal end of an apparatus into a body lumen, the apparatus carrying an expandable member on the distal end in a contracted condition;

delivering fluid through a first lumen of the apparatus such that the fluid passes through an interior of the balloon and exits an open valve adjacent the balloon;

sealing the valve; and

delivering fluid through the first lumen with the valve sealed, thereby expanding the balloon from the contracted condition to an expanded condition.

30. The method of claim 29, wherein the balloon comprises elastic material, the method further comprising:

axially compressing the balloon in the expanded condition while the valve remains sealed, thereby changing at least one of a shape and a size of the balloon.

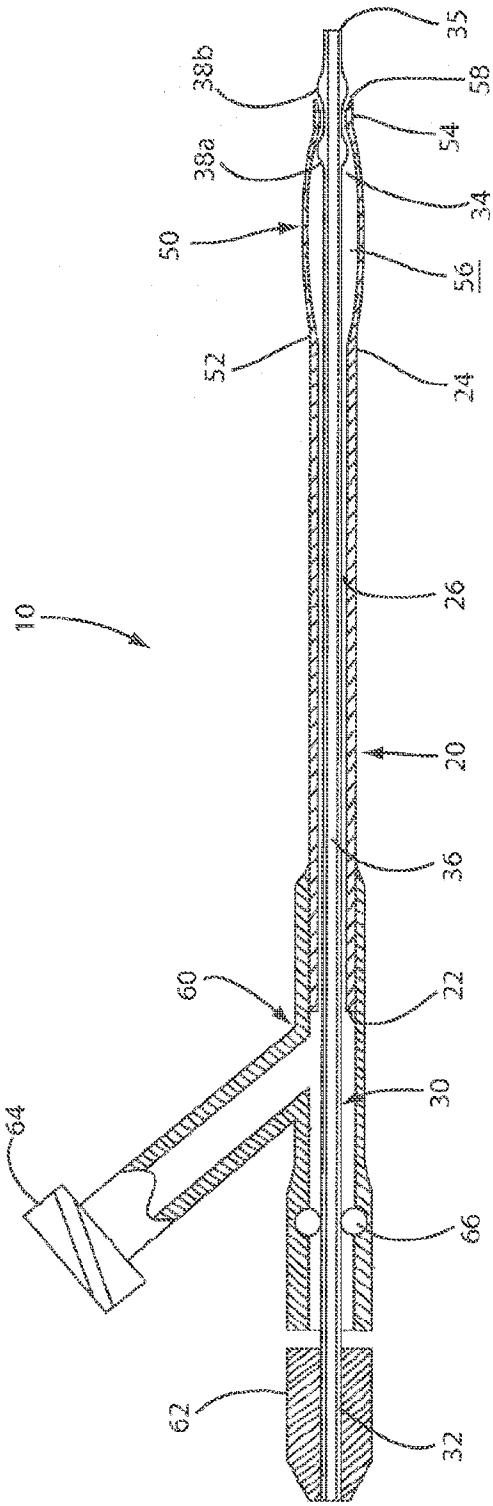


FIG. 1

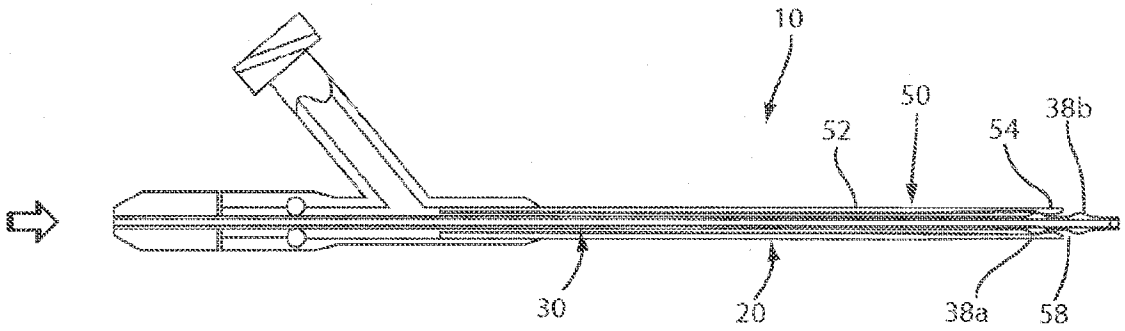


FIG. 2

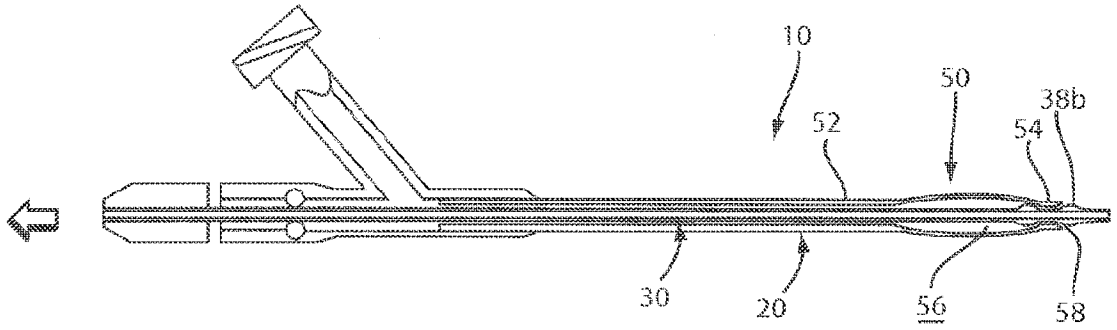


FIG. 3

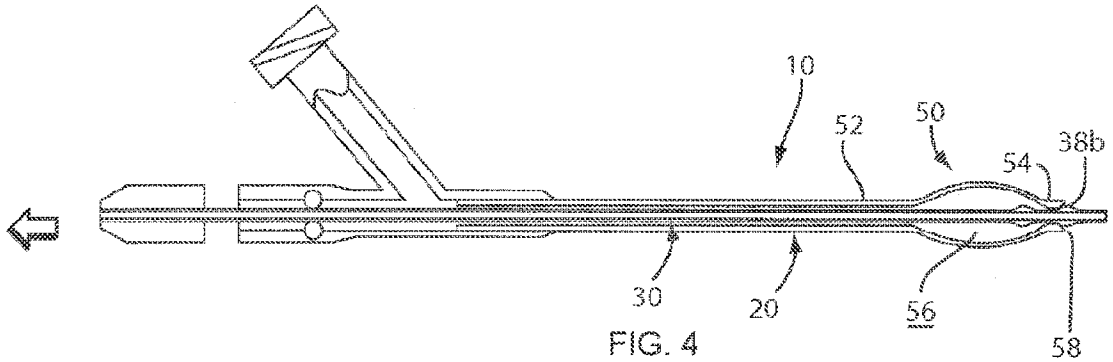


FIG. 4

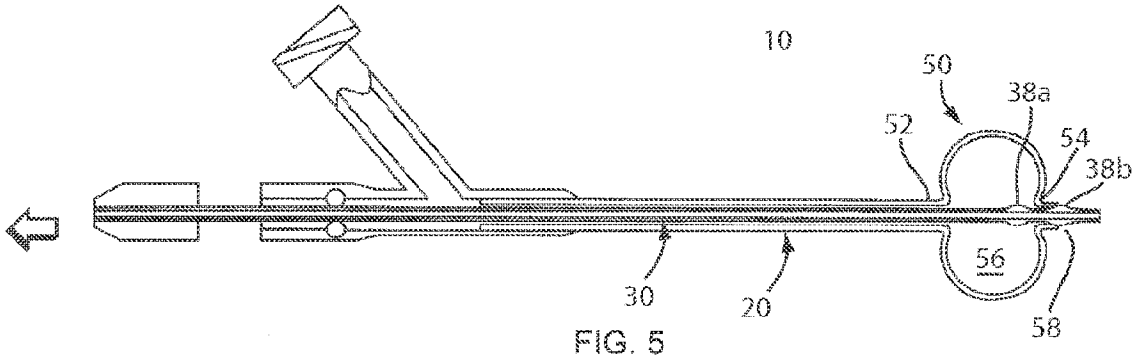


FIG. 5

FIG. 6A

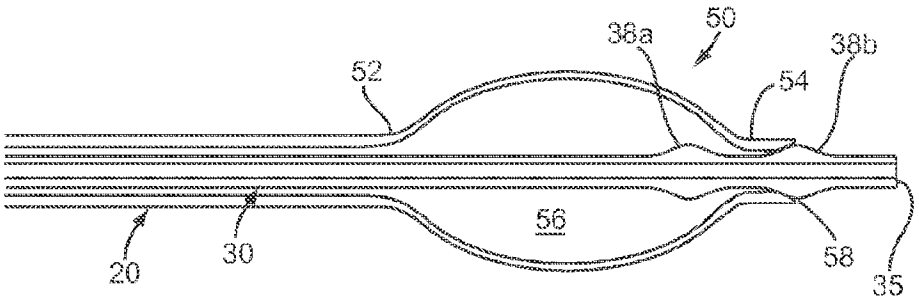


FIG. 6B

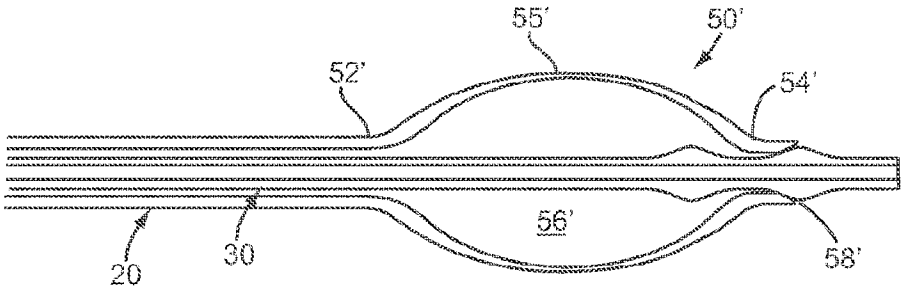


FIG. 6C

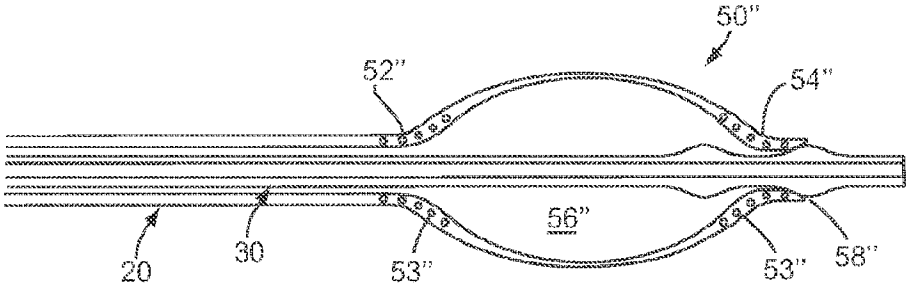
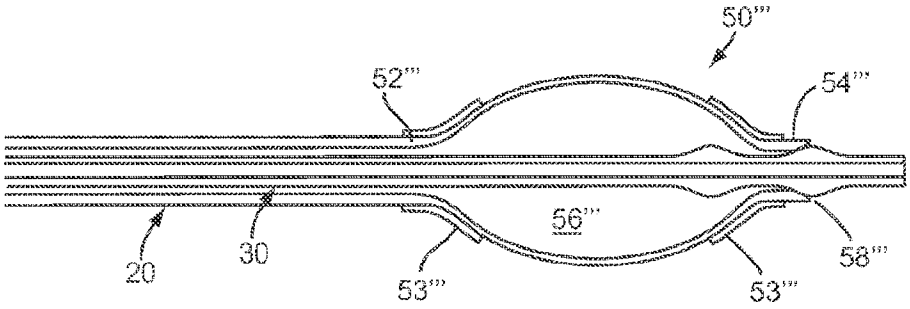
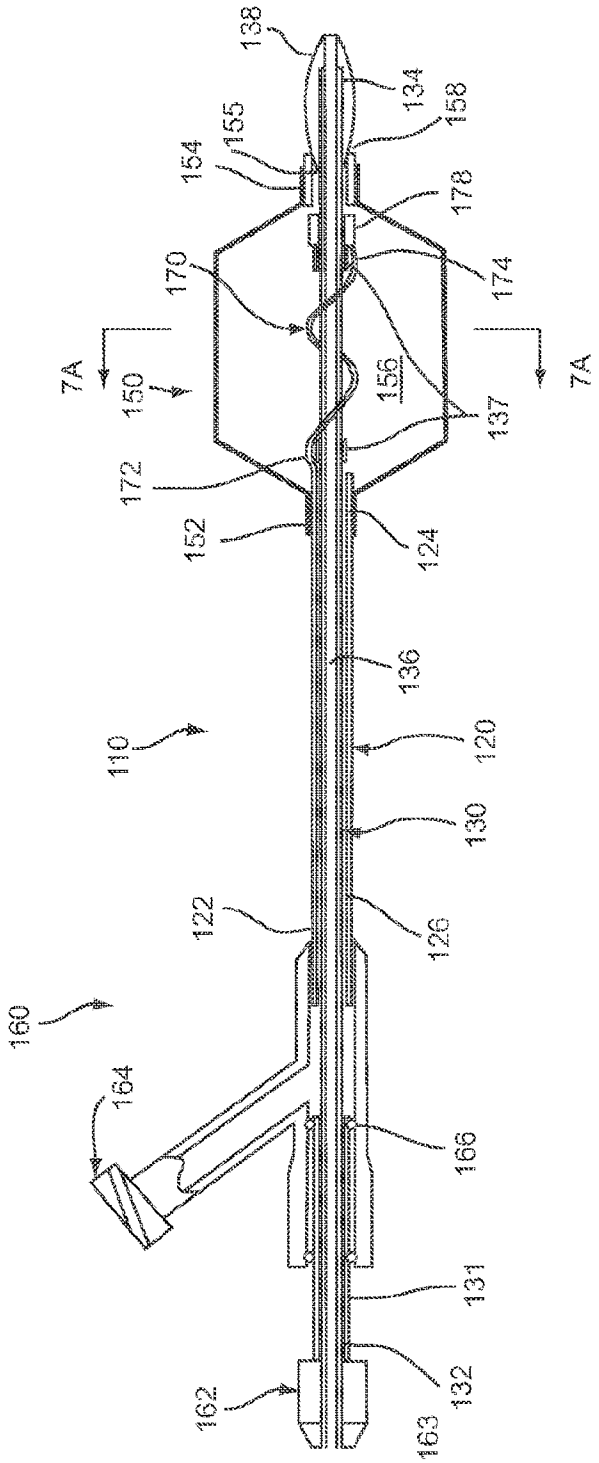


FIG. 6D




138
134
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178
170
174
7A
150
156
137
7A
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FIG. 7

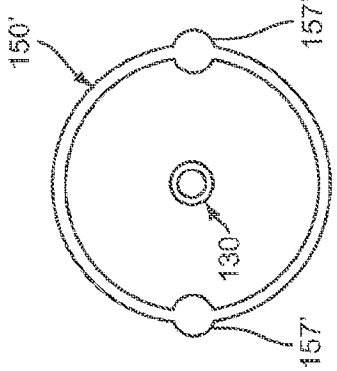


FIG. 7D

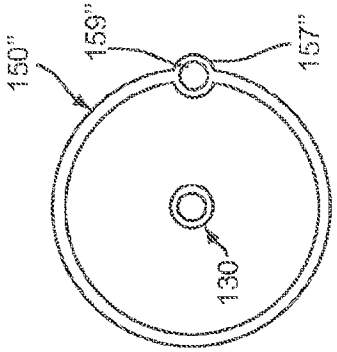


FIG. 7C

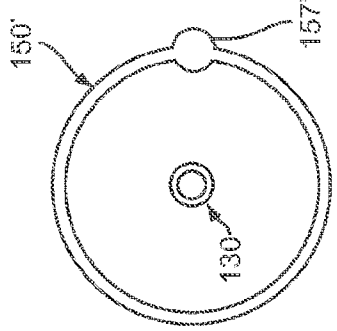


FIG. 7B

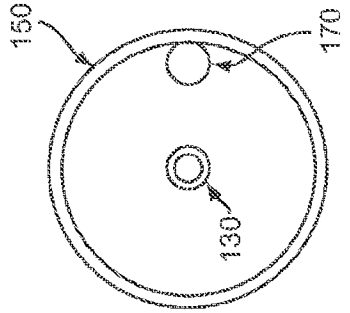


FIG. 7A

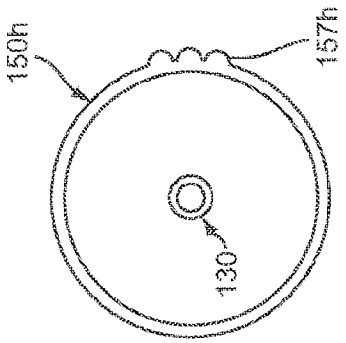


FIG. 7H

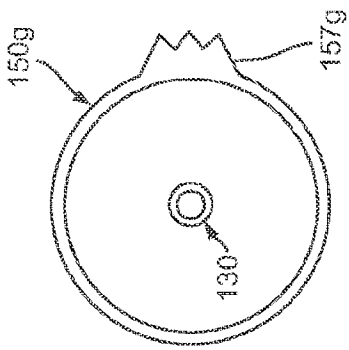


FIG. 7G

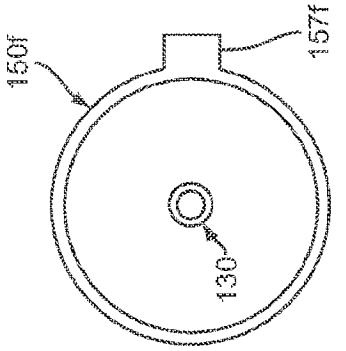


FIG. 7F

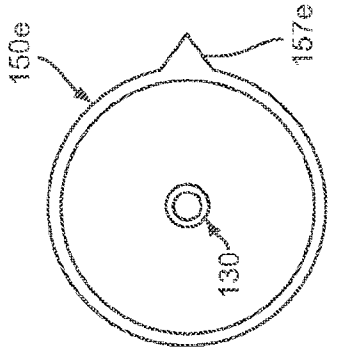
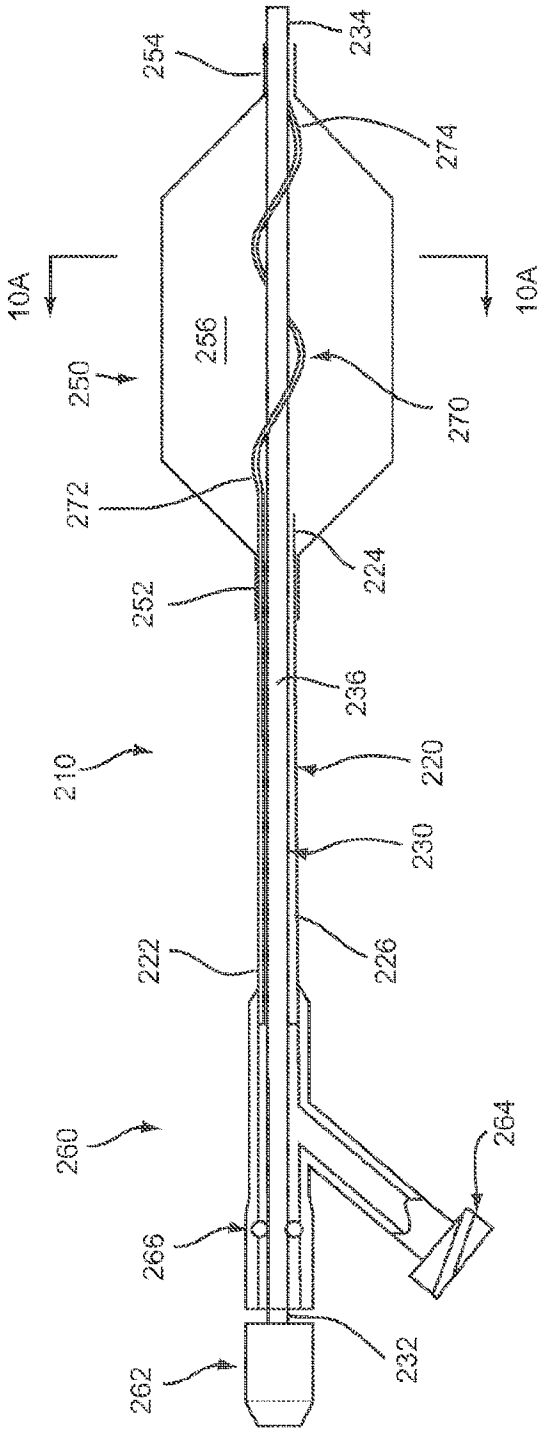


FIG. 7E


254
234
274
10A
10A
256
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232
262

FIG. 8

FIG. 9A

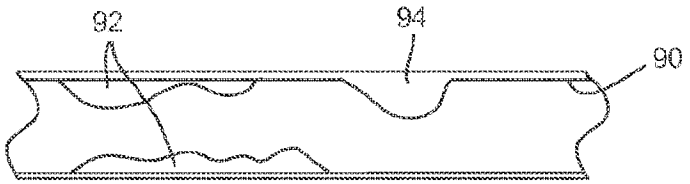


FIG. 9B

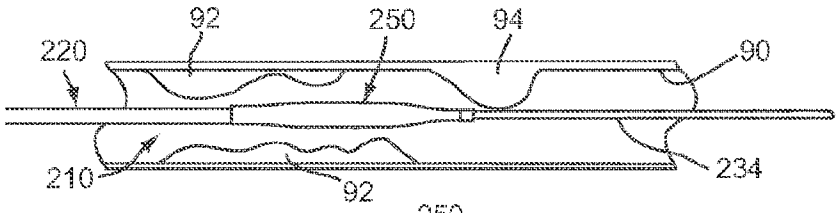


FIG. 9C

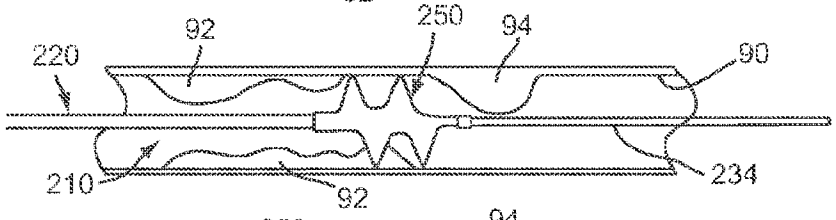


FIG. 9D

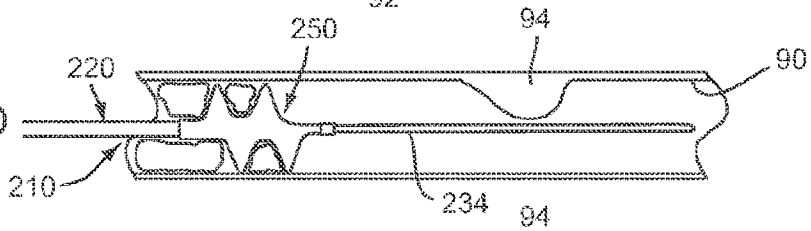


FIG. 9E

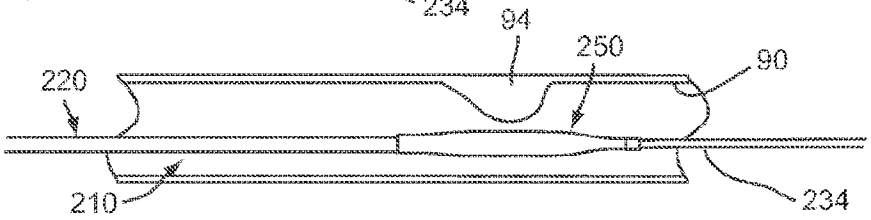


FIG. 9F

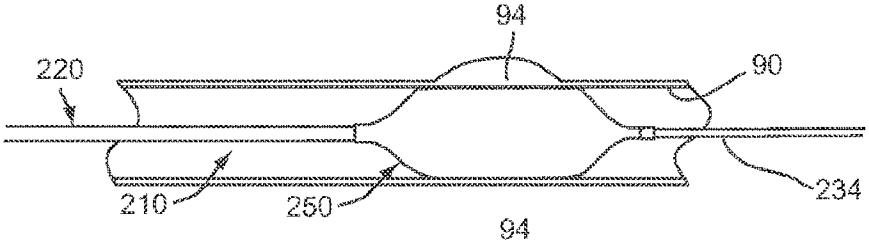
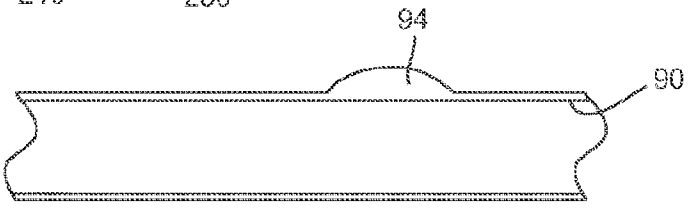


FIG. 9G



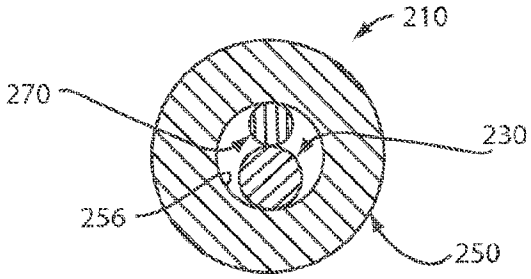


FIG. 10A

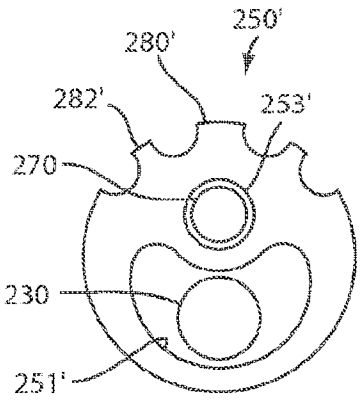


FIG. 10B

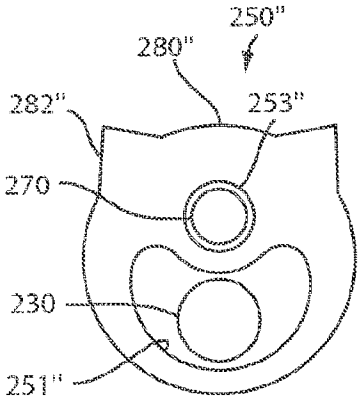


FIG. 10C

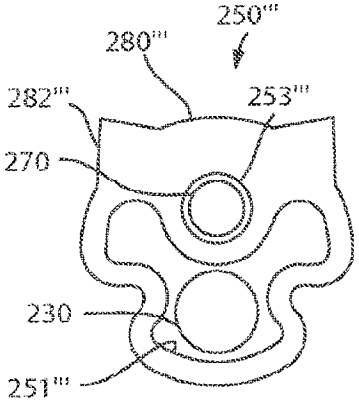


FIG. 10D

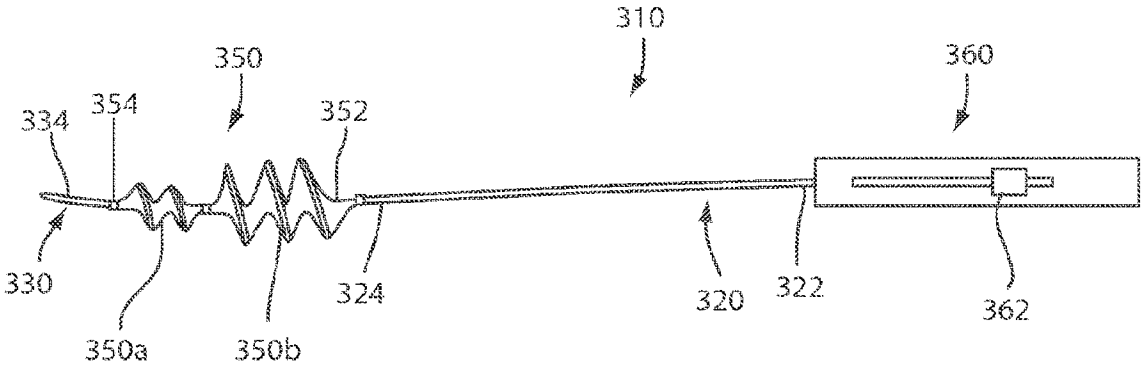

310
350
360
334
354
352
330
324
320
322
362
350a
350b

FIG. 11

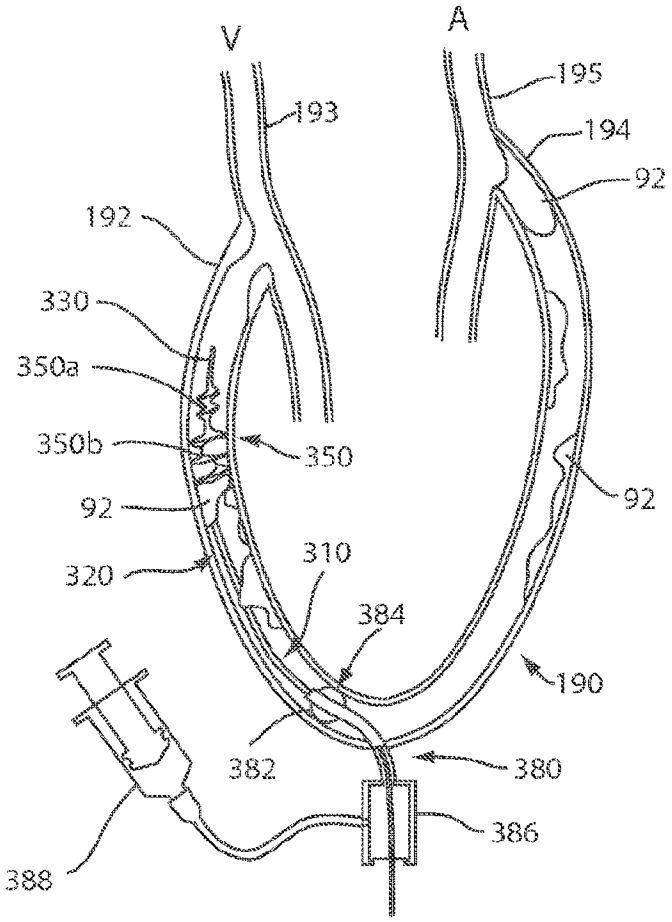

V
A
195
193
194
92
192
330
350a
350b
350
92
92
310
320
384
190
382
380
386
388

FIG. 12

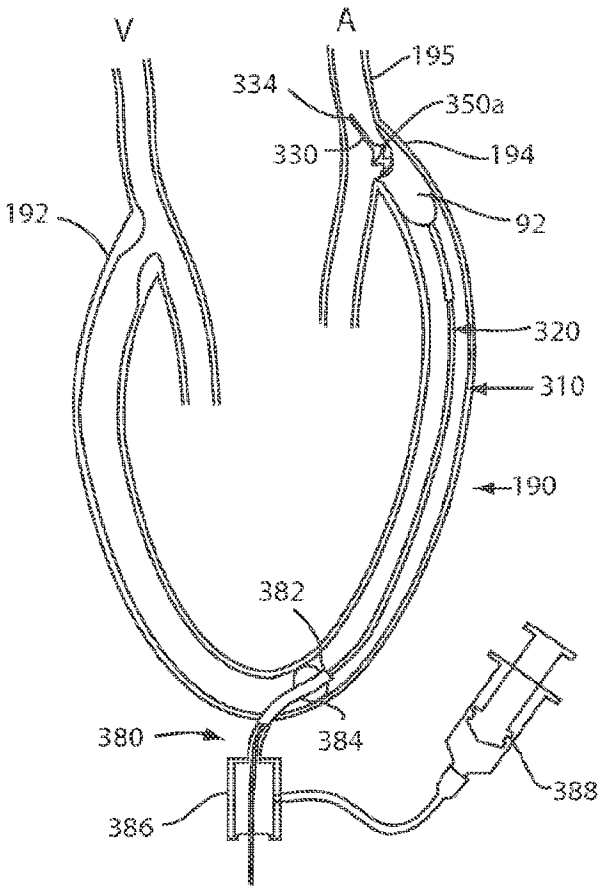

V
A
195
334
350a
330
194
92
192
320
310
190
382
384
380
388
386

FIG. 13

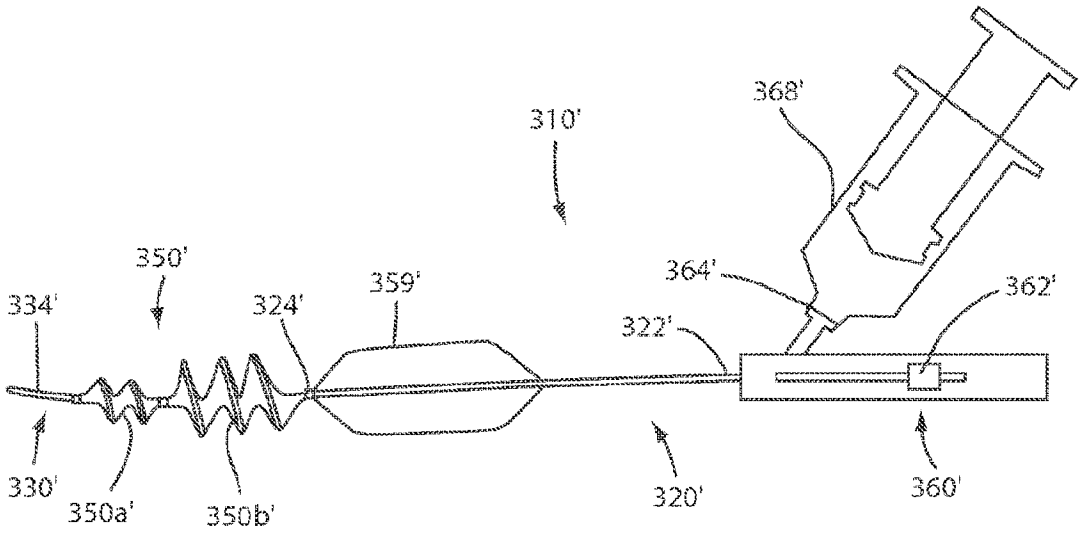

368'
310'
350'
364'
362'
334'
324'
359'
322'
330'
350a'
350b'
320'
360'

FIG. 14

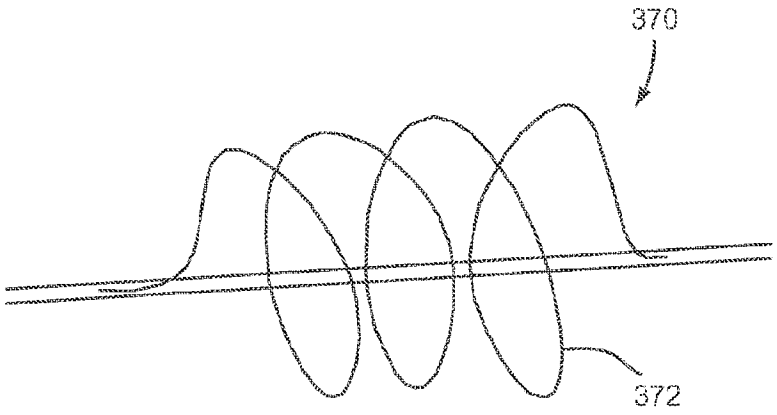


FIG. 15A

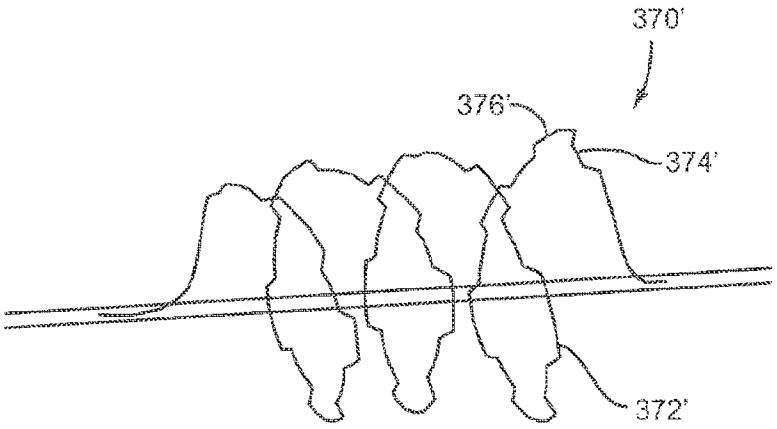


FIG. 15B

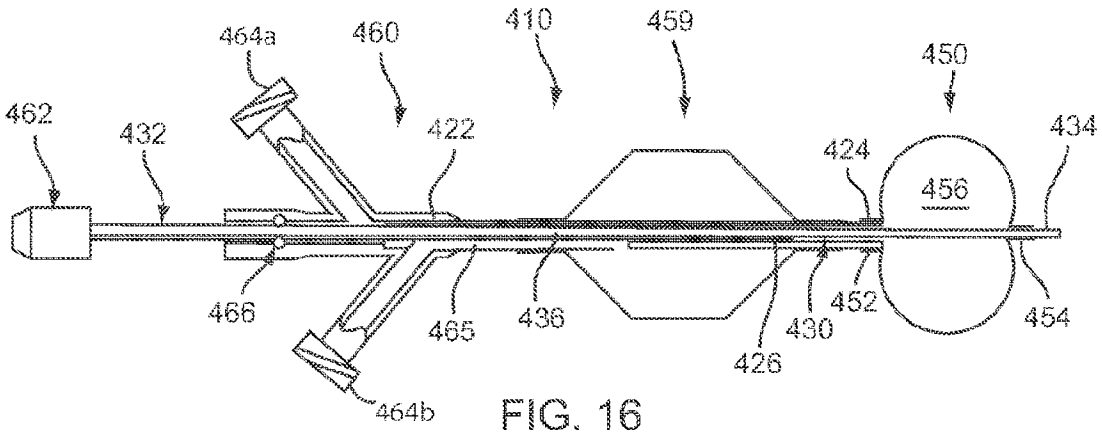


FIG. 16

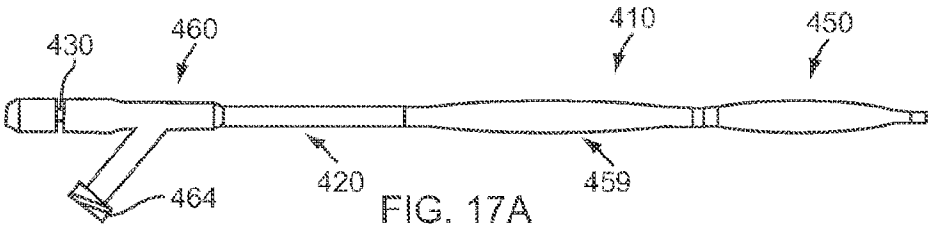


FIG. 17A

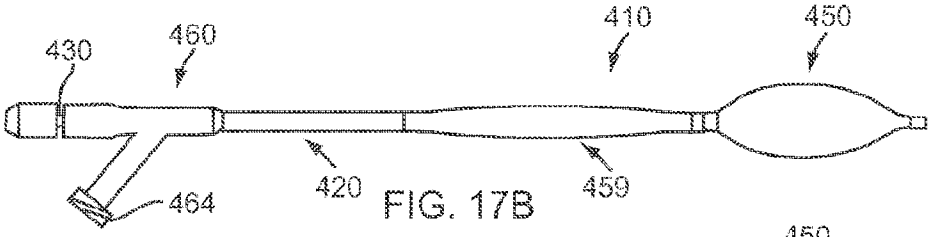


FIG. 17B

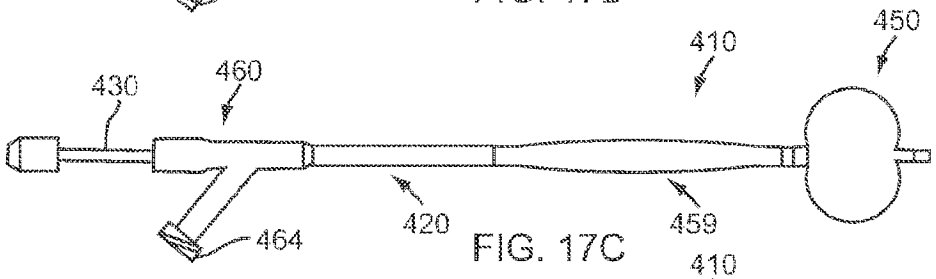


FIG. 17C

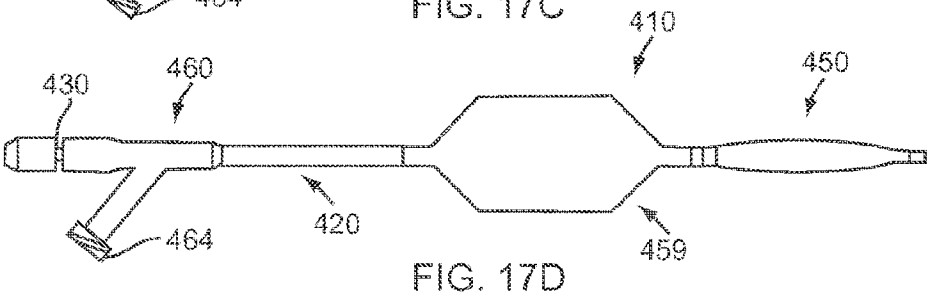


FIG. 17D

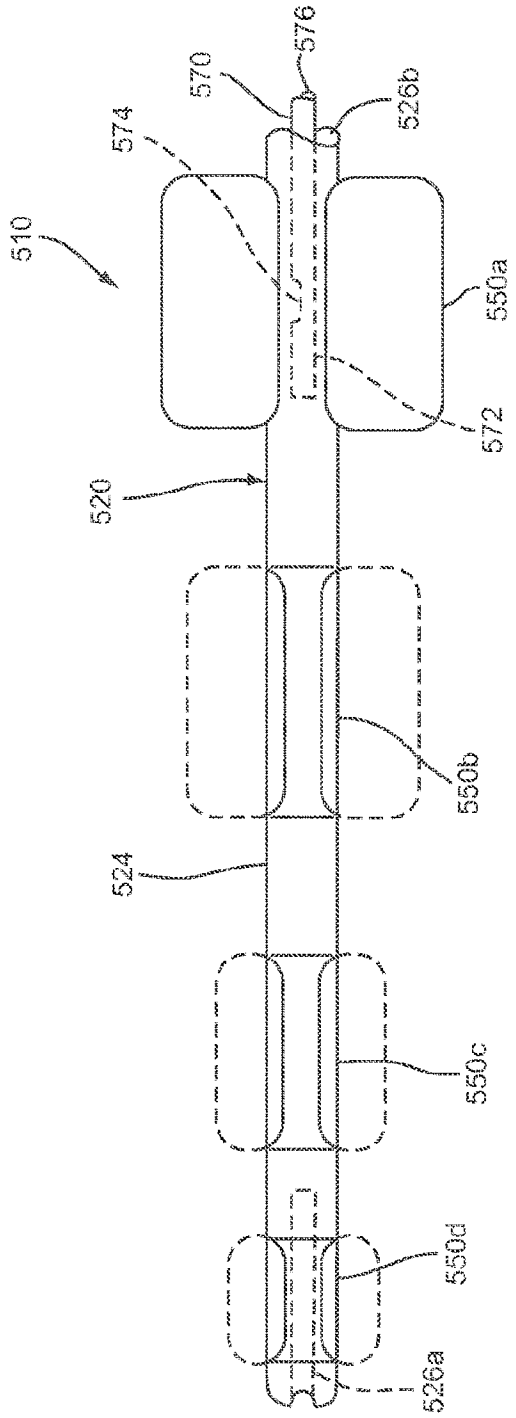
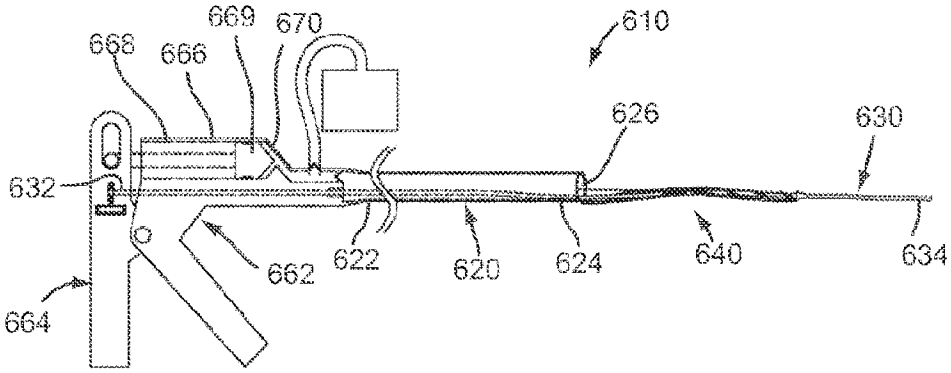


FIG. 18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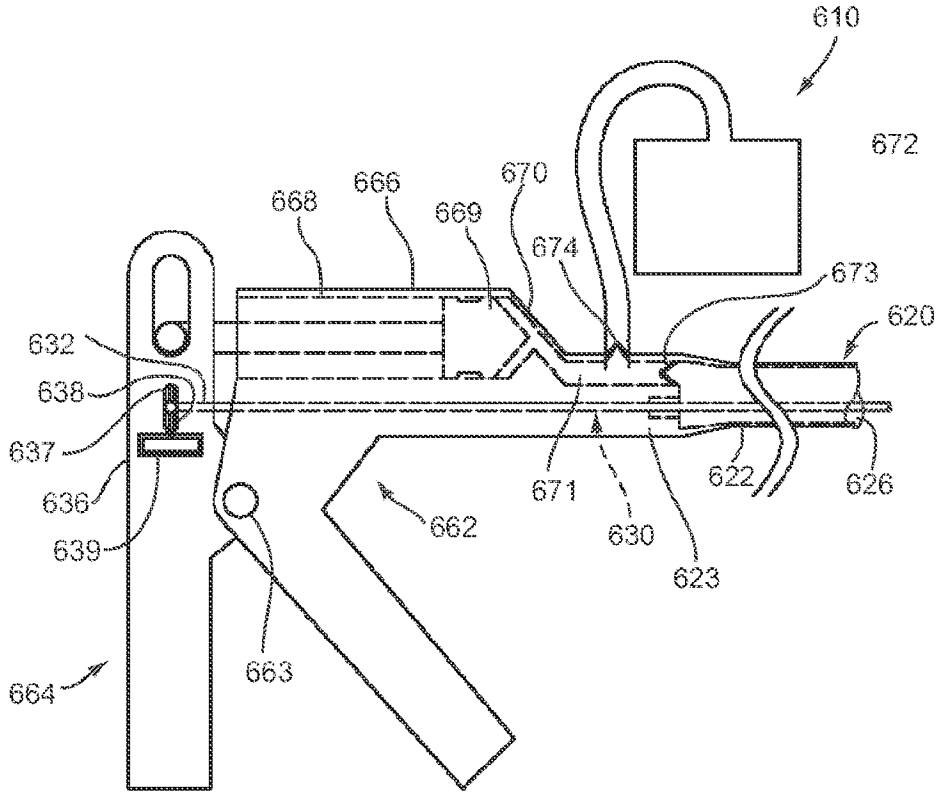
634
664

FIG. 19


610
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663
664

FIG. 20

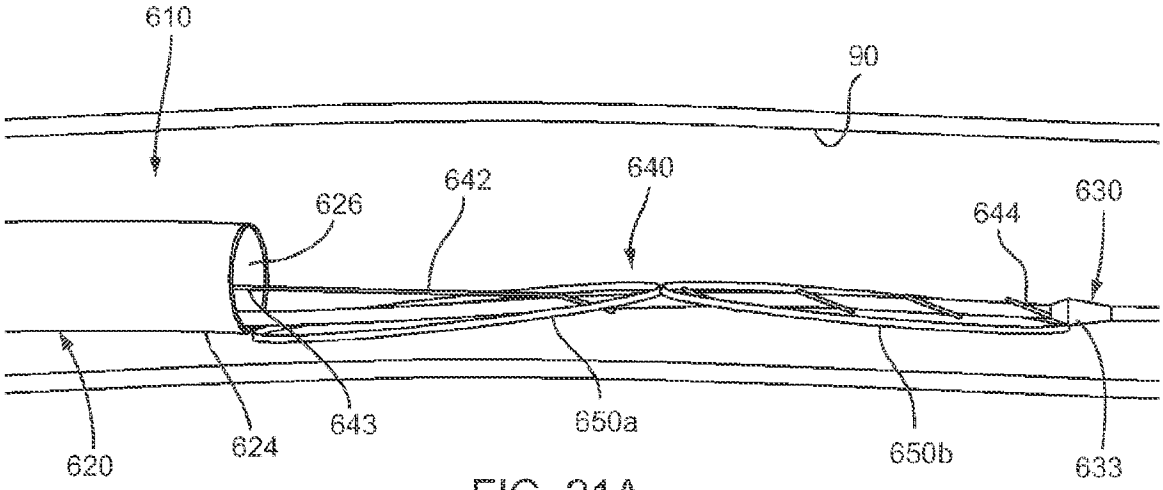


FIG. 21A

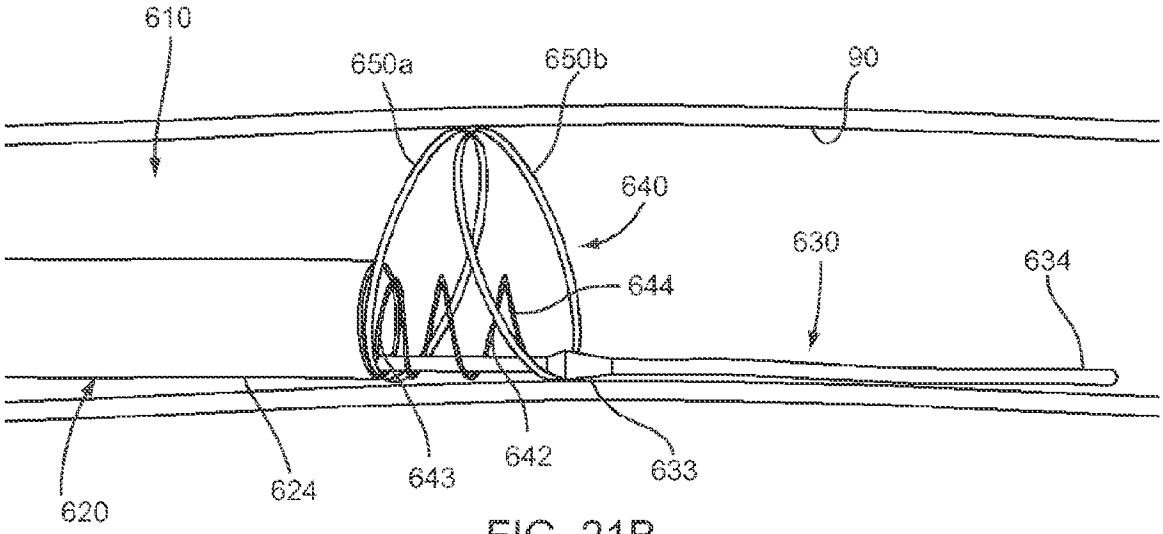


FIG. 21B

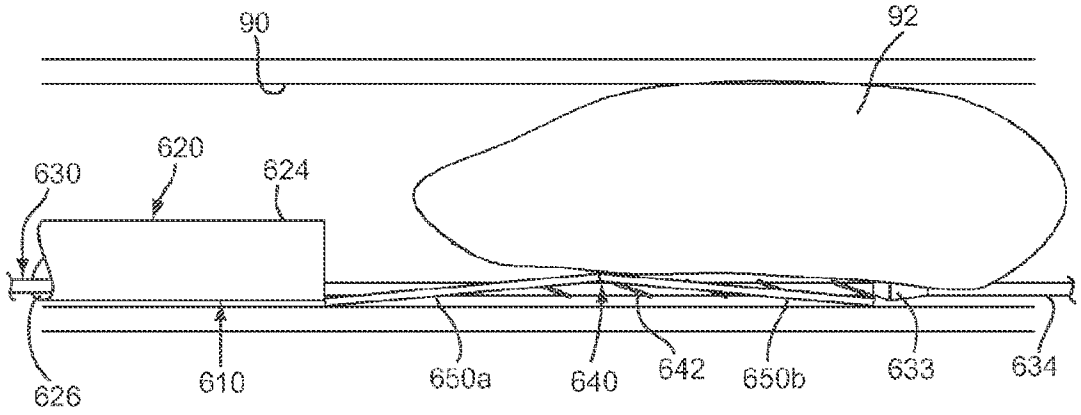


FIG. 22A

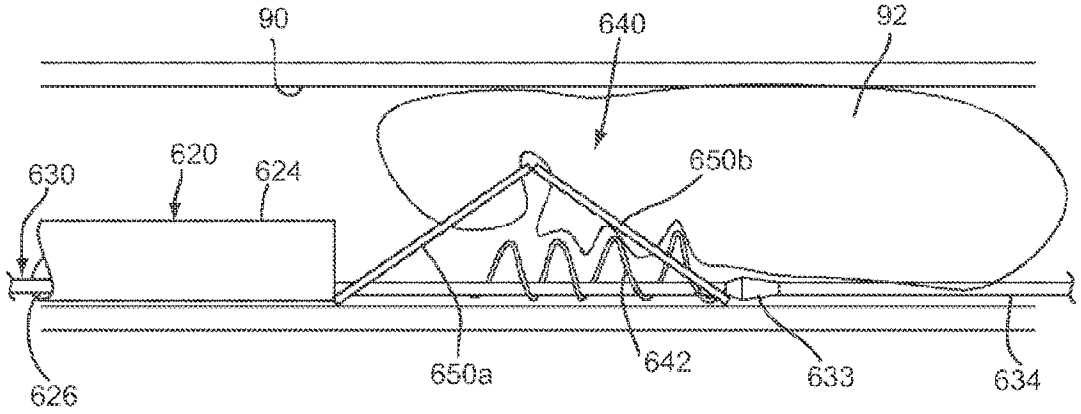


FIG. 22B

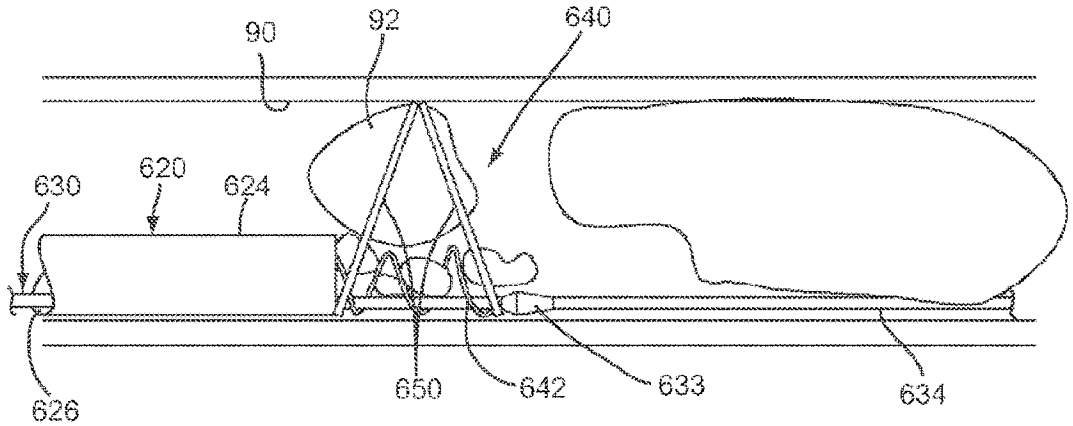


FIG. 22C

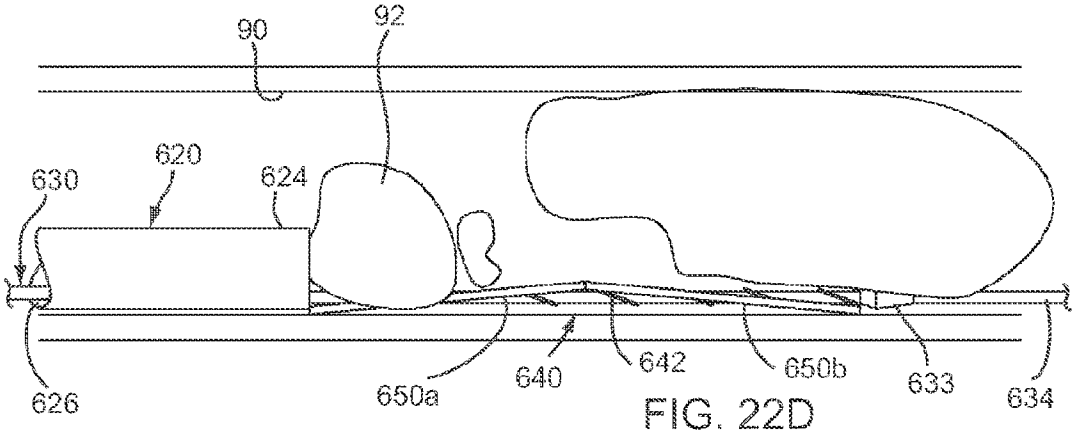


FIG. 22D

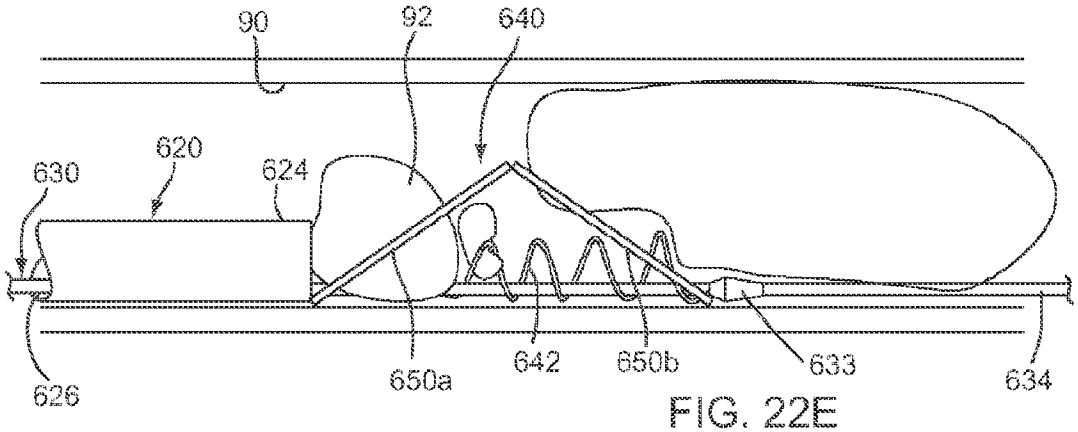


FIG. 22E

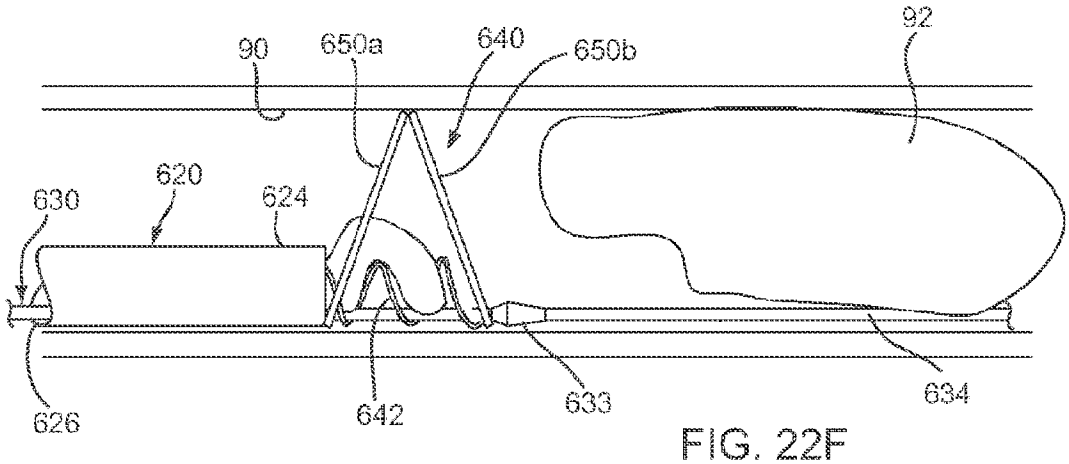


FIG. 22F

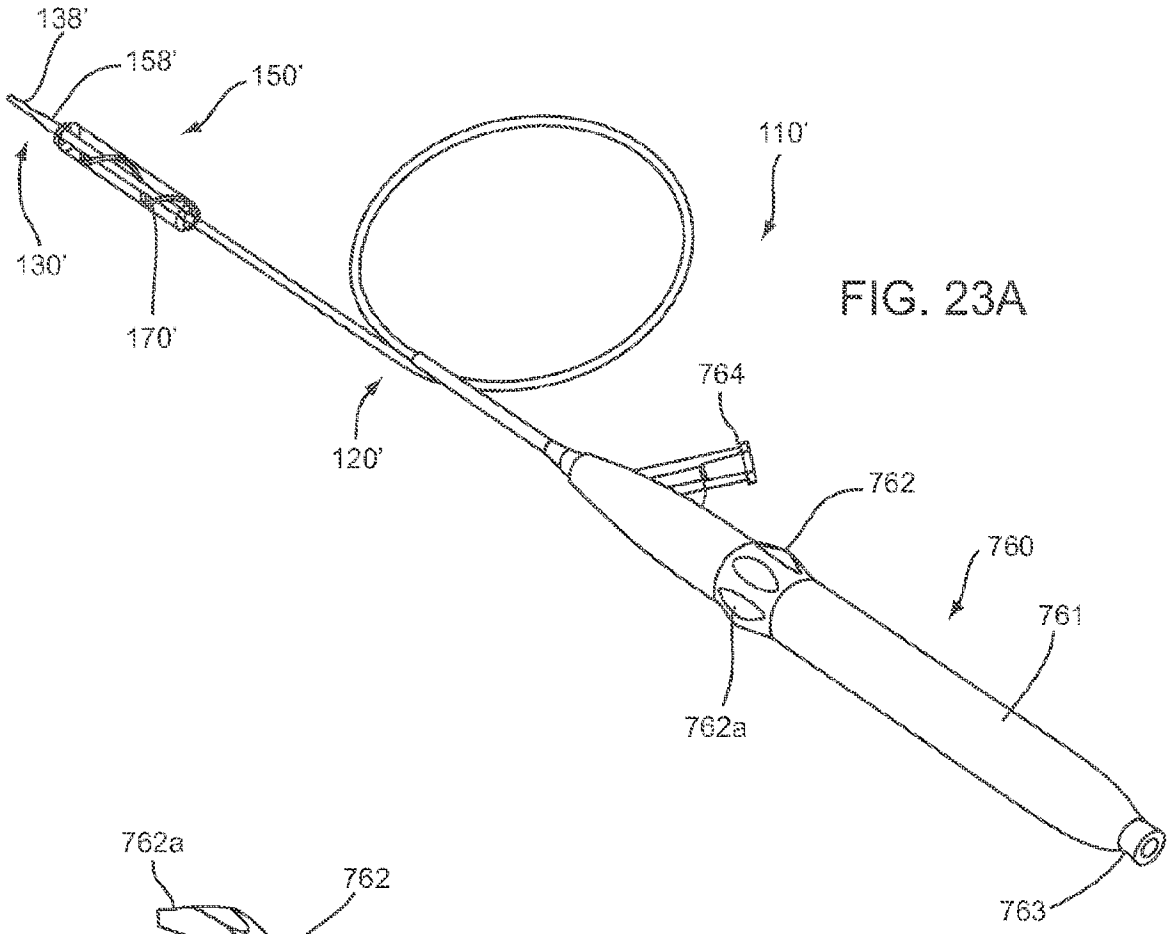


FIG. 23A

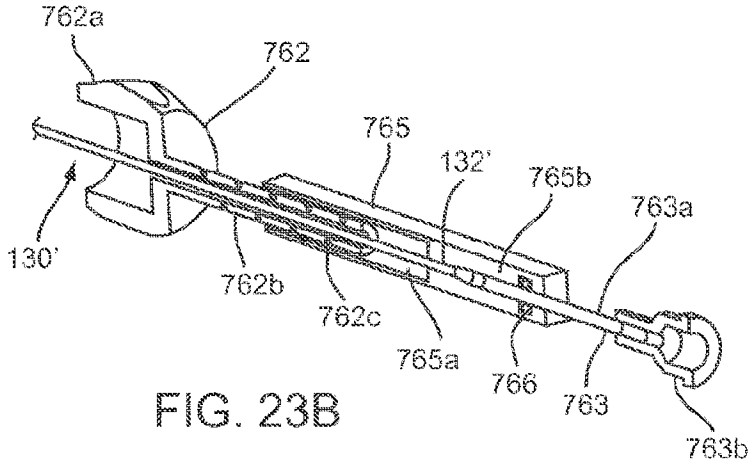


FIG. 23B

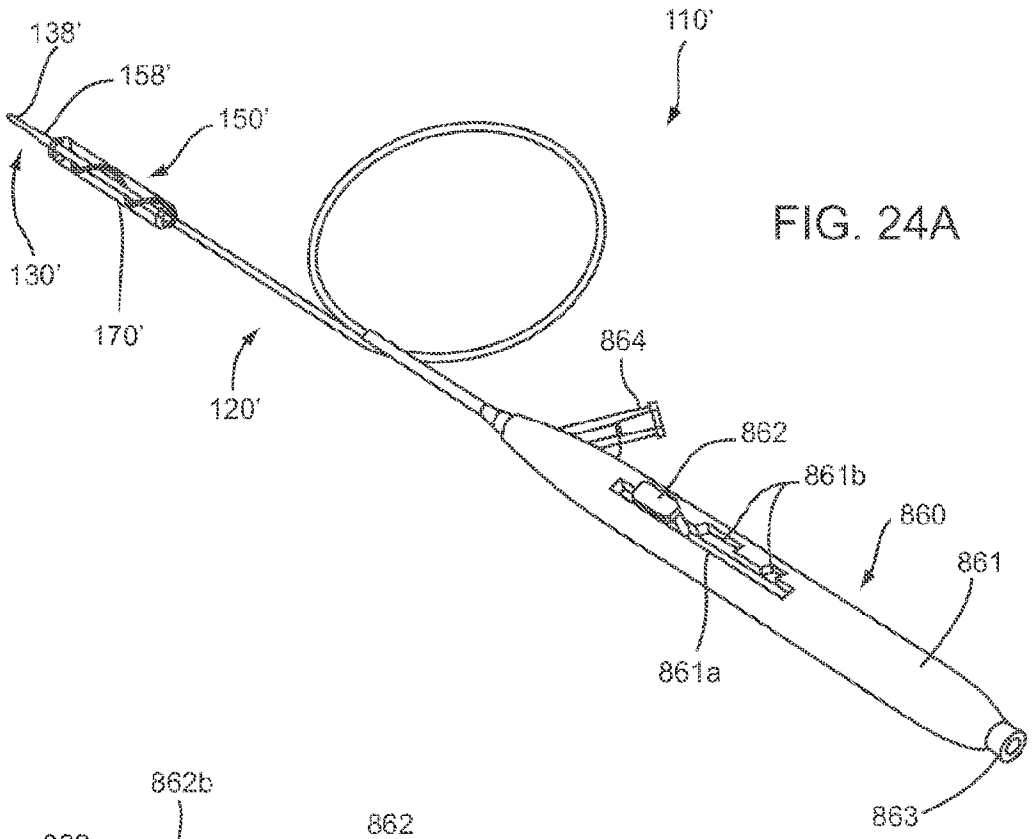


FIG. 24A

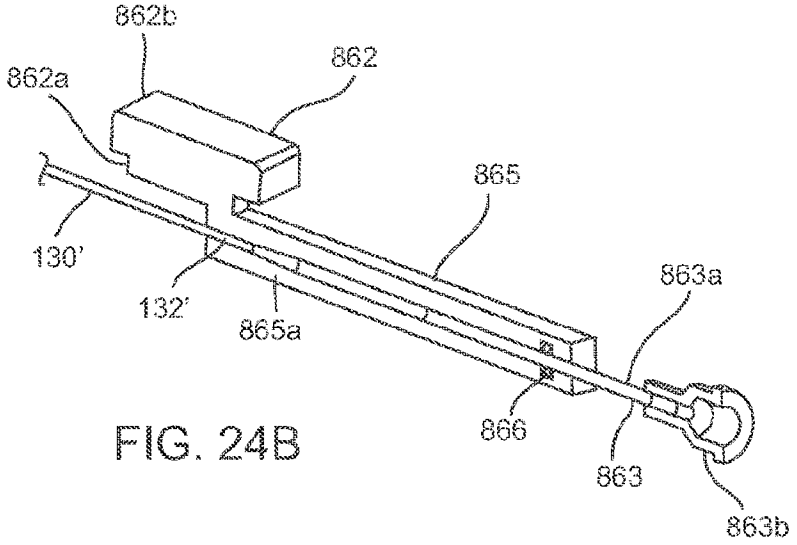


FIG. 24B

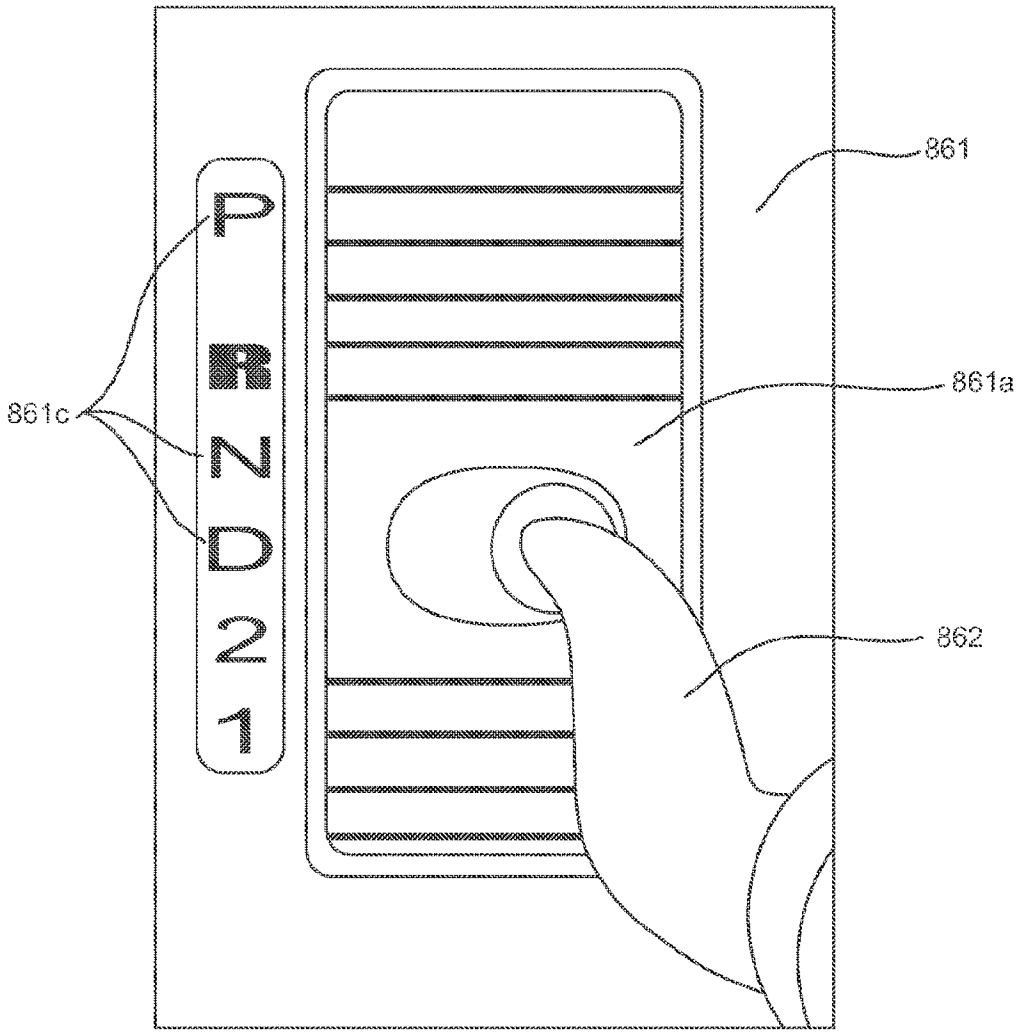


FIG. 24C

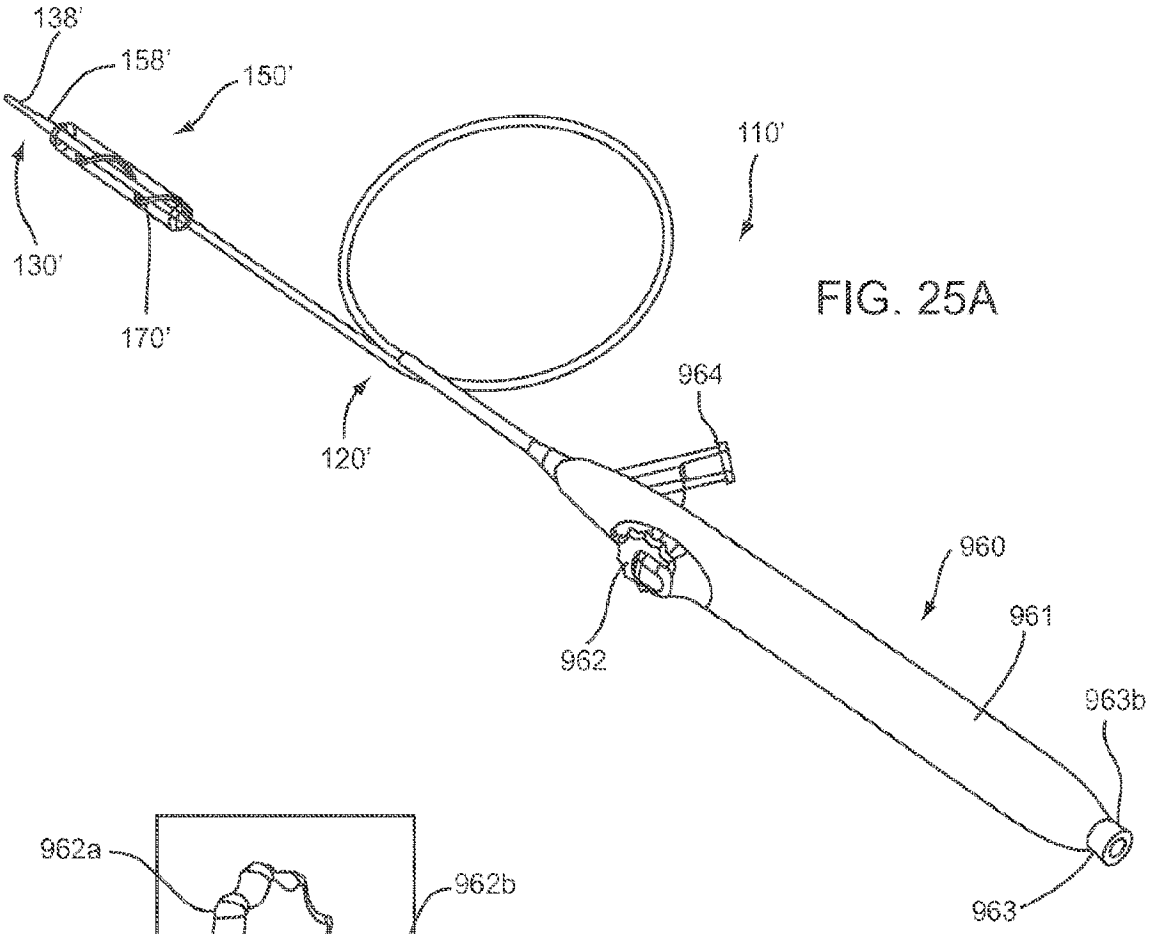


FIG. 25A

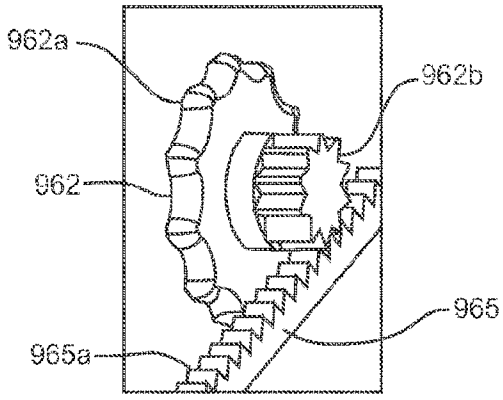


FIG. 25B

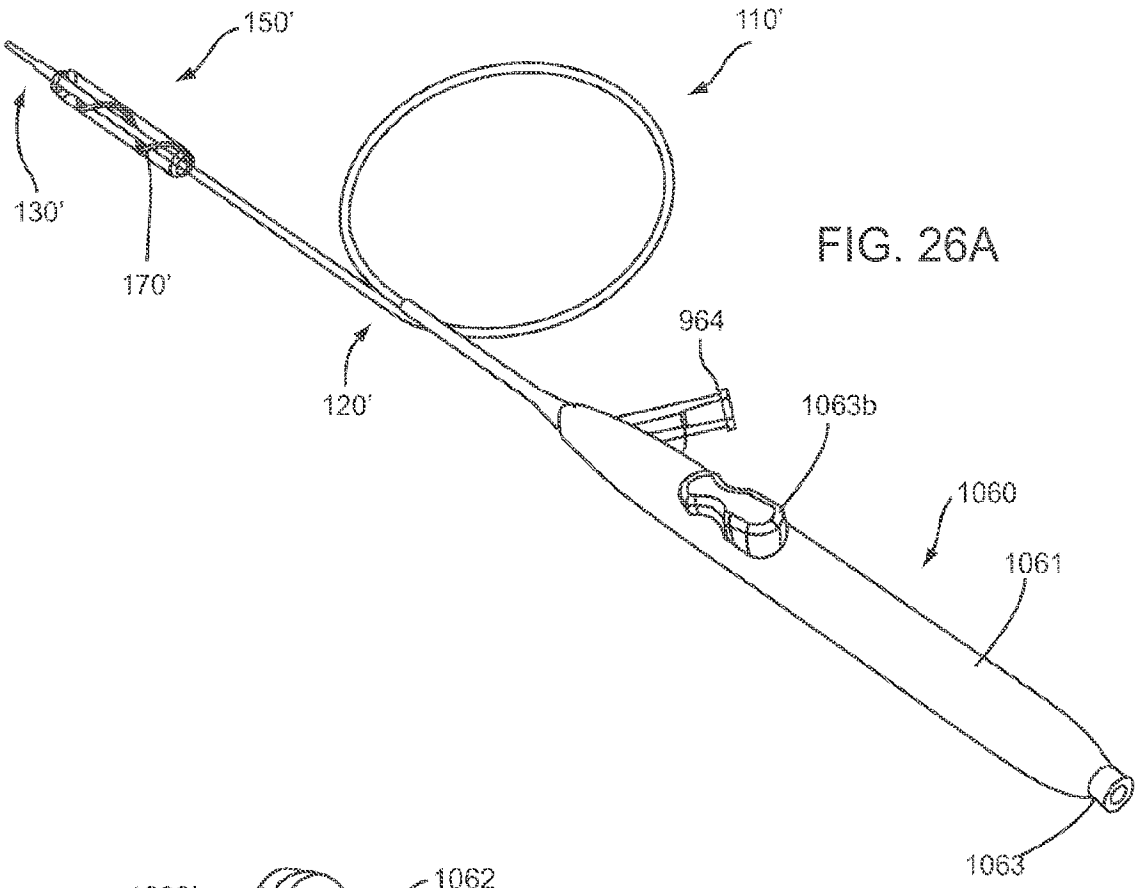


FIG. 26A

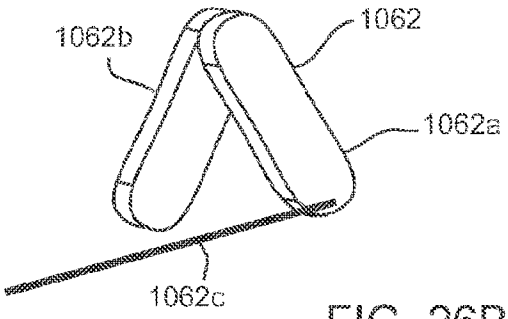


FIG. 26B

DESCRIPTION CN116852845A

Multilayer catheter main body and its catheter assembly

[0001]

Technical field

[0002]

The present invention mainly relates to a multi-layer catheter body and its catheter assembly for guiding, operating or distally supporting for neurovascular applications.

In particular, the catheter body provides excellent distal flexibility and proximal stability for tracking inside the neurovascular, as well as excellent external and internal smoothness for implant delivery.

[0003]

Background technology

[0004]

Almost every neurovascular device placement or treatment occurs on or above the neck.

Therefore, catheters used in the neurovascular system must be able to traverse tortuous blood vessels.

When designing catheters for neurovascular applications, engineers must strike a balance between functionality and structure, with the basic goals of tracking, flexibility, pushability, and torque (transmittance or torsion) of the catheter.

[0005]

PTFE material has excellent wear resistance and high smoothness, and is an ideal choice for the inner wall of the catheter.

When the medical device is pushed through the tight catheter lumen, the smooth lumen surface of the PTFE inner layer reduces the friction between the medical device and the catheter. Dip coating and extrusion are two common methods for manufacturing PTFE liners. The conversion plating method is a method to obtain a polytetrafluoroethylene lining. This process can be performed on the mandrel as part of the catheter body construction process. Once the coating is cured, additional components of the catheter, such as nylon sheath, braided tubing, are built on the cured dip coating mandrel. Although the dip coating process seems to be a simple process from the beginning, it has some limitations. The dip coating may have an uneven surface that resembles orange peel. Sometimes there are many cross-section lines on the surface of the dip coating, which is called flutter, which is caused by the vibration during the dip coating process. The surface of the dip coating may also have pits, depressions, or even holes in the cured layer, which are caused by contaminants (including moisture) during the dip coating process. These defects will negatively affect the smoothness of the catheter lumen and seriously affect the use of the catheter. Although these defects can be solved in different ways, the high precision of the dip coating process usually brings greater cost and time.

[0006]

Extrusion of PTFE tubing is another way to make the inner layer of PTFE tubing.

Although extruded PTFE has the lowest coefficient of friction, a typical extruded PTFE tube has a wall thickness of about 0.001". This wall thickness may result in an increase in the overall rigidity of the catheter, which is not an ideal method to pass through tortuous passages in the nerves and blood vessels.

[0007]

The ideal neurovascular catheter should have the smallest outer diameter to transport medical devices/implants through small blood vessels and the largest inner diameter

This eventually leads to the need for the inner layer of ultra-thin catheters. However, with the ultra-thin inner layer of the catheter, engineers need to incorporate the catheter body supporting components, such as the metal wire layer covering the inner layer of the catheter, the braided mesh layer or the coil layer, to enhance the pushability and bending resistance of the catheter. In order to maintain the integrity of the catheter structure, a minimum contact pressure is required between the wire layer and the inner layer of the catheter. Generally, such a minimum contraction pressure will increase the roughness of the inner surface of the inner layer of the catheter and significantly reduce the smoothness of the inner surface.

[0008]

Therefore, it is necessary to develop a new catheter for neurovascular to meet the high standards of pushability, trackability, flexibility and torsion speed, and a large cavity is needed to achieve maximum extraction. Suction flow, smaller outer diameter allows the catheter to penetrate into smaller blood vessels without causing additional vascular damage to the target treatment site; smooth outer surface, and extremely high inner surface smoothness to reduce thro.

[0009]

Summary of the invention

[0010]

The purpose of the present invention is to provide a multi-layer catheter body and catheter assembly for the delivery and placement of medical equipment.

The invention can meet the goals of high standards of pushability, trackability, flexibility and twistability, and at the same time has a large cavity to achieve the maximum suction flow; a smaller outer diameter enables the catheter to go deeper in the blood vessel, it will not cause additional blood vessel damage to the target treatment location; the outer surface is smooth; at the same time, it has a very high inner surface smoothness.

[0011]

In the first aspect of the present invention, a multilayer catheter body is provided. The catheter body is used to deliver and place medical devices. The catheter body includes an inner layer, a first intermediate layer, and a second intermediate layer in order from the cavity to the outside. And the outer layer, the inner layer is a thin-walled tube, and the tube lumen of the inner layer has a smooth wall surface, the first middle layer is a coil layer, and the first middle layer is wound by flat wire; The ratio of the width to the thickness of the flat wire is at least 2:1, the second middle layer is a braided layer, and the second middle layer is braided by metal wires, the hardness of the distal end of the outer layer is less than that of the outer layer. The hardness of the proximal end of the outer layer; the outer layer is bonded to the inner layer through the wire gap between the first intermediate layer and the second intermediate layer.

[0012]

In another preferred embodiment, the outer layer is composed of multiple materials, wherein a material with soft hardness is used as the distal end of the outer layer, a material with medium hardness is used as the middle section of the outer layer, and a material with hard hardness is used as the proximal part of the outer layer.

[0013]

In another preferred embodiment, the ratio of the outer diameter of the inner layer of the catheter body to its wall thickness is at least 10:1.

[0014]

In another preferred embodiment, the smallest inner diameter of the inner layer of the catheter body is 0.8 mm.

[0015]

In another preferred embodiment, the maximum thickness of the flat wire of the first intermediate layer is 0.30 mm.

[0016]

In another preferred embodiment, the minimum width of the flat wire of the first intermediate layer is 0.08 mm.

[0017]

In another preferred embodiment, the first intermediate layer covers at least 30% of the outer surface of the inner layer.

[0018]

In another preferred embodiment, the maximum thickness of the second intermediate layer is 0.035 mm.

[0019]

In another preferred embodiment, the wall thickness of the catheter body is at least 0.03 mm.

[0020]

In another preferred example, the wall thickness of the catheter body is 0.03-0.3mm, preferably, 0.05-0.2mm, more preferably, 0.07-0.15mm.

[0021]

In another preferred embodiment, the inner layer and the outer layer have the same length.

[0022]

In another preferred embodiment, the first intermediate layer is formed by winding at least two wires in the same direction.

[0023]

In another preferred embodiment, the first intermediate layer is formed by winding at least two wires in opposite directions.

[0024]

In another preferred embodiment, the second intermediate layer covers at least the proximal end and the intermediate section of the first intermediate layer.

[0025]

In a second aspect of the present invention, a catheter assembly is provided. The catheter assembly includes the above-mentioned multilayer catheter body and a catheter proximal end control mechanism. The catheter proximal end control mechanism is used to control the advancement, retreat, and Reverse.

In addition, the catheter proximal control mechanism can be used for the introduction and connection of other medical devices. For example, other channels can be opened for placing guide wires or micro catheters or implant delivery devices and other delivery devices, and can also be used with pressure extension tubes etc. The connection is made, and the thrombus and other suction are carried out under the action of external suction.

[0026]

In another preferred embodiment, the second intermediate layer is at least 20 mm shorter than the first intermediate layer.

[0027]

In another preferred embodiment, the first intermediate layer and the second intermediate layer are sandwiched between the inner layer and the outer layer.

[0028]

In another preferred embodiment, the second intermediate layer is located between the first intermediate layer and the outer layer.

[0029]

In another preferred embodiment, the ratio of the outer diameter to the inner diameter of the catheter body is at least 1.2:1.

[0030]

It should be understood that within the scope of the present invention, the above-mentioned technical features of the present invention and the technical features specifically described in the following (such as the embodiments) can be combined with each other to form a new or preferred technical solution.

Due to space limitations, I will not repeat them one by one here.

[0031]

Description of the drawings

[0032]

In order to explain the embodiments of the present invention or the technical solutions in the prior art more clearly, the following will briefly introduce the drawings that need to be used in the description of the embodiments or the prior art. Obviously, the drawings in the following description are only These are some embodiments of the present invention. For those of ordinary skill in the art, other drawings can be obtained based on these drawings without creative work.

[0033]

Figure 1A is a front view of a catheter assembly with a catheter body and a catheter proximal control mechanism according to an embodiment of the present invention.

[0034]

Fig. 1B is a perspective view of a main structure of a multilayer catheter according to an embodiment of the present invention.

[0053]

131, 231-Materials.cdl.

[0054]

detailed description

[0055]

After extensive and in-depth research and extensive screening, the inventor developed a multilayer catheter body and catheter assembly for the delivery and placement of medical equipment for the first time. Compared with the prior art, the catheter body of the present invention has Good torque and torsion resistance (anti-winding) characteristics, with a flexible distal part that can reach the predetermined treatment position, and provide treatment without damaging the surrounding blood vessels, and in the smallest possible outer contour and as large as possible A delicate balance is maintained between the lumens to facilitate the delivery of medical implants and move in the lumens of other catheters to attract and occlude occluded blood vessels. In addition, the body of the catheter can be visible under X-ray fluoroscopy, which is convenient for the operator. Based on observations, the present invention has been completed.

[0056]

the term

[0057]

As used herein, the term "lumen" refers to pipes, delivery tubes, or general tubular spaces or cavities in the body, including veins, arteries, blood vessels, capillaries, intestines, and the like.

The term "lumen" can also refer to a tubular space in a tube, sheath, hollow needle, tube, or the like.

[0058]

As used herein, the term "proximal" refers to being close to the operator (less entry into the human body), and "distal" refers to being away from the operator (further into the human body).

When positioning a medical device in a patient, "distal" refers to the direction relatively far away from the catheter insertion position, and "proximal" refers to the direction relatively close to the catheter insertion position.

[0059]

As used herein, the term "silk" can be a strand, a rope, a fiber, a yarn, a filament, a cable, a thread, or the like, and these terms can be used interchangeably.

[0060]

As used herein, the term "sheath" can also be described as "catheter", therefore, these terms can be used interchangeably.

[0061]

The invention provides a multi-layered catheter body and a catheter assembly for delivering and placing medical equipment. It is a catheter body and a catheter assembly with a specific structure.

[0062]

Typically, the catheter body includes an inner layer, a first middle layer, a second middle layer, and an outer layer.

The first intermediate layer is composed of flat wires with a width-to-thickness ratio of at least 2:1.

The material of the outer jacket layer includes a distal end portion of the outer sleeve formed of a soft material, a middle section portion of the outer sleeve formed of a medium-hard material, and a distal end portion of the outer sleeve formed of a high-hardness material.

[0063]

According to an embodiment of the present invention, the ratio of the outer diameter to the thickness of the inner layer of the catheter body is at least 10:1.

The minimum inner diameter of the inner layer is 0.6mm.

According to an embodiment of the present invention, the maximum thickness of the first intermediate layer of the catheter body is 0.08 mm.

According to another embodiment of the present invention, the minimum width of the first intermediate layer of the catheter body is 0.08 mm.

[0064]

According to an embodiment of the present invention, the first intermediate layer of the catheter body covers at least 30% of the outer cavity surface of the inner layer.

In another embodiment, the coverage area between the first intermediate layer of the catheter body and the outer cavity surface of the inner catheter wire is between 30-75%, depending on the required stiffness.

Those skilled in this technology should know that the smaller the coverage area between the first intermediate layer and the inner layer, the more flexible the entire catheter.

[0065]

According to an embodiment of the present invention, the maximum thickness of the second braided intermediate layer of the catheter body is 0.05 mm.

[0066]

According to an embodiment of the present invention, the inner layer of the catheter has the same length as the outer jacket layer of the catheter body.

According to another embodiment of the present invention, the first intermediate layer and the second braided intermediate layer are encapsulated in the inner layer of the catheter and the outer sheath layer.

[0067]

According to an embodiment of the present invention, the outer sheath layer is connected to the inner layer through the gap between the filaments forming the first intermediate layer (30) and the second woven intermediate layer.

[0068]

According to an embodiment of the present invention, the first intermediate layer of the catheter body is composed of at least two filaments wound in the same direction.

According to another embodiment of the present invention, the first intermediate layer of the catheter body is composed of at least two reverse-wound filaments.

[0069]

According to an embodiment of the present invention, the second woven middle layer (40) is located between the first middle layer and the outer jacket layer.

According to another embodiment of the present invention, the second woven middle layer is placed at least at the proximal end and the middle of the first middle layer.

According to another embodiment of the present invention, the second woven middle layer is at least 20 mm shorter than the first middle layer.

[0070]

according to an embodiment of the present invention, the ratio of the outer diameter of the catheter body to the inner cavity diameter is at least 1.2:1.

[0071]

The main advantages of the present invention include

[0072]

(a) Have a large cavity to achieve maximum contrast flow.

[0073]

(b) With a smaller outer diameter, the catheter can penetrate into smaller blood vessels without causing accidental blood vessel damage to the target treatment site.

[0074]

(c) It has extremely high outer surface smoothness and inner surface smoothness, which is easy to push.

[0075]

(d) With a developing ring, it is convenient to track the position of the catheter.

[0076]

(e) The distal end has good flexibility, the proximal end has good stability, and is more flexible.

[0077]

(1) The catheter has good flexural resistance and is easy to pass through tortuous distal blood vessels.

[0078]

(2) It has excellent anti-collapse performance and can resist external suction and external pressure.

[0079]

The following description and figures list some specific details to provide an understanding of various embodiments of the current patent.

Those with ordinary skills in related technologies should understand that they can practice other embodiments of existing patents without requiring one or more of the details described herein.

Therefore, the applicant does not intend to limit or in any way limit the scope of the claims appended to these details.

Although in the following disclosure, various processes are described with reference to steps and sequences, these steps and the sequence of steps should not be regarded as necessary conditions for practicing all embodiments of the present invention.

[0080]

Unless specifically described otherwise, all numbers expressing quantities, metrics, and other attributes or parameters used in the specifications and claims should be understood as being modified by the word "about" in all embodiments.

Therefore, unless otherwise stated, it should be understood that the numerical parameters specified in the following specifications and appended claims are approximate values.

At least, it should not try to limit the application of the principle of equivalence to the scope of the claims, but should read the numerical parameters based on the number of significant figures reported and the application of general rounding techniques.

[0081]

It should be understood that when these words, such as "composition" (and any tense composition), "have" (and any tense have), "include" (and any tense include) or "include" (and any tense) when used, it specifically refers to the existence of the stated characteristics, integers, steps, operations, elements, and/or components, but does not exclude one or more other characteristics, integers, steps, operations, elements, components, and / Or the existence or addition of its group.

[0082]

We will further understand that although terms such as first, second, and third can be used to describe various limitations, elements, components, regions, layers and/or sections, these limitations, elements, components, regions, layers and/or sections should not be restricted by these terms.

These terms are only used to distinguish one limitation, element, component, region, layer or section from another limitation, element, component, region, layer or section.

Therefore, the first limitation, element, component, region, layer or section discussed below may be referred to as the second limitation, element, component, region, layer or section without departing from the currently applied patent.

[0083]

It is further understood that when an element is referred to as being "on", "attached to", "connected" or "coupled" to another element, it can be directly located at or above the other element, or connected or coupled to another element or one or more intermediate elements.

In contrast, when an element is said to be "directly on", "directly attached to", "directly connected" or "directly coupled" to another element, there are no intervening elements.

Other terms used to describe the relationship between elements should be interpreted in a similar way (for example, "between" and "directly between", "nearby" and "directly neighbor", etc.).

[0084]

To further understand, when the first element is called "within", "above" and/or "inside" the second element, the first element can be located in: the internal space of each element, within a part of the second element (for example, in the wall of the second element), located on the external and/or internal surface of the second element, and a combination of one or more of them.

[0085]

Space-related terms, such as "below", "below", "lower", "above", "upper", etc., can be used to describe one element and/or feature and another element and/or the relationship between features, as shown in the figure.

It is further understood that the spatially related terms are intended to include different orientations of the equipment in use and/or operation, and at the same time include the orientations shown in the figures.

For example, if the device in the graphic is turned over, elements described as "below" and/or "below" other elements or characteristics will be "above" other elements or characteristics.

The device can be oriented in other directions (for example, rotated 90 degrees or other orientations), and correspondingly interpreted in spatially relative terms.

[0086]

The term "reduction" and similar words used herein mean a reduction in quantity, including reduction to zero.

Reducing the likelihood of occurrence should include preventing occurrence.

[0087]

The term "and/or" as used herein shall be regarded as a specific disclosure of each characteristic or component of two specified characteristics or components, one of which has or does not have the other.

For example, "A and/or B" should be considered as specific disclosures of (i) A, (ii) B, and (iii) A and B, as if listed separately here.

[0088]

The term "diameter" used here to describe a non-circular geometry should be regarded as an approximation of the diameter of an imaginary circle of the described geometry.

For example, when describing the cross-section, such as the cross-section of a member, the term "diameter" should be used to indicate the diameter of an imaginary circle having the same cross-sectional area as the cross-section of the member.

[0089]

The "major axis" and "minor axis" of the component used herein respectively refer to the length and diameter of the smallest volume imaginary cylinder that can completely surround the component.

[0090]

For the sake of clarity, certain features of the invention described in the context of separate embodiments may also be provided in combination in a single embodiment.

On the contrary, for the sake of brevity, various features of the invention described in the context of a single embodiment may also be provided separately or in any suitable sub-combination.

For example, all the features listed in any statement (whether independent or dependent) can be combined in any given way.

[0091]

Example

[0092]

This embodiment relates to a single-lumen, large-caliber, thin-walled catheter.

The catheter structure of this embodiment provides excellent distal end flexibility, excellent proximal pushability and torsion, superior external smoothness and superior inner surface smoothness.

[0093]

As shown in Figures 1A-1B, the catheter body (10) has a four-layer structure.

The inner layer (20) of the catheter body (10) is a full-length ultra-thin inner layer of the catheter, wherein the inner cavity (21) extends from one end to the other end.

The first intermediate layer (30) of the catheter body (10) includes a flat coil (31) wound on the outer surface (24) of the inner layer of the inner catheter.

The second intermediate layer (40) of the catheter body (10) includes braided wires placed on the outer surface of the first intermediate layer (30).

The outer layer (50) of the catheter body (10) includes a tube placed on the outer surface of the second middle layer (40) of the catheter body (10). The outer layer (50) melts and flows through the two middle layers (30, 40), } And adhere to the inner layer (20) of the catheter body (10).

In addition, according to an embodiment of the patent, the outer layer (50) and the inner layer (20) of the catheter body (10) actually have the same length, and the two middle layers (30, 40) of the catheter body (10) are slightly shorter than The outer layer (50) and the inner layer (20) can be encapsulated between the outer layer (50) and the inner layer (20).

[0094]

Continuing to refer to Figure 1A, a radiopaque imaging ring is fixed at the distal end of the catheter body (10) assembly, and the imaging ring is visible under fluorescence.

Figure 1A also shows that the proximal end (14) of the catheter body is connected to the proximal end control mechanism (8) of the catheter.

The design of the specific proximal control mechanism can vary according to the expected application.

Therefore, FIG. 1A is only an example for the purpose of explaining the present invention.

[0095]

According to an embodiment of the present invention, the general length of the catheter body (10) is 1150-1400mm, the outer diameter is 1.4-2.7mm, and the inner diameter is 1.3-2.3mm.

Those skilled in the art should understand that the overall length and dimensions of the catheter body (10) assembly can be easily modified to suit specific applications.

Therefore, the numbers disclosed here should be regarded as references and should not be regarded as limited to the range shown.

[0096]

1B, according to an embodiment of the present invention, the inner layer (20) of the catheter body (10) has a tubular profile, and its inner cavity (21) extends from one end to the other end.

According to an embodiment of the present invention, the inner layer (20) of the catheter body (10) has a length of 1150-1400mm, an outer diameter of 1.75-1.85mm, an inner diameter of 1.70-1.80mm, and a wall thickness of 0.013-0.032mm. The ratio of diameter to inner diameter is 1.018-0.015.

According to one embodiment of the present invention, when the medical device/implant passes through the catheter, the inner layer (20) of the catheter body (10) directly contacts the medical device/implant.

The inner layer (20) of the catheter body (10) provides sufficient lubricity and reduces the force required to push the device/implant through the inner cavity (21).

According to an embodiment of the present invention, the ratio of the wall thickness to the inner diameter of the inner layer (20) of the catheter body (10) disclosed in the present invention is 0.007-0.017.

[0097]

According to an embodiment of the present invention, the inner layer (20) of the catheter body (10) is made of extruded PTFE (polytetrafluoroethylene).

In another embodiment, the inner layer (20) of the catheter body (10) is made of expanded polytetrafluoroethylene, which is also called ePTFE.

The ePTFE inner layer (20) is made by carefully expanding polytetrafluoroethylene using a non-standard manufacturing process, such as heating the extruded polytetrafluoroethylene to a desired temperature, and then expanding its inner diameter on a mandrel.

Such a post-extrusion process will produce an enlarged inner diameter and ultra-thin tubular walls with microscopic pores.

The prepared ePTFE inner layer (20) has the physical properties of air permeability, softness and flexibility, and feels smooth and elastic, like a film.

The ePTFE inner layer (20) also has high tensile strength, chemical inertness, watertightness under low pressure, low dielectric constant, and good radial expansion and UV resistance.

[0098]

Those skilled in the art should understand that although the purpose of the extruded and expanded polytetrafluoroethylene tube described here is to explain the present invention, the inner layer (20) of the catheter body (10) can be made of other materials, such as FEP (fluorine Ethylene propylene), HDPE (high density polyethylene), LDPE (low density polyethylene), PET (polyethylene terephthalate), PP (polypropylene), polyamide/block polyether polyamide. Any manufacturing process known in this field, such as direct extrusion and/or post-extrusion axial stretching and/or radial expansion, is adopted to realize ultra-thin cavity wall.

[0099]

Continuing to refer to Fig. 1B, the first intermediate layer (30) of the catheter body (10) includes a coil (31) wound on the outer surface of the inner layer (20) of the catheter.

The first intermediate layer (30) is added on the inner layer (20) of the catheter as a support, which increases the circumferential strength and enhances the lateral flexibility of the distal end, and the bending resistance is better.

According to one embodiment, the wire used to compose the first intermediate layer (30) of the catheter body (10) is in a flat form.

Those skilled in the art should understand that FIG. 1B is to illustrate and explain the four-layer structure of the catheter body according to an embodiment of the present invention.

Figure 1B does not actually show the length or relative length of the layers of the catheter body.

[0100]

That is, as shown in FIG. 2A, the cross-sectional width of the wire (100) is greater than its thickness.

Therefore, in this embodiment, the inner layer (20) of the catheter body (10) has the largest contact area with the first intermediate layer (30).

Since the inner layer (20) of the catheter body (10) has an ultra-thin wall thickness, the larger the contact area between the first intermediate layer (30) and the outer surface of the inner layer (20), the smoother the inner cavity of the inner layer (20).

Those skilled in the art should understand that under the same coil width, the thicker the coil, the better its bending resistance.

Therefore, a design balance must be achieved between bending resistance and the overall profile of the small catheter body (10).

[0101]

According to an embodiment in Fig. 2A, the width of the coil (31) is 0.03-0.11 mm, and the thickness is 0.02-0.05 mm.

In one embodiment, the width of the coil (31) is 0.003" and the thickness is 0.0015".

According to another embodiment of the present invention, the cross-sectional area of the wire (100) forming the first intermediate layer (30) is 0.001-0.007 mm2, and the width-to-thickness ratio is at least 2:1.

According to one embodiment, the first intermediate layer (30) covers at least 38% of the area of the outer surface of the inner layer (20).

According to another embodiment of the present invention, the pitch of the coil (31) is 0.10-0.20mm and the minimum gap between each spiral turn is 0.025mm.

In another embodiment, the coil (31) can be left-handed or right-handed.

[0102]

According to another embodiment of the present invention, the first intermediate layer (30) is a [illegible] pitch.

According to another embodiment of the present invention, the wire (100) forming the first [illegible] constant thickness and width throughout its length.

However, in another embodiment of the present invention, in order to obtain the ideal maneuverability of the catheter body (10) while maintaining the flexibility of the distal end of the catheter body (10), the spiral coil (31) is placed near the catheter body (10). The pitch of the tip is small, and the pitch of the distal end of the catheter body (10) is larger, and a gradual change is realized at the transition.

In another embodiment of the present invention, the wire (100) forming the spiral coil (31) has a larger width at the proximal end of the catheter body (10) while maintaining the same thickness of the wire. The distal end of) has a smaller width and achieves a gradual change at the transition.

[0103]

Those skilled in the art should understand the round coil. When the flat coil has the same cross-sectional area as the round coil, the bending resistance of the two coils is equivalent, but the flat coil can reduce the wall thickness by at least 33%.

Therefore, the embodiments of the present invention provide a nominal increase in the radial profile of the catheter.

In other words, the present invention provides the greatest possibility of reducing the outer diameter of the catheter as much as possible while maintaining the size of the inner diameter.

[0104]

According to an embodiment of the present invention, the flat wire (100) forming the first intermediate layer (30) may be formed of stainless steel, tungsten, cobalt-chromium alloy and other materials.

In another embodiment, the flat wire (100) forming the first intermediate layer (30) may be formed of a superelastic material such as Nitinol.

In one embodiment, when the catheter is entangled during use, the Nitinol may allow the first intermediate layer (30) to restore its pre-configured circular tubular shape.

[0105]

Figure 2A shows a single wire spiral coil (31).

Those skilled in the art should know that multi-wire coils (131, 231) can also be incorporated into the structure of the first intermediate layer (30).

For example, as shown in FIG. 2B, the multi-wire coil (131) forming the first intermediate layer (30) can be composed of two wires (110, 120), each wire is made of a different material and wound in the same direction.

In this way, the first intermediate layer (30) can possess the mechanical properties of the comprehensive strength of the two materials.

In another embodiment, as shown in Fig. 2C, the multi-wire coil (231) constituting the first intermediate layer (30) can be composed of two wires (130, 140), and each wire is made of a different material and wound in opposite directions.

According to one embodiment, as shown in the two embodiments of Figs. 2B-2C, the two wires (130, 140) can be wound alternately so that they are basically in the same layer.

In another embodiment, one wire can be wound around a coil formed by another wire.

Those skilled in the art should know that the structure of each wire (110, 120, 130, 140), including its width, thickness, coil pitch and winding angle, can be adjusted individually to achieve the best results.

According to one embodiment, the multi-wire coil (131, 231) includes 2-4 wires.

In another embodiment, the multi-wire coil (131, 231) can be wound left-handed or right-handed.

In another embodiment, the pitch of the multi-wire coil (131, 231) may be 0.07-0.6 mm.

In other embodiments, the width of the wire used for the multi-wire coil is 0.04-0.15 mm, and the thickness is 0.03-0.08 mm.

[0106]

Continuing to refer to FIG. 1B, according to one of the embodiments, the second intermediate layer (40) is placed outside the first intermediate layer (30).

The second intermediate layer (40) is made of tubular braided metal wire (41).

The tubular braided metal wire (41) strengthens the axial and torsion control of the catheter main body (10), and reduces or almost eliminates the delay caused by the clinician's pushing, pulling or rotating operation.

[0107]

Fig. 3 shows an embodiment of a weaving pattern.

According to an embodiment of the present invention, the tubular braided metal wire (41) as the second intermediate layer (40) is composed of 16 wires, which is a conventional braiding pattern.

In another embodiment, the second intermediate layer (40) is composed of 16 wires and has a conventional diamond weaving pattern, which can provide better torsion and flexural properties than the conventional weaving pattern.

Those skilled in the art should understand that the weaving pattern and the number of threads can be changed.

Therefore, the content disclosed here should not be taken as limiting the scope of the present invention.

[0108]

According to one embodiment, the second intermediate layer (40) is placed outside the first intermediate layer (30), as shown in Fig. 1B.

According to one embodiment, the thickness of the conventional second intermediate layer (40) is 0.025-0.088 mm, and the thickness of each braided wire used is 0.013-0.0038 mm.

According to an embodiment of the present invention, the length of the second intermediate layer (40) is 1150-1400 mm, which is substantially equal to the length of the first intermediate layer (30).

According to another embodiment, the length of the second intermediate layer (40) is 1100-1350 mm, which is much smaller than the length of the first intermediate layer (30), and the second intermediate layer (40) only covers the first intermediate layer (30). The middle and proximal end portions of the first intermediate layer (30) do not cover the distal end portion.

But according to another embodiment, the second intermediate layer (40) is 2 cm shorter than the first intermediate layer (30) at the distal end of the first intermediate layer (30), as shown in Fig. 1B.

[0109]

Continuing to refer to Fig. 1B, according to one embodiment, the outer layer (50) of high molecular polymer is placed on the outside of the second intermediate layer (40) to form the outer layer of the catheter.

According to one embodiment, the outer layer (50) has an original tubular configuration and is placed outside the second intermediate layer (40).

Then the entire catheter shaft (10) assembly is subjected to a reflow soldering process, and a composite catheter body (10) is formed by melting the outer layer (50) and/or the inner layer material.

According to one embodiment, the material of the outer layer (50) melts and flows into the gaps between the braided wires of the second middle layer (40) and the first middle layer (30), and adheres to the inner layer (20) of the catheter shaft (10).

Those skilled in the art should understand that the temperature used to melt the outer layer (50) to form a bond with the inner layer (20) of the catheter body (10) is balanced to allow sufficient material to flow through the gap between the wires. In addition, grooves and narrow channels will not be introduced into the lumen surface of the inner layer (20) of the catheter shaft (10), and the grooves and narrow channels will affect the smoothness of the catheter lumen.

[0110]

According to one embodiment, the outer layer (50) is made of a single material, such as nylon or Pebax, and has a stable hardness.

According to another embodiment, the outer layer (50) has a hardness of 25-60D (Shore 25-60D), a length of 80-930 mm, an outer diameter of 2.0-2.5 mm, and a wall thickness of 0.025-0.13 mm.

According to one embodiment, the outer layer (50) covers the entire length of the two intermediate layers (30, 40) and the entire length of the inner layer (20) of the catheter shaft (10).

[0111]

Reference is now made to Figure 8, which shows another embodiment of the outer layer (50).

According to one embodiment, the outer layer (50) is composed of multiple sections each of which is a material of different hardness.

For example, as shown in Fig. 8, the distal portion of the outer layer (50) is made of an ultra-low hardness material, such as TPU with a hardness of about 80A (HS).

The proximal part of the outer layer (50) is made of a relatively high hardness material, such as nylon with a hardness of about 70D (HS).

The transition section between the distal end and the proximal end of the outer layer (50) is made of a relatively high hardness material, such as Pebax with a hardness in the range of 35D-82D. Therefore, the low-hardness distal outer layer enables the catheter body (10) assembly to have excellent elasticity to pass through tortuous small blood vessels. The high-hardness proximal section of the outer layer (50) enables the catheter shaft (10) to have rigidity and excellent maneuverability. The transition section realizes the gradual transformation from the distal super soft section to the proximal rigid and support section.

[0112]

Continuing to refer to Figure 4, according to one embodiment, the length of the distal section of the outer layer (50) is 100-200mm, the length of the transition section of the outer layer (50) is 10-30mm, and the length of the proximal section of the outer layer (50) is 1000-1100mm.

According to one embodiment, the distal section, the transition section and the proximal section of the outer layer (50) all have approximately the same thickness.

[0113]

According to another embodiment of the present invention, additional coatings can be added to the catheter composition described in the present invention.

For example, a hydrophilic coating is added to obtain a smooth surface so that the catheter can be transported more easily in the blood vessel.

[0114]

Even if not specifically described above, those skilled in the art should understand that one or more radiopaque marking points can facilitate visualization by imaging equipment (for example, fluoroscope, X-ray, CT scan, nuclear magnetic resonance, ultrasound imaging).

A marking point as disclosed herein can be applied to any part of the catheter shaft (10) of the present invention. A radiopaque marking point can be attached, forged, crimped, or otherwise arranged and fixed on the catheter shaft (10) or on the surface thereof. The radiopaque marking points can be made of tantalum, tungsten, platinum, platinum, iridium, gold, or alloys of these materials or other materials known to those skilled in the art. The radiopaque marking points can also be composed of a variety of paramagnetic materials, which include one or more elements with atomic numbers of 21-29, 42, 44, and 58-70, such as chromium (B), magnesium (B), iron (B), iron (B), cobalt (B), copper (B), nickel (B), praseodymium (B), ruthenium (B), samarium (B), ytterbium (B), gadolinium (B) terbium (B), dysprosium (B), holmium (B), erbium (B) or other MRI visible materials known to those skilled in the art.

[0115]

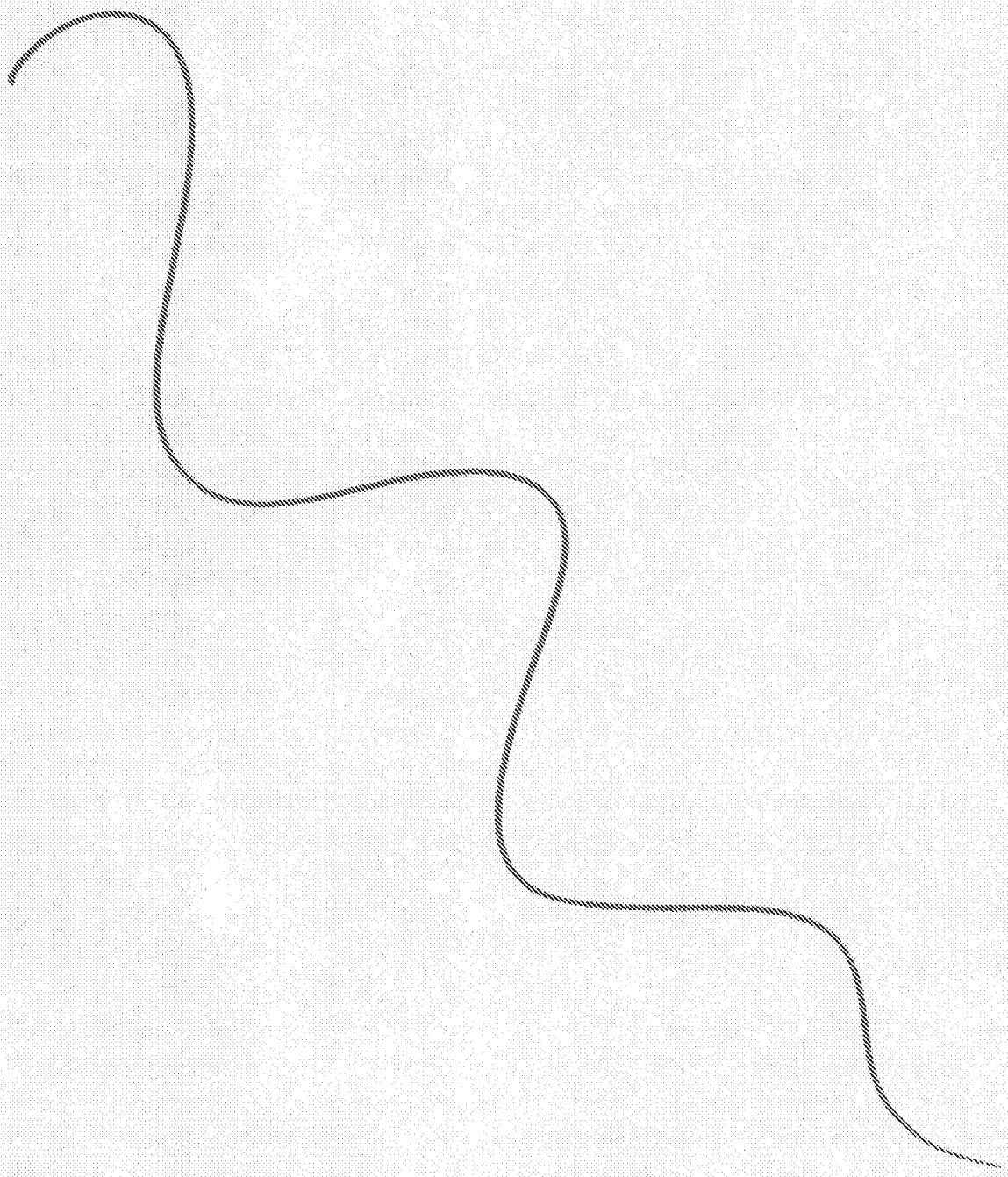
Those skilled in the art should understand that even though most of the exemplary embodiments of the catheter body (10) described above are suitable for intracranial vascular applications, the exemplary embodiments of the present invention can also be used for any other suitable partially occlusive interventional applications.

For example, the exemplary embodiments of the present invention can be used for delivery of vascular occlusion devices, stents, aspiration, stent thrombus extractors for the treatment of ischemic stroke, and the like. In other examples, the exemplary embodiments of the present invention can be used to accurately deliver implants into blood vessels, such as cerebral blood vessels, open blood vessels, or other locations.

[0116]

The foregoing description and related drawings present a number of current representative embodiments.

Based on the foregoing teachings, various modifications and alternative designs will be apparent to those skilled in the art without departing from the spirit of the present invention or beyond the scope of the present invention, and the scope is defined by the appended claims rather than the foregoing description indicates. All changes and changes falling within the equivalent scope and meaning of the present invention are deemed to be included in the scope of the present invention.



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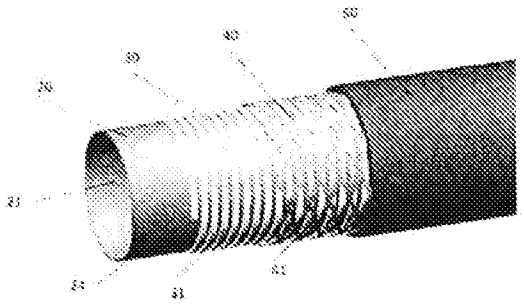
(54)发明名称

多层导管主体及其导管组件

(57)摘要

本发明提供了一种多层导管主体及其导管组件，用于输送和放置医疗器械，以及抽吸去除堵塞。该导管主体由内到外依次包括内层、第一中间层、第二中间层以及外层；内层为一薄壁管，内层的管内腔具有光滑的壁面；第一中间层为线圈层，第一中间层由扁丝绕制而成，扁丝的宽度和厚度之比为至少为2:1；第二中间层为编织层，第二中间层由金属丝编织而成；外层远端的硬度小于外层近端的硬度；外层通过第一中间层和第二中间层的丝间隙粘接到内层上。本发明可以满足高标准的推送性、可追踪性、柔韧性和可扭性的目标，可以实现大的抽吸流量，能够深入到更小的血管中，而不会对目标治疗位置造成额外的损伤；具有极高的内表面顺滑性和外表面顺滑性。



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1.一种多层导管主体，其特征在于，所述导管主体用于输送和放置医疗器械，所述导管主体由内到外依次包括内层、第一中间层、第二中间层以及外层；

所述内层为一薄壁管，所述内层的管内腔具有光滑的壁面；

所述第一中间层为线圈层，所述第一中间层由扁丝绕制而成，所述扁丝的宽度和厚度之比为至少为2:1；

所述第二中间层为编织层，所述第二中间层由金属丝编织而成；

所述外层远端的硬度小于所述外层近端的硬度；

所述外层通过所述第一中间层和所述第二中间层的丝间隙粘接到所述内层上。

2.如权利要求1所述的导管主体，其特征在于，所述导管主体的内层的外径与其壁厚比至少为10:1。

3.如权利要求1所述的导管主体，其特征在于，所述第一中间层的扁丝的最大厚度为0.06mm。

4.如权利要求1所述的导管主体，其特征在于，所述第一中间层覆盖至少30%的所述内层的外表面。

5.如权利要求1所述的导管主体，其特征在于，所述第二中间层的最大厚度为0.066mm。

6.如权利要求1所述的导管主体，其特征在于，所述导管主体的壁厚至少为0.03mm。

7.如权利要求1所述的导管主体，其特征在于，所述第一中间层由至少两根丝沿相同方向缠绕而成。

8.如权利要求1所述的导管主体，其特征在于，所述第一中间层由至少两根丝沿相反方向缠绕而成。

9.如权利要求1所述的导管主体，其特征在于，所述第二中间层至少覆盖所述第一中间层的近端和中间段。

10.如权利要求1所述的导管主体，其特征在于，所述导管主体的外径和内径之比至少为1.2:1。

多层导管主体及其导管组件

技术领域

[0001] 本发明主要涉及一种用于神经血管应用的导引、抽吸或远端支撑的多层导管主体及其导管组件。特别地，该导管主体提供了卓越的远端柔韧性和近端稳定性用于在神经血管内部跟踪，以及优秀的外部顺滑性和内部顺滑性以用于植入物的输送。

背景技术

[0002] 几乎每一种神经血管装置的放置或治疗都发生在颈部或颈部以上。因此，神经血管系统内使用的导管必须能够穿越曲折的血管。在设计用于神经血管的导管时，工程师必须在功能性和结构性之间取得平衡，并以导管的可跟踪性、灵活性、推送性和扭矩(透过率或扭转力)为基本目标。

[0003] 聚四氟乙烯材料具有卓越的耐磨性和高顺滑性，是导管内壁的理想选择。当推送医疗设备通过紧的导管内腔时，聚四氟乙烯内层光滑的内腔表面减少了医疗设备和导管之间的摩擦。浸渍涂层和挤压是制造聚四氟乙烯内衬的两种常用方法。浸镀法是获得聚四氟乙烯内衬的一种方法。这个过程可以在作为导管主体构建过程的一部分的芯轴上进行。一旦涂层固化，导管的附加组件，例如尼龙护套、编织管，就建立在固化浸渍涂层芯轴上。浸涂工艺虽然从一开始看起来是一个简单的过程，但也有一些局限性。浸渍涂层可能存在不均匀地类似于橘子皮的表面。有时浸渍涂层表面会出现许多横截面线，称为颤振，这是由于浸渍涂层过程中的振动造成的。浸渍涂层的表面也可能有凹坑、凹陷、甚至固化层中的刺，其是由浸渍涂层过程中的污染物(包括水分)造成的。这些缺陷都会对导管腔内的顺滑性产生负面影响，严重影响导管的使用。虽然这些缺陷可以用不同的方法来解决，但浸涂工艺的高精度通常会带来更大的成本和时间。

[0004] 挤压聚四氟乙烯管是制造聚四氟乙烯导管内层的另一种方法。虽然挤压聚四氟乙烯具有最低的摩擦系数，但一个典型的挤压聚四氟乙烯管壁厚约0.001″。这种壁厚可能导致导管整体刚性的增加，这不是一个理想的方法来穿过神经血管内曲折的通路。

[0005] 理想的神经血管导管应该有最小的外径来通过细小的血管，最大的内径来运送医疗器械/植入物。这不可避免地导致对超薄导管内层的需求。然而，伴随超薄的导管内层，工程师需要纳入导管主体支撑组件，如覆盖导管内层的金属丝层，编织网管层或线圈层，以增强导管的推送性和抗弯折性。为了保持导管结构的完整性，金属丝层和导管内层之间需要最小的接触压力。通常，这样的最小收缩压力会导致导管内层的内表面粗糙度增加，并显著降低内表面顺滑性。

[0006] 因此，有必要研制一种新的用于神经血管的导管，以满足高标准的推送性、可追踪性、柔韧性和可扭性的目标，同时需要一个大的腔体来实现最大限度的抽吸流量；更小的外径使导管能够深入到更小的血管中，而不会对目标治疗位置造成额外的血管损伤；外表面顺滑；同时具有极高的内表面顺滑性，以减少用力。

发明内容

[0007] 本发明的目的在于提供一种用于输送和放置医疗设备的多层导管主体及其导管组件，本发明可以满足高标准的推送性、可追踪性、柔韧性和可扭性的目标，同时具有大的腔体来实现最大限度的抽吸流量、更小的外径使导管能够深入到更小的血管中，而不会对目标治疗位置造成额外的血管损伤；外表面顺滑；同时具有极高的内表面顺滑性。

[0008] 在本发明的第一方面提供了一种多层导管主体，所述导管主体用于输送和放置医疗器械，所述导管主体由内到外依次包括内层、第一中间层、第二中间层以及外层；所述内层为一薄壁管，所述内层的管内腔具有光滑的壁面；所述第一中间层为线圈层，所述第一中间层由扁丝绕制而成，所述扁丝的宽度和厚度之比为至少为2:1；所述第二中间层为编织层，所述第二中间层由金属丝编织而成；所述外层远端的硬度小于所述外层近端的硬度；所述外层通过所述第一中间层和所述第二中间层的丝间隙粘接到所述内层上。

[0009] 在另一优选例中，所述外层由多种材料组成，其中硬度软的材料作为外层远端，硬度中等的材料作为外层中间段，以及硬度硬的材料作为外层近端部分。

[0010] 在另一优选例中，所述导管主体的内层的外径与其壁厚比至少为10:1。

[0011] 在另一优选例中，所述导管主体的内层的最小内径为0.8mm。

[0012] 在另一优选例中，所述第一中间层的扁丝的最大厚度为0.06mm。

[0013] 在另一优选例中，所述第一中间层的扁丝的最小宽度为0.08mm。

[0014] 在另一优选例中，所述第一中间层覆盖至少30%的所述内层的外表面。

[0015] 在另一优选例中，所述第二中间层的最大厚度为0.066mm。

[0016] 在另一优选例中，所述导管主体的壁厚至少为0.03mm。

[0017] 在另一优选例中，所述导管主体的壁厚为0.03~0.3mm；优选地，0.06~0.2mm；更佳地，0.07~0.18mm。

[0018] 在另一优选例中，所述内层和所述外层的长度相同。

[0019] 在另一优选例中，所述第一中间层由至少两根丝沿相同方向缠绕而成。

[0020] 在另一优选例中，所述第一中间层由至少两根丝沿相反方向缠绕而成。

[0021] 在另一优选例中，所述第二中间层至少覆盖所述第一中间层的近端和中间段。

[0022] 在本发明的第二方面提供了一种导管组件，所述导管组件包括上述的多层导管主体和导管近端控制机构，所述导管近端控制机构用于操控所述导管主体前进、后退和扭转。此外，所述导管近端控制机构可用于其它医疗器械的导入和连接，例如，可以开设其他通道用于放置导丝或微导管或植入物输送件等输送装置，也可与压力延长管等进行连接，在外界抽吸力的作用下进行血栓等抽吸。

[0023] 在另一优选例中，所述第二中间层至少比所述第一中间层短20mm。

[0024] 在另一优选例中，所述第一中间层和第二中间层被封闭在所述内层和所述外层之间。

[0025] 在另一优选例中，所述第二中间层位于所述第一中间层和所述外层之间。

[0026] 在另一优选例中，所述导管主体的外径和内径之比至少为1.2:1。

[0027] 应理解，在本发明范围内中，本发明的上述各技术特征和在下文(如实施例)中具体描述的各技术特征之间都可以互相组合，从而构成新的或优选的技术方案。限于篇幅，在此不再一一累述。

附图说明

[0028] 为了更清楚地说明本发明实施例或现有技术中的技术方案，下面将对实施例或现有技术描述中所需要使用的附图做简单地介绍，显而易见地，下面描述中的附图仅仅是本发明的一些实施例，对于本领域普通技术人员来讲，在不付出创造性劳动的前提下，还可以根据这些附图获得其他的附图。

[0029] 图1A是根据本发明的一个实施例的具有导管主体和导管近端控制机构的导管组件的主视图；

[0030] 图1B是根据本发明的一个实施例的多层导管主体结构的透视图；

[0031] 图2A是根据本发明的一个实施例的导管主体的第一中间层的主视图；

[0032] 图2B是根据本发明的另一个实施例的导管主体的第一中间层的主视图；

[0033] 图2C是根据本发明的又一个实施例的导管主体的第一中间层的透视图；

[0034] 图3是根据本发明的一个实施例的导管主体的第二中间层的主视图；

[0035] 图4是根据本发明的一个实施例的导管主体的外层的透视图。

[0036] 各附图中，各标示如下：

[0037] 8-导管近端控制机构；

[0038] 10-导管主体；

[0039] 14-导管主体的近端；

[0040] 20-内层；

[0041] 21-内腔；

[0042] 24-内层的外表面；

[0043] 30-第一中间层；

[0044] 31-线圈；

[0045] 40-第二中间层；

[0046] 41-管状编织金属丝；

[0047] 50-外层；

[0048] 100、110、120、130、140-线；

[0049] 131、231-多线线圈。

具体实施方式

[0050] 本发明人经过广泛而深入的研究，通过大量筛选，首次开发了一种用于输送和放置医疗设备的多层导管主体及其导管组件，与现有技术相比，本发明的导管主体内具有良好的扭矩和抗扭(抗缠绕)特性，具有能够到达预定治疗位置的灵活的远端部分，并在不损伤周围血管的情况下提供治疗，且在尽可能小的外部轮廓和尽可能大的内腔之间保持一个微妙的平衡，以便输送医用植入物，在其他导管内腔移动以吸引疏通闭塞的血管，此外，这种导管主体在X射线透视下还可以是可见的，便于操作者观察，在此基础上完成了本发明。

[0051] 术语

[0052] 如本文所用，术语"内腔"是指主体体内的管道、输送管或一般的管状空间或腔体，包括静脉、动脉、血管、毛细血管、肠道等。"内腔"一词也可以指导管内、鞘、空心针、管或类似物中的管状空间。

[0053] 如本文所用，术语"近端"是指靠近操作者（较少进入人体），"远端"是指远离操作者（较远进入人体），在患者体内定位医疗器械时，"远端"指相对远离导管插入位置的方向，"近端"指相对靠近导管插入位置的方向。

[0054] 如本文所用，术语"丝"可以是一股线、一根绳子、一根纤维、一根纱线、一根细丝、一根电缆、一根线或类似的东西，这些术语可以互换使用。

[0055] 如本文所用，术语"臂"也可以描述为"导管"，因此，这些术语可以互换使用。

[0056] 本发明提供了一种用于输送和放置医疗设备的多层导管主体及其导管组件，它是一种具有特定结构的导管主体及其导管组件。

[0057] 典型地，所述导管主体包括内层、第一中间层、第二中间层和外层。第一中间层由宽厚比至少为2:1的扁丝构成。所述外套层的材料，包括柔软材料形成的外套管远端部分、中等硬度材料形成的外套管中段部分和高硬度材料形成的外套管近端部分。

[0058] 根据本发明的一个实施例，导管主体的内层的外径与厚度比至少为10:1。内层的最小内径为0.8mm。根据本发明的一个实施例，导管主体的第一中间层的最大厚度为0.06mm。根据本发明的另一个实施例，导管主体的第一中间层的最小宽度为0.08mm。

[0059] 根据本发明的一个实施例，所述导管主体的第一中间层至少覆盖所述内层的外腔表面的30%的区域。在另一个实施例中，根据所需的刚度，导管主体的第一中间层与内导管线的外腔表面之间的覆盖面积在30-75%之间。熟练掌握这门技术的人应该知道，第一中间层与内层之间的覆盖面积越小，整个导管就越灵活。

[0060] 根据本发明的一个实施例，导管主体的第二编织中间层的最大厚度为0.03mm。

[0061] 根据本发明的一个实施例，导管内层与导管主体的外夹套层长度相同。根据本发明的另一个实施例了第一中间层和第二编织中间层封装在导管内层和外护套层内。

[0062] 根据本发明的一个实施例，外护套层通过形成第一中间层（30）和第二编织中间层的丝之间的间隙与内层连接。

[0063] 根据本发明的一个实施例，导管主体的第一中间层由至少两根沿同一方向缠绕的丝构成。根据本发明的另一个实施例，导管主体的第一中间层由至少两根反向缠绕的丝构成。

[0064] 根据本发明的一个实施例，所述第二编织中间层（40）位于第一中间层和外夹套层之间。根据本发明的另一个实施例，第二编织中间层至少置于第一中间层的近端和中部。根据本发明的另一个实施例，第二编织中间层至少比第一中间层短20毫米。

[0065] 根据本发明的一个实施例，导管主体的外径与内腔直径之比至少为1.2:1。

[0066] 本发明的主要优点包括：

[0067] (a)具有大的腔体来实现最大限度的抽吸流量；

[0068] (b)具有更小的外径使导管能够深入到更小的血管中，而不会对目标治疗位置造成额外的血管损伤；

[0069] (c)具有极高的外表面顺滑性和内表面顺滑性，便于推送；

[0070] (d)具有显影环，便于追踪导管位置；

[0071] (e)远端柔韧性好，近端稳定性好，更加灵活；

[0072] (f)导管抗折性能好，便于通过迂曲的远端血管；

[0073] (g)具有优良的抗塌陷性能，可以抵抗内部抽吸力和外部压力。

[0074] 下面的描述和图中列出了一些具体的细节，以提供对当前专利的各种实施例的理解。那些在相关技术中具有普通技能的人要明白，他们可以实践现有专利的其他实施例，而不需要本文描述的一个或多个细节。因此，申请人无意限制或以任何方式限制附加在这些细节上的权利要求范围。虽然在接下来的披露中，各种过程都是参照步骤和顺序来描述的，但这些步骤和步骤的顺序不应该被作为实践本发明所有实施例的必要条件。

[0075] 除非另有具体描述，否则在规范和权利要求书中使用的所有表示数量、度量和其他属性或参数的数字都应被理解为在所有实施例中都被"大约"一词修饰。因此，除非另有说明，应了解下列规格书和所附权利要求中规定的数值参数是近似值。至少，不应试图将等同原则的适用限制在权利要求的范围内，而应根据所报告的有效数字的数目和一般圆整技术的应用来读取数值参数。

[0076] 要明白当这些字，如"组成"（和任何时态的组成），"有"（和任何时态的有），"包括"（和任何时态的包括）或"包含"（和任何时态的包含）被使用时，特指所陈述的特性，整数，步骤，操作，元素，和/或组件的存在，但不排除一个或多个其他特性、整数、步骤、操作、元素、组件和/或其分组的存在或添加。

[0077] 我们将进一步理解，尽管第一、第二，第三等术语可用于描述各种限制、元素、组件、区域、层和/或节，但这些限制、元素，组件、区域、层和/或节不应受这些术语的限制。这些术语仅用于区分一个限制、元素、组件、区域、层或节与另一个限制、元素、组件、区域、层或节。因此，下面讨论的第一个限制、元素，组件、区域、层或节可以称为第二个限制、元素、组件、区域、层或节，而不偏离当前应用的专利。

[0078] 进一步的理解是，当一个元素被称为"在……之上"、"附加于"、"连接"或"耦合"到另一个元素时，它可以直接位于或离于另一个元素，或者连接或耦合到另一个元素或一个或多个中间元素。相比之下，当一个元素被称为"直接在……之上"、"直接附加于"、"直接连接"或"直接耦合"到另一个元素时，则不存在中间元素。用于描述元素之间关系的其他词汇应该以类似的方式解释（例如，"介于……之间"与"直接介于……之间"、"邻近"与"直接近邻"等）。

[0079] 进一步理解，当第一个元素被称为"在……之内"，"在……之上"和/或"在……内部"于第二个元素，第一个元素可以位于：第二个元素的内部空间，第二个元素的一部分内（例如，在第二个元素壁内）；位于第二元素的外部和/或内部表面；以及其中一个或多个的组合。

[0080] 空间相关术语，如"在……之下"，"在下面"、"较低的"、"在……上面"、"上部的"等，可用于描述一个元素和/或特征与另一个元素和/或特征之间的关系，如图中所示。进一步的理解是，空间相关术语是为了包括在使用和/或操作中的设备的不同方向，同时包括图中所示的方向。例如，如果将图形中的设备翻转过来，则描述为"在下面"和/或"在……之下"其他元素或特性的元素将位于"在……上面"其他元素或特性。该装置可以朝向其他方向（例如旋转90度或其他方向），并相应地用空间相关术语来解释。

[0081] 这里使用的术语"减少"等类似词汇，含义包括数量的减少，包括减少到零。减少发生的可能性应包括预防发生。

[0082] 此处使用的术语"和/或"应被视为两个指定特性或组件的每个特性或组件的特定披露，其中一个具有或不具有另一个。例如，"A和/或B"应被视为（i）A、（ii）B和（iii）A和B的

具体披露，就像这里单独列出的一样。

[0083] 这里用来描述非圆几何体的术语"直径"应被视为近似所描述几何体的假想圆的直径。例如，在描述横截面时，如构件的横截面，应采用"直径"一词来表示与所述构件横截面具有相同横截面积的假想圆的直径。

[0084] 这里使用的组件的"长轴"和"短轴"分别是指能够完全环绕组件的最小体积假想圆柱体的长度和直径。

[0085] 为清楚起见，本发明在单独实施例的上下文中描述的某些特征也可以组合在单个实施例中提供。相反，为简洁起见，在单个实施例的上下文中描述的本发明的各种特征也可以单独提供或以任何适当的子组合形式提供。例如，任何声明中列出的所有特性(不管是独立的还是非独立的)都可以以任何给定的方式组合在一起。

[0086] 实施例

[0087] 本实施例涉及一种单腔、大口径、壁薄的导管。本实施例的导管结构提供了优异的远端柔顺性、优异的近端推送性和扭转性、优越的外部顺滑性和优越的内表面顺滑性。

[0088] 如图1A-1B所示，导管主体(10)为四层结构。导管主体(10)的内层(20)为全长的超薄导管内层，其中内腔(21)从一端延伸到另一端。所述导管主体(10)的第一中间层(30)包括绕在所述内导管内层的外表面(24)上的扁平线圈(31)。所述导管主体(10)的第二中间层(40)包括置于第一中间层(30)外表面上的编织丝。导管主体(10)的外层(50)包括一个放置在导管主体(10)的第二中间层(40)外表面的管子，外层(50)融化后流过两个中间层(30、40)并与导管主体(10)的内层(20)粘附在一起。此外，根据专利的一个实施例，导管主体(10)的外层(50)和内层(20)通常有相同的长度，导管主体(10)的两个中间层(30、40)略短于外层(50)和内层(20)，以便于能够封装在外层(50)和内层(20)之间。

[0089] 继续参阅图1A，在导管主体(10)组件的远端固定有一个不透射线的显影环，该显影环在荧光下可视。图1A还显示导管主体的近端(14)与导管近端控制机构(8)相连。具体的近端控制机构的设计可以根据预期的应用情况而异。因此，图1A只是一个例子，目的是解释本发明。

[0090] 根据本发明的一个实施例，导管主体(10)的一般长度为1100~1400mm，外径为1.4~2.7mm，内径为1.2~2.3mm。本领域技术人员应该了解导管主体(10)总成的总长度和尺寸可以很容易地修改以适合特定的应用。因此，此处披露的数字应被视为参考，不应被视为仅限于所示出的范围。

[0091] 参照图1B，根据本发明的一个实施例，导管主体(10)的内层(20)具有管状轮廓，其内腔(21)从一端延伸到另一端。根据本发明的一个实施例，导管主体(10)的内层(20)的长度为1150~1400mm，外径为1.75~1.85mm，内径为1.73~1.83mm，壁厚为0.013~0.032mm，外径和内径之比为1.014~0.015。根据本发明的一个实施例，当医疗设备/植入物通过导管时，导管主体(10)的内层(20)直接与医疗设备/植入物接触。所述导管主体(10)的内层(20)提供了足够的润滑性，减小推动设备/植入物通过内腔(21)所需的力。根据本发明的一个实施例，本发明公开的导管主体(10)的内层(20)的壁厚与内径之比为0.007~0.017。

[0092] 根据本发明的一个实施例，导管主体(10)的内层(20)由挤压的(extruded)PTFE(聚四氟乙烯)制成。在另一个实施例中，导管主体(10)的内层(20)由膨胀聚四氟乙烯制成，其也被称为ePTFE。ePTFE内层(20)是通过使用非标准制造工艺小心膨胀聚四氟乙烯制成

的，例如将挤压的聚四氟乙烯加热到所需的温度，然后在芯轴上扩大其内径。这样的后挤压工艺将产生一个扩大的内径和超薄管状壁与微观孔隙。所制得的ePTFE内层(20)具有透气、柔软、柔韧的物理特性，手感光滑有弹性，像一层膜。ePTFE内层(20)还具有高线性强度、化学惰性、在低压下保持水密，具有低介电常数、并具有良好的径向膨胀和抗紫外线性能。

[0093] 本领域技术人员应该理解，尽管此处描述的挤压的和膨胀的聚四氟乙烯管的目的是解释本发明，导管主体(10)的内层(20)可以由其他材料，如FEP(氟化乙烯丙烯)、HDPE(高密度聚乙烯)、LDPE(低密度聚乙烯)、PET(聚对苯二甲酸乙二醇酯)、PP(聚丙烯)、聚酰胺/嵌段聚醚聚酰胺，采用该领域已知的任何制造工艺，如直接挤压和/或后挤压轴向拉伸和/或径向膨胀等工艺，实现超薄腔壁。

[0094] 继续参照图1B，导管主体(10)的第一中间层(30)包括绕在导管内层(20)的外表面上的线圈(31)。在导管内层(20)上增加第一中间层(30)作为支撑，在增加周向强度的同时，增强远端侧向柔顺性，抗弯性更佳。根据一个实施例，用于组成导管主体(10)第一中间层(30)的线为扁平形态。本领域技术人员应理解图1B是为了说明和解释本发明的一个实施例的导管主体的四层结构。图1B并不实际表示导管主体各层的长度或相对长度。

[0095] 也就是说，如图2A所示，线(100)的横截面宽度大于其厚度。因此，本实施中导管主体(10)的内层(20)与第一中间层(30)有最大接触面积。由于导管主体(10)的内层(20)具有超薄壁厚，第一中间层(30)与内层(20)的外表面接触面积越大，内层(20)的内腔越光滑。本领域技术人员应该了解，在相同的线圈宽度下，线圈越厚，其抗弯折性能越好。因此，必须在抗弯折性和小的导管主体(10)整体轮廓之间实现设计平衡。

[0096] 根据图2A中的一个实施例，线圈(31)的宽度为0.04-0.11mm，厚度为0.02-0.06mm。在一个实施例中，线圈(31)的宽度为0.003″，厚度为0.0015″。根据本发明的另一个实施例，形成第一中间层(30)的线(100)的横截面积为0.001-0.007mm^2，宽厚比至少为2:1。根据一个实施例，第一中间层(30)至少覆盖所述内层(20)的外表面38%的面积。根据本发明的另一个实施例，线圈(31)的螺距为0.12-0.25mm，每个螺旋距间的最小间隙为0.025mm。在另一个实施例中，线圈(31)可以为左旋，也可以为右旋。

[0097] 根据本发明的另一个实施例，第一中间层(30)是具有恒定螺距的螺旋线圈(31)。根据本发明的另一个实施例，形成第一中间层(30)的线(100)在其整个长度中具有恒定的厚度和宽度。然而在本发明的另一个实施例中，为了在保持导管主体(10)远端柔顺性的同时获得导管主体(10)理想的可操纵性，螺旋线圈(31)在导管主体(10)的近端的螺距较小，在导管主体(10)的远端的螺距较大，且在过度处实现渐进的变化。在本发明的另一个实施例中，在保持线的厚度相同情况下，形成螺旋线圈(31)的线(100)在导管主体(10)的近端有较大的宽度，在导管主体(10)的远端有较小的宽度，并在过度处实现渐进的变化。

[0098] 本领域技术人员应该理解圆线圈，当扁平线圈拥有和圆线圈相同的横截面积时，两种线圈的抗弯折性能相当，但扁平线圈可以减少至少33%的壁厚。因此，本发明中的实施例提供了导管径向剖面的最小增加量。换句话说，本发明提供了在保持内径大小的同时，尽可能的减小导管的外径的一个最大可能。

[0099] 根据本发明的一个实施例，形成第一中间层(30)的扁线(100)可以用不锈钢、钨、钴铬合金和其他材料形成。在另一个实施例中，形成第一中间层(30)的扁线(100)可由镍钛等超弹性材料形成。在一个实施例中，当导管在使用过程中纠缠时，镍钛可以允许第一中间

层(30)恢复其预先配置的圆形管腔形状。

[0100] 图2A示出了单线螺旋线圈(31)。本领域技术人员应该知道，多线线圈(131、231)也可以被纳入到第一中间层(30)的构造中。例如，如图2B所示，形成第一中间层(30)的多线线圈(131)可以由两根线(110、120)组成，每根线采用不同的材料，向同一方向绕制而成。这样，第一中间层(30)就可以拥有两种材料的综合强度的力学性能。另一个实施例如图2C所示，构成第一中间层(30)的多线线圈(231)可由两根导线(130、140)组成，每根导线采用不同的材料，向相反方向绕制。根据一个实施例，如图2B-2C的两个实施例所示，两根导线(130、140)可以交替缠绕，使它们基本上处于同一层。在另一个实施例中，一根线可以绕在另一根线形成的线圈上。本领域技术人员应该知道，每根线(110、120、130、140)的结构，包括它的宽度、厚度、线圈的螺距和绕制的角度，都可以单独调整，以达到最佳的效果。根据一个实施例，多线线圈(131、231)包括2-4根线。在另一个实施例中，多线线圈(131、231)可以左旋或右旋绕制。在另一个实施例中，多线线圈(131、231)的螺距可为0.07-0.5mm。在其他实施例中，用于多线线圈的导线的宽度为0.04-0.11mm，厚度为0.02-0.06mm。

[0101] 继续参照图1B，根据其中一个实施例，第二中间层(40)置于第一中间层(30)的外部。第二中间层(40)由管状编织金属丝(41)而成。所述管状编织金属丝(41)加强了导管主体(10)的轴向和扭转控制，减少或几乎消除临床医生推拉或旋转操作所产生的延迟。

[0102] 图3示出了一种编织模式实施例。根据本发明的一个实施例，作为第二中间层(40)的管状编织金属丝(41)由16根丝组成，为常规编织模式。在另一个实施例中，第二中间层(40)由16根丝组成并且为常规钻石编织模式，其可以提供比常规编织模式更好的扭转和抗折性能。本领域技术人员应该理解编织模式和丝数可以改变。所以在此披露的内容不应该作为限制本发明包含的范围。

[0103] 根据一个实施例，第二中间层(40)置于第一中间层(30)的外侧，如图1D所示。根据一个实施例，常规的第二中间层(40)的厚度为0.025-0.066mm，其使用的每根编织丝的厚度为0.013-0.0033mm。根据本发明的一个实施例，第二中间层(40)长度为1150-1400mm，基本等同第一中间层(30)的长度。根据另一个实施例，第二中间层(40)的长度为1100-1350mm，远小于第一中间层(30)的长度，这种第二中间层(40)仅覆盖第一中间层(30)的中间和近端部分，没有覆盖第一中间层(30)的远端部分。但是根据另一个实施例，第二中间层(40)在第一中间层(30)的远端处比第一中间层(30)短2cm，如图1B所示。

[0104] 继续参考图1B，根据一个实施例，高分子聚合物外层(50)放在第二中间层(40)外形成导管外层。根据一个实施例，外层(50)为原始管状配置，置于在第二中间层(40)外。然后整个导管轴(10)组件经受回流焊接过程，由此外层(50)和/或内层材料融化形成一根复合的导管主体(10)。根据一个实施例，外层(50)材料融化并流到第二中间层(40)的编织丝间隙以及第一中间层(30)，并黏附到导管轴(10)的内层(20)。本领域技术人员应该理解用于熔化外层(50)以与导管主体(10)的内层(20)形成粘结的温度是平衡的，以允许足够的材料流过金属丝之间的间隙，并且不会在导管轴(10)的内层(20)的内腔表面引入凹槽和狭道，凹槽和狭道则会影响导管内腔的顺滑性。

[0105] 根据一个实施例，外层(50)由单种材料，如尼龙或Pebax制成，有稳定的硬度。根据另一个实施例，外层(50)的硬度为25-80D(Shore 25-80D)，长度为20-500mm，外径为2.0-2.5mm，壁厚为0.025-0.13mm。根据一个实施例，外层(50)覆盖了两个中间层(30、40)的全长

和导管轴(10)的内层(20)的全长。

[0106] 现在参考图4，其示出了另外一个外层(50)的实施例。根据一个实施例，外层(50)有多段组成，每段为不同硬度的材料。例如，如图4所示，外层(50)的远端部分由超低硬度材料制成，如硬度约60A(HS)的TPU。外层(50)的近端部分由相对较高硬度的材料制成，如硬度约75D(HS)的尼龙。外层(50)的远端和近端中间的过渡段，是由相对高硬度的材料制成，如硬度在30D-63D范围内的Pebax。因此，低硬度远端外层使导管主体(10)组件具有优异的弹性，以穿过迂曲的小血管。外层(50)高硬度的近端段使导管轴(10)具有刚性和优异的操控性。过渡段实现了由远端超软段到近端刚性和支撑段渐变的转化。

[0107] 继续参考图4，根据一个实施例，外层(50)的远端段长为100-200mm，外层(50)的过渡段长度为10-30mm，外层(50)的近端段长为1000-1200mm。根据一个实施例，外层(50)的远端段、过渡段和近端段都有大致相同的厚度。

[0108] 根据本发明的另一个实施例，可以将附加的涂层添加到本发明中描述的导管组成中。例如，添加亲水涂层，以获得光滑表面，从而使得导管可以更轻松地在血管内输送。

[0109] 即使在上文中没有具体描述，本领域技术人员应该理解一个或多个不透射线标记点可有助于通过影像设备(例如荧光镜，X射线，CT扫描，核磁共振，超声成像)可视化。如本文披露的一个标记点可以施加到本发明的导管轴(10)任何部位。一个不透射线标记点可以粘接、锻打、压握或者其他方式安置、固定在到导管轴(10)内或其表面。不透射线标记点可以由钽、钨、铂、铱、铑、金、或这些材料的合金或其他本领域技术人员已知的材料制成。不透射线标记点也可以由多种顺磁性材料组成，该顺磁性材料包括一种或多种原子数为21-29、42、44以及58-70的元素，如铬(III)、镁(II)、铁(III)、铁(II)、钴(II)、铜(II)、镍(II)、锆(III)、锰(III)，钐(III)、锝(III)、钒(III)、氧(III)、钛(III)、铕(III)或者其他本领域技术人员知晓的核磁可见材料。

[0110] 本领域技术人员应该理解，即使以上表述的关于导管主体(10)的大多数示例实施例适用于颅内血管应用，本发明的示例实施例也可以用于任何其他合适的微创伤介入应用。例如，本发明的示例实施例可用于输送血管封堵装置，支架，抽吸(aspiration)，治疗缺血性中风的支架取栓器等等。在其它示例中，本发明的示例实施例可被用于精准输送植入物进入血管，如脑血管，畅通的血管，或者其他部位。

[0111] 前面的描述和相关附图提出了多个当前代表性的实施例。根据前述教导，在不脱离本发明的精神或超出本发明的范围的情况下，各种修改和替代设计对于本领域技术人员将是显而易见的，所述范围是由所附权利要求限定而不是由前述说明指示。所有落入本发明等同范围和意义下的改变和变化都被视为包含在本发明的范围内。

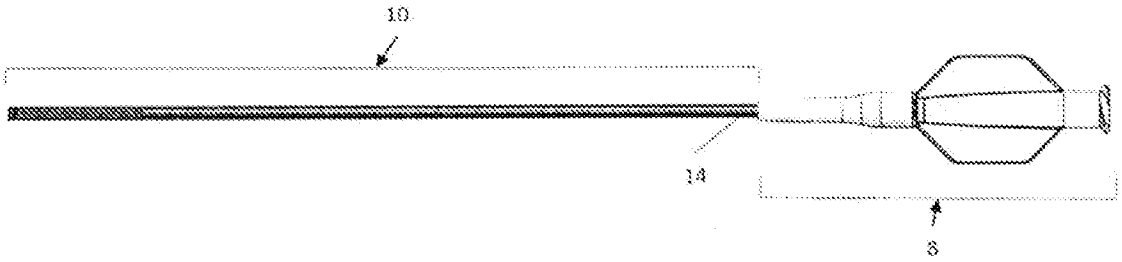

图1A

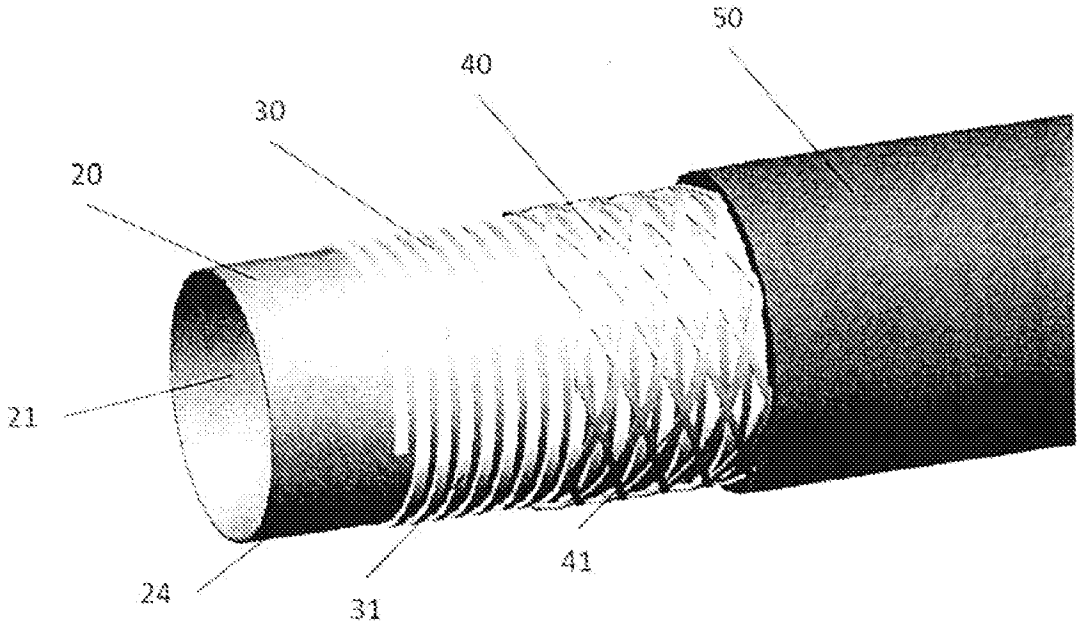

图1B

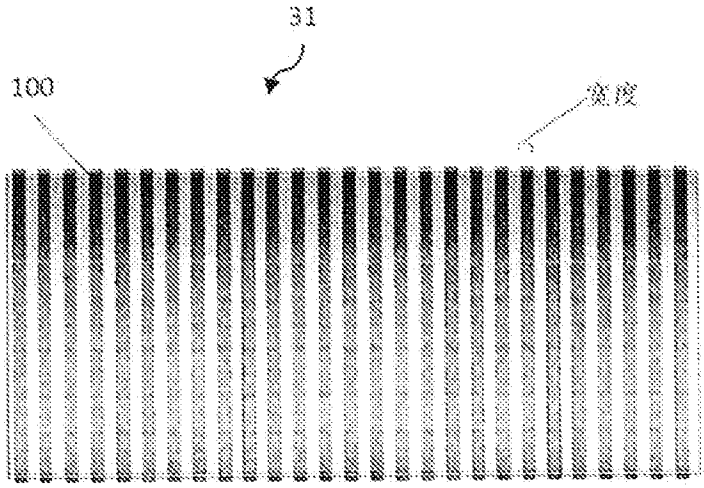

图2A

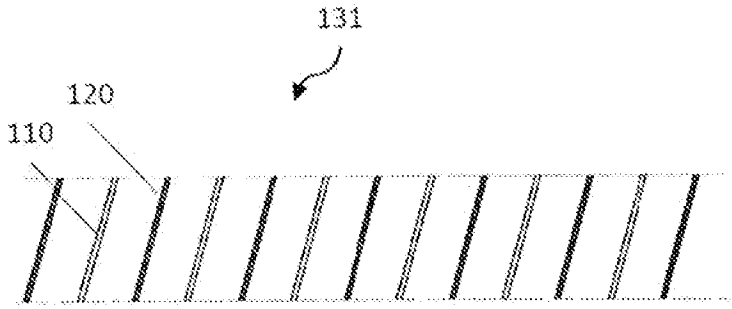

图2B

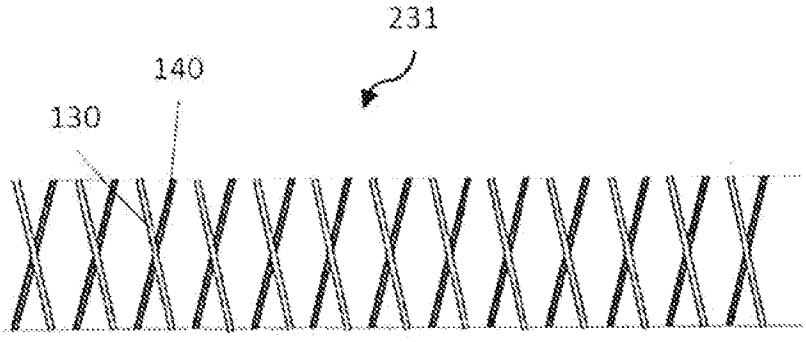

图2C

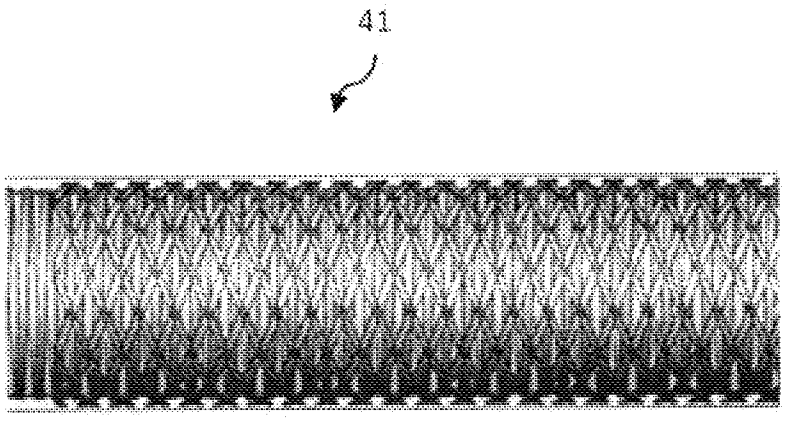

图3

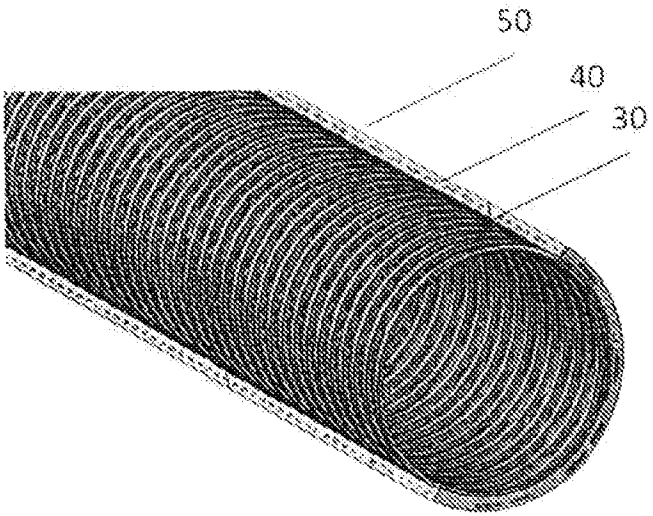

图4

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-PCT5		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2017/035543	1 June 2017 (01-06-2017)	3 June 2016 (03-06-2016)
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 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of:

[X] the international application in the language in which it was filed

[ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [ ] **Certain claims were found unsearchable** (See Box No. II)

3. [ ] **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. 6B

[ ] as suggested by the applicant

[ ] as selected by this Authority, because the applicant failed to suggest a figure

[X] as selected by this Authority, because this figure better characterizes the invention

b. [ ] none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/035543

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; figures page 8, line 12 - page 11, line 5	1-19
Y	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19) paragraphs [0152], [0153], [0167] - [0170]; figures 10, 13B	1-19
X,P	WO 2017/058280 A1 (GW MEDICAL LLC) 6 April 2017 (2017-04-06) the whole document	1-7,9-19

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"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
2 August 2017	14/08/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Giménez Burgos, R

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2017/035543

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2498349 A	17-07-2013	EP 2802275 A1	19-11-2014
		GB 2498349 A	17-07-2013
		US 2015005781 A1	01-01-2015
		WO 2013106146 A1	18-07-2013
WO 2012009675 A2	19-01-2012	US 2014005712 A1	02-01-2014
		WO 2012009675 A2	19-01-2012
WO 2017058280 A1	06-04-2017	US 9463035 B1	11-10-2016
		US 2017086864 A1	30-03-2017
		WO 2017058280 A1	06-04-2017

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

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/US2017/035543	01.06.2017	03.06.2016

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. 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	1-19
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-19
Industrial applicability (IA)	Yes:	Claims	1-19
	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 V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D1 GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC)

D2 WO 2012/009675 A2 (LAZARUS EFFECT, INC.)

2 Independent claim 1, lack of inventive step (Article 33(3) PCT).

The subject matter of claim 1, notwithstanding the lack of clarity objection raised in Item VIII below, does not involve an inventive step in the sense of Article 33(3) PCT and the criteria of Article 33(1) PCT are therefore not met.

2.1 Document **D1** (Figs.: 1- 3; page 8, line 12- page 11, line 5) is regarded as being the prior art closest to the subject matter of claim 1, and discloses

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

an elongate inversion support catheter (12) having a distal end and a distal end opening;

an elongated puller (20) extending within the elongate inversion support catheter (12);

a flexible tractor (14) having a free first end (18) and a second end (16) that is coupled to a distal end region of the elongate puller (20), wherein the flexible tractor (14) is inverted over the elongate puller (20) and is held within the elongate inversion support catheter (12) in a collapsed first configuration (Fig.: 1);

wherein the flexible tractor (14) comprises a braided wire basket made of shape memory material, that bias the flexible tractor free end (18) to expand; and

wherein the end section of the biased flexible tractor (14) has a diameter that is larger than an outer diameter of the elongate inversion support catheter (12) when the flexible tractor (14) is in the expanded second configuration.

2.2 The subject matter of claim 1 therefore differs from this known mechanical thrombectomy system in that the flexible tractor is tubular; such as to configure the apparatus suitable to be used over a guide wire or to allow the passage of a clot engaging member within.

2.3 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.

2.4 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** (Fig.: 13G) 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.

2.5 It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to use a tubular flexible tractor with corresponding effect in the mechanical thrombectomy apparatus of **D1**, thereby arriving at claim 1.

3 Independent claim 19, lack of inventive step (Article 33(3) PCT).

The same reasoning applies, mutatis mutandis, to the subject matter of the corresponding independent claim 19, which therefore is also considered not inventive over documents **D1** and **D2**.

4 Dependent claims 2- 18 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 apparatus 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	06/04/2017	15/02/2016	28/09/2016

Re Item VII

Certain defects in the international application

5 The independent claims 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, document **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).

6 The features of the 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 documents **D1** and **D2** is not mentioned in the description, nor are these documents identified therein.

Re Item VIII

Certain observations on the international application

8 The application does not meet the requirements of Article 6 PCT, because claims 1 and 19 are not clear.

The term "annular bias" used in claims 1 and 19 is vague and unclear and leaves the reader in doubt as to the meaning of the technical feature to which it refers, thereby rendering the definition of the subject matter of said claim unclear, Article 6 PCT.

An "annular bias" only defines a characteristic or an effect; and does not infer the inclusion of an additional element capable of creating such characteristic or effect.

It is clear from the description on paragraph [00078] that the annular bias is obtained by coupling an annular bias *element* (525, 625) to the first end of the flexible tractor (544, 644), and consequently the inclusion of this feature is essential to the definition of the invention.

Since independent claims 1 and 19 do not contain "an annular bias *element* (525, 625) coupled to the first end of the flexible tractor (544, 644)", it does not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

9 Although claims 1 and 19 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.

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(56)对比文件
US 7285126 B2,2007.10.23, 说明书第11栏第2段至第13栏第4段,图10-14.
US 2004/0006361 A1,2004.01.08, 全文.
US 2002/0010487 A1,2002.01.24, 全文.

审查员 王婷婷

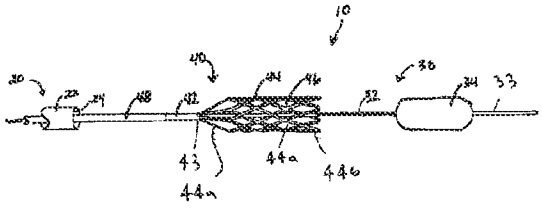
权利要求书1页 说明书13页 附图14页

(54)发明名称

流动恢复系统

(57)摘要

提供了用于移除体腔内的阻塞性物质的装置和方法。所述装置包括从套管可部署的剥离器装置，剥离器装置包括由轴承载且位于约束管内的可扩展笼。该轴相对于约束管可移动，以在体腔内部署和扩展笼，使得笼的开放端被定向为朝向阻塞性物质。笼前进以捕获物质或者通过在物质之外扩展并被收回的可扩展部件将物质引入笼中。笼撤回到约束管内以径向向内地压缩笼。穿过笼中的孔延伸的物质通过约束管的锋利的边缘被削切。然后通过套管从体腔抽吸更小的、被削切的颗粒。



CN 102186427 B

1. 一种用于从体腔移除阻塞性物质的系统，包括：

外部管状部件，包括近端、被确定尺寸以被引入体腔的远端、以及在所述近端与所述远端之间延伸的腔；

阻塞装置，能够从所述管状部件被部署至将要被移除的阻塞性物质之外的位置，所述阻塞装置包括位于其远端上的可扩展部件；以及

剥离器装置，包括在轴的远端上承载的可扩展笼和约束管，所述约束管用于使所述笼保持在收缩形态以允许所述剥离器装置通过管状部件腔被引入到所述体腔中，所述笼在体腔内能够从所述约束管的远端被部署并且能够扩展至扩展形态，所述笼包括与处于所述扩展形态的笼的内部连通的开放端，以将阻塞性物质捕获到所述笼的内部，

其中，所述笼包括管状结构，所述管状结构包括在所述笼的开放端和闭合端之间延伸的壁，所述笼包括在所述开放端与所述闭合端之间延伸的多个支杆，由此在所述壁中限定了多个孔，

所述多个支杆包括通常在所述笼的开放端和闭合端之间轴向延伸的第一组支杆，以及在所述第一组支杆的相邻支杆之间不连续延伸的第二组支杆，从而限定网状壁结构，

所述第一组支杆具有比所述第二组支杆更大的刚性，使得所述笼关于其纵轴在第一方向的旋转引起所述笼径向扩展。

2. 如权利要求 1 所述的系统，其中，所述阻塞装置能够相对于所述剥离器装置移动，使得扩展的可扩展部件将置于所述可扩展部件与所述笼之间的阻塞性物质引导至所述笼的开放端内，以将所述物质捕获到所述笼的内部。

3. 如权利要求 1 所述的系统，其中，所述笼能够在体腔内扩展之后缩回到所述约束管中，使得所述笼的闭合端可滑动地与所述约束管的远端接合并且使得所述笼向所述收缩形态被压缩。

4. 如权利要求 3 所述的系统，其中，所述笼包括管状结构，所述管状结构包括在所述笼的开放端和闭合端之间延伸的壁，所述壁包括限定了期望孔隙尺寸的多个孔，从而当随着所述笼缩回到所述约束管中，所述笼可滑动地与所述约束管的远端接合时，由所述笼捕获的通过所述孔延伸的阻塞性物质通过所述约束管的远端而与所述笼分离。

5. 如权利要求 4 所述的系统，进一步包括真空源，所述真空源连接至所述管状部件的腔，以将与所述笼分离的阻塞性物质抽吸到所述管状部件的腔中。

6. 如权利要求 1 所述的系统，其中，所述剥离器装置的轴包括在其近端和远端之间延伸的腔，以在该腔中可滑动地接纳所述阻塞装置，所述可扩展部件处于收缩形态。

7. 如权利要求 1 所述的系统，进一步包括从所述笼的开放端向远侧延伸的多个远末端。

流动恢复系统

[0001] 相关申请

[0002] 本申请要求共同未决的 2008 年 9 月 22 日提交的第 61/099,171 号美国临时专利申请、2009 年 1 月 9 日提交的第 61/143,603 号美国临时申请和 2009 年 2 月 12 日提交的第 61/152,227 号美国临时专利申请的优先权，其全部公开通过引用明确并入本文。

技术领域

[0003] 本发明通常涉及用于处理患者体腔（例如，管状移植物 (tubulargraft)、主动脉 - 静脉瘘 (aorto-venous fistula)、血管等）内的阻塞性物质（例如，血栓，器官狭窄）和 / 或不期望物质的装置。更具体地，本发明涉及用于移除或以其它方式捕获体腔内的血栓或其它阻塞性物质的装置，以及制造和使用这种装置的方法。

背景技术

[0004] 患者脉管系统内的血管或其它体腔内的流动可能由于各种原因而变得缩窄或最终中断。例如，炎症和 / 或细胞增殖可能导致血管逐渐变窄。此外，这种变窄或血管内的其它流动问题可能导致血栓的形成。

[0005] 移除粘附至血管壁的不期望物质（例如，血栓）的一种方法可涉及使装置（例如，Fogarty（福格蒂）栓子清除气囊）前进至附着的阻塞性物质之外的一点，将装置扩展至血管内部的尺寸，然后撤回扩展的装置，以将附着的物质清扫出血管。虽然这种方法经常是成功的，但是也存在一些情况：附着的物质没有脱离血管壁，并且甚至在多次通过后仍然留在血管内。

[0006] 移除附着的物质的另一种方法是推进可以刮擦附着的物质的表面或与附着的物质缠绕在一起的旋转结构，从而迫使附着的物质脱离血管壁。Arrow Treratola 装置具有若干径向向外扩展以接触血管壁的螺 旋线。通过连接至装置的机头中电动机的驱动轴使这些线高速旋转。在操作过程中，当 Treratola 装置前进时，它摩擦血管的内壁。一旦与附着的物质接合 (engage)，装置刮擦该物质的内表面，而且在许多情况下，装置可冲破附着的物质与血管壁之间的界面。在这种情况下，附着的物质可从血管壁脱落，并且缠绕在 Treratola 装置的螺旋线上。

[0007] 虽然这可解决从血管壁移除附着的物质的直接目标，但是往往很难从血管本身移除物质，因为 Treratola 装置没有提供任何方法来解开 (unwind) 或抽吸物质。当 Treratola 装置从血管移除时，它通常通过紧贴的孔，例如导引器套管。任何缠绕在 Treratola 装置上的物质在该 Treratola 装置进入套管时被推落，因此这些物质仍然留在血管中。

[0008] 因此，从主动脉 - 静脉瘘、血管或其它体腔中移除物质的装置和方法是有用的。

发明内容

[0009] 本发明涉及处理患者体腔（例如管状移植物、主动脉 - 静脉瘘、血管等）的装置。更具体地，本发明涉及用于移除或以其它方式捕获体腔内的血栓或其它阻塞性物质的装

置，以及制造和使用这种装置的方法。

[0010] 根据一个实施方式，提供了用于从体腔移除阻塞性物质的系统。所述系统包括外部管状部件，其包括近端、远端、以及在近端与远端之间延伸的腔。任选地，环形可扩展阻塞部件可设置在外部管状部件远端上。该系统还包括剥离器装置，其可插入通过腔并且包括细长轴、连接至细长轴远端的可扩展笼、以及包括具有锋利的边缘的远端开口的约束管，其中，轴和笼相对于约束管轴向可移动。可选地，约束管固定地连接至外部管状部件的内表面，或者约束管可独立于外部管状部件可移动。

[0011] 笼可包括多个孔，并且约束管的远端锋利的边缘被配置为当将笼撤回到约束管时削切通过孔突出的阻塞性物质。任选地，笼的内表面可包括多个向内突出的倒钩。笼可包括远端伸出结构和/或厚支杆以及与厚支杆连接在一起的薄支杆。任选地，一根或多根控制线可连接至 笼的远端伸出结构，其中，控制线可被配置为当笼处于扩展形态时，将伸出结构一起拉向闭合形态。任选地，驱动轴可操作地连接至笼，以使笼在通过体腔前进期间旋转，或者该系统可包括促动器从而手动地旋转笼。在示例性实施方式中，所述远端伸出结构可具有平滑边缘、具有沟槽的边缘或蜿蜒的边缘。

[0012] 在示例性实施方式中，系统可进一步包括具有可扩展处理元件的细长处理部件，可扩展处理元件选择性地可扩展以当笼处于扩展形态时将体腔内的阻塞性物质引入到笼中。细长处理部件可插入通过穿过剥离器装置轴中的腔。可选地，细长处理部件可插入通过邻近剥离器装置轴的外部管状部件腔。任选地，在这个可选实施方式中，笼可包括细长处理部件可通过的不间断的路径或其它开口。

[0013] 根据另一实施方式，提供了用于从体腔移除阻塞性物质的方法，包括将外部管状部件引入到体腔内，外部管状部件包括腔和远端开口。可通过管状部件腔将剥离器装置引入到体腔内。在示例性实施方式中，剥离器装置包括细长轴，连接至细长轴远端的可扩展笼，以及具有远端开口的约束管。通过使细长轴相对于约束管向远侧前进可将可扩展笼部署在约束管远端开口的外部，并且使其在体腔内扩展。可将阻塞性物质捕获到笼内，然后将笼向近侧撤回到约束管中。当笼收缩时，通过笼中的孔突出的物质可被削切，例如，通过约束管远端开口的锋利的边缘被削切。附加地或者可选地，可将削切的物质抽吸到外部管状部件远端开口中。任选地，方法还可包括在外部管状部件远端上扩展阻塞部件，例如以防止阻塞性物质紧邻地经过外部管状部件的远端。

[0014] 在示例性实施方式中，所述方法还可包括将将包括远端可扩展处理元件的细长处理部件引导通过外部管状部件腔并引入到体腔中，使得处于收缩形态的可扩展处理元件位于阻塞性物质的远侧，并且笼被定位在阻塞性物质的近侧。可扩展处理元件可以被扩展并且将可扩展处理元件向近侧朝向可扩展笼撤回，使得阻塞性物质被撤到笼的开放端内。

[0015] 在另一示例性实施方式中，所述方法还可包括使可扩展笼朝向阻塞性物质前进并且在推进期间使笼旋转，直至阻塞性物质缠绕在笼的 远端部。笼的旋转可引起所述阻塞性物质与血管壁分离，并且笼可撤回到约束管中。所述撤回步骤可从笼远端部释放阻塞性物质和/或将阻塞性物质撤到约束管中。任选地，笼可一次或多次地重新部署、扩展和/或撤回，例如以分离阻塞性物质和/或将阻塞性物质撤到笼中。

[0016] 根据另一实施方式，提供了用于从体腔移除阻塞性物质的装置，包括：外部管状部件，包括近端、被确定尺寸以被引入体腔的远端、以及在近端与远端之间延伸的腔；细长轴，

包括近端和远端并且在管状部件腔内轴向可移动；以及可扩展的剥离器笼，包括附接至轴的远端的第一端和第二自由端。当笼被置于管状部件腔内时笼可从收缩形态扩展，当笼从管状部件腔被部署时笼可从扩展形态扩展。

[0017] 在一个实施方式中，笼包括管状结构，管状结构包括在第一端与第二端之间延伸的壁，第二端限定了与处于扩展形态的笼的内部连通的开口，以将阻塞性物质捕获到笼的内部。壁可包括多个支杆 / 孔，使得当笼在将阻塞性物质捕获到笼内之后撤回到管状部件腔时，管状部件的远端可滑动地与笼的壁接合，或者以其它方式分离由笼捕获的穿过孔延伸的阻塞性物质，并且将笼压缩回到收缩形态。

[0018] 根据又一实施方式，提供了用于从体腔移除阻塞性物质的系统，包括：外部管状部件，包括近端、被确定尺寸以被引入体腔的远端、以及在近端与远端之间延伸的腔；阻塞装置，从管状部件可被部署至将要被移除的阻塞性物质之外的位置，阻塞装置包括位于其远端上的可扩展部件；以及剥离器装置。剥离器装置可包括轴的远端上承载的可扩展笼以及用于使笼保持在收缩形态的约束管，例如以允许将剥离器装置通过管状部件引入体腔中。笼可从约束管的远端可部署并且在体腔内可扩展至扩展形态。在一个实施方式中，笼可包括与处于扩展形态的笼的内部连通的开放端，以将阻塞性物质捕获到笼的内部。

[0019] 考虑下面结合附图的描述，本发明的其它方面和特征将会变得显而易见。

附图说明

[0020] 应理解的是，图中所示的示例性装置不必按照比例绘制，主要用于强调而非说明所示实施方式的各个方面和特征。

[0021] 图 1 是包括从进入套管可部署的剥离器装置和闭塞装置的流动恢复系统的示例性实施方式的侧视图；

[0022] 图 2A 是可包含在图 1 的系统中的进入套管的截面侧视图，该图包括位于进入套管的远端上的可扩展部件；

[0023] 图 2B 是可包含在图 1 的系统中的进入套管的可选实施方式的截面侧视图，该图包括位于进入套管的远端上的可扩展部件；

[0024] 图 3 是可包含在图 1 的系统中的剥离器装置的笼的内表面的细部；

[0025] 图 4A 和图 4B 是可包含在图 1 的系统的剥离器装置中的约束管的示例性实施方式的截面侧视图；

[0026] 图 5 是进入装置的可选实施方式的截面侧视图，该进入装置包括可包含在图 1 系统中的整合的约束管；

[0027] 图 6 是包括从进入套管可部署的剥离器装置和闭塞装置的流动恢复系统的另一示例性实施方式的侧视图；

[0028] 图 7 至图 10 示出了患者身体内体腔的截面视图，其示出了移除体腔内阻塞性物质的方法；

[0029] 图 11A 和图 11B 分别是处于扩展形态和收缩形态的剥离器装置的另一示例性实施方式的透视图；

[0030] 图 12A 是可以并入图 11A 和图 11B 的剥离器装置笼的平面样式的俯视图；

[0031] 图 12B 是图 12A 的平面样式的一部分的细部；

[0032] 图 13 是图 11A 和图 11B 中所示的剥离器装置笼沿方向 A 旋转的详细透视图；

[0033] 图 14A 和图 14B 是剥离器装置笼的另一示例性实施方式的截面图，该剥离器装置包括控制线，分别用于在开放结构与闭合结构之间引导笼的远端；

[0034] 图 14C 是图 14A 和图 14B 的剥离器装置笼的可选示例性实施方式的截面图，该剥离器装置包括控制线以及围绕控制线的套管，以在开放结构与闭合结构之间引导笼；

[0035] 图 15A 至图 15C 是可设置在剥离器装置笼（如图 11A 和图 11B 中所示的笼）上的远末端的可选实施方式的侧视图；以及

[0036] 图 16A 至图 16H 是患者身体内体腔的截面视图，其示出了移除体腔内阻塞性物质的另一方法。

具体实施方式

[0037] 转到附图，图 1 示出了用于处理体腔的装置 10 的示例性实施方式，装置 10 例如用于从体腔（诸如血管、主动脉 - 静脉瘘、管状移植物等）内移除血栓、血块、物体、碎片和 / 或其它不期望的或阻塞性物质。通常，装置 10 包括外部进入套管或其它管状部件 20、以及任选地阻塞装置 30 和剥离器 (macerator) 装置 40，它们一起可提供流动恢复系统，例如以从患者身体的体腔内移除阻塞性物质。另外，这种系统可包括一个或多个未示出的附加部件，例如，一根或多根导引线 (guidewire)、注射器或膨胀介质和 / 或真空的其它源等。

[0038] 套管 20 可以是细长的管状体（例如，导引器或手术 (procedure) 套管），包括近端（未示出）、被确定尺寸以被引入体腔内的远端 22、以及在近端与远端 22 之间延伸的腔 24。套管 20 可被配置为经皮置于体腔内，例如包括圆的或其它基本上无损伤的末端，从而便于推入到患者身体内的体腔内和 / 或沿着患者身体内的体腔前进。

[0039] 套管 20 可具有沿着其长度基本均匀的结构，或可选地，该结构可以是变化的。例如，套管 20 的近端部可以是基本刚性或半刚性的以通过推动或以其它方式操纵近端来方便装置 10 的前进。附加地或可选地，套管 20 的远端部可以是柔性的，例如以便于折弯和 / 或在弯曲的解剖结构中前进而不存在扭结或弯曲变形的高风险。在示例性实施方式中，形成套管 20 的材料可以是诸如金属、塑料（例如 PEEK、GrilamedL25 等）、或复合材料。套管 20 的长度可约在 5cm 至 130cm 之间，外径约在 1.6 毫米至 2.0 毫米之间，腔 24 的直径可约在 1.4 毫米与 1.8 毫米之间。

[0040] 任选地，套管 20 可在近端（未示出）上包括握柄或套筒 (hub)。如下进一步描述，握柄可成形为便于握住或操纵装置 10 或装置 10 的单独部件。另外，握柄可包括与例如围绕剥离器装置 40 和 / 或阻塞装 置 30 的腔 24 连通的端口，例如以将流体注入腔 24 和 / 或从腔 24 抽吸物质。如下进一步描述，例如，注射器、真空管线等可连接至端口，以抽吸容纳在套管 20 的腔 24 内和 / 或在体腔内邻近远端 22 放置的阻塞性物质。

[0041] 任选地，套管 20 可包括由远端 22 承载的可扩展 (expandable) 部件或其它阻塞元件，例如以在体腔内固定套管 20 和 / 或密封体腔以防止在手术期间流体流过远端 22。例如，图 2A 示出了体腔 50 内的套管 20’，该套管 20’ 包括位于其远端 22’ 上的可扩展部件 26’。如果需要，可扩展部件 26’ 可以是柔性气囊（例如由柔性材料制成，其可根据运送到气囊 26’ 中的膨胀介质的量成比例地弹性扩展）、半柔性气囊或非柔性气囊（例如 PTA 气囊）。在这个实施方式中，套管 20’ 可包括从套管 20’ 的近端延伸到远端 22’ 且与气囊 26’ 的内

部连通的膨胀腔（未示出）。诸如具有盐溶液或其它流体的注射器等的膨胀介质和/或真空的源（未示出）可连接至套管 20' 的近端，以经由膨胀腔将膨胀介质运送到气囊 26' 中和/或从气囊 26' 中抽吸流体，例如，以便于在手术后使气囊收缩。可选地，可扩展部件 26' 可以是以机械或其它方式可扩展的，例如，包括可扩展框架、或者在膜（未示出）内或以其它方式连接至膜（未示出）的其它结构。

[0042] 可扩展部件 26' 可从低轮廓、收缩形态（例如，抵靠套管 20' 的外表面布置以便于套管 20' 的引入）扩展，并且可从高轮廓、扩展形态扩展，例如以与其内引入套管 20' 的体腔 50 的内表面接合或以其它方式接触。在扩展形态中，可扩展部件 26' 可在体腔 50 内提供基本的流体密封，例如以防止沿着体腔 50 的大量生理流动，否则其可能允许松散物质的颗粒移动经过套管 20 进入患者身体的其它部位，在那里颗粒可能造成伤害。附加地或可选地，可扩展部件 26' 还可基本上固定和/或稳定体腔 50 内的套管，例如，以防止在处理过程中体腔 50 内的套管 20' 因疏忽而移动。

[0043] 在使用过程中，在套管 20' 被引入时，可扩展部件 26' 可保持低轮廓形态，然后一旦套管 20' 被定位在正被处理的体腔 50 内，则可扩展部件 26' 扩展至高轮廓形态。当阻塞性物质从体腔 50 经由套管 20' 或 装置 10 的其它部件移除时，可扩展部件 26' 可保持扩展状态，如下进一步描述。一旦体腔 50 被充分处理，则可扩展部件 26' 可收缩以恢复体腔 50 内的生理流动。

[0044] 在图 2B 中所示的可替换实施方式中，可提供包括可扩展部件 26" 的进入套管 20"，可扩展部件 26" 延伸到套管 20" 的远端 22" 之外以为套管 20" 提供可扩展的远末端。因此，可扩展部件 26" 可提供从增大的远末端向套管 20" 的腔 24" 的圆锥形过渡或其它过渡，例如，如果需要，可在可扩展部件 26" 的远末端内或邻近可扩展部件 26" 的远末端执行阻塞性物质的剥离。在剥离期间，阻塞性物质的颗粒可在套管 20" 的腔 24" 内或者邻近套管 20" 的腔 24" 释放。在 2009 年 8 月 8 日提交的第 PCT/US09/53237 号申请中可得到进入套管 20" 和/或可扩展部件 26" 的更多信息，该申请的全部公开通过引用明确并入本文。

[0045] 回到图 1，阻塞装置 30 通常包括轴或其它细长部件 32，其包括近端（未示出）和远端 33，远端 33 被确定尺寸以被引导例如经由腔 24 穿过套管 20，并且在远端 33 上承载有可扩展的阻塞或处理部件 34。通常，阻塞部件 34 从收缩形态（未示出）（例如，其尺寸适合被引导通过套管 20 的腔 24）扩展，并从扩展形态（图 1 所示）扩展，以与体腔的壁接合或以其它方式接触，其中阻塞部件 34 在体腔内扩展。在示例性实施方式中，阻塞部件 34 可以是可扩展成基本上球形或圆筒形的气囊，例如柔性气囊、半柔性气囊或非柔性气囊。在这个实施方式中，轴 32 可包括与阻塞部件 34 的内部连通的膨胀腔（未示出），例如，以选择性地扩展和收缩阻塞部件 34。任选地，阻塞部件 34 可包括芯线和/或螺旋结构（未示出），例如使得阻塞部件可在扩展形态中采用螺旋形。在 2009 年 7 月 2 日提交的第 12/497,135 号共同未决申请中公开了可用于阻塞部件 30 的示例性装置，该申请的全部公开通过引用明确地并入本文。可选地，如果需要，阻塞部件 34 可包括框架或其它机械上可扩展的结构（未示出）。

[0046] 继续参照图 1，剥离器装置 40 通常包括轴或其它细长部件 42，其包括近端（未示出）和远端 43、以及在远端 43 上承载的可扩展笼 44，远端 43 被确定尺寸以适配于套管 20 的腔 24 内。任选地，如下进一步 描述，轴 42 可包括腔或其它轨道（未示出），以可滑动地

容纳通过该腔或其它轨道的阻塞部件 30。附加地或可选地，如下进一步描述，轴 42 可包括一个或多个附加腔（未示出），例如用于接收导引线或其它轨（也未示出），一个或多个促动器线或线缆（也未示出）等。

[0047] 如图所示，笼 44 是开放的或多孔的可扩展结构，其包括连接至轴 42 的闭合的近端或第一端 44a 以及开放的远端或第二端 44b，例如，以在笼 44 内容纳接收的阻塞性物质，如下进一步描述。通常，笼 44 包括在第一端 44a 与第二端 44b 之间和 / 或围绕笼 44 的外周延伸的多个支杆 (struts)44a，由此例如至少邻近第一端 44a 限定了包括多个孔 46 的圆筒形外壁或其它管状外壁。支杆 44a 和 / 或孔 46 可被确定尺寸以适应笼 44 的扩展和 / 或收缩，和 / 或限定期望的孔隙尺寸，一旦比期望孔隙尺寸大的颗粒被捕获到笼 44 内，则该期望的孔隙尺寸防止该颗粒逃脱，如下进一步描述。

[0048] 笼 44 从例如适于低轮廓、收缩形态（未示出）（以适于被引导通过套管 20）和高轮廓、扩展形态（图 1 所示）扩展，在高轮廓、扩展形态中，笼 44 径向向外扩展，例如以接触的体腔的壁，其中笼 44 在体腔内被部署 (deploy) 和 / 或扩展。任选地，如图 3 所示，笼 44 可包括从支杆 44a 径向向内突出的多个倒钩或其它特征 41，例如以与被捕获到笼 44 内的阻塞性物质接合和 / 或对其提供附加的牵引力，如下进一步描述。

[0049] 笼 44 可由例如能够在收缩形态与扩展形态之间弹性或塑性地变化一次或多次的多种材料形成。例如，笼 44 可由弹性或超弹性材料形成，例如金属（如不锈钢、镍钛合金等）、塑料或复合材料。在示例性实施方式中，笼 44 可由管形成，该管的一个或多个部分通过激光切割、蚀刻、机械切割等被移除以限定支杆 44a 和 / 或孔 46。可选地，笼 44 可由片形成，该片的一个或多个部分也通过激光切割、蚀刻、机械切割、冲压等被移除以限定支杆 44a 和 / 或孔 46，该片可例如通过焊接、钎焊、用粘接剂粘合、熔化等将片的边缘附接在一起以卷成管状形状。

[0050] 然后，例如通过绕着闭合端 44a 压接、粘接剂粘合、熔接、缠绕轴环、线或其它材料等，绕着轴 42 的远端 43 基本上永久地附接闭合 端 44a，从可使笼 44 附接至轴 42。因此，闭合端 43 可固定在收缩形态，而笼 44 的其余部分可自由地从收缩形态扩展至扩展形态。在示例性实施方式中，笼 44 可由超弹性材料形成，该超弹性材料可被加热处理以将扩展形态设计到笼 44 中，并且允许笼 44 被弹性压缩并保持在收缩形态。

[0051] 因此，在图 1 所示的实施方式中，笼 44 可以是自扩展结构，例如，径向向内弹性地可压缩至收缩形态，而偏移 (bias) 以向扩展形态扩展。可选地，笼 44 可例如通过剥离器装置 40 近端上连接至笼 44 的促动器（未示出）进行机械地扩展和收缩。

[0052] 为了将自扩展笼 44 维持在收缩形态，例如在被引导通过套管 20 期间或者从套管 20 被部署之前，剥离器装置 40 可包括绕着轴 42 可滑动地布置的约束管 48。约束管 48 可以是细长的管状体，包括近端（未示出）、远端 48a、以及在近端与远端 48a 之间延伸的腔 49，腔 49 被确定尺寸以接收轴 42 和处于收缩形态的笼 44。可选地，可围绕笼 44 设置其它可移动的约束件，以将笼 44 维持在收缩形态，直至期望在体腔内部署笼 44 并使其扩展，其它可移动的约束件例如为围绕笼 44 缠绕的一根或多根可移除的线、撕开的套等（未示出）。

[0053] 约束管 48 的远端 48a 可被确定尺寸以可滑动地布置在套管 20 内，例如，以容纳剥离器装置 40 被引导通过套管 20 的腔 24。约束管 48、轴 42 和笼 44 可轴向地相对彼此移动，例如，以允许笼 44 被收回到约束管 48 内和 / 或从约束管 48 被部署。因此，例如在通过套

管 20 将笼 44 引入体腔期间，约束管 48 可将笼 44 维持在收缩形态，并允许笼 44 从约束管 48 被部署，使得笼 44 呈现扩展形态。

[0054] 轴 42 和 / 或约束管 48 的近端（未示出）可延伸或以其它方式连接至套管 20 的近端，并且可从套管 20 的近端被驱动。例如，套管 20 可在其近端上包括握柄或套筒（未示出），该握柄或套筒可包括一个或多个促动器以从套管 20 的远端 22 推动剥离器装置 40，和 / 或使笼 44 从约束管 48 被部署以及用约束管 48 包覆笼 44。轴 42 和 / 或约束管 48 可延伸到握柄内，或者在轴 42 和 / 或约束管 48 与握柄上的一个或多个促动器之间可连接有一个或多个线缆、线、杆、或其它促动器元件（未 示出）。

[0055] 例如，第一促动器（例如滑动器、按钮、转盘等）可设置在握柄（未示出）上，以相对于套管 20 推动和 / 或收回整个剥离器装置 40，例如以使笼 44 从套管 20 的远端 22 被部署但仍然被约束管 48 所包覆。然后例如另一滑动器、按钮、转盘等（也未示出）的第二促动器可被激活，以例如通过相对于约束管 48 推动轴 42 和笼 44 或者在基本上不移动笼 44 的情况下收回约束管 48，从而露出笼 44。在上面通过引用并入的第 12/497,135 号申请中公开了可设置在装置 10 上的示例性握柄和 / 或促动器。

[0056] 可选地，套管 20 和剥离器装置 40 可以是结构上分离的装置，并且剥离器装置 40 可例如经由套管 20 近端的端口或其它开口被引入到套管 20 中。例如，握柄或套筒（未示出）可设置在套管 20 的近端上，握柄或套筒包括与腔 24 连通的端口（未示出），在腔 24 中可容纳剥离器装置 40 和 / 或其它装置的引入。任选地，端口可包括一个或多个密封件（例如止血密封件），在其内可容纳接收的剥离器装置 40，并且提供基本地流体密封以防止体液从腔 24 漏出。在这个可选实施方式中，剥离器装置 40 本身可包括位于其近端上的握柄或套筒（未示出），该握柄或套筒包含一个或多个促动器（也未示出）以与上文所述的促动器相似的方式相对于约束管 48 操纵轴 42 和笼。

[0057] 任选地，以类似方式，阻塞装置 30 可连接至套管 20 和 / 或剥离器装置 40，例如用装置 10 的握柄上的一个或多个促动器（未示出）来部署和 / 或撤回阻塞装置 30。可选地，阻塞装置 30 可以是与套管 20 和 / 或剥离器装置 40 分离的装置，并且剥离器装置 40 可包括用于接收阻塞装置 20 的端口，例如与上述端口相似。

[0058] 任选地，如图 4A 和图 4B 所示，约束管 48 可被配置以便于移除由笼 44 捕获的过量物质。例如，约束管 48 的远端 48a 可包括滑动或以其它方式与笼支杆 44a 相互作用的一个或多个特征，例如以当笼 44 在将阻塞性物质捕获到笼 44 内之后撤回到约束管 48 中时，切除延伸到笼孔 46 外的过量物质。因此，当笼 44 进入约束管 48 并且向收缩形态压缩时，约束管 48 的远端 48a 上的特征可削切或以其它方式切除突 出到笼孔 46 外的过量物质。

[0059] 在图 4A 中所示的示例性实施方式中，约束管 48 的远端 48a 可包括围绕与腔 49 连通的远端开口 43 延伸的锋利的边缘 47，锋利的边缘 47 适于削切可能通过笼 44 的孔 46 突出的过量的阻塞性物质。在图 4A 中所示的示例性实施方式中，锋利的边缘 47 可以是单地 (single-ground) 边缘，例如在撤回期间，锋利的边缘 47 可沿着笼 44 的外表面削切以切割或以其它方式分离通过孔 46 延伸的阻塞性物质。可选地，如图 4B 所示，约束管 48' 可被设置为包括围绕远端开口 43' 延伸的双地 (double-ground) 边缘 47'。双地锋利的边缘 47' 可以以与单地边缘 47 类似的方式切割过量的阻塞性物质，但是由于笼进入约束管 48' 的腔 49'，所以双地锋利的边缘 47' 更加抗损。例如，由于切割边缘 47' 的直径稍稍大于约束管

48' 的腔 49' 本身的直径，所以在笼 44 的撤回期间，切割边缘 47' 可以不接触笼 44 的外表面，而是与笼 44 保持微小的间隔。

[0060] 在图 5 中所示的可选实施方式中，可以省略图 4A 和图 4B 中示出的约束管 48，套管 60 可用于在笼 44 被引入期间将笼 44（未示出）约束在收缩形态和 / 或在笼 44 的撤回期间移除过量物质。与前面的实施方式类似，套管 60 包括近端（未示出）、远端 62、以及在近端与远端 62 之间延伸的腔 64。与前面的实施方式不同，套管 60 包括并入到远端 64（例如在腔 64 内）中的约束管 48"。约束管 48"可以是相对短的管状体，其在腔 64 中以短距离延伸并且包括围绕远端开口 43" 的露出且锋利的边缘 47"，例如单地或双地边缘，与前面的实施方式类似。约束管 48"可以基本上永久地附接在腔 64 内或例如通过用粘接剂粘合、干涉配合 (interference fit)、熔接、声波焊接等的其它方式连接至远端 62，从而提供从远端开口 43" 到腔 64 的过渡。

[0061] 在使用过程中，笼 44 可从腔 64 被推进并且离开远端开口 43"，于是笼 44 可自由地向扩展形态扩展。在将不期望物质捕获到笼 44 内之后（如本文的其它地方进一步描述），笼 44 可通过远端开口 43" 撤回到套管 60 中，于是当笼 44 收缩时，穿过笼 44 的孔 46 延伸的过量阻塞性物质可通过锋利的边缘 47" 被切割或以其它方式分离。

[0062] 在其它可选的实施方式中，图 1 所示的套管 20 可用于在引入和 / 或撤回期间约束笼 44，并且约束管 48 完全可以省略。与前面的实施方式不同，然而，当笼 44 撤回到套管 20 时，由于套管 20 与被引导通过套管 20 的约束管 48 相比直径相对较大，所以笼 44 可以不收缩成较小的尺寸。在这个可选的实施方式中，在笼 44 撤回到套管 20 之后，阻塞性物质的一部分可能留在笼 44 中。换句话说，剥离器装置笼 44 可用于在不切除过量阻塞性物质的情况下捕捉并移除阻塞性物质。可选地，套管 20 本身可包括锋利的远端边缘（未示出），或者锋利的末端可附接到套管 20 的远端 22（也未示出），例如以在笼 44 的撤回期间切割过量的阻塞性物质，而笼 44 内的阻塞性物质被撤回到套管 20 中笼 44 内。

[0063] 进一步参照图 1，在示出的实施方式中，剥离器装置 40 的轴 42 包括腔以可滑动地接收阻塞装置 30 的轴 32，例如，使得剥离器装置 40 和阻塞装置 30 具有同心、相对彼此伸缩的布置。可选地，如图 6 所示，可以设置装置 10'，其中，剥离器装置 40 和阻塞装置 30 被设置为相对于外套管 20 并排布置。在这个可替换的实施方式中，套管 20、阻塞装置 30 和剥离器装置 40 可以以与上述实施方式类似的方式构造。任选地，剥离器装置 40 可包括笼 44，笼 44 包括由笼 44 的支杆 44a 限定的不间断路径 45，该不间断路径 45 沿着笼 44 的至少一部分轴向地延伸，以容纳穿过笼 44 的阻塞装置 30，并且允许笼 44 基本上完全闭合到收缩形态。

[0064] 在这个实施方式中，阻塞装置 30 和剥离器装置 40 可被接纳在套管 20 的共同腔 24 中，如图 6 所示。可选地，套管 20 可包括彼此相邻布置的分离的腔（未示出），每个腔用于接收阻塞装置 30 和剥离器装置 40 中的一个。除此以外，装置 10' 的结构和操作可以与参照图 1 的装置 10 所描述的结构和操作相似。

[0065] 转到图 7 至图 10，示出了在体腔 50 内移除物质（例如血栓或其它阻塞性物质 52）的示例性方法。体腔 50 可以是例如在相邻动脉与静脉之间连通的患者胳膊内的血管、主动脉 - 静脉瘘、管状移植物、异种移植物等。可选地，本文所述的装置和方法可用于处理患者身体内 的其它位置，例如患者的脉管系统或其它体腔。虽然结合图 7 至图 10 示出并描述

了图 1 所示的装置 10，但是应该意识到的是，本文所述方法可以使用本文所述的任意装置和系统来执行。

[0066] 通常，该方法可涉及捕获扩展的阻塞部件 34 与扩展的笼 44 之间的血栓或其它阻塞性物质，例如，使得该物质可由笼 44 捕获，碎成更小颗粒，在笼 44 内被移除，和 / 或通过套管 20 从体腔 50 抽出。最初，如图 7 所示，套管 20 可例如通过常规方法从进入位置经皮引入到体腔 50 中，并且被操纵以在体腔 50 内定位套管 20 的远端 22，邻近阻塞性物质 52 并且与其间隔。任选地，如果套管 20 包括位于远端 22 上的可扩展部件，例如如图 2A 或 2B 所示的气囊 26、26'，那么在远端 22 被置于体腔 50 内的期望位置之后，可扩展部件（未示出）可以在任意时间扩展，例如以防止套管 20 的随后移动和 / 或基本上密封体腔 50 以防止流体紧邻套管 20 流过。

[0067] 附加地或可选地，例如在将套管 20 的远端 22 引入到体腔 50 中之后的任何时间，可将抽吸应用于套管 20 的腔 24。例如，注射器或真空管线可连接到套管 20 的近端，并且被激活以将基本持续的真空应用到腔 24 以将体腔 50 内的松散物质拉到腔 24 中。

[0068] 然后将阻塞装置 30 从套管 20 引入到体腔 50 中，并且使处于低轮廓结构（未示出）的阻塞部件 34 前进穿过物质 52。例如，阻塞装置 30 可被加载到套管 20 的腔 24 中并且经过套管 20 的长度进入到体腔 50 中，或者阻塞装置 30 可在手术和仅在从套管 20 被部署之前被整合到或预加载到套管 20 中。可选地，阻塞装置 30 的远末端可充分小和 / 或尖锐以自由地穿过物质 52，和 / 或可以是圆的或其它基本上无创伤的以沿着体腔 50 的壁经过物质 52。一旦阻塞部件 34 被定位在物质 52 之外的远侧，那么阻塞部件 34 被扩展到如图 7 所示的高轮廓状态。

[0069] 接下来，参照图 8，剥离器装置 40 可从套管 20 被部署，例如在阻塞装置 30 的轴 32 的上方或邻近阻塞装置 30 的轴 32。可推进剥离器装置 40 直至笼 44（在约束管 48 内维持在收缩形态）布置在物质 52 的与扩展的阻塞部件 34 相反的近侧或者与扩展的阻塞部件 34 相反地邻近物质 52。因此，阻塞性物质 52 的一侧可被阻塞部件 34 限制，并 且其另一侧被剥离器装置 40 限制。一旦笼 44 在体腔 50 内被定位，笼 44 就可在体腔 50 内扩展，例如通过使笼从约束管 48 被部署，于是笼 44 可如图 8 所示弹性径向向外扩展以接触体腔的壁。

[0070] 转向图 9，然后阻塞装置 30 可向近侧朝向笼 44 被收回，以朝向剥离器装置笼 44 拉动体腔 50 内的物质 52 并使其进入剥离器装置笼 44，如图所示。可选地，笼 44 可朝向阻塞装置 30 前进以将物质 52 捕获到笼 44 中，通过阻塞部件 34 防止物质 52 离开笼向远侧移动。如上所述，如果笼 44 包括例如如图 3 所示的倒钩 41，那么倒钩 41 可部分刺入或以其它方式与被捕获到笼 44 内的物质 52 接合，例如以防止物质 52 相对于笼 44 移动。

[0071] 任选地，阻塞装置 30 和 / 或剥离器装置 40 可包括锁定机构，例如一个或多个协作制动装置、凸片或其它特征（未示出），当阻塞装置 30 已经被放置在距笼 44 预定距离的位置处（例如如图 9 所示，基本上邻近笼 44 使得阻塞装置 30 基本上封住笼 44 内的阻塞性物质 52）时，锁定机构可基本上相对于笼 44 固定阻塞装置 30。可选地，锁定机构可设置在装置 10 的近端上，例如在握柄（未示出）上，该锁定机构可被锁定和解锁以选择性地相对于笼 44 固定阻塞装置 30。随着锁定机构的接合，阻塞装置 30 可以不被引导向远侧远离笼 44，例如使得阻塞装置 30 的随后运动与笼 44 的运动连接在一起。

[0072] 转向图 10，然后剥离器装置笼 44 和扩展的阻塞部件 34 可向近侧朝向套管 20 被引

导，例如，直至笼 44 进入约束管 48。如果在此之前没有应用真空，那么真空源可被激活以将体腔 50 内释放的物质抽吸到套管 24 的腔 24 中，如图所示。当笼 44 被拉回到约束管 48 时，笼 44 可径向向内被压缩，由此迫使物质 52 的一个或多个部分穿过笼 44 的孔 46。通过孔 46 露出的物质 52 的一个或多个部分可被削切，例如通过约束管 48 的锋利的远端边缘 47、47'（未示出，见图 4A 和图 4B）被削切，以在体腔 50 内使物质 52 碎成很多更小的颗粒 53。松散颗粒 53 可以从体腔 50 例如通过抽吸穿过套管腔 24 被移除，如图所示。注意的是，减小的颗粒尺寸可随着笼 44 中孔 46 的尺寸而变化。因此，可选择笼孔 46 的尺寸，以将物质 52 的颗粒尺寸减小至所需的最大横 截面，例如使得减小的直径的颗粒 53 可以可靠地通过套管 20 被移除，而基本上不存在堵塞套管腔 24 的风险。

[0073] 在一个实施方式中，当笼 44 撤回到约束管 48 中（在约束管 48 中笼 44 的内部空间最小）时，笼 44 可被压缩至收缩形态，从而通过笼 44 的孔 46 挤压基本上所有被捕获的物质 52。然后将挤压和 / 或削切的颗粒 53 抽吸到套管 20 的腔 24 中。可选地，笼 44 可在收缩形态中具有充足的内部空间，使得当笼 44 完全撤回到约束管 48 中时，至少一些被捕获的物质可留在笼 44 内。

[0074] 随着笼 44 完全撤回到约束管 48 中，剥离器装置 40 和阻塞装置 30 可撤回到套管 20 中，并且装置 10 从患者身体被移除。可选地，阻塞装置 30 可被收缩并且使阻塞装置 30 前进穿过体腔 50 内阻塞性物质的另一部分（未示出）。在这个可选实施方式中，然后可例如通过重复上述步骤重新部署剥离器装置 40 以捕获并移除物质。可选地，如果需要，整个装置 10 可被引入到另一体腔（未示出）内，并且阻塞装置 30 和剥离器装置 40 被重新部署以捕获和 / 或移除患者身体的其它区域中的阻塞性物质。

[0075] 一旦足够的物质已经被移除，那么阻塞装置 30 的阻塞部件 34 可被收缩，并且阻塞装置 30 可撤回到剥离器装置 40 中，或者如果剥离器装置 40 已经撤回到套管 20 中，那么阻塞装置 30 可撤回到套管 20 中。套管 20 内的抽吸可以是不连续的，套管 20 上的可扩展部件可被收缩（如果设置在套管 20 上），并且套管 20 可从体腔 50 撤出。

[0076] 转向图 11A 至图 13，示出了剥离器笼 144 的另一实施方式，其可包括在本文所描述的任意装置和 / 或系统中。通常，剥离器笼 144 包括闭合的近端或第一端 144a 和开放的远端或第二端 144b，与前面的笼 44 相似。笼 144 可包括在第一端 144a 与第二端 144b 之间和 / 或绕着笼 144 的外周延伸的多个支杆 116、118，由此限定了包括多个孔 146 的圆筒形外壁或其它管状外壁，与前面的笼 44 相似。

[0077] 笼 144 的闭合端 144a 可包括轴环 (collar) 部分 141，其可附接至剥离器装置轴 42（未示出，见例如图 1），而笼 144 开放的远端 143 可包括多个向远侧伸出的元件或远末端 112。例如，图 11A 示出了处 于扩展形态的笼 144，其中，例如由于轴环部分 141 附接至轴（未示出）所以轴环部分 141 保持被压缩，并且笼 144 限定了从闭合端 144a 向开放端 144b 延伸的基本上连续的直径。图 11B 示出了处于压缩形态的笼 144，例如其中，笼 144 可被约束或以其它方式压缩在轴的周围和 / 或在约束管（也未示出）内。

[0078] 与图 1 的笼 44 不同，如在图 12A 和图 12B 中最佳见到的，笼 144 包括至少两种不同类型的支杆 116，118。例如，笼 144 可包括多个较厚的支杆 116，其沿着笼 144 的长度基本连续地延伸，例如在第一端 144a 与第二端 144b 之间的第一螺旋结构中。此外，笼 144 可包括多个较薄的支杆 118，其可与相邻的厚支杆 116 连接在一起。如图所示，与厚支杆 116

不同，薄支杆 118 不是基本连续的，而是可以不连续模式螺旋地和 / 或圆周地围绕笼 44 延伸。任选地，薄支杆 118 还可具有弯曲或其它特征，例如相对变薄或穿孔的部分，这允许薄支杆 118 与厚支杆 116 相比相对容易弯曲。孔 146 可由厚支杆 116 与薄支杆 118 之间的间隔限定，从而限定了笼 144 所需的孔隙尺寸。可通过与前面所述的材料和方法相似的材料和方法来形成笼 144。

[0079] 笼 144 的开放端 144b 上的远末端 112 可以为笼 144 提供基本无损伤的远端，例如以防止刺穿其内部署有笼 144 的体腔的壁或对其造成其它伤害。附加地或可选地，远末端 112 可以足够的柔韧以允许远末端 112 在使用过程中螺旋地扭转和 / 或彼此互锁。图 15A 至图 15C 示出了远末端的可选结构，可在笼 144 上设置远末端，例如以便于与体腔内的阻塞性物质接合和 / 或移除体腔内的阻塞性物质。例如，图 15A 示出了远末端 112a 的示例性实施方式，远末端 112a 包括具有平滑前缘 125 的基本直的结构。

[0080] 可选地，图 15B 示出了远末端 112b 的另一示例性实施方式，远末端 112b 包括沿着远末端 112b 的长度间隔分布的一系列槽或凹口 126，例如其可允许远末端 112b 互相缠绕和 / 或与捕获的或通过远末端 112b 以其它方式接合的阻塞性物质缠绕，以便于移除，如下面参照图 16A 至 16H 的进一步描述。例如，当笼 144 旋转时，远末端 112b 和阻塞性物质可缠绕在一起，例如使得其它远末端 112b 和 / 或阻塞性物 质的一个或多个部分可进入槽 126，并且远末端 112b 彼此互锁。图 15C 示出了远末端 112c 的又一示例性实施方式，远末端 112c 包括蜿蜒的样式 (pattern)127。在这个实施方式中，蜿蜒的样式 127 的内弯部 128 可提供使远末端 112c 和 / 或阻塞性物质可缠绕在一起的多个区域，例如与图 15A 的远末端 112a 中所示的提供平滑边缘 125 相比。

[0081] 图 11A 至图 13 中所示的笼 144 的一个优势是，笼 144 可便于部署笼 144 和 / 或使笼 144 前进进入或穿过体腔内的阻塞性物质。与此相反，图 1 中所示的笼 44 一旦在体腔内被部署则通常保持静止，例如，而阻塞装置 40 被收回以将阻塞性物质收到笼 44 中。例如，图 11A 至图 13 的笼 144 可便于将物质 52 拉到笼 144 的开放端 144a 内和 / 或使阻塞性物质与体腔 50 的壁分离。

[0082] 在向远侧前进过程中，笼 144 可例如通过手动或通过连接到装置 10 的握柄（未示出）中的电动机的驱动轴（见例如图 1）同时前进和旋转。这可导致在笼 144 前进时，笼 144 的远末端 112 沿着体腔 50 的内壁例如以螺旋方式行进。当遇到血栓或其它阻塞性物质时，远末端 112 可在物质 52 与体腔 50 的壁之间穿过，从而将物质 50 定位在笼 144 内。

[0083] 笼 144 的远末端 112 可便于分离物质和 / 或将物质捕获到笼 144 内。例如远末端 112 的边缘可提供这样的笼 144 的远侧前缘，即其不是基本光滑的圆柱体，而是限定了起伏的表面。因此，当笼 144 旋转时，笼 144 的远末端 112 可通过重复与物质 52 接触而起到锯的作用，这可增加物质 52 从体腔 50 的壁脱落和 / 或被捕获到笼 144 内的机会。为了进一步确保笼 144 的前缘在不期望物质与体腔 50 的壁之间穿过，远末端 112 和 / 或支杆 116、118 的边缘还可起到沿着体腔 50 的壁削切的刀片的作用以将附着的物质拉到笼 144 中。因此，支杆 116、118 可切割或以其它方式分离体腔 50 与阻塞性物质 52 之间的界面。

[0084] 远末端 112 可被形成使得它们基本符合笼 144 的圆柱形形状，例如虽然可选地远末端 112 可径向向外偏移，但是限定了与扩展的笼 144 的其余部分类似的直径，例如以确保远末端 112 在体腔 50 的壁与阻塞性物质 52 之间穿过和 / 或加强远末端 112 与体腔 50 的

壁的接合。可选 地，远末端 112 可偏移以径向向内延伸，例如相对于装置 10 的中心纵轴横向地向内延伸，例如以防止伤害体腔 50 壁的高风险。

[0085] 此外，支杆 116、118 的不同厚度和 / 或形状可提供这样的笼 144，根据笼 40 的旋转方向，笼 144 以不同方式响应。例如，图 13 中的箭头“A”表示笼 144 旋转的第一方向。如果在这个旋转期间笼 144 与体腔 50 壁（未示出）接触的部分中遇到阻力，那么可能发生扭曲。由于厚支杆 116 具有较高的抗弯曲性而薄支杆 118 容易弯曲，所以扭曲可能不会折弯厚支杆 116，但是可能导致薄支杆 118 弯曲成以在相邻的支杆 116、118 之间限定更大的角度，并且使笼 144 径向向外扩展。这可增加剥离器笼 144（例如，厚支杆 116 的前缘）与体腔 50 的壁之间的接触力，从而可增加从体腔 50 的壁移除阻塞性物质并且将阻塞性物质捕获到笼 144 内的机会。可选地，厚支杆 116 的前缘可包括锋利的边缘或其它特征，这可增强切割或与体腔 50 内附着的物质的其它接合。

[0086] 如果笼 144 在与“A”相反的第二方向旋转，那么由于薄支杆 118 的低断裂强度，扭曲可能导致薄支杆 118 弯曲以减小相邻的支杆 116、118 之间的角度，并且笼 144 可能不会以与第一方向类似的方式径向向外扩展。关于旋转方向的这种各向异性可能是有用的，因为笼 144 可在“A”方向前进和旋转以与阻塞性物质接合并使附着的阻塞性物质与血管壁分离，例如，使物质进入笼 144。扭曲还可引起笼 144 向外扩展以更好地附着或接合血管壁。如果笼 144 遇到过多的阻力，那么笼 144 可沿第二方向旋转，例如以释放阻力而不引起径向扩展。根据薄支杆 118 与厚支杆 116 之间的刚度差，笼 144 在第二方向的旋转还可引起笼 144 径向地收缩以进一步便于释放。

[0087] 转向图 14A 至图 14C，示出了可扩展笼 144 的又一个实施方式，其可包括选择性地打开和 / 或闭合笼 144 的开放远端 143 的促动机构。例如，通过例如使用连接至每个远末端 112 的控制元件（例如，一个或多个线或细丝 114）径向向内收缩远末端 112，可基本上闭合笼 144 的开放远端 143。可选地，单一控制元件（未示出）可穿过每个远末端 112，例如圆周地且连续地穿过多个远末端中的孔（未示出），使得 控制元件上的向近侧的拉力可使远末端 122 折弯或以其它方式径向向内引导远末端 122。任选地，如果需要，可提供锁定机构（未示出）以将远末端 122 固定在闭合的方向。可选地，远末端 122 可彼此互锁，例如如上所述，以将远末端 122 固定在闭合的方向。

[0088] 图 14A 示出了远端 143 开放，笼 144 处于扩展形态，例如控制元件 114 松驰并且远末端 112 偏移至基本上轴向开放的结构。图 14B 示出了远末端 112 弯曲或以其它方式向内朝向闭合形态被引导，例如在向近侧的拉力被施加到控制元件 114 之后。远末端 112 的结构通过提供例如变薄的支杆宽度、变薄的支杆厚度、穿孔部分等（未示出）的一个或多个优选的弯曲特征可有助于这种弯曲，以提供远末端 112 的铰接区域。在可选实施方式中，如图 14C 所示，管状部件 113 可在控制元件 114 上前进以引起远末端 112 径向向内弯曲。

[0089] 图 14B 和图 14C 中所示的闭合结构可允许被捕获到笼 144 内的阻塞性物质被基本上保留在其内，例如，不需要本文其它地方所述的可扩展的阻塞部件 34。在这些可选实施方式中，笼 144 可简单地撤回到约束管或者进入套管（未示出）中，从而径向向内压缩笼 144。当笼被压缩（例如如上所述被抽吸）时，随着远末端 112 的闭合，所捕获的物质不会简单地从笼 144 的远端 143 逃脱，而是保留在笼 144 内通过孔 146 突出（在图 14B 和 14C 中未示出）。可选地，所捕获的物质可以也如上所述随着笼 144 撤回到约束管或套管中。

[0090] 转向图 16A 至图 16H，示出了另一示例性方法，例如通过图 11A 至图 13 所示的笼 144 从血管或其它体腔 150 内移除阻塞性物质。与前述实施方式相似，可经由进入套管和 / 或约束管 148 将笼 144 引入体腔 150。如图 16A 所示，笼 144 已经在体腔 150 内被部署和扩展，使得开放的远端 143 邻近待移除的阻塞性物质 152 布置。一旦笼 144 完全扩展，笼 144 就可在体腔内朝向阻塞性物质 152 前进和旋转。

[0091] 转向图 16B，笼 144 的远端 143 可与物质 152 接合，例如使得远末端 112 在一定程度上在物质 152 与体腔 152 的壁之间穿过，但是当它们与物质 152 缠绕在一起时还可以自由变形。任选地，在笼 144 前进之前，阻塞装置（未示出）可被引导通过物质 152 并且阻塞部件在 物质 152 之外扩展。因此，在笼 144 前进时，阻塞部件可防止物质 152 远离笼 144 向远侧移动。

[0092] 另外参照图 16C，当笼 144 进一步旋转时，远末端 112 可至少部分地绕着物质 152 缠绕或者绕着彼此缠绕，由此在笼 144 与物质 152 之间产生机械接合。然后可将笼 144 的进一步旋转传递至物质 152，这样可引起物质 152 扭转和 / 或以其它方式脱离体腔 150 的壁。在缠绕和进一步旋转之后，被缠绕的物质 152 可完全从体腔 150 的壁移除，如图 16D 所示。

[0093] 如图 16E 所示，与前述实施方式类似，然后可将笼 144 撤回到进入套管和 / 或约束管 148，从而将笼 144 径向向内地压缩至收缩形态。由于笼 144 的远末端 112 基本上是直的并且在它们的远端上是自由的（即，笼 144 在其远端上是开放端并且未附接至芯线），所以当笼 144 撤回到进入套管 20 时，远末端 112 可松开并且物质 152 被释放。因此，如图所示，分离的物质 152 可在体腔 50 内保持松驰。

[0094] 此后，如图 16F 所示，笼 144 可从约束管 148 或套管被重新部署，并且再次通过邻近松散物质 152 布置的开放端 143 扩展。然后例如通过阻塞装置 134 将物质 152 拉入笼 144 的开放端 143，阻塞装置 134 可以是之前在物质 152 之外部署的相同装置，或者是在重新部署笼 144 之前或之后被引入到体腔 150 中且位于物质 152 之外的不同装置。

[0095] 参照图 16G，然后将其内具有捕获的物质 152 的笼 144 撤回到套管 20 或约束管（未示出）中，与前面的实施方式类似。如本文其它地方所讨论的，当笼 144 被压缩时，通过笼 144 的孔 146 突出的任何物质都可被削切或以其它方式分离，例如以确保笼 144 不会在套管 20 的末端被卡住。如图 16H 所示，笼 144 可完全撤回到套管 20 中，并且物质 152 的任何剩余松散颗粒可通过套管腔被抽吸，与前面的实施方式类似。例如，如上所述，可通过套管 20 随时将真空应用到体腔 150 内以抽吸体腔 150 内的松散颗粒，例如当笼 144 使物质与体腔 150 的壁分离时或者在其之后被释放的。这些步骤中的任意步骤都可根据需要重复多次，以移除任何剩余物质。

[0096] 应理解，对于具体实施方式来说，文中的任何实施方式所示的元 件或部件都是示例性的，并且可用于或结合至文中所公开的其它实施方式。

[0097] 虽然本发明可以进行各种修改、和替换形式，但其具体实施例已在附图中示出并在文中详细描述。然而，应理解，本发明并不限制于所公开的具体形式或方法，相反，本发明包括落入所附权利要求范围内的所有修改、等同和替代。

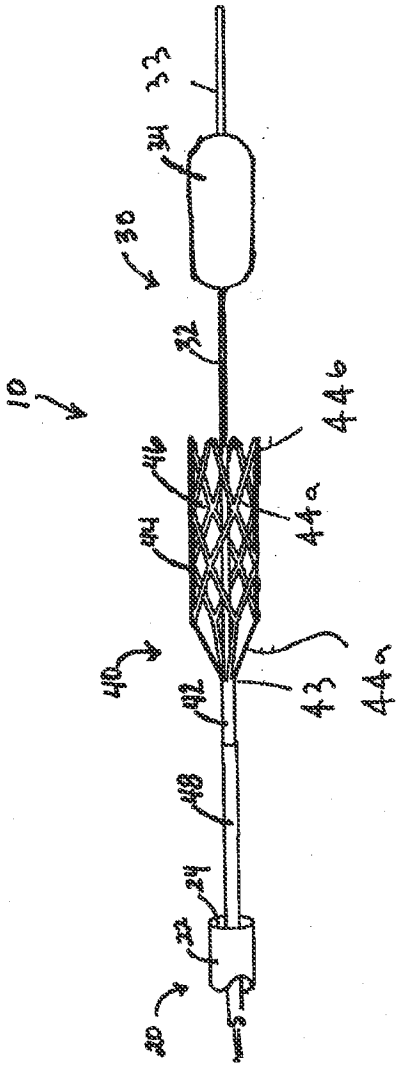

10
32
34
30
22
46
46a
46b
44
44a
40
42
43
44c
48
24
22
20

图 1

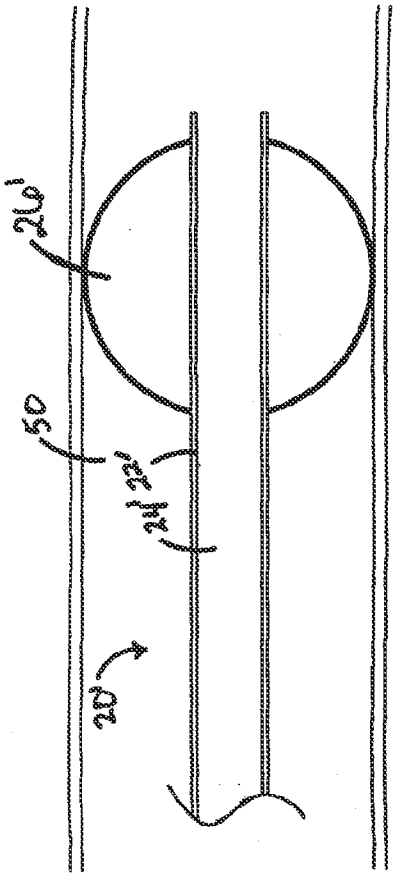

210'
50
24'
22'
20'

图 2A

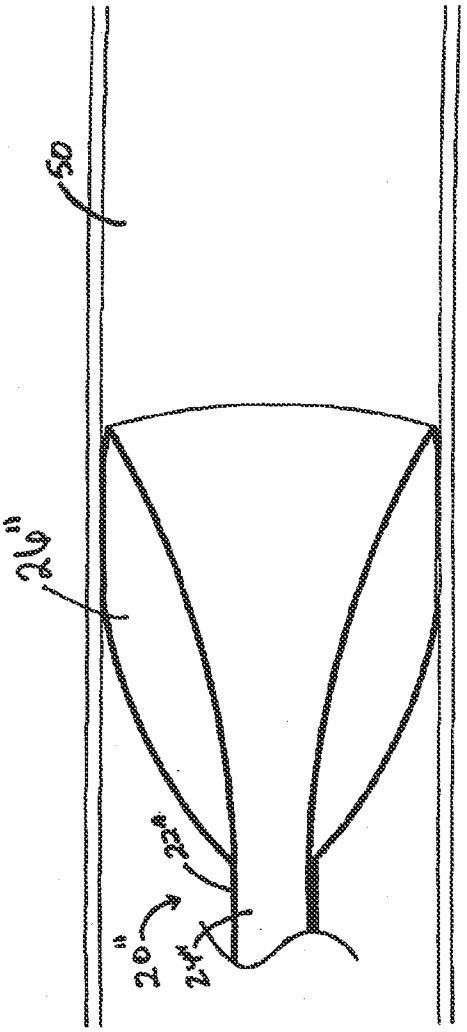


图 2B

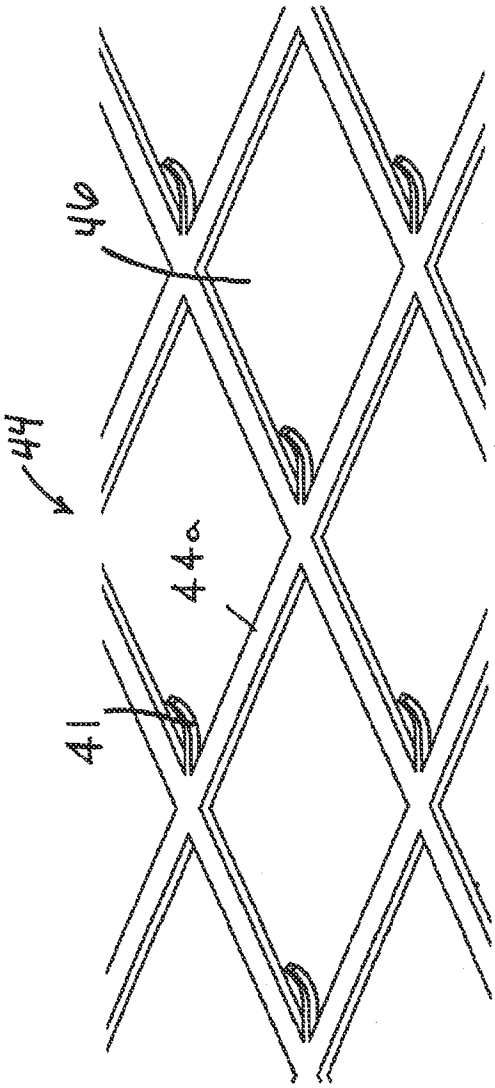


图 3

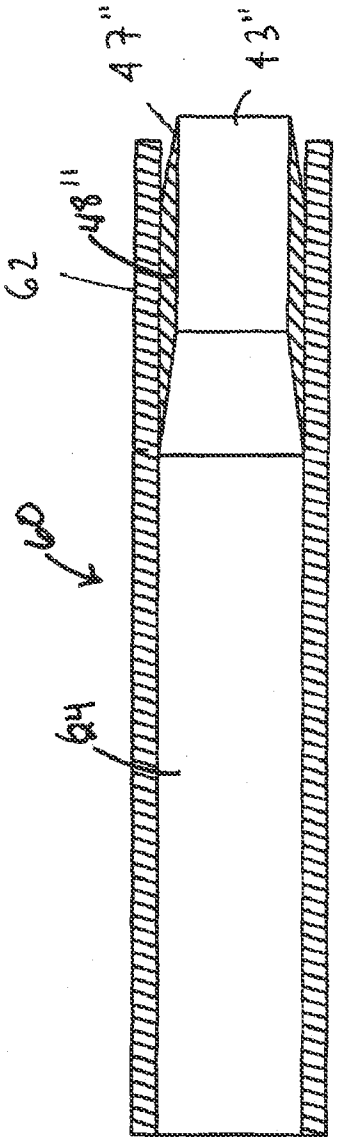


图 5

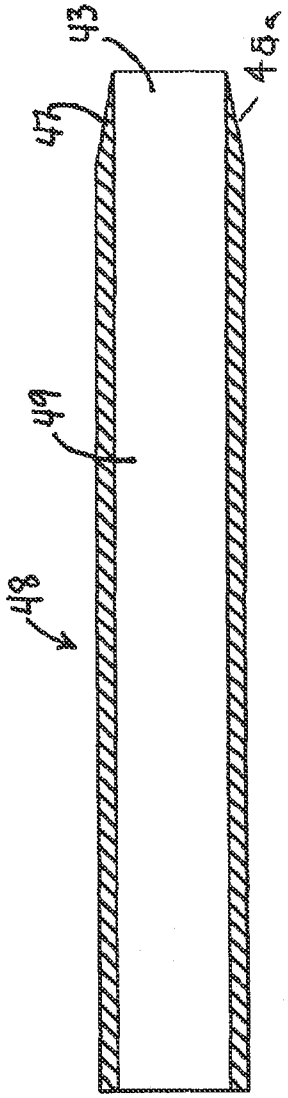


图 4A

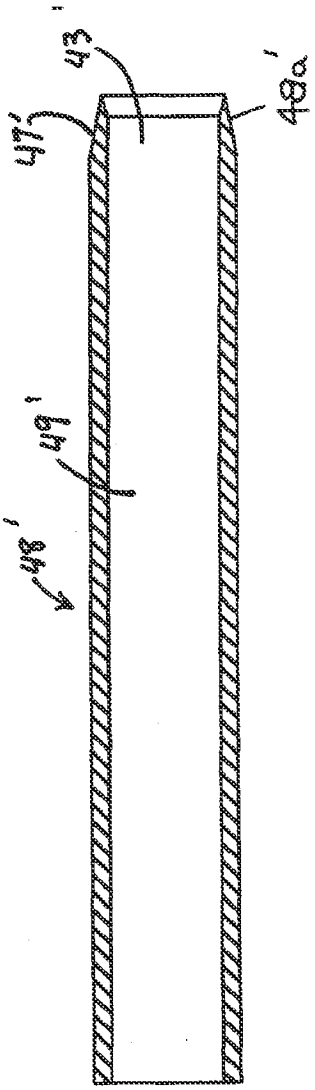


图 4B

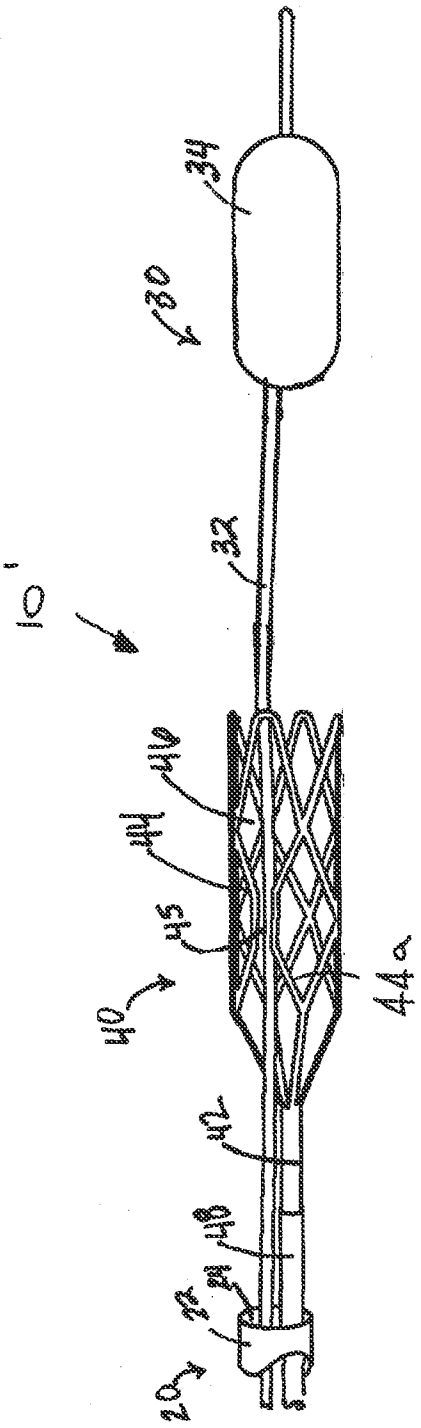


图 6

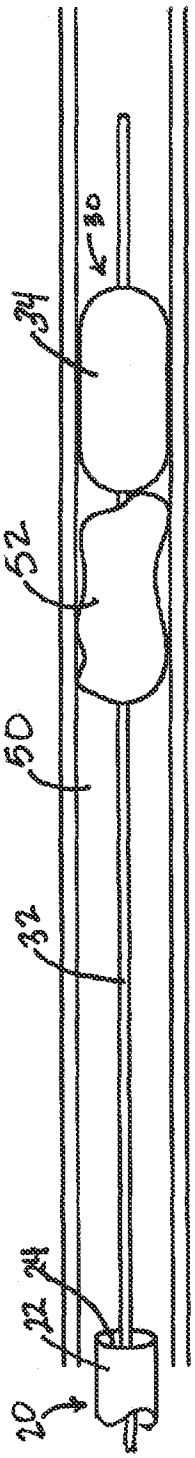


图 7

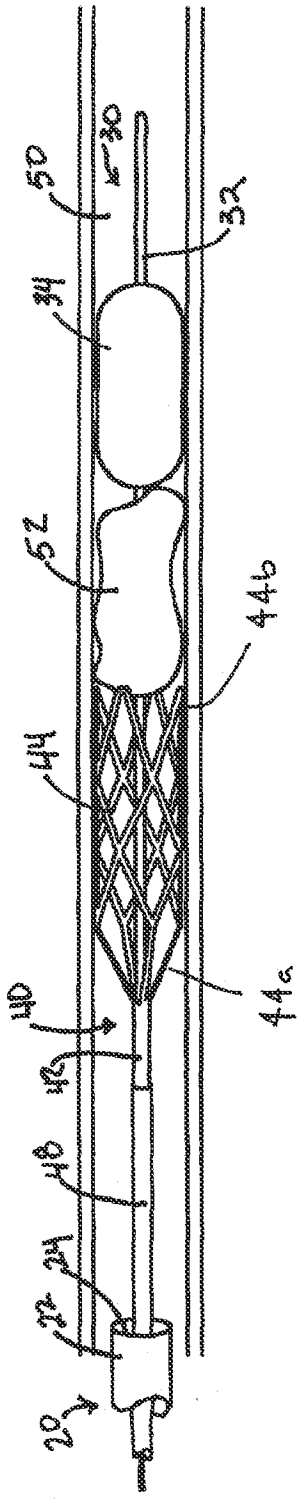

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图 8

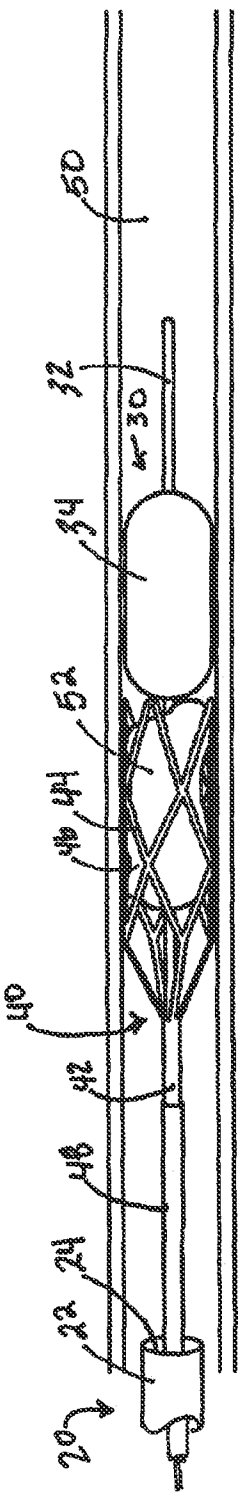
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图 9

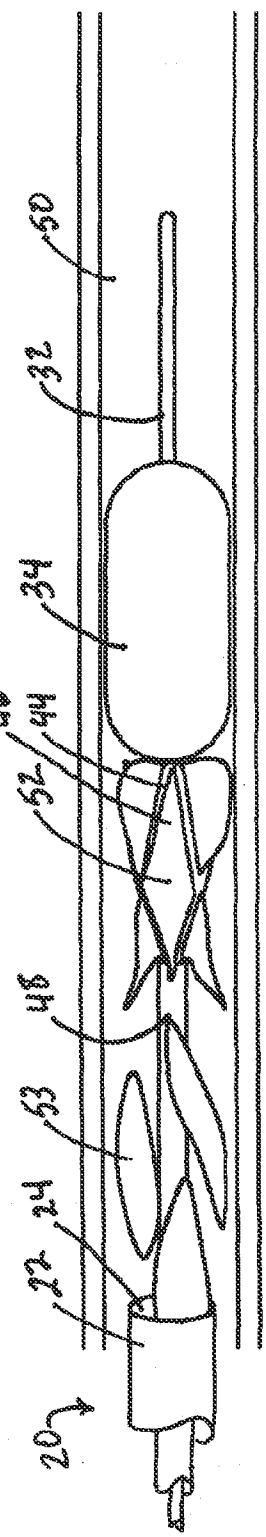
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图 10

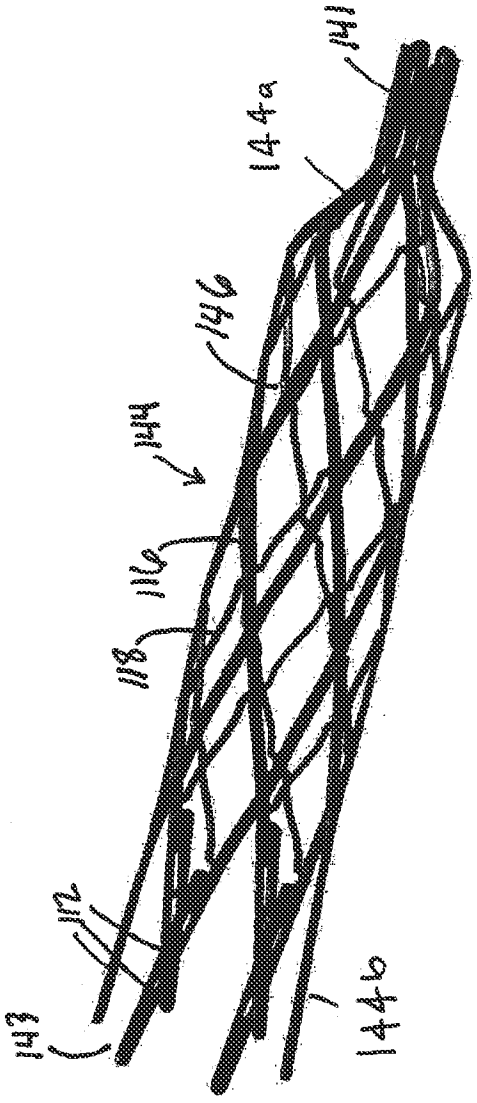
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图 11A

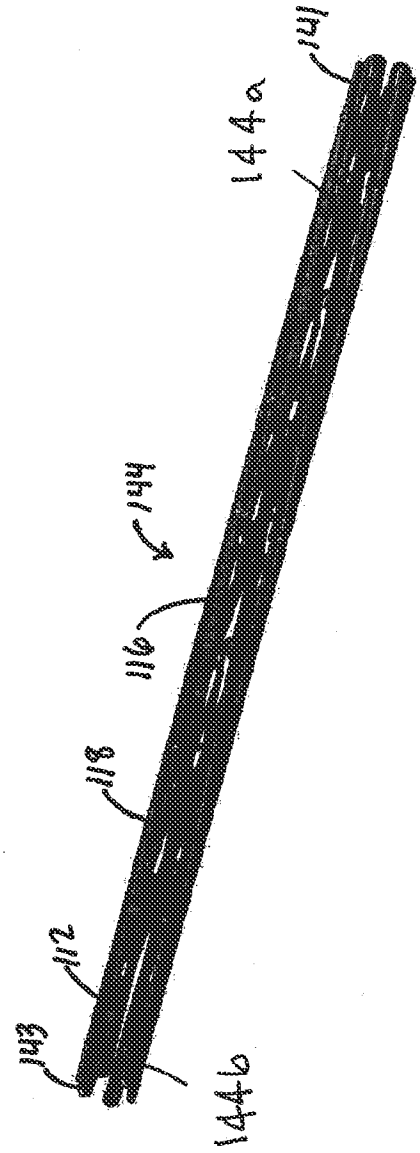
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图 11B

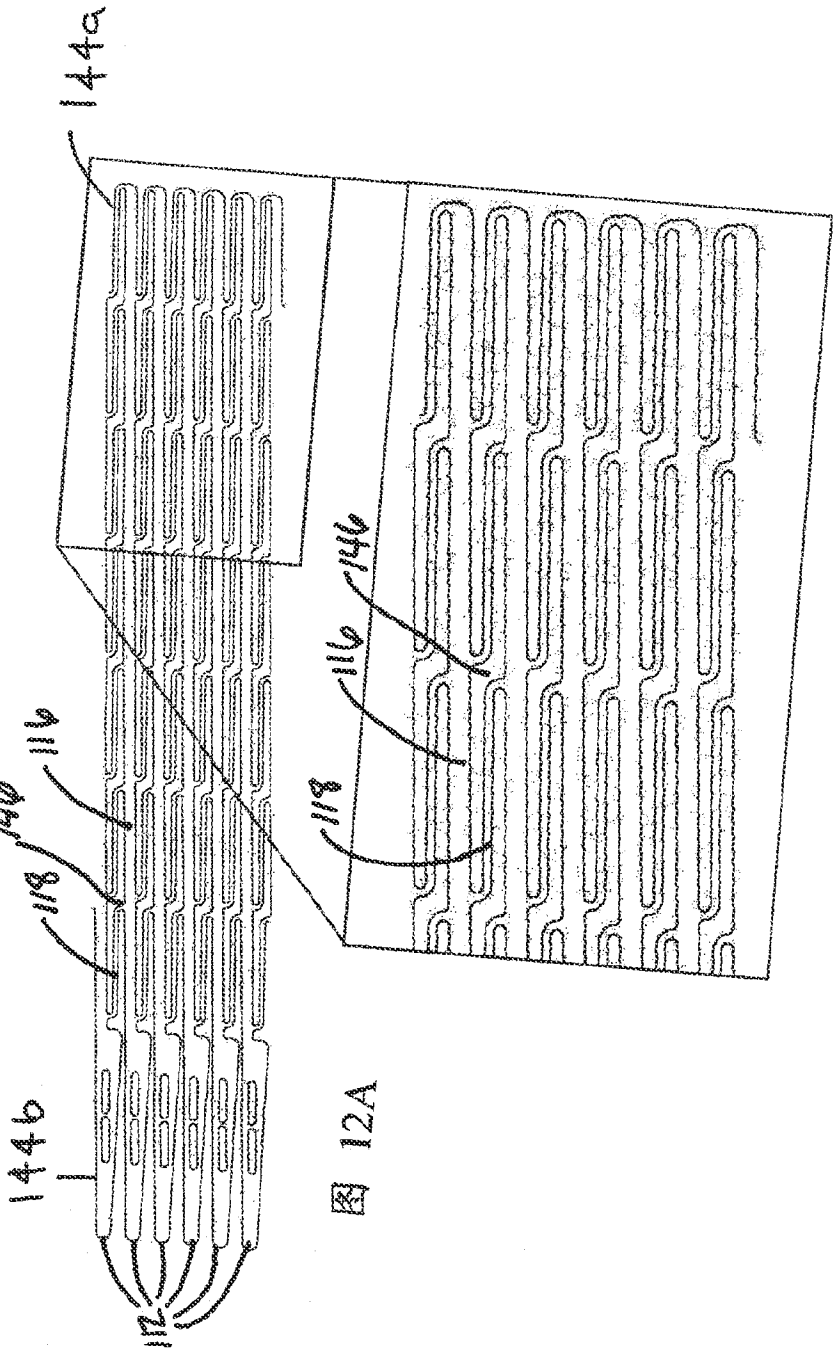


图 12A

图 12B

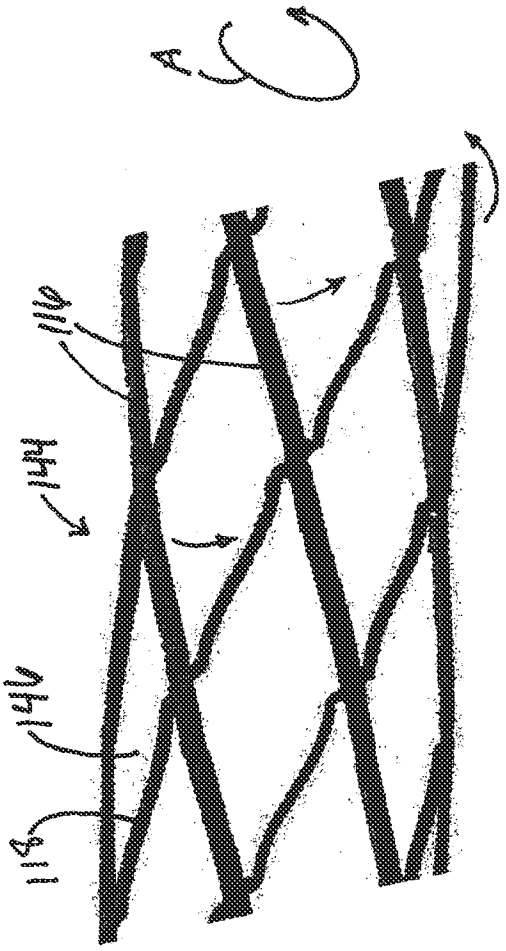
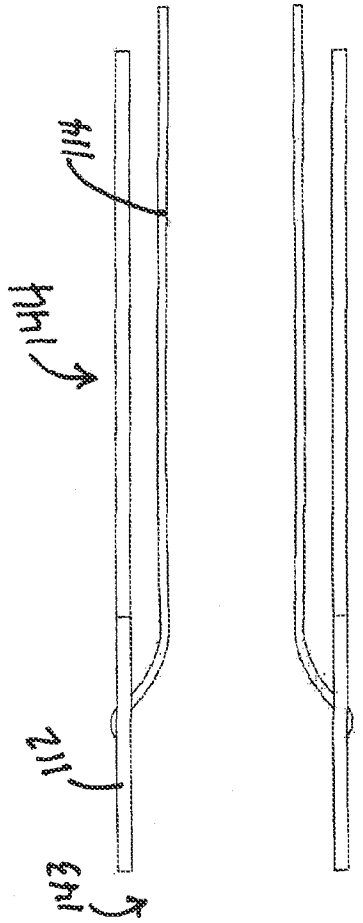


图 13



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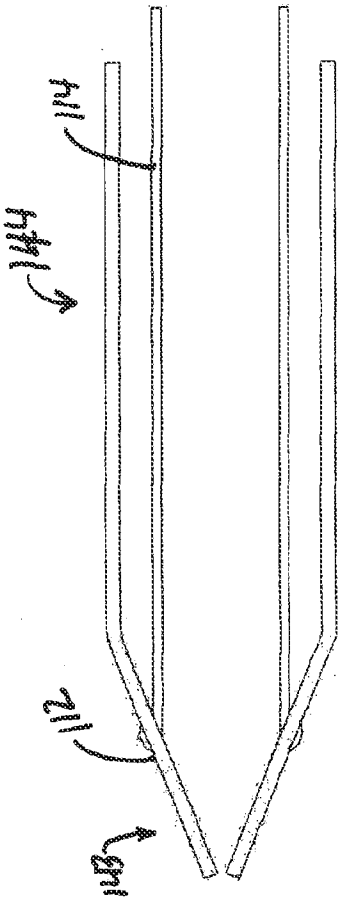


图 14B

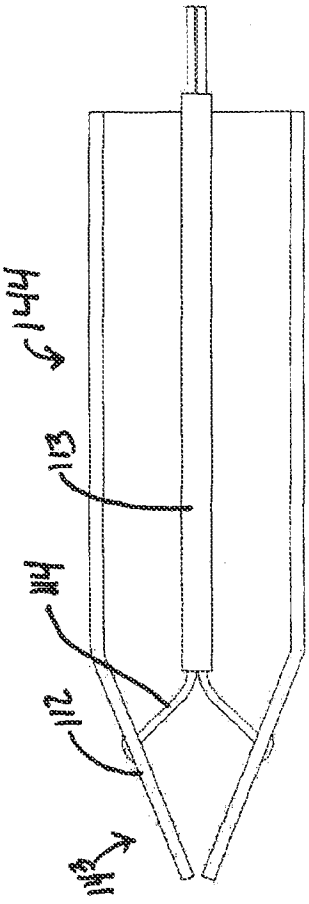


图 14C

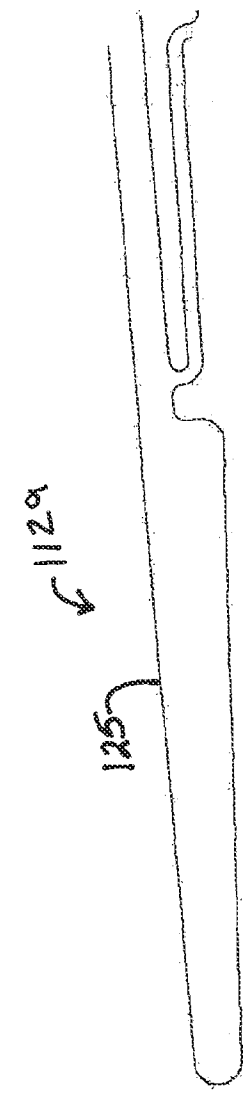


图 15A

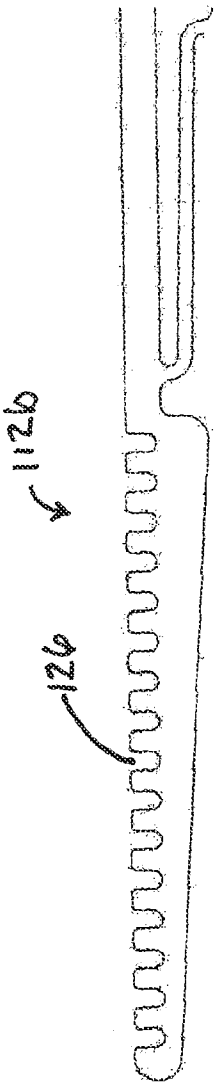


图 15B

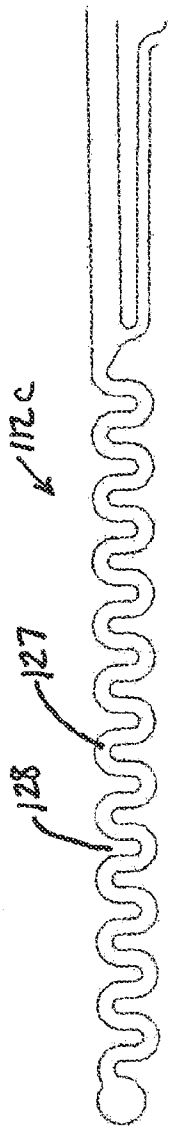


图 15C

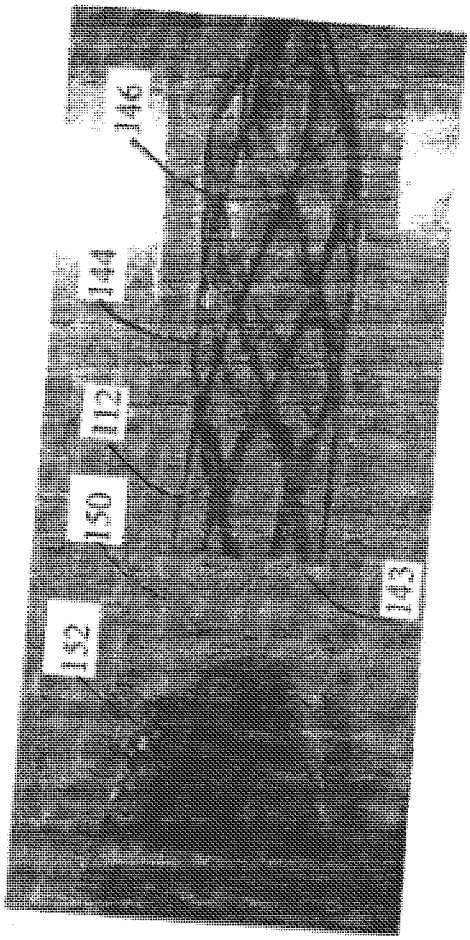
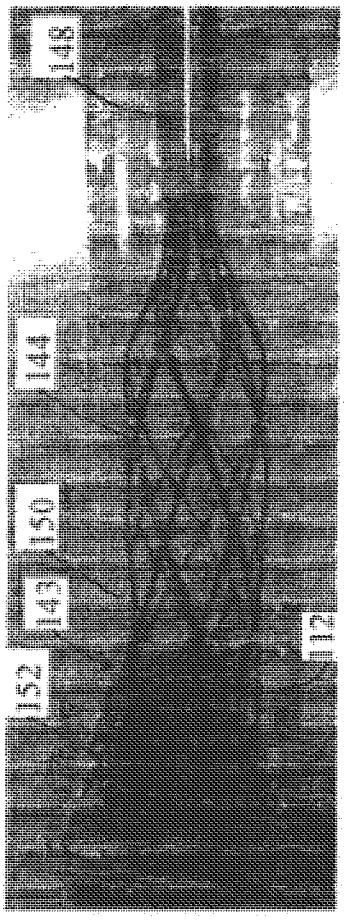


图 16A



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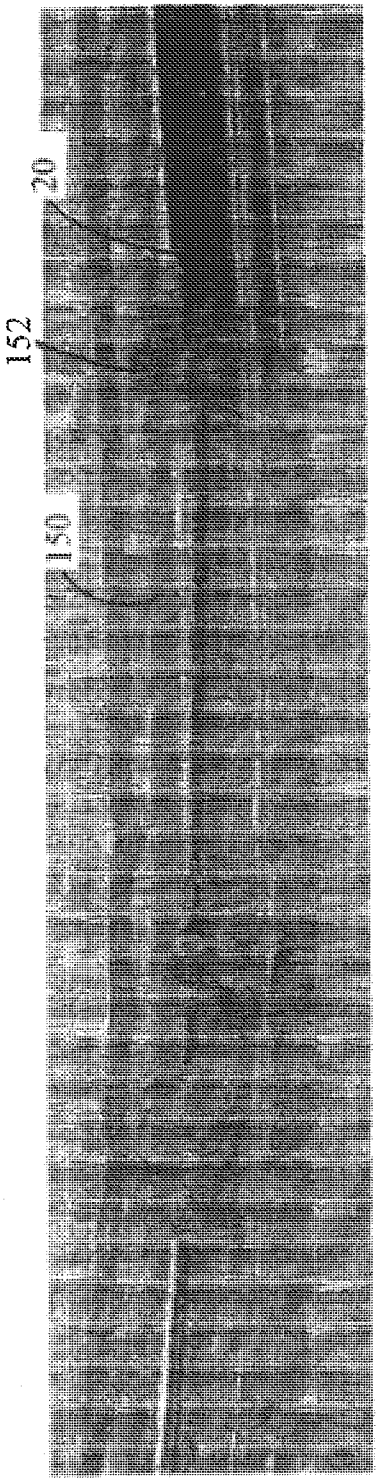

图 16E

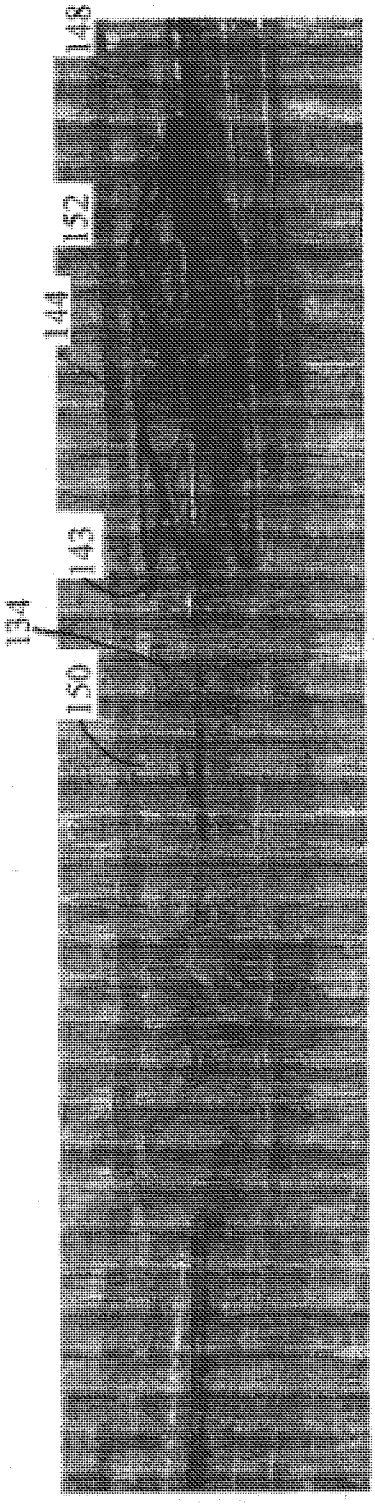

图 16F

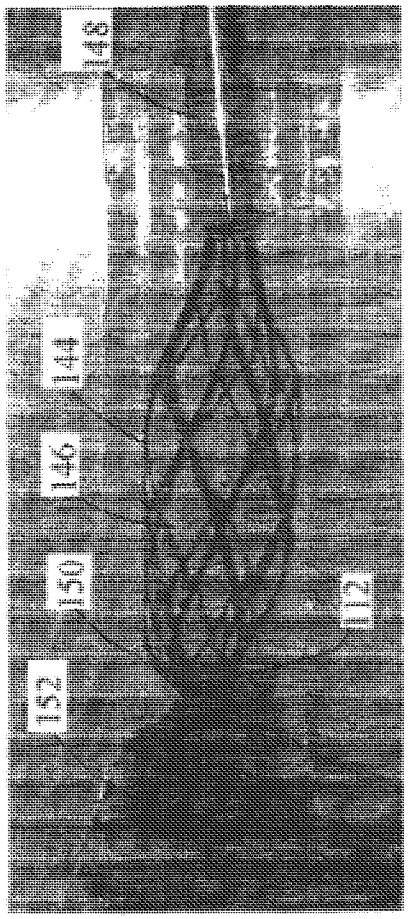

图 16C

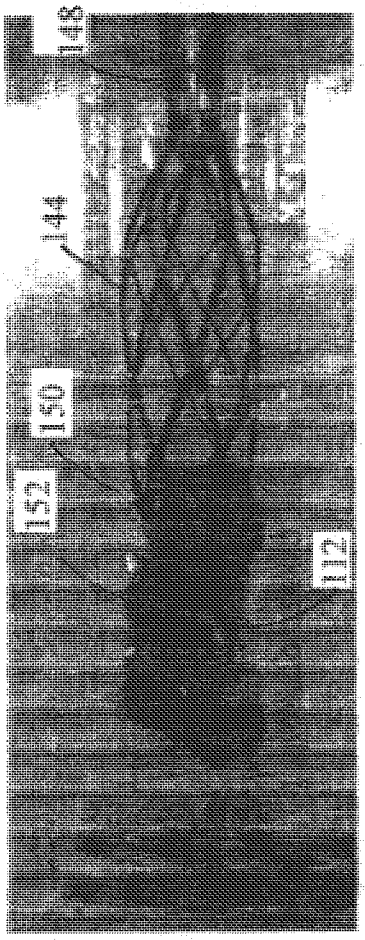

图 16D

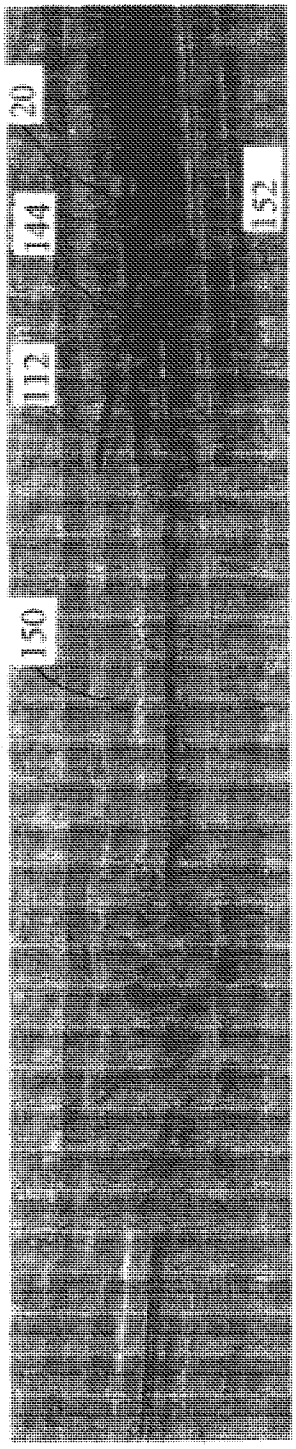

图 16G

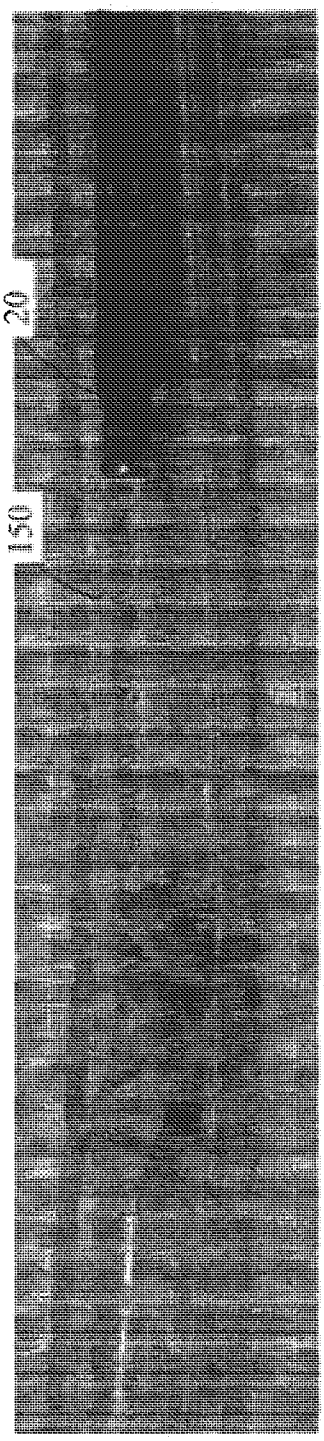

图 16H

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(54) Title: DEVICES FOR REMOVAL OF ACUTE BLOCKAGES FROM BLOOD VESSELS

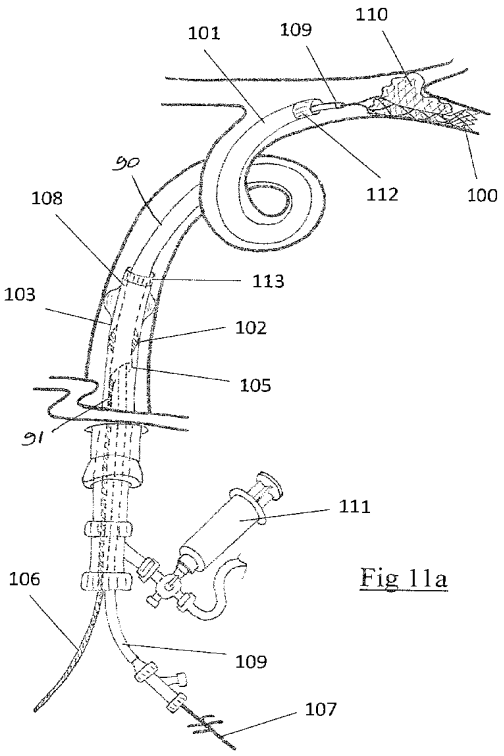

Fig 11a

(57) Abstract: A catheter 101 provides a proximal seal 102 against a guide catheter inner lumen 103 so that aspiration may be applied through a guide catheter 108 and thus take advantage of the large proximal lumen. The catheter 101 is a rapid exchange (RX) catheter with an exit port 105 that defines a transfer port for aspiration and provides a deliverability advantage of minimal frictional engagement with the guide catheter 108 proximal of the exit port 105. Aspiration can be applied to the lumen of the guide catheter 108 and is directed to and effective at the tip of the Rx aspiration catheter 101 due to the presence of flow a restrictor or seal 102 between the outer surface of the Rx aspiration catheter 101 and the inner guide catheter 108. This seals the lumen between the outside of the Rx aspiration catheter 101 and the inner surface of the guide catheter 03 and prevents backflow of blood into the tip of guide catheter 108 reducing the effectiveness of the aspiration. An expansile tip 112 of the Rx catheter 101 facilitates aspiration and retrieval of the clot 110 by expanding under load. The expansile tip 112 can also partially or fully occlude the vessel providing flow arrest and thereby improving aspiration effectiveness.

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DEVICES FOR REMOVAL OF ACUTE BLOCKAGES FROM BLOOD VESSELS

Field of the Invention

This invention relates to devices intended for removing acute blockages from blood vessels. Acute obstructions may include clot, misplaced devices, migrated devices, large emboli and the like. Thromboembolism occurs when part or all of a thrombus breaks away from the blood vessel wall. This clot (now called an embolus) is then carried in the direction of blood flow. An ischemic stroke may result if the clot lodges in the cerebral vasculature. A pulmonary embolism may result if the clot originates in the venous system or in the right side of the heart and lodges in a pulmonary artery or branch thereof. Clots may also develop and block vessels locally without being released in the form of an embolus - this mechanism is common in the formation of coronary blockages. The invention is particularly suited to removing clot from cerebral arteries in patients suffering acute ischemic stroke (AIS), from coronary native or graft vessels in patients suffering from myocardial infarction (MI), and from pulmonary arteries in patients suffering from pulmonary embolism (PE) and from other peripheral arterial and venous vessels in which clot is causing an occlusion.

Summary of Invention

According to the invention there is provided a catheter for assisting in the retrieval of a clot from a vessel comprising a distal end and a proximal end, a distal segment and a proximal segment and a lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment and a flow restrictor located on the outer surface of the catheter distal of the transfer port.

In one case the catheter is an aspiration catheter for aspirating a clot.

In one embodiment the flow restrictor is actuatable between engaged and disengaged configuration. The catheter may comprise an actuator for selectively engaging and/or disengaging the flow restrictor.

In one case the flow restrictor comprises a framework and a membrane coupled to the framework, the framework being movable by the actuator between an expanded configuration and a retracted configuration.

The aspiration catheter may comprise a proximal flow restrictor proximate the proximal end of the distal segment and a distal flow restrictor spaced distally from the proximal flow restrictor.

In one case the distal end of the catheter comprises a mouth for reception of clot. The mouth may be defined by an expansile tip.

In one embodiment the distal segment includes a hinge adjacent to the distal mouth. The hinge may be defined by a region of the distal segment which is configured to have lateral flexibility.

In one case the mouth has an expanded configuration and a retracted configuration. The catheter may comprise a control member for controlling the movement of the mouth between the expanded and retracted configurations.

In one embodiment the mouth comprises a number of segments and the control member is configured to move at least some of the segments. The control member may comprise a draw string or the like.

In another aspect the invention provides a catheter for aspirating a clot in a vessel comprising a distal end and a proximal end, a distal segment and a proximal segment and a lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment wherein the distal end of the catheter comprises a mouth for reception of clot. The mouth may be defined by an expansile tip. In one case the catheter has a flow restrictor located on the outer surface of the catheter distal of the transfer port.

Also provided is a system for treating an occlusion in a vessel the system comprising:-
a first catheter and a second catheter;
the first catheter comprising a proximal end, a distal end and a lumen extending between the proximal end and the distal end, the lumen of the first catheter further comprising a proximal segment and a distal segment;
the second catheter comprising a distal end and a proximal end, a distal segment and a proximal segment, and a lumen, said lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment;
the first catheter being configured to facilitate aspiration through the lumen;

the transfer port being configured to transmit aspiration in the proximal lumen of the first catheter into the lumen of the distal segment of the second catheter and the distal end of the second catheter being configured to receive clot into at least a portion of the lumen of the second catheter.

In one embodiment the system further comprises a flow restrictor between the first catheter and the distal segment of the second catheter, distal of the transfer port. The flow restrictor may be located on the inner surface of the first catheter. Alternatively or additionally the flow restrictor is located on the outer surface of the second catheter.

In one embodiment there is a proximal flow restrictor proximate the proximal end of the distal segment of the second catheter and a distal flow restrictor spaced distally from the proximal flow restrictor.

In one case the distal end of the second catheter comprises a mouth for reception of clot. The mouth may be defined by an expansile tip.

In one embodiment the transfer port comprises a rapid exchange port.

In one case the first catheter is a guide catheter. The second catheter may be an intermediate catheter.

The system may also include a microcatheter which is adapted to be advanced through the first catheter and the second catheter. The system may further comprise a clot engaging device for delivery from the microcatheter.

Also provided is a method of removing a clot from a vessel, the method comprising:-
providing a guide catheter and an intermediate catheter, the intermediate catheter having a distal mouth and being configured such that it is advancable within the lumen of the guide catheter;
inserting the guide catheter into a first vessel proximal of an occlusion;
advancing the intermediate catheter through the lumen of the guide catheter until the tip of the intermediate catheter extends distal of the guide catheter into a second vessel adjacent to the occlusion;

applying aspiration to the proximal end of the guide catheter;

the intermediate catheter being configured to direct said aspiration through the distal lumen of the intermediate catheter to aspirate the clot into the mouth of said intermediate catheter.

The aspiration catheter may comprise a distal end, a proximal end, a distal segment, a proximal segment and a lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment.

In one embodiment the method comprises restricting flow between the outside surface of the intermediate catheter and the inside surface of the guide catheter.

In one embodiment the method comprises the step, before or after aspiration, of delivering a microcatheter to the occlusion and deploying a clot capture device from the microcatheter. The method may comprise advancing the microcatheter to the clot, deploying a clot capture device from the microcatheter, retracting the microcatheter to a location proximal of a transport port at the proximal end of a distal segment of the aspiration catheter.

In a further aspect the invention provides method of removing an occlusion from a vessel comprising:-

providing a first aspiration catheter and a second aspiration catheter, the second aspiration catheter extending distal of the first aspiration catheter and further comprising a transfer lumen proximal of the distal end of the first aspiration catheter;

inserting the first catheter into a first vessel proximal of the occlusion;

advancing the second catheter through the lumen of the first catheter until the tip of the second catheter extends distal of the first catheter into a second vessel and is substantially opposing the occlusion; and

aspirating through the proximal lumen of the first catheter so as to urge the clot into the distal lumen of the second catheter.

The method may comprise restricting flow between the outside surface of the second catheter and the inside surface of the first catheter.

The method may comprise the step, before or after aspiration, of delivering a microcatheter to the occlusion and deploying a clot capture device from the microcatheter. In one case the

method as comprises the step, prior to aspiration, of retracting the microcatheter to a location proximal of the transfer port.

In one embodiment the first aspiration catheter is a guide catheter. In one case the second aspiration catheter is an intermediate catheter.

In one aspect the invention provides a clot receptor device. In one case the device is a catheter which may include rapid exchange features. In one embodiment the device provides a self-expanding aspiration catheter with flow-arrest.

The aspiration assist device has a distal end which expands to seal against the vessel proximal of the clot and provides a large open mouth to receive clot easily without risk of dislodging the clot from the thrombectomy device (if used).

The inner rapid exchange expandable device is delivered through an outer catheter, which may be a conventional intermediate or aspiration catheter or a distal access catheter (DAC). In one case it is a tailored catheter with an extremely trackable distal section for ease of access. This outer catheter trackability is possible because the distal section does not require much axial stiffness, as neither clot not thrombectomy device are retracted directly into it.

The rapid exchange (RX) expanding device may be supplied within the outer catheter (about 15cm proximal of the distal end) and both are delivered together over a microcatheter (or wire) until the outer catheter tip approaches the clot. The inner RX expanding device is advanced to the distal end of the outer, and the outer is then retracted to deploy the self expanding RX device.

The Rx device seals against the vessel wall and against the inner lumen of the outer catheter to allow highly effective aspiration, and its distal end expands to provide a large opening and reception space to receive the target clot and thrombectomy device (if used).

In another similar embodiment the self expanding aspiration catheter has a full length tubular proximal shaft, rather than a rapid exchange shaft, so that it does not require a proximal seal and aspiration can be applied by applying a vacuum force to its proximal hub.

The invention also provides a rapid exchange aspiration catheter.

The catheter provides a proximal seal against guide catheter inner lumen so that aspiration may be applied through the guide taking advantage of the large proximal lumen.

The catheter having deliverability advantages of minimal frictional engagement with guide or microcatheter proximal of exit port.

Retracting the microcatheter just proximal of exit port (rather than completely removing it) creates a large aspiration advantage.

Also provided is a removable microcatheter hub that enables physician to advance a DAC over the microcatheter after the microcatheter (and thrombectomy device) are already in position (as bail, out for example).

Brief Description of the Drawings

Figs. 1 and 2 illustrate a clot receptor device and system according to the invention;
Figs. 3 to 9 illustrate various alternative clot receptors;
Figs. 10 and 11 illustrate a rapid exchange aspiration catheter according to the invention;
Figs. 12 and 13 illustrate various proximal and distal seals;
Figs. 14 to 37 illustrate various alternative distal ends and expansile tips of a clot collector device of the invention;
Fig. 38 illustrates an alternative rapid exchange configuration
Figs. 39 to 46 illustrate a removable microcatheter hub according to the invention;
Figs. 47 to 51 illustrate the creation of the distal segment with a continuous and smooth stiffness profile;
Figs. 52 to 55 illustrate a dual lumen aspiration catheter according to the invention;
Figs. 56 to 59 illustrate a clot receptor device and system according to the invention;
Fig. 60 illustrates a clot receptor device according to the invention;
Figs. 61a-c illustrate a clot receptor device and system according to the invention:
Fig. 62 illustrates a portion of a clot receptor device and system according to the invention;
Fig. 63 illustrates a clot receptor device according to the invention;
Figs. 64a-d illustrate an expansile tip of a clot collector device of the invention and
Fig. 65 illustrates a rapid exchange aspiration catheter according to the invention.

Detailed Description of the Drawings

Fig. 1 illustrates a clot receptor device 2 of this invention being used in the retrieval of a clot 1 from the blood vessel of a patient. The clot receptor device 2 comprises an elongate proximal shaft 13 and a tubular expansile distal section 4. The proximal end 5 of the expansile distal section 4 is configured to seal against the inner lumen of a distal section 6 of a catheter 7 through which it is advanced, while the distal end 8 of the expansile distal section is configured to seal against the wall of the blood vessel. The proximal seal against the lumen of the intermediate catheter 7 enables an aspiration force (such as a vacuum or a negative pressure differential, as may be induced by retracting a syringe plunger or through a vacuum pump) to be transmitted through the intermediate catheter 7 to the clot receptor device 2 and thus to the clot. The low profile proximal shaft 13 of the clot receptor device 2 minimizes the space occupied within the intermediate catheter 7, maximising the effectiveness of the transmission of this vacuum / aspiration force to and trough the clot receptor 2. The seal at the proximal end of the clot receptor 2 may be provided by the expansile body of the clot receptor 2 opposing the lumen of the intermediate catheter 7. Other embodiments of this seal include a soft cuff of a foam or fibre construction, or polymer leafs or leaflets, or a balloon cuff, or a stent-like construction with a membrane cover, or combinations of these or other designs

The distal end 8 of the expansile distal section 4 is configured to open to a larger diameter than the proximal end, typically at least 50% larger, and in some embodiments up to 500% larger or more, depending on the relative size of the target blood vessel and the lumen of the catheter 7 through which the device is advanced. The large open mouth of the distal end 8 of the clot receptor 2 provides an easy path for retraction of clot into its interior space, and once within this space the clot can be safely retrieved from the patient. In one embodiment the inner lumen of the clot receptor device 2 has a profiled surface (like a sharkskin, or backward facing teeth) which allows clot to slide easily into the device, but resist the clot from escaping back out of the device.

Figs 2a to 2f illustrate a typical method of use of such a device and system. The method may include at least some of the following steps: Accessing an arterial blood vessel of a patient using conventional means such as an introducer 10 and guide catheter or sheath 11, advancing a microcatheter 12 up to and across a target occlusive clot with the aid of a guidewire 17, removing the guidewire 17 and advancing a mechanical thrombectomy device 15 such as a stent-retriever through the microcatheter 12 to the target clot 1, retracting the microcatheter 12 at least a few cm to deploy a mechanical thrombectomy device 15 within the clot 1, advancing an

intermediate catheter 7 containing the clot receptor device 2 up to a position just proximal of the clot 1 (or within the clot, or considerably proximal of the clot if vessel disease or tortuosity makes access difficult), advancing the clot receptor device 2 up the distal end of the intermediate catheter 7 (or up to and out of the catheter and into or over the clot), retracting the intermediate catheter 7 a short distance to deploy the clot receptor device 2, aspirating through the intermediate catheter 7 using a syringe or pump to suck blood and the target clot into the clot receptor device 2, withdrawing the mechanical thrombectomy device 15 into the clot receptor 2 while continuing to aspirate, withdrawing the clot receptor device 2 and its contents at least partially into the lumen of the intermediate catheter 7, withdrawing the intermediate catheter 7, clot receptor device 2, clot and mechanical thrombectomy device 15 through the guide or sheath 11 and out of the patient.

Many variants of this method are possible.

For example it may be desirable to withdraw the clot 1 and mechanical thrombectomy device 15 through the clot receptor 2, intermediate catheter 7 and guide 11 and out of the patient while leaving the intermediate catheter 7 and clot receptor 2 in place. This allows the physician to retain a protective seal in the vessel to prevent the escape of any clot particles that may be dislodged, and also preserves a means of quick and easy access back to the target site with a microcatheter and thrombectomy device in case additional passes are needed to completely clear the vessel.

Another method variant involves removing the clot receptor device 2 and thrombectomy device 15 together through the intermediate catheter 7, leaving the intermediate catheter 7 in place for easy re-access to the target site.

Yet another method variant involves using the clot receptor device 2 as the primary clot retrieval tool, without the aid of a mechanical thrombectomy device such as a stent-retriever. The clot receptor 2 is configured to expand and seal against the vessel wall adjacent the proximal end of the clot, thus aspirating through the intermediate catheter 7 and clot receptor 2 provides a highly effective suction force to draw the clot into the clot receptor 2. If the clot passes through the clot receptor 2 and into the intermediate catheter 7 it may be aspirated through the intermediate catheter 7 and right out of the patient. If the clot is too large or too firm to pass through the clot receptor 2 then the clot receptor 2 may be withdrawn into the intermediate catheter 7. Because

the clot receptor 2 has a smooth and funnel shaped exterior it can be easily retracted into the intermediate catheter 7 even when containing a bulky and/or firm clot.

The distal end 8 of the clot receptor device 2 is intended to open up upon exiting the catheter through which it is delivered to provide a large open mouth approximately equal in size to the inner diameter of the vessel in which it is located and provide a seal against this vessel or significant flow restriction such that when a suction force is applied through the clot receptor 2 this force causes blood and clot distal of the receptor 2 to flow into the receptor 2 rather than blood proximal of the receptor 2. This flow occurs because the pressure inside the clot receptor 2 is lower than that outside (distal and proximal) of the clot receptor 2. If the seal were not present two flow paths into the clot receptor 2 would exist and the less restricted proximal flow path would dominate, reducing the effectiveness of the clot retraction.

In order to adequately seal against the vessel wall the clot receptor 2 should have either a) a high radial force or hoop strength so that the pressure gradient created by the application of suction/aspiration does not collapse the clot receptor or create a flow path past it or b) a seal construction such that the presence of a pressure gradient across the clot receptor 2 serves to tighten the seal rather than reduce it. The geometry and construction of the clot receptor sealing end should be such that it can conform well to the vessel wall, which may be not be effectively circular (such as when close to bifurcations for example, or when inclined at an angle to the vessel wall).

Thus one embodiment of the distal portion of a clot receptor may comprise a self-expanding frame with a relatively non-porous cover, such that the cover prevents any significant passage of blood through the wall of the clot receptor, and the self expanding frame has sufficient radial or hoop strength to resist the pressure gradient created by the application of suction/aspiration. The cover may be a polymeric membrane, or may be a woven or braided or knitted structure. In one embodiment the membrane is a polymer membrane, preferably with a high elastic strain limit and a low modulus to permit its expansion by a low radial force frame structure. A preferred membrane is a polyurethane membrane, which might be extruded or blow moulded or ideally dip coated directly onto the frame. The membrane may be coated with a low friction coating such as a hydrophobic silicone or a hydrophilic material. In one embodiment the membrane is a hydrophilic material itself, comprising a hydrogel with sufficient thickness and modulus to retain its structure under the force of aspiration. Other suitable materials for this cover include PTFE,

ETFE and PFA. Materials such as PET, UHMWPE, PET and PEN would be particularly suitable for use in the making of a cover that is woven, braided, knitted or otherwise formed from fibres

Another embodiment of the distal portion of a clot receptor may comprise a combination of a self-expanding frame with a relatively non-porous membrane cover, and a plurality of flexible leaflets or vanes disposed around its outer circumference in a manner similar to that of a leaflet valve. In yet other embodiments the additional seal provided by these flexible leaflets is instead provided by an outer cuff, and this outer cuff may comprise a compressible material such as a foam or a hydrogel or a fibre bundle or a shaped polymer.

In yet another embodiment the expansion of the distal end of the clot receptor may be actuatable by the user, by retraction of a pull wire within the device shaft for example, or by inflation of a balloon cuff.

Some of the various embodiments of the distal end of the clot receptor are illustrated in Figs. 3 to 9.

Fig. 3 depicts one embodiment of the distal end of the clot receptor comprising a stent-like self-expanding frame 25 with an outer membrane covering 27. A proximal shaft 21 is connected to the frame and membrane at a proximal entry port 20. The proximal end 24 of the expansile section is configured to gently appose the wall of a catheter through which it is delivered, while the distal end 23 is configured to expand and appose the vessel wall, creating a large opening 22 into the internal reception space. The frame structure 25 is in one embodiment a Nitinol structure laser cut from a tube or sheet, and in another embodiment is a wire structure, wound or braided from Nitinol or stainless steel or other such biocompatible metallic material as are commonly used in the construction of stents or snares. The membrane 27 may comprise a lip 26 which is folded over and wrapped inside the frame 25.

Figs 4 and 5 depict a typical embodiment of the distal end of the clot receptor. Fig. 4 shows a clot receptor 30 housed in an outer intermediate catheter 31, positioned in a vessel 32. The distal end 35 of the clot receptor is folded to wrap it into a suitable profile to fit into the lumen of the intermediate catheter 31. Fig. 5 shows the deployed clot receptor upon retraction of the intermediate catheter 31, such that distal end 35 has expanded and is contacting the vessel wall 32, and proximal end 34 is sealing against the inner lumen of the intermediate catheter 31. In

another embodiment the distal end 35 expands to a smaller diameter than that of the vessel, but a larger diameter than that of the intermediate catheter.

The intermediate catheter inner lumen may be as small as 0.75mm or as large as 2.0mm, but is preferably between 1.0mm and 1.7mm. The clot receptor distal end may be configured to expand to a diameter equal to or slightly larger than the target vessel in order to provide a seal, or to a diameter slightly smaller than the target vessel in cases where a low profile, deliverable device is a higher priority than a perfect seal. In one embodiment configured for use in middle cerebral arteries of the brain, the clot receptor distal end is configured to expand to a diameter of between 2mm and 4mm. In another embodiment such as might be used in the internal carotid artery, the clot receptor distal end is configured to expand to a diameter of between 4mm and 7mm.

Figs 6a and 6b illustrate the collapsed (for delivery) and expanded forms of the distal end of a clot receptor 40 of this invention. In this case the mechanism of collapse for delivery through an intermediate catheter is a creasing and folding mechanism, similar to that used to wrap angioplasty balloons. The material of the distal expansile end 42 is configured into pleats or folds 41 to wrap it efficiently into delivery form.

Figs 7a and 7b illustrate the collapsed (for delivery) and expanded forms of the distal end of a clot receptor 50 of this invention. In this case the mechanism of collapse for delivery through an intermediate catheter is a rolling mechanism, with an unrolling mechanism taking place for expansion. The distal expansile end 52 exists in its minimum strain state when fully expanded as shown in Fig. 7b. It is configured with a seam 51 running from its distal most end to a point distal of its proximal end. The seam allows the self-expanding clot receptor to be rolled up like a cigarette paper to assume a lower profile shape for delivery.

Figs 8a and 8b illustrate the collapsed (for delivery) and expanded forms of a frame 60 of the distal end of a clot receptor of this invention. This frame may be formed from Nitinol or another material with a sufficient elastic strain limit such that this limit is not exceeded when the device is collapsed for delivery through an intermediate catheter. In one embodiment the frame is laser cut from a Nitinol tube or sheet, and comprises struts 61 connected at crowns 62. The distal end of the frame comprises terminal crowns 63, which may be formed with atraumatic ends of a higher radius of curvature than that used for the more proximal crowns. The frame may be covered with a polymeric membrane as described earlier.

Fig. 9 illustrates the expanded form of a frame 70 of the distal end of a clot receptor of this invention, which is similar to frame 60 of Fig. 8 but is formed from wires 73 rather than cut from a tube or sheet. One advantage of such a structure is that non superelastic materials (such as SS, MP35N or other materials commonly used in the manufacture of balloon expandable stents) can be used in its construction. This is because a much lower strain is induced in the frame in moving from its expanded to collapsed state, because the wires are free to move and slide relative to one another, even at crossover points 72. The wires form crowns 71 of a large and gentle radius at the distal end of the frame, rendering the tip of the device atraumatic to a blood vessel.

Referring to Figs. 10 and 11 there is illustrated an aspiration catheter 101 according to the invention. In Fig. 11a the aspiration catheter 101 is illustrated as part of a clot retrieval system for retrieval of a clot 110. The clot retrieval system further comprises a clot engaging device 100, a microcatheter 109 through which the clot engaging device is delivered and a guide catheter 108 through which the aspiration catheter 100 and microcatheter 109 are delivered. The aspiration catheter 101 comprises a distal segment 90 and a proximal segment 91. The distal segment 90 comprises a distal end provided with a distal tip 112 and a proximal end provided by a transfer port 105. A lumen of the distal segment 90 extends proximal of the distal end 112 and terminates at the transfer port 105. The proximal segment 91 extends from the distal segment 90 and in this case is provided by a proximal shaft 106. A flow restrictor 102 is located on the outer surface of the aspiration catheter 101 distal of the transfer port 105. The aspiration catheter 101 provides a proximal seal 102 against a guide catheter inner lumen 103 so that aspiration may be applied through the guide catheter 108 and thus take advantage of a large proximal lumen.

Fig.10 shows a simplified view of a distal region of the system, illustrating more clearly how the aspiration catheter flow restrictor 102 interacts with the inner lumen of the guide catheter 108. The guide catheter 108 may also have a flow restrictor component such as the inflatable balloon portion 104 shown in this illustration.

The aspiration catheter 101 is a rapid exchange (RX) catheter in which the exit port 105 defines a transfer port for aspiration and provides a deliverability advantage of minimal frictional engagement with the guide catheter 108 proximal of the exit port 105.

In some cases a microcatheter 109 may be provided through which a clot capture device 100 is delivered. Retracting the microcatheter 109 just proximal of the exit port 105 (rather than completely removing it) creates large aspiration advantage.

In one case the microcatheter 109 and the Rx aspiration catheter 101 are introduced together into the guide catheter 108.

The guide wire and microcatheter 109 are then advanced across the clot 110. The guidewire can be removed and a clot retrieval device such as a stent retriever device 100 is introduced.

Using the microcatheter 109 for support, the Rx aspiration catheter 101 can be forwarded to a position proximal to the clot 110 by pushing the proximal shaft 106 or handle into the guide catheter 108. The stentriever device 100 can be deployed by retracting the micro catheter 109.

The Rx aspiration catheter 101 can then be forwarded to contact the clot 110 or be positioned just proximal to or at the proximal face of the clot 110. The microcatheter 109 can then be retracted sufficiently to be proximal of the Rx port 105 of the Rx aspiration catheter 101. This facilitates an increased lumen for aspiration without the necessity of removing the microcatheter 109 fully from the intermediate / aspiration catheter.

Aspiration can be applied to the lumen of the guide catheter 108 with a manual syringe 111 or vacuum pump. This aspiration is directed to and effective at the distal tip 12 of the Rx aspiration catheter 101 due to the presence of the flow restrictor or seal 102 between the outer surface of the Rx aspiration catheter 101 and the inner guide catheter 108. This seals the lumen between the outside of the Rx aspiration catheter 101 and the inner lumen 103 of the guide catheter 108 and prevents backflow of blood into the tip of the guide catheter 108 which would reduce the effectiveness of the aspiration. The seal 102 may not need to stop flow in the lumen completely but needs to restrict flow sufficiently so as not to have a significant effect on aspiration performance. This seal 102 can be generated in a number of ways such as those described in Figs 12 to 13l. In some cases the seal 102 is located on the inside surface of the guide catheter 108 and/or on the outside surface of the aspiration catheter 101.

The Rx aspiration catheter 101 is constructed of a proximal handle (not shown) to facilitate grip and a proximal shaft 106 constructed from a wire or tube formed preferably from Nitinol,

stainless steel, PEEK or some other similar material. An additional seal may be provided on a proximal haemostasis valve to assist in sealing against the proximal shaft 106. The material of the shaft 106 has high compressive and tensile strength and may have a low friction coating or jacket to minimise insertion and retraction forces. The low friction coating or jacket could be formed from PTFE, HDPE or a similar material.

The Rx exit port 105 on the aspiration catheter 101 can facilitate forwarding a microcatheter 109 through the port 105 and through the distal section 90 of the Rx catheter 101 prior to insertion into the guide catheter 108. The Rx exit port 105 may be formed in a funnel shape to make it easier to forward a microcatheter 109 into the port even in position in the guide catheter 108. The port 105 may be formed from a moulded component or from the tubing of the distal section 90 of the catheter 101.

The distal section of the Rx aspiration catheter 101 has good push and trackability characteristics to allow it to be forwarded to the target location. Therefore it may be constructed of one or more materials to give a reducing stiffness profile along the length. A braided wire or coil wire construction or combination of both may be used to improve compressive strength and track ability. Linear wire supports running parallel to the tube axis may also be used.

A top layer of low friction material may be applied to the distal section of the catheter 101 or alternatively a hydrophilic coating or silicon oil coating may be applied to the surface. The inner lining of the distal section of the catheter 101 consists of PTFE or similar low friction material to minimise insertion and retraction forces.

The seal 102 on the outer surface of the Rx aspiration catheter 101 distal section 90 prevents or significantly reduces blood flow travelling from the guide catheter distal tip 113 to the Rx port 105 of the Rx aspiration catheter 101 as shown in Fig. 12a. Various embodiments of proximal seals 102 are illustrated in Figs. 12 to 13l.

In another embodiment of the device shown in Fig. 12b an additional seal 114 is provided on the distal end of the catheter 101 to seal between the Rx catheter and the target vessel. This seal 114 is spaced distally from the proximal flow restrictor 102 and occludes blood flow in the vessel and improves aspiration effectiveness without the need for a balloon guide catheter. The seal 114 can be constructed in a similar manner to those shown in Figs 12a to 13l.

The seal 102 can be formed from an outer sleeve on the catheter which may be smooth or have a grooved or profiled surface 116 as shown in Fig. 13a. Fig. 13j shows a profiled surface with a spiral groove 125. The seal could also be formed from one or more moulded rings with a sealing lip or "O" ring profile 117 as shown in Fig. 13b. It could also be formed from an inflatable balloon 115 which is inflated by injecting saline through a lumen in the shaft and catheter as shown in Figs 12a, 12b and 13g.

In another embodiment illustrated in Fig. 13d the seal 102 can be constructed of fibres in a brush / bristle configuration 119 or from a fibre mesh 123 formed of PET fibres or similar material as shown in Fig. 13h. Similarly the seal could be formed of a sponge material 121 which is compressed when inserted into the lumen of the guide catheter 108 as shown in Fig. 13f.

In a further embodiment the seal 102 could be provided by a body 124 formed from a hydrophilic 124 or similar material which swells and increases in diameter when in contact with saline or blood. The seal 102 may also be formed by having a close tolerance clearance fit between the outer diameter of the distal end of the Rx aspiration catheter 101 and the inner diameter of the guide catheter 103. In another embodiment, the seal 102 is formed from a lip 118 or membrane 120 which restricts flow particularly in one direction as shown in Figs 13c and 13e.

In another embodiment of the seal 102 shown in Figs 13k and 13l, the occlusion between the Rx aspiration catheter 101 and the guide catheter 108 is achieved through longitudinal compression of the aspiration catheter 101. This can be achieved by having an expansile section 127 which increases in diameter when the catheter is under compression. The compression can be a result of retrieving clot 110 and the stentriever device 100 into the tip 112 or may be manually actuated through a pull wire 126. This pull wire 126 may run through a separate lumen from the proximal end of the device as shown in the cross sectional view A-A in Fig. 13l.

The clot 110 and stentriever type device 100 can be fully or partially retrieved into the Rx aspiration catheter 101 as controlled by the physician and depending on the resistance felt by the user or clot obstruction of the lumen as indicated by an increase in vacuum / loss of suction. The expansile tip 112 of the Rx aspiration catheter 101 facilitates aspiration and retrieval of the clot 110 and stentriever device 100 by expanding under load to reduce the retraction force and lessen the risk of scraping clot off the surface of the stentriever device 100. The expansile tip

112 can also partially or fully occlude the vessel providing flow arrest improving aspiration effectiveness.

The expansile tip 112 can be formed in a number of ways and various embodiments are shown in Figs 14 to 37.

In one embodiment the expansile tip 112 can be formed from a co-extrusion of materials with different properties such as a soft expansile polymer 131 co-extruded with a higher modulus polymer 130 to provide longitudinal support. A fully expansile ring 132 could then be connected to this tip as shown in Fig. 14. The tip 112 may also include one or multiple metallic wire supports 133 as shown in Figs 15 and 24. In another embodiment shown in Fig. 18 the tip has a skived profile to increase contact area with the clot during retrieval or aspiration. The tip may be formed with holes 134 or perforations 137 to allow it to split and change shape when a device 100 and clot 110 is retracted into the tip as shown in Figs 16 and 17. These features can be combined with tip constructions containing materials of different durometers such as shown in Figs 16, 17, 18, 21 and 25. In these embodiments the tip materials 143, 136, 146, 151, 164 have a lower durometer and are more expansile than the support materials 135, 144, 145, 150, 165. These support materials may be embedded within the wall of the tubing or may be on the inner or outer surface. They may also be formed in a spline, coil, stripe, 'U' shape or other configuration to provide longitudinal support to the expansile material to prevent it collapsing or buckling under compressive load, such as occurs during retrieval of a clot or stentriever device, or during insertion through a guide or access catheter. Fig. 19 shows another embodiment where multiple holes 139 produce a lattice or framework in the tip. Single or multiple protrusions or "teeth" 141 may also be applied to the inner surface 142 at the distal tip to improve grip on the clot as shown in Fig. 20.

The expansile tip may be pre shaped to form a flared profile (Fig. 22a) or a tapered profile as shown in Fig. 22b. Alternatively the tip shape may be a combination of these profiles such as bulbous or 'pear' shaped as shown in Fig. 23a to 23d. In the configuration shown in Fig. 23a the tip 160 has an increased diameter larger than the proximal catheter diameter 161 which then tapers to a reduced diameter 162 for ease of insertion. In the configuration shown in Fig. 23b the tip 166 has an increased diameter larger than the proximal catheter diameter 161 which then tapers to a reduced diameter 167, however the reduced diameter 167 is still larger than the proximal catheter diameter 161. This tip configuration provides benefits of improved aspiration

effectiveness and reduced retrieval force but also low insertion force and trackability benefits due to the distal tip radius or taper 167. The tip radius 167 also prevents the tip snagging on a bifurcation on insertion, such as at the ostium of the ophthalmic artery in the internal carotid artery. Fig. 23c shows how the tip 160 elongates during insertion through a guide or access catheter 108, while Fig. 23d shows the tip 160 expanding to accommodate the retrieval of a clot 110 and stentriever device 100. The profiled tips can also be constructed using multiple materials of varying durometer and expansile characteristics.

The expansile tip 112 could also be profiled and contain one or more slot cuts 170 to facilitate expansion as shown in Figs 26, 29 and 30. Other embodiments of profiled tips to facilitate expansion and retrieval of the clot 110 and stentriever device 100 are shown in Figs 27 and 28.

In another embodiment of the Rx aspiration catheter tip 112 shown in Fig. 31, the distal end of the tip has a collar 171 which tracks closely over the guidewire. This helps direct the catheter over the guidewire to the target location reducing the risk of snagging. The tip configuration shown in Fig. 32 has a flattened section 173 which contains a large number of aspiration pores 174, and aspiration windows 172. This design potentially increases the contact area with the clot improving grip where the catheter is used without a stentriever device. Fig. 33 shows an end view of Fig. 32 with the arrows indicating the direction of blood flow.

Referring to Figs. 34 to 35 there is illustrated a catheter with an expandable distal end 180, which is expanded by means of a lifebelt shaped annular balloon 181 at or adjacent its distal end. The balloon is inflated by injecting a fluid through an inflation lumen 182 running from the proximal to distal end of the device. The distal end of the catheter has a ring of petals 183 which act as a seal or occluder to limit the volume of blood flowing from proximal of the tip into the catheter, when aspirating through the catheter. The petals 183 may be formed from a polymeric material. Fig. 34a shows the tip in the collapsed configuration and Fig. 34b shows the tip when the annular balloon 181 is inflated. Fig. 35 shows an additional embodiment where the catheter has an Rx construction with the inflation lumen 182 running through the shaft to the proximal end of the device.

In another embodiment of the catheter tip 112, shown in Figs 36a and 36b, the tip 184 is constructed so that it can invert as the stentriever device 100 and clot 110 are retrieved into the

catheter. This can reduce the retraction force and constrain the clot so fragments are not released during the retrieval process. Fig. 36b shows the tip after inversion.

Referring to Figs. 37a and 37b there is illustrated a clot retrieval catheter with a self-expanding distal tip 190 that is constrained by a tapered cap 191 for ease of deliver and atraumatic access to a target site. The cap component 191 can be retracted to allow the catheter mouth 192 to expand, creating a large opening to accept clot or other material into its lumen. The cap component 191 has a distal end whose outer diameter is ideally lower than that of the catheter shaft immediately proximal of the cap, and an inner lumen sized to enable the device to be advanced over a thrombectomy device shaft and microcatheter. The cap component 191 may also comprise a guide tube 193 to aid the device in moving smoothly over a thrombectomy device shaft or microcatheter.

In another embodiment of the device shown in Fig. 38 the distal section of the catheter 194 is shortened so that distance X is typically between 5 and 50 mm long. This device can be forwarded over the shaft of the stentriever device 100 to the target location to facilitate partial or full retrieval of the stentriever 100 into the expansile tip 112. In this embodiment the distal section 194 is forwarded out of the guide catheter 108 and does not translate aspiration to the distal tip 112, but has improved trackability and access performance to reach the target vessels due to reduced friction and pushability of the wire shaft. The short length distal section 194 and tip 112 are connected to a shaft 106 constructed from a wire or tube formed preferably from Nitinol, stainless steel, PEEK or some other similar material. The shaft material has high compressive and tensile strength and has a low friction coating or jacket to minimise insertion and retraction forces. The expansile tip 112 can be constructed in a similar manner to those shown in Figs 14 to 37.

The Rx aspiration catheter 101, microcatheter 109, stentriever device 100 and clot 110 can be retracted as a unit back to the tip of the guide catheter 113 and then fully into the guide catheter 108. The guide or access catheter 108 may also have an expansile tip 113 to facilitate retraction of the devices and clot, with a reduced force and lower risk of dislodging the clot from the devices. This expansile tip 113 on the guide catheter may be constructed in a similar manner to those shown in Figs 14 to 37. Likewise the expansile tip 112 construction and seal 102 construction shown in Figs 12 to 37 may also be applied to a standard length intermediate or aspiration catheter.

The Rx aspiration catheter 101, microcatheter 109, stentriever device 100 and clot 110 can then be retrieved from the guide catheter 108 and removed fully from the patient.

Referring to Figs. 39 to 46 there is illustrated a removable microcatheter hub according to the invention. The removable hub enables a physician to advance an intermediate or access catheter over the microcatheter after the microcatheter (and thrombectomy device) are already in position (as bail out for example). It is not possible with a standard microcatheter to forward an intermediate or access catheter over the proximal end as the fixed hub is in the way, therefore the standard microcatheter has to be removed to introduce an intermediate catheter.

Use of a microcatheter with a removable hub that facilitates the use of an extension wire facilitates improved control on the microcatheter position as the intermediate catheter is introduced.

In Figs. 39 to 46 the following numerals are used:

300 detachable hub
301 microcatheter shaft
302 strain relief element extending from microcatheter hub
303 internal connector (see Figs. 42/43 for detail)
304 end of microcatheter shaft which has detached
305 extendable shaft for intermediate catheter exchange
306 internal thread on microcatheter hub
307 microcatheter connector
308 O-ring seal
309 external thread on microcatheter connector
310 bond
311 closed end to prevent outbleed
312 bond
313a extension wire
313b extension wire housing
314 laser cut hypotube which acts as a core reinforcement for microcatheter
315 stiff proximal shaft so that it can be gripped and pulled/twisted during microcatheter removal

316 compressible O-ring which locks the microcatheter into recess incorporated into moulded catheter hub

317 detachable hub

318 extension tube

319 spring clip – e.g. stainless steel or Nitinol

320 injection moulded hub

D1 0.021 inch ID approx.

D2 0.029 inch OD approx.

D3 0.039 inch OD approx.

D4 0.045 inch OD approx.

Fig. 39 shows the microcatheter hub 300 assembled with the microcatheter shaft 301. Fig. 40 shows the microcatheter shaft after detachment and Fig. 41 shows the mating end of the extendable shaft 305. By connecting the extendable shaft 305 to the microcatheter shaft 301 the working length of the catheter is increased to facilitate forwarding an intermediate or access catheter over the microcatheter while maintaining positional control. The extendable shaft 305 can then be removed and the detachable hub reconnected to the microcatheter.

Fig. 42 illustrates the construction of the microcatheter connector 307 and detachable hub 300. The detachable hub 300 can be screwed onto the microcatheter connector 307 due to thread 309 on the connector and the mating thread 306 on the hub. 'O' ring 308 prevents any blood loss or air ingress between the connector 307 and the hub 300 when tightened.

Fig. 43 shows a section view of an embodiment of the extendable shaft 305 which utilises an extension wire 313a and extension wire hub 313b. The extension wire 313a and hub 313b are shown screwed onto the microcatheter shaft 301and connector 307.

Figs 44 to 46 show another embodiment of a detachable hub where the microcatheter shaft 301 is connected to the detachable hub 317 by a compressible 'O' ring 316. The 'O' ring 316 sits in a groove on the moulded hub 320 which is connected to the microcatheter shaft 301. The 'O' ring is compressed by rotating part of the housing 321 on the detachable hub 317. The extension tube 318 can be pushed over the moulded hub 320 on the microcatheter shaft 301 after the hub 317

has been removed. The extension tube 318 is then held in position by the spring clip 319 engaging with the groove on the moulded hub 320.

Figs. 47 to 50 illustrate a method of manufacture of a large diameter aspiration catheter. The aspiration catheter is highly trackable so that it can be navigated to tortuous/distal cerebrovascular location.

Fig. 47 is a graph of lateral stiffness with distance from the tip.

Fig. 48 illustrated a conventional diagram in which different tubular segments 200, 201, 202, 203, 204 are of different materials. The segments are used to create a stepped material stiffness profile (gradually increasing modulus/share hardness).

Fig. 49 illustrates a distal segment according to the invention in which a smooth stiffness profile is created by blending elements 205, 206 of different modulus. For example, tapered tubes 205, 206 (Figs. 50, 51) may be placed on a mandrel overlapping each other and use heat to cause them to melt and flow into each other. The resultant tube may then be applied to a threaded or spiral wire or unreinforced base, or use as a stand-alone catheter.

Referring to Figs. 52 to 55 there is illustrated a dual lumen aspiration catheter to aid with aspiration and prevent the lumen of the catheter getting blocked with clot.

Lumen A – a smaller diameter lumen can be used to retrieve the device into and cause the clot to shear off. The distal end of *Lumen A* could be flush with or recessed from the distal tip of *Lumen B*.

Lumen B – the larger lumen would have aspiration constantly applied to it, to aspirate the clot that is sheared off the device when it is retrieved into the smaller lumen (*Lumen A*).

The smaller lumen A may have an inner diameter to facilitate the introduction of a microcatheter through the lumen. The microcatheter can then be inserted through this lumen and across the clot as per standard procedure. The stentriever device can then be deployed across the clot. Retrieving the stentriever and clot into the catheter causes the clot to be sheared off the stentriever within the aspiration catheter. This configuration prevents the clot snagging on the

struts of the stentriever device and blocking the aspiration lumen. The larger diameter lumen may have a diameter of about 0.058 inch and may have aspiration applied to it to aspirate the clot as the device is being retrieved into the smaller diameter lumen.

One clot receptor catheter tip according to the invention the clot receptor tip is expanded by means of a balloon, which may be attached to the shaft of a thrombectomy device, or to a microcatheter, or may be integral to the clot receptor catheter itself.

One embodiment of such a device is shown in these Figs 56 to 59. The device comprises a thrombectomy device 400 with an inflation lumen 402 extending from the proximal end of the shaft to a balloon 401 at the distal end of the shaft, and an clot receptor catheter 404 with a flexible expandable distal section 405. The thrombectomy device 400 is expanded in the clot 403. Either the thrombectomy device and clot are then retrieved towards the clot receptor catheter 404 or the clot receptor catheter is advanced towards the thrombectomy device. The balloon 401 at the distal end of the device is positioned so that the distal end is in line with the distal end of an intermediate catheter. The balloon is expanded to plastically deform 406 the distal end of the clot receptor catheter and then deflated. The resultant open mouth 407 of the clot receptor catheter allows the entire device and clot to be retrieved into the intermediate catheter. This prevents loss of clot on retrieval into a small lumen of a conventional intermediate catheter. The expansile distal portion 405 of the clot receptor catheter may be formed of a polymeric material with a low modulus and a high elongation strain to break of greater than 100%, and ideally greater than 300%. It may also comprise a support structure of a metallic material such as stainless steel which can be plastically deformed by the balloon and can then retain its deformed shape with sufficient integrity to accept the thrombectomy device and clot.

The balloon expandable tip of the invention can be applied to any catheter – standard or rapid exchange, and can be used with or without a thrombectomy device to aid in the aspiration and/or retrieval of clot from blood vessels.

Fig. 60 illustrates an RX clot removal catheter 500. This device 500 is very similar in design and in use to that shown in figs 11a-d, except that the element 504 is an actuatable flow restrictor or seal, which can be selectively engaged or disengaged by the operator. The catheter 500 comprises a proximal elongate shaft 501 and a distal generally tubular portion 502. The distal portion 502 comprises reinforcement member 507 and a polymeric cover member 510, and

extends from an entry/exit port 517 to a distal clot reception tip 503. The cover member 510 may comprise multiple layers and segments. A low friction inner layer may be employed as a lining for the lumen of the tubular section, a highly compliant membrane 506 may be employed to cover the actuatable flow restrictor / seal region, and a low modulus polymer may be employed to cover the main tubular body. The distal end or tip 503 may comprise any of the designs shown elsewhere in this document. In a preferred embodiment the tip 503 is connected to the distal end of the tubular portion 502 by a hinge element 511. This hinge element may simply be a short region of the tubular section configured to have a high degree of lateral flexibility relative to the rest of the tubular section. This flexibility may be achieved by having a short region of the tubular section without any reinforcement element 507, or alternatively the reinforcement at that region could be a highly flexible reinforcement such as a generally spiral metallic coil.

The actuatable flow restrictor or seal 504 comprises a framework 508, with a membrane covering 506. The framework 508 is at least partially collapsible by retraction of actuation member 512, which runs through proximal elongate shaft 501 and is connected at its proximal end to slider element 514, which is in turn slidably constrained within handle 513, and coupled to spring element 515. Proximal elongate shaft 501 may comprise a tube of stainless steel, Nitinol or other metallic or high modulus polymeric material, and may contain a liner in order to provide a low friction internal surface against which the actuation member 512 may slide. The shaft 501 may be tapered or may be slotted in order to provide a smooth transition in stiffness over its length. In the embodiment shown a portion of the shaft material has been removed from the distal portion 516 of shaft 501 in order to provide an exit port for actuation member 512 and to provide a connection member to the proximal end of tubular portion 502. This distal portion 516 may also be flattened, which may assist in creating a similar curvature to that of the tubular portion 502 so that the two portions can be smoothly joined together by welding, soldering, bonding or other appropriate method of fixation. The main body of the shaft may also have an oval or somewhat flattened profile, as this may be beneficial in allowing the user to seal a haemostasis valve around the shaft and a microcatheter when the two are side by side in the guide/sheath as shown previously in Fig. 11a.

The reinforcement member 507 may be formed from a metal (such as stainless steel or Nitinol or MP35N or other suitable alloy) or from a high modulus polymer material. In one embodiment (as shown) the reinforcent is formed from a tube from which sections 509 have been cut away to add lateral flexibility while maintaining column and hoop strength.

In the catheter illustrated in Fig. 60 the actuatable seal 504 is located adjacent to the proximal end of the distal tubular section, where it also forms the exit/entry port to the proximal end of the distal tubular section 502, but it could be positioned more distally in other variants of the invention. Once the catheter has been advanced to a position proximal of or adjacent the target clot the seal can be actuated to effect a seal between the proximal portion of the tubular section of the RX clot removal catheter and the inner lumen of the guide catheter. A vacuum force can then be applied to the proximal end of the guide catheter using a syringe or pump. This vacuum force will create a low pressure region inside the guide catheter which will extend (via the seal) into the distal tubular portion of the RX clot removal catheter. This low pressure will create a pressure gradient at the tip of RX clot removal catheter which will encourage the flow of clot into the catheter.

In some scenarios, such as when retrieving a firm clot with a high fibrin content, it may not be possible to aspirate the clot fully into and through the RX clot removal catheter, and the clot may become lodged at the tip of the catheter. In such a case it may be necessary to remove the RX clot removal catheter with the clot through the guide catheter and out of the patient. It may be desirable to create reverse flow in the cerebral vasculature during this retrieval process in order to prevent the escape and distal migration of any fragments of the clot being retrieved. This can be done by disengaging the RX clot removal catheter seal so that the low pressure zone is redirected into the distal lumen of the guide catheter. Thus pressure gradient between the blood in the cerebral vasculature and the fluid within the guide catheter lumen causes a flow of the blood from the high pressure region to the low pressure region. The seal as shown can also serve to create a guiding feature to assist the advancement of another device into the tubular distal section of the clot removal catheter. This might be advantageous if for example the catheter was used as a primary clot debulking tool - so that it was advanced to a target clot and aspiration was applied to it through the guide catheter to remove the occlusive clot but was not successful in removing all of the clot. In this case a microcatheter (and guidewire if desired) could be advanced through the RX clot removal catheter and across the remaining clot so that a thrombectomy device could then be advanced through the microcatheter. The thrombectomy device and remaining clot could then be withdrawn into the RX clot removal catheter (under aspiration if desired) to complete the recanalisation of the patient's vessel.

Figures 61a – 61c illustrate a method of use of the RX clot removal catheter 500. This catheter can be used in a similar manner and for a similar purpose to catheter 101 illustrated previously in figures 10 and 11, except that the seal / flow restrictor of catheter 500 can be selectively activated or deactivated by the user. The catheter can be used as the primary clot retrieval device as shown in figures 61a-c, or as an adjunctive device as shown in figures 11a-d. Fig. 61a shows the catheter 500 advanced through a guide catheter 550 towards a target clot 555 located in blood vessel 554. In this case the catheter 550 has an external flow restrictor in the form of a balloon at its distal end.

The method of use of such a system could entail: Accessing the patient's vasculature using standard methods, advancing a guiding catheter or sheath 550 to a region proximal of the target occlusive clot 555, advancing the RX clot removal catheter 500 through the guide/sheath to a location proximal or adjacent to or within the target clot as shown in Fig. 61a (which may be achieved with the aid of a microcatheter and/or guidewire and/or thrombectomy device), activating the proximal flow restrictor/seal 504 of the catheter 500 to connect the lumens of the two catheters, inflating the external balloon (if present and if desired) at the end of the guide/sheath, aspirating using a syringe 556 or vacuum pump (not shown) through the a connector 551 attached to the proximal end of the guide/sheath 550 so that a pressure gradient is created which sucks blood and clot into the mouth 503 of the Rx clot removal catheter 500 and through the catheter 500 and the guide/sheath 550 and into the syringe as shown in Fig. 61b. If any clot remains caught in the end of the catheter tip 503 (as may happen if the clot has a significant organized fibrin component such as may occur in clots originating from a heart valve or an atrial appendage for example) it may be necessary to withdraw the catheter 500 and the trapped clot 555 together through guide/sheath 550 and out of the patient as shown in Fig. 61c. In such a scenario the flow restrictor/seal 504 may be de-activated so as to enable a vacuum force applied by the syringe to the guide/sheath to be transmitted to the distal end 553 of the guide/sheath and thus create flow reversal and draw blood and any clot fragments 557 back into the tip of the guide/sheath as the captured clot is retracted.

Fig. 62 depicts another system of this invention which functions in a similar manner to the previously described Rx catheter systems, but in this case the flow restrictor or seal between the inside of the guide/sheath 600 and the outside of the Rx catheter 603 is created by a sealing element 602 attached to the inside of the guide/sheath 600. This sealing element 602 may

comprise an inflatable balloon, similar to the external flow restricting balloon 601 shown on the outside of the guide/sheath.

Fig. 63 depicts another system of this invention in which an Rx clot retrieval catheter 650 has two flow restrictor / seal elements 651 and 652. The more proximal restrictor 651 is used to restrict flow between the Rx catheter 650 and the guide catheter 655 within which it is positioned, while the more distal restrictor 652 is used to create a flow restriction within vessel 656. The combination of these two flow restrictors means that a vacuum or negative pressure can be applied to the proximal end of guide catheter 655 and transmitted to the distal end of Rx catheter 650 in such a way that any blood aspirated into the mouth of Rx catheter 650 is not supplied from the body of blood proximal to seal 652 in vessel 656.

This system enables a physician to use a standard guide or sheath to rapidly create an access path to the region of the target occlusion, and then use the Rx catheter 650 to quickly access and aspirate the target clot from the vessel. This system provides a major advantage in the speed and ease with which a physician will be able to access and retrieve the clot. The provision of the distal vessel seal 652 on the Rx catheter rather than on the guide or sheath means that this seal can be placed more distally in the vasculature, past the petris portion of the carotid vasculature when used in the ICA for example, which means less likelihood of vessel collapse when a suction force is applied, and less likelihood of vessel spasm.

In a preferred embodiment the flow restrictors / seals are actuatable and are formed from compliant balloons, which are inflated via a hollow shaft 657 by means of a syringe or inflator 653 applied to handle 654 of the Rx catheter 650. In other embodiments the proximal flow restrictor may be passive (i.e. it cannot be selectively activated or inactivated) as shown in several other designs in this disclosure. In yet other embodiments the distal seal may be actuated by means of an actuating member rather than an inflation lumen.

Most of the Rx (rapid exchange) catheters disclosed herein share some common features and geometry. Taking catheter 500 of Fig. 60 as an example: They have a distal generally tubular portion 502 comprising an inner lumen which starts with an opening or entry/exit port 517 and ends in a distal tip or mouth 503 into which clot is received. They have a proximal elongate shaft 501 which is connected at its distal end to the entry/exit port 517 and at its proximal end in some embodiments to a handle 513. The preferred geometry of these catheters depends on the target

clot location. For clots located in the anterior or posterior cerebral anatomy the distal tubular portion 502 is preferably greater than 10cm (so that it can extend from within the distal end of a guide/sheath which may be located in an internal carotid artery or a vertebral artery, right up to the proximal face of a target clot), and less than 40cm so that the minimum possible length of tubular portion 502 is located within the lumen of the guide/sheath, thus maximising the internal volume of the combined guide/Rx catheter system for optimum aspiration efficacy).

The optimal internal and external diameters of the Rx catheter depends very much on the site of the target clot and the size of the guide catheter or sheath through which the catheter is to be advanced. In the case of retrieval of occlusive clots from cerebral vessels the likely vessel diameters range from approximately 1.5mm up to 6mm, with 3mm being a very typical diameter. Guide catheters / sheaths used in these scenarios have typically an internal diameter of between 0.060" and 0.095", so that a suitable system might consist of a guide catheter with an internal diameter of 0.078" and an Rx clot retrieval catheter whose distal tubular section has an outside diameter of 0.070" and an inside diameter of 0.062". Such a system provides a very significant benefit in terms of flow resistance over an equivalently sized conventional combination of a guide and intermediate/aspiration (not rapid exchange) catheter. In particular the effective proximal lumen of the system of this invention is that of the guide catheter (0.078"), while the effective proximal lumen of the conventional system would be that of the intermediate/aspiration catheter (0.062"). This results in a significantly lower flow restriction in the Rx system of the invention, which means that for a given vacuum / suction force applied to the proximal end of the system, a much greater flow will be created through the system of this invention. While a conventional (not rapid exchange) intermediate/aspiration catheter may be stepped in diameter to maximise its proximal internal diameter, this proximal internal diameter must always be significantly smaller than the guide/sheath in which it is positioned. This is not the case in the system of this invention.

Yet another embodiment of this invention is shown in Figures 64a-d, which depict a distal end configuration which could be employed with any of the clot retrieval catheters previously shown. The catheter distal end 700 has an integrated control member 701, which forms a loop 704 at the tip where it is connected to tip members 703 so that it acts like a draw string when pulled. The tip may comprise relatively stiff members 703 interspersed with relatively compliant members 702, so that the tip has both axial stiffness (to permit effective operation of the drawstring mechanism) and radial compliance (to allow expansion and contraction of the tip).

Therefore when actuated by pulling as shown in Fig. 64b, the control member causes the tip of the catheter to reduce in diameter. This can improve the ability of the catheter to track through tortuousity and across obstacles such as the origin of the ophthalmic artery.

Similarly when the control member is pushed forward it can cause or allow the catheter tip to expand forming a funnel shape as shown in Fig. 64c. This can improve the ability of the catheter to aspirate clots and also act as a flow restrictor in the vessel.

In use the control member may be pulled back during insertion of the catheter to improve accessibility. It can then be forwarded to increase the diameter of the tip and aspirate the occlusion.

If the occlusion or blood clot can only be partially aspirated, then the tip diameter can be reduced again by pulling the control member, causing the clot to be trapped as shown in Fig. 64d, reducing the risk of the clot travelling to a new territory during retraction of the catheter and improving dislodgement.

The flaps 703 of the catheter tip are not rigidly connected to the integrated control member 701 but form a loop which can slide over the control member. The control member distal end 706 may also be fixed to the inner surface of the catheter.

Referring to Fig. 65 there is illustrated an aspiration catheter 801 according to this invention in use in a thrombectomy procedure. The catheter 801 is similar to catheter 101 of Figs 10 and 11 and provides a proximal seal 802 against a guide catheter inner lumen 803 so that aspiration applied by syringe 811 (or a pump or by other means) through guide catheter 808 (via a rotating haemostasis valve (RHV) 814) can be transferred through to the distal end 812 of the aspiration catheter. Thrombectomy device 800 is shown deployed within clot 810, having been delivered through microcatheter 809 by means of proximal shaft 807. The method of use of the system illustrated is very similar to that described in Figs 11a-d, except that in this embodiment the proximal end 815 of the microcatheter 809 and proximal end 806 of Rx aspiration catheter 801 are positioned within separate branches of a rotating hemostasis valve (RHV) 813. This configuration provides significant ease of use advantages over the configuration described in Fig. 11. In particular the RHV 813 can be more easily sealed around the proximal shaft 806 of the

aspiration catheter to prevent any air ingress (or fluid leakage) during aspiration. In addition the user has better control over the aspiration catheter 801, microcatheter 809 and thrombectomy device 800 relative to the guide catheter 808, and can use RHVs 813 and 814 to lock and hold the aspiration catheter or microcatheter independently of each other.

One embodiment of the method of use of such a system could consist of the following steps: Accessing an arterial blood vessel of a patient using conventional means such as an introducer and guide catheter 808 and/or sheath, advancing Rx aspiration catheter 801 through a first branch of RHV 813 attached to proximal end of guide catheter 808, advancing a microcatheter 809 through a second branch of RHV 813 and through the aspiration catheter 801 and guide catheter 808 up to and across a target occlusive clot 810 with or without the aid of a guidewire, removing the guidewire (if used) and advancing a mechanical thrombectomy device 800 such as a stent-retriever through the microcatheter 809 to the target clot 810, retracting the microcatheter 809 at least a few cm to deploy a mechanical thrombectomy device 800 within the clot 810, advancing the aspiration catheter 801 up to a position just proximal of the clot 810 (or within the clot, or considerably proximal of the clot if vessel disease or tortuosity makes access difficult), optionally creating flow arrest by inflating the balloon of the guide catheter 808 (if used, or by other means), aspirating through the aspiration catheter 801 using a syringe 811 or pump connected to the guide catheter 808 while withdrawing the mechanical thrombectomy device 800 towards and into the distal mouth 812 of the aspiration catheter 801, withdrawing the clot 810, mechanical thrombectomy device 800 and microcatheter 809 through the aspiration catheter 801 and guide catheter 808 and out of the patient while continuing to aspirate.

A possible variant of the final step of the above method could involve removing the aspiration catheter along with the clot 810, mechanical thrombectomy device 800 and microcatheter 809. This variant is useful if a large and/or firm clot is encountered which the physician cannot (or does not wish to) fully withdraw into the mouth of the aspiration catheter. In such a situation the RHV 813 must be removed once the exit port 805 of the aspiration catheter 801 reaches the RHV 813.

Another method of use of such an Rx aspiration catheter system is to retrieve clot using aspiration without the use of a thrombectomy device. The rapid exchange shaft of this invention provides great advantages in terms of speed, deliverability, ease of use and aspiration lumen. A microcatheter or other similar catheter and guidewire nay be used to provide support to assist in

tracking the aspiration catheter to the target site in a similar manner to that illustrated in either Fig. 65 or Figs 11a-d.

It will be apparent from the foregoing description that while particular embodiments of the present invention have been illustrated and described, various modifications can be made without departing from the spirit and scope of the invention. For example, while the embodiments described herein refer to particular features, the invention includes embodiments having different combinations of features. The invention also includes embodiments that do not include all of the specific features described.

The invention is not limited to the embodiments hereinbefore described which may be varied in construction and detail.

Claims

1. A catheter for assisting in the retrieval of a clot from a vessel comprising a distal end and a proximal end, a distal segment and a proximal segment and a lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment and a flow restrictor located on the outer surface of the catheter distal of the transfer port.

2. A catheter as claimed in claim 1 wherein the flow restrictor is actuatable between engaged and disengaged configuration.

3. A catheter as claimed in claim 2 comprising an actuator for selectively engaging and/or disengaging the flow restrictor.

4. A catheter as claimed in claim 2 or 3 wherein the flow restrictor comprises a framework and a membrane coupled to the framework, the framework being movable by the actuator between an expanded configuration and a retracted configuration.

5. A catheter as claimed in any of claims 1 to 4 comprising a proximal flow restrictor distal of the proximal end of the distal segment and a distal flow restrictor spaced distally from the proximal flow restrictor.

6. A catheter as claimed in any of claims 1 to 5 wherein the distal end of the catheter comprises a mouth for reception of clot.

7. A catheter as claimed in claim 6 wherein the mouth is defined by an expansile tip.

8. A catheter as claimed in claim 6 or 7 wherein the distal segment includes a hinge adjacent to the distal mouth.

9. A catheter as claimed in claim 8 wherein the hinge is defined by a region of the distal segment which is configured to have lateral flexibility.

10. A catheter as claimed in any of claims 6 to 9 wherein the mouth has an expanded configuration and a retracted configuration.

11. A catheter as claimed in claim 10 comprising a control member for controlling the movement of the mouth between the expanded and retracted configurations.

12. A catheter as claimed in claim 11 wherein the mouth comprises a number of segments and the control member is configured to move at least some of the segments.

13. A catheter as claimed in claim 12 wherein the control member comprises a drawstring.

14. A catheter for aspirating a clot in a vessel comprising a distal end and a proximal end, a distal segment and a proximal segment and a lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment wherein the distal end of the catheter comprises a mouth for reception of clot.

15. A catheter as claimed in claim 13 having a flow restrictor located on the outer surface of the catheter distal of the transfer port.

16. A catheter as claimed in claim 15 wherein the mouth is defined by an expansile tip.

17. A catheter as claimed in claim 15 or 16 wherein the distal segment includes a hinge adjacent to the distal mouth.

18. A catheter as claimed in claim 17 wherein the hinge is defined by a region of the distal segment which is configured to have lateral flexibility.

19. A catheter as claimed in any of claims 15 to 18 wherein the mouth has an expanded configuration and a retracted configuration.

20. A catheter as claimed in claim 19 comprising a control member for controlling the movement of the mouth between the expanded and retracted configurations.

21. A catheter as claimed in claim 20 wherein the mouth comprises a number of segments and the control member is configured to move at least some of the segments.

22. A catheter as claimed in claim 21 wherein the control member comprises a draw string.

23. A catheter as claimed in any of claims 1 to 22 wherein the catheter is an aspiration catheter for aspirating a clot.

24. A system for treating an occlusion in a vessel the system comprising:-

a first catheter and a second catheter;

the first catheter comprising a proximal end, a distal end and a lumen extending between the proximal end and the distal end, the lumen of the first catheter further comprising a proximal segment and a distal segment;

the second catheter comprising a distal end and a proximal end, a distal segment and a proximal segment, and a lumen, said lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment;

the first catheter being configured to facilitate aspiration through the lumen;

the transfer port being configured to transmit aspiration in the proximal lumen of the first catheter into the lumen of the distal segment of the second catheter and the distal end of the second catheter being configured to receive clot into at least a portion of the lumen of the second catheter.

25. A system as claimed in claim 24 wherein the second catheter is a catheter as claimed in any of claims 1 to 23.

26. A system as claimed in claim 24 further comprising a flow restrictor between the first catheter and the distal segment of the second catheter, distal of the transfer port.

27. A system as claimed in claim 26 wherein the flow restrictor is located on the inner surface of the first catheter.

28. A system as claimed in claim 26 or 27 wherein the flow restrictor is located on the outer surface of the second catheter.

29. A system as claimed in any of claims 26 to 28 comprising a proximal flow restrictor distal of the proximal end of the distal segment of the second catheter and a distal flow restrictor spaced distally from the proximal flow restrictor.

30. A system as claimed in any of claims 24 to 29 wherein the distal end of the second catheter comprises a mouth for reception of clot.

31. A system as claimed in claim 30 wherein the mouth is defined by an expansile tip.

32. A system as claimed in any of claims 24 to 31 wherein the transfer port comprises a rapid exchange port.

33. A system as claimed in any of claims 24 to 32 wherein the first catheter is a guide catheter.

34. A system as claimed in any of claims 24 to 33 wherein the second catheter is an intermediate catheter.

35. A system as claimed in any of claims 24 to 34 further comprising a microcatheter which is adapted to be advanced through the first catheter and the second catheter.

36. A system as claimed in claim 35 further comprising a clot engaging device for delivery from the microcatheter.

37. A system as claimed in claim 33 wherein the guide catheter is mounted in a proximal rotating haemostasis valve through which aspiration is applied.

38. A system as claimed in claim 35 or 36 wherein a proximal end of the microcatheter and a proximal end of the aspiration catheter are locatable within separate branches of a proximal rotating haemostasis valve.

39. A method of removing a clot from a vessel, the method comprising:-

providing a guide catheter and an intermediate catheter, the intermediate catheter having a distal mouth and being configured such that it is advancable within the lumen of the guide catheter;

inserting the guide catheter into a first vessel proximal of an occlusion;

advancing the intermediate catheter through the lumen of the guide catheter until the tip of the intermediate catheter extends distal of the guide catheter into a second vessel adjacent to the occlusion;

applying aspiration to the proximal end of the guide catheter;

the intermediate catheter being configured to direct said aspiration through the distal lumen of the intermediate catheter to aspirate the clot into the mouth of said intermediate catheter.

40. A method as claimed in claim 39 wherein the aspiration catheter comprises a distal end, a proximal end, a distal segment, a proximal segment and a lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment.

41. A method as claimed in claim 39 or 40 comprising restricting flow between the outside surface of the intermediate catheter and the inside surface of the guide catheter.

42. A method as claimed in any of claims 39 to 41 comprising the step, before or after aspiration, of delivering a microcatheter to the occlusion and deploying a clot capture device from the microcatheter.

43. A method as claimed in claim 42 comprising advancing the microcatheter to the clot, deploying a clot capture device from the microcatheter, retracting the microcatheter to a location proximal of a transport port at the proximal end of a distal segment of the aspiration catheter.

44. A method of removing an occlusion from a vessel comprising:-

providing a first aspiration catheter and a second aspiration catheter, the second aspiration catheter extending distal of the first aspiration catheter and further comprising a transfer lumen proximal of the distal end of the first aspiration catheter;

inserting the first catheter into a first vessel proximal of the occlusion;

advancing the second catheter through the lumen of the first catheter until the tip of the second catheter extends distal of the first catheter into a second vessel and is substantially opposing the occlusion; and

aspirating through the proximal lumen of the first catheter so as to urge the clot into the distal lumen of the second catheter.

45. A method as claimed in claim 44 comprising restricting flow between the outside surface of the second catheter and the inside surface of the first catheter.

46. A method as claimed in claim 44 or 45 comprising the step, before or after aspiration, of delivering a microcatheter to the occlusion and deploying a clot capture device from the microcatheter.

47. A method as claimed in claim 46 comprising the step, prior to aspiration, of retracting the microcatheter to a location proximal of the transfer port.

48. A method as claimed in any of claims 44 to 47 wherein the first aspiration catheter is a guide catheter.

49. A method as claimed in any of claims 44 to 48 wherein the second aspiration catheter is an intermediate catheter.

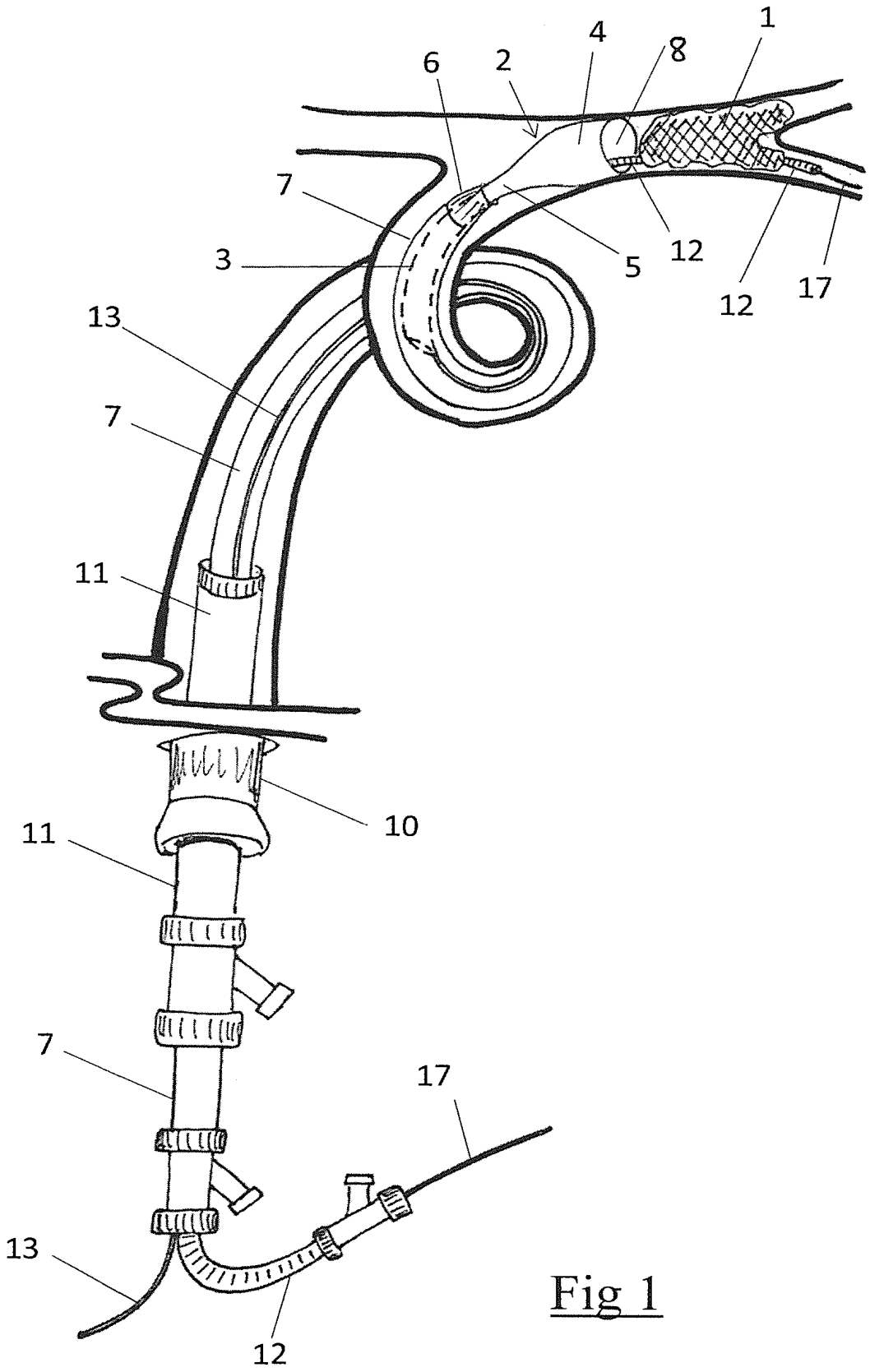


Fig 1

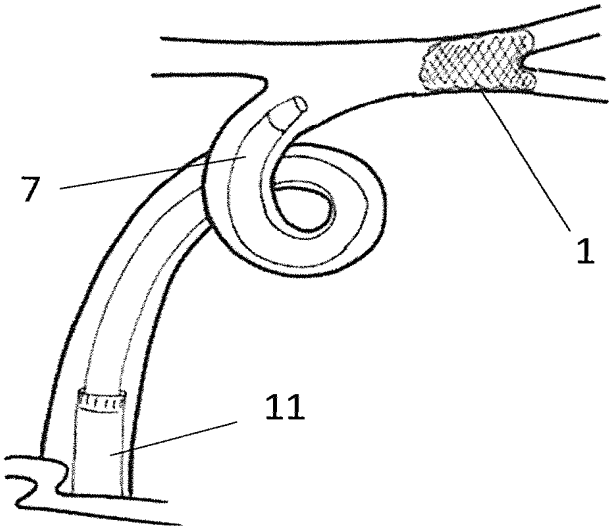


Fig 2a

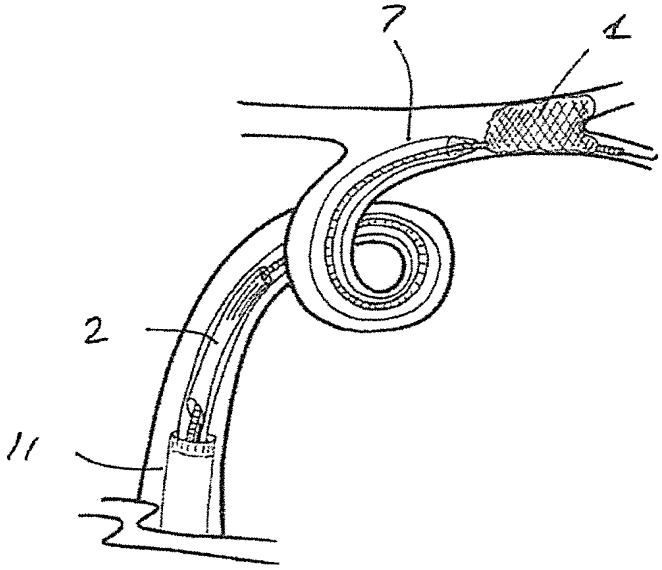


Fig 2b

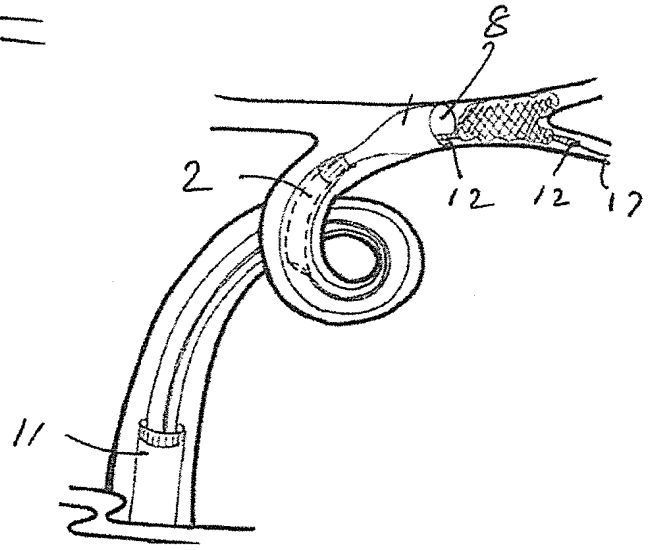


Fig 2c

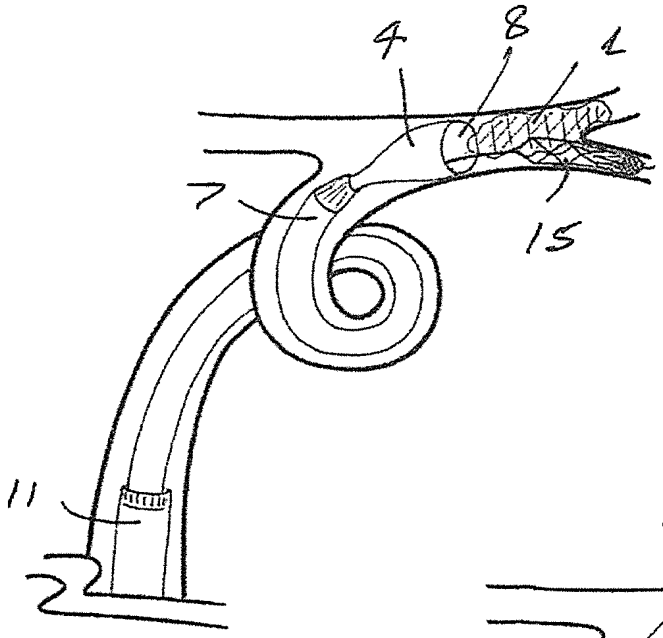


Fig 2d

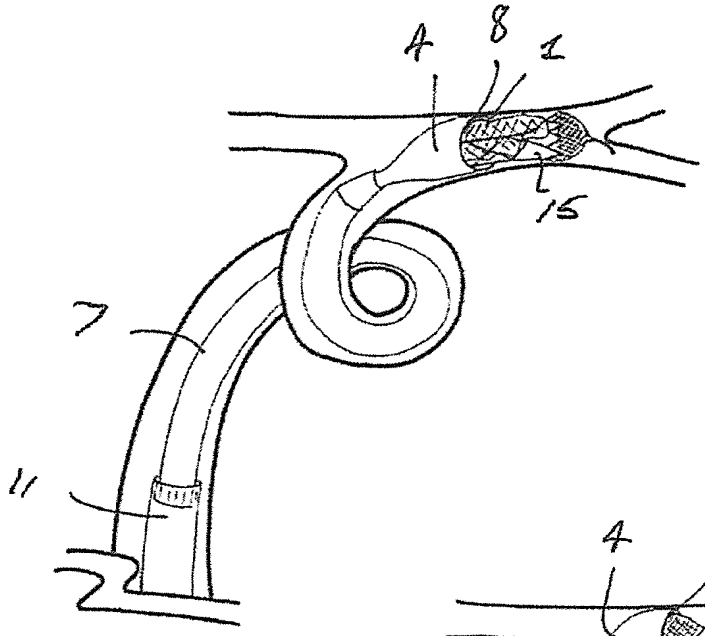


Fig 2e

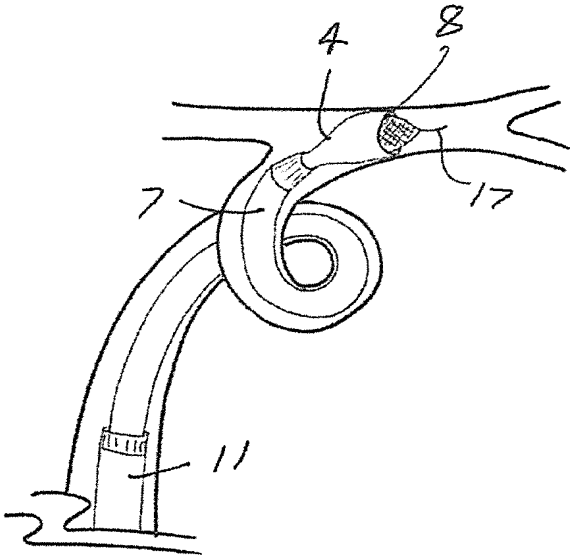


Fig 2f

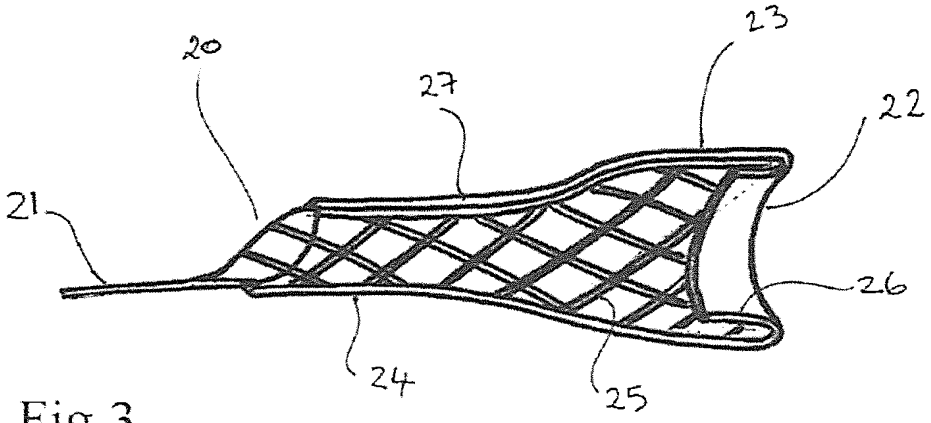


Fig 3

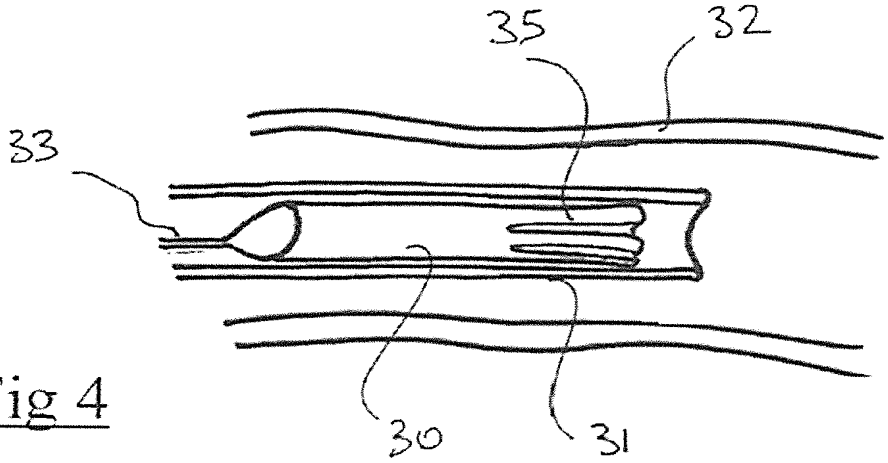


Fig 4

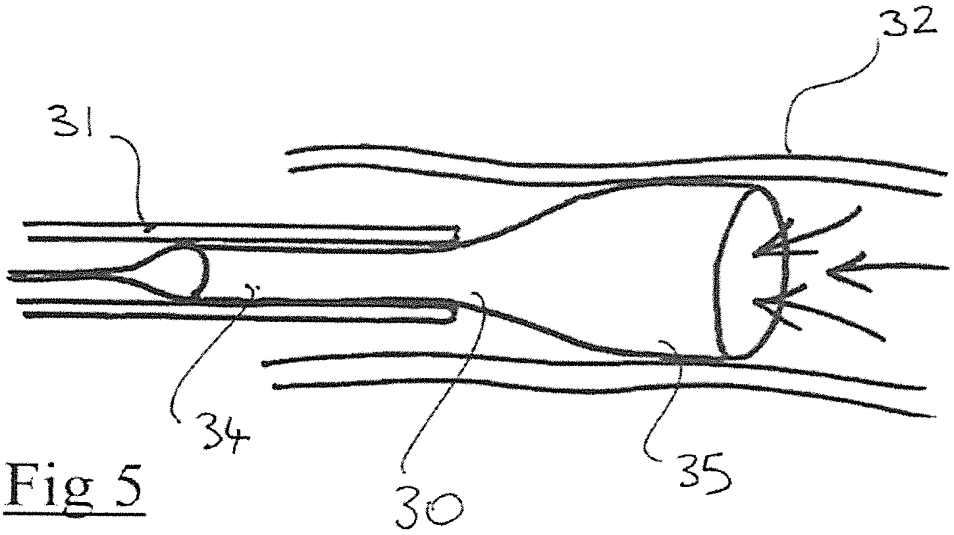


Fig 5

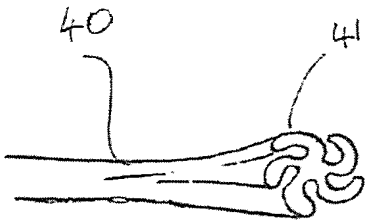


Fig 6a

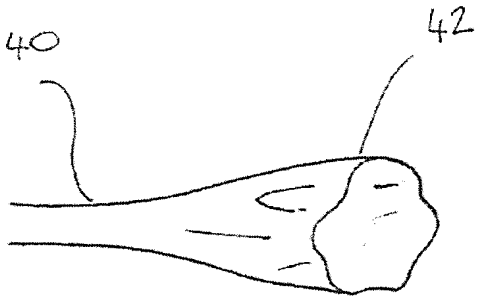


Fig 6b

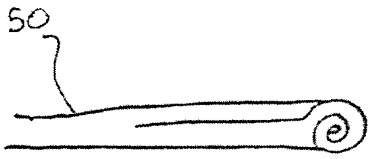


Fig 7a

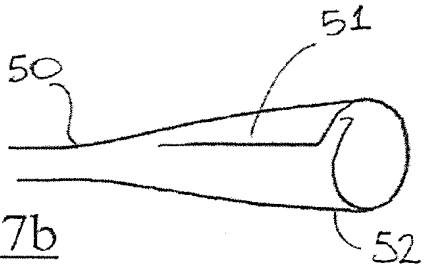


Fig 7b

Fig 8a

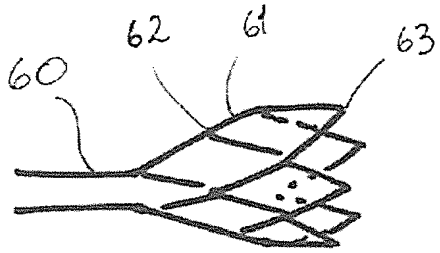


Fig 8b

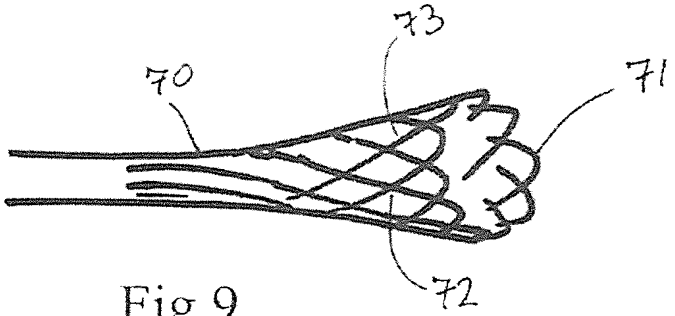


Fig 9

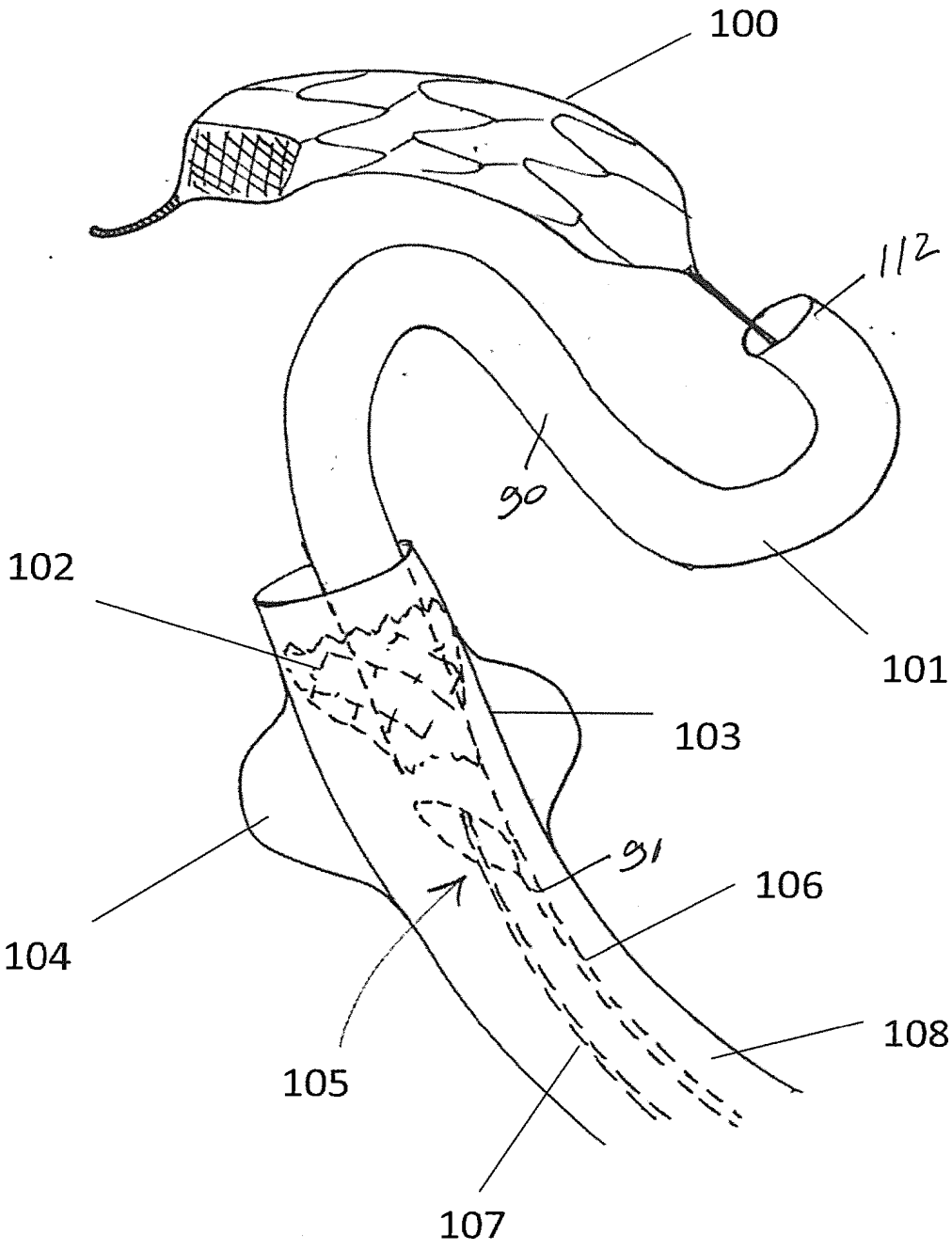


Fig 10

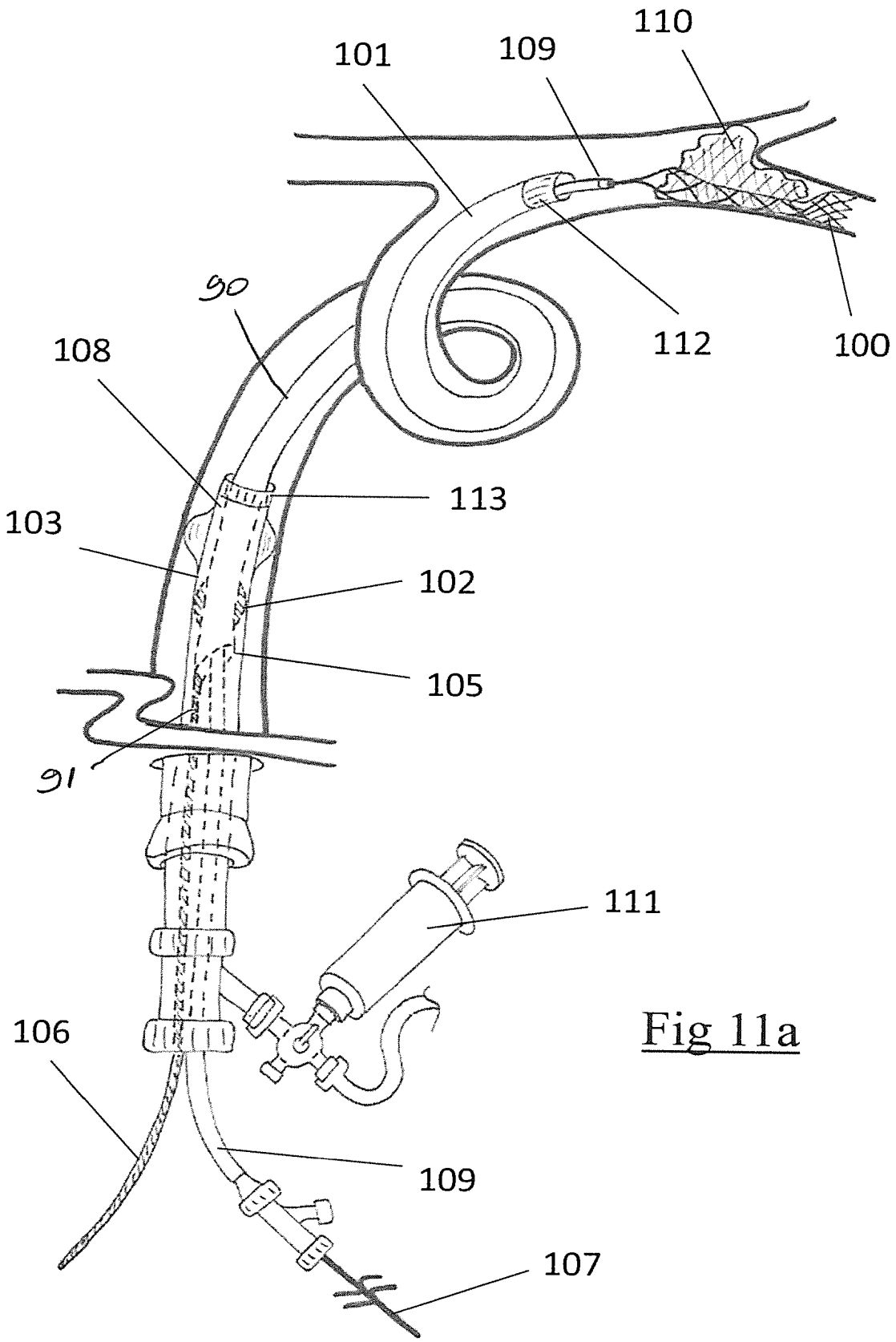


Fig 11a

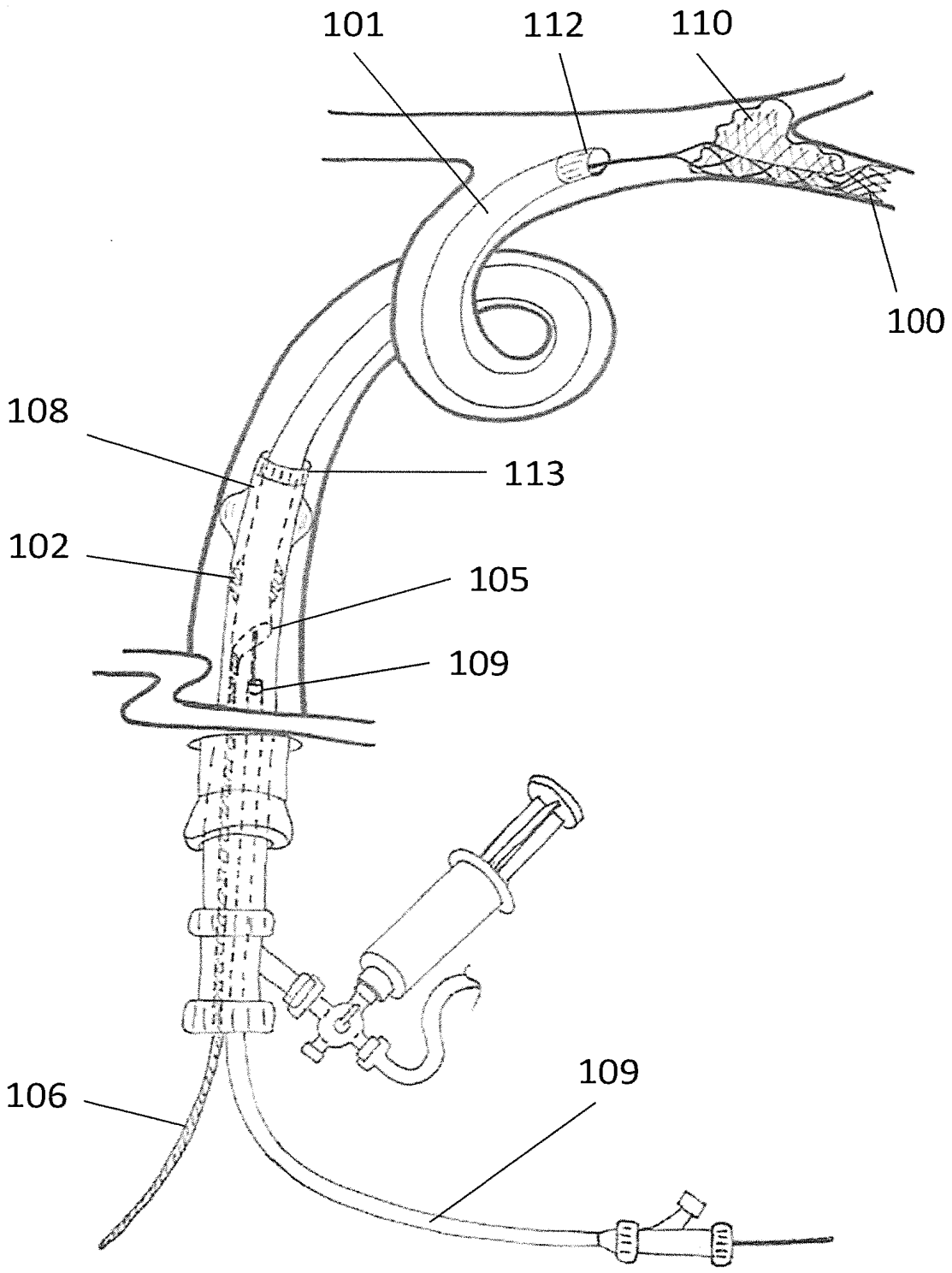


Fig 11b

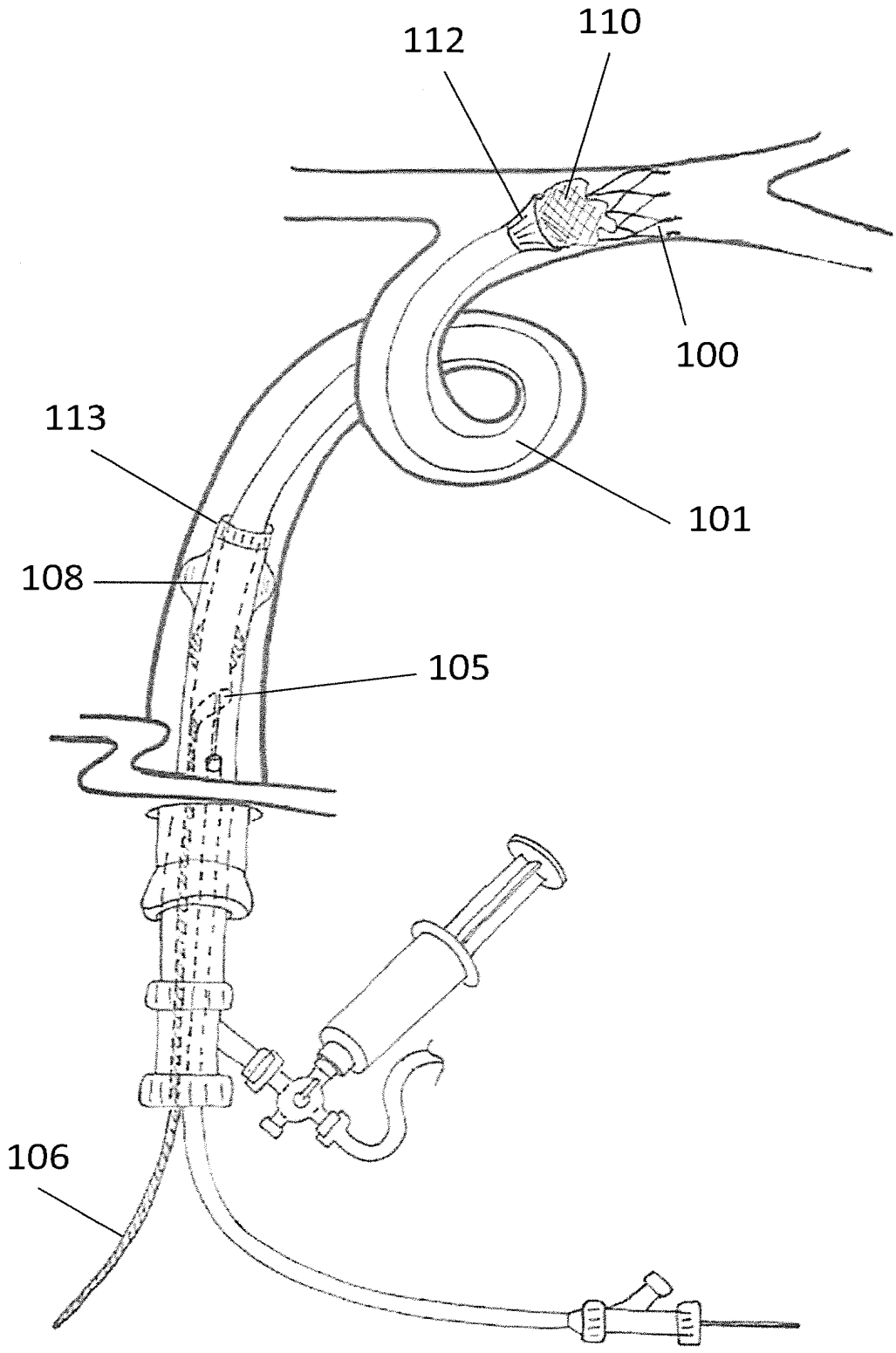


Fig 11c

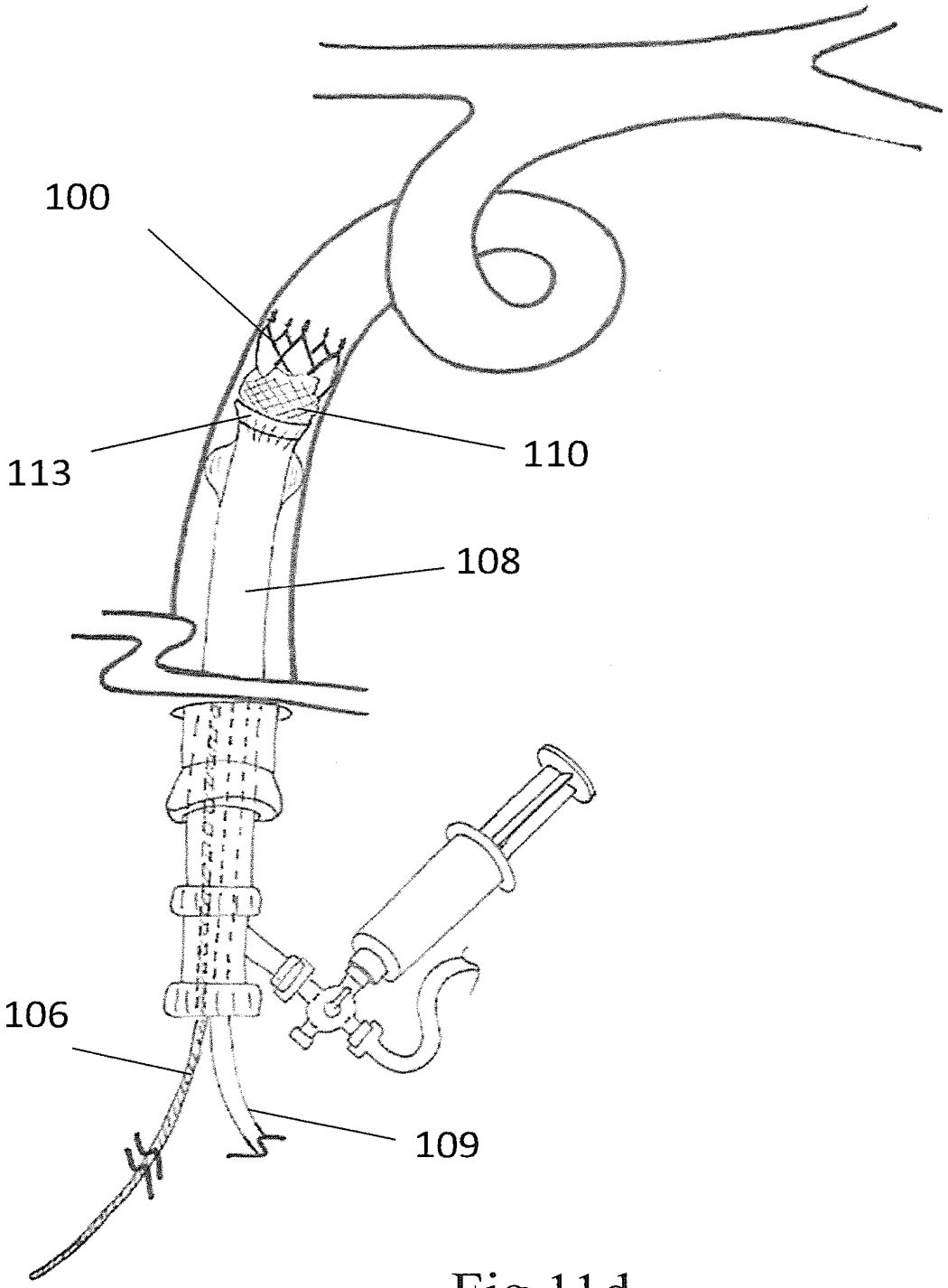


Fig 11d

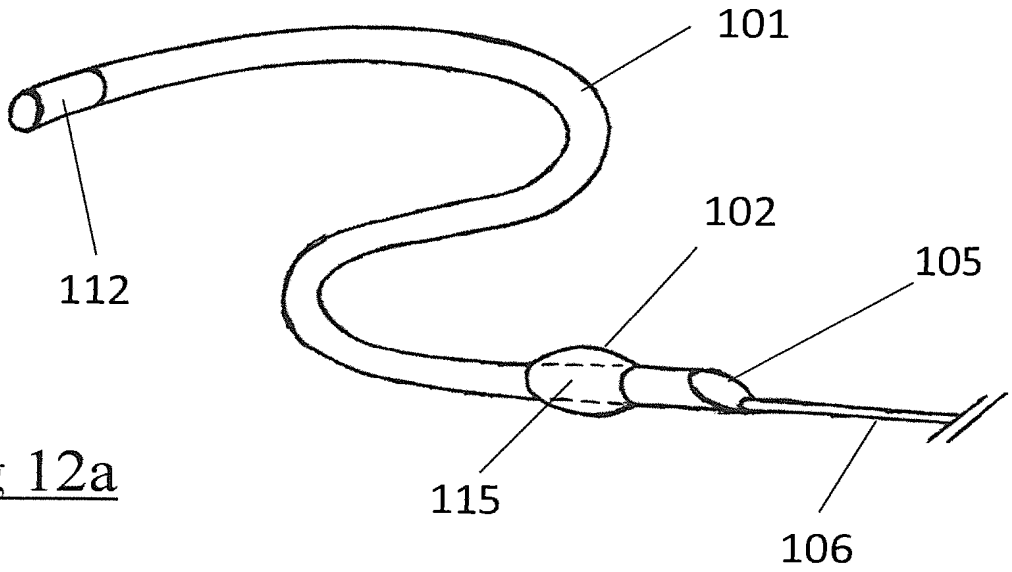


Fig 12a

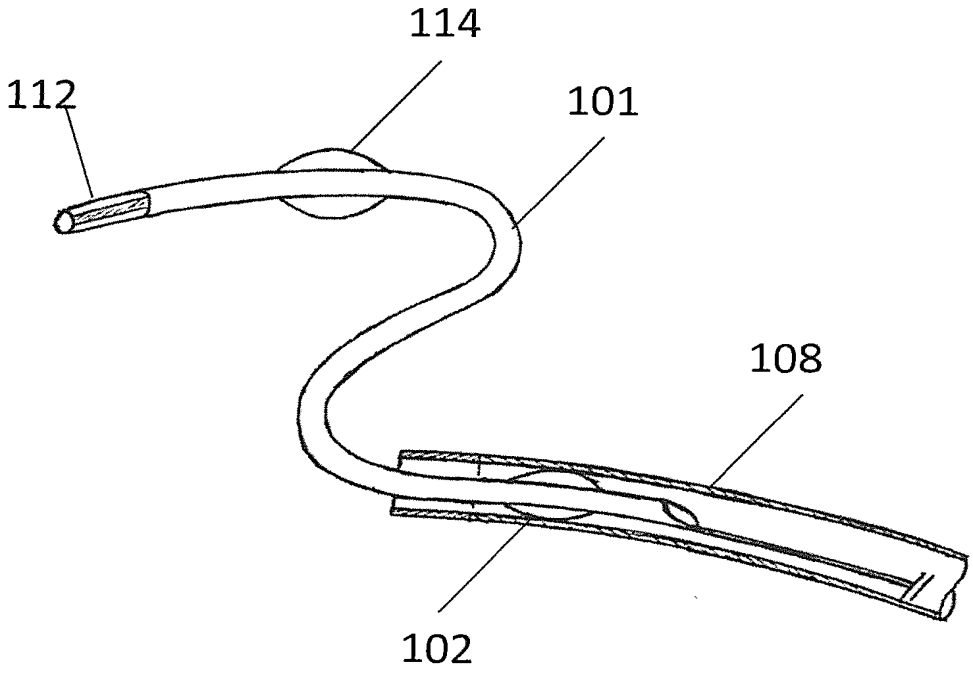


Fig 12b

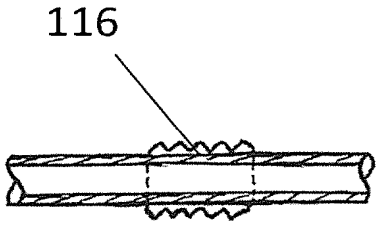


Fig 13a

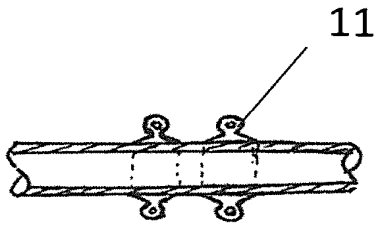


Fig 13b

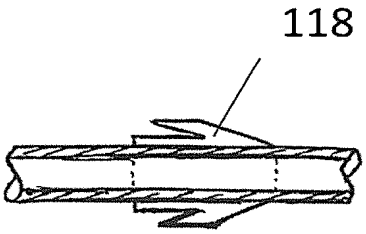


Fig 13c

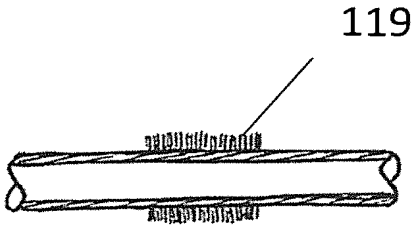


Fig 13d

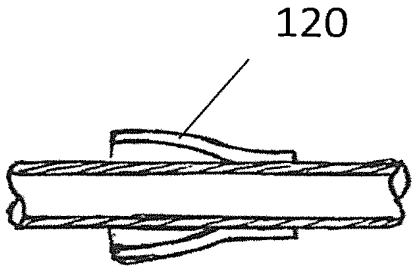


Fig 13e

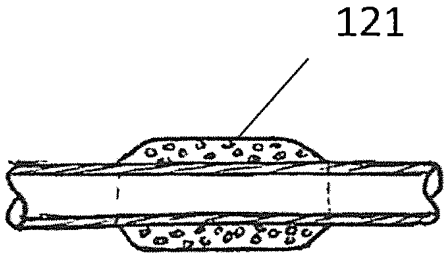


Fig 13f

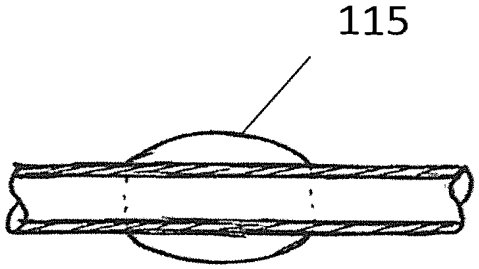


Fig 13g

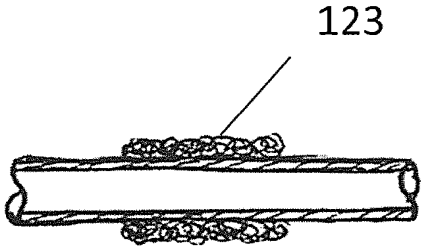


Fig 13h

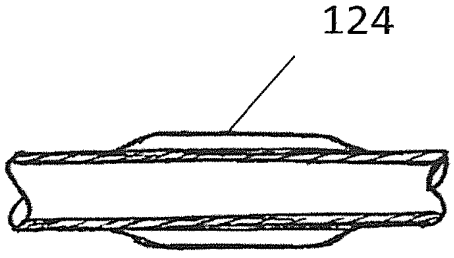


Fig 13i

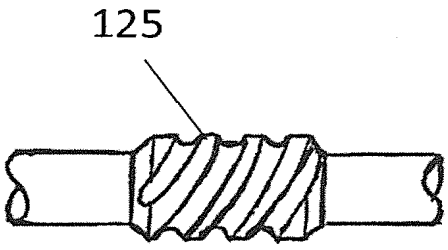


Fig 13j

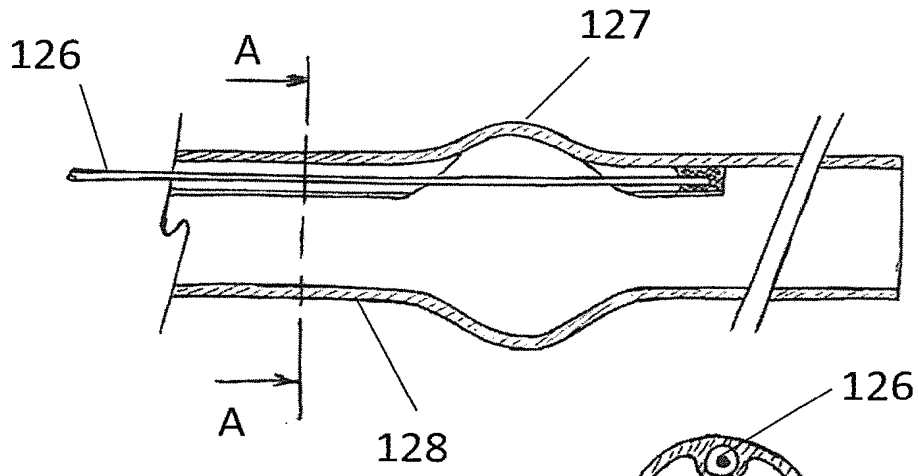


Fig 13k

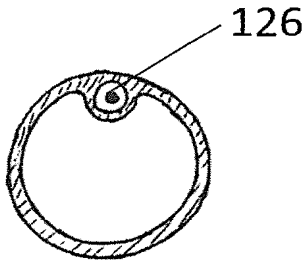


Fig 13L

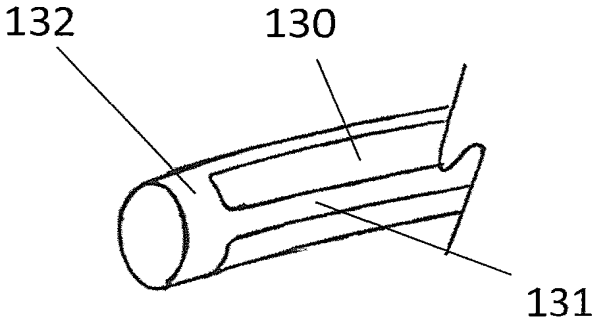


Fig 14

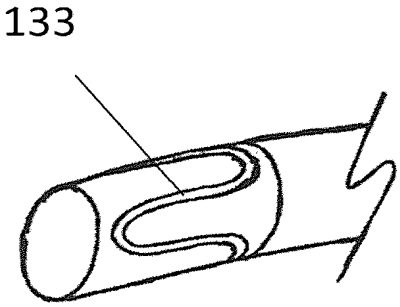


Fig 15

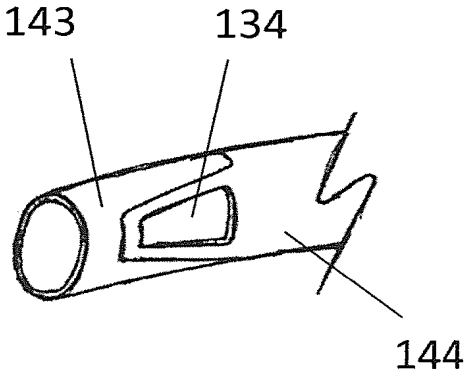


Fig 16

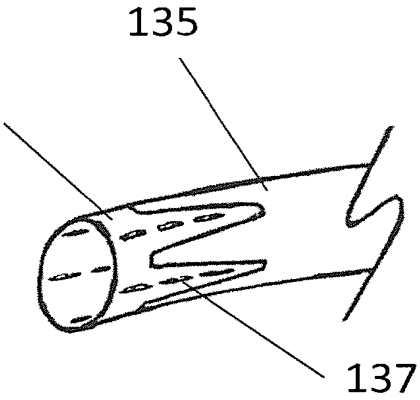


Fig 17

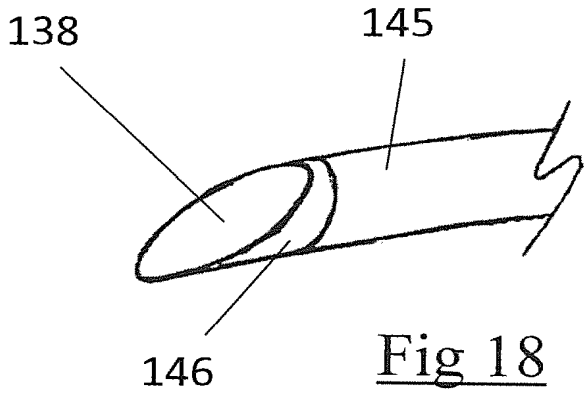


Fig 18

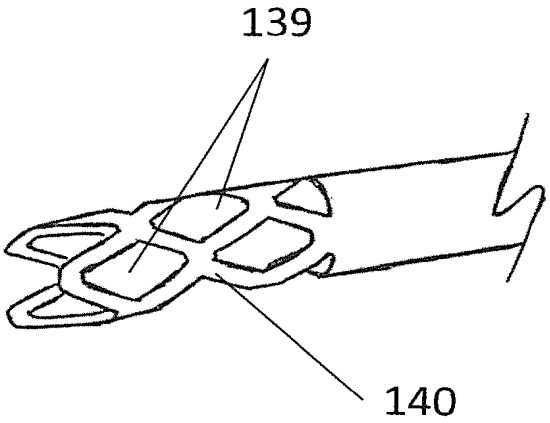


Fig 19

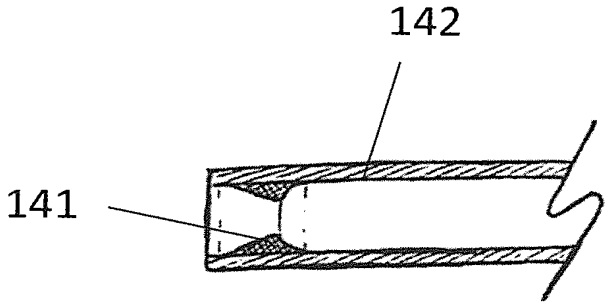


Fig 20

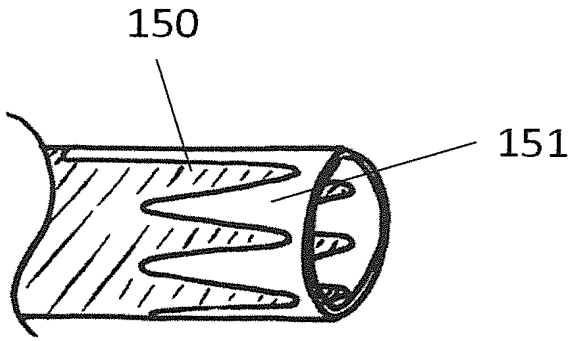


Fig 21

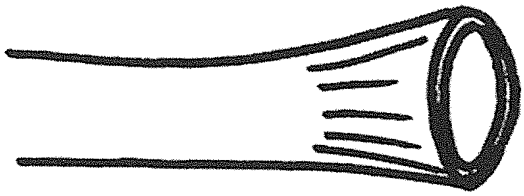


Fig 22a

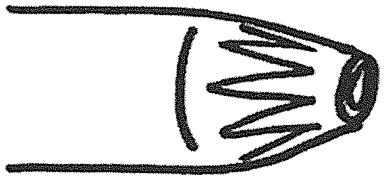


Fig 22b

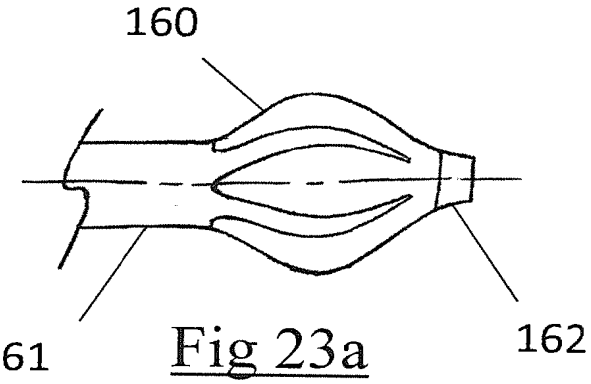


Fig 23a

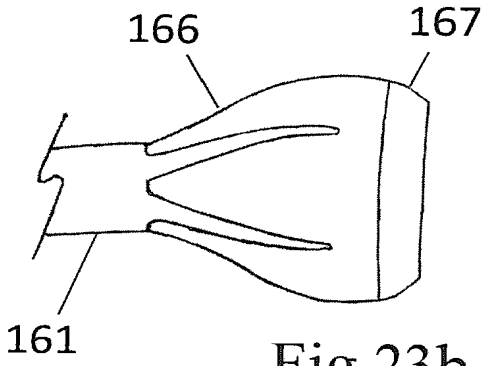


Fig 23b

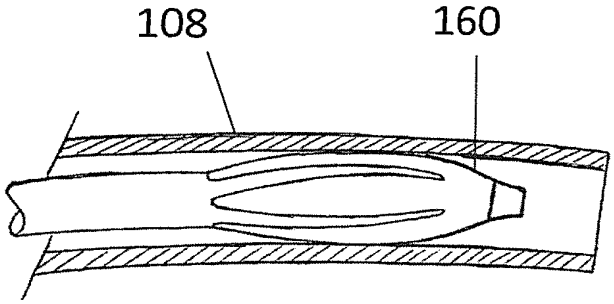


Fig 23c

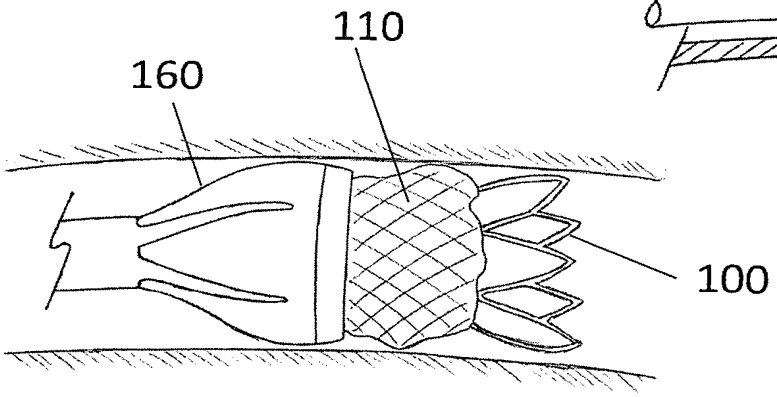


Fig 23d

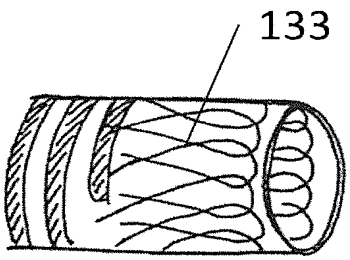


Fig 24

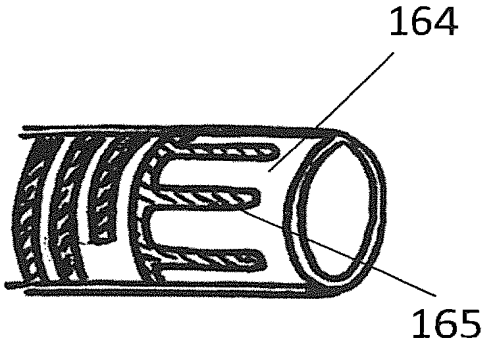


Fig 25

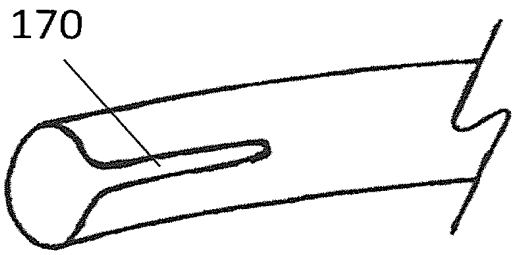


Fig 26

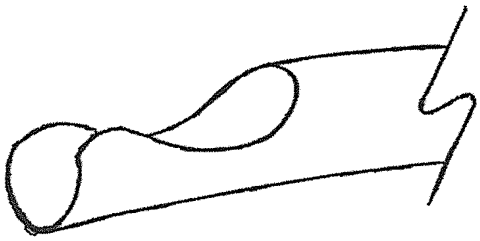


Fig 28

Fig 27

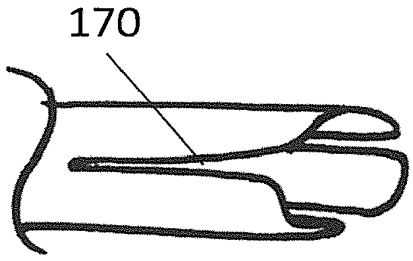


Fig 29

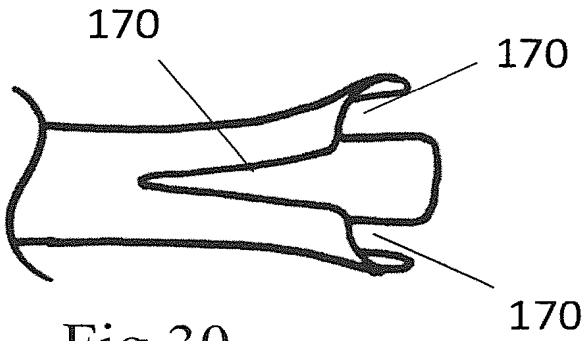


Fig 30

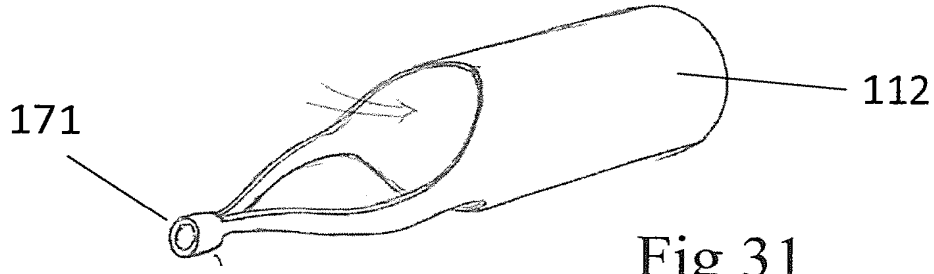


Fig 31

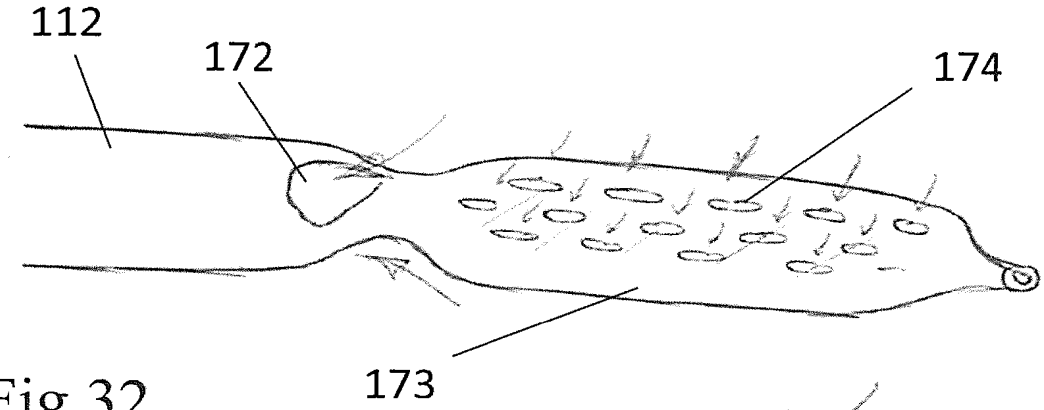


Fig 32

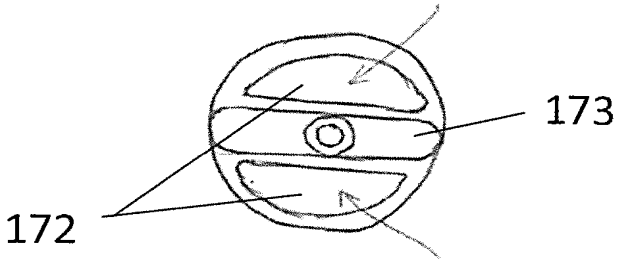


Fig 33

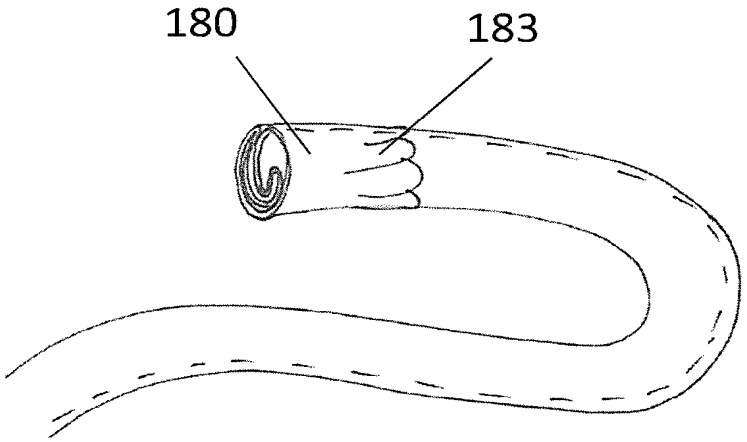


Fig 34a

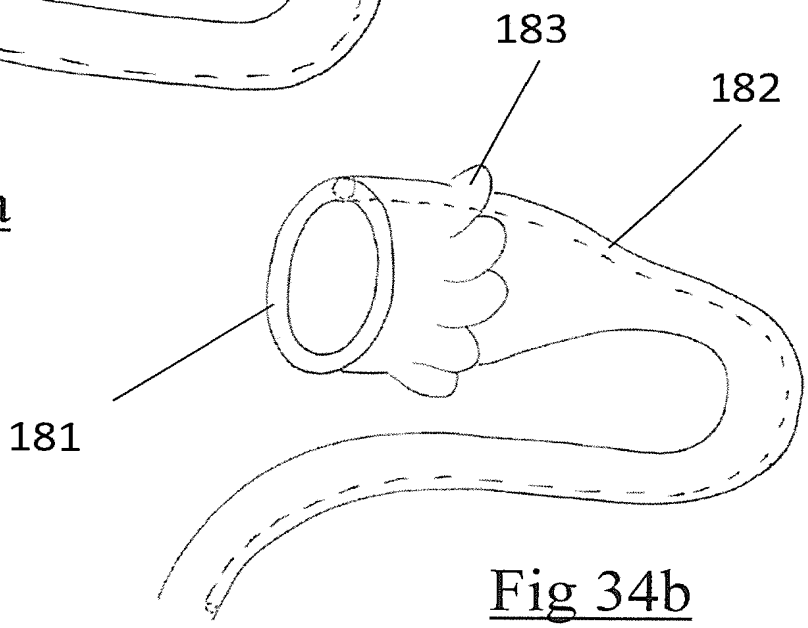
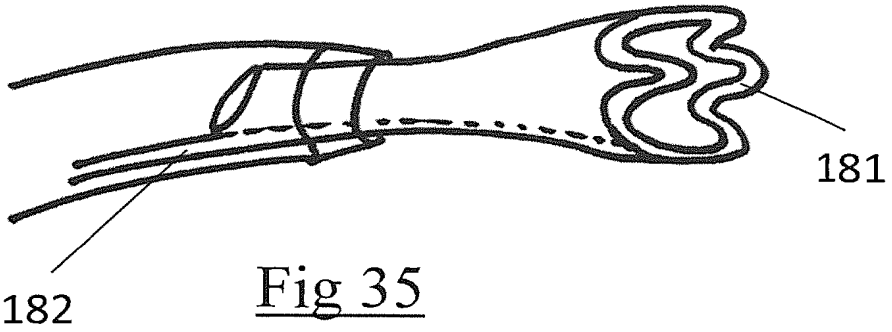


Fig 34b



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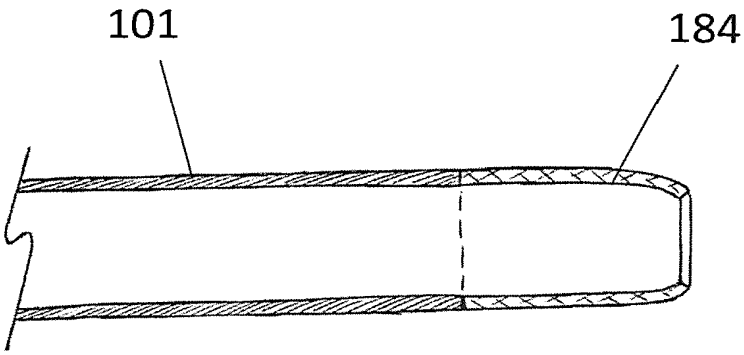

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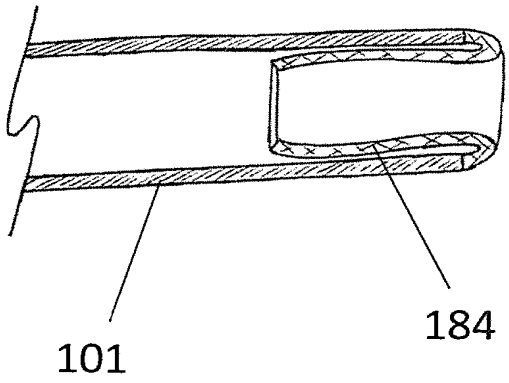

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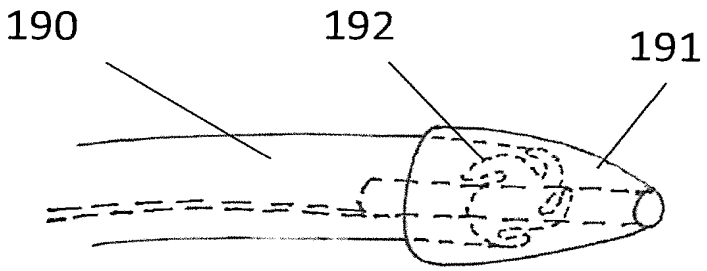
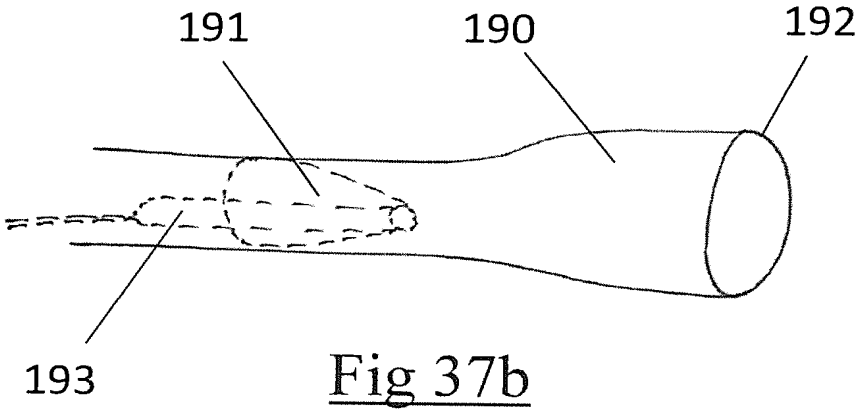


Fig 37a



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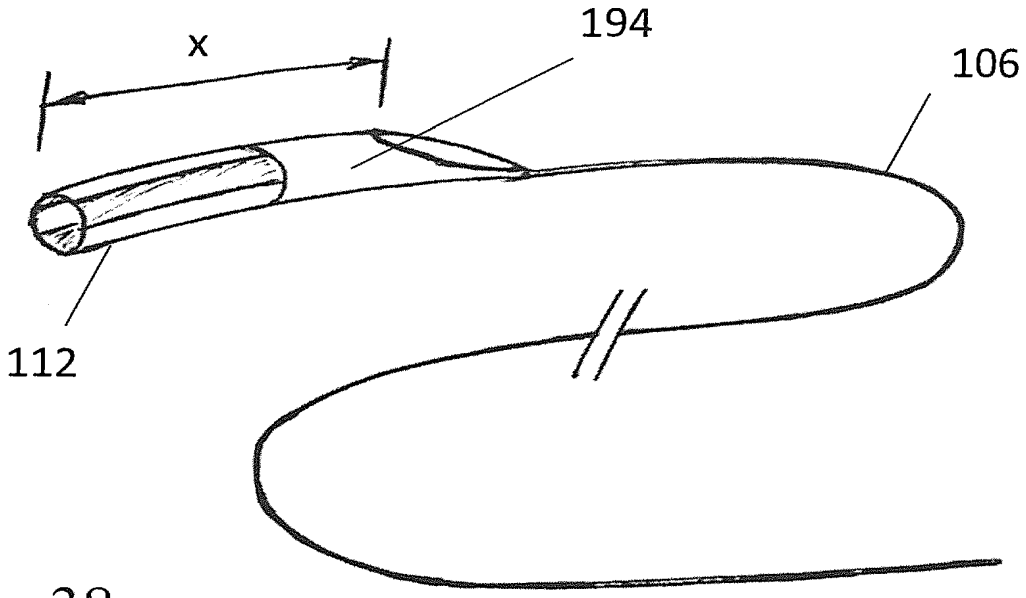


Fig 38

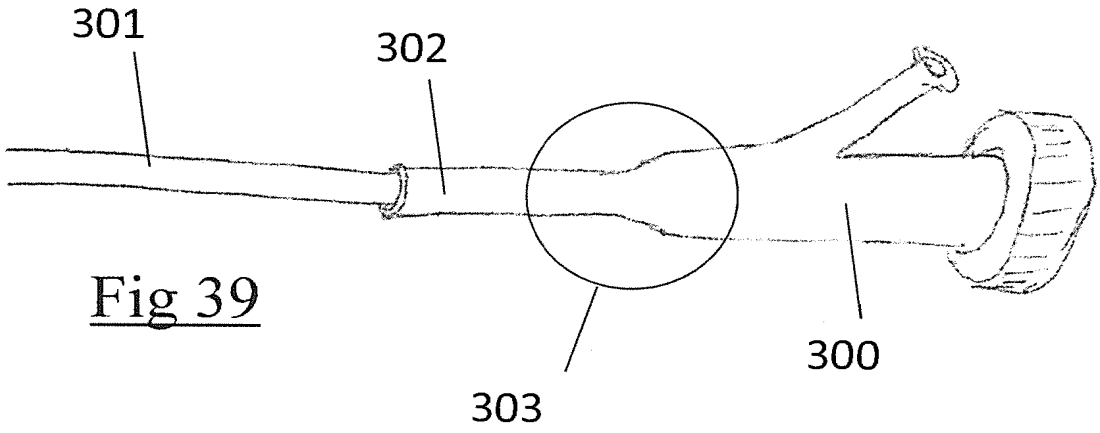
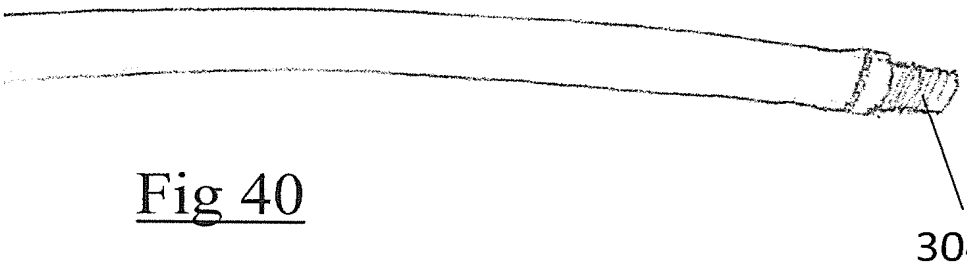


Fig 39



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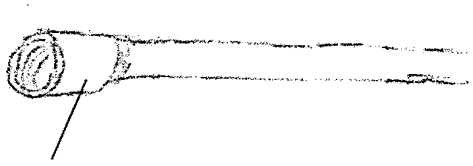

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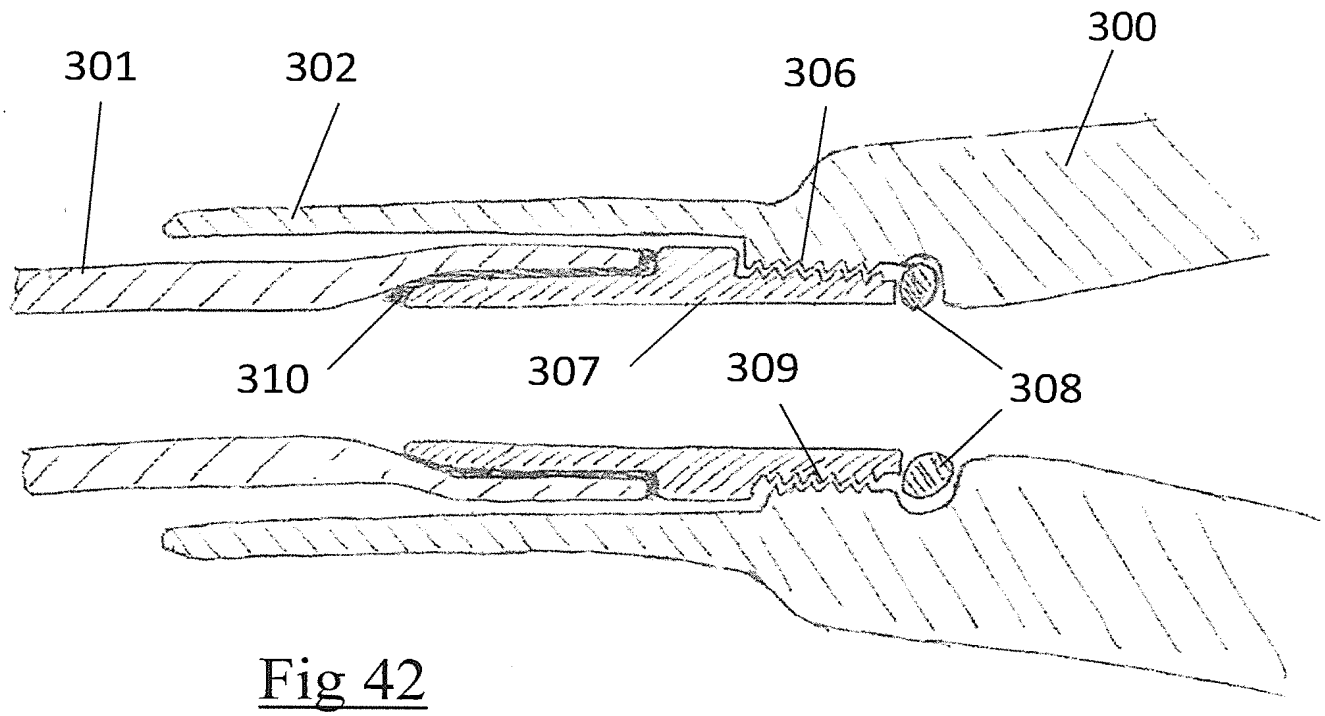
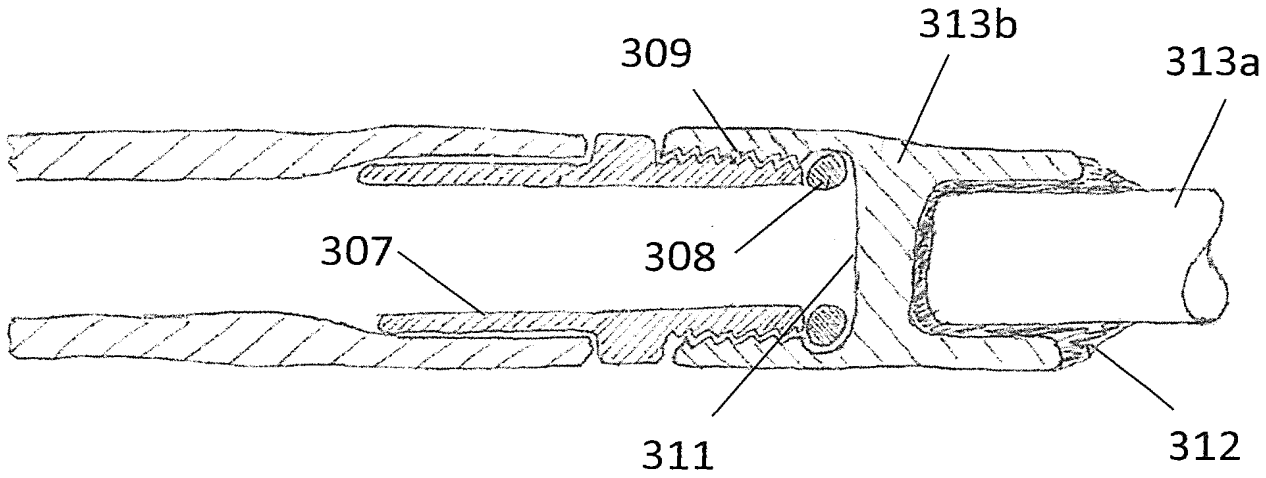


Fig 42



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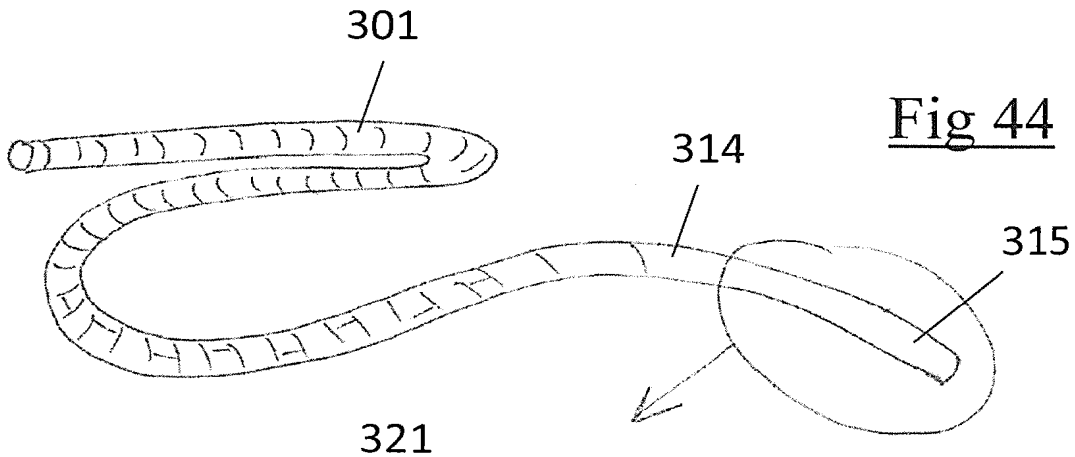


Fig 44

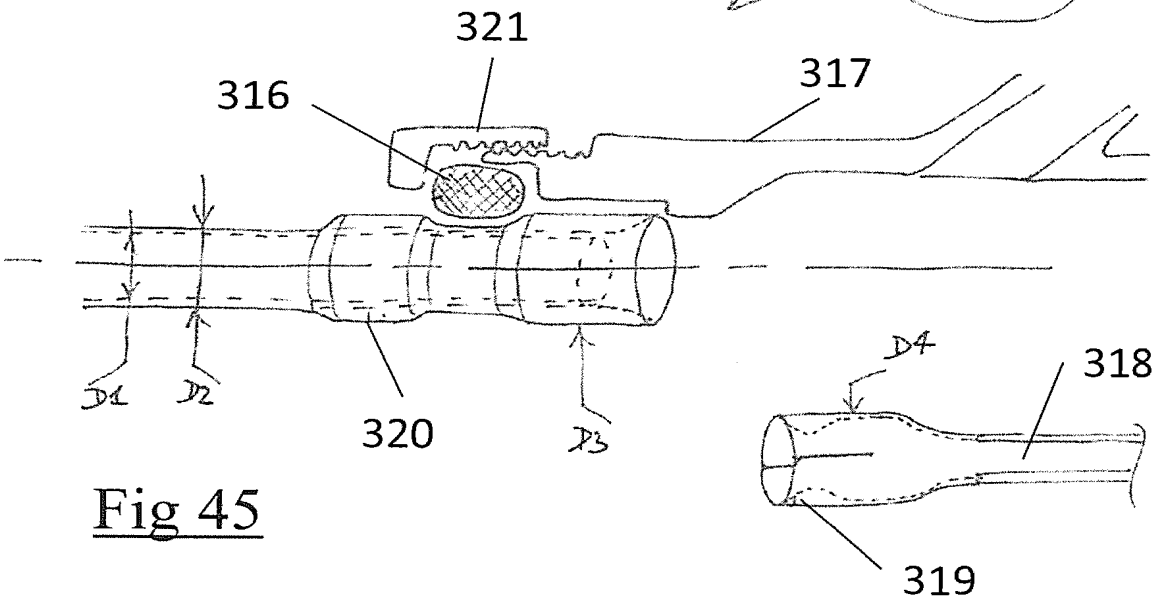


Fig 45

Fig 46

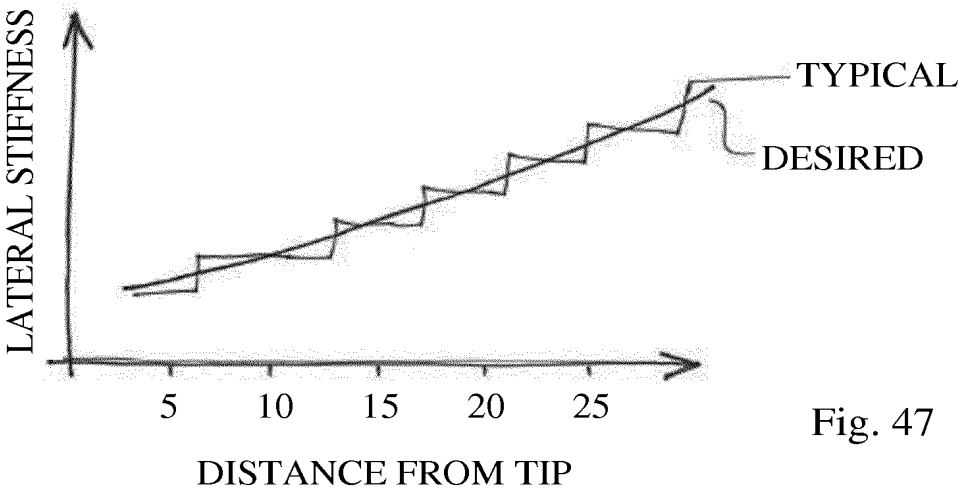
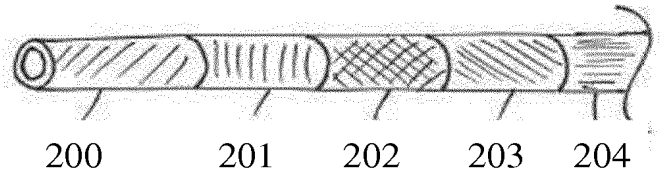


Fig. 47



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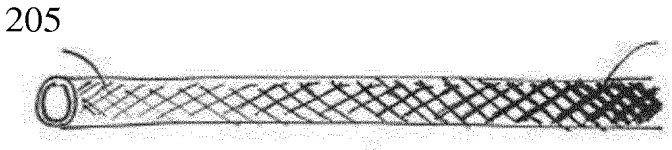


Fig. 49

Fig. 50

Fig. 51

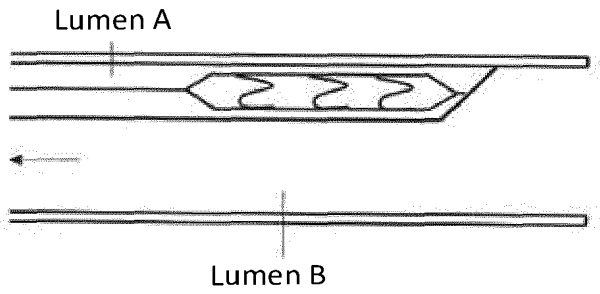


Fig. 53

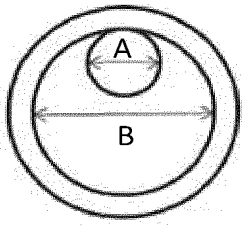


Fig. 52

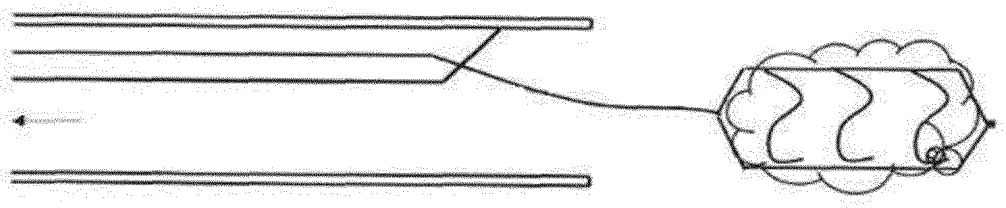
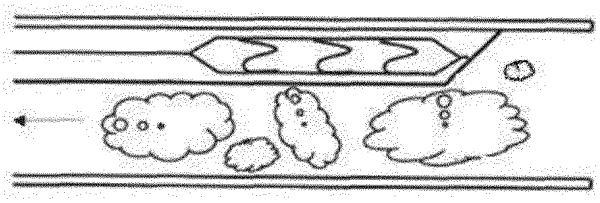


Fig. 54



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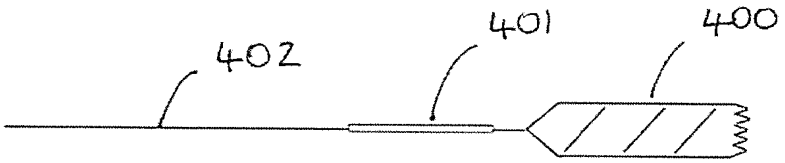


Fig 56

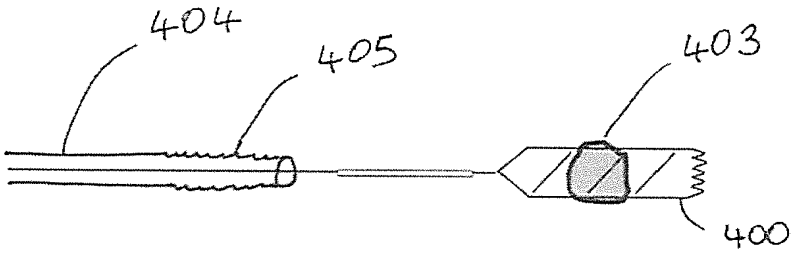
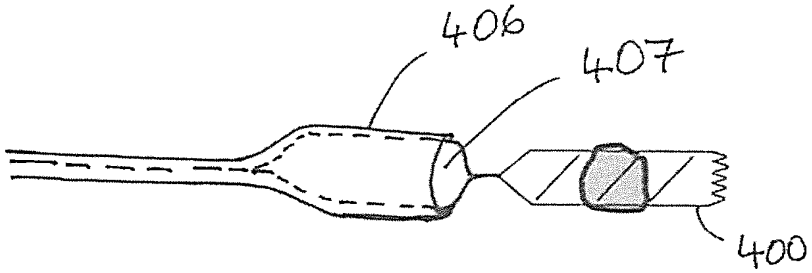


Fig 57



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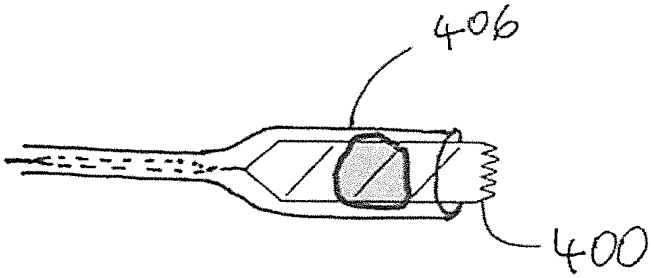

Fig 59

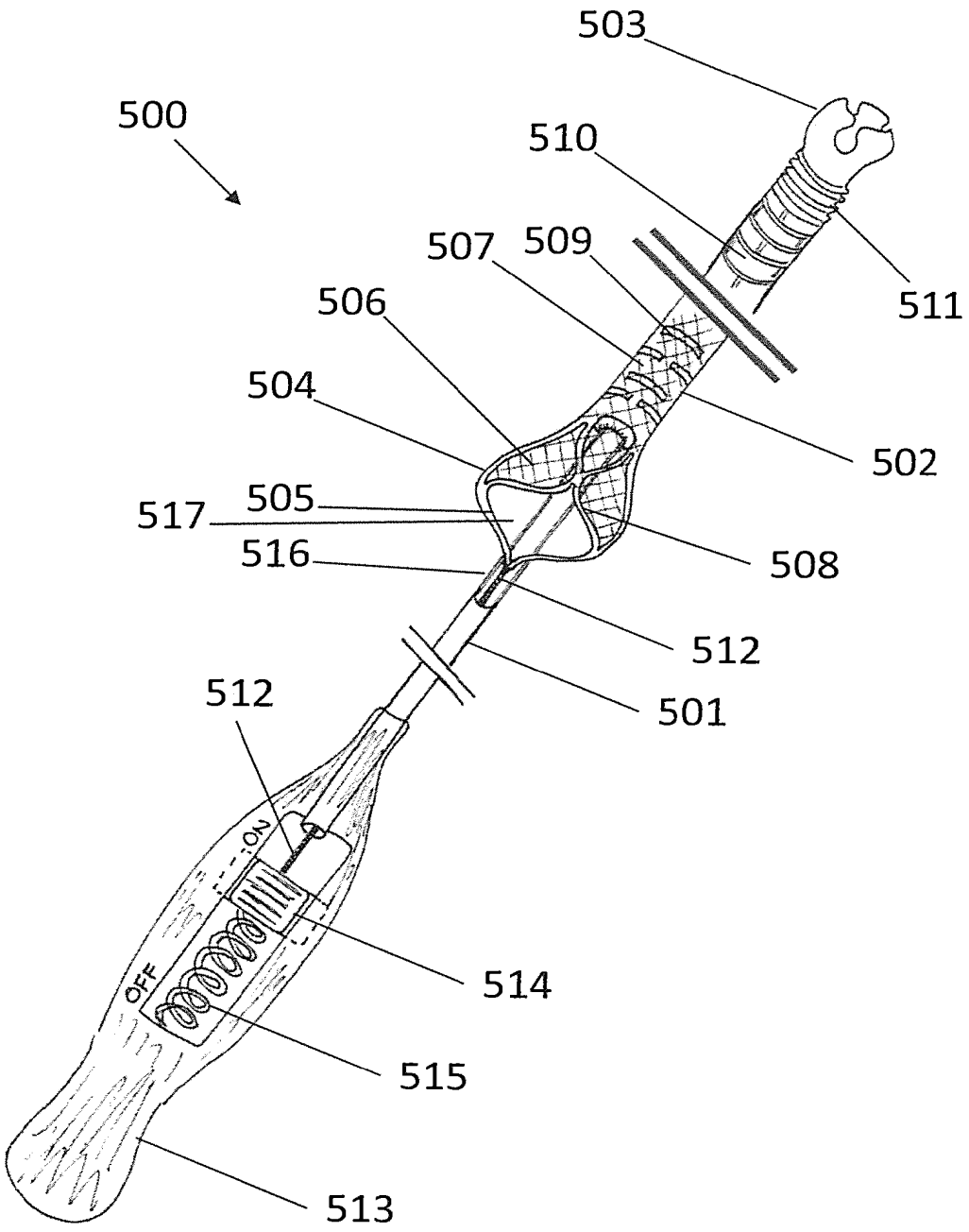
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Fig 60

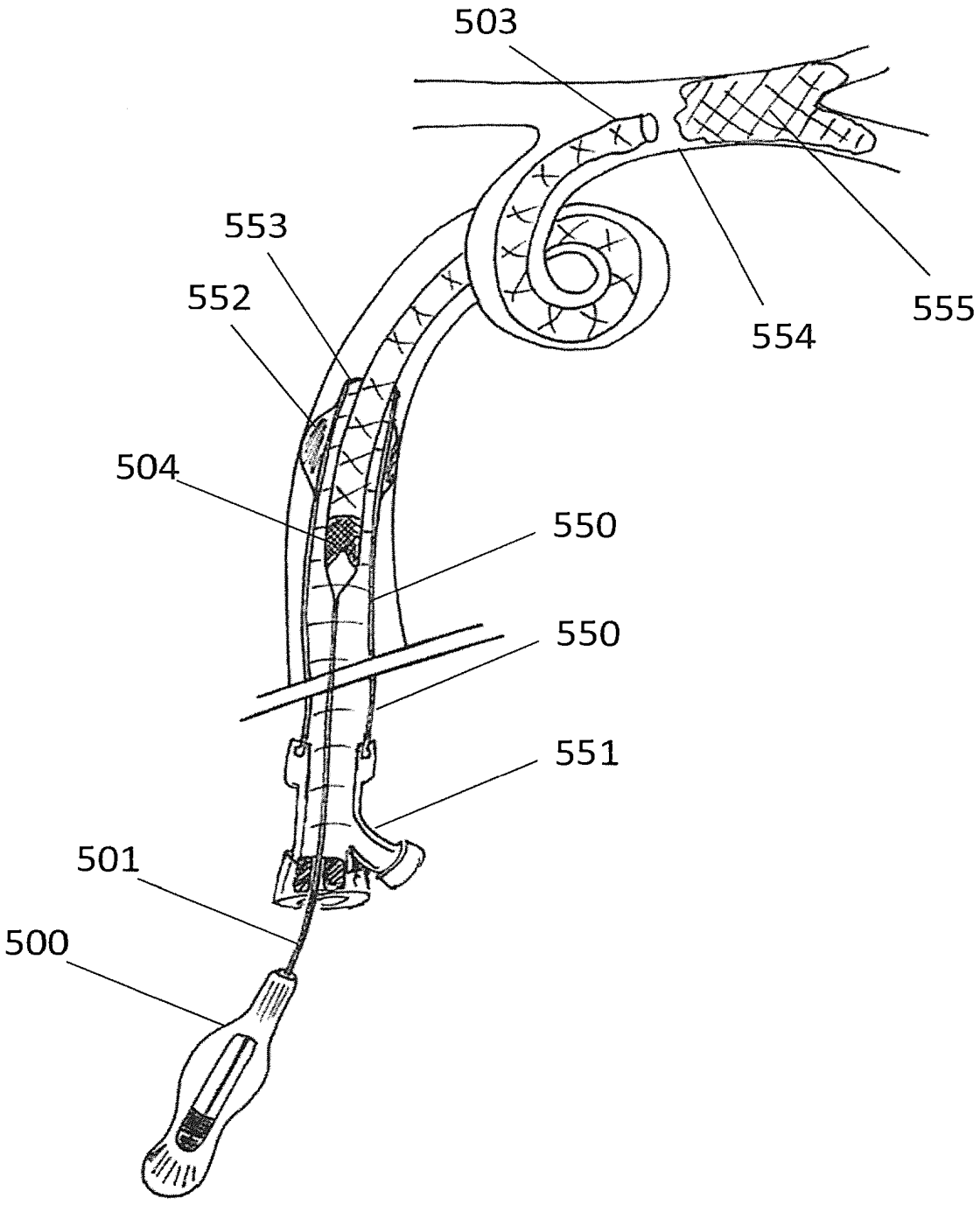

Fig 61a

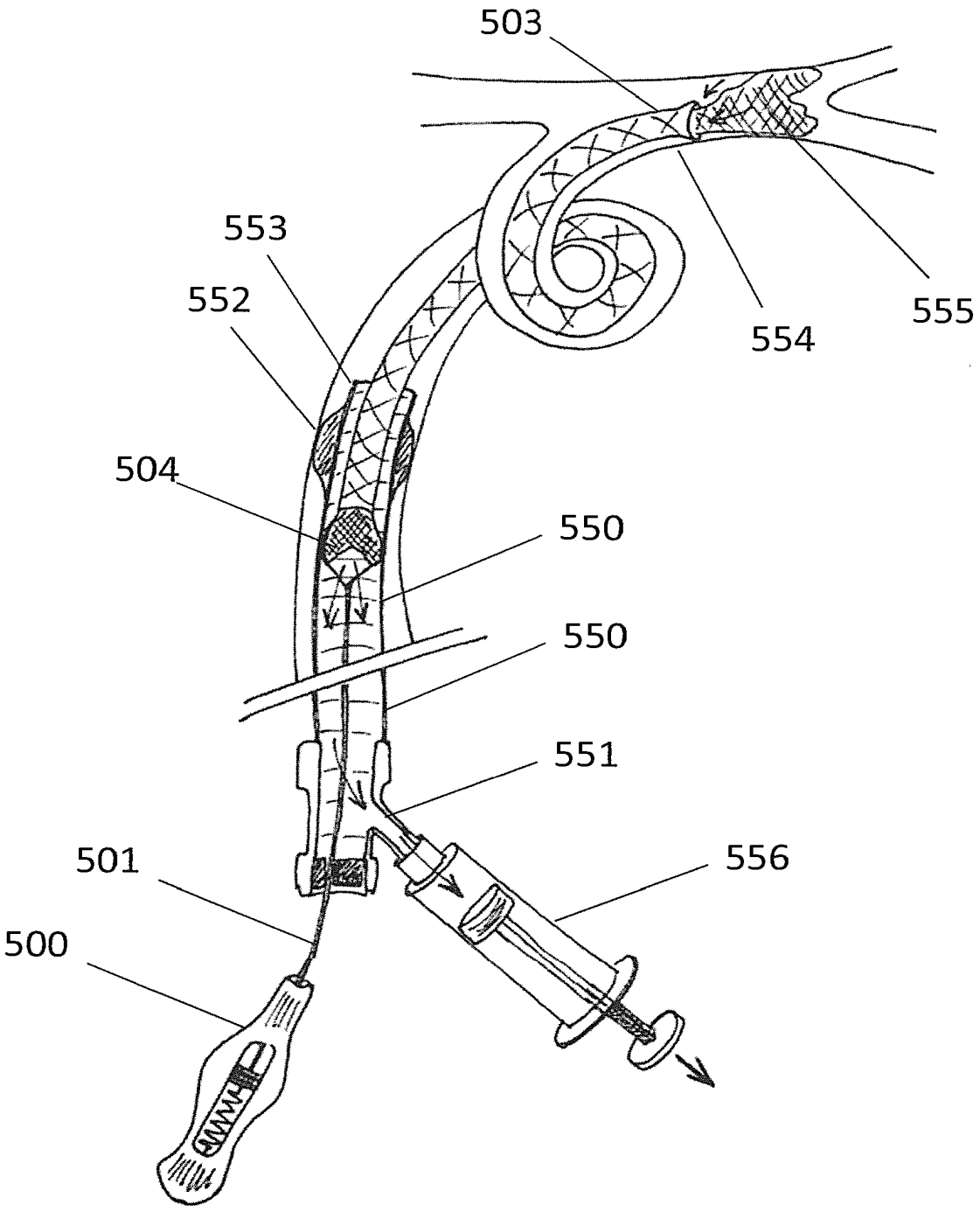

Fig 61b

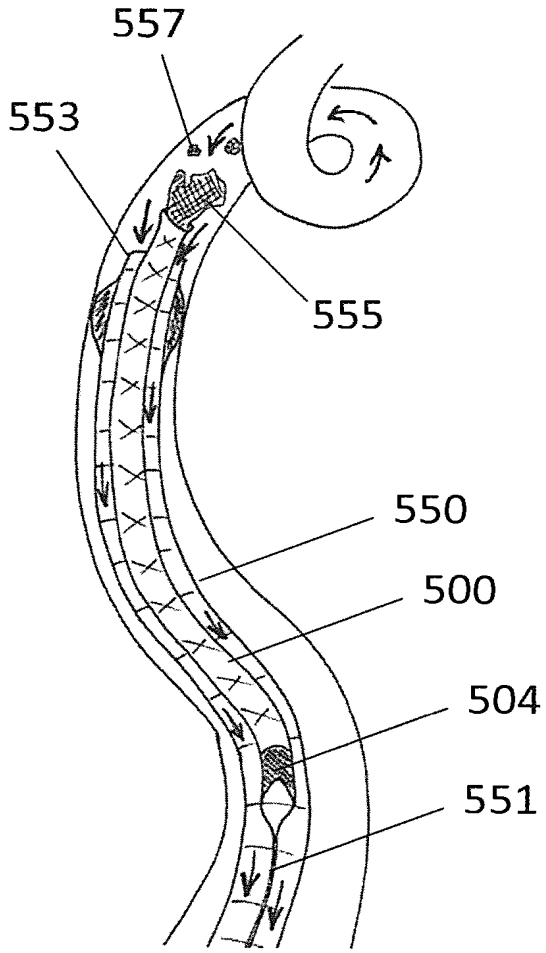

Fig 61c

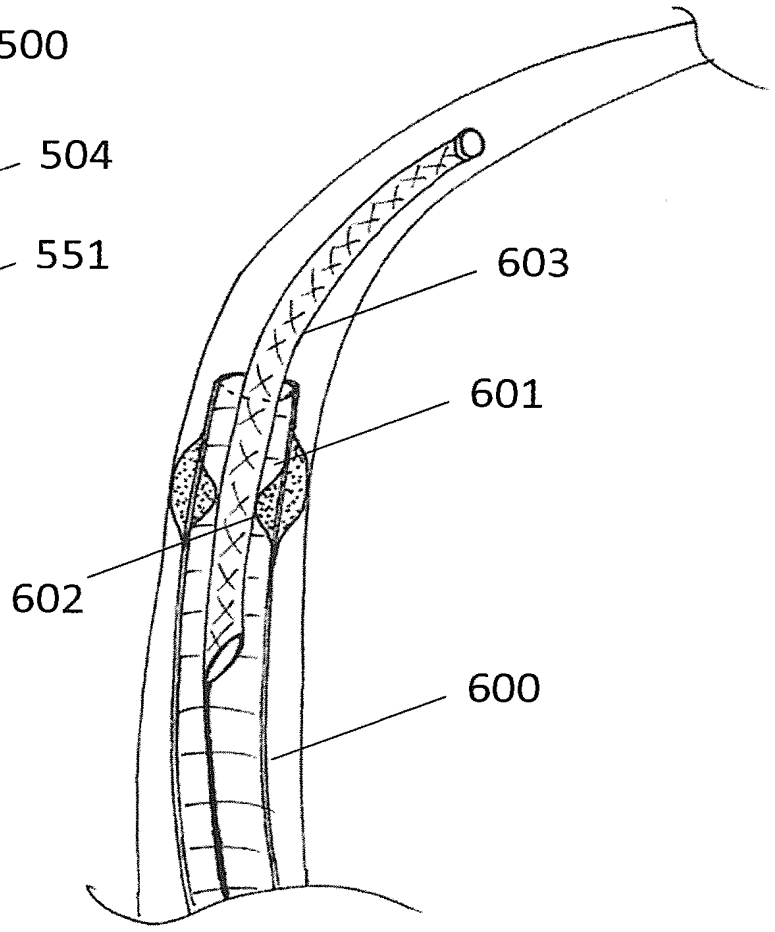

Fig 62

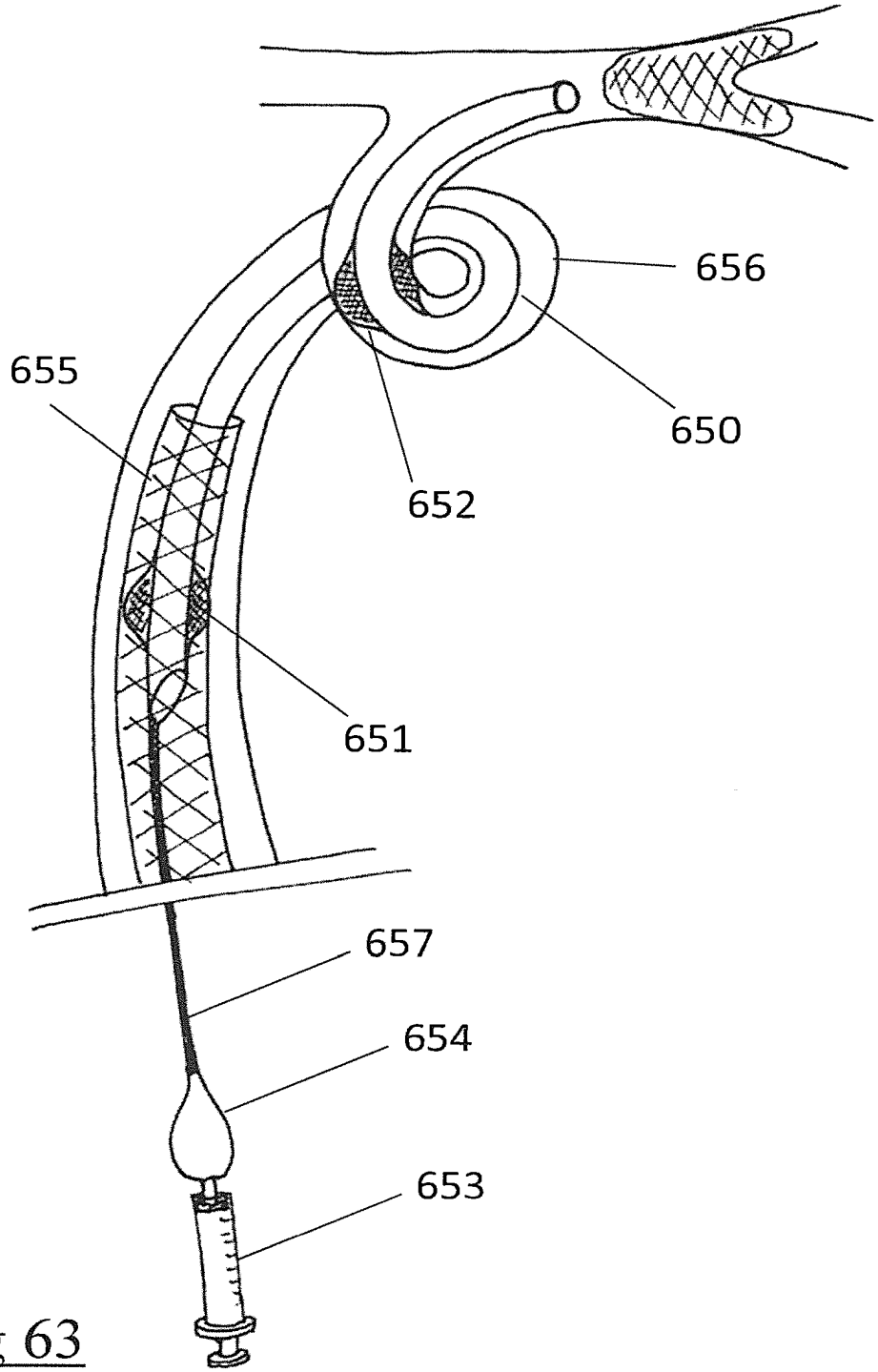

Fig 63

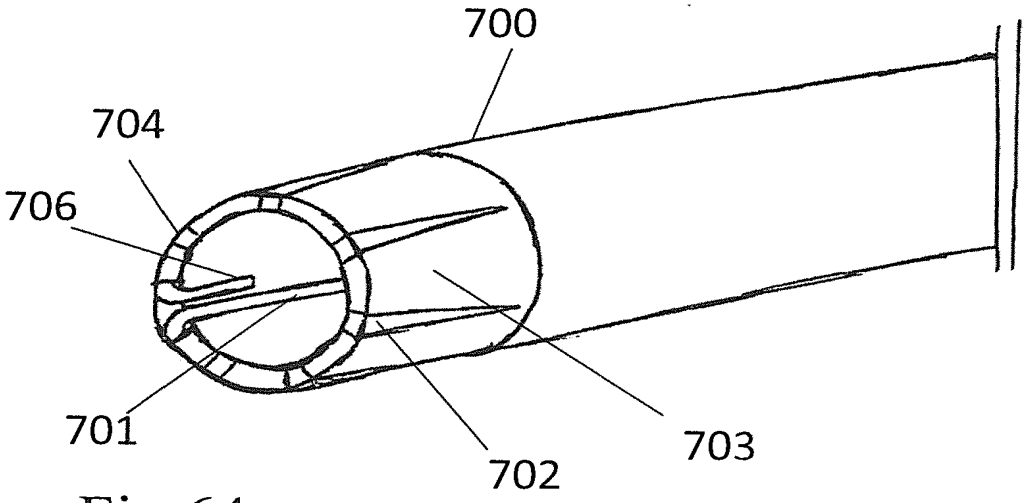

Fig 64a

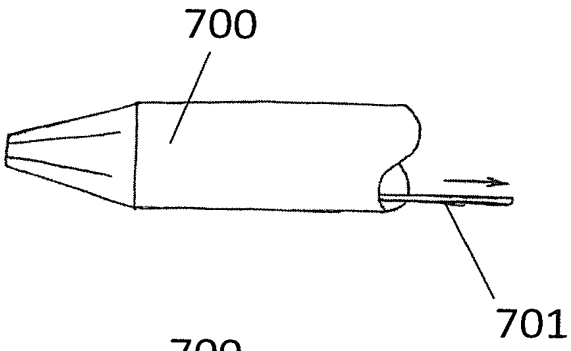

Fig 64b

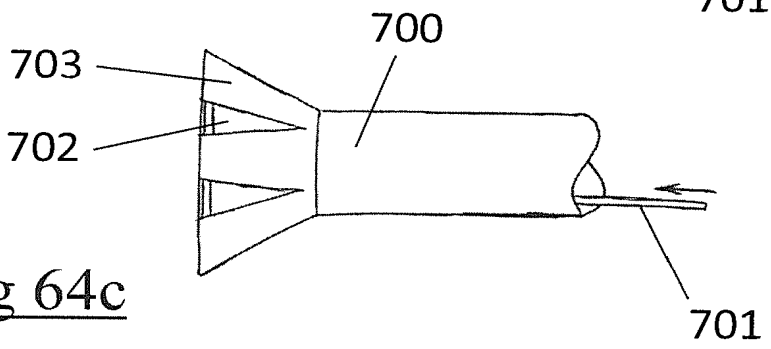

Fig 64c

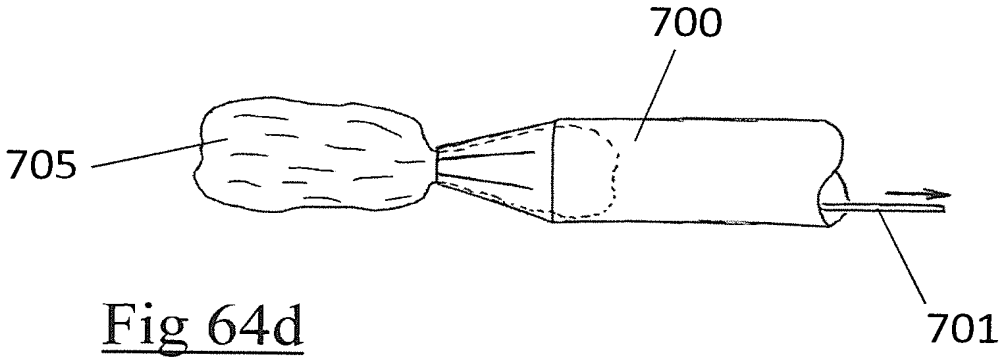

Fig 64d

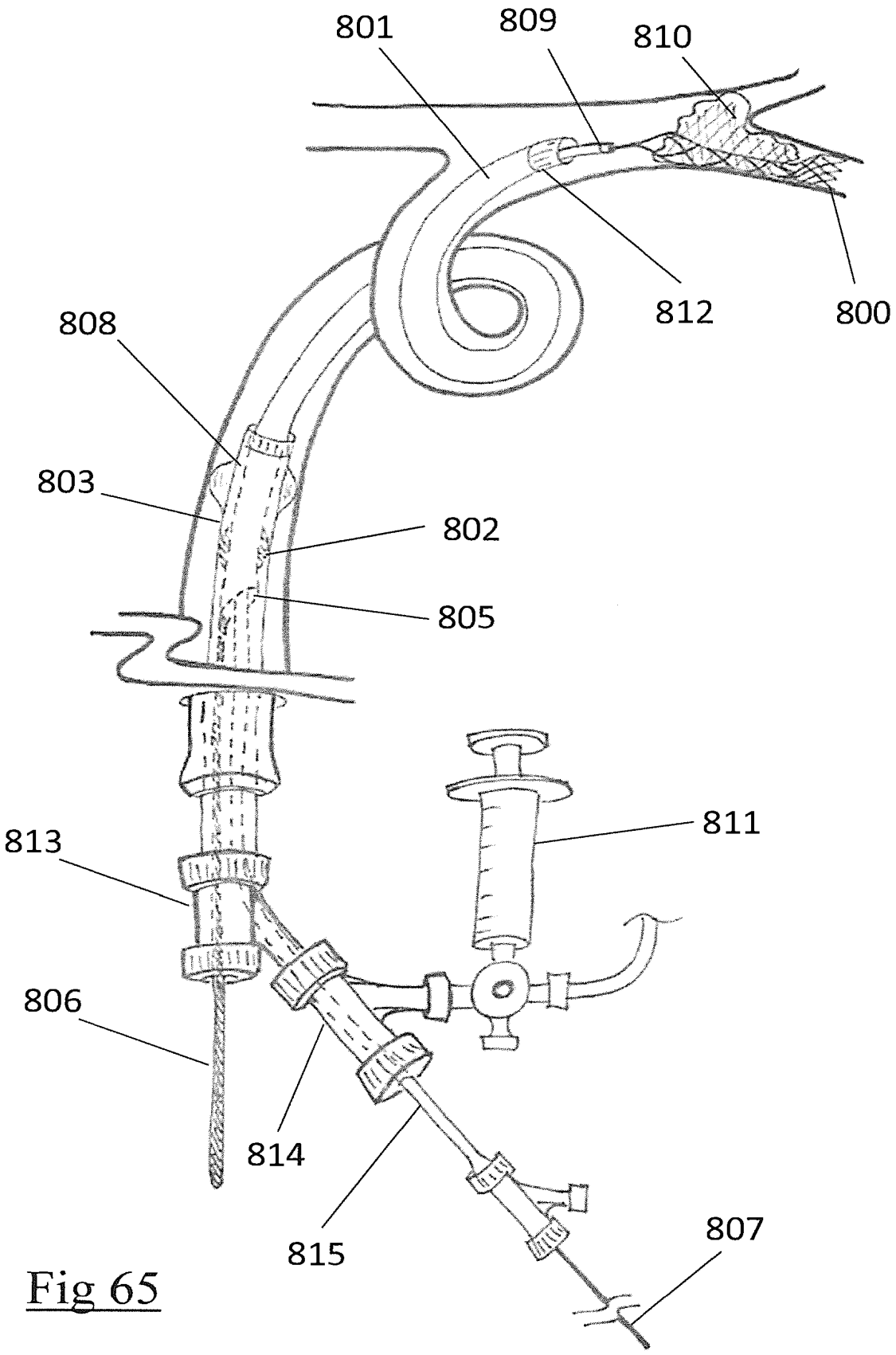

Fig 65

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2015/063104

A. CLASSIFICATION OF SUBJECT MATTER
INV. 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

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	US 8 057 497 B1 (RAJU SESHADRI [US] ET AL) 15 November 2011 (2011-11-15)	1-7, 10-12, 14-16, 19-21, 23-34, 36-38
Y	column 4, lines 17,18, 29-64; figures 2,2a,6 page 5, lines 33-40 page 7, lines 61-67	8,9,13, 17,18, 22,35

Y	US 5 769 871 A (MERS KELLY WILLIAM C [US] ET AL) 23 June 1998 (1998-06-23) column 4, line 64 - column 5, line 13; figures 1-3	8,9,13, 17,18, 22,35

	-/--	

[X] Further documents are listed in the continuation of Box C.

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Date of the actual completion of the international search	Date of mailing of the international search report
2 July 2015	09/07/2015

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	Lee, Ronan

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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 2010/004607 A1 (WILSON SCOTT [US] ET AL) 7 January 2010 (2010-01-07) paragraphs [0007], [0016]; figures 2,4	1-38
A	WO 99/56801 A2 (MICROVENTION INC [US]) 11 November 1999 (1999-11-11) page 21, line 22 - page 23, line 5; figure 6	1-38

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2015/063104

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 8057497 B1	15-11-2011	US 8057497 B1	15-11-2011
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		WO 9956801 A2	11-11-1999

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(30) Priority Data:
62/671,143 14 May 2018 (14.05.2018) US

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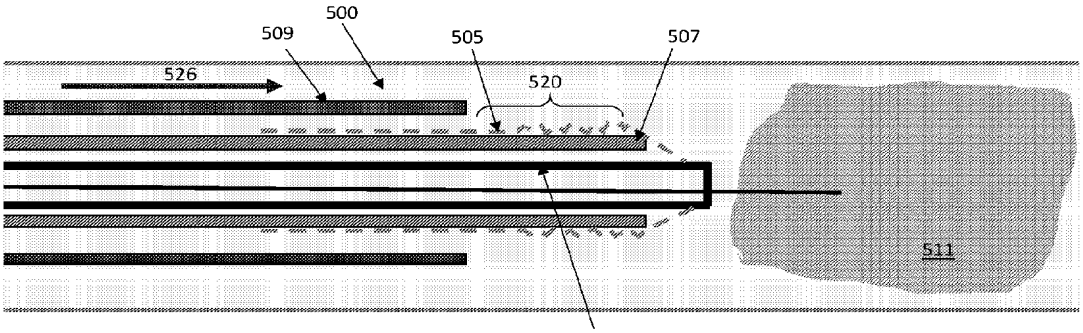

FIG. 5D

(57) **Abstract:** Inverting tube thrombectomy apparatus for removing clot that are configured to prevent compression of the apparatus that may separate the distal end of the apparatus from the clot and may make it difficult to advance the apparatus to engage with the clot, particularly in a tortious vessel. The apparatuses and methods of using them described herein may be adapted to prevent tension in the flexible tube that is rolling and inverting over the distal end of the inversion support catheter when capturing a clot. Also described herein are inverting tube thrombectomy apparatus that are configured to reload either automatically or manually within the vessel to capture additional clot material.

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INVERTING THROMBECTOMY APPARATUSES AND METHODS OF USE

FIELD

[0001] The apparatuses and methods described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses and methods.

BACKGROUND

[0002] Many vascular problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery. It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue, such as blood clots, from within a patient's vasculature may improve patient conditions and quality of life.

[0003] Mechanical thrombectomy devices may be particularly advantageous. There is a definite need for thrombectomy devices, and particularly a mechanical thrombectomy devices that can be easily and accurately delivered through the often tortious anatomy in the peripheral and central vasculature, then reliably deployed to remove clot material. Further, there is a need for devices that are easy and intuitive to operate. 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

[0004] Described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and methods of using and making them. These apparatuses may also be referred to as inverting mechanical thrombectomy apparatuses and/or inverting tube thrombectomy apparatuses.

[0005] In particular, described herein are inverting tube thrombectomy apparatuses that may be deployed within even the most tortious vessels of the anatomy and may maintain their proximity to the clot during operation. Generally, the inverting tube thrombectomy

apparatuses described herein may include an inner puller (which may be configured as a puller catheter), an inverting flexible tube attached at a distal end region of the puller, and an outer inversion support catheter; the flexible tube may initially extend over an external region at the distal end of the inversion support catheter. All or a portion of the inversion support catheter, flexible tube and puller may be housed within an intermediate (e.g., delivery) catheter. In operation, the puller may be pulled to roll and invert the flexible tube over the open distal end of the inversion support catheter. This rolling and inversion of the flexible tube may capture a material, such as a clot, and pull it into the inner lumen of the inversion support catheter as the flexible tube is rolled and inverted.

[0006] Specifically, the inverting tube thrombectomy apparatuses and methods of operating them may prevent or reduce compression of the distal end of the inversion support catheter that may otherwise separate the end of the apparatus from the clot (e.g., kick back) and make further tracking of the apparatus within a tortious vessel difficult. Thus, in some variations of inverting tube thrombectomy apparatuses, pulling on the inverting tube (e.g., woven/braided/etc. tractor) compresses the distal end of the inversion support catheter (particularly in tortious anatomy), and causes it to separate from the clot and make additional tracking difficult within the tortious vessel.

[0007] Thus, any of the apparatuses described herein may be configured to prevent tension in the external portion of the flexible tube that is on the outer surface of the inversion support catheter before and/or during rolling and inverting the flexible tube over the distal end of the inversion support catheter.

[0008] Also described herein are methods for removing a clot (or multiple portions of a clot, or multiple clots) from a vessel. For example, a method of removing a clot from a vessel may include: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an inversion support catheter, a puller catheter slideable within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller catheter and a second end coupled to the inversion support catheter; applying aspiration through a lumen in the puller catheter to hold the clot on a distal end of the puller catheter; pushing the inversion support catheter distally to form slack in the flexible tube; and pulling the puller catheter proximally relative to the inversion support catheter to roll and invert the inversion support catheter over the distal end of the inversion support catheter and pull the clot into the inversion support

catheter. This process may be repeated multiple times without removing the apparatus from the vessel.

[0009] For example, described herein are methods of removing a clot from a vessel, the method comprising: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an inversion support catheter, a puller catheter slideable within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller catheter and a second end coupled to the inversion support catheter; applying aspiration through a lumen of the puller catheter to hold the clot on a distal end of the puller catheter; pushing the inversion support catheter distally to expand the flexible tube radially outward; pulling the puller catheter proximally while advancing the inversion support catheter distally to roll and invert the inversion support catheter over the distal end of the inversion support catheter and pull the clot into the inversion support catheter; and pulling the clot proximally though the lumen of the puller catheter.

[00010] Thus, pushing the inversion support catheter distally to form slack in the flexible tube may include expanding the flexible tube radially outward from the puller catheter.

[00011] Any of these methods may include pulling the clot proximally though the lumen of the puller catheter. For example, pulling the clot proximally through the lumen of the puller catheter may comprise aspirating the clot through the puller catheter, and/or using a wire to draw the clot proximally through the lumen of the puller catheter.

[00012] Any of these methods may include reloading the inverting tube thrombectomy apparatus while still in the vessel so that additional clot may be removed with the same device. Thus, any of these methods may include removing a second clot with the inverting tube thrombectomy apparatus. Reloading the inverting tube thrombectomy apparatus may comprise advancing the puller catheter distally relative to the inversion support catheter. Reloading may be done automatically or manually. For example, advancing the puller catheter distally may releasing the puller catheter so that a bias advances the puller catheter distally (e.g., automatically or semi-automatically).

[00013] In any of these methods, pulling the puller catheter proximally may comprise applying vacuum through the lumen of the puller catheter. Vacuum may be applied through the entire procedure (e.g., continuously) or through just a portion of the procedure, e.g., when drawing the clot proximally through the lumen of the puller catheter.

[00014] Any of these methods may include the use of an inverting tube thrombectomy apparatus that includes an intermediate catheter; the inversion support catheter and the puller catheter may be held (slidably held) within the intermediate catheter for delivery and may be extended from the intermediate catheter when the distal end is near the clot.

[00015] For example, in some variations, the apparatus and/or method of using it may be configured to form slack in an external portion of the flexible tube on the outer surface of the inversion support catheter. Slack may be formed by driving the second end of the flexible tube (that may not be attached to anything, including the intermediate catheter or the inversion support catheter) distally over the inversion support catheter. In some variations the second end of the flexible tube may be held between the inversion support catheter outer surface and the intermediate catheter. For example, in an un-deployed state, the inverting tube thrombectomy apparatus may be tracked through the vasculature with most of the flexible tube, inversion support catheter and puller housed within the intermediate catheter. This assembly may be tracked through the vasculature over a guidewire, for example, in some variations, the puller and the attached first end of the flexible tube may be extended slightly out of the distal end of the intermediate catheter. Once deployed at the clot, the intermediate catheter may be withdrawn proximally (or the pusher, flexible tube and/or inversion support catheter extended distally out of the intermediate catheter) but leaving a portion of the second end of the flexible tractor between the intermediate catheter and the inversion support catheter; advancing the intermediate catheter distally may then bunch up (form slack) the flexible tube. The pusher may be held fixed, advanced distally or (in the variation described below, pulled proximally). Alternatively, in some variations the intermediate catheter may be fully removed from over the flexible tube and advancing it distally may push on the end of the flexible tube (which may include a cuff), to drive the flexible tube distally. The second end of the flexible tube may be adapted so that it may be pushed by the intermediate catheter. As mentioned, the second end of the flexible tube may include a cuff, which may be a region of relative stiffness compared to the adjacent region of the flexible tube.

[00016] In some variations, apparatus and method are configured to both push on the second end of the flexible tube distally, and pull on the first end by pulling the puller (e.g., puller catheter) proximally. This may limit or reduce tension on the outside portion of the tractor. Thus, in any of these methods, the intermediate catheter may be pushed distally at the same time the puller is pulled proximally (at the same, or different rates) to reduce tension on the outside portion of the flexible tube, thereby reducing the compressive force applied to the distal end of the inversion support catheter.

[00017] For example, described herein are method of removing a clot from a vessel that may include: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; positioning the puller and inversion support catheter adjacent to the clot; and pushing a proximal end region of the external portion of the flexible tube distally over the inversion support catheter during one or both of: before or while pulling the puller proximally so that the external portion of the flexible tube rolls and inverts over the distal end of the inversion support catheter.

[00018] Pushing the proximal end region of the external portion of the flexible tube may include pushing the proximal end region of the external portion of the flexible tube by advancing the intermediate catheter distally. Alternatively or additionally, the proximal end region of the external portion of the flexible tube (which may be referred to as the second end of the flexible tube) may be pushed by a different member, such as a push wire or rod.

[00019] In some variations, pushing the proximal end region of the external portion of the flexible tube comprises pushing the proximal end region of the external portion of the flexible tube before pulling the puller proximally to form slack in the external portion of the flexible tube. Slack may refer to a region in which the flexible tube is not under tension, and may be loose; in some variations the slack region may be bunched up on itself. In some variations the slack region may be compressed, so that it expands (e.g., when pulled from the first end) easily.

[00020] In some variations, pushing the proximal end region of the external portion of the flexible tube comprises pushing the intermediate catheter distally to push the proximal end region of the external portion of the flexible tube distally while pulling the puller proximally, wherein the flexible tube is not attached to the intermediate catheter.

[00021] In any of the apparatuses and methods described herein, the flexible tube may be unattached to the intermediate catheter. For example, the second end of the flexible tube may be loose.

[00022] In any of the methods and apparatuses described herein, a vacuum may be applied through the puller. Thus, the apparatus, and particularly the puller, may be adapted to include

a lumen or passage for applying suction. This suction may be used to pull the clot out from the flexible tube once it has been all or partially engulfed, e.g., by the flexible tube.

[00023] In general, any of the methods described herein may include capturing the clot within the flexible tube as the puller is pulled proximally.

[00024] For example, a method of removing a clot from a vessel may include: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; positioning the puller and inversion support catheter adjacent to the clot; forming slack in the external portion of the flexible tube; and pulling the puller proximally so that the external portion of the flexible tube rolls and inverts over the distal end of the inversion support catheter so that the slack in the external portion of the flexible tube is withdrawn into the inversion support catheter.

[00025] In any of these methods pulling the puller proximally may comprise withdrawing all or a majority of the slack into the inversion support catheter before a second end of the flexible tube is moved distally over the inversion support catheter. For example, pulling the puller proximally may comprise withdrawing the slack into the inversion support catheter while applying 1 pound or less of force (e.g., applying 0.75 or less pounds of force, applying 0.5 pounds or less of force, applying 0.4 pounds or less of force, applying 0.3 pounds or less of force, applying 0.25 pounds or less of force, applying 0.2 pounds or less of force, applying 0.1 pound or less of force, etc.) proximally against the distal end of the inversion support catheter.

[00026] In any of the methods described herein, pulling the puller proximally may comprise withdrawing the slack into the inversion support catheter without causing the distal end of the inversion support catheter to withdraw from the clot within the vessel. Thus, the methods described herein may prevent the kickback (e.g., separation from the clot) described above.

[00027] Forming slack may comprise advancing the intermediate tube distally to push at least part of the external portion of the flexible tube distally to form slack in the external portion of the flexible tube over the inversion support catheter. For example, forming slack

may comprise axially compressing the external portion of the flexible tube on the inversion support catheter by driving the second end of the flexible tube distally. Forming slack may include driving a second end of the flexible tube distally without moving the puller proximally.

[00028] For example, a method of removing a clot from a vessel may include: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; positioning the puller and inversion support catheter adjacent to the clot; advancing the intermediate tube distally relative to the pusher to push at least part of the external portion of the flexible tube distally to form slack in the external portion of the flexible tube over the inversion support catheter; pulling the puller proximally so that the external portion of the flexible tube rolls and inverts over the distal end of the inversion support catheter so that the slack in the external portion of the flexible tube is withdrawn into the inversion support catheter; and capturing the clot with the rolling flexible tube to draw the clot into the inversion support catheter.

[00029] Any of the methods described herein may include reducing the tension on the flexile tube (and particularly the portion of the flexible tube that rolls and inverts over the distal end of the inversion support catheter). For example, a method of removing a clot from a vessel may include: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; and positioning the puller and inversion support catheter adjacent to the clot; and pushing a proximal end region of the external portion of the flexible tube distally over the inversion support catheter while pulling the puller proximally so that the

external portion of the flexible tube rolls and inverts over the distal end of the inversion support catheter.

[00030] In some variations, pushing the proximal end region of the external portion may comprise pushing the intermediate catheter distally to drive the proximal end region of the external portion distally.

[00031] Also described herein are apparatuses, including in systems, for removing a clot. For example the apparatus comprising: an intermediate catheter; an inversion support catheter within a lumen of the intermediate catheter; a puller within a lumen of the inversion support catheter; a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; and a handle coupled to the intermediate catheter and the puller, wherein the handle is configured to, when activated by a control on the handle, automatically advance the intermediate catheter while one or more of: holding the puller fixed or withdrawing the puller proximally as the intermediate catheter is advanced.

[00032] The methods and apparatuses described herein may alternatively or additionally include automatic reloading. For example, described herein are apparatuses and methods of using them that automatically reload the flexible tube after it has been inverted and rolled into the inversion support catheter, so that additional (or a different) clot may be captured. Clot that has already been captured within the inverted flexible tube may be removed proximally through the puller (e.g., puller catheter), using a vacuum and/or a wire within the puller. This may allow the device to be repeatedly used to remove clot without requiring the device to be removed from the body. Thus, the apparatus may repeated peck or bite at a clot by repeatedly rolling and inverting the flexible tube into the inversion support catheter, clearing the portion of the clot captured from the flexible tube into the puller, then automatically and/or manually everting the flexible tube back over the distal end and out of the inversion support catheter. In some variations the inversion support catheter may include a narrower inner diameter region near the distal end than more proximal regions, so that the flexible tube within the inversion support catheter may expand outwards slightly more proximally within the inversion support catheter, which may help release the compressed clot from the flexible tube. In some variations, the flexible tube may be lubricious (e.g., coated, etc.) within the inverted configuration (e.g., within the inversion support catheter). The suction through the puller be applied continuously or intermittently. The suction pressure may be monitored to confirm removal of the clot from the flexible tube before re-setting.

[00033] For example, described herein are methods of removing clot from a vessel, the method comprising: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to the clot, wherein the inverting tube thrombectomy apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller within a lumen of the inversion support catheter, and a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; and positioning the puller and inversion support catheter adjacent to the clot; pulling the puller proximally to roll the external portion of the flexible tube over a distal end of the inversion support catheter so that it inverts and is drawn into the inversion support catheter, capturing clot and pulling clot material into the inversion support catheter; applying a vacuum though the puller to suction the clot proximally through the puller; and pulling a second end of the flexible tube proximally to roll and evert the external portion of the flexible tube over the distal end of the inversion support catheter so that it extends proximally over the inversion support catheter.

[00034] In some variations, the method may repeat the step to remove additional clot. For example, the method may include repeating (e.g., cycling) one or more times, the steps of pulling the puller, applying the vacuum and pulling the second end of the flexible tube to remove additional clot material.

[00035] In any of these methods, applying the vacuum may comprise turning the vacuum on while or after the puller is pulled proximally. Pulling the second end of the flexible tube may comprise releasing the puller to allow a bias force to pull the second end of the flexible tube proximally.

BRIEF DESCRIPTION OF THE DRAWINGS

[00036] 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:

[00037] FIG. 1A illustrates one example of an intermediate catheter ("delivery catheter" or I.C.) that may be used with a mechanical thrombectomy apparatus as described herein.

[00038] FIGS. 1B-1C2 illustrate components of a mechanical thrombectomy apparatus (also referred to herein as an inverting tube thrombectomy apparatus); FIG. 1B shows an example of an elongate inversion support catheter that is configured to include a plurality of slots (shown here as transverse slots) arranged along the catheter in order to enhance flexibility of the elongate inversion support catheter while providing sufficient column strength to resist buckling as the tractor tube is drawn proximally to invert. The slot pattern of FIG. 1B is intended as a single example only. Other slot/cut-out patterns may be used. FIGS. 1C1 and 1C2 show a flexible tubes attached to a puller (e.g., puller catheter in FIG. 1C1, or puller wire in FIG. 1C2). The flexible tubes are shown attached at a first end to a distal end region of the puller; in FIG. 1C1 the puller is a puller catheter (PMC) while in FIG. 1C2 the puller is a guidewire. The flexible tube is shown schematically and may be a knitted, woven, or braided material.

[00039] FIGS. 2A-2C illustrate the operation of an inverting tractor mechanical thrombectomy apparatus (e.g., inverting tube thrombectomy apparatus) as described above. FIG. 2A shows the assembled apparatus in which the flexible tube is coupled to the puller and within the elongate inversion support catheter with the flexible tube inverting over the distal end of the elongate inversion support catheter. FIG. 2B shows the apparatus of FIG. 2A delivered within a vessel near a clot. FIG. 2C shows the operation of the apparatus to withdraw the clot by pulling proximally on the flexible tube from within the elongate inversion support catheter so that the flexible tube is pulled to roll over and evert from the inverted configuration on the outside of the distal end of the elongate inversion support catheter into the un-inverted configuration within the elongate inversion support catheter, pulling the clot with it.

[00040] FIG. 3A is an example of a preloaded assembly of an inverting tube thrombectomy apparatus including an intermediate catheter that may be used as described in order to the apparatus though a tortious vessel to a clot location. In this example, all of the other components of the inverting tube thrombectomy apparatus (elongate inversion support catheter) may be held within the intermediate catheter (and may be locked in this position) until deployed, while the pusher (e.g., PMC) and flexible tube are partially extending distally. A guidewire may also be used.

[00041] FIG. 3B shows the inverting tube thrombectomy apparatus of FIG. 3A with the inversion support catheter advanced distally.

[00042] FIGS. 4A-4B illustrate one example of an inverting tube thrombectomy apparatus within a tortious anatomy that may pull away from the clot when deploying the flexible tube

(e.g., when rolling the flexible tube over the distal end and into the inversion support catheter. In FIG. 4A, the inverting tube thrombectomy apparatus is positioned adjacent to the clot. In FIG. 4, in the tortious anatomy, once the puller is pulled proximally to invert the flexile tube (also referred to herein as the tractor tube) over the distal end of the inversion support catheter, the inverting tube thrombectomy apparatus, and particularly the inversion support catheter, may compress, causing the distal face of the flexible tube and the elongate support catheter to pull away from the clot. In a tortious anatomy, such as shown in FIGS. 4A-4B, it may be particularly difficult to advance the apparatus back to the clot (and forward), particularly while the puller pulling the flexible tube over the distal end of the inversion support catheter applies a proximal force against the inversion support catheter.

[00043] FIGS. 4C and 4D illustrate another example of the 'kickback' that may occur in an inverting tube thrombectomy apparatus which may be difficult to correct for in a tortious vessel. In FIG. 4C the inverting tube thrombectomy apparatus (e.g., the distal face of the puller, attached flexible tube and/or inversion support catheter) is positioned adjacent to the clot. In FIG. 4D the puller is withdrawn proximally, rolling the flexible tube over the distal end of the inversion support catheter and into the lumen of the inversion support catheter. In this example, pulling the flexible tube over the distal end moves the distal end away from the clot.

[00044] FIGS. 5A-5L illustrate one example of a method of operating an inverting tube thrombectomy apparatus to remove a clot that alleviates the tension (compressive force) applied by pulling the flexible tube over the distal end opening of the inversion support catheter, preventing the separation of the inverting tube thrombectomy apparatus from the clot. In this example, the method includes forming slack in an external portion of the flexible tube prior to pulling the puller proximally to roll the flexible tube and invert it over the distal end face of the inversion support catheter.

[00045] FIGS. 6A-6C illustrate an example of a method for removing a clot using an inverting tube thrombectomy apparatus that prevents pull back of the end of the inverting tube thrombectomy apparatus from the clot. In this example, the method includes reducing tension in flexible tube as it is rolled and inverted over the distal end of the inversion support catheter by introducing slack (in this example, compressing the flexible tube) prior to rolling and inverting the flexible tube over the distal end face of the inversion support catheter.

[00046] FIGS. 7A-7B illustrate an example of a method of removing a clot using an inverting tube thrombectomy apparatus that prevents pull back of the end of the inverting tube thrombectomy apparatus from the clot. In this example, the method includes

coordinating pushing the second (unattached) end of the flexible tube distally (e.g., by pushing on the intermediate catheter) and pulling the puller proximally.

[00047] FIG. 8 is an example of an inverting tube thrombectomy apparatus that is configured to automatically reload to remove multiple 'bites' of clot without needing to be removed from within the vessel. In FIG. 8, the inverting tube thrombectomy apparatus includes the flexible tube (e.g., a woven tube) a puller, and an inversion support catheter; a return bias (e.g., in this example, a coil spring) is attached to the second end of the flexible tube to reset the flexible tube on the outside of the inversion support catheter after it is rolled and inverted into the inversion support catheter and released.

[00048] FIGS. 9A-9D illustrate a method of removing a clot including automatically reloading the flexible tube without having to remove it from the vessel.

[00049] FIGS. 10A-10B show another example of an inverting tube thrombectomy apparatus that is configured to automatically reload to remove multiple 'bites' of clot without needing to be removed from within the vessel. FIG. 10A schematically illustrates an example of an inverting tube thrombectomy apparatus that includes a self-biased flexible tube that is coupled to an outer region of the inversion support catheter. FIG. 10B shows an example of an embodiment of the inverting tube thrombectomy apparatus including a self-biased flexible tube configured as a stacked braid.

[00050] FIGS. 11A-11F illustrate an example of a method of removing clot and automatically reloading the flexible tube without having to remove it from the vessel.

[00051] FIG. 12 is a schematic illustration (not to scale) of one variation of an apparatus for removing one or more clot(s) from a vessel. This apparatus may be configured to remove multiple clots by repeatedly withdrawing clot and resetting to an initial position; clot material may be withdrawn through the lumen of the puller catheter (e.g., inner catheter).

DETAILED DESCRIPTION

[00052] In general, described herein are inverting tube thrombectomy apparatus having a flexible tube, configured as an inverting flexible tube or an inverting tractor tube ("tractor tube") that may be pulled proximally to invert over and into the distal end of an elongate inversion support catheter. An end of the tractor tube may be coupled to a puller (e.g., pull wire, pull catheter, etc.) to provide the proximal pulling force. In particular, described herein are apparatuses and methods of using them that improve or enhance the ease of use, including tracking of the apparatus within a tortious vessel to remove a clot by rolling the flexible tube into the elongate inversion support catheter and grabbing the clot.

[00053] In general, the apparatus described herein may be configured to prevent compression of the apparatus (e.g., the inversion support catheter) when pulling the puller to roll and invert the flexible tube into the inversion support catheter, which may separate the distal end of the apparatus from the clot and may make it difficult to advance the apparatus to engage with the clot, particularly in a tortious vessel. Any of the apparatuses described herein (and methods of using them) may be adapted to prevent tension in the flexible tube in the region of the flexible tube that is rolling and inverting over the distal end of the inversion support catheter. For example, tension may be reduced in the region of the flexible tube (the external portion of the flexible tube) by pushing from the second, usually loose or unattached, end of the flexible tube on the outside of the inversion support catheter. The flexible tube may be pushed by a member, including a dedicated wire, rod, etc., or by an outer or intermediate catheter. In some variations, the method may include pushing the end (e.g., the second end, opposite from the first end attached to the puller) of the flexible tube distally to form a slack region.

[00054] FIGS. 1A-C2 and 2A-2C illustrate examples of inverting tube thrombectomy apparatus and methods of operating them to remove a clot, respectively.

[00055] An inverting tube thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an inversion support catheter having a distal end and a distal annulus (distal end opening), and a flexible tube assembly (which may be referred to as a tractor tube or tractor tube assembly) including a flexible tube coupled to an elongate puller that is positioned within the elongate inversion support catheter. The flexible tube is configured to roll and invert over the distal end opening of the elongate inversion support catheter when pulled proximally by the puller. Knitted tractor tubes are of particular interested and described herein, although it should be understood that other tractor tubes, e.g., woven, braided, etc., may be used.

[00056] Tracking of any of the inverting tractor mechanical thrombectomy apparatus described herein may include an intermediate catheter (I.C.) as a delivery catheter along with a guidewire. For example, FIG. 1A illustrates an example of a typical intermediate catheter 101. Note that in some variations an intermediate catheter is not needed or used and the inverting tractor mechanical thrombectomy apparatus may be delivered to the deployment site near the clot to be removed without the need for an intermediate catheter.

[00057] FIG. 1B illustrates one example of an inversion support catheter. In this example, the elongated inversion support catheter 103 is formed of a normally high column-strength material (such as a metal, e.g. Nitinol) having a number openings (e.g., cut-out regions) or

slots along the length to provide enhanced flexibility. The distal end of the elongate inversion support catheter is open 105. Either the entire length or a portion of the length may be cut/slotted as described. The elongate inversion support catheter includes a catheter body having a distal end region that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 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] In FIG. 1B, the elongate inversion support catheter is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of compressive force is applied (e.g., able to withstand at least about 500g, at least about 700 g, at least about 600 g, at least about 500 g, at least about 400 g, at least about 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include an elongate inversion support catheter that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like. In FIG. 1B the catheter 103 of the elongate inversion support catheter may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00059] The inversion support catheter may be solid (e.g., may not include the cuts/slots shown in FIG. 1B).

[00060] In some variations the distal end 105 of the elongate inversion support catheter is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in

some variations the distal tip (end) may be curved or radiused, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[00061] FIG. 1C1 shows an example of a flexible tube 111 coupled to a puller 113, forming a pullable tractor assembly 140. In this example, the tractor tube 111 is shown integrated with the puller 113 and extending back over the puller. The puller in this example is a catheter (e.g. a micro catheter, also referred to herein as a PMC or pull micro catheter). In this example, the opposite end of the flexible tractor tube 111 is open and free (e.g., not connected to the puller or catheter, e.g. elongate inversion support catheter, intermediate catheter, etc.). This open, free, end may be adapted to be expanded and held open, e.g., by shape setting back on itself and/or by including an annular bias, to enhance deployment and positioning of the catheter between the flexible tractor tube and the puller. In FIGS. 1C1 and 1C2, the tractor tube is formed of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The flexible tube 111 is shown extended from the puller in a first configuration. The relaxed outer diameter of the flexible tractor in this first configuration may have 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, or it may be approximately the same. The flexible and tubular tractor 111 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The tractor 111 may be configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first configuration to a radial diameter that is between 1.1 and 10 times (e.g., between 1.1x and 5x, between 1.1x and 4x, etc.) the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained. In FIG. 1C2, the tractor tube 111 is shown coupled to a guidewire (non-hollow structure) 115. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00062] The flexible tubes (e.g., tractor tubes) described herein generally comprises a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support. The flexible tube may be formed of a knitted material, and may be configured (e.g., sized, oriented, etc.) to roll smoothly over the distal end opening of the elongate inversion support catheter. The flexible tube may be configured so that it is doubly biased, in order to prevent jamming and to grab and compress relatively large clots as it rolls and inverts into the elongate inversion support catheter at the distal end opening of the elongate inversion support catheter; the flexible tube may be biased so that it has an expanded (e.g., relaxed) un-inverted configuration having an outer diameter that is approximately the

same or slightly larger than the inner diameter of the elongate inversion support catheter, which may be referred to as a second configuration of the flexible tube. The flexible tube may also be further biased so that it has an expanded (e.g., relaxed) inverted configuration (which may be referred to as a first configuration) having an inner and outer diameter that is larger than the outer diameter of the elongate inversion support catheter. The inner diameter in this first configuration may be greater than 1.2x (e.g., between 1.2x and 10x, between 1.2x and 8x, between 1.2x and 6x, between 1.2x and 5x, between 1.2x and 3x, etc.) the outer diameter of the inversion support catheter. Thus, when the flexible tube is placed in and over the distal end of the inversion support catheter, a first (inner) portion of the tractor tube is within the distal end of the elongate inversion support catheter in the un-inverted configuration and it is biased to expand towards (and in some configuration against) the inner diameter of the inversion support catheter; the region of the flexible tube that is inverted over the distal end opening of the inversion support catheter and extends proximally down the outside of the inversion support catheter is in an inverted configuration in which the inner diameter of the flexible tube is biased to be larger than the outer diameter of the inversion support catheter. This double-biased configuration may be a result of the weave pattern (e.g., knitting), and/or a shape setting of the material forming the tractor tube, which may be a shape memory material. As a result, the inverting portion of the flexible tube, where it rolls an inverts over itself at the distal end of the inversion support catheter may be prevented from collapsing on itself as the tractor tube is rolled and pulled into the inversion support catheter. In some variations this configuration may also result in a somewhat flattened (e.g., and in some cases "trumpet shaped") distal end face that is rolling over the distal end opening of the elongate inversion support catheter. The trumpet-shaped distal end may have a teardrop-shaped cross-section. In some variations, the distal end face of the flexible tube may be T-shaped.

[00063] Also described herein are variations in which the first configuration of the flexible tube on the outside of the inversion support catheter (which may be referred to herein as an elongate inversion support catheter) maybe flush or nearly flush with the outer diameter of the inversion support catheter, e.g., within 50%, 40%, 30%, 20%, etc. of the outer diameter of the inversion support catheter.

[00064] The flexible tube may be coupled to a puller that is within the lumen of the inversion support. The puller may be a wire, filament, rod or more preferably a catheter or tube (and may be referred to herein as a pull micro catheter or "PMC" for convenience). A

guidewire may be passed through the flexible tube, and therefore through the inversion support and the tractor tube. As will be described herein, this may be used for positioning.

[00065] The inversion support catheter may be configured as a catheter having a distal end opening into which the tractor inverts. The flexible tube may invert and rolls back into itself and may be drawn into the inversion support in a conveyor-like motion; the outward-facing region rolls around to become an inward-facing region, e.g., within the lumen of the inversion support catheter. The rolling motion may thus draw a clot or other object within a vessel into the inversion support. The inversion support catheter may be shaped or configured to have a sufficient column strength to withstand the compressive pulling force of the flexible tube as it is drawn (and rolled, inverting) into the distal end of the inversion support catheter. The inversion support catheter may be slotted (e.g., may include a plurality of slots or openings) to provide increased flexibility as well as column strength. However, as will be described herein, many inversion support catheters may become less flexible (e.g., more rigid) when a compressive force is applied to the flexible tube, either as a result of pulling the flexible tube proximally, either from within the inversion support catheter, or from the outside of the inversion support catheter as the flexible tube brushes against the vessel and/or a delivery catheter when being driven distally towards a clot.

[00066] The methods and apparatuses described herein may be used with any of the apparatuses and methods described, for example, in U.S. app. no. 15/291,015, filed on 10/11/2016 ("Mechanical Thrombectomy Apparatuses and Methods") and U.S. app. no. 15/496570, filed on 4/25/2017 ("Anti-Jamming and Macerating Thrombectomy Apparatuses and methods"), previously incorporated by reference in their entirety.

[00067] The inverting tube thrombectomy apparatus (e.g., a mechanical thrombectomy apparatus) may be inserted through a vessel such as a blood vessel, artery, etc., until a distal end, or a distal-most end, of the inverting tube thrombectomy apparatus is proximate to a clot. The clot may be immediately adjacent to the end of the apparatus, or it may be within a few cm (e.g., within 1 cm, within 2 cm, within 3 cm, within 4 cm, etc.). This may be detected by visualization, such as fluoroscopy. Thus the apparatuses described herein may include one or more markers for visualization. Contrast may be used to visualize the clot and/or may be released from the apparatus. The apparatus may be deployed in a pre-loaded/pre-assembled configuration, as will be described in more detail below.

[00068] In any of these methods described herein, the flexible tube may be knitted and/or the apparatus may be configured with the opening into the vacuum lumen (e.g., through the puller catheter) at the distal-most end of the device, so that the flexible tube extends behind

(proximal) the distal-facing end of the puller catheter. For example, the method of removing a clot from a vessel may include: advancing an inverting tube thrombectomy apparatus through a vessel until a distal end of the inverting tube thrombectomy apparatus is proximate to a clot, wherein the inverting tube thrombectomy apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller catheter within a lumen of the elongate support catheter, and a knitted tube having a first end coupled at a distal end region of the puller catheter, wherein knitted tube inverts over a distal end of the inversion support catheter and extends proximally between the intermediate catheter and the inversion support catheter, further wherein the knitted tube comprises a filament that is knitted to form a plurality of interlocking loop stitches; advancing the puller catheter distally so that a distal face of puller catheter extends distally from the inverting tube thrombectomy apparatus further than the knitted tube; applying a vacuum through the puller catheter to engage the clot with the distal face of the puller catheter; and pulling the puller catheter proximally to roll the knitted tube over a distal end of the inversion support catheter so that the knitted tube inverts over the distal end of the inversion support catheter, captures the clot, and pulls the clot proximally into the inversion support catheter.

[00069] The second end of the flexible tube may comprise a cuff that is less flexible that a region of the tube adjacent to the cuff. As will be described in more detail below, the cuff may be formed as a material attached to or applied onto/over the end of the flexible tube. For example, the second end of the flexible tube may comprise a cuff formed of a polymeric material applied onto/over the knitted tube. The cuff may be slit or cut (e.g., all or partially along its length) to provide some flexibility when pulling over or around the end of the tube. For example, the cuff may include longitudinal slits along its length. The cuff may have a durometer that is greater than the durometer of the flexible tube (e.g., knitted tube). The cuff, in some variations, is thicker than the flexible tube. In any of the variations described herein, the cuff may be radiopaque (e.g., by including a radiopaque material, such as platinum) on or within the cuff.

[00070] FIG. 2A illustrates an example of a deployed inverting tube thrombectomy apparatus 200. In FIG. 2B the inverting tractor mechanical thrombectomy apparatus is shown deployed near a clot 209 within a vessel. In the deployed configuration the puller 201 (shown here as a puller micro catheter) is held within the elongate inversion support catheter so that the flexile tube 203 extends from the end of the puller and expands toward the inner radius of the elongate inversion support catheter 207; at the distal end opening of the elongate inversion support catheter the flexible tube inverts over itself and extends proximally in an

inverted configuration over the distal end of the elongate inversion support catheter. As shown in FIG. 2C, by pulling the puller proximally, the flexible tube may roll and invert over the distal end opening of the elongate inversion support catheter, drawing the adjacent clot into the elongate inversion support catheter, as shown.

[00071] FIG. 2A the inversion support catheter is positioned between the flexible tube and the puller so that the flexible tube can be pulled proximally by pulling on the puller and rolling the flexible tube into the elongate inversion support catheter so that it inverts. The portion of the flexible tube that is inverted over the distal end of the elongate inversion support catheter has an outer diameter that is greater than the outer diameter of the elongate inversion support catheter. In some variations the diameter (e.g., inner diameter) of the external portion of the flexible tube outside of the inversion support catheter may be approximately the same diameter (e.g., within 1.01x and 1.3x) of the outer diameter of the inversion support catheter. In some variations, the flexible tube may be biased so that it has a relaxed expanded configuration with a diameter that is greater than the outer diameter (OD) of the elongate inversion support catheter; in addition, the flexible tube may also be configured (e.g., by heat setting, etc.) so that when the flexible tube is inverted and rolled over the distal end opening into the elongate inversion support catheter, the inverted flexible tube within the elongate inversion support catheter has an outer diameter that is greater than the inner diameter of the elongate inversion support catheter (e.g., greater than 0.1x, 0.5x 0.6x, 0.7x, 0.75x, 0.8x, 0.9x, 1x, etc. the inner diameter, ID, of the elongate inversion support catheter. This combination of an un-inverted diameter of the flexible tube of greater than the diameter of the OD of the elongate inversion support catheter and an inverted diameter of the flexible tube of greater than about 0.7x the ID of the elongate inversion support catheter is surprisingly helpful for preventing jamming of the apparatus, both when deploying the apparatus and when rolling the flexible tube over the distal end opening of the elongate inversion support catheter to grab a clot. The flexible tube may be expandable and may be coupled to the puller as shown. In some variations the flexible tube and the puller may comprise the same material but the flexible tube may be more flexible and/or expandable, or may be connected to elongate puller (e.g., a push/pull wire or catheter).

[00072] In FIG. 2C the clot may be drawn into the elongate inversion support catheter by pulling the flexible tube proximally into the distal end of the elongate inversion support catheter, as indicated by the arrows 211, 211' showing pulling of the inner portion of the flexible tube, resulting in rolling the flexible tube over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled

into the catheter, shown by arrows. The end (e.g., the second end) of the flexible tube outside of the catheter may be "loose" relative to the outer wall of the catheter.

[00073] In general the inverting tube thrombectomy apparatuses described herein may be highly flexible, both before actuating and during operation. For example, the flexible tube may not increase the stiffness/flexibility of the catheter of the elongate inversion support, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortious vessels of the neurovasculature. Described herein are flexible tubes 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 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.

[00074] As mentioned, the flexible tubes may be woven, braided and/or knitted materials. For woven and braided materials, which may include a plurality of fibers that are woven or braided to form the inverting tube, these structures may be tuned to prevent jamming and/or to reduce the force necessary to pull the flexible tube and invert over the catheter tip. For example, the mechanical atherectomy apparatus may include a braid-type flexible tube that can roll freely around the tip of catheter even in a tortuous anatomy and when grabbing clot by tuning one or more of the braid structure; minimizing the braid angle; including a hydrophilic coating on the distal aspect of the catheter outer diameter (OD) or the inner diameter (ID) of the braid (e.g., flexible tube); including a radiused wall on the catheter; and/or increasing the stiffness of the distal tip region relative to adjacent proximal regions. Alternatively it may be advantages to have a hydrophilic coating on 1, 3, 5, 10, or 15 cm of the distal ID or the entire catheter ID. This may even enhance aspiration of the clot without a tracking element.

[00075] As mentioned, the flexible tube (e.g., braided, woven, knitted, etc.) may be configured to collapse down into the inner diameter (ID) of the catheter as little as possible. For example the flexible tube may collapse to an ID that is greater than, equal to, or within 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter inner diameter (ID)/Catheter Tip OD, since, when the flexible tube is being pulled around catheter tip it may create axial tension on the flexible tube (e.g., braid, knit, etc.) that can inadvertently cause the flexible

tube to jam on the catheter tip. When flexible tube is pulled around catheter tip, the flexible tube is being pulled in the axial orientation creating axial tension on flexible tube structure as the flexible tube is being pulled through the catheter ID. By having the flexible tube elements jam at an ID greater than or equal to 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter ID (or in some variations, OD), when being axially tensioned, the flexible tube is less likely to grab/synch down onto the catheter tip, helping the braid roll around the catheter tip with less axial force applied by the user. If less axial force is required by the user to pull the flexible tube structure around the tip then the catheter tip is less likely to buckle or deflect when retracting the flexible tube. It may be advantageous to minimize the chance the catheter tip will buckle. The flexible tube can be tuned to "jam" at a specific ID by controlling any of the following variables and in any combination: selecting a specific number of braid ends, selecting the size/diameter of the braid ends; selecting the braid material (e.g., multifilament or monofilament); heat setting the bias on the braid (e.g., braid diameter); and selecting a braid pattern, e.g., 1x2, 1x1 or any other pattern.

[00076] The braid angle may be minimized to prevent locking up of the rolling of the flexible tube over the catheter end opening. Typically, the lower the braid angle (e.g., 45 degrees or less, 40 degrees or less, 35 degrees or less, 30 degrees or less, 25 degrees or less, 20 degrees or less, etc.) the less likely it is to have the braid cross over points catch on the catheter tip.

[00077] In any of the variations described herein, the catheter and/or a surface of the flexible tube may be coated to enhance rolling over the distal end region of the catheter. It may be helpful to have a hydrophilic coating on the distal aspect of the catheter OD or the ID of the flexible tube so the flexible tube can more easily side over the catheters distal end and around the tip of the catheter when pulled through the inside of the catheter.

[00078] The radius wall of the catheter tip may be chosen/set to within a range that allows sliding. For example, it may be helpful for the tip of the catheter to have the largest radius possible but at least 0.0025" radius wall on the catheter, ideally approximately 0.005" radius wall.

[00079] The stiffness of the distal of the elongate inversion support catheter may be sufficiently stiff to prevent collapse as the flexible tube is pulled; it may also be lubricious (e.g., by a coating or material property). The distal most section of the elongate inversion support catheter tip (e.g., the last 5mm) may be fabricated of a material which is stiff enough and lubricious enough so the distal tip of the catheter does not collapse or buckle inward ward

when the braid structure is rolling around the catheter tip. Thus, the distal tip may have a stiffness that is greater than the more proximal region at the distal end of the catheter.

[00080] It may be helpful or desirable to have pores in the flexible tube. A lack of gaps or small pore size may limit the ability of the braid to grab clot. Alternatively or additionally, it may be desirable to form a braid structure with texture. One example is to braid two or more different diameter braid ends into the same structure: the difference in braid end diameters will help form a texture to the braid structures outer surface, aiding the grabbing of the clot when rolling the braid-dozer around the catheter tip.

[00081] As an alternative (or in addition) the flexible tube may be configured to lock so it does not compress in diameter during axial load by adding a coating, laminate or adhesive to the braid at a desired diameter. Adding a thin coating, laminate or adhesive can inhibit the braid elements from sliding with respect to each other, thereby locking the braid to a specific diameter. The coating can be applied while leaving the majority of the pores and pore area substantially open. Examples of thin coatings include urethanes and silicones with and without hydrophilic coatings and hydrophilic coatings with no tie layer.

[00082] FIG. 3A shows one example of a pre-loaded inverting tube thrombectomy apparatus for removing a clot from a vessel that may be delivered through a tortious anatomy. In this example, the apparatus may include an intermediate catheter 303 having a distal end 305. The intermediate catheter (I.C.) may be considered part of the inverting mechanical thrombectomy apparatus, although in other variations it may be considered a separate component that is used with the inverting mechanical thrombectomy apparatus. The apparatus also includes an elongate inversion support catheter 307 within the lumen of the intermediate catheter. The elongate inversion support catheter 307 has a distal end 311 and a distal end opening. The apparatus also includes a puller 319 extending distally within the elongate inversion support catheter and a flexible tube 315 extending proximally from a distal end region of the puller. The puller extends from the distal end of the intermediate catheter and the distal end opening of the elongate inversion support catheter.

[00083] In the configuration shown in FIG. 3A, the elongate inversion support catheter is held within the lumen of the intermediate catheter so that the distal end opening of the elongate inversion support catheter is proximal to the distal end opening of the intermediate catheter by a first distance 325. This distance may be between about 1mm and about 10 cm (e.g., between about 2 mm and about 10 mm, between about 2 mm and about 20 mm, between about 2mm and about 30 mm, etc.). The elongate inversion support catheter may be fixed in position relative to the intermediate catheter, so that as the two move together, until

released. For example, the proximal ends of the intermediate catheter and the elongate inversion support catheter may be removably coupled.

[00084] The flexible tube in the pre-assembled apparatus of FIG. 3 extends between the elongate inversion support catheter and the intermediate catheter for some second distance along the length 323 of the elongate inversion support catheter. Securing the end of the flexible tube between the I.C. and the distal end of the elongate inversion support catheter may help both hold it in place, so that the flexible tube may be pushed formed (e.g., in compression). For example, the second length 323 may be between about 1 mm and about 50 cm (e.g., between about 5 cm and about 10 cm, between about 1 cm and about 20 cm, between about 1 cm and about 10 cm, between about 2 cm and about 20 cm, between about 2 cm and about 10 cm, etc.).

[00085] The portion of the flexible tube 315 and puller 319 (e.g., pull micro catheter, or pmc) in this pre-loaded example may extend distally and ride over the guidewire 317. The flexible tube and puller may also be longitudinally fixed relative to the intermediate catheter 303 (e.g., by releasably locking, e.g., at the distal end region) or they may be somewhat longitudinally slideable (and, in some variations, prevented from exceeding a range of, e.g., between about 1 mm and 20 cm from the distal end opening 305 of the intermediate catheter.

[00086] In this example, the portion 327 of the flexible tube 315 that extends outside of the intermediate catheter 303 may be between about 1 mm and about 20 cm (e.g., between about 1 cm and about 7cm, between about 1 cm and about 10 cm, between about 1 cm and about 15 cm, between about 2 cm and about 10 cm, between about 2 cm and about 7 cm, etc.). As mentioned, this distance may be fixed (e.g., by fixing the puller with respect to the push catheter and/or I.C.), or variable. In any of these variations, the puller may extend some distance 329 beyond the distal attachment site for the flexible tube, or the flexible tube may be attached at the distal end of the puller. The distance from the attachment site of the flexible tube and the distal end of the puller may be between about 0 mm and about 10 cm, for example (e.g., between about 1 mm and about 10 cm, between about 1 mm and about 5 cm, etc.).

[00087] FIG. 3B shows the apparatus of FIG. 3A, but with the inversion support catheter 307 advanced distally. In this example, the distal opening 311 of the inversion support catheter 307has been pushed distally toward the attachment site of the flexible tube, and any clot. Once in position, the puller may be pulled proximally to invert the flexible tube into the inversion support catheter.

FLEXIBLE TUBES HAVING SLACK

[00088] FIGS. 4A-4B and 4C-4D illustrate kickback when using an inverting tube thrombectomy apparatus. For example, in FIG., 4A, a model of a tortious vessel 403 (e.g., a neurovascular region) is shown; the vessel is transparent to show a clot 411 and an inverting tube thrombectomy apparatus 400 that has been positioned with the distal end 401 adjacent to the clot. This example of an inverting tube thrombectomy apparatus includes a puller with a flexible tube attached near the distal end, and an inversion support catheter, The puller extends within the lumen of the inversion support catheter and the flexible tube extend from within the lumen of the inversion support catheter, out of the distal end of the inversion support catheter where it everts over itself to extend proximally along the outside from the distal end of the inversion support catheter. The second end of the flexible tube may be held between the outer surface of the inversion support catheter and an inner surface of an intermediate catheter, or it may be fully released from intermediate catheter. When positioned next to the clot 411 in FIG. 4A, the distal end of the catheter and therefore the inverting face of the flexible tube, may be positioned next to the clot. Pulling the puller proximally will roll and invert the flexible tube (the outer portion of the flexible tube) over the distal end of the inversion support catheter. However, as shown in FIG. 4B, the force applied by the flexible tube pulling proximally against the inversion support catheter (even a high column-strength inversion support catheter as shown in FIG. 1B) may compresses the distal end of the inversion support catheter slightly, and/or may causes it to separate from the clot. In FIG. 4B, the same device after pulling the puller proximally is shown with the distal end separated slightly from the clot (space 422). This compressive force may also make additional distal tracking of the deployed device difficult within the tortious vessel.

[00089] FIGS. 4C and 4D illustrate another example of this. In FIG. 4C the distal end 401 of the inverting tube thrombectomy apparatus 400 is adjacent to the clot 411. Pulling the puller proximally to roll and invert the flexible tube into the inversion support catheter may pull the distal end of the inverting tube thrombectomy apparatus 400 away from the clot 411, as shown in FIG. 4D, introducing a gap 422.

[00090] In order to prevent this kickback, the tension on the flexible tube may be reduced or eliminated. For example, FIGS. 5A-5L illustrate one example of a method of removing a clot that reduces or eliminates the tension on the portion of the flexible tube that is rolling and inverting over the distal end of the apparatus. In FIG. 5A, a sectional view through an inverting tube thrombectomy apparatus is shown. The inverting tube thrombectomy

apparatus includes a puller 503 (shown as a puller catheter) with a flexible tube 505 (e.g., a woven tube, knitted tube, etc.) attached near the distal end, and an inversion support catheter 507. The puller extends within the lumen of the inversion support catheter and the flexible tube extend from within the lumen of the inversion support catheter, out of the distal end of the inversion support catheter where it everts over itself to extend proximally along the outside from the distal end of the inversion support catheter. The second end of the flexible tube may be held between the outer surface of the inversion support catheter and an inner surface of an intermediate catheter 509, as shown. In FIG. 5A, the apparatus may be tracked over a guidewire 513 to be positioned adjacent to a clot 511. Thus, the apparatus may be pre-loaded with an intermediate catheter to the face of a clot. In FIG. 5B, the inversion support catheter 507 may be advanced distally towards the clot, as shown by arrow 521. The intermediate catheter 509 may then be pulled back, as shown by the arrow 524 in FIG. 5C to completely or partially unsheathe the flexible tube 505, exposing the outer portion of the flexible tube over the inversion support catheter 507. For example, in some variations the intermediate catheter may be pulled back is 30-95% of the length of the flexible tube 505.

[00091] To prevent kickback when inverting the flexible tube, slack 520 may be added to the outer portion of the flexible tube, as shown in FIG. 5D. In this example, slack 520 (shown as a bunching up of the flexible tube on the outside of the inversion support catheter before the distal end) may be added to the flexible tube by pushing the intermediate catheter distally 526 (e.g., approximately 50% of the exposed length of the flexible tube, e.g., the outer flexible tube region). In woven flexible tubes, this may compress the weave. Thereafter, the device may be operated, e.g., by pulling the puller, to roll and invert the flexible tube and grab clot. For example in FIG. 5E, the guidewire is first removed, and aspiration (e.g., vacuum) may be applied through the lumen of the puller (and/or the inversion support catheter) to connect to the clot. The apparatus may also be additionally tracked distally slightly, to capture the clot 511 as shown in FIG. 5F. For example, when aspiration is being applied, the apparatus 500 may be advanced 527 (the intermediate catheter, inversion support catheter and/or puller, all or some of which may be locked together proximally) distally until flow through the puller stops, indicating that the clot is on the puller (e.g., "corked"), as shown in FIG. 5F.

[00092] Once positioned, the puller may be pulled proximally 532 while advancing the inversion support catheter and intermediate catheter (together), as shown in FIGS. 5G-5J, to capture clot. Additional slack may be added during this process by, for example, advancing the intermediate catheter independently of the rest of the device; alternatively or additionally,

the flexible tube may be released from between the intermediate catheter and the inversion support catheter, as shown in FIG. 5I. As shown in FIGS. 5K and 5L, the clot may be removed fully into the inversion support catheter and/or the intermediate catheter (as shown in FIG. 5L) by withdrawing first the puller and then the rest of the apparatus proximally, while applying aspiration (e.g., suction) through the intermediate catheter.

[00093] FIGS. 6A-6C illustrate another example of a method of removing a clot while preventing kickback by releasing tension on the flexible tube. In FIG. 6A, an example of an apparatus 600 (similar to that shown in FIG. 5A, above) is positioned adjacent to a clot 603. As described above, before pulling the puller to roll and invert the flexible tube into the inversion support catheter, the outside region of the flexible tube may be compressed to form slack, for example, by advancing the intermediate catheter distally, after partially or completely removing from over the flexible tube, to push the flexible tube distally. Thereafter, in FIG. 6B, the puller may be pulled proximally while advancing the intermediate catheter to capture clot. In FIG. 6C, the intermediate catheter may be fully unsheathed from over the flexible tube, and more of the clot may be ingested by the rolling, inverting flexible tube.

[00094] FIGS. 7A-7B illustrate an alternative variation in which the tension on the flexible tube may be reduced or eliminated when rolling and inverting the outer portion of the flexible tube by coordinating the application of both a distal pushing force on the second end of the flexible and a pulling force on the first end of the flexible tube when pulling the puller proximally. In FIG. 7A, the apparatus 700 includes a puller 703 to which the flexible tube 705 is attached near the distal end of the puller. An inversion support catheter 707 is between the puller and the flexible tube, and an intermediate catheter 709 extends over the majority of the length of the apparatus. In FIG. 7A, the apparatus is shown deployed, but prior to rolling/inverting the flexible tube 705. In FIG. 7B, tension that may otherwise apply a compressive force on the distal end of the inversion support catheter may be reduced or eliminated by applying a distal force (e.g., by advancing the intermediate catheter distally 721 in this example) before or while pulling 723 the puller proximally to roll and invert the flexible tube over the distal end. The puller may be pulled slightly faster than the rate at which the intermediate catheter is advanced distally, as the flexible tube may extend slightly within the inversion support catheter.

AUTOMATIC RELAOADING

[00095] FIGS. 8-11F illustrate apparatuses and methods that automatically reload the flexible tube after grabbing all or a portion of clot. For example, in FIG. 8, the apparatus includes a bias (an external bias) for pulling the flexible tube from within the inversion support catheter back outside of the inversion support catheter (rolling and everting). In FIG. 8, the apparatus 800 includes a puller 803 and a flexible tube (e.g., woven, knitted, etc.). A fist end of the flexible tube 805 is attached near the distal end region of the puller. The puller is within the lumen of an inversion support catheter 807, and the flexible tube extends over the outer surface of the inversion support catheter. A region 806 of the flexible tube extends on the outside of the inversion support catheter. The second end (or a region at the second end) of the flexible tube is connected to a bias 811, shown here as a spring element. The spring may be heat set in a compressed configuration, as shown. A distal end of the bias 815 is attached to the second end of the flexible tube (or a cuff, not shown, on the flexible tube). Another, e.g., a proximal end 817, of the spring may be attached to the inversion support catheter 807, as shown.

[00096] FIGS. 9A-9D illustrate the operation of an apparatus such as that shown in FIG. 8, which is biased to return the flexible tube to the outside of the inversion support catheter. The amount of bias may be set so that the force applied is relatively low (e.g., pushing the puller distally may allow the flexible tube to reset (e.g., evert and roll back) the flexible tube to the outside of the inversion support catheter; alternatively the bias may be higher, so that the bias resets the flexible tube after just releasing the puller.

[00097] In FIG. 9A, the apparatus 900 may be approximated near the clot and aspiration (e.g., suction) applied through the lumen of the puller 903, as shown, until the clot is attached to the puller ("corked"). The puller 903 may then be pulled proximally, as shown in FIG. 9B, to roll 933 the flexible tube 905 and invert it into the inversion support catheter 907, capturing the clot. Pulling the puller proximally also pulls against the bias 911. The puller may be pulled until it reaches a stop, which may be set by the bias (spring 911) or by a mechanical stop, or both. Once The clot or portion of the clot within the inversion support catheter that has been engulfed by the flexible tube may then be aspirated proximally down the puller, as shown in FIG. 9C. Once cleared from the flexible tube, which may be detected by monitoring the suction through the puller (e.g., showing a drop in suction pressure when the clot is removed proximally from the flexible tube), the flexible tube may be reset outside of the inversion support catheter as shown in FIG. 9D, by applying a small force driving the

puller distally, allowing the spring (bias) to evert and roll the flexible tube back out of the inversion support catheter and over the outside surface, as shown. This processes may be repeated 915 as many times as desired; large clots may be removed by taking multiple bites in this manner, or multiple different clots may be removed with the same apparatus. The apparatus shown in FIGS. 8 and 9A-9D may include an intermediate catheter (not shown).

[00098] The flexible tube, as described above, may be any appropriate flexible tube. For example, the flexible tube may be a braid (e.g., braid structure). In some variations the flexible tube may be a braid of a flat or round wire that is braided and heat set (as described above, it may be heat set to have an inner diameter in tension that is greater than the outer diameter of the inversion support catheter). For example the flexible tube may be formed as a braid of 144 strands of 0.001" NiTi filaments that are braided at large braid angle (e.g., having a very smooth surface). In some variations, the braid may include a low durometer polymer laminate or covering, on all or braid part of braid length. In some variations, the braid may be configured as a knit structure. The knit may be formed of a round or flat wire having a circular knit structure. The apparatus may be heat set so that the ID of the flexible tube when tensioned is greater than the outer diameter of the inversion support catheter. A knit may include a low durometer polymer laminate or covering, on all or braid part of braid length.

[00099] Any appropriate bias may be used. For example, the bias may be a spring such as a metallic or polymeric spring. The spring may be heat set in a closed pitch form. For example, the spring may be a metal or metallic material such as NiTi, Cobalt Cr, stainless steel, etc. The spring may be, e.g., a polymeric tubing spring, such as a spring formed of a silicone, urethane, latex or other elastic material.

[000100] In some variations, an additional element, such as a wire, may be used to assist the clot in removing/releasing from the flexible tube. For example, a wire have a bent or bendable distal end may be used to help pull the clot out of the distal end of the puller.

[000101] FIGS. 10A-11F illustrate another example of an apparatus including a bias to restore the flexible tube to the outside of the apparatus. In this variations, the flexible tube is biased to return to the outside of the inversion support catheter. For example, in FIG. 10A, the apparatus 1000 includes a puller 1003 to which a flexible tube 1005 is attached at a first end to the distal end region of the puller. The puller has a relatively large outer diameter (in both this example and the example shown above in FIG. 8), but is slidably held within the inner lumen of the inversion support catheter 1007. In addition, the flexible tube 1005 is attached at the second end to the outside of the inversion support catheter at an attachment

region 1009. In FIG. 10A, the flexible tube is biased to spring back to this configuration (e.g., a loading or insertion configuration), in which the flexible tube is outside of the inversion support catheter. In this example the flexible tube is attached proximal to the distal end of the puller; any appropriate distance from the distal end of the puller may be used (e.g., more than 0.1 mm, 0.2 mm, 0.3 mm. 0.5 mm, 1 mm, 2 mm, 3 mm, etc. and/or less than about 0.1 mm, 0.2 mm, 0.3 mm, 0.5 mm, 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, etc.). Alternatively the flexible tube may be attached to the distal end of the puller (e.g., flush with the distal end).

[000102] In some variations, the flexible tube is configured as a braid that has a stacked configuration when attached to the outside of the inversion support catheter with the puller distal end aligned with the end of the inversion support catheter. In FIG. 10B, for example, a flexible tube shown as a weave formed of a Nitinol material having a stacked braid configuration is illustrated.

[000103] FIGS. 11A-11F illustrate the operation of an apparatus such as the one shown in FIG. 10A. In FIG. 11A, the apparatus is deployed near the clot 1109 with the puller 1103 extended distally ahead of the rest of the apparatus. In FIG. 11B, aspiration may be used to attach the clot 1109 to the puller (shown with the clot "corked" on the distal end of the puller). Thereafter, the inversion support catheter 1107 may be advanced 1131 distally to compress 1133 the weave of the flexible tube 1105, causing it to stack up as shown in FIG. 11C into a stacked configuration. This configuration is equivalent to forming slack in the flexible tube as described above. While (optionally, but preferably) still applying aspiration through the puller, the inversion support catheter 1107 may be advanced distally 1137 (as shown in FIG. 11D), against the clot, and at least partially over it. The inversion support catheter (e.g., the outer catheter) may be advanced distally so that the distal end of the inversion support catheter extends to or past the end of the puller, which may advance the flexible tube over the clot. The inversion support catheter may then be advanced distally while pulling the puller proximally, to roll and invert the flexible tube, as shown in FIG. 11E, to further ingest the clot, as shown. Alternatively the inversion support catheter may be held still while pulling the puller proximally; in some variations the inversion support catheter and puller are moved in a coordinated manner, either together simultaneously or incrementally and alternately.

[000104] The clot within the puller may be removed proximally (e.g., by aspiration and/or mechanically, such as using a wire), as shown in FIG. 11F. In addition, the puller may be advanced distally to evert and roll the flexible tube back out of the inversion support catheter.

This process may then be repeated (shown by dashed arrow 1139) to remove additional clot material. In any of these variations, the clot may be cut after a certain amount of it has entered into the device, e.g., by a separate or integrated cutter (such as a wire, etc.). This may allow repeated bites of clot to be removed using the same device.

[000105] Although not shown explicitly in FIG. 11C, the apparatus shown may also include an intermediate catheter, e.g., within which the inversion support catheter (outer catheter) and the puller (pull catheter, inner pull catheter or inner catheter) may move into and/or out of, as shown in FIGS. 5K-5L, above).

[000106] FIG. 12 illustrates one example of an apparatus (e.g., a system) for removing a clot, a series of clots and/or multiple clots, as described herein. The schematic shown in FIG. 12 is not to scale. For example, in FIG. 12, the apparatus includes an inversion support catheter 1211 and a puller catheter 1215 within a lumen of the inversion support catheter 1211. The puller catheter, as described above, may have a large inner diameter to allow removal of clot through the puller catheter inner lumen. For example, the inner diameter of the puller catheter may be about 75% (or about 80% or about 85% or about 90% or about 95%) or more than the inner diameter of the inversion support catheter. In some variations the outer diameter of the puller catheter is within 15% or less of the inner diameter of the inversion support catheter (e.g., within 12%, within 10%, within 8%, within 7%, within 5%, etc.). Thus the puller catheter may slide within the inversion support catheter, but may maximize the inner diameter of the inversion support catheter in order to pass clot through the puller catheter.

[000107] A flexible tube 1217 is connected to the distal end region of the puller catheter and to an outer surface of the distal end region (or distal end) of the inversion support catheter, as shown. Thus, the flexible tube has a first end coupled at a distal end region of the puller catheter, and a second end coupled at an outer surface of a distal end region of the inversion support catheter. As mentioned above, the flexible tube may be any appropriate material for grabbing clot, such as a woven, knitted or braided material, including metallic woven, knitted and/or braided materials. The flexible tube may be biased or may include a biasing element that is pre-biased to drive the flexible tube to the initial (delivery) configuration, such as shown in FIG. 10A. For example, in some variation the flexible tube includes a shape memory material, such as Nitinol, that is biased to return to the predetermined shape.

[000108] In FIG. 12, an intermediate catheter is not shown, but may be included and the inversion support catheter, puller catheter and flexible tube may be passed through the intermediate catheter.

[000109] The apparatus shown in FIG. 12 also includes a handle 1205 coupled to the inversion support catheter and the puller catheter. The handle is shown schematically in FIG. 12, but may be shaped for held-held use; alternatively the handle may be part of a base unit that is not hand-held. As shown, the handle includes a vacuum port 1219 that couples to a vacuum 1225, and may couple the vacuum line to a lumen of the puller catheter.

[000110] The handle may include one or more controls 1203, 1207, 1209 that may control the operation of the apparatus and particular the relative movement of the puller catheter and the inversion support catheter. The proximal end regions of the puller catheter and the inversion support catheters may be coupled to one or more actuators within the handle (not visible) to drive axial movement (distal/proximal movement) of these members. For example the handle may be configured to, when activated by one or more controls on the handle, advance the inversion support catheter distally before concurrently advancing the inversion support catheter distally while withdrawing the puller catheter proximally, as described in the methods illustrated in FIGS. 11A-11F (and particularly FIG. 11C and FIG. 11D-11E described above). In any of these variations, the handle may be configured to reset the inversion support catheter proximally and the puller catheter distally, e.g., to reset the puller catheter and the inversion support catheter to the delivery configuration. For example, the apparatus may include a control 1209 that may release the inner and/or outer catheters (e.g., the puller catheter and/or inversion control catheter) to allow the device to return to the delivery catheter; alternatively the control may actively move the inner and outer catheters to the delivery configuration.

[000111] The handle may be further configured to apply vacuum through the puller catheter while advancing the inversion support catheter distally before concurrently advancing the inversion support catheter distally while withdrawing the puller catheter proximally. For example, the handle may include control logic that applies the negative pressure (e.g., vacuum from the vacuum device 1225) when the actuators within the handle move the inversion support catheter distally while moving the puller catheter proximally. The control logic within the handle may be software, hardware or firmware, and may coordinate operation of the handle. For example the handle may be configured to separately and/or jointly move the inner catheter (puller catheter) and the outer catheter (inversion support

catheter), as mentioned above, and/or to coordinate the application of suction (e.g., vacuum) through the puller catheter.

[000112] Separate controls on the handle may control the movements involved in the different stages of the operation. For example, the handle may include a first control to advance the inversion support catheter distally and a second control to advance the inversion support catheter distally while withdrawing the puller catheter proximally. Alternatively or additionally, the first control may advance the inversion support catheter distally and may separately advance the inversion support catheter distally while withdrawing the puller catheter proximally. In some variations, the handle is configured to advance the inversion support catheter distally to a predetermined distance (e.g., 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 1 cm, 1.5 cm, 2 cm, 3 cm, etc.) before advancing the inversion support catheter distally while withdrawing the puller catheter proximally to a variable distance and/or to a second predetermined distance (e.g., 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 1 cm, 1.5 cm, 2 cm, 3 cm, 4 cm, 5 cm, 6 cm, 7 cm, 8 cm, 9 cm, etc.).

[000113] 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.

[000114] 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 "/".

[000115] 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.

[000116] 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.

[000117] 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.

[000118] 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.

[000119] 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.

[000120] 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.

[000121] 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 system for removing a clot, the system comprising:

an inversion support catheter;

a puller catheter within a lumen of the inversion support catheter;

a flexible tube having a first end coupled at a distal end region of the puller catheter, and a second end coupled at an outer surface of a distal end region of the inversion support catheter; and

a handle coupled to the inversion support catheter and the puller catheter, the handle comprising a vacuum port configured to couple a lumen of the puller catheter to a vacuum, further wherein the handle is configured to, when activated by one or more controls on the handle, advance the inversion support catheter distally before concurrently advancing the inversion support catheter distally while withdrawing the puller catheter proximally.

2. The apparatus of claim 1, wherein the first end of the flexible tube is coupled proximal to the distal end of the puller catheter by greater than 0.5 mm.

3. The apparatus of claim 1 or 2, wherein the handle is further configured to reset the inversion support catheter proximally and the puller catheter distally.

4. The apparatus of any of claims 1-3, further wherein the flexible tube further comprises a bias configured to extend the puller catheter distally relative to the inversion support catheter.

5. The apparatus of any of claims 1-4, wherein the flexible tube comprises a woven or knitted material.

6. The apparatus of any of claims 1-4, wherein the flexible tube comprises a braided material.

7. The apparatus of any of claims 1-6, wherein the handle is further configured to apply vacuum through the puller catheter while advancing the inversion support catheter distally before concurrently advancing the inversion support catheter distally while withdrawing the puller catheter proximally.

8. The apparatus of any of claims 1-7, wherein the handle comprises a first control to advance the inversion support catheter distally and a second control to advance the inversion support catheter distally while withdrawing the puller catheter proximally.

9. The apparatus of any of claims 1-7, wherein the handle comprises a first control to advance the inversion support catheter distally and to separately advance the inversion support catheter distally while withdrawing the puller catheter proximally.

10. The apparatus of any of claims 1-7, wherein the handle is configured to advance the inversion support catheter distally to a predetermined distance before advancing the inversion support catheter distally while withdrawing the puller catheter proximally.

11. The apparatus of any of claims 1-10, wherein the outer diameter of the puller catheter is within about 10% of the inner diameter of the inversion support catheter.

12. A system for removing a clot, the system comprising:

an intermediate catheter;

an inversion support catheter within a lumen of the intermediate catheter;

a puller within a lumen of the inversion support catheter;

a flexible tube having a first end coupled at a distal end region of the puller, wherein flexible tube inverts over a distal end of the inversion support catheter and an external portion of the flexible tube extends proximally over the inversion support catheter; and

a handle coupled to the intermediate catheter and the puller, wherein the handle is configured to, when activated by a control on the handle, automatically advance the intermediate catheter while one or more of: holding the puller fixed or withdrawing the puller proximally as the intermediate catheter is advanced.

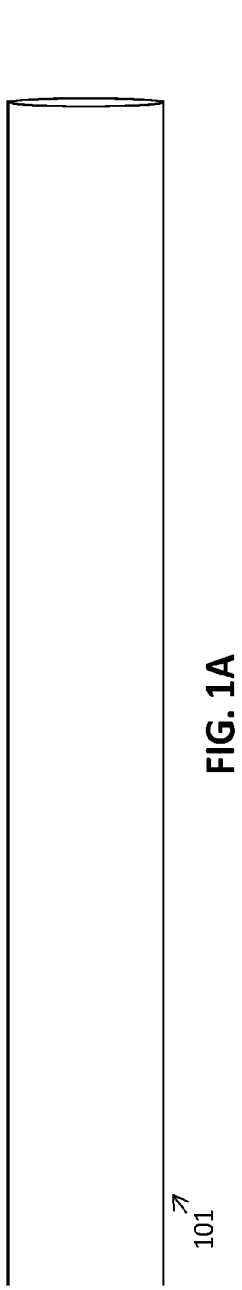

FIG. 1A

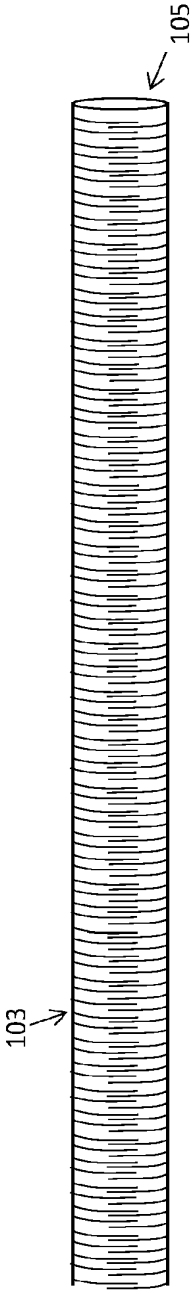

FIG. 1B

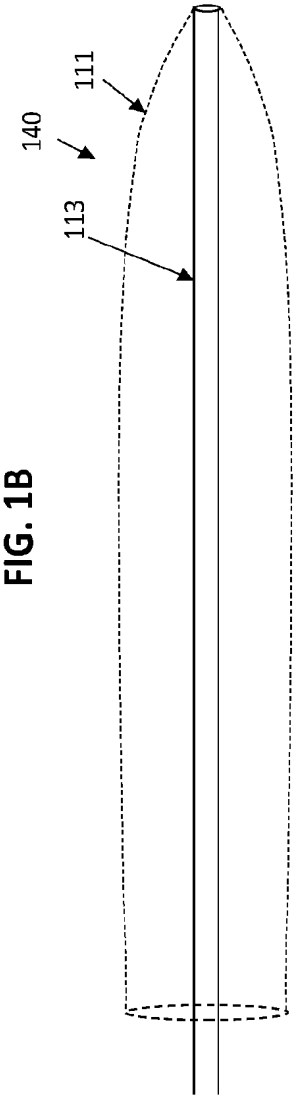

FIG. 1C1

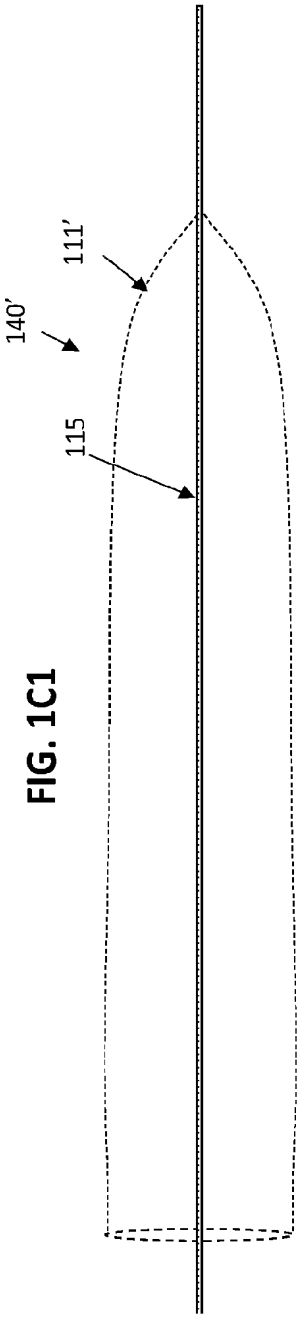

FIG. 1C2

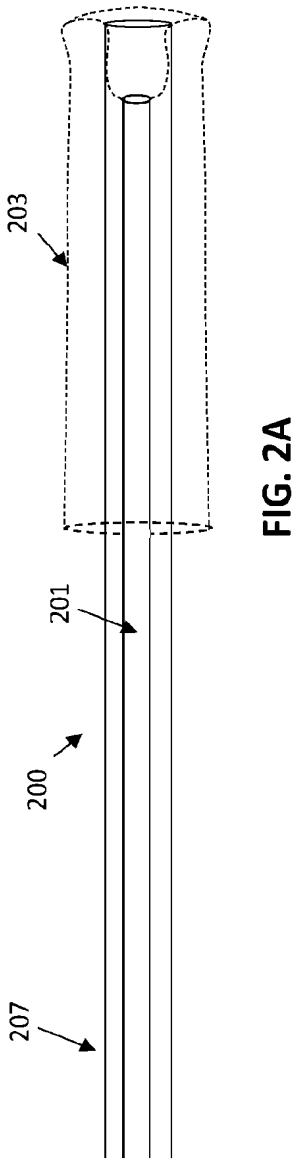

FIG. 2A

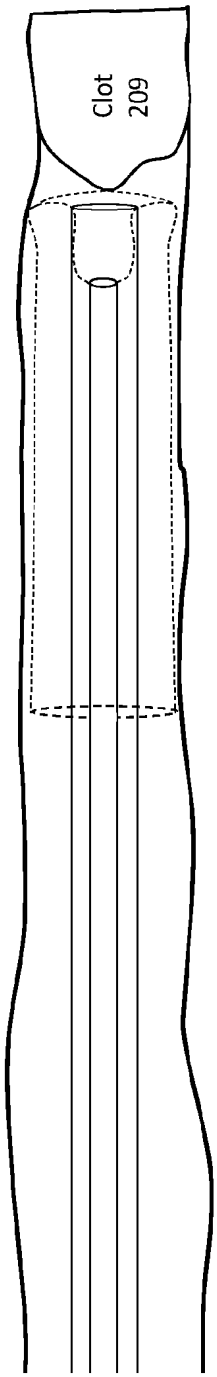

FIG. 2B

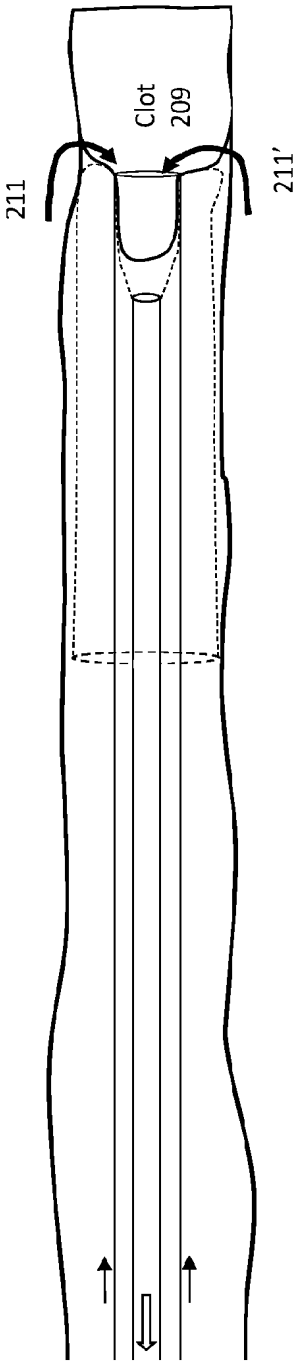

FIG. 2C

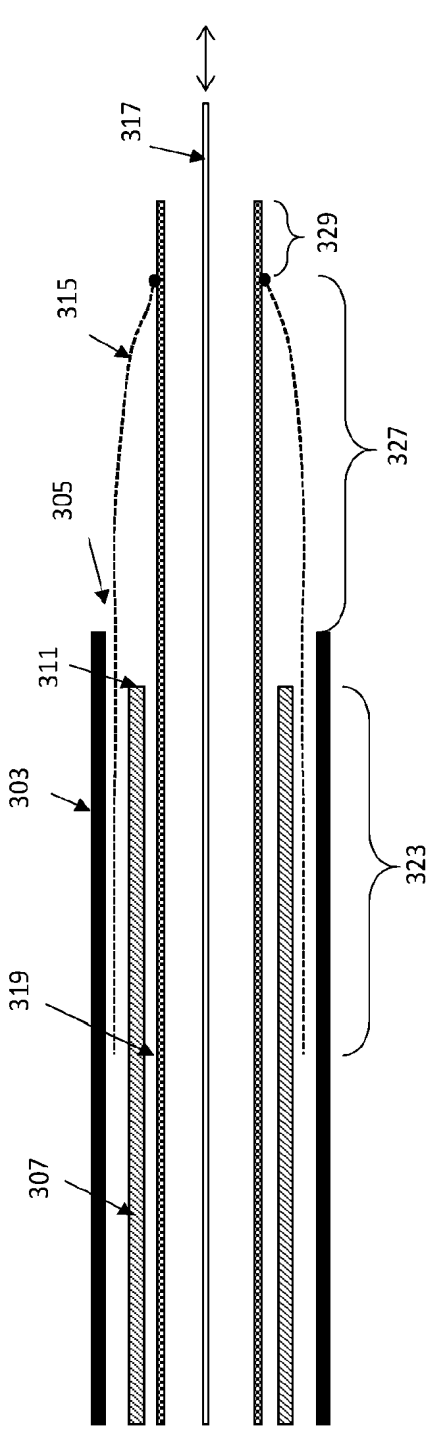
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FIG. 3A

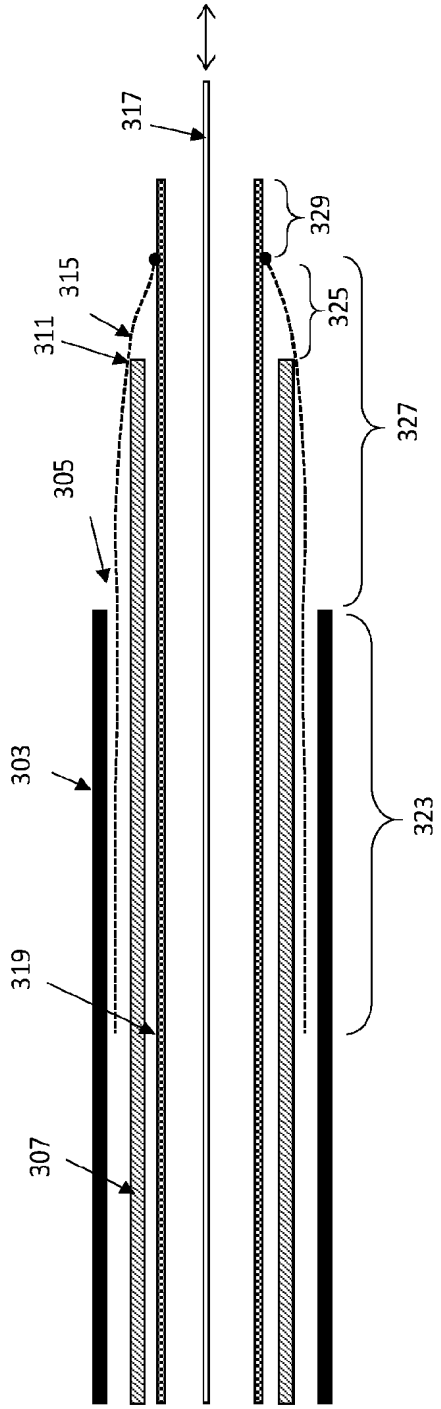
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FIG. 3B

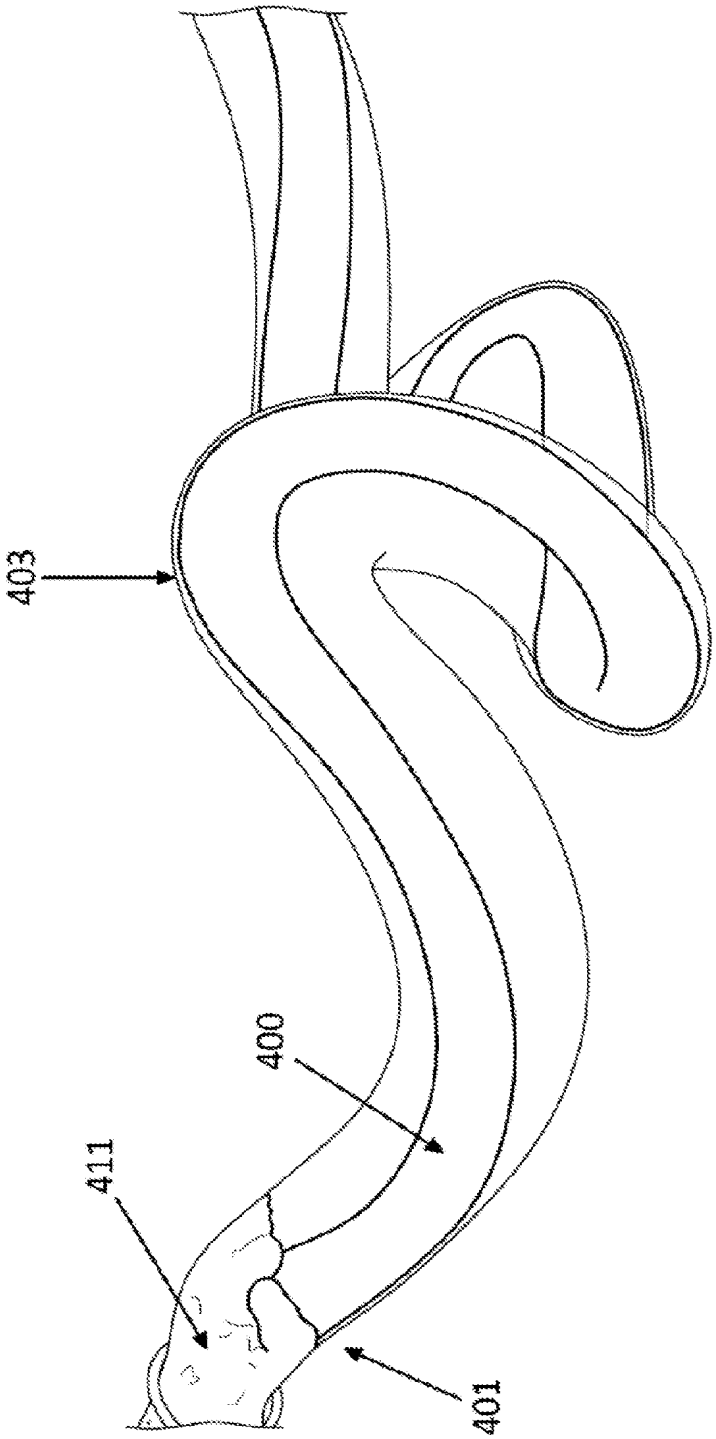


FIG. 4A

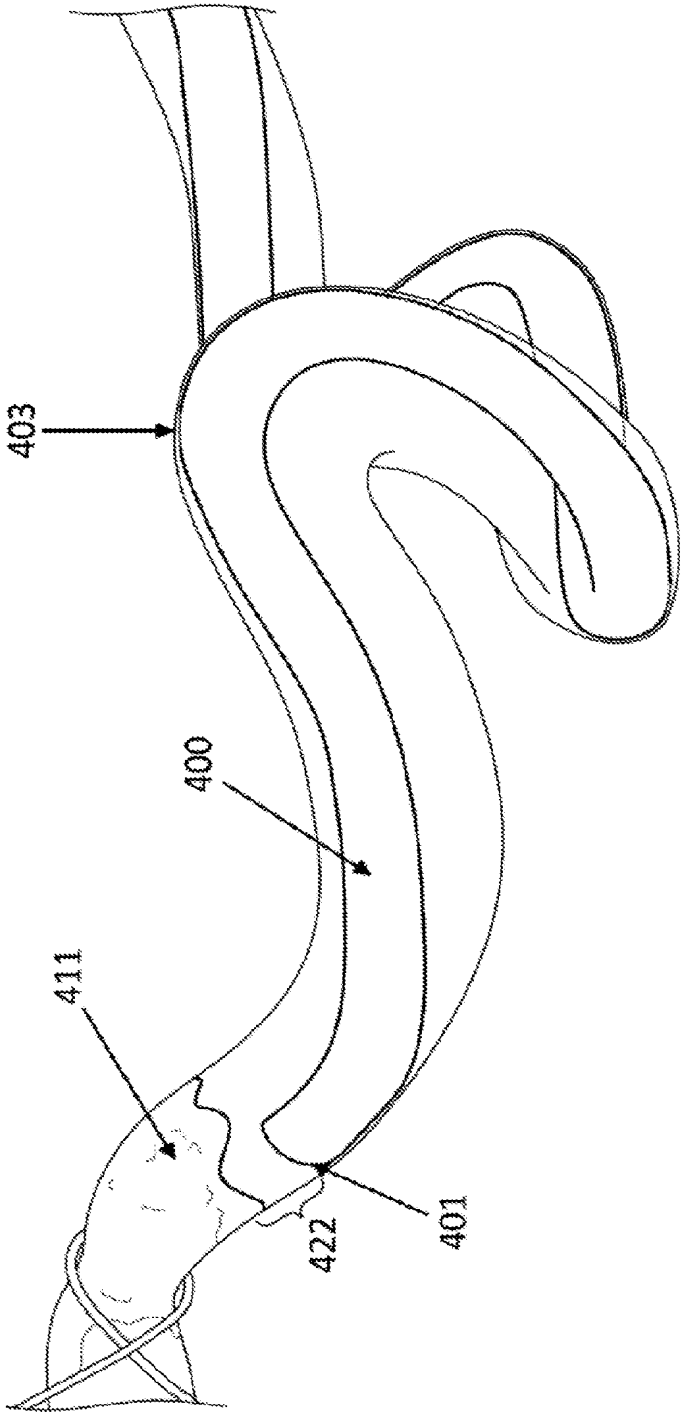


FIG. 4B

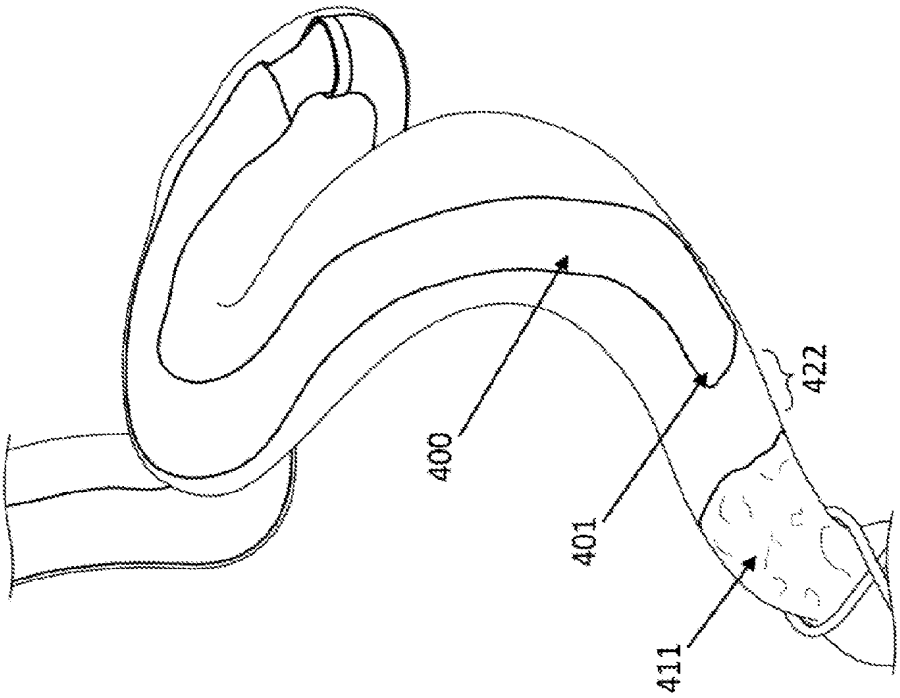


FIG. 4D

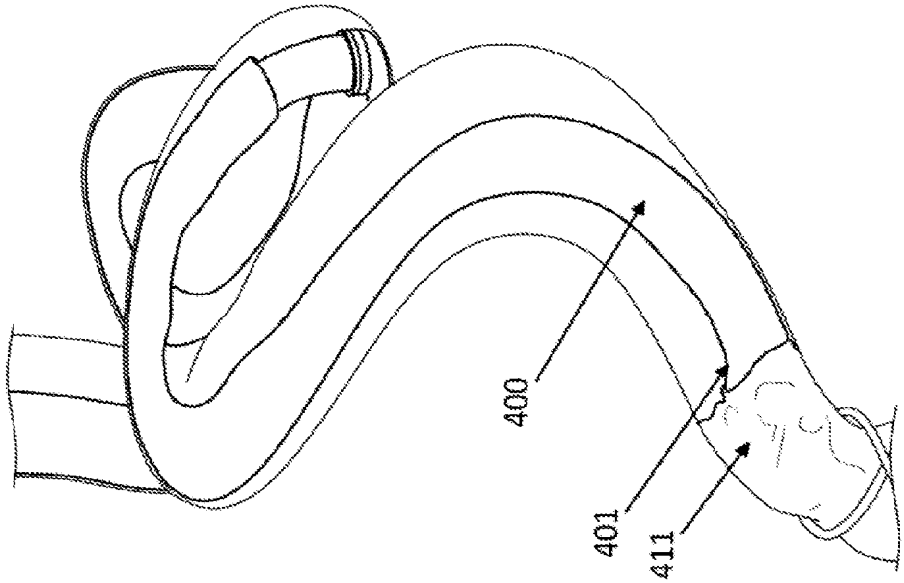


FIG. 4C

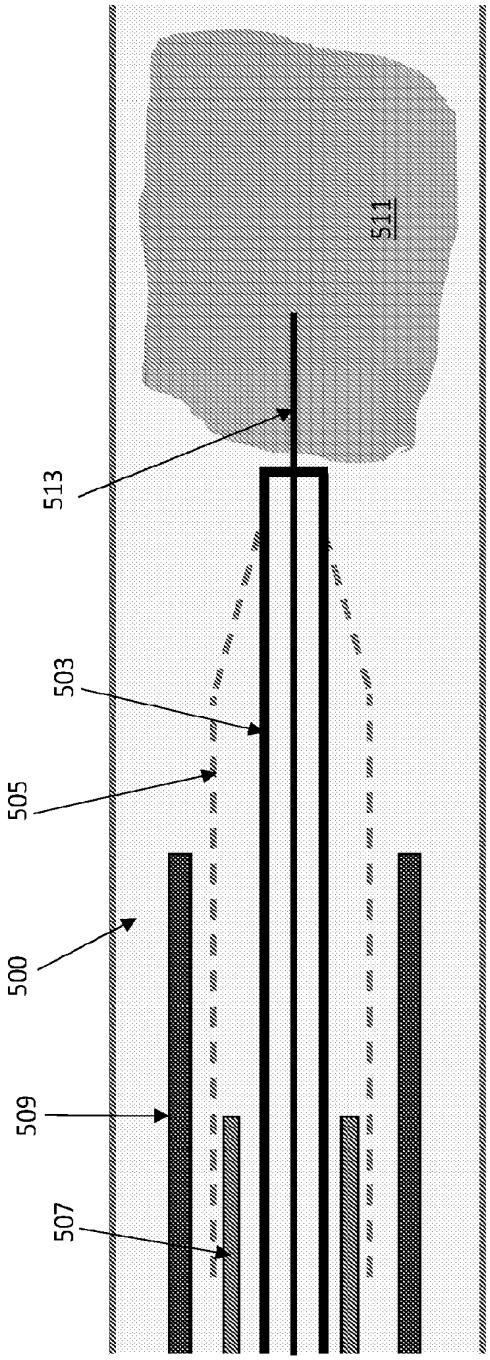


FIG. 5A

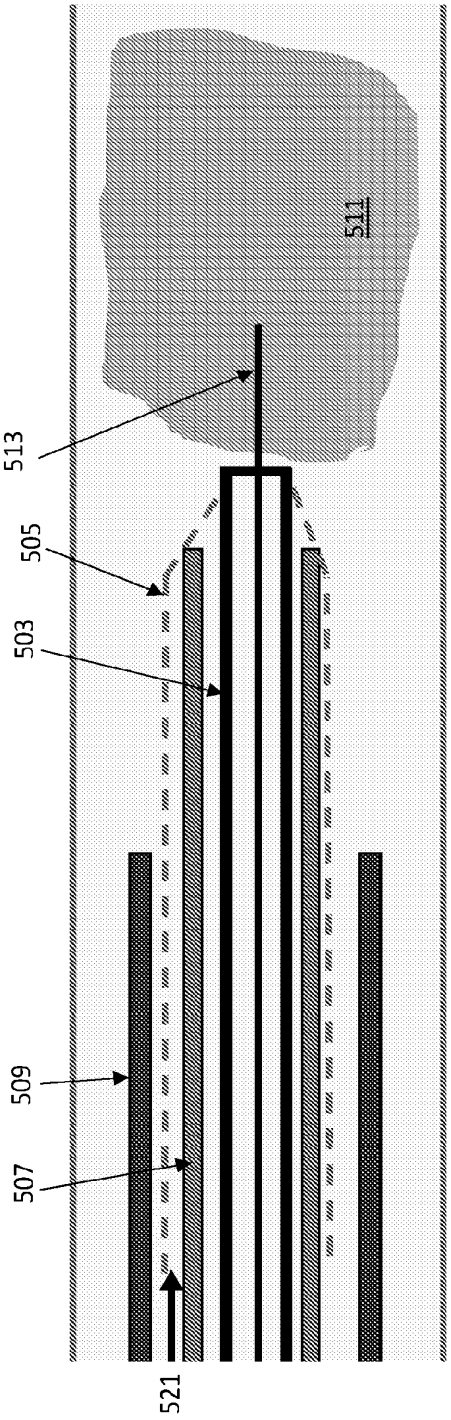


FIG. 5B

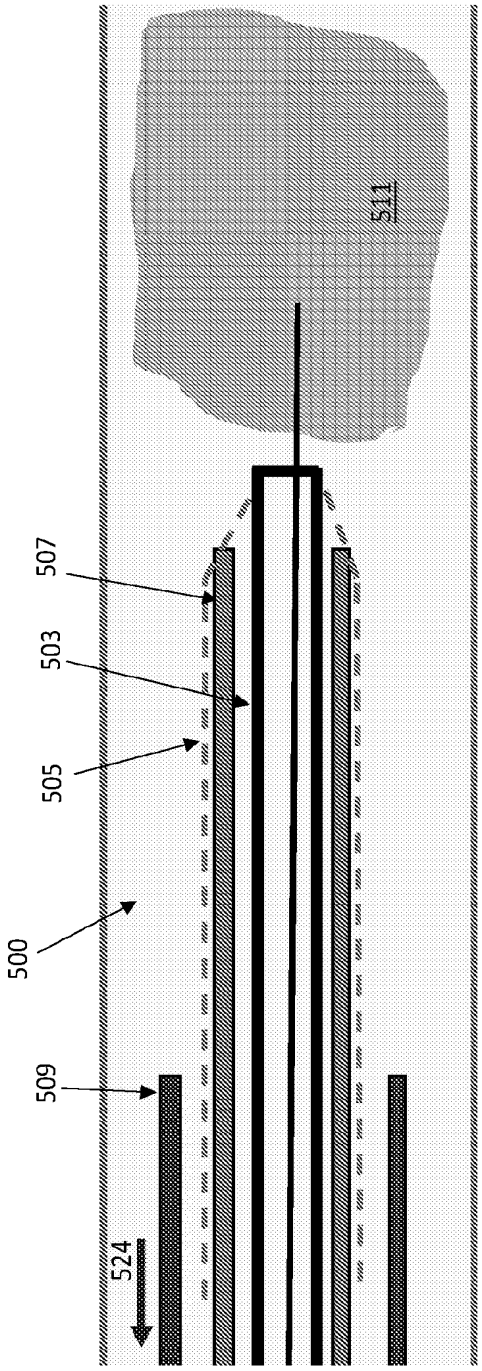


FIG. 5C

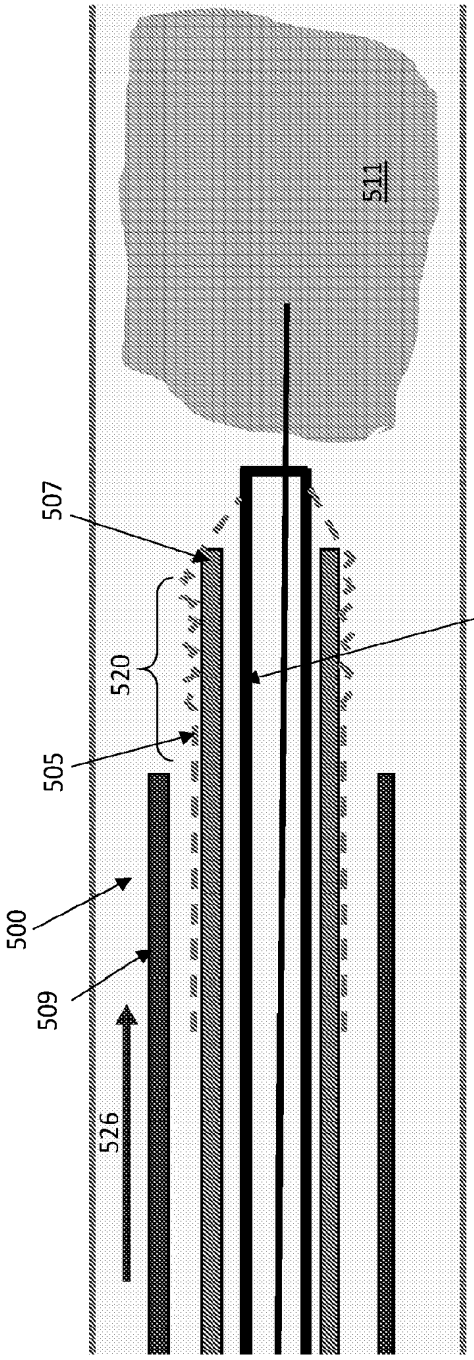
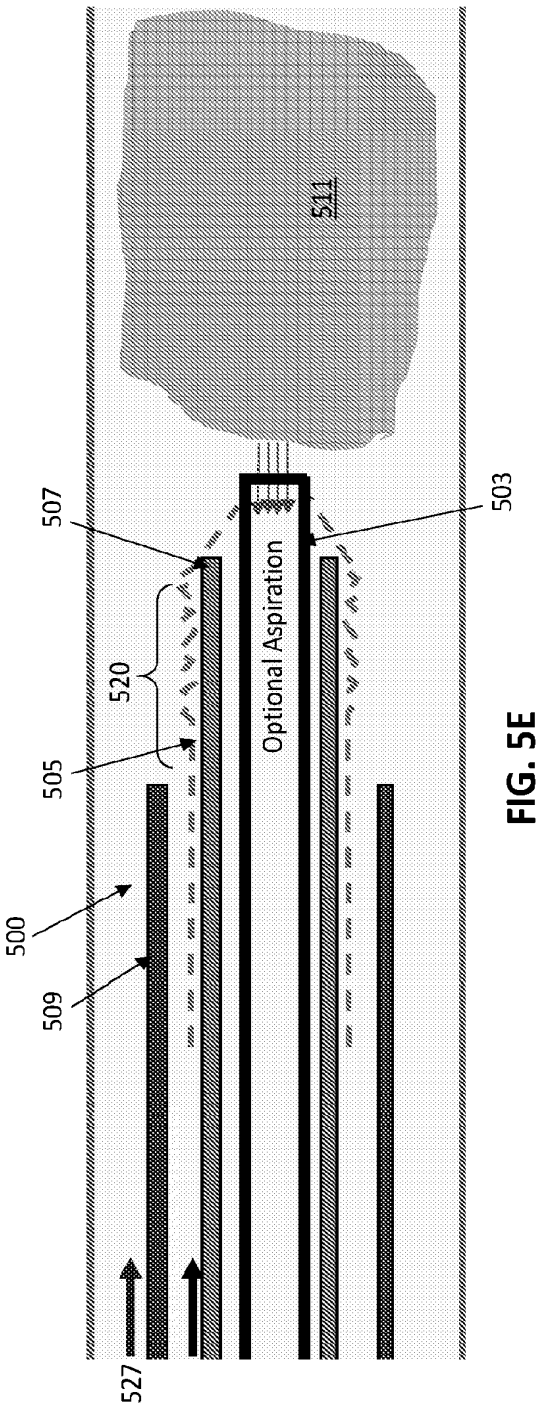


FIG. 5D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Optional Aspiration
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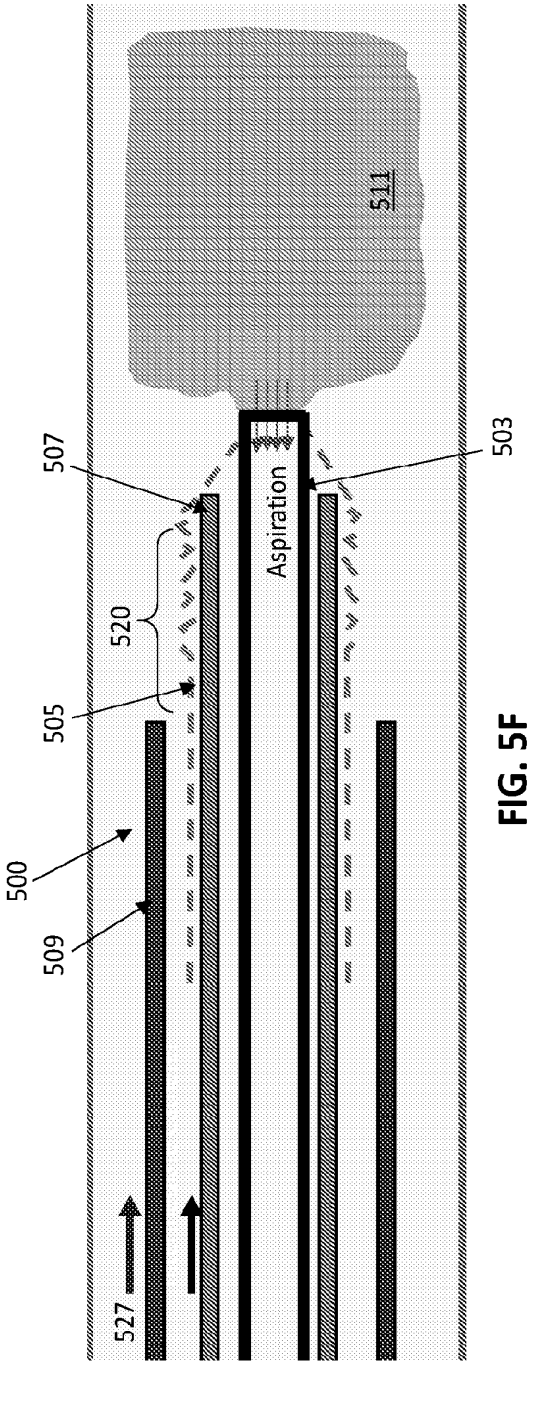
FIG. 5E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Aspiration
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FIG. 5F

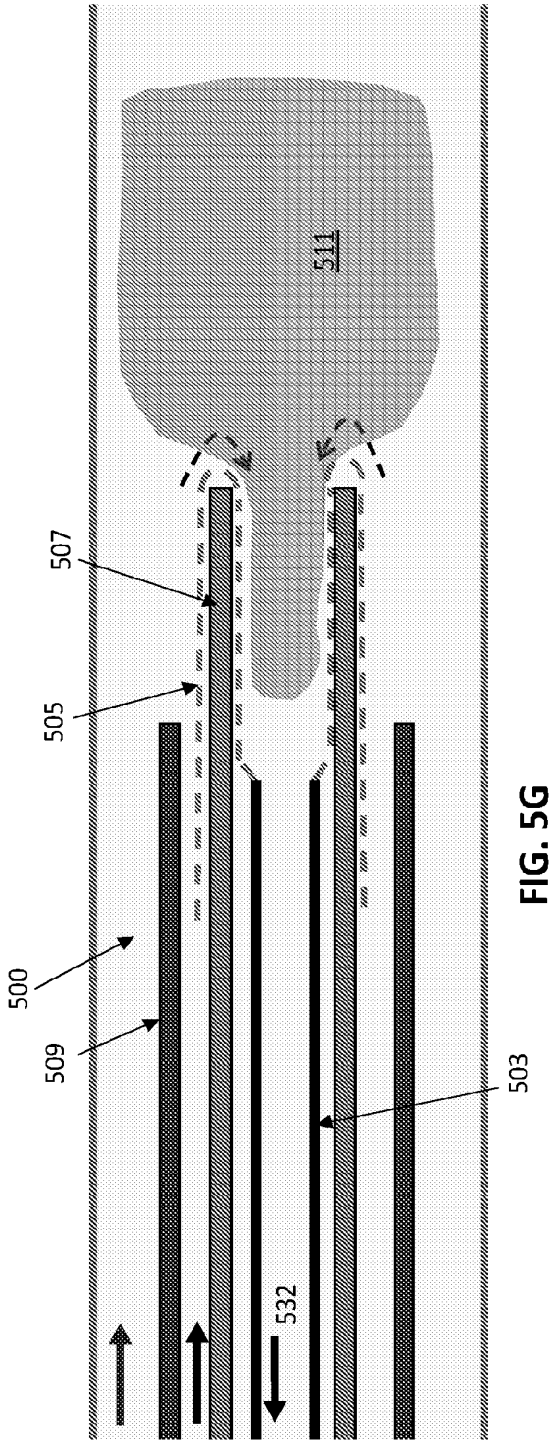

FIG. 5G

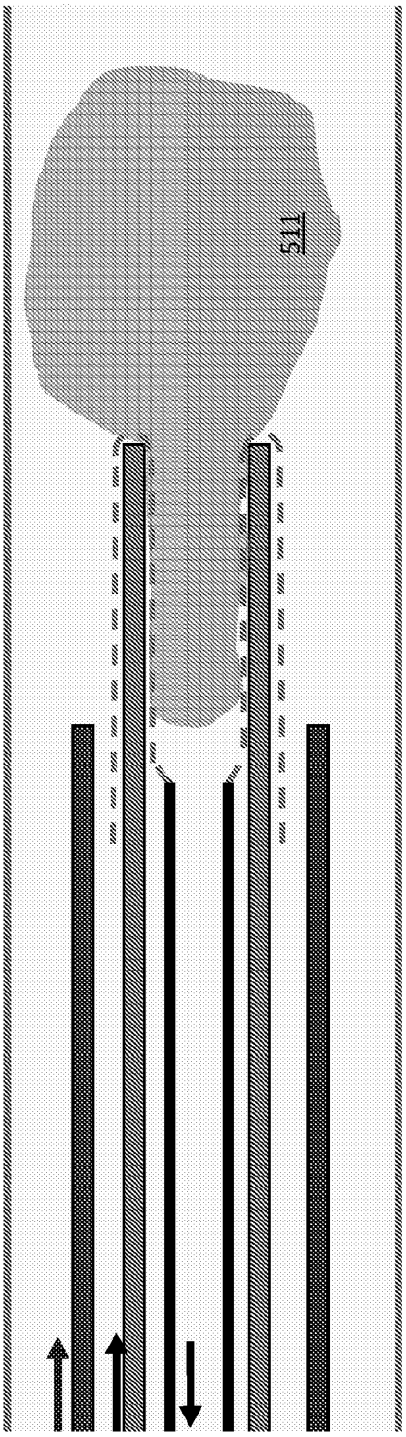

FIG. 5H

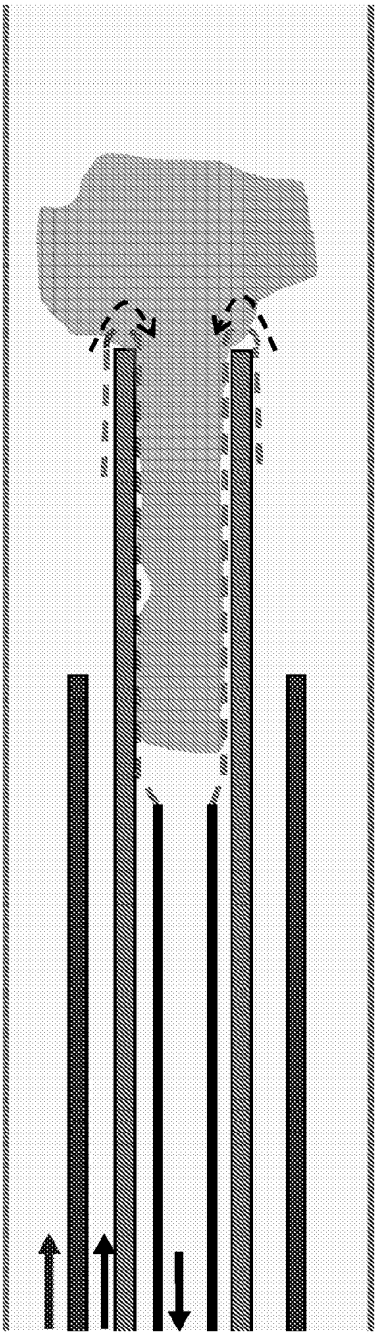

FIG. 5I

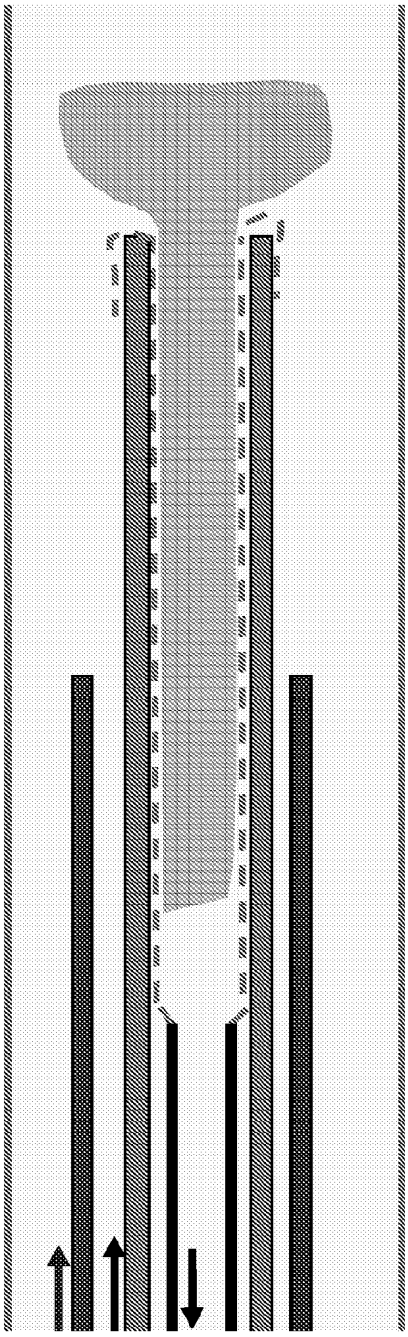

FIG. 5J

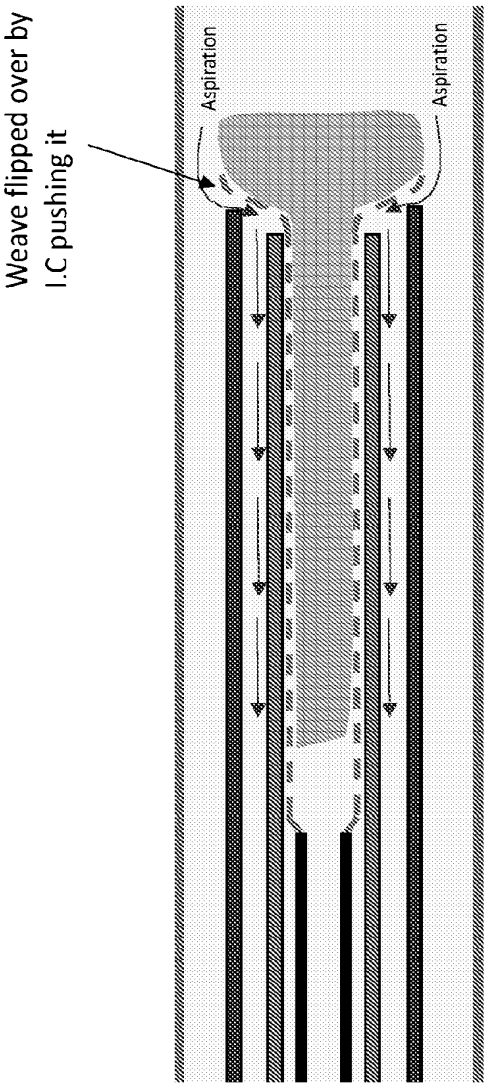
Weave flipped over by
I.C pushing it
Aspiration
Aspiration

FIG. 5K

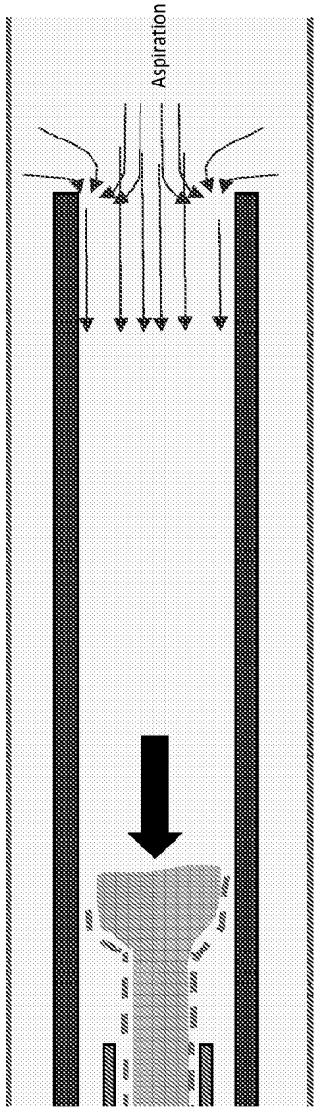
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FIG. 5L

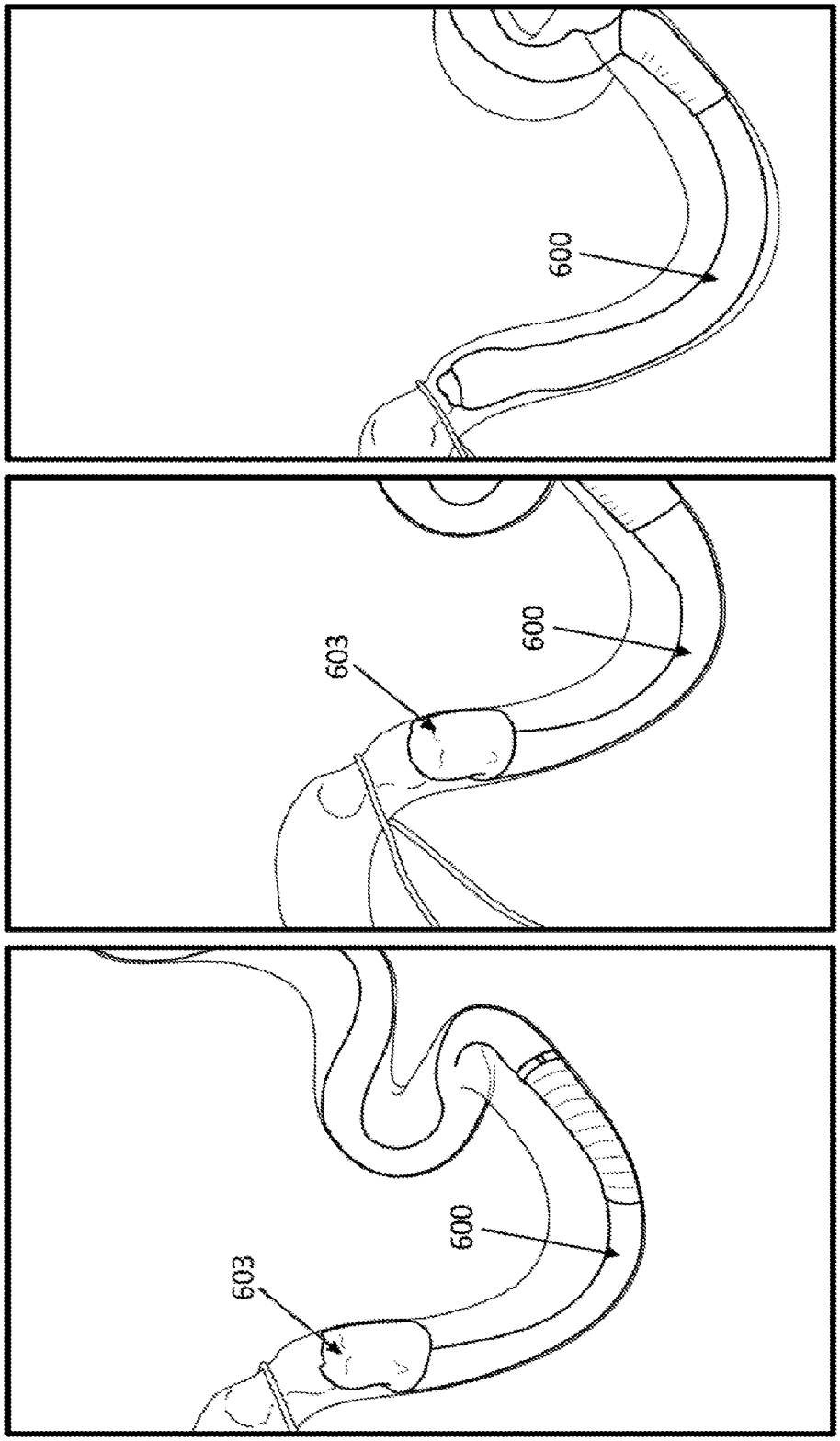


FIG. 6C

FIG. 6B

FIG. 6A

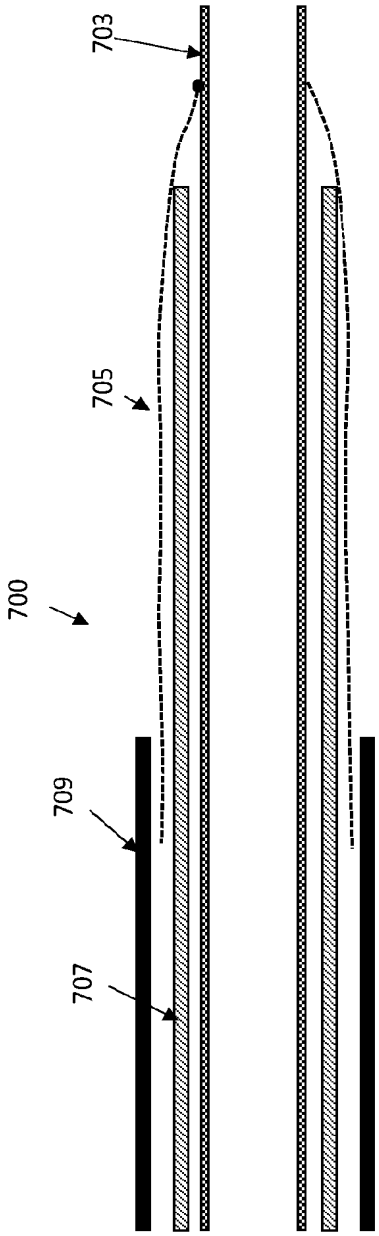


FIG. 7A

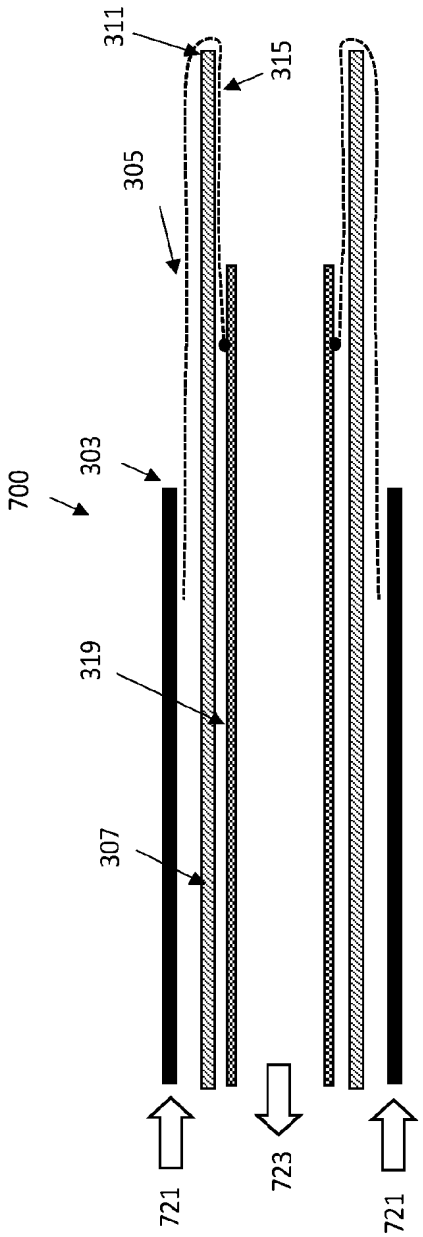


FIG. 7B

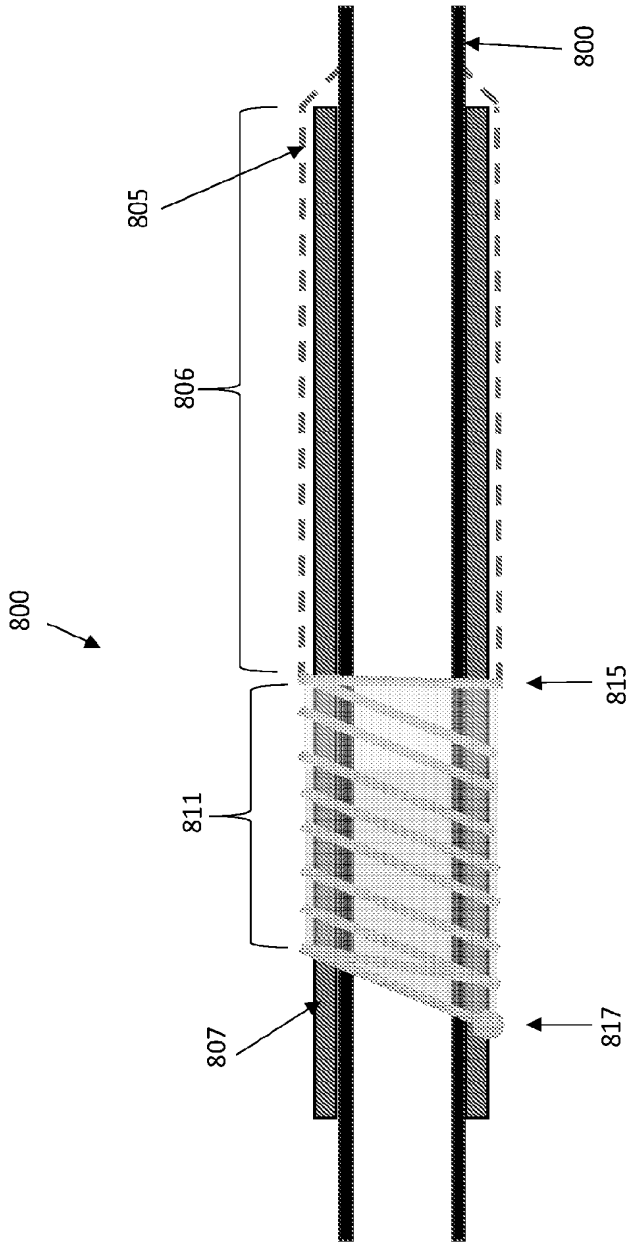
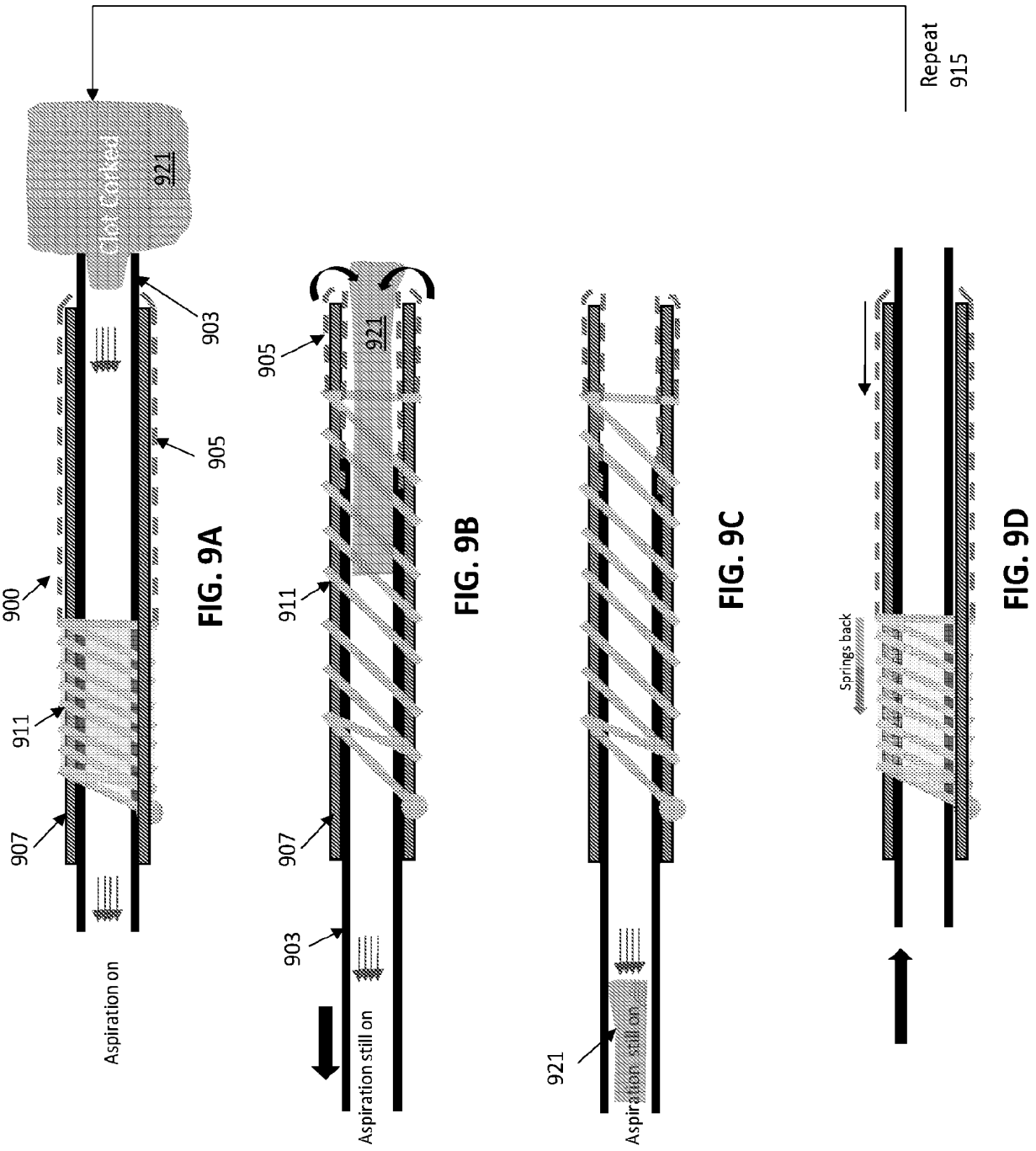


FIG. 8


Repeat
915
Clot Contact
921
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Aspiration on
FIG. 9A
905
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Aspiration still on
FIG. 9B
921
Aspiration still on
FIG. 9C
Springs back
FIG. 9D

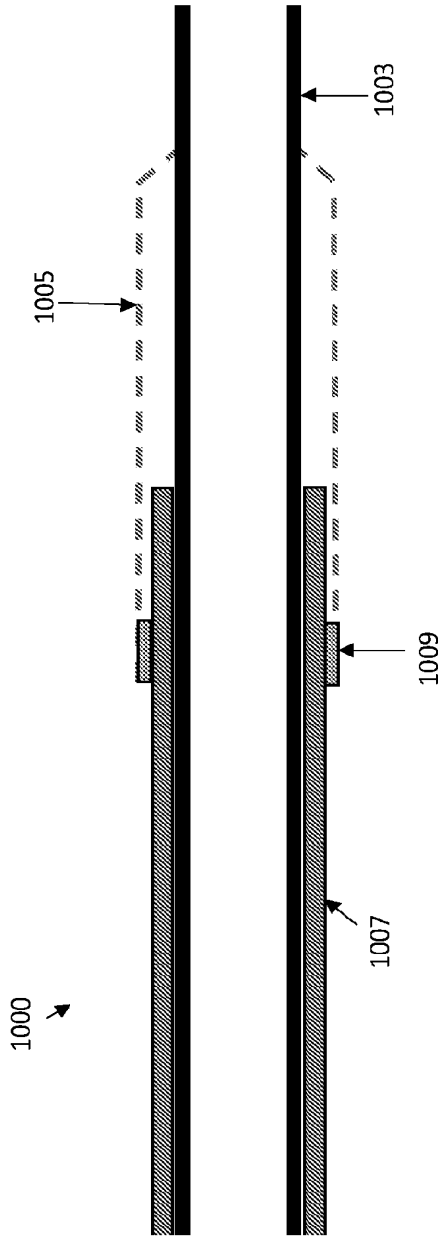

FIG. 10A

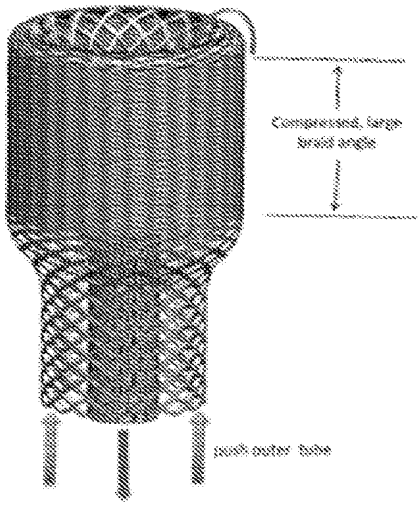

FIG. 10B

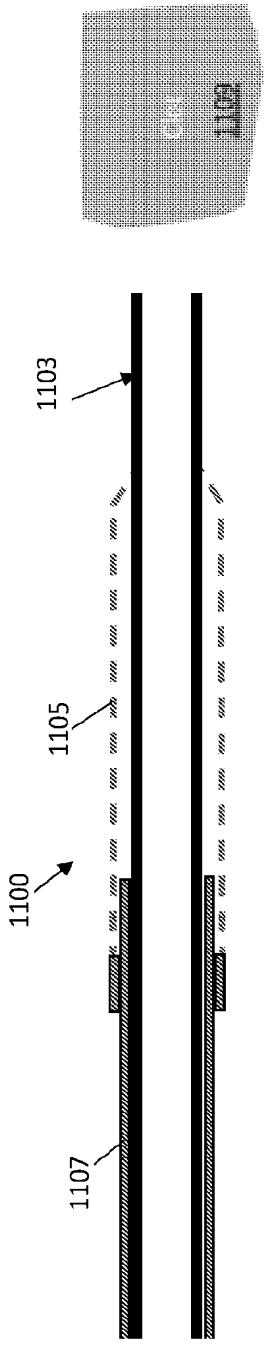

FIG. 11A

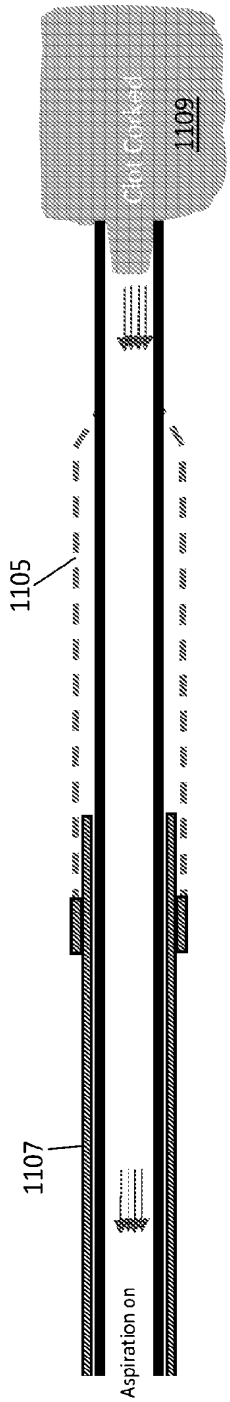

FIG. 11B

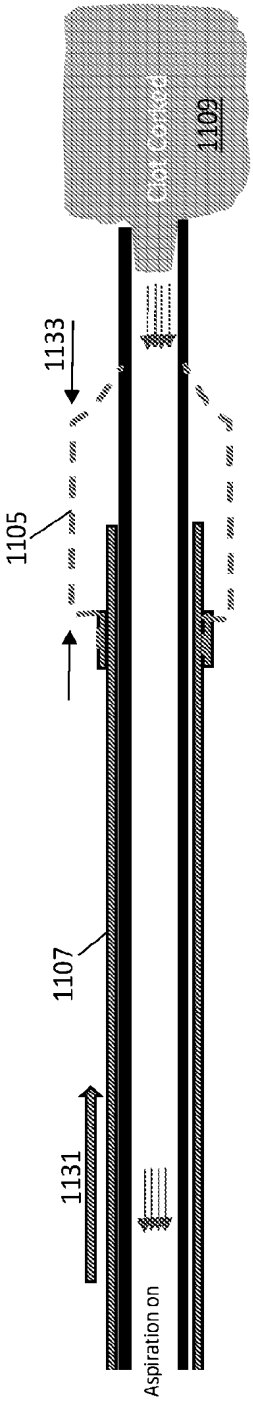

FIG. 11C

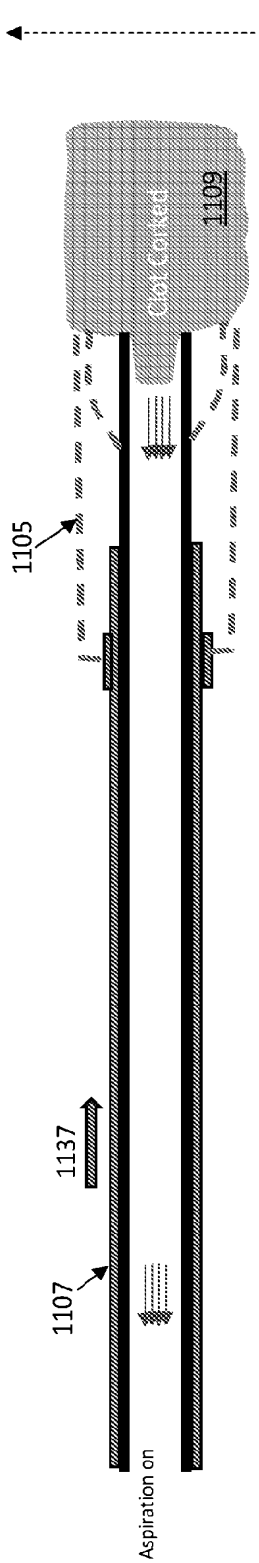

FIG. 11D

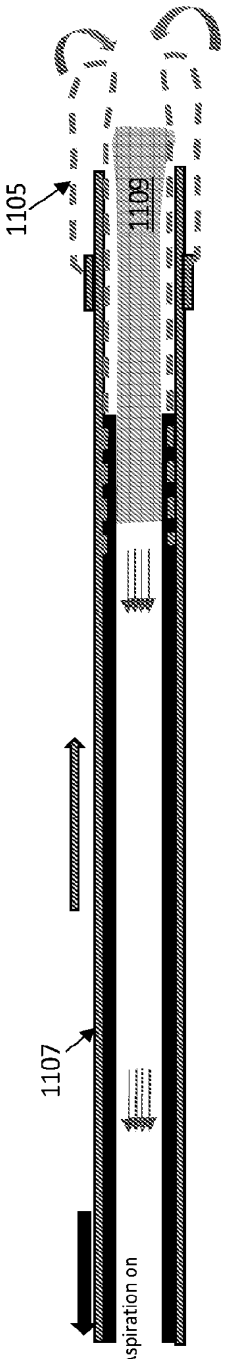

FIG. 11E

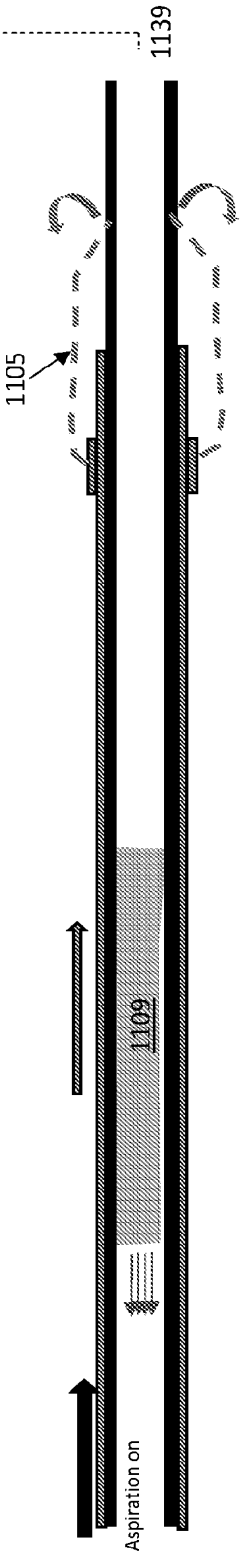

FIG. 11F

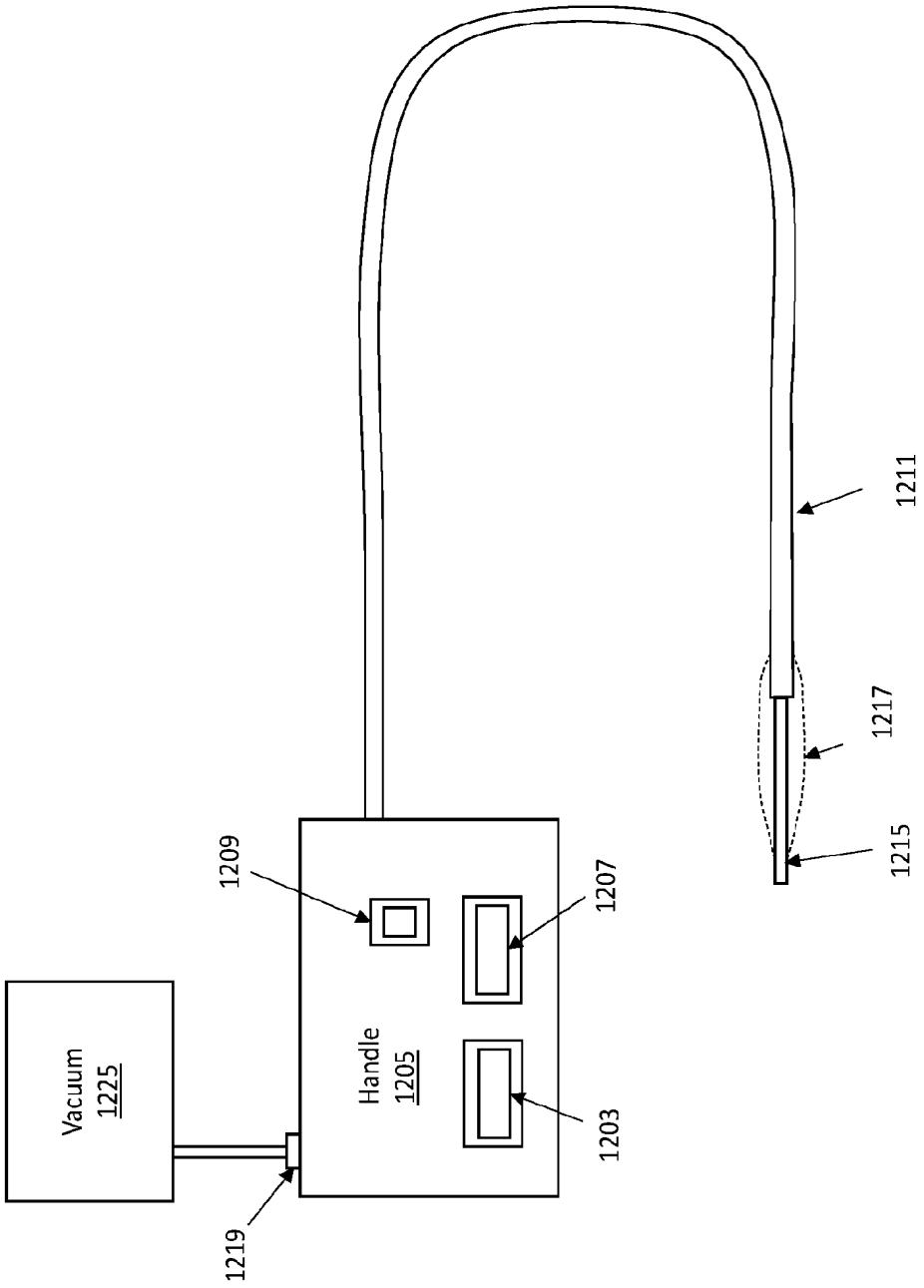

FIG. 12
(not to scale)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/032061

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/22 A61B17/221 A61B17/34
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	US 2017/086864 A1 (GREENHALGH E SKOTT [US] ET AL) 30 March 2017 (2017-03-30) cited in the application figure 6A figure 8 figure 10A figure 36 paragraph [0134] - paragraph [0136] paragraph [0141] - paragraph [0142] paragraph [0158] paragraph [0188] paragraph [0193] ----- -/--	1-12

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 July 2019	23/07/2019

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	Biegler, Marcel

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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 2017/303948 A1 (WALLACE MICHAEL P [US] ET AL) 26 October 2017 (2017-10-26) cited in the application figures 2A-C figures 41A-B figures 38A-B figures 39A-C paragraph [0125] - paragraph [0126] paragraph [0130] - paragraph [0132] paragraph [0210] paragraph [0213] paragraph [0218]	1,12
A	US 5 389 100 A (BACICH STEVEN R [US] ET AL) 14 February 1995 (1995-02-14) figure 2 column 1, line 15 - line 68	1
A	US 2013/116721 A1 (TAKAGI TOSHIAKI [JP] ET AL) 9 May 2013 (2013-05-09) paragraph [0088]; figures 9A-C	1-12

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2019/032061

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		US 2013116721 A1	09-05-2013
		WO 2012001826 A1	05-01-2012

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PCT/US2021/059718

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17 November 2021 (17.11.2021)

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(26) Publication Language: English

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(71) Applicant: **INARI MEDICAL, INC.** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US).

(72) Inventors: **DOLENDO, Edward Enriquez**; 9 Parker, Suite #100, Irvine, California 92618 (US). **BRODT, Thomas Robert**; 9 Parker, Suite #100, Irvine, California 92618 (US). **TU, Thomas M.**; 9 Parker, Suite #100, Irvine, California 92618 (US).

(74) Agent: **WILLIAMS, Matthew S.** et al.; PERKINS COIE LLP, P.O. Box 1247, Seattle, Washington 98111-1247 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

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

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(54) Title: CATHETERS HAVING SHAPED DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS

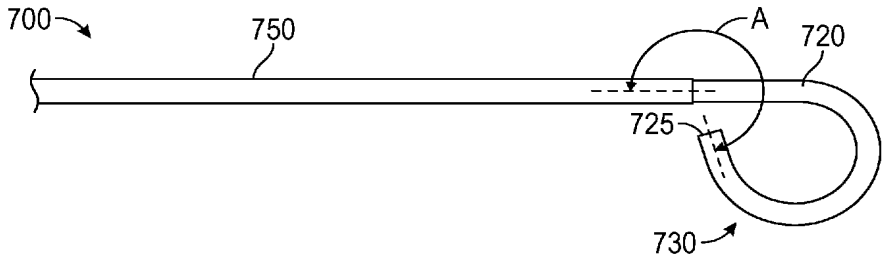

FIG. 7C

(57) Abstract: Disclosed herein are aspiration guide catheters having a pre-shaped distal portion configured to deflect away from a longitudinal axis of the catheter, and associated systems and methods. In some embodiments, an aspiration guide catheter includes an inner liner defining a lumen and having a proximal region and a distal region. The catheter further includes a braid of wires over the inner liner, and a wire coiled around the braid over at least a portion of the distal region of the inner liner. At least a portion of the braid over the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region. The catheter can further include an outer sheath over the braid, the wire, and the inner liner.

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CATHETERS HAVING SHAPED DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/115,512, filed November 18, 2020, and titled "CATHETERS HAVING SHAPED DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to catheters having shaped (e.g., pre-shaped) distal potions, such as a distal curved portion, to facilitate positioning of the catheter in hard-to-reach regions of the vasculature of a patient.

BACKGROUND

[0003] Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

[0004] When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. Infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

[0005] In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT arises most commonly when there is a propensity for stagnated blood (e.g., long distance air travel, immobility, etc.) and clotting (e.g., cancer, recent surgery, such as orthopedic surgery, etc.). DVT causes harm by: (1) obstructing drainage of venous blood from the legs leading to swelling, ulcers, pain, and infection, and (2) serving as a reservoir for blood clots to travel to other parts of the body including the heart, lungs, brain (stroke), abdominal organs, and/or extremities.

[0006] In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs, and therefore the entire body, and result in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting in low blood oxygen and buildup of blood carbon dioxide.

[0007] There are many existing techniques to reestablish blood flow through an occluded vessel. One common surgical technique, an embolectomy, involves incising a blood vessel and introducing a balloon-tipped device (such as the Fogarty catheter) to the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to translate the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Although such surgical techniques have been useful, exposing a patient to surgery may be traumatic and best avoided when possible. Additionally, the use of a Fogarty catheter may be problematic due to the possible risk of damaging the interior lining of the vessel as the catheter is being withdrawn.

[0008] Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating vessel stenosis, but it is generally not effective for treating acute thromboembolisms as none of the occlusive material is removed and the vessel will re-stenos after dilation. Another percutaneous technique involves placing a catheter near the clot and infusing streptokinase, urokinase, or other thrombolytic agents to dissolve the clot. Unfortunately, thrombolysis typically takes hours to days to be successful. Additionally, thrombolytic agents can cause hemorrhage and in many patients the agents cannot be used at all.

[0009] Various devices exist for performing a thrombectomy or removing other foreign material. However, such devices have been found to have structures which are either highly complex, cause trauma to the treatment vessel, or lack sufficient retaining structure and thus cannot be appropriately fixed against the vessel to perform adequately. Furthermore, many of the devices have highly complex structures that lead to manufacturing and quality control difficulties as well as delivery issues when passing through tortuous or small diameter catheters.

Less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all the clot material.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0011] Figure 1 is a partially schematic side view of a clot treatment system including a catheter in accordance with embodiments of the present technology.

[0012] Figure 2 is an enlarged, partial cut-away side view of a portion of a proximal region of the catheter of Figure 1 in accordance with embodiments of the present technology.

[0013] Figure 3A is an enlarged, partial cut-away side view, and Figure 3B is an enlarged, partial cut-away perspective view, of a portion of a distal region of the catheter of Figure 1 in accordance with embodiments of the present technology.

[0014] Figure 3C is an enlarged cross-sectional view of the distal region of the catheter of Figure 1 taken along the line 3C-3C in Figure 3B in accordance with embodiments of the present technology.

[0015] Figures 4A and 4B are side views of the distal portion of the catheter of Figure 1 during a procedure for removing clot material from within a blood vessel of a patient in accordance with embodiments of the present technology.

[0016] Figures 5A and 5B are side views of the distal portion of the catheter of Figure 1 during a procedure for removing clot material from within a blood vessel of a patient in accordance with additional embodiments of the present technology.

[0017] Figure 6 illustrates various shapes for the distal portion of the catheter of Figure 1 in accordance with additional embodiments of the present technology.

[0018] Figures 7A–7C are side views of a distal portion of a clot treatment system in accordance with additional embodiments of the present technology.

DETAILED DESCRIPTION

[0019] The present technology is generally directed to aspiration guide catheters having a pre-shaped distal portion for improved flexibility through tortuous/hard-to-reach vascular

anatomy, and associated systems and methods. In some embodiments, an aspiration guide catheter includes an inner liner defining a lumen and having a proximal region and a distal region. The catheter can further include a braid of wires over the inner liner, and a wire coiled around the braid over at least a portion of the distal region of the inner liner. At least a portion of the braid over the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region to define a distal shaped portion of the catheter. In some embodiments, the distal shaped portion of the catheter can comprise a curved portion. The catheter can further include an outer sheath over the braid, the wire, and the inner liner and securing these components together.

[0020] In some aspects of the present technology, the catheter is configured to be steered to and positioned in difficult-to-reach regions of the anatomy (e.g., the venous anatomy) of a patient while still having a relatively large lumen (e.g., 20 French, 24 French, greater than 24 French). More particularly, the catheter can have an improved torque response and flexibility compared to conventional catheters having the same lumen size. For example, the braid can provide good torque response along the entire length of the catheter, while the shaped portion is configured to flex into and be positioned within the difficult-to-reach regions of the anatomy. In some embodiments, the outer sheath can have a hardness that decreases in the distal direction to provide (i) good pushability/torquability at the proximal region and (ii) good flexibility at the distal region. Further, the coil can be configured to provide a selected hoop strength at the distal region while still allowing the catheter to flex. For example, the coil can inhibit or even prevent kinking or other unwanted movement of the catheter when the lumen is aspirated during a clot removal procedure.

[0021] Certain details are set forth in the following description and in Figures 1–7C to provide a thorough understanding of various embodiments of the present technology. In other instances, well-known structures, materials, operations, and/or systems often associated with intravascular procedures, clot removal procedures, catheters, and the like are not shown or described in detail in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. Those of ordinary skill in the art will recognize, however, that the present technology can be practiced without one or more of the details set forth herein, and/or with other structures, methods, components, and so forth.

[0022] The terminology used below is to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain examples of

embodiments of the technology. Indeed, certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

[0023] The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope unless expressly indicated. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles and features without departing from the present technology. In addition, those of ordinary skill in the art will appreciate that further embodiments of the present technology can be practiced without several of the details described below.

[0024] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

[0025] Figure 1 is a partially schematic side view of a clot treatment system 100 in accordance with embodiments of the present technology. The clot treatment system 100 can also be referred to as an aspiration assembly, a clot removal system, and/or a thrombectomy system. In the illustrated embodiment, the clot treatment system 100 includes a tubing assembly 110 fluidly coupled to a catheter 120 via a valve 102. In general, the clot treatment system 100 (i) can include features generally similar or identical to those of the clot treatment systems described in detail in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety, and/or (ii) can be used to

treat/remove clot material from a patient (e.g., a human patient) using any of the methods described in detail therein.

[0026] In the illustrated embodiment, the catheter 120 includes (i) a proximal region or portion 122, (ii) an intermediate region 124 adjacent to and distal of the proximal region 122, (iii) a distal region 126 adjacent to and distal of the intermediate region 124, and (iv) a distal tip region 128 adjacent to and distal of the distal region 126 (collectively "regions 122–128"). The catheter 120 further defines a lumen 121 extending entirely therethrough from the proximal region 122 to the distal tip region 128. The proximal region 122 defines a proximal terminus 123 of the catheter 120, and the distal tip region 128 defines a distal terminus 125 of the catheter 120. In the illustrated embodiment, the distal tip region 128 includes a marker band 129, such as a radiopaque marker configured to facilitate visualization of the position of the catheter 120 during a medical procedure (e.g., a clot removal procedure) using the catheter 120.

[0027] In some embodiments, the proximal region 122 has a first length, the intermediate region 124 has a second length less than the first length, the distal region 126 has a third length greater than the second length but less than the first length, and the distal tip region 128 has a fourth length less than the first, second, and third lengths. For example, the first length can be between about 20.0–28.0 inches (e.g., about 24.0 inches), the second length can be between about 2.0–3.0 inches (e.g., about 2.50 inches), the third length can be between about 11.00–15.00 inches (e.g., about 13.25 inches), and the fourth length can be between about 0.10–0.50 inch (e.g., about 0.25 inch). In other embodiments, the lengths of one or more of the regions 122–128 can be different.

[0028] In some embodiments, the catheter 120 can have varying flexibilities, shapes, thicknesses, and/or other properties in/along the various regions 122–128. For example, the distal region 126 can include a shaped portion 130 configured (e.g., heat set) to deflect away from a longitudinal axis Z of the catheter 120 relative to the rest of the distal region 126, the intermediate region 124, and the proximal region 122. That is, the shaped portion 130 can be configured to deflect away from the longitudinal axis Z that is aligned with the proximal region 122, the intermediate region 124, and/or the unshaped portion of the distal region 126 proximal to the shaped portion 130. In the illustrated embodiment, the shaped portion 130 has a generally curved shape. In some embodiments, the shaped portion 130 can move between (i) a relaxed position in which the shaped portion 130 has the curved shape illustrated in Figure 1 and (ii) a constrained position in which the shaped portion 130 is more closely aligned with the

longitudinal axis Z, as shown in phantom lines in Figure 1. In some embodiments, the shaped portion 130 has (i) a length L that can be between about 1.0–5.0 inches (e.g., about 2.35 inches), (ii) a bend radius R of between about 0.5–1.0 inch (e.g., about 0.8 inch, less than about 0.8 inch), and/or (iii) a bend angle A of between about 165–195 degrees (e.g., about 180 degrees) or greater than 195 degrees (e.g., between about 250–290 degrees, about 270 degrees). In other embodiments, the bend angle A can be less than 165 degrees.

[0029] In other embodiments, the shaped portion 130 can have other dimensions and/or shapes. For example, Figure 6 illustrates various shapes for the shaped portion 130 of the catheter 120 in accordance with additional embodiments of the present technology. The shaped portion 130 can have any of the shapes illustrated in Figure 6, such as a Tiger curve shape, a Jacky curve shape, an Amplatz left shape, an LCB shape, an RCB shape, a Judkins left shape, a Judkins right shape, a Multipurpose A2 shape, an IM shape, a 3D LIMA shape, a IM VB-1 shape, and so on.

[0030] The valve 102 is fluidly coupled to the lumen 121 of the catheter 120 and can be integral with or coupled to the proximal region 122 of the catheter 120. In some embodiments, the valve 102 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 102 as various components such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and so on are inserted through the valve 102 to be delivered through the catheter 120 to a treatment site in a blood vessel. The valve 102 includes a branch or side port 104 configured to fluidly couple the lumen 121 of the catheter 120 to the tubing assembly 110. In some embodiments, the valve 102 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.

[0031] In the illustrated embodiment, the tubing assembly 110 fluidly couples the catheter 120 to a pressure source 106, such as a syringe. The tubing assembly 110 can include one or more tubing sections 112 (individually labeled as a first tubing section 112a and a second tubing section 112b), at least one fluid control device 114 (e.g., a valve), and at least one connector 116 (e.g., a Toomey tip connector) for fluidly coupling the tubing assembly 110 to the pressure source 106 and/or other suitable components. In some embodiments, the fluid control device 114 is a stopcock that is fluidly coupled to (i) the side port 104 of the valve 102 via the first tubing section 112a and (ii) the connector 116 via the second tubing section 112b. The fluid

control device 114 is externally operable by a user to regulate the flow of fluid therethrough and, specifically, from the lumen 121 of the catheter 120 to the pressure source 106. In some embodiments, the connector 116 is a quick-release connector (e.g., a quick disconnect fitting) that enables rapid coupling/decoupling of the catheter 120 and the fluid control device 114 to/from the pressure source 106.

[0032] Figure 2 is an enlarged, partial cut-away side view of a portion of the proximal region 122 of the catheter 120 in accordance with embodiments of the present technology. Figure 3A is an enlarged, partial cut-away side view, and Figure 3B is an enlarged, partial cut-away perspective view, of a portion of the distal region 126 of the catheter 120 in accordance with embodiments of the present technology. Referring to Figures 1–3B together, the catheter 120 includes an outer sheath 230 and an inner liner 232 extending through/defining each of the regions 122–128. The outer sheath 230 is positioned over (e.g., radially outside of) the inner liner 232. The outer sheath 230 can also be referred to as an outer jacket, an outer shaft, or an outer layer, and the inner liner 232 can also be referred to as an inner layer, an inner sheath, or an inner shaft.

[0033] The catheter 120 further includes (i) a braid 234 extending along each of the regions 122–128 between the outer sheath 230 and the inner liner 232 and (ii) a coil 336 (Figures 3A–3C) extending at least partially along the distal region 126 between the braid 234 and the outer sheath 230. In some embodiments, the coil 336 can extend from the distal region 126 at least partially (e.g., entirely) along the intermediate region 124 and/or the proximal region 122. In certain embodiments, the coil 336 is omitted in the proximal region 122 but extends substantially entirely along the intermediate region 124 and the distal region 126.

[0034] In some embodiments, the outer sheath 230 can be formed from a plastic material, elastomeric material, and/or thermoplastic elastomer (TPE) material. In some embodiments, the outer sheath 230 can be formed from a TPE manufactured by Arkema S.A., of Colombes, France, such as the TPEs manufactured under the trademark "Pebax." In some embodiments, the outer sheath 230 can have a varying hardness (e.g., durometer), thickness, flexibility, rigidity, and/or other property in one or more of the different regions 122–128. For example, the outer sheath 230 can have a first hardness along the proximal region 122, a second hardness along the intermediate region 124 that is less than the first hardness, a third hardness along the distal region 126 that is less than the first hardness and the second hardness, and a fourth hardness in the distal tip region 128 that is greater than third hardness. In some embodiments, the first hardness and

the fourth hardness can each be between about 65D–75D (e.g., about 72D), the second hardness can be between about 50D–60D (e.g., about 55D), and the third hardness can be between about 30D–40D (e.g., about 35D). In other embodiments, one or more of the regions 122–128 can have a different hardness.

[0035] The inner liner 232 defines the lumen 121 and, in some embodiments, can be formed of a lubricious material that facilitates the movement (e.g., distal advancement, proximal retraction) of various components through the lumen 121, such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and the like. In some embodiments, the inner liner 232 can be formed from a polymer material, a fluoropolymer material (e.g., polytetrafluoroethylene (PTFE)), and/or another material having a high degree of lubricity. In some embodiments, the inner liner 232 can have a diameter D (Figure 2) of greater than about 6 French, greater than about 10 French, greater than about 16 French, greater than about 20 French, greater than about 24 French, or greater. In some embodiments, the diameter D is about 8 French, about 16 French, about 20 French, or about 24 French. In certain embodiments, the diameter D of the inner liner 232 is the same in each of the regions 122–128 while, in other embodiments, the diameter D can vary along one or more of the regions 122–128.

[0036] The braid 234 can include wires, filaments, threads, sutures, fibers, or the like (collectively "wires 238") that have been woven or otherwise coupled, attached, formed, and/or joined together at a plurality of interstices 239. Accordingly, the braid 234 can also be referred to as a braided structure, a braided filament structure, a braided filament mesh structure, a mesh structure, a mesh filament structure, and the like. In some embodiments, the wires 238 can comprise metals, polymers, and/or composite materials. At least a portion of the wires 238 at the shaped portion 130 of the catheter 120 can be formed from a shape memory material, a shape memory alloy, and/or a shape memory polymer, such as nickel-titanium alloys (e.g., nitinol). In some embodiments, individual ones of the wires 238 can be rolled flat wires having a cross-sectional dimension of between about 0.001–0.005 inch (e.g., about 0.002 inch) by about 0.002–0.005 inch (e.g., about 0.0033 inch).

[0037] In the illustrated embodiment, the coil 336 is a single wire wound around the braid 234 and the inner liner 232. In other embodiments, the coil 336 can include more than one wire wound about the braid 234. For example, the coil 336 can include multiple wires wound over one another and/or multiple wires wound to at least partially overlap one another to form a

braided or overlapping coil structure on the braid 234. In other embodiments, the coil 336 can be formed directly over the inner liner 232, and the braid 234 can be formed over the coil 336. The coil 336 can be formed from a metallic or other suitably strong material, such as nickel-titanium alloys (e.g. nitinol), platinum, cobalt-chrome alloys, stainless steel, tungsten, and/or titanium. In some embodiments, the coil 336 can include a shape memory material at least at the shaped portion 130 of the catheter 120.

[0038] Figure 3C is an enlarged cross-sectional view of a portion of the distal region 126 of the catheter 120 taken along the line 3C-3C in Figure 3B in accordance with embodiments of the present technology. In the illustrated embodiment, the outer sheath 230 has a first thickness T_1, the coil 336 has a second thickness T_2 less than the first thickness T_1, the braid 234 has a third thickness T_3 less than the first thickness T_1 but greater than the second thickness T_2, and the inner liner 232 has a fourth thickness T_4 less than the first, second, and third thicknesses T_{1-3}. For example, the first thickness T_1 can be between about 0.005–0.010 inch (e.g., between about 0.006–0.007 inch, about 0.006 inch, about 0.007 inch), the second thickness T_2 can be between about 0.001–0.005 inch (e.g., about 0.003 inch), the third thickness T_3 can be between about 0.002–0.006 inch (e.g., about 0.004 inch), and the fourth thickness T_4 can be between about 0.001–0.004 inch (e.g., about 0.002 inch). In other embodiments, one or more of the first through fourth thicknesses T_{1-4} can be different.

[0039] In some embodiments, the catheter 120 can be formed about a mandrel or other elongate member. For example, the inner liner 232 can first be positioned about the mandrel. Then, the braid 234 can be formed (e.g., wound, braided) about the inner liner 232 around the mandrel. Next, the coil 336 can be wound around the mandrel about the braid 234 over the intermediate region 124 and the distal region 126 (e.g., of the inner liner 232 and the braid 234). In some embodiments, the marker band 129 can be positioned about the mandrel at the distal tip region 128. Next, the outer sheath 230 can be positioned over the inner liner 232, the braid 234, and the coil 336, and then heat shrunk or otherwise secured thereto. In some embodiments, the outer sheath 230 can be fused to the coil 336, the braid 234, and/or the inner liner 232 to secure these components of the catheter 120 together.

[0040] Finally, the shaped portion 130 of the catheter 120 can be shaped using a heat setting or other suitable process to have the curved shape illustrated in Figure 1, or another shape (e.g., any of the shapes shown in Figure 6). For example, as is known in the art of heat setting shape memory structures, a fixture, mandrel, or mold may be used to hold the shaped portion

130 in its desired shape, and then the shaped portion 130 can be subjected to an appropriate heat treatment such that the wires 238 of the braid 234 and/or the coil 336 assume or are otherwise shape-set to the outer contour of the mandrel or mold. In some embodiments, only the wires 238 of the braid 234 include a shape memory material that is shaped via the heat setting process. In other embodiments, the coil 336 can alternatively or additionally include a shape memory material that is shaped via the heat setting process. The heat setting process may be performed in an oven or fluidized bed, as is well-known. Therefore, the heat setting process can impart a desired shape, geometry, bend, and/or curve in the super-elastic and/or shape memory material or materials used to form the braid 234 and/or the coil 336. Accordingly, the shaped portion 130 may be radially constrained without plastic deformation (e.g., as shown in phantom in Figure 1) and will self-expand on release of the radial constraint to the position illustrated in Figure 1.

[0041] In some aspects of the present technology, the catheter 120 is configured to be steered to and positioned in difficult-to-reach regions of the anatomy (e.g., venous anatomy) of a patient while still having a relatively large size (e.g., 20 French, 24 French, greater than 24 French). More particularly, the catheter 120 can have an improved torque response and flexibility compared to conventional catheters having the same size. For example, the braid 234 can provide good torque response along the entire length of the catheter 120 because the braid 234 extends entirely through each of the regions 122–128 of the catheter 120. Moreover, the varying hardness (e.g., distally decreasing hardness) of the outer sheath 230 can provide (i) good torque response and/or pushability at the proximal region 122 and (ii) increased flexibility at the intermediate and distal regions 124, 126. Additionally, the shaped portion 130 is configured (e.g., shaped, sized, positioned) to flex into and be positioned within the difficult-to-reach regions of the anatomy. Further, the coil 336 can provide increased hoop strength at the distal region 126 while still allowing the catheter 120 to flex. For example, the coil 336 can inhibit or even prevent kinking or other unwanted movement of the catheter 120 when the lumen 121 is aspirated during a clot removal procedure.

[0042] Figures 4A and 4B are side views of the distal region 126 of the catheter 120 of the clot treatment system 100 during a procedure for removing clot material PE (e.g., a pulmonary embolism) from within a blood vessel BV (e.g., a pulmonary blood vessel) of a patient (e.g., a human patient) in accordance with embodiments of the present technology. As noted above, in some embodiments the clot removal procedure illustrated in Figures 4A and 4B can be generally similar or identical to any of the clot removal procedures disclosed in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM

AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety.

[0043] With reference to Figures 1 and 4A together, the catheter 120 can be advanced through the patient to proximate the clot material PE with the blood vessel BV (e.g., advanced to a treatment site within the blood vessel BV). In some embodiments, the catheter 120 can be advanced through the blood vessel BV until the distal terminus 125 of the catheter 120 is positioned proximate to a proximal portion of the clot material PE. In some embodiments, the position of the distal terminus 125 can be confirmed or located via visualization of the marker band 129 using fluoroscopy or another imaging procedure (e.g., a radiographic procedure). In other embodiments, the distal terminus 125 can be positioned at least partially within the clot material PE or distal of the clot material PE.

[0044] In some aspects of the present technology, the shaped portion 130 helps the catheter 120 flex/bend into tortuous (e.g., hard-to-reach) regions of the blood vessel BV. For example, in the illustrated embodiment the shaped portion 130 has flexed around a bend 440 in the blood vessel BV that can have a relatively small radius of curvature. The portion of the blood vessel BV distal of the bend 440 can be difficult to reach due to the required approach angle, varying anatomy of the blood vessel BV, and/or irregularities due to illness of the patient. In some embodiments, the blood vessel BV can be a portion of left pulmonary artery, the temporal arteries, the inferior vena cava, or the right atrium. In some embodiments, the clot material PE can be a clot in transit (CIT) within the right atrium.

[0045] In some embodiments, before advancing the catheter 120 to the position shown in Figure 4A, the catheter 120 can be rotated to align the shaped portion 130 with the bend 440 (e.g., to at least generally align a deflection direction of the shaped portion 130 with the bend 440). In contrast to the catheter 120 of the present technology, conventional catheters of the same size may be too stiff to easily position proximate the clot material PE. For example, such conventional catheters may "rainbow" over the clot material PE by following or tracking along the wall of the blood vessel BV at the outside of the bend 400. In addition to the shaped portion 130, both (i) the varying hardness of the outer sheath 230 (Figures 2–3C) and (ii) the flexibility of the braid 234 (Figures 2–3C) and the coil 446 (Figures 3A–3C) can help the catheter 120 flex through the anatomy of the blood vessel BV to the desired position proximate the clot material PE.

[0046] Access to the pulmonary vessels can be achieved through the patient's vasculature, for example, via the femoral vein. In some embodiments, the clot treatment system 100 can include an introducer (e.g., a Y-connector with a hemostasis valve; not shown) that can be partially inserted into the femoral vein. A guidewire (not shown) can be guided into the femoral vein through the introducer and navigated through the right atrium, the tricuspid valve, the right ventricle, the pulmonary valve, and into the main pulmonary artery. Depending on the location of the clot material PE, the guidewire can be guided to one or more of the branches of the right pulmonary artery and/or the left pulmonary artery. In some embodiments, the guidewire can be extended entirely or partially through the clot material PE. In other embodiments, the guidewire can be extended to a location just proximal of the clot material PE. After positioning the guidewire, the catheter 120 can be placed over the guidewire and advanced to the position proximate to the clot material PE as illustrated in Figure 4A. In some embodiments, the guidewire can then be withdrawn while, in other embodiments, the guidewire can remain and can be used to guide other catheters (e.g., delivery catheters, additional aspiration guide catheters), interventional devices, etc., to the treatment site. It will be understood, however, that other access locations into the venous circulatory system of a patient are possible and consistent with the present technology. For example, the user can gain access through the jugular vein, the subclavian vein, the brachial vein, or any other vein that connects or eventually leads to the superior vena cava. Use of other vessels that are closer to the right atrium of the patient's heart can also be advantageous as it reduces the length of the instruments needed to reach the clot material PE.

[0047] With reference to Figures 1 and 4B together, the pressure source 106 is configured to generate (e.g., form, create, charge, build-up) a vacuum (e.g., negative relative pressure) and store the vacuum for subsequent application to the catheter 120. For example, after positioning the catheter 120 proximate the clot material PE, a user can first close the fluid control device 114 before generating the vacuum in the pressure source 106 by, for example, withdrawing the plunger of a syringe coupled to the connector 116. In this manner, a vacuum is charged within the pressure source 106 (e.g., a negative pressure is maintained) before the pressure source 106 is fluidly connected to the lumen 121 of the catheter 120. To aspirate the lumen 121 of the catheter 120, the user can open the fluid control device 114 to fluidly connect the pressure source 106 to the catheter 120 and thereby apply or release the vacuum stored in the pressure source 106 to the lumen 121 of the catheter 120.

[0048] Opening of the fluid control device 114 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing assembly 110 and the catheter 120, thereby generating a suction pulse throughout the catheter 120. In particular, the suction is applied at the distal tip region 128 of the catheter 120 to suck/aspirate at least a portion of the clot material PE into the lumen 121 of the catheter 120, as shown in Figure 4B. In one aspect of the present technology, pre-charging or storing the vacuum in the pressure source 106 before applying the vacuum to the lumen 121 of the catheter 120 is expected to generate greater suction forces and corresponding fluid flow velocities at and/or near the distal tip region 128 of the catheter 120 compared to simply activating the pressure source 106 while it is fluidly connected to the catheter 120.

[0049] Sometimes, as shown in Figure 4B, discharging the vacuum stored in the pressure source to aspirate the lumen 121 of the catheter 120 may remove substantially all (e.g., a desired amount) of the clot material PE from the blood vessel BV. That is, a single aspiration pulse may adequately remove the clot material PE from the blood vessel BV. In other embodiments, a portion of the clot material PE may remain in the blood vessel BV. In such instances, the user may wish to again apply vacuum pressure (conduct an "aspiration pass") to remove all or a portion of the remaining clot material PE in the blood vessel BV. In such instances, the pressure source 106 can be disconnected from the tubing assembly 110 and drained (e.g., aspirated clot removal removed) before the pressure source 106 is reconnected to the tubing assembly 110 and activated once again. After removing a desired amount of the clot material PE, the catheter 120 can be withdrawn from the patient.

[0050] In some aspects of the present technology, the relatively great flexibility and torquability of the catheter 120 allow the catheter 120 to be positioned in difficult-to-reach areas of the blood vessel BV (or elsewhere in the vasculature of the patient) without reducing the size of the lumen 121. It is expected that the increased size of the lumen 121 will provide greater suction forces over a smaller period of time (e.g., will provide a larger vacuum impulse). In some embodiments, the greater suction forces can facilitate the removal of clot material from a blood vessel of a patient even where the clot material is strongly lodged or attached within the blood vessel (e.g., a chronic clot). Accordingly, in contrast to conventional catheters, the catheter 120 can be used to generate greater aspirational forces for improved clot removal in hard-to-reach places of the vasculature. In additional aspects of the present technology, the coil 336 (Figures 3A–3C) can provide a high hoop strength along the distal region 126 of the catheter 120 that inhibits or even prevents kinking or other unwanted movement of the catheter 120 when

the pressure source 106 is used to generate a suction pulse at the distal region 126 of the catheter 120.

[0051] Figures 5A and 5B are side views of the distal region 126 of the catheter 120 of the clot treatment system 100 during another procedure for removing the clot material PE from within the blood vessel BV in accordance with additional embodiments of the present technology. As noted above, in some embodiments the clot removal procedure illustrated in Figures 5A and 5B can be generally similar or identical to any of the clot removal procedures disclosed in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety.

[0052] Referring first to Figure 5A, the catheter 120 ("first catheter 120") can be advanced through the patient to proximate the clot material PE with the blood vessel BV as described in detail above with reference to Figure 4A. As shown in Figure 5A, in some embodiments a second catheter 550 can then be advanced over the first catheter 120 to proximate the clot material PE. The second catheter 550 can define a lumen 552 having a larger size (e.g., 20 French or greater, 24 French or greater) than the lumen 121 of the first catheter 120. In some embodiments, the second catheter 550 has a greater stiffness than the first catheter 120. In other embodiments, the second catheter 550 can be larger than but generally similar or identical to the first catheter 120 (e.g., having a distal heat-set shaped portion).

[0053] Accordingly, the first catheter 120 can act as a guide or rail for guiding the advancement of the second catheter 550 to proximate the clot material PE. In some aspects of the present technology, the larger size and/or stiffness of the second catheter 550 could make the second catheter 550 difficult to navigate to proximate the clot material PE (e.g., across the bend 440) without the first catheter 120 acting as a guide. That is, the first catheter 120 can be flexibly positioned proximate the clot material PE and used to guide the larger and/or stiffer second catheter 550 into a position it would otherwise be difficult or impossible to do so.

[0054] The second catheter 550 can be part of a clot treatment system (not shown) having features generally similar or identical to that of the clot treatment system 100 of Figure 1 including, for example, a fluid control device and a pressure source. Accordingly, with reference to Figure 5B, the pressure source can be used to generate a vacuum in the lumen 552 of the second catheter, and the fluid control device can be opened to fluidly connect the pressure source to the second catheter 550 and thereby apply or release the vacuum stored in the pressure source

to the lumen 552 of the second catheter 550. Opening of the fluid control device instantaneously or nearly instantaneously applies the stored vacuum pressure to the second catheter 550, thereby generating a suction pulse throughout the second catheter 550 that can suck at least a portion of the clot material PE into the lumen 552 of the second catheter 550. In some embodiments, the clot treatment system 100 (Figure 1) can also be operated to aspirate the clot material PE into the lumen 121 of the lumen 121 of the first catheter 120, as described in detail above with reference to Figures 4A and 4B. In some aspects of the present technology, the larger size of the lumen 552 of the second catheter 550 can be used to generate greater suction forces than the smaller lumen 121 of the first catheter 120. After removing a desired amount of the clot material PE, the first and second catheters 120, 550 can be withdrawn from the patient.

[0055] Referring to Figures 4A–5B together, in some embodiments one or more additional devices can be advanced through the catheter 120. For example, one or more aspiration catheters, mechanical thrombectomy devices, and/or the like can be advanced through the catheter 120 to proximate the clot material PE to aid in the clot removal process. In some such embodiments, the shaped portion 130 can facilitate the advancement of the one or more additional devices through the catheter 120. For example, the one or more additional devices can track through the shaped portion 130 of the catheter 120 to at and/or proximate the clot material PE.

[0056] Figures 7A–7C are side views of a distal portion of a clot treatment system 700 in accordance with embodiments of the present technology. Referring to Figures 7A–7C together, the clot treatment system 700 can include some features that are least at generally similar in structure and function, or identical in structure and function, to the corresponding features of the clot treatment system 100 described in detail above with reference to Figures 1–6, and can operate in a generally similar or identical manner to the clot treatment system 100. In the illustrated embodiment, for example, the clot treatment system 700 includes a first catheter 720 (e.g., a pre-shaped catheter) that can be advanced through a larger second catheter 750. The first catheter 720 can have a shaped distal portion 730 (obscured in Figure 7A) including a distal tip or terminus 725. In some embodiments the first catheter 720 has a size of about 20 French or greater than 20 French, and the second catheter 750 has a size of about 24 French or greater than 24 French.

[0057] Figures 7A–7C illustrate the sequential deployment of the shaped distal portion 730 from within the second catheter 750. More specifically, the shaped distal portion 730 is (i)

positioned substantially within and constrained by the second catheter 750 in Figure 7A, (ii) positioned partially within and partially outside the second catheter 750 in Figure 7B, and (iii) positioned substantially outside of (e.g., distal of) and constrained by the second catheter 750 in Figure 7C. In the illustrated embodiment, the shaped distal portion 730 is configured (e.g., heat set) to deflect away from a longitudinal axis Z (Figures 7A) of the first and second catheters 720, 750 to have a generally curved shape. In some embodiments, the shaped distal portion 730 can deflect by an angle A of between about between about 250–290 degrees (e.g., about 255 degrees, about 260 degrees, about 270 degrees) when fully unconstrained by the second catheter 750 as shown in Figure 7C. The shaped distal portion 730 can be deployed from the second catheter 750 via advancement of the first catheter 720 relative to the second catheter 750 and/or retraction of the second catheter 750 relative to the first catheter 720. That is, for example, the second catheter 750 can be retracted off of the shaped distal portion 730 such that the shaped distal portion 730 is no longer constrained by the second catheter 750 and thereby able to deflect away from the longitudinal axis Z as shown in Figure 7C.

[0058] Several aspects of the present technology are set forth in the following examples:

1. An aspiration catheter, comprising:

an inner liner defining a lumen and having a proximal region and a distal region;

a braid of wires over the inner liner, wherein a deflectable portion of the braid over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained;

a wire coiled over at least a portion of the distal region of the inner liner; and

an outer sheath over the braid, the wire, and the inner liner.

2. The aspiration catheter of example 1 wherein the wires in the deflectable portion of the braid is pre-shaped to deflect away from the longitudinal axis.

3. The aspiration catheter of example 1 or example 2 wherein the deflectable portion of the braid is configured to deflect away from the longitudinal axis to have a bend angle of between about between about 165–195 degrees when the aspiration catheter is unconstrained.

4. The aspiration catheter of example 1 or example 2 wherein the deflectable portion of the braid is configured to deflect away from the longitudinal axis to have a bend angle of between about 270 degrees when the aspiration catheter is unconstrained.

5. The aspiration catheter of any one of examples 1–4 wherein the lumen has a diameter of 20 French or greater.

6. The aspiration catheter of any one of examples 1–5 wherein the lumen has a diameter of 24 French or greater.

7. The aspiration catheter of any one of examples 1–6 wherein the inner liner is formed from polytetrafluoroethylene material, and wherein the outer sheath is formed from a thermoplastic elastomer material.

8. The aspiration catheter of any one of examples 1–7 wherein the outer sheath has a first hardness over the proximal region of the inner liner, and wherein the outer sheath has a second hardness over the distal region of the inner liner that is less than the first hardness.

9. An aspiration catheter, comprising:

a proximal region defining a longitudinal axis;

an intermediate region extending from the proximal region;

a distal region extending from the intermediate region;

an inner lining defining a lumen and extending through the proximal region, the intermediate region, and the distal region;

a braid of wires extending over the inner liner and through the proximal region, the intermediate region, and the distal region, wherein a deflectable portion of the braid in the distal region is configured to deflect away from the longitudinal axis when the aspiration catheter is unconstrained;

a wire coiled in the distal region; and

an outer sheath extending over the braid, the wire, and the inner liner and through the proximal region, the intermediate region, and the distal region.

10. The aspiration catheter of example 9 wherein the deflectable portion of the braid is configured to deflect away from the longitudinal axis to have a bend angle of between about between about 165–195 degrees when the aspiration catheter is unconstrained.

11. The aspiration catheter of example 9 or example 10 wherein the outer sheath has (a) a first hardness in the proximal region of between about 65D–75D, (b) a second hardness in the intermediate region of between about 50D–60D, and (c) a third hardness in the distal region of between about 30D–40D.

12. The aspiration catheter of any one of examples 9–11 wherein the outer sheath has (a) a first hardness in the proximal region, (b) a second hardness in the intermediate region less than the first hardness, and (c) a third hardness in the distal region less than the second hardness.

13. The aspiration catheter of example 12 wherein (a) the proximal region has a first length, (b) the intermediate region has a second length less than the first length, and (c) the distal region has a third length greater than the second length and less than the first length.

14. The aspiration catheter of example 13 wherein the first length is between about 20.0–28.0 inches, the second length is between about 2.0–3.0 inches, and the third length is between about 11.00–15.00 inches.

15. A method of removing clot material from a blood vessel, the method comprising:

advancing an aspiration catheter through the blood vessel, wherein the aspiration catheter includes a distal portion and a proximal portion, wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion;

positioning a distal tip of the aspiration catheter proximate the clot material;

activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and

opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter.

16. The method of example 15 wherein the distal portion of the aspiration catheter is configured to deflect away from the longitudinal axis in a deflection direction, and wherein the method further comprises rotating the aspiration catheter such that the deflection direction is at least partially aligned with a bend in the blood vessel.

17. The method of example 15 or example 16 wherein the aspiration catheter has a size of 20 French or greater.

18. The method of any one of examples 15–17 wherein the distal portion of the aspiration catheter is configured to deflect away from the longitudinal axis to have a bend angle of between about between about 165–195 degrees when the aspiration catheter is unconstrained.

19. The method of any one of examples 15–17 wherein the distal portion of the aspiration catheter is configured to deflect away from the longitudinal axis to have a bend angle of about 270 degrees when the aspiration catheter is unconstrained.

20. The method of any one of examples 15–19 wherein the distal portion of the aspiration catheter includes—

an inner liner defining a lumen;

a braid of wires extending over the inner liner;

a wire coiled around the braid; and

an outer sheath extending over the braid.

[0059] 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.

[0060] 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.

[0061] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. An aspiration catheter, comprising:

an inner liner defining a lumen and having a proximal region and a distal region;

a braid of wires over the inner liner, wherein a deflectable portion of the braid over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained;

a wire coiled over at least a portion of the distal region of the inner liner; and

an outer sheath over the braid, the wire, and the inner liner.

2. The aspiration catheter of claim 1 wherein the wires in the deflectable portion of the braid is pre-shaped to deflect away from the longitudinal axis.

3. The aspiration catheter of claim 1 wherein the deflectable portion of the braid is configured to deflect away from the longitudinal axis to have a bend angle of between about between about 165–195 degrees when the aspiration catheter is unconstrained.

4. The aspiration catheter of claim 1 wherein the deflectable portion of the braid is configured to deflect away from the longitudinal axis to have a bend angle of between about 270 degrees when the aspiration catheter is unconstrained.

5. The aspiration catheter of claim 1 wherein the lumen has a diameter of 20 French or greater.

6. The aspiration catheter of claim 1 wherein the lumen has a diameter of 24 French or greater.

7. The aspiration catheter of claim 1 wherein the inner liner is formed from polytetrafluoroethylene material, and wherein the outer sheath is formed from a thermoplastic elastomer material.

8. The aspiration catheter of claim 1 wherein the outer sheath has a first hardness over the proximal region of the inner liner, and wherein the outer sheath has a second hardness over the distal region of the inner liner that is less than the first hardness.

9. An aspiration catheter, comprising:

a proximal region defining a longitudinal axis;

an intermediate region extending from the proximal region;

a distal region extending from the intermediate region;

an inner lining defining a lumen and extending through the proximal region, the intermediate region, and the distal region;

a braid of wires extending over the inner liner and through the proximal region, the intermediate region, and the distal region, wherein a deflectable portion of the braid in the distal region is configured to deflect away from the longitudinal axis when the aspiration catheter is unconstrained;

a wire coiled in the distal region; and

an outer sheath extending over the braid, the wire, and the inner liner and through the proximal region, the intermediate region, and the distal region.

10. The aspiration catheter of claim 9 wherein the deflectable portion of the braid is configured to deflect away from the longitudinal axis to have a bend angle of between about between about 165–195 degrees when the aspiration catheter is unconstrained.

11. The aspiration catheter of claim 9 wherein the outer sheath has (a) a first hardness in the proximal region of between about 65D–75D, (b) a second hardness in the intermediate region of between about 50D–60D, and (c) a third hardness in the distal region of between about 30D–40D.

12. The aspiration catheter of claim 9 wherein the outer sheath has (a) a first hardness in the proximal region, (b) a second hardness in the intermediate region less than the first hardness, and (c) a third hardness in the distal region less than the second hardness.

13. The aspiration catheter of claim 12 wherein (a) the proximal region has a first length, (b) the intermediate region has a second length less than the first length, and (c) the distal region has a third length greater than the second length and less than the first length.

14. The aspiration catheter of claim 13 wherein the first length is between about 20.0–28.0 inches, the second length is between about 2.0–3.0 inches, and the third length is between about 11.00–15.00 inches.

15. A method of removing clot material from a blood vessel, the method comprising:

advancing an aspiration catheter through the blood vessel, wherein the aspiration catheter includes a distal portion and a proximal portion, wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion;

positioning a distal tip of the aspiration catheter proximate the clot material;

activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and

opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter.

16. The method of claim 15 wherein the distal portion of the aspiration catheter is configured to deflect away from the longitudinal axis in a deflection direction, and wherein the method further comprises rotating the aspiration catheter such that the deflection direction is at least partially aligned with a bend in the blood vessel.

17. The method of claim 15 wherein the aspiration catheter has a size of 20 French or greater.

18. The method of claim 15 wherein the distal portion of the aspiration catheter is configured to deflect away from the longitudinal axis to have a bend angle of between about between about 165–195 degrees when the aspiration catheter is unconstrained.

19. The method of claim 15 wherein the distal portion of the aspiration catheter is configured to deflect away from the longitudinal axis to have a bend angle of about 270 degrees when the aspiration catheter is unconstrained.

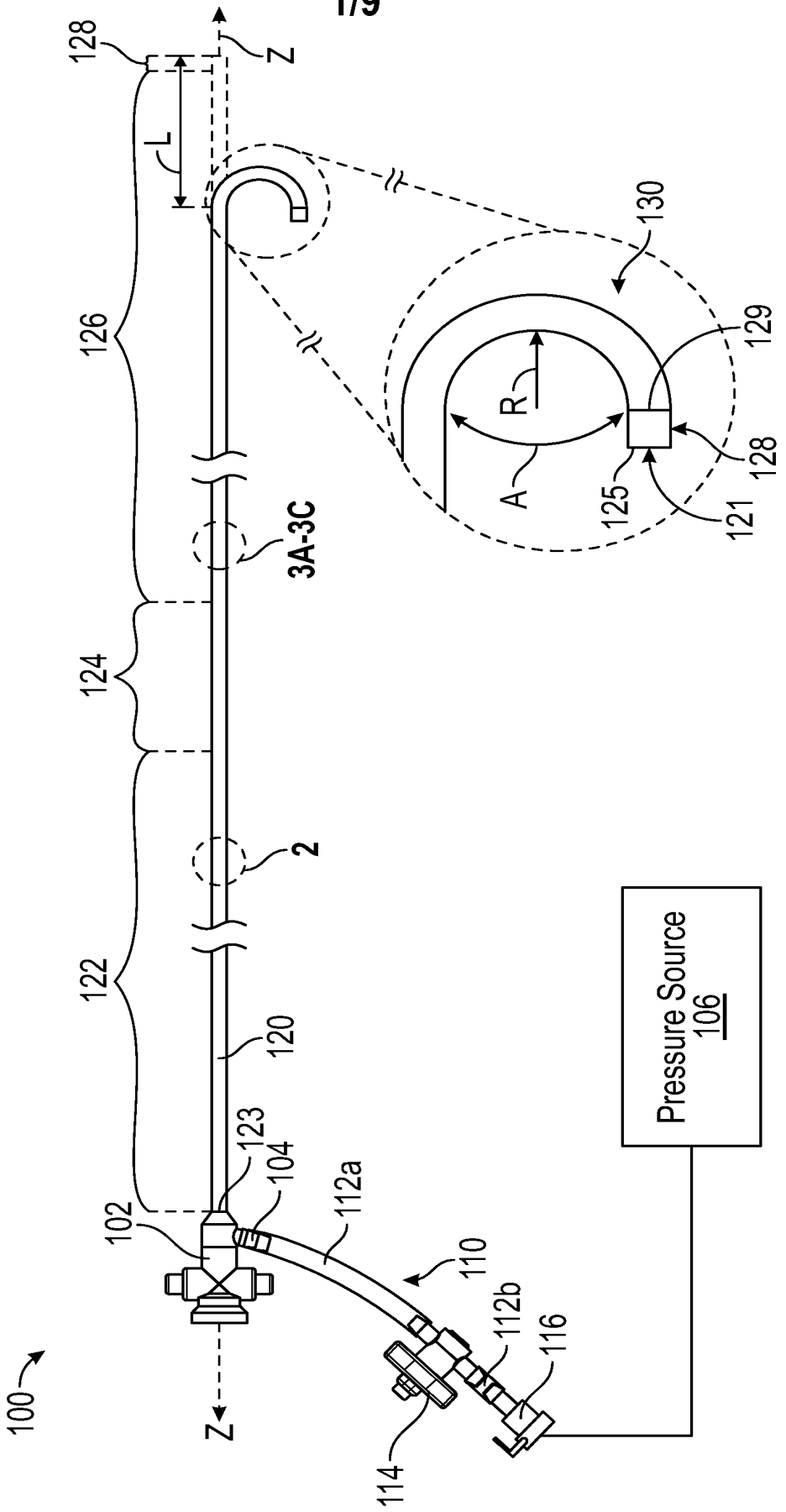
20. The method of claim 15 wherein the distal portion of the aspiration catheter includes—

an inner liner defining a lumen;

a braid of wires extending over the inner liner;

a wire coiled around the braid; and

an outer sheath extending over the braid.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112b
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Pressure Source
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FIG. 1

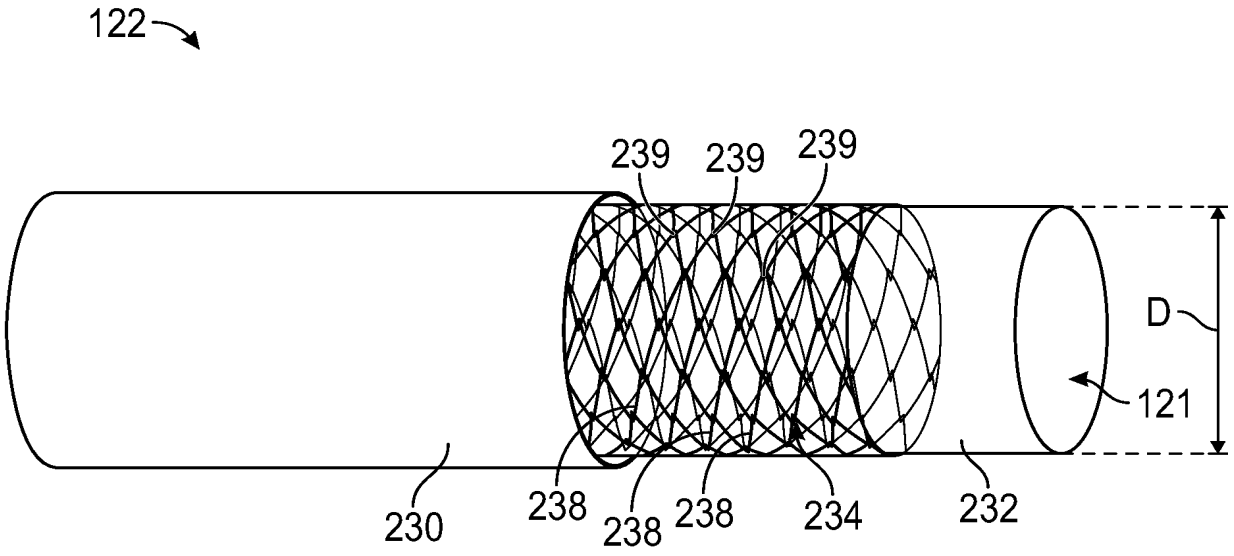
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FIG. 2

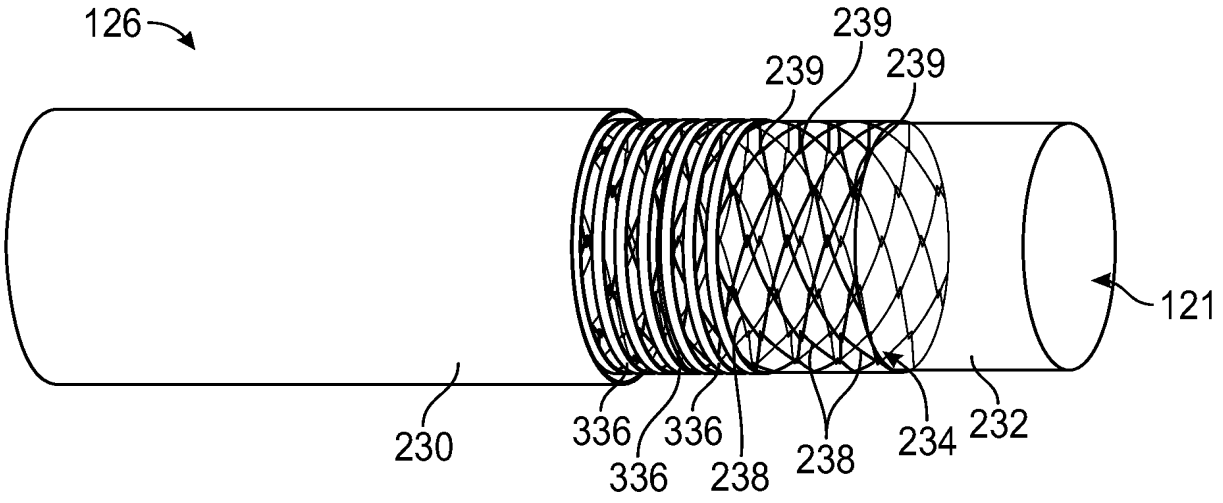
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FIG. 3A

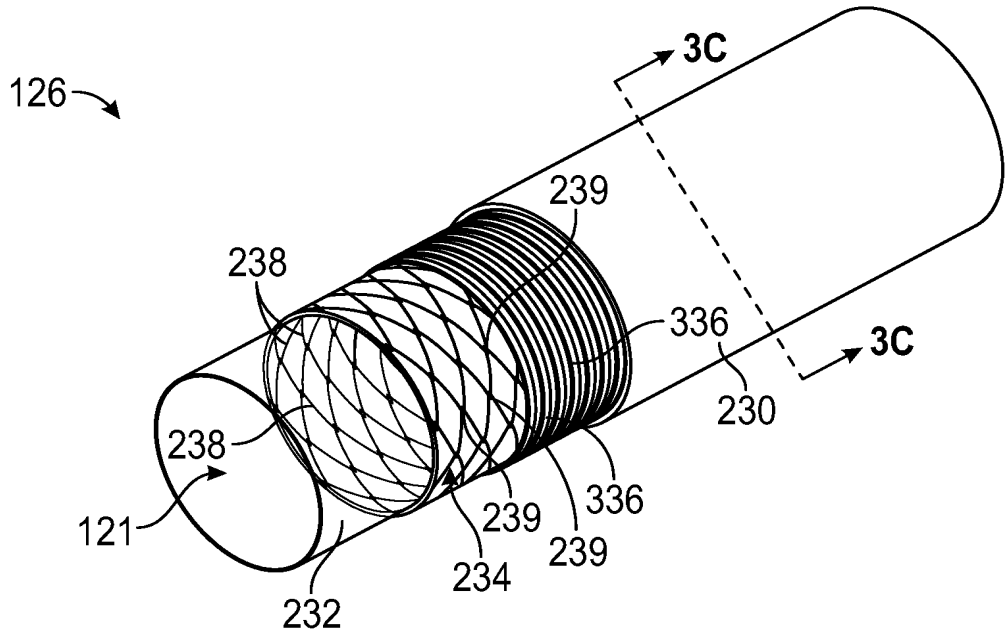
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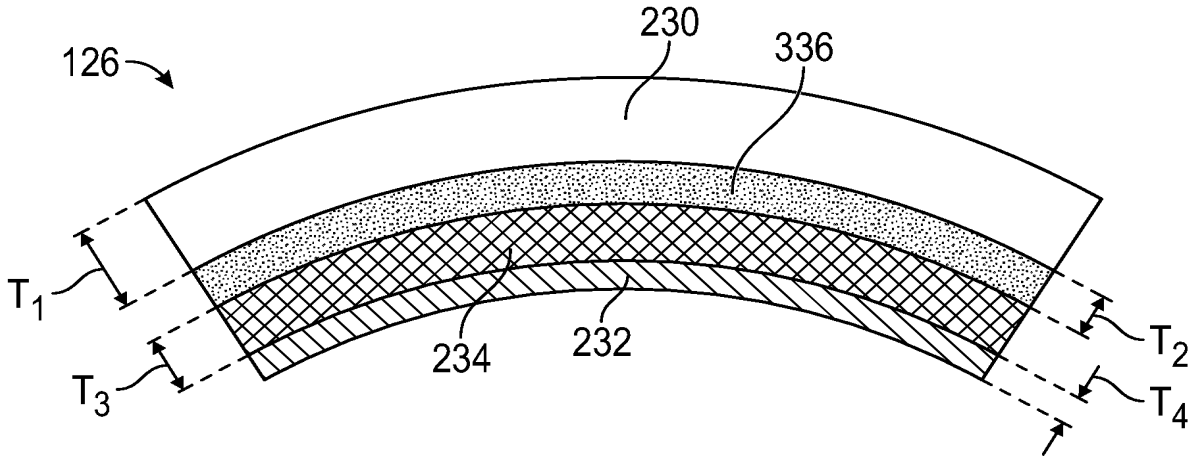
FIG. 3B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T2
T4

FIG. 3C

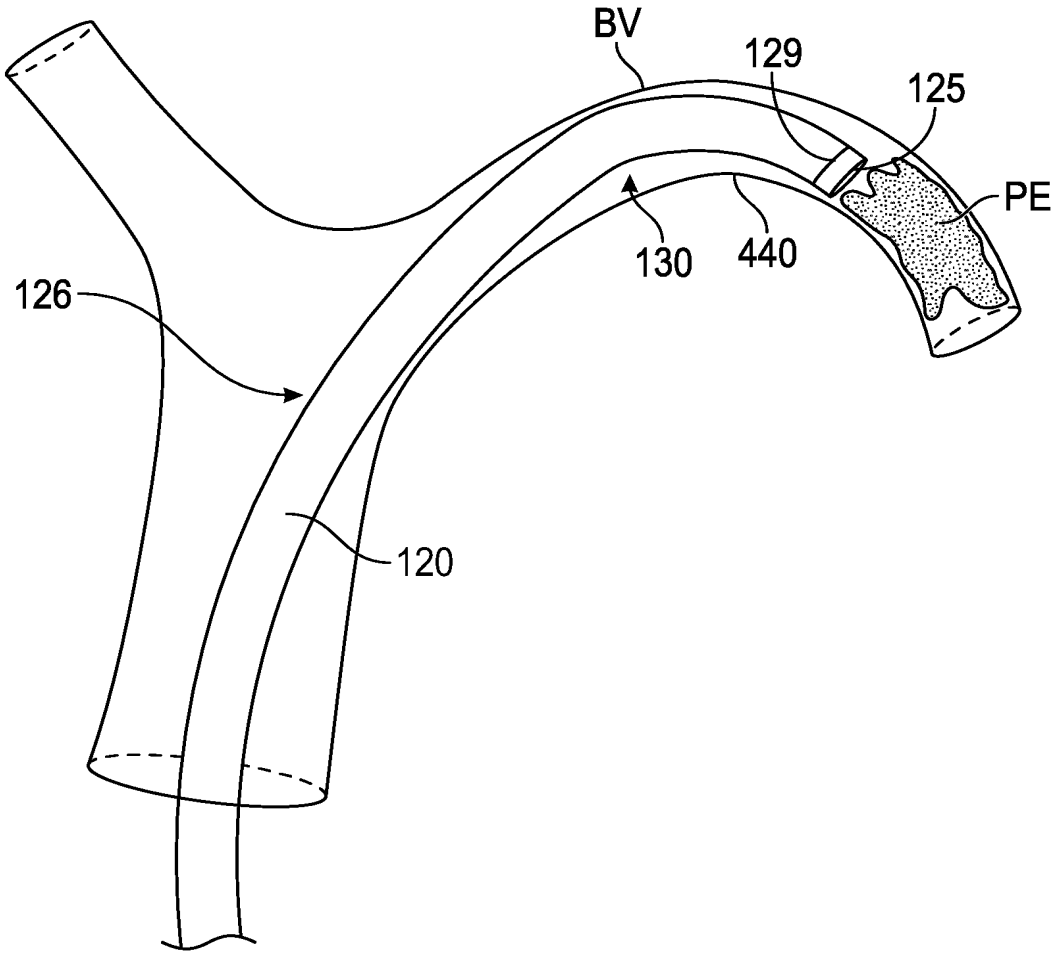

FIG. 4A

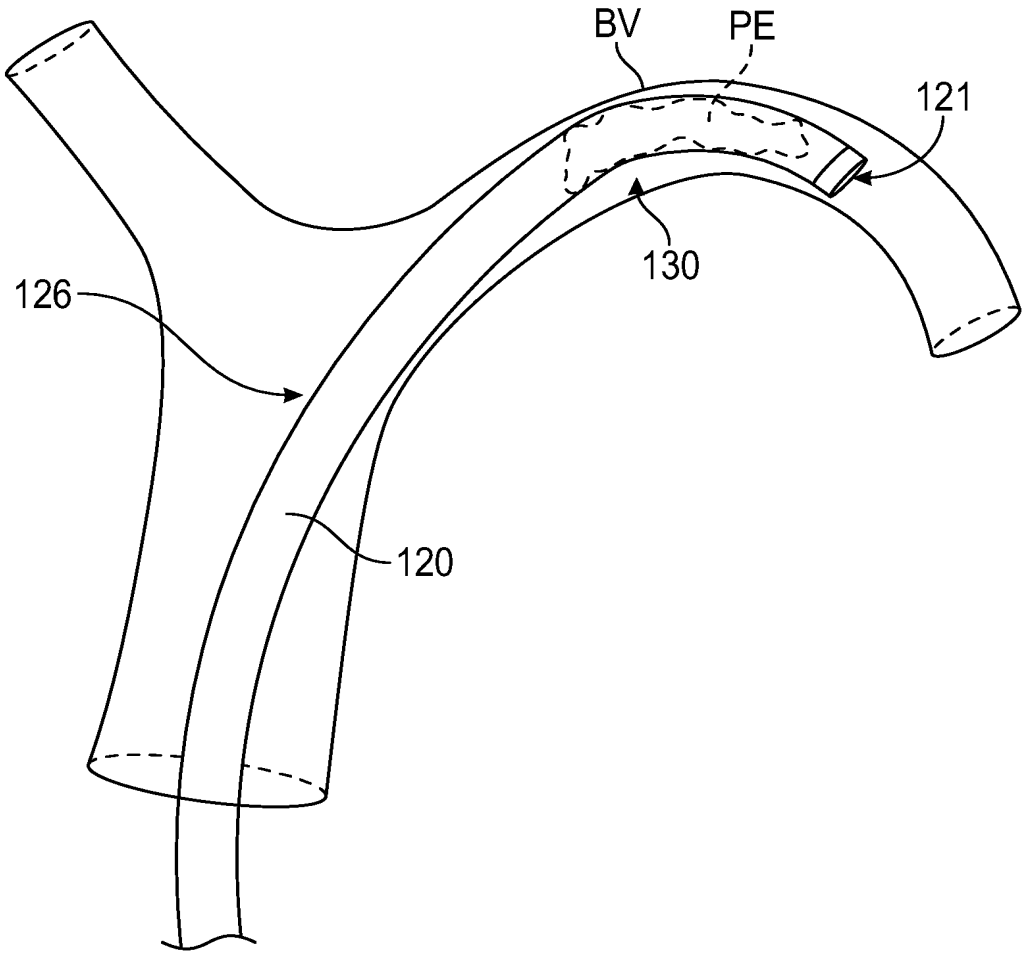

FIG. 4B

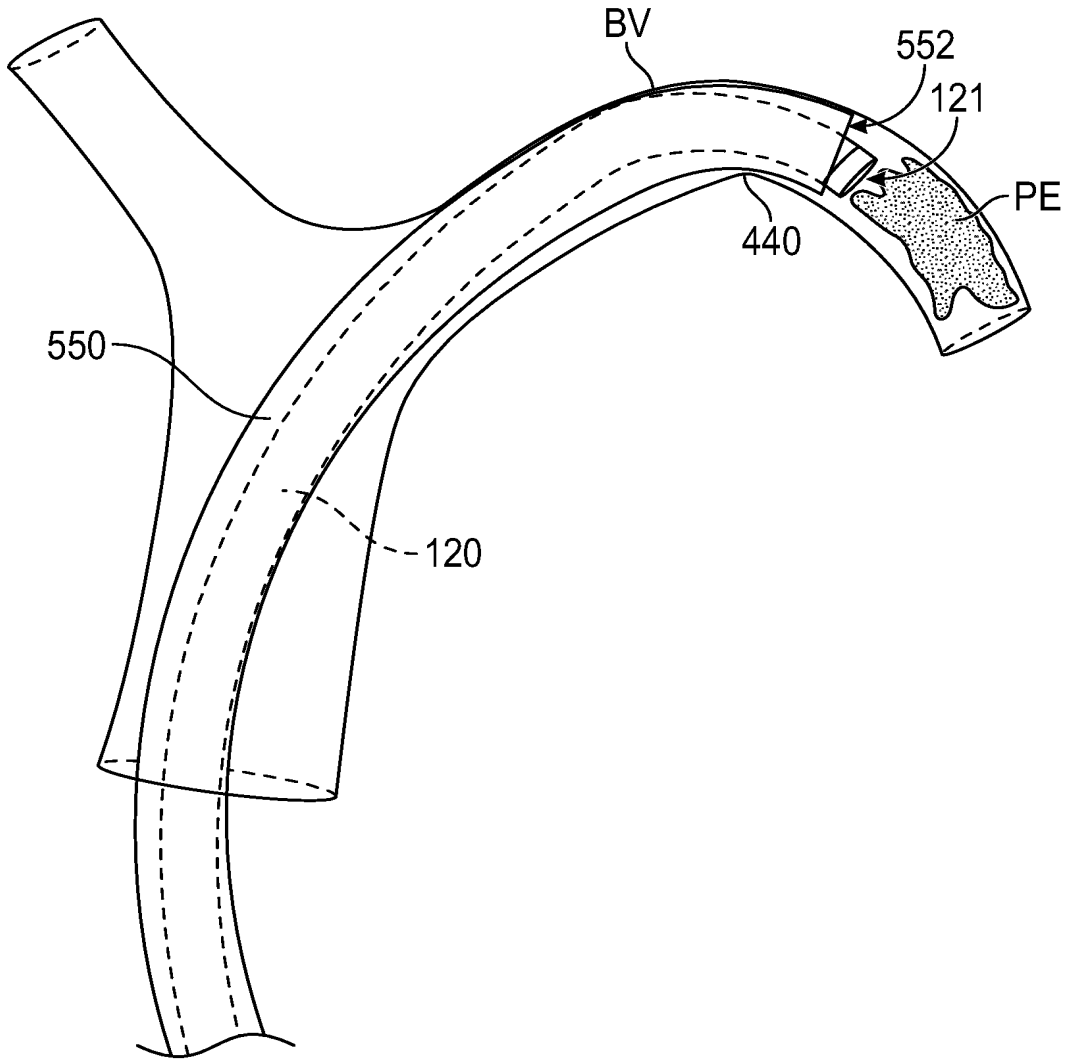

FIG. 5A

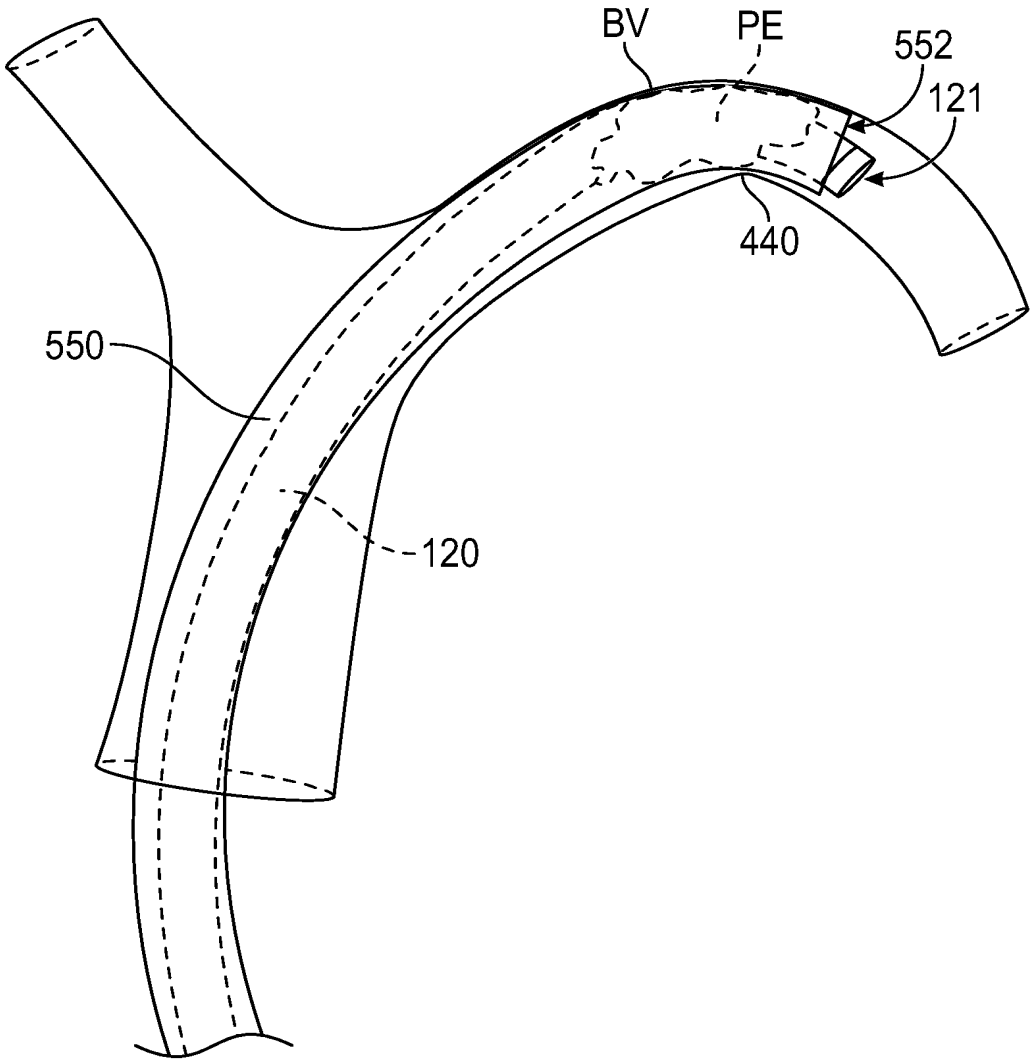

FIG. 5B

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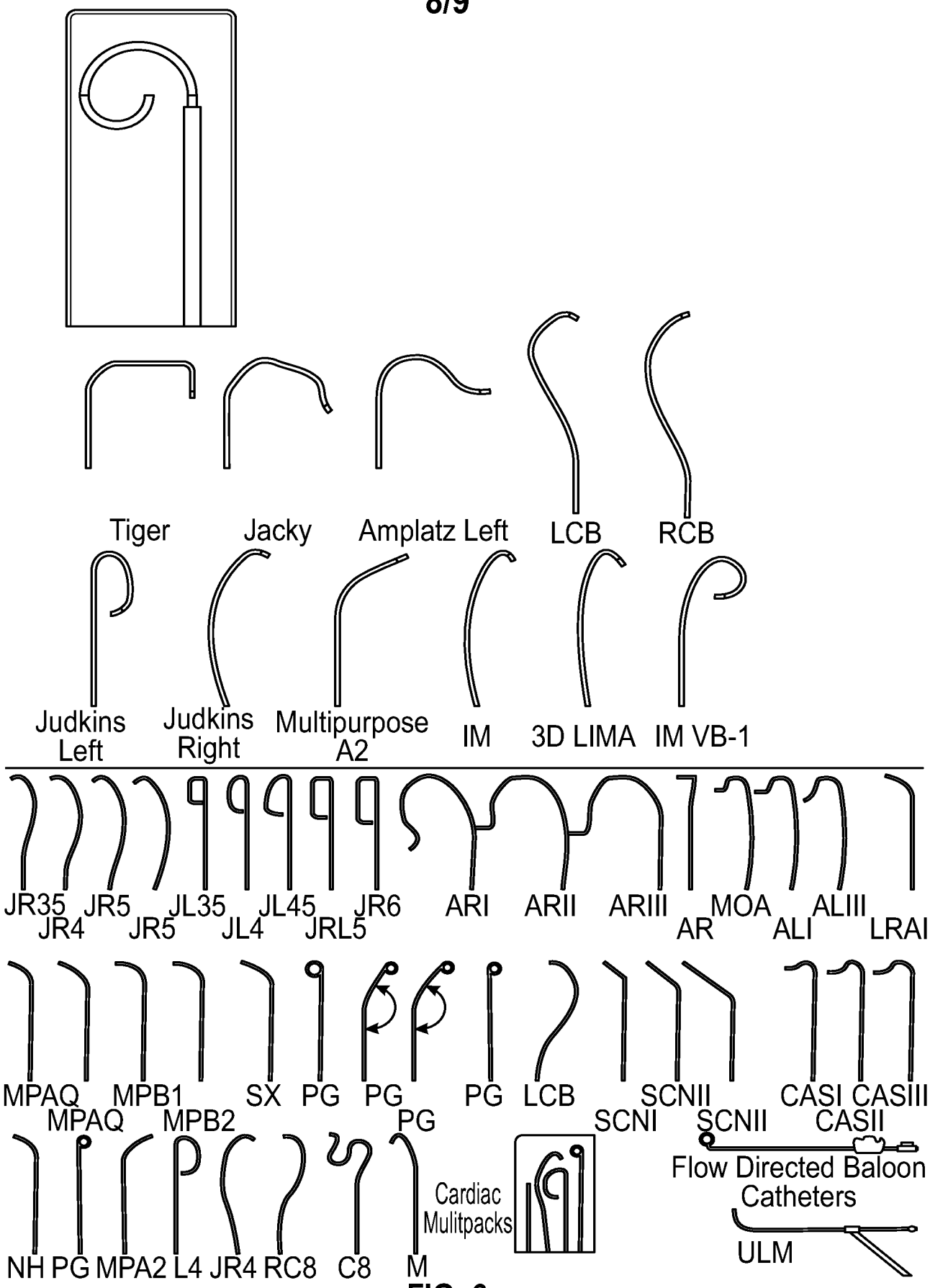
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ULM

FIG. 6

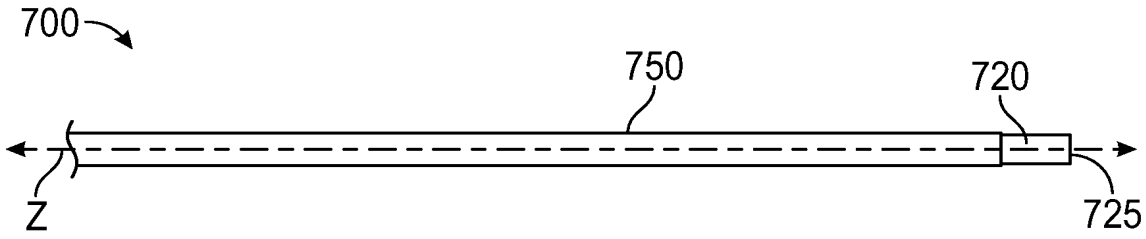

FIG. 7A

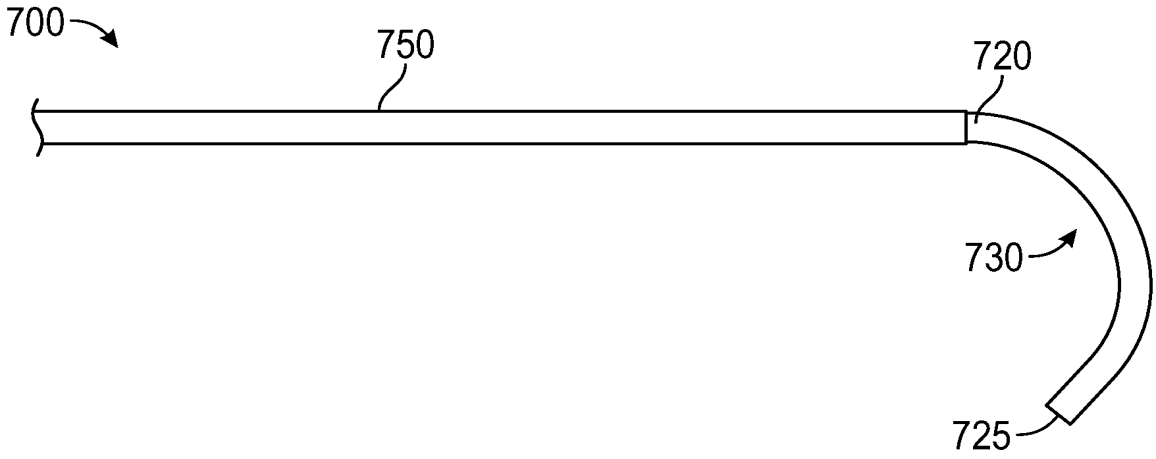

FIG. 7B

FIG. 7C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/59718

A. CLASSIFICATION OF SUBJECT MATTER
IPC - A61M 25/00; A61B 17/22 (2022.01)
CPC - A61M 25/0041; A61M 25/0045

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.
Y	CN 110652645 A (Shanghai Warbey Medical Technology Co Ltd) 07 January 2020 (07.01.2020), entire document, especially	1-14
Y	US 2006/0074401 A1 (Ross) 06 April 2006 (06.04.2006), entire document, especially	1-14
A	US 2016/0151605 A1 (GMEDIX, INC.) 02 June 2016 (02.06.2016), entire document	1-14
A	US 2013/0197454 A1 (Terumo Kabushiki Kaisha) 01 August 2013 (01.08.2013), entire document	1-14

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
03 March 2022	MAR 22 2022
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/59718

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-14 directed to an aspiration catheter.

Group II: Claims 15-20 directed to a method of removing clot material from a blood vessel.

-*-Continued in Supplemental Box-*-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-14

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/US 21/59718

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

The invention of Group II includes the special technical feature of positioning a distal tip of the aspiration catheter proximate the clot material; activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter, not required in Group I.

The inventions of Groups I-II share the technical features of an aspiration catheter, comprising: a distal portion and a proximal portion, wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion. Specifically, Groups I and II are related as an apparatus (Group I) and methods for using the apparatus (Group II). The apparatus is known in prior art as shown in CN 110652645 A to Shanghai Warbey Medical Technology Co Ltd (hereinafter "Shanghai"). Therefore, Groups I and II lack unity since the shared technical features do not represent a contribution over Shanghai:

Shanghai discloses of an aspiration catheter (Fig 1A-1B; para [0093]-[0099]; para [0115] further teaches wherein the catheter can be used for aspiration), comprising: a distal portion (left half of 10; Fig 1A-1B; para [0093]) and a proximal portion (right half of 10; Fig 1A-1B; para [0093]), wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion (Fig 1A-1B; para [0076]; Shanghai teaches wherein the distal region of the aspiration catheter has good flexibility wherein the flexibility of the distal end of the catheter allows for a distal end of the braid of wires within the distal end of the catheter taught by Shanghai to be flexible and deflectable with respect to the longitudinal axis of the proximal portion taught by Shanghai).

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

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

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
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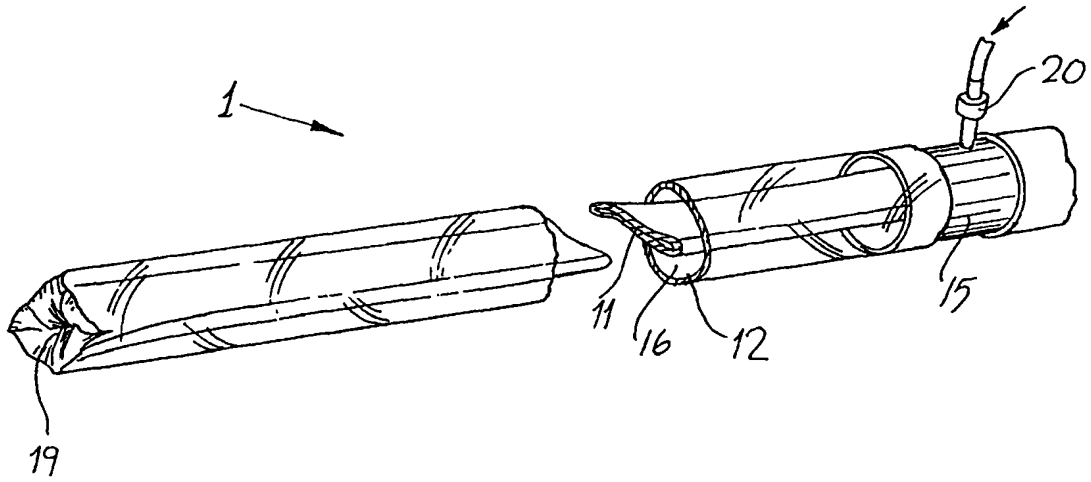

(57) Abstract

A medical device may comprise an introducer (1) for introducing an object such as an instrument through a body opening such as the throat. The device (1) comprises a tubular sleeve (10) of pliable plastics material which is turned axially back on itself to define inner and outer sleeves sections (11, 12). The inner sleeve section (11) defines an inner lumen (19) and the sleeve may be twisted to centralise the lumen. The sleeve is pre-shaped to define a desired non-linear shape. A chamber (16) between the inner and outer sleeve section (11, 12) is inflatable. The device may also be deployed remotely for example, for balloon angioplasty.

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A MEDICAL DEVICE COMPRISING AN EVERTABLE SLEEVE

Introduction

The invention relates to a medical device, particularly for use in minimally invasive and endoluminal surgical and medical techniques. In particular the invention relates to an introducer for introducing an instrument into the body through an opening. More specifically, the invention relates to a device to assist in the introduction of endoscopic devices into the lumen of a natural bodily orifice, in particular the rectum and colon.

The introduction of an instrument or the like through a body opening such as the throat or rectum is traumatic for the patient and difficult for the medical practitioner as such openings lead into a complex passageway(s) through which the instruments must be passed. Therefore great skill and experience is required.

Background of the Invention.

The practise of gastroenterology has been much improved due to the development of the fibre-optic endoscope. Modern endoscopes consist of a control section attached to a long flexible shaft with a steerable tip. The flexible shaft carries several tubes for light, air, water and suction. In some cases a biopsy channel with a larger bore to allow therapeutic procedures to be performed is included. Light is transmitted through non-coherent fibre-optic bundles. Older scopes used coherent fibre-optic bundles for transmission of the image but these are largely obsolete now and video-endoscopes are the norm. These use fibre-optic bundles for light transmission only and use a CCD TV camera for image acquisition. The camera output is then transmitted through wire pairs.

Endoscopes use a torque control mechanism that allows the endoscope to be steered through the passage of interest using control wheels on the handle at the proximal end. Steering is achieved by turning control knobs on the control section

of the endoscope. There are usually two knobs, one for lateral control and another for vertical control. These control wheels are attached to guide wires that run up through the endoscope and are attached to the tip.

An endoscope is typically 100-150 centimetres long and may be inserted into either end of the digestive system. Generally the devices have specific design features adapted to the bodily opening through which the endoscope is inserted. The endoscope is pushed from the bottom and guided through tortuous passages using external manipulation.

In the upper gastrointestinal tract the insertion of the device presents relatively little difficulty. This is due to the short length of the upper GI tract and the relatively straight anatomy. Difficulty is encountered when attempting to advance into the proximal end of the small intestine for example to examine the pancreato-duodenal junction.

In the lower GI tract the picture is quite different. The lower GI tract is made up of the rectum and the large intestine or colon. The colon, in a textbook arrangement of its anatomy, extends upwards from the lower right quadrant, traverses the width of the body just below the diaphragm, extends downwards along the left side of the abdomen and then loops in a retrograde manner before linking up with the rectum and the anus. Even with this textbook arrangement, the large intestine is difficult to cannulate with a flexible endoscope due to the flexible nature of the endoscope shaft and the floppy nature of the colon. It is even more difficult with the more realistic lumen anatomies. In some people the sigmoid colon can be very long and is unfixed, except by its mesentery, and so can be extremely difficult to cannulate due to its predisposition to form loops when an endoscope is pushed through it. Some anatomical landmarks, such as the recto-sigmoidal junction, the splenic flexure and the hepatic flexure, are difficult to pass through simply because of their tortuous nature. Problems traversing these areas are exacerbated by looping of the endoscope in the sigmoid colon.

Endoscopy is a difficult technique that can only be mastered after performing many hundreds of examinations. The ability to speedily cannulate the bowel and traverse the entire colon all the way to the caecum is a skill that is only enjoyed by a minority of endoscopists. Published research on the subject of difficulty encountered in endoscopy shows that the procedure fails in up to 15% of cases where failure is defined as inability to reach or visualise the caecum. Up to 35% of cases are considered to be difficult as defined by extended duration of the procedure and experience of pain by the patient. Other research shows that up to 29% of cases are considered to be technically difficult.

Several devices have been described in the prior art to assist in the practise of lower GI endoscopy.

US-A-3805770 describes an endoscope guide and lubricating means comprising a cylindrical spongy member to guide and lubricate the endoscope as it enters the anus. This device however does not address the problems associated with looping of the scope in the sigmoid colon and resulting problems crossing the splenic and hepatic flexures.

US-A-4207872 describes a sleeve device for positioning on the end of an endoscope to assist it in advancing through a body passage. The device has protrusions extending perpendicularly from the sleeve that may be expanded and retracted using fluid pressure. Upon repetitious expansion and retraction of the protrusions using pulsing pressure within the device, the device assists in advancing the scope along the body passage. There is likely to be considerable internal friction between the device and the inner wall of the body passage.

US-A-4321915 describes a device consisting of an everting tube which includes a pressure and evacuation valve to allow eversion and retraction of the tube. The tube is slidably attached to a fibre-optic bundle for vision. Whilst this device allows a means of vision to be advanced up the confines of a body passage it cannot be used with existing endoscopes because of its size. It is proposed for use

in small narrow bore tubes such as the urethra. There is a similar problem with the device disclosed in US-A-4615331. This device consists of an everting tube which has a plurality of folds which telescope open as the everting tube advances.

US-A-4676228 describes a device that is removably attached to the front end of an endoscope to assist in pulling the scope through the colon. It consists of two inflatable cuff sections that are alternatively inflated and deflated whilst being moved towards and away from each other. In this way the endoscope is dragged up through the colon in short steps. This procedure is lengthy and complex. In addition, there is considerable friction between the colon and the scope.

US-A-4971033 describes a flexible endoscope with a working channel designed to cause the tube to stiffen when fluid pressure is applied to the channel. The channel takes up space in the endoscope that is more appropriately used for either vision, suction, insufflation or tissue sampling. In addition, an endoscope is stiffened along a particular section or along its entire length which exacerbates the difficulty of passing the endoscope though the floppy sigmoid colon.

US-A-5045070 describes an everting tube for entering body cavitys and depoloying a tube for administration of drugs or therapy through the tube. The device is designed for introducing a channel attached to the tube and is not designed for introducing a removable endoscope or the like.

WO-A-97/32515 describes a semi-toroidal tube for introducing an endoscope into a body cavity for examination and therapeutic purposes. The device is a tubular endless body that everts at its distal end and inverts at its proximal end when advanced through a duct such as the human colon. WO-A-99/01171 describes a similar device with the addition of corrugations designed to assist in the passage of the endless tube around the anatomy of the colon.

US-A-5941815 describes a sigmoid splint device for use in endoscopy. The device is intended to be used to keep the sigmoid colon from looping while the operator is attempting to cross more difficult junctions.

In general, such known devices are either difficult to use, cause discomfort to the patient, can only be advanced incrementally, do not cater for complex nature and shape of tortuous body passageways.

There is a need for an improved medical device which will address at least some of these problems and which may be especially used as an introducer to navigate the lower gastrointestinal tract with minimum discomfort to the patient.

Statements of Invention

According to the invention there is provided a medical device for insertion in a body opening or an incision comprising:

a sleeve of pliable material, the sleeve having a twisted sleeve section to define a reduced lumen section;

the sleeve having an outer sleeve section and an inner sleeve section;

a chamber for pressurised fluid defined between the inner and outer sleeve sections;

the inner sleeve section defining a lumen to receive an object;

the pressurised sleeve being evertable on engagement of an object in the lumen and axial movement of an object relative thereto so that the twisted inner sleeve section is rolled over outwardly to become an outer untwisted sleeve section and the untwisted outer sleeve section is correspondingly rolled over inwardly to become a twisted inner sleeve section.

Preferably the sleeve is turned axially back on itself to define an outer sleeve section and a twisted inner sleeve section.

In one embodiment the device the sleeve sections define a continuous endless track which may be advanced by engaging an object in the lumen.

In one embodiment the device includes a guide collar for locating relative to a datum, a sleeve section being movable relative to the collar on engaging an object into the lumen and/or on passage of an object through the lumen. In a preferred arrangement the free ends of the sleeve are joined to the collar.

The device preferably includes an inflation port for inflation of the enclosed chamber between the sleeve sections.

In a preferred arrangement the device includes adjustment means for adjusting the twist in the sleeve.

In one embodiment of the invention at least portion of the sleeve has a non linear shape. Usually, the non linearity corresponds to a desired predetermined shape. The non linearity may be in at least two, and typically in three dimensions

In one embodiment the sleeve is biassed into the non linear shape.

The sleeve may be sculpted or formed into the non linear shape.

In one embodiment the device includes guide means through which the sleeve and/or an object is advanced. Typically, the guide means includes a ring means for placing in a body opening or incision through which the sleeve and/or an object is advanced.

In another embodiment of the invention the device includes a delivery means for delivery of the device to a remote location. In one case, the delivery means is a tube such as a catheter or cannula.

In one aspect the device defines a transporter for delivery or retrieval of an object to or from a desired location.

In another aspect the device defines an introducer for introducing an object such as an instrument to a desired location.

In a further aspect the device is an expandable element. The expandable element may be a balloon for angioplasty.

Brief Description of Drawings

The invention will be more clearly understood from the following description thereof given by way of example only, in which :-

Fig. 1 is a perspective view from a proximal end of an introducer according to the invention.

Fig. 2 is a perspective view from a a distal end of the introducer of Fig. 1;

Fig. 3 is a cross sectional view of the introducer in one position of use;

Fig. 4 is a cross sectional view of the introducer in another position;

Fig. 5 is an end view of the introducer;

Figs 6 and 7 are diagrammatic view illustrating one method for manufacturing the introducer;

Figs 8 and 9 are side partially cross sectional view of other introducers;

Figs 10 to 14 are cross sectional views illustrating the operation of an expandable medical device according to the invention;

Fig. 15 is side, partially cross section view of the device of Figs 10 to 14, in use; and

Fig. 16 is an enlarged view of a detail of Fig. 15.

Figs 17 to 25 are diagrams illustrating the principles of operation of the invention.

Fig. 27 is a perspective view of an introducer device in an untwisted configuration;

Fig. 28 is a plan view of the device of Fig. 27;

Fig. 29 is a cross sectional view of the line A-A in Fig. 28;

Fig. 30 is a perspective view of the introducer device of Fig. 27 in a twisted configuration;

Fig. 31 is a plan view of the device of Fig. 30; and

Fig. 32 is a cross sectional view on the line B-B in Fig. 31.

Detailed Description

Referring initially to Figs 1 to 7 there is illustrated a medical device according to the invention which in this case is configured as an introducer 1 for introducing an object such as an instrument through a body opening such as the throat or rectum.

The device 1 comprises an elongate tubular sleeve 10 of pliable material, especially a suitable biocompatible gas impermeable plastics material which is turned axially back on itself to define an inner sleeve section 11 and an outer sleeve section 12. The sleeve sections 11, 12 are joined in this case via a collar 15, to define an enclosed inflatable chamber 16 therebetween. The inner sleeve section 11 defines an inner lumen 19 and the sleeve is twisted to centralise the lumen 19. An inflation port 20 is provided for inflating the chamber 16 between the inner and outer sleeve sections.

It will be particularly apparent that the device of the invention may be readily advanced through a complex passageway such as the bowel or the like. It may therefore be used for cannulating such a passageway.

Figs 6 and 7 illustrate the twisting of the sleeve 10. The free ends of the sleeve 10 are rotated relative to one another prior to or after final assembly to the collar 15. The twist will be apparent with reference to the points marked X. Such a twist may be provided when the device is in situ and is adjustable in situ.

The present invention provides a device that permits an endoscope or similar instrument to pass easily through the body's natural canals for purposes of performing an endoscopic examination of those canals. The introducer allows the user to easily pass beyond junctions such as the sigmoid colon, splenic and hepatic flexures and other convolutions of the body's inner canals in the upper or lower gastrointestinal tracts. In addition, the device allows pain free cannulation of the body's canals by substantially eliminaring friction and rubbing contact between the endoscope and the walls of the canal under examination. Further the device is easy to manufacture and is convenient and simple to use.

Referring to Figs 8 and 9 there are illustrated other devices 50, 51 according to the invention which may be twisted or not. The devices are pre-shaped for a particular use. The devices may be biassed to form a desired non linear shape on eversion. In this case the device has sculpted sections 52, 53 to confirm, an eversion to a desired shape. It will be noted that the sculpted section 53 is initially part of the inner sleeve section. On eversion, it become unparalleled into a section of desired shape. The devices may be formed by moulding and/or sculpting to define the desired shape dependent to the passageway to be navigated.

The devices address two significant problems in lower GI endoscopy: the problem of friction between the endoscope and the colon and the problem caused difficulty in navigating bends and convolutions in the colon. Such a device would place itself between the colon and the endoscope such that the scope passed through the lumen of the colon without touching the side walls of the colon. Some conventional introducers can address this problem, especially in a straight section of colon, but will have difficulties when the colon is in any way convoluted or has a tight junction or bend. In reality all colons have such a twisted layout. In the case of conventional devices the device may fail to turn at the bend and will simply push up against the side wall of the colon causing pain and possibly damage to the mesentry. In serious cases the wall of the colon may be perforated.

The devices of the invention are predisposed to bend at certain points or gradually slope in a certain direction. In this way the device, for example, can be inserted into the rectum and will be disposed towards following the bend of the sigmoid colon or turn at the splenic flexure as it moves through the colon. The device may be predisposed to bend at more than one point. For example, it could be constructed in such a manner that it would gradually curve through the sigmoid colon and then straighten out to traverse the descending colon. A further turn could be constructed into the device so that it would turn at the splenic flexure. By preshaping the everting tube in this manner it would be possible to plan all the bends and convolutions in a passageway to be navigated.

The device may be used as a transporter for delivery or retrieval of an object. It has the effect of providing a substantially frictionless tunneling action. The device may be used endoluminally. The device may be used for example to provide a soft tissue dissector or an envaginator and may be delivered through a delivery device such as a tubular sleeve, catheter or the like. The device itself may be used in medical procedures such as in the form of a balloon which may be linear or non linear.

Referring to Figs 10 to 16 there is illustrated a device 60 similar to that of Figs 1 to 7 which is deliverable through a tube 6 such as a cannula. A pressure is applied to push the device 61 out through an end opening of the tube 61 as illustrated in Figs 10 to 12. To retract the device a suction force is applied to draw the device 60 back into the tube 61 as illustrated in Figs 13 and 14.

Referring in particular to Figs 15 and 16 there is illustrated one mechanism which may be used to deliver the device 60 through the tube 61 and to remotely control the operation of the device 60. Air is delivered through an air delivery tube 65 extending through the outer tube 61. The air delivery tube 65 has a central outlet 66 for driving the device 60 and one or more entry ports 67 for delivery of inflation air into the air chamber 69 defined by the device 60. In this way the inflation of the device 60 can be readily remotely controlled. The device 60 may

be used, for example for tissue dissection or for delivery/deployment of a balloon angioplasty, stent or the like.

The Twisted Tube

Consider the hollow cylindrical tube shown in Fig. 17. The wall of the cylinder defines a lumen through its centre. Consider a linear element A-B. if the upper edge of the tube is rotated through some angle point A will move to the position

shown in the middle sketch. The element A-B will still define a straight line. The tube will distort into a nominally hour glass shape with a reduced lumen at mid height. The diameter of the lumen at the neck of the tube is dependant on the angle of twist. When the upper edge is rotated through 180° the lumen will close down to zero diameter. At any horizontal plane through a twisted tube the material must be wrinkled and hence under compressive hoop stress. If the height of the tube remains unaltered then the element A-B in a twisted tube, being longer than in a plain tube, must be under tensile axial stress. If the tube is free of axial constraint the overall length of the tube will reduce.

Lumen Diameter vs. Angle of Twist

Fig. 18 a shows the lumen diameter (D2) as a proportion of the tube diameter (D1)for angels of twist (E) from 0 to 180 degrees. The lumen diameter is calculated as:

$$D2 = D1 \cos(E/2).$$

As can be seen the lumen diameter is independent of the tube length

Elongate object passed through twisted tube

As can be clearly seen from Figs 18a and 18b the angle of twist necessary to collapse the lumen of a tube to the diameter of an elongate object passed therethrough is dependant on the ratio of the tube diameter and the diameter of the elongate object. The angle of twist can be calculated from:

$$\text{Cos.}^{-1}(E/2) = D2/D1$$

Where E = angle of twist

D1 = tube diameter

D2 = diameter of elongate object

Although depicted as of circular profile, a tube of sufficiently compliant material will conform to any non recursive profile. For such a profile D2 is taken as the smallest diameter which can be inscribed within the profile.

Twin walled pressure vessels under internal pressure

Consider a thin walled tube as shown in Fig. 19a. One end of the tube is folded back on itself as shown in Fig. 19b and the fee ends conjoined. What is defined is essentially a twin walled tube (or two coaxial tubes conjoined at their ends) with an enclosed volume between the two walls. The introduction of a pressurised fluid into the enclosed volume will cause the outer tube to behave like a pressurised aircraft fuselage, that is it will be subject to tensile axial and hoop stresses. The inner tube will be subject to tensile axial stress and compressive hoop stress. As a result the lumen will collapse in to a nominally duck bill configuration but constrained by the outer tube.

Greater control of the lumen can be obtained by the introduction of a twist into the tube. The tube shown in Fig. 20a is twisted as shown in Fig. 20b. One end of the tube is folded back on itself, as shown in Fig. 20c, and the free ends conjoined. As in the previous example this configuration defines two coaxial conical vessels conjoined at their bases and at the apex. However the common apex is not constrained to remain in this configuration. In reality in the inner and outer tubes are free to behave as individual tubes each with half of the original twist and as such the composite tube can better be defined as two coaxial hour glass tubes as shown in Fig. 20d, each containing half the original total twist. As both the inner and outer tubes are necked they each are subject to compressive hoop stresses. The introduction of a pressurised fluid into the enclosed volume produces what is believed to be a novel response.

Firstly, consider the outer tube. It is a necked hour glass tube with compressive hoop stresses. The introduction of the pressurised fluid induces tensile hoop stresses, negating the compressive hoop stresses induced by the twist. Since, to remain in its twisted configuration, the tube must have compressive hoop stresses and since the pressurised fluid overcomes these compressive stresses the tube must untwist and take on a nominally cylindrical configuration, see Fig. 20e. Since the inner and outer tubes are conjoined, as the outer tube untwists the inner tube twists more in response. Since the outer tube now has no twist the inner tube must have all the twist. If the original total twist were 180° then the lumen would close totally. Additionally, the material defining the inner tube will be central within the diameter of the outer tube. This configuration will for brevity be called a Cyclops.

Translation of an elongate object through a Cyclops

Consider the arrangement depicted in Fig. 21a. A shaft is passed through a Cyclops with the lumen in mutual contact with the shaft. The outside diameter of the Cyclops is resting in mutual contact with a fixed surface. Consider points of contact A, between the Cyclops and the fixed surface, and B, between the shaft and the lumen of the Cyclops. As the shaft is translated, as shown in Fig. 21b, Point A remains fixed whilst the leading end of the lumen rolls out. Since the Cyclops does not change in overall length the trailing end of outside diameter rolls in as depicted. It will be apparent that the shaft translates to the right twice as far as the Cyclops. This, of course, is exactly the motion of a caterpillar track. From this point of view a Cyclops could be considered as a three dimensional caterpillar track. Since points A and B on the Cyclops do not move relative to their corresponding positions on the shaft and the fixed surface there is no frictional resistance to the translation of the shaft. In Fig. 21c the Cyclops has translated to the right by approximately its own length. The material which had originally formed the inner tube has rolled out to become the outer tube and vice versa. In other words the Cyclops has turned inside out. Since the inner tube of the

Cyclops is in a twisted configuration and since the point B remains in contact with the same point on the shaft the shaft rotates about its axis as depicted by arrow C (in this instance approx. 120°). In order to obtain this translation the resistance required to be overcome is that generated as the leading and trailing ends of the Cyclops deform as they roll out and roll in respectively.

Effects of an introduced member

Assume that the Cyclops in Fig. 22 has a 180° twist and is filled with a fluid under pressure. The lumen is closed by the action of the twist. As the shaft enters the Cyclops the pliable nature of the material of the Cyclops allows it to envelop the leading edge of the shaft as shown in Fig. 22b. As can be seen the effective volume of the Cyclops decreases. There will be a resulting increase of the fluid pressure causing the lumen to exert a greater pressure on the shaft. As the shaft proceeds through the Cyclops, see Fig. 22c, the pressure increases to it's maximum. (P1V1=P2V2). If it is not desirable that there be such a pressure increase then the supply of fluid could be controlled by a pressure regulator.

Forces acting on the Lumen due to axial component of pressure

Fig. 23a depicts a Cyclops subject to internal pressure P. A force (Faxial) is induced in the Cyclops. Since the cross sectional area of the Cyclops is uniform the system is in force balance. A proportion of this force is taken by the outside cylinder and the remainder is taken by the material which constitutes the lumen. If a shaft, or similar, is pressed against one end of the Cyclops an imbalance is introduced. Consider the material of the inner tube in isolation. Fig. 23b, F represents the proportion of the axial force taken by the inner tube. As with the Cyclops as a whole this is in force balance. When an imposed force (Fimp) is applied to one end of the inner tube the net force acting at the left end of the tube is now less than that acting on the right hand end. The system is in an unbalanced situation. The inner tube must therefore translate to the right hand side.

Cyclops as an axial force limiter

Fig. 24a depicts a Cyclops with two independent shafts inserted, one in each end. Shaft B is in contact with a fixed surface. The fluid pressure within the Cyclops causes the lumen material to be maintained in tension. A force F is applied to shaft A, Fig. 24b. This force is transferred to shaft B via the lumen material and is reacted by the fixed surface. Force F exerts a compressive axial force on the lumen material. As force F increases the applied compressive force begins to negate the axial tensile force induced by the pressurised fluid. When force F becomes greater than the initial tensile force the lumen material goes into axial compression. This will cause the lumen material to buckle. The maximum axial force that the inner tube of a Cyclops can transmit is equal to the tensile force induced into the inner sleeve by the pressurised fluid.

Effects of the tube preform shape

Consider the tube preform shown in Fig. 25a. The lower portion defines a circular elbow with an upper section configured as a plain cylinder. If the cylindrical section is inverted as indicated, with or without a twist, and the free ends of the preform conjoined a basic Cyclops is formed. The elbow section must wrinkle up in order to lie within the plain cylinder as shown in Fig. 25b. As previously, the introduction of a pressurised fluid into the enclosed cavity formed will cause the elbow section to collapse forming a closed lumen and the cylindrical section to inflate, see Fig. 25c. The plain cylinder, being on the outside of the structure, will determine the shape of the inflated Cyclops. The Cyclops will be in force balance. If a force is applied to the lower end of the lumen the net force on the lumen will cause the Cyclops to translate. The upper portion of the lumen will roll out and the lower end of the cylindrical wall will roll in, Fig. 25d.

Since the outside wall of the Cyclops is now made up of part of the original plain cylinder and part of the elbow section the inflation pressure will cause the Cyclops to take on the form of this composite profile, the Cyclops will appear to bend as it translates. Figs 25d shows the Cyclops completely inverted. All of the elbow section forms the outer wall and all of the plain cylindrical section forms the inner tube. As such the Cyclops has take on the form of the elbow section. It will be noted that lumen material follows the shortest line between the ends of the Cyclops. For simplicity of illustration the Cyclops has been represented as translating in two space. It will be apparent that if the preform were "sculpted" or moulded such that its axis were three dimensional then as the Cyclops translated the path of translation would follow a three dimensional path. It will also be appreciated that the preform need not be of a regular cross section. Variations in tube diameter along it's length is possible.

Referring to Figs. 26(a) to 26(d) there is illustrated the roll-out or eversion of a pre-shaped device, in this case an introducer device 100. The device 100 is in this case pre-shaped or sculpted to roll-out in a non-linear shape corresponding to a desired predetermined shape. The non linearity may be in two, and in this case three dimensions. The introducer 100 is initially in the shape of a tubular sleeve. On eversion the introducer first turns in one direction (Fig. 26(b)), then in another direction (Fig. 26(c)) and, finally in a still further direction illustrated in Fig. 26(d). Such an arrangement greatly facilitates the navigation of the device along torturous routes.

Referring to Figs. 27 to 32 there is illustrated another introducer device 100 according to the invention which is similar to the devices described above and like parts are identified by the same reference numerals. In particular, the device 100 is similar to and operates in a similar manner to the introducer described above with reference to Figs. 1 to 7. In this case the introducer is adjustable to vary the degree of twist in the elongate tubular sleeve 10 from an untwisted configuration illustrated in Figs. 27 to 29 to a twisted configuration illustrated in Figs. 30 to 32.

The sleeve 10 is attached at one end 101 to a first shaft section 102 and is attached on the other end 103 to a second shaft section 104. The shaft sections 102, 104 have a respective male projection 105 and a complementary female recess 106 which interengage to facilitate relative rotation therebetween. The shaft sections 102, 104 have respective handles formed by knobs 107, 108 to facilitate manipulation to vary the degree of twist. In use, the shaft section 104 may be turned by the knob 108 to any desired extent, for example from the untwisted configuration of Fig. 27 to the twisted configuration of Fig. 30. The variation in the twist may be effected prior to insertion of the device and/or when the device is in situ.

Reference is also made to appropriate alternatives and modifications which are outlined in our parallel applications referenced ATRO1/C, ATRO12/C, ATRO15/C, ATRO16/C, ATRO17/C, the entire contents of which are incorporated herein by reference.

The invention is not limited to the embodiments hereinbefore described which may be varied in detail.

Claims

1. A medical device for insertion in a body opening or an incision comprising:

a sleeve of pliable material, the sleeve having a twisted sleeve section to define a reduced lumen section;

the sleeve having an outer sleeve section and an inner sleeve section;

a chamber for pressurised fluid defined between the inner and outer sleeve sections;

the inner sleeve section defining a lumen to receive an object;

the pressurised sleeve being evertable on engagement of an object in the lumen and axial movement of an object relative thereto so that the twisted inner sleeve section is rolled over outwardly to become an outer untwisted sleeve section and the untwisted outer sleeve section is correspondingly rolled over inwardly to become a twisted inner sleeve section.

2. A device as claimed in claim 1 wherein the sleeve is turned axially back on itself to define an outer sleeve section and a twisted inner sleeve section.

3. A device as claimed in claim 1 or 2 wherein the sleeve sections define a continuous endless track which may be advanced by engaging an object in the lumen.

4. A device as claimed in any preceding claim including a guide collar for locating relative to a datum, a sleeve section being movable relative to the collar on engaging an object into the lumen and/or on passage of an object through the lumen.

5. A device as claimed in claim 4 wherein the free ends of the sleeve are joined to the collar.

6. A device as claimed in any preceding claim including an inflation port for inflation of the enclosed chamber between the sleeve sections.

7. A device as claimed in any preceding claim including adjustment means for adjusting the twist in the sleeve.

8. A device as claimed in any preceding claim wherein at least portion of the sleeve has a non linear shape.

9. A device as claimed in claim 8 wherein the non linearity corresponds to a desired predetermined shape.

10. A device as claimed in claim 8 or 9 wherein the non linearity is on at least two dimensions.

11. A device as claimed in any of claims 8 to 9 wherein the non linearity is in three dimensions.

12. A device as claimed in any of claims 8 to 11 wherein the sleeve is biassed into the non linear shape.

13. A device as claimed in any of claims 8 to 12 wherein the sleeve is sculpted or formed into the non linear shape.

14. A device as claimed in any preceding claim including guide means through which the sleeve and/or an object is advanced.

15. A device as claimed in claim 14 wherein the guide means includes a ring means for placing in a body opening or incision through which the sleeve and/or an object is advanced.

16. A device as claimed in any preceding claim including a delivery means for delivery of the device to a remote location.

17. A device as claimed in claim 16 wherein the delivery means is a tube.

18. A device as claimed in claim 15 or 16 wherein the delivery means is a catheter.

19. A device as claimed in any preceding claim wherein the device defines a transporter for delivery or retrieval of an object to or from a desired location.

20. A device as claimed in any preceding claim wherein the device defines an introducer for introducing an object such as an instrument to a desired location.

21. A device as claimed in any of claims 1 to 18 wherein the device is an expandable element.

22. A device as claimed in claim 21 wherein the expandable element is a balloon for angioplasty.

23. A medical device substantially as hereinbefore described with reference to the accompanying drawings.

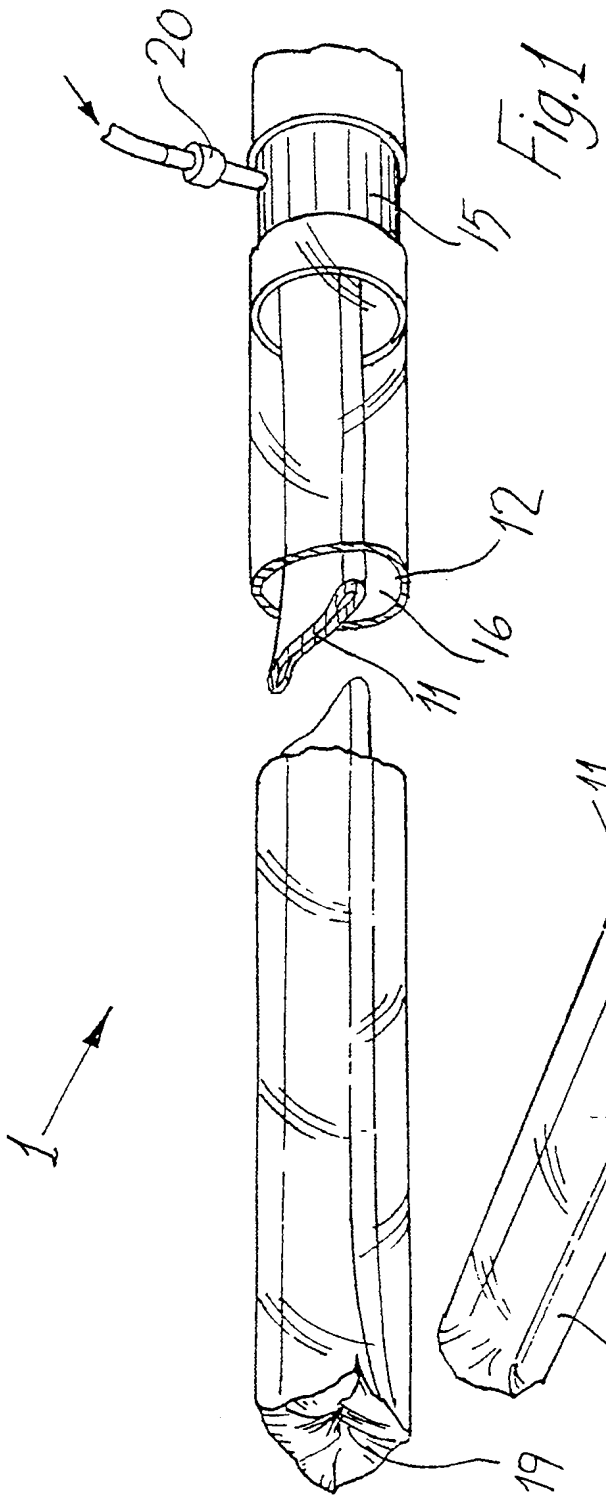


Fig.1

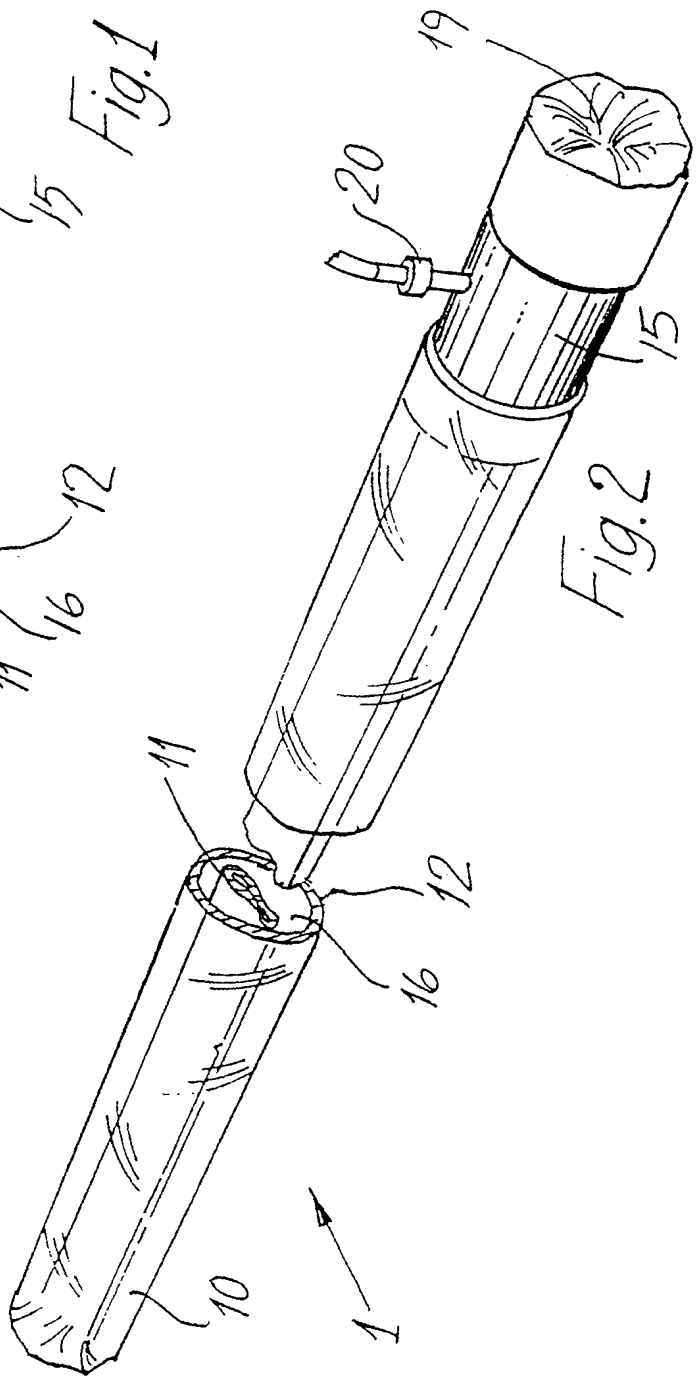


Fig.2

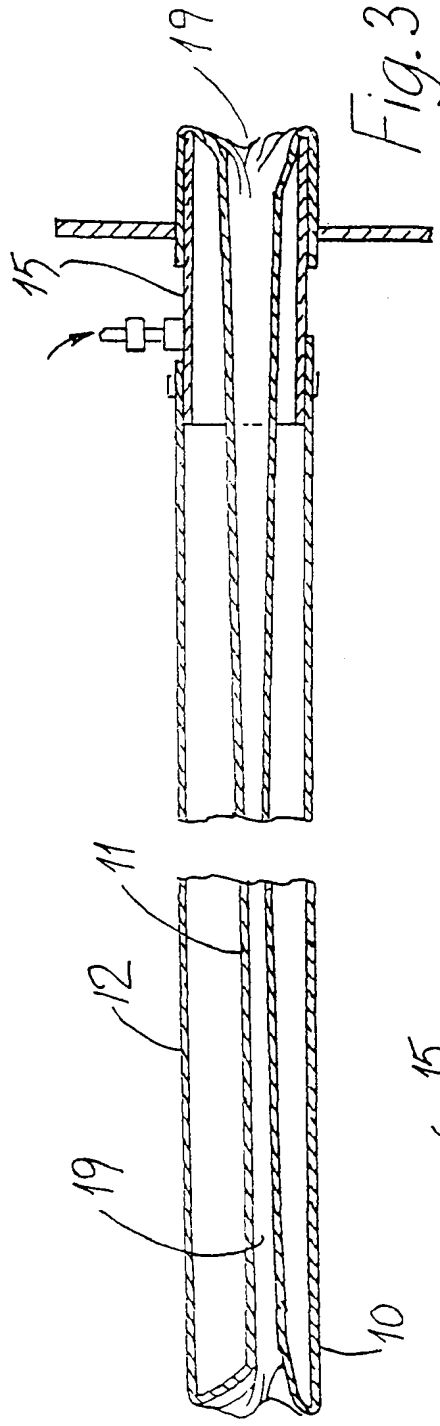


Fig. 3

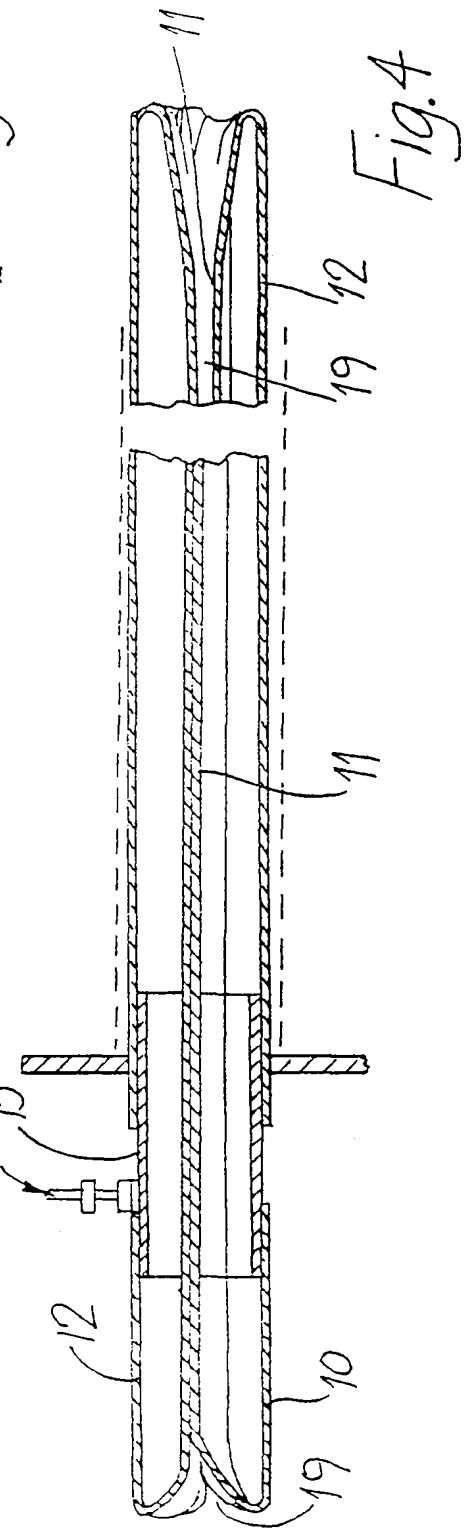


Fig. 4

Fig.6

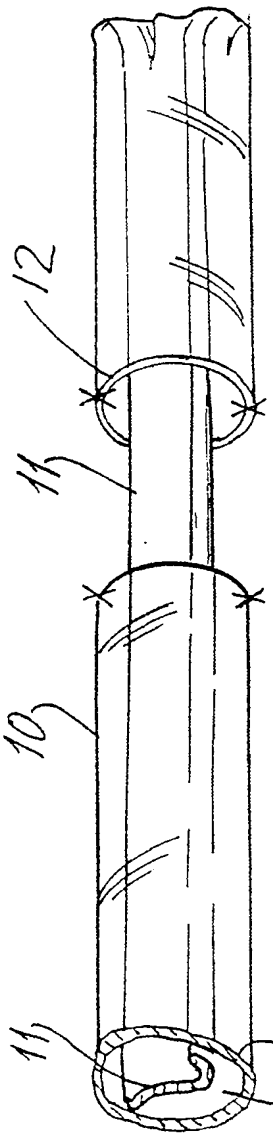


Fig.7

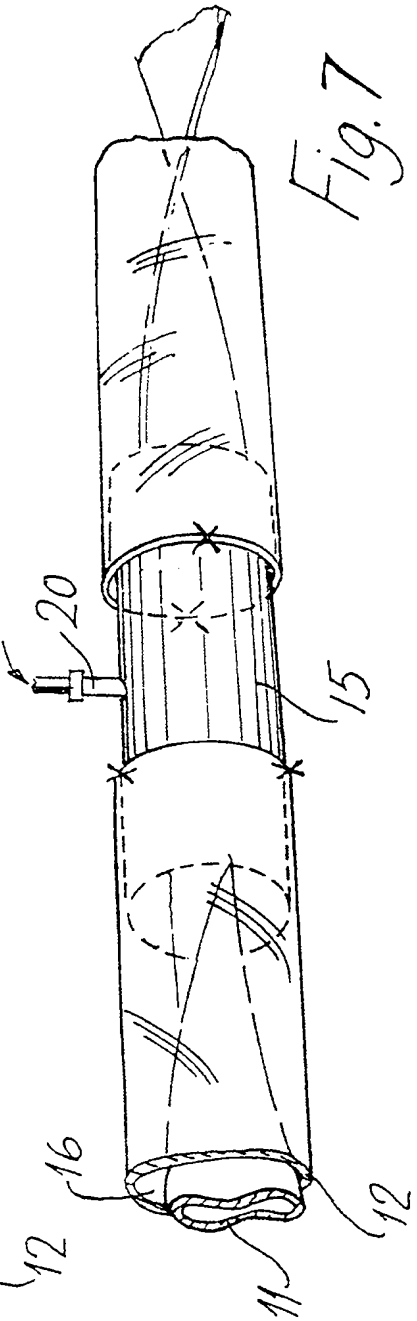
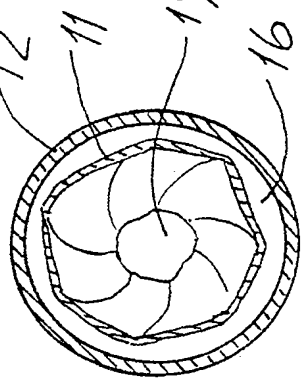


Fig.5



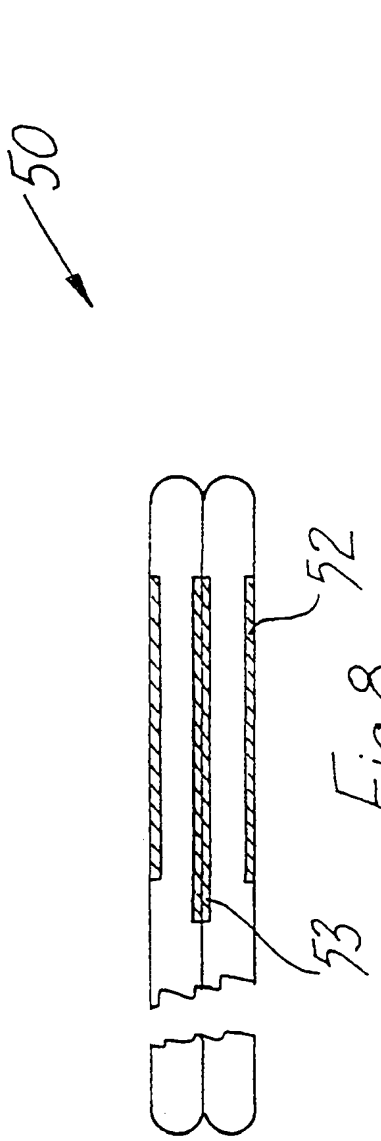


Fig.8

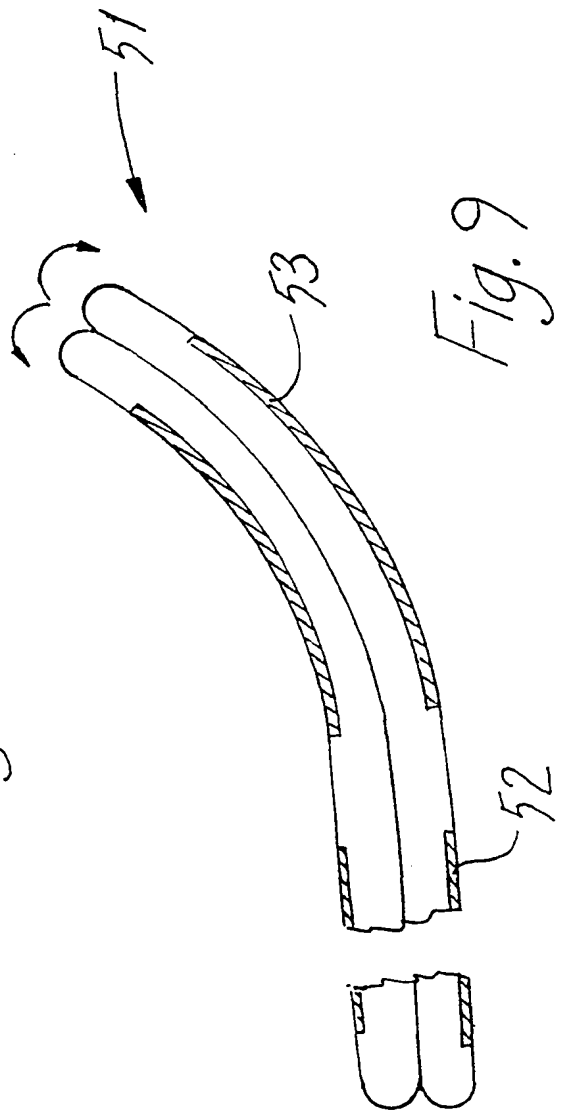


Fig.9

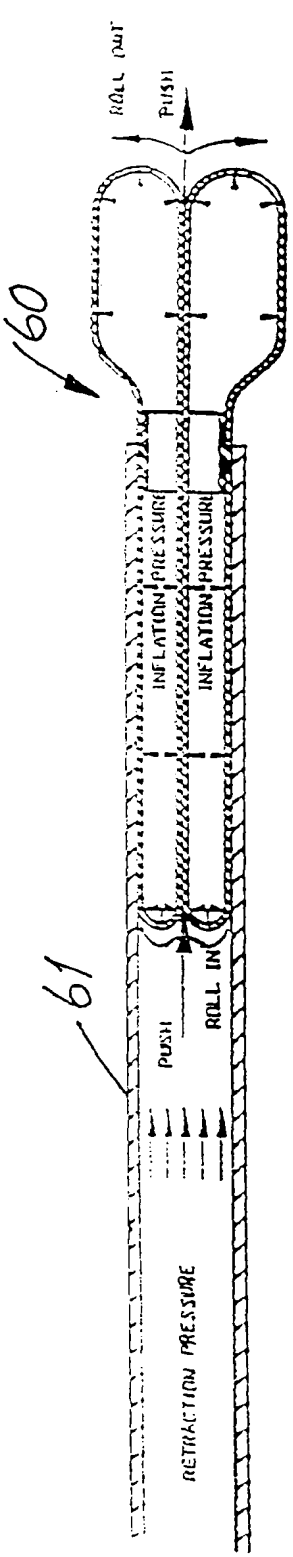
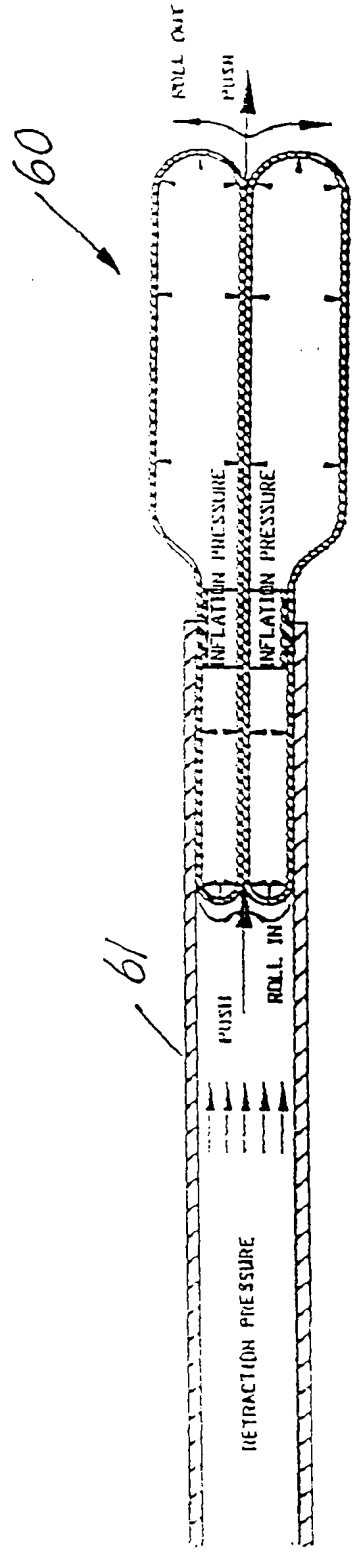

ROLL OUT
PUSH
60
INFLATION PRESSURE
INFLATION PRESSURE
61
PUSH
ROLL IN
RETRACTION PRESSURE

Fig. 10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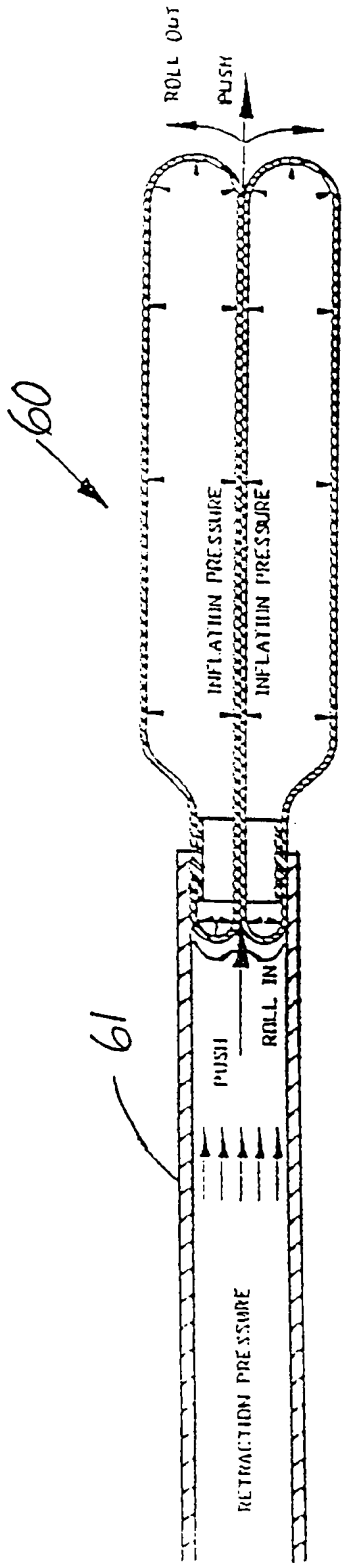
PUSH
60
INFLATION PRESSURE
INFLATION PRESSURE
61
PUSH
ROLL IN
RETRACTION PRESSURE

Fig. 11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PUSH
60
INFLATION PRESSURE
INFLATION PRESSURE
61
PUSH
ROLL IN
RETRACTION PRESSURE

Fig. 12

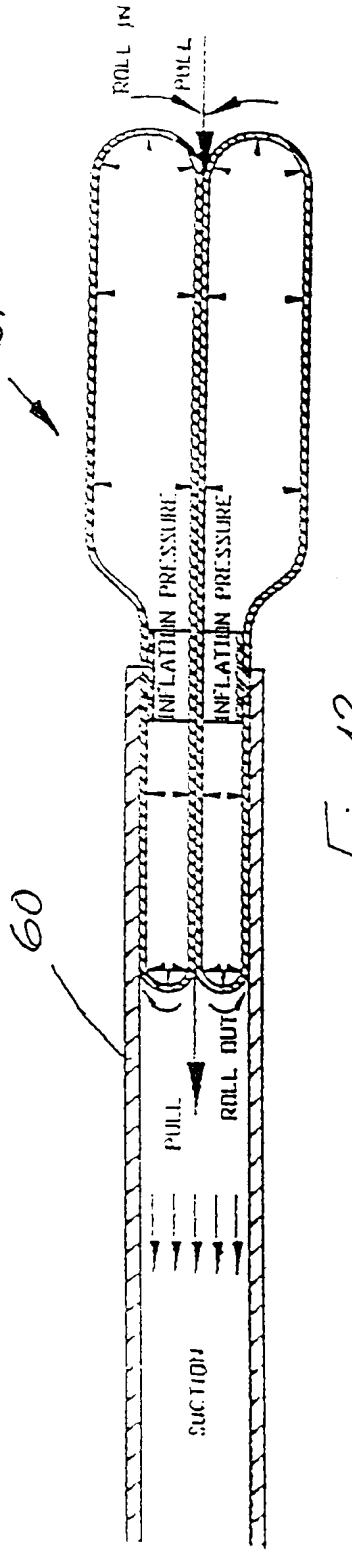
ROLL IN
PULL
61
INFLATION PRESSURE
INFLATION PRESSURE
60
PULL
ROLL OUT
SUCTION

Fig. 13

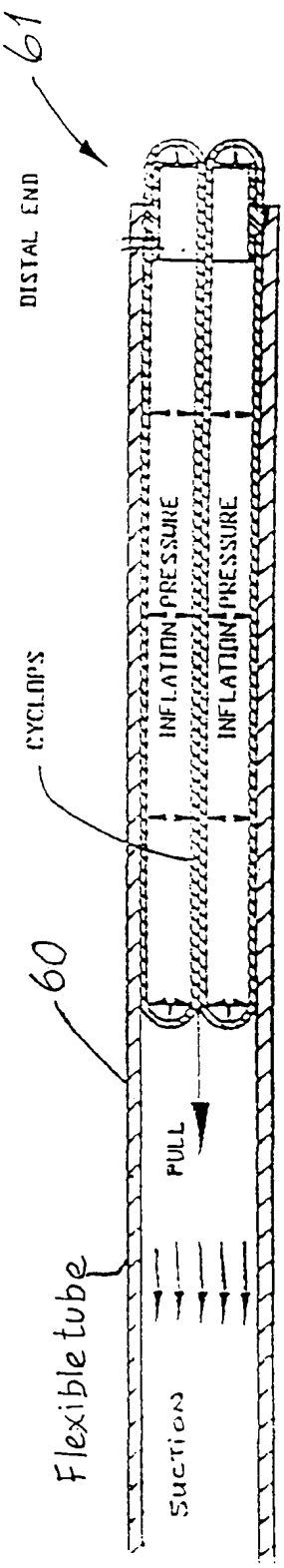

Fig. 14

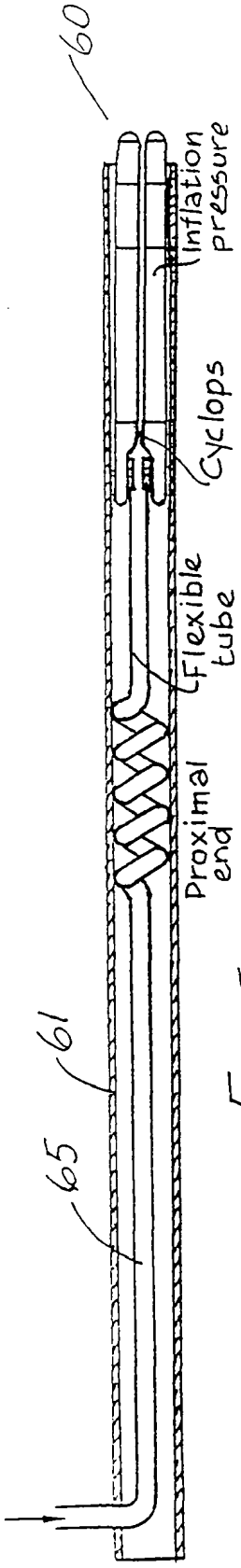

Fig. 15

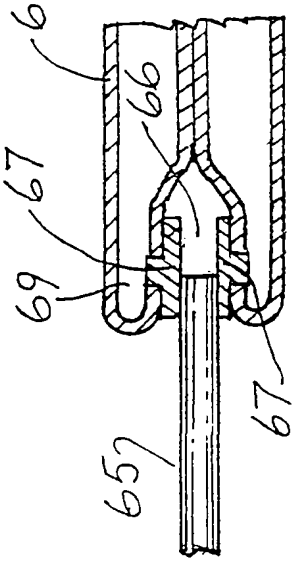

Fig. 16

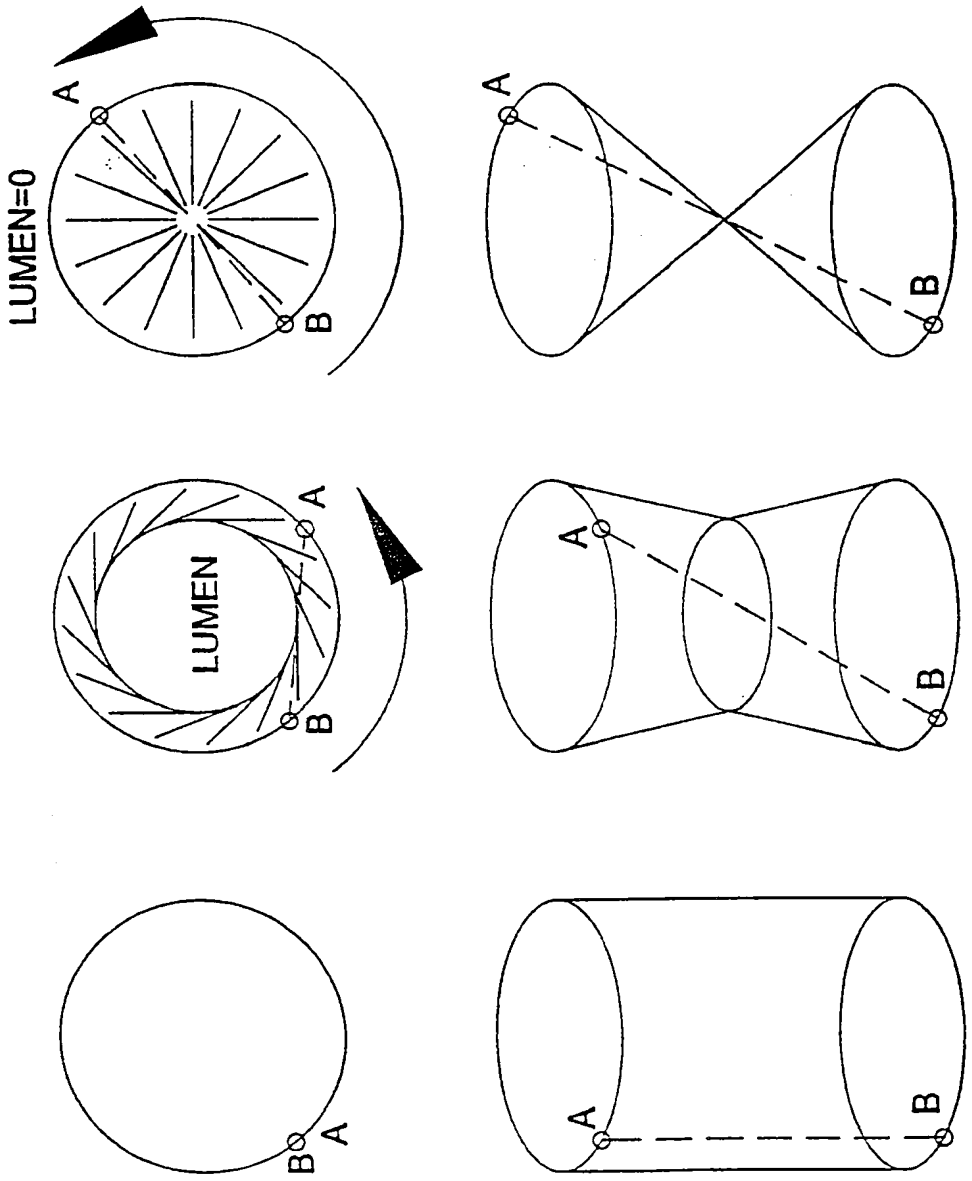

Fig. 17 The Twisted Tube

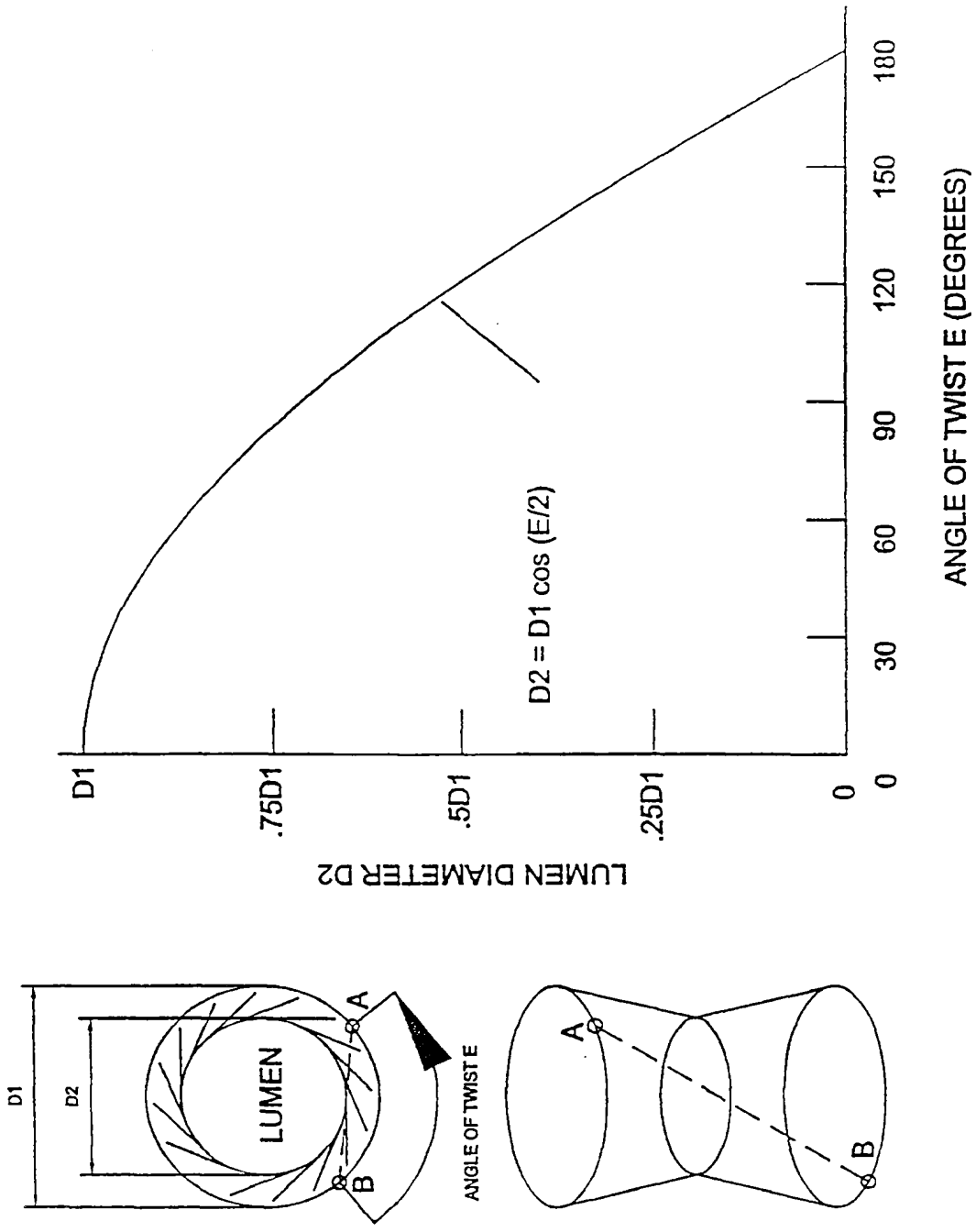

Fig.18a Angle of twist vs lumen

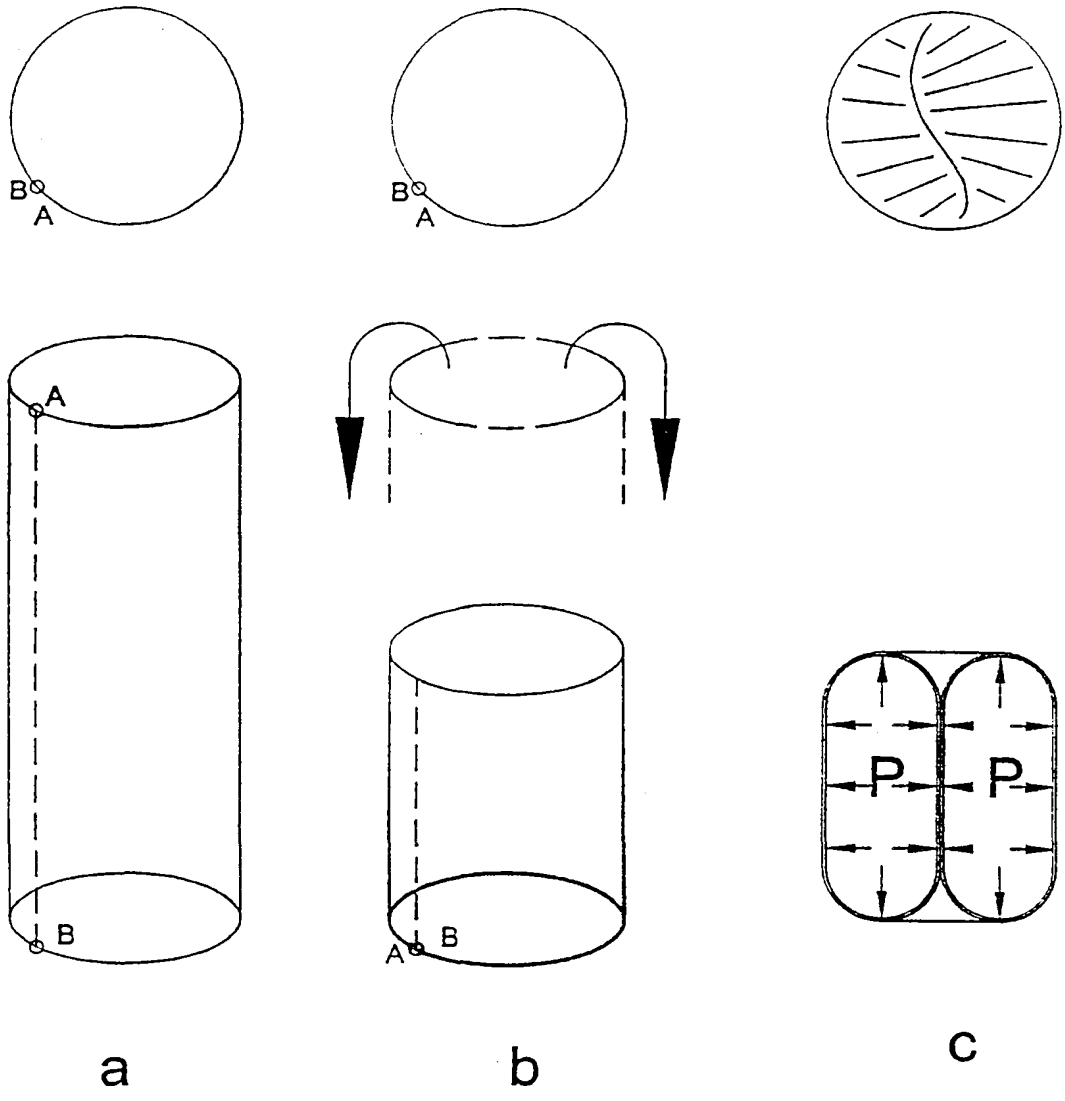

Fig.19 Twin Walled vessel under internal pressure

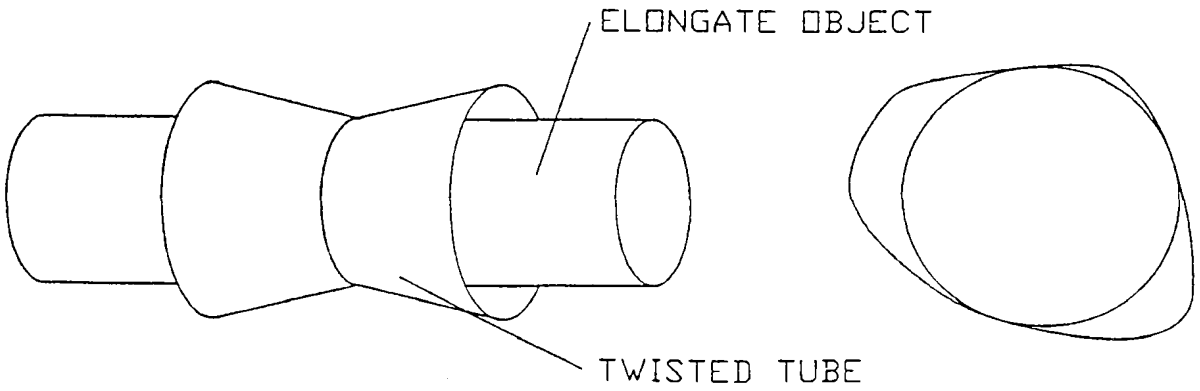

Fig.18b Twisted tube with elongate object passing therethrough

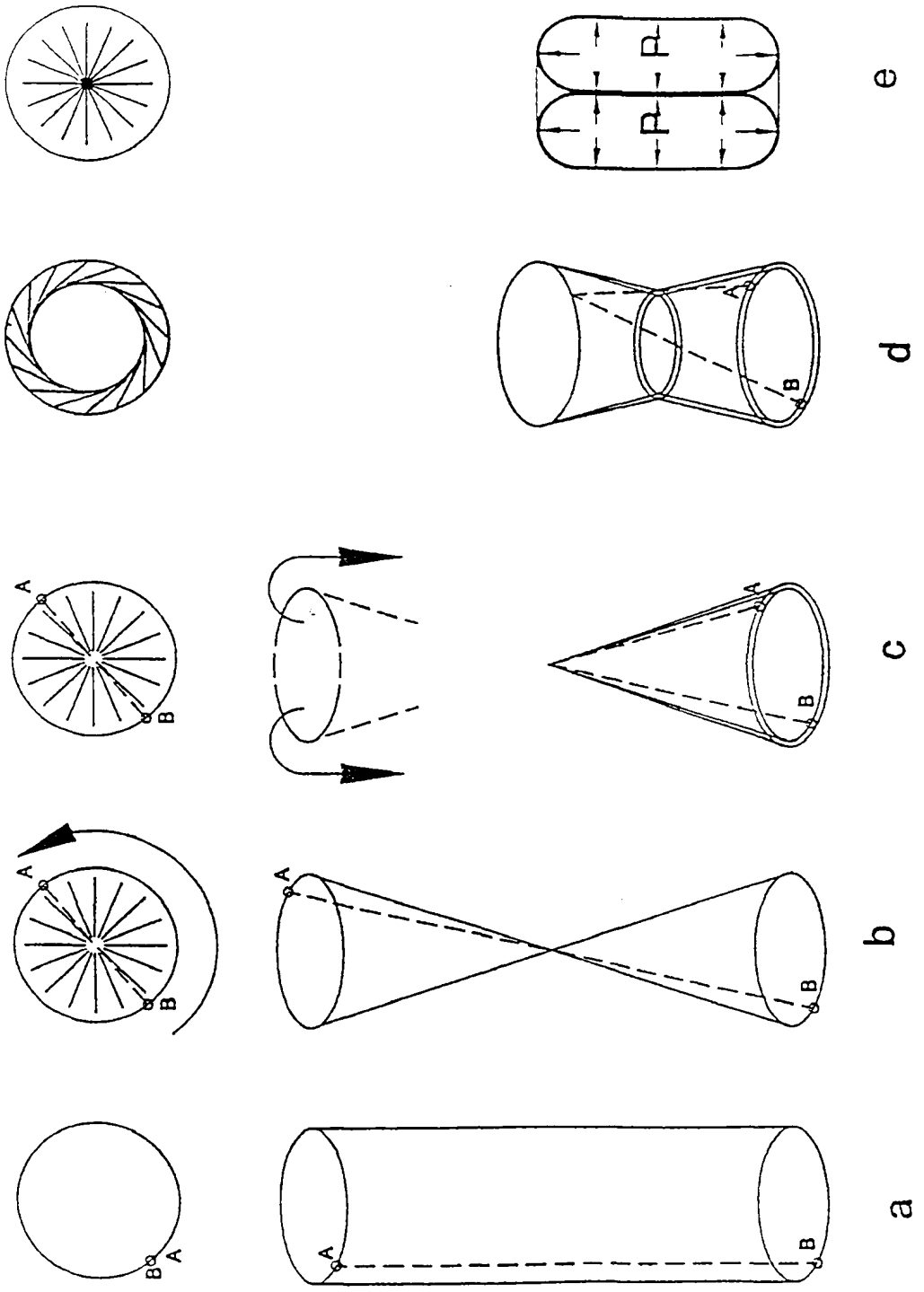

Fig.20 Twin walled tube with twist subject to internal pressure

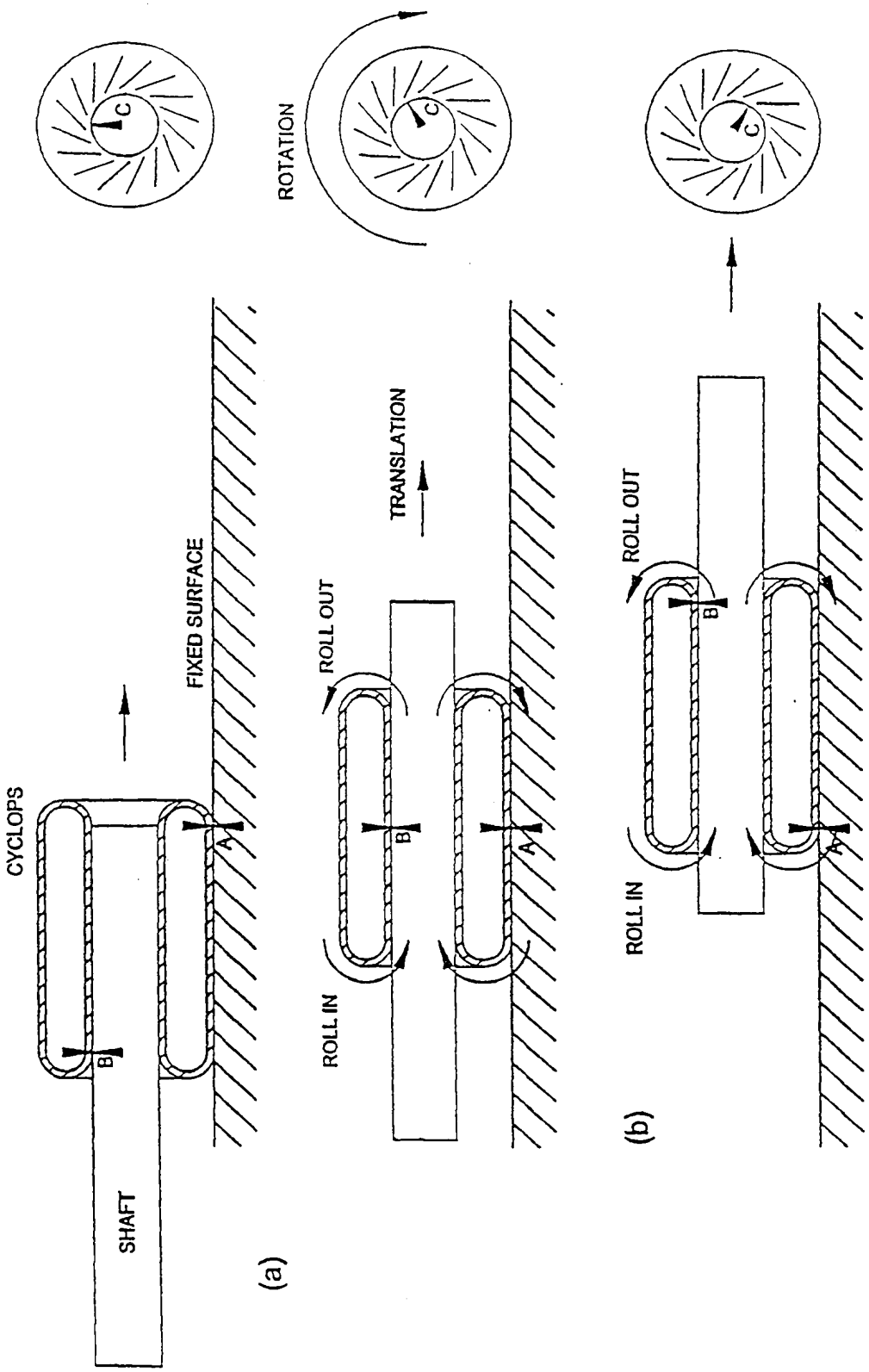

Fig.21 Translation of a shaft within a Cyclops

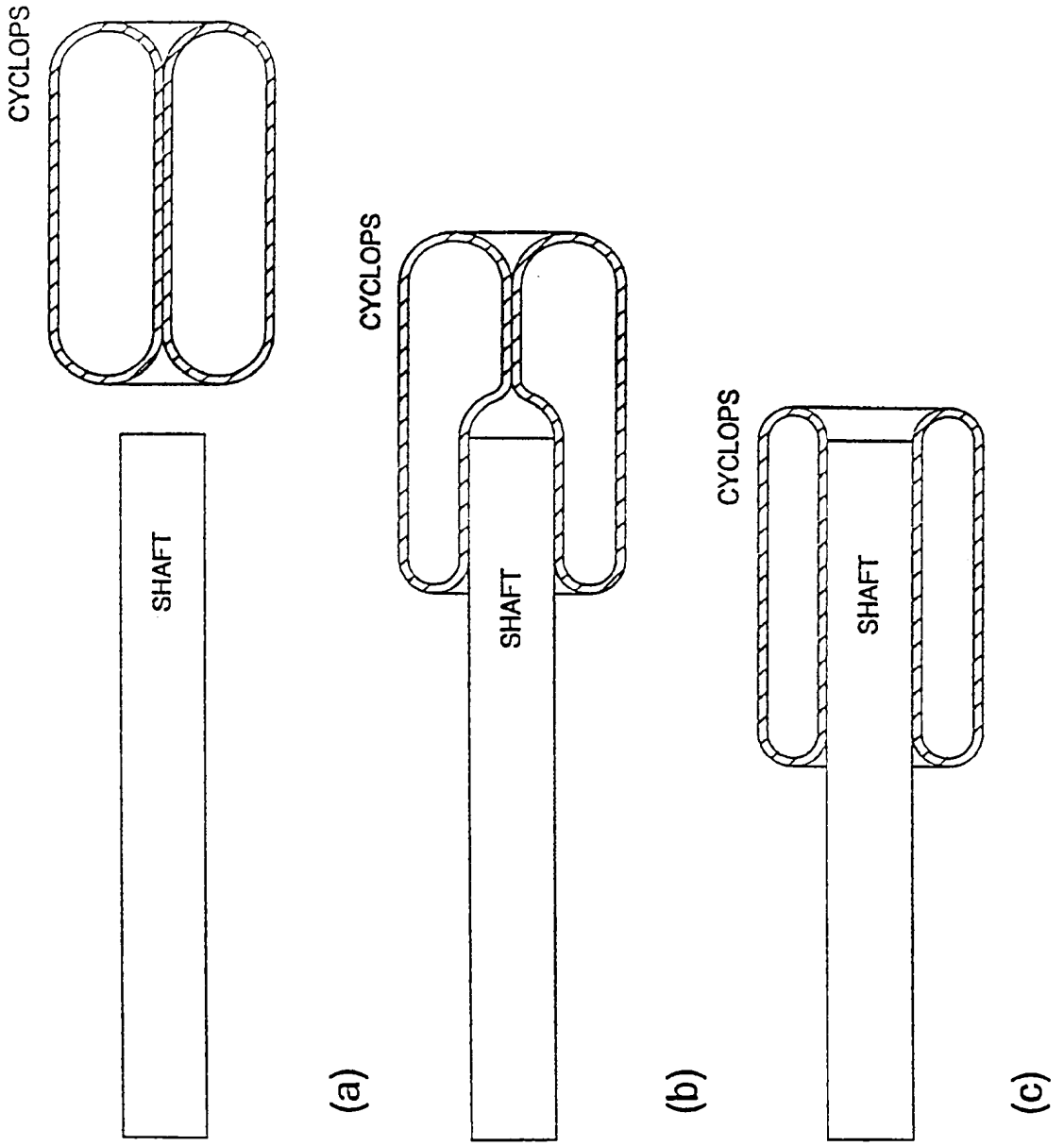

Fig.22 The deformation of a Cyclops as a shaft enters and translates

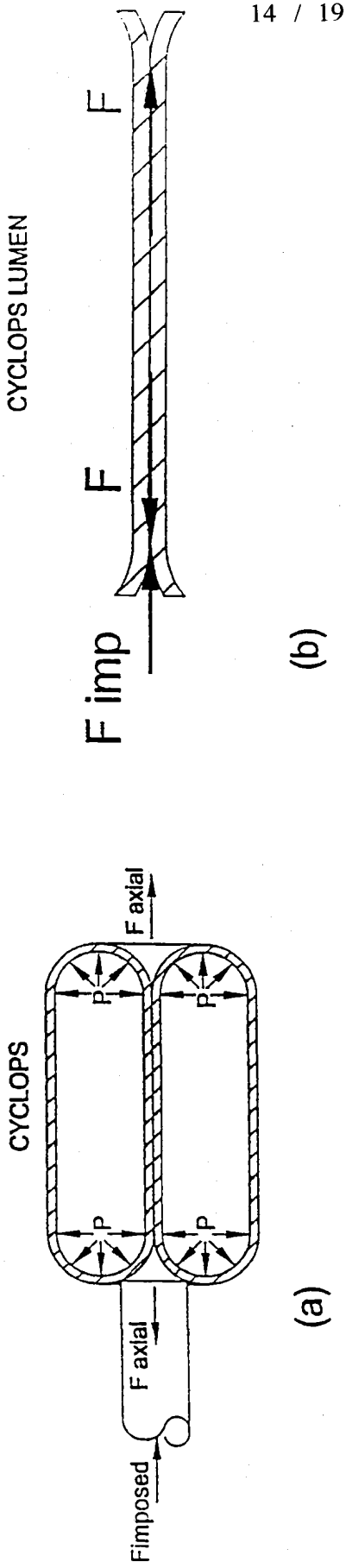

Fig 23 Forces acting on Cyclops lumen due to axial component of pressure

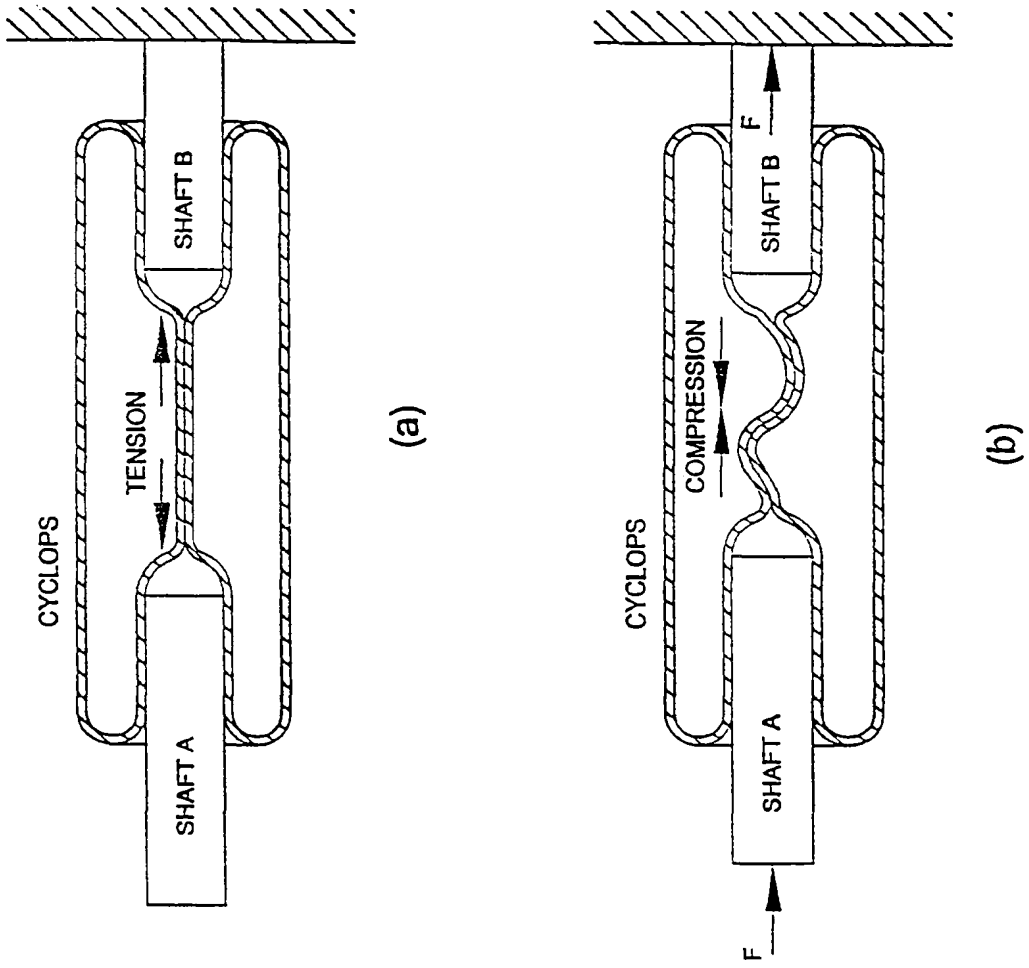

Fig.24 Stiffness of Cyclops lumen

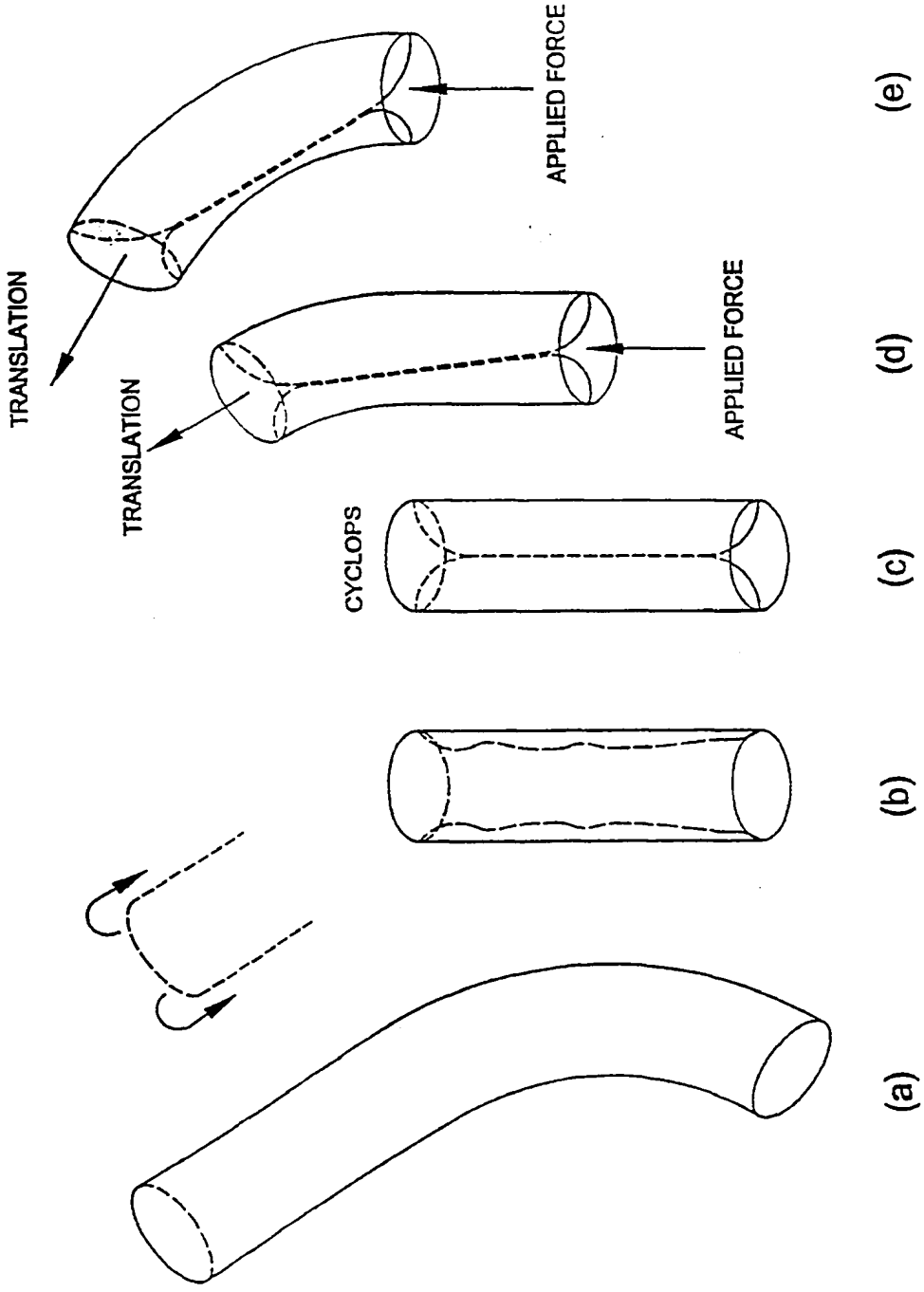

Fig.25 Effects of tube preform shape

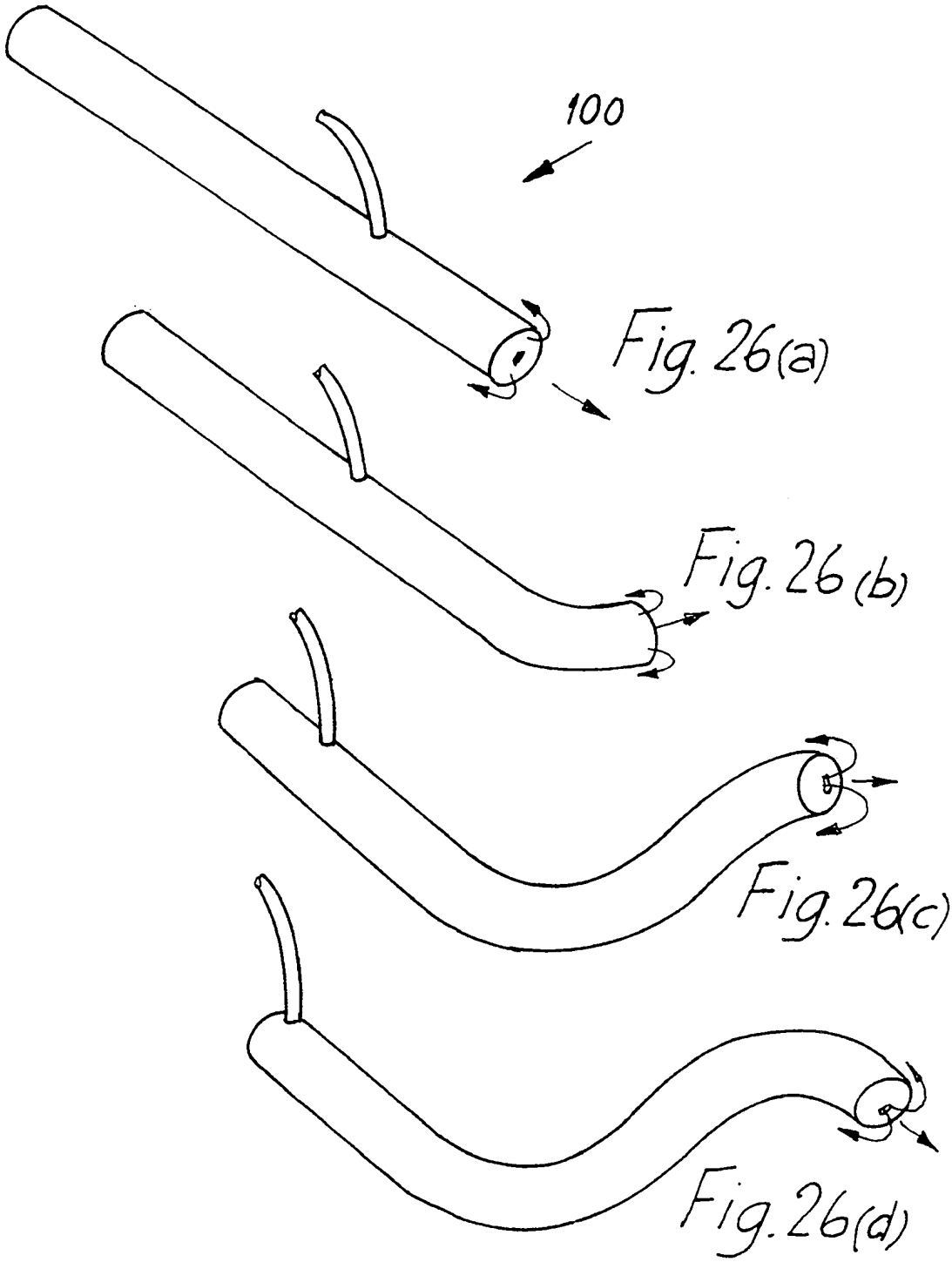

Fig. 26(a)

Fig. 26(b)

Fig. 26(c)

Fig. 26(d)

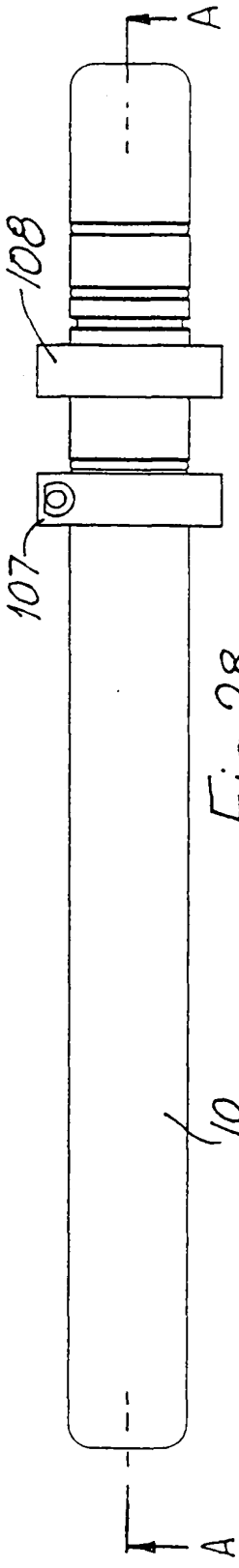

Fig. 28

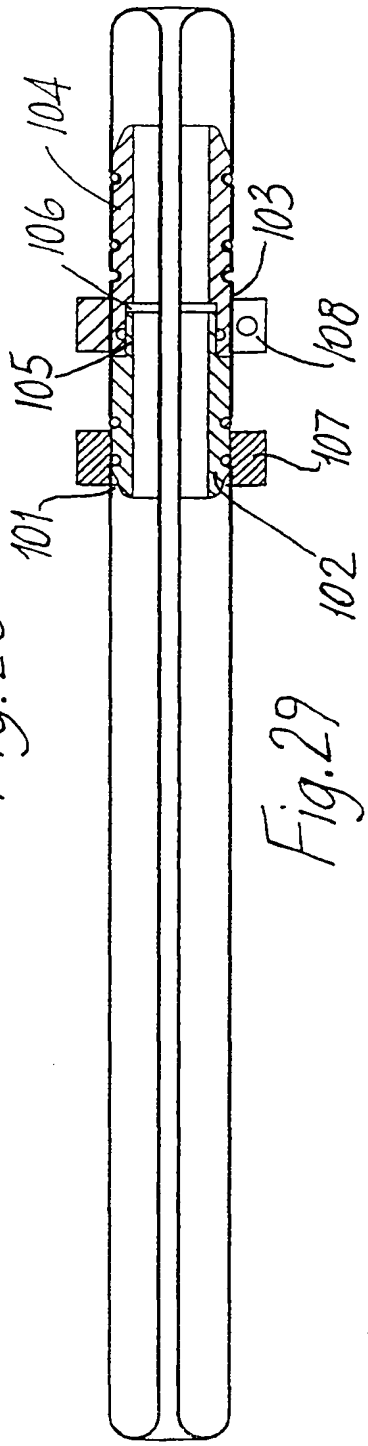

Fig. 29

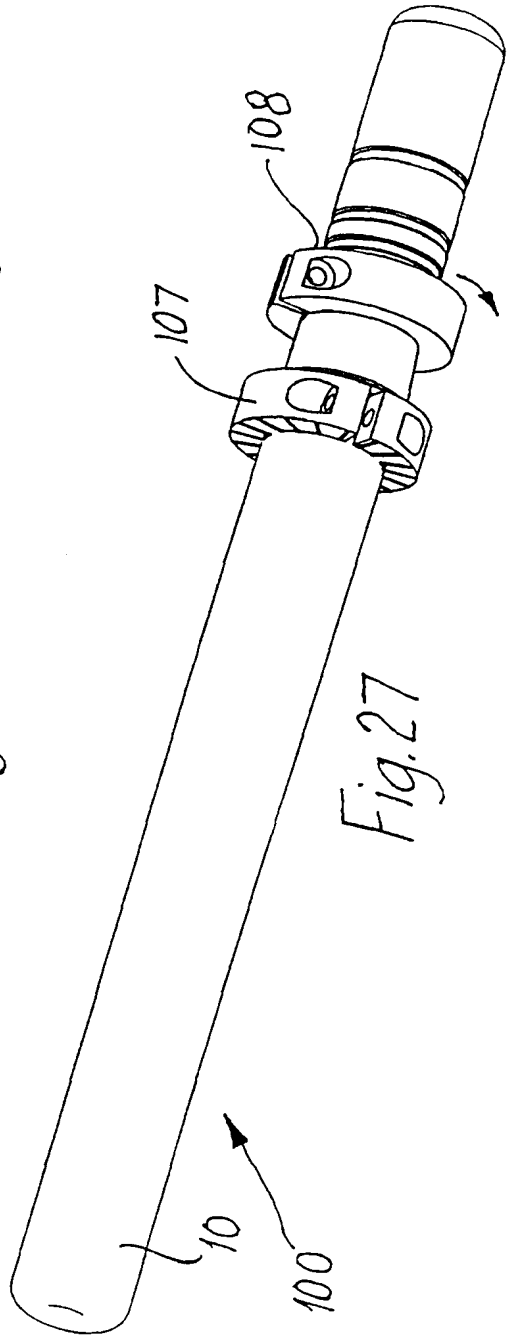

Fig. 27

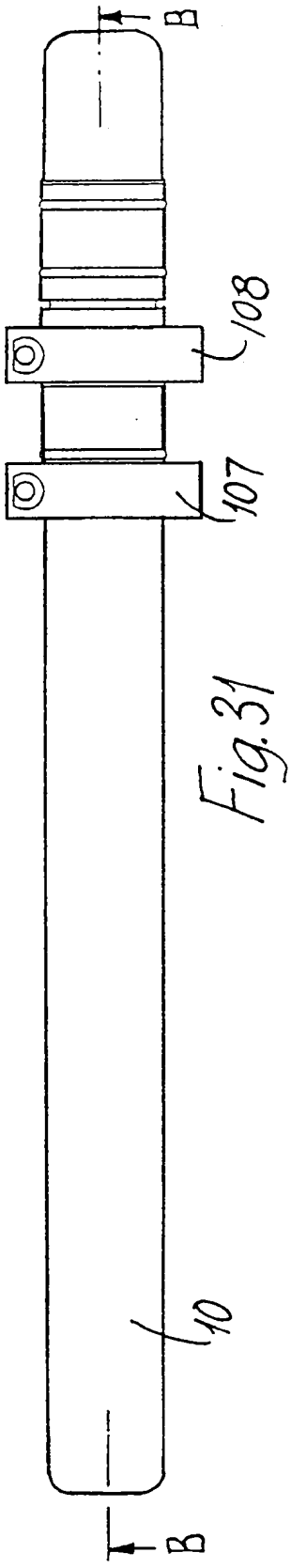

Fig.31

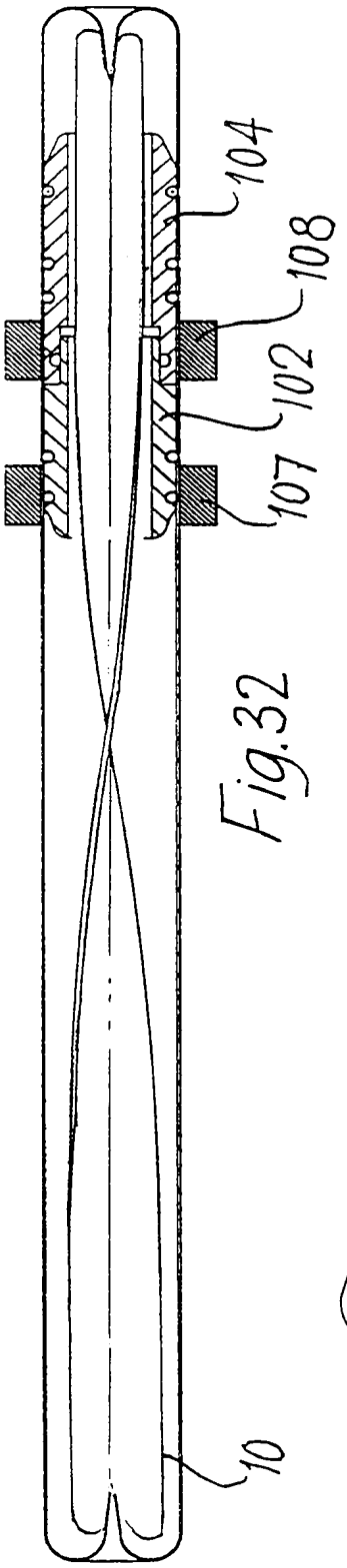

Fig.32

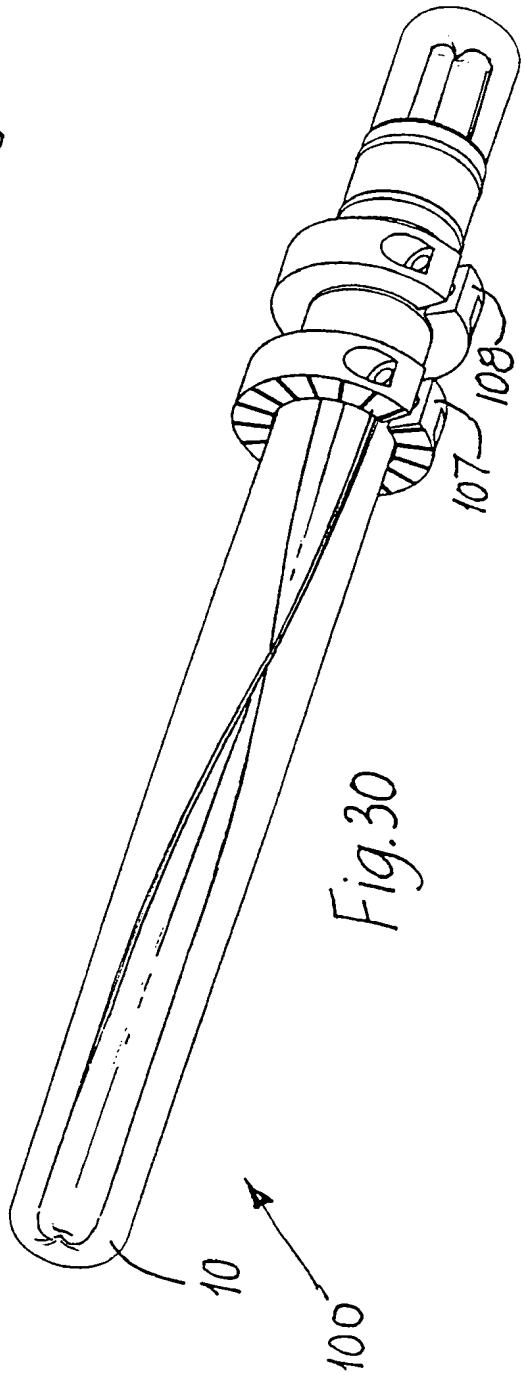

Fig.30

INTERNATIONAL SEARCH REPORT

Inta ional Application No
PCT/IE 99/00124

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/34 A61M25/01

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 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 practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 634 937 A (MOLLENAUER KENNETH H ET AL) 3 June 1997 (1997-06-03) column 10, line 16 - line 50	1
A	US 5 636 645 A (OU HONZEN) 10 June 1997 (1997-06-10) cited in the application column 6, line 34 - line 54	1
A	WO 98 48724 A (CARROLL MAUREEN E ;NIEMANN ALLISON C (US); STAMM EDWARD I JR (US);) 5 November 1998 (1998-11-05) cited in the application figure 6B & US 5 906 577 A	1

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 February 2000	07/03/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Gérard, B

2

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

INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/IE 99/00124

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 37 39 532 C (ZERBST EKKEHARD) 8 December 1988 (1988-12-08) column 3, line 14 - line 21	1

2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IE 99/00124

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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.: 23
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 RULE 6.2(a) PCT

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 II Observations where unity of invention is lacking (Continuation of item 2 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 fee, this Authority did not invite payment of any additional fee.

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.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. ional Application No
PCT/IE 99/00124

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5634937 A	03-06-1997	WO 9636283 A US 5964781 A	21-11-1996 12-10-1999
US 5636645 A	10-06-1997	NONE	
WO 9848724 A	05-11-1998	US 5906577 A AU 7274698 A	25-05-1999 24-11-1998
DE 3739532 C	08-12-1988	NONE	

Form PCT/ISA/210 (patent family annex) (July 1992)

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13 October 2011 (13.10.2011)

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(74) Agents: **WELTHAGEN, Dieter, Hein** et al.; Adams & Adams, PO Box 1014, 0001 Pretoria (ZA).

(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, QA, RO, RS, RU, RW, 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, 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 the identity of the inventor (Rule 4.17(i))*

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

— *of inventorship (Rule 4.17(iv))*

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: AN INVERSIBLE TUBULAR MEMBER AND A GRIPPING DEVICE INCLUDING SUCH A MEMBER

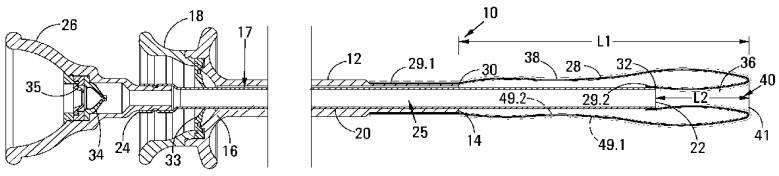


FIG 4

(57) Abstract: This invention relates to a gripping device (10), e.g. a surgical retrieval device. The device includes an inversible tubular member (28), which is composed of interengaged stitches of resiliently flexible filamentary material and which is progressively transformable between an everted condition and an inverted condition. The device includes also actuation means (12,20) carrying the inversible tubular member and operable for effecting progressive inversion and eversion of the inversible tubular member. Through progressive inversion of the inversible tubular member, an object can be gripped thereby.

WO 2012/049652 A1

AN INVERSIBLE TUBULAR MEMBER AND A GRIPPING DEVICE INCLUDING SUCH A MEMBER

THIS INVENTION relates to an inversible tubular member and to a gripping device including such a member.

According to a first aspect of the invention there is provided an inversible tubular member which is substantially round in cross-section and progressively transformable between an everted condition and an inverted condition, with a transformation end being defined intermediate an everted length and an inverted length of the inversible tubular member during such transformation and with the inverted length and the everted length defining opposite to the transformation end respectively an inverted end and an everted end of the inversible tubular member, in which:

the inversible tubular member is composed of interengaged stitches of resiliently flexible filamentary material;

with the inversible tubular member at least partially inverted, the inverted length has sufficient stiffness to cause eversion of the inversible tubular member at the transformation end upon axial displacement of the inverted end towards the transformation end, for a length of the inverted length up to X times an average relaxed outer diameter of the inverted length;

X>=2.0;

with the inversible tubular member at least partially everted, the everted length has sufficient stiffness to cause inversion of the inversible tubular member at the transformation end upon axial displacement of the everted end towards the transformation end, for a length of the everted length up to Y times an average relaxed outer diameter of the inverted length; and

Y>=2.0.

In a particular embodiment of the inversible tubular member of the invention:

with the inversible tubular member at least partially everted, the everted length has sufficient stiffness to cause inversion of the inversible tubular member at the transformation end upon axial displacement of the everted end towards the transformation end, for a length of the everted length up to Z times the average relaxed outer diameter of the inverted length, whilst one half of a sphere of diameter 1.5 times an average relaxed outer diameter of the inverted length is received in the inversible tubular member at the transformation end; and

$Z>=2.0$.

The applicant has found that, by suitable selection of the filamentary material, pattern of the stitches, and so forth, the following values are achievable:

$X>=5.0$ with the inverted length not restrained against lateral buckling;

$X>=30$ with the inverted length restrained against lateral buckling, for example by the everted length;

$Y>=50$; and

$Z>=3.0$.

In a particular embodiment of the inversible tubular member, it may define in the everted condition a larger outer diameter than in the inverted condition. Preferably, the inner diameter of the inversible tubular member in the everted condition is larger than its outer diameter in the inverted condition. As a result, during inversion and eversion, friction between an inverted length and an everted length of the inversible tubular member will be minimized.

The stitches may be knitted stitches of at least one length of the filamentary material.

The stitches may be plaited stitches, each defining a loop.

The filamentary material may be a monofilament material, for example a polymer such as Nylon. Alternatively, the filamentary material may be a multifilament material, for example stranded stainless steel wiring.

The filamentary material may be a superelastic material.

The filamentary material may be a shape memory material, e.g. Nitinol.

The inversible tubular member may have a substantially constant cross-section along its length in each of the inverted and everted conditions.

Alternatively, the inversible tubular member may have a variable diameter along its length in each of the inverted and everted conditions. Such a variable diameter may be achieved by varying the stitch size, or the number of stitches per circumferential row, along the length. Alternatively, if the properties of the filamentary material permit, a variable diameter may be achieved by heating, setting, and cooling of the filamentary material. The Applicant believes that such variable diameter may be useful in at least one envisaged application of the inversible tubular member, i.e. grabbing of an object, as is described below.

The filamentary material may be coated in a coating of a different material. The coating may, for example, serve to alter at least one surface property of the filamentary material, for example its coefficient of friction. In the case of the filamentary material being a multifilament material, the coating may serve to bind the filaments of the multifilament material together.

According to a second aspect of the invention there is provided a gripping device including:

an inversible tubular member which is substantially round in cross-section and progressively transformable between an everted condition and an inverted condition, with a transformation end being defined intermediate an everted length and an inverted length of the inversible tubular member during such transformation and with the inverted length and the everted length defining opposite to the transformation end respectively an inverted end and an everted end of the inversible tubular member, the inversible tubular member being composed of interengaged stitches of resiliently flexible filamentary material; and

actuation means carrying the inversible tubular member and operable for effecting progressive inversion and eversion of the inversible tubular member,

the inversible tubular member defining a transformation end where the progressive inversion and eversion occurs, with such inversion providing for gripping an object in the inversible tubular member.

The gripping device may be used for gripping an object, as is described below. The inversible tubular member must have rigidity sufficient for performing the method.

In the gripping device, the inversible tubular member may be an inversible tubular member, in accordance with the first aspect of the invention. Accordingly, further features of the inversible tubular member of the gripping device may be the same as any of the features of the inversible tubular member of the first aspect of the invention, as described above. Also, it is envisaged that the following relationship may apply in the inversible tubular member, where X and Y are as defined above:

$$X>=Y>=5.0$$

The applicant envisages that the gripping device of the second aspect of the invention may be used for the retrieval of loose objects from small or deep cavities where other forms of access may be difficult or impossible. It may also be used for gripping objects while they are being manipulated, modified, inspected, dissected, or excised. Typical applications could include capture and manipulation/removal of objects/organs during laparoscopic surgery, capture and removal of objects from natural body orifices, and capture and manipulation/removal of objects in/from pipes or machinery.

The gripping device may include a membrane over at least a part of a surface of the inversible tubular member which is an outer surface in the everted condition. Alternatively or additionally, the gripping device may include a membrane over at least a part of a surface of the inversible tubular member which is an inner surface in the everted condition.

In a particular embodiment of the gripping device, the actuation means includes:

an outer tubular member defining a distal end, i.e. a front end, and a proximal end, i.e. a rear end, and a longitudinal passage extending between the distal end and the

proximal end, the distal end being peripherally attached to an everted end of the inversible tubular member; and

an inner elongate member received within the passage and defining a distal end and a proximal end, the distal end being peripherally attached to an opposite inverted end of the inversible tubular member,

the outer tubular member and the inner elongate member being slidingly displaceable relative to each other to effect the progressive inversion and eversion.

In the said particular embodiment, the actuation means may include:

a first hand grip formation on the proximal end of the outer tubular member; and

a second hand grip formation on the proximal end of the inner elongate member,

the hand grip formations being manually relatively displaceable for effecting the relative sliding displacement of these members.

Still in the said particular embodiment, the inversible tubular member may be retractable into the outer tubular member.

Still in the said particular embodiment, the inner elongate member may be received within the outer tubular member in a snug sliding fit to provide sealing between these members to a required pressure, which is not less than 15 mmHg. Such sealing may be required in certain medical applications of the gripping device, as envisaged by the applicant.

Alternatively, the said particular embodiment may include sealing means, for example a circular sealing ring, sealing between the inner elongate member and the outer tubular member to a required pressure, which is not less than 15 mmHg.

Still in the said particular embodiment, the inner elongate member may define therethrough a longitudinal passage, permitting insertion of an elongate surgical or other instrument through it. This may be required in certain medical applications, for example laparoscopic applications, of the gripping device, as envisaged by the applicant. The inner elongate member may have sealing means sealing the longitudinal passage defined therethrough, the sealing means being configured to permit passage of an elongate surgical or other instrument through it and to seal around the instrument. The

sealing means may, for example, include a duckbill for sealing the longitudinal passage when there is no instrument in the passage and a circular seal for sealing around an instrument when present in the passage.

Still in the said particular embodiment, the inversible tubular member may be releasable from the outer tubular member and the inner elongate member. In this case, the gripping device may include a first coupling secured to the everted end of the inversible tubular member, the first coupling being releasably engageable with the distal end of the outer tubular member; and a second coupling secured to an end of an inverted length of the inversible tubular member opposite to the transformation end, the second coupling being releasably engageable with the distal end of the inner tubular member. The first and second couplings may be interengageable through relative displacement of the outer tubular member and the inner elongate member.

Still in the said particular embodiment, the outer tubular member may include a distal end portion that is radially expandable for operatively accommodating therein a length of the inversible tubular member and an object therein where the size of the object requires radial expansion of the end portion. The distal end portion may define therein an arrangement of slits which are angularly spaced about the central axis of the tubular member to provide for the expansion. The distal end portion may be resiliently flexible to provide for the expansion.

According to a third aspect of the invention, there is provided a method of gripping an object, the method including:

providing an inversible tubular member which is substantially round in cross-section and progressively transformable between an everted condition and an inverted condition with a transformation end being defined intermediate an everted length and an inverted length of the inversible tubular member during such transformation, the inversible tubular member being composed of interengaged stitches of resiliently flexible filamentary material;

with at least a part of the length of the inversible tubular member in the everted condition, contacting the transformation end of the said part with the object; and

progressively inverting the said part at the transformation end, thus causing the inversible tubular member to grip the object.

Clearly, in order to perform the method, the inversible tubular member must have sufficient rigidity.

The inversible tubular member used in the method may be an inversible tubular member, in accordance with the first aspect of the invention.

The method may include at least partially drawing the object into the inversible tubular member by the progressive inverting of the inversible tubular member.

The applicant has found that, due to flexibility in the inversible tubular member, the method may be used to grip and draw into the inversible tubular member an object having a size substantially larger than the outer diameter of the said part of the length of the inversible tubular member in the everted condition. The applicant has further found that, by suitably sizing the inversible tubular member, it is able to grip and draw in very fragile objects.

According to a fourth aspect of the invention there is provided a method of making an inversible tubular member, in accordance with the first aspect of the invention, the method including forming stitches in a suitable filamentary material and inter-engaging them to define the inversible tubular member.

In one possible implementation of the method, both the forming and inter-engaging of the stitches may be performed in a knitting process.

In another possible implementation of the method, a series of the stitches may be formed in the filamentary material and thereafter the stitches may be interengaged in a knitting process. The series of stitches may, for example, be formed as a series of loops in the filamentary material by forming the filamentary material into a helix and then flattening the helix.

The knitting process, where applicable, may be performed by means of a knitting spool.

Further features of the invention, in its various aspects, will become apparent from the description below of example embodiments of the invention, with reference to and as illustrated in the accompanying diagrammatic drawings. In the drawings:

Figure 1 shows a side/rear three-dimensional view of a first embodiment of a gripping device, in accordance with the invention, including an inversible tubular member, in accordance with the invention;

Figure 2 shows an enlarged side/front three-dimensional view of a distal end portion of the device of Figure 1;

Figure 3 shows a broken side view of the device of Figure 1;

Figure 4 shows a broken long section of the device of Figure 1;

Figure 5 shows a detail long section of an end part of the device of Figure 1 and an object gripped thereby;

Figure 6 shows a detail of an inverted length of the inversible tubular member of Figure 1;

Figure 7 shows a detail of an everted length of the inversible tubular member of Figure 1;

Figure 8 shows a detail illustrating a step in a method, in accordance with the invention, of making the inversible tubular member of Figure 1;

Figure 9 shows a detail IX of Figure 8;

Figure 10 shows a detail long section of an end part of a second embodiment of a gripping device, in accordance with the invention, and an object gripped thereby, the device being for the most part identical to the gripping device of Figure 1;

Figure 11 shows a long section of a third embodiment of a gripping device, in accordance with the invention;

Figure 12 shows a detail XII of Figure 11;

Figure 13 shows a detail XIII of Figure 12; and

Figure 14 shows a three-dimensional view of a fourth embodiment of a gripping device, in accordance with the invention, including an inversible tubular member, in accordance with the invention.

In Figures 1 to 4, a first embodiment of a gripping device, in accordance with the invention, more particularly a laparoscopic surgical retrieval device, is designated generally by the reference numeral 10.

The retrieval device 10 includes:

an outer tubular member 12 defining a distal end 14, a proximal end 16, and a longitudinal passage 17 extending from the distal end 14 to the proximal end 16;

a first hand grip formation 18 around the proximal end 16 of the outer tubular member 12;

an elongate inner member in the form of an inner tubular member 20 defining a distal end 22, a proximal end 24, and a longitudinal passage 25 extending from the distal end 22 to the proximal end 24, the inner tubular member 20 being snugly and slidingly received through the passage 17 of the outer tubular member 12;

a second hand grip formation 26 on the proximal end 24 of the inner tubular member 20; and

a tubular member 27.

The tubular member 27 comprises:

a first length 29.1, secured around the distal end 14 of the outer tubular member 12;

a second length 29.2, secured around the distal end 22 of the inner tubular member 20; and

a third length 28, which is an inversible tubular member, in accordance with the invention, and which extends from the length 29.1 to the length 29.2.

The entire tubular member 27 was formed as an inversible tubular member, in accordance with the invention. However, the lengths 29.1 and 29.2 of the tubular member 27 clearly are now restrained and therefore no longer inversible.

The inversible tubular member 28 has:

an everted end 30, secured to the distal end 14 of the outer tubular member 12 via the first length 29.1; and

an opposite, inverted end 32, secured to the distal end 22 of the inner tubular member 20 via the second length 29.2.

It is known that in certain laparoscopic procedures, it is required for a surgical retrieval device to seal up to a particular pressure, being a pressure maintained inside a

peritoneal cavity during surgery. Accordingly, the retrieval device 10 includes a seal 33 effectively sealing between the inner tubular member 20 and the outer tubular member 12. The seal 33 seals up to a prescribed pressure, which is not less than 15 mmHg. Alternatively, the inner tubular member 20 may be received sufficiently snugly within the outer tubular member 12 to seal to a prescribed pressure, which is not less than 15 mmHg.

The passage 25 extends also through the hand grip formation 26. The retrieval device 10 includes also, within a widened proximal end of the passage 25, sealing means in the form of a circular seal 35 and a duckbill 34, both capable of sealing up to at least 15 mmHg. Another surgical device may be inserted through the retrieval device 10, particularly through the circular seal 35, the duckbill 34, and the passage 25. The circular seal 35 is for sealing around such a surgical device. The duckbill 34 is for sealing when there is no such surgical device present.

A length 38 of the inversible tubular member 28, having a length L1, is in an everted condition and a length 36 of the inversible tubular member 28, having a length L2, is in an everted condition. The inverted length 36 defines therein a cavity 40 which forms an extension of the passage 25. At a peripheral boundary between the inverted length 36 and the everted length 38 is defined a transformation end 41 of the inversible tubular member 28. As will be described below, the gripping device 10 is operable to effect progressive inversion and eversion of the inversible tubular member 28 at the transformation end 41, meaning that L1 and L2 are variable.

The inversible tubular member 28 has a total length L = L1 + L2 of about six times a natural or relaxed outer diameter of the inverted length 36. The diameter of the inversible tubular member 28 may be variable along its length when it is entirely everted. In an alternative embodiment (not shown), the diameter of the inversible tubular member may be at least substantially constant along its length when it is entirely everted.

With the inversible tubular member 28 completely everted (not shown), then by relative forward displacement of the hand grip formation 18 and the outer tubular member 12 with respect to the hand grip formation 26 and the inner tubular member 20, the end 30

of the inversible tubular member 28 is linearly relatively displaced towards the transformation end 41 and the inversible tubular member 28 is progressively inverted, i.e. the inverted length 36 and the space or cavity 40 defined therein are progressively extended away from the distal end 22 of the inner tubular member 20. The everted length 38 clearly must have sufficient rigidity to cause such inversion.

With reference particularly to Figure 5, by such inversion, an object 42 can be gripped by means of the inversible tubular member 28 and drawn into the cavity 40. Figure 5 will be referred to again below.

With the inversible tubular member 28 completely inverted (not shown) within the outer tubular member 12, then by relative rearward displacement of the hand grip formation 18 and outer tubular member 12 with respect to the hand grip formation 26 and the inner tubular member 20, the end 32 of the inversible tubular member 28 is linearly relatively displaced towards the transformation end 41 and the inversible tubular member 28 is progressively everted, i.e. the inverted length 36 and the space or cavity 40 defined therein are progressively shortened. The inverted length 36 clearly must have sufficient rigidity to cause such eversion.

With reference now to Figure 6, the inversible tubular member 28 (of which only a small portion is shown) is composed of interengaged plait stitches 43, each including a loop 44, the stitches 43 being made of a resiliently flexible filamentary material in the form of nylon filament 46. The same applies to the entire tubular member 27, of which the inversible tubular member 28 forms a part.

The loops 44 may be formed and interengaged in a knitting process, for example using a knitting spool. Alternatively, a series of the loops 44 may be formed in the nylon filament 46 prior to interengaging the loops in a knitting or similar process. This may be done by forming the filament 46 into a helix and then flattening the helix.

Figure 6 shows the portion of the inversible tubular member 28 in the inverted condition. Figure 7 shows essentially the same portion of the inversible tubular member 28 in the everted condition.

Figures 8 and 9 show a step in a method, in accordance with the invention, for making the inversible tubular member 28. The nylon filament 46 is knitted such as to form circumferential rows, of which three rows 48.1, 48.2, and 48.3 are shown, in a helix pattern. In this case, the rows 48.1 and 48.2 have already been completed and the row 48.3 is being formed. Two loops 44.1 and 44.2 respectively in the rows 48.2 and 48.3 have been interengaged and two loops 44.3 and 44.4 in the respective rows are about to be interengaged. Such stitches are known in relation to, for example, yarn as plaited stitches and therefore do not require further elaboration herein.

At the time of making the inversible tubular member 28, the loops 44 are in the arrangement shown in Figure 6, the loops 44 being on the inside of the inversible tubular member 28. This arrangement corresponds to the inverted condition of the inversible tubular member 28, as referred to herein. This arrangement is referred to below as the "inner loop arrangement".

By everting the inversible tubular member 28 into its everted condition, the loops 44 are transformed into the arrangement shown in Figure 7, in which the loops 44 are on the outside of the inversible tubular member 28. This arrangement is referred to below as the "outer loop arrangement".

The inventor has found in practice that an inversible tubular member such as the inversible tubular member 28 naturally defines in its inverted condition an outer diameter which is smaller than its outer diameter in the everted condition. The bias created in the knitting process as the loops 44 are formed causes adjacent loops to overlap in the inverted condition while they are constrained to a side-by-side arrangement in the everted condition. This creates two stable diameters respectively for the inversible tubular member 28 in the inverted and everted conditions, meaning that there is very low friction and minimal interference between the inverted length 36 and the everted length 38 (see Figure 4).

A possible further explanation of the two diameters is given below:

All of the loops 44, having been constructed as a helical spring either during or before the knitting process, have a tendency to want to return to a stacked, helical arrangement. This results in two forces on the loops:

A force pulling the loops 44 together due to the fact that the apex of the loop is highly flexed and creates a tendency for the loop to attempt to decrease its rate of flexure. As the loop is attached to its neighbouring loops by the roots 31 this effect pulls neighbouring loops together as each attempts to expand; and

A moment around the axis of symmetry of each loop 44 which attempts to return the loops to a parallel arrangement.

In the inner loop arrangement, the root 31 between loops in the next row passes on the inside of the curvature and the loops 44 are therefore not fully constrained in rotation and are able to rotate slightly about their axes. This rotation also allows them to overlap with the loops 44 to either side. As the loops 44 are not restricted from circumferential overlap, the force created by the highly flexed apex of the loops 44 is able to pull the loops 44 together and they partially overlap each other which results in a smaller circumference and, thus results in a smaller diameter.

In the outer arrangement the loops 44 are unable to rotate due to the root 31 of the next row now passing over the loops 44 and following the increased path of the outside of the curvature. This creates an inward force on the loops 44 and they are restricted from rotation and circumferential overlap (at 45 in Figure 7). The moment about their axes further tensions the roots and the side-by-side arrangement now creates a greater circumference and, thus results in a greater diameter.

The loops in the outer loop arrangement are also restricted from longitudinal overlap (at 47 in Figure 7), which increases the longitudinal stiffness and rigidity of the everted length of the inversible tubular member and provides the rigidity required for the everted length to withstand the forces of inversion and ingesting a captured object without crumpling and without the need for alternative support.

Referring now particularly to Figures 1 and 5, in order to use the retrieval device 10 for gripping the object 42, say during a laparoscopic procedure on a person, the hand grip formations 18 and 26 are pushed together until substantially the entire inversible tubular

member 28 is in the everted condition as an extension to the outer tubular member 12. The inversible tubular member 28 and outer tubular member 12 is then at least partially inserted into the body through a standard laparoscopic port. The object 42 is contacted by the transformation end 41 of the inversible tubular member 28. The hand grip formations 18 and 26 are progressively pulled apart so that the inversible tubular member 28 grips the object 42 and draws it into the cavity 40. This is an example of the method of the third aspect of the invention.

In the inversible tubular member 28, the loops 44 on the outside of the everted length 38 point in the distal direction. As the loops 44 approach the transformation end 41 during inversion, they do not project past the outer diameter of the inversible tubular member 28. As they pass the end 41, they project inwardly into the cavity 40 and proximally for a short travel distance. This behavior of the loops 44 enhances grip of the loops 44 on the object 42.

The applicant has found with the prototype of the retrieval device 10 that the inversible tubular member 28 will stretch sufficiently for ingesting a sphere of a diameter of 1.5 times the average relaxed outer diameter of the inverted length 36. Take a case where the inversible tubular member 28 is halfway inverted when the sphere is halfway into the inversible tubular member 28 at the transformation end 41. In this case, the applicant has found that further inversion occurs at the transformation end 41.

Optionally, a membrane 49.1 (shown in broken lines in Figure 4) may be applied over the surface of the inversible tubular member 28 which is an outer surface in the everted condition. Alternatively or additionally, such a membrane 49.2 may be applied over the opposite surface. Such a membrane may, for example, serve to prevent spillage of toxins from tissue removed during a surgical procedure.

As was stated above, the diameter of the inversible tubular member 28 may be variable along its length when it is entirely everted. This may be achieved by varying the sizes of the loops, or the number of loops per row, along the length of the inversible tubular member. Alternatively, if the properties of the filamentary material permit, a variable diameter may be achieved by heating, setting, and cooling of the material.

In Figure 10, a second embodiment of a gripping device in the form of a laparoscopic surgical retrieval device, in accordance with the invention, of which only a part is shown, is designated generally by the reference numeral 50.

The retrieval device 50 is for the most part identical to the retrieval device 10 of Figures 1 to 9 and therefore like features, where shown, will again be designated by the same reference numerals as before and these features will not be described again. Moreover, the retrieval device 50 differs from the retrieval device 10 only in respect of the orientation of its inversible tubular member 28. In this case, the loops 44 on the outside of the everted length 38 of the length of the inversible tubular member 28 point in the proximal direction.

As the loops 44 approach the transformation end 41 during inversion, they project past the outer diameter of the inversible tubular member 28. As they pass the transformation end 41, they do not project inwardly into the cavity 40. This behavior of the loops 44 means that the transformation end 41 can effectively gather material over an area larger than its outer diameter 28. This feature may also aid gripping and drawing in of an object 52 which tends to break apart.

In Figure 11, a third embodiment of a gripping device in the form of a laparoscopic surgical retrieval device, in accordance with the invention, of which only a part is shown, is designated generally by the reference numeral 54.

The retrieval device 54 is for the most part identical to the retrieval device 10 of Figures 1 to 9 and therefore like features, where shown, will again be designated by the same reference numerals as before and these features will not be described again.

With reference to Figures 11 to 13 generally, the retrieval device 54 includes:

a tubular first coupling 56 to which the everted end 30 of the inversible tubular member 28 is peripherally attached; and

a tubular second coupling 58 to which the inverted end 32 of the inversible tubular member 28 is peripherally attached.

By relative axial displacement, the second coupling 58 fits into the first coupling 56 in a snug fit. These couplings define complementary clip-in formations 60 for retaining the coupling 58 in the coupling 56.

The coupling 56 defines an outer screw thread 62 complementary to an inner screw thread 64 defined by the distal end of the outer tubular member 12.

The coupling 58 defines an inner screw thread 66 complementary to an outer screw thread 68 defined by the distal end of the inner tubular member 20.

The extractor device 54 provides the following operation. With the couplings 56 and 58 engaged respectively with the tubular members 12 and 20 by screwing them in, the device 54 is used similarly to the use of the retrieval device 10 as described above to grip an object in a body of, say, a person. The tubular members 12 and 20 are relatively longitudinally displaced until the object is at least partially within the cavity 40 and the clip-in formations 60 are interengaged. The tubular members 12 and 20 are then unscrewed from the respective couplings 56 and 58, which may require the inversible tubular member 28 to be held by means of another surgical instrument.

The inversible tubular member 28 has a diameter which may vary substantially along its length to facilitate operative holding of an object received therein.

In Figure 14, a fourth embodiment of a gripping device in the form of a laparoscopic surgical retrieval device, in accordance with the invention, of which only a part is shown, is designated generally by the reference numeral 70.

The retrieval device 70 is for the most part identical to the retrieval device 10 of Figures 1 to 9 and therefore like features, where shown, will again be designated by the same reference numerals as before and these features will not be described again.

An outer tubular member 12 of the retrieval device 70 is made of a resiliently flexible material, e.g. polypropylene. It includes an end portion 71 defining therein four elongate slits 72 (only two shown), angularly evenly spaced about its central axis. As such, the end portion 71 is split into four fingers 74 (only three shown). Distal ends of the fingers

74 have an everted end of a tubular member 27, which includes an inversible tubular member 28, secured to their outsides. An opposite end of the inversible tubular member 28 is secured to an inner tubular member (see reference numeral 20 in Figure 4).

The inversible tubular member 28 is shown almost entirely in an inverted condition. The fingers 74 are shown resiliently deformed into a flared out or expanded condition and similarly, the inversible tubular member 28 is shown in a radially expanded condition. Such expansion will, in use of the retrieval device 70, be caused by an "oversized" ingested object (not shown) in the inversible tubular member 28.

It will be understood that, in an ex-factory condition of the retrieval device 70, the fingers 74 were more closely spaced and defined a circumference substantially the same as that of the remainder of the tubular member 12.

Other features and operation of the retrieval device 70 are essentially the same as those of the retrieval device 10 of Figures 1 to 9. Expansion of the end portion 71 merely facilitates ingestion of larger objects than would have been the case with the retrieval device 10.

In all of the above examples, the gripping device of the invention was intended for surgical use. It must be appreciated, however, that a similar gripping device may be configured for other uses, for example an industrial use. It may be suitably scaled up or down for a required application. For certain heavier duty applications, the resiliently flexible filamentary material may, for example, be a multifilament material, for example stranded stainless steel wiring or cabling.

It is envisaged that, generally in all practical embodiments of the gripping device of the invention, requirements a), b), and c) below will apply. The numbers in brackets refer to equivalent features of the retrieval device 10 of Figures 1 to 9.

a) With the inversible tubular member (28) at least partially inverted, the inverted length (36) must have sufficient stiffness to cause eversion of the inversible tubular member at the transformation end (41) upon axial displacement of the inverted end (32) towards the transformation end, for a length of the inverted length (L2) up to X times an

average relaxed outer diameter of the inverted length, with X>=2.0. In some possible embodiments, X>=5.0.

b) With the inversible tubular member (28) at least partially everted, the everted length (38) must have sufficient stiffness to cause inversion of the inversible tubular member at the transformation end (41) upon axial displacement of the everted end (30) towards the transformation end, for a length (L1) of the everted length up to Y times an average relaxed outer diameter of the inverted length, with Y>=2.0. In some possible embodiments, Y>=5.0

c) With the inversible tubular member (28) at least partially everted, the everted length (38) must have sufficient stiffness to cause inversion of the inversible tubular member at the transformation end (41) upon axial displacement of the everted end (30) towards the transformation end, for a length (L1) of the everted length up to Z times the average relaxed outer diameter of the inverted length, whilst one half of a sphere of diameter 1.5 times an average relaxed outer diameter of the inverted length is received in the inversible tubular member at the transformation end, with Z>=2.0.

CLAIMS:

1. A gripping device including:

an inversible tubular member which is substantially round in cross-section and progressively transformable between an everted condition and an inverted condition, with a transformation end being defined intermediate an everted length and an inverted length of the inversible tubular member during such transformation and with the inverted length and the everted length defining opposite to the transformation end respectively an inverted end and an everted end of the inversible tubular member, the inversible tubular member being composed of interengaged stitches of resiliently flexible filamentary material; and

actuation means carrying the inversible tubular member and operable for effecting progressive inversion and eversion of the inversible tubular member,

the inversible tubular member defining a transformation end where the progressive inversion and eversion occurs, with such inversion providing for gripping an object in the inversible tubular member.

2. A gripping device as claimed in claim 1, in which:

with the inversible tubular member at least partially inverted, the inverted length has sufficient stiffness to cause eversion of the inversible tubular member at the transformation end upon axial displacement of the inverted end towards the transformation end, for a length of the inverted length up to X times an average relaxed outer diameter of the inverted length;

$X>=2.0$;

with the inversible tubular member at least partially everted, the everted length has sufficient stiffness to cause inversion of the inversible tubular member at the transformation end upon axial displacement of the everted end towards the transformation end, for a length of the everted length up to Y times an average relaxed outer diameter of the inverted length; and

$Y>=2.0$.

3. A gripping device as claimed in any of the preceding claims, in which:

$X>=Y>=5.0$

4. A gripping device as claimed in any of the preceding claims, in which:

with the inversible tubular member at least partially everted, the everted length has sufficient stiffness to cause inversion of the inversible tubular member at the transformation end upon axial displacement of the everted end towards the transformation end, for a length of the everted length up to Z times the average relaxed outer diameter of the inverted length, whilst one half of a sphere of diameter 1.5 times an average relaxed outer diameter of the inverted length is received in the inversible tubular member at the transformation end; and

$Z>=2.0$

5. A gripping device as claimed in any of the preceding claims, which defines in the everted condition a larger outer diameter than in the inverted condition.

6. A gripping device as claimed in claim 5, of which the inner diameter in the everted condition is larger than its outer diameter in the inverted condition.

7. A gripping device as claimed in any of the preceding claims, in which the stitches are knitted stitches of at least one length of the filamentary material.

8. A gripping device as claimed in claim 7, in which the stitches are plaited stitches, each defining a loop.

9. A gripping device as claimed in any of the preceding claims, in which the filamentary material is a monofilament material.

10. A gripping device as claimed in any of the preceding claims, in which the filamentary material is a multifilament material.

11. A gripping device as claimed in any of the preceding claims, in which the filamentary material is a superelastic material.

12. A gripping device as claimed in any of the preceding claims, in which the filamentary material is a shape memory material.

13. A gripping device as claimed in any of the preceding claims, in which the inversible tubular member has a variable diameter along its length.

14. A gripping device as claimed in any of the preceding claims, which includes a membrane over at least a part of a surface of the inversible tubular member which is an outer surface in the everted condition.

15. A gripping device as claimed in any of the preceding claims, which includes a membrane over at least a part of a surface of the inversible tubular member which is an inner surface in the everted condition.

16. A gripping device as claimed in any of the preceding claims, in which the actuation means includes:

an outer tubular member defining a distal end, i.e. a front end, and a proximal end, i.e. a rear end, and a longitudinal passage extending between the distal end and the proximal end, the distal end being peripherally attached to an everted end of the inversible tubular member; and

an inner elongate member received within the passage and defining a distal end and a proximal end, the distal end being peripherally attached to an opposite inverted end of the inversible tubular member,

the outer tubular member and the inner elongate member being slidingly displaceable relative to each other to effect the progressive inversion and eversion.

17. A gripping device as claimed in claim 16, which includes:

a first hand grip formation on the proximal end of the outer tubular member; and

a second hand grip formation on the proximal end of the inner elongate member,

the hand grip formations being manually relatively displaceable for effecting the relative sliding displacement of these members.

18. A gripping device as claimed in any of claims 16 to 17, in which the inversible tubular member is retractable into the outer tubular member.

19. A gripping device as claimed in any of claims 16 to 18, in which the inner elongate member is received within the outer tubular member in a snug sliding fit to provide

sealing between these members to a required pressure, which is not less than 15 mmHg.

20. A gripping device as claimed in any of claims 16 to 18, which includes sealing means sealing between the inner elongate member and the outer tubular member to a required pressure, which is not less than 15 mmHg.

21. A gripping device as claimed in any of claims 16 to 20, in which the inner elongate member defines therethrough a longitudinal passage, permitting insertion of an elongate surgical or other instrument through it.

22. A gripping device as claimed in claim 21, in which the inner elongate member has sealing means sealing the longitudinal passage defined therethrough, the sealing means being configured to permit passage of an elongate surgical or other instrument through it and to seal around the instrument.

23. A gripping device as claimed in any of claims 16 to 22, in which the inversible tubular member is releasable from the outer tubular member and the inner elongate member.

24. A gripping device as claimed in claim 23, which includes:

a first coupling secured to the everted end of the inversible tubular member, the first coupling being releasably engageable with the distal end of the outer tubular member; and

a second coupling secured to an end of an inverted length of the inversible tubular member opposite to the transformation end, the second coupling being releasably engageable with the distal end of the inner tubular member;

25. A gripping device as claimed in claim 24, in which the first and second couplings are interengageable through relative displacement of the outer tubular member and the inner elongate member.

26. A gripping device as claimed in any of claims 16 to 25, in which the outer tubular member includes a distal end portion that is radially expandable for operatively

accommodating therein a length of the inversible tubular member and an object therein where the size of the object requires radial expansion of the end portion.

27. A gripping device as claimed in claim 26, in which the distal end portion defines therein an arrangement of slits which are angularly spaced about the central axis of the tubular member to provide for the expansion.

28. A gripping device as claimed in any of claims 26 to 27, in which the distal end portion is resiliently flexible to provide for the expansion.

29. An inversible tubular member which is substantially round in cross-section and progressively transformable between an everted condition and an inverted condition, with a transformation end being defined intermediate an everted length and an inverted length of the inversible tubular member during such transformation and with the inverted length and the everted length defining opposite to the transformation end respectively an inverted end and an everted end of the inversible tubular member, in which:

the inversible tubular member is composed of interengaged stitches of resiliently flexible filamentary material;

with the inversible tubular member at least partially inverted, the inverted length has sufficient stiffness to cause eversion of the inversible tubular member at the transformation end upon axial displacement of the inverted end towards the transformation end, for a length of the inverted length up to X times an average relaxed outer diameter of the inverted length;

X>=2.0;

with the inversible tubular member at least partially everted, the everted length has sufficient stiffness to cause inversion of the inversible tubular member at the transformation end upon axial displacement of the everted end towards the transformation end, for a length of the everted length up to Y times an average relaxed outer diameter of the inverted length; and

Y>=2.0.

30. An inversible tubular member as claimed in claim 29, in which:

with the inversible tubular member at least partially everted, the everted length has sufficient stiffness to cause inversion of the inversible tubular member at the

transformation end upon axial displacement of the everted end towards the transformation end, for a length of the everted length up to Z times the average relaxed outer diameter of the inverted length, whilst one half of a sphere of diameter 1.5 times an average relaxed outer diameter of the inverted length is received in the inversible tubular member at the transformation end; and

Z>=2.0.

31. An inversible tubular member as claimed in any of claims 29 to 30, which defines in the everted condition a larger outer diameter than in the inverted condition.

32. An inversible tubular member as claimed in claim 31, of which the inner diameter in the everted condition is larger than its outer diameter in the inverted condition.

33. An inversible tubular member as claimed in any of claims 29 to 32, in which the stitches are knitted stitches of at least one length of the filamentary material.

34. An inversible tubular member as claimed in any of claims 29 to 33, in which the stitches are plaited stitches, each defining a loop.

35. An inversible tubular member as claimed in any of claims 29 to 34, in which the filamentary material is a monofilament material.

36. An inversible tubular member as claimed in any of claims 29 to 34, in which the filamentary material is a multifilament material.

37. An inversible tubular member as claimed in any of claims 29 to 36, in which the filamentary material is a superelastic material.

38. An inversible tubular member as claimed in any of claims 29 to 37, in which the filamentary material is a shape memory material.

39. An inversible tubular member as claimed in any of claims 29 to 38, which has a variable diameter along its length in each of the inverted and everted conditions.

40. An inversible tubular member as claimed in claim 39, in which the variable diameter has been achieved by heating, setting, and cooling of the filamentary material.

41. A method of gripping an object, the method including:

providing an inversible tubular member which is substantially round in cross-section and progressively transformable between an everted condition and an inverted condition with a transformation end being defined intermediate an everted length and an inverted length of the inversible tubular member during such transformation, the inversible tubular member being composed of interengaged stitches of resiliently flexible filamentary material;

with at least a part of the length of the inversible tubular member in the everted condition, contacting the transformation end of the said part with the object; and

progressively inverting the said part at the transformation end, thus causing the inversible tubular member to grip the object.

42. A method as claimed in claim 41, in which the inversible tubular member is an inversible tubular member as claimed in any of claims 29 to 40.

43. A method as claimed in any of claims 41 to 42, which includes at least partially drawing the object into the inversible tubular member by the progressive inverting of the inversible tubular member.

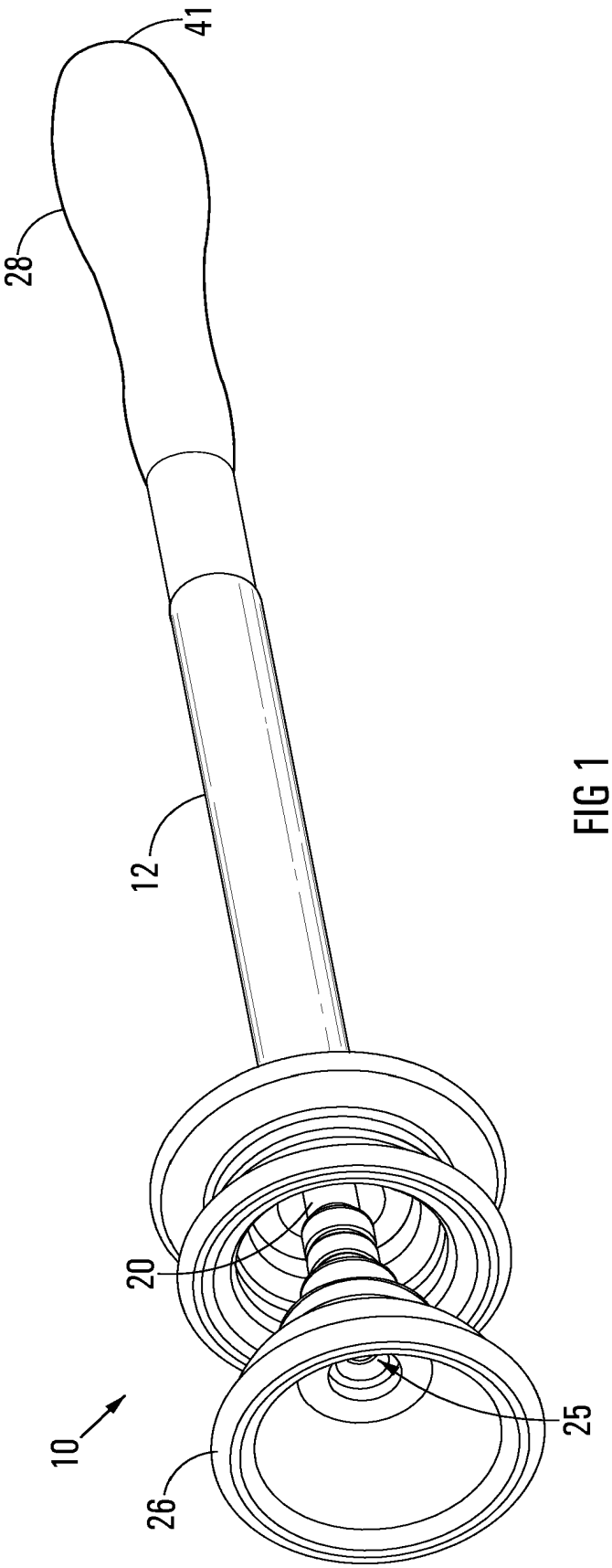


FIG 1

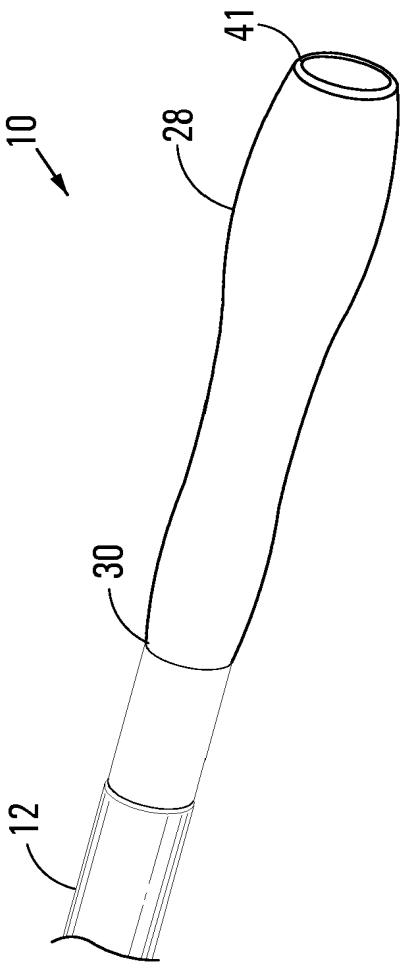
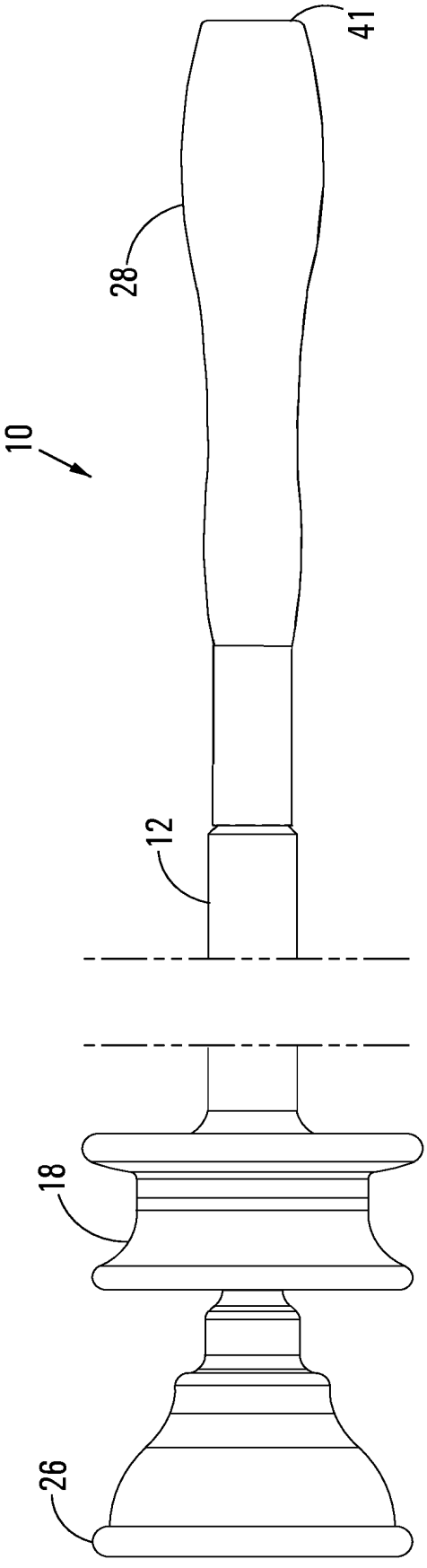


FIG 2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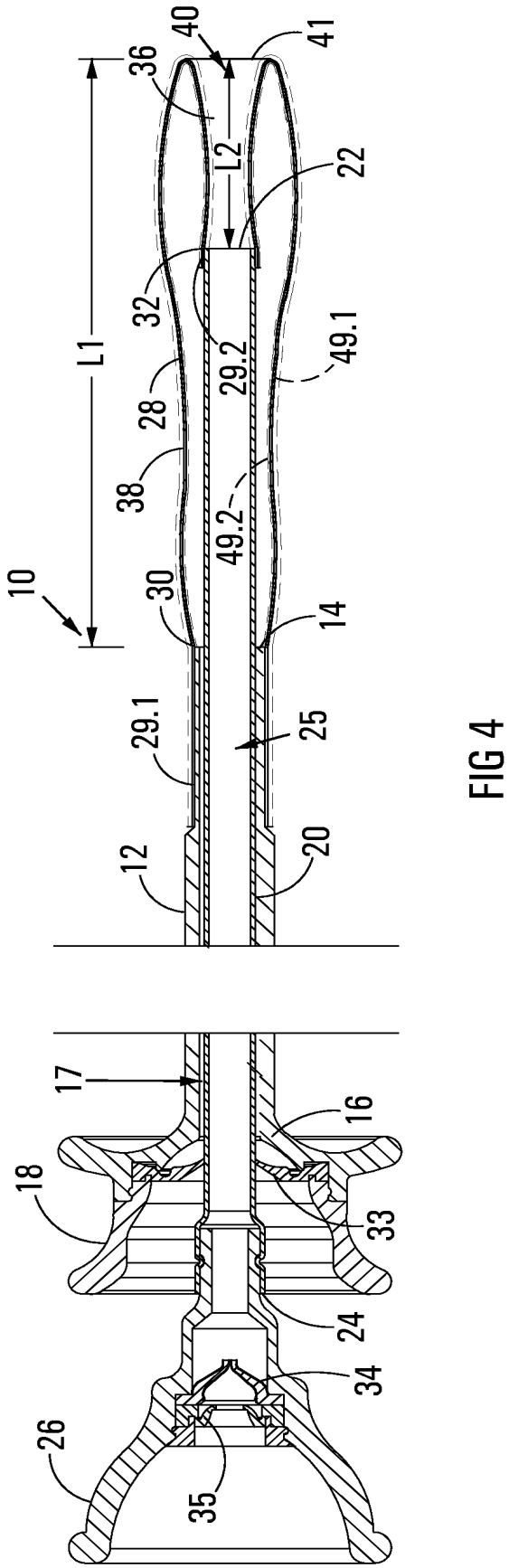
26

FIG 3


10
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L2
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L1
29.2
49.1
28
38
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FIG 4

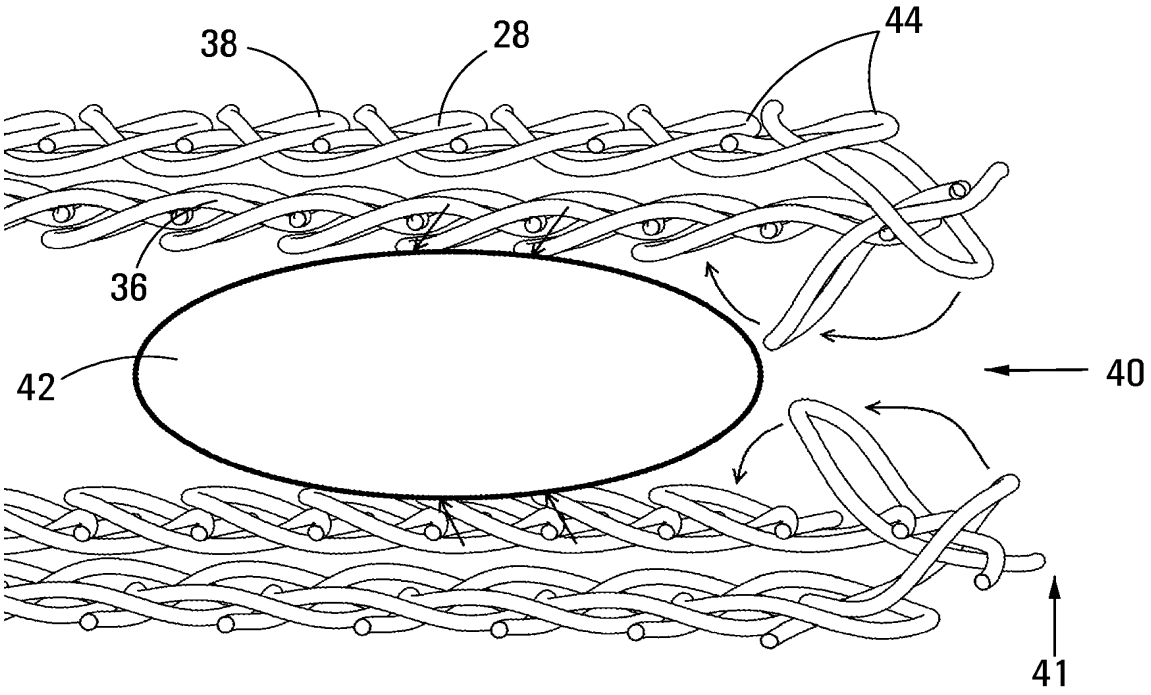

FIG 5

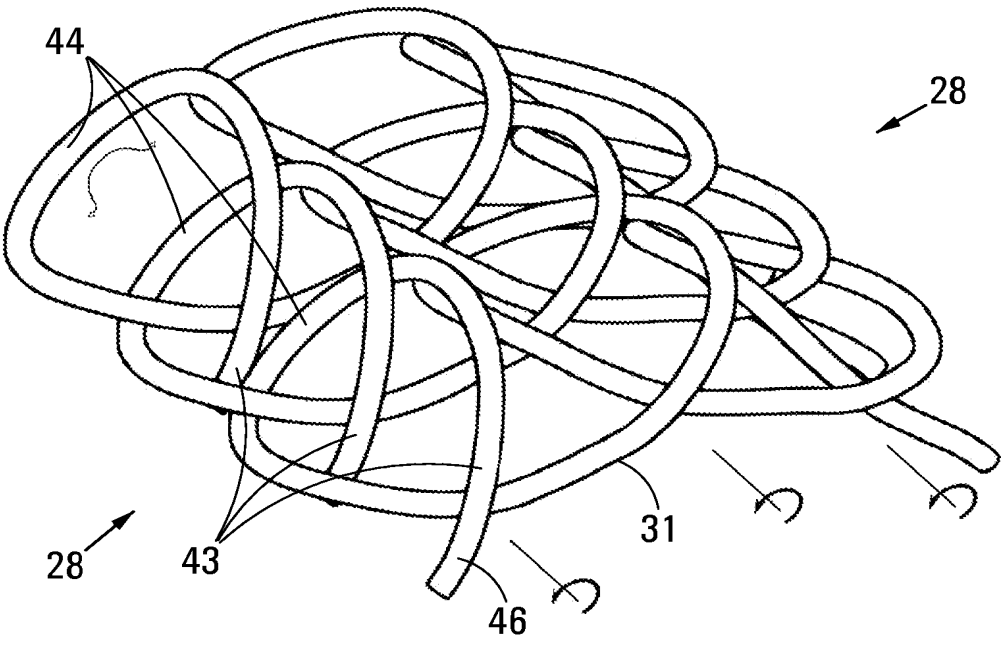

FIG 6

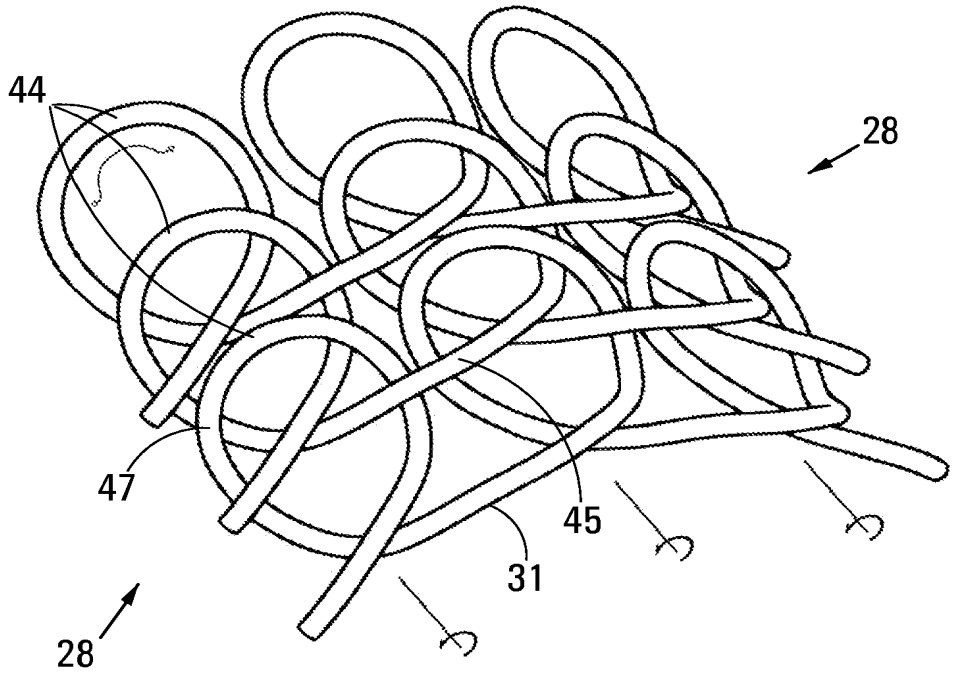

FIG 7

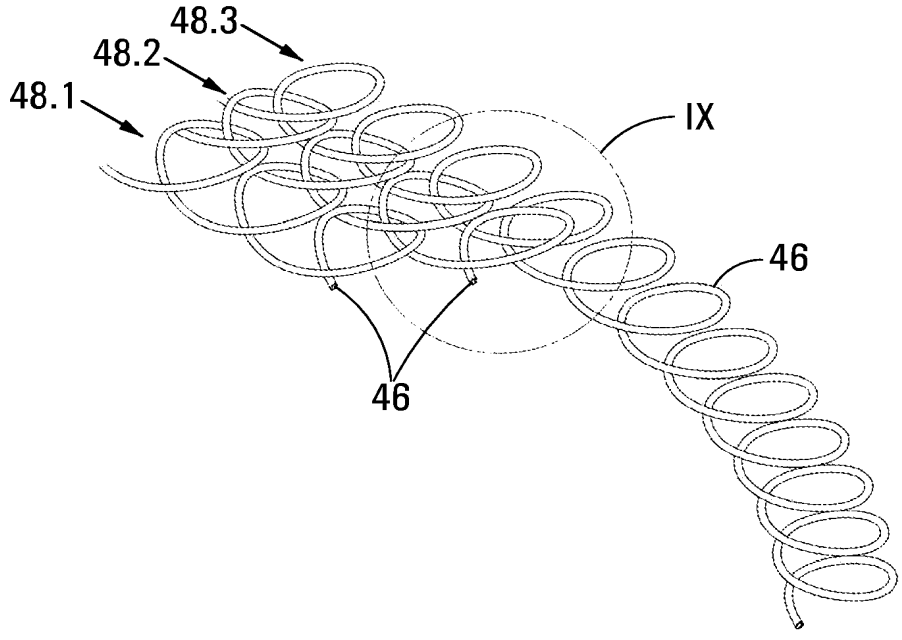

FIG 8

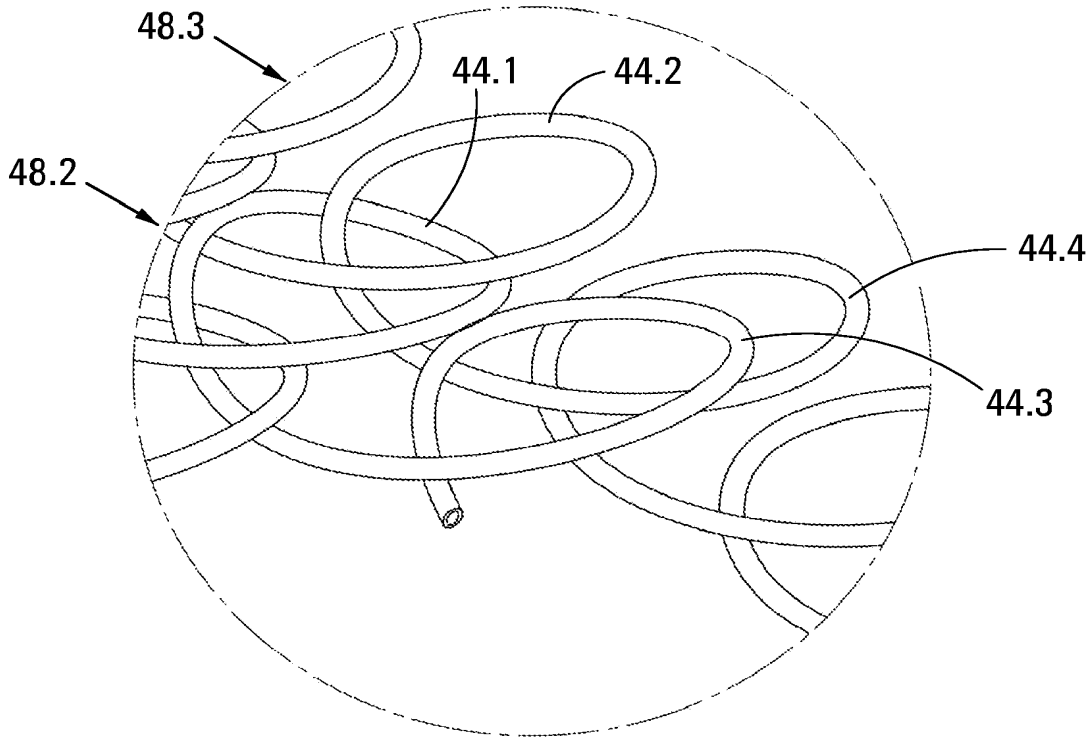

FIG 9

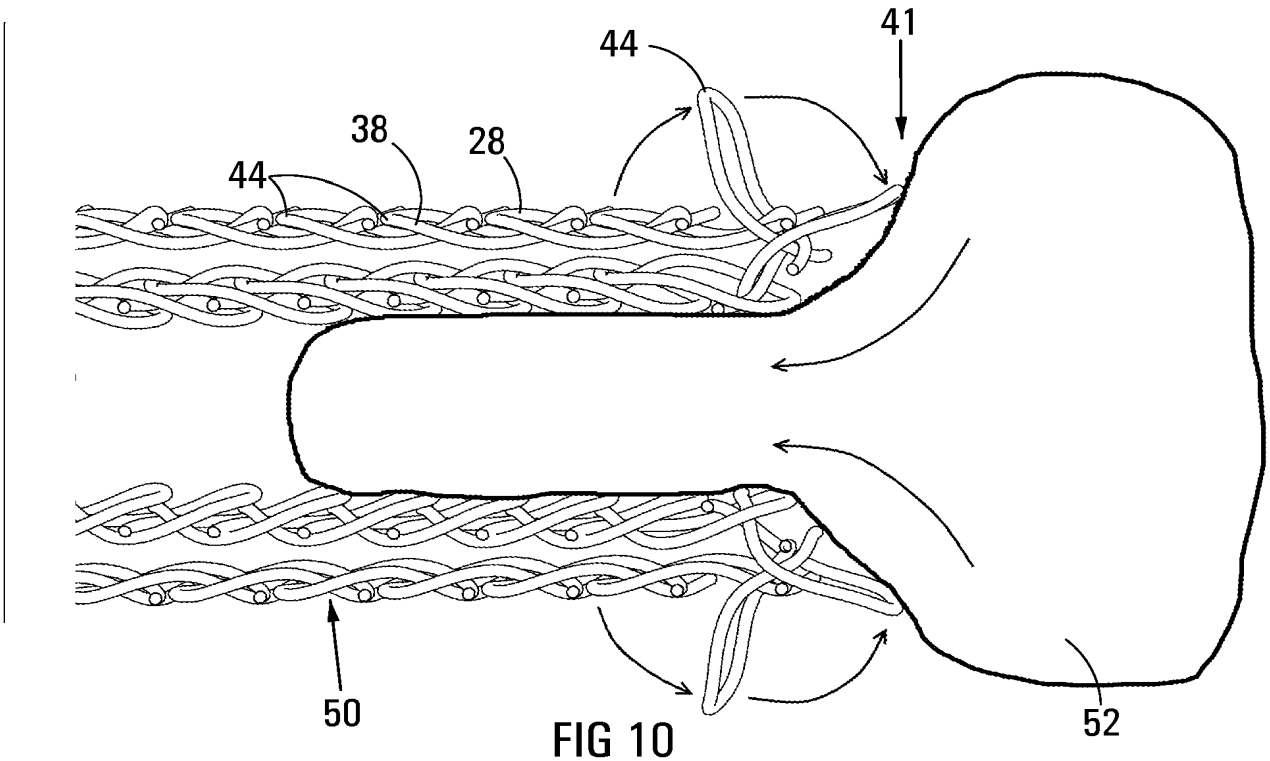

FIG 10

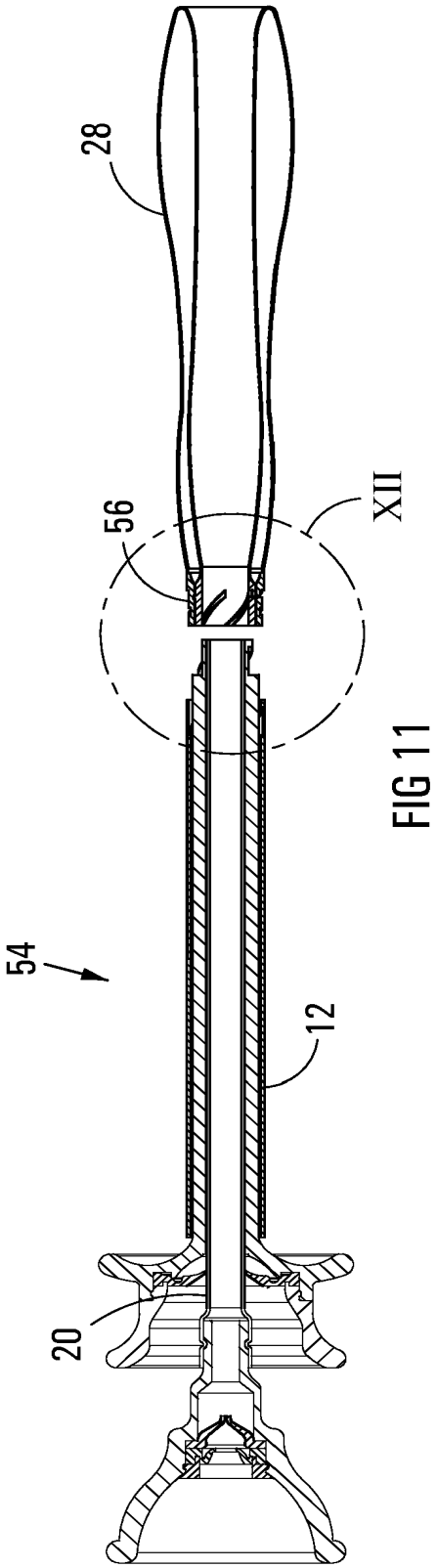

FIG 11

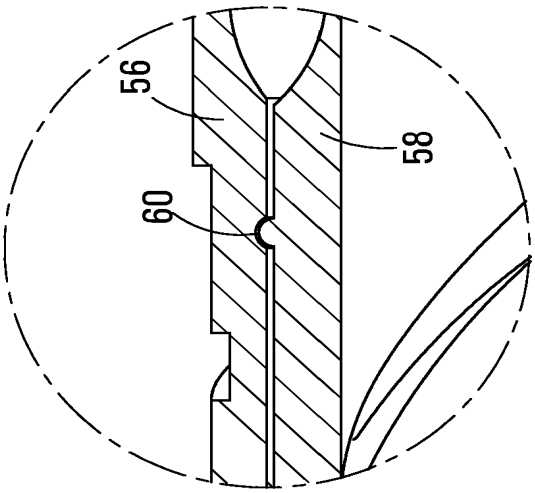

FIG 13

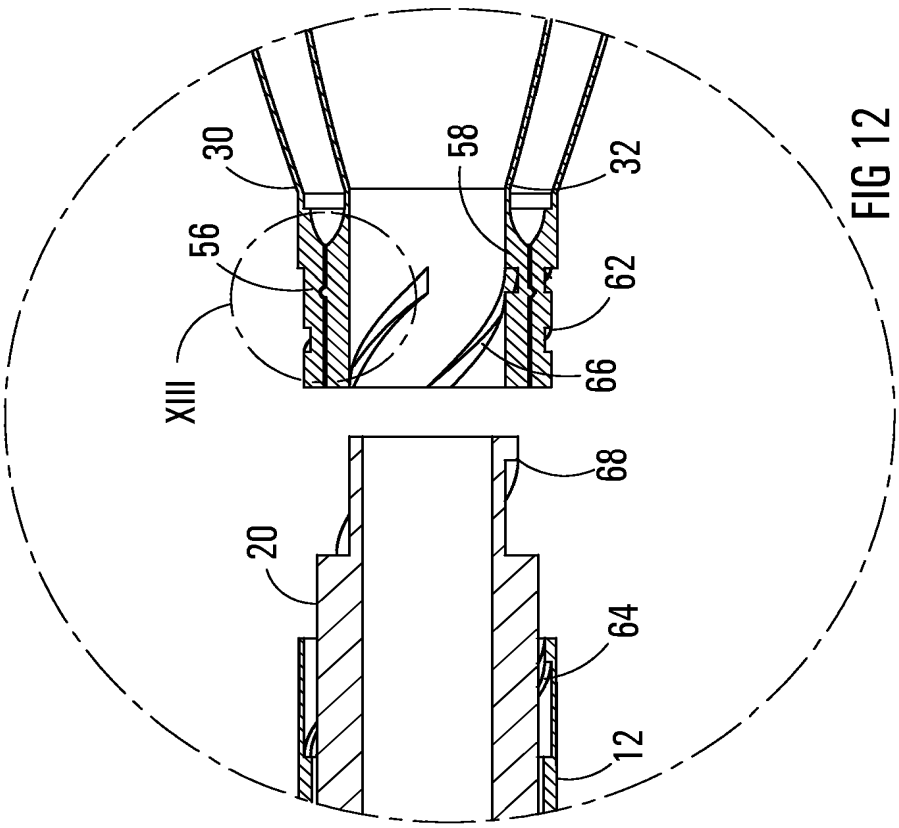

FIG 12

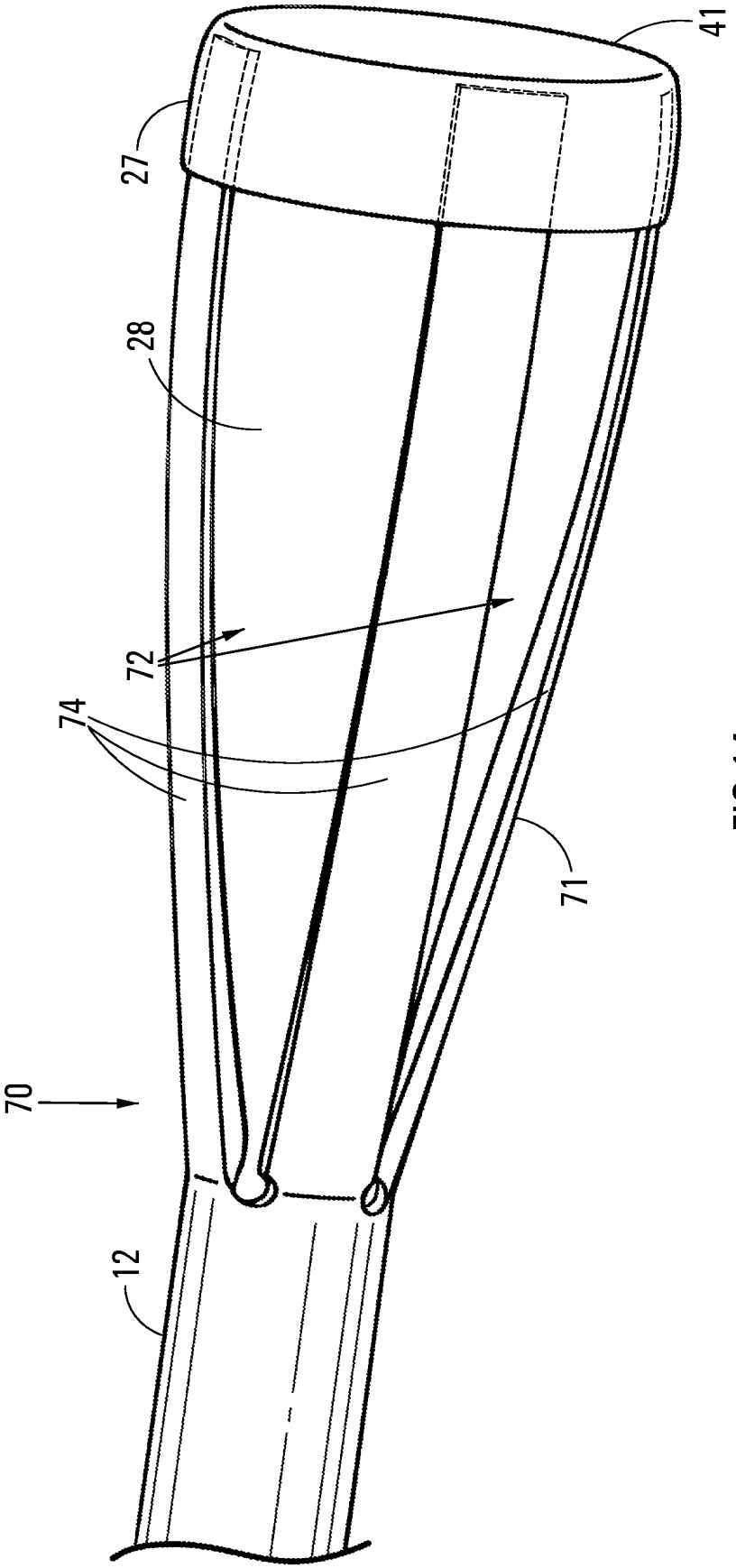

FIG 14

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/054535

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/00 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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 2009/086482 A1 (LAZARUS EFFECT INC [US]; MARTIN BRIAN B [US]; FOLLMER BRETT [US]; AGUI) 9 July 2009 (2009-07-09) figures 13A,13B paragraph [0159] - paragraph [0162] -----	1-13,16, 17,21, 29-39 18
X	US 2010/137846 A1 (DESAI RUPESH [US] ET AL) 3 June 2010 (2010-06-03) figures 1-5 -----	1,7-13, 16,17,21
Y	US 2010/249815 A1 (JANTZEN ALEXANDRA E [US] ET AL) 30 September 2010 (2010-09-30) figures 1-5 -----	18

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 January 2012	20/03/2012

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	Schießl, Werner

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2011/054535

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.: 41-43
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 surgeryRule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [X] Claims Nos.: 40
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [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.:

1-13, 16-18, 21, 29-39

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-13, 16-18, 21, 29-39

   A gripping device providing specific ratios of the inverted / everted length and the average relaxed outer diamter of the inverted length for which the respective length has sufficient stiffness to cause eversion / inversion (see claims 2 to 4 and 29), or in which the inversible tubular member is retractable into the outer tubular member (claim 18). These features allow a more secure and complete gripping of objects having a diameter of about the average relaxed outer diameter of the inverted length.

   ---

2. claims: 14, 15

   A gripping device including a membrane over the inner or outer surface of the inversible tubular member in the the everted condition (claims 14, 15)

   ---

3. claims: 19, 20, 22

   A gripping device providing a sealing between the an outer tubular member and an inner elongate member of the actuation means, or of the longitudinal passage of the inner elongate member (claims 19, 20, 22) to enable use of the device in laparoscopic procedures.

   ---

4. claims: 23-28

   A gripping device wherein the inversible tubular member is releasably engageable with the distal ends of the outer tubular member and the inner elongate member (claims 24), or wherein the dital end portion of the outer tubular member is radially expandable (claim 26). Thereby the device is capable to grip objects substantially larger than the outer diameter of the outer tubular member.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 41-43

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

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Continuation of Box II.2

Claims Nos.: 40

Present claim 40 relates to a product defined by reference to a process of manufacturing it. In the present context this is considered to lead to a lack of clarity because the claim does not clearly identify the structural features encompassed by the manufacturing steps defined. This makes it impossible to compare the claim to the prior art. As a result, the application does not comply with the requirement of clarity under Article 6 PCT.

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 Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2011/054535

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2009086482 A1	09-07-2009	CN 102036611 A	27-04-2011
		EP 2231037 A1	29-09-2010
		JP 2011508635 A	17-03-2011
		US 2009299393 A1	03-12-2009
		WO 2009086482 A1	09-07-2009
US 2010137846 A1	03-06-2010	EP 2355717 A1	17-08-2011
		US 2010137846 A1	03-06-2010
		WO 2010065556 A1	10-06-2010
US 2010249815 A1	30-09-2010	NONE	

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

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

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02 November 2017 (02.11.2017)

WIPO | PCT

(10) International Publication Number
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A61B 17/22 (2006.01) *A61B 17/221* (2006.01)

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25 April 2017 (25.04.2017)

(25) Filing Language: English

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(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

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(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))*
— *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))*

WO 2017/189550 A1

(54) Title: PRE-LOADED INVERTING TRACTOR THROMBECTOMY APPARATUSES AND METHODS

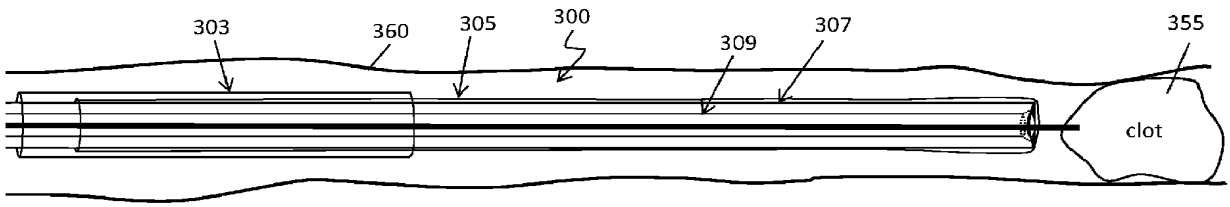

FIG. 3A

(57) Abstract: Mechanical thrombectomy apparatuses including an inverting, rolling conveyor region ("tractor") at the distal end that are configured to grab and remove thrombus material. In particular, described herein are mechanical thrombectomy apparatuses that are 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.

PRE-LOADED INVERTING TRACTOR THROMBECTOMY APPARATUSES AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims priority to U.S. provisional patent application no. 62/327,024, filed on April 25, 2016 and titled "DOZER THROMBECTOMY SYSTEM"; U.S. provisional patent application no. 62/345,152, filed on June 3, 2016, and titled "DOZER THROMBECTOMY SYSTEM 2"; and U.S. provisional patent application no. 62/357,677, 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 and methods described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses and methods.

BACKGROUND

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

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

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

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

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

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

SUMMARY OF THE DISCLOSURE

[00011] Described herein are mechanical thrombectomy apparatuses (devices, methods, systems, etc.) that include a distal inverting tube of highly flexible material, referred to herein as a tractor, that is pulled to continuously invert over a distal opening, such as the distal end of a catheter or annulus, in a rolling manner. This rolling can be used, alone or on conjunction with a vacuum or mechanical thrombus (e.g., "clot") grabber, to grab, capture and remove a clot from a vessel. As mentioned, the tractor may be formed of a material having many openings and may therefore be flexible, and loose, and may be biased so as to flare open within the vessel when deployed. Prior to positioning the apparatus for grabbing the clot, it may be particularly desirable to prevent the tractor from deploying (e.g., sliding axially axially, expanding, etc.) so as to allow accurate tracking within the body as well as to ensure reliable operation of the device. Thus, it may be helpful to pin or hold the tractor, and particularly the end of the tractor that has not been inverted (e.g., within a catheter and/or within the tractor itself) prior to deployment. However, holding or and/or retaining the tractor prior to deployment must be properly balanced. If too much force is required to deploy the tractor, the force may cause the apparatus to kink, collapse, and/or jam. If the tractor can be deployed with too little force may deploy prematurely. Further, since the apparatus is likely to be used in highly tortious vessels of the body, including arteries such as the internal carotid artery, it must be retained in a manner that does not inhibit overall flexibility of the device, or trigger premature release when navigating through the vessels.

[00012] In general, an inverting tractor apparatus may include a tractor (e.g., tractor region, tractor portion, etc.) comprising a flexible tube of material that inverts as it rolls over itself at a distal end. The inverting/rolling portion may be performed over an annulus that may be separately maneuvered relative to the tractor; the annual may be part of a catheter (e.g., the distal end of a catheter) or may be attached to a wire or other element having sufficient column strength to prevent the annulus (distal opening) over which the tractor is inverting from being collapsed or pulled proximally as the tractor is rolled.

[00013] In operation, the tractor inverts and may roll back into itself. When an outer catheter is used, the tractor may be drawn into the catheter. The annulus about which the tractor inverts at the distal end region of the apparatus is supported by a structure (e.g., rod, hypotube, catheter) that typically is more rigid (has a much larger column strength) than the tractor. Thus, as the tractor rolls, it produces a conveyor-like motion as a formerly outward-facing tractor region rolls around to become an inward-facing region within the lumen of the tractor and/or within the lumen of the catheter. This conveyor or rolling motion may draw a clot (or other object) from a vessel into the catheter.

[00014] The mechanical thrombectomy apparatuses described herein include pre-loaded inverting tractor thrombectomy apparatuses (e.g., devices, systems, etc.). These apparatuses may be configured to prevent premature release of the tractor. Any of these apparatuses may include, for example, a tractor hold that prevents the end of the tractor that is "outside" of the inner lumen from sliding axially and inverting until deployment. The tractor hold may include a housing, and particularly a housing extends only a slight distance proximally (therefor preventing increasing the stiffness of the apparatus or otherwise inhibiting maneuverability/tracking). The tractor hold may include hydrophobic and/or hydrophilic surfaces, e.g., coatings, on the outside end region of the tractor and/or the outer portion of a catheter over which the tractor rolls; these hydrophobic/hydrophilic surfaces may be arranged in a pattern. Any of the tractor holds described herein may include a releasable attachment, such as an adhesive, a mechanical attachment such as a clamp or interference region or the like. Any of the tractor holds may include a pair of engaging portions, such as a stop or hold (e.g., a tractor hold or stop element on the catheter) and a lock (e.g., a tractor lock, such as a ring on the end region of the tractor).

[00015] As mentioned, any of these apparatuses may include an inverting annuls that may be part of an elongate member having sufficient column strength to resist collapsing or deflecting when the tractor is pulled proximally through the annuls to roll over and invert. The annulus may be the distal end of a catheter, or a portion of a catheter, or it may be a ring or cylindrical region to which an elongate support (e.g., wire, rod, hypotube, or any combination of these, including concentric or sequential arrangements). The annulus is typically a ring-shaped opening (the opening of which may be any shape, including but not limited to round, oval, triangular, square, rectangular, etc.), over which the tractor is inverted, and this annulus is typically connected to an elongate supporting member. The annulus may be integral with the elongate supporting member. The annulus and elongate support member may together be referred to as an elongate inversion support. As mentioned this elongate

inversion support may generically be referred to herein as a catheter, which may include a tube, rod, hypotube, wire, shaft, etc. having an annuls or distal end opening over which the tractor is inverted so that the tractor rolls over the distal end opening (annulus) when an end of the tractor that is more radially positioned in the apparatus is pulled proximally. Also described herein are a variety of elongate inversion supports (e.g., catheters), as the shape (e.g., outer diameter) of the inverting support may affect the retention of the tractor prior to deployment.

[00016] For example, described herein are mechanical thrombectomy apparatuses for removing a clot from a vessel that include: an elongate inversion support (e.g., a catheter) having a proximal end and a distal end and a distal annulus (e.g., distal end opening); a tractor comprising a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter; a puller coupled to first end of the tractor, wherein the puller extends within the catheter to the proximal end of the catheter; and a tractor hold attached to an outer diameter of the catheter proximal to the distal end of the catheter, wherein the tractor hold secures a second end of the tractor that extends over the distal end of the catheter until a force greater than a threshold force is applied by pulling the first of the tractor proximally within the catheter. Any of these apparatuses may include a guidewire lumen extending through the catheter, the puller and the tractor, and configured to pass a guidewire.

[00017] In any of these variations, the tractor hold may be a housing. The housing may be a cylinder that is pinned or closed on one (e.g., the proximal) end, leaving an annular opening for the outermost end of the tractor.

[00018] The tractor hold may not extend to the proximal end of the catheter. For example, the tractor hold may extend proximally along the catheter for less than 10 cm (e.g. for less than 9 cm less than 8 cm, less than 7 cm, less than 6 cm, less than 5 cm, etc.).

[00019] In any of these variations, 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 50 g force and 2000 g force (e.g., between 50 g of force and 1700 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).

[00020] 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.

[00021] 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.

[00022] In any of these variations, the catheter (elongate inversion support) may include comprises a larger outer diameter region and a smaller outer diameter region that is proximal to the larger outer diameter region; the annulus (distal end opening) may be at the distal end of the elongate inversion support. The the tractor hold may secure the tractor at one or more of: over the smaller outer diameter region, and between the larger outer diameter region and the smaller outer diameter region. The outer diameter of the tractor hold may be flush with the larger outer diameter region. The tractor hold may reside in a narrowing (necked) region of the catheter to avoid forming a larger-diameter region. Any of these elongate inversion supports (e.g., catheters) having regions of different diameter may have a gradual (angled) or rapid (e.g., stepped) transition between the larger outer diameter and the smaller outer diameter.

[00023] The tractor hold may comprise one or more of: a polyether block amide, a polyolefin, a polyethylene, a polypropylene, a polyethylene terephthalate (PET), and a Polytetrafluoroethylene (PTFE).

[00024] The apparatus may include a tractor lock on the second end of the tractor, wherein the tractor lock engages with the tractor hold to secure the tractor lock on a proximal side of the tractor hold until the threshold force is applied by pulling the first of the tractor proximally within the catheter. For example, the tractor lock may be a ring affixed to the end region of the tractor. The tractor lock may be a band configured to slide over the outer diameter of the catheter. The tractor hold may be a projection extending from the outer diameter of the catheter. Either or both the tractor lock and tractor hold may be elastic (e.g., compliant, rubbery, etc.) so that pulling above the threshold deployment force may cause the tractor tractor lock to release from the tractor hold.

[00025] For example, described herein are mechanical thrombectomy apparatuses for removing a clot from a vessel, the apparatus comprising: a catheter having a proximal end and a distal end and a distal end opening, wherein the catheter comprises a larger outer diameter region and a smaller outer diameter region that is proximal to the larger outer diameter region; a tractor comprising a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter; a puller coupled to first end of the tractor, wherein the puller extends within the catheter to the proximal end of the catheter; and a tractor hold on an outer diameter of the catheter proximal to the distal end of the catheter, wherein the tractor hold secures a second end of the tractor that extends over the distal end of the catheter until a force greater than a threshold force is applied by pulling the first of the tractor proximally within the catheter, further wherein the tractor hold secures the tractor at one or more of: over the smaller outer diameter region, and between the larger outer diameter region and the smaller outer diameter region.

[00026] Also described herein are methods of removing a clot using a mechanical thrombectomy apparatus. These methods may include: positioning a distal end of the mechanical thrombectomy apparatus adjacent to a clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter; disengaging a second end of the tractor from a tractor hold that secures the second end of the tractor to an outer diameter of the catheter by applying a first force that is greater than a threshold force (threshold deployment force) to the first end of the tractor; pulling the distal 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 drawing the clot into the catheter with the inverting tractor.

[00027] Disengaging the second end of the tractor from the tractor hold may include disengaging the second end of the tractor from a tractor hold that is attached to an outer diameter of the catheter. For example, disengaging the second end of the tractor from the tractor hold may comprise disengaging the second end of the tractor from a tractor hold that extends proximally along the catheter for less than 10 cm.

[00028] Disengaging the second end of the tractor from the tractor hold may include disengaging the second end of the tractor from a tractor hold that is open at a distal-facing end; a proximal end of the tractor hold may be attached to the outer diameter of the catheter. Disengaging the second end of the tractor from the tractor hold may include disengaging the second end of the tractor from a tractor hold that secures the second end of the tractor over a smaller outer diameter region of the catheter that is distal to a larger outer diameter region of the catheter.

[00029] Disengaging the second end of the tractor from the tractor hold may comprise disengaging the second end of the tractor from a tractor hold that secures the second end of the tractor between a larger outer diameter region of the catheter and a larger outer diameter region of the catheter, wherein the larger diameter outer region is distal to the smaller outer diameter region. Disengaging the second end of the tractor from the tractor hold may comprise disengaging a tractor hold from a tractor lock, wherein the tractor lock is on the second end of the tractor. Disengaging the second end of the tractor from the tractor hold may include compressing either or both the tractor hold and a tractor lock on the second end of the tractor so that the tractor lock moves from a position proximal to the tractor hold to a position that is distal to the tractor hold.

[00030] As mentioned, the deployment threshold may be between 0.5 N and 50 N. For example, disengaging the second end of the tractor from the tractor hold may comprise pulling the first end of the tractor with the first force wherein the threshold force is between 1 N and 20 N.

[00031] In any of the apparatuses described herein the puller to which the tractor is coupled may be configured to extend from the distal end of the apparatus further than the tractor. In any of these apparatuses, the puller may be a tube (inner catheter, hypotube, etc.), and may be inserted into the clot, or may be used to draw a vacuum, apply an agent (e.g., anticoagulant, etc.) or the like. For example, described herein are mechanical thrombectomy apparatuses for removing a clot from a vessel that include: a catheter having a proximal end

and a distal end and a distal end opening; a tractor comprising a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter; a puller having a proximal end and a distal end, wherein the first end of the tractor is coupled to the puller at a region that is proximal to the distal end, further wherein the puller extends within the catheter to the proximal end of the catheter. Any of these apparatuses may include a guidewire lumen extending through the catheter, the puller and the tractor, and configured to pass a guidewire.

[00032] For example, the apparatus may further include a stop between the distal end of the puller and the distal end opening. For example, the apparatus may include a stop on the puller between the distal end of the puller and the first end of the tractor, wherein first end of the tractor is coupled to a sliding ring configured to slide over the puller until it engages the stop. Any of these apparatuses may include a 2 mm or greater distance between the distal end of the puller and the region of the puller to which the first end of the tractor is coupled.

[00033] As mentioned, the proximal end of the puller may be configured to couple to a vacuum source. For example, the proximal end of the puller may include a valve, e.g., a Tuohy-Borst valve/rotating hemostasis valve (RHV).

BRIEF DESCRIPTION OF THE DRAWINGS

[00034] 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:

[00035] FIGS. 1A-1H illustrate an example of an apparatus for mechanically removing an object such as a clot form a body region. FIG. 1A shows an example of an elongate inversion support portion of an apparatus, configured as a catheter portion. For example, at least the distal end of the elongate inversion support may be configured as a catheter. FIG. 1B shows an enlarged view of a distal end (opening) of the catheter of the elongate inversion support of FIG. 1A, showing the aperture formed by the distal end opening; FIG. 1C shows an example of a distal tractor region of a flexible tube (tractor tube) extending from a puller (the puller in this example is configured as a catheter. The tractor is shown in a first (e.g., un-inverted) configuration) and may be biased open, e.g., by heat setting, to have an outer

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

[00036] 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).

[00037] FIGS. 2A-2C illustrate a mechanical thrombectomy apparatus deploying prematurely within a vessel.

[00038] FIGS. 3A-3C illustrate a method of operating a mechanical thrombectomy apparatus that includes a tractor hold to prevent premature deployment.

[00039] FIGS. 4A-4C illustrate examples of mechanical thrombectomy apparatuses including a tractor hold that secures the tractor to the outer diameter of the catheter until release.

[00040] FIGS. 5A-5C illustrate examples of mechanical thrombectomy apparatus including a tractor hold as described herein.

[00041] FIG. 6A illustrates a catheter for a mechanical thrombectomy apparatus with an outer diameter that steps up from a first proximal outer diameter to a second, larger distal

outer diameter. FIGS. 6B-6D illustrate the catheter of FIG. 6A as part of different mechanical thrombectomy apparatuses having tractor holds that secure the tractor to the catheter.

[00042] FIG. 7A-7L illustrate examples of different elongate inversion supports for mechanical thrombectomy apparatuses. FIGS. 7A-7B illustrate a catheter portion of an elongate inversion support having both different diameters (e.g., a larger-diameter distal catheter connected to a smaller-diameter proximal region extending longitudinally in the proximal-to-distal axis), and a plurality of openings (e.g., cut-out regions, holes, etc.). FIGS. 7C-7D illustrate a catheter of an elongate inversion support having a plurality of opening formed therethrough. FIGS. 7E-7F illustrate another variation of a catheter of an elongate inversion support having a distal catheter region and an elongate support member formed by skive cutting the catheter. FIGS. 7G-7H illustrate another variation of an elongate inversion support having a distal catheter region and an elongate support member extending from the catheter region. FIGS. 7I-7J illustrate another variation of an elongate inversion support having a plurality or openings along the distal-to-proximal length. FIGS. 7K-7L illustrate another variation of an elongate inversion support having a minimal catheter region at the distal end forming a distal end opening that is connected to an elongate support (e.g., wire, tube, bar, rod, etc.).

[00043] FIGS. 8A-8D illustrate another example of an elongate inversion support that may be used as part of a mechanical thrombectomy apparatus. FIG. 8A shows the elongate inversion support. FIG. 8B shows a variation of the elongate inversion support of FIG. 8A including guide rings for the puller and tractor. FIG. 8C shows the elongate inversion support of FIG. 8B with the tractor and puller attached. FIG. 8D shows a mechanical thrombectomy apparatuses including that shown in FIG. 8C with an additional outer catheter.

[00044] FIGS. 9A-9C illustrate mechanical thrombectomy apparatuses, including apparatuses having pullers that may extend distally of the catheter (FIGS. 9B and 9C).

[00045] FIGS. 10A-10C illustrate an example of a mechanical thrombectomy apparatuses having a tractor hold configured to engage a tractor lock on the tractor.

[00046] FIG. 11A illustrates a method for removing clot using an intermediate catheter (e.g., sleeve) and a vacuum, in which a mechanical thrombectomy apparatus is extended from a distal end of the intermediate catheter to remove a clot.

[00047] FIG. 11B illustrates a method for removing clot using an intermediate catheter (e.g., sleeve) and a vacuum, in which a mechanical thrombectomy apparatus removes a clot that has been drawn into the distal end of the intermediate catheter.

[00048] FIGS. 12A-12C illustrates an example of the operation of a mechanical thrombectomy apparatus with an expandable distal end region (e.g., expandable distal end opening in the elongate inversion support.

DETAILED DESCRIPTION

[00049] In general, described herein are mechanical thrombectomy apparatuses having 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.

[00050] 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.

[00051] 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.

[00052] 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.

[00053] For example, FIG. 1A shows one variation of a catheter of an elongate inversion support that may form part of the apparatuses described herein. In this example, the elongate inversion support includes a catheter 100 having a distal end region 103 that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing harness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00054] 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.

[00055] 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).

[00056] 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).

[00057] 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.

[00058] 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.

[00059] 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.

[00060] 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.

[00061] 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.

[00062] 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.

[00063] An example of premature deployment is shown in FIGS. 2A-2C. For example, in FIG. 2A, the tractor 200 is guided over a guidewire 205 to a clot 255 (alternatively, the apparatus may be delivered without using a guidewire). In this example, the apparatus includes a tractor 203 that extends over and into a catheter 210. The inner end of the tractor is connected to a puller 207 (shown in this example as an inner catheter). The outer end 211 of the catheter is loose and is shown slightly expanded over the catheter outer diameter. As the apparatus is advanced distally towards the clot, shown in FIG. 2B, the tractor is, by virtue of being deployed, driven into the catheter prematurely, shortening the length of the tractor that is outside of the catheter and available to roll for capture of the clot. Further, the loose outer end of the tractor may interfere with accurate positioning of the apparatus. FIG. 2C illustrates the premature deployment compromising the rolling of the tractor 315. Once the tractor is prematurely deployed, moving it back and forth in the vessel to position it may result in the tractor, which may contact the vessel wall when deployed, folding or tangling, as shown in FIG. 2C.

[00064] In general, the apparatuses described herein are configured to prevent premature movement of the tractor on an outside, e.g., outer diameter, of the catheter during catheter access to a target location.

[00065] Any of the variations described herein may include a tractor hold that includes a sticky, tacky, gummy, or adhesive material on the tractor or between the tractor and the catheter over a portion of the tractor that is held against the outer diameter of the catheter. For example, as illustrated in FIGS. 4A-4C, the apparatus may include a sticky substance, like silicone, impregnated on the end of the tractor that is wrapped over the catheter (e.g., the outer end of the tractor, which may be referred to as the proximal-most most end of tractor). The sticky material may impregnated over a small portion of the tractor (e.g., local regions at

or near the proximal end and/or discrete regions, or patterns including spots, bands, etc. along the length of the outer portion of the tractor. The presence of the sticky regions may prevent premature slipping of the tractor (e.g., braid, woven, etc.) with respect to the catheter. For example, a silicone impregnated braid may sit on or over a section of the catheter that is not coated with a hydrophilic coating before the tractor is pulled around distal end opening of the catheter, which may help prevent the tractor from prematurely slipping off or over the catheter. As mentioned, a sticky (e.g., tacky, adhesive, gummy, etc.) region may be present on the entire tractor, on just an inside surface of the tractor (e.g., the surface that faces the catheter when applied over the outer diameter of the catheter), on both inner and outer surface of the tractor, and/or in discrete locations (including patterns) of the portion of the tractor outside of the catheter. For example, the apparatus may include a plurality of regions of sticky material arranged over the length of the proximal end of the tractor. In some variations the sticky material is arranged in a pattern. The material applied may be referred to as sticky with respect to the catheter (e.g., causing temporary and/or releasable attachment between the catheter and the tractor). In some variations, the sticky material may be coated or applied to the outer diameter of the catheter. When arranged in a pattern (e.g., on the tractor and/or OD of the catheter), the pattem of sticky material locations on the tractor (and/or catheter) may be arranged in multiple, non-contiguous locations along the length or the tractor. Pattems may include stripes, spirals, rings, spots, etc.

[00066] Alternatively or additionally, the tractor may be temporarily secured to the outside of the catheter through other methods to provide a temporary attachment of the tractor to the catheter outer diameter (OD). For example, a temporary attachment may be presented between the tractor and the catheter OD such that, when axial tension if applied to the tractor, e.g., by the user pulling the tractor to pull the tractor around catheter tip, the temporary attachment (e.g., a temporary bond, temporary securement, etc.) between the tractor and the catheter OD may be released, allowing the braid to slide relative to the catheter. Alternatively or in addition to the use of a sticky material between the tractor and the catheter, temporary attachments between the tractor and the OD of catheter may include: hydrophilic coatings on the tractor and/or catheter, and/or spot (including micro-spot) boding between the catheter and the tractor.

[00067] For example a hydrophilic surface on the tractor (e.g., inner face of the tractor) and/or catheter OD may be applied as a coating. The tractor may be pre-assembled onto the catheter and a hydrophilic/hydrophobic surface may provide a temporary attachment between the catheter and the tractor. A layer of hydrophilic coating (or two adjacent layers) may

secure the tractor to the catheter OD, and may help the apparatus track through a body vessel/lumen to the target location, after which the tractor may be deployed by pulling to separate the surfaces of the tractor and catheter OD, and to allow the tractor to roll over the distal end opening freely so that it may engage with a clot and draw it into the apparatus. In some variations, a hydrophilic coating may be separately applied to the tractor and/or the catheter. For example, the catheter OD and tractor may be separately coated with a hydrophilic coating and then assembled. When the apparatus is assembled (e.g., with the tractor over catheter distal end region, inverted and within the catheter), the coating on both subassemblies (e.g., tractor and catheter) may cold flow together. When the assembly is wetted in the body during catheter access and when approaching the target clot to be removed, the user may pull the tractor proximally (by pulling on the puller attached to the inner end of the tractor) which may slide the tractor with respect to the catheter OD, disengaging the tractor hold.

[00068] Alternatively the tractor hold can be formed by spot- or selectively bonding the tractor to the catheter OD. A spot or micro-bond may be adequate to prevent premature sliding of the tractor relative to the catheter OD during catheter access. For example, a spot bond or a plurality of micro-bonds can be created, e.g., by heat bonding (melting) or applying adhesive to attach the tractor to the catheter OD. The micro bonds can be placed circumferentially at several locations along the length of the braid, continuously along the braid/catheter contact length or in any other pattern, as discussed above.

[00069] FIG. 4A illustrates an example of a thermoplastic polyurethane (TPU) 404 that may be used to temporarily secure the tractor 406 to the outer diameter of the catheter; once in position, the distal end of the catheter (internal to the catheter) may be pulled proximally to break the material (in this example, pellathane) and release the tractor so that it may be rolled distally over the catheter to draw a clot into the catheter. In this example, the frangible (e.g., breakable) material is coated over a region on the catheter and/or tractor (shown here as a braided tractor) that does not include a hydrophilic coating). For example, the frangible material may be applied over a region that is masked (uncoated) from hydrophilic coating.

[00070] In FIGS. 4B and 4C, examples of mechanical thrombectomy apparatuses 400, 400' are shown, each having an outer catheter 409, and a tractor that extends over the distal end region of the catheter, and inverts over the distal end opening (annulus 411) of the catheter, and into the catheter where it connects to a puller 407. In FIG. 4B, the tractor is releasably adhered to the outer diameter of the catheter by a sticky (e.g., hydrophilic) region 414 that engages the outer end of the tractor to a region on the outer diameter of the catheter.

Thus, in order to pull the tractor proximally within the catheter and therefore roll the tractor over and into the distal end opening as described above (and shown, e.g., in FIG. 3C), an initial deployment force threshold (e.g., between 0.5 N and 50 N) may be required. Once the force is applied and the tractor is deployed to axially move distally over the outer surface, roll, invert and into the catheter, the force required to continue rolling may be substantially (e.g., the deployment force threshold may be 1.1x, 1.2x, 1.5x, 1.7x, 2x, 3x, 4x, 5x, 10x, or more the force required to roll the apparatus).

[00071] Similarly, in FIG. 4C, the apparatus may include a plurality of spot attachments 424 at the outer end of the tractor. As mentioned, there spots may be an adhesive attached into (e.g., into the mesh, etc.) of the tractor, or between the tractor and the outer diameter of the catheter. In both FIGS. 4B and 4C, the tractor may be held slightly in tension over the distal end region of the catheter, preventing the tractor from deploying and expanding, including expanding at the distal tip region (forming the trumpet-shaped opening such as shown in FIGS. 2A-2B).

[00072] Alternatively or additionally, any of the apparatuses described herein may include a tractor hold that is configured as a housing or garage for holding the outer end of the tractor, as shown in FIGS. 3A-3C and FIGS. 5A-5C. In these examples the tractor hold extends only partially down the catheter, which may prevent the hold from increasing the flexibility and maneuverability of the apparatus in the lumen. FIGS. 3A-3C illustrate the method of use of a variation of a mechanical thrombectomy apparatus 300 including a tractor hold 303. In this example, the tractor hold is positioned over the catheter, as shown in FIG. 3A, and holds the outer end of the tractor 305 against the outer diameter of the catheter 307. The tractor is connected to the puller 309. The tractor hold may be attached to the catheter (e.g., at a proximal end of the hold) or it may be applied over the catheter (e.g., shrink-wrapped over the catheter and the outer end of the tractor. The apparatus 300 may be guided over a guidewire 319, as shown, or it may be directed to the clot 355 within the vessel 360 without the use of a guidewire.

[00073] Once the distal end of the apparatus is near the clot, as shown in FIG. 3A, a force greater than a deployment threshold force (e.g., the force required to pull the tractor out of the tractor hold 303, leaving the tractor hold behind, and allowing the tractor to roll 382 over the distal end opening of the catheter, as illustrated in FIG. 3C. The apparatus may be advanced distally while pulling the inner end of the tractor proximally with the puller to invert and roll the tractor into the catheter. The tractor may then grab a clot and pull it into the catheter, as shown.

[00074] Similarly, in FIGS. 5A-5C, the apparatus 500 includes a tractor 503 coupled to a puller 507 at an inner end that is within a catheter 509. In this example, the outer end 504 of the tractor is pinned against the outer diameter of the catheter by a tractor hold 501 configured as a garage or housing. The housing may hold the end of the tractor lightly or it may secure it against the catheter more tightly, depending on the desired deployment threshold. In FIG. 5A, the tractor hold is secured to the outer diameter of the catheter by a weld or welds 505. Similarly in FIGS. 5B and 5C the tractor hold is secured by either being shrunk-fit to the outer diameter at the proximal end 515, or by an adhesive or glue 525, respectively.

[00075] In all of the examples shown in FIGS. 3A-3C and 5A-5C, the tractor hold extends only slightly down the length of the catheter, e.g., a few cm (e.g., less than 10 cm, less than 9 cm, less than 8 cm, less than 7 cm, less than 6 cm, less than 5 cm, less than 4 cm, less than 3 cm, etc.).

[00076] In any of the variations described herein, the elongate inversion support may have a different outer diameter along its axial (longitudinal) length. For example, although the catheter shown in FIG. 1A has a uniform diameter along its length, other apparatuses may include a catheter having a larger diameter at the distal end region than at more proximal regions, as shown in FIGS. 6A-8C. For example, in FIG. 6A, the elongate inversion support is a catheter having a larger outer diameter at the distal end than at the proximal end. The transition between the two regions is a step 605. The annular region (distal end opening 607) therefore has the same, larger, outer diameter as the distal end region. FIGS. 6B-6C, illustrates examples in which a tractor is held over the outer diameter and may be secured by a tractor hold. In general, particularly where the tractor is configured to contract down onto the tractor, simply having the transition, and particularly a rapid (including step) transition between a region of larger diameter and a region of smaller diameter, as shown in FIG. 6A, may help secure the tractor over the catheter. In FIG. 6B, the same catheter shown in FIG. 6A has had a tractor 603 attached so that it extends along the distal outer diameter region, inverts over the distal end opening 607, and into the catheter inner lumen, where it is connected to or integral with a puller 609. In FIG. 6B, the outer end of the tractor is held in place with a tractor hold 613; in this example, the tractor hold 613 is one or more arms that hold the tractor against the smaller inner diameter immediately adjacent to the step up to the larger diameter region of the catheter.

[00077] In FIG. 6B, the tractor hold is a narrower catheter 623 that extends proximally; the tractor is held between the distal opening of the tractor hold and the step up to the larger

diameter catheter 601. The outer surfaces of the tractor hold and the catheter 601 may be flush, e.g., having the same height. In FIG. 6B, if the tractor hold extends proximally far enough (e.g., to or beyond the end of the catheter) it may be actively disengaged, reducing or eliminating the deployment threshold force.

[00078] FIG. 6D shows another example of a tractor lock 633, similar to that shown in FIG. 6C, only extending partially proximally down the catheter. In any of these variations the tractor hold may be fixed to the outer diameter or it may be movable (e.g., slideable) relative to the outer diameter of the catheter.

[00079] FIGS. 7A-7L illustrate different variations of catheters that may be used as part of any of the apparatuses described herein. For example, FIG. 7A shows an example of a catheter 700 having a larger-diameter distal end region that also includes a plurality of openings, slots, holes, windows, slits, etc. 709. These openings may provide for delivery of fluid (including drugs) to the site of use, and/or removal of material, e.g., the application of vacuum through the apparatus, particularly useful when used with an intermediate catheter into which the apparatus (e.g., an elongate inversion support, a puller and tractor) is inserted, as will be described in greater detail below. FIG. 7B shows the apparatus of FIG. 7A with an attached puller and tractor.

[00080] FIGS. 7C and 7D illustrate another variation of a catheter that may be used as part of any of the apparatuses described herein, including, as here, catheters that have a plurality of cut-out regions. Similarly, FIGS. 7E and 7F show an example including a catheter having a large proximal skive region, leaving the majority of the outer diameter much smaller than at the distal end region, as shown. In addition, the distal end of the catheter may include openings, slots, cut-out regions, etc. 725. FIG. 7F shows the catheter of FIG. 7E with a tractor 714 coupled on an inner end to a puller 713. The puller is still pulled within the lumen of the catheter. A similar example is shown in FIGS. 7G and 7H, however instead of being skived, the elongate inversion support includes a distal portion formed of a catheter having cut-out regions 725 that is coupled to a rod, pole, wire or (as shown) a hypotube. This hypotube may be used as a guidewire lumen and/or as a channel for a stiffening or support member that may, once the device is positioned, enhance the column strength to allow pulling of the tractor proximally when inverting the tractor to roll.

[00081] FIGS. 7I and 7J illustrate an example of a catheter (FIG. 7I) and an apparatus including the catheter (7J) in which the sides of the catheter have been slotted, which may provide enhanced flexibility while maintaining column strength. An apparatus including the catheter of FIG. 7I is shown in FIG. 7J, also including a tractor and puller.

[00082] FIG. 7K is an example of an elongate inversion support in which the distal end is a cylinder 716, formed, for example, from a very small portion of a catheter. The distal end opening (annulus 707) may be used to invert the tractor, as shown in FIG. 7L. The elongate shaft 717 of the elongate inversion support may be a rod, tube, wire, etc. as described above. An additional outer catheter 726 may be included in any of these apparatuses, as shown in the exemplary apparatus shown in FIG. 7L, which includes the elongate inversion support of FIG. 7K.

[00083] FIGS. 8A-8D also illustrate another example of an elongate inversion support having a distal annulus or aperture 743, shown in this example a ring (e.g., toroid ring) bonded to a hypotube 746 (which may alternatively be a rod, wire, small-diameter catheter, etc.); as mentioned above, a stiffening member may be inserted into the elongate body of the elongate inversion support prior to or during pulling of the tractor proximally through the distal annulus. FIG.8B shows a similar variations of the elongate inversion support of FIG. 8A, only with a plurality of guides 750 extending down the length of the support into which the tractor puller and/or tractor may be held, as illustrated in FIG. 8C. In this example, the tractor 810 extends over the elongate inversion support and can be pulled proximally by the tractor puller 812. Although the tractor puller is shown as a catheter, in any of the apparatuses described herein, the tractor puller may instead be a wire, hypotube, etc. as mentioned above. FIG. 8D is an apparatus similar to that shown in FIG. 8C with the addition of an outer catheter 809.

RELEASABLE LOCK

[00084] In some variations, the tractor hold and distal end region of the catheter to which it is applied over may be configured as (or may include) a releasable lock, in addition to or instead of the tractor holds described above (e.g., a sticky materials, frangible release, housing, etc.). For example, the catheter may include a tractor hold comprising a friction lock (e.g., bump, protrusion, enlarged diameter, region, O-ring, etc.) on the outer diameter of the catheter that engages with a locking region (e.g., construction, inward-pointing bump, sticky coating, etc.) on the outer (e.g., proximal) end region of the tractor. The locking region on the outer end portion of the tractor may be proximally beyond the locking region (e.g., friction bump) on the catheter, so that the catheter locking region may be initially held beneath the tractor. When force is applied (e.g., deployment force applied by the user) to pull the tractor region proximally from the inside of the tractor, the force may overcome the locking engagement between the tractor locking region (e.g., constriction, inwardly-facing

protrusion, etc.) and the locking catheter locking region (e.g., friction bump, radial enlargement, O-ring, etc.) and the tractor may be released roll distally over the catheter. See FIGS. 10A-10C for an example of this arrangement. Note that this releasable lock may be used in combination with any of the features described above. In FIG. 10A-10C, the tractor 1007 includes a tractor lock 1006 at the outer end of the tractor. FIG. 10A shows just the tractor and puller 1003. The mechanical thrombectomy apparatus 1000 shown in FIG. 10B also includes a catheter 1011, and the catheter includes a tractor hold 1009. The tractor hold engages with the tractor lock; in FIG. 10B, the tractor hold is a protrusion that holds the tractor lock on the tractor on a proximal side of the tractor hold, until sufficient force is applied above the deployment threshold to deploy the tractor by pulling the tractor lock distally over the tractor hold, allowing the tractor 1007 to deploy and/or expanded, and be rolled over the distal end opening of the catheter, to capture a clot.

[00085] In any of these variations, but particularly the locking variations described herein, the tractor region may be held in tension, although tension is not necessary. Alternatively or additionally, a second outer cover or catheter may be used, or may be absent.

APPARATUSES HAVING DISTAL-EXTENDING PULLERS

[00086] In any of the variations described herein, the puller may extend more distally than the tractor in the apparatus. For example, a pre-assembled apparatus having the distal end of a tractor puller (e.g., catheter, hypotube, wire, etc.) that extends more distally beyond the catheter(s) or the rest of the apparatus may be used to help capture the clot. As mentioned above, any of these variations may include the use of a vacuum, e.g., for aspirating the clot. The vacuum may be applied through the puller. It may be easier to grab onto a clot when using aspiration to initiate the grabbing.

[00087] For example, FIG. 9A illustrates an example of a mechanical thrombectomy apparatus similar to that described above. The tractor 903 is connected to a puller 905 and the tractor extends along the outer diameter 901 of the catheter. In some variations, the tractor may be infused, bonded or laminated with a stiffening element in part to make it less likely that the tractor collapses in diameter when the dozer catheter is pulled and allows for vacuum applied to the applied to the proximal end of the tractor puller 905 to exert force/vacuum on the clot via the distal end of the assembly, as shown in FIGS. 9B and 9C.

[00088] In FIG. 9B, the tractor is coupled to a portion of the tractor puller 905 that is proximal 921 to a distal end of the puller. Thus, as the puller is extended distally, the tip may

extend past the distal end of the catheter, prior to inverting the tractor. FIG. 9B also shows an (optional) tractor hold 917

[00089] In FIG. 9C, the apparatus includes a stop element attached at or near the distal end of the puller 905. A sliding ring 911 on the tractor may be used to allow the puller to slide distally without pulling on the tractor; only when the puller is withdrawn proximally far enough that the stop 909 engages with the sliding ring 911 does the puller pull the tractor proximally, and invert the tractor over the distal end opening of the catheter, rolling the tractor an pulling in any clot material, which may be aided by the application of vacuum 914 through the puller. Thus, this arrangement may allow the user to extend the tractor puller distally at lengths beyond the distal end of the catheter without pulling the tractor distally.

[00090] In any of the variations described herein, including those shown in FIGS. 9A-9C, the apparatus may be coupled to a valve 923 for connection to a vacuum source 914. The vacuum may be connected to the elongate inversion support (e.g., catheter) and/or to the puller, as shown in FIGS. 9A-9C.

[00091] Any of the apparatus variations described herein may include a lubricous coatings such as hydrophilic coatings applied on the OD &/or ID of the tractor, on any and all sections, and/or on the outer or inner diameter of the elongate inversion support (e.g., catheter).

[00092] In general, the apparatuses described herein may allow delivery of a guidewire and/or a smaller catheter through the outer catheter and tractor, which may be useful for both guidewire operation (for clot access) and also for applying optional vacuum. In addition, the tractors described herein may have minimal to no collapsing when they are inverted inside the outer catheter when under axial tension, which may prevent jamming on the catheter distal tip and may reduce the amount and/or volume of clot that can be extracted. Further, any of the tractors described herein may have adequate coarseness to grab the clot, yet still roll smoothly around the distal annulus. Typically, the tractor does not adversely affect catheter tracking, as it may be extremely flexible and slippery.

[00093] As just discussed above, the pre-loaded tractors described herein may not slide with respect to the OD of catheter during vessel access. The tractor may only slide on the OD of catheter when the user pulls the tractor puller.

[00094] In general, the user may advance the elongate inversion support (e.g., catheter) forward while holding the tractor puller fixed, thereby enveloping clot in place rather than pulling clot to catheter. Further, the tractor may be biased (e.g., heat-shaped) to a preferred configuration to help grab clot effectively and roll nicely around the catheter tip. In general,

the distal end of the catheter (tip) may be stiffer than the catheter section just proximal to the tip (to allow rolling of dozer around tip). The tip may include a lubricious coating. The catheter tip may have a radius of > 0.00025", > 0.00035", > 0.0004", > 0.0004", > 0.00025", or < 0.0005" to allow rolling of tractor more easily. For example, the catheter tip hardness may be greater than >72D, and/or may be formed of a polymeric material such as PTFE, nylon, PEEK, stainless steel, etc.

[00095] In some variations, the distal region (e.g., distal 5 cm, 10 cm, etc.) of the catheter allows for tracking through 1/8" diameter radius and also has a limited axial compress to <10% of the distal catheter length during axial compression loads of, e.g., 100g, 200g, and 300g, etc. when pulling in the dozer and grabbing clot.

[00096] As mentioned above, any of these apparatuses may allow for the delivery of guidewire and/or smaller catheter through aspiration catheter. In general, the tractor may be configured to have a Poisson ratio <1.5 (e.g., <1.2, <1.1, etc.) when under tension (this helps prevent the tractor from jamming on catheter tip).

[00097] In any of the variations described herein, the tractor and/or catheter may be radiopaque. For example, a band or region may be radiopaque. The entire tractor may be radiopaque, e.g., NiTi wire filled with PT or Tantalum (DFT wire) may be used to form the tractor. Alternatively, the proximal and/or distal end of the tractor may have radiopaque markers.

[00098] The apparatuses described herein may be used to remove materials such as clots, including to prevent or treat stroke. For example, the apparatuses described herein may be used to track up through the siphon of the carotid artery, which is typically highly tortious. When pulled, the tractor may roll around the catheter distal end without locking up, while still grabbing clot. As mentioned, any of these apparatuses may also work in combination with a vacuum. The use of a vacuum may be unnecessary, but may be beneficial, particularly when initially engaging the clot with the tractor region and/or the distal end of the catheter. Any of the apparatuses described herein may also be configured to grab a clot in a large variety of vessels, including those ranging from 1.5 mm to 3.5 mm, even when the catheter has approximately the same outer diameter as the inner diameter of the vessel, or where the catheter is otherwise corked in the vessel.

APPARATUSES ADAPTED FOR USE WITH ASPIRATION

[00099] As mentioned, any of the apparatuses described herein may be adapted for use with a vacuum to apply suction (e.g. aspiration) to assist in clot removal. Although the

device may be used without the use of aspiration, in some instances clot removal may be aided by the use of the mechanical atherectomy apparatuses described herein. Furthermore, traditional techniques for removing a clot using aspiration (e.g., using a simple flexible catheter, commonly referred to as an intermediate catheter) may be improved by the use of the mechanical atherectomy apparatuses described herein. Use of aspiration alone often results in clogging of the intermediate (aspiration) catheter and may therefore have trouble removing the entire clot, particularly in the tortious vessels. Any of the apparatuses described herein may be used with an intermediate catheter, and may be adapted for use with vacuum clot removal technique, including being adapted to permit vacuum to be applied while the apparatus is within the lumen of the intermediate catheter, so that aspiration may still be applied from the distal end of the intermediate catheter and/or the apparatus, as well as permitting aspiration to be applied while the apparatus is extended distally from the intermediate catheter. The applied vacuum may aid in initially gasping or grabbing the thrombus. The vacuum may be applied from the distal end of the apparatus and/or of an intermediate or outer catheter or sleeve that is used with the apparatuses (e.g., elongate inversion support and inverting tractor). Also described herein are apparatuses that are adapted for use with a vacuum, including for use with an intermediate or outer catheter through which the apparatus may be delivered to the clot. The apparatus may grab clot from within the outer catheter, or it may be extended distally out of the intermediate or outer catheter. For example, FIGS. 7A-8D, described above and in additional detail below, are examples of elongate inversion supports that may be used in any of the apparatuses described; these elongate inversion supports may be particularly well suited to applying aspiration from the intermediate catheter.

[000100] FIG. 11A shows an example of a configuration in which an outer/intermediate catheter or sleeve that is highly flexible may be maneuvered, for example with a guidewire, to a distal end of the device. Thus, the intermediate catheter may be maneuvered near, or adjacent to, the thrombus. As in any of these methods of use described herein, imaging (such as fluoroscopy, contrast imaging, etc.) may be used. Once in positioned, the guidewire may be removed or left in place, and the apparatus including the elongate inversion support and inverting tractor may be extended within the intermediate catheter/sleeve. In FIG. 11A, the intermediate catheter 4104 is shown positioned within the vessel 4109 distally. As with any of the illustrations here, in the vessel maybe highly tortious and branching, although for convenience it is shown as straight in the figures. The apparatus 4100 is extended distally through the intermediate catheter, and extends out of the distal opening of the intermediate

catheter to grab the clot 4111, as shown. The puller 4105 may thus be drawn proximally (to the left in the figure) to pull the tractor 4103 from over the catheter portion of the elongate inversion support 4113, so that it inverts and rolls into the lumen of the elongate inversion support, capturing and drawing the clot in with it. The clot may be compressed.

[000101] Thus, this configuration may be referred to as a vessel cleaner. In addition to the rolling of the tractor to grab and pull the clot, the clot may be pulled by a vacuum applied from one or both of the intermediate catheter 4121 and/or the elongate inversion support 4123. Vacuum may be applied, e.g., within the intermediate catheter, before the apparatus is positioned distally (or even within the intermediate catheter at all) or after it has been extended distally from the intermediate catheter. This configuration shown in FIG. 11A may introduce the tractor through outer catheter to the face of clot. As mentioned, the mechanical thrombectomy apparatus may be extended distally from the intermediate catheter either by pushing it out distally and/or by pulling back the intermediate catheter to deploy all or part of the tractor into vessel, as shown. If vacuum is applied through the catheter, the catheter forming the elongate inversion support may be jacketed or sealed to allow aspiration through this catheter.

[000102] Optionally pull vacuum through outer and/or inner and/or puller. As mentioned, thereafter the tractor may be pulled proximally relative to the the elongate inversion support to pull the clot. The intermediate catheter may then be advanced distally and/or the mechanical thrombectomy apparatus may be withdrawn proximally to remove the apparatus once the clot has been removed. Thereafter an angiogram may be taken to confirm that the clot has been removed.

[000103] Alternatively, in FIG. 11B, a clot may be removed using the intermediate catheter to draw a vacuum with the mechanical thrombectomy apparatus within the lumen (e.g., near the distal end, but not extending fully from the distal end) of the intermediate catheter. As described for FIG. 11A, in FIG. 11B the intermediate catheter may be inserted into the vessel (e.g., using a guidewire) so that the distal end is positioned near the clot. Suction may be used to draw the clot into the intermediate catheter either before the mechanical thrombectomy device is inserted or after it has been inserted.

[000104] In FIG. 11B, the elongate inversion support 4113' is particularly well suited for use with a vacuum applied through the intermediate catheter 4104 surrounding the apparatus. For example, in FIG. 11B, the elongate inversion support 4113' include a distal catheter region 4125 that extends just a few cm from the distal end opening in which the clot is drawn. The elongate inversion support then tapers down to an elongate support, which may be

formed by a wire, hypotube or skived region. This configuration may prevent the catheter from blocking the lumen of the intermediate catheter and and therefore increasing the resistance of the vacuum before it can reach the open distal end and apply suction to drawn the clot. Alternatively or additionally, the outer diameter of the catheter portion of the elongate inversion support may be sized to allow more of the vacuum to pass. For example, the apparatus may be sized such that there is at least about 0.002 inches or greater (e.g., 0.003, 0.004, 0.005, 0.006, etc., inches) between the outer diameter of the catheter and the inner diameter of the intermediate catheter ("outer catheter"). This may also permit unimpeded rolling of the tractor over the distal end opening of the elongate inversion support.

[000105] In operation, the method of removing clot such as shown in FIG. 11B may include pulling at least the tip of a clot into the intermediate catheter through the use of a vacuum 4121. Typically the clot may clog within the intermediate catheter; the mechanical thrombectomy apparatuses described herein may be used to remove the clot from within the intermediate catheter. For example, while maintaining vacuum, the mechanical thrombectomy apparatus may be inserted (or it may be preloaded in intermediate catheter as mentioned) and the tractor puller 4105 may be pulled to pull the clot out of the intermediate catheter and the vessel, compress and/or macerate it and pull it into the apparatus and therefore the intermediate catheter, where it can be withdrawn proximally, e.g., by removing the mechanical thrombectomy apparatus. As mentioned, an angiogram may be taken through intermediate catheter (e.g., leaving it in place in case the mechanical thrombectomy apparatus needs to be re-inserted and used to remove more clot) to confirm clot has been removed.

[000106] As mentioned, a full catheter such as shown in FIG. 11A may block or prevent the vacuum from reaching the distal end of the intermediate vessel. Therefore it may be beneficial to adapt the mechanical thrombectomy apparatus so that it can be used with vacuum within an intermediate catheter or sleeve, as shown in FIG. 11B. This may be achieved as mentioned above, by minimizing the larger-diameter catheter portion of the elongate inversion support forming the distal end opening over which the tractor inverts. Returning now to FIGS. 7A-8D, in FIG. 7A, the elongate inversion support 700 has a distal catheter portion 701 having a larger diameter than the more proximal region 703, and also includes a plurality of openings, holes, gaps, cut-out regions, slots, etc. 709 that may allow the flow of vacuum through the elongate inversion support more easily. The elongate inversion support shown also includes a distal end 707 into which a tractor 711 inverts, as shown in FIG. 7B. IN FIG. 7B, the elongate inversion support is shown transparent so that the puller 713 and tractor within the elongate inversion support is visible.

[000107] Similarly, in FIGS. 7B and 7C, the entire length of the elongate inversion support includes a plurality of cut-out regions 713 which may increase the ability to allow the flow of a vacuum or other fluid within the apparatus, but may still allow the elongate inversion support to provide column strength to resist collapsing up to at least 500 g of compressive longitudinal force applied by, e.g., pulling on the tractor. Similarly, the elongate inversion support of FIGS. 7E and 7F show a skived catheter that also includes openings 709 along its length. The puller and tractor 412 are shown within the elongate inversion support in FIG. 7F. FIGS. 7G and 7H illustrate an example in which rather than a skived portion of the catheter, the distal catheter region of the elongate inversion support is formed by a wire, bar, tube, 721 etc., that is attached to the catheter at the distal end. The catheter may also optionally include openings 709. The elongate inversion support of FIGS. 7I and 7J includes openings 709' along all or much of its length (particularly near the distal end region) as shown.

[000108] Finally, the variation of the elongate inversion support shown in FIG. 7K includes a minimal catheter portion (cylinder 716) that is connected to a wire, bar, tube, hypotube, skived region, etc. 717.

[000109] FIGS. 8A-8D illustrate the operation of a similar minimal elongate inversion support 800. In this example, the apparatus includes a distal aperture 743 bonded securely to a wire, bar, tube, hypotube, skived region, etc. 746 forming an elongate support. The elongate support may be hollow (e.g., may include a lumen for a guidewire) or solid. The elongate support may also include one or more additional support guides 750 as shown in FIG. 8B. These supports may help contain the puller and/or tractor within the elongate inversion support. Any of the elongate inversion supports described herein may include additional support guides. The elongate inversion support of FIG. 8B is shown with a tractor 711 and puller 713 in FIG. 8C. As mentioned, this variation may be particularly well suited for use with an intermediate (e.g., "outer") catheter, sleeve, or the like 809, as shown in FIG. 8D.

EXPANDABLE DISTAL ENDS

[000110] Any of the mechanical thrombectomy apparatuses described herein may include an elongate inversion support having a distal end that is expandable from a smaller diameter aperture (e.g., distal end opening) to a larger-diameter aperture. This expansion may be performed by pulling the clot within the catheter. For example, FIGS. 12A-12C illustrates the operation of an example of an elongate inversion support configured as a catheter having

an expandable distal end. In this variation the catheter distal end 4401 may include slots or slits 4403 formed or cut, e.g., by laser-cutting, in the distal end of the catheter of the elongate inversion support. The apparatus may be operated as described above, positioning near (e.g., against or adjacent to) a clot, and pulling proximally on the puller to draw the tractor 4405 into the catheter, as shown in FIG. 12B. Although the apparatuses described herein may generally compress a clot greatly, compression may be made easier and/or more efficient by providing a more gradual decrease in radial diameter. As shown in FIG. 12B, when the tractor is rolled over the distal end opening and inverted, the clot maybe drawn in along with the tractor. As the large clot 4413 is brought into the distal end opening, the distal end opening may expand and open along the slots or slits 4403, as shown in FIG. 12C, so that the distal end opening flares out. In some variations an elastic sleeve, gasket, ring or cover (not shown in FIG. 12A-12C) may be included at least partially covering the distal end to prevent the edge from catching the tractor. For example, and elastic or stretchable layer may cover the cut distal end so that the distal end may be opened to form an outward flare. In FIG. 12C the outward-flared distal end is shown forming a funnel-shape into which the clot may be pulled. This funnel-shaped opening may help compress the clot so that it may be drawn into the mechanical thrombectomy apparatus.

[000111] In some variations the elongate inversion support may be configured to have, or to assume, a funnel-shape at the distal-facing end. The distal-facing end may always have a funnel-shaped mouth at the distal end opening, or the distal end opening may be configured to assume a funnel shape, as shown in FIGS. 12A-12C. In some variations the distal end of the elongate inversion support is configured to be elastic in a radial directly, but maintain stiffness along the proximal-to-distal axis (in compressive load). For example, the distal end of the elongate inversion support may be configured with strands or rods extending in the proximal-to-distal axis that have a high compressive load strength, but which may separate from each other to enlarge the distal end opening; for example they may be connected by rings in which more distal rings are more elastic/stretchable than more proximal rings.

[000112] 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.

[000113] 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 "/".

[000114] 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.

[000115] 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.

[000116] 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.

[000117] 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.

[000118] 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.

[000119] 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.

[000120] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

What is claimed is:

1. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:
    a catheter having a proximal end and a distal end and a distal end opening;
    a tractor comprising a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter;
    a puller coupled to the first end of the tractor, wherein the puller extends within the catheter to the proximal end of the catheter; and
    a tractor hold attached to an outer diameter of the catheter proximal to the distal end of the catheter, wherein the tractor hold secures a second end of the tractor to an outside surface of the catheter until a force greater than a threshold force is applied by pulling the first of the tractor proximally within the catheter
    wherein the threshold force is between 50 g of force and 500 g of force.

2. The apparatus of claim 1, further comprising a guidewire lumen extending through the catheter, the puller and the tractor, and configured to pass a guidewire.

3. The apparatus of claim 1, further wherein the tractor hold does not extend to the proximal end of the catheter.

4. The apparatus of claim 1, wherein the tractor hold extends proximally along the catheter for less than 10 cm.

5. The apparatus of claim 1, wherein the tractor hold compresses the tractor against the catheter.

6. The apparatus of claim 1, wherein the tractor hold is configured to hold the second end of the tractor until the threshold force is applied, wherein the threshold force is between 200 g of force and 500 g of force.

7. The apparatus of claim 1, wherein tractor is biased to expand beyond an outer diameter of the distal end of the catheter in a first relaxed configuration, further wherein the tractor is biased to expand to a second relaxed configuration having an outer diameter that is greater than an inner diameter of the distal end of the catheter, wherein the tractor converts between the first configuration and the second configuration by inverting.

8. The apparatus of claim 1, wherein a proximal end of the tractor hold is attached to the catheter.

9. The apparatus of claim 1, wherein the catheter comprises a larger outer diameter region and a smaller outer diameter region that is proximal to the larger outer diameter region, further wherein the tractor hold secures the tractor at one or more of: over the smaller outer diameter region, and between the larger outer diameter region and the smaller outer diameter region.

10. The apparatus of claim 9, wherein an outer diameter of the tractor hold is flush with the larger outer diameter region.

11. The apparatus of claim 9, further comprising a stepped transition between the larger outer diameter and the smaller outer diameter.

12. The apparatus of claim 1, wherein the tractor hold comprises one or more of: a polyether block amide, a polyolefin, a polyethylene, a polypropylene, a polyethylene terephthalate (PET), and a Polytetrafluoroethylene (PTFE).

13. The apparatus of claim 1, further comprising a tractor lock on the second end of the tractor, wherein the tractor lock engages with the tractor hold to secure the tractor lock on a proximal side of the tractor hold until the threshold force is applied by pulling the first of the tractor proximally within the catheter.

14. The apparatus of claim 13, wherein the tractor lock comprises a band configured to slide over the outer diameter of the catheter.

15. The apparatus of claim 13, wherein the tractor hold comprises a projection extending from the outer diameter of the catheter.

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

a catheter having a proximal end and a distal end and a distal end opening, wherein the catheter comprises a larger outer diameter region and a smaller outer diameter region that is proximal to the larger outer diameter region;

a tractor comprising a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter;

a puller coupled to first end of the tractor, wherein the puller extends within the catheter to the proximal end of the catheter; and

a tractor hold on an outer diameter of the catheter proximal to the distal end of the catheter, wherein the tractor hold secures a second end of the tractor that extends over the distal end of the catheter until a force greater than a threshold force is applied by pulling the first of the tractor proximally within the catheter, further wherein the tractor hold secures the tractor at one or more of: over the smaller outer diameter region, and between the larger outer diameter region and the smaller outer diameter region.

17. A method of removing a clot using a mechanical thrombectomy apparatus, the method comprising:

positioning a distal end of the mechanical thrombectomy apparatus adjacent to 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 diameter of the catheter by applying a first force that is greater than a threshold force to the first end of the tractor;

pulling the distal 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

drawing the clot into the catheter with the inverting tractor.

18. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises disengaging the second end of the tractor from a tractor hold attached to an outer diameter of the catheter.

19. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises disengaging the second end of the tractor from a tractor hold that extends proximally along the catheter for less than 10 cm.

20. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises disengaging the second end of the tractor from a tractor hold that is open at a distal-facing end and wherein a proximal end of the tractor hold is attached to the outer diameter of the catheter.

21. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises disengaging the second end of the tractor from a tractor hold that secures the second end of the tractor over a smaller outer diameter region of the catheter that is distal to a larger outer diameter region of the catheter.

22. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises disengaging the second end of the tractor from a tractor hold that secures the second end of the tractor between a larger outer diameter region of the catheter and a larger outer diameter region of the catheter, wherein the larger diameter outer region is distal to the smaller outer diameter region.

23. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises disengaging a tractor hold from a tractor lock, wherein the tractor lock is on the second end of the tractor.

24. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises compressing either or both the tractor hold and a tractor lock on the second end of the tractor so that the tractor lock moves from a position proximal to the tractor hold to a position that is distal to the tractor hold.

25. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises pulling the first end of the tractor with the first force wherein the threshold force is between 50 g of force and 500 g of force.

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

a catheter having a proximal end and a distal end and a distal end opening;

a tractor comprising a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter;

a puller having a proximal end and a distal end, wherein the first end of the tractor is coupled to the puller at a region that is proximal to the distal end, further wherein the puller extends within the catheter to the proximal end of the catheter;

a guidewire lumen extending through the catheter, the puller and the tractor, and configured to pass a guidewire.

27. The apparatus of claim 26, further comprising a stop between the distal end of the puller and the distal end opening.

28. The apparatus of claim 26, further comprising a stop on the puller between the distal end of the puller and the first end of the tractor, wherein first end of the tractor is coupled to a sliding ring configured to slide over the puller until it engages the stop.

29. The apparatus of claim 26, wherein there is 2 mm or greater distance between the distal end of the puller and the region of the puller to which the first end of the tractor is coupled.

30. The apparatus of claim 26, wherein the proximal end of the puller is configured to couple to a vacuum source.

31. The apparatus of claim 26, wherein the proximal end of the puller comprises a Tuohy-Borst valve/rotating hemostasis valve (RHV).

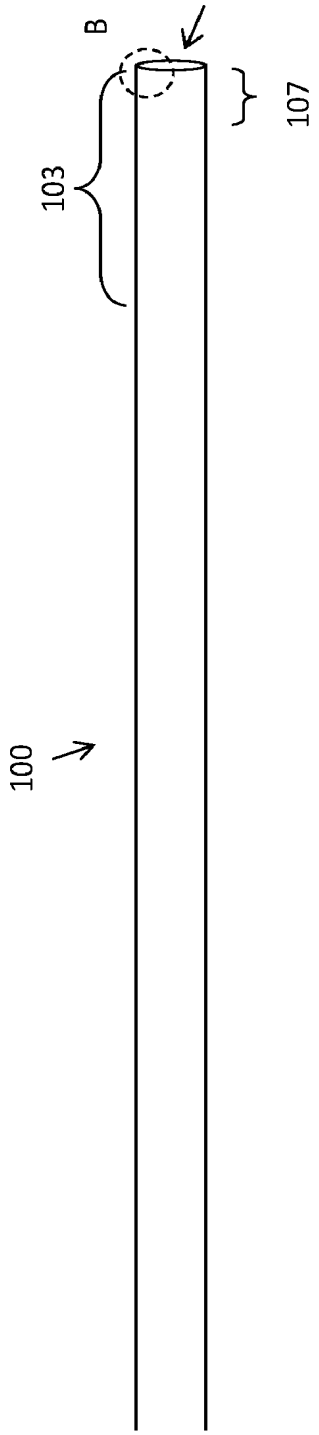

FIG. 1A

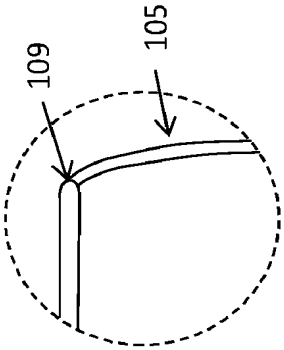

FIG. 1B

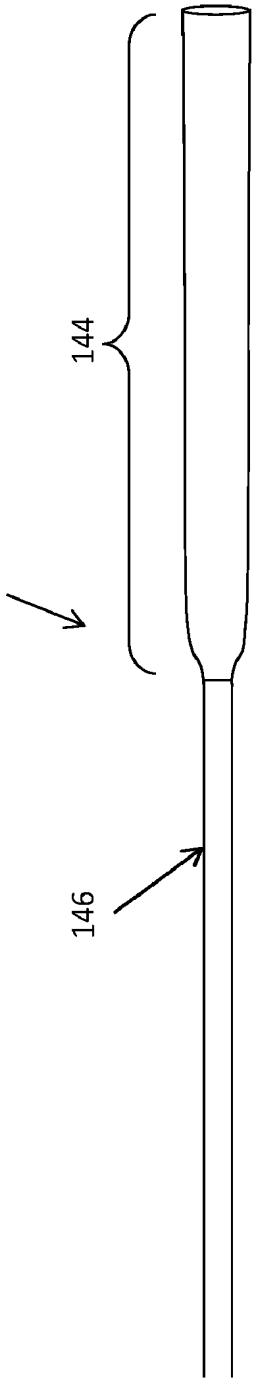

FIG. 1C

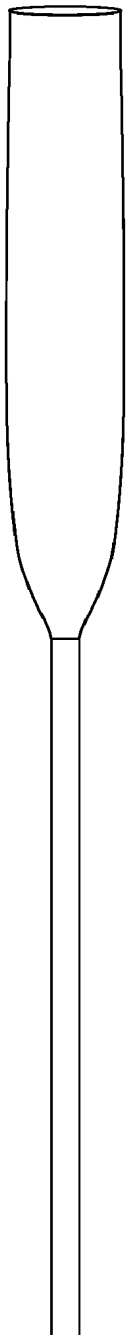

FIG. 1D

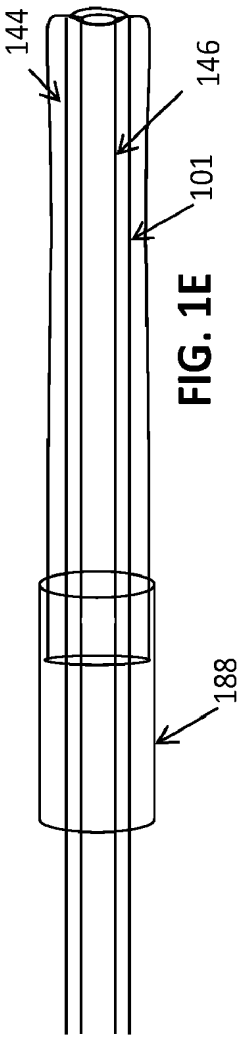

FIG. 1E

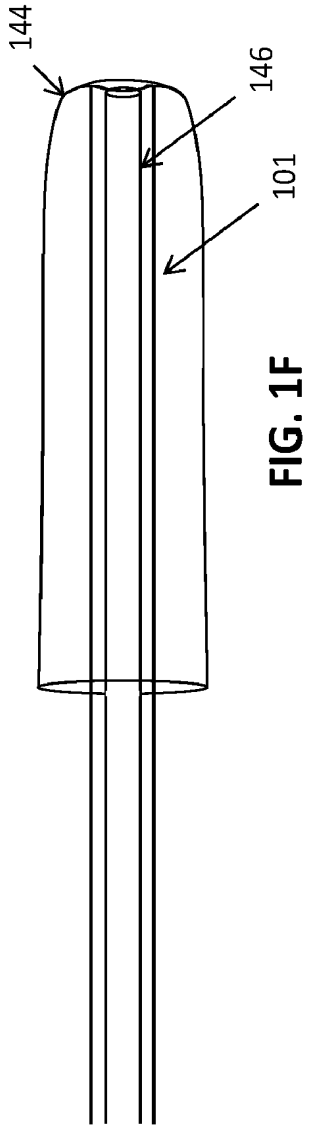

FIG. 1F

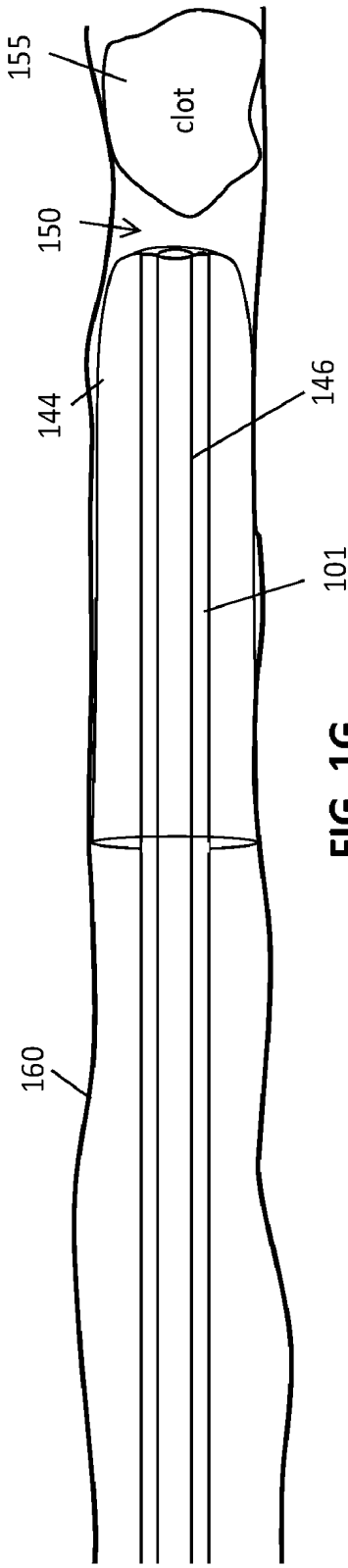

FIG. 1G

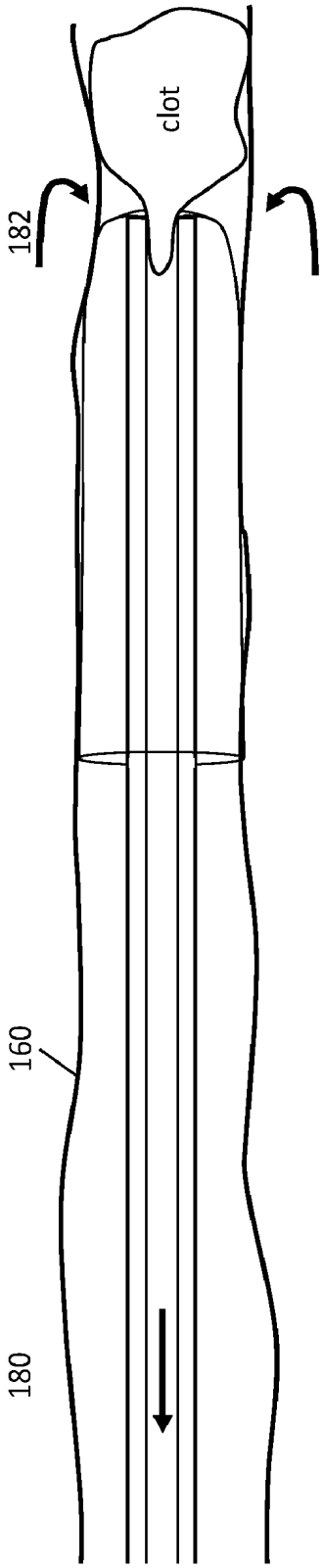

FIG. 1H

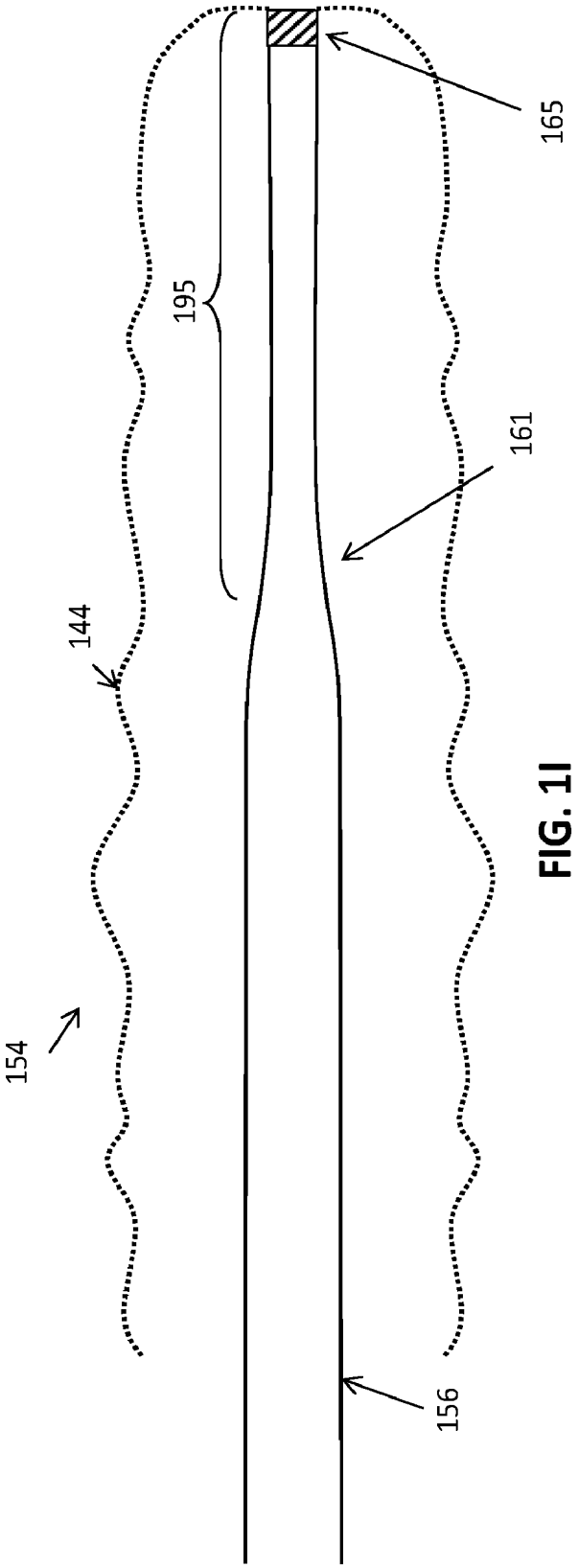

FIG. 1I

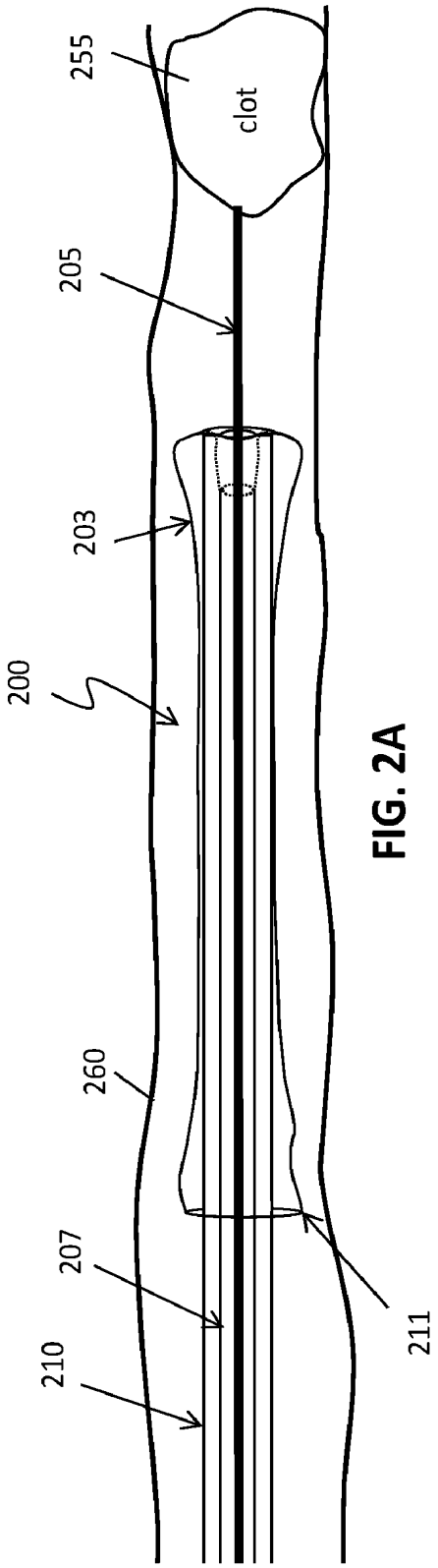

FIG. 2A

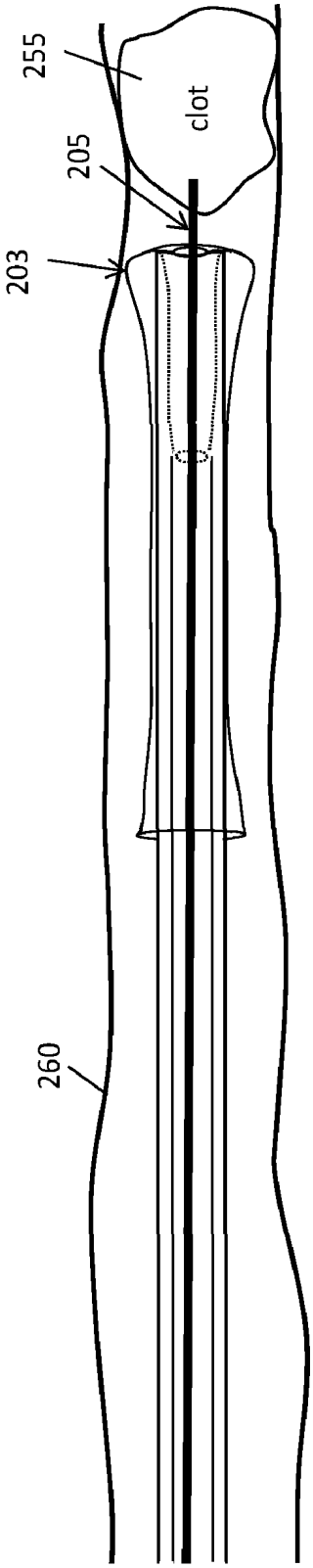

FIG. 2B

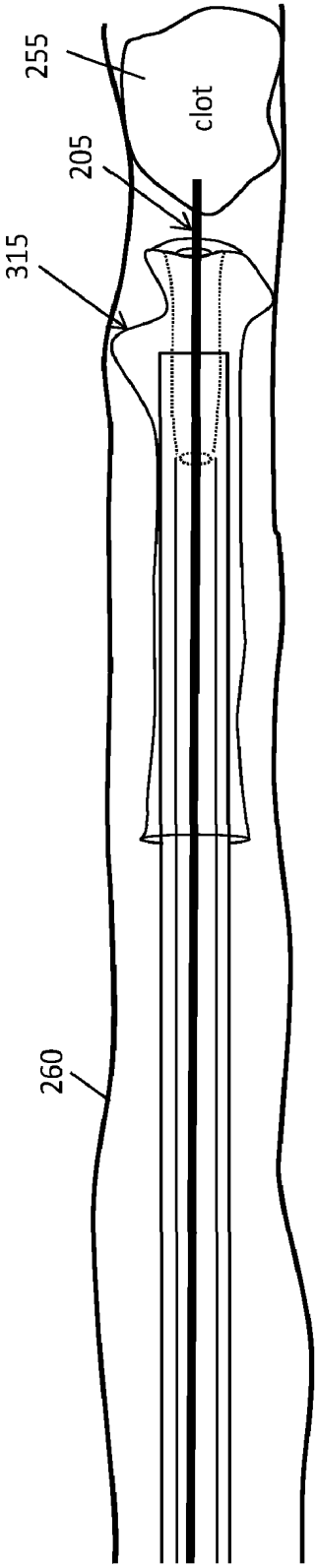

FIG. 2C

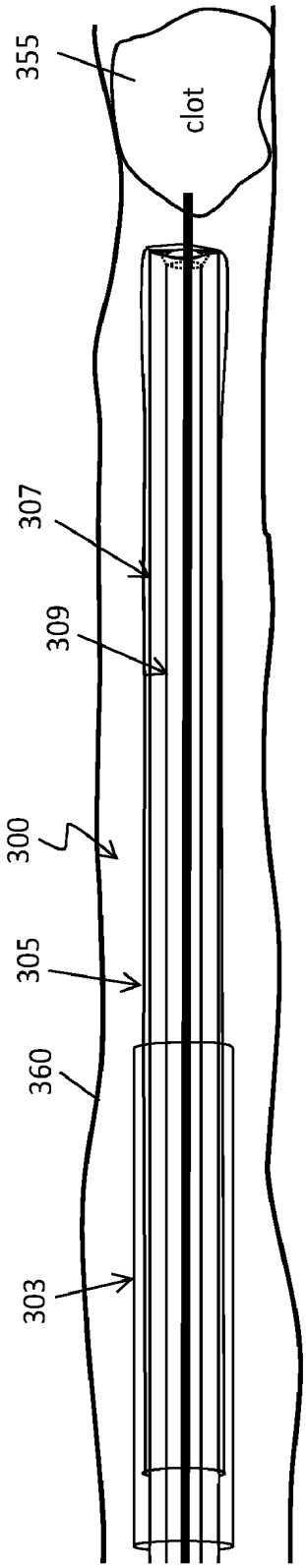

FIG. 3A

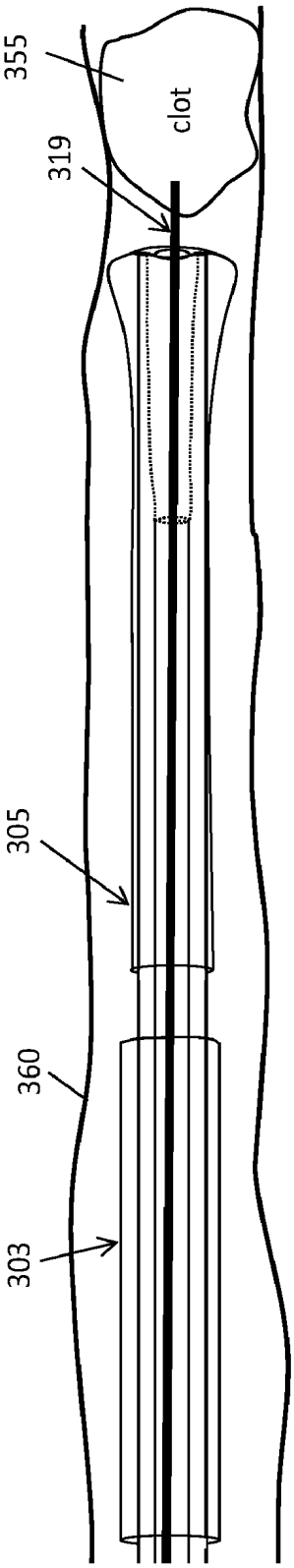

FIG. 3B

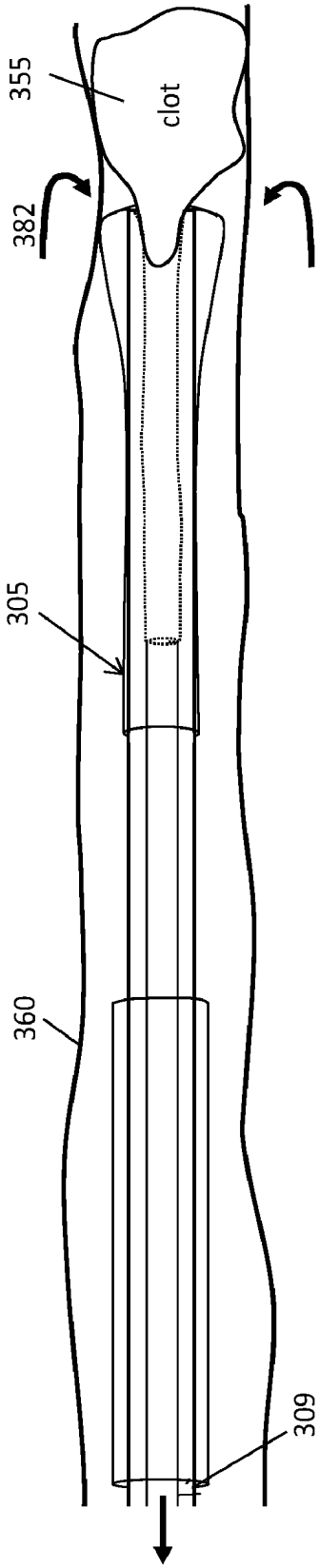

FIG. 3C

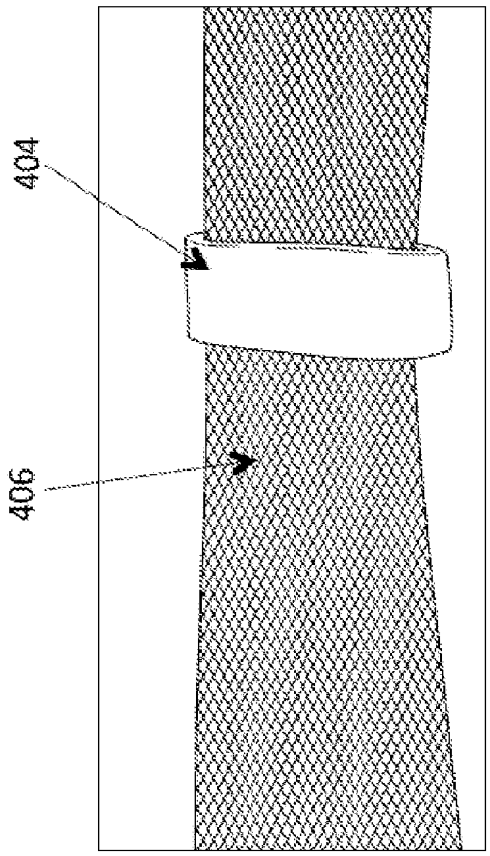

FIG. 4A

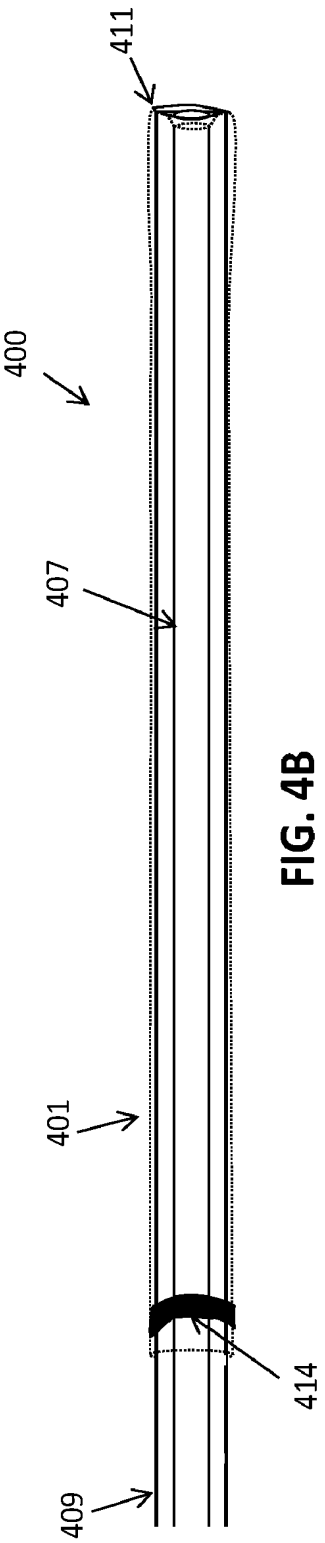

FIG. 4B

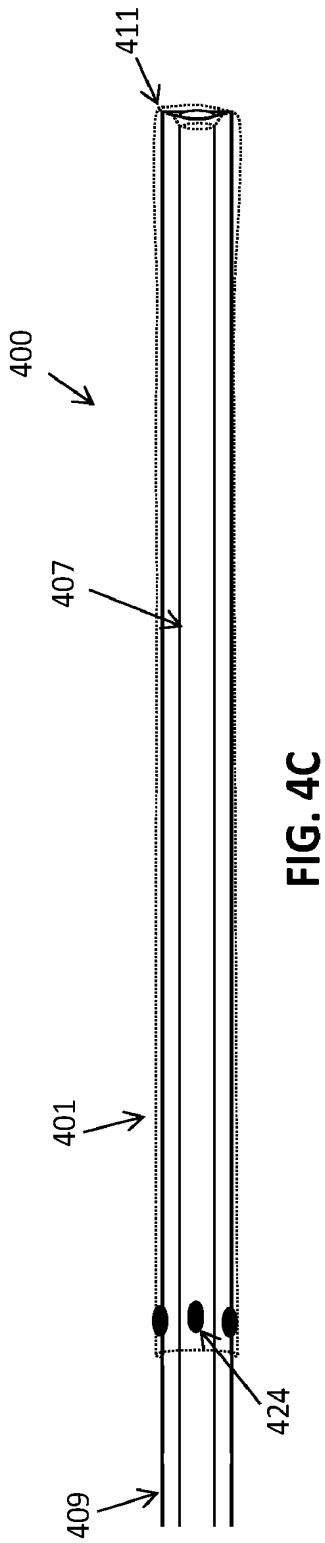

FIG. 4C

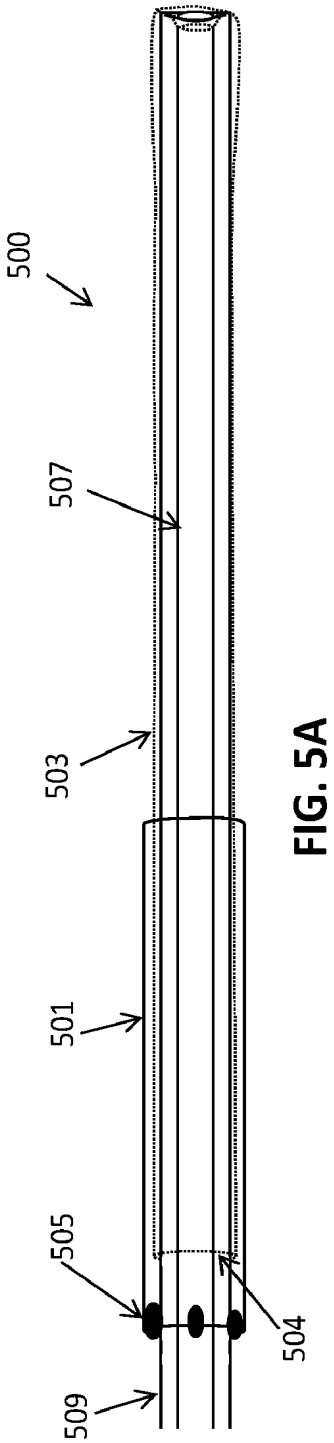

FIG. 5A

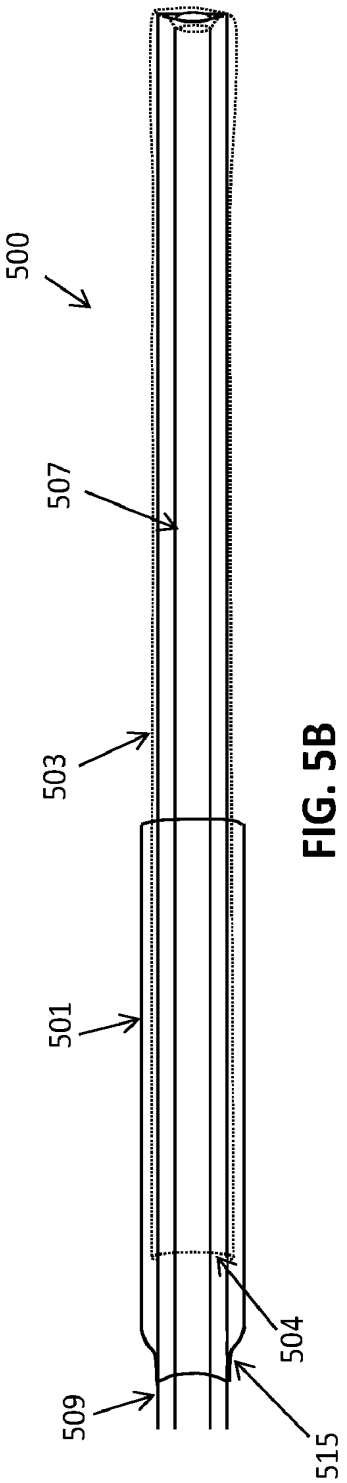

FIG. 5B

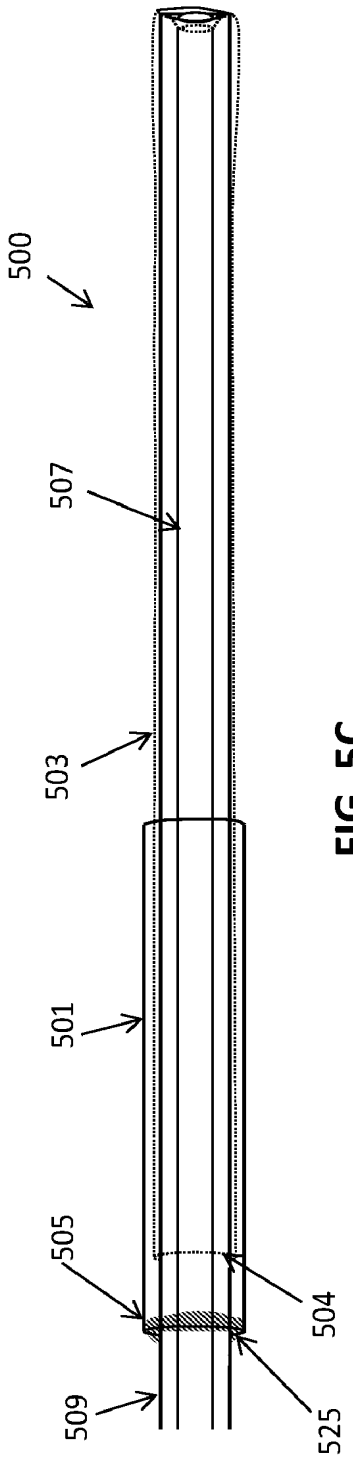

FIG. 5C

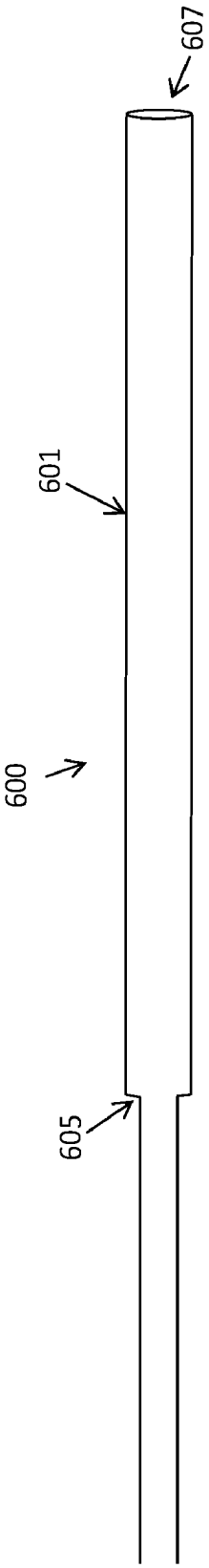

FIG. 6A

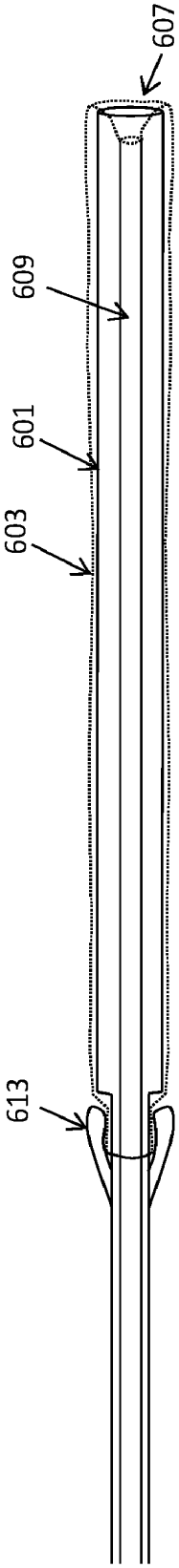

FIG. 6B

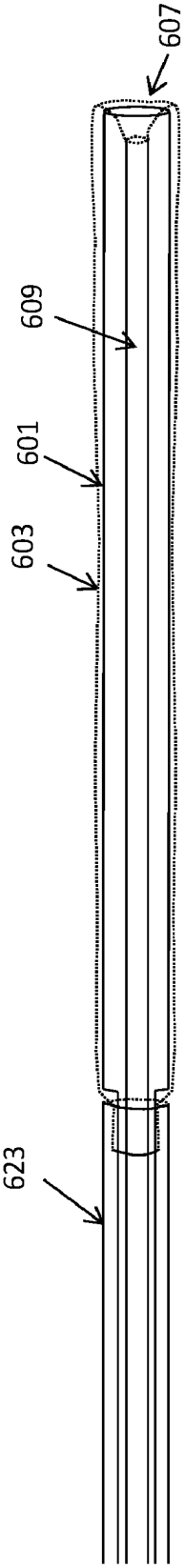

FIG. 6C

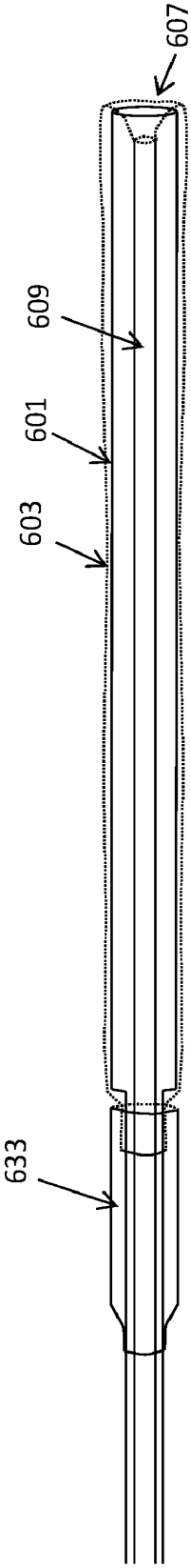

FIG. 6D

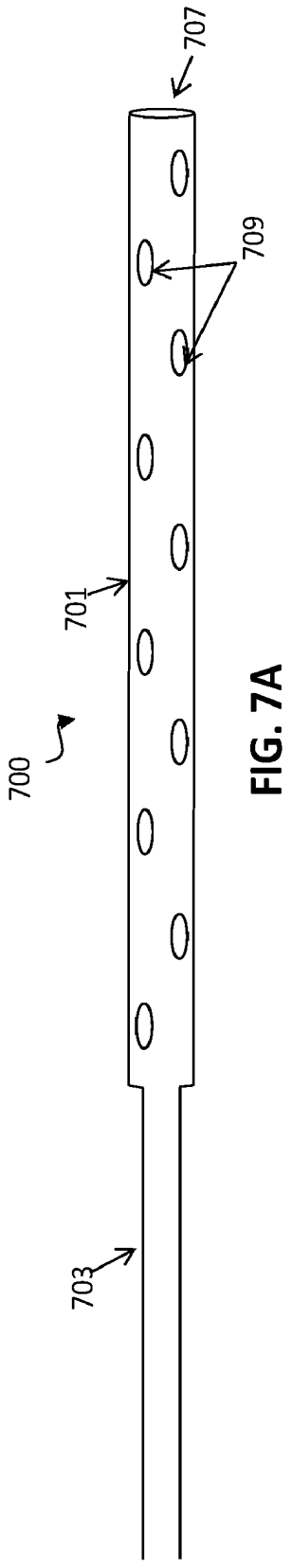

FIG. 7A

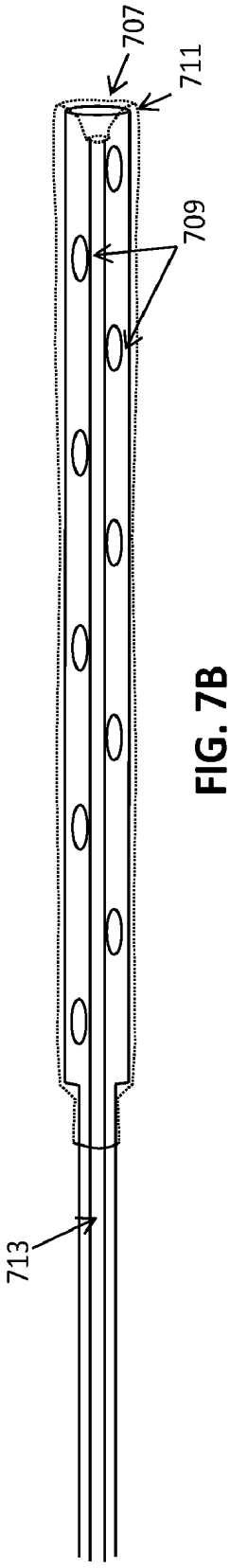

FIG. 7B

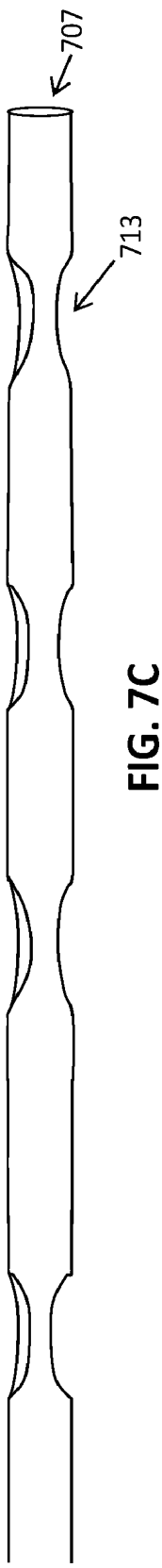

FIG. 7C

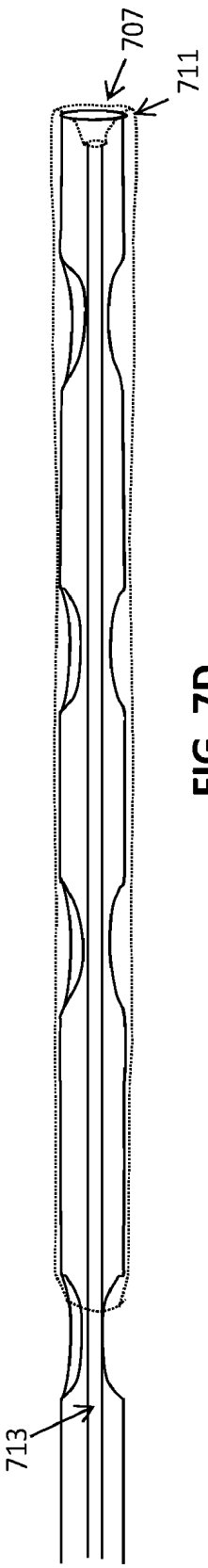

FIG. 7D

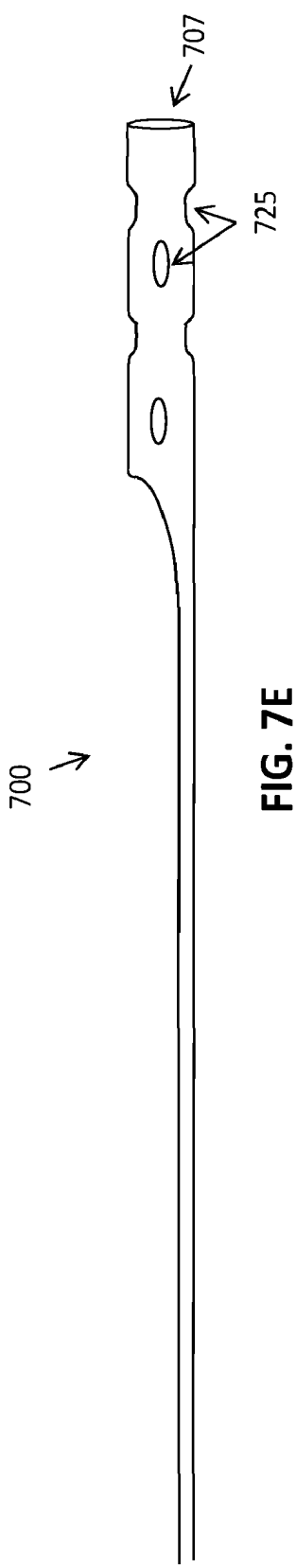

FIG. 7E

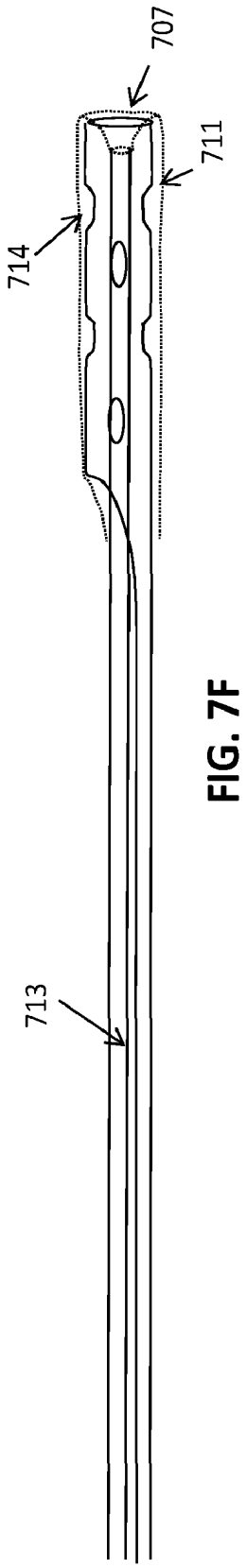

FIG. 7F

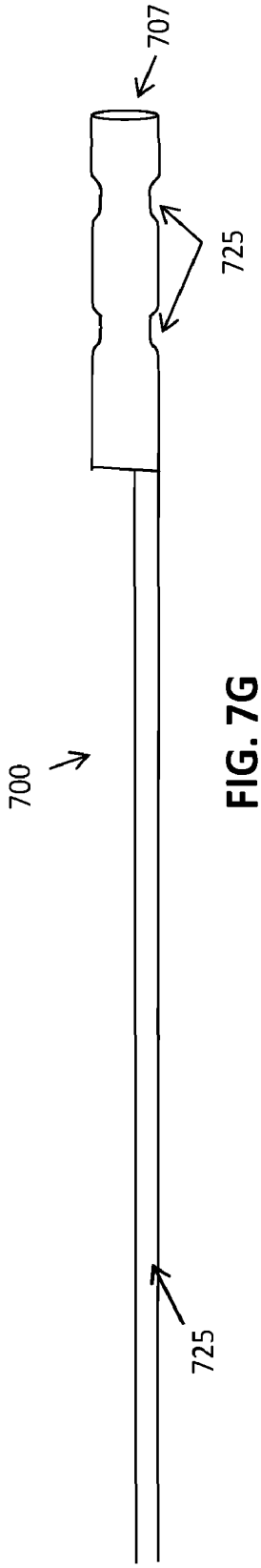

FIG. 7G

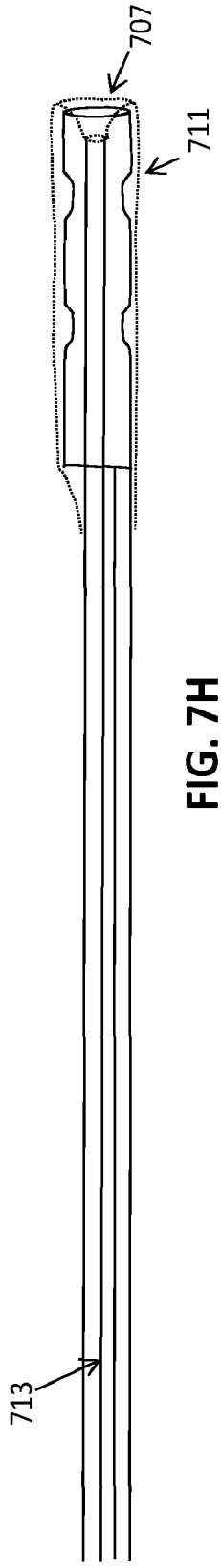

FIG. 7H

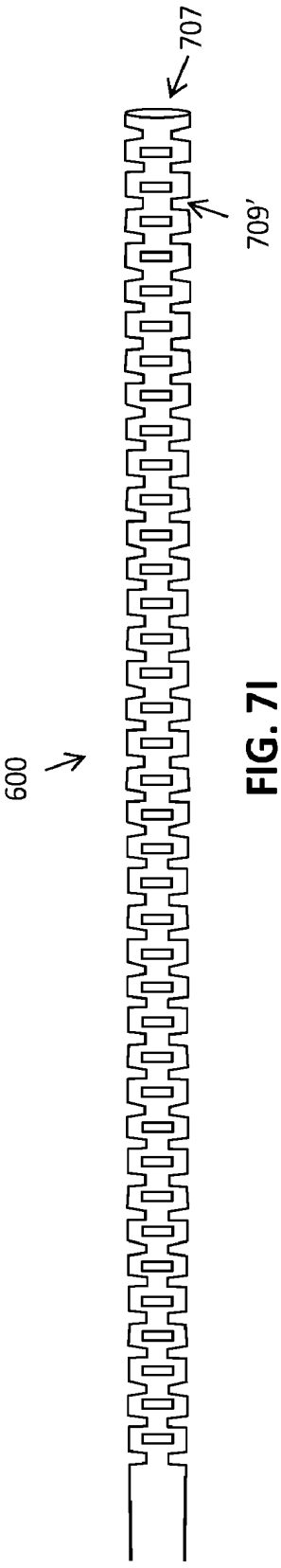

FIG. 7I

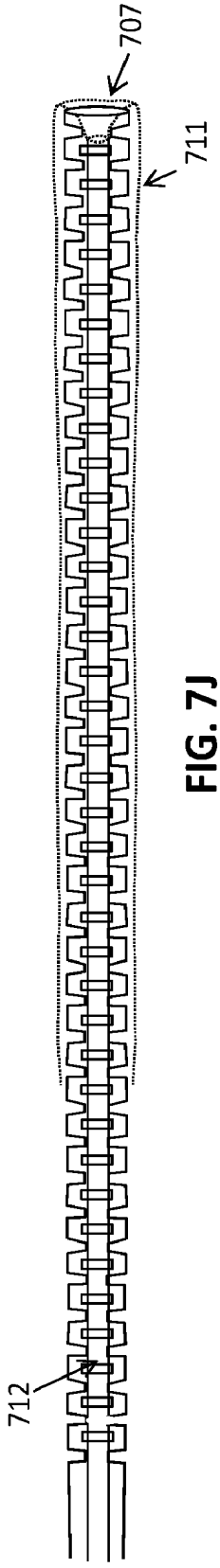

FIG. 7J

FIG. 7K

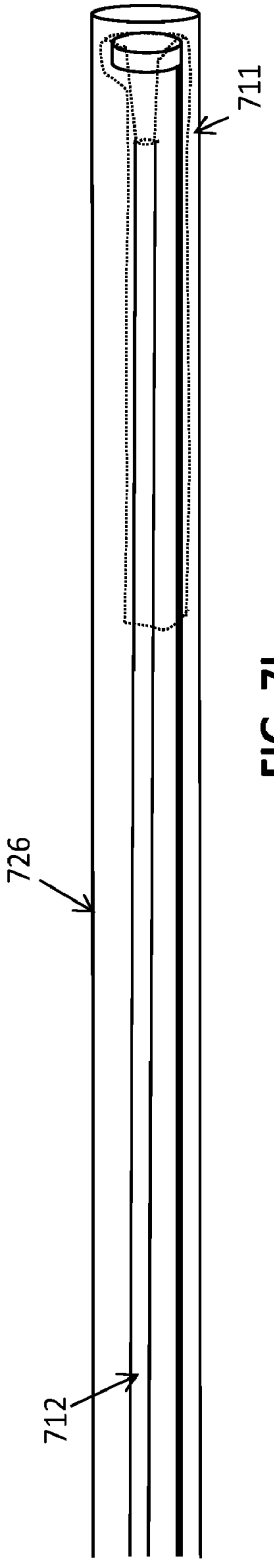

FIG. 7L

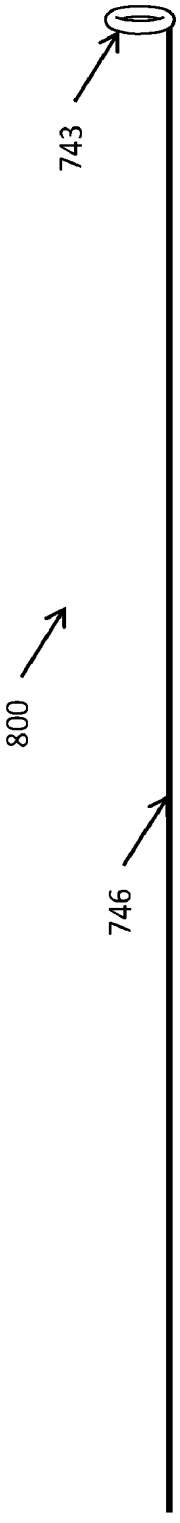

FIG. 8A

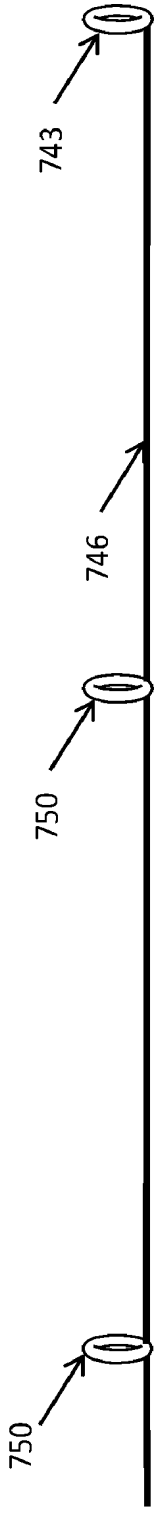

FIG. 8B

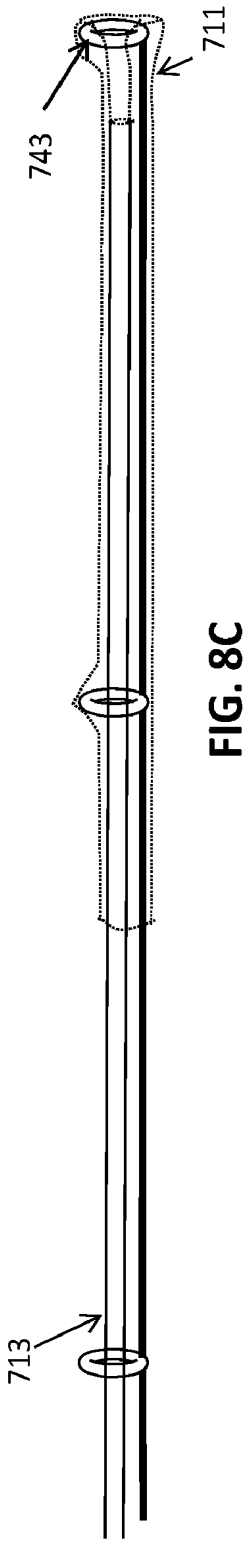

FIG. 8C

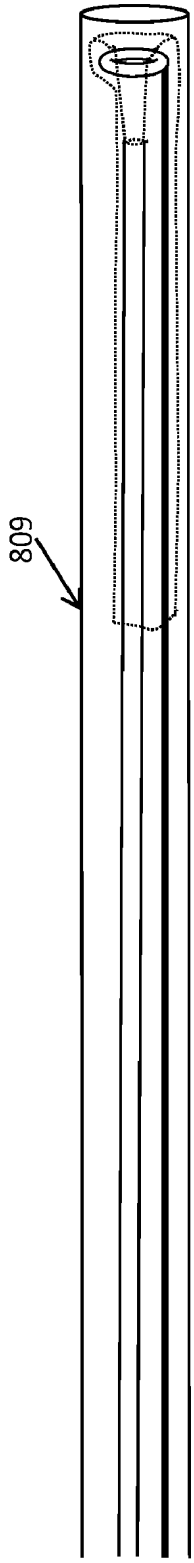

FIG. 8D

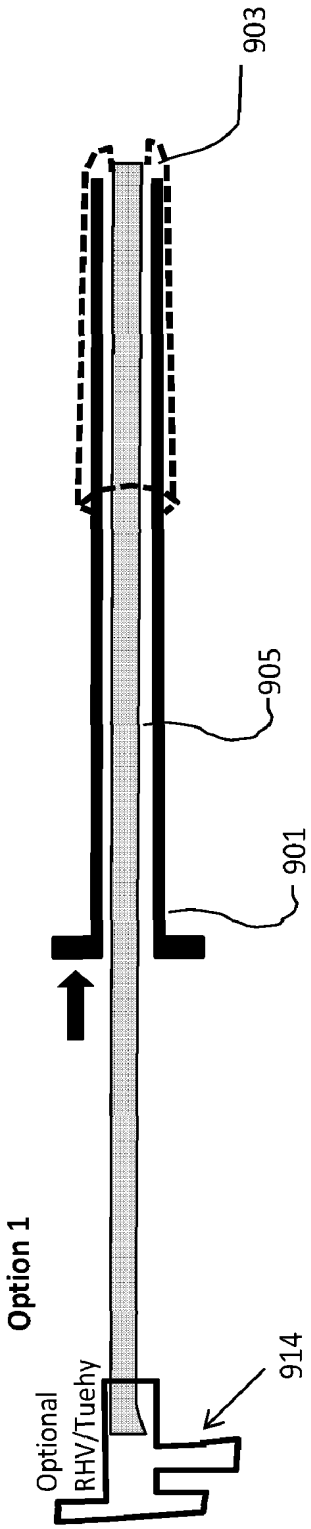

FIG. 9A

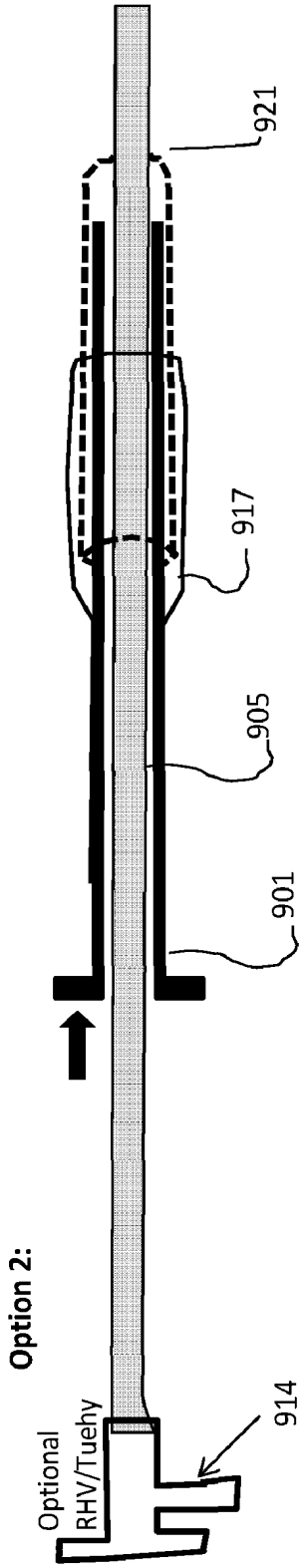

FIG. 9B

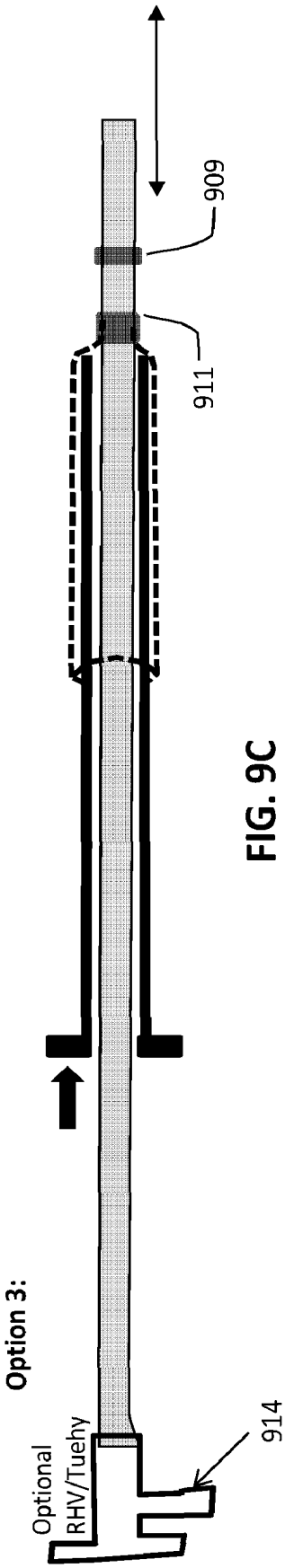

FIG. 9C

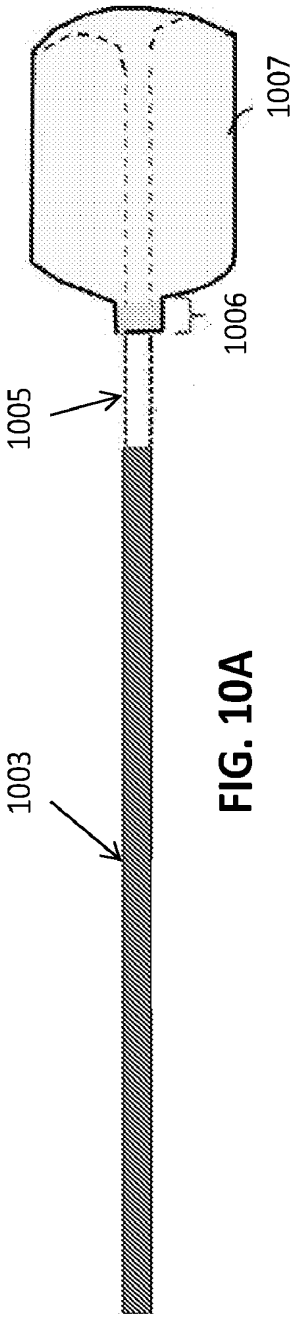

FIG. 10A

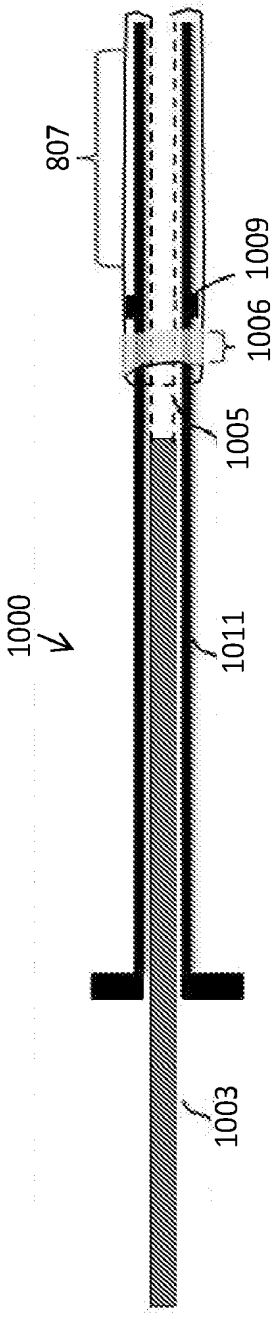

FIG. 10B

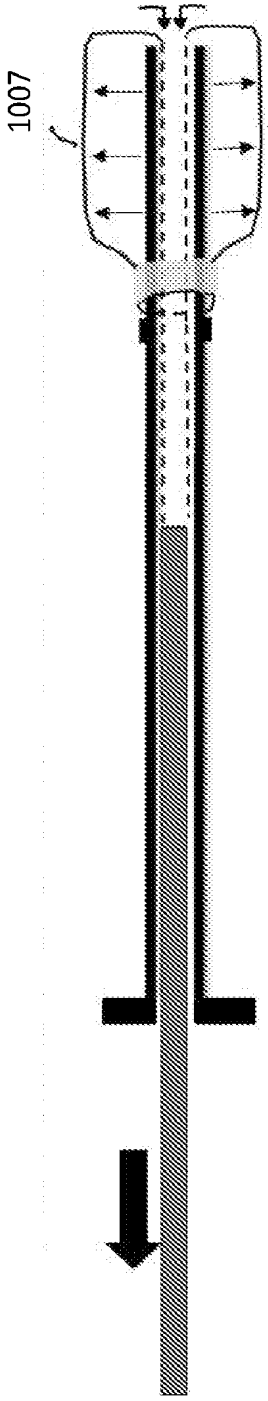

FIG. 10C

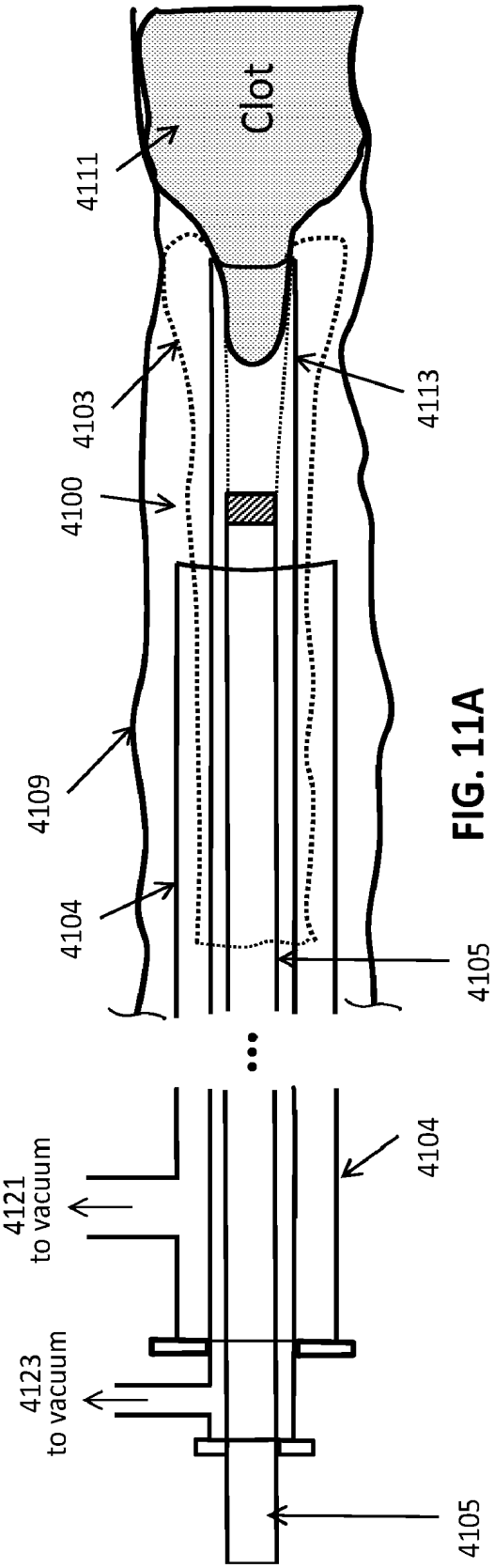

FIG. 11A

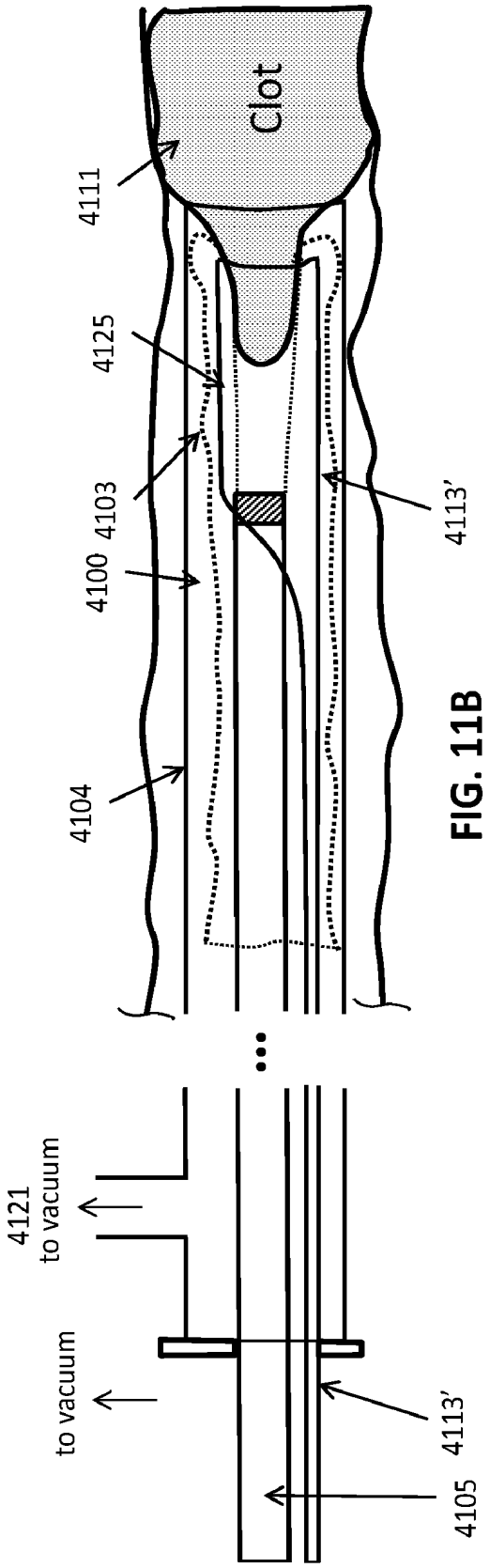

FIG. 11B

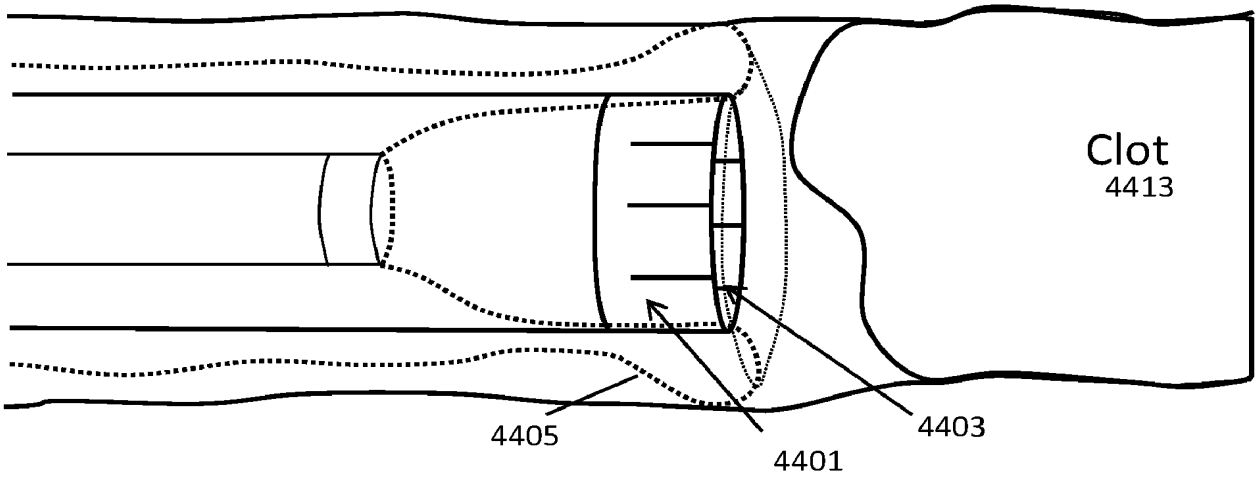

FIG. 12A

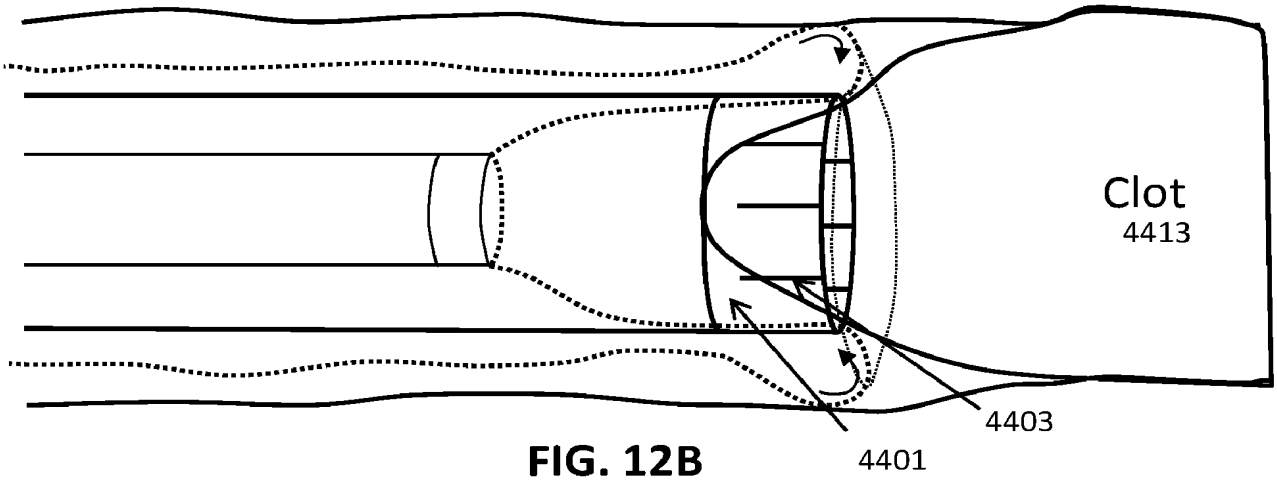

FIG. 12B

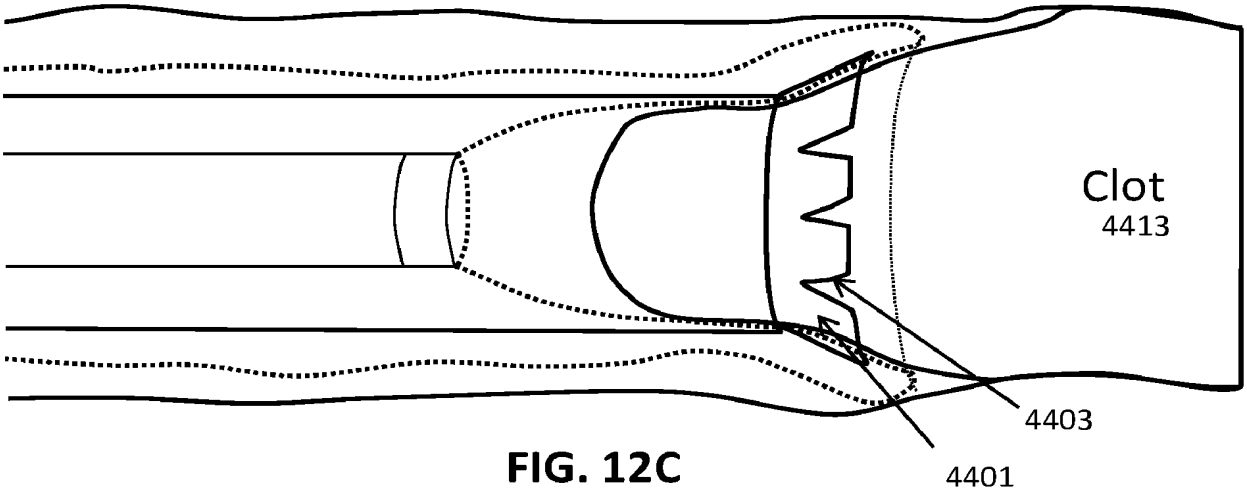

FIG. 12C

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; figures page 8, line 12 - page 11, line 16	1,16
A	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19) paragraphs [0152], [0153], [0167] - [0170]; figures 10, 13B	1,16

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 June 2017	29/08/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Giménez Burgos, R

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Form PCT/ISA/210 (second sheet) (April 2005)

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 17-25
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-16

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-16

A mechanical thrombectomy apparatus comprising: a catheter, a tractor, a puller and a tractor hold to secure an end of the tractor to an outside surface of the catheter until a force greater than a threshold force is applied by pulling the tractor proximally within the catheter.

---

2. claims: 26-31

A mechanical thrombectomy apparatus comprising: a catheter, a tractor, a puller and a guide wire lumen extending through the catheter, the puller and the tractor, and configured to pass a guide wire.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 17-25

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2498349 A	17-07-2013	EP 2802275 A1	19-11-2014
		GB 2498349 A	17-07-2013
		US 2015005781 A1	01-01-2015
		WO 2013106146 A1	18-07-2013
WO 2012009675 A2	19-01-2012	US 2014005712 A1	02-01-2014
		WO 2012009675 A2	19-01-2012

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

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International Bureau

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02 November 2017 (02.11.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/189591 A1

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

(21) International Application Number:
PCT/US2017/029440

(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

(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: INVERTING MECHANICAL THROMBECTOMY APPARATUSES AND METHODS OF USE IN THE VASCULATURE

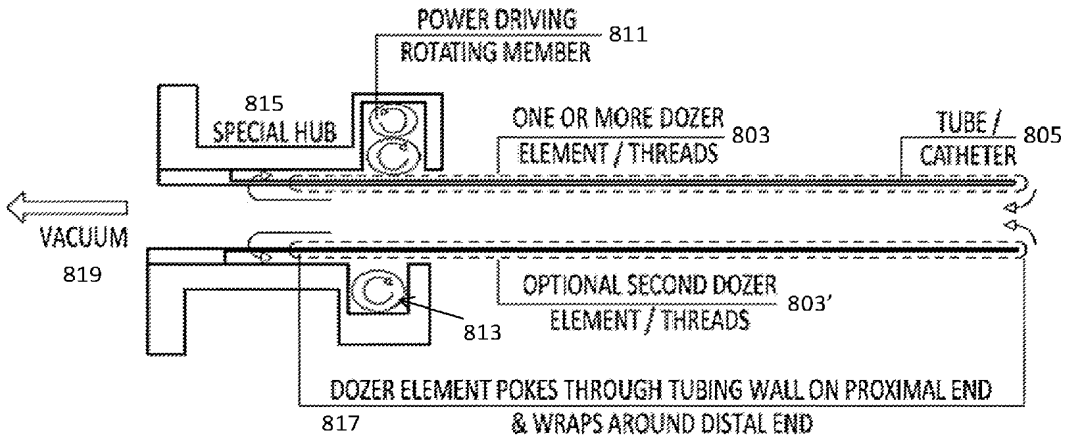

FIG. 8A

(57) Abstract: Mechanical thrombectomy apparatuses (devices, systems, etc.) are configured for being positioned within a vessel and used to remove a thrombus, e.g., clot, from within a vessel. One such system includes an inverting tractor thrombectomy apparatus having a tractor comprising a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support by extending the tractor region and/or a puller coupled to the tractor distally beyond the end of the catheter.

WO 2017/189591 A1

INVERTING MECHANICAL THROMBECTOMY APPARATUSES AND METHODS OF USE IN THE VASCULATURE

FIELD

[0001] The apparatuses and methods described herein relate to inverting mechanical thrombectomy apparatuses and methods of their use.

BACKGROUND

[0002] 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.

[0003] 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.

[0004] 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.

[0005] 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.

[0006] 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

[0007] Described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and methods for using them to remove a thrombus, e.g., clot, from within a vessel. These mechanical thrombectomy apparatuses may be inverting tractor thrombectomy apparatuses. Typically, the mechanical thrombectomy apparatuses described herein are inverting tractor thrombectomy apparatuses that includes a tractor (e.g., tractor region, tractor portion, etc.) comprising a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support. The elongate inversion support typically comprises a catheter having a distal end opening into which the tractor inverts. The flexible tractor inverts and rolls back into itself and may be drawn into the elongate inversion support in a conveyor-like motion; the outward-facing region rolls around to become an inward-facing region, e.g., within the lumen of the elongate inversion support. The rolling motion may thus draw a clot or other object within a vessel into the elongate inversion support.

[0008] Before these apparatuses can remove a clot from a vessel, however, they must be positioned within the vessel adjacent to the clot to be removed. As described herein, the inverting tractor thrombectomy apparatuses described herein may be accurately positioned either with our without the use of a guidewire or guide sleeve within a vessel by taking advantage of the rolling motion of tractor at the distal end of the apparatus. The arrangement of the tractor, elongate inversion support (e.g. which may be or may include a catheter) and the puller connected to the tractor may be used to easily and accurately position the apparatus

adjacent a clot and remove the clot in a manner that may be both easier and more efficient than other methods.

[0009] Further described herein are systems and methods for advancing an inverting tractor thrombectomy apparatus forward in the vasculature. These systems and methods may use use the rolling motion of the tractor to move through the vasculature including over/around clot.

[00010] For example, described herein are systems and methods for removing a clot from a vessel using a mechanical thrombectomy apparatus. The mechanical thrombectomy apparatus may include an elongate inversion support (comprising or consisting of a catheter) that extends in a long axis from a proximal end to a distal end, a puller extending distally within the elongate inversion support (e.g. catheter) and a flexible and tubular tractor, wherein the tractor is coupled to a distal end region of the puller and further wherein the tractor is inverted over a distal end opening of the catheter so that the tractor extends proximally over the catheter. Illustrative methods using the apparatus may include: advancing the puller distally within the elongate inversion support (e.g., catheter) and within the vessel towards a clot, so that the tractor extends from the puller distally beyond the distal end opening of the catheter, forming a gap between the tractor and the distal end opening of the catheter; advancing the catheter distally over the puller and into the gap; and drawing the clot into the catheter with the tractor by pulling the tractor proximally within the catheter so that the tractor rolls and inverts over the distal end opening of the catheter.

[00011] Further illustrative methods include repeating the advancing steps one or more times. For example the method may include: advancing the puller distally within the elongate inversion support (e.g., catheter) and within the vessel towards a clot, so that the tractor extends from the puller distally beyond the distal end opening of the catheter, forming a gap between the tractor and the distal end opening of the catheter; advancing the catheter distally over the puller and into the gap; repeating the advance steps until the distal end opening of the catheter is adjacent to the clot; and drawing the clot into the catheter with the tractor by pulling the tractor proximally within the catheter so that the tractor rolls and inverts over the distal end opening of the catheter.

[00012] These illustrative methods for advancing the clot pulling apparatus may therefore be described as "inchworm" type advancement, as the tractor is extended from within the catheter to distally extend in the vessel, then the catheter may follow the tractor distally. In any of these methods, the tractor may be 'reset' back into the catheter (as it may otherwise be left deployed out of the catheter along vessel), by pulling it back into the catheter. For

example, the tractor may be pulled back into the catheter by pulling proximally on the puller once the catheter distal end opening is positioned against the distal-facing tractor (the region doubling-back or inverting over itself) so that the tractor can roll over the distal end opening. Resetting or repositioning the tractor in this manner may require that the apparatus be configured to prevent jamming (e.g., "anti-jamming"), including one or more of: having a lubricious and/or smooth tip, having a tip region that is more rigid than the more proximal regions of the tip, and/or having a tractor that is biased to have a first relaxed configuration that has an outer diameter that is greater than the inner diameter of the catheter and a second relaxed configuration that has an inner diameter that is greater than the outer diameter of the catheter, where the tractor converts between the first and second configurations by inverting over itself (e.g., over the distal end opening of a catheter). These configurations may prevent the tractor for buckling when pushed out of the distal end opening or when pulled back into the distal end opening of the catheter.

[00013] The repeated steps of inching forward by extending the tractor distally (e.g., pushing the puller coupled to the tractor distally, including distally out of the distal opening of the catheter), then advancing the catheter into the gap formed by the folded-over tractor, e.g., the gap between the distal end opening of the catheter and the tractor, may also include resetting the tractor by pulling the tractor back into the catheter once the distal end of the catheter has been advanced. The steps of advancing the tractor distally from the distal- end of the catheter and advancing the catheter behind the tractor (and optionally pulling the tractor back into the catheter by pulling proximally while holding the catheter fixed (or advancing it distally) may be repeated until the apparatus is adjacent to the clot; thereafter the clot can be removed as discussed above, by pulling the puller proximally to draw the tractor into the catheter.

[00014] In general, drawing the clot into the catheter may include advancing the catheter distally while pulling the pusher proximally. Further, the apparatus may be advanced distally (or retracted proximally) without the use of a guidewire or guide catheter. For example, advancing the puller distally may comprise advancing the puller without using a guidewire extending distal to the puller. Advancing the puller may comprise extending the distal end of the puller out of the distal end opening of the catheter. Alternatively the puller may remain in the catheter when advanced distally.

[00015] The tractor may be any appropriate tractor, including a woven, braided, or knitted tractor, or a tractor formed of a solid sheet of material (e.g., that may be cut or perforated). For example, advancing the puller may comprise extending the tractor distally within the

vessel, further wherein the tractor comprises a woven flexible and tubular tractor. Advancing the puller may comprise extending the tractor distally within the vessel, further wherein the tractor comprises a knitted tractor.

[00016] The systems described herein include a puller and tractor having a lumen (e.g., central lumen) through which a guidewire may be advanced. For example, advancing the puller may comprise extending the tractor distally within the vessel, further wherein the puller comprises a central lumen configured to pass a guidewire therethrough.

[00017] Further, the systems and methods described herein may be used (and performed) in any vessel within the body, including peripheral and neurovascular vessels. For example, these systems and methods may be used (performed) within an internal carotid artery (e.g., advancing the puller may comprise advancing the puller within an internal carotid artery).

[00018] Also described herein are systems including a mechanical thrombectomy apparatus that may be positioned within a vessel for removing a clot from within the vessel, in which the mechanical thrombectomy apparatus includes a puller within a first catheter that is within a second catheter, wherein the puller and second catheter are connected by a flexible and tubular tractor. For purposes of illustration, a method using such system may comprise: advancing the puller distally through the first catheter and the second catheter and within the vessel towards a clot, so that the flexible and tubular tractor extends from the puller beyond a distal end opening of the first catheter and beyond a distal end opening of the second catheter; advancing the outer catheter distally through the vessel by one or more of: holding the position of the first catheter within the vessel and pulling the puller proximally within the first catheter; or moving the first catheter distally relative to the puller; and drawing the clot into the first catheter with the flexible and tubular tractor by pulling the flexible and tubular tractor proximally within the first catheter so that the flexible and tubular tractor rolls and inverts over the distal end opening of the catheter. Any of these methods may also include repeating the advancing steps until the clot is adjacent to the distal end of the puller.

[00019] Drawing the clot into the catheter may further include advancing the first catheter distally while pulling the pusher proximally. Advancing the puller distally may include advancing the puller without using a guidewire extending distal to the puller. Advancing the puller may include extending the flexible and tubular tractor distally within the vessel further wherein the flexible and tubular tractor comprises a woven flexible and tubular tractor. Alternatively, advancing the puller may include extending the flexible and tubular tractor distally within the vessel further wherein the flexible and tubular tractor comprises a knitted flexible and tubular tractor.

[00020] Advancing the puller may comprise extending the flexible and tubular tractor distally within the vessel further wherein the puller has a central lumen configured to pass a guidewire therethrough, and drawing the clot into the first catheter may comprise uncoupling the flexible and tubular tractor from the second catheter.

[00021] Also described herein are mechanical thrombectomy apparatus for removing a clot from a vessel that include a motorized or motor-driven tractor. For example described herein are apparatuses including: a flexible catheter having a distal end and a distal end opening; a tractor comprising a flexible belt that extends within the catheter, inverts over the distal end opening of the catheter and extends along the outer diameter of the catheter; a power drive at a proximal end of the flexible catheter configured to drive the tractor around the catheter so that it inverts over the distal end opening of the catheter; and a guidewire lumen through the catheter and the tractor configured to pass a guidewire.

[00022] The flexible belt may comprise a flexible tube. In some variations, the tractor comprises a plurality of flexible belts that each extend within the catheter, invert over the distal end opening of the catheter and extend along the outer diameter of the catheter.

[00023] The the power drive may be configured to engage with the flexible belt on an outer surface of the catheter. The power drive may comprise an annular ring surrounding the catheter and the tractor.

[00024] Any of these apparatuses may include an outer catheter configured to enclose the flexible catheter and tractor, wherein the flexible catheter and tractor may be inserted through the body within the outer catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[00025] 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:

[00026] FIGS. 1A-1H illustrate an example of a mechanical thrombectomy apparatus for mechanically removing an object such as a clot form a body region. FIG. 1A shows an example of an elongate inversion support portion of an apparatus, configured as a catheter. 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.

[00027] 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).

[00028] FIGS. 2A-2E illustrate a method of positioning a mechanical thrombectomy apparatus within a vessel and/or removing a clot from a vessel using the mechanical thrombectomy apparatus. In FIGS. 2A-2E the apparatus is shown inching distally within the vessel towards the clot using the tractor, so that the clot may be captured and removed by the tractor. In FIGS. 2A-2E the apparatus is advanced distally without the use of a guidewire.

[00029] FIGS. 3A-3D illustrate a method of positioning a mechanical thrombectomy apparatus within a vessel and/or removing a clot from a vessel using the mechanical thrombectomy apparatus similar to that shown in FIGS. 2A-2E only using a guidewire.

[00030] FIGS. 4A-4D illustrate a method of positioning a mechanical thrombectomy apparatus within a vessel and/or removing a clot from a vessel using the mechanical thrombectomy apparatus in which the distal end of the puller, to which one end of the tractor is attached, is extended distally from the catheter.

[00031] FIGS. 5A-5C illustrate a method of positioning a mechanical thrombectomy apparatus within a vessel and/or removing a clot from a vessel using the mechanical thrombectomy apparatus similar to that shown in FIGS. 4A-4D but include the use of a guidewire.

[00032] FIGS. 6A-6B illustrates another method of positioning a mechanical thrombectomy apparatus within a vessel and/or removing a clot from a vessel using the mechanical thrombectomy apparatus, in which the apparatus include a tractor that is connected (attached) to both the pusher and an outer catheter or element.

[00033] FIG. 7 illustrates one region (e.g., the internal carotid artery) in which the apparatuses and methods described herein may be used.

[00034] FIG. 8A-8B illustrate an example of a mechanical thrombectomy apparatus for removing a clot from a vessel that include a motorized or motor-driven tractor. FIG. 8A shows the apparatus in a side view, schematically illustrating the internal components. FIG. 8B is an example of a catheter and tractor(s) that may be used with an apparatus such as the one shown in FIG. 8A.

[00035] FIGS. 9A-9B illustrate a method of operating a mechanical thrombectomy apparatus for removing a clot from a vessel that include a motorized or motor-driven tractor, such as the one shown in FIGS. 8A-8B. FIG. 9C illustrates a motorized or motor-driven (e.g., "power driven) continuous tractor that is loaded into a larger catheter (e.g., an intermediate catheter).

DETAILED DESCRIPTION

[00036] Described herein are mechanical thrombectomy apparatuses, including manually drive and power-driven apparatuses, and methods of using them. In particular, described herein are methods of positioning these apparatuses within a vessel and/or removing clot with them that may include extending the tractor region and/or the puller distally of the distal end of the apparatus to assist in advancing the apparatus distally.

[00037] Any of the mechanical thrombectomy apparatuses described herein may have an inverting tractor that is configured to prevent jamming and grab a blood clot. These

apparatuses may include an elongate elongate inversion support support that supports an annulus over which the tractor inverts at the distal end. The tractor may comprise a flexible tube that doubles back over (e.g., inverts) over the distal end of the elongate inverting support (e.g., a catheter) so that it extends into the annuls opening of the elongate inverting support and an inner puller coupled to the inner end of the tractor that the tractor can be pulled proximally to pull and invert the tractor over the annulus at the distal end of the elongate inverting support to roll and capture a clot. The apparatus may include a guidewire lumen extending through the elongate inverting support, and/or tractor puller that is configured to pass a guidewire.

[00038] The apparatuses described herein may be adapted to prevent jamming, e.g., by including a coating (e.g., hydrophilic, lubricious coating, etc.) or the like to enhance the sliding and inverting of the tractor over the distal end. Further, any of these apparatuses may include one or more projections that are configured to enhance grabbing and/or maceration of a clot. Grabbing of a clot may be particularly, but not exclusively, helpful when the tractor is lubricious. Although lubricious tractors may may resist jamming and require less force to operate, e.g., inverting over the distal end of the catheter, it may be more difficult to initially grab or grasp clot when the tractor is more lubricious. It may also be particularly helpful to include projections that are retracted along the length of the tractor adjacent to the outer diameter of the elongate inverting support (e.g., catheter), for example, when positioning the apparatus within a vessel, but extend the projections outward from the tractor when rolling and inverting to grab a clot.

[00039] In general, a mechanical thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an elongate inversion support having a distal end and a distal annulus, and a flexible tractor assembly at least partially inverted and configured to roll and invert over the distal annulus of the elongate inverting support.

[00040] In many of the examples described herein, the elongate inversion support is a catheter (or a portion of a catheter at the distal end) and the annulus is formed by the distal end opening of the catheter; the tractor extends within the catheter and doubles back over the distal end of the catheter to extend over the outer diameter of the catheter at the distal end of the catheter, although it may extend proximal for any appropriate distance (including between 1-30 cm, between 2-20 cm, greater than 1 cm, 2 cm, 3 cm, 4 cm, 5 cm, 6 cm, 7 cm cm, 8 cm, 9 cm, 10 cm, 11 cm, 12 cm, 15 cm, 20 cm, etc.). The end of the tractor within the catheter may be coupled to a puller (e.g., at a proximate puller region connected to the distal or inner end of the tractor). The tubular tractor may include an elongate lumen that is configured to

allow passage of a guidewire. The tubular tractor may also be configured to slide along the long axis within the catheter lumen and invert over the distal end opening of the catheter when the proximal end region is pulled proximally. The tractor may be referred to herein as a tractor assembly, tractor portion, tractor tube, or simply a tractor, and is typically positioned and longitudinally slideable within the catheter, and arranged so a portion of the tractor (sometimes referred to as the "distal tractor region" or "distal-facing" tractor region) doubles back over itself.

[00041] For example, FIG. 1A shows one variation of a catheter of an elongate inversion support that may form part of the apparatuses described herein. In this example, the elongate inversion support includes a catheter 100 having a distal end region 103 that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing harness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00042] In FIG. 1A, the elongate inversion support is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of of compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include a elongate inversion support that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like (as will be described in greater detail below in reference to FIGS. 42A-43D) or may be skived. Thus, any of the apparatuses and methods described herein may be adapted for use with an elongate inversion support that

is not limited to catheters, including elongate inversion supports that include a portion of a catheter, or that include a ring or other structure forming the annulus at the distal end. In FIG. 1A the catheter 100 of the elongate inversion support may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00043] 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).

[00044] 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).

[00045] 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.

[00046] 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.

[00047] 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.

[00048] In general the mechanical thrombectomy apparatuses described herein may be highly flexible, both before actuating and during operation. For example, the flexible tractor may not increase the stiffness/flexibility of the catheter of the elongate inversion support, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortious vessels of the neurovasculature. Described herein are flexible tractor tube portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

ILLUSTRATIVE METHODS OF ADVANCING AN INVERTING TRACTOR APPARATUS

[00049] For purposes of better understanding the mechanical thrombectomy systems and apparatuses disclosed herein, various methods of their use will now be described. In one such method, a mechanical thrombectomy apparatus is be advanced distally within a vessel and may grab and engulf a clot that is located distally by using the tractor to extend distally ahead of the apparatus, and in some cases pull (e.g., against the vessel walls) to guide or draw the catheter distally forward. This method of advancement may be referred to as "inchworm" or 'worm-like" motion within the vessel. For example, FIGS. 2A-2E illustrate a first method of advancing a mechanical thrombectomy apparatus and/or removing a clot from a vessel using the mechanical thrombectomy apparatus. In this example, the apparatus includes a catheter 205 extending proximally to distally, a puller 207 (shown as a thin tube or hypotube, though it may be a wire or rod, as mentioned above), extending distally within the catheter and a flexible and tubular tractor 209. The tractor is coupled to a distal end region of the puller 217

and the tractor is inverted over a distal end opening of the catheter 219 so that the tractor extends proximally over the outside (outer diameter) of the catheter. In operation, the apparatus may be advanced distally (e.g., towards a clot 213) in a vessel 211, as shown in FIGS. 2B-2D. In FIG. 2B, the puller is pushed distally 220 (shown by arrows on the left) to advanced distally within the catheter and within the vessel towards a clot, so that the tractor extends from the puller distally beyond the distal end opening of the catheter 218, forming a gap 219 between the tractor and the distal end opening of the catheter. This gap is an annular, distal-facing cavity (e.g. pouch) formed in the tractor, and into which the distal end opening of the catheter may be advanced, as shown in FIG. 2C. In FIG. 2C, the catheter is advanced distally over the puller and into the gap. Following this step, the tractor is extended further outside of the catheter, and is in contact with the walls of the vessel 211, through it does not have to be. The outer diameter of the expanded tractor maybe narrower than the vessel inner diameter (ID) or it may be greater than then ID of the vessel (and may therefore touch against them.

[00050] When advancing the catheter distally 222 (shown in arrows on left) and into the gap, the puller may be held in position relative to the catheter. In variations in which the tractor contacts the outer diameter of the vessel, this contact may hold the tractor in place against the vessel wall.

[00051] The steps of FIGS. 2B and 2C may be repeated multiple times to continue to advance the apparatus distally, however, in some variations it may be beneficial to retract or reset the tractor back into the catheter, e.g., by withdrawing the puller proximally to pull the tractor back into the catheter. This is illustrated in FIG. 2D. In this example, the puller 207 is withdrawn proximally 224 (arrows on left), so that the tractor coupled to the puller 217 is pulled back into the catheter after inverting over the distal end opening of the catheter. It may be beneficial to perform this step after the catheter has been extended distally fully, e.g., until it pushes distally against the back of the inverting (bent-over) region, as shown in FIG. 2D. One the tractor has been sufficiently retracted, the steps shown in FIGS. 2B-2C may be repeated, as shown in FIG. 2E, until the distal end opening of the catheter is adjacent to the clot. After positioning next to the clot (and in some cases adjacent to it), vacuum may be applied to pull the clot into contact with the apparatus, and/or the device may be advanced by pushing the catheter distally while pulling the puller proximally to roll and invert the tractor into the catheter (see., e.g., FIG. 1H).

[00052] The method of advancing the apparatus described in FIGS. 2A-2E above may be particularly helpful in advancing the apparatus within a vessel even without the use of a

guidewire or equivalent (e.g., guide catheter). However this method may also be used with a guidewire, as illustrated in FIGS. 3A-3D. In this example, the apparatus 300 is otherwise the same as shown in FIGS. 2A-2E, but may include or be used with a guidewire 355. In general, the same steps may be performed as discussed above. Alternatively, before or after a cycle of inching forward as describe in FIGS. 2A-2E, the apparatus may be slid distally along the guidewire toward the clot. Thus, in some variations, this method may be used to help navigate the apparatus within congested or tortious regions where advancing by sliding may not be as effective.

[00053] Another method of advancing an apparatus distally using the tractor is illustrated in FIGS. 4A-4D. This method is also similar to that shown in FIGS. 2A-2E and 3A-3C above, but may extend the tractor portion even further distally using the pusher, so that the pusher extends past the distal end of the apparatus, out of the catheter. In contrast, in FIGS. 2A-2E, the pusher remains substantially within the catheter, thus smaller 'steps' may be taken by the device.

[00054] In FIG. 4A, the apparatus is similar to that discussed above, including a puller 407 that is connected at a distal end region 417 to a tractor 403. The tractor is inverted over the distal end opening of a catheter 405. The apparatus may be advanced within a vessel 411 towards a clot 413, as shown in FIG. 4B, by advancing the inner puller 407 distally 420 so that the puller distal end (and attached tractor) extends distally from the catheter distal end opening. The tractor may tent, forming a gap 419 or pouch between the distal end of the catheter and the distal face of the tractor (distal-facing end). In this example, the gap 419 is formed between the distal end of the catheter and the end of the puller. Thereafter, as shown in FIG. 4C, the catheter may be advanced distally 422 within the gap of the tractor. In both this example and the example shown in FIGS. 2A-2E, the puller and tractor may be advanced distal of the catheter distally while the outer portion of the tractor remains over the catheter, e.g. the second end of the tractor 414 that is shown extended over the outer diameter of the catheter remain proximal to the distal end of the catheter. Once positioned near the clot 413, the tractor may be rolled into the catheter by pulling proximally on the puller and (optionally) advancing the apparatus distally by pushing the catheter distally.

[00055] If the distal end of the apparatus (e.g., the distal-facing, inverting tractor) is not adjacent to the clot 413, the steps above can be repeated, either with or without retracting the tractor into the catheter (e.g., by pulling proximally on the puller). FIG. 4D illustrates an example of retracting the tractor into the catheter by pulling proximally on the puller 424.

[00056] FIGS. 5A-5C illustrate the method of FIGS. 4A-4C with a guidewire 515. The apparatus may be the same (e.g., may include a puller 507 coupled at a distal end 517 to a flexible tractor 503 that is inverted over the distal end opening of a catheter 505 and extending along the outer surface of the catheter). The steps may be the same as discussed above, including advancing the tractor and puller distally by pushing the puller distally 520 towards a clot 513, as shown in FIG. 5B. The catheter may then be advanced (by sliding over the guidewire) as shown in FIG. 5C into the gap or pouch formed by the tractor 519. Once positioned near the clot 513, the tractor may be rolled into the catheter by pulling proximally on the puller and (optionally) advancing the apparatus distally by pushing the catheter distally.

[00057] FIGS. 6A-6B illustrate another method for advancing an apparatus distally, in which both ends of the tractor 603 are coupled to axially movable elements. For example, in FIG. 6A the first end of the tractor 603 is coupled to a puller 607 within the catheter 605. In addition, the second end of the tractor is shown coupled to an outer axially movable member (second or outer catheter 619). This tri-axial system may be used to inchworm the apparatus distally by alternately holding and pulling on the various pullers and catheters. For example, in FIG. 6A, the tip of the apparatus may be advanced distally toward a clot by holding the catheter fixed, allowing the puller to float (e.g., not constraining it) and pulling the outer catheter proximally 640. As a result, the outer portion of the flexible tractor may be pulled proximally, pulling the puller and opposite end of the tractor distally, as shown in FIG. 6B. Thereafter, the puller may be held in place, the outer catheter may be free to move axially, and the catheter may be advanced distally into the gap formed by the tractor, which may drive the tractor distally (e.g., back to the configuration shown in FIG. 6A) and pull the outer catheter distally. These steps may be repeated as necessary. In some variations the outer catheter may be removably attached to the tractor, and the tractor may be pulled proximally to separate from the outer catheter.

[00058] A guidewire may also be used with this method. In this example, tip advancement of the apparatus may take advantage of the outer (e.g., guide) catheter stiffness (e.g., bending and column stiffness) to aid in catheter tip advancement. This may be particularly helpful in neurovascular regions, such as shown in FIG. 7.

[00059] FIG. 7 illustrate the uses of the methods described herein to advance the apparatus 701 within a neurovascular structure such as the internal carotid segment in the head. For example, the distal tip of the apparatus may be positioned at the distal tip of the internal carotid segment; once positioned, an advancement method such as one of those described

herein may be used drive the apparatus distally forward towards the clot. Such a method may create a pushing force forward from the internal carotid artery without sacrificing the trackability of the apparatus or the small outer diameter of the apparatus.

[00060] The apparatuses described herein may also be used to advance other apparatuses (including catheters and tubes). For example, any of these apparatuses and methods may be used in reverse (e.g. pulling proximally on an outer portion of the catheter) to pull an apparatus within the lumen of the tractor distally for delivery at an internal vessel site.

[00061] Thus, to advance a tool (e.g., a tube, etc.) into the patient, a tractor inserted into the body (which may be advanced as descried herein, even for use without performing a thrombectomy or in addition to a thrombectomy) may be pulled from the outside of the catheter proximally (e.g., with an overtube or pull wire) to invert the tractor in the opposite direction from out of the catheter. As the tractor on the OD of the catheter is pulled proximally, it may advance a tool (e.g., tube) inside the apparatus to the target location in the patient. This mechanism could be used in a variety of applications including; passing mature clot or vessel lesion, placing an intubation system (e.g., in a throat), providing rectal or vaginal access, performing NOTES surgery, inserting a tool such as a trocar, inserting a scope into a body region (e.g., gastrointestinal region, colon, blood vessel lumen, etc.), inserting a robotic tool, crossing a calcified vessel, etc. Other applications of the apparatuses and methods of removing and/or placing material using the apparatuses described herein may include include removal of tissue, such as gall bladder removal and removal of fat (liposuction). For example a cutting or ablative tool may be passed down the middle of the apparatus, through the catheter, the puller and the tractor, and extended from the distal end, where it may be used to cut tissue that may then be pulled out of the body using the tractor by pulling the tractor proximally within the catheter. Note that this method may be used to remove both the tool and/or the cut tissue. Thus, despite referring to these apparatuses as mechanical mechanical thrombectomy apparatuses herein, any of these devices may be adapted for uses not limited to thrombectomy, and may alternatively be referred to as mechanical tractor apparatuses.

[00062] Also described herein are powered mechanical thrombectomy apparatuses in which the tractor may be driven by a driver such as an electrical motor. For example, FIG. 8A illustrates an example of a power driven tractor in a mechanical thrombectomy apparatus. The apparatus may drive the tractor continuously in a loop, thus the tractor may be configured as a closed loop, belt or toroid of material that extends around a catheter. The power drive may run the apparatus in either the forward or reverse directions. In FIG. 8A,

the tractor comprises a plurality of belts 803 that extend around and through the catheter 805. A drive motor 811 drives rotation of the belts. In FIG. 8A the drive motor drives a ring 813 that can therefor drive multiple belts forming the tractor or in some variations, a single torus that passes over the supporting catheter. The catheter may include holes or openings 817 into which the belts forming the tractor may reside. The belts extend along the length of the catheter 805. In this example, a hub 815 holds the proximal end of the catheter and holds the belts against the drive motor and/or drive ring that is driven by the drive motor, and may also connect to a vacuum 819.

[00063] FIG. 8B shows an enlarged view of a catheter and tractor that may be used with the apparatus shown in FIG. 8A. FIG. 8B shows the catheter 805 including a plurality of belts 803, 803' forming the tractor. The belts pass through an opening in the catheter at the proximal end, but roll over the distal end of the catheter, and extend along the outer and inner longitudinal axis.

[00064] FIGS. 9A-9B illustrates an example of operation of a power driven mechanical thrombectomy apparatus configured to grab a clot. In FIG. 9A, the apparatus 900 is similar to that shown in FIG. 8A, above, including a plurality of belts 903, 903' forming the tractor, and an internal catheter 905; the bests rotate down the length of the catheter. Note that the catheter may be rigid or flexible. The catheter may include channels, and/or notches or other guide along its length for guiding and/or enclosing the belts at various portions. In FIG. 9A, the apparatus is positioned adjacent to a clot 924. The clot may initially be grabbed using aspiration (e.g., vacuum). In FIG. 9B, the apparatus may is shown after grabbing the clot, and compressing it within the catheter.

[00065] Note that the power-driven mechanical thrombectomy apparatuses shown in FIGS. 9A and 9B do not include a puller, as the motor may act like a puller. In some variations a separate puller may be used.

[00066] As mentioned above, any of the apparatuses described herein may be used with an additional outer catheter, including the powered apparatuses described herein. For example, FIG. 9C illustrates an example of a powered apparatus 900 used with an intermediate catheter having a larger OD than the powered mechanical thrombectomy apparatus. In this example, the length of the apparatus is slightly greater or almost equal to the length of the intermediate catheter 930, so that just the distal end region of the apparatus, including the inverting tractor (belts) is accessible and/or sticks out 933 of the intermediate catheter. Alternatively, the apparatus may be retracted into the outer (intermediate) catheter slightly, or may extend substantially from the end of the outer catheter.

[00067] 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.

[00068] 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.

[00069] 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 "/".

[00070] 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.

[00071] 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.

[00072] 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.

[00073] 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.

[00074] 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.

[00075] 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.

[00076] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the

above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

What is claimed is:

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

a flexible catheter having a distal end and a distal end opening;

a tractor comprising a flexible belt that extends within the catheter, inverts over the distal end opening of the catheter and extends along the outer diameter of the catheter;

a power drive at a proximal end of the flexible catheter configured to drive the tractor around the catheter so that it inverts over the distal end opening of the catheter; and

a guidewire lumen through the catheter and the tractor configured to pass a guidewire.

2. The apparatus of claim 1, wherein the flexible belt comprises a flexible tube.

3. The apparatus of claim 1, wherein the tractor comprises a plurality of flexible belts that each extend within the catheter, invert over the distal end opening of the catheter and extend along the outer diameter of the catheter.

4. The apparatus of claim 1, wherein the power drive is configured to engage with the flexible belt on an outer surface of the catheter.

5. The apparatus of claim 1, wherein the power drive comprises an annular ring surrounding the catheter and the tractor.

6. The apparatus of claim 1, further comprising an outer catheter configured to enclose the flexible catheter and tractor, wherein the flexible catheter and tractor may be inserted through the body within the outer catheter.

7. A method of removing a clot from a vessel using a mechanical thrombectomy apparatus including a catheter extending from a proximal end to a distal end, a puller extending distally within the catheter and a flexible and tubular tractor, wherein the tractor is coupled to a distal end region of the puller and further wherein the tractor is inverted over a distal end opening of the catheter so that the tractor extends proximally over the catheter, the method comprising:

advancing the puller distally within the catheter and within the vessel towards a clot, so that the tractor extends from the puller distally beyond the distal end opening of the catheter, forming a gap between the tractor and the distal end opening of the catheter;

advancing the catheter distally over the puller and into the gap;

repeating the advance steps until the distal end opening of the catheter is adjacent to the clot; and

drawing the clot into the catheter with the tractor by pulling the tractor proximally within the catheter so that the tractor rolls and inverts over the distal end opening of the catheter.

8. The method of claim 7, wherein repeating further comprises comprising pulling the pusher proximally within the catheter to invert a portion of the tractor over the distal end opening of the catheter.

9. The method of claim 7, wherein drawing the clot into the catheter further comprises advancing the catheter distally while pulling the pusher proximally.

10. The method of claim 7, wherein advancing the puller distally comprises advancing the puller without using a guidewire extending distal to the puller.

11. The method of claim 7, wherein advancing the puller comprises extending the distal end of the puller out of the distal end opening of the catheter.

12. The method of claim 7, wherein advancing the puller comprises extending the tractor distally within the vessel, further wherein the tractor comprises a woven flexible and tubular tractor.

13. The method of claim 7, wherein advancing the puller comprises extending the tractor distally within the vessel, further wherein the tractor comprises a knitted tractor.

14. The method of claim 7, wherein advancing the puller comprises extending the tractor distally within the vessel, further wherein the puller comprises a central lumen configured to pass a guidewire therethrough.

15. The method of claim 7, wherein advancing the puller comprises advancing the puller within an internal carotid artery.

16. A method of removing a clot from a vessel using a mechanical thrombectomy apparatus having a puller within a first catheter that is within a second catheter, wherein the puller and second catheter are connected by a flexible and tubular tractor, the method comprising:

advancing the puller distally through the first catheter and the second catheter and within the vessel towards a clot, so that the flexible and tubular tractor extends from the puller beyond a distal end opening of the first catheter and beyond a distal end opening of the second catheter;

advancing the outer catheter distally through the vessel by one or more of: holding the position of the first catheter within the vessel and pulling the puller proximally within the first catheter; or moving the first catheter distally relative to the puller; and

drawing the clot into the first catheter with the flexible and tubular tractor by pulling the flexible and tubular tractor proximally within the first catheter so that the flexible and tubular tractor rolls and inverts over the distal end opening of the catheter.

17. The method of claim 16, further comprising repeating the advancing steps until the clot is adjacent to the distal end of the puller.

18. The method of claim 16, wherein drawing the clot into the catheter further comprises advancing the first catheter distally while pulling the pusher proximally.

19. The method of claim 16, wherein advancing the puller distally comprises advancing the puller without using a guidewire extending distal to the puller.

20. The method of claim 16, wherein advancing the puller comprises extending the flexible and tubular tractor distally within the vessel further wherein the flexible and tubular tractor comprises a woven flexible and tubular tractor.

21. The method of claim 16, wherein advancing the puller comprises extending the flexible and tubular tractor distally within the vessel further wherein the flexible and tubular tractor comprises a knitted flexible and tubular tractor.

22. The method of claim 16, wherein advancing the puller comprises extending the flexible and tubular tractor distally within the vessel further wherein the puller has a central lumen configured to pass a guidewire therethrough.

23. The method of claim 16, wherein advancing the puller comprises advancing the puller within an internal carotid artery.

24. The method of claim 16, wherein drawing the clot into the first catheter comprises uncoupling the flexible and tubular tractor from the second catheter.

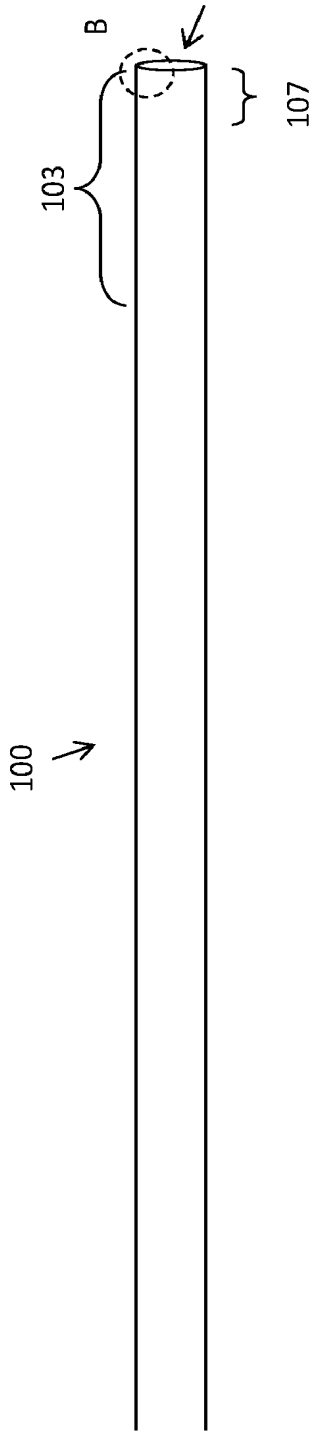

FIG. 1A

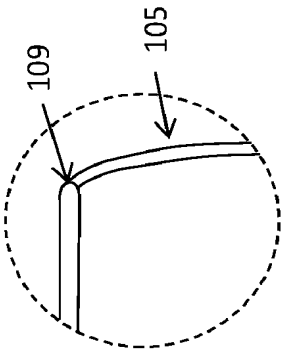

FIG. 1B

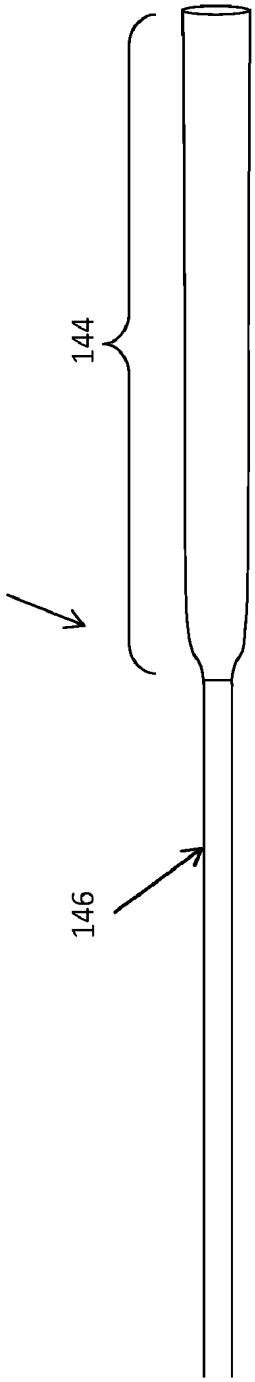

FIG. 1C

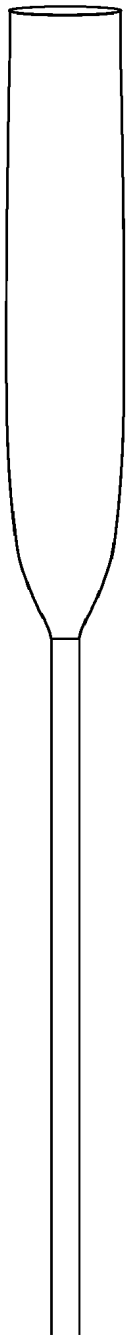

FIG. 1D

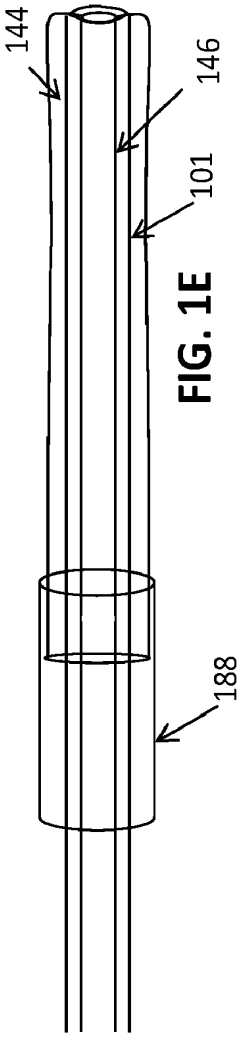

FIG. 1E

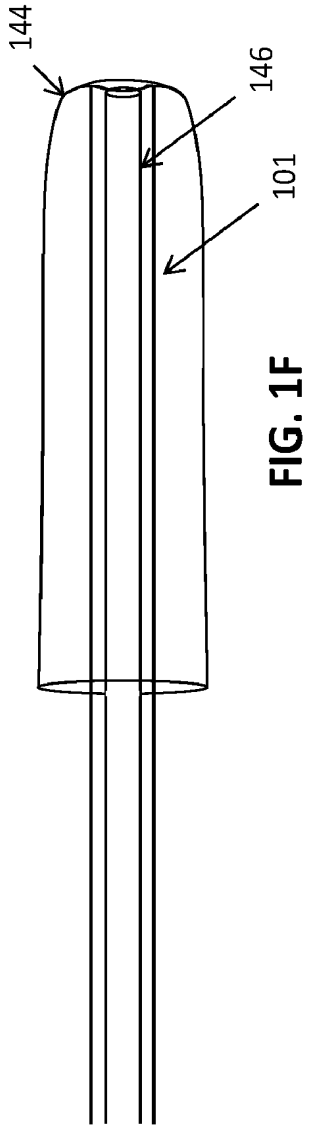

FIG. 1F

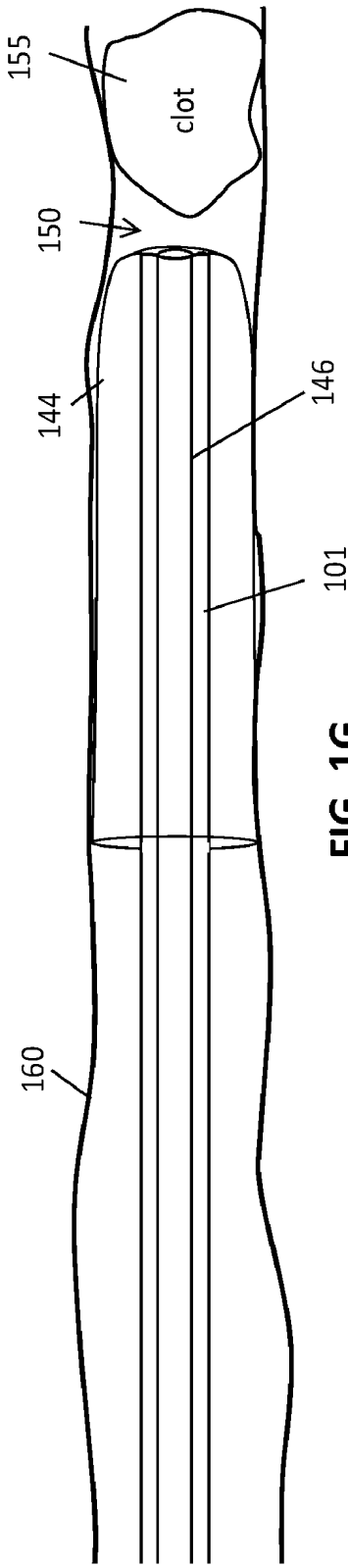

FIG. 1G

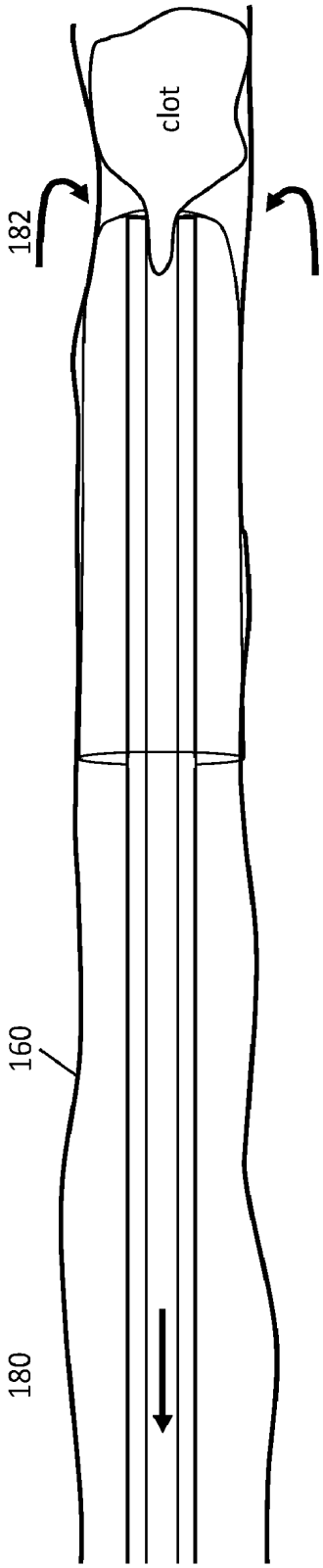

FIG. 1H

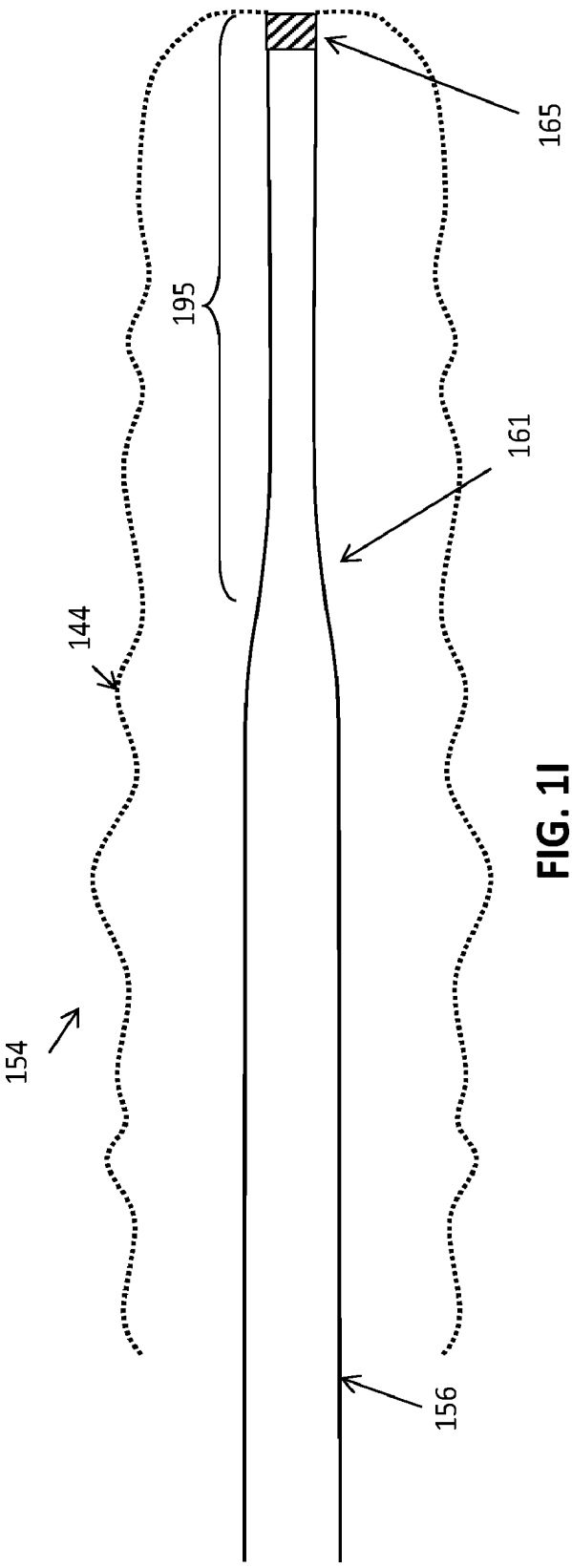

FIG. 1I

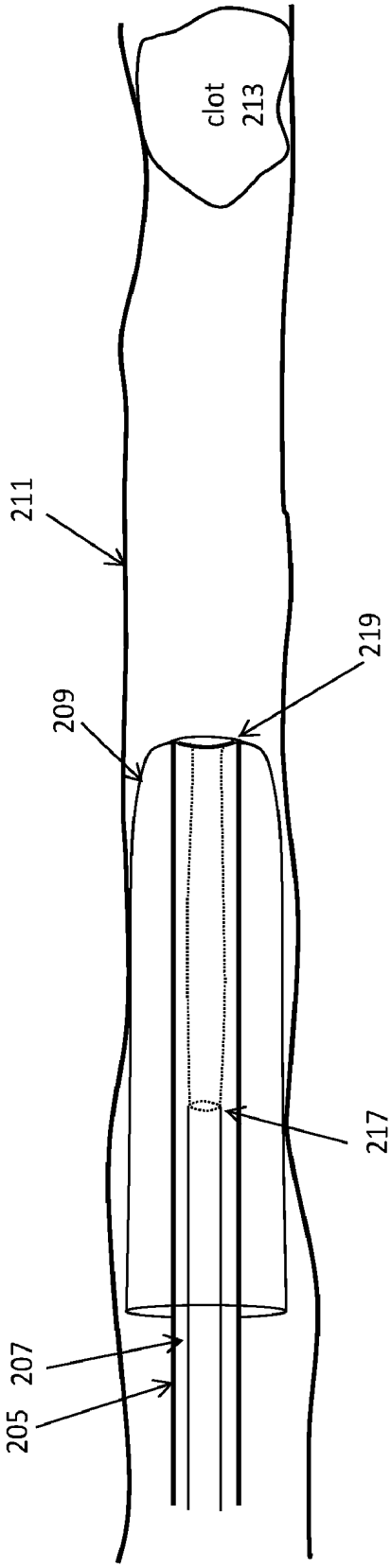

FIG. 2A

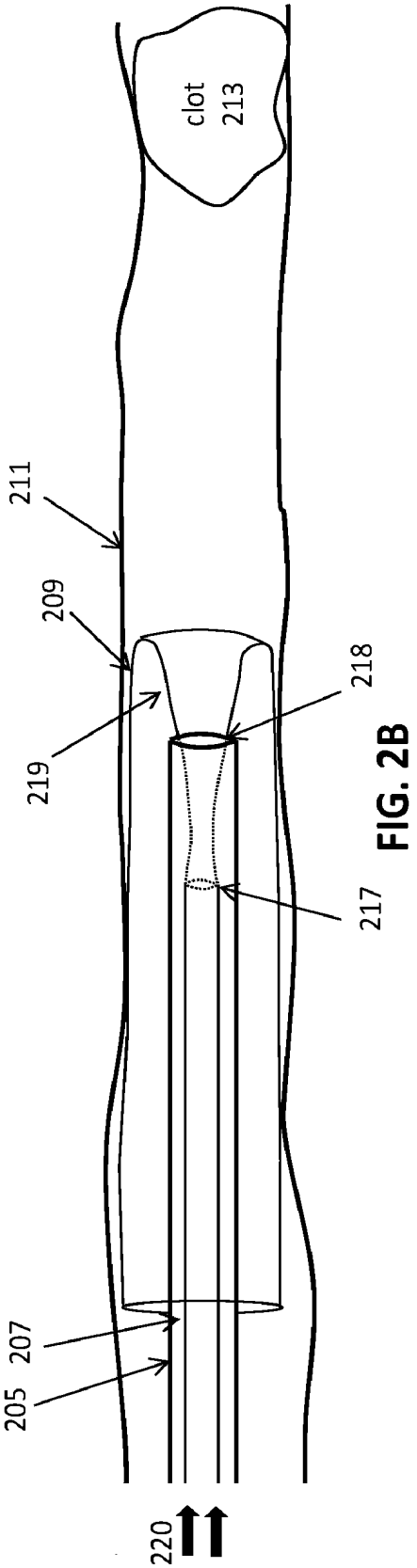

FIG. 2B

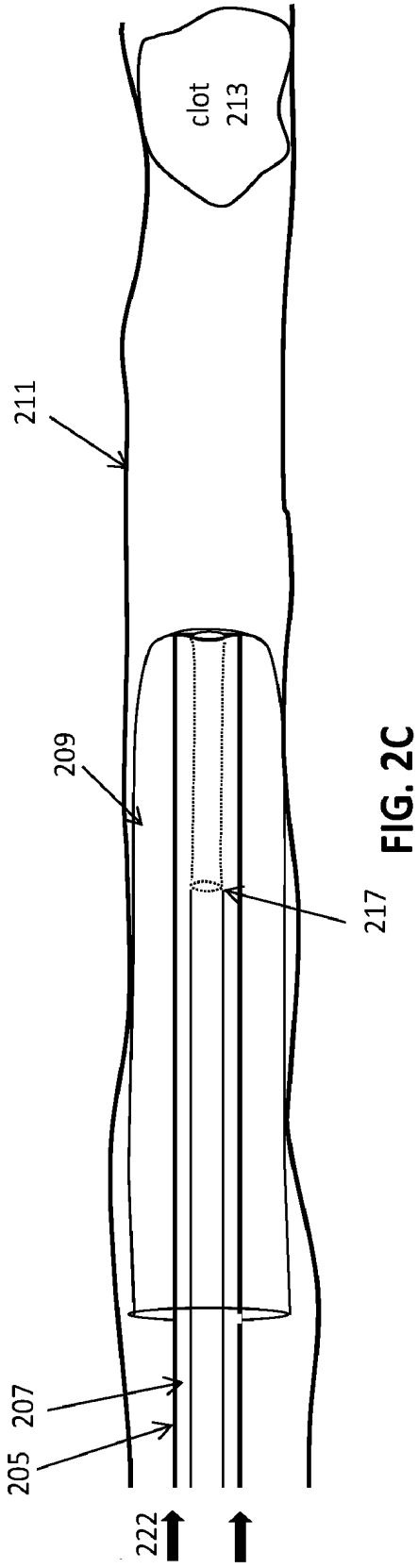

FIG. 2C

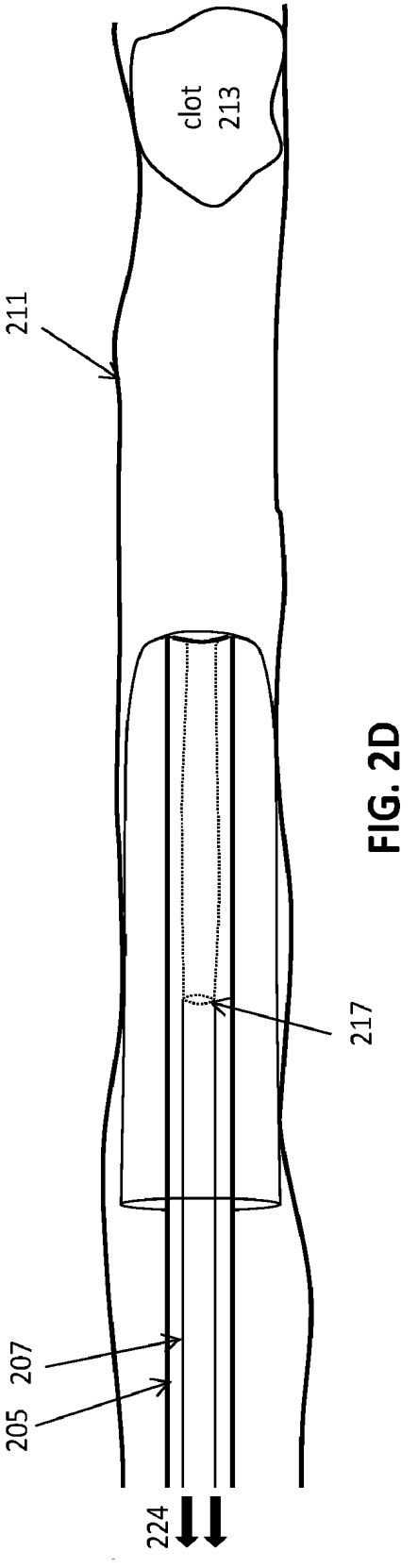

FIG. 2D

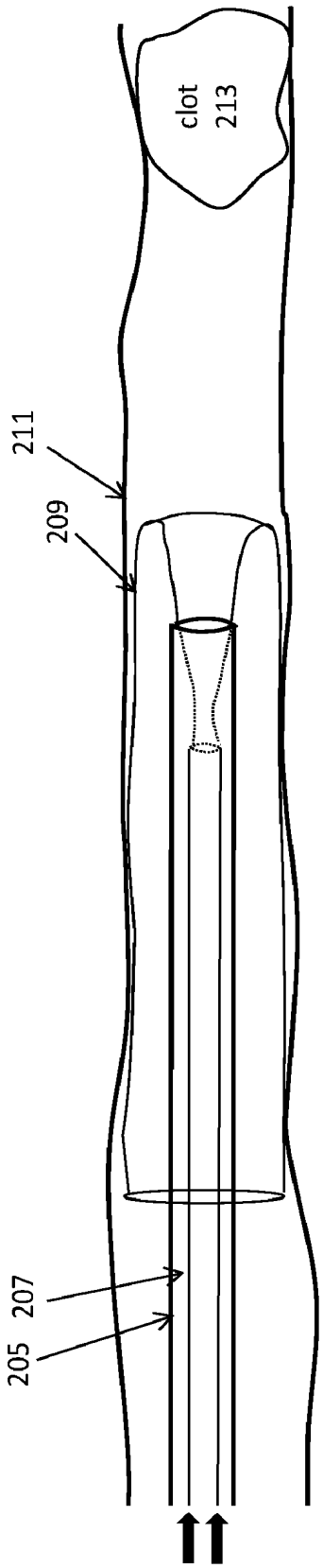

FIG. 2E

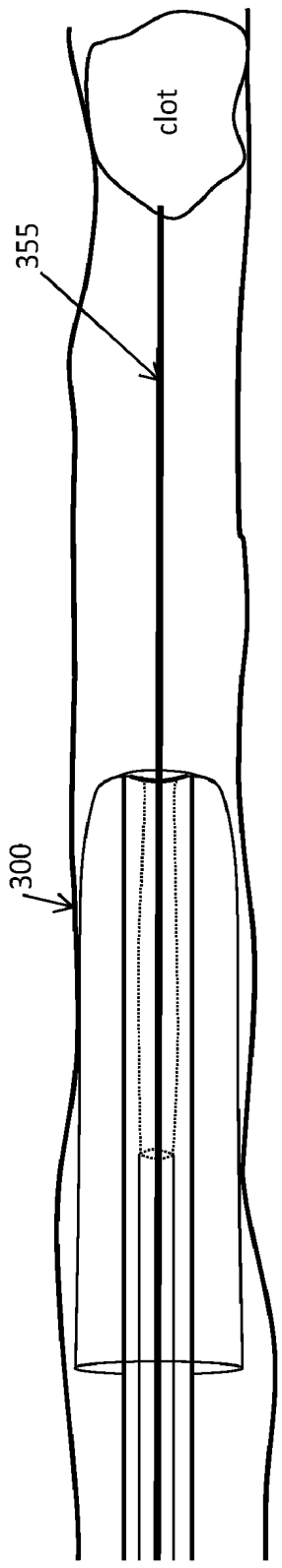

FIG. 3A

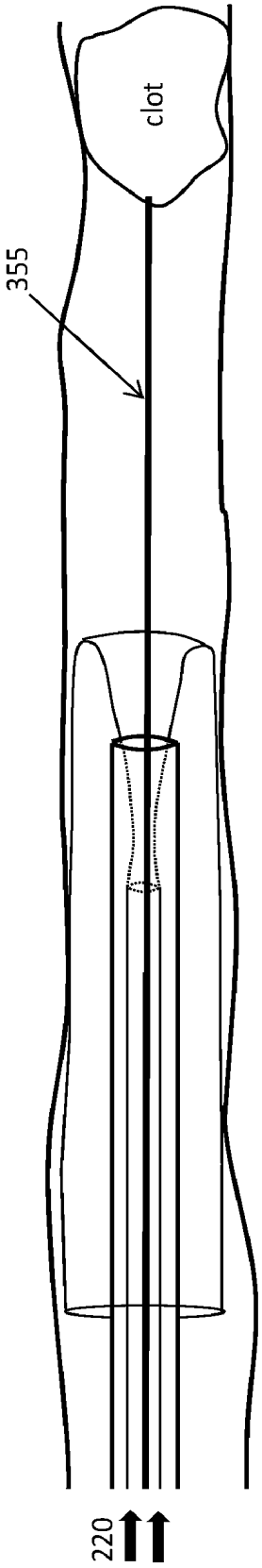

FIG. 3B

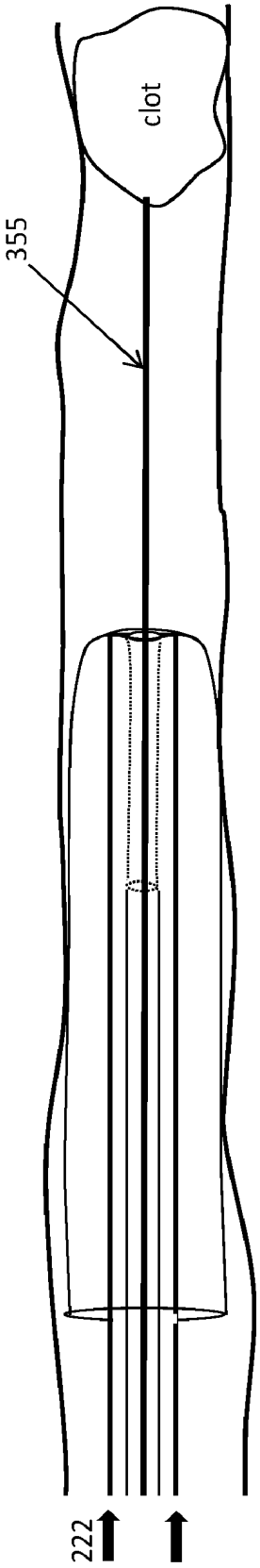

FIG. 3C

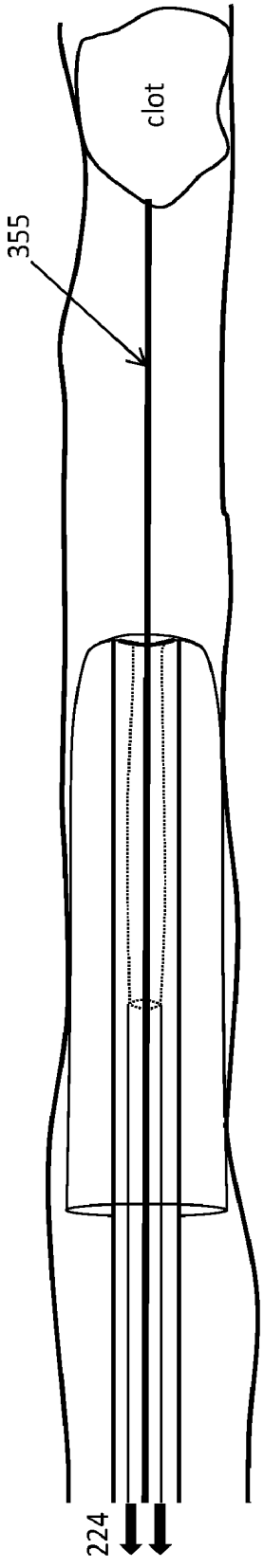

FIG. 3D

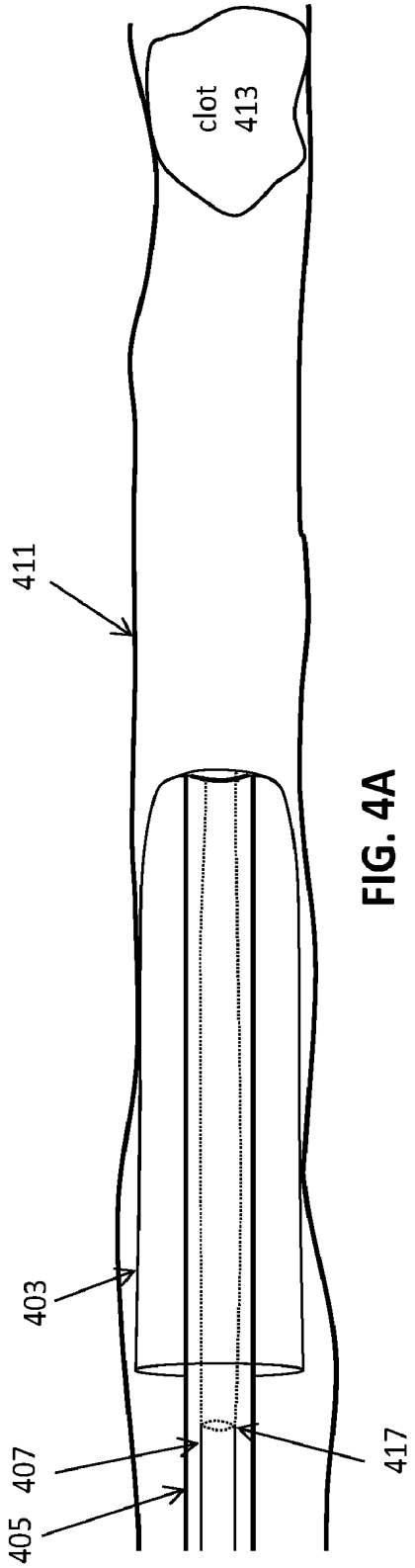

FIG. 4A

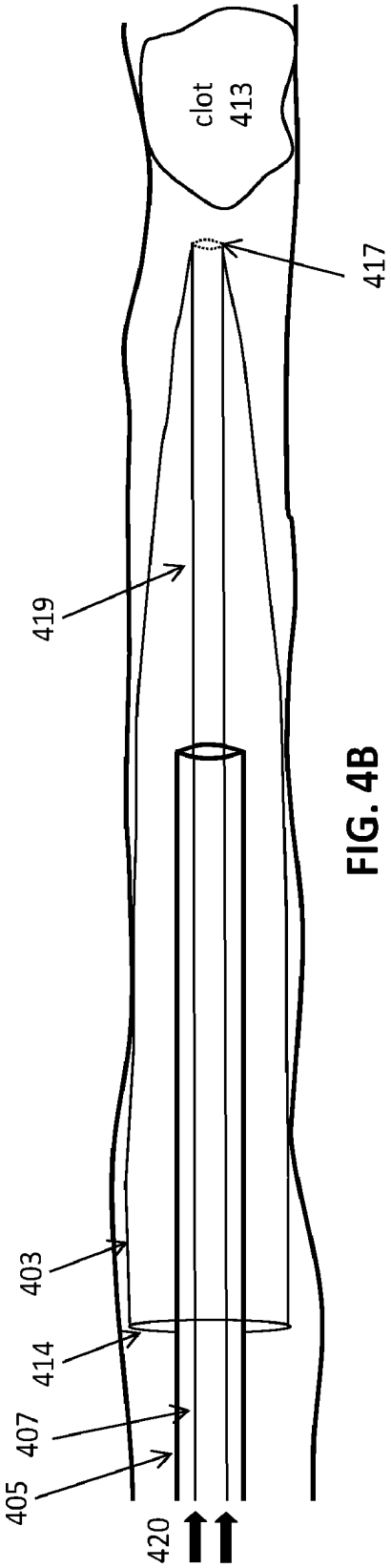

FIG. 4B

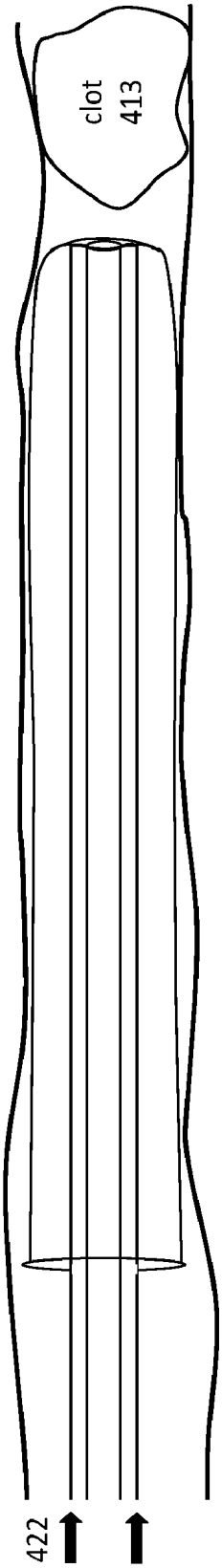

FIG. 4C

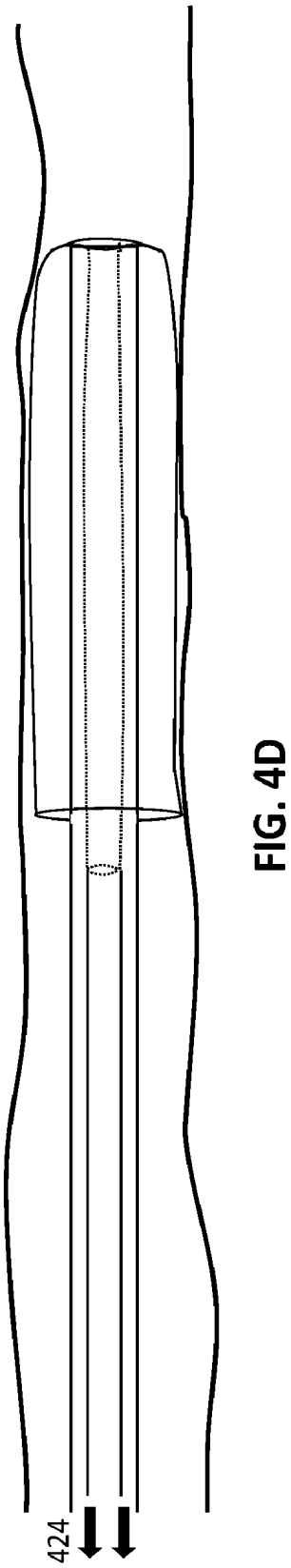

FIG. 4D

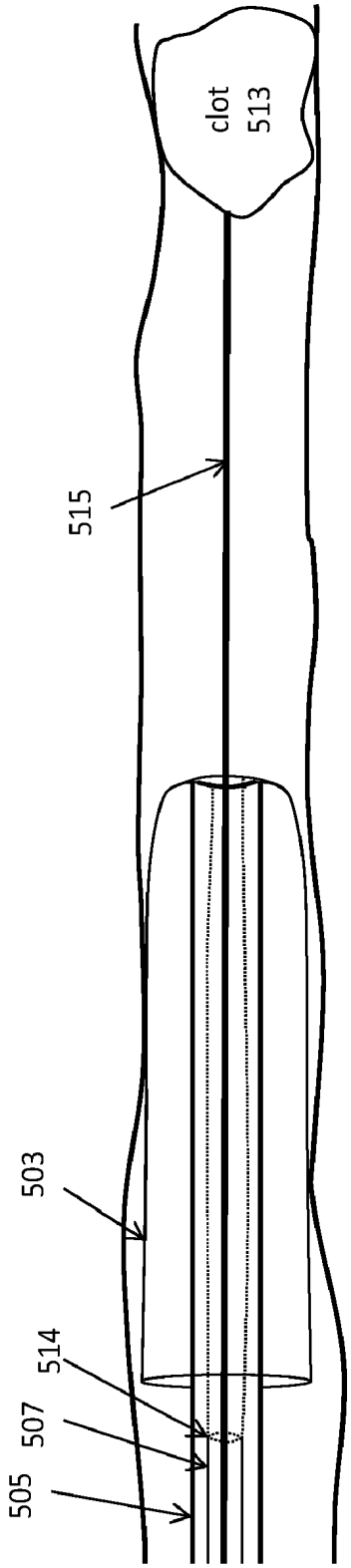

FIG. 5A

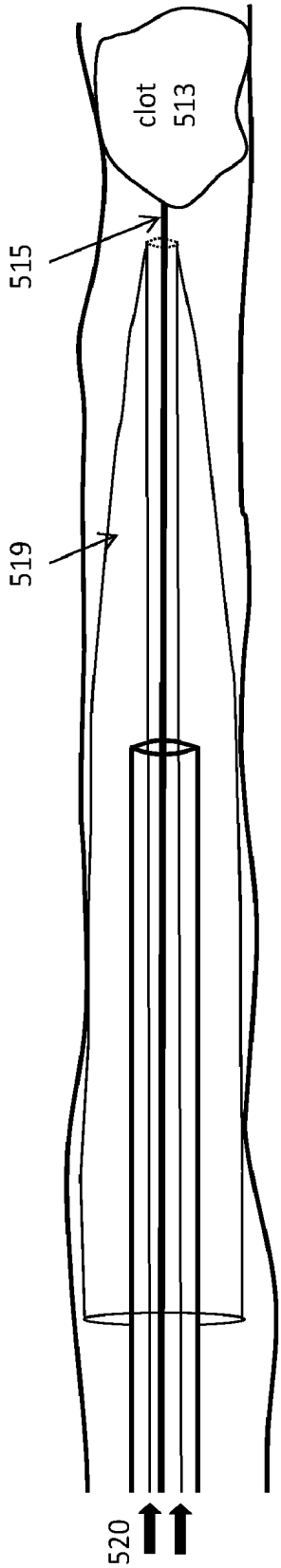

FIG. 5B

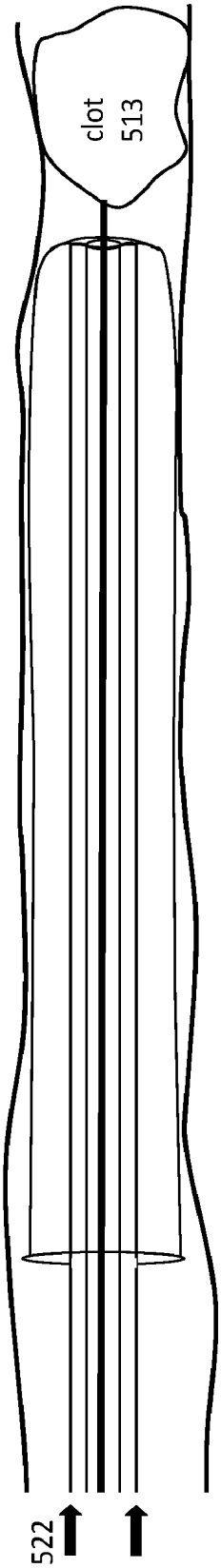

FIG. 5C

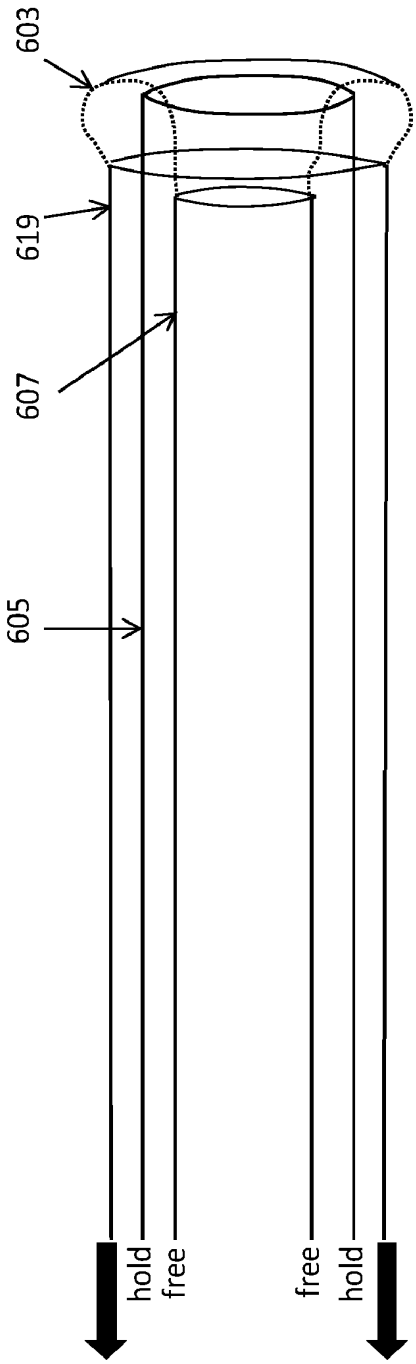

FIG. 6A

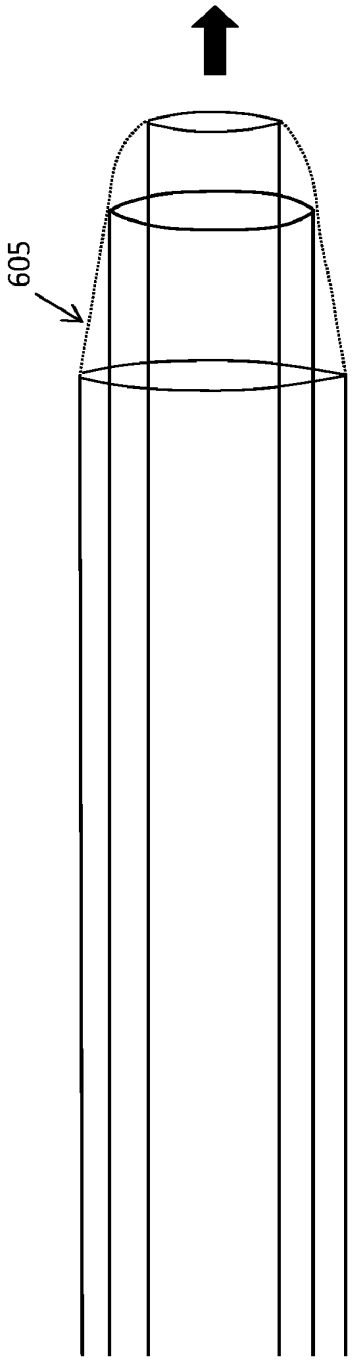

FIG. 6B

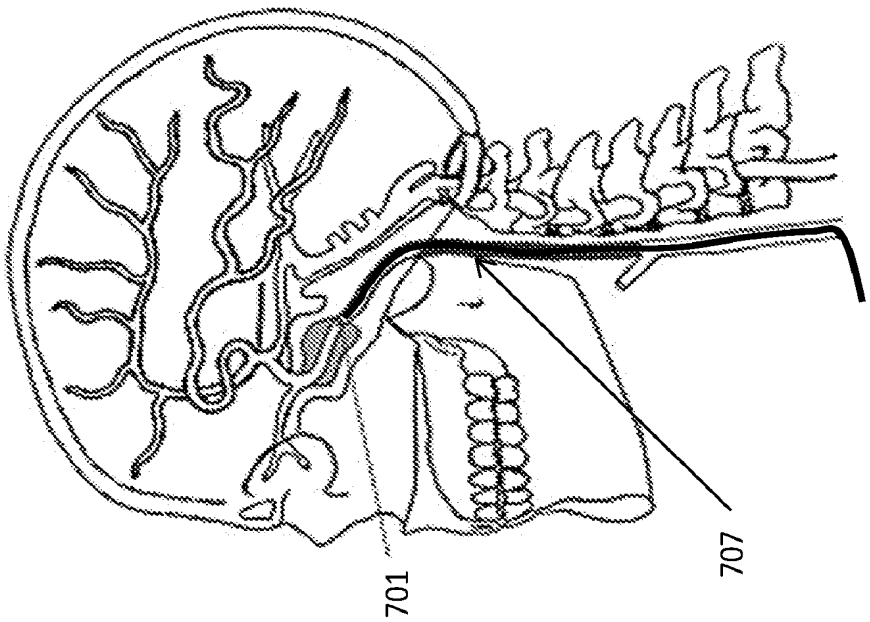

FIG. 7

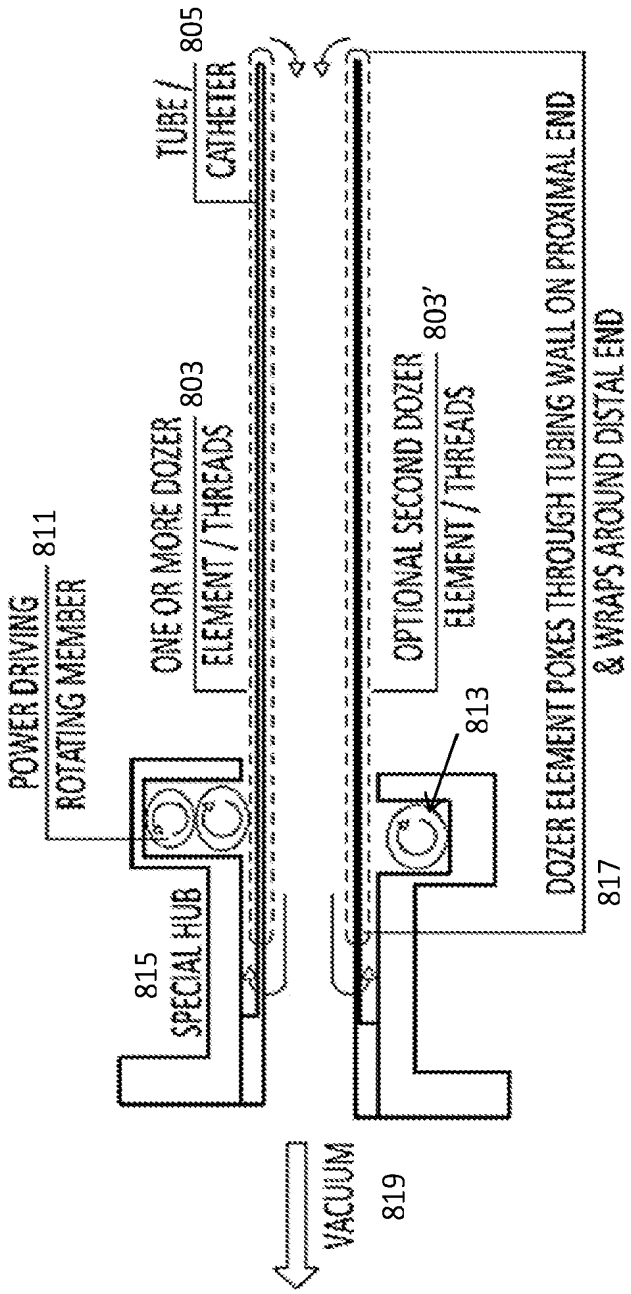
POWER DRIVING
ROTATING MEMBER
811
815
SPECIAL HUB
ONE OR MORE DOZER
ELEMENT / THREADS
803
TUBE /
CATHETER
805
OPTIONAL SECOND DOZER
ELEMENT / THREADS
803'
813
DOZER ELEMENT POKES THROUGH TUBING WALL ON PROXIMAL END
& WRAPS AROUND DISTAL END
817
VACUUM
819

FIG. 8A

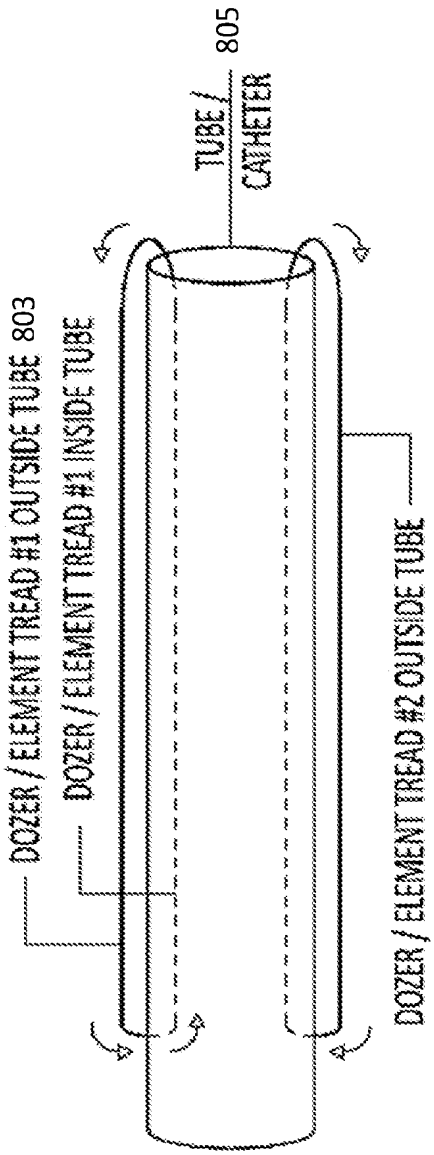
DOZER / ELEMENT TREAD #1 OUTSIDE TUBE 803
DOZER / ELEMENT TREAD #1 INSIDE TUBE
TUBE /
CATHETER
805
DOZER / ELEMENT TREAD #2 OUTSIDE TUBE
803'

FIG. 8B

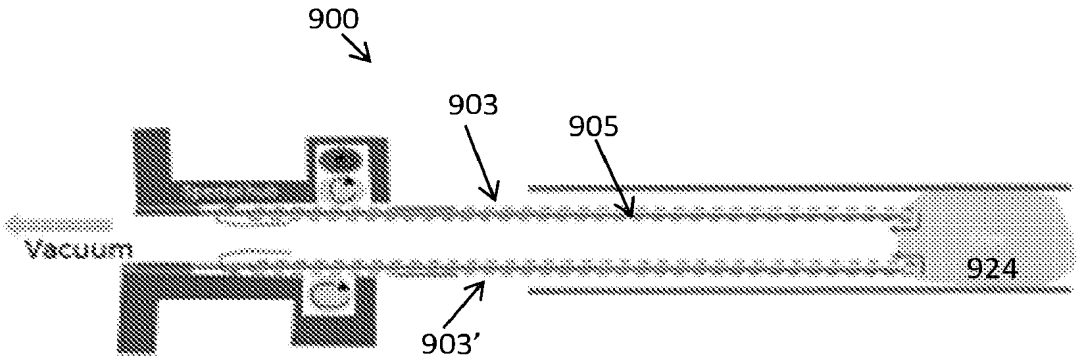

FIG. 9A

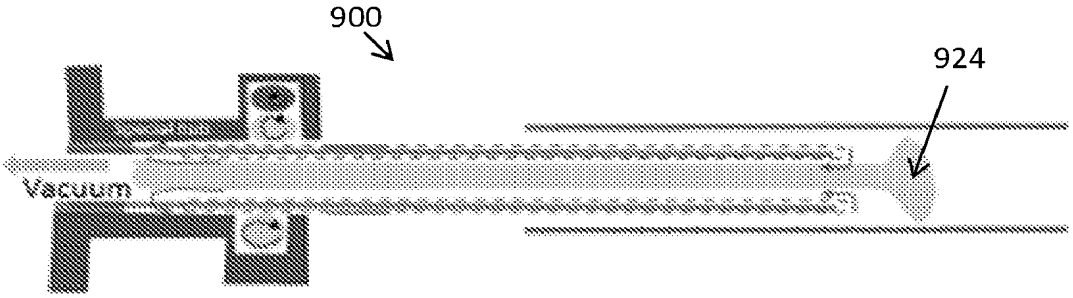

FIG. 9B

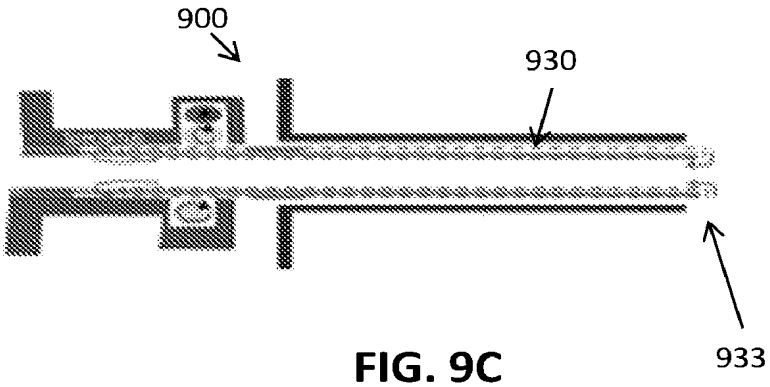

FIG. 9C

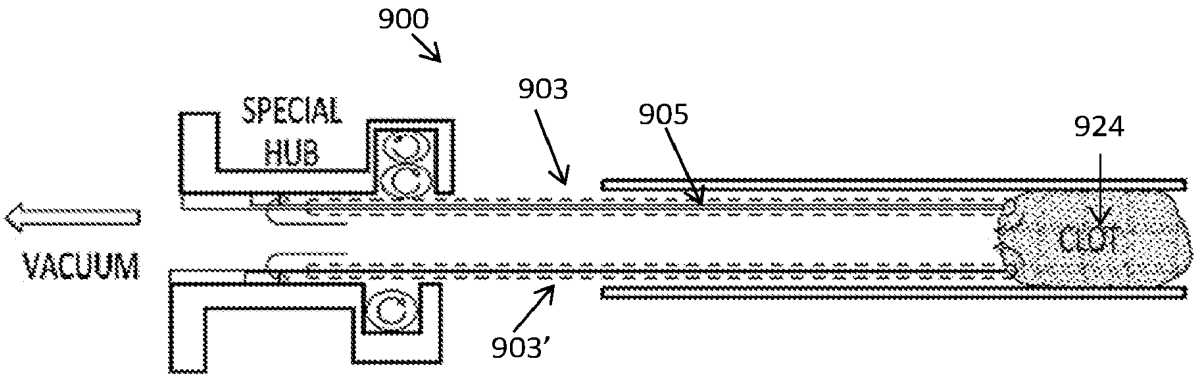

FIG. 9A

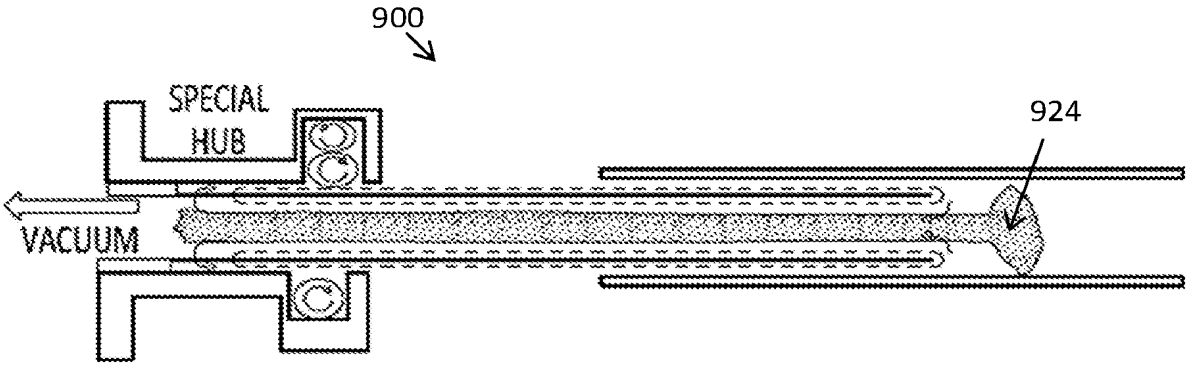

FIG. 9B

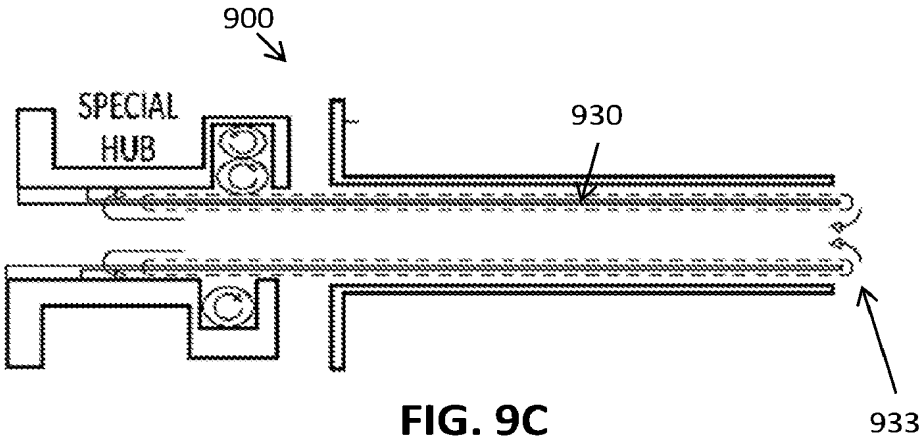

FIG. 9C

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19) paragraphs [0152], [0153], [0167] - [0170]; figures 10, 13B	1
A	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; figures page 8, line 12 - page 11, line 16	1
A	US 2013/096571 A1 (MASSICOTTE ET AL.) 18 April 2013 (2013-04-18) abstract; figures	1
A	US 2006/089533 A1 (ZIEGLER ET AL.) 27 April 2006 (2006-04-27) figures	1

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 June 2017	07/07/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Giménez Burgos, R

1

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00/32118 A1 (ATROPOS LIMITED) 8 June 2000 (2000-06-08) figures	1
A,P	WO 2017/058280 A1 (GW MEDICAL LLC) 6 April 2017 (2017-04-06) the whole document	1

1

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/029440

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 7-24
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 7-24

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2017/029440

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2012009675 A2	19-01-2012	US 2014005712 A1	02-01-2014
		WO 2012009675 A2	19-01-2012
GB 2498349 A	17-07-2013	EP 2802275 A1	19-11-2014
		GB 2498349 A	17-07-2013
		US 2015005781 A1	01-01-2015
		WO 2013106146 A1	18-07-2013
US 2013096571 A1	18-04-2013	US 2007038227 A1	15-02-2007
		US 2013096571 A1	18-04-2013
		WO 2007022055 A1	22-02-2007
US 2006089533 A1	27-04-2006	BR PI0617790 A2	09-08-2011
		EP 1945091 A2	23-07-2008
		IL 191079 A	31-01-2012
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		US 2008045790 A1	21-02-2008
		US 2010198011 A1	05-08-2010
		WO 2007050370 A2	03-05-2007
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		AU 1405600 A	19-06-2000
		EP 1135071 A1	26-09-2001
		IE 991011 A1	12-07-2000
		IE 991013 A1	12-07-2000
		US 2002016607 A1	07-02-2002
		WO 0032118 A1	08-06-2000
		WO 0032119 A1	08-06-2000
WO 2017058280 A1	06-04-2017	US 9463035 B1	11-10-2016
		US 2017086864 A1	30-03-2017
		WO 2017058280 A1	06-04-2017

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

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
29 November 2012 (29.11.2012)

WIPO | PCT

(10) International Publication Number
WO 2012/162437 A1

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

(21) International Application Number:
PCT/US2012/039216

(22) International Filing Date:
23 May 2012 (23.05.2012)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/489,183 23 May 2011 (23.05.2011) US
61/489,254 24 May 2011 (24.05.2011) US

(71) Applicant *(for all designated States except US)*: **LAZARUS EFFECT, INC.** [US/US]; 560 Division St, Campbell, California 95008 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **MARTIN, Brian B.** [US/US]; 767 El Solyo Heights Drive, Felton, California 95018 (US). **DIECK, Martin S.** [US/US]; 235 Cherry Lane, Campbell, California 95008 (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, QA, RO, RS, RU, RW, 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, 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:

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

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

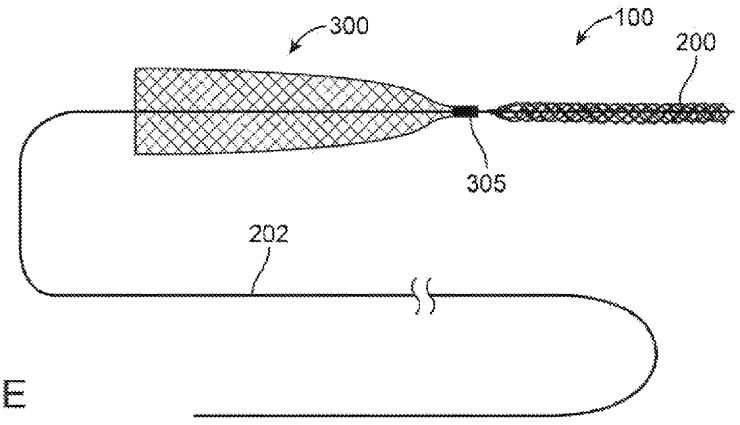

FIG. 2E

(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 2012/162437 A1

RETRIEVAL SYSTEMS AND METHODS FOR USE THEREOF

RELATED APPLICATIONS

[0001] This application is a non-provisional of U.S. Provisional Application Nos. 61/489,183 filed May 23, 2012 entitled RETRIEVAL SYSTEMS AND METHODS FOR USE THEROF, and 61/489,254 filed May 24, 2012 entitled STENT RETRIEVER WITH INTEGRATED PROTECTION the entirety of each of which is incorporated by reference.

FIELD OF THE INVENTION

[0002] The devices described herein are intended to retrieve obstructions from the body. Such devices have applicability throughout the body, including clearing of blockages within body lumens and providing passive protection of such, such as the vasculature, by providing a capturing portion that can translate and/or mobilize the obstruction within the body lumen.

BACKGROUND OF THE INVENTION

[0003] A large number of medical procedures require the use of medical device(s) to remove an obstruction from a body lumen, vessel, or other organ. An inherent risk in such procedures is that mobilizing or otherwise disturbing the obstruction can potentially create further harm if the obstruction or a fragment thereof dislodges from the retrieval device. If a particle or the obstruction breaks free from the device and flows downstream, it is highly likely that the particle or obstruction will become trapped in smaller and more tortuous anatomy. In many cases, the physician will no longer be able to use the same retrieval device to again remove the obstruction because the size of the device may prevent advancing the device to the site of the new obstruction.

[0004] Even in successful procedures, a physician must proceed with caution to prevent the walls of the vessel or body lumen from imparting undesired forces to shear or dislodge the obstruction as it is translated through the body during removal. These forces have the potential of breaking portions or fragments of the obstruction away. In some cases, the obstruction can simply break free from the retrieval device and can lodge in a new area causing more concern than the original blockage.

[0005] Procedures for restoring flow within the cerebral vasculature as a result of ischemic stroke are one example of where these issues present a concern. The brain relies on its arteries and veins to supply oxygenated blood from the heart and lungs and to remove carbon dioxide

and cellular waste from brain tissue. 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. To access the cerebral vasculature a physician typically advances a catheter from a remote part of the body (typically a leg) through the vasculature and into the cerebral region of the vasculature. Once within the cerebral region, the physician deploys a device for retrieval of the obstruction causing the blockage. Concerns about dislodged obstructions or the migration of dislodged fragments increases the duration of the procedure at time when restoration of blood flow is paramount. Furthermore, a physician might be unaware of one or more fragments that dislodge from the initial obstruction and cause blockage of smaller more distal vessels.

[0006] Many physicians currently use stents to perform thrombectomy (i.e. clot removal) to resolve ischemic stroke. Typically, the physician deploys the stent into the clot, in an attempt to push the clot to the side of the vessel and re-establish blood to flow. Tissue plasminogen activator ("Tpa") is often injected into the bloodstream through an intravenous line. The TPA must travel in the blood stream until it reaches the clot that is causing the blockage. Once the Tpa contacts the clot, it begins to break up the clot with the hope of restoring blood flow to the affected areas. Tpa is also often administered to supplement the effectiveness of the stent. Yet, if attempts at clot dissolution are ineffective or incomplete, the physician can attempt to remove the stent while it is expanded against or enmeshed within the clot. In doing so, the physician must effectively drag the clot from the vessel, in a proximal direction, into a guide catheter located within vessels in the patients neck (typically the carotid artery). While this procedure has been shown to be effective in the clinic and easy for the physician to perform, there remain some distinct disadvantages using this approach.

[0007] The stent may not sufficiently hold onto the clot as it drags the clot to the cathter. In such a case, the clot might not move from the vessel. Another risk is that use of the stent might mobilize the clot might from the original blockage site, but the clot might not adhere to the stent during translation toward the catheter. This is a particular risk when translating through bifurcations and tortuous anatomy. Furthermore, blood flow can migrate the clot (or fragments of the clot) into a branching vessel at a bifurcation. If the clot is successfully brought to the guide catheter in the carotid artery, yet another risk is that the clot may be "stripped" or "sheared" from the stent as the stent enters the guide catheter. Regardless, simply dragging an expanded stent (either fully or partially expanded) can result in undesired

trauma to the vessel. In most cases, the stent is oversized compared to the vessel. Dragging a fixed metallic (or other) structure can pull the arteries and/or strip the cellular lining from the vessel, causing further trauma such as a hemorrhagic stroke (leakage of blood from a cerebral vessel). Also, the stent can become lodged on plaque on the vessel walls resulting in further vascular damage.

[0008] In view of the above, there remains a need for improved devices and methods that can remove occlusions from body lumens and/or vessels. While the discussion focuses on applications in the cerebral vasculature, the improved devices and methods described below have applications outside of the area of ischemic stroke.

SUMMARY OF THE INVENTION

[0009] 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.

[0010] The devices discussed herein include interventional medical devices for retrieving and securing an obstruction within a vessel lumen. In one example the device comprisesa shaft having a flexibility to navigate through tortuous anatomy, the shaft a distal portion and a proximal portion; a capturing structure located at a distal portion of the shaft comprising a plurality of struts, the capturing structure having a reduced profile for positioning in or adjacent to the obstruction and an expanded profile, such that when expanded into the obstruction, the struts at least partially enmesh with the obstruction such that subsequent movement of the capturing structure permits dislocation of at least a portion of the obstruction from the lumen; an eversible cover having a fixed section affixed relative to a proximal end of the capturing structure, a free section extending in a proximal direction from the distal section and a cover wall extending from the fixed section to the free section, where the eversible cover is expandable such that at least a portion of the eversible cover has a diameter equal to or greater than the capturing structure, the eversible cover being axially compliant such that when the shaft is moved proximally within the lumen, in some cases friction between the cover wall and the lumen resists proximal movement of the cover wall to cause the eversible

cover to evert over the capturing structure allowing for the free section of the cover to be distal to the fixed end of the capturing portion. Evert or eversible generally includes movement of the device within the cover causing the cover to turn inside out as it protects and covers the retrieval device. The covers disclosed herein can be expandable through self-expanding configurations, or via actuated expansion (e.g., a shape memory alloy, spring expansion, or other actuation).

[0011] In one example, the device includes a configuration where the eversible cover, capturing structure, and shaft are a unitary structure. The device can also be configured so that each wire located at an end of the free section loops back to the cover causing the wires at the end of the free section to be continuous.

[0012] In another variation at least a portion of the cover wall adjacent to the distal end has a set shape that is everted upon expansion. The device can also optionally include a catheter body, where in a delivery configuration, the shaft, capturing structure and eversible cover are located within the catheter body and where the capturing structure is advanceable in and out of a distal end of the catheter body.

[0013] The device can also be configured so that the fixed section of the eversible cover comprises a pre-set shape to reduce a force required to evert the evertable cover.

[0014] The retrieval devices can comprise any number of capturing or retrieval device such as a filter, an artherectomy device, a rotational cutter, an aspiration device, stent based retrievers and retrieval baskets.

[0015] The methods described herein can include methods of securing an obstruction within a vessel. In one example, the method can comprise: positioning a catheter within a vessel; advancing a shaft having a retrieval device affixed thereto out of the catheter; advancing an eversible cover out of the catheter such that a fixed end of the eversible cover is affixed adjacent to a proximal end of the retrieval device and a free end of the eversible cover is moveable relative to the shaft and retrieval device; expanding a at least a portion of the eversible cover against a portion of a wall of the vessel; manipulating the retrieval device to become at least partially enmeshed with the obstruction; and proximally translating the shaft and retrieval device with at least a portion of the obstruction affixed thereto such that resistance of the eversible cover against the vessel resists movement of the eversible cover causing the free section of the eversible cover to evert over the proximally translated retrieval device.

[0016] In another variation, the methods can include further withdrawing the shaft from the vessel such that during withdrawal the eversible cover forms a protective barrier over the

obstruction to lessen shearing forces caused by the vessel and reduce dislodging portions of the obstruction from the retrieval device.

[0017] Another variation of a method includes a method of preparing a retrieval device comprising: providing a retrieval device having been previously removed from a body of a patient where the retrieval device includes a protective cover where a fixed end of the protective cover is affixed adjacent to a proximal end of the retrieval device and where a free end is located distally to the fixed end covering the retrieval device and is moveable relative to the second end; reversing the protective cover by moving the free end proximally of the fixed while the fixed end remains affixed adjacent to the proximal end of the retrieval device; inserting the retrieval device and cover into a catheter where the free end of the cover is proximal to the fixed end of the cover and retrieval device such that upon deployment from the catheter, the free end of the cover deploys proximally to the fixed end of the cover.

[0018] In another example, the devices described herein can include medical device retrieval systems for securing an obstruction within a vessel lumen and for use with a catheter configured to be navigated through the vasculature. In one variation, the device comprises an elongated stent comprising a plurality of struts, the stent being collapsible for positioning in the catheter during delivery and having an expanded profile such that when expanded the struts are configured to engage the obstruction; a shaft fixedly attached to the elongated stent and having a flexibility to navigate through tortuous anatomy; a fluid permeable cover having a distal end coupled to a proximal end of the elongated stent a cover wall defining a cavity and extending along the shaft, and a proximal end being moveable relative to the shaft, where the fluid permeable cover is collapsible for positioning in the catheter during delivery and is expandable upon deployment from the catheter such that at least a portion of the fluid permeable cover is expandable; where the fluid permeable cover is axially pliable such that when the device is deployed in the vessel the frictional forces between the vessel and the fluid permeable cover permit proximal movement of the shaft and elongated stent to cause inversion of the fluid permeable cover wall such that the fluid permeable cover wall everts over the elongated stent.

[0019] Another variation of a device includes an interventional medical device for use with a catheter configured for delivery through vasculature for securing an obstruction within a vessel lumen. For example, the device can comprise a shaft having a flexibility to navigate through tortuous anatomy, the shaft having a distal portion and a proximal portion; a capturing device comprising a sidewall, the capturing device fixedly located at a distal portion of the shaft and having a reduced profile for positioning in the catheter and an expanded

profile, such that upon deployment from the catheter, the capturing device expands to force a portion of the sidewall into the obstruction to at least partially attach to the obstruction; a cover having a distal end coupled adjacent to a proximal end of the capturing structure, a proximal end and a cover wall extending therebetween, where the proximal end of the cover is slidable relative to the distal end, where the cover is expandable such that when located in the catheter the cover is in a reduced delivery state and upon advancement from the catheter the cover expands with the proximal end located proximally of the distal end, where the cover wall is compliant such that when deployed from the catheter and the shaft is pulled in a proximal direction frictional forces between the vessel and the cover wall or proximal end cause the cover to invert as the cover wall inverts over the capturing device to surround the capturing device.

[0020] Another variation of the device include an interventional medical device for securing a retrieval device having one or more obstructions located therein for removal from a body. In one such example the medical device includesa sheath having a flexibility to navigate through tortuous anatomy, the sheath a distal portion and a proximal portion and a lumen extending therethrough; an eversible cover having a fixed section affixed to the distal portion of the sheath, a free section extending in a proximal direction from the fixed section and a cover wall extending from the fixed section to the free section, where the eversible cover is expandable, the eversible cover being axially compliant such that when the retrieval device is positioned through the sheath lumen moved in a proximal direction against the eversible cover, the eversible cover everts over the retrieval device allowing for the free section of the cover to be distal to the retrieval device.

[0021] Another variation of the method includes advancing a shaft having a retrieval device affixed thereto to the obstruction; advancing a protective device over the shaft, the protective device comprising a sheath having an eversible cover, where a fixed end of the eversible cover is affixed to a distal portion of the sheath and a free end of the eversible cover is located proximal to the fixed end; positioning the fixed end of the eversible cover adjacent to the retrieval device and expanding at least a portion of the eversible cover against a portion of a wall of the vessel; proximally translating the shaft and retrieval device with at least a portion of the obstruction affixed thereto such that resistance of the eversible cover against the vessel resists movement of the eversible cover causing the free section of the eversible cover to evert over the proximally translated retrieval device.

[0022] The capturing portions described herein can include a stent retrieval device for expanding against one or more occlusive bodies in a vasculature. In one example, the stent

retrieval device includes an elongate shaft having a flexibility to navigate through tortuous anatomy, the elongate shaft having a distal portion and a proximal portion; a plurality of filaments that diverge from the distal portion of the elongate shaft to form an expandable elongated stent body having a open distal end and a fluid permeable closed proximal end and a cavity therebetween, where divergence of the filaments at the distal portion of the elongate shaft forms the fluid permeable closed proximal end; where the plurality of filaments extending along the shaft are free of any connection joints in the distal portion to permit increased flexibility of the distal portion as it navigates though tortuous anatomy; and one or more connection joints proximal to the distal portion where the connection joints secure the plurality of filaments to the shaft.

[0023] The stent retrieval can also include at least one of the plurality of filaments that comprise at least two wires twisted together, the elongated stent body further comprising at least one intersection of filaments, where the wires of each filament are interwoven to provide increased outward radial strength of the elongated stent body and such that the wires slide relative to each other as the elongated stent body expands or compresses in diameter to reduce a force required to linearize the elongated stent body.

[0024] The stent retrieval device can have an exterior surface of the elongated stent body that comprises an irregular surface formed by intersection of filaments.

[0025] The stent retrieval device can also have intersection of filaments comprising a barb or knuckle and where a plurality of barbs or knuckles are radially spaced about the elongated stent body. The stent retrieval device can also have an intersection of filaments that comprises a barb or knuckle and where a plurality of barbs or knuckles are aligned with an axis of the elongated stent body.

[0026] 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.

[0027] 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.

[0028] 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.

[0029] 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.

[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 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, 11/825,975 filed September 10, 2007; 12/344,378 filed 12/26/2008, 13/012,727 filed 1/24/2011, and 13/226,222 filed 9/6/2011; 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

[0032] Each of the following figures diagrammatically illustrates aspects of the invention. Variation of the invention from the aspects shown in the figures is contemplated.

[0033] Fig. 1 illustrates an example of a device according to the present invention when used in a system for removing obstructions from body lumens.

[0034] Figs. 2A to 2C illustrate working ends of various coverable retrieval devices.

[0035] Figs. 2D and 2E show variations of retrieval devices.

[0036] Fig. 2F shows an independent eversible cover on a delivery sheath.

[0037] Figs. 3Ato 3C illustrates an example of a coverable retrieval device where the cover everts about the retrieval structure.

[0038] Fig. 4A to 4I illustrates an example where an improved retrieval device with passive protection retrieves a clot from tortuous anatomy.

[0039] Figs. 4J and 4K illustrate examples of an obstruction or other material captured within a retrieval device with a cover further protecting the loaded retrieval device.

[0040] Fig. 5A illustrates a retrieval device having a retrieval structure adjacent to a double layer cover.

[0041] Fig. 5B shows a funnel with a free end that tapers down about the delivery wire.

[0042] Figs. 5C and 5D show a fixed end of a cover that is pre-shaped to reduce the force required to evert the cover wall.

[0043] Fig. 5E shows alternate variation of a passive cover integrated into a retrieval device.

[0044] Fig. 5F illustrates a cover having a pre-set flattened cover wall at a fixed end of the retrieval structure.

[0045] Figs. 5G to 5I illustrate various layered covers.

[0046] Fig. 5J shows a cover that is constructed directly onto the retrieval structure rather than the delivery shaft.

[0047] Figs. 5K and 5L show a variation of a cover and retrieval device where the cover is first mounted in a distal direction and then inverted in a proximal direction.

[0048] Figs. 6A to 6L illustrate a variation of covers for use as describe herein.

[0049] Figs. 7A to 7C show additional variations of covers.

[0050] Fig. 8 illustrates a variation of a proximal and distal end of an additional retrieval device.

[0051] Figs. 9A to 9C illustrate wires of different constructions within a delivery wire or shaft.

[0052] Figs. 10A to 10E illustrate additional variations of covers for use as described above.

[0053] Figs. 11A to 11C illustrate additional variations of covers for use with the devices and methods described herein.

[0054] Figs. 12A to 12E illustrate various stent designs for increasing the ability of a stent to adhere to an occlusion within a vessel.

[0055] Fig. 12G illustrates a proximal end of the stent structure.

DETAILED DESCRIPTION

[0056] 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.

[0057] Fig. 1 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. As stated herein, the present devices and methods are useful in other regions of the body including the vasculature and other body lumens or organs. For exemplary purposes, the discussion shall focus on uses of these devices and method in the vasculature.

[0058] 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.

[0059] 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.

[0060] Fig. 2A illustrates a working end of a coverable retrieval device **100**. Typically, the device includes a capturing or retrieval structure **200**. In the illustrated example, the retrieval structure **200** comprises an elongated stent structure. However, unless specifically noted, the capturing structure can comprise any number of devices, including but not limited to a filter, an artherectomy device, a rotational cutter, an aspiration catheter.

[0061] The retrieval structure **200** is located at a distal end of a delivery wire **202**. In one variation, the retrieval structure **200** can be permanently affixed to the delivery wire **200** by such methods including, but not limited to adhesive bonding, soldering, welding, polymer joining, or any other conventional method. In some variations, the retrieval device **200** can be formed from one or more wires forming the delivery wire 202 or shaft **202**. The delivery wire **202** can have sufficient column strength such that it can axially advance and retract the device **100** within the vasculature as the physician manipulates a non-working end of the delivery wire **202** outside of the body. Accordingly, the delivery wire **202** should have a length that is sufficient to extend from the target area, e.g., the cerebral vasculature, to the entry point on the body. Alternatively, additional variations of the device **100** can allow for the use of a support member or catheter that positions the retrieval structure **200** as needed. Additional features of the retrieval structure **200** can be found in the commonly assigned patents and applications cited herein an incorporated by reference.

[0062] The coverable retrieval device **100** further includes a cover **300** (also referred to as a funnel or sheath) affixed relative to a proximal end **206** of the retrieval structure **200**. By being affixed relative to a proximal end **206**, a distal end **204** of the retrieval structure **200** can move relative to the cover **300** so that the cover **300** everts over the proximal end **206** of the structure **200** when the cover **300** is expanded within a vessel and as the structure **200** is withdrawn into the distal end **302** of the cover **300**. This mechanism is discussed in detail below.

[0063] Figs. 2B and 2C illustrate alternative variations of a coverable retrieval device **100**. As shown in Fig. 2B and 2C, the distal end **302** of the cover **300** can be spaced from the proximal end **206** of the retrieval structure **200**. Alternatively, the distal end **302** of the cover **300** can extend over a portion of the retrieval structure **200**. In some variations, at least a section of the cover **300** expands to a greater diameter than a diameter of the retrieval structure **200**. This allows the cover **300** to expand to a vessel wall where the vessel holds the cover stationary while the device is pulled proximally through the cover to evert the cover. In alternate variations, the cover **300** expands to the same or lesser diameter than the retrieval structure **200** or other device.

[0064] Fig. 2D shows a retrieval device **100** with a catheter **112** (usually a microcatheter). The retrieval device **100** can comprise a single unitary device of a cover **300** and retrieval structure **200** (in this case the retrieval structure is an elongated stent structure). One benefit of a unitary device is that additional devices complicates the procedure and can increase the duration of what is ordinarily a time sensitive procedure. The retrieval device **100** can be positioned through the catheter **112** that includes a hub **114**. As a result, the physician only needs to manipulate the unitary retrieval device **100** and the catheter/microcatheter **112**. The retrieval device **100** is loaded into the catheter **112** for placement at the target site. In addition, the retrieval device can be reloaded if the procedure must be repeated. The cover **300** and retrieval structure **200** described herein can comprise any construction described herein or as known by those skilled in the art.

[0065] Fig. 2E shows a retrieval device **100** with a cover **300** and retrieval device **200** with a radiopaque marker **305** therebetween. As shown, variations of the device **100** do not require a catheter or microcatheter.

[0066] Fig. 2F illustrates an eversible cover **300** located on a sheath **330** having a lumen **332** extending therethrough. A separable retrieval device **200** can be coupled to the cover **300** and sheath **330** by inserting the wire **202** of the cover retrieval device **200** through the lumen **332** of the sheath **330**. In this variation, the eversible cover **300** can be used with any number of different interventional tools. The separate devices can be assembled prior to delivery into the patient. Alternatively, the devices can be positioned within the body and subsequently joined once the retrieval device **200** engages the target area.

[0067] Fig. 3A illustrates an example of a coverable retrieval device **100** where the cover **300** is in the process of everting about the retrieval structure **200**. As shown, arrow **50** illustrates a force applied on the wire **202** in a proximal direction. Arrows **52** illustrate a resistance force applied by the friction of the expanded cover **300** against a vessel or similar wall. This friction force **52** prevents or resists proximal movement of the free end **304** of the cover **300** while the fixed end **302** moves in a proximal direction with the proximal end **206** of the retrieval structure **200**. This action causes a wall **306** of the cover **300** to evert over the retrieval structure **200**. Ultimately, and as shown in Fig. 3B, the free end **304** of the cover **300** ends up distally over the fixed end **302**. As shown, the wall of the everted cover **300** provides a safety type cover for the retrieval device **200**. In additional variations, the fixed end **302** of the cover can actually be slidable or moveable along the delivery wire **202**. However, the similar principle as discussed above shall apply to cause everting of the cover **300** over the retrieval structure **200**.

[0068] Fig. 3C illustrates another variation of a coverable retrieval device **100** after the cover **300** is everted about the retrieval structure **200**. In this variation, the free end **304** of the cover **300** ends up distally of the fixed end **302** and tapers or collapses towards the free end **304**. The cover **300** can be shape set so that prior to eversion the cover is as shown above where the forces acting on the cover wall **306** expand outwards, but after eversion the forces on the cover wall **306** cause the tapering or collapsing as shown in Fig. 3C.

[0069] In accordance with the illustrations discussed above, the cover **300** can be made so that the cover wall **306** is atraumatic when dragged across a lumen wall. The cover can be manufactured from any number of materials including a fabric, a reinforced fabric, a braid, weave, or any such material that allows for expansion against a wall of the body lumen or vessel as well as to allow everting of a wall **306** of the cover over the retrieval device **200**. The cover wall **306** can also comprise combinations of these materials such as braids of polymer material with metal fibers, soft braids with coil reinforcements or various other combinations.

[0070] The cover wall can comprise a mesh that can include any medically acceptable materials such as a Nitinol 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. Moreover the cover can comprise any number of configurations. For example, the cover can comprise a single layer wall or a multi layer wall, the open end of the cover could be made to have terminated ends such as by using continuous wire loops formed during the braiding process. Alternatively, the ends can be cut and then terminated by encasing in polymer, laser welds, or by folding inward for a discreet length and then terminating

[0071] In one example, the cover **300** comprises a continuous wire construction as described in earlier commonly assigned patent applications incorporated by reference. In one variation the cover **300** comprises a finely braided wire, such as 48-96 wires of .0005" to 0.002" diameter fine Nitinol wire or similar. Additionally, the wire can comprise cobalt chromium, stainless steel, or similar, or drawn filled tube (dft) with platinum core. In additional variations, a flat wire or oval wire can be used. The wire does not need to be uniform. Instead, a number of different types of wires can be used. Some of the individual wires could be platinum alloys for added radiopacity.

[0072] Fig. 4A to 4I illustrates an example where an improved retrieval device **100** with passive protection retrieves a clot **2** from tortuous anatomy. Fig. 4A illustrates a clot **2** that obstructs blood flow in a vessel **6**. As noted herein, the vessel **6** can comprise any vessel in

cerebral vasculature, coronary or peripheral vasculature. Alternatively, the device and methods for use are not limited to use in the vasculature . Variations of the principles, concepts, method and devices described herein can be applicable wherever a retrieval device can be used. Fig. 4A also illustrates a guide sheath or access catheter **108** that is advanced within the vessel. During a procedure, the physician will advance the access catheter **108** as far distally as possible. However, due to the size of the access catheter **108**, a physician typically positions it a distance away from the obstruction **2**. As shown, there can be any number of bifurcations **8** in the vessel **6** located between the access catheter **108** and the obstruction **2**. As discussed herein, in some variations, the access catheter **108** can be used to remove the obstruction **2** from the body once the obstruction is captured by a retrieval device. However, the greater the distance between the initial location of the obstruction **2** and the location of the access catheter **108**, the greater the risk that the obstruction **2** can break free from the retrieval device or become dislodged due to anatomic or environmental features, including but not limited to bifurcations, the wall of the lumen, the tortuousity of the anatomy, vessel wall plaque, etc.

[0073] Fig. 4B illustrates an optional catheter **112** that advances from the access catheter **108** to the site of the obstruction **2**. Once at the site, the catheter **112** can deploy a retrieval device (not shown in Fig. 4B) so that the retrieval device can engage the clot **2**. Alternatively, the catheter **112** can traverse the obstruction **2** as shown in Fig. 4C and deploy a portion of the retrieval device **100** distally to the obstruction **2**. The physician then manipulates the retrieval device **100** to secure the obstruction **2**. For example, the physician can deploy the retrieval structure **200** distally to the obstruction **6** and withdraw the retrieval structure **200** proximally to secure the obstruction **2**. In another variation, the physician can position the retrieval structure **200** within the catheter **2** while the catheter **112** is through or adjacent to the obstruction **2**. Then, the physician can withdraw the catheter **112** to expose the retrieval structure **200** so that it secures to the obstruction **2** after expansion. In the illustrated example, the retrieval structure **200** comprises an elongated stent type structure that expands (or is expanded) to enmesh or secure to the obstruction. Although not illustrated, the system can include a distal capture filter or basket as described in any of the commonly assigned applications incorporated by reference herein.

[0074] Next, as shown in Fig. 4E, the physician can further withdraw the catheter **112** to expose a cover **300** as described above. In many cases, the physician exposes the cove **300** once the retrieval structure **200** is engaged with the obstruction **2**. This sequential process allows for easier repositioning of the retrieval structure **200** if necessary. Alternatively, the

cover **300** can be deployed prior to engaging the retrieval structure **200** with the obstruction **2**. If necessary, the physician can apply a proximal force on the delivery wire **202** while withdrawing the catheter **112** to prevent inadvertent movement of the obstruction **2** and retrieval device **200**.

[0075] Fig. 4F illustrates the stage with a fully exposed the cover **300** and a catheter **112** moved closer towards the access sheath **108**. As shown, the free end **304** of the cover **300** is proximal to fixed end **302** of the cover **300**. As also noted above, the cover **300** can be a shape memory alloy that expands against the walls of the vessel 6 upon reaching body temperature. Alternatively, the cover **300** can be self expanding upon deployment into the vessel **6**. In some variations, the cover wall **306** comprises a porous material or construction that allows blood to continue to flow through the cover **300**.

[0076] In addition, some variations of the retrieval device **100** include a cover **300** that has at least a section that expands to a greater diameter or dimension than the retrieval structure **200**. This allows for expansion of the cover **300** against the wall of the vessel **6**. In most variation, expansion of the cover **300** provides sufficient friction against the walls of the vessel to overcome column strength of the cover walls **306** allowing for everting of the cover walls **306** over the retrieval structure **200** and obstruction **2** as discussed herein. As noted above, in alternate variations the cover **300** can expand a diameter or dimension that is equal to or less than the retrieval structure **200**.

[0077] Figs. 4G illustrates proximal movement of the delivery wire **202**, which causes proximal translation of the obstruction **2** and retrieval structure **200**. Because the cover **300** is expanded against the walls of the vessel **6** the free end **304** of the cover **300** does not move or moves less than the fixed end **306** of the cover **300**. The fixed end **306** moves with the obstruction **2** and retrieval structure **200** in a proximal direction causing the cover walls **306** to evert over the obstruction **2** and retrieval structure **200**. Unlike a conventional funnel, the everting cover functions similar to a conveyor belt type movement as the obstruction and retrieval structure move together. This action allows for a passive type of protection since cover **300** does not need to be actuated over the obstruction **2** and retrieval structure **200** and can be performed in a quick manner by simply withdrawing the deployed retrieval device **100**.

[0078] Fig. 4H illustrates a stage where the fixed end **306** of the cover **300** is now proximal to the free end **304**. As shown, the everted cover **300** forms a protective sheath or cover over the obstruction **2** and the retrieval structure **200**. Fig. 4H also illustrates how the cover **300** protects the obstruction **2** and retrieval structure **200** as they are pulled along the vessel and navigate the tortuous anatomy, walls of the vessel, as well as bifurcations **8**. The cover **300**

and cover wall **306** also protects the vasculature from the surface of the retrieval structure **200** and obstruction **2**.

[0079] Fig. 4I shows the obstruction **2** and retrieval structure **200** protected by the cover **300** as the retrieval device **100** is positioned against or within the access catheter **108** in preparation for removal from the body. The retrieval device **100** can remain outside of the access catheter **108** as the physician removes both devices from the body. Alternatively, the cover **300** can assist in pulling the retrieval device **100** and obstruction **2** into the access catheter **108** by compressing the obstruction **2** as it is pulled into the access catheter **108**.

[0080] Figs. 4J and 4K illustrate examples of an obstruction or other material **2** captured within a retrieval device **2** with a cover **300** further protecting the loaded retrieval device **200**.

[0081] Figs. 5A to 5K show a variety of cover configurations. Fig. 5A illustrates a retrieval device **100** having a retrieval structure **200** adjacent to a double layer cover **300** with an exterior wall **306** and an interior wall **308**.

[0082] Fig. 5B shows a cover **300** with a free end **304** that tapers down about the delivery wire **202** where the cover **300** will eventually form a double wall configuration when the cover **300** everts over the retrieval structure **200**. The tapered free end **304** limits the cover **304** from moving once the retrieval structure **200** reaches the free end **304** thereby forming double wall protection over the retrieval structure **200.**

[0083] Figs. 5C and 5D show how a fixed end **302** of a cover **300** can be pre-shaped to reduce the force required to evert the cover wall **306** or to lower the threshold to trigger passive covering of the retrieval structure by the cover.

[0084] Fig. 5E shows alternate variation of a passive cover **300** integrated into a retrieval device **100**. In this variation, the retrieval device **100** includes a control shaft or wire **202** to manipulate the working end of the retrieval device **100**. The cover **300** floats along the shaft **202** between two fixed anchors or nodes **220, 222**. The cover **300** can float or slide between the fixed nodes **220, 222**. The nodes **220, 222**can comprise radiopaque marker bands, glue joints, or any other mechanical obstructions capable of stopping the translation of cover **300**. When the device **100** advances through a microcatheter, the rear or proximal node **220** limits rearward movement of the cover **300**. When positioned appropriately, the microcatheter can be withdrawn to expose the retrieval device **200** and cover **300** as described herein. When the retrieval structure **200** engages the obstruction (not shown) the retrieval device **100** can be withdrawn by pulling on the delivery shaft **202**. While this occurs, the cover **300**, being expanded against the vessel remains stationary (or moves at a slower rate than the obstruction and retrieval structure **200** due to the friction against the vessel wall). The retrieval structure

200 and clot enter the cover 300, causing the distal node 222 to make contact with the near end 320 of the cover 300. This contact causes the retrieval structure 200 and cover 300 to translate as an integrated unit. It should be appreciated that the cover could be a single layer or double layer cover, and could have any of the wire design variables and termination variables described herein.

[0085] Fig. 5F illustrates a cover having a pre-set flattened cover wall 304 at a fixed end 302 that is spaced from a proximal end of the retrieval structure 200. Figs. 5G to 5I illustrate various layered covers 300. The layered covers allow for shortening the axial length of the cover and therefore shortens the required translation length. Layering of the cover wall 306 allows for a shortened deployed length of the cover 300 when deployed in the vessel or body structure. As the cover 300 everts over the retrieval structure 200 the layered wall 306 extends. As a result, shortening the length reduces the length that the cover 300 extends into the proximal vessels and reduces the length of that the retrieval structure 200 must travel to become protected by the cover 300. This also helps shorten the distance required to move the device 100 to complete eversion of the cover 300.

[0086] Fig. 5J shows a cover 300 that is constructed directly onto the retrieval structure 200 rather than the delivery shaft 202. This construction also assists in reducing the distance necessary to complete passive protection of the retrieval structure by the cover.

[0087] Fig. 5K show a variation of a cover 300 that is mounted in a distal direction over the retrieval device 200 and then everted in a proximal direction over the wires or shaft 202 as shown by arrows 230. Once everted, as shown by Fig. 5L, the device 100 is ready for deployment as discussed herein.

[0088] Figs. 6A to 6B illustrate a variation of a cover 350 for use as describe herein. Additionally, the cover 350 can be used with any obstruction retrieval device not limited to the retrieval baskets and stents described herein. The covers 350 disclosed herein 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). In use, the covers can be sized for use with guide catheters, micro-catheters, and/or distal access catheters. The covers can include any number of radiopaque marker bands to allow non-invasive imaging of the device (see marker 390 affixed between cover 350 and shaft 212 in Fig. 7B as one example). In any case, once the retrieval device captures a clot or obstruction, as described above, the device and clot are protected by the cover so that the cover eliminates or reduces direct contact between the interior of the wall of the vessel and the clot.

[0089] Figs. 6A to 6C show a variation in which a cover is created from one or more mesh tubes **372**. Fig. 6B 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. 6C, this creates a double walled cover having an exterior wall **378** separated from an interior wall **380**. In one example, such a spacing or gap could range between 0.001 inches to 0.100 inches. However, any range is contemplated within alternative variations of the device. In some variations the inverted cover **350** is heat set to maintain a separation between layers or walls **378 380** of the cover **350**. Typically, if the cover **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 cover **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 cover **350**. In some variations, both ends of the mesh **374** and **376** are affixed to the catheter,shaft or wire.

[0090] In many variations, the cover 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 cover is heat set so that the inner layer has cushioning and the ability to deflect to assist in movement of the inner layer. Fig. 5C also illustrates a coer **350** having a tapered design.

[0091] Figs. 6D to 6L illustrate additional variations of cover construction to produce covers 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. 6E this produces a dual layer cover 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 cover 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. 6F, the cover 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, wire or other catheter device as described herein.

[0092] Fig. 6G illustrates another example of a cover 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 cover. As shown in Fig. 6H, the cover 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 cover **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 cover **350** can be shape set to taper from the opening.

[0093] Figs. 6I to 6L illustrate another example of the construction of a multi-wall cover. As shown in Fig. 6I, 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. 6J. Next, the first end **374** is everted or folded back in direction **420** to produce the configuration of Fig. 6K. Finally, the first end **374** is folded again in direction **420** so that the ends **374** and **376** are even to produce the cover configuration shown in Fig. 6K. Again, one end of the cover **350** can be set to form the tapered shape while the other respective end can be affixed to a catheter or shaft.

[0094] Although the covers of the present disclosure are presented without additional structures, it should be noted that these covers are coupled with a shaft or other member so that the cover can be advanced within the target anatomy to assist in removal of a device, structure, or debris from the site.

[0095] Figs. 7A to 7C show addition variations of covers **350**. Fig. 7A illustrates a cover in which the cover wall as defined by the inner layer **380** and outer layer **378** is set in a shape that varies along a length of the cover. For example, the end adjacent to the cover 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 cover walls that vary in thickness are within the scope of this disclosure.

[0096] One of the benefits of using a cover **350** as described herein is that the cover 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 cover eliminates the need for total occlusion of blood flow. Fig. 7B illustrates a further improvement on a cover **350** that aids in flow reduction. As shown, the cover **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 cover is more flexible and conformable. Additional mesh layers can be added to any of the cover designs to alter flow characteristics or even provide reinforcement to the cover. 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 cover or even the entire cover. Deployment of a cover can reduce blood flow by 30% to 40%. Adding additional layers or coatings can additionally reduce flow.

[0097] Fig. 7C shows another variation of a cover **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 cover wall of any of the covers or can be deposited on the cover using the polymeric coatings. In some examples, the covers described herein can range from a length of 10 mm up to 50 mm. The OD at the opening of the cover can range from 7 mm and could range between 4 mm to 10 mm. Again, any range of dimensions is contemplated within the disclosure.

[0098] The covers described herein can further be stacked on a device. For example, two or more covers can be placed on a device to provide added protection.

[0099] The cover/rentry devices described herein can be constructed of any material currently used in vascular applications, including those discussed above. Furthermore, fabrication of the cover from a DFT material can provide additional benefits as the entire cover remains radiopaque and can be imaged non-invasively. Furthermore, the covers 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.

[0100] Fig. 8 illustrates another variation of a retrieval device **400** including a distal capture portion **426** coupled to one or more leading wires in the form of a main bundle **402**. The main bundle extends through a sheath **106** that includes a proximal capture portion **460**. The configuration of the retrieval device **400** 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.

[0101] An end **464** of the proximal capture portion **460** 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 **402** can optionally terminate at a handle **442**. As noted above, in certain variations, the main bundle is joined to a stiffer wire or stiffer bundle of wires. This allows

the device **400** to have a very flexible distal section with a relatively stiffer proximal section. The device **400** can have a proximal bundle **403** that comprises either the exposed wires or a covering/tube over the wires. In certain variations, the bundle or wire **402**, **403** can be encapsulated with a coating. The device also includes a cover **300** adjacent to the retrieval device.

[0102] The proximal end of the sheath **106** includes a sheath handle **444**. As discussed herein, axial movement of the bundle **402** or proximal bundle **403** (typically at the handle **442**) results in movement **126**, or translation of the bundle within the sheath **106**. This action moves the distal capture portion **426** (as shown by arrows **126**). In certain variations, the device **400** is loaded into a microcatheter (not shown but discussed above) that is delivered to the site of the obstruction and crosses the obstruction.

[0103] In some variations, the sheath hub **444** includes one or more locking hubs **446**. Where actuation (either axial or rotational) of the locking hub **446** locks the main bundle **402** relative to the sheath handle **444** and sheath **106**. It follows that such locking action also locks the distal capture portion **426** relative to the proximal capture portion **460**. A variety of methods can be employed to increase a frictional interference between the locking hub **446** and the proximal bundle **403**. As a result, when a physician determines a length of an obstruction, the physician can set a spacing between the capturing portions **426 460** by locking the proximal bundle **403** relative to the sheath hub **444**. Accordingly, the proximal bundle **403** 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 **444** can include additional injection ports to deliver fluid or other substances through the sheath **106**.

[0104] As noted above, the device **400** can be used with a micro-catheter. In those variations it is important that the device **400** is loaded without damaging the distal bundle **402**, capture portions **426 460**, and/or sheath **106**. As a result, the device **400** can include an optional cover **486** that reduces the proximal capture portion **460** (and /or the distal capture portion **426**) for loading within the microcatheter and/or sheath **106**.

[0105] Another variation of the device **400** includes an insertion tool **480** slidably affixed to the sheath **480**. Because variations of the device **400** can be extremely flexible, the insertion tool **480** can be used to provide column strength to the sheath **106**, bundle **402** or other components as the device **400** is pushed into the microcatheter. The insertion tool comprises a rigid section **482** and a frictional coupler **484**. The rigid section **282** has a column strength that supports the device **400** to prevent buckling. The frictional coupler **484** can be a flexible material that allows an operator to squeeze or grip the coupler **484** to create a temporary

frictional interface between the loading tool **480** and the device **400** (typically the sheath **106**). Such an action allows axial advancement of the device **400** as the loading tool **480** is advanced into the microcatheter. Once the rigid section **482** is fully inserted into the microcatheter, the operator releases the frictional coupler **484** and can withdraw the loading tool **480** from the catheter without withdrawing the device **400**. The insertion tool **480** can also include an optional loading tube **486** slidably coupled to the rigid section **482**. When used, the cover **486** can withdraw the proximal and distal capturing portion **226 260** within the loading tube **486**. The loading tube **486** then couples to a microcatheter allowing the capturing portions to advance therein as the rigid section **482** and frictional coupler **484** advance the device **400** relative to the loading tube **486**.

[0106] Figs. 9A to 9C show cross sectional views taken along the line 9A-9A in Fig. 2A. As shown, the wire form construction described herein allows for a number of configurations depending on the particular application. For example, the individual wires **254** (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. 9A illustrates one possible variation in which a number of circular wires **254** are included around another larger wire **256**. 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. 9B, one or more wires **256** can have a different cross-sectional shape or size

than a reminder of the wires **254**. Clearly, any number of variations is within the scope of this disclosure. This construction can apply to the retrieval portion, capturing portion and/or the covering portion of the device.

[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. 9C, such a DFT wire **252** comprises a first material or shell **258** over a second material **260** 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] Another aspect applicable to all variations of the devices is to configure the devices or portions thereof that engage the obstruction to improve 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).

[0113] 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 **370** 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.

[0114] In addition to additives, the device can be coupled to an RF or other power source (such as **14** or **16** in Fig. 1), 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.

[0115] Figs. 10A to 10E illustrate additional variations of covers **300** for use as described above. For example, as show in Fig. 10A, a cover **300** can comprise a single wire, coil, or laser cut tube **350**. Alternatively, as shown in Fig. 10B, the cover **300** can comprises two or more **350**, **352** wires or coils. Fig. 10C shows a cover **300** comprising a coil **350** inside a mesh structure **354**. A variation of the device shown in Fig. 10C can include a compliant atraumatic mesh **354** that is radially supported by the coil (whether interior or exterior to the mesh). The coil **350** provides the outward force against the vessel. Fig. 10D illustrates a polymeric film or membrane **356** coupled to a coil **350**. The polymeric film **356** can be permeable to fluid flow or impermeable. Fig. 10E illustrates a dual layer braid construction having an inner braid **358** and an outer braid **360**. The braids can be constructed to have unique properties. For example, the inner braid **358** can be composed of fewer wires or larger diameter wires, such that it provides an expansion force against the vessel wall. The outer braid **360** can comprise a softer construction and increased compliance. Accordingly, it can be comprised of a number of smaller diameter wires having a denser pattern to provide increased surface area to protect the obstruction as it is removed from the body. Alternatively,

these two constructional elements (e.g., braids of varying diameters) can be combined into a single layer or even multiple layers for the cover.

[0116] Fig. 11A illustrates yet another variation of a device **100** having a retrieval structure **200** and cover **300** where the cover is simply fabricated from the same material as the retrieval structure so long as it functions as described herein. The variation can optionally include one or more barbs **370** to increase resistance against a vessel wall.

[0117] Fig. 11B and 11C illustrate a variation where the cover 300 comprises a balloon material. Fig. 11B illustrates the balloon cover 370 prior to deployment. Fig. 11C illustrates the balloon cover 370 once deployed.

[0118] The retrieval devices described herein can optionally comprise elongated stents 400 as shown in Figs. 12A to 12E. These stents 400 can include any number of features to better assist the stent 400 in becoming enmeshed into the obstruction. For example, Fig. 12A illustrates a variation of a stent 400 affixed to a shaft 412. As noted herein, the shaft 412 can include a lumen extending therethrough. Alternatively, the shaft 412 can include a solid member with the stent 400 affixed to a distal end thereof. The variation shown in Fig. 12A includes a stent where a distal end 414 that is "closed off" by intersecting elements or wires 402 403. Accordingly, any of the variations of the stents disclosed herein can include an open lumen type stent or a closed lumen type stent as shown in Fig. 12A. As noted herein, the wires forming the stent 400 can comprise a single wire that is wound from a first direction (e.g., from proximal to distal) and then wound back in a second direction (e.g., from distal to proximal).

[0119] Fig. 12A also illustrates a stent 400 comprised of twisted wires 402 or elements. For example, Fig. 12B shows a magnified view of the section 12B in Fig. 12A. As illustrated, the elements 402 403 are twisted to increase the surface area at the exterior perimeter of the stent 400. The twisting or spiraling of the elements 402 403 creates additional surface area to increase the ability of the stent 400 to capture debris, thrombus, foreign body, etc. as the stent is expanded against the debris. The twisting elements 402 403 can twist along the entire length of the stent 400 or along one or more portions of the stent. In certain variations, the twisting of the elements 402 403 is sufficiently loose such that as the stent expands into a clot or obstruction, the twisted pairs slightly separate to allow material to become trapped between the elements making up the pairs. The construction shown in Figs. 12A and 12B also provide an additional benefit to a retrieval stent. In the illustrated variation, the twisted or spiraling elements interlock with crossing elements to form intersections 405 that provided added radial expansive force. As shown, a first twisted element 407 passes in between elements 402 403 of

an intersecting element 409. When in an expanded state, the element on the interior of the intersection 405 (in this case element 403) provides an added outward radial force against the intersection 405. However, since the elements are not affixed but instead are slidable at the intersection 405, the force required to linearlize and compress the stent 400 is reduced due to the fact that the intersections are not affixed but slidable over the adjacent elements. This reduced linearization force allows the stent to be compressed to a small diameter for positioning within a microcatheter but allow for a significant radial expansive force once removed from the microcatheter. This design allows for a reduction in radial force of the stent against the vessel wall when the stent is pulled and removed from the vessel. However, this design also provides a high degree of radial force due to the interweaving of elements when the stent is deployed in the vessel prior to withdrawal of the stent.

[0120] Figs. 12C to 12F illustrate another variation of types of stents 400 that have an irregular surface at an exterior of the stent 400 that is formed by an intersection of elements 402 403. The intersection or crossing of the elements forms a type of barb or knuckle 416 that creates an irregular surface on the exterior of the stent 400. Fig. 12C illustrates a variation of a stent 400 having a plurality of knuckles 52 that are radially spaced about an axis 390 of the stent 400. Fig. 12E shows another variation of a stent 400 with knuckles 416 aligned with an axis 390 of the stent 400 as shown in Fig. 12D. Although the figures show the axial and radial aligned knuckles 416 on separate devices, both types of knuckles 416 can be incorporated into a single stent structure. Varying the alignment of knuckles can permit increased radial force as the stent expands into the obstruction or increased flexibility as the stent navigates through tortuous anatomy.

[0121] Fig. 12G illustrates a proximal end of the stent structure 400 as shown, a plurality of elements 402 and 403 extend along the shaft 412 and diverge to form the fluid permeable closed proximal end of the stent structure 400. The elements 402 and 403 that extend along the shaft 412 can be covered by a sheath, tube, spiral cut tube, or any structure 418 that prevents separation of the elements 402 403. A variation of the stent structure 402 includes a construction where the elements 402 403 are not glued, welded, or have any similar type of joint in the distal portion 420 of the shaft 412. Instead, the joint 411 is located proximal to the distal section of the shaft 412 in an intermediate section 422. Because joints or other similar features reduce flexibility of the joined structure, positioning the joints 411 in a proximal area allows the the distal portion 420 of the shaft to remain flexible.

[0122] 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.

[0123] 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.

[0124] 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.

[0125] 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. An interventional medical device for retrieving and securing an obstruction within a vessel lumen, the device comprising:

   a shaft having a flexibility to navigate through tortuous anatomy, the shaft a distal portion and a proximal portion;

   a capturing structure located at a distal portion of the shaft comprising a plurality of struts, the capturing structure having a reduced profile for positioning in or adjacent to the obstruction and an expanded profile, such that when expanded into the obstruction, the struts at least partially enmesh with the obstruction such that subsequent movement of the capturing structure permits dislocation of at least a portion of the obstruction from the lumen;

   an eversible cover having a fixed section affixed relative to a proximal end of the capturing structure, a free section extending in a proximal direction from the fixed section and a cover wall extending from the fixed section to the free section, where the eversible cover is expandable, the eversible cover being axially compliant such that when the shaft is moved proximally within the lumen, the eversible cover everts over the capturing structure allowing for the free section of the cover to be distal to the fixed end of the capturing portion.

2. The medical device of claim 1, where the eversible cover, capturing structure, and shaft are a unitary structure.

3. The medical device of claim 1, where each wire located at an end of the free section loops back to the cover causing the wires at the end of the free section to be continuous.

4. The medical device of claim 1, where at least a portion of the cover wall adjacent to the distal end has a set shape that is everted upon expansion.

5. The medical device of claim 1, further comprising a catheter body, where in a delivery configuration, the shaft, capturing structure and eversible cover are located within the catheter body and where the capturing structure is advanceable in and out of a distal end of the catheter body.

6. The medical device of claim 1, where the eversible cover comprises a plurality of layers forming the cover wall.

7. The medical device of claim 1, where the free section of the eversible cover partially restricts about the shaft without being attached to the shaft.

8. The medical device of claim 1, where a portion of the cover wall extends distally beyond the fixed section when the eversible cover is expanded.

9. The medical device of claim 1, where the fixed section of the eversible cover comprises a pre-set shape to reduce a force required to evert the evertable cover.

10. The medical device of claim 1, where the cover wall is layered in an undulating pattern upon deployment.

11. The medical device of claim 1, where the capturing structure comprises an elongated stent structure.

12. The medical device of claim 1, where the capturing structure comprises a device selected from a group consisting of a filter, an artherectomy device, a rotational cutter, an aspiration device, stent based retrievers and retrieval baskets.

13. The medical device of claim 1, where the cover is self expanding.

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

15. The medical device of claim 1, where the cover 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.

16. The medical device of claim 15, where the first porous section comprises a first braid density and the second porous section comprises a second braid density.

17. The medical device of claim 15, where the first porous section comprises an additional braid layer.

18. The medical device of claim 15, where the first porous section prevents fluid from flowing therethrough.

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

20. The medical device of claim 15, where the first porous section comprises a circumferential area of the cover.

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

22. The medical device of claim 21, further comprising at least one medicament on or in the polymeric layer.

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

24. The medical device of claim 1, where the cover comprises a mesh material

25. The medical device of claim 24, where the mesh material comprises a single continuous wire.

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

27. The medical device of claim 24, where at least a portion of the mesh material is fabricated from a radiopaque material.

28. The medical device of claim 1, where the eversible cover comprises at least one wire coiled such that turns of the coil form the cover wall.

29. The medical device of claim 28, where the cover further comprises a braid adjacent to the coil.

30. The medical device of claim 28, where the cover further comprises a film coupled to the coil.

31. The medical device of claim 1, where the eversible cover comprises at least one barb or knuckle at an exterior surface of the cover wall.

32. The medical device of claim 1, where the eversible cover comprises an inner braided layer and an outer braided layer, where the outer braided layer is relatively more compliant than the inner braided layer.

33. A method of securing an obstruction within a vessel, the method comprising:

positioning a catheter within a vessel;

advancing a shaft having a retrieval device affixed thereto out of the catheter;

advancing an eversible cover out of the catheter such that a fixed end of the eversible cover is adjacent to a proximal end of the retrieval device and a free end of the eversible cover is moveable relative to the shaft and retrieval device;

expanding at least a portion of the eversible cover against a portion of a wall of the vessel;

manipulating the retrieval device to become at least partially enmeshed with the obstruction; and

proximally translating the shaft and retrieval device with at least a portion of the obstruction affixed thereto such that resistance of the eversible cover against the vessel resists movement of the eversible cover causing the free section of the eversible cover to evert over the proximally translated retrieval device.

34. The method of claim 33, further comprising further withdrawing the shaft from the vessel such that during withdrawal the eversible cover forms a protective barrier over the obstruction to lessen shearing forces caused by the vessel and reduce dislodging portions of the obstruction from the retrieval device.

35. A method of preparing a retrieval device comprising:

providing a retrieval device *having been previously removed from a body of a patient* where the retrieval device includes a protective cover where a fixed end of the protective cover is affixed adjacent to a proximal end of the retrieval device and where a free end is located distally to the fixed end covering the retrieval device and is moveable relative to the second end;

reversing the protective cover by moving the free end proximally of the fixed while the fixed end remains affixed adjacent to the proximal end of the retrieval device;

inserting the retrieval device and cover into a catheter where the free end of the cover is proximal to the fixed end of the cover and retrieval device such that upon deployment from the catheter, the free end of the cover deploys proximally to the fixed end of the cover.

36. A method of securing an obstruction within a vessel, the method comprising:

advancing a shaft having a retrieval device affixed thereto to the obstruction;

advancing a protective device over the shaft, the protective device comprising a sheath having an eversible cover, where a fixed end of the eversible cover is affixed to a distal portion of the sheath and a free end of the eversible cover is located proximal to the fixed end;

positioning the fixed end of the eversible cover adjacent to the retrieval device and expanding at least a portion of the eversible cover against a portion of a wall of the vessel;

proximally translating the shaft and retrieval device with at least a portion of the obstruction affixed thereto such that resistance of the eversible cover against the vessel resists movement of the eversible cover causing the free section of the eversible cover to evert over the proximally translated retrieval device.

37. A medical device retrieval system for securing an obstruction within a vessel lumen and for use with a catheter configured to be navigated through the vasculature, the device comprising:

an elongated stent comprising a plurality of struts, the stent being collapsible for positioning in the catheter during delivery and having an expanded profile such that when expanded the struts are configured to engage the obstruction;

a shaft fixedly attached to the elongated stent and having a flexibility to navigate through tortuous anatomy;

a fluid permeable cover having a distal end coupled to a proximal end of the elongated stent a cover wall defining a cavity and extending along the shaft, and a proximal end being moveable relative to the shaft, where the fluid permeable cover is collapsible for positioning in the catheter during delivery and is expandable upon deployment from the catheter such that a portion of the fluid permeable cover is expandable;

where the fluid permeable cover is axially pliable such that when the device is deployed in the vessel and frictional forces are applied against the fluid permeable cover, proximal movement of the shaft and elongated stent cause inversion of the fluid

permeable cover wall such that the fluid permeable cover wall everts over the elongated stent.

38. An interventional medical device for use with a catheter configured for delivery through vasculature and for securing an obstruction within a vessel lumen, the device comprising:

a shaft having a flexibility to navigate through tortuous anatomy, the shaft having a distal portion and a proximal portion;

a capturing device comprising a sidewall, the capturing device fixedly located at a distal portion of the shaft and having a reduced profile for positioning in the catheter and an expanded profile, such that upon deployment from the catheter, the capturing device expands to force a portion of the sidewall into the obstruction to at least partially attach to the obstruction;

a cover having a distal end coupled adjacent to a proximal end of the capturing structure, a proximal end and a cover wall extending therebetween, where the proximal end of the cover is slidable relative to the distal end, where the cover is expandable such that when located in the catheter the cover is in a reduced delivery state and upon advancement from the catheter the cover expands with the proximal end located proximally of the distal end, where the cover wall is compliant such that when deployed from the catheter and the shaft is pulled in a proximal direction frictional forces between the vessel and the cover wall or proximal end cause the cover to invert as the cover wall inverts over the capturing device to surround the capturing device.

39. An interventional medical device for securing a retrieval device having one or more obstructions located therein for removal from a body, the medical device comprising:

a sheath having a flexibility to navigate through tortuous anatomy, the sheath a distal portion and a proximal portion and a lumen extending therethrough;

an eversible cover having a fixed section affixed to the distal portion of the sheath, a free section extending in a proximal direction from the fixed section and a cover wall extending from the fixed section to the free section, where the eversible cover is expandable, the eversible cover being axially compliant such that when the retrieval device is positioned through the sheath lumen and moved in a proximal direction against the eversible cover, the eversible cover everts over the retrieval device allowing for the free section of the cover to be distal to the retrieval device.

40. A stent retrieval device for expanding against one or more occlusive bodies in a vasculature, the stent retrieval device comprising:

an elongate shaft having a flexibility to navigate through tortuous anatomy, the elongate shaft having a distal portion and a proximal portion;

a plurality of filaments that diverge from the distal portion of the elongate shaft to form an expandable elongated stent body having a open distal end and a fluid permeable closed proximal end and a cavity therebetween, where divergence of the filaments at the distal portion of the elongate shaft forms the fluid permeable closed proximal end;

where the plurality of filaments extending along the shaft are free of any connection joints in the distal portion to permit increased flexibility of the distal portion as it navigates though tortuous anatomy; and

one or more connection joints proximal to the distal portion where the connection joints secure the plurality of filaments to the shaft.

41. The stent retrieval device of claim 40, wherein at least one of the plurality of filaments comprise at least two wires twisted together, the elongated stent body further comprising at least one intersection of filaments, where the wires of each filament are interwoven to provide increased outward radial strength of the elongated stent body and such that the wires slide relative to each other as the elongated stent body expands or compresses in diameter to reduce a force required to linearize the elongated stent body.

42. The stent retrieval device of claim 40, where the exterior surface of the elongated stent body comprises an irregular surface formed by intersection of filaments.

43. The stent retrieval device of claim 42, where the intersection of filaments comprises a barb or knuckle and where a plurality of barbs or knuckles are radially spaced about the elongated stent body.

44. The stent retrieval device of claim 42, where the intersection of filaments comprises a barb or knuckle and where a plurality of barbs or knuckles are aligned with an axis of the elongated stent body.

45. The stent retrieval device of claim 42, where the elongated stent body comprises a plurality of barbs or knuckles radially spaced about the elongated stent body and a plurality of barbs or knuckles axially aligned with an axis of the elongated stent body.

46. The stent retrieval device of claim 40, where at least one filament comprises a drawn filled tube material.

47. The stent retrieval device of claim 40, where at least one filament comprises at least one wire comprised of a first material and at least a second wire comprised of at least a second material different from the first material.

48. The stent retrieval device of claim 40, where at least one filament comprises at least one wire comprised of a first material and at least a second filament having at least one wire comprised of at least a second material different from the first material.

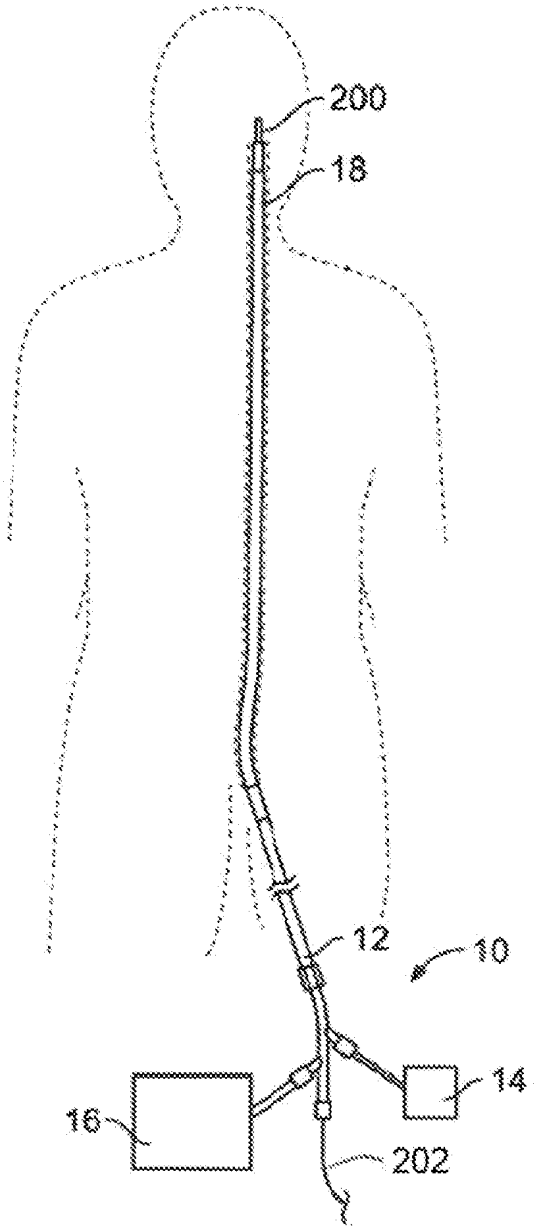

FIG.1

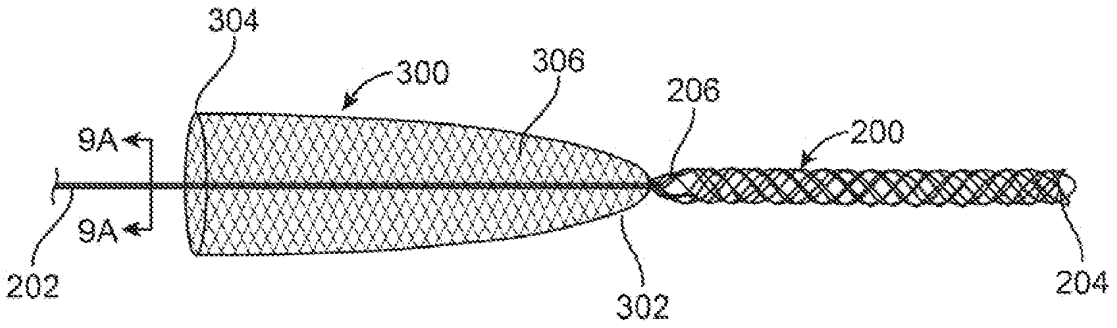

FIG. 2A

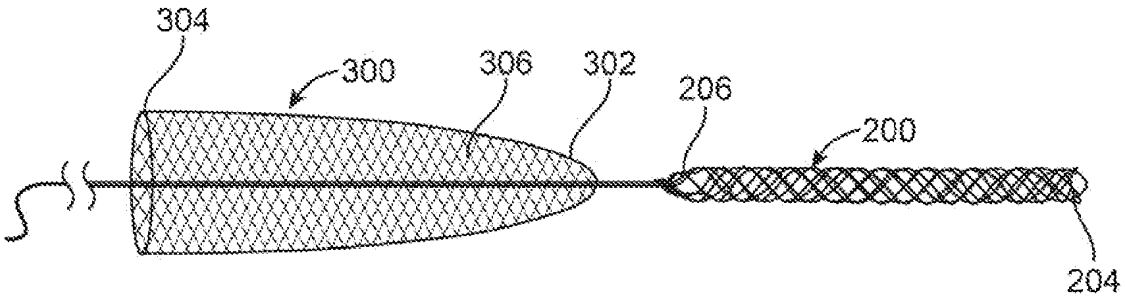

FIG. 2B

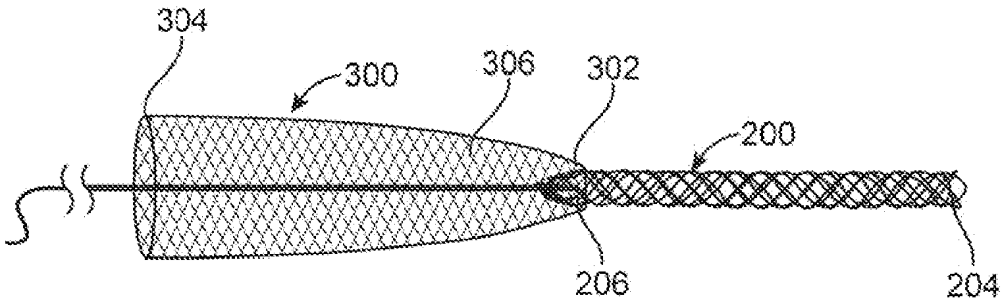

FIG. 2C

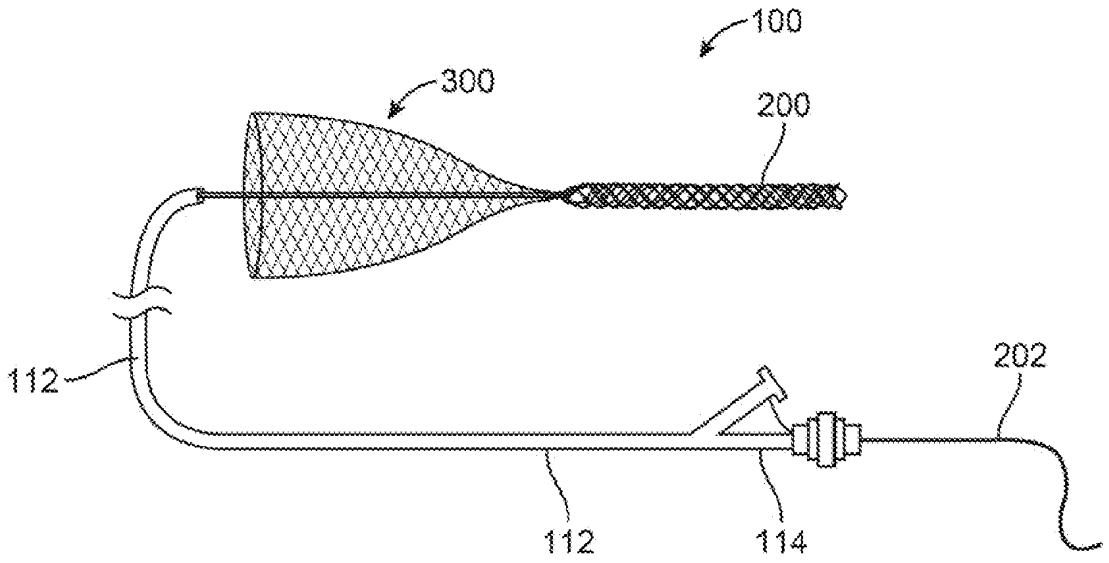

FIG. 2D

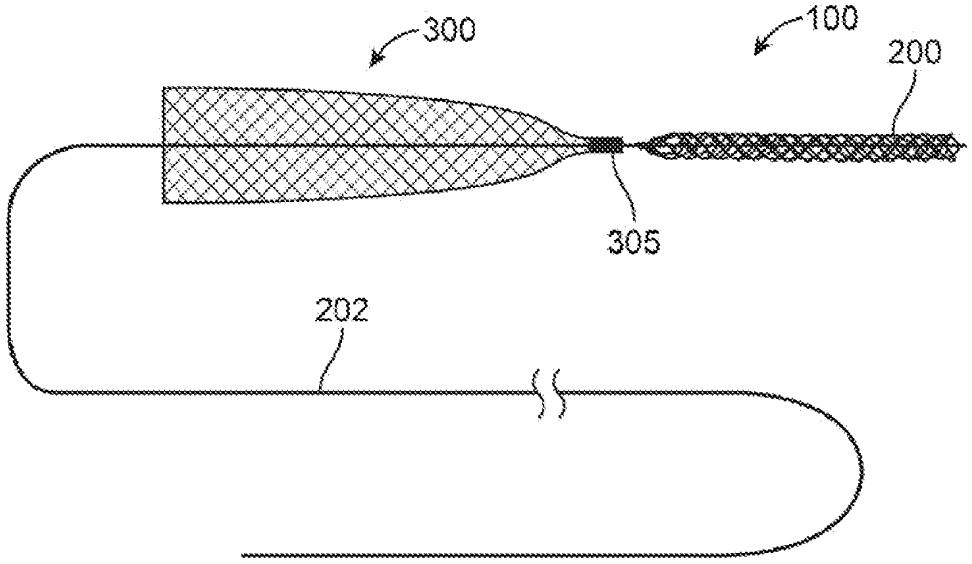

FIG. 2E

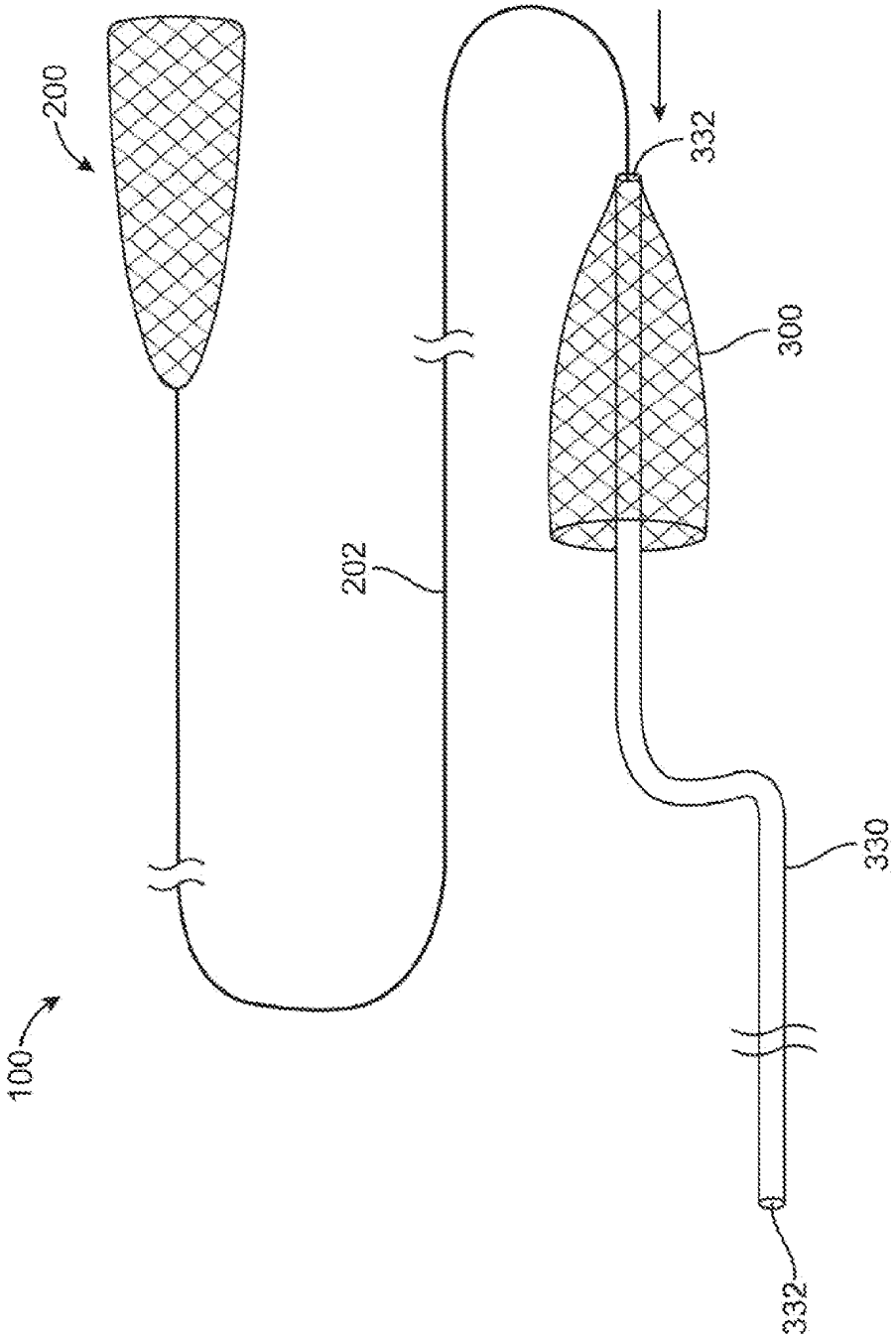

FIG. 2F

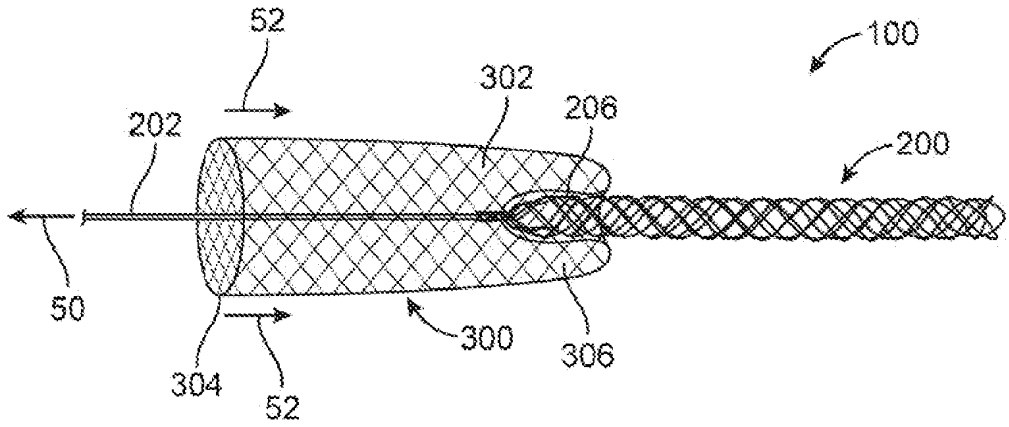

FIG. 3A

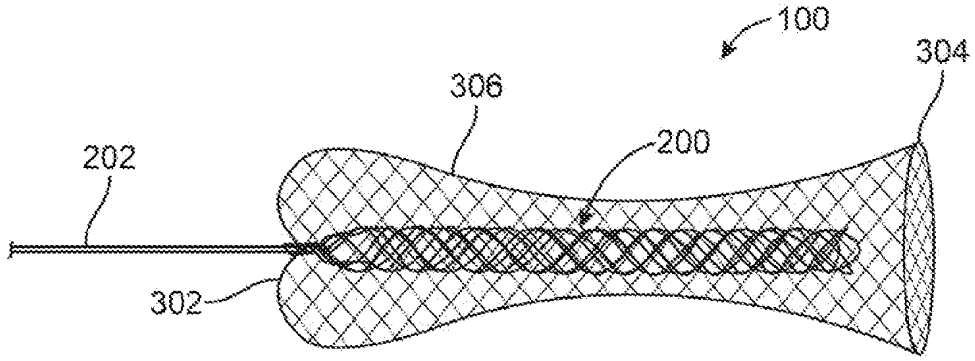

FIG. 3B

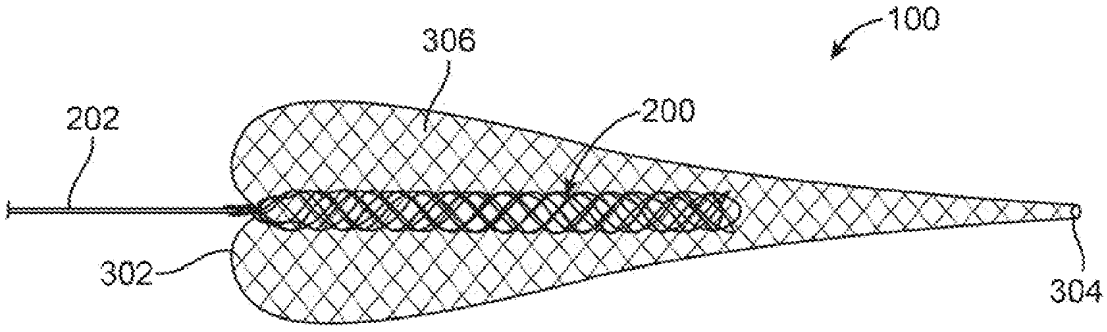

FIG. 3C

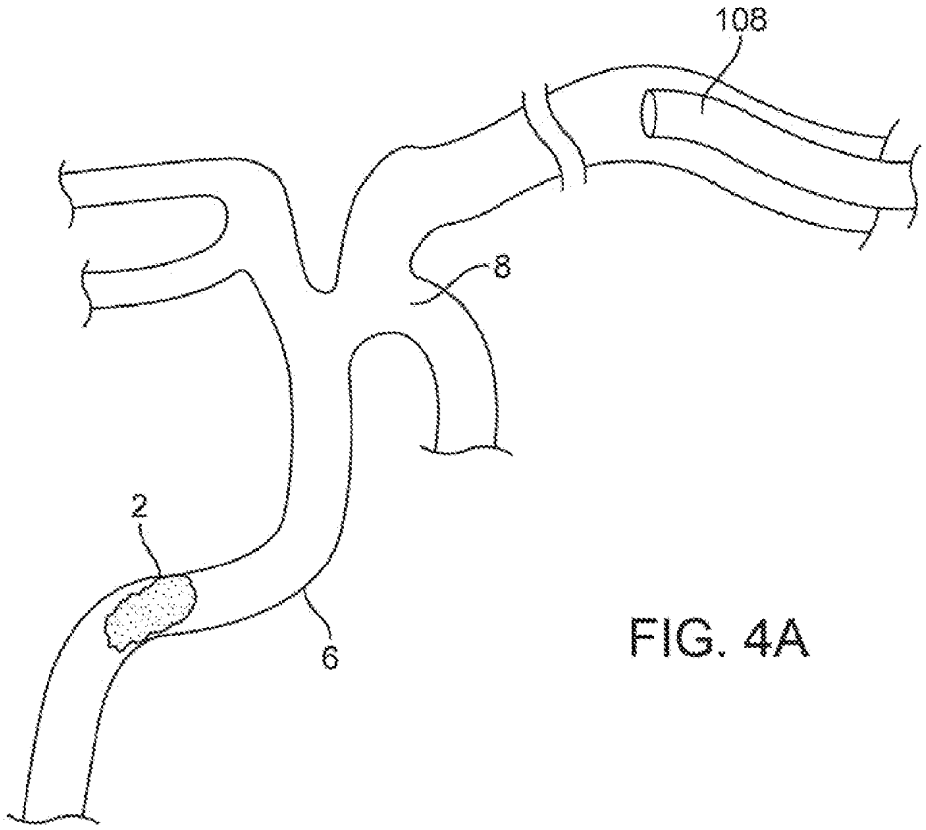

FIG. 4A

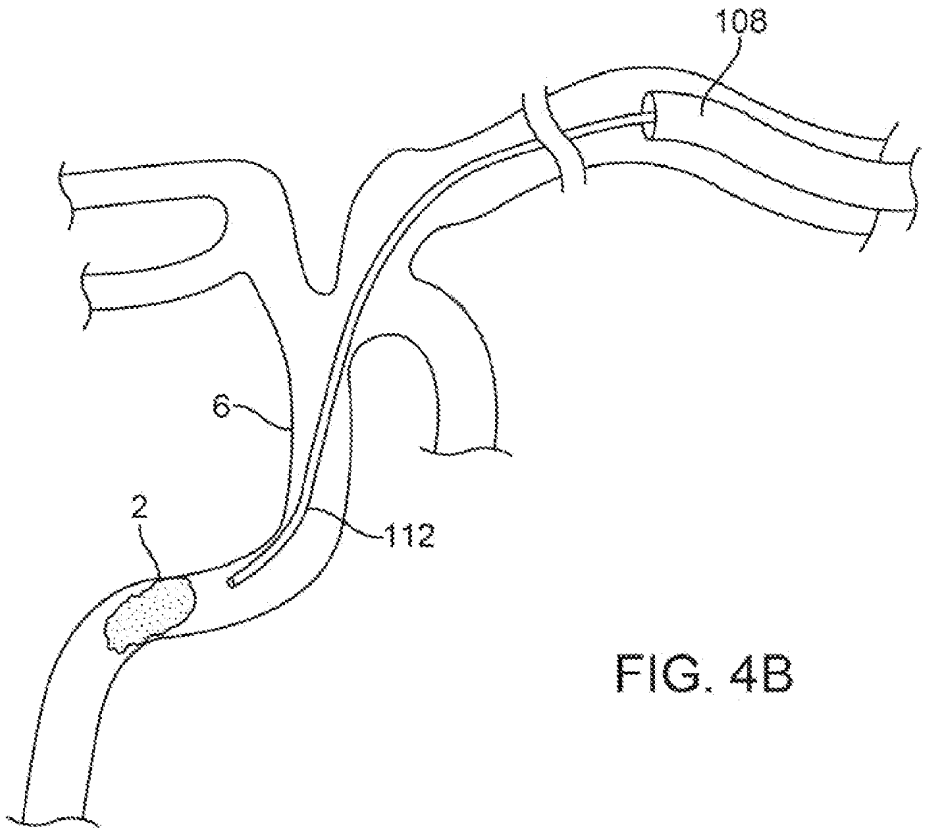

FIG. 4B

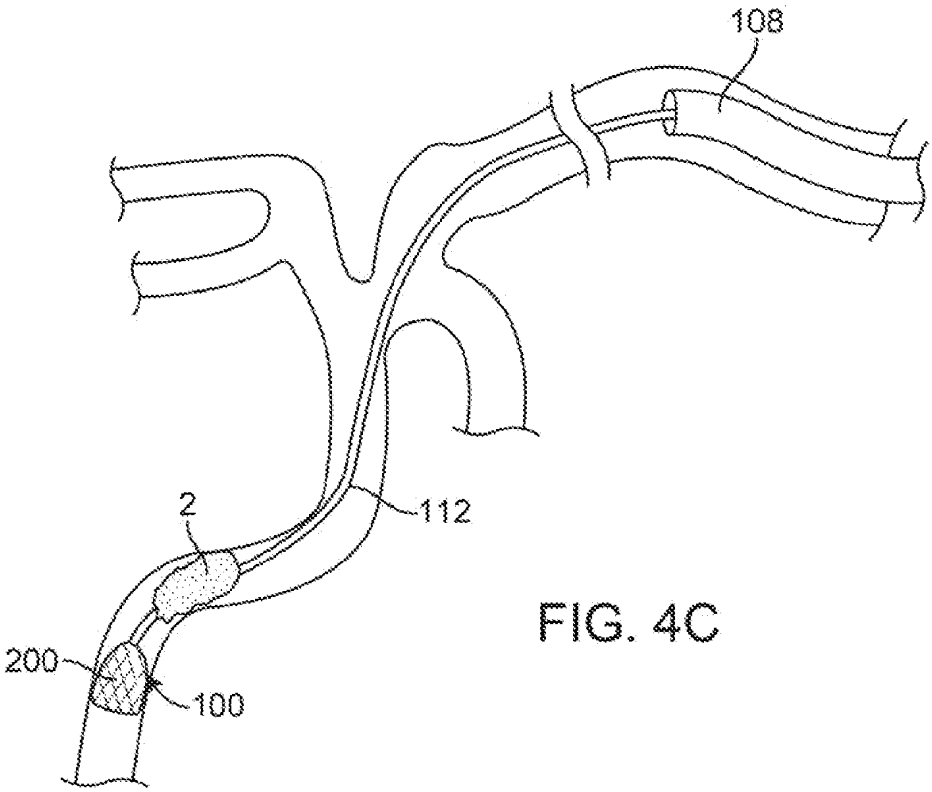

FIG. 4C

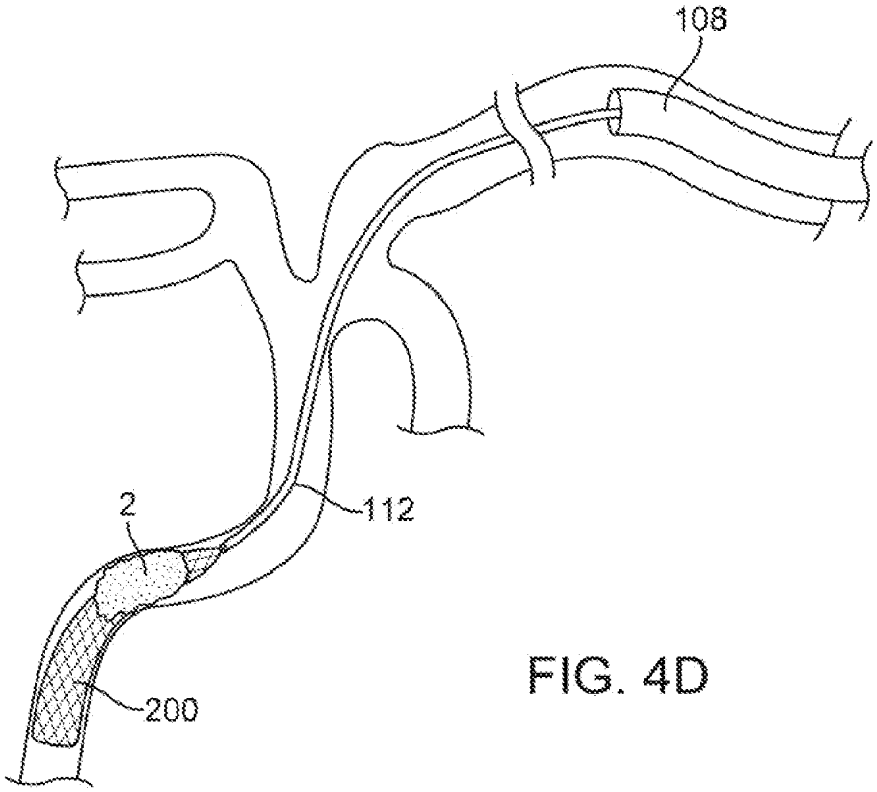

FIG. 4D

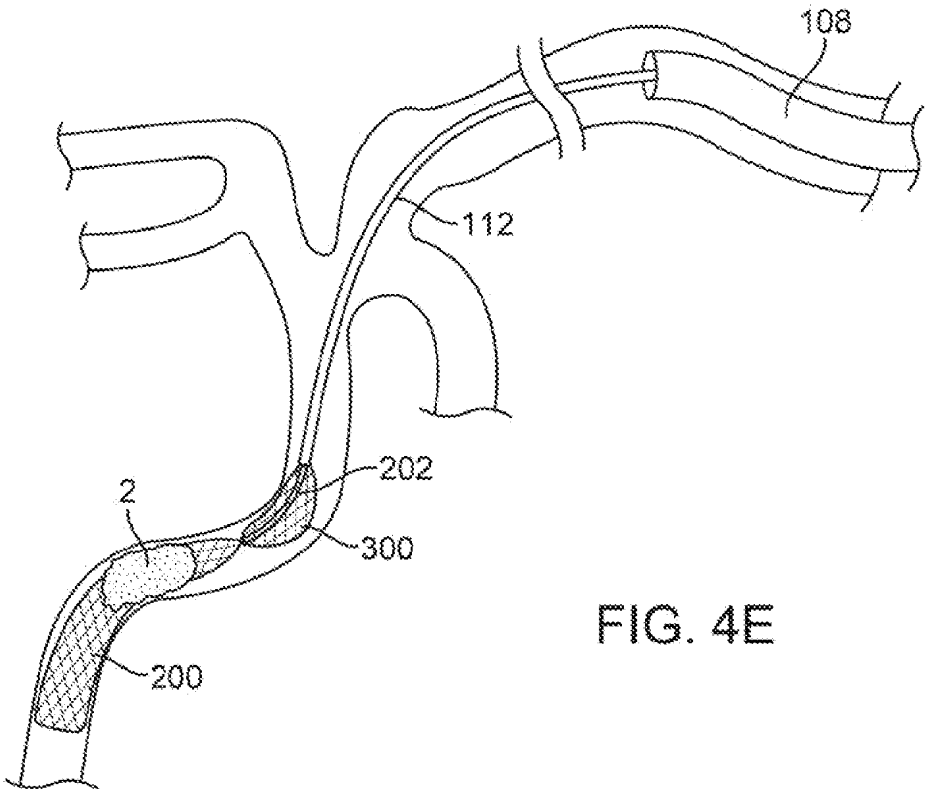

FIG. 4E

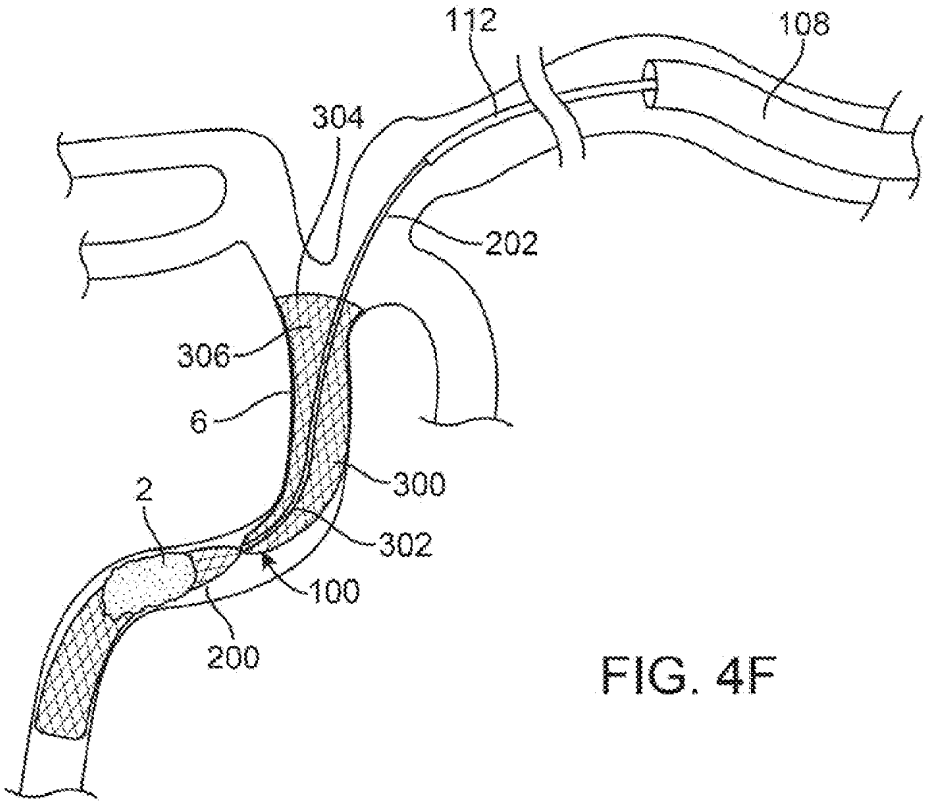

FIG. 4F

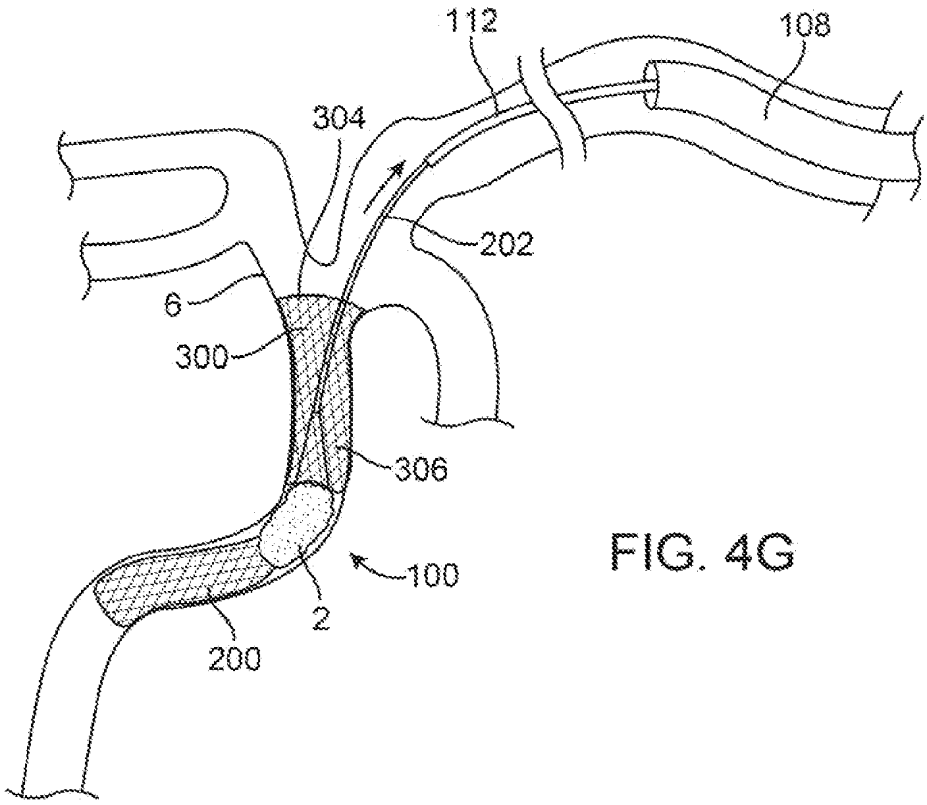

FIG. 4G

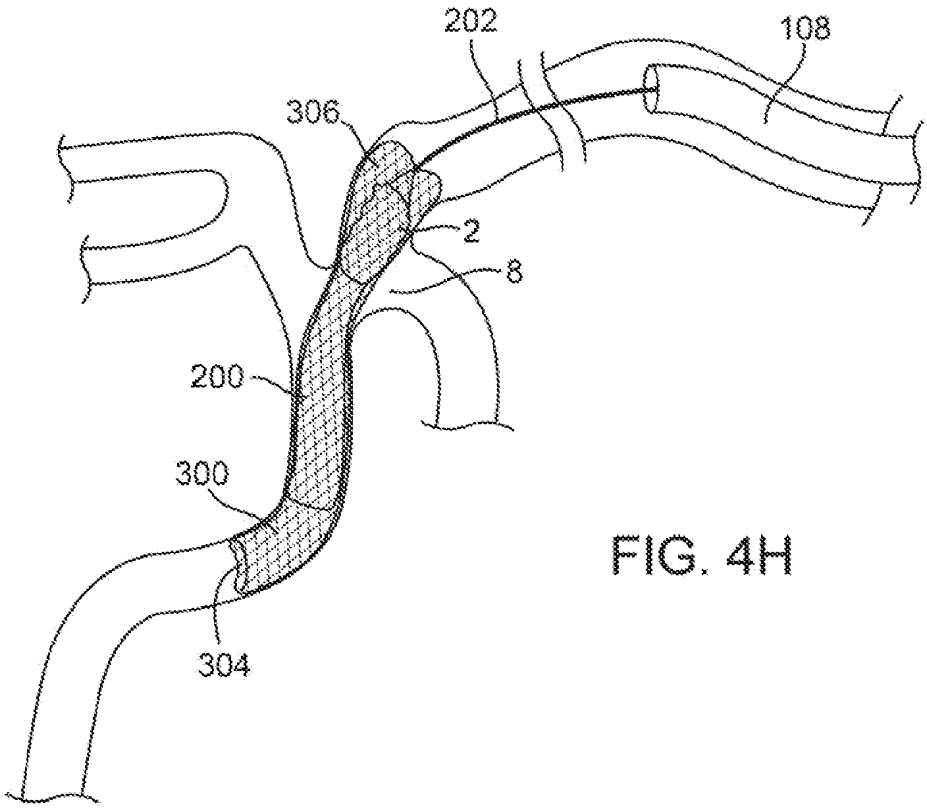

FIG. 4H

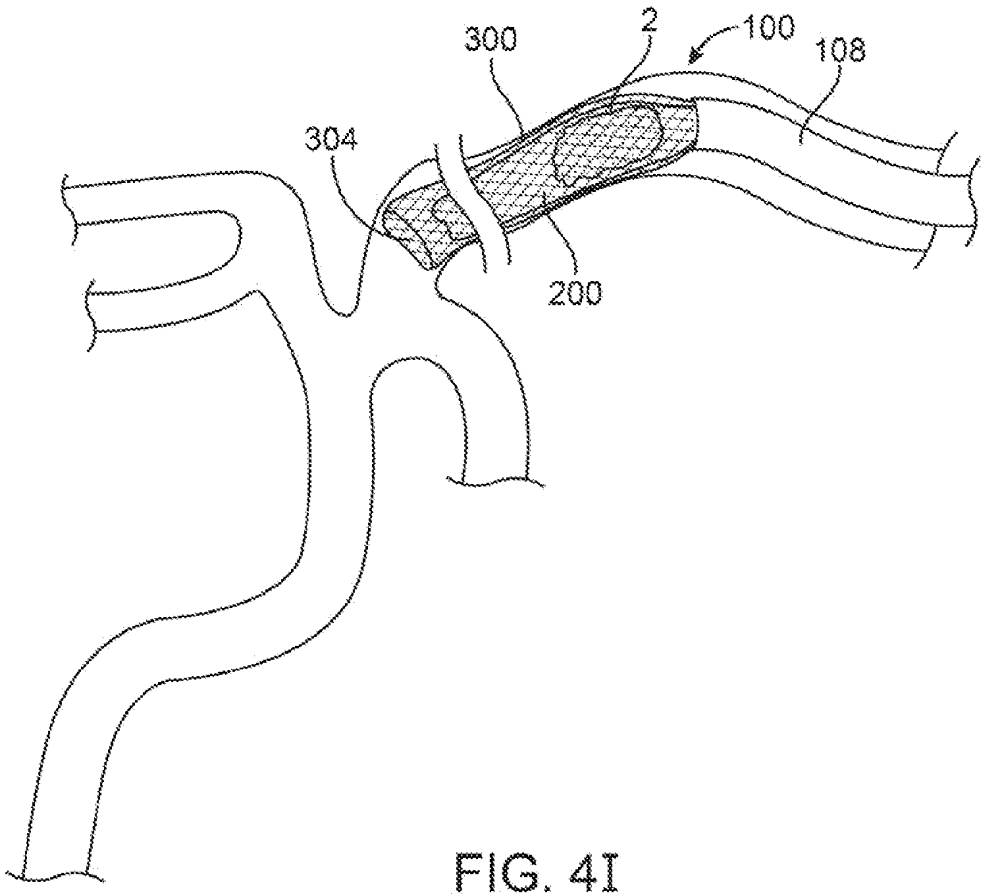

FIG. 4I

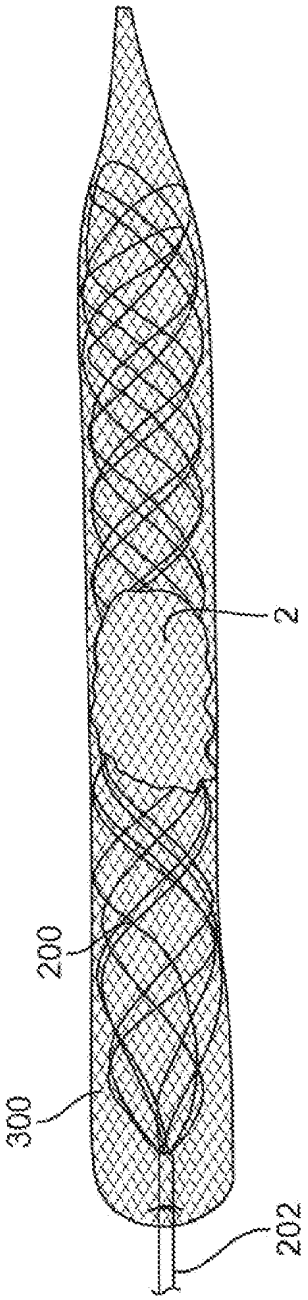

FIG. 4J

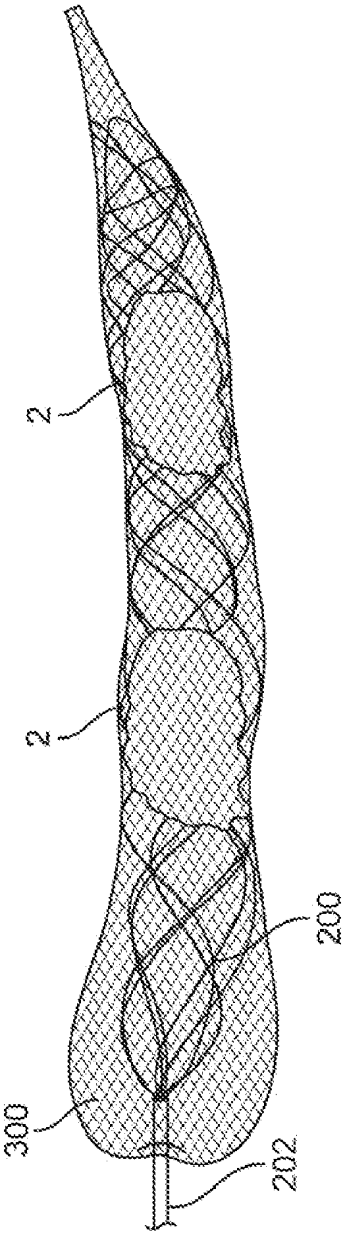

FIG. 4K

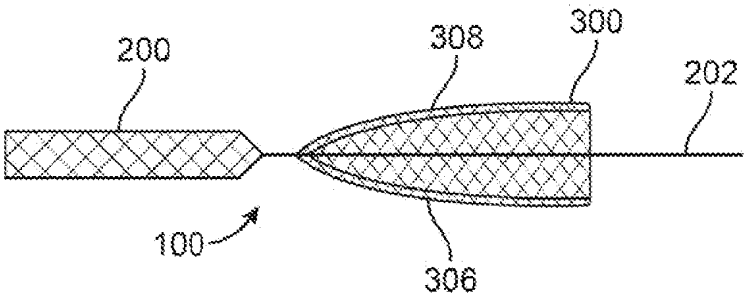

FIG. 5A

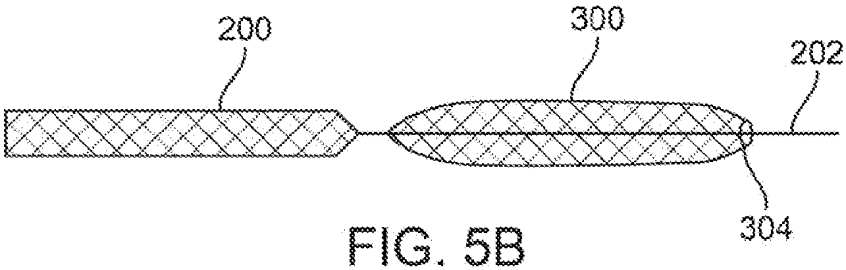

FIG. 5B

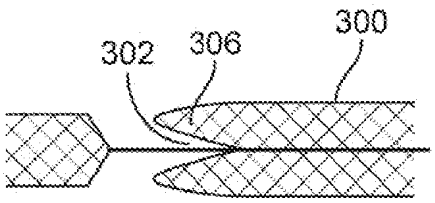

FIG. 5C

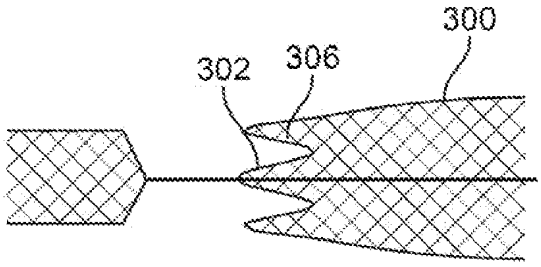

FIG. 5D

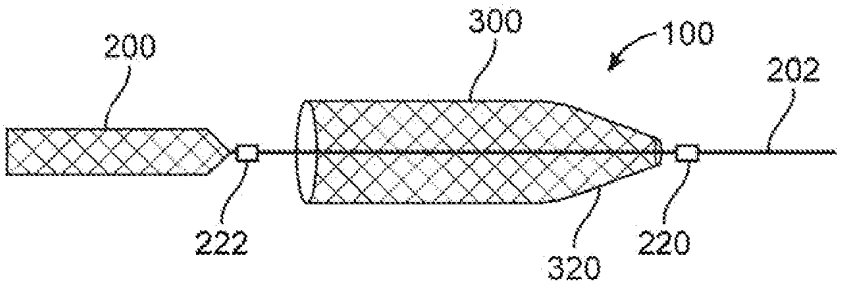

FIG. 5E

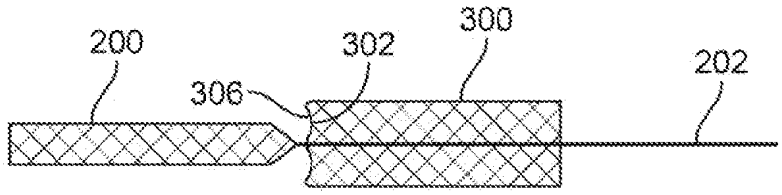

FIG. 5F

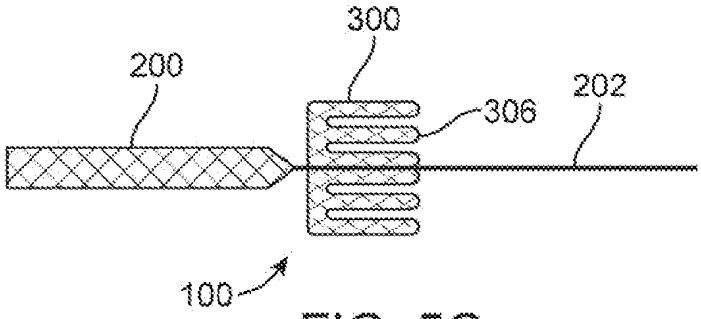

FIG. 5G

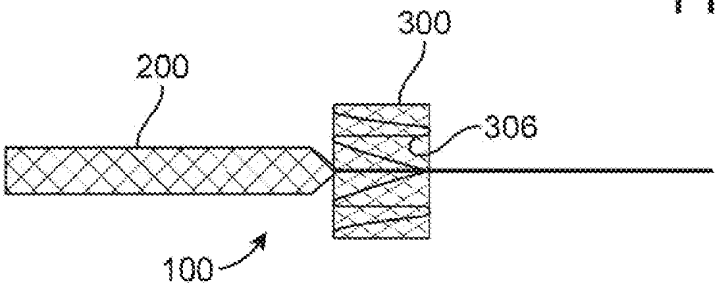

FIG. 5H

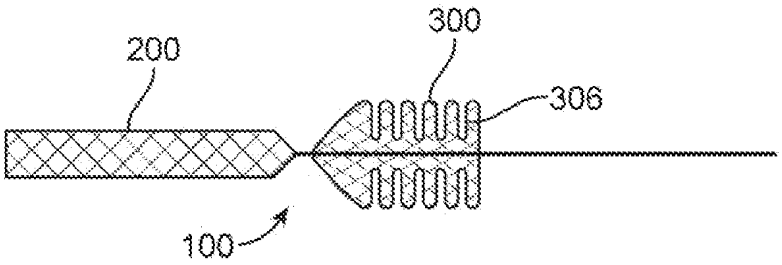

FIG. 5I

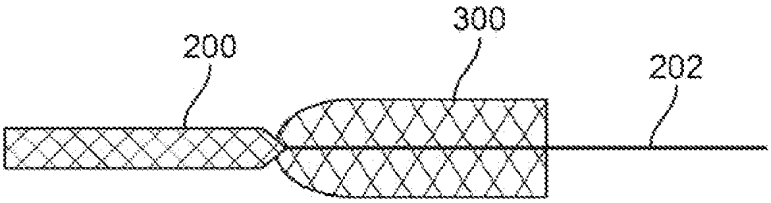

FIG. 5J

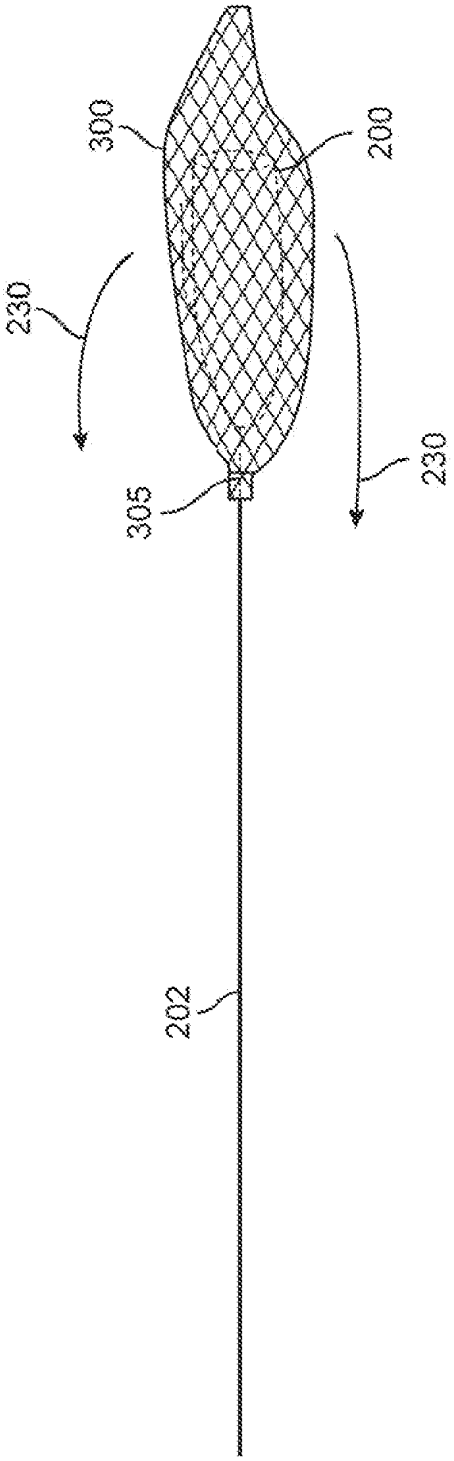

FIG. 5K

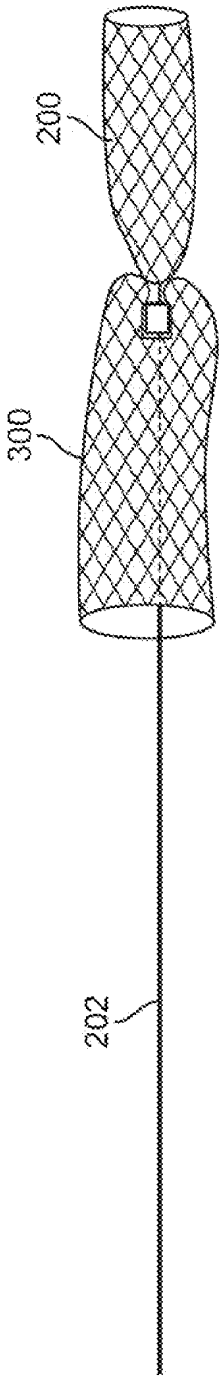

FIG. 5L

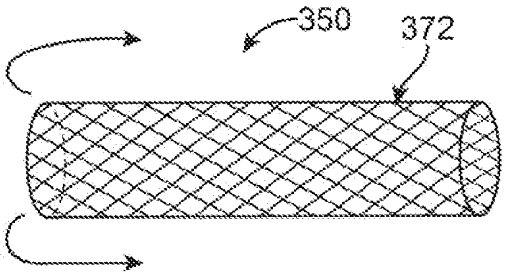

FIG. 6A

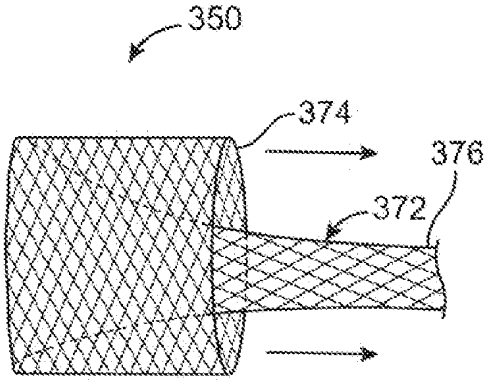

FIG. 6B

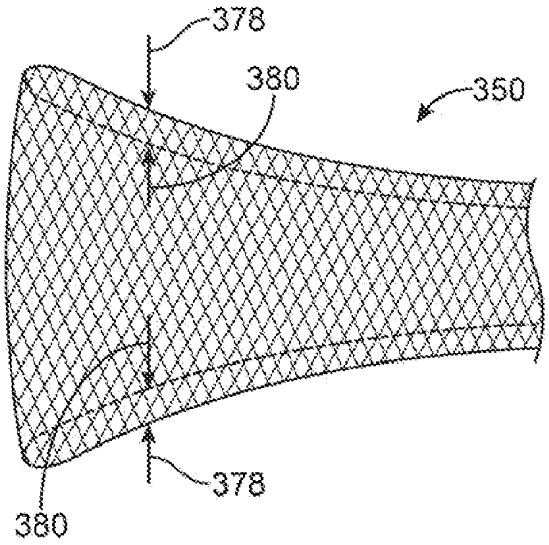

FIG. 6C

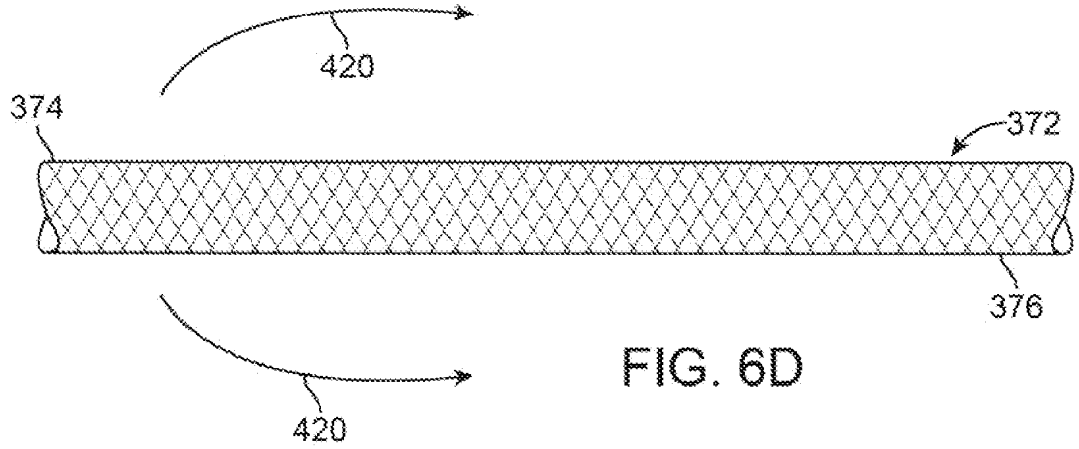

FIG. 6D

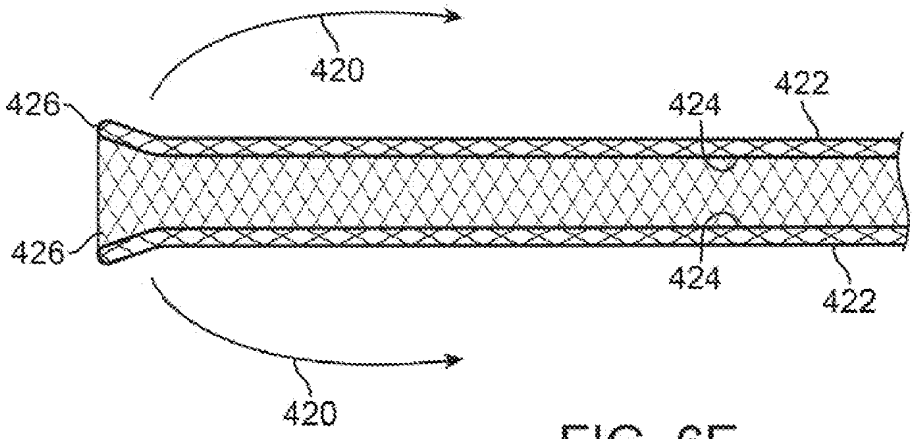

FIG. 6E

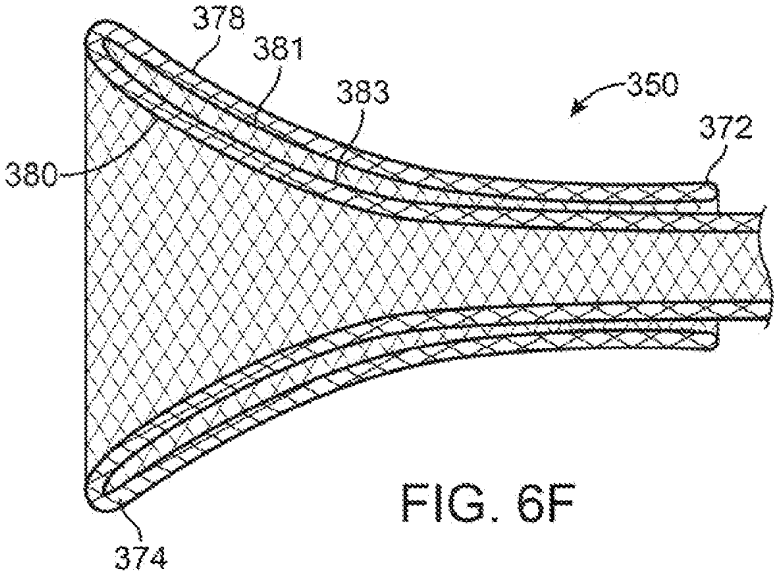

FIG. 6F

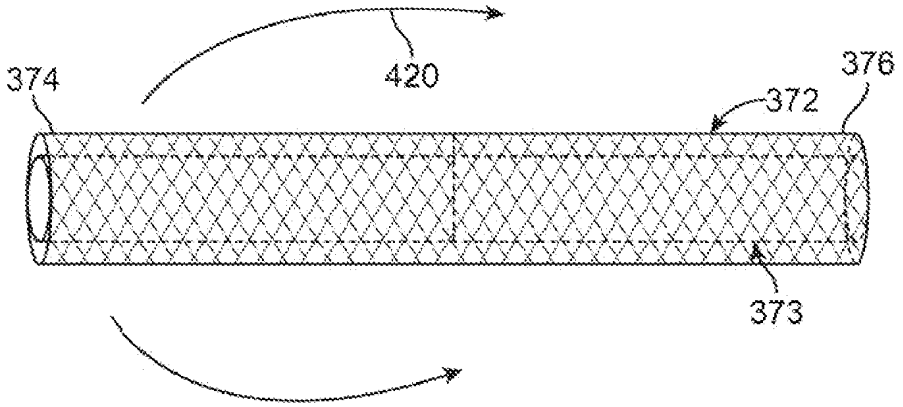

FIG. 6G

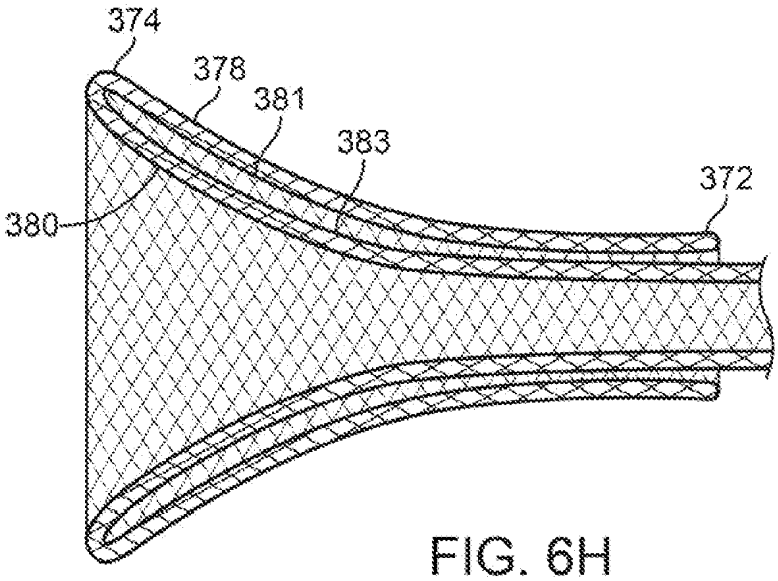

FIG. 6H

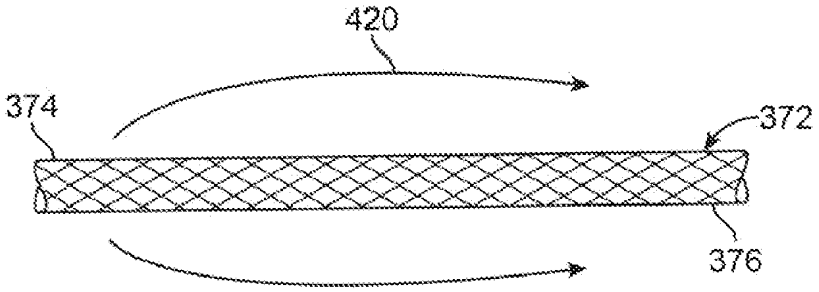

FIG. 6I

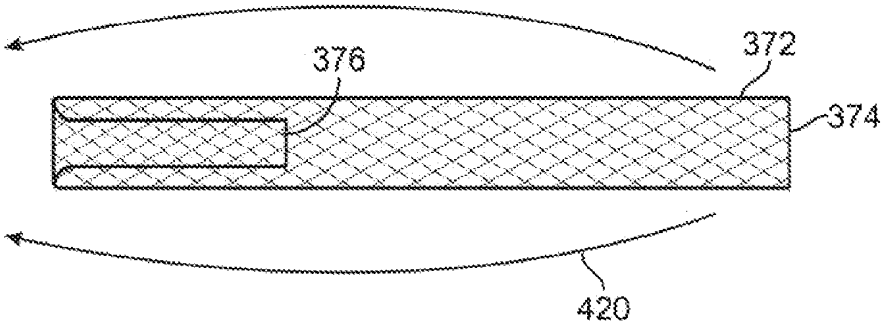

FIG. 6J

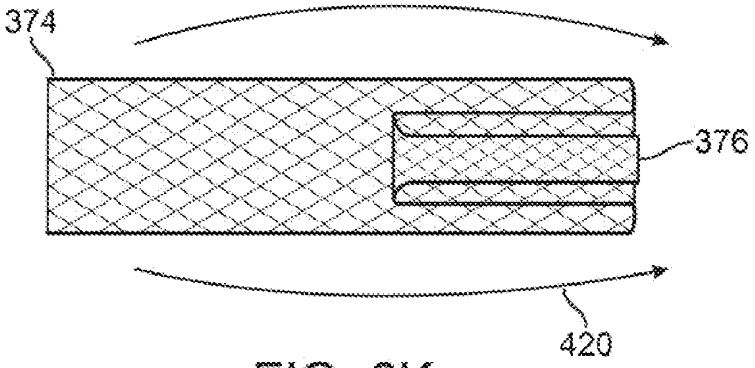

FIG. 6K

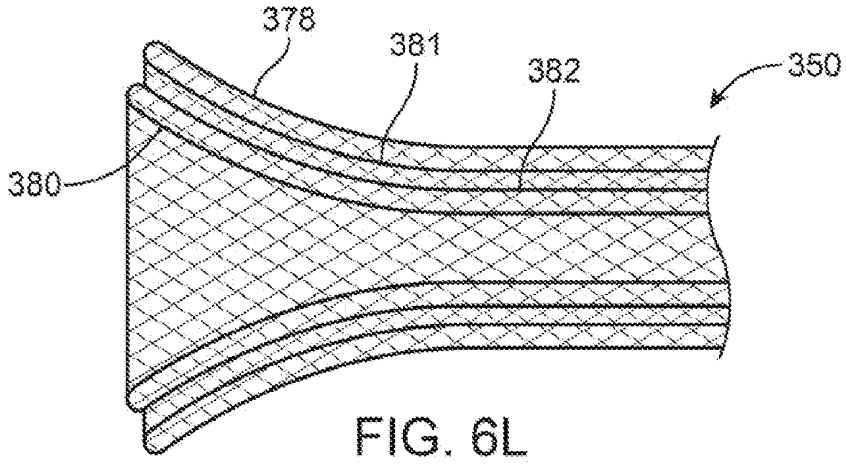

FIG. 6L

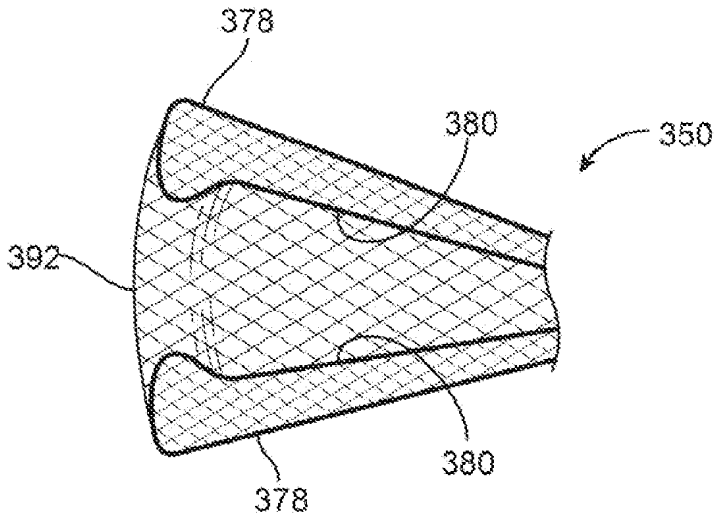

FIG. 7A

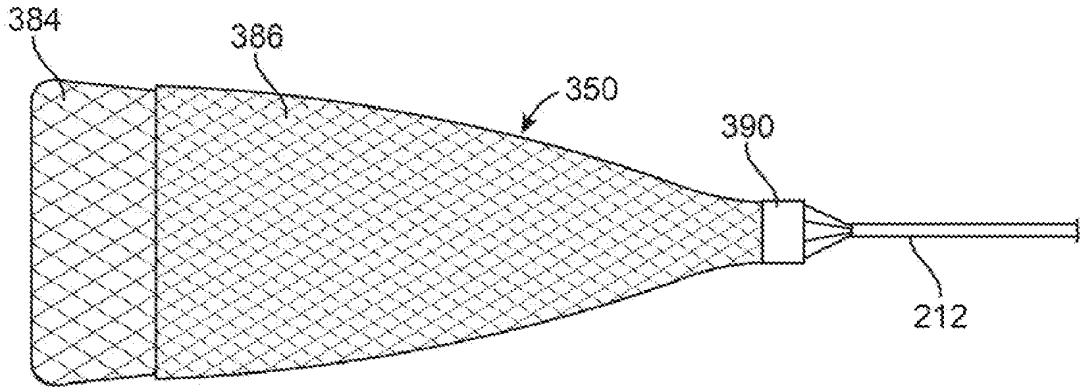

FIG. 7B

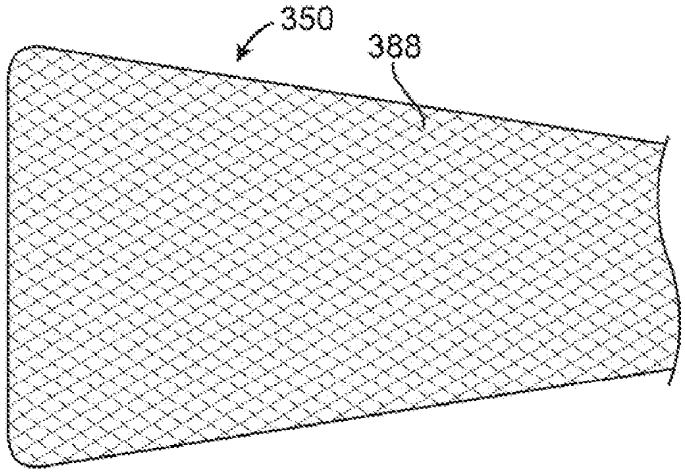

FIG. 7C

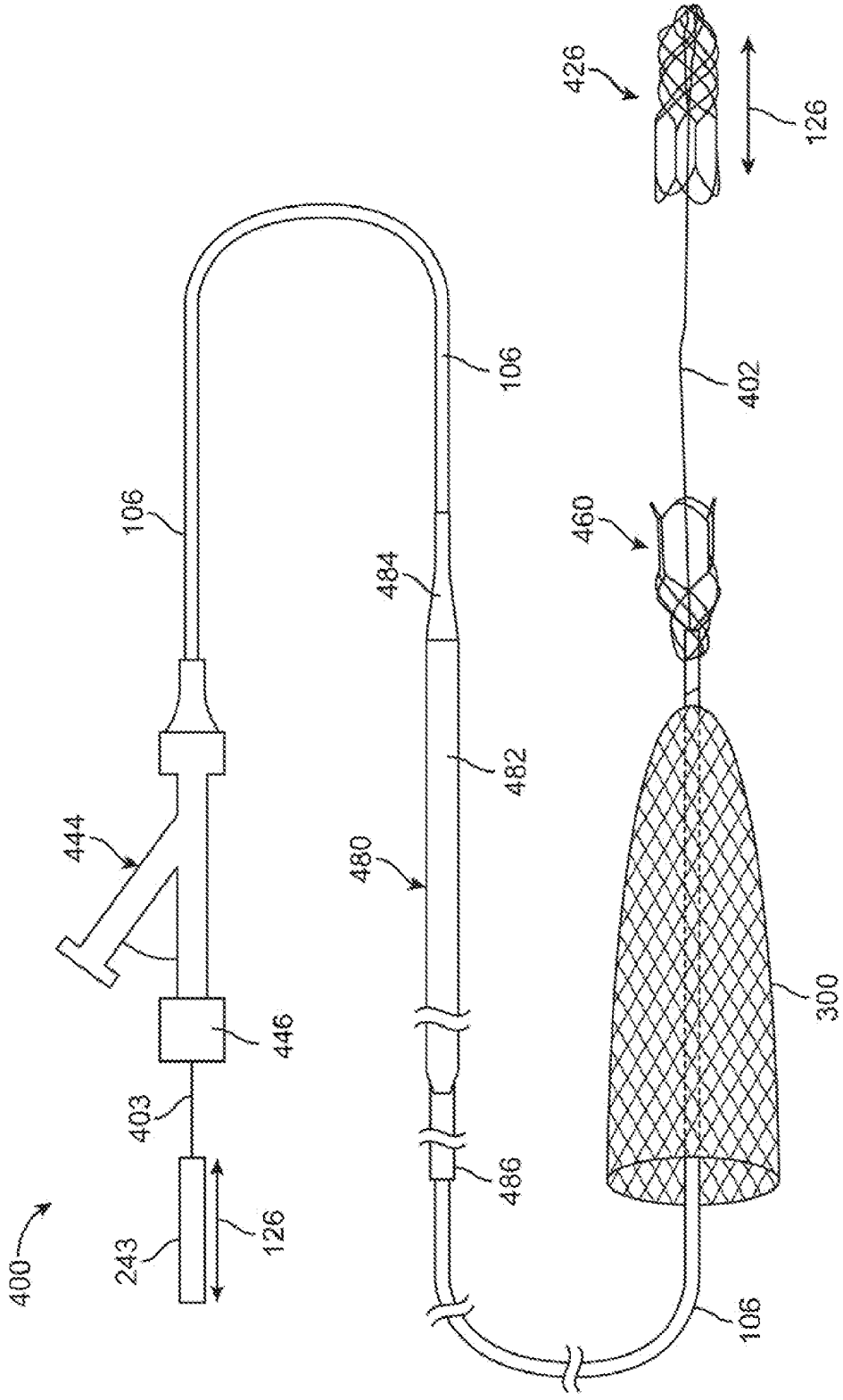
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FIG. 8

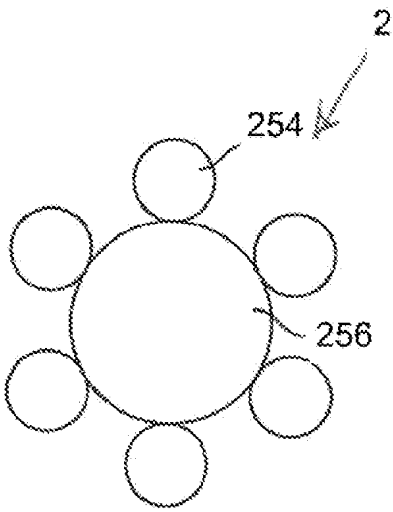


FIG. 9A

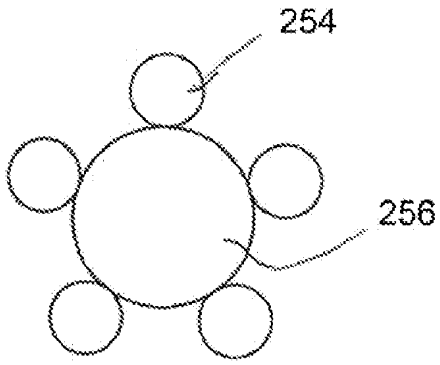


FIG. 9B

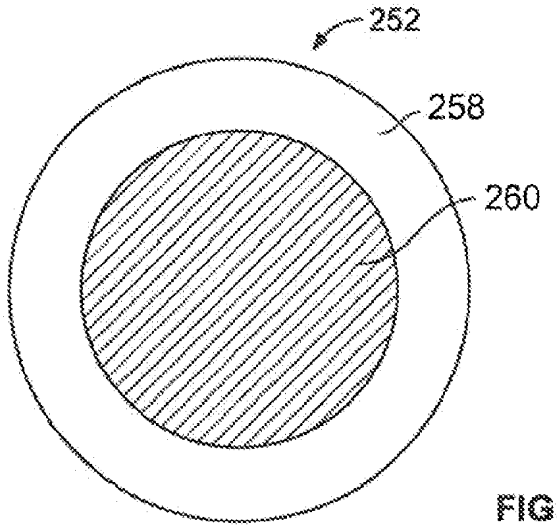


FIG. 9C

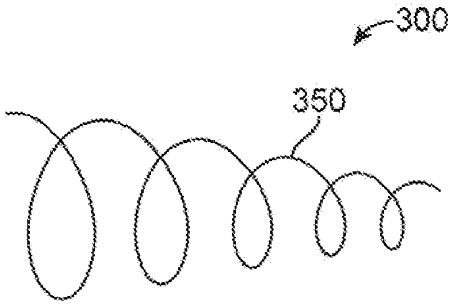


FIG. 10A

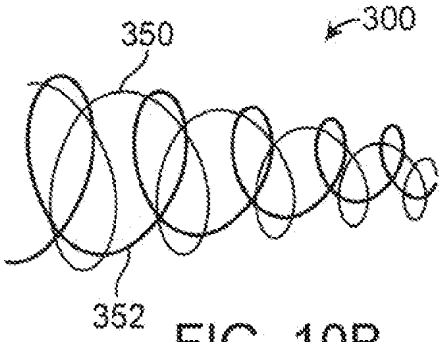


FIG. 10B

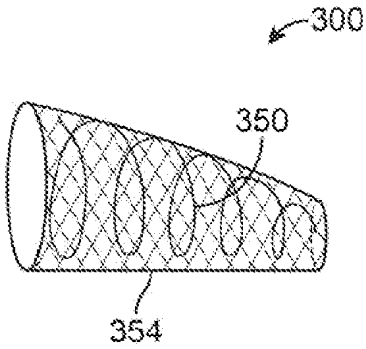


FIG. 10C

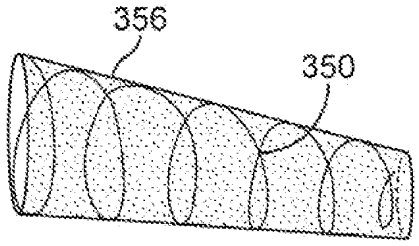


FIG. 10D

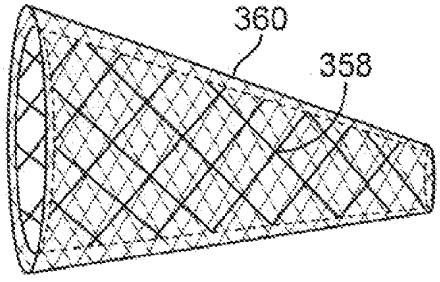


FIG. 10E

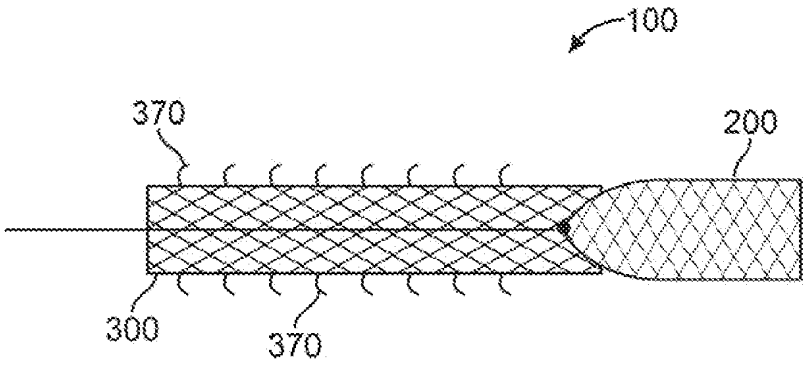


FIG. 11A

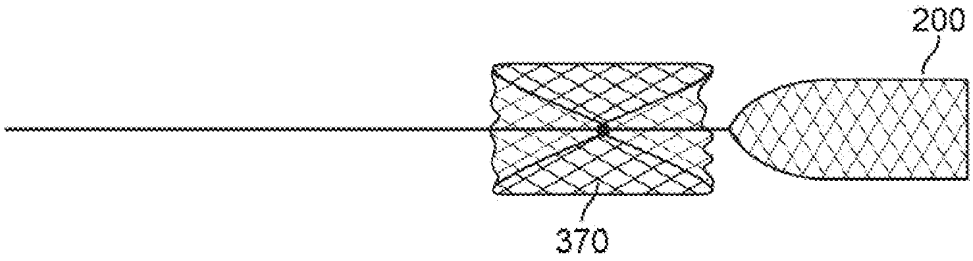


FIG. 11B

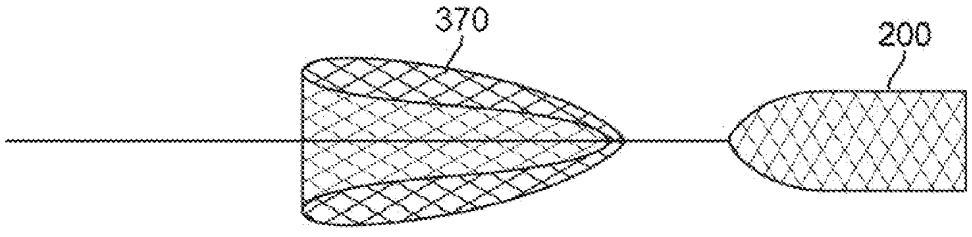


FIG. 11C

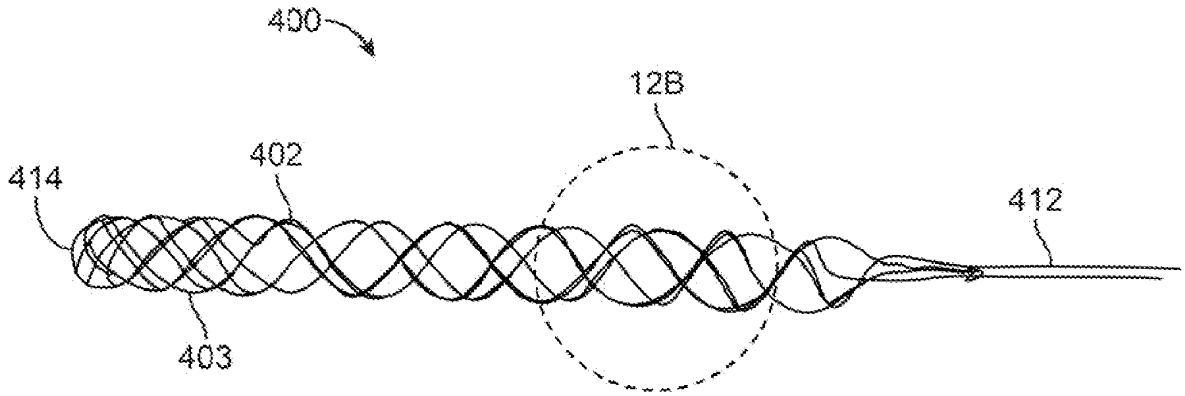


FIG. 12A

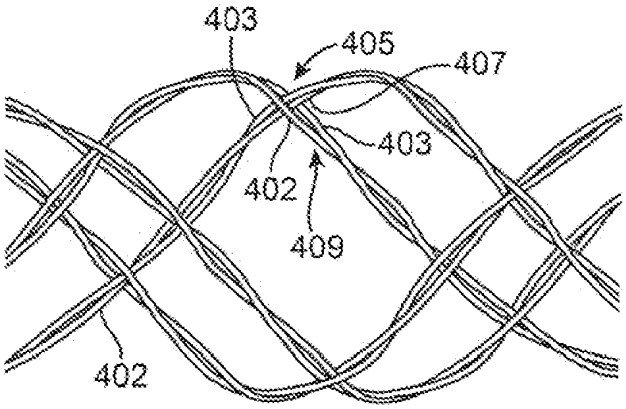


FIG. 12B

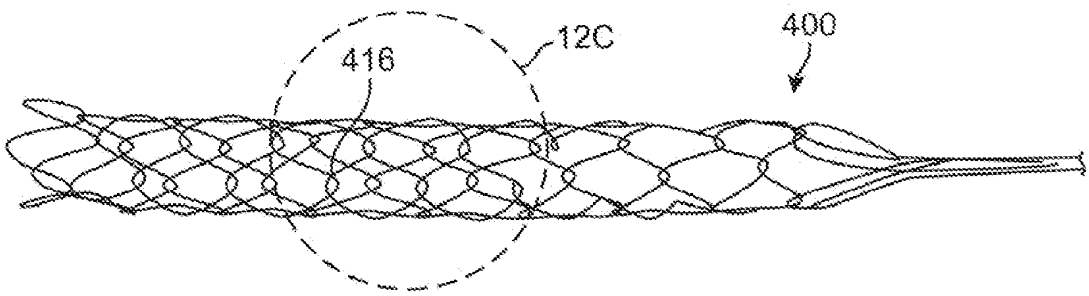
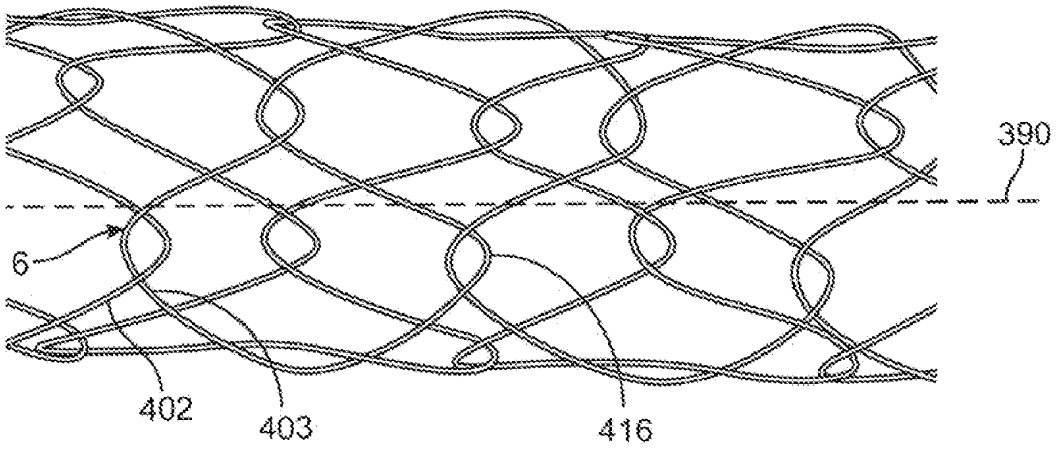


FIG. 12C



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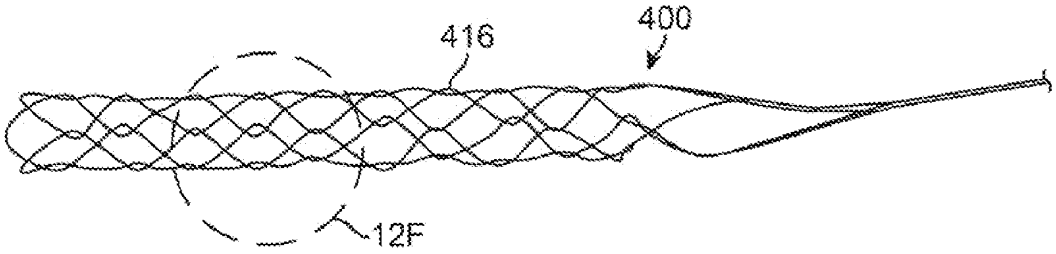

FIG. 12E

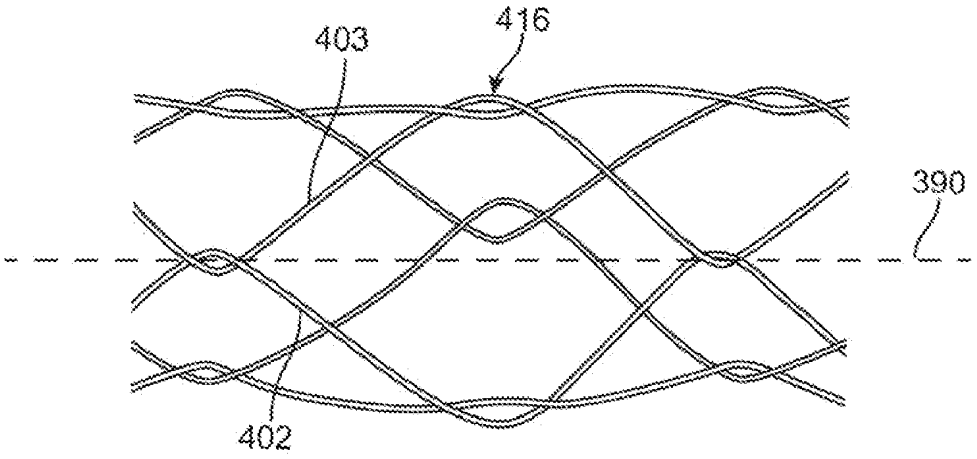

FIG. 12F

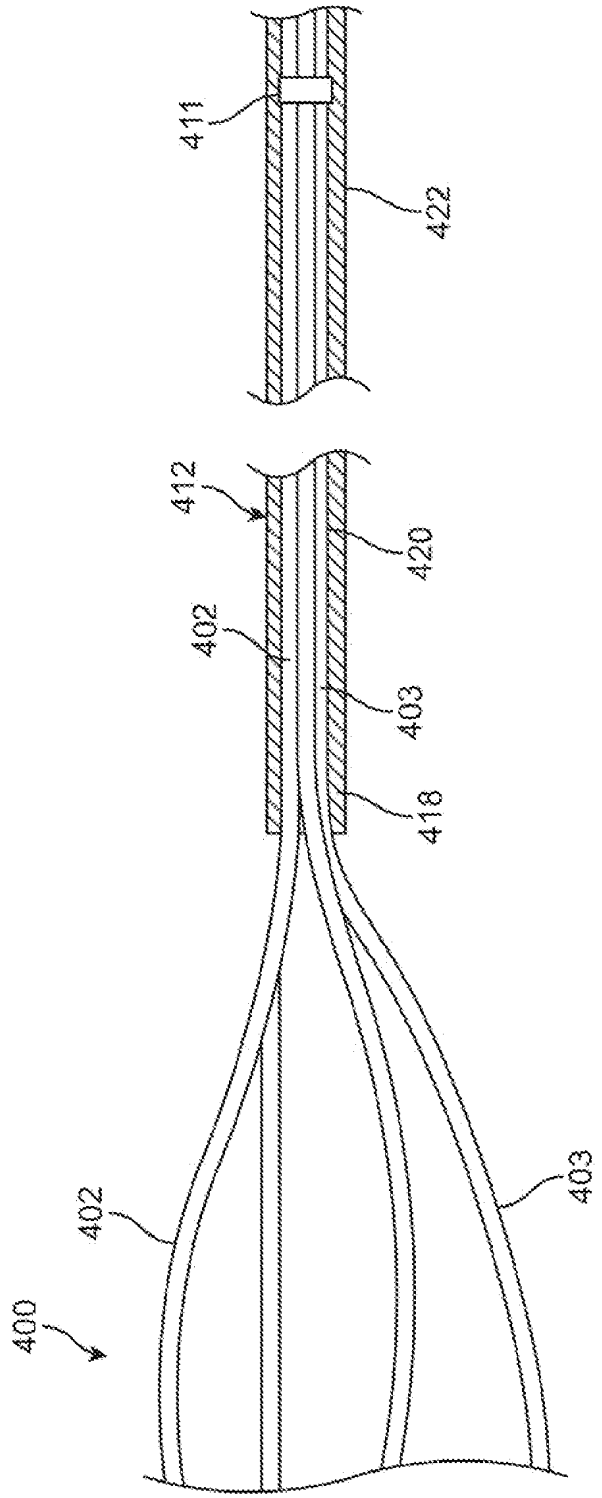

FIG. 12G

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 12/39216

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/22 (2012.01)
USPC - 606/159
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC: 606/159

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 606/170, 1, 180, 200 (keyword limited; terms 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
Search Terms Used: drug, medication, medicament, film, coat$3, layer, inner, outer, braid$3, polymer$2, inver$4, ever$4, sheath, sleeve, cover, stent, strut, remov$3, retriev$3, radiopaque, plaque, obstruction, clot, thromb$2, reus$4, basket, reposition$3, net$4, web$4

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 2009/0299393 A1 (MARTIN et al) 03 December 2009 (03.12.2009) fig 3H, 5B, para [0017], [0072]-[0073], [0108]-[0109], [0141]	40-48 --- 3, 11-12, 25-26, 31, 33-34, 36-38
X	US 2005/0085826 A1 (NAIR et al.) 21 April 2005 (21.04.2005) Entire document, especially para[0034]- para[0039] and figs. 1, 4-9.	39
X --- Y	US 2010/0076452 A1 (SEPETKA et al) 25 March 2010 (25.03.2010) fig 13, 14, 15, 16, 17, 18, 22, 26, 52, para [0089]-[0091], [0095], [0100], [0116]	1-2, 4-5, 7-8, 14, 23-24 --- 3, 6, 9-13, 15-22, 25-34, 36-38
Y	US 2005/0283186 A1 (BERRADA et al) 22 December 2005 (22.12.2005) fig 3A, 3B, 20A, para [0081], [0128], [0142], [0149]	6, 9-10, 13, 15-22, 27-30, 32
Y	US 2005/0234505 A1 (DIAZ et al) 20 October 2005 (20.10.2005) para [0054]	35
Y	US 2009/0287291 A1 (BECKING et al) 21 April 2009 (21.04.2009) para [0095]	17, 32
Y	US 2010/0185210 A1 (HAUSER et al) 22 July 2010 (22.07.2010) para [0053]	22

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Date of the actual completion of the international search	Date of mailing of the international search report
06 August 2012 (06.08.2012)	06 SEP 2012
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08/943,358	3 October 1997 (03.10.97)	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).

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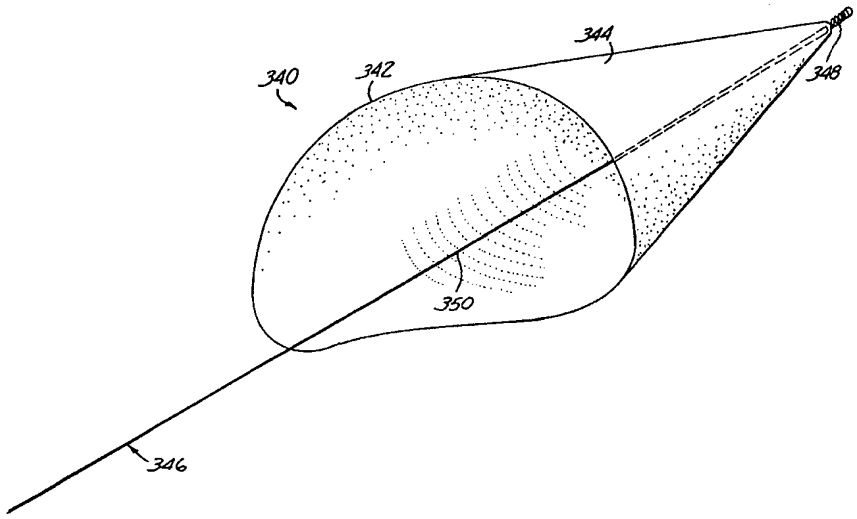
(74) Agents: KELLY, Joseph, R.; Westman, Champlin & Kelly, P.A., International Centre, Suite 1600, 900 Second Avenue South, Minneapolis, MN 55402–3319 (US) et al.

(54) Title: DISTAL PROTECTION DEVICE AND METHOD



(57) Abstract

An emboli capturing system (366) captures emboli in a body lumen. A first elongate member (346) has a proximal end and a distal end. An expandable emboli capturing device (344) is mounted proximate the distal end of the first elongate member (346), and is movable between a radially expanded position and a radially contracted position. When in the expanded position, the emboli capturing device (344) forms a basket with a proximally opening mouth (368). A second elongate member (376) has a proximal and a distal end with a lumen extending therebetween. The lumen is sized to slidably receive a portion of the first elongate member (346). An expandable delivery device (378) is mounted to the distal end of the second elongate member (376) and is movable from a radially retracted position to a radially expanded position. The delivery device has a receiving end (382) configured to receive the emboli capturing device (344), and retains at least the mouth (368) of the emboli capturing device (344) in a radially retracted position.

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CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

DISTAL PROTECTION DEVICE AND METHOD

BACKGROUND OF THE INVENTION

The present invention deals with an emboli capturing system. More specifically, the present invention deals with an emboli capturing system and method for capturing embolic material in a blood vessel during an atherectomy or thrombectomy procedure.

Blood vessels can become occluded (blocked) or stenotic (narrowed) in one of a number of ways. For instance, a stenosis may be formed by an atheroma which is typically a harder, calcified substance which forms on the lumen walls of the blood vessel. Also, the stenosis can be formed of a thrombus material which is typically much softer than an atheroma, but can nonetheless cause restricted blood flow in the lumen of the blood vessel. Thrombus formation can be particularly problematic in a saphenous vein graft (SVG).

Two different procedures have developed to treat a stenotic lesion (stenosis) in vasculature. The first is to deform the stenosis to reduce the restriction within the lumen of the blood vessel. This type of deformation (or dilatation) is typically performed using balloon angioplasty.

Another method of treating stenotic vasculature is to attempt to completely remove either the entire stenosis, or enough of the stenosis to relieve the restriction in the blood vessel. Removal of the stenotic lesion has been done through the use of radio frequency (RF) signals transmitted via conductors, and through the use of lasers, both of which treatments are meant to ablate (i.e., super heat and vaporize) the stenosis. Removal of the stenosis has also been accomplished using thrombectomy or atherectomy. During

thrombectomy and atherectomy, the stenosis is mechanically cut or abraded away from the vessel.

Certain problems are encountered during thrombectomy and atherectomy. The stenotic debris which is separated from the stenosis is free to flow within the lumen of the vessel. If the debris flows distally, it can occlude distal vasculature and cause significant problems. If it flows proximally, it can enter the circulatory system and form a clot in the neural vasculature, or in the lungs, both of which are highly undesirable.

Prior attempts to deal with the debris or fragments have included cutting the debris into such small pieces (having a size on the order of a blood cell) that they will not occlude vessels within the vasculature. However, this technique has certain problems. For instance, it is difficult to control the size of the fragments of the stenotic lesion which are severed. Therefore, larger fragments can be severed accidentally. Also, since thrombus is much softer than an atheroma, it tends to break up easier when mechanically engaged by a cutting instrument. Therefore, at the moment that the thrombus is mechanically engaged, there is a danger that it can be dislodged in large fragments which would occlude the vasculature.

Another attempt to deal with debris severed from a stenosis is to remove the debris, as it is severed, using suction. However, it may be necessary to pull quite a high vacuum in order to remove all of the pieces severed from the stenosis. If a high enough vacuum is not used, all of the severed pieces will not be removed. Further, when a high vacuum is used, this can tend to cause the vasculature to collapse.

A final technique for dealing with the fragments of the stenosis which are severed during atherectomy is to place a device distal to the stenosis during atherectomy to catch the pieces of the stenosis as they are severed, and to remove those pieces along with the capturing device when the atherectomy procedure is complete. Such capture devices have included expandable filters which are placed distal of the stenosis to capture stenosis fragments. Problems are also associated with this technique. For example, delivery of such devices in a low profile, pre-deployment configuration can be difficult. Further, some devices include complex and cumbersome actuation mechanisms. Also, retrieving such capture devices, after they have captured emboli, can be difficult as well.

SUMMARY OF THE INVENTION

An emboli capturing system captures emboli in a body lumen. A first elongate member has a proximal end and a distal end. An expandable emboli capturing device is mounted proximate the distal end of the first elongate member, and is movable between a radially expanded position and a radially contracted position. When in the expanded position, the emboli capturing device forms a basket with a proximally opening mouth. A second elongate member has a proximal and a distal end with a lumen extending therebetween. The lumen is sized to slidably receive a portion of the first elongate member. An expandable delivery device is mounted to the distal end of the second elongate member and is movable from a radially retracted position to a radially expanded position. The delivery device has a receiving end configured to receive the emboli capturing device,

and retains at least the mouth of the emboli capturing device in a radially retracted position.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a distal protection device of the present invention in a deployed position.

FIG. 2 shows the distal protection device shown in FIG. 1 in a collapsed position.

FIG. 3 shows an end view of a portion of the distal protection device shown in FIGS. 1 and 2.

FIG. 4 shows a cross-sectional view of a portion of the distal protection device shown in FIGS. 1-3 in the deployed position.

FIG. 5 shows a second embodiment of the distal protection device according to the present invention in a deployed position.

FIG. 6 shows an end view of the distal protection device shown in FIG. 5.

FIG. 7 shows a cross-sectional view of the distal protection device shown in FIGS. 5 and 6 in the collapsed position.

FIG. 8 shows a third embodiment of a distal protection device according to the present invention in a deployed position.

FIG. 9 is a side sectional view of an alternate embodiment illustrating how the expandable members of the present invention are attached to a guidewire.

FIG. 10 is a sectional view taken along section lines 10-10 in FIG. 9.

FIGS. 11A and 11B show a fourth and fifth embodiment, respectively, of a distal protection device according to the present invention in a deployed position.

FIG. 12 illustrates the operation of a distal protection device in accordance with the present invention.

FIGS. 13A-17B show additional embodiments of distal protection devices which expand and collapse based on movement of a mechanical actuator.

FIGS. 18A-18D illustrate an additional embodiment of a distal protection device which is deployed and collapsed using a rolling flap configuration.

FIG. 19 illustrates another embodiment in accordance with the present invention in which the protection device is deployed using fluid pressure and a movable collar.

FIGS. 20A and 20B illustrate another aspect of the present invention in which two longitudinally movable members used to deploy the distal protection device are disconnectably locked to one another.

FIGS. 21A-21C illustrate another embodiment in accordance with the present invention in which the protection device is formed with a shape memory alloy frame and an attached filter or mesh mounted to the frame.

FIGS. 22A-22C illustrate another embodiment in accordance with the present invention in which the distal protection devices shown in FIGS. 21A-21C are delivered and deployed.

FIGS. 23A-23E illustrate another embodiment in accordance with the present invention in which the distal protection devices shown in FIGS. 21A-21C are retrieved.

FIGS. 24A-24C illustrate another embodiment in accordance with the present invention in which the

distal protection devices shown in FIGS. 21A-21C are retrieved.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 illustrates protection device 10 in a deployed position within the lumen of a blood vessel 12. Protection device 10 preferably includes hollow guidewire 14 (or a hypotube having the same general dimensions as a guidewire) having a coil tip 16, and a capturing assembly 18. Capturing assembly 18, in the embodiment shown in FIG. 1, includes an inflatable and expandable member 20 and mesh 22.

An interior of expandable member 20 is preferably coupled for fluid communication with an inner lumen of guidewire 14 at a distal region of guidewire 14. When deployed, inflatable member 20 inflates and expands to the position shown in FIG. 1 such that capturing assembly 18 has an outer periphery which approximates the inner periphery of lumen 12.

Mesh 22 is preferably formed of woven or braided fibers or wires, or a microporous membrane, or other suitable filtering or netting-type material. In one preferred embodiment, mesh 22 is a microporous membrane having holes therein with a diameter of approximately 100 μm. Mesh 22 can be disposed relative to inflatable member 20 in a number of different ways. For example, mesh 22 can be formed of a single generally cone-shaped piece which is secured to the outer or inner periphery of inflatable member 20. Alternatively, mesh 22 can be formed as a spiral strip which is secured about the outer or inner periphery of inflatable member 20 filling the gaps between the loops of inflatable member 20. Alternatively, mesh 22 can be formed of a number of discrete pieces which are assembled onto inflatable member 20.

Hollow guidewire 14 preferably has a valve 24 coupled in a proximal portion thereof. During operation, a syringe is preferably connected to the proximal end of guidewire 14, which preferably includes a fluid hypotube. The syringe is used to pressurize the fluid such that fluid is introduced through the lumen of hollow guidewire 14, through valve 24, and into inflatable member 20. Upon being inflated, inflatable member 20 expands radially outwardly from the outer surface of guidewire 14 and carries mesh 22 into the deployed position shown in FIG. 1. In this way, capturing assembly, or filter assembly, 18 is deployed distally of stenosis 26 so that stenosis 26 can be severed and fragmented, and so the fragments from stenosis 26 are carried by blood flow (indicated by arrow 28) into the basket or chamber formed by the deployed filter assembly 18. Filter assembly 18 is then collapsed and removed from vessel 12 with the fragments of stenosis 26 contained therein.

FIG. 2 illustrates protection device 10 with filter assembly 18 in the collapsed position. Similar items to those shown in FIG. 1 are similarly numbered. FIG. 2 illustrates that mesh 22 is easily collapsible with inflatable member 20. In order to collapse filter assembly 18, fluid is preferably removed from inflatable member 20 through the lumen of hollow guidewire 14 and through two-way valve 24. This can be done using the syringe to pull a vacuum, or using any other type of suitable fluid removal system.

Inflatable member 20 is preferably formed of a material having some shape memory. Thus, when inflatable member 20 is collapsed, it collapses to approximate the outer diameter of hollow guidewire 14. In one preferred embodiment, inflatable member 20 is

formed of a resilient, shape memory material such that it is inflated by introducing fluid under pressure through the lumen in hollow guidewire 14 into inflatable member 20. When pressure is released from the lumen in hollow guidewire 14, inflatable member 20 is allowed to force fluid out from the interior thereof through two-way valve 24 and to resume its initial collapsed position. Again, this results in filter assembly 18 assuming its collapsed position illustrated in FIG. 2.

FIG. 3 illustrates a view taken from the distal end of device 10 with mesh 22 removed for clarity. FIG. 3 shows that, when inflatable member 20 is deployed outwardly, mesh 22 (when deployed between the loops of inflatable member 20) forms a substantially lumen-filling filter which allows blood to flow therethrough, but which provides a mechanism for receiving and retaining stenosis fragments carried into mesh 22 by blood flow through the vessel.

FIG. 3 also shows that inflatable member 20 preferably has a proximal end portion 29 which is connected to the outer periphery of guidewire 14. Although end 29 need not be connected to guidewire 14, it is preferably connected using adhesive or any other suitable connection mechanism. By fixedly connecting proximal end portion 29 to guidewire 14, this increases the stability of the filter assembly 18 upon deployment.

FIG. 4 is a cross-sectional view of a portion of protection device 10. FIG. 4 shows protection device 10 with filter assembly 18 in the expanded or deployed position. FIG. 4 also better illustrates that guidewire 14 is hollow and has a longitudinal lumen 30 extending therethrough. Longitudinal lumen 30 is connected in fluid communication with an interior of inflatable member 20 through aperture 32 which is provided in the

wall of guidewire 14. FIG. 4 also shows that, in one preferred embodiment, a core wire 34 extends through lumen 30 from a proximal end thereof where it is preferably brazed to a portion of a hypotube which may be connected to the proximal portion of guidewire 14. The core wire 34 extends to the distal end of guidewire 14 where it is connected to coil tip 16. In one preferred embodiment, coil tip 16 is brazed or otherwise welded or suitably connected to the distal portion of core wire 34.

FIG. 4 further shows that, in the preferred embodiment, inflatable member 20 inflates to a generally helical, conical shape to form a basket opening toward the proximal end of guidewire 14. FIG. 4 further illustrates, in the preferred embodiment, mesh 22 has a distal portion 38 which is connected to the exterior surface of guidewire 14, at a distal region thereof, through adhesive 36 or any other suitable connection mechanism.

FIG. 5 illustrates a second embodiment of a distal protection device 40 in accordance with the present invention. Device 40 includes hollow guidewire 42, filter assembly 44 and coil tip 16. Filter assembly 44 includes a plurality of inflatable struts 46 and mesh 47. Each strut 46 has a distal end 48 and proximal end 50. Inflatable struts 46 also have an interior which is coupled in fluid communication, through distal end 48 thereof, with the lumen in hollow guidewire 42. Struts 46 are preferably configured such that, upon being inflated, the proximal ends 50 deploy radially outwardly away from the outer surface of hollow guidewire 42 to assume a dimension which approximates the inner dimension of lumen 58 in which they are inserted.

Mesh 47, as with mesh 22 shown in FIG. 1, is deployed either on the outer or inner surface of inflatable struts 46, such that, when the inflatable struts 46 are deployed radially outwardly, mesh 47 forms a generally conical basket opening toward the proximal end of hollow guidewire 42. As with the embodiment shown in FIG. 1, mesh 47 can be applied to either the outer or the inner surface of struts 46. It can be applied to struts 46 as one unitary conical piece which is adhered about distal ends 48 of struts 46 using adhesive (or about the distal end of guidewire 42 using adhesive) and secured to the surface of the struts 46 also using adhesive. Alternatively, mesh 47 can be applied to struts 46 in a plurality of pieces which are individually or simultaneously secured to, and extend between, struts 46.

FIG. 6 is an end view of distal protection device 40 shown in FIG. 5 taken from the distal end of distal protection device 40. When struts 46 are deployed outwardly, mesh 47 forms a substantially lumen-filling filter which allows blood to flow therethrough, but which provides a mechanism for receiving and retaining stenosis fragments from stenosis 56 carried into mesh 47 by blood flow through the vessel.

FIG. 7 is a cross-sectional view of a portion of distal protection device 40 shown in FIGS. 5 and 6. FIG. 7 shows filter assembly 44 in the collapsed position in which it approximates the outer diameter of guidewire 42. FIG. 7 also shows that, in the preferred embodiment, the distal ends 48 of struts 46 are in fluid communication with an inner lumen 52 in hollow guidewire 42 through apertures 54 in the wall of guidewire 42.

FIG. 8 illustrates another embodiment of a distal protection device 60 in accordance with the

present invention. Distal protection device 60 is similar to those shown in other figures, and similar items are similarly numbered. However, distal protection device 60 includes hollow guidewire 63 which has a lumen in fluid communication with an interior of a pair of inflatable struts 62. Inflatable struts 62 have an inner surface 64 which is generally concave, or hemispherical, or otherwise appropriately shaped such that it extends about a portion of the outer surface of hollow guidewire 63. Mesh portions 66 extend between the inflatable struts 62 so that inflatable struts 62 and mesh portions 66, when deployed outwardly as shown in FIG. 8, form a basket shape which opens toward the proximal end of hollow guidewire 63.

FIG. 9 illustrates another system for attaching inflatable struts to a hollow guidewire for a distal protection device 70 in accordance with the present invention. Distal protection device 70 is similar to the distal protection devices shown in the previous figures in that a plurality of inflatable struts 72 are provided and preferably have a mesh portion extending therebetween. For the sake of clarity, the mesh portion is eliminated from FIG. 9. However, it will be understood that, when deployed, distal protection device 70 forms a generally basket-shaped filter assembly which opens toward the proximal end of hollow guidewire 74.

In the embodiment shown in FIG. 9, hollow guidewire 74 has a distal end 75 which is open. An endcap 76 is disposed about the distal end 75 of hollow guidewire 74 and defines an internal chamber or passageway 78. Endcap 76 has a proximal end 80 which has openings therein for receiving the ends of inflatable struts 72. Thus, in order to inflate

inflatable struts 72, the operator pressurizes fluid within the lumen of hollow guidewire 74 forcing fluid out through distal end 75 of hollow guidewire 74, through passageway 78, and into inflatable struts 72. In order to collapse distal protection device 70, the operator draws a vacuum which pulls the fluid back out of inflatable struts 72, through passageway 78 and, if necessary, into the lumen of hollow guidewire 74.

FIG. 10 is an end view of endcap 76 taken along lines 10-10 in FIG. 9. FIG. 10 shows that proximal end 80 of endcap 76 preferably includes a first generally central aperture 82 for receiving the distal end of hollow guidewire 74. Aperture 82 is sized just larger than, or approximating, the outer diameter of hollow guidewire 74 such that it fits snugly over the distal end 75 of hollow guidewire 74. Endcap 76 is then fixedly connected to the distal end 75 of hollow guidewire 74 through a friction fit, a suitable adhesive, welding, brazing, or another suitable connection technique.

FIG. 10 also shows that proximal end 80 of endcap 76 includes a plurality of apertures 84 which are spaced from one another about end 80. Apertures 84 are sized to receive open ends of inflatable struts 72. In the preferred embodiment, inflatable struts 72 are secured within apertures 84 using a suitable adhesive, or another suitable connection technique. Also, in the preferred embodiment, spring tip 16 is embedded in, or otherwise suitably connected to, endcap 76.

FIGS. 11A and 11B show two other preferred embodiments of a distal protection device in accordance with the present invention. FIG. 11A shows distal protection device 90 which includes hollow guidewire 92 having a lumen running therethrough, inflatable member

94 and mesh portion 96. FIG. 11A shows that inflatable member 94, when inflated, forms a ring about the outer surface of hollow guidewire 92. The ring has an inner periphery 98 which is spaced from the outer surface of hollow guidewire 92 substantially about the entire radial periphery of hollow guidewire 92. Mesh portion 96 extends between the outer surface of hollow guide 92 and the inner periphery 98 of inflatable member 94. Thus, a substantially disc-shaped filter assembly is provided upon deployment of distal protection device 90. As with the other embodiments, deployment of distal protection device 90 is accomplished by providing fluid through the inner lumen of hollow guidewire 92 into an interior of inflatable member 94 which is in fluid communication with the inner lumen of hollow guidewire 92.

In one preferred embodiment, end 100 of inflatable member 94 is coupled to a coupling portion 102 of inflatable member 94 such that stability is added to inflatable member 94, when it is inflated.

FIG. 11B illustrates another distal protection device 104 which includes a hollow guidewire 106 and an inflatable member 108. Device 104 is similar to distal protection device 90 except that, rather than having only a single inflatable ring upon deployment of distal protection device 104, a plurality of generally equal-diameter rings are formed into a helix shape. In the preferred embodiment, distal protection device 104 includes a mesh sleeve 110 which extends about the outer or inner surface of the helix formed by inflatable member 108. In one embodiment, mesh sleeve 110 is connected to the outer surface of hollow guidewire 106 in a region 112 proximate, but distal of, inflatable member 108. In another preferred embodiment, the

proximal end of mesh sleeve 110 is connected to the outer perimeter of inflatable member 108. Thus, distal protection device 104 forms a generally basket-shaped filter assembly which opens toward a proximal end of guidewire 106.

As with the other embodiments, both distal protection device 90 shown in FIG. 11A and distal protection device 104 shown in FIG. 11B are preferably collapsible. Therefore, when collapsed, the distal protection devices 90 and 104 preferably have an outer dimension which approximates the outer dimension of hollow guidewires 92 and 106, respectively. Further, as with the other embodiments, distal protection devices 90 and 104 can either be biased in the deployed or collapsed positions, and deployment and collapse can be obtained either by pulling a vacuum, or pressurizing the fluid within the lumen of the hollow guidewires 92 and 106.

FIG. 12 illustrates the use of a distal protection device in accordance with the present invention. For the sake of clarity, the present description proceeds with respect to distal protection device 10 only. Device 10 is shown filtering stenosis fragments from the blood flowing through the lumen of vessel 12. FIG. 12 also shows a dilatation device 120 which can be any suitable dilatation device for dilating, cutting, fragmenting, or abrading, portions of stenosis 26. In the preferred embodiment, device 120 is used in an over-the-wire fashion over hollow guidewire 14. Thus, filter assembly 18 is first advanced (using guidewire 14) distal of stenosis 26. Then, filter assembly 18 is deployed outwardly to the expanded position. Dilatation device 120 is then advanced over guidewire 14 to stenosis 26 and is used to fragment or

abrade stenosis 26. The fragments are received within the basket of filter assembly 18. Filter assembly 18 is then collapsed, and filter assembly 18 and dilatation device 120 are removed from vessel 12. Alternatively, dilatation device 120 can be removed first and filter assembly 18 is then removed along with guidewire 14.

It should be noted that the stenosis removal device (or atherectomy catheter) 120 used to fragment stenosis 26 can be advanced over guidewire 14. Therefore, the device according to the present invention is dual functioning in that it captures emboli and serves as a guidewire. The present invention does not require adding an additional device to the procedure. Instead, the present invention simply replaces a conventional guidewire with a multi-functional device.

FIGS. 13A-17B illustrate embodiments of various distal protection devices wherein deployment and contraction of the distal protection device is accomplished through a mechanical push/pull arrangement.

FIGS. 13A and 13B illustrate a distal protection device 122. FIG. 13A shows device 122 in an undeployed position and FIG. 13B shows device 122 in a deployed position. Distal protection device 122 includes a slotted Nitinol tube 124 which has a lumen 126 extending therethrough. Tube 124 has a plurality of slots 128 at a distal region thereof. The distal portion of slots 128 are covered by mesh 130 which, in the preferred embodiment, is a flexible microporous membrane. Device 122 also preferably includes a mandrel 132 which extends through the inner lumen 126 of tube 124 and is attached to the distal end of tube 124. In the preferred embodiment, mandrel 132 is attached to the distal end of tube 124 by an appropriate adhesive, brazing, welding, or another suitable connection

technique. Tube 124 also has, on its inner periphery in a proximal region thereof, a plurality of locking protrusions 134. Lock protrusions 134 are preferably arranged about a proximal expandable region 136 disposed on mandrel 132.

In order to deploy device 122 into the deployed position shown in FIG. 13B, the operator preferably first advances tube 124 distally of the lesion to be fragmented. In the preferred embodiment, tube 124 has a size on the order of a guidewire, such as a 0.014 inch outer diameter. Therefore, it easily advances beyond the stenosis to be fragmented. The operator then pushes on the proximal region of tube 124 and pulls on the proximal end of mandrel 132. This causes two things to happen. First, this causes the struts formed by slots 128 to expand radially outwardly, and carry with them, microporous membrane 130. Thus, microporous membrane 130 forms a generally basket-shaped filter assembly which opens toward the proximal end of tube 124. In addition, proximal expandable member 136 expands and engages protrusions 134. This locks device 122 in the deployed and expanded position. In order to move the device 122 to the collapsed position, the physician simply pushes on mandrel 132 and pulls on the proximal end of tube 124. This causes device 122 to return to the undeployed position shown in FIG. 13A.

It should be noted that device 122 can optionally be provided with a stainless steel proximal hypotube attachment. Also, the struts defined by slots 128 can be expanded and retracted using a fluid coupling instead of a mandrel. In other words, the proximal end of tube 124 can be coupled to a pressurizable fluid source. By making slots 128 very thin, and pressurizing the fluid, the struts expand outwardly. Further, by

pulling vacuum on the pressurizable fluid, the struts collapse.

FIG. 14A illustrates distal protection device 140 which is similar to that shown in FIGS. 13A and 13B, except that the struts 142 are formed of a metal or polymer material and are completely covered by mesh 144. Mesh 144 includes two mesh portions, 146 and 148. Mesh portion 146 is proximal of mesh portion 148 on device 140 and is a relatively loose mesh which will allow stenosis fragments to pass therethrough. By contrast, mesh 148 is a fairly tight mesh, or a microporous membrane, (or simply loose mesh portion 146 with a microporous membrane or other suitable filter material bonded or cast or otherwise disposed thereover) which does not allow the fragments to pass therethrough and therefore captures and retains the fragments therein. The mesh portions can provide a memory set which, in the relaxed position, is either deployed or collapsed.

FIG. 14B illustrates a device 150 which is similar to device 140 shown in FIG. 14A, except struts 142 are eliminated and the two mesh portions 146' and 148' are simply joined together at a region 152. Also, the two mesh portions 146' and 148' are not two different discrete mesh portions but are formed of the same braided mesh material wherein the braid simply has a different pitch. The wider pitch in region 146' provides a looser mesh, whereas the narrower pitch in region 148' provides a tighter mesh that traps the embolic material.

FIG. 14C illustrates a distal protection device 160 which is similar to that shown in FIG. 14A. However, rather than simply providing a slotted tube, distal protection device 160 includes a plurality of struts 162 on a proximal region thereof and a plurality

of struts 164 on the distal region thereof. Struts 162 are spaced further apart than struts 164 about the periphery of protection device 160. Therefore, struts 162 define openings 166 which are larger than the openings 168 defined by struts 164 and allow stenosis fragments to pass therethrough. Also, struts 164 have secured to the interior surface thereof a filter or mesh portion 170. When deployed, filter portion 170 forms a substantially basket-shaped filter device opening toward the proximal region of tube 172.

FIG. 15 illustrates the operation of another distal protection device 176. Distal protection device 176 includes a tube 178 and a push/pull wire 180. Tube 178 has, at the distal end thereof, a filter assembly 182. Filter assembly 182 includes a plurality of preferably metal struts 184 which have a microporous membrane, or other suitable mesh 186 disposed thereon. Tube 178 also preferably includes end cap 188 and umbrella-like expansion structure 190 disposed at a distal region thereof. Expansion structure 190 is connected to the distal region of tube 178 and to metal struts 184 such that, when push/pull wire 180 is pulled relative to tube 178, expansion member 190 exerts a radial, outwardly directed force on struts 184 causing them to expand radially outwardly relative to the outer surface of tube 178. This causes microporous membrane or mesh 186 to be deployed in a manner opening toward the proximal end of tube 178 to catch embolic material. Struts 184 can also be formed of an appropriate polymer material.

FIGS. 16A and 16B illustrate a protection device in accordance with another embodiment of the present invention. FIG. 16A illustrates distal protection device 192. Device 192 includes guidewire

194, actuator wire 196, and filter assembly 198. Filter assembly 198 includes an expandable ring 200, such as an expandable polymer or metal or other elastic material, which has attached thereto mesh 202. Mesh 202 is also attached to guidewire 194 distally of ring 200. Actuator wire 196 is attached to sleeve or sheath 204 which is positioned to fit about the outer periphery of expandable ring 200, when expandable ring 200 is in the collapsed position.

Thus, when sheath 204 is moved distally of expandable ring 200, expandable ring 200 has shape memory which causes it to expand into the position shown in FIG. 16A. Alternatively, when sheath 204 is pulled proximally by pulling actuator wire 196 relative to guidewire 194, sheath 204 collapses ring 200 and holds ring 200 in the collapsed position within sheath 204. Manipulating wires 194 and 196 relative to one another causes device 192 to move from the deployed position to the collapsed position, and vice versa.

FIG. 16B is similar to device 192 except that, instead of having an expandable ring 200 connected at one point to wire 194, distal protection device 206 includes expandable member 208 which is formed of an elastic coil section of wire 194. Thus, elastic coil section 208 has a shape memory which causes it to expand into the generally helical, conical shape shown in FIG. 16B. However, when sheath 204 is pulled proximally relative to expandable member 208, this causes sheath 204 to capture and retain expandable member 208 in a collapsed position. When sheath 204 is again moved distally of expandable member 208, expandable member 208 returns to its expanded position shown in FIG. 16B carrying with it mesh 210 into a deployed position. In the preferred embodiment, sheath 204 is formed of a

suitable polymer material and expandable member 208 and expandable ring 200 are preferably formed of Nitinol.

FIGS. 17A and 17B illustrate the operation of another distal protection device 212. Protection device 212 includes guidewire 214 and filter assembly 216. In the preferred embodiment, filter assembly 216 includes a wire braid portion 218 which extends from a distal region of guidewire 214 proximally thereof. Braid portion 218 is formed of braided filaments or fibers which have a shape memory causing them to form a deployed, basket-shaped filter, such as that shown in FIG. 17A, in the unbiased position. Braided portion 218 terminates at its proximal end in a plurality of eyelets 220. One or more cinch wires 222 are preferably threaded through eyelets 220. By pushing on guidewire 214 and pulling on cinch wires 222, the operator is able to cinch closed, and pull proximally, the proximal portion of mesh 218. This causes mesh 218 to collapse tightly about the outer surface of wire 214.

Therefore, during operation, the operator holds mesh 218 in the collapsed position and inserts protection device 212 distally of the desired stenosis. The operator then allows cinch wire 222 to move distally relative to guidewire 214. This allows mesh 218 to open to the deployed position shown in FIG. 17A which has an outer diameter that approximates the inner diameter of the lumen within which it is disposed. Filter assembly 216 is then disposed to capture embolic material from blood flowing therethrough. Once the embolic material is captured, the operator again moves cinch wire 222 proximally relative to guidewire 214 to collapse filter assembly 216 and capture and retain the embolic material in filter assembly 216. The device 212 is then removed.

FIG. 17B shows distal protection device 212 except that in the embodiment shown in FIG. 17B, protection device 212 is not disposed distally of the stenosis, but rather proximally. This results, for example, in an application where the blood flow is proximal of the stenosis rather than distal. Further, in the embodiment shown in FIG. 17B, guidewire 214 is preferably hollow and the cinch wire 222 extends through the lumen therein. By pushing on guidewire 214, a force is exerted on mesh 218 in the distal direction. This causes cinch wire 222 to tightly close the distal opening in filter assembly 216 and to collapse mesh portion 218. By contrast, by allowing cinch wire 222 to move distal relative to hollow guidewire 214, mesh portion 218 expands and filter assembly 216 is deployed as shown in FIG. 17B.

FIGS. 18A and 18B illustrate a distal protection device 250 in accordance with another aspect of the present invention. Device 250 includes inner wire 252 and outer tube 254. In the preferred embodiment, inner wire 252 is a core wire and outer tube 254 has a lumen 256 therein large enough to accommodate longitudinal movement of inner wire 252 therein. Also, in the preferred embodiment, inner wire 252 has, coupled to its distal end 258, a spring tip 260.

Device 250 includes expandable mesh or braid portion 262. Expandable portion 262 has a proximal end 264 which is attached to the distal end 266 of tube 254. Also, expandable member 262 has a distal end 268 which is attached to the distal end 258 of inner wire 252.

Expandable member 262 is preferably a mesh or braided material which is coated with polyurethane. In one preferred embodiment, a distal portion of expandable member 262 has a tighter mesh than a proximal portion

thereof, or has a microporous membrane or other suitable filtering mechanism disposed thereover. In another preferred embodiment, expandable member 262 is simply formed of a tighter mesh or braided material which, itself, forms the filter. FIG. 18A illustrates device 250 in a collapsed, or insertion position wherein the outer diameter of mesh portion 262 closely approximates the outer diameters of either inner wire 252 or outer tube 254.

FIG. 18B illustrates device 250 in the deployed position in which expandable member 262 is radially expanded relative to the collapsed position shown in FIG. 18A. In order to deploy device 250, the outer tube 254 is moved distally with respect to inner wire 252 such that the distal ends 266 and 258 of wires 254 and 252 move longitudinally toward one another. Relative movement of ends 266 and 258 toward one another causes the mesh of expandable member 262 to buckle and fold radially outwardly. Thus, the outer diameter of expandable member 262 in the deployed position shown in FIG. 18B closely approximates the inner diameter of a vessel within which it is deployed.

FIG. 18C illustrates device 250 in a partially collapsed position. In FIG. 18C, the distal end 266 of outer tube 254 and the distal end 258 of inner wire 252 are moved even closer together than they are as shown in FIG. 18B. This causes expandable mesh portion 262 to fold over itself and form a rolling, proximally directed flap 270. As longitudinal movement of inner wire 252 proximally with respect to outer tube 254 continues, mesh portion 262 continues to fold over itself such that the rolling flap portion 270 has an outer radial diameter which continues to decrease. In other words, expandable mesh portion 262 continues to fold over

itself and to collapse over the outer periphery of outer tube 254.

FIG. 18D illustrates device 250 in a fully collapsed position in which it retains emboli captured therein. In FIG. 18D, the distal end 266 of outer tube 254 has been advanced as far distally as it can relative to the distal end 258 of inner wire 252. This causes expandable mesh portion 262 to fold all the way over on itself such that it lies against, and closely approximates the outer diameter of, outer tube 254. Device 250 thus captures any emboli filtered from the vessel within which it was deployed, and can be removed while retaining that embolic material.

FIG. 19 illustrates device 280 which depicts a further aspect in accordance with the present invention. Device 280 includes outer tube 282, core wire 284, transition tube 286, movable plunger 288, expandable member 290, fixed collar 292 and bias member 294.

In the preferred embodiment, tube 282 comprises a proximal hypotube which is coupled to a plunger that selectively provides fluid under pressure through an inflation lumen 296. Inner wire 284 is preferably a tapered core wire which terminates at its distal end in a spring coil tip 298 and which is coupled at its proximal end 300 to transition tube 286. Transition tube 286 is preferably an outer polymer sleeve either over hypotube 282, or simply disposed by itself and coupled to a hypotube 282. Transition tube 286 is capable of withstanding the inflation pressure provided by the fluid delivered through the inflation lumen 296.

Movable collar 288 is preferably slidably engageable with the interior surface of transition tube

286 and with the exterior surface of core wire 284, and is longitudinally movable relative thereto. Slidable collar 288 has, attached at its distal end, bias spring 294 which is preferably coiled about core wire 284 and extends to fixed collar 292. Fixed collar 292 is preferably fixedly attached to the exterior surface of a distal portion of core wire 284.

Expandable member 290 is preferably formed, at a proximal portion thereof, of either discrete struts, or another suitable frame (such as a loose mesh) which allows blood and embolic material to flow therethrough. The proximal end 302 of expandable member 290 is coupled to a distal region of movable collar 288. The distal portion of expandable member 290 is preferably formed of a filtering material which is suitable for allowing blood flow therethrough, but which will capture embolic material being carried by the blood.

In one preferred embodiment, spring 294 is biased to force collars 288 and 292 away from one another. Thus, as spring 294 urges collars 288 and 292 away from one another, collar 288 retracts within transition tube 286 pulling expandable member 290 into a collapsed position about core wire 284. However, in order to deploy collapsible member 290 as shown in FIG. 19, the operator preferably actuates a plunger (not shown) which delivers pressurized fluid through lumen 296. The pressurized fluid enters transition tube 286 and travels about the outer periphery of inner core wire 284, thus forcing movable collar 288 to move distally along core wire 284. This overcomes the spring force exerted by spring 294 thus causing collars 288 and 292 to move toward one another, relatively. This motion causes expandable member 290 to buckle and expand outwardly to the deployed position shown in FIG. 19.

Expandable member 290 is collapsed by releasing the pressure applied through lumen 296 (i.e., by causing the plunger to move proximally). This allows spring 294 to again urge collars 288 and 292 away from one another to collapse expandable member 290. In an alternative embodiment, the frame supporting expandable member 290 is imparted with a memory (such as a heat set, or a thermally responsive material which assumes a memory upon reaching a transition temperature) such that the resting state of the frame supporting expandable member 290 is in a collapsed position. This eliminates the need for spring 294. The expandable member 290, in that preferred embodiment, is expanded using the hydraulic pressure provided by the pressurized fluid introduced through lumen 296, and it is collapsed by simply allowing the memory in expandable member 290 to force fluid from transition tube 286 back through lumen 296.

FIGS. 20A and 20B illustrate another aspect in accordance with the present invention. A device 310 includes a mesh portion 312 supported by a frame 314. Expansion of frame 314 to the radially expanded position shown in FIG. 20A is driven by an expandable member, such as a balloon, 316 which is coupled to frame 314. Balloon 316 is coupled to a distal end of a distal hypotube 318, which is formed of a suitable material, such as nitinol. It should be noted that the distal tip of hypotube 318 includes a spring tip 320.

Distal hypotube 318 is shown coupled to a proximal hypotube 322 which has a tapered portion 324 therein. In the preferred embodiment, proximal hypotube 322 is formed of a suitable material, such as stainless steel. A plunger 326 is longitudinally movable within

the lumen of both proximal hypotube 322 and distal hypotube 318.

Frame 314, and consequently mesh portion 312, are deployed by the operator moving plunger 326 distally within the lumens of hypotubes 318 and 322. This causes pressurized fluid to enter balloon 316, thereby inflating balloon 316 and driving deployment of frame 314 and mesh 312. In order to collapse frame 314 and mesh 312, the operator preferably moves plunger 326 proximally within the lumens of tubes 318 and 322 to withdraw fluid from within balloon 316. Alternatively, mesh 312 or frame 314 can have a memory set which is either in the inflated or collapsed position such that the operator need only affirmatively move frame 314 and mesh 312 to either the deployed or collapsed position, whichever is opposite of the memory set.

In either case, it is desirable that the operator be able to lock plunger 326 in a single longitudinal position relative to hypotubes 318 and 322. Thus, device 310 includes a locking region 328.

FIG. 20B illustrates locking region 328 in greater detail. FIG. 20B illustrates that, in locking region 328, plunger 326 has a plurality of grooves 330 formed in the outer radial surface thereof. Also, in accordance with the present invention, FIG. 20B illustrates that one of hypotubes 318 or 322 has an inwardly projecting portion 332. In one preferred embodiment, inwardly projecting portion 332 includes an inwardly extending, deflectable, annular rim which extends inwardly from either hypotube 318 or 322. In another preferred embodiment, the inwardly projecting portion 332 includes a plurality of discrete fingers which extend inwardly from one of hypotubes 318 or 322

and which are angularly displaced about the interior periphery of the corresponding hypotube 318 or 322.

In operation, as the operator advances plunger 326 distally within the lumens of hypotubes 318 and 322, inwardly projecting portion 332 rides along the exterior periphery of plunger 326 until it encounters one of grooves 330. Then, inwardly projecting portion 332 snaps into the groove 330 to lock plunger 326 longitudinally relative to tubes 318 and 322.

It should be noted that, in the preferred embodiment, both inwardly projecting portions 332 and grooves 330 are formed such that, when gentle pressure is exerted by the operator on plunger 326 relative to hypotubes 318 and 322, projection portions 332 follow the contour of grooves 330 up and out of grooves 330 so that plunger 326 can again be freely moved within the lumens of hypotubes 318 and 322. Thus, the relative interaction between projecting portions 332 and grooves 330 provides a ratcheting type of operation wherein plunger 326 can be releasably locked into one of a plurality longitudinal positions relative hypotubes 318 and 322, since a plurality of grooves 330 are provided. Plunger 326 can be moved back and forth longitudinally within the lumens of hypotubes 318 and 322 in a ratcheting manner and can be locked into one of a plurality of relative longitudinal positions because there are a plurality of grooves 330 in the exterior of plunger 326. It should also be noted, however, that in another preferred embodiment, a plurality of sets of inwardly projecting portions 332 are provided along the inner longitudinal surface of hypotubes 318 and/or 322. In that case, only a single groove 330 needs to be formed in the exterior surface of plunger 326, and the same type of ratcheting locking operation is obtained.

In the preferred embodiment, at least the exterior of hypotubes 318 and 322, and preferably the exterior of plunger 326, are tapered. This allows device 310 to maintain increased flexibility. It should also be noted that, in the preferred embodiment, hypotubes 318 and 322 are preferably sized as conventional guidewires.

FIG. 21A illustrates a protection device in accordance with another embodiment of the present invention. FIG. 21A illustrates distal protection device 340. Device 340 is similar to devices 192 and 206 shown in FIGS. 16A and 16B. However, in the preferred embodiment, device 340 includes hoop-shaped frame 342, filter portion 344, and wire 346. Hoop-shaped frame 342 is preferably a self-expanding frame formed of a wire which includes a shape memory alloy. In a more preferred embodiment hoop-shaped frame 342 is formed of a nitinol wire having a diameter in a range of approximately 0.002 - 0.004 inches.

Filter portion 344 is preferably formed of a polyurethane material having holes therein such that blood flow can pass through filter 344, but emboli (of a desired size) cannot pass through filter 344 but are retained therein. In one preferred embodiment, filter material 344 is attached to hoop-shaped frame 342 with a suitable, commercially available adhesive. In another preferred embodiment, filter 344 has a proximal portion thereof folded over hoop-shaped frame 342, and the filter material is attached itself either with adhesive, by stitching, or by another suitable connection mechanism, in order to secure it about hoop-shaped frame 342. This connection is preferably formed by a suitable adhesive or other suitable connection mechanism.

Also, the distal end of filter 344 is preferably attached about the outer periphery of wire 346, proximate coil tip 348 on wire 346.

In one preferred configuration, filter 344 is approximately 15 mm in longitudinal length, and has a diameter at its mouth (defined by hoop-shaped frame 342) of a conventional size (such as 4.0 mm, 4.5 mm, 5 mm, 5.5 mm, or 6 mm). Of course, any other suitable size can be used as well.

Also, in the preferred configuration, filter 344 is formed of a polyurethane material with the holes laser drilled therein. The holes are preferably approximately 100 μm in diameter. Of course, filter 344 can also be a microporous membrane, a wire or polymer braid or mesh, or any other suitable configuration.

Wire 346 is preferably a conventional stainless-steel guidewire having conventional guidewire dimensions. For instance, in one embodiment, wire 346 is a solid core wire having an outer diameter of approximately 0.014 inches and an overall length of up to 300 cm. Also, in the preferred embodiment, wire 346 has a distal end 350, in a region proximate filter 344, which tapers from an outer diameter at its proximal end which is the same as the outer diameter of the remainder of wire 346, to an outer diameter of approximately 0.055 inches at its distal end. At distal region 350, guidewire 346 is preferably formed of stainless steel 304.

Of course, other suitable guidewire dimensions and configurations can also be used. For example guidewires having an outer diameter of approximately 0.018 inches may also be used. For other coronary applications, different dimensions may also be used, such as outer diameters of approximately 0.010 inches to

0.014 inches. Further, it will be appreciated that the particular size of wire 346 will vary with application. Applications involving neural vasculature will require the use of a smaller guidewire, while other applications will require the use of a larger guidewire. Also, wire 346 can be replaced by a hollow guidewire, or hypotube of similar, or other suitable dimensions.

In addition, in order to make wire 342, hoop 346, or filter 344 radiopaque, other materials can be used. For example, radiopaque loaded powder can be used to form a polyurethane sheath which is fitted over wire 346 or hoop 342, or which is implemented in filter 344. Also, hoop 342 and wire 346 can be gold plated in order to increase radiopacity. Also, marker bands can be used on wire 346 or filter 344 to increase the radiopacity of the device.

In operation, hoop 342 (and thus filter 344) is preferably collapsed to a radially contracted position which more closely approximates the outer diameter of wire 346. Methods of performing this contraction are described later in the specification. Once retracted to a more low profile position, wire 346 is manipulated to position hoop 342 and filter 344 distal of a restriction to be treated. Then, the restraining force which is used to restrain hoop 342 in the predeployment, low profile position is removed, and the superelastic properties of nitinol hoop 342 (or the shape memory properties of another shape memory alloy) are utilized in allowing hoop 342 to assume its shape memory position. This causes hoop 342 to define a substantially lumen filling mouth to filter 344 which is positioned distal of the restriction to be treated.

A suitable dilatation device is then advanced over wire 346 and is used to treat the vascular

restriction. Emboli which are carried by blood flow distal of the restriction are captured by filter 344. After the dilatation procedure, filter 344, along with the emboli retained therein, are retrieved from the vasculature. Various retrieval procedures and devices are described later in the specification.

By allowing hoop-shaped frame 342 to be unattached to wire 346, and only connected to wire 346 through filter 344 (or other super structure used to support filter 344), wire 346 is allowed to substantially float within hoop 342. This configuration provides some advantages. For instance, hoop 342 can better follow the vasculature without kinking or prolapsing (i.e., without collapsing upon itself). Thus, certain positioning or repositioning of filter 344 can be accomplished with less difficulty.

FIG. 21B illustrates a protection device 352 in accordance with another embodiment of the present invention. Protection device 352 is similar to protection device 340, and similar items are similarly numbered. However, rather than having simply a hoop-shaped frame 342 to support filter 344, and drive filter 344 into its expanded and deployed position, device 352 includes frame 354 which includes a hoop-shaped portion 356, and a pair of tails 358 and 360.

Tails 358 and 360 extend proximally from hoop-shaped portion 356 to an attachment region 362. In the preferred embodiment, tails 358 and 360 are attached to wire 346 at attachment region 362 by soldering, welding, brazing, adhesive, or any other suitable attachment mechanism. In the embodiment shown in FIG. 21B, attachment sleeve 364, formed of a weldable material, is attached at its inner periphery to tails 358 and 360.

Sleeve 364 is then attached, using welding or brazing, to wire 346.

By providing tails 358 and 360, frame 354 is directly connected to wire 346. However, tails 358 and 360 are provided so that the point of attachment of frame 354 to wire 346 is located several millimeters proximal of hoop-shaped portion 356. This provides some additional structural integrity to frame 354, but still allows frame 354 to substantially float about wire 346 in the region of hoop-shaped frame portion 356.

FIG. 21C illustrates a protection device 366 in accordance with another embodiment of the present invention. Protection device 366 is similar to protection devices 340 and 352 shown in FIGS. 21A and 21B, and similar items are similarly numbered. However, device 366 includes hoop-shaped frame 368. Frame 368 is similar to frame 342 shown in FIG. 21A. However, unlike frame 342, hoop 368 does not allow wire 346 to float freely therein. Instead, hoop 368 is directly attached to wire 346 at attachment point 370. This causes hoop-shaped frame 368 and filter 344 to reside eccentrically about wire 346.

FIGS. 22A-22C illustrate one preferred embodiment for delivering one of devices 340, 352 and 366. For the sake of clarity, only device 352 is illustrated in FIGS. 22A-22C.

FIG. 22A illustrates delivery device 372. In the preferred embodiment, delivery device 372 includes proximal hub 374, shaft 376, and distal retaining section 378. Also, in one preferred embodiment, device 372 also includes marker band 380. In the preferred embodiment, delivery device 372 is similar to a conventional balloon catheter in that proximal hub 374 is a conventional hub, and shaft 376 is a conventional

balloon catheter shaft. Further, distal retaining section 378 is preferably a conventional angioplasty balloon having an inflated diameter of approximately 1.5 - 2.0 millimeters, but having its distal end cutoff such that the distal end 382 of balloon 378 is open.

Prior to insertion of device 372 into the vasculature, hoop-shaped frame 354 is retracted into its low profile deployment position and is withdrawn through end 382 into balloon 378. Then, the distal end of balloon 378 is exposed to heat to heat shrink or heat set the distal end of balloon 378 around the radially retracted device 352. Device 372, including device 352, is then inserted in the vasculature either through a preplaced guide catheter, along with a guide catheter, or simply without a guide catheter utilizing coil tip 348.

In any case, once device 372 is properly placed such that balloon 378 is located distal of the restriction to be treated, distal protection device 352 is then removed from within heat collapsed balloon 378. In one preferred embodiment, the physician simply accomplishes longitudinal movement of wire 346 relative to catheter 376. For instance, the physician may simply hold wire 346 longitudinally in place and withdraw catheter 376 proximally relative to wire 346 by pulling on hub 374. This causes balloon 378 to move proximally relative to device 352, and thereby to expose device 352 to the vasculature.

FIG. 22B illustrates another preferred embodiment for removing device 352 from within balloon 378. In the embodiment shown in FIG. 22B, syringe 384, which contains fluid, is inserted into coupling 386 in hub 374. The physician then introduces pressurized fluid into the lumen of catheter 376. The pressurized

fluid advances down the lumen of catheter 376 to the distal end where it encounters collapsed balloon 378. The pressure exerted on balloon 378 by the pressurized fluid causes balloon 378 to open radially. Then, the physician withdraws catheter 376 relative to device 352 thereby exposing device 352 to the vasculature.

In any case, once device 352 is no longer restrained by balloon 378, device 352 assumes its shape memory position in the vasculature, as illustrated in FIG. 22C. Thus, device 352 substantially forms a lumen-filling basket or filter which allows blood to pass distally therethrough, but which retains or captures embolic material carried by the blood flow. The physician then simply removes device 372 from the vasculature, leaving device 352 in place during subsequent procedures. In one preferred embodiment, shaft 376 includes a predefined slit or score from a region just proximal of marker band 380 to, or through, hub 374. Thus, as the physician removes device 372, it can be peeled away from device 352. Also, or alternatively, device 372 can be provided with an aperture in shaft 376 near its distal end. The proximal end of wire 346 will thus lie outside of shaft 376. Wire 346 can enter shaft 376 through the aperture and extend through the distal end of shaft 376. This also facilitates easier withdrawal of device 372 over wire 346.

FIGS. 23A-23E illustrate one preferred embodiment for retrieving one of the devices 340, 352 and 366 described in FIGS. 21A-21C. For the sake of clarity, only device 352 is illustrated in FIGS. 23A-23E. FIG. 23A illustrates retrieval device 388. Retrieval device 388 is preferably formed of proximal shaft 390, mesh portion 392, and end cap 394. Items

390, 392 and 394 preferably each have lumens therein to define a passageway for receiving wire 346. Also, wire 346 may optionally be provided with an positive stop 396 (which can be embodied as a radiopaque marker band). Optional stop 396 may also simply be an annular ring attached to wire 346 proximate to filter 344, or may be any other suitable stop.

Proximal shaft 390 is preferably simply a polymer or nitinol tube sized and configured to track over wire 346. End cap 394 is also preferably formed to track over wire 346, but also contains radiopaque material to serve as a distal marker band for retrieval device 388. Mesh 392 is preferably a braid or mesh formed of wire or polymer material having sufficient flexibility that it can be deflected as described below.

Mesh 392 preferably has a proximal end coupled to proximal shaft 390, by adhesive, welding, or other suitable attachment mechanisms. Mesh 392 also preferably includes a distal end connected to end cap 394, also by a suitable connection mechanism.

In order to retrieve filter 344, which likely contains embolic material, device 388 is inserted in the low profile position shown in FIG. 23A, over wire 346, to a position proximate filter 344. Then, device 388 is advanced toward filter 344, until end cap 394 abuts positive stop 396, or the hoop-shaped frame 354. Continued advancement of proximal shaft 390 relative to wire 346 causes compression of mesh 392. This results in a radial expansion of an intermediate portion of mesh 392 (between the proximal and distal ends of mesh 392). The radial expansion of mesh portion 392 is illustrated in FIG. 23B.

By continuing to advance proximal shaft 390 relative to wire 346, the intermediate portion of mesh

392 is configured to bend over on itself such that it is axially displaced toward filter 344, in the direction generally indicated by arrows 398 in FIG. 23C. In the preferred embodiment, mesh 392 is sized and configured such that, with continued advancement of proximal shaft 390 relative to wire 346, this action continues as shown in FIGS. 23D and 23E until the intermediate portion of mesh 392 encompasses at least the mouth of filter 344. Also, in the preferred embodiment, the intermediate portion of mesh 392, when driven as described above, engages and contracts the mouth of filter 344 to a lower profile position, such as that shown in FIG. 23E. In yet another preferred embodiment, mesh 392 is sized and configured to substantially engulf the entire filter 344.

Once at least the mouth of filter 344 is encompassed by mesh 392, device 388, along with device 352, are simply withdrawn from the vasculature. In one preferred embodiment in which a guide catheter is used, devices 388 and 352 are simply withdrawn either into the guide catheter and the guide catheter is removed with those devices, simultaneously, or devices 388 and 352 are removed from the guide catheter prior to removal of the guide catheter. In another preferred embodiment, in which no guide catheter is used, devices 388 and 352 are simply removed from the vasculature simultaneously.

It will also be appreciated, of course, that rather than providing device 388 with a single proximal tube 390 and end cap 394, a second actuation tube or wire can also be provided which is attached to end cap 394, and which extends back through the lumen in proximal tube 390 and is longitudinally movable relative to proximal shaft 390. In that way, the actuation wire or elongate member can be used to pull cap 394 closer to

the distal portion of proximal shaft 390 in order to accomplish the action illustrated in FIGS. 23A-23E. This feature is also illustrated in FIGS. 18A-18D which illustrate the mesh portion folded proximally rather than distally.

FIGS. 24A-24C illustrate another preferred embodiment in accordance with the present invention, for retrieving any of the distal protection devices 340, 352 or 366 shown in FIGS. 21A-21C. For the sake of clarity, only device 352 is illustrated in FIGS. 24A-24C.

FIG. 24A illustrates retrieval device 400. Retrieval device 400 preferably includes retrieval sheath 402, proximal locking device 404, dilator sheath 405, and nose cone 406. In the preferred embodiment, retrieval sheath 402 is preferably formed of polyether block amide (PEBAX) material having an outer diameter of approximately six French (i.e., approximately 2 mm) and having a shore D hardness of approximately 40. Also, retrieval sheath 402 preferably has a wall thickness of approximately 0.004 inches. Dilator sheath 405, and nose cone 406, are preferably formed of low density polyethylene, or high density polyethylene. Sheath 405 preferably has an outer diameter which is approximately equal to the inner diameter of sheath 402. In addition, the inner diameter of sheath 405 and nose cone 406 is preferably just large enough to fit over, and track over, wire 346. Nose cone 406 preferably has a proximal portion which is either attached to, or formed integrally with, sheath 405. The outer diameter of the proximal portion of nose cone 406 is also approximately the same as the outer diameter of sheath 405. However, nose cone 406 also preferably has a distal portion which tapers, or reduces along preferably a smooth curve, to

an outer diameter which terminates at the inner diameter of nose cone 406.

Proximal locking device 404 is preferably any suitable, and commercially available, locking device which can be configured to lock dilator sheath 405 to guidewire 346.

In order to retrieve device 352 from the vasculature, device 400 is preferably advanced over guidewire 346 to a position shown in FIG. 24B, in which the distal portion of nose cone 406 is closely proximate, or adjacent to, either optional stop 396 or the mouth of filter 344. Then, proximal locking device 404 is actuated to lock dilator sheath 405 to wire 346 so that wire 346 and dilator sheath 405 (as well as nose cone 406) can be moved as a unitary piece.

Next, wire 346 (and hence dilator sheath 405 and nose cone 406) are withdrawn longitudinally relative to retrieval sheath 402. This causes the mouth of filter 344 to enter within the distal opening in retrieval sheath 402. This results in device 352 being positioned relative to sheath 402 as shown in FIG. 24C. Of course, wire 346, dilator sheath 405 and nose cone 406 can be withdrawn further into sheath 402 such that the entire filter 344, and wire tip 348, are disposed within the lumen of sheath 402.

In any case, once at least the mouth of filter 344 is within sheath 402, device 352 is configured to be removed from the vasculature. This can be accomplished by either removing dilator sheath 405, nose cone 406 and device 352 as a unitary piece, leaving sheath 402 in place for later removal, or by removing sheath 402 with the remainder of the system, either through a guide catheter or simply through the vasculature, simultaneously. Also, where a guide catheter is used,

device 352 and device 400 can be removed through the guide catheter leaving the guide catheter in place, or the guide catheter can be removed simultaneously with the other devices 352 and 400.

It should be noted that all of the devices according to the present invention can optionally be coated with an antithrombotic material, such as heparin (commercially available under the tradename Duraflow from Baxter), to inhibit clotting.

Thus, in accordance with one preferred embodiment of the present invention, the superelastic properties of nitinol are used to form a frame at least in the area of the mouth of the distal protection filter. Thus, the distal protection device can be deployed, retrieved, and re-deployed any number of times without incurring plastic deformation. In addition, in other preferred embodiments in accordance with the present invention, various deployment and retrieval techniques and systems are provided which address various problems associated with such systems.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. An emboli capturing system for capturing emboli in a body lumen, comprising:

a first elongate member having a proximal end and a distal end;

an expandable emboli capturing device mounted proximate the distal end of the first elongate member, the emboli capturing device being movable between a radially expanded position and a radially retracted position, the expandable emboli capturing device forming a basket with a proximally opening mouth when in the radially expanded position;

a second elongate member having a proximal end and a distal end and a lumen extending between the proximal and distal ends,the lumen being sized to slidably receive a portion of the first elongate member therein; and

an expandable delivery device mounted to the distal end of the second elongate member and being movable from a radially retracted position to a radially expanded position, the delivery device having a receiving end configured to receive the emboli capturing device, the delivery device retaining at least the mouth of the emboli capturing device in the radially retracted position when the delivery device is in the radially retracted position, the emboli capturing device being longitudinally movable out from within the delivery device when the

delivery device is in the radially expanded position.

2. The emboli capturing system of claim 1 and further comprising:

a retrieval device, configured to be longitudinally movable relative to the emboli capturing device in the body lumen and having a receiving end configured to receive at least the mouth of the emboli capturing device when the emboli capturing device is in the radially expanded position.

3. The emboli capturing system of claim 2 wherein the retrieval device comprises the expandable delivery device in the radially expanded position.

4. The emboli capturing system of claim 2 wherein the receiving end of the retrieval device is contractible from a radially expanded position to a radially contracted position to at least partially collapse the emboli capturing device therein.

5. The emboli capturing system of claim 4 wherein the retrieval device comprises:

a third elongate member having proximal and distal ends and a lumen extending therebetween, the lumen being sized to slidably receive at least a portion of the first elongate member therein, the lumen at the distal end of the third elongate member forming the receiving end and being sized to receive a most radially expanded portion of the emboli capturing device; and

a fourth elongate member movable within the lumen of the third elongate member, the

fourth elongate member having an intermediate region sized to substantially fill the receiving end and a distal tip having an outer diameter less than an outer diameter of the intermediate region.

6. The emboli capturing system of claim 5 wherein the distal tip of the fourth elongate member is configured with an aperture therein sized to track over the first elongate member.

7. The emboli capturing system of claim 6 wherein the fourth elongate member is formed in a substantially conical shape between the distal tip thereof and the intermediate region thereof.

8. The emboli capturing system of claim 2 wherein the retrieval device includes:

a third elongate member having proximal and distal ends and a lumen extending therebetween, the lumen being sized to slidably receive at least a portion of the first elongate member; and

a mesh sleeve having a first end coupled to the third elongate member, a second end distal of the first end and an intermediate portion between the first and second ends, the mesh sleeve being configured such that relative longitudinal movement of one of the first and second ends thereof relative to another of the first and second ends thereof drives movement of the mesh portion from a radially retracted position, to a radially expanded position in which the intermediate

portion expands radially outward relative to the first and second ends, and to a collapsed position in which the mesh sleeve bends such that the intermediate portion is displaced in a direction toward one of the first and second ends of the mesh sleeve.

9. The emboli capturing system of claim 8 wherein the retrieval device is configured such that sufficient longitudinal movement of the emboli capturing device toward the mesh sleeve causes the emboli capturing device to drive the second end of the mesh sleeve toward the first end of the mesh sleeve.

10. The emboli capturing system of claim 9 wherein the mesh sleeve is sized to encompass at least the mouth of the emboli capturing device as the mesh sleeve moves from the radially expanded position to the collapsed position.

11. The emboli capturing system of claim 2 wherein the retrieval device includes:

a third elongate member having proximal and distal ends and a lumen extending therebetween, the lumen being sized to slidably receive at least a portion of the first elongate member;

a fourth elongate member longitudinally movable relative to the third elongate member; and

a mesh sleeve having a first end coupled to the third elongate member and a second end coupled to the fourth elongate member and an intermediate portion between the first and second ends, the mesh sleeve being configured such that

relative longitudinal movement of one of the third and fourth elongate members relative to another of the third and fourth elongate members drives movement of the mesh portion from a radially retracted position, to a radially expanded position in which the intermediate portion expands radially outward relative to the first and second ends, and to a collapsed position in which the mesh sleeve bends such that the intermediate portion is displaced in a direction toward one of the first and second ends of the mesh sleeve.

12. The emboli capturing system of claim 1 wherein the receiving end of the delivery device is defined by a portion of a dilatation balloon.

13. The emboli capturing system of claim 1 wherein the receiving end of the delivery device is thermally shrunk over at least the mouth of the emboli capturing device to retain the emboli capturing device in the radially contracted position during delivery.

14. The emboli capturing system of claim 1 wherein the receiving end of the delivery device is movable from the radially retracted position to the radially expanded position by delivery of pressurized fluid through the lumen in the second elongate member.

15. The emboli capturing system of claim 1 wherein the emboli capturing device is a self-expanding device biased in the radially expanded position.

16. The emboli capturing system of claim 15 wherein the emboli capturing device includes:

a frame formed of a shape memory alloy; and

a filter portion supported by the frame, the filter portion being configured to permit blood flow therethrough and to capture emboli carried by blood flow therethrough.

17. The emboli capturing system of claim 16 wherein the filter portion has a first end connected to the first elongate member and a second end connected to the frame and wherein the frame comprises:

a loop disposed about the first elongate member to define the mouth of the emboli capturing device.

18. The emboli capturing system of claim 17 wherein the loop is directly connected to the first elongate member.

19. The emboli capturing system of claim 17 wherein the shape memory alloy comprises an alloy having superelastic properties.

20. The emboli capturing system of claim 19 wherein the shape memory alloy includes nitinol.

21. The emboli capturing system of claim 20 wherein the emboli capturing device is substantially conical in shape.

22. The emboli capturing system of claim 21 wherein the filter portion comprises a polyurethane member having a plurality of holes therein.

23. The emboli capturing system of claim 1 wherein the first elongate member comprises a guidewire.

24. A method of capturing emboli carried by flow of fluid through a body lumen, the method comprising:

providing a first elongate member having a proximal end and a distal end;

providing an expandable emboli capturing device mounted proximate the distal end

of the first elongate member, the emboli capturing device being movable between a radially expanded position and a radially retracted position, the expandable emboli capturing device defining a proximally opening mouth when in the radially expanded position;

providing a second elongate member having a proximal end and a distal end and a lumen extending between the proximal and distal ends, the lumen being sized to slidably receive a portion of the first elongate member therein;

providing an expandable delivery device mounted to the distal end of the second elongate member and being movable from a radially retracted position to a radially expanded position, the delivery device having a receiving end configured to receive the emboli capturing device, the delivery device retaining at least the mouth of the emboli capturing device in the radially retracted position when the delivery device is in the radially retracted position;

inserting the expandable delivery device into the lumen with the mouth of the emboli capturing device retained in the radially retracted position within the delivery device;

expanding the expandable delivery device into the radially expanded position; and

longitudinally moving the delivery device relative to the emboli capturing device

to remove the emboli capturing device from within the delivery device.

25. The method of claim 24 and further comprising:

providing a retrieval device, configured to be longitudinally movable relative to the emboli capturing device in the body lumen and having a receiving end configured to receive at least the mouth of the emboli capturing device when the emboli capturing device is in the radially expanded position; and

longitudinally moving the delivery device relative to the emboli capturing device such that at least the mouth of the emboli capturing device is in the receiving end of the retrieval device.

26. The method of claim 25 wherein the receiving end of the retrieval device is contractible from a radially expanded position to a radially contracted position, and further comprising:

contracting the receiving end of the retrieval device to at least partially collapse the emboli capturing device therein.

27. The method of claim 26 wherein providing a retrieval device comprises:

providing a third elongate member having proximal and distal ends and a lumen extending therebetween, the lumen being sized to slidably receive at least a portion of the first elongate member therein, the lumen at the distal end of the third elongate member forming the

receiving end and being sized to receive a most radially expanded portion of the emboli capturing device;

providing a fourth elongate member movable within the lumen of the third elongate member, the fourth elongate member having an intermediate region sized to substantially fill the receiving end and a distal tip having an outer diameter less than an outer diameter of the intermediate region;

advancing the third and fourth elongate members over the first elongate member, with the intermediate region of the fourth elongate member positioned within the third elongate member to fill the receiving end thereof, to a point proximate the emboli capturing device;

withdrawing the distal tip of the fourth elongate member within the lumen of the third elongate member; and

positioning at least the mouth of the emboli capturing device within the receiving end of the retrieval device.

28. The method of claim 27 and further comprising:

withdrawing the first, third, and fourth elongate members from the body lumen.

29. The method of claim 25 wherein providing the retrieval device includes:

providing a third elongate member having proximal and distal ends and a lumen extending therebetween, the lumen being sized to slidably receive at least a portion of the first elongate member;

providing a mesh sleeve having a first end coupled to the third elongate member, a second end distal of the first end and an intermediate portion between the first and second ends, the mesh sleeve being configured such that relative longitudinal movement of one of the first and second ends thereof relative to another of the first and second ends thereof drives movement of the mesh portion from a radially retracted position, to a radially expanded position in which the intermediate portion expands radially outward relative to the first and second ends, and to a collapsed position in which the mesh sleeve bends such that the intermediate portion is displaced in a direction toward one of the first and second ends of the mesh sleeve;

advancing the third elongate member into the body lumen over the first elongate member to a point proximate the mouth of the emboli capturing device; and

accomplishing relative longitudinal movement of the emboli capturing device and the mesh sleeve toward one another, driving the second end of the mesh sleeve toward the first end of the mesh sleeve such that the mesh sleeve encompasses at least the mouth of the emboli capturing device as the mesh sleeve moves from the radially expanded position to the collapsed position.

30. The method of claim 24 wherein expanding comprises:

delivering pressurized fluid through the lumen in the second elongate member.

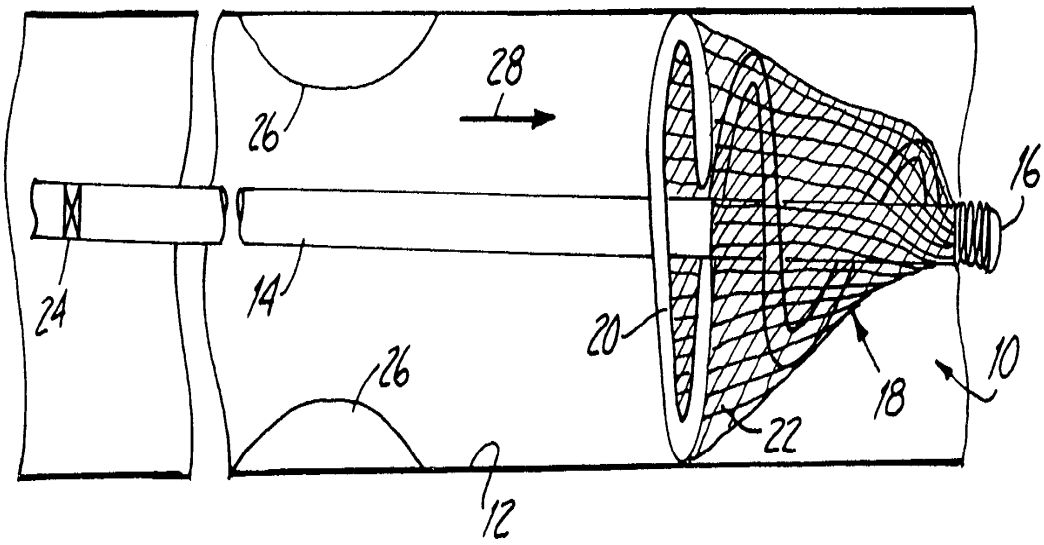

Fig.1

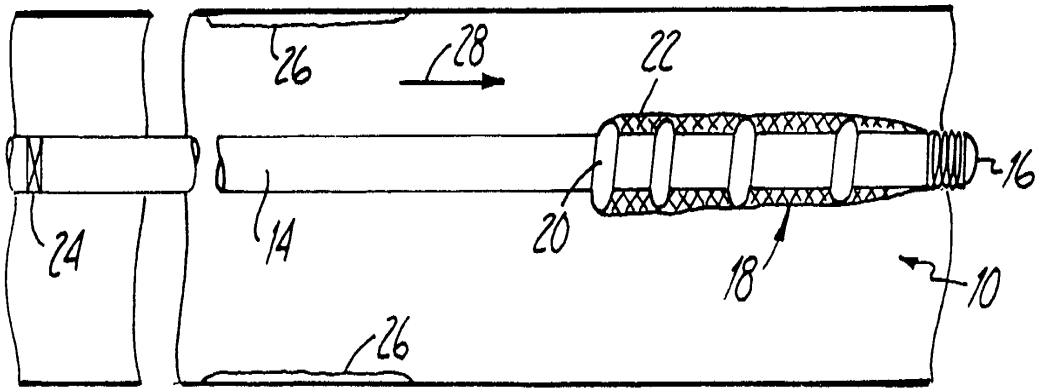

Fig.2

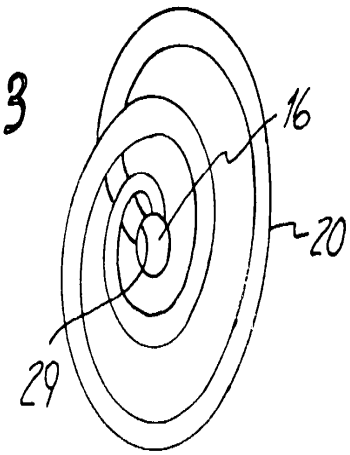

Fig.3

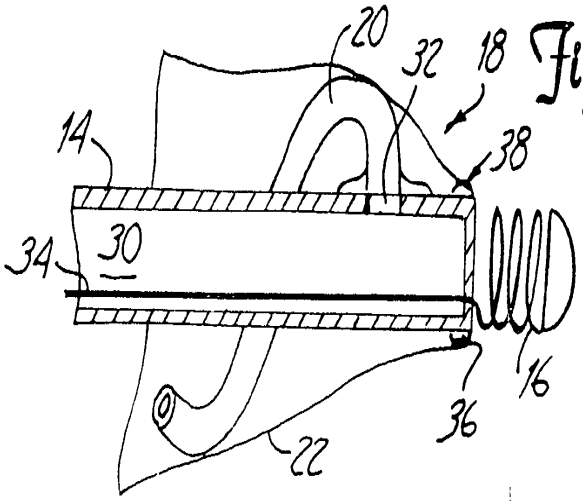

Fig.4

SUBSTITUTE SHEET (rule 26)

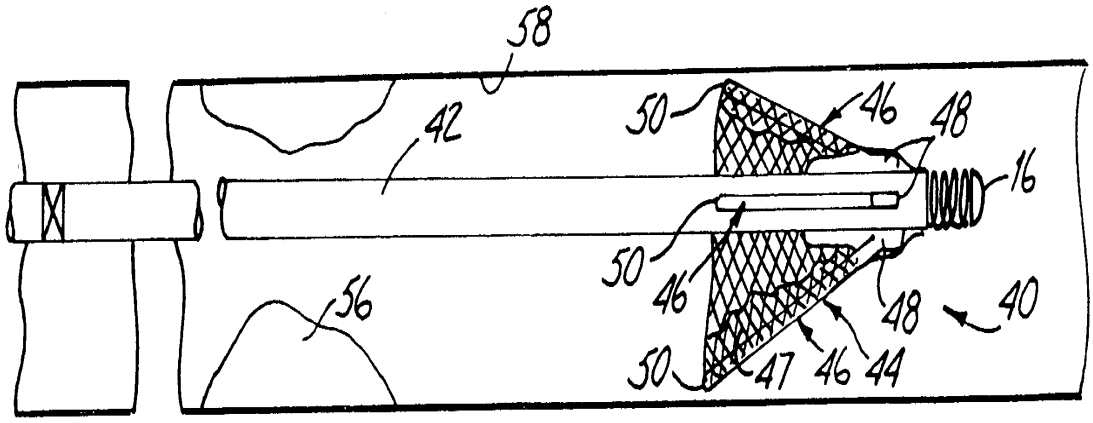

Fig.5

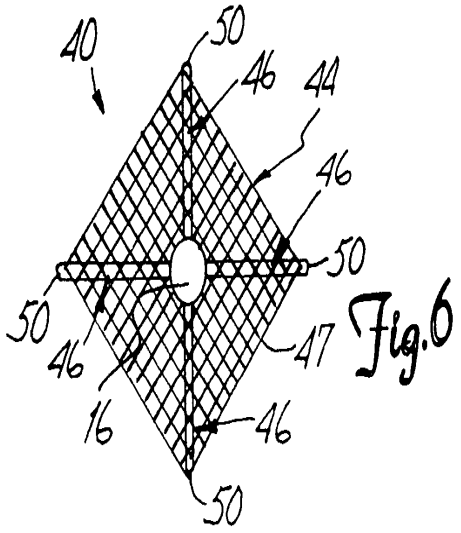

Fig.6

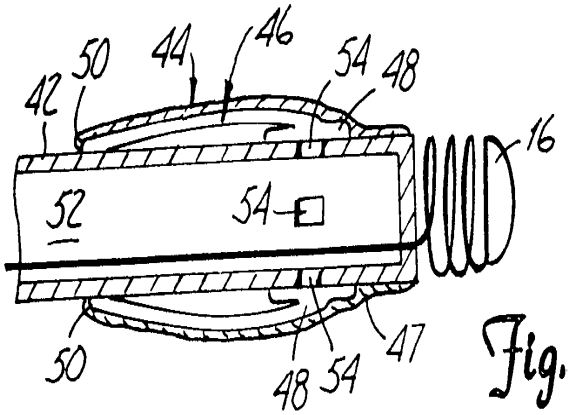

Fig.7

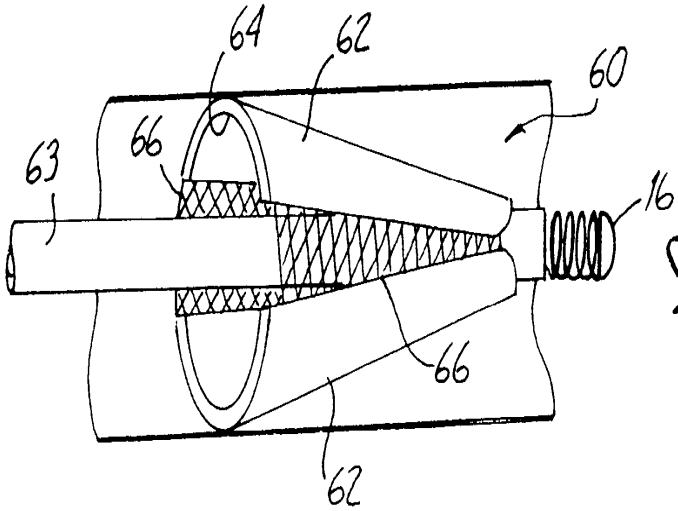

Fig.8

Fig. 9

Fig. 10

Fig. 11A

Fig. 11B

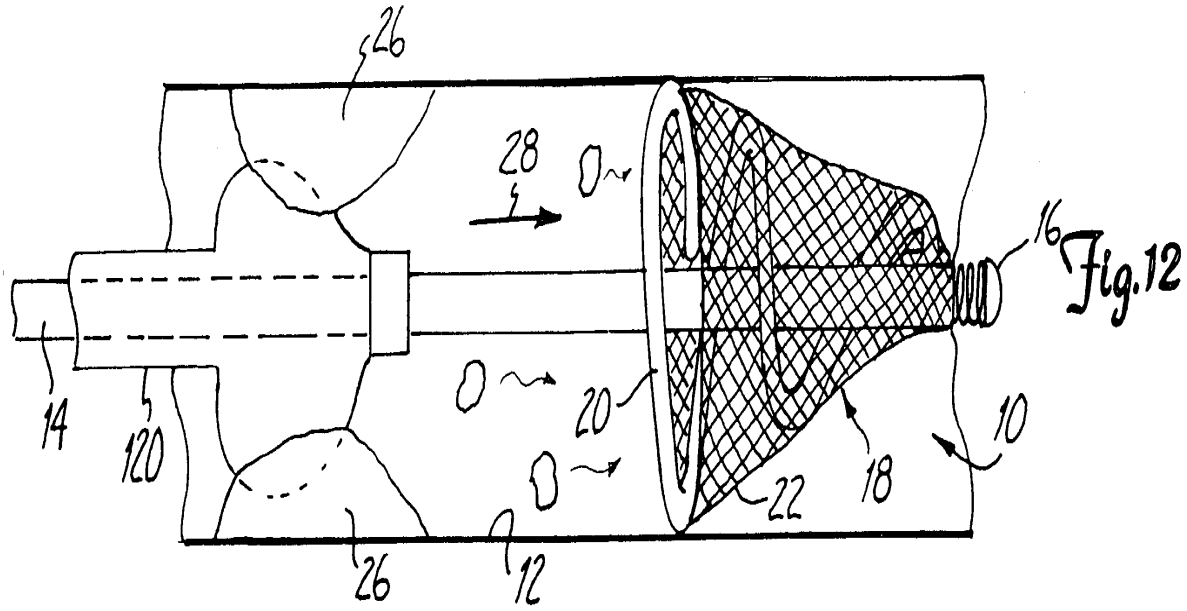

Fig.12

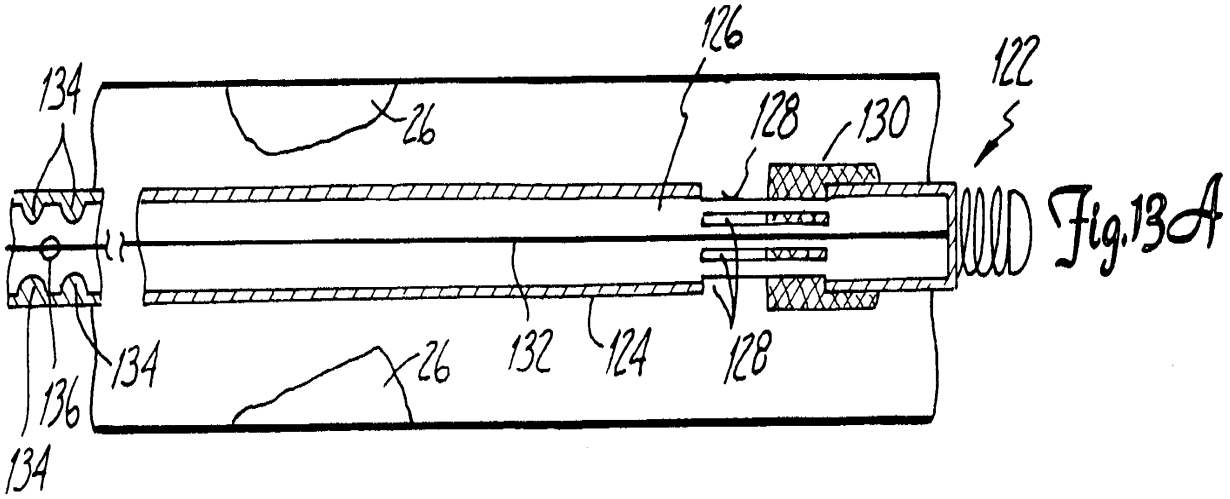

Fig.13A

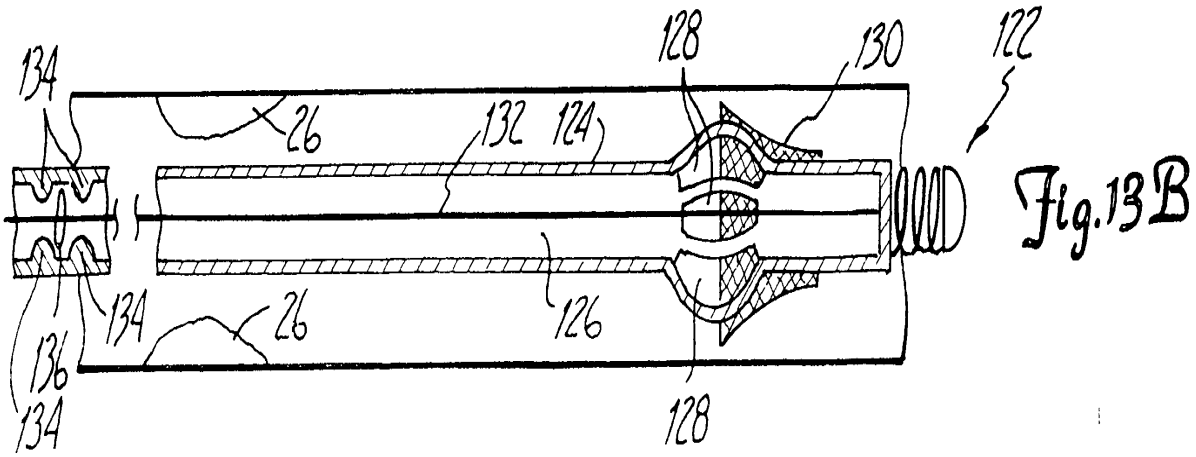

Fig.13B

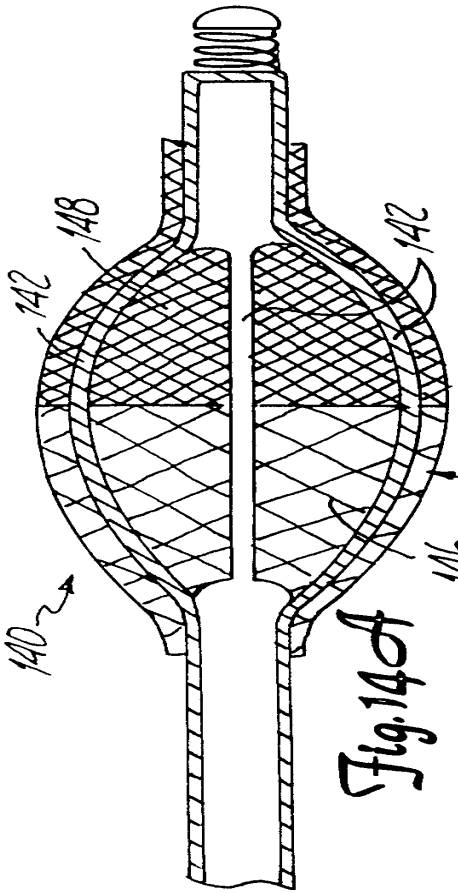

Fig. 14A

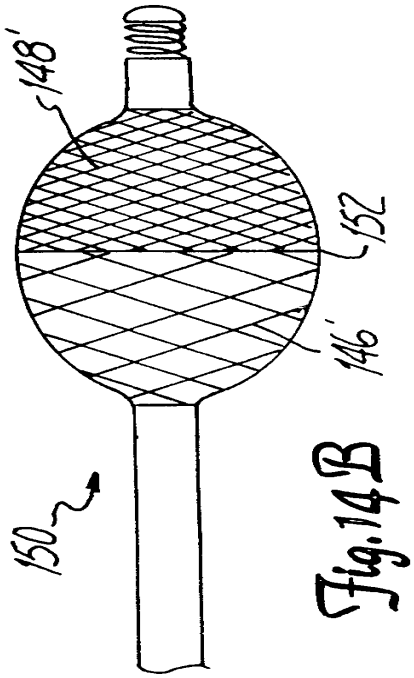

Fig. 14B

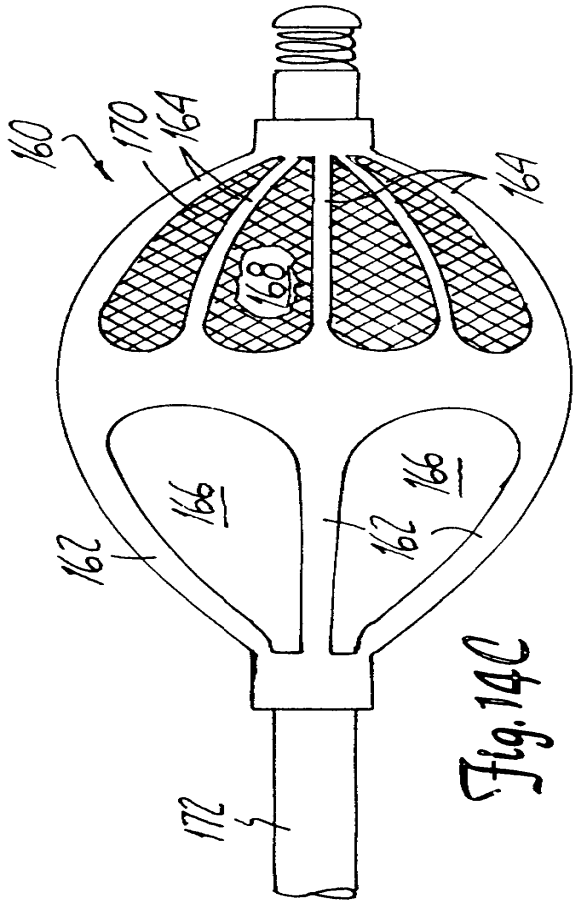

Fig. 14C

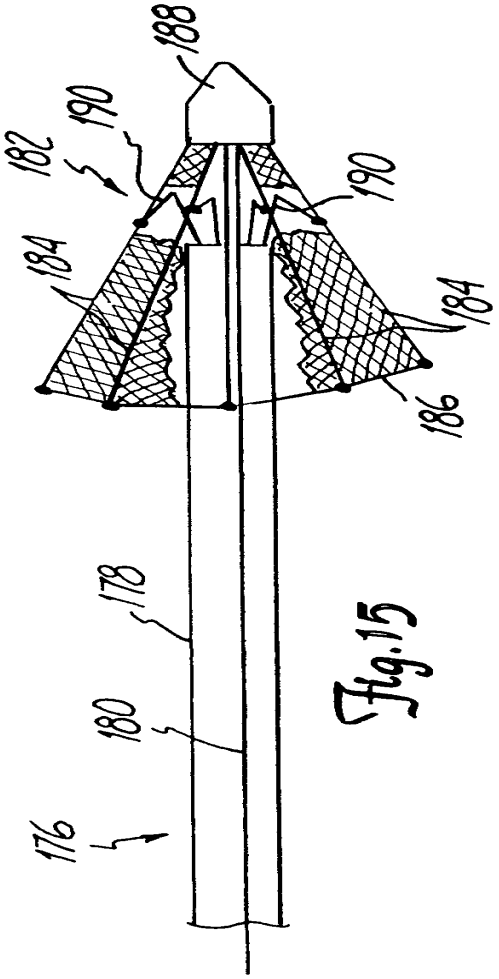

Fig. 15

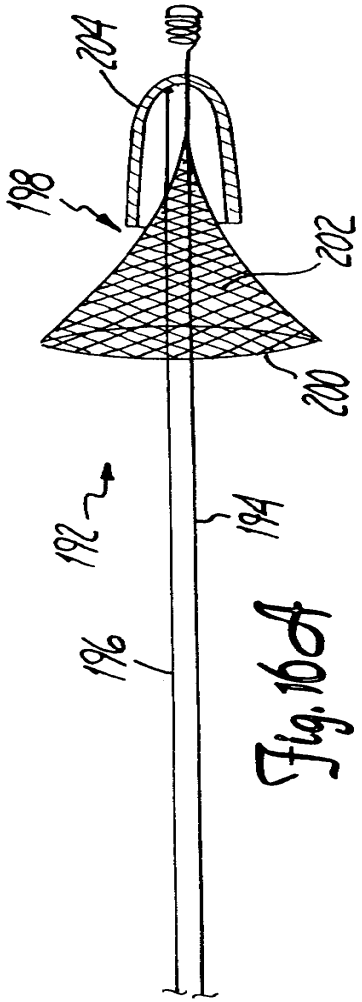

Fig. 16A

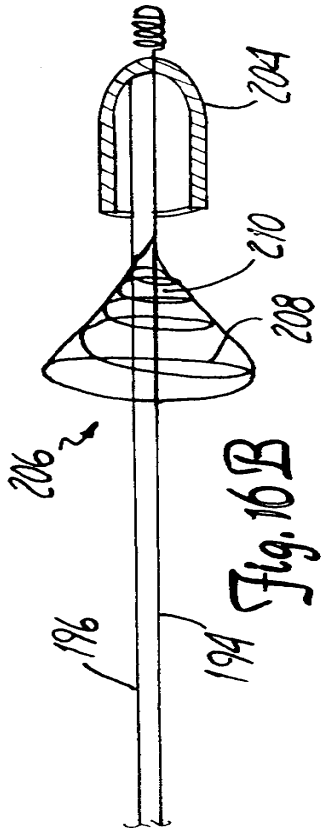

Fig. 16B

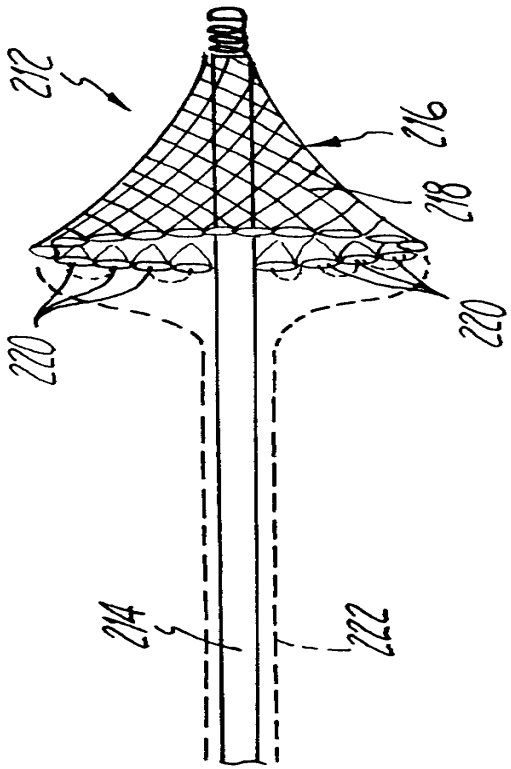

Fig. 17A

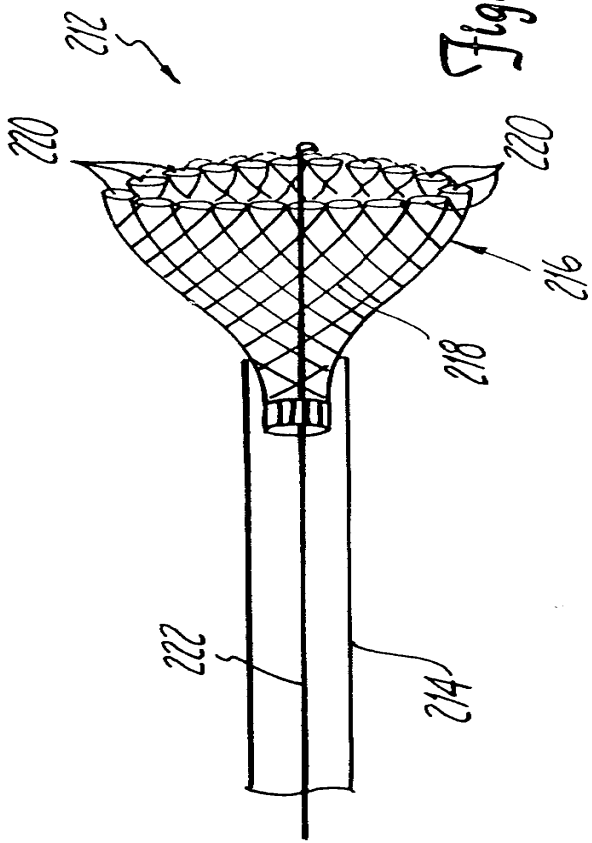

Fig. 17B

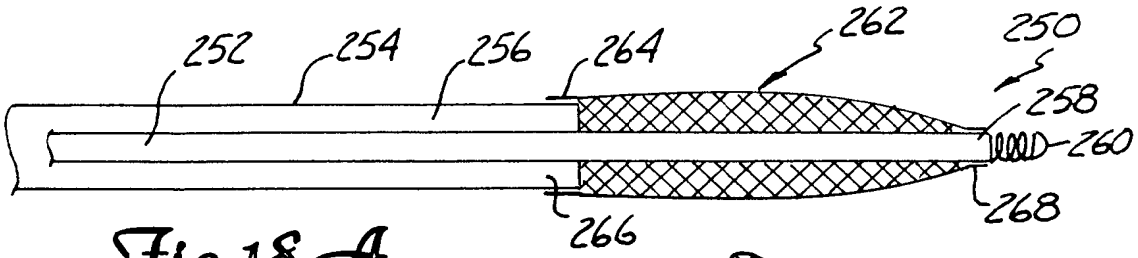

Fig. 18A

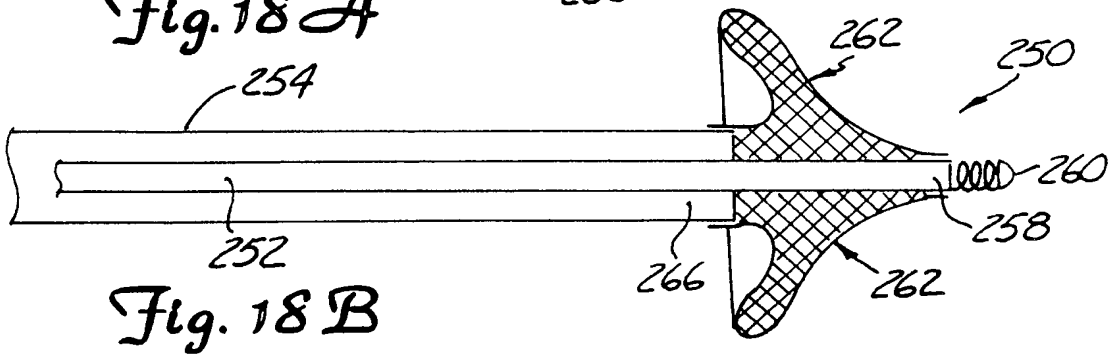

Fig. 18B

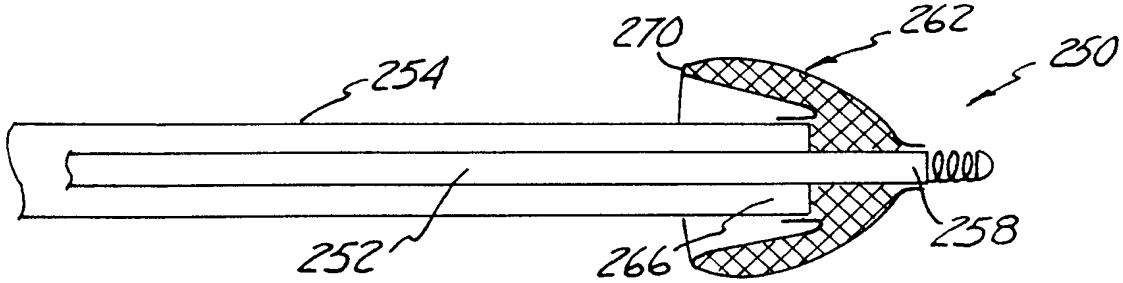

Fig. 18C

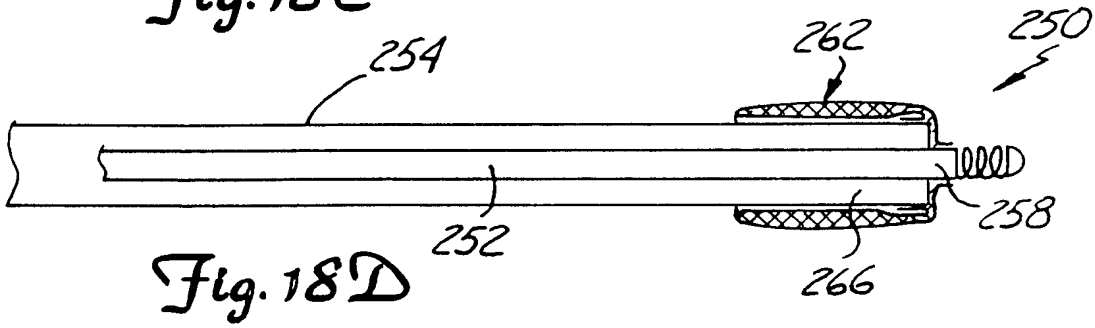

Fig. 18D

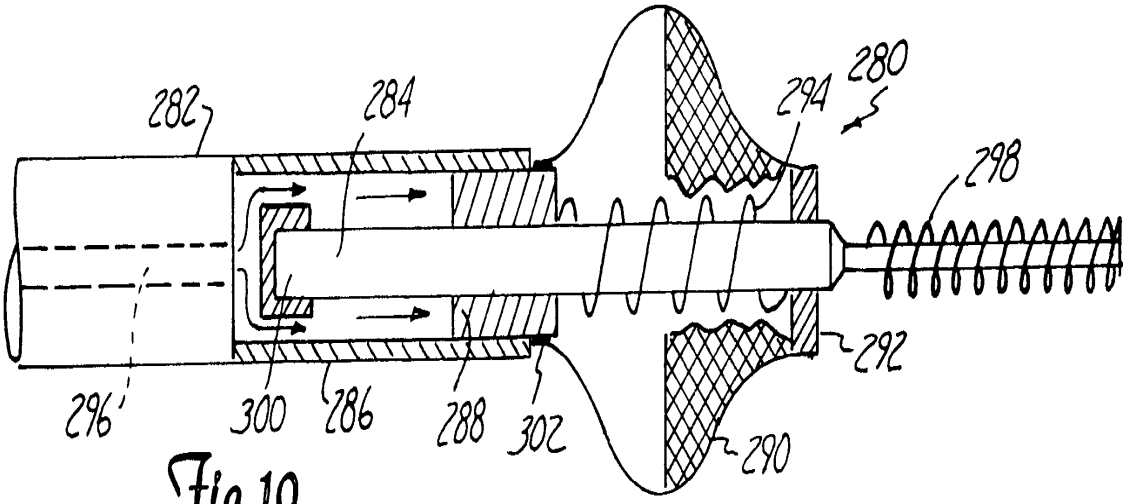

Fig. 19

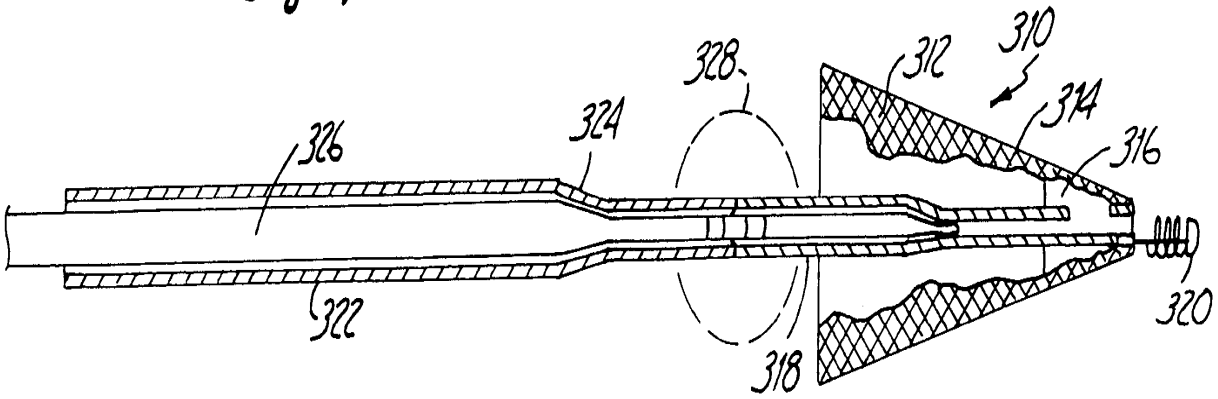

Fig. 20A

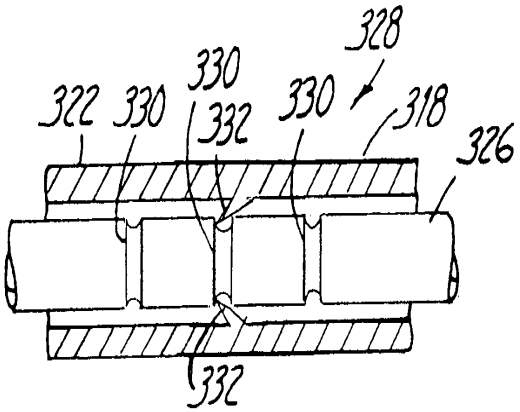

Fig. 20B

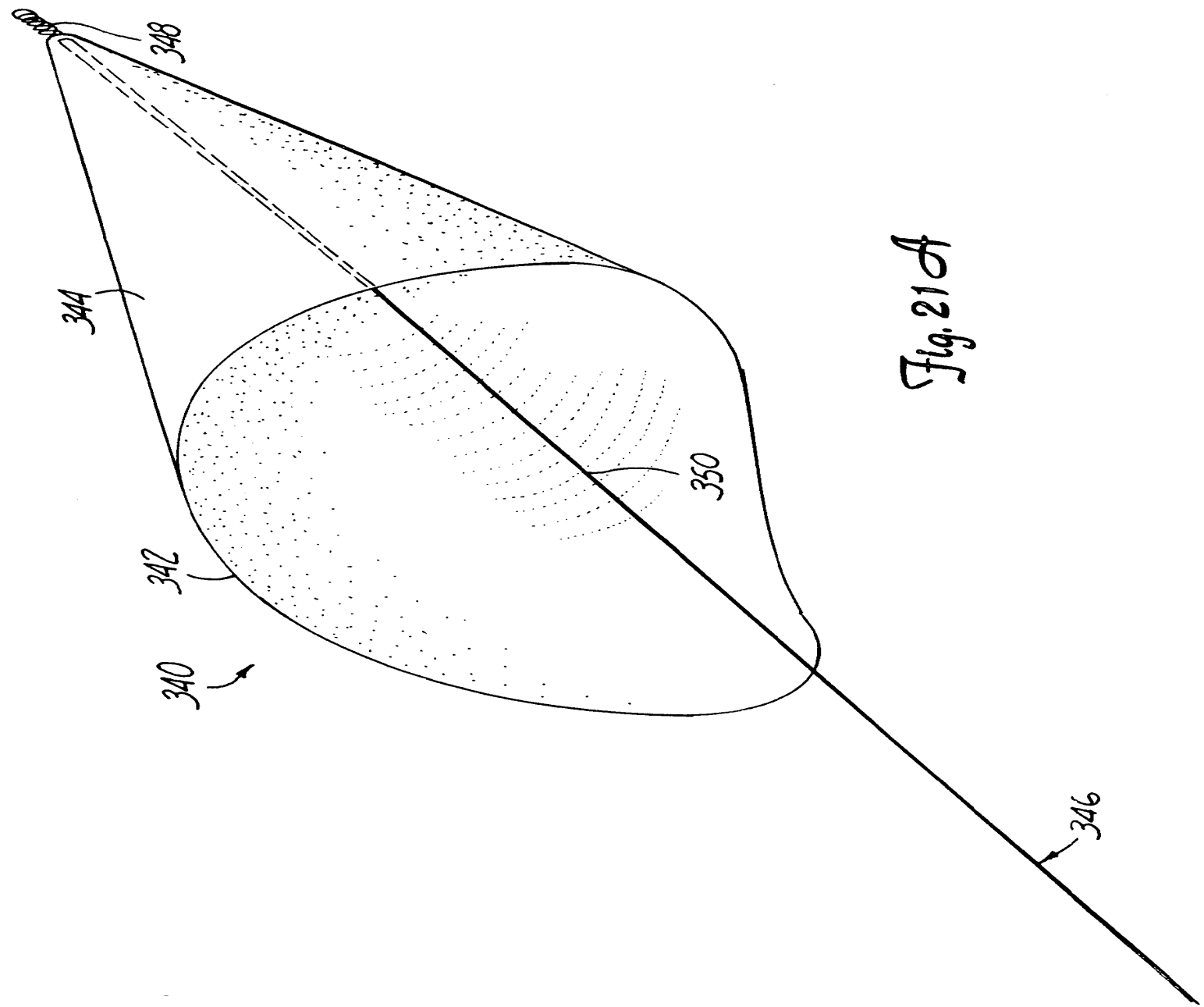

Fig. 21A

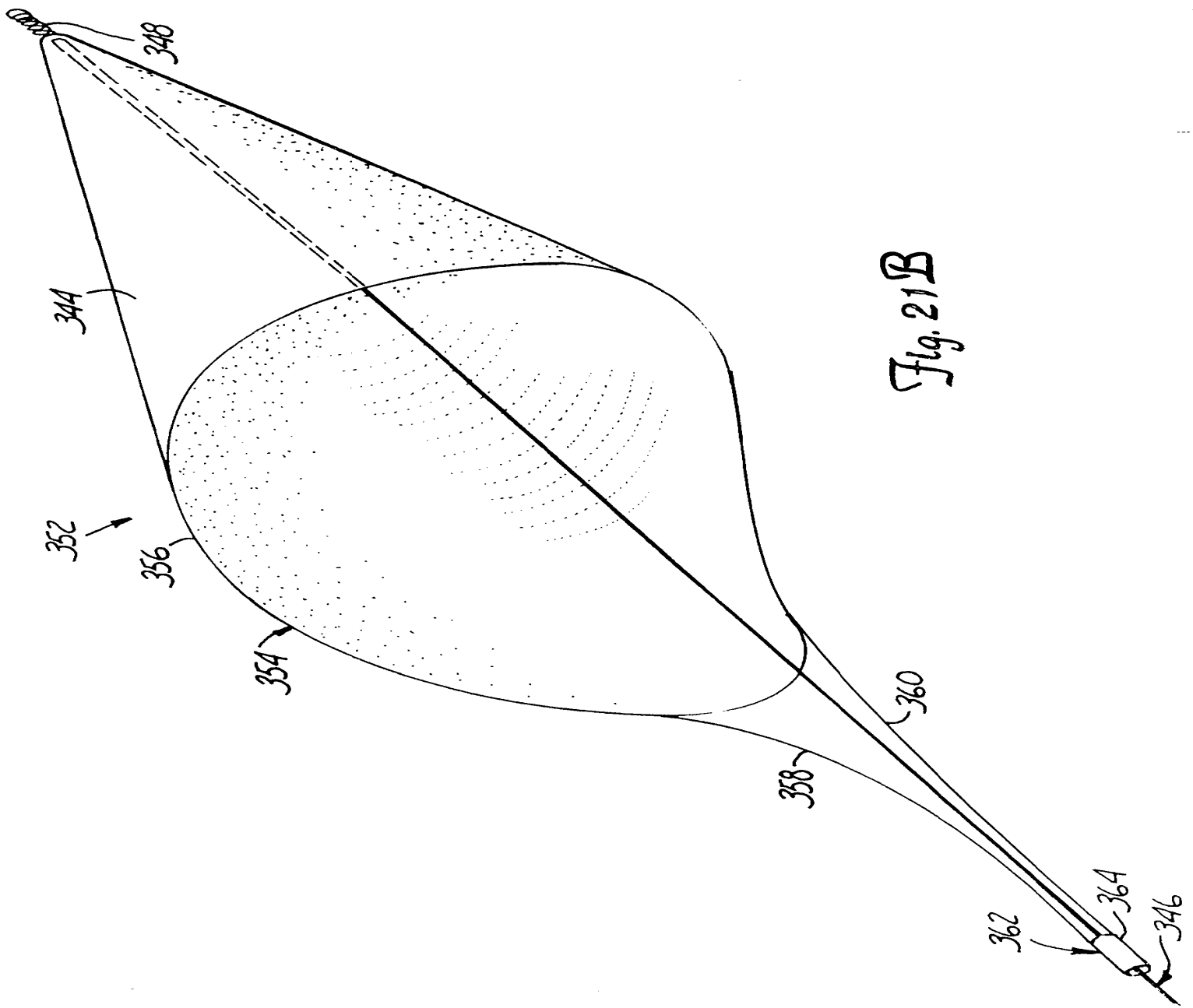

Fig. 21B

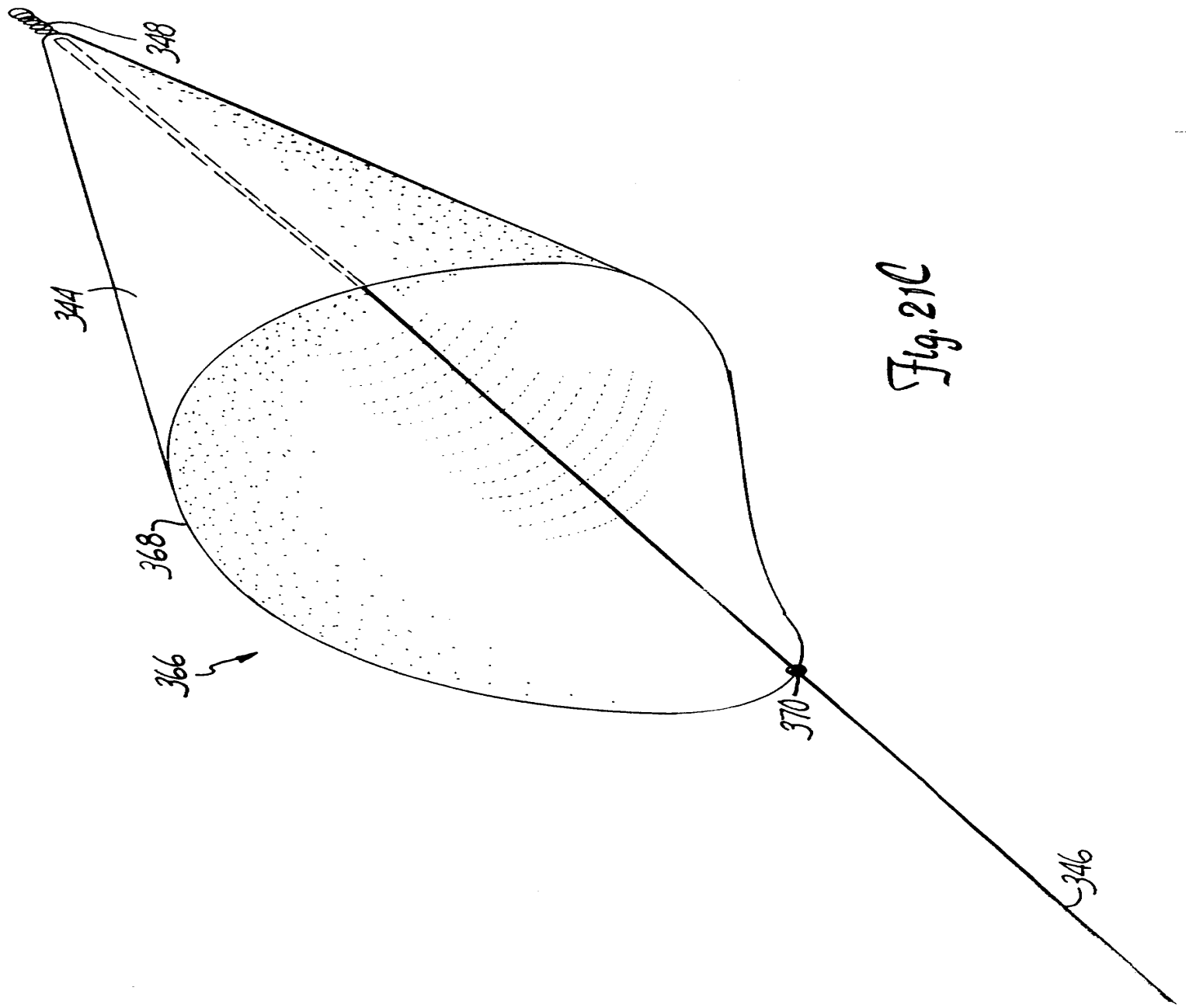

Fig. 21C

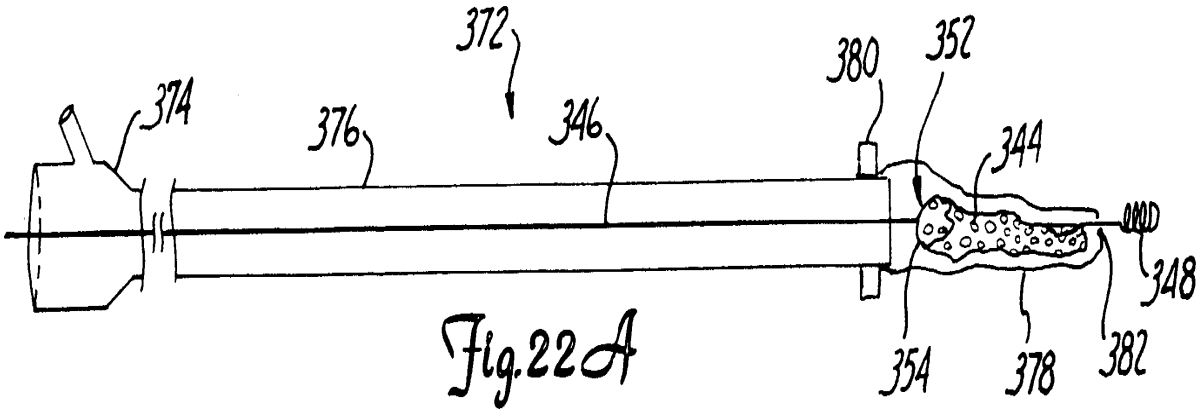

Fig. 22A

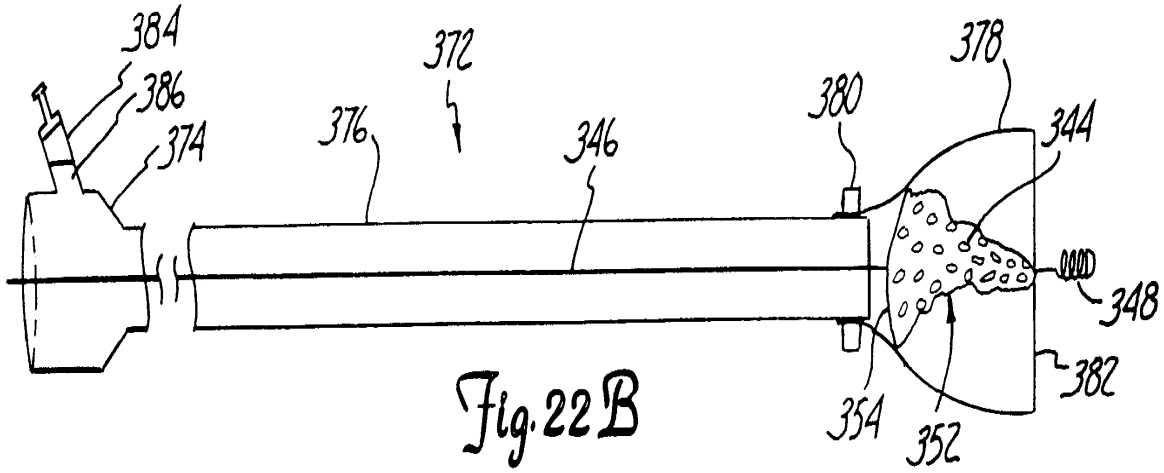

Fig. 22B

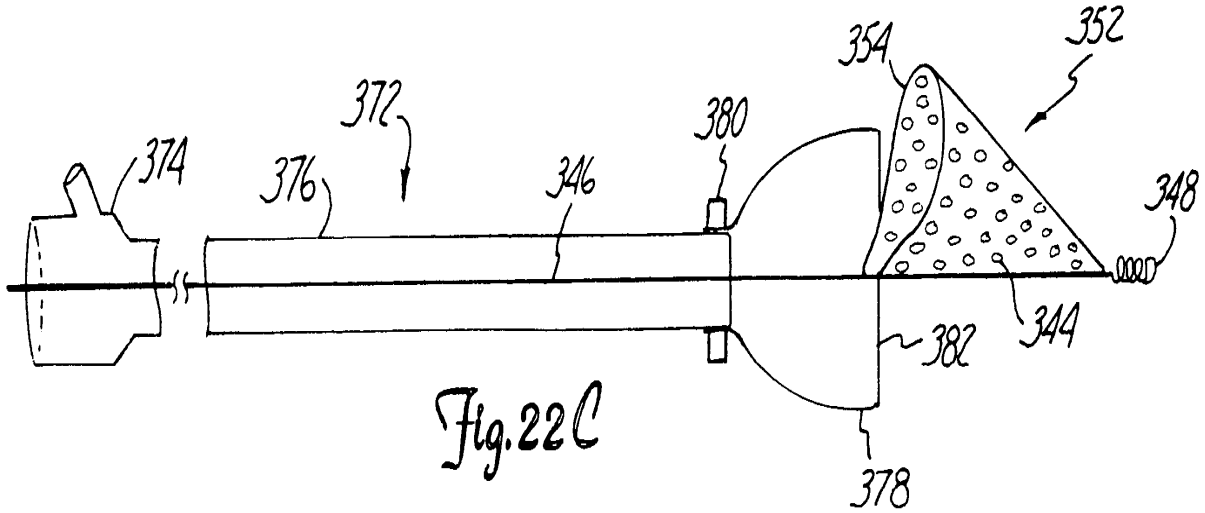

Fig. 22C

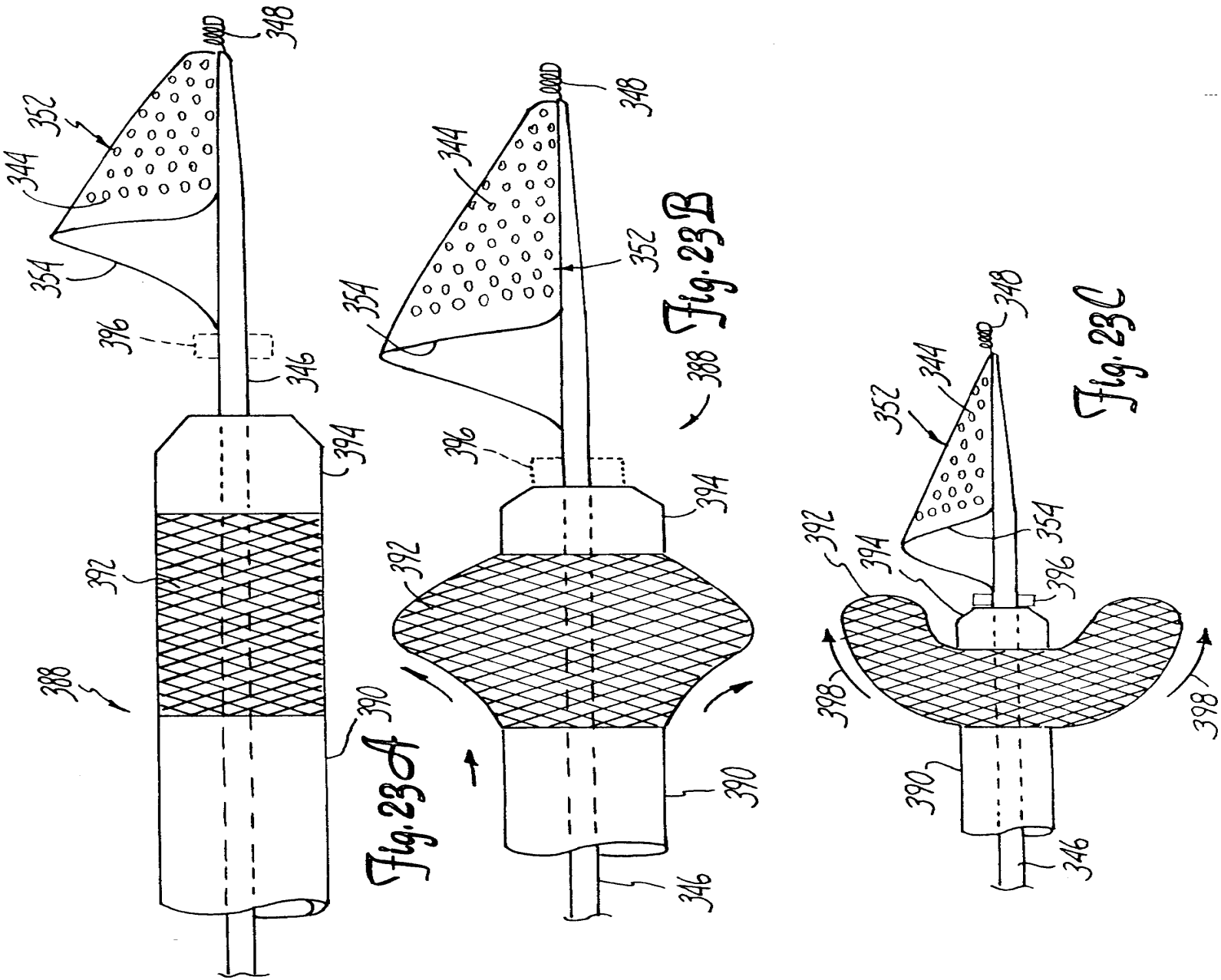
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Fig. 23A
Fig. 23B
Fig. 23C
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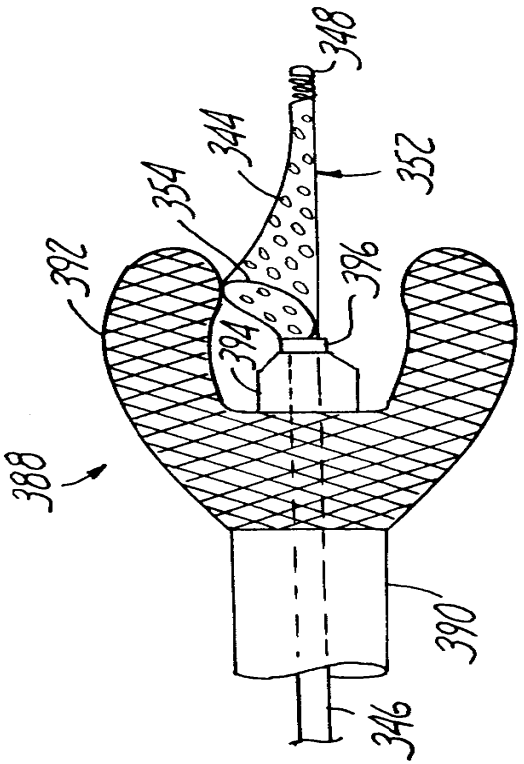


Fig. 23D

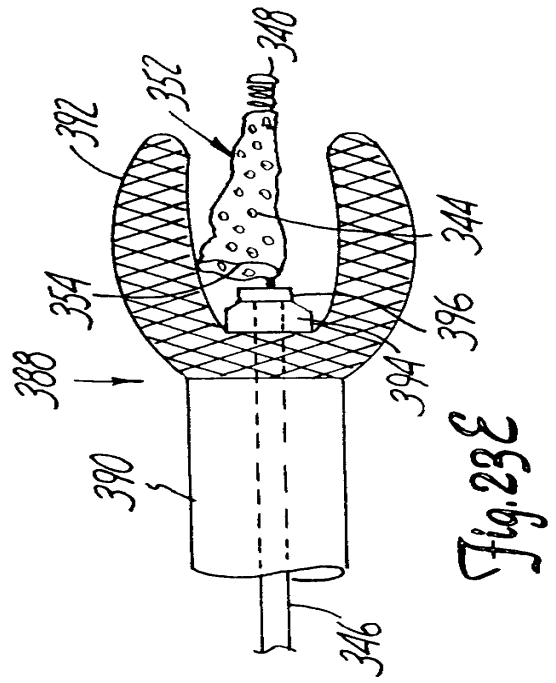


Fig. 23E

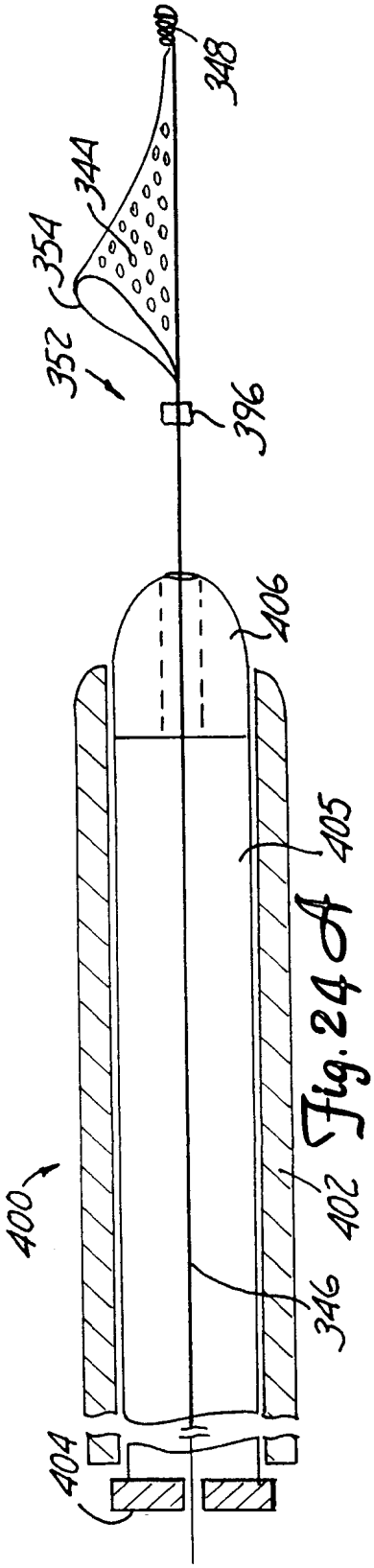


Fig. 24 A

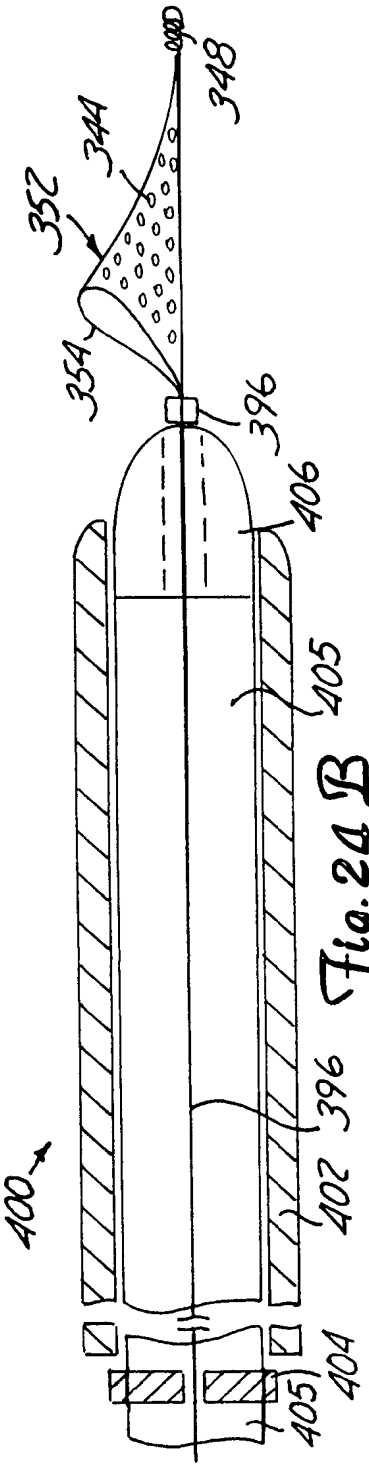


Fig. 24 B

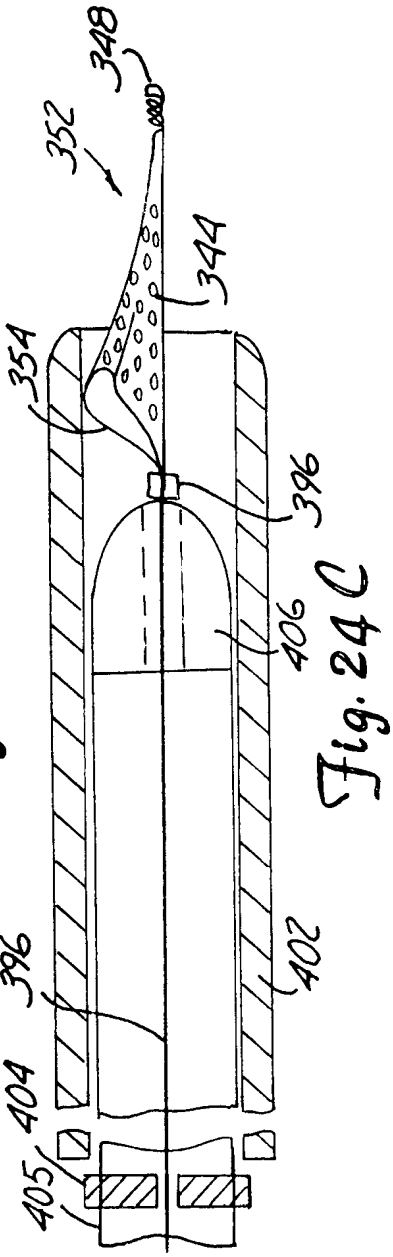


Fig. 24 C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/02961

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 29/00
US CL :604/22; 606/194, 198, 200
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/22, 104; 606/159, 180, 191, 194, 195, 198, 200

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,102,415 A (GUENTHER ET AL) 07 APRIL 1992, COL. 2 LINES 1-61.	1-30
A	US 4,723,549 A (WHOLEY ET AL) 09 FEBRUARY 1988, COL. 2 LINES 3-36.	1-30
A	US 5,071,407 A (TERMIN ET AL) 10 DECEMBER 1991, COL. 2 LINES 20-68, AND COL. 3 LINES 1-57.	1-30

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 02 JUNE 1998	Date of mailing of the international search report 23 JUN 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer GARY JACKSON Telephone No. (703) 308-4302

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

Espacenet

Bibliographic data: JP2006094876 (A) — 2006-04-13

MEDICAL TREATMENT INSTRUMENT

Inventor(s): KATO TOMIHISA ± (KATO TOMIHISA)

Applicant(s): ASAHI INTECC CO LTD ± (ASAHI INTECC CO LTD)

Classification: **- international:** ***A61B17/00; A61B17/221***
- cooperative:

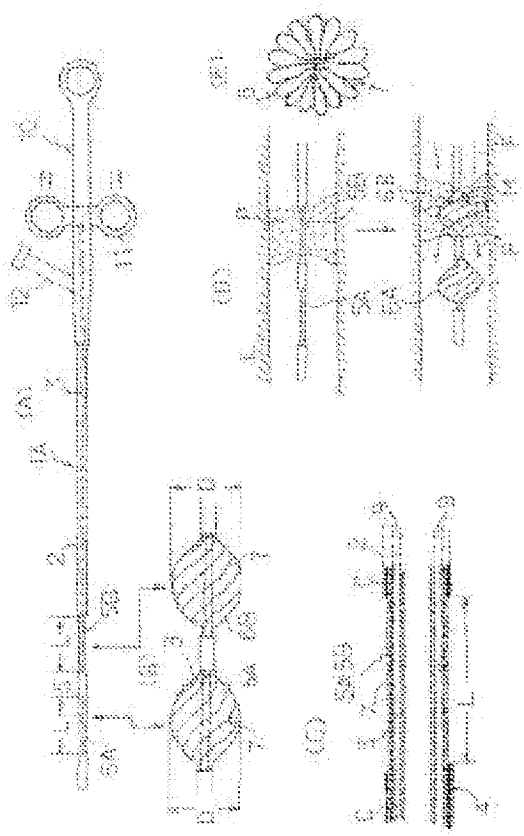
Application number: JP20040280779 20040928

Priority number(s): JP20040280779 20040928

Also published as: JP4324535 (B2)

Abstract of JP2006094876 (A)

PROBLEM TO BE SOLVED: To provide a high-quality medical treatment instrument which can execute a therapy to remove a foreign substance in a celom or a thrombus rapidly, accurately and simply. ; SOLUTION: This medical treatment instrument is so constituted that a therapy section in the celom is disposed at a pointed head region of a slender and flexible main linear section 2, wherein the main linear section 2 comprises a hollow stranded wire coil 4 in which a core material for an operation 3 is inserted, and the therapy section in the celom is so constituted that it is a plurality of spans arrangement of expanded and contracted diameter sections 5A and 5B with the length L comprising the coiled wires 7 of the hollow stranded wire coil 4, and the expanded and contracted diameter sections 5A and 5B can be basket-type expanded diameter variants 6A and 6B comprising the coiled wires 7 and can



become contracted diameter variants changed from the expanded diameter variants by a pulling/pushing operation of the core material for the operation 3. ;

(19)日本国特許庁(JP)　(12)公開特許公報(A)　(11)特許出願公開番号
特開2006-94876
(P2006-94876A)
(43)公開日　平成18年4月13日(2006.4.13)

(51)Int.Cl.		F I			テーマコード（参考）
A61B 17/00	(2006.01)	A61B	17/00	320	4C060
A61B 17/221	(2006.01)	A61B	17/22	310	

審査請求 未請求　請求項の数 12　OL　（全 12 頁）

(21)出願番号　特願2004-280779 (P2004-280779)
(22)出願日　平成16年9月28日 (2004.9.28)

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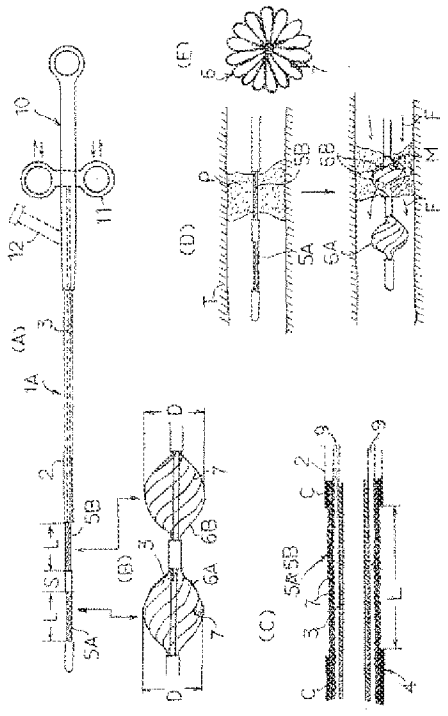
(54)【発明の名称】医療用処置具

(57)【要約】
【課題】　体腔内異物・血栓の除去治療が、迅速的確にして容易に治療できる高品質の医療用処置具を提供する。
【解決手段】　細長可撓性の主線条部２の先端部位に体腔内治療部を設けた医療用処置具において、主線条部２が操作用芯材３を内挿した中空撚線コイル体４から成ると共に、体腔内治療部が中空撚線コイル体４のコイル素線７から成る長さＬの膨縮径部５Ａ・５Ｂの複数スパン配設にして、操作用芯材３のプル・プッシュ操作によって、前記膨縮径部５Ａ・５Ｂのコイル素線７によるバスケット状膨径変体６Ａ・６Ｂと、その膨径変体からの縮径変体を自在にした構造が特徴である。
【選択図】　図１



【特許請求の範囲】
【請求項1】
細長可撓性の主線条部の先端部位に体腔内治療部を設けた医療用処置具において、前記主線条部が操作用芯材を内挿した中空撚線コイル体から成ると共に、前記体腔内治療部が、前記中空撚線コイル体のコイル素線から成る膨縮径部の複数スパン連設にして、前記操作用芯材のプル・プッシュ操作によって、前記膨縮径部のコイル素線によるバスケット状膨径変体と、該バスケット状膨径変体からの縮径変体を自在にした構造を特徴とする医療用処置具。
【請求項2】
複数スパン配設の膨縮径部が、相互に異なる長さに設定された請求項１に記載の医療用処置具。
【請求項3】
細長可撓性の主線条部の先端部位に体腔内治療部を設けた医療用処置具において、前記主線条部が、操作用芯材を内挿した中空撚線コイル体から成る外側主線条部と内側主線条部の２層管構造にして、前記体腔内治療部が、前記２層の中空撚線コイル体のコイル素線から成る内外２層の膨縮径部にして、前記操作用芯材のプル・プッシュ操作による前記膨縮径部のコイル素線による内包外包形態の２層のバスケット状膨径変体と、該バスケット状膨径変体からの縮径変体を自在にした構造を特徴とする医療用処置具。
【請求項4】
外側主線条部と内側主線条部の中空撚線コイル体のコイル撚り方向が、相互に逆方向の組合せから成る請求項３に記載の医療用処置具。
【請求項5】
主線条部または外側主線条部に可撓性鞘管を設けた請求項１～請求項４のいずれかに記載の医療用処置具。
【請求項6】
中空撚線コイル体の内周または操作用芯材の中空部を液体流路に成す請求項１～請求項５のいずれかに記載の医療用処置具。
【請求項7】
操作用芯材のプル・プッシュ操作の手元操作部に、主線条部と操作用芯材の相対位置のセットロック手段を設けた請求項１～請求項６のいずれかに記載の医療用処置具。
【請求項8】
膨縮径部に、膨大変体の全周または一部を被覆する弾性質被膜を設けた請求項１～請求項７のいずれかに記載の医療用処置具。
【請求項9】
中空撚線コイル体のコイル素線が、単線または撚り線の撚合線から成る請求項１～請求項８のいずれかに記載の医療用処置具。
【請求項10】
中空撚線コイル体のコイル素線が、異種金属の組合せから成る請求項１～請求項８のいずれかに記載の医療用処置具。
【請求項11】
中空撚線コイル体のコイル素線が、異形断面形状から成る請求項１～請求項８のいずれかに記載の医療用処置具。
【請求項12】
中空撚線コイル体のコイル外周が、縮径加工された形状から成る請求項１～請求項の８いずれかに記載の医療用処置具。

【発明の詳細な説明】
【技術分野】
【0001】
本発明は、血管内の血栓や胆管内の胆石等の体腔内異物の除去治療・肺塞栓症治療・血液透析治療等に用いる医療用処置具に関するものである。

【背景技術】
【0002】
血管等の体腔内異物の除去治療に用いる医療用処置具として、体腔内に挿入する細長可撓性の線条体の先端部分に異物除去手段を備え、体外に出した手元操作部を押し・引き・回転操作して該異物の除去治療をする医療用処置具は特許文献１～３に例示する背景技術がある。
【0003】
即ち、その特許文献１のものは、線条体の先端部分に「弾性質円板形状または放射線状突設形状の弾性質の除去ブラシ」から成る異物除去手段を備え、その除去ブラシによって血管内血栓等の体腔内異物を容易にかき取り除去する構造に設定されている。
【0004】
そして、特許文献２のものは血管内の血塊治療具にして、線条体の先端部位に「リボン・ワイヤの素線をクロス編成した拡縮自在の２個のボール部」をピッチ配設した構造を有し、そのボール部によって血栓を除去捕集したり血栓溶解剤注入して血流再開治療を施すように成っている。
【0005】
そして、特許文献３のものは、可撓性線条体のシース体の先端部位に、該シースから突出状態で拡大羽根を呈し、かつ、該シースへの引き込み収納可能な「らせん集合体のバスケット部」によって尿管・胆管内の結石等の体腔内異物を捕捉除去治療する構造を特徴としている。
【0006】
【特許文献1】特開２００３－３８５００公報
【特許文献2】特表２００３－５２１２５９公報
【特許文献3】特表２００２－５１６１３９公報
【発明の開示】
【発明が解決しようとする課題】
【0007】
以上の背景技術の特許文献１・２のものは体腔内に挿入する線条体の先端部分に設けた除去ブラシ・ボール状部の体腔内治療部によって血栓等を除去治療する構造にして、病変部個個の形態に適するサイズに調整セット不能であり、かつ、単に摺擦削りするに限ぎず、また特許文献３のもののバスケット部もシースへの出入によって若干のサイズ変形は可能であるものの、病変部の個個の形態にマッチングさせる的確なサイズ変更は不能にして、いずれも体腔内異物を迅速的確にして容易に除去する治療性に欠ける。
【0008】
そして、以上の背景技術のいずれも体腔内治療部を構成する要部が、構造複雑にして成形加工性に劣ると共に、病変部の個個に適する多様サイズのものを準備する必要があるので、成形加工性に劣ると共に、コスト高にして、かつ日常管理・治療前準備（病変部の個個に適合するサイズのものを択一する作業）が煩雑に成る。以上の諸難点がある。
【0009】
本発明は、以上の背景技術の難点を解消して当該治療性の特段の向上を図ると共に、加工生産性に優れる高品質・高性能の「体腔内治療部つき医療用処置具」を提供するものである。
【課題を解決するための手段】
【0010】
以上の技術課題を解決する本発明は（その基本形態を示す図１参照）「細長可撓性の主線条部２の先端部位に体腔内治療部を設けた医療用処置具において、主線条部２が操作用芯材３を内挿した中空撚線コイル体４から成ると共に、体腔内治療部が中空撚線コイル体４のコイル素線７から成る長さＬの膨縮径部５Ａ・５Ｂの複数スパン配設にして、操作用芯材３のプル・プッシュ操作によって、前記膨縮径部５Ａ・５Ｂのコイル素線７によるバスケット状膨径変体６Ａ・６Ｂと、その膨径変体からの縮径変体を自在にした構造」を特

徴とする第１発明のの医療用処置具１Aと、

【0011】

（基本形態を示す図２参照）同じく主線条部に体腔内治療部を設けたものにおいて、「主線条部２が操作用芯材３を内挿した中空撚線コイル体４から成る外側主線条部２Aと内側主線条部２Bの２層管構造にして、体腔内治療部が、前記２層の中空撚線コイル体４のコイル素線７から成る長さＬ１・Ｌ２の内外２層の膨縮径部５Ｃ・５Ｄにして、操作用芯材３のプル・プッシュ操作による膨縮径部５Ｃ・５Ｄのコイル素線７による内包外包形態の２層のバスケット状膨径変体６Ｃ・６Ｄと、その膨径変体からの縮径変体を自在にした構造」と特徴とする第２発明の医療用処置具１Ｂに成っている。なお、膨径変体６Ｃ・６Ｄの相対形態は図示実線の略相似形態、または内側の膨径変体６Ｄの頂点が外側の膨径変体６Ｃの内周に内接・近接する非略相似形態のいずれでも良い。

【0012】

即ち、以上の構成の医療用処置具１Ａ・１Ｂは、主として血栓・血餅病変部の治療や肺塞栓症治療に用いるものにして、血管内へ挿入する細長可撓性の主線条部２を「外層被覆Ｃつき中空撚線コイル体４」で形成すると共に、その主線条部２の先端部位に「外層被覆Ｃを若干長剥離してコイル素線７を露出した膨縮径部５Ａ～５Ｄ」を設け、治療時に体外に出す手元操作部１０で操作用芯材３をプル操作することによって、膨縮径部５Ａ～５Ｄを強制短縮させて、その膨縮径部５Ａ～５Ｄのコイル素線７が個個に外方へスパイラル状に膨大径した「スパイラル素線７群から成る任意径バスケット形態の膨径変体６Ａ～６Ｄ」に成し、その膨径変体６Ａ～６Ｄによって血管Ｔの血栓・血餅病変部Ｐ等の治療を行い、その治療後には前記プル操作をフリーにすることによるコイル素線７の自力弾性による復元力、または操作用芯材３のプッシュ操作によって、縮径してストレート状の膨縮径部５Ａ～５Ｄに復元縮径変体する膨縮変体自在にした思想から成るものである。

【0013】

そして、前記第１・第２発明とも、その膨縮径部５を複数セットにする共通の上位概念構成から成り、前記第１発明のものは「膨縮径部５のスパン配設」前記第２発明のものは「同一ポイントへの膨縮径部５の２重配設」の下位概念構成を特徴にしている。なお前記の中空撚線コイル体４とは、特開２００２－２７５７７４公報等に示される多数のコイル素線を同一円周上に撚合構成した可撓性線状体の中空撚線コイル体」を意味し、膨縮径部５Ａ～５Ｄ以外の部分は外層被覆Ｃを存在させて操作用芯材３の操作力に関係なく正常な可撓性管体を維持させる形態に構成すると共に、操作用芯材３は主線条部２の先端に固定され、主線条部２・内側主線条部２Ｂと相対滑り自在に挿入設定される。そして、その主線条部２・２Ａ・２Ｂの内周と操作用芯材３の中空部のいずれかの単数または複数を薬液・血液の流体流路９として機能させる。

【0014】

そして、前記基本構成の医療用処置具１Ａ・１Ｂは作用効果のさらなる向上を図る意図から下記の態様が必要に応じて採択される。即ち、前記第１発明のものは膨縮径部５Ａ・５Ｂの長さＬ１・Ｌ２を大小異サイズに設定し、異なる膨大径Ｄの膨径変体６に成す態様を採択し、前記第２発明のものは、膨縮径部５Ｃ・５Ｄを撚り方向を相反方向に成す中空撚線コイル体４の態様にする。

【0015】

さらに、前記第１・第２発明のいずれも「中空撚線コイル体４の内周を治療用薬液の液体流路に成す態様」「膨径変体６の膨径サイズのセットロック手段の付設」「膨径変体６の全部または１部を被覆する弾性質被覆の付設」「中空撚線コイル体４の素線７が、単線または撚り線の撚合線形態・異種金属の組合せ・異形断面線」「中空撚線コイル体４の外周を強制縮径加工した形状」「主線条部２・外側主線条部２Ａに弾性鞘管を設ける」以上の態様を採択する。

【発明の効果】

【0016】

前記構成の本発明の医療用処置具１Aは（図１（Ｃ）（Ｄ）参照）膨縮径部５Ａ・５Ｂ

をストレート状縮径状にして血管Ｔに挿入して、病変部Ｐを突き通して後方の膨縮径部５Ｂを病変部Ｐにセットし、しかるのち膨縮径部５Ａ・５Ｂを必要径の膨径変体６Ａ・６Ｂに成すと共に、必要に応じて薬液注吸入部１２から血塊溶解剤（ウロキナーゼ・ＴＰＡ）の薬液Ｍを中空撚線コイル体４の内周の液体流路９から注入して「押し・引き・回転」操作して病変部Ｐを治療する。

【0017】

以上の治療手法において、膨径変体６は病変部Ｐの個別状態に適する小なる径から図示点線の圧縮状態にすることによる図１（Ｅ）に示す花弁状拡大形態に至る多様な変体形状の設定が自在にして、スパイラル状のリブ線の集合から成るので外力に対する機械的形状安定性に優れ、かつ押し・引き・回転操作が可能であることから、スパイラル状のコイル素線７群から成るバスケット形態の膨径変体６Ｂの病変部Ｐへの喰い込みとコイル素線７個個の血塊引き掻き作用の複合によって極めて効率的にして美麗な血塊除去治療ができる。

【0018】

そして、膨径変体６の存在によって病変部Ｐの血流Ｆを確保すると共に、前方の膨径変体６Ａが後方の膨径変体６Ｂによって剥離した血栓等の体腔内異物の受け入れバスケット部として機能して、血流Ｆによる流動異物の捕捉作用を成し、流動異物による末梢血管の閉塞トラブルを防止作用する。

【0019】

さらに、注入された薬液Ｍは、その出口側の膨径変体６Ｂの入口側のスパイラル状の素線７群によってスパイラル流を生じるので、病変部への薬液Ｍの接触が効果的にして有効な血塊溶解ができる。以上の主たる特有の作用効果がある。

【0020】

一方、前記構成の医療用処置具１Ｂは（図２（Ｄ）参照）前記の医療用処置具１Ａと同様に血管Ｔの狭窄病変部Ｐに膨縮径部５Ｃ・５Ｄをセットし、しかるのち所要径の膨径変体６Ｃ・６Ｄに変体させて必要に応じて薬液注入して治療するにおいて、下記の特有の作用効果が存在する。即ち、膨径変体６Ｃ・６Ｄは同じく押圧外力に耐する形状安定性が良く、狭窄病変部Ｐの血塊・血餅の抵抗によって外側の膨縮径部５Ｃの円滑な膨径変体６Ｃが困難なケースや、円滑に拡径変体した膨経変体６Ｃを治療の為に押し・引き・回転操作したとき形状崩れを容易に生ずるケースでも、内側の膨径変体６Ｄが膨径変体６Ｃを内側から支承して機械的強度を補充して大なる変形・崩れを防止作用し、血流Ｆを確保しながら血塊・血餅の迅速良好な溶解除去作用を可能にする。

【0021】

そして、その内外２重の膨径変体６Ｃ・６Ｄを形成する中空撚線コイル体４が２重管形態となるので、その２重管のそれぞれの内周から薬液Ｍの放出が可能になり、治療作用のさらなる向上ができる。なお、以上の本発明の医療用処置具１Ａ・１Ｂは血液透析治療用・肺塞栓症治療用としても有用に使用できる（この用法と、それによる作用効果は実施例において詳述する）。

【0022】

さらに、本発明の医療用処置具１Ａ・１Ｂは、体腔内治療部の要部が中空撚線コイル体４の任意ポイントの外層被覆Ｃを必要長剥離するのみで成形加工ができるので、背景技術のものより成形加工性が特段に向上すると共に、単一の医療用処置具１Ａ・１Ｂによって多様な形態の病変部治療が可能にして、特段の低コスト性と日常管理性が確保され、当該治療性能の向上と治療コストの低減ができる特有の主たる作用効果が存在する。

【発明を実施するための最良の形態】

【0023】

以下、前記基本形態の好ましい実施例諸元と、前記基本形態に基づく好ましい実施例を説明する。

【実施例】

【0024】

まず、図１に示す基本形態の１実施例の諸元は下記のとおりである。即ち、前記基本形態の血栓・血餅病変部治療用の医療用処置具１Ａの好ましい実施例の諸元は「主線条部２が「１×７の撚合線のコイル素線７の８本」から成るコイル体にポリエチレン・ポリプロピレン・ポリアミド等の外層被覆Ｃを施した内直径＝０．２粍・外直径＝０．５５粍の中空撚線コイル体４」「操作用芯材３が１×７の中実撚合線にして外直径＝０．１２粍」「膨縮径部５Ａ・５Ｂが長さＬ=５．０粍、スパンＳ=６粍」である。以上の諸元の実施例のものは前記の主たる作用効果が円満に享受できる。

【0025】

続いて、図３～図５を参照して医療用処置具１Ａの他の実施例を説明する。即ち、図３に示すものは膨縮径部５Ａ・５Ｂをスパン配設したものにおいて、膨縮径部５Ａ・５Ｂの長さＬ１・Ｌ２がＬ１＜Ｌ２の大小不等に設定され、後方大径の膨径変体６Ｂと前方小径の膨径変体６Ａの組合せ構成に成っている。なお、この構成のものはＬ１・Ｌ２のそれぞれのコイル素線７の３６０°捻回スパンが、Ｌ１・Ｌ２のそれぞれの長さと同一の中空撚線コイル体４を用いて膨径変体作用をより容易になす構成としても良い。

【0026】

この大小不等構成のものは、血管内治療において血管末梢側に位置する膨径変体６Ａが小径となるので血管内配設の形態が好ましくなると共に（図３（Ｃ）参照）後方の膨径変体６Ｂを細長形態にして長い病変部へフィットセットすることができる。

【0027】

そして、図４のものは膨縮径部５が３個連設スパン配設形態に形成されている。この図４のものは膨径変体６の膨径を大にして偏平ブラシ形態にすることによって、血管内異物の除去ブラシとして機能させると共に、後述する「膨径変体６の外周に弾性質被膜を付設する」ことによって、ブラッシング除去した体腔内異物Ｄの挟み込み捕捉回収」が可能となる。なお、この態様のものは異物Ｄの挟み込み捕捉作用を良好にさせる為に（図４（Ｃ）参照）膨縮径部５の長さをコイル素線７の３６０°撚回スパンにして異物キャッチ力を強くする形態が好ましい。そして、この図４（Ｃ）の形態にすると膨径変体６Ａ～６Ｃの機械的強度が特段に向上するので、血管壁にこびりついている血塊・血餅の掻き取り回収ができると共に、捕獲した異物Ｄの体外への取り出し中の落下防止ができる。

【0028】

次に図５を参照して、透析治療用に応用した医療用処置具１Ａの１実施例を説明する。即ち、この透析治療用のものは「膨径変体６Ａ・６Ｂを血液の取入れ部」「操作用芯材３の中空部を血液の戻し部」として機能させるものにして、縮径状態の膨縮径部５Ａ・５Ｂを腕動脈の所要ポイントに挿入セットして必要サイズの膨径変体６Ａ・６Ｂに成し、しかるのち、主線条部２の内周の液体流路９を往路用吸引路として液体注吸入部１２から血液Ｆを吸引して血液透析部２３を通して透析処理し、その透析血液Ｆを体外に出している操作用芯材３の中空部の後端に注入して操作用芯材３の中空部を復路用の液体流路９として機能させ、その先端開口部から血管Ｔ内に復流させて透析治療する。

【0029】

なお、この透析治療用の医療用処置具１Ａの好ましい実施例の諸元は、「主線条部２が、線材７本の撚合線のコイル素線７から成るコイル体に同じく外層被覆Ｃを施した内直径＝３．２粍・外直径＝４．０粍の中空撚線コイル体４」「操作用芯材３が、ステンレス材・Ｎｉ－Ｔｉ材等の中空線材、または極細線の撚合線から成る中空線条体にして、外直径２．０粍・内直径＝１．６粍」「膨縮径部５Ａ・５Ｂが、それぞれの長さＬ=１４粍、スパンＳ=８粍」である。

【0030】

以上の透析治療用のものは（図５（Ｂ）参照）膨径変体６を血管内の要所にセットして液体注吸入部１２から被透析血液を往路用の「主線条部２の内周の液体流路９」を通して吸い取って血液透析部（図示しない）を通過させて透析し、その透析血液を復路用の「操作用芯材３の中空部の液体流路９」を通して操作用芯材３の先端開口部から血管Ｔ内に還流させて血液透析治療する。

【0031】
以上の用法において、膨径変体６は血管の任意ポイントに自在にセット可能にして、かつ機械的形状安定性に優れるので血管壁によって容易に押圧変形することなく効率的な血液吸い取りができると共に、中空撚線コイル体４は全長に亘って金属線の撚合線で形成された高引張強度体であることから、治療中に例えば血管のスパスム現象（けいれん）の異常が発生して当該部位が血管内拘束されたとき、その高引張強度によってその拘束から即時引き抜き可能にして治療トラブルの発生を有効に防止することができる。
【0032】
さらに、血液取入れ部の膨径変体６Ａ・６Ｂが少なるスパンＳを介して並列存在するので血液Ｆの取り入れ性が顕著になると共に、膨径変体６を通過する血流は、膨径状態のコイル素線７のスパイラル形状に沿って誘導流されるスパイラル流となるので、血液吸引部等で生ずる有害な血液乱流の発生と「それによる治療用処置具の当該部位の振動発生」を防止して、円滑効率的な血液抜きが可能にして極めて有効かつ高効率の血液透析治療ができる。
【0033】
次に、前記基本形態の体腔内異物除去治療用の医療用処置具１Ｂの好ましい実施例の諸元を説明する。即ち、外側主線条部２Ａが「０．０４粍直径線材の１×７撚りの直径＝０．１２粍の撚合線」のコイル素線から成るコイル体に同じく外層被覆Ｃを施した「外直径＝１．８粍、内直径＝１．２粍」、内側主線条部２Ｂが「直径＝０．０４粍のコイル素線７本から成るコイル体に同じく外層被覆Ｃを施した外直径＝１．０粍、内直径＝０．５粍」操作用芯材３が「０．１２粍直径の線材の１×７の撚合線にして、外直径＝０．３６粍の中実線」「膨縮径部５Ｃ・５Ｄの長さが２６粍と１４粍」である。以上の医療用処置具１Ｂは前記の作用効果が円満に享受できる。
【0034】
続いて図６を参照して医療用処置具１Ｂの他の実施例を説明する。即ち、この図６のものは外側主線条部２Ａと内側主線条部２Ｂのコイル素線７が相互に逆方向の撚り方向に設定されている。この図６のものは２層の膨径変体６Ｃ・６Ｄのコイル素線７の撚り方向が逆になるので、外・内主線条部２Ａ・２Ｂのそれぞれの内周の流体流路から放出した薬液Ｍの膨径変体６Ｃ・６Ｄのスパイラル素線によるスパイラル流が相互に逆方向となり、薬液Ｍの乱流・拡散作用を生じて血栓・血餅等を溶解させる薬液投与効果が一段と向上する。
【0035】
さらに、医療用処置具１Ｂは、前記の体腔内異物の除去治療用以外に下記治療用として有用に活用できる。即ち、前記の透析治療用の医療用処置具１Ａと類似諸元にすることによって透析治療用として活用可能にして、前記透析治療用処置具１Ａと同様な作用効果が享受できる。そして、医療用処置具１Ａ・１Ｂのいずれも下記説明の肺塞栓症治療用として有用に活用できる。
【0036】
即ち、飛行機エコノミークラス症候群と呼ばれる旅行者血栓症や、手術中・手術後の長時間寝たきり等によって下肢または骨盤内の静脈で形成された血栓が、肺に運ばれて肺動脈に詰まって心肺停止をもたらす症状において、静脈へ本発明の治療用処置具１Ａ・１Ｂの膨縮径部を挿入して血栓を捕獲回収することによって、血栓の肺への移動を防止する治療が可能にして、特に医療用処置具１Ｂの膨径変体６Ｃ・６Ｄの二重構造のものは、その捕獲回収作用が特段に的確にできる。
【0037】
次に図７～図１０を参照して医療用処置具１Ａ・１Ｂ共通の他の態様実施例を説明する。即ち、図７のものは、前記各実施例の膨径変体６の外周の全部または２／３等の１部に「ポリウレタン・ポリエステル・シリコンゴム等から成る５０～６０ミクロン膜厚にして無孔シートまたは微細孔シートの弾性質被覆２０」が覆着付設されている。この実施例のものは、被覆２０によって病変部Ｐから剥離した微細異物の捕捉回収が高能率にできると

共に血管壁を傷めるおそれはない。

【0038】

次に図８を参照して、前記基本形態の医療用処置具１Ａ・１Ｂに設ける膨径変体６の膨径度のセットロック手段の実施例を説明する。

【0039】

詳しくは、主線条部２の後端は治療時に体外に出す手元操作部１０に連結されており、この手元操作部１０は、後端外周を雄ねじ部１６に成して主線条部２の後端を連結した中空管体のボス部１５と、このボス部１５の雄ねじ部１６に螺合する雌ねじ部１７を前端内周に有して操作用芯材３を中空部に挿通する中空管体の進退操作部１４との２部材の組合せから成り、この進退操作部１４の回転操作によるボス部１５との相対進退によって操作用芯材３の進退操作（主線条部２に対する進退操作）ができる。

【0040】

即ち、主線条部２に内挿した操作用芯材３は後端が手元操作部１０の進退操作部１４に連結されており、この進退操作部１４の押し引き操作によって主線条部２に内挿した操作用芯材３を進退させ、膨縮径部５の長さ変化による膨径変体６と縮径変体ができる。そして、そのボス部１５の雄ねじ部１６にはロックナット１８が螺合されており、このロックナット１８を進退操作部１４の前端に接合させて締付けることによって、ボス部１５と進退操作部１４の相対位置をロックして膨径変体６の膨径度を最適に保持したり、解除できるセットロック手段が設定されている。

【0041】

以上のセットロック手段を有するのものは、操作用芯材３と主線条部２の相対位置のセットロックと解除が可能にして、膨径変体６のサイズを病変部の大小多様サイズの所要径にマッチングさせてセットロックして当該治療ができるので、治療性が向上すると共に長時間治療も可能になる特有の作用効果がある。なお、このセットロック手段は外側・内側主線条部２Ａ・２Ｂを、ボス部１５に連結することによって医療用処置具１Ｂにも適用する。

【0042】

次に図９に示すものは、前記基本形態のものにおいて膨縮径部５以外の主線条部２・２Ａの主要部が、弾性質薄肉の鞘管２１に遊挿されており、この鞘管２１が外周を構成して血管内挿入する形態に成っている。この鞘管２１つきのものは若干の径大をもたらすものの鞘管２１の内周も薬液Ｍの液体流路９として活用したり、鞘管２１の内側遊隙を剥離した小血塊片等の吸引回収路として活用できる。

【0043】

次に図１０に示す他の態様実施例を説明する。即ち、まず図１０（Ａ）に示すものは主線条部２の中空撚線コイル体４のコイル素線が、図示７Ａ・７Ｂのようにステンレス鋼線・Ｎｉ－Ｔｉ合金線・タングステン線等の異種金属の組合せに成っている。このＮｉ－Ｔｉ合金線使用のものは膨径変体６の形状記憶性・超弾性特性によって反復使用による曲りぐせ発生の防止と特段の形状安定性を図ることができる。

【0044】

次に図１０（Ｂ）のものは主線条部２の中空撚線コイル体４が円形加工後にスエージング加工または外周ダイス引き加工によって外周が強制縮径加工されている。この縮径加工形態のものは、縮径による細径化と加工による剛性向上効果があり、長手方向または径方向の縮径部位および縮径度を調整することによって長手方向の先柔後剛の好ましい形態設定が可能になる。

【0045】

そして、図１０（Ｃ）のものは主線条部２の中空撚線コイル体４のコイル素線７Ｃが断面矩形状の異形形状に設定されている。この平板素線を用いると主線条部２の外径細径化または「液体流路９として活用する内径の増径化による流路拡大」が可能になるメリット作用がある。

【0046】

一方、図１０（Ｄ）のものは膨縮径部５の両端の主線条部２の外周に、膨縮径部５の反復変体の応力を受ける外周を押えロックする「コイル体・リング体」等からなる変形防止用の結束部２２が施してある。この図１０（Ｄ）のものは、その部位の外側チューブ体２の変体反復による「変形・ほぐれ」を防止するので膨縮径部５の変体形状が安定して変体反復性が向上する。そして、結束部２２を放射線不透過材にすると体腔内の膨径変体６の視認性が確保できる。

【0047】

なお、主線条部２の中空撚線コイル体４のコイル素線７は、治療中の視認性を確保する金・白金・タングステン等の放射線不透過線にしたり、異種材質の組合せにしたり、単線にすることがあり、さらに手元操作部１０は（図１参照）、指先によってスライド移動させる指先操作片１１の形態等にすることがあり、前記セットロック手段は、別物品クランプによるクランプロック形態・クランプピンのセットロックでも良い。

【0048】

さらに、中空撚線コイル体４の外層被覆Ｃは、膨径時の操作用芯材３の引張りによる圧縮反力を円滑に享受するため、比較的硬質材料が好ましく、熱可塑性樹脂のみならず「フェノール樹脂・エポキシ樹脂等の熱硬化性樹脂」でも良く、またステンレス鋼管・アルミニウム管等によって形成しても良い。そして操作用芯材３は可撓性中空線・可撓性中実線のいずれの形態であっても良い。そして（図５参照）前記の血液透析治療用等に用いるものにおいて、操作用芯材３内を流体流路として用いる場合は、図示点線のように操作用芯材３を伸長して、その端部に「進退操作部１４に固定した接続具２４」を設け、血液透析部２３から引き出したホース２５に接続する構造にすることがある。

【図面の簡単な説明】

【0049】

【図1】第１発明の医療用処置具の基本形態を示し、（Ａ）はその正面図、（Ｂ）はその膨径変体の説明図、（Ｃ）は膨縮径部の構造説明図、（Ｄ）（Ｅ）はその作用説明図

【図2】第２発明の医療用処置具の基本形態を示し、（Ａ）はその正面図、（Ｂ）はその膨径変体の説明図、（Ｃ）は膨縮径部の構造説明図、（Ｄ）はその作用説明図

【図3】第１発明の医療用処置具の実施例を示し、（Ａ）はその要部正面図、（Ｂ）（Ｃ）はその作用説明図

【図4】第１発明の医療用処置具の他の実施例を示し、（Ａ）はその要部正面図、（Ｂ）（Ｃ）はその作用説明図

【図5】第１発明の医療用処置具の他の実施例を示し、（Ａ）はその全体正面図、（Ｂ）はその作用説明図

【図6】第２発明の医療用処置具の他の実施例の要部説明図

【図7】本発明の医療用処置具の他の実施例の要部説明図

【図8】本発明の医療用処置具のセットロック手段の１実施例の説明図

【図9】本発明の医療用処置具の他の実施例の要部説明図

【図10】本発明の医療用処置具の他の実施例を示し、（Ａ）～（Ｄ）ともその要部説明図

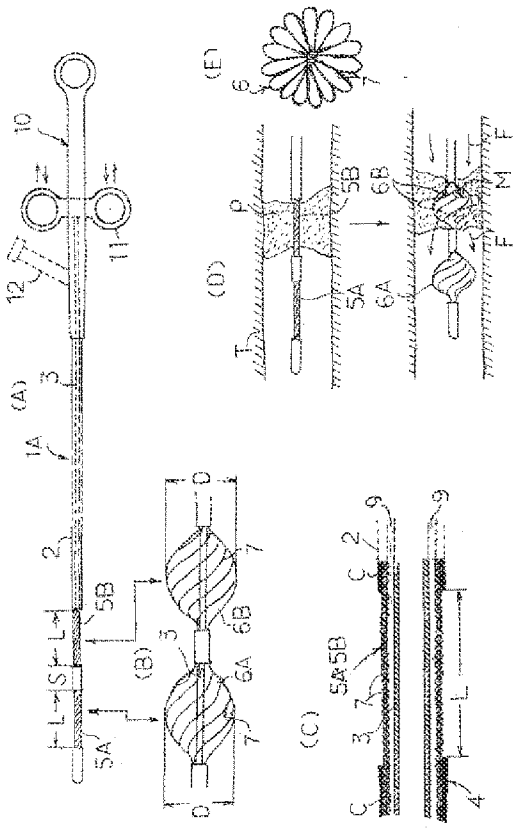
【符号の説明】

【0050】

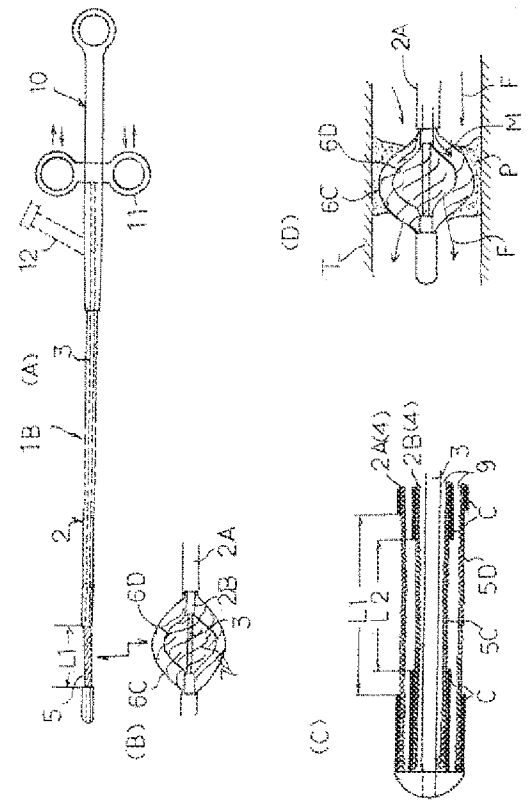
１Ａ　第１発明の医療用処置具
１Ｂ　第２発明の医療用処置具
２　主線条部
２Ａ　外側主線条部
２Ｂ　内側主線条部
３　操作用芯材
４　中空撚線コイル体
５　膨縮径部
６　膨径変体
７　コイル素線

９　液体流路
１０　手元操作部
１４　進退操作部
１５　ボス部
１８　ロックナット
２０　弾性質被覆
２１　鞘管
２２　結束部
Ｃ　外層被覆
Ｄ　体腔内異物
Ｆ　血流
Ｍ　薬液
Ｐ　病変部
Ｔ　血管

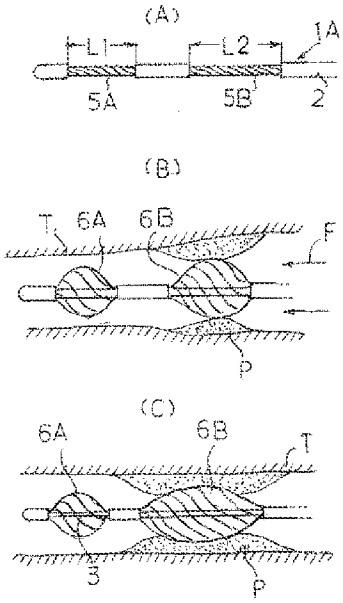
【図1】



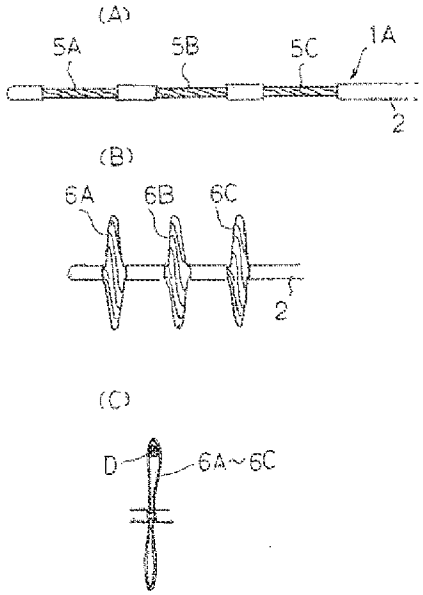
【図2】



【図3】


(A)
L1
L2
1A
5A
5B
2
(B)
T
6A
6B
F
P
(C)
6A
6B
T
3
P

【図4】


(A)
5A
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5C
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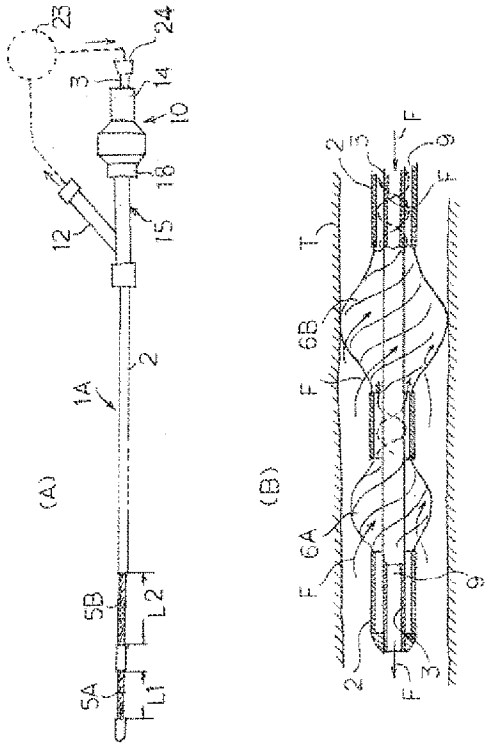
(B)
6A
6B
6C
2
(C)
D
6A～6C

【図5】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5B
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5A
L1
(B)
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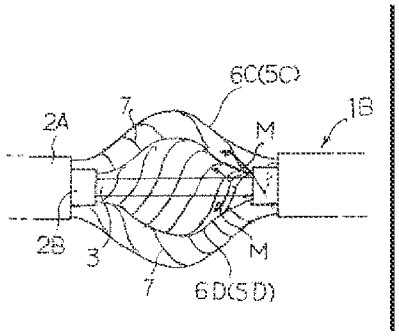
2
13
9
T
6B
6A
3

【図6】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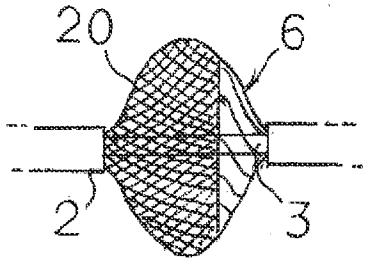
2B
3
6D(5D)

【図7】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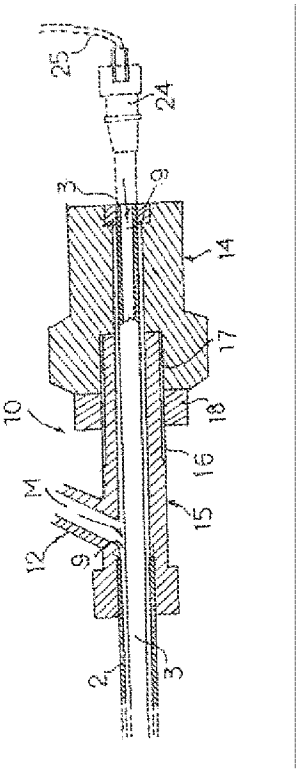
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M
15
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3

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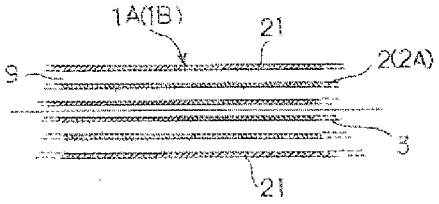
1A(1B)
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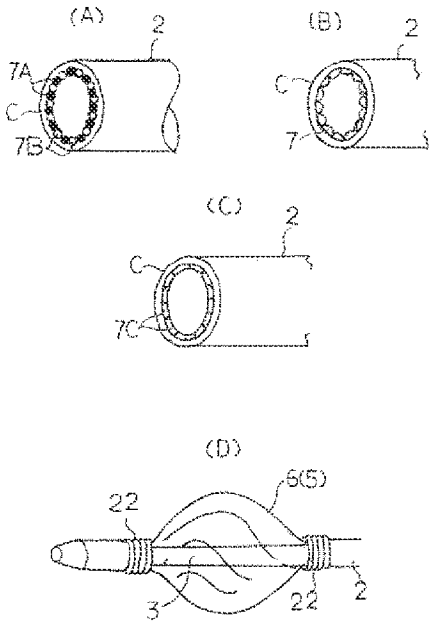
9
3
21

【図10】


(A)
2
7A
C
7B
(B)
2
C
7
(C)
2
C
7C
(D)
5(5)
22
3
22
2

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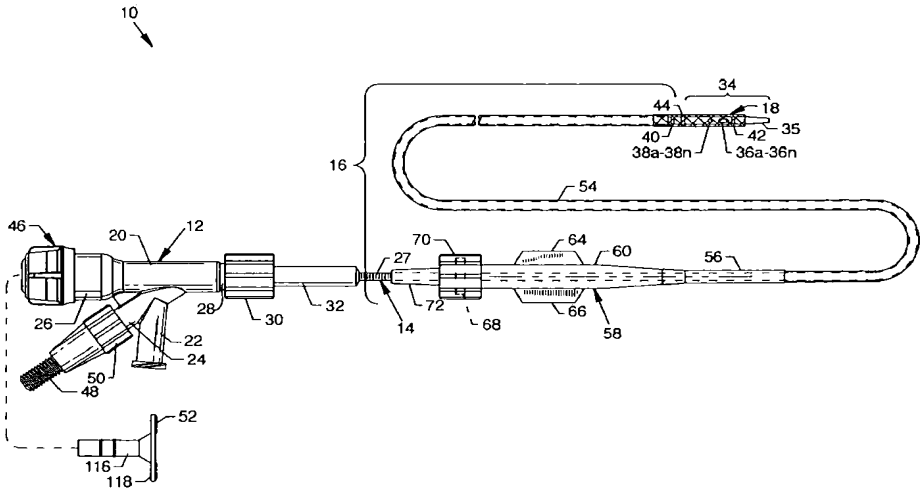
(54) Title: CROSS STEAM THROMBECTOMY CATHETER WITH FLEXIBLE AND EXPANDABLE CAGE



(57) Abstract: A cross stream thrombectomy catheter with a flexible and expandable cage preferably formed of nitinol for removal of hardened and aged thrombotic material stubbornly attached to the interior of a blood vessel. The cage, which can be mesh or of straight or spiral filament design, is located close to inflow and outflow orifices at the distal portion of a catheter tube and is deployed and extended at a thrombus site for intimate contact therewith and for action of a positionable assembly and subsequent rotation and lineal actuation to abrade, grate, scrape, or otherwise loosen and dislodge difficult to remove thrombus which can interact with cross stream flows to exhaust free and loosened thrombotic particulate through the catheter tube. An alternative embodiment discloses a mechanism involving a threaded tube in rotatable engagement with an internally threaded sleeve to incrementally control the deployment and expansion of the flexible and expandable cages.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

CROSS STREAM THROMBECTOMY CATHETER WITH FLEXIBLE AND EXPANDABLE CAGE

CROSS REFERENCES TO RELATED APPLICATIONS

[0001] None.

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

[0002] The present invention is for a thrombectomy catheter, and more particularly, relates to a cross stream thrombectomy catheter with a flexible and expandable cage which is deployable and expandable about the distal region of the cross stream thrombectomy catheter for abrasive contact with and for abrasive removal of hardened thrombus or other foreign material in addition to and in cooperation with ablative cross stream flow. This device is used in the removal of tissues or highly organized, old thrombus in the most difficult of cases where simple water jet thrombectomy procedures may be ineffective.

DESCRIPTION OF THE PRIOR ART

[0003] Prior art thrombectomy catheters incorporating water jet technology encounter difficulty in dealing with old and difficult thrombus. Thrombus consistency can vary tremendously depending upon factors such as the age of the clot, conditions under which it was formed, the hematology of the patient and other factors. This is especially true in the case of deep vein thrombosis, where the thrombus can vary from fresh soft clot to older more organized clot. This more organized thrombus is the most difficult to remove. Furthermore, the large veins in the legs present the need to remove large volumes of clot that are not only larger in diameter but can extend for longer distances. In the case of

lysins, the distances the chemical must diffuse is longer. This results in longer treatment times and hence more complications, such as hemorrhagic stroke. In the case of mechanical agitators, such as the Bacchus Trellis device, the device is limited in its operating diameter. If the device is designed to operate in a large diameter, the forces to operate the device would increase and the mechanical integrity of the agitator would need to increase (i.e., diameter of the wire) and grow larger, both of which make the device more difficult to deliver and operate. The use of the AngioJet®, a rheolytic cross stream thrombectomy catheter, includes an inherent ability to remove thrombus of larger diameter than the catheter's diameter. However, the disruptive strength of the device falls off with the radial distance from the catheter. Hence, at some radial distance the clot is stronger than the disruptive force generated by the AngioJet® cross stream flow patterns. In the case of organized thrombus, this radial distance from the catheter is smaller than for softer thrombus. The present invention adds another dimension to water jet thrombectomy by dealing with very difficult thrombus. Water jet thrombectomy procedures in general can be limited in ability, but adding mechanical disruption of difficult to remove thrombus to water jet ablation is actually taking thrombectomy procedures to another level. By combining mechanical agitation; i.e., abrasive intimate contact of thrombus by a flexible and expandable cage component, with a rheolytic thrombectomy catheter (AngioJet®), larger diameters of thrombus can be cleared than can be cleared by mechanical agitators or rheolytic cross stream thrombectomy catheters individually. This combination also extends to combining the use of the AngioJet® with lysins. By disrupting

thrombus with flow, the lysins can be mixed better with the thrombus, and the lysins soften the clot such that AngioJet® is more effective. Furthermore, such a technique enables shorter treatment times compared to the use of either AngioJet® or lysins alone. Consequently, the combination of mechanical agitators with AngioJet® and even with lysins represents synergistic efficiencies in the removal of thrombus.

SUMMARY OF THE INVENTION

[0004] The general purpose of the present invention is to provide a cross stream thrombectomy catheter with a flexible and expandable cage formed, preferably, of nitinol, and to provide a method of use. This disclosure describes the invention of a cross stream thrombectomy catheter combined with flexible and expandable nitinol cages which are expandable and deployable at the distal region by action of a positionable assembly. At times, thrombus in vessels may be so old and so organized that water jet thrombectomy procedures become ineffective at removing this material. In terms of mechanical advantage, a solid material, such as metal, can apply a force that is magnitudes higher than a fluid. The use of a rigid member can apply much more force to a substance than a fluid can, as fluids tend to take the path of least resistance and may flow around debris rather than remove it. However, a rigid member, if designed correctly, will be more effective in "ploughing" through a material and disrupting the material and will be able to disrupt even the most difficult of materials found within blocked vessels. Therefore, flexible and expandable nitinol cages of suitable porous qualities and configurations have been combined with a water jet thrombectomy catheter to optimize ability to remove very difficult tissues within vessels. When combined therewith, the flexible and expandable cages are used in a fashion similarly used as a grater to aggressively break up the difficult to remove thrombus material, whereas the water jet thrombectomy catheter is used to wash and flush the blood vessel and remove both loosened soft and difficult to remove thrombus debris.

[0005] The first embodiment of the instant invention includes a catheter tube having distally located inflow and outflow orifices with a distally located flexible and expandable nitinol mesh cage located over and about the distal end of the catheter tube, and more specifically, over and about the inflow and outflow orifices. A manifold connects to the proximal end of the catheter tube, the manifold providing for connection to pressurizing and evacuation equipment known in the art. A positionable assembly having a sheath and a connected manual actuator is located coaxially about the catheter tube. The distal end of the sheath is connected to a free-floating proximal end of the flexible and expandable cage of nitinol mesh, and the proximal end of the sheath is connected to the manual actuator. The distal end of the flexible and expandable mesh cage is fixedly secured to the catheter tube at a fixed position at or near the distal end of the catheter tube. The manual actuator is slideably positioned along the catheter tube to correspondingly urge movement of the sheath to displace the proximal end of the flexible and expandable mesh cage with respect to the distal end of the flexible and expandable mesh cage to deploy and expand the flexible and expandable mesh cage or to collapse and retract the flexible and expandable mesh cage. In use, the catheter tube and portion of the positionable assembly are advanced to and through a thrombus site, wherein the flexible and expandable mesh cage is expanded and deployed and actuated in a to and fro action, a rotary action, or a combination thereof, where such actions are incorporated by intimate contact to abrade, grate, scrape, or otherwise loosen and dislodge difficult to remove thrombus. Loosened thrombus can be acted upon by cross stream jets for entrainment for

maceration and/or for evacuation through the catheter tube. When the flexible and expandable cage is collapsed and retracted, the catheter tube can be maneuvered from the former thrombus site and from the vasculature. A first alternative embodiment includes the majority of structure of the device just described, but substitutes a mechanism in which a threaded tube rotatingly engages an internally threaded sleeve to rotatably and incrementally operate the sheath and flexible and expandable mesh cage to deploy and expand the flexible and expandable mesh cage to a known and indicated specific size parameter and to maintain such specific size at a desired setting as required.

[0006] According to one or more embodiments of the present invention, there is provided a cross stream thrombectomy catheter with a flexible and expandable mesh cage including a manifold, an introducer, a catheter tube connected to the manifold, inflow and outflow orifices at the distal end of the catheter tube, a high pressure tube with a fluid jet emanator, a flexible and expandable mesh cage preferably of nitinol material having a distal and stationary end attached to the distal region of the catheter tube, a positionable assembly including a manual actuator and attached sheath which is positionable, each aligned over and about the greater portion of the catheter tube where the distal end of the sheath attaches to the proximal and positionable end of the flexible and expandable mesh cage and the proximal end of the sheath attaches to a positionable hand actuator where the positionable assembly is coaxial to and operated along and about a central region of the catheter tube. Alternatively and in other embodiments, a flexible and expandable cage having straight or spiral filament

construction, preferably of preshaped and preformed nitinol material, includes a proximal end fixed to the catheter tube rather than to the sheath and a distal end freely and slideably aligned over and about the catheter tube. In these embodiments, the distal portion of the sheath slides over the flexible and expandable cage having straight or spiral filament construction and compresses the preshaped and preformed nitinol material of the flexible and expandable cage having straight or spiral filament construction for insertion into the vasculature to await later urging of the sheath proximally to reveal and allow expansion of the flexible and expandable cage having straight or spiral filament construction. The flexible and expandable cages having straight or spiral filament construction can be advanced to and through a thrombus site, wherein the flexible and expandable cages having straight or spiral filament construction are expanded and deployed and actuated in a to and fro action, a rotary action, or a combination thereof in a manner as previously described for the first embodiment, where such actions are incorporated by intimate contact to abrade, grate, scrape, or otherwise loosen and dislodge difficult to remove thrombus. An additional benefit of the use of the flexible and expandable cages having straight or spiral filament construction is that some loosened and dislodged thrombus particulate can frictionally engage the converging filaments at each end of the cage or be captured by surrounding collapsed cage structure and be removed from the thrombus site when the catheter and cage are withdrawn from the thrombus site.

[0007] Such alternative embodiments include other configurations of flexible and expandable cages, preferably of nitinol material, wherein a cut tube of

nitinol is fashioned having opposed uncut distal and proximal tube ends and either straight filament or spiral filament central sections between the opposed uncut distal and proximal tube ends.

5

[0008] One significant aspect and feature of the present invention is a cross stream thrombectomy catheter that is combined with a flexible and expandable mesh cage or a straight or spiral filament flexible and expandable cage for the purpose of removing highly organized, old thrombus.

[0009] Another significant aspect and feature of the present invention is a cross stream thrombectomy catheter combined with a flexible and expandable mesh cage or a straight or spiral filament flexible and expandable cage, each such cage serving as a mechanical agitator and/or cutter device.

[0010] Still another significant aspect and feature of the present invention is a cross stream thrombectomy catheter combined with a flexible and expandable mesh cage that is deployed by the action of a sheath which is placed over the catheter tube and moved along the catheter tube by manual action.

[0011] A further significant aspect and feature of the present invention is a cross stream thrombectomy catheter which can incorporate rapid exchange technology in combination with a flexible and expandable mesh cage or a straight or spiral filament flexible and expandable cage.

[0012] Yet another significant aspect and feature of the present invention is a cross stream thrombectomy catheter combined with a flexible and expandable cage that is made of a nitinol mesh or other configuration of nitinol and that has its distal end fixed to a catheter tube and its proximal end attached to a sheath so as to move freely with the sheath and along the catheter tube between deployed and collapsed positions.

[0013] A further significant aspect and feature of the present invention is a cross stream thrombectomy catheter combined with a flexible and expandable preset memory shape nitinol cage that is caused to deploy via the action of a sheath which exposes and reveals the preset memory shape nitinol cage. The preset memory shape nitinol cage is attached only at its proximal end to the catheter tube, the distal end being free to slide along the catheter tube.

[0014] Still another significant aspect and feature of the present invention is a cross stream thrombectomy catheter combined with a flexible and expandable cage that is of a straight nitinol filament design, or of a spiral nitinol filament design, or of some other nitinol configuration or design and that has its proximal end fixed to a catheter tube and its distal end free to move freely along the catheter tube by action of a sheath which revealingly deploys or collapses and captures the flexible and expandable straight nitinol filament design cage, or spiral nitinol filament design cage, or other nitinol configuration or design cage.

[0015] Another significant aspect and feature of the present invention is the use of flexible and expandable cages of various designs which, with respect to thrombus, can be actuated in to and fro motion, rotary motion, or motion combinations.

[0016] Yet another significant aspect and feature of the present invention is the use of flexible and expandable cages of nitinol mesh or straight or spiral filaments of nitinol which can be heat set to maintain a predetermined memory shape.

[0017] A still further significant aspect and feature of the present invention is a cross stream

thrombectomy catheter combined with a flexible and expandable mesh cage, a straight filament flexible and expandable cage, or a spiral filament flexible and expandable cage, which can be over the outflow and inflow orifices, distal to the outflow and inflow orifices, or somewhere proximal to the outflow and inflow orifices.

[0018] A further significant aspect and feature of the present invention is a cross stream thrombectomy catheter which can use saddle jet emanator or other jet emanator technology combined with a flexible and expandable mesh cage, a straight filament flexible and expandable cage, or a spiral filament flexible and expandable cage.

[0019] A further significant aspect and feature of the present invention is a cross stream thrombectomy catheter combined with a flexible and expandable mesh cage or with a straight or spiral filament flexible and expandable cage that is deployed from a location about the catheter tube.

[0020] Another significant aspect and feature of the present invention is the capture of loosened thrombus particles by converging straight or spiral filaments of nitinol in flexible and expandable cages and/or by the collapsed cage structure.

[0021] Still another significant aspect and feature of the present invention is a cross stream thrombectomy catheter combined with a flexible and expandable mesh cage or with a straight or spiral filament flexible and expandable cage that is deployed by the action of a sheath which is located over and about the catheter tube and moved along the catheter tube by a screw-type arrangement having size indication to gain

precise expansion control instead of being moved in a less precise manual fashion.

[0022] Still another significant aspect and feature of the present invention is a cross stream thrombectomy catheter with a flexible and expandable mesh cage, or a straight or spiral filament flexible and expandable cage, which can be utilized solely as a cross stream thrombectomy catheter without exercising the abrading functions of the flexible and expandable mesh cage, or the straight or spiral filament flexible and expandable cage.

[0023] A further significant aspect and feature of the present invention is a cross stream thrombectomy catheter that uses guidewire position directional flow technology, such as is disclosed in copending patent application number 11/009,720 entitled "Enhanced Cross Stream Mechanical Thrombectomy Catheter with Backloading Manifold" filed on December 10, 2004, combined with a flexible and expandable cage.

[0024] Having thus briefly described embodiments of the present invention and having mentioned some significant aspects and features of the present invention, it is the principal object of the present invention to provide a cross stream thrombectomy catheter with a flexible and expandable cage.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] Other objects of the present invention and many of the attendant advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, in which like reference numerals designate like parts throughout the figures thereof and wherein:

[0026] **FIG. 1** is a plan view of the visible components of a cross stream thrombectomy catheter with a flexible and expandable cage constituting one embodiment of the present invention;

[0027] **FIG. 2** shows the elements of **FIG. 1** where major components and assemblies have been separated to facilitate description;

[0028] **FIG. 3** is an exploded isometric view of the cross stream thrombectomy catheter with flexible and expandable cage;

[0029] **FIG. 4** illustrates the alignment of **FIGS. 5a, 5b and 5c**;

[0030] **FIGS. 5a, 5b and 5c** together illustrate a side view in partial cross section of the components of the aforementioned cross stream thrombectomy catheter with flexible and expandable cage showing only part of the full length of the catheter tube and, in **FIG. 5a**, depicting a portion of a guidewire;

[0031] **FIG. 6** is a view in cross section showing the tip and the flexible and expandable mesh cage and other important and related components of the aforementioned cross stream thrombectomy catheter with flexible and expandable cage engaged in the dislodging and extraction of difficult to remove thrombus or other types

of objectionable material adhering, clinging or otherwise affixed to the interior wall of a blood vessel;

[0032] **FIG. 7**, a first alternative embodiment, is a plan view of the visible components of a cross stream thrombectomy catheter with flexible and expandable cage;

[0033] **FIG. 8** shows the elements of **FIG. 7** in a partially cutaway view where major components and assemblies have been separated to facilitate description;

[0034] **FIG. 9** is an exploded isometric view of the first alternative embodiment cross stream thrombectomy catheter with flexible and expandable cage;

[0035] **FIG. 10** is a cross section view of the rotary actuation system of the first alternative embodiment cross stream thrombectomy catheter with expandable cage along line 10-10 of **FIG. 7**;

[0036] **FIG. 11**, a second alternative embodiment, is a side view of an expanded straight filament flexible and expandable cage;

[0037] **FIG. 12** is a side view of the straight filament flexible and expandable cage in a configuration such as it would appear when constrained by a sheath;

[0038] **FIG. 13** is a distal end view of the expanded straight filament flexible and expandable cage;

[0039] **FIG. 14**, a third alternative embodiment, is a side view of an expanded spiral filament flexible and expandable cage;

[0040] **FIG. 15** is a side view of the spiral filament flexible and expandable cage in a configuration such as it would appear when constrained by a sheath;

[0041] **FIG. 16** is a distal end view of the expanded spiral filament flexible and expandable cage;

[0042] **FIG. 17** is a view in partial cross section of the straight filament flexible and expandable cage constrained by the sheath; and,

[0043] **FIG. 18** is a view in partial cross section of the straight filament flexible and expandable cage and of the components shown in **FIG. 17** where the sheath has been positioned proximally, whereby intimate and constraining contact between the sheath and the straight filaments no longer occurs.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0044] **FIG. 1** is a plan view of the visible components of a cross stream thrombectomy catheter with flexible and expandable cage 10 constituting an embodiment of the present invention, and **FIG. 2** shows the elements of **FIG. 1** where major components and assemblies have been separated to facilitate description. Such major components and assemblies include a one-piece manifold 12 having multiple structures extending therefrom or attached thereto, a catheter tube 14, a positionable assembly 16, and a tubular-shaped flexible and expandable mesh cage 18 including a proximal end 18a which is connected to the distal end of a sheath 54 at the distal end of the positionable assembly 16, and including a distal end 18b which is attached to the distal region of the catheter tube 14. A central section 18c of the flexible and expandable mesh cage 18 is located between the proximal end 18a and the distal end 18b of the flexible and expandable mesh cage 18.

[0045] The visible portion of the one-piece manifold 12 includes a central tubular body 20, a high pressure connection branch 24 extending angularly from the central tubular body 20, an exhaust branch 22 extending angularly from the high pressure connection branch 24, a cavity body 26 extending proximally from the central tubular body 20, and a threaded connection port 28 partially shown extending distally from the central tubular body 20. The proximal region of the catheter tube 14 includes incremental markings 27 and secures to the manifold 12 by the use of a connector 30 accommodated by the threaded connection port 28. The proximal end of the catheter tube 14 extends through and seals against the interior of a strain relief 32 and through the

connector 30 to communicate with the manifold 12. The catheter tube 14, including a lumen 15 (**FIG. 3**), extends distally to a tip 34 having a tapered portion 35, the catheter tube 14 and tip 34 including the tapered portion 35 being flexible in design. The tip 34 of the catheter tube 14 includes a plurality of inflow orifices 36a-36n and a plurality of outflow orifices 38a-38n, and also includes radiopaque marker bands 40 and 42, the function of which are disclosed and described in detail in previous patent applications and patents owned by the assignee. A stop 44, which can be annular and which is best illustrated in **FIG. 5c**, is also secured around and about the tip 34 at the distal portion of the catheter tube 14. Also shown is a hemostatic nut 46 aligned to and snappingly engaged with the proximal region of the cavity body 26 and a threaded high pressure connection port 48 secured to the high pressure connection branch 24 by a Luer connector 50. An introducer 52 is also shown.

[0046] **FIG. 1** shows the positionable assembly 16 and the flexible and expandable mesh cage 18 engaged over and about various portions of the catheter tube 14, and **FIG. 2** shows the positionable assembly 16 and flexible and expandable mesh cage 18 removed from, distanced from, and shown separately from the catheter tube 14 for the purpose of clarity. The flexible sheath 54 is appropriately sized to be slidingly engaged over the catheter tube 14. The sheath 54 extends along the length of the catheter tube 14 where the distal end of the sheath 54 aligns to a variable location at or near the tip 34 which is short of the radiopaque marker band 40, preferably as shown in **FIG. 5c**. The proximal end of the sheath 54 aligns within the distal end of a strain relief tube 56 and secures suitably

therein, as shown in **FIG. 5b**. The flared proximal end of the strain relief tube 56 aligns with and about the tapered distal end of a manual actuator 58 shown in detail in **FIG. 5b** such manual actuator 58 having a tubular body 60, a passage 62, handles 64 and 66, and a proximally located threaded end 68. A connector 70 having a tubular extension 72 extending continuously therefrom engages the threaded end 68 of the manual actuator 58.

[0047] **FIG. 3** is an exploded isometric view of the cross stream thrombectomy catheter with flexible and expandable cage 10, and **FIGS. 5a, 5b and 5c**, aligned as shown in **FIG. 4**, together illustrate a side view in partial cross section of the components of the cross stream thrombectomy catheter with flexible and expandable cage 10 showing only part of the full length of the catheter tube 14 and depicting a portion of a guidewire 74 (**FIG. 5a**) such as is incorporated in the use thereof. **FIG. 5c** is illustrated in a scale slightly larger than that of **FIGS. 5a and 5b** for the purpose of clarity. The catheter tube 14, which also serves and functions as an exhaust tube, and a high pressure tube 76 are foreshortened and shown as partial lengths for the purpose of clarity.

[0048] With reference to **FIG. 3** and **FIGS. 5a, 5b and 5c** together, the instant embodiment is further described. The manifold 12 includes connected and communicating passageways and cavities including a high pressure connection branch passageway 78 within the high pressure connection branch 24, an exhaust branch passageway 80 within the exhaust branch 22, and a tapered central passageway 82 extending from and through the threaded connection port 28 and through the central tubular body 20, through an orifice 94, through a cavity extension 85, to and communicating with a cavity 84, which preferably is cylindrical, located central to the cavity body 26. Threads 86 are located about the exterior of the cavity body 26 at the proximal region of the manifold 12.

[0049] Beneficial to the instant embodiment is the use of a self-sealing hemostatic valve 88 the shape of and the functions of which are described later in detail. The self-sealing hemostatic valve 88 is aligned in and housed

in the cavity 84 at the proximal region of the manifold 12 along with flexible washers 89 and 91 which align to opposing sides of the self-sealing hemostatic valve 88. The cavity 84 is tubular including a cavity wall 90 and a planar surface 92 which is annular and circular and which intersects the cavity wall 90. The orifice 94 is common to the cavity extension 85 and the tapered central passageway 82. The hemostatic nut 46 includes a centrally located cylindrical boss 96, a beveled entryway 97 leading to a passageway 98 extending through and in part defining the cylindrical boss 96, and internal threads 100. The proximal end of the manifold 12 utilizes the threads 86 for attachment of the hemostatic nut 46 to the manifold 12 where the internal threads 100 of the hemostatic nut 46 rotatingly engage the threads 86 of the manifold 12 to cause the cylindrical boss 96 to bear directly against the flexible washer 89 to cause the self-sealing hemostatic valve 88 to expandingly seal against the guidewire 74 where such sealing is effective during static or actuated states of the manual actuator 58. The self-sealing hemostatic valve 88 and flexible washers 89 and 91 are captured in the distal region of the cavity 84 by engagement of the hemostatic nut 46 to the cavity body 20 of the manifold 12. Use of the flexible washers 89 and 91 is incorporated to minimize distortion of the hemostatic seal 88 when the cylindrical boss 96 is tightened to compress the hemostatic valve 88. Also included in the hemostatic nut 46 is an annular lip 102 which can be utilized for snap engagement of an introducer 52 or other particular styles or types of introducers, as required.

[0050] Also shown is a ferrule 104 which aligns within a passageway 106 of the threaded high pressure connection port 48, the combination of which aligns

partially within the interior passageway 108 of the Luer connector 50. One end of the high pressure tube 76 is utilized for delivery of high pressure ablation liquids and suitably secures in a center passage of the ferrule 104 to communicate with the passageway 106 of the threaded high pressure connection port 48. The high pressure tube 76 also extends through the high pressure connection branch passageway 78, through part of the tapered central passageway 82, through coaxially aligned components including lumen 15 in the catheter tube 14, the connector 30 and the strain relief 32, thence through the balance of the length of the lumen 15 in the catheter tube 14, through support ring 110 and radiopaque marker band 40, through the stop 44, and to the grooved support ring 112 at the tip 34 where termination is provided in the form of a fluid jet emanator 114 described in other applications and patents owned by the assignee. The high pressure tube 76 can also be attached to the support ring 110, such as by welding or other suitable means, and can function as support for the catheter tube 14 in the region beneath the radiopaque marker 40. Support of the catheter tube 14 in the region beneath the radiopaque marker 42 can be provided by the grooved support ring 112 which is connected to and which extends from the fluid jet emanator 114. The introducer 52 having a centrally located hollow shaft 116 and an actuating handle 118 is also shown.

[0051] In **FIGS. 2 and 3**, the flexible and expandable mesh cage 18, preferably of nitinol, is shown separated from the general structure of the invention involving the distal end of the positionable assembly 16 at the distal end of the sheath 54 and involving the distal portion of the catheter tube 14 just distal of the

radiopaque marker band 42. Shown particularly in **FIG. 5c** is the attachment of the flexible and expandable mesh cage 18. Adhesive 120 is utilized to attach the proximal end 18a of the flexible and expandable mesh cage 18 to the distal end of the sheath 54, and adhesive 122 is utilized to attach the distal end 18b of the flexible and expandable mesh cage 18 to the distal end of the catheter tube 14 adjacent to a tapered portion 35. Also shown is the radiopaque marker 40 secured over and about the catheter tube 14 and the underlying support ring 110 as well as the radiopaque marker 42 secured over and about the catheter tube 14 and underlying grooved support ring 112. The annular stop 44 is also shown appropriately secured over and about the catheter tube 14 to limit distal movement of the sheath 54 along and about the catheter tube 14. The fluid jet emanator 114 is shown secured by association with the grooved support ring 112 within the catheter tube 14 distal to the inflow orifices 36a-36n.

MODE OF OPERATION

[0052] **FIG. 6** is a view in cross section showing the tip 34 and the flexible and expandable mesh cage 18 and other important and related components of the cross stream thrombectomy catheter with flexible and expandable cage 10 engaged in the dislodging and extraction of difficult to remove thrombus 124 or other types of objectionable material adhering, clinging or otherwise affixed to the interior wall of a blood vessel 126. A high pressure source as commonly utilized in the art is utilized to supply high pressure delivery of saline or other suitable medium to the threaded high pressure connection port 48 for delivery by the high pressure tube 76 to the fluid jet emanator 114; and a vacuum source as known in the art may be utilized to aid in evacuation of the catheter tube 14 through connection to the exhaust branch 22. With reference to **FIG. 6** and implied reference to previously described figures, the mode of operation is further described.

[0053] In practice, the cross stream thrombectomy catheter with flexible and expandable cage 10 is engaged over and about the previously shown guidewire 74, which would have been previously inserted into the vasculature of a patient until the tip 34 and the flexible and expandable mesh cage 18 and other important and closely located related components negotiate passage through but remain within the general buildup area of thrombus 124. Such loading and engagement occurs where the proximal end of the guidewire 74 enters the tip 34 and lumen 15 of the catheter tube 14 and where the proximal guidewire tip is negotiated by the fluid jet emanator 114, the catheter tube 14, the tapered central passageway 82, and the orifice 94 which centers the guidewire 74 to the

self-sealing hemostatic valve 88 and passage therethrough for sealing about the guidewire 74. Loading continues through the passageway 98 and beveled entryway 97 of the hemostatic nut 46. The guidewire 74 may or may not be removed depending upon future utilization requirements and is not shown in **FIG. 6**.

[0054] Upon suitable positioning within the vasculature, the cross stream thrombectomy catheter with flexible and expandable cage 10 is then utilized to engage and dislodge, loosen or otherwise displace difficult to remove thrombus 124 or other types of objectionable material adhering, clinging or otherwise affixed to the interior wall of a blood vessel 126 and break it into particulate suitable for removal through the flexible and expandable mesh cage 18 and through the lumen 15 of the catheter tube 14. To operate the device, the operator manually grasps both the manifold 12 and the manual actuator 58 and positions one or the other or both components to cause the positionable assembly 16 to be slidingly positioned in a distal direction with respect to the manifold 12 and the attached catheter tube 14. During such positioning, the translatory distal end of sheath 54 upon which the proximal end 18a of the flexible and expandable mesh cage 18 is secured is urged closer to the distal end 18b of the flexible and expandable mesh cage 18 which is secured in a fixed position about the tip 34. Such action causes forced outward deployment and expansion of the flexible and expandable mesh cage 18 where the central section 18c thereof expands radially to a rounded or bulbous conforming shape, whereby suitable intimate contact and engagement against the thrombus 124 occurs whether the thrombus is soft or is difficult to remove. The incremental markings 27 on the catheter tube 14 with

reference to the proximal end of the tubular extension 72 of the connector 70 can be helpful to the operator in determining the degree or amount of expansion of the flexible and expandable mesh cage 18 before or during actual use of the cross stream thrombectomy catheter with flexible and expandable cage 10. Fluoroscopy, X-rays or other such suitable techniques also can be employed to view the positioning, expansion, progress and other desired aspects involving use of the cross stream thrombectomy catheter with flexible and expandable cage 10.

[0055] Once the flexible and expandable mesh cage 18 is properly positioned for use and expanded, as just described, the entire cross stream thrombectomy catheter with flexible and expandable cage 10 is actuated to incorporate intimate contact to abrade, grate, scrape or otherwise loosen and dislodge and remove thrombus 124, especially difficult to remove hardened thrombus, from the interior wall of the blood vessel 126, preferably with the simultaneous use of high pressure saline or other medium as emanated as fluid jet streams 128 from the fluid jet emanator 114 and by the introduction of suction in the lumen 15 of the catheter tube 14. Whilst maintaining the relative position of the manifold 12 and attached catheter tube 14 to the positionable assembly 16, the operator can reciprocatingly actuate the cross stream thrombectomy catheter with flexible and expandable cage 10 in a to and fro motion along the longitudinal axis of the catheter tube 14 and the flexible and expandable mesh cage 18 to cause the expanded and deployed flexible and expandable mesh cage 18 to frictionally abrade, grate, scrape or otherwise loosen and dislodge difficult to remove thrombus 124. The constitution of the flexible and

expandable mesh cage 18 is a woven mesh having surfaces being suitable for loosening action including abrasion, grating and scraping when forcibly and movingly contacting the thrombus 124, as well as being suitable for the passage of thrombus particulate therethrough. Additional loosening action is also effective around and about the longitudinal axis where rotational actuation of the deployed flexible and expandable mesh cage 18 about the longitudinal axis of the catheter tube 14 and the flexible and expandable mesh cage 18 occurs. Combining the to and fro motion along the longitudinal axis of the flexible and expandable mesh cage 18 and the catheter tube 14 with the rotational actuation of the flexible and expandable mesh cage 18 about the longitudinal axis of the catheter tube 14 and the flexible and expandable mesh cage 18 results in multiple direction applied forcible loosening action to produce enhanced loosening.

[0056] Loosened thrombus particulates 124a-124n are produced by the loosening action including abrasion, grating and scraping incurred when forcibly and movingly contacting the thrombus 124, as just described, where such particulates 124a-124n are removed by interaction with cross stream jets 130a-130n. Fluid jet streams 128 projected rearwardly from the fluid jet emanator 114 along the catheter tube 14 exit the outflow orifices 38a-38n as a plurality of cross stream jets shown generally at 130a-130n and re-enter the relatively low pressure inflow orifices 36a-36n. Upon re-entry, a portion of the cross stream jets 130a-130n along with rearwardly directed flow of fluid jet streams 128 aided by suction applied at the exhaust branch 22 at the proximal end of the catheter tube 14 are exhausted through the exhaust branch 22 of the manifold 12. Accordingly, any thrombus

particulates 124a-124n entrained therein are also exhausted through catheter tube 14 and the exhaust branch 22. As the flexible and expandable mesh cage 18 and the catheter tube 14 are actuated in one or more fashions, as previously described, for loosening of the thrombus 124, loosened thrombus particulates 124a-124n which first are located outside of the flexible and expandable mesh cage 18 are drawn through the open walls of the flexible and expandable mesh cage 18 and entrained by and into the flow of the cross stream jets 130a-130n. The cross stream jets 130a-130n are utilized in several other ways. Cross stream jets 130a-130n are used to pass through the central section 18c of the flexible and expandable mesh cage 18 to break loose and entrain any softer deposits of thrombus 124 which may still be attached to the interior wall of the blood vessel 126. The cross stream jets 130a-130n are further utilized for impinging ablation, maceration and breakdown of the thrombus particulates 124a-124n entrained therein and within the inner confines of the flexible and expandable mesh cage 18. The cross stream jets 130a-130n also deliver thrombus particulates 124a-124n through the inflow orifices 36a-36n for additional impingement and maceration by the fluid jet streams 128. In the above procedures, the introduction of lysins through the structure of the invention can be incorporated to further assist in the breaking down and softening of the soft or hard thrombus material.

[0057] **FIG. 7**, a first alternative embodiment, is a plan view of the visible components of a cross stream thrombectomy catheter with a flexible and expandable cage 10a, and **FIG. 8** shows the elements of **FIG. 7** where major components and assemblies have been separated to facilitate description. The first alternative embodiment includes a rotary actuation system 150 for precise control of the opening, sizing, and incremental control of the flexible and expandable mesh cage 18 at the distal end of a redesignated positionable assembly 16a which replaces the positionable assembly 16 of the first embodiment. The inclusion of the rotary actuation system 150 provides additional control over the expanding or contracting size of the flexible and expandable mesh cage 18, whereby the operator does not rely solely on use of the stop 44 for limiting of the opening of the flexible and expandable mesh cage 18.

[0058] Facilitation of the rotary actuation system 150 into functionability with the first alternative embodiment is made by replacement of the strain relief 32, the connector 70, and the tubular extension 72 of the first embodiment by the multiple members of the rotary actuation system 150 having at least a rotary actuator 152, a spindle connector 154, a threaded tube 156 and a sleeve 158, shown generally in **FIG. 7**. In doing so, the rotary actuator 152, the spindle connector 154, and the greater majority of the threaded tube 156 join the manual actuator 58, the strain relief tube 56 and the sheath 54 to become a positionable assembly designated as positionable assembly 16a and as such the rotary actuator 152, the spindle connector 154 and the greater majority of the threaded tube 156 are common to the rotary actuation system 150 and the positionable assembly 16a.

[0059] FIG. 8 illustrates the elements of FIG. 7 in a partially cutaway view where major components and assemblies have been separated to facilitate description. More specifically, the sleeve 158 is shown disengaged from the threaded tube 156, the rotary actuator 152 and the spindle connector 154. As also shown in FIG. 10, the sleeve 158 is tubular in shape including an internally located passage 160 having threads 162 along a greater portion thereof. A connector 164 at the proximal end of the sleeve 158 is integral to and continuous with the structure of the sleeve 158 and secures the sleeve 158 over and about the threaded connection port 28 of the manifold 12. A portion of the length of the threaded tube 156 includes external threads 166, while the unthreaded portion includes incremental markings 168 therealong at a location distal to the threads 166, and additionally includes a passage 170, as shown in FIG. 10, for passage and accommodation of the catheter tube 14. The distal end of the threaded tube 156 permanently secures to the rotary actuator 152 as shown in FIG. 10. The rotary actuator 152 is rotatably attached to the spindle connector 154 and is free to be manually rotated about the longitudinal axis of each, whereby the threads 166 of the threaded tube 156 in engagement with the threads 162 of the sleeve 158 cooperatively and threadingly interact to cause displacement of the positionable assembly 16a with respect to the sleeve 158 along the catheter tube 14 to influence the shape of the flexible and expandable mesh cage 18.

[0060] **FIG. 9** is an exploded isometric view of the cross stream thrombectomy catheter with flexible and expandable cage 10a, and **FIG. 10** is a cross section view of the rotary actuation system 150 of the cross stream thrombectomy catheter with expandable cage 10a along line 10-10 of **FIG. 7**. With reference to **FIGS. 9 and 10**, the first alternative embodiment is further described with particular attention to the rotary actuation system 150. Illustrated in particular is the relationship of the components of the rotary actuation system 150, wherein certain components, such as the sleeve 158, are stationary with respect to other components of the rotary actuation system 150 and where other components, such as the threaded tube 156, the attached rotary actuator 152, and the spindle connector 154, are longitudinally positionable and translatory with respect to the stationary components of the rotary actuation system 150.

[0061] Stationary components of the rotary actuation system 150 involve the connector 164 of the sleeve 158 which engages the threaded connection port 28 of the manifold 12 wherein a cylindrical male fixture 172 of the connector 164 engages the tapered central passageway 82 of the manifold 12 to fixingly secure the sleeve 158 to the manifold 12. A bore 174 in the cylindrical male fixture 172 accommodates the catheter tube 14 which affixes therein, such as with adhesive or by other methods known in the art. The positionally fixed catheter tube 14 extends from the bore 174 distally to pass through a portion of the passage 160 having threads 162 and thence through the passage 170 of the threaded tube 156 and then through the rotary actuator 152 and the spindle connector 154 to distal paths along the

manual actuator 58 and to locations distal thereto, as previously described.

[0062] Translatory and positionable components of the rotary actuation system 150 involve the threaded tube 156, the rotary actuator 152, and the spindle connector 154, collectively, employed to urge the manual actuator 58, the strain relief tube 56, and the sheath 54 along the catheter tube 14. The spindle connector 154 threadingly engages the threaded end 68 of the manual actuator 58 to cause a distally extending cylindrical male fixture 176 of the spindle connector 154 to sealingly engage the passage 62 of the manual actuator 58. A portion of the spindle connector 154 includes a proximally extending cylindrical spindle 178 including an integral ring 180 which engages an annular groove 182 located on the wall of a receptor cavity 184 of the rotary actuator 152 where such an arrangement allows rotary movement of the rotary actuator 152 about the cylindrical spindle 178 of the spindle connector 154. A continuous inner passage 186 extending through the cylindrical male fixture 176 and through the cylindrical spindle 178 is of sufficient diameter to freely and without significant friction pass over and about the fixed position catheter tube 14. The rotary actuator 152 includes a proximally extending cylindrical male fixture 188 having an inner passage 190 of sufficient diameter to freely and without significant friction pass over and about the fixed position catheter tube 14. A resilient seal washer 192 is also included within the rotary actuator 152 which seals about the catheter tube 14. The passage 170 of the threaded tube 156 accommodates the cylindrical male fixture 188 of the rotary actuator 152 and affixes

thereto, such as with adhesive or by other methods known in the art.

MODE OF OPERATION

[0063] The mode of operation of the cross stream thrombectomy catheter with a flexible and expandable cage 10a, the first alternative embodiment, is similar in a majority of functions to that of the cross stream thrombectomy catheter with a flexible and expandable cage 10, the major differences being the use of the rotary actuation system 150 in lieu of the previously described positioning of the manual actuator 58, where in operation of the first embodiment the operator manually grasps both the manifold 12 and the manual actuator 58 and positions one or the other or both components to cause the positionable assembly 16 to be slidingly positioned in a distal or proximal direction with respect to the manifold 12 and the attached catheter tube 14. During such positioning, the translatory distal end of catheter tube 14, upon which the proximal end 18a of the flexible and expandable mesh cage 18 is secured, is brought closer to the distal end 18b of the flexible and expandable mesh cage 18 which is in a fixed position about the tip 34. Such action causes forced outward deployment and expansion of the flexible and expandable mesh cage 18 where the central section 18c thereof expands radially to a rounded or bulbous conforming shape, whereby suitable intimate contact and engagement against the difficult to remove thrombus 124 occurs.

[0064] The use of the rotary actuation system 150 in the first alternative embodiment also provides for use of the flexible and expandable mesh cage 18, as previously described, but the method of actuation is more precise and better controlled. Preparation for use of the cross stream thrombectomy catheter with a flexible and expandable cage 10a including the rotary actuation

system 150 is the same as for the first embodiment. Operation of the rotary actuation system 150 of the first alternative embodiment is accomplished by operating the rotary actuator 152 in a direction to cause rotation of the attached threaded tube 156 within the sleeve 158 while at the same time grasping either or both the manifold 12 or the manual actuator 58 to stabilize each against resultant rotation. As the rotary actuator 152 is operated in the proper direction to cause wanted deployment and expansion of the flexible and expandable mesh cage 18, the connected threaded tube 156 is correspondingly rotated, whereby the mutually engaged threads 166 of the threaded tube 156 and the threads 162 of the sleeve 158 force the threaded tube 156, the rotary actuator 152, the spindle connector 154, the manual actuator 58, the strain relief tube 56, and the sheath 54 distally along and about the catheter tube 14, whereby the distally directed distal end of the sheath 54 causes deployment and expansion of the flexible and expandable mesh cage 18, as previously described. The operator can readily observe and reference the incremental markings 168 on the threaded tube 156 with respect to the distal end of the sleeve 158 to determine the amount of travel of the threaded tube 156, and thus determine the amount of deployment and/or expansion of the flexible and expandable mesh cage 18. Any suitable type of calibration can be used as required where one could simply note the lineal displacement of the threaded tube or where the percentage of expansion could be indicated by appropriate markings or by other useful markings. Once the desired expansion of the flexible and expandable mesh cage 18 is achieved, the operator can cease adjusting the rotary actuator 152, whereby the expanded dimension of the flexible and

expandable mesh cage 18 is maintained and locked by the interrelationship of the mutually engaged threads 166 of the threaded tube 156 and the threads 162 of the sleeve 158; i.e., the sheath 54 is held immovable and locked in position over and about the catheter tube 14. The cross stream thrombectomy catheter with a flexible and expandable cage 10a as a unit can then be unilaterally positioned to and fro or in rotary motion to cause abrasive contacting and removal of thrombus within the vasculature, as previously described. In both the cross stream thrombectomy catheter with a flexible and expandable cage 10 and the first alternative embodiment, the flexible and expandable mesh cage 18 can be collapsed and returned to a minimum profile by reversing the expansion and deployment processes in order to facilitate removal of the cross stream thrombectomy catheter with a flexible and expandable cage 10 and the cross stream thrombectomy catheter with a flexible and expandable cage 10a from the vasculature.

[0065] Although the flexible and expandable mesh cage 18 is shown at a location over and about the inflow orifices 36a-36n and the outflow orifices 38a-38n, other relationships and arrangements of components can also be utilized. One such arrangement includes locating the flexible and expandable mesh cage 18 proximal to the outflow orifices 38a-38n and another arrangement includes locating the flexible and expandable mesh cage 18 distal to the inflow orifices 36a-36n where in each arrangement the cross stream jets function separately from the flexible and expandable mesh cage 18. Further, either embodiment of the invention can be used solely as a cross stream thrombectomy catheter without enlisting the use of the flexible and expandable mesh cage 18.

[0066] **FIG. 11**, a second alternative embodiment, is a side view of an expanded straight filament flexible and expandable cage 200 which can be used as a device in lieu of the similarly attached flexible and expandable mesh cage 18 shown collapsed in **FIGS. 1, 5c and 7**, or which can be alternatively attached and incorporated as shown in **FIGS. 17 and 18**.

[0067] When used as a direct replacement for the expandable mesh cage 18, the straight filament flexible and expandable cage 200 can include a preformed collapsed shape heat set such as shown in **FIG. 12**, which minimizes the profile for insertion into the vasculature or into other devices such as, but not limited to, other catheters or sheaths.

[0068] In the latter case involving alternative attachment, the straight filament flexible and expandable cage 200 includes a heat set preformed expanded shape for use at the distal end of the combined sheath 54 and catheter tube 14 where the sheath 54 constrains members of the underlying straight filament flexible and expandable cage 200 (**FIG. 17**), wherein the sheath 54 is subsequently urged proximally to disengage from constrainment functions to allow expansion of the straight filament flexible and expandable cage 200 in an attempt to regain memory shape, as later described in detail. The term straight filament is best referenced to the compressed or restrained state of the straight filaments 202a-202n as shown in **FIG. 12** where each filament is substantially straight. Upon encountering an uncompressed or unrestrained state, the filaments attempt to return to the expanded arcuate memory position. If any one filament is viewed in alignment with the centerline of the straight filament flexible and expandable cage 200, such viewing portrays a "straight"

filament. The straight filament flexible and expandable cage 200, preferably of nitinol, includes a proximal end 200a, a distal end 200b, each of uncut tubular nitinol material, and a central section 200c of straight filament (as opposed to spiral filament) tubular material consisting of a plurality of equally spaced straight filaments 202a-202n each being flexible, compressible and expandable and of one piece, and being continuous between and with the proximal end 200a and the distal end 200b and located in radial and equal spaced distribution bridging between the proximal end 200a and the distal end 200b of the straight filament flexible and expandable cage 200 and having spaces 204a-204n between the straight filaments 202a and 202n. In the expanded state, the straight filaments 202a-202n of the straight filament flexible and expandable cage 200 converge at both the proximal end 200a and the distal end 200b, as shown at 205 and 207, respectively. Correspondingly, the spaces 204a-204n are widely spaced in the central portion of the straight filament flexible and expandable cage 200 and are narrowly spaced at both the proximal end 200a and the distal end 200b, as shown at 205 and 207, respectively. The shapes of the straight filaments 202a-202n are heat set to maintain a preset outwardly bowed arcuate and curved shape. The straight filaments 202a-202n are covered by the sheath 54 which exerts constraining forces along and about the straight filaments 202a-202n of the straight filament flexible and expandable cage 200. Subsequent proximal movement of the sheath 54 allows expansion of the straight filament flexible and expandable cage 200 for use. When used instead of the flexible and expandable mesh cage 18, such as shown in **FIGS. 1, 5c and 7**, heat set shaping is not

necessarily required. The illustration also shows the straight filament flexible and expandable cage 200 expandingly configured such as for use in the vasculature when substituted for the flexible and expandable mesh cage 18 where the sheath 54 is not incorporated for the purpose of constraint.

[0069] FIG. 12 is a side view of the straight filament flexible and expandable cage 200 in a configuration such as it would appear when constrained by the sheath 54 (not shown). Constrainment by the sheath 54 compressively forces the straight filaments 202a-202n inwardly to decrease the size of the spaces 204a-204n and also forces the straight filaments 202a-202n to maintain an elongated configuration, thereby and resultantly forcing the distal end 202b in a distal direction along the catheter tube 14 and away from the proximal end 200a. The illustration also shows the straight filament flexible and expandable cage 200 configured for insertion into the vasculature, such as when substituted for the flexible and expandable mesh cage 18 when the sheath 54 is not incorporated for the purpose of constraint.

[0070] FIG. 13 is a distal end view of the expanded straight filament flexible and expandable cage 200 showing the distribution and alignment of the straight filaments 202a-202n about the center of the straight filament flexible and expandable cage 200.

[0071] **FIG. 14**, a third alternative embodiment, is a side view of an expanded spiral filament flexible and expandable cage 210 which can be used as a device in lieu of the similarly attached flexible and expandable mesh cage 18 shown in **FIGS. 1, 5c and 7**, or which can be alternatively attached and incorporated in a similar manner such as shown in **FIGS. 17 and 18.**

[0072] When used as a direct replacement for the expandable mesh cage 18, the spiral filament flexible and expandable cage 210 can include a preformed collapsed shape heat set such as shown in **FIG. 15** which minimizes the profile for insertion into the vasculature or into other devices such as, but not limited to, other catheters or sheaths.

[0073] In the latter case involving alternative attachment, the spiral filament flexible and expandable cage 210 includes a heat set preformed expanded shape for use at the distal end of the combined sheath 54 and catheter tube 14 where the sheath 54 constrains members of the underlying spiral filament flexible and expandable cage 210, wherein the sheath 54 is subsequently urged proximally to disengage from constrainment functions to allow expansion of the spiral filament flexible and expandable cage 210 in an attempt to regain memory shape, as later described in detail. The term spiral filament is best referenced to the compressed or restrained state of the spiral filaments 212a-212n, as shown in **FIG. 15**, where each filament portrays a spiral. Upon encountering an uncompressed or unrestrained state, the filaments attempt to return to the expanded spiral memory position where if any one of the filaments 212a-212n is viewed with respect to the centerline of the spiral filament flexible and expandable cage 210, such viewing portrays a "spiral"

filament. The spiral filament flexible and expandable cage 210, preferably of nitinol, includes a proximal end 210a, a distal end 210b, each of uncut tubular material, and a central section 210c of spiral filament material consisting of a plurality of spirally shaped and spaced filaments 212a-212n each being flexible, compressible and expandable and of one piece, and being continuous between and with the proximal end 210a and the distal end 210b and located in radial and variable spaced distribution bridging between the proximal end 210a and the distal end 210b of the spiral filament flexible and expandable cage 210 and having variably spaced spaces 214a-214n between the spiral shaped filaments 212a-212n. For purposes of clarity, only the spiral shaped filaments 212a-212j nearest the viewer are shown to best illustrate the geometrical configuration and relationship of the spiral shaped filaments 212a-212n.

[0074] In the expanded state, the spiral filaments 212a-212n of the spiral filament flexible and expandable cage 210 converge at both the proximal end 210a and the distal end 200b, as shown at 209 and 211, respectively. Correspondingly, the spaces 214a-214n are widely spaced in the central portion of the spiral filament flexible and expandable cage 210 and are narrowly spaced at both the proximal end 210a and the distal end 210b, as shown at 209 and 211, respectively. The shapes of the filaments 212a-212n are heat set to maintain a preset outwardly bowed and twisting spiral shape. The filaments 212a-212n are covered by the sheath 54 which exerts constraining forces along and about the filaments 212a-212n of the spiral filament flexible and expandable cage 210. Subsequent proximal movement of the sheath 54 allows expansion of the spiral filament flexible

and expandable cage 210 for use. When used instead of the flexible and expandable mesh cage 18, such as shown in **FIGS. 1, 5c and 7**, heat set shaping is not necessarily required. The illustration also shows the spiral filament flexible and expandable cage 210 expandingly configured, such as for use in the vasculature when substituted for the flexible and expandable mesh cage 18 where the sheath 54 is not incorporated for the purpose of constraint.

[0075] FIG. 15 is a side view of the spiral filament flexible and expandable cage 210 in a configuration such as it would appear when constrained by the sheath 54 (not shown). Constrainment by the sheath 54 compressively forces the spiral shaped filaments 212a-212n inwardly to decrease the size of the spaces 214a-214n and also forces the filaments 212a-212n to maintain an elongated configuration, thereby and resultantly forcing the distal end 210b in a distal direction along the catheter tube 14 and away from the proximal end 210a. The illustration also shows the spiral filament flexible and expandable cage 210 configured for insertion into the vasculature, such as when substituted for the flexible and expandable mesh cage 18 when the sheath 54 is not incorporated for the purpose of constraint.

[0076] FIG. 16 is a distal end view of the expanded spiral filament flexible and expandable cage 210 showing the distribution and alignment of the spiral shaped filaments 212a-212n about the center of the spiral filament flexible and expandable cage 210.

[0077] **FIG. 17** is a view in partial cross section of the straight filament flexible and expandable cage 200 constrained by the sheath 54 at the distal tip 34 in substitution for the positionable and expandable mesh cage 18 shown in the first embodiment and the first alternative embodiment of **FIGS. 1 and 7**, respectively. The proximal end 200a of the straight filament flexible and expandable cage 200 aligns over and about the catheter tube 14 at a location near the radiopaque band 40 and is affixed thereto by the use of an adhesive 216. The opposed distal end 200b of the straight filament flexible and expandable cage 200 aligns over and about the catheter tube 14 generally at a location distal to the plurality of inflow orifices 36a-36n and is not fixedly secured thereto, such as by adhesive, but is free to be urged or reactively positioned along and about the underlying catheter tube 14 in alignment with a substantially annular space 218 between the distal end 200b and the catheter tube 14.

[0078] **FIG. 18** is a view in partial cross section of the straight filament flexible and expandable cage 200 and of the components shown in **FIG. 17** where the sheath 54 has been positioned proximally, whereby intimate and constraining contact between the sheath 54 and the straight filaments 202a-202n no longer occurs. Such positioning allows the straight filaments 202a-202n to attempt to return to the memory position, thus allowing expansion and outward positioning of the straight filaments 202a-202n to attempt to return to the preset outwardly bowed arcuate and curved shape. As the straight filaments 202a-202n attempt to return to the memory position, the distal end 200b of the straight filament flexible and expandable cage 200 is urged proximally along and about the space 218 and the distal portion of the catheter tube 14 by preset memory forces of the expanding straight filaments 202a-202n.

[0079] Operation of the invention when using the straight filament flexible and expandable cage 200 is very much the same as previously described with reference to **FIG. 6**, but the straight filament flexible and expandable cage 200 is delivered to the thrombus site under the cover of the encompassing sheath 54 which is actuated proximally to deploy the straight filament flexible and expandable cage 200. Both to and fro linear motion and rotary motion of the straight filament flexible and expandable cage 200 and combinations thereof are incorporated into use. Use of the invention with the straight filament flexible and expandable cage 200 allows penetration of the thrombus by the straight filaments 202a-202n especially utilizing a linear ploughing penetration where the longitudinal profile, as shown in **FIG. 13**, of each of the straight filaments 202a-202n presents minimum frontal area for creation of thin paths through the thrombus, thereby easing to and fro linear penetration. Several to and fro reciprocating linear passes of the expanded straight filament flexible and expandable cage 200 followed by additional to and fro reciprocating linear passes where the expanded straight filament flexible and expandable cage 200 is rotatingly reoriented about its longitudinal axis at the ends of one or more linear passes can serve to plough several and multiple different paths through the thrombus, thereby weakening the thrombus structure. Rotary motion of the expanded straight filament flexible and expandable cage 200 can be incorporated with intimate contact to abrade, grate, scrape, or otherwise loosen and disturb or otherwise dislodge difficult to remove thrombus where the expanded straight filament flexible and expandable cage 200 is positioned in the thrombus and rotated about its longitudinal axis. Rotary motion of the

expanded straight filament flexible and expandable cage 200 can be incorporated by itself or in combination with multiple reoriented to and fro linear reciprocating passes thereof or also by combining rotary motion and to and fro reciprocating non-linear motion (simultaneous push/pull and twist) where such intimate contact actions are incorporated to abrade, grate, scrape, or otherwise loosen and dislodge difficult to remove thrombus. Loosened thrombus can be acted upon by cross stream jets for entrainment for maceration and/or for evacuation through the catheter tube. During operation of a thrombectomy catheter having a straight filament flexible and expandable cage 200 in a to and fro and/or a rotary motion to cause the deployed straight filament flexible and expandable cage 200 to frictionally abrade, grate, scrape, or otherwise loosen and dislodge difficult to remove thrombus, the particles of such thrombus can be engaged in the spaces 204a-204n, especially at the narrowed spaces 204a-204n formed by the converging straight filaments 202a-202n, such as shown at 205 and 207. Further and more emphatic frictional engagement of thrombus particles between the straight filaments 202a-202n can occur as the spaces 204a-204n are forced to close during collapsing of the straight filament flexible and expandable cage 200 by the constraining action of the distally actuated sheath 54. Additionally, when the straight filaments 202a-202n are compressed by the sheath 54, any stray particulate which is not exhausted through the catheter tube 14 and in close proximity about the region of the catheter tube 14 surrounded by the straight filaments 202a-202n can be contained in the inner space formed by the closely spaced and compressed straight filaments 202a-202n which assume

a cylindrical shape. Thrombus particles which are capturingly engaged by the collapsed straight filament flexible and expandable cage 200 are removed from the vasculature when the catheter tube 14 and the positionable assembly 16 are removed from the vasculature. When the straight filament flexible and expandable cage 200 is collapsed and retracted, the tubular catheter 14 can be maneuvered from the former thrombus site and from the vasculature.

[0080] Operation of the invention when using the spiral filament flexible and expandable cage 210 is very much the same as previously described with relation to **FIG. 6** concerning the flexible and expandable mesh cage 18. As with the straight filament flexible and expandable cage 200, the spiral filament flexible and expandable cage 210 is delivered to the thrombus site under the cover of the encompassing sheath 54 which is thereafter actuated proximally to deploy the spiral filament flexible and expandable cage 210.

[0081] The spiral filament flexible and expandable cage 210 can be used instead of the straight filament flexible and expandable cage 200 where the spiral filament flexible and expandable cage 210 is mounted in a similar fashion, as just described above with reference to **FIGS. 17 and 18.** The spiral filament flexible and expandable cage 210 is delivered to the thrombus site under the cover of the encompassing sheath 54 which is then actuated proximally to deploy and expose the spiral filament flexible and expandable cage 210 within the vasculature. The spiral filament flexible and expandable cage 210 can be incorporated into use with to and fro linear motion, with rotary motion, or with a combination of to and fro linear motion and rotary motion. During to

and fro actuation of the spiral filament flexible and expandable cage 210, a wide total contact circular path is made by the overlapping profile of the plurality of spiral filaments 212a-212n (see **FIG. 16**) instead of multiple thin paths such as are made by the straight filaments 202a-202n of the straight filament flexible and expandable cage 200. Therefore, use of the spiral filament flexible and expandable cage 210 can hasten the thrombectomy process. Rotary motion can also be effective using intimate contact to abrade, grate, scrape, or otherwise loosen and dislodge difficult to remove thrombus. An additional benefit is that the rotating spiral filaments 212a-212n can also slice or peel thrombus from the main thrombus buildup due to the angular incidence of the spiral filaments 212a-212n with the thrombus buildup. Another benefit of the spiral filament flexible and expandable cage 210 is that, with reference to profile, contact is made along multiple spiral broadly encompassing regions as opposed to contact along thin multiple straight paths using straight filaments where straight filaments could fall into the thin ploughed paths for temporary captured hindrance to further rotation. During operation of a thrombectomy catheter having a spiral filament flexible and expandable cage 210 in a to and fro and/or a rotary motion or other suitable motion to cause the deployed spiral filament flexible and expandable cage 210 to frictionally abrade, grate, scrape, or otherwise loosen and dislodge difficult to remove thrombus, the particles of such thrombus can be engaged in the spaces 214a-214n, especially at the narrowed spaces 214a-214n formed by the converging spiral filaments 212a-212n, such as shown at 209 and 211. Further and more emphatic frictional engagement of thrombus particles between the spiral filaments 212a-212n

can occur as the spaces 214a-214n are forced to close during collapsing of the spiral filament flexible and expandable cage 210 by the constraining action of the distally actuated sheath 54. Additionally, when the spiral filaments 212a-212n are compressed by the sheath 54, any stray particulate which is not exhausted through the catheter tube 14 and in close proximity about the region of the catheter tube 14 surrounded by the spiral filaments 212a-212n can be contained in the inner space formed by the closely spaced and compressed spiral filaments 212a-212n which assume a cylindrical shape. Thrombus particles which are capturingly engaged by the collapsed spiral filament flexible and expandable cage 210 are removed from the vasculature when the catheter tube 14 and the positionable assembly 16 are removed from the vasculature.

[0082] Multiple arrangements, combinations, and uses of component members can be utilized. For instance, the first embodiment of the cross stream thrombectomy catheter with a flexible and expandable cage 10 (**FIG. 1**) and the first alternative embodiment of the cross stream thrombectomy catheter with a flexible and expandable cage 10a (**FIG. 7**) are shown featuring the flexible and expandable mesh cage 18 where the cross stream thrombectomy catheter with flexible and expandable cage 10 includes the sheath 54 which is simply and manually actuated to cause expanding deployment of the flexible and expandable mesh cage 18, and the first alternative embodiment features the sheath 54 which is actuated incrementally and precisely by use of the rotary actuation system 150 to cause expanding deployment of the flexible and expandable mesh cage 18. Each of the above embodiments demonstrates the use of a flexible and

expandable mesh cage 18 being deployed at the distal end of the sheath 54 in different manners.

[0083] Use of the second alternative embodiment (straight filament flexible and expandable cage 200) or the third alternative embodiment (spiral filament flexible and expandable cage 210) at the distal end of the sheath 54 of the first embodiment (cross stream thrombectomy catheter with flexible and expandable cage 10), and use of the second alternative embodiment (straight filament flexible and expandable cage 200) or the third alternative embodiment (spiral filament flexible and expandable cage 210) at the distal end of the sheath 54 of the first alternative embodiment (cross stream thrombectomy catheter with flexible and expandable cage 10a) are other uses and examples of various arrangements, combinations, and uses of components of the first embodiment, wherein such uses can incorporate the sheath 54 to house or reveal or to collapse and capture the straight or spiral filament flexible and expandable cages 200 and 210. The flexible and expandable mesh cage 18 could also be mounted to the catheter where the proximal end is secured thereto and where the distal end is free to slide along and about the distal end of the catheter 14, much in the same manner as shown in the second alternative embodiment, involving the use of the sheath 54 to house or reveal the flexible and expandable mesh cage 18.

[0084] PARTS LIST

10	cross stream thrombectomy catheter with flexible and expandable cage	40	radiopaque marker band
		42	radiopaque marker band
		44	stop
10a	first alternative embodiment of cross stream thrombectomy catheter with flexible and expandable cage	46	hemostatic nut
		48	threaded high pressure connection port
		50	Luer connector
		52	introducer
		54	sheath
12	manifold	56	strain relief tube
14	catheter tube		
15	lumen	58	manual actuator
16	positionable assembly	60	tubular body
		62	passage
16a	positionable assembly	64	handle
		66	handle
18	flexible and expandable mesh cage	68	threaded end
		70	connector
18a	proximal end	72	tubular extension
18b	distal end	74	guidewire
18c	central section	76	high pressure tube
		78	high pressure connection branch passageway
20	central tubular body		
22	exhaust branch		
24	high pressure connection branch		
26	cavity body	80	exhaust branch passageway
27	incremental markings	82	tapered central passageway
28	threaded connection port	84	cavity
		85	cavity extension
30	connector	86	threads
32	strain relief	88	self-sealing hemostatic valve
34	tip		
35	tapered portion	89	flexible washer
36a-n	inflow orifices	90	cavity wall
38a-n	outflow orifices	91	flexible washer

92	planar surface
94	orifice
96	boss
97	beveled entryway
98	passageway
100	internal threads
102	annular lip
104	ferrule
106	passageway
108	interior passageway
110	support ring
112	grooved support ring
114	fluid jet emanator
116	shaft
118	actuating handle
120	adhesive
122	adhesive
124	thrombus
124a-n	thrombus particulates
126	blood vessel
128	fluid jet streams
130a-n	cross stream jets
150	rotary actuation system
152	rotary actuator
154	spindle connector
156	threaded tube
158	sleeve
160	passage
162	threads
164	connector
166	threads
168	incremental markings
170	passage
172	cylindrical male fixture
174	bore
176	cylindrical male fixture
178	cylindrical spindle
180	ring
182	annular groove
184	receptor cavity
186	passage
188	cylindrical male fixture
190	inner passage
192	seal washer
200	straight filament flexible and expandable cage
200a	proximal end
200b	distal end
200c	central section
202a-n	straight filaments
204a-n	spaces
205	(reference arrow)
207	(reference arrow)
209	(reference arrow)
211	(reference arrow)
210	spiral filament flexible and expandable cage
210a	proximal end
210b	distal end
210c	central section
212a-n	spiral filaments
214a-n	spaces
216	adhesive
218	space

[0085] Various modifications can be made to the present invention without departing from the apparent scope thereof.

IT IS CLAIMED:

1 A thrombectomy catheter comprising:

a. a catheter tube having a distal end and a proximal end;

b. a porous cage distally located on the catheter tube, the porous cage characterized as capable of radial expansion and radial contraction;

c. a proximally located control means regulating radial expansion and radial contraction of the porous cage;

d. at least one outflow orifice and at least one inflow orifice situated on the catheter tube adjacent the distal end of the catheter; and,

e. a manifold connected to the proximal end of the catheter tube, the manifold providing for connection to pressurizing and/or evacuation equipment and providing fluid communication with the at least one outflow orifice and the at least one inflow orifice, such that a cross stream jet may be established between the at least one outflow orifice and the at least one inflow orifice.

2. The thrombectomy catheter of claim 1, wherein the at least one outflow orifice and the at least one inflow orifice are located within the porous cage.

3. The thrombectomy catheter of claim 1, wherein the at least one outflow orifice and the at least one inflow orifice are located proximal to the porous cage.

4. The thrombectomy catheter of claim 1, wherein the at least one outflow orifice and the at least one inflow orifice are located distal to the porous cage.

5. The thrombectomy catheter of claim 1, wherein the porous cage is characterized, when radially expanded, by having an external surface suitable for loosening thrombus by converting thrombus to particulate form.

6. The thrombectomy catheter of claim 1, wherein the porous cage includes nitinol.

7. The thrombectomy catheter of claim 6, wherein the nitinol of the porous cage has a preset memory shape, which preset memory shape predisposes the porous cage to radially expand.

8. The thrombectomy catheter of claim 6, wherein the preset memory shape is a heat set memory shape.

9. The thrombectomy catheter of claim 1, wherein the porous cage is a mesh cage.

10. The thrombectomy catheter of claim 9, wherein the porous mesh cage is a porous woven mesh cage.

11. The thrombectomy catheter of claim 1, wherein the porous cage includes a plurality of flexible filaments.

12. The thrombectomy catheter of claim 1, wherein the porous cage, when contracted, includes a plurality of straight filaments, the plurality of straight filaments arranged in a longitudinally oriented parallel manner such

that the plurality of straight filaments together define a generally tubular configuration.

13. The thrombectomy catheter of claim 12, wherein the straight filaments of the porous cage are formed of nitinol.

14. The thrombectomy catheter of claim 13, wherein the straight nitinol filaments have a preset memory shape, which preset memory shape predisposes the straight nitinol filaments to assume an arcuate shape and the predisposed arcuate shape of each of the straight nitinol filaments of the plurality being directed such that the porous cage is predisposed to radially expand.

15. The thrombectomy catheter of claim 14, wherein the preset memory shape is a heat set memory shape.

16. The thrombectomy catheter of claim 1, wherein the porous cage, when contracted, includes a plurality of spiral filaments, the plurality of spiral filaments arranged in a helically oriented parallel manner such that the plurality of spiral filaments together define a generally tubular configuration.

17. The thrombectomy catheter of claim 16, wherein the spiral filaments of the porous cage are formed of nitinol.

18. The thrombectomy catheter of claim 17, wherein the spiral nitinol filaments have a preset memory shape, which preset memory shape predisposes the spiral nitinol filaments to a bowed twisted shape and the bowed twisted shape of each of the spiral nitinol filaments of the plurality being directed such that the porous cage is predisposed to radially expand.

19. The thrombectomy catheter of claim 18, wherein the preset memory shape is a heat set memory shape.

20. The thrombectomy catheter of claim 1, wherein the porous cage has a distal end and a proximal end.

21. The thrombectomy catheter of claim 20, wherein expansion of the porous cage includes compression between the distal end and the proximal end of the porous cage.

22. The thrombectomy catheter of claim 20, wherein the distal end of the porous cage is fixed to the catheter tube and the proximal end of the porous cage is free floating and movable along and over the catheter tube.

23. The thrombectomy catheter of claim 1, wherein the proximally located control means includes a manual actuator longitudinally slidable over a proximally located segment of the catheter tube, the manual actuator operating a sheath extending distally over the catheter tube.

24. The thrombectomy catheter of claim 22, wherein the proximally located control means includes a manual actuator longitudinally slidable over a proximally located segment of the catheter tube, the manual actuator operating a sheath extending distally over the catheter tube and connecting to the free floating and movable proximal end of the porous cage.

25. The thrombectomy catheter of claim 1, wherein the proximally located control means includes a mechanism in which a threaded tube rotatingly engages an internally threaded sleeve to rotatably and incrementally operate a sheath, the sheath extending distally over the catheter tube.

26. The thrombectomy catheter of claim 1, wherein the proximally located control means includes a mechanism in which a threaded tube rotatingly engages an internally threaded sleeve to rotatably and incrementally operate a sheath, the sheath extending distally over the catheter

tube to the porous cage and wherein the sheath moves incrementally between covering and thereby constraining the porous cage and revealing and thereby deploying the porous cage by allowing the porous cage radially expand.

27. The thrombectomy catheter of claim 26, wherein either the distal end or the proximal end of the porous cage is fixed to the catheter tube and the opposite end of the porous cage is free floating about the catheter tube.

28. The thrombectomy catheter of claim 1, further comprising indicia associated with the proximally located control means, said indicia arranged to coordinate a desired setting of the proximally located control means with a known and indicated specific size parameter of radial expansion of the porous cage.

29. The thrombectomy catheter of claim 1, wherein the proximally located control is mechanically linked to the porous cage by a sheath encasing and movable relative to the catheter tube.

30. The thrombectomy catheter of claim 29, wherein actuation of the manual actuator of the proximally located control moves the sheath such that the proximal and distal ends of porous cage are moved closer together and the porous cage thereby radially expands.

31. The thrombectomy catheter of claim 1, wherein the proximally located control means further includes indicia for aid in selecting a desired degree of expansion of the porous cage.

32. A thrombectomy method for removing resistant thrombus from a resistant thrombus site in vasculature comprising the steps of:

a. providing a catheter having a distally located positionable and radially expandable and contractable porous cage with at least one outflow orifice and at least one inflow orifice associated with the porous cage and a manifold connected to the proximal end of the catheter tube, the manifold providing for connection to pressurizing and/or evacuation equipment and providing fluid communication with the at least one outflow orifice and the at least one inflow orifice;

b. positioning the porous cage, in radially contracted condition, at the thrombus site;

c. radially expanding the porous cage;

d. manipulating the radially expanded porous cage against the resistant thrombus so as to disrupt and loosen portions of the thrombus as thrombus particulates;

e. establishing a cross stream flow between the at least one outflow orifice and the at least one inflow orifice;

f. entraining the disrupted and loosened portions of the thrombus as thrombus particles in the cross stream flow; and,

g. evacuating at least a portion of the cross stream flow with entrained thrombus particles through the manifold.

33. The thrombectomy method of claim 32, wherein the radial expansion and contraction of the porous cage is controlled by a proximal control on the catheter tube.

34. The thrombectomy method of claim 33, wherein the radial expansion and contraction is conveyed from the proximal control to the porous cage by a movable sheath located about the catheter tube.

35. The thrombectomy method of claim 34, wherein the porous cage is bias and predisposed to radial expansion and the sheath encases and constrains the porous cage.

36. The thrombectomy method of claim 34, wherein the porous cage has a distal end and a proximal end and the sheath regulates the spacing being the proximal end and the distal end of the porous cage.

37. The thrombectomy method of claim 33, wherein the proximal control includes indicia for aid in selecting a desired degree of expansion of the porous cage.

38. (new) A method of making a porous cage for a thrombectomy catheter comprising the steps of:

a. providing a tube having a proximal end and a distal end; and,

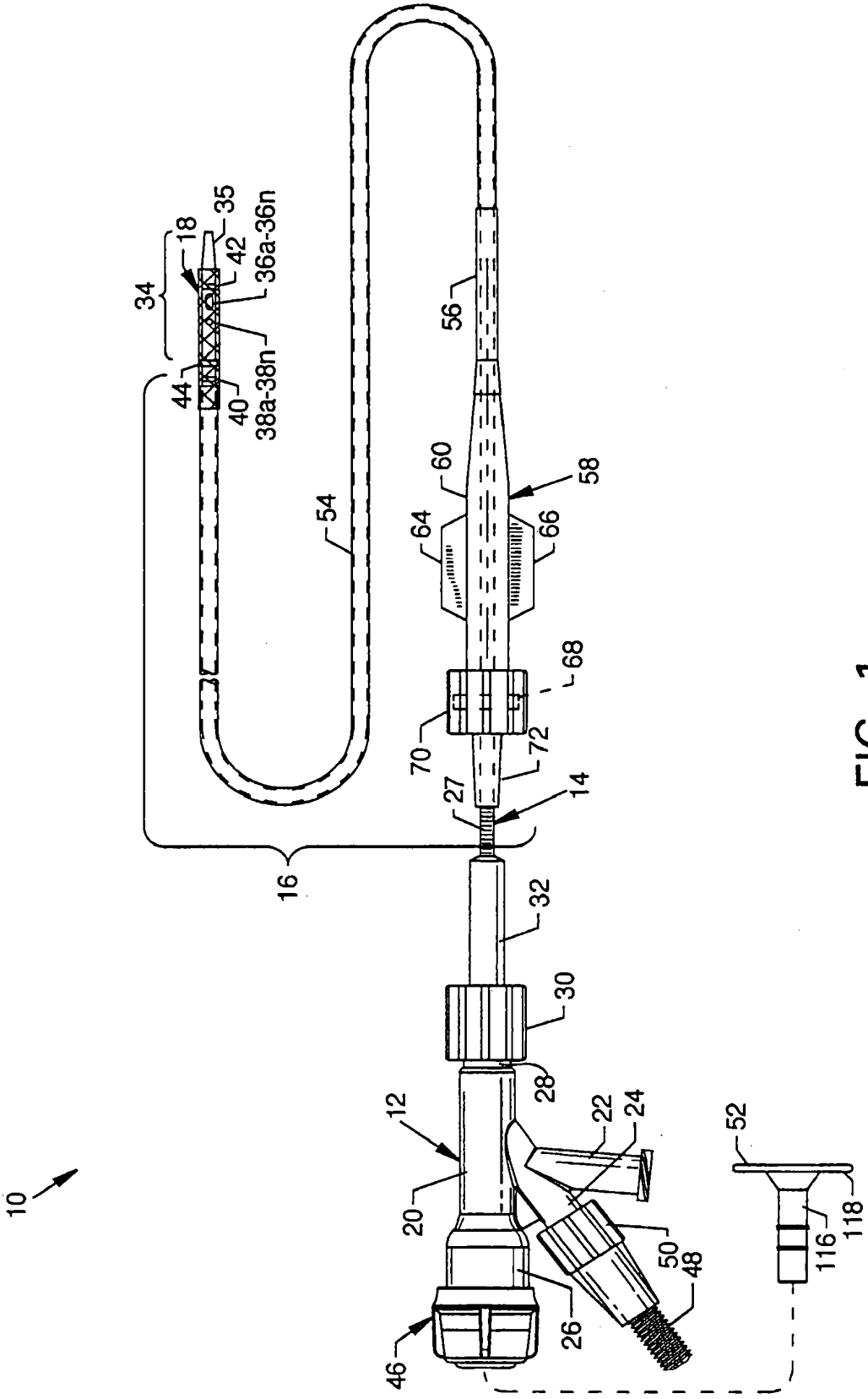
b. cutting the tube to form a plurality of filaments extending between the proximal end and the distal end.

39. The method of claim 38, wherein the filaments are straight.

40. The method of claim 38, wherein the filaments are spiral.

41. The method of claim 38, wherein the tube is formed of nitinol.

42. The method of claim 41, further comprising the step of presetting an expanded memory shape in the filaments.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36a-36n
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FIG. 1

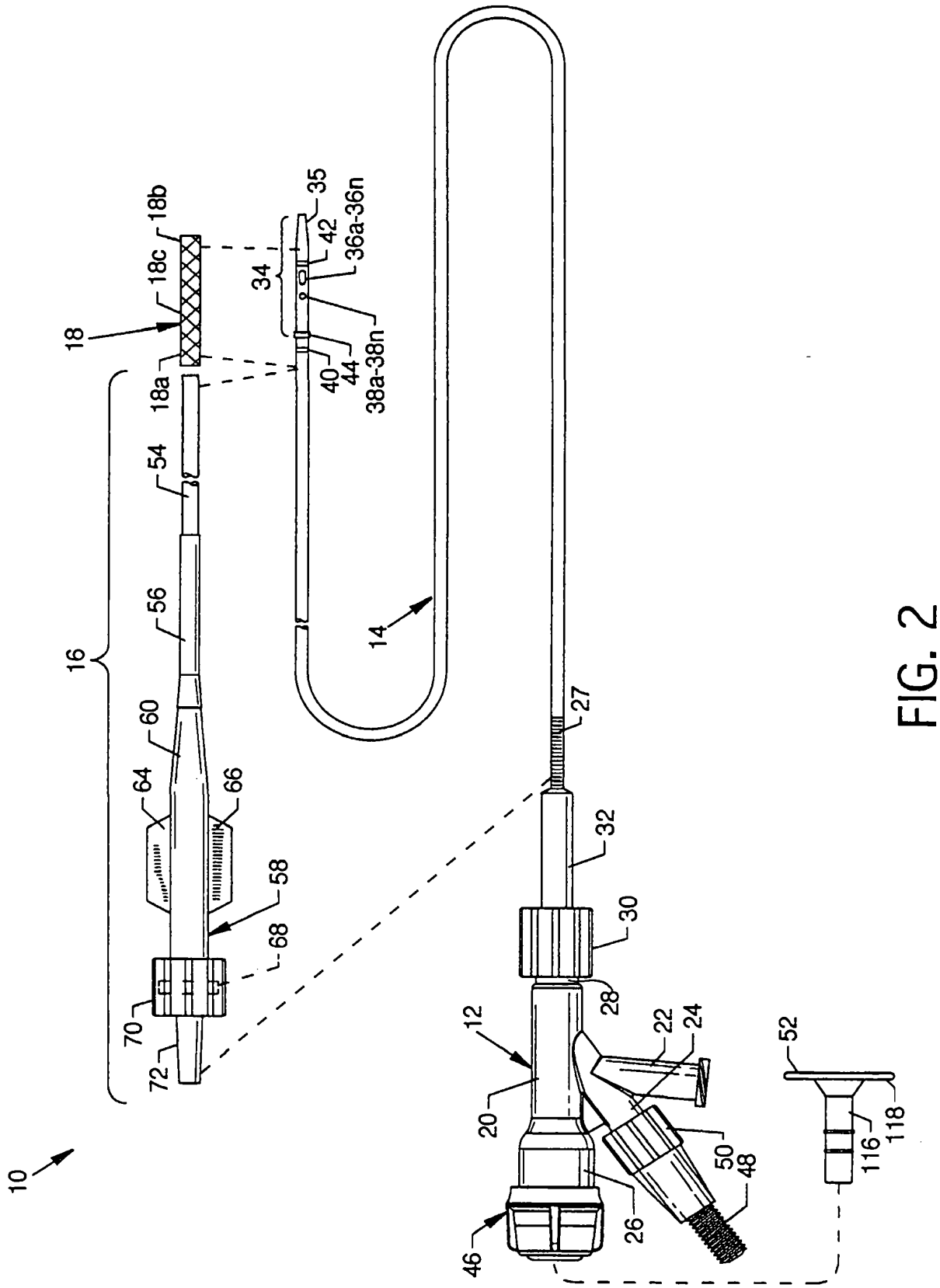
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FIG. 2

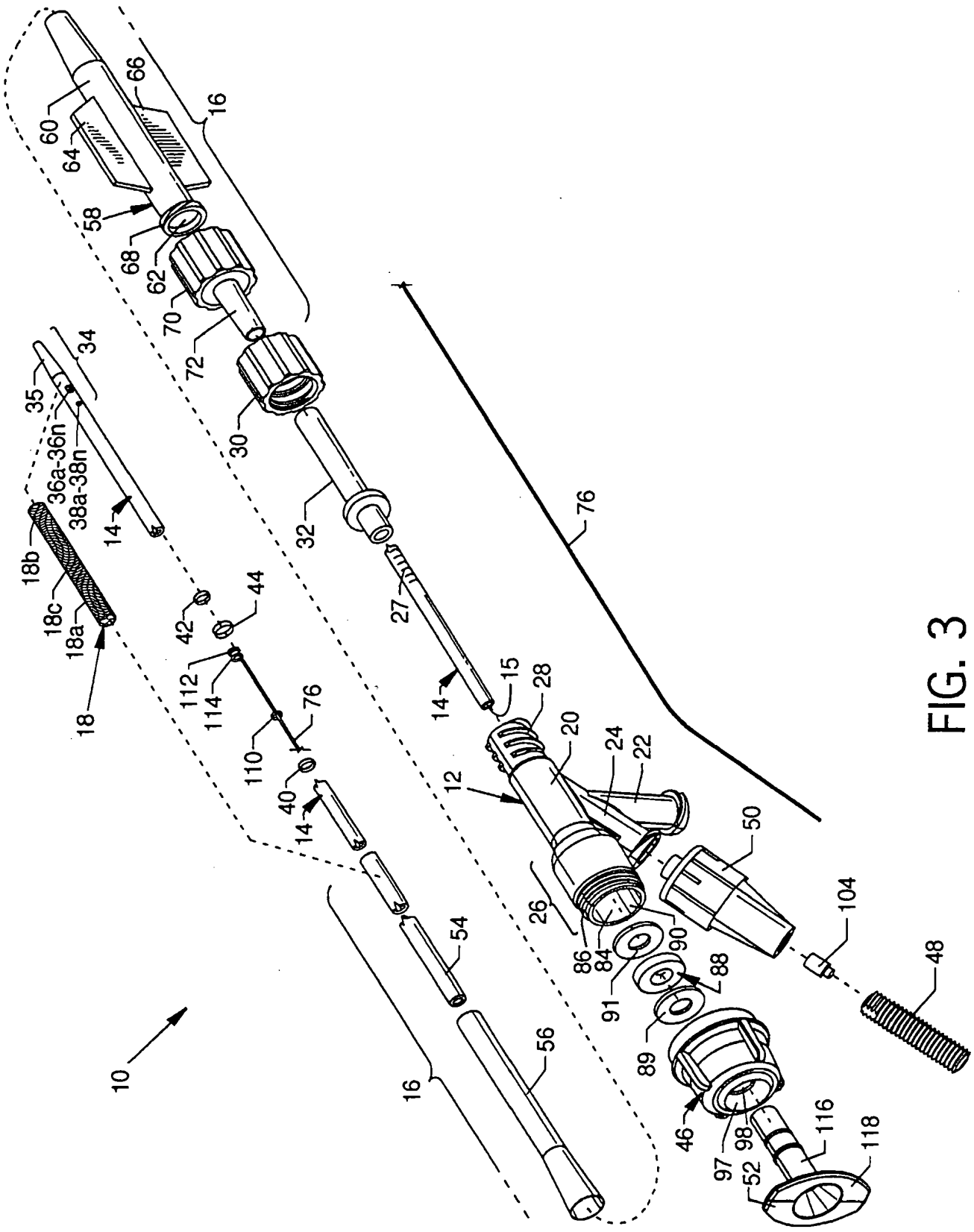
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FIG. 3

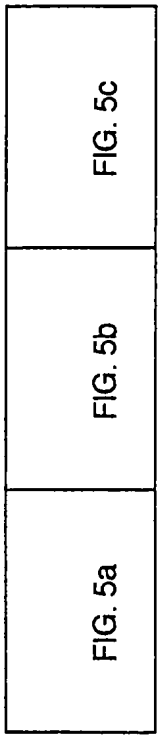

FIG. 4

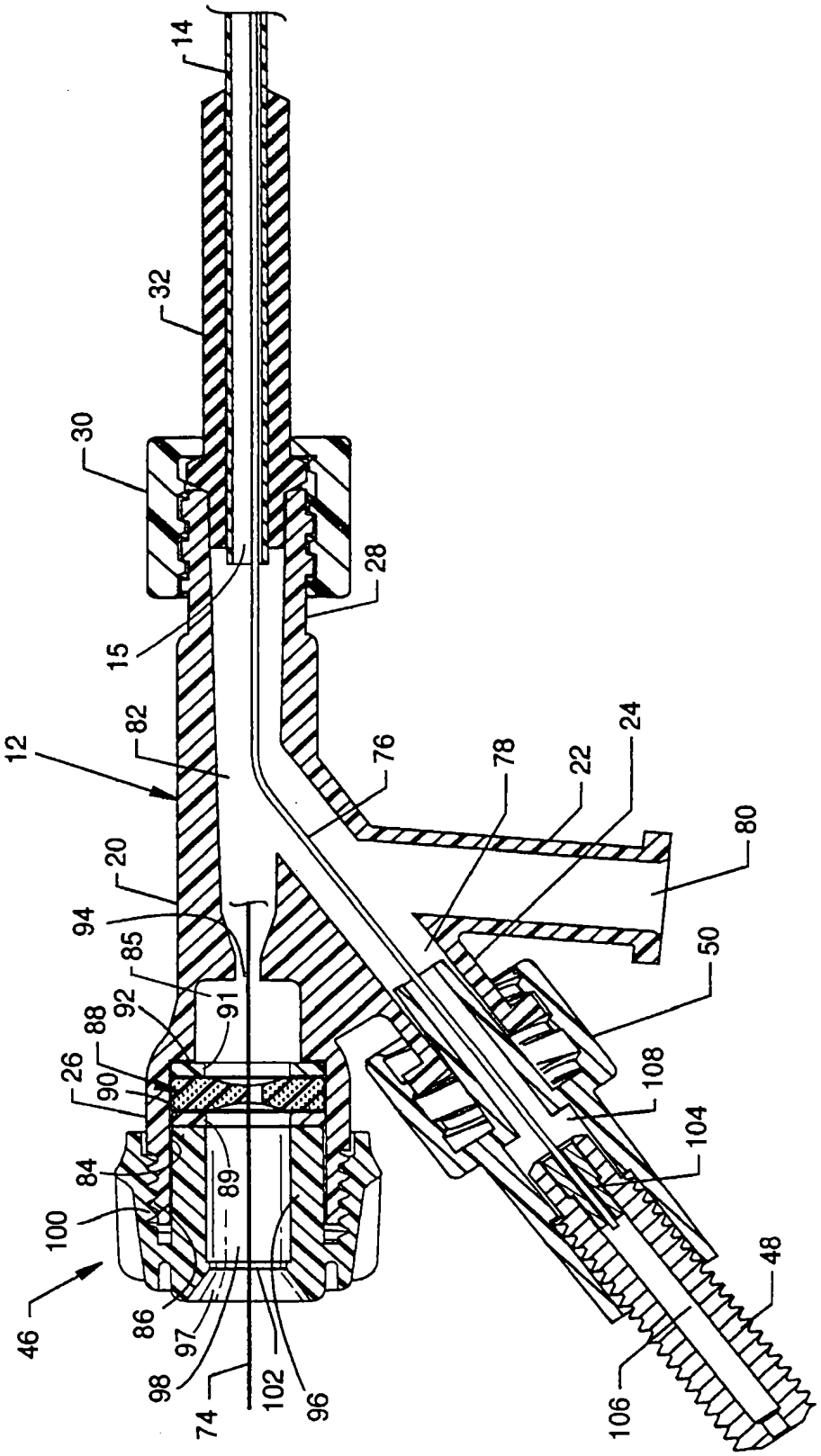
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FIG. 5a

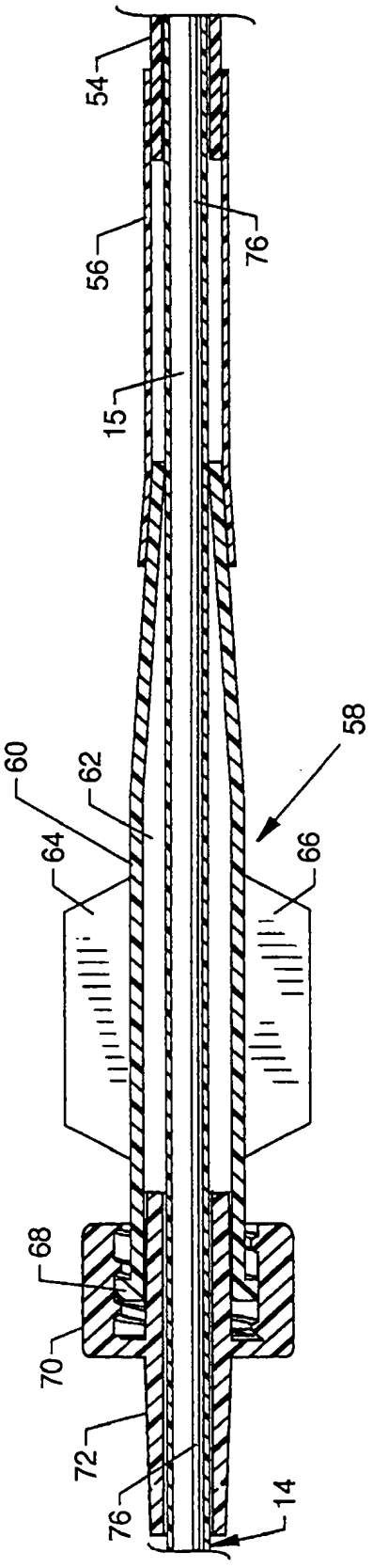
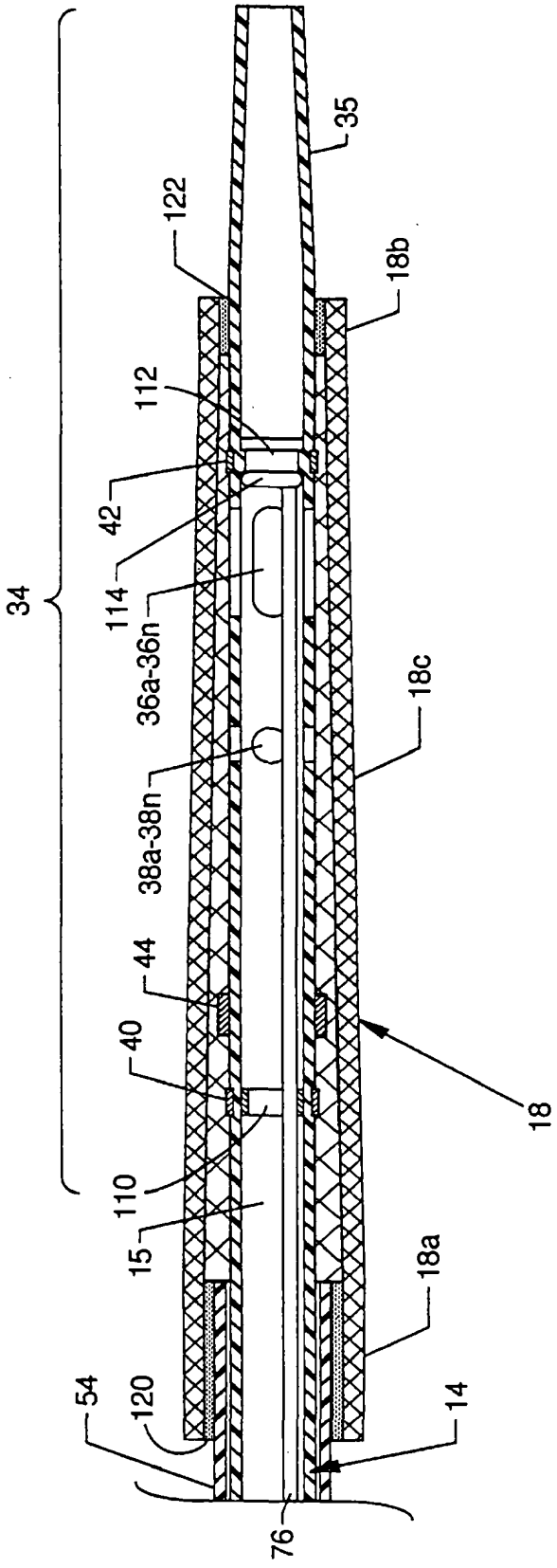


FIG. 5b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18b
112
42
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18c
38a-38n
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18
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18a
54
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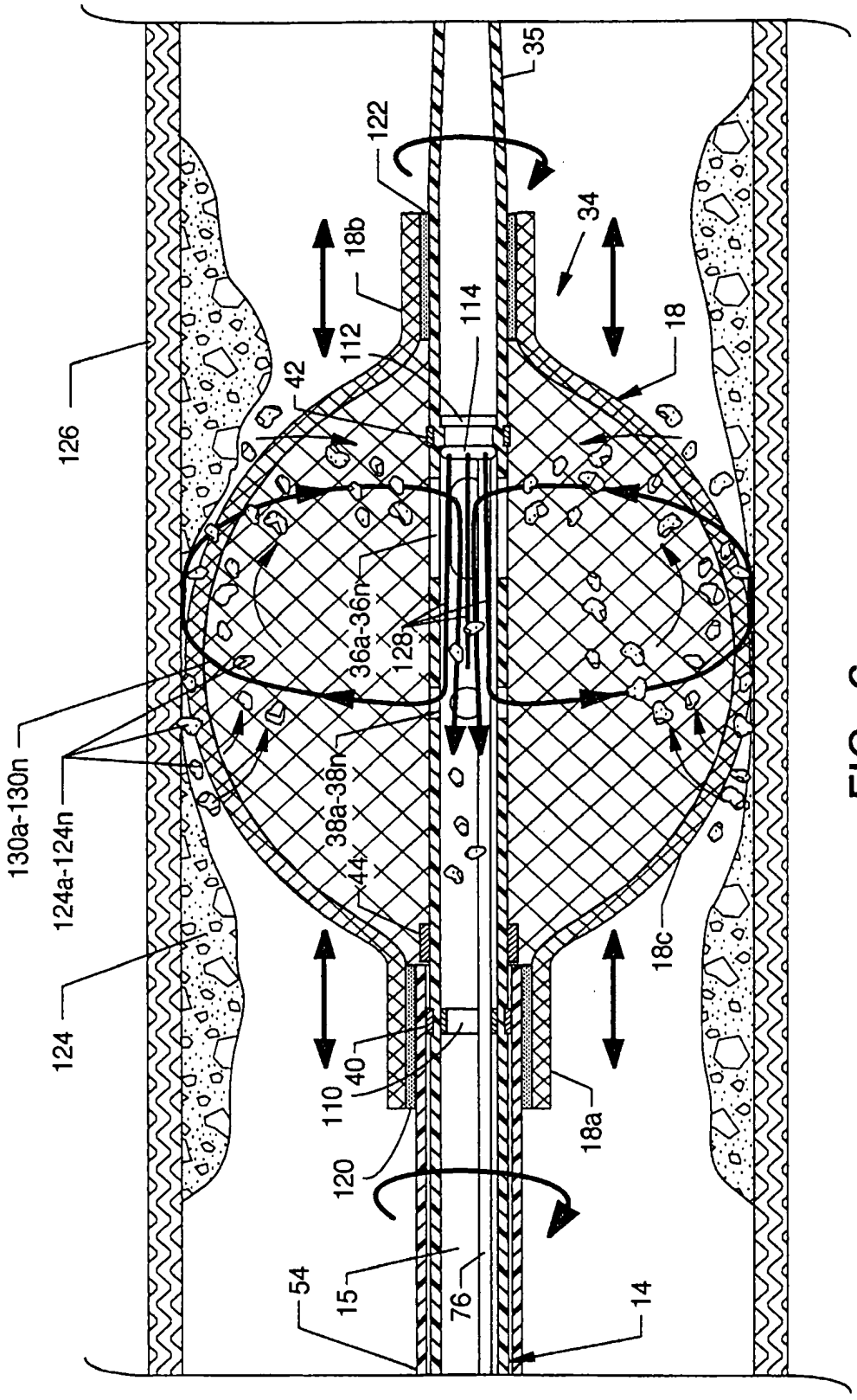
14
76

FIG. 5c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18a
120
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76
14

FIG. 6

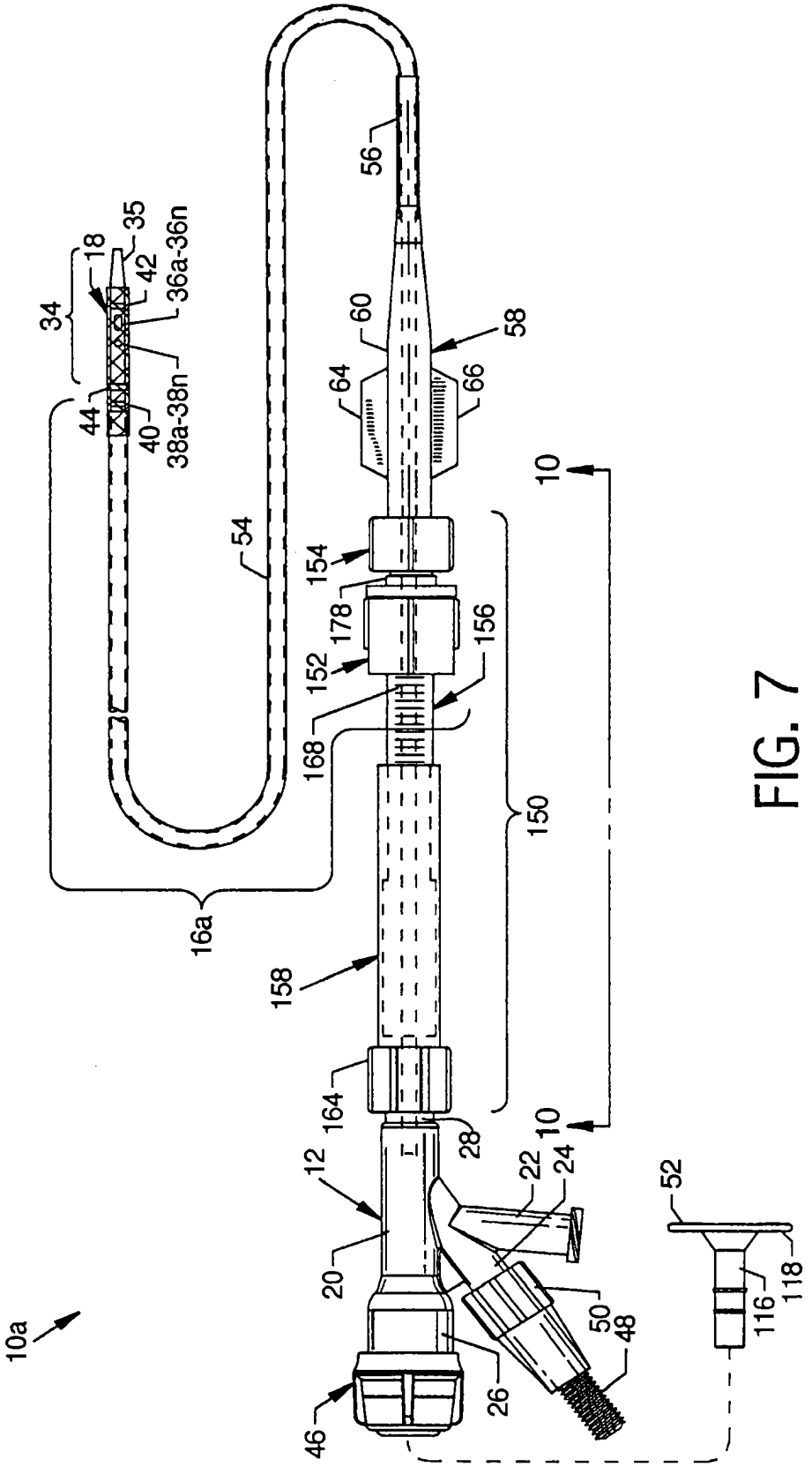
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FIG. 7

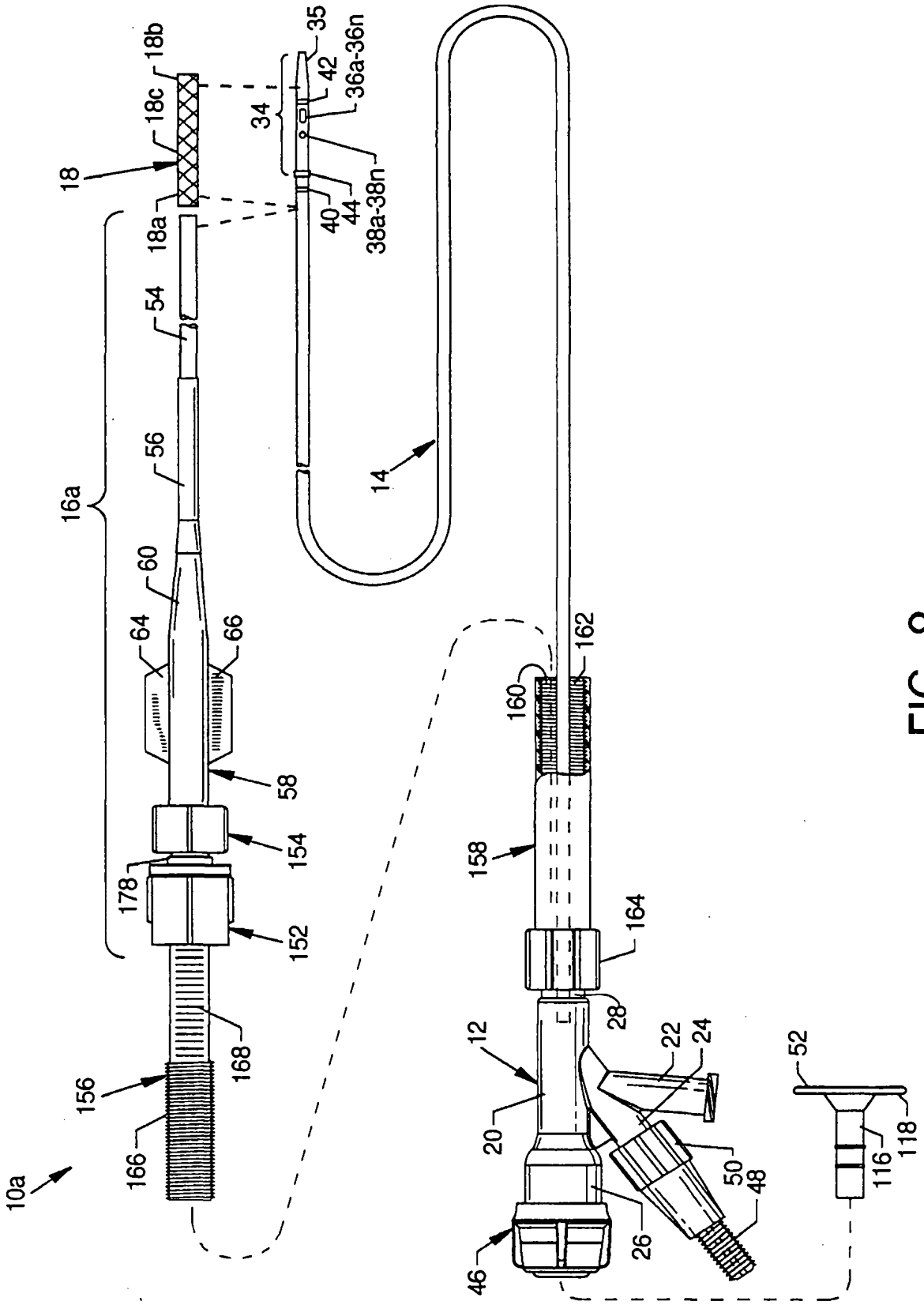
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FIG. 8

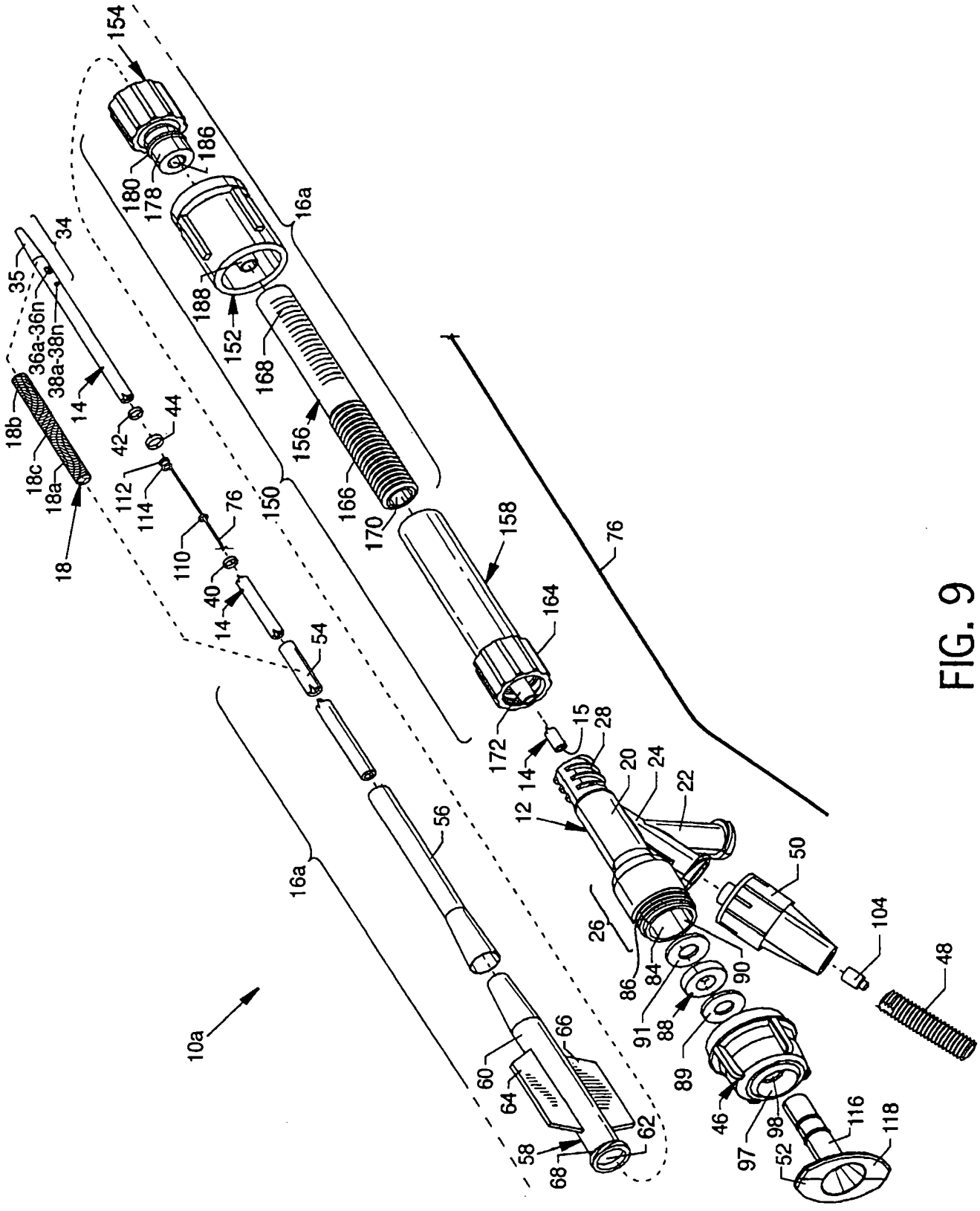
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FIG. 9

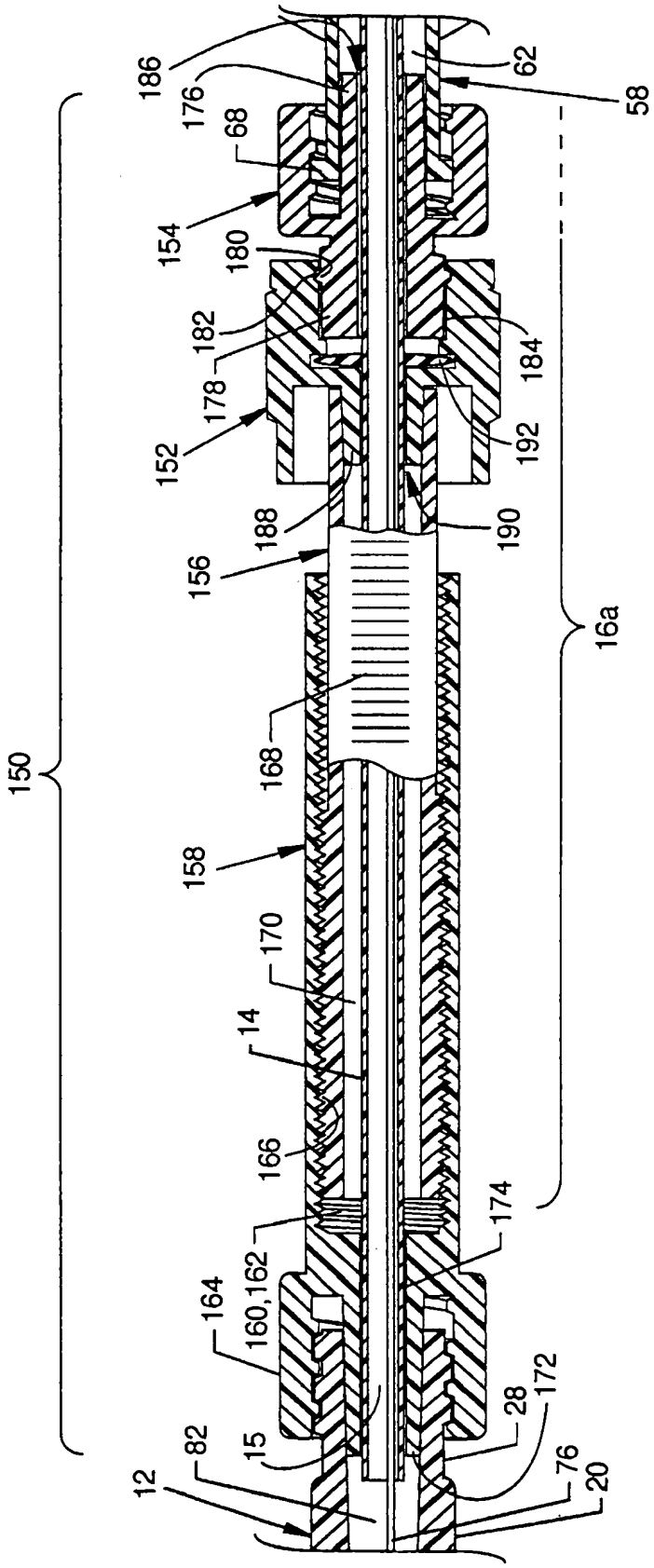
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FIG. 10

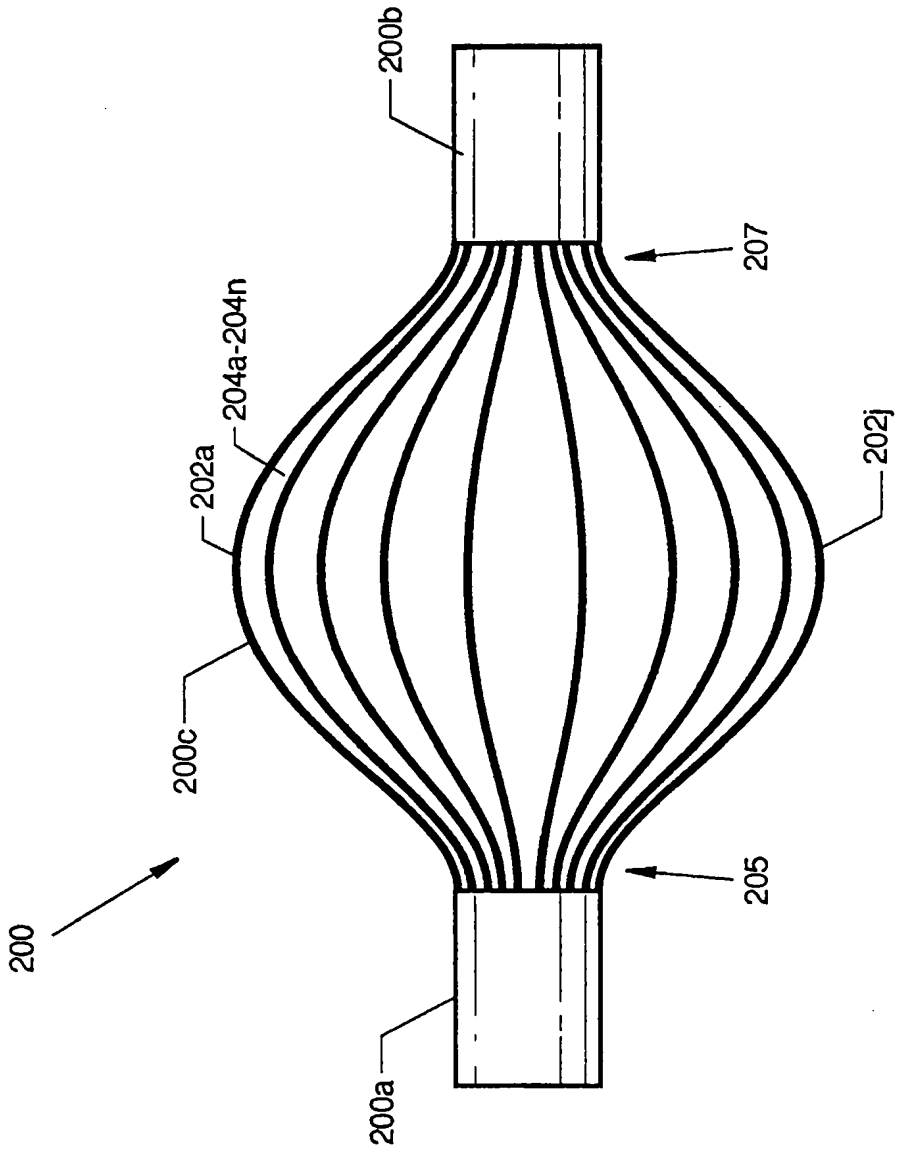

FIG. 11

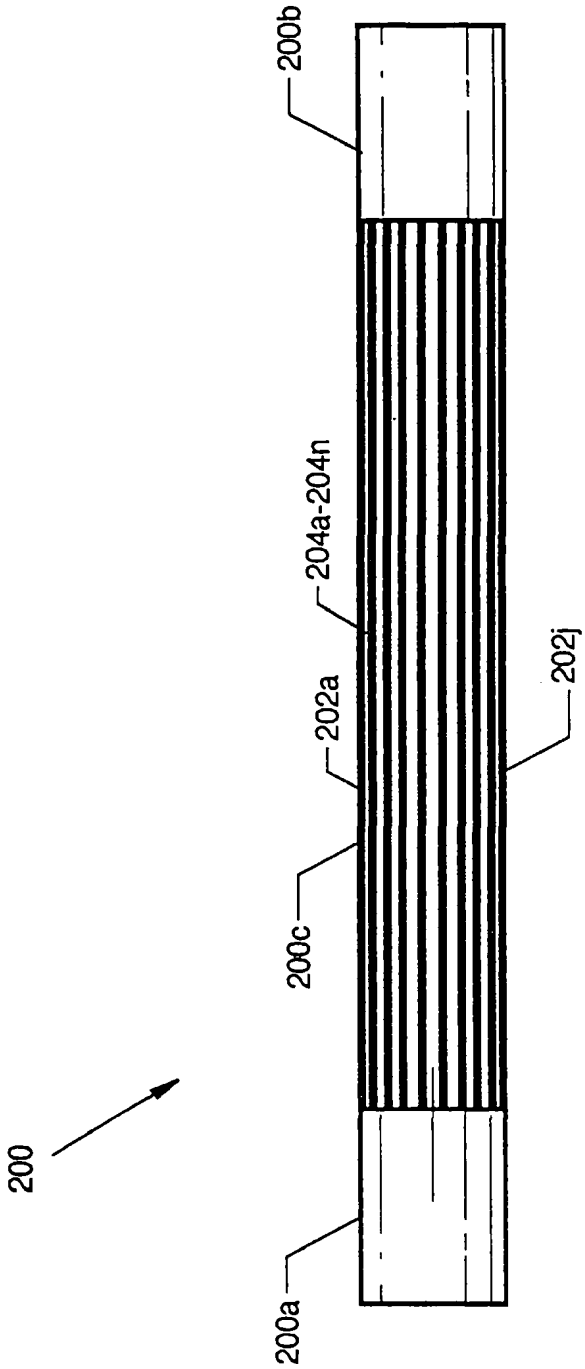

FIG. 12

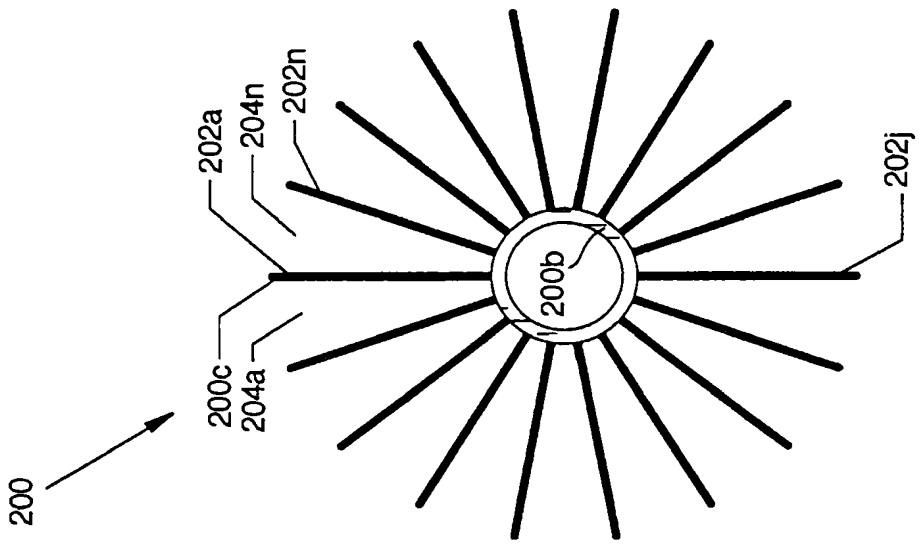

FIG. 13

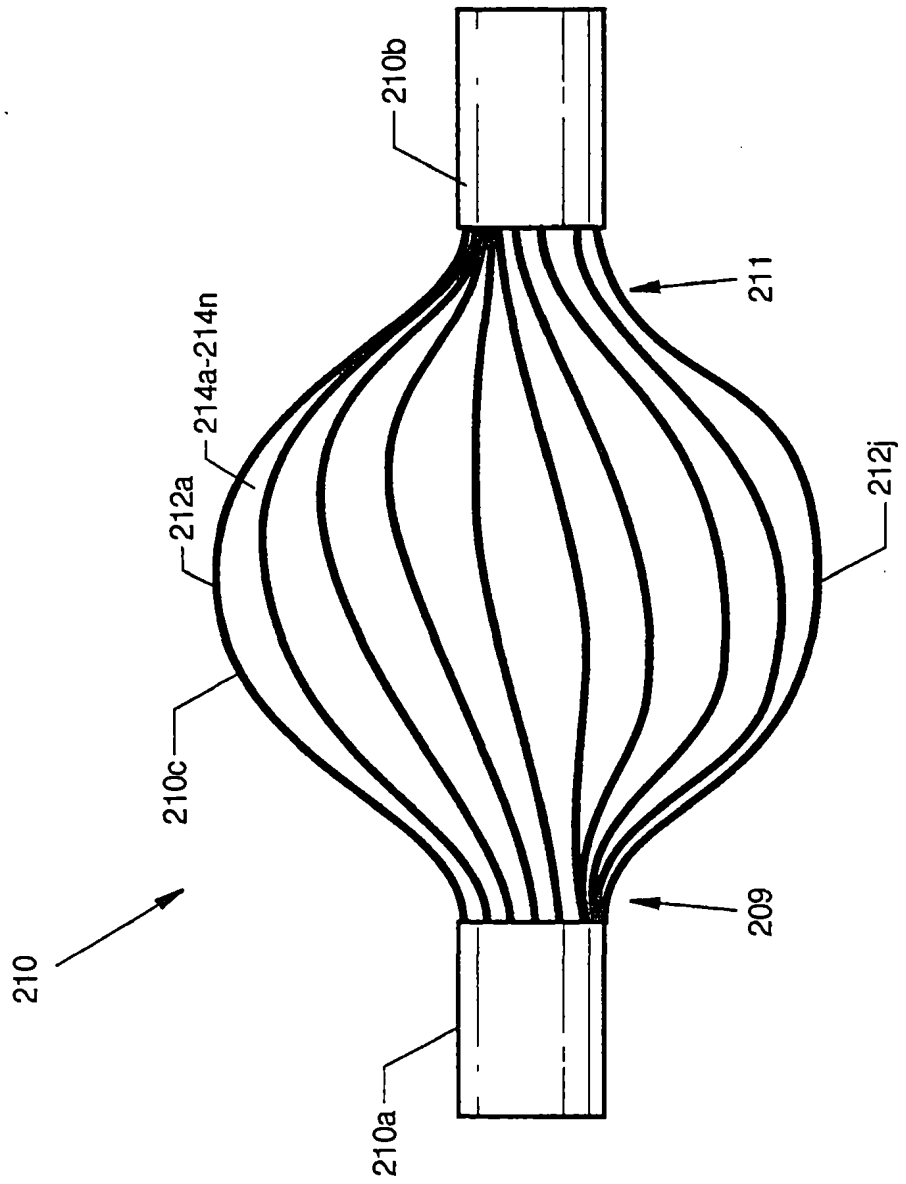

FIG. 14

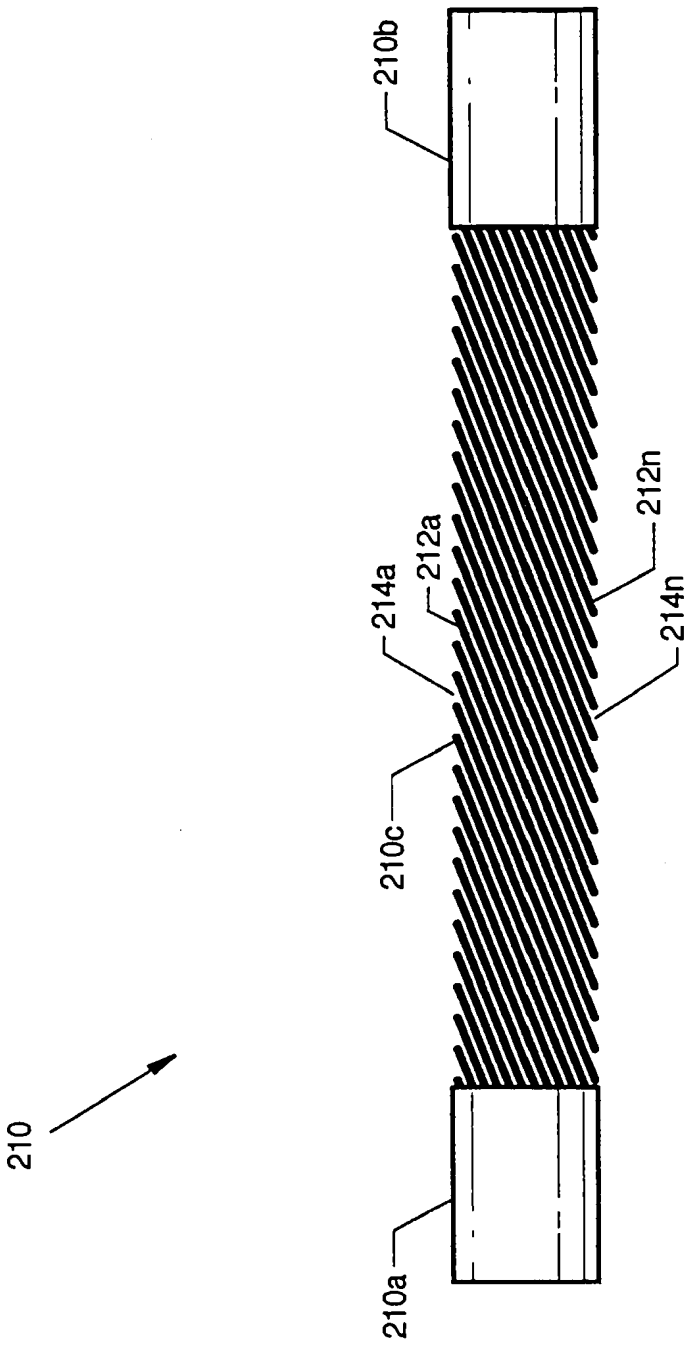

FIG. 15

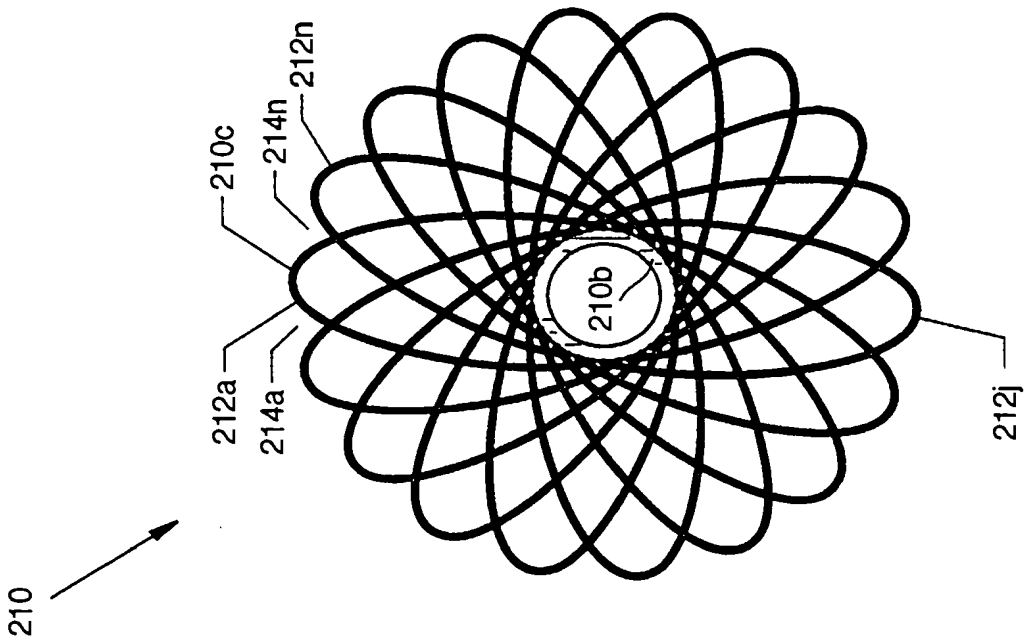

FIG. 16

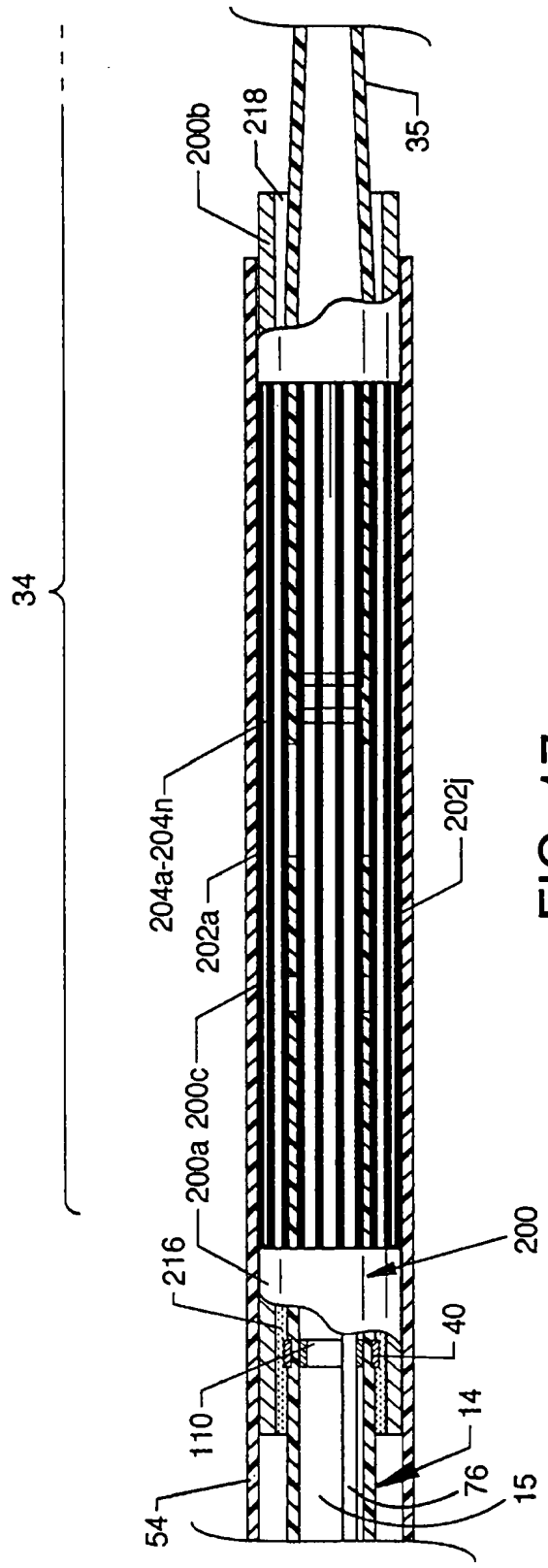
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FIG. 17

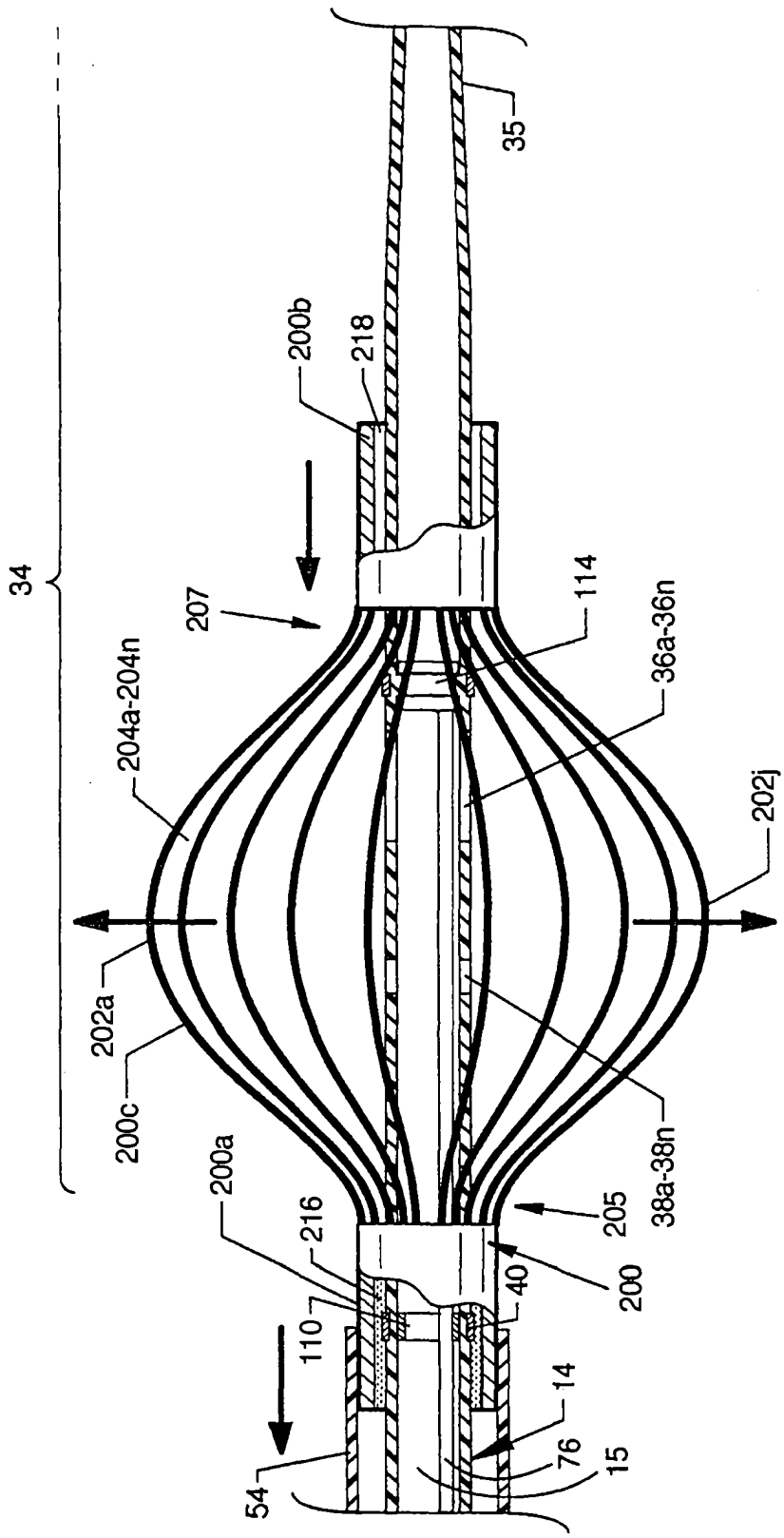
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FIG. 18

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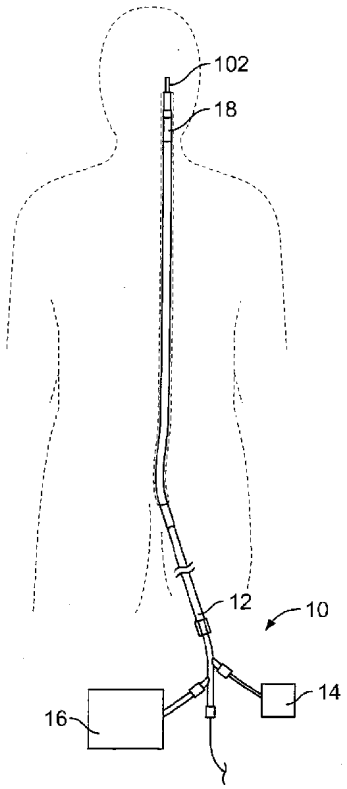
(54) Title: METHODS AND DEVICES FOR RESTORING BLOOD FLOW WITHIN BLOCKED VASCULATURE



(57) Abstract: The devices and methods described herein relate to clearing of blockages within body lumens, such as the vasculature, by addressing the frictional resistance on the obstruction prior to attempting to translate and/or mobilize the obstruction within the body lumen.

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METHODS AND DEVICES FOR RESTORING BLOOD FLOW WITHIN BLOCKED VASCULATURE

FIELD OF THE INVENTION

[0001] The devices and methods described herein relate to clearing of blockages within body lumens, such as the vasculature, by addressing the frictional resistance on the obstruction prior to attempting to translate the obstruction within the body lumen. In one variation, the devices and methods described below may treat conditions of ischemic stroke by remove blockages within arteries leading to the brain. Accordingly, variations of such methods and devices must navigate tortuous anatomy and vasculature without causing unacceptable damage to the anatomy. Also, the devices and methods first secure and surround the obstruction (such as a clot) prior to significantly moving the clot within the anatomy.

BACKGROUND OF THE INVENTION

[0002] Ischemic stroke occurs when a blockage in an artery leading to the brain 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.

[0003] The infarction may not develop or may be greatly limited given a rapid clearing of the blockage to reestablish the flow of blood. However, if left untreated, ischemic stroke may lead to the permanent loss of brain tissue, and can be marked by full or partial paralysis, loss of motor control, memory loss, or death.

[0004] Several different diseases may lead to an ischemic stroke. Typically, deposition of cholesterol (artherosclerosis), formation of blood clots, or other objects in the vessels may disrupt blood flow and lead to ischemic stroke. Furthermore, the substances that cause the blockages may break free from larger vessels outside the brain and become lodged within narrower arteries closer to the brain (embolism).

[0005] Ischemic stroke may be divided into thrombotic strokes and embolic strokes. A thrombotic stroke occurs when the building and rupturing of atheromatous plaque within the brain blocks cerebral arteries. Clinically referred to as cerebral thrombosis or cerebral infarction, this condition represents approximately 10% of all strokes. An embolic stroke occurs when a clot or emboli forms somewhere other than in the brain, such as in the cervical carotid artery or in the heart, and travels in the bloodstream until the clot becomes lodged and can not travel any further. When such a condition occurs in the arteries supplying the brain, the condition results in almost immediate physical and neurological effects.

[0006] While these are the most common causes of ischemic stroke, there are many other possible causes. Examples include use of drugs, trauma to the blood vessels of the neck, or blood clotting disorders.

[0007] Apart from surgical techniques, medical practitioners could address such blockages with the use of Tissue Plasminogen Activator (t-PA). However, t-PA must be

used within the first three hours of the onset of stroke symptoms and may take hours or even days to successfully restore flow. In addition, t-PA carries an increased risk of intracerebral hemorrhage. It is currently believed that the use of t-PA results in a 30% success rate as well as a 6% major complication rate. In view of these limitations, the majority of stroke patients in the U.S. do not receive t-PA treatment.

[0008] In addition, there are a number of surgical techniques used to remove blockages. For example, an embolectomy, involves incising a blood vessel and introducing a balloon-tipped device (such as the Fogarty catheter) to the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to translate the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Concentric Medical, Inc. of Mountain View, CA supplies devices for an interventional approach to the removal of obstructions. Concentric supplies a Merci ® Retriever system as a device based approach for the removal of clots. This system engages and ensnares a clot. Once captured, a balloon catheter inflates to temporarily halt forward blood flow while the clot is withdrawn. The clot is then pulled into the catheter and out of the body.

[0009] Typically, the existing means to remove obstructions do not address the frictional forces that act on the obstruction during removal of the obstruction. For example, some conventional devices engage the clot from the distal (or downstream) side. As the device is pulled proximally (or upstream), the device attempts to either engulf or ensnare the clot. However, due to the consistency of the clot and because the clot is typically well lodged within the vessel, the act of pulling the clot in a proximal direction cause the clot to also compress in an axial direction. This axial compression (when viewed along the

axis of the vessel) causes a contemporaneous radial expansion of the clot (when viewed relative to the vessel). As a result, the increase in diameter of the clot causes an increase in the frictional forces applied against the arterial wall. Thus, by not addressing the frictional forces acting on the obstruction, the process of removing the clot may actually increase the static force that would otherwise be required to remove or translate the clot within the vessel. Unfortunately, increasing the amount of force applied upon one side of the clot also increases the probability of complications during the procedure (e.g., fragmenting the clot, failing to remove the clot, failure to fully engulf/ensnare the clot, and/or device failure) and can cause potential damage to the surrounding vessel.

[0010] While there are other drugs and suppliers of devices for removal of blockages, there remains a need for methods and devices that improve the success rate and/or reduce the complication rate in restoring flow and thereby limit the damage from an ischemic stroke.

SUMMARY OF THE INVENTION

[0011] It should be noted that the present methods and devices may be used to treat blockages leading to ischemic stroke as well as to treat blockages (caused by "obstructions") within other parts of the body (i.e., unless specifically noted, the devices and methods are not simply limited to the cerebral 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.)

[0012] In one variation of the devices described herein, the device allows for surrounding the obstruction prior to attempting to translate or move the obstruction within the vessel. It should be noted that although minimal axial movement of the obstruction may take place, the device surrounds the obstruction before such movement causes significant distortion to the geometry of the obstruction resulting in an increase in the static force required to remove the obstruction from the vessel.

[0013] In another variation of the device, the device may include a low friction mode (such as a set of parallel wires, or wires extending axially along the lumen or vessel) that converts to an increased friction mode (such as a compressed set of wires acting on the obstruction or a twisted set of wires acting on the obstruction). The increase in friction is an increase in the friction between the obstruction and the device (as opposed to the vessel wall. In some cases, the low friction modes is a low surface area mode and the high friction mode is a high surface area mode. When configured in the low friction mode, the device is better suited to engage the obstruction without the undesirable effect of prematurely mobilizing the obstruction or compacting the obstruction (e.g., when wires are slid across the obstruction in a transverse motion). Upon engaging the obstruction, the device will conform to a high friction mode with respect to the obstruction (in some cases the device will have an increased surface area mode). This high friction mode permits the device to better grip the obstruction for ultimate removal of the obstruction.

[0014] The operation of the devices and method described herein secure the obstruction, overcome the elastic forces of the obstruction, then remove the obstruction from the anatomy without losing or fractionating the obstruction. In one variation of the invention, this is accomplished by the obstruction removal device interacting with the

obstruction in the following manner: (1) the traversing filaments traverse the obstruction by passing either through the obstruction or between the obstruction and the vascular wall; (2) the traversing portion is pulled proximally to engage the surrounding portion of the device around the obstruction, the surrounding portion engaging the obstruction without causing significant mobilization of the obstruction; (3) the obstruction removal device is pulled further proximally and the surrounding portion now mobilizes the obstruction.

[0015] As shown below, variations of the devices have a configuration that provides a path for a portion of the device to surround the obstruction. The paths are made using traversing filaments that allow for low frictional translation of a surrounding portion of the device over the obstruction without causing axial translation of the obstruction. This mechanism is described in more detail below.

[0016] Once in the proper position, a portion of the device (e.g., a surrounding portion) increases the frictional contact with the obstruction to disperse the pulling force more evenly across the obstruction. The increase points of contact allow for removal of the obstruction through tortuous anatomy while ensuring that the obstruction will not escape the encapsulation.

[0017] The surrounding portion may be fabricated in a variety of ways. For example, the surrounding portion may comprise one or more filaments. The surrounding portion may comprise a filter/bag, a coil, helical filament, a mesh structure, corrugated sheet, braided filaments, single wound or crossing filaments, tubes, membranes, films, solid wires, filled tubes, castings. Furthermore, the surrounding portion may have one or more ports,

openings, slits, and/or holes. The surrounding portion may be made by photochemical etching, mechanical drilling, weaving, braiding, laser cutting, or other means.

[0018] It should be noted that reference to surrounding or securing the obstruction includes partially and/or fully surrounding, engulfing, encapsulating, and/or securing the obstruction. In any case, the surrounding portion engages the obstruction prior to translation of the obstruction within the lumen. As noted herein, a portion of the device may convert into a surrounding section (e.g., when traversing wires reorient to increase the friction acting on the obstruction). Accordingly, the traversing section converts into a surrounding section.

[0019] The various devices described herein rely on a reduced profile for delivery and an expanded profile for ultimate removal of the clot. The devices, or components of the devices, may expand when released from a constraint, which allows the device, or component, to assume a predetermined shape. Alternatively, or in combination, the devices may be actuated to assume the expanded profiles. For example, the devices may be shape memory alloys that assume a profile when reaching a predetermined temperature (e.g., body temperature, or another temperature via delivery of energy to the shape memory alloy to trigger a phase change). Actuation may also include use any expandable member (such as a coiled spring, balloon, wedge, etc.) that mechanically or fluidly forces expansion of the device. These modes are well known by those skilled in the art and are intended to be within the scope of the disclosure. When combined with the inventive concepts disclosed herein, such combinations fall within the inventive scope of this disclosure.

[0020] As noted above, the filaments of the invention may be used to translate the device or may be used to form the surrounding section. Accordingly, the filaments may be single wound or crossing filaments, tubes, membranes, films, solid wires, filled tubes, castings or any similar structure. Moreover, the cross section of such filaments may vary as required (e.g., circular, oval, rectangular, square, or any such shape.) The filaments may be constructed from metals, polymers, composites, hydrogels, membranes, shape memory metals, shape memory polymers, or shape memory alloys, superelastic metals, superelastic polymers, or superelastic alloys, or combinations thereof. The filaments may have uniform diameters or varying diameters. The characteristics of the filament may be selected to better suit their required function. For example, they can be stiff, floppy, or even have different zones of flexibility. Moreover, the filaments may be braided or woven members, or the construction may provide that the filaments cross at one or many points in an overlapping, interwoven, criss-crossing or similar manner.

[0021] It should be noted that in some variations of the invention, all or some of the filaments (used in the surrounding portion of the device) can be designed to increase their ability to adhere to the obstruction. For example, the filaments of the surrounding portion may be coupled to an energy source (e.g., RF, ultrasonic, or thermal energy) to "weld" to the obstruction. Application of energy to the filaments may allow the surrounding portion to deform into the obstruction and "embed" within the obstruction. Alternatively, the filaments may impart a positive charge to the obstruction to partially liquefy the obstruction sufficiently to allow for easier removal. Alternatively, a negative charge could be applied to further build thombus and nest the device for better pulling force. The filaments may 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.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] Each of the following figures diagrammatically illustrates aspects of the invention. Variation of the invention from the aspects shown in the figures is contemplated.

[0023] Fig. 1 illustrates a system for removing obstructions from body lumens.

[0024] Fig. 2A illustrates an example of an obstruction lodged within a body lumen.

[0025] Figs. 2B to 2F illustrate advancement of a catheter beyond an obstruction and placement of traversing wires around the obstruction.

[0026] Fig. 3A illustrates an obstruction removal device once converted to a high friction mode.

[0027] Figs. 3B to 3E, show variations of a device having filaments that do not cross one another over the length of the obstruction when converted to a high friction mode.

[0028] Fig. 3F to 3G illustrate positioning a surrounding portion and translating the surrounding portion over the obstruction.

[0029] Figs. 3H to 3I illustrate an obstruction removal device deployed distally to an obstruction and then translated proximally over the obstruction.

[0030] Figs. 4A to 4E illustrate various additional configurations of devices able to assume a high friction mode covering over an obstruction.

[0031] Fig. 4F illustrates a variation of a device using an end of a catheter for converting the device to a high friction mode.

[0032] Figs. 5A to 5B illustrate another variation of a portion of an obstruction removal device configured to convert from a low friction mode to a high friction mode.

[0033] Figs. 6A to 6G illustrate various configurations of connectors for use with obstruction removal devices.

[0034] Figs. 6H to 6I illustrate a variation of a leading wire and connector having an unconstrained shape that is selected to be larger or simply different than the intended vessel to provide increased stability upon deployment.

[0035] Fig. 7A to 7D illustrates variations in which the connector is offset.

[0036] Figs. 8A to 8B illustrate hooks, fibers, and/or barbs for increasing the ability of the device to remove obstructions.

[0037] Figs. 9A to 9C illustrate additional variations of obstruction removal devices.

[0038] Figs. 10A to 10H also illustrate additional variations of obstruction removal devices, focusing mainly on variations of the surrounding portion.

[0039] Figs. 11A to 11C illustrate a variation where use of mechanical expansion distends the vessel wall and loosens the obstruction from the vessel.

DETAILED DESCRIPTION

[0040] 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.

[0041] Fig. 1 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

[0042] It is noted that any number of catheters or microcatheters maybe used to locate the catheter/microcatheter **12** carrying the obstruction removal device (not illustrated) 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.

[0043] 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.

[0044] Figs. 2A to 2F show one example of the deployment of the basic structure of connectors and traversing filaments about an obstruction in a vessel. The figures are intended to demonstrate the initial placement of the connectors and filaments immediately prior to removal of the obstruction either using a filter or by torquing, rotating and/or twisting the near connector relative to the far connector. This action converts the device from a low

friction device to a high friction device (where the low/high friction is the friction between the device and the obstruction). This action may also be referred to as a low surface area mode converting to a high surface area mode (in cases where the device extends beyond the obstruction and relative motion between ends of the device causes the device to shrink in axial length as it is twisted.) In addition, the number of connectors used, the shape of the connectors, as well as the number of filaments is intended to be for illustrative purposes only. It is contemplated that any variation of connector and/or filament may be deployed in a similar manner.

[0045] Fig. 2A illustrates an example of 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.

[0046] Fig. 2B shows another variation where a microcatheter **102** traverses the obstruction **2** between the wall of the vessel **6** and the obstruction **2**. As shown, the open end of the microcatheter **102** is distal to the obstruction **2** and is now positioned to deploy devices for removal of the obstruction **2**. This variation shows the device after removal of any guidewire. However, 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.

[0047] Fig. 2C illustrates deployment of a far connector **110** from within the microcatheter **102** distal to the obstruction **2**. The far connector **110** can be self-expanding such that it assumes, or moves towards, the expanded profile (as shown) upon deployment from the constraint of the microcatheter **102**.

[0048] The connectors **108**, **110** and/or traversing filaments **112** are designed to expand to the wall of the vessel when released from the catheter. This action allows the device **100** to surround the obstruction **2** prior to attempting to dislodge it. The components of the obstruction removal device **100** (e.g., the leading wires **106**, the connectors **108 110**, the traversing filaments **112**, and/or the surrounding portion **114**) may be fabricated from any biocompatible material that permits the function as described herein. In some variations, the material may comprise a shape memory or super-elastic alloy such as nitinol.

[0049] Fig. 2D shows withdrawal of the microcatheter **102** to the proximal side **3** of the obstruction **2**. The spacing between the far connector **110** and the obstruction **2** may vary. In some cases, the far connector **110** will move closer towards the obstruction **2** during spacing of the traversing filaments **112** as discussed below. The far connector **110** remains in place either using the inherent friction of the connector against the vessels and/or obstruction **2**. Alternatively, or in combination, a wire-type member (not shown) may provide an opposing force against the connector **110** as the catheter **102** moves proximal to the obstruction **2**.

[0050] As discussed herein, the obstruction removal devices include a plurality of filaments affixed between connectors. Since the far connector **110** is deployed at the distal side **4** of the obstruction **2**, withdrawal of the microcatheter **102** results in the plurality of filaments **112** spanning across the obstruction **2** as shown.

[0051] Fig. 2E illustrates deployment of a near connector **108**. Although the illustrated variation depicts the near connector **108** as being deployed from within the microcatheter **102**, alternative variations of the device include a near connector **108** that is located about the exterior of the microcatheter **102** or that is located about another delivery device (not shown) that is external to the microcatheter **102**. In this case, the near connector **108** is similar in profile and design to the far connector **110**. Accordingly, the near connector **108** self expands within the vessel **6** upon deployment from the microcatheter **102**. In some variations of the device, the near and far connectors **108, 110** may have different shapes or profiles. In any case, the profile of the connectors should be sufficient to expand the traversing wires sufficiently within the vessel to prepare for ensnaring or encapsulation of the obstruction **2**.

[0052] Fig. 2E also illustrates a connecting or leading wire/member **106** that couples the microcatheter **102** to the near connector **108**. The term leading wire, leading member, lead wire, etc. is intended to encompass a wire, tube, or any other structure that organizes and sometimes houses the smaller traversing filaments and/or near connectors described herein. Naturally, variations of the device include a leading wire **106** that is affixed to the far connector or the traversing wires. Moreover, the illustration depicts a single leading wire **106**. However, as noted below, the device can include a number of traversing wire **106** affixed to the near and/or far connectors **108, 110**.

[0053] Fig. 2F illustrates spacing the traversing filaments/wires **112** from simply spanning the obstruction **2** (as depicted in Fig. 2E). This action causes the filaments **112** to span the obstruction **2** while reorienting towards an exterior of the obstruction **2**. As noted herein, the traversing filaments **112** may remain partially or fully within the obstruction **2**. However, given that the filaments are spaced about the connectors, the filaments shall separate radially over the obstruction allowing for the subsequent ensnaring and removal.

[0054] Spacing the filaments may occur via a number of modes such as tensioning, expanding, spreading separating and/or withdrawing the filaments. In certain variations of the device, the filaments are moveable relative to a near connector and/or a far connector. Such a feature allows application of tension to the filaments while keeping the connector in place. This causes the filament to enter a state of tension for spacing about the wall of the vessel. Alternatively, the filaments may be fixed relative to the connectors. Upon deployment the filaments either self expand or are actuated to space about the vessel wall for eventual translation of the device over the obstruction. Regardless of the mode used, the filaments are intended to be positioned at or near a surface of the obstruction so that they can reduce the effects of any friction between the obstruction and the lumen or vessel wall.

[0055] Figs. 3A to 3I provide illustrations of device variations that ensnare the obstruction **2** after the device is in the configuration demonstrated by Fig. 2F above. Figs. 3A, 3C, and 3E represent variations of the device **100** after transforming from a low friction mode to a higher friction mode for removal of the obstruction. Figs. 3F and 3G illustrate a variation where a surrounding portion or filter covers the obstruction for its ultimate removal from the body.

[0056] Fig. 3A illustrates rotation of the near connector **108** relative to the far connector **110** to ensnare the obstruction **2** within the traversing wires **112**. As noted herein, either connector may rotate while another connector remains stationary. Alternatively, each connector may rotate with the rate of rotation for one connector being slower than another. In yet another variation, each connector may be rotated in opposite directions.

[0057] Although the variation shows only four traversing wires **112** any number of wires may be used so long as the rotation converts the traversing wires **112** into a relatively increased friction mode as compared to the low friction mode (when the traversing wires are in a parallel configuration). The low friction mode is represented by Fig. 2F. Fig. 3A illustrates the obstruction removal device **100** after rotation of the sets of traversing filaments and connectors. The result is that the obstruction **2** becomes ensnared (and/or encapsulated) and may be removed from the body. It should be noted that the same effect may be achieved by only rotating one connector or set of wires while keeping the other connector or set of wires stationary.

[0058] The rotation of the connector **108** can be performed in any number of ways as known to those skilled in the art. However, as shown in Fig. 3A, the lead wire **106** may comprise additional secondary wires attached to the connector **108**. So rotation of the connector **108** may occur via rotation of the lead wire and/or microcatheter. In any case, once the device assumes the increased friction mode condition, the obstruction **2** can be moved laterally within the vessel for removal.

[0059] Figs. 3A to 3E illustrate various configurations where relative rotation of the connectors **108**, **110** convert the device into a high friction mode. In Fig. 3A, the traversing filaments **112** twist and cross one another over the length of the obstruction **2**. However,

as shown in Figs. 3B to 3E, variations of the device **100** can have filaments **112** that do not cross one another over the length of the obstruction **2**. Although these variations are depicted to have single connectors on each end and four filaments, the design of the devices may vary as required by the particular application. In addition, the variations shown in Fig. 3B to 3E are shown without any catheter or leading wire for convenience to better illustrate the conversion of the device from a low friction mode to a high friction mode. Naturally, rotation of the catheter and/or lead wire will cause relative rotation between connectors.

[0060] In Fig. 3B, the device **100** is in a similar position as that shown in Fig. 2E. However, Fig. 3B shows a variation of a device **100** that is is selected to have a length greater than the targeted obstruction **2**. Upon rotation, the traversing filaments **112** remain uncrossed over the length of the obstruction **2**. In some cases, the filaments **112** may experience some twisting and will not remain parallel. However, the filaments **112** twist at twist points **116** that are proximal to and distal to the obstruction **2**. The relative motion of the connectors **108**, **110** as well as the twist point **116** causes the filaments **112** to exert a compressive force on the obstruction **2** without crossing one another over the length of the construction. Accordingly, while the surface area in contact between the filaments **112** and obstruction **2** remains relatively the same, the compressive action of the filaments **112** onto the obstruction converts the device **100** to a high friction mode on the obstruction.

[0061] Fig. 3D illustrates another variation of a device in a similar position as that shown in Fig. 2E. However, Fig. 3D shows a variation of a device **100** that extends proximally from the near end of the obstruction **2**. The relative motion between connectors **108**, **110**

causes a twist point **116** that is proximal to the obstruction **2**. As with the previous variation, the twist point **116** forces the filaments **112** against the obstruction **2** without crossing one another over the length of the obstruction **2**. As a result, the device **100** is now in high friction mode. In some cases, the filaments **112** may experience some twisting and will not remain parallel.

[0062] The variation of Figs. 3D and 3E also show the device **100** as including a cap or cover **118** about the distal connector **110**. The cap or cover **118** may be a bag, mesh, a continuation of the filaments **112**, and/or a surrounding portion **114** as discussed herein. The cap or cover **118** reduces the likelihood that the obstruction is driven through the far connector **110** during conversion of the device **100** from a low friction mode to a high friction mode.

[0063] Fig. 3F illustrates another variation of a device where the far connector **110** includes a filter or surrounding portion **114**. In variations of the device, the filter **114** is sufficiently permeable to allow blood flow therethrough. As noted above, the surrounding portion **114** may be any structure that covers, encapsulates, engulfs, and/or ensnares the obstruction either fully or partially. Accordingly, although the surrounding portion **114** is illustrated as a filter/bag, the surrounding portion **114** may comprise a coil, helical wire, a plurality of filaments, mesh structure, corrugated sheet, braided filaments, single wound or crossing filaments, tubes, filled tubes, castings, solid wires, membranes, films, capturing sections, (and may include ports, openings, slits, and/or holes made from photochemical etching, mechanical drilling) or any other structure that may translate or remove the obstruction **2** once the frictional component is addressed.

[0064] In this variation, the obstruction removal device **100** includes leading filaments **106** connected to a near connector **108**. In this example, the lead filament **106** may be a single wire or filament. Alternatively, the lead filament may comprise a single wire with a plurality of wires connecting the single wire to the ring.

[0065] As with the above examples, the illustrated variation shows the connector **108** as comprising a loop. However, as described herein, the connectors may also comprise various alternate shapes (e.g., 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, a flower shape, and a figure 8, other shapes, etc.) The near connector **108** is joined to a far connector **110** via a plurality of filaments **112**. It is noted that the inventive device shall include at least one, but preferably two or more traversing filaments **112**. It is further noted that the obstruction removal device **100** may be part of or integrated with the microcatheter **102**.

[0066] Fig. 3G illustrates withdrawal of the microcatheter **102** and the proximal translation of device **100** to place the surrounding portion **114** over the obstruction **2**. As the obstruction removal device **100** translates proximally, the traversing filaments **112** locate towards the exterior region of the obstruction **2**. As discussed above, the connectors **108**, **110** and traversing filaments **112** are designed to expand to (or near to) the perimeter of the wall of the vessel **2** and will usually locate to an exterior of the obstruction **2**. However, variations of the device and method include situations where the filaments locate substantially, but not fully, towards the outer region of the obstruction. In any case, the location of the filaments **112** will sufficiently overcome the frictional forces discussed herein. In the illustrated variation, the traversing filaments **112** substantially

span the length of the obstruction **2** by extending across the (proximal) **3** and (distal) **4** sides. These traversing filaments **112** provide paths for movement of the device **100** around the obstruction **2**. These paths allow for the surrounding portion **114** to engulf the entire obstruction **2** so that it may be removed from the vasculature and body.

[0067] Fig. 3H depicts an obstruction removal device **100** similar to that shown in Fig. 3F. However, in this variation, the near and far connectors **108, 110** are both deployed distally to the obstruction **2** and then translated back over the obstruction **2.** As shown, this deployment allows the traversing filaments **112** and the surrounding portion **114** to separate prior to contacting the occlusion **2**. Next, the entire device **100** is pulled over the occlusion **2** as described above. The variation of the device shown in figs 3F and 3H addresses the frictional forces that act between the obstruction and the vessel wall. Conventional devices that provide a bag attached to a wire (such as a vascular filter or distal protection device), are typically unable to remove the obstruction because they cannot overcome these frictional forces that lodge the clot against the vessel wall. Typically, such conventional devices are only designed to "catch" free floating clots. The traversing filaments described herein are configured to be positioned surrounding the obstruction. Their low friction with respect to the clot and the vessel allows for positioning of the filaments without disrupting or further compacting the clot against the vessel wall. Once the filaments surround or are spaced about the obstruction, they reduce the friction between the clot and vessel wall by reducing points of contact. Once these filaments surrounded the clot, they permit translation of the device to permit an encapsulating section **114** to surround the obstruction for removal.

[0068] Fig. 3I illustrates the device **100** of Fig. 3H when translated over the obstruction **2**. Eventually, the device **100** is pulled so that the surrounding portion or blood permeable filter **114** covers the obstruction **2** (as shown in Figs. 3F and 3G.

[0069] Fig. 4A illustrates another variation of a portion of an obstruction removal device **120** that is able to convert from a low friction mode covering to a higher friction mode covering. As noted above, this variation allows the medical practitioner to engage an obstruction with sparse coverage or low friction mode to overcome frictional forces. Upon properly engaging the obstruction, the device configuration allows conversion to a high friction mode for removal of the device and obstruction.

[0070] As shown, this variation of the obstruction removal device **120** includes two sets of traversing filaments **122, 124** and accompanying connectors **108, 110,** and **126, 128**. The first set **122** comprises a first near connector **108** and first far connector **110** with the accompanying traversing filaments. The second set **124** comprises the second near connector **126** and second far connector **128** with the accompanying traversing filaments **124**. The second set **124** is coaxially located over the first set **122**. The materials of the components may be as described above. In any case, the components are designed to expand to the perimeter of the vessel wall upon release from the catheter.

[0071] Fig. 4B shows the conversion of the obstruction removal device converting from a low friction mode (from Fig. 4A) to the high friction mode. For example, the first near connector **108** may be rotated relative to the second near connector **126** (where the second near connector may remain still or it may be rotated in an opposite direction relative to the first near connector as shown by the arrows). As a result, the traversing

filaments **122**, **124** deform in opposite directions to form a braid-type pattern increasing the friction mode over the obstruction.

[0072] Fig. 4C illustrates another variation of an obstruction removal device **100** in a low friction mode state. In this variation, the device **100** includes a near connector **108**, a far connector **110** with traversing filaments between the connectors **108**, **110**. The device **100** also includes an additional connector **132** with non-rotating filaments **134** extending to the far connector **110**. Fig. 4D illustrates the device **100** of Fig. 4C when the near connector **108** is rotated as shown by arrow **136**. However, the additional connector **132** and associated filaments **134** do not rotate. Upon rotation of the near connector **108** and twisting of the filaments **112**, all of the filaments **112** and **134** compress the obstruction over the length of the filaments. Such a feature creates additional friction on the obstruction by the device.

[0073] Fig. 4E shows another variation of an obstruction removal device **100** configured to move between low and high friction mode states. This variation includes additional support rings **138** located between connectors **108**, **110** and within the filaments **112**. The support rings keep the device **100** at a relatively constant diameter upon assuming the increased friction mode state. The support rings may be slightly undersized compared to the connectors, allowing the filaments to slightly compress the obstruction when converted to a high friction mode, but limiting the amount of compression by limiting the resulting diameter. The support rings **138** can be freely placed within the traversing filaments **112**. Alternatively, the rings **138** can be attached to one or more than one filament **112** to prevent undesired migration during deployment of the device.

[0074] Fig. 4F illustrates one example of a microcatheter **102** having a near connector **108** located externally to the catheter **102** with traversing filaments **112** extending out of the catheter and through the connector **108**. In this variation, rotation or torquing of the catheter **102** twists the filaments **112** resulting in increased friction mode of the filaments **112** over an obstruction. Fig. 4F illustrates an additional connector **132** having stationary filaments **134**. This variation of the device includes the external connector **108** directly coupled to a far connector (not shown.)

[0075] Fig. 5A illustrates a variation of the device **120** having only connectors **108** at one side of the device **120**. In this variation, the device **120** may still include two sets **108, 122 of** connectors and two sets of traversing filaments **112, 124.** Fig. 5B illustrates the variation of Fig. 5A after conversion to a high friction mode over the obstruction **2.** As discussed herein, the connectors may be other structures than loops. Moreover, variations of the invention include connectors that may be drawn down to a smaller size to facilitate removal from the body after securing the obstruction. This may be accomplished by torquing the device or part thereof, by re-sheathing part or all of the device, or by any mechanical means designed into the features of the device itself. Any of these actions, or combination thereof, may also serve to compress or decrease the diameter of the obstruction itself to facilitate removal from the body.

[0076] In another variation, the devices described herein may be assembled or constructed in-situ. For example, components of the device may include connectors, portions of the connectors, traversing elements, and/or surrounding sections. Any combination of these components can be placed in sequential fashion. Doing so forms a completed structure from deployment of a number of individual components. The end result is the formation

of a device as shown in the figures. Accordingly, such components of the device may be separately deployed in a manner that requires "assembly" of the components by a medical practitioner during the procedure.

[0077] Figs. 6A-6G illustrate variations of the connectors **108, 110**. Fig. 6A shows a loop-shaped connector **108, 110** having attachment points **140** for the filaments (not shown). As noted above, the connectors can be self-expanding or actuated to expand. The connectors may be fabricated from a polymer, a shape memory metal, polymer, or alloy, a super-elastic metal, polymer, or alloy, or any type of acceptable medical grade alloy, polymer, or composite structure. Also, the devices described herein can be fabricated from solid material, sheet or film, hollow or solid or filled rod or wire, braids, coils, etc. In the case of the polymer, additional strength may be added by constructing a composite layered device. For example, a hydrogel polymer with a hydrophilic fiber net inside that acts as exoskeleton to strengthen underlying polymer. As discussed herein, some variations of the device may include a distal connector having a cap or cover to prevent the obstruction from escaping as the device is removed. Furthermore, the sizing of the connectors within the vessel can assist in controlling relative rotation between connectors. For example, as a connector moves towards its expanded shape and engages a vessel or lumen wall, the rotational friction between the connector and lumen wall may prevent rotation. Accordingly, an adjacent connector may have a smaller expanded profile so that the connector experiences less friction when rotated.

[0078] Fig. 6A also illustrates the connector as having attachment points **140** for coupling the filaments to the connectors. These attachment points may allow for movement of the filaments relative to the connector to tension or separate the connectors (as described

above.) The filaments may also be coupled such that they are fixed relative to the connectors. In such a case, pulling of the lead wire will cause the entire assembly (e.g., connectors, filaments, and/o surrounding portion) to translate through the vessel.

[0079] Figs. 6B through 6G show various configurations of connectors for use in the present device. The connectors may be cut from sheets, fabricated from wire, molded, stamped, laser cut, photo or chemically etched, or fabricated in any other customary manner. Moreover, the connectors **108, 110** shown may be used in the near and/or far ends of the traversing wires. Different connector profiles may be incorporated into the device. In most cases, as shown, the connectors will form an arcuate shape so that they can expand against a vessel wall without causing trauma to the vessel. To illustrate the connector configurations, Figs. 6B to 6E are shown without any accompanying traversing filaments.

[0080] Fig. 6B shows a connector **108, 110**that is a loop shape as shown above. However, alternative configurations include a discontinuous profile, as illustrated in Fig. 6C and an overlapping profile, as illustrated in Fig. 6D. Such constructions allows the connector to adjust to varying diameters of body lumens. It is noted that a device may comprise loops of either construction. It should be also noted that although loops are shown, other variations may work equally well. Variations of the invention include connectors that may be drawn down to a smaller size to facilitate removal from the body once the obstruction is secured. This may be accomplished by torquing the device or part thereof, by re-sheathing part or all of the device or by any mechanical means designed into the features of the device itself. Any of these actions, or combination thereof, may also serve to compress or decrease the diameter of the obstruction itself to facilitate removal from the body. In addition, the overlapping connector, as shown in Fig. 6D, may include a

sliding ring type fastener that allows the overlapping connector loop to expand in the same plane.

[0081] In another example, the device may be fabricated from a polymer composite that makes up the fasteners, filaments, bags, etc. where the polymeric composite 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.

[0082] Fig. 6E shows a connector **108**, **110** having multiple sections **146**. As noted above, the connector sections **146** are arcuate shaped to minimize trauma to a vessel wall. However, other shapes are also intended to be within the scope of this disclosure.

[0083] Figs. 6B through 6G also illustrate various configurations of leading wires **106**. The connectors may have any number of leading wires. In some variations, it may be desirable to space the leading wires about the profile of the connector to aid in uniform movement of the device as it is pulled over the obstruction in the vessel.

[0084] Fig. 6F and 6G illustrate additional variations of leading wires **106** comprising shaped wire structures that form a "c" portion **142** of the connector. In one variation, when constrained the "c" shaped portions **142** move together to allow for delivery within the catheter. Upon release from the catheter, the portions **142** assume their resting shape and

expand within the vessel. The connecting portions **142** can be selected to have a size that is slightly greater than that of the vessel. Sizing the device relative to the target vessel may assist in placing the connecting portions **142** and accompanying traversing wires **112** against the wall of the vessel.

[0085] Fig. 6G shows an additional variation where a portion **144** of a leading wire **106** also has a "c" or semi-circular shape. In this configuration, the "c" shaped portion **144** of the leading wire **106** can also be sized relative to the target vessel. Accordingly, the portion **144** of the leading wire **106** functions to drive the connecting portion **142** against the vessel wall, while the shape of the connecting portion **142** also drives the traversing wire **112** against the vessel wall.

[0086] Fig. 6H illustrates another variation of a leading wire **106** having an unconstrained shape that is selected to be larger than the intended 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 this variation, the leading wire **106** has portions **144** that extend in opposite directions. This configuration is intended for illustrative purposes only. Variations include connecting portions pointing in an orthogonal direction from the main lead wire **106**, oblique, parallel (as shown), or a combination thereof. In any case, the unconstrained shape is intended to have a larger profile or size than the intended vessel. Moreover, the unconstrained shape may have an entirely different profile than the intended vessel. As shown in the figures, the profile of the device extends radially from the vessel. So when the device and leading wire are released, the leading wire 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.

[0087] Fig. 6I shows the same device of Fig. 6H when released from a microcatheter, sheath, or tube when in the vessel. Once released, the leading wire **106** and accompanying portions 144 attempt to revert to the unconstrained shape (as shown in Fig. 6H). However, the vessel 6 restrains the leading wire **106** and portions **144** such that the portions **144** act on the walls of the vessel. This feature allows for improved stability when deploying the leading wires and attached connectors and filaments within the vessel.

[0088] Figs. 7A through 7C illustrate variations of connectors **108, 110** where the connector portions are axially spaced by an offset **152**. One benefit of placing the connector portions **142, 146** in different planes is that the device may be delivered via a smaller microcatheter because the connector portions may be collapsed to a smaller diameter. Fig. 7A illustrates an offset **152** between connector portions **142** where each portion **142** is coupled to leading wires **148, 150** of varying lengths. Fig. 7B illustrates connector portions **146** spaced axially along a leading wire **106** to provide a gap **152**. Fig. 7C illustrates a connector **108, 110** having multiple components **146** where one or more components is axially spaced to provide a gap **152**. Fig. 7D shows a variation **108, 110** having a flower shape where each connector portion **146** is non-planar such that the gap **152** occurs over the length of the connector portion **146**.

[0089] 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 traversing filament and/or

surrounding portion may be coated with a hydrogel or adhesive that bonds to a thrombus. Accordingly, as the surrounding portion covers the clot, or as the device twists about the clot, the combination of the additive and the mechanical structure of the device may improve the effectiveness of the device in removing the obstruction.

[0090] Such improvements may also be mechanical or structural. For example, as shown in Fig. 8A, the traversing members may have hooks, fibers, or barbs **154** that grip into the obstruction when the device converts to a high friction mode. The hooks, fibers, or barbs **154** may also be incorporated into the surrounding portion. However, it will be important that such features do not hinder the ability of the practitioner to remove the device from the body. For example, Fig. 8B illustrates a magnified view of the area 8B from Fig. 8A. As illustrated, the barbs may be configured such that rotation in a particular direction causes the barbs to adhere to the obstruction. Such a configuration could also allow lateral movement without the barbs interfering with the vessel.

[0091] In addition to additives, the device can be coupled to an RF or other power source (such as **14** or **16** in Fig. 1), 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.

[0092] 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.

[0093] Although not illustrated, the devices and methods described herein may also be useful in removing obstructions lodged within bifurcations in the anatomy. Generally, bifurcations greatly increase the frictional forces on the obstructions since the obstruction tends to be lodged in both branching sections of the bifurcation. In such cases, the use of the presently described devices and methods may also include an additional "puller" device that advances beyond the portion of the obstruction partially located in the bifurcated vessel.

[0094] 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.

[0095] Figs. 9A through 9C illustrate additional variations of obstruction removal devices. In these variations, the traversing filaments **112** may comprise a mesh of wires or single connector. Figs. 9A to 9B illustrate a variation in which the connector **108** comprises a wire rather than a loop. However, the filaments and connectors should be configured to expand to the perimeter of the vessel wall as described previously.

[0096] Figs. 10A-10H illustrate various additional embodiments of obstruction removal devices **130** according to the present invention. In these variations, the connector **108** may form a rigid wire or hard polymer to assist in placement of the device **130**. The surrounding portion **132** may be fabricated from less rigid filaments that increase the point of contact

with the obstruction. The surrounding portion may also have filaments that undergo a phase change from non-rigid (or less rigid) to rigid.

[0097] It should be noted that any number of traversing filaments **112** or sets may be used in these variations.

[0098] In additional aspect of the invention, as shown in Fig. 11A to 11C, the methods and or devices may include expansion of the vessel wall adjacent to the obstruction either with a balloon, coil, or similar mechanical expansion means, drugs, fluids, etc. Such an improvement may aid where the obstruction expands part of the vessel wall thereby increasing the amount of force required for displacement. By distending the vessel wall as described above, the forces on the obstruction may be reduced allowing for ease of removal. Fig. 11A illustrates an obstruction **2** embedded within the vessel **6**. Figs. 11B to 11C illustrate variations where use of a coil (Fig. 11B) or a non-distensible balloon **162** (Fig. 11C) proximal to the obstruction **2** distends the vessel wall to loosen the obstruction **2** from the vessel. Accordingly, devices (whether described herein or other conventional devices) may then remove the obstruction **2**.

[0099] In those variations with a mechanical expansion means, the expansion means may be located on the delivery catheter of the obstruction removal device, on a wire member of the device, and/or on a separate catheter or wire used in combination with the first delivery catheter. However, variations of such configurations are within the scope of the invention.

[00100] In addition, devices and methods described herein may also use balloons proximal to the obstruction to stop or slow blood flow thereby preventing the blood from dislodging part or all of the obstruction.

[00101] 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.

CLAIMS

We claim:

1. An intravascular apparatus for removing an obstruction from a vessel of a patient, the device comprising:

a microcatheter having a size and flexibility to navigate within a neurovascular region of the patient;

a near connector having a first expanded profile when unconstrained, such that on deployment in the vessel the near connector expands towards the first expanded profile;

a far connector being collapsible to fit within the microcatheter and having a second expanded profile when unconstrained, such that on deployment in the vessel the second connector expands towards the second expanded profile;

at least one lead filament coupling the near connector to the microcatheter; and

a plurality of traversing filaments extending between the near and far connectors, and spaced apart on each connector such that spacing the traversing filaments causes the filaments to move towards a wall of the vessel.

2. The intravascular apparatus of claim 1, further comprising a blood permeable member affixed to the far connector, the blood permeable filter being collapsible to fit within the microcatheter.

3. The intravascular apparatus of claim 2, where the blood permeable member comprises a structure selected from the group consisting of a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a corrugated sheet, a braided wires, a single wound wire, a plurality of crossing wires, a tube, a membrane, and a film.

4. The intravascular apparatus of claim 2, further comprising a plurality of hook shaped members located on the blood permeable member.

5. The intravascular apparatus of claim 1, further comprising a third connector located adjacent to the near connector, and a plurality of non-rotating filaments extending

between the far connector and the third connector, where the first connector is rotatable relative to the far and third connectors to cause the plurality of traversing filaments to form a mesh pattern.

6. The intravascular apparatus of claim 1, where the near and far connectors are rotatable relative to each other to cause at least a section of the plurality of filaments to cross one another.

7. The intravascular apparatus of claim 6, where the near connector is stationary and the far connector is rotatable.

8. The intravascular apparatus of claim 6, where the far connector is stationary and the near connector is rotatable..

9. The intravascular apparatus of claim 6, where the far connector and the near connector are rotatable in opposite directions.

10. The intravascular apparatus of claim 1, where the near connector comprises a shape selected from 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, a flower shape, and a figure 8.

11. The intravascular apparatus of claim 1, where the far connector comprises a shape selected from 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, a flower shape, and a figure 8.

12. The intravascular apparatus of claim 1, further comprising a plurality of hook shaped members located on at least one filament.

13. The intravascular apparatus of claim 1, where the near connector is collapsible to fit within the microcatheter.

14. The intravascular apparatus of claim 1, where the near connector is affixed to an exterior of the microcatheter.

15. The intravascular apparatus of claim 1, where the near connector comprises a plurality of near connector portions.

16. The intravascular apparatus of claim 15, where at least one of the near connector portions is axially spaced from another near connector portion.

17. The intravascular apparatus of claim 1, where the far connector comprises a plurality of far connector portions.

18. The intravascular apparatus of claim 17, where at least one of the far connector portions is axially spaced from another far connector portion.

19. The intravascular apparatus of claim 1, further comprising at least one support ring within the filament.

20. The intravascular apparatus of claim 1, where the near connector, the lead filament, and the plurality of traversing filaments, are collapsible to fit within the microcatheter and are self-expanding upon deployment from the microcatheter.

21. The intravascular apparatus of claim 1, where the near connector, the lead filament, and the plurality of traversing filaments, are collapsible to fit within the microcatheter and are actuated to expand upon deployment from the microcatheter.

22. The intravascular apparatus of claim 1, further comprising a balloon located on the microcatheter, where on expansion the balloon expands the vessel allowing for removal of the obstruction.

23. The intravascular apparatus of claim 1, further comprising an expandable coil located on the microcatheter and having an expanded profile, where deployment of the coil causes expansion of the vessel allowing for removal of the obstruction.

24. The intravascular apparatus of claim 1, where at least one of the traversing filaments is moveable relative to the near connector so that tension may be applied to the respective filament to spread the filaments.

25. The intravascular apparatus of claim 1, where at least one of the traversing filaments is moveable relative to the far connector so that tension may be applied to the respective filament to spread the filaments.

26. The intravascular apparatus of claim 1, where at least one of the traversing filaments is moveable relative to the near and far connectors so that tension may be applied to the respective filament to spread the filaments.

27. The intravascular apparatus of claim 1, where the filaments are fixed relative to the near and far connectors such that axial movement of the lead wire causes axial movement of the near and far connectors and filaments.

28. An intravascular apparatus for removing an obstruction from a vessel of a patient, the device comprising:

a microcatheter having a size and flexibility to navigate within a neurovascular region of the patient;

a near connector having a first expanded profile when unconstrained, such that on deployment in the vessel the near connector expands towards the first expanded profile;

at least one lead filament coupling the near connector to the microcatheter; and

a plurality of traversing filaments connected to the near connector and spaced apart on the near connector such that spacing the traversing filaments causes the filaments to move towards a wall of the vessel.

29. The intravascular apparatus of claim 28, further comprising a blood permeable member affixed to the far connector, the blood permeable filter being collapsible to fit within the microcatheter.

30. The intravascular apparatus of claim 29, where the blood permeable member comprises a structure selected from the group consisting of a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a corrugated sheet, a braided wires, a single wound wire, a plurality of crossing wires, a tube, a membranes, and a film.

31. The intravascular apparatus of claim 29, further comprising a plurality of hook shaped members located on the blood permeable member.

32. The intravascular apparatus of claim 28, further comprising a second connector located adjacent to the near connector, and a plurality of non-rotating filaments connected to the second connector, where the first connector is rotatable relative to the second connectors to cause the plurality of traversing filaments to form a helical pattern.

33. The intravascular apparatus of claim 28, where the near and far connectors are rotatable relative to each other to cause at least a section of the plurality of filaments to cross one another.

34. The intravascular apparatus of claim 33, where the far connector is stationary and the near connector is rotatable..

35. The intravascular apparatus of claim 33, where the far connector and the near connector are rotatable in opposite directions.

36. The intravascular apparatus of claim 28, where the near connector comprises a shape selected from 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, a flower shape, and a figure 8.

37. The intravascular apparatus of claim 28, where the first expanded profile comprises an arcuate shape.

38. The intravascular apparatus of claim 28, further comprising a plurality of hook shaped members located on at least one filament.

39. The intravascular apparatus of claim 28, where the near connector is collapsible to fit within the microcatheter.

40. The intravascular apparatus of claim 28, where the near connector is affixed to an exterior of the microcatheter.

41. The intravascular apparatus of claim 28, where the near connector comprises a plurality of near connector portions.

42. The intravascular apparatus of claim 41, where at least one of the near connector portions is axially spaced from another near connector portion.

43. The intravascular apparatus of claim 28, further comprising at least one support ring within the filament.

44. The intravascular apparatus of claim 28, where the near connector, the lead filament, and the plurality of traversing filaments, are collapsible to fit within the microcatheter and are self-expanding upon deployment from the microcatheter.

45. The intravascular apparatus of claim 28, where at least one of the traversing filaments is moveable relative to the near connector so that tension may be applied to the respective filament to spread the filaments.

46. The intravascular apparatus of claim 28, where the filaments are fixed relative to the near connector such that axial movement of the lead wire causes axial movement of the near connector and filaments.

47. An intravascular apparatus for removing an obstruction from a vessel, the device comprising:

a microcatheter having a size and flexibility to navigate within a neurovascular region of the patient;

a near connector being self expanding and having a first expanded profile when unconstrained, such that on deployment in the vessel the near connector self expands towards the first expanded profile;

a far connector being collapsible to fit within the microcatheter and being self-expanding to assume a second expanded profile when unconstrained, such that on deployment in the vessel the second connector expands towards the second expanded profile and expands within the vessel;

at least one lead filament coupling the near connector to the microcatheter;

a plurality of traversing filaments extending between the near and far connectors, and spaced apart on each connector such that spreading the traversing filaments causes the filaments to move towards an exterior of the obstruction; and

a blood permeable filter member affixed to the far connector, the blood permeable filter being collapsible to fit within the microcatheter and self-expanding to expand in the vessel upon deployment.

48. The intravascular apparatus of claim 47, where the blood permeable member comprises a structure selected from the group consisting of a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a corrugated sheet, a braided wires, a single wound wire, a plurality of crossing wires, a tube, a membranes, and a film.

49. The intravascular apparatus of claim 47, further comprising a plurality of hook shaped members located on the blood permeable member.

50. The intravascular apparatus of claim 47, further comprising a third connector located adjacent to the near connector, and a plurality of non-rotating filaments extending between the far connector and the third connector, where the first connector is rotatable relative to the far and third connectors to cause the plurality of traversing filaments to form a helical pattern.

51. The intravascular apparatus of claim 47, where the near connector comprises a shape selected from 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, a flower shape, and a figure 8.

52. The intravascular apparatus of claim 47, where the far connector comprises a shape selected from 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, a flower shape, and a figure 8.

53. The intravascular apparatus of claim 47, where the first expanded profile comprises an arcuate shape.

54. The intravascular apparatus of claim 47, further comprising a plurality of hook shaped members located on at least one filament.

55. The intravascular apparatus of claim 47, where the near connector is collapsible to fit within the microcatheter.

56. The intravascular apparatus of claim 47, where the near connector is affixed to an exterior of the microcatheter.

57. The intravascular apparatus of claim 47, where the near connector comprises a plurality of near connector portions.

58. The intravascular apparatus of claim 57, where at least one of the near connector portions is axially spaced from another near connector portion.

59. The intravascular apparatus of claim 47, where the far connector comprises a plurality of far connector portions.

60. The intravascular apparatus of claim 59, where at least one of the far connector portions is axially spaced from another far connector portion.

61. The intravascular apparatus of claim 47, further comprising at least one support ring within the filament.

62. The intravascular apparatus of claim 47, where the a near connector, the lead filament, and the plurality of traversing filaments, are collapsible to fit within the microcatheter and are self-expanding upon deployment from the microcatheter.

63. An intravascular apparatus for removing an obstruction from a vessel of a patient, the device comprising:

a microcatheter having a size and flexibility to navigate within a neurovascular region of the patient;

a first and second near connector, each being self expanding and having a first expanded profile when unconstrained, such that on deployment in the vessel the near connectors expand towards the first expanded profile;

at least a firstfar connector, being collapsible to fit within the microcatheter and having a second expanded profile when unconstrained, such that on deployment in the vessel the far connectors expand towards the second expanded profile and expands within the vessel;

at least one lead filament coupling at least one of the near connectors to the microcatheter;

a plurality of first filaments extending between the first near and far connector;

a plurality of second traversing filaments extending between the second near and far connector;

where the first near and far connectors are coaxial with the second near and far connectors such that rotation of the first near connector relative to the second near connector causes the first and second traversing filaments to form a mesh shape.

64. The intravascular apparatus of claim 63, further comprising a second far connector where a first portion of the plurality of second traversing elements extend to the first far connector and a second portion of the plurality of second traversing elements extend to the second far connector.

65. The intravascular apparatus of claim 63, further comprising a blood permeable member affixed to the far connector, the blood permeable filter being collapsible to fit within the microcatheter.

66. The intravascular apparatus of claim 65, where the blood permeable member comprises a structure selected from the group consisting of a basket, a filter, a bag,

a coil, a helical wire structure, a mesh, a corrugated sheet, a braided wires, a single wound wire, a plurality of crossing wires, a tube, a membranes, and a film.

67. The intravascular apparatus of claim 65, further comprising a plurality of hook shaped members located on the blood permeable member.

68. The intravascular apparatus of claim 63, where the expanded profile of the near connectors comprise a shape selected from 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, a flower shape, and a figure 8.

69. The intravascular apparatus of claim 63, where the expanded profile of the far connectors a shape selected from 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, a flower shape, and a figure 8.

70. The intravascular apparatus of claim 63, further comprising a plurality of hook shaped members located on at least one filament.

71. The intravascular apparatus of claim 63, where the near connectors are collapsible to fit within the microcatheter.

72. The intravascular apparatus of claim 63, where at least one of the near connectors is affixed to an exterior of the microcatheter.

73. The intravascular apparatus of claim 63, where the near connectors comprise a plurality of near connector portions.

74. The intravascular apparatus of claim 73, where at least one of the near connector portions is axially spaced from another near connector portion.

75. The intravascular apparatus of claim 63, where the far connectors comprise a plurality of far connector portions.

76. The intravascular apparatus of claim 75, where at least one of the far connector portions is axially spaced from another far connector portion.

77. The intravascular apparatus of claim 63, further comprising at least one support ring within the filament.

78. The intravascular apparatus of claim 63, where the near connector, the lead filament, and the plurality of traversing filaments, are collapsible to fit within the microcatheter and are self-expanding upon deployment from the microcatheter.

79. A method for removing an obstruction from a blood vessel, the method comprising the steps of:

advancing an obstruction removal device comprising at least a plurality of filaments from a near end of the obstruction to beyond a far end of the obstruction;

expanding at least one filament towards a wall of the blood vessel;

withdrawing the plurality of filaments, such that the filament is located towards an exterior of and span across at least a portion of the obstruction; and

surrounding the obstruction with at least a portion of the obstruction removal device.

80. The method of claim 79, where withdrawing the plurality of filaments comprises relocating the plurality of filaments without substantially dislocating or mobilizing the obstruction within the blood vessel.

81. The method of claim 79, further comprising withdrawing the surrounded obstruction from the blood vessel by withdrawing the obstruction removal device from the vessel.

82. The method of claim 79, where the obstruction removal device further comprises a surrounding portion attached to an end portion of the filaments, and where surrounding the obstruction comprises continuing to withdraw the plurality of filaments until the surrounding portion covers the obstruction.

83. The method of claim 4, where the surrounding portion comprises a structure selected from the group consisting of a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a corrugated sheet, a braided wires, a single wound wire, a plurality of crossing wires, a tube, a membranes, a filled tube, a solid wire, a casting, and a film.

84. The method of claim 79, where withdrawing the plurality of filaments comprises locating the surrounding portion of the device substantially around the obstruction without substantially dislocating or mobilizing the obstruction within the blood vessel.

85. The method of claim 79, where surrounding the obstruction comprises rotating a first portion of the plurality of filaments relative to a second portion of the plurality of filaments to wrap the plurality of filaments around the obstruction.

86. The method of claim 7, where the plurality of filaments comprises a plurality of sets of filaments, and where rotation of the plurality of filaments comprises rotating one set relative to another set.

87. The method of claim 79, where advancing the obstruction removal device comprises advancing the obstruction removal device through the obstruction.

88. The method of claim 79, where advancing the obstruction removal device comprises advancing the obstruction removal device around the obstruction.

89. The method of claim 79, further comprising advancing a catheter adjacent to the obstruction and where advancing the obstruction removal device comprises advancing the obstruction removal device through the catheter to the obstruction.

90. The method of claim 79, after surrounding the obstruction, further comprising withdrawing at least a portion of the obstruction removal device within the catheter and removing the catheter from the vessel.

91. The method of claim 79, where the plurality of filaments comprise a mesh of filaments.

92. The method of claim 79, where the plurality of filaments each comprise a first and second end and where each end is attached to at least a near connector.

93. The method of claim 92, where the near connector comprises a shape selected from 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, a flower shape, and a figure 8.

94. The method of claim 92, where the near connector is discontinuous.

95. The method of claim 92, where the near connector is adjustable in size.

96. The method of claim 92, where the near connector has a 3-dimensional profile such that portions thereof lie in a plurality of planes.

97. The method of claim 92, where the near connector comprises a plurality of connector sections.

98. The method of claim 79, where the plurality of filaments each comprise a first and second end and where the second end is attached to at least a far connector.

99. The method of claim 98, where the plurality of filaments comprises a plurality of sets of filaments such that the first set of filaments is connected to the near and far connector and where additional sets of filaments are each connected to at least two additional connectors.

100. The method of claim 98, where the far connector comprises a shape selected from 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, a flower shape, and a figure 8.

101. The method of claim 98, where far near connector is discontinuous.

102. The method of claim 98, where far connector is adjustable in size.

103. The method of claim 98, where far connector has a 3-dimensional profile such that portions thereof lie in a plurality of planes.

104. The method of claim 98, where the far connector comprises a plurality of connector sections.

105. The method of claim 79, where the obstruction comprises a blood clot, plaque, cholesterol, thrombus, a naturally occurring foreign body, a non-naturally occurring foreign body or a combination thereof.

106. The method of claim 79, further comprising expanding the vessel adjacent to the obstruction to decrease a friction between the vessel and the obstruction.

107. The method of claim 106, where expanding the vessel comprises expanding a balloon member adjacent to the obstruction.

108. The method of claim 106, where expanding the vessel comprises expanding a coil member adjacent to the obstruction.

109. A method for removing an obstruction from a blood vessel, the method comprising:

converting an obstruction removal device into a high friction mode, from a low friction mode over the obstruction, where the high friction mode increases frictional contact between the obstruction removal device and the obstruction; and

withdrawing the traversing device and obstruction from the blood vessel.

110. The method of claim 109, further comprising positioning the obstruction removal device comprising at least a plurality of filaments over the obstruction in a low friction mode, where the low friction mode encounters low frictional forces over the obstruction.

111. The method of claim 109, where translating the traversing device comprises translating the traversing device over the obstruction without dislocating or mobilizing the obstruction within the blood vessel.

112. The method of claim 109, where converting the traversing device comprises rotating a first portion of the plurality of filaments relative to a second portion of the plurality of filaments to wrap the plurality of filaments around the obstruction.

113. The method of claim 109, where the plurality of wires comprises a plurality of sets of filaments, and where rotation of the plurality of filaments comprises rotating one set relative to another set.

114. The method of claim 109, where advancing the obstruction removal device comprises advancing the obstruction removal device through the obstruction.

115. The method of claim 109, where advancing the obstruction removal device comprises advancing the obstruction removal device around the obstruction.

116. The method of claim 109, where the plurality of filaments comprise a mesh of filaments.

117. The method of claim 109, where the plurality of filaments each comprise a first and second end and where each end is attached to at least a near connector.

118. The method of claim 117, where the connector comprises a shape selected from 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, a flower shape, and a figure 8.

119. The method of claim 118, where the connector has a 3-dimensional profile such that portions thereof lie in a plurality of planes.

120. The method of claim 118, where the connector comprises a plurality of connector sections.

121. The method of claim 117, where the connector is discontinuous.

122. The method of claim 117, where the connector is adjustable in size.

123. The method of claim 117, where second end is attached to at least a far connector.

124. The method of claim 117, where the plurality of filaments comprises a plurality of sets of filaments such that the first set of filaments is connected to the near and far connector and where additional sets of filaments are each connected to at least two additional connectors.

125. The method of claim 109, where the obstruction comprises a blood clot, plaque, cholesterol, thrombus, a naturally occurring foreign body, a non-naturally occurring foreign body, or combination thereof.

126. The method of claim 109, where converting the obstruction removal device into the high friction mode comprises rotating a near portion of the obstruction removal device relative to a far portion of the obstruction removal device.

127. The method of claim 126, comprises rotating the near connector while holding the far connector stationary.

128. The method of claim 126, comprises rotating the far connector while holding the near connector stationary.

129. The method of claim 126, comprises rotating the near connector and rotating the near connector in an opposite direction.

130. The method of claim 126, further comprising a plurality of filaments extending from the near portion to the far portion of the obstruction removal device, where rotating the near portion causes the filaments adjacent to the near portion to twist and cross proximal to the obstruction causing a section of the filaments engaging the obstruction to apply a compressive force on the obstruction without twisting and crossing over one another over a length of the obstruction.

131. The method of claim 130, where rotating the portions also causes the filaments adjacent to the far portion to twist and cross distally to the obstruction.

132. The method of claim 126, further comprising a plurality of filaments extending from the near portion to the far portion of the obstruction removal device, where rotating the portions causes the filaments to twist over the obstruction causing a compressive force on the obstruction.

133. The method of claim 109, further comprising expanding a balloon member adjacent to the obstruction to expand the vessel.

134. The method of claim 109, further comprising expanding a coil member adjacent to the obstruction to expand the vessel.

135. A method for removing an obstruction from a blood vessel, the method comprising the steps of:

advancing an obstruction removal device within the blood vessel, where the obstruction removal device comprises a near and far connector each having a reduced profile and each having an expanded shape when unconstrained, where the obstruction removal device includes a plurality of filaments extending between the connectors;

positioning the far connector distal to the far end of the obstruction, such that the far connector expands towards the expanded shape in the vessel;

positioning the near connector proximal to the near end of the obstruction such that the near connector expands towards the expanded shape in the vessel and such that the filaments span across the obstruction;

spacing at least one of the filaments from an adjacent filament such that the respective filament separate about the obstruction;

ensnaring the obstruction removal device about the obstruction; and

withdrawing the obstruction removal device and obstruction from the blood vessel.

136. The method of claim 135, where spacing the filaments comprises tensioning the filaments.

137. The method of claim 135, where ensnaring the obstruction removal device comprises rotating the near connector relative to the far connector to wrap the filaments about the obstruction.

138. The method of claim 137, comprises rotating the near connector while holding the far connector stationary.

139. The method of claim 137, comprises rotating the far connector while holding the near connector stationary.

140. The method of claim 137, comprises rotating the near connector and rotating the far connector in an opposite direction.

141. The method of claim 137, further comprising a third connector adjacent to the near connector, and a plurality of non-rotating filaments connecting joining the far connector and the third connector, where the third connector remains stationary during rotation of the near connector.

142. The method of claim 135, where spacing the filament occurs without substantially dislocating or mobilizing the obstruction within the blood vessel.

143. The method of claim 135, further comprising a blood permeable member located distal to the far connector, where ensuring the obstruction removal device comprises translating the obstruction removal device until the blood permeable bag covers the obstruction.

144. The method of claim 143, where the blood permeable member comprises a structure selected from the group consisting of a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a corrugated sheet, a braided wires, a single wound wire, a plurality of crossing wires, a tube, a filled tube, a casting, a solid wire, a membranes, and a film.

145. The method of claim 135, where ensnaring the obstruction removal device about the obstruction comprises withdrawing the plurality of filaments and locating a capturing portion of the device substantially around the obstruction without dislocating or mobilizing the obstruction within the blood vessel.

146. The method of claim 135, where advancing the obstruction removal device comprises advancing the obstruction removal device through the obstruction.

147. The method of claim 135, where advancing the obstruction removal device comprises advancing the obstruction removal device around the obstruction.

148. The method of claim 135, further comprising advancing a catheter through the obstruction and where advancing the obstruction removal device comprises advancing the obstruction removal device through the catheter.

149. The method of claim 135, where the arcuate shape comprises a shape selected from 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, a flower shape, and a figure 8.

150. The method of claim 135, where the connector is discontinuous.

151. The method of claim 135, where the obstruction comprises a blood clot, plaque, cholesterol, thrombus, a naturally occurring foreign body, a non-naturally occurring foreign body or a combination thereof.

152. The method of claim 135, further comprising expanding a balloon member adjacent to the obstruction to expand the vessel.

153. The method of claim 135, further comprising expanding a coil member adjacent to the obstruction to expand the vessel.

154. A method for removing an obstruction from a blood vessel, the method comprising the steps of:

advancing an obstruction removal device within the blood vessel, where the obstruction removal device comprises a near connector being constrained in a reduced profile and having an expanded profile when unconstrained, where the obstruction removal device includes a plurality of filaments connected to the near connector;

positioning the near connector proximal to the near end of the obstruction such that the near connector portion expands towards the expanded shape in the vessel and such that the filaments span across the obstruction;

spacing at least one of the filaments from an adjacent filament such that the respective filament separate about the obstruction;

ensnaring the obstruction removal device about the obstruction; and

withdrawing the obstruction removal device and obstruction from the blood vessel.

155. The method of claim 154, where ensnaring the obstruction removal device comprises rotating the near connector to wrap the filaments about the obstruction.

156. The method of claim 154, where spacing the filament occurs without substantially dislocating or mobilizing the obstruction within the blood vessel.

157. The method of claim 156, where ensnaring the obstruction removal device comprises locating a blood permeable member over the obstruction.

158. The method of claim 156, where the blood permeable member comprises a structure selected from the group consisting of a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a corrugated sheet, a braided wires, a single wound wire, a plurality of crossing wires, a tube, a filled tube, a casting, a solid wire, a membrane, and a film.

159. The method of claim 156, where ensaring the obstruction removal device about the obstruction comprises locating a blood permeable member over the obstruction without dislocating or mobilizing the obstruction within the blood vessel.

160. The method of claim 154, where advancing the obstruction removal device comprises advancing the obstruction removal device through the obstruction.

161. The method of claim 154, where advancing the obstruction removal device comprises advancing the obstruction removal device around the obstruction.

162. The method of claim 154, further comprising advancing a catheter through the obstruction and where advancing the obstruction removal device comprises advancing the obstruction removal device through the catheter.

163. The method of claim 154, where the near connector comprises a shape selected from 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, a flower shape, and a figure 8.

164. The method of claim 154, where the connector is discontinuous.

165. The method of claim 154, where the obstruction comprises a blood clot, plaque, cholesterol, thrombus, a naturally occurring foreign body, a non-naturally occurring foreign body or a combination thereof.

166. The method of claim 154, further comprising expanding a balloon member adjacent to the obstruction to expand the vessel.

167. The method of claim 154, further comprising expanding a coil member adjacent to the obstruction to expand the vessel.

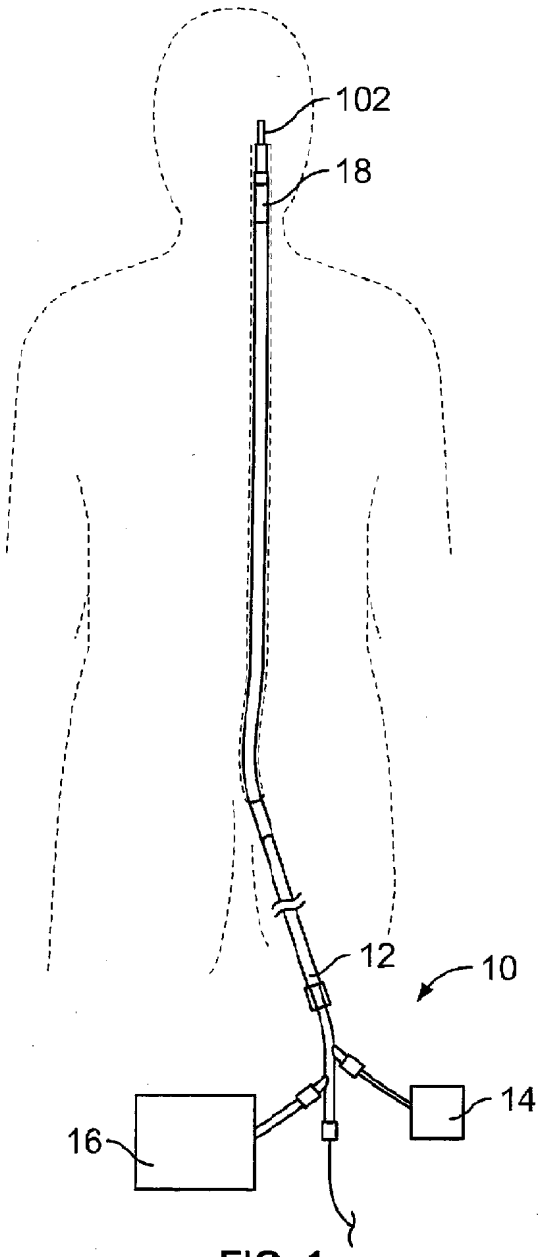

FIG. 1

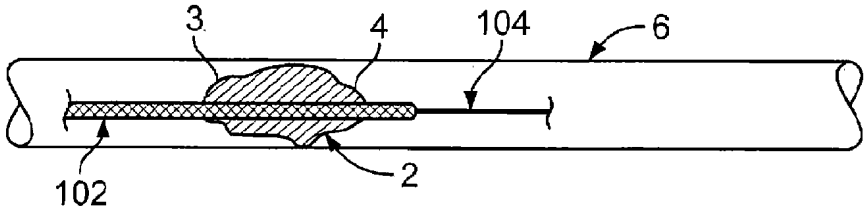

FIG. 2A

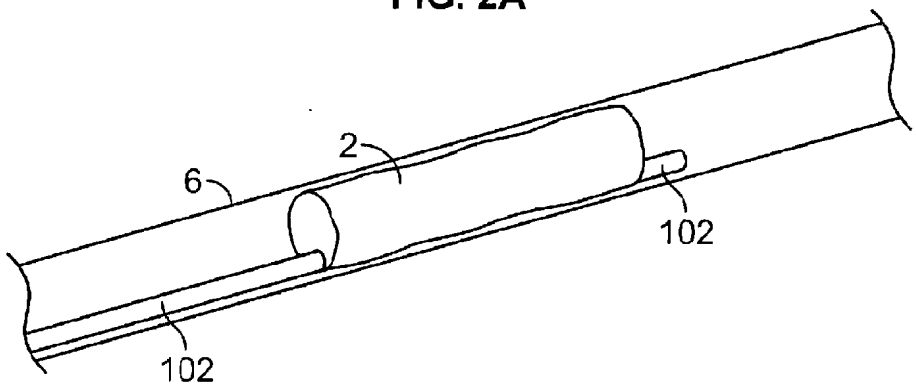

FIG. 2B

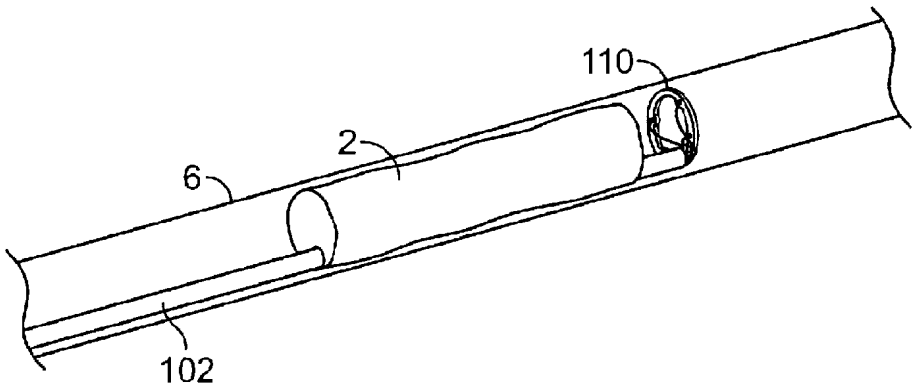

FIG. 2C

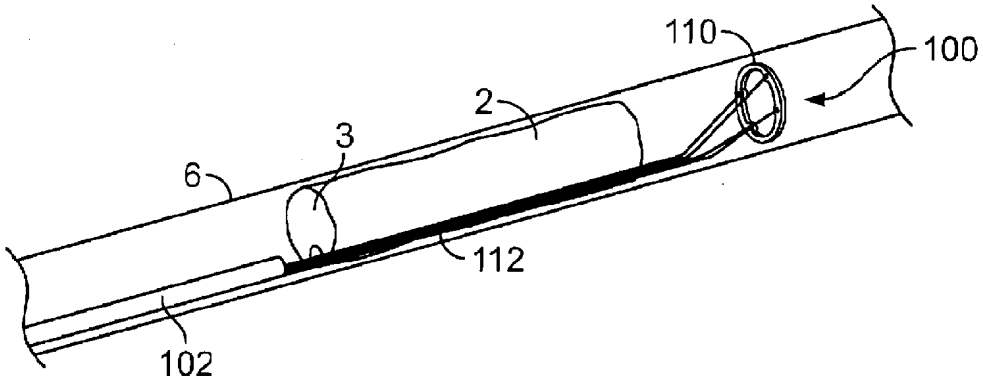

FIG. 2D

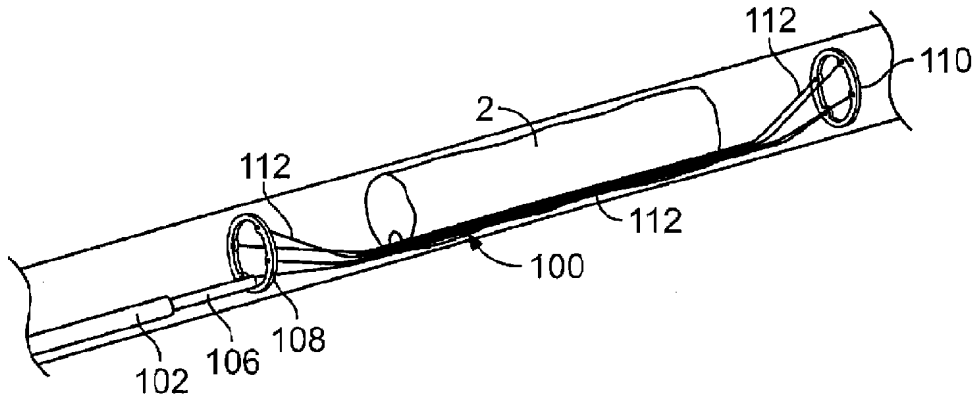

FIG. 2E

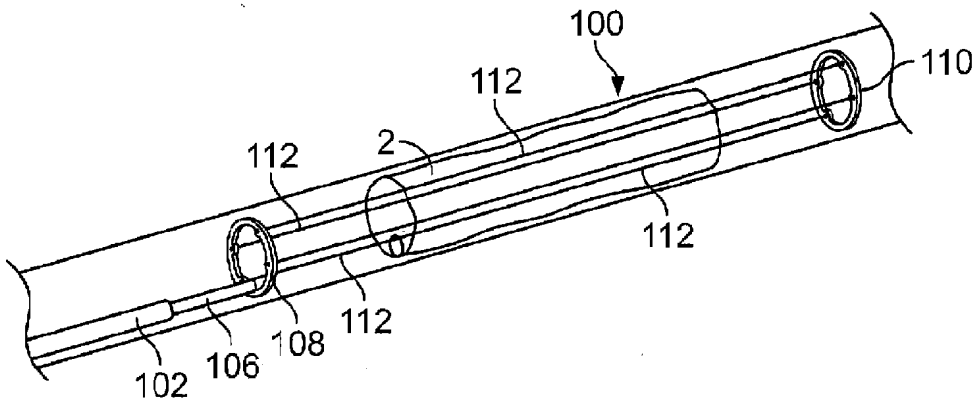

FIG. 2F

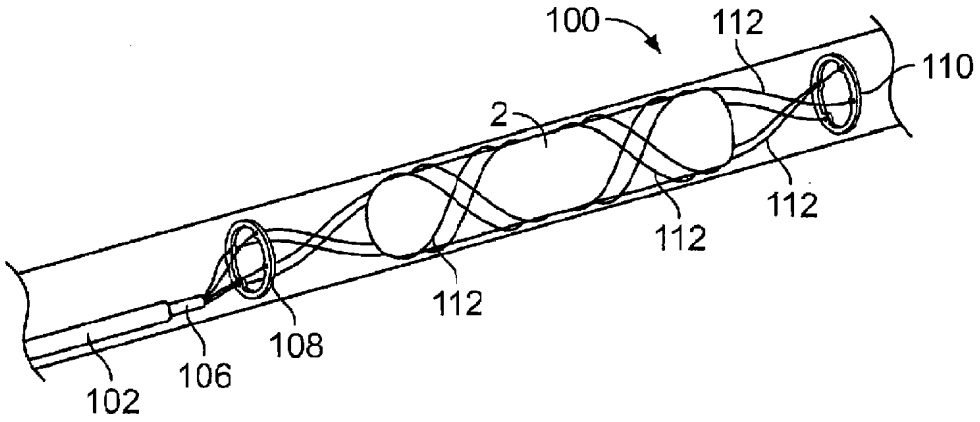

FIG. 3A

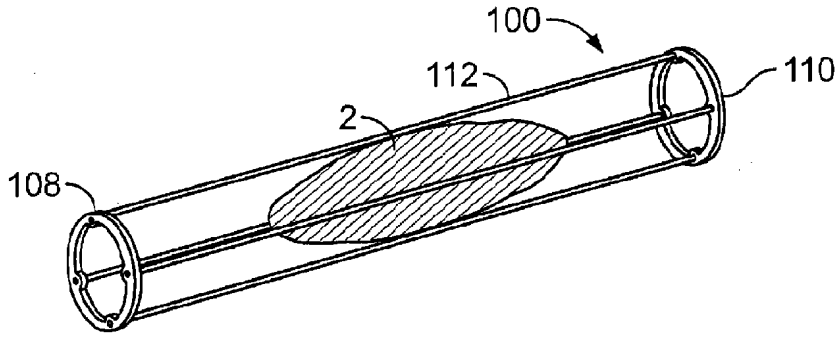

FIG. 3B

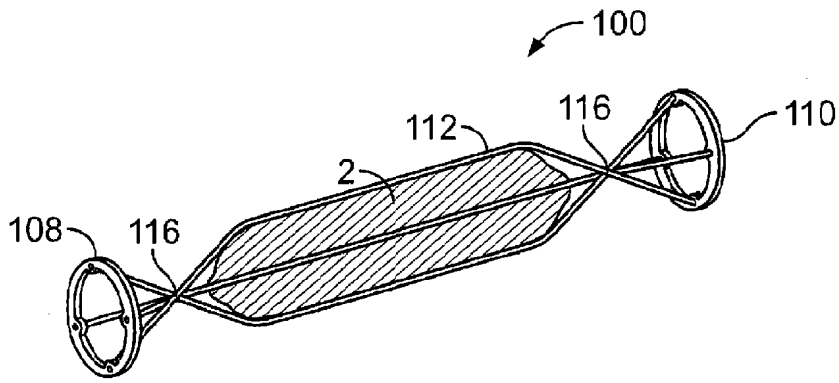

FIG. 3C

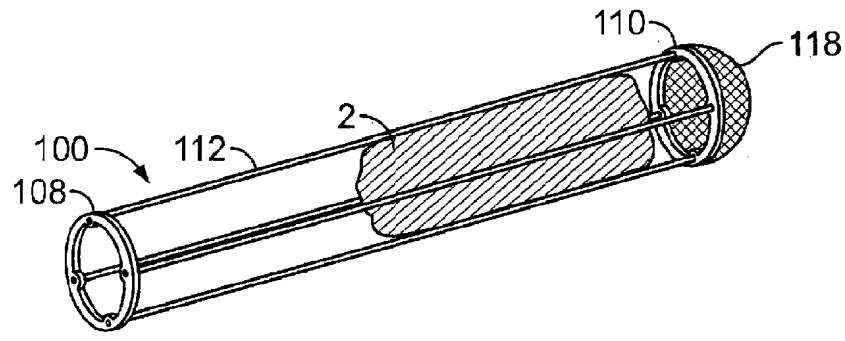

FIG. 3D

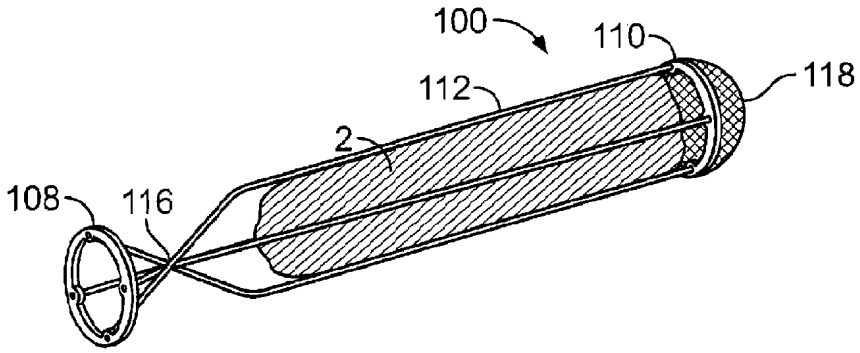

FIG. 3E

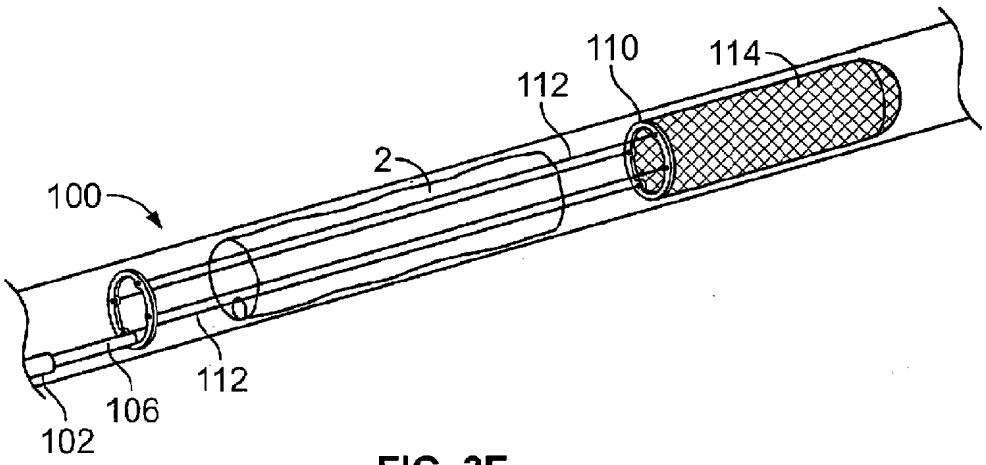

FIG. 3F

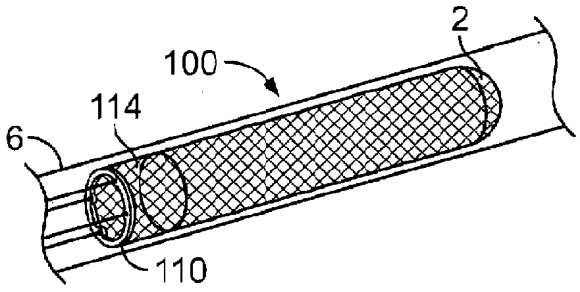

FIG. 3G

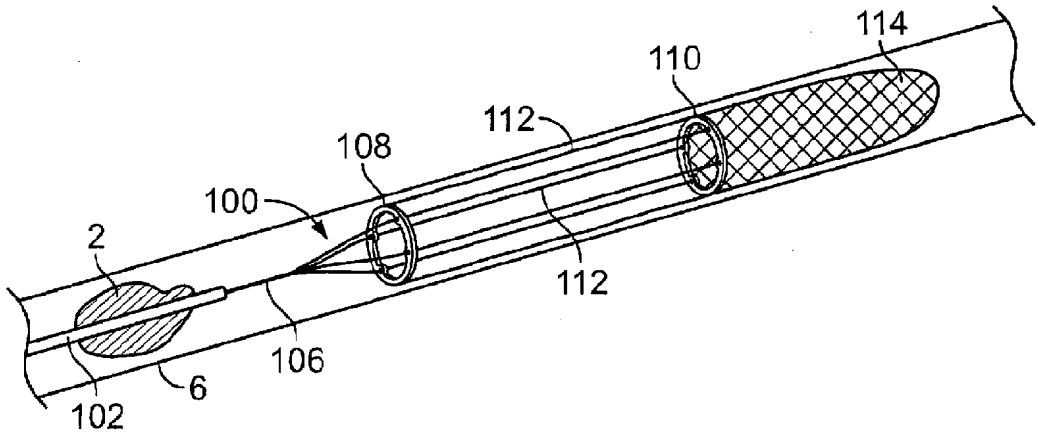

FIG. 3H

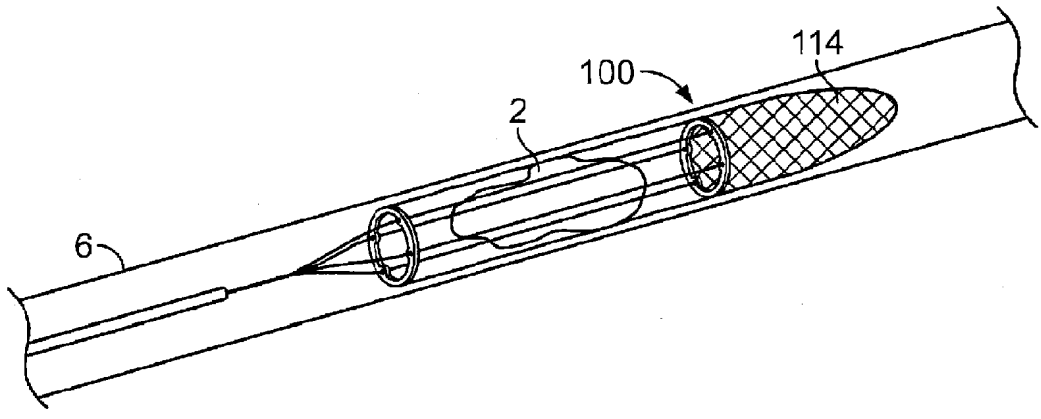

FIG. 3I

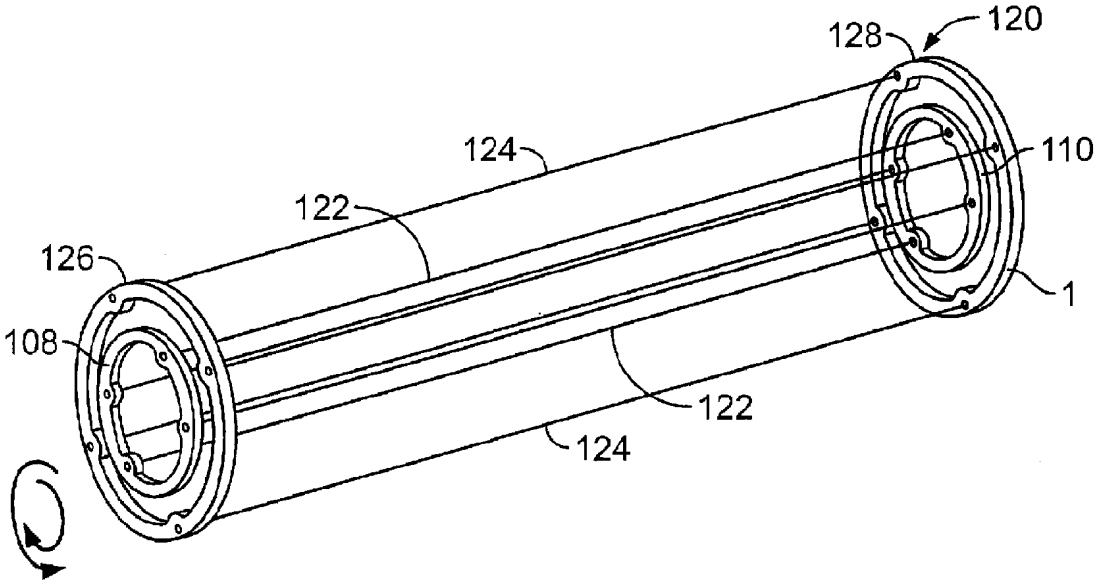

FIG. 4A

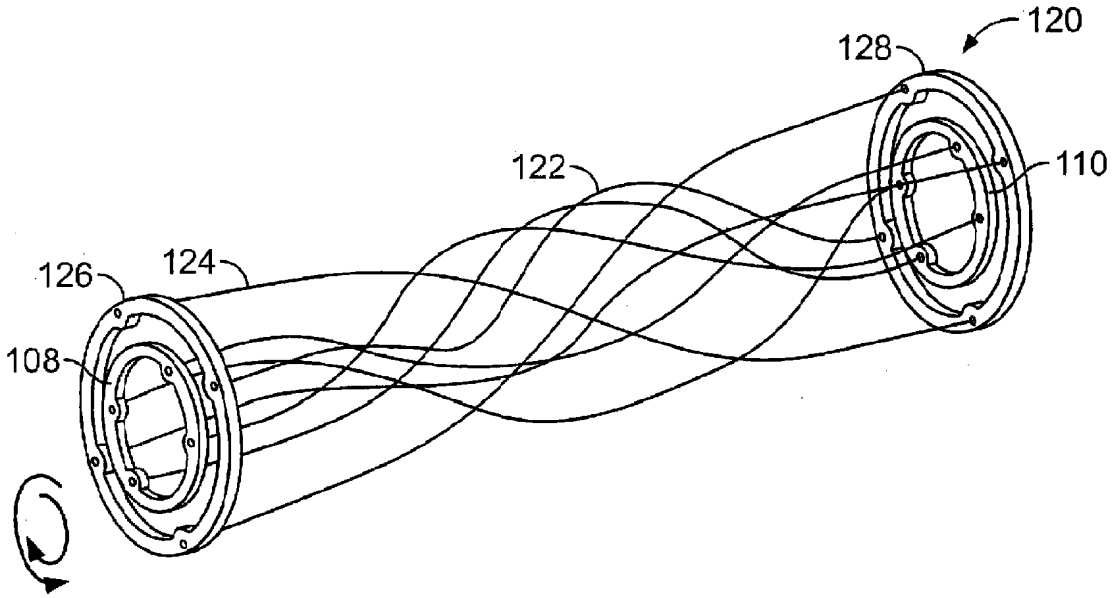

FIG. 4B

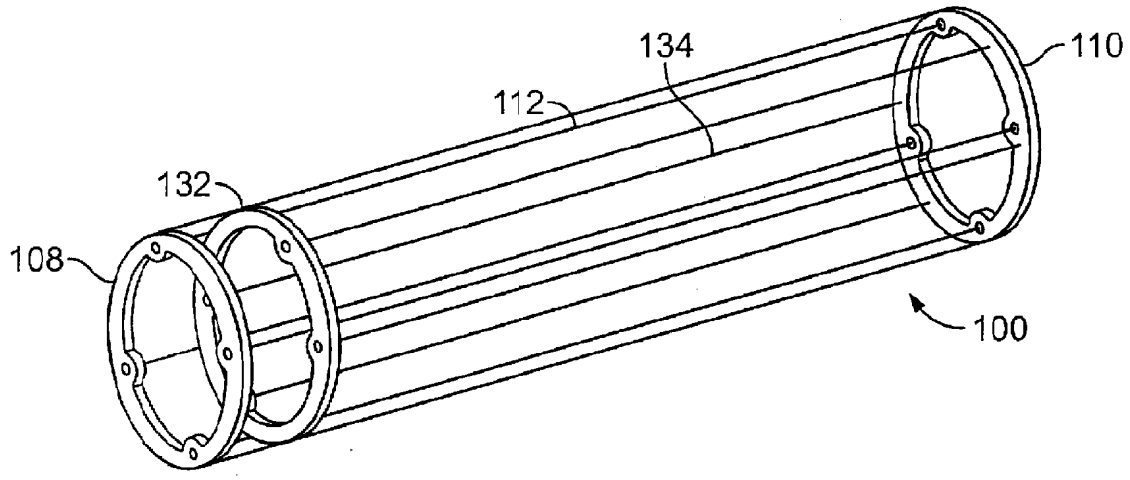

FIG. 4C

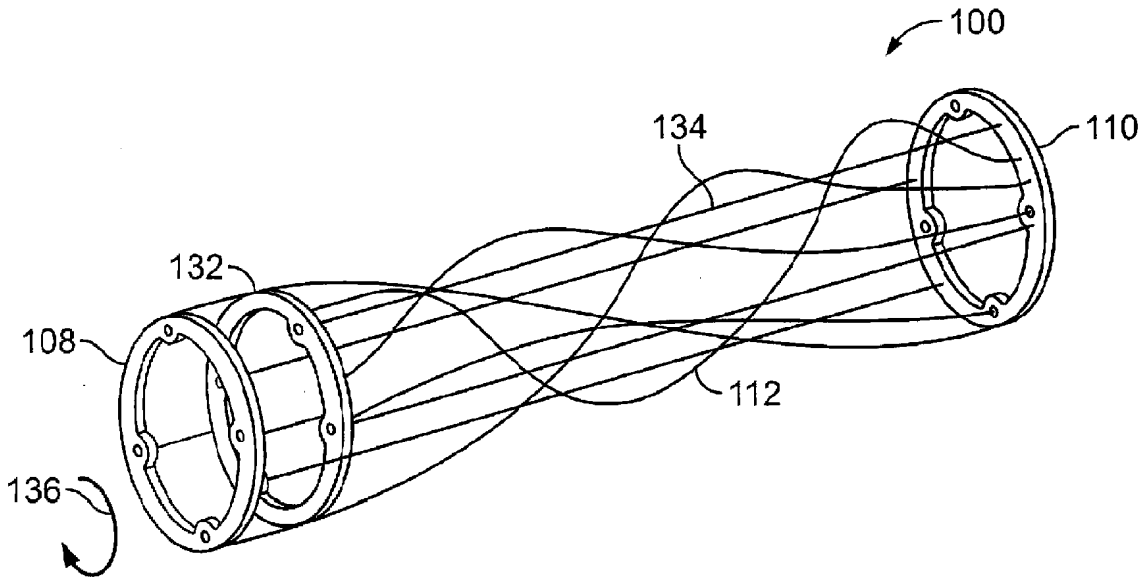

FIG. 4D

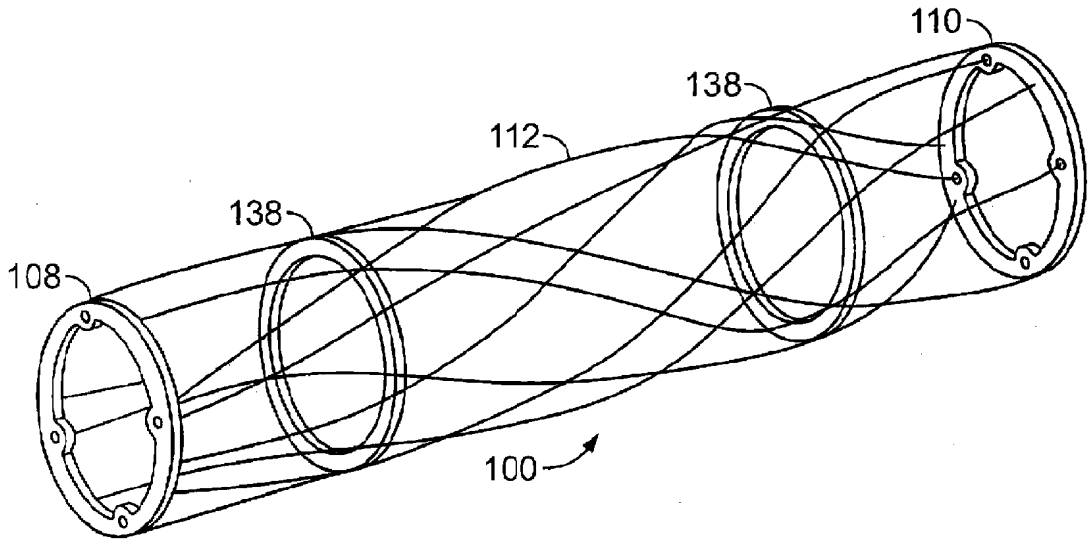

FIG. 4E

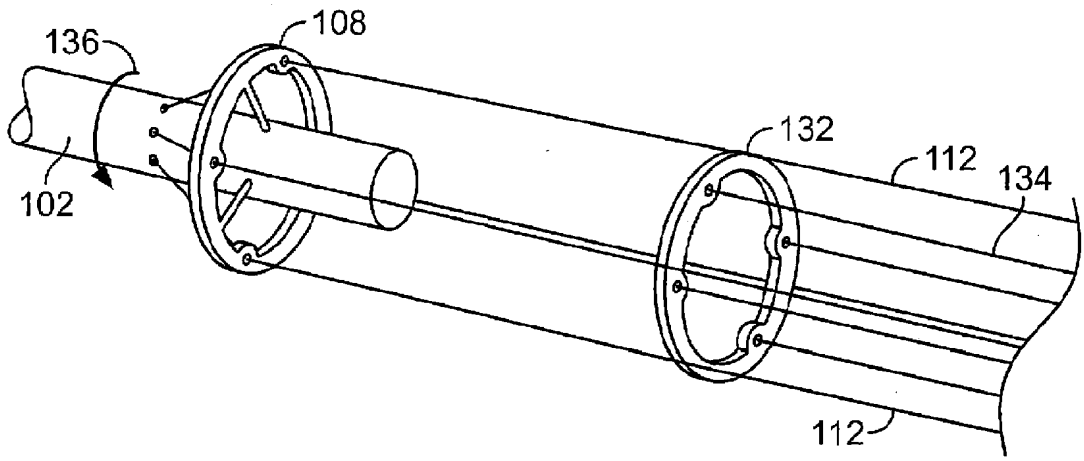

FIG. 4F

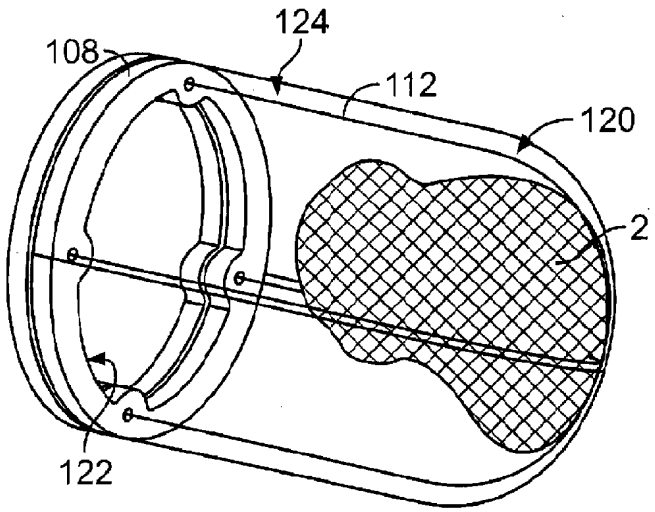

FIG. 5A

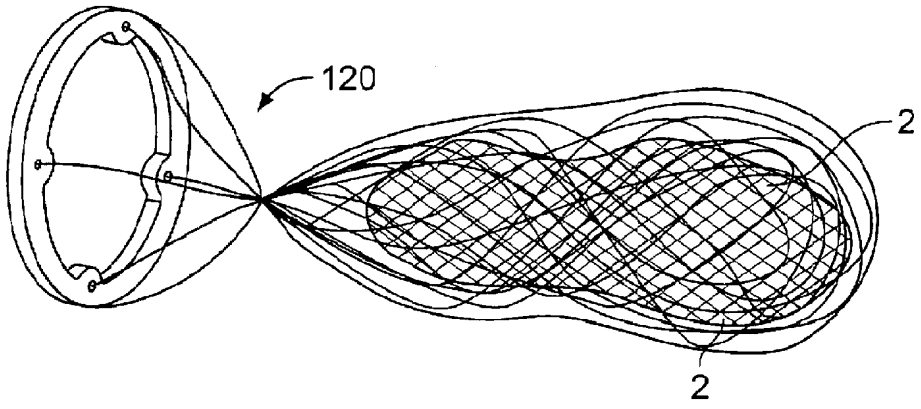

FIG. 5B

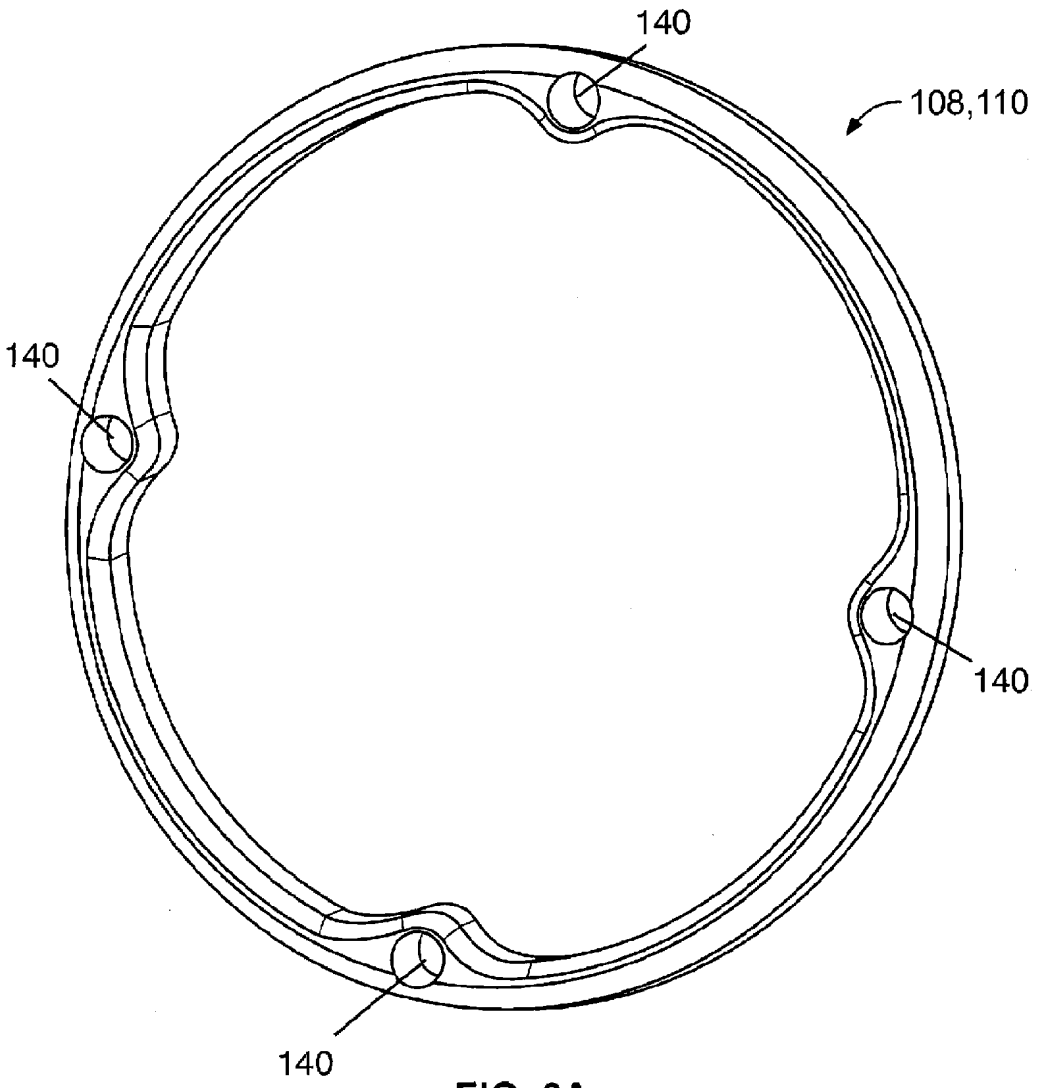

FIG. 6A

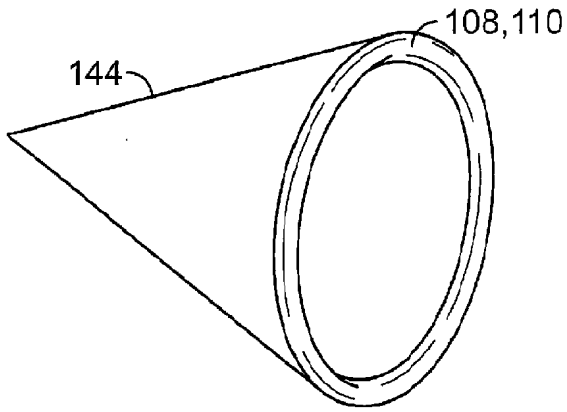

FIG. 6B

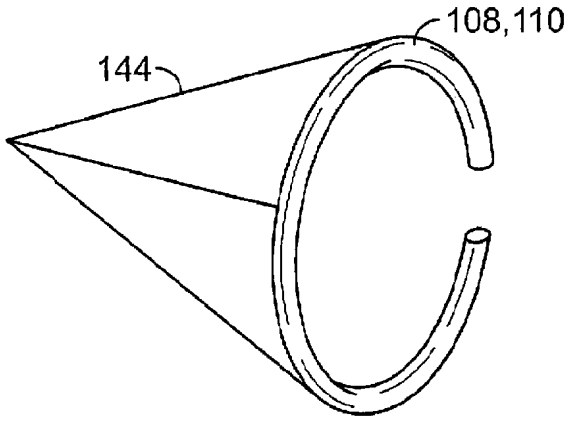

FIG. 6C

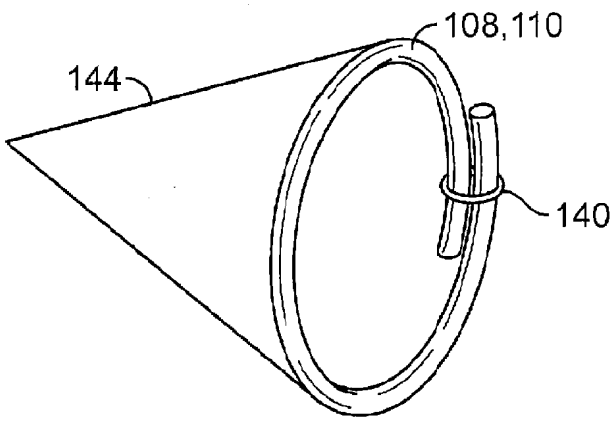

FIG. 6D

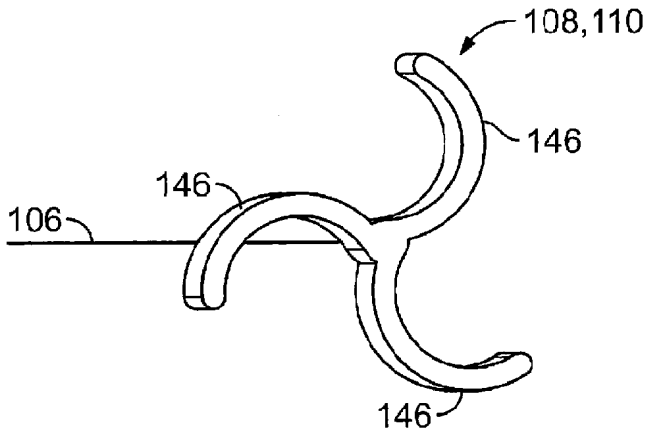

FIG. 6E

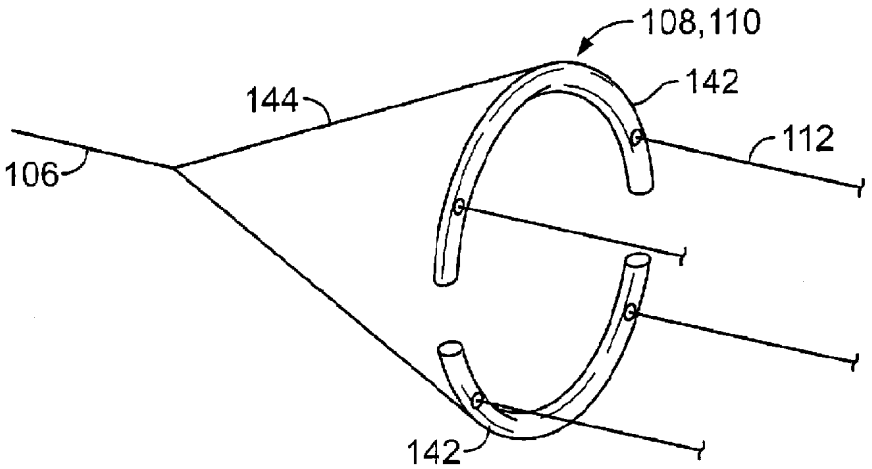

FIG. 6F

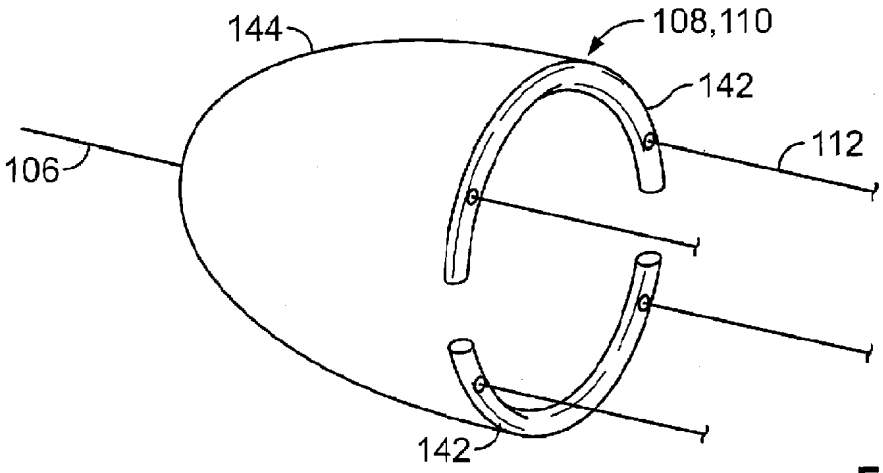

FIG. 6G

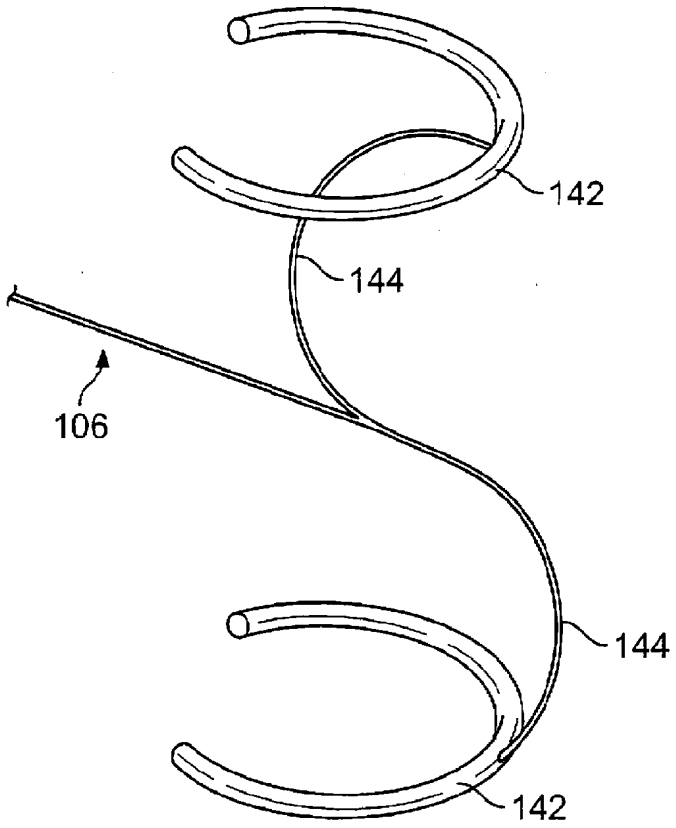

FIG. 6H

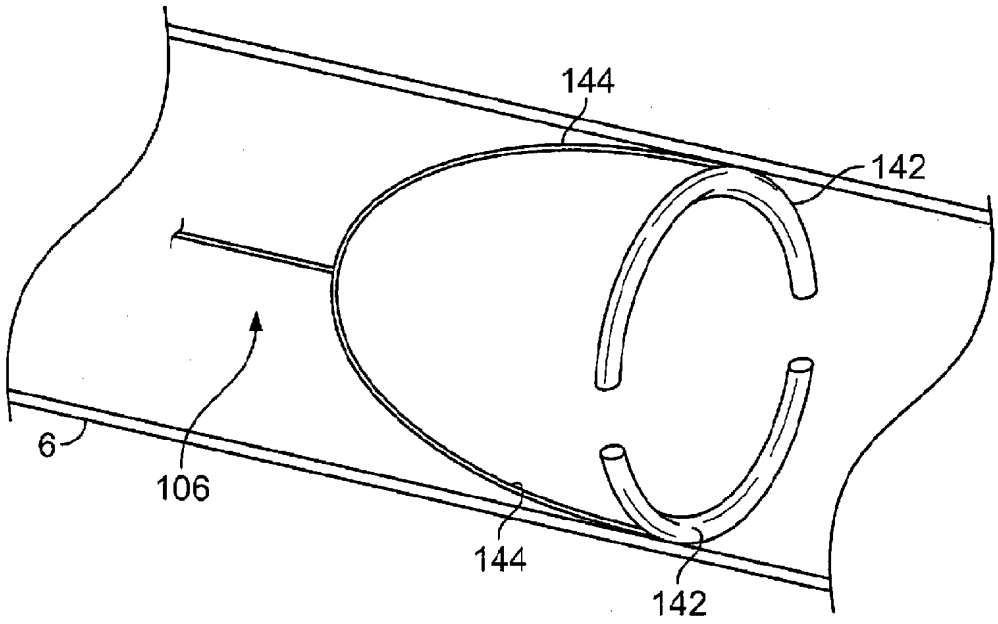

FIG. 6I

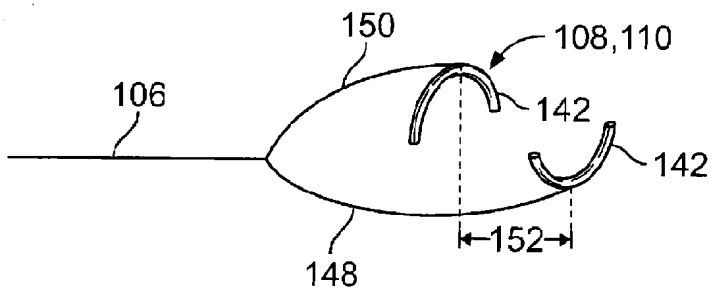

FIG. 7A

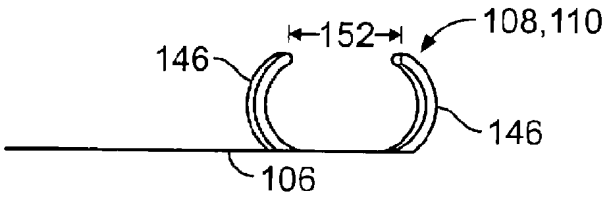

FIG. 7B

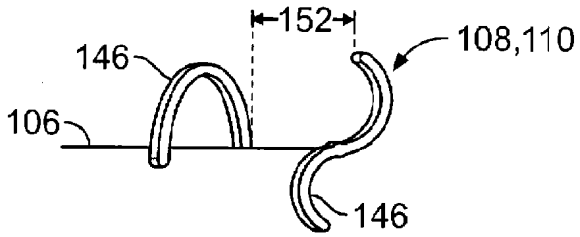

FIG. 7C

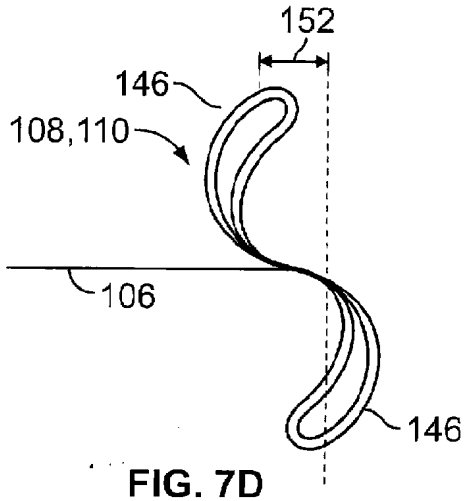

FIG. 7D

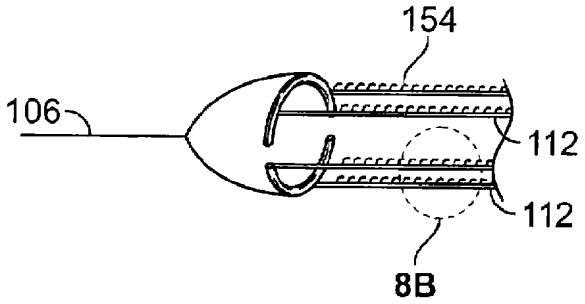

FIG. 8A

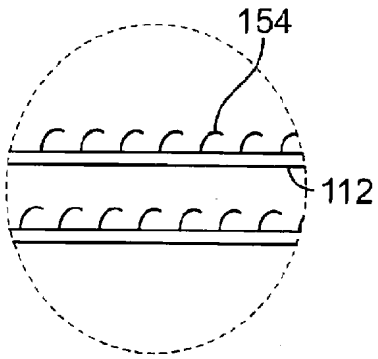

FIG. 8B

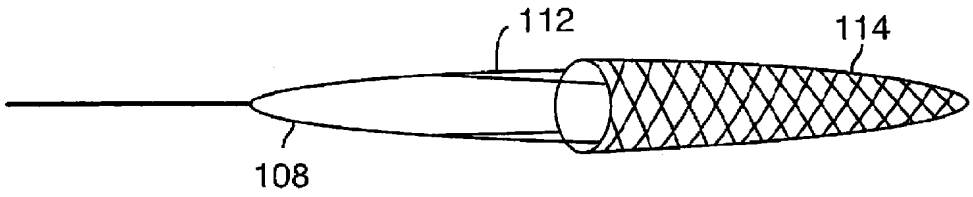

FIG. 9A

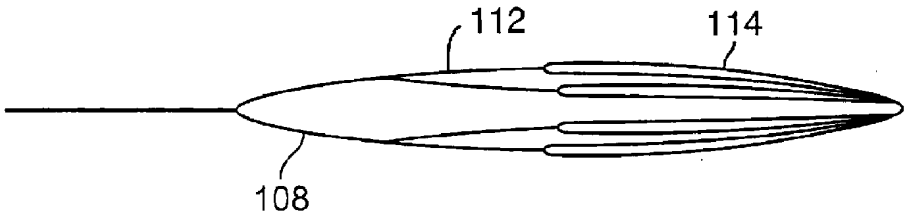

FIG. 9B

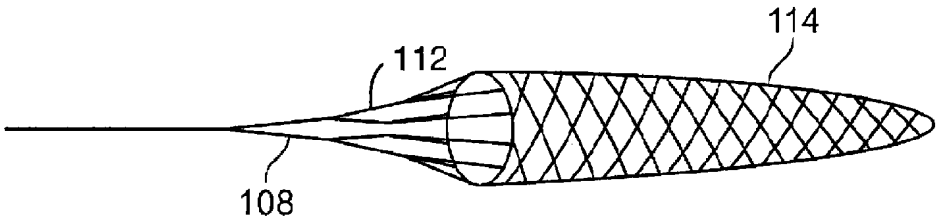

FIG. 9C

FIG. 10A

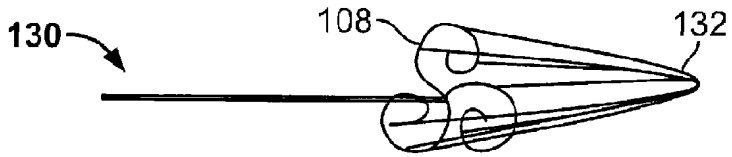

FIG. 10B

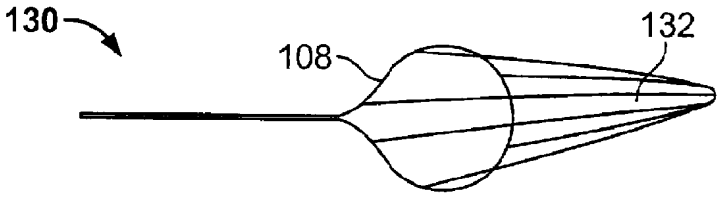

FIG. 10C

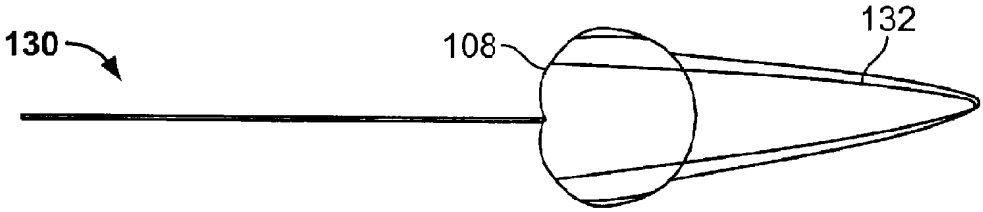

FIG. 10D

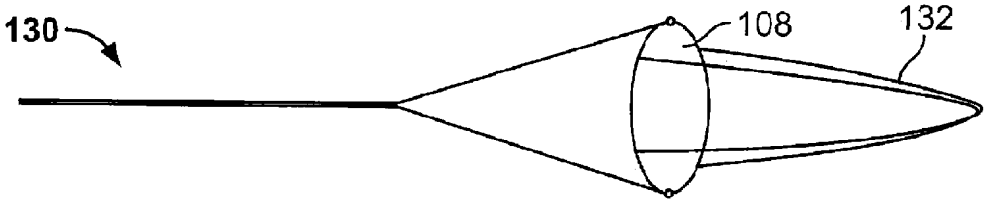

FIG. 10E

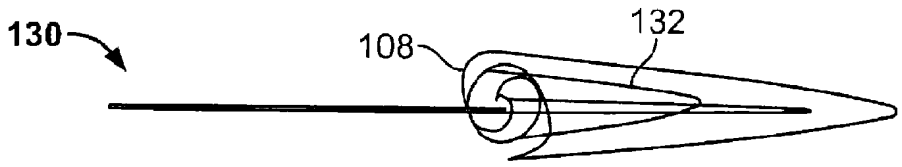

FIG. 10F

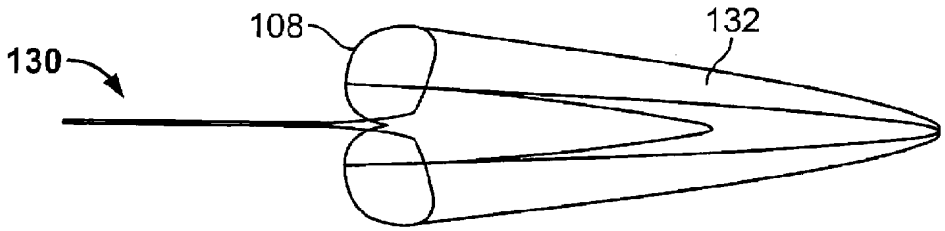

FIG. 10G

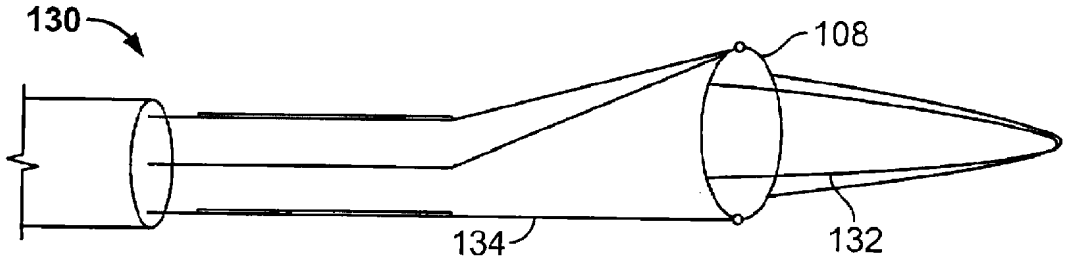

FIG. 10H

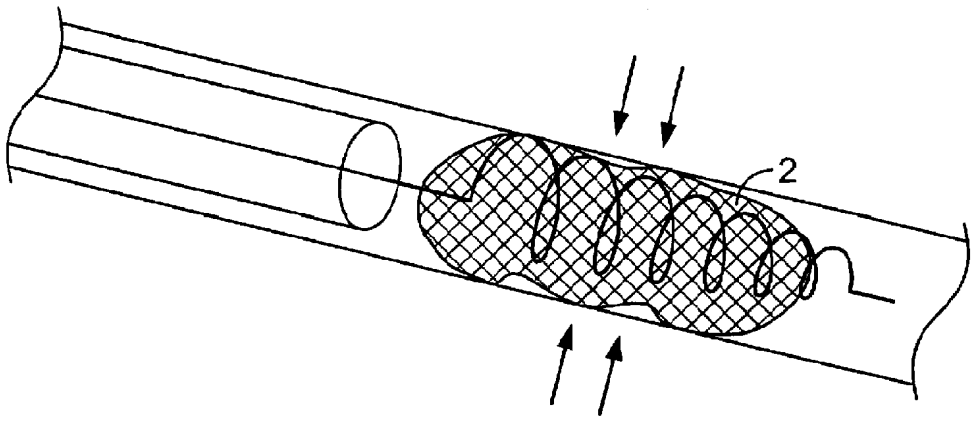

FIG. 11A

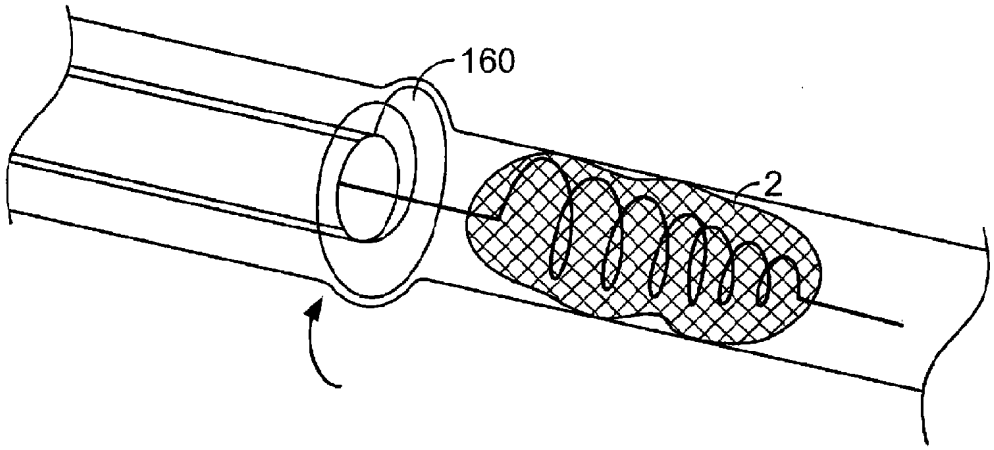

FIG. 11B

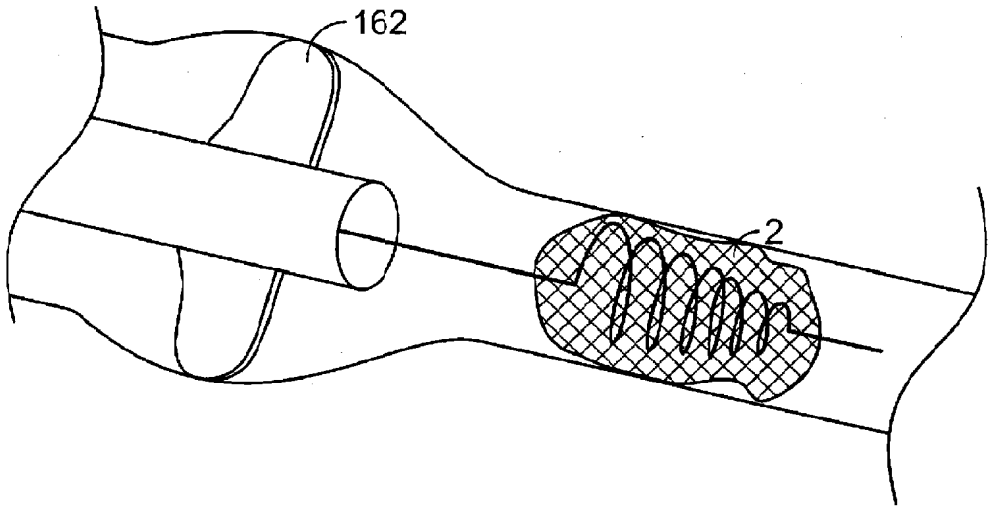

FIG. 11C