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 by placing guide wires or more 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 enclosed 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-Multi-wire coil.

[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.

[0056]

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.

[0058]

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 30 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 suction flow.

[0073]

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

[0074]

(c) It has extremely high body 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]

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

[0078]

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

[0079]

The following description and figures list some specific details to provide an understanding to 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 adjacent", 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 relative 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 directions), and correspondingly interpreted in spatially related terms.

[0086]

The term "reduction" and similar words used here 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 fluid 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) usually 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 1.2-2.3mm.

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 1.76-1.88mm, an inner diameter of 1.78-1.83mm, and a wall thickness of 0.013-0.032mm. The ratio of diameter to inner diameter is 1.014-0.015.

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 linear 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 0.10-0.22mm, 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 that 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 minimal 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 lumen shape.

[0105]

Figure 3A 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 (130, 140), 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 complementary strengths 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 0.07-0.5 mm.

In other embodiments, the width of the wire wound for the multi-wire coil is 0.04-0.11 mm, and the thickness is 0.02-0.06 mm.

[0105]

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 wires (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 catheter'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 0.025-0.065 mm, and the thickness of each braided wire used is 0.013-0.0533 mm.

According to an embodiment of the present invention, the length of the second intermediate layer (40) is 1150-1600 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 3 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 25-80D (Shore 25-80D), a length of 30-930 mm, an outer diameter of 2.5-3.5 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 4, 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. 4, the distal portion of the outer layer (50) is made of an ultra-low hardness material, such as TPU with a hardness of about 90A (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 20D-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 10-200mm, and the length of the proximal section of the outer layer (50) is 1000-1200mm.

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 in 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 (Cr), magnesium (Mg), iron (Fe), iron (Fe), cobalt (Co), copper (Cu), nickel (Ni), praseodymium (Pr), ruthenium (Ru), samarium (Sm), ytterbium (Yb), gadolinium (Gd), terbium (Tb), dysprosium (Dy), holmium (Ho), erbium (Er) or other MRI visible materials known to those skilled in the art.

[0115]

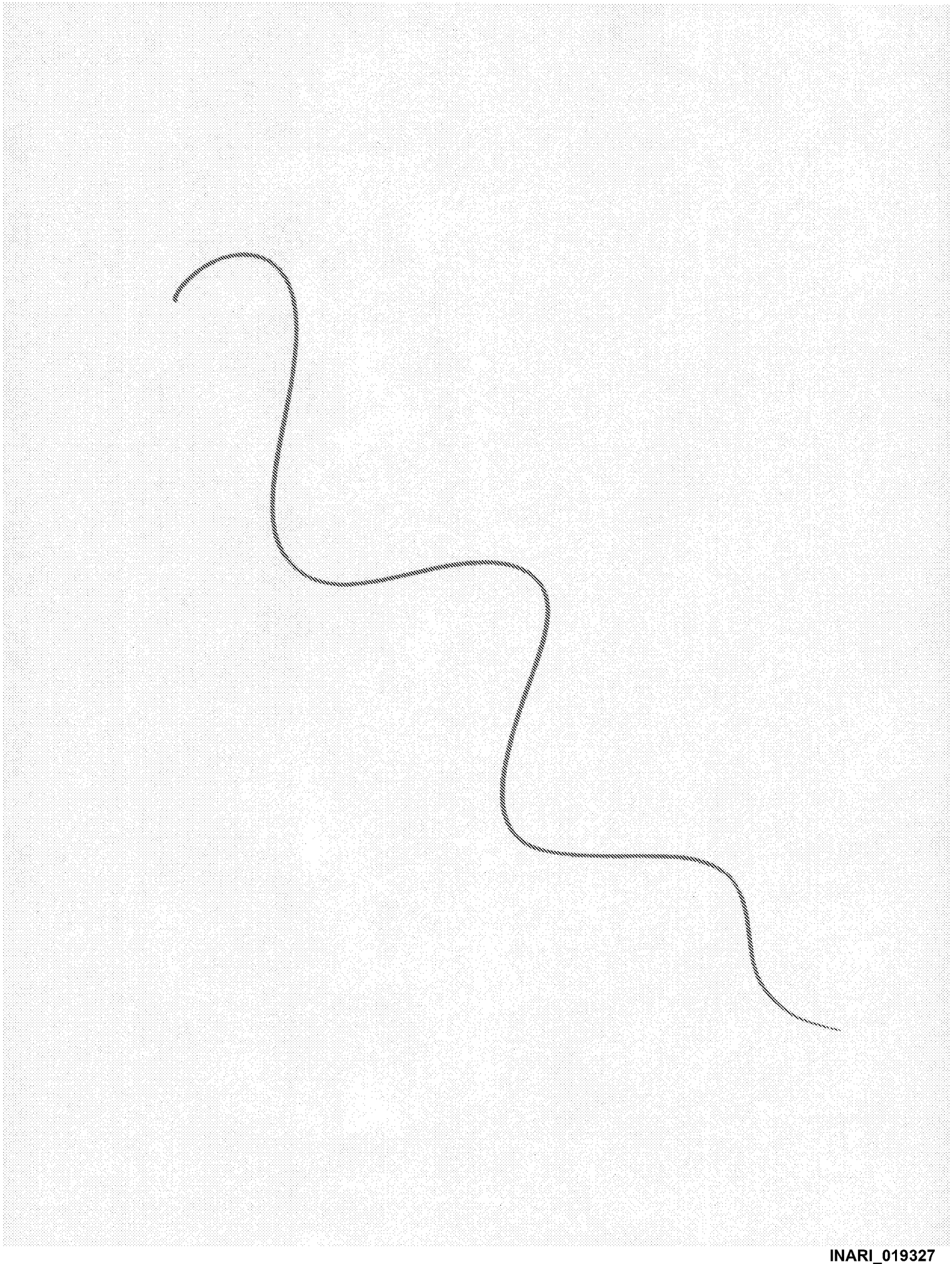
Those skilled in the art should understand that even though most of the exemplary embodiments of the catheter body (10) described above are suitable for intracranial vascular applications, the exemplary embodiments of the present invention can also be used for any other suitable minimally invasive interventional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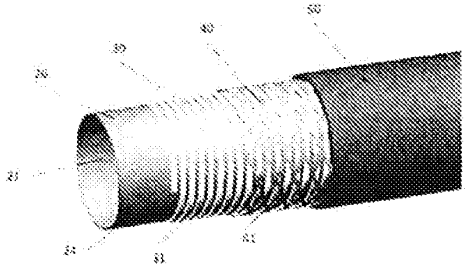
(54)发明名称

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。

INARI_019329

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、甚至固化层中的洞，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。

INARI_019330

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。

INARI_019331

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。

INARI_019332

[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近端部分、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远端部分。

[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，它可以直接位于或高于另一个元素，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

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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

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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1B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

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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)、锝(III)、钼(III)，钐(III)、铕(III)、钆(III)、钬(III)、钕(III)、镝(III)、钬(III)、铒(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。

INARI_019338

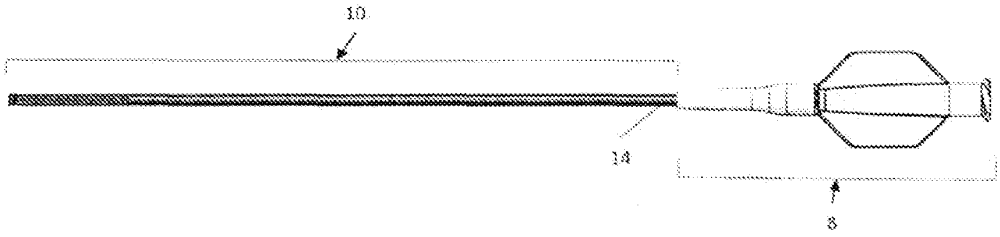

图1A

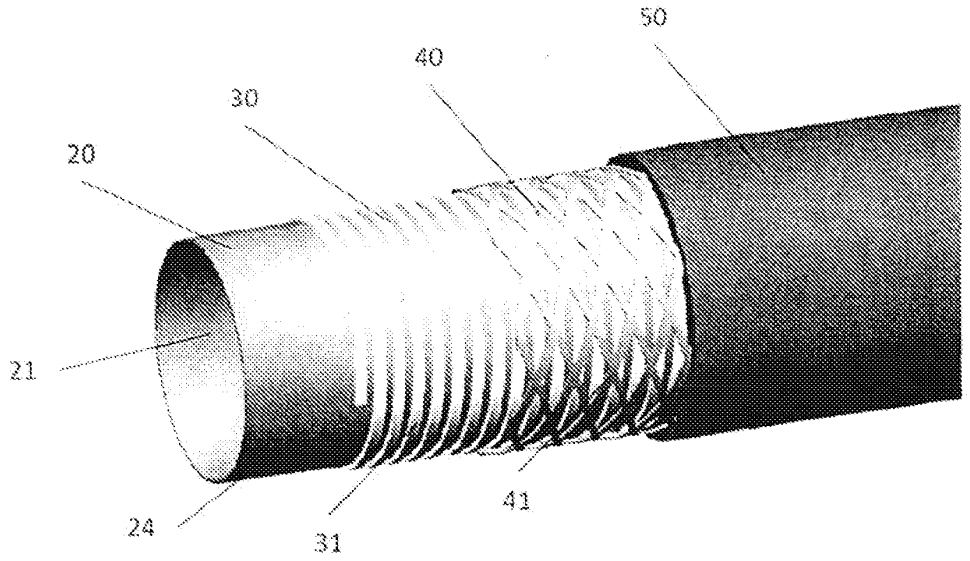

图1B

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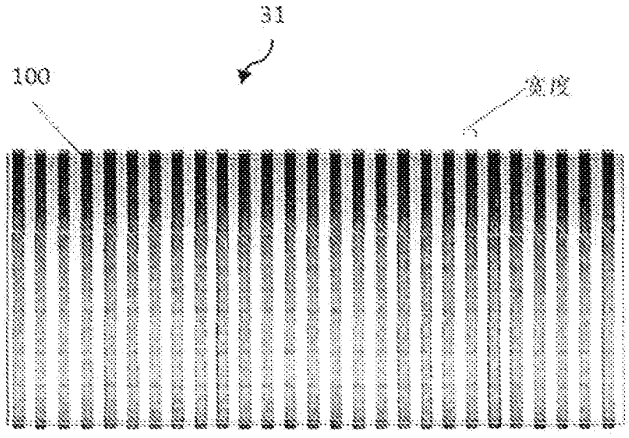

图2A

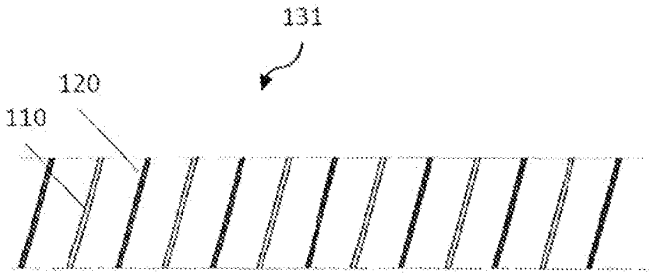

图2B

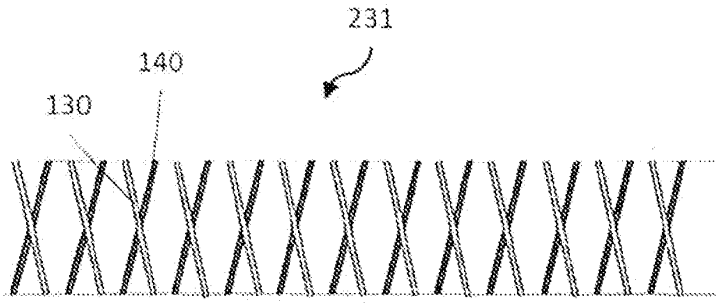

图2C

INARI_019340

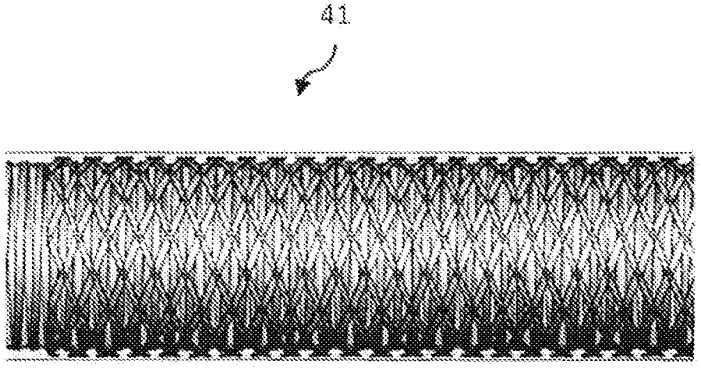

图3

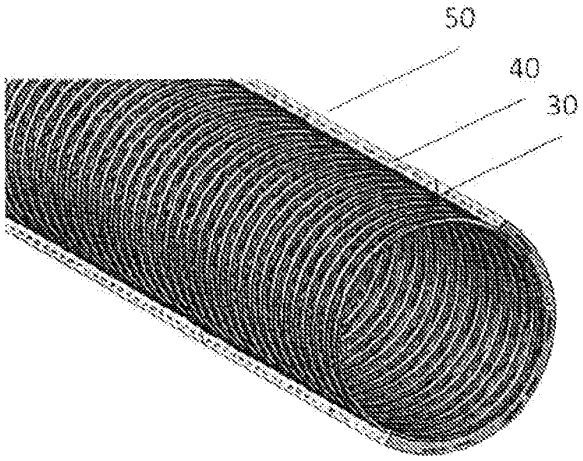

图4

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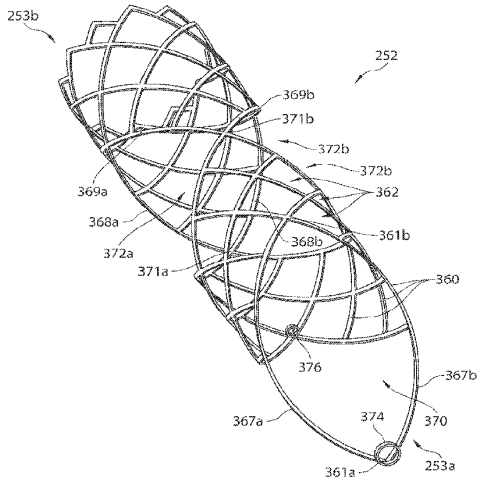

FIG. 3A

(57) Abstract: Systems and methods for the intravascular treatment of clot material within a blood vessel of a human patient are disclosed herein. In one embodiment, a system includes a coring element for coring and separating the clot material. The coring element can comprise a unitary structure having a first region, a second region, a third region, and a fourth region. The first region is adjacent to a proximal portion of the unitary structure and includes a first mouth configured to core and separate the clot material. The second region is distal of the first region, generally tubular, and includes a first plurality of interconnected struts. The third region is distal of the second region and includes a second mouth configured to core and separate the vascular thrombus. The fourth region is distal of the third region, generally tubular, and includes a second plurality of interconnected struts.

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DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 62/949,967, filed December 18, 2019, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to systems, methods, and devices for extracting thrombi from blood vessels of human patients. In particular, some embodiments of the present technology relate to systems for thrombus extraction from the peripheral vasculature of a human patient.

BACKGROUND

[0003] Thrombosis is the local coagulation or clotting of the blood in a part of the circulatory system, and a thrombus is a blood clot formed in situ within the vascular system. A venous thrombus is a blood clot that forms within a vein. A common type of venous thrombosis is a deep vein thrombosis (DVT), which is the formation of a blood clot within a deep vein (e.g., predominantly in the legs). Nonspecific signs of a thrombosis may include pain, swelling, redness, warmness, and engorged superficial veins.

[0004] If the thrombus breaks off (embolizes) and flows towards the lungs, it can become a life-threatening pulmonary embolism (PE) (e.g., a blood clot in the lungs). In addition to the loss of life that can arise from PE, DVT can cause significant health issues such as post thrombotic syndrome, which can cause chronic swelling, pressure, pain, and ulcers due to valve and vessel damage. Further, DVT can result in significant health-care costs either directly or indirectly through the treatment of related complications and inability of patients to work.

[0005] Three processes are believed to result in venous thrombosis. First is a decreased blood flow rate (venous stasis), second is an increased tendency to clot (hypercoagulability), and the third is changes to the blood vessel wall. DVT formation typically begins inside the valves of the calf veins where the blood is relatively oxygen deprived, which activates certain biochemical pathways. Several medical conditions increase the risk for DVT, including diabetes, cancer,

trauma, and antiphospholipid syndrome. Other risk factors include older age, surgery, immobilization (as with bed rest, orthopedic casts, and sitting on long flights), combined oral contraceptives, pregnancy, the postnatal period, and genetic factors. The rate of DVT increases dramatically from childhood to old age and, in adulthood, about 1 in 1,000 adults develop DVT annually.

[0006] Although current devices and methods of prevention and/or treatment of DVT exist, there are a number of shortcomings that have yet to be resolved, such as high incidence of DVT re-occurrence, use of devices not designed to remove large clot volumes, and/or complicated treatments involving multiple treatment devices and/or pharmaceuticals. Accordingly, new devices, systems, and methods of treating thrombus, and particularly DVT are desired.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0008] Figure 1 is a side view of a thrombectomy system configured in accordance with an embodiment of the present technology.

[0009] Figures 2A and 2B are side views of a thrombus extraction assembly of the thrombectomy system including a thrombus extraction device in a partially-expanded configuration and a fully-expanded configuration, respectively, configured in accordance with embodiments of the present technology.

[0010] Figures 3A–3D are an isometric view, a side view, a top view, and a rear view, respectively, of a coring element of the thrombus extraction device configured in accordance with embodiments of the present technology.

[0011] Figure 4 is an enlarged side view of the thrombus extraction device coupled to a distal portion of the thrombus extraction assembly and in the fully-expanded configuration in accordance with an embodiment of the present technology.

[0012] Figures 5A and 5B are side views of a dilator assembly of the thrombectomy system in a first configuration and a second configuration, respectively, configured in accordance with embodiments of the present technology.

[0013] Figure 6 is an enlarged cross-sectional side view of a portion of the thrombectomy system including a self-expanding funnel configured in accordance with an embodiment of the present technology.

[0014] Figures 7A–7D are side views of the dilator assembly positioned within an introducer assembly of the thrombectomy system and illustrating various stages in a process or method for deploying the self-expanding funnel in accordance with embodiments of the present technology.

[0015] Figures 8A, 8C, and 8D are cross-sectional side views, and Figure 8B is an enlarged cross-sectional isometric view, of a control assembly of the dilator assembly configured in accordance with embodiments of the present technology.

[0016] Figures 9A–9C, are cross-sectional side views of a control assembly configured in accordance with another embodiment of the present technology.

[0017] Figures 10A and 10B are partially cross-sectional side views of a control assembly configured in accordance with another embodiment of the present technology.

[0018] Figure 11 is a schematic view of an introduction technique for accessing a thrombus for treatment with the thrombectomy system in accordance with an embodiment of the present technology.

[0019] Figures 12A–12C are side views, and Figures 12D–12K are enlarged side views, of the thrombectomy system positioned within a blood vessel during a thrombectomy procedure in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0020] The present technology is generally directed to methods and systems for removing clot material (e.g., a thrombus) from a blood vessel of a human patient. In some embodiments, a system for removing clot material (e.g., a thrombectomy system) includes a thrombus extraction device including (i) a coring element configured to core and separate the clot material from the vessel wall and (ii) a capture element configured to capture the cored and separated clot material. In some embodiments, the coring element comprises a unitary structure having a first region adjacent to a proximal portion of the unitary structure, a second region distal of the first region, a third region distal of the second region, and a fourth region distal of the third region. The first region can include a first mouth configured to core and separate the clot material and the third region can include a second mouth configured to core and separate the clot material. The second

and fourth regions can each be generally tubular and can include a plurality of interconnected struts. In one aspect of the present technology, the first and second mouths are radially offset such that at least one of the first and second mouths is positioned and oriented to effectively core and separate the clot material from within the blood vessel during a thrombus extraction procedure using the thrombus extraction device.

[0021] In some embodiments, the thrombectomy system includes a dilator assembly for deploying an expandable funnel coupled to a distal portion of an introducer sheath. The dilator assembly can include a first shaft defining a lumen, a second shaft slidably positioned within the lumen of the first shaft, and a retention sheath coupled to the second shaft and configured to receive and constrain the funnel therein. A control assembly including an actuator is operably coupled to the first and second shafts. Movement of the actuator to a first position is configured to distally advance the first and second shafts together to deploy the funnel from the retention sheath. Movement of the actuator to a second position is configured to distally advance the first shaft relative to the second shaft such that first shaft and the retention sheath define a generally uniform (e.g., constant diameter) outer surface. In one aspect of the present technology, the generally uniform outer surface of the dilator assembly is unlikely to snag or otherwise damage the funnel or vessel as the dilator assembly is retracted through the introducer sheath. In another aspect of the present technology, the dilator assembly can be coupled to the introducer sheath to inhibit or even prevent unintentional, premature deployment of the funnel.

[0022] Although many of the embodiments are described below with respect to devices, systems, and methods for treating vascular thrombi (e.g., deep vein thrombosis (DVT)), other applications and other embodiments in addition to those described herein are within the scope of the technology (e.g., intravascular procedures other than the treatment of emboli, intravascular procedures for treating cerebral embolism, intravascular procedures for treating pulmonary embolism). In general, for example, the devices, systems, and methods of the present technology can be used to extract any formation of material in a vessel (e.g., a venous or arterial vessel), such as cancerous growths, vegetation, and the like. Additionally, several other embodiments of the technology can have different configurations, states, components, or procedures than those described herein. Moreover, it will be appreciated that specific elements, substructures, advantages, uses, and/or other features of the embodiments described with reference to Figures 1–12K can be suitably interchanged, substituted or otherwise configured with one another in accordance with additional embodiments of the present technology. Furthermore, suitable elements of the embodiments described with reference to Figures 1–12K can be used as standalone

and/or self-contained devices. A person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described below with reference to Figures 1–12K.

[0023] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to use in a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

[0024] The headings provided herein are for convenience only and should not be construed as limiting the subject matter disclosed.

I. Selected Embodiments of Thrombectomy Systems

[0025] Figure 1 is a side view of a thrombectomy system 100 (which can also be referred to as a thrombus extraction system, clot removal system) configured in accordance with an embodiment of the present technology. In the illustrated embodiment, the thrombectomy system 100 includes an introducer assembly 102, an obturator or dilator assembly 104 (shown positioned within the introducer assembly 102), and a thrombus extraction assembly 106. In general, the thrombectomy system 100 can be used to (i) access a portion of a blood vessel (e.g., a venous vessel of a human patient) containing a thrombus (e.g., clot material) and (ii) remove all or portions of that thrombus from the blood vessel. More specifically, for example, the introducer assembly 102 and the dilator assembly 104 can be partially advanced into the vasculature of the patient (e.g., a blood vessel or venous vessel of the patient). The dilator assembly 104 can be actuated to deploy a self-expanding funnel (e.g., as shown in Figures 7A–7C) and then removed from the introducer assembly 102. Next, the thrombus extraction assembly 106 and an attached thrombus extraction device can be partially inserted through the introducer assembly 102 and deployed at and/or near the location of a thrombus for capturing the thrombus. Finally, the thrombus extraction assembly 106 and/or the introducer assembly 102 can be removed from the patient along with the captured thrombus. In some embodiments, the thrombectomy system 100 and/or methods of operating the thrombectomy system 100 to remove a thrombus from a patient can include some features the same as or similar to the thrombectomy systems described in detail

in (i) U.S. Patent No. 9,700,332, filed September 16, 2016, and titled "INTRAVASCULAR TREATMENT OF VASCULAR OCCLUSION AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS," and/or (ii) U.S. Patent No. 10,098,651, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," both of which are incorporated herein by reference in their entirety.

[0026] In the illustrated embodiment, the introducer assembly 102 includes an elongate sheath 112, which can also be referred to as a shaft, catheter, and the like. The sheath 112 defines a lumen (obscured in Figure 1; e.g., identified as lumen 688 in Figure 6) and includes a proximal portion 113a and a distal portion 113b. The proximal portion 113a can terminate at a proximal end, and the distal portion 113b can terminate at a distal end. The lumen of the sheath 112 is sized to slidably receive the dilator assembly 104 and the thrombus extraction assembly 106. For example, the dilator assembly 104 is shown partially positioned within the sheath 112 in Figure 1. The sheath 112 can be elastic and/or flexible and can have any suitable length and diameter. In some embodiments, the sheath 112 can have an outer diameter of at least 10 French, at least 12 French, at least 14 French, at least 18 French, at least 20 French, at least 22 French, at least 26 French, greater than 26 French, between 10 French and 26 French, between 14 French and 24 French, between 15 French and 21 French, between 16 French and 22 French, and/or any other or intermediate size. In some embodiments, the lumen of the sheath 112 can have an internal diameter of at least 2 French, at least 10 French, at least 14 French, at least 18 French, at least 20 French, at least 22 French, between 11 French and 12 French, between 10 French and 22 French, between 14 French and 21 French, between 16 French and 20 French, and/or any other or intermediate size. In some embodiments, the sheath 112 can include a radiopaque marker (not shown) positioned, for example, at the distal portion 113b thereof.

[0027] The introducer assembly 102 further includes a sealable hub 114 coupled to the proximal portion 113a of the sheath 112. The sealable hub 114 is configured to allow access to the lumen of the sheath 112 and can be self-sealing and/or can comprise a self-sealing seal. For example, in the illustrated embodiment the sealable hub 114 is a hemostasis valve that is configured to maintain hemostasis during a thrombus extraction procedure by preventing fluid flow in the proximal direction through the sealable hub 114 as various components—such as portions of the dilator assembly 104 and/or the thrombus extraction assembly 106—are inserted through the sealable hub 114 to be delivered through the sheath 112 to a treatment site in a blood vessel. More specifically, the sealable hub 114 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND

METHODS OF USE," which is incorporated herein by reference in its entirety. The sealable hub 114 can include one or more buttons or actuators that enable an operator to selectively seal/unseal the sealable hub 114.

[0028] The introducer assembly 102 can further include an aspiration port 116 connected to the sealable hub 114 (e.g., to a side port of the sealable hub 114) and/or the sheath 112 (e.g., to the proximal portion 113a of the sheath 112) via, for example, a connecting tube 118. The aspiration port 116 can be connected to a syringe connector 117 that can be selectively coupled to a syringe or other aspiration device, or the aspiration port 116 can be connected to other suitable elements. In some embodiments, the introducer assembly 102 includes a fluid control device 119 configured to selectively fluidly connect the aspiration port 116 to the lumen of the sheath 112. In the illustrated embodiment, the fluid control device 119 is a stopcock operably coupled to the connecting tube 118 between the lumen of the sheath 112 and the aspiration port 116. In other embodiments, the fluid control device 119 can be a clamp or another suitable valve.

[0029] The dilator assembly 104 can include a control assembly 120 operably coupled to a retention sheath 122 via a first shaft (obscured in Figure 1; e.g., identified as first shaft 580 in Figures 5A and 5B). In the illustrated embodiment, the first shaft of the dilator assembly 104 extends through the sealable hub 114 and the sheath 112 such that the retention sheath 122 is positioned distal of the distal portion 113b of the sheath 112. Moreover, the control assembly 120 is releasably coupled to (e.g., mated to, fixed to) the sealable hub 114. Accordingly, the introducer assembly 102 can carry or hold the dilator assembly 104. As described in greater detail below with reference to Figures 5A–7D, the dilator assembly 104 (e.g., the retention sheath 122) is configured to (i) hold/constrain a self-expanding funnel (obscured in Figure 1; e.g., identified as funnel 690 in Figure 6) that is attached to the distal portion 113b of the sheath 112, and (ii) release/deploy the self-expanding funnel. More specifically, for example, the control assembly 120 can include an actuator 124 that is movable (e.g., in the direction of arrow A in Figure 1) to advance the retention sheath 122 relative to the sheath 112 (and the self-expanding funnel) attached thereto to deploy/release the self-expanding funnel.

[0030] In some embodiments, the thrombectomy system 100 can further include a loading tool 108 (e.g., a loading funnel) for use in loading the self-expanding funnel into the dilator assembly 104 (e.g., into the retention sheath 122). In the illustrated embodiment, the loading tool 108 defines a lumen 127 therethrough and includes a first portion 126 of varying diameter (e.g., a tapered portion such as a funnel portion) and a second portion 128 of generally constant diameter

(e.g., a shaft portion). In other embodiments, the second portion 128 can have a partially varying diameter. The first portion 126 is configured (e.g., sized and shaped) to receive the self-expanding funnel and to move the self-expanding funnel to the constrained configuration as the self-expanding funnel is advanced through the first portion 126. The lumen 127 of the loading tool 108 can be sized to allow the retention sheath 122 to pass completely through the loading tool 108.

[0031] In the illustrated embodiment, the thrombus extraction assembly 106 includes a catheter portion 130 and a handle portion 140 ("handle 140") operably coupled to the catheter portion 130. In operation, the handle 140 is configured to be actuated/manipulated by a user to control (e.g., deploy) one or more components of the catheter portion 130 and/or a thrombus extraction device (not shown in Figure 1; e.g., identified as thrombus extraction device 250 in Figures 2A and 2B) coupled to the catheter portion 130.

[0032] In the illustrated embodiment the catheter portion 130 includes an outer shaft 132, an intermediate shaft 133, and an inner shaft 134 slidably and coaxially aligned relative to one another. For example, each of the shafts 132–134 can define a lumen (e.g., a central, axial lumen) and (i) the intermediate shaft 133 can be configured (e.g., sized and shaped) to slidably fit within the lumen of the outer shaft 132 and (ii) the inner shaft 134 can be configured to slidably fit within the lumen of the intermediate shaft 133. In some embodiments, the outer shaft 132 is configured (e.g., sized) to slidably fit within the sheath 112 of the introducer assembly 102 and can have, for example, a size of at least 8 French, at least 10 French, at least 11 French, at least 12 French, at least 14 French, at least 16 French, between 8 French and 14 French, between 11 French and 12 French, and/or any other or intermediate size. By this arrangement, each of the shafts 132–134 can be displaced longitudinally relative to one another and relative to the sheath 112 of the introducer assembly 102. In some embodiments, each of the shafts 132–134 can have the same length while, in other embodiments, one or more of the shafts 132–134 can have different lengths. For example, in some embodiments the intermediate shaft 133 can be longer than the outer shaft 132 and the inner shaft 134 can be longer than the intermediate shaft 133. In other embodiments, the catheter portion 130 can comprise any number of shafts (e.g., catheters, sheaths) that are slidable relative to one another and/or configured to be positioned coaxially relative to one another. For example, in some embodiments the catheter portion can include three intermediate shafts as described in detail in U.S. Patent No. 10,098,651, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," which is incorporated herein by reference in its entirety.

[0033] The handle 140 includes a proximal portion 141a (e.g., a plunger portion) and a distal portion 141b (e.g., a locking portion). In the illustrated embodiment, the intermediate shaft 133 is coupled to and extends distally from the distal portion 141b of the handle 140. The distal portion 141b of the handle 140 can include a lock feature 142 such as, for example, a spinlock. The lock feature 142 is configured to selectively engage and/or lockingly engage with a mating feature 135 located near a proximal portion 136a of the outer shaft 132. In some embodiments, the outer shaft 132 can slide proximally over the intermediate shaft 133 until the lock feature 142 engages with the mating feature 135 to thereby secure the position of the outer shaft 132 relative to the intermediate shaft 133. In some embodiments, the intermediate shaft 133 is relatively longer than the outer shaft 132 such that a portion of the intermediate shaft 133 extends distally from a distal portion 136b of the outer shaft 132 when the outer shaft 132 is lockingly engaged with the lock feature 142.

[0034] In the illustrated embodiment, the handle 140 further includes a plunger 144 (e.g., an actuator) operably coupled to the inner shaft 134 and movable between a first, non-extended position (e.g., as shown in Figures 1 and 2A) and a second, extended position (e.g., as shown in Figure 2B). Thus, movement of the plunger 144 relative to the handle 140 displaces the inner shaft 134 relative to the handle 140, the outer shaft 132, and/or the intermediate shaft 133. For example, withdrawing the plunger 144 proximally from the first position to the second position can withdraw the inner shaft 134 through the intermediate shaft 133. In some embodiments, the inner shaft 134 can have a length such that the inner shaft 134 extends distally past a distal terminus of the intermediate shaft 133 when the plunger 144 is in both the first and second positions. In some embodiments, the plunger 144 can be lockable in the first position and/or the second position to lock the position of the inner shaft 134. In other embodiments, the plunger 144 can be operably coupled to other components of the catheter portion 130 such as, for example, the intermediate shaft 133 and/or one or more additional shafts (not shown).

[0035] In the illustrated embodiment, the thrombus extraction assembly 106 further includes a first flush port 138 connected to the outer shaft 132 and a second flush port 148 connected to the handle 140. The first flush port 138 can be fluidly connected to the lumen of the outer shaft 132 to allow flushing of the lumen of the outer shaft 132. The second flush port 148 can be fluidly connected to the lumen of the intermediate shaft 133 (e.g., via an internal portion of the handle 140) to allow flushing of the lumen of the intermediate shaft 133.

[0036] The thrombus extraction assembly 106 can include and/or be coupled to a thrombus extraction device configured to core and capture a thrombus from the patient. Figures 2A and 2B, for example, are side views of the thrombus extraction assembly 106 of Figure 1 operably coupled to a thrombus extraction device 250 configured in accordance with embodiments of the present technology. The thrombus extraction device 250 is shown in a deployed and partially-expanded configuration in Figure 2A and a deployed and fully-expanded configuration in Figure 2B. The thrombus extraction device 250 can be in an undeployed, constrained (e.g., unexpanded) position when positioned within the outer shaft 132.

[0037] Referring to Figures 2A and 2B together, the thrombus extraction device 250 includes an expandable coring element 252 and an expandable capture element 254 coupled to (e.g., attached to, connected to, integrally formed with) the coring element 252. The coring element 252 is positioned proximal of the capture element 254. In the illustrated embodiment, the coring element 252 includes (i) a proximal portion 253a coupled to the intermediate shaft 133 (e.g., to a distal portion of the intermediate shaft 133) and (ii) a distal portion 253b coupled to a proximal portion 255a of the capture element 254. Further, a distal portion 255b of the capture element 254 is coupled to the inner shaft 134 (e.g., to a distal portion of the inner shaft 134). As shown, the outer shaft 132 is proximally displaced relative to the handle 140 such that the mating feature 135 of the outer shaft 132 contacts/engages the lock feature 142 of the handle 140. Due to this positioning of the outer shaft 132 relative to the handle 140, each of the intermediate shaft 133, the inner shaft 134, and the thrombus extraction device 250 extend distally beyond the distal portion 136b of the outer shaft 132.

[0038] In some embodiments, the thrombus extraction device 250 can further include an atraumatic tip 258. In some embodiments, the atraumatic tip 258 can include a radiopaque marker to aid in intravascularly positioning the thrombus extraction device 250 within the patient. The thrombus extraction device 250 can additionally or alternatively include one or more radiopaque markers located on, for example, the outer shaft 132 (e.g., the distal portion 136b of the outer shaft 132) the intermediate shaft 133 (e.g., the distal portion of the intermediate shaft 133), and or other components of the thrombus extraction device 250. In some embodiments, the atraumatic tip 258 can define a channel configured to receive a guidewire therethrough.

[0039] In the partially-expanded configuration shown in Figure 2A, the plunger 144 of the handle 140 is in the first position. In contrast, in the fully-expanded configuration shown in Figure 2B, the plunger 144 is in the second position (e.g., proximally retracted away from the handle

140) such that the inner shaft 134 is proximally retracted relative to the intermediate shaft 133. This proximal retraction of the inner shaft 134 relative to the intermediate shaft 133 forces the coring element and capture element 254 to fully expand, as described in greater detail below with reference to Figure 4.

[0040] The thrombus extraction assembly 106 can comprise one or several features configured to secure the thrombus extraction device 250, and specifically the coring element 252 and/or the expandable capture element 254 in the fully-expanded position. As used herein, full expansion describes a condition in which the thrombus extraction device 250 is continually biased toward expansion by one or several forces in addition to the self-expanding forces arising from the thrombus extraction device 250. In some embodiments, full expansion occurs when the thrombus extraction device 250 is deployed and when the plunger 144 is in the second position (e.g., when the inner shaft 134 is proximally retracted relative to the intermediate shaft 133). Alternatively or additionally, full-expansion can occur when the thrombus extraction device 250 is deployed and biased towards expansion via a spring connected either directly or indirectly to the thrombus extraction device 250. Accordingly, when the thrombus extraction device 250 is fully expanded, forces less than a minimal radial compressive force do not change the diameter of the thrombus extraction device 250. Therefore, when fully-expanded, the thrombus extraction device 250 can maintain at least a desired radial force on a blood vessel when the thrombus extraction device 250 is drawn through that blood vessel. In some embodiments, the dimensions of the thrombus extraction device 250 can be selected such that the thrombus extraction device 250 apposes a wall of the blood vessel and/or applies a desired force to the wall of the blood vessel when fully expanded.

[0041] In some embodiments, the plunger 144 can be locked in the second position by, for example, rotating the plunger 144 with respect to the handle 140 to thereby engage one or several locking features on the plunger 144 and/or in the handle 140. Locking the plunger 144 in the second position secures the position of the inner shaft 134 relative to the intermediate shaft 133, thereby securing the thrombus extraction device 250 in the fully-expanded position. In other embodiments, the inner shaft 134 and the intermediate shaft 133 can be directly locked together via for example, (i) a static coupling in which the position of the inner shaft 134 is fixed relative to the position of the intermediate shaft 133 or (ii) a dynamic coupling in which the position of the inner shaft 134 relative to the intermediate shaft 133 is limited (rather than fixed). For example, the inner shaft 134 can be dynamically locked to the plunger 144 via a compliance spring

(e.g., a tension spring, compression spring), which allows limited movement of the inner shaft 134 relative to the intermediate shaft 133 when the plunger 144 is locked in the second position.

II. Selected Embodiments of Coring Elements

[0042] Figures 3A–3D are an isometric view, a side view, a top view, and a (proximally-facing) rear view, respectively, of the coring element 252 of the thrombus extraction device 250 of Figures 2A and 2B configured in accordance with embodiments of the present technology. Referring to Figures 3A–3D together, the coring element 252 comprises a plurality of struts 360 that together define a plurality of interstices or pores 362. The struts 360 can have a variety of shapes and sizes and, in some embodiments, the struts 360 can have a thickness and/or diameter between about 0.05–0.15 inch, between about 0.075–0.125 inch, between about 0.09–0.1 inch, about 0.096 inch, and/or other dimensions. In general, the struts 360 can together form a unitary fenestrated structure that is configured to core and separate a portion of a thrombus (e.g., a vascular thrombus) from a blood vessel containing the thrombus. In some embodiments, the coring element 252 can comprise a stent or stent-like device.

[0043] As best shown in Figures 3B and 3C, the coring element 252 includes a first region 363 including the proximal portion 253a, a second region 364 distal of the first region 363, a third region 365 distal of the second region 364, and a fourth region 366 distal of the third region 365 and including the distal portion 253b. The second region 364 and the fourth region 366 can be generally tubular. The first region 363 and the third region 365 have relatively fewer of the struts 360 compared to the second region 364 and the fourth region 366. For example, the first region 363 can include a pair of curved struts 367 (identified individually as first strut 367a and second strut 367a as best shown in Figures 3A and 3C) that curve in opposite directions around a central axis L of the coring element 252 and intersect and/or terminate at a pair of first junctions 361 (identified individually as a lower first junction 361a and an upper first junction 361b) to define a proximal, first mouth 370. The third region 365 can include (i) a pair of curved lower struts 368 (identified individually as a first lower strut 368a and a second lower strut 368b shown together in Figure 3A) that extend distally from a lower second junction 371a and curve around the central axis L and (ii) a pair of curved upper struts 369 (identified individually as a first upper strut 369a and a second upper strut 369b shown together in Figures 3A and 3C) that extend distally from an upper second junction 371b and curve around the central axis L. The lower and upper struts 368, 369 together define a distal first mouth portion 372a and a distal second mouth portion 372b (collectively "a second mouth 372"). In the illustrated embodiment, the first mouth portion 372a

is rotationally offset from the second mouth portion 372b. In other embodiments, the first mouth portion 372a can be positioned differently relative to the second mouth portion 372b (e.g., in a different rotational and/or longitudinal direction) and/or the second mouth 372 can comprise more than two separate portions (e.g., three, four, or more openings). In general, the first and second mouths 370, 372 can be defined by/in regions of the coring element 252 having different porosities.

[0044] In some embodiments, the coring element 252 is made from a shape memory material such as a shape memory alloy and/or a shape memory polymer. For example, the coring element 252 can comprise nitinol and/or a nitinol alloy. Similarly, the coring element 252 can be made using a variety of techniques including welding, laser welding, cutting, laser cutting, and/or expanding. For example, the coring element 252 can first be laser cut from a piece of nitinol (e.g., a nitinol tube) and then blown up and/or expanded. In general, the size (e.g., the length and diameter) of the coring element 252 can be selected based on the size (e.g., diameter) of the blood vessel from which thrombus is to be extracted. In some embodiments, the coring element 252 can have a length M of between about 0.2–5 inches (e.g., between about 1.5–2.5 inches, between about 1.75–2.25 inches, between about 1.9–2.0 inches, between about 1.5–1.8 inches, about 1.6 inches, about 1.7 inches, about 1.96 inches, about 3.0 inches, about 4.0 inches, smaller than 0.5 inch). In some embodiments, in the fully-expanded position unconstrained within a vessel, the coring element 252 can have a diameter D of between about 2–50 mm (e.g., between about 4–25 mm, between about 6 20 mm, between about 8–16 mm). In some embodiments, the length M of the coring element 252 can be selected based on the fully expanded and unconstrained diameter D of the coring element 252 to prevent undesired tipping and/or rotation of the coring element 252 within the blood vessel during operation. In general, the length M and the unconstrained diameter D of the coring element 252 will vary depending on the size of the vessel the coring element 252 is designed for. For example, the coring element 252 will generally have a smaller length M and diameter D when designed for smaller (e.g., 4 mm) vessels rather than larger (e.g., 25–35 mm) vessels.

[0045] The coring element 252 is configured to core (e.g., shear, separate) thrombus from within the blood vessel when the coring element is advanced/retracted through the thrombus in the fully-expanded configuration. For example, as described in greater detail below with reference to Figures 12D–12K, the coring element 252 can be withdrawn proximally through the thrombus to core the thrombus. As the coring element 252 is withdrawn through the thrombus the fully-expanded diameter of the coring element 252 will flexibly adapt to match the diameter of the

blood vessel. More particularly, the first and second mouths 370, 372 are configured (e.g., sized, shaped, and/or positioned) to provide most of the coring function (e.g., coring force) during operation of the coring element 252. For example, proximally-facing surfaces of the struts 367 can define a first leading edge that cuts through and cores the thrombus. Similarly, proximally-facing surfaces of the lower and upper struts 368, 369 can define a second leading edge that can also cut through and core the thrombus. In some embodiments, portions of the struts 367, the lower struts 368, and/or the upper struts 369 can be sharpened and/or can include a cutting element (e.g., a knife or knife edge) attached thereto or otherwise integrated with to further facilitate coring of the thrombus.

[0046] In one aspect of the present technology, the first mouth 370 and the second mouth 372 are longitudinally offset relative to one another. Moreover, the leading edges of the struts 367 and the leading edges of the lower and upper struts 368, 369 are oriented differently such that, for example, the first mouth 370 and the second mouth 372 are oriented at different angles when the coring element 252 is within the blood vessel. The arrangement can be more effective at coring thrombus compared to, for example, coring elements including only a single mouth (e.g., including only the first mouth 370). It is expected that the coring element 252 provides a greater coring length for engaging the wall of the blood vessel and coring (e.g., adherent) thrombus than coring elements with only a single mouth. Moreover, the coring element 252 can be relatively flexible at the first region 363 and third region 365 which include fewer struts 360 than the second region 364 and fourth region 366. For example, the coring element 252 can flex/bend at the first junctions 361 and/or the second junctions 371. In some embodiments, the first and second junctions 361, 371 enable the coring element 252 to flex in different directions (e.g., laterally and vertically). In one aspect of the present technology, this ability of the coring element 252 to flex can allow the coring element 252 to maintain a selected orientation—even when moved through tortuous vessels. In another aspect of the present technology, the arrangement of the first and second mouths 370 and 372 ensures that at least one of the first mouth 370, the first mouth portion 372a, and the second mouth portion 372b is positioned and oriented to effectively core thrombus from within the blood vessel during a thrombus extraction procedure using the coring element 252. In some embodiments, the first mouth 370 and/or the second mouth 372 can further facilitate the collapse of the coring element 252 to the non-expanded configuration.

[0047] In the embodiment illustrated in Figures 3A–3D, a first connection feature 374 and a second connection feature 376 are coupled to the coring element 252. As described in greater detail below with reference to Figure 4, the intermediate shaft 133 (Figure 1) can be operably

coupled to the first connection feature 374 and the inner shaft 134 can be operably coupled to the second connection feature 376 for controlling operation (e.g., movement and expansion) of the coring element 252. In the illustrated embodiment, the first connection feature 374 is a ring coupled to the proximal portion 253a of the coring element 252 and, more specifically, to the lower first junction 361a. In other embodiments, the first connection feature 374 can be positioned on a different portion of the coring element 252 (e.g., at the upper first junction 361b, on one of the struts 367). Similarly, the second connection feature 376 can also be a ring and can be coupled to one or more of the struts 360 in the second region 364 or another region of the coring element 252. As best seen in Figure 3D, in some embodiments the first connection feature 374 can have a diameter E_1 that is greater than a diameter E_2 of the second connection feature 376, and the first and second connection features 374, 376 can be axially aligned along an axis extending parallel to the central axis L of the coring element 252. In other embodiments, the first and second connection features 374, 376 can have other shapes and/or configurations and/or can be arranged differently relative to one another. The first and second connection features 374, 376 can be the same material as the coring element 252 or can be a different material than the coring element 252. Likewise, the first and second connection features 374, 376 can be integrally formed with the coring element 252 and/or can be attached to the coring element 252 via, for example, one or more of welds, adhesives, mechanical fasteners, and the like.

[0048] Figure 4 is an enlarged side view of the thrombus extraction device 250 coupled to a distal portion of the thrombus extraction assembly 106 and in the fully-expanded configuration in accordance with an embodiment of the present technology. In the illustrated embodiment, the coring element 252 is coupled to the intermediate shaft 133 (e.g., to a distal portion of the intermediate shaft 133) via the first connection feature 374. In some embodiments, the coring element 252 is fixedly coupled to the intermediate shaft 133 such that movement of the intermediate shaft 133 also moves the coring element 252. The proximal portion 255a of the capture element 254 is connected to the distal portion 253b of the coring element 252. In some embodiments, the capture element 254 is formed on the distal portion 253b of the coring element 252 such that the thrombus extraction device 250 is a unitary/integral structure. For example, the capture element 254 can comprise a mesh (e.g., a braided filament mesh structure) that is woven onto the distal portion 253b of the coring element 252. In some embodiments, the distal portion 255b of the capture element 254 is coupled to the to the inner shaft 134 (e.g., to a distal portion of the inner shaft 134).

[0049] In the illustrated embodiment, the inner shaft 134 slidably extends through the second connection feature 376. That is, the inner shaft 134 can have an outer diameter that is less than the diameter E_2 (Figure 4) of the second connection feature 376 such that the second connection feature 376 is slidable along the inner shaft 134. The inner shaft 134 can include a stop feature 478 configured to engage the second connection feature 376 of the coring element 252 to effect expansion of the coring element 252. In some embodiments, the stop feature 478 can comprise a polymeric member and/or a metallic member that is affixed to a portion of the inner shaft 134 that is distal of the second connection feature 376.

[0050] The stop feature 478 is configured (e.g., sized and shaped) to contact and engage the second connection feature 376 when the inner shaft 134 is withdrawn proximally relative to the coring element 252 via, for example, movement of the plunger 144 (Figures 1–3) from the first position to the second position. By this arrangement, the coring element 252 is selectively coupled to the inner shaft 134 such that the stop feature 478 can apply a proximally-directed force to the coring element 252 that can expand all or a portion of the coring element 252 to the fully-expanded configuration. For example, movement of the inner shaft 134 can forcibly expand at least the first region 363 (Figures 3B and 3C) of the coring element which is between the first and second connection features 374, 376. In some embodiments, the second connection feature 376 can be positioned differently with respect to the coring element 252 such that more or less of the coring element 252 is forcibly expanded when the stop feature 478 is pulled against the second connection feature 376.

[0051] In some embodiments, the capture element 254 can comprise a braided filament mesh structure, such as a braid of elastic filaments having a generally tubular, elongated portion 477 and a distal tapered portion 479. In other embodiments, the capture element 254 can be any porous structure and/or can have other suitable shapes, sizes, and configurations. Because the distal portion 255b of the capture element 254 is coupled to the inner shaft 134, axial movement of the inner shaft 134 expands/shortens and collapses/lengthens the capture element 254. For example, proximal movement of the inner shaft 134 can compress the capture element 254 along its longitudinal axis such that (i) a radius of the capture element 254 increases and (ii) the length of the capture element 254 decreases. Conversely, distal movement of the inner shaft 134 can stretch the capture element 254 along its longitudinal axis such that (i) the radius of the capture element 254 decreases and (ii) the length of the capture element 254 increases. In some embodiments, with reference to Figures 2A, 2B, and 4 together, distal movement of the plunger 144 can move the capture element 252 to a fully-collapsed position before the plunger 144 reaches

the fully-depressed first position shown in Figure 2A. Thus, continued distal movement of the plunger 144 (e.g., from the second position toward the first position) can pull the coring element 252 to cause the coring element 252 to collapse/longitudinally extend. That is, the plunger 144, the inner shaft 134, and the capture element 254 can collectively act to elongate/collapse the coring element 252 as the plunger 144 is distally depressed while the capture element 254 is fully collapsed. In other embodiments, the inner shaft 134 can be selectively decoupled from the capture element 254 such that proximal displacement of the inner shaft 134 expands the coring element 252 without effecting any movement of the capture element 254. In some embodiments, the capture element 254 can have a length (i) in the collapsed configuration of between about 5–30 inches (e.g., between about 10–20 inches, about 16 inches) and (ii) in the expanded configuration of between about 1–25 inches (e.g., between about 10–20 inches, about 11 inches).

[0052] In some embodiments, the capture element 254 can be formed by a braiding machine and/or a weaving machine while, in other embodiments, the capture element 254 can be manually braided and/or woven. In some embodiments, the capture element 254 is formed as a tubular braid and is then further shaped using a heat setting process. The braid can be a tubular braid of fine metal wires such as nitinol (nickel-titanium alloy), platinum, cobalt-chrome alloy, stainless steel, tungsten or titanium. In some embodiments, the capture element 254 can be formed at least in part from a cylindrical braid of elastic filaments. Thus, the braid may be radially constrained without plastic deformation such that it can self-expand on release of the radial constraint. Such a braid of elastic filaments can be referred to herein as a "self-expanding braid." In some embodiments, the thickness of the braid filaments can be less than about 0.15 mm. In some embodiments, the braid may be fabricated from filaments and/or wires with diameters ranging from about 0.05–0.25 mm. In some embodiments, braid filaments of different diameters may be combined to impart different characteristics including: stiffness, elasticity, structure, radial force, pore size, embolic capturing or filtering ability, and so on. In some embodiments the capture element 254 and/or the coring element 252 can be coated to reduce their surface friction/abrasiveness (e.g., for arterial applications). Likewise, the capture element 254 and/or the coring element 252 can be covered with a film (e.g., via dipping or spray coating) to create a non-permeable membrane to contain clot without allowing the clot to become embedded in the interstices of the capture element 254 and/or the coring element 252, thereby facilitating ease of cleaning. In some embodiments, the number of filaments used to form the capture element 254 can be between about 20–300 (e.g., including 144 filaments, 244 filaments). In some embodiments, the size of the pores formed by the capture element 254 (e.g., in the elongated

portion 477) can be between about 0.05–4.0 mm (e.g., between about 0.5 mm–2.5 mm, less than 0.4 mm).

III. Selected Embodiments of Dilator Assemblies and Associated Methods

[0053] Figures 5A and 5B are side views of the dilator assembly 104 of Figure 1 in a first configuration and a second configuration, respectively, configured in accordance with embodiments of the present technology. Referring to Figures 5A and 5B together, the dilator assembly 104 includes a first shaft or sheath 580 extending between and operably coupling the control assembly 120 and the retention sheath 122. The dilator assembly 104 can further include a second shaft or sheath 582 slidably positioned over the first shaft 580 and operably coupled to the control assembly 120. Put differently, the second shaft 582 can define a lumen sized to slidably receive the first shaft 580 such that the first and second shafts 580, 582 are axially displaceable relative to one another. In the illustrated embodiment, the first shaft 580 is longer than the second shaft 582 such that the retention sheath 122 is positioned distal of a distal portion 583b (opposite a proximal portion 583a) of the second shaft 582. The control assembly 120 further includes a housing 595 configured to engage (e.g., mate with) the sealable hub 114 of the introducer assembly 102 (Figure 1).

[0054] The retention sheath 122 includes a proximal portion 585a and a distal portion 585b. In the illustrated embodiment, the distal portion 585a includes an atraumatic tip 584 and the proximal portion 585a includes a first engagement feature 586. Similarly, the distal portion 583b of the second shaft 582 includes a second engagement feature 589. In some embodiments, the atraumatic tip 584 is radiopaque.

[0055] When the dilator assembly 104 is in the first configuration shown in Figure 5A, the second shaft 582 is proximally positioned (e.g., withdrawn) relative to the first shaft 580 such that the first engagement feature 586 does not engage the second engagement feature 589. As described in greater detail below with reference to Figure 7A, when the dilator assembly 104 is in the first configuration, the first engagement feature 586 is configured to engage (e.g., connect with, mate with) the distal portion 113b of the sheath 112 of the introducer assembly 102 (Figure 1). In some embodiments, the engagement of the first engagement feature 586 with the sheath 112 can form a seal.

[0056] When the dilator assembly 104 is in the second configuration (Figure 5B), the second engagement feature 589 of the second shaft 582 is configured to engage the first engagement feature 586 of the retention sheath 122. As shown, the second shaft 582 can have a diameter that

is equal to or substantially equal to the outer diameter of the retention sheath 122 such that the dilator assembly 104 has a uniform or substantially uniform (e.g., smooth) outer surface in the second configuration. That is, there is no step or discontinuity in the outer surface between, for example, the first shaft 580 and the retention sheath 122. In other embodiments, the second shaft 582 and the retention sheath 122 can have different diameters, and the first and second engagement features 586, 589 can be configured to provide a smooth transition between the second shaft 582 and the retention sheath 122. In some embodiments, the engagement of the first engagement feature 586 with the second engagement feature 589 can form a seal. In some embodiments, the operator can move the dilator assembly 104 from the first configuration to the second configuration by actuating the actuator 124 of the control assembly 120 (e.g., by advancing the actuator 124 in the direction of arrows A). More specifically, as described in greater detail below with reference to Figures 7A–7D, actuation of the actuator 124 can distally advance (i) the first and second shafts 580, 582 together relative to the sheath 112 and then (ii) the second shaft 582 relative to the first shaft 580.

[0057] Figure 6 is an enlarged cross-sectional side view of a portion of the thrombectomy system 100 shown in Figure 1. More particularly, Figure 6 shows a self-expanding funnel 690 coupled to the distal portion 113b of the sheath 112 of the introducer assembly 102 and restrained within the retention sheath 122 of the dilator assembly 104 in accordance with an embodiment of the present technology. In the illustrated embodiment, the retention sheath 122 includes a shell portion 692 coupled to the tip 584 and defining a lumen 693. In some embodiments, the shell portion 692 and the tip 584 are integrally formed together while, in other embodiments, the tip 584 can be a separate component that is coupled to the shell portion 692 by, for example, positioning at least a portion of the tip 584 in the lumen 693 and securing the shell portion 692 to the tip 584 (e.g., via an adhesive, friction fit).

[0058] The first shaft 580 of the dilator assembly 104 extends through a lumen 688 of the sheath 112 and at least partially through the lumen 693 of the shell portion 692. In the illustrated embodiment, a portion of the tip 584 snuggly receives a distal portion (e.g., a distal portion) of the first shaft 580 to secure the first shaft 580 to the retention sheath 122. In other embodiments, the first shaft 580 can be coupled to the retention sheath 122 in other manners. As further shown in Figure 6, the first shaft 580 and the tip 584 can define a continuous lumen 691 for receiving a guidewire (not shown). In some embodiments, the guidewire can have a diameter of about 0.038 inch, 0.035 inch, about 0.018 inch, 0.014 inch, greater than about 0.38 inch, less than about 0.1 inch, or less than about 0.05 inch.

[0059] In the illustrated embodiment, an inner diameter F_1 of the shell portion 692 is greater than an external diameter F_2 of the first shaft 580 such that an annular retaining/receiving space 694 is formed between the outer surface of the first shaft 580 and the inner surface of the shell portion 692. The receiving space 694 is configured (e.g., sized and shaped) to receive and/or retain the funnel 690 in a constrained configuration. Accordingly, in some embodiments the funnel 690 can have a diameter substantially matching the inner diameter F_1 of the shell portion 692 when the funnel 690 is in the constrained configuration. In some embodiments, the first engagement feature 586 of the retention sheath 122 can engage (e.g., sealingly engage) the distal portion 113b of the sheath 112 when the funnel 690 is retained within the retention sheath 122.

[0060] Figures 7A–7D are side views illustrating various stages in a process or method for deploying the funnel 690 in accordance with embodiments of the present technology. Referring first to Figure 7A, the dilator assembly 104 is initially positioned within the introducer assembly 102 in the first configuration (Figure 5A) such that (i) the housing 595 of the control assembly 120 is coupled to/engages the sealable hub 114 and (ii) the first engagement feature 586 of the retention sheath 122 sealingly engages the distal portion 113b of the sheath 112. In other embodiments, the first engagement feature 586 need not sealingly engage the sheath 112. In the initial position shown in Figure 7A, the actuator 124 of the control assembly 120 is in a first position (e.g., a fully-retracted position) and the funnel 690 is contained in the constrained configuration within the retention sheath 122, as shown in Figure 6.

[0061] In the arrangement shown in Figure 7A, the introducer assembly 102 and the dilator assembly 104 (collectively "assemblies 102, 104") can be used to percutaneously access a venous vessel of a patient through, for example an access site such as a popliteal access site, a femoral access site, an internal jugular access site, and/or other access site. In some embodiments, the assemblies 102, 104 are inserted through another introducer sheath (not shown). In some embodiments, the assemblies 102, 104 are advanced within the venous vessel to a treatment position in which the distal portion 113b of the sheath 112 is proximate to (e.g., proximal of) a thrombus in the venous vessel.

[0062] Referring to Figure 7B, after positioning the assemblies 102, 104, the funnel 690 (shown as transparent in Figures 7B and 7C for the sake of clarity) can be deployed by, for example, moving the actuator 124 from the first position (Figure 7B) to a second position (e.g., an intermediate position, a mid-stroke position, a drop-off position) to distally advance the first and second shafts 580, 582 together relative to the sheath 112. The distal advancement of the first

shaft 580 causes the retention sheath 122 to move distally over and away from the funnel 690. The funnel 690 self-expands to an expanded (e.g., unconstrained) configuration when the funnel 690 is no longer constrained by the retention sheath 122. In other embodiments, the control assembly 120 is configured such that moving the actuator 124 from the first position to the second position distally advances only the first shaft 580 of the dilator assembly 104 rather than both the first and second shafts 580, 582 together.

[0063] The funnel 690 can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, in the expanded configuration, the funnel 690 can have (i) a maximum diameter greater than and/or equal to the diameter D of the coring element 252 (Figures 3B and 3C) when the coring element 252 is in the fully-expanded configuration and (ii) a minimum diameter substantially equal to an outer diameter of the sheath 112. In some embodiments, the funnel 690 can have a length N that is greater than and/or equal to the length M of the coring element 252 (Figures 3A–3D) such that the coring element 252 can be received and contained within the funnel 690. In other embodiments, the length N of the funnel 690 can be less than the length M of the coring element 252. In some embodiments, the funnel 690 can have a conically shaped portion, and specifically, a truncated-conically shaped portion. In some embodiments, the funnel 690 can be formed from at least one of a castellated nitinol braid, a nitinol braided stent, a laser cut nitinol, a laser cut polymer tube, an injection molded polymeric structure, or an inflatable balloon. In some embodiments, the funnel 690 can comprise a mesh having a pore size sufficiently small to prevent the passage of thrombus through the pores of the mesh. In some embodiments, the funnel 690 can be permeable to blood.

[0064] Referring to Figure 7C, after the funnel 690 has been deployed, the dilator assembly 104 can be moved to the second configuration (Figure 5B). For example, the operator can move the actuator 124 of the control assembly 120 from the second position (Figure 7B) to a third position (e.g., a fully-advanced position) to distally advance the second shaft 582 relative to the first shaft 580 until the second engagement feature 589 of the second shaft 582 engages the first engagement feature 586 of the retention sheath 122. As shown in Figure 7D, after moving the dilator assembly 104 to the second configuration, the dilator assembly 104 can be fully retracted and withdrawn from the introducer assembly 102. For example, the dilator assembly 104 can be proximally retracted through the lumen of the sheath 112 and out of the sealable hub 114 of the introducer assembly 102.

[0065] Referring to Figures 7A–7D together, in one aspect of the present technology, moving the dilator assembly 104 to the second configuration before retracting the dilator assembly 104 from the introducer assembly 102 can inhibit or even prevent the dilator assembly 104 from damaging the funnel 690 or other components of the introducer assembly 102 during retraction of the dilator assembly 104. More specifically, if the dilator assembly 104 did not include the second shaft 582, proximal retraction of the retention sheath 122 into the sheath 112 could cause the retention sheath 122 (e.g., the first engagement feature 586) to snag or damage the deployed funnel 690. However, because the second shaft 582 has a diameter that is equal to or substantially equal to the outer diameter of the retention sheath 122, the dilator assembly 104 has a uniform or substantially uniform (e.g., smooth) outer surface in the second configuration, and is therefore less likely to snag or otherwise damage the funnel 690, the sealable hub 114, and/or other components of the introducer assembly 102 during retraction. In other embodiments, the second shaft 582 and the retention sheath 122 can have different diameters, and the first and second engagement features 586, 589 can be configured to provide a smooth transition between the second shaft 582 and the retention sheath 122.

[0066] In another aspect of the present technology, the movement of the actuator 124 from the first position to the third position both (i) advances the first and second shafts 580, 582 together to deploy the funnel 690 (e.g., as the actuator 124 moves from the first position to the second position) and (ii) advances the second shaft 582 relative to the first shaft 580 (e.g., as the actuator 124 moves from the second position to the third position) so that the dilator assembly 104 has a generally uniform outer diameter. This "dual-action" allows the control assembly 120 to be coupled to the sealable hub 114 during both the deployment of the funnel 690 and the advancement of the second shaft 582 toward the first shaft 580. This can advantageously inhibit or prevent the inadvertent advancement of the retention sheath 122 and therefore the premature deployment of the funnel 690. For example, the dilator assembly 104 and the introducer assembly 102 must often be fully removed from the patient for reloading of the funnel 690 if the funnel 690 is prematurely deployed—potentially increasing the trauma to the patient and the duration of the thrombectomy procedure. In contrast, some conventional dilator assemblies include a dilator that is "floating" (e.g., not locked to or engaged with an introducer assembly) such that an inadvertent bump or other force on the dilator assembly can cause corresponding movement of the dilator assembly.

[0067] Figures 8A, 8C, and 8D are cross-sectional side views, and Figure 8B is an enlarged cross-sectional isometric view, of the control assembly 120 configured in accordance with embodiments of the present technology. In Figures 8A and 8B the actuator 124 is in the first

position shown in Figure 7A, in Figure 8C the actuator 124 is in the second position shown in Figure 7B, and in Figure 8D the actuator 124 is in the third position shown in Figure 7C.

[0068] Referring first to Figure 8A, the control assembly 120 includes a proximal portion 801a and a distal portion 801b and defines a lumen 802 extending therethrough between the proximal and distal portions 801a, b. In the illustrated embodiment, the control assembly 120 includes a sealable member 804 at or proximate the proximal portion 801a and a connection portion 806 at or proximate the distal portion 801b. The sealable member 804 can be configured to selectively seal the lumen 802 of the control assembly 120 and, in some embodiments, can receive a guidewire (not shown) therethrough. The connection portion 806 is configured to mate/engage with the sealable hub 114 of the introducer assembly 102 to secure the control assembly 120 thereto, as described in detail above with reference to Figures 7A–7C. For example, in some embodiments the connection portion 806 can include a snap feature (e.g., having one or more teeth, flanges), a twist lock (e.g., a bayonet- or luer-type fitting), and/or other feature for engaging and/or locking to the sealable hub 114.

[0069] Referring to Figures 8A and 8B together, in the illustrated embodiment the control assembly 120 further includes a first shaft hub 810 and a second shaft hub 850. The first shaft hub 810 is configured to be coupled to the first shaft 580 of the dilator assembly 104, and the second shaft hub 850 is configured to be coupled to the second shaft 582 of the dilator assembly 104. The first and second shafts 580, 582 are not shown in Figures 8A–8D for the sake of clarity. In the illustrated embodiment, the second shaft hub 850 is connected to (e.g., integrally formed with) the actuator 124, which extends outside the housing 595 and is configured to be advanced distally and/or retracted proximally by the operator. The first shaft hub 810 includes a first body portion 812 and one or more first engagement or snap features 814 (only one first engagement feature 814 is visible in Figures 8A–8D) that extend radially and/or axially away from the first body portion 812 and into a corresponding first track 830 formed in the housing 595. The second shaft hub 850 similarly includes a second body portion 852 and second engagement or snap features 854 (e.g., a pair of similar or identical second engagement features 854) that extend radially and/or axially away from the second body portion 852 and into a corresponding second track 840 formed in the housing 595.

[0070] In the illustrated embodiment, the first track 830 includes one or more proximal detents 832 (obscured in Figures 8A and 8B; shown in Figure 8C), one or more distal detents 834, and a distal terminus 835. In some embodiments, the first track 830 can include a pair of opposing

(e.g., radially opposite) proximal detents 832 and a pair of opposing distal detents 834. The second track 840 includes a first portion 842 having a first track width or height G_1 (Figure 8A) and a second portion 844 having a second track width or height G_2 (Figure 8A) greater than the first track width G_1. In some embodiments, the transition (e.g., a slope or step) between the first and second portions 842, 844 of the second track 840 is generally aligned over and/or proximate to the distal detents 834 of the first tack 830.

[0071] In operation, the first and second shaft hubs 810, 850 are configured to slide within the lumen 802 along the first and second tracks 830, 840, respectively. In some embodiments, the first engagement features 814 and/or the second engagement features 854 are flexible such that they can flex/bend as the first and second shaft hubs 810, 850 move along the first and second tracks 830, 840. The configuration/arrangement of the first and second shaft hubs 810, 850 and the first and second tracks 830, 840—for example, the arrangement of the proximal and distal detents 832, 834, the first portion 842, and/or the second portion 844—can facilitate the movement of the dilator assembly 104 from the first configuration (Figure 5A) to the second configuration (Figure 5B).

[0072] More specifically, in the first position shown in Figures 8A and 8B, the actuator 124 is positioned at a most proximal position along the housing 595. For example, the first shaft hub 810 can abut a proximal wall portion 807 of the housing 595. In the first position, the first portion 842 of the second track 840 compresses (e.g., presses, constrains) the second engagement features 854 of the second shaft hub 850 radially inward toward and into engagement with the first shaft hub 810 (e.g., with the first body portion 812). Put differently, a distance (e.g., diameter) of the second shaft hub 850 between the second engagement features 854 can be greater than the first diameter G_1 when the second shaft hub 850 is in a relaxed state, unconstrained by the first portion 842 of the second track 840. By this arrangement, the second shaft hub 850 is secured to the first shaft hub 810 such that movement of the actuator 124 along the first portion 842 of the second track 840 moves both the first and second shaft hubs 810, 850. In some embodiments, the first body portion 812 of the first shaft hub 810 can include various features (e.g., grooves, channels, teeth) for mating with the second engagement features 854 of the second shaft hub 850 to thereby secure the first and second shaft hubs 810, 850 together.

[0073] Moreover, in the first position, at least a portion of the first engagement features 814 of the first shaft hub 810 can be positioned proximal of the proximal detents 832 (Figures 8C and 8D). The proximal detents 832 can thus retain the first shaft hub 810—and the second shaft hub

850 and the actuator 124 secured thereto—in the first position until a predetermined force is applied to the actuator 124 in the distal direction. In one aspect of the present technology, this arrangement can inhibit the unintended distal advancement of the first shaft 580—and thus the premature deployment of the funnel 690 (Figures 7A–7C). In some embodiments, when the predetermined force is applied to the actuator 124, the first engagement features 814 flex inwardly such that first shaft hub 810 can slide distally thereby.

[0074] Accordingly, referring to Figures 8A–8C together, the actuator 124 can be advanced distally from the first position to the second position shown in 8C after the first engagement features 814 disengage the proximal detents 832. As the actuator 124 is moved distally, the first and second shaft hubs 810, 850 move distally together—thereby advancing the first and second shafts 580, 582 together as shown in Figure 7B—until the first shaft hub 810 reaches the distal terminus 835 of the first track 830 and/or the second shaft hub 840 reaches the second portion 844 of the second track 840. More specifically, the distal terminus 835 and/or the distal detents 834 of the first track 830 can engage the first engagement features 814 to prevent the first shaft hub 810 (and thus the first shaft 580) from moving farther distally. At the same time, the greater-diameter second portion 844 of the second track 840 allows the second engagement features 854 to move radially outward (e.g., flex radially outward toward the relaxed state) and out of engagement with first shaft hub 810. That is, the control assembly 120 is configured such that the second engagement features 854 of the second shaft hub 850 reach the transition point between the first and second portions 842, 844 of the first track 840 at substantially the same time as the first engagement features 814 of the first shaft hub 810 reach/engage the distal detents 834 of the first track 830.

[0075] Accordingly, as shown in Figure 8D, the second shaft hub 850 can leave the first shaft hub 810 behind and advance further distally to the third position. As the second shaft hub 850 moves distally while the first shaft hub 810 remains stationary, the second shaft 582 is advanced distally toward the retention sheath 122 as shown in Figure 7C. In some embodiments, the second shaft hub 850 can abut a distal wall portion 809 of the housing 595 in the third position.

[0076] Referring to Figures 5A–8D together, in one aspect of the present technology, the control assembly 120 facilitates the movement of the dilator assembly 104 from the first configuration to the second configuration with only as a single movement of the actuator 124 from the first to third positions. As described above, this advantageously allows the control assembly 120 to be coupled to the sealable hub 114 at all times during deployment of the funnel 690, which

controls deployment of the funnel 690 and prevents the funnel 690 from inadvertently being deployed. This is expected to reduce the potential for the other components of the system, such as the retention sheath 122, from catching on the funnel 690 as the dilator is retracted through the sheath 112. Moreover, deployment of the funnel 690 and advancement of the second shaft 582 are achieved by a single stroke and are thus greatly simplified.

[0077] In some embodiments, the actuator 124 can be moved proximally (e.g., from the third position toward the first position) to facilitate loading of the funnel 690. For example, the dilator assembly 104 can be inserted into the sheath 112 when the control assembly 120 is in the third position such that the retention sheath 122 extends from the distal portion 113b of the sheath 112 and distally beyond the funnel 690. The operator can then move the actuator 124 to the second position, thereby forcing the second shaft hub 850 into engagement with the first shaft hub 810 via the narrowing of the second track 840 from the second portion 844 to the first portion 842. The loading tool 108 (Figure 1) can then be slid proximally over the retention sheath 122 and the funnel 690 until the funnel 690 is fully encapsulated by the loading tool 108 and/or until the funnel 690 is in the constrained configuration. The operator can then move the actuator 124 from the second position to the first position to retract the retention sheath 122 over the funnel 690 to thereby load/capture the funnel 690 within the receiving space 694 of the retention sheath 122. Finally, the loading tool 108 can be removed.

[0078] In other embodiments, control assemblies in accordance with the present technology can include other components and/or configurations for facilitating the dual-action of (i) advancing the first and second shafts 580, 582 to deploy the funnel 690 and (ii) advancing the second shaft 582 relative to the first shaft 580 to provide a uniform outer surface that facilitates retraction of the dilator assembly 104. Figures 9A–9C, for example, are cross-sectional side views of a control assembly 920 including the actuator 124 in the first position, the second position, and the third position (Figures 7A–7C) configured in accordance with another embodiment of the present technology.

[0079] The control assembly 920 can include some features generally similar to the control assembly 120 described in detail above with reference to Figures 8A–8D. For example, referring to Figures 9A–9C together, the control assembly 920 includes a first shaft hub 910 coupled to the first shaft 580 of the dilator assembly 104, and a second shaft hub 950 coupled to the second shaft 582 of the dilator assembly 104. In the illustrated embodiment, the second shaft hub 950 is connected to (e.g., integrally formed with) the actuator 124, which extends outside a housing 995

of the control assembly 920 and is configured to be advanced distally and/or retracted proximally by the operator. The first and second shaft hubs 910, 950 are configured to slide at least partially through a lumen 902 extending through the housing 995.

[0080] In the illustrated embodiment, the control assembly 920 further includes an elongate member 960 (shown as transparent in Figures 9A–9C for the sake of clarity) having (i) a proximal portion 961a positioned proximal of the first shaft hub 910 and (ii) a distal portion 961b positioned distal of the first shaft hub 910 and coupled to the second shaft hub 950. The first shaft hub 910 can be slidably positioned within the elongate member 960. A biasing member 964, such as a compression spring, extends between the proximal portion 961a of the elongate member 960 and the first shaft hub 910. In some embodiments, a proximal portion 965a of the biasing member 964 is connected to the proximal portion 961a of the elongate member 960 and a distal portion 965b of the biasing member 964 is connected to the first shaft hub 910.

[0081] The control assembly 920 can further include a stop member 970 coupled to the first shaft 580 (e.g., to a proximal portion of the first shaft 580). The stop member 970 is configured to slide at least partially through the lumen 902 of the housing during operation of the control assembly 920 and can be fully contained within the housing 995 (e.g., as shown in Figures 9B and 9C) and/or can extend fully or partially outside of the housing 995 (e.g., as shown in Figure 9A). As shown in Figure 9B, the stop member 970 has a dimension (e.g., diameter) H_1 that is greater than a dimension H_2 of a stop portion 972 of the housing 995. By this arrangement, the stop member 970 is configured to contact the stop portion 972 of the housing 995 to thereby prevent the first shaft 580 (and the retention sheath 122 attached thereto) from advancing farther distally.

[0082] Referring to Figure 9A, in the first position, the first shaft hub 910 engages (e.g., mates with) the second shaft hub 950 such that distal advancement of the actuator 124 moves both the first and second shaft hubs 910, 950. Moreover, the biasing member 964 is at equilibrium and thus does not exert any force on, for example, the first shaft hub 910. In some embodiments, the actuator 124 and/or the second shaft hub 950 can include first engagement features 954 (e.g., bumps, projections) that can engage (e.g., mate with) corresponding first detents 957 in the housing 995 to releasably secure the actuator 124 in the first position until a predetermined force is applied to the actuator in the distal direction. In some embodiments, when the predetermined force is applied to the actuator 124, the first engagement features 954 can flex outwardly and out of the first detents 957 to permit the first and second shaft hubs 910, 950 to move distally.

[0083] Accordingly, referring to Figures 9A and 9B together, the actuator 124 can be advanced distally from the first position to the second position after the first engagement features 954 disengage the first detents 957. As the actuator 124 is moved distally, the first and second shaft hubs 910, 950 move distally together—thereby advancing the first and second shafts 580, 582 together as shown in Figure 7B—until the stop member 970 reaches and contacts the stop portion 972 of the housing 995. More specifically, the biasing member 964 can exert a force against the first shaft hub 910 to move the first shaft hub 910 together with the second shaft hub 950. When the stop member 970 contacts the stop portion 972, the first shaft hub 910 is stopped from advancing farther distally.

[0084] Accordingly, referring to Figures 9B and 9C together, the second shaft hub 950 can leave the first shaft hub 910 behind as the actuator 124 is moved farther distally to the third position. As the second shaft hub 950 moves distally while the first shaft hub 910 remains stationary, the second shaft 582 is advanced distally toward the retention sheath 122 as shown in Figure 7C. In some embodiments, the second shaft hub 950 can abut a distal wall portion 909 of the housing 995 in the third position, which prevents the second shaft hub 950 from advancing farther. As further shown in Figure 9C, advancing the second shaft hub 950 to the third position compresses the biasing member 964 between the first shaft hub 910, which remains stationary, and the proximal portion 961a of the elongate member 960 which continues to move with the second shaft hub 950. In some embodiments, the bias force exerted by the biasing member 964 can facilitate the subsequent movement of the actuator 124 from the third position to the second position. In some embodiments, the actuator 124 can include second engagement features 958 (e.g., bumps, projections) that can engage (e.g., mate with) corresponding second detents 959 in the housing 995 to releasably secure the actuator 124 in the third position until a predetermined force is applied to the actuator in the proximal direction. In some embodiments, this force can be less than that required to disengage the first engagement features 954 from the first detents 957 due to the biasing force of the biasing member 964. In other embodiments, the detents 959 can comprise a track (e.g., an L-shaped track), and the second shaft hub 950 can be rotated to rotate the second engagement features 958 into the track to releasably secure the actuator 124 in the third position.

[0085] In other embodiments, the stop member 970 is not configured to stop distal advancement of the first shaft 580. Rather, the stop member 970 can instead be a luer flush port 970 (or another component) that simply moves together with the first shaft 580, or can be omitted altogether. In such embodiments, the first shaft hub 910 can move along a track (not shown)

formed in the housing 995 in a similar manner as the first shaft hub 810 described in detail with reference to Figures 8A–8D. For example, the first shaft hub 910 can include first engagement or snap features 914 (only one first engagement feature 914 is visible in Figures 9A–9C) that extend (i) radially and/or axially away from a body portion of the first shaft hub 910, (ii) out of the elongate member 960, and (iii) into the track in the housing 995. The track can include a detent or other feature (not shown) configured (e.g., positioned and shaped) to stop the first shaft hub 910 from moving farther distally when the first shaft hub 910 reaches the second position shown in Figure 9B.

[0086] Figures 10A and 10B are partially cross-sectional side views of a control assembly 1020 configured in accordance with another embodiment of the present technology. In general, the control assembly is movable between (i) the first position (shown in Figure 10A) in which the second shaft 582 is retracted proximally relative to the first shaft 580 as shown in Figures 5A and 7A and (ii) the third position (shown in Figure 10B) in which the second shaft 582 is advanced distally relative to the first shaft 580 to form a generally uniform outer surface of the dilator assembly 104 as shown in Figures 5B and 7C. In one aspect of the present technology, the control assembly 1020 does not include the intermediate second position (Figure 7B), but instead fluidly moves between the first and third positions.

[0087] The control assembly 1020 can include some features generally similar to the control assembly 120 and/or the control assembly 920 described in detail above with reference to Figures 8A–9C. For example, referring to Figures 10A and 10B together, the control assembly 1020 includes an actuator 1024 (e.g., a plunger 1024) that is movable relative to/through a lumen 1002 of a housing 1095. The plunger 1024 is coupled to (i) a first shaft hub 1010 that is coupled to the first shaft 580 of the dilator assembly 104 and (ii) a second shaft hub 1050 that is coupled to the second shaft 582 of the dilator assembly 104. The first and second shafts 580, 582 are not shown in Figures 10A and 10B for the sake of clarity.

[0088] In the illustrated embodiment, the second shaft hub 1050 includes engagement features 1054 that are configured (e.g., sized and shaped) to engage with a corresponding stop portion 1056 formed in the housing 1095 when the plunger 1024 is in the first position shown in Figure 10A. The first shaft hub 1010 is configured to slide along a track 1080 formed in/along a portion of the plunger 1024. In some embodiments, the track 1080 includes at least one detent 1084 at a distal portion thereof and configured to stop/block distal advancement of the first shaft

hub 1010. In other embodiments, the housing 1095 can include a flange or other component configured to stop distal advancement of the first shaft hub 1010.

[0089] A first biasing member 1064 (e.g., a compression spring) extends between and operably couples (e.g., connects) the first shaft hub 1010 and a proximal portion 1096 of the housing 1095. A second biasing member 1066 (e.g., a compression spring) extends between and operably couples (e.g., connects) the first and second shaft hubs 1010, 1050. In the first position shown in Figure 10A, both of the first and second biasing members 1064, 1066 are compressed and under load and therefore urge the first and second shaft hubs 1010, 1050, respectively, distally. In some embodiments, the first biasing member 1064 has a larger compression force than the second biasing member 1066.

[0090] In the first position shown in Figure 10A, the plunger 1024 is locked in a proximally retracted position by the engagement of the engagement features 1054 with the stop portion 1056 of the housing 1095. To move the control assembly 1020 to the third position shown in Figure 10B, the operator can rotate the plunger 1024 (e.g., as indicated by arrow I in Figure 10A) to unlock the second shaft hub 1050 and the plunger 1024. When the plunger 1024 is unlocked, the first biasing member 1064 is configured to drive the first shaft hub 1010 distally until the first shaft hub 1010 is stopped by/within the detent 1084. In one aspect of the present technology, because the first biasing member 1064 is stronger than the second biasing member 1066, the second biasing member 1066 remains substantially compressed until the first shaft hub 1010 engages the detent 1084. Therefore, both the first and second shaft hubs 1010, 1050—and thus both the first and second shafts 580, 582—move together until the first shaft hub 1010 reaches the detent 1084. Then, the second biasing member 1066 is configured to drive the second shaft hub 1050 distally relative to the first shaft hub 1010 (e.g., away from the first shaft hub 1010). In the third position shown in Figure 10B, the first and second biasing members 1064, 1066 can bias the first and second shaft hubs 1010, 1050 distally to maintain the control assembly 1020 in the third position. By this arrangement, the first and second shafts 580, 582 are automatically moved from the first configuration (Figure 5A) to the second configuration (Figure 5B)—deploying the funnel and readying the dilator assembly 104 for retraction as shown in Figures 7A–7D.

[0091] In other embodiments, the first and second biasing members 1064, 1066 can be arranged in an opposite configuration. For example, the first biasing member 1064 can extend between and operably couple the first and second shaft hubs 1010, 1050, and the second biasing member 1066 can extend between and operably couple the second shaft hub 1050 and a distal

portion 1098 of the housing 1096. Likewise, the second biasing member 1066 can have a larger compression force than the first biasing member 1064. Thus, the first and second biasing members 1064, 1066 can bias the control assembly 1020 to the first position. To move the control assembly 1020 to the third position, the user can advance the plunger 1024 against the compression forces of the first and second biasing members 1064, 1066 until the second shaft hub 1050 reaches the third position. In some embodiments, the user can then rotate the plunger 1024 to lock the control assembly 1020 in the third position.

IV. Selected Embodiments of Thrombectomy Methods

[0092] Figure 11 is a schematic view of an introduction technique for accessing a thrombus 1190 for treatment with the thrombectomy system 100 in accordance with an embodiment of the present technology. The thrombus 1190 (e.g., clot material) can be located in a blood vessel 1196 and accessed through an access site 1192 such as the popliteal access site, or other venous or arterial access sites. The introducer assembly 102 can extend from the popliteal access site 1192, or other venous or arterial access sites, to a deployment position 1194 at which the self-expanding funnel 690 can be deployed and which can be proximate to the thrombus 1190. As described in greater detail below with reference to Figures 12A–12K, the thrombus extraction device 250 can be passed through the thrombus 1190 in the direction of blood flow and then retracted through the thrombus 1190 in a direction with blood flow. During retraction, the coring element 252 can core/separate the thrombus 1190 and the capture element 254 can capture all or a portion of the thrombus 1190. In some embodiments, some or all of the thrombus extraction device 250 can extend into one of the iliac veins and/or the inferior vena cava.

[0093] More particularly, Figures 12A–12C are side views, and Figures 12D–12M are enlarged side views, of the thrombectomy system 100 positioned within the blood vessel 1196 during a thrombectomy procedure to treat (e.g., remove) the thrombus 1190 in accordance with embodiments of the present technology.

[0094] Figure 12A illustrates the thrombectomy system 100 intravascularly positioned within the blood vessel 1196 after (i) deploying the self-expanding funnel 690 (e.g., as described in detail with reference to Figures 5A–10B), (ii) removing the dilator assembly 104 from the introducer assembly 102, and (iii) advancing the outer shaft 132 of the thrombus extraction assembly 106 through the sheath 112 and the thrombus 1190. The distal advance of the outer shaft 132 through the thrombus 1190 can be either with or against the direction of blood flow.

[0095] Figure 12B illustrates the thrombectomy system 100 after advancing the thrombus extraction device 250 through the outer shaft 132 to a deployed position distal of the thrombus 1190. In some embodiments, the thrombus extraction device 250 can be constrained within the outer shaft 132 and inserted, together with the outer shaft 132, into the lumen of the sheath 112 via the sealable hub 114. In some embodiments, the thrombus extraction device 250 can be deployed by advancing the thrombus extraction device 250 beyond the distal portion 136b of the sheath 112 and/or by retracting the outer shaft 132 relative to the thrombus extraction device 250 until the thrombus extraction device 250 is beyond the distal portion 136b of the outer shaft 132.

[0096] Figure 12C illustrates the thrombectomy system 100 after fully-expanding the thrombus extraction device 250. In some embodiments, at least a portion of the coring element 252 and/or the capture element 254 contact a wall 1297 of the blood vessel 1196 in the fully-expanded position. As described in detail above with reference to Figures 2A and 2B, in some embodiments the thrombus extraction device 250 can be fully expanded by moving the plunger 144 from the first position to the second position and securing the plunger 144 in the second position to thereby fix the relative position of the inner shaft 134 with respect to the intermediate shaft 133.

[0097] In general, Figures 12D–12K illustrate the proximal retraction of the thrombus extraction device 250 through the thrombus 1190 to capture at least a portion of the thrombus 1190, and the subsequent joint retraction of the thrombus extraction device 250 and the captured thrombus 1190 into the funnel 690 and the sheath 112.

[0098] Referring first to Figure 12D, proximal retraction of the thrombus extraction device 250 causes the coring element 252 to separate and/or core a distal portion 1298b of the thrombus 1190 from the wall 1297 of the blood vessel 1196. As shown in Figure 12E, continued proximal retraction of the thrombus extraction device 250 through the thrombus 1190 causes the capture element 254 to capture the distal portion 1298b of the thrombus 1190 therein. Figures 12F–12H illustrate further proximal retraction of the thrombus extraction device 250 which causes further separation, coring, and/or capture of the thrombus 1190. As seen in Figure 12H, a proximal portion 1298a of the thrombus 1190 is cored and captured as the thrombus extraction device 250 is proximally retracted toward the funnel 690 and the sheath 112.

[0099] As described in detail above with reference to Figures 3A–4, the coring element 252 can include both the first mouth 370 and the second mouth 372 (identified in Figure 12D). Thus, the first mouth 370, the first mouth portion 372a, and/or the second mouth portion 372b can

facilitate the coring/separating of the thrombus 1190 during proximal retraction of the thrombus extraction device 250. In one aspect of the present technology, the first mouth 370 and the second mouth 372 are radially offset relative to one another which can increase the coring effectiveness—even when the blood vessel 1196 is very tortuous and/or the thrombus 1190 is strongly adhered to the wall 1297 of the blood vessel 1196—by ensuring that at least one of the first mouth 370 and the second mouth 372 is positioned and oriented to effectively core the thrombus 1190.

[0100] In some embodiments, as shown in Figures 12I and 12G, the thrombus extraction device 250 can be proximally retracted until the proximal portion 253a of the coring element 252 is contained (e.g., positioned) within the funnel 690. More specifically, the thrombus extraction device 250 can be proximally retracted until all or a portion of the first mouth 370 and/or the second mouth 372 of the coring element 252 are contained within the funnel 690. In some embodiments, when one or both of the first and second mouths 370, 372 are positioned within the funnel 690, the thrombus extraction device 250 can be moved or transformed from the expanded deployed state to the compressed state to compress and secure the thrombus 1190 captured by the thrombus extraction device 250. In some embodiments, for example, the intermediate shaft 133 (Figure 12H) can be unlocked and/or decoupled from the inner shaft 134 (e.g., via user actuation of the plunger 144 shown in Figures 1–2B) such that the inner shaft 134 can be advanced distally relative to the intermediate shaft 133 to collapse or compress the thrombus extraction device 250.

[0101] After the thrombus extraction device 250 has been collapsed, the thrombus extraction device 250 can be proximally retracted through the funnel 690 and into the sheath 112 as depicted in Figure 12K. The thrombus extraction device 250 can continue to be proximally retracted until the thrombus extraction device 250 and the captured thrombus 1190 are fully contained within the sheath 112. In some embodiments, the thrombus extraction device 250 and the captured thrombus 1190 can then be withdrawn through the sheath 112 and the sealable hub 114 (Figure 12B).

[0102] In some embodiments, a vacuum (e.g., a pre-charged vacuum) can be applied to the sheath 112 at any point during retraction of the thrombus extraction device 250. In some embodiments, application of the vacuum can generate instantaneous or nearly instantaneous suction at the distal portion of the sheath 112 that can aspirate any remaining portions of the thrombus 1190 into and/or through the sheath 112. For example, the generated suction can aspirate any of the thrombus 1190 that captured or extruded by the funnel 690. Moreover, in some embodiments, application of a vacuum can facilitate smooth retraction of the captured thrombus

1190 through the sheath 112. For example, a burst of suction generated by application of the vacuum can help inhibit clogging of the sheath 112, and/or help resolve (e.g., break apart) a clog formed in the sheath 112 during retraction.

V. Examples

[0103] Several aspects of the present technology are set forth in the following examples:

1. A coring element for coring a vascular thrombus within a blood vessel of a patient, the coring element comprising:

a unitary structure having—

a first region adjacent to a proximal portion of the unitary structure, wherein the first region includes a first mouth configured to core the vascular thrombus;

a second region distal of the first region, wherein the second region is generally tubular and includes a first plurality of interconnected struts;

a third region distal of the second region, wherein the third region includes a second mouth configured to core the vascular thrombus; and

a fourth region distal of the third region, wherein the fourth region is generally tubular and includes a second plurality of interconnected struts.

2. The coring element of example 1 wherein the first mouth is radially offset from the second mouth.

3. The coring element of example 1 or example 2 wherein the unitary structure extends along a longitudinal axis, and wherein the first region includes a pair of first curved struts that curve in opposite directions around the longitudinal axis and intersect at a pair of first junctions to define the first mouth.

4. The coring element of any one of examples 1–3 wherein the unitary structure extends along a longitudinal axis, wherein the third region includes (a) a pair of upper curved struts that curve around the longitudinal axis and intersect each other at an upper junction and (b) a pair of lower curved struts that curve around the longitudinal axis and intersect each other at a lower junction, and wherein the lower and upper curved struts define the second mouth.

5. The coring element of example 4 wherein the lower and upper curved struts define (a) a first mouth portion opening in a first direction generally orthogonal to the longitudinal axis and (b) a second mouth portion opening in a second direction generally orthogonal to the longitudinal axis, and wherein the first and second mouth portions define the second mouth.

6. The coring element of example 5 wherein the first direction is generally opposite to the second direction.

7. The coring element of any one of examples 1–6 wherein the coring element is expandable from a compressed delivery configuration to an expanded deployed configuration.

8. The coring element of example 7 wherein the coring element is configured to self-expand.

9. The coring element of example 8 wherein the coring element is made from a shape memory material.

10. The coring element of any one of examples 1–9 wherein the fourth region of the unitary structure is configured to be connected to a braided filament mesh structure.

11. A dilator assembly for deploying an expandable funnel coupled to a distal portion of an introducer sheath, the dilator assembly comprising:

a first shaft defining a lumen;

a second shaft slidably positioned within the lumen of the first shaft;

a retention sheath coupled to the second shaft and configured to receive and constrain the funnel therein; and

a control assembly including an actuator operably coupled to the first and second shafts, wherein movement of the actuator from a first position to a second position advances the first and second shafts together to deploy the funnel from the retention sheath, and wherein movement of the actuator from the second position to a third position advances the first shaft relative to the second shaft.

12. The dilator assembly of example 11 wherein the retention sheath has substantially a same outer diameter as the first shaft.

13. The dilator assembly of example 11 or example 13 wherein movement of the actuator from the second position to the third position brings a distal portion of the first shaft into contact with a proximal portion of the retention sheath.

14. The dilator assembly of any one of examples 11–13 wherein the control assembly includes—

a housing;

a first shaft hub slidably positioned within the housing and coupled to the first shaft; and

a second shaft hub slidably positioned within the housing and coupled to the second shaft.

15. The dilator assembly of example 14 wherein the first shaft hub is configured to engage the second shaft hub when the actuator is moved from the first position to the second position such that the first and second shafts advance together.

16. The dilator assembly of example 14 or example 15 wherein the first shaft hub is configured to disengage the second shaft hub when the actuator is moved from the second position to the third position such that first shaft advances relative to the second shaft.

17. The dilator assembly of any one of examples 14–16 wherein the first shaft hub is configured to engage the second shaft hub when the actuator is moved from the first position to the second position such that the first and second shafts advance together, and wherein the first shaft hub is configured to disengage the second shaft hub when the actuator is moved from the second position to the third position such that first shaft advances relative to the second shaft.

18. The dilator of assembly of any one of examples 14–17 wherein the second shaft hub includes a first engagement feature, wherein the housing includes a second engagement feature, and wherein the first engagement feature is configured to engage the second engagement feature at the second position to prevent movement of the second shaft hub when the actuator is moved from the second position to the third position.

19. The dilator assembly of example 18 wherein the first engagement feature is a snap feature, and wherein the second engagement feature is a detent formed in the housing.

20. The dilator assembly of any one of examples 14–19, further comprising a biasing member operably coupled to the first shaft hub, wherein the biasing member is configured to bias the first shaft hub from the third position toward the second position.

21. The dilator assembly of any one of examples 11–20 wherein the control assembly further includes a housing, wherein the actuator is movable relative to the housing, wherein the movement of the actuator from the first position to the second position is distal movement of the actuator relative to the housing, and wherein the movement of the actuator from the second position to the third position is further distal movement of the actuator relative to the housing.

22. The dilator assembly of any one of examples 11–21, further comprising the introducer sheath and the funnel.

23. A system for capturing a vascular thrombus within a blood vessel of a patient, the system comprising:

an introducer sheath having a distal portion;

an expandable funnel coupled to the distal portion of the introducer sheath;

a dilator assembly configured to be inserted through the introducer sheath and to deploy the expandable funnel, wherein the dilator assembly includes—

a first shaft defining a lumen;

a second shaft slidably positioned within the lumen of the first shaft;

a retention sheath coupled to the second shaft and configured to receive and constrain the funnel therein; and

a control assembly including an actuator operably coupled to the first and second shafts, wherein movement of the actuator from a first position to a second position distally advances the first and second shafts together to deploy the funnel from the retention sheath, and wherein movement of the actuator from the second position to a third position advances the first shaft relative to the second shaft; and

a clot removal device configured to be inserted through the introducer sheath to capture at least a portion of the vascular thrombus.

24. The system of example 23 wherein the clot removal device includes an expandable coring element coupled to an expandable capture element, wherein the coring element is configured to separate at least a portion of the vascular thrombus from a wall of the blood vessel, and wherein the capture element is configured to capture and retain the portion of the vascular thrombus separated from the wall of the blood vessel.

25. The system of example 23 or example 24 wherein the funnel has a first length when deployed from the retention sheath, and wherein the coring element has a second length when expanded that is less than the first length.

26. A system for capturing a vascular thrombus within a blood vessel of a patient, the system comprising:

an introducer sheath having a distal portion;

an expandable funnel coupled to the distal portion of the introducer sheath;

a dilator assembly configured to be inserted through the introducer sheath and to deploy the expandable funnel; and

a clot removal device configured to be inserted through the introducer sheath, wherein the clot removal device includes an expandable coring element coupled to an expandable capture element, wherein the coring element includes a first region including a first mouth and a second region including a second mouth, wherein the first and second mouths are configured to separate at least a portion of the vascular thrombus from a wall of the blood vessel, and wherein the capture element is configured to capture and retain the portion of the vascular thrombus separated from the wall of the blood vessel.

27. The system of example 26 wherein the first mouth is radially offset from the second mouth.

28. The system of example 27 wherein the coring element is formed from a unitary structure including a plurality of struts, wherein the struts define the first and second mouths,

wherein the struts further define a plurality of interstices, and wherein the first and second mouths are larger than each of the interstices.

VI. Conclusion

[0104] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0105] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0106] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A coring element for coring a vascular thrombus within a blood vessel of a patient, the coring element comprising:

a unitary structure having—

a first region adjacent to a proximal portion of the unitary structure, wherein the first region includes a first mouth configured to core the vascular thrombus;

a second region distal of the first region, wherein the second region is generally tubular and includes a first plurality of interconnected struts;

a third region distal of the second region, wherein the third region includes a second mouth configured to core the vascular thrombus; and

a fourth region distal of the third region, wherein the fourth region is generally tubular and includes a second plurality of interconnected struts.

2. The coring element of claim 1 wherein the first mouth is radially offset from the second mouth.

3. The coring element of claim 1 wherein the unitary structure extends along a longitudinal axis, and wherein the first region includes a pair of first curved struts that curve in opposite directions around the longitudinal axis and intersect at a pair of first junctions to define the first mouth.

4. The coring element of claim 1 wherein the unitary structure extends along a longitudinal axis, wherein the third region includes (a) a pair of upper curved struts that curve around the longitudinal axis and intersect each other at an upper junction and (b) a pair of lower curved struts that curve around the longitudinal axis and intersect each other at a lower junction, and wherein the lower and upper curved struts define the second mouth.

5. The coring element of claim 4 wherein the lower and upper curved struts define (a) a first mouth portion opening in a first direction generally orthogonal to the longitudinal axis and

(b) a second mouth portion opening in a second direction generally orthogonal to the longitudinal axis, and wherein the first and second mouth portions define the second mouth.

6. The coring element of claim 5 wherein the first direction is generally opposite to the second direction.

7. The coring element of claim 1 wherein the coring element is expandable from a compressed delivery configuration to an expanded deployed configuration.

8. The coring element of claim 7 wherein the coring element is configured to self-expand.

9. The coring element of claim 8 wherein the coring element is made from a shape memory material.

10. The coring element of claim 1 wherein the fourth region of the unitary structure is configured to be connected to a braided filament mesh structure.

11. A dilator assembly for deploying an expandable funnel coupled to a distal portion of an introducer sheath, the dilator assembly comprising:

a first shaft defining a lumen;

a second shaft slidably positioned within the lumen of the first shaft;

a retention sheath coupled to the second shaft and configured to receive and constrain the funnel therein; and

a control assembly including an actuator operably coupled to the first and second shafts, wherein movement of the actuator from a first position to a second position advances the first and second shafts together to deploy the funnel from the retention sheath, and wherein movement of the actuator from the second position to a third position advances the first shaft relative to the second shaft.

12. The dilator assembly of claim 11 wherein the retention sheath has substantially a same outer diameter as the first shaft.

13. The dilator assembly of claim 11 wherein movement of the actuator from the second position to the third position brings a distal portion of the first shaft into contact with a proximal portion of the retention sheath.

14. The dilator assembly of claim 11 wherein the control assembly includes—

a housing;

a first shaft hub slidably positioned within the housing and coupled to the first shaft; and

a second shaft hub slidably positioned within the housing and coupled to the second shaft.

15. The dilator assembly of claim 14 wherein the first shaft hub is configured to engage the second shaft hub when the actuator is moved from the first position to the second position such that the first and second shafts advance together.

16. The dilator assembly of claim 14 wherein the first shaft hub is configured to disengage the second shaft hub when the actuator is moved from the second position to the third position such that first shaft advances relative to the second shaft.

17. The dilator assembly of claim 14 wherein the first shaft hub is configured to engage the second shaft hub when the actuator is moved from the first position to the second position such that the first and second shafts advance together, and wherein the first shaft hub is configured to disengage the second shaft hub when the actuator is moved from the second position to the third position such that first shaft advances relative to the second shaft.

18. The dilator of assembly of claim 14 wherein the second shaft hub includes a first engagement feature, wherein the housing includes a second engagement feature, and wherein the first engagement feature is configured to engage the second engagement feature at the second position to prevent movement of the second shaft hub when the actuator is moved from the second position to the third position.

19. The dilator assembly of claim 18 wherein the first engagement feature is a snap feature, and wherein the second engagement feature is a detent formed in the housing.

20. The dilator assembly of claim 14, further comprising a biasing member operably coupled to the first shaft hub, wherein the biasing member is configured to bias the first shaft hub from the third position toward the second position.

21. The dilator assembly of claim 11 wherein the control assembly further includes a housing, wherein the actuator is movable relative to the housing, wherein the movement of the actuator from the first position to the second position is distal movement of the actuator relative to the housing, and wherein the movement of the actuator from the second position to the third position is further distal movement of the actuator relative to the housing.

22. The dilator assembly of claim 11, further comprising the introducer sheath and the funnel.

23. A system for capturing a vascular thrombus within a blood vessel of a patient, the system comprising:

an introducer sheath having a distal portion;

an expandable funnel coupled to the distal portion of the introducer sheath;

a dilator assembly configured to be inserted through the introducer sheath and to deploy the expandable funnel, wherein the dilator assembly includes—

a first shaft defining a lumen;

a second shaft slidably positioned within the lumen of the first shaft;

a retention sheath coupled to the second shaft and configured to receive and constrain the funnel therein; and

a control assembly including an actuator operably coupled to the first and second shafts, wherein movement of the actuator from a first position to a second position distally advances the first and second shafts together to deploy the funnel from the retention sheath, and wherein movement of the actuator from the second position to a third position advances the first shaft relative to the second shaft; and

a clot removal device configured to be inserted through the introducer sheath to capture at least a portion of the vascular thrombus.

24. The system of claim 23 wherein the clot removal device includes an expandable coring element coupled to an expandable capture element, wherein the coring element is configured to separate at least a portion of the vascular thrombus from a wall of the blood vessel, and wherein the capture element is configured to capture and retain the portion of the vascular thrombus separated from the wall of the blood vessel.

25. The system of claim 23 wherein the funnel has a first length when deployed from the retention sheath, and wherein the coring element has a second length when expanded that is less than the first length.

26. A system for capturing a vascular thrombus within a blood vessel of a patient, the system comprising:

an introducer sheath having a distal portion;

an expandable funnel coupled to the distal portion of the introducer sheath;

a dilator assembly configured to be inserted through the introducer sheath and to deploy the expandable funnel; and

a clot removal device configured to be inserted through the introducer sheath, wherein the clot removal device includes an expandable coring element coupled to an expandable capture element, wherein the coring element includes a first region including a first mouth and a second region including a second mouth, wherein the first and second mouths are configured to separate at least a portion of the vascular thrombus from a wall of the blood vessel, and wherein the capture element is configured to capture and retain the portion of the vascular thrombus separated from the wall of the blood vessel.

27. The system of claim 26 wherein the first mouth is radially offset from the second mouth.

28. The system of claim 27 wherein the coring element is formed from a unitary structure including a plurality of struts, wherein the struts define the first and second mouths, wherein the struts further define a plurality of interstices, and wherein the first and second mouths are larger than each of the interstices.

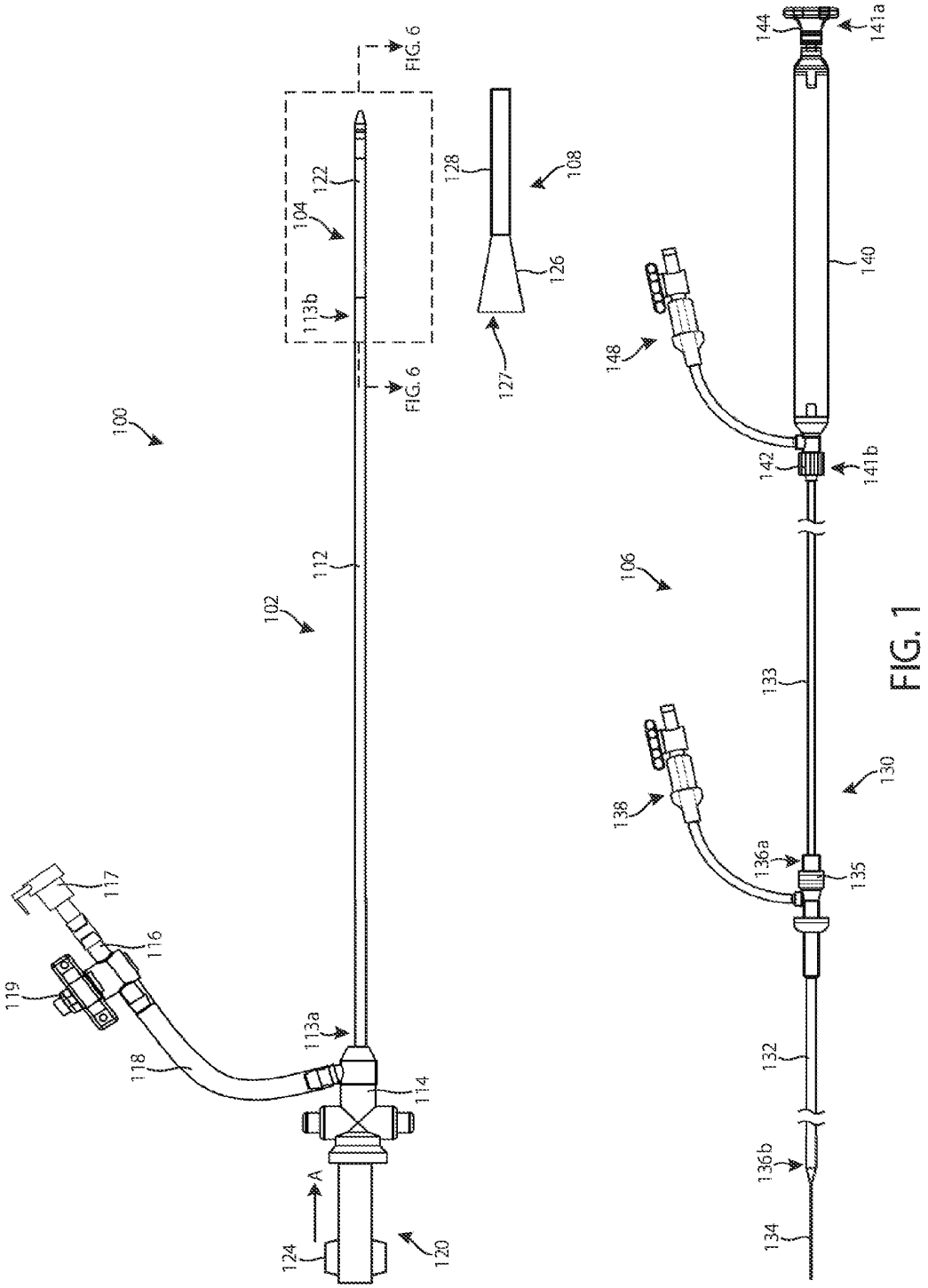
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FIG. 6
FIG. 6

FIG. 1

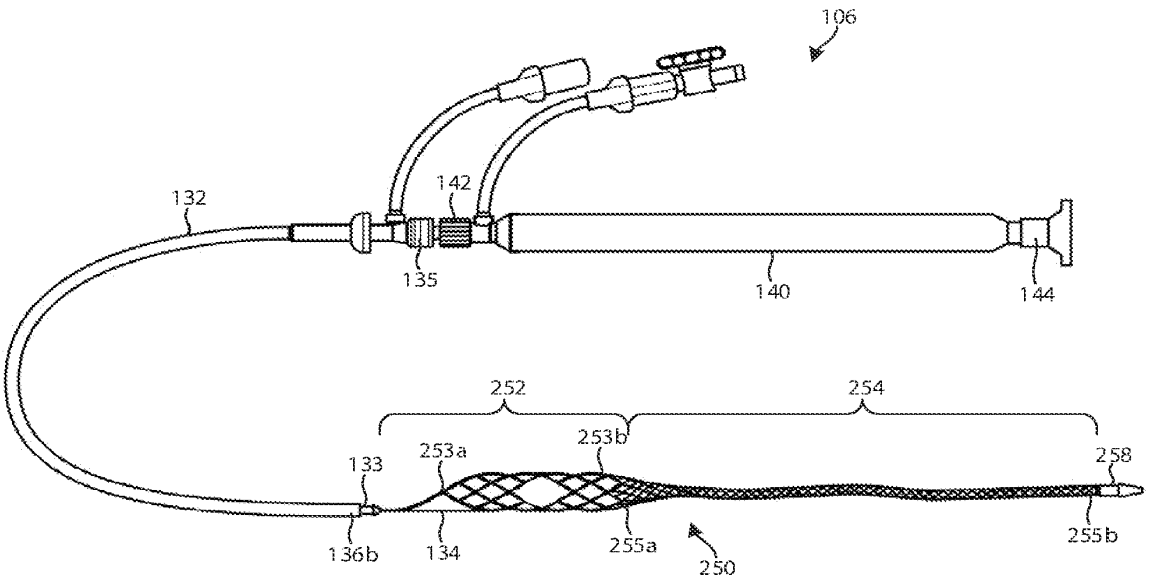
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FIG. 2A

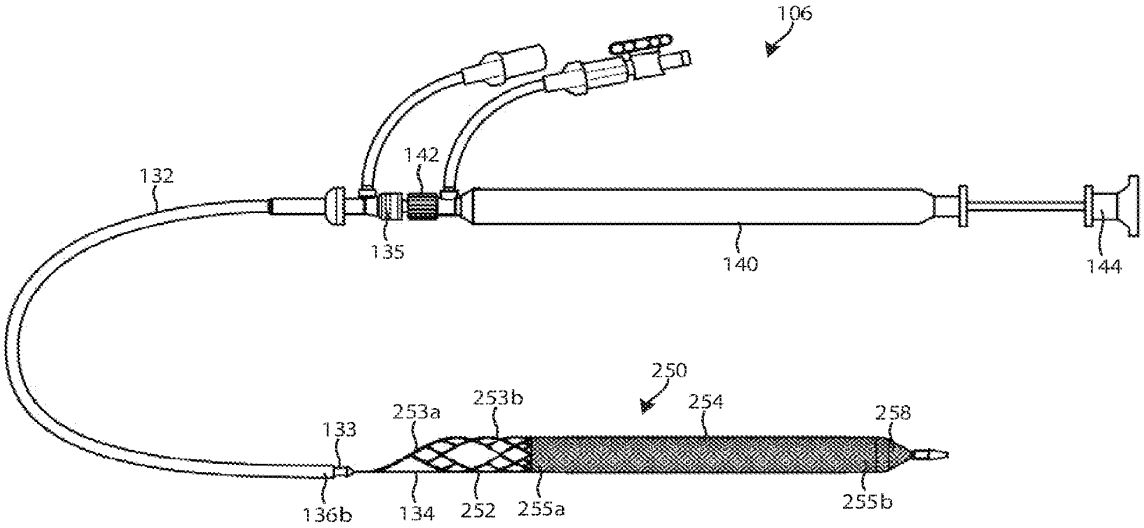
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FIG. 2B

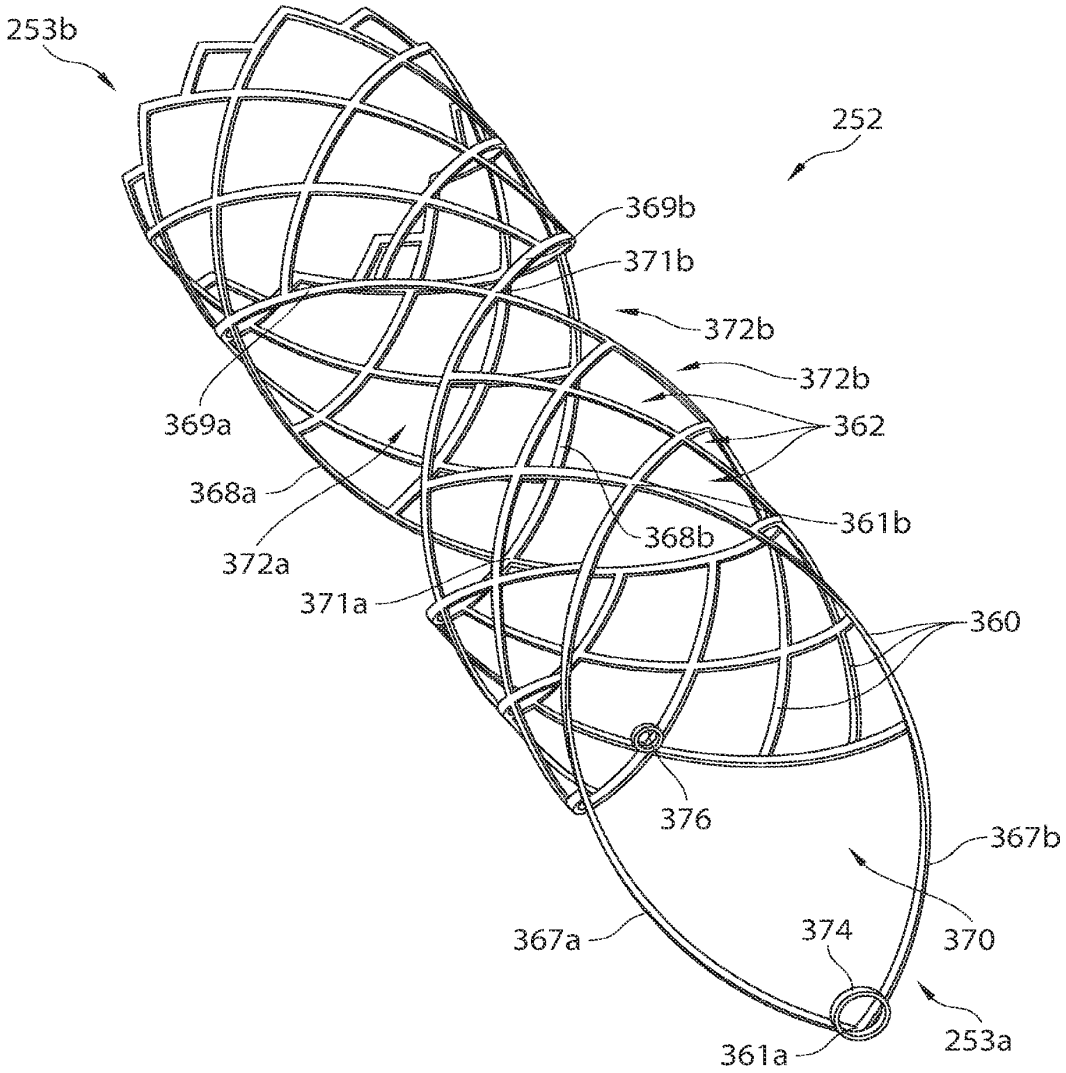
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FIG. 3A

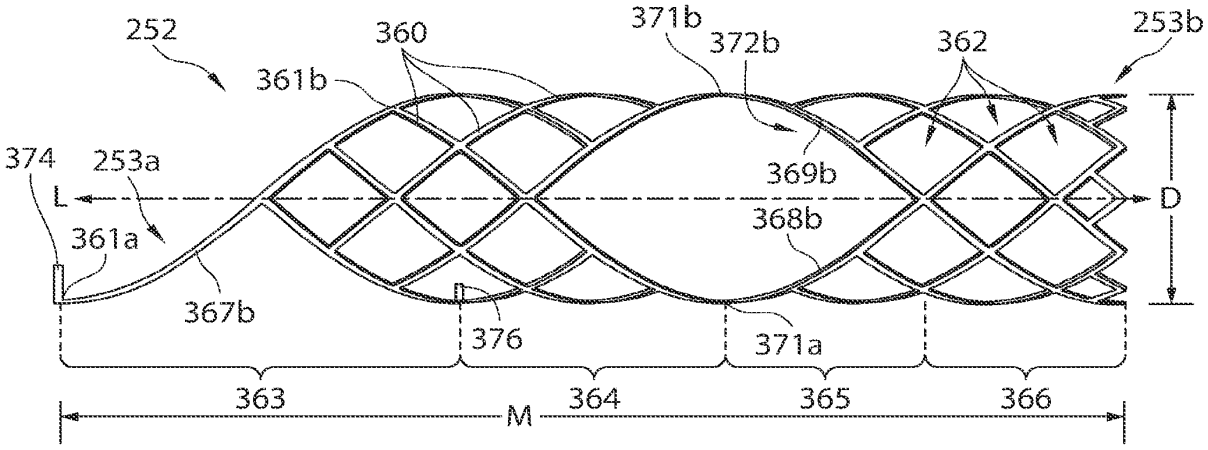
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FIG. 3B

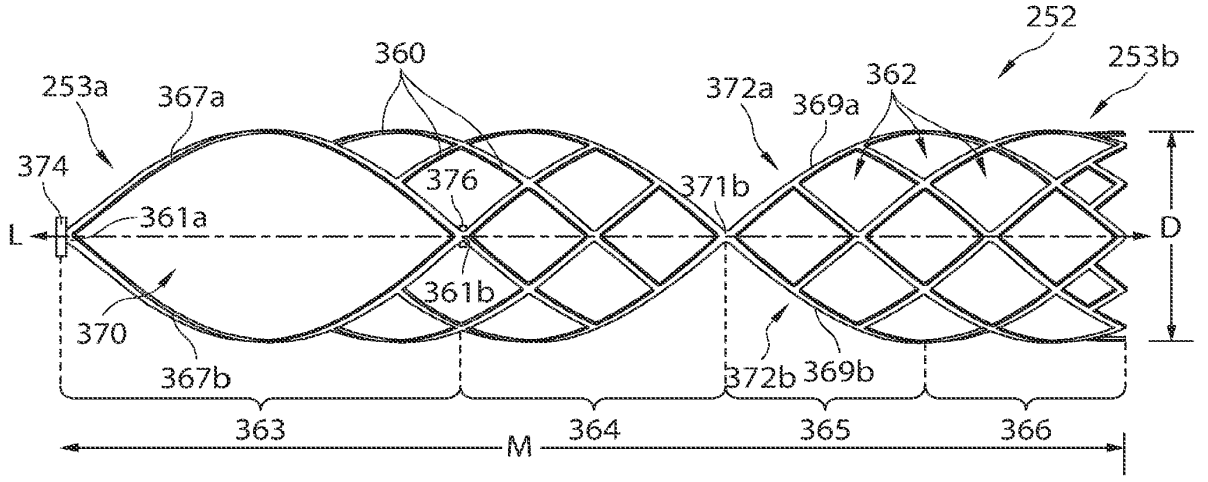
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FIG. 3C

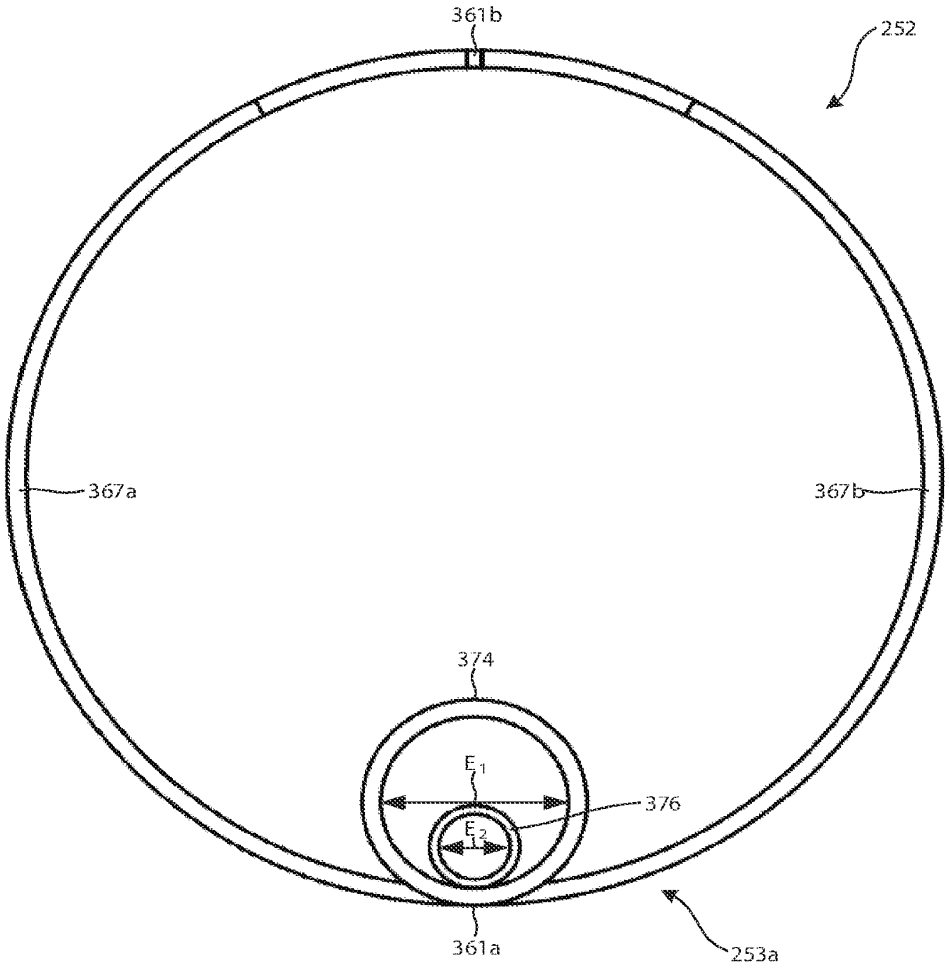


FIG. 3D

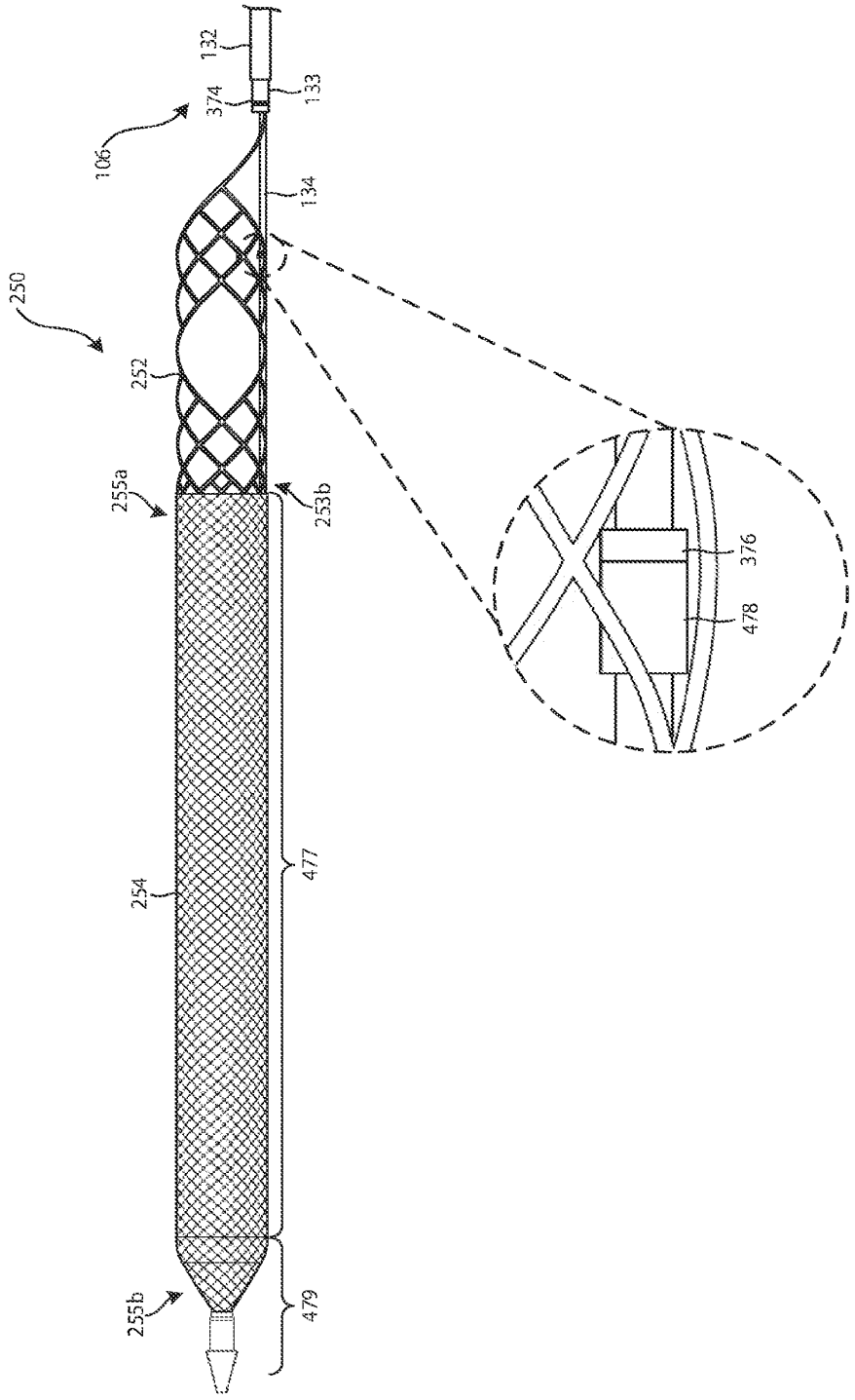


FIG. 4

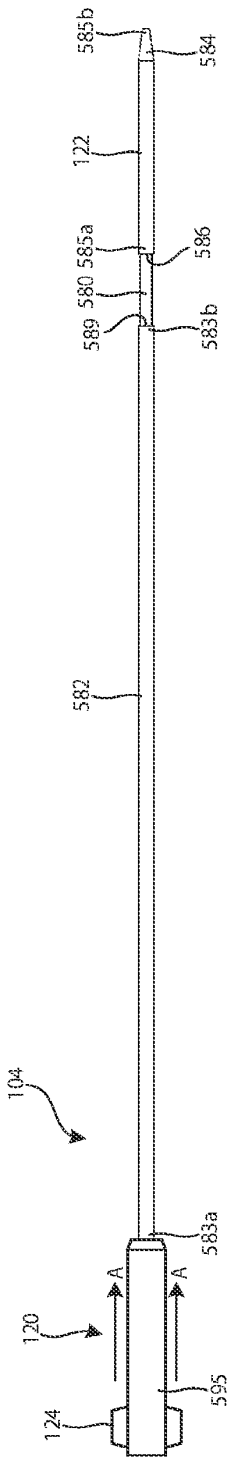


FIG. 5A

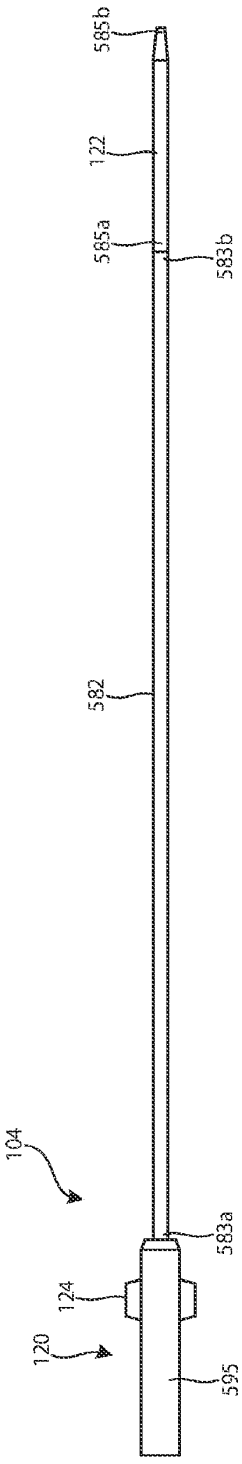


FIG. 5B

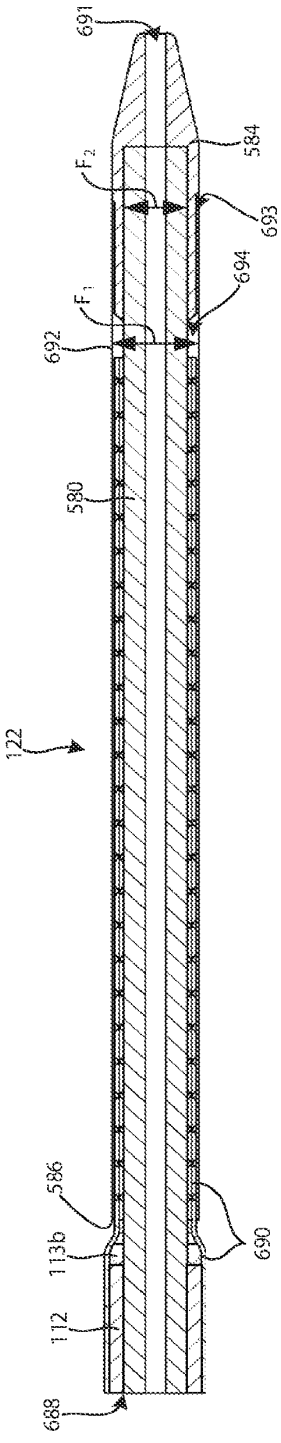


FIG. 6

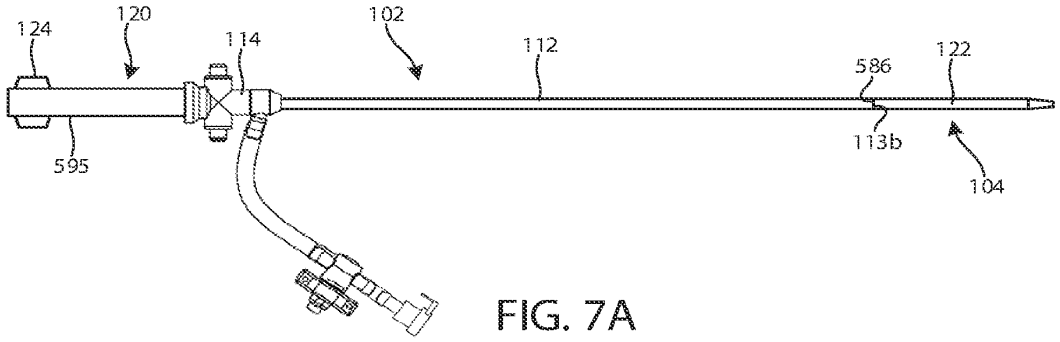


FIG. 7A

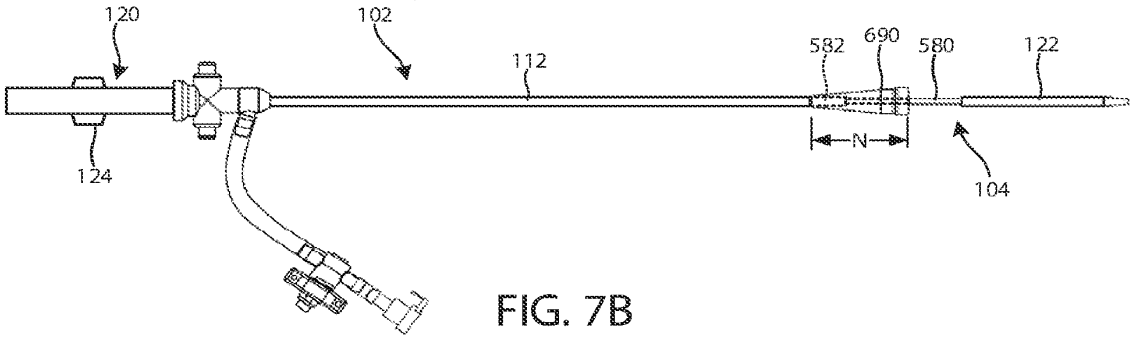


FIG. 7B

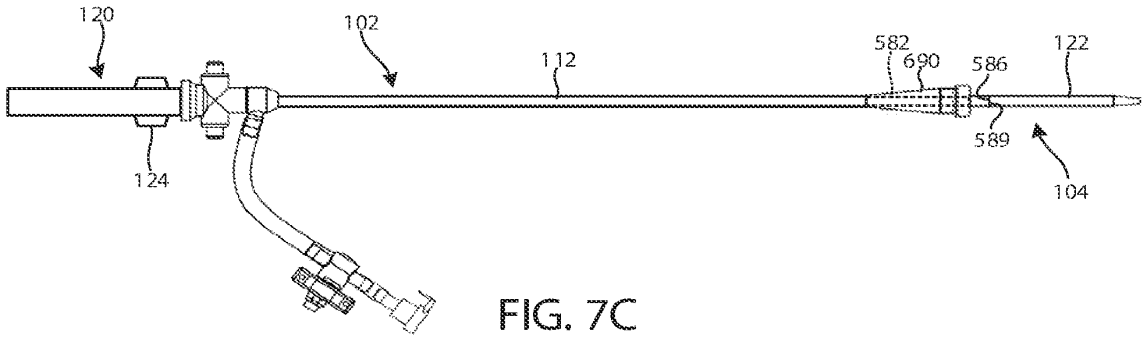


FIG. 7C

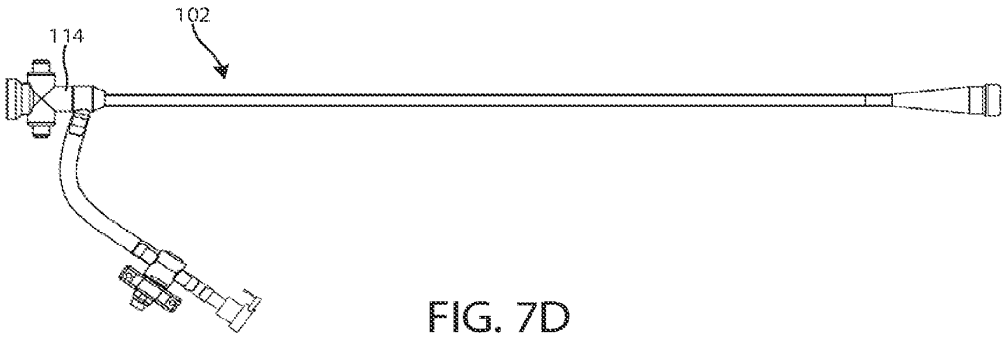
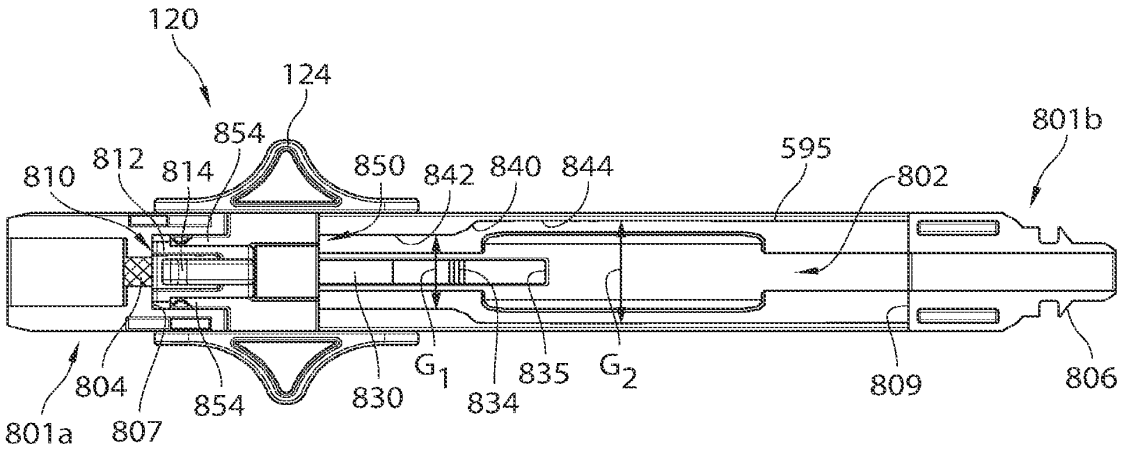


FIG. 7D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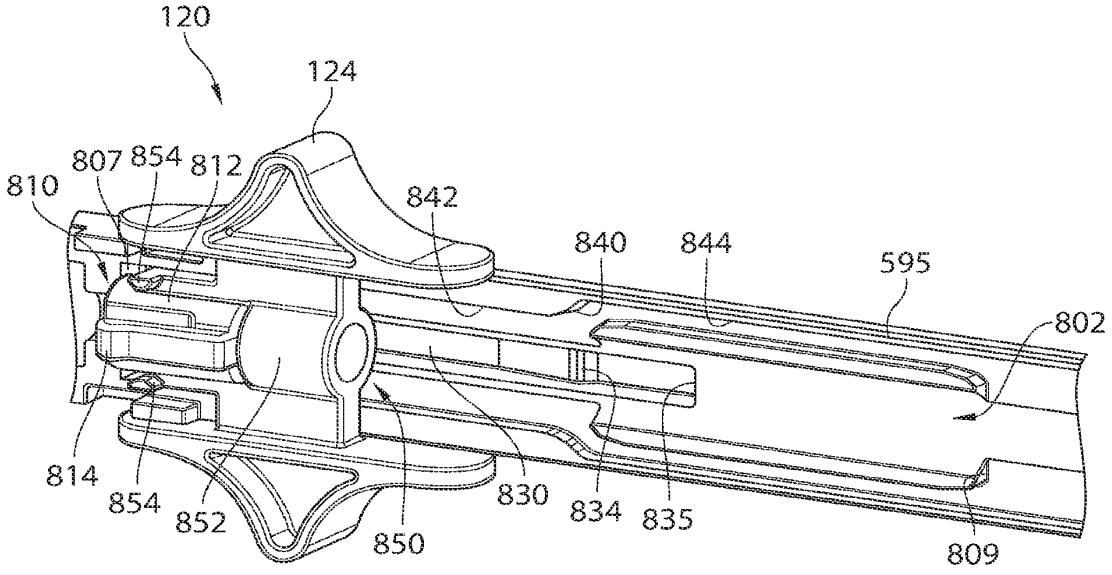
842
840
844
595
802
801b
804
807
854
830
G_1
834
835
G_2
809
806
801a

FIG. 8A


120
124
807
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802
814
854
852
850
830
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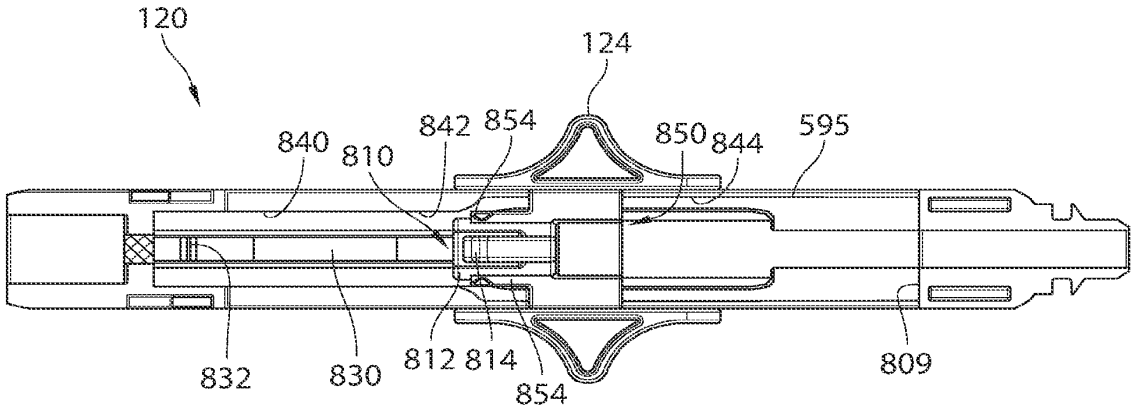
835
809

FIG. 8B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124
840
842
854
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844
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810
832
830
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814
854
809

FIG. 8C

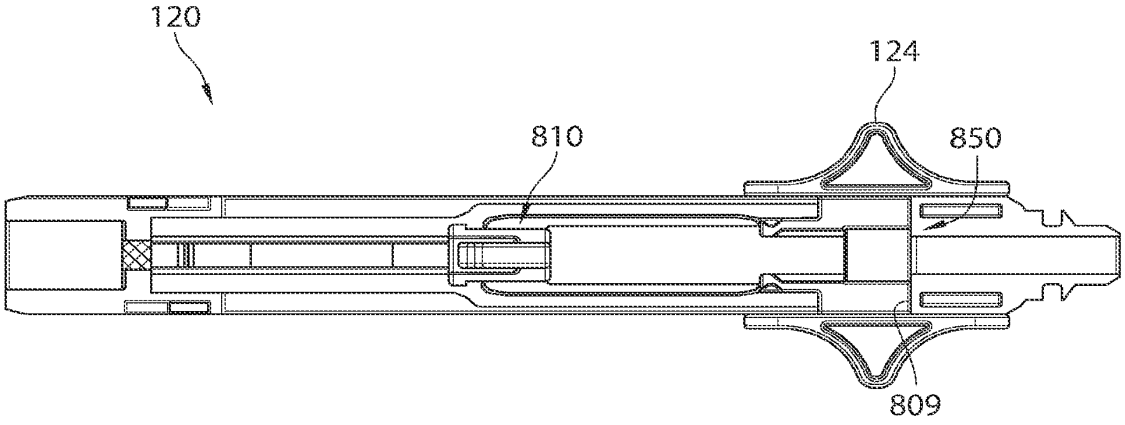
120
124
810
850
809

FIG. 8D

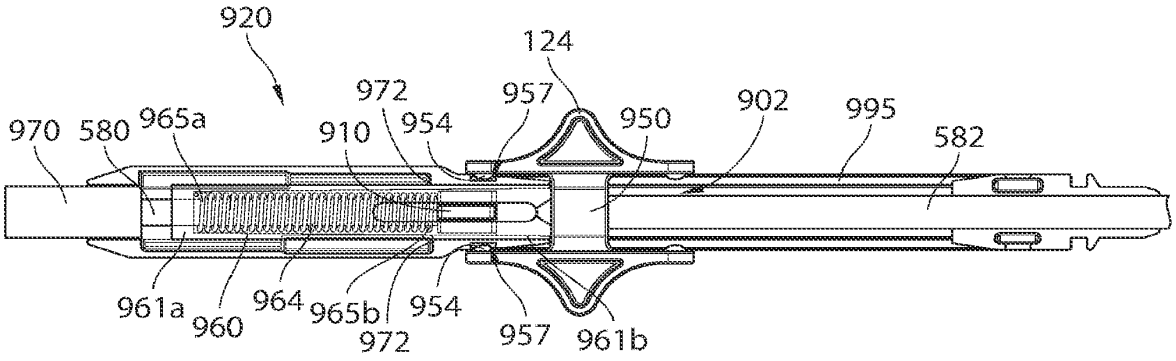

FIG. 9A

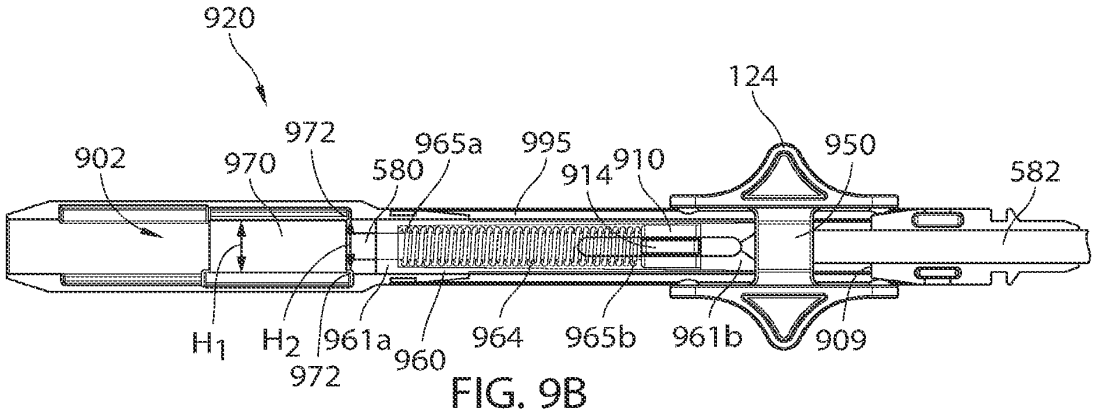

FIG. 9B

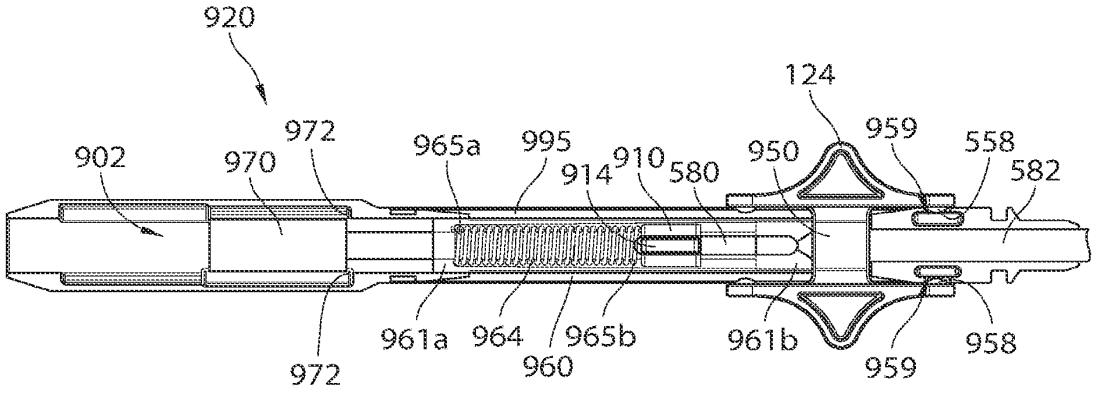

FIG. 9C

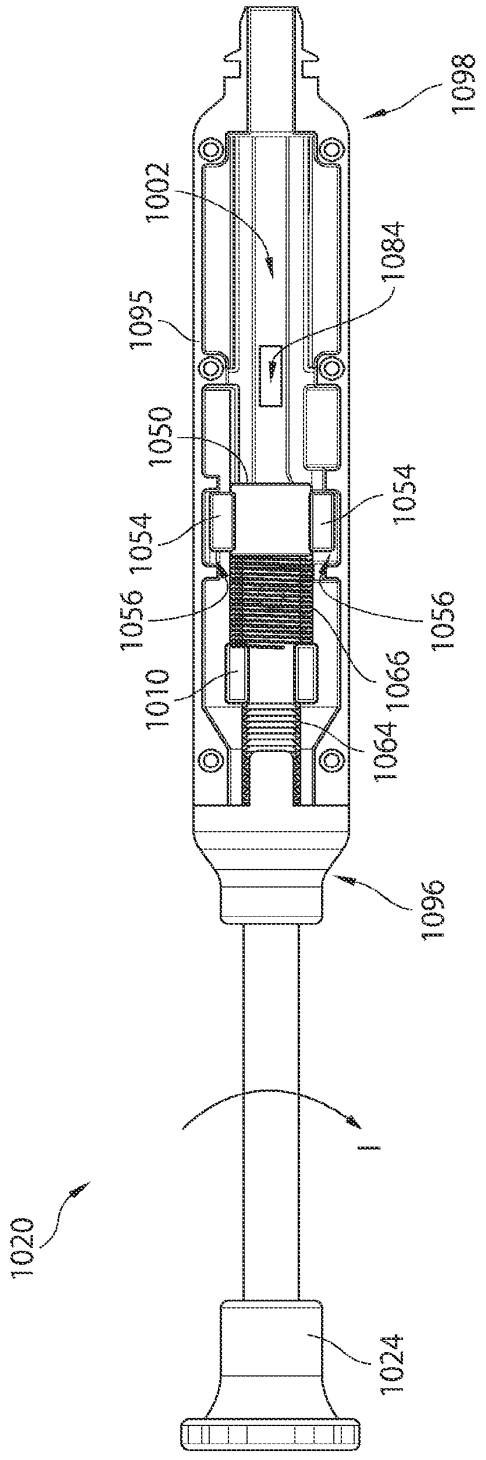

FIG. 10A

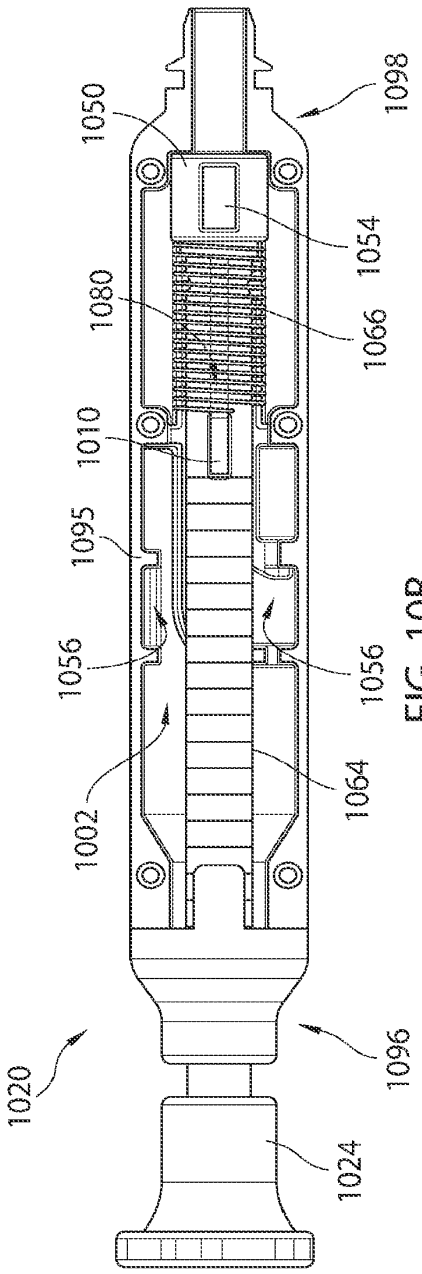

FIG. 10B

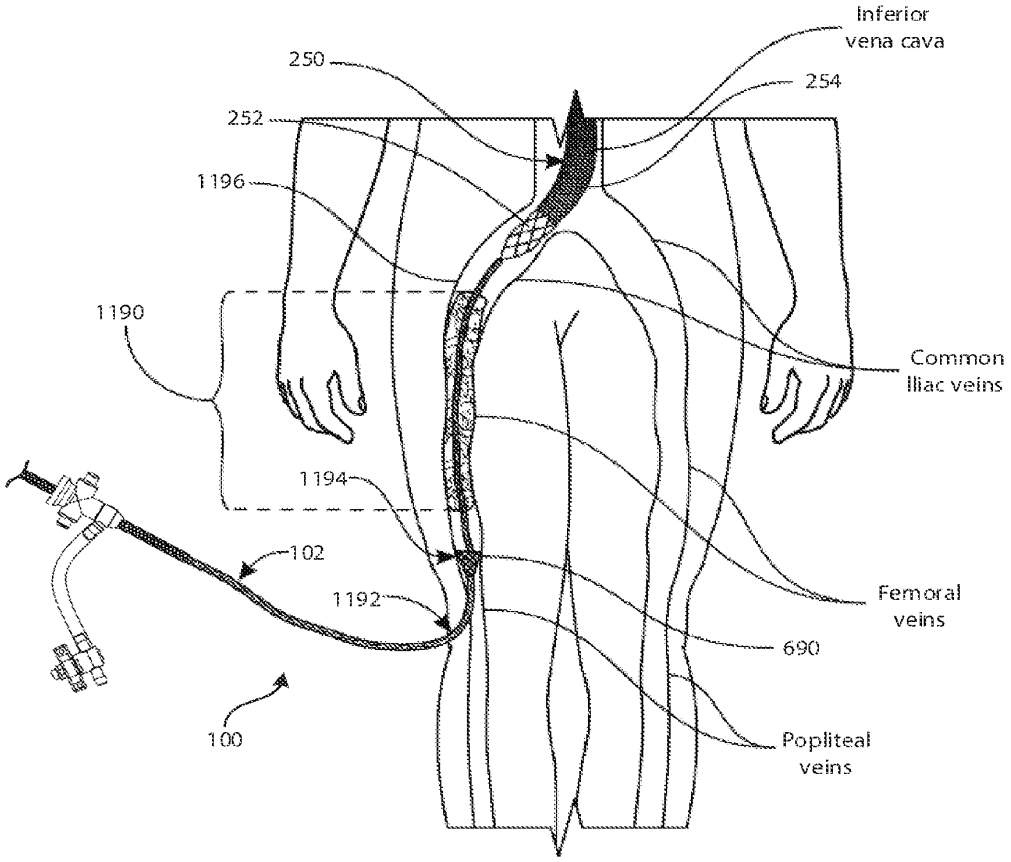
Inferior
vena cava
250
254
252
1196
1190
Common
Iliac veins
1194
102
1192
Femoral
veins
690
100
Popliteal
veins

FIG. 11

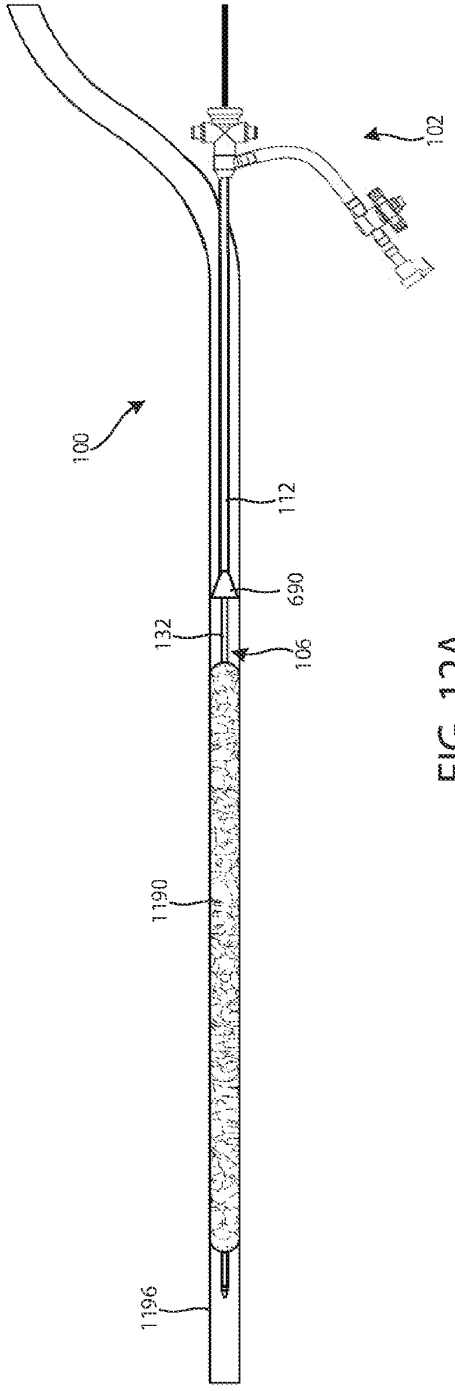

FIG. 12A

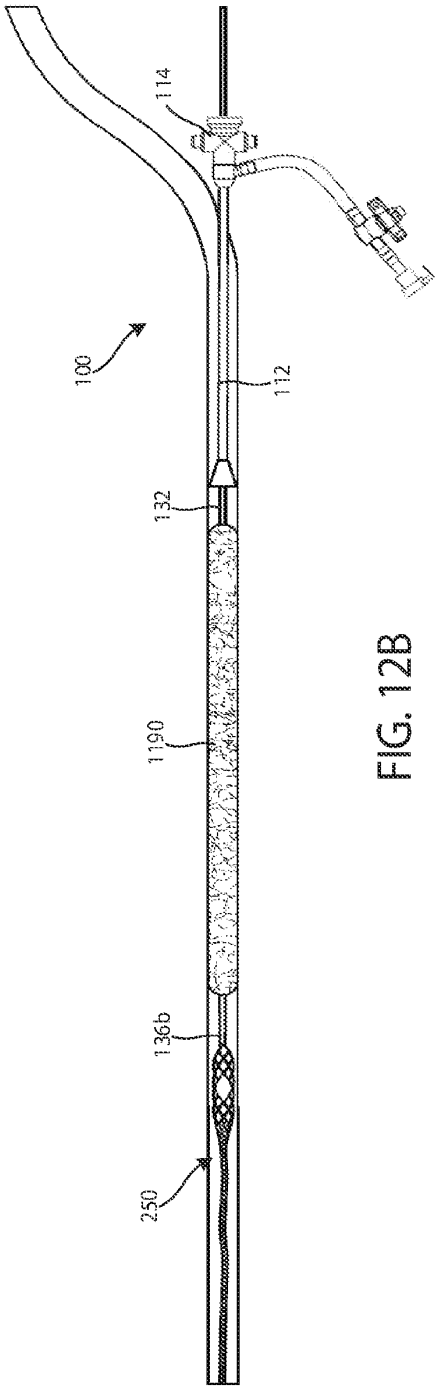

FIG. 12B

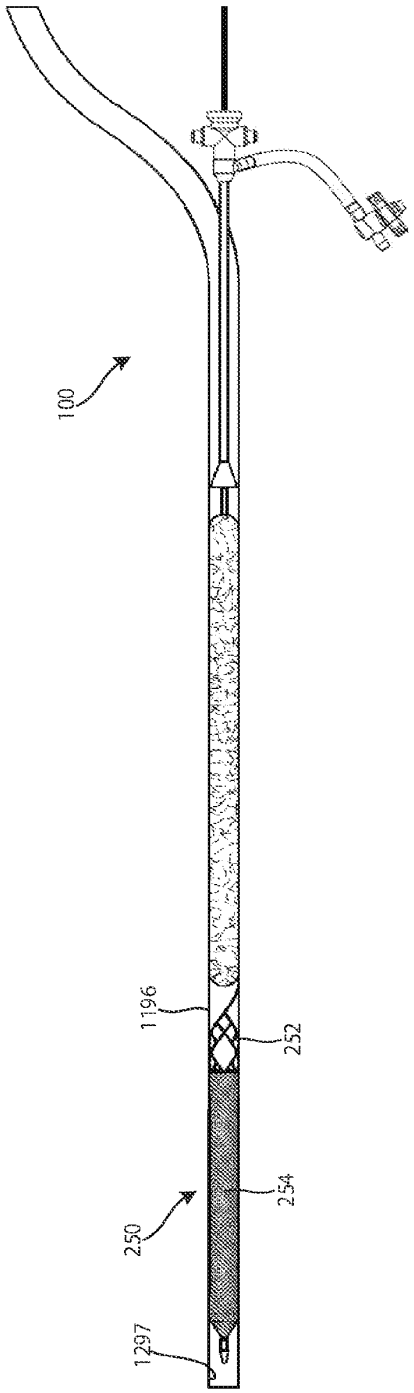

FIG. 12C

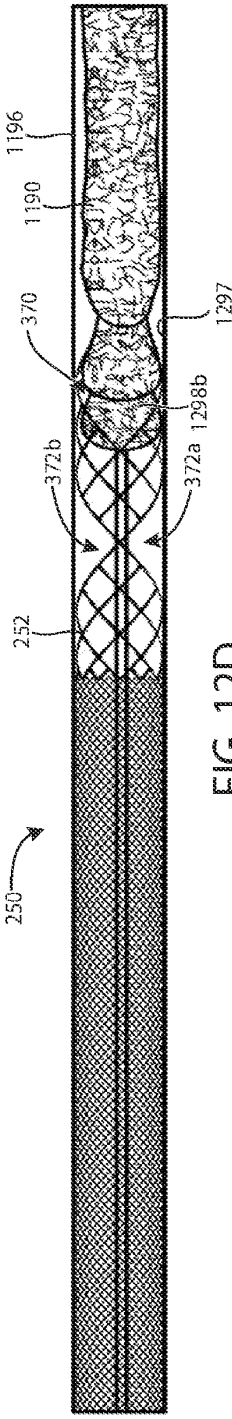

FIG. 12D

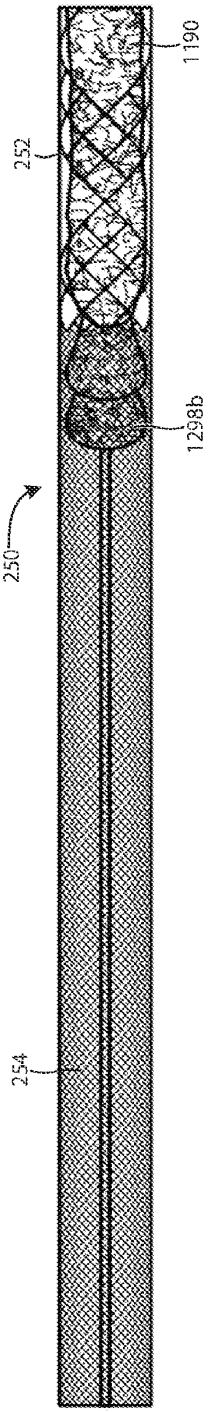

FIG. 12E

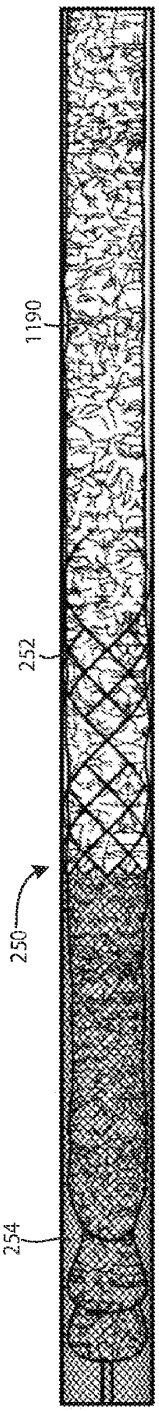

FIG. 12F

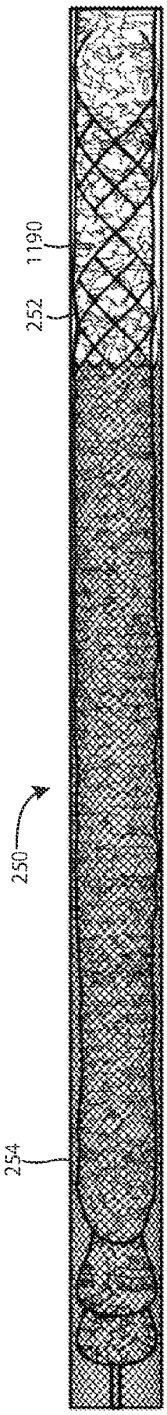

FIG. 12G

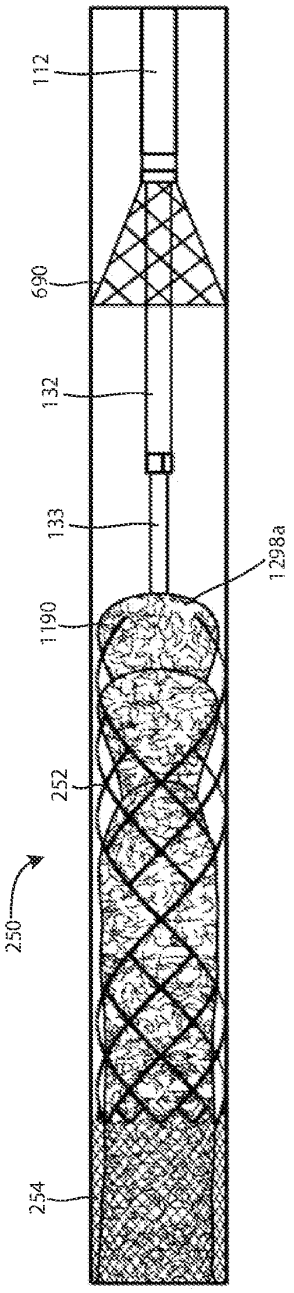

FIG. 12H

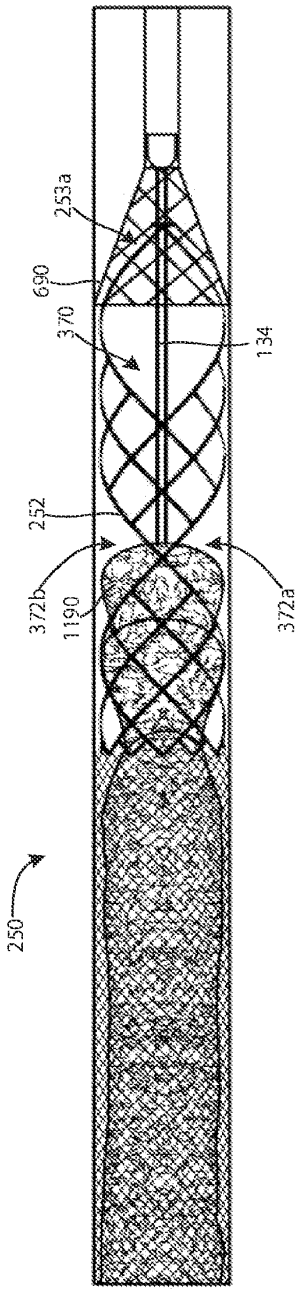

FIG. 12I

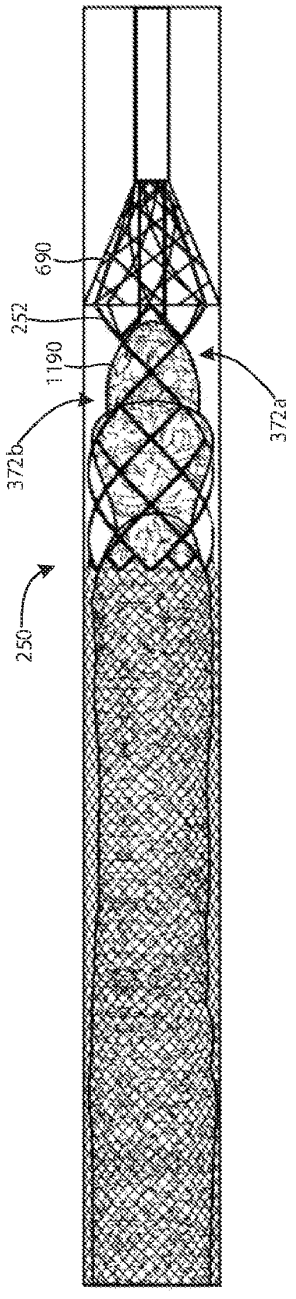

FIG. 12J

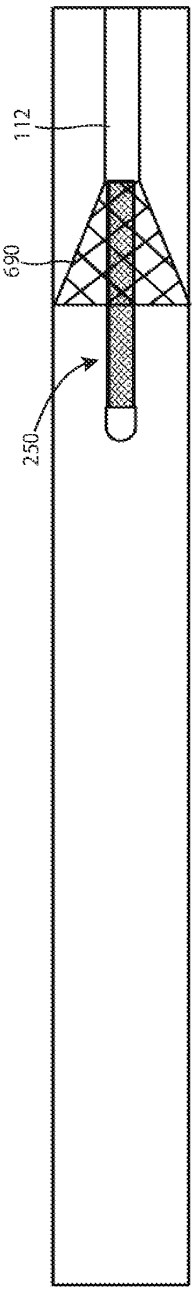

FIG. 12K

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/065645

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/221; A61B 17/22; A61B 17/3207; A61B 17/34; A61F 2/01; A61F 2/86 (2021.01)

CPC - A61B 17/221; A61B 17/320725; A61B 17/3415; A61B 2017/22041; A61B 2017/22094; A61B 2017/2212; A61B 2017/2215; A61B 2017/320741; A61F 2/011; A61F 2/013; A61F 2002/016; A61F 2002/018; A61F 2230/0069 (2021.02)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

see Search History document

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

see Search History document

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

see Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014/0371779 A1 (NEURAVI LIMITED) 18 December 2014 (18.12.2014) entire document	1-10
A	US 2011/0160763 A1 (FERRERA et al) 30 June 2011 (30.06.2011) entire document	1-10
A	US 2017/0112513 A1 (INARI MEDICAL) 27 April 2017 (27.04.2017) entire document	1-10
A	US 2018/0092652 A1 (INARI MEDICAL, INC.) 05 April 2018 (05.04.2018) entire document	1-10

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 March 2021	APR 14 2021
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver Telephone No. PCT Helpdesk: 571-272-4300

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/065645

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
See extra sheet(s).

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

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

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

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-10

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/065645

Continued from Box No. III Observations where unity of invention is lacking

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

Group I, claims 1-10, are drawn to a coring element for coring a vascular thrombus within a blood vessel of a patient.

Group II, claims 11-28, are drawn to a dilator assembly for deploying an expandable funnel coupled to a distal portion of an introducer sheath.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of the Group I invention: the coring element comprising: a unitary structure having a first region adjacent to a proximal portion of the unitary structure, wherein the first region includes a first mouth configured to core the vascular thrombus; a second region distal of the first region, wherein the second region is generally tubular and includes a first plurality of interconnected struts; a third region distal of the second region, wherein the third region includes a second mouth configured to core the vascular thrombus; and a fourth region distal of the third region, wherein the fourth region is generally tubular and includes a second plurality of interconnected struts as claimed therein is not present in the invention of Group II. The special technical feature of the Group II invention: a dilator assembly for deploying an expandable funnel coupled to a distal portion of an introducer sheath, the dilator assembly comprising: a first shaft defining a lumen; a second shaft slidably positioned within the lumen of the first shaft; a retention sheath coupled to the second shaft and configured to receive and constrain the funnel therein; and a control assembly including an actuator operably coupled to the first and second shafts, wherein movement of the actuator from a first position to a second position advances the first and second shafts together to deploy the funnel from the retention sheath, and wherein movement of the actuator from the second position to a third position advances the first shaft relative to the second shaft as claimed therein is not present in the invention of Group I.

Groups I and II lack unity of invention because even though the inventions of these groups require the technical feature of capturing a vascular thrombus within a blood vessel of a patient, this technical feature is not a special technical feature as it does not make a contribution over the prior art.

Specifically, US 2018/0092652 A1 to Inari Medical, Inc. teaches capturing a vascular thrombus within a blood vessel of a patient (The method includes retracting the thrombus extraction device proximally so that the coring portion cores and separates a portion of the vascular thrombus from the venous vessel wall while the mesh structure captures the vascular thrombus portion. The method includes withdrawing the thrombus extraction device from the patient to remove the vascular thrombus portion from the venous vessel, para. 0008. One aspect of the present disclosure relates to a method for removal of thrombus from a blood vessel in a body of a patient, which blood vessel can be an artery or a vein, para. 0017).

Since none of the special technical features of the Group I or II inventions are found in more than one of the inventions, unity of invention is lacking.

(19)中华人民共和国国家知识产权局

(12)发明专利申请

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(22)申请日 2016.02.15

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62/284,752 2015.10.08 US
62/245,560 2015.10.23 US

(62)分案原申请数据
201680056752.7 2016.02.15

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迈克尔·P·华莱士

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

(51)Int.Cl.
A61B 17/22(2006.01)
A61B 17/221(2006.01)
A61B 17/00(2006.01)

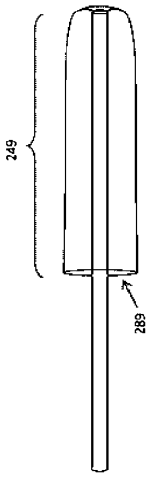
权利要求书2页 说明书31页 附图83页

(54)发明名称

机械取栓装置

(57)摘要

一种用于从血管去除凝块而没有堵塞的机械取栓装置，包括：导管，具有远侧端部区域和远侧端部开口，其中，远侧端部区域的在远侧端部开口处的硬度大于远侧端部区域的紧邻远侧端部开口的区域的硬度，进一步其中，远侧端部开口具有圆形唇缘轮廓；柔性管，在导管内延伸并且在导管的远侧端部上翻折回来，其中，柔性管被配置成当在导管内向近侧拉动柔性管的第一端部时在远侧端部开口上滑动并翻转；以及穿过导管和柔性管的导丝腔，被配置成使导丝通过。



CN 111281482 A

1.一种用于从血管去除凝块而不堵塞的机械取栓装置,所述装置包括:

导管,具有远侧端部区域和远侧端部开口,其中,所述远侧端部区域的在所述远侧端部开口处的硬度大于所述远侧端部区域的紧邻所述远侧端部开口的硬度,进一步其中,所述远侧端部开口具有圆形唇缘轮廓;

柔性管,在所述导管内延伸并且在所述导管的所述远侧端部上翻折回来,其中,所述柔性管被配置成当在所述导管内向近侧拉动所述柔性管的第一端部时在所述远侧端部开口上滑动并翻转;以及

穿过所述导管和所述柔性管的导丝腔,被配置成使导丝通过。

2.根据权利要求1所述的装置,其中,所述柔性管具有大于5cm的长度,并且所述柔性管被配置成使得通过向所述柔性管的远侧端部施加小于1000克的力,能将所述柔性管收回到所述导管中。

3.根据权利要求1所述的装置,其中,所述柔性管包括编织管。

4.根据权利要求1所述的装置,其中,所述柔性管的在所述导管的所述远侧端部上翻折回来的区域形成唇缘,所述唇缘相对于所述导管的长轴线具有5°至60°之间的滚动角度(Φ)。

5.根据权利要求1所述的装置,其中,延伸穿过所述导管并且在所述导管的所述远侧端部上翻折回来的所述柔性管使所述导管的远侧5cm的刚度增加小于所述导管的所述远侧5cm的所述刚度的15%,而不使所述柔性管延伸穿过所述导管和在所述导管的所述远侧端部上翻折回来。

6.根据权利要求1所述的装置,还包括位于所述柔性管上的可释放附件,所述可释放附件被配置成当以大于0.01N的预定力阈值的力拉动所述柔性管时释放。

7.根据权利要求1所述的装置,其中,所述柔性管被配置成当所述柔性管在所述导管中被轴向地且向近侧拉动时径向地压缩5%至20%之间。

8.根据权利要求1所述的装置,还包括在所述导管和所述柔性管上延伸的外导管。

9.根据权利要求1所述的装置,其中,所述柔性管被配置成当在所述导管内向近侧拉动所述柔性管的第一端部时在所述远侧端部开口上翻转,其中,所述柔性管具有低泊松比,使得网状的所述柔性管当被用足够的力在所述导管内向近侧拉动时的直径大于所述导管的内径的一半,以在所述远侧端部开口上翻转。

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

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

12.根据权利要求1所述的装置,还包括真空连接件,所述真空连接件用于将所述导丝腔耦接到真空以通过所述导丝腔施加真空。

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

14.根据权利要求1所述的装置,还包括:拉动器,其中,所述柔性管的远侧端部耦接到

INARI_019409

所述拉动器的远侧端部;以及外导管,所述外导管布置在所述导管上且邻近于所述柔性管的近侧端部,所述装置还包括具有控制器的手柄,所述控制器被配置成协调推进所述外导管以向远侧推动所述柔性管的所述近侧端部和向近侧拉动所述拉动器以将所述柔性管的所述近侧端部拉入所述导管。

15.根据权利要求1所述的装置,所述柔性管被能释放地保持,并且所述柔性管被配置成当用大于0.01N的预定力阈值的力拉动所述柔性管时释放。

INARI_019410

机械取栓装置

[0001] 本申请是申请日为2016年2月15日、申请号为201680056752.7的中 国专利发明申请“机械取栓装置和方法”的分案申请。

[0002] 相关申请的交叉引用

[0003] 本专利申请要求以下临时专利申请中的每一个的优先权，其中的每一 个的全部内容通过引证结合于本文：2015年9月28日提交的美国临时专 利申请第62/284,300号；2015年10月8日提交的美国临时专利申请第 62/284,752号；以及2015年10月23日提交的美国临时专利申请第 62/245,560号。

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

技术领域

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

背景技术

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

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

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

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

[0010] 导管导向取栓术和溶栓治疗通常被认为创伤小，不太可能降低与常规 手术技术

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

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

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

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

发明内容

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

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

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的物体拉入导管的主体。

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

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

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

[0019] 如上所述，将导管的远侧端部朝向凝块推进通过血管的步骤可以包括 在导丝上推进。导管可以在导丝上向远侧滑动或者与导丝一起向远侧延伸 (或向近侧收回)。内(牵引器)管可以被保持在导管内(例如，在远侧 端部附近、中间区域或者在近侧端部附近)，或

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者在一些变型中，可以在 将导管定位在脉管内之后插入。导管的远侧端部可以定位在待去除的物体 (例如，凝块)处、附近或邻近，或者它可以分开预定的距离，例如以允 许通过将远侧牵引器区域延伸出导管的远侧端部之外并且扩张以准备将 物体取回到导管中来设定用于装置的空间。

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

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

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

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

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

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

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区域被允许在血管内扩张。

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

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

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

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

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

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

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

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状记忆材料(例如,形状记忆合金)。在一些变型中,偏置元件被 包括在可扩张的第一端部区域中或与可扩张的第一端部区域成一体以扩 张使得远侧牵引器区域。可扩张的第一端部区域可以扩张至接触血管的内 膜。在一些变型中,装置可以被配置(例如,设定尺寸,包括确定可扩张 的第一端部区域的尺寸),使得远侧牵引器区域的最远侧端部与血管腔接触。因此,本文所描述的变型中的任一个可以附加地或可替代地包括偏置 元件,诸如圈、环、支架等以推动可扩张的远侧端部区域,使得其可以通 过施加增加的径向力将其扩张开来而与脉管接触。在一些变型中,该开口 偏置(圈、螺旋、环等)位于远侧牵引器区域的可扩张的第一端部区域的 远侧端部处或附近。

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

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

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

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

[0037] 如上所述,可扩张的第一端部区域可以包括既可扩张又能够抓取物体 (例如凝块)的任何适当材料。例如,远侧牵引器区域的可扩张的第一端 部区域可以包括邻近于可

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较少扩张的第二端部区域耦接的网状物。例如，可扩张的第一端部区域可以是以下中的一种或多种：机织材料、网状编织 材料、针织材料或穿设有多个开口的膜材料。可较少扩张的第二端部区域 可以由相同的材料制成，或者其可以由不同的材料制成。可较少扩张的第二端部区域可以具有相同的结构(例如机织等)或者其可以具有不同的结 构，包括可扩张的第一端部区域的结构的可较少扩张变型。例如，可较少 扩张的第二端部区域可以是非多孔的(例如非机织的、非针织的等，或固 体材料)或较少多孔的(例如，紧密机织的小空隙针织孔、紧密编织物)。在一些变型中，可较少扩张的第二端部区域可包括位于可扩张的第一端部 区域(例如，具有中间可扩张性)与第二端部区域的不可扩张部分之间的 过渡区域。通常，远侧牵引器区域的可较少扩张的第二端部包括不可扩张 的结构和材料。

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

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

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

[0041] 本文还描述了用于从血管去除凝块的机械取栓设备，该设备包括：导 管，其具有远侧端部和远侧端部开口，其中导管具有内径和外径；管的位 于导管内的远侧牵引器区域，其中，远侧牵引器区域包括可扩张的远侧端 部区域以及靠近于可扩张的远侧端部区域的可较少扩张的远侧端部区域，远侧牵引器区域被配置成使得可扩张的远侧端部区域在

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可较少扩张的远 侧端部区域上翻转;穿过导管和管的导丝腔,该导丝腔包括远侧牵引器区域,其中,导丝腔被配置成使导丝通过;以及近侧手柄,其耦接至管并且 被配置成引起导管与管之间的相对运动,使得从导管的内径内释放远侧牵 引器区域,使得可扩张的远侧端部区域可以扩张至大于外径的直径,使得 可以在可扩张的远侧端部区域与可较少扩张的远侧端部区域之间推进导 管,并且可以向近侧拉该管以在导管的远侧端部上拉动可扩张的远侧端部 区域,使得可扩张的远侧端部区域滚动到导管的远侧端部中、翻转、收缩 并被拉入导管。

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

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

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

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

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

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

[0048] 如上清楚所述,柔性管通常包括远侧牵引器区域,远侧牵引器区域具 有可扩张的第一端部区域以及邻近于第一端部区域的可较少(或不可)扩 张的第二端部区域。因此,柔性管可以包括网状管。

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

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

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

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

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

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

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

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

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

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

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

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

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外部扩张到大于导管的内径的1.5倍的直径。

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

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

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

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

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

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

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

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

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

[0070] 本文还描述了机械地去除取栓的方法,包括:将导丝至少推进到血管 中的凝块的

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近侧端部;在导丝上向远侧推进取栓(例如凝块去除)装置,其中,取栓装置包括具有远侧端部和远侧端部开口的导管以及沿着导管的外径且在导管的远侧端部上延伸的柔性管,使得导丝穿过导管的腔以及柔性管;从离开导管的外径向近侧拉动柔性管并将柔性管拉动到导管腔中,使得柔性管在远侧端部开口上滑动并翻转;以及当柔性管被拉入导管时将凝块拉入翻转的柔性管。

[0071] 机械地去除取栓的方法可以包括:推进导丝邻近血管中的凝块;在导丝上向远侧推进取栓装置,其中,取栓装置包括具有远侧端部和远侧端部开口的导管以及沿着导管的外径且在导管的远侧端部上延伸的柔性管,使得导丝穿过导管的腔以及柔性管;从离开导管的外径向近侧拉动柔性管并在导管的远侧端部开口的圆形唇缘上将柔性管拉动到导管腔中,使得柔性管在远侧端部开口上滑动并翻转,其中,远侧端部开口的硬度大于紧邻远侧端部的区域的硬度;以及当柔性管被拉入导管时将凝块拉入翻转的柔性管。

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

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

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

附图说明

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

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

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性管和/或向远侧朝向凝块推进导管而去除凝块，使得可扩张的第一端部区 域当其被拉入导管的远侧端部中时翻转，将凝块拉动到导管中。

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

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

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

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

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

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

[0083] 图8示出了包括可选真空源的取栓装置。

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

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

[0086] 图10B示出了用于如本文所描述的装置的近侧手柄的另一示例，其包 括用于控制

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(单独或一起)导管和/或内柔性牵引器管的致动的控制器。

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

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

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

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

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

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

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

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

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

[0096] 图19A和图19B示出了用于组装如本文所述的装置的组装方法。

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

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

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域，其包括在导管的远 侧端部区域上翻折的可扩张的第一端部区域。图21D示出了将凝块拉入导 管中的图21C的装置。

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

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

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

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

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

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

[0105] 图27A和图27B示出了穿过26A至图26B的装置的截面图。

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

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

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

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

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

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

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

[0113] 图35A至图35C示出了如图34所示的装置的操作，其中通过将远侧 牵引器区域的可扩张的第一端部区域拉回到压缩凝块(图35A至图35B) 的导管中(例如，在牵引器组件的

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拉动器区域上拉动)而将凝块拉入导管；释放牵引器组件和/或向远侧推动牵引器组件可以进一步破碎凝块并将其 从远侧牵引器区域释放，使得其可以利用手动或动力真空源向近侧抽吸 (图35C)。

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

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

[0116] 图38A和图38B示出了装置和使用该装置从血管中去除材料的方法 的另一变型，其中该装置是“无限”牵引机构，其中大量的牵引器材料(例 如，网状物)储存在一个外保持区域中，其被卷起但在扩充使用上不是必 须的。

具体实施方式

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

[0118] 本文所描述的装置(例如，用于从血管去除凝块的机械取栓装置)可 以是包括具有远侧端部和远侧端部开口的细长导管的组件以及至少部分 位于导管内的柔性牵引器组件，其中，牵引器组件的远侧端部区域被配置 为远侧牵引器区域，远侧牵引器区域至少部分地在导管内延伸并且在导管 的远侧端部上翻折回来。牵引器组件可以包括连接到远侧牵引器区域的近 侧推动器区域。柔性牵引器组件包括配置成允许导丝通过的细长腔。柔性牵引器组件还被配置成在近侧端部区域被向近侧拉动时沿着导管腔内的 长轴线滑动并且在导管的远侧端部开口上翻转。牵引器组件在本文可被称 为柔性牵引器组件、柔性牵引器部分、柔性牵引器管或简单的柔性管，并 且典型地定位在导管内并且可在导管内纵向可滑动，并且布置成使得远侧 端部区域(“远侧牵引器区域”)在导管的远侧端部上翻折回来。

[0119] 例如，图1A示出了可形成本文所描述的装置的一部分的导管的一种 变型。在该示例中，导管100包括远侧端部区域103，远侧端部区域包括 远侧端部105。除了非常远侧尖端(远侧端部105)可以实质上比紧邻其 的区域较不柔软之外，远侧端部区域可以具有增加的柔软度(通过硬度计 测量，例如肖氏硬度计)。因此，虽然远侧尖端区域(例如，最远侧的x线性尺寸，其中x为10cm、7cm、5cm、4cm、3cm、2cm、1cm、9mm、 8mm、7mm、6mm、5mm、4mm、3mm)具有从近侧端部到远侧端部 延伸的增加的柔软度/减小的硬度，非常远侧端部区域107(例如，测量为 最远侧的z线性尺寸，其中z为1cm、9mm、8mm、7mm、6mm、5mm、 4mm、3mm、2mm、1mm、0.8mm、0.5mm、0.3mm、0.2mm等，并 且z总是比x小至少三倍)的硬度大于紧邻其的区域的硬度，并且可以与 远侧尖端区域的最近侧区域一样硬或比其更硬。

[0120] 导管100也可以被称为内导管或牵引器导管。可以使用任何适当类型 的导管，包括适用于神经血管使用的微导管。

[0121] 在一些变型中，导管的远侧端部105适于使得远侧牵引器区域可以在 导管的远侧端部上滑动并翻转而不被捕获(束缚)或没有实质摩擦。例如， 在一些变型中，远侧尖端(端部)可以是弯曲的或倒圆的109，如图1B 所示。特别是在外表面上(例如从外径到内径的过

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渡)。在一些变型中，远侧尖端包括一个或多个通道，如图25A至图28所示和所述的，包括围绕面向远侧的边缘的通道，以引导远侧牵引器区域的滑动。

[0122] 图1C示出了柔性牵引器管140的示例。在图1C中，管是柔性的并且细长(具有通常比导管101大的长度)，并且包括远侧牵引器区域142，该远侧牵引器区域包括配置成紧邻近侧区域146上折叠的最远侧可扩张的第一端部区域144，其可以是可较少扩张的第二端部区域。通常，可扩张的远侧端部区域被配置成在不受约束时扩张至介于导管的内径的直径的1.3倍至10倍之间的径向直径。图1D示出了处于扩张配置的图1C的可扩张的远侧端部区域。因此可扩张的远侧端部区域可以被偏置以扩张打开。可扩张的远侧端部区域可以形成为网状物、机织物或材料片，并且通常适于抓取待去除的物体(例如血凝块)。

[0123] 图1C中一般性示出的柔性牵引器管被示出为图1E中的可扩张的远侧端部区域在其本身上(例如在更近侧的可较少扩张的第二端部区域上)翻折回来。在图1E中，可扩张的远侧端部区域收缩，而在图1F中，可扩张的远侧端部区域扩张。通常，可扩张的远侧端部区域可以与近侧的可较少扩张的第二端部区域区分开，然而在一些变型中，整个柔性牵引器管可以包括在导管内被推动和/或拉动且不包括近侧的可较少扩张的远侧端部区域的可扩张的材料(例如，网状物、机织物等)。

[0124] 图1G和图1H示出了使用诸如由图1A和图1E的部件组装的装置的装置去除凝块。在该示例中，该装置被配置为包括导管101和柔性牵引器管的取栓装置，该柔性牵引器管包括可扩张的远侧端部区域144，该可扩张的远侧端部区域在导管的远侧端部区域上延伸并且在导管的远侧端部上翻折，使得可扩张的远侧端部区域与内近侧的可较少扩张的(在该示例中，可较少扩张的包括不可扩张的)第二远侧端部区域146连续，该第二远侧端部区域在导管内向近侧延伸并形成可使导丝通过的内腔。柔性牵引器管(未示出)的近侧端部可以包括推动器/拉动器构件，该推动器/拉动器构件可以是与远侧端部区域(远侧牵引器区域140)连续的杆或其它构件。在图1G中，装置被示出在凝块155附近的血管160内定位并展开。通过将远侧牵引器区域140取回到导管101中，可以将凝块拉入导管中，如箭头180所示，其示出了柔性牵引器管的内部部分的拉动(例如，使用手柄，未示出)，从而导致将可扩张的远侧端部区域拉动到导管远侧端部中并翻转可扩张的远侧端部区域，使得其被拉动到导管中，如箭头182所示。可扩张的远侧端部区域的远侧端部可相对于导管的外壁“松动”，或者其可被去除附接或在一些变型中永久附接。

[0125] 通常，定位这些装置并致动它们可能是具有挑战性的，这是因为它们在致动之前和操作期间都必须是高度柔性的。例如，一般来说，柔性牵引器管必须不能增加导管的刚度/柔性，并且特别是导管的远侧端部区域过多，或者对于操纵来说过于困难和/或危险，特别是在神经血管系统的侵蚀血管内。本文所描述的是柔性牵引器管部分，其增加了小于预定百分比(例如，小于10%、12%、15%、18%、20%、25%、30%等)的导管的最后y cm(例如，最远侧的20cm、18cm、15cm、12cm、10cm、9cm、8cm、7cm、6cm、5cm、4cm、3cm、2cm、1cm等)的刚度。例如，本文所描述的是柔性牵引器管部分，其穿过导管并且在导管的远侧端部上翻折回来，但是在没有柔性管延伸穿过其中并且在导管的远侧端部上翻折回来的情况下，将导管的远侧5cm的刚度增加小于导管的远侧5cm的刚度的15%。

[0126] 例如，图2A示出了柔性牵引器管201。在该示例中，柔性牵引器管包括在近侧推动器区域201的远侧的远侧牵引器区域242，该远侧牵引器区域具有可扩张的第一端部区域

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244以及可较少扩张的第二端部区域 246。整个柔性牵引器管是中空的并且可以使导丝通过(未示出)。柔性牵 引器管的各个区域可以由相同的材料(例如,机织的、编织的等细丝(filament)或多个细丝)制成,或者它们可以由不同的材料制成。

[0127] 图2B示出了具有远侧牵引器区域的柔性牵引器管,或者至少由多个 机织纤维形成的可扩张的第一端部区域244'。可替代地,可扩张的第一端 部区域可由一个(或多个)针织纤维或机织和针织纤维的组合形成。可扩 张的第一端部区域可以通过纤维或机织/针织图案的形状设定特性或通过 包含一个或多个偏置构件(例如,环、弹簧、带、细丝等)而被偏置地打 开(如图所示),其倾向于至少将可扩张的第一端部区域的远侧端部区域 偏置打开。

[0128] 图2C示出了由包括多个开口(例如,孔、穿孔、通道、窗口等)的 材料片形成的可扩张的第一端部区域的另一变型。这些开口可以是任何尺 寸,包括不均匀尺寸(例如尺寸的范围)或均匀尺寸。穿过片的这些开口 的尺寸可取决于所使用的材料,例如聚合物材料(PTFE)、硅树脂材料、 聚氨酯、形状记忆合金等。在一些变型中,片的孔隙率大于>60%(大于 70%、大于75%、大于80%、大于85%等、在60%至95%之间、在65% 至95%之间、在70%至95%之间等)是有益的。

[0129] 在这些变型中的任一个中,远侧牵引器区域被配置成使得其可以在其 本身上被翻转(例如,翻折),如图2D所示。在一些变型中,该装置可被 执行为使得可扩张的第一端部区域在其本身上和/或在导管的远侧端部区 域上翻转,或者其可以被配置成使得其可以在体内(例如在血管内)在 导管的远侧端部展开和翻转。通常,在装置可被致动之前,导管可以插入 可扩张的第一端部区域与柔性牵引器管上的可扩张的第一端部区域的近 侧的区域之间,在一些变型中,其可以是可较少扩张的第二远侧端部区域。该空间289可以通过在可扩张的第一端部区域的远侧端部处或附近的偏置 构件而保持打开。如所提到的,该可扩张的第一端部区域开口偏置构件可 以是环、带、弹簧、线圈等,并且可以由偏置元件(例如,形状设定材料, 诸如形状记忆合金)、橡胶或其他聚合物材料等制成。

[0130] 尽管存在相关的挑战,但是本文所描述的装置的体内展开可以为操作 装置的用户提供许多优点。图3A至图3F示出了配置用于体内展开的取栓 装置的一个示例。在该示例中,该装置包括导管301,该导管可以使用导 丝313定位(如同本文所描述的变型中的任一个)。导丝可以延伸到或进 入(或穿过)待去除的物体,其示出为在血管360内的图3A中的凝块355。装置的导管可以与导丝一起插入或在导丝之后插入,并且在有或没有柔性 牵引器管在导管的远侧端部处或附近的情况下,可以将导管定位在凝块附 近(例如,邻近或紧邻)。在图3A中,在导丝已经定位之后,定位导管, 并且如图3B所示,从血管中取出导管。导丝可以是线材,较小的导管或 可以定位(例如,操纵)到凝块和/或穿过凝块的装置的组合。在定位导管 之后,包括远侧牵引器区域342的内柔性牵引器管340被推动穿过导管至 导管的远侧端部区域,如图3C所示。在该示例中,形成远侧牵引器区域 的柔性牵引器管的远侧端部包括示出为网状物344的可扩张的第一端部区 域,该网状物在近侧端部处(推动器区域305)连接到与柔性牵引器管的 其余部分连续的近侧的不可扩张的第二端部区域。可扩张的第一端部区域 的机织网状物344在收缩(非扩张)配置中在管状第二端部区域/推动器区 域的外侧上预先翻转,并且可以滑动穿过导管的腔,并且(当导丝留在适 当的位置或用于调节该位置时)在导丝(未示出)上滑动。如图3D所示, 柔性牵引器管的远侧牵引器区域

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然后可以通过延伸(在该示例中,向远侧 推动柔性牵引器管和/或向近侧拉动导管)而暴露于导管的外侧,从而允许 远侧牵引器区域(示为网状物)344的可扩张的第一端部区域沿着第一端 部区域的长度扩张。在图3D中,这显示为可以完全扩张至血管的内膜的 支架状结构,在可扩张的第一端部区域与可较少扩张的(在此情况下是不 可扩张的)第二端区域346之间形成分离。特别地,第一端部区域的扩张 可以大于导管的内腔的直径的1.3倍(例如,大于1.5倍、大于2倍、大 于2.2倍、大于2.5倍、大于3倍、大于3.5倍、大于4倍、大于5倍、大于6倍、大于7倍、大于8倍、大于9倍、大于10倍等)。

[0131] 在图3D中,导管在远侧牵引器区域的第一端部区域与第二端部区域 之间向远侧滑动。然后可以通过向近侧拉动柔性牵引器管(例如,近侧牵 引器区域)和/或向远侧推进导管中的一者或两者,而可以通过将可扩张的 第一端部区域向近侧取回到导管中来移除凝块。在一些变型中,既推进该 装置(特别是导管),同时又取回可扩张的第一端部区域并将其翻转到导 管中可能是有益的。可以比取回柔性牵引器管更快地推进导管。

[0132] 如图3F所示,凝块355可以被拉入到具有可扩张的第一端部区域的 导管中。

[0133] 体内展开方法和装置的另一种变型示于图4A至图4F中。在该示例中, 柔性牵引器管的自扩张的第一端部区域被配置成当其被推出导管时在导 管的端部上自扩张,使得它将在导管的远侧端部上滑动。如以上对于图3A 至图3B所描述,可以使用导丝413等来定位该装置。在图4A中,将导 管401定位在邻近待去除的凝块455的导丝413上。在图4B中,导丝可 以(可选地)被去除,或者(优选地)保留在位。包括远侧牵引器区域的 柔性牵引器管434然后可以在导管内向远侧移动并且以可扩张的第一端部 区域444延伸出远侧端部,使得其在远侧端部上翻转466并且在远侧端部 区域上向近侧滑动,如图4C所示。该过程可以通过在脉管的腔内向远侧 推动装置来辅助,因为第一端部区域444的扩张可以帮助将其抵靠血管的 壁固定,如图4D至图4E所示。一旦暴露,通过向近侧拉动柔性牵引器 管434和/或向远侧端部推进组件(或至少导管),可扩张的第一端部区域 可以取回到装置中,如图4F所示。凝块455然后可以被拉入装置中。

[0134] 图5A至图5E示出了使用机械取栓装置的体内展开和取栓(凝块去 除)方法的另一变型。在图5A中,包括导管501和内柔性牵引器管534 的装置500(例如,在导丝上,未示出)被推进至凝块555附近。在该示 例中(其可以与本文所描述的方法中的任一个相关),该装置与柔性牵引 器构件一起定位,该柔性牵引器构件具有未展开的远侧牵引器区域,该远侧牵引器区域已经在远侧定位在装置的远侧端部区域附近。如图5B所示, 处于图5A中导管501内的收缩配置的可扩张的第一端部区域544被推出 导管的远侧端部并扩张至腔的壁,如图5B和图5C所示。一旦推出并扩 张,可向远侧推进导管和导管内的柔性牵引器管的部分,如图5D所示, 导致可扩张的第一端部区域544翻转,在导管501的远侧端部区域上翻折。通过图5E,装置已经在凝块555附近展开并且可以如已经描述的那样被 致动以去除凝块,但是将远侧牵引器区域的可扩张的第一端部区域拉动到 导管中,使得它翻转并将凝块拉入导管中。导管可以可选地同时被推进。注意,上述体内展开的方法也可以用于加载用于插入体内的装置,以便将 导管径向地定位在柔性牵引器管的可扩张的第一端部区域与较近侧部分 之间。

[0135] 图6A示出了具有柔性牵引器管634的取栓装置的另一变型的示例, 该柔性牵引器管634具有形成于编织(例如机织)或针织材料的该示例中 的柔性第一(远侧)端部区域

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644，其中，柔性第一端部区域(牵引器区 域)在导管601的远侧端部上翻转并且附接到柔性牵引器管634的近侧端 部区域。如在本文所描述的装置中的任一个中，柔性牵引器管的该近侧端 部区域可以是海波管、导管或者在导管内可推动/可拉动并且在其远侧端部 附接到柔性牵引器区域(例如，远侧牵引器区域)(包括在一些变型中的 可扩张的第一端部区域)的层压机织物/网状物或机织材料。注意，在一些 变型中，远侧牵引器区域(第一端部区域)可以是不可扩张的，但是可以 只是柔性的。

[0136] 在图6A中，附接到柔性牵引器管的远侧牵引器区域的第一端部区域 被外导管或套筒(保护器)677覆盖。在该示例中，该装置还包括在内导 管601与保护器导管或套筒677之间的中间导管679。在一些变型中，柔 性第一端部区域644可以附接到该中间导管，包括可拆卸地附接使得向近 侧拉动柔性牵引器管634将使其脱离并允许网状物(柔性第一端部区域 644)在血管中展开。在图6A所示的变型中，柔性第一端部区域644未附 接至中间导管679。

[0137] 本文所描述的装置中的任一个，包括图6A中所示的装置，可以与如 图6B所示的导丝633一起使用(并且可以包括导丝)。图7A至7D示出 了图6A至图6B中所示的设备的操作以去除凝块755。在该装置中，柔性 牵引器管734的近侧端部可以耦接到真空源(未示出)，该真空源当向近 侧取回牵引器管734以在导管的端部上翻转远侧牵引器区域时可以被致动。在图7A中，装置位于凝块755附近。在图7B中，通过如箭头所示 拉动柔性牵引器管734而翻转远侧牵引器区域并将其拉动到导管中。在该 示例中，远侧牵引器区域不被扩张，这是因为它仍然被外套筒777覆盖， 如图7B和图7C所示。可以通过推动或通过向近侧拉动远侧牵引器端部 区域(在该示例中示为网状物744)的动作以使其在导管的远侧端部上翻 转中的一者或两者，向远侧朝向凝块或者在凝块上推进该装置。一旦凝块 被去除，装置可以被取回并从血管中被拉出，如图7D所示。

[0138] 如上所述，这些变型中的任一个可以包括一个或多个真空源。图8示 出了包括真空源的一个示例，其示出了耦接到柔性牵引器管834的腔的近 侧端部处的第一可选真空源。例如，与真空和牵引器管834耦接的可以是 旋转止血阀(RHV)，如图所示。在图8中，在(可选)外导管877和内 导管801或(可选)中间导管878之间形成第二(可选)真空连接。可以在该方法的任何适当部分处施加真空，包括在柔性牵引器管834的收回期 间去除凝块。

[0139] 如上所述，本文所描述的装置中的任一个可以包括导丝并且可以在手 术期间将导丝留在适当的位置。图9A至9D示出了当导丝913留在适当 的位置时去除物体(例如凝块)的方法。在该示例中，该装置类似于图6A 至图6B中所示的装置，并且可以包括可选的真空源。在图9A中，包括 远侧牵引器区域944的柔性第一端部区域944的翻转部分的导管的远侧端 部定位成邻近凝块，并且通过向近侧拉动而被致动以将凝块拉入导管中， 如图9B所示。在该示例中，凝块已经被导丝913穿透，因此具有翻转的 牵引器区域的导管尖端可以通过推动导管927和/或通过向近侧拉动牵引 器管919而在导丝上被向前推进。这可以继续直到整个凝块在导管内，如 图9C所示。

[0140] 在本文所描述的变型中的任一个中，该装置可以包括一个或多个标 记，或者可以被配置成与一种或多种对比剂一起使用以帮助使所描述的方 法可视化。进一步地，这些方法中的任一种都可以包括可视化。可视化可 以是间接的(例如，使用荧光镜检查或等效技术)，或者可以是直接的， 例如使用一个光纤用于直接使该装置可视化(例如，通过装置的

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腔)。

[0141] 在图9D中,具有捕获物体(例如凝块)的牵引器管可以从装置的近 侧去除并且可以检查所去除的材料(例如,通过组织学/细胞学检查)。随 后或同时去除导管。如上所述,当去除物体(例如凝块)时,可能期望在 柔性牵引器管向近侧拉回(未示出)的同时(向近侧)拉回导丝。在一些 变型中,远侧牵引器区域(例如,编织/机织或针织区域)可以抓取导管内 的导丝并且还可以帮助在凝块上或朝向凝块向远侧推进该装置,如下面在 图36以及图37A至图37C中更详细地描述的。

[0142] 通常,抓取器(远侧牵引器区域)的滚动效果通过导管相对于远侧牵 引器区域的运动而被致动。如果远侧牵引器区域向近侧固定并且导管被推 进,则远侧牵引器区域可以具有1:1的抓取比。如果远侧牵引器区域被 拉动通过导管,则抓取效果可能被放大。例如,当远侧牵引器区域被拉回 (通过拉动牵引器管)并且当内导管被向远侧推动1个单元时翻转进入内 导管中在导管内的近侧的1个单元,抓取效果大约是2倍。如果当内导管 向远侧推进一个单元时,远侧牵引器区域被取回到导管中向近侧两个单 元,则抓取效果可以是大约3倍。远侧牵引器区域和导管的同时运动可以 通过手柄来协调。

[0143] 通常,本文所描述的装置中的任一个可以包括手柄。手柄可以与柔性 牵引器管和/或导管(例如内导管)和/或任何外导管(例如保护器、套筒 等)耦接。手柄可被配置成允许柔性牵引器管和/或导管的选择性的分开致 动和/或这些部件的协调运动。图10A和图10B示出了可以使用的手柄的 示例。在图10A中,手柄包括驱动机构以拉回牵引器管,并且因此在导管 的远侧端部上翻转远侧牵引器区域和/或相对于远侧牵引器区域推进导管。在图10A中,手柄包括可旋转手柄1001,该可旋转手柄与导管驱动器1003 耦接。手柄连接到导管1005和具有远侧牵引器区域1011的内部柔性牵引 器管1009两者。手柄可以被配置成使得导管的推进(向远侧)与牵引器 管的拉动(向近侧)的比率可以被选择和/或可以取决于导管驱动螺纹的螺 距或其他机械机构。

[0144] 手柄的另一个变型在图10B中示出。在该示例中,手柄可以附接到牵 引器管以拉动(或推动)牵引器管1017,并且因此在导管的远侧端部上翻 转远侧牵引器区域,并且手柄的另一部分可以耦接到导管以推动/拉动导管 1015。

[0145] 图11A示出了手柄机构1107的另一个变型,该手柄机构被配置成通 过在附件部位1105处耦接到牵引器管的近侧端部来拉动本文所述的装置 中的任一个的抓取器(远侧牵引器区域),和/或通过耦接到导管的近侧端 部来推进导管。手柄机构的另一个示例在图11B中示意性地示出,其示出 了杠杆机构1109和与可以固定或可调节的内牵引器管耦接的耦接件。

[0146] 在本文所描述的装置中的任一个(例如,机械取栓装置)中,远侧牵 引器区域可以被预加载在导管中/上,使得它可以通过向近侧拉动耦接到远 侧牵引器区域的牵引器管和/或向远侧推进导管而被致动。在其中远侧牵引 器区域包括在导管的远侧端部上翻折的柔性和/或可扩张的第一端部区域 (例如,由网状物和/或机织物材料形成)的预加载变型中,装置可以是适 于防止第一端部区域在已经被定位在凝块处或凝块附近之前无意地移位 和/或扩张。

[0147] 图12A和图12B示出了附接到导管外侧的远侧牵引器区域的可释放 附件的示例。通过施加应用于柔性牵引器管的近侧端部的适当量的力(例 如拉力)可以释放这些附件中

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的任一个。例如，如图12A所示，远侧牵引 器区域（示为网状物1204）的外远侧端部被从外导管或管1203延伸的肩 部或衬垫覆盖）。类似地，在图12B中，远侧牵引器区域（示为网状物1204） 的外远侧端部被单独的带、环或衬垫1209覆盖。通过添加细丝（例如在 编织或机织变型中，附加编织细丝）、通过添加涂层、通过热定形至较大 直径，和/或通过添加轴向编织间拉线，当张紧（例如在牵引器管上向近侧 拉动）时，可以防止远侧牵引器区域收缩或直径减小。

[0148] 本文所描述的变型中的任一个可包括作为柔性牵引器管的一部分的 近侧拉杆或拉线。进一步地，牵引器管的近侧端部区域可能比远侧端部（远 侧牵引器区域）柔性更小。图13A和图13B示出了柔性牵引器管的示例。 在图13A中，管包括近侧锥形区域，其中，远侧牵引器区域1305由向近 侧1307渐缩（tapered，锥化）到拉线的材料（例如，网状物/机织材料） 形成，为导丝1309留出空间并允许远侧牵引器区域在导管上翻转。近侧 拉线部分可由形成远侧牵引器区域的细丝形成，例如，在其中机织或编织 远侧牵引器区域的变型中。这些细丝可以通过例如其他材料（诸如有助于 使其更硬或更柔顺的聚合物）来增强。图13B示出了另一个示例，其中， 柔性牵引器管的近侧端部由拉线1315形成，该拉线可以是单独的材料或 附接到拉线的远侧端部并形成远侧牵引器区域1317的编织线束的延伸部。

[0149] 本文所描述的装置中的任一个可以被处理或适应为减少在导管端部 上翻转远侧牵引器区域所需的力。例如，在一些变型中，远侧端部可以被 处理为润滑的，或者远侧牵引器区域的全部或一部分可以被处理以提高费 力性。例如，在一些变型中，仅远侧牵引器区域的一部分（例如最初在导 管的远侧端部上相互作用/翻转的部分）被处理；远侧牵引器区域的其余部 分不被处理。图14示出了此类装置的一个示例。在图14中，可扩张和/ 或柔性第一端部区域（其定位于导管外侧）的最近侧端部1405用润滑涂 层处理或由润滑材料形成。第一端部区域的剩余部分（未按比例示出）不 是润滑的1403。由于较近侧区域1405暴露于血管和导管的远侧端部，所 以它可以更有效地追踪目标或者允许装置追踪目标以及更有效地开始在 远侧端部上翻转。该区域可以以任何适当的方式制成润滑的，包括但不限于涂层，诸如疏水/亲水涂层，并且形成或包括更润滑的聚合物材料（例如 PTFE）。

[0150] 通常，本文所描述的远侧牵引器区域中的任一个可以适于包括不同的 轮廓，包括预先设定以具有（例如，形状设定）可以更容易地在远侧端部 上滑动/移动和/或抓取凝块或其他目标物体以用于去除的轮廓。例如，图 15A至图15D示出了具有形成不同远侧牵引器区域的不同远侧端部轮廓 的牵引器管。例如，在图15A中，远侧牵引器区域包括由通过多个拉线连 接到牵引器管的近侧端部的由编织/网状或机织材料形成的最远侧可扩张 和/或柔性第一端部区域1505。这些拉线1517可以由形成编织/网状或机 织的远侧端部区域的相同线材或细丝形成。图15B示出了另一种变型，其 中，多个离散的编织/网状或机织的远侧端部区域通过拉线1515连接；这 些拉线区域1515可以是比编织/网状或机织区域1516更少可扩张的和/或 柔性的。在图15C中，远侧端部区域被编织/网状或机织，但预先设定为 具有不同的直径。因此这些区域沿其长度可以具有不同的形状；当这些形 状被拉入导管中时，这些形状可被热定形以更好地抓取或破碎凝块。图 15D示出了编织或支架状第一端部区域1521的示例，其通过形成编织/网 状或机织的远侧牵引器的相同细丝的相同细丝或束连接到牵引器管1520 的海波管或其他更近侧端部区域1523。

[0151] 本文所描述的装置中的任一个还可以或可替代地包括附接到导管的 外表面上的

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多个可释放附件，从而将远侧牵引器区域（并且特别是远侧端 部部分）固定到外表面。在图16中，示出了形成可释放附件的三个环1603、16.3'、1603"，其将远侧牵引器区域1644的远侧端部固定到导管1601的外 侧。在该示例中，聚合物涂层/膜与编织物附接或成一体，形成远侧牵引器 区域以帮助防止其过早地滑出或滑离导管（例如，直到由使用者拉动）。 该装置可以包括沿着导管的长度径向定位的多个附件，如图所示，以帮助 其保持固定到导管输送系统的外径。在一些变型中，这些可释放附件是弹 性构件（例如聚氨酯环），但可以是脆的，并且允许破坏以释放远侧牵引 器区域。

[0152] 图17示出了另一种变型，其中，可释放附件定位成使得远侧牵引器 区域的一部分被弹簧加载（偏置）以驱动它在导管远侧端部上滚动并进入 导管腔中。在图17中，远侧牵引器区域1704的远侧端部可被固定（固定、 附接或松动但受约束），并且在导管的远侧端部附近的较近侧端部区域可 被可释放地固定到导管1707。例如，聚合物涂层或膜可以附接到远侧牵引 器区域（在图17中示出为编织物1744）并且被耦接以使远侧牵引器区域 1705的在远侧端部1704与可释放附接部位1707之间的一部分保持张紧 （例如，压缩）。然后释放可释放附件1707可以施加驱动围绕导管远侧端 部的远侧牵引器区域的力，以帮助将凝块拉入装置中，并减小翻转远侧牵 引器区域所需的力。

[0153] 如上所述，形成远侧牵引器区域（并且特别是最远侧柔性和/或可扩张 的第一端部区域）的材料可以由任何适当的材料形成。例如，该材料可以 包括织物、机织物、针织物、编织物、缝合物、管和/或平片。该材料可以 具有任何合适的厚度，例如在0.0005"至0.015"的壁厚之间，并且可以具 有从低至高孔隙率的任何合适间隔/尺寸（孔隙率）的孔。远侧牵引器区域 的全部或一部分可以是不透射线的或无线电透明的。在机织、针织、编织 或缝制的变型中，材料可以由多丝或单丝形成。不同尺寸的细丝可以混合 在一起（例如，大和/或小）以通过增加或减少织物表面纹理来改变抓取效 果。在一些变型中，材料（包括形成材料的细丝）可以是基于聚合物的（例 如PET、尼龙、聚丙烯、PTFE、ePTFE）、弹性和非弹性的（例如PU、硅 酮、橡胶、莱卡）、金属细丝（例如镍钛、包括DFT的拉伸充填的镍钛， 即带Pt内芯的镍钛、钢、不锈钢、钴铬合金等）以及金属和聚合物细丝 的混合物。织物的端部可以是激光切割/焊接或自由切割。在一些变型中， 远侧牵引器区域的全部或部分包括膜或片。该膜可以在0.0005"至0.008" 厚度之间。该膜可以通过管挤出或片形成并且卷成管。在一些变型中，膜 是纱线增强的。膜可以是开槽的（例如，可以包括被切割的孔和/或狭缝以 改进抓持或滑入导管）。在一些变型中，膜具有纹理化表面（例如，翻转 时暴露的纹理化内表面）。膜可形成具有沿长度具有脊和/或环（径向环） 和/或线和/或具有锯齿形图案的管。纹理化内表面可以包括大丝和小丝的 混合物，和/或可以由更多孔的较密度的织物形成。

[0154] 在一些变型中，抓取器元件的可视性是期望的，但并非始终需要。例 如，如上所述，标记可以位于设备上。在一些变型中，可能期望看到结构 的整个结构或近侧端部和远侧端部。例如，材料可以是镍钛诺或在铂材料 （DFT）上拉制的镍钛诺以增强可视性。

[0155] 变型中的任一个可以包括位于编织结构中的任一个的内侧的旋转螺 旋钻元件以协助将凝块拉回到毂。如上所述，这些装置中的任一个都可以 包括真空源。向系统添加真空可能有助于远侧牵引器区域将凝块/栓塞拉入 导管中的能力。所施加的真空可以是稳定的/恒定的、倾斜的或脉动的。

[0156] 在一些变型中，使用它们的装置和方法可以包括阻流近侧球囊（例如， 定位在凝

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块附近)，其可以在手术期间减少凝块上的压力。

[0157] 本文所描述的装置和方法可以用于捕获活检样品(例如，来自乳房或 任何其他器官)。例如，当执行腹腔镜手术时，可以使用这些装置去除较 大的组织段(例如，癌症、胆囊等)。

[0158] 当形成远侧牵引器区域的材料是机织/编织材料时，所得到的网状结构 可具有范围从1cm到100cm长以围绕导管的外径(OD)的编织物长度，优选地长度为在约3cm至30cm之间。

[0159] 在这些变型中的任一种中，牵引器管和/或导管(包括远侧牵引器区域) 可以被构造成使得可以拉动远侧牵引器区域，使得远侧牵引器区域以最小 的力在导管远侧端部的外径周围被拉入(翻转)，使得导管尖端不会在血 管中弯曲或显著变形(例如，蛇形扭动)，其中，拉力小于约：50克、100 克、300克、500克、800克、1000克、2千克、3千克、5千克、8千克、10千克、15千克、20千克等。

[0160] 在其中抓取器(远侧牵引器区域)至少在远侧端部(例如，可扩张的 和/或柔性第一端部区域)上构造为机织(例如编织)结构的变型中，形成 机织结构的细丝的示例可以包括：镍钛、镍钛-PT DFT线材(Pt内部的镍 钛管)、PET、PP、尼龙、Algiloy、SS、混合材料。当使用时，镍钛可能 被蚀刻以使其非常平滑。细丝端部的数量可以是约：16、24、36、48、77、 96、144或这些整数之间的任何数量。任何编织结构都可以使用。例如， 示例性编织结构可以包括1×1(1×1)、1×2、2×2等。在一些变型中， 形成机织和/或针织材料的细丝包括单丝，例如所具有的外径(O.D.)尺寸 约为：0.0005”、0.00075”、0.001”、0.0015”、0.002”、0.003”或在本文列 出的整数之间的尺寸或直径尺寸的组合。如上所述，这些装置可以适用于 使用的神经脉管系统，例如假设2mm至3mm脉管内径(ID)。例如，如 本文所描述的适于神经脉管应用的装置可以包括韧炼至3mm至7mm OD 的0.001”至0.002”聚合物编织物的36个至72个端部。在一些变型中， 远侧牵引器区域包括24个编织线材，其具有以45度角度编织的在2mm心轴上韧炼的0.0005”至0.0015”或0.002”的扁平镍钛线材。可替代地， 在一个变型中，远侧牵引器区域包括编织材料，该编织材料由以45度角 度编织的在2mm心轴上韧炼的0.002”厚度的镍钛线材的24个线材形成。 在一个示例中，远侧牵引器区域包括编织材料，该编织材料包括以45度 角度编织的在2mm心轴上韧炼的0.002”DFT镍钛线材的24个线材。在 一个示例中，远侧牵引器区域包括机织材料，该机织材料包括与在2mm 心轴上的0.002”镍钛线材的8个附加端部混合的0.003”线材的8个端部。 在一个示例中，远侧牵引器区域包括编织材料，该编织材料包括在2mm 心轴上韧炼的0.002”铂铱线材的16个端部。在一个示例中，远侧牵引器 区域包括编织材料，该编织材料包括具有0.002”直径的外径的PP单丝的 24个端部。在一个示例中，远侧牵引器区域包括编织材料，该编织材料包 括0.003”PP单丝的12个端部。在一个示例中，远侧牵引器区域包括编 织材料，该编织材料包括0.003”PP单丝的16个端部。在一个示例中， 远侧牵引器区域包括编织材料，该编织材料包括1x1、90度编织角度、8 mm心轴的0.001”PET或PP的72个端部。在一个示例中，远侧牵引器 区域包括编织材料，该编织材料包括1x1、75度编织角度、6mm心轴的 0.001”PET或PP的36个端部。在一个示例中，远侧牵引器区域包括编 织材料，该编织材料包括1x1、90度编织角度、8mm心轴的0.002”PET 或PP的48个端部。在一个示例中，远侧牵引器区域包括编织材料，该 编织材料包括1x1、70度编织角度、6mm心轴的0.002”PET或PP的48 个端部。

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[0161] 在其中远侧牵引器区域包括网状物的变型中，管状网状物可由针织或 替代结构形成，该针织或替代结构被构造成使得当网状牵引器被轴向拉动 并且围绕导管尖端的外侧并进入导管ID中时，径向压缩(管状网状物内 径ID的变化)经受直径减小5％至20％。这种5％至20％网状物直径的减 小可以有助于在将网状物拉动到导管中时抓取凝块或异物，而不会产生很 大的径向压缩力使得在拉动时管状网状物结合在导管尖端上并且不容易围绕导管尖端滚动。相反，当向近侧拉入时，机织的网状物可在导管内收 缩20％至60％之间，这可提供其他所去除材料的凝块的大量压缩。

[0162] 在其中该装置被配置用于外围血管(例如，具有4mm至8mm血管 ID)的变型中，远侧牵引器区域可以被配置用于该应用。例如，远侧牵引 器区域可以包括具有形成在4mm心轴上并被韧炼的0.009”PP单丝的24 个端部的编织材料。远侧牵引器区域可以包括具有4mm心轴韧炼的 0.008”PP单丝的编织材料。远侧牵引器区域可以包括具有4mm心轴韧 炼的0.006”PP单丝的72个端部的编织材料。远侧牵引器区域可以包括 具有4mm心轴韧炼的36个端部的编织材料。远侧牵引器区域可以包括 具有心轴韧炼的0.004”DFT镍钛的48个端部的编织材料。

[0163] 在其中装置被配置为活检装置(例如，具有4mm至12mm样本大小) 的变型中，该装置可以是机织材料，其包括在10mm心轴上形成的PP 007” 单丝的72个端部。在一些变型中，装置(例如，远侧牵引器区域)可以 包括在1mm心轴上形成的0.004”镍钛的48个端部。在一些变型中，装 置(例如，远侧牵引器区域)可以包括在12mm心轴上的PP 0.008”单丝 的48个端部。

[0164] 在本文所描述的变型中的任一个中，所述装置可以被配置成具有相对 低的摩擦。特别地，远侧牵引器区域可以具有低摩擦力以允许在收回凝块 时更容易和/或可靠地拉动穿过导管。如上所述，这些变型中的任一个可以 包括润滑材料和/或涂层，包括在抓取器(远侧牵引器区域)上使用或涂覆 一种或多种以下材料：PET、PP、PTFE、ePTFE。当形成装置的材料是小 直径细丝金属结构时，细丝的直径可以在0.0005”至0.003”之间。材料 可以是镍钛、不锈钢、MP35n、Ti、铂、铂铱、钴铬合金等。

[0165] 在远侧牵引器区域是网状物(例如，机织和/或针织材料)的变型中， 远侧牵引器区域相对于导管直径的直径可以取决于机织/针织结构。例如， 当编织时，比率可以在2至1之间或更大；当经编时，比率在1.5至1之 间或更大。当形成为激光管时，比例在1.1至1之间或更大。类似地，对 于编织管或带结构，导管内部的编织角度应该在导管内侧在编织角度的0 度至45度之间，并且在导管外侧在编织角度的约20度至90度之间。在 远侧牵引器区域包括针织编织(例如，经编)管的变型中，该装置可以包 括每英寸12个至16个端部。对于具有0.0035”ID导管的装置：可以使 用20至40D PET复丝的12个至16个端部，或者可以使用0.0007”至0.003” PET或聚丙烯(Polypro)或PTFE单丝的12个至16个端部，或者可以使 用0.0007”至0.002”镍钛、不锈钢、MP35n等的12个至16个端部。

[0166] 如上所述，在一些变型中，远侧牵引器区域由ePTFE形成为片(例如， 形成为管或带)。这种材料可以是薄壁的(例如厚度在0.0005”至0.003” 之间)，被认为是有壁厚的(在0.0005”至0.002”之间)，并且可以在导 管尖端上折叠/起作用。该材料可能包括0.001”至0.004”，带有支架状的 激光图案。

[0167] 包括不同形状的远侧牵引器区域的装置的设计的其他示例可以是导 管ID的功

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能。例如，在一些变型中，装置可以选择导管ID、细丝的数量、 细丝的直径/长度、弯曲/滚动刚度的刚度、泊松比、抓取器的内表面的摩 擦(和/或纹理)等。较小直径的导管比较大直径的导管可能需要更少的网 状物细丝或者更小的ePTFE管IDS。例如，在编织远侧牵引器区域的一些 变型中，该装置可以包括具有远侧牵引器区域的0.072"ID导管，该远侧 牵引器区域具有以90度编织角度编织在6mm心轴上的0.0008"至0.002" 镍钛线材的24个至72个端部。在一些变型中，远侧牵引器区域由以90 度编织角度编织在6mm心轴上的0.0008"至0.002PP单丝的24个至72 个端部形成。在一些变型中，远侧牵引器区域由针织编织物(假定0.072" 导管)形成，并且可以包括在3mm心轴上韧炼的16个端部或40D PET 复丝自由经编针织物。在一些变型中，远侧牵引器区域由在3mm心轴上 韧炼的经编针织的0.002"PP单丝的16个端部形成。在具有由ePTFe管 形成的远侧牵引器区域(同样，假设0.072"导管)的变型中，远侧牵引 器区域可以是0.002"厚的3mm的管。可替代地，远侧牵引器区域可以 是0.002"厚的3mm的管激光器，其被开槽以收缩和抓取凝块。

[0168] 如所提及的，在一些变型中，该装置被配置成在远侧牵引器区域中包 括抓持内网状表面。例如，该装置可以包括具有较大直径编织细丝和/或混 合直径细丝的激光开槽ePTFE管。在一些变型中，抓持内网状表面可以用 作为经编针织成型管的针织编织物形成。此类结构可以具有自然的宏观结 构以允许网状物滚动和抓持凝块，因为细丝不会平行于导管进入导管ID， 而是它们相对于导管长轴线是垂直或环状的。对于其中远侧牵引器区域由 ePTFE激光开槽材料(材料片)形成的示例，该结构可以包括切割成允许 泊松比影响管直径同时产生抓持纹理以抓取凝块的狭缝。

[0169] 通常，通过使用自扩张的和/或较硬的远侧牵引器区域(例如，远侧牵 引器区域的自扩张的和/或柔性第一端部区域)，可以增强远侧牵引器区域 在抓取凝块中的有效性)。当远侧牵引器区域的第一端部区域由编织物形 成时，较硬的细丝(例如，由较大直径的细丝、较硬的材料、较大数量的 纤维等形成)可导致远侧牵引器的更扩张的第一端部区域，如图18A至图 18C所示。在图18A中，较柔软的远侧牵引器区域不会扩张超出导管的 OD相当大的距离。图18B示出了远侧牵引器区域的略微更硬/更可扩张的 第一端部区域。图18C示出了最可扩张的远侧牵引器区域1801，其可以 最佳地扩张至血管1803的内膜。

[0170] 如图18A至图18C所示，可扩张的牵引器区域的唇缘的嘴部可相对 于导管OD的长轴线形成切向角度或滚动角度(Φ)。该角度可以在大约 5°至60°的范围内(例如，10°至60°、10°至50°、10°至45°、 10°至40°等，并且优选地至少为10度)。本发明人惊奇地发现，在一些 变型中，当牵引器区域被收回到导管中时与管具有至少约10度(例如10° 至60°、10°至50°、10°至45°、10°至40°)的滚动角度可防止导 管尖端上的束缚或堵塞。网状管可以被修改(例如，在远侧尖端或端部区 域处)，包括通过修改远侧尖端的刚度和/或形状，以确保滚动角度大于10 度。可替代地或与保持最小滚动角度的组合，可能期望在导管最远侧尖端处保持管材料ID与导管的O.D之间的物理空间或间隙(参见例如图18A 至图18C)。间隙可能需要大于0.1mm、0.2mm、0.3mm、0.4mm、0.5mm、 0.7mm、0.8mm或1.0mm，以确保当管收回时，管围绕导管的远侧端部 滚动。

[0171] 在这些变型中的任一个中，如上所述，远侧牵引器区域可以是润滑的 (例如，亲水涂层、硅树脂涂层、薄氨基甲酸酯或其他薄弹性体涂层)。可以包括一个或多个聚合物编织物端部以增强润滑性(例如，聚丙烯、尼 龙等)。进一步地，编织角可保持较小(例如，小于70

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度、50度、45度 等)以允许更好的拉动。当远侧牵引器区域在导管的尖端周围/上方滚动时，可以测量该角度。增加机织物的端部的数量也可以防止第一端部区域在导 管内的锁定，使得编织元件之间的间隙/空间更小并且当远侧牵引器区域在 导管的端部上滚动时不太可能阻碍导管尖端。当形成为编织元件时，这些 装置中的任一个还可以包括轴向元件，该轴向元件在拉动时不太可能收缩 或直径减小，并且因此当在尖端上滚动时不太可能挂在导管开口上。当使 用镍钛(例如>0.0001"直径)时使用稍大的编织细丝也是有利的；直径 越大，编织物可变形以锁定到导管尖端的可能性就越小。如上所述，在一 些变型中，远侧牵引器区域可被热定形以在向远侧推进时在导管的远侧端 部上自动滚动。

[0172] 图19A和图19B示出了用于形成远侧牵引器区域的翻折回来配置的 替代方法。在图19A中，管状远侧牵引器区域1903可以耦接到拉动器/ 推动器1901，然后如上所述在导管尖端上翻转。在图19B中，管状编织 物1905穿过编织物向远侧附接到线材/拉动器1901并被拉动以在导管的远 侧端部上使其翻转。

[0173] 通常，远侧牵引器区域的第一端部区域可具有任何适当的形状(参见 图15A至图15D)。图20A和图20B示出了可以形成远侧牵引器区域的渐 缩机织物的示例。在图20A中，编织物具有锥形侧面轮廓，其可以附接到 拉动器(柔性牵引器管的近侧端部)并且翻转。本文所述的编织物中的任 何一种可以包括标记线材(例如，DFT、金、铂、铂铱等)以帮助可视化(例如，荧光镜)。在图20B中，网状物比图20A中更突然地渐缩。

[0174] 如上所述，通常，本文所描述的导管中的任一个可适用于这些装置。例如，合适的导管可以是高度柔性的，并具有良好的柱刚度(例如，当向 远侧推进时其长度不会缩短)。导管可以具有高角度编织物加强元件。例 如，导管可以具有穿过近侧端部至远侧端部的高角度编织物(70度至85 度，小线材镍钛、不锈钢、钴铬、MP35N、扁平或圆形线材)，以及针对导管的远侧1cm至5cm的较小编织角度。这将允许当施加轴向压缩时和 /或在内扩张力(例如血块)下导管的内径扩张。

[0175] 通常，这些导管中的任一个都可以包括改变的刚度/顺应性。例如，近 侧三分之一(1/3)可能较硬；中间部分可能不太硬，而远侧20％(1/5) 可能是最不硬的。进一步地，导管的远侧尖端可以具有如图1A和图1B 中所描述的适当的半径(曲线)。通常，半径应该是平滑且圆形的，而不 是方形的。另外，导管的远侧尖端可以由足够硬的材料(约72D或更硬) 制成，以允许编织物滚动而不抓取尖端。例如，导管尖端可以具有硬质金 属结构以减少摩擦(例如，不锈钢、Pt等)。当拉动远侧牵引器区域时导 管尖端压缩/弯曲越少越好。在一些变型中，导管包括附加加强件，诸如编 织增强件而不是线圈加强件，以防止导管最后5cm至10cm的编织物屈 曲。因此，如本文所描述的，在一些变型中，导管的尖端可由润滑和/或硬质材料制成，以当编织物围绕导管尖端被拉动或被推动时帮助减少编织物 与导管尖端的摩擦。润滑材料可以包括诸如PTFE、FEP和/或亲水涂层的 粉状聚合物。如尼龙之类的硬质材料或不锈钢之类的金属材料、铂和PT 铱合金可用于该尖端，并且向近侧熔合/附接到较柔软材料。如果硬质尖端 被放置在导管尖端的远侧端部上，则其长度可能是短的(例如<5mm并且 优选地<3mm)，因此它不会不利地影响导管追踪。

[0176] 图21A至图21D示出了用于去除凝块的装置的示例。在该示例中， 远侧牵引器区域由拉下到0.071"的导管上的10mm(扩张)直径的大约 72个端部的细旦尼尔PET网状物形成，如图21A和图21B所示。图21A 示出了在耦接到导管之前的可扩张的第一端部区域的示例。

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图21B示出了 通过拉动柔性(牵引器)管的近侧端部将血管(玻璃管)内的可扩张的第 一端区域拉入导管中。图21C示出了装置的远侧端部区域,其包括在导管 的远侧端部区域上翻折的可扩张的第一端部区域。图21D示出了将凝块拉 入导管中的图21C的装置。

[0177] 另一个示例检查了由具有72个端部和0.001”直径细丝的6mm编织 物形成的远侧牵引器区域,该细丝滚动进入0.071”ID导管并且在0.071”ID导管上翻折。成功去除20cm长的“中等硬度”5mm凝块。图22示 出了在将其向近侧拉出导管之后具有所捕获的凝块的图21D的可扩张的 第一端部区域。

[0178] 图23A至图23D示出了如本文所述的机械取栓装置,其捕获血凝块 并将其拉入装置中。图23E示出了在柔性牵引器管已经从导管去除(例如 向近侧)之后保持在柔性牵引器管内的凝块。

[0179] 在本文所描述的一些变型中,远侧牵引器区域不是由机织或针织材料 形成,而是由纵向布置(例如,平行或近似平行布置)的条或束构成。例 如,图24是包括柔性牵引器构件的装置的另一个示例,其中,远侧牵引 器区域由多个细丝形成,该多个细丝布置位未机织或编织的材料条(纵向 平行)。这些条可以是细丝或管等。

[0180] 图25A至图25F示出了柔性牵引器组件的远侧牵引器区域的另一变 型,其中,可扩张的第一端部区域(例如,远侧牵引器区域的远侧端部区 域)由多个细丝或条形成,类似于图24中所示的;如图25A至图24所示, 导管的远侧端部包括通道;这些条可以装配在这些通道内,如图25C至图 25D所示。图25E和图25F示出了穿过图25C和图25D的截面图。图25A、图25C和图25E示出了侧视图并且图25B、图25D和图25F示出了轴向 视图。在该示例中,导管尖端包括细丝/条2503在其中行进的通道2502。 形成远侧牵引器区域的条附接到柔性牵引器管2505的更近侧的拉动器区 域,如图25E所示。

[0181] 图26A和图26B示出了具有外套筒(例如,外导管或释放保护器导 管或其他外套筒/保护器)的图25A至图25F的装置的变型

[0182] 图27A至图27B示出了穿过图26A至图26B的装置的截面图。

[0183] 图28是包括柔性牵引器组件的远侧牵引器区域的装置,柔性牵引器 组件具有多个纵向平行的(非机织/编织)细丝或条,其中,细丝或条的远 侧端部通过远侧连接件彼此连接。

[0184] 图29示出了装置中的柔性牵引器组件的远侧牵引器区域,其中,纵 向平行的(非机织/编织)细丝或条包括抓取元件。

[0185] 图30A至图30C示出了具有抓取元件的细丝/条的示例。抓取元件(和 /或包括它们的细丝)可以用作本文所描述的变型中的任一个的一部分,包 括机织或编织的远侧牵引器区域。带有抓取元件的对于细丝/条的其他选择 可以包括编织条、网状物/机织条和微线圈。

[0186] 在本文所描述的这些配置中的任一种中,该装置可以适于允许远侧牵 引器区域的往复运动,从导管的远侧端部的外侧至内侧并回到外侧而循 环。例如,图31示出了其中远侧牵引器区域适于往复运动(例如,推动 和拉动)使得可扩张的第一端部区域可被拉入导管中并且从导管翻转出的 变型。在该示例中,牵引器管(拉动器)3105附接到远侧牵引器区域3144, 该远侧牵引器区域可以附接(并且在一些变型中不附接)到内导管3101 上的第二导管3109。中间导管3109可以耦接到拉动器3105,并且两者一 起往复运动,使得编织物

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在导管3101的内侧来回往复运动。这可以帮助 破碎凝块，这可能特别是在与抽吸一起使用时。

[0187] 图32示出了如本文所述的装置的另一示例，其中，远侧牵引器区域 的柔性第一端部区域的最远侧端部3205不可释放地固定到导管3201的外 侧的远侧端部；可扩张的第一端部区域3209的其余部分具有足够的弹性/ 柔性以被拉入导管中(用其拉动凝块3255)。然后柔性牵引器组件可以被 收回并且整个装置被取回。该示例可能包括可选的真空3260。

[0188] 图33是装置的另一个示例，其中，柔性牵引器组件的拉动器部分3305 由与远侧牵引器区域3344相同的材料形成，但可以层压或以其他方式加 强以具有比远侧牵引器区域更小的柔性/可拉伸性。

[0189] 图34示出了另一个示例，其中，远侧牵引器区域3444适于当拉入导 管3401中时压缩凝块3455。图35A至图35C示出了如图34所示的装置 的操作，其中，凝块3455通过将远侧牵引器区域的可扩张的第一端部区 域取回到压缩凝块的导管中(例如在牵引器组件的牵引器区域3505上拉 动)而被拉入导管中(图35A至图35B)；释放牵引器组件和/或向远侧推动牵引器组件可以进一步破碎凝块并且将其从远侧牵引器区域释放，使得 它可以向近侧分段(图35C)。

[0190] 图36示出了一种装置和使用方法的示例，其中，向近侧拉柔性牵引 器组件可以向远侧推进装置穿过导丝上的主体(例如血管)，该导丝可以 被处理以接合远侧牵引器区域。在该示例中，该装置可以被配置成拉动具 有形成远侧牵引器区域3644的网状物的内牵引器管(导管3605)，该远侧 牵引器区域附接到其远侧端部并且在导管3601的远侧端部上翻转。拉动 柔性牵引器管3605使编织物在导管3601的开口上滚动。形成远侧牵引器 区域(例如，远侧牵引器区域的第一端部区域)的网状物/编织物被构造成 当拉伸负载施加到该结构上并且锁定/抓取内线材(导丝3677)时在直径 上收缩。该内导丝可能具有抓取线材的粘性、粗糙或多变的表面辅助网状 物/编织物。当网状物/编织物抓取在导丝上时，牵引器管由于反作用力而 将在脉管中被向前驱动。可替代地，用户将能够在拉回牵引管的同时能够容易地将外导管3601向前推进穿过血管。

[0191] 图37A至图37C示出了另一种装置和使用方法，其中，向近侧拉柔 性牵引器组件可以向远侧推进该装置。在图37A中，远侧牵引器区域3744 附接至中间导管3703(可包括可选的外导管3705)，并且远侧牵引器区域3744的相对端部结合至在该导管的内径内的内导管3701的远侧端部。在 图37B中，向远侧推进内导管，从而使远侧牵引器区域在侧向和前方扩张。如图37C所示，然后可以向远侧推动外导管和内导管，以使装置向远侧移 动。

[0192] 在一些变型中，远侧柔性牵引器区域可以被保持预先加载在导管的外 侧，例如以卷或束的形式被保持预先加载在导管的远侧端部区域上，使得 其可以被逐渐拉出外存储区域并且在导管的远侧端部上滚动和翻转。一个 此类变型的示例示出在图38A和图38B中，该示例性装置可用于从血管 内去除材料，如图38B所示，并且可以称为“无限(infinite)”牵引器机 构，因为大量(例如，大于50cm、大于60cm、大于70cm、大于80cm、 大于90cm、大于100cm、大于150cm、200cm、大于300cm、大于400 cm、大于500cm等)的牵引器材料(例如，网状物)可存储在外保持区 域中，其被卷起但在扩大使用上不是必要的。

[0193] 在图38A中，该装置可以包括导管(内导管)3811并且远侧牵引器 区域3806由在导管的远侧端部附近的壳体区域3813中卷起的网状物3803 形成。通过在导管内向近侧拉动

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远侧牵引器区域，凝块3805可被拉入导 管中。由于大量远侧牵引器区域可能存储在近侧并且向近侧被取回，因此 这种变化对于非常长的手术或者需要去除大量材料的情况可能是有用的。

[0194] 这种变型可以允许使用者展开较长长度的网状物，这对于更刚度的工 具(诸如在手术期间的刚度海波管)可能是有利的，例如，在吸脂手术中 去除脂肪、去除脑内出血或更大的外周血管凝块中的凝块。

[0195] 如上所述，在本文所描述的变型中的任一个中，远侧牵引器构件可以 是机织(例如针织)或编织的网状材料。网状物可以是针织材料，包括例 如纬编针织物、圆形针织物、经编针织物和/或编织针织物。

[0196] 当特征或元件在本文中被称为“在”另一特征或元件“上”时，其可 以直接在另一特征或元件上，或者也可以存在中间特征和/或元件。相反， 当特征或元件被称为“直接在”在另一特征或元件“上”时，不存在中间 特征或元件。还将理解，当特征或元件被称为“连接”、“附接”或“耦接” 到另一特征或元件时，其可直接连接、附接或耦接到另一特征或元件，或 者可能存在中间特征或元件。相反，当特征或元件被称为“直接连接”、“直 接附接”或“直接耦接”到另一特征或元件时，不存在中间特征或元件。 虽然相对于一个实施例进行了描述或示出，但是所描述或示出的特征和元 件可以应用于其他实施例。本领域的技术人员还将认识到，对“邻近”另 一个特征设置的结构或特征的提及可以具有与邻近特征重叠或位于其下 面的部分。

[0197] 本文所使用的术语仅用于描述特定实施例的目的，而不意图限制本发 明。例如，如本文所使用的，除非上下文另外明确指出，否则单数形式“一”， “一个”和“该”也旨在包括复数形式。将进一步理解，当在本说明书中 使用时，术语“包括”和/或“包含”指定所述特征、步骤、操作、元件和 /或部件的存在，但不排除一个或多个其他特征、步骤、操作、元件、部件 和/或其组合的存在或添加。如本文所使用的，术语“和/或”包括相关所 列项目中的一个或多个的任何和所有组合，并且可以缩写为“/”。

[0198] 为便于描述，本文可以使用诸如“在...之下”、“在...下方”、“下”、“在... 上”、“上”等的空间相对术语以描述一个元件或特征与另一个元件或特征 的关系，如图所示。将理解，空间相对术语旨在包括除了附图中所描绘的 方位之外的装置在使用或操作中的不同方位。例如，如果附图中的设备是 翻转的，则被描述为在其他元件或特征“之下”或“下方”的元件将被定 向为“在”其他元件或特征“上”。因此，示例性术语“在...下面”可以包括上方和下方两种方向。设备可以以其他方式定向(旋转90度或以其他 方位)并且相应地解释在本文所使用的空间相对描述符。类似地，除非另 外特别指出，否则术语“向上”、“向下”、“竖直”、“水平”等仅用于解释 的目的。

[0199] 虽然术语“第一”和“第二”在本文中可以用于描述各种特征/元件(包 括步骤)，但除非上下文另有指示，否则这些特征/元件不应受这些术语限 制。这些术语可以用于区分一个特征/元件与另一个特征/元件。因此，下 面论述的第一特征/元件可以被称为第二特征/元件，并且类似地，在不脱 离本发明的教导的情况下，下面所论述的第二特征/元件可以被称为第一特 征/元件。

[0200] 在整个说明书和所附的权利要求书中，除非上下文另有要求，否则词 语“包含”以及诸如“包含了”和“其包含”的变型意味着各种部件可以 在方法和物品中共同采用(例如，

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包括设备和方法的组合物和装置)。例 如,术语“其包含”将被理解为暗示包含任何陈述的元件或步骤,但不排 除任何其他元件或步骤。

[0201] 如在本说明书和权利要求书中所使用的,包括在示例中所使用的并且 除非另有明确说明,即使术语没有明确出现,所有的数字也可以读作像 “约”或“大约”这样的词语开头。当描述幅度和/或位置以指示所描述的 值和/或位置在值和/或位置的合理预期范围内时,可以使用短语“约”或 “大约”。例如,数值可以具有所述值(或值的范围)的+/-0.1%的值、 所述值(或值的范围)的+/-1%的值、所述值(或值的范围)的+/-2% 的值、所述值(或值的范围)的+/-5%的值、所述值(或值的范围)的+/ -10%的值等。本文给出的任何数值也应被理解为包括约或大约该值,除 非上下文另有指示。例如,如果公开了值“10”,则“约10”也被公开。 本文列举的任何数值范围旨在包括其中所包含的所有子范围。还应理解, 当公开值时,“小于或等于”该值、“大于或等于该值”以及值之间的可能 范围也被公开,如本领域技术人员所适当理解的。例如,如果公开了值“X”, 则还公开了“小于或等于X”以及“大于或等于X”(例如,其中X是数 值)。还应该理解,在整个申请中,数据以多种不同的格式提供,并且该 数据表示端点和起点以及数据点的任何组合的范围。例如,如果公开了特 定的数据点“10”和特定的数据点“15”,则可以理解,大于、大于或等 于、小于、小于或等于并且等于10和15被认为是公开的以及在10和15 之间。还应该理解,还公开了两个特定单元之间的每个单元。例如,如果 公开了10和15,则还公开了11、12、13和14。

[0202] 尽管以上描述了各种说明性实施例,但是在不脱离如权利要求所描述 的本发明的范围的情况下可以对各种实施例进行多种改变中的任何一种。例如,其中执行各种所描述的方法步骤的顺序通常可以在替代实施例中改 变,并且在其他替代实施例中,可以完全跳过一个或多个方法步骤。各种 设备和系统实施例的可选特征可以包括在一些实施例中而不包括在其他 实施例中。因此,前面的描述主要是为了示例性的目的而提供的,并且不应该被解释为限制如在权利要求中所阐述的本发明的范围。

[0203] 本文包括的示例和说明通过说明而非限制的方式示出了其中可以实 践主题的特定实施例。如上所述,其他实施例可以被利用并从中导出,使 得可以在不脱离本公开的范围的情况下进行结构和逻辑替换和改变。本发 明主题的此类实施例在本文中可以单独地或共同地由术语“发明”引用, 仅仅是为了方便,并且无意将本申请的范围自愿地限制到任何单个发明或 发明构思,如果事实上公开了不止一个的话。因此,尽管本文已经说明和 描述了具体实施例,但是为了实现相同目的而计算出的任何布置都可以替 代所示的具体实施例。本公开旨在覆盖各种实施例的任何和所有修改或变 型。上述实施例的组合以及本文中未具体描述的其它实施例对于本领域技 术人员在查看以上描述时将是显而易见的。

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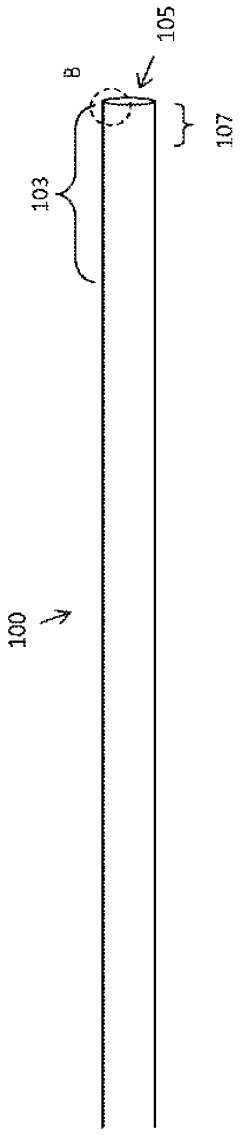


图1A

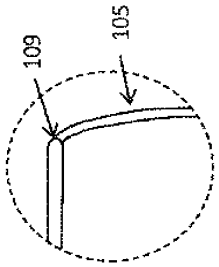


图1B

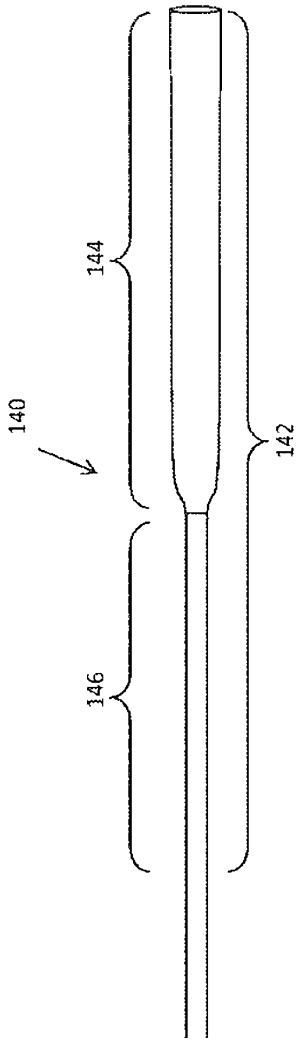


图1C

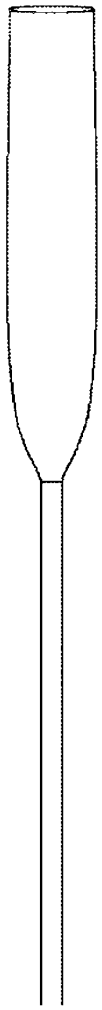


图1D

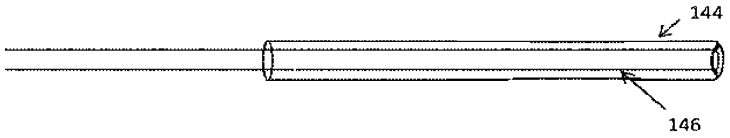


图1E

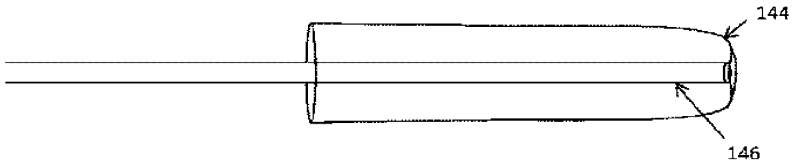


图1F

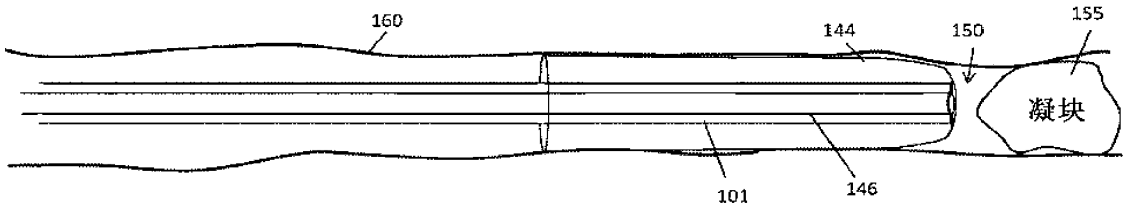
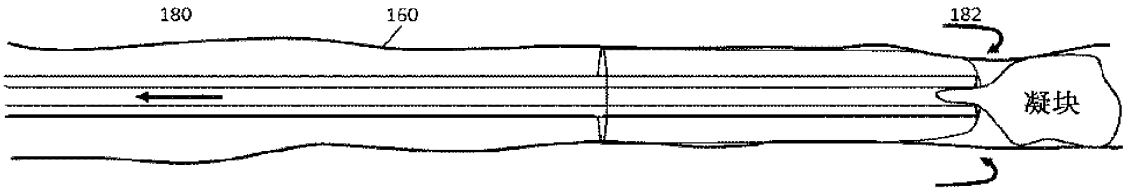


图1G



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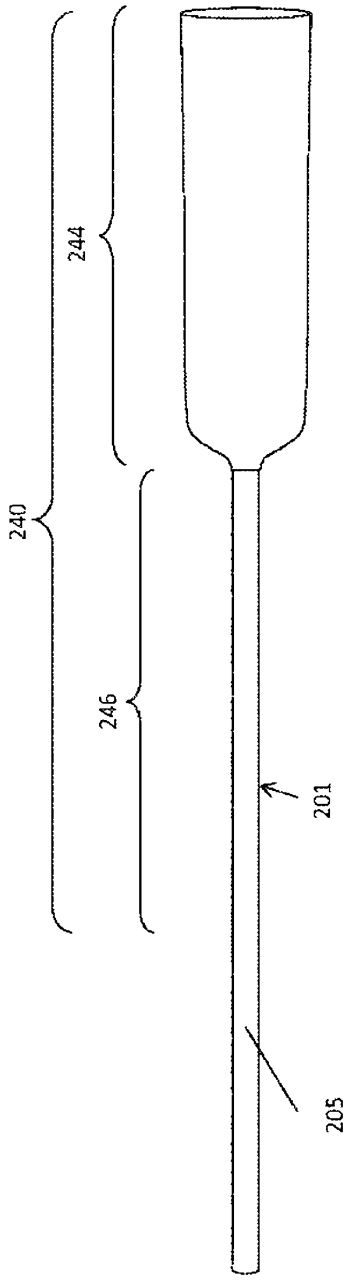

图2A

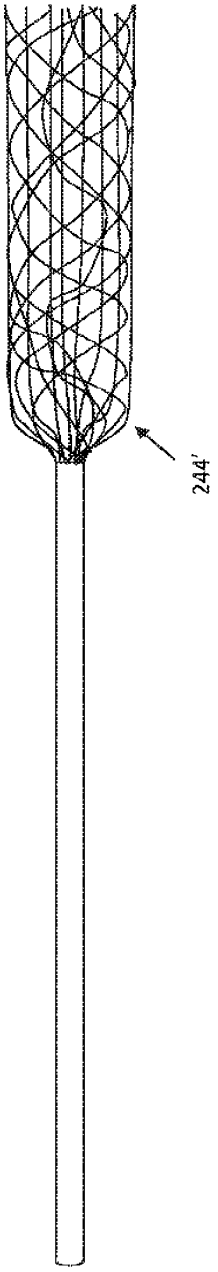

图2B

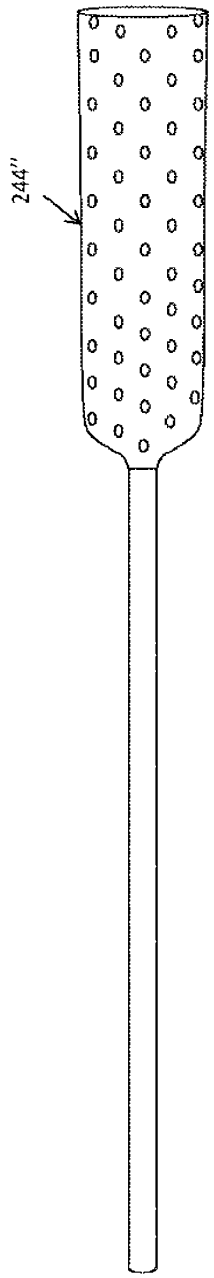

图2C

INARI_019448

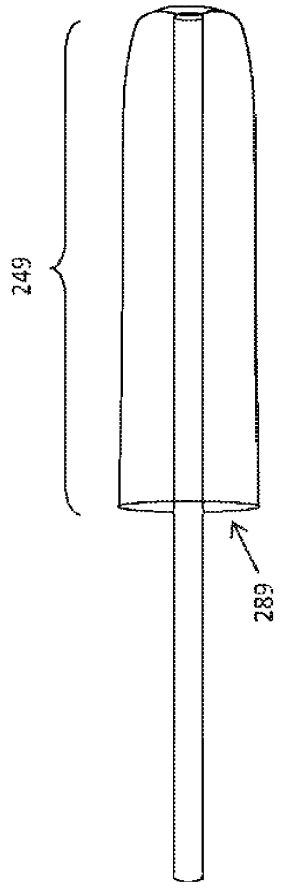

图2D

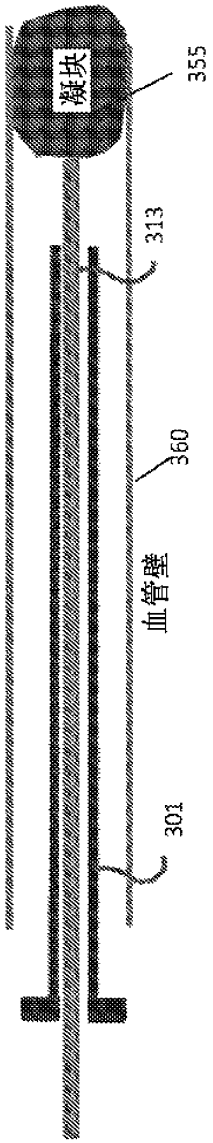

图3A

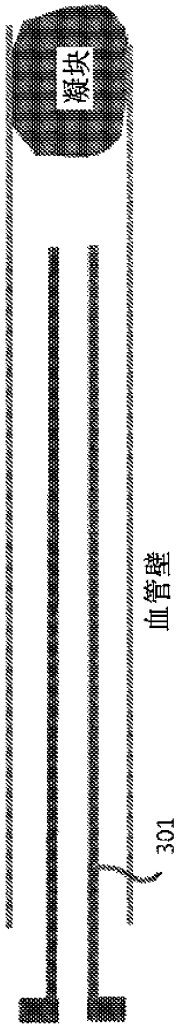

图3B

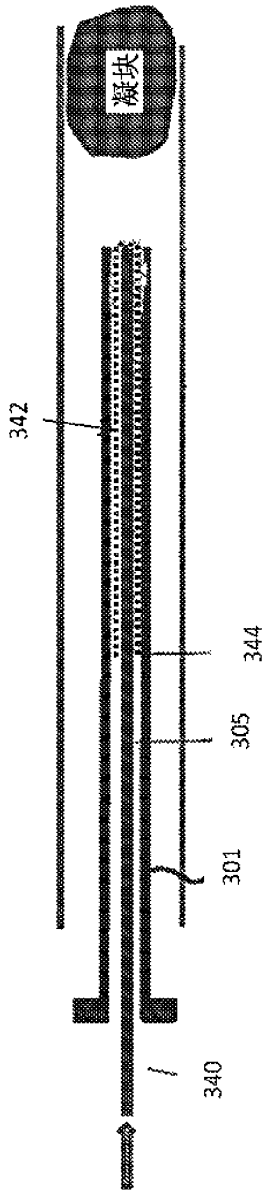

图3C

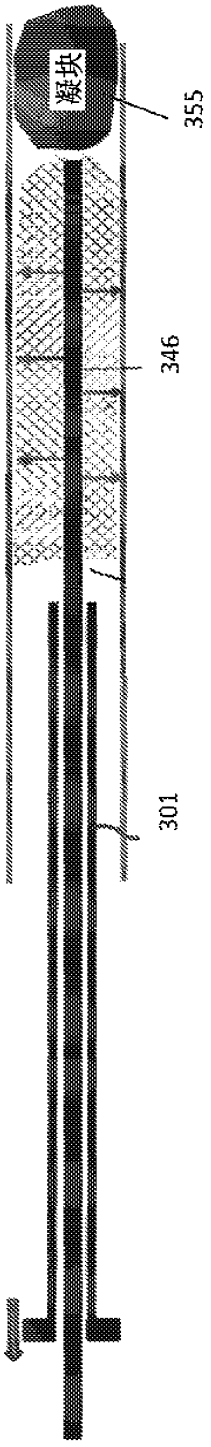

图3D

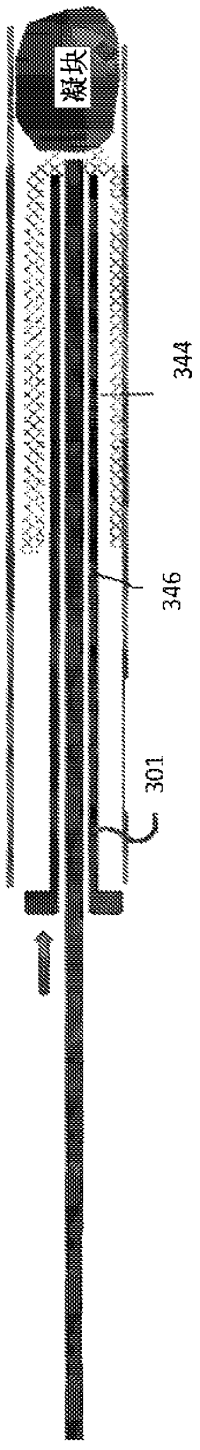

图3E

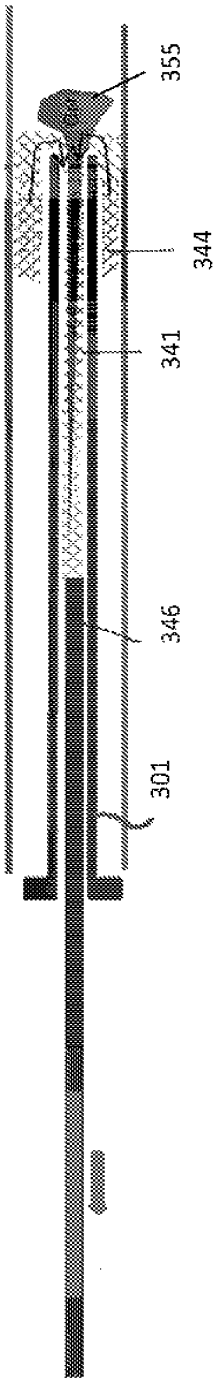

图3F

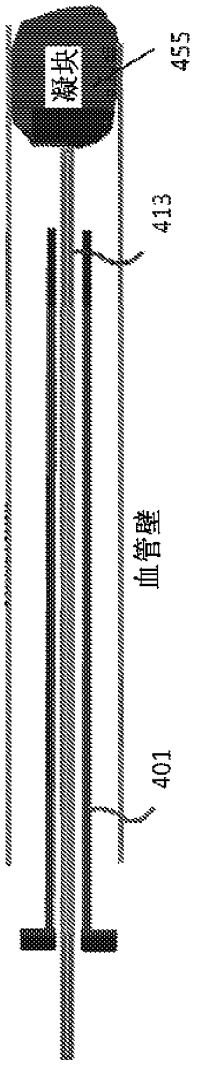

图4A

INARI_019456

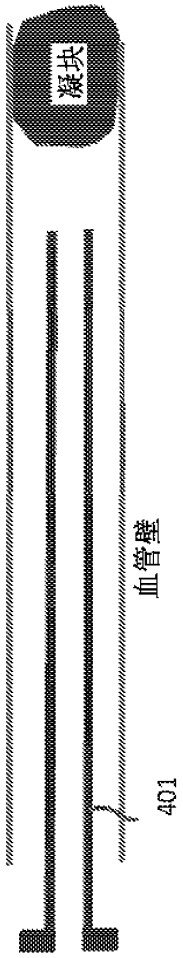

图4B

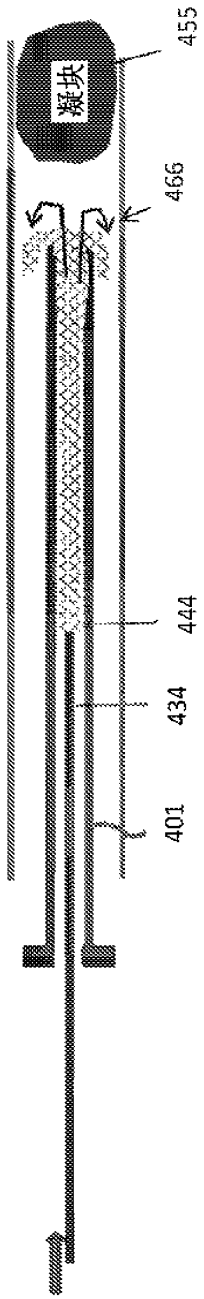

图4C

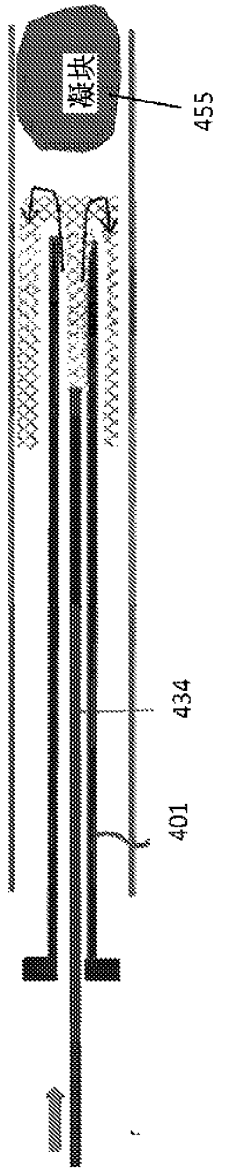

图4D

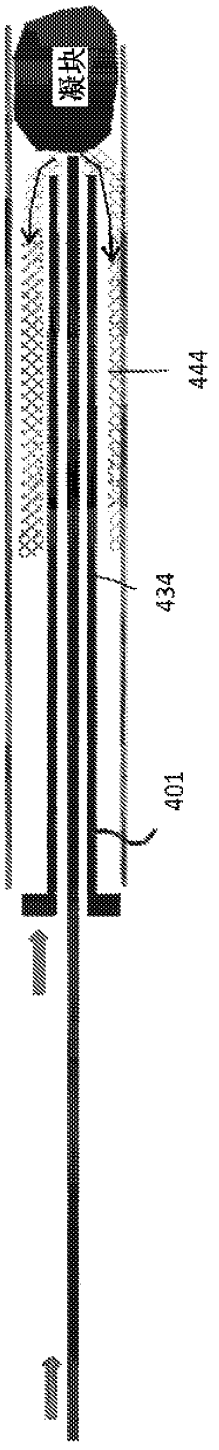

图4E

53

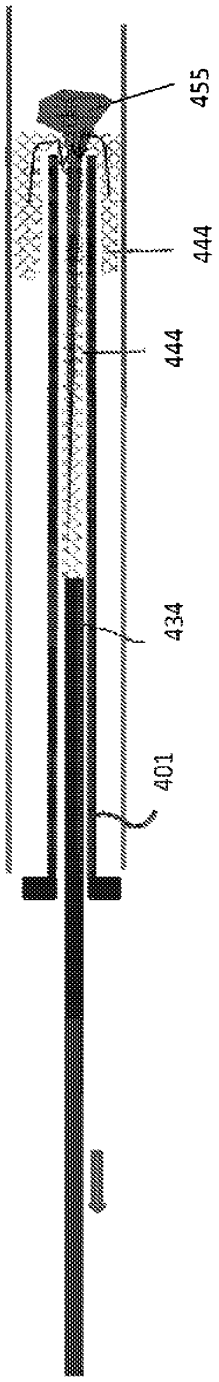

图4F

INARI_019461

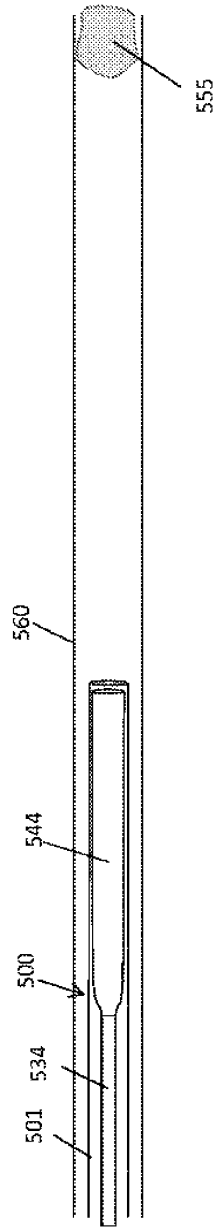

图5A

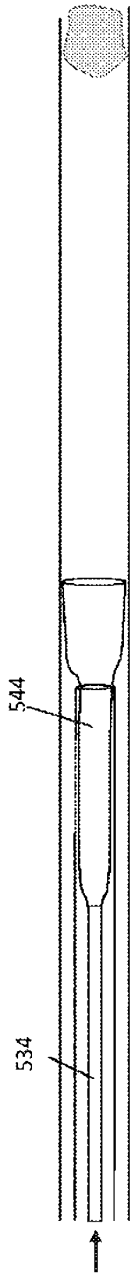

图5B

INARI_019463

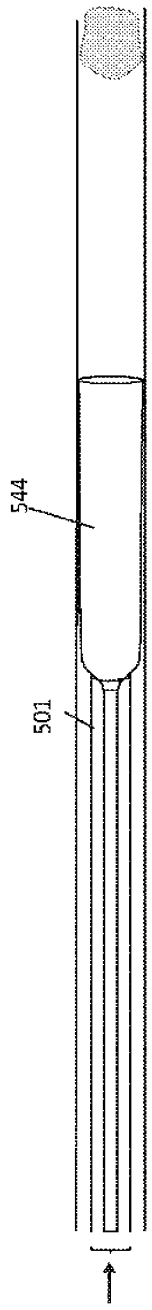

图5C

INARI_019464

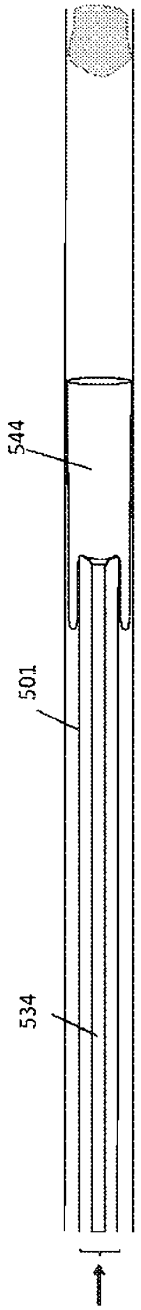

图5D

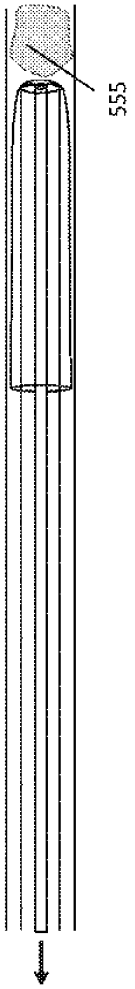

图5E

INARI_019466

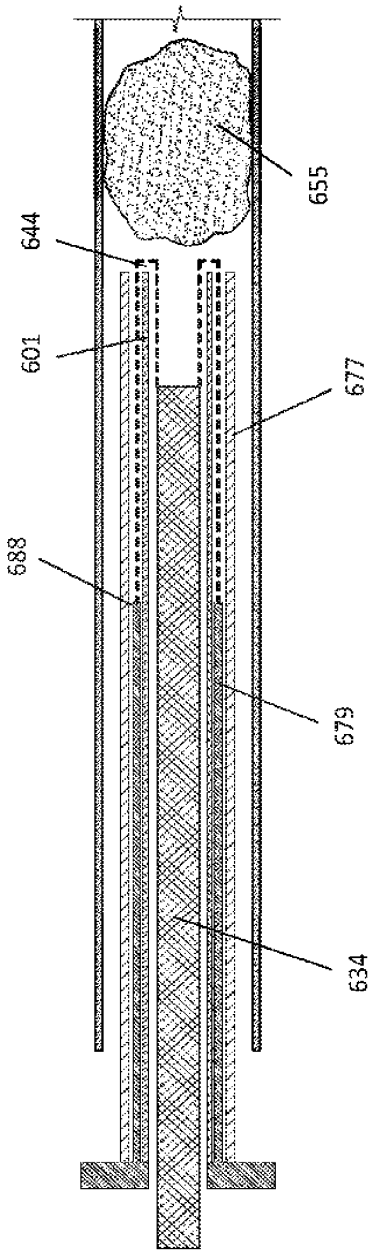

图6A

60

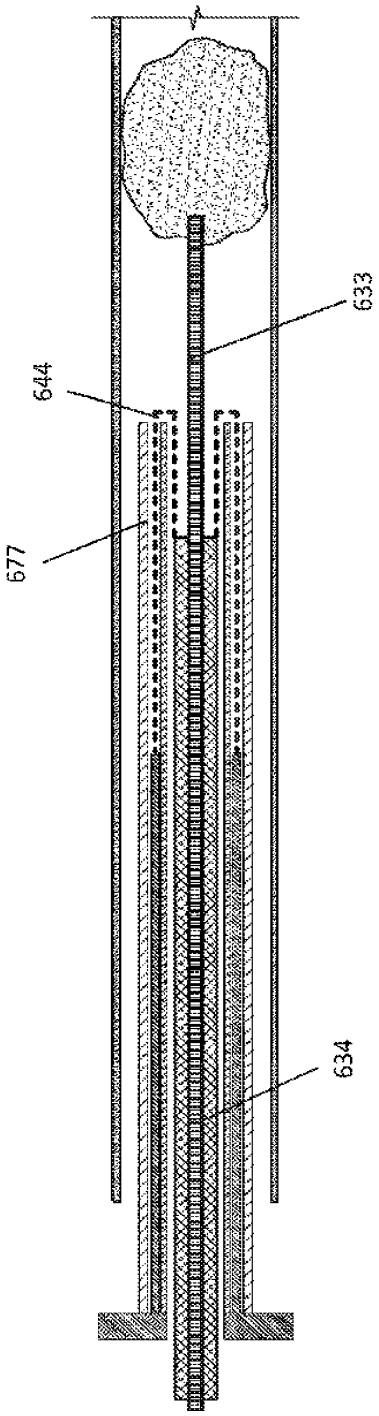

图6B

61

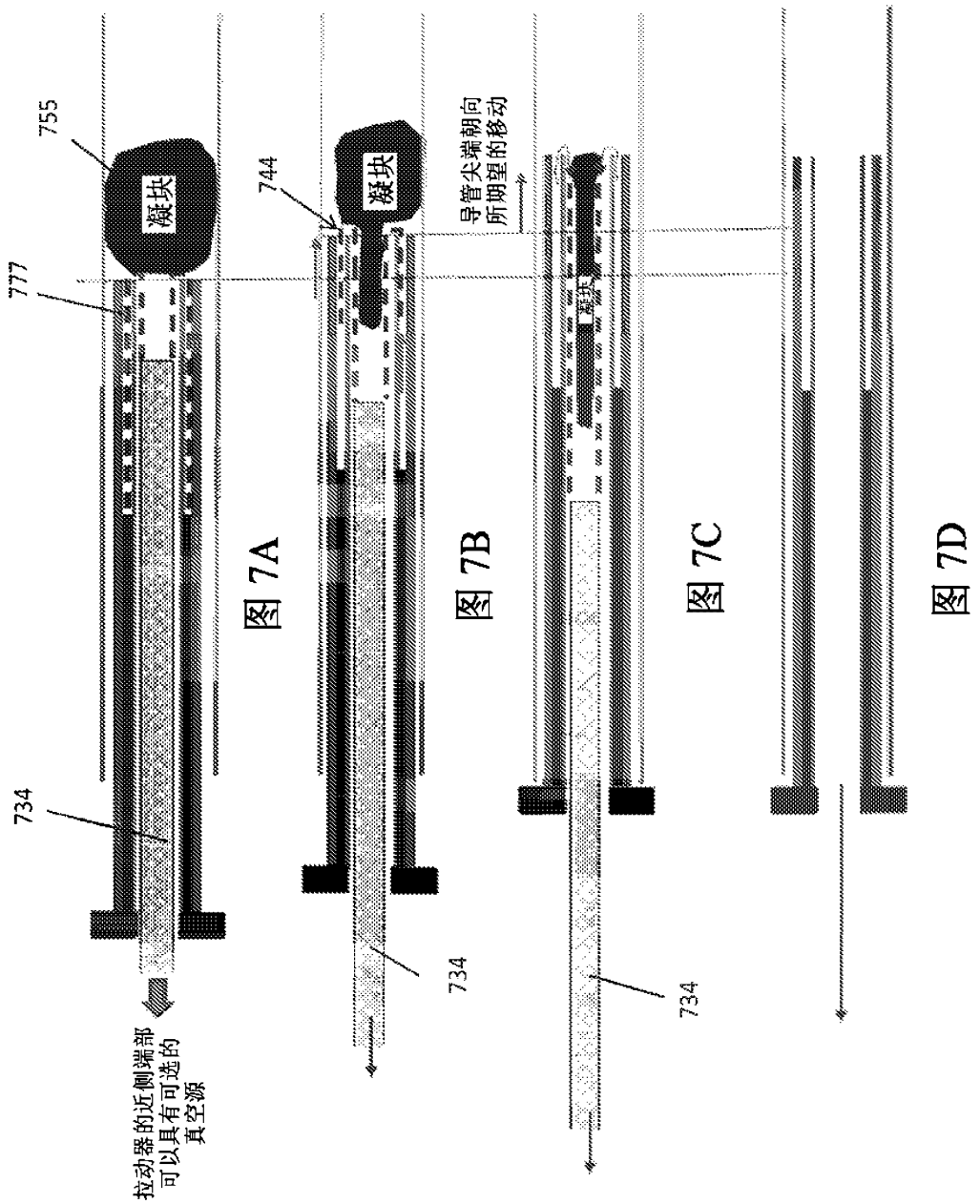

图 7A 图 7B 图 7C 图 7D

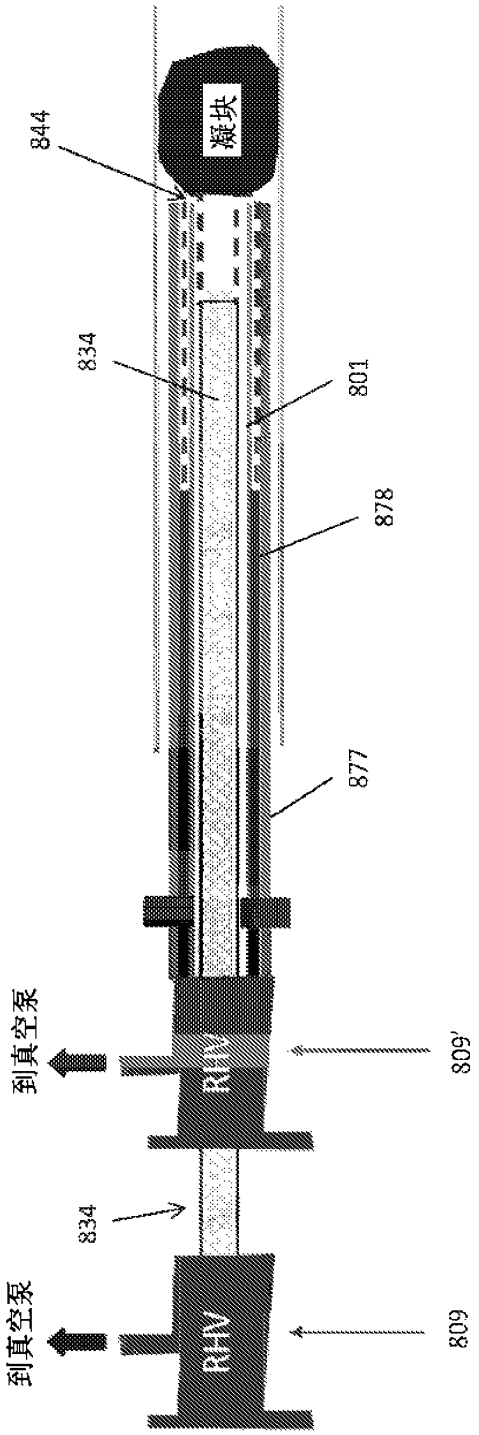

图8

63

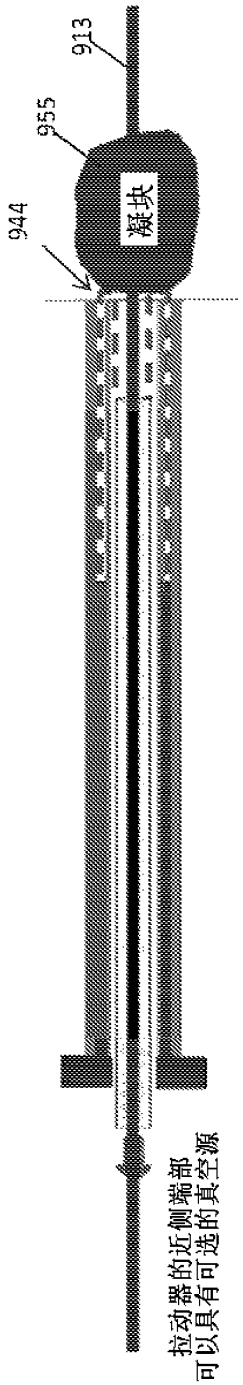

图9A

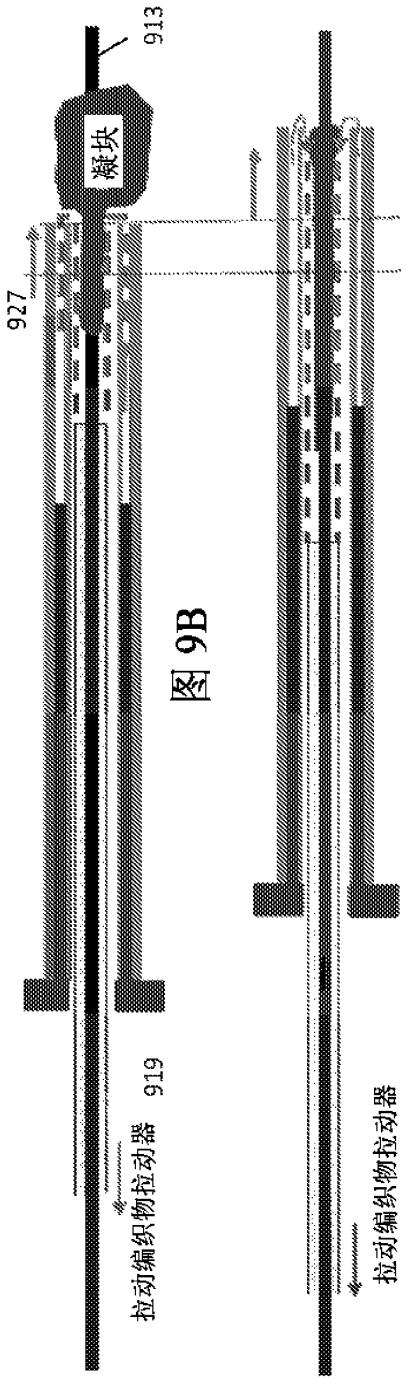

图 9B

图 9C

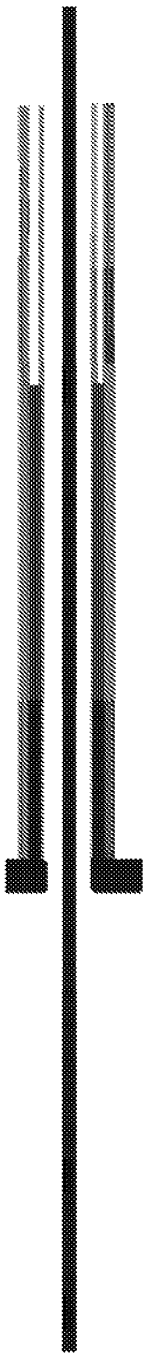

图9D

INARI_019473

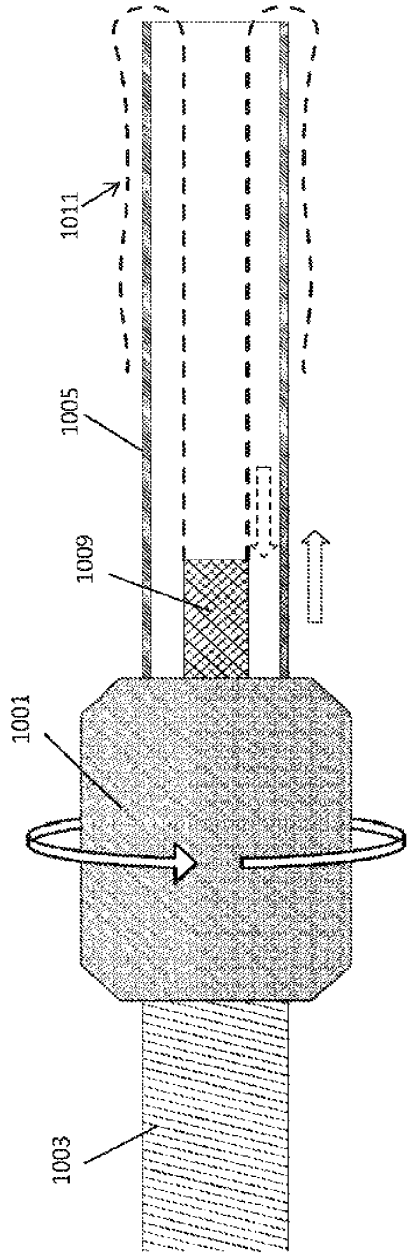

图10A

INARI_019474

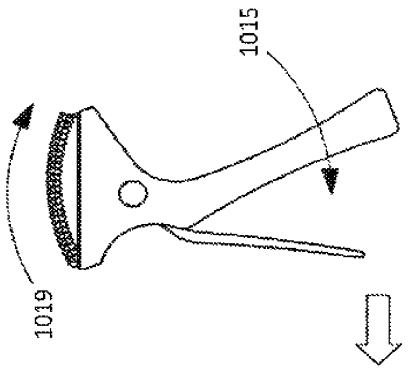

图10B

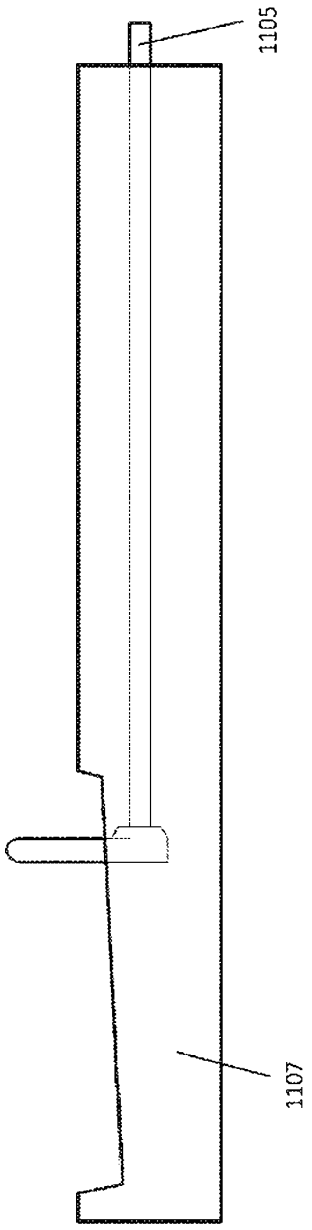

图11A

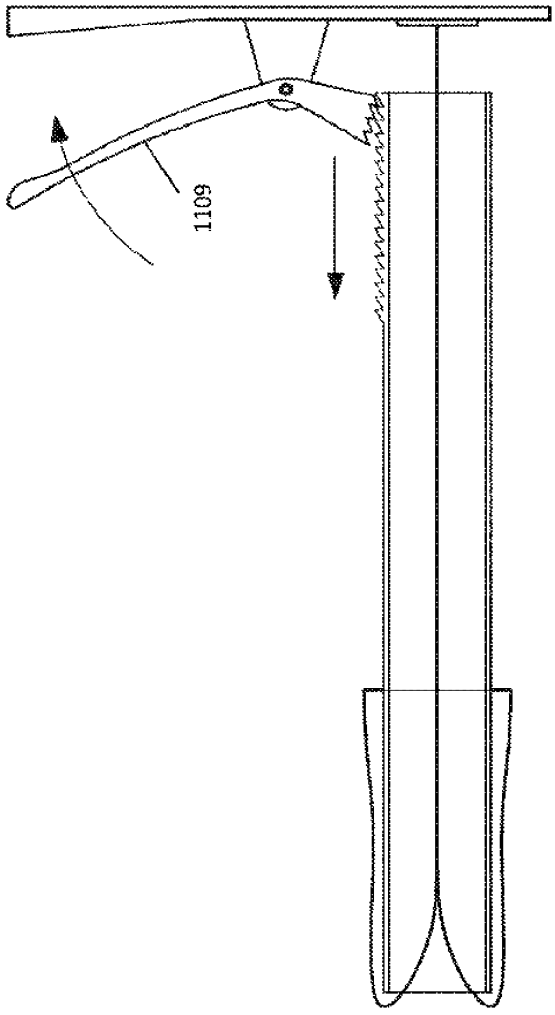

图11B

INARI_019477

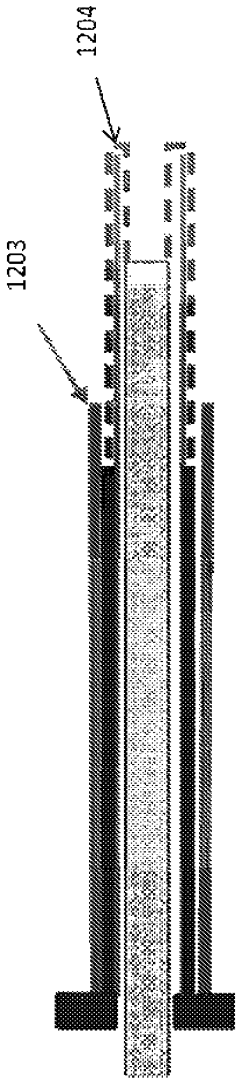

图12A

INARI_019478

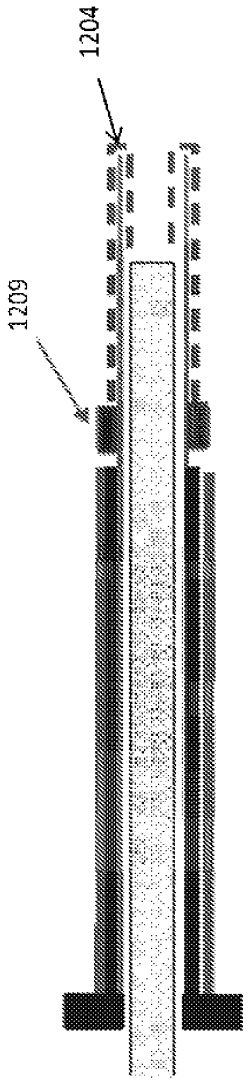

图12B

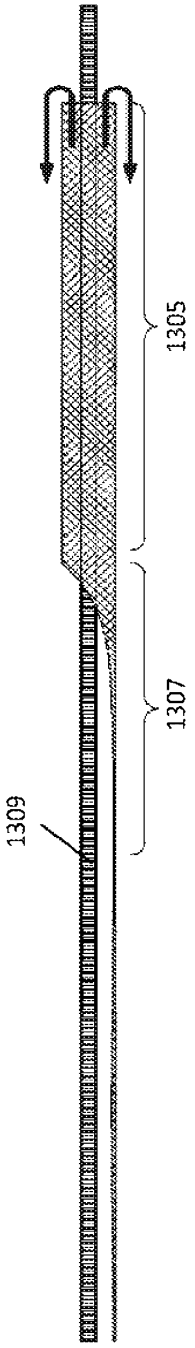

图13A

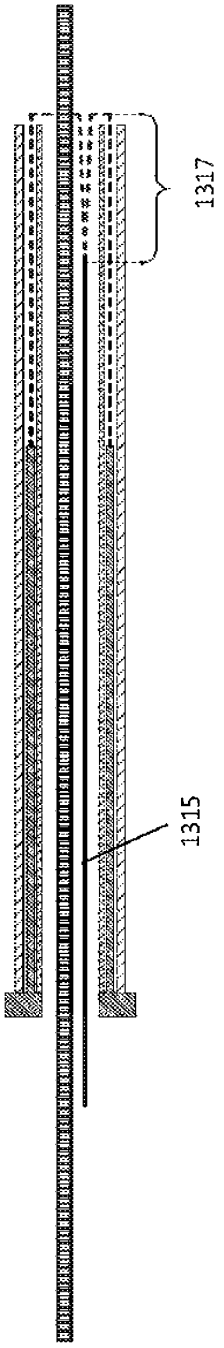

图13B

INARI_019481

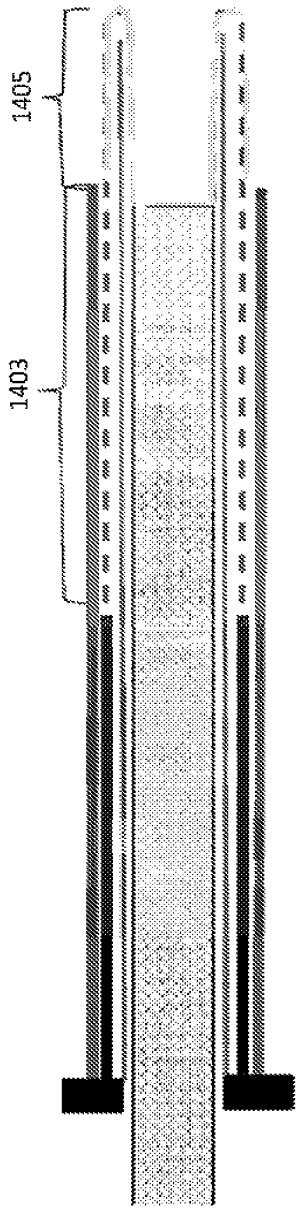

图14

INARI_019482

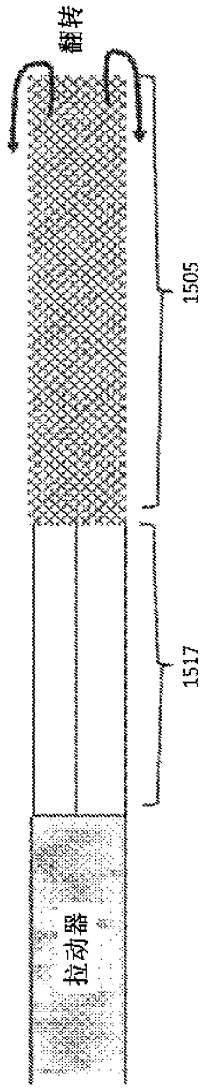

图15A

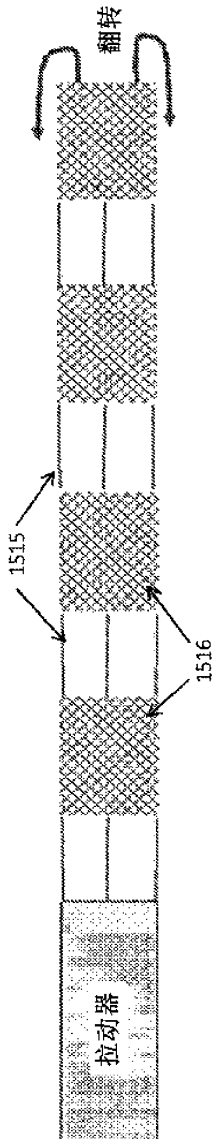

图15B

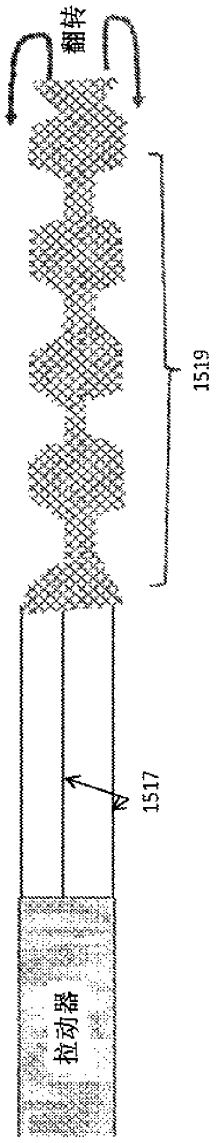

图15C

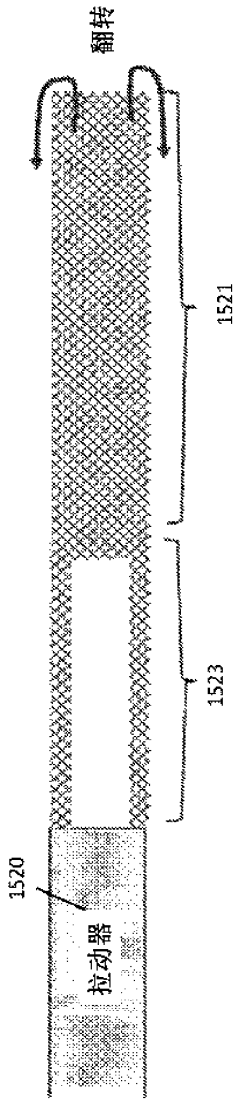

图15D

INARI_019486

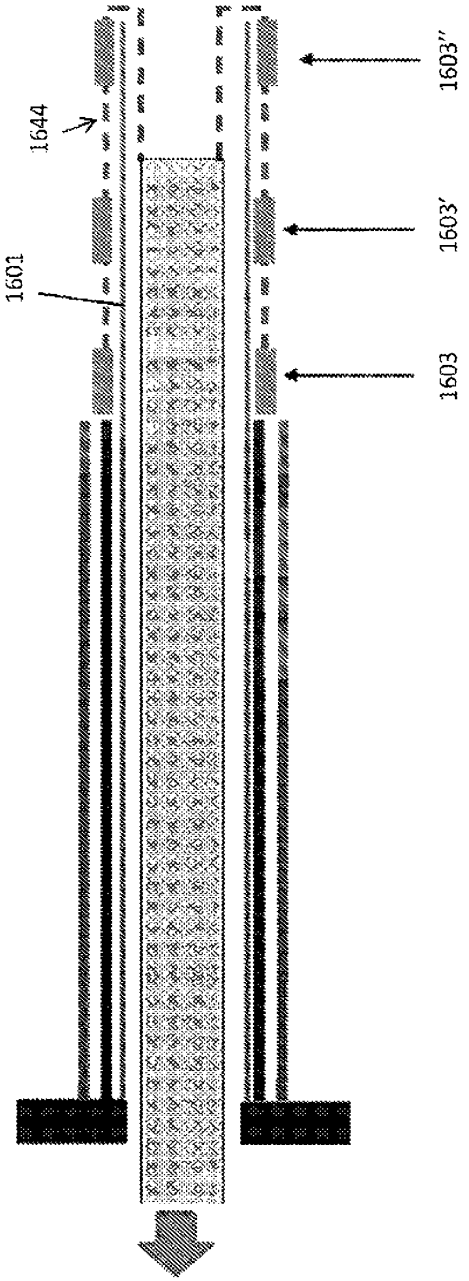

图16

INARI_019487

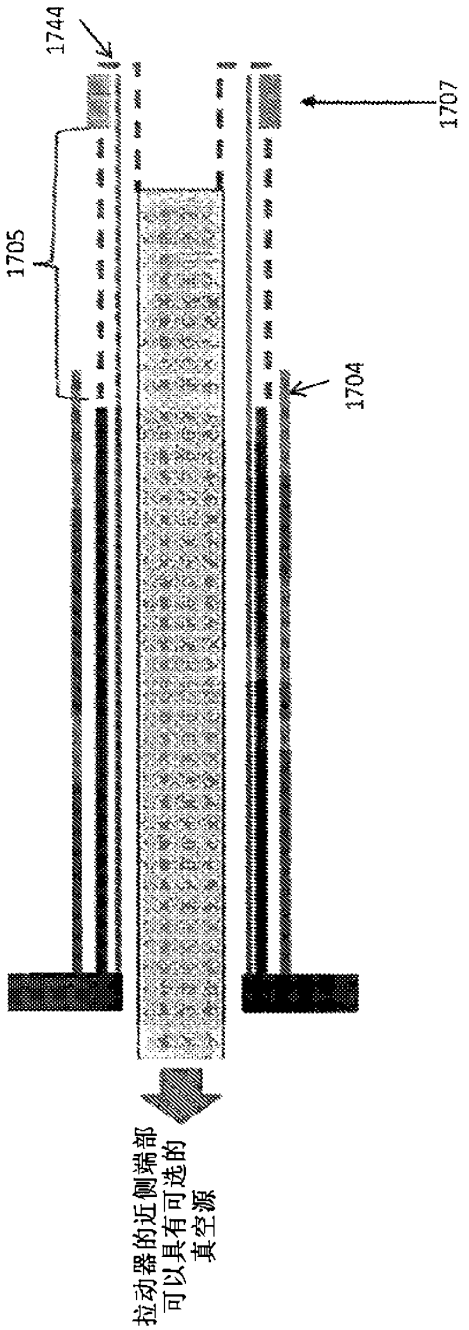

图17

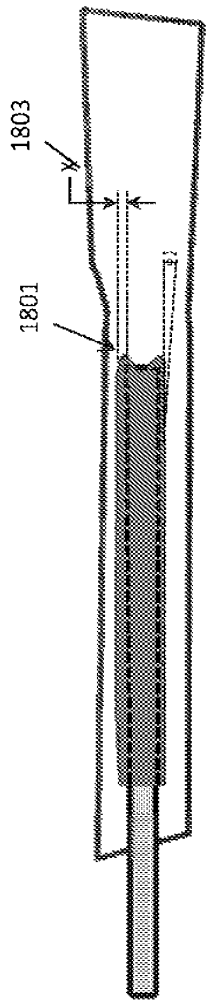

图18A

INARI_019489

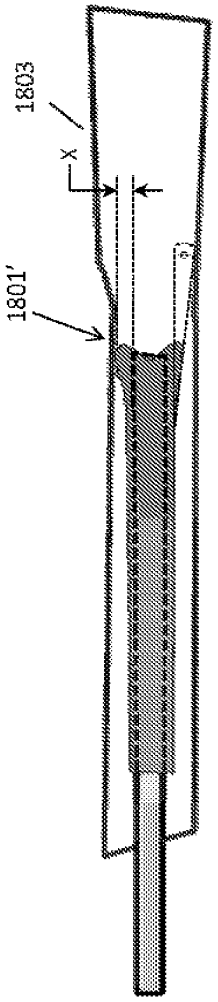

图18B

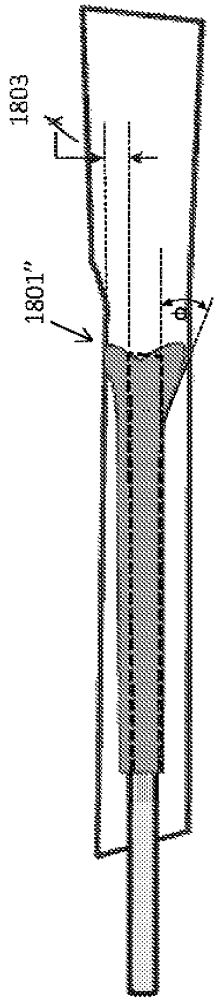

图18C

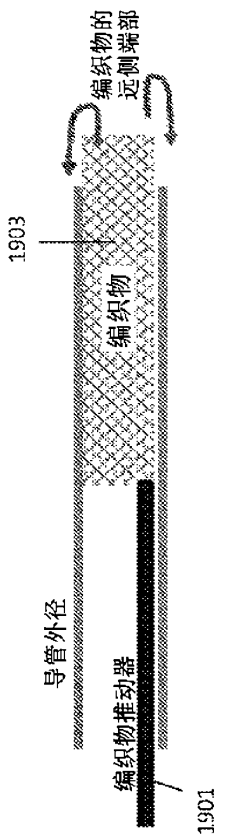

图19A

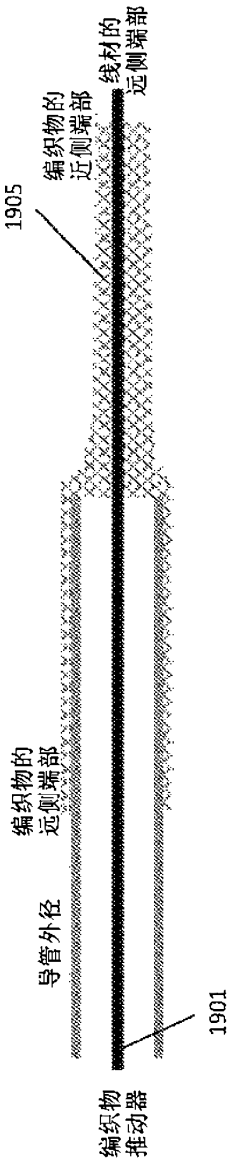

图19B

图20A

图20B

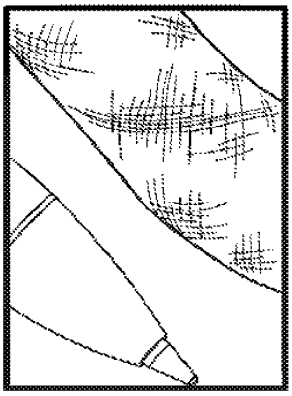

图21A

INARI_019495

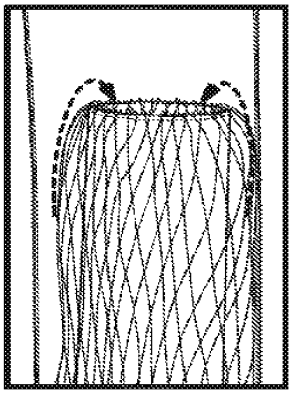

图21B

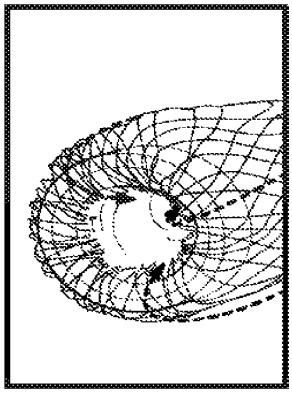

图21C

INARI_019496

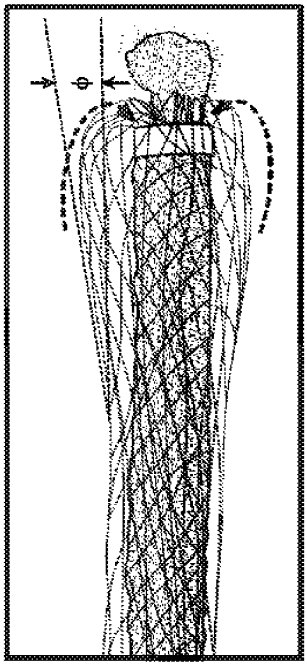

图21D

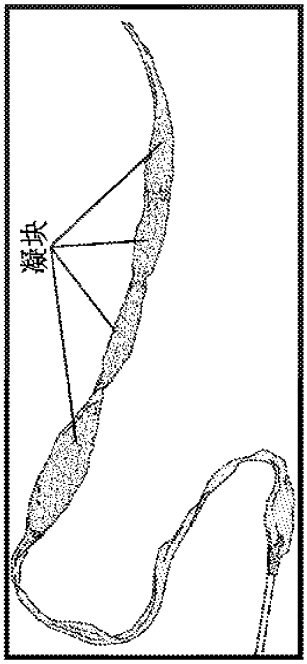

图22

90

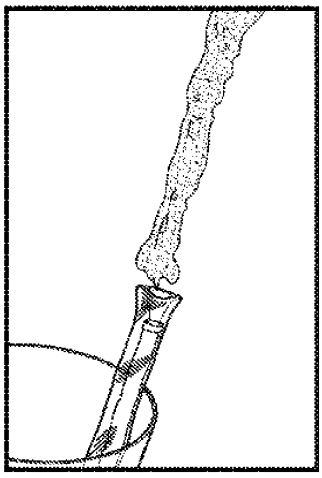

图23A

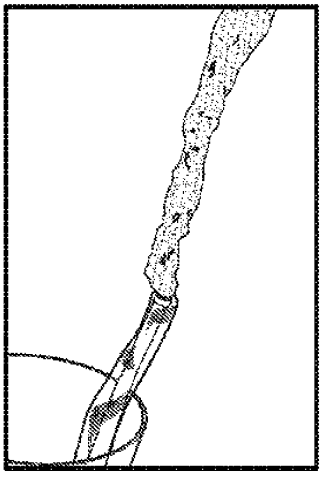

图23B

INARI_019498

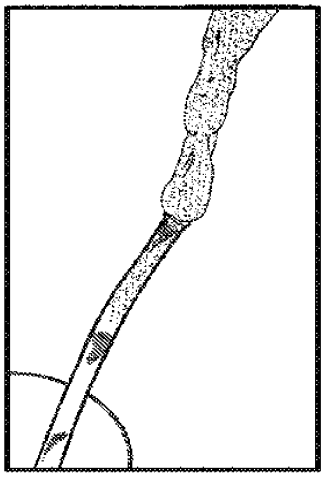

图23C

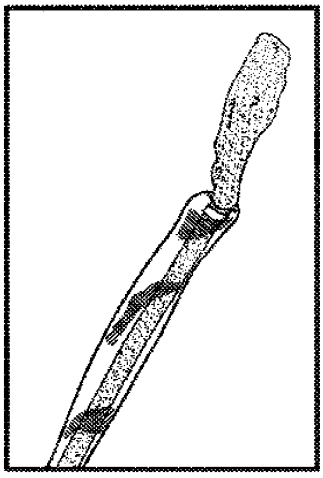

图23D

INARI_019499

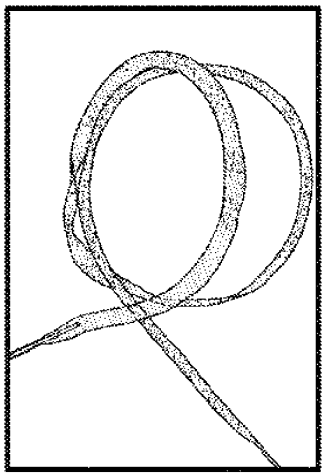

图23E

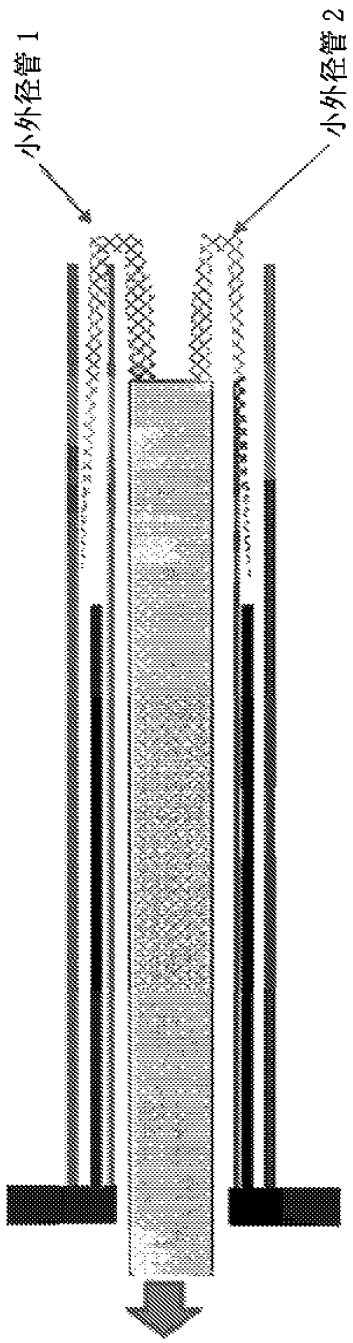

图24

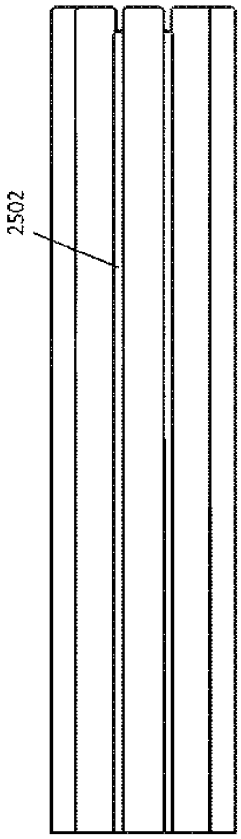

图25A

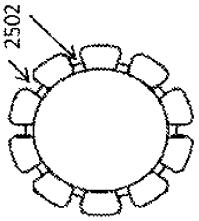

图25B

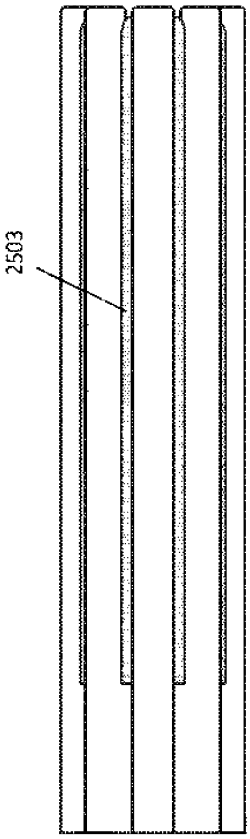

图25C

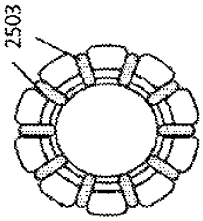

图25D

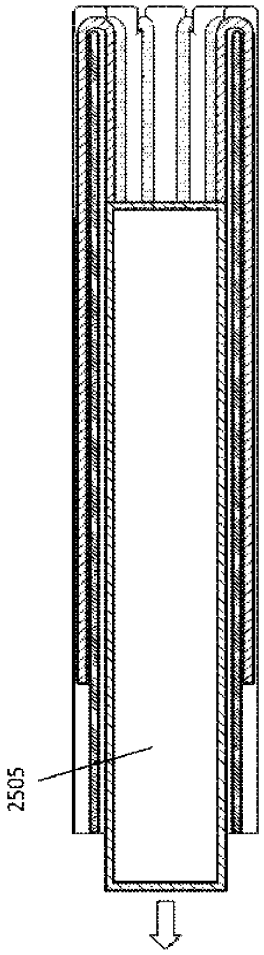

图25E

图25F

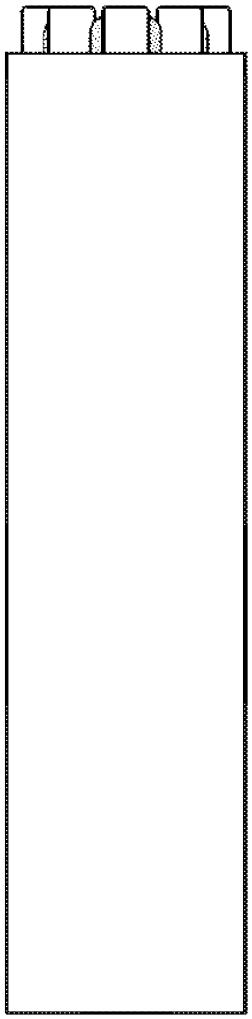

图26A

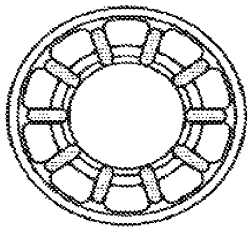

图26B

98

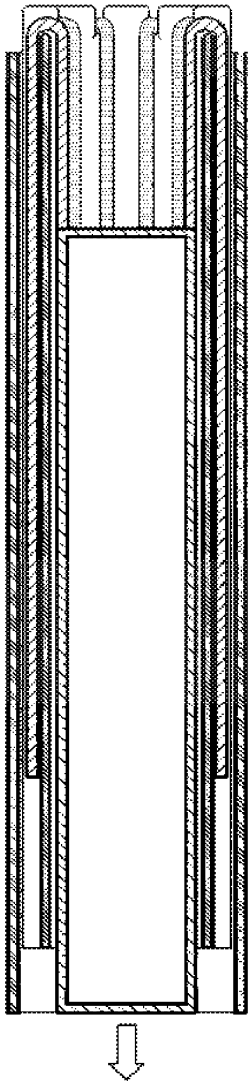

图27A

图27B

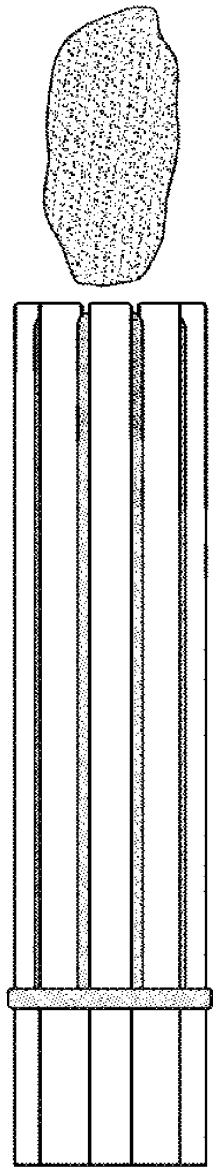

图28

100

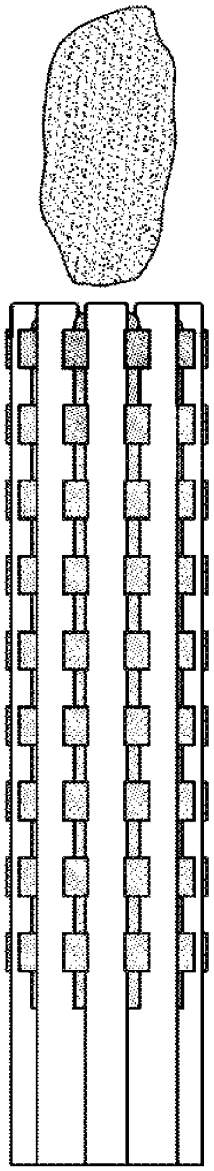

图29

101

图30A

102

图30B

103

图30C

104

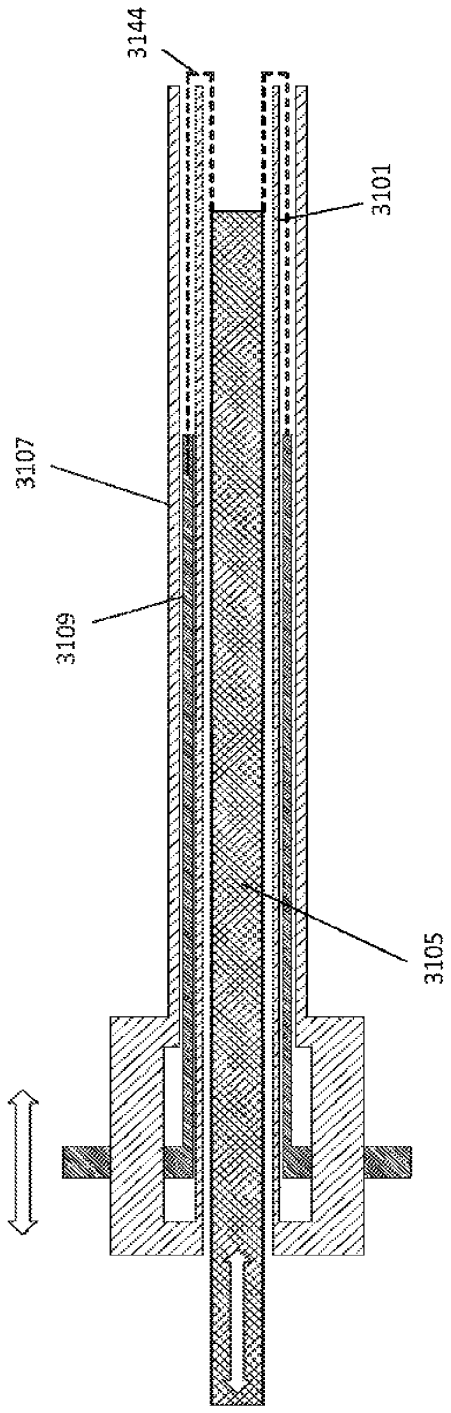

图31

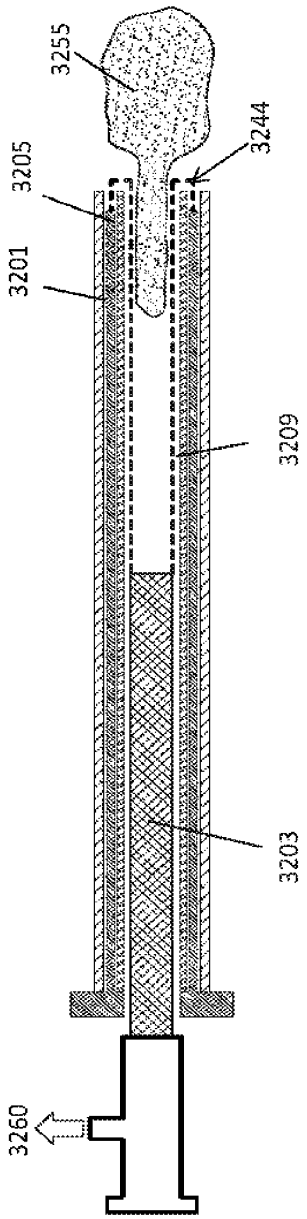

图32

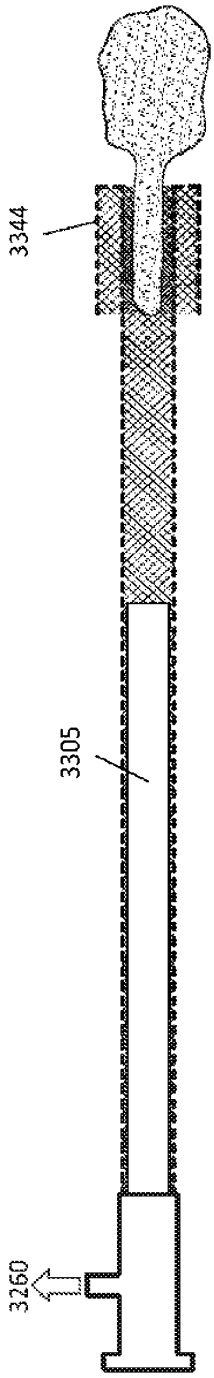

图33

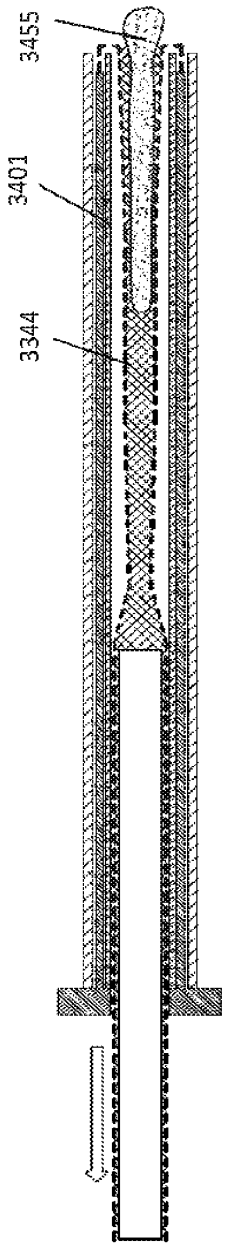

图34

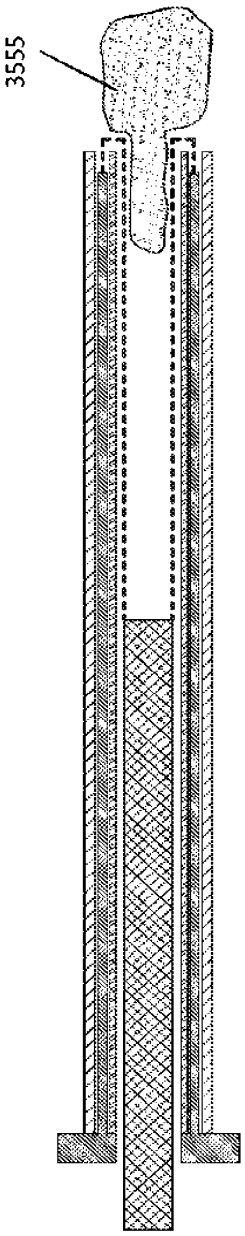

图35A

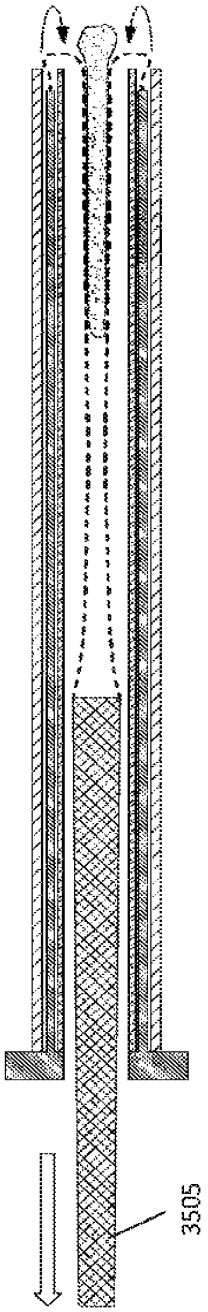

图35B

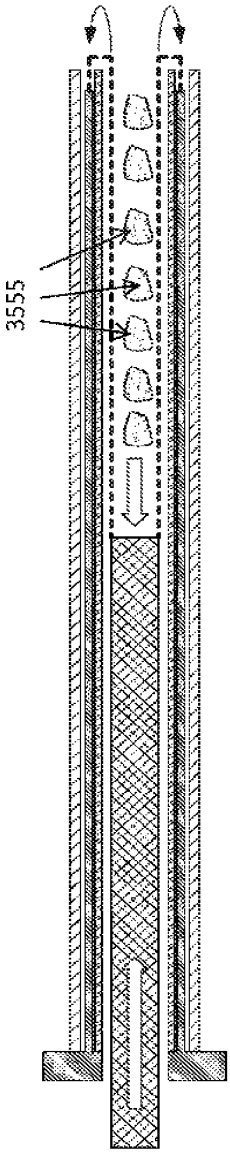

图35C

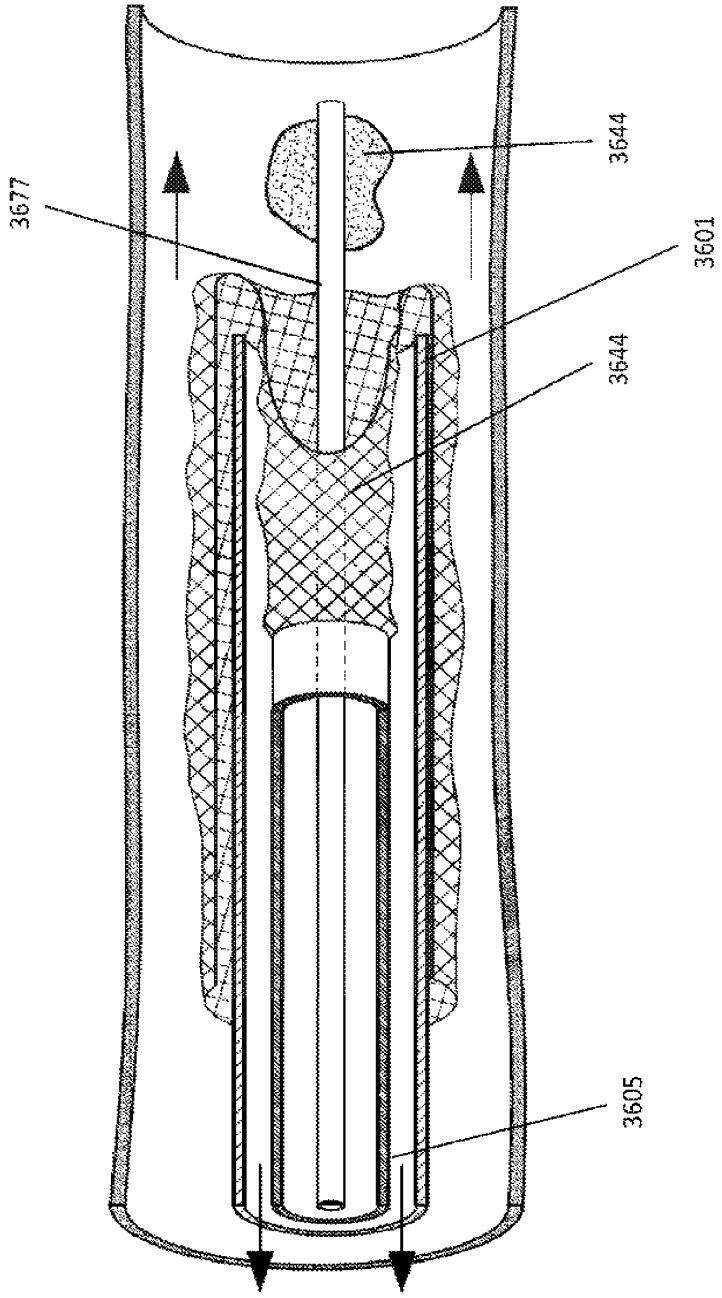

图36

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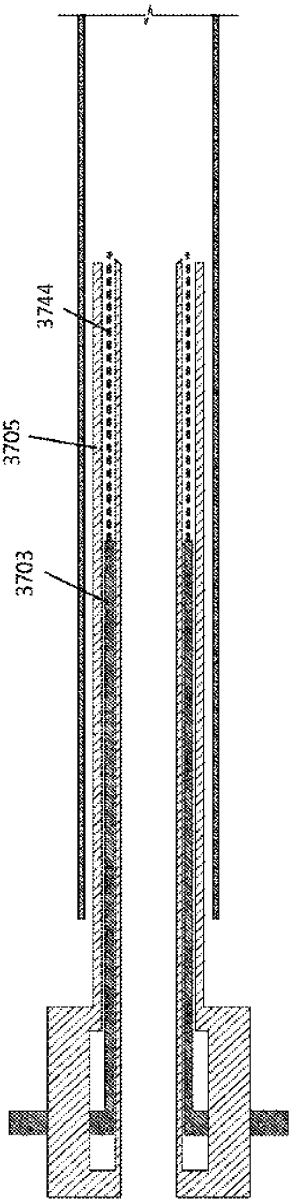

图37A

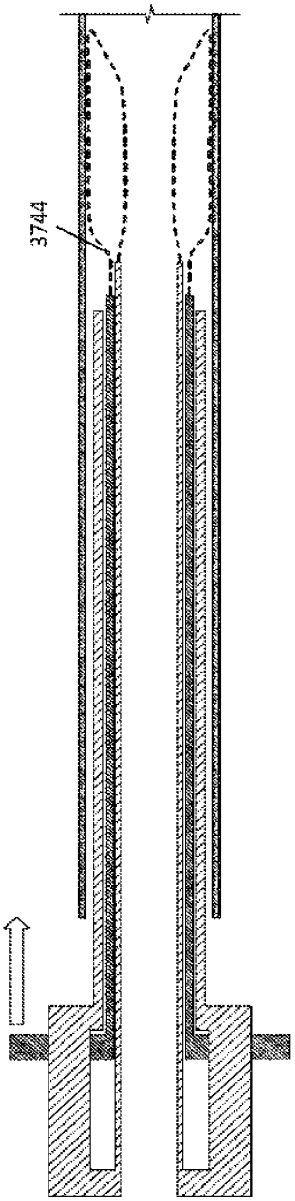

图37B

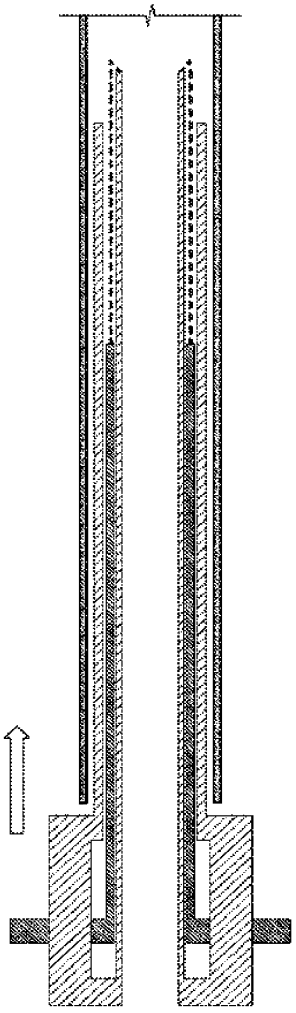

图37C

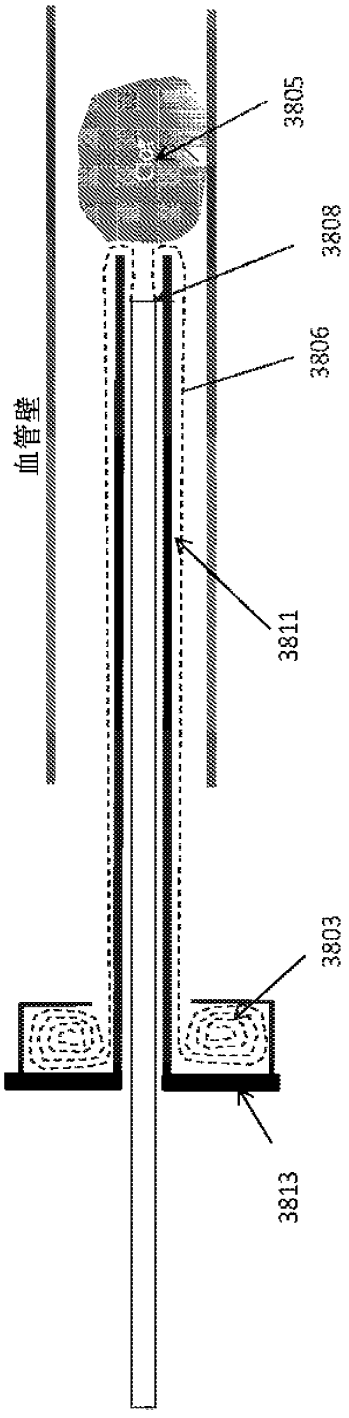

图38A

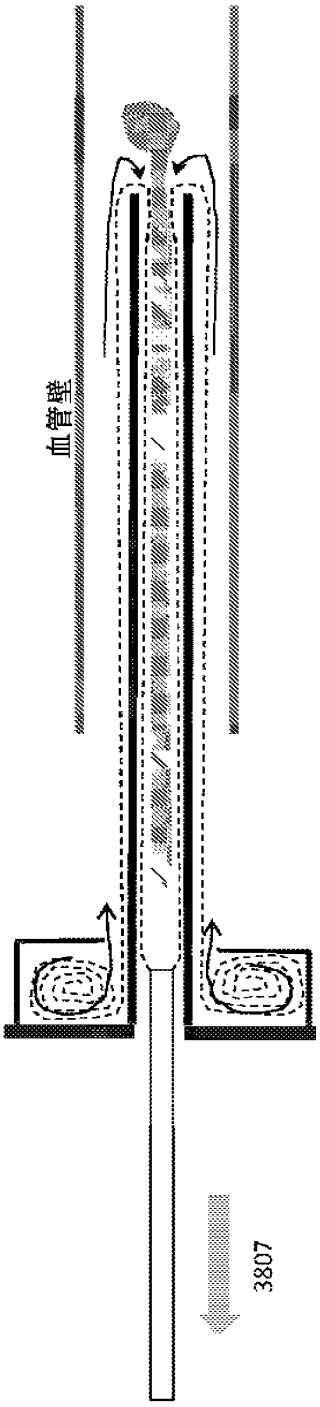

图38B

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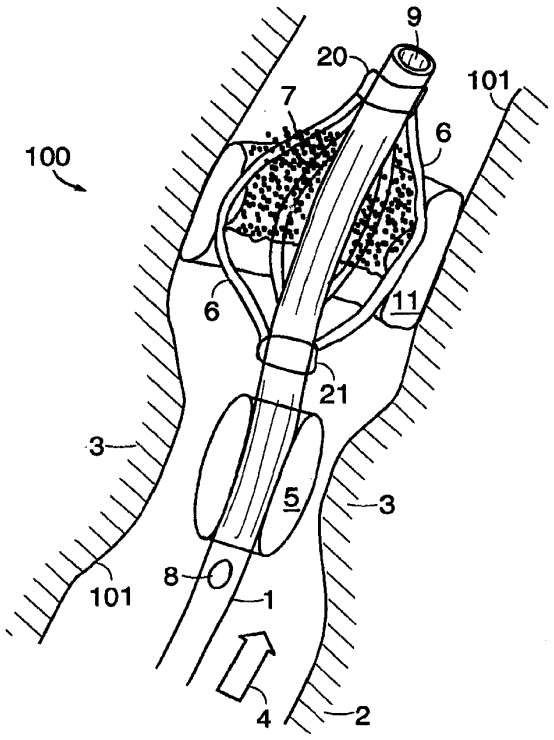
(54) **Title:** CATHETER-FILTER SET HAVING A COMPLIANT SEAL

(57) **Abstract**

A catheter-filter set in an embodiment may be used in a vas through which a biological fluid may flow. This embodiment includes a tubular member, having a lumen disposed along its length and an insertion end for insertion into the vas. The lumen defines a longitudinal axis and a radial direction perpendicular thereto. The embodiment also has a filter, coupled to the tubular member and having a circumference, for trapping undesired particles. Finally, the embodiment includes a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forms a seal against the interior wall of the vas. Other embodiments are also provided.



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CATHETER-FILTER SET HAVING A COMPLIANT SEAL

Technical Field

The present invention relates to catheter-filter sets, including those for use in angioplasty and other procedures.

Background Art

A large number of medical procedures utilize catheters. A catheter is defined herein and within the appended claims as a tubular, flexible instrument for insertion into a body cavity. Catheters may facilitate the withdrawal or introduction of fluids or other substances and may, in combination with other coupled components, perform a variety of other useful functions.

Catheters coupled with inflatable balloons provide the means to facilitate the unblocking of and the relief of constriction within various body passageways and vessels. Such angioplasty procedures can replace other more invasive surgical procedures and provide acceptable solutions to correct life threatening conditions. However, these procedures carry a risk of serious secondary problems associated with the transmission of unwanted material downstream of the operative site. Any material, such as plaque built up in arterial vessels, which does not adhere to the interior vas wall or is in another way removed from the vessel following treatment becomes a likely source of downstream blockage. In arterial angioplasty, embolic ischemic damage distal to the angioplasty site is a major complication of the procedure. Mobile arterial plaque is a major factor linked with ischemic stroke or end organ/limb infarction. In particular, carotid

artery angioplasty is not a favored practice at present due to the risk of emboli and resulting stroke.

Some catheters coupled with downstream filtering capability have been previously disclosed. Several utilize wire mesh filters which are generally not compliant and do not accommodate localized changes in vessel diameter and shape which may be caused by on-going fluid flow restoration and pulsatility. Other designs contain deployment structures which may make insertion prior to and retraction after completion of a procedure problematic or unduly risky.

Typical prior art catheter arrangements are disclosed in United States patents 4,723,549; 4,794,928; 5,662,671; and 5,695,519. These documents are hereby incorporated herein by reference.

Summary of the Invention

Various embodiments of the present invention solve problems of the prior art by providing radial compliance to accommodate localized changes in vessel diameter and shape which may be caused by on-going fluid flow restoration and pulsatility. Furthermore, some embodiments of the invention provide a device that is biased to return to its lowest profile condition in the absence of active operator input to facilitate making arterial angioplasty, particularly in the cerebral and coronary beds, more fail-safe. Various embodiments of the invention avoid asperities or protrusions which can traumatize or otherwise damage or irritate interior vas walls. Similarly various embodiments provide for cushioning of the filter element against the vas wall when it is deployed. This cushioning effect is balanced with the requirement of effective sealing of the vas to prevent any unwanted downstream flow of matter.

Accordingly, in a first embodiment of the invention there is provided a catheter-filter set for use in a vas through which a biological fluid may flow. This embodiment includes a tubular member, having a lumen disposed along its length and an insertion end for insertion into the vas. The lumen defines a longitudinal axis and a radial direction perpendicular thereto. The embodiment also has a filter, coupled to the tubular member and having a circumference, for trapping undesired particles. (Unless the context otherwise requires, the term

"particles" as used in this description and the accompanying claims refers to substances to be removed from a vas, and may include thrombotic material.) Finally, the embodiment includes a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forming a seal against the interior wall of the vas. In further embodiments, the resilient member may be inflatable, such as a balloon, or alternatively may be an O-ring or sleeve. The outer surface of the resilient member may form the seal with the interior wall or may otherwise effectuate the seal. In a related embodiment the resilient member is a balloon having an anterior for receiving an inflation fluid and a shape so that when the balloon is inflated there is provided a passageway permitting fluid flow through the filter. In accordance with another related embodiment, the balloon is toroidal in shape and may have anisotropic elasticity so that during inflation its interior cross-section expands relatively less than its radial extent. Alternatively or in addition, the catheter-filter set may include an elastic member coupled to the balloon and the tubular member for causing the balloon to be radially confined when not deployed. In yet another variation, regardless whether a balloon is utilized, the filter has a stowed position where the filter is radially confined and disposed in the lumen so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, where the filter is radially expanded.

Various embodiments of the present invention have a range of potential applications. The application of embodiments to angioplasty procedures wii be apparent to those skilled in the art. In addition, through either standard open technique or laparoscopic technique, retrieval of common duct stones in the biliary tree is facilitated by catheter passage utilizing embodiments herein. Similarly, through either standard open technique or cystographic technique, retrieval of ureteral and bladder duct stones is, also, facilitated by catheter passage via endoscopic or surgical methods. A catheter coupled with an inflatable balloon may also be utilized to effect balloon sphincteroplasty and stone retrieval. Embodiments herein provide improved devices to effectively retrieve such stones and to avoid their further passage or migration downstream.

Embodiments herein may also employable as a temporary filtering device for the vena cava. In the process of lytic treatment for deep venous thrombosis, there is a risk of clot (thrombus) breaking loose and causing pulmonary embolism, a potentially fatal event. Although filters exist for vena cava use, these are permanent structures with attendant long term morbidity. Having an effective and retractable filter which is in place only for the time of significant risk, *i.e.*, during deep venous clot lysis, would allow protection from pulmonary embolism and avoidance of the long term sequelae of a permanent filter insertion.

Discussion of medical procedures and associated devices in this description may focus, for example, upon arterial (blood circulation), biliary, and ureteral systems. This focus in no way limits the applicability of embodiments herein to any and all other uses for catheters with filtration capability known to those skilled in the art.

In another embodiment, there is provided a catheter-filter set having a tubular member, which has a first lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas. The lumen defines a longitudinal axis and a radial direction perpendicular thereto. The embodiment also has a filter, coupled to the tubular member proximal to the insertion end, wherein the filter has a stowed position and a deployed position, and a non-inflatable actuator, coupled to the filter, for causing the filter to move from the stowed position to the deployed position, wherein, absent operation of the actuator, the filter is biased to be in the stowed position. In a related embodiment, the set also includes a vas conditions-modifying element located upstream from the filter; this element may be an angioplasty balloon. In yet another related embodiment, the tubular member has a second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter, permitting unimpeded, downstream fluid flow to bypass the filter. In further embodiment, the set has a plurality of resilient ribs, each rib having a first end coupled to the tubular member, each rib also coupled to the filter, the ribs having a stowed condition in which they are parallel to the

longitudinal axis and a deployed condition in which at least a portion of each rib is disposed radially outward from the tubular member. Each rib may have a second end slidably mounted on the tubular member and coupled to the actuator. The catheter-filter set may further include a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forming a seal against the interior wall of the vas.

In another embodiment in accordance with the present invention, there is provided a catheter-filter set having:

a. a tubular member, having a lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto; and

b. a filter, coupled to the tubular member proximal to the insertion end, wherein the filter has a stowed position wherein the filter is radially confined and disposed in the lumen so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, wherein the filter is radially expanded.

Brief Description of the Drawings

Figs. 1A and 1B are longitudinal views of a catheter-filter set, in the deployed and the stowed conditions, respectively, used in a vas as part of an angioplasty device and using a toroidal balloon according to an embodiment of the invention.

Figs. 2A and 2B are longitudinal views of a portion of a catheter-filter set, in the stowed and the deployed conditions, respectively, illustrating generally filter deployment according to an embodiment of the invention utilizing ribs for structuring the filter.

Figs. 3A and 3B are longitudinal views of a catheter-filter set, in accordance with a tether deployment embodiment of the invention, showing stowed and deployed conditions, respectively.

Figs. 4A and 4B are longitudinal views of a catheter-filter set, in accordance with a balloon deployment embodiment of the invention, showing stowed and deployed conditions, respectively.

Fig. 5 is a longitudinal view of a catheter-filter set in accordance with an embodiment using balloon deployment wherein elastic bands bias the set in a stowed condition.

Figs. 6A and 6B are stowed and deployed conditions respectively of an embodiment similar to that of Figs. 4A and 4B, but wherein the ribs are normally twisted in a stowed condition, in which the embodiment is biased.

Fig. 7A is a cross-sectional view of a catheter-filter set in the deployed condition illustrating a balloon deployment design according to an embodiment of the invention in which the balloon has a passageway to permit fluid flow therethrough. Figs. 7B and 7C are longitudinal views of the same embodiment in the stowed and the deployed conditions, respectively.

Fig. 8A is a cross-sectional view of a catheter-filter set according to an embodiment of the invention, using for deployment a balloon 11 that is asymmetrically disposed with respect to the tubular member. Fig. 8B is a longitudinal view of the same embodiment in the deployed condition. Fig. 8C shows detail of the catheter-balloon interface.

Fig. 9 is a view of a catheter-filter set according to an embodiment of the invention utilizing a retractable O-ring.

Fig. 10 is a perspective view of a catheter-filter set according to an embodiment of the invention that is similar to the embodiment of Fig. 9, but utilizing a sleeve in lieu of the O-ring.

Fig. 11A is a perspective view of a catheter-filter set according to an embodiment of the invention utilizing a tethered O-ring, shown in the deployed condition. Fig. 11B is a longitudinal view of the same embodiment in the stowed condition.

Detailed Description of Specific Embodiments

Various embodiments of the catheter-filter set described herein address a number of shortcomings inherent in previous designs. Some desirable features

for the filter portion of the set are that it be easily confined in a radial direction for ease of set insertion and removal, that it be capable of capturing and safely removing all particles flowing downstream in a vas, and additionally, it should be designed so as to minimize the risk of accidental deployment and to collapse into position for removal in the event of failure. It should be atraumatic to the native vas wall and should accommodate changes in vas diameter.

Figs. 1A and 1B are longitudinal views of a catheter-filter set, in the deployed and the stowed conditions, respectively, used in a vas as part of an angioplasty device and using a toroidal balloon according to an embodiment of the invention. Fig. 1A shows a catheter **1** inserted into a vas **2**. The vas may be constricted or otherwise blocked at a location **3**. Downstream fluid flow is indicated by arrow **4**. An angioplasty balloon **5** affixed to the catheter and inflatable (by means well known in the art) is positioned proximate to location **3**. During and after the angioplasty balloon **5** inflation process, unwanted particles may flow downstream from location 3. A plurality of resilient ribs **6** (four are shown in this view) are coupled to the catheter **1** by two collars, one collar **20** at a downstream end and the other collar **21** at an opposing, upstream end of the catheter. In this embodiment, one of collars **20** and **21** is fixed relative to the catheter **1** and the other of the collars is free to slide along the catheter **1**. The ribs **6** and both collars **20** and **21** are positioned at a location downstream from location **3** and the angioplasty balloon **5**. A filter **7** is shown attached to the ribs **6** and to the catheter **1**. A toroidal balloon **11**, which is distinct from the angioplasty balloon **5**, is attached to the ribs **6**. In this embodiment, the toroidal balloon **11** is mounted approximately midway along the length of the ribs **6** and positioned radially outward from the catheter **1**. (The filter **7** is represented in this figure and figures below by a dot or hash pattern; for clarity of representation, the dot or hash pattern is not shown to occupy the entire region occupied by the filter. It will be understood, however, that when deployed the filter, together with any accompanying structure, such as the balloon **11**, will occupy the entire cross section of the vas so as to operate in an effective manner known in the art.)

Fig. 1B shows that, in accordance with the embodiment in the stowed condition, the ribs parallel to the longitudinal axis of the catheter **1** facilitating set **100** insertion into and retraction out of the vas **2** minimizing trauma to the vas wall **101**. During insertion and retraction of set **100** and catheter **1** into and out of the vas **2**, the uninflated toroidal balloon **11** is collapsed and radially confined against the ribs **6** and the uninflated angioplasty balloon **5** is collapsed against the catheter **1**. As illustrated in Fig. 1A, when the toroidal balloon **11** is inflated (in accordance with means well known in the art), one of collars **20** and **21** slides toward the other collar causing at least a portion of each of the ribs **6** and the filter **7** to be disposed radially outward from the catheter **1**. The toroidal balloon **11** effectively spans any radial distance between, on the one hand, the vas wall **101**, and on the other hand, the ribs **6** with the expanded filter **7**. The toroidal balloon **11** thus forms a compliant seal between the set **100** and the vas wall **101**.

After this compliant seal has been established, the angioplasty balloon **5** may then be inflated to unblock the vas **2** at location **3**. The deployed filter **7** may then capture unwanted particles flowing downstream during and after operation and subsequent deflation of the angioplasty balloon **5**. After the procedure, the toroidal balloon **11** is deflated, and the set **100** returns to the position shown in Fig. 1B for retraction from the vas **2**. Unwanted particles are trapped within the filter **7** and are safely removed from the vas **2** upon retraction of the set **100**. Additionally, biasing components (for example, as discussed below in connection with later figures) may be used in connection with the set **100** to insure the return to the position shown in Fig. 1B after deflation of the toroidal balloon **11**. These components may include, and are not limited to, elastic bands coupled to one or more elements of the ribs **6**, the filter **7**, and collars **20** and **21**.

Also shown in Fig. 1A, an inlet port **8** is provided by the catheter **1** at a location upstream from the angioplasty balloon **5** and an outlet port **9** is provided downstream from the filter **7**. The ports are in communication with a lumen of the catheter; the lumen may be the same as the lumen used for other purposes or may be a separate dedicated lumen. The result of this structure is an auto-perfusion pathway from inlet port **8** through a catheter lumen to the outlet port **9**

to permit the unimpeded flow of a quantity of fluid during the time in which the medical procedure is being performed. The feature is advantageous when deleterious results may occur from even short intervals of downstream fluid starvation or depletion. Hypoperfusion during angioplasty balloon inflation is primarily relevant to the cerebral and coronary beds. Carotid artery angioplasty, in which the brain is immediately downstream from the location **3**, is a prime example of a procedure benefiting from an auto-perfusion pathway. In many arterial applications, given the normal magnitude of blood pressures, there may be provided a lumen having an internal diameter of 1 to 2 mm. Even when blood flow is not as high as normal, the reduced rate of flow may nevertheless significantly reduce the risk of tissue damage caused by a complete interruption of flow in the cerebral and coronary beds.

Figs. 2A and 2B are longitudinal views of a portion of a catheter-filter set, in the stowed and the deployed conditions, respectively, illustrating generally filter deployment according to an embodiment of the invention utilizing ribs **6** for structuring the filter **7**. Fig. 2A shows the ribs **6** and the filter **7** coupled to and juxtaposed with the catheter **1** in conjunction with the downstream collar **20**. In Fig. 2B the ribs **6**, which are resilient, are expanded radially from the catheter **1** to form a convex shape. The expanded ribs **6** support the filter **7** as shown. Preferably, the ribs **6** are free from asperities. The ribs **6** may be made of any resilient material with sufficient rigidity to support and to enable deployment of the filter **7**. The number of ribs **6** may be selected to be sufficiently large to facilitate a seal of the filter **7** with the interior wall of the vas **2** but not so numerous as to significantly obstruct fluid flow or convenient operation of the set. In the embodiment of Figs. 2A and 2B, the ribs **6** are disposed radially outward from the filter **7**. In other embodiments of the invention, the ribs **6** may be disposed radially inward from the filter **7**, so that, when stowed, the resilient ribs **6** lie immediately adjacent to the catheter **1**. Such other embodiments may deploy in a fashion analogous to opening of an umbrella. The ribs **6** may have one free end as in Figs. 2A and 2B, or be coupled to the catheter **1** at both ends and bow in the middle for deployment as for example in Figs 1A and 1B. The

filter 7 may beneficially be made of a porous, compliant material in a manner known in the art. Suitable materials may include, but are not limited to, woven nylon, plastic resins such as PTFE sold under the Teflon trademark by Dupont of Wilmington, Delaware, other woven polymer, porous silicone rubber and latex rubber. Suitable materials are sufficiently porous to permit a small downstream flow of fluid yet capable of collecting any dangerous particles. For example, calculations suggest that, for an arterial application, a woven material with a fiber porosity of 90% and a spacing of 200 microns may pose little impediment to normal blood flow while trapping undesirable particles..

Figs. 3A and 3B are longitudinal views of a catheter-filter set, in accordance with a tether deployment embodiment of the invention, showing stowed and deployed conditions, respectively. As shown in Fig. 3B, the ribs **6** of this embodiment are attached to the catheter **1** at both ends by collars **20** and **21**. The upstream end collar **21** is free to slide along the catheter **1** while the downstream end collar **20** is fixed. Collar **21** is tethered with line **30** so that an operator can, by applying an upstream force to line **30** slide collar **21** downstream toward collar **20.** This action urges the ribs **6** to form a convex shape and to expand radially from the catheter **1.** As Figs. 3A and 3B show, tethering may be accomplished by attaching one end of line **30** to collar **21**, feeding the line **30** through a port **31** provided by the catheter **1** at a position downstream from collar **21.** The line passes into a lumen of the catheter and exits the catheter **1** upstream at its retraction end. The ribs **6** may expand to the full radial extent of the vas 2. Other material, as discussed in connection with other figures, may be coupled to the ribs **6** proximate to their approximate midpoint in length to provide better sealing action and cushioning at the interface with the vas wall **101.** (For example, the toroidal balloon of Figs. 1A and 1B may be employed; alternatively, any suitable resilient sleeve or O-ring may be utilized.) The ribs **6** will return to the stowed position of Fig. 3A, in accordance with the embodiment of the invention, with the elimination of the applied upstream force on line **30.** This provides a set **100** which is biased to remain in and revert to the stowed position. Such bias provides for assured collapsibility upon retraction and offers

a high degree of fail-safe operation by minimizing the chance of accidental deployment.

Another embodiment according to the invention provides a filter deployment technique using an inflatable toroidal balloon **11** with ribs **6** which have their upstream end uncoupled to the catheter **1**. The stowed position is shown in Fig. 4A; the deployed position in Fig. 4B. Operation of this embodiment is similar to that of Figs. 1A and 1B with respect to the use of a toroidal balloon and to that of Figs. 2A and 2B with respect to the ribs **6**. A tube **40** is provided for inflation fluid communication between a lumen disposed within the catheter **1** and the toroidal balloon **11**. The opposing ends of tube **40** are, respectively, inserted and remain within ports **41**, provided by the catheter **1**, and **42**, provided by the toroidal balloon **11**. The ends of tube **40** may be secured in the ports **41** and **42** with adhesives or using other methods in a manner known in the art. The uninflated toroidal balloon **11**, as shown in Fig. 4A is coupled to the upstream ends of the ribs **6** and juxtaposed with the catheter **1**. As shown in Fig. 4B, with inflation of the toroidal balloon **11**, the resilient ribs **6** expand radially from the catheter **1** to form a convex shape supporting the filter **7**. At its most radially outward extent, the inflated toroidal balloon **11** effects a compliant seal between the set **100** and the vas wall **101**. The toroidal balloon **11** may be made by wrapping fiber around it so that its expansion will be constrained in such a way that the diameter of its inflatable cross-section increases to a lesser degree than its radial (perpendicular to the catheter axis) dimension. In fact, this mode of inflation can be produced by any material that is anisotropic having a high stiffness (or Young's modulus) in the direction of the fiber wrapping and a low stiffness in the direction perpendicular to the wrapping. The inflation of the toroidal balloon provides the necessary structural rigidity needed to withstand the forces associated with downstream fluid flow (in particular, arterial blood flow) while the set **100** is in the deployed condition.

Fig. 5 is a longitudinal view of a catheter-filter set in accordance with an embodiment using balloon deployment wherein elastic bands **50** are employed to bias the set in a stowed condition. The bands **50** are coupled to an upstream collar

51 and a second downstream collar 52. Both collars 51 and 52 are coupled to the catheter 1; the second downstream collar 52 is positioned at a distance farther downstream along the catheter 1 than collar 20 to which optional ribs 6 may be coupled. This embodiment provides a set 100 which is biased to revert to the stowed condition. On deflation of the toroidal balloon 11, the bands 50 act to force the balloon 11, the ribs 6, and the filter 7, with any entrapped particles within, to revert to the stowed condition for safe retraction.

Figs. 6A and 6B are stowed and deployed conditions respectively of an embodiment similar to that of Figs. 4A and 4B, but wherein the ribs are normally twisted in a stowed condition, in which the embodiment is biased. The ribs 6 (which are here differently shaded to permit differentiation in the figure), when in a relaxed, unstressed configuration, fit snugly about the catheter 1 bore in a helical arrangement, as shown in Fig. 6A. The filter 7 is gathered together inside the ribs while the cushioning balloon 11 lies outside the ribs 6 but deflated into a collapsed configuration. The ribs 6 in this embodiment are attached at both the upstream and downstream ends to collars 21 and 20 respectively. The collars 21 and 20 are constrained so as to prevent movement in the longitudinal direction, but the downstream collar 20 can be rotated by rotation of a stiff line 60 threaded through a lumen 61 of the catheter 1. Rotation of the downstream collar 20 causes the ribs 6 to bow outward into the deployed position illustrated in Fig. 6B. Once deployed, the balloon 11 can be inflated to provide a resilient seal against the interior wall of the vas 101 while maintaining an open space between the balloon 11 and catheter 1 for fluid flow. Bowing of the ribs deploys the filter 7 attached to the inner surface of the balloon 11 so that it can function as a trap for debris released from an upstream site. Retraction of the ribs 6 occurs when the stiff line 60 is allowed to rotate back to its original position and the balloon 11 is deflated. The filter set is therefore biased closed in that when pressure is relieved from the balloon 11 and the torque exerted on the stiff line 60 is released, the ribs 6 and filter 7 revert to their stowed position.

Fig. 7A is a cross-sectional view of a catheter-filter set in the deployed condition illustrating a balloon deployment design according to an embodiment

of the invention in which the balloon has a passageway to permit fluid flow therethrough. Figs. 7B and 7C are longitudinal views of the same embodiment in the stowed and the deployed conditions, respectively. In this embodiment, the inflation balloon **11** takes on the shape of two "Ds" back-to-back. The advantage of this embodiment is that the catheter **1** passes directly through the inflatable portion of the balloon **11**, avoiding the need for a separate inflation line that might be prone to rupture because of its small diameter. Fig. 7A shows the balloon in a view along the axis of the vas **2** looking in the downstream direction. The catheter **1** can be seen passing through at the center, and is sealed to the balloon at the points where it passes through the balloon membrane. The catheter has a port inside the balloon **11** that is used for balloon inflation. The filter **7** is seen in Fig. 7A through the openings in the balloon **11** through which the fluid is free to flow. Fig. 7B shows the balloon **11** in the retracted or stowed position. Elastic bands **50** hold the deflated balloon **11**, so that it is radially confined, tight against the catheter **1**. The filter **7** is gathered together and held against the catheter **1** in part by the elastic bands **50**. Deployment is accomplished by inflation of the balloon **11**, a process that forces the balloon **11** into its double-D shape shown in longitudinal view in Fig. 7C. The inflated balloon **11** of Fig. 7C forms a flexible seal against the vas wall **101** and deploys the filter **7**. The filter in this embodiment is firmly tethered to the catheter at its downstream end to aid in gathering the filter **7** to the catheter on balloon deflation. The balloon **11** is made from a flexible but relatively inextensible polymer so that on inflation, it takes the shape shown.

Fig. 8A is a cross-sectional view of a catheter-filter set according to an embodiment of the invention, using for deployment a balloon **11** that is asymmetrically disposed with respect to the tubular member. Fig. 8B is a longitudinal view of the same embodiment in the deployed condition. Fig. 8C shows detail of the catheter-balloon interface. This embodiment increases the area available for flow through the "doughnut hole" of the balloon **11** and, like the embodiment of Figs. 7A through 7C, avoids the need for a separate inflation tube connecting the balloon **11** with the catheter **1**. In this embodiment, the

catheter **1** passes through the toroidal balloon **11** at location **80** on its circumference; a seal is provided between the balloon **11** and the catheter so that the balloon can be inflated through a port as in the embodiment of Figure 7. In the stowed position, shown in Figure 8A, an elastic band **50** attached to the balloon 11 at a point diametrically opposite to the inflation site **80** draws the balloon **11** in the upstream direction. When and as the balloon **11** is deflated, it and filter **7** are collapsed radially against the catheter 1 bore under the force of the elastic band **50**. Additional elastic bands may be optionally used on the downstream side to help gather together the filter 7 on deflation. The filter is deployed by inflation of balloon **11** through the port at location **80** as illustrated in Figure 8B. Balloon inflation also seals the balloon **11** in a flexible manner against the wall of the vas. In the process of balloon inflation, the catheter **1** is displaced off center toward the wall of the vas so as to increase the area available for flow. All flow still passes through the filter **7**.

Fig. 9 is a perspective view of a catheter-filter set according to an embodiment of the invention utilizing a retractable O-ring. The downstream end of the catheter **1** is pictured at a location downstream of a suitable vas-modifying element. The filter **7** is fastened to an O-ring **90** which in turn, is coupled to a set of resilient ribs **6** (four of which are shown). When in the deployed position (shown) the ribs **6** are pushed out of the downstream end of the catheter **1**. The resilience of the O-ring **90** (optionally, in combination with shape memory of the ribs **6**) causes the ribs **6** to separate as the O-ring **90** deploys into its natural circular shape, producing a seal against the wall of the vas. In so doing, the O-ring **90** expands the filter **7** so that it can trap debris released from an upstream location. The filter **7** is returned to its original undeployed position by retracting the ribs **6** into the catheter **1**, exerting a radially-inward force on the O-ring **90**, causing it to buckle into a
multi-lobed pattern with outside radial dimension much smaller than in the deployed position. The ribs **6** can be drawn into the catheter **1** by means of a stiff tether line **91** attached to the ribs **6** at their upstream end **92** within the catheter lumen. The tether line **91** must be sufficiently rigid that it can exert the force

needed to deploy the filter **7** and the O-ring **90**. For ease of retrieval, the filter **7** can be sheathed by a second catheter that slides on the outer bore of the catheter **1**, slipping over the buckled O-ring **90** and filter **7**.

Fig. 10 is a perspective view of a catheter-filter set according to an embodiment of the invention that is similar to the embodiment of Fig. 9, but utilizing a cylindrical sleeve **93** in lieu of the O-ring **90**. An advantage of the sleeve is that the filter **7** can be entirely contained within the sleeve **93** when the ribs and filter are in the retracted position, thus eliminating the necessity for a second catheter.

Fig. 11A is a perspective view of a catheter-filter set according to an embodiment of the invention utilizing a tethered O-ring, shown in the deployed condition. Fig. 11B is a longitudinal view of the same embodiment in the stowed condition. This embodiment shows that an O-ring **191** may be employed in situations in which the filter **7** is attached upstream of the end of the catheter **1**. Deployment, in this embodiment, is accomplished when the operator relaxes the force applied by the line **121** which passes through the wall of the catheter **1** at point **122**. The line **121** is attached to a collar **21** that can slide freely along the bore of the catheter **1**. When force is relaxed, the resilience of the O-ring **191** that exerts a tension in a plurality of tether lines **200** (two are shown) pulls the collar **21** in the downstream direction. The O-ring **191**, selected to be of an outer diameter when fully extended slightly larger than the normal diameter of the vas, provides a flexible seal against the wall of the vas when the tension force in tethers **200** is reduced. A filter **7** is attached around the circumference of the O-ring **191** and is deployed when the O-ring is allowed to expand to fill the vas. The O-ring **191** is also attached to a plurality of additional tethers **201** (two are shown) that are rigidly fixed to the downstream collar **20**. All tether lines **200** and **201** are inextensible and, in this embodiment, are attached at points distributed roughly equidistant around the circumference of the O-ring **191.** To retract and stow the filter, the operator pulls on the line **121** and the O-ring buckles into the configuration shown in Figure 11B due to the alternating

attachments of the tether lines **200** and **201**. The buckling of the O-ring **191** also helps to gather together the filter **7**.

Although the invention has been described with reference to several preferred embodiments, it will be understood by one of ordinary skill in the art that various modifications can be made without departing from the spirit and the scope of the invention, as set forth in the claims hereinbelow.

What is claimed is:

1. A catheter-filter set for use in a vas through which a biological fluid may flow, the vas having an interior wall, the fluid flow defining downstream and upstream directions, there being a risk of the presence of undesired particles in the fluid, the catheter-filter set comprising:

a. a tubular member, having a lumen disposed along its length and an insertion end for insertion into the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto;

b. a filter, coupled to the tubular member and having a circumference, for trapping undesired particles; and

c. a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forming a seal against the interior wall.

2. A catheter-filter set according to claim 1, wherein the resilient member is an O-ring.

3. A catheter-filter set according to claim 1, wherein the resilient member is a sleeve.

4. A catheter-filter set according to claim 1, wherein the resilient member is a balloon having an interior for receiving an inflation fluid and a shape so that when the balloon is inflated there is provided a passageway permitting fluid flow through the filter.

5. A catheter-filter set according to claim 4, further comprising an elastic member coupled to the balloon and the tubular member for causing the balloon to be radially confined when not deployed.

6. A catheter-filter set according to claim 4, wherein the balloon is toroidal and its interior has a cross-section.

7. A catheter-filter set according to claim 6, wherein the resilient balloon has anisotropic elasticity so that during inflation its interior cross-section expands relatively less than its radial extent.

8. A catheter filter set according to claim 1, such that the filter has a stowed position where the filter is radially confined and disposed in the lumen so that

the catheter-filter set may be inserted into and removed from the vas, and a deployed position, where the filter is radially expanded.

9. A catheter-filter set for use in a vas through which a biological fluid may flow, the vas having an interior wall, the fluid flow defining downstream and upstream directions, there being a risk of the presence of undesired particles in the fluid, the catheter-filter set comprising:

a. a tubular member, having a first lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto;

b. a filter, coupled to the tubular member proximal to the insertion end, wherein the filter has a stowed position wherein the filter is radially confined so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, wherein the filter is radially expanded; and

c. a non-inflatable actuator, coupled to the filter, for causing the filter to move from the stowed position to the deployed position;

wherein, absent operation of the actuator, the filter is biased to be in the stowed position.

10. A catheter-filter set according to claim 9, further comprising:

d. a vas conditions-modifying element, associated with the tubular member and located upstream from the filter.

11. A catheter-filter set according to claim 9 wherein element (d) is an angioplasty balloon.

12. A catheter-filter set according to claim 9, wherein the tubular member has a second lumen, the second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter, permitting unimpeded, downstream fluid flow to bypass the filter.

13. A catheter-filter set according to claim 12, wherein the second lumen has a diameter of from approximately 1 mm to approximately 2 mm.

14. A catheter-filter set according to claim 9, further comprising:

d. a plurality of resilient ribs, each rib having a first end coupled to the tubular member, each rib also coupled to the filter, the ribs having a stowed condition in which they are parallel to the longitudinal axis and having a deployed condition in which at least a portion of each rib is disposed radially outward from the tubular member.

15. A catheter-filter set according to claim 14, wherein the filter, in the deployed position, has a maximum radial extent and each rib, in the deployed condition, radially extends a distance less than the maximum radial extent of the filter.

16. A catheter-filter set according to claim 14, wherein each rib has a second end slidably mounted on the tubular member and coupled to the actuator.

17. A catheter-filter set according to claim 16, wherein each rib is coupled to a collar slidably mounted on the tubular member.

18. A catheter-filter set according to claim 14, further comprising:

e. a vas conditions-modifying element, associated with the tubular member and located upstream from the filter.

19. A catheter-filter set according to claim 18 wherein element (e) is an angioplasty balloon.

20. A catheter-filter set according to claim 18, wherein the tubular member has a second lumen, the second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter, permitting unimpeded, downstream fluid flow to bypass the filter.

21. A catheter-filter set according to claim 20, wherein the second lumen has a diameter of from approximately 1 mm to approximately 2 mm.

22. A catheter-filter set according to claim 9, further comprising:

d. a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forming a seal against the interior wall.

23. A catheter-filter set according to claim 22, further comprising:

e. a plurality of resilient ribs, each rib having a first end coupled to the tubular member, each rib also coupled to the filter, the ribs having a

stowed condition in which they are parallel to the longitudinal axis and having a deployed condition in which at least a portion of each rib is disposed radially outward from the tubular member.

24. A catheter-filter set according to claim 23, wherein the filter, in the deployed position, has a maximum radial extent and each rib, in the deployed condition, radially extends a distance less than the maximum radial extent of the filter.

25. A catheter-filter set according to claim 23, wherein each rib has a second end slidably mounted on the tubular member and coupled to the actuator.

26. A catheter-filter set according to claim 25, wherein each rib is coupled to a collar slidably mounted on the tubular member.

27. A catheter-filter set according to claim 23, further comprising:

f. a vas conditions-modifying element, associated with the tubular member and located upstream from the filter.

28. A catheter-filter set according to claim 27 wherein element (f) is an angioplasty balloon.

29. A catheter-filter set according to claim 23, wherein the tubular member has a second lumen, the second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter, permitting unimpeded, downstream fluid flow to bypass the filter.

30. A catheter-filter set according to claim 29, wherein the second lumen has a diameter of from approximately 1 mm to approximately 2 mm.

31. A catheter-filter set according to claim 22, wherein the resilient member is an O-ring.

32. A catheter-filter set according to claim 22, wherein the resilient member is a sleeve.

33. A catheter-filter set according to claim 22, wherein the resilient member is a resilient balloon having an interior for receiving an inflation fluid and a shape so that when the resilient balloon is inflated there is provided a passageway permitting fluid flow through the filter.

34. A catheter-filter set according to claim 33, wherein the resilient balloon is toroidal and its interior has a cross-section.

35. A catheter-filter set according to claim 34, wherein the resilient balloon has anisotropic elasticity so that during inflation its interior cross-section expands relatively less than its radial extent.

36. A catheter-filter set for use in a vas through which a biological fluid may flow, the vas having an interior wall, the fluid flow defining downstream and upstream directions, there being a risk of the presence of undesired particles in the fluid, the catheter-filter set comprising:

a. a tubular member, having a lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto; and

b. a filter, coupled to the tubular member proximal to the insertion end, wherein the filter has a stowed position wherein the filter is radially confined and disposed in the lumen so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, wherein the filter is radially expanded.

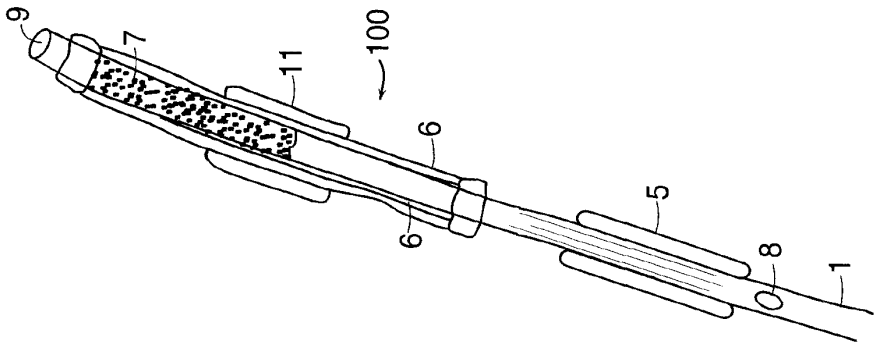

FIG. 1B

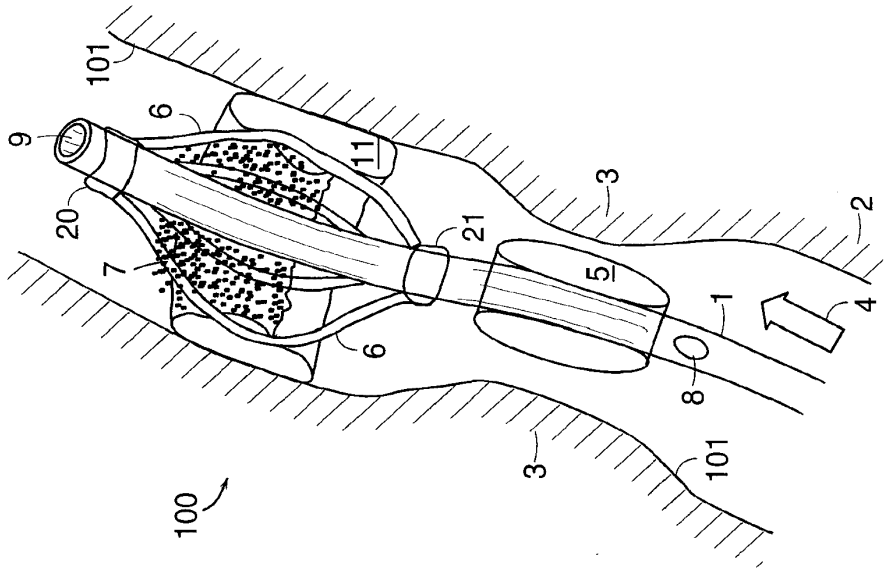

FIG. 1A

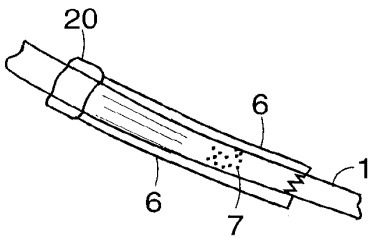

FIG. 2A

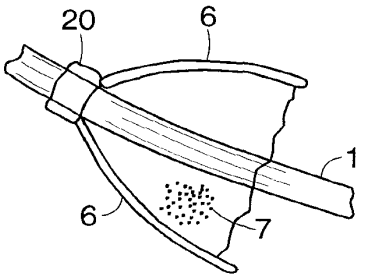

FIG. 2B

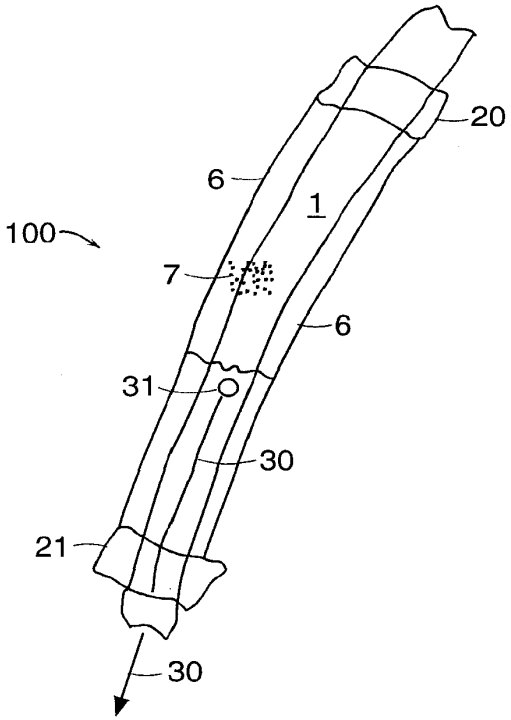

FIG. 3A

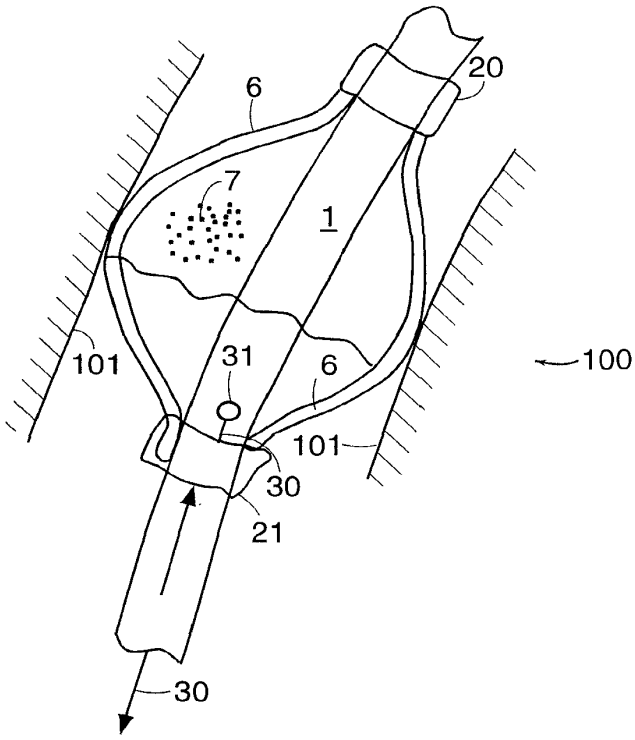

FIG. 3B

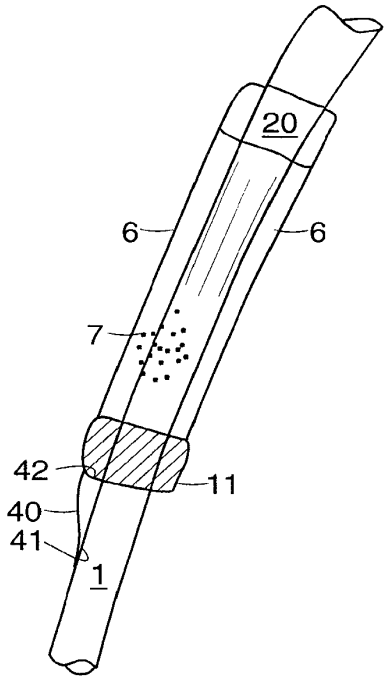

FIG. 4A

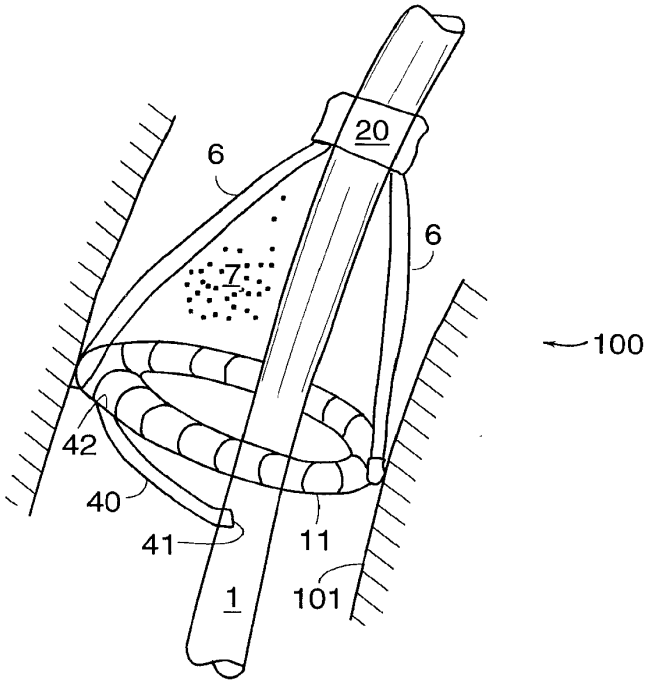

FIG. 4B

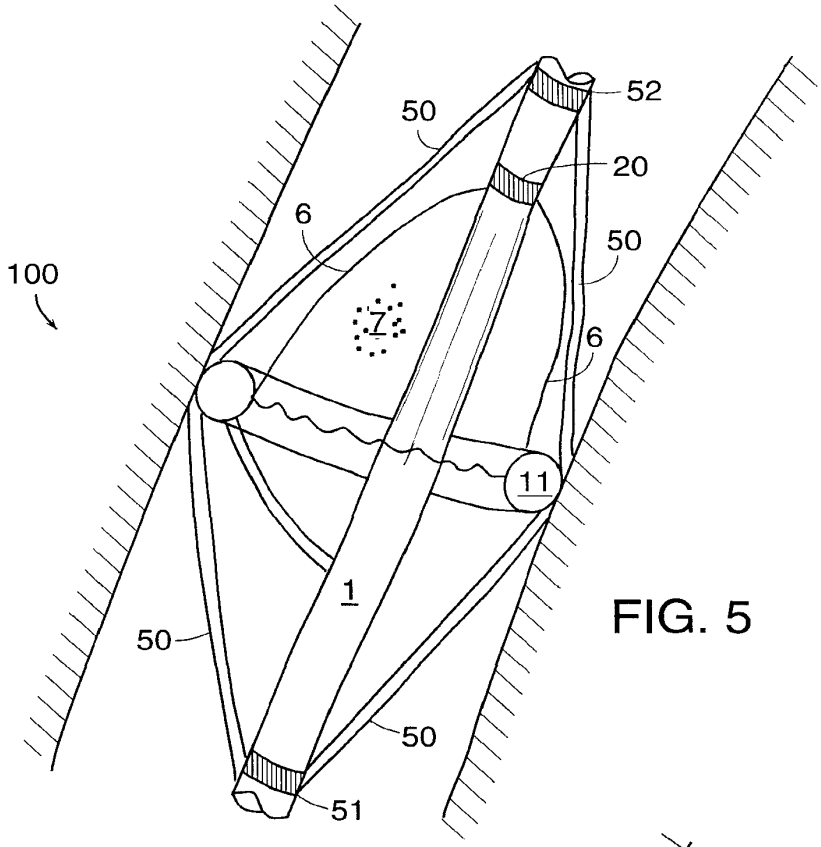

FIG. 5

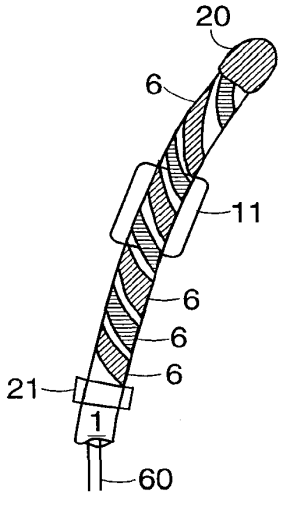

FIG. 6A

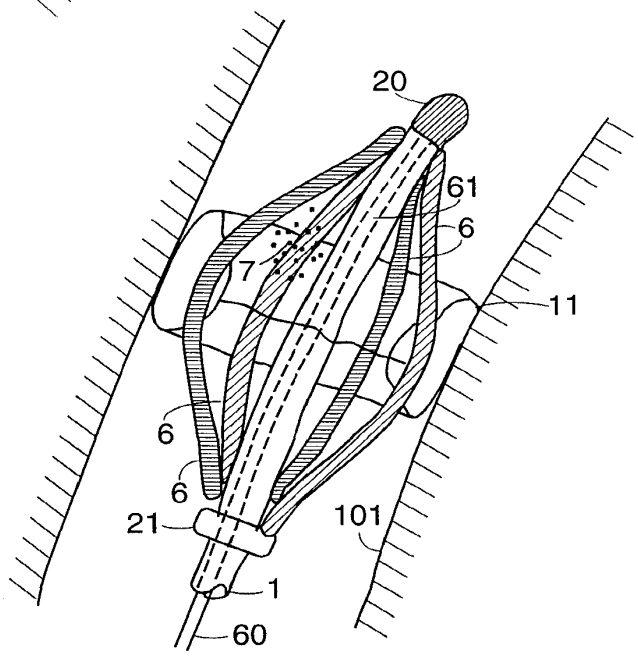

FIG. 6B

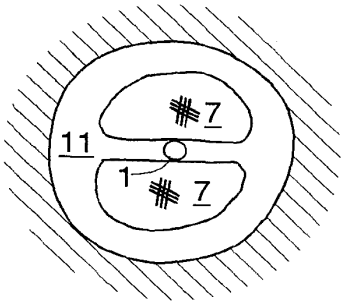

FIG. 7A

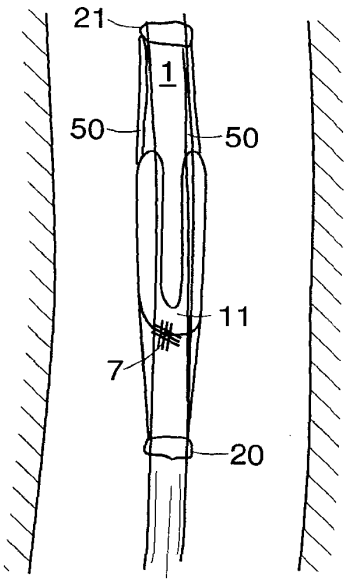

FIG. 7B

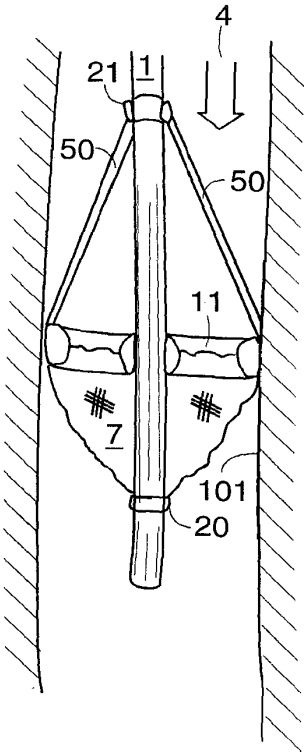

FIG. 7C

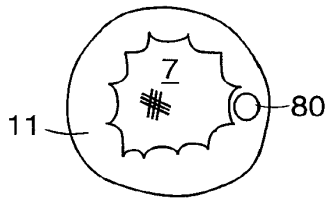

FIG. 8A

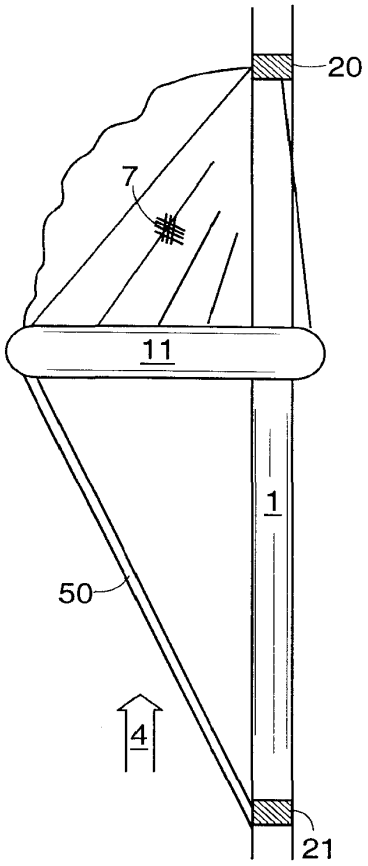

FIG. 8B

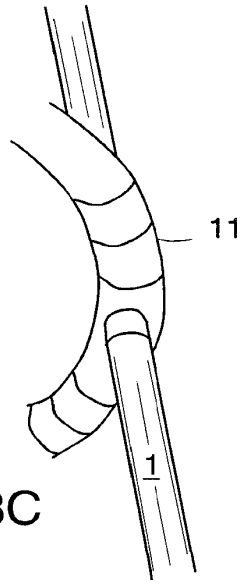

FIG. 8C

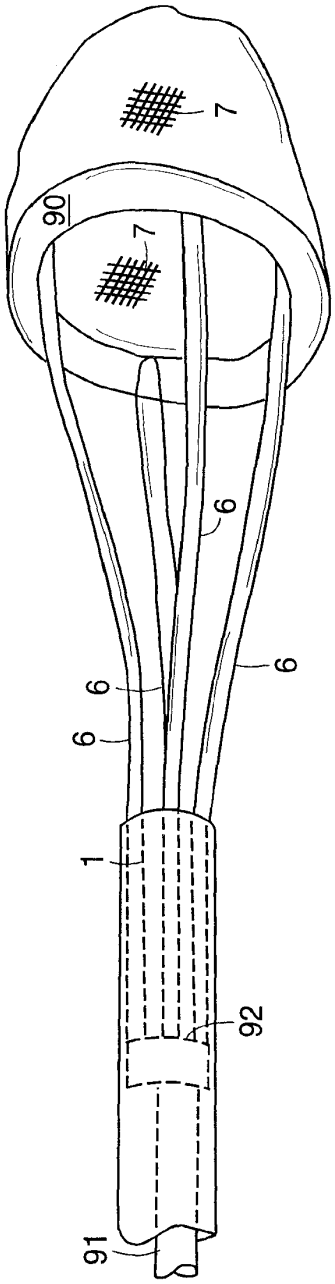

FIG. 9

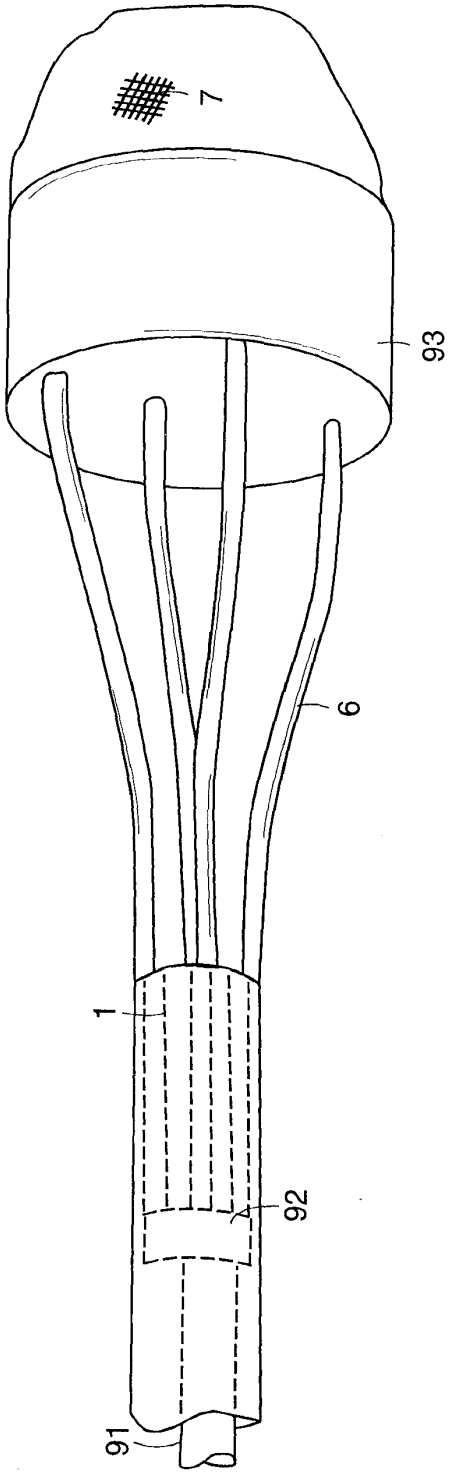

FIG. 10

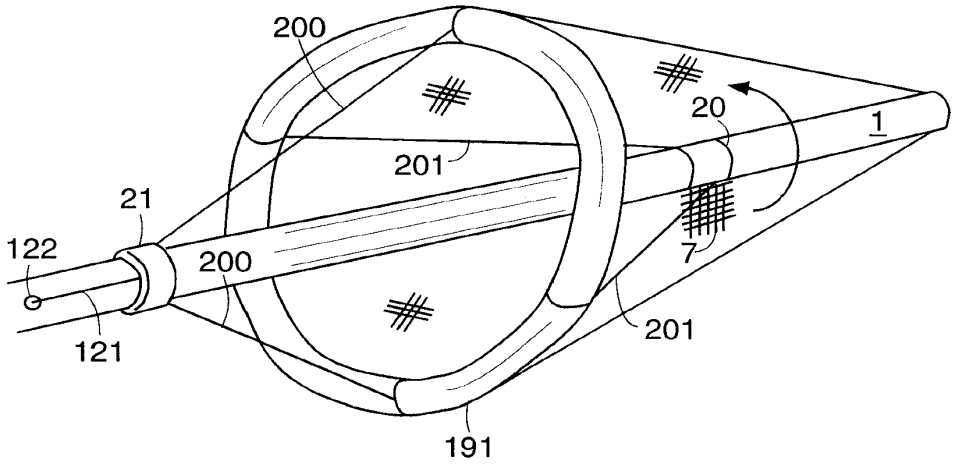

FIG. 11A

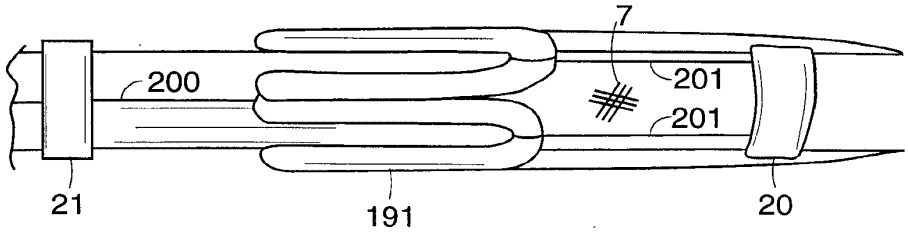

FIG. 11B

INTERNATIONAL SEARCH REPORT

Ir. ..ational Application No
PCT/US 98/10220

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/01 A61M29/02

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61B

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

Electronic data base consulted during the international search (name of data base and. where practical. search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document. with indication. where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 95 05209 A (TECH. DEV. CENTER) 23 February 1995 see page 13, line 29 - page 15, line 11 see page 7, line 6 - line 10; figures 1,13-15 ---	1-4,6-8, 36 5,9-35
Y	US 4 723 549 A (WHOLEY ET AL.) 9 February 1988 cited in the application see column 3, line 2 - line 66; figures 1-6 --- -/--	5,9-35

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publicationdate 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 theinternational search	Date of mailing of the international search report
21 August 1998	02/09/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Moers, R

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

INARI_019557

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/10220

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE WPI Week 8122 8 July 1981 Derwent Publications Ltd., London, GB; AN 78-70163A XP002075206 & SU 764 684 A (CHELY MED. INST.) see abstract; figures 1-5	1-3,9,36
X	US 5 053 008 A (BAJAJ) 1 October 1991	1,36
A	see column 7, line 55 - column 8, line 47; figures 1-4	3,7,32, 35
A	US 5 470 314 A (WALINSKY PAUL) 28 November 1995 see column 7, line 13 - line 18	7,35

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INARI_019558

INTERNATIONAL SEARCH REPORT

Information on patent family members

Ir. .ational Application No
PCT/US 98/10220

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9505209 A	23-02-1995	AU 7567394 A	14-03-1995
US 4723549 A	09-02-1988	NONE	
US 5053008 A	01-10-1991	NONE	
US 5470314 A	28-11-1995	NONE	

Form PCT/ISA/210 (patent family annex) (July 1992)

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW S. WILLIAMS
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

RECEIVED
PATENT DOCKETING

JAN 25 2022

PERKINS COIE LLP

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 111552-8025WO00	Date of mailing *(day/month/year)* JAN 20 2022 **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 21/45072	International filing date *(day/month/year)* 06 August 2021 (06.08.2021)
Applicant INARI MEDICAL, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   How? Directly to the International Bureau preferably through ePCT, or on paper to:
   The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland

   For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
   - ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
   - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   The applicant may **submit comments on an informal basis on the written opinion of the International Searching Authority** to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

   Shortly after the expiration of **18 months from the priority date, the international application will be published** by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis* 3).

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

   Within **22 months from the priority date, the applicant may request that a supplementary international search be carried out** by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

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/220 (revised January 2020)

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
111552-8025WO00		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 21/45072	06 August 2021 (06.08.2021)	06 August 2020 (06.08.2020)
Applicant INARI MEDICAL, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☒ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

   a. the figure of the **drawings** to be published with the abstract is Figure No. 18

   ☒ as suggested by the applicant.

   ☐ as selected by this Authority, because the applicant failed to suggest a figure.

   ☐ as selected by this Authority, because this figure better characterizes the invention.

   b. ☐ none of the figures is to be published with the abstract.

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/45072

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

Group I: Claims 1-15 directed to an automatically-locking syringe.

Group II: Claims 16-20 directed to a clot treatment system.

Group III: Claims 21-28 directed to a syringe having a barrel and a vacuum indicator having a transparent tube and an indicator with a visual characteristic.

-*- See Supplemental Box -*-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

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

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

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-15

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/45072

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61M 5/32; A61M 5/315 (2021.01)

CPC - A61M 5/32; A61M 5/502; A61M 5/3243; A61M 5/150641; A61M 5/3234; A61M 5/3232; A61M 5/5013; A61M 2005/5026; A61M 2005/3247; A61M 2005/3223; A61M 5/315

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2013/0126559 A1 (COWAN et al.) 23 May 2013 (23.05.2013); entire document, especially para [0028], and Fig. 1-2.	1-10
A	US 2004/0122359 A1 (WENZ et al.) 24 June 2004 (24.06.2004); entire document, especially para [0063]-[0066], and Fig. 7.	1-15
A	WO 2011/073176 A1 (NOVARTIS AG) 23 June 2011 (23.06.2011); especially pg 6 ln 33 to pg 7 ln 2, and Fig. 1-3.	10-15
A, P	WO 2021/067134 A1 (BECTON, DICKINSON AND COMPANY) 8 April 2021 (08.04.2021); entire document.	1-15
A	US 2004/0267272 A1 (HENNIGES et al.) 30 December 2004 (30.12.2004); entire document.	1-15

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 December 2021	JAN 20 2022
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

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

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/US 21/45072

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

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

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a lock plate, not required by the claims of Groups II-III.

The invention of Group II includes the special technical feature of a catheter, not required by the claims of Groups I or III.

The invention of Group III includes the special technical feature of a transparent tube and an indicator movably positioned within the tube, not required by the claims of Groups I-II.

COMMON TECHNICAL FEATURES

Groups I and III share the common technical feature of a syringe having a barrel and a plunger movable through the barrel.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 5,788,463 A (CHAN) (hereinafter Chan), which discloses a syringe (10; Fig. 1-10; col 4 ln 66 to col 5 ln 20) having a barrel (50; Fig. 1-10; col 5 ln 21-23) and a plunger movable through the barrel (60; Fig. 1-10; col 5 ln 21-23).

Groups II-III share the common technical feature of a vacuum indicator.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by Chan, which discloses a vacuum indicator (15; Fig. 1-10; col 8 ln 36-50).

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

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

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW S. WILLIAMS
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

RECEIVED
PATENT DOCKETING

JAN 25 2022

PERKINS COIE LLP

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	JAN 20 2022

Applicant's or agent's file reference	FOR FURTHER ACTION
111552-8025WO00	See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 21/45072	06 August 2021 (06.08.2021)	06 August 2020 (06.08.2020)

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

IPC - A61M 5/32; A61M 5/315 (2021.01)

CPC - A61M 5/32; A61M 5/502; A61M 5/3243; A61M 5/150641; A61M 5/3234; A61M 5/3232; A61M 5/5013; A61M 2005/5026; A61M 2005/3247; A61M 2005/3223; A61M 5/315

Applicant INARI MEDICAL, INC.

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 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 notified 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/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	2 December 2021	Kari Rodriquez PCT Help Desk Telephone No. 571-272-4300

Form PCT/ISA/237 (cover sheet) (revised January 2019)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/45072

Box No. I Basis of this 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(b)).

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:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/45072

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:

   ☐ paid additional fees.

   ☐ paid additional fees under protest and, where applicable, the protest fee.

   ☐ paid additional fees under protest but the applicable protest fee was not paid.

   ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

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

Group I: Claims 1-15 directed to an automatically-locking syringe.

Group II: Claims 16-20 directed to a clot treatment system.

Group III: Claims 21-28 directed to a syringe having a barrel and a vacuum indicator having a transparent tube and an indicator with a visual characteristic.

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

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a lock plate, not required by the claims of Groups II-III.

The invention of Group II includes the special technical feature of a catheter, not required by the claims of Groups I or III.

The invention of Group III includes the special technical feature of a transparent tube and an indicator movably positioned within the tube, not required by the claims of Groups I-II.

COMMON TECHNICAL FEATURES

Groups I and III share the common technical feature of a syringe having a barrel and a plunger movable through the barrel.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 5,788,463 A (CHAN) (hereinafter Chan), which discloses a syringe (10; Fig. 1-10; col 4 ln 66 to col 5 ln 20) having a barrel (50; Fig. 1-10; col 5 ln 21-23) and a plunger movable through the barrel (60; Fig. 1-10; col 5 ln 21-23).

Groups II-III share the common technical feature of a vacuum indicator.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by Chan, which discloses a vacuum indicator (15; Fig. 1-10; col 8 ln 36-50).

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

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

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-15

Form PCT/ISA/237 (Box No. IV) (revised January 2019)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/45072

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**

1. Statement

Novelty (N)	Claims	1-15	YES
	Claims	None	NO
Inventive step (IS)	Claims	1-15	YES
	Claims	None	NO
Industrial applicability (IA)	Claims	1-15	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-15 meet the criteria of PCT Article 33(2)-(3) because as will be shown, the prior art does not teach nor fairly suggest the claimed limitations.

The prior art is exemplified by (1) US 2013/0126559 A1 (COWAN et al.) (hereinafter Cowan); (2) US 2004/0122359 A1 (WENZ et al.) (hereinafter Wenz); and (3) WO 2011/073176 A1 (NOVARTIS AG) (hereinafter Novartis).

(1) Cowan teaches an automatically-locking syringe (8; Fig. 1-2; para [0028]), comprising:
a barrel (10; Fig. 1-2; para [0028]);
a plunger slidably positioned within the barrel (16; Fig. 1-2; para [0028]),
wherein the plunger is movable between a depressed position and a withdrawn position (depression and withdrawing action of 16 within 10; Fig. 1-2; para [0028]), and
wherein the plunger includes a lock feature (ratchet teeth upon 16; Fig. 1-2; para [0028]); and
a lock plate coupled to the barrel (18; Fig. 1-2; para [0028]),
wherein the lock plate includes a biasing member configured to bias the lock plate to a locking position (30; Fig. 1-2; para [0035]).

(2) Wenz teaches a syringe (Fig. 7; para [0063]-[0066]), comprising:
a barrel (unlabeled barrel through which 5 extends; Fig. 7; para [0064]),
a plunger (5; Fig. 7; para [0064]),
a lock plate (31, 32, 33, 34; Fig. 7; para [0064]-[0066]),
said lock plate having an opening extending therethrough (opening of 31, 32, 33, 34 through which 5 extends; Fig. 7),
wherein the plunger is slidably positioned in the opening (5 extending through opening of 31, 32, 33, 34; Fig. 7).

(3) Novartis teaches a syringe (2; Fig. 1-3; pg 6 ln 33 to pg 7 ln 2), comprising:
a first arm (22; Fig. 1-3; pg 7 ln 20-28),
a second arm (24; Fig. 1-3; pg 7 ln 20-28),
wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position (outward bias of 22 away from 18; Fig. 1-3; pg 8 ln 25 to pg 9 ln 3).

-*- See Supplemental Box -*-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-*- Box V.2 - Citations and explanations -*-

As pertaining to claim 1, Cowan teaches an automatically-locking syringe (8; Fig. 1-2; para [0028]), comprising:
a barrel (10; Fig. 1-2; para [0028]);
a plunger slidably positioned within the barrel (16; Fig. 1-2; para [0028]),
wherein the plunger is movable between a depressed position and a withdrawn position (depression and withdrawing action of 16 within 10; Fig. 1-2; para [0028]), and
wherein the plunger includes a lock feature (ratchet teeth upon 16; Fig. 1-2; para [0028]); and
a lock plate coupled to the barrel (18; Fig. 1-2; para [0028]),
wherein the lock plate includes a biasing member configured to bias the lock plate to a locking position (30; Fig. 1-2; para [0035]);
but is silent wherein comprising:
said lock plate having an opening extending therethrough,
wherein the plunger is slidably positioned in the opening,
wherein-
when the plunger is moved from the depressed position to the withdrawn position, the lock feature is configured to engage the lock plate to drive the lock plate to a position away from the locking position to thereby permit the lock feature to pass through the opening, and
after the lock feature passes through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.
Further, Wenz teaches a syringe (Fig. 7; para [0063]-[0066]), comprising:
a barrel (unlabeled barrel through which 5 extends; Fig. 7; para [0064]),
a plunger (5; Fig. 7; para [0064]),
a lock plate (31, 32, 33, 34; Fig. 7; para [0064]-[0066]),
said lock plate having an opening extending therethrough (opening of 31, 32, 33, 34 through which 5 extends; Fig. 7),
wherein the plunger is slidably positioned in the opening (5 extending through opening of 31, 32, 33, 34; Fig. 7),
but the prior art does not teach nor fairly suggest:when the plunger is moved from the depressed position to the withdrawn position, the lock feature is configured to engage the lock plate to drive the lock plate to a position away from the locking position to thereby permit the lock feature to pass through the opening, and
after the lock feature passes through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.
The lock plate as claimed by the Applicant is driven away to prevent depression movement of the plunger through the barrel. There exists no motivation without benefit of hindsight for modification of the syringe of Cowan as modified by Wenz such the plunger is inhibited from depression movement as opposed to withdrawing movement, such that the claimed limitations are met.

As pertaining to claims 2-9, the prior art does not teach nor fairly suggest the claimed limitations, because claims 2-9 depend from claim 1.

As pertaining to claim 10, Wenz teaches an automatically-locking syringe (Fig. 7; para [0063]-[0066]), comprising:
a barrel (unlabeled barrel through which 5 extends; Fig. 7; para [0064]) including a flange (14; Fig. 7; para [0064]);
a plunger slidably positioned within the barrel (5; Fig. 7; para [0064]),
wherein the plunger is aligned along a longitudinal axis (longitudinal alignment of 5; Fig. 7), and
wherein the plunger is movable along the longitudinal axis between a depressed position and a withdrawn position (movement of 5 through unlabeled barrel; Fig. 7; para [0064]);
a lock member coupled to the plunger (31, 32, 33, 34; Fig. 7; para [0064]-[0066]),
wherein the lock member includes a body (body of 31; Fig. 7; para [0064]);
but is silent wherein:
the lock member includes a first arm hingedly coupled to the body,
wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position; and
an actuator including a second arm,
wherein the actuator is movable between a first position and a second position, and
wherein the second arm is configured to engage the first arm in the second position to drive the first arm ~~inwardly~~ toward the longitudinal axis away from the locking position.
Further, Novartis teaches a syringe (2; Fig. 1-3; pg 6 ln 33 to pg 7 ln 2), comprising:
a first arm (22; Fig. 1-3; pg 7 ln 20-28),
a second arm (24; Fig. 1-3; pg 7 ln 20-28),
wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position (outward bias of 22 away from 18; Fig. 1-3; pg 8 ln 25 to pg 9 ln 3),
but the prior art does not teach nor fairly suggest employment of the elements of Novartis upon the syringe of Wenz such that the claimed limitations are met.
There exists no motivation without benefit of hindsight for employment of the first arm and second arm of Novartis upon the syringe of Wenz, such that the second arm engages directly with the first arm in order to unlock the plunger for withdrawing.

As pertaining to claims 11-15, the prior art does not teach nor fairly suggest the claimed limitations, because claims 11-15 depend from claim 10.

Claims 1-15 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

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(54) **Title:** INVERTING THROMBECTOMY APPARATUSES AND METHODS OF USE

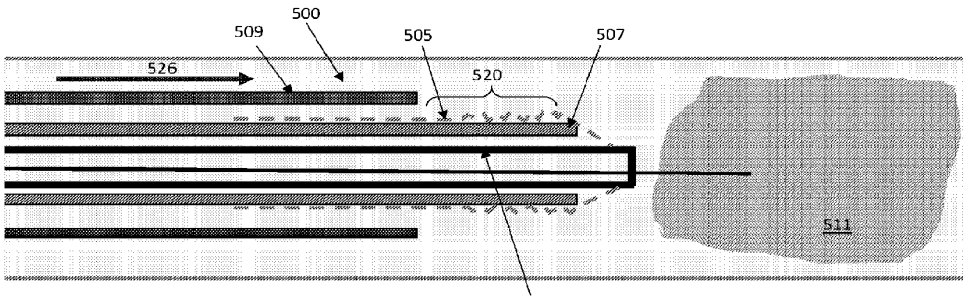

FIG. 5D

(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.

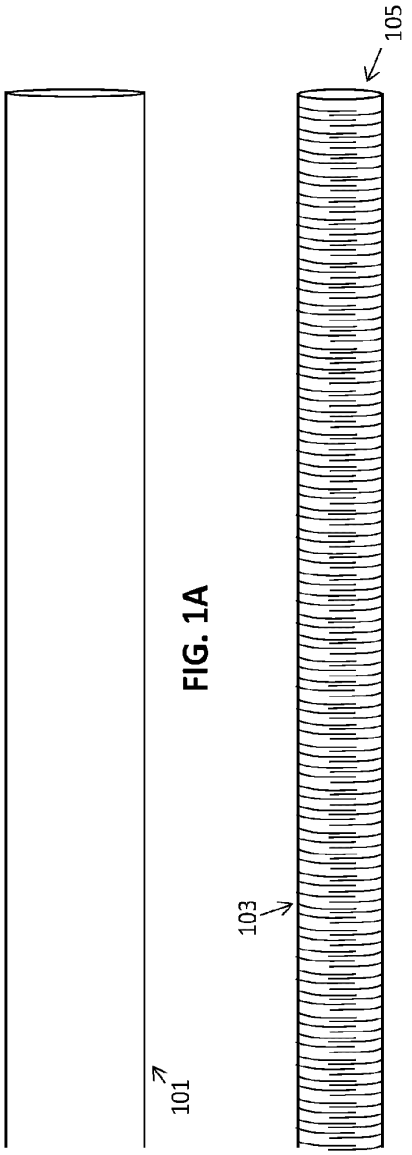


FIG. 1A

FIG. 1B

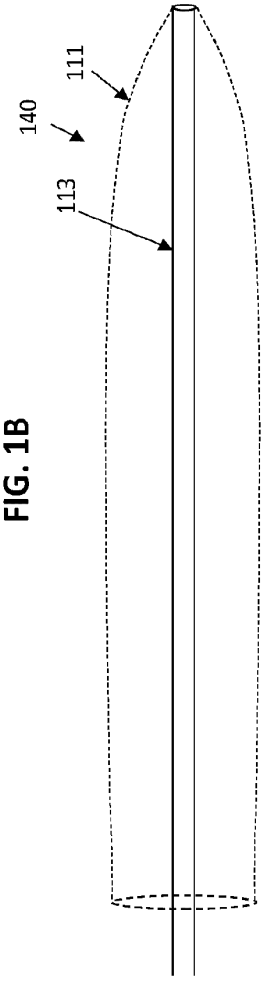


FIG. 1C1

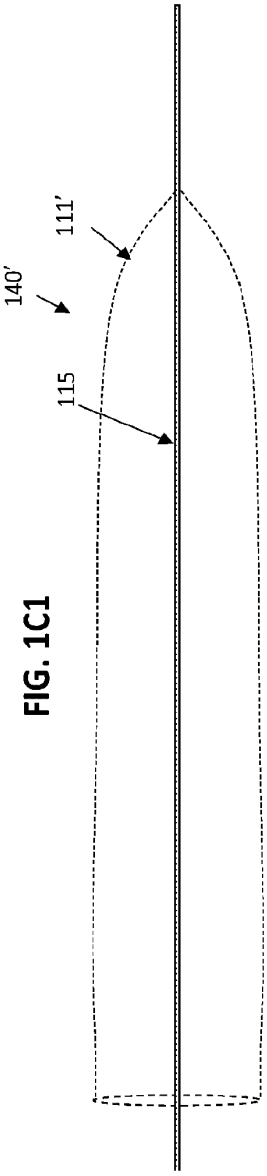


FIG. 1C2

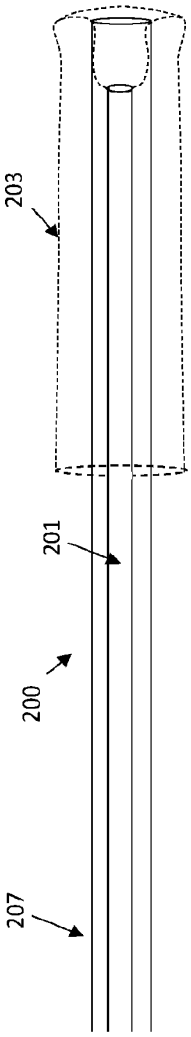


FIG. 2A

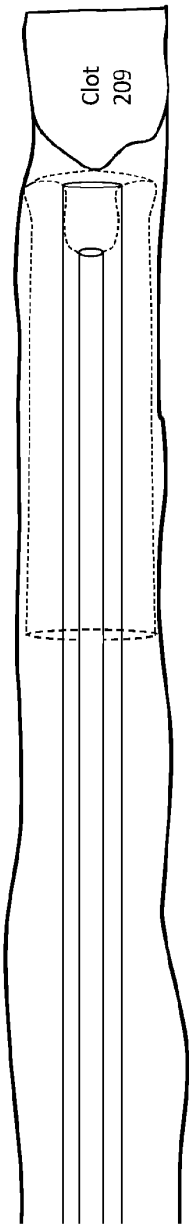


FIG. 2B

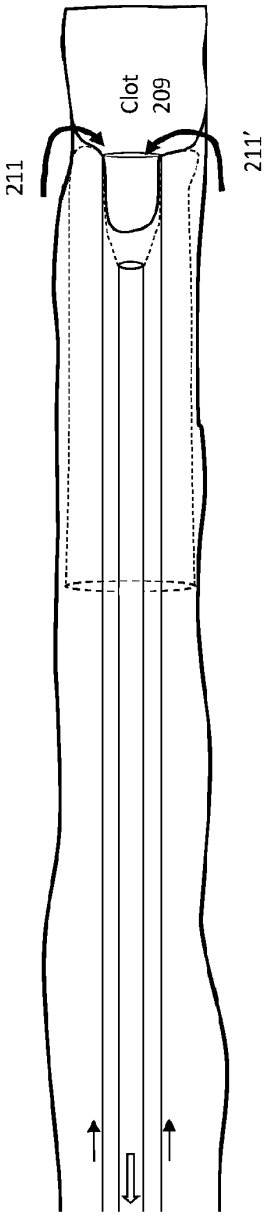


FIG. 2C

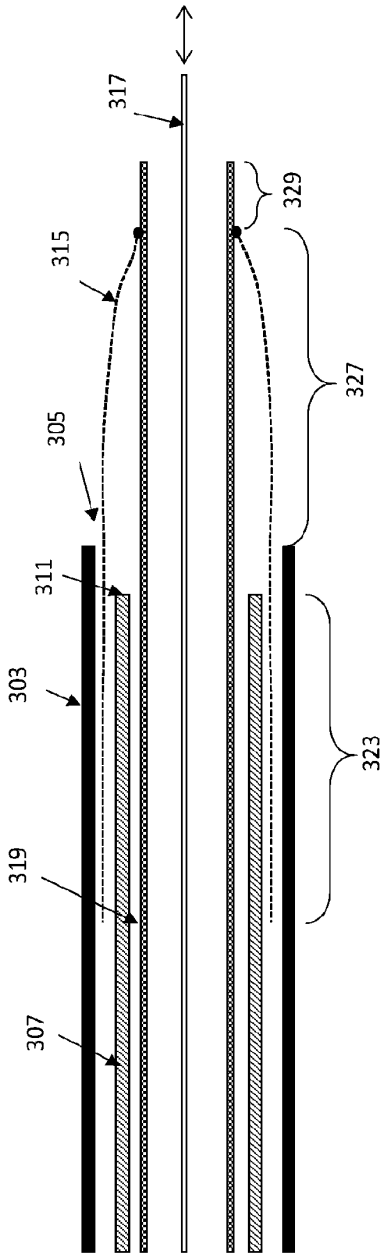

317
315
329
305
327
311
303
323
319
307

FIG. 3A

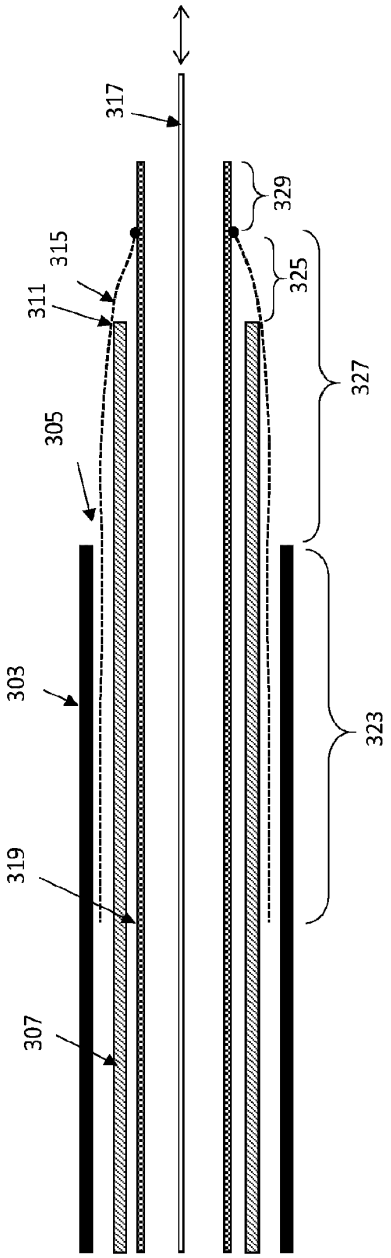

317
329
315
325
311
305
327
303
323
319
307

FIG. 3B

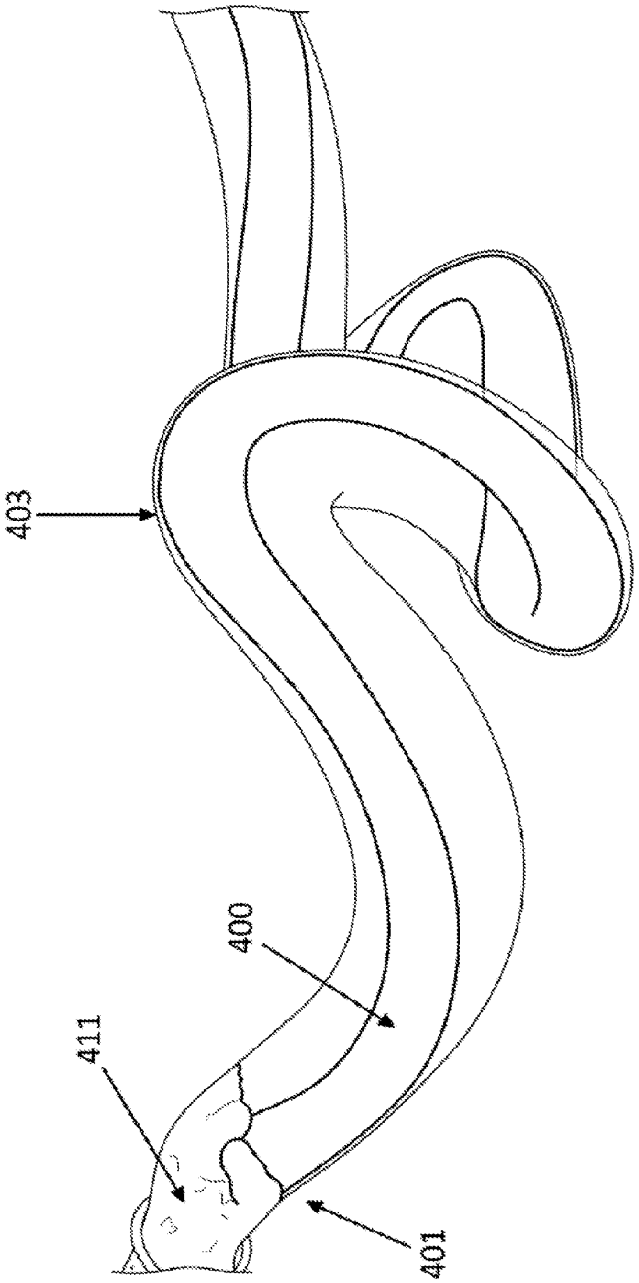


FIG. 4A

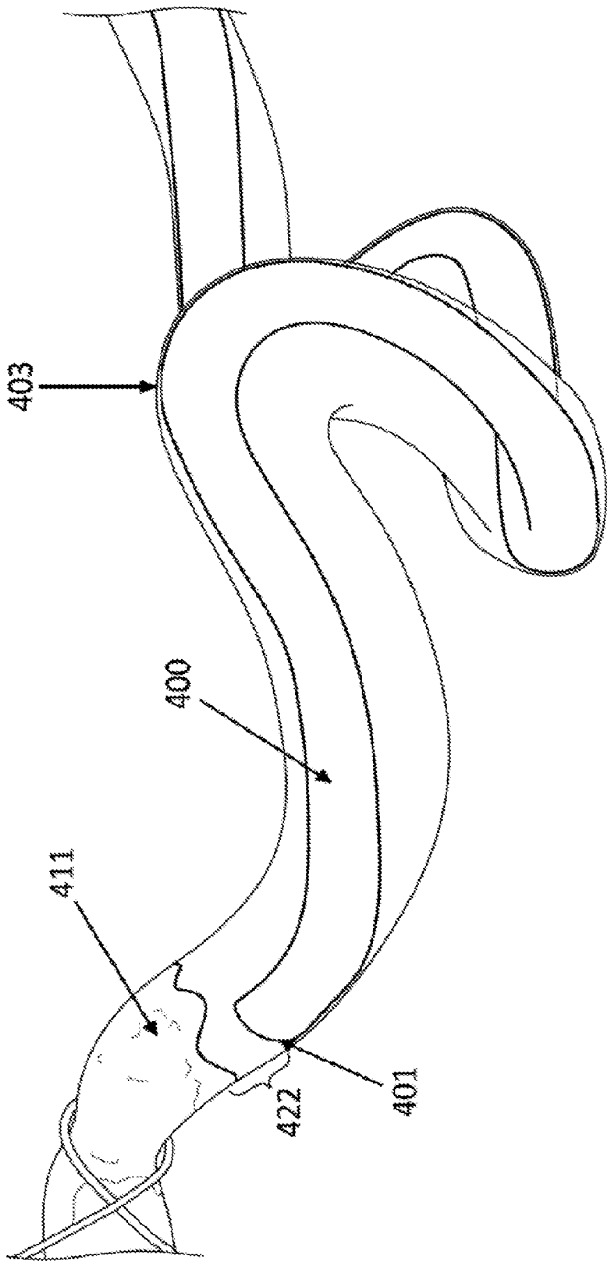


FIG. 4B

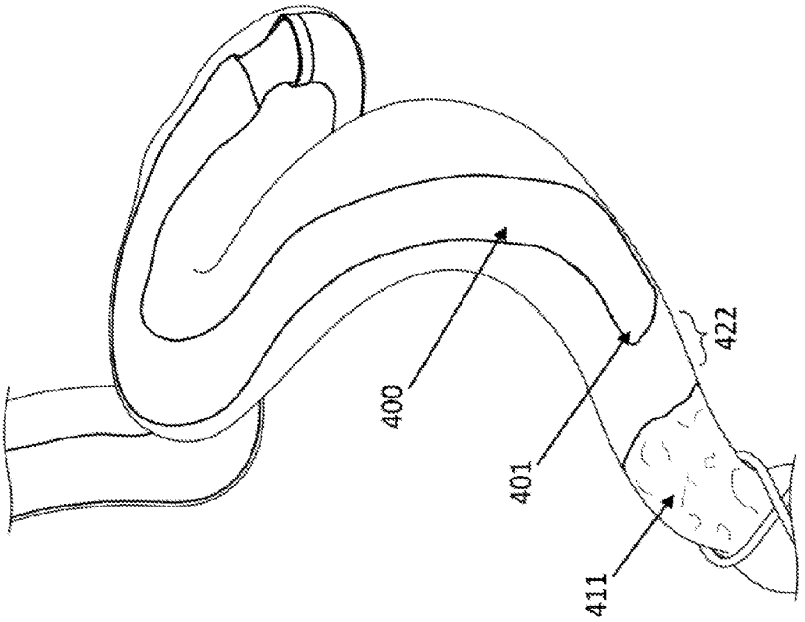


FIG. 4D

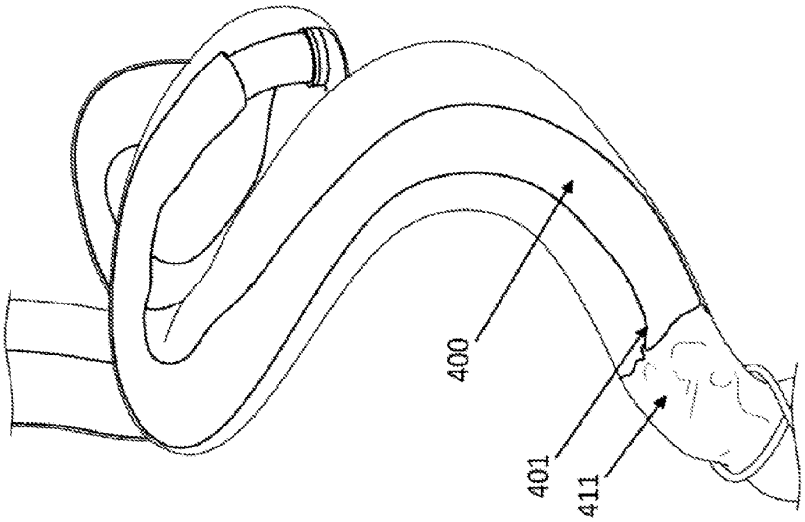


FIG. 4C

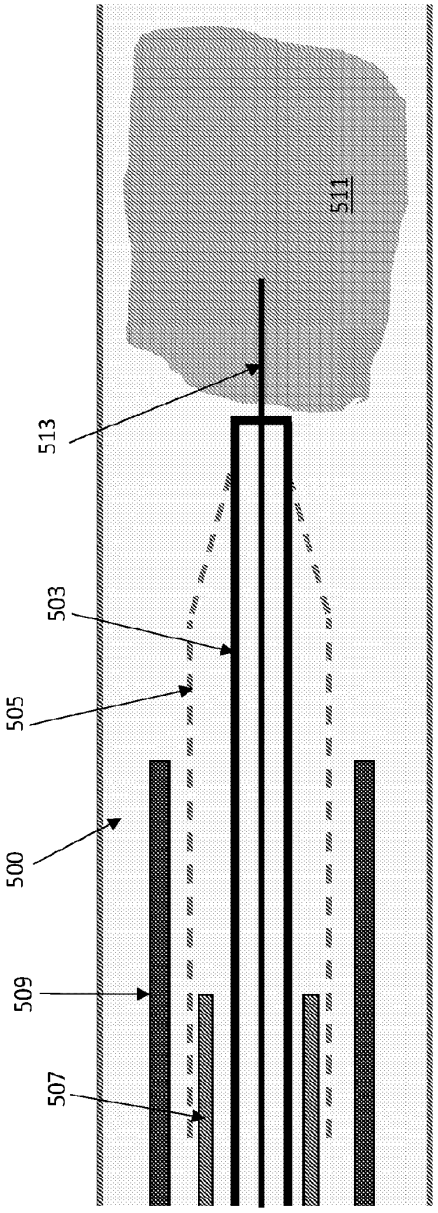


FIG. 5A

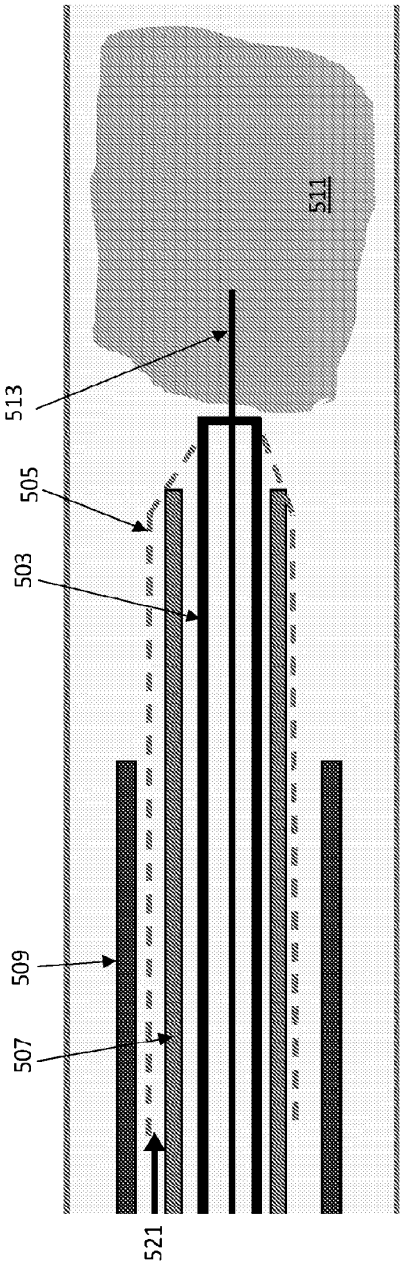


FIG. 5B

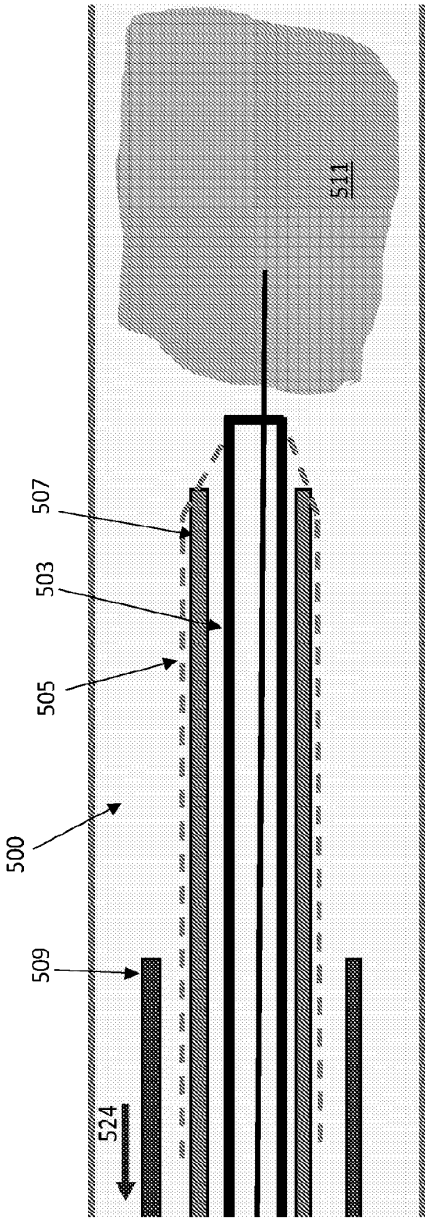


FIG. 5C

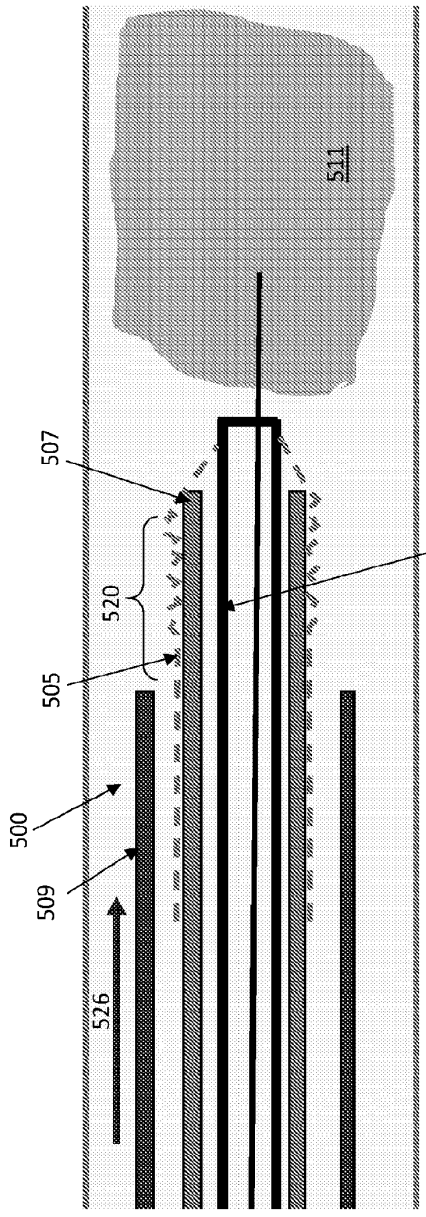


FIG. 5D

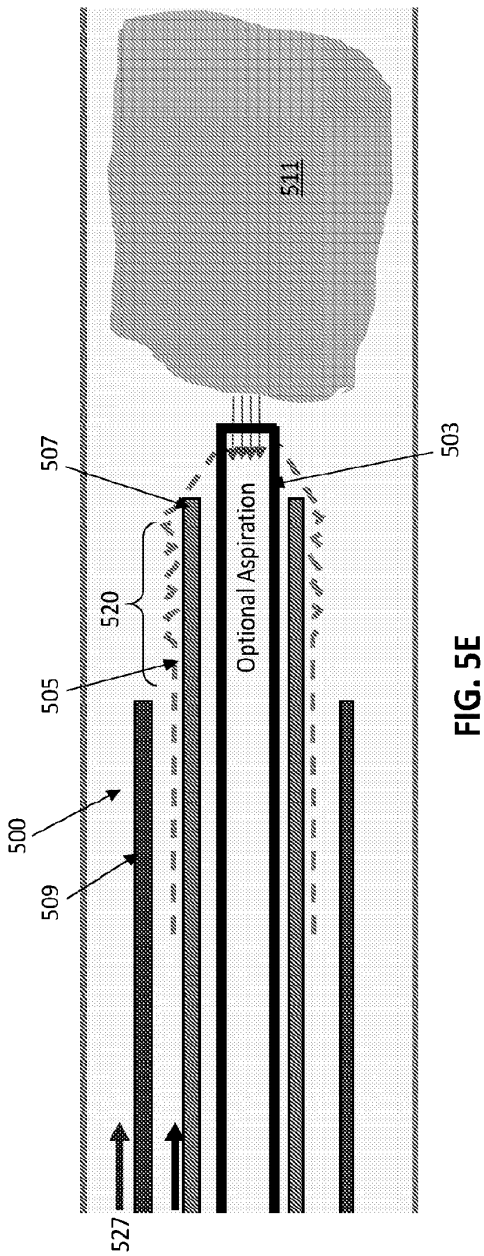

511
507
503
520
505
Optional Aspiration
500
509
527

FIG. 5E

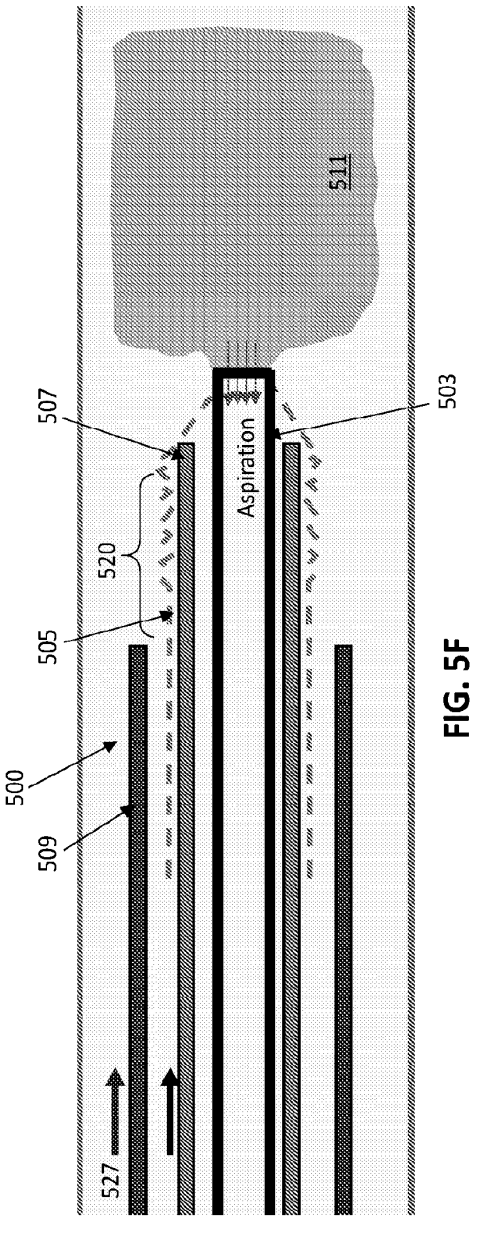

511
507
503
520
505
Aspiration
500
509
527

FIG. 5F

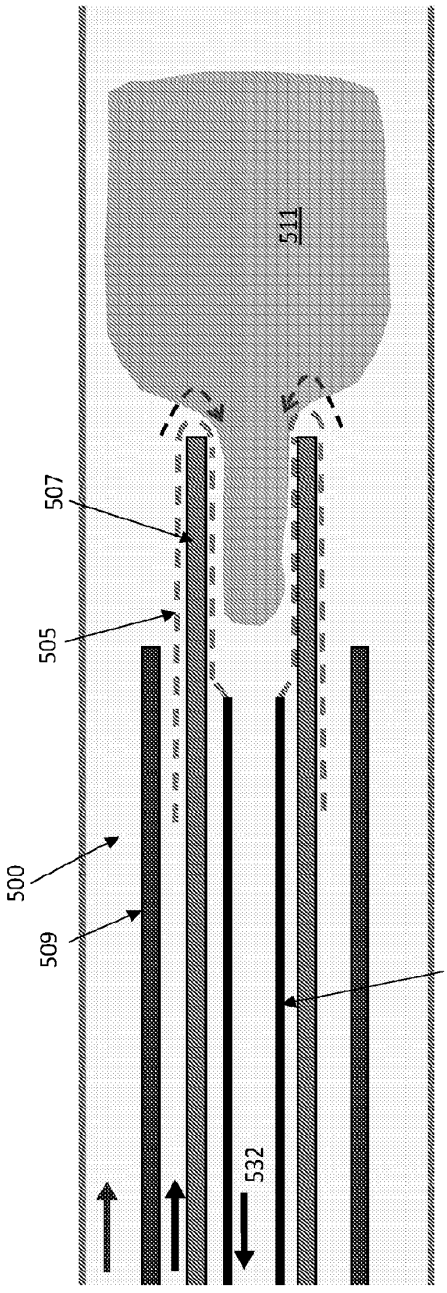


FIG. 5G

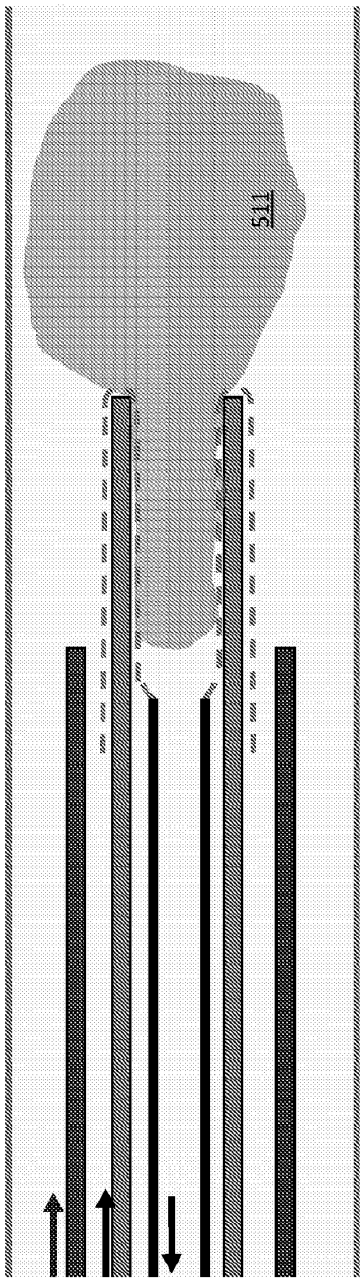


FIG. 5H

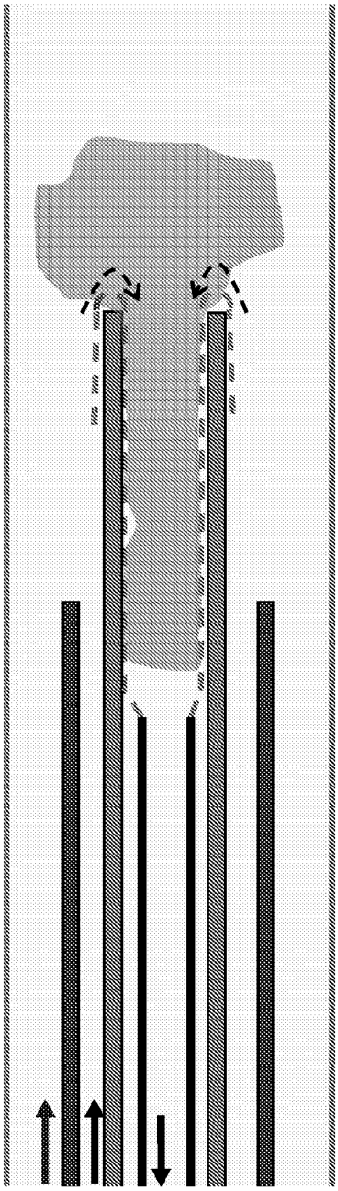


FIG. 5I

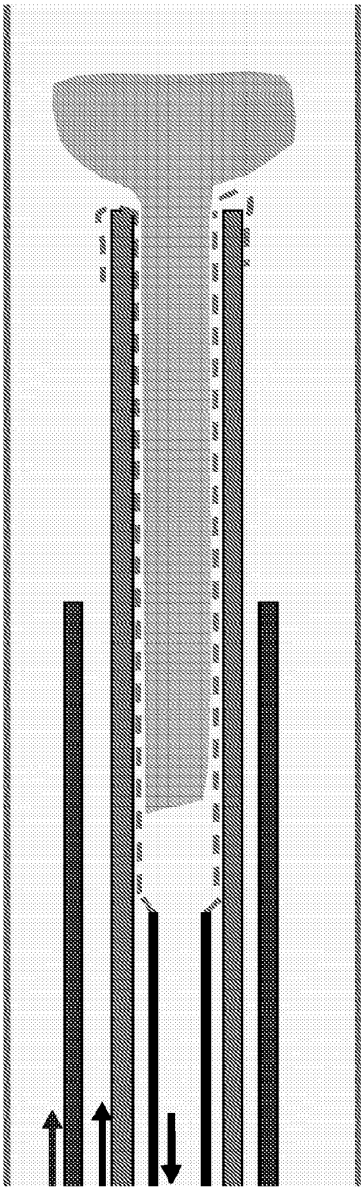


FIG. 5J

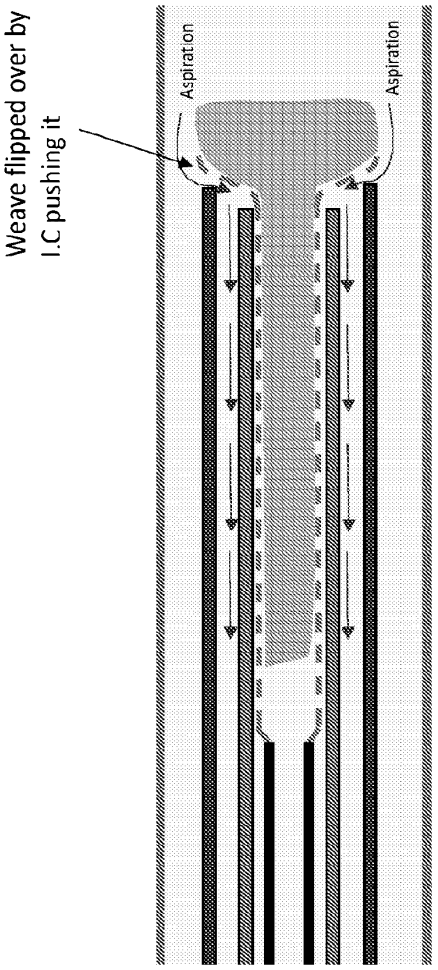

Weave flipped over by
I.C pushing it
Aspiration
Aspiration

FIG. 5K

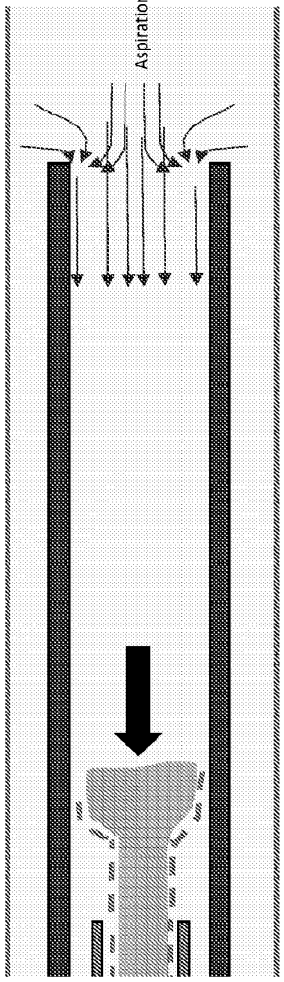

Aspiration

FIG. 5L

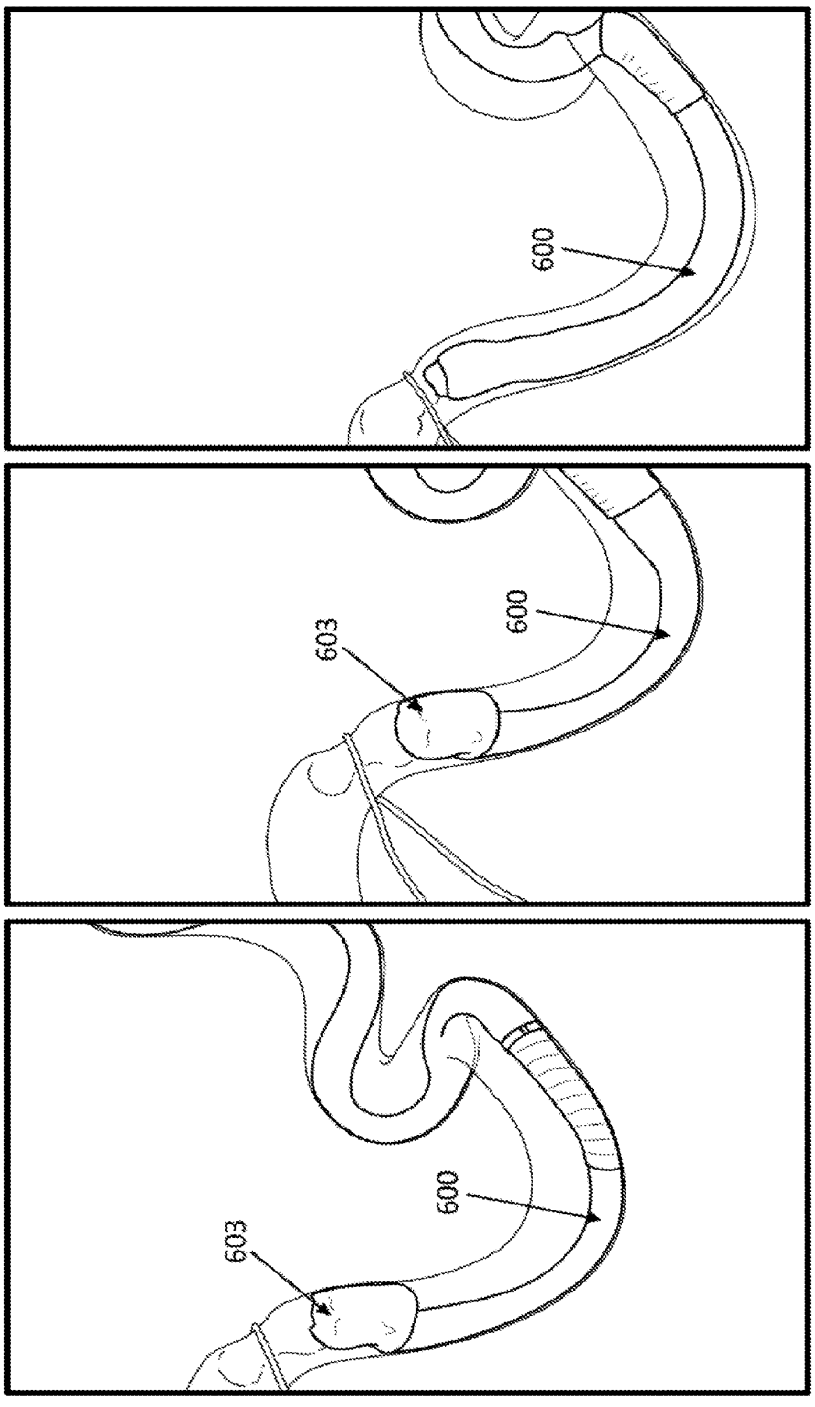


FIG. 6C

FIG. 6B

FIG. 6A

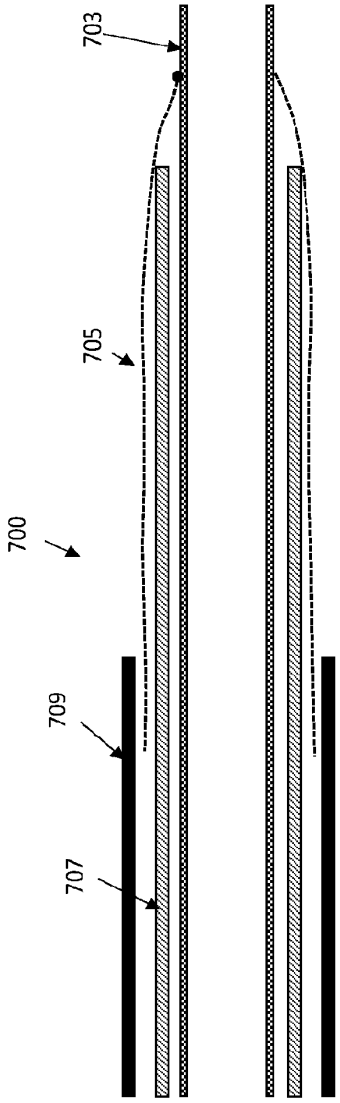


FIG. 7A

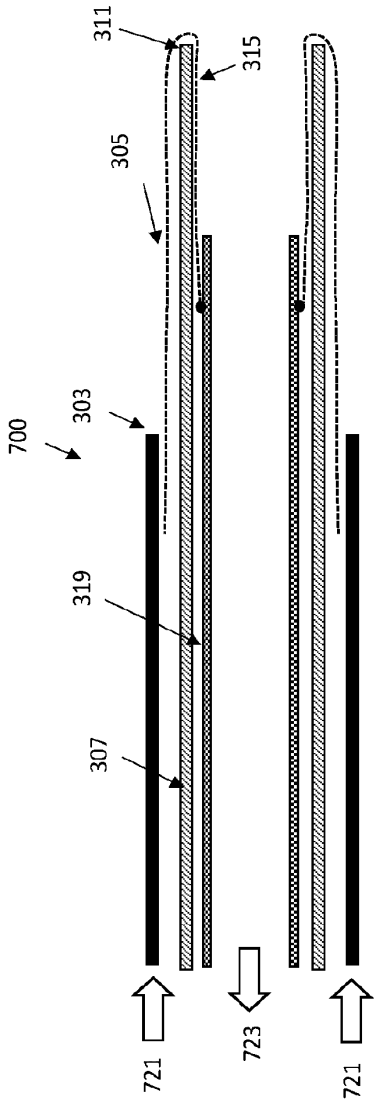


FIG. 7B

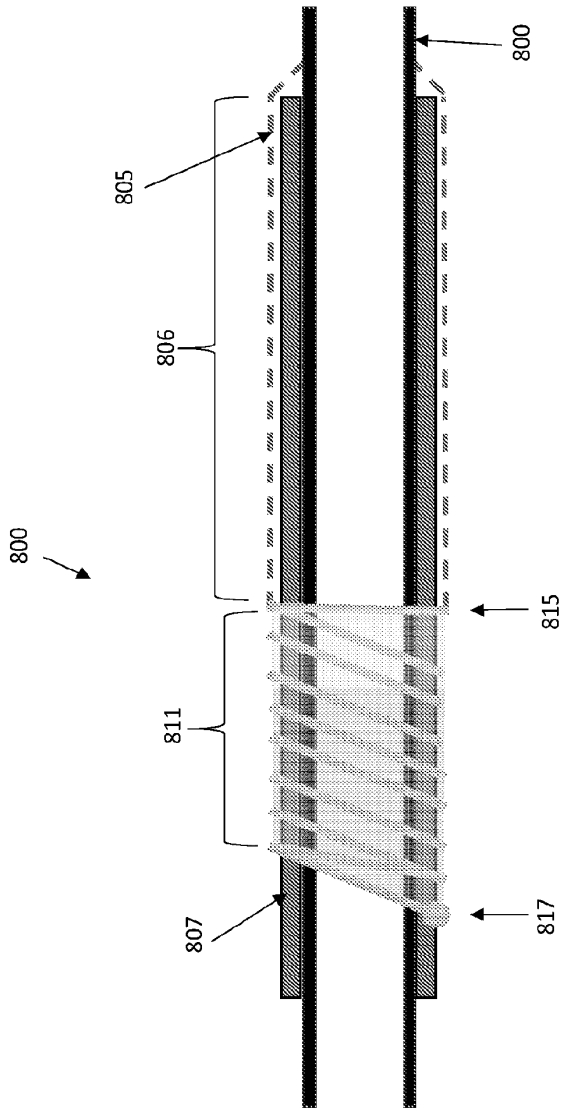
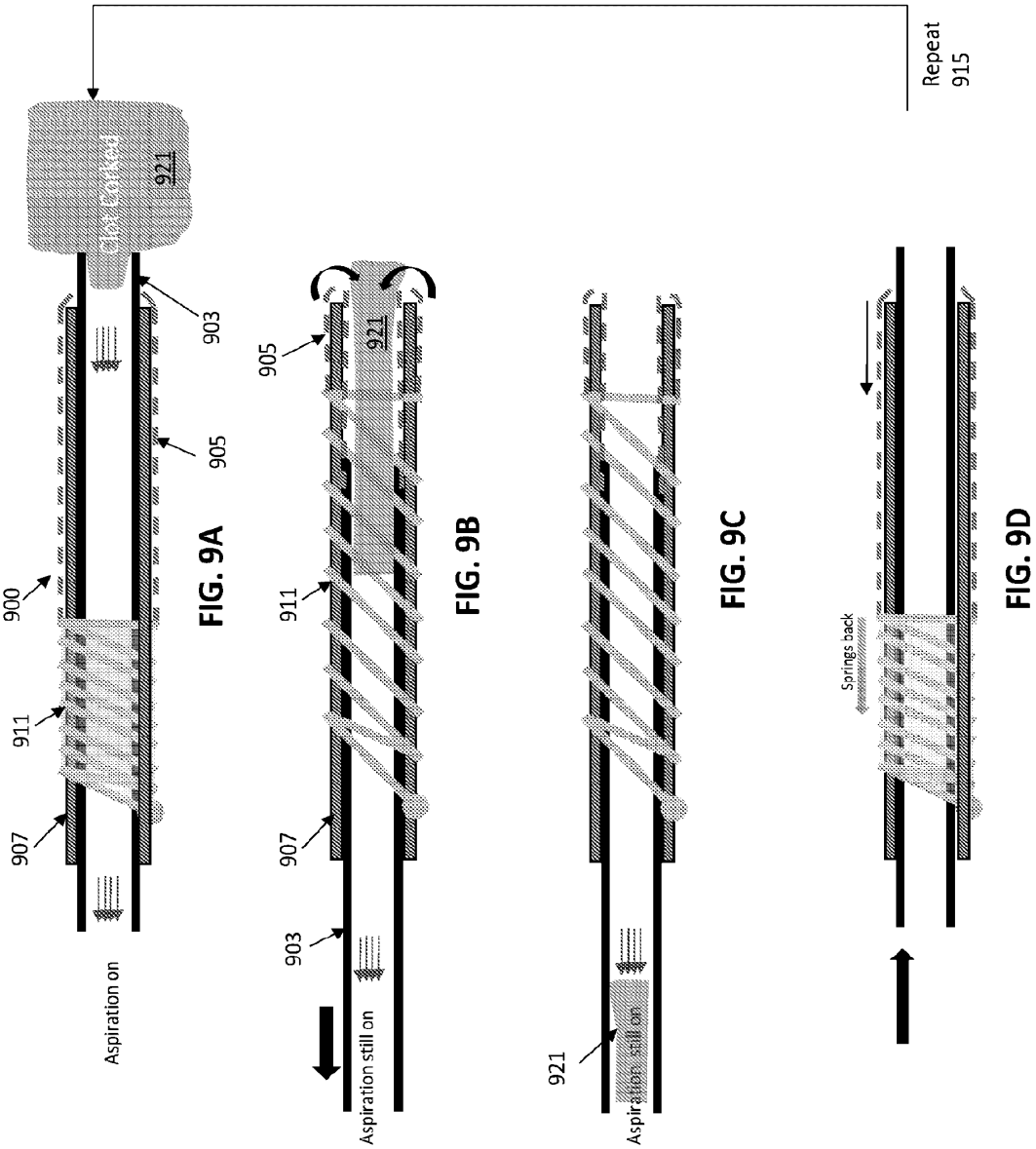


FIG. 8


Repeat
915
Clot Contact
921
903
905
900
911
907
Aspiration on
FIG. 9A
905
921
911
907
903
Aspiration still on
FIG. 9B
921
Aspiration still on
FIG. 9C
Springs back
FIG. 9D

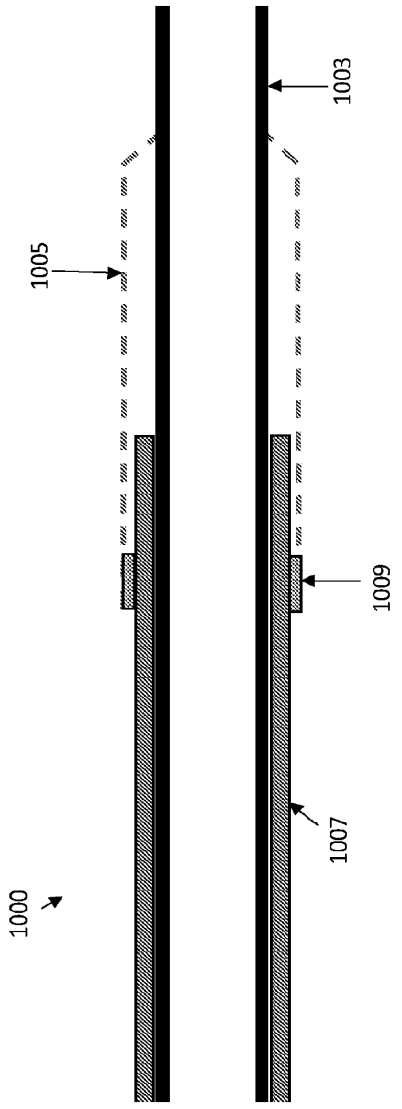


FIG. 10A

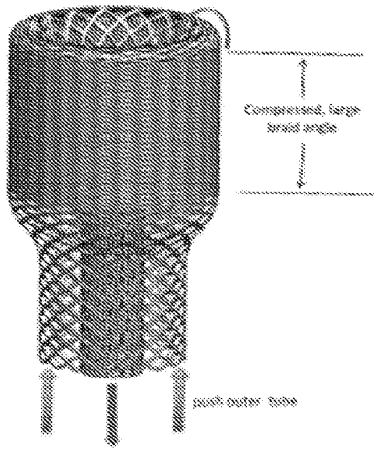


FIG. 10B

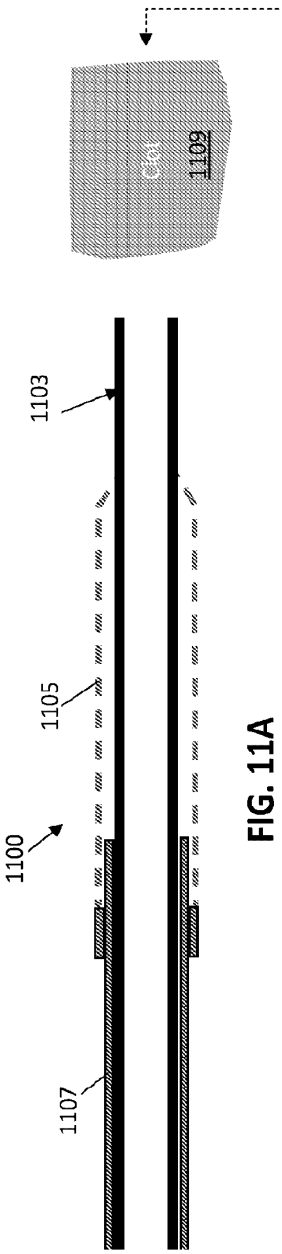


FIG. 11A

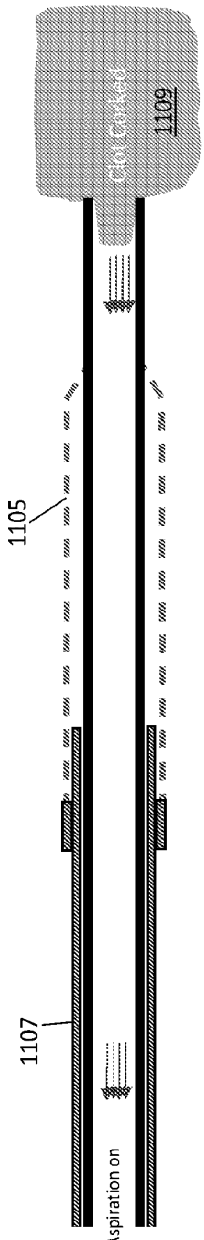


FIG. 11B

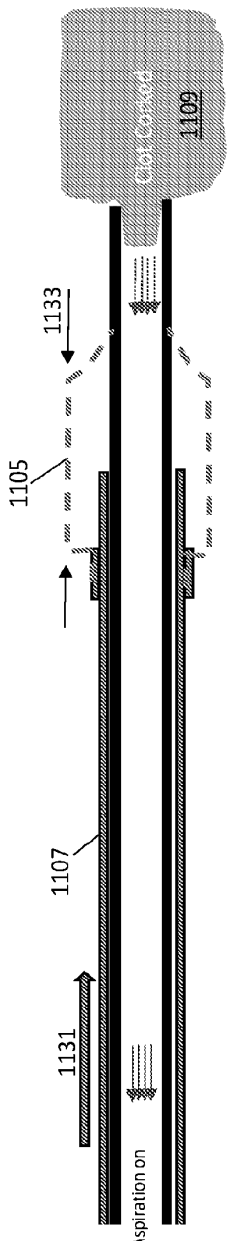


FIG. 11C

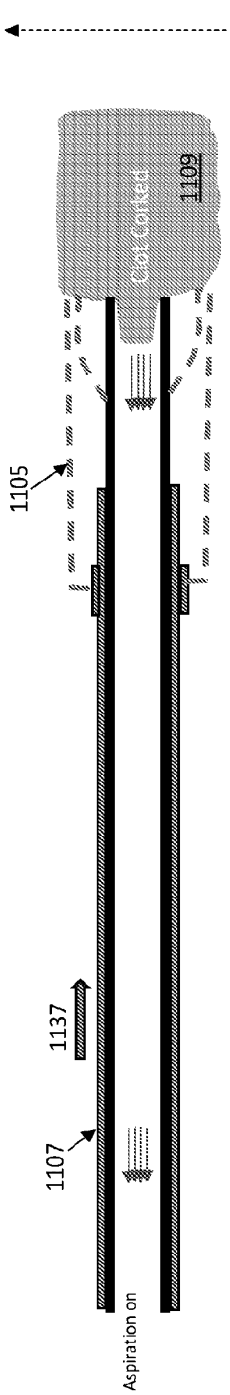


FIG. 11D

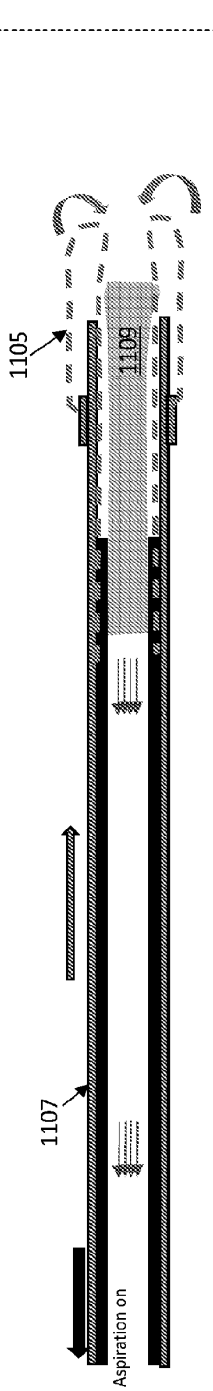


FIG. 11E

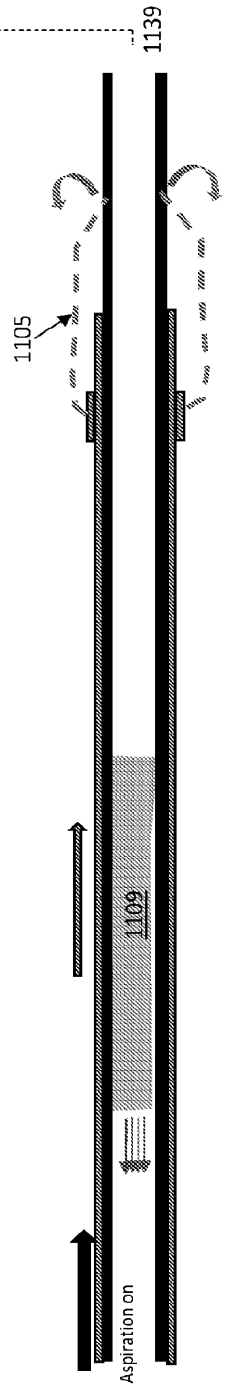


FIG. 11F

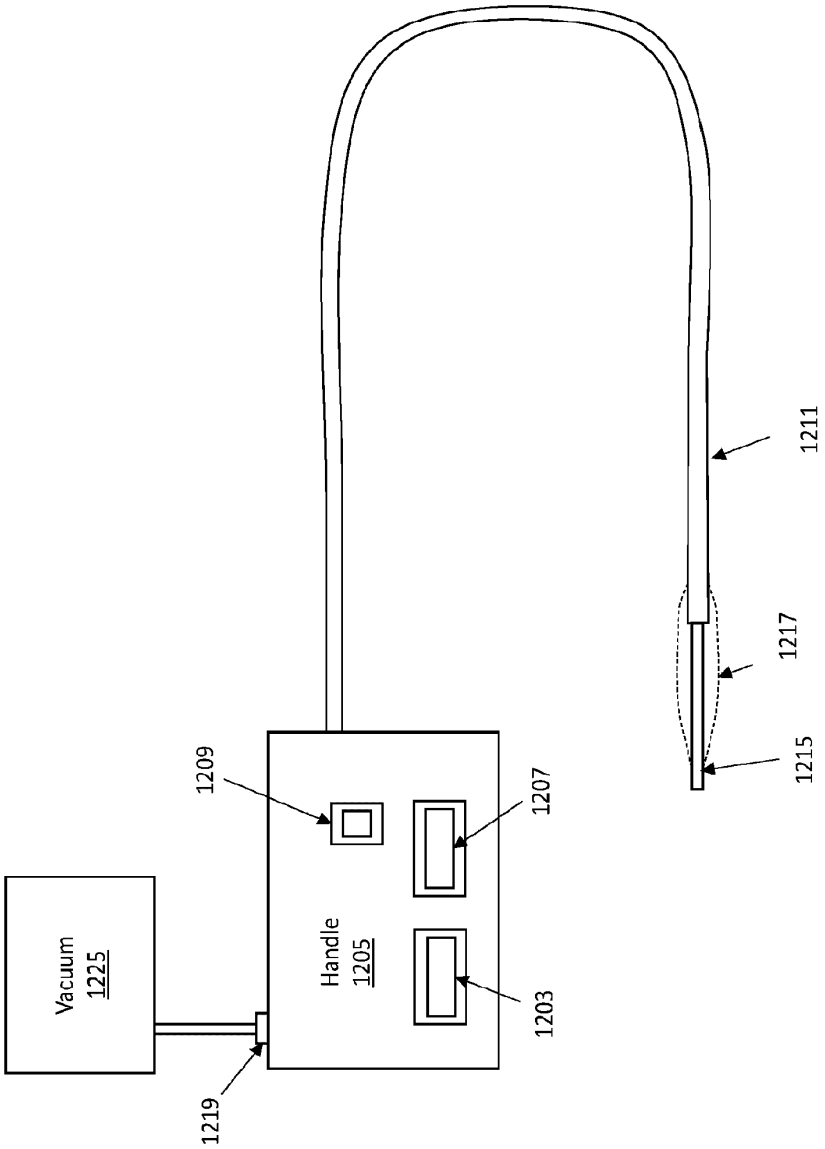


FIG. 12
(not to scale)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/032061

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/22 A61B17/221 A61B17/34
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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.

* 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
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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Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2017/303948 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

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2019/032061

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2017086864 A1	30-03-2017	CN 108348319 A	31-07-2018
		EP 3355829 A1	08-08-2018
		EP 3406208 A1	28-11-2018
		JP 2018529495 A	11-10-2018
		US 9463035 B1	11-10-2016
		US 2017086864 A1	30-03-2017
		WO 2017058280 A1	06-04-2017
US 2017303948 A1	26-10-2017	CN 109890304 A	14-06-2019
		EP 3448280 A2	06-03-2019
		US 2017303948 A1	26-10-2017
		US 2019117244 A1	25-04-2019
		US 2019133622 A1	09-05-2019
		WO 2017189535 A2	02-11-2017
US 5389100 A	14-02-1995	AU 657798 B2	23-03-1995
		CA 2080535 A1	07-05-1993
		DE 69216209 D1	06-02-1997
		DE 69216209 T2	17-04-1997
		EP 0541258 A1	12-05-1993
		JP 2669515 B2	29-10-1997
		JP H05208051 A	20-08-1993
		US 5389100 A	14-02-1995
US 2013116721 A1	09-05-2013	CN 102958457 A	06-03-2013
		EP 2589344 A1	08-05-2013
		JP 4846044 B1	28-12-2011
		JP 2012010880 A	19-01-2012
		US 2013116721 A1	09-05-2013
		WO 2012001826 A1	05-01-2012

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

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

ABSTRACT

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

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STEERABLE MEDICAL DELIVERY DEVICES AND METHODS OF USE

CROSS-REFERENCE

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

BACKGROUND OF THE INVENTION

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

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

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

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

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

SUMMARY OF THE INVENTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

INCORPORATION BY REFERENCE

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

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] The novel features of the invention are set forth with particularity in the disclosure herein. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the disclosure are utilized, and the accompanying drawings of which:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DETAILED DESCRIPTION OF THE INVENTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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Claims

1. A steerable medical device, comprising:

a steerable portion;

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

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

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

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

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

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

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

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

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

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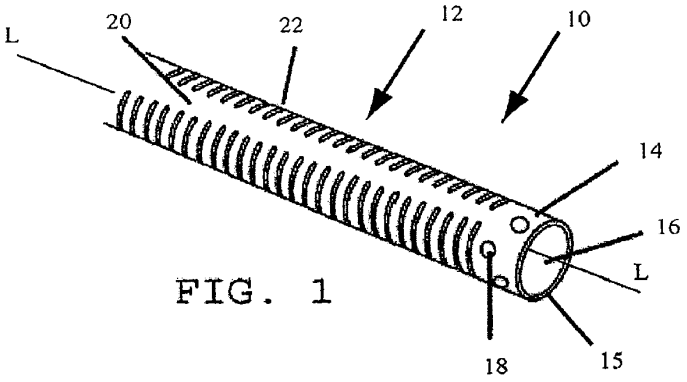

FIG. 1

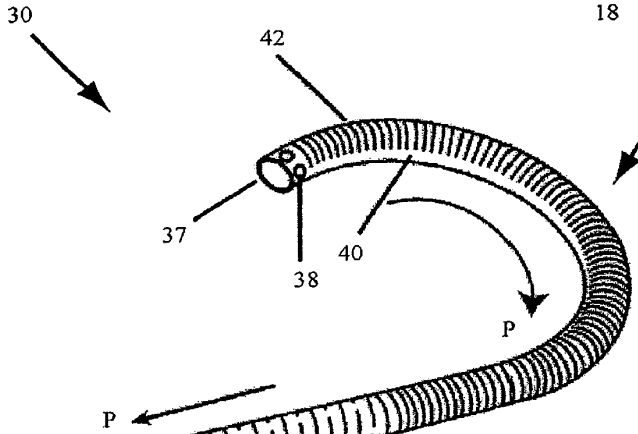

FIG. 2a

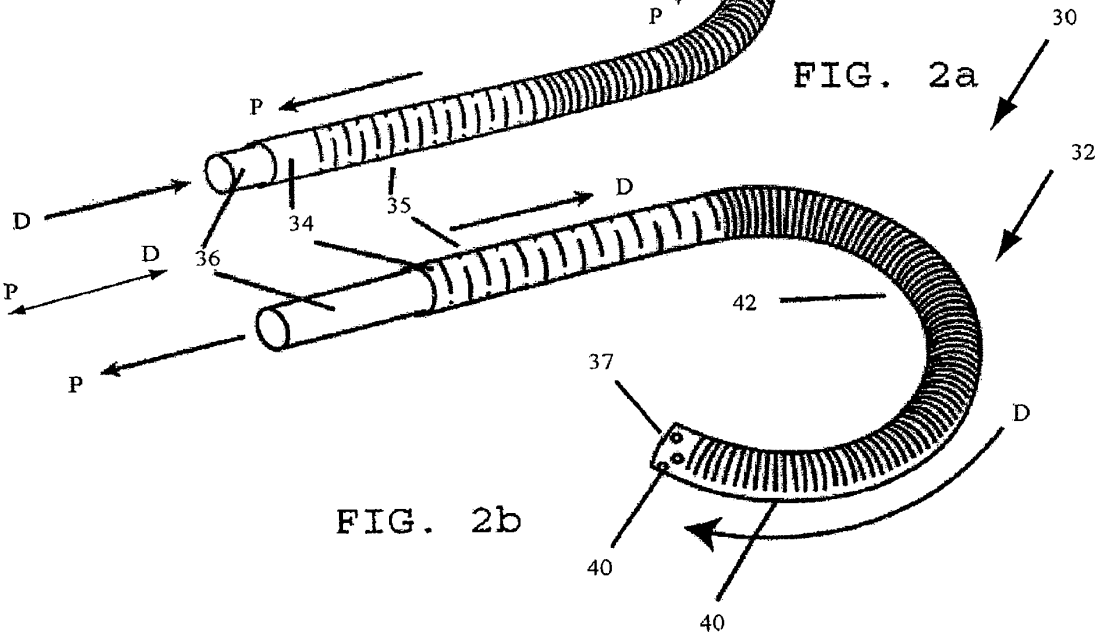

FIG. 2b

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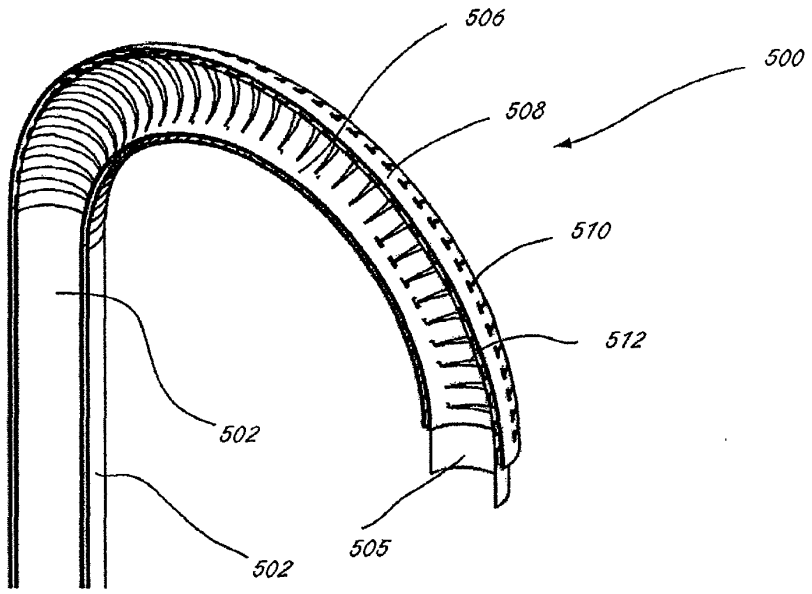

Fig 2e

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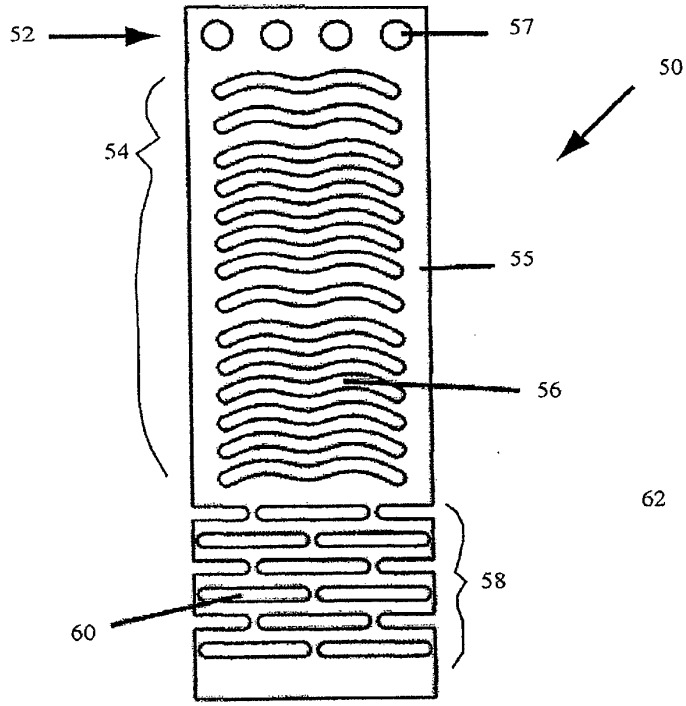

FIG. 3

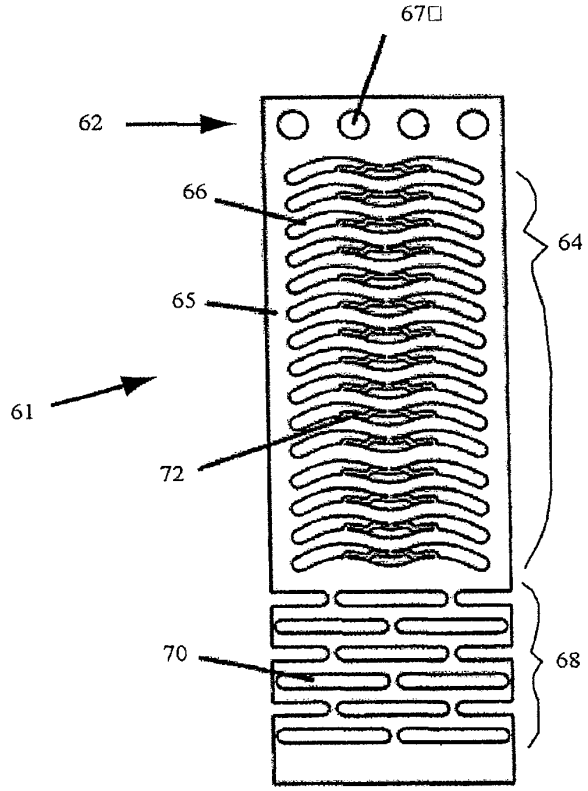

FIG. 4

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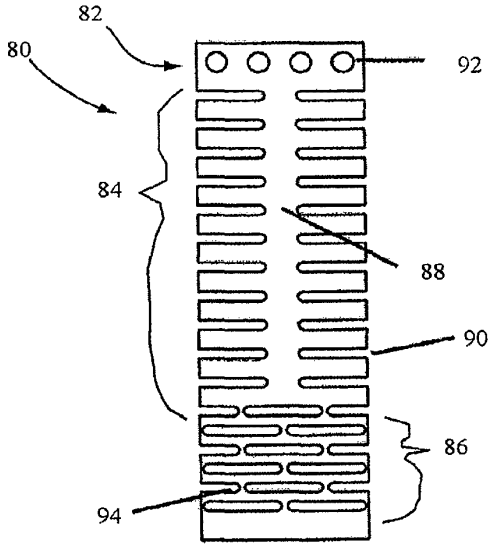

FIG. 5

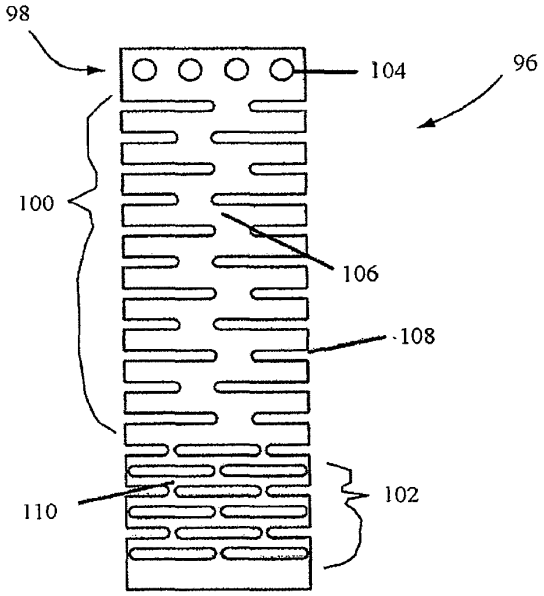

FIG. 6

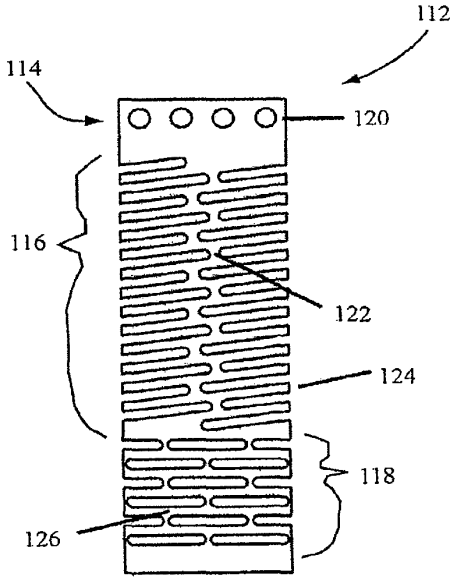

FIG. 7a

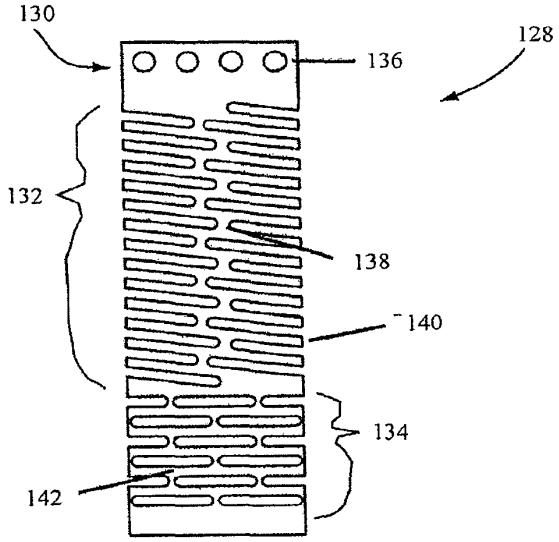

FIG. 7b

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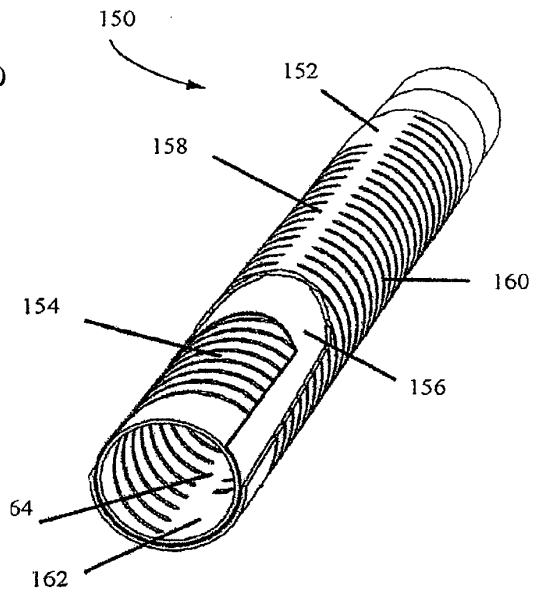

FIG. 8

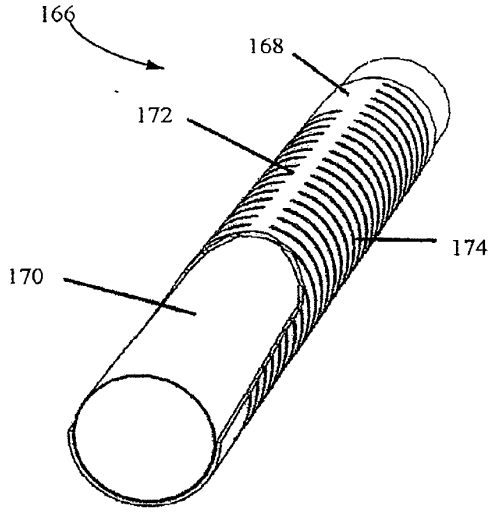

FIG. 9

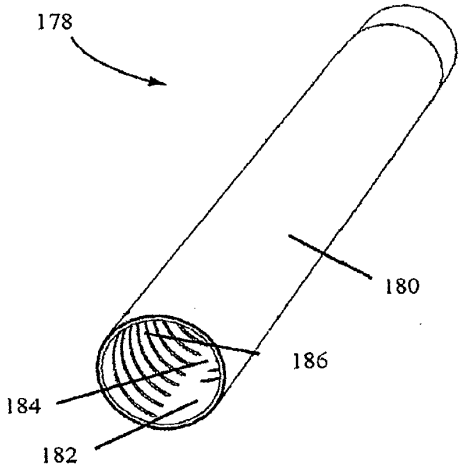

FIG. 10

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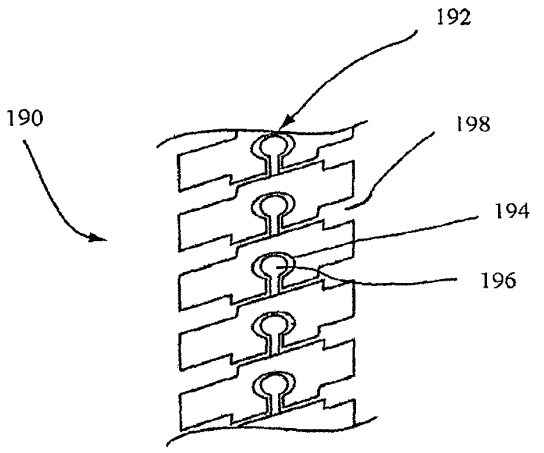

Fig 11A

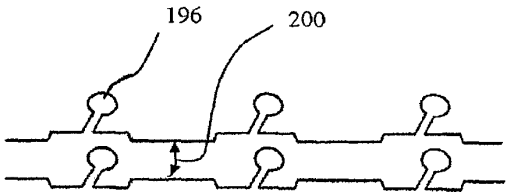

Fig 11B

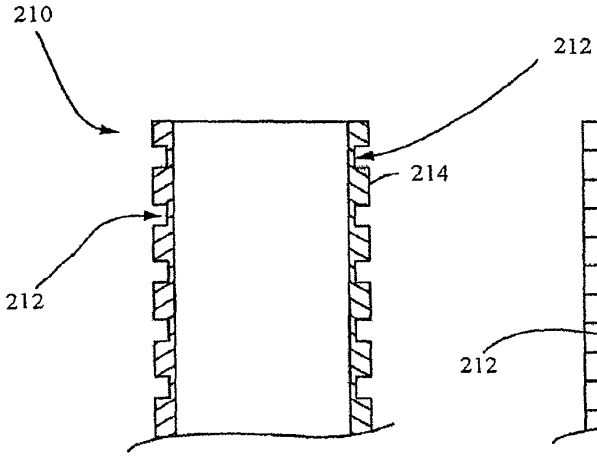

Fig 12A

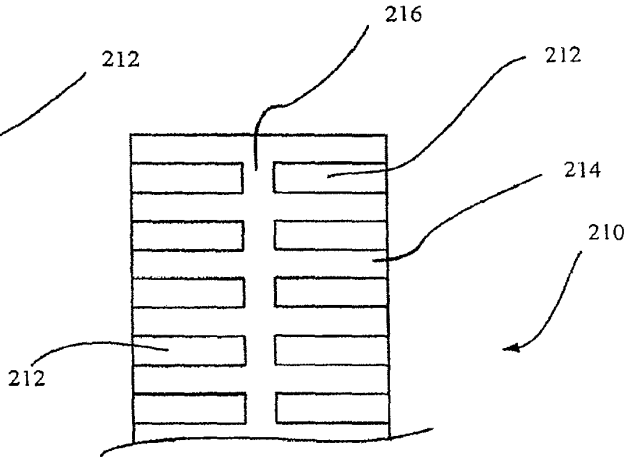

Fig 12B

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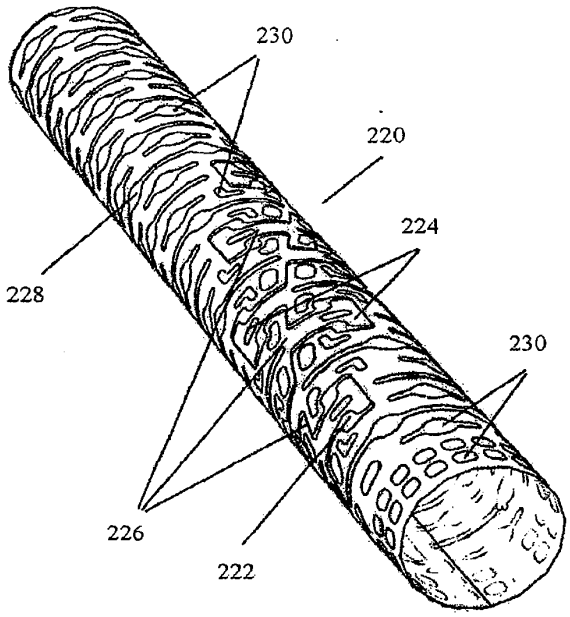

Fig 13a

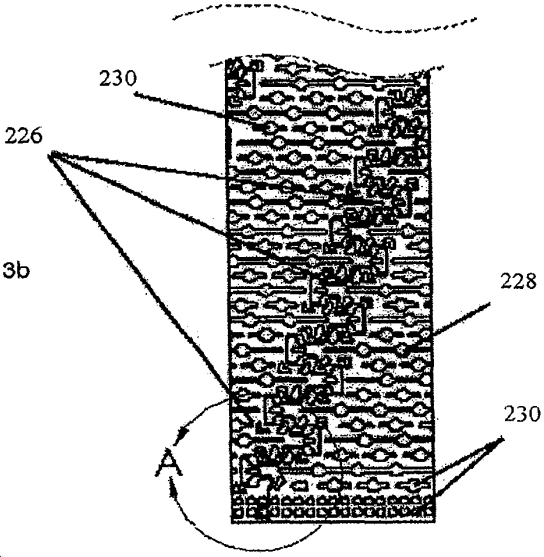

Fig 13b

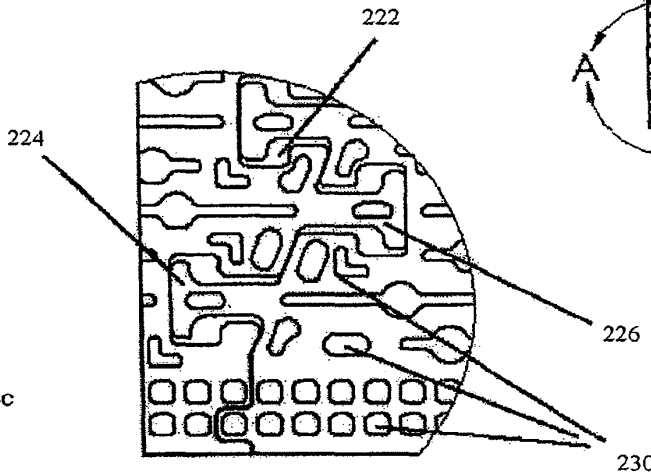

Fig 13c

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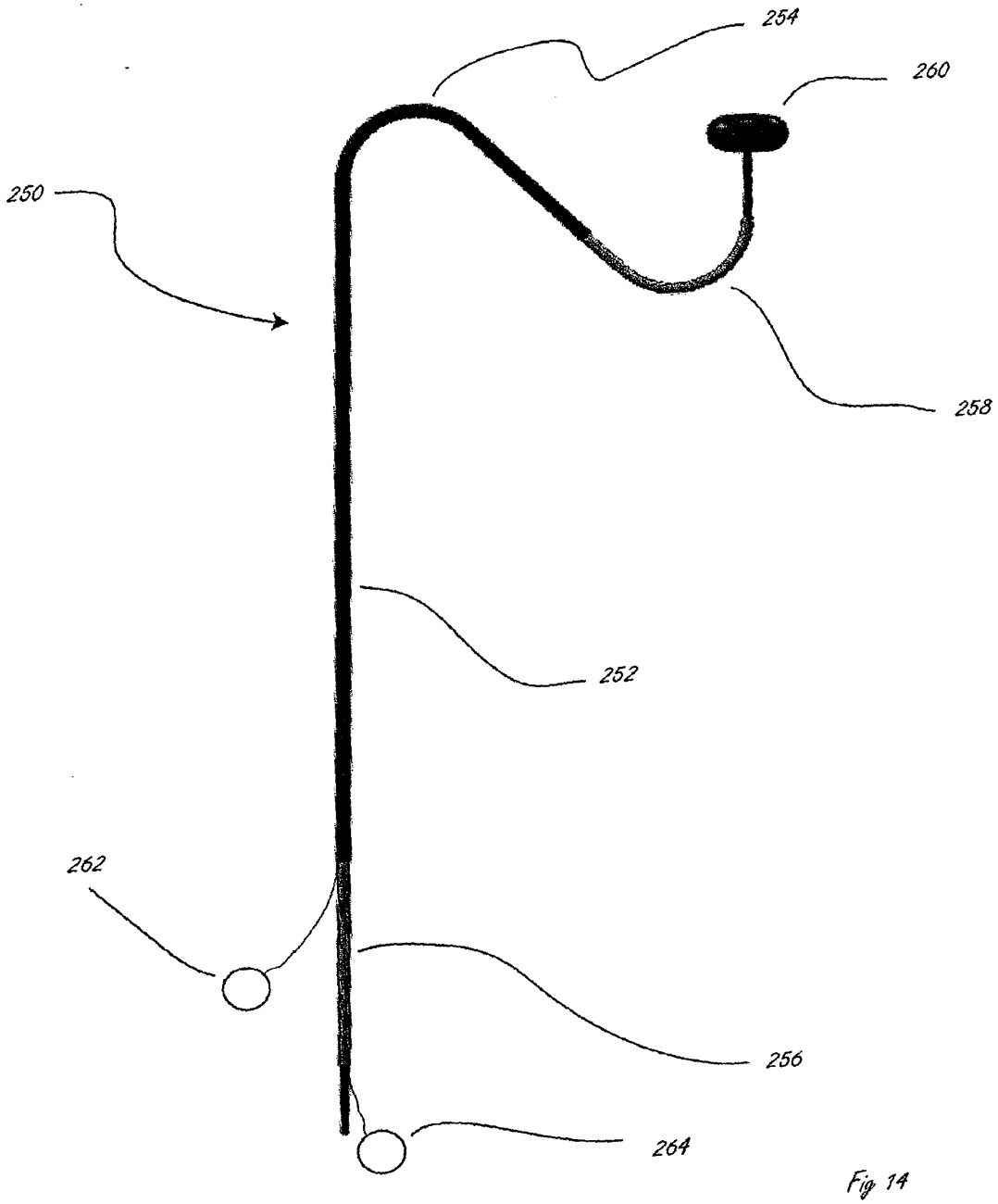

Fig 14

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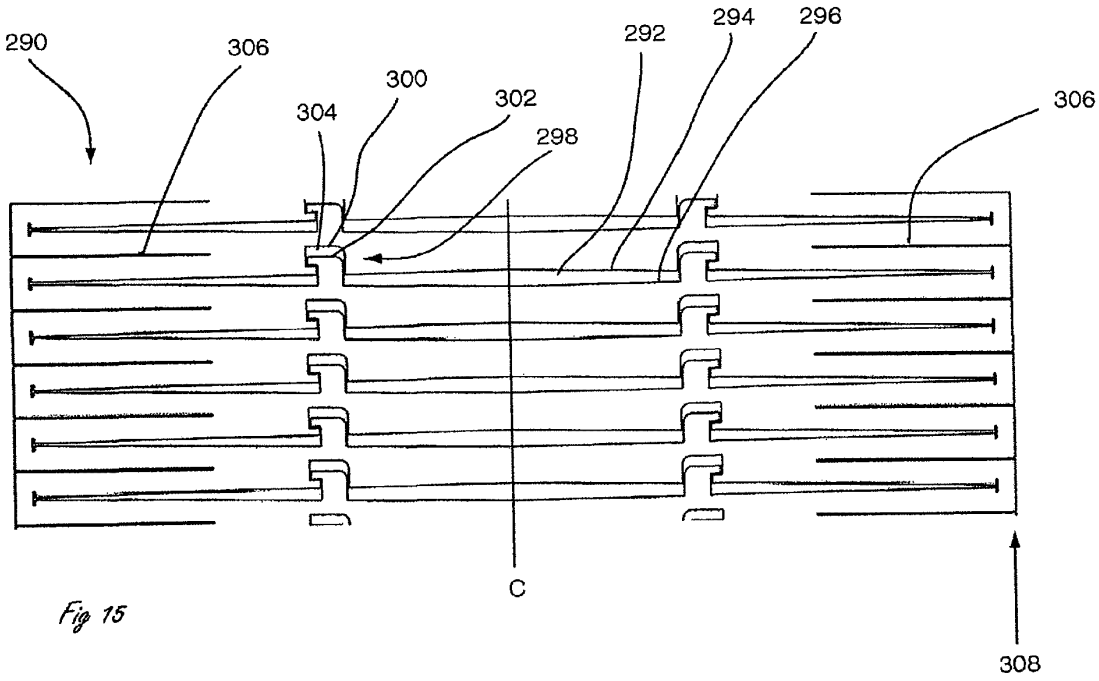

Fig 15

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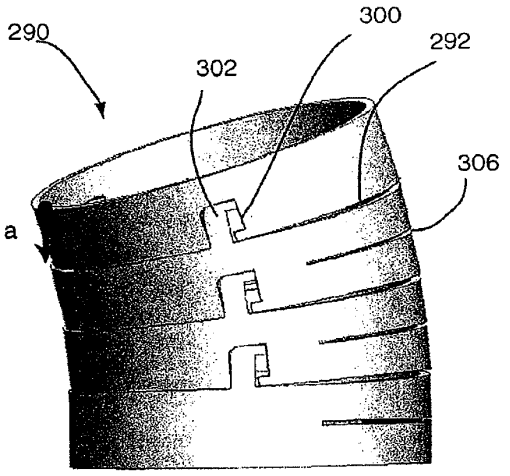

Fig 16a

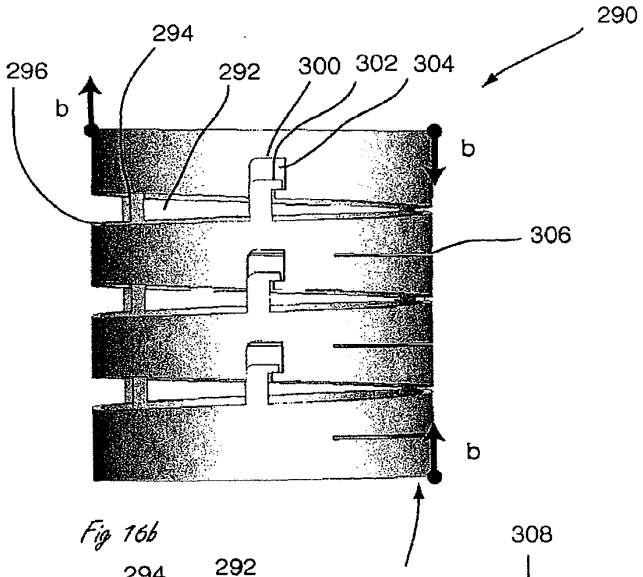

Fig 16b

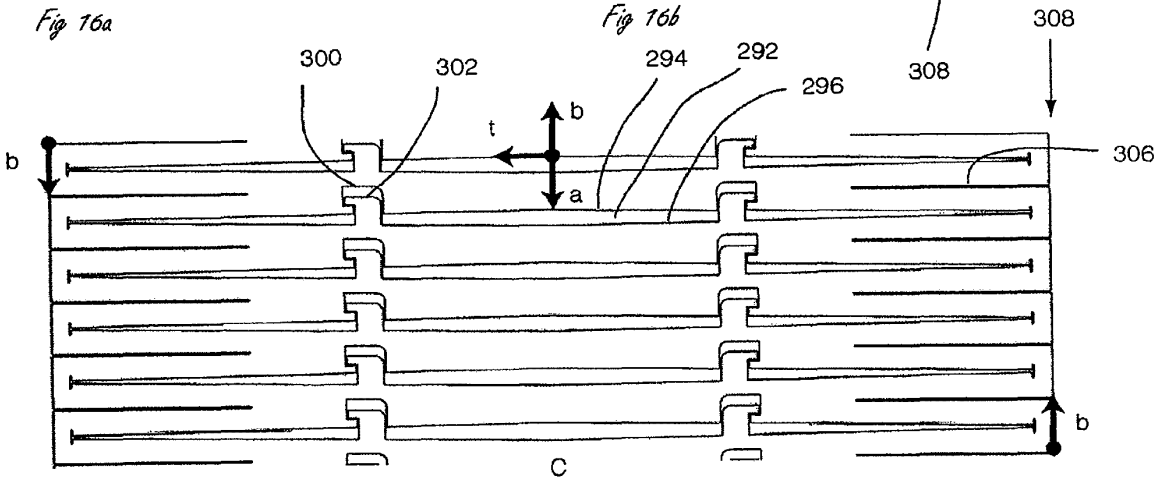

Fig 16c

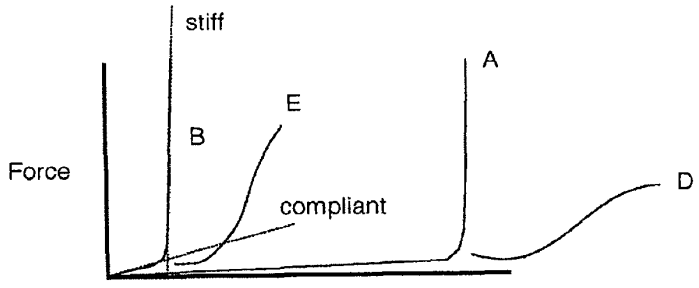

Fig 17

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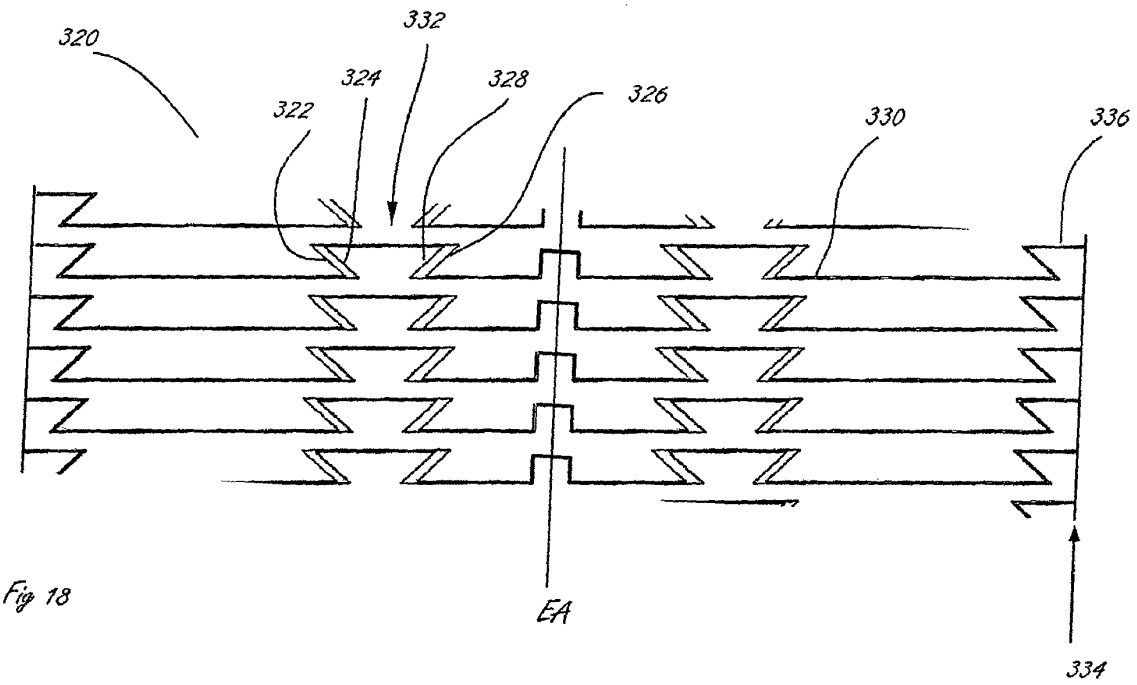

Fig 18

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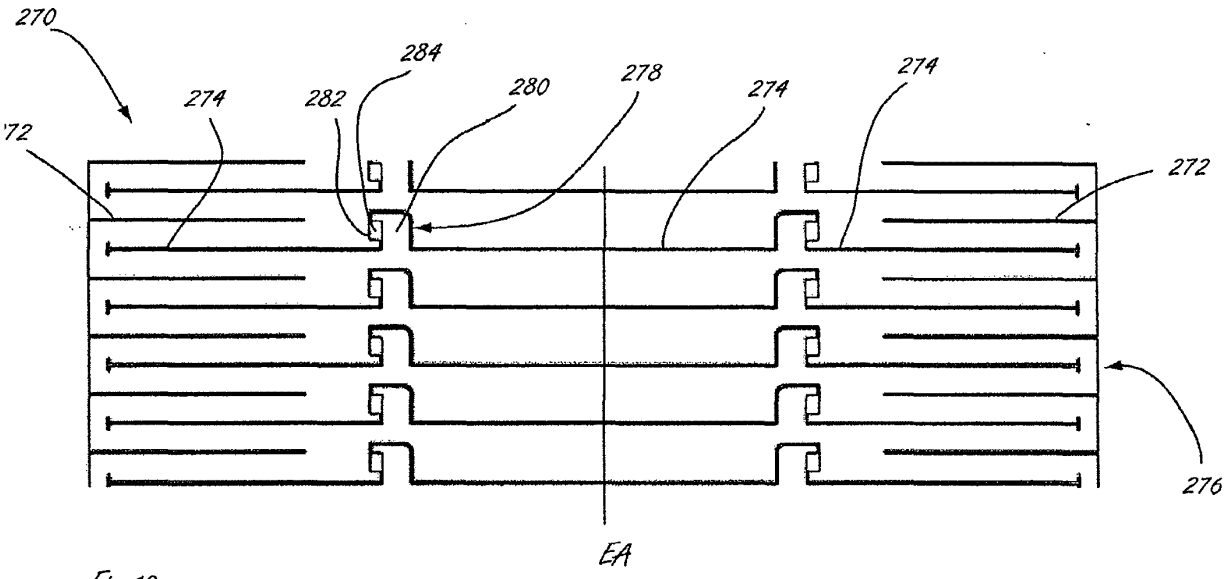

Fig 19

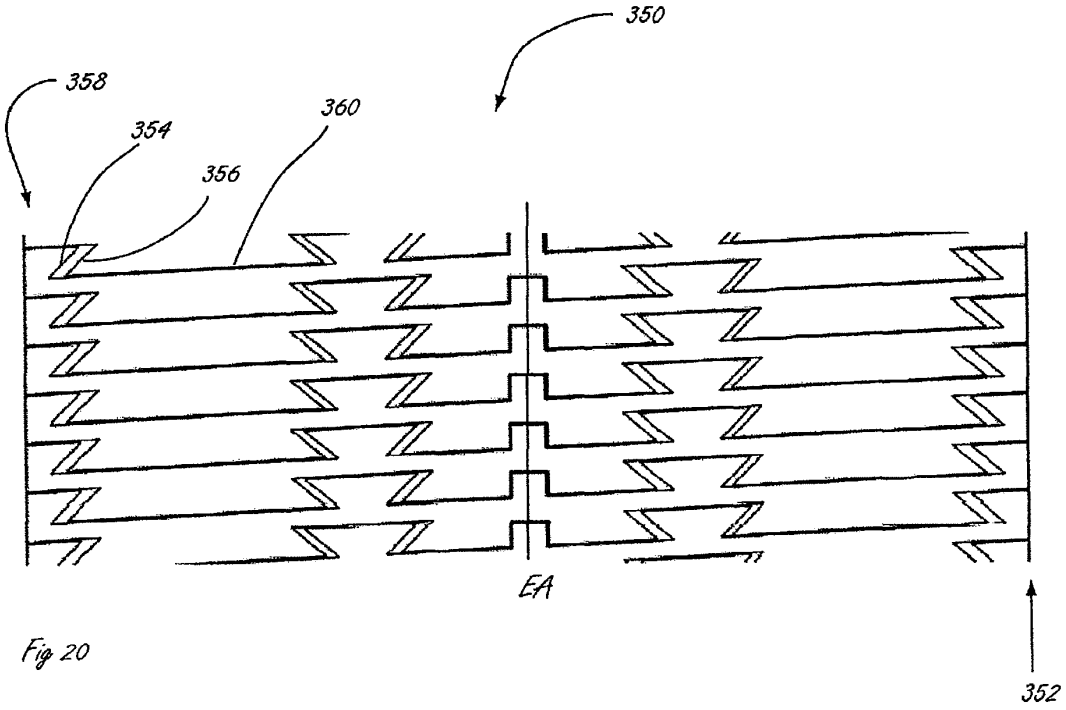

Fig 20

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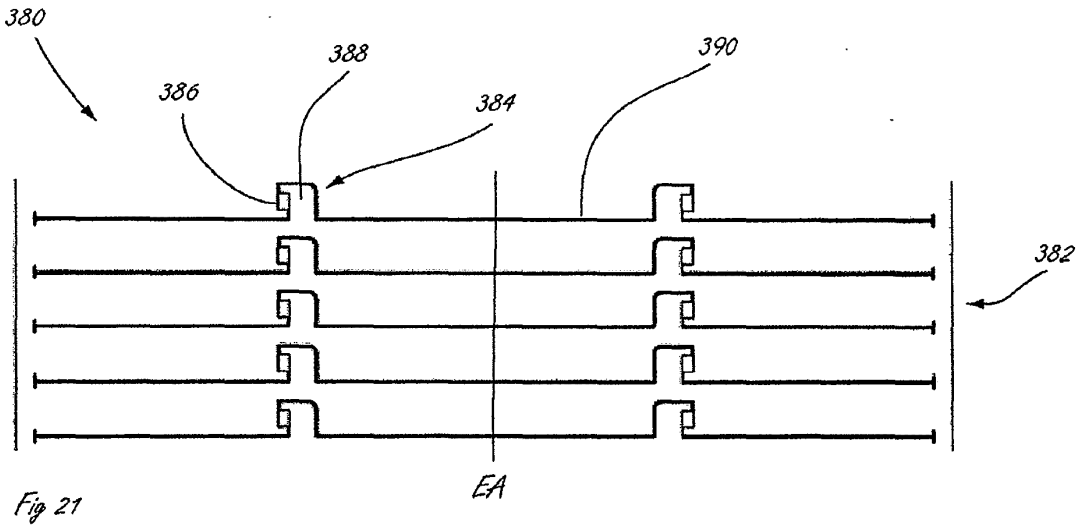

Fig 21

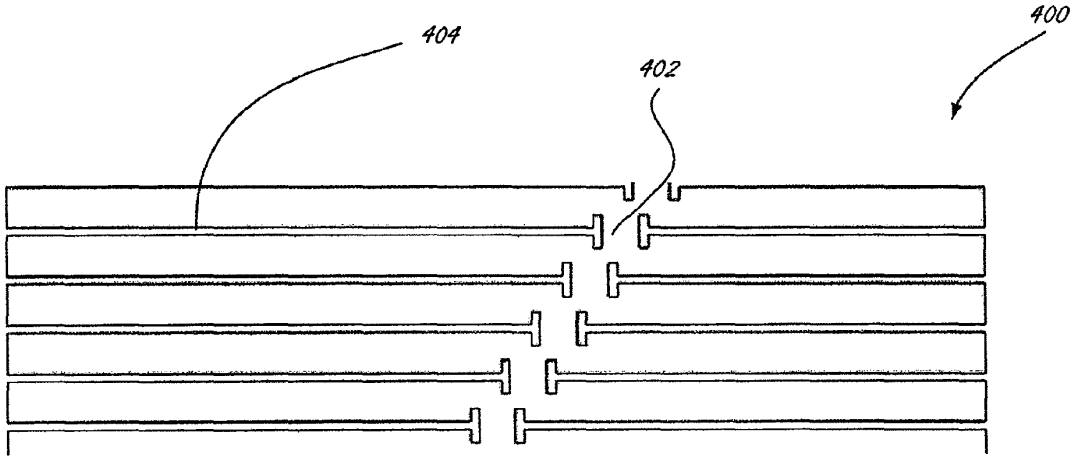

Fig 22

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Fig 23

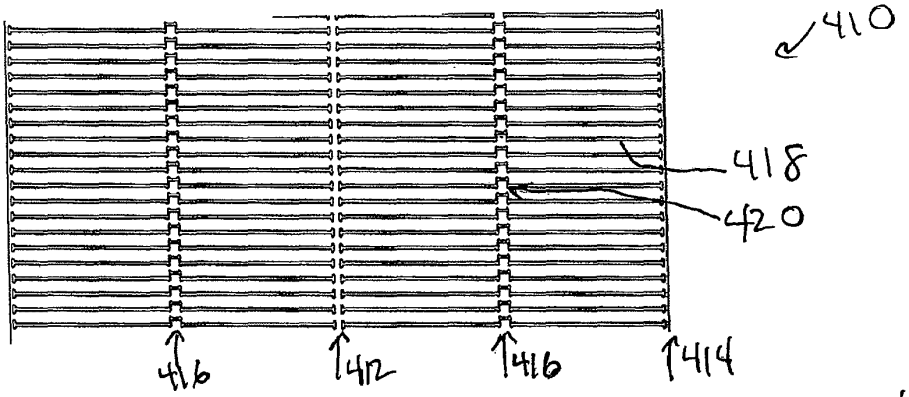


Fig 24

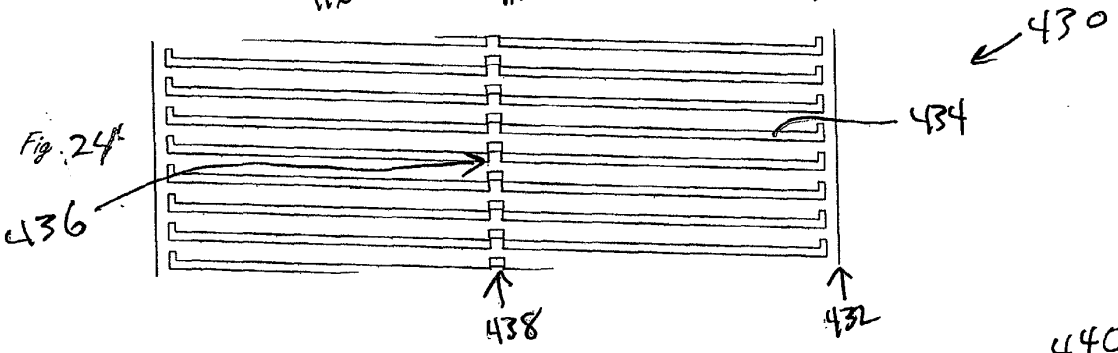


Fig 25

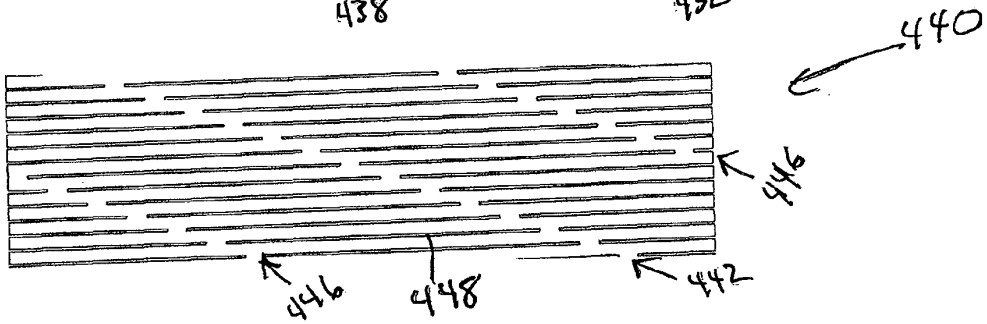
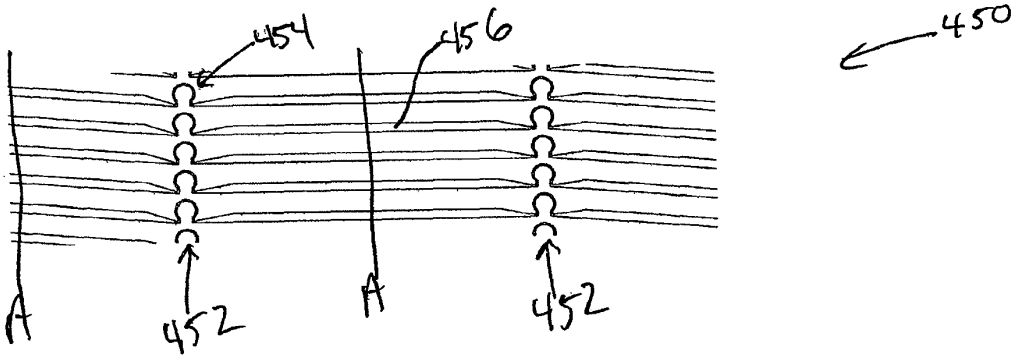


Fig 26



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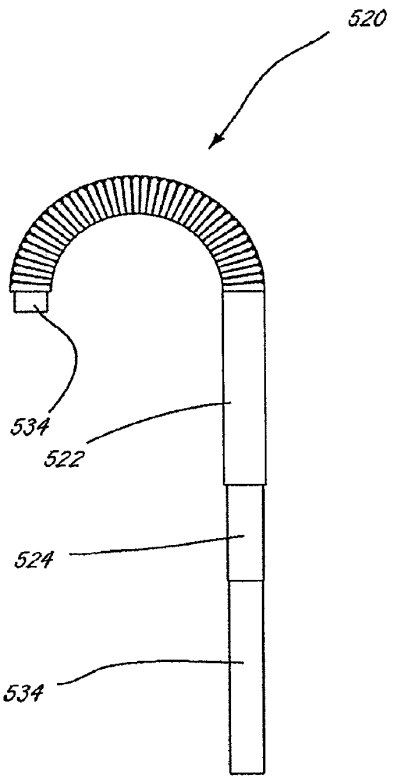

Fig 27

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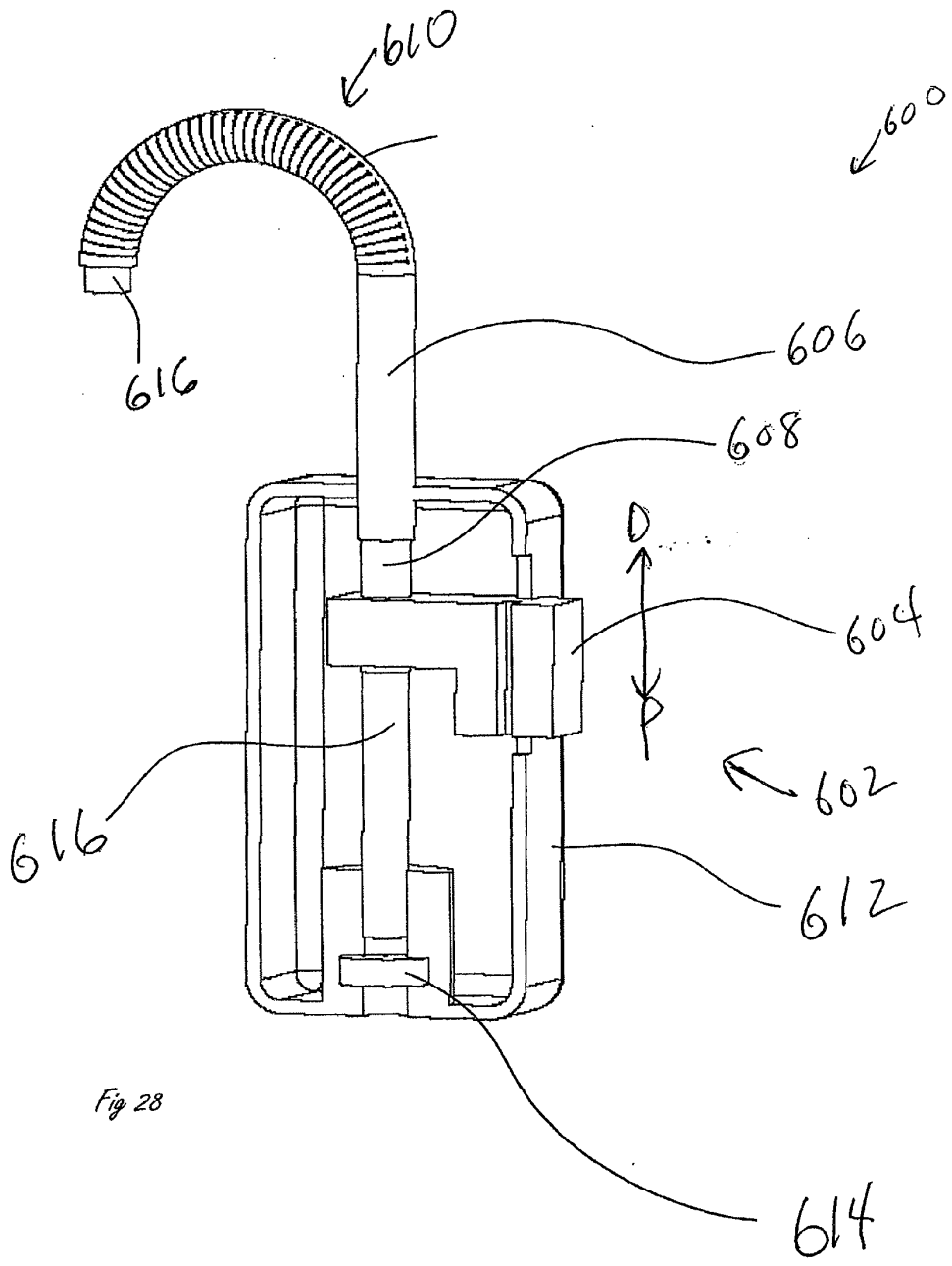

Fig 28

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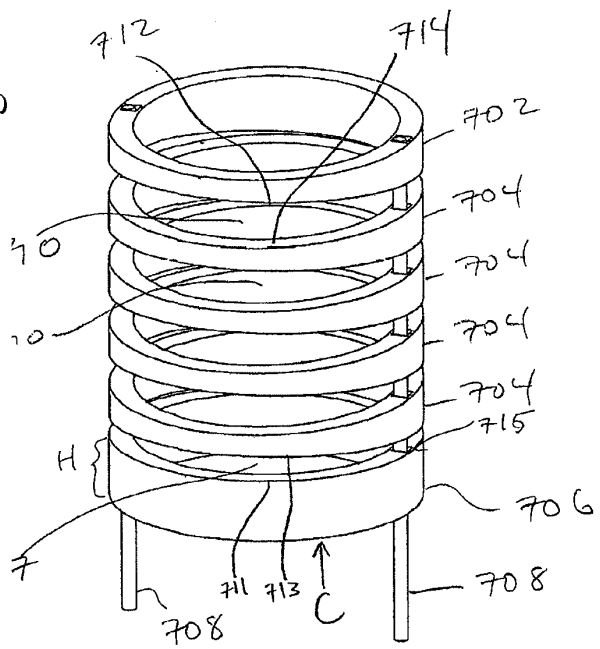

FIG. 29A

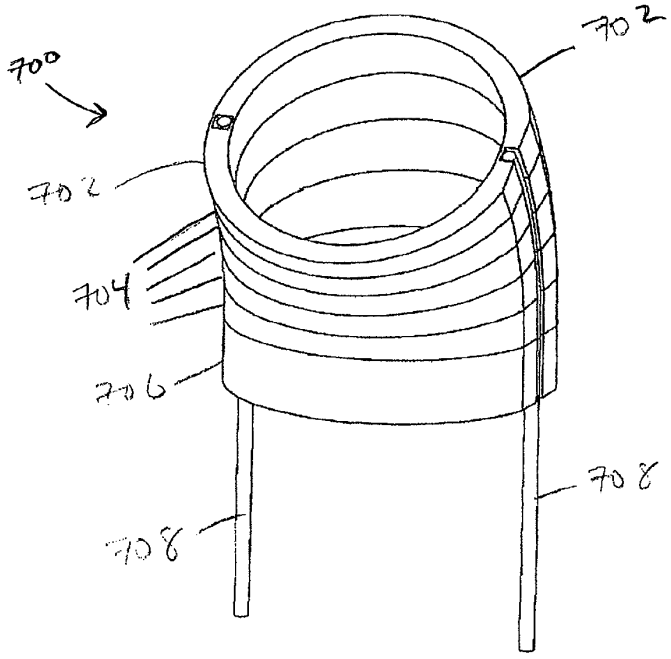

FIG. 29B

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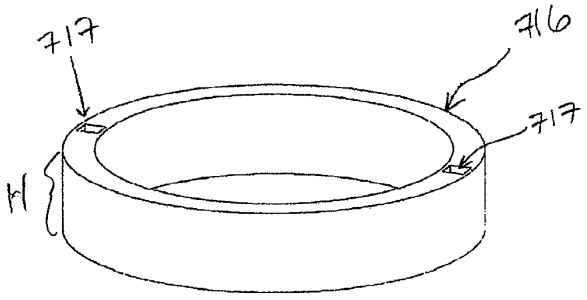

FIG. 30A

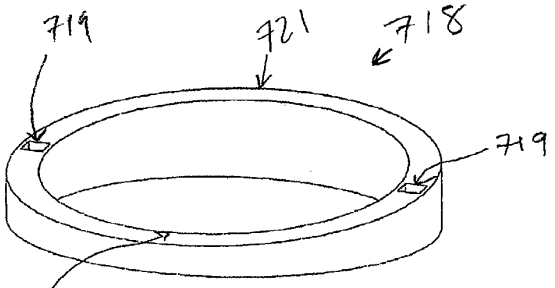

FIG. 30B

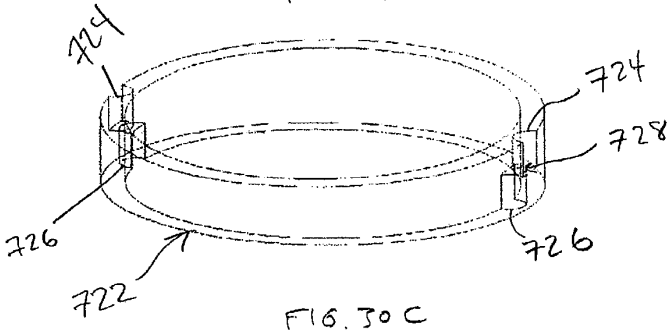

FIG. 30C

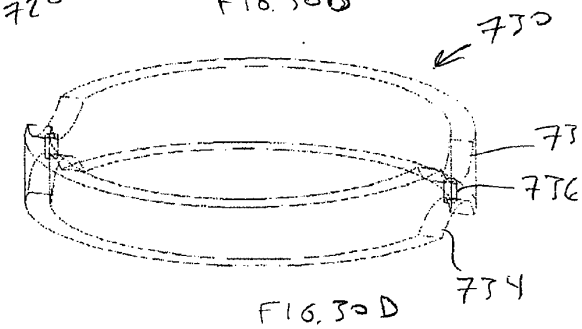

FIG. 30D

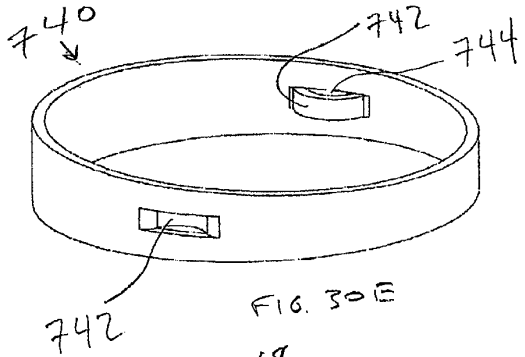

FIG. 30E

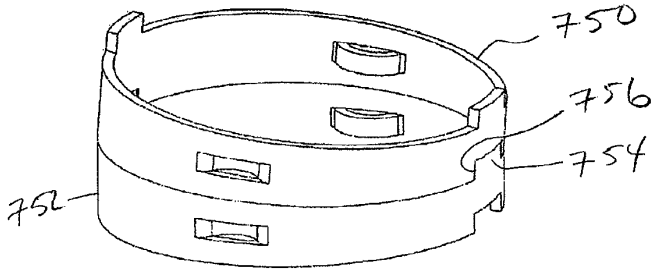

FIG. 30F

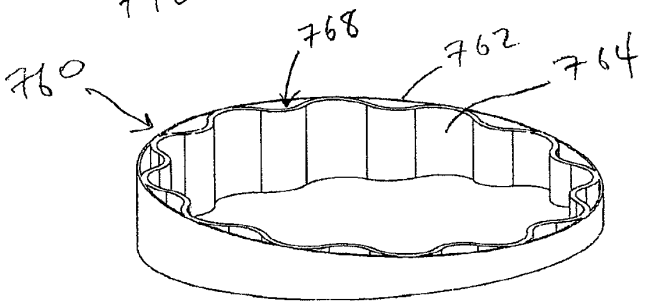

FIG. 30G

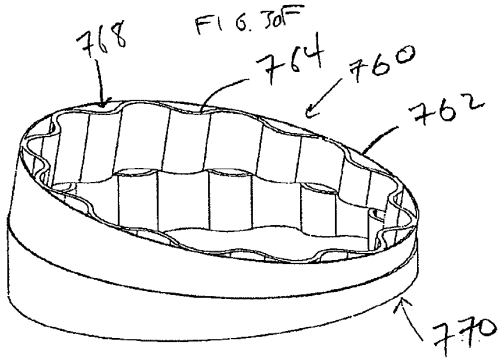

FIG. 30H

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

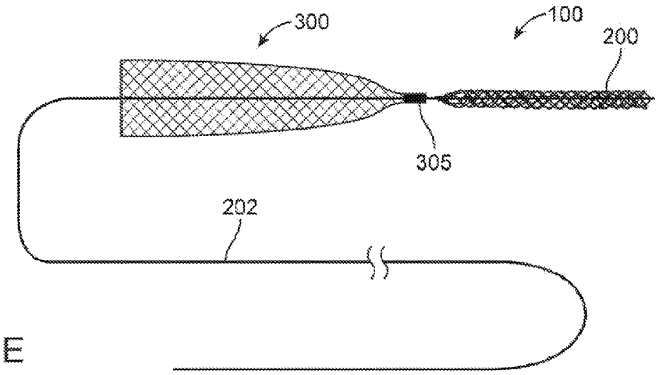

FIG. 2E

(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.

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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.

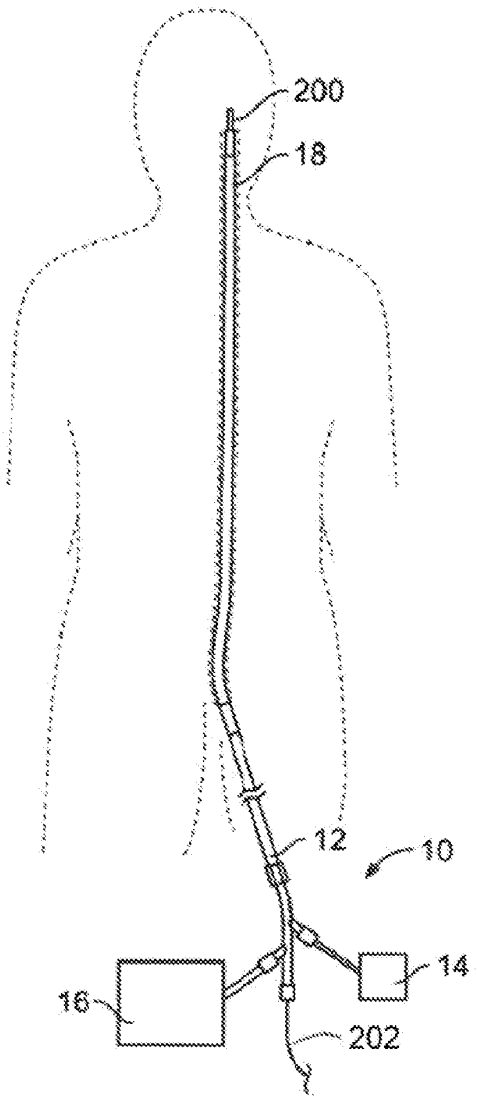


FIG.1

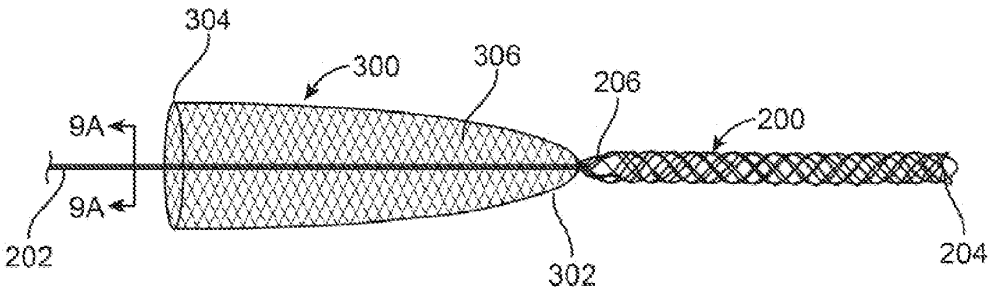


FIG. 2A

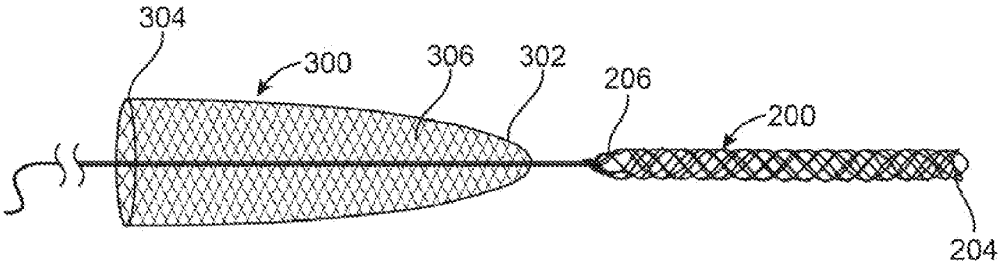


FIG. 2B

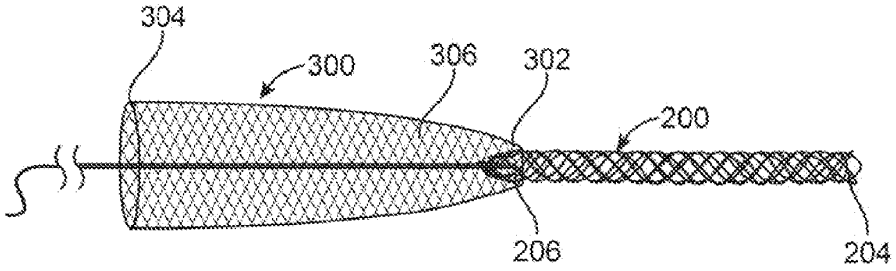


FIG. 2C

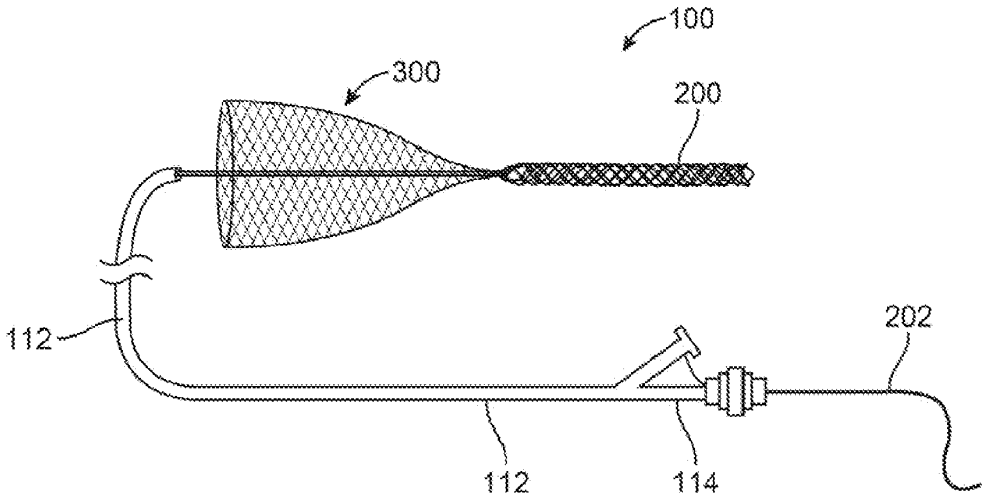


FIG. 2D

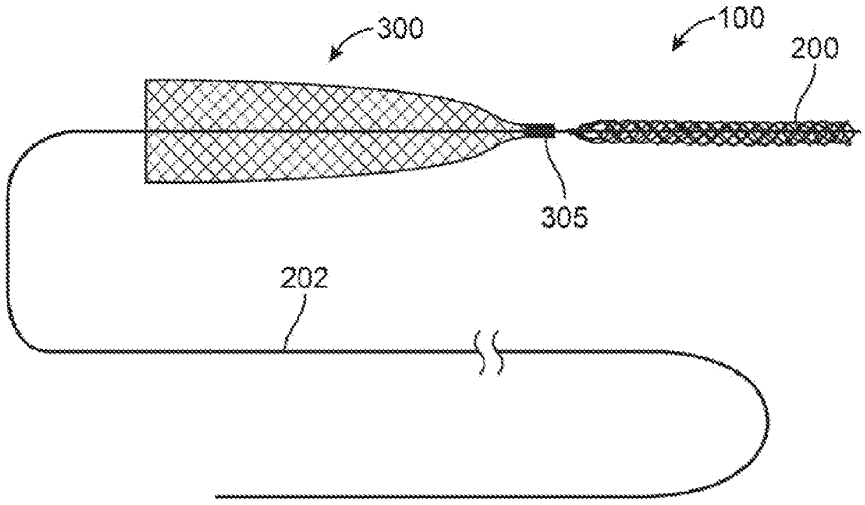


FIG. 2E

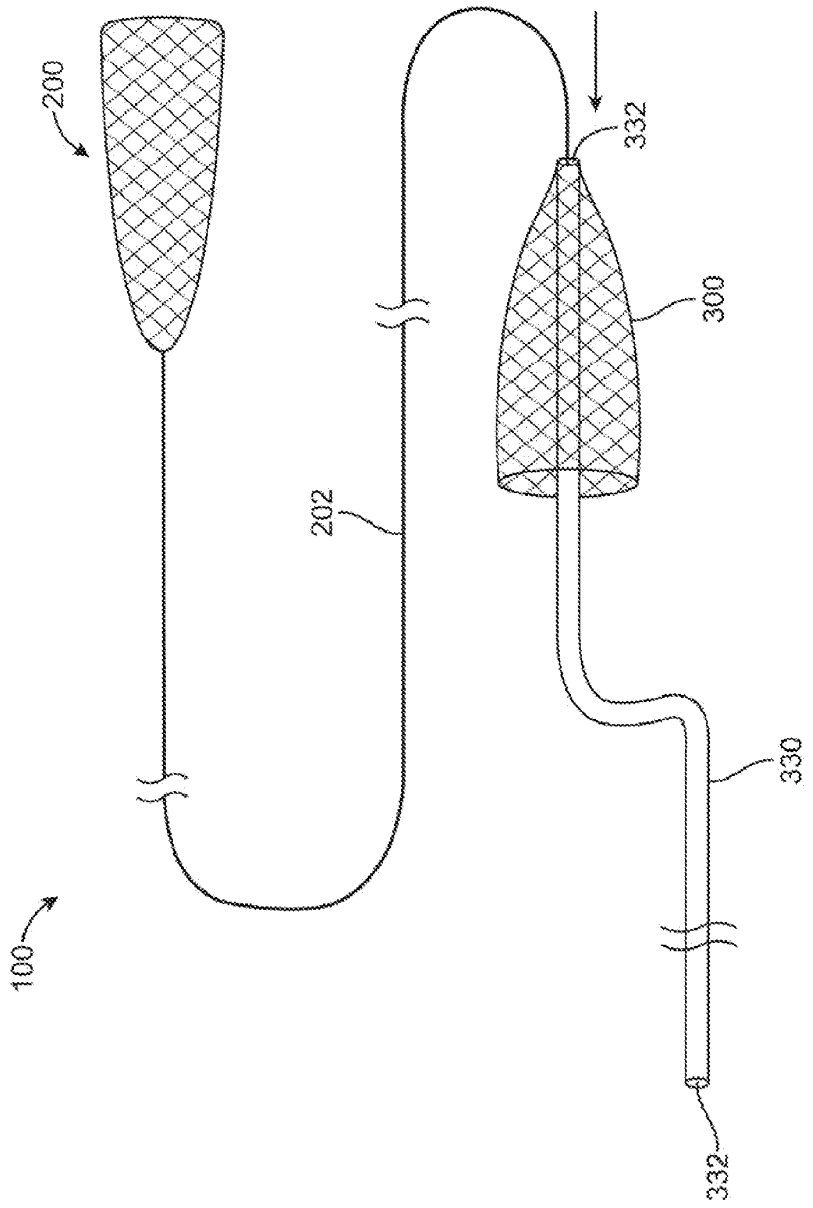


FIG. 2F

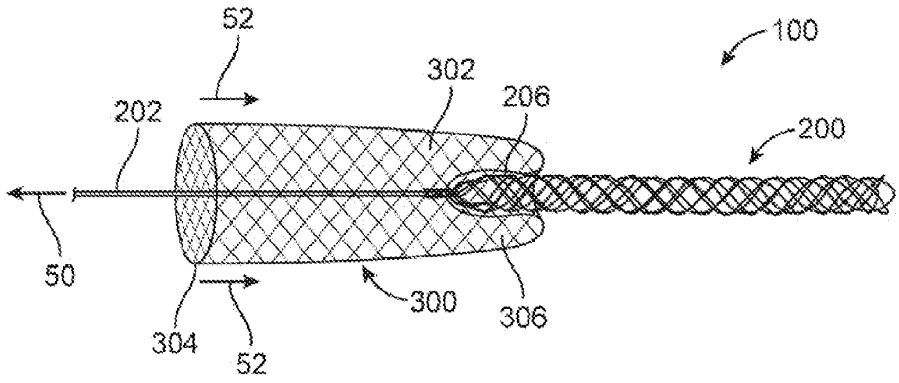


FIG. 3A

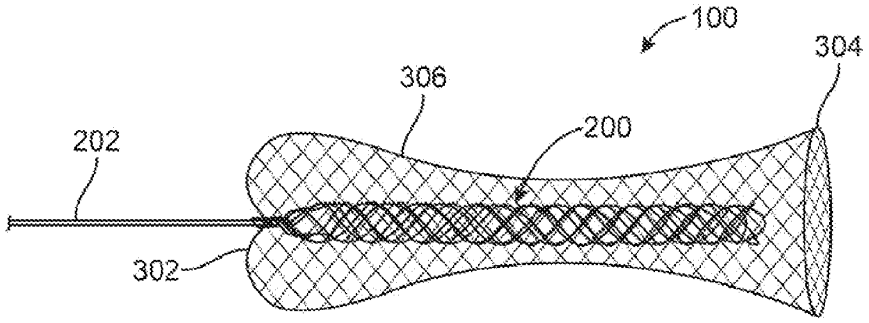


FIG. 3B

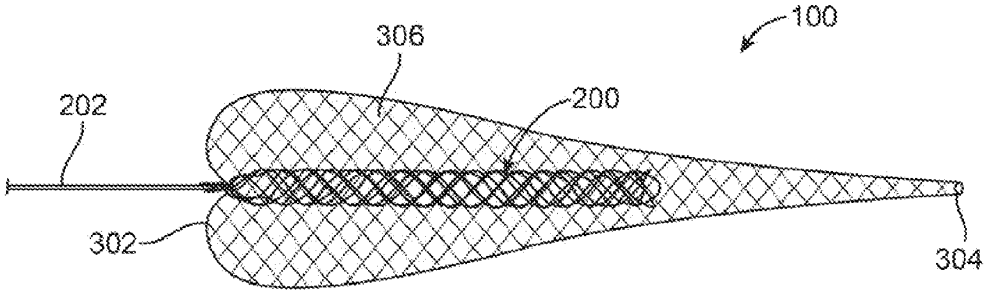


FIG. 3C

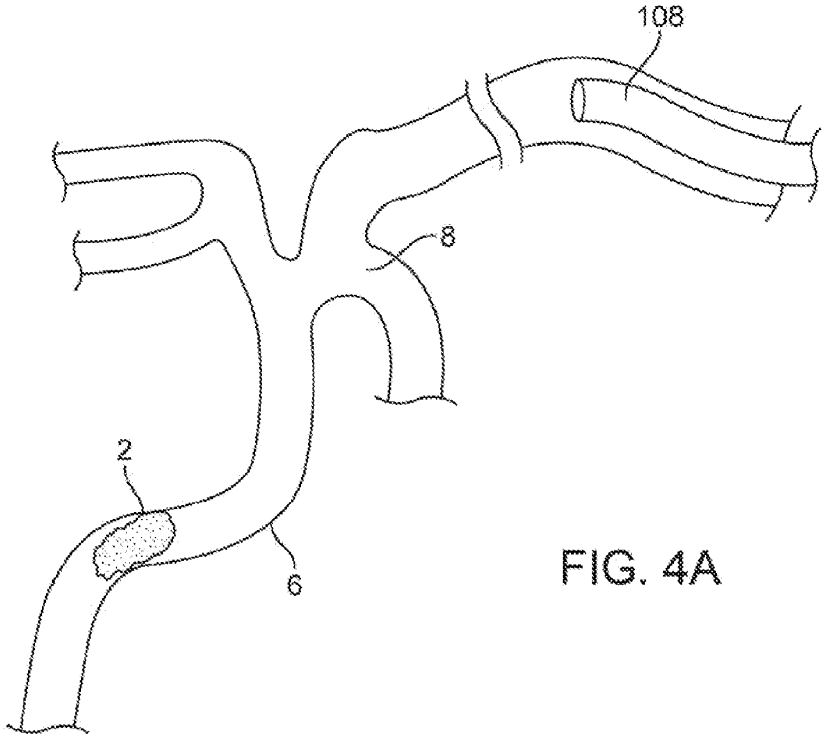


FIG. 4A

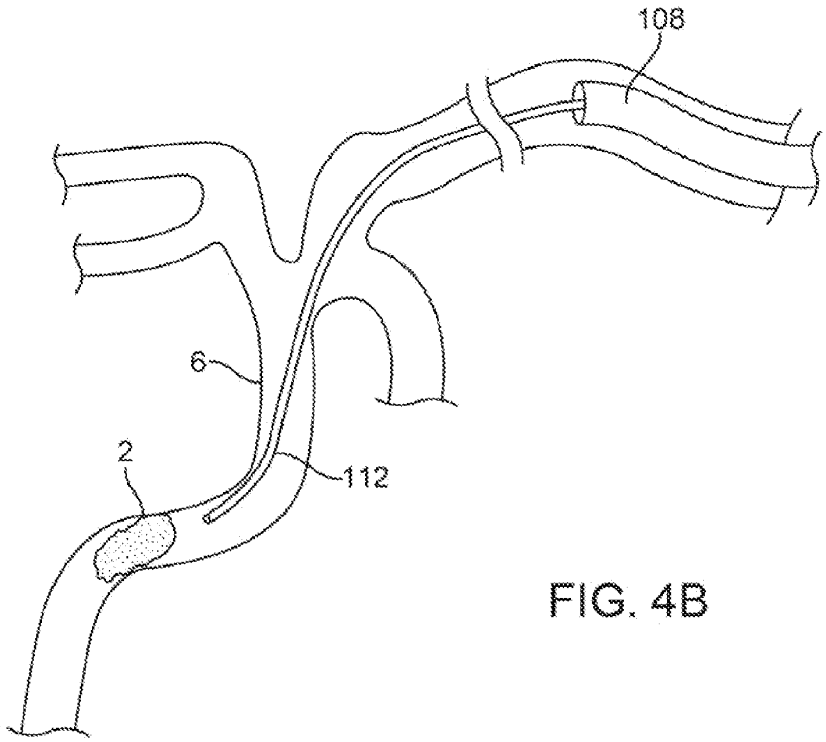


FIG. 4B

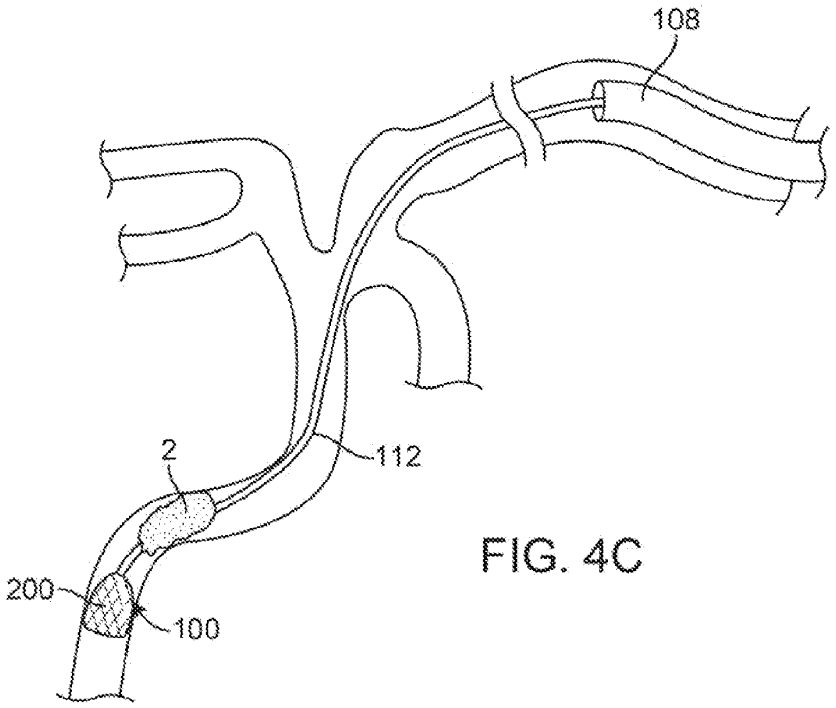


FIG. 4C

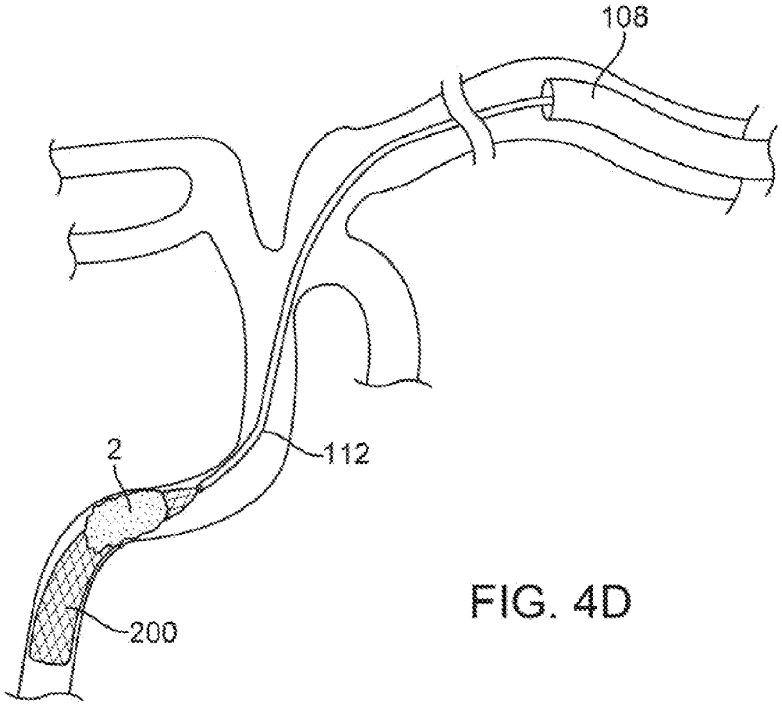


FIG. 4D

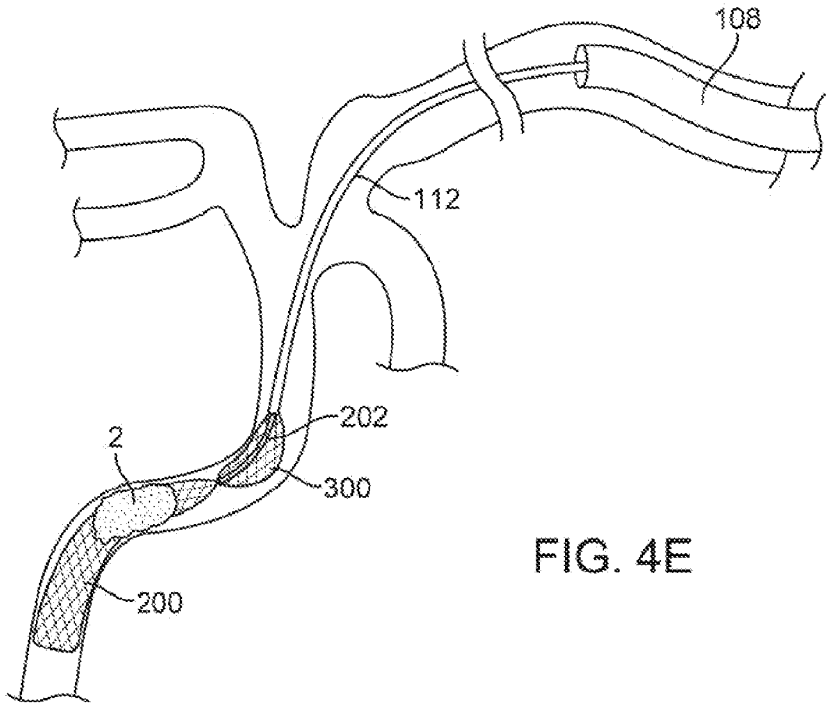


FIG. 4E

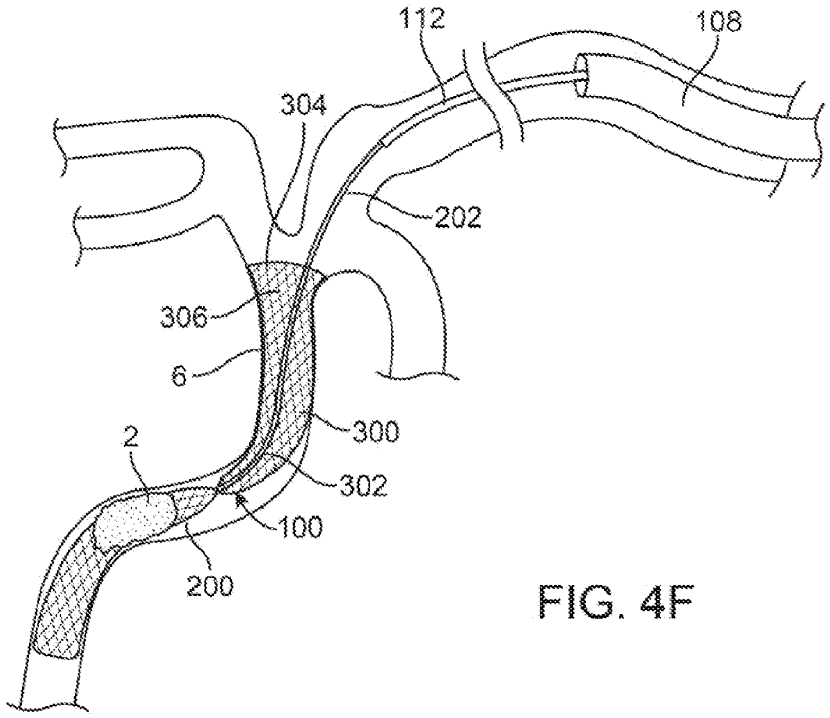


FIG. 4F

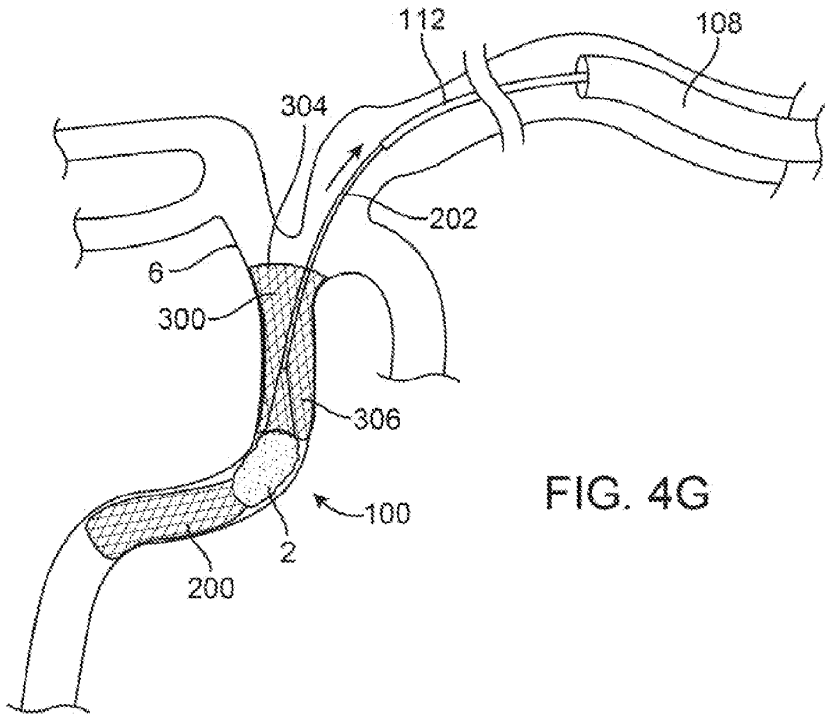


FIG. 4G

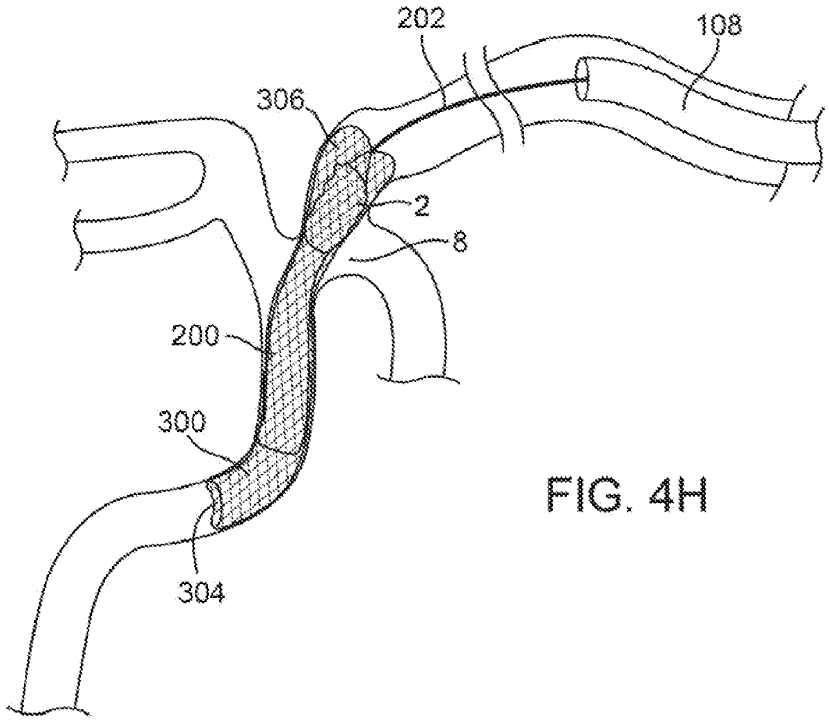


FIG. 4H

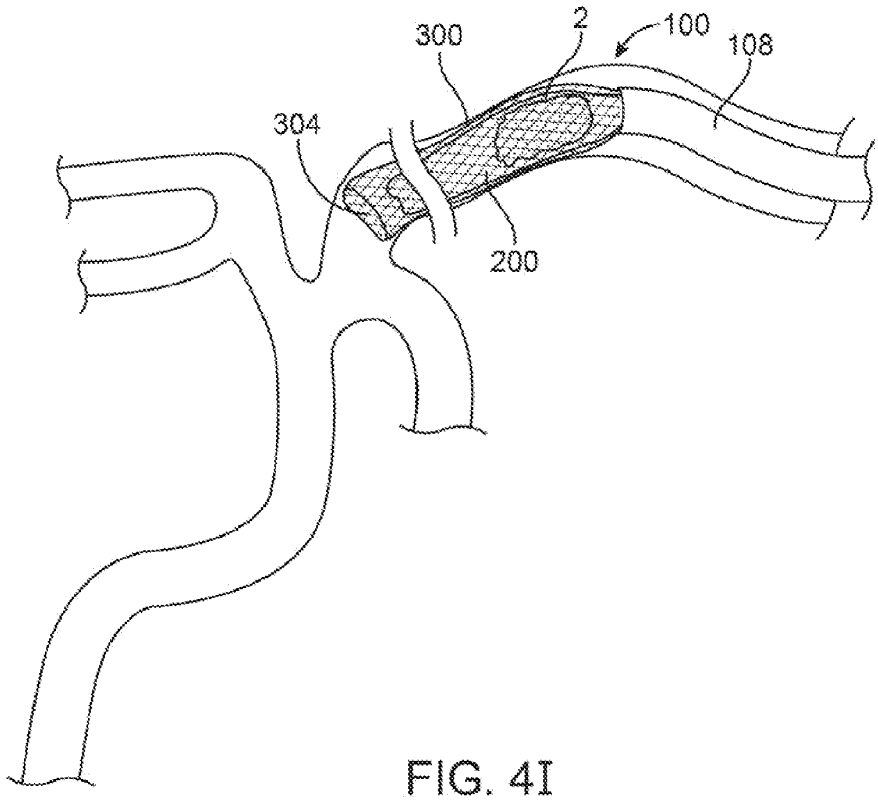


FIG. 4I

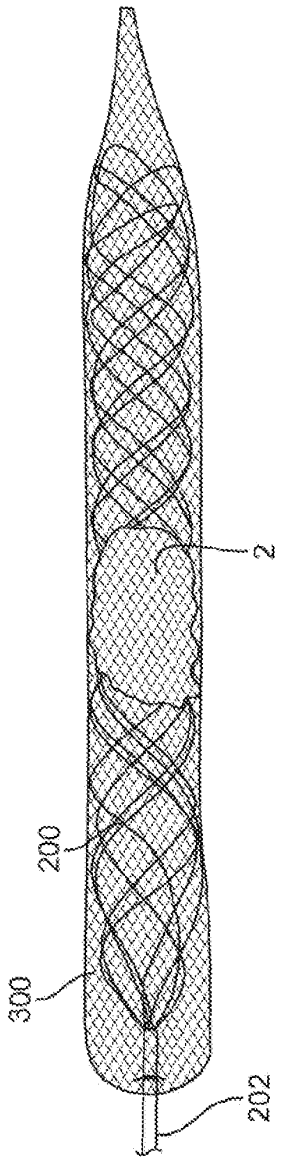


FIG. 4J

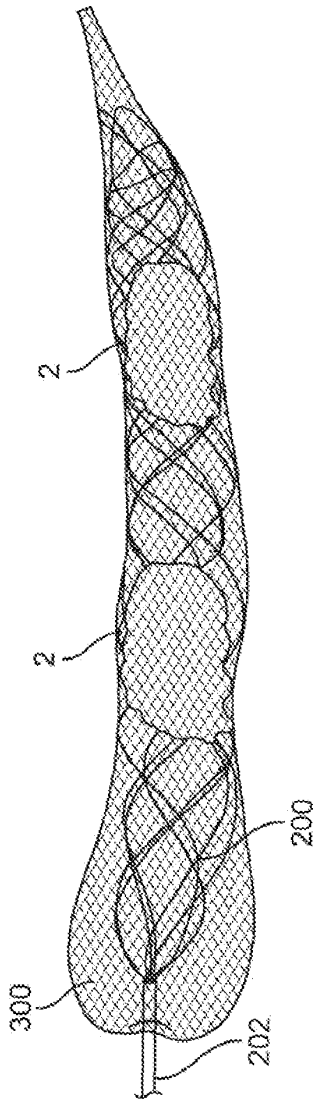


FIG. 4K

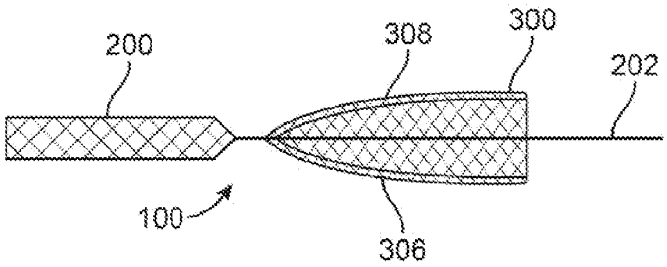


FIG. 5A

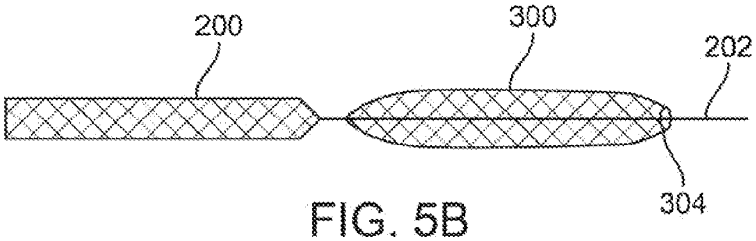


FIG. 5B

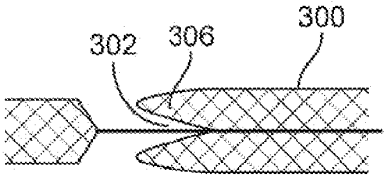


FIG. 5C

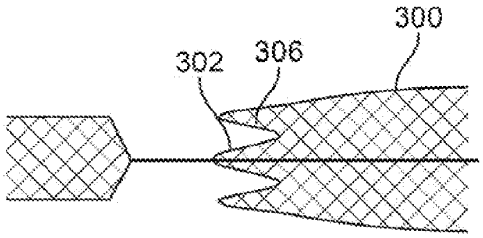


FIG. 5D

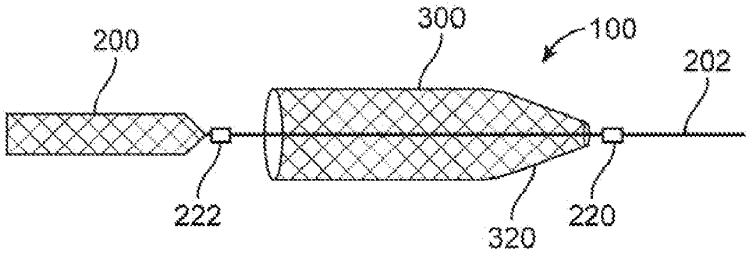


FIG. 5E

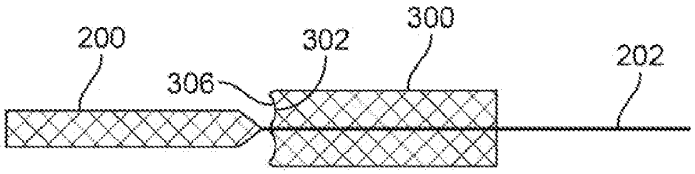


FIG. 5F

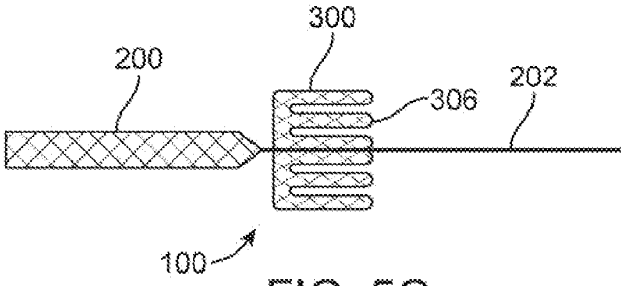


FIG. 5G

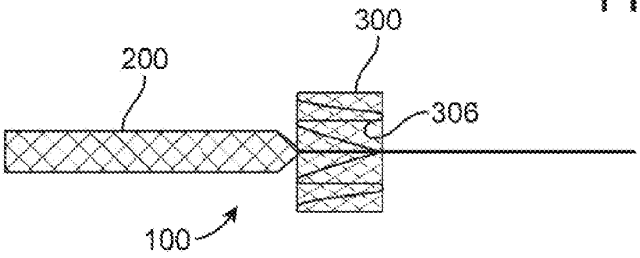


FIG. 5H

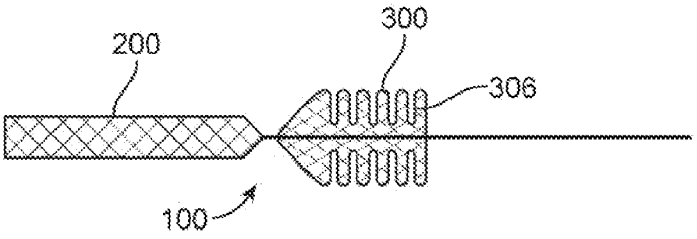


FIG. 5I

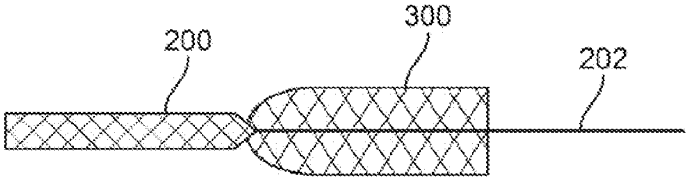


FIG. 5J

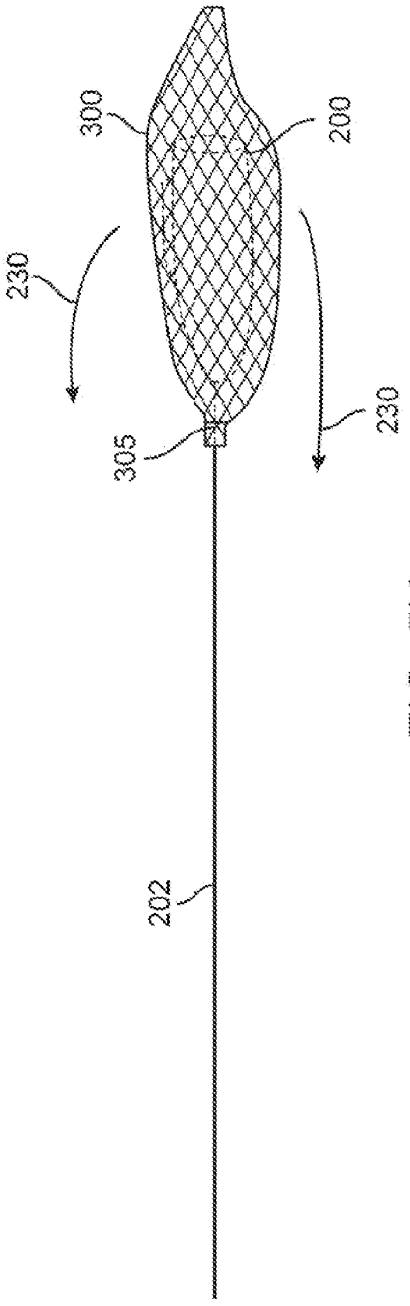


FIG. 5K

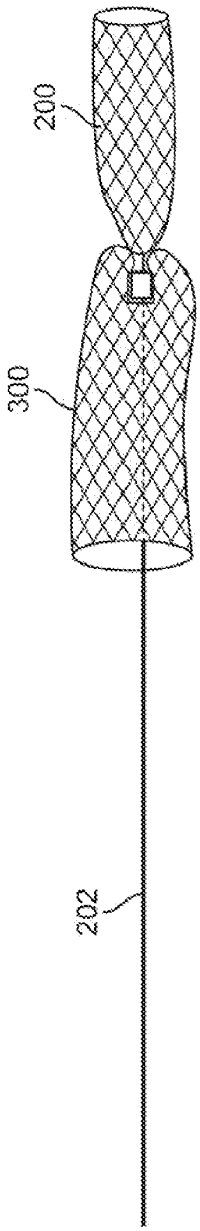


FIG. 5L

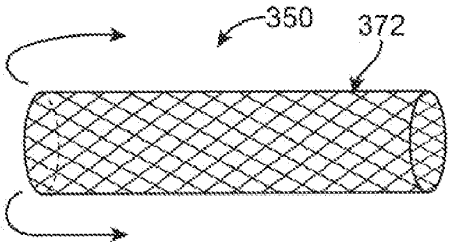


FIG. 6A

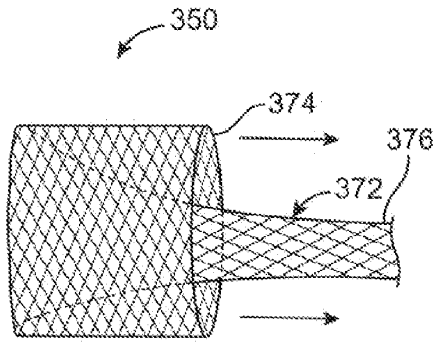


FIG. 6B

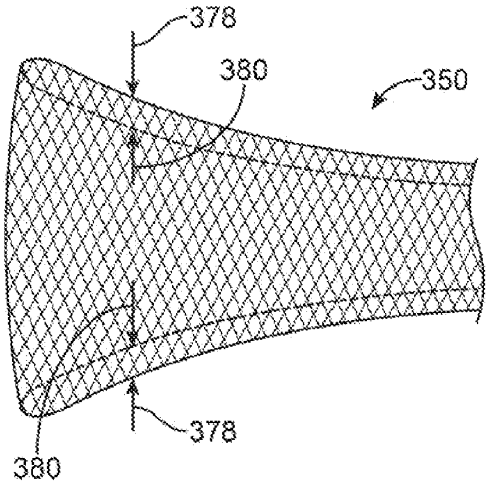


FIG. 6C

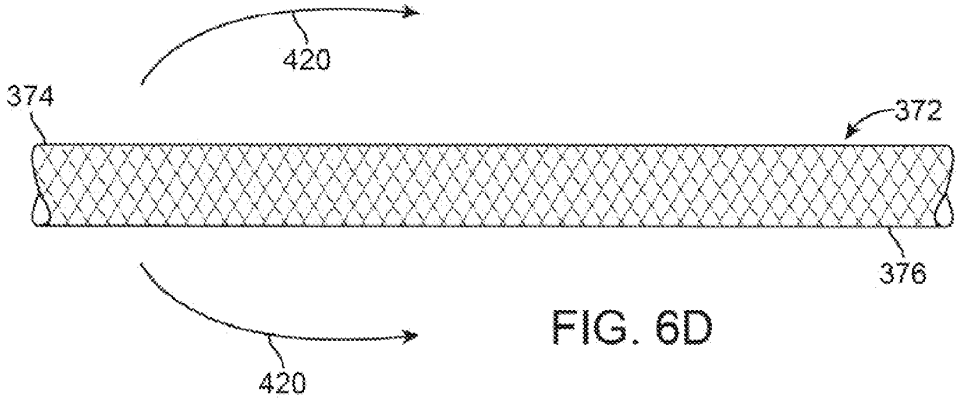


FIG. 6D

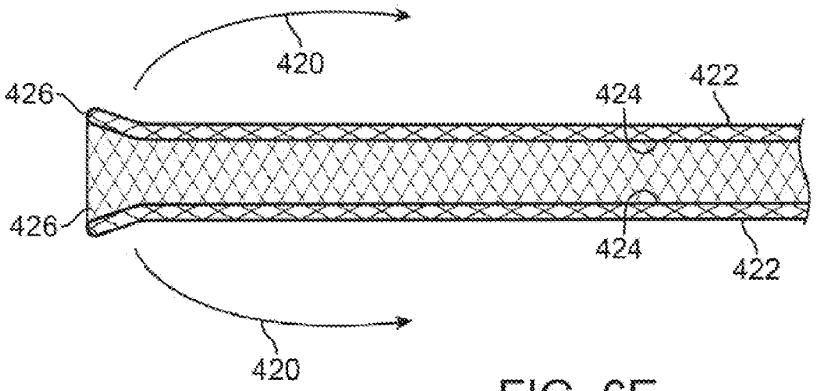


FIG. 6E

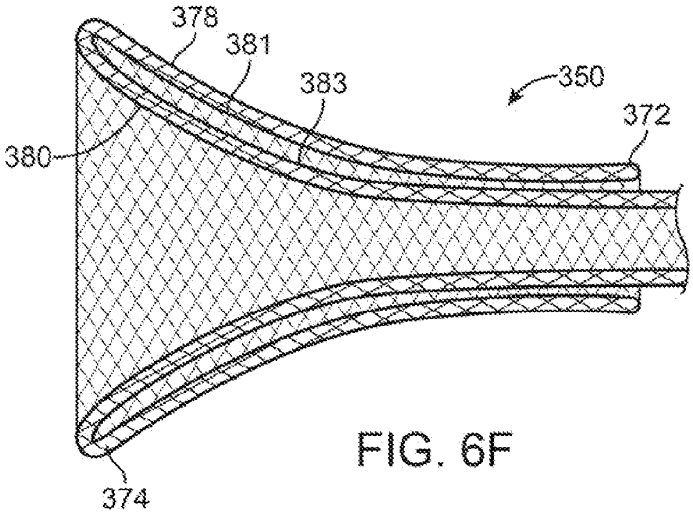


FIG. 6F

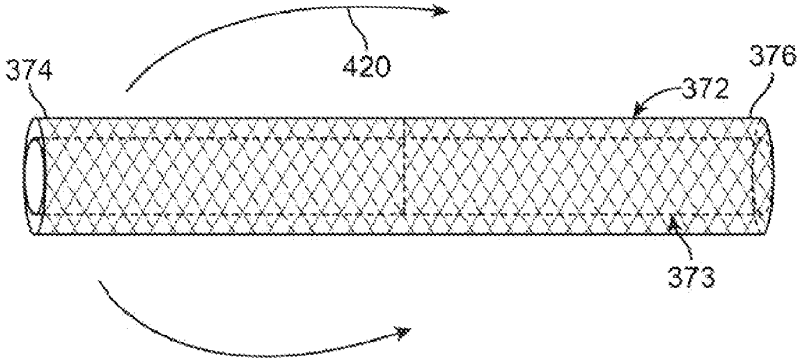


FIG. 6G

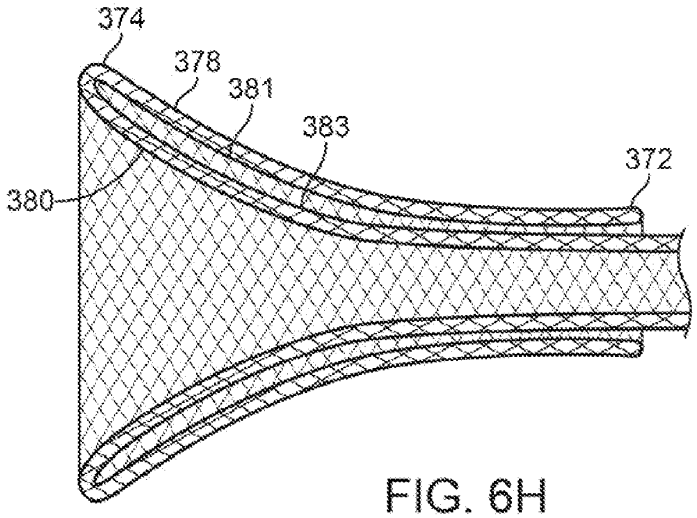


FIG. 6H

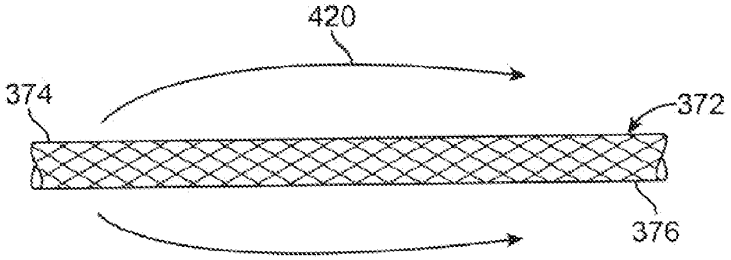


FIG. 6I

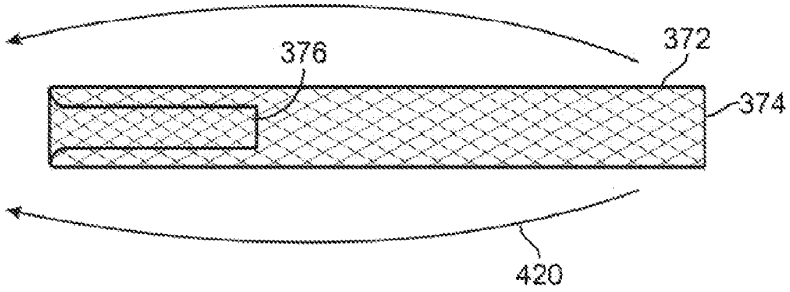


FIG. 6J

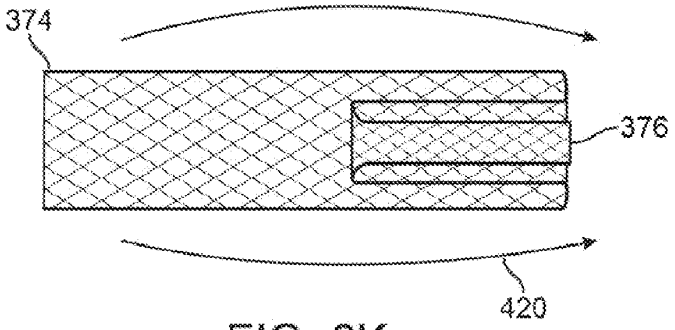


FIG. 6K

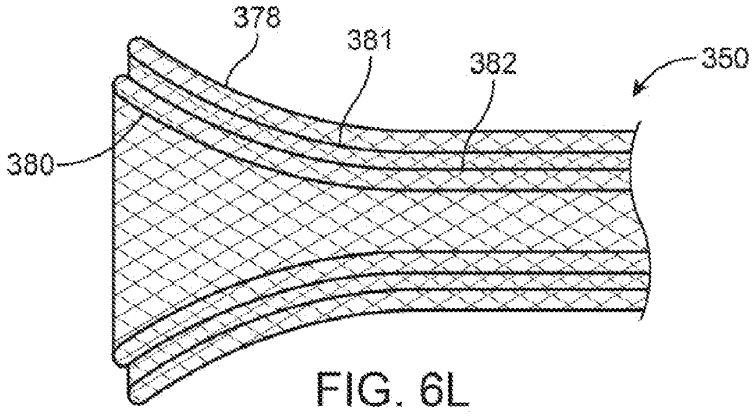


FIG. 6L

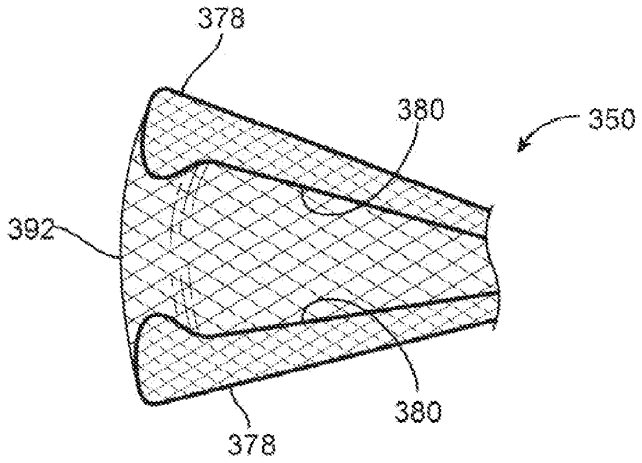


FIG. 7A

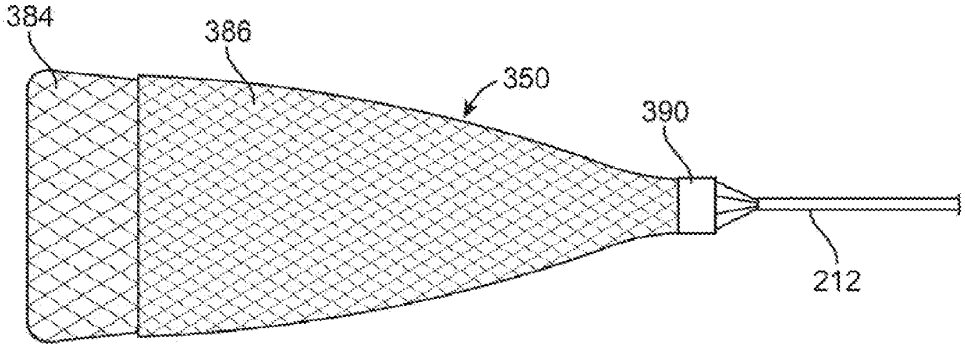


FIG. 7B

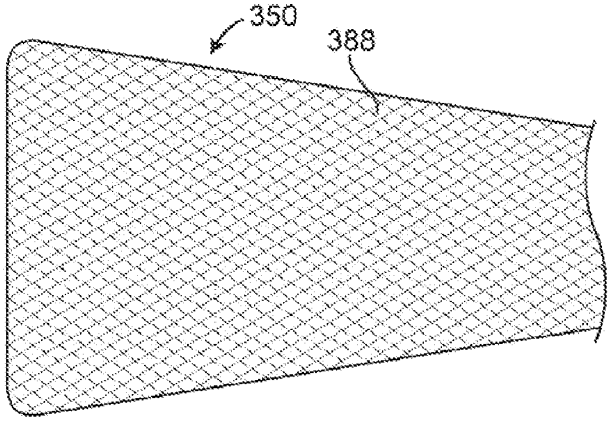
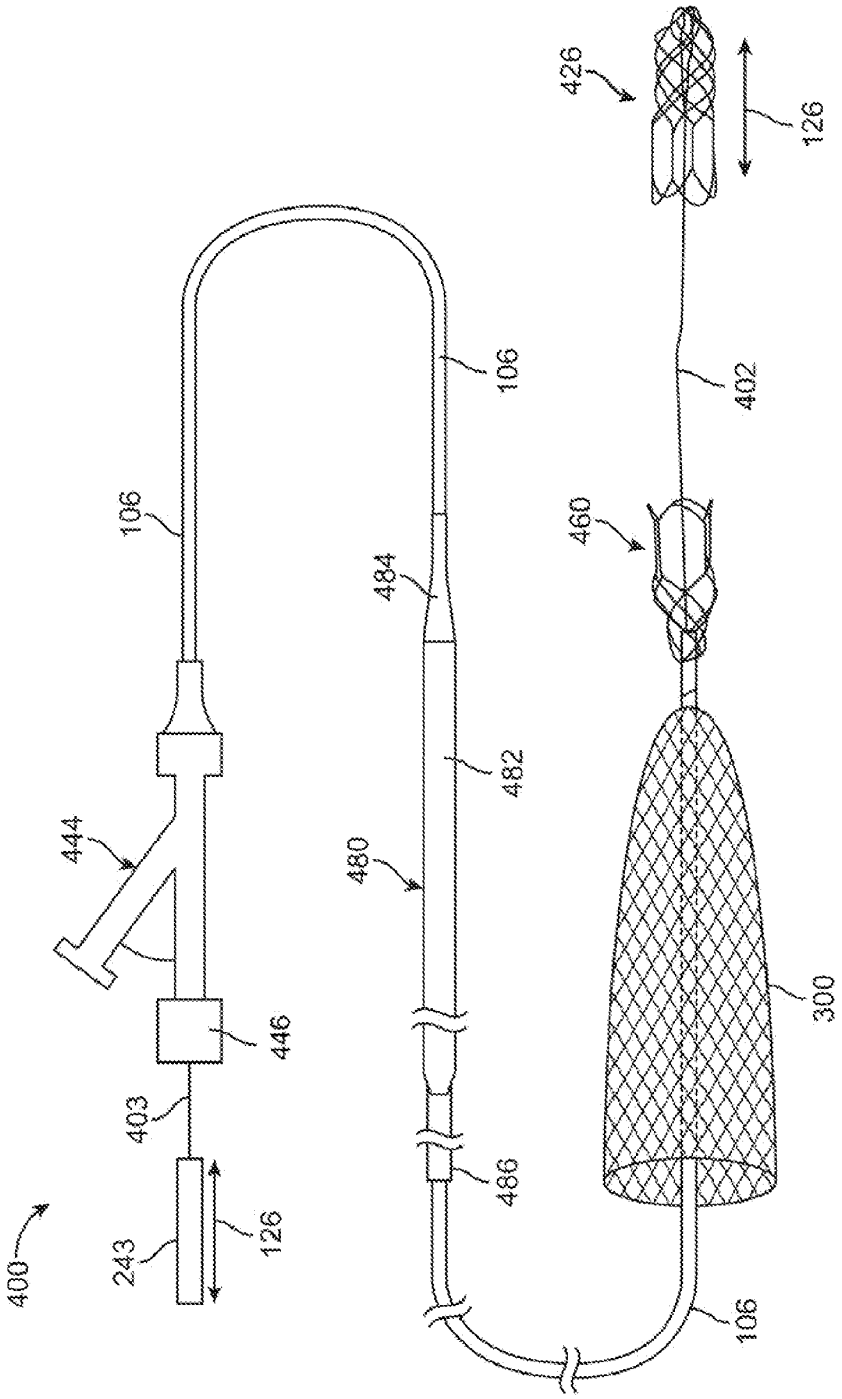


FIG. 7C


426
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243
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400
106

FIG. 8

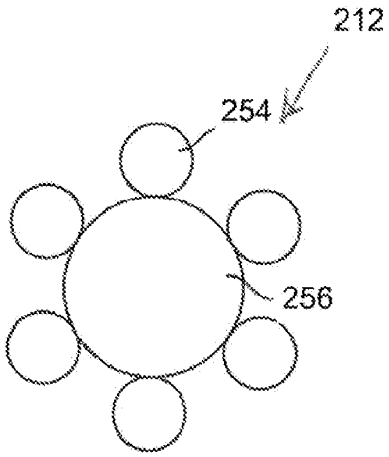

FIG. 9A

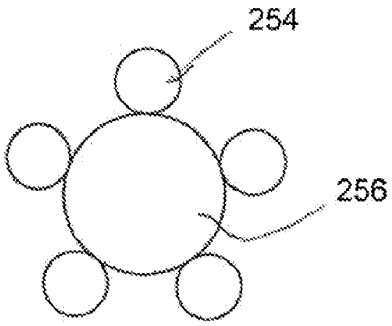

FIG. 9B

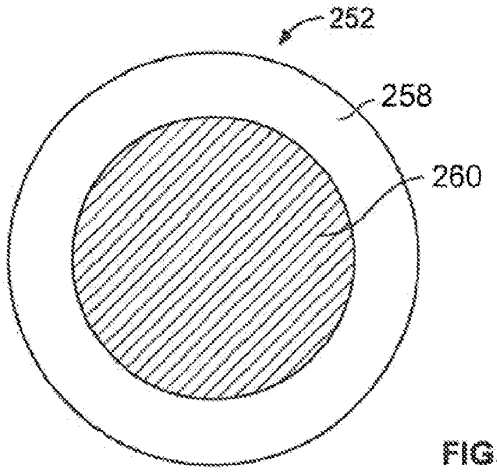

FIG. 9C

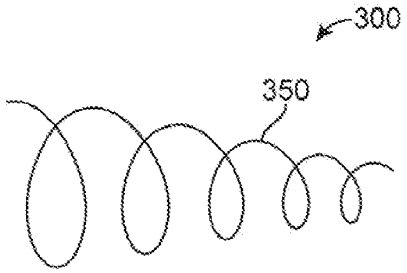

FIG. 10A

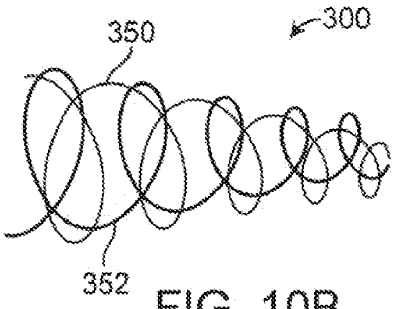

FIG. 10B

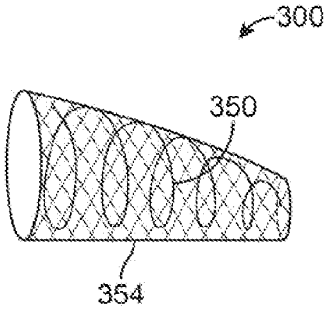

FIG. 10C

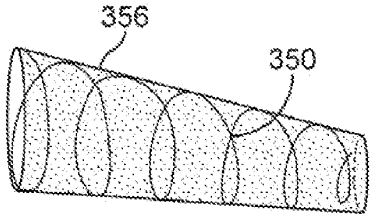

FIG. 10D

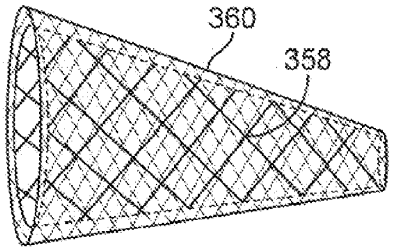

FIG. 10E

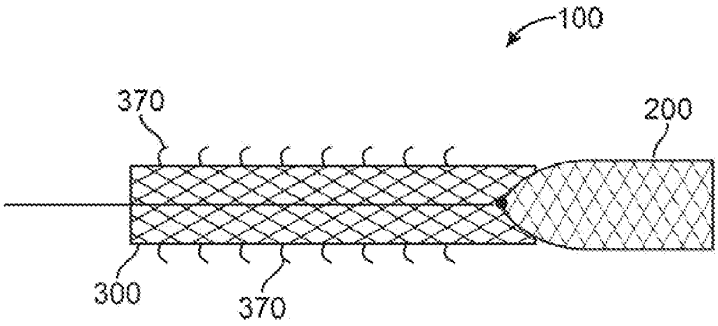

FIG. 11A

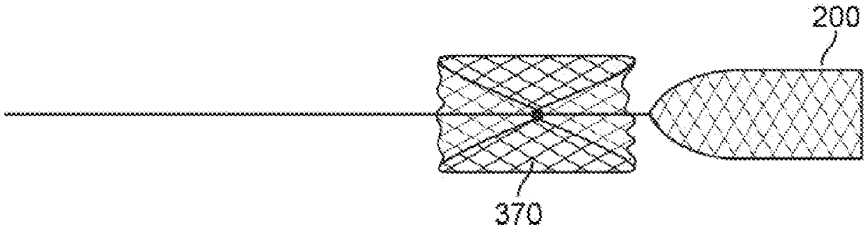

FIG. 11B

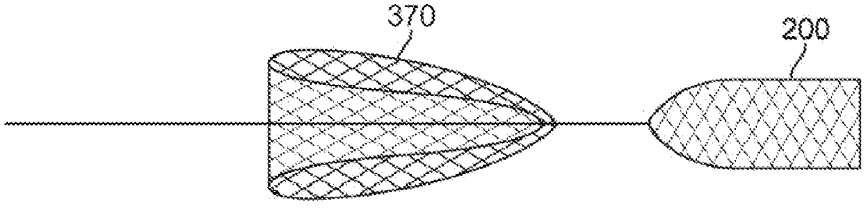

FIG. 11C

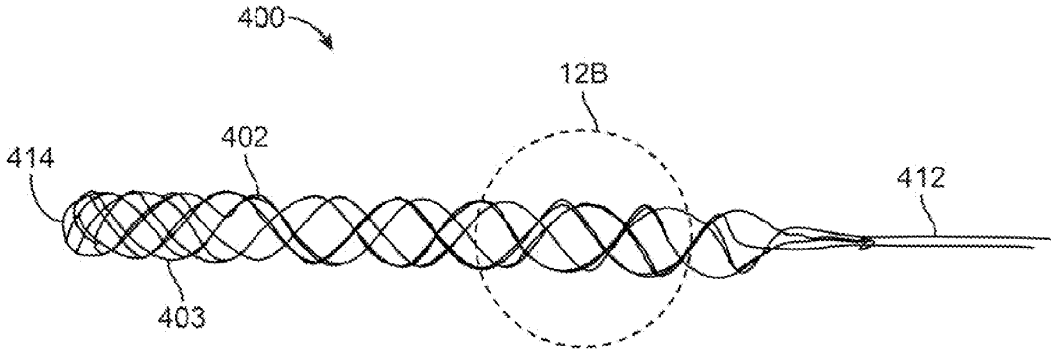

FIG. 12A

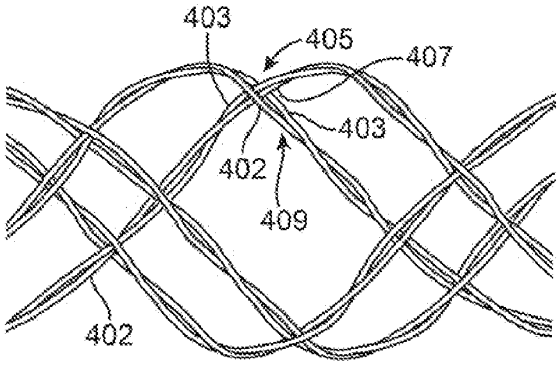

FIG. 12B

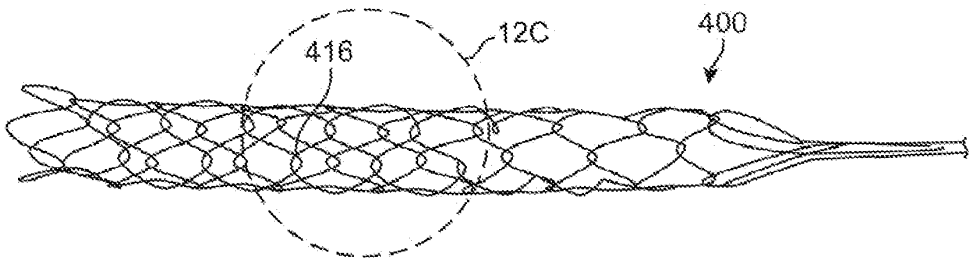

FIG. 12C

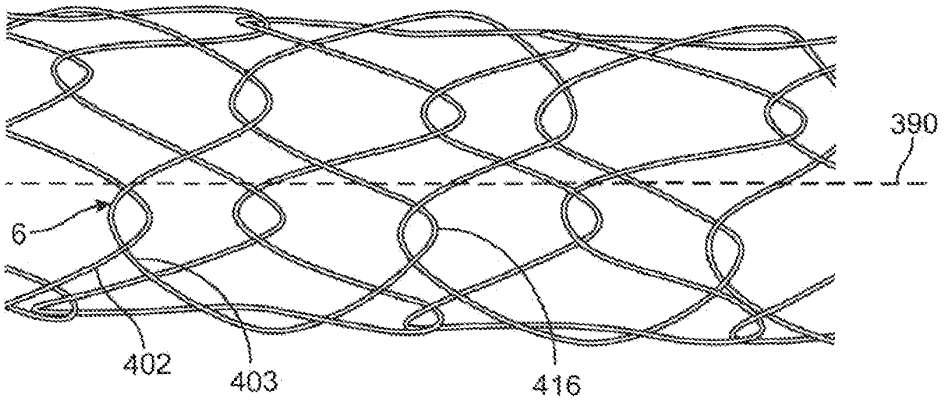

FIG. 12D

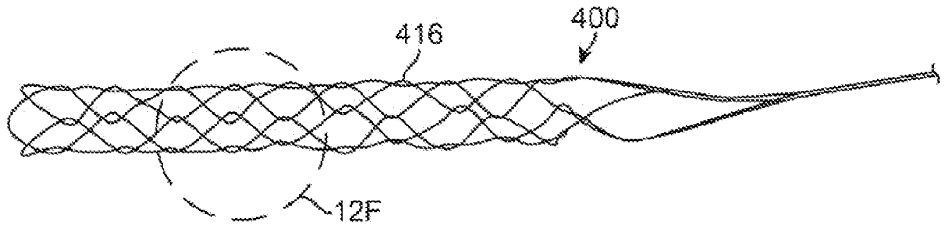

FIG. 12E

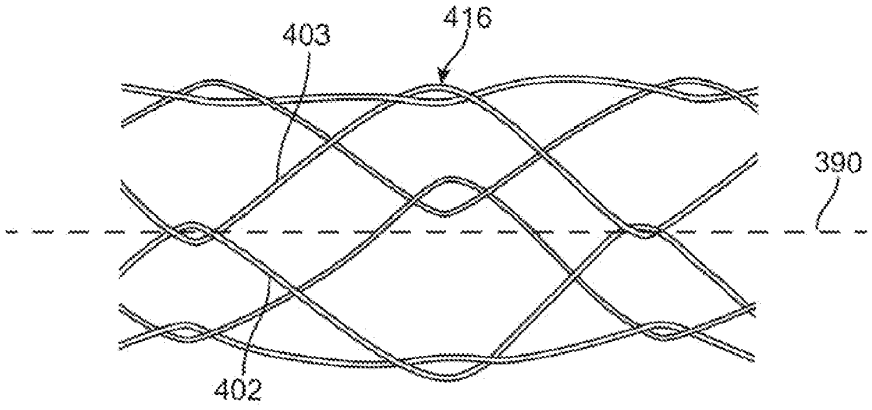

FIG. 12F

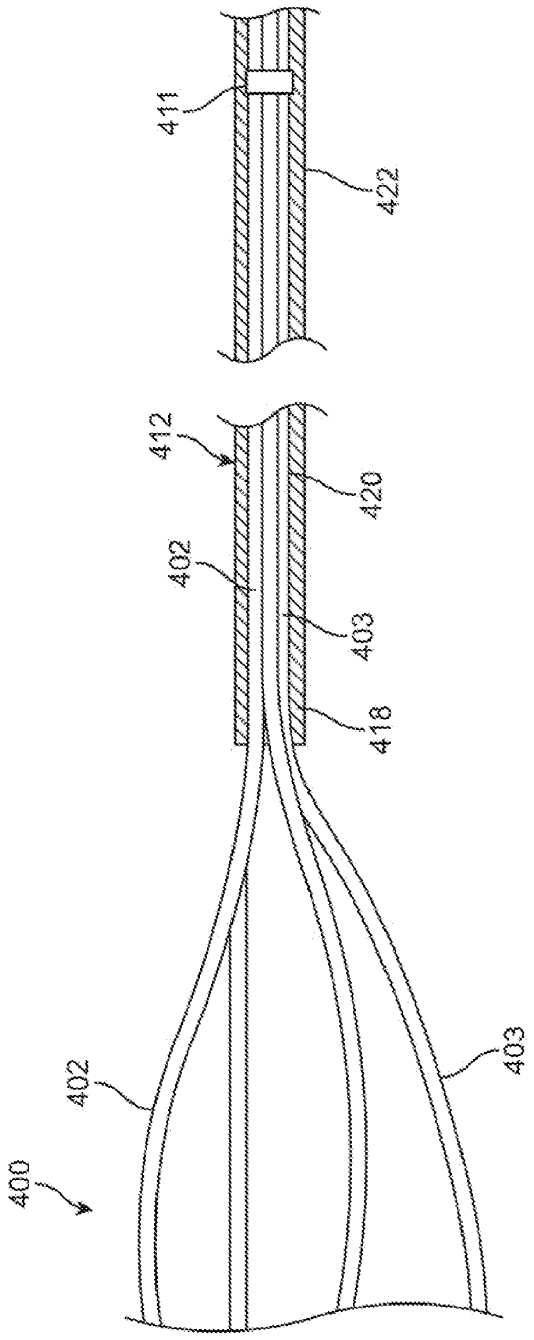

FIG. 12G

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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06 August 2012 (06.08.2012)	06 SEP 2012
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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(54) **Guiding tool for wound closure element**

Führungswerkzeug für Wundverschluss

Outil de guidage pour fermeture de plaie

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(56) References cited:
WO-A-01/13800
US-A- 5 620 461
US-A- 5 649 950
US-A- 5 725 519

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Description

[0001] The present invention relates generally to sealing of a percutaneous incision or puncture in the wall of a vessel, duct, lumen or hollow organ in the body of a living being, by positioning a sealing device in said incision or puncture, where the incision or puncture is smaller than said sealing device. In particular the invention relates to a guiding tool for enabling the correct positioning of such a sealing device, ensuring a leak-proof sealing.

Background of the Invention

[0002] In recent years a number of devices and apparatuses have been developed enabling the closure or occlusion of e.g. punctures in the femoral artery following catheterization. Instead of applying a pressure to the puncture site for a period of time sufficient for blood clot formation to occur, the new methods are e.g. based on providing a plug, commonly referred to as an "artery plug", in the puncture. The plug is made of a resorbable material, such that it can be left in place until the tissue has recovered properly and the wound or puncture is healed. The plug can be made of collagen, and applied to the outside of a vessel against a counteracting element, also made of a resorbable material, introduced into the interior of the vessel. A locking means secures the collagen plug in place. A device of this kind is disclosed in US-5,935,147 (Kensey et al). The sealing action is thus performed by the externally applied collagen plug. However, a certain percentage of applied plugs will not be leak-proof and often further compression by other devices or manually must be applied.

[0003] Alternatively, a plug can be made of two members such that a first member is positioned within a vessel and acts as the occluding member, and a second member is positioned outside the vessel and locked to the first member by a locking means. In order to ensure leak-proof action, the first member is larger than the puncture in all directions, i.e. it will cover a surface larger than the area of the puncture. In order to make this possible, the first member is foldable. A device of this kind is disclosed in our own EP-application EP-00850184.3 (corresponding to US patent application serial No. 09/704,726).

[0004] US-A-5 649 950 discloses a loading device for a collapsible occluder. This device has a conical lumen. US-A-5 649 950 corresponds to the preamble of claim 1.

[0005] The problem facing all systems wherein a folding or deformation of an element is needed in order to introduce the element into a vessel or through any tissue wherein the hole is smaller than the element itself, is that it can be difficult to achieve a reproducible unfolding, that accurately seals the hole from the inside. Also, in many cases the closure element is provided inside an introducer member such as a tube, in a folded state, already at the time of manufacture of the kit comprising all components. If the kit is stored for extended periods of time, and even for shorter times, the folded closure element most likely does not unfold properly at the time of use. To avoid the risk of permanent deformation, the closure element could be inserted into the introducer device by the physician, but this would require an extra manipulation, and it might be very difficult to maintain the sterility of the devices in such a case.

Summary of the Invention

[0006] Thus, in view of the problem with the prior art devices, it is the object of the present invention to improve the rate of successful sealing operations using wound closure devices, when foldable or deformable closure elements are introduced into a vessel through a hole, smaller than the element itself, and to enable the folding and unfolding operation to take place during the sealing operation, and to avoid manipulation of the closure element by the physician at the time of performing the sealing operation.

[0007] This object is achieved by the provision of a guiding tool which in a controlled manner deforms or folds a wound closure element such that it after having been introduced through a puncture, unfolds and regains its original shape in a reproducible and controllable manner, and thereby provides adequate sealing at an excellent rate of success, this procedure taking place at the time of performing the sealing operation. The guiding tool according to the invention is defined in claim 1.

Brief Description of the Drawings

[0008]

Fig. 1 a-c is a schematic illustration of a system for wound closure during operation thereof;

Fig. 2a illustrates an embodiment of the guiding tool not belonging to the invention in cross section;

Fig. 2b is a view in longitudinal cross section of a second embodiment of the inventive guiding tool;

Fig. 2c illustrates cross sections at A-E in Fig. 2b;

Fig. 2d is a perspective cut view in two different directions of a third preferred embodiment of the inventive guiding tool;

Fig. 3a is a cross section view of a closure element; and

Fig. 3b is a top view of a closure element.

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Detailed Description of the Invention

[0009] Fig. 1a-c illustrates the procedure of inserting a wound closure (occlusion) element 2 in a blood vessel 4 and clamping it by means of a locking member 6. Thereby, an incision 8 is made in the blood vessel 4 in question, and an introducer tube 10 is inserted into the vessel 4, see Fig. 1a. Then, a folded, or in some other manner deformed closure element 2 is passed through said introducer tube 10 and into the vessel 4. The closure element 2 is secured to e.g. a suture 12, and some rigid elongated element 14 such as a steel pin or pusher rod (not shown) can be used to guide the closure element 2 through the tube 10 and into the vessel 4, where it unfolds. Once the closure element 2 has unfolded inside the vessel 4, the pusher rod and the introducer tube 10 are withdrawn from the vessel but maintained close to the exterior of the vessel 4. Then, the closure element 2 is pulled back using the suture 12, so as to be located in a position where it is held against the interior vessel wall 16, Fig. 1b. An essentially disk shaped locking element 18, having a central hole, is provided on the suture 12, the suture running through said hole, such that the locking member can be moved along the suture 12 to be brought into contact with the exterior vessel wall 20. By the provision of suitable friction enhancing means 19 on the very distal end of the suture, the locking element can be pushed against the wall of the vessel while engaging the portion of the suture having higher friction, and thereby cause a locking of the closure element, Fig. 1c. This principle is used in e.g. US-5,916,236.

[0010] It is important that the closure element unfolds in a reproducible way, such that it will contact the inner vessel wall around the circumference of the incision. If the closure element is delivered to the user in a folded state, in position inside the introducer, as a "kit" ready for use by a physician, and the kit has been stored on a shelf for some time, it may happen that the closure element has become permanently deformed, and will not assume the desired shape (which may be to regain its original shape) inside the vessel. Such an event would of course dramatically increase the risk that the closure element will not fulfill its function, and cause a leakage.

[0011] Therefore, in accordance with the present invention, there is provided a guiding tool that is connectable to an introducer of the type discussed above, the closure element being provided in said guiding tool in an unfolded state. Thereby the actual deformation or folding of the closure element, necessary to enable insertion through the incision (which is smaller than the closure element) and into the blood vessel, is not performed until the time of performing the operation of inserting the closure element. In this way, the closure element will not be subjected to a prolonged deformation during storage.

[0012] An embodiment not falling under the invention is illustrated in Fig. 2a. It comprises a body in the shown embodiment in the form of an elongated tube like member 20 (although cylindrical outer symmetry is no requirement), having an inner lumen 22 that has a first diameter in the proximal end portion 24 and over a fraction of its length (up to the dotted line X), forming a space 26 in which an closure element (not shown) can be housed without being deformed. Over a second fraction of the length, from the dotted line X and up to the distal end 26 portion, the lumen becomes narrower, rendering the 22 lumen cone shaped over this portion. Finally there is a connection portion 28, connectable to an introducer tube (such as the tube 10 in Fig. 1a). The exit diameter is equal to or slightly smaller than the inner diameter of the introducerbe, i.e. small enough to enable passing the closure element into the blood vessel.

[0013] In Fig. 2b a second embodiment of the guiding tool according to the present invention is illustrated. It is adapted for a closure element 30 having the general shape shown in Figs. 3a and 3b. The closure element suitable for use with the illustrated embodiment of the guiding tool, has a thick mid portion 32, that is generally elongated, and has peripheral wings 34 or edges, which are substantially thinner, and thus more flexible than the mid portion 32. The peripheral shape is like a slightly distorted ellipse, but could in principle be circular, the wings 34 thereby forming rather a collar or a brim surrounding the mid portion. Other shapes are also possible. A suitable kind of closure element is disclosed and claimed in our copending EP-00850184.3. In view of its flexibility, the wings 34 or brim are foldable such that the entire element will have a smallest dimension in a folded state that fits well within an incision or puncture in a blood vessel, thereby enabling insertion into said vessel.

[0014] Thus, the embodiment of the guiding tool according to the present invention shown in Fig. 2b, comprises an essentially tubular element 42 having a proximal end 44 and a distal end 46 and a lumen 48 extending between said distal 46 end and said proximal end 44. There is further a wound closure element introduction opening 50 in the proximal end 44, and a wound closure element exit opening 52 in the distal end 46. The distal end is shaped so as to be connectable to an introducer tube, like the one described above in connection with Fig. 1.

[0015] The lumen 48 has inner walls 54 provided with wound closure element deformation surfaces 56, adapted to deform a wound closure element during passage thereof, past said surfaces 56, through the guiding tool, from an essentially undeformed or unfolded state to a deformed or folded state. The effect of this deformation/folding should be such that the overall dimension of the wound closure element is changed to render it capable of passing through the puncture in the blood vessel. Also, after passage through said incision or puncture it must regain a shape that is capable of providing a sealing action against the inner wall of the vessel.

[0016] In Fig. 2b there is also shown a pusher rod 51, having a fork like configuration, that is used to push the

closure element 30 through the introducer and into the blood vessel. This pusher rod is retracted once the element is properly located inside the vessel.

[0017] In the embodiment shown in Fig. 2b the deformation surfaces 56 have a specific design, illustrated by a sequence in Fig. 2c, which are cross section views through the lumen at the positions indicated with corresponding letters A, B, C, D, E in Fig. 2b. Thus, there is one guiding surface 56 for each wing on the closure element 30, and a guiding recess 60 in which the thicker mid portion 32 of the closure element 30 will run during its passage through the guiding tool. The guiding surfaces will initially have an orientation such that the wings 34 of the unfolded or undeformed closure element 30, when inserted into the guiding tool in the introduction opening, will rest thereon in a position and orientation causing no deformation (referred to as a "horizontal" orientation; position A in Fig. 2c). Thereby the nominal shape of the closure element 30 is preserved also during extended storage. In a direction towards the exit opening, the guiding surfaces will gradually become elevated (A-B-C-D-E in Fig 2c) from the initial, essentially horizontal orientation, and also curved such that they form what could be referred to as a "quasi-conical" lumen inside the tool. At the end of the lumen, near the exit opening, the guiding surfaces will have reached a state where the cross section of the lumen is essentially circular, and where the diameter corresponds to the inner diameter of the introducer tube.

[0018] Preferably, there are guiding rails 62 provided above the guiding surfaces 56, such that the wings or brims 34 of the closure element 30 will be kept down during the process of pushing it with the pusher rod through the guiding tool, thereby preventing inadvertent tilting or incorrect behavior of the closure element during the movement through said guiding tool. The rails are preferably integrated in the "roof" of the lumen. However, they can also be provided as an insert and attached by suitable means inside the lumen.

[0019] In a further variation of the above described embodiment, the interior lumen of the guiding tool essentially has a cross section that exactly corresponds to the cross section of the closure element. This lumen would then form a guiding slot inside the tool, whereby the slot would be shaped so as to gradually change from a cross section corresponding to the above mentioned "horizontal orientation" to an essentially circular cross section, the diameter of which would be smaller than the incision through which the closure element is to be inserted. There must however be a space above the closure element for the access by the pushing rod needed for advancing the closure element through the tool and the introducer.

[0020] The sequence A-E in Fig. 2c illustrates the folding process, and it is clearly seen that the closure element reaches a folded state where it conforms to the circular cross section of the introducer tube, which is connected to the guiding tool at the exit end thereof.

[0021] Another embodiment of the guiding tool is shown in Fig. 2d, showing perspective cuts through the device at two orientations perpendicular to each other. Like reference numerals are used for like elements in Figs. 2c and 2d. Like in the above described embodiment, this embodiment of the guiding tool comprises an essentially tubular element 42 having a proximal end 44 and a distal end 46 and a lumen 48 extending between said distal 46 end and said proximal end 44. There is further a wound closure element introduction opening 50 in the proximal end 44, and a wound closure element exit opening 52 in the distal end 46. The distal end is shaped so as to be connectable to an introducer tube.

[0022] Also in this embodiment, the lumen 48 has inner walls 54 also provided with wound closure element deformation surfaces 56, adapted to deform a wound closure element during passage thereof, past said surfaces 56, through the guiding tool, from an essentially undeformed state to a deformed state.

[0023] However, the deformation surfaces have a different design in this embodiment. Namely, one wall of the inner lumen is flat such that the closure element can be placed essentially flat thereon, in an unfolded state, e.g. during shelf storage, corresponding to the "horizontal orientation" discussed above in connection with Fig. 2b, but with the thicker mid portion facing upwards. Towards the exit opening the lumen is shaped as cone, much like in the first embodiment of Fig. 2a, whereby the final diameter of the inner lumen corresponds to a diameter smaller than the diameter of the opening in the blood vessel through which the closure element is to be introduced. About half-way along the conical portion of the lumen, there are provided a pair of deflection surfaces 64, having a "steeper" angle than the over-all cone angle of the lumen. These surfaces will engage the peripheral brim or collar portions of the closure element, such that they are deflected or bent downwards from the essentially flat initial position. Also, the pusher rod discussed above will cause the closure element not to lie completely flat, but slightly angled with the trailing edge at a slightly elevated position compared to the leading edge. Furthermore, said pusher rod will assist in keeping the leading edge forced against the flat surface.

[0024] In order to facilitate correct positioning of the closure element during insertion, also in this case there may be provided guiding rails like those described above.

[0025] The invention having been described with reference to preferred embodiments thereof can be subject to alterations and modifications by the man skilled in the art, and the scope of the invention is limited only by the appended claims.

Claims

1. A guiding tool for controllable and reversible folding or deformation of a wound closure element (2) be-

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fore insertion of said wound closure element into a percutaneous incision or puncture in the wall (4) of a vessel, duct, lumen or hollow organ in the body of a living being, said incision or puncture being smaller than said wound closure element in an unfolded or undeformed state, said tool comprising a body (20) having a distal end (26) and a proximal end (24) and a lumen (22) extending between said distal end and said proximal end; a wound closure element introduction opening (50) in the proximal end, and a wound closure element exit opening (52) in the distal end;

characterized in that

said lumen has inner walls (54) provided with wound closure element guiding surfaces (56, 64) in the form of separate deflection elements protruding from the inner wall of said lumen, for reversibly reducing the spatial extension of a wound closure element during its passage through the guiding tool, by engaging a peripheral brim or collar portions of the closure element, such that they are deflected or bent downwards from an essentially flat initial position, whereby said wound closure element is capable of passing through said incision or puncture, and whereby it after passage through said incision or puncture assumes a shape that is capable of providing a sealing action against said incision or puncture.

2. The tool as claimed in claim 1, wherein said guiding surfaces (56) in the proximal end of said tool are essentially flat, and in a direction towards the distal end, gradually becomes elevated and also curved such that they form a quasi-conical lumen inside the tool, and wherein the guiding surfaces, at the distal end of the lumen, near the exit opening, will have reached a state where the cross section of the lumen is essentially circular.

3. The tool as claimed in claim 1 or 2, wherein there are guiding rails (62) provided above the guiding surfaces (56), such that wings or rims (34) of a closure element (30) will be kept down during the process of pushing through the guiding tool, said guiding rails (62) being arranged to prevent the closure element from inadvertent tilting or other incorrect behavior during its movement through the guiding tool.

4. The tool as claimed in claim 1, wherein said introduction opening is larger than said exit opening, and optionally is provided with a sealing plug (53) to prevent leakage of body fluid.

5. The tool as claimed in claim 1, wherein said guiding surfaces (56) gradually change from the proximal end, where they do not affect the nominal shape of the wound closure element (30), towards the distal end where they force the wound closure element (30) to assume a shape that conforms to the inner lumen of an introducer tube, connectable to the distal end of said guiding tool.

6. The tool as claimed in claim 1, wherein said lumen is cone shaped at least in the distal region of said guiding tool, and has a large enough diameter in the proximal region of the guiding tool, that the nominal shape of the wound closure element (30) is not affected, and a small enough diameter in the distal end that the wound closure element conforms to the inner lumen of an introducer tube, connectable to the distal end of said guiding tool.

7. The tool as claimed in claim 1, wherein the proximal region of the tool is essentially cylindrical, forming a storage compartment for said closure element (30), in which the nominal shape of the wound closure element is not affected.

8. A system for the introduction and securing of a wound closure element into a percutaneous incision or puncture in the wall of a vessel, duct, lumen or hollow organ in the body of a living being, said incision or puncture being smaller than said wound closure element in an unfolded or undeformed state, said system comprising

a wound closure element (30);

an introducer tube (10) for introducing said wound closure element into said incision;

a pusher device for enabling the passage of said wound closure element through said introducer; and

a tool as claimed in claim 1, connectable to said introducer.

Patentansprüche

1. Führungswerkzeug zum gesteuerten und reversiblen Falten oder Verformen eines Wundverschlusselements (2) vor der Einführung dieses Wundverschlusselements in einen perkutanen Schnitt oder eine perkutane Punktur in der Wand (4) eines Gefäßes, eines Kanals, eines Lumens oder eines hohlen Organs im Körper eines Lebewesens, wobei der Schnitt oder die Punktur kleiner ist als das Wundverschlusselement in einem ungefalteten oder nichtverformten Zustand, wobei das Werkzeug einen Körper (20) mit einem distalen Ende (26) und einem proximalen Ende (24) sowie einem Lumen (22) aufweist, das sich zwischen dem distalen und dem proximalen Ende erstreckt, eine Einführöffnung (50) für das Wundverschlusselement in dem proximalen Ende und eine Ausgangsöffnung (52) für das Wundverschlusselement in dem distalen Ende;

dadurch gekennzeichnet, dass

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das Lumen Innenwände (54) hat, die mit Führungsflächen (56, 64) für das Wundverschlusselement in Form von separaten Ablenkelementen versehen sind, die von der Innenwand des Lumens hervorstehen, um die räumliche Ausdehnung eines Wundverschlusselements während seines Durchgangs durch das Führungswerkzeug durch Ineingriffbringen eines Außenrands oder Kragenbereichs des Verschlusselements reversibel zu reduzieren, so dass diese aus einer im Wesentlichen flachen anfänglichen Position abgelenkt oder nach unten gebogen werden, wobei das Wundverschlusselement durch den Schnitt oder die Punktur hindurchtreten kann und wobei es nach dem Durchtritt durch den Schnitt oder die Punktur eine Gestalt annimmt, die eine Dichtungswirkung gegen den Schnitt oder die Punktur bieten kann.

2. Werkzeug nach Anspruch 1, wobei die Führungsflächen (56) am proximalen Ende des Werkzeugs im Wesentlichen flach sind und in Richtung des distalen Endes nach und nach erhaben und auch gekrümmt werden, so dass sie ein quasi konisches Lumen innerhalb des Werkzeugs bilden, und wobei die Führungsflächen am distalen Ende des Lumens in der Nähe der Ausgangsöffnung einen Zustand erreicht haben werden, wo der Querschnitt des Lumens im Wesentlichen kreisförmig ist.

3. Werkzeug nach Anspruch 1 oder 2, wobei Führungsschienen (62) oberhalb der Führungsflächen (56) vorgesehen sind, so dass Flügel oder Kanten (34) eines Verschlusselements (30) während des Vorgangs des Hindurchdrückens durch das Führungswerkzeug unten gehalten werden, wobei die Führungsschienen (62) so angeordnet sind, dass ein unbeabsichtigtes Kippen oder anderweitiges unkorrektes Verhalten des Verschlusselements während seiner Bewegung durch das Führungswerkzeug hindurch verhindert wird.

4. Werkzeug nach Anspruch 1, wobei die Einführöffnung größer ist als die Ausgangsöffnung und optional mit einem Dichtungsverschluss (53) versehen ist, um ein Auslaufen von Körperflüssigkeit zu verhindern.

5. Werkzeug nach Anspruch 1, wobei die Führungsflächen (56) sich von dem proximalen Ende, wo sie die Nenngestalt des Wundverschlusselements (30) nicht beeinflussen, in Richtung des distalen Endes, wo sie das Wundverschlusselement (30) dazu zwingen, eine Gestalt einzunehmen, die sich dem inneren Lumen einer Einführröhre anpasst, verbindbar mit dem distalen Ende des Führungswerkzeugs, nach und nach verändern.

6. Werkzeug nach Anspruch 1, wobei das Lumen zumindest im distalen Bereich des Führungswerkzeugs kegelförmig ist und im proximalen Bereich des Führungswerkzeugs einen Durchmesser hat, der groß genug ist, um die Nenngestalt des Wundverschlusselements (30) nicht zu beeinflussen, und im distalen Ende einen Durchmesser hat, der klein genug ist, damit sich das Wundverschlusselement an das innere Lumen einer Einführröhre, verbindbar mit dem distalen Ende des Führungswerkzeugs, anpasst.

7. Werkzeug nach Anspruch 1, wobei der proximale Bereich des Werkzeugs im Wesentlichen zylindrisch ist und ein Aufbewahrungsabteil für das Verschlusselement (30) bildet, wobei die Nenngestalt des Wundverschlusselements nicht beeinträchtigt wird.

8. System zum Einführen und Sichern eines Wundverschlusselements in einen perkutanen Schnitt oder eine perkutane Punktur in der Wand eines Gefäßes, eines Kanals, eines Lumens oder eines hohlen Organs im Körper eines Lebewesens, wobei der Schnitt oder die Punktur kleiner ist als das Wundverschlusselement in einem ungefalteten oder nicht-deformierten Zustand, wobei das System Folgendes aufweist:

ein Wundverschlusselement (30) ;

eine Einführröhre (10) zum Einführen des Wundverschlusselements in den Schnitt;

eine Druckeinrichtung zum Ermöglichen des Durchgangs des Wundverschlusselements durch die Einführröhre hindurch; und

ein Werkzeug nach Anspruch 1, das mit der Einführröhre verbindbar ist.

Revendications

1. Outil de guidage pour le repliement ou la déformation contrôlables et réversibles d'un élément de fermeture de plaie (2) avant l'insertion dudit élément de fermeture de plaie dans une incision percutanée ou un orifice dans la paroi (4) d'un vaisseau, d'un canal, d'une ouverture ou d'un organe creux dans le corps d'un être vivant, où ladite incision ou ledit orifice est plus petit que ledit élément de fermeture de plaie à l'état non replié ou non déformé, ledit outil comprenant un corps (20) avec une extrémité distale (26) et une extrémité proximale (24) et une ouverture (22) entre lesdites extrémités distale et proximale, une ouverture d'introduction (50) de l'élément de fermeture de plaie à l'extrémité proximale et une ouverture de sortie (52) de l'élément de

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fermeture de plaie à l'extrémité distale, **caractérisé en ce que** ledit passage présente des parois internes (54) offrant des surfaces de guidage (56, 64) de l'élément de fermeture de plaie sous la forme d'éléments déflecteurs distincts disposés en saillie sur la paroi interne dudit passage et destinés à réduire de manière réversible l'extension dans l'espace d'un élément de fermeture de plaie pendant son passage dans l'outil de guidage en agissant sur un bord ou collet périphérique de l'élément de fermeture de manière à ce qu'il soit fléchi où replié vers le bas à partir d'une position initiale essentiellement plane, si bien que ledit élément de fermeture de plaie peut passer au travers de ladite incision ou dudit orifice et, après son passage dans ladite incision ou ledit orifice, reprendre une forme telle qu'il soit en mesure d'exercer une action de fermeture sur ladite incision ou ledit orifice.

2. Outil selon la revendication 1, où lesdites surfaces de guidage (56) dans l'extrémité proximale dudit outil sont essentiellement planes et, en direction de l'extrémité distale, remontent et se courbent progressivement de manière à former une ouverture pratiquement conique à l'intérieur de l'outil et où les surfaces de guidage, à l'extrémité distale de l'ouverture, près de l'ouverture de sortie, atteignent une position telle que la section de l'ouverture est essentiellement circulaire.

3. Outil selon la revendication 1 ou 2, où il existe au-dessus des surfaces de guidage (56) des rails de guidage (62) tels que les ailes ou bords (34) de l'élément de fermeture (30) sont maintenus en position basse pendant l'opération de poussée au travers de l'outil de guidage, lesdits rails de guidage (62) étant disposés de manière à éviter que l'élément de fermeture ne puisse inopinément basculer ou mal se positionner pendant son mouvement au travers de l'outil de guidage.

4. Outil selon la revendication 1, où ladite ouverture d'introduction est plus grande que ladite ouverture de sortie et peut en option être dotée d'un bouchon étanche (53) destiné à éviter l'épanchement des fluides corporels.

5. Outil selon la revendication 1, où lesdites surfaces de guidage (56) changent progressivement, entre l'extrémité proximale, où elles n'affectent pas la forme nominale de l'élément de fermeture de plaie (30), et l'extrémité distale, où elles forcent l'élément de fermeture de plaie (30) à prendre une forme correspondant à l'ouverture interne d'un tube d'introduction pouvant être connecté à l'extrémité distale dudit outil de guidage.

6. Outil selon la revendication 1, où ledit passage est de forme conique, au moins dans la région distale dudit outil de guidage, et possède un diamètre suffisamment grand dans la région proximale de l'outil de guidage pour que la forme nominale de l'élément de fermeture de plaie (30) ne soit pas affectée et un diamètre suffisamment petit dans la région distale pour que l'élément de fermeture de plaie corresponde à l'ouverture interne d'un tube d'introduction pouvant être connecté à l'extrémité distale dudit outil de guidage.

7. Outil selon la revendication 1, où la région proximale de l'outil est essentiellement cylindrique, formant un compartiment de stockage pour ledit élément de fermeture de plaie (30), où la forme nominale de celui-ci n'est pas affectée.

8. Système pour l'introduction et la fixation d'un élément de fermeture de plaie dans une incision percutanée ou un orifice dans la paroi d'un vaisseau, d'un canal, d'une ouverture ou d'un organe creux du corps d'un être vivant, ladite incision ou ledit orifice étant plus petit que ledit élément de fermeture de plaie à l'état non replié ou non déformé, ledit système comprenant

un élément de fermeture de plaie (30),

un tube d'introduction (10) pour introduire ledit élément de fermeture de plaie dans ladite incision,

un dispositif de poussage permettant de faire passer ledit élément de fermeture de plaie dans ledit tube d'introduction, et

un outil selon la revendication 1, pouvant être connecté audit tube d'introduction.

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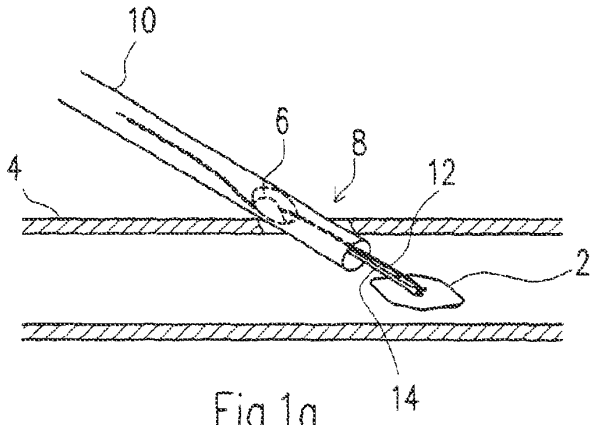

Fig.1a

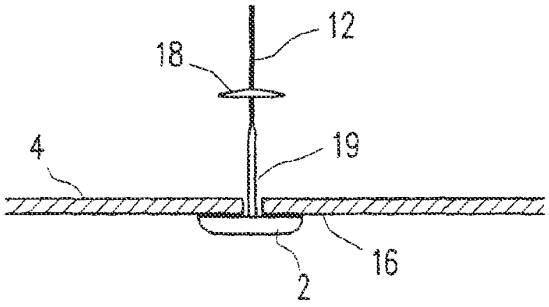

Fig.1b

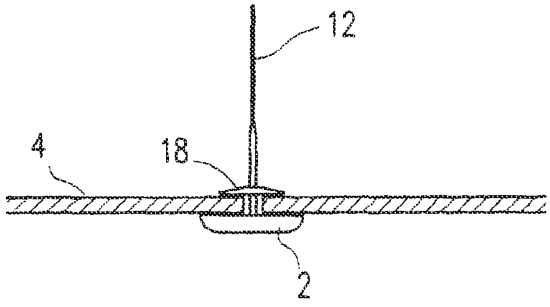

Fig.1c

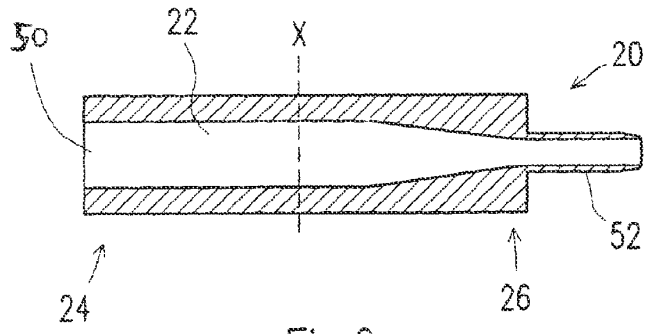

Fig.2a

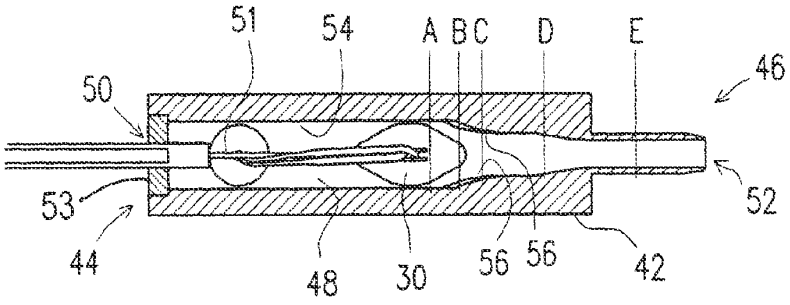

Fig.2b

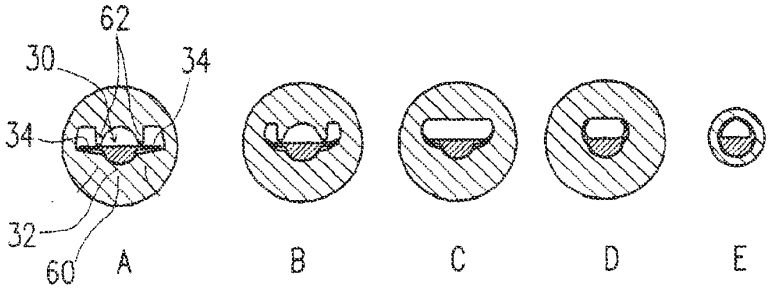

Fig.2c

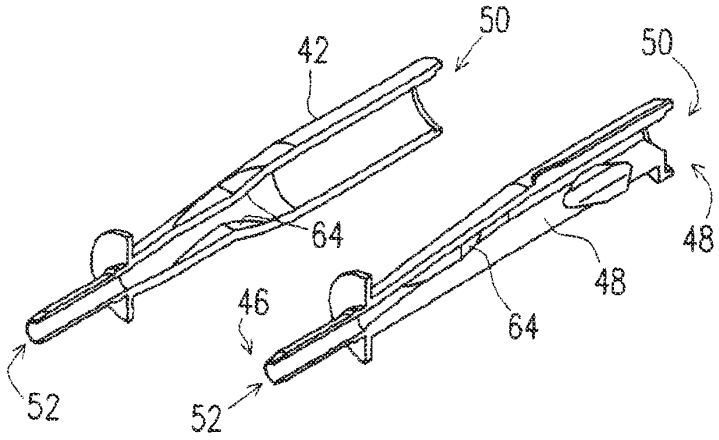

Fig.2d

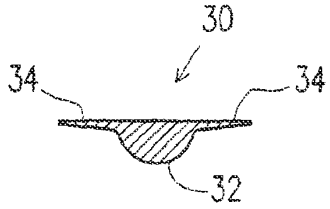

Fig.3a

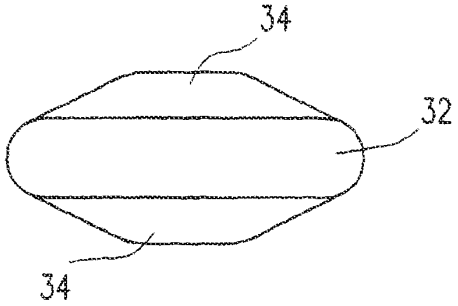

Fig.3b

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(54) Title: CATHETERS HAVING STEERABLE DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS

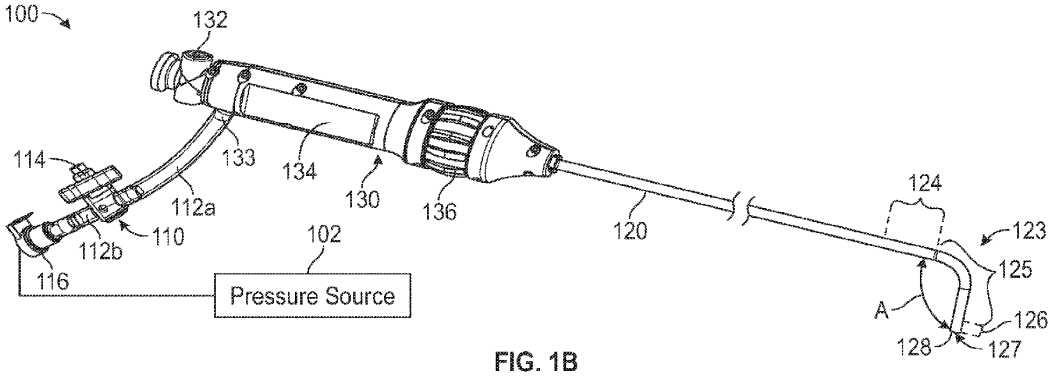

FIG. 1B

(57) Abstract: Disclosed herein are clot removal systems including steerable catheters, and associated systems and methods. In some embodiments, a clot removal system includes (i) an aspiration catheter having a proximal region and a distal region and (ii) a handle coupled to the proximal region of the catheter and having an actuator. The distal region of the catheter can include a deflectable member, and the clot removal system can include a pull wire extending between the actuator and the deflectable member. Actuation of the actuator is configured to pull the pull wire to deflect the deflectable member to deflect the distal region relative to the proximal region. The deflection can facilitate steering of the catheter to hard-to-reach (e.g., tortuous) portions of the anatomy of a patient.

[Continued on next page]

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CATHETERS HAVING STEERABLE DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/115,515, filed November 18, 2020, and titled "CATHETERS HAVING STEERABLE DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to clot removal systems including catheters (e.g., large bore aspiration catheters) having a steerable distal portion to, for example, facilitate positioning of the catheter in hard-to-reach regions of the vasculature of a patient.

BACKGROUND

[0003] Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

[0004] When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. Infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

[0005] In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT arises most commonly when there is a propensity for stagnated blood (e.g., long distance air travel, immobility, etc.) and clotting (e.g., cancer, recent surgery, such as orthopedic surgery, etc.). DVT causes harm by: (1) obstructing drainage of venous blood from the legs leading to swelling, ulcers, pain, and infection, and (2) serving as a reservoir for blood clots to travel to other parts of the body including the heart, lungs, brain (stroke), abdominal organs, and/or extremities.

[0006] In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs, and therefore the entire body, and result in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting in low blood oxygen and buildup of blood carbon dioxide.

[0007] There are many existing techniques to reestablish blood flow through an occluded vessel. One common surgical technique, an embolectomy, involves incising a blood vessel and introducing a balloon-tipped device (such as the Fogarty catheter) to the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to translate the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Although such surgical techniques have been useful, exposing a patient to surgery may be traumatic and best avoided when possible. Additionally, the use of a Fogarty catheter may be problematic due to the possible risk of damaging the inner lining of the vessel as the catheter is being withdrawn.

[0008] Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating vessel stenosis, but it is generally not effective for treating acute thromboembolisms as none of the occlusive material is removed and the vessel will re-stenos after dilation. Another percutaneous technique involves placing a catheter near the clot and infusing streptokinase, urokinase, or other thrombolytic agents to dissolve the clot. Unfortunately, thrombolysis typically takes hours to days to be successful. Additionally, thrombolytic agents can cause hemorrhage and in many patients the agents cannot be used at all.

[0009] Various devices exist for performing a thrombectomy or removing other foreign material. However, such devices have been found to have structures which are either highly complex, cause trauma to the treatment vessel, or lack sufficient retaining structure and thus cannot be appropriately fixed against the vessel to perform adequately. Furthermore, many of the devices have highly complex structures that lead to manufacturing and quality control difficulties as well as delivery issues when passing through tortuous or small diameter catheters.

Less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all the clot material.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0011] Figures 1A and 1B are partially schematic side and isometric views, respectively, of a clot removal system in accordance with embodiments of the present technology.

[0012] Figure 2 is an enlarged, partially cut-away side view of a portion of a proximal region of a catheter of the clot removal system of Figures 1A and 1B in accordance with embodiments of the present technology.

[0013] Figure 3A is an enlarged, partially cut-away side view, and Figure 3B is an enlarged, partially cut-away isometric view, of a portion of an intermediate region of the catheter of Figures 1A and 1B in accordance with embodiments of the present technology.

[0014] Figures 4A and 4B are a distally-facing isometric view and an enlarged proximally-facing isometric view, respectively, of a deflectable member of a deflectable region of the catheter of Figures 1A and 1B in accordance with embodiments of the present technology.

[0015] Figures 4C and 4D are isometric views of a proximal ring and a distal ring, respectively, of the deflectable member of Figures 4A and 4B in accordance with embodiments of the present technology.

[0016] Figure 5A is a partially cross-sectional side view of a handle and a portion of the proximal region of the catheter of the clot removal system of Figures 1A and 1B in accordance with embodiments of the present technology; and Figure 5B is an enlarged cross-sectional isometric view of a portion of the handle shown in Figure 5A.

[0017] Figures 6A and 6B are a distally-facing isometric view and a side view, respectively, of a deflectable member in accordance with additional embodiments of the present technology.

[0018] Figure 6C is top view of a flat pattern that can be cut to integrally form a proximal ring and a tube portion of the deflectable member of Figures 6A and 6B in accordance with

embodiments of the present technology; and Figure 6D is an enlarged top view of a portion of the pattern shown in Figure 6C.

[0019] Figures 7A–7C are side views of a portion of the catheter of the clot removal system of Figures 1A and 1B during a procedure for removing clot material from within a blood vessel of a patient in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0020] The present technology is generally directed to clot removal systems including aspiration catheters having a deflectable/steerable distal portion for improved flexibility through hard-to-reach (e.g., tortuous) vascular anatomy of a patient, and associated systems and methods. In some embodiments, a clot removal system in accordance with embodiments of the present technology includes (i) an aspiration catheter having a proximal region and a distal region and (ii) a handle coupled to the proximal region of the catheter and having an actuator. The distal region of the catheter can include a deflectable member, and the clot removal system can include a pull wire extending between the actuator and the deflectable member. Actuation of the actuator is configured to pull the pull wire to deflect the deflectable member to deflect the distal region relative to the proximal region. The deflection can facilitate steering of the catheter to the hard-to-reach portions of the anatomy of the patient.

[0021] In some embodiments, the deflectable member includes a proximal ring, a distal ring, and a tube portion extending between the proximal and distal rings. The proximal ring can include an annular member coupled (e.g., welded) thereto and configured to slidably receive the pull wire. The distal ring can be configured to be fixedly attached (e.g., welded) to the pull wire. The tube portion can include a plurality of openings (e.g., circumferentially extending openings) that define a plurality of ribs. The ribs can flex away from each other when the actuator is actuated to pull the pull wire. In some embodiments, the tube portion further includes a spine extending between the proximal and distal rings and generally aligned with the pull wire.

[0022] In some embodiments, the catheter further includes an intermediate region between the proximal and distal regions. The catheter can include a braid of wires extending along the proximal and distal regions, and a coil extending over the braid along the intermediate region.

[0023] In some aspects of the present technology, the catheter is configured to be steered to and positioned in difficult-to-reach regions of the anatomy of a patient while still having a relatively large size (e.g., 20 French, 24 French, greater than 24 French). More particularly, the

catheter can have an improved torque response and flexibility compared to conventional catheters having the same size. For example, the braid can provide good torque response along the proximal and intermediate regions of the catheter. Additionally, the deflectable region can be configured (e.g., shaped, sized) to be positioned within and steered/flexed into the difficult-to-reach regions of the anatomy. Further, the coil can provide increased hoop strength at the intermediate region while still allowing the catheter to flex. For example, the coil can inhibit or even prevent kinking or other unwanted movement of the catheter when the catheter is aspirated during a clot removal procedure.

[0024] Certain details are set forth in the following description and in Figures 1–7C to provide a thorough understanding of various embodiments of the present technology. In other instances, well-known structures, materials, operations, and/or systems often associated with intravascular procedures, clot removal procedures, catheters, and the like are not shown or described in detail in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. Those of ordinary skill in the art will recognize, however, that the present technology can be practiced without one or more of the details set forth herein, and/or with other structures, methods, components, and so forth.

[0025] The terminology used below is to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain examples of embodiments of the technology. Indeed, certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

[0026] The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope unless expressly indicated. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles and features without departing from the present technology. In addition, those of ordinary skill in the art will appreciate that further

embodiments of the present technology can be practiced without several of the details described below.

[0027] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures. The systems of the present technology can be used in any orientation suitable to the user.

[0028] Figures 1A and 1B are partially schematic side and isometric views, respectively, of a clot removal system 100 in accordance with embodiments of the present technology. The clot removal system 100 can also be referred to as an aspiration assembly, a clot treatment system, and/or a thrombectomy system. Referring to Figures 1A and 1B together, the clot removal system 100 includes a tubing assembly 110 coupled to a catheter 120 via a handle 130. In general, the clot removal system 100 (i) can include features generally similar or identical to those of the clot removal systems described in detail in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety, and/or (ii) can be used to treat/remove clot material from a patient (e.g., a human patient) using any of the methods described in detail therein.

[0029] Referring to Figure 1A, the catheter 120 can include (i) a proximal region or portion 121, (ii) an intermediate region 122 adjacent to and distal of the proximal region 121, and (iii) a distal region 123 adjacent to and distal of the intermediate region 122. Referring to Figure 1B, the distal region 123 can further include a transition region 124, a deflectable region 125 (e.g., a flexible region, steerable region, deformable region) distal of the transition region 124, and a tip region 126 distal of the deflectable region 125. Referring again to Figures 1A and 1B together, the catheter 120 further defines a lumen 127 extending therethrough from the proximal region 121 to the tip region 126. The proximal region 121 defines a proximal terminus (obscured by the handle 130 in Figures 1A and 1B; e.g., a proximal terminus 529 shown in Figure 5A) of the catheter 120 that can be positioned within the handle 130, and the tip region 126 defines a distal terminus 128 of the catheter 120.

[0030] In some embodiments, the proximal region 121 has a first length, the intermediate region 122 has a second length less than the first length, and the distal region 123 has a third length less than the first and second lengths. For example, the first length can be between about 50–100 millimeters (e.g., about 80 millimeters), the second length can be between about 10–50 millimeters (e.g., about 25 millimeters), and the third length can be between about 1.0–10 millimeters (e.g., about 4.2 millimeters). In some embodiments, the transition region 124 can have a length of between about 0.1–5.0 millimeters (e.g., about 0.6 millimeters), the deflectable region 125 can have a length of between about 1.0–10 millimeters (e.g., about 3.0 millimeters), and the tip region 126 can have a length of between about 0.1–5.0 millimeters (e.g., about 0.6 millimeters). In other embodiments, the lengths of one or more of the regions 121–126 can be different. In some embodiments, the catheter 120 can have varying flexibilities, shapes, thicknesses, and/or other properties in/along the various regions 121–126.

[0031] In the illustrated embodiment, the handle 130 includes and/or is coupled to a valve 132. The valve 132 can include a branch or side port 133 configured to fluidly couple the lumen 127 of the catheter 120 to the tubing assembly 110, and can be integral with or coupled to the proximal region 121 of the catheter 120. In some embodiments, the valve 132 is a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by inhibiting or even preventing fluid flow in the proximal direction through the valve 132 as various components such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and so on are inserted through the valve 132 to be delivered through the catheter 120 to a treatment site in a blood vessel. In some embodiments, the valve 132 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety.

[0032] In the illustrated embodiment, the tubing assembly 110 fluidly couples the catheter 120 to a pressure source 102, such as a syringe. The tubing assembly 110 can include one or more tubing sections 112 (individually labeled as a first tubing section 112a and a second tubing section 112b), at least one fluid control device 114 (e.g., a valve), and at least one connector 116 (e.g., a Toomey tip connector) for fluidly coupling the tubing assembly 110 to the pressure source 102 and/or other suitable components. In some embodiments, the fluid control device 114 is a stopcock that is fluidly coupled to (i) the side port 133 of the valve 132 via the first tubing section 112a and (ii) the connector 116 via the second tubing section 112b. The fluid control device 114 is externally operable by a user to regulate the flow of fluid therethrough and,

specifically, from the lumen 127 of the catheter 120 to the pressure source 102. In some embodiments, the connector 116 is a quick-release connector (e.g., a quick disconnect fitting) that enables rapid coupling/decoupling of the catheter 120 and the fluid control device 114 to/from the pressure source 102.

[0033] In the illustrated embodiment, the handle 130 includes a housing 134 and an actuator 136. The actuator 136 can be operably coupled to the catheter 120 and movable (e.g., rotatable) relative to the housing 134 to deflect (e.g., steer, flex) the deflectable region 125 from (i) a first position (e.g., an unflexed position, an aligned position) shown in Figure 1A in which the deflectable region 125 is generally aligned with the intermediate region 122 and/or the proximal region 121 to (ii) a second position (e.g., a flexed position) shown in Figure 1B in which the deflectable region 125 is deflected relative to the intermediate region 122 and/or the proximal region 121. That is, the actuator 136 can be configured to deflect the deflectable region 125 away from a longitudinal axis generally aligned with the proximal region 121 and/or the intermediate region 122. In some embodiments, the deflectable region 125 can have a bend angle A in the second position (Figure 1B) of greater than about 30 degrees, greater than about 50 degrees, greater than about 70 degrees, greater than about 90 degrees, or greater. In some embodiments, the bend angle A is about 90 degrees.

[0034] Figure 2 is an enlarged, partially cut-away side view of a portion of the proximal region 121 of the catheter 120 in accordance with embodiments of the present technology. Figure 3A is an enlarged, partially cut-away side view, and Figure 3B is an enlarged, partially cut-away isometric view, of a portion of the intermediate region 122 of the catheter 120 in accordance with embodiments of the present technology. Referring to Figures 1–3B together, the catheter 120 includes an outer sheath 240 and an inner liner 242 extending through/defining each of the regions 121–126. The outer sheath 240 is positioned over (e.g., radially outside of) the inner liner 242. The outer sheath 240 can also be referred to as an outer jacket, an outer shaft, or an outer layer, and the inner liner 242 can also be referred to as an inner layer, an inner sheath, or an inner shaft.

[0035] In some embodiments, the outer sheath 240 can be formed from a plastic material, elastomeric material, and/or thermoplastic elastomer (TPE) material. In some embodiments, the outer sheath 240 can be formed from a TPE manufactured by Arkema S.A., of Colombes, France, such as the TPEs manufactured under the trademark "Pebax." In some embodiments, the outer sheath 240 can have a varying hardness (e.g., durometer), thickness, flexibility, rigidity, and/or

other property in one or more of the different regions 121–126. For example, the outer sheath 240 can have (i) a first hardness along the proximal region 121 of between about 65D–75D (e.g., about 72D), (ii) a second hardness along the intermediate region 122 of between about 30D–40D (e.g., about 35D), (iii) a third hardness along the transition region 124 of between about 50D–60D (e.g., about 55D), (iv) a fourth hardness along the deflectable region of between about 20D–30D (e.g., about 25D), and (v) a fifth hardness along the tip region 126 of between about 50D–60D (e.g., about 55D). In other embodiments, the outer sheath 240 can have a different hardness or other property along one or more of the regions 121–126.

[0036] The inner liner 242 can be formed of a lubricious material that facilitates the movement (e.g., distal advancement, proximal retraction) of various components through the lumen 127, such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and the like. In some embodiments, the inner liner 242 can be formed from a polymer material, a fluoropolymer material (e.g., polytetrafluoroethylene (PTFE)), and/or another material having a high degree of lubricity. In some embodiments, the inner liner 242 can define a diameter D (Figure 2) of the lumen 127, and the diameter D can be greater than about 6 French, greater than about 10 French, greater than about 16 French, greater than about 20 French, greater than about 24 French, or greater. In some embodiments, the diameter D is about 8 French, about 16 French, about 20 French, or about 24 French. In certain embodiments, the diameter D of the inner liner 242 is the same in each of the regions 121–126 while, in other embodiments, the diameter D can vary along one or more of the regions 121–126.

[0037] The catheter 120 can further include a braid 244 extending along the proximal region 121 and the intermediate region 122 between the outer sheath 240 and the inner liner 242. In some embodiments, the braid 244 terminates at or before the distal region 123 such that the braid 244 does not extend along the transition region 124, the deflectable region 125, or the tip region 126. In the illustrated embodiment, the catheter 120 further includes a coil 346 (Figures 3A and 3B) extending at least partially along the intermediate region 122 between the braid 244 and the outer sheath 240. In some embodiments, the coil 346 extends only along the intermediate region 122 and does not extend into the proximal region 121 or the distal region 123.

[0038] The braid 244 can include wires, filaments, threads, sutures, fibers, or the like (collectively "wires 248") that have been woven or otherwise coupled, attached, formed, and/or joined together at a plurality of interstices 249. Accordingly, the braid 244 can also be referred to as a braided structure, a braided filament structure, a braided filament mesh structure, a mesh

structure, a mesh filament structure, and the like. In some embodiments, the wires 248 can comprise metals, polymers, and/or composite materials. In some embodiments, individual ones of the wires 248 can be rolled flat wires having a cross-sectional dimension of between about 0.0005–0.005 inch (e.g., about 0.002 inch) by about 0.002–0.005 inch (e.g., about 0.0033 inch).

[0039] In the illustrated embodiment, the coil 346 is a single wire wound around the braid 244 and the inner liner 242 along the intermediate region 122. In other embodiments, the coil 346 can include more than one wire wound about the braid 244. For example, the coil 346 can include multiple wires wound over one another and/or multiple wires wound to at least partially overlap one another to form a braided or overlapping coil structure on the braid 244. In other embodiments, the coil 346 can be formed directly over the inner liner 242, and the braid 244 can be formed over the coil 346. The coil 346 can be formed from a metallic or other suitably strong material, such as nickel-titanium alloys (e.g. nitinol), platinum, cobalt-chrome alloys, stainless steel, tungsten, and/or titanium.

[0040] Figures 4A and 4B are a distally-facing isometric view and an enlarged proximally-facing isometric view, respectively, of a deflectable member 450 of the deflectable region 125 of the catheter 120 in accordance with embodiments of the present technology. The deflectable member 450 can be positioned between the outer sheath 240 and the inner liner 242 (Figures 2–3B), which are both omitted in Figures 4A and 4B for clarity. In the illustrated embodiment, the deflectable member 450 includes a proximal ring 452, a distal ring 454, and a tube portion 456 extending between the proximal ring 452 and the distal ring 454. The deflectable member 450 can be formed from a flexible metallic material—such as nickel-titanium alloys (e.g. nitinol), platinum, cobalt-chrome alloys, stainless steel, tungsten, and/or titanium—or another suitably strong and flexible material. Similarly, the deflectable member 450 can be manufactured (e.g., laser cut) as a single integral piece, or one or more of the proximal ring 452, the distal ring 454, and the tube portion 456 can be separately manufactured and then coupled (e.g., welded, tack welded, adhered, fastened) together.

[0041] Figures 4C and 4D are isometric views of the proximal ring 452 and the distal ring 454, respectively, in accordance with embodiments of the present technology. Referring to Figures 4A–4C together, the proximal ring 452 can include an annular body 462 having an outer surface 461 and an inner surface 463. An annular member 464 can be coupled (e.g., welded, tack welded, adhered, fastened) to the inner surface 463 of the annular member 464 and can define/include a lumen 465. Referring to Figures 4A and 4D together, the distal ring 454 can

include an annular body 468 having an outer surface 467 and an inner surface 469. Referring to Figures 4A–4D together, the lumen 465 of the annular body 462 is configured to slidably receive a pull wire 458 (Figure 4D). The pull wire 458 can be coupled (e.g., welded, tack welded, adhered, fastened) to the inner surface 469 of the distal ring 454 and can extend from the distal ring 454 to the handle 130 (Figure 1), as described in greater detail below with reference to Figures 5A and 5B.

[0042] Referring again to Figures 4A and 4B together, the tube portion 456 can include a plurality of openings 451 extending partially about a circumference of the tube portion 456 to define a spine 453 and a plurality of ribs 455. In the illustrated embodiment, the spine 453 extends generally parallel to a longitudinal axis L (Figure 4A) of the deflectable member 450 and is generally aligned with the annular member 464 and the pull wire 458 (Figure 4D). That is, the pull wire 458 can extend through the tube portion 456 generally parallel to the spine 453. In some embodiments, the openings 451 are generally elongate openings that extend (i) generally parallel to one another and (ii) circumferentially about the longitudinal axis L such that, for example, the ribs 455 have a generally similar or identical shape. The openings 451 and/or the ribs 455 can all have the same dimensions as shown in Figures 4A and 4B while, in other embodiments, some or all of the openings 451 and/or the ribs 455 can have different dimensions and/or arrangements about the tube portion 456. In some embodiments, the tube portion 456 can be a laser-cut hypo tube.

[0043] Referring to Figures 2–4D together, in some embodiments the deflectable member 450 can be positioned between the outer sheath 240 and the inner liner 242 such that (i) the outer sheath 240 extends over/along the outer surface 461 of the proximal ring 452, an outer surface of the tube portion 456, and the outer surface 467 of the distal ring 454 and (ii) the inner liner 242 extends over/along the inner surface 463 of the proximal ring 452, an inner surface of the tube portion 456, and the inner surface 469 of the distal ring 454. In some embodiments, some or all of the pull wire 458 can be coated with PTFE or another suitable material (e.g., a fluoropolymer material). For example, the PTFE material can be omitted where the pull wire 458 is attached to the distal ring 454. The PTFE or other coating material can help inhibit the outer sheath 240 from adhering to the pull wire 458—thereby allowing the pull wire 458 to be moved relative to the deflectable member 450 after the outer sheath 240 is applied thereover.

[0044] Referring to Figures 1–3B together, in some embodiments the transition region 124 and the tip region 126 can include only the outer sheath 240 and the inner liner 242. In some

embodiments, the transition region 124 and/or the tip region 126 can include a marker band (not shown), such as a radiopaque marker configured to facilitate visualization of the position of the catheter 120 during a medical procedure (e.g., a clot removal procedure) using the catheter 120. For example, the transition region 124 and the tip region 126 can each include a radiopaque marker to facilitate visualization of the deflectable region 125 of the catheter 120.

[0045] Referring to Figures 1–4D together, in some embodiments, the catheter 120 can be formed about a mandrel or other elongate member. For example, the inner liner 232 can first be positioned about the mandrel. Then, the braid 244 can be formed (e.g., wound, braided) about the inner liner 242 around the mandrel (e.g., along the proximal and intermediate regions 121, 122) and/or the deflectable member 450 can be positioned about the inner liner 242 around the mandrel (e.g., along the deflectable region 125). Next, the coil 346 can be wound around the mandrel about the braid 244 over the intermediate region 122. Next, the outer sheath 240 can be positioned over the inner liner 242, the braid 244, the coil 346, and the deflectable member 450, and then heat shrunk or otherwise secured thereto. In some embodiments, the outer sheath 240 can be fused to the inner liner 242, the braid 244, the coil 346, and/or the deflectable member 450 to secure these components of the catheter 120 together.

[0046] Figure 5A is a partially cross-sectional side view of the handle 130 and a portion of the proximal region 121 of the catheter 120 in accordance with embodiments of the present technology. Figure 5B is an enlarged cross-sectional isometric view of a portion of the handle 130 shown in Figure 5A. Referring to Figures 5A and 5B, together, the housing 134 defines a proximal chamber 570 (e.g., a volume, lumen, compartment) and a distal chamber 572 that can be separated by the actuator 136. The valve 132 can be coupled to the housing 134 (e.g., a proximal portion of the housing 134) and positioned at least partially within the proximal chamber 570.

[0047] In the illustrated embodiment, the handle 130 includes a hollow tube member 574 positioned at least partially within the proximal chamber 570. The tube member 574 can include a proximal end portion 571a and a distal end portion 571b coupled to (e.g., secured to) the actuator 136. The tube member 574 can define a lumen 573 extending between the proximal and distal end portions 571a-b, and the tube member 574 can have a threaded inner surface 575 extending at least partially along the lumen 573. The actuator 136 can be a rotatable member, such as a wheel, grip wheel, or dial that is rotatable relative to the housing 134 to rotate the tube member 574 within the proximal chamber 570.

[0048] In the illustrated embodiment, the handle 130 further includes a catheter support or guide 576 extending at least partially through (i) the distal chamber 572, (ii) the actuator 136 (e.g., through a lumen in the actuator), (iii) the lumen 573 of the tube member 574, and (iv) the proximal chamber 570. In some embodiments, the catheter guide 576 defines a lumen 577 extending therethrough and includes a proximal flange portion 578 that can be secured to the housing 134. In some embodiments, the catheter guide 576 is fixed to the housing 134 such that the catheter guide 576 does not rotate when the actuator 136 is actuated to move the tube member 574. The proximal region 121 of the catheter 120 can extend into the handle 130, through the lumen 577 in the catheter guide 576, and to the valve 132. The proximal terminus 529 of the catheter 120 can be fluidly coupled to the valve 132. Accordingly, the catheter 120, the catheter guide 576, and the tube member 574 can be coaxially aligned. In other embodiments, the catheter guide 576 can be omitted.

[0049] The handle 130 can further include a shuttle member 580 positioned at least partially in the lumen 573 of the tube member 574 over the catheter guide 576 (e.g., over an outer surface thereof). In some embodiments, the shuttle member 580 is a hollow member slidably positioned over the catheter guide 576 and movable relative to the catheter 120. In the illustrated embodiment, the shuttle member 580 includes a threaded portion 582 having a threaded outer surface 583 and an anchor portion 584 extending from the threaded portion 582. The threaded outer surface 583 is configured to engage the threaded inner surface 575 of the tube member 574 such that, for example, movement of the tube member 574 drives the shuttle member 580 to move through the lumen 573 over the catheter guide 576 and relative to the catheter 120.

[0050] In the illustrated embodiment, the pull wire 458 extends along the catheter 120 into the handle 130 where it secured to the anchor portion 584 of the shuttle member 580. More specifically, the pull wire 458 can extend from the distal ring 454 of the deflectable member 450 (Figure 4D) and through/along the transition, intermediate, and proximal regions 124, 122, 121 of the catheter 120 (Figures 1A and 1B) to the handle 130. For example, the pull wire 458 can be routed (i) through a lumen formed in the wall of the catheter 120 or (ii) simply between the outer sheath 240 and inner liner 242 (Figures 2–3B). In the illustrated embodiment, the pull wire 458 exits the catheter 120 and the catheter guide 476 (e.g., via openings therein) and enters the distal chamber 572. From the distal chamber 572, the pull wire 458 can extend through the actuator 136 and through the lumen 573 of the tube member 574 to the anchor portion 584. As best seen in Figure 5B, in some embodiments the pull wire 458 can be secured to anchor portion

584 via a screw 581 or other fastener. In some embodiments, the handle 130 can further include a biasing member 585, such as a coil spring, coupled to and/or over the pull wire 458. The biasing member 585 can be configured to smooth/distribute tension loads on the pull wire 458 during operation that might otherwise damage the pull wire 458 and/or various components of the handle 130.

[0051] Referring to Figures 1A, 1B, and 4A–5B together, the deflectable region 125 (and correspondingly the deflectable member 450) is in the first position and the handle 130 is in a corresponding first position in which the shuttle member 580 is positioned distally within the lumen 473 of the tube member 574 proximate to the actuator 136 and/or the distal end portion 571b of the tube member 574. To move the deflectable region 125 to the second (e.g., bent) position, a user can rotate the actuator 136 in a first direction to rotate the tube member 574. The rotation of the tube member 574 can drive the shuttle member 580 to move proximally through the lumen 573 in a direction toward the proximal end portion 571a of the tube member 574 via the engagement of the threaded outer surface 583 with the threaded inner surface 575. That is, the handle 130 is configured to translate the rotational movement of the actuator 136 into linear movement of the shuttle member 580. As the shuttle member 580 moves proximally, the shuttle member 580 pulls the pull wire 458 proximally and increases the tension therein. The pull wire 458 thus moves (e.g., slides) proximally through the lumen 465 in the annular member 464 of the deflectable member 450 and, because the pull wire 458 is fixedly attached to the distal ring 454 of the deflectable member 450, the pull wire 458 urges the distal ring 454 proximally relative to the proximal ring 452. This differential force causes the tube portion 456 of the deflectable member 450 to bend toward the second position shown in Figure 1B. More specifically, because the pull wire 458 is aligned with the spine 453 of the deflectable member 450, the spine 453 can define an inner radius of the bend while the ribs 455 flex away from one another, thereby increasing a size of the openings 451. To return the deflectable region 125 from the second position to the first position, the user can rotate the actuator 136 in a second direction opposite the first direction to translate the shuttle member 580 distally through the lumen 573 to decrease the tension in the pull wire 458, thereby allowing the deflectable member 450 to return to the relaxed position shown in Figures 4A and 4B.

[0052] In other embodiments, the handle 130 can include other features for moving/driving the shuttle member 580 through the housing 134 to tension the pull wire 458. For example, the actuator 136 can be a slider, clip, or other actuator movable relative to the housing 134.

[0053] Referring to Figures 1A–5B together, in some aspects of the present technology, the catheter 120 is configured to be steered to and positioned in difficult-to-reach regions of the anatomy of a patient while still having a relatively large size (e.g., 20 French, 24 French, greater than 24 French). More particularly, the catheter 120 can have an improved torque response and flexibility compared to conventional catheters having the same size. For example, the braid 234 can provide good torque response along the proximal and intermediate regions 121, 122 of the catheter 120. Moreover, the varying hardness (e.g., distally decreasing hardness) of the outer sheath 240 can provide (i) good torque response and/or pushability at the proximal region 121 and (ii) increased flexibility at the intermediate and distal regions 122, 123. Additionally, the deflectable region 125 is configured (e.g., shaped, sized) to be positioned within and steered/flexed into the difficult-to-reach regions of the anatomy. Further, the coil 346 can provide increased hoop strength at the intermediate region 122 while still allowing the catheter 120 to flex. For example, the coil 346 can inhibit or even prevent kinking or other unwanted movement of the catheter 120 when the lumen 127 is aspirated during a clot removal procedure.

[0054] Figures 6A and 6B are a distally-facing isometric view and a side view, respectively, of a deflectable member 650 in accordance with additional embodiments of the present technology. The deflectable member 650 is configured to be positioned in the deflectable region 125 of the catheter 120 (Figure 1) and can include some features generally similar or identical to the deflectable member 450 described in detail above with reference to Figures 4A–4D. For example, in the illustrated embodiment the deflectable member 650 includes a proximal ring 652, a distal ring 654, and a tube portion 656 extending between the proximal ring 652 and the distal ring 654. The proximal ring 652 includes an annular member 664 coupled thereto and configured to slidably receive the pull wire 458. The pull wire 458 can extend through the tube portion 656 and be fixedly secured (e.g., welded) to the distal ring 654.

[0055] In the illustrated embodiment, the tube portion 656 includes a plurality of openings 651 (identified individually as first openings 651a and second openings 651b) extending partially about a circumference of the tube portion 656 to define a plurality of ribs 655 (identified individually as first ribs 655a and second ribs 655b). In some embodiments, the first openings 651a are generally elongate openings that extend (i) generally parallel to one another and (ii) circumferentially about a longitudinal axis M of the deflectable member 650 such that, for example, the first ribs 655a have a generally similar or identical shape. Similarly, the second openings 651b can each have an elongate tapered shape and can extend (i) generally parallel to one another and (ii) circumferentially about the longitudinal axis M of the deflectable member

650 such that, for example, the second ribs 655b have a generally similar or identical shape. In the illustrated embodiment, the second ribs 655b have a smaller dimension (e.g. width) in a direction along the longitudinal axis M than the first ribs 655a. Accordingly, the second ribs 655b can be relatively more flexible than the first ribs 655a.

[0056] In some embodiments, the pull wire 458 can extend over/adjacent to the first ribs 655a. Accordingly, referring to Figures 5–6B together, actuation of the actuator can 136 pull the pull wire 458 to urge the distal ring 654 proximally relative to the proximal ring 652. This differential force causes the tube portion 656 of the deflectable member 650 to bend such that, for example, a portion of the first ribs 655a define an inner radius of the bend while the second ribs 655b flex away from one another, thereby increasing a size of the second openings 651b (e.g., and conversely decreasing a size of the first openings 651a).

[0057] In some embodiments, all or a portion of the deflectable member 650 can be manufactured as a single integral piece. For example, Figure 6C is top view of flat pattern that can be cut to integrally form the proximal ring 652 and the tube portion 656 of the deflectable member 650 in accordance with embodiments of the present technology. Figure 6D is an enlarged top view of a portion of the pattern shown in Figure 6C. Referring to Figures 6C and 6D together, the pattern can be laser cut from a single piece of material (e.g., stainless steel), formed to have the three-dimensional tubular shape shown in Figures 6A and 6B, and then welded or otherwise adhered together to form the deflectable member 650.

[0058] Figures 7A–7C are side views of a portion of the catheter 120 of the clot removal system 100 during a procedure for removing clot material PE (e.g., a pulmonary embolism) from within a blood vessel BV (e.g., a pulmonary blood vessel) of a patient (e.g., a human patient) in accordance with embodiments of the present technology. As noted above, in some embodiments the clot removal procedure illustrated in Figures 7A–7C can be generally similar or identical to any of the clot removal procedures disclosed in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety.

[0059] With reference to Figures 1A–7A together, the catheter 120 can be advanced through the patient toward and/or proximate to the clot material PE within the blood vessel BV (e.g., advanced to a treatment site within the blood vessel BV). In some embodiments, however, the blood vessel BV can include a hard-to-reach (e.g., tortuous) region, such as a region beyond a bend 790 in the blood vessel BV that can have a relatively small radius of curvature. The

region of the blood vessel BV distal of the bend 790 can be difficult to reach due to the required approach angle, varying anatomy of the blood vessel BV, and/or irregularities due to illness of the patient.

[0060] Accordingly, with reference to Figures 1A–5B and 7B together, the deflectable region 125 can be moved fully or partially from the first position (Figure 1A) to the second position (Figure 1B) before and/or during further advancement of the catheter 120 toward the clot material PE. More specifically, the user can actuate (e.g., rotate) the actuator 136 of the handle to pull the pull wire 458 to deflect the deflectable member 450 to deflect the deflectable region 125, as described in detail above. In some embodiments, the catheter 120 can be advanced through the blood vessel BV until the distal terminus 128 of the catheter 120 is positioned proximate to a proximal portion of the clot material PE. In some embodiments, the position of the distal terminus 128 can be confirmed or located via visualization of a marker band (not shown; e.g., in/along the tip region 126) using fluoroscopy or another imaging procedure (e.g., a radiographic procedure). In other embodiments, the distal terminus 128 can be positioned at least partially within the clot material PE or distal of the clot material PE.

[0061] In some aspects of the present technology, moving the deflectable region 125 to the second position helps the catheter 120 flex/bend around the bend 790 and into the hard-to-reach region of the blood vessel BV distal thereof. In some embodiments, before advancing the catheter 120 to the position shown in Figure 7B, the catheter 120 can be rotated to align the deflectable region 125 with the bend 790. In contrast, conventional catheters of the same size may be too stiff to easily position proximate the clot material PE. For example, such conventional catheters may "rainbow" over the clot material PE by following or tracking along the wall of the blood vessel BV at the outside of the bend 790. In addition to the deflectable region 125, both (i) the varying hardness of the outer sheath 240 (Figures 2–3B) and (ii) the flexibility of the braid 244 (Figures 2–3B) and the coil 346 (Figures 3B and 3C) can help the catheter 120 flex through the anatomy of the blood vessel BV to the desired position proximate the clot material PE.

[0062] Access to the pulmonary vessels can be achieved through the patient's vasculature, for example, via the femoral vein. In some embodiments, the clot removal system 100 can include an introducer (e.g., a Y-connector with a hemostasis valve; not shown) that can be partially inserted into the femoral vein. A guidewire (not shown) can be guided into the femoral vein through the introducer and navigated through the right atrium, the tricuspid valve, the right

ventricle, the pulmonary valve, and into the main pulmonary artery. Depending on the location of the clot material PE, the guidewire can be guided to one or more of the branches of the right pulmonary artery and/or the left pulmonary artery. In some embodiments, the guidewire can be extended entirely or partially through the clot material PE. In other embodiments, the guidewire can be extended to a location just proximal of the clot material PE. After positioning the guidewire, the catheter 120 can be placed over the guidewire and advanced to the position proximate to the clot material PE as illustrated in Figure 7B. In some embodiments, the guidewire can then be withdrawn while, in other embodiments, the guidewire can remain and can be used to guide other catheters (e.g., delivery catheters, additional aspiration guide catheters, etc.), interventional devices, etc., to the treatment site. It will be understood, however, that other access locations into the venous circulatory system of a patient are possible and consistent with the present technology. For example, the user can gain access through the jugular vein, the subclavian vein, the brachial vein, or any other vein that connects or eventually leads to the superior vena cava. Use of other vessels that are closer to the right atrium of the patient's heart can also be advantageous as it reduces the length of the instruments needed to reach the clot material PE.

[0063] With reference to Figures 1A, 1B, and 7C together, the pressure source 102 is configured to generate (e.g., form, create, charge, build-up) a vacuum (e.g., negative pressure) and store the vacuum for subsequent application to the catheter 120. For example, after positioning the catheter 120 proximate the clot material PE, a user can first close the fluid control device 114 before generating the vacuum in the pressure source 102 by, for example, withdrawing the plunger of a syringe coupled to the connector 116. In this manner, a vacuum is charged within the pressure source 102 (e.g., a negative pressure is maintained) before the pressure source 102 is fluidly connected to the lumen 127 of the catheter 120. To aspirate the lumen 127 of the catheter 120, the user can open the fluid control device 114 to fluidly connect the pressure source 102 to the catheter 120 and thereby apply or release the vacuum stored in the pressure source 102 to the lumen 127 of the catheter 120.

[0064] Opening of the fluid control device 114 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing assembly 110 and the catheter 120, thereby generating a suction pulse throughout the catheter 120. In particular, the suction is applied at the tip region 126 of the catheter 120 to suck/aspirate at least a portion of the clot material PE into the lumen 127 of the catheter 120, as shown in Figure 7C. In one aspect of the present technology, pre-charging or storing the vacuum in the pressure source 102 before applying the

vacuum to the lumen 127 of the catheter 120 is expected to generate greater suction forces and corresponding fluid flow velocities at and/or near the tip region 126 of the catheter 120 compared to simply activating the pressure source 102 while it is fluidly connected to the catheter 120.

[0065] Sometimes, as shown in Figure 7C, discharging the vacuum stored in the pressure source to aspirate the lumen 127 of the catheter 120 may remove substantially all (e.g., a desired amount) of the clot material PE from the blood vessel BV. That is, a single aspiration pulse may adequately remove the clot material PE from the blood vessel BV. In other embodiments, a portion of the clot material PE may remain in the blood vessel BV. In such instances, the user may wish to again apply vacuum pressure (conduct an "aspiration pass") to remove all or a portion of the remaining clot material PE in the blood vessel BV. In such instances, the pressure source 102 can be disconnected from the tubing assembly 110 and drained (e.g., aspirated clot removal removed) before the pressure source 102 is reconnected to the tubing assembly 110 and activated once again. After removing a desired amount of the clot material PE, the catheter 120 can be withdrawn from the patient.

[0066] In some aspects of the present technology, the relatively great flexibility and torquability of the catheter 120 allow the catheter 120 to be positioned in difficult-to-reach areas of the blood vessel BV (or elsewhere in the vasculature of the patient) without decreasing the size of the lumen 127 and while keeping the lumen 127 of constant diameter throughout. It is expected that the increased size of the lumen 127 will provide greater suction forces over a smaller period of time (e.g., will provide a larger vacuum impulse). In some embodiments, the greater suction forces can facilitate the removal of clot material from a blood vessel of a patient even where the clot material is strongly lodged or attached within the blood vessel (e.g., a chronic clot). Accordingly, in contrast to conventional catheters, the catheter 120 can be used to generate greater aspirational forces for improved clot removal in hard-to-reach places of the vasculature. In additional aspects of the present technology, the coil 336 (Figures 3B and 3C) can provide a high hoop strength that inhibits or even prevents kinking or other unwanted movement of the catheter 120 when the pressure source 102 is used to generate a suction pulse at the distal region 123 of the catheter 120.

[0067] Although described in the context of removing clot material from pulmonary blood vessels, in other embodiments the clot removal system 100 can be used to remove clot from other locations in the body of the patient. For example, the clot removal system 100 can used to aspirate or otherwise remove clot material (e.g., stationary or in transit) and/or vegetation from

the heart (e.g., the right atrium, tricuspid valve, pulmonary valve), the vena cava, the renal arteries, and so on.

[0068] Several aspects of the present technology are set forth in the following examples:

1. An aspiration catheter, comprising:

a proximal region; and

a distal region including a deflectable member, wherein the deflectable member includes—

a proximal ring;

a distal ring configured to be fixedly attached to a pull wire; and

a tube portion extending between the proximal and distal rings, wherein the tube portion includes a plurality of openings extending therethrough to define a plurality of ribs, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally.

2. The aspiration guide catheter of example 1 wherein the tube portion includes a spine extending in a direction between the proximal and distal rings, wherein the ribs extend away from the spine, and wherein the spine is configured to extend generally parallel to and over the pull wire.

3. The aspiration catheter of example 1 or example 2 wherein the proximal region and the distal region define a lumen having a diameter of 20 French or greater.

4. The aspiration catheter of any one of examples 1–3, further comprising an intermediate region between the proximal and distal regions, wherein the proximal region and the intermediate region include a braid of wires extending therethrough.

5. The aspiration catheter of example 4 wherein the intermediate region includes a wire coiled around the braid.

6. The aspiration catheter of any one of examples 1–5 wherein the tube portion extends along a longitudinal axis in a relaxed state, and wherein the openings extend

circumferentially about the longitudinal axis and generally parallel to one another in the relaxed state.

7. The aspiration catheter of any one of examples 1–6 wherein the proximal ring includes an annular member configured to slidably receive the pull wire therethrough.

8. A clot removal system, comprising:

an aspiration catheter including a proximal region and a distal region, wherein the distal region includes a deflectable member;

a handle coupled to the proximal region of the aspiration catheter, wherein the handle includes an actuator; and

a pull wire extending between the actuator and the deflectable member, wherein actuation of the actuator is configured to pull the pull wire to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region.

9. The clot removal system of example 8 wherein the aspiration catheter extends along an axis, and wherein the actuation of the actuator is configured to deflect the distal region of the aspiration catheter away from the axis by about 90 degrees or greater.

10. The clot removal system of example 8 or example 9 wherein the aspiration guide catheter has a size of 20 French or greater.

11. The clot removal system of any one of examples 8–10 wherein the deflectable member has a tubular shape that extends along a longitudinal axis, and wherein the deflectable member includes (a) a spine extending parallel to the longitudinal axis and (b) a plurality of ribs extending from the spine and circumferentially about the longitudinal axis.

12. The clot removal system of example 11 wherein the deflectable member has a distal portion and a proximal portion, and wherein the pull wire is attached to the distal portion of the deflectable member.

13. The clot removal system of example 12 wherein the actuation of the actuator is configured pull the distal portion proximally relative to the proximal portion.

14. The clot removal system of example 12 or example 13 wherein the ribs define a plurality of openings therebetween, and wherein the actuation of the actuator is configured pull the distal portion of the deflectable member proximally relative to the proximal portion to bend the spine and increase a size of the openings.

15. The clot removal system of any one of examples 8–14 wherein the aspiration catheter further includes—

an intermediate region between the proximal and distal regions;

an inner liner extending through the proximal, intermediate, and distal regions;

a braid of wires extending through the proximal and intermediate regions over the inner liner;

a wire extending through the intermediate region and coiled around the braid; and

an outer liner extending through the proximal, intermediate, and distal regions over the inner liner, the braid, and the wire, wherein the deflectable member is positioned between the inner and outer liners in the distal region.

16. The clot removal system of example 15 wherein—

the distal region further includes a proximal transition region, a distal tip region, and a deflectable region between the proximal transition region and the distal tip region;

the deflectable member is positioned in the deflectable region;

the outer liner has a first hardness in the proximal transition region, a second hardness in the deflectable region, and a third hardness in the distal tip region; and

the second hardness is less than the first hardness and less than the third hardness.

17. A method of removing clot material from a blood vessel, the method comprising:

advancing an aspiration catheter through the blood vessel, wherein the aspiration catheter includes a distal portion and a proximal portion;

actuating a handle coupled to the aspiration catheter to deflect the distal portion of the aspiration catheter away from a longitudinal axis of the proximal portion;

positioning a distal tip of the aspiration catheter proximate to the clot material;

activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and

opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter.

18. The method of example 17 wherein actuating the handle to deflect the distal portion of the aspiration catheter includes deflecting the distal portion of the aspiration catheter away from the longitudinal axis in a deflection direction, and wherein the method further comprises rotating the aspiration catheter such that the deflection direction is at least partially aligned with a bend in the blood vessel.

19. The method of example 17 or example 18 wherein the aspiration catheter has a size of 20 French or greater.

20. The method of any one of examples 17–19 wherein the aspiration catheter includes a deflectable member positioned in the distal portion, and wherein actuating the handle includes rotating an actuator of the handle to pull a pull wire coupled to the deflectable portion proximally to deflect the deflectable member to deflect the distal portion of the aspiration catheter.

[0069] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0070] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the

description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0071] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. An aspiration catheter, comprising:

a proximal region; and

a distal region including a deflectable member, wherein the deflectable member includes—

a proximal ring;

a distal ring configured to be fixedly attached to a pull wire; and

a tube portion extending between the proximal and distal rings, wherein the tube portion includes a plurality of openings extending therethrough to define a plurality of ribs, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally.

2. The aspiration guide catheter of claim 1 wherein the tube portion includes a spine extending in a direction between the proximal and distal rings, wherein the ribs extend away from the spine, and wherein the spine is configured to extend generally parallel to and over the pull wire.

3. The aspiration catheter of claim 1 wherein the proximal region and the distal region define a lumen having a diameter of 20 French or greater.

4. The aspiration catheter of claim 1, further comprising an intermediate region between the proximal and distal regions, wherein the proximal region and the intermediate region include a braid of wires extending therethrough.

5. The aspiration catheter of claim 4 wherein the intermediate region includes a wire coiled around the braid.

6. The aspiration catheter of claim 1 wherein the tube portion extends along a longitudinal axis in a relaxed state, and wherein the openings extend circumferentially about the longitudinal axis and generally parallel to one another in the relaxed state.

7. The aspiration catheter of claim 1 wherein the proximal ring includes an annular member configured to slidably receive the pull wire therethrough.

8. A clot removal system, comprising:

an aspiration catheter including a proximal region and a distal region, wherein the distal region includes a deflectable member;

a handle coupled to the proximal region of the aspiration catheter, wherein the handle includes an actuator; and

a pull wire extending between the actuator and the deflectable member, wherein actuation of the actuator is configured to pull the pull wire to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region.

9. The clot removal system of claim 8 wherein the aspiration catheter extends along an axis, and wherein the actuation of the actuator is configured to deflect the distal region of the aspiration catheter away from the axis by about 90 degrees or greater.

10. The clot removal system of claim 8 wherein the aspiration guide catheter has a size of 20 French or greater.

11. The clot removal system of claim 8 wherein the deflectable member has a tubular shape that extends along a longitudinal axis, and wherein the deflectable member includes (a) a spine extending parallel to the longitudinal axis and (b) a plurality of ribs extending from the spine and circumferentially about the longitudinal axis.

12. The clot removal system of claim 11 wherein the deflectable member has a distal portion and a proximal portion, and wherein the pull wire is attached to the distal portion of the deflectable member.

13. The clot removal system of claim 12 wherein the actuation of the actuator is configured pull the distal portion proximally relative to the proximal portion.

14. The clot removal system of claim 12 wherein the ribs define a plurality of openings therebetween, and wherein the actuation of the actuator is configured pull the distal portion of the deflectable member proximally relative to the proximal portion to bend the spine and increase a size of the openings.

15. The clot removal system of claim 8 wherein the aspiration catheter further includes—

an intermediate region between the proximal and distal regions;

an inner liner extending through the proximal, intermediate, and distal regions;

a braid of wires extending through the proximal and intermediate regions over the inner liner;

a wire extending through the intermediate region and coiled around the braid; and

an outer liner extending through the proximal, intermediate, and distal regions over the inner liner, the braid, and the wire, wherein the deflectable member is positioned between the inner and outer liners in the distal region.

16. The clot removal system of claim 15 wherein—

the distal region further includes a proximal transition region, a distal tip region, and a deflectable region between the proximal transition region and the distal tip region;

the deflectable member is positioned in the deflectable region;

the outer liner has a first hardness in the proximal transition region, a second hardness in the deflectable region, and a third hardness in the distal tip region; and

the second hardness is less than the first hardness and less than the third hardness.

17. A method of removing clot material from a blood vessel, the method comprising:

advancing an aspiration catheter through the blood vessel, wherein the aspiration catheter includes a distal portion and a proximal portion;

actuating a handle coupled to the aspiration catheter to deflect the distal portion of the aspiration catheter away from a longitudinal axis of the proximal portion;

positioning a distal tip of the aspiration catheter proximate to the clot material;

activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and

opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter.

18. The method of claim 17 wherein actuating the handle to deflect the distal portion of the aspiration catheter includes deflecting the distal portion of the aspiration catheter away from the longitudinal axis in a deflection direction, and wherein the method further comprises rotating the aspiration catheter such that the deflection direction is at least partially aligned with a bend in the blood vessel.

19. The method of claim 17 wherein the aspiration catheter has a size of 20 French or greater.

20. The method of claim 17 wherein the aspiration catheter includes a deflectable member positioned in the distal portion, and wherein actuating the handle includes rotating an actuator of the handle to pull a pull wire coupled to the deflectable portion proximally to deflect the deflectable member to deflect the distal portion of the aspiration catheter.

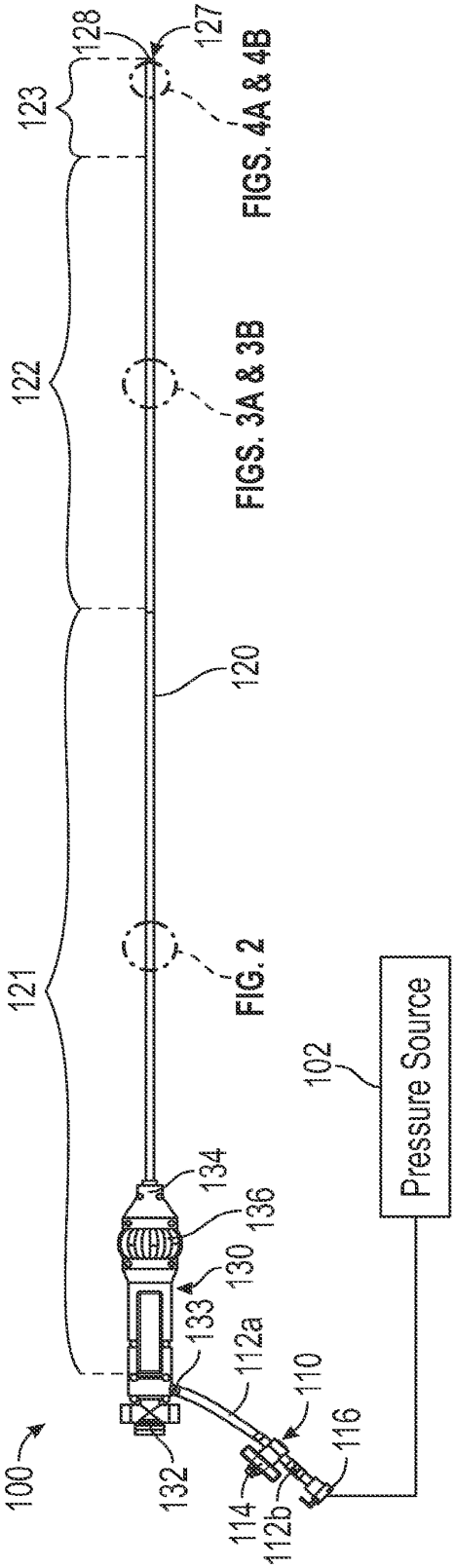
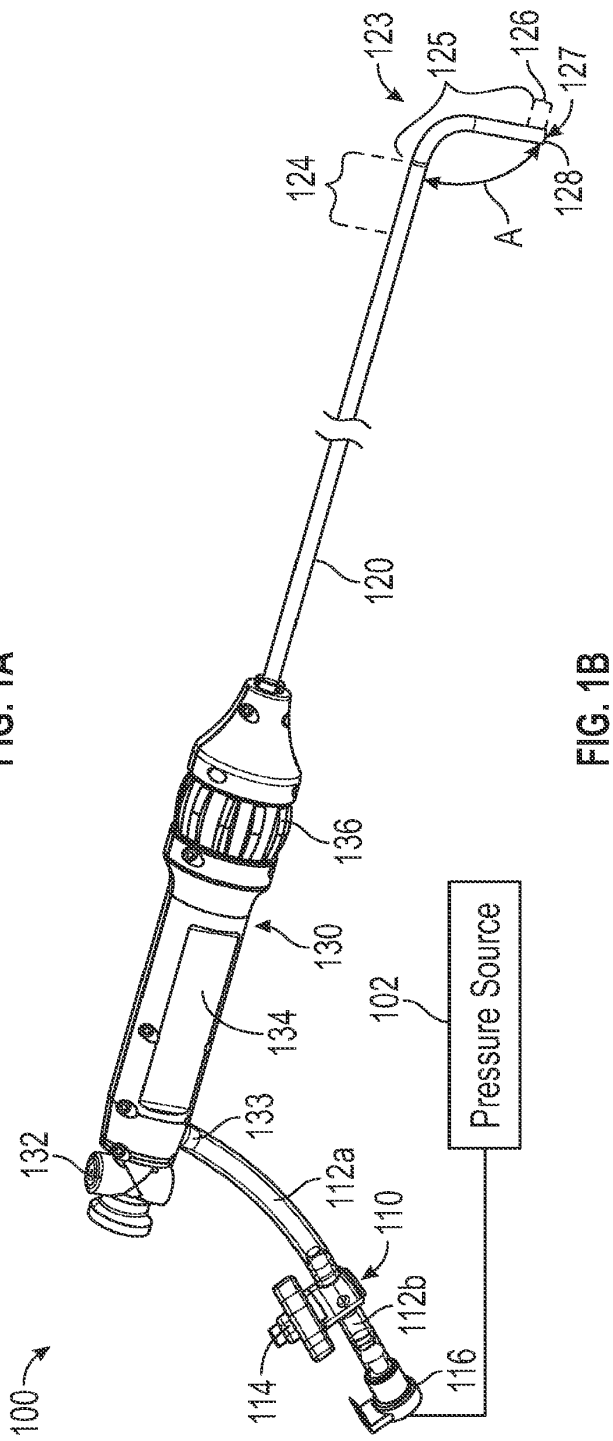

100
121
122
123
128
127
120
134
136
130
133
112a
110
132
114
112b
116
102
Pressure Source
FIG. 2
FIGS. 3A & 3B
FIGS. 4A & 4B

FIG. 1A


100
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125
126
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A
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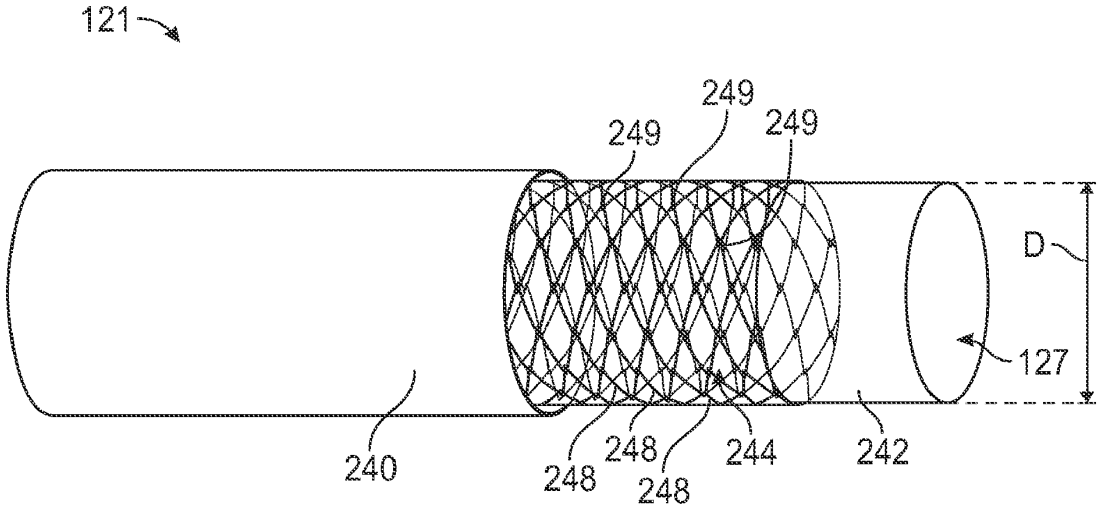
133
132
112a
110
112b
114
116
102
Pressure Source

FIG. 1B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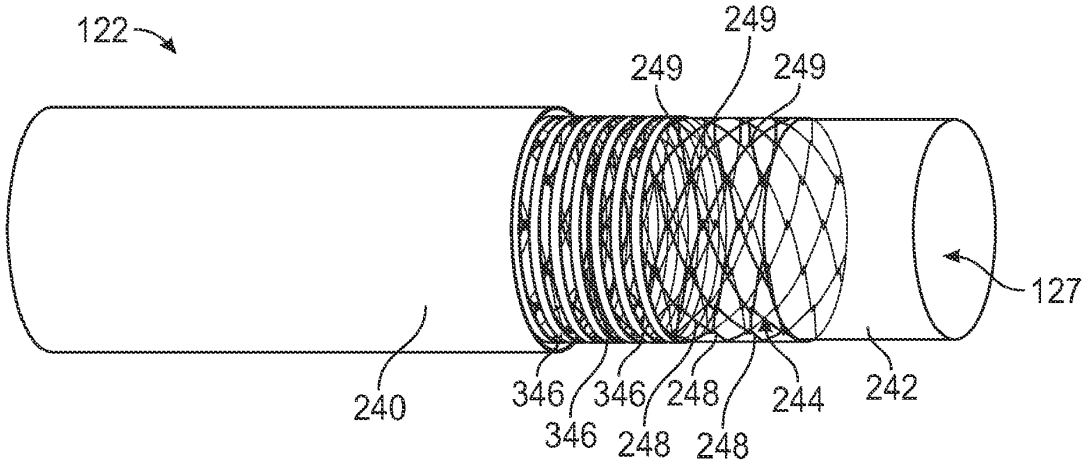
242

FIG. 2


122
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242

FIG. 3A

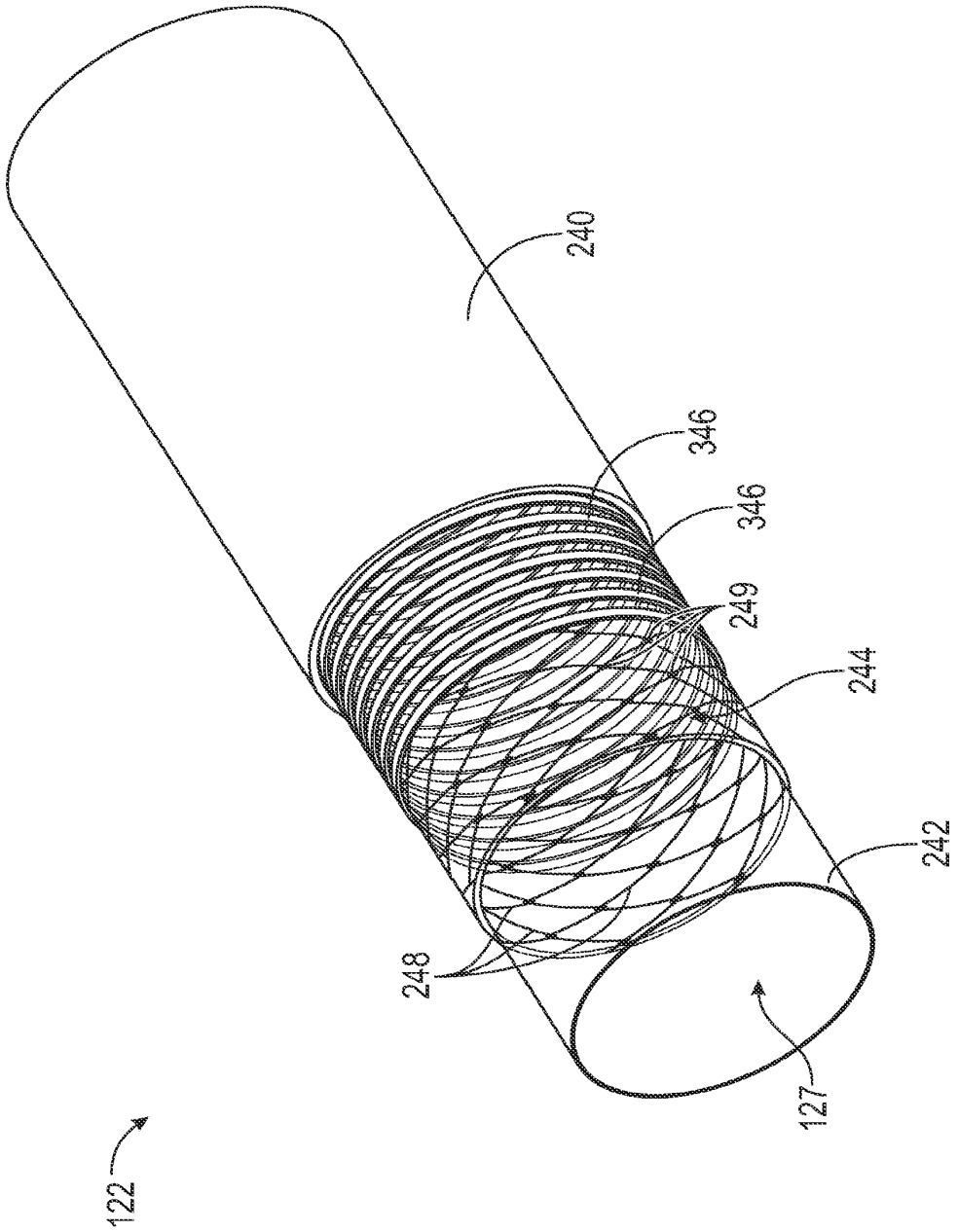
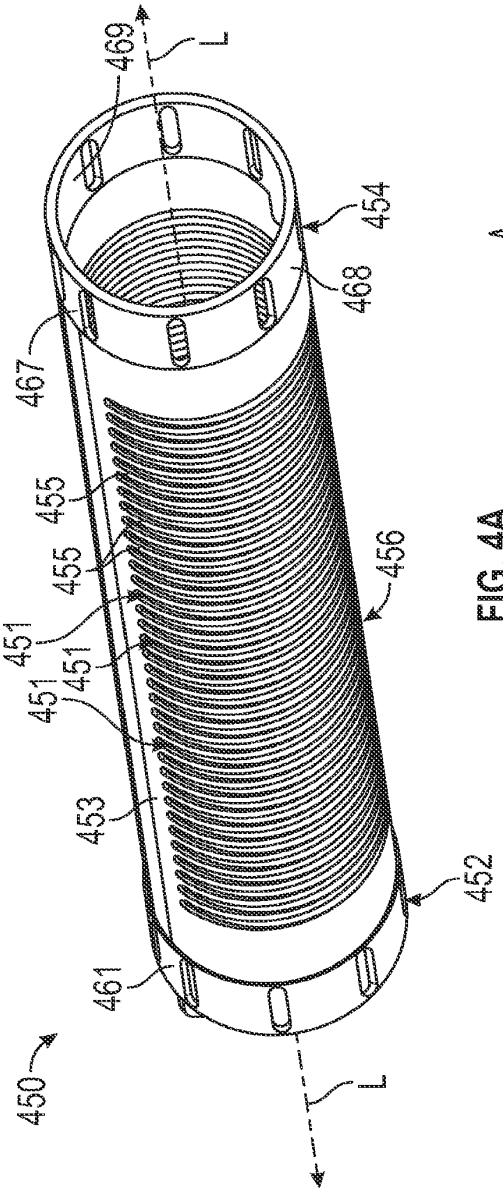


FIG. 3B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L
454
468
467
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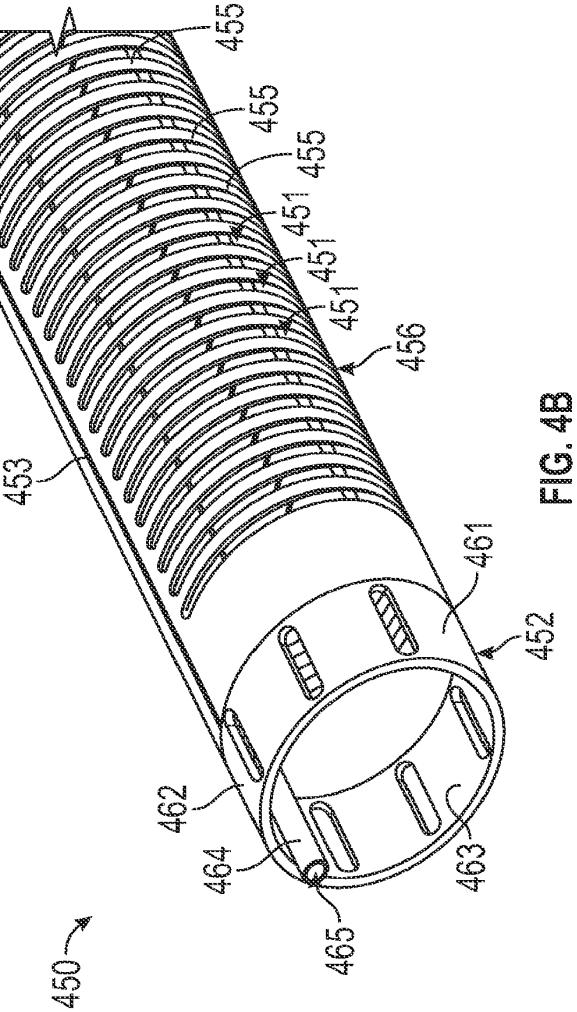
455
456
451
451
451
453
452
461
450
L

FIG. 4A


455
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465
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FIG. 4B

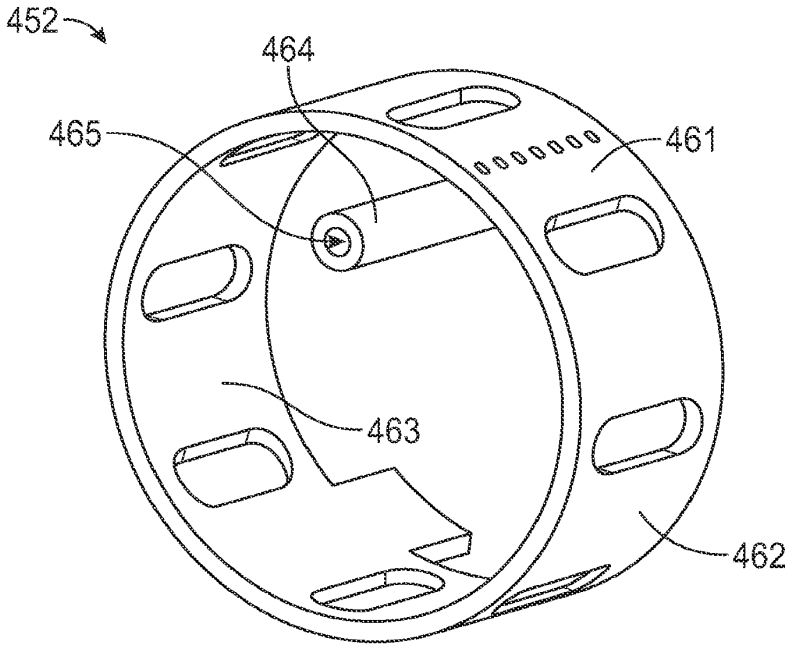

FIG. 4C

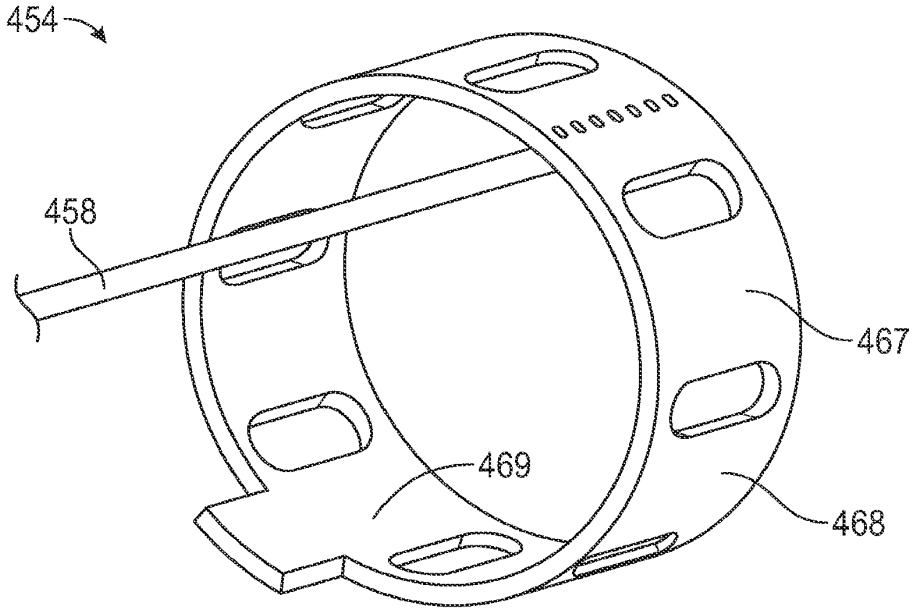

FIG. 4D

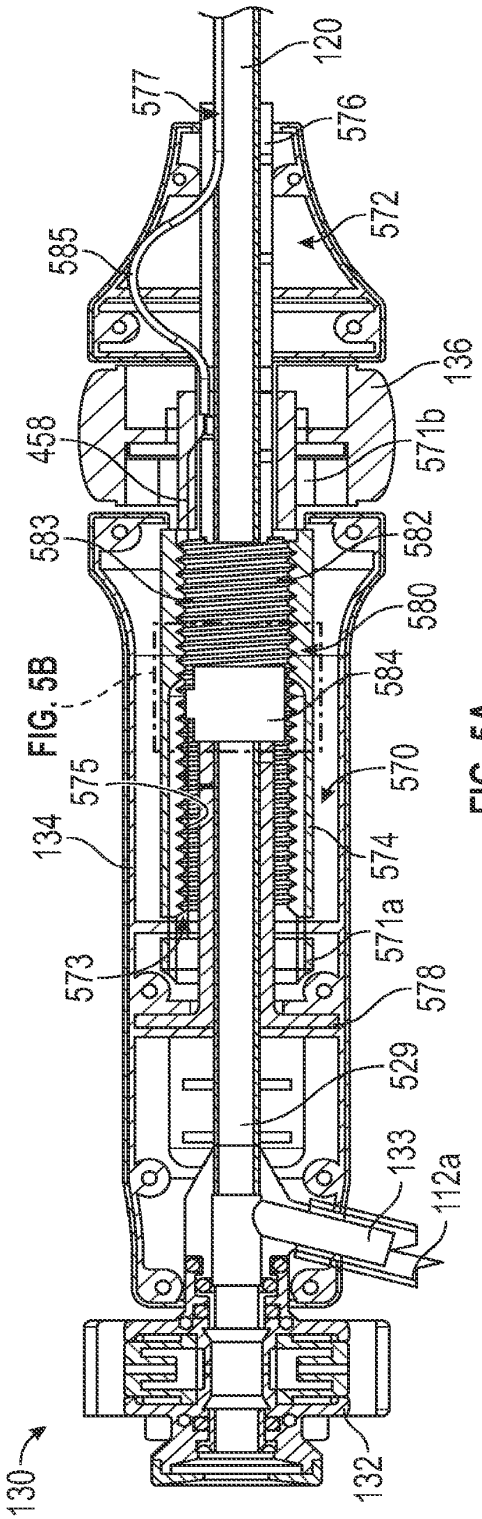

FIG. 5A

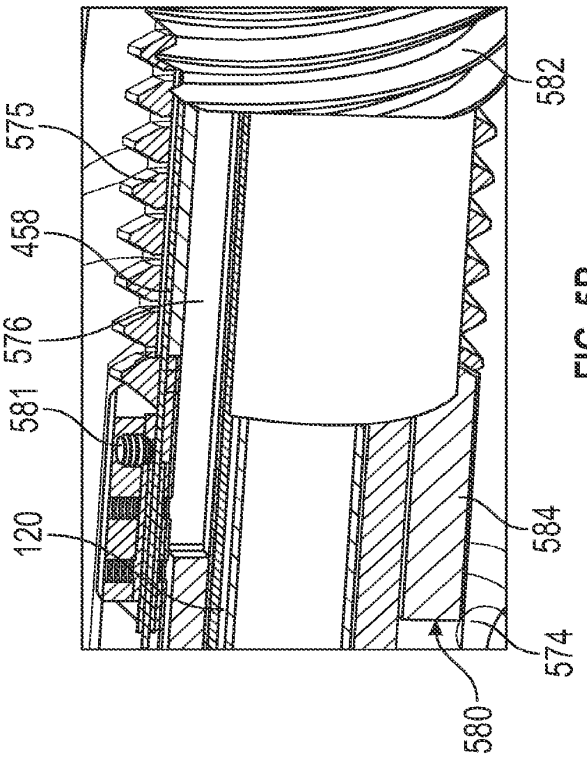

FIG. 5B

FIG. 5B

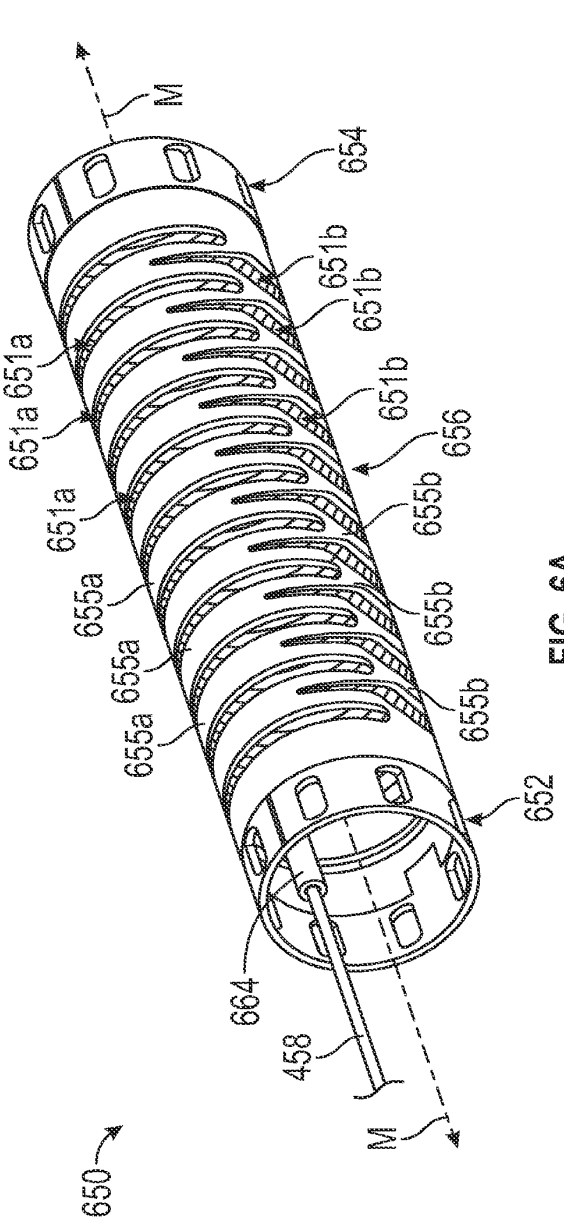
650
M
654
651b
651a
656
655b
655a
652
664
458

FIG. 6A

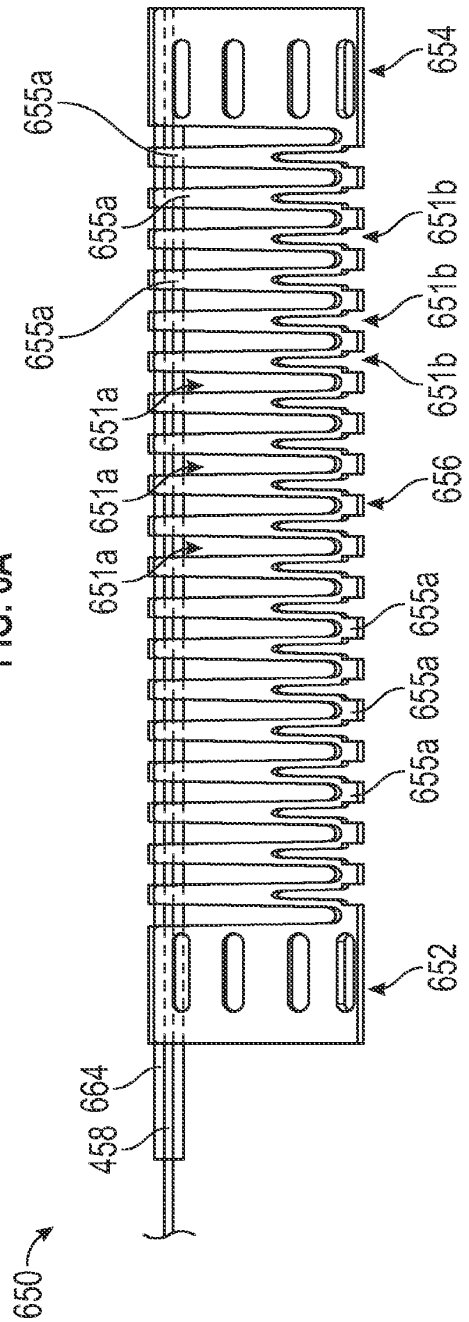
650
654
655a
651b
651a
656
652
664
458

FIG. 6B

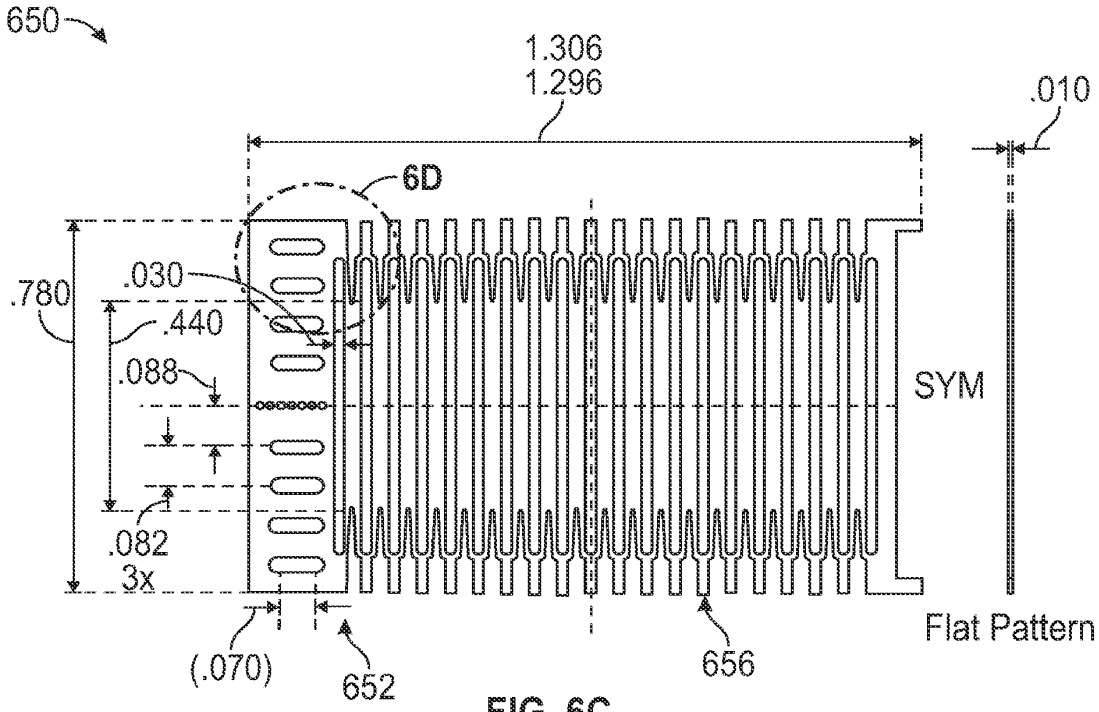
650
1.306
1.296
.010
6D
.780
.030
.440
.088
.082
3x
SYM
(.070)
652
656
Flat Pattern

FIG. 6C

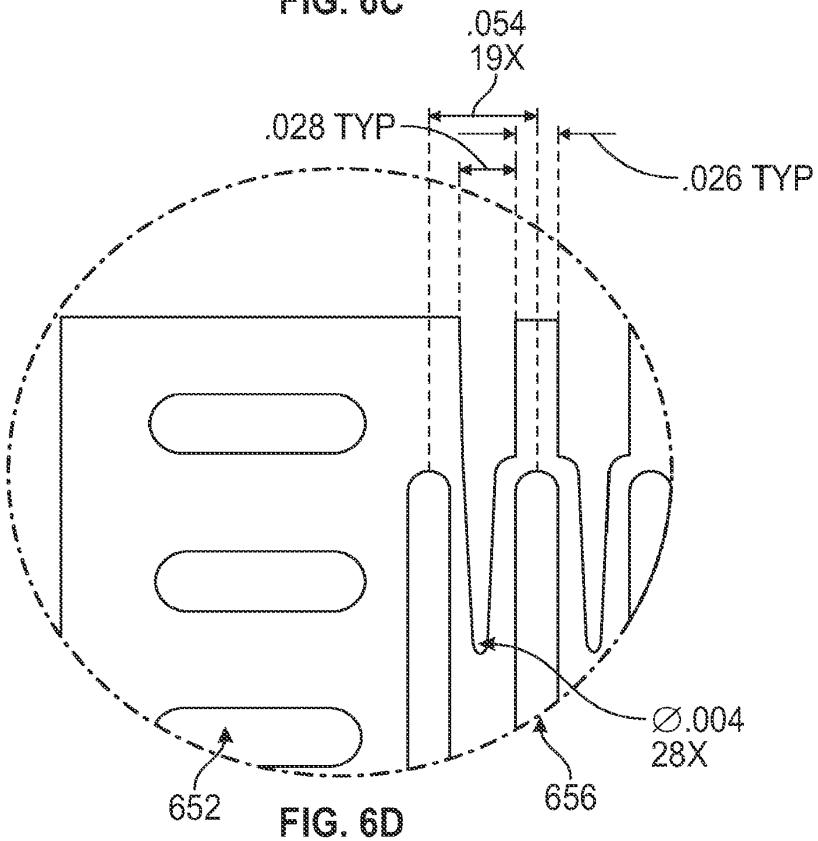
.054
19X
.028 TYP
.026 TYP
∅.004
28X
652
656

FIG. 6D

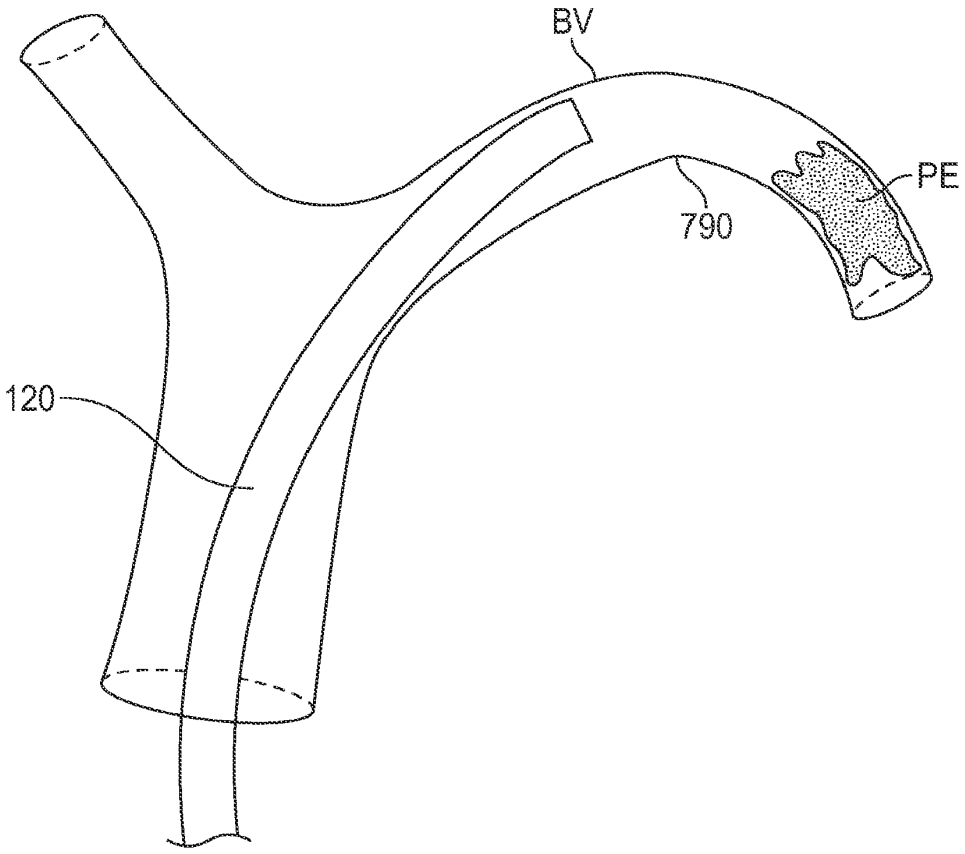

FIG. 7A

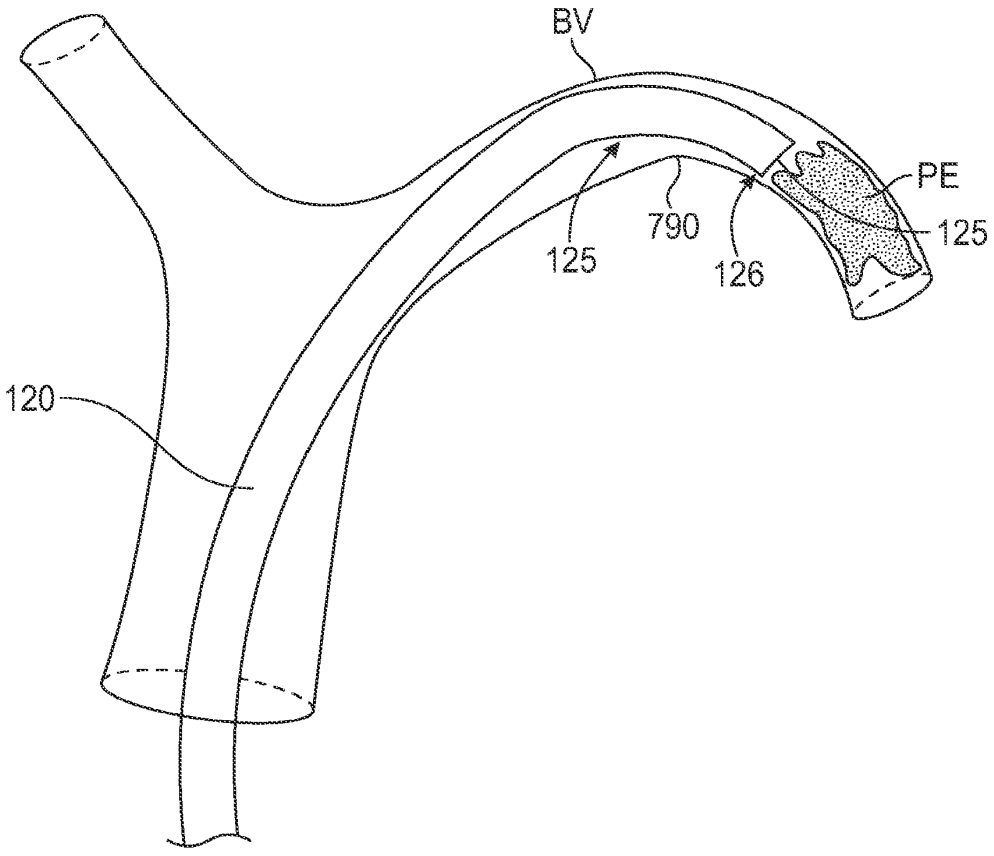

FIG. 7B

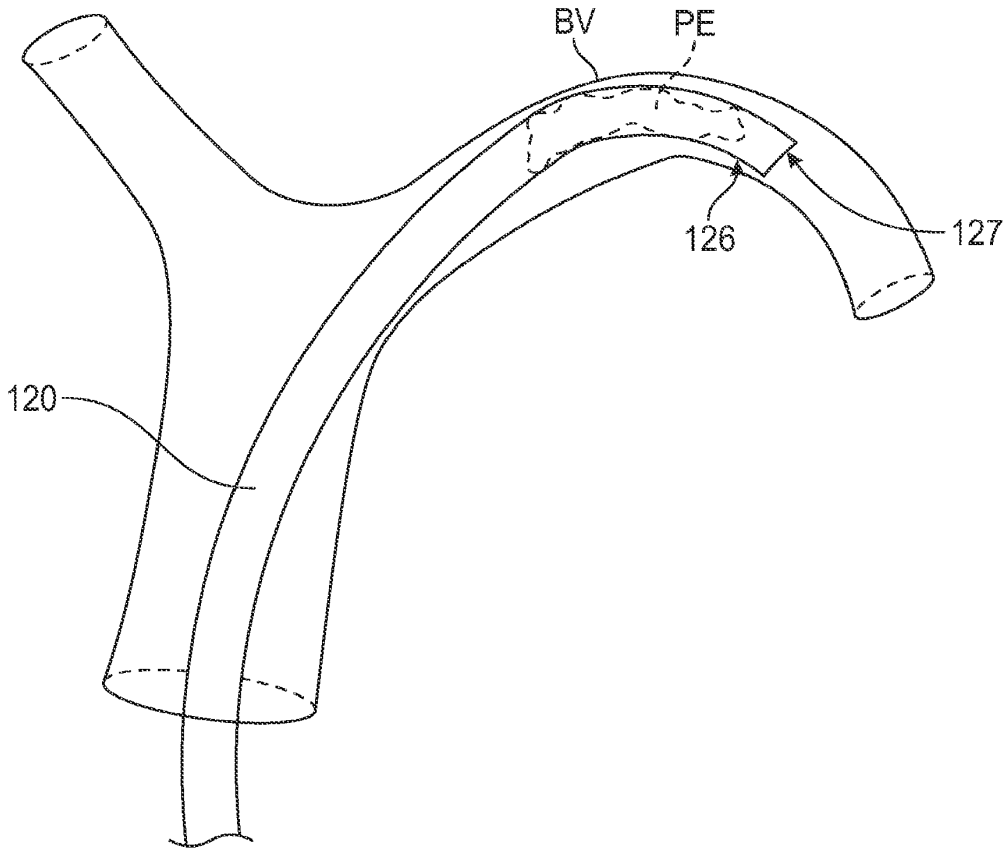

FIG. 7C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/59735

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-7 directed to a proximal ring; a distal ring and a tube portion.

Group II: Claims 8-20 directed to a handle and an actuator.

-*-Continued in Supplemental Box-*-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

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

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

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-7

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/59735

A. CLASSIFICATION OF SUBJECT MATTER
IPC - A61M 25/00 (2022.01)
CPC - A61M 25/0147; A61M 25/0138

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2019/246240 A1 (INTUITIVE SURGICAL OPERATIONS, INC.) 26 December 2019 (26.12.2019), entire document, especially Fig 4A, 4C; para [0071]-[0084]	1-3, 6-7
Y		4-5
Y	US2010/0016837 A1 (Howat) 21 January 2010 (21.01.2010), entire document, especially Fig 1-8; para [0034]-[0042]	4-5
A	US 2004/0138525 A1 (Saadat et al.) 15 July 2004 (15.07.2004), entire document	1-7
A	US 2020/0113412 A1 (AMBU A/S) 16 April 2020 (16.04.2020), entire document	1-7
A	US 2009/0192495 A1 (Ostrovsky et al.) 30 July 2009 (30.07.2009), entire document	1-7

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 February 2022	MAR 22 2022
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

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

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/59735

-*-Box No. III - Observations where unity of invention is lacking-*-

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

SPECIAL TECHNICAL FEATURES

The Invention of Group I includes the special technical feature of a proximal ring; a distal ring configured to be fixedly attached to a pull wire; and a tube portion extending between the proximal and distal rings, wherein the tube portion includes a plurality of openings extending therethrough to define a plurality of ribs, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally, not required by Group II.

The invention of Group II includes the special technical feature of a handle coupled to the proximal region of the aspiration catheter, wherein the handle includes an actuator; and pull wire extending between the actuator and the deflectable member, wherein actuation of the actuator is configured to pull the pull wire, not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of an aspiration catheter including a proximal region and a distal region, wherein the distal region includes a deflectable member; and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2004/0138525 A1 to Saadat et al. (hereinafter "Saadat"), which discloses an aspiration catheter (30; Fig 21A-21B; para [0097]; see analogous Fig 41, para [0125] describing tool arm 30 used for aspiration, wherein the tool arm 30 is interpreted as an aspiration catheter) including a proximal region (proximal half of 30; Fig 21A-21B; para [0097]; the proximal half of 30 being the bottom-most half of the entire tool arm 30 in the orientation shown in Fig 21A) and a distal region (distal half of 30; Fig 21A-21B; para [0097]; the distal half of 30 being the top-most half of the entire tool arm 30 in the orientation shown in Fig 21A), wherein the distal region includes a deflectable member (portion of 30 from bottom slot 132 to the distal-most end of 30; Fig 21A-21B; para [0097]); and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region (96; Fig 21A-21B; para [0097]; pullwire 96 is shown to be attached to the portion of 30 extending distally from distal-most slot 132 via fixation point 104 wherein pulling the pullwire 96 causes the distal tip of tool arm 30 to deflect relative to the proximal region of tool arm 30).

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

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

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(12)发明专利申请

(10)申请公布号 CN 104068910 A
(43)申请公布日 2014.10.01

(21)申请号 201310100144.X

(22)申请日 2013.03.26

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(74)专利代理机构 中原信达知识产权代理有限责任公司 11219
代理人 蔡石蒙 车文

(51)Int.Cl.
A61B 17/22(2006.01)

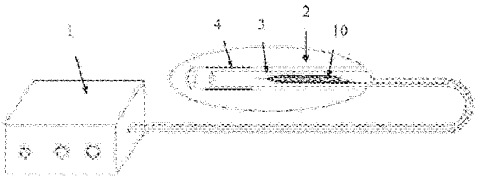
权利要求书1页 说明书4页 附图5页

(54)发明名称

血管取栓系统

(57)摘要

本发明提供一种血管取栓系统。所述取栓系统包括导引导丝、推拉导丝、外鞘管、能够相对于外鞘管移动的内管和取栓器，导引导丝穿过内管，内管则被套在外鞘管内，且内管能够沿着导引导丝移动，该取栓器与推拉导丝相连，安装好的推拉导丝和取栓器被压握入内管内，且所述取栓器能够通过推拉导丝推拉而在收回位置和展开位置之间转换，在收回位置，取栓器被回收到内管内，在展开位置，取栓器被推出内管。所述取栓系统还包括抽吸装置，该抽吸装置与内管相连通，且内管上设有抽吸孔。根据本发明的取栓系统，既可以方便的捕捉大块血栓，又可以通过抽吸防止小块血栓的脱落，解决了血管远端血管再次栓塞的问题，同时有效减少了取栓后并发症的概率。



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1. 一种取栓系统，其特征在于，其包括导引导丝、推拉导丝、外鞘管、能够相对于外鞘管移动的内管和取栓器，导引导丝穿过内管，内管则被套在外鞘管内，且内管能够沿着导引导丝移动，该取栓器与推拉导丝相连，安装好的推拉导丝和取栓器被压握入内管内，且所述取栓器能够通过推拉导丝推拉而在收回位置和展开位置之间转换，在收回位置，取栓器被回收到内管内，在展开位置，取栓器被推出内管，所述取栓系统还包括抽吸装置，该抽吸装置与内管相连通，且内管上设有抽吸孔。

2. 根据权利要求 1 所述的取栓系统，其中取栓器包括外层支架和内层支架，内外层支架均构成为网状，且外层支架包覆在内层支架外，两者之间形成间隙。

3. 根据权利要求 2 所述的取栓系统，其中外层支架与内层支架在近端相连接或在近端和远端均相连接。

4. 根据权利要求 2 或 3 所述的取栓系统，其中内外层支架的近端和 / 或远端具有椭圆形开口或圆形开口，或为封闭的。

5. 根据权利要求 1-3 中任一项所述的取栓系统，其中推拉导丝与取栓器的牵引连接点布置成在展开位置贴近血管壁。

6. 根据权利要求 1-3 中任一项所述的取栓系统，其中取栓器在展开位置整体呈近似圆柱形。

7. 根据权利要求 1-3 中任一项所述的取栓系统，其中取栓器被构造有内凹和 / 或外凸的结构。

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血管取栓系统

技术领域

[0001] 本发明涉及医疗器械，具体涉及一种介入血管的医疗器械，特别涉及一种血管取栓系统。

背景技术

[0002] 血管内血栓是临床上的常见病和多发病，而颅内血栓又是重中之重，它造成脑栓塞，具有发病率高、致残率高、死亡率高和复发率高的特点，是中老年人致死和致残的主要疾病。而随着老年人口的不断增加和生活水平的提高，脑血管病的发病率在不断升高。根据调查，我国目前每年有 300 万的新增脑血栓群体，而急性脑血栓占脑卒中的比例也由 55.8% 上升到 81.6%，成为脑部第一大疾病。

[0003] 血管的再通是治疗急性缺血性脑卒中的关键。目前颅内血栓的治疗方法主要有两种：药物溶栓和机械取栓。

[0004] 药物溶栓治疗是把溶栓剂注入病变所在的血管内的病灶附近，在病灶局部瞬间地形成很高的溶栓剂浓度，加快血栓溶解速度，进而增加血管再通的机会。但是，根据美国国立神经疾病与卒中研究院(NINDS)的研究结果，静脉溶栓应在发病 3 小时内进行，动脉溶栓时间窗为 6 小时之内。由于药物溶栓治疗时间窗较短，而且溶栓治疗只适用于体积较小的血栓，其对大体积血栓栓塞的治疗效果并不理想，所以最终大约只有 3 ～ 5% 的患者适合做药物溶栓治疗。

[0005] 机械取栓是将取栓器输送至病变位置，然后通过鞘管将血栓取出至体外。机械取栓包括以下几种方法：捕捉取栓、抽吸取栓、旋切取栓等。捕捉取栓在取人块血栓时效果最好，但是容易造成血管壁上的斑块和破碎的血栓块脱落后流向远端血管造成新的栓塞；抽吸取栓在取小块栓子时效果较好，在取大块血栓时为了防止堵塞抽吸管需要反复捣碎血栓后再抽吸，过程麻烦而且很容易伤到血管；旋切取栓对血管壁造成的损伤较大，很容易引起并发症。

[0006] 中国实用新型专利 CN201020104685.1 公开了一种用于人体血管内血栓抽吸导管，其包括依次连接的管座、加强管、单腔管、双腔管、尖端管和显影标记。该取栓系统在抽吸腔的远端有 1-4 个开孔，增加了导管的通过性和血栓抽吸能力，并减小在手术过程中对人体血管的损伤，同时提高导管的跟踪性和推送性。

[0007] 中国发明专利申请 CN201110222609.X 和中国实用新型专利 CN201120281795.X 公开了一种血栓抽吸导管，其包括抽吸管，所述抽吸管包括管座，所述管座连接导管，所述抽吸管的外壁上可活动的套设有套管，所述套管包括 Y 型连接头、双腔管及球囊，所述 Y 型连接头连接双腔管，球囊设置于双腔管的远端外壁上，所述抽吸管内可插入干扰金属丝，所述干扰金属丝的远端可伸出抽吸管的远端外。该取栓系统可以快速清除散布在血管广泛区域的血栓及处理冠脉末梢微血管的栓塞，而且当遇到体积大及高黏稠的血栓时，可利用干扰金属丝打散血栓后再进行抽吸。

[0008] 美国专利申请 US2010/0049147A1 公开了另外一种血栓抽吸导管。美国专利申请

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US2007/0161963A1 也公开了一种血栓切除术抽吸导管系统。

[0009] 上述抽吸取栓系统在取小块栓子时效果较好，但是在取大块血栓时为了防止堵塞抽吸管需要反复捣碎血栓后再抽吸，过程麻烦而且很容易伤到血管。

[0010] 中国发明专利申请 01114889.6 公开了一种可用于颅内血管的可回收血栓临时滤器，其由过滤器、导向头、导引杆、连接件和外鞘组成，其中过滤器由形状记忆合金丝编织而成。美国专利申请 2011/0160763 也公开了一种可用于颅内血管的取栓装置，其包括骨架，骨架可由形状记忆合金丝编织而成，以捕获血栓。

[0011] 上述取栓系统在捕获血栓之后回收时，血栓固定不牢固、容易脱落，而且结构复杂。

[0012] 此外，利用目前的取栓装置，在取栓过程中血管壁上的斑块和破碎的血栓块很容易脱落，流向远端血管，造成新的栓塞。据报道，约有 70% 的血管介入取栓手术中观察到了有血栓碎片和碎块流向远端血管，这增加了患者血管再栓塞的风险。

[0013] 因此，需要一种改进的血管取栓装置，这种装置应满足以下几个条件：1）取栓过程简单、方便；2）柔顺性好，捕获率高，支撑力适中，取栓过程中不会损伤血管内壁；3）在捕获血栓之后回收时，血栓固定牢固、不易脱落。总之，既要具有良好的取栓效果，又要能够有效防止小血栓的脱落同时又不会损伤血管造成严重的并发症。

发明内容

[0014] 有鉴于此，本发明提供了一种改进的取栓系统，该系统解决了现有技术中存在的血管壁斑块和碎血栓块容易脱落而造成远端血管再次栓塞的问题，而且柔顺性好、捕获率高。

[0015] 根据本发明的一方面，本发明提出一种血管取栓系统，其包括导引导丝、推拉导丝、外鞘管、能够相对于外鞘管移动的内管和网状取栓器，导引导丝穿过内管，内管则被套在外鞘管内，且内管能够沿着导引导丝移动，该取栓器与推拉导丝相连，安装好的推拉导丝和取栓器被压握入内管内，且所述取栓器能够通过推拉导丝推拉而在收回位置和展开位置之间转换，在收回位置，取栓器被回收到内管内，在展开位置，取栓器被推出内管，所示取栓系统还包括抽吸装置，该抽吸装置与内管相连通，且内管上设有抽吸孔。本发明的取栓系统将捕捉取栓与抽吸取栓相结合，既可以方便的捕捉大块血栓，又可以通过抽吸防止小块血栓的脱落，解决了血管远端血管再次栓塞的问题，同时有效减少了取栓后并发症的概率。

[0016] 根据本发明的优选实施例，外鞘管在远端还设有可膨胀封堵球囊。

[0017] 根据本发明的优选实施例，内管上设有 1 ～ 4 个抽吸孔，这些抽吸孔可以是导管远端的开口，也可以是导管侧壁上的开孔。开口和开孔的形状可以是圆形、椭圆形或其他形状。开孔可以对称分布、间隔分布或随机分布。

[0018] 根据本发明的优选实施例，取栓器既可以通过激光切割金属管材、片材而获得，也可以通过金属丝编织而获得，其中金属管、片、丝材可以是镍钛合金、钴镍合金、不锈钢等。这样使取栓器的柔顺性和贴壁性良好。

[0019] 另外，优选地，取栓器的近端和远端均可以是开口的或封闭的。取栓器整体还可以是近似圆柱状、内凹状或外凸状等。取栓器还可以是单层结构，或是双层或多层结构。

[0020] 根据本发明的优选实施例，取栓器整体长度为 15 ～ 60mm，直径为 2 ～ 6mm，壁厚为

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0.04 ～ 0.12mm。

[0021] 优选地，推拉导丝与取栓器的牵引连接点布置成在展开位置贴近血管壁。这样可提高大体积血栓的有效捕获率。

[0022] 优选地，取栓器在展开位置整体呈近似圆柱形。这样使取栓器具有良好的径向支撑力，从内管中释放到血管后具有较好的血管贴壁性。

[0023] 取栓时，通过血管造影确定血栓的位置，然后把内管输送至栓塞处远端，回撤内管，将取栓器从血栓中间释放，利用封堵球囊在远端封堵住血管，然后先回撤取栓器进入内管中，之后再打开抽吸装置进行抽吸。然后，关闭抽吸装置，将内管向远端移动 5 ～ 20mm，之后再次打开抽吸装置抽吸剩余小块血栓，然后关闭抽吸装置。最后，将内管收进外鞘管内，撤出体外。

[0024] 根据本发明的血管取栓系统，可以有效捕获斑块和血栓碎片，增加了血栓捕获稳定性，防止了血栓脱落，从而降低再栓塞的风险。另外，本发明的血管取栓系统结构简单，取栓过程方便容易。

附图说明

[0025] 通过下面参照附图对本发明实施例进行的详细描述，本发明的特征及其优点将是显而易见的。在图中：

[0026] 图 1 是本发明实施例的取栓系统的总体示意图。

[0027] 图 2-9 是本发明的内管的实施例的示意图。

[0028] 图 10-20 显示了本发明的取栓器的实施例的示意图。

具体实施方式

[0029] 下面参照图 1-20 详细描述本发明的实施例。

[0030] 为了便于描述，以下描述使用了术语“近端”和“远端”，其中“近端”指的是离操作端近的一端，远端指的是远离操作端的一端。

[0031] 如图 1 所示，取栓系统包括抽吸装置 1、外鞘管 2、内管 3 和取栓器 10 组成。取栓器 10 为网状并与取栓系统的推拉导丝（未示出）相连，安装好的推拉导丝和取栓器 10 被压握入内管 3 内。取栓器 10 可通过推拉导丝的推拉而在收回位置和展开位置之间转换，在收回位置，取栓器 10 收回到内管 3 内，在展开位置，取栓器 10 被推出到内管 3 外。另外，取栓系统还包括导引导丝（未示出），导引导丝穿过内管 3，用以在血管内引导取栓系统。外鞘管 2 在远端处设有可膨胀封堵球囊 4。

[0032] 此外，取栓器 10 上还设有显影标记（未示出），以帮助定位取栓器 10。可以理解的是，内管 3 和外鞘管 2 上也可以设有显影标记。

[0033] 内管上设有 1 ～ 4 个抽吸孔，这些抽吸孔可以仅是内管远端的开口，如图 2 和 6 所示，也可以是在远端开口基础上在导管侧壁上再开一些抽吸孔，如图 3 ～ 5 和图 7 ～ 9 所示。开口和开孔可以是圆形、椭圆形或其他形状，可以单独、对称、间隔或随机分布。

[0034] 取栓器可以是单层结构，如图 10 ～ 14 的取栓器 10 所示。取栓器 10 的近端和远端均可以是封闭的或开口的。另外，如图 14 所示，取栓器 10 可以构造有外凸和内凹结构。

[0035] 取栓器也可以是双层结构。如图 15 ～ 20 所示。取栓器 10’ 为支架套支架结构，

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整体呈近似圆柱形，其包括两部分，即内层支架 20 和外层支架 30，其中内外层支架均构成为网状，外层支架包覆在内层支架外，且两者之间留有间隙。取栓器 10'的内外层的近端远端可以是只近端连接，如图 16、17、19 和 20 所示，也可以是近远端都连接，如图 15 和 18 所示。连接可以是焊接连接、利用金属套管连接或利用金属丝缠绕连接等。

[0036] 当然，取栓器也可以是多层结构。

[0037] 取栓器通过激光切割具有形状记忆效应的金属管材（如镍铁合金等）而形成并经热处理定型。当然，取栓器也可以通过切割具有形状记忆效应的金属片材，然后卷曲，热处理定型而形成。取栓器的合适尺寸如下：长度为 15 ～ 60mm，直径为 2 ～ 6mm，壁厚为 0.04 ～ 0.12mm。也可以用高弹性的高分子材料来代替金属材料。上述合适的材料是本领域技术人员所熟知的，在此不再详细描述。

[0038] 推拉导丝与取栓器的牵引连接点布置为在展开位置贴近血管壁。这样可提高大体积血栓的有效捕获率。

[0039] 本发明的取栓系统的使用方法如下。

[0040] 介入治疗时，首先通过血管造影确定血管病变位置，然后将取栓装置 1 导入血管内，使导引导丝穿过病变位置，再使内管 3 沿导引导丝穿过病变位置并通过内管 3 上的显影标记（未示出）定位，期间取栓器 10 一直位于内管 3 内，处于收回位置。然后，回撤导引导丝，通过推拉导丝将取栓器 10 推到内管 3 远端，回撤内管 3 至病变位置，将取栓器 10 释放，通过取栓器 10 上的显影标记可定位取栓器 10。由于形状记忆金属的形状记忆效应或高弹性高分子材料的弹性作用，取栓器 10 在血液温度的作用下转换到展开位置，贴靠血管壁。然后，利用封堵球囊 4 在远端封堵住血管，拉动推拉导丝，回撤取栓器 10 捕获血栓，直至将取栓器 10 收回到内管 3 内。然后，打开抽吸装置 1 进行抽吸，之后关闭抽吸装置，接着将内管向远端移动 5 ～ 20mm，之后再次打开抽吸装置抽吸剩余小块血栓，然后关闭抽吸装置。再将内管 3 收回到外鞘管 2 中。最后，将取栓装置 1 整体撤出人体外，完成取栓过程。

[0041] 采用目前的取栓系统取栓时，血管壁上的斑块和破碎的的血栓块很容易因外力作用破碎脱落，流向远端血管而造成新的栓塞，增加患者的手术风险。本发明的设计将捕提取栓与抽吸取栓这两种方式相结合，在取栓时可以通过抽吸将脱落的小块血栓吸入抽吸管，同时通过捕获可以将大体积的血栓拉入抽吸管，避免了捕获取栓时小块血栓易脱落和抽吸取栓时不易捕获大块血栓的缺点，且操作方便，再通率高。

[0042] 本发明的取栓系统可适合于颅内血管取栓，也可以适合于其它血管内取栓。本领域技术人员可以理解，以上描述只是示例性的。在不背离本发明的思想和范围的情况下，本领域技术人员仍可以对本发明作出多种修改和变化。

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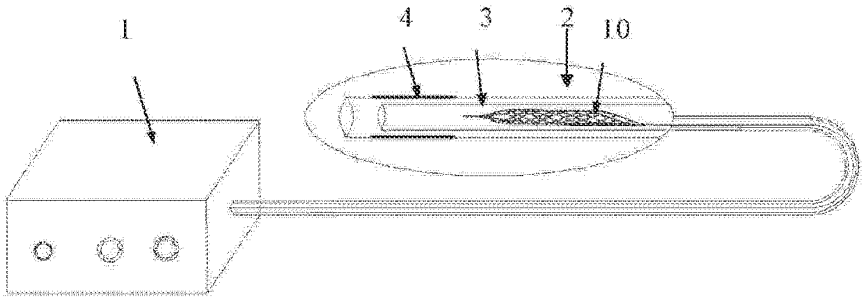

图 1

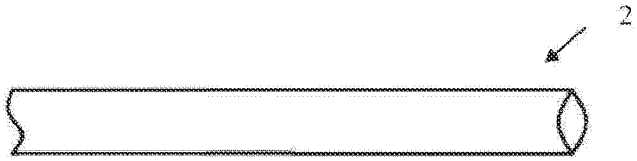

图 2

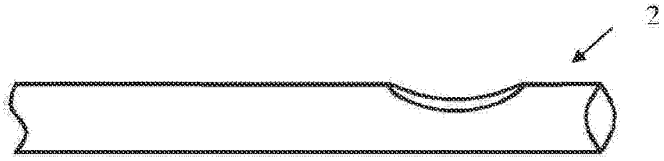

图 3

图 4

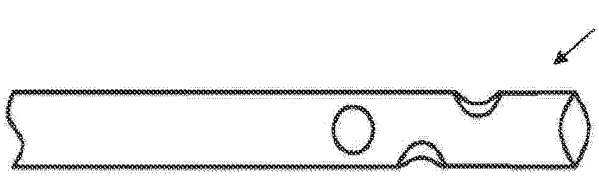

图 5

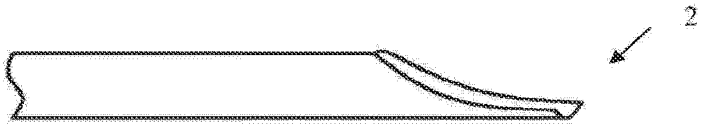

图 6

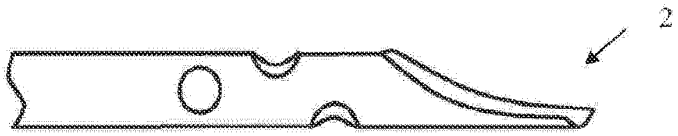

图 7

图 8

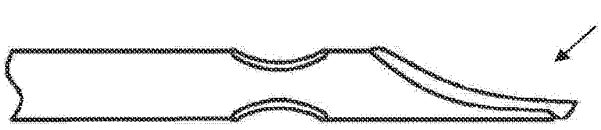

图 9

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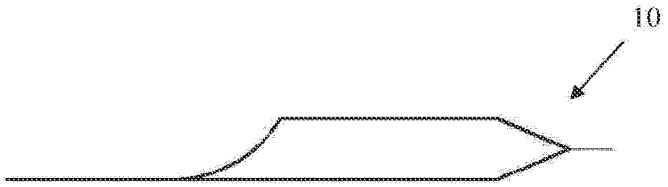


图 10

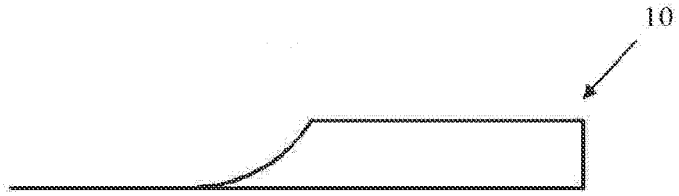
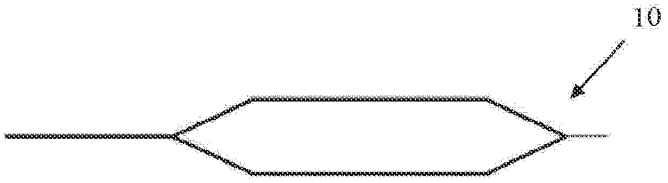


图 11



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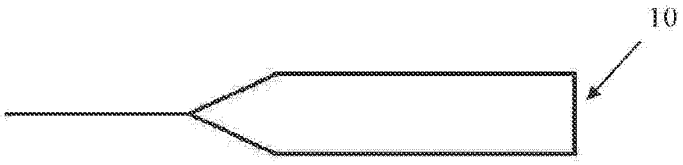

图 13

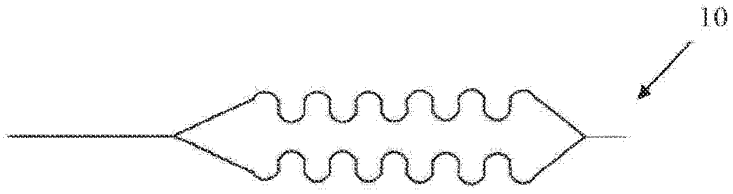

图 14

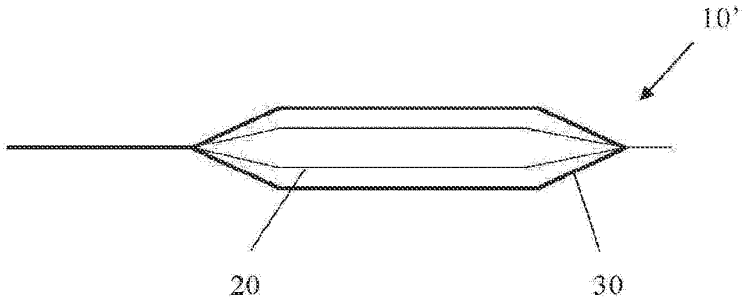

图 15

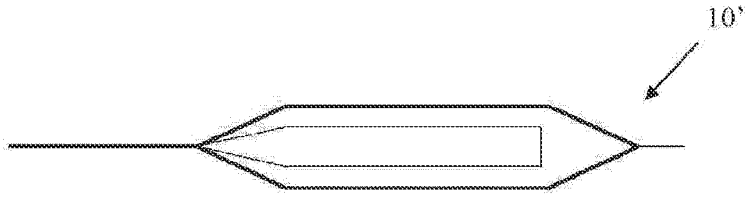

图 16

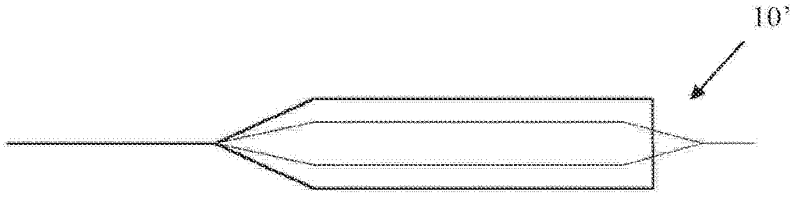

图 17

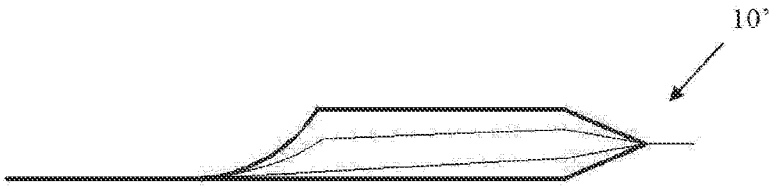

图 18

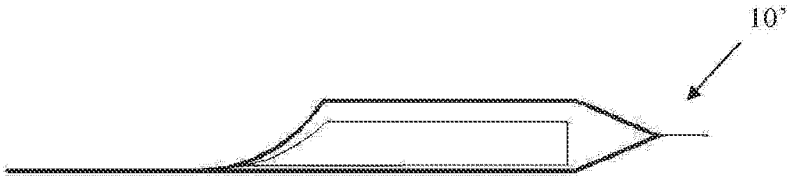

图 19

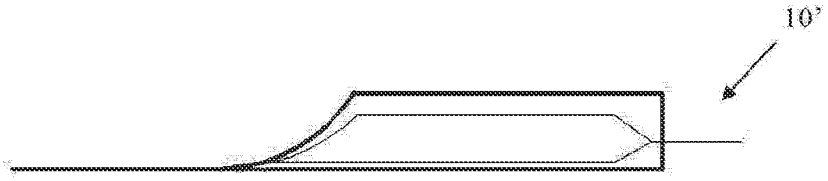

图 20

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(54) **Title**: AN INVERSIBLE TUBULAR MEMBER AND A GRIPPING DEVICE INCLUDING SUCH A MEMBER

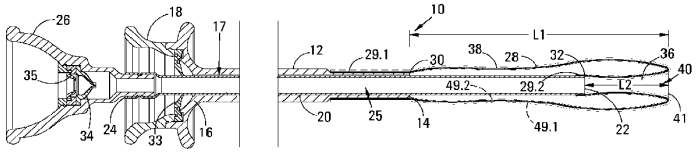

FIG 4

(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.

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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.

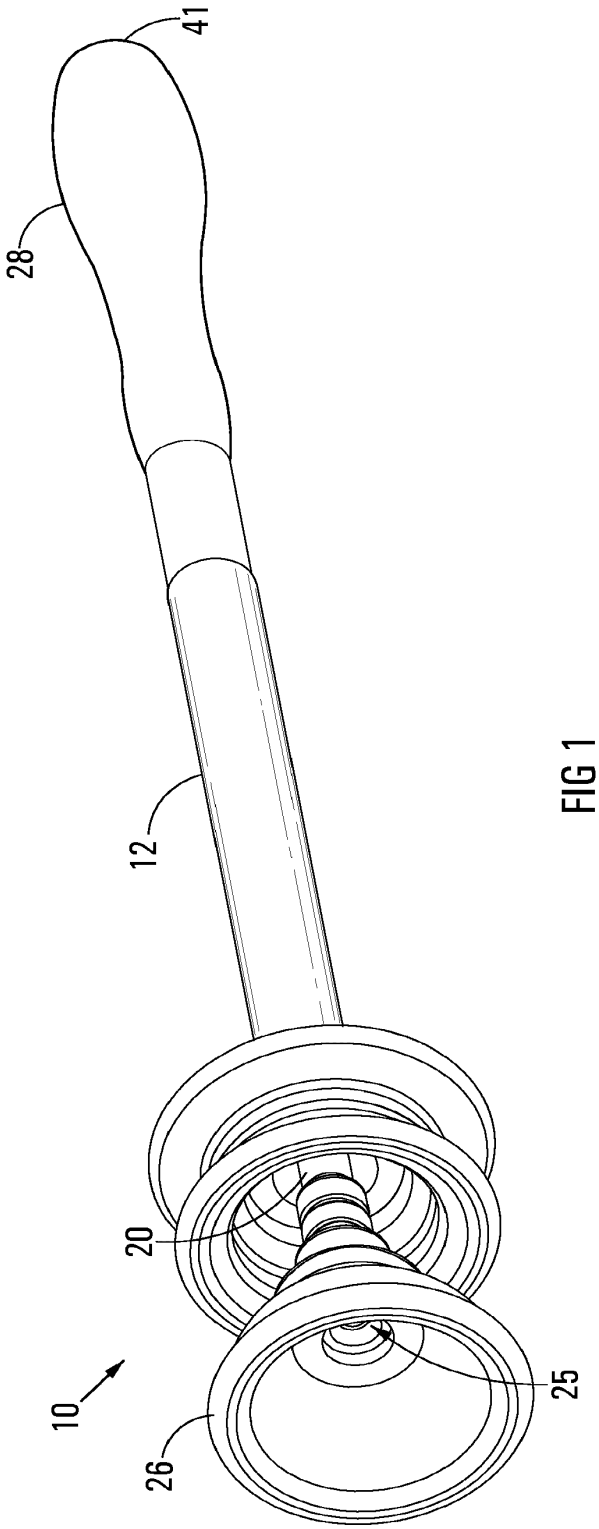


FIG 1

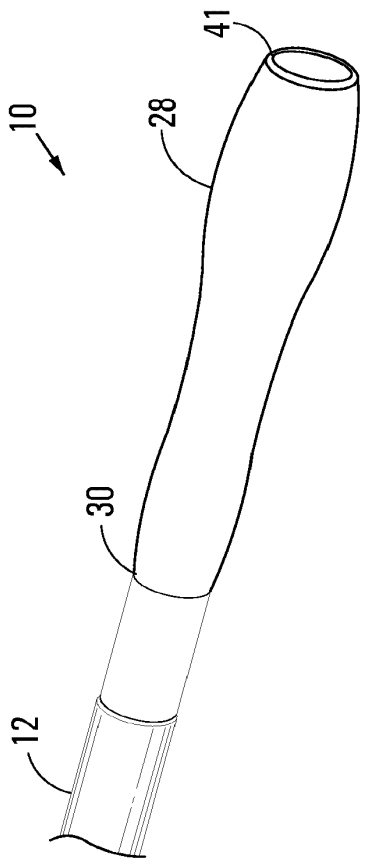
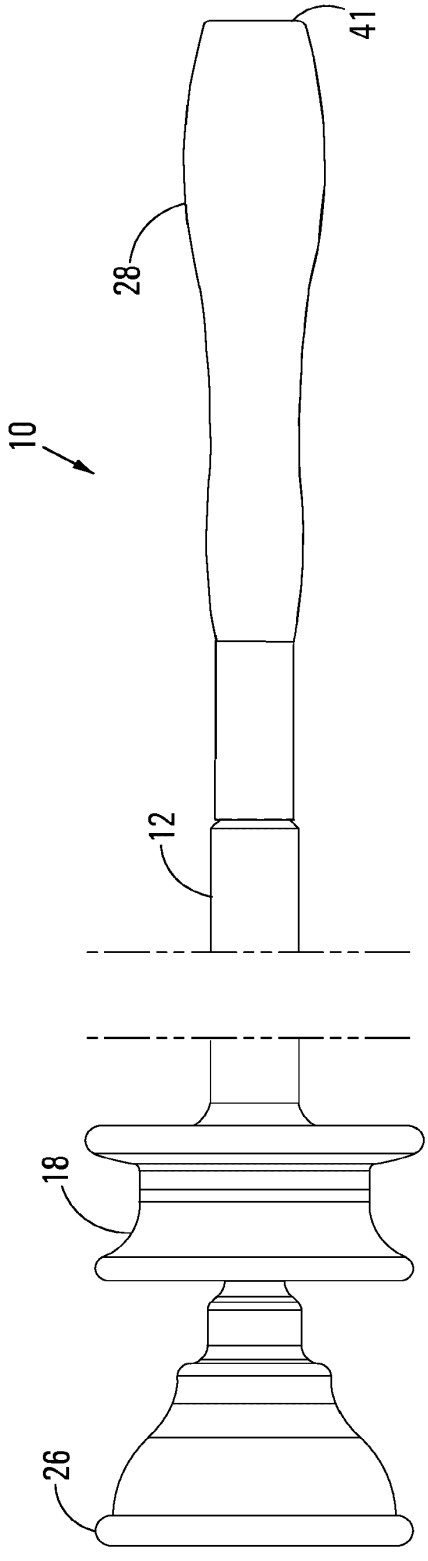


FIG 2


41
28
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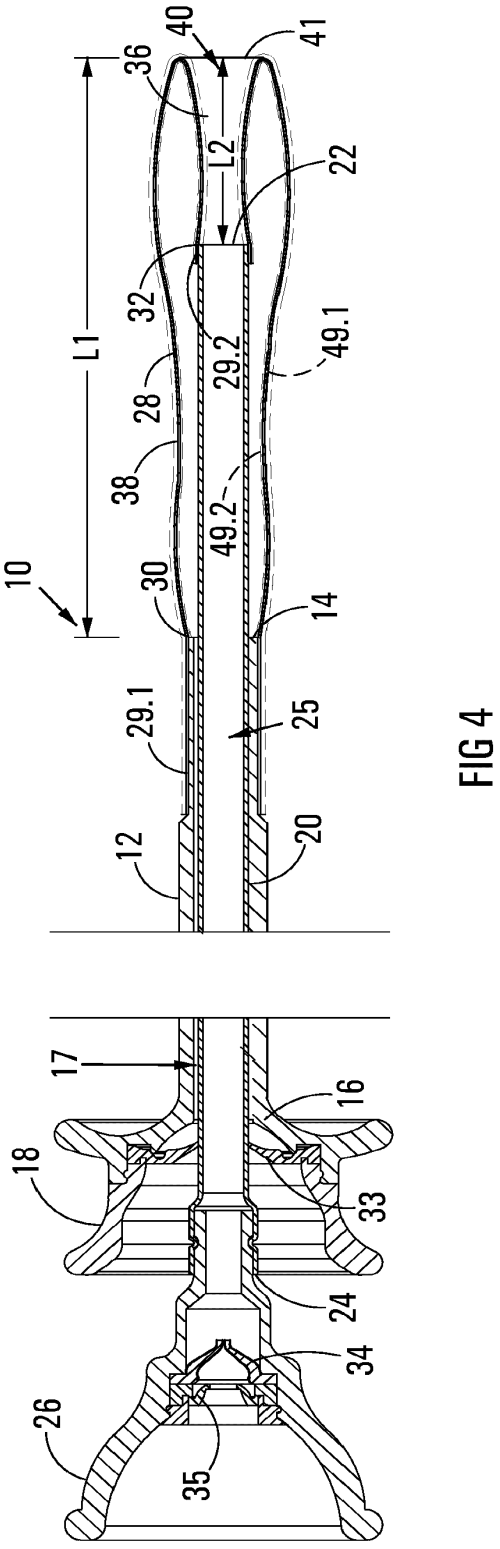
12
18
26

FIG 3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41
36
L2
22
32
29.2
49.1
L1
28
38
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FIG 4

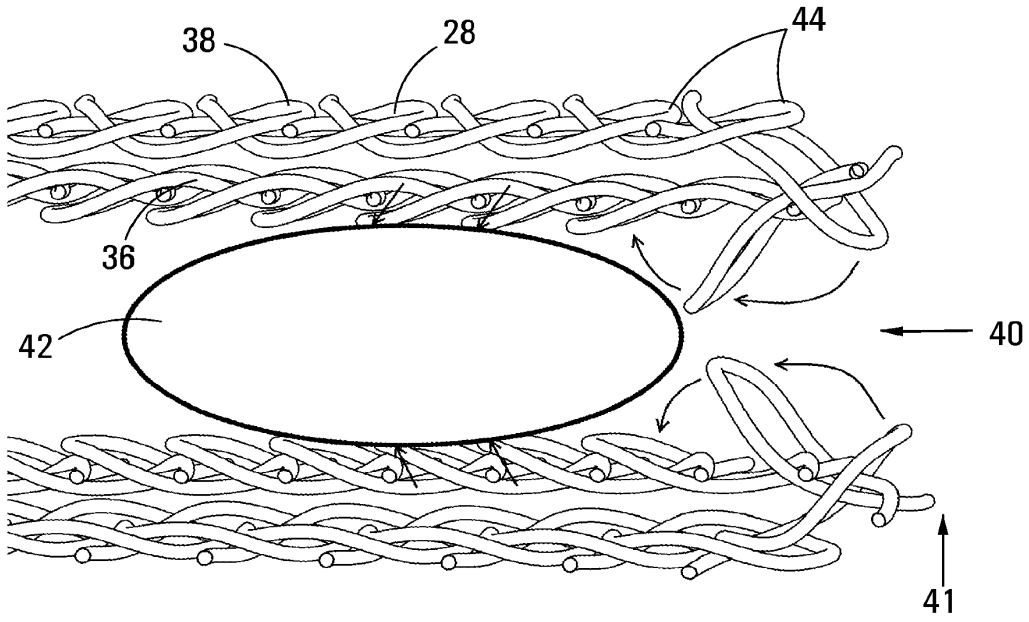

FIG 5

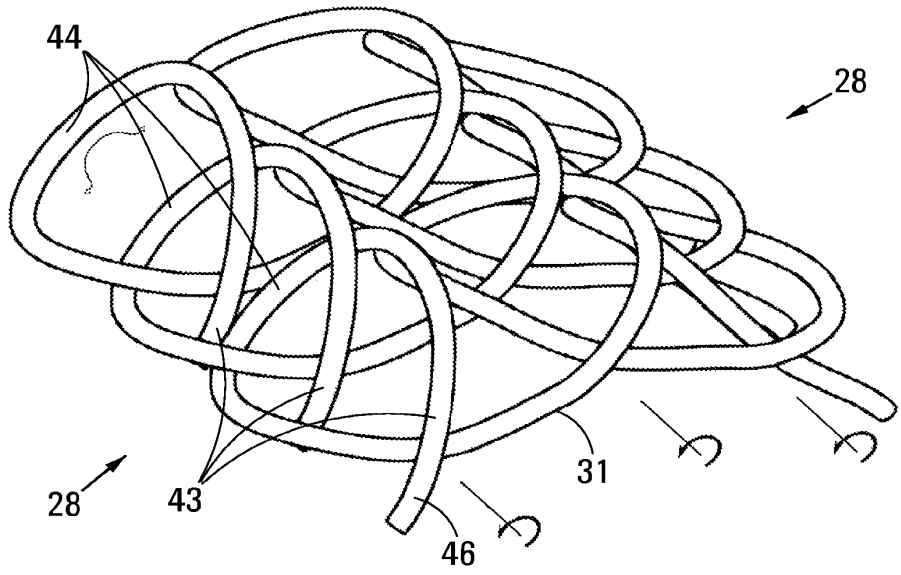

FIG 6

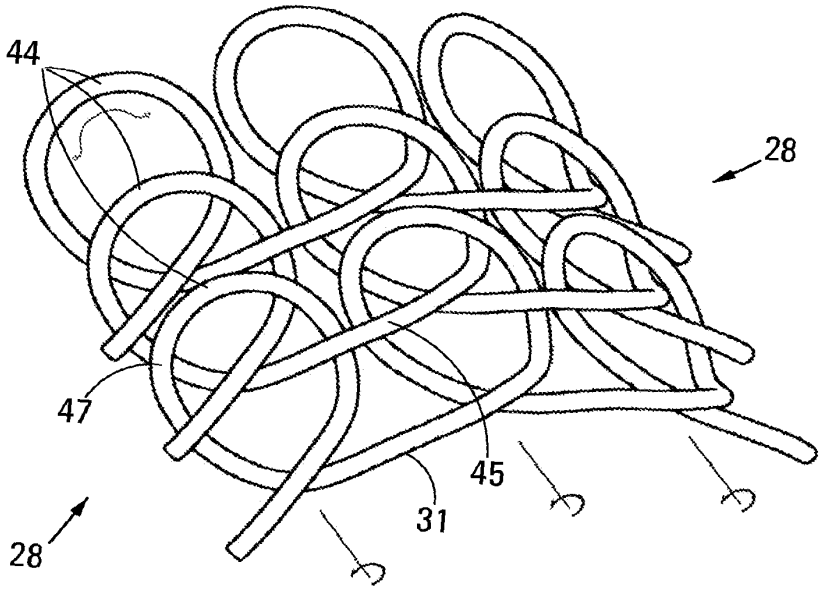

FIG 7

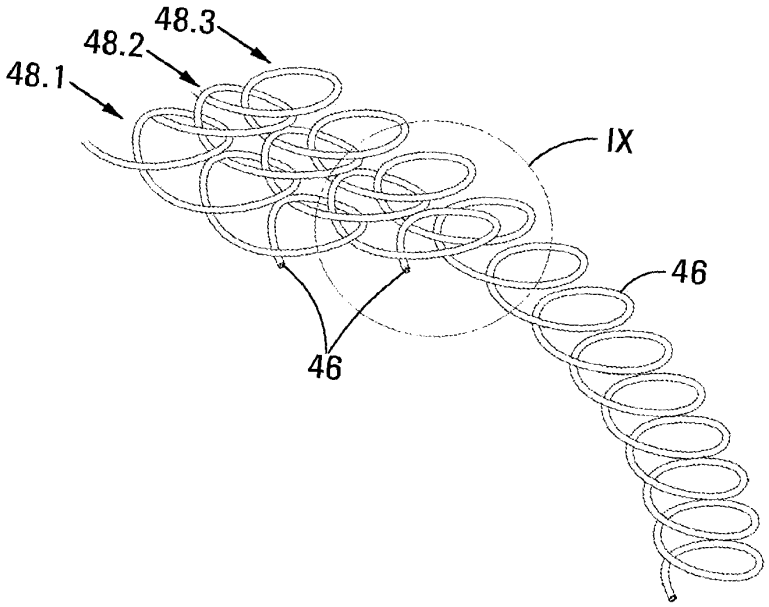

FIG 8

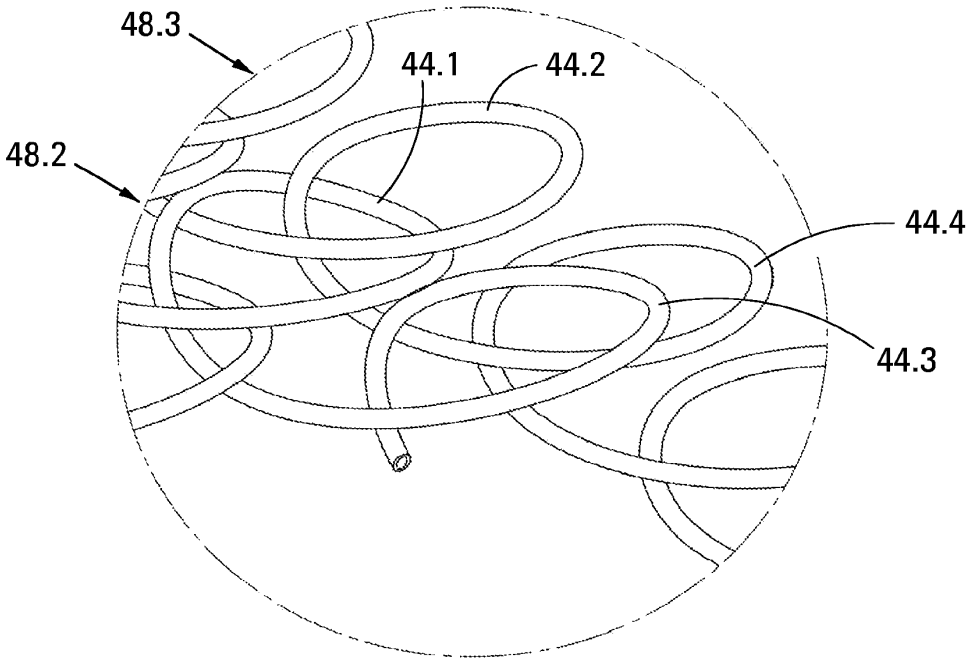

FIG 9

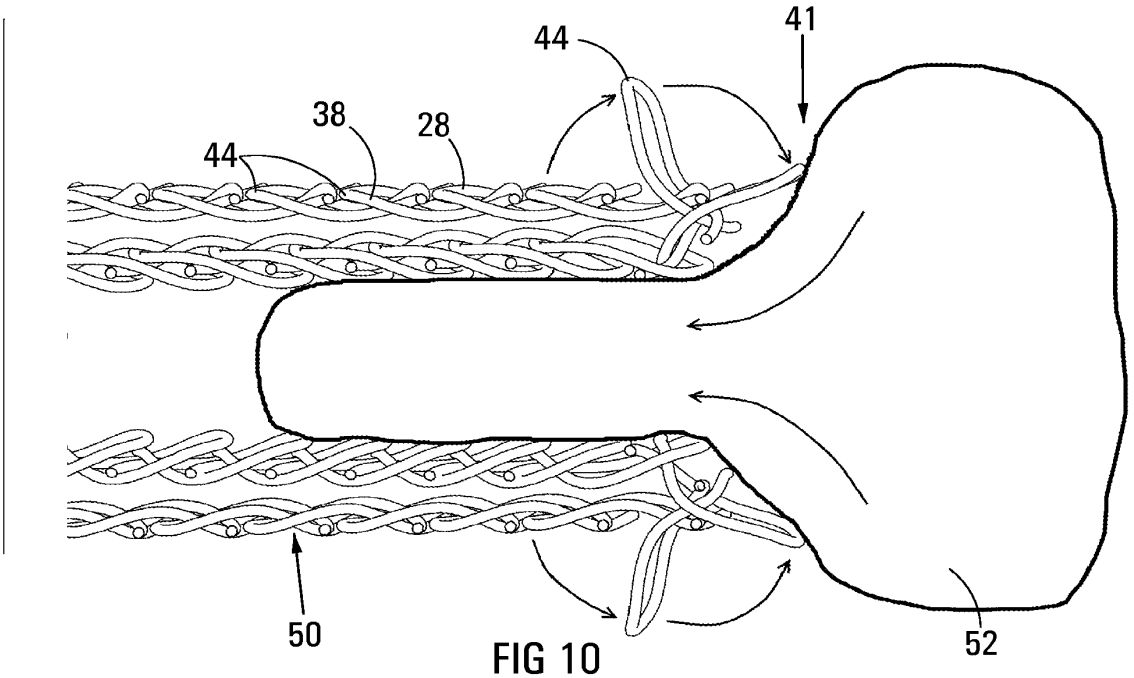

FIG 10

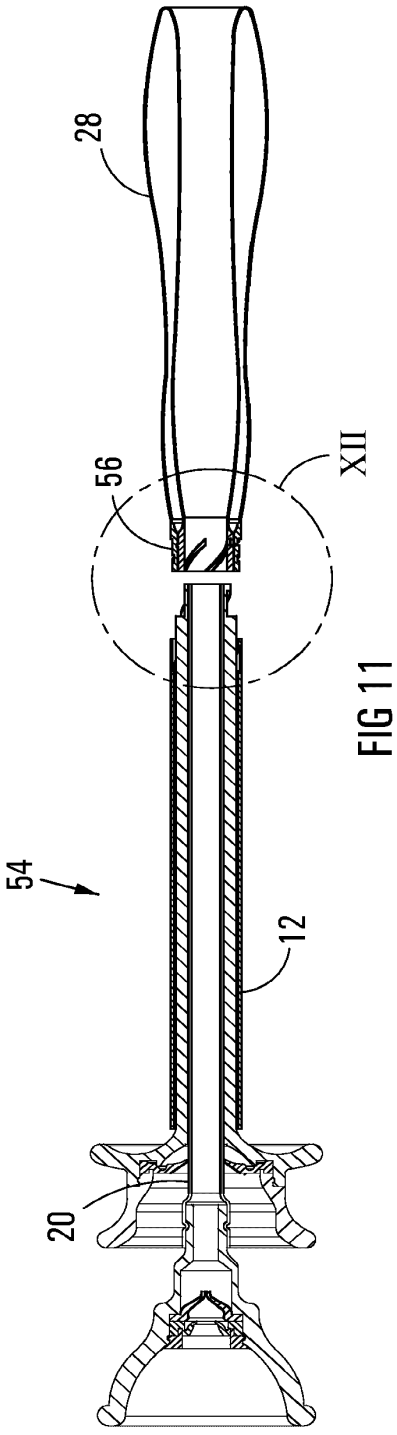

FIG 11

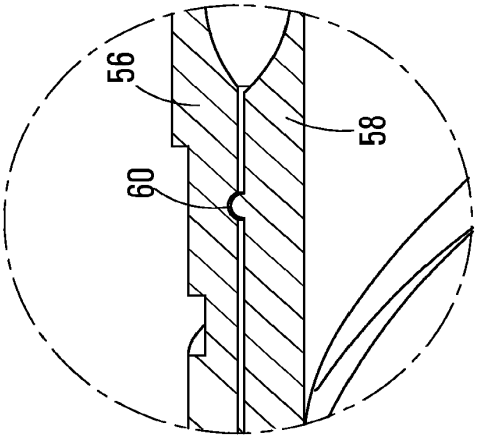

FIG 13

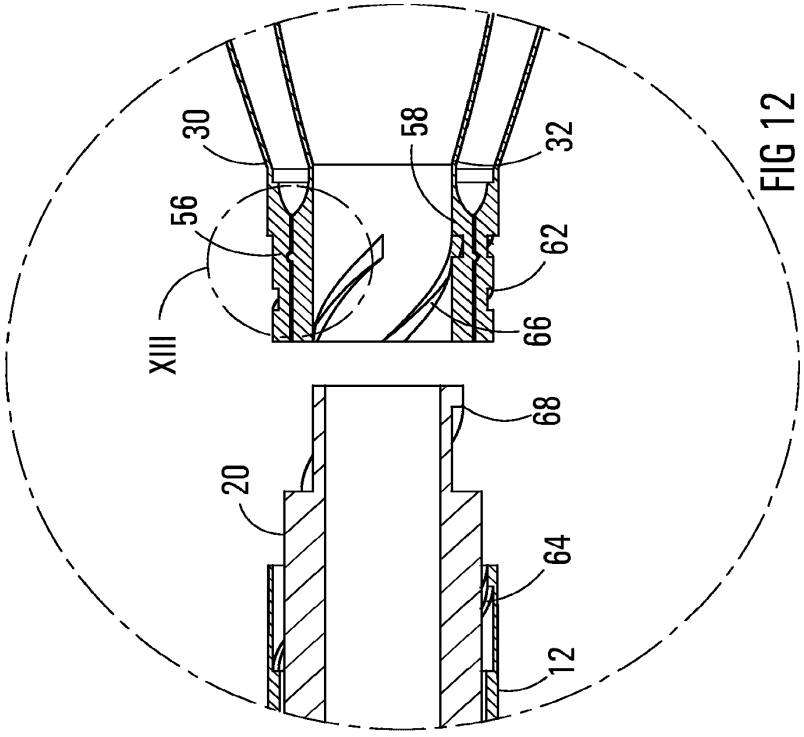

FIG 12

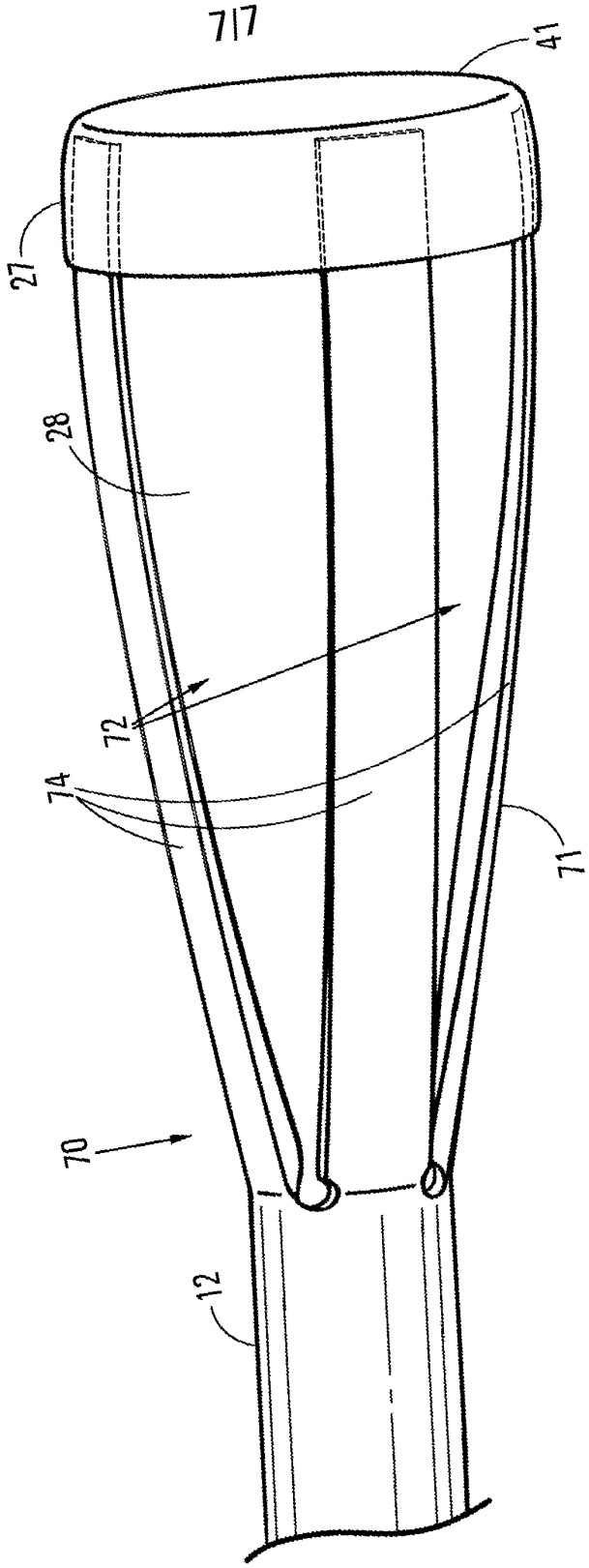

FIG 14

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.

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

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-13, 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

---

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)

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(54) Title: RECAPTURABLE FUNNEL CATHETERS, AND ASSOCIATED SYSTEMS AND METHODS

Fig. 10C

(57) Abstract: Systems and methods for the intravascular treatment of clot material within a blood vessel of a human patient are disclosed herein. In one embodiment, a funnel catheter assembly includes an outer shaft and an inner shaft extending through and coaxial with the outer shaft. An expandable funnel can be coupled to a distal portion of the inner shaft. The funnel catheter assembly further includes a control assembly operably coupled to the proximal portion of the outer shaft and configured to move the outer shaft between a first position and a second position. In the first position, the outer shaft is positioned at least partially over the funnel to constrain the funnel in a compressed state. In the second position, the outer shaft is retracted proximally relative to the funnel such that the funnel can expand to an expanded state.

WO 2021/248042 A1

RECAPTURABLE FUNNEL CATHETERS, AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/035,605, filed June 5, 2020, and titled "RECAPTURABLE FUNNEL CATHETERS, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to systems, methods, and devices for embolic protection during procedures for extracting thrombi from blood vessels of human patients.

BACKGROUND

[0003] Thrombosis is the local coagulation or clotting of the blood in a part of the circulatory system, and a thrombus is a blood clot formed in situ within the vascular system. A venous thrombus is a blood clot that forms within a vein. A common type of venous thrombosis is a deep vein thrombosis (DVT), which is the formation of a blood clot within a deep vein (e.g., predominantly in the legs). Nonspecific signs of a thrombosis may include pain, swelling, redness, warmness, and engorged superficial veins.

[0004] If the thrombus breaks off (embolizes) and flows towards the lungs, it can become a life-threatening pulmonary embolism (PE) (e.g., a blood clot in the lungs). In addition to the loss of life that can arise from PE, DVT can cause significant health issues such as post thrombotic syndrome, which can cause chronic swelling, pressure, pain, and ulcers due to valve and vessel damage. Further, DVT can result in significant health-care costs either directly or indirectly through the treatment of related complications and inability of patients to work.

[0005] Three processes are believed to result in venous thrombosis. First is a decreased blood flow rate (venous stasis), second is an increased tendency to clot (hypercoagulability), and the third is changes to the blood vessel wall. DVT formation typically begins inside the valves of the calf veins where the blood is relatively oxygen deprived, which activates certain biochemical pathways. Several medical conditions increase the risk for DVT, including

diabetes, cancer, trauma, and antiphospholipid syndrome. Other risk factors include older age, surgery, immobilization (as with bed rest, orthopedic casts, and sitting on long flights), combined oral contraceptives, pregnancy, the postnatal period, and genetic factors. The rate of DVT increases dramatically from childhood to old age and, in adulthood, about 1 in 1,000 adults develop DVT annually.

[0006] Although current devices and methods of prevention and/or treatment of DVT exist, there are a number of shortcomings that have yet to be resolved, such as high incidence of DVT re-occurrence, use of devices not designed to remove large clot volumes, and/or complicated treatments involving multiple treatment devices and/or pharmaceuticals. Accordingly, new devices, systems, and methods of treating thrombus, and particularly DVT are desired.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0008] Figure 1 is a partially transparent and partially cross-sectional side view of a funnel catheter assembly in accordance with embodiments of the present technology.

[0009] Figures 2A and 2B are side views of the funnel catheter assembly in a first position and a second position, respectively, in accordance with embodiments of the present technology.

[0010] Figure 3 is a side view of the funnel catheter assembly in the first position with a dilator inserted therethrough in accordance with embodiments of the present technology.

[0011] Figure 4 is a side view of the funnel catheter assembly including a non-self-expanding funnel in accordance with embodiments of the present technology.

[0012] Figures 5–8 are schematic views illustrating various thrombectomy techniques for removing a thrombus from a blood vessel of a human patient utilizing the funnel catheter assembly in accordance with embodiments of the present technology.

[0013] Figures 9A and 9B are enlarged, partially transparent side and side cross-sectional views, respectively, of a portion of a funnel catheter assembly in accordance with additional embodiments of the present technology.

[0014] Figures 10A–10C are side views of the funnel catheter assembly of Figures 9A and 9B in a sheathed position, a partially-unsheathed or intermediate position, and an unsheathed position, respectively, in accordance with embodiments of the present technology

[0015] Figure 11 is a flow diagram of a process or method for operating the funnel catheter assembly during an intravascular procedure in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0016] The present technology is generally directed to methods and systems for removing clot material (e.g., a thrombus) from a blood vessel of a human patient. More particularly, the present technology is directed to funnel catheter assemblies configured to provide embolic protection during a clot removal or other intravascular procedure. In some embodiments, a funnel catheter assembly includes an outer shaft and an inner shaft extending through and coaxial with the outer shaft. An expandable funnel, such as a self-expanding funnel, can be coupled to a distal portion of the inner shaft. The funnel catheter assembly further includes a control assembly operably coupled to the proximal portion of the outer shaft. The funnel catheter assembly can be actuated by an operator (e.g., a physician) to move the outer shaft between a first position and a second position. In the first position, the outer shaft is positioned at least partially over the funnel to constrain the funnel in a compressed state. In the second position, the outer shaft is retracted proximally relative to the funnel such that the funnel can expand to an expanded state. Accordingly, the funnel catheter assembly enables the funnel to be unsheathed and sheathed during an intravascular procedure via the movement of the outer shaft between the first and second positions.

[0017] In one aspect of the present technology, the control assembly is operable to compress the funnel after it has been expanded within a blood vessel of a patient. This can permit the funnel catheter assembly to be repositioned within the blood vessel without fully withdrawing the funnel catheter assembly from the patient. Similarly, the funnel catheter assembly can be fully withdrawn from the patient (e.g., at the conclusion of a thrombectomy procedure) in the first position with the funnel compressed inside the outer shaft. Thus, the funnel catheter assembly is configured to inhibit or even prevent the funnel from contacting the wall of the blood vessel during movement of the funnel catheter assembly within the blood vessel. This can help inhibit injury/damage to the patient that could otherwise be caused by the moving the funnel through a blood vessel or an associated organ in the expanded state.

[0018] Although many of the embodiments are described below with respect to devices, systems, and methods for treating vascular thrombi (e.g., deep vein thrombosis (DVT)), other applications and other embodiments in addition to those described herein are within the scope of the technology (e.g., intravascular procedures other than the treatment of emboli, intravascular procedures for treating cerebral embolism, intravascular procedures for treating pulmonary embolism, etc.). In general, for example, the devices, systems, and methods of the present technology can be used to extract any formation of material in a vessel (e.g., a venous or arterial vessel), such as cancerous growths, vegetation, etc. Additionally, several other embodiments of the technology can have different configurations, states, components, or procedures than those described herein. Moreover, it will be appreciated that specific elements, substructures, advantages, uses, and/or other features of the embodiments described with reference to Figures 1–11 can be suitably interchanged, substituted or otherwise configured with one another in accordance with additional embodiments of the present technology. Furthermore, suitable elements of the embodiments described with reference to Figures 1–11 can be used as standalone and/or self-contained devices. A person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described below with reference to Figures 1–11.

[0019] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," etc. are not meant to limit the referenced component to use in a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

[0020] The headings provided herein are for convenience only and should not be construed as limiting the subject matter disclosed.

I. Selected Embodiments of Funnel Catheter Assemblies

[0021] Figure 1 is a partially transparent and partially cross-sectional side view of a funnel catheter assembly 100 in accordance with embodiments of the present technology. In the illustrated embodiment, the funnel catheter assembly 100 includes an elongate outer shaft 102 and an elongate inner shaft 104 coaxial with the outer shaft 102. The outer and inner shafts 102,

104 ("shafts 102, 104") can also be referred to as sheaths, catheters, hollow members, and so on. The outer shaft 102 defines a lumen 106 and includes a proximal portion 107a and a distal portion 107b. The inner shaft 104 extends through the lumen 106 of the outer shaft 102 and similarly defines a lumen 108 and includes a proximal portion 109a and a distal portion 109b. The proximal portions 107a and 109a can each terminate at a proximal end/terminus, and the distal portions 107b and 109b can each terminate at a distal end/terminus. The shafts 102, 104 can be elastic and/or flexible and can have any suitable length and diameter.

[0022] In the illustrated embodiment, the funnel catheter assembly 100 further includes a sealable hub 110 coupled to the proximal portion 109a of the inner shaft 104. In some embodiments, as described in greater detail below with reference to Figures 9A–9C, the sealable hub 110 can be rotatable coupled to the inner shaft 104 such that the sealable hub 110 can rotate independently of the inner shaft 104. The sealable hub 110 is configured to allow access to the lumen 108 of the inner shaft 104 and can be self-sealing and/or can comprise a self-sealing seal. For example, in the illustrated embodiment the sealable hub 110 is a hemostasis valve that is configured to maintain hemostasis (e.g., during a thrombus extraction procedure) by inhibiting or even preventing fluid flow in the proximal direction through the sealable hub 110 as, for example, various components (e.g., dilator assemblies, thrombus extraction devices, etc.) are inserted through the sealable hub 110 to be delivered through the inner shaft 104 to a treatment site in a blood vessel. More specifically, the sealable hub 110 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety. The sealable hub 110 can include one or more buttons or actuators that enable an operator to selectively seal/unseal the sealable hub 110.

[0023] The funnel catheter assembly 100 can further include an aspiration port 112 connected to the sealable hub 110 (e.g., to a side port of the sealable hub 110) and/or the inner shaft 104 (e.g., to the proximal portion 109a of the inner shaft 104) via, for example, a connecting tube 114. The aspiration port 112 can be connected to a syringe connector 116 that can be selectively coupled to a syringe or other aspiration device, or the aspiration port 112 can be connected to other suitable elements. In some embodiments, the funnel catheter assembly 100 includes a fluid control device 118 configured to selectively fluidly connect the aspiration port 112 to the lumen 108 of the inner shaft 104. In the illustrated embodiment, the fluid control device 118 is a stopcock operably coupled to the connecting tube 114 between the lumen 108 of the inner shaft 104 and the aspiration port 112. In other embodiments, the fluid control device

118 can be a clamp or another suitable valve. In some embodiments, a vacuum source (not shown; e.g., a syringe) can be coupled to the syringe connector 116 and used to aspirate the lumen 108 of the inner shaft 104. In some embodiments, as described in greater detail below with reference to Figures 9A–9C, the aspiration port 112 and the connecting tube 114 can be rotatable relative to the sealable hub 110 and/or the inner shaft 104.

[0024] In the illustrated embodiment, a funnel 120 is coupled to the distal portion 109b of the inner shaft 104. As described in greater detail below, in operation of the funnel catheter assembly 100 during an intravascular procedure, the funnel 120 is configured to expand (e.g., radially expand) into apposition with a blood vessel and/or other bodily lumen (e.g., of an organ) and act as a proximal or distal thrombus/embolic protection device that inhibits any thrombus from moving past the funnel 120 and embolizing in an unwanted location (e.g., the right heart, the pulmonary arteries, another arterial space, etc.). The funnel 120 can be fused to the distal portion 109b of the inner shaft 104, and/or attached to the inner shaft 104 via welding, adhesives, fasteners, etc. In Figure 1, the funnel catheter assembly 100 is in a first position/state/configuration in which the distal portion 107b of the outer shaft 102 extends beyond the distal portion 109b of the inner shaft 104 such that the funnel 120 is at least partially (e.g., entirely) positioned within the lumen 106 of the outer shaft 102. The funnel 120 can be configured to expand (e.g., self-expand) and, accordingly, the funnel 120 can be in a first, constrained position/state/configuration when the funnel catheter assembly 100 is in the first position. In some embodiments, the funnel 120 can be formed from at least one of a castellated nitinol braid, a nitinol braided stent, a laser cut nitinol, a laser cut polymer tube, an injection molded polymeric structure, or an inflatable balloon. In some embodiments, the funnel 120 can comprise a mesh having a pore size sufficiently small to prevent the passage of thrombus through the pores of the mesh. In some embodiments, the funnel 120 can be permeable to blood. In some embodiments, the funnel 120 can include a covering over at least a portion thereof that is permeable or non-permeable to blood.

[0025] In the illustrated embodiment, the proximal portion 107a of the outer shaft 102 is operably coupled to a control assembly 130. The control assembly 130 is operable to move the outer shaft 102 distally and proximally relative to the inner shaft 104 to constrain and release the funnel 120 from within the lumen 106 of the outer shaft 102. More specifically, in the illustrated embodiment the control assembly 130 includes (i) a housing 132 having a proximal portion 133a and a distal portion 133b, and (ii) an actuation member 134 operably/movably coupled to the housing 132. The housing 132 defines a lumen 135 extending between the proximal and distal

portions 133a, b thereof. The proximal portion 133a of the housing 132 can be coupled to the sealable hub 110. In some embodiments, the proximal portion 133a of the housing 132 is integrally formed with the sealable hub 110.

[0026] In the illustrated embodiment, the actuation member 134 includes a body portion 136 positioned within the lumen 135 of the housing 132 and coupled to the proximal portion 107a of the outer shaft 102 via, for example, adhesive, fasteners, welding, etc. The actuation member 134 further includes one or more grip members 138 extending from the body portion 136 to outside of the lumen 135. More specifically, the grip members 138 can extend through corresponding slots 140 formed in/along the housing 132. The housing 132 can define a proximal terminus 142a and a distal terminus 142b for each of the slots 140. In some embodiments, the control assembly 130 can include one, or more than the illustrated two of the grip members 138 and corresponding slots 140.

[0027] In operation, an operator (e.g., a physician) can slide the actuation member 134 along the housing 132 to distally advance and proximally retract the outer shaft 102 relative to the inner shaft 104 to constrain and release the funnel 120, respectively. More specifically, Figures 2A and 2B are side views of the funnel catheter assembly 100 in the first position and in a second position, respectively, in accordance with embodiments of the present technology. Referring to Figures 1–2B together, to move the funnel catheter assembly 100 from the first position (Figures 1 and 2A) to the second position (Figure 2B), the operator can grip the grip members 138 of the actuation member 134 and slide the grip members 138 proximally (e.g., in the direction of arrow P in Figure 2A) relative to the housing 132 to drive the body portion 136 through the lumen 135 to thereby drive the outer shaft 102 proximally relative to the inner shaft 104. The funnel 120 is released/unsheathed from within the lumen 106 of the outer shaft 102 as the distal portion 107b of the outer shaft 102 moves proximally past the funnel 120, thereby allowing the funnel 120 to expand. In some embodiments, the actuation member 134 can abut the proximal termini 142a of the slots 140 in the second position such that the housing 132 inhibits further proximal movement of the outer shaft 102.

[0028] In some embodiments, the distal terminus of the outer shaft 102 is positioned at or proximal of the distal terminus of the inner shaft 104 in the second position such that the funnel 120 is fully released from (e.g., positioned fully outside of) the lumen 106 of the outer shaft 102. In other embodiments, the distal terminus of the outer shaft 102 can be positioned distal of the distal terminus of the inner shaft 104 in the second position such that the funnel 120 is only

partially released from the lumen 106 of the outer shaft 102. Moreover, as shown in Figure 2B, the funnel 120 can have a conically shaped portion 222 (e.g., a truncated-conically shaped portion) and a cylindrical portion 224 once expanded. In other embodiments, the funnel 120 can have other suitable shapes. For example, in some embodiments the funnel 120 can be inverted relative to the embodiment shown in Figure 2B. That is, the cylindrical portion 224 of the funnel 120 can be coupled to the distal portion 109b of the inner shaft 104 while the conically shaped portion 222 extends distally from the cylindrical portion 224.

[0029] To move the funnel catheter assembly 100 from the second position (Figure 2B) to the first position (Figures 1 and 2A), the operator can grip the grip members 138 of the actuation member 134 and slide the grip members 138 distally (e.g., in the direction of arrow D in Figure 2B) relative to the housing 132 to drive the body portion 136 through the lumen 135 to thereby drive the outer shaft 102 distally relative to the inner shaft 104. The funnel 120 is captured/sheathed in the lumen 106 of the outer shaft 102 as the distal portion 107b of the outer shaft 102 moves distally over the funnel 120, thereby collapsing/compressing the funnel 120 within the lumen 106. In some embodiments, the actuation member 134 can abut the distal termini 142b of the slots 140 in the first position such that the housing 132 inhibits further distal movement of the outer shaft 102.

[0030] In some embodiments the actuation member 134 is configured to be releasably secured/locked to the housing 132 in the first and second positions to inhibit or even prevent unintended movement of the actuation member 134. For example, referring again to Figure 1, the housing 132 of the control assembly 130 can include (i) proximal engagement members 144a (e.g., tabs, protrusions, etc.) configured to engage the actuation member 134 in the first position and (ii) distal engagement members 144b configured to engage the actuation member 134 in the second position. More specifically, in some embodiments the proximal and distal engagement members 144a, b can mate with corresponding slots/grooves in the actuation member 134 (e.g., formed in/on the grip members 138) to releasably secure the actuation member 134 in the first or second positions via a snap fit arrangement.

[0031] In some embodiments, the inner shaft 104 is sized to slidably receive one or more medical instruments inserted through the sealable hub 110 during an intravascular procedure using the funnel catheter assembly 100, such as a thrombectomy procedure. Figure 3, for example, is a side view of the funnel catheter assembly 100 in the first position with a dilator 350 inserted through the sealable hub 110 and the lumen 108 of the inner shaft 104 (Figure 1) in

accordance with embodiments of the present technology. The dilator 350 can extend entirely through the inner shaft 104 and past the distal terminus of the distal portion 107b of the outer shaft 102 such that a distal tip 352 (e.g., an atraumatic tip) is positioned beyond the distal terminus of the outer shaft 102.

[0032] In some embodiments, the dilator 350 and the funnel catheter assembly 100 together define an introducer assembly that can be inserted into a patient (e.g., a human patient) and subsequently used to introduce intravascular medical devices into the patient. For example, the dilator 350 and the funnel catheter assembly 100 can be inserted into and advanced together through a blood vessel of the patient to a target location in the blood vessel. The dilator 350 can then be retracted proximally through the funnel catheter assembly 100, and the funnel catheter assembly 100 can be moved to the second position to expand the funnel 120 at the target location.

[0033] Referring to Figures 1–3 together, in one aspect of the present technology the inner shaft 104 is the "working" shaft of the funnel catheter assembly 100 that can be aspirated and/or receive various medical components (e.g., the dilator 350). In contrast, the outer shaft 102 is used to compress/expand the funnel 120. Accordingly, the shafts 102, 104 can be sized to maximize the size of the inner shaft 104 to permit larger-sized components to be inserted therethrough, or to provide greater aspiration force/power. For example, the outer shaft 102 can have an inner diameter that is only slightly greater than an outer diameter of the inner shaft 104. In some embodiments, the inner shaft 104 can have an outer diameter of at least 10 French, at least 12 French, at least 14 French, at least 18 French, at least 20 French, at least 22 French, at least 26 French, greater than 26 French, between 10 French and 26 French, between 14 French and 24 French, between 15 French and 21 French, between 16 French and 22 French, and/or any other or intermediate size. In some embodiments, the lumen 108 of the inner shaft 104 can have an internal diameter of at least 2 French, at least 10 French, at least 14 French, at least 18 French, at least 20 French, at least 22 French, between 11 French and 12 French, between 10 French and 22 French, between 14 French and 21 French, between 16 French and 20 French, and/or any other or intermediate size.

[0034] In another aspect of the present technology, the control assembly 130 is operable, via the movement of the actuation member 134 from the second position to the first position, to compress the funnel 120 after it has been expanded within a blood vessel. This can permit the funnel catheter assembly 100 to be repositioned within the blood vessel without fully withdrawing the funnel catheter assembly 100 from the patient. For example, after (i)

introducing the funnel catheter assembly 100 into the blood vessel with the dilator 350 and (ii) removing the dilator 350, the funnel catheter assembly 100 can be repositioned proximally simply by moving the funnel catheter assembly 100 back to the first position to collapse the funnel 120 and then retracting the funnel catheter assembly 100 proximally. To reposition the funnel catheter assembly 100 distally, the dilator 350 can be reinserted and the funnel catheter assembly 100 pushed proximally in the first position with the funnel 120 compressed. Similarly, the funnel catheter assembly 100 can be fully withdrawn from the patient (e.g., at the conclusion of a thrombectomy procedure) in the first position with the funnel 120 compressed in the lumen 106 of outer shaft 102. Thus, the funnel catheter assembly 100 is configured to inhibit or even prevent the funnel 120 from contacting the wall of the blood vessel during advancement/withdrawal. This can help inhibit injury/damage to the patient that could otherwise be caused by the moving the funnel 120 through the blood vessel or an associated organ in the expanded state.

[0035] In some embodiments, the funnel catheter assembly 100 and/or methods of operating the funnel catheter assembly 100 can include some features the same as or similar to the thrombectomy systems (e.g., the introducer assemblies) described in detail in (i) U.S. Patent No. 9,700,332, filed September 16, 2016, and titled "INTRAVASCULAR TREATMENT OF VASCULAR OCCLUSION AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS," and/or (ii) U.S. Patent No. 10,098,651, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," both of which are incorporated herein by reference in their entirety.

[0036] In other embodiments, the control assembly 130 can be configured to drive the distal and proximal movement of the outer shaft 102 in other manners. For example, the actuation member 134 can comprise a rotatable member (e.g., a ring gear, corkscrew, rotatable handle, etc.) coupled to the outer shaft 102. In some embodiments, the rotatable member can be a ratcheting member that is rotatable to a plurality of discreet positions between the first and second positions.

[0037] Similarly, in other embodiments the control assembly 130 can be operably coupled to the inner shaft 104 rather than the outer shaft 102. Accordingly, operation of the control assembly 130 can move the inner shaft 104 and the sealable hub 110 relative to the outer shaft 102 to move the funnel catheter assembly 100 between the first and second positions to constrain/compress and release/expand the funnel 120, respectively.

[0038] In yet other embodiments, the funnel 120 can be operably coupled to the outer shaft 102 such that movement of the outer shaft 102 between the first and second positions expands the funnel 120. More specifically, for example, Figure 4 is a side view of the funnel catheter assembly 100 including a non-self-expanding funnel 420 in accordance with embodiments of the present technology. In some embodiments, the funnel 420 can have a similar shape as the funnel 120 described in detail above with reference to Figures 1–3, but can be formed of one or more non-self-expanding materials such as metal (e.g., a non-heat-activated metal), plastic, fiber, polymer, etc. In the illustrated embodiment, the funnel 420 is coupled to (i) the distal portion 109b of the inner shaft 104 (Figure 1) and (ii) the distal portion 107b of the outer shaft 102 via a plurality of flexible tethers 426. The tethers 426 are configured (e.g., shaped, sized, and/or positioned) such that movement of the control assembly 130 from the first position to the second position pulls the tethers 426 to thereby pull and expand the funnel 420 as it is unsheathed from within the outer shaft 102.

[0039] In some embodiments, the funnel catheter assembly 100 can include one or more features for actuating/manipulating the funnel 420 (or the funnel 120 described in detail with reference to Figures 1–3). For example, the control assembly 130 can include an actuation member 454 (shown schematically) operably coupled to the funnel 420 via one or more control lines 462 (e.g., wires, tethers, rigid members etc.). The actuation member 454 can be a slider, rotatable member, or other component configured to exert a force on the funnel 420 via the control lines 462. In some embodiments, the control lines 462 can be asymmetrically/eccentrically coupled to the funnel 420 such that actuation of the actuation member 454 bends the funnel 420 away from a longitudinal axis of the shafts 102, 104. In one aspect of the present technology, this arrangement can be used to help steer the funnel 420 into a tortuous region of a patient (e.g., a tortuous vessel, the left atrial appendage (LAA), etc.) that may otherwise be difficult to position the funnel 420 in. Additionally or alternatively, the funnel catheter assembly 100 can include one or more components (e.g., pull wires) for steering (e.g., bending, deflecting, etc.) the outer shaft 102 and/or the inner shaft 104 to facilitate positioning of the funnel 420.

II. Selected Embodiments of Procedures Utilizing Funnel Catheter Assemblies for Embolic Protection

[0040] Referring to Figures 1–4 together, the funnel catheter assembly 100 can be used in a myriad of procedures to capture thrombi and inhibit the thrombi from embolizing in portions

of a patient's vasculature. For example, Figures 5–8 are schematic views illustrating various thrombectomy techniques for removing a thrombus T from a blood vessel BV of a human patient utilizing the funnel catheter assembly 100 in accordance with various embodiments of the present technology.

[0041] Referring first to Figure 5, in some embodiments the thrombus T (e.g., clot material) can be accessed through a popliteal access site 560. The funnel catheter assembly 100 can extend from the popliteal access site 560 to a deployment position 562 in the blood vessel BV at which the funnel 120 (or the funnel 420) can be deployed. The deployment position 562 can be proximate to and proximal of the thrombus T. The funnel 120 can at least partially appose a wall of the blood vessel BV after the funnel catheter assembly 100 is moved from the first position to the second position to expand the funnel 120, as described in detail above with reference to Figures 1–4.

[0042] In the illustrated embodiment, a thrombus extraction device 564 has been (i) inserted through the funnel catheter assembly 100, (ii) passed through the thrombus T in the direction of blood flow, and (iii) expanded distal of the thrombus T. The thrombus extraction device 564 can include a coring element 565 (e.g., a stent-like device) and a capture element 566 (e.g., a braided mesh bag). In some embodiments, some or all of the thrombus extraction device 564 can extend into one of the iliac veins and/or the inferior vena cava. After expansion distal of the thrombus T, the thrombus extraction device 564 can be retracted through the thrombus T and into the lumen 108 of the inner shaft 104 (Figure 1) through the funnel 120. During retraction, the coring element 565 can core/separate the thrombus T and the capture element 566 can capture all or a portion of the thrombus T. In some embodiments, the thrombus extraction device 564 and the associated thrombectomy procedure can be generally similar or identical to the thrombus extraction devices and associated methods described in detail in (i) U.S. Patent No. 9,700,332, filed September 16, 2016, and titled "INTRAVASCULAR TREATMENT OF VASCULAR OCCLUSION AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS," and/or (ii) U.S. Patent No. 10,098,651, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," both of which are incorporated herein by reference in their entirety.

[0043] In one aspect of the present technology, as the thrombus extraction device 564 and the captured thrombus T are retracted through the funnel 120, the funnel 120 can capture/retain any of the thrombus T that breaks free of the thrombus extraction device 564 as the thrombus

extraction device 564 is compressed into the inner shaft 104. Accordingly, the funnel 120 can inhibit portions of the thrombus T from traveling upstream where they could potentially embolize. In some embodiments, a vacuum (e.g., a pre-charged vacuum) can be applied to the inner shaft 104 (e.g., via a syringe coupled to the syringe connector 116 shown in Figure 1) at any point during retraction of the thrombus extraction device 564. In some embodiments, application of the vacuum can generate instantaneous or nearly instantaneous suction at the distal portion 109b of the inner shaft 104 that can aspirate any remaining portions of the thrombus T into and/or through the inner shaft 104.

[0044] Referring next to Figure 6, in some embodiments the thrombus T (not shown in Figure 6; e.g., positioned lower in the iliac or femoral veins) can be accessed through an internal jugular access site 670, and the funnel catheter assembly 100 can be inserted into the patient's body via the internal jugular access site 670. The funnel catheter assembly 100 can extend from the internal jugular access site 670 to a deployment position 672 at which the funnel 120 (or the funnel 420) can be deployed proximal to the thrombus T. In the illustrated embodiment, the outer shaft 102 and the inner shaft 104 (obscured in Figure 6) extend from the internal jugular access site 670 through the superior vena cava and the inferior vena cava to the deployment position 672 in one of the common iliac veins. In some embodiments, the deployment position 672 can be located in, for example, the inferior vena cava, one of the iliac veins, the femoral vein, the popliteal vein, before or beyond the iliac arch, or any other location proximate to and/or proximal to the thrombus T. In some embodiments, the thrombus extraction device 564 can be inserted through the funnel catheter assembly 100 and withdrawn through the thrombus T to capture the thrombus T, as described in detail above with reference to Figure 5.

[0045] In one aspect of the present technology, accessing the thrombus T via the internal jugular access site 670 allows the funnel 120 to be positioned downstream of the thrombus T. Accordingly, the funnel 120 can capture any of the thrombus T that may break off and be carried downstream toward the heart during operation of the thrombus extraction device 564. In another aspect of the present technology, the funnel 120 can be compressed—for example, by moving the actuation member 134 from the second position to the first position as described in detail above with reference to Figures 1–4—before withdrawing the funnel catheter assembly 100 at the conclusion of the thrombectomy procedure. This prevents the funnel 120 from being withdrawn in the expanded configuration through the heart of the patient (e.g., through the right atrium) which could potentially damage the heart.

[0046] Referring next to Figure 7, in some embodiments the thrombus T can be accessed by the thrombus extraction device 564 through the popliteal access site 560 using a separate introducer assembly 774, while the funnel catheter assembly 100 can be inserted into the patient's body via the internal jugular access site 670 (Figure 6). The funnel 120 can be expanded at the deployment position 672 during a thrombectomy procedure using the thrombus extraction device 564. The funnel 120 can therefore capture any of the thrombus material T that may break away and flow downstream during the procedure. In the illustrated embodiment, the thrombus extraction device 564 is inserted through an outer shaft 776 of the introducer assembly 774. In one aspect of the present technology, in comparison to using the funnel catheter assembly 100 as the introducer for the thrombus extraction device 564, the outer shaft 776 can be made relatively larger than the inner shaft 104 because the outer shaft 102 need not be positioned thereabout for constraining the funnel 120. This can permit the thrombus extraction device 564 to be made larger and/or enable greater aspiration forces to be generated through the outer shaft 776.

[0047] Referring next to Figure 8, in some embodiments the thrombus T can be accessed by the thrombus extraction device 564 through the popliteal access site 560 using the introducer assembly 774, while the funnel catheter assembly 100 can be inserted into the patient's body via a femoral access site 880. The funnel catheter assembly 100 can traverse the common iliac veins to the deployment position 672, or another suitable deployment position.

[0048] In other embodiments, the funnel catheter assembly 100 can be inserted into a patient's body via other venous or arterial access sites, and can be used in a myriad of different procedures. For example, additional applications of the funnel catheter assembly 100 include but are not limited to:

[0049] Internal jugular vein (IJ) access for deployment in the inferior vena cava (IVC) for treatment of lower extremity deep vein thrombsis (DVT);

[0050] IJ access for deployment in the IVC for removal of IVC filters and/or treatment of thrombus located in the IVC;

[0051] IJ access for deployment in the deep veins of the lower extremity veins (iliac, femoral, popliteal veins, etc.) for treatment of lower extremity DVT;

[0052] Common femoral vein (CFV) access for deployment in the superior vena cava (SVC) for treatment of upper extremity DVT and/or SVC thrombus;

[0053] CFV access for deployment in the upper extremity veins (brachiocephalic, subclavian, axillary veins, etc.) for treatment of upper extremity DVT and/or SVC thrombus;

[0054] CFV access for deployment in the pulmonary arteries (PAs) for treatment of pulmonary embolism;

[0055] CFV access with transseptal access for deployment in the left atrium ostium and the left atrial appendage (LAA) for thrombus removal;

[0056] Internal Carotid Artery (ICA) accesss for deployment in the common carotid artery (CCA) for carotid endarterectomy (CEA);

[0057] ICA accesss for deployment in descending thoracic aorta for treatment of thoraco-abdominal and/or abdominal aortic (AA) thrombus and/or aorto-arterial thrombosis;

[0058] ICA accesss for deployment in the descending/thoracic aorta for treatment of renal thrombosis;

[0059] ICA accesss for intra-atrterial placement for treament of superior mesenteric artery (SMA) thrombosis (MAT);

[0060] Common Femoral Artery (CFA) access for treatment of atherosclerosis in the brachial artery, radial artery, popiteal artery, or dorsalis pedis artery;

[0061] CFA access for deployment in the common iliac artery for treatment of aorto-arterial thrombosis and/or occlusions;

[0062] CFA access for deployment in the abdominal aorta for treatment of renal artery thrombosis; and/or

[0063] CFA access for deployment in the aorta for treatment of thoraco-abdominal and/or AA thrombus and/or aorto-arterial thrombosis.

[0064] Figures 9A and 9B are enlarged, partially transparent side and side cross-sectional views, respectively, of a portion of a funnel catheter assembly 900 in accordance with additional embodiments of the present technology. Referring to Figures 9A and 9B together, the funnel catheter assembly 900 can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the funnel catheter assembly 100 described in detail above with reference to Figures 1–8, and can operate

in a generally similar or identical manner to the funnel catheter assembly 100. In the illustrated embodiment, for example, the funnel catheter assembly 900 includes the sealable hub 110, the connecting tube 114, the aspiration port 112, the outer shaft 102, and the inner shaft 104 (obscured in Figure 9A). The funnel catheter assembly 900 further includes a control assembly 930 including a housing 932 and an actuation member 934 having a pair of grip member 938. As shown in Figure 9B, the actuation member 934 includes a hub 936 positioned within the housing 932 and coupled to the outer shaft 102 (e.g., the proximal portion 107a of the outer shaft 102). The actuation member 934 is movable (e.g., slidable) relative to the housing 932 to advance/retract the outer shaft 102 relative to the inner shaft 104 and a funnel (e.g., the funnel 120 shown in Figures 10B and 10C) attached to a distal portion thereof.

[0065] The funnel catheter assembly 900 is in a first, sheathed position in Figure 9A in which the funnel is constrained by the outer shaft 102 and in a second, unsheathed position in Figure 9B in which the funnel is not constrained by the outer shaft 102. Referring to Figure 9A, in some embodiments the housing 932 can include a marking 931 indicating a position of the actuation member 934 in which the funnel is in the unsheathed position. In some embodiments, a proximal portion 933a of the housing 932 can include gripping features, such as a groove 935, a cross-hatched pattern 937, and/or other features for increasing the grip-ability of the housing 932. In some embodiments, an operator can grip the housing 932 (e.g., via the groove 935 and/or the pattern 937) while moving (i) the actuation member 934 relative to the housing 932 and/or (ii) the housing 932 relative to the actuation member 934. In some embodiments, the funnel catheter assembly 900 can further include a lock mechanism 911 that can be attached to the sealable hub 110 (e.g., to buttons thereof) to lock the sealable hub 110 in the open/unsealed position.

[0066] In the illustrated embodiment, the funnel catheter assembly 900 further includes a rotatable side port 950 fluidly connecting the sealable hub 110, the connecting tube 114, and the inner shaft 104. Figure 9C is an enlarged isometric cross-sectional view of a portion of the sealable hub 110, the rotatable side port 950, and the control assembly 930 in accordance with embodiments of the present technology. Referring to Figure 9C, the side port 950 defines a lumen 952 that provides a fluid path from the inner shaft 104 to the sealable hub 110. In the illustrated embodiment, the side port 950 includes a first groove 954 and a second groove 956 that each extend circumferentially about an outer surface of the side port 950. The sealable hub 110 includes a first projection 964 positioned in the first groove 954 and the housing 932 includes a second projection 966 positioned in the second groove 956. The engagement of the first and

second projections 964, 966 in the first and second grooves 954, 956 couples the housing 932 to the sealable hub 110. Moreover, the first and second projections 964, 966 are rotatable within the first and second grooves 954, 956 such that the sealable hub 110, the side port 114, and the housing 932 can each rotate independently of one another while remaining coupled together.

[0067] In some embodiments, the control assembly 930 can further include a connector 958 coupled to the proximal portion 109a of the inner shaft 104 and positioned at least partially between the side port 950 and the housing 932. The connector 958 can be rotatable within the housing 932 such that the housing 932 can rotate independently of the connector 958 and the inner shaft 104. Accordingly, in some aspects of the present technology rotation of the sealable hub 110, the side port 950 (e.g., the aspiration port 112 shown in Figures 9B and 9C), and/or the housing 932 will not substantially rotate the inner shaft 104. This can help inhibit the funnel attached to the inner shaft 104 from rotating within a vessel during a procedure using the funnel catheter assembly 900—while still allowing for movement of the sealable hub 110, the side port 950, and/or other components of the funnel catheter assembly 900.

[0068] Figures 10A–10C are side views of the funnel catheter assembly 900 in the sheathed position, a partially-unsheathed or intermediate position, and the unsheathed position, respectively, in accordance with embodiments of the present technology. Referring to Figures 10A–10C together, the funnel catheter assembly 900 can be moved between the sheathed and unsheathed positions by moving the actuation member 934 relative to the housing 932 and/or by moving the housing 932 (and the coupled sealable hub 110) relative to the actuation member 934. In some embodiments, for example, the operator can slide the actuation member 134 relative to the housing 932 in the direction indicated by the arrow P in Figure 10B to retract the outer shaft 102 to unsheathe the funnel 120. In some aspects of the present technology, moving the actuation member 934 rather than the housing 932 moves only the outer shaft 102 such that the funnel 120 remains in a constant or generally constant position (e.g., stationary position). In other embodiments, the operator can advance the housing 932 relative to the actuation member 934 in the direction indicated by the arrow D in Figure 10A to unsheathe the funnel 120. In some aspects of the present technology, moving the housing 932 relative to the actuation member 934 advances the inner shaft 104 and the funnel 120 distally relative to the outer shaft 102.

[0069] In the unsheathed position shown in Figure 10C, the actuation member 934 can be positioned adjacent or near the marking 931 to indicate to the operator that the funnel 120 is deployed. In some embodiments, to re-sheathe the funnel 120 (e.g., from the unsheathed position

shown in Figure 10C to the sheathed position shown in Figure 10A), the operator can retract the housing 932 relative to the actuation member 934 (e.g., in the direction of the arrow P) to pull the funnel 120 into the outer shaft 102. In some aspects of the present technology, such a retracting motion can be intuitive to the user as the motion of the housing 932 is in the same direction as the removal/collapse of the funnel 120. Nevertheless, in other embodiments the operator can advance the actuation member 934 relative to the housing 932 to sheathe the funnel 120 within the outer shaft 102.

[0070] Figure 11 is a flow diagram of a process or method 1110 for operating the funnel catheter assembly 100 and/or the funnel catheter assembly 900 (collectively referred to as "the funnel catheter assembly") during an intravascular procedure in accordance with embodiments of the present technology. Although some features of the method 1110 are described in the context of the embodiments shown in Figures 1–10C for the sake of illustration, one skilled in the art will readily understand that the method 1110 can be carried out using other suitable systems and/or devices described herein.

[0071] At block 1111, the method 1110 includes inserting the funnel catheter assembly into a patient's body via a vascular site. For example, the dilator 350, the outer shaft 102, and inner shaft 104 can be inserted together through a venous or arterial access site.

[0072] At block 1112, the method 1110 includes advancing the funnel catheter assembly to a deployment position within the vasculature of the patient. For example, the dilator 350, the outer shaft 102, and inner shaft 104 can be advanced together through the vasculature to the selected deployment position. The funnel catheter assembly can be advanced in the first position such that the funnel 120 is constrained/compressed within the outer shaft 102. The deployment position can be a portion of a blood vessel, a portion of the heart, or another suitable location.

[0073] At block 1113, the method 1110 includes expanding the funnel 120 at the deployment position. For example, the control assembly 130 of the funnel catheter assembly 100 can be moved from the first position to the second position to release/unsheathe the funnel 120 from within the outer shaft 102, thereby allowing the funnel 120 to expand at the deployment position. Likewise, the actuation member 934 can be slid relative to the housing 932 to unsheathe the funnel 120. After expansion, the funnel 120 can appose/contact the anatomy surrounding the deployment position, such as a wall of a blood vessel. In some embodiments, the dilator 350 can be removed from the funnel catheter assembly before expanding the funnel 120.

[0074] At block 1114, the method 1110 optionally includes compressing and repositioning the funnel 120. For example, the control assembly 130 can be moved from the second position to the first position to constrain/sheathe the funnel 120 within the outer shaft 102. Likewise, the housing 932 of the funnel catheter assembly 900 can be retracted proximally relative to the actuation member (and/or the actuation member 934 can be advanced distally relative to the housing) to sheathe the funnel 120. Then, the funnel catheter assembly can be repositioned to a different deployment position (block 1112) and expanded once again (block 1113). In some embodiments, the dilator 350 can be reinserted into the funnel catheter assembly 100 before repositioning the funnel catheter assembly 100.

[0075] At block 1115, the method 1110 includes maintaining the funnel 120 in the expanded position during an intravascular procedure. As described in detail above, the funnel 120 can capture thrombi that break free during the intravascular procedure to inhibit their embolization elsewhere in the vasculature of the patient.

[0076] At block 1116, the method 1110 includes compressing the funnel 120 and withdrawing the funnel catheter assembly 100 from the patient. For example, the control assembly 130 of the funnel catheter assembly 100 can be moved from the second position to the first position to constrain/sheathe the funnel 120 within the outer shaft 102, and the funnel catheter assembly 100 can then be withdrawn proximally to and from the vascular access site. Likewise, the housing 932 of the funnel catheter assembly 900 can be retracted proximally relative to the actuation member (and/or the actuation member 934 can be advanced distally relative to the housing) to sheathe the funnel 120.

III. Examples

[0077] Several aspects of the present technology are set forth in the following examples:

1. A funnel catheter assembly, comprising:

an outer shaft defining a lumen;

an inner shaft extending through the lumen and having a proximal portion and a distal portion;

an expandable funnel coupled to the distal portion of the inner shaft; and

a control assembly configured to move the funnel between a first position and a second position, wherein—

in the first position, the funnel is constrained within the lumen of the outer shaft, and

in the second position, the funnel is positioned at least partially outside the lumen of the outer shaft such that the funnel can expand.

2. The funnel catheter assembly of example 1 wherein the control assembly is coupled to the outer shaft and configured to move the outer shaft relative to the inner shaft.

3. The funnel catheter assembly of example 1 or example 2 wherein the control assembly includes an actuator movable to move the funnel between the first and second positions.

4. The funnel catheter assembly of example 3 wherein the actuator is a slider.

5. The funnel catheter assembly of any one of examples 2–4 wherein the funnel includes a proximal portion and a distal portion, and wherein the proximal portion of the funnel is coupled to the distal portion of the inner shaft.

6. The funnel catheter of example 5 wherein the distal portion of the funnel is coupled to the outer shaft.

7. The funnel catheter assembly of any one of examples 1–6, further comprising a sealable hub and a side port, wherein the side port is rotatably coupled between the control assembly and the sealable hub.

8. A funnel catheter assembly, comprising:

an outer shaft defining an outer lumen;

an inner shaft extending through the outer lumen and having a proximal portion and a distal portion;

an expandable funnel coupled to the distal portion of the inner shaft; and

a control assembly operably coupled to the proximal portion of the outer shaft and configured to move the outer shaft between a first position and a second position, wherein—

in the first position, the outer shaft is positioned at least partially over the funnel to radially constrain the funnel, and

in the second position, the outer shaft is retracted proximally relative to the funnel such that the funnel can radially expand.

9. The funnel catheter assembly of example 8 wherein the control assembly includes a housing and an actuation member, wherein the actuation member is coupled to a proximal portion of the outer shaft, and wherein the actuation member is slidable along the housing to move the outer shaft between the first and second positions.

10. The funnel catheter assembly of example 8 or example 9 wherein the funnel is configured to self-expand.

11. The funnel catheter assembly of example 8 or example 9 wherein the funnel is non-self-expanding, wherein the funnel is further coupled to a distal portion of the outer shaft, and wherein movement of the outer shaft from the first position to the second position is configured to expand the funnel.

12. The funnel catheter assembly of example 11 wherein a distal portion of the funnel is coupled to the distal portion of the outer shaft via one or more tethers.

13. The funnel catheter assembly of any one of examples 8–12 wherein the inner shaft defines an inner lumen sized to receive a dilator.

14. A method of operating a funnel catheter assembly during an intravascular procedure on a patient, the method comprising:

at least partially inserting an inner shaft, an outer shaft, and a funnel of the funnel catheter assembly into the vasculature of the patient;

advancing the inner shaft, the outer shaft, and the funnel together to a deployment position within the vasculature of the patient, wherein the funnel is sheathed within a lumen of the outer shaft during the advancement;

moving the outer shaft relative to the inner shaft to unsheathe the funnel and permit the funnel to expand to an expanded position;

maintaining the funnel in the expanded position during at least a portion of the intravascular procedure;

moving the outer shaft relative to the inner shaft and/or moving the inner shaft relative to the outer shaft to sheath the funnel within the lumen of the outer shaft; and

withdrawing the funnel catheter assembly from the patient.

15. The method of example 14 wherein the funnel is self-expandable, and wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes permitting the funnel to self-expand to the expanded position.

16. The method of example 14 or example 15 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes moving a slider of a control assembly of the funnel catheter assembly from a first position to a second position, and wherein the slider is coupled to a proximal portion of the outer shaft.

17. The method of any one of examples 14–16 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes rotating a rotatable element of a control assembly of the funnel catheter assembly from a first position to a second position.

18. The method of any one of examples 14, 16, and 17 wherein the funnel is non-self-expanding, and wherein the method further comprises actuating the funnel to expand to the expanded position.

19. The method of any one of examples 14–18 wherein—

inserting the inner shaft, the outer shaft, and the funnel into the vasculature of the patient further includes at least partially inserting a dilator positioned within the inner shaft into the vasculature of the patient; and

advancing the inner shaft, the outer shaft, and the funnel further includes advancing the inner shaft, the outer shaft, the funnel, and the dilator together to the deployment position.

20. The method of any one of examples 14–19 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes moving the outer shaft in a first

direction, and wherein the method further comprises moving the outer shaft relative to the inner shaft to sheath the funnel by moving the outer shaft in a second direction opposite to the first direction.

IV. Conclusion

[0078] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0079] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0080] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A funnel catheter assembly, comprising:

an outer shaft defining a lumen;

an inner shaft extending through the lumen and having a proximal portion and a distal portion;

an expandable funnel coupled to the distal portion of the inner shaft; and

a control assembly configured to move the funnel between a first position and a second position, wherein—

in the first position, the funnel is constrained within the lumen of the outer shaft, and

in the second position, the funnel is positioned at least partially outside the lumen of the outer shaft such that the funnel can expand.

2. The funnel catheter assembly of claim 1 wherein the control assembly is coupled to the outer shaft and configured to move the outer shaft relative to the inner shaft.

3. The funnel catheter assembly of claim 1 wherein the control assembly includes an actuator movable to move the funnel between the first and second positions.

4. The funnel catheter assembly of claim 3 wherein the actuator is a slider.

5. The funnel catheter assembly of claim 1 wherein the funnel includes a proximal portion and a distal portion, and wherein the proximal portion of the funnel is coupled to the distal portion of the inner shaft.

6. The funnel catheter of claim 5 wherein the distal portion of the funnel is coupled to the outer shaft.

7. The funnel catheter assembly of claim 1, further comprising a sealable hub and a side port, wherein the side port is rotatably coupled between the control assembly and the sealable hub.

8. A funnel catheter assembly, comprising:

an outer shaft defining an outer lumen;

an inner shaft extending through the outer lumen and having a proximal portion and a distal portion;

an expandable funnel coupled to the distal portion of the inner shaft; and

a control assembly operably coupled to the proximal portion of the outer shaft and configured to move the outer shaft between a first position and a second position, wherein—

in the first position, the outer shaft is positioned at least partially over the funnel to radially constrain the funnel, and

in the second position, the outer shaft is retracted proximally relative to the funnel such that the funnel can radially expand.

9. The funnel catheter assembly of claim 8 wherein the control assembly includes a housing and an actuation member, wherein the actuation member is coupled to a proximal portion of the outer shaft, and wherein the actuation member is slidable along the housing to move the outer shaft between the first and second positions.

10. The funnel catheter assembly of claim 8 wherein the funnel is configured to self-expand.

11. The funnel catheter assembly of claim 8 wherein the funnel is non-self-expanding, wherein the funnel is further coupled to a distal portion of the outer shaft, and wherein movement of the outer shaft from the first position to the second position is configured to expand the funnel.

12. The funnel catheter assembly of claim 11 wherein a distal portion of the funnel is coupled to the distal portion of the outer shaft via one or more tethers.

13. The funnel catheter assembly of claim 8 wherein the inner shaft defines an inner lumen sized to receive a dilator.

14. A method of operating a funnel catheter assembly during an intravascular procedure on a patient, the method comprising:

at least partially inserting an inner shaft, an outer shaft, and a funnel of the funnel catheter assembly into the vasculature of the patient;

advancing the inner shaft, the outer shaft, and the funnel together to a deployment position within the vasculature of the patient, wherein the funnel is sheathed within a lumen of the outer shaft during the advancement;

moving the outer shaft relative to the inner shaft to unsheathe the funnel and permit the funnel to expand to an expanded position;

maintaining the funnel in the expanded position during at least a portion of the intravascular procedure;

moving the outer shaft relative to the inner shaft and/or moving the inner shaft relative to the outer shaft to sheath the funnel within the lumen of the outer shaft; and

withdrawing the funnel catheter assembly from the patient.

15. The method of claim 14 wherein the funnel is self-expandable, and wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes permitting the funnel to self-expand to the expanded position.

16. The method of claim 14 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes moving a slider of a control assembly of the funnel catheter assembly from a first position to a second position, and wherein the slider is coupled to a proximal portion of the outer shaft.

17. The method of claim 14 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes rotating a rotatable element of a control assembly of the funnel catheter assembly from a first position to a second position.

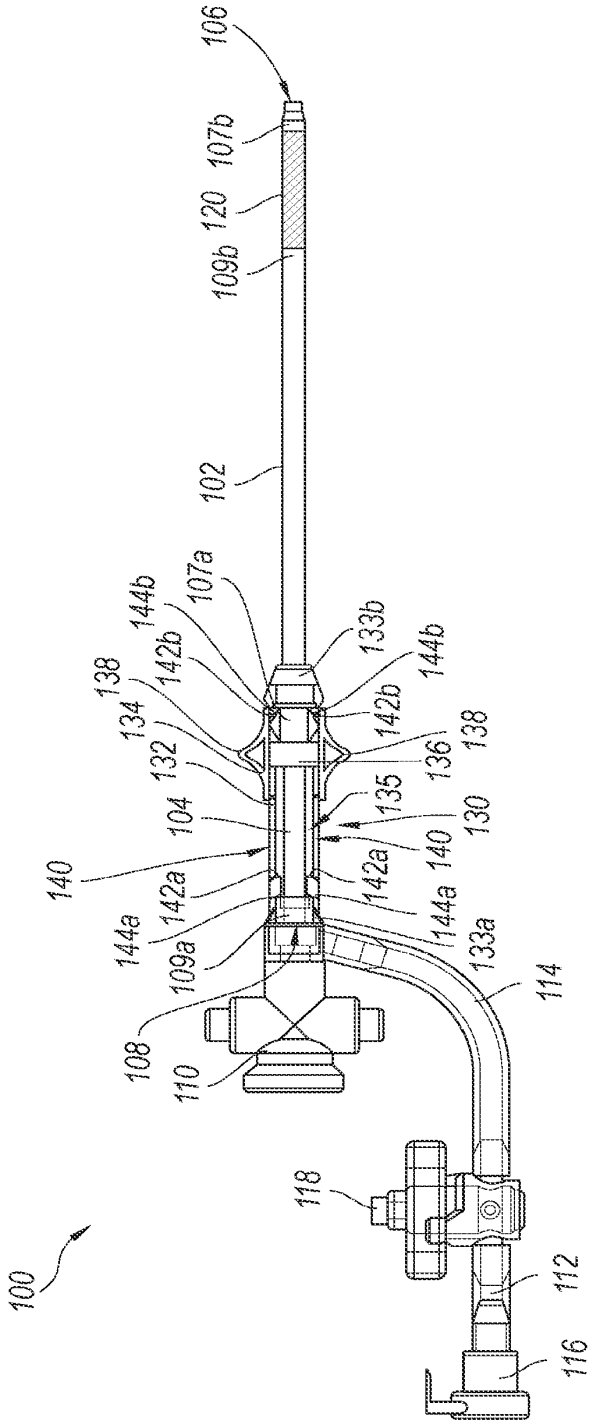
18. The method of claim 14 wherein the funnel is non-self-expanding, and wherein the method further comprises actuating the funnel to expand to the expanded position.

19. The method of claim 14 wherein—

inserting the inner shaft, the outer shaft, and the funnel into the vasculature of the patient further includes at least partially inserting a dilator positioned within the inner shaft into the vasculature of the patient; and

advancing the inner shaft, the outer shaft, and the funnel further includes advancing the inner shaft, the outer shaft, the funnel, and the dilator together to the deployment position.

20. The method of claim 14 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes moving the outer shaft in a first direction, and wherein the method further comprises moving the outer shaft relative to the inner shaft to sheath the funnel by moving the outer shaft in a second direction opposite to the first direction.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109b
102
107a
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142b
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133b
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136
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142a
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133a
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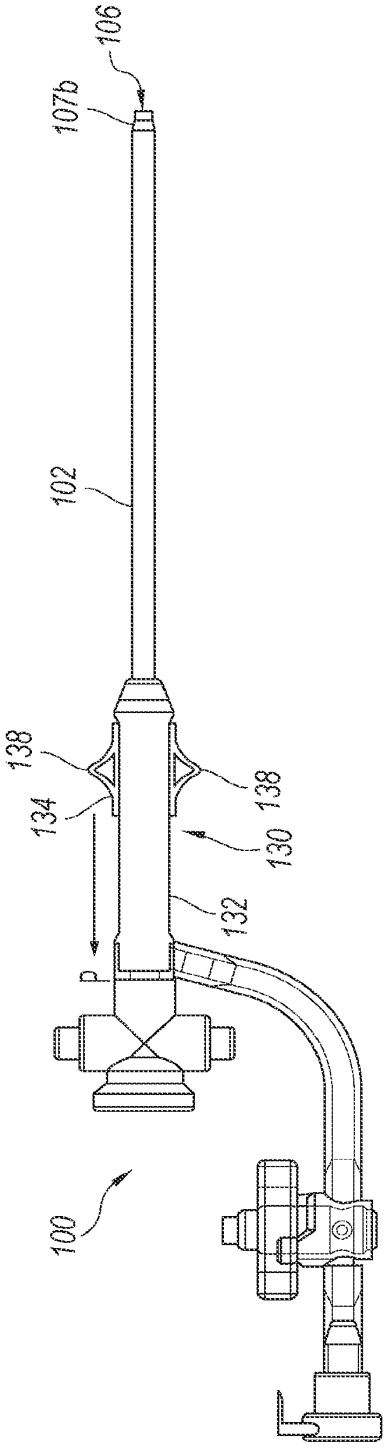
118
112
116
100

Fig. 1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107b
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138
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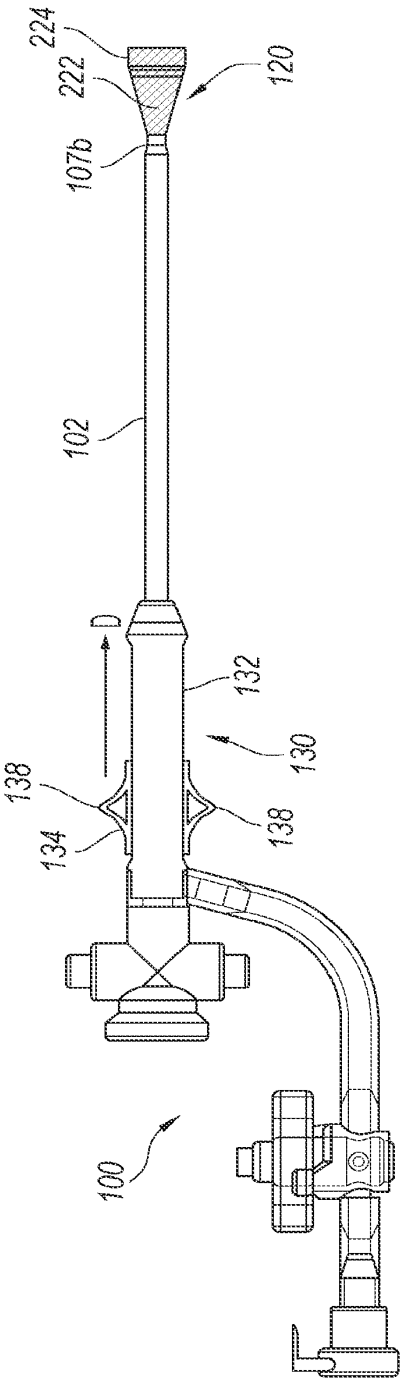
130
138
132
P
100

Fig. 2A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222
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107b
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D
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130
138
134
138
100

Fig. 2B

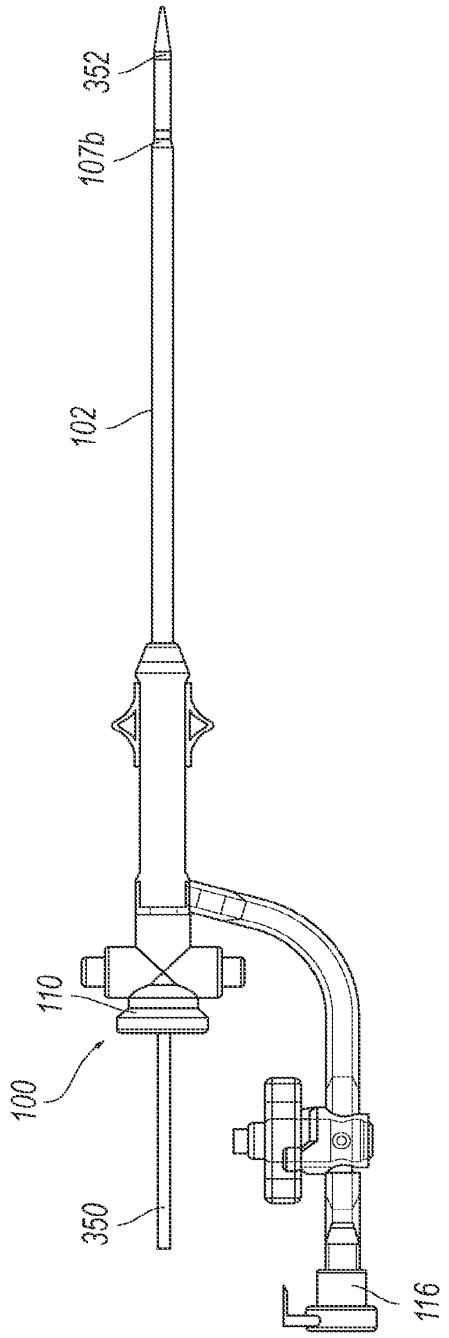


Fig. 3

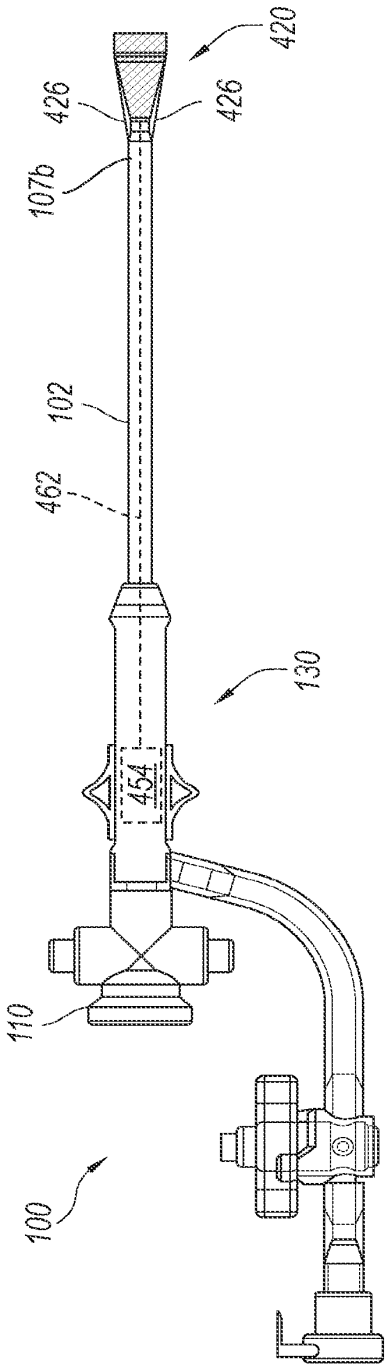


Fig. 4

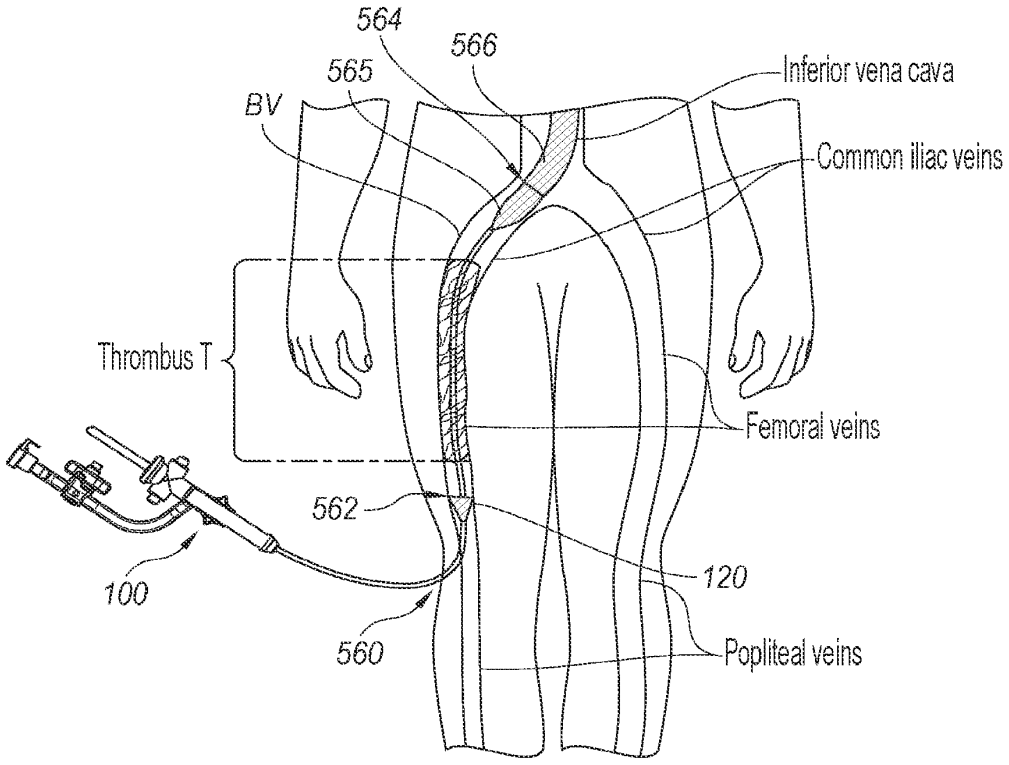

564
566
565
BV
Inferior vena cava
Common iliac veins
Thrombus T
Femoral veins
562
120
100
560
Popliteal veins

Fig. 5

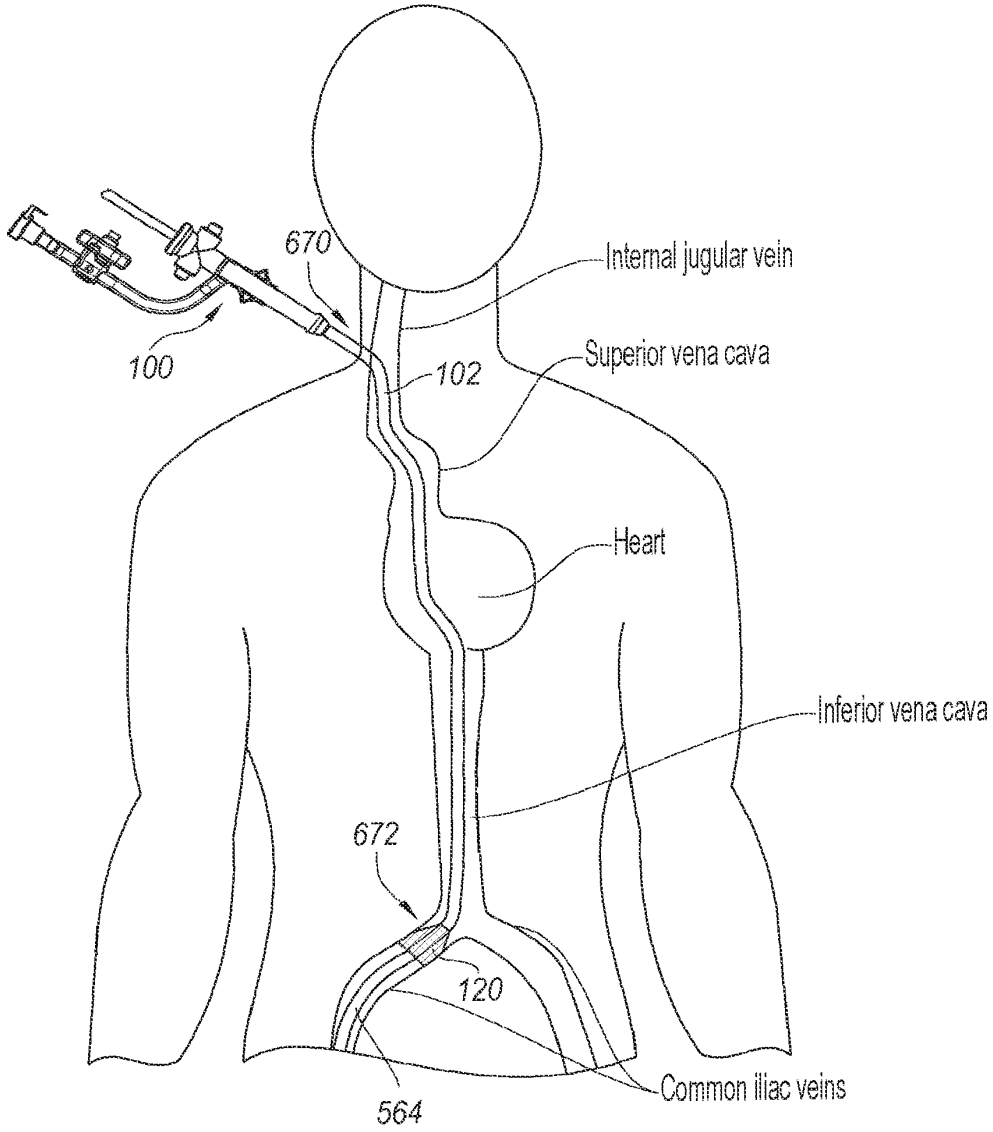
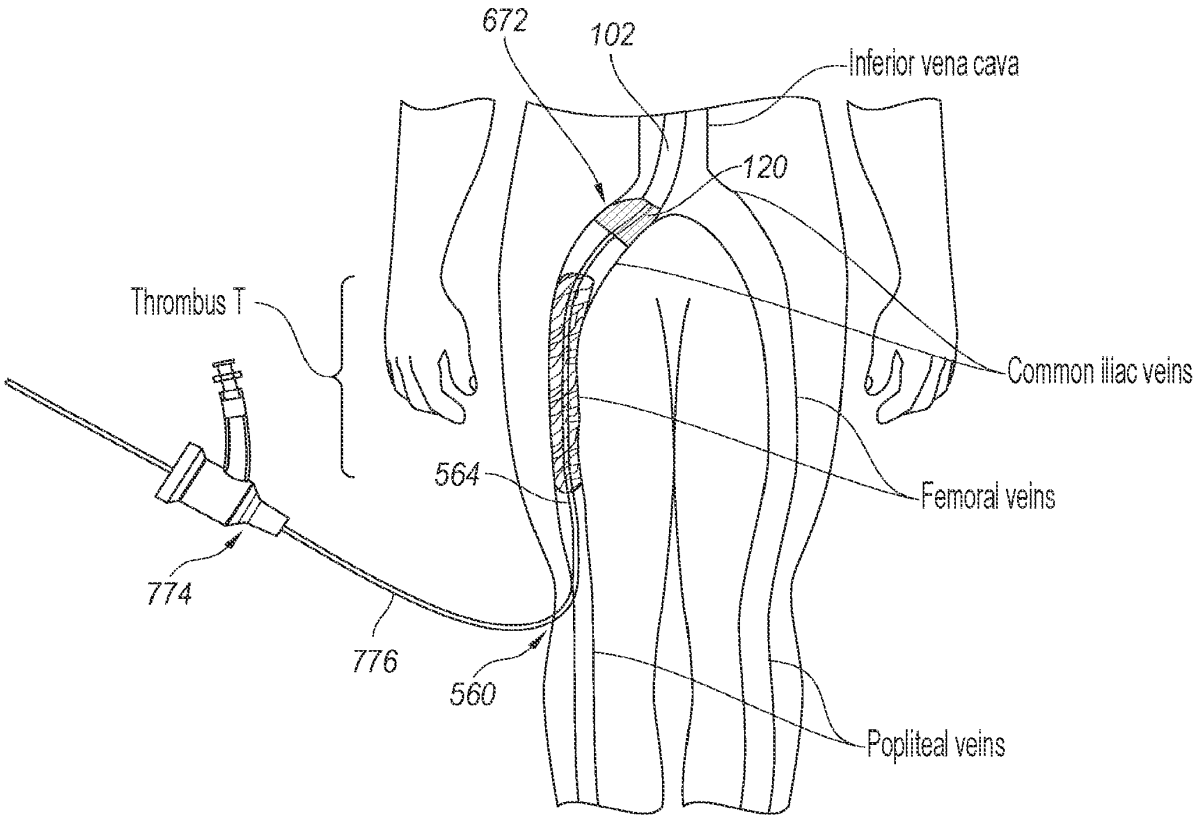

670
Internal jugular vein
100
102
Superior vena cava
Heart
Inferior vena cava
672
120
564
Common iliac veins

Fig. 6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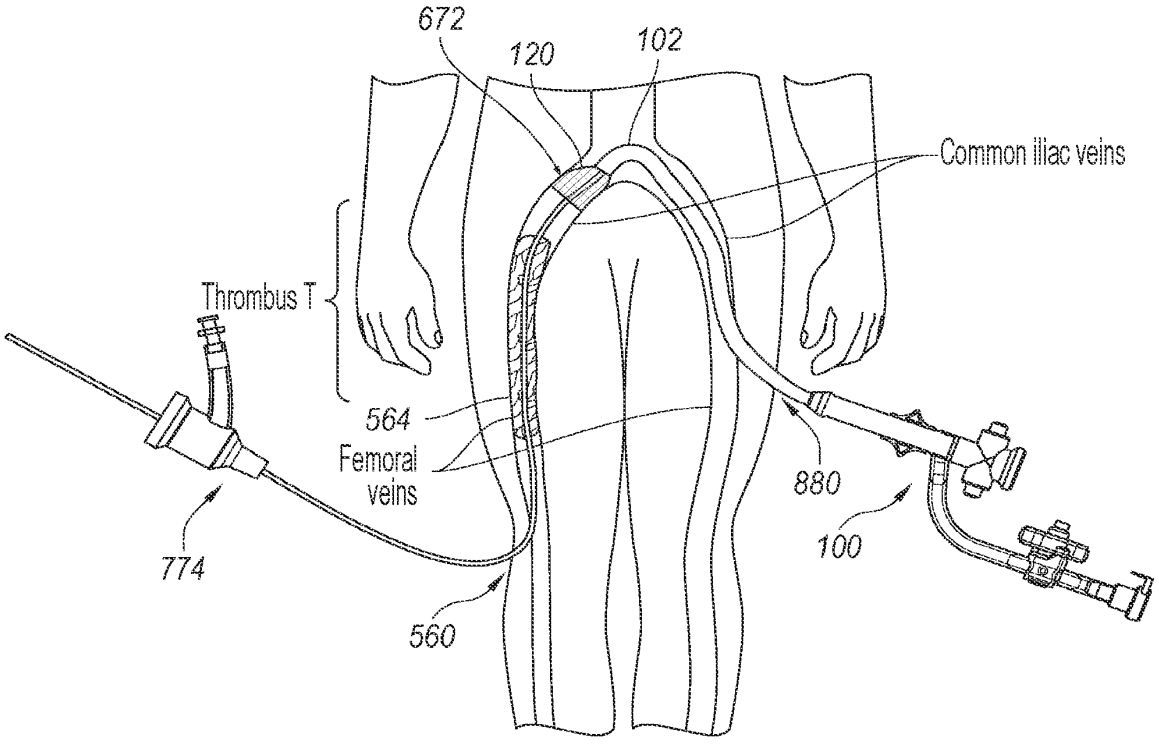
Inferior vena cava
120
Thrombus T
Common iliac veins
564
Femoral veins
774
776
560
Popliteal veins

Fig. 7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Common iliac veins
Thrombus T
564
Femoral veins
880
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774
560

Fig. 8

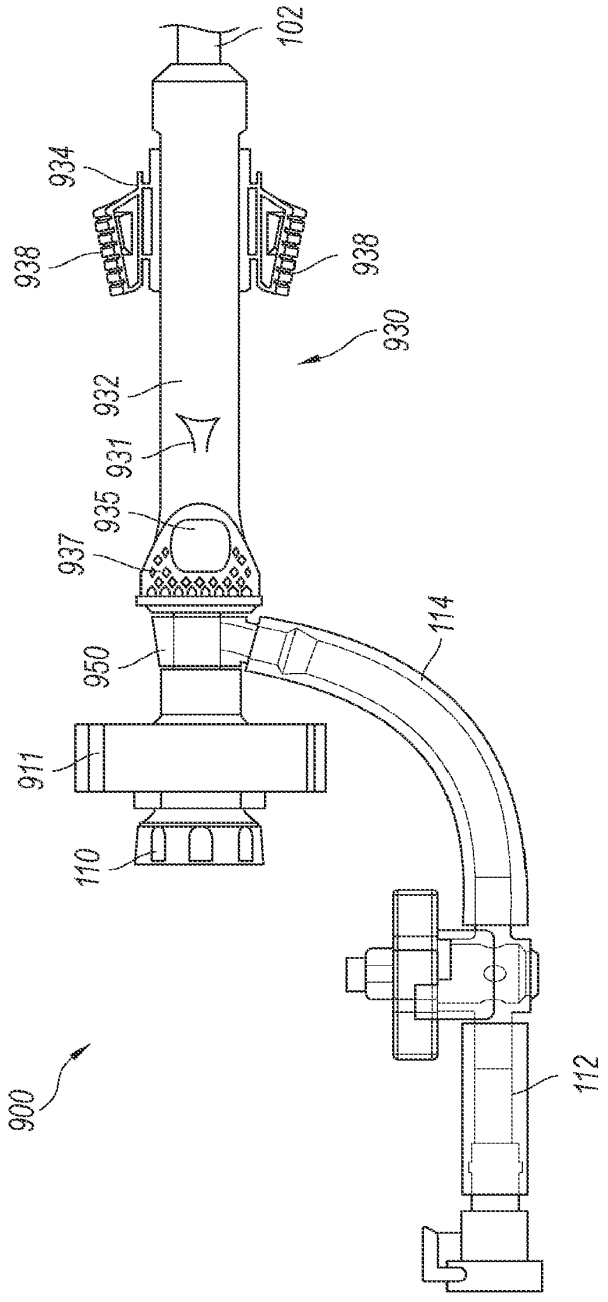

Fig. 9A

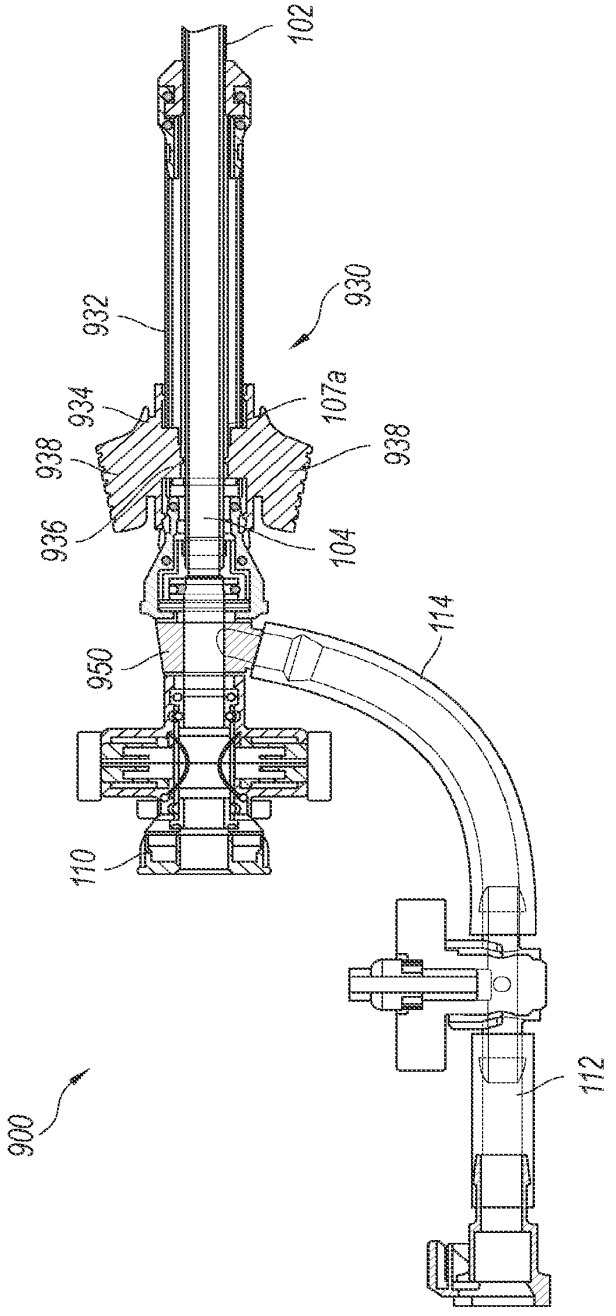

Fig. 9B

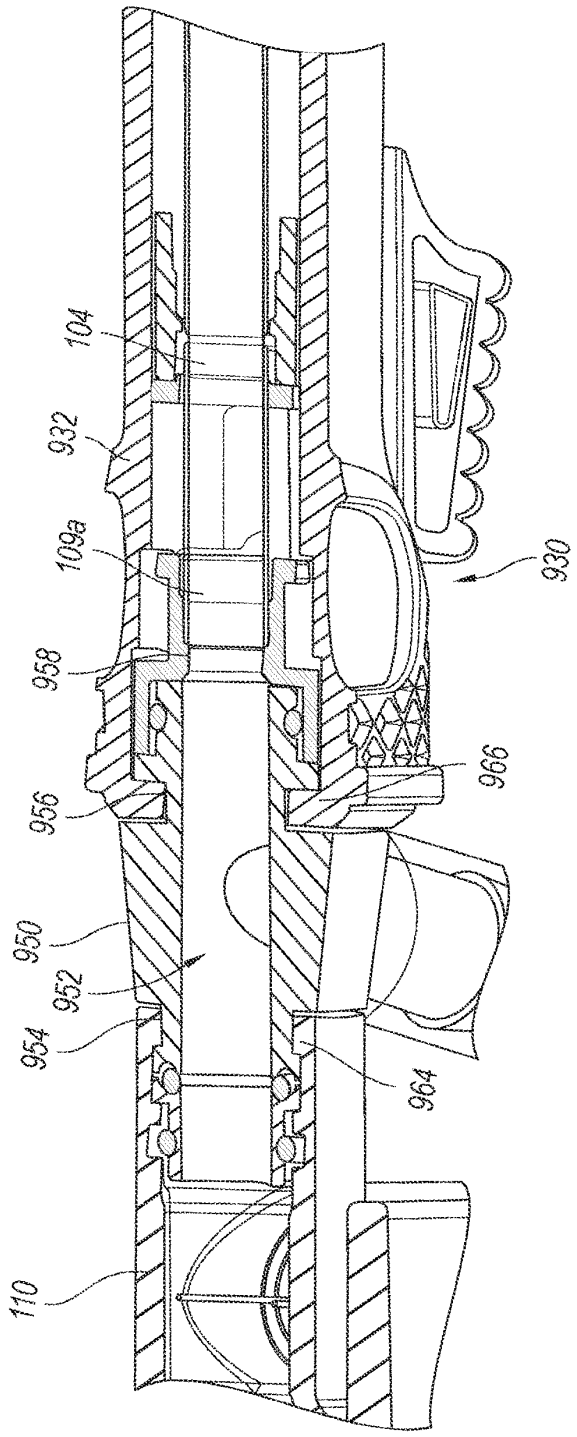

Fig. 9C

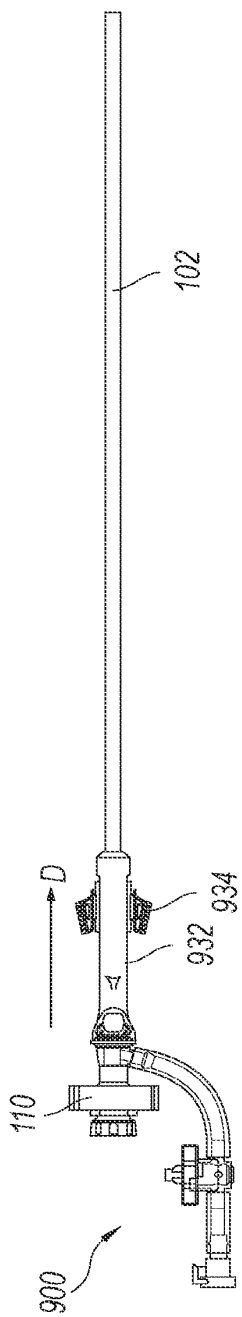

Fig. 10A

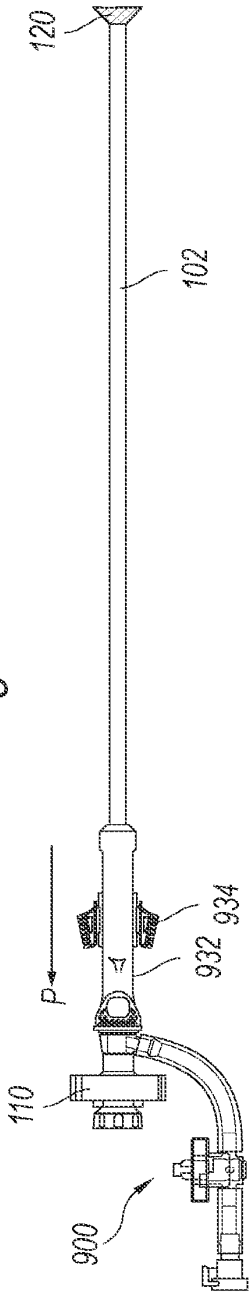

Fig. 10B

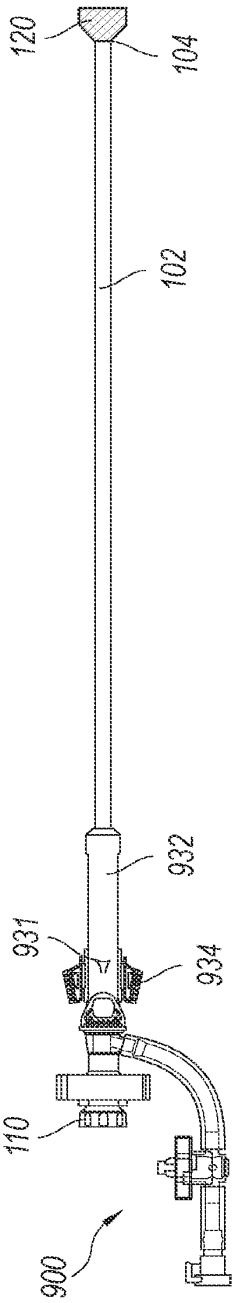

Fig. 10C

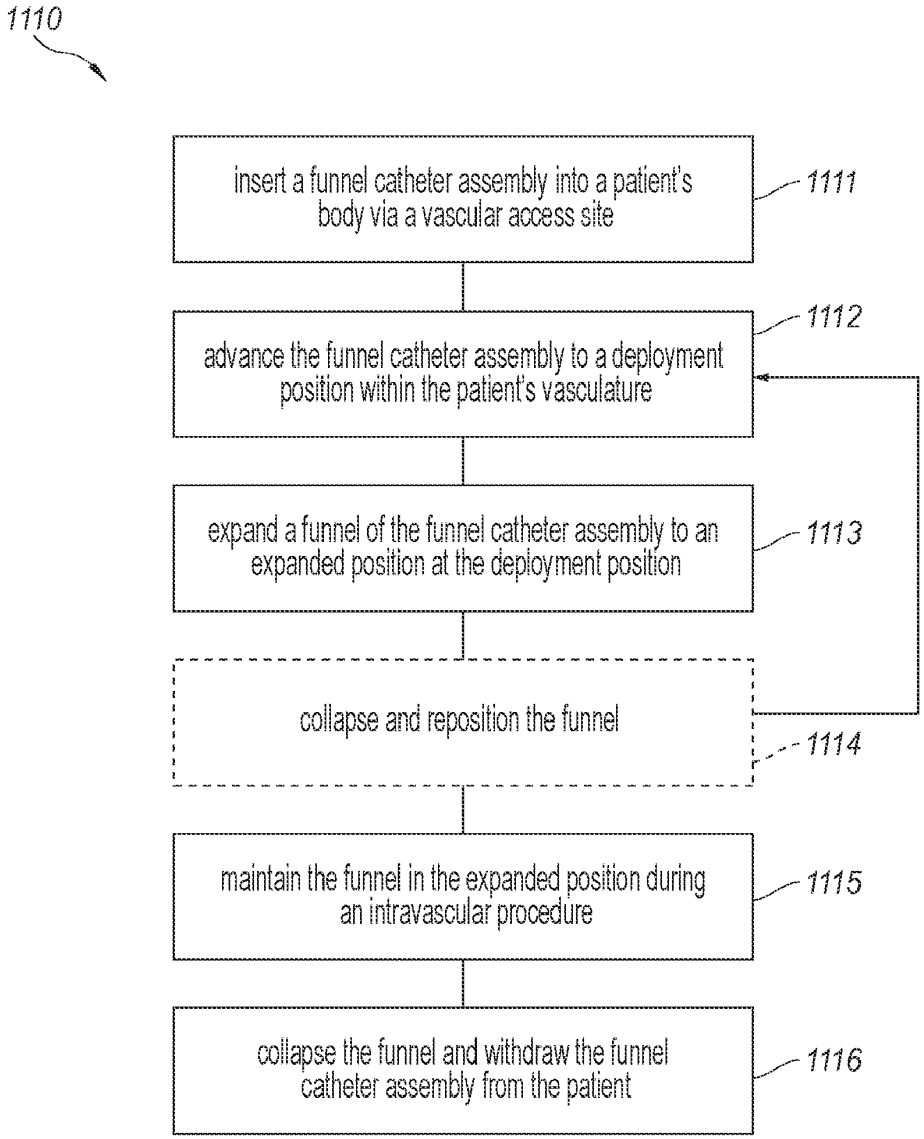
1110
insert a funnel catheter assembly into a patient's body via a vascular access site
1111
advance the funnel catheter assembly to a deployment position within the patient's vasculature
1112
expand a funnel of the funnel catheter assembly to an expanded position at the deployment position
1113
collapse and reposition the funnel
1114
maintain the funnel in the expanded position during an intravascular procedure
1115
collapse the funnel and withdraw the funnel catheter assembly from the patient
1116

Fig. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/35965

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 17/00, A61B 17/22, A61B 17/3207, A61M 25/10, A61M 1/00 (2021.01)

CPC - A61M 2025/1045, A61B 17/22, A61B 17/221, A61B 2217/005, A61M 2025/109

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 5,011,488 A (Ginsburg) 30 April 1991 (30.04.1991), entire document	1-10, 13-17, 19-20 ---------- 18
X	US 5,800,457 (Gelbfish) 1 Septemebr 1998 (01.09.1998), entire document	8, 11-12
Y	WO 2009/082513 A1 (Tex Medical) 2 July 2009 (02.07.2009), entire document	18
A	US 2002/0161392 A1 (Dubrul) 31 October 2002 (31.10.2002), entire document	1-20
A	WO 2018/148174 A1 (KP Medcure, Inc) 16 August 2018 (16.08.2018), entire document	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 August 2021	SEP 28 2021
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

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

Patent Translate
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Notice

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DESCRIPTION CN110852845A

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 neurovasculature, as well as excellent external and internal smoothness for implant delivery.

[0003]

Background technique

[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 (transmission 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 inevitably 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 goals, 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 blood.

[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 kinkability, 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 inside 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 0.6 mm.

[0015]

In another preferred embodiment, the maximum thickness of the flat wire of the first intermediate layer is 0.10 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 0.025 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 weaving 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 by placing guide wires or more 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 enclosed 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-Multi-wire coil.

[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.

[0056]

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.

[0058]

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 suction flow.

[0073]

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

[0074]

(c) It has extremely high body 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]

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

[0078]

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

[0079]

The following description and figures list some specific details to provide an understanding to 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 relative 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 here 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 to 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]

Examples

[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 torque, 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 first 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 adheres 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) usually 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 fluoroscopy.

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 1.2-2.3mm.

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 1.76-1.88mm, an inner diameter of 1.78-1.83mm, and a wall thickness of 0.013-0.032mm. The ratio of diameter to inner diameter is 1.014-0.015.

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 linear 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 0.10-0.22mm, 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 it has a smaller width and achieves a gradual change at the transition.

[0103]

Those skilled in the art should understand that 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 minimal 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 lumen shape.

[0105]

Figure 3A 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 (130, 140), 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 0.07-0.5 mm.

In other embodiments, the width of the wire wound for the multi-wire coil is 0.04-0.11 mm, and the thickness is 0.02-0.06 mm.

[0105]

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 wires (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 catheter'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 0.025-0.065 mm, and the thickness of each braided wire used is 0.013-0.0533 mm.

According to an embodiment of the present invention, the length of the second intermediate layer (40) is 1150-1600 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 3 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 30-930 mm, an outer diameter of 2.5-3.5 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 4, 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. 4, the distal portion of the outer layer (50) is made of an ultra-low hardness material, such as TPU with a hardness of about 90A (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 20D-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 10-20mm, and the length of the proximal section of the outer layer (50) is 1000-1200mm.

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 (Cr), magnesium (Mg), iron (Fe), iron (Fe), cobalt (Co), copper (Cu), nickel (Ni), praseodymium (Pr), rhodium (Rh), samarium (Sm), ytterbium (Yb), gadolinium (Gd), terbium (Tb), dysprosium (Dy), holmium (Ho), erbium (Er) or other MRI visible materials known to those skilled in the art.

[0115]

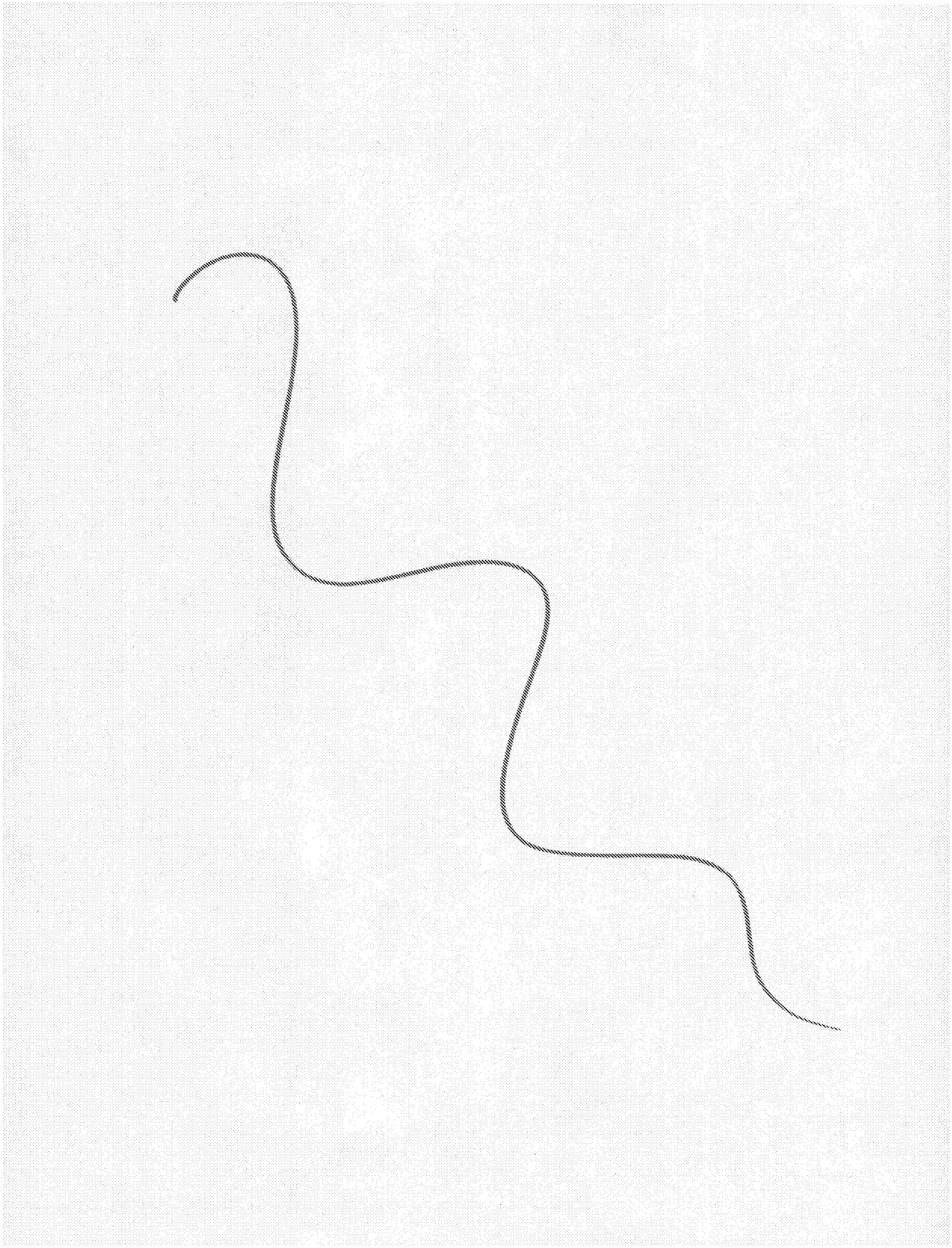
Those skilled in the art should understand that even though most of the exemplary embodiments of the catheter body (10) described above are suitable for intracranial vascular applications, the exemplary embodiments of the present invention can also be used for any other suitable minimally invasive interventional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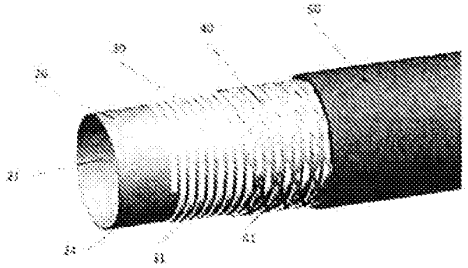
(54)发明名称

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。

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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、甚至固化层中的洞，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。

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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。

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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。

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[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近端部分、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远端部分。

[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，它可以直接位于或高于另一个元素，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

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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

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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1B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

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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、铂、铱、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)、镨(III)、铷(III),钐(III)、镱(III)、钆(III)、铽(III)、镝(III)、钬(III)、铒(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。

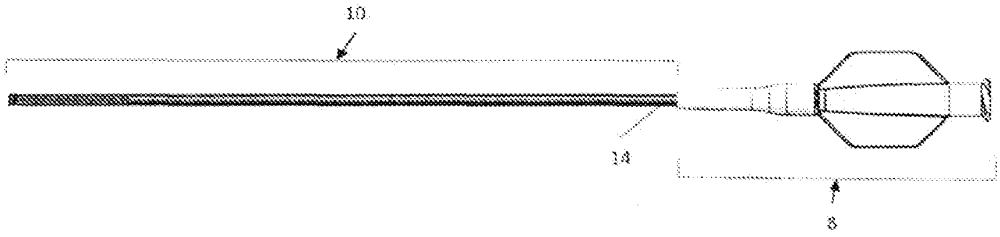

图1A

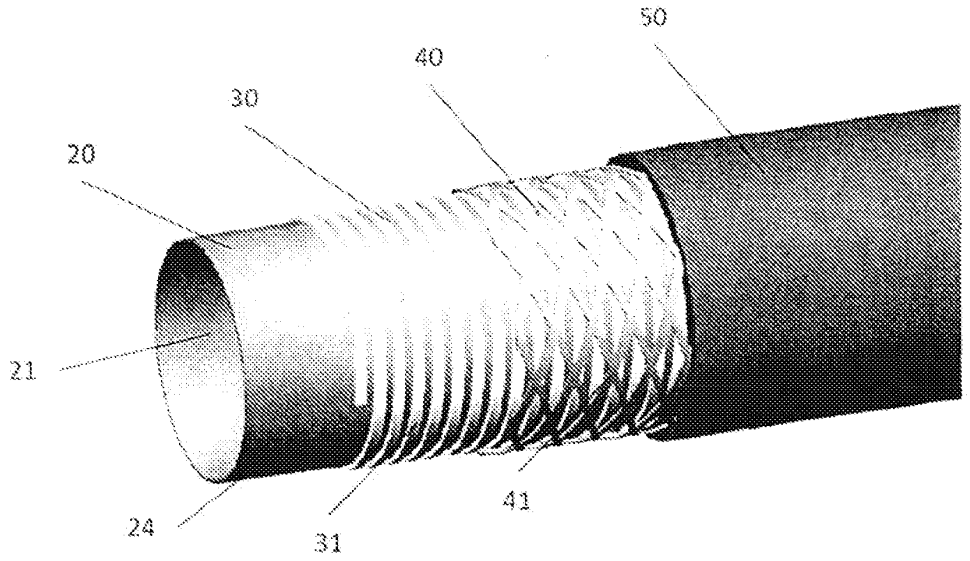

图1B

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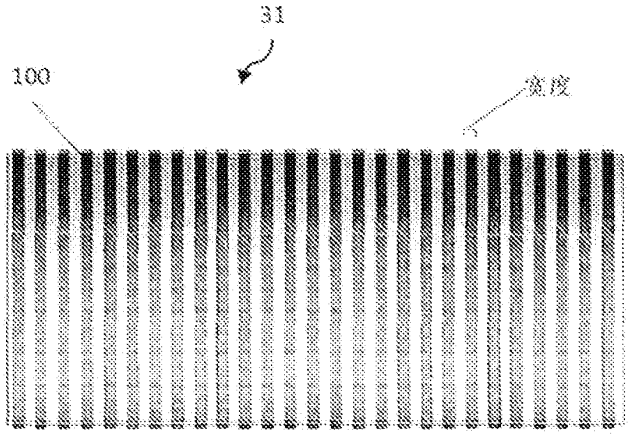

图2A

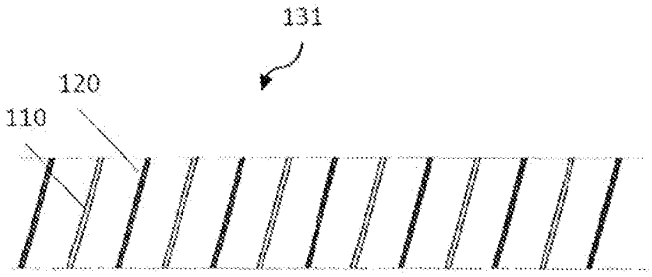

图2B

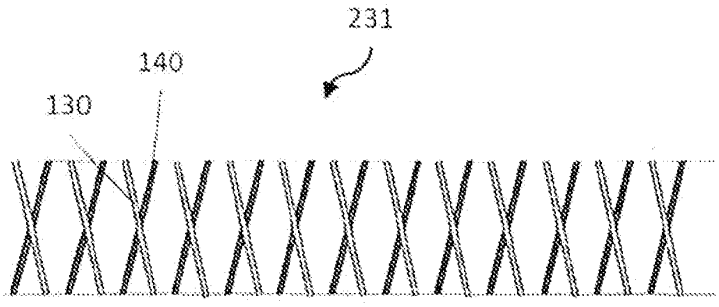

图2C

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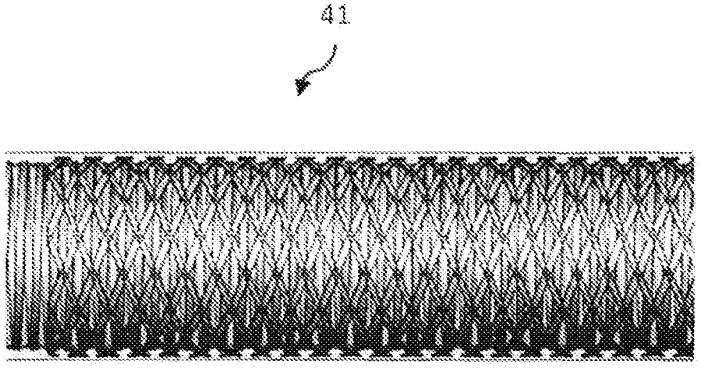

图3

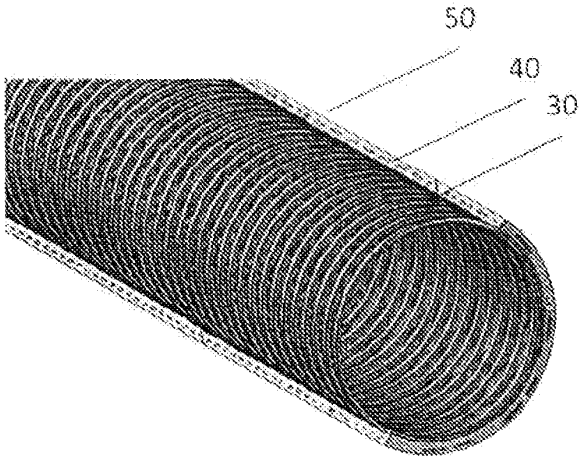

图4

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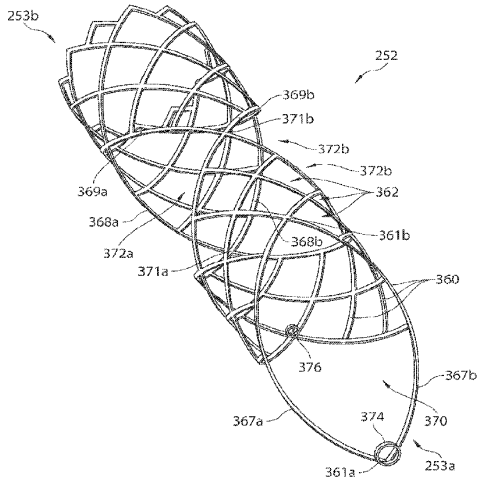

FIG. 3A

(57) Abstract: Systems and methods for the intravascular treatment of clot material within a blood vessel of a human patient are disclosed herein. In one embodiment, a system includes a coring element for coring and separating the clot material. The coring element can comprise a unitary structure having a first region, a second region, a third region, and a fourth region. The first region is adjacent to a proximal portion of the unitary structure and includes a first mouth configured to core and separate the clot material. The second region is distal of the first region, generally tubular, and includes a first plurality of interconnected struts. The third region is distal of the second region and includes a second mouth configured to core and separate the vascular thrombus. The fourth region is distal of the third region, generally tubular, and includes a second plurality of interconnected struts.

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DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 62/949,967, filed December 18, 2019, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to systems, methods, and devices for extracting thrombi from blood vessels of human patients. In particular, some embodiments of the present technology relate to systems for thrombus extraction from the peripheral vasculature of a human patient.

BACKGROUND

[0003] Thrombosis is the local coagulation or clotting of the blood in a part of the circulatory system, and a thrombus is a blood clot formed in situ within the vascular system. A venous thrombus is a blood clot that forms within a vein. A common type of venous thrombosis is a deep vein thrombosis (DVT), which is the formation of a blood clot within a deep vein (e.g., predominantly in the legs). Nonspecific signs of a thrombosis may include pain, swelling, redness, warmness, and engorged superficial veins.

[0004] If the thrombus breaks off (embolizes) and flows towards the lungs, it can become a life-threatening pulmonary embolism (PE) (e.g., a blood clot in the lungs). In addition to the loss of life that can arise from PE, DVT can cause significant health issues such as post thrombotic syndrome, which can cause chronic swelling, pressure, pain, and ulcers due to valve and vessel damage. Further, DVT can result in significant health-care costs either directly or indirectly through the treatment of related complications and inability of patients to work.

[0005] Three processes are believed to result in venous thrombosis. First is a decreased blood flow rate (venous stasis), second is an increased tendency to clot (hypercoagulability), and the third is changes to the blood vessel wall. DVT formation typically begins inside the valves of the calf veins where the blood is relatively oxygen deprived, which activates certain biochemical pathways. Several medical conditions increase the risk for DVT, including diabetes, cancer,

trauma, and antiphospholipid syndrome. Other risk factors include older age, surgery, immobilization (as with bed rest, orthopedic casts, and sitting on long flights), combined oral contraceptives, pregnancy, the postnatal period, and genetic factors. The rate of DVT increases dramatically from childhood to old age and, in adulthood, about 1 in 1,000 adults develop DVT annually.

[0006] Although current devices and methods of prevention and/or treatment of DVT exist, there are a number of shortcomings that have yet to be resolved, such as high incidence of DVT re-occurrence, use of devices not designed to remove large clot volumes, and/or complicated treatments involving multiple treatment devices and/or pharmaceuticals. Accordingly, new devices, systems, and methods of treating thrombus, and particularly DVT are desired.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0008] Figure 1 is a side view of a thrombectomy system configured in accordance with an embodiment of the present technology.

[0009] Figures 2A and 2B are side views of a thrombus extraction assembly of the thrombectomy system including a thrombus extraction device in a partially-expanded configuration and a fully-expanded configuration, respectively, configured in accordance with embodiments of the present technology.

[0010] Figures 3A–3D are an isometric view, a side view, a top view, and a rear view, respectively, of a coring element of the thrombus extraction device configured in accordance with embodiments of the present technology.

[0011] Figure 4 is an enlarged side view of the thrombus extraction device coupled to a distal portion of the thrombus extraction assembly and in the fully-expanded configuration in accordance with an embodiment of the present technology.

[0012] Figures 5A and 5B are side views of a dilator assembly of the thrombectomy system in a first configuration and a second configuration, respectively, configured in accordance with embodiments of the present technology.

[0013] Figure 6 is an enlarged cross-sectional side view of a portion of the thrombectomy system including a self-expanding funnel configured in accordance with an embodiment of the present technology.

[0014] Figures 7A–7D are side views of the dilator assembly positioned within an introducer assembly of the thrombectomy system and illustrating various stages in a process or method for deploying the self-expanding funnel in accordance with embodiments of the present technology.

[0015] Figures 8A, 8C, and 8D are cross-sectional side views, and Figure 8B is an enlarged cross-sectional isometric view, of a control assembly of the dilator assembly configured in accordance with embodiments of the present technology.

[0016] Figures 9A–9C, are cross-sectional side views of a control assembly configured in accordance with another embodiment of the present technology.

[0017] Figures 10A and 10B are partially cross-sectional side views of a control assembly configured in accordance with another embodiment of the present technology.

[0018] Figure 11 is a schematic view of an introduction technique for accessing a thrombus for treatment with the thrombectomy system in accordance with an embodiment of the present technology.

[0019] Figures 12A–12C are side views, and Figures 12D–12K are enlarged side views, of the thrombectomy system positioned within a blood vessel during a thrombectomy procedure in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0020] The present technology is generally directed to methods and systems for removing clot material (e.g., a thrombus) from a blood vessel of a human patient. In some embodiments, a system for removing clot material (e.g., a thrombectomy system) includes a thrombus extraction device including (i) a coring element configured to core and separate the clot material from the vessel wall and (ii) a capture element configured to capture the cored and separated clot material. In some embodiments, the coring element comprises a unitary structure having a first region adjacent to a proximal portion of the unitary structure, a second region distal of the first region, a third region distal of the second region, and a fourth region distal of the third region. The first region can include a first mouth configured to core and separate the clot material and the third region can include a second mouth configured to core and separate the clot material. The second

and fourth regions can each be generally tubular and can include a plurality of interconnected struts. In one aspect of the present technology, the first and second mouths are radially offset such that at least one of the first and second mouths is positioned and oriented to effectively core and separate the clot material from within the blood vessel during a thrombus extraction procedure using the thrombus extraction device.

[0021] In some embodiments, the thrombectomy system includes a dilator assembly for deploying an expandable funnel coupled to a distal portion of an introducer sheath. The dilator assembly can include a first shaft defining a lumen, a second shaft slidably positioned within the lumen of the first shaft, and a retention sheath coupled to the second shaft and configured to receive and constrain the funnel therein. A control assembly including an actuator is operably coupled to the first and second shafts. Movement of the actuator to a first position is configured to distally advance the first and second shafts together to deploy the funnel from the retention sheath. Movement of the actuator to a second position is configured to distally advance the first shaft relative to the second shaft such that first shaft and the retention sheath define a generally uniform (e.g., constant diameter) outer surface. In one aspect of the present technology, the generally uniform outer surface of the dilator assembly is unlikely to snag or otherwise damage the funnel or vessel as the dilator assembly is retracted through the introducer sheath. In another aspect of the present technology, the dilator assembly can be coupled to the introducer sheath to inhibit or even prevent unintentional, premature deployment of the funnel.

[0022] Although many of the embodiments are described below with respect to devices, systems, and methods for treating vascular thrombi (e.g., deep vein thrombosis (DVT)), other applications and other embodiments in addition to those described herein are within the scope of the technology (e.g., intravascular procedures other than the treatment of emboli, intravascular procedures for treating cerebral embolism, intravascular procedures for treating pulmonary embolism). In general, for example, the devices, systems, and methods of the present technology can be used to extract any formation of material in a vessel (e.g., a venous or arterial vessel), such as cancerous growths, vegetation, and the like. Additionally, several other embodiments of the technology can have different configurations, states, components, or procedures than those described herein. Moreover, it will be appreciated that specific elements, substructures, advantages, uses, and/or other features of the embodiments described with reference to Figures 1–12K can be suitably interchanged, substituted or otherwise configured with one another in accordance with additional embodiments of the present technology. Furthermore, suitable elements of the embodiments described with reference to Figures 1–12K can be used as standalone

and/or self-contained devices. A person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described below with reference to Figures 1–12K.

[0023] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to use in a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

[0024] The headings provided herein are for convenience only and should not be construed as limiting the subject matter disclosed.

I. Selected Embodiments of Thrombectomy Systems

[0025] Figure 1 is a side view of a thrombectomy system 100 (which can also be referred to as a thrombus extraction system, clot removal system) configured in accordance with an embodiment of the present technology. In the illustrated embodiment, the thrombectomy system 100 includes an introducer assembly 102, an obturator or dilator assembly 104 (shown positioned within the introducer assembly 102), and a thrombus extraction assembly 106. In general, the thrombectomy system 100 can be used to (i) access a portion of a blood vessel (e.g., a venous vessel of a human patient) containing a thrombus (e.g., clot material) and (ii) remove all or portions of that thrombus from the blood vessel. More specifically, for example, the introducer assembly 102 and the dilator assembly 104 can be partially advanced into the vasculature of the patient (e.g., a blood vessel or venous vessel of the patient). The dilator assembly 104 can be actuated to deploy a self-expanding funnel (e.g., as shown in Figures 7A–7C) and then removed from the introducer assembly 102. Next, the thrombus extraction assembly 106 and an attached thrombus extraction device can be partially inserted through the introducer assembly 102 and deployed at and/or near the location of a thrombus for capturing the thrombus. Finally, the thrombus extraction assembly 106 and/or the introducer assembly 102 can be removed from the patient along with the captured thrombus. In some embodiments, the thrombectomy system 100 and/or methods of operating the thrombectomy system 100 to remove a thrombus from a patient can include some features the same as or similar to the thrombectomy systems described in detail

in (i) U.S. Patent No. 9,700,332, filed September 16, 2016, and titled "INTRAVASCULAR TREATMENT OF VASCULAR OCCLUSION AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS," and/or (ii) U.S. Patent No. 10,098,651, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," both of which are incorporated herein by reference in their entirety.

[0026] In the illustrated embodiment, the introducer assembly 102 includes an elongate sheath 112, which can also be referred to as a shaft, catheter, and the like. The sheath 112 defines a lumen (obscured in Figure 1; e.g., identified as lumen 688 in Figure 6) and includes a proximal portion 113a and a distal portion 113b. The proximal portion 113a can terminate at a proximal end, and the distal portion 113b can terminate at a distal end. The lumen of the sheath 112 is sized to slidably receive the dilator assembly 104 and the thrombus extraction assembly 106. For example, the dilator assembly 104 is shown partially positioned within the sheath 112 in Figure 1. The sheath 112 can be elastic and/or flexible and can have any suitable length and diameter. In some embodiments, the sheath 112 can have an outer diameter of at least 10 French, at least 12 French, at least 14 French, at least 18 French, at least 20 French, at least 22 French, at least 26 French, greater than 26 French, between 10 French and 26 French, between 14 French and 24 French, between 15 French and 21 French, between 16 French and 22 French, and/or any other or intermediate size. In some embodiments, the lumen of the sheath 112 can have an internal diameter of at least 2 French, at least 10 French, at least 14 French, at least 18 French, at least 20 French, at least 22 French, between 11 French and 12 French, between 10 French and 22 French, between 14 French and 21 French, between 16 French and 20 French, and/or any other or intermediate size. In some embodiments, the sheath 112 can include a radiopaque marker (not shown) positioned, for example, at the distal portion 113b thereof.

[0027] The introducer assembly 102 further includes a sealable hub 114 coupled to the proximal portion 113a of the sheath 112. The sealable hub 114 is configured to allow access to the lumen of the sheath 112 and can be self-sealing and/or can comprise a self-sealing seal. For example, in the illustrated embodiment the sealable hub 114 is a hemostasis valve that is configured to maintain hemostasis during a thrombus extraction procedure by preventing fluid flow in the proximal direction through the sealable hub 114 as various components—such as portions of the dilator assembly 104 and/or the thrombus extraction assembly 106—are inserted through the sealable hub 114 to be delivered through the sheath 112 to a treatment site in a blood vessel. More specifically, the sealable hub 114 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND

METHODS OF USE," which is incorporated herein by reference in its entirety. The sealable hub 114 can include one or more buttons or actuators that enable an operator to selectively seal/unseal the sealable hub 114.

[0028] The introducer assembly 102 can further include an aspiration port 116 connected to the sealable hub 114 (e.g., to a side port of the sealable hub 114) and/or the sheath 112 (e.g., to the proximal portion 113a of the sheath 112) via, for example, a connecting tube 118. The aspiration port 116 can be connected to a syringe connector 117 that can be selectively coupled to a syringe or other aspiration device, or the aspiration port 116 can be connected to other suitable elements. In some embodiments, the introducer assembly 102 includes a fluid control device 119 configured to selectively fluidly connect the aspiration port 116 to the lumen of the sheath 112. In the illustrated embodiment, the fluid control device 119 is a stopcock operably coupled to the connecting tube 118 between the lumen of the sheath 112 and the aspiration port 116. In other embodiments, the fluid control device 119 can be a clamp or another suitable valve.

[0029] The dilator assembly 104 can include a control assembly 120 operably coupled to a retention sheath 122 via a first shaft (obscured in Figure 1; e.g., identified as first shaft 580 in Figures 5A and 5B). In the illustrated embodiment, the first shaft of the dilator assembly 104 extends through the sealable hub 114 and the sheath 112 such that the retention sheath 122 is positioned distal of the distal portion 113b of the sheath 112. Moreover, the control assembly 120 is releasably coupled to (e.g., mated to, fixed to) the sealable hub 114. Accordingly, the introducer assembly 102 can carry or hold the dilator assembly 104. As described in greater detail below with reference to Figures 5A–7D, the dilator assembly 104 (e.g., the retention sheath 122) is configured to (i) hold/constrain a self-expanding funnel (obscured in Figure 1; e.g., identified as funnel 690 in Figure 6) that is attached to the distal portion 113b of the sheath 112, and (ii) release/deploy the self-expanding funnel. More specifically, for example, the control assembly 120 can include an actuator 124 that is movable (e.g., in the direction of arrow A in Figure 1) to advance the retention sheath 122 relative to the sheath 112 (and the self-expanding funnel) attached thereto to deploy/release the self-expanding funnel.

[0030] In some embodiments, the thrombectomy system 100 can further include a loading tool 108 (e.g., a loading funnel) for use in loading the self-expanding funnel into the dilator assembly 104 (e.g., into the retention sheath 122). In the illustrated embodiment, the loading tool 108 defines a lumen 127 therethrough and includes a first portion 126 of varying diameter (e.g., a tapered portion such as a funnel portion) and a second portion 128 of generally constant diameter

(e.g., a shaft portion). In other embodiments, the second portion 128 can have a partially varying diameter. The first portion 126 is configured (e.g., sized and shaped) to receive the self-expanding funnel and to move the self-expanding funnel to the constrained configuration as the self-expanding funnel is advanced through the first portion 126. The lumen 127 of the loading tool 108 can be sized to allow the retention sheath 122 to pass completely through the loading tool 108.

[0031] In the illustrated embodiment, the thrombus extraction assembly 106 includes a catheter portion 130 and a handle portion 140 ("handle 140") operably coupled to the catheter portion 130. In operation, the handle 140 is configured to be actuated/manipulated by a user to control (e.g., deploy) one or more components of the catheter portion 130 and/or a thrombus extraction device (not shown in Figure 1; e.g., identified as thrombus extraction device 250 in Figures 2A and 2B) coupled to the catheter portion 130.

[0032] In the illustrated embodiment the catheter portion 130 includes an outer shaft 132, an intermediate shaft 133, and an inner shaft 134 slidably and coaxially aligned relative to one another. For example, each of the shafts 132–134 can define a lumen (e.g., a central, axial lumen) and (i) the intermediate shaft 133 can be configured (e.g., sized and shaped) to slidably fit within the lumen of the outer shaft 132 and (ii) the inner shaft 134 can be configured to slidably fit within the lumen of the intermediate shaft 133. In some embodiments, the outer shaft 132 is configured (e.g., sized) to slidably fit within the sheath 112 of the introducer assembly 102 and can have, for example, a size of at least 8 French, at least 10 French, at least 11 French, at least 12 French, at least 14 French, at least 16 French, between 8 French and 14 French, between 11 French and 12 French, and/or any other or intermediate size. By this arrangement, each of the shafts 132–134 can be displaced longitudinally relative to one another and relative to the sheath 112 of the introducer assembly 102. In some embodiments, each of the shafts 132–134 can have the same length while, in other embodiments, one or more of the shafts 132–134 can have different lengths. For example, in some embodiments the intermediate shaft 133 can be longer than the outer shaft 132 and the inner shaft 134 can be longer than the intermediate shaft 133. In other embodiments, the catheter portion 130 can comprise any number of shafts (e.g., catheters, sheaths) that are slidable relative to one another and/or configured to be positioned coaxially relative to one another. For example, in some embodiments the catheter portion can include three intermediate shafts as described in detail in U.S. Patent No. 10,098,651, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," which is incorporated herein by reference in its entirety.

[0033] The handle 140 includes a proximal portion 141a (e.g., a plunger portion) and a distal portion 141b (e.g., a locking portion). In the illustrated embodiment, the intermediate shaft 133 is coupled to and extends distally from the distal portion 141b of the handle 140. The distal portion 141b of the handle 140 can include a lock feature 142 such as, for example, a spinlock. The lock feature 142 is configured to selectively engage and/or lockingly engage with a mating feature 135 located near a proximal portion 136a of the outer shaft 132. In some embodiments, the outer shaft 132 can slide proximally over the intermediate shaft 133 until the lock feature 142 engages with the mating feature 135 to thereby secure the position of the outer shaft 132 relative to the intermediate shaft 133. In some embodiments, the intermediate shaft 133 is relatively longer than the outer shaft 132 such that a portion of the intermediate shaft 133 extends distally from a distal portion 136b of the outer shaft 132 when the outer shaft 132 is lockingly engaged with the lock feature 142.

[0034] In the illustrated embodiment, the handle 140 further includes a plunger 144 (e.g., an actuator) operably coupled to the inner shaft 134 and movable between a first, non-extended position (e.g., as shown in Figures 1 and 2A) and a second, extended position (e.g., as shown in Figure 2B). Thus, movement of the plunger 144 relative to the handle 140 displaces the inner shaft 134 relative to the handle 140, the outer shaft 132, and/or the intermediate shaft 133. For example, withdrawing the plunger 144 proximally from the first position to the second position can withdraw the inner shaft 134 through the intermediate shaft 133. In some embodiments, the inner shaft 134 can have a length such that the inner shaft 134 extends distally past a distal terminus of the intermediate shaft 133 when the plunger 144 is in both the first and second positions. In some embodiments, the plunger 144 can be lockable in the first position and/or the second position to lock the position of the inner shaft 134. In other embodiments, the plunger 144 can be operably coupled to other components of the catheter portion 130 such as, for example, the intermediate shaft 133 and/or one or more additional shafts (not shown).

[0035] In the illustrated embodiment, the thrombus extraction assembly 106 further includes a first flush port 138 connected to the outer shaft 132 and a second flush port 148 connected to the handle 140. The first flush port 138 can be fluidly connected to the lumen of the outer shaft 132 to allow flushing of the lumen of the outer shaft 132. The second flush port 148 can be fluidly connected to the lumen of the intermediate shaft 133 (e.g., via an internal portion of the handle 140) to allow flushing of the lumen of the intermediate shaft 133.

[0036] The thrombus extraction assembly 106 can include and/or be coupled to a thrombus extraction device configured to core and capture a thrombus from the patient. Figures 2A and 2B, for example, are side views of the thrombus extraction assembly 106 of Figure 1 operably coupled to a thrombus extraction device 250 configured in accordance with embodiments of the present technology. The thrombus extraction device 250 is shown in a deployed and partially-expanded configuration in Figure 2A and a deployed and fully-expanded configuration in Figure 2B. The thrombus extraction device 250 can be in an undeployed, constrained (e.g., unexpanded) position when positioned within the outer shaft 132.

[0037] Referring to Figures 2A and 2B together, the thrombus extraction device 250 includes an expandable coring element 252 and an expandable capture element 254 coupled to (e.g., attached to, connected to, integrally formed with) the coring element 252. The coring element 252 is positioned proximal of the capture element 254. In the illustrated embodiment, the coring element 252 includes (i) a proximal portion 253a coupled to the intermediate shaft 133 (e.g., to a distal portion of the intermediate shaft 133) and (ii) a distal portion 253b coupled to a proximal portion 255a of the capture element 254. Further, a distal portion 255b of the capture element 254 is coupled to the inner shaft 134 (e.g., to a distal portion of the inner shaft 134). As shown, the outer shaft 132 is proximally displaced relative to the handle 140 such that the mating feature 135 of the outer shaft 132 contacts/engages the lock feature 142 of the handle 140. Due to this positioning of the outer shaft 132 relative to the handle 140, each of the intermediate shaft 133, the inner shaft 134, and the thrombus extraction device 250 extend distally beyond the distal portion 136b of the outer shaft 132.

[0038] In some embodiments, the thrombus extraction device 250 can further include an atraumatic tip 258. In some embodiments, the atraumatic tip 258 can include a radiopaque marker to aid in intravascularly positioning the thrombus extraction device 250 within the patient. The thrombus extraction device 250 can additionally or alternatively include one or more radiopaque markers located on, for example, the outer shaft 132 (e.g., the distal portion 136b of the outer shaft 132) the intermediate shaft 133 (e.g., the distal portion of the intermediate shaft 133), and or other components of the thrombus extraction device 250. In some embodiments, the atraumatic tip 258 can define a channel configured to receive a guidewire therethrough.

[0039] In the partially-expanded configuration shown in Figure 2A, the plunger 144 of the handle 140 is in the first position. In contrast, in the fully-expanded configuration shown in Figure 2B, the plunger 144 is in the second position (e.g., proximally retracted away from the handle

140) such that the inner shaft 134 is proximally retracted relative to the intermediate shaft 133. This proximal retraction of the inner shaft 134 relative to the intermediate shaft 133 forces the coring element and capture element 254 to fully expand, as described in greater detail below with reference to Figure 4.

[0040] The thrombus extraction assembly 106 can comprise one or several features configured to secure the thrombus extraction device 250, and specifically the coring element 252 and/or the expandable capture element 254 in the fully-expanded position. As used herein, full expansion describes a condition in which the thrombus extraction device 250 is continually biased toward expansion by one or several forces in addition to the self-expanding forces arising from the thrombus extraction device 250. In some embodiments, full expansion occurs when the thrombus extraction device 250 is deployed and when the plunger 144 is in the second position (e.g., when the inner shaft 134 is proximally retracted relative to the intermediate shaft 133). Alternatively or additionally, full-expansion can occur when the thrombus extraction device 250 is deployed and biased towards expansion via a spring connected either directly or indirectly to the thrombus extraction device 250. Accordingly, when the thrombus extraction device 250 is fully expanded, forces less than a minimal radial compressive force do not change the diameter of the thrombus extraction device 250. Therefore, when fully-expanded, the thrombus extraction device 250 can maintain at least a desired radial force on a blood vessel when the thrombus extraction device 250 is drawn through that blood vessel. In some embodiments, the dimensions of the thrombus extraction device 250 can be selected such that the thrombus extraction device 250 apposes a wall of the blood vessel and/or applies a desired force to the wall of the blood vessel when fully expanded.

[0041] In some embodiments, the plunger 144 can be locked in the second position by, for example, rotating the plunger 144 with respect to the handle 140 to thereby engage one or several locking features on the plunger 144 and/or in the handle 140. Locking the plunger 144 in the second position secures the position of the inner shaft 134 relative to the intermediate shaft 133, thereby securing the thrombus extraction device 250 in the fully-expanded position. In other embodiments, the inner shaft 134 and the intermediate shaft 133 can be directly locked together via for example, (i) a static coupling in which the position of the inner shaft 134 is fixed relative to the position of the intermediate shaft 133 or (ii) a dynamic coupling in which the position of the inner shaft 134 relative to the intermediate shaft 133 is limited (rather than fixed). For example, the inner shaft 134 can be dynamically locked to the plunger 144 via a compliance spring

(e.g., a tension spring, compression spring), which allows limited movement of the inner shaft 134 relative to the intermediate shaft 133 when the plunger 144 is locked in the second position.

II. Selected Embodiments of Coring Elements

[0042] Figures 3A–3D are an isometric view, a side view, a top view, and a (proximally-facing) rear view, respectively, of the coring element 252 of the thrombus extraction device 250 of Figures 2A and 2B configured in accordance with embodiments of the present technology. Referring to Figures 3A–3D together, the coring element 252 comprises a plurality of struts 360 that together define a plurality of interstices or pores 362. The struts 360 can have a variety of shapes and sizes and, in some embodiments, the struts 360 can have a thickness and/or diameter between about 0.05–0.15 inch, between about 0.075–0.125 inch, between about 0.09–0.1 inch, about 0.096 inch, and/or other dimensions. In general, the struts 360 can together form a unitary fenestrated structure that is configured to core and separate a portion of a thrombus (e.g., a vascular thrombus) from a blood vessel containing the thrombus. In some embodiments, the coring element 252 can comprise a stent or stent-like device.

[0043] As best shown in Figures 3B and 3C, the coring element 252 includes a first region 363 including the proximal portion 253a, a second region 364 distal of the first region 363, a third region 365 distal of the second region 364, and a fourth region 366 distal of the third region 365 and including the distal portion 253b. The second region 364 and the fourth region 366 can be generally tubular. The first region 363 and the third region 365 have relatively fewer of the struts 360 compared to the second region 364 and the fourth region 366. For example, the first region 363 can include a pair of curved struts 367 (identified individually as first strut 367a and second strut 367a as best shown in Figures 3A and 3C) that curve in opposite directions around a central axis L of the coring element 252 and intersect and/or terminate at a pair of first junctions 361 (identified individually as a lower first junction 361a and an upper first junction 361b) to define a proximal, first mouth 370. The third region 365 can include (i) a pair of curved lower struts 368 (identified individually as a first lower strut 368a and a second lower strut 368b shown together in Figure 3A) that extend distally from a lower second junction 371a and curve around the central axis L and (ii) a pair of curved upper struts 369 (identified individually as a first upper strut 369a and a second upper strut 369b shown together in Figures 3A and 3C) that extend distally from an upper second junction 371b and curve around the central axis L. The lower and upper struts 368, 369 together define a distal first mouth portion 372a and a distal second mouth portion 372b (collectively "a second mouth 372"). In the illustrated embodiment, the first mouth portion 372a

is rotationally offset from the second mouth portion 372b. In other embodiments, the first mouth portion 372a can be positioned differently relative to the second mouth portion 372b (e.g., in a different rotational and/or longitudinal direction) and/or the second mouth 372 can comprise more than two separate portions (e.g., three, four, or more openings). In general, the first and second mouths 370, 372 can be defined by/in regions of the coring element 252 having different porosities.

[0044] In some embodiments, the coring element 252 is made from a shape memory material such as a shape memory alloy and/or a shape memory polymer. For example, the coring element 252 can comprise nitinol and/or a nitinol alloy. Similarly, the coring element 252 can be made using a variety of techniques including welding, laser welding, cutting, laser cutting, and/or expanding. For example, the coring element 252 can first be laser cut from a piece of nitinol (e.g., a nitinol tube) and then blown up and/or expanded. In general, the size (e.g., the length and diameter) of the coring element 252 can be selected based on the size (e.g., diameter) of the blood vessel from which thrombus is to be extracted. In some embodiments, the coring element 252 can have a length M of between about 0.2–5 inches (e.g., between about 1.5–2.5 inches, between about 1.75–2.25 inches, between about 1.9–2.0 inches, between about 1.5–1.8 inches, about 1.6 inches, about 1.7 inches, about 1.96 inches, about 3.0 inches, about 4.0 inches, smaller than 0.5 inch). In some embodiments, in the fully-expanded position unconstrained within a vessel, the coring element 252 can have a diameter D of between about 2–50 mm (e.g., between about 4–25 mm, between about 6 20 mm, between about 8–16 mm). In some embodiments, the length M of the coring element 252 can be selected based on the fully expanded and unconstrained diameter D of the coring element 252 to prevent undesired tipping and/or rotation of the coring element 252 within the blood vessel during operation. In general, the length M and the unconstrained diameter D of the coring element 252 will vary depending on the size of the vessel the coring element 252 is designed for. For example, the coring element 252 will generally have a smaller length M and diameter D when designed for smaller (e.g., 4 mm) vessels rather than larger (e.g., 25–35 mm) vessels.

[0045] The coring element 252 is configured to core (e.g., shear, separate) thrombus from within the blood vessel when the coring element is advanced/retracted through the thrombus in the fully-expanded configuration. For example, as described in greater detail below with reference to Figures 12D–12K, the coring element 252 can be withdrawn proximally through the thrombus to core the thrombus. As the coring element 252 is withdrawn through the thrombus the fully-expanded diameter of the coring element 252 will flexibly adapt to match the diameter of the

blood vessel. More particularly, the first and second mouths 370, 372 are configured (e.g., sized, shaped, and/or positioned) to provide most of the coring function (e.g., coring force) during operation of the coring element 252. For example, proximally-facing surfaces of the struts 367 can define a first leading edge that cuts through and cores the thrombus. Similarly, proximally-facing surfaces of the lower and upper struts 368, 369 can define a second leading edge that can also cut through and core the thrombus. In some embodiments, portions of the struts 367, the lower struts 368, and/or the upper struts 369 can be sharpened and/or can include a cutting element (e.g., a knife or knife edge) attached thereto or otherwise integrated with to further facilitate coring of the thrombus.

[0046] In one aspect of the present technology, the first mouth 370 and the second mouth 372 are longitudinally offset relative to one another. Moreover, the leading edges of the struts 367 and the leading edges of the lower and upper struts 368, 369 are oriented differently such that, for example, the first mouth 370 and the second mouth 372 are oriented at different angles when the coring element 252 is within the blood vessel. The arrangement can be more effective at coring thrombus compared to, for example, coring elements including only a single mouth (e.g., including only the first mouth 370). It is expected that the coring element 252 provides a greater coring length for engaging the wall of the blood vessel and coring (e.g., adherent) thrombus than coring elements with only a single mouth. Moreover, the coring element 252 can be relatively flexible at the first region 363 and third region 365 which include fewer struts 360 than the second region 364 and fourth region 366. For example, the coring element 252 can flex/bend at the first junctions 361 and/or the second junctions 371. In some embodiments, the first and second junctions 361, 371 enable the coring element 252 to flex in different directions (e.g., laterally and vertically). In one aspect of the present technology, this ability of the coring element 252 to flex can allow the coring element 252 to maintain a selected orientation—even when moved through tortuous vessels. In another aspect of the present technology, the arrangement of the first and second mouths 370 and 372 ensures that at least one of the first mouth 370, the first mouth portion 372a, and the second mouth portion 372b is positioned and oriented to effectively core thrombus from within the blood vessel during a thrombus extraction procedure using the coring element 252. In some embodiments, the first mouth 370 and/or the second mouth 372 can further facilitate the collapse of the coring element 252 to the non-expanded configuration.

[0047] In the embodiment illustrated in Figures 3A–3D, a first connection feature 374 and a second connection feature 376 are coupled to the coring element 252. As described in greater detail below with reference to Figure 4, the intermediate shaft 133 (Figure 1) can be operably

coupled to the first connection feature 374 and the inner shaft 134 can be operably coupled to the second connection feature 376 for controlling operation (e.g., movement and expansion) of the coring element 252. In the illustrated embodiment, the first connection feature 374 is a ring coupled to the proximal portion 253a of the coring element 252 and, more specifically, to the lower first junction 361a. In other embodiments, the first connection feature 374 can be positioned on a different portion of the coring element 252 (e.g., at the upper first junction 361b, on one of the struts 367). Similarly, the second connection feature 376 can also be a ring and can be coupled to one or more of the struts 360 in the second region 364 or another region of the coring element 252. As best seen in Figure 3D, in some embodiments the first connection feature 374 can have a diameter E_1 that is greater than a diameter E_2 of the second connection feature 376, and the first and second connection features 374, 376 can be axially aligned along an axis extending parallel to the central axis L of the coring element 252. In other embodiments, the first and second connection features 374, 376 can have other shapes and/or configurations and/or can be arranged differently relative to one another. The first and second connection features 374, 376 can be the same material as the coring element 252 or can be a different material than the coring element 252. Likewise, the first and second connection features 374, 376 can be integrally formed with the coring element 252 and/or can be attached to the coring element 252 via, for example, one or more of welds, adhesives, mechanical fasteners, and the like.

[0048] Figure 4 is an enlarged side view of the thrombus extraction device 250 coupled to a distal portion of the thrombus extraction assembly 106 and in the fully-expanded configuration in accordance with an embodiment of the present technology. In the illustrated embodiment, the coring element 252 is coupled to the intermediate shaft 133 (e.g., to a distal portion of the intermediate shaft 133) via the first connection feature 374. In some embodiments, the coring element 252 is fixedly coupled to the intermediate shaft 133 such that movement of the intermediate shaft 133 also moves the coring element 252. The proximal portion 255a of the capture element 254 is connected to the distal portion 253b of the coring element 252. In some embodiments, the capture element 254 is formed on the distal portion 253b of the coring element 252 such that the thrombus extraction device 250 is a unitary/integral structure. For example, the capture element 254 can comprise a mesh (e.g., a braided filament mesh structure) that is woven onto the distal portion 253b of the coring element 252. In some embodiments, the distal portion 255b of the capture element 254 is coupled to the to the inner shaft 134 (e.g., to a distal portion of the inner shaft 134).

[0049] In the illustrated embodiment, the inner shaft 134 slidably extends through the second connection feature 376. That is, the inner shaft 134 can have an outer diameter that is less than the diameter E_2 (Figure 4) of the second connection feature 376 such that the second connection feature 376 is slidable along the inner shaft 134. The inner shaft 134 can include a stop feature 478 configured to engage the second connection feature 376 of the coring element 252 to effect expansion of the coring element 252. In some embodiments, the stop feature 478 can comprise a polymeric member and/or a metallic member that is affixed to a portion of the inner shaft 134 that is distal of the second connection feature 376.

[0050] The stop feature 478 is configured (e.g., sized and shaped) to contact and engage the second connection feature 376 when the inner shaft 134 is withdrawn proximally relative to the coring element 252 via, for example, movement of the plunger 144 (Figures 1–3) from the first position to the second position. By this arrangement, the coring element 252 is selectively coupled to the inner shaft 134 such that the stop feature 478 can apply a proximally-directed force to the coring element 252 that can expand all or a portion of the coring element 252 to the fully-expanded configuration. For example, movement of the inner shaft 134 can forcibly expand at least the first region 363 (Figures 3B and 3C) of the coring element which is between the first and second connection features 374, 376. In some embodiments, the second connection feature 376 can be positioned differently with respect to the coring element 252 such that more or less of the coring element 252 is forcibly expanded when the stop feature 478 is pulled against the second connection feature 376.

[0051] In some embodiments, the capture element 254 can comprise a braided filament mesh structure, such as a braid of elastic filaments having a generally tubular, elongated portion 477 and a distal tapered portion 479. In other embodiments, the capture element 254 can be any porous structure and/or can have other suitable shapes, sizes, and configurations. Because the distal portion 255b of the capture element 254 is coupled to the inner shaft 134, axial movement of the inner shaft 134 expands/shortens and collapses/lengthens the capture element 254. For example, proximal movement of the inner shaft 134 can compress the capture element 254 along its longitudinal axis such that (i) a radius of the capture element 254 increases and (ii) the length of the capture element 254 decreases. Conversely, distal movement of the inner shaft 134 can stretch the capture element 254 along its longitudinal axis such that (i) the radius of the capture element 254 decreases and (ii) the length of the capture element 254 increases. In some embodiments, with reference to Figures 2A, 2B, and 4 together, distal movement of the plunger 144 can move the capture element 252 to a fully-collapsed position before the plunger 144 reaches

the fully-depressed first position shown in Figure 2A. Thus, continued distal movement of the plunger 144 (e.g., from the second position toward the first position) can pull the coring element 252 to cause the coring element 252 to collapse/longitudinally extend. That is, the plunger 144, the inner shaft 134, and the capture element 254 can collectively act to elongate/collapse the coring element 252 as the plunger 144 is distally depressed while the capture element 254 is fully collapsed. In other embodiments, the inner shaft 134 can be selectively decoupled from the capture element 254 such that proximal displacement of the inner shaft 134 expands the coring element 252 without effecting any movement of the capture element 254. In some embodiments, the capture element 254 can have a length (i) in the collapsed configuration of between about 5–30 inches (e.g., between about 10–20 inches, about 16 inches) and (ii) in the expanded configuration of between about 1–25 inches (e.g., between about 10–20 inches, about 11 inches).

[0052] In some embodiments, the capture element 254 can be formed by a braiding machine and/or a weaving machine while, in other embodiments, the capture element 254 can be manually braided and/or woven. In some embodiments, the capture element 254 is formed as a tubular braid and is then further shaped using a heat setting process. The braid can be a tubular braid of fine metal wires such as nitinol (nickel-titanium alloy), platinum, cobalt-chrome alloy, stainless steel, tungsten or titanium. In some embodiments, the capture element 254 can be formed at least in part from a cylindrical braid of elastic filaments. Thus, the braid may be radially constrained without plastic deformation such that it can self-expand on release of the radial constraint. Such a braid of elastic filaments can be referred to herein as a "self-expanding braid." In some embodiments, the thickness of the braid filaments can be less than about 0.15 mm. In some embodiments, the braid may be fabricated from filaments and/or wires with diameters ranging from about 0.05–0.25 mm. In some embodiments, braid filaments of different diameters may be combined to impart different characteristics including: stiffness, elasticity, structure, radial force, pore size, embolic capturing or filtering ability, and so on. In some embodiments the capture element 254 and/or the coring element 252 can be coated to reduce their surface friction/abrasiveness (e.g., for arterial applications). Likewise, the capture element 254 and/or the coring element 252 can be covered with a film (e.g., via dipping or spray coating) to create a non-permeable membrane to contain clot without allowing the clot to become embedded in the interstices of the capture element 254 and/or the coring element 252, thereby facilitating ease of cleaning. In some embodiments, the number of filaments used to form the capture element 254 can be between about 20–300 (e.g., including 144 filaments, 244 filaments). In some embodiments, the size of the pores formed by the capture element 254 (e.g., in the elongated

portion 477) can be between about 0.05–4.0 mm (e.g., between about 0.5 mm–2.5 mm, less than 0.4 mm).

III. Selected Embodiments of Dilator Assemblies and Associated Methods

[0053] Figures 5A and 5B are side views of the dilator assembly 104 of Figure 1 in a first configuration and a second configuration, respectively, configured in accordance with embodiments of the present technology. Referring to Figures 5A and 5B together, the dilator assembly 104 includes a first shaft or sheath 580 extending between and operably coupling the control assembly 120 and the retention sheath 122. The dilator assembly 104 can further include a second shaft or sheath 582 slidably positioned over the first shaft 580 and operably coupled to the control assembly 120. Put differently, the second shaft 582 can define a lumen sized to slidably receive the first shaft 580 such that the first and second shafts 580, 582 are axially displaceable relative to one another. In the illustrated embodiment, the first shaft 580 is longer than the second shaft 582 such that the retention sheath 122 is positioned distal of a distal portion 583b (opposite a proximal portion 583a) of the second shaft 582. The control assembly 120 further includes a housing 595 configured to engage (e.g., mate with) the sealable hub 114 of the introducer assembly 102 (Figure 1).

[0054] The retention sheath 122 includes a proximal portion 585a and a distal portion 585b. In the illustrated embodiment, the distal portion 585a includes an atraumatic tip 584 and the proximal portion 585a includes a first engagement feature 586. Similarly, the distal portion 583b of the second shaft 582 includes a second engagement feature 589. In some embodiments, the atraumatic tip 584 is radiopaque.

[0055] When the dilator assembly 104 is in the first configuration shown in Figure 5A, the second shaft 582 is proximally positioned (e.g., withdrawn) relative to the first shaft 580 such that the first engagement feature 586 does not engage the second engagement feature 589. As described in greater detail below with reference to Figure 7A, when the dilator assembly 104 is in the first configuration, the first engagement feature 586 is configured to engage (e.g., connect with, mate with) the distal portion 113b of the sheath 112 of the introducer assembly 102 (Figure 1). In some embodiments, the engagement of the first engagement feature 586 with the sheath 112 can form a seal.

[0056] When the dilator assembly 104 is in the second configuration (Figure 5B), the second engagement feature 589 of the second shaft 582 is configured to engage the first engagement feature 586 of the retention sheath 122. As shown, the second shaft 582 can have a diameter that

is equal to or substantially equal to the outer diameter of the retention sheath 122 such that the dilator assembly 104 has a uniform or substantially uniform (e.g., smooth) outer surface in the second configuration. That is, there is no step or discontinuity in the outer surface between, for example, the first shaft 580 and the retention sheath 122. In other embodiments, the second shaft 582 and the retention sheath 122 can have different diameters, and the first and second engagement features 586, 589 can be configured to provide a smooth transition between the second shaft 582 and the retention sheath 122. In some embodiments, the engagement of the first engagement feature 586 with the second engagement feature 589 can form a seal. In some embodiments, the operator can move the dilator assembly 104 from the first configuration to the second configuration by actuating the actuator 124 of the control assembly 120 (e.g., by advancing the actuator 124 in the direction of arrows A). More specifically, as described in greater detail below with reference to Figures 7A–7D, actuation of the actuator 124 can distally advance (i) the first and second shafts 580, 582 together relative to the sheath 112 and then (ii) the second shaft 582 relative to the first shaft 580.

[0057] Figure 6 is an enlarged cross-sectional side view of a portion of the thrombectomy system 100 shown in Figure 1. More particularly, Figure 6 shows a self-expanding funnel 690 coupled to the distal portion 113b of the sheath 112 of the introducer assembly 102 and restrained within the retention sheath 122 of the dilator assembly 104 in accordance with an embodiment of the present technology. In the illustrated embodiment, the retention sheath 122 includes a shell portion 692 coupled to the tip 584 and defining a lumen 693. In some embodiments, the shell portion 692 and the tip 584 are integrally formed together while, in other embodiments, the tip 584 can be a separate component that is coupled to the shell portion 692 by, for example, positioning at least a portion of the tip 584 in the lumen 693 and securing the shell portion 692 to the tip 584 (e.g., via an adhesive, friction fit).

[0058] The first shaft 580 of the dilator assembly 104 extends through a lumen 688 of the sheath 112 and at least partially through the lumen 693 of the shell portion 692. In the illustrated embodiment, a portion of the tip 584 snuggly receives a distal portion (e.g., a distal portion) of the first shaft 580 to secure the first shaft 580 to the retention sheath 122. In other embodiments, the first shaft 580 can be coupled to the retention sheath 122 in other manners. As further shown in Figure 6, the first shaft 580 and the tip 584 can define a continuous lumen 691 for receiving a guidewire (not shown). In some embodiments, the guidewire can have a diameter of about 0.038 inch, 0.035 inch, about 0.018 inch, 0.014 inch, greater than about 0.38 inch, less than about 0.1 inch, or less than about 0.05 inch.

[0059] In the illustrated embodiment, an inner diameter F_1 of the shell portion 692 is greater than an external diameter F_2 of the first shaft 580 such that an annular retaining/receiving space 694 is formed between the outer surface of the first shaft 580 and the inner surface of the shell portion 692. The receiving space 694 is configured (e.g., sized and shaped) to receive and/or retain the funnel 690 in a constrained configuration. Accordingly, in some embodiments the funnel 690 can have a diameter substantially matching the inner diameter F_1 of the shell portion 692 when the funnel 690 is in the constrained configuration. In some embodiments, the first engagement feature 586 of the retention sheath 122 can engage (e.g., sealingly engage) the distal portion 113b of the sheath 112 when the funnel 690 is retained within the retention sheath 122.

[0060] Figures 7A–7D are side views illustrating various stages in a process or method for deploying the funnel 690 in accordance with embodiments of the present technology. Referring first to Figure 7A, the dilator assembly 104 is initially positioned within the introducer assembly 102 in the first configuration (Figure 5A) such that (i) the housing 595 of the control assembly 120 is coupled to/engages the sealable hub 114 and (ii) the first engagement feature 586 of the retention sheath 122 sealingly engages the distal portion 113b of the sheath 112. In other embodiments, the first engagement feature 586 need not sealingly engage the sheath 112. In the initial position shown in Figure 7A, the actuator 124 of the control assembly 120 is in a first position (e.g., a fully-retracted position) and the funnel 690 is contained in the constrained configuration within the retention sheath 122, as shown in Figure 6.

[0061] In the arrangement shown in Figure 7A, the introducer assembly 102 and the dilator assembly 104 (collectively "assemblies 102, 104") can be used to percutaneously access a venous vessel of a patient through, for example an access site such as a popliteal access site, a femoral access site, an internal jugular access site, and/or other access site. In some embodiments, the assemblies 102, 104 are inserted through another introducer sheath (not shown). In some embodiments, the assemblies 102, 104 are advanced within the venous vessel to a treatment position in which the distal portion 113b of the sheath 112 is proximate to (e.g., proximal of) a thrombus in the venous vessel.

[0062] Referring to Figure 7B, after positioning the assemblies 102, 104, the funnel 690 (shown as transparent in Figures 7B and 7C for the sake of clarity) can be deployed by, for example, moving the actuator 124 from the first position (Figure 7B) to a second position (e.g., an intermediate position, a mid-stroke position, a drop-off position) to distally advance the first and second shafts 580, 582 together relative to the sheath 112. The distal advancement of the first

shaft 580 causes the retention sheath 122 to move distally over and away from the funnel 690. The funnel 690 self-expands to an expanded (e.g., unconstrained) configuration when the funnel 690 is no longer constrained by the retention sheath 122. In other embodiments, the control assembly 120 is configured such that moving the actuator 124 from the first position to the second position distally advances only the first shaft 580 of the dilator assembly 104 rather than both the first and second shafts 580, 582 together.

[0063] The funnel 690 can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, in the expanded configuration, the funnel 690 can have (i) a maximum diameter greater than and/or equal to the diameter D of the coring element 252 (Figures 3B and 3C) when the coring element 252 is in the fully-expanded configuration and (ii) a minimum diameter substantially equal to an outer diameter of the sheath 112. In some embodiments, the funnel 690 can have a length N that is greater than and/or equal to the length M of the coring element 252 (Figures 3A–3D) such that the coring element 252 can be received and contained within the funnel 690. In other embodiments, the length N of the funnel 690 can be less than the length M of the coring element 252. In some embodiments, the funnel 690 can have a conically shaped portion, and specifically, a truncated-conically shaped portion. In some embodiments, the funnel 690 can be formed from at least one of a castellated nitinol braid, a nitinol braided stent, a laser cut nitinol, a laser cut polymer tube, an injection molded polymeric structure, or an inflatable balloon. In some embodiments, the funnel 690 can comprise a mesh having a pore size sufficiently small to prevent the passage of thrombus through the pores of the mesh. In some embodiments, the funnel 690 can be permeable to blood.

[0064] Referring to Figure 7C, after the funnel 690 has been deployed, the dilator assembly 104 can be moved to the second configuration (Figure 5B). For example, the operator can move the actuator 124 of the control assembly 120 from the second position (Figure 7B) to a third position (e.g., a fully-advanced position) to distally advance the second shaft 582 relative to the first shaft 580 until the second engagement feature 589 of the second shaft 582 engages the first engagement feature 586 of the retention sheath 122. As shown in Figure 7D, after moving the dilator assembly 104 to the second configuration, the dilator assembly 104 can be fully retracted and withdrawn from the introducer assembly 102. For example, the dilator assembly 104 can be proximally retracted through the lumen of the sheath 112 and out of the sealable hub 114 of the introducer assembly 102.

[0065] Referring to Figures 7A–7D together, in one aspect of the present technology, moving the dilator assembly 104 to the second configuration before retracting the dilator assembly 104 from the introducer assembly 102 can inhibit or even prevent the dilator assembly 104 from damaging the funnel 690 or other components of the introducer assembly 102 during retraction of the dilator assembly 104. More specifically, if the dilator assembly 104 did not include the second shaft 582, proximal retraction of the retention sheath 122 into the sheath 112 could cause the retention sheath 122 (e.g., the first engagement feature 586) to snag or damage the deployed funnel 690. However, because the second shaft 582 has a diameter that is equal to or substantially equal to the outer diameter of the retention sheath 122, the dilator assembly 104 has a uniform or substantially uniform (e.g., smooth) outer surface in the second configuration, and is therefore less likely to snag or otherwise damage the funnel 690, the sealable hub 114, and/or other components of the introducer assembly 102 during retraction. In other embodiments, the second shaft 582 and the retention sheath 122 can have different diameters, and the first and second engagement features 586, 589 can be configured to provide a smooth transition between the second shaft 582 and the retention sheath 122.

[0066] In another aspect of the present technology, the movement of the actuator 124 from the first position to the third position both (i) advances the first and second shafts 580, 582 together to deploy the funnel 690 (e.g., as the actuator 124 moves from the first position to the second position) and (ii) advances the second shaft 582 relative to the first shaft 580 (e.g., as the actuator 124 moves from the second position to the third position) so that the dilator assembly 104 has a generally uniform outer diameter. This "dual-action" allows the control assembly 120 to be coupled to the sealable hub 114 during both the deployment of the funnel 690 and the advancement of the second shaft 582 toward the first shaft 580. This can advantageously inhibit or prevent the inadvertent advancement of the retention sheath 122 and therefore the premature deployment of the funnel 690. For example, the dilator assembly 104 and the introducer assembly 102 must often be fully removed from the patient for reloading of the funnel 690 if the funnel 690 is prematurely deployed—potentially increasing the trauma to the patient and the duration of the thrombectomy procedure. In contrast, some conventional dilator assemblies include a dilator that is "floating" (e.g., not locked to or engaged with an introducer assembly) such that an inadvertent bump or other force on the dilator assembly can cause corresponding movement of the dilator assembly.

[0067] Figures 8A, 8C, and 8D are cross-sectional side views, and Figure 8B is an enlarged cross-sectional isometric view, of the control assembly 120 configured in accordance with embodiments of the present technology. In Figures 8A and 8B the actuator 124 is in the first

position shown in Figure 7A, in Figure 8C the actuator 124 is in the second position shown in Figure 7B, and in Figure 8D the actuator 124 is in the third position shown in Figure 7C.

[0068] Referring first to Figure 8A, the control assembly 120 includes a proximal portion 801a and a distal portion 801b and defines a lumen 802 extending therethrough between the proximal and distal portions 801a, b. In the illustrated embodiment, the control assembly 120 includes a sealable member 804 at or proximate the proximal portion 801a and a connection portion 806 at or proximate the distal portion 801b. The sealable member 804 can be configured to selectively seal the lumen 802 of the control assembly 120 and, in some embodiments, can receive a guidewire (not shown) therethrough. The connection portion 806 is configured to mate/engage with the sealable hub 114 of the introducer assembly 102 to secure the control assembly 120 thereto, as described in detail above with reference to Figures 7A–7C. For example, in some embodiments the connection portion 806 can include a snap feature (e.g., having one or more teeth, flanges), a twist lock (e.g., a bayonet- or luer-type fitting), and/or other feature for engaging and/or locking to the sealable hub 114.

[0069] Referring to Figures 8A and 8B together, in the illustrated embodiment the control assembly 120 further includes a first shaft hub 810 and a second shaft hub 850. The first shaft hub 810 is configured to be coupled to the first shaft 580 of the dilator assembly 104, and the second shaft hub 850 is configured to be coupled to the second shaft 582 of the dilator assembly 104. The first and second shafts 580, 582 are not shown in Figures 8A–8D for the sake of clarity. In the illustrated embodiment, the second shaft hub 850 is connected to (e.g., integrally formed with) the actuator 124, which extends outside the housing 595 and is configured to be advanced distally and/or retracted proximally by the operator. The first shaft hub 810 includes a first body portion 812 and one or more first engagement or snap features 814 (only one first engagement feature 814 is visible in Figures 8A–8D) that extend radially and/or axially away from the first body portion 812 and into a corresponding first track 830 formed in the housing 595. The second shaft hub 850 similarly includes a second body portion 852 and second engagement or snap features 854 (e.g., a pair of similar or identical second engagement features 854) that extend radially and/or axially away from the second body portion 852 and into a corresponding second track 840 formed in the housing 595.

[0070] In the illustrated embodiment, the first track 830 includes one or more proximal detents 832 (obscured in Figures 8A and 8B; shown in Figure 8C), one or more distal detents 834, and a distal terminus 835. In some embodiments, the first track 830 can include a pair of opposing

(e.g., radially opposite) proximal detents 832 and a pair of opposing distal detents 834. The second track 840 includes a first portion 842 having a first track width or height G_1 (Figure 8A) and a second portion 844 having a second track width or height G_2 (Figure 8A) greater than the first track width G_1. In some embodiments, the transition (e.g., a slope or step) between the first and second portions 842, 844 of the second track 840 is generally aligned over and/or proximate to the distal detents 834 of the first tack 830.

[0071] In operation, the first and second shaft hubs 810, 850 are configured to slide within the lumen 802 along the first and second tracks 830, 840, respectively. In some embodiments, the first engagement features 814 and/or the second engagement features 854 are flexible such that they can flex/bend as the first and second shaft hubs 810, 850 move along the first and second tracks 830, 840. The configuration/arrangement of the first and second shaft hubs 810, 850 and the first and second tracks 830, 840—for example, the arrangement of the proximal and distal detents 832, 834, the first portion 842, and/or the second portion 844—can facilitate the movement of the dilator assembly 104 from the first configuration (Figure 5A) to the second configuration (Figure 5B).

[0072] More specifically, in the first position shown in Figures 8A and 8B, the actuator 124 is positioned at a most proximal position along the housing 595. For example, the first shaft hub 810 can abut a proximal wall portion 807 of the housing 595. In the first position, the first portion 842 of the second track 840 compresses (e.g., presses, constrains) the second engagement features 854 of the second shaft hub 850 radially inward toward and into engagement with the first shaft hub 810 (e.g., with the first body portion 812). Put differently, a distance (e.g., diameter) of the second shaft hub 850 between the second engagement features 854 can be greater than the first diameter G_1 when the second shaft hub 850 is in a relaxed state, unconstrained by the first portion 842 of the second track 840. By this arrangement, the second shaft hub 850 is secured to the first shaft hub 810 such that movement of the actuator 124 along the first portion 842 of the second track 840 moves both the first and second shaft hubs 810, 850. In some embodiments, the first body portion 812 of the first shaft hub 810 can include various features (e.g., grooves, channels, teeth) for mating with the second engagement features 854 of the second shaft hub 850 to thereby secure the first and second shaft hubs 810, 850 together.

[0073] Moreover, in the first position, at least a portion of the first engagement features 814 of the first shaft hub 810 can be positioned proximal of the proximal detents 832 (Figures 8C and 8D). The proximal detents 832 can thus retain the first shaft hub 810—and the second shaft hub

850 and the actuator 124 secured thereto—in the first position until a predetermined force is applied to the actuator 124 in the distal direction. In one aspect of the present technology, this arrangement can inhibit the unintended distal advancement of the first shaft 580—and thus the premature deployment of the funnel 690 (Figures 7A–7C). In some embodiments, when the predetermined force is applied to the actuator 124, the first engagement features 814 flex inwardly such that first shaft hub 810 can slide distally thereby.

[0074] Accordingly, referring to Figures 8A–8C together, the actuator 124 can be advanced distally from the first position to the second position shown in 8C after the first engagement features 814 disengage the proximal detents 832. As the actuator 124 is moved distally, the first and second shaft hubs 810, 850 move distally together—thereby advancing the first and second shafts 580, 582 together as shown in Figure 7B—until the first shaft hub 810 reaches the distal terminus 835 of the first track 830 and/or the second shaft hub 840 reaches the second portion 844 of the second track 840. More specifically, the distal terminus 835 and/or the distal detents 834 of the first track 830 can engage the first engagement features 814 to prevent the first shaft hub 810 (and thus the first shaft 580) from moving farther distally. At the same time, the greater-diameter second portion 844 of the second track 840 allows the second engagement features 854 to move radially outward (e.g., flex radially outward toward the relaxed state) and out of engagement with first shaft hub 810. That is, the control assembly 120 is configured such that the second engagement features 854 of the second shaft hub 850 reach the transition point between the first and second portions 842, 844 of the first track 840 at substantially the same time as the first engagement features 814 of the first shaft hub 810 reach/engage the distal detents 834 of the first track 830.

[0075] Accordingly, as shown in Figure 8D, the second shaft hub 850 can leave the first shaft hub 810 behind and advance further distally to the third position. As the second shaft hub 850 moves distally while the first shaft hub 810 remains stationary, the second shaft 582 is advanced distally toward the retention sheath 122 as shown in Figure 7C. In some embodiments, the second shaft hub 850 can abut a distal wall portion 809 of the housing 595 in the third position.

[0076] Referring to Figures 5A–8D together, in one aspect of the present technology, the control assembly 120 facilitates the movement of the dilator assembly 104 from the first configuration to the second configuration with only as a single movement of the actuator 124 from the first to third positions. As described above, this advantageously allows the control assembly 120 to be coupled to the sealable hub 114 at all times during deployment of the funnel 690, which

controls deployment of the funnel 690 and prevents the funnel 690 from inadvertently being deployed. This is expected to reduce the potential for the other components of the system, such as the retention sheath 122, from catching on the funnel 690 as the dilator is retracted through the sheath 112. Moreover, deployment of the funnel 690 and advancement of the second shaft 582 are achieved by a single stroke and are thus greatly simplified.

[0077] In some embodiments, the actuator 124 can be moved proximally (e.g., from the third position toward the first position) to facilitate loading of the funnel 690. For example, the dilator assembly 104 can be inserted into the sheath 112 when the control assembly 120 is in the third position such that the retention sheath 122 extends from the distal portion 113b of the sheath 112 and distally beyond the funnel 690. The operator can then move the actuator 124 to the second position, thereby forcing the second shaft hub 850 into engagement with the first shaft hub 810 via the narrowing of the second track 840 from the second portion 844 to the first portion 842. The loading tool 108 (Figure 1) can then be slid proximally over the retention sheath 122 and the funnel 690 until the funnel 690 is fully encapsulated by the loading tool 108 and/or until the funnel 690 is in the constrained configuration. The operator can then move the actuator 124 from the second position to the first position to retract the retention sheath 122 over the funnel 690 to thereby load/capture the funnel 690 within the receiving space 694 of the retention sheath 122. Finally, the loading tool 108 can be removed.

[0078] In other embodiments, control assemblies in accordance with the present technology can include other components and/or configurations for facilitating the dual-action of (i) advancing the first and second shafts 580, 582 to deploy the funnel 690 and (ii) advancing the second shaft 582 relative to the first shaft 580 to provide a uniform outer surface that facilitates retraction of the dilator assembly 104. Figures 9A–9C, for example, are cross-sectional side views of a control assembly 920 including the actuator 124 in the first position, the second position, and the third position (Figures 7A–7C) configured in accordance with another embodiment of the present technology.

[0079] The control assembly 920 can include some features generally similar to the control assembly 120 described in detail above with reference to Figures 8A–8D. For example, referring to Figures 9A–9C together, the control assembly 920 includes a first shaft hub 910 coupled to the first shaft 580 of the dilator assembly 104, and a second shaft hub 950 coupled to the second shaft 582 of the dilator assembly 104. In the illustrated embodiment, the second shaft hub 950 is connected to (e.g., integrally formed with) the actuator 124, which extends outside a housing 995

of the control assembly 920 and is configured to be advanced distally and/or retracted proximally by the operator. The first and second shaft hubs 910, 950 are configured to slide at least partially through a lumen 902 extending through the housing 995.

[0080] In the illustrated embodiment, the control assembly 920 further includes an elongate member 960 (shown as transparent in Figures 9A–9C for the sake of clarity) having (i) a proximal portion 961a positioned proximal of the first shaft hub 910 and (ii) a distal portion 961b positioned distal of the first shaft hub 910 and coupled to the second shaft hub 950. The first shaft hub 910 can be slidably positioned within the elongate member 960. A biasing member 964, such as a compression spring, extends between the proximal portion 961a of the elongate member 960 and the first shaft hub 910. In some embodiments, a proximal portion 965a of the biasing member 964 is connected to the proximal portion 961a of the elongate member 960 and a distal portion 965b of the biasing member 964 is connected to the first shaft hub 910.

[0081] The control assembly 920 can further include a stop member 970 coupled to the first shaft 580 (e.g., to a proximal portion of the first shaft 580). The stop member 970 is configured to slide at least partially through the lumen 902 of the housing during operation of the control assembly 920 and can be fully contained within the housing 995 (e.g., as shown in Figures 9B and 9C) and/or can extend fully or partially outside of the housing 995 (e.g., as shown in Figure 9A). As shown in Figure 9B, the stop member 970 has a dimension (e.g., diameter) H_1 that is greater than a dimension H_2 of a stop portion 972 of the housing 995. By this arrangement, the stop member 970 is configured to contact the stop portion 972 of the housing 995 to thereby prevent the first shaft 580 (and the retention sheath 122 attached thereto) from advancing farther distally.

[0082] Referring to Figure 9A, in the first position, the first shaft hub 910 engages (e.g., mates with) the second shaft hub 950 such that distal advancement of the actuator 124 moves both the first and second shaft hubs 910, 950. Moreover, the biasing member 964 is at equilibrium and thus does not exert any force on, for example, the first shaft hub 910. In some embodiments, the actuator 124 and/or the second shaft hub 950 can include first engagement features 954 (e.g., bumps, projections) that can engage (e.g., mate with) corresponding first detents 957 in the housing 995 to releasably secure the actuator 124 in the first position until a predetermined force is applied to the actuator in the distal direction. In some embodiments, when the predetermined force is applied to the actuator 124, the first engagement features 954 can flex outwardly and out of the first detents 957 to permit the first and second shaft hubs 910, 950 to move distally.

[0083] Accordingly, referring to Figures 9A and 9B together, the actuator 124 can be advanced distally from the first position to the second position after the first engagement features 954 disengage the first detents 957. As the actuator 124 is moved distally, the first and second shaft hubs 910, 950 move distally together—thereby advancing the first and second shafts 580, 582 together as shown in Figure 7B—until the stop member 970 reaches and contacts the stop portion 972 of the housing 995. More specifically, the biasing member 964 can exert a force against the first shaft hub 910 to move the first shaft hub 910 together with the second shaft hub 950. When the stop member 970 contacts the stop portion 972, the first shaft hub 910 is stopped from advancing farther distally.

[0084] Accordingly, referring to Figures 9B and 9C together, the second shaft hub 950 can leave the first shaft hub 910 behind as the actuator 124 is moved farther distally to the third position. As the second shaft hub 950 moves distally while the first shaft hub 910 remains stationary, the second shaft 582 is advanced distally toward the retention sheath 122 as shown in Figure 7C. In some embodiments, the second shaft hub 950 can abut a distal wall portion 909 of the housing 995 in the third position, which prevents the second shaft hub 950 from advancing farther. As further shown in Figure 9C, advancing the second shaft hub 950 to the third position compresses the biasing member 964 between the first shaft hub 910, which remains stationary, and the proximal portion 961a of the elongate member 960 which continues to move with the second shaft hub 950. In some embodiments, the bias force exerted by the biasing member 964 can facilitate the subsequent movement of the actuator 124 from the third position to the second position. In some embodiments, the actuator 124 can include second engagement features 958 (e.g., bumps, projections) that can engage (e.g., mate with) corresponding second detents 959 in the housing 995 to releasably secure the actuator 124 in the third position until a predetermined force is applied to the actuator in the proximal direction. In some embodiments, this force can be less than that required to disengage the first engagement features 954 from the first detents 957 due to the biasing force of the biasing member 964. In other embodiments, the detents 959 can comprise a track (e.g., an L-shaped track), and the second shaft hub 950 can be rotated to rotate the second engagement features 958 into the track to releasably secure the actuator 124 in the third position.

[0085] In other embodiments, the stop member 970 is not configured to stop distal advancement of the first shaft 580. Rather, the stop member 970 can instead be a luer flush port 970 (or another component) that simply moves together with the first shaft 580, or can be omitted altogether. In such embodiments, the first shaft hub 910 can move along a track (not shown)

formed in the housing 995 in a similar manner as the first shaft hub 810 described in detail with reference to Figures 8A–8D. For example, the first shaft hub 910 can include first engagement or snap features 914 (only one first engagement feature 914 is visible in Figures 9A–9C) that extend (i) radially and/or axially away from a body portion of the first shaft hub 910, (ii) out of the elongate member 960, and (iii) into the track in the housing 995. The track can include a detent or other feature (not shown) configured (e.g., positioned and shaped) to stop the first shaft hub 910 from moving farther distally when the first shaft hub 910 reaches the second position shown in Figure 9B.

[0086] Figures 10A and 10B are partially cross-sectional side views of a control assembly 1020 configured in accordance with another embodiment of the present technology. In general, the control assembly is movable between (i) the first position (shown in Figure 10A) in which the second shaft 582 is retracted proximally relative to the first shaft 580 as shown in Figures 5A and 7A and (ii) the third position (shown in Figure 10B) in which the second shaft 582 is advanced distally relative to the first shaft 580 to form a generally uniform outer surface of the dilator assembly 104 as shown in Figures 5B and 7C. In one aspect of the present technology, the control assembly 1020 does not include the intermediate second position (Figure 7B), but instead fluidly moves between the first and third positions.

[0087] The control assembly 1020 can include some features generally similar to the control assembly 120 and/or the control assembly 920 described in detail above with reference to Figures 8A–9C. For example, referring to Figures 10A and 10B together, the control assembly 1020 includes an actuator 1024 (e.g., a plunger 1024) that is movable relative to/through a lumen 1002 of a housing 1095. The plunger 1024 is coupled to (i) a first shaft hub 1010 that is coupled to the first shaft 580 of the dilator assembly 104 and (ii) a second shaft hub 1050 that is coupled to the second shaft 582 of the dilator assembly 104. The first and second shafts 580, 582 are not shown in Figures 10A and 10B for the sake of clarity.

[0088] In the illustrated embodiment, the second shaft hub 1050 includes engagement features 1054 that are configured (e.g., sized and shaped) to engage with a corresponding stop portion 1056 formed in the housing 1095 when the plunger 1024 is in the first position shown in Figure 10A. The first shaft hub 1010 is configured to slide along a track 1080 formed in/along a portion of the plunger 1024. In some embodiments, the track 1080 includes at least one detent 1084 at a distal portion thereof and configured to stop/block distal advancement of the first shaft

hub 1010. In other embodiments, the housing 1095 can include a flange or other component configured to stop distal advancement of the first shaft hub 1010.

[0089] A first biasing member 1064 (e.g., a compression spring) extends between and operably couples (e.g., connects) the first shaft hub 1010 and a proximal portion 1096 of the housing 1095. A second biasing member 1066 (e.g., a compression spring) extends between and operably couples (e.g., connects) the first and second shaft hubs 1010, 1050. In the first position shown in Figure 10A, both of the first and second biasing members 1064, 1066 are compressed and under load and therefore urge the first and second shaft hubs 1010, 1050, respectively, distally. In some embodiments, the first biasing member 1064 has a larger compression force than the second biasing member 1066.

[0090] In the first position shown in Figure 10A, the plunger 1024 is locked in a proximally retracted position by the engagement of the engagement features 1054 with the stop portion 1056 of the housing 1095. To move the control assembly 1020 to the third position shown in Figure 10B, the operator can rotate the plunger 1024 (e.g., as indicated by arrow I in Figure 10A) to unlock the second shaft hub 1050 and the plunger 1024. When the plunger 1024 is unlocked, the first biasing member 1064 is configured to drive the first shaft hub 1010 distally until the first shaft hub 1010 is stopped by/within the detent 1084. In one aspect of the present technology, because the first biasing member 1064 is stronger than the second biasing member 1066, the second biasing member 1066 remains substantially compressed until the first shaft hub 1010 engages the detent 1084. Therefore, both the first and second shaft hubs 1010, 1050—and thus both the first and second shafts 580, 582—move together until the first shaft hub 1010 reaches the detent 1084. Then, the second biasing member 1066 is configured to drive the second shaft hub 1050 distally relative to the first shaft hub 1010 (e.g., away from the first shaft hub 1010). In the third position shown in Figure 10B, the first and second biasing members 1064, 1066 can bias the first and second shaft hubs 1010, 1050 distally to maintain the control assembly 1020 in the third position. By this arrangement, the first and second shafts 580, 582 are automatically moved from the first configuration (Figure 5A) to the second configuration (Figure 5B)—deploying the funnel and readying the dilator assembly 104 for retraction as shown in Figures 7A–7D.

[0091] In other embodiments, the first and second biasing members 1064, 1066 can be arranged in an opposite configuration. For example, the first biasing member 1064 can extend between and operably couple the first and second shaft hubs 1010, 1050, and the second biasing member 1066 can extend between and operably couple the second shaft hub 1050 and a distal

portion 1098 of the housing 1096. Likewise, the second biasing member 1066 can have a larger compression force than the first biasing member 1064. Thus, the first and second biasing members 1064, 1066 can bias the control assembly 1020 to the first position. To move the control assembly 1020 to the third position, the user can advance the plunger 1024 against the compression forces of the first and second biasing members 1064, 1066 until the second shaft hub 1050 reaches the third position. In some embodiments, the user can then rotate the plunger 1024 to lock the control assembly 1020 in the third position.

IV. Selected Embodiments of Thrombectomy Methods

[0092] Figure 11 is a schematic view of an introduction technique for accessing a thrombus 1190 for treatment with the thrombectomy system 100 in accordance with an embodiment of the present technology. The thrombus 1190 (e.g., clot material) can be located in a blood vessel 1196 and accessed through an access site 1192 such as the popliteal access site, or other venous or arterial access sites. The introducer assembly 102 can extend from the popliteal access site 1192, or other venous or arterial access sites, to a deployment position 1194 at which the self-expanding funnel 690 can be deployed and which can be proximate to the thrombus 1190. As described in greater detail below with reference to Figures 12A–12K, the thrombus extraction device 250 can be passed through the thrombus 1190 in the direction of blood flow and then retracted through the thrombus 1190 in a direction with blood flow. During retraction, the coring element 252 can core/separate the thrombus 1190 and the capture element 254 can capture all or a portion of the thrombus 1190. In some embodiments, some or all of the thrombus extraction device 250 can extend into one of the iliac veins and/or the inferior vena cava.

[0093] More particularly, Figures 12A–12C are side views, and Figures 12D–12M are enlarged side views, of the thrombectomy system 100 positioned within the blood vessel 1196 during a thrombectomy procedure to treat (e.g., remove) the thrombus 1190 in accordance with embodiments of the present technology.

[0094] Figure 12A illustrates the thrombectomy system 100 intravascularly positioned within the blood vessel 1196 after (i) deploying the self-expanding funnel 690 (e.g., as described in detail with reference to Figures 5A–10B), (ii) removing the dilator assembly 104 from the introducer assembly 102, and (iii) advancing the outer shaft 132 of the thrombus extraction assembly 106 through the sheath 112 and the thrombus 1190. The distal advance of the outer shaft 132 through the thrombus 1190 can be either with or against the direction of blood flow.

[0095] Figure 12B illustrates the thrombectomy system 100 after advancing the thrombus extraction device 250 through the outer shaft 132 to a deployed position distal of the thrombus 1190. In some embodiments, the thrombus extraction device 250 can be constrained within the outer shaft 132 and inserted, together with the outer shaft 132, into the lumen of the sheath 112 via the sealable hub 114. In some embodiments, the thrombus extraction device 250 can be deployed by advancing the thrombus extraction device 250 beyond the distal portion 136b of the sheath 112 and/or by retracting the outer shaft 132 relative to the thrombus extraction device 250 until the thrombus extraction device 250 is beyond the distal portion 136b of the outer shaft 132.

[0096] Figure 12C illustrates the thrombectomy system 100 after fully-expanding the thrombus extraction device 250. In some embodiments, at least a portion of the coring element 252 and/or the capture element 254 contact a wall 1297 of the blood vessel 1196 in the fully-expanded position. As described in detail above with reference to Figures 2A and 2B, in some embodiments the thrombus extraction device 250 can be fully expanded by moving the plunger 144 from the first position to the second position and securing the plunger 144 in the second position to thereby fix the relative position of the inner shaft 134 with respect to the intermediate shaft 133.

[0097] In general, Figures 12D–12K illustrate the proximal retraction of the thrombus extraction device 250 through the thrombus 1190 to capture at least a portion of the thrombus 1190, and the subsequent joint retraction of the thrombus extraction device 250 and the captured thrombus 1190 into the funnel 690 and the sheath 112.

[0098] Referring first to Figure 12D, proximal retraction of the thrombus extraction device 250 causes the coring element 252 to separate and/or core a distal portion 1298b of the thrombus 1190 from the wall 1297 of the blood vessel 1196. As shown in Figure 12E, continued proximal retraction of the thrombus extraction device 250 through the thrombus 1190 causes the capture element 254 to capture the distal portion 1298b of the thrombus 1190 therein. Figures 12F–12H illustrate further proximal retraction of the thrombus extraction device 250 which causes further separation, coring, and/or capture of the thrombus 1190. As seen in Figure 12H, a proximal portion 1298a of the thrombus 1190 is cored and captured as the thrombus extraction device 250 is proximally retracted toward the funnel 690 and the sheath 112.

[0099] As described in detail above with reference to Figures 3A–4, the coring element 252 can include both the first mouth 370 and the second mouth 372 (identified in Figure 12D). Thus, the first mouth 370, the first mouth portion 372a, and/or the second mouth portion 372b can

facilitate the coring/separating of the thrombus 1190 during proximal retraction of the thrombus extraction device 250. In one aspect of the present technology, the first mouth 370 and the second mouth 372 are radially offset relative to one another which can increase the coring effectiveness—even when the blood vessel 1196 is very tortuous and/or the thrombus 1190 is strongly adhered to the wall 1297 of the blood vessel 1196—by ensuring that at least one of the first mouth 370 and the second mouth 372 is positioned and oriented to effectively core the thrombus 1190.

[0100] In some embodiments, as shown in Figures 12I and 12G, the thrombus extraction device 250 can be proximally retracted until the proximal portion 253a of the coring element 252 is contained (e.g., positioned) within the funnel 690. More specifically, the thrombus extraction device 250 can be proximally retracted until all or a portion of the first mouth 370 and/or the second mouth 372 of the coring element 252 are contained within the funnel 690. In some embodiments, when one or both of the first and second mouths 370, 372 are positioned within the funnel 690, the thrombus extraction device 250 can be moved or transformed from the expanded deployed state to the compressed state to compress and secure the thrombus 1190 captured by the thrombus extraction device 250. In some embodiments, for example, the intermediate shaft 133 (Figure 12H) can be unlocked and/or decoupled from the inner shaft 134 (e.g., via user actuation of the plunger 144 shown in Figures 1–2B) such that the inner shaft 134 can be advanced distally relative to the intermediate shaft 133 to collapse or compress the thrombus extraction device 250.

[0101] After the thrombus extraction device 250 has been collapsed, the thrombus extraction device 250 can be proximally retracted through the funnel 690 and into the sheath 112 as depicted in Figure 12K. The thrombus extraction device 250 can continue to be proximally retracted until the thrombus extraction device 250 and the captured thrombus 1190 are fully contained within the sheath 112. In some embodiments, the thrombus extraction device 250 and the captured thrombus 1190 can then be withdrawn through the sheath 112 and the sealable hub 114 (Figure 12B).

[0102] In some embodiments, a vacuum (e.g., a pre-charged vacuum) can be applied to the sheath 112 at any point during retraction of the thrombus extraction device 250. In some embodiments, application of the vacuum can generate instantaneous or nearly instantaneous suction at the distal portion of the sheath 112 that can aspirate any remaining portions of the thrombus 1190 into and/or through the sheath 112. For example, the generated suction can aspirate any of the thrombus 1190 that captured or extruded by the funnel 690. Moreover, in some embodiments, application of a vacuum can facilitate smooth retraction of the captured thrombus

1190 through the sheath 112. For example, a burst of suction generated by application of the vacuum can help inhibit clogging of the sheath 112, and/or help resolve (e.g., break apart) a clog formed in the sheath 112 during retraction.

V. Examples

[0103] Several aspects of the present technology are set forth in the following examples:

1. A coring element for coring a vascular thrombus within a blood vessel of a patient, the coring element comprising:

a unitary structure having—

a first region adjacent to a proximal portion of the unitary structure, wherein the first region includes a first mouth configured to core the vascular thrombus;

a second region distal of the first region, wherein the second region is generally tubular and includes a first plurality of interconnected struts;

a third region distal of the second region, wherein the third region includes a second mouth configured to core the vascular thrombus; and

a fourth region distal of the third region, wherein the fourth region is generally tubular and includes a second plurality of interconnected struts.

2. The coring element of example 1 wherein the first mouth is radially offset from the second mouth.

3. The coring element of example 1 or example 2 wherein the unitary structure extends along a longitudinal axis, and wherein the first region includes a pair of first curved struts that curve in opposite directions around the longitudinal axis and intersect at a pair of first junctions to define the first mouth.

4. The coring element of any one of examples 1–3 wherein the unitary structure extends along a longitudinal axis, wherein the third region includes (a) a pair of upper curved struts that curve around the longitudinal axis and intersect each other at an upper junction and (b) a pair of lower curved struts that curve around the longitudinal axis and intersect each other at a lower junction, and wherein the lower and upper curved struts define the second mouth.

5. The coring element of example 4 wherein the lower and upper curved struts define (a) a first mouth portion opening in a first direction generally orthogonal to the longitudinal axis and (b) a second mouth portion opening in a second direction generally orthogonal to the longitudinal axis, and wherein the first and second mouth portions define the second mouth.

6. The coring element of example 5 wherein the first direction is generally opposite to the second direction.

7. The coring element of any one of examples 1–6 wherein the coring element is expandable from a compressed delivery configuration to an expanded deployed configuration.

8. The coring element of example 7 wherein the coring element is configured to self-expand.

9. The coring element of example 8 wherein the coring element is made from a shape memory material.

10. The coring element of any one of examples 1–9 wherein the fourth region of the unitary structure is configured to be connected to a braided filament mesh structure.

11. A dilator assembly for deploying an expandable funnel coupled to a distal portion of an introducer sheath, the dilator assembly comprising:

a first shaft defining a lumen;

a second shaft slidably positioned within the lumen of the first shaft;

a retention sheath coupled to the second shaft and configured to receive and constrain the funnel therein; and

a control assembly including an actuator operably coupled to the first and second shafts, wherein movement of the actuator from a first position to a second position advances the first and second shafts together to deploy the funnel from the retention sheath, and wherein movement of the actuator from the second position to a third position advances the first shaft relative to the second shaft.

12. The dilator assembly of example 11 wherein the retention sheath has substantially a same outer diameter as the first shaft.

13. The dilator assembly of example 11 or example 13 wherein movement of the actuator from the second position to the third position brings a distal portion of the first shaft into contact with a proximal portion of the retention sheath.

14. The dilator assembly of any one of examples 11–13 wherein the control assembly includes—

a housing;

a first shaft hub slidably positioned within the housing and coupled to the first shaft; and

a second shaft hub slidably positioned within the housing and coupled to the second shaft.

15. The dilator assembly of example 14 wherein the first shaft hub is configured to engage the second shaft hub when the actuator is moved from the first position to the second position such that the first and second shafts advance together.

16. The dilator assembly of example 14 or example 15 wherein the first shaft hub is configured to disengage the second shaft hub when the actuator is moved from the second position to the third position such that first shaft advances relative to the second shaft.

17. The dilator assembly of any one of examples 14–16 wherein the first shaft hub is configured to engage the second shaft hub when the actuator is moved from the first position to the second position such that the first and second shafts advance together, and wherein the first shaft hub is configured to disengage the second shaft hub when the actuator is moved from the second position to the third position such that first shaft advances relative to the second shaft.

18. The dilator of assembly of any one of examples 14–17 wherein the second shaft hub includes a first engagement feature, wherein the housing includes a second engagement feature, and wherein the first engagement feature is configured to engage the second engagement feature at the second position to prevent movement of the second shaft hub when the actuator is moved from the second position to the third position.

19. The dilator assembly of example 18 wherein the first engagement feature is a snap feature, and wherein the second engagement feature is a detent formed in the housing.

20. The dilator assembly of any one of examples 14–19, further comprising a biasing member operably coupled to the first shaft hub, wherein the biasing member is configured to bias the first shaft hub from the third position toward the second position.

21. The dilator assembly of any one of examples 11–20 wherein the control assembly further includes a housing, wherein the actuator is movable relative to the housing, wherein the movement of the actuator from the first position to the second position is distal movement of the actuator relative to the housing, and wherein the movement of the actuator from the second position to the third position is further distal movement of the actuator relative to the housing.

22. The dilator assembly of any one of examples 11–21, further comprising the introducer sheath and the funnel.

23. A system for capturing a vascular thrombus within a blood vessel of a patient, the system comprising:

an introducer sheath having a distal portion;

an expandable funnel coupled to the distal portion of the introducer sheath;

a dilator assembly configured to be inserted through the introducer sheath and to deploy the expandable funnel, wherein the dilator assembly includes—

a first shaft defining a lumen;

a second shaft slidably positioned within the lumen of the first shaft;

a retention sheath coupled to the second shaft and configured to receive and constrain the funnel therein; and

a control assembly including an actuator operably coupled to the first and second shafts, wherein movement of the actuator from a first position to a second position distally advances the first and second shafts together to deploy the funnel from the retention sheath, and wherein movement of the actuator from the second position to a third position advances the first shaft relative to the second shaft; and

a clot removal device configured to be inserted through the introducer sheath to capture at least a portion of the vascular thrombus.

24. The system of example 23 wherein the clot removal device includes an expandable coring element coupled to an expandable capture element, wherein the coring element is configured to separate at least a portion of the vascular thrombus from a wall of the blood vessel, and wherein the capture element is configured to capture and retain the portion of the vascular thrombus separated from the wall of the blood vessel.

25. The system of example 23 or example 24 wherein the funnel has a first length when deployed from the retention sheath, and wherein the coring element has a second length when expanded that is less than the first length.

26. A system for capturing a vascular thrombus within a blood vessel of a patient, the system comprising:

an introducer sheath having a distal portion;

an expandable funnel coupled to the distal portion of the introducer sheath;

a dilator assembly configured to be inserted through the introducer sheath and to deploy the expandable funnel; and

a clot removal device configured to be inserted through the introducer sheath, wherein the clot removal device includes an expandable coring element coupled to an expandable capture element, wherein the coring element includes a first region including a first mouth and a second region including a second mouth, wherein the first and second mouths are configured to separate at least a portion of the vascular thrombus from a wall of the blood vessel, and wherein the capture element is configured to capture and retain the portion of the vascular thrombus separated from the wall of the blood vessel.

27. The system of example 26 wherein the first mouth is radially offset from the second mouth.

28. The system of example 27 wherein the coring element is formed from a unitary structure including a plurality of struts, wherein the struts define the first and second mouths,

wherein the struts further define a plurality of interstices, and wherein the first and second mouths are larger than each of the interstices.

VI. Conclusion

[0104] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0105] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0106] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A coring element for coring a vascular thrombus within a blood vessel of a patient, the coring element comprising:

a unitary structure having—

a first region adjacent to a proximal portion of the unitary structure, wherein the first region includes a first mouth configured to core the vascular thrombus;

a second region distal of the first region, wherein the second region is generally tubular and includes a first plurality of interconnected struts;

a third region distal of the second region, wherein the third region includes a second mouth configured to core the vascular thrombus; and

a fourth region distal of the third region, wherein the fourth region is generally tubular and includes a second plurality of interconnected struts.

2. The coring element of claim 1 wherein the first mouth is radially offset from the second mouth.

3. The coring element of claim 1 wherein the unitary structure extends along a longitudinal axis, and wherein the first region includes a pair of first curved struts that curve in opposite directions around the longitudinal axis and intersect at a pair of first junctions to define the first mouth.

4. The coring element of claim 1 wherein the unitary structure extends along a longitudinal axis, wherein the third region includes (a) a pair of upper curved struts that curve around the longitudinal axis and intersect each other at an upper junction and (b) a pair of lower curved struts that curve around the longitudinal axis and intersect each other at a lower junction, and wherein the lower and upper curved struts define the second mouth.

5. The coring element of claim 4 wherein the lower and upper curved struts define (a) a first mouth portion opening in a first direction generally orthogonal to the longitudinal axis and

(b) a second mouth portion opening in a second direction generally orthogonal to the longitudinal axis, and wherein the first and second mouth portions define the second mouth.

6. The coring element of claim 5 wherein the first direction is generally opposite to the second direction.

7. The coring element of claim 1 wherein the coring element is expandable from a compressed delivery configuration to an expanded deployed configuration.

8. The coring element of claim 7 wherein the coring element is configured to self-expand.

9. The coring element of claim 8 wherein the coring element is made from a shape memory material.

10. The coring element of claim 1 wherein the fourth region of the unitary structure is configured to be connected to a braided filament mesh structure.

11. A dilator assembly for deploying an expandable funnel coupled to a distal portion of an introducer sheath, the dilator assembly comprising:

a first shaft defining a lumen;

a second shaft slidably positioned within the lumen of the first shaft;

a retention sheath coupled to the second shaft and configured to receive and constrain the funnel therein; and

a control assembly including an actuator operably coupled to the first and second shafts, wherein movement of the actuator from a first position to a second position advances the first and second shafts together to deploy the funnel from the retention sheath, and wherein movement of the actuator from the second position to a third position advances the first shaft relative to the second shaft.

12. The dilator assembly of claim 11 wherein the retention sheath has substantially a same outer diameter as the first shaft.

13. The dilator assembly of claim 11 wherein movement of the actuator from the second position to the third position brings a distal portion of the first shaft into contact with a proximal portion of the retention sheath.

14. The dilator assembly of claim 11 wherein the control assembly includes—

a housing;

a first shaft hub slidably positioned within the housing and coupled to the first shaft; and

a second shaft hub slidably positioned within the housing and coupled to the second shaft.

15. The dilator assembly of claim 14 wherein the first shaft hub is configured to engage the second shaft hub when the actuator is moved from the first position to the second position such that the first and second shafts advance together.

16. The dilator assembly of claim 14 wherein the first shaft hub is configured to disengage the second shaft hub when the actuator is moved from the second position to the third position such that first shaft advances relative to the second shaft.

17. The dilator assembly of claim 14 wherein the first shaft hub is configured to engage the second shaft hub when the actuator is moved from the first position to the second position such that the first and second shafts advance together, and wherein the first shaft hub is configured to disengage the second shaft hub when the actuator is moved from the second position to the third position such that first shaft advances relative to the second shaft.

18. The dilator of assembly of claim 14 wherein the second shaft hub includes a first engagement feature, wherein the housing includes a second engagement feature, and wherein the first engagement feature is configured to engage the second engagement feature at the second position to prevent movement of the second shaft hub when the actuator is moved from the second position to the third position.

19. The dilator assembly of claim 18 wherein the first engagement feature is a snap feature, and wherein the second engagement feature is a detent formed in the housing.

20. The dilator assembly of claim 14, further comprising a biasing member operably coupled to the first shaft hub, wherein the biasing member is configured to bias the first shaft hub from the third position toward the second position.

21. The dilator assembly of claim 11 wherein the control assembly further includes a housing, wherein the actuator is movable relative to the housing, wherein the movement of the actuator from the first position to the second position is distal movement of the actuator relative to the housing, and wherein the movement of the actuator from the second position to the third position is further distal movement of the actuator relative to the housing.

22. The dilator assembly of claim 11, further comprising the introducer sheath and the funnel.

23. A system for capturing a vascular thrombus within a blood vessel of a patient, the system comprising:

an introducer sheath having a distal portion;

an expandable funnel coupled to the distal portion of the introducer sheath;

a dilator assembly configured to be inserted through the introducer sheath and to deploy the expandable funnel, wherein the dilator assembly includes—

a first shaft defining a lumen;

a second shaft slidably positioned within the lumen of the first shaft;

a retention sheath coupled to the second shaft and configured to receive and constrain the funnel therein; and

a control assembly including an actuator operably coupled to the first and second shafts, wherein movement of the actuator from a first position to a second position distally advances the first and second shafts together to deploy the funnel from the retention sheath, and wherein movement of the actuator from the second position to a third position advances the first shaft relative to the second shaft; and

a clot removal device configured to be inserted through the introducer sheath to capture at least a portion of the vascular thrombus.

24. The system of claim 23 wherein the clot removal device includes an expandable coring element coupled to an expandable capture element, wherein the coring element is configured to separate at least a portion of the vascular thrombus from a wall of the blood vessel, and wherein the capture element is configured to capture and retain the portion of the vascular thrombus separated from the wall of the blood vessel.

25. The system of claim 23 wherein the funnel has a first length when deployed from the retention sheath, and wherein the coring element has a second length when expanded that is less than the first length.

26. A system for capturing a vascular thrombus within a blood vessel of a patient, the system comprising:

an introducer sheath having a distal portion;

an expandable funnel coupled to the distal portion of the introducer sheath;

a dilator assembly configured to be inserted through the introducer sheath and to deploy the expandable funnel; and

a clot removal device configured to be inserted through the introducer sheath, wherein the clot removal device includes an expandable coring element coupled to an expandable capture element, wherein the coring element includes a first region including a first mouth and a second region including a second mouth, wherein the first and second mouths are configured to separate at least a portion of the vascular thrombus from a wall of the blood vessel, and wherein the capture element is configured to capture and retain the portion of the vascular thrombus separated from the wall of the blood vessel.

27. The system of claim 26 wherein the first mouth is radially offset from the second mouth.

28. The system of claim 27 wherein the coring element is formed from a unitary structure including a plurality of struts, wherein the struts define the first and second mouths, wherein the struts further define a plurality of interstices, and wherein the first and second mouths are larger than each of the interstices.

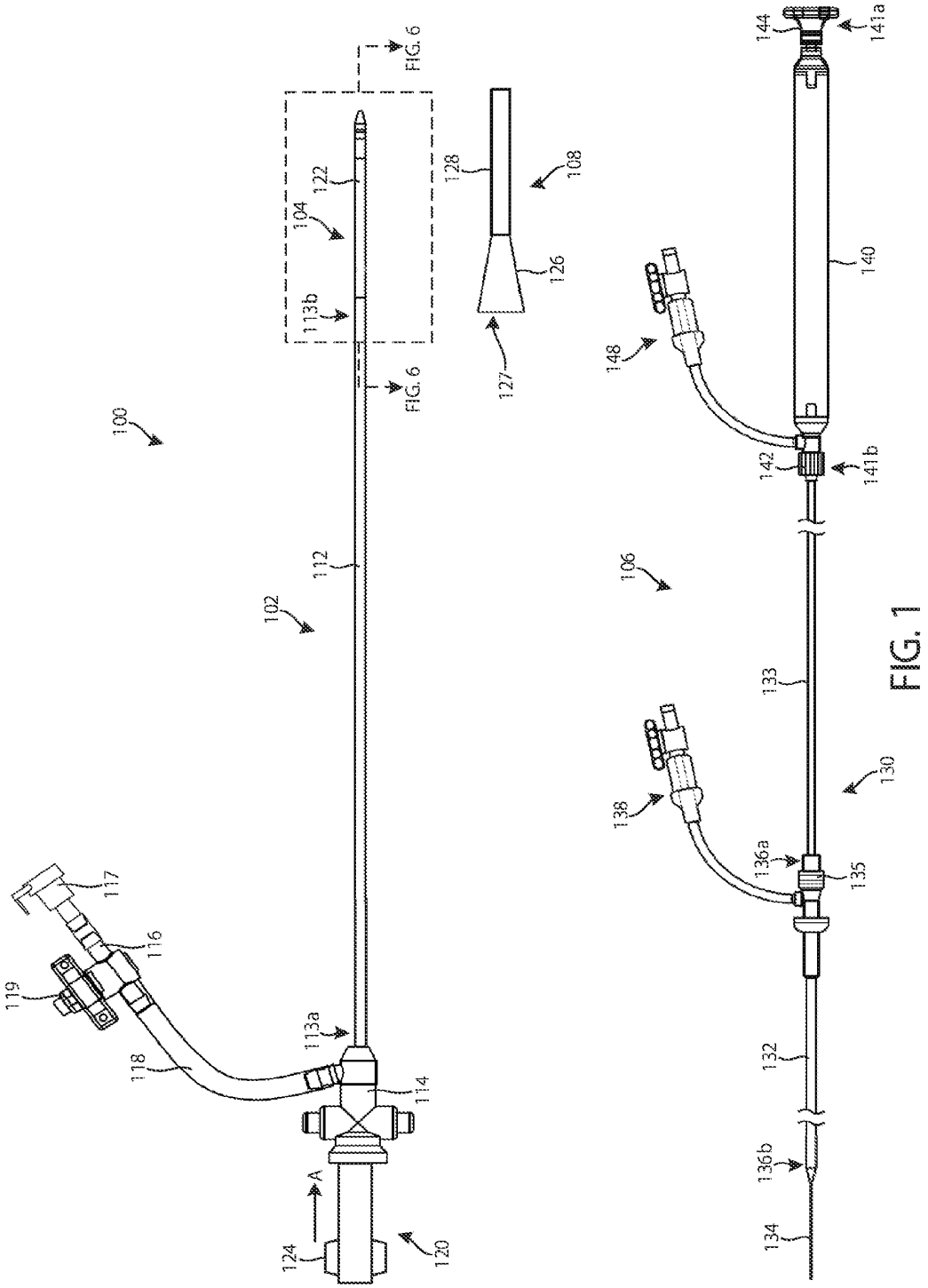
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FIG. 6
FIG. 6

FIG. 1

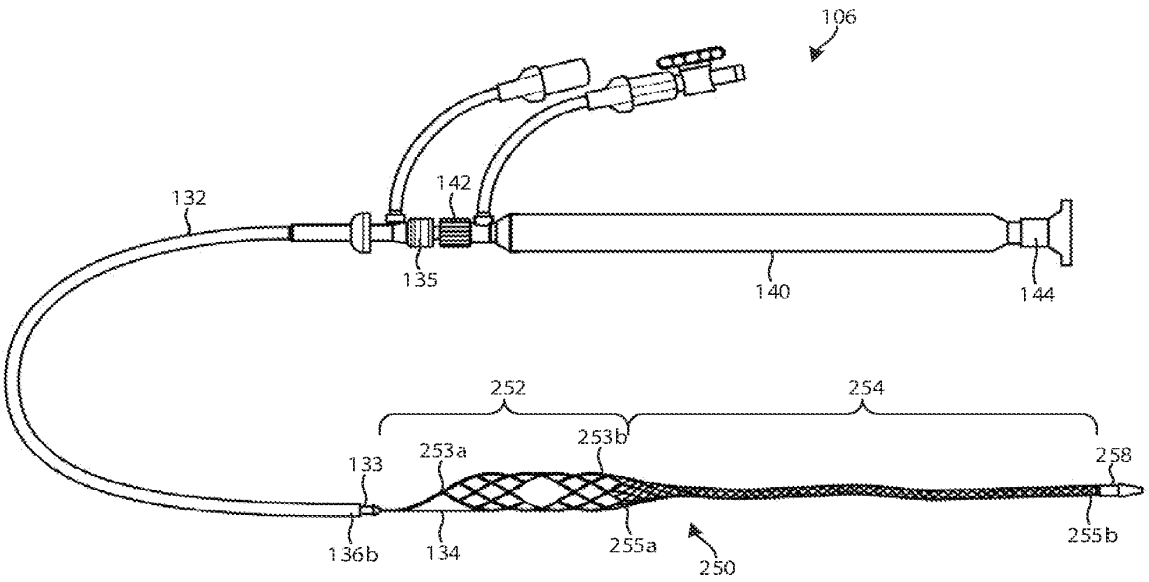
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FIG. 2A

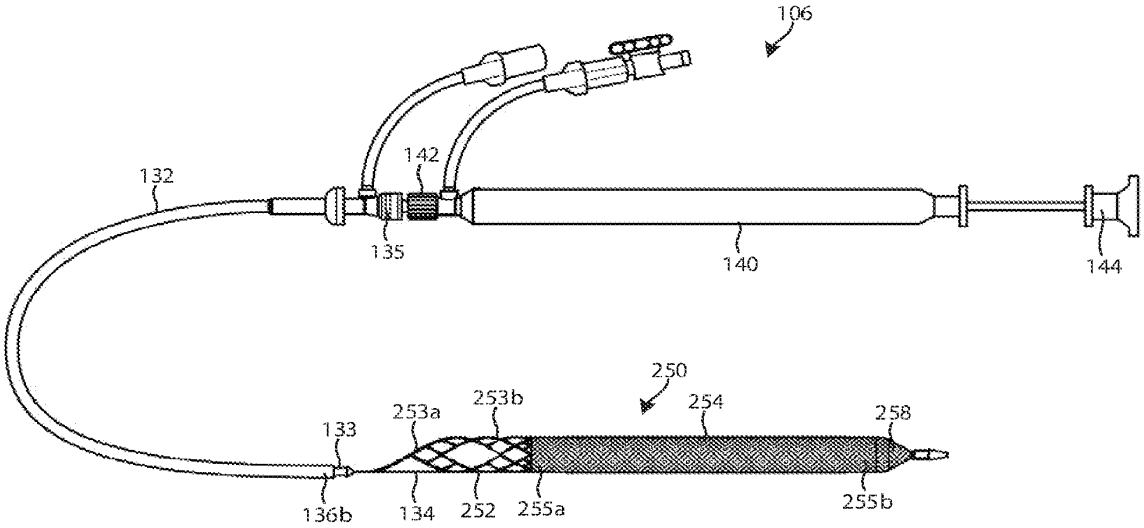
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FIG. 2B

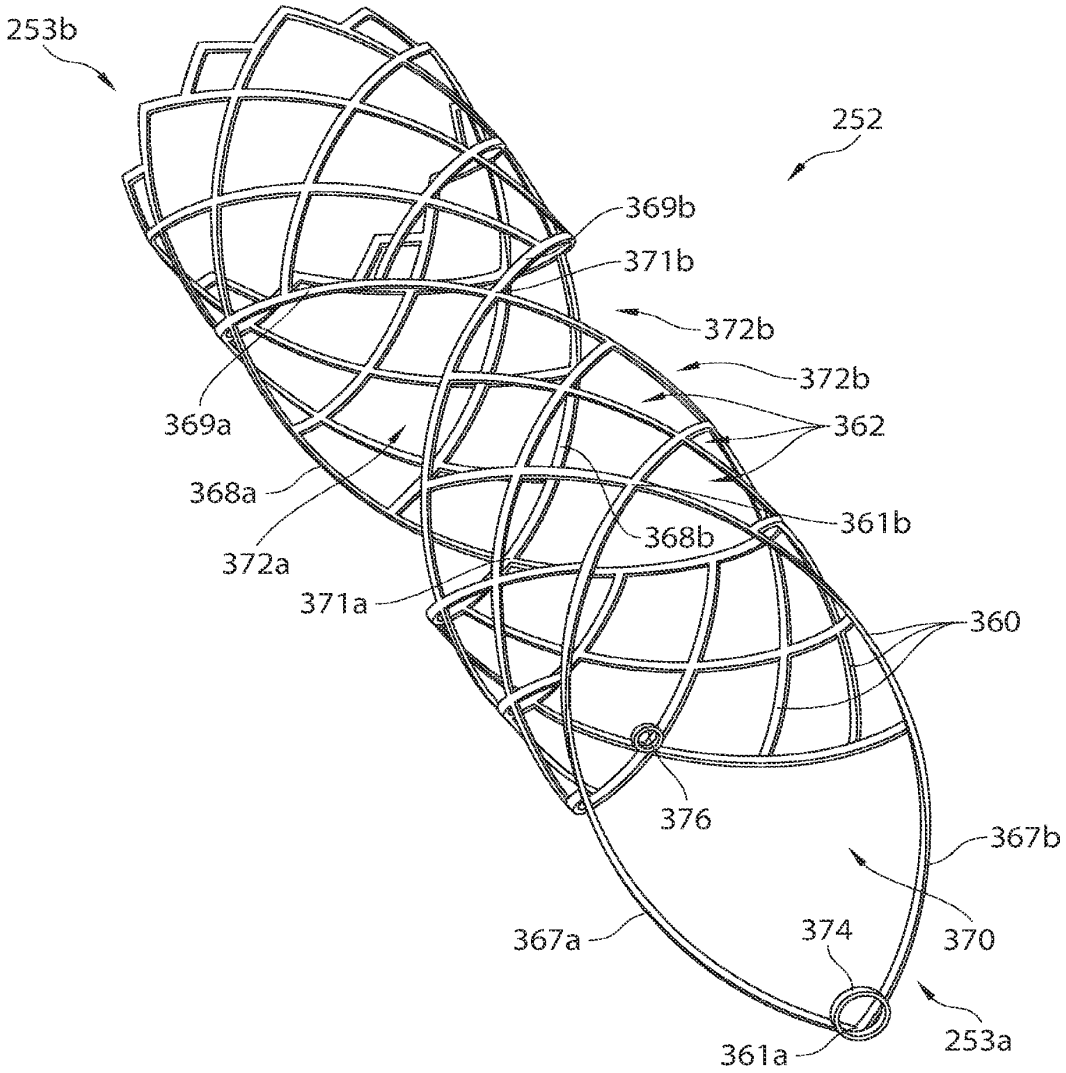
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FIG. 3A

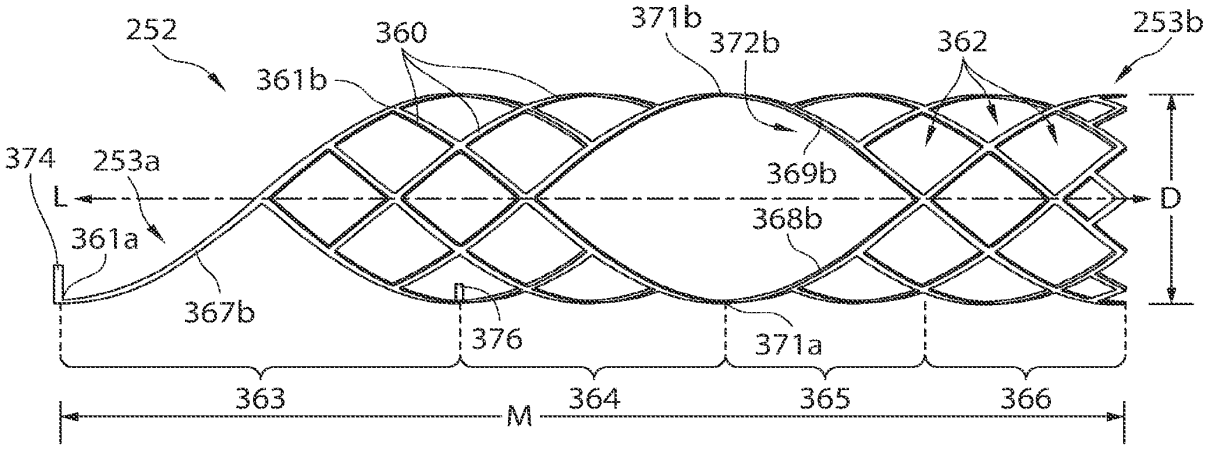
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FIG. 3B

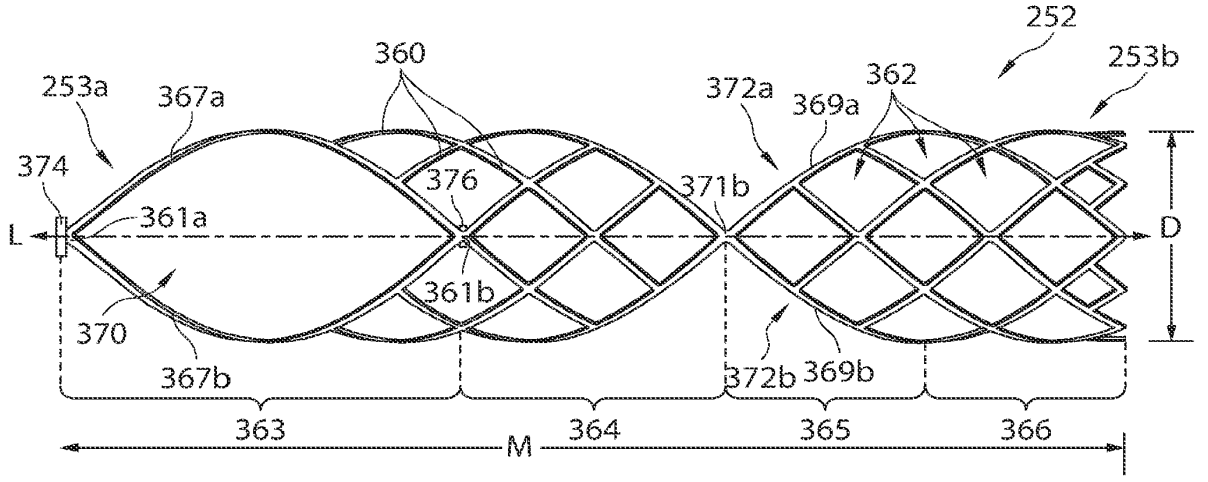
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FIG. 3C

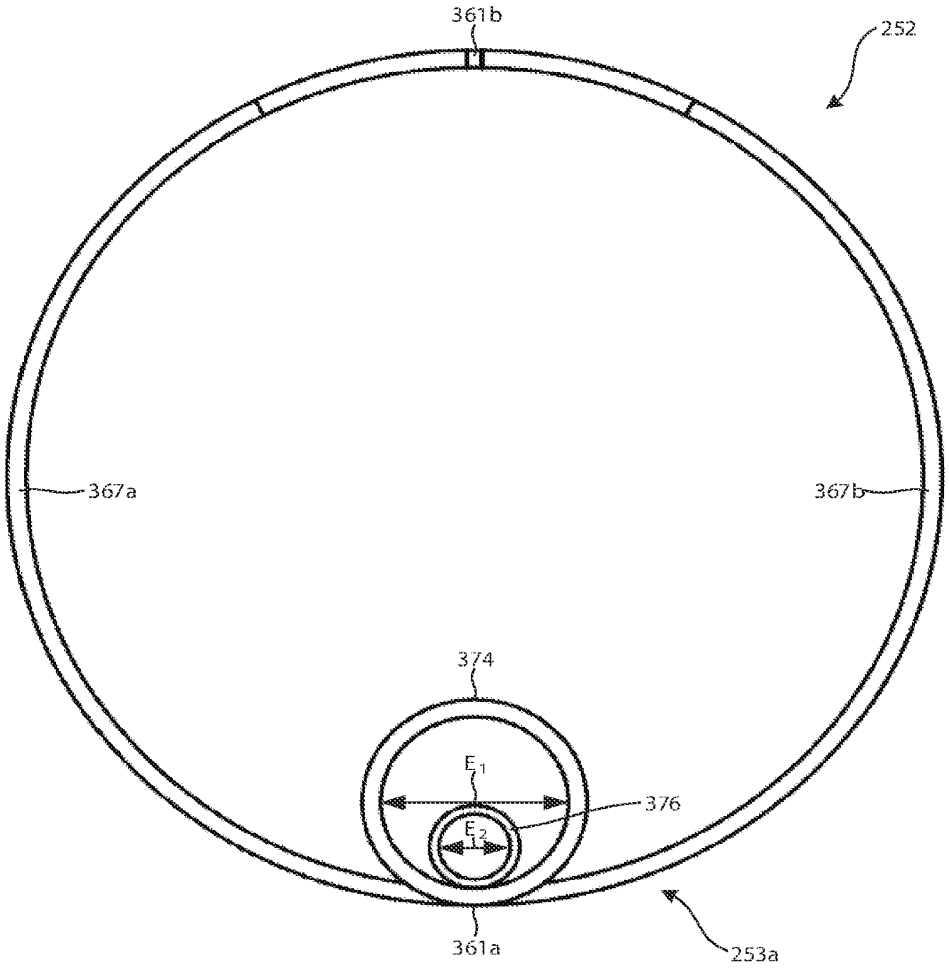

FIG. 3D

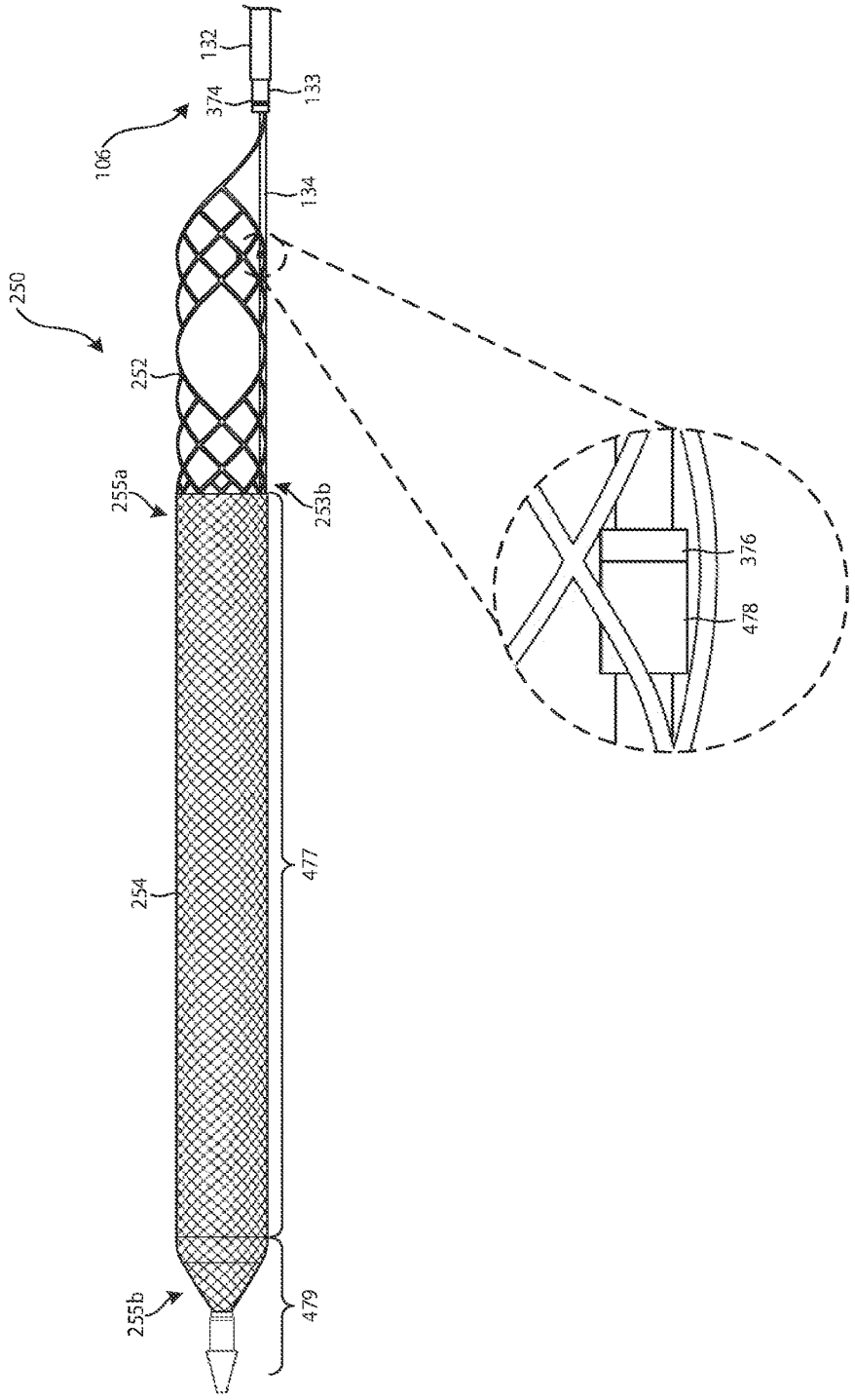

FIG. 4

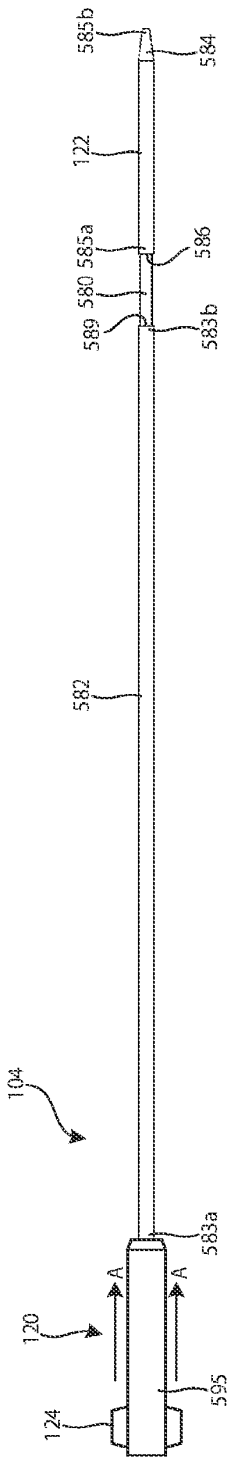

FIG. 5A

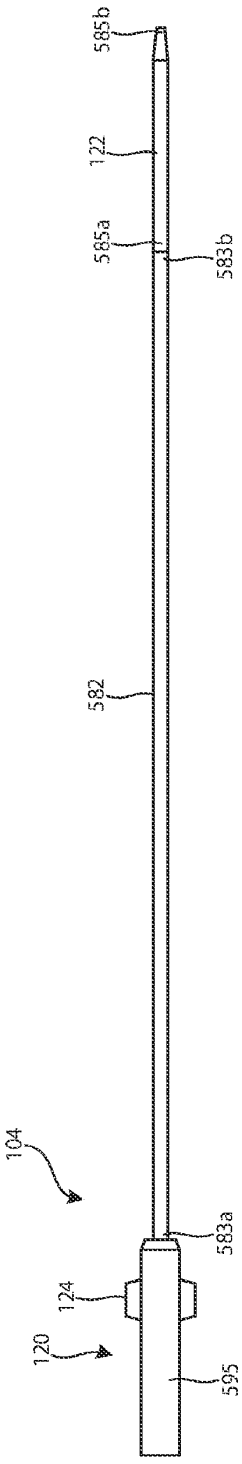

FIG. 5B

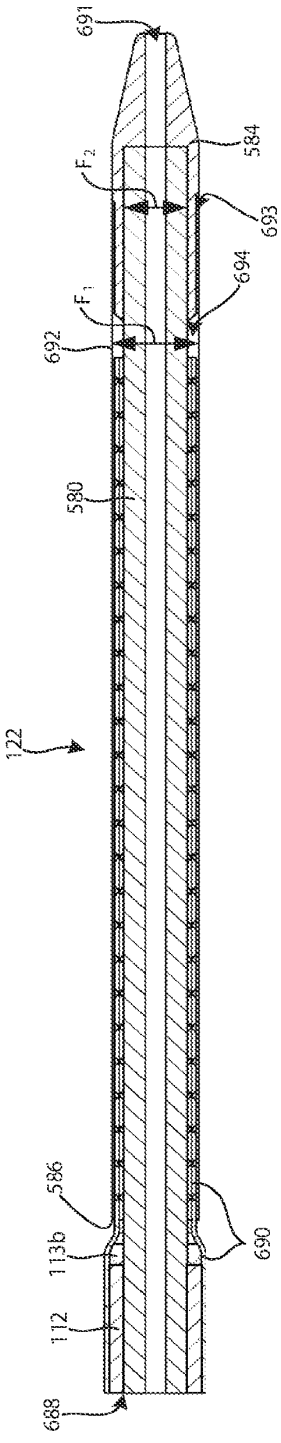

FIG. 6

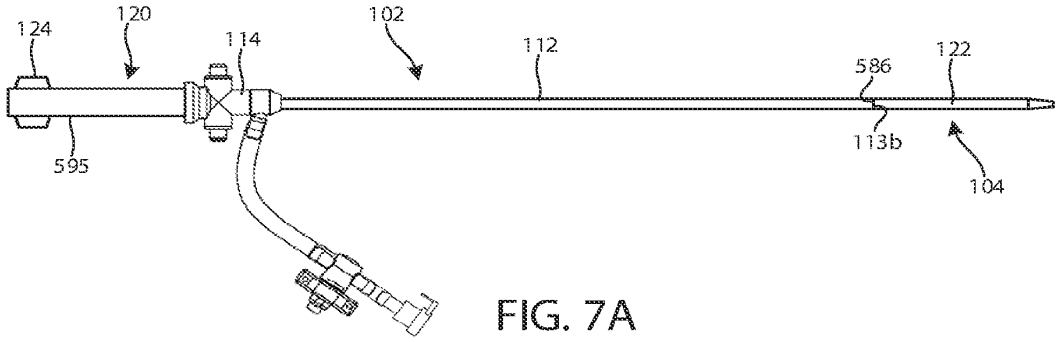

FIG. 7A

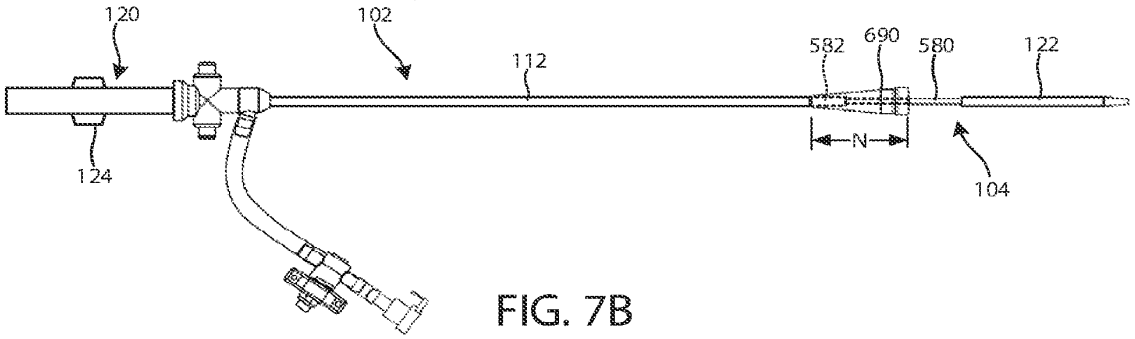

FIG. 7B

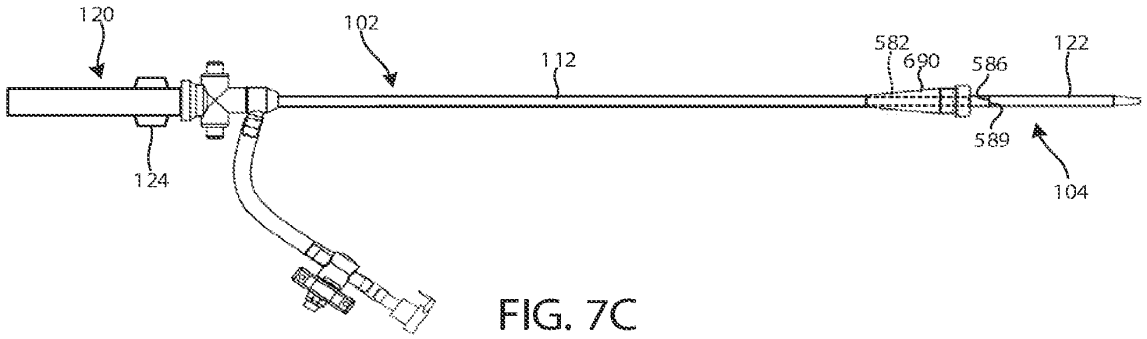

FIG. 7C

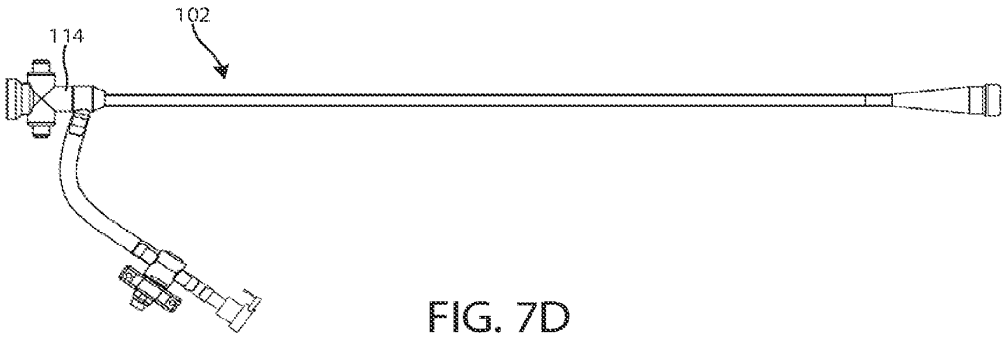

FIG. 7D

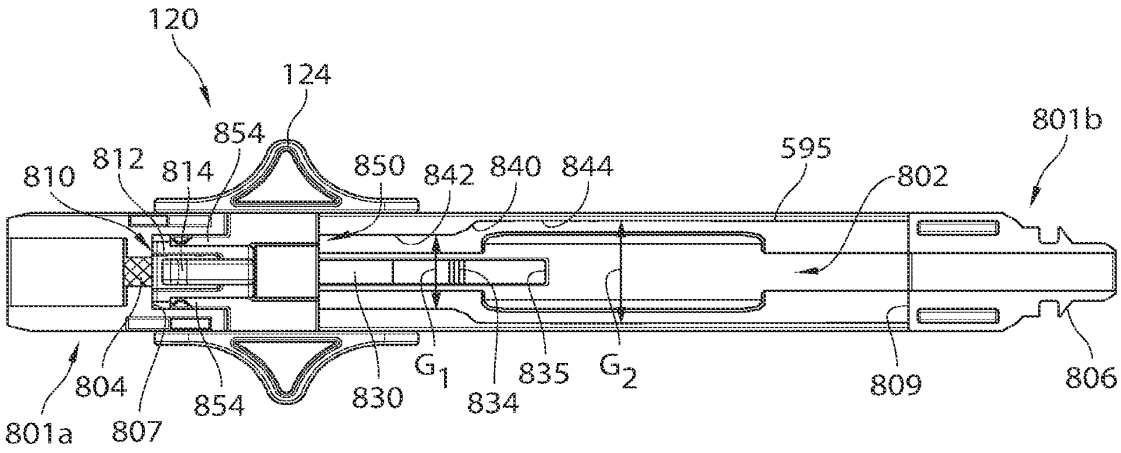
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FIG. 8A

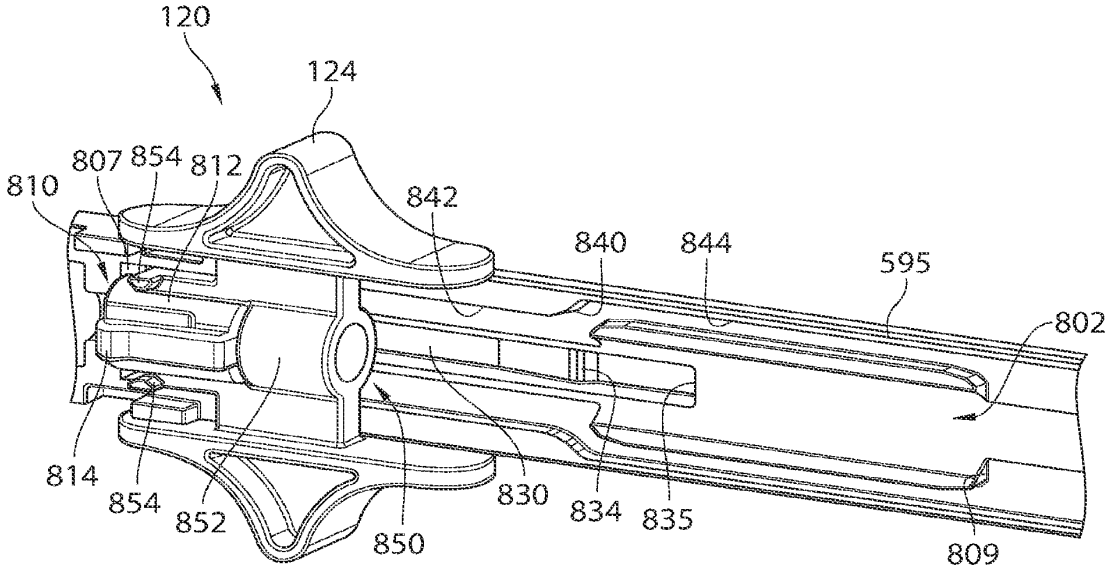
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FIG. 8B

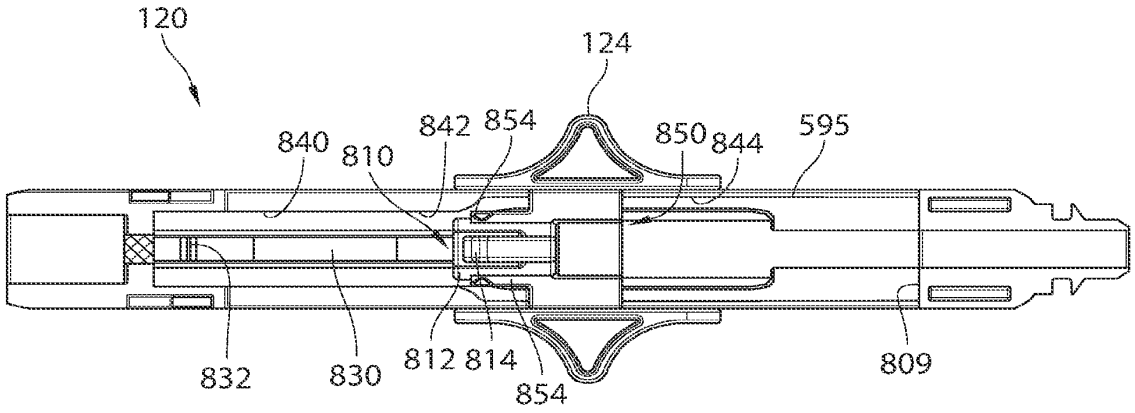
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FIG. 8C

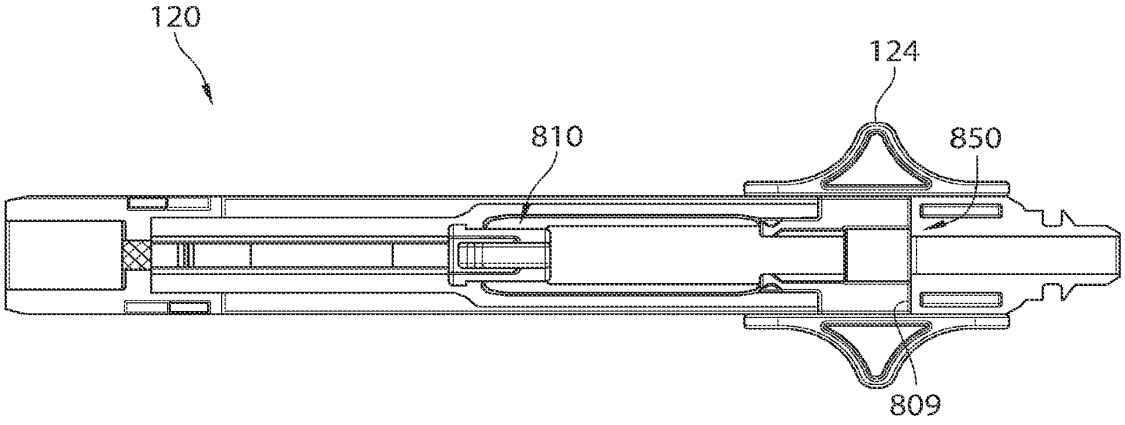
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FIG. 8D

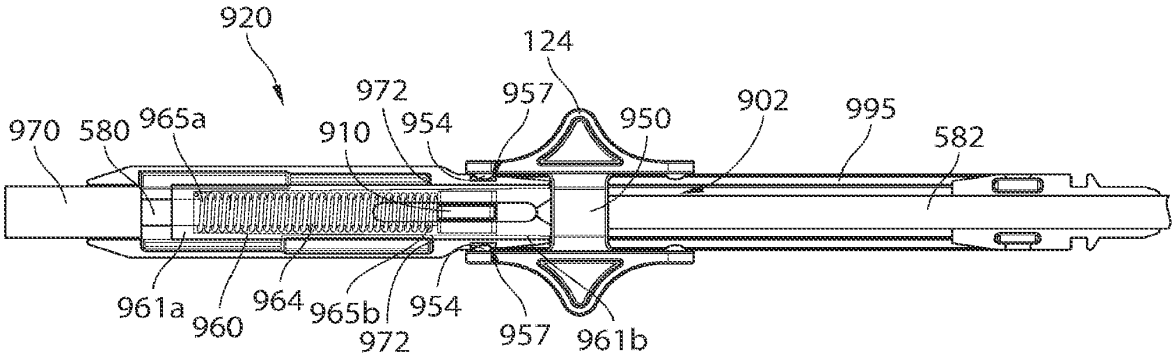


FIG. 9A

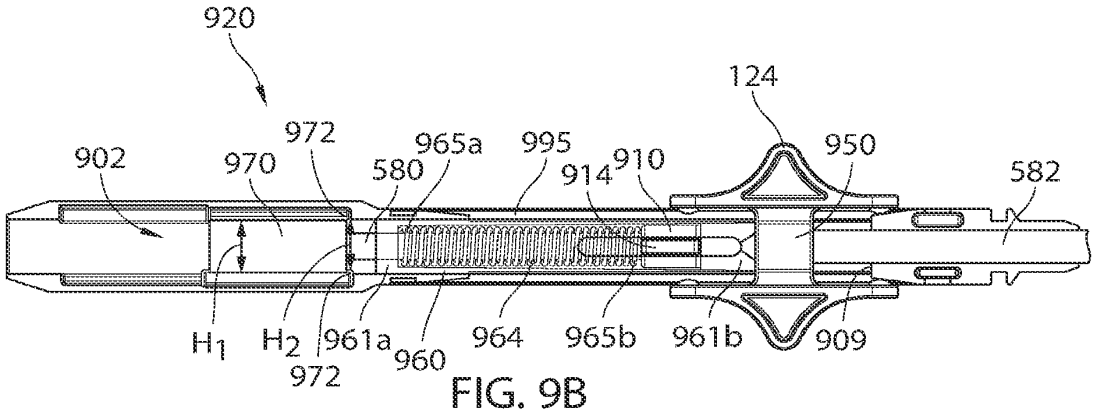


FIG. 9B

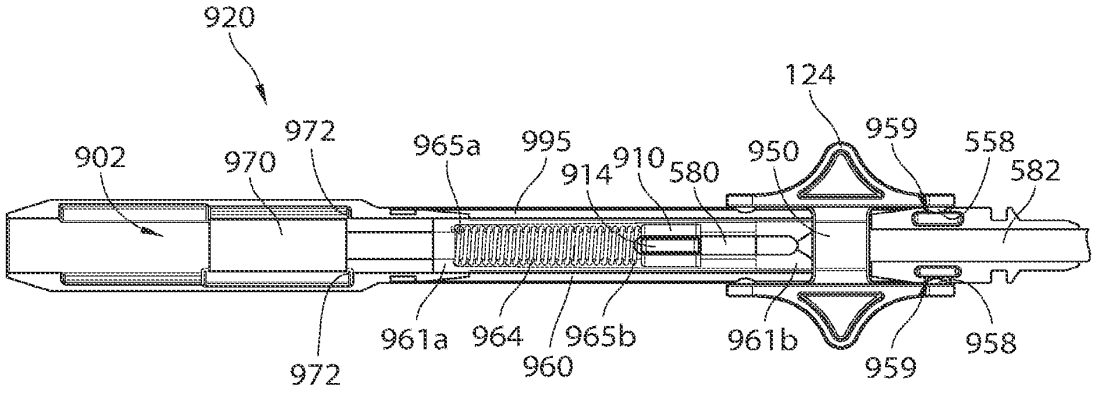


FIG. 9C

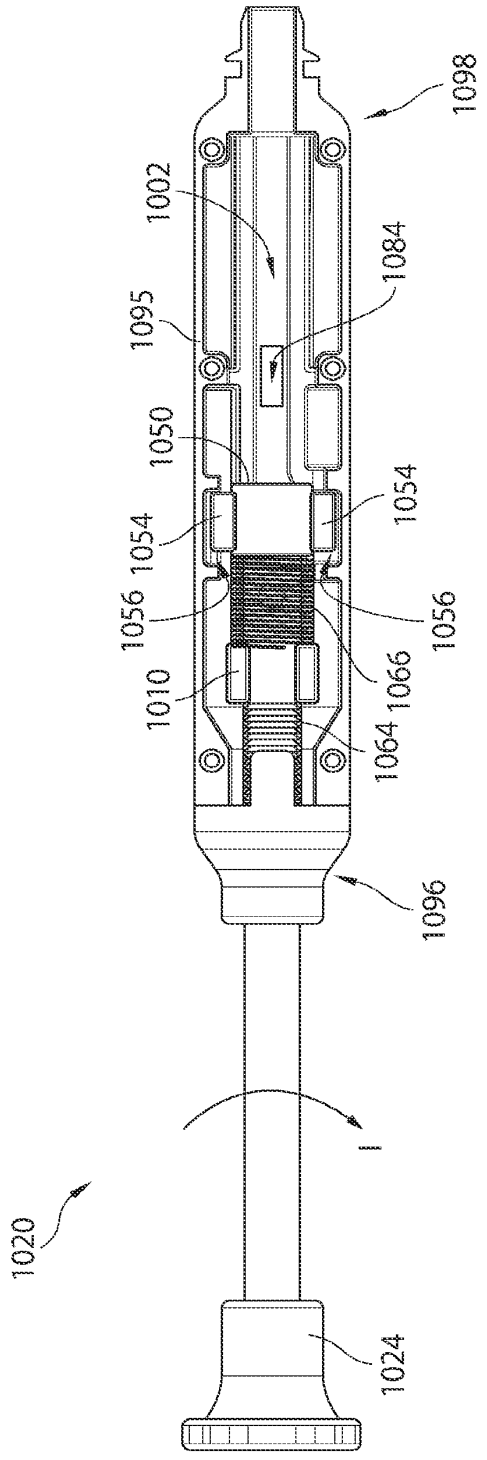


FIG. 10A

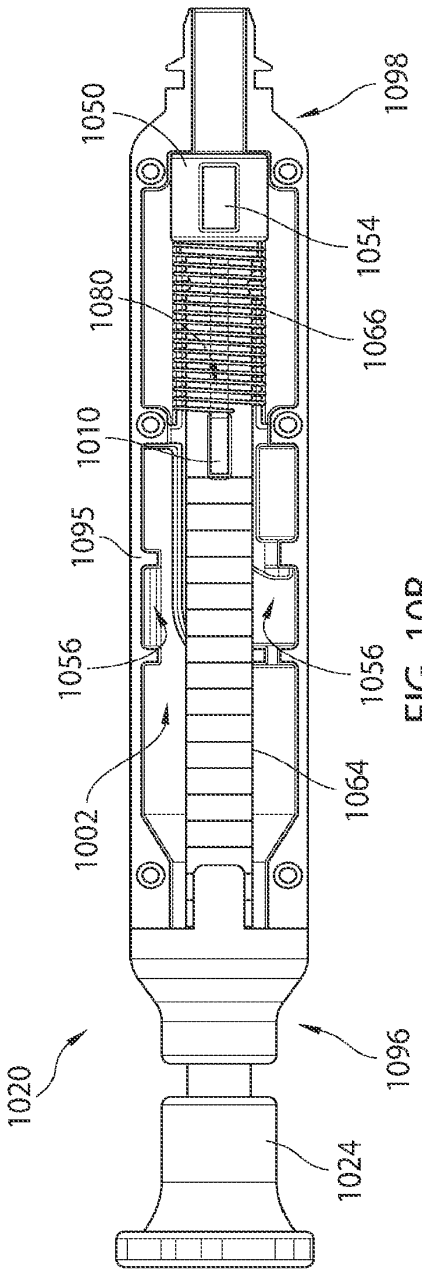
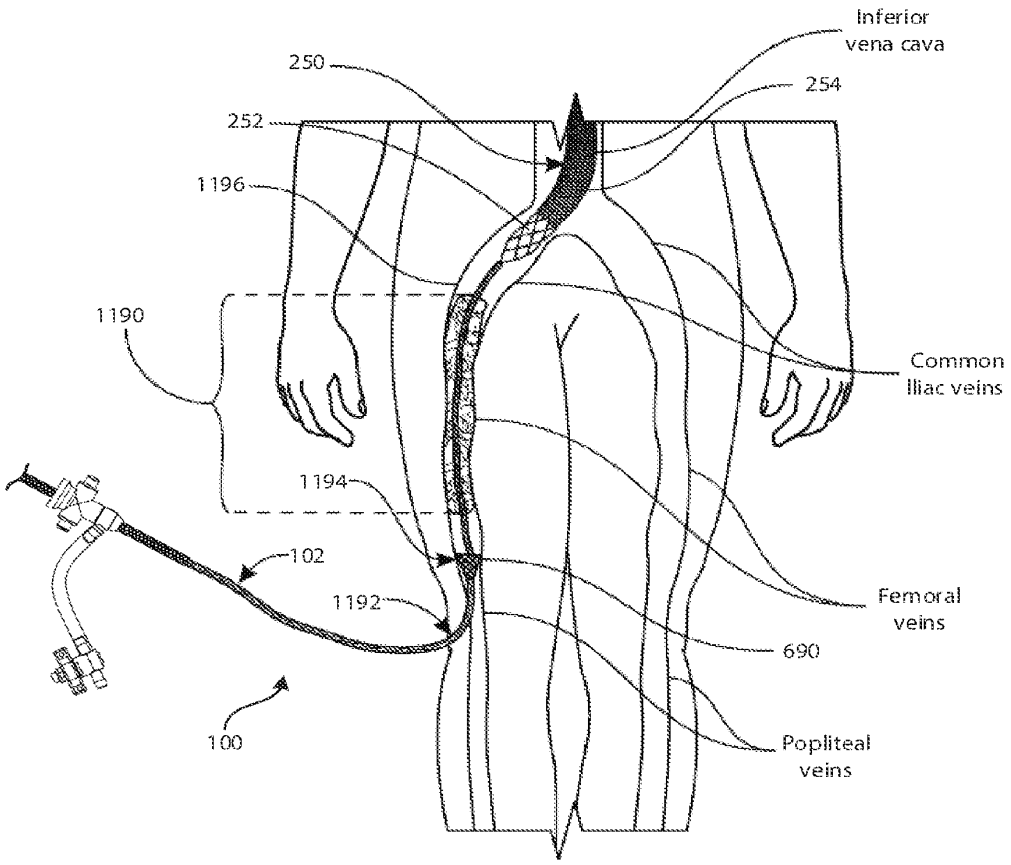


FIG. 10B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veins
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Popliteal
veins

FIG. 11

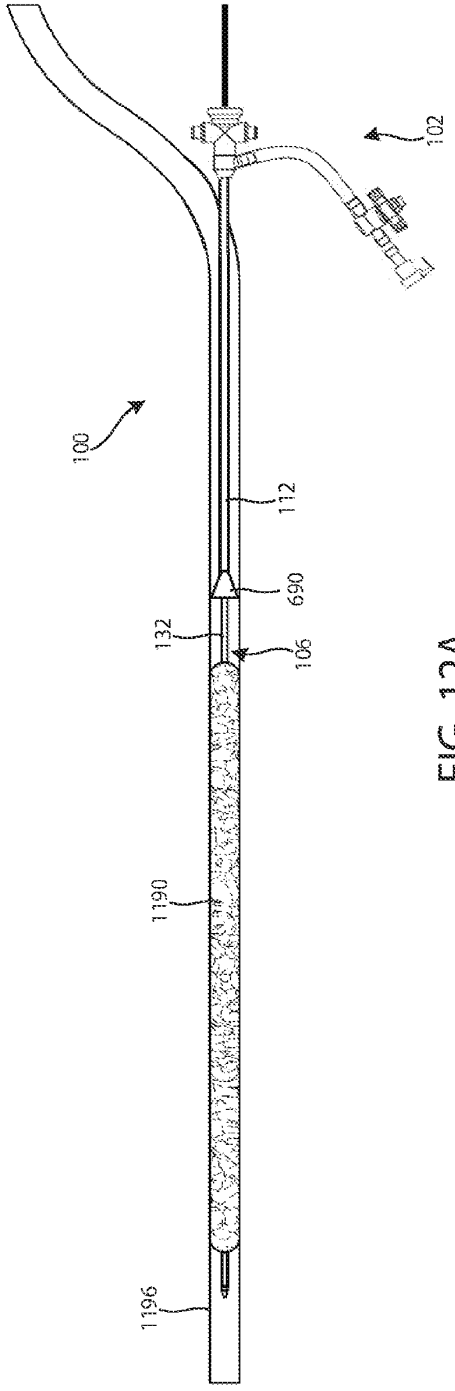

FIG. 12A

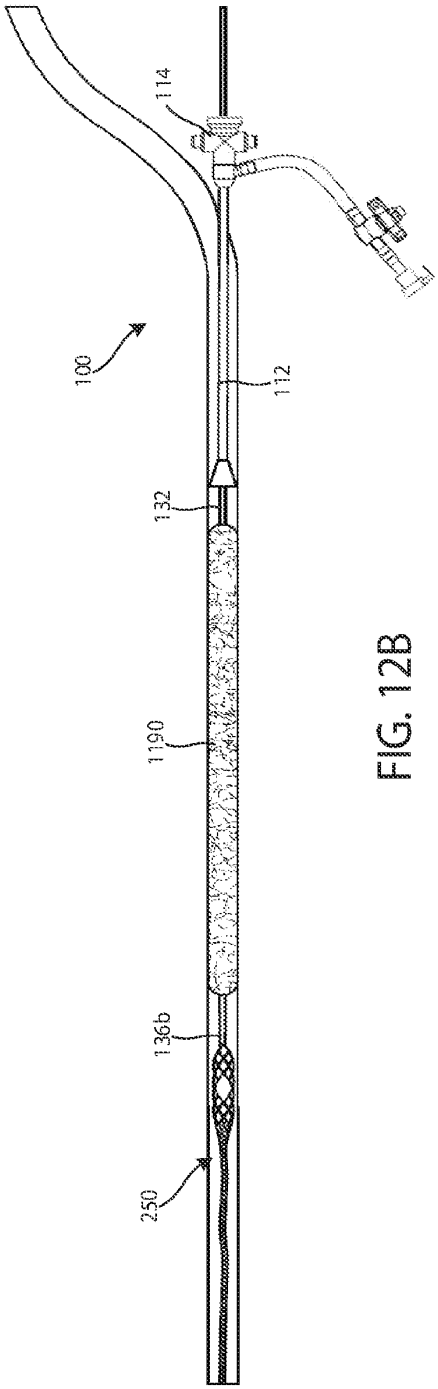

FIG. 12B

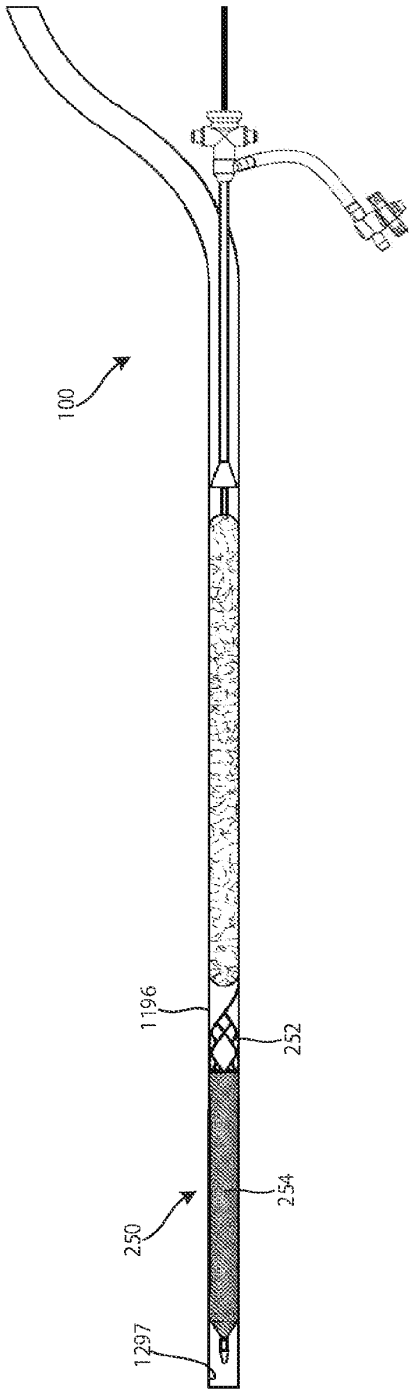

FIG. 12C

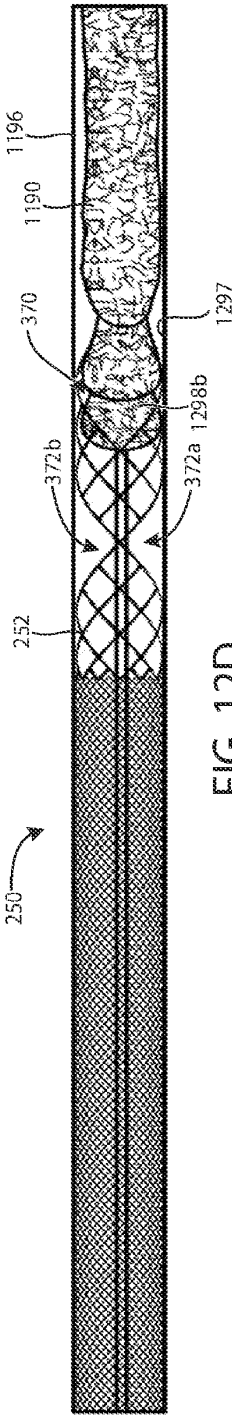

FIG. 12D

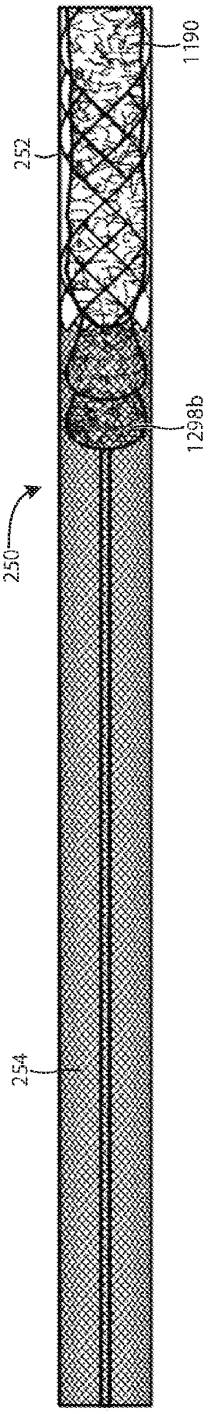

FIG. 12E

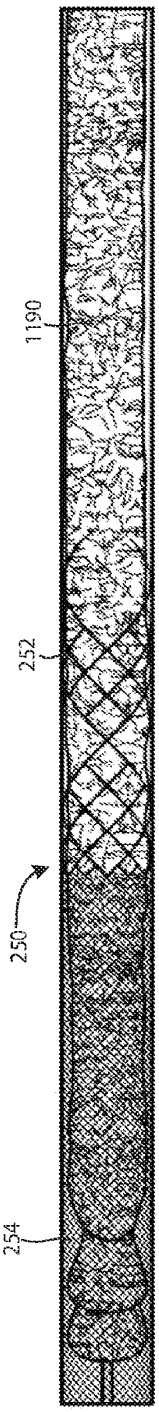

FIG. 12F

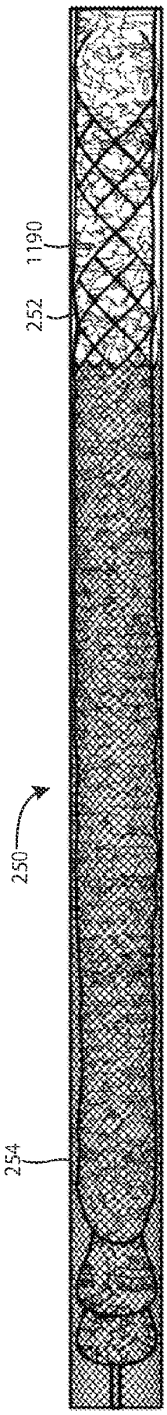

FIG. 12G

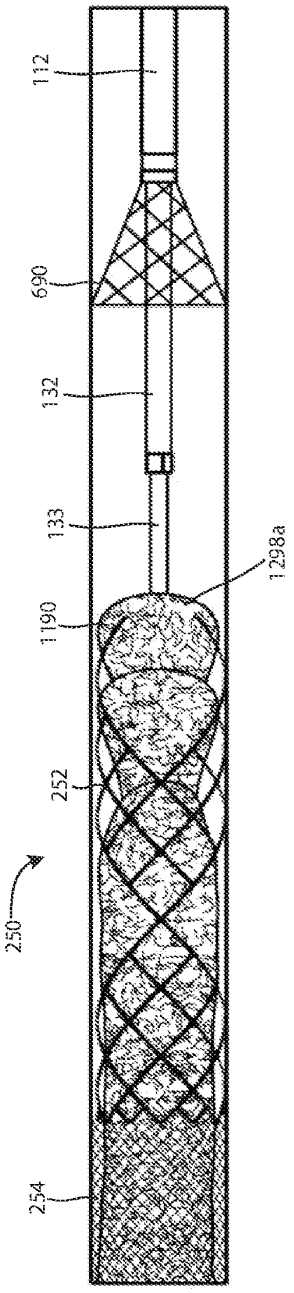

FIG. 12H

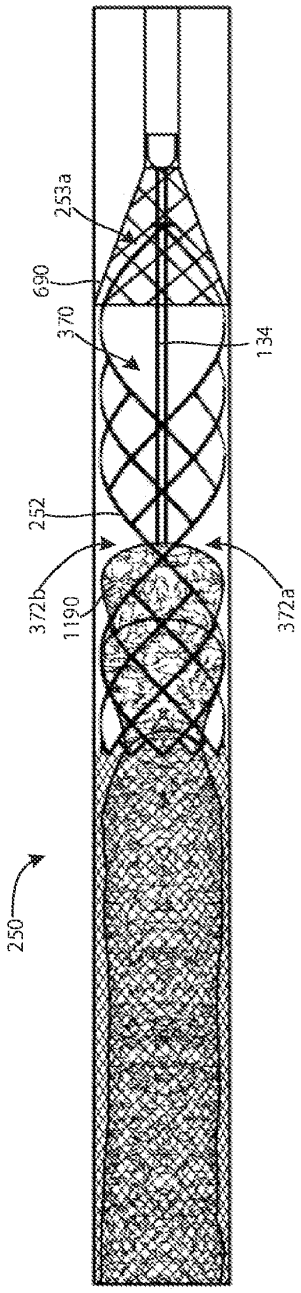

FIG. 12I

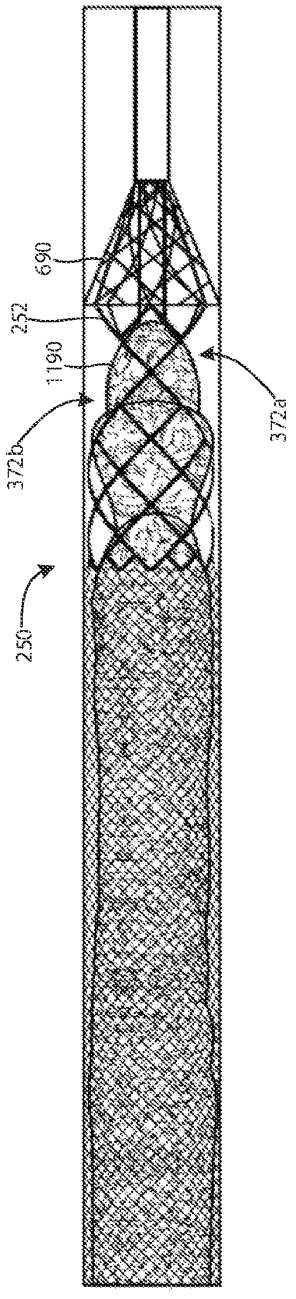

FIG. 12J

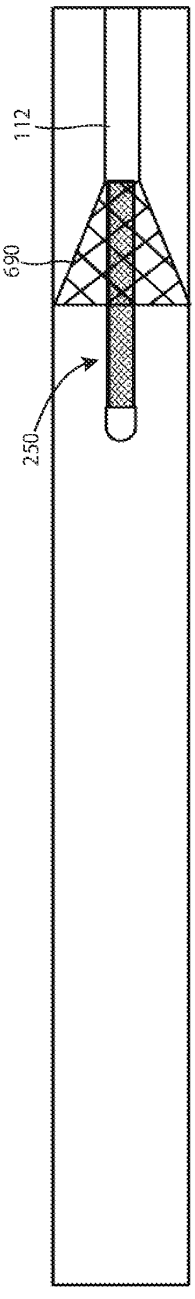

FIG. 12K

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/065645

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/221; A61B 17/22; A61B 17/3207; A61B 17/34; A61F 2/01; A61F 2/86 (2021.01)

CPC - A61B 17/221; A61B 17/320725; A61B 17/3415; A61B 2017/22041; A61B 2017/22094; A61B 2017/2212; A61B 2017/2215; A61B 2017/320741; A61F 2/011; A61F 2/013; A61F 2002/016; A61F 2002/018; A61F 2230/0069 (2021.02)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

see Search History document

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

see Search History document

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

see Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014/0371779 A1 (NEURAVI LIMITED) 18 December 2014 (18.12.2014) entire document	1-10
A	US 2011/0160763 A1 (FERRERA et al) 30 June 2011 (30.06.2011) entire document	1-10
A	US 2017/0112513 A1 (INARI MEDICAL) 27 April 2017 (27.04.2017) entire document	1-10
A	US 2018/0092652 A1 (INARI MEDICAL, INC.) 05 April 2018 (05.04.2018) entire document	1-10

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 March 2021	APR 14 2021
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver Telephone No. PCT Helpdesk: 571-272-4300

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/065645

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
See extra sheet(s).

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

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

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

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-10

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/065645

Continued from Box No. III Observations where unity of invention is lacking

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

Group I, claims 1-10, are drawn to a coring element for coring a vascular thrombus within a blood vessel of a patient.

Group II, claims 11-28, are drawn to a dilator assembly for deploying an expandable funnel coupled to a distal portion of an introducer sheath.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of the Group I invention: the coring element comprising: a unitary structure having a first region adjacent to a proximal portion of the unitary structure, wherein the first region includes a first mouth configured to core the vascular thrombus; a second region distal of the first region, wherein the second region is generally tubular and includes a first plurality of interconnected struts; a third region distal of the second region, wherein the third region includes a second mouth configured to core the vascular thrombus; and a fourth region distal of the third region, wherein the fourth region is generally tubular and includes a second plurality of interconnected struts as claimed therein is not present in the invention of Group II. The special technical feature of the Group II invention: a dilator assembly for deploying an expandable funnel coupled to a distal portion of an introducer sheath, the dilator assembly comprising: a first shaft defining a lumen; a second shaft slidably positioned within the lumen of the first shaft; a retention sheath coupled to the second shaft and configured to receive and constrain the funnel therein; and a control assembly including an actuator operably coupled to the first and second shafts, wherein movement of the actuator from a first position to a second position advances the first and second shafts together to deploy the funnel from the retention sheath, and wherein movement of the actuator from the second position to a third position advances the first shaft relative to the second shaft as claimed therein is not present in the invention of Group I.

Groups I and II lack unity of invention because even though the inventions of these groups require the technical feature of capturing a vascular thrombus within a blood vessel of a patient, this technical feature is not a special technical feature as it does not make a contribution over the prior art.

Specifically, US 2018/0092652 A1 to Inari Medical, Inc. teaches capturing a vascular thrombus within a blood vessel of a patient (The method includes retracting the thrombus extraction device proximally so that the coring portion cores and separates a portion of the vascular thrombus from the venous vessel wall while the mesh structure captures the vascular thrombus portion. The method includes withdrawing the thrombus extraction device from the patient to remove the vascular thrombus portion from the venous vessel, para. 0008. One aspect of the present disclosure relates to a method for removal of thrombus from a blood vessel in a body of a patient, which blood vessel can be an artery or a vein, para. 0017).

Since none of the special technical features of the Group I or II inventions are found in more than one of the inventions, unity of invention is lacking.

(19)中华人民共和国国家知识产权局

(12)发明专利

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(51)Int.Cl.
A61F 2/01(2006.01)
审查员 付林峰

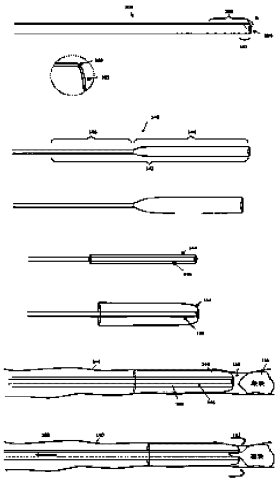
权利要求书2页 说明书31页 附图83页

(54)发明名称

机械取栓装置和方法

(57)摘要

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



CN 108348319 B

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

导管，具有远侧端部、远侧端部开口和内径；

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

穿过所述导管和所述柔性管的导丝腔，被配置成使导丝通过。

2.根据权利要求1所述的机械取栓装置，其中，所述柔性管包括针织管。

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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机械取栓装置和方法

[0001] 相关申请的交叉引用

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

[0003] 通过引用结合

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

技术领域

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

背景技术

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

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

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

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

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

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

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

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

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

发明内容

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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区域之间，同时可扩张的第一端部区域在可较少扩张的第二端部区域上翻折。

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

附图说明

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

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

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

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

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

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

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

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

[0083] 图8示出了包括可选真空源的取栓装置。

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

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

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

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

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

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

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合剂、焊接件(例如,脆的粘合剂或其他附件)、卡扣配合件、抓持件等。

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

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

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

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

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

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

[0096] 图19A和图18B示出了用于组装如本文所述的装置的组装方法。

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

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

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

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

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

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

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

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

[0105] 图27A和图27B示出了穿过26A至图26B的装置的截面图。

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

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

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

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

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

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

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

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

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

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

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

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

具体实施方式

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

[0118] 本文所描述的装置（例如，用于从血管去除凝块的机械取栓装置）可以是包括具有远侧端部和远侧端部开口的细长导管的组件以及至少部分位于导管内的柔性牵引器组件，其中，牵引器组件的远侧端部区域被配置为远侧牵引器区域，远侧牵引器区域至少部分地在导管内延伸并且在导管的远侧端部上翻折回来。牵引器组件可以包括连接到远侧牵引器区域的近侧推动器区域。柔性牵引器组件包括配置成允许导丝通过的细长腔。柔性牵引器组件还被配置成在近侧端部区域被向近侧拉动时沿着导管腔内的长轴线滑动并且在导管的远侧端部开口上翻转。牵引器组件在本文可被称为柔性牵引器组件、柔性牵引器部分、柔性牵引器管或简单的柔性管，并且典型地定位在导管内并且可在导管内纵向可滑动，并且布置成使得远侧端部区域（“远侧牵引器区域”）在导管的远侧端部上翻折回来。

[0119] 例如，图1A示出了可形成本文所描述的装置的一部分的导管的一种变型。在该示例中，导管100包括远侧端部区域103，远侧端部区域包括远侧端部105。除了非常远侧尖端（远侧端部105）可以实质上比紧邻其的区域较不柔软之外，远侧端部区域可以具有增加的柔软度（通过硬度计测量，例如肖氏硬度计）。因此，虽然远侧尖端区域（例如，最远侧的x线性尺寸，其中x为10cm、7cm、5cm、4cm、3cm、2cm、1cm、9mm、8mm、7mm、6mm、5mm、4mm、3mm）具有从近侧端部到远侧端部延伸的增加的柔软度/减小的硬度，非常远侧端部区域107（例如，测量为最远侧的z线性尺寸，其中z为1cm、9mm、8mm、7mm、6mm、5mm、4mm、3mm、2mm、1mm、0.8mm、0.5mm、0.3mm、0.2mm等，并且z总是比x小至少三倍）的硬度大于紧邻其的区域的硬度，并且可以与远侧尖端区域的最近侧区域一样硬或比其更硬。

[0120] 导管100也可以被称为内导管或牵引器导管。可以使用任何适当类型的导管，包括适用于神经血管使用的微导管。

[0121] 在一些变型中，导管的远侧端部105适于使得远侧牵引器区域可以在导管的远侧端部上滑动并翻转而不被捕获（束缚）或没有实质摩擦。例如，在一些变型中，远侧尖端（端部）可以是弯曲的或倒圆的109，如图1B所示。特别是在外表面上（例如从外径到内径的过渡）。在一些变型中，远侧尖端包括一个或多个通道，如图25A至图28所示和所述的，包括围绕面向远侧的边缘的通道，以引导远侧牵引器区域的滑动。

[0122] 图1C示出了柔性牵引器管140的示例。在图1C中，管是柔性的并且细长（具有通常比导管101大的长度），并且包括远侧牵引器区域142，该远侧牵引器区域包括配置成紧邻近侧区域146上折叠的最远侧可扩张的第一端部区域144，其可以是可较少扩张的第二端部区域。通常，可扩张的远侧端部区域被配置成在不受约束时扩张至介于导管的内径的直径的1.3倍至10倍之间的径向直径。图1D示出了处于扩张配置的图1C的可扩张的远侧端部区域。因此可扩张的远侧端部区域可以被偏置以扩张打开。可扩张的远侧端部区域可以形成为网状物、机织物或材料片，并且通常适于抓取待去除的物体（例如血凝块）。

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[0123] 图1C中一般性示出的柔性牵引器管被示出为图1E中的可扩张的远侧端部区域在其本身上(例如在更近侧的可较少扩张的第二端部区域上)翻折回来。在图1E中,可扩张的远侧端部区域收缩,而在图1F中,可扩张的远侧端部区域扩张。通常,可扩张的远侧端部区域可以与近侧的可较少扩张的第二端部区域区分开,然而在一些变型中,整个柔性牵引器管可以包括在导管内被推动和/或拉动且不包括近侧的可较少扩张的远侧端部区域的可扩张的材料(例如,网状物、机织物等)。

[0124] 图1G和图1H示出了使用诸如由图1A和图1E的部件组装的装置的装置去除凝块。在该示例中,该装置被配置为包括导管101和柔性牵引器管的取栓装置,该柔性牵引器管包括可扩张的远侧端部区域144,该可扩张的远侧端部区域在导管的远侧端部区域上延伸并且在导管的远侧端部上翻折,使得可扩张的远侧端部区域与内近侧的可较少扩张的(在该示例中,可较少扩张的包括不可扩张的)第二远侧端部区域146连续,该第二远侧端部区域在导管内向近侧延伸并形成可使导丝通过的内腔。柔性牵引器管(未示出)的近侧端部可以包括推动器/拉动器构件,该推动器/拉动器构件可以是与远侧端部区域(远侧牵引器区域140)连续的杆或其它构件。在图1G中,装置被示出在凝块155附近的血管160内定位并展开。通过将远侧牵引器区域140取回到导管101中,可以将凝块拉入导管中,如箭头180所示,其示出了柔性牵引器管的内部部分的拉动(例如,使用手柄,未示出),从而导致将可扩张的远侧端部区域拉动到导管远侧端部中并翻转可扩张的远侧端部区域,使得其被拉动到导管中,如箭头182所示。可扩张的远侧端部区域的远侧端部可相对于导管的外壁“松动”,或者其可被去除附接或在一些变型中永久附接。

[0125] 通常,定位这些装置并致动它们可能是具有挑战性的,这是因为它们在致动之前和操作期间都必须是高度柔性的。例如,一般来说,柔性牵引器管必须不能增加导管的刚度/柔性,并且特别是导管的远侧端部区域过多,或者对于操纵来说过于困难和/或危险,特别是在神经血管系统的侵蚀血管内。本文所描述的是柔性牵引器管部分,其增加了小于预定百分比(例如,小于10%、12%、15%、18%、20%、25%、30%等)的导管的最后ycm(例如,最远侧的20cm、18cm、15cm、12cm、10cm、9cm、8cm、7cm、6cm、5cm、4cm、3cm、2cm、1cm等)的刚度。例如,本文所描述的是柔性牵引器管部分,其穿过导管并且在导管的远侧端部上翻折回来,但是在没有柔性管延伸穿过其中并且在导管的远侧端部上翻折回来的情况下,将导管的远侧5cm的刚度增加小于导管的远侧5cm的刚度的15%。

[0126] 例如,图2A示出了柔性牵引器管201。在该示例中,柔性牵引器管包括在近侧推动器区域201的远侧的远侧牵引器区域242,该远侧牵引器区域具有可扩张的第一端部区域244以及可较少扩张的第二端部区域246。整个柔性牵引器管是中空的并且可以使导丝通过(未示出)。柔性牵引器管的各个区域可以由相同的材料(例如,机织的、编织的等细丝(filament)或多个细丝)制成,或者它们可以由不同的材料制成。

[0127] 图2B示出了具有远侧牵引器区域的柔性牵引器管,或者至少由多个机织纤维形成的可扩张的第一端部区域244'。可替代地,可扩张的第一端部区域可由一个(或多个)针织纤维或机织和针织纤维的组合形成。可扩张的第一端部区域可以通过纤维或机织/针织图案的形状设定特性或通过包含一个或多个偏置构件(例如,环、弹簧、带、细丝等)而被偏置地打开(如图所示),其倾向于至少将可扩张的第一端部区域的远侧端部区域偏置打开。

[0128] 图2C示出了由包括多个开口(例如,孔、穿孔、通道、窗口等)的材料片形成的可扩

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张的第一端部区域的另一变型。这些开口可以是任何尺寸，包括不均匀尺寸(例如尺寸的范围)或均匀尺寸。穿过片的这些开口的尺寸可取决于所使用的材料，例如聚合物材料(PTFE)、硅树脂材料、聚氨酯、形状记忆合金等。在一些变型中，片的孔隙率大于>60％(大于70％、大于75％、大于80％、大于85％等、在60％至95％之间、在65％至95％之间、在70％至95％之间等)是有益的。

[0129] 在这些变型中的任一个中，远侧牵引器区域被配置成使得其可以在其本身上被翻转(例如，翻折)，如图2D所示。在一些变型中，该装置可被执行为使得可扩张的第一端部区域在其本身上和/或在导管的远侧端部区域上翻转，或者其可以被配置成使得其可以在体内(例如在血管内)在导管的远侧端部展开和翻转。通常，在装置可被致动之前，导管可以插入可扩张的第一端部区域与柔性牵引器管上的可扩张的第一端部区域的近侧的区域之间，在一些变型中，其可以是可较少扩张的第二远侧端部区域。该空间289可以通过在可扩张的第一端部区域的远侧端部处或附近的偏置构件而保持打开。如所提到的，该可扩张的第一端部区域开口偏置构件可以是环、带、弹簧、线圈等，并且可以由偏置元件(例如，形状设定材料，诸如形状记忆合金)、橡胶或其他聚合物材料等制成。

[0130] 尽管存在相关的挑战，但是本文所描述的装置的体内展开可以为操作装置的用户提供许多优点。图3A至图3F示出了配置用于体内展开的取栓装置的一个示例。在该示例中，该装置包括导管301，该导管可以使用导丝313定位(如同本文所描述的变型中的任一个)。导丝可以延伸到或进入(或穿过)待去除的物体，其示出为在血管360内的图3A中的凝块355。装置的导管可以与导丝一起插入或在导丝之后插入，并且在有或没有柔性牵引器管在导管的远侧端部处或附近的情况下，可以将导管定位在凝块附近(例如，邻近或紧邻)。在图3A中，在导丝已经定位之后，定位导管，并且如图3B所示，从血管中取出导管。导丝可以是线材，较小的导管或可以定位(例如，操纵)到凝块和/或穿过凝块的装置的组合。在定位导管之后，包括远侧牵引器区域342的内柔性牵引器管340被推动穿过导管至导管的远侧端部区域，如图3C所示。在该示例中，形成远侧牵引器区域的柔性牵引器管的远侧端部包括示出为网状物344的可扩张的第一端部区域，该网状物在近侧端部处(推动器区域305)连接到与柔性牵引器管的其余部分连续的近侧的不可扩张的第二端部区域。可扩张的第一端部区域的机织网状物344在收缩(非扩张)配置中在管状第二端部区域/推动器区域的外侧上预先翻转，并且可以滑动穿过导管的腔，并且(当导丝留在适当的位置或用于调节该位置时)在导丝(未示出)上滑动。如图3D所示，柔性牵引器管的远侧牵引器区域然后可以通过延伸(在该示例中，向远侧推动柔性牵引器管和/或向近侧拉动导管)而暴露于导管的外侧，从而允许远侧牵引器区域(示为网状物)344的可扩张的第一端部区域沿着第一端部区域的长度扩张。在图3D中，这显示为可以完全扩张至血管的内膜的支架状结构，在可扩张的第一端部区域与可较少扩张的(在此情况下是不可扩张的)第二端区域346之间形成分离。特别地，第一端部区域的扩张可以大于导管的内腔的直径的1.3倍(例如，大于1.5倍、大于2倍、大于2.2倍、大于2.5倍、大于3倍、大于3.5倍、大于4倍、大于5倍、大于6倍、大于7倍、大于8倍、大于9倍、大于10倍等)。

[0131] 在图3D中，导管在远侧牵引器区域的第一端部区域与第二端部区域之间向远侧滑动。然后可以通过向近侧拉动柔性牵引器管(例如，近侧牵引器区域)和/或向远侧推进导管中的一者或两者，而可以通过将可扩张的第一端部区域向近侧取回到导管中来移除凝块。

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在一些变型中，既推进该装置(特别是导管)，同时又取回可扩张的第一端部区域并将其翻转到导管中可能是有益的。可以比取回柔性牵引器管更快地推进导管。

[0132] 如图3F所示，凝块355可以被拉入到具有可扩张的第一端部区域的导管中。

[0133] 体内展开方法和装置的另一种变型示于图4A至图4F中。在该示例中，柔性牵引器管的自扩张的第一端部区域被配置成当其被推出导管时在导管的端部上自扩张，使得它将在导管的远侧端部上滑动。如以上对于图3A至图3B所描述，可以使用导丝413等来定位该装置。在图4A中，将导管401定位在邻近待去除的凝块455的导丝413上。在图4B中，导丝可以(可选地)被去除，或者(优选地)保留在位。包括远侧牵引器区域的柔性牵引器管434然后可以在导管内向远侧移动并且以可扩张的第一端部区域444延伸出远侧端部，使得其在远侧端部上翻转466并且在远侧端部区域上向近侧滑动，如图4C所示。该过程可以通过在脉管的腔内向远侧推动装置来辅助，因为第一端部区域444的扩张可以帮助将其抵靠血管的壁固定，如图4D至图4E所示。一旦暴露，通过向近侧拉动柔性牵引器管434和/或向远侧端部推进组件(或至少导管)，可扩张的第一端部区域可以取回到装置中，如图4F所示。凝块455然后可以被拉入装置中。

[0134] 图5A至图5E示出了使用机械取栓装置的体内展开和取栓(凝块去除)方法的另一变型。在图5A中，包括导管501和内柔性牵引器管534的装置500(例如，在导丝上，未示出)被推进至凝块555附近。在该示例中(其可以与本文所描述的方法中的任一个相关)，该装置与柔性牵引器构件一起定位，该柔性牵引器构件具有未展开的远侧牵引器区域，该远侧牵引器区域已经在远侧定位在装置的远侧端部区域附近。如图5B所示，处于图5A中导管501内的收缩配置的可扩张的第一端部区域544被推出导管的远侧端部并扩张至腔的壁，如图5B和图5C所示。一旦推出并扩张，可向远侧推进导管和导管内的柔性牵引器管的部分，如图5D所示，导致可扩张的第一端部区域544翻转，在导管501的远侧端部区域上翻折。通过图5E，装置已经在凝块555附近展开并且可以如已经描述的那样被致动以去除凝块，但是将远侧牵引器区域的可扩张的第一端部区域拉动到导管中，使得它翻转并将凝块拉入导管中。导管可以可选地同时被推进。注意，上述体内展开的方法也可以用于加载用于插入体内的装置，以便将导管径向地定位在柔性牵引器管的可扩张的第一端部区域与较近侧部分之间。

[0135] 图6A示出了具有柔性牵引器管634的取栓装置的另一变型的示例，该柔性牵引器管634具有形成于编织(例如机织)或针织材料的该示例中的柔性第一(远侧)端部区域644，其中，柔性第一端部区域(牵引器区域)在导管601的远侧端部上翻转并且附接到柔性牵引器管634的近侧端部区域。如在本文所描述的装置中的任一个中，柔性牵引器管的该近侧端部区域可以是海波管、导管或者在导管内可推动/可拉动并且在其远侧端部附接到柔性牵引器区域(例如，远侧牵引器区域)(包括在一些变型中的可扩张的第一端部区域)的层压机织物/网状物或机织材料。注意，在一些变型中，远侧牵引器区域(第一端部区域)可以是不可扩张的，但是可以只是柔性的。

[0136] 在图6A中，附接到柔性牵引器管的远侧牵引器区域的第一端部区域被外导管或套筒(保护器)677覆盖。在该示例中，该装置还包括在内导管601与保护器导管或套筒677之间的中间导管679。在一些变型中，柔性第一端部区域644可以附接到该中间导管，包括可拆卸地附接使得向近侧拉动柔性牵引器管634将使其脱离并允许网状物(柔性第一端部区域644)在血管中展开。在图6A所示的变型中，柔性第一端部区域644未附接至中间导管679。

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[0137] 本文所描述的装置中的任一个，包括图6A中所示的装置，可以与如图6B所示的导丝633一起使用(并且可以包括导丝)。图7A至7D示出了图6A至图6B中所示的设备的操作以去除凝块755。在该装置中，柔性牵引器管734的近侧端部可以耦接到真空源(未示出)，该真空源当向近侧取回牵引器管734以在导管的端部上翻转远侧牵引器区域时可以被致动。在图7A中，装置位于凝块755附近。在图7B中，通过如箭头所示拉动柔性牵引器管734而翻转远侧牵引器区域并将其拉动到导管中。在该示例中，远侧牵引器区域不被扩张，这是因为它仍然被外套筒777覆盖，如图7B和图7C所示。可以通过推动或通过向近侧拉动远侧牵引器端部区域(在该示例中示为网状物744)的动作以使其在导管的远侧端部上翻转中的一者或两者，向远侧朝向凝块或者在凝块上推进该装置。一旦凝块被去除，装置可以被取回并从血管中被拉出，如图7D所示。

[0138] 如上所述，这些变型中的任一个可以包括一个或多个真空源。图8示出了包括真空源的一个示例，其示出了耦接到柔性牵引器管834的腔的近侧端部处的第一可选真空源。例如，与真空和牵引器管834耦接的可以是旋转止血阀(RHV)，如图所示。在图8中，在(可选)外导管877和内导管801或(可选)中间导管878之间形成第二(可选)真空连接。可以在该方法的任何适当部分处施加真空，包括在柔性牵引器管834的收回期间去除凝块。

[0139] 如上所述，本文所描述的装置中的任一个可以包括导丝并且可以在手术期间将导丝留在适当的位置。图9A至9D示出了当导丝913留在适当的位置时去除物体(例如凝块)的方法。在该示例中，该装置类似于图6A至图6B中所示的装置，并且可以包括可选的真空源。在图9A中，包括远侧牵引器区域944的柔性第一端部区域944的翻转部分的导管的远侧端部定位成邻近凝块，并且通过向近侧拉动而被致动以将凝块拉入导管中，如图9B所示。在该示例中，凝块已经被导丝913穿透，因此具有翻转的牵引器区域的导管尖端可以通过推动导管927和/或通过向近侧拉动牵引器管919而在导丝上被向前推进。这可以继续直到整个凝块在导管内，如图9C所示。

[0140] 在本文所描述的变型中的任一个中，该装置可以包括一个或多个标记，或者可以被配置成与一种或多种对比剂一起使用以帮助使所描述的方法可视化。进一步地，这些方法中的任一种都可以包括可视化。可视化可以是间接的(例如，使用荧光镜检查或等效技术)，或者可以是直接的，例如使用一个光纤用于直接使该装置可视化(例如，通过装置的腔)。

[0141] 在图9D中，具有捕获物体(例如凝块)的牵引器管可以从装置的近侧去除并且可以检查所去除的材料(例如，通过组织学/细胞学检查)。随后或同时去除导管。如上所述，当去除物体(例如凝块)时，可能期望在柔性牵引器管向近侧拉回(未示出)的同时(向近侧)拉回导丝。在一些变型中，远侧牵引器区域(例如，编织/机织或针织区域)可以抓取导管内的导丝并且还可以帮助在凝块上或朝向凝块向远侧推进该装置，如下面在图36以及图37A至图37C中更详细地描述的。

[0142] 通常，抓取器(远侧牵引器区域)的滚动效果通过导管相对于远侧牵引器区域的运动而被致动。如果远侧牵引器区域向近侧固定并且导管被推进，则远侧牵引器区域可以具有1:1的抓取比。如果远侧牵引器区域被拉动通过导管，则抓取效果可能被放大。例如，当远侧牵引器区域被拉回(通过拉动牵引器管)并且当内导管被向远侧推动1个单元时翻转进入内导管中在导管内的近侧的1个单元，抓取效果大约是2倍。如果当内导管向远侧推进一个

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单元时，远侧牵引器区域被取回到导管中向近侧两个单元，则抓取效果可以是大约3倍。远侧牵引器区域和导管的同时运动可以通过手柄来协调。

[0143] 通常，本文所描述的装置中的任一个可以包括手柄。手柄可以与柔性牵引器管和/或导管(例如内导管)和/或任何外导管(例如保护器、套筒等)耦接。手柄可被配置成允许柔性牵引器管和/或导管的选择性的分开致动和/或这些部件的协调运动。图10A和图10B示出了可以使用的手柄的示例。在图10A中，手柄包括驱动机构以拉回牵引器管，并且因此在导管的远侧端部上翻转远侧牵引器区域和/或相对于远侧牵引器区域推进导管。在图10A中，手柄包括可旋转手柄1001，该可旋转手柄与导管驱动器1003耦接。手柄连接到导管1005和具有远侧牵引器区域1011的内部柔性牵引器管1009两者。手柄可以被配置成使得导管的推进(向远侧)与牵引器管的拉动(向近侧)的比率可以被选择和/或可以取决于导管驱动螺纹的螺距或其他机械机构。

[0144] 手柄的另一个变型在图10B中示出。在该示例中，手柄可以附接到牵引器管以拉动(或推动)牵引器管1017，并且因此在导管的远侧端部上翻转远侧牵引器区域，并且手柄的另一部分可以耦接到导管以推动/拉动导管1015。

[0145] 图11A示出了手柄机构1107的另一个变型，该手柄机构被配置成通过在附件部位1105处耦接到牵引器管的近侧端部来拉动本文所述的装置中的任一个的抓取器(远侧牵引器区域)，和/或通过耦接到导管的近侧端部来推进导管。手柄机构的另一个示例在图11B中示意性地示出，其示出了杠杆机构1109和与可以固定或可调节的内牵引器管耦接的耦接件。

[0146] 在本文所描述的装置中的任一个(例如，机械取栓装置)中，远侧牵引器区域可以被预加载在导管中/上，使得它可以通过向近侧拉动耦接到远侧牵引器区域的牵引器管和/或向远侧推进导管而被致动。在其中远侧牵引器区域包括在导管的远侧端部上翻折的柔性和/或可扩张的第一端部区域(例如，由网状物和/或机织物材料形成)的预加载变型中，装置可以是适于防止第一端部区域在已经被定位在凝块处或凝块附近之前无意地移位和/或扩张。

[0147] 图12A和图12B示出了附接到导管外侧的远侧牵引器区域的可释放附件的示例。通过施加应用于柔性牵引器管的近侧端部的适当量的力(例如拉力)可以释放这些附件中的任一个。例如，如图12A所示，远侧牵引器区域(示为网状物1204)的外远侧端部被从外导管或管1203延伸的肩部或衬垫覆盖)。类似地，在图12B中，远侧牵引器区域(示为网状物1204)的外远侧端部被单独的带、环或衬垫1209覆盖。通过添加细丝(例如在编织或机织变型中，附加编织细丝)、通过添加涂层、通过热定形至较大直径，和/或通过添加轴向编织间拉线，当张紧(例如在牵引器管上向近侧拉动)时，可以防止远侧牵引器区域收缩或直径减小。

[0148] 本文所描述的变型中的任一个可包括作为柔性牵引器管的一部分的近侧拉杆或拉线。进一步地，牵引器管的近侧端部区域可能比远侧端部(远侧牵引器区域)柔性更小。图13A和图13B示出了柔性牵引器管的示例。在图13A中，管包括近侧锥形区域，其中，远侧牵引器区域1305由向近侧1307渐缩(tapered，锥化)到拉线的材料(例如，网状物/机织材料)形成，为导丝1309留出空间并允许远侧牵引器区域在导管上翻转。近侧拉线部分可由形成远侧牵引器区域的细丝形成，例如，在其中机织或编织远侧牵引器区域的变型中。这些细丝可以通过例如其他材料(诸如有助于使其更硬或更柔顺的聚合物)来增强。图13B示出了另一

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个示例，其中，柔性牵引器管的近侧端部由拉线1315形成，该拉线可以是单独的材料或附接到拉线的远侧端部并形成远侧牵引器区域1317的编织线束的延伸部。

[0149] 本文所描述的装置中的任一个可以被处理或适应为减少在导管端部上翻转远侧牵引器区域所需的力。例如，在一些变型中，远侧端部可以被处理为润滑的，或者远侧牵引器区域的全部或一部分可以被处理以提高费力性。例如，在一些变型中，仅远侧牵引器区域的一部分（例如最初在导管的远侧端部上相互作用/翻转的部分）被处理；远侧牵引器区域的其余部分不被处理。图14示出了此类装置的一个示例。在图14中，可扩张和/或柔性第一端部区域（其定位于导管外侧）的最近侧端部1405用润滑涂层处理或由润滑材料形成。第一端部区域的剩余部分（未按比例示出）不是润滑的1403。由于较近侧区域1405暴露于血管和导管的远侧端部，所以它可以更有效地追踪目标或者允许装置追踪目标以及更有效地开始在远侧端部上翻转。该区域可以以任何适当的方式制成润滑的，包括但不限于涂层，诸如疏水/亲水涂层，并且形成或包括更润滑的聚合物材料（例如PTFE）。

[0150] 通常，本文所描述的远侧牵引器区域中的任一个可以适于包括不同的轮廓，包括预先设定以具有（例如，形状设定）可以更容易地在远侧端部上滑动/移动和/或抓取凝块或其他目标物体以用于去除的轮廓。例如，图15A至图15D示出了具有形成不同远侧牵引器区域的不同远侧端部轮廓的牵引器管。例如，在图15A中，远侧牵引器区域包括由通过多个拉线连接到牵引器管的近侧端部的由编织/网状或机织材料形成的最远侧可扩张和/或柔性第一端部区域1505。这些拉线1517可以由形成编织/网状或机织的远侧端部区域的相同线材或细丝形成。图15B示出了另一种变型，其中，多个离散的编织/网状或机织的远侧端部区域通过拉线1515连接；这些拉线区域1515可以是比编织/网状或机织区域1516更少可扩张的和/或柔性的。在图15C中，远侧端部区域被编织/网状或机织，但预先设定为具有不同的直径。因此这些区域沿其长度可以具有不同的形状；当这些形状被拉入导管中时，这些形状可被热定形以更好地抓取或破碎凝块。图15D示出了编织或支架状第一端部区域1521的示例，其通过形成编织/网状或机织的远侧牵引器的相同细丝的相同细丝或束连接到牵引器管1520的海波管或其他更近侧端部区域1523。

[0151] 本文所描述的装置中的任一个还可以或可替代地包括附接到导管的外表面上的多个可释放附件，从而将远侧牵引器区域（并且特别是远侧端部部分）固定到外表面。在图16中，示出了形成可释放附件的三个环1603、16.3'、1603"，其将远侧牵引器区域1644的远侧端部固定到导管1601的外侧。在该示例中，聚合物涂层/膜与编织物附接或成一体，形成远侧牵引器区域以帮助防止其过早地滑出或滑离导管（例如，直到由使用者拉动）。该装置可以包括沿着导管的长度径向定位的多个附件，如图所示，以帮助其保持固定到导管输送系统的外径。在一些变型中，这些可释放附件是弹性构件（例如聚氨酯环），但可以是脆的，并且允许破坏以释放远侧牵引器区域。

[0152] 图17示出了另一种变型，其中，可释放附件定位成使得远侧牵引器区域的一部分被弹簧加载（偏置）以驱动它在导管远侧端部上滚动并进入导管腔中。在图17中，远侧牵引器区域1704的远侧端部可被固定（固定、附接或松动但受约束），并且在导管的远侧端部附近的较近侧端部区域可被可释放地固定到导管1707。例如，聚合物涂层或膜可以附接到远侧牵引器区域（在图17中示出为编织物1744）并且被耦接以使远侧牵引器区域1705的在远侧端部1704与可释放附接部位1707之间的一部分保持张紧（例如，压缩）。然后释放可释放

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附件1707可以施加驱动围绕导管远侧端部的远侧牵引器区域的力，以帮助将凝块拉入装置中，并减小翻转远侧牵引器区域所需的力。

[0153] 如上所述，形成远侧牵引器区域(并且特别是最远侧柔性和/或可扩张的第一端部区域)的材料可以由任何适当的材料形成。例如，该材料可以包括织物、机织物、针织物、编织物、缝合物、管和/或平片。该材料可以具有任何合适的厚度，例如在0.0005”至0.015”的壁厚之间，并且可以具有从低至高孔隙率的任何合适间隔/尺寸(孔隙率)的孔。远侧牵引器区域的全部或一部分可以是不透射线的或无线电透明的。在机织、针织、编织或缝制的变型中，材料可以由多丝或单丝形成。不同尺寸的细丝可以混合在一起(例如，大和/或小)以通过增加或减少织物表面纹理来改变抓取效果。在一些变型中，材料(包括形成材料的细丝)可以是基于聚合物的(例如PET、尼龙、聚丙烯、PTFE、ePTFE)、弹性和非弹性的(例如PU、硅酮、橡胶、莱卡)、金属细丝(例如镍钛、包括DFT的拉伸充填的镍钛，即带Pt内芯的镍钛、钢、不锈钢、钴铬合金等)以及金属和聚合物细丝的混合物。织物的端部可以是激光切割/焊接或自由切割。在一些变型中，远侧牵引器区域的全部或部分包括膜或片。该膜可以在0.0005”至0.008”厚度之间。该膜可以通过管挤出或片形成并且卷成管。在一些变型中，膜是纱线增强的。膜可以是开槽的(例如，可以包括被切割的孔和/或狭缝以改进抓持或滑入导管)。在一些变型中，膜具有纹理化表面(例如，翻转时暴露的纹理化内表面)。膜可形成具有沿长度具有脊和/或环(径向环)

[0154] 和/或线和/或具有锯齿形图案的管。纹理化内表面可以包括大丝和小丝的混合物，和/或可以由更多孔的较密度的织物形成。

[0155] 在一些变型中，抓取器元件的可视性是期望的，但并非始终需要。例如，如上所述，标记可以位于设备上。在一些变型中，可能期望看到结构的整个结构或近侧端部和远侧端部。例如，材料可以是镍钛诺或在铂材料(DFT)上拉制的镍钛诺以增强可视性。

[0156] 变型中的任一个可以包括位于编织结构中的任一个的内侧的旋转螺旋钻元件以协助将凝块拉回到毂。如上所述，这些装置中的任一个都可以包括真空源。向系统添加真空可能有助于远侧牵引器区域将凝块/栓塞拉入导管中的能力。所施加的真空可以是稳定的/恒定的、倾斜的或脉动的。

[0157] 在一些变型中，使用它们的装置和方法可以包括阻流近侧球囊(例如，定位在凝块附近)，其可以在手术期间减少凝块上的压力。

[0158] 本文所描述的装置和方法可以用于捕获活检样品(例如，来自乳房或任何其他器官)。例如，当执行腹腔镜手术时，可以使用这些装置去除较大的组织段(例如，癌症、胆囊等)。

[0159] 当形成远侧牵引器区域的材料是机织/编织材料时，所得到的网状结构可具有范围从1cm到100cm长以围绕导管的外径(OD)的编织物长度，优选地长度为在约3cm至30cm之间。

[0160] 在这些变型中的任一种中，牵引器管和/或导管(包括远侧牵引器区域)可以被构造成使得可以拉动远侧牵引器区域，使得远侧牵引器区域以最小的力在导管远侧端部的外径周围被拉入(翻转)，使得导管尖端不会在血管中弯曲或显著变形(例如，蛇形扭动)，其中，拉力小于约：50克、100克、300克、500克、800克、1000克、2千克、3千克、5千克、8千克、10千克、15千克、20千克等。

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[0161] 在其中抓取器(远侧牵引器区域)至少在远侧端部(例如,可扩张的和/或柔性第一端部区域)上构造为机织(例如编织)结构的变型中,形成机织结构的细丝的示例可以包括:镍钛、镍钛-PT DFT线材(Pt内部的镍钛管)、PET、PP、尼龙、Algiloy、SS、混合材料。当使用时,镍钛可能被蚀刻以使其非常平滑。细丝端部的数量可以是约:16、24、36、48、77、96、144或这些整数之间的任何数量。任何编织结构都可以使用。例如,示例性编织结构可以包括1×1(1×1)、1×2、2×2等。在一些变型中,形成机织和/或针织材料的细丝包括单丝,例如所具有的外径(O.D.)尺寸约为:0.0005”、0.00075”、0.001”、0.0015”、0.002”、0.003”或在本文列出的整数之间的尺寸或直径尺寸的组合。如上所述,这些装置可以适用于使用的神经脉管系统,例如假设2mm至3mm脉管内径(ID)。例如,如本文所描述的适于神经脉管应用的装置可以包括韧炼至3mm至7mm OD的0.001”至0.002”聚合物编织物的36个至72个端部。在一些变型中,远侧牵引器区域包括24个编织线材,其具有以45度角度编织的在2mm心轴上韧炼的0.0005”至0.0015”或0.002”的扁平镍钛线材。可替代地,在一个变型中,远侧牵引器区域包括编织材料,该编织材料由以45度角度编织的在2mm心轴上韧炼的0.002”厚度的镍钛线材的24个线材形成。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括以45度角度编织的在2mm心轴上韧炼的0.002”DFT镍钛线材的24个线材。在一个示例中,远侧牵引器区域包括机织材料,该机织材料包括与在2mm心轴上的0.002”镍钛线材的8个附加端部混合的0.003”线材的8个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括在2mm心轴上韧炼的0.002”铂铱线材的16个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括具有0.002”直径的外径的PP单丝的24个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括0.003”PP单丝的12个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括0.003”PP单丝的16个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括1x1、90度编织角度、8mm心轴的0.001”PET或PP的72个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括1x1、75度编织角度、6mm心轴的0.001”PET或PP的36个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括1x1、90度编织角度、8mm心轴的0.002”PET或PP的48个端部。在一个示例中,远侧牵引器区域包括编织材料,该编织材料包括1x1、70度编织角度、6mm心轴的0.002”PET或PP的48个端部。

[0162] 在其中远侧牵引器区域包括网状物的变型中,管状网状物可由针织或替代结构形成,该针织或替代结构被构造成使得当网状牵引器被轴向拉动并且围绕导管尖端的外侧并进入导管ID中时,径向压缩(管状网状物内径ID的变化)经受直径减小5%至20%。这种5%至20%网状物直径的减小可以有助于在将网状物拉动到导管中时抓取凝块或异物,而不会产生很大的径向压缩力使得在拉动时管状网状物结合在导管尖端上并且不容易围绕导管尖端滚动。相反,当向近侧拉入时,机织的网状物可在导管内收缩20%至60%之间,这可提供其他所去除材料的凝块的大量压缩。

[0163] 在其中该装置被配置用于外围血管(例如,具有4mm至8mm血管ID)的变型中,远侧牵引器区域可以被配置用于该应用。例如,远侧牵引器区域可以包括具有形成在4mm心轴上并被韧炼的0.009”PP单丝的24个端部的编织材料。远侧牵引器区域可以包括具有4mm心轴韧炼的0.008”PP单丝的编织材料。远侧牵引器区域可以包括具有4mm心轴韧炼的0.006”PP单丝的72个端部的编织材料。远侧牵引器区域可以包括具有4mm心轴韧炼的36个端部的编

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织材料。远侧牵引器区域可以包括具有心轴韧炼的0.004”DFT镍钛的48个端部的编织材料。

[0164] 在其中装置被配置为活检装置(例如,具有4mm至12mm样本大小)的变型中,该装置可以是机织材料,其包括在10mm心轴上形成的PP 007”单丝的72个端部。在一些变型中,装置(例如,远侧牵引器区域)可以包括在1mm心轴上形成的0.004”镍钛的48个端部。在一些变型中,装置(例如,远侧牵引器区域)可以包括在12mm心轴上的PP 0.008”单丝的48个端部。

[0165] 在本文所描述的变型中的任一个中,所述装置可以被配置成具有相对低的摩擦。特别地,远侧牵引器区域可以具有低摩擦力以允许在收回凝块时更容易和/或可靠地拉动穿过导管。如上所述,这些变型中的任一个可以包括润滑材料和/或涂层,包括在抓取器(远侧牵引器区域)上使用或涂覆一种或多种以下材料:PET、PP、PTFE、ePTFE。当形成装置的材料是小直径细丝金属结构时,细丝的直径可以在0.0005”至0.003”之间。材料可以是镍钛、不锈钢、MP35n、Ti、铂、铂铱、钴铬合金等。

[0166] 在远侧牵引器区域是网状物(例如,机织和/或针织材料)的变型中,远侧牵引器区域相对于导管直径的直径可以取决于机织/针织结构。例如,当编织时,比率可以在2至1之间或更大;当经编时,比率在1.5至1之间或更大。当形成为激光管时,比例在1.1至1之间或更大。类似地,对于编织管或带结构,导管内部的编织角度应该在导管内侧在编织角度的0度至45度之间,并且在导管外侧在编织角度的约20度至90度之间。在远侧牵引器区域包括针织编织(例如,经编)管的变型中,该装置可以包括每英寸12个至16个端部。对于具有0.0035”ID导管的装置:可以使用20至40D PET复丝的12个至16个端部,或者可以使用0.0007”至0.003”PET或聚丙烯(Polypro)或PTFE单丝的12个至16个端部,或者可以使用0.0007”至0.002”镍钛、不锈钢、MP35n等的12个至16个端部。

[0167] 如上所述,在一些变型中,远侧牵引器区域由ePTFE形成为片(例如,形成为管或带)。这种材料可以是薄壁的(例如厚度在0.0005”至0.003”之间),被认为是有壁厚的(在0.0005”至0.002”之间),并且可以在导管尖端上折叠/起作用。该材料可能包括0.001”至0.004”,带有支架状的激光图案。

[0168] 包括不同形状的远侧牵引器区域的装置的设计的其他示例可以是导管ID的功能。例如,在一些变型中,装置可以选择导管ID、细丝的数量、细丝的直径/长度、弯曲/滚动刚度的刚度、泊松比、抓取器的内表面的摩擦(和/或纹理)等。较小直径的导管比较大直径的导管可能需要更少的网状物细丝或者更小的ePTFE管IDS。例如,在编织远侧牵引器区域的一些变型中,该装置可以包括具有远侧牵引器区域的0.072”ID导管,该远侧牵引器区域具有以90度编织角度编织在6mm心轴上的0.0008”至0.002”镍钛线材的24个至72个端部。在一些变型中,远侧牵引器区域由以90度编织角度编织在6mm心轴上的0.0008”至0.002PP单丝的24个至72个端部形成。在一些变型中,远侧牵引器区域由针织编织物(假定0.072”导管)形成,并且可以包括在3mm心轴上韧炼的16个端部或40D PET复丝自由经编针织物。在一些变型中,远侧牵引器区域由在3mm心轴上韧炼的经编针织的0.002”PP单丝的16个端部形成。在具有由ePTFe管形成的远侧牵引器区域(同样,假设0.072”导管)的变型中,远侧牵引器区域可以是0.002”厚的3mm的管。可替代地,远侧牵引器区域可以是0.002”厚的3mm的管激光器,其被开槽以收缩和抓取凝块。

[0169] 如所提及的,在一些变型中,该装置被配置成在远侧牵引器区域中包括抓持内网状表面。例如,该装置可以包括具有较大直径编织细丝和/或混合直径细丝的激光开槽

ePTFE管。在一些变型中，抓持内网状表面可以用作为经编针织成型管的针织编织物形成。此类结构可以具有自然的宏观结构以允许网状物滚动和抓持凝块，因为细丝不会平行于导管进入导管ID，而是它们相对于导管长轴线是垂直或环状的。对于其中远侧牵引器区域由ePTFE激光开槽材料（材料片）形成的示例，该结构可以包括切割成允许泊松比影响管直径同时产生抓持纹理以抓取凝块的狭缝。

[0170] 通常，通过使用自扩张的和/或较硬的远侧牵引器区域（例如，远侧牵引器区域的自扩张的和/或柔性第一端部区域），可以增强远侧牵引器区域在抓取凝块中的有效性）。当远侧牵引器区域的第一端部区域由编织物形成时，较硬的细丝（例如，由较大直径的细丝、较硬的材料、较大数量的纤维等形成）可导致远侧牵引器的更扩张的第一端部区域，如图18A至图18C所示。在图18A中，较柔软的远侧牵引器区域不会扩张超出导管的OD相当大的距离。图18B示出了远侧牵引器区域的略微更硬/更可扩张的第一端部区域。图18C示出了最可扩张的远侧牵引器区域1801，其可以最佳地扩张至血管1803的内膜。

[0171] 如图18A至图18C所示，可扩张的牵引器区域的唇缘的嘴部可相对于导管OD的长轴线形成切向角度或滚动角度（Φ）。该角度可以在大约5°至60°的范围内（例如，10°至60°、10°至50°、10°至45°、10°至40°等，并且优选地至少为10度）。本发明人惊奇地发现，在一些变型中，当牵引器区域被收回到导管中时与管具有至少约10度（例如10°至60°、10°至50°、10°至45°、10°至40°）的滚动角度可防止导管尖端上的束缚或堵塞。网状管可以被修改（例如，在远侧尖端或端部区域处），包括通过修改远侧尖端的刚度和/或形状，以确保滚动角度大于10度。可替代地或与保持最小滚动角度的组合，可能期望在导管最远侧尖端处保持管材料ID与导管的O.D之间的物理空间或间隙（参见例如图18A至图18C）。间隙可能需要大于0.1mm、0.2mm、0.3mm、0.4mm、0.5mm、0.7mm、0.8mm或1.0mm，以确保当管收回时，管围绕导管的远侧端部滚动。

[0172] 在这些变型中的任一个中，如上所述，远侧牵引器区域可以是润滑的（例如，亲水涂层、硅树脂涂层、薄氨基甲酸酯或其他薄弹性体涂层）。可以包括一个或多个聚合物编织物端部以增强润滑性（例如，聚丙烯、尼龙等）。进一步地，编织角可保持较小（例如，小于70度、50度、45度等）以允许更好的拉动。当远侧牵引器区域在导管的尖端周围/上方滚动时，可以测量该角度。增加机织物的端部的数量也可以防止第一端部区域在导管内的锁定，使得编织元件之间的间隙/空间更小并且当远侧牵引器区域在导管的端部上滚动时不太可能阻碍导管尖端。当形成为编织元件时，这些装置中的任一个还可以包括轴向元件，该轴向元件在拉动时不太可能收缩或直径减小，并且因此当在尖端上滚动时不太可能挂在导管开口上。当使用镍钛（例如>0.0001”直径）时使用稍大的编织细丝也是有利的；直径越大，编织物可变形以锁定到导管尖端的可能性就越小。如上所述，在一些变型中，远侧牵引器区域可被热定形以在向远侧推进时在导管的远侧端部上自动滚动。

[0173] 图19A和图19B示出了用于形成远侧牵引器区域的翻折回来配置的替代方法。在图19A中，管状远侧牵引器区域1903可以耦接到拉动器/推动器1901，然后如上所述在导管尖端上翻转。在图19B中，管状编织物1905穿过编织物向远侧附接到线材/拉动器1901并被拉动以在导管的远侧端部上使其翻转。

[0174] 通常，远侧牵引器区域的第一端部区域可具有任何适当的形状（参见图15A至图15D）。图20A和图20B示出了可以形成远侧牵引器区域的渐缩机织物的示例。在图20A中，编

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织物具有锥形侧面轮廓，其可以附接到拉动器(柔性牵引器管的近侧端部)并且翻转。本文所述的编织物中的任何一种可以包括标记线材(例如，DFT、金、铂、铂铱等)以帮助可视化(例如，荧光镜)。在图20B中，网状物比图20A中更突然地渐缩。

[0175] 如上所述，通常，本文所描述的导管中的任一个可适用于这些装置。例如，合适的导管可以是高度柔性的，并具有良好的柱刚度(例如，当向远侧推进时其长度不会缩短)。导管可以具有高角度编织物加强元件。例如，导管可以具有穿过近侧端部至远侧端部的高角度编织物(70度至85度，小线材镍钛、不锈钢、钴铬、MP35N、扁平或圆形线材)，以及针对导管的远侧1cm至5cm的较小编织角度。这将允许当施加轴向压缩时和/或在内扩张力(例如血块)下导管的内径扩张。

[0176] 通常，这些导管中的任一个都可以包括改变的刚度/顺应性。例如，近侧三分之一(1/3)可能较硬；中间部分可能不太硬，而远侧20％(1/5)可能是最不硬的。进一步地，导管的远侧尖端可以具有如图1A和图1B中所描述的适当的半径(曲线)。通常，半径应该是平滑且圆形的，而不是方形的。另外，导管的远侧尖端可以由足够硬的材料(约72D或更硬)制成，以允许编织物滚动而不抓取尖端。例如，导管尖端可以具有硬质金属结构以减少摩擦(例如，不锈钢、Pt等)。当拉动远侧牵引器区域时导管尖端压缩/弯曲越少越好。在一些变型中，导管包括附加加强件，诸如编织增强件而不是线圈加强件，以防止导管最后5cm至10cm的编织物屈曲。因此，如本文所描述的，在一些变型中，导管的尖端可由润滑和/或硬质材料制成，以当编织物围绕导管尖端被拉动或被推动时帮助减少编织物与导管尖端的摩擦。润滑材料可以包括诸如PTFE、FEP和/或亲水涂层的粉状聚合物。如尼龙之类的硬质材料或不锈钢之类的金属材料、铂和PT铱合金可用于该尖端，并且向近侧熔合/附接到较柔软材料。如果硬质尖端被放置在导管尖端的远侧端部上，则其长度可能是短的(例如<5mm并且优选地<3mm)，因此它不会不利地影响导管追踪。

[0177] 图21A至图21D示出了用于去除凝块的装置的示例。在该示例中，远侧牵引器区域由拉下到0.071”的导管上的10mm(扩张)直径的大约72个端部的细旦尼尔PET网状物形成，如图21A和图21B所示。图21A示出了在耦接到导管之前的可扩张的第一端部区域的示例。图21B示出了通过拉动柔性(牵引器)管的近侧端部将血管(玻璃管)内的可扩张的第一端区域拉入导管中。图21C示出了装置的远侧端部区域，其包括在导管的远侧端部区域上翻折的可扩张的第一端部区域。图21D示出了将凝块拉入导管中的图21C的装置。

[0178] 另一个示例检查了由具有72个端部和0.001”直径细丝的6mm编织物形成的远侧牵引器区域，该细丝滚动进入0.071”ID导管并且在0.071”ID导管上翻折。成功去除20cm长的“中等硬度”5mm凝块。图22示出了在将其向近侧拉出导管之后具有所捕获的凝块的图21D的可扩张的第一端部区域。

[0179] 图23A至图23D示出了如本文所述的机械取栓装置，其捕获血凝块并将其拉入装置中。图23E示出了在柔性牵引器管已经从导管去除(例如向近侧)之后保持在柔性牵引器管内的凝块。

[0180] 在本文所描述的一些变型中，远侧牵引器区域不是由机织或针织材料形成，而是由纵向布置(例如，平行或近似平行布置)的条或束构成。例如，图24是包括柔性牵引器构件的装置的另一个示例，其中，远侧牵引器区域由多个细丝形成，该多个细丝布置位未机织或编织的材料条(纵向平行)。这些条可以是细丝或管等。

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[0181] 图25A至图25F示出了柔性牵引器组件的远侧牵引器区域的另一变型，其中，可扩张的第一端部区域(例如，远侧牵引器区域的远侧端部区域)由多个细丝或条形成，类似于图24中所示的；如图25A至图24B所示，导管的远侧端部包括通道；这些条可以装配在这些通道内，如图25C至图25D所示。图25E和图25F示出了穿过图25C和图25D的截面图。图25A、图25C和图25E示出了侧视图并且图25B、图25D和图25F示出了轴向视图。在该示例中，导管尖端包括细丝/条2503在其中行进的通道2502。形成远侧牵引器区域的条附接到柔性牵引器管2505的更近侧的拉动器区域，如图25E所示。

[0182] 图26A和图26B示出了具有外套筒(例如，外导管或释放保护器导管或其他外套筒/保护器)的图25A至图25F的装置的变型

[0183] 图27A至图27B示出了穿过图26A至图26B的装置的截面图。

[0184] 图28是包括柔性牵引器组件的远侧牵引器区域的装置，柔性牵引器组件具有多个纵向平行的(非机织/编织)细丝或条，其中，细丝或条的远侧端部通过远侧连接件彼此连接。

[0185] 图29示出了装置中的柔性牵引器组件的远侧牵引器区域，其中，纵向平行的(非机织/编织)细丝或条包括抓取元件。

[0186] 图30A至图30C示出了具有抓取元件的细丝/条的示例。抓取元件(和/或包括它们的细丝)可以用作本文所描述的变型中的任一个的一部分，包括机织或编织的远侧牵引器区域。带有抓取元件的对于细丝/条的其他选择可以包括编织条、网状物/机织条和微线圈。

[0187] 在本文所描述的这些配置中的任一种中，该装置可以适于允许远侧牵引器区域的往复运动，从导管的远侧端部的外侧至内侧并回到外侧而循环。例如，图31示出了其中远侧牵引器区域适于往复运动(例如，推动和拉动)使得可扩张的第一端部区域可被拉入导管中并且从导管翻转出的变型。在该示例中，牵引器管(拉动器)3105附接到远侧牵引器区域3144，该远侧牵引器区域可以附接(并且在一些变型中不附接)到内导管3101上的第二导管3109。中间导管3109可以耦接到拉动器3105，并且两者一起往复运动，使得编织物在导管3101的内侧来回往复运动。这可以帮助破碎凝块，这可能特别是在与抽吸一起使用时。

[0188] 图32示出了如本文所述的装置的另一示例，其中，远侧牵引器区域的柔性第一端部区域的最远侧端部3205不可释放地固定到导管3201的外侧的远侧端部；可扩张的第一端部区域3209的其余部分具有足够的弹性/柔性以被拉入导管中(用其拉动凝块3255)。然后柔性牵引器组件可以被收回并且整个装置被取回。该示例可能包括可选的真空3260。

[0189] 图33是装置的另一个示例，其中，柔性牵引器组件的拉动器部分3305由与远侧牵引器区域3344相同的材料形成，但可以层压或以其他方式加强以具有比远侧牵引器区域更小的柔性/可拉伸性。

[0190] 图34示出了另一个示例，其中，远侧牵引器区域3444适于当拉入导管3401中时压缩凝块3455。图35A至图35C示出了如图34所示的装置的操作，其中，凝块3455通过将远侧牵引器区域的可扩张的第一端部区域取回到压缩凝块的导管中(例如在牵引器组件的牵引器区域3505上拉动)而被拉入导管中(图35A至图35B)；释放牵引器组件和/或向远侧推动牵引器组件可以进一步破碎凝块并且将其从远侧牵引器区域释放，使得它可以向近侧分段(图35C)。

[0191] 图36示出了一种装置和使用方法的示例，其中，向近侧拉柔性牵引器组件可以向

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远侧推进装置穿过导丝上的主体(例如血管),该导丝可以被处理以接合远侧牵引器区域。在该示例中,该装置可以被配置成拉动具有形成远侧牵引器区域3644的网状物的内牵引器管(导管3605),该远侧牵引器区域附接到其远侧端部并且在导管3601的远侧端部上翻转。拉动柔性牵引器管3605使编织物在导管3601的开口上滚动。形成远侧牵引器区域(例如,远侧牵引器区域的第一端部区域)的网状物/编织物被构造成当拉伸负载施加到该结构上并且锁定/抓取内线材(导丝3677)时在直径上收缩。该内导丝可能具有抓取线材的粘性、粗糙或多变的表面辅助网状物/编织物。当网状物/编织物抓取在导丝上时,牵引器管由于反作用力而将在脉管中被向前驱动。可替代地,用户将能够在拉回牵引管的同时能够容易地将外导管3601向前推进穿过血管。

[0192] 图37A至图37C示出了另一种装置和使用方法,其中,向近侧拉柔性牵引器组件可以向远侧推进该装置。在图37A中,远侧牵引器区域3744附接至中间导管3703(可包括可选的外导管3705),并且远侧牵引器区域3744的相对端部结合至在该导管的内径内的内导管3701的远侧端部。在图37B中,向远侧推进内导管,从而使远侧牵引器区域在侧向和前方扩张。如图37C所示,然后可以向远侧推动外导管和内导管,以使装置向远侧移动。

[0193] 在一些变型中,远侧柔性牵引器区域可以被保持预先加载在导管的外侧,例如以卷或束的形式被保持预先加载在导管的远侧端部区域上,使得其可以被逐渐拉出外存储区域并且在导管的远侧端部上滚动和翻转。一个此类变型的示例示出在图38A和图38B中,该示例性装置可用于从血管内去除材料,如图38B所示,并且可以称为“无限(infinite)”牵引器机构,因为大量(例如,大于50cm、大于60cm、大于70cm、大于80cm、大于90cm、大于100cm、大于150cm、200cm、大于300cm、大于400cm、大于500cm等)的牵引器材料(例如,网状物)可存储在外保持区域中,其被卷起但在扩大使用上不是必要的。

[0194] 在图38A中,该装置可以包括导管(内导管)3811并且远侧牵引器区域3806由在导管的远侧端部附近的壳体区域3813中卷起的网状物3803形成。通过在导管内向近侧拉动远侧牵引器区域,凝块3805可被拉入导管中。由于大量远侧牵引器区域可能存储在近侧并且向近侧被取回,因此这种变化对于非常长的手术或者需要去除大量材料的情况可能是有用的。

[0195] 这种变型可以允许使用者展开较长长度的网状物,这对于更刚度的工具(诸如在手术期间的刚度海波管)可能是有利的,例如,在吸脂手术中去除脂肪、去除脑内出血或更大的外周血管凝块中的凝块。

[0196] 如上所述,在本文所描述的变型中的任一个中,远侧牵引器构件可以是机织(例如针织)或编织的网状材料。网状物可以是针织材料,包括例如纬编针织物、圆形针织物、经编针织物和/或编织针织物。

[0197] 当特征或元件在本文中被称为“在”另一特征或元件“上”时,其可以直接在另一特征或元件上,或者也可以存在中间特征和/或元件。相反,当特征或元件被称为“直接在”在另一特征或元件“上”时,不存在中间特征或元件。还将理解,当特征或元件被称为“连接”、“附接”或“耦接”到另一特征或元件时,其可直接连接、附接或耦接到另一特征或元件,或者可能存在中间特征或元件。相反,当特征或元件被称为“直接连接”、“直接附接”或“直接耦接”到另一特征或元件时,不存在中间特征或元件。虽然相对于一个实施例进行了描述或示出,但是所描述或示出的特征和元件可以应用于其他实施例。本领域的技术人员还将认识

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到，对“邻近”另一个特征设置的结构或特征的提及可以具有与邻近特征重叠或位于其下面的部分。

[0198] 本文所使用的术语仅用于描述特定实施例的目的，而不意图限制本发明。例如，如本文所使用的，除非上下文另外明确指出，否则单数形式“一”，“一个”和“该”也旨在包括复数形式。将进一步理解，当在本说明书中使用时，术语“包括”和/或“包含”指定所述特征、步骤、操作、元件和/或部件的存在，但不排除一个或多个其他特征、步骤、操作、元件、部件和/或其组合的存在或添加。如本文所使用的，术语“和/或”包括相关所列项目中的一个或多个的任何和所有组合，并且可以缩写为“/”。

[0199] 为便于描述，本文可以使用诸如“在...之下”、“在...下方”、“下”、“在...上”、“上”等的空间相对术语以描述一个元件或特征与另一个元件或特征的关系，如图所示。将理解，空间相对术语旨在包括除了附图中所描绘的方位之外的装置在使用或操作中的不同方位。例如，如果附图中的设备是翻转的，则被描述为在其他元件或特征“之下”或“下方”的元件将被定向为“在”其他元件或特征“上”。因此，示例性术语“在...下面”可以包括上方和下方两种方向。设备可以以其他方式定向（旋转90度或以其他方位）并且相应地解释在本文所使用的空间相对描述符。类似地，除非另外特别指出，否则术语“向上”、“向下”、“竖直”、“水平”等仅用于解释的目的。

[0200] 虽然术语“第一”和“第二”在本文中可以用于描述各种特征/元件（包括步骤），但除非上下文另有指示，否则这些特征/元件不应受这些术语限制。这些术语可以用于区分一个特征/元件与另一个特征/元件。因此，下面论述的第一特征/元件可以被称为第二特征/元件，并且类似地，在不脱离本发明的教导的情况下，下面所论述的第二特征/元件可以被称为第一特征/元件。

[0201] 在整个说明书和所附的权利要求书中，除非上下文另有要求，否则词语“包含”以及诸如“包含了”和“其包含”的变型意味着各种部件可以在方法和物品中共同采用（例如，包括设备和方法的组合物和装置）。例如，术语“其包含”将被理解为暗示包含任何陈述的元件或步骤，但不排除任何其他元件或步骤。

[0202] 如在本说明书和权利要求书中所使用的，包括在示例中所使用的并且除非另有明确说明，即使术语没有明确出现，所有的数字也可以读作像“约”或“大约”这样的词语开头。当描述幅度和/或位置以指示所描述的值和/或位置在值和/或位置的合理预期范围内时，可以使用短语“约”或“大约”。例如，数值可以具有所述值（或值的范围）的+/－0.1％的值、所述值（或值的范围）的+/－1％的值、所述值（或值的范围）的+/－2％的值、所述值（或值的范围）的+/－5％的值、所述值（或值的范围）的+/－10％的值等。本文给出的任何数值也应被理解为包括约或大约该值，除非上下文另有指示。例如，如果公开了值“10”，则“约10”也被公开。本文列举的任何数值范围旨在包括其中所包含的所有子范围。还应理解，当公开值时，“小于或等于”该值、“大于或等于该值”以及值之间的可能范围也被公开，如本领域技术人员所适当理解的。例如，如果公开了值“X”，则还公开了“小于或等于X”以及“大于或等于X”（例如，其中X是数值）。还应该理解，在整个申请中，数据以多种不同的格式提供，并且该数据表示端点和起点以及数据点的任何组合的范围。例如，如果公开了特定的数据点“10”和特定的数据点“15”，则可以理解，大于、大于或等于、小于、小于或等于并且等于10和15被认为是公开的以及在10和15之间。还应该理解，还公开了两个特定单元之间的每个单元。例

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如，如果公开了10和15，则还公开了11、12、13和14。

[0203] 尽管以上描述了各种说明性实施例，但是在不脱离如权利要求所描述的本发明的范围的情况下可以对各种实施例进行多种改变中的任何一种。例如，其中执行各种所描述的方法步骤的顺序通常可以在替代实施例中改变，并且在其他替代实施例中，可以完全跳过一个或多个方法步骤。各种设备和系统实施例的可选特征可以包括在一些实施例中而不包括在其他实施例中。因此，前面的描述主要是为了示例性的目的而提供的，并且不应该被解释为限制如在权利要求中所阐述的本发明的范围。

[0204] 本文包括的示例和说明通过说明而非限制的方式示出了其中可以实践主题的特定实施例。如上所述，其他实施例可以被利用并从中导出，使得可以在不脱离本公开的范围的情况下进行结构和逻辑替换和改变。本发明主题的此类实施例在本文中可以单独地或共同地由术语“发明”引用，仅仅是为了方便，并且无意将本申请的范围自愿地限制到任何单个发明或发明构思，如果事实上公开了不止一个的话。因此，尽管本文已经说明和描述了具体实施例，但是为了实现相同目的而计算出的任何布置都可以替代所示的具体实施例。本公开旨在覆盖各种实施例的任何和所有修改或变型。上述实施例的组合以及本文中未具体描述的其它实施例对于本领域技术人员在查看以上描述时将是显而易见的。

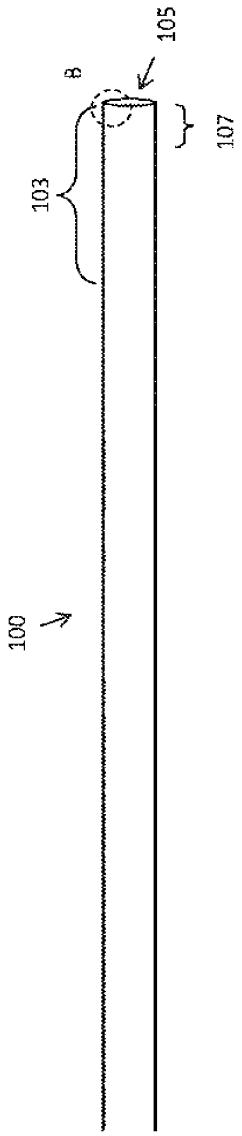


图1A

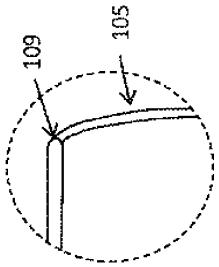


图1B

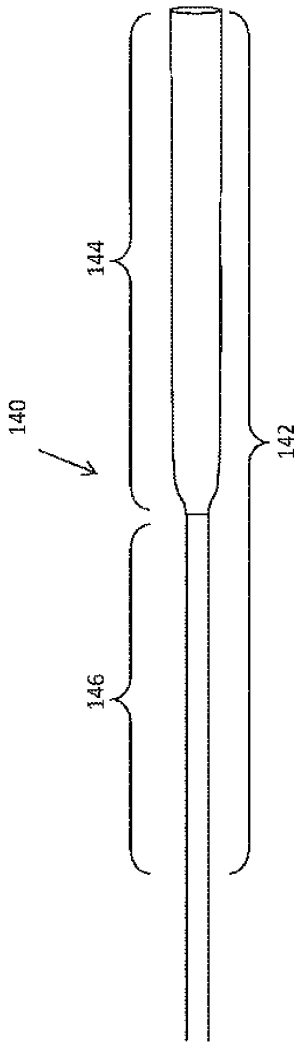


图1C

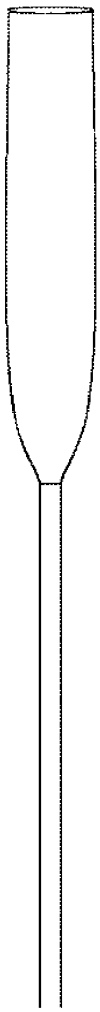


图1D

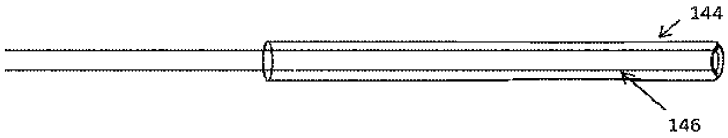


图1E

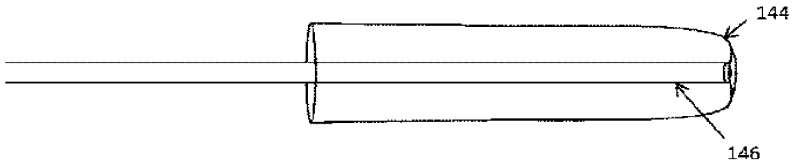
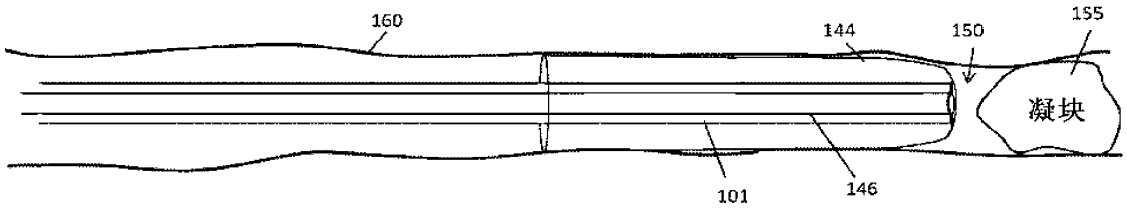


图1F



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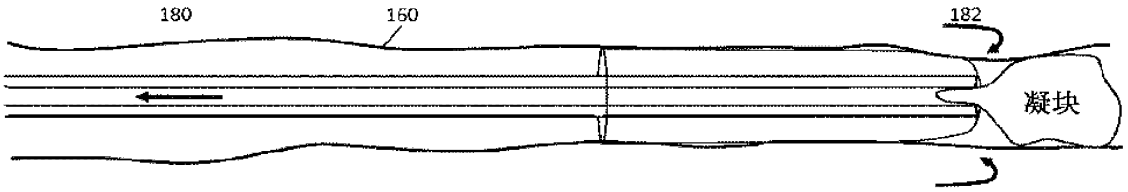


图1H

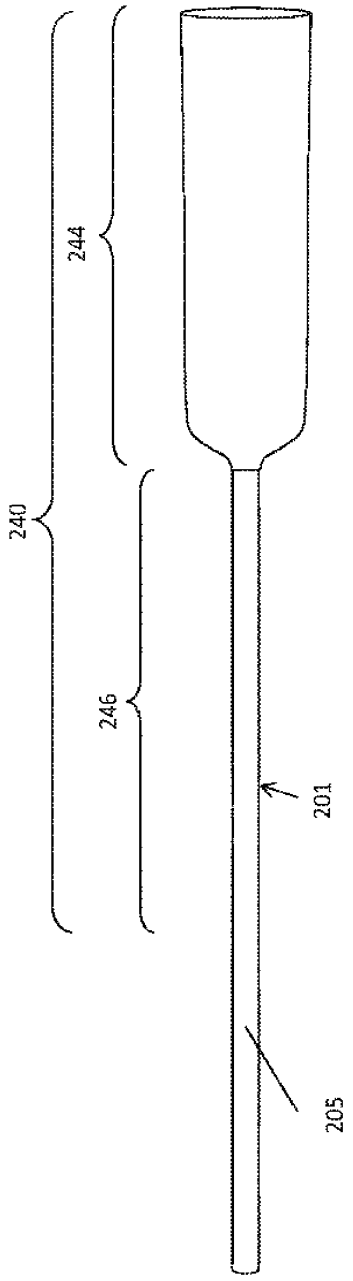


图2A

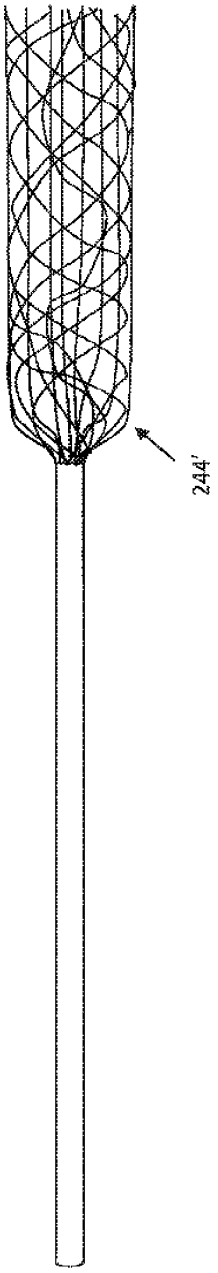


图2B

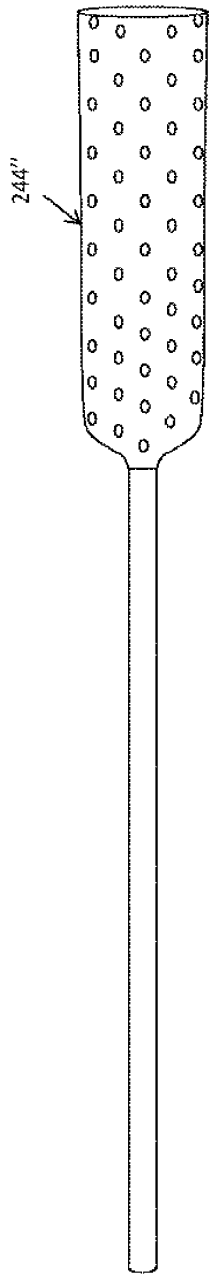


图2C

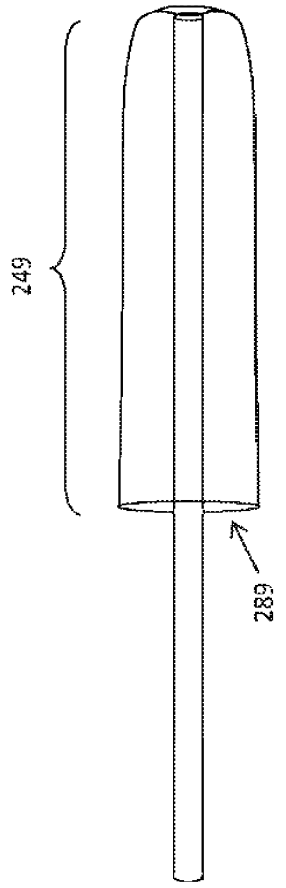


图2D

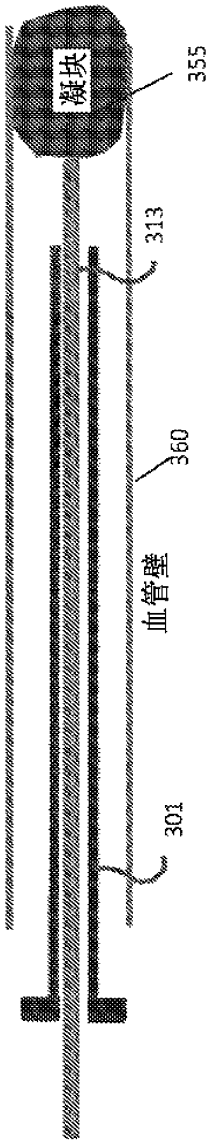
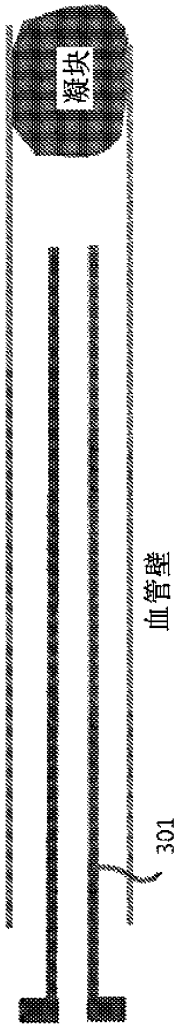


图3A



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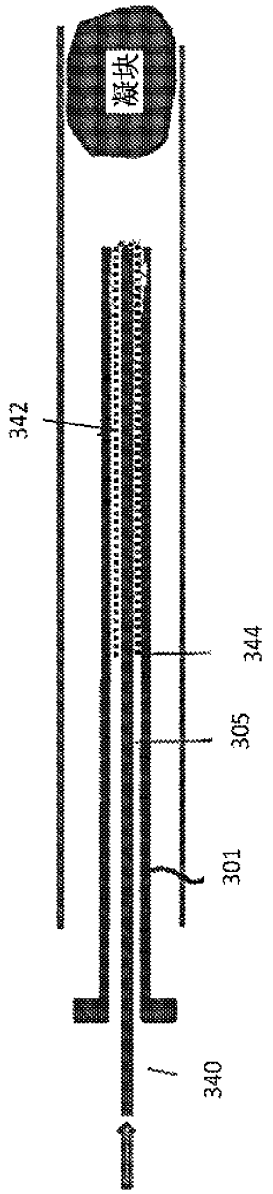

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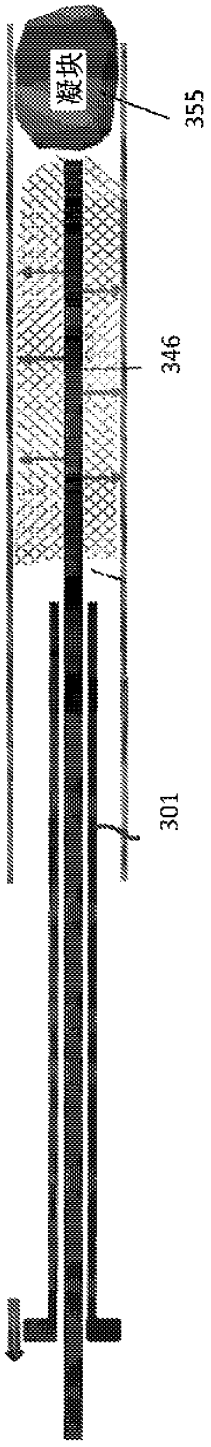

图3D

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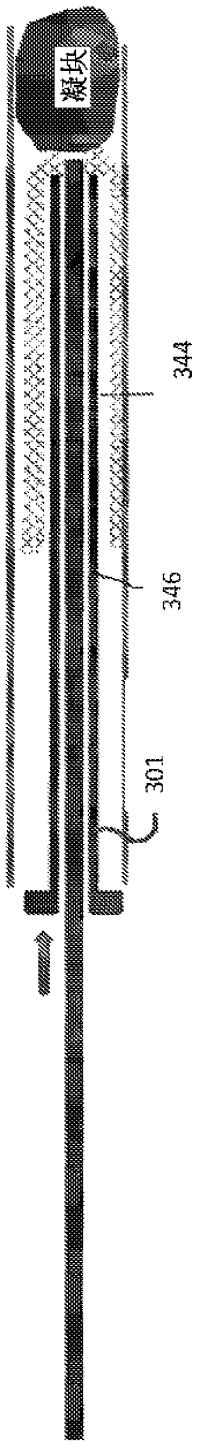


图3E

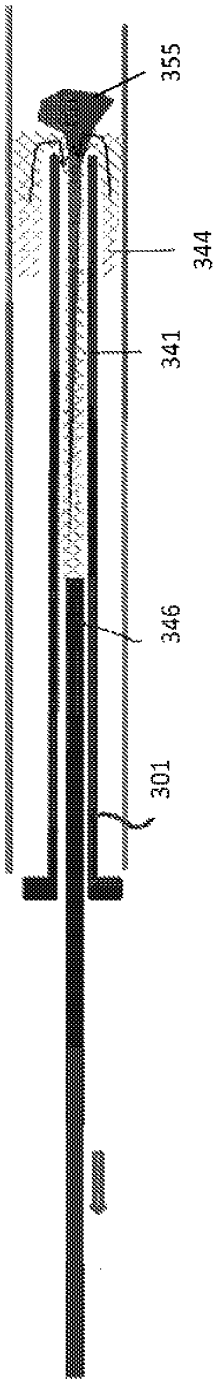


图3F

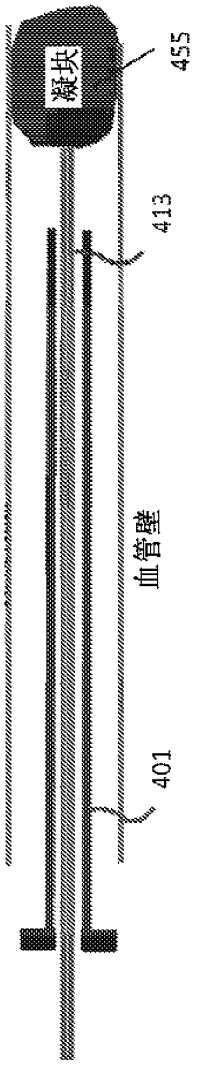


图4A

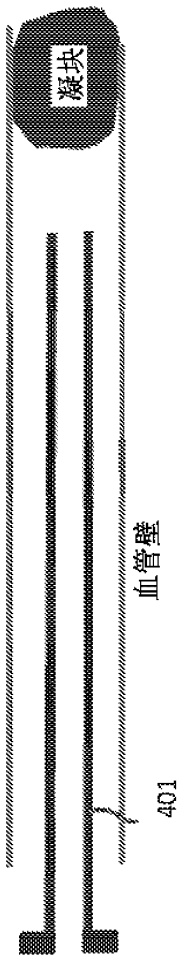
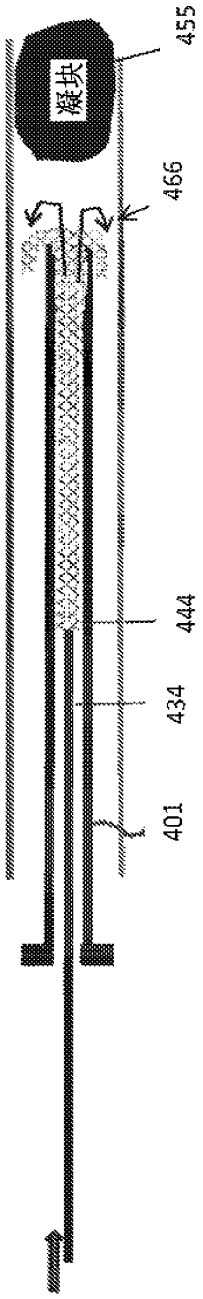


图4B



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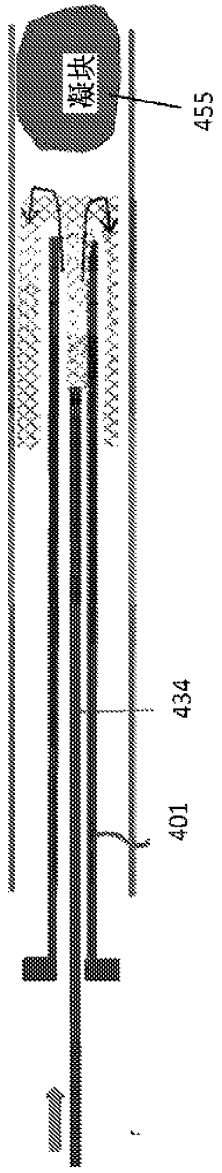
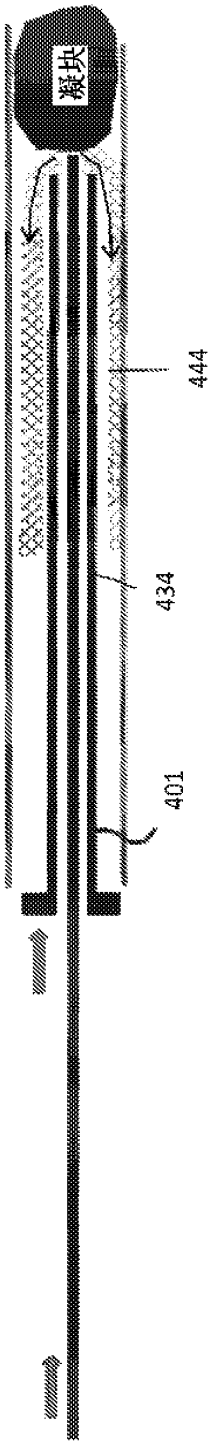


图4D



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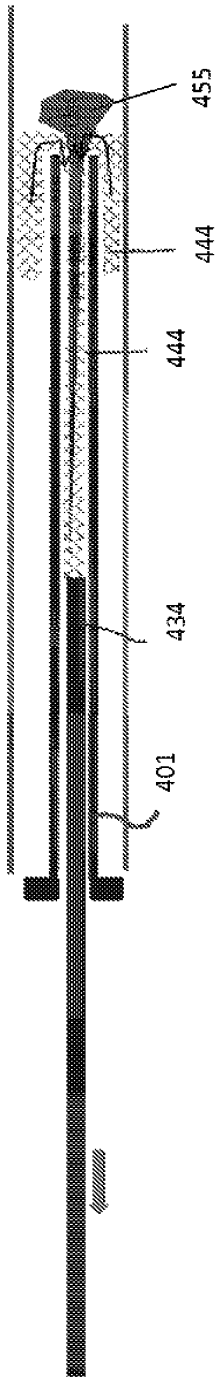

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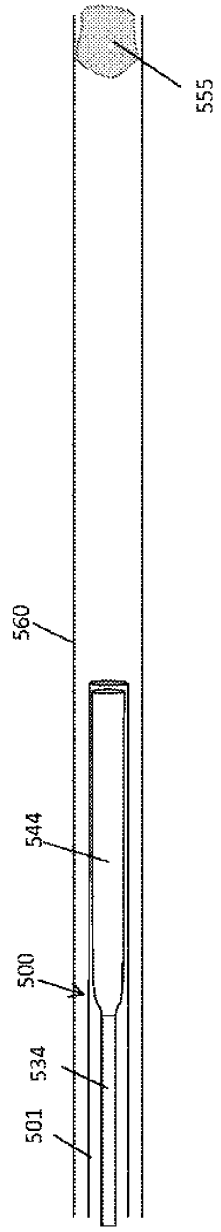


图5A

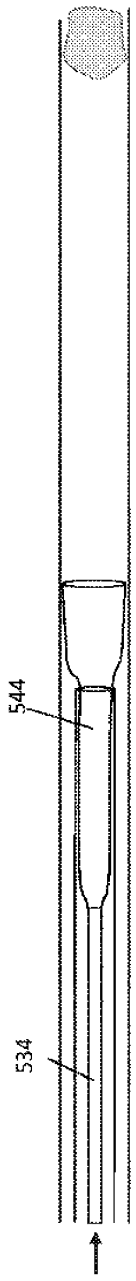
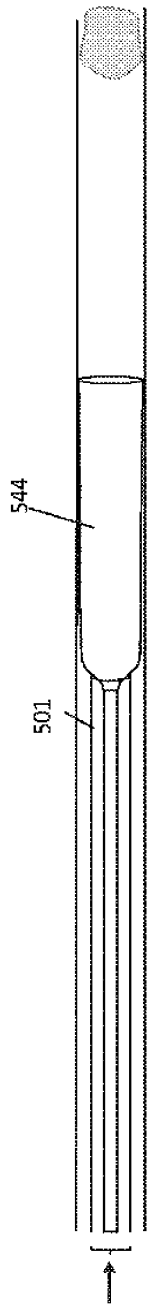


图5B



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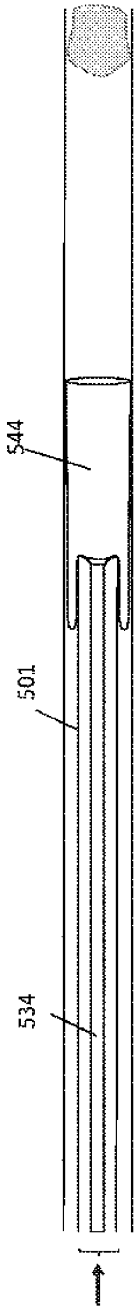

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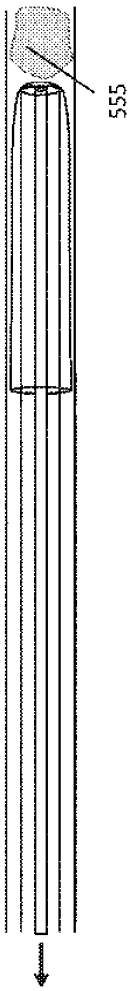

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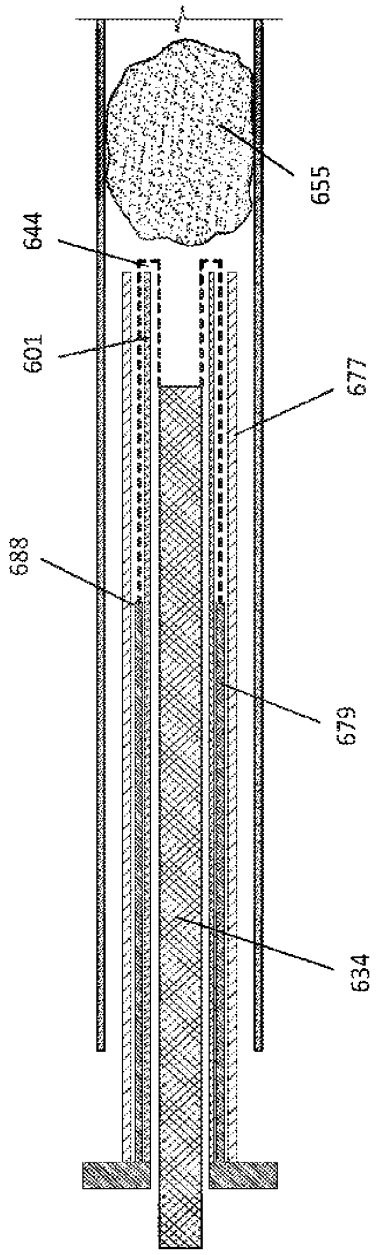

图6A

60

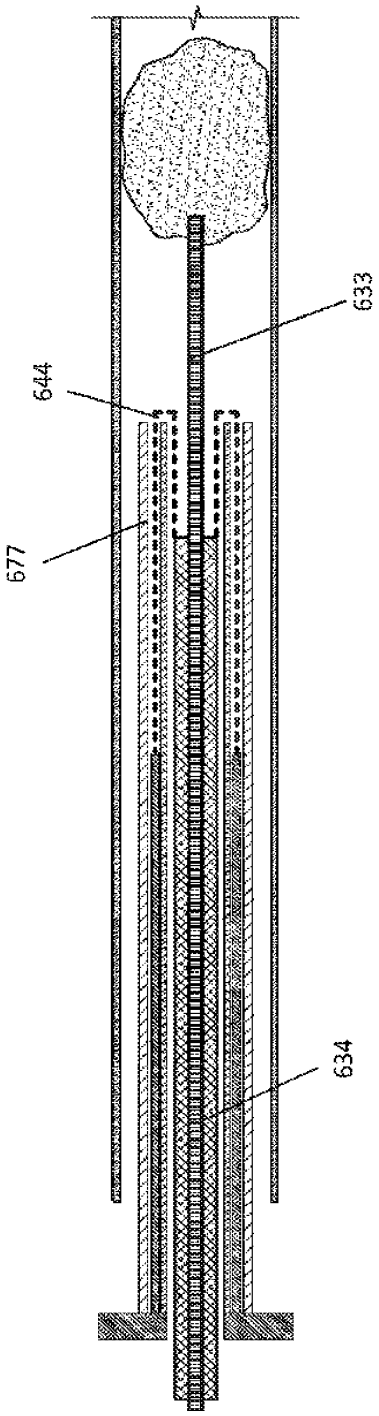

图6B

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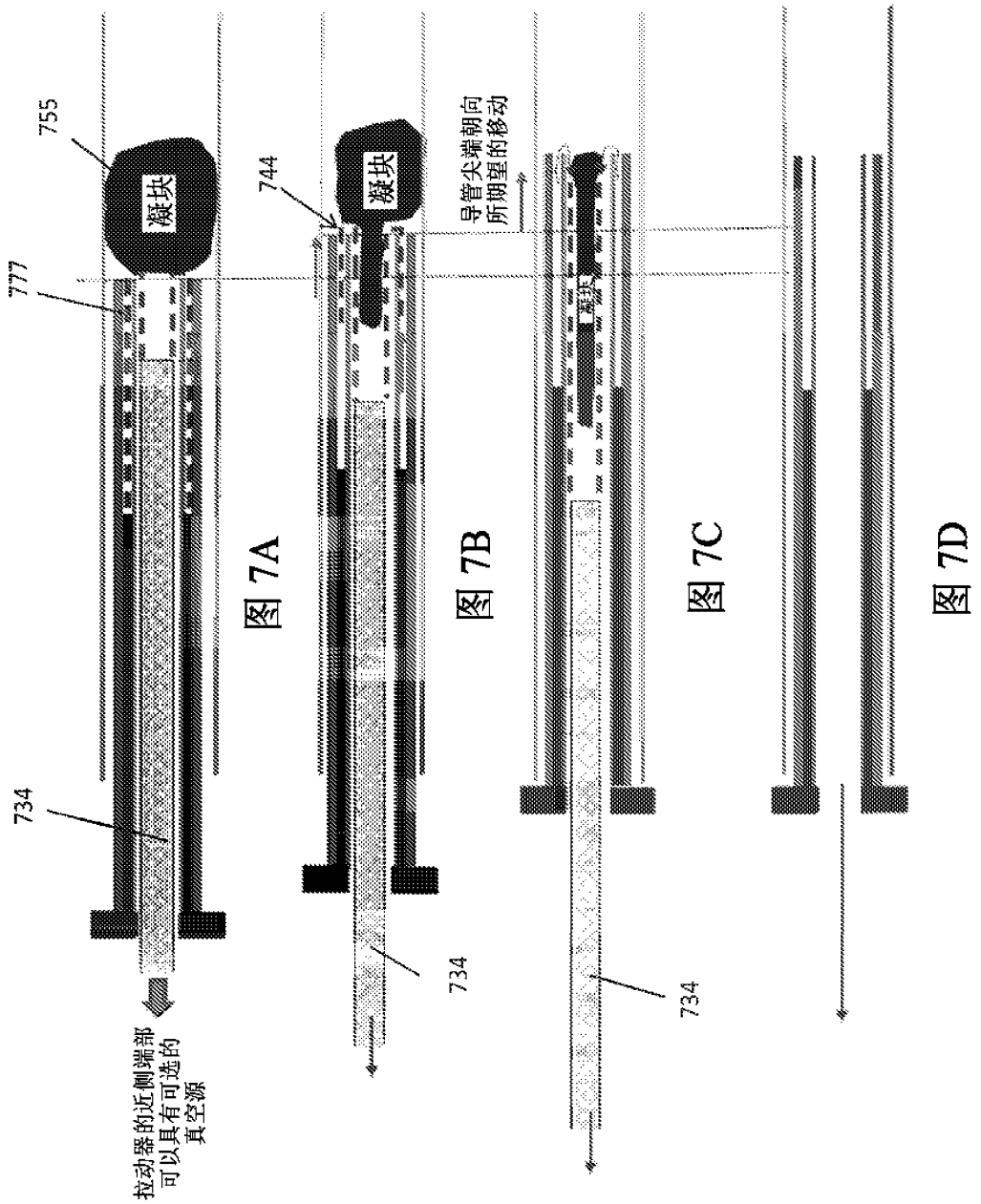

755
凝块
777
734
拉动器的近侧端部
可以具有可选的
真空源
图 7A
744
凝块
734
导管尖端朝向
所期望的移动
图 7B
凝块
734
图 7C
图 7D

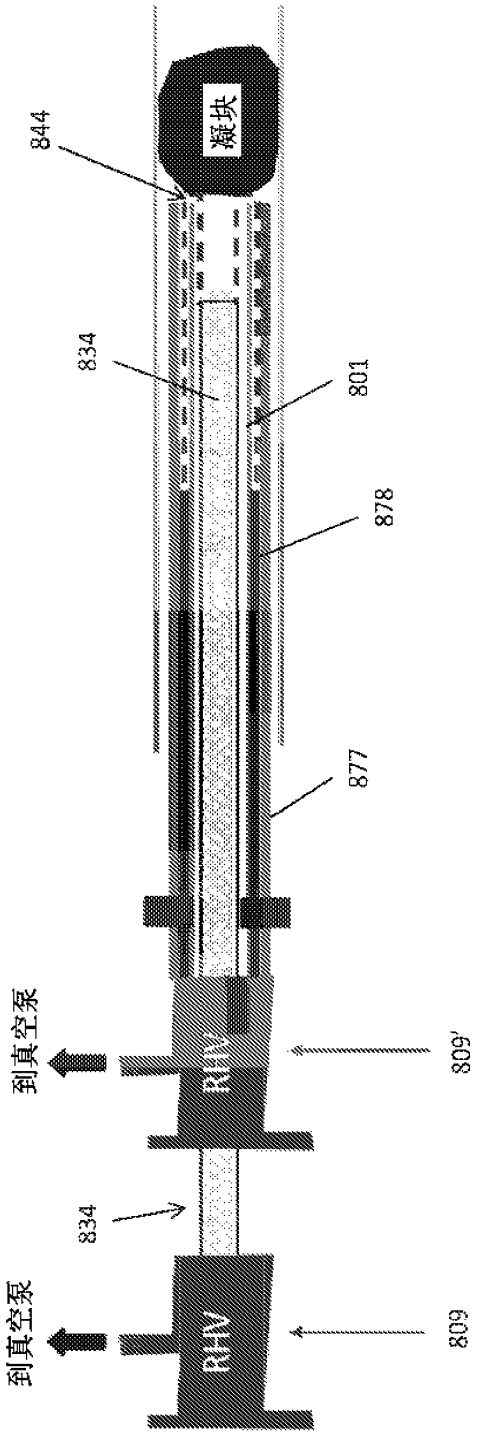


图8

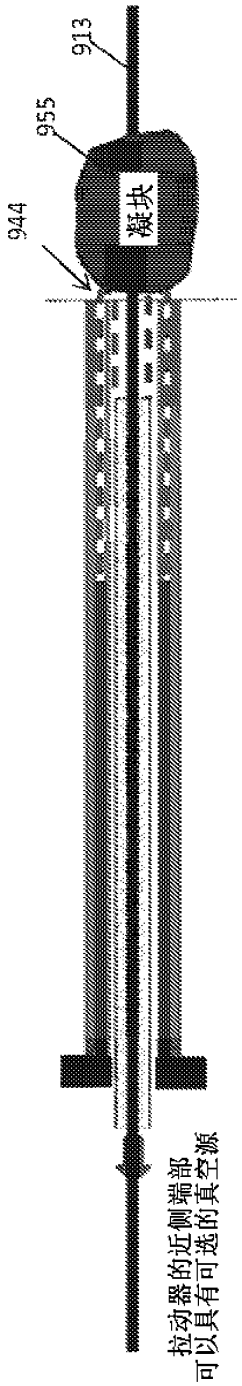


图9A

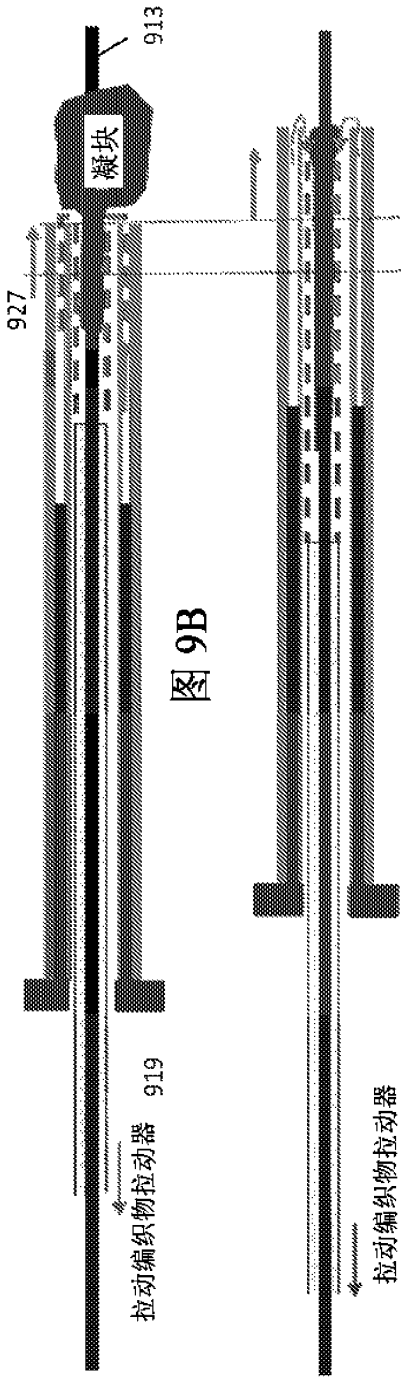


图 9B

图 9C

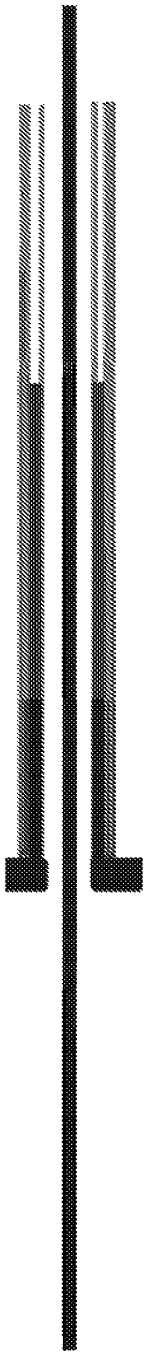


图9D

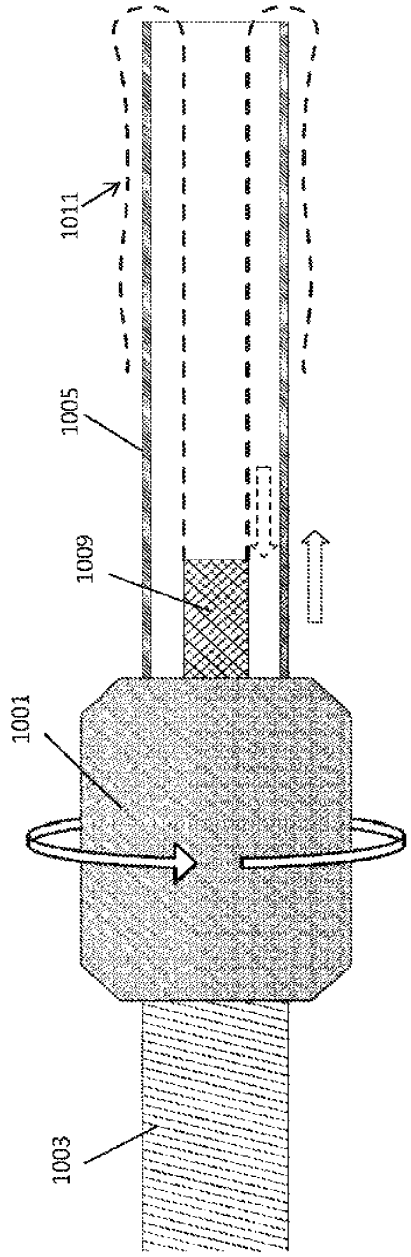


图10A

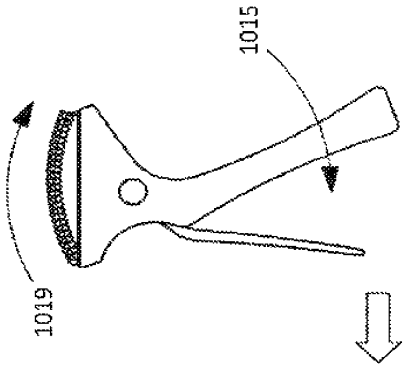


图10B

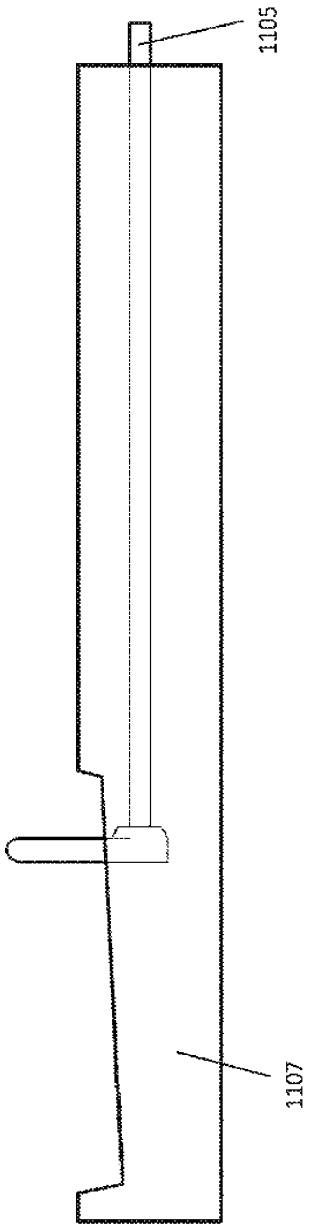


图11A

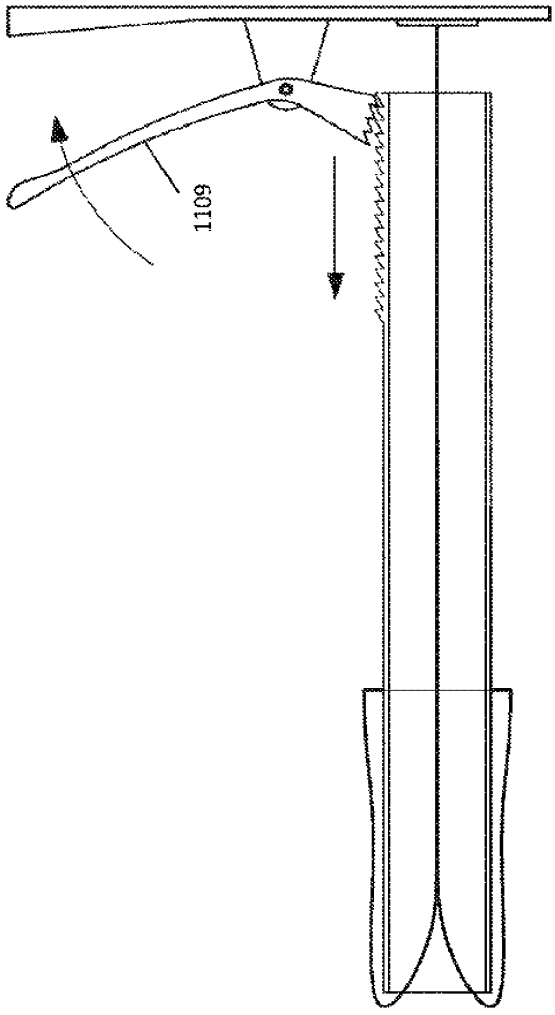


图11B

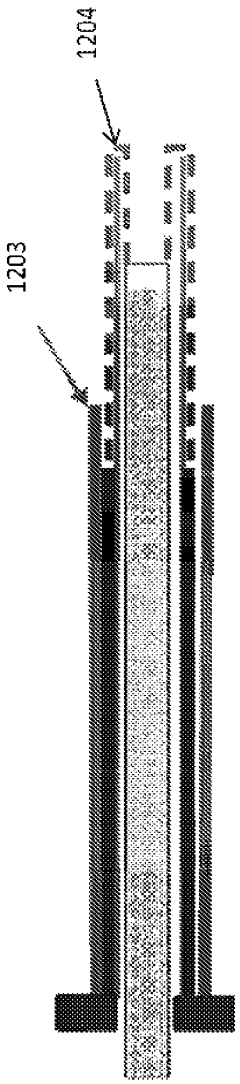


图12A

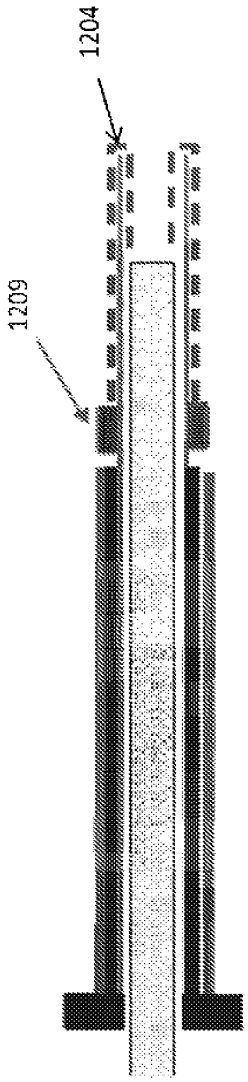


图12B

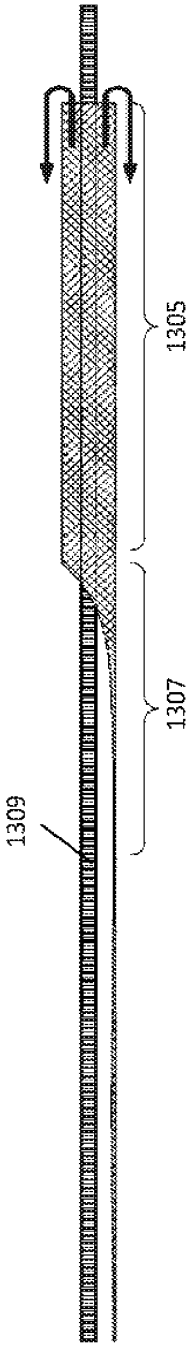


图13A

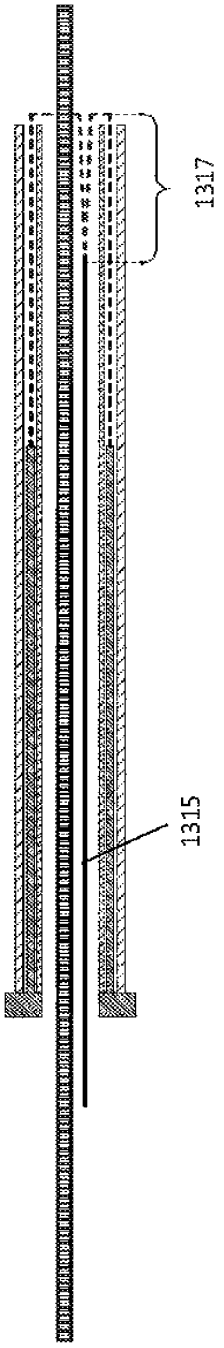


图13B

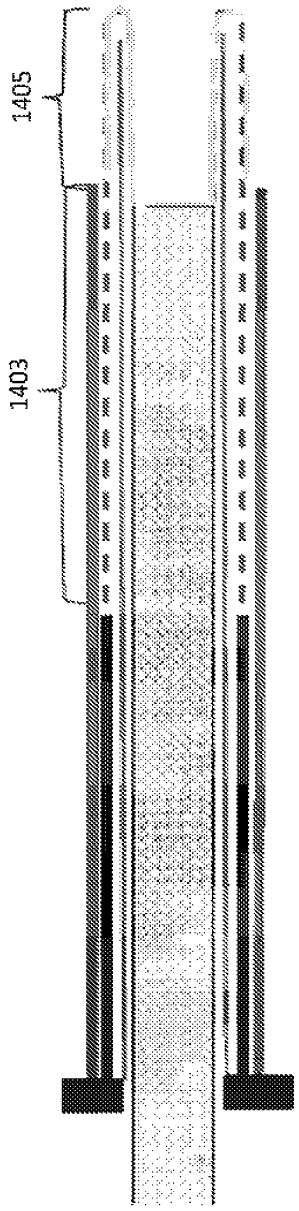


图14

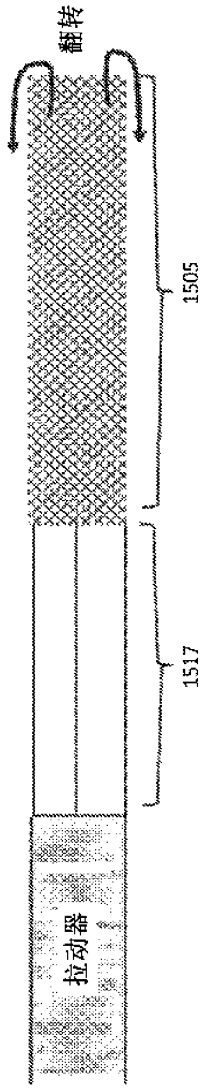


图15A

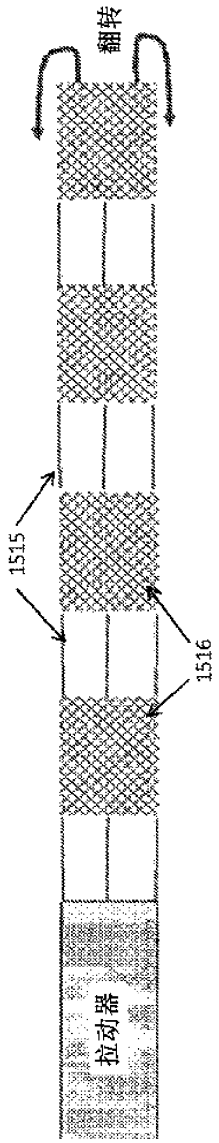


图15B

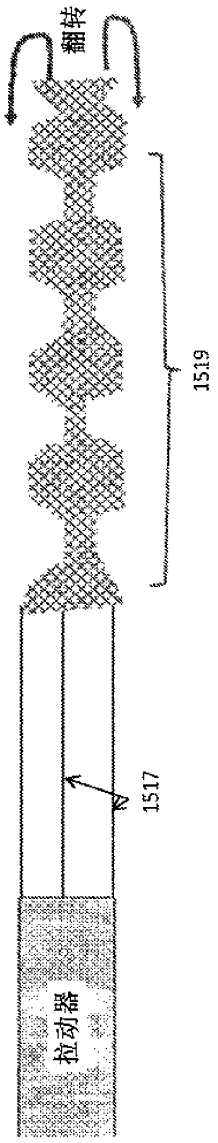


图15C

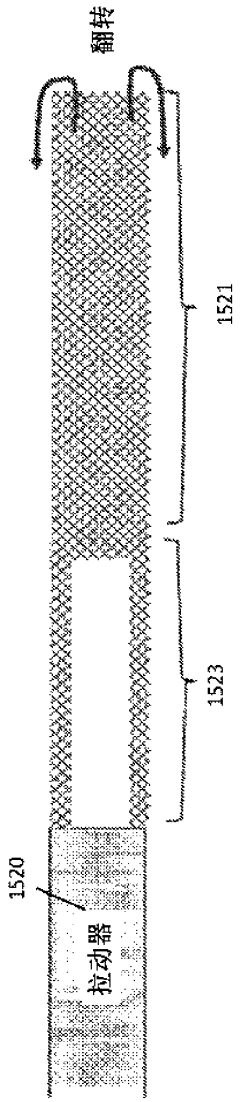
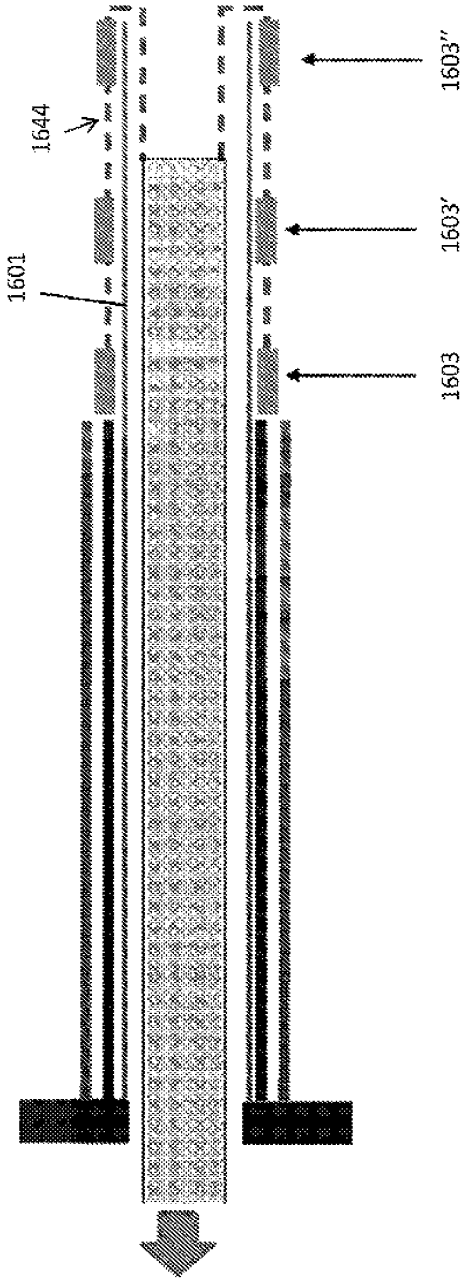


图15D



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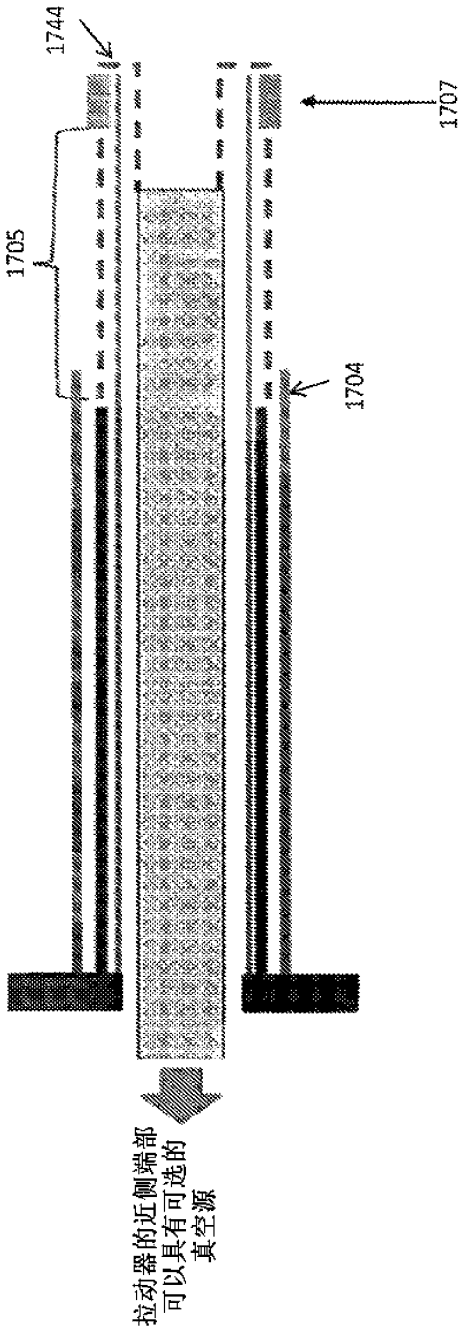
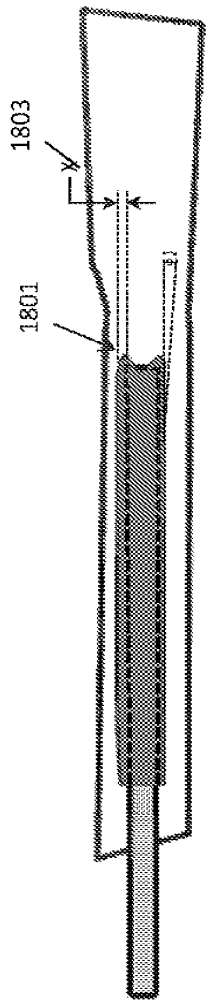


图17



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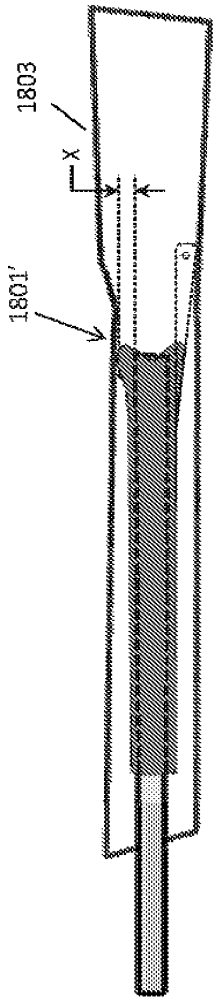


图18B

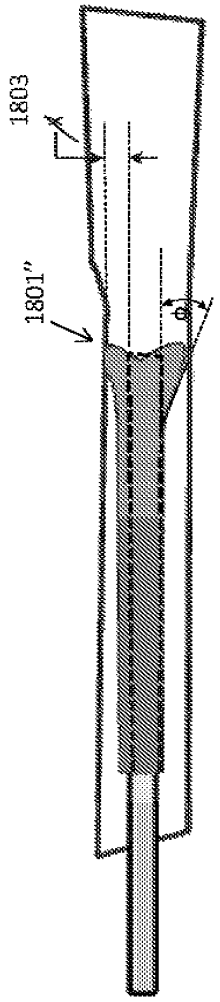


图18C

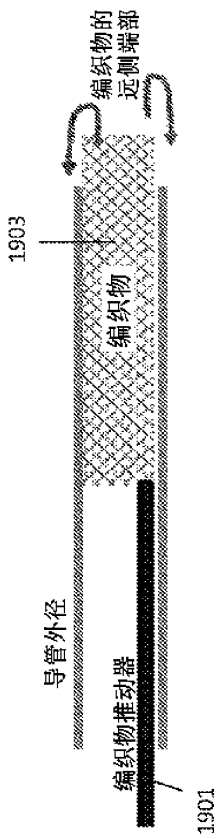


图19A

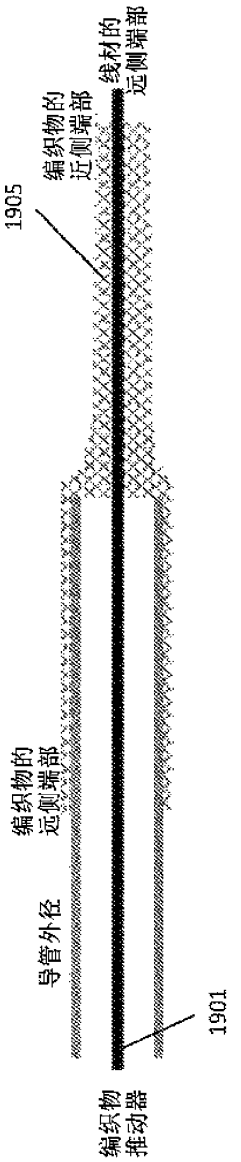


图19B

图20A

图20B

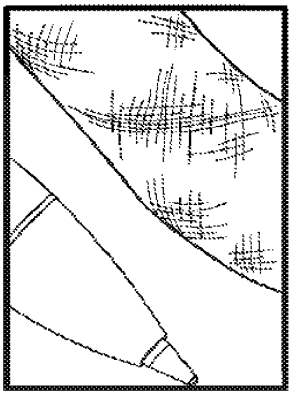
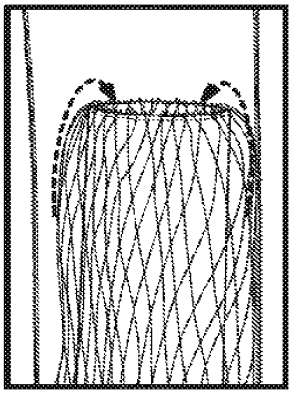


图21A



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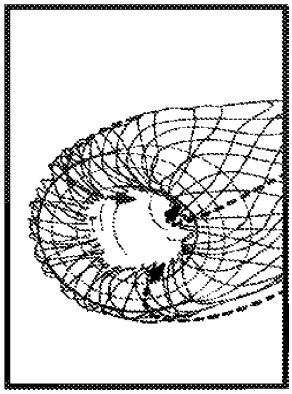

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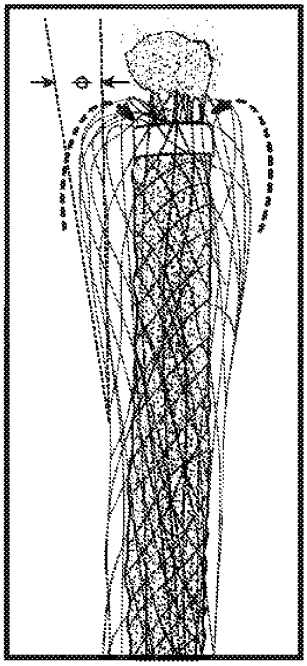

图21D

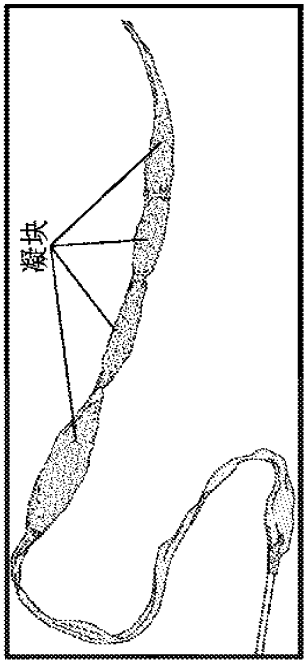

图22

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图23A

图23B

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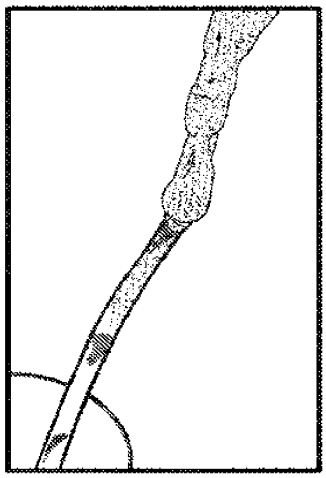

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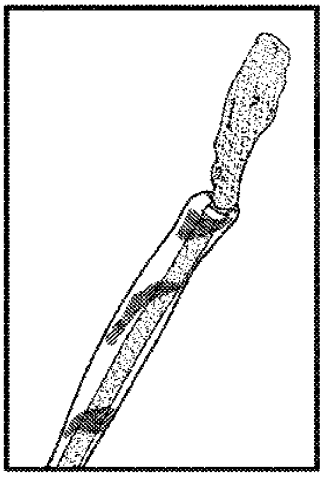

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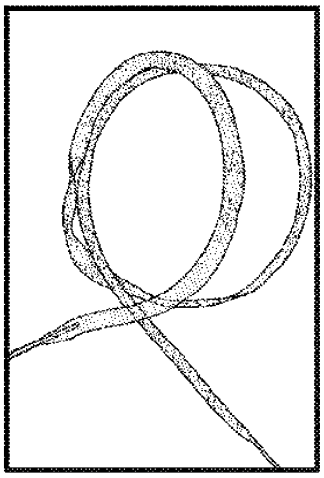


图23E

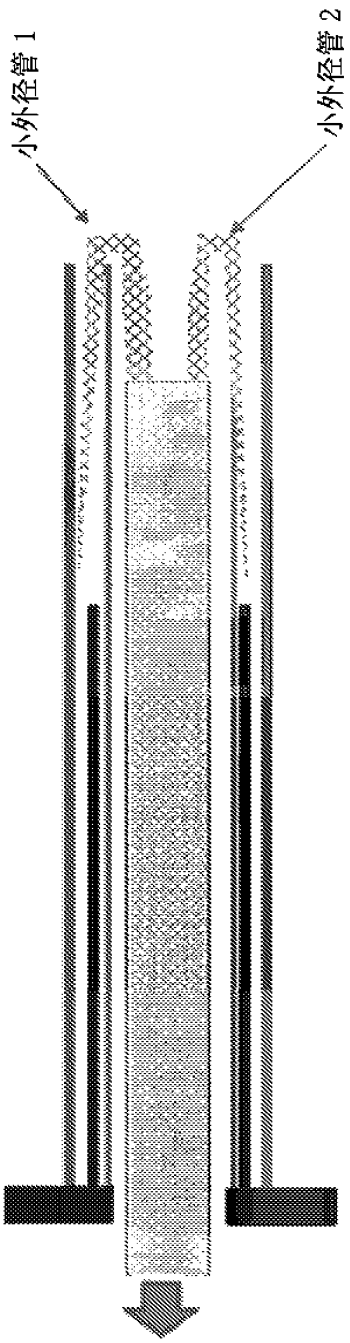
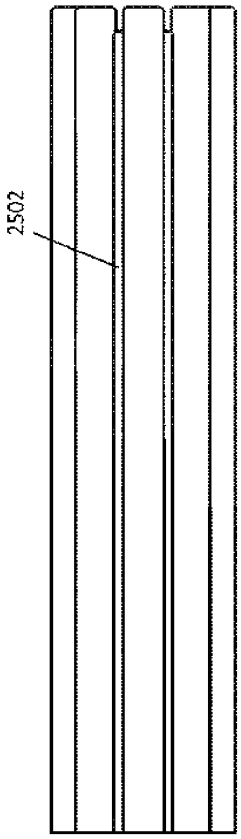


图24



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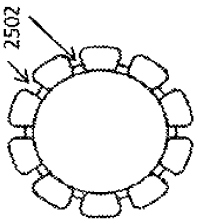
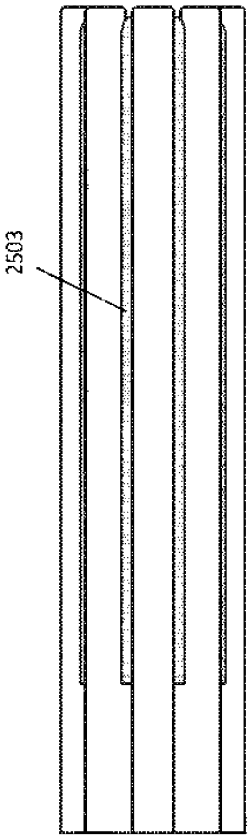


图25B



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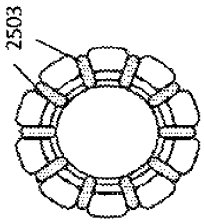

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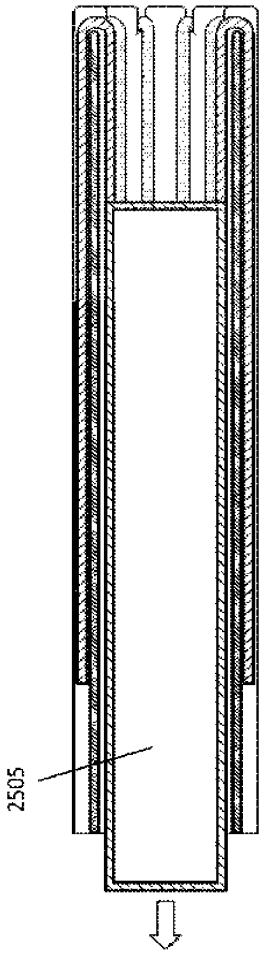

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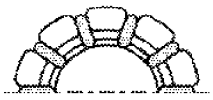

图25F

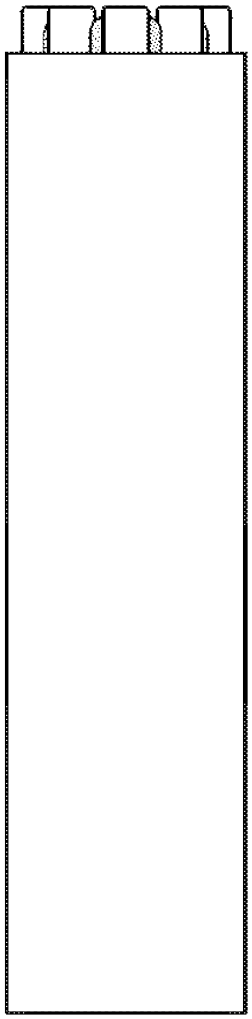

图26A

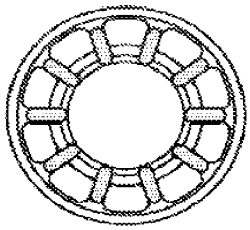

图26B

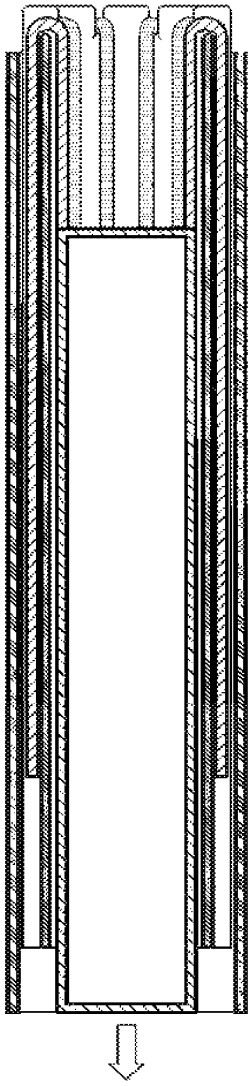

图27A

图27B

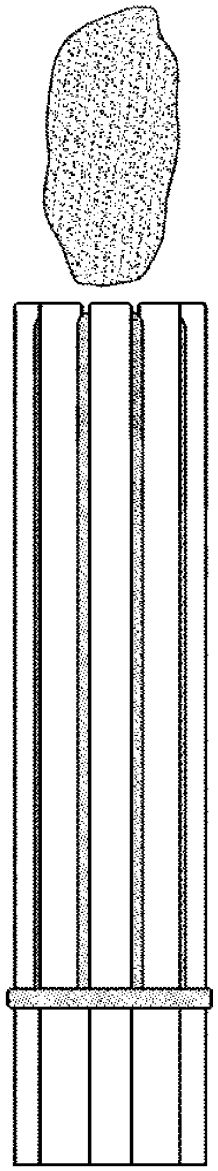

图28

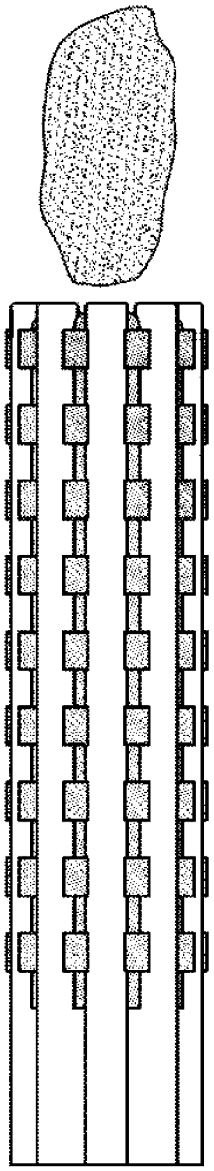

图29

101

图30A

图30B

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图30C

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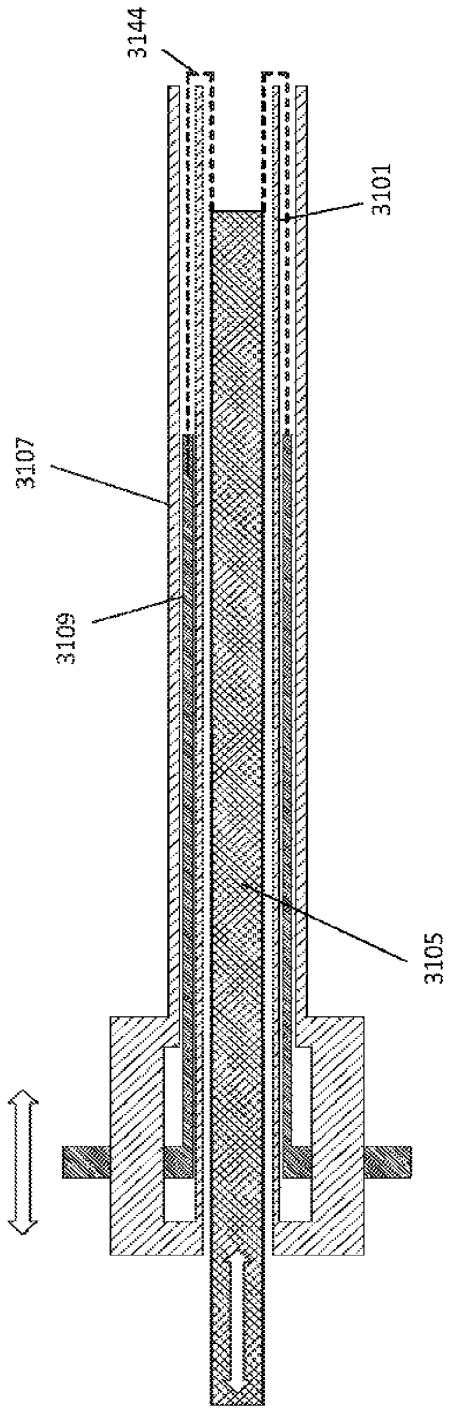


图31

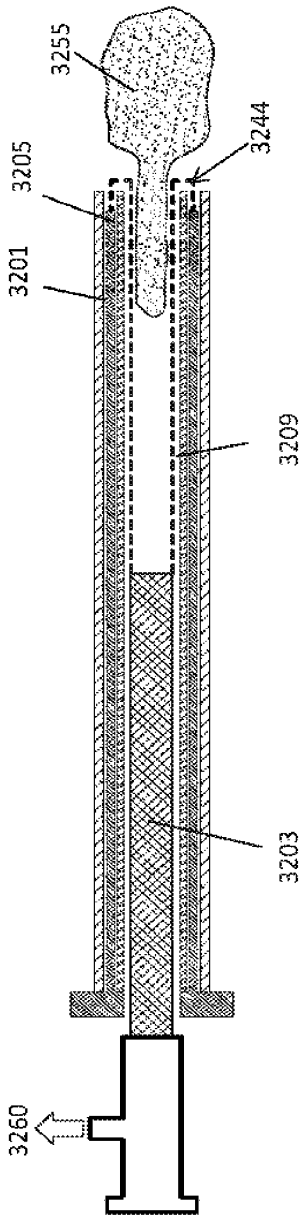


图32

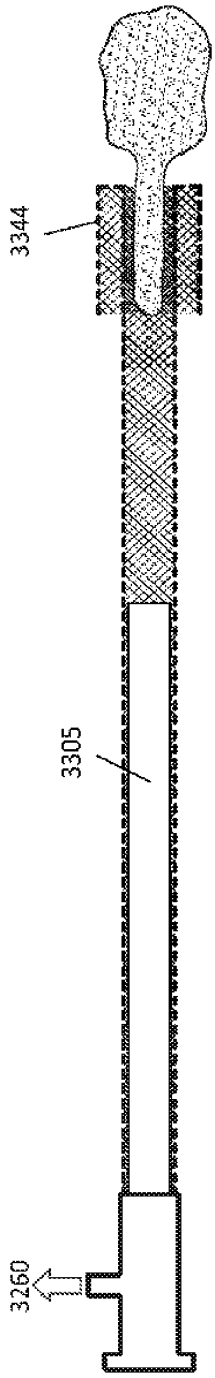


图33

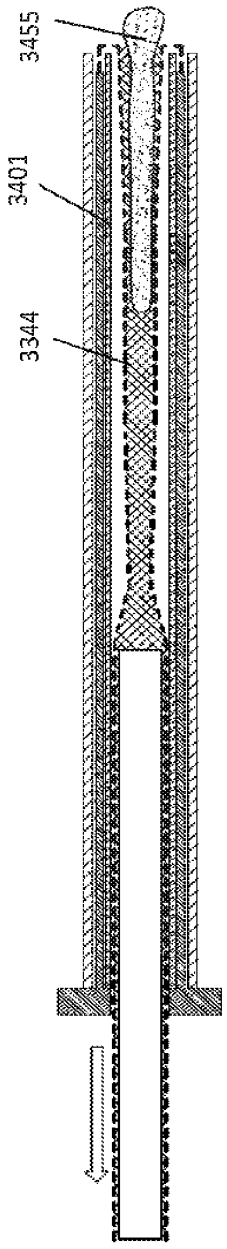


图34

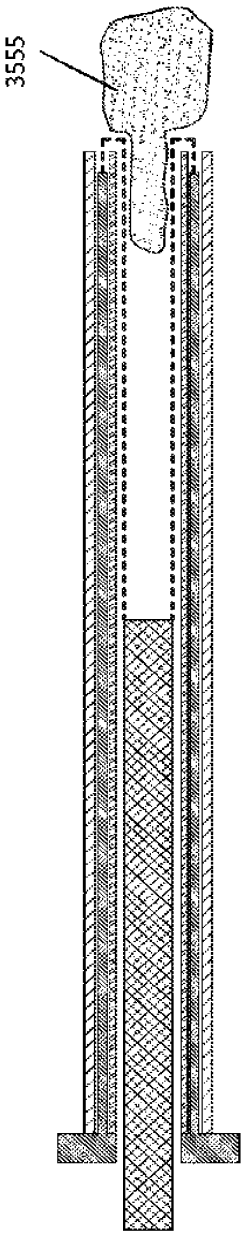
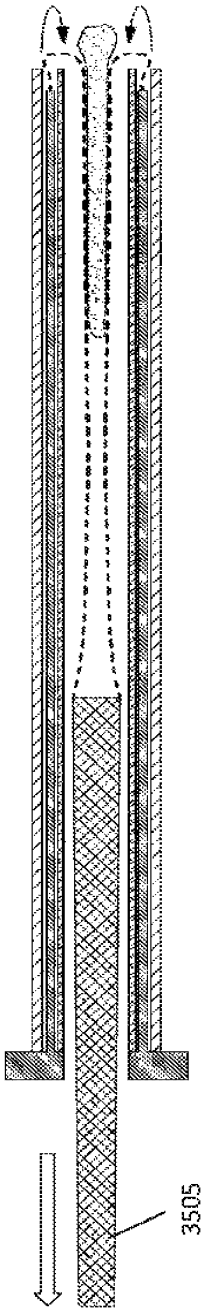


图35A



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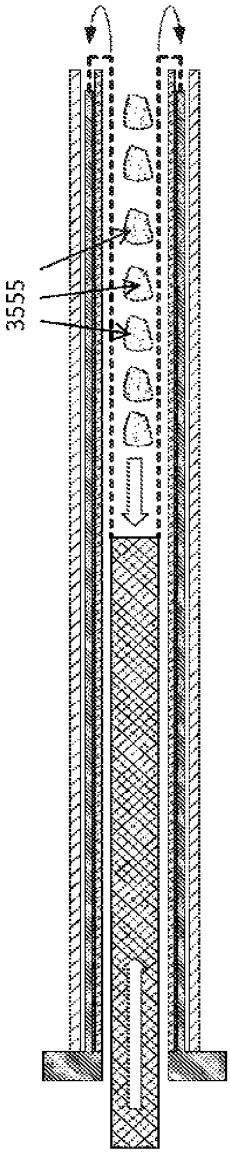

图35C

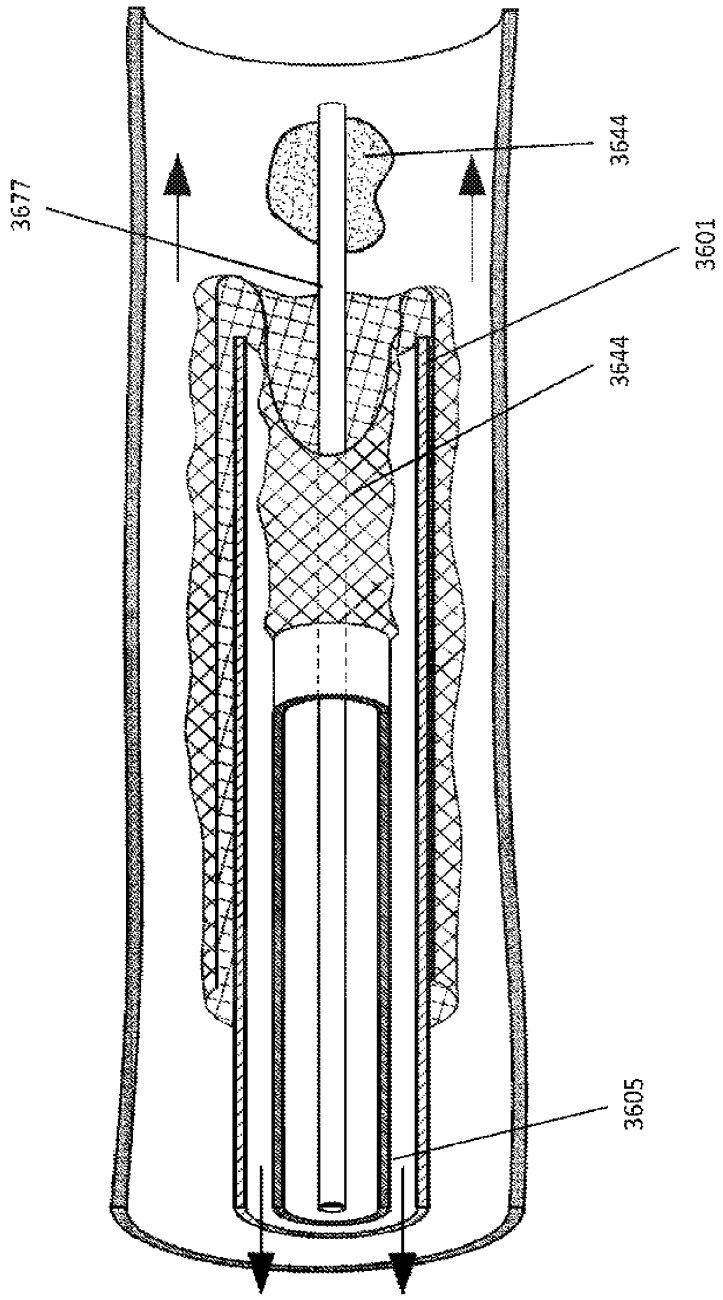

图36

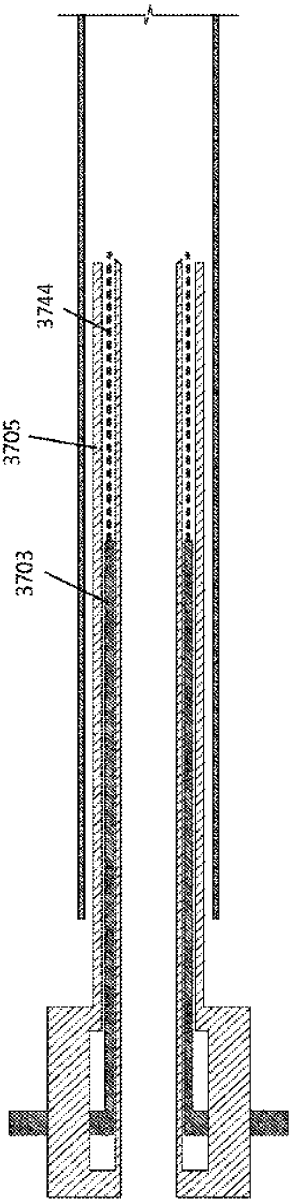

图37A

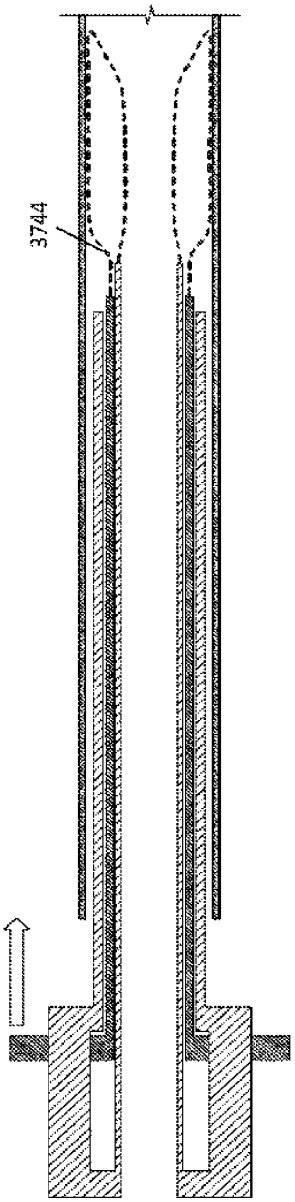

图37B

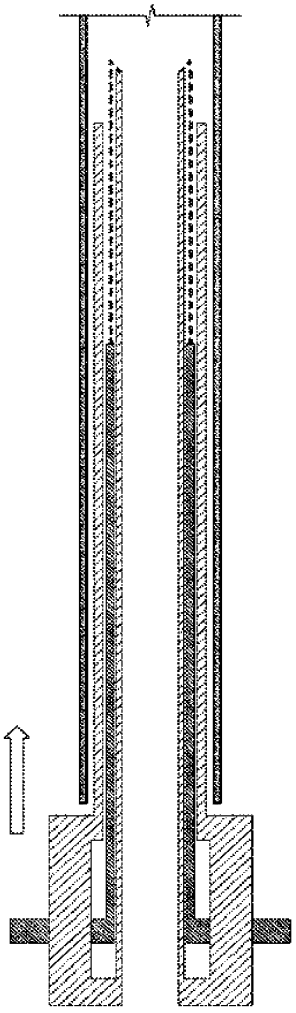

图37C

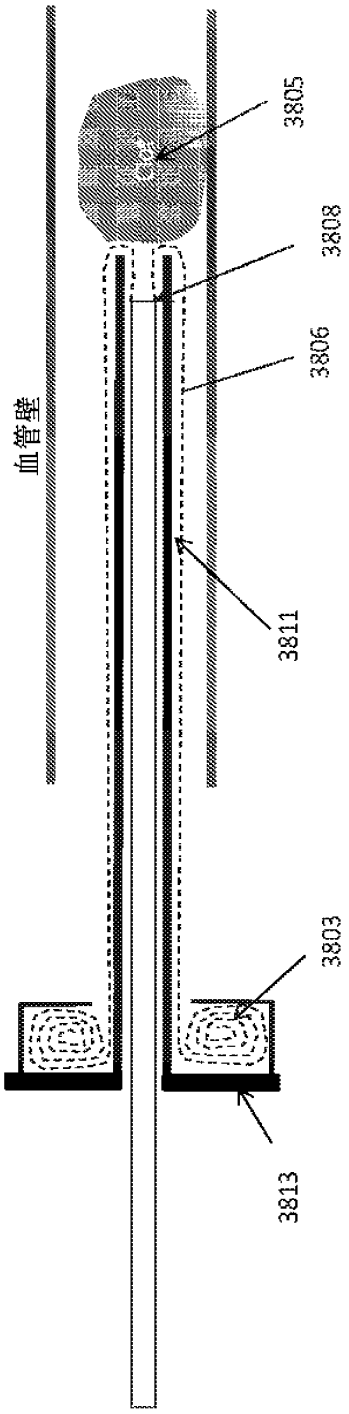

图38A

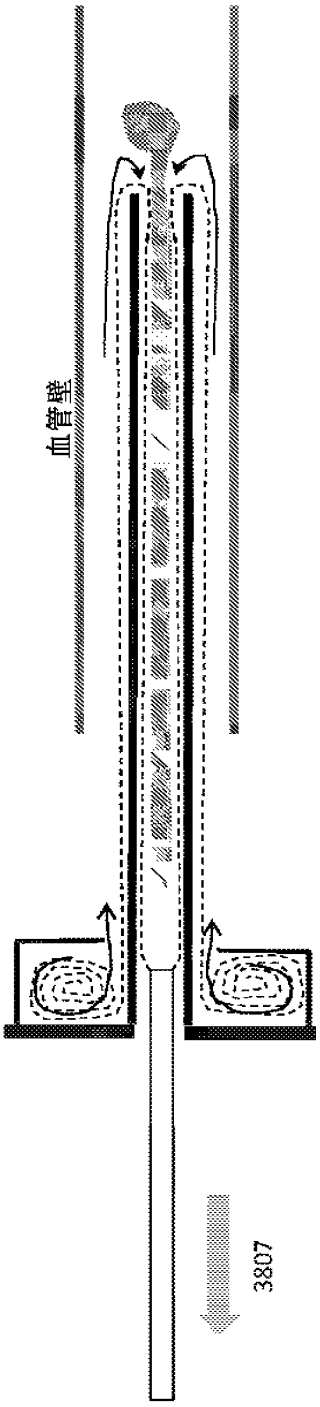

图38B

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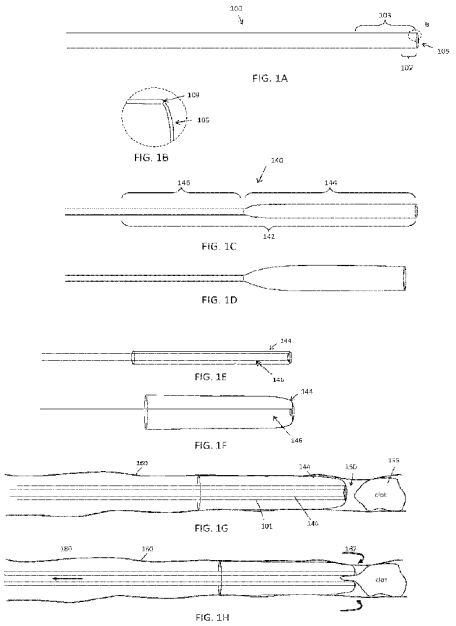
(54) Title: MECHANICAL THROMBECTOMY APPARATUSES AND METHODS



(57) Abstract: Methods and apparatuses for mechanically removing objects from a body. In particular, described herein are thrombectomy methods and mechanical thrombectomy apparatuses for removal of blood clots from within a lumen of a blood vessel.

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MECHANICAL THROMBECTOMY APPARATUSES AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims priority to each of the following provisional patent applications, each of which is herein incorporated by reference in its entirety: U.S. Provisional Patent Application No. 62/284,300, filed September 28, 2015; U.S. Provisional Patent Application No. 62/284,752, filed October 8, 2015; and U.S. Provisional Patent Application No. 62/245,560, filed October 23, 2015.

INCORPORATION BY REFERENCE

[0002] All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

[0003] The apparatuses and methods described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses and methods.

BACKGROUND

[0004] It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue (e.g., blood clots) from the vasculature may improve patient conditions and quality of life.

[0005] Many vascular system problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery.

[0006] When a thrombus forms, it may effectively stop the flow of blood through the zone of formation. If the thrombus extends across the interior diameter of an artery, it may cut off the flow of blood through the artery. If one of the coronary arteries is 100% thrombosed, the flow of blood is stopped in that artery, resulting in a shortage of oxygen carrying red blood cells, e.g., to supply the muscle (myocardium) of the heart wall. Such a thrombosis is unnecessary to prevent loss of blood but can be undesirably triggered within an artery by damage to the arterial wall from atherosclerotic disease. Thus, the underlying disease of atherosclerosis may not cause acute oxygen deficiency (ischemia) but can trigger acute ischemia via induced thrombosis. Similarly, thrombosis of one of the carotid arteries can lead to stroke because of insufficient oxygen supply to vital nerve centers in the cranium. Oxygen deficiency reduces or prohibits muscular activity, can cause chest pain (angina pectoris), and can lead to

death of myocardium which permanently disables the heart to some extent. If the myocardial cell death is extensive, the heart will be unable to pump sufficient blood to supply the body's life sustaining needs. The extent of ischemia is affected by many factors, including the existence of collateral blood vessels and flow which can provide the necessary oxygen.

[0007] Clinical data indicates that clot removal may be beneficial or even necessary to improve outcomes. For example, in the peripheral vasculature, inventions and procedures can reduce the need for an amputation by 80 percent. The ultimate goal of any modality to treat these conditions of the arterial or venous system is to remove the blockage or restore patency, quickly, safely, and cost effectively. This may be achieved by thrombus dissolution, fragmentation, thrombus aspiration or a combination of these methods.

[0008] Catheter directed thrombectomy and thrombolysis are commonly perceived to be less traumatic, less likely to decrease the morbidity and mortality associated with conventional surgical techniques. In recent years, direct administration of chemical lysing agents into the coronary arteries has shown to be of some benefit to patients who have thrombosed coronary arteries. In this procedure, a catheter is placed immediately in front of the blockage and a drip of streptokinase is positioned to be directed at the upstream side of the thrombus. Streptokinase is an enzyme which is able in time to dissolve the fibrin molecule. This procedure can take several hours and is not always successful in breaking up the thrombus. Furthermore, it can lead to downstream thrombus fragments (emboli) which can lead to blockage of small diameter branches. U.S. Pat. No. 4,646,736 discloses a thrombectomy device that permits rapid removal of an obstructive thrombus. However, the device is characterized by small catheter tip size and thus is unable to exert significant total force on clot masses. Also, a clot which is not in good position of purchase on a vessel wall in the "line of fire" of the rotating wire is not fibrinectomized. This is especially true of clots floating free in the blood stream, since it is virtually impossible to revolve within these clots in the absence of a constraint such as fingers.

[0009] Further disadvantages to this thrombectomy device include the difficulty of keeping the clot in the space above the wire during all degrees of rotation as the wire is moved sideways during rotation, which is sometimes necessary to sweep the arterial lumen. In fact, sweeping out an entire arterial lumen with a rotating wire is virtually impossible in all but the smallest, i.e., less than 1.5 mm diameter, arteries. An additional and serious possible disadvantage is that fragments of the clot may be embolized downstream.

[0010] Another approach for capturing emboli is described in U.S. patent application 2015/0005781. This application describes a catheter with a basket extending from the distal end. An actuator, such as a rod or cable, can be pulled proximally to retract the basket into the catheter. Unfortunately, the basket occludes the inside of the lumen, preventing the concurrent use with a positioning and/or supporting guidewire, and the basket must be held in or near the distal end of the catheter. Depending on the stiffness of the material (e.g., clot) being removed, retrieval of the basket often collapses the distal end of the catheter, preventing its use, and the basket can be difficult to pull into the catheter, particularly when holding a clot. This may result in sheering the clot. Finally the basket must be preloaded into the distal

end of the catheter prior to insertion into the vessel, and preloading may be both difficult and time consuming, and may risk disrupting the device prior to deployment.

[0011] Thus, there is a definite need for a thrombectomy device, and particularly a mechanical thrombectomy device that can be more effective in removing tissue such as clots from within a body. Described herein are apparatuses (devices, systems and kit) and methods of using them, that may address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[0012] In general, described herein are medical apparatuses, including medical devices and systems including these medical devices, and methods of operating these medical devices, for collecting objects, including but not limited to blood clots (thrombi), tissue (biopsies, small tumors, polyps, calcifications, kidney stones, etc.). The apparatuses described herein typically include an elongate catheter having a lumen and a distal end and with a distal end opening into the lumen. The catheter may be low-profile neurovascular catheters (e.g., microcatheters, insertion catheters, etc.) having any appropriate diameter (e.g., <1 Fr, 1Fr-6Fr, 1Fr-9 Fr, etc.). A flexible tractor assembly or portion (e.g., which may be referred to herein as a flexible tractor tube or simply a flexible tube) is typically positioned and longitudinally slideable within the catheter, and arranged so that the distal end region ("distal tractor region") doubles back over the distal end of the catheter. The flexible tube ("tractor tube") is generally elongate and hollow and configured to slide and invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter. The distal end forming the distal tractor region may be tubular or not (e.g., it may be formed of strips of material, etc.). The combined catheter and flexible tractor assembly also forms a guidewire lumen through the catheter and the flexible tube that is configured to pass a guidewire.

[0013] In use, a guidewire may be configured to slide through the apparatus (and may form part of the apparatus) to allow positioning and in some variations support, typically without interfering with the operation of the tractor tube drawing an object such as a blood clot into the body of the catheter.

[0014] In addition to the catheter having a flexible tractor tube that is arranged within the catheter and inverted or doubled over the distal end of the catheter, the apparatuses described herein may include one or more features or elements that permit these devices to operate within a vasculature without collapsing, particularly at their distal ends, despite applying a pulling moment over the distal edge/opening of the preferably quite soft distal end. Further, these apparatuses may be adapted to minimize the force required to withdraw the distal tractor region into the catheter and invert over the distal end opening of the catheter, without damaging or weakening the distal tractor region, preventing a failure mode in which the flexible tractor tube within the apparatus breaks, binds up, jams or tangles on its self or with the catheter. For example, as will be described in greater detail below, any of these apparatuses may include a selectively lubricious region at or near the distal end of the catheter. The catheter end may be shaped to allow inverting of the flexible tractor region of the distal end of the tube. In addition, the end profile of the catheter (e.g., the distal-most 5 mm, 4 mm, 3 mm, 2mm, 1mm, etc.)

may have an arrangement of stiffnesses (e.g., durometers) that prevent collapse/buckling of the catheter. Alternatively or additionally, the flexible tractor tube may be adapted for "sweeping" as much of the vessel around the catheter to collect objects from within the vessel while still allowing relatively low-force retraction into the catheter and inverting over the distal end of the catheter. The tractor portion of the flexible tube, which may refer to a distal portion of the tube within the catheter, may generally include a distal expandable (first) end region that is adjacent, either immediately adjacent or separated by a spacer region, to a second less-expandable (or non-expandable) end region. The second end region is proximal (when both the first end region and the second end regions are drawn into the catheter) to the first end region. The flexible tractor tube may extend all the way through the catheter to a proximal end and/or proximal handle, or it may end before the proximal end of the catheter and be connected to a puller. The puller may be another, possible less flexible tube, or a wire, rod, string, etc. The flexible tractor tube is generally configured to have a lumen through it (e.g., central lumen or radially offset lumen) through which a guidewire may be passed, passing through the apparatus, including the catheter and the flexible tractor tube. The flexible tractor tube may generally be operated (e.g., pulled proximally and in some variations pushed distally) while a guidewire is within this lumen.

[0015] The apparatus may be pre-loaded for deployment of the distal tractor region and capture of an object within a vessel, or in some variations it may be loaded *in vivo*, after or during positioning a guidewire and/or the catheter within a blood vessel. For example, in some variations, the apparatus may be adapted for use *in vivo* by holding the distal tractor region retracted into the catheter until the catheter is within the vessel, and preferably near the object to be removed. Once positioned, the distal tractor region of the flexible tube within the catheter may be distally extended from the catheter, expanded to form the capture shape that can be drawn and inverted over the distal end of the catheter either with or without advancing the catheter distally. Thus, the distal tractor portion may be safely and securely delivered to the necessary site within the lumen without risk to damage to the apparatus or the body.

[0016] For example, a method of performing a mechanical thrombectomy to remove a clot from a blood vessel may include: advancing a distal end of a catheter through the blood vessel towards the clot; exposing a distal tractor region of a tube that is within the catheter from the distal end of the catheter, wherein the distal tractor region comprises an expandable first end region and a less expandable second end region proximal to the expandable first end region; allowing the expandable first end region to expand within the blood vessel; positioning the distal end of the catheter so that a distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region while the expandable first end region is doubled over the less expandable second end region; and drawing the clot into the catheter by rolling the expandable first end region rolls over the distal end of the catheter so that the expandable first end region inverts as the expandable first end region is pulled into the catheter.

[0017] The step of advancing the distal end of the catheter through the blood vessel towards the clot may include advancing over a guidewire, as mentioned. The catheter may be slid distally over the guidewire or extended distally (or retracted proximally) with the guidewire. The inner (tractor) tube may

be held within the catheter (e.g., near the distal end, a middle region, or near the proximal end) or in some variations it may be inserted after positioning the catheter within the vessel. The distal end of the catheter may be positioned at, near or adjacent the object to be removed (e.g., the clot), or it may be separated by a predetermined distance, e.g., to allow space for the apparatus to set up by extending the distal tractor region out of the distal end of the catheter and expand in preparation for withdrawing the object into the catheter.

[0018] Thus, once positioned, the apparatus may be deployed by exposing the distal tractor region and positioning the distal end of the catheter and in some variations the guidewire, to allow the object to be captured and drawn into the catheter. The distal tractor region may be exposed by pulling the catheter proximally while either holding the flexible tube including the distal tractor region stationary (e.g., relative to the blood vessel) and/or by extending the flexible tube distally.

[0019] As mentioned, the flexible tube may include a distal tractor region that includes a first end region that is expandable. This end region is generally porous (e.g., formed of a mesh, knit, woven, or other material, including solid material having multiple openings therethrough) and adapted to grab the object (e.g. clot) to be removed. This first end region is generally expandable to between about 1.3x and about 10x the inner diameter of the catheter (e.g., between about 1.5 and about 7x, between about 1.5x and about 5x, between about 1.5 and about 4x, between about 1.5x and about 3x, etc.). This first distal end region forming the tractor portion is generally adjacent to the second end region that is less expandable (or not substantially expandable). The second region may extend proximally all the way down the catheter, or partially down the catheter. In general, the first end region of the tractor portion is exposed from out of the catheter and used to capture the clot or other object; the second end region may be exposed during positioning but may otherwise remain within the catheter during operation.

[0020] Thus, exposing a distal tractor region of a tube that is within the catheter from the distal end of the catheter may include extending or pushing the distal tractor region out of the distal end of the catheter. In some variations the distal tractor region is pre-formed so that the first expandable distal end region is doubled over the second distal end region; in other variations the first distal end region is in-line, distal to, the less expandable second distal end region. The catheter may then be moved distally so that a distal end region of the catheter (including the distal end) is extended in a gap radially between the expanded expandable first end region of the distal tractor region and the less-expandable second end region.

[0021] In any of the variations in which the distal tractor region is pushed out of the distal end of the catheter, e.g., during this initial *in vivo* set up phase, the flexible tube, and particularly the distal tractor region, may be configured or otherwise adapted to allow pushing out of catheter without binding up. Binding within the catheter of an expandable tube may occur if the expandable first end region in particular becomes caught on the inner walls of the catheter, preventing deployment. In some variations the expandable first end region is configured as a mesh tubular member having filaments (e.g. Nitinol, polymeric, etc.) having between about 24 to 144 stands, having a thickness of 0.0005 inches to 0.005 in diameter, wherein the mesh tubular member extends in a longitudinal axis, further wherein the mesh

tubular member has a length that is greater than 5 cm, forms a braid angle between crossing strands in a direction of the longitudinal axis of about 35 degrees or less when being pulled and inverted around the distal end of the catheter and expands to a diameter of greater than 1.5 times an inner diameter of the catheter outside of the catheter when unconstrained. Within this configuration, the tubular member has been found to be pushable.

[0022] In other variations, when the expandable first distal end region is pushed or extended out of the distal end of the catheter, it may be configured (e.g., pre-shaped, shape-set, etc.) to invert over the distal end of the catheter and expand. The catheter may be moved distally, aiding in pushing this expandable first end region of the distal tractor region proximally relative to the outside of the catheter.

[0023] In any of these methods, the distal tractor region may include the expandable first end region and a less expandable second end region proximal to the expandable first end region, and the expandable first end region is permitted to expand within the blood vessel.

[0024] Thus, towards the end of the deployment phase, the distal end of the catheter is typically positioned so that the distal end region of the catheter is radially between the less expandable second end region and the expandable first end region of the distal tractor region while the expandable first end region is doubled over the less expandable second end region.

[0025] Thereafter, an object (e.g., clot) may be drawn into the catheter by rolling the expandable first end region over the distal end of the catheter so that the expandable first end region inverts as the expandable first end region is pulled into the catheter.

[0026] As mentioned, positioning may include distally advancing the distal end of the catheter so that the distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region.

[0027] A guidewire may be used with any of the methods described herein. For any of the methods described herein may include advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until the distal end of the catheter is proximate to the clot. The guidewire may be inserted into or through the clot, or it may be positioned just before the clot. The guidewire may be left in during clot removal, or it may be partially or completely withdrawn first. For example, any of these methods may include advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until the distal end of the catheter is proximate to the clot, further wherein drawing the clot into the catheter comprises advancing the catheter towards the clot over the guidewire while rolling the expandable first end region over the distal end of the catheter.

[0028] Drawing the clot into the catheter generally includes rolling the distal tractor region (e.g., the expandable first end region) over the distal end of the catheter. The apparatus may also be moved distally during actuation of the distal tractor region. For example, drawing the clot into the catheter may include withdrawing the tube proximally (to roll the distal tractor region over the distal end) and/or withdrawing the tube proximally while advancing the catheter distally.

[0029] In any of these methods, drawing the clot into the catheter may include withdrawing the tube proximally while advancing the catheter distally, wherein the tube is withdrawn at a different rate than the catheter is advanced. It may be beneficial in some configurations to advance the catheter distally more rapidly than the tube (distal tractor region) is drawn proximally. In some variations, the catheter may be advanced more slowly than the tube (distal tractor region) is withdrawn proximally. Alternatively in some variations, they are moved at the same rate. The rate of motion may be determined for the flexible tube by looking at the proximal motion (e.g., of the second end region) within the catheter.

[0030] In general the expandable first end region of the distal tractor region is expandable and may form a distal-facing mouth or lip that can engage with an object such as a clot. The mouth of lip of the expandable tractor region may form a tangent angle or roll angle (as described below in greater detail in reference to FIGS. 18 and 21D) with respect to the long axis of the catheter outer diameter (OD) in the range of 5-60 degrees and preferable at least 10 degrees (e.g., 10°-60°, 10°-50°, 10°-45°, etc.). As long as the roll angle is at least 10 degrees with the tube is retracted into the catheter, the tube should not bind or jam on the catheter tip. The mesh tube may be constructed by modifying is stiffness to ensure the roll angle in greater than 10 degrees. Alternatively or in combination to maintaining a minimum roll angle it may be desirable to maintain a physical space or gap between the tube material ID and the O.D of the catheter (as described in greater detail in FIG. 18, below) at the catheters most distal tip. The gap may need to be greater than, e.g., 0.1, mm 0.2 mm, 0.3 mm, 0.4 mm, 0.5 mm, 0.7 mm, 0.8 mm, 0.9 mm, 1.0 mm, etc. to ensure the tube rolls around the distal end of the catheter when the tube is retracted. The expanded material (e.g., a mesh, woven, braided, kitted, perforated, etc. material) may be allowed to expand within the blood vessel by itself. Thus the expandable first region may be self-expandable. The expandable first end region of the distal tractor region may be pre-biased to expand. In some variation a shape memory material (e.g., shape memory alloy) is used. In some variations a biasing element is included in or integral to the expandable first end region to expand so that the distal tractor region. The expandable first end region may expand to make contact with an intima of the blood vessel. In some variations the apparatus may be configured (e.g., sized, including sizing the expandable first end region) so that the distal-most end of the distal tractor region makes contact with the vessel lumen. Thus, any of the variations described herein may additionally or alternatively include a biasing element such as a loop, ring, scaffold, or the like to push the expandable distal end region open so that it can make contact with the vessel by applying an increased radial force to expand it open. In some variations this opening bias (loop, helix, ring, etc.) is located at or near the distal end of the expandable first end region of the distal tractor region.

[0031] Any of the variations described herein may include an expandable catheter tip. For example, in some variation the durometer of the catheter tip may be sufficiently soft to compress proximally when the distal tractor region is drawn proximally into the catheter; compressing the distal tip axially may expand it slightly (e.g., so that it may flare out) at the distal end.

[0032] As mentioned, exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter may comprise pushing the distal tractor region out of the distal end of the

catheter. Alternatively or additionally, exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter may comprise pulling the catheter proximally. For example, exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter may comprise pushing the distal tractor region out of the distal end of the catheter to expose the expandable first end region already inverted over the less expandable second end region.

[0033] In some variations, exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises extending the expandable first end region out of the distal end of the catheter so that the expandable first end region inverts over the distal end of the catheter as the expandable first end region is extended.

[0034] The expandable first end region of the distal tractor region may be any appropriate length, and any portion of this length (all of it, 90%, 80%, 70%, 60%, 50%, 40%, etc.) may be exposed during this set-up period. For example, in some variations, exposing the distal tractor region of the tube may comprise exposing at least 5 mm of the expandable first end. The expandable first end region may be, e.g. 5 mm or greater (e.g., 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, 50, 55, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 200, 300, 400, 500 mm, etc. between about 5 mm and 500 mm, between about any lower value of 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, 50, 55, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 200 mm and any larger value of 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, 50, 55, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 200, 300, 400, 500 mm, where the lower value is always lower than the larger value). In any of these variations, when exposing the distal tractor region, either just the expandable first distal end region may be exposed out of the catheter (e.g., when pushing the expandable distal end region out distally and allowing it to invert over the distal end of the catheter) or both the expandable first distal end region and the less expandable second distal end region may all or partially exposed. For example, exposing at least 1 cm of the expandable first end region and at least 1 cm of the less expandable second end region. The expandable first end region may be inverted (doubled back) over the less expandable second end region.

[0035] As mentioned, the expandable first end region may comprise any appropriate material that is both expandable and able to grip the object (e.g., clot). For example the expandable first end region of the distal tractor region may comprise a mesh that is coupled adjacent to the less expandable second end region. For example the expandable first end region may be one or more of: a woven material, a mesh braided material, a knitted material, or a film material with multiple openings therethrough. The less expandable second end region may be made of the same material or it may be made of a different material. The less expandable second end region may have the same structure (e.g., woven, etc.) or it may have a different structure, including a less-expandable variation of the structure of the expandable first end region. For example the less expandable second end region may be a non-porous (e.g. non-woven, non-knitted, etc. or solid material) or less porous (e.g., tightly woven, small pore size knitted holes, tight braid). In some variation the less expandable second end region may include a transition region between the expandable first end region (e.g., having an intermediate expandability) and a non-expandable portion

of the second end region. In general, the less expandable second end portion of the distal tractor region include non-expandable structures and materials.

[0036] A method of performing a mechanical thrombectomy to remove a clot from a blood vessel may include: advancing a distal end of a catheter through the blood vessel towards the clot; exposing a distal tractor region of a tube that is within the catheter from the distal end of the catheter, wherein the distal tractor region comprises an expandable first end region and a less expandable second end region proximal to the expandable fist end region and configured so that the expandable first end region is inverted over the less expandable second end region; allowing the expandable first end region to expand within the blood vessel so that the distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region; and drawing the clot into the catheter by advancing the catheter distally and withdrawing the tube proximally within the catheter so that the expandable first end region rolls over the distal end of the catheter and inverts as the expandable first end region is pulled into the catheter.

[0037] As mentioned, the expandable first end region may be inverted over the less expandable second end region before exposing the distal tractor region. Alternatively, exposing the distal tractor region may include inverting the expandable distal end region over the less expandable second end region as the distal tractor region is exposed. In general, exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter may include pushing the distal tractor region out of the distal end of the catheter. Exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter may include pulling the catheter proximally.

[0038] A method of performing a mechanical thrombectomy to remove a clot from a blood vessel may include: advancing a distal end of a catheter through the blood vessel towards the clot; exposing a distal tractor region of a tube that is within the catheter out of the distal end of the catheter, wherein the distal tractor region comprises an expandable first end region and a less expandable second end region, wherein exposing comprises extending the expandable first end region out of the distal end of the catheter so that the expandable first end region inverts over the distal end of the catheter as the expandable first end region is extended; allowing the expandable first end region to expand within the blood vessel as it is extended out of the distal end of the catheter so that a distal end region of the catheter is between the less expandable second end region and the expandable first end region; and drawing the clot into the catheter by withdrawing the tube proximally within the catheter so that the expandable distal end region rolls over the distal end of the catheter, collapses, and inverts as the expandable distal end region is pulled into the catheter. Exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter may include pushing the distal tractor region out of the distal end of the catheter. Alternatively or additionally, exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter may include withdrawing the catheter proximally relative to the distal tractor region of the tube.

[0039] Also described herein are mechanical thrombectomy devices for removing a clot from a vessel, the device comprising: a catheter having a distal end and a distal end opening, wherein the catheter

has an inner diameter and an outer diameter; a distal tractor region of a tube within the catheter, wherein the distal tractor region comprises an expandable distal end region and a less expandable distal end region proximal to the expandable distal end region, the distal tractor region configured so that the expandable distal end region is inverted over the less expandable distal end region; a guidewire lumen through the catheter and the tube, including the distal tractor region, wherein the guidewire lumen is configured to pass a guidewire; and a proximal handle coupled to the tube and configured to cause relative motion between the catheter and the tube such that the distal tractor region is released from within the inner diameter of the catheter so that the expandable distal end region may expand to a diameter that is greater than the outer diameter so that the catheter may be advanced between the expandable distal end region and the less expandable distal end region and the tube may be drawn proximally to pull the expandable distal end region over the distal end of the catheter so that the expandable distal end region rolls into the distal end of the catheter, inverts, collapses and is drawn into the catheter.

[0040] For example, a mechanical thrombectomy device for removing a clot from a vessel may include: a catheter having a distal end and a distal end opening, wherein the catheter has an inner diameter and an outer diameter; a tube having a distal tractor region within the catheter, wherein the distal tractor region comprises an expandable distal end region and a less expandable distal end region that is proximal to the expandable distal end region, further wherein the expandable distal end region is biased to invert over the less expandable distal end region as it is exposed from the distal end of the catheter; a guidewire lumen through the catheter and the tube, including the distal tractor region, wherein the guidewire lumen is configured to pass a guidewire; and a proximal handle coupled to the tube and configured to cause relative motion between the catheter and the tube such that the distal tractor region is released from within the inner diameter of the catheter so that the expandable distal end region may expand to a diameter that is greater than the outer diameter and the tube may be drawn proximally to pull the expandable distal end region over the distal end of the catheter so that the expandable distal end region rolls into the distal end of the catheter, inverts, collapses and is drawn into the catheter.

[0041] Also generally described herein are mechanical thrombectomy apparatuses. For example, described herein are mechanical thrombectomy apparatus for removing a clot from a vessel, including: a catheter having a distal end and a distal end opening; a flexible tube extending within the catheter and doubling back over the distal end of the catheter, wherein the flexible tube is configured to slide and invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter; and a guidewire lumen through the catheter and the flexible tube that is configured to pass a guidewire.

[0042] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: a catheter having a distal end and a distal end opening, wherein the distal end opening has a durometer that is greater than a durometer of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile; a flexible tube extending within the catheter and doubling back over the distal end of the catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter; and a guidewire

lumen through the catheter and the flexible tube configured to pass a guidewire. The catheter distal end durometer may be greater than 60A shore hardness or greater than 40D shore hardness.

[0043] A mechanical thrombectomy apparatus for removing a clot from a vessel that include: an inner catheter having a distal end and a distal end opening; a flexible tube extending though the catheter and doubling back over the distal end of the inner catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the inner catheter; an outer catheter extending over the inner catheter and flexible tube; a lubricious region of the flexible tube extending between a distal end of the outer catheter and the distal end opening of the inner catheter, wherein the majority of the flexible tube is not lubricious; and a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.

[0044] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: an inner catheter having a distal end and a distal end opening; a flexible tube extending though the catheter and doubling back over the distal end of the inner catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the inner catheter; a releasable attachment between the flexible tube and an outer surface of the catheter, configured to release when the flexible tube is pulled with a predetermined force (e.g., that is greater than 0.01 N); and a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.

[0045] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: a catheter having a distal end, a distal end opening and an inner diameter; a flexible tube extending through the catheter and doubling back over the distal end of the catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter, the flexible tube having a low Poisson's ratio, such that the flexible tube has a diameter of greater than half the inner diameter of the catheter when pulled proximally within the catheter with sufficient force to invert over the distal end opening; and a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire. The flexible tubes having a low Poisson's ratio may be less than 0.5 or in the range of 0.05 to 0.5 or 0.1 to 0.3.

[0046] As already mentioned above the flexible tube typically includes the distal tractor region having an expandable first end region and a less- (or non-) expandable second end region proximally adjacent to the first end region. Thus, the flexible tube may comprise a mesh tube.

[0047] In general, the catheters forming part of the apparatuses described herein are highly flexible, as would be appropriate for the tortious paths taken, e.g. by neurovascular catheters. In some variations, the aggregate stiffness of the assembled apparatus (having the flexible tube wrapped over the distal end and ready for operation) is within a predetermined percentage (e.g., within 10%, within 12%, within 15%, within 16%, within 17%, within 18%, within 19%, within 20%, within 25%, within 30%, etc.) of the original stiffness of the catheter without the flexible tube. For example, the flexible tube extending through the catheter and doubling back over the distal end of the catheter may increases the stiffness of a distal 5cm of the catheter by less than a predetermined percentage (e.g., 15%) of the stiffness of the distal

5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[0048] In any of the variations described herein, the distal tractor region of the flexible tube is adapted to grab an object, e.g., clot. In particular, the flexible tube may be porous or have at least one porous section having a pore pattern having a longitudinal separation between pores of less than a predetermined distance (e.g., about 0.005 inches) in width. As used in this example "pores" includes windows, openings, gaps, etc. between strands of mesh (weave, etc.) as well as pores formed through a solid sheet of material. In general, for woven (and particularly braided) expandable first end region materials, smaller filaments may be better at grabbing, and therefore smaller pore sizes may be preferred. The optimal sizing may depend on the material, including filament size, pore percentage, size of the spacing of pores, pore diameters, etc. For example, in some variations it is beneficial to have a porosity of greater than >60% (greater than 70%, greater than 75%, greater than 80%, greater than 85%, etc., between 60-95, 65-95, 70-95%, etc.) and a fiber diameter (for woven materials) that is <0.005. The effective pore size of the flexible tubular member required to make sure the clot or foreign body is grabbed may range from 50 to 1000 micrometers (μm), or in the range of 100-200μm, 100-300μm, 100-500μm or 500-1000 μm. The flexible tubular member may have a variety of pore sizes along its length.

[0049] In general, as used herein a woven material includes any material formed by weaving multiple strands of material in an interlacing pattern (e.g., interlacing strands, filaments, lengths of material, etc.). A mesh is one type of woven material. A woven material is typically more stretchable/expandable in certain directions (on the bias directions) depending on the elasticity of the material forming the weave. Woven materials are typically run in parallel or nearly parallel paths. A knitted material may be more flexible and generally refers to a single path or course that is meandering, forming loops that may be symmetrically arranged and interlocking. Woven material may be highly stretchable/flexible. Knitted constructs tend to be less stretchable but yet still highly flexible.

[0050] In any of the apparatuses described herein, and particularly the pre-loaded or pre-formed versions, the apparatus may include a releasable attachment between the flexible tube and an outer surface of the catheter, configured to release when the flexible tube is pulled with a force that is greater than a predetermined force threshold. For example, the releasable force threshold may be greater than about 0.001 N, greater than about 0.005 N, greater than about 0.01 N, greater than about 0.03 N, greater than about 0.05 N, greater than about 0.08 N, greater than about 0.1 N, greater than about 0.3 N, greater than about 0.5 N, etc.).

[0051] In any of the apparatuses described herein, the flexible tube may comprise a plurality of strips of flexible material, wherein the strips are arranged in parallel with the long axis of the flexible tube. Alternatively or additionally, in any of these variations, the distal end opening may comprise a plurality of notches or channels into which fibers or strips forming the flexible tube are drawn as the flexible tube inverts over the distal end opening.

[0052] In any of the apparatuses described herein, the flexible tube may comprise a polymeric tube having a plurality of holes therethrough. For example, the flexible tube may comprise a distal end, a

proximal end and a body region there between, wherein the body region transitions from a more flexible distal end to a stiffer proximal end.

[0053] As mentioned above, in any of the variations described herein, the distal end of the catheter (e.g., the distal opening region) may be adapted to prevent collapsing when inverting the distal tractor region over the catheter opening but still be soft enough to provide appropriate use for neurovascular applications. For example, any of the apparatuses described herein may have a durometer at the distal end (e.g., at the distal end opening/rim) that is greater than a durometer of a region immediately proximal to the distal end. Any of these distal end openings may have a rounded lip profile. In general, though the durometer of the distal end region may decrease (becoming 'softer') the durometer of the very distal end (the opening) may be high. This, along with a rounded end shape, may reduce the force needed to invert the distal tractor region (e.g., the expandable first end region) as it is drawn into the catheter, while preventing collapse of the distal end region of the catheter.

[0054] Any of the apparatuses described herein may also include a handle adapted to draw the flexible tube proximally relative to the catheter. The handle may be attached or attachable to the catheter and/or the flexible tube and may include separate controls for actuating each independently or, more preferably, in a coordinated manner (or toggle between these two modes). For example, any of these apparatuses may include a drive handle coupled to a proximal end region of the catheter, wherein the drive handle comprises a control configured to coordinate advancing of the catheter distally while retracting the flexible tube proximally when actuated.

[0055] Any of these apparatuses may also include an outer catheter extending over the catheter and flexible tube. The outer catheter may extend over the catheter and the flexible tube and may keep an external portion of the distal tractor region (outside of the catheter) collapsed until it has been delivered. Any of these apparatuses may include a lubricious region of the flexible tube extending between a distal end of the outer catheter and the distal end opening, wherein the majority of the flexible tube is not lubricious. This lubricious region may reduce the initial force required to start actuating the apparatus.

[0056] In any of the apparatuses described herein, the flexible tube may be configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter and the flexible tube may have a low Poisson's ratio such that the flexible tube (which may be a mesh tube) may have a diameter of greater than half the inner diameter of the catheter when pulled proximally within the catheter with sufficient force to invert over the distal end opening.

[0057] Any of these apparatuses may include a puller (e.g., an elongate puller) within the catheter and coupled to a distal end of the flexible tube. The puller is typically configured to draw the flexible tube proximally, though in some variation it may also move it distally. For example, any of these apparatuses may also include an elongate puller within the catheter and coupled to a distal end of the flexible tube, wherein the elongate puller comprises a hypotube having an inner lumen that is continuous with the guidewire lumen though the flexible tube.

[0058] As mentioned, in some variations, the flexible tube comprises a soft outer mesh that is pushable. For example the distal tractor region (and particularly the expandable first end region) may be

formed from 24 to 144 stands, having a thickness of 0.0020 inches or less in diameter, wherein the mesh tubular member extends in a longitudinal axis, further wherein the mesh tubular member has a length that is greater than 5 cm, forms a braid angle between crossing strands in a direction of the longitudinal axis of about 35 degrees or less when being pulled and inverted around the distal end of the catheter and expands to a diameter of greater than 1.5 times an inner diameter of the catheter outside of the catheter when unconstrained.

[0059] When the flexible tube is formed of strands (e.g., woven, braided, etc.) the strands may be formed of any of the following; monofilament polymer, multifilament polymer, NiTi filament, NiTi tube with radiopaque metallic center, Cobalt chromium alloy filament, Cobalt chromium alloy tube with radiopaque metallic center, Nylon, Polyester, Polyethylene terephthalate, and Polypropylene.

[0060] As mentioned, any of these apparatuses may be configured so that the flexible tube (e.g., expandable distal end region) are releasably held onto the catheter. For example any of these apparatuses may include a retaining ring around a distal end region of the flexible tube configured to releasably hold the flexible tube against the catheter.

[0061] In any of these variations, the flexible tube may be shape set to have different diameter when within the catheter after being pulled proximally into the catheter. In general, the flexible tube may include a plurality of woven or one (or more) knitted filaments. In some variations the entire (or majority of the) flexible tube is formed of a woven or knitted filament(s), and the proximal end of the flexible tube may form a tapered opening opposite from a filament or bundle of filaments forming a pull wire. Alternatively or additionally, the flexible tube may be formed from a sleeve of polymer having a thickness less than 0.020 inches, wherein the sleeve comprises a perforation pattern in which the perforations extend through the polymer. The perforation pattern may comprise perforations having a shaped consisting of one or more of: round holes, rectangular holes and zig-zag shapes.

[0062] Any of these apparatuses may include a pull wire coupled to one side of a proximal end of the flexible tube configured to be drawn proximally to pull the flexible tube within the catheter.

[0063] In general, the flexible tube may be any appropriate length. For example, the flexible tube may be between 3 to 200 cm (e.g., between 3 to 150 cm, 3 to 100 cm, 3 to 50 cm, etc.).

[0064] In any of the apparatuses described herein, the flexible tube of the apparatus may be configured so that the flexible tube may be retracted into the catheter by applying less than a predetermined amount of force (e.g., 500 grams of force, 450 grams of force, 400 grams of force, 350 grams of force, 300 grams of force, 250 grams of force, 200 grams of force, 150 grams of force, etc.) to a distal end of the flexible tube.

[0065] In any of these variations, the flexible tube may include a taper between the first end and a second end of the flexible tube. In some variations, the flexible tube may extend within the entire length of the catheter so that a proximal end of the flexible tube is configured to be pulled proximally away from the proximal end of the catheter to slide and invert the flexible tube over the distal end opening.

[0066] Any of the apparatuses described herein may also include a vacuum source. For example any of these apparatuses may include a guidewire vacuum pump coupled to a proximal end of the guidewire

lumen and configured to apply vacuum therethrough. For example, any of these apparatuses may include an outer catheter vacuum pump coupled to a space between the catheter and the flexible tube and configured to apply a vacuum within a lumen of the catheter between an inner wall of the catheter and the flexible tube.

[0067] As mentioned, the apparatus may include a puller, wherein a distal end of the flexible tube is coupled to a distal end of the puller. An outer catheter may be arranged over the catheter adjacent to a proximal end of the flexible tube. Any of these apparatuses may also include a handle having a control configured to coordinate advancing of the outer catheter to push the proximal end of the flexible tube distally and pulling the puller proximally to drawn the proximal end of the flexible tube into the catheter. For example, an apparatus as described herein may include: a puller, wherein a distal end of the flexible tube is coupled to a distal end of the puller; an outer catheter slideably arranged over the catheter coupled to a proximal end of the flexible tube; and a handle having a control configured to coordinate advancing of the outer catheter distally to push the proximal end of the flexible tube distally while pulling of the puller proximally to drawn the proximal end of the flexible tube into the catheter or pulling the outer catheter proximally to pull the proximal end of the flexible tube proximally while pushing of the puller distally to push the proximal end of the flexible tube out of the catheter.

[0068] Also described herein are methods of mechanically removing a thrombectomy including: advancing a guidewire at least to the proximal end of a clot in a blood vessel; advancing a thrombectomy (e.g. clot removal) apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening and a flexible tube extending along an outer diameter of the catheter and over the distal end of the catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube; pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that the flexible tube slides and inverts over the distal end opening; and drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

[0069] A method of mechanically removing a thrombectomy may include: advancing a guidewire adjacent a clot in a blood vessel; advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening and a flexible tube extending along an outer diameter of the catheter and over the distal end of the catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube; pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen over a rounded lip of the distal end opening of the catheter so that the flexible tube slides and inverts over the distal end opening, wherein the distal end opening has a durometer that is greater than a durometer of a region immediately proximal to the distal end; and drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

[0070] A method of mechanically removing a thrombectomy may include: advancing a guidewire adjacent a clot in a blood vessel; advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises an inner catheter having a distal end and a distal end

opening, a flexible tube extending along an outer diameter of the inner catheter and over the distal end of the catheter, and an outer catheter securing a distal end region of the flexible tube against the outer diameter of the inner catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube; pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that a lubricious proximal leader region of the flexible tube slides and inverts over the distal end opening, until a non-lubricious distal region of the flexible tube is drawn into the inner catheter; and drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

[0071] A method of mechanically removing a thrombectomy may include: advancing a guidewire adjacent a clot in a blood vessel; advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening and a flexible tube extending along an outer diameter of the catheter and over the distal end of the catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube; pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that the flexible tube slides and inverts over the distal end opening; pulling or pushing the flexible tube distally out of the distal end of the catheter so that the flexible tube slides and inverts over the distal end opening and over the outer diameter of the catheter; and drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

[0072] In any of the methods described herein, the guidewire may be positioned at least partially within the clot in the blood vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

[0073] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0074] FIGS. 1A-1H illustrate one variation of an apparatus for mechanically removing an object such as a clot form a body region. FIG. 1A shows a catheter portion of the apparatus; FIG. 1B shows an enlarged view of a distal end (opening) of the catheter; FIG. 1C shows an example of a distal tractor region of a flexible tube (tractor tube), showing the expandable first end region of the flexible tube in a collapsed (non-expended) configuration, while FIG. 1D shows the same distal tractor region with the expandable first end region expanded. FIG. 1E shows an assembled mechanical thrombectomy apparatus with the flexible tube extending through the catheter and doubling back over the distal end of the catheter so that the expandable first end region of the flexible tube (forming part of the distal tractor region) is at least partially outside of the catheter and in a non-expanded state. FIG. 1F shows the apparatus of FIG. 1E with the expandable first end region expanded. FIGS. 1G and 1H illustrate the use of the apparatus of FIGS. 1E and 1F to remove a clot by drawing the flexible tube proximally and/or advancing the catheter distally towards the clot so that the expandable first end region inverts as it is drawn into the distal end of the catheter, pulling the clot into the catheter.

[0075] FIGS. 2A-2D show variations of flexible tubes (tractor tubes) that may be part of the apparatuses described herein. FIG. 2A shows the distal end of the flexible tube including the distal tractor region comprising the expandable first end region at the distal end, adjacent to a less-expandable second end region. In FIG. 2B the expandable first end region is formed of a plurality of woven fibers. In FIG. 2C the expandable first end region is formed of a sheet of material having a plurality of small pores throughout. In FIG. 2D the expandable first end region is doubled over the less-expandable second end region.

[0076] FIGS. 3A-3F illustrate the *in vivo* deployment and operation of one example of a mechanical thrombectomy apparatus. In this example, the distal tractor region is pushed through the catheter after positioning the catheter near a clot until the distal tractor region is exposed from the distal end of the clot (FIGS. 3A-3D) so that the expandable first end region expands to the intima of the vessel; the catheter is then advanced between the expandable first end region and the less-expandable second end region (FIGS. 3D-3E), and the expandable first end region is drawn into the catheter so that it inverts and pulls the clot into the catheter (FIGS. 3E-3F).

[0077] FIGS. 4A-4F illustrate *in vivo* deployment and operation of another example of a mechanical thrombectomy apparatus. In this example, the expandable first end region of the flexible (tractor) tube is deployed after positioning the catheter portion (FIGS. 4A-4B) by extending the expandable first end region out of the distal end of the catheter so that the expandable first end region double-back over the distal end region of the catheter (FIGS. 4C-4D). Once exposed and deployed, the expandable first end region may be drawn back into the catheter with or without advancing the catheter distally to pull the clot into the catheter (FIG. 4F).

[0078] FIGS. 5A-5E illustrate *in vivo* deployment and operation of another example of a mechanical thrombectomy apparatus in which the expandable first end region is extended distally out of the end of the catheter after it has been positioned within the vessel near the clot (FIGS. 5A-5C). Once the expandable first end region has been extended and allowed to expand within the vessel, the catheter and the rest of the flexible tube within the catheter may be advanced distally (FIG. 5D) so that the expandable first end region doubled over the distal end as shown. Thereafter the expandable first end region may be drawn back into the catheter with or without advancing the catheter distally to pull the clot into the catheter (FIG. 5E).

[0079] FIGS. 6A and 6B illustrate a mechanical thrombectomy apparatus including a catheter and flexible tube (tractor tube) extending through the catheter and doubling back over the distal end of the catheter (forming the distal tractor region) and an outer catheter or release protector catheter over the distal tractor region. FIG. 6A shows the apparatus positioned near a clot; FIG. 6B shows the apparatus used with a guidewire through the guidewire lumen of the apparatus for positioning and operating the apparatus.

[0080] FIGS. 7A-7D illustrate operation of a thrombectomy apparatus as shown in FIGS. 6A-6B, showing positioning the distal end/distal tractor region adjacent to the clot (FIG. 7A), then pulling the clot into the catheter (FIGS. 7B-7C) and finally removal of the clot and flexible tractor tube (FIG. 7D).

[0081] FIG. 8 shows a thrombectomy apparatus including an optional vacuum source.

[0082] FIGS. 9A-9D illustrate operation of a thrombectomy apparatus as described herein in combination with a guidewire. The guidewire may pass through the clot completely or partially and the apparatus may be actuated over the guidewire, providing enhanced stability and efficacy.

[0083] FIG. 10A shows one variation of a handle (proximal) handle for actuating an apparatus such as the thrombectomy apparatuses described herein. The handle may be coupled and may, separately or in a coordinated fashion, actuate movement of the catheter and flexible (tractor) tube, including the distal tractor region.

[0084] FIG. 10B shows another example of a proximal handle for an apparatus as described herein, which includes controllers for controlling (separately or together) actuation of the catheter and/or inner flexible tractor tube.

[0085] FIG. 11A shows another example of a proximal handle for an apparatus including a thrombectomy apparatus as described herein.

[0086] FIG. 11B is a mechanical schematic illustrating operation of a handle for an apparatus as described herein.

[0087] FIGS. 12A and 12B illustrate variations in which the expandable first end region of the flexible tractor tube of the apparatus is releasably secured to an outer surface of the catheter; prior to actuation of the apparatus, so that the distal tractor region can be drawn into the distal end of the catheter, the releasable attachment may be detached. In FIG. 12A an outer tubing (e.g., an outer catheter or release protector catheter over the distal tractor region) covers at least the end of the expandable distal end region. In FIG. 12B the expandable first end region of the distal tractor region may include a band, adhesive, weld (e.g., frangible adhesive or other attachment), clap, grasper, or the like, releasably securing the expandable first end region to the outer diameter of the catheter.

[0088] FIGS. 13A and 13B illustrate examples of the proximal end region (puller region) of the flexible (e.g., tractor) tube of the apparatuses described herein. FIG. 13A shows an example in which the proximal end of the tractor tube forms a pull wire that is radially offset from the lumen of the tube; a guidewire may still pass through the lumen of the tube (and catheter) for operation of the device, as shown. FIG. 13B shows an example in which the pull wire (or rod, member, etc.) is formed of a separate material than the rest of the flexible tractor tube.

[0089] FIG. 14 illustrates a distal tractor region including a limited lubricious region near a proximal end region of the expandable first end region of the distal tractor region; other portions of the expandable first end region may not be lubricious, nor may other portions of the rest of the distal tractor region.

[0090] FIGS. 15A-15D illustrate flexible (tractor) tubes having shaped expandable first end regions. In particular, these different expandable first end regions may be pre-set to different diameters which may help draw in and/or break the clot up within the catheter. FIG. 15A shows a first example in which the expandable first end regions is coupled to a puller portion by a plurality of pull wires. The expandable first end regions is shown not inverted over the more proximal portion of the flexible tubular member (tractor tube) in these examples. FIG. 15B shows a plurality of expandable end regions connected by a

plurality of pull wires that may not be radially expandable. FIG. 15C shows an expandable first end region having a plurality of pre-set diameters. FIG. 15D shows an expandable first end region coupled to a more proximal puller portion of the tractor tube by two or more bundles of the filaments forming the expandable first end region.

[0091] FIG. 16 illustrates another example of an expandable first end region that includes a plurality of releasable attachments to the outer diameter of the catheter; these releasable attachments (which may be frangible, elastic, etc.) can be released by applying sufficient force to allow the distal tractor region to be pulled into the catheter for actuating the apparatus.

[0092] FIG. 17 illustrates an example in which the expandable first end region is loaded (e.g., spring loaded, compressed, etc.) over the outer diameter of the distal end region of the catheter and releasably locked or otherwise held in place, e.g. by a reliable attachment; this releasable attachment may prevent deployment of the apparatus until actuation, and the loading of the expandable first end region may make it easier for the distal tractor region to invert over the distal end of the catheter to draw a clot into the apparatus.

[0093] FIGS. 18A-18C illustrate examples of expandable first end regions having different stiffnesses.

[0094] FIGS. 19A and 18B illustrate assembly methods for assembling an apparatus as descried herein.

[0095] FIGS. 20A and 20B illustrate exemplary profiles of expandable first end regions that may be used as part of a distal tractor region of an apparatus as described herein.

[0096] FIGS. 21A-21D show examples of apparatuses used to remove clots. FIG. 21A shows an example of an expandable first end region prior to coupling to a catheter. FIG. 21B illustrates the expandable first end region within a vessel (glass tube) being drawn into a catheter by pulling the proximal end of the flexible (tractor) tube. FIG. 21C shows the distal end region of the apparatus including the expandable first end regions doubled over the distal end region of the catheter. FIG. 21D illustrates the apparatus of FIG. 21C drawing a clot into the catheter.

[0097] FIG. 22 shows the expandable first end region of FIG. 21D with the captured clot after drawing it proximally out of the catheter.

[0098] FIGS. 23A-23D illustrate a mechanical thrombectomy apparatus as described herein capturing a blood clot and drawing it into the apparatus.

[0099] FIG. 23E illustrates the clot held within the flexible tractor tube after the flexible tractor tube has been removed from the catheter (e.g., proximally).

[0100] FIG. 24 is another example of an apparatus including a flexible tractor member in which the distal tractor region is formed of a plurality of filaments that are arranged as strips of material (longitudinally parallel) that are not woven or braided. These strips may be filaments, or tubes, etc.

[0101] FIGS. 25A-25F illustrate another variation of a distal tractor region of a flexible tractor assembly in which the expandable first end region (e.g., the distal end region of the distal tractor region) is formed of a plurality of filaments or strips, similar to that shown in FIG. 24; the distal end of the

catheter includes channels, as shown in FIGS. 25A-24B; the strips may fit within these channels, as shown in FIGS. 25C-25D. FIGS. 25E and 25F show sectional views through FIGS. 25C and 25D.

[0102] FIGS. 26A and 26B show a variation of the apparatus of FIGS. 25A-25F with an outer sleeve (e.g., an outer catheter or release protector catheter or other outer sleeve/protector)

[0103] FIGS. 27A and 27B show a sectional view through the apparatus of FIGS. 26A-26B.

[0104] FIG. 28 is an apparatus including a distal tractor region of a flexible tractor assembly having a plurality of longitudinally-parallel (non-woven/braided) filaments or strips in which the distal ends of the filaments or strips are connected to each other by a distal connector.

[0105] FIG. 29 shows a distal tractor region of a flexible tractor assembly in an apparatus in which the longitudinally-parallel (non-woven/braided) filaments or strips include grabbing elements.

[0106] FIGS. 30A-30C illustrate example of filaments/strips with grabbing elements. Grabbing elements (and/or filaments including them) may be used as part of any of the variations described herein, including woven or braided distal tractor regions.

[0107] FIG. 31 illustrates a variation in which the distal tractor region is adapted to be reciprocated (e.g., pushed and pulled) so that the expandable first end region may be draw into and reversed out of the catheter.

[0108] FIG. 32 illustrates another example of an apparatus as described herein in which the distal-most end of the expandable first end region is fixed to a portion of the distal end of the catheter; the rest of the expandable first end region is sufficiently elastic/flexible to be drawn into the catheter (pulling a clot with it). The flexible tractor assembly may then be left retracted and the entire apparatus withdrawn. This example may include an optional vacuum.

[0109] FIG. 33 is another example of an apparatus in which the puller portion of the flexible tractor assembly is formed of the same material as the distal tractor region but may be laminated or otherwise reinforced to have less flexibility/stretchability than the distal tractor region.

[0110] FIG. 34 illustrates another example in which the distal tractor region is adapted to compress the clot when draw into the catheter.

[0111] FIGS. 35A-35C illustrate operation of an apparatus as shown in FIG. 34 in which the clot is drawn into the catheter by withdrawing the expandable first end region of the distal tractor region into the catheter (e.g., pulling on the puller region of the tractor assembly) which compresses the clot (FIGS. 35A-35B); releasing the tractor assembly and/or pushing it distally may further break up the clot and release it from the distal tractor region so that it may be suctioned up proximally with a manual or powered vacuum source (FIG. 35C).

[0112] FIG. 36 illustrates an example of an apparatus and method of use in which drawing the flexible tractor assembly proximally may advance the apparatus distally through the body (e.g., vessel) over a guidewire, which may be treated to engage the distal tractor region.

[0113] FIGS. 37A-37C illustrate an apparatus and method of use in which drawing the flexible tractor assembly proximally may advance the apparatus distally.

[0114] FIGS. 38A and 38B illustrate another variation of an apparatus and method of using the apparatus to remove material from within a vessel, wherein the apparatus is an "infinite" tractor mechanism, in which a large amount of tractor material (e.g., mesh) is stored in an external holding region, wound-up but dispensable over an extended use.

DETAILED DESCRIPTION

[0115] In general, described herein are methods and apparatuses for mechanically removing objects from a body. Although these methods and apparatuses may be adapted for use to remove a variety of objects from a variety of regions of the body, they may be particularly well suited for removal of blood clots from within a lumen of a blood vessel. Thus described herein are mechanical thrombectomy apparatuses (e.g., device and systems).

[0116] The apparatuses described herein (e.g., mechanical thrombectomy apparatus for removing a clot from a vessel) may be assemblies including an elongate catheter having a distal end and a distal end opening, and a flexible tractor assembly at least partially within the catheter, where the distal end region of the tractor assembly is configured as a distal tractor region that at least partially extends within the catheter and doubles back over the distal end of the catheter. The tractor assembly may include a proximate pusher region which is connected to the distal tractor region. The flexible tractor assembly includes an elongate lumen that is configured to allow passage of a guidewire. The flexible tractor assembly is also configured to slide along the long axis within the catheter lumen and invert over the distal end opening of the catheter when the proximal end region is pulled proximally. The tractor assembly may be referred to herein as a flexible tractor assembly, flexible tractor portion, flexible tractor tube, or simply a flexible tube, and is typically positioned and longitudinally slideable within the catheter, and arranged so that the distal end region ("distal tractor region") doubles back over the distal end of the catheter.

[0117] For example, FIG. 1A shows one variation of a catheter that may form part of the apparatuses described herein. In this example, the catheter 100 includes a distal end region 103 that includes a distal end 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal tip (distal end 105) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing harness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[0118] The catheter 100 may also be referred to as the inner catheter or the tractor catheter. Any appropriate type of catheter may be used, including microcatheters appropriate for neurovascular use.

[0119] In some variations the distal end 105 of the catheter is adapted so that the distal tractor region may slide and invert over the distal end of the catheter without being caught (binding) or without substantial friction. For example, in some variations the distal tip (end) may be curved or radiused 109 as shown in FIG. 1B, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter). In some variations the distal tip includes one or more channels, as shown and described in FIGS. 25A-28, including channels around the distal-facing edge, to guide the sliding of the distal tractor region.

[0120] FIG. 1C shows an example of a flexible tractor tube 140. In FIG. 1C, the tube is flexible and elongate (having a generally greater length than the catheter 101), and includes a distal tractor region 142 that includes a distal-most expandable first end region 144 that is configured to fold over the immediately proximal region 146, which may be a less-expandable second end region. In general the expandable distal end region is configured to expand to a radial diameter that is between 1.3 and 10 times the diameter of the inner diameter of the catheter when unconstrained. FIG. 1D shows the expandable distal end region of FIG. 1C in an expanded configuration. Thus the expandable distal end region may be biased to expand open. The expandable distal end region may be formed as a mesh, woven or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[0121] The flexible tractor tube shown generically in FIG. 1C is shown with the expandable distal end region doubled back over itself (e.g. over the more proximal less-expandable second end region) in FIG. 1E. In FIG. 1E, the expandable distal end region is collapsed, while in FIG. 1F the expandable distal end region is expanded. In general, the expandable distal end region may be distinguished from the proximal less-expandable second end region, however in some variations the entire flexible tractor tube may comprise and expandable material (e.g., mesh, weave, etc.) that is pushed and/or pulled within the catheter and does not include a proximal less-expandable distal end region.

[0122] FIGS. 1G and 1H illustrate the removal of a clot using an apparatus such as the apparatus assembled from the components of FIGS. 1A and 1E. In this example the apparatus is configured as a thrombectomy apparatus including a catheter 101 and a flexible tractor tube that includes an expandable distal end region 144 that extends over the distal end region of the catheter and doubles-over the distal end of the catheter so that the expandable distal end region is continuous with an inner proximal less-expandable (in this example, less-expandable includes non-expandable) second distal end region 146 that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The proximal end of the flexible tractor tube (not shown) may include a pusher/puller member that may be a rod or other member that is continuous with the distal end region (distal tractor region140). In FIG. 1G the apparatus is shown positioned and deployed within the vessel 160 near the clot 155. The clot may be drawn into the catheter by withdrawing the distal tractor region 140 into the catheter 101, as indicated by the arrow 180 showing pulling of the inner portion of the flexible tractor tube (e.g., using a handle, not shown) resulting in pulling the expandable distal end region into the catheter distal end and inverting the expandable distal end region so that it is pulled into the catheter, shown by arrows 182. The distal end of

the expandable distal end region may be "loose" relative to the outer wall of the catheter, or it may removal attached or in some variations permanently attached.

[0123] In general, positioning these apparatuses and actuating them may be challenging because they must be highly flexible, both before actuating and during operation. For example, in general, the flexible tractor tube must not increase the stiffness/flexibility of the catheter, and particularly the distal end region of the catheter too much, or it may be too difficult and/or dangerous to maneuver, particularly within tortious vessels of the neurovasculature. Described herein are flexible tractor tube portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[0124] For example, FIG. 2A shows a flexible tractor tube 201. In this example, the flexible tractor tube includes a distal tractor region 242 with an expandable first end region 244 and a less-expandable second end region 246 that is distal to a proximal pusher region 201. The entire flexible tractor tube is hollow and may pass a guidewire (not shown). The various regions of the flexible tractor tube may be made of the same material (e.g., a woven, braided, etc. filament or filaments) or they may be made of different materials.

[0125] FIG. 2B shows a flexible tractor tube having a distal tractor region, or at least the expandable first end region 244' formed of a plurality of woven fibers. Alternatively the expandable first end region may be formed of one (or more) knitted fibers, or a combination of woven and knitted fibers. The expandable first end region may be biased open (as shown) by a shape-setting property of the fibers or woven/knitted pattern or by the inclusion of one or more biasing members (e.g., rings, springs, bands, filaments, etc.) that tend to bias at least the distal end region of the expandable first end region open.

[0126] FIG. 2C illustrates another variation of an expandable first end region formed of a sheet of material that includes a plurality of openings (e.g., pores, perforations, passages, windows, etc.). These openings may be any sizes, including non-uniform sizes (e.g. a range of sizes) or uniform sizes. The sizing of these opening through the sheet may depend on the material used, e.g., polymeric material (PTFE), silicone materials, polyurethanes, shape memory alloys, etc. In some variations it is beneficial to have a porosity of greater than >60% (greater than 70%, greater than 75%, greater than 80%, greater than 85%, etc., between 60-95, 65-95, 70-95%, etc.) of the sheet.

[0127] In any of these variations, the distal tractor region is configured so that it may be inverted (e.g., doubled over) itself, as shown in FIG. 2D. In some variations the apparatus may be performed so that the expandable first end region is inverted over the itself and/or over the distal end region of the catheter, or it may be configured so that it can be deployed and inverted over the distal end of the catheter *in vivo* (e.g., within the blood vessel). In general, before the apparatus can be actuated the catheter may be inserted between the expandable first end region and the region proximal to the expandable first end

region on the flexible tractor tube, which may, in some variations, be the less-expandable second distal end region. This space 289 may be held open by a biasing member at or near the distal end of the expandable first end region. As mentioned, this expandable first end region opening biasing member may be a ring, band, spring, coil, or the like, and may be made of a biasing element (e.g., shape-set material, such as a shape memory alloy), rubber or other polymeric material, or the like.

[0128] In vivo deployment of the apparatuses described herein may provide a number of advantages for users operating the apparatus, despite associated challenges. FIGS. 3A-3F illustrates one example of a thrombectomy apparatus that is configured for in vivo deployment. In this example, the apparatus includes a catheter 301 that may be positioned (as with any of the variations described herein) using a guidewire 313. The guidewire may be extend to or into (or through) the object to be removed, shown as clot 355 in FIG. 3A within a blood vessel 360. The catheter of the apparatus may be inserted with or after the guidewire, and the catheter may be positioned near (e.g., adjacent to or immediately adjacent to) the clot with or without the flexible tractor tube at or near the distal end of the catheter. In FIG. 3A the catheter is positioned after the guidewire has been positioned, and, as shown in FIG. 3B, is removed from the vessel. The guidewire may be a wire, smaller catheter or combination of devices that may be positioned (e.g., steered) to and/or through the clot. Following positioning of the catheter, the inner flexible tractor tube 340 including the distal tractor region 342 is pushed through the catheter to the distal end region of the catheter, as shown in FIG. 3C. In this example the distal end of the flexible tractor tube forming the distal tractor region includes an expandable first end region shown as a mesh 344 that is connected to a proximal less-expandable second end region that is continuous with the rest of the flexible tractor tube, at the proximal end (pusher region 305). The braided mesh 344 of the expandable first end region is pre-inverted over the outside of the tubular second end region/pusher region in a collapsed (non-expanded) configuration, and can be slide through the inner lumen of the catheter, and (when the guidewire is left in position or used adjust the position) over the guidewire (not shown). As shown in FIG. 3D, the distal tractor region of the flexible tractor tube may then be exposed to the outside of the catheter by extending (in this example either pushing the flexible tractor tube distally and/or pulling the catheter proximally, allowing the expandable first end region of the distal tractor region (shown as mesh) 344 to expand along the length of the first end region. In FIG. 3D this is shown as a stent-like structure that may expand fully to the intima of the vessel forming a separation between the expandable first end region and the less-expandable (in this case non-expandable) second end region 346. In particular the expansion of the first end region may be greater than 1.3 times the diameter of the inner lumen of the catheter (e.g., greater than 1.5x, greater than 2x, greater than 2.2x, greater than 2.5x, greater than 3x, greater than 3.5x, greater than 4x, greater than 5x, greater than 6x, greater than 7x, greater than 8x, greater than 9x, greater than 10x, etc.).

[0129] In FIG. 3D, the catheter is slid distally between the first and second end regions of the distal tractor region. The clot may then be removed by withdrawing the expandable first end region proximally into the catheter either or both by pulling the flexible tractor tube (e.g., proximal puller region) proximally and/or advancing the catheter distally. In some variations it may be beneficial to both advance the

apparatus and particularly the catheter, while withdrawing the expanded first end region and inverting it into the catheter. The catheter may be advanced more quickly than the flexible tractor tube is withdrawn.

[0130] As shown in FIG. 3F, the clot 355 may be drawn in to the catheter with the expandable first end region.

[0131] Another variation of an *in vivo* deployment method and apparatus is shown in FIGS. 4A-4F. In this example, the self-expanding first end region of the flexible tractor tube is configured to self-expand over end of the catheter as it is pushed out of the catheter so that it will slide over the distal end of the catheter. As described above for FIGS. 3A-3B, the apparatus may be positioned using a guidewire 413 or the like. In FIG. 4A, the catheter 401 is positioned over the guidewire 413 adjacent to the clot 455 to be removed. In FIG. 4B the guidewire may be (optionally) removed, or (preferably) left in place. The flexible tractor tube 434 including the distal tractor region may then be moved distally within the catheter and extended with the expandable first end region 444 out of the distal end so that it inverts 466 over the distal end and slide proximally over the distal end region, as shown in FIG. 4C. This process may be aided by pushing the apparatus distally within the lumen of the vessel, as the expansion of the first end region 444 may help secure it against the wall of the vessel, as shown in FIGS. 4D-4E. Once exposed, the expandable first end region may be withdrawn into the apparatus by pulling the flexible tractor tube 434 proximally and/or advancing the assembly (or at least the catheter) distally, as shown in FIG. 4F. The clot 455 may then be drawn into the apparatus.

[0132] FIGS. 5A-5E illustrate another variation of an *in vivo* deployment and thrombectomy (clot removal) method using a mechanical thrombectomy apparatus. In FIG. 5A, the apparatus 500 including a catheter 501 and an inner flexible tractor tube 534 is advanced (e.g., over a guidewire, not shown) to be near a clot 555. In this example (which may be relevant to any of the methods described herein) the apparatus is positioned with the flexible tractor member having the un-deployed distal tractor region already positioned distally near the distal end region of the apparatus. As shown in FIG. 5B, the expandable first end region 544, which is in a collapsed configuration within the catheter 501 in FIG. 5A, is pushed out of the distal end of the catheter and expands to the walls of the lumen as shown in FIGS. 5B-5C. Once pushed out and expanded, the catheter and the portion of the flexible tractor tube within the catheter may be advanced distally, as shown in FIG. 5D, causing the expandable first end region 544 to invert, doubling over the distal end region of the catheter 501. By FIG. 5E, the apparatus has been deployed near the clot 555 and may be actuated as already described to remove the clot, but pulling the expandable first end region of the distal tractor region into the catheter, so that it inverts and draws the clot into the catheter. The catheter may optionally be simultaneously advanced. Note that the method of in vivo deployment described above may also be used to load an apparatus for insertion into a body in order to position the catheter radially between the expandable first end region and the more proximal portion of the flexible tractor tube.

[0133] FIG. 6A illustrates an example of another variation of a thrombectomy apparatus having a flexible tractor tube 634 with a flexible first (distal) end region 644 formed in this example of a braided (e.g., woven) or knitted material, where the flexible first end region (tractor region) is inverted over the

distal end of a catheter 601 and attached to the proximal end region of the flexible tractor tube 634. As in any of the apparatuses described herein this proximal end region of the flexible tractor tube may be a hypotube, catheter, or laminated weave/mesh or woven material that is pushable/pullable within the catheter and is attached at its distal end to the flexible tractor region (e.g., distal tractor region), including in some variations an expandable first end region. Note that in some variations the distal tractor region (the first end region) may not be expandable but may be just flexible.

[0134] In FIG. 6A, the first end region of the distal tractor region attached to the flexible tractor tube is covered by an outer catheter or sleeve (protector) 677. In this example, the apparatus also includes a mid-catheter 679 between the inner catheter 601 and the protector catheter or sleeve 677. In some variations the flexible first end region 644 may be attached to this mid catheter, including removably attached so that pulling the flexible tractor tube 634 proximally will disengage it and allow the mesh (the flexible first end region 644) to deploy in the vessel. In the variation shown in FIG. 6A the flexible first end region 644 is not attached to the middle catheter 679.

[0135] Any of the apparatuses described herein, including the apparatus shown in FIG. 6A may be used with (and may include) a guidewire 633 as shown in FIG. 6B. FIGS. 7A-7D illustrate the operation of the apparatus shown in FIGS. 6A-6B to remove a clot 755. In this apparatus the proximal end of the flexible tractor tube 734 may be coupled to a vacuum source (not shown) which may be actuated when withdrawing the tractor tube 734 proximally to invert the distal tractor region over the end of the catheter. In FIG. 7A the apparatus is positioned near the clot 755. In FIG. 7B, the distal tractor region is inverted and pulled into the catheter by pulling the flexible tractor tube 734 as shown by the arrow. In this example the distal tractor region is not expanded because it remains covered by the outer sleeve 777, as shown in FIGS. 7B and 7C. The apparatus may be advanced distally toward/over the clot either or both by pushing or by the action of pulling the distal tractor end region (shown in this example as a mesh 744) proximally to invert it over the distal end of the catheter. Once the clot is removed, the apparatus may be withdrawn and pulled out of the vessel, as shown in FIG. 7D.

[0136] As mentioned above, any of these variations may include one or more vacuum sources. FIG. 8 illustrates one example including a vacuum source showing a first optional vacuum source at the proximal end coupled to the lumen of the flexible tractor tube 834. For example, the coupling with the vacuum and the tractor tube 834 may be a rotating hemostatic value (RHV) as shown. In FIG. 8 a second (optional) vacuum connection is made between the (optional) outer catheter 877 and the inner catheter 801 or an (optional) middle catheter 878. Vacuum may be applied at any appropriate portion of the method, including during retraction of the flexible tractor rube 834 to remove the clot.

[0137] As mentioned, any of the apparatuses described herein may include a guidewire and may leave the guidewire in position during the procedure. FIGS. 9A-9D illustrate a method of removing an object (e.g., clot) when leaving a guidewire 913 in position. In this example, the apparatus is similar to the apparatus shown in FIGS. 6A-6B, and may include an optional vacuum source. In FIG. 9A the distal end of the catheter including the inverting portion of the flexible first end region 944 of the distal tractor region 944 is placed adjacent to the clot and actuated by pulling proximally to draw the clot into the

catheter as shown in FIG. 9B. In this example the clot has been penetrated by the guidewire 913, thus the catheter tip with the inverting tractor region may be advanced forward over the guidewire by pushing on the catheter 927 and/or by pulling the tractor tube proximally 919. This may be continued until the entire clot is within the catheter, as shown in FIG. 9C.

[0138] In any of the variations described herein, the apparatus may include one or more markers or may be configured for use with one or more contrast agent to assist in visualizing the methods described. Further any of these methods may include visualization. Visualization may be indirect (e.g., using fluoroscopy or equivalent techniques) or direct, e.g., using one optical fibers for direct visualization down the apparatus (e.g., thought the lumen of the apparatus).

[0139] In FIG. 9D, the tractor tube with the captured object (e.g. clot) may be removed proximally from the apparatus and the removed material may be examined (e.g., via histological/cytological examination). The catheter may be subsequently or simultaneously removed. As mentioned above, when removing the object (e.g., clot) it may be desirable to pull back (proximally) the guidewire at the same time that the flexible tractor tube is pulled back proximally (not shown). In some variations, the distal tractor region (e.g., braided/woven or knitted region) may grab onto the guidewire within the catheter and which may also help propel the apparatus distally over/toward the clot, as described in more detail in FIGS. 36 and 37A-37C, below.

[0140] In general, the rolling effect of the grabber (the distal tractor region) is activated by the motion of the catheter relative to the distal tractor region. If the distal tractor region is fixed proximally and the catheter is advanced, the distal tractor region may have a 1:1 grab ratio. If the distal tractor region is pulled though the catheter, the grabbing effect may be amplified. For example when the distal tractor region is pulled back (by pulling the tractor tube) and inverted into the inner catheter 1 unit to proximally within the catheter as the inner catheter is pushed 1 unit to distally, the grabbing effect is approximately 2x. If the distal tractor region is withdrawn into the inner catheter proximally two units as the inner catheter is advanced distally one unit, the grabbing effect may be approximately 3x. The concurrent motion of the distal tractor region and the catheter may be coordinated by a handle.

[0141] In general, any of the apparatuses described herein may include a handle. The handle may couple with the flexible tractor tube and/or the catheter (e.g., inner catheter) and/or any outer catheter (e.g., protector, sleeve, etc.). The handle may be configured to allow selective, separate actuation of the flexible tractor tube and/or the catheter and/or coordinate motion of these components. FIGS. 10A and 10B illustrate examples of handles that may be used. In FIG. 10A, the handle includes a drive mechanism to pull back the tractor tube, and therefore invert the distal tractor region over the distal end of the catheter and/or advance the catheter relative to the distal tractor region. In FIG. 10A, the handle include rotatable handle 1001couled to a catheter drive 1003. The handle connects to both the catheter 1005 and the inner flexible tractor tube 1009 having a distal tractor region 1011. The handle may be configured so that the ratio of the advancing (distally) of the catheter versus the pull (proximally) of the tractor tube may be selected and/or may depend on a thread pitch of the catheter drive thread or other mechanical mechanism.

[0142] Another variation of a handle is shown in FIG. 10B. In this example the handle may be attached to the tractor tube to pull (or push) 1017 the tractor tube and therefore invert the distal tractor region over the distal end of the catheter, and another portion of the handle may be coupled to the catheter to push/pull the catheter 1015.

[0143] FIG. 11A shows another variation of a handle mechanism 1107 configured to pull the grabber (distal tractor region) of any of the apparatuses described herein by coupling to the proximal end of the tractor tube at an attachment site 1105, and/or advance the catheter by coupling to the proximal end of the catheter. Another example of a handle mechanism is shown schematically in FIG. 11B, showing a levering mechanism 1109 and a coupling to the inner tractor tube that may be fixed or adjustable.

[0144] In any of the apparatuses (e.g., mechanical thrombectomy apparatuses) described herein, the distal tractor region may be preloaded in/on the catheter so that it can be actuated by pulling the tractor rube coupled to the distal tractor region proximally and/or advancing the catheter distally. In pre-loaded variations in which the distal tractor region includes a flexible and/or expandable first end region (e.g., formed of a mesh and/or weave of material) that is doubled over the distal end of the catheter, the apparatus may be adapted to prevent inadvertent dislodging and/or expansion of the first end region before it has been positioned at or near the clot.

[0145] FIGS. 12A and 12B illustrate examples of releasable attachments for the distal tractor regions attached to the outside of the catheter. Any of these attachments may be released by the application of an appropriate amount of force (e.g. pulling force) applied to the proximal end of the flexible tractor tube. For example in FIG. 12A, the outer distal end of the distal tractor region (shown as mesh 1204) is covered by a shoulder or sock extending from an outer catheter or tubing 1203). Similarly in FIG. 12B, the outer distal end of the distal tractor region (shown as mesh 1204) is covered by a separate band, ring, or sock 1209. The distal tractor region may be prevented from collapsing or reducing in diameter when tension (e.g. pulling proximally on the tractor tube) by adding filaments (e.g., in braided or woven variations, additional braid filaments), by adding a coating, by heat setting to a larger diameter, and/or by adding an axial inter-braiding pull wire.

[0146] Any of the variations described herein may include a proximal pull rod or pull wire as part of the flexible tractor tube. Further, the proximal end region of tractor tube may be less flexible than the distal end (distal tractor region). FIGS. 13A and 13B illustrate examples of flexible tractor tubes. In FIG. 13A, the tube includes a proximal taper region in which the distal tractor region 1305 is formed of a material (e.g., mesh/woven material) that tapers proximally 1307 into a pull wire, leaving room for a guidewire 1309 and permitting the distal tractor region to invert over a catheter. The proximal pull-wire portion may be formed of the filaments forming the distal tractor region, e.g., in variations in which the distal tractor region is woven or braided. These filaments may be reinforced, e.g., by other materials such as polymers that help make it stiffer or more compliant. FIG. 13B shows another example in which the proximal end of the flexible tractor tube is formed of a pull wire 1315 that may be a separate material or an extension of the braid wire bundle attached to the distal end of the pull wire and forming the distal tractor region 1317.

[0147] Any of the apparatuses described herein may be treated or adapted to reduce the force required to invert the distal tractor region over the end of the catheter. For example in some variations either the distal end may be treated to be lubricious, or all or a portion of the distal tractor region may be treated to enhance laboriousness. For example, in some variations only a portion of the distal tractor region, e.g., the portion that initially interacts/inverts over the distal end of the catheter is treated; the rest of the distal tractor region is not treated. FIG. 14 shows an example of such an apparatus. In FIG. 14, the proximal-most end 1405 of the expandable and/or flexible first end region (that is positioned outside of the catheter) is treated with a lubricous coating or formed of a lubricious material. The remaining portion (not shown to scale) of the first end region is not as lubricous 1403. Since the more proximal region 1405 is exposed to the vessel and the distal end of the catheter, it may more effectively track the target or allow the apparatus to track the target as well as start inverting over the distal end more effectively. This region may be made lubricious in any appropriate manner, including but not limited to coatings such as hydrophobic/hydrophilic coatings, and forming or including a more lubricious polymeric material (e.g. PTFE).

[0148] In general, any of the distal tractor regions described herein may be adapted to include different profiles, including pre-set to have (e.g., shape-set) profiles that may more readily slide/move over the distal end and/or grab a clot or other target object for removal. For example, FIGS. 15A-15D illustrate tractor tubes having different distal end profiles forming different distal tractor regions. In FIG. 15A for example, the distal tractor region includes a distal-most expandable and/or flexible first end region 1505 that is formed of a braided/mesh or woven material that is connected to proximal end of the tractor tube by a plurality of pull wires. These pull wires 1517 may be formed by the same wires or filaments forming the braided/mesh or woven distal end region. FIG. 15B shows another variation in which a plurality of discrete braided/mesh or woven distal end regions are connected by pull wires 1515; these pull wire regions 1515 may be less-expandable and/or flexible than the braided/mesh or woven regions 1516. In FIG. 15C, the distal end regions are braided/mesh or woven but pre-set to have different diameters. Thus these regions may have different shapes along their length; these shapes may be heat set to better grab or break up clot as they are pulled into the catheter. FIG. 15D illustrates an example of a braid or stent-like first end region 1521 that is connected to hypotube or other more proximal end region of the tractor tube 1520 by the same filaments or bundles of the same filaments forming the braided/mesh or woven distal tractor region 1523.

[0149] Any of the apparatuses described herein may also or alternatively include a plurality of releasable attachments to the outer surface of the catheter securing the distal tractor region (and particularly the distal end portion) to the outer surface. In FIG. 16, three rings 1603, 16.3', 1603'' forming releasable attachment are shown securing the distal end of the distal tractor region 1644 to an outside of a catheter 1601. In this example, a polymer coating/film is attached or integrated with the braid forming the distal tractor region to help prevent it from sliding or slipping off of the catheter prematurely (e.g., until pulled by a user). The apparatus can include multiple attachments, as shown, radially positioned along the length of the catheter to help it stay secure to the outer diameter of the

catheter delivery system. In some variations these releasable attachments are elastic member (e.g., a urethane ring) but may be frangible, and allowed to break to free the distal tractor region.

[0150] FIG. 17 shows another variation in which the releasable attachment is positioned so that a portion of the distal tractor region is spring-loaded (biased) to drive it in rolling over the distal end of the catheter and into the catheter lumen. In FIG. 17, The distal end of the distal tractor region 1704 may be secured (fixed, attached or loose but constrained) and a more proximal end region near the distal end of the catheter may be releasably secured to the catheter 1707. For example, a polymeric coating or film may be attached to the distal tractor region (shown as a braid 1744 in FIG. 17) and coupled to hold a portion of the distal tractor region 1705 between the distal end 1704 and releasable attachment site 1707 in tension (e.g., compressed). Release of the releasable attachment 1707 may then apply a force driving the distal tractor region around the distal end of the catheter, helping pull the clot into the apparatus, and reducing the force necessary to invert the distal tractor region.

[0151] As mentioned above, the material forming the distal tractor region may, and in particular the distal-most flexible and/or expandable first end region may be formed of any appropriate material. For example, the material may comprise a fabric, a weave, a knit, a braided, a sewn, a tube, and/or a flat sheet. The material may have any appropriate thickness, e.g., between 0.0005 to 0.015" wall thickness, and may have pores of any appropriate spacing/dimension (porosity) from low to high porosity. All or a portion of the distal tractor region may be radiopaque or radio transparent. In woven, knitted, braided or sewn variations, the material may be formed of multi- or mono-filaments. Different size filaments can be mixed together (e.g., big and/or small) to change gripping effect by increasing or decreasing fabric surface texture. In some variations the material (including the filaments forming the material) may be polymer based (e.g., PET, Nylon, Polypropylene, PTFE, ePTFE), elastic and non-elastic (e.g., PU, Silicone, rubber, lycra), metal filaments (e.g., Niti, drawn filled Niti indcluding DFT, i.e., Niti with Pt inner core, steel, stainless steel, cobalt chrome, etc.), and mix of metallic and polymer filaments. The ends of the fabric can be laser cut/welded or free cut. In some variations all or part of the distal tractor region includes a film or sheet. The film may be between 0.0005 to 0.008" thick. The film may be formed by tube extrusion or sheet and rolled into a tube. In some variations the film is yarn reinforced. The film may be slotted (e.g., may include holes and/or slits cut to improve gripping or sliding into the catheter. In some variations the film has a textured surface (e.g., textured inner surface that is exposed when inverted). The film may form a tube having ridges and/or rings (radial rings) and/or lines down the length, and/or a saw tooth pattern. A textured inner surface my include a mix of big and small filaments, and/or may be formed of more porous, less dense fabrics.

[0152] In some variation, the visibility of the grabber element is desirable but not required throughout. For example, as mentioned above markers may be located on the device. In some variations it may be desirable to see the entire structure or proximal and distal end of structure. For example, the material could be Nitinol or Nitinol drawn over platinum material (DFT) to enhance visibility.

[0153] Any of the variations may include a rotational auger element in the inside of any of the braid constructs to assist in pulling the clot back to the hub. As mentioned, any of these apparatuses may

include a vacuum source. The addition of the vacuum to the system may aid the ability of the distal tractor region to pull clot/emboli into the catheter. The vacuum applied may be stead/constant, ramped or pulsatile.

[0154] In some variations the apparatus and methods for using them may include a flow stopping proximal balloon (e.g., to be positioned proximal to clot), that may reduce pressure on clot during the procedure.

[0155] The apparatuses and methods described herein may be used to capture biopsy samples (e.g., from breast or any other organs). For example, these apparatuses can be used to remove bigger tissue segments (e.g., cancer, gallbladders, etc.) when a laproscopic procedure is performed.

[0156] When the material forming the distal tractor region is a woven/braided material, the resulting mesh structure may have a braid length ranging from 1 to 100cm long to around the outer diameter (O.D.) of the catheter, with a preferred length of between about 3-30cm.

[0157] In any of these variations, the tractor tube and/or catheter (including the distal tractor region) may be constructed so the distal tractor region may be pulled so that the distal tractor region is drawn (inverted) around the outer diameter of the catheter distal end with a minimal force so the catheter tip does not buckle or significant deform (e.g., snake) in the blood vessel, wherein the pull forces are less than about: 50 grams, 100 grams, 300 grams, 500 grams, 800 gram, 1000 grams, 2 kg, 3 kg, 5 kg, 8 kg, 10 kg, 15 kg, 20 kg, etc.

[0158] In variations in which the grabber (distal tractor region) is constructed as a woven (e.g., braided) structure at least on a distal end (e.g., the expandable and/or flexible first end region), examples of the filaments forming the woven structure may include: NiTi, NiTi-PT DFT wire (NiTi tube over Pt inner), PET, PP, Nylon, Algiloy, SS, hybrid materials. When used, NiTi may be etched to make is very smooth. The number of filament ends may be about: 16, 24, 36, 48, 77, 96, 144 or any number between these integers. Any braid construction may be used. For example, an exemplary braid construction may include 1 over 1 (1x1), 1x2, 2x2, etc. In some variations the filaments forming the woven and/or knitted material comprises a monofilament, e.g., having an outer diameter (O.D.) size of about: 0.0005", 0.00075", 0.001", 0.0015", 0.002", 0.003" or an combination of sizes or diameter size which is between the integers list herein. As mentioned, these apparatuses may be adapted for neuro vasculature used, e.g., assuming 2-3mm vessel inner diameter (ID). For example, an apparatus appropriate for neurovascular applications as described herein may include between 36 to 72 ends of a 0.001"to 0.002" polymer braid annealed to 3-7mm OD. In some variations, the distal tractor region includes 24 braided wires having an OD of 0.0005" by 0.0015" or 0.002" of flat Niti wire, annealed on a 2 mm mandrel, braided at a 45 degree angle. Alternatively in one variation the distal tractor region comprises a braided material formed from 24 wires of a 0.002" thickness Niti wire, annealed on a 2 mm mandrel, braided at a 45 degree angle. In one example, the distal tractor region comprises a braided material including 24 wires 0.002" DFT Niti wire, annealed on a 2 mm mandrel, braided at a 45 degree angle. In one example, the distal tractor region comprises a braided material including 8 ends of 0.003" wire mixed with 8 additional ends of 0.002" Niti wire on a 2 mm mandrel. In one example, the distal tractor region comprises a braided material including

16 ends of 0.002" platinum iridium wire, annealed on a 2 mm mandrel. In one example, the distal tractor region comprises a braided material including 24 ends of PP monofilament, having an outer diameter of 0.002" diameter. In one example, the distal tractor region comprises a braided material including 12 ends of 0.003" PP monofilament. In one example, the distal tractor region comprises a braided material including 16 ends of 0.003" PP mono. In one example, the distal tractor region comprises a braided material including 72 ends, 0.001" PET or PP, 8 mm mandrel, 90 degree braid angle, 1x1. In one example, the distal tractor region comprises a braided material including 36 ends, 0.001" PET or PP, 6 mm mandrel, 75 deg braid angle, 1x1. In one example, the distal tractor region comprises a braided material including 48 ends, 0.002" PET or PP, 8 mm mandrel, 90 degree braid angle, 1x1. In one example, the distal tractor region comprises a braided material including 24 ends, 0.002" PET or PP, 6mm mandrel, 70 degree braid angle, 1x1.

[0159] In variations in which the distal tractor region comprises a mesh, the tubular mesh may be formed from a knit or alternative structure that is constructed so it's radially compression (change in tubular mesh inner diameter, ID) experiences a 5-20% reduction in diameter when the mesh tractor is pulled axially and around the outside of the catheter tip and into the catheter ID. This 5-20% mesh diameter reduction, may aid in grabbing the clot or foreign object when pulling the mesh into the catheter, without generating so much radially compression force that the tubular mesh binds on the catheter tip when pulled and does not easily roll around the catheter tip. In contrast a woven mesh may collapse between 20-60% within the catheter when drawn proximally, which may provide a substantial amount of compression of a clot of other removed material.

[0160] In variations in which the apparatus is configured for use in the peripheral vessels (e.g., having between a 4 to 8mm vessel ID), the distal tractor region may be configured for this application. For example, the distal tractor region may include a braided material having 24 ends of PP, 0.009" PP monofilament formed on a 4 mm mandrel and annealed. The distal tractor region may include a braided material having 48 ends of PP 0.008" mono, 4 mm mandrel annealed. The distal tractor region may include a braided material having 72 ends 0.006" PP mono 4 mm mandrel annealed. The distal tractor region may include a braided material having 36 ends of .004" Niti, 4 mm mandrel annealed. The distal tractor region may include a braided material having 48 ends of 0.004" DFT Niti mandrel annealed.

[0161] In variations in which the apparatus is configured as a biopsy device (e.g., having a 4-12 mm sample size), the apparatus may be a woven material including 72 ends of PP .007" mono formed on a 10 mm mandrel. In some variations, the apparatus (e.g., the distal tractor region) may include 48 ends of 0.004" Niti formed on a 1mm mandrel. In some variations, the apparatus (e.g., the distal tractor region) may include 48 ends of PP 0.008" mono on a 12 mm mandrel.

[0162] In any of the variations described herein the apparatus may be configured to have a relatively low friction. In particular the distal tractor region may have a low friction to allow it to be more easily and/or reliably pulled through the catheter when retracting a clot. As already mentioned above, any of these variations may include a lubricous material and/or coating including using or coating one or more of the following materials on the grabber (distal tractor region): PET, PP, PTFE, ePTFE. When the material

forming the apparatus is a small diameter filament metallic structures, the filaments may be between 0.0005 to 0.003" in diameter. The material may be Niti, Stainless, MP35n, Ti, Platinum, Platinum Iridum, cobalt chromium allowy etc.

[0163] In variations in which the distal tractor region is a mesh (e.g., woven and/or kitted material), the diameter of the distal tractor region relative to the catheter diameter may be depended on the woven/knitted structure. For example, when braided, the ratio may be between 2 to 1 or greater; when warp knit, the ratio is between: 1.5 to 1 or greater. When formed as a lasered tube, the ratio is between 1.1 to 1 or greater. Similarly for braided tube or tape structures, the braid angle inside of the catheter should be between 0 to 45 degrees of the braid angle inside catheter, and between about 20 to 90 degrees of the braid angle outside catheter. In variations in which the distal tractor region includes a knit braid (e.g., a warp knit) tube, the apparatus may include 12 to 16 ends per inch. For an apparatus having a 0.0035" ID catheter: 12 to 16 ends of 20-40D PET multifilament may be used, or 12 to 16 ends of 0.0007 to .003" PET or Polypro or PTFE monofilament, or 12 to 16 ends of .0007 to .002" NITI, stainless, MP35n, etc.

[0164] As mentioned above, in some variations the distal tractor region is formed of ePTFE as a sheet (e.g., formed into a tube or tape). This material may be thin walled (e.g., between 0.0005 to 0.003" thick), think walled (between 0.0005 to 0.002"), and may fold/role over catheter tip. The material may include a 0.001 to 0.004" with lasered pattern that is stent-like.

[0165] Other examples of designs for apparatuses including distal tractor region of different shapes may be a function of catheter ID. For example, in some variations the apparatus may select the catheter ID, number of filaments, diameter/length of filaments, stiffness of bending/rolling stiffness, Poisson's ratio, friction (and/or texture) of the inner surface of the grabber, etc. Smaller diameter catheters may require less mesh filaments or smaller ePTFE tube IDS's than larger diameter catheters. For example, in some variations in which the distal tractor region is braided, the apparatus may include a 0.072" ID catheter having a distal tractor region with 24 to 72 ends of 0.0008" to 0.002 Niti wire, braided on a 6 mm mandrel at a 90 degrees braid angle. In some variations the distal tractor region is formed of 24 to 72 ends of 0.0008" to 0.002 PP monofil, braided on a 6 mm mandrel at a 90 degrees braid angle. In some variations the distal tractor region is formed of a knit braid (assume .072" catheter) and may include 16 ends or 40D PET multifil free warp-knitted, annealed on a 3 mm mandrel. In some variations the distal tractor region is formed of 16 ends of 0.002" PP monofil warp-knitted, annealed on a 3 mm mandrel. In variations having a distal tractor region formed of ePTFe tubes (again, assuming a 0.072" catheter), the distal tractor region may be 0.002" thick, 3mm tube. Alternatively, the distal tractor region may be a 0.002" thick, 3mm tube laser slotted to collapse and grab clot.

[0166] As mentioned, in some variations the apparatus is configured to include a gripping inner mesh surface in the distal tractor region. For example the apparatus may include a laser slotted ePTFE tube having larger diameter braid filaments and/or mixed diameter filaments. In some variations a gripping inner mesh surface may be formed with a knit braid that is a warp knit formed tube. Such a structure may have a natural macro structure to allow mesh rolling and gripping of clot, since filaments

do not enter catheter ID parallel to catheter, but rather they are perpendicular or looped relative to catheter long axis. For examples in which the distal tractor region is formed of an ePTFE laser slotted (sheet of) material, the structure may include slots cut to allow Poisson ratio to effect tube diameter while creating grippy texture to grab clot.

[0167] In general, the effectiveness of the distal tractor region in grabbing a clot may be enhanced by using self-expanding and/or stiffer distal tractor region (e.g., self-expanding and/or flexible first end regions of the distal tractor region). When the first end region of the distal tractor region is formed of a braid, stiffer filaments (e.g., formed of bigger diameter filaments, stiffer materials, larger number of fibers, etc.) may result in more expanded first end regions of the distal tractor region, as illustrated in FIGS. 18A-18C. In FIG. 18A a softer distal tractor region does not expand out beyond the OD of the catheter any substantial distance. FIG. 18B shows a slightly stiffer/more expandable first end region of the distal tractor region. FIG. 18C shows the most expandable distal tractor region 1801, which may optimally expand to the intima of the vessel 1803.

[0168] As shown in FIGS. 18A-18C, the mouth of lip of the expandable tractor region may form a tangent angle or roll angle (ϕ) with respect to the long axis of the catheter OD. This angle may be in the range of approximately 5° to 60° degrees (e.g., 10°-60°, 10°-50°, 10°-45°, 10°-40°, etc., and preferable at least 10 degrees). The inventors have surprisingly found that, in some variations, having a roll angle of at least about 10 degrees (e.g., 10°-60°, 10°-50°, 10°-45°, 10°-40°) with the tube as the tractor region is retracted into the catheter may prevent binding or jamming on the catheter tip. The mesh tube may be modified (e.g., at the distal tip or end region), including by modifying the stiffness and/or shape of the distal tip, to ensure the roll angle in greater than 10 degrees. Alternatively or in combination to maintaining a minimum roll angle it may be desirable to maintain a physical space or gap between the tube material ID and the O.D of the catheter (see, e.g., FIGS. 18A-18C) at the catheters most distal tip. The gap may need to be greater than 0.1 mm, 0.2 mm, 0.3 mm, 0.4 mm, 0.5 mm, 0.7 mm, 0.8 mm, or 1.0mm to ensure the tube rolls around the distal end of the catheter when the tube is retracted.

[0169] In any of these variations, the distal tractor region may be lubricious (e.g., hydrophilic coating, silicone coating, thin urethane or other thin elastomeric coating) as mentioned above. One or more polymeric braid ends may be included to enhance lubricity (e.g., polypropylene, nylon, etc.). Further, the braid angle may be kept small (e.g., less than 70 degrees, 50 degrees, 45 degrees, etc.) to allow better pulling. This angle may be measured when the distal tractor region is rolling around/over the tip of the catheter. Increasing the number of ends of the weave may also prevent locking of the first end region within the catheter, so that gaps/spaces between the braid elements are smaller and less likely to snag on the catheter tip when rolling the distal tractor region over the end of the catheter. Any of these apparatuses may also include an axial element when formed as a braided element that is less likely to collapse or reduce in diameter when pulled, and therefore less likely to hang up on the catheter opening when rolling over the tip. It may also be advantageous to use slightly larger braid filaments when using Niti (e.g., >0.0001" diameter); the greater the diameter, the less likely the braid may deform to lock onto

the catheter tip. As mentioned above, in some variations the distal tractor region may be heat set to automatically roll over the distal end of the catheter when advanced distally.

[0170] FIGS. 19A and 19B illustrate alternative methods for forming the doubled-back configuration of the distal tractor region. In FIG. 19A, the tubular distal tractor region 1903 may be coupled to a puller/pusher 1901 and then inverted over the catheter tip as mentioned above. In FIG. 19B, the tubular braid 1905 is attached distally through the braid to a wire/puller 1901 and pulled to invert it over the distal end of the catheter.

[0171] In general, the first end region of the distal tractor region may have any appropriate shape (refer to FIGS. 15A-15D). FIGS. 20A and 20B illustrate examples of tapered woven braids that may form the distal tractor region. In. FIG. 20A, the braid has a tapered side profile that may be attached to a puller (proximal end of the flexible tractor tube) and inverted. Any of the braids described herein may include a marker wire (e.g., DFT, gold, Pt, Pt iridium, etc.) to help with visualization (e.g., fluoroscopically). In FIG. 20B, the mesh is tapered more abruptly than in FIG. 20A.

[0172] As described above, in general, any of the catheters described herein may be adapted for use with these apparatuses. For example an appropriate catheter may be highly flexible with a good column stiffness (e.g., will not shorten in length when advanced distally). The catheter can have a high angle braid reinforcing element. For example, the catheter may have a high angle braid through proximal to distal end (70-85 degrees, small wire Niti, Stainless, cobalt chrome, MP35N, flat or round wire), and a lower braid angle for the distal 1 to 5 cm of the catheter. This will allow the id of the catheter to expand when axial compression is applied, and/or under an internal expanding force (e.g., clot).

[0173] In general, any of these catheters may include a changing stiffness/compliance. For example, the proximal third (1/3) may be stiffer; the middle section may be less stiff, and the distal 20% (1/5) may be the least stiff. Further, the distal tip of the catheter may have an appropriate radius (curve) as described in FIGS. 1A and 1B. In general, the radius should be smooth and round, and not square. In addition, the distal tip of the catheter may be made of a hard enough material (~72D or harder) to allow braid to roll and not grab onto tip. For example, the catheter tip may have a hard metallic structure to reduce friction (e.g., stainless steel, Pt, etc.). The less the catheter tip compresses/buckles when pulling the distal tractor region, the better. In some variations the catheter includes an additional reinforcement such as a braid reinforcement rather than a coil reinforcement, to prevent braid buckling for the last 5-10 cm of the catheter. Thus, as described herein, in some variations, the tip of the catheter may be made of a lubricous and/or hard material to help reduce the braid to catheter tip friction when the braid is pulled or pushed around the catheter tip. Lubricous materials may include flour-polymers like PTFE, FEP and/or hydrophilic coatings. Hard materials like Nylons, or metallics like stainless steel, Platinum and PT iridium alloys could be used at the tip and fused/attached to softer materials proximally. If a hard tip is put on the distal end of the catheter tip it may be short in length (e.g., < 5mm and preferably < 3mm) so it does not adversely affect catheter tracking.

[0174] FIGS. 21A-21D show examples of apparatuses used to remove clots. In this example, the distal tractor region was formed of a fine Denier PET mesh of approximately 72 ends that is 10 mm

(expanded) diameter pulled down onto a 0.071" catheter, as shown in FIGS. 21A and 21B. FIG. 21A shows an example of an expandable first end region prior to coupling to a catheter. FIG. 21B illustrates the expandable first end region within a vessel (glass tube) being drawn into a catheter by pulling the proximal end of the flexible (tractor) tube. FIG. 21C shows the distal end region of the apparatus including the expandable first end regions doubled over the distal end region of the catheter. FIG. 21D illustrates the apparatus of FIG. 21C drawing a clot into the catheter.

[0175] Another example examined a distal tractor region formed from a 6 mm braid having 72 ends and 0.001" diameter filaments rolling into and doubled over a 0.071" ID catheter. A 'medium hard' 5 mm clot that was 20 cm long was successfully removed. FIG. 22 shows the expandable first end region of FIG. 21D with the captured clot after drawing it proximally out of the catheter.

[0176] FIGS. 23A-23D illustrate a mechanical thrombectomy apparatus as described herein capturing a blood clot and drawing it into the apparatus. FIG. 23E illustrates the clot held within the flexible tractor tube after the flexible tractor tube has been removed from the catheter (e.g., proximally).

[0177] In some variations described herein the distal tractor region is not formed of a woven or knitted material, but is instead composed of strip or bundles of longitudinally arranged (e.g., in parallel or near-parallel arrangement). For example, FIG. 24 is another example of an apparatus including a flexible tractor member in which the distal tractor region is formed of a plurality of filaments that are arranged as strips of material (longitudinally parallel) that are not woven or braided. These strips may be filaments, or tubes, etc.

[0178] FIGS. 25A-25F illustrate another variation of a distal tractor region of a flexible tractor assembly in which the expandable first end region (e.g., the distal end region of the distal tractor region) is formed of a plurality of filaments or strips, similar to that shown in FIG. 24; the distal end of the catheter includes channels, as shown in FIGS. 25A-24B; the strips may fit within these channels, as shown in FIGS. 25C-25D. FIGS. 25E and 25F show sectional views through FIGS. 25C and 25D. FIGS. 25A, 25C and 25E show side views and FIGS. 25B, 25D and 25F show axial views. In this example, the catheter tip includes channels 2502 into which the filaments/strips 2503 run. The strips forming the distal tractor region are attached to the more proximate puller region of the flexible tractor tube 2505, shown in FIG. 25E.

[0179] FIGS. 26A and 26B show a variation of the apparatus of FIGS. 25A-25F with an outer sleeve (e.g., an outer catheter or release protector catheter or other outer sleeve/protector)

[0180] FIGS. 27A-27B show a sectional view through the apparatus of FIGS. 26A-26B.

[0181] FIG. 28 is an apparatus including a distal tractor region of a flexible tractor assembly having a plurality of longitudinally-parallel (non-woven/braided) filaments or strips in which the distal ends of the filaments or strips are connected to each other by a distal connector.

[0182] FIG. 29 shows a distal tractor region of a flexible tractor assembly in an apparatus in which the longitudinally-parallel (non-woven/braided) filaments or strips include grabbing elements.

[0183] FIGS. 30A-30C illustrate example of filaments/strips with grabbing elements. Grabbing elements (and/or filaments including them) may be used as part of any of the variations described herein,

including woven or braided distal tractor regions. Other options for filaments/strips with grabbing elements may include braided strips, mesh/woven strips, and micro-coils.

[0184] In any of these configuration described herein, the apparatus may be adapted to allow reciprocation of the distal tractor region, cycling from outside to inside and back outside of the distal end of the catheter. For example, FIG. 31 illustrates a variation in which the distal tractor region is adapted to be reciprocated (e.g., pushed and pulled) so that the expandable first end region may be draw into and reversed out of the catheter. In this example, the tractor tube (puller) 3105 is attached to the distal tractor region 3144 that may be attached (and in some variations is not attached) to a second catheter 3109 over the inner catheter 3101. The mid-catheter 3109 can be coupled to the puller 3105 and the two reciprocated together so that the braid reciprocated back and forth inside of the catheter 3101. This may help break up a clot, which may be particularly when used with suction.

[0185] FIG. 32 illustrates another example of an apparatus as described herein in which the distal-most end 3205 of the flexible first end region of the distal tractor region is non-releasably fixed to the distal end of the outside of the catheter 3201; the rest of the expandable first end region 3209 is sufficiently elastic/flexible to be drawn into the catheter (pulling a clot 3255 with it). The flexible tractor assembly may then be left retracted and the entire apparatus withdrawn. This example may include an optional vacuum 3260.

[0186] FIG. 33 is another example of an apparatus in which the puller portion 3305 of the flexible tractor assembly is formed of the same material as the distal tractor region 3344 but may be laminated or otherwise reinforced to have less flexibility/stretchability than the distal tractor region.

[0187] FIG. 34 illustrates another example in which the distal tractor region 3444 is adapted to compress the clot 3455 when draw into the catheter 3401. FIGS. 35A-35C illustrate operation of an apparatus as shown in FIG. 34 in which the clot 3455 is drawn into the catheter by withdrawing the expandable first end region of the distal tractor region into the catheter (e.g., pulling on the puller region 3505 of the tractor assembly) which compresses the clot (FIGS. 35A-35B); releasing the tractor assembly and/or pushing it distally may further break up the clot and release it from the distal tractor region so that it may be sectioned up proximally (FIG. 35C).

[0188] FIG. 36 illustrates an example of an apparatus and method of use in which drawing the flexible tractor assembly proximally may advance the apparatus distally through the body (e.g., vessel) over a guidewire, which may be treated to engage the distal tractor region. In this example, the apparatus may be configured to pull the inner tractor tube (catheter 3605) which has the mesh forming the distal tractor region 3644 attached to its distal end and inverting over the distal end of the catheter 3601. Pulling the flexible tractor tube 3605 makes the braid roll over the opening of the catheter 3601. The mesh/braid forming the distal tractor region (e.g., the first end region of the distal tractor region) is constructed to collapse in diameter when tensile loads are applied to this structure and lock/grab onto inner wire (guidewire 3677). This inner guidewire may have a tacky, rough or knobby surface aid mesh/braid grabbing onto wire. As the mesh/braid grabs onto the guidewire, the tractor tube, as a

reactionary force, will be driven forward in the vessel. Alternatively the user will be able to easily advance outer catheter 3601 forward through vessel while pulling back on the tractor tube.

[0189] FIGS. 37A-37C illustrate another apparatus and method of use in which drawing the flexible tractor assembly proximally may advance the apparatus distally. In FIG. 37A, the distal tractor region 3744 is attached to a middle catheter 3703 (an optional outer catheter 3705 may be included) and the opposite end of the distal tractor region 3744 is bonded to the distal end of the inner catheter 3701 within the inner diameter of this catheter. In FIG. 37B the inner catheter is advanced distally, expanding the distal tractor region both laterally and forward. As shown in FIG. 37C, the outer and inner catheters may then be pushed distally to move the apparatus more distally.

[0190] In some variations the distal and flexible tractor region may be held pre-loaded outside of the catheter, e.g., in a roll or bundle, over the distal end region of the catheter, so that it can be gradually pulled out of the external storage region and rolled and inverted over the distal end of the catheter. An example of one such variation is shown in FIGS. 38A and 38B. this exemplary apparatus may be used to remove material from within a vessel as shown in FIG. 38B, and may be referred to as an "infinite" tractor mechanism because a large amount (e.g., greater than 50 cm, greater than 60 cm, greater than 70 cm, greater than 80 cm, greater than 90 cm, greater than 100 cm, greater than 150 cm, 200 cm, greater than 300 cm, greater than 400 cm, greater than 500 cm, etc.) of tractor material (e.g., mesh) may be stored in an external holding region, wound-up but dispensable over an extended use.

[0191] In FIG. 38A, the apparatus may include the catheter (inner catheter) 3811 and the distal tractor region 3806 is formed of a mesh that is rolled up 3803 in a housing region 3813 proximal to the distal end of the catheter. The clot 3805 may be drawn into the catheter by pulling the distal tractor region proximally within the catheter. Because a great deal of distal tractor region may be stored and withdrawn proximally, this variation may be useful for very long procedures or where there is a lot of material to be removed.

[0192] This variation may allow a user to unroll a long length of mesh, which may be advantageous for more rigid tools, such as, for example, a rigid hypotube during surgery, for example, removing fat in a liposuction procedure, removing clot in an intracerebral hemorrhage or a larger peripheral vascular clot.

[0193] As mentioned above, in any of the variations described herein, the distal tractor member may be a woven (e.g., knit) or braided mesh material. The mesh may be a knit material, including, for example a weft knit, circular knit, warp braid knit, and/or braid knit.

[0194] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no

intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[0195] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[0196] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[0197] Although the terms "first" and "second" may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[0198] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising" means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term "comprising" will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

[0199] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or "approximately," even if the term does not expressly appear. The phrase "about" or "approximately" may be used when describing magnitude and/or position to indicate that the value and/or position described is

within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For example, if the value "10" is disclosed, then "about 10" is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that "less than or equal to" the value, "greater than or equal to the value" and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value "X" is disclosed the "less than or equal to X" as well as "greater than or equal to X" (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point "10" and a particular data point "15" are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[0200] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[0201] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

What is claimed is:

1. A method of performing a mechanical thrombectomy to remove a clot from a blood vessel, the method comprising:
   advancing a distal end of a catheter through the blood vessel towards the clot;
   exposing a distal tractor region of a tube that is within the catheter from the distal end of the catheter, wherein the distal tractor region comprises an expandable first end region and a less expandable second end region proximal to the expandable first end region;
   allowing the expandable first end region to expand within the blood vessel;
   positioning the distal end of the catheter so that a distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region while the expandable first end region is doubled over the less expandable second end region; and
   drawing the clot into the catheter by rolling the expandable first end region over the distal end of the catheter so that the expandable first end region inverts as the expandable first end region is pulled into the catheter.

2. The method of claim 1, wherein positioning comprises distally advancing the distal end of the catheter so that the distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region.

3. The method of claim 1, further comprising advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until the distal end of the catheter is proximate to the clot.

4. The method of claim 1, further comprising advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until the distal end of the catheter is proximate to the clot, further wherein drawing the clot into the catheter comprises advancing the catheter towards the clot over the guidewire while rolling the expandable first end region over the distal end of the catheter.

5. The method of claim 1, wherein drawing the clot into the catheter comprises withdrawing the tube proximally.

6. The method of claim 1, wherein drawing the clot into the catheter comprises withdrawing the tube proximally while advancing the catheter distally.

7. The method of claim 1, wherein drawing the clot into the catheter comprises withdrawing the tube proximally while advancing the catheter distally, wherein the tube is withdrawn at a different rate than the catheter is advanced.

8. The method of claim 1, wherein allowing the expandable first end region to expand within the blood vessel comprises allowing a biasing element in the expandable first end region to expand so that the distal tractor region makes contact with an intima of the blood vessel.

9. The method of claim 1, wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises pushing the distal tractor region out of the distal end of the catheter.

10. The method of claim 1, wherein exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter comprises pulling the catheter proximally.

11. The method of claim 1, wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises pushing the distal tractor region out of the distal end of the catheter to expose the expandable first end region already inverted over the less expandable second end region.

12. The method of claim 1, wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises extending the expandable first end region out of the distal end of the catheter so that the expandable first end region inverts over the distal end of the catheter as the expandable first end region is extended.

13. The method of claim 1, wherein exposing the distal tractor region of the tube comprises exposing at least 5 mm of the expandable first end region and at least 5 mm of the less expandable second end region.

14. The method of claim 1, wherein exposing the distal tractor region comprises exposing at least 1 cm of the expandable first end region inverted over at least 1 cm of the less expandable second end region.

15. The method of claim 1, wherein the expandable first end region comprises a mesh that is coupled adjacent to the less expandable second end region.

16. The method of claim 1, wherein the expandable first end region comprises one or more of: a woven material, a mesh braided material, a knitted material, or a film material with multiple openings therethrough.

17. The method of claim 1, wherein advancing comprises advancing the distal end of the catheter through the blood vessel to position the distal end adjacent to the clot.

18. A method of performing a mechanical thrombectomy to remove a clot from a blood vessel, the method comprising:

advancing a distal end of a catheter through the blood vessel towards the clot;

exposing a distal tractor region of a tube that is within the catheter from the distal end of the catheter, wherein the distal tractor region comprises an expandable first end region and a less expandable second end region proximal to the expandable fist end region and configured so that the expandable first end region is inverted over the less expandable second end region;

allowing the expandable first end region to expand within the blood vessel so that the distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region; and

drawing the clot into the catheter by advancing the catheter distally and withdrawing the tube proximally within the catheter so that the expandable first end region rolls over the distal end of the catheter and inverts as the expandable first end region is pulled into the catheter.

19. The method of claim 18, wherein the expandable first end region is inverted over the less expandable second end region before exposing the distal tractor region.

20. The method of claim 18,wherein the exposing the distal tractor region comprises inverting the expandable distal end region over the less expandable second end region as the distal tractor region is exposed.

21. The method of claim 18, further comprising, before exposing the distal tractor region, advancing a guidewire within the blood vessel to the clot and advancing the catheter over the guidewire through the blood vessel until a distal end of the catheter is proximate to the clot.

22. The method of claim 18, further comprising, before exposing the distal tractor region, advancing a guidewire within the blood vessel to the clot and advancing the catheter over the guidewire

through the blood vessel until a distal end of the catheter is proximate to the clot and leaving the guidewire in place while drawing the clot into the catheter.

23. The method of claim 18, wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises pushing the distal tractor region out of the distal end of the catheter.

24. The method of claim 18, wherein exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter comprises pulling the catheter proximally.

25. The method of claim 18, wherein exposing the distal tractor region of the tube comprises exposing at least 5 mm of the expandable first end region and at least 5 mm of the less expandable second end region.

26. The method of claim 18, wherein the expandable first end region of the distal tractor region comprises a mesh that is coupled adjacent to the less expandable second end region.

27. The method of claim 18, wherein the expandable first end region comprises one or more of: a woven material, a mesh braided material, or a film material with multiple openings therethrough.

28. A method of performing a mechanical thrombectomy to remove a clot from a blood vessel, the method comprising:

advancing a distal end of a catheter through the blood vessel towards the clot;

exposing a distal tractor region of a tube that is within the catheter out of the distal end of the catheter, wherein the distal tractor region comprises an expandable first end region and a less expandable second end region, wherein exposing comprises extending the expandable first end region out of the distal end of the catheter so that the expandable first end region inverts over the distal end of the catheter as the expandable first end region is extended;

allowing the expandable first end region to expand within the blood vessel as it is extended out of the distal end of the catheter so that a distal end region of the catheter is between the less expandable second end region and the expandable first end region; and

drawing the clot into the catheter by withdrawing the tube proximally within the catheter so that the expandable distal end region rolls over the distal end of the catheter, collapses, and inverts as the expandable distal end region is pulled into the catheter.

29. The method of claim 28, further comprising advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until a distal end of the catheter is proximate to the clot.

30. The method of claim 28, wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises pushing the distal tractor region out of the distal end of the catheter.

31. The method of claim 28, wherein exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter comprises withdrawing the catheter proximally relative to the distal tractor region of the tube.

32. The method of claim 28, wherein exposing the distal tractor region of the tube comprises exposing at least 5 mm of the expandable first end region and at least 5 mm of the less expandable second end region.

33. The method of claim 28, wherein the expandable first end region comprises a mesh that is coupled adjacent to the less expandable second end region.

34. The method of claim 28, wherein the expandable first end region comprises one or more of: a woven material, a mesh braided material, or a film material with multiple openings therethrough.

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

a catheter having a distal end and a distal end opening;

a flexible tube extending within the catheter and doubling back over the distal end of the catheter, wherein the flexible tube is configured to slide and invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter; and

a guidewire lumen through the catheter and the flexible tube that is configured to pass a guidewire.

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

a catheter having a distal end and a distal end opening, wherein the distal end opening has a **durometer that is greater than a durometer of a region immediately proximal to the distal end**, further wherein the distal end opening has a rounded lip profile;

a flexible tube extending within the catheter and doubling back over the distal end of the catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter; and

a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.

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

an inner catheter having a distal end and a distal end opening;

a flexible tube extending though the catheter and doubling back over the distal end of the inner catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the inner catheter;

an outer catheter extending over the inner catheter and flexible tube;

a **lubricious region of the flexible tube extending between a distal end of the outer catheter and the distal end opening of the inner catheter**, wherein the majority of the flexible tube is not lubricious; and

a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.

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

an inner catheter having a distal end and a distal end opening;

a flexible tube extending though the catheter and doubling back over the distal end of the inner catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the inner catheter;

a releasable attachment between the flexible tube and an outer surface of the catheter, configured to release when the flexible tube is pulled with a predetermined force that is greater than 0.01 N; and

a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.

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

a catheter having a distal end, a distal end opening and an inner diameter;

a flexible tube extending through the catheter and doubling back over the distal end of the catheter, wherein the flexible tube is configured to invert over the distal end opening

when a first end of the flexible tube is pulled proximally within the catheter, the **flexible tube having a low Poisson's ratio**, such that the flexible tube has a diameter of greater than half the inner diameter of the catheter when pulled proximally within the catheter with sufficient force to invert over the distal end opening; and

a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.

40. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a mesh tube.

41. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube extending through the catheter and doubling back over the distal end of the catheter increases the stiffness of a distal 5cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

42. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube has at least one porous section having a pore pattern having a longitudinal separation between pores of less than about 0.005 inches in width.

43. The apparatus of claims 35, 36, 37 and 39, further comprising a releasable attachment between the flexible tube and an outer surface of the catheter, configured to release when the flexible tube is pulled with a force that is greater than a predetermined force threshold.

44. The apparatus of claim 43, wherein the releasable force threshold is 0.01 N.

45. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a plurality of strips of flexible material, wherein the strips are arranged in parallel.

46. The apparatus of claims 35, 36, 37, 38 and 39, wherein the distal end opening comprises a plurality of notches or channels into which fibers or strips forming the flexible tube are drawn as the flexible tube inverts over the distal end opening.

47. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a polymeric tube having a plurality of holes therethrough.

48. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a distal end, a proximal end and a body region there between, wherein the body region transitions from a more flexible distal end to a stiffer proximal end.

49. The apparatus of claims 35, 37, 38 and 39, wherein the distal end opening has a durometer that is greater than a durometer of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile

50. The apparatus of claims 35, 36, 37, 38 and 39, further comprising a handle adapted to draw the flexible tube proximally relative to the catheter.

51. The apparatus of claims 35, 36, 38 and 39, further comprising an outer catheter extending over the catheter and flexible tube.

52. The apparatus of claims 35, 36, 38 and 39, further comprising an outer catheter extending over the catheter and flexible tube and a lubricious region of the flexible tube extending between a distal end of the outer catheter and the distal end opening, wherein the majority of the flexible tube is not lubricious.

53. The apparatus of claims 35, 36, 37 and 38, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter wherein the flexible tube has a low Poisson's ratio such that the flexible mesh tube has a diameter of greater than half the inner diameter of the catheter when pulled proximally within the catheter with sufficient force to invert over the distal end opening.

54. The apparatus of claims 35, 36, 37, 38 and 39, further comprising an elongate puller within the catheter and coupled to a distal end of the flexible tube.

55. The apparatus of claims 35, 36, 37, 38 and 39, further comprising an elongate puller within the catheter and coupled to a distal end of the flexible tube, wherein the elongate puller comprises a hypotube having an inner lumen that is continuous with the guidewire lumen though the flexible tube.

56. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a soft outer mesh member formed from 48 to 144 stands, having a thickness of 0.0020 inches or less in diameter, wherein the mesh tubular member extends in a longitudinal axis, further wherein the mesh tubular member has a length that is greater than 5 cm, forms a braid angle between crossing strands in a direction of the longitudinal axis of about 35 degrees or less when being pulled and inverted around the distal end of the catheter and expands to a diameter of greater than 1.5 times an inner diameter of the catheter outside of the catheter when unconstrained.

57. The apparatus of claim 56, where the strand is formed of any of the following; monofilament polymer, multifilament polymer, NiTi filament, NiTi tube with radiopaque metallic center, Nylon, Polyester, Polyethylene terephthalate, and Polypropylene, .

58. The apparatus of claims 35, 36, 37, 38 and 39, further comprising a drive handle coupled to a proximal end region of the catheter, wherein the drive handle comprises a control configured to coordinate advancing of the catheter distally while retracting the flexible tube proximally when actuated.

59. The apparatus of claims 35, 36, 37, 38 and 39, further comprising a retaining ring around a distal end region of the flexible tube configured to hold the flexible tube against the catheter.

60. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube is shape set to have different diameter when within the catheter after being pulled proximally into the catheter.

61. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a plurality of woven or knitted filaments.

62. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a plurality of woven or knitted filaments, and further wherein the proximal end of the flexible tube forms a tapered opening opposite from a bundle of filaments forming a pull wire.

63. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube is formed from a sleeve of polymer having a thickness less than 0.020 inches, wherein the sleeve comprises a perforation pattern in which the perforations extend through the polymer.

64. The apparatus of claim 63, wherein the perforation pattern comprises perforations having a shaped consisting of one or more of: round holes, rectangular holes and zig-zag shapes.

65. The apparatus of claims 35, 36, 37, 38 and 39, further comprising a pull wire coupled to one side of a proximal end of the flexible tube configured to be drawn proximally to pull the flexible tube within the catheter.

66. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube is 3 to 50 cm.

67. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube of the apparatus is configured so that the flexible tube may be retracted into the catheter by applying less than 300 grams of force to a distal end of the flexible tube.

68. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a taper between the first end and a second end of the flexible tube.

69. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube extends within the entire length of the catheter so that a proximal end of the flexible tube is configured to be pulled proximally away from the proximal end of the catheter to slide and invert the flexible tube over the distal end opening.

70. The apparatus of claim 35, 36, 37, 38 and 39, further comprising a guidewire vacuum pump coupled to a proximal end of the guidewire lumen and configured to apply vacuum therethrough.

71. The apparatus of claims 35, 36, 37, 38 and 39, further comprising an outer catheter vacuum pump coupled to a space between the catheter and the flexible tube and configured to apply a vacuum within a lumen of the catheter between an inner wall of the catheter and the flexible tube.

72. The apparatus of claims 35, 36, 37, 38 and 39, further comprising a puller, wherein a distal end of the flexible tube is coupled to a distal end of the puller and an outer catheter arranged over the catheter adjacent to a proximal end of the flexible tube, further comprising a handle having a control configured to coordinate advancing of the outer catheter to push the proximal end of the flexible tube distally and pulling the puller proximally to drawn the proximal end of the flexible tube into the catheter.

73. The apparatus of claims 35, 36, 37, 38 and 39, further comprising:

a puller, wherein a distal end of the flexible tube is coupled to a distal end of the puller;

an outer catheter slideably arranged over the catheter coupled to a proximal end of the flexible tube; and

a handle having a control configured to coordinate advancing of the outer catheter distally to push the proximal end of the flexible tube distally while pulling of the puller proximally to drawn the proximal end of the flexible tube into the catheter or pulling the outer catheter proximally to pull the proximal end of the flexible tube proximally while pushing of the puller distally to push the proximal end of the flexible tube out of the catheter.

74. A method of mechanically removing a thrombectomy, the method comprising:

advancing a guidewire at least to the proximal end of a clot in a blood vessel;

advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening and a flexible tube extending along an outer diameter of the catheter and over the distal end of the

catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube;

pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that the flexible tube slides and inverts over the distal end opening; and

drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

75. A method of mechanically removing a thrombectomy, the method comprising:

advancing a guidewire adjacent a clot in a blood vessel;

advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening and a flexible tube extending along an outer diameter of the catheter and over the distal end of the catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube;

pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen over a rounded lip of the distal end opening of the catheter so that the flexible tube slides and inverts over the distal end opening, wherein the distal end opening has a durometer that is greater than a durometer of a region immediately proximal to the distal end; and

drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

76. A method of mechanically removing a thrombectomy, the method comprising:

advancing a guidewire adjacent a clot in a blood vessel;

advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises an inner catheter having a distal end and a distal end opening, a flexible tube extending along an outer diameter of the inner catheter and over the distal end of the catheter, and an outer catheter securing a distal end region of the flexible tube against the outer diameter of the inner catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube;

pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that a lubricious proximal leader region of the flexible tube slides and inverts over the distal end opening, until a non-lubricious distal region of the flexible tube is drawn into the inner catheter; and

drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

77. A method of mechanically removing a thrombectomy, the method comprising:

advancing a guidewire adjacent a clot in a blood vessel;

advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening and a flexible

tube extending along an outer diameter of the catheter and over the distal end of the catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube;

pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that the flexible tube slides and inverts over the distal end opening;

pulling or pushing the flexible tube distally out of the distal end of the catheter so that the flexible tube slides and inverts over the distal end opening and over the outer diameter of the catheter; and

drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

78. The method of claims 74, 75, 76, and 77, wherein the guidewire is positioned at least partially within the clot in the blood vessel.

79. A mechanical thrombectomy device for removing a clot from a vessel, the device comprising:

a catheter having a distal end and a distal end opening, wherein the catheter has an inner diameter and an outer diameter;

a distal tractor region of a tube within the catheter, wherein the distal tractor region comprises an expandable distal end region and a less expandable distal end region proximal to the expandable distal end region, the distal tractor region configured so that the expandable distal end region is inverted over the less expandable distal end region;

a guidewire lumen through the catheter and the tube, including the distal tractor region, wherein the guidewire lumen is configured to pass a guidewire; and

a proximal handle coupled to the tube and configured to cause relative motion between the catheter and the tube such that the distal tractor region is released from within the inner diameter of the catheter so that the expandable distal end region may expand to a diameter that is greater than the outer diameter so that the catheter may be advanced between the expandable distal end region and the less expandable distal end region and the tube may be drawn proximally to pull the expandable distal end region over the distal end of the catheter so that the expandable distal end region rolls into the distal end of the catheter, inverts, collapses and is drawn into the catheter.

80. A mechanical thrombectomy device for removing a clot from a vessel, the device comprising:

a catheter having a distal end and a distal end opening, wherein the catheter has an inner diameter and an outer diameter;

a tube having a distal tractor region within the catheter, wherein the distal tractor region comprises an expandable distal end region and a less expandable distal end region that is proximal to the expandable distal end region, further wherein the expandable distal

end region is biased to invert over the less expandable distal end region as it is exposed from the distal end of the catheter;

a guidewire lumen through the catheter and the tube, including the distal tractor region, wherein the guidewire lumen is configured to pass a guidewire; and

a proximal handle coupled to the tube and configured to cause relative motion between the catheter and the tube such that the distal tractor region is released from within the inner diameter of the catheter so that the expandable distal end region may expand to a diameter that is greater than the outer diameter and the tube may be drawn proximally to pull the expandable distal end region over the distal end of the catheter so that the expandable distal end region rolls into the distal end of the catheter, inverts, collapses and is drawn into the catheter.

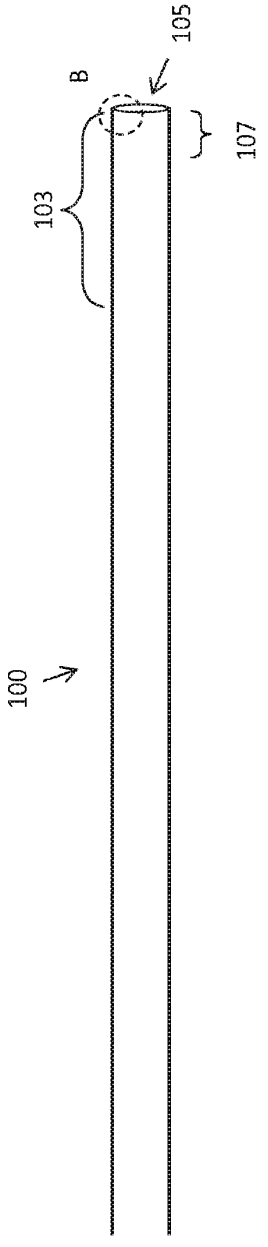


FIG. 1A

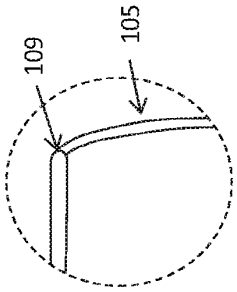


FIG. 1B

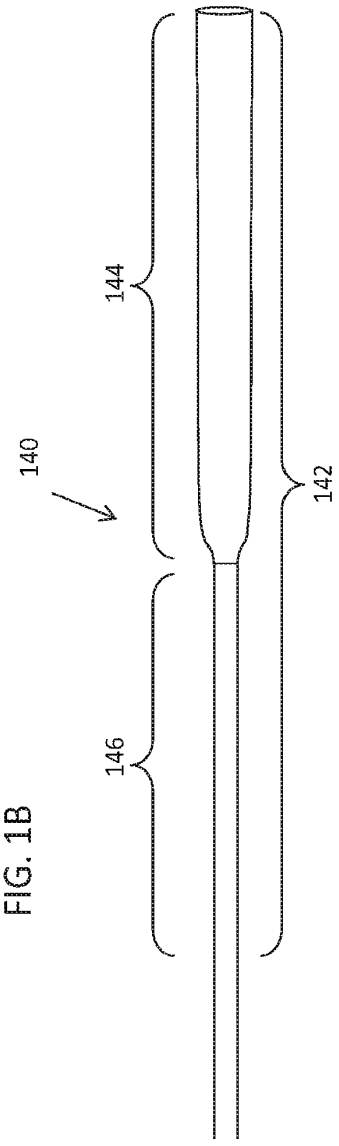


FIG. 1C

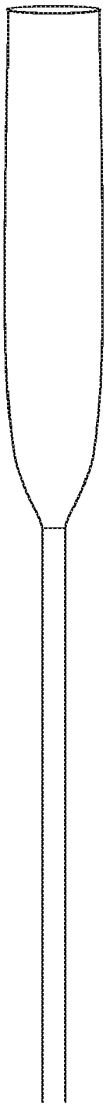


FIG. 1D

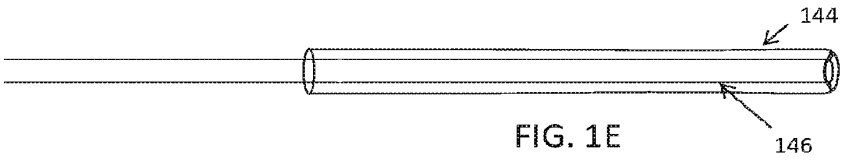


FIG. 1E

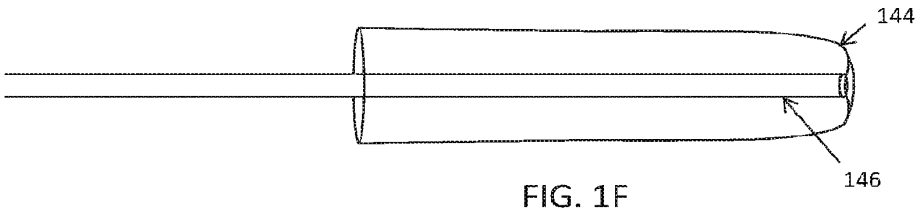


FIG. 1F

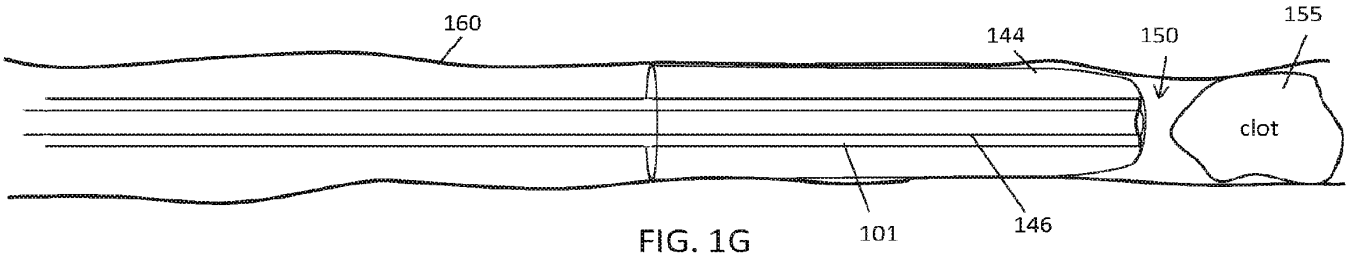


FIG. 1G

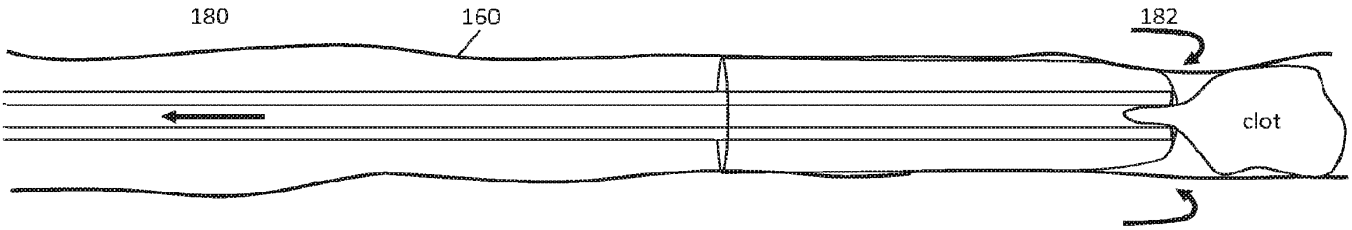


FIG. 1H

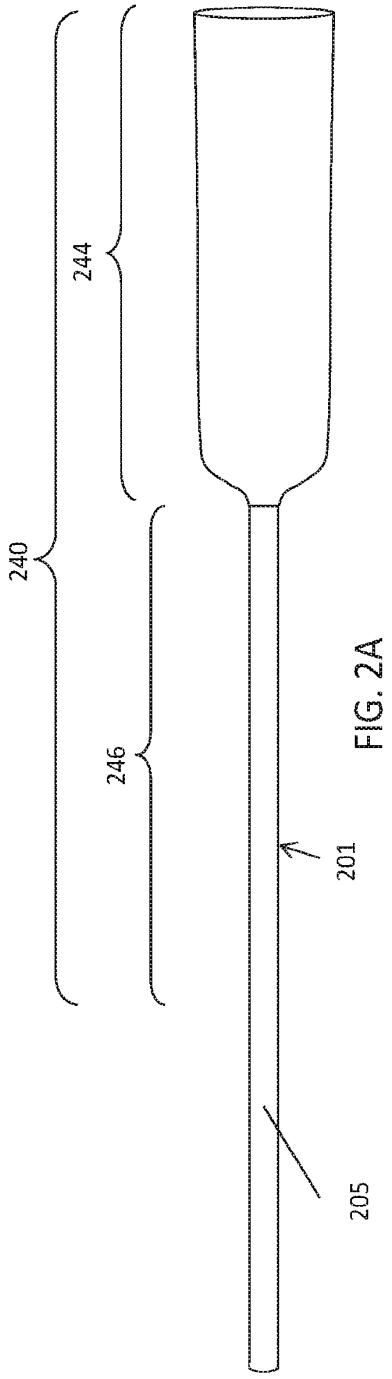


FIG. 2A

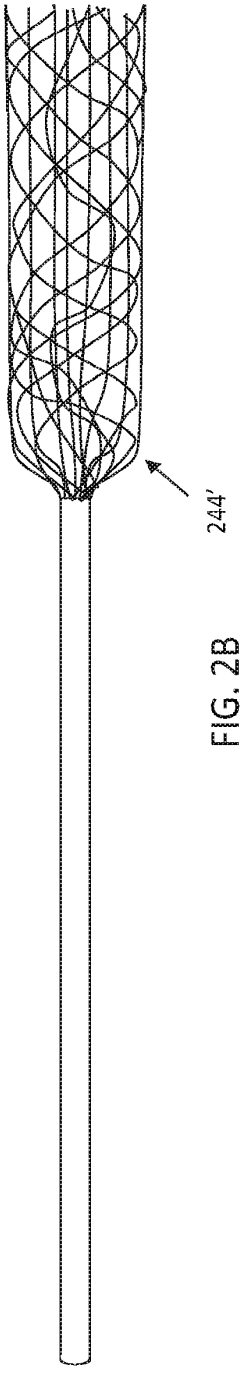


FIG. 2B

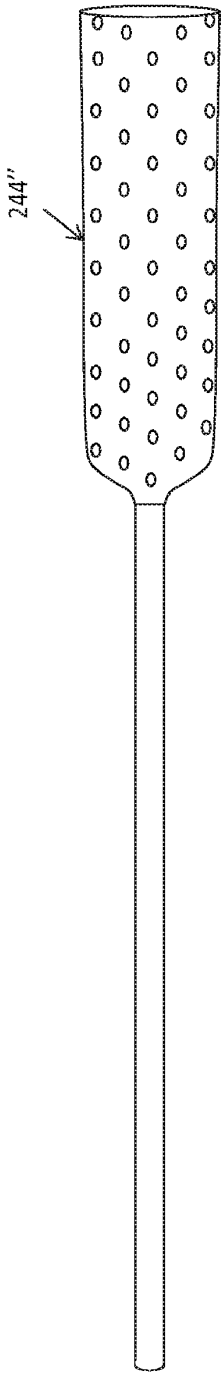


FIG. 2C

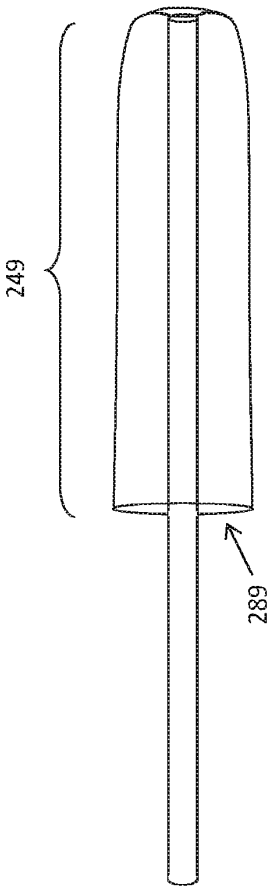


FIG. 2D

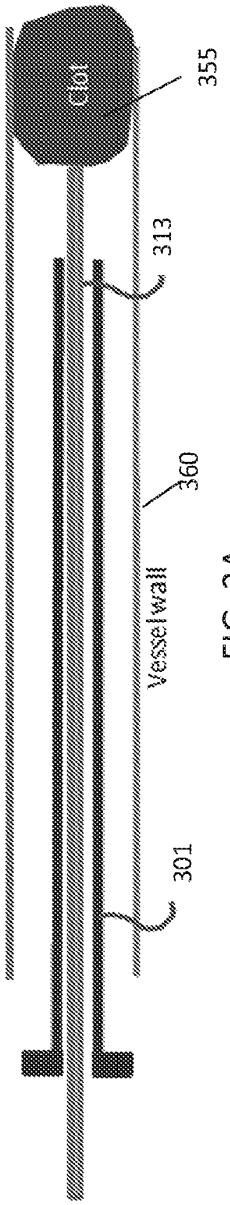


FIG. 3A

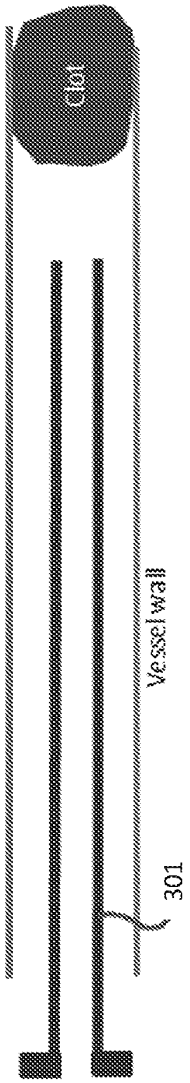


FIG. 3B

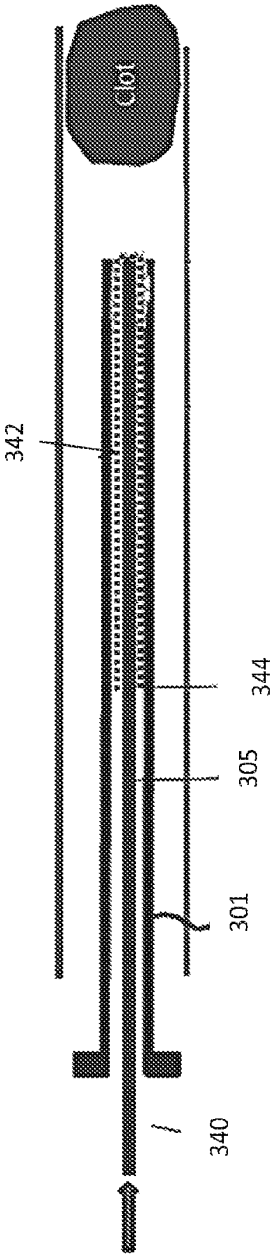


FIG. 3C

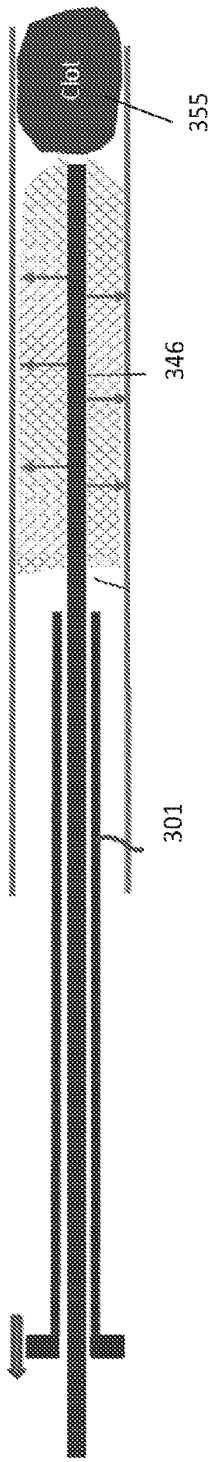


FIG. 3D

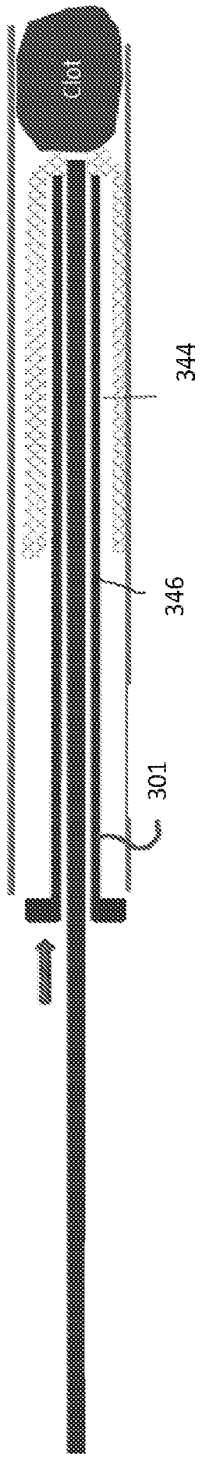


FIG. 3E

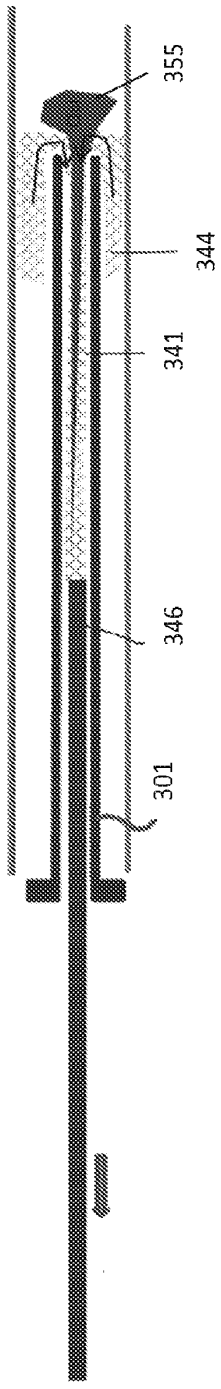


FIG. 3F

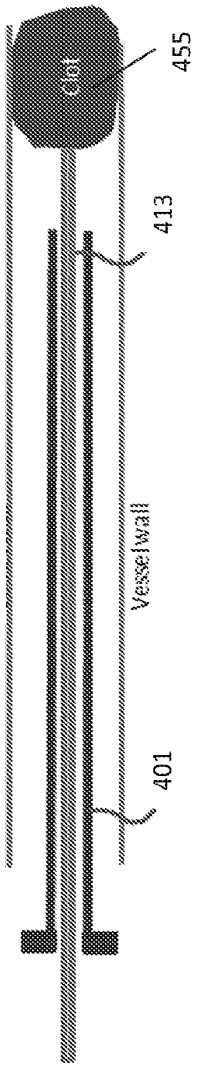


FIG. 4A

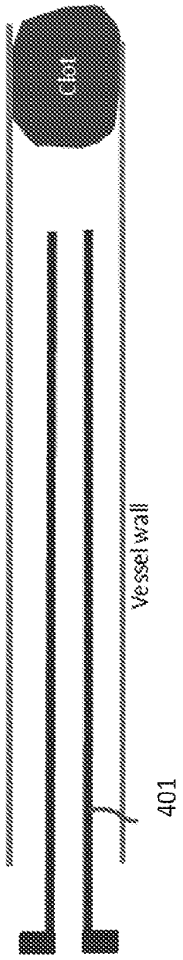


FIG. 4B

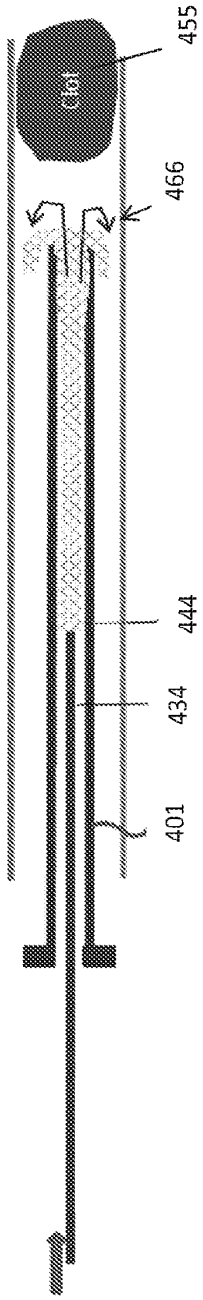


FIG. 4C

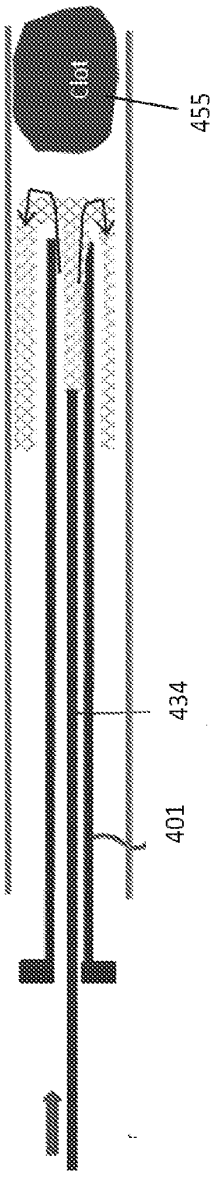


FIG. 4D

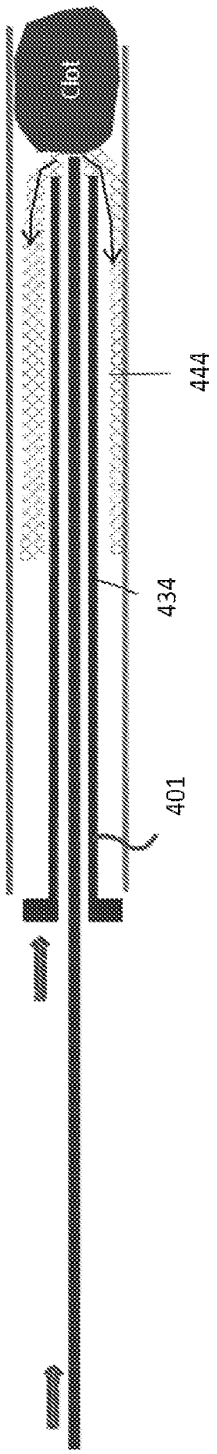


FIG. 4E

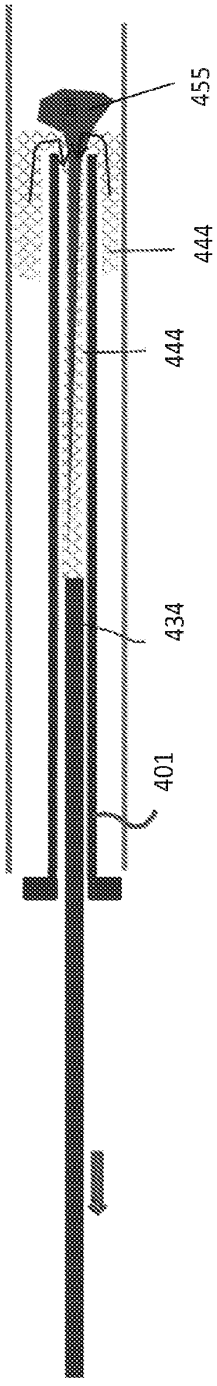
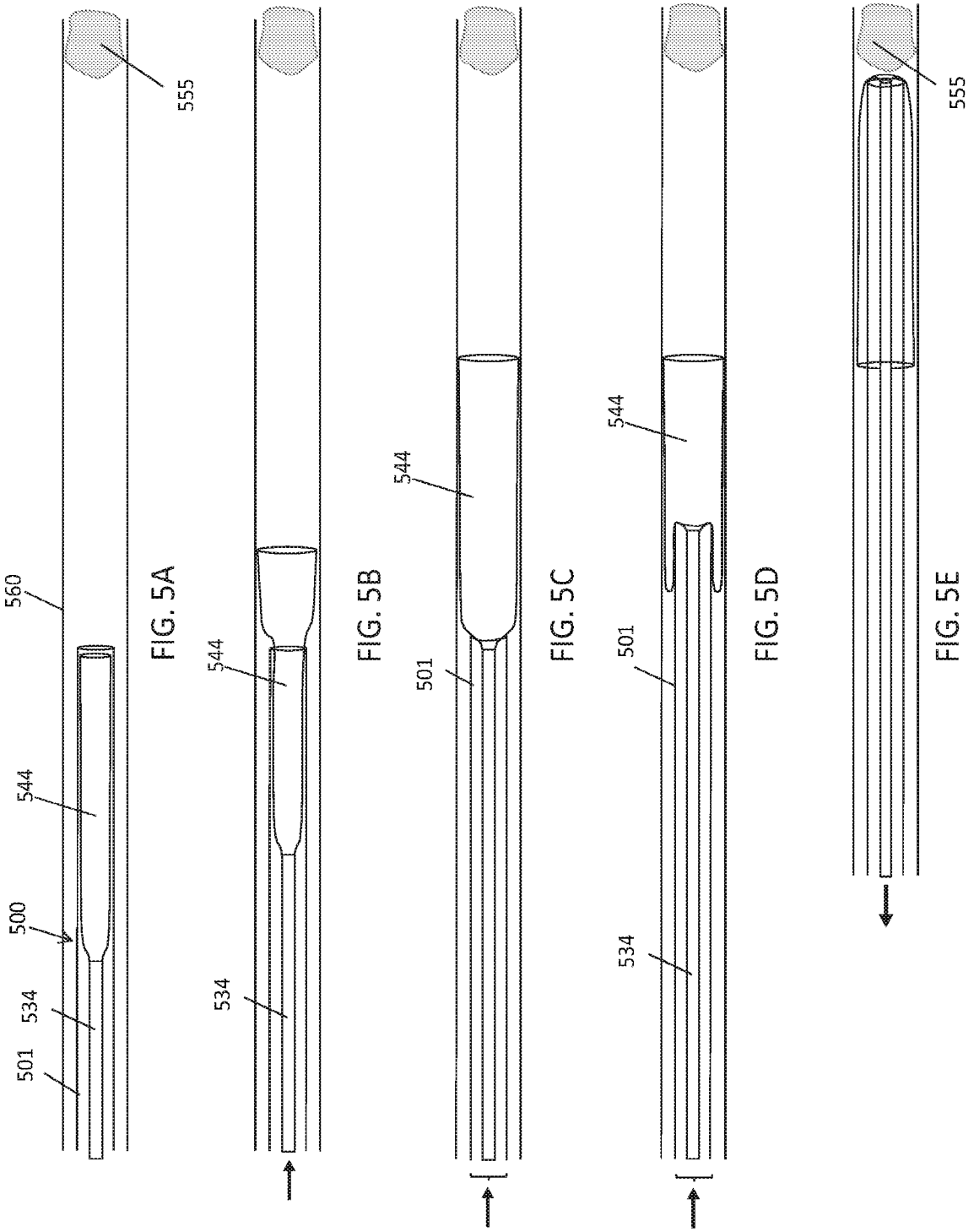


FIG. 4F


555
560
544
500
534
501
FIG. 5A
555
544
534
FIG. 5B
544
501
FIG. 5C
544
501
534
FIG. 5D
555
FIG. 5E

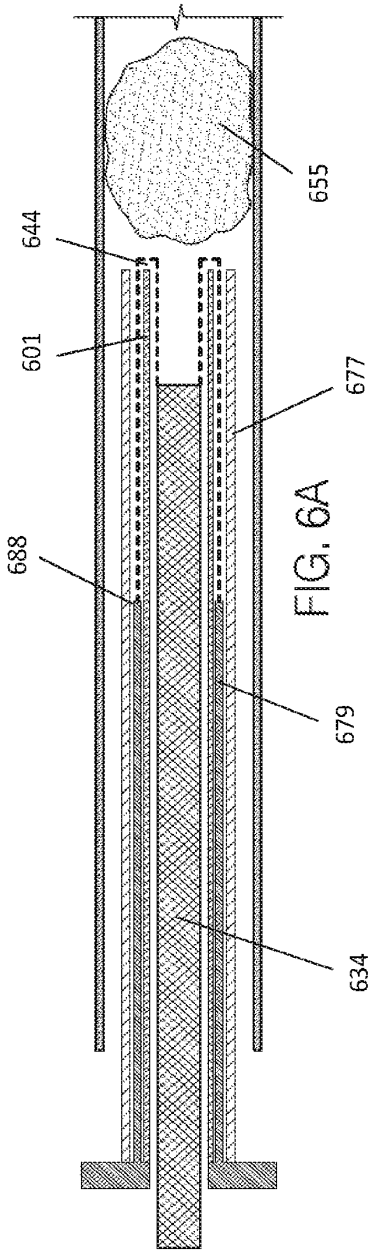


FIG. 6A

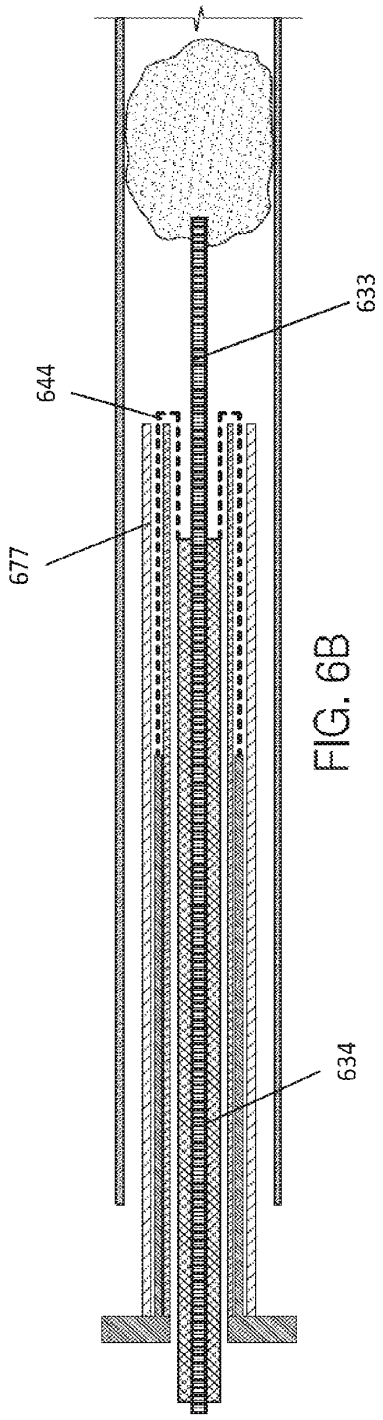


FIG. 6B

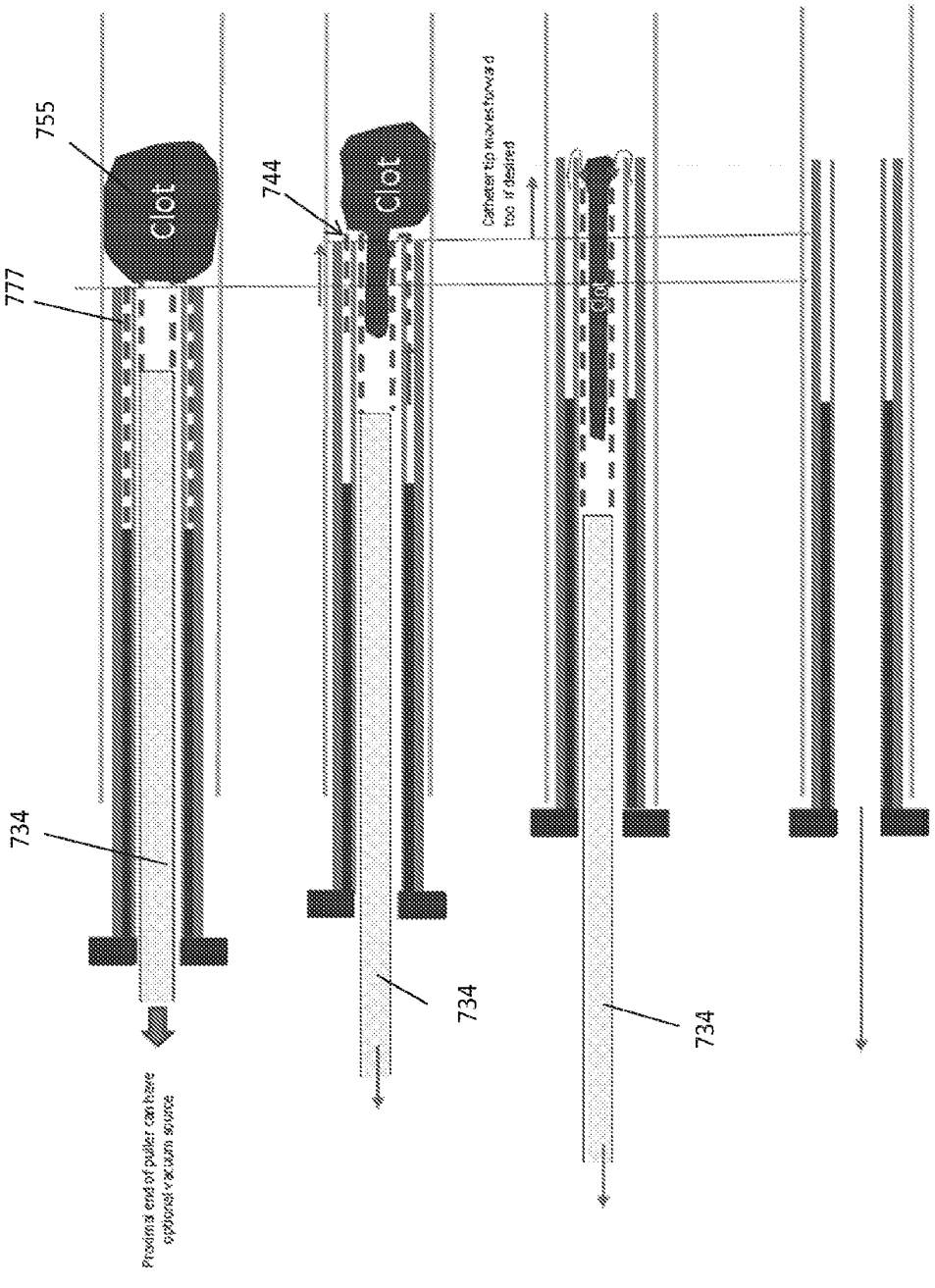


FIG. 7A FIG. 7B FIG. 7C FIG. 7D

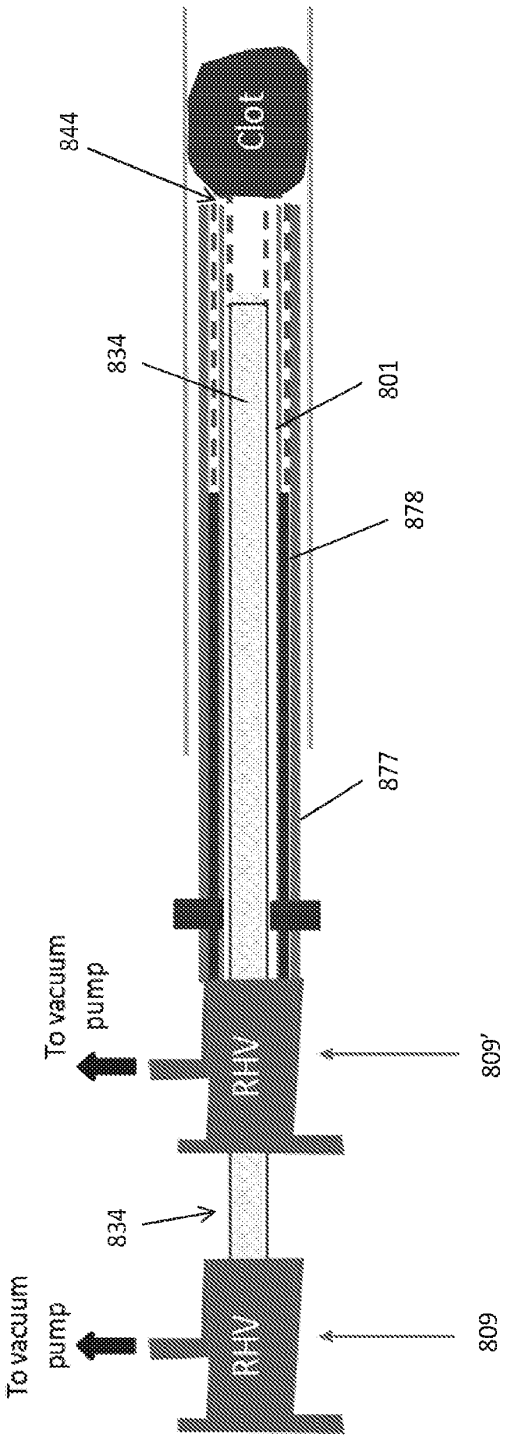

844
Clot
834
801
878
877
To vacuum pump
RHV
809'
834
To vacuum pump
RHV
809

FIG. 8

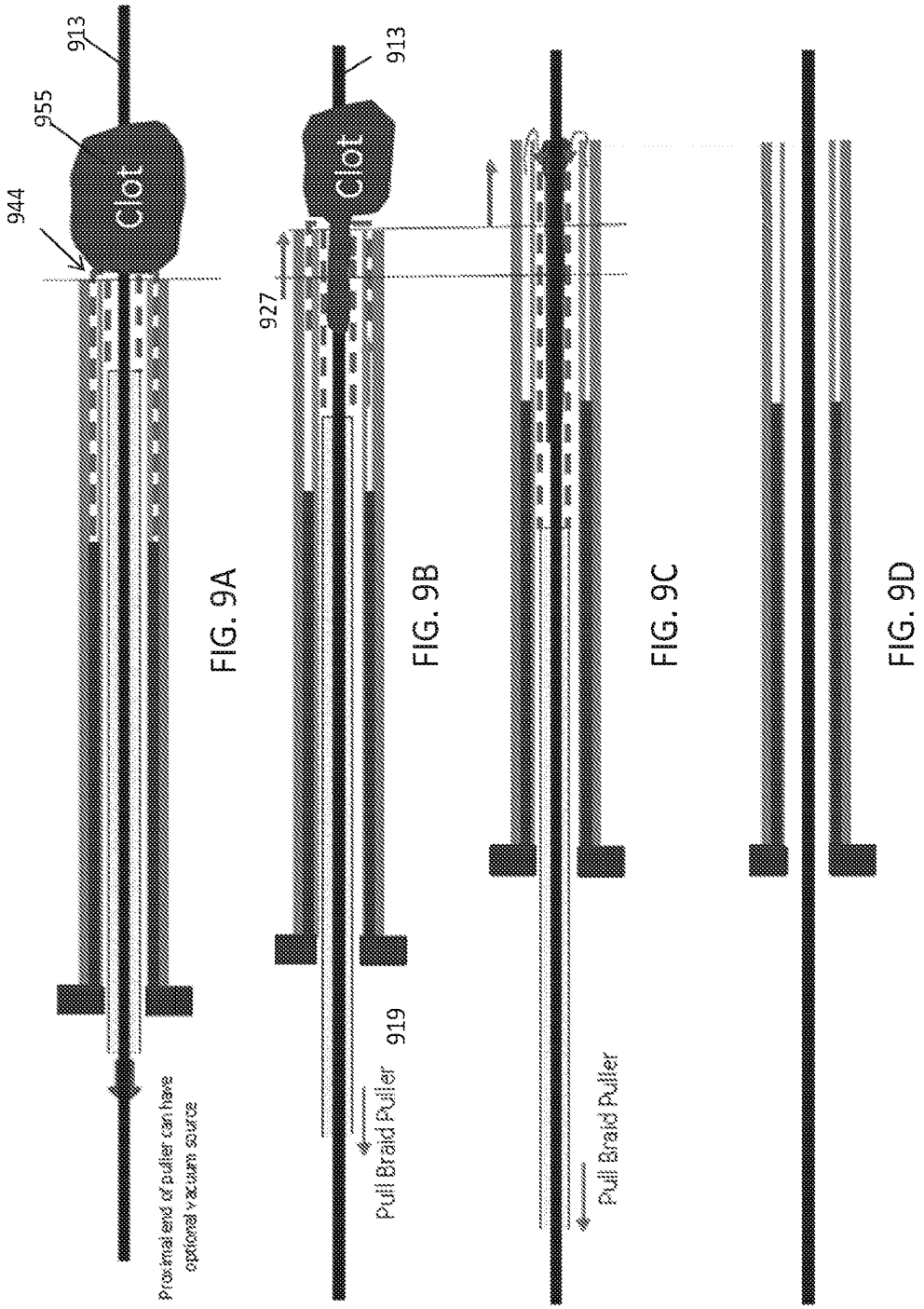


FIG. 9A

FIG. 9B

FIG. 9C

FIG. 9D

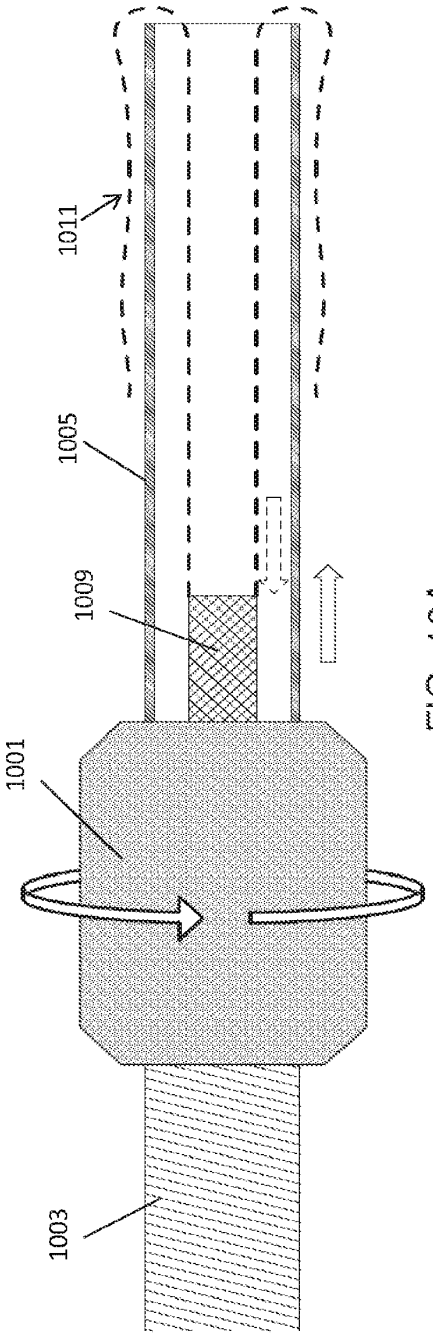


FIG. 10A

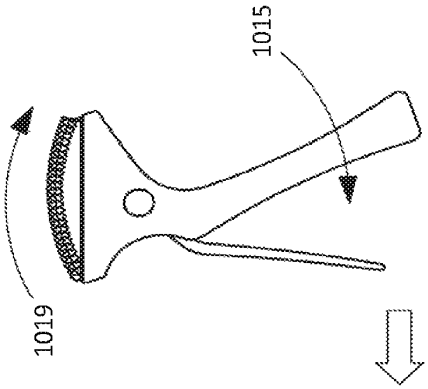


FIG. 10B

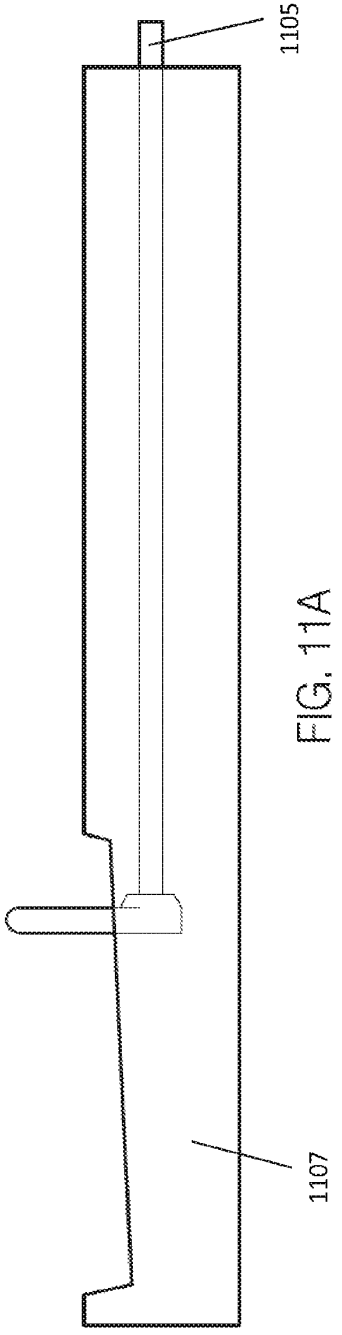


FIG. 11A

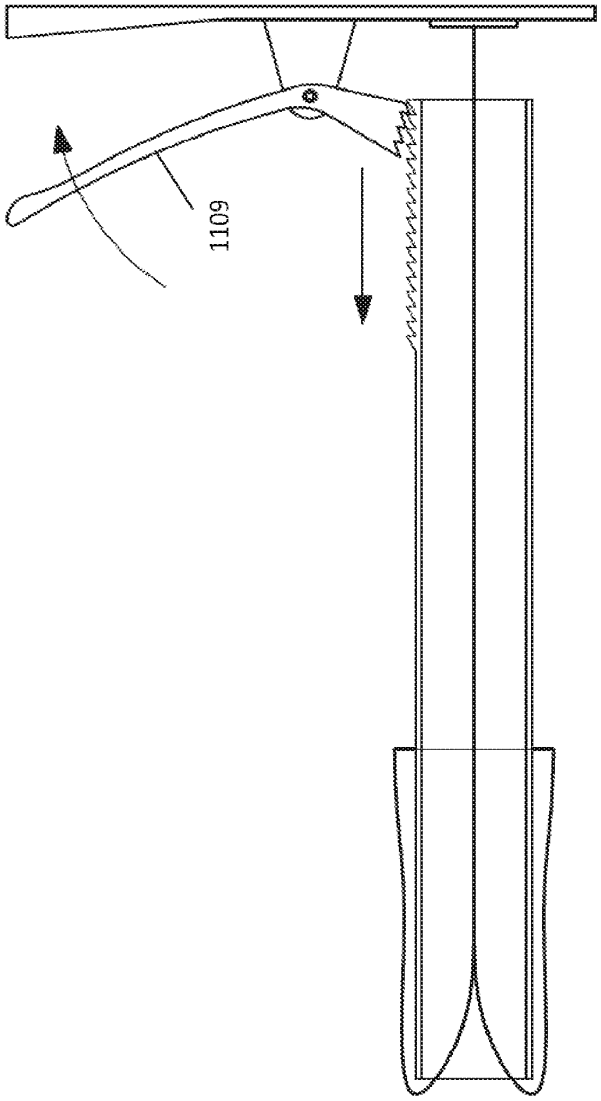


FIG. 11B

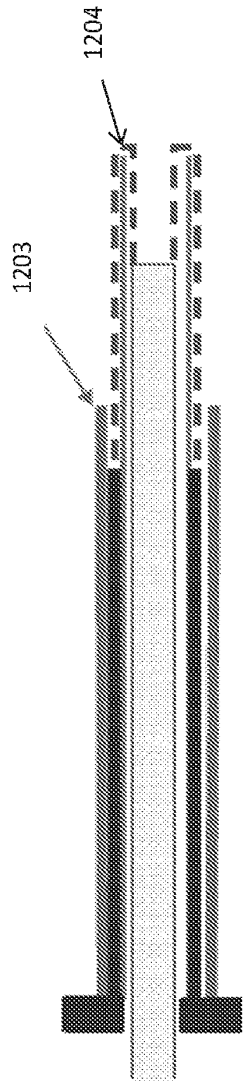


FIG. 12A

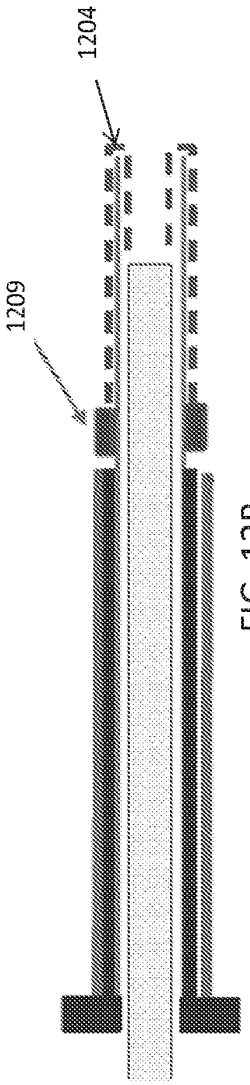


FIG. 12B

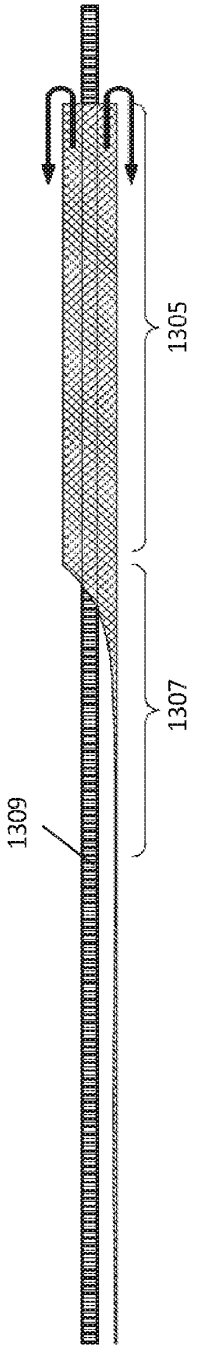


FIG. 13A

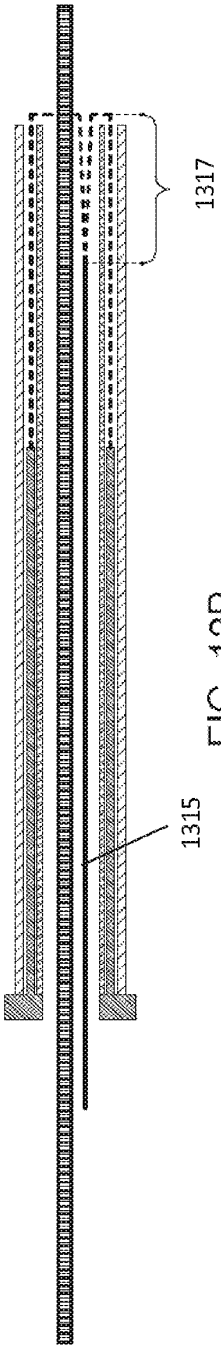


FIG. 13B

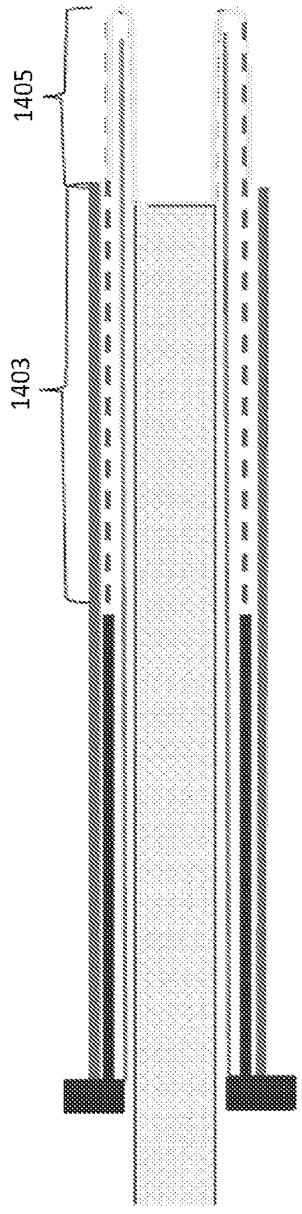


FIG. 14

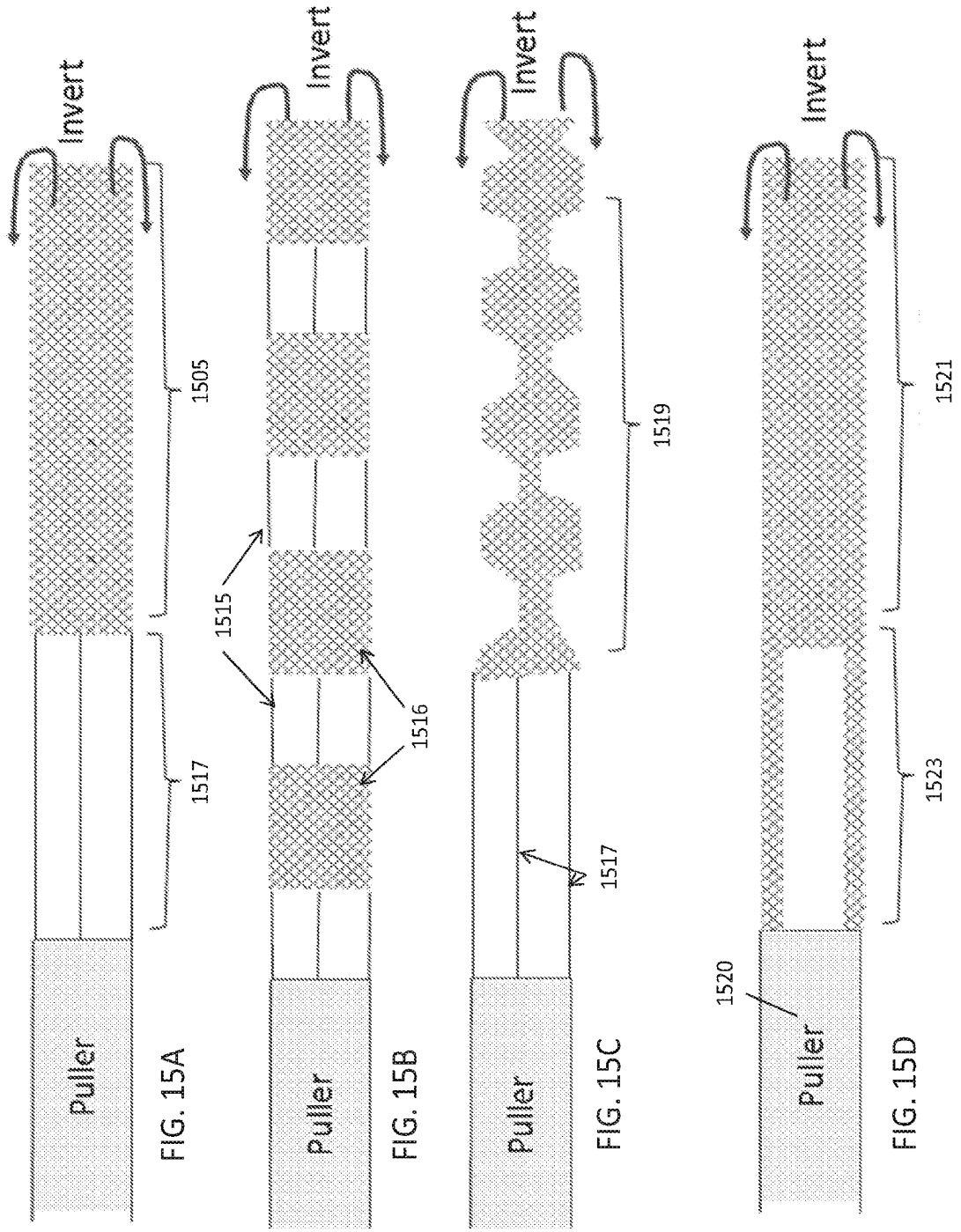


FIG. 15A FIG. 15B FIG. 15C FIG. 15D

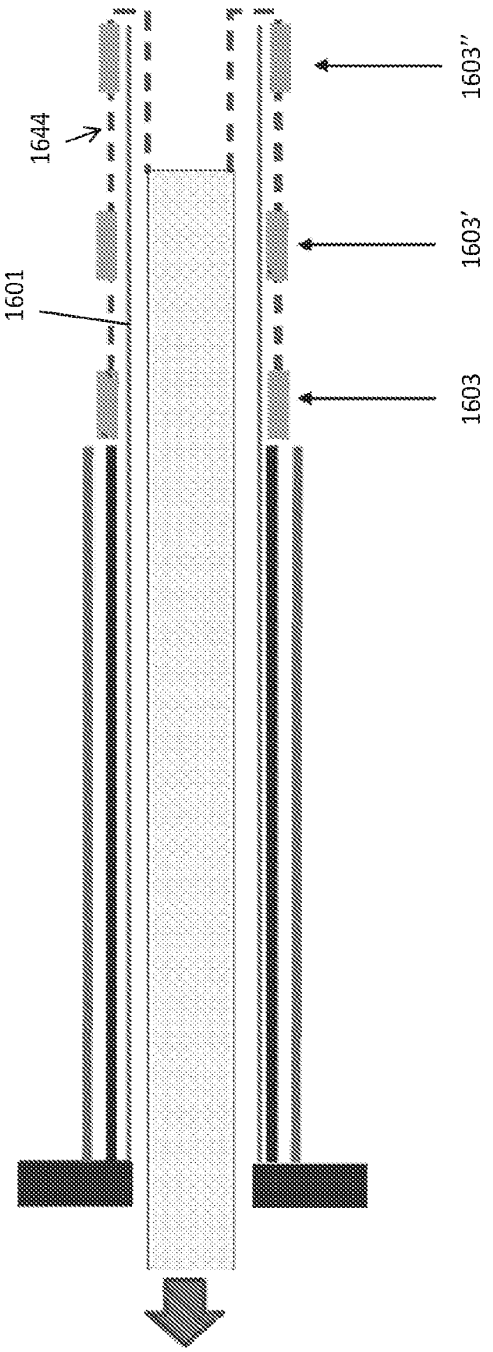

1644
1601
1603''
1603'
1603

FIG. 16

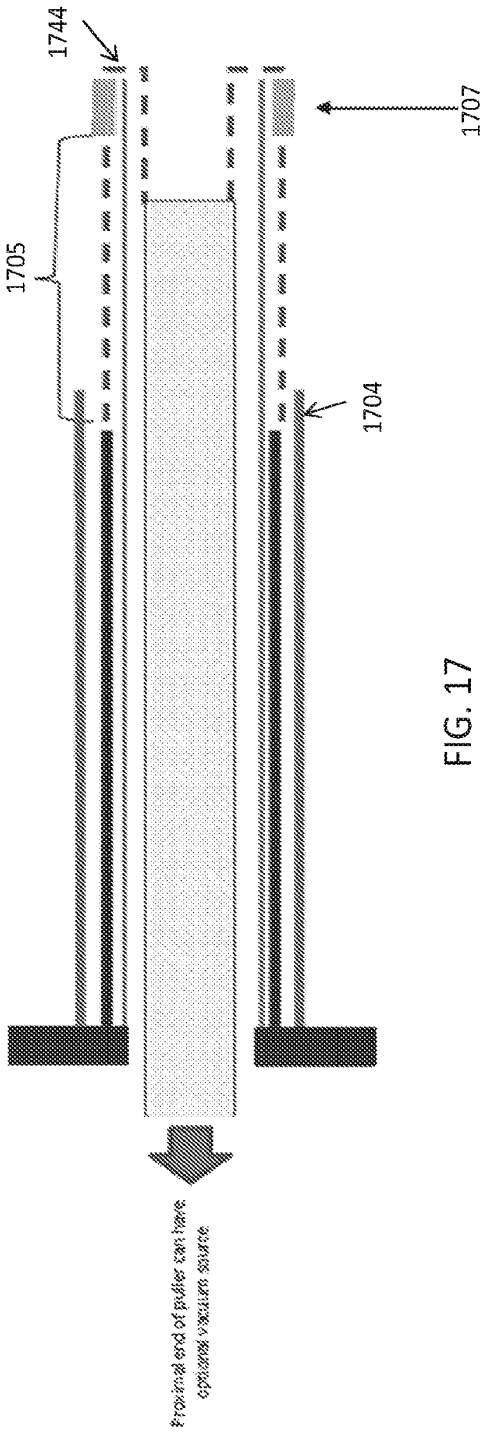

1744
1707
1705
1704
Proximal end of probe can have optional vacuum source

FIG. 17

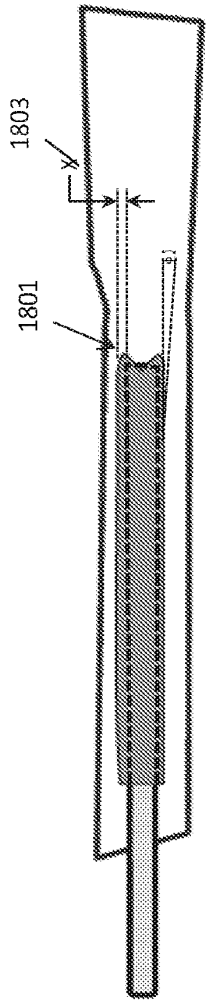


FIG. 18A

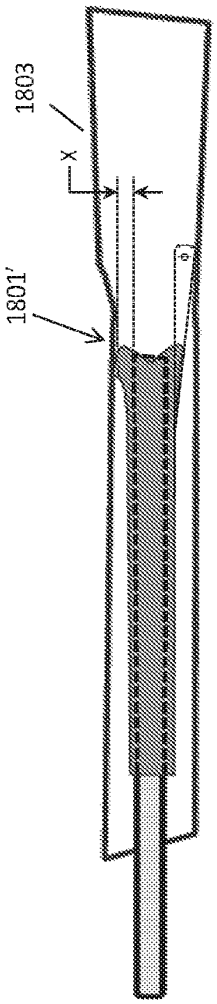


FIG. 18B

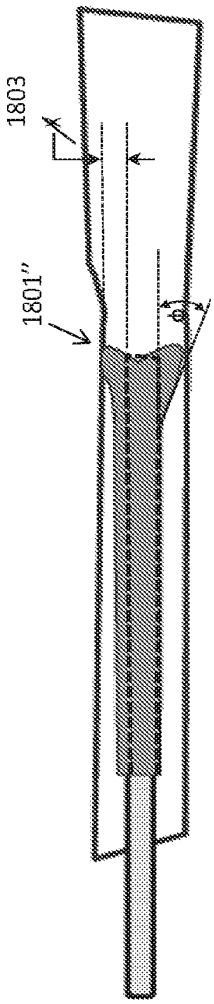


FIG. 18C

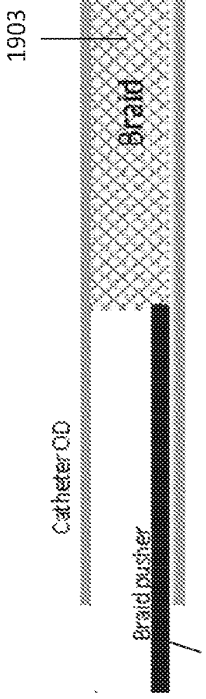


FIG. 19A

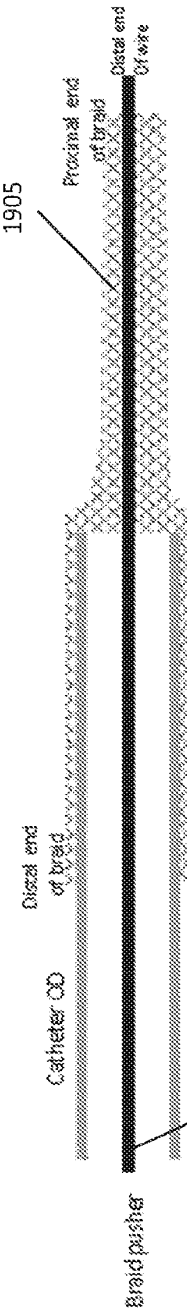


FIG. 19B

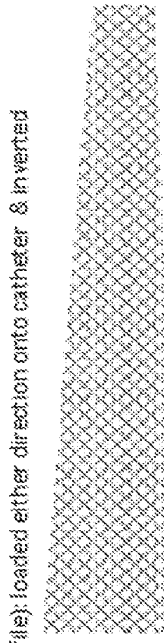


FIG. 20A

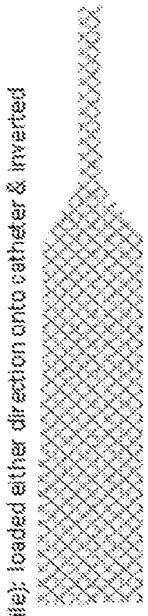


FIG. 20B

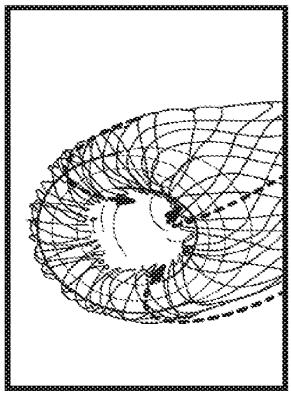


FIG. 21C

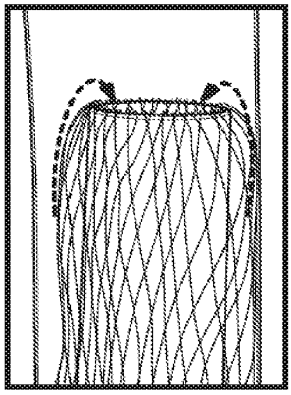


FIG. 21B

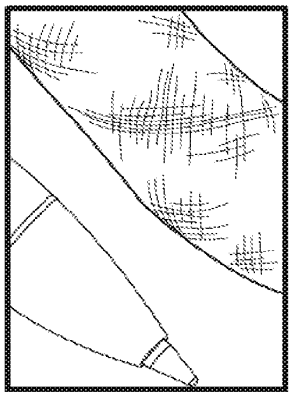


FIG. 21A

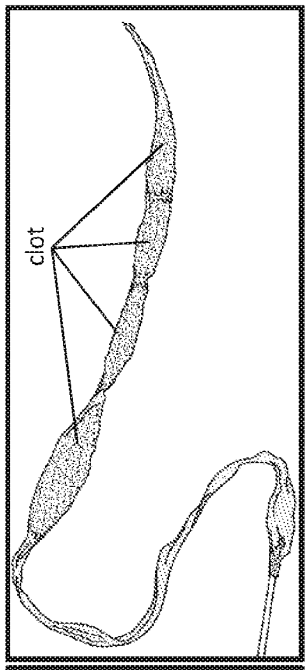


FIG. 22

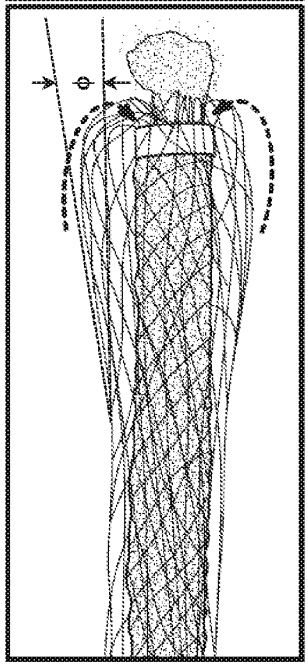


FIG. 21D

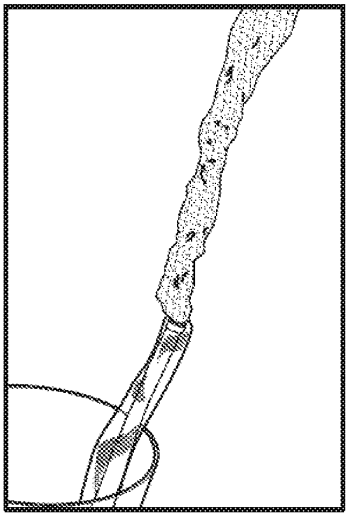


FIG.23B

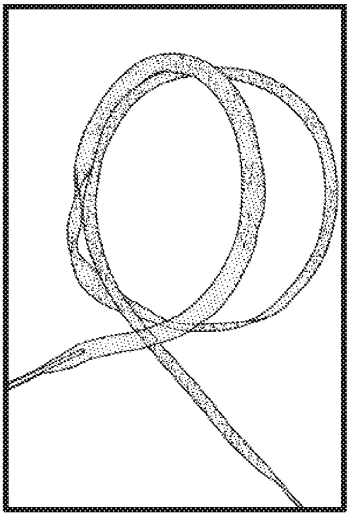


FIG.23E

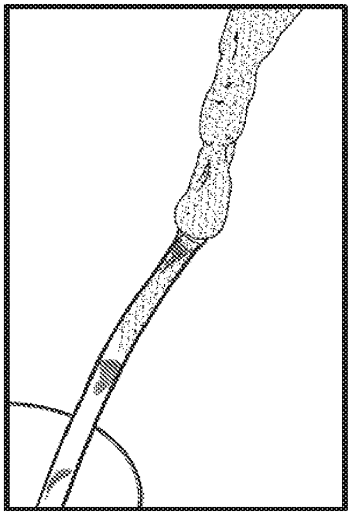


FIG. 23C

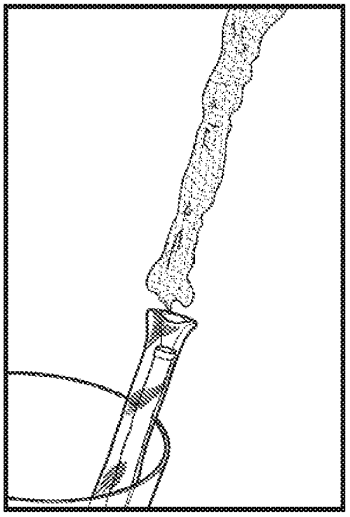


FIG.23A

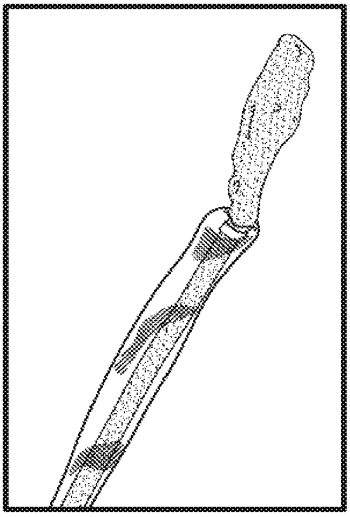


FIG.23D

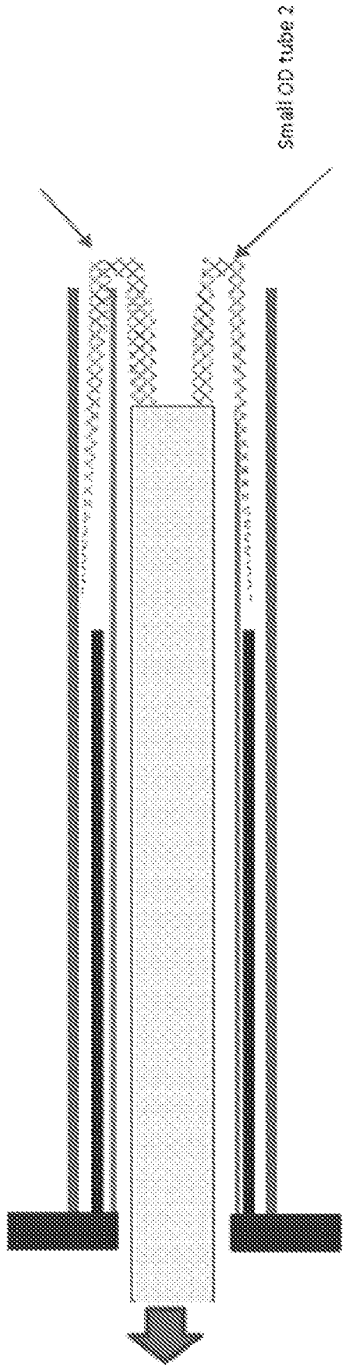


FIG. 24

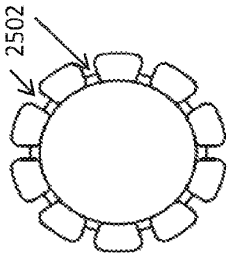


FIG. 25B

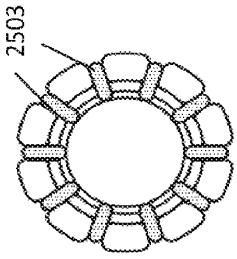


FIG. 25D

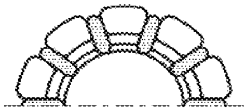


FIG. 25F

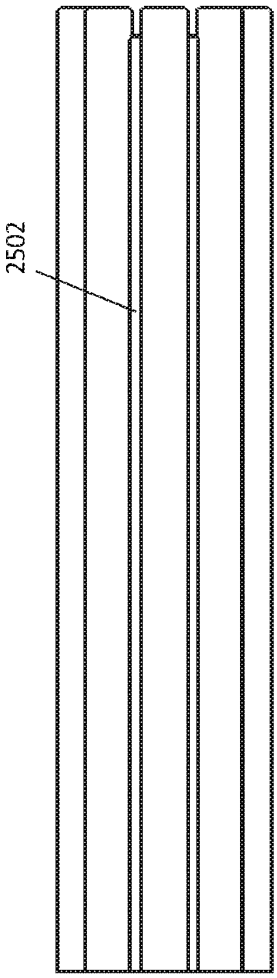


FIG. 25A

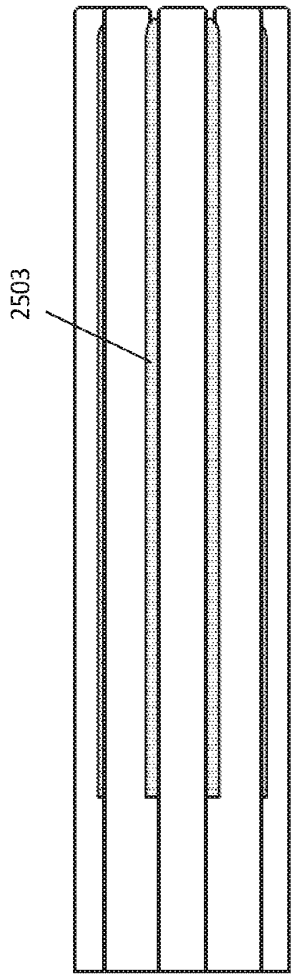


FIG. 25C

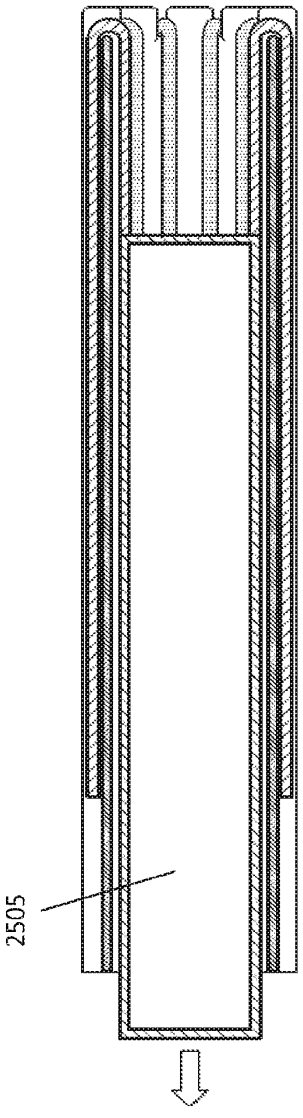


FIG. 25E

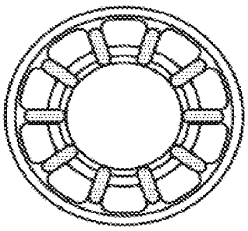


FIG. 26B

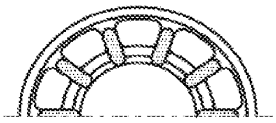


FIG. 27B

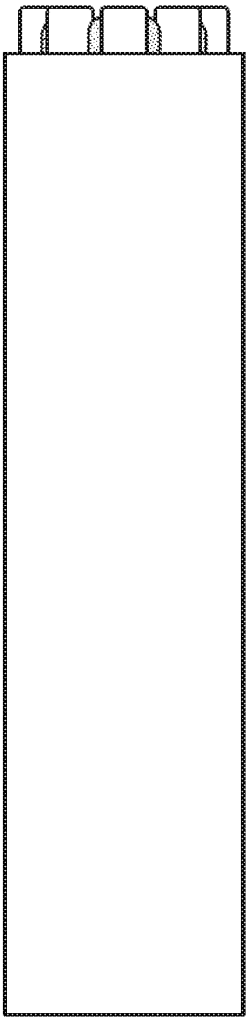


FIG. 26A

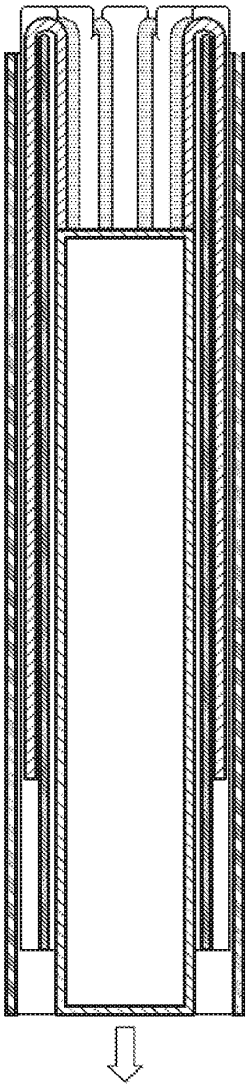


FIG. 27A

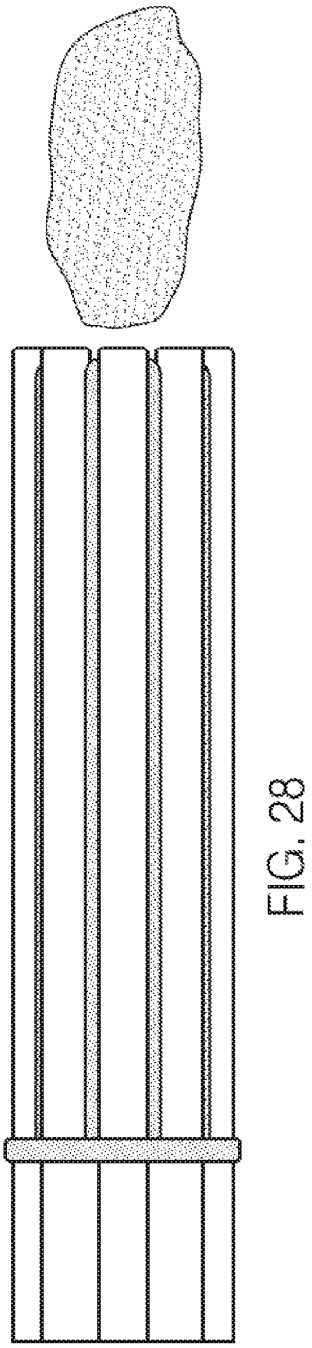


FIG. 28

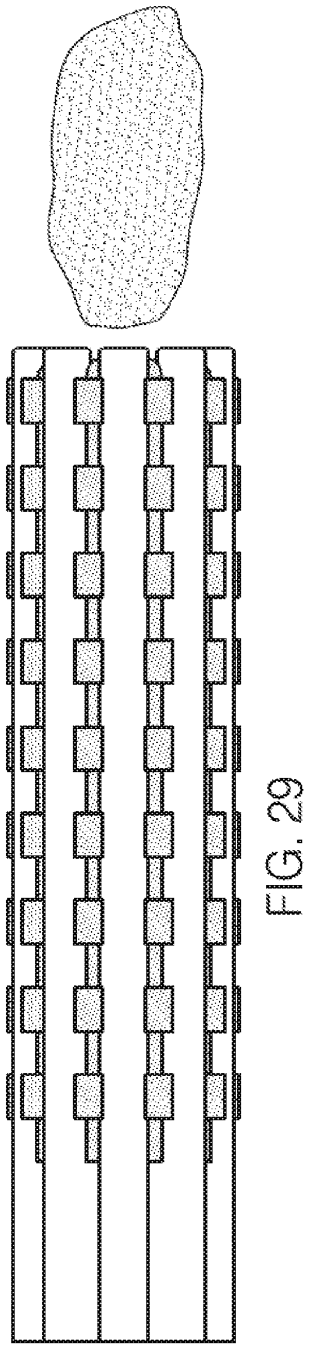


FIG. 29

FIG. 30A

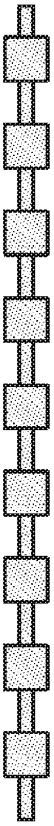


FIG. 30B

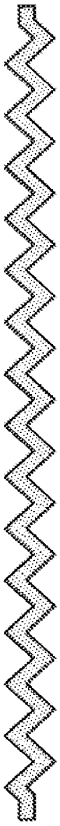


FIG. 30C

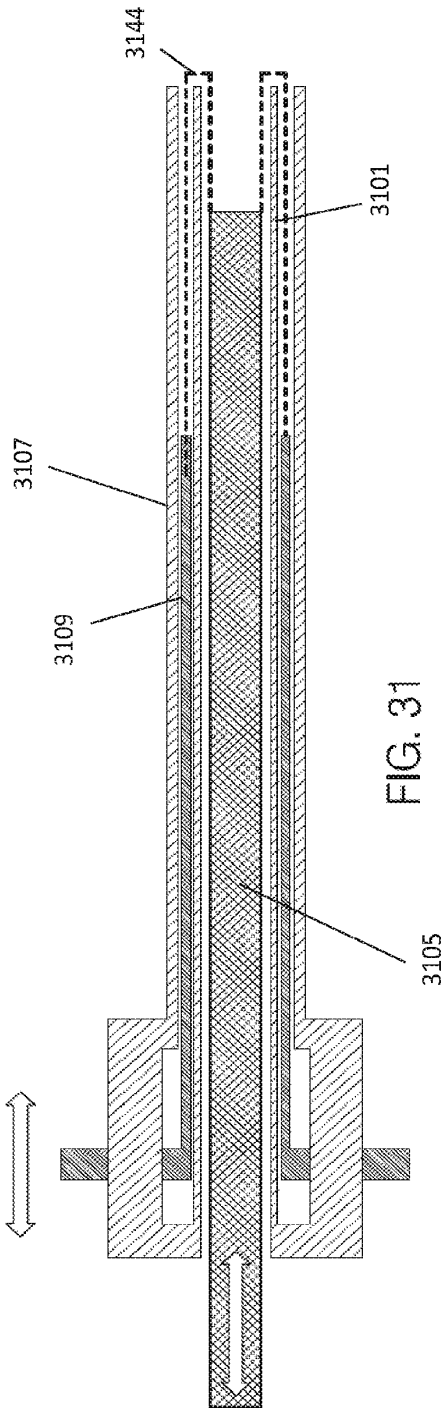


FIG. 31

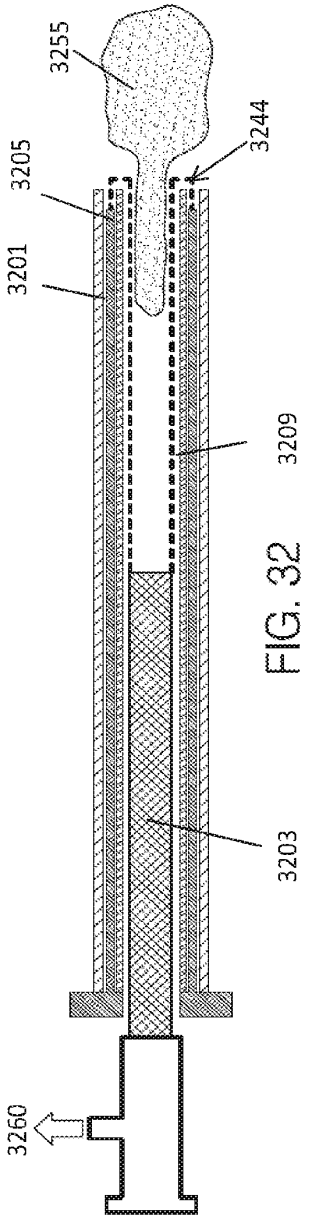


FIG. 32

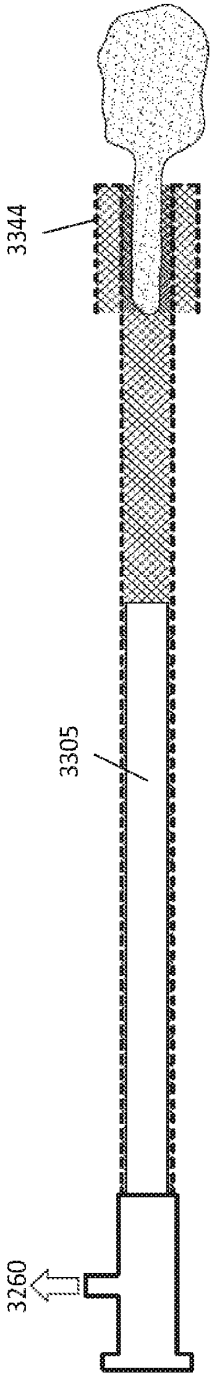


FIG. 33

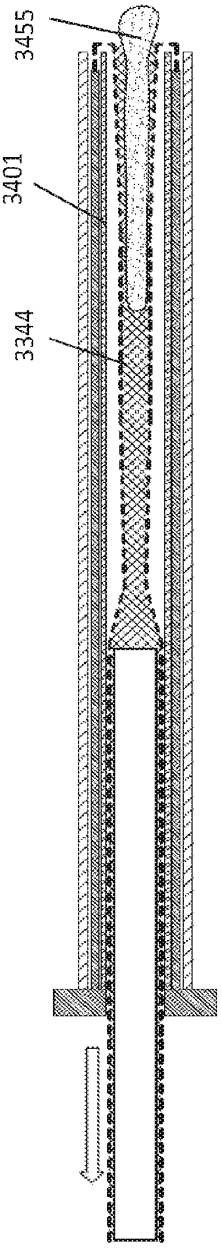


FIG. 34

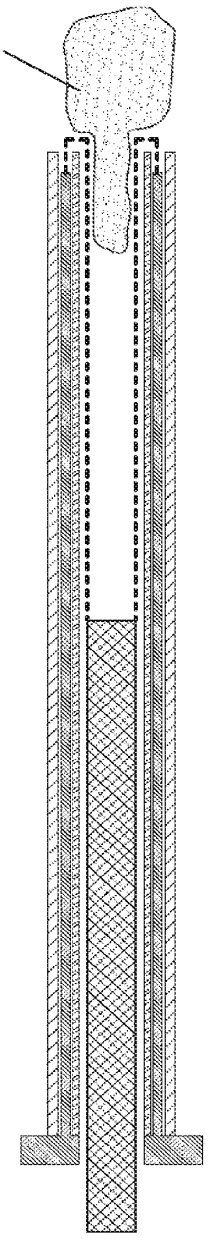


FIG. 35A

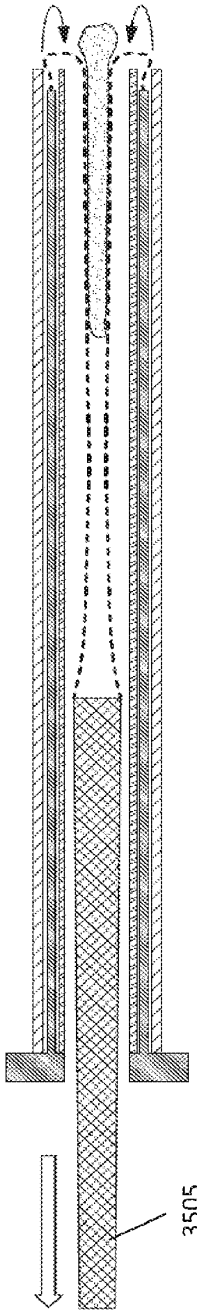


FIG. 35B

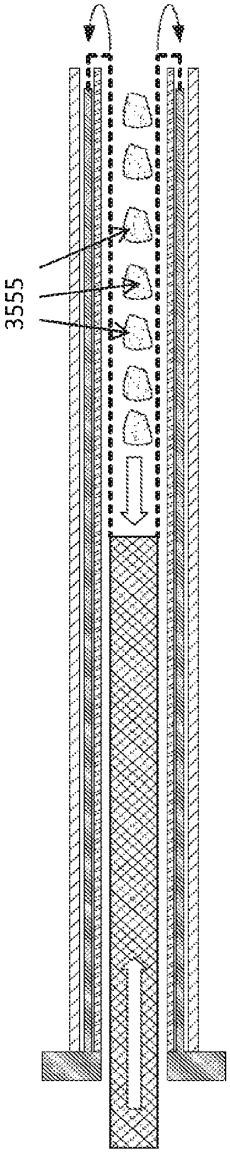


FIG. 35C

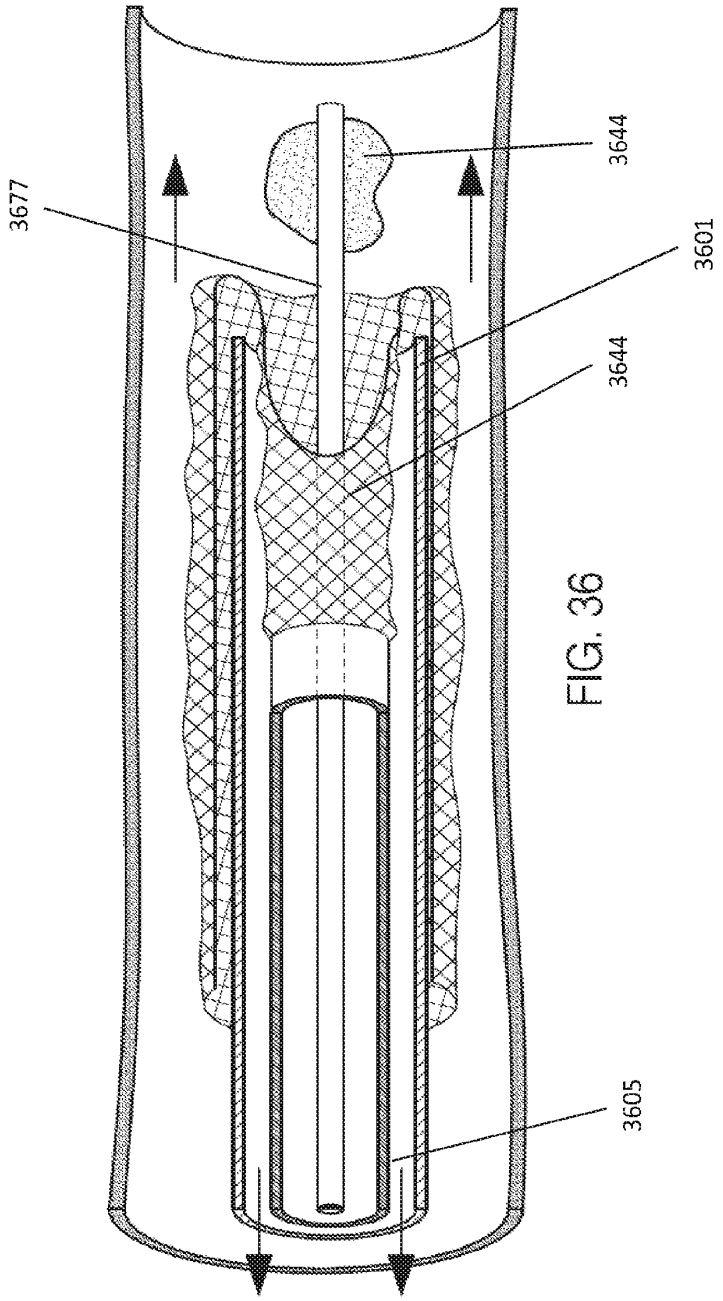


FIG. 36

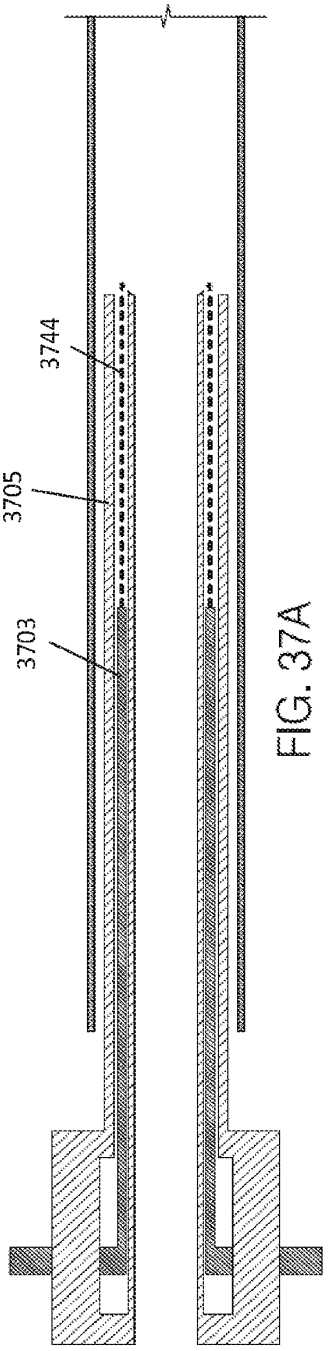


FIG. 37A

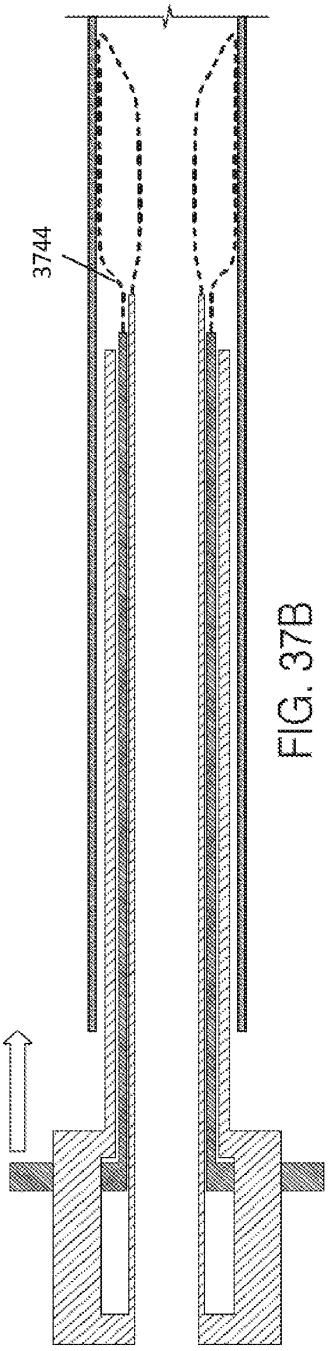


FIG. 37B

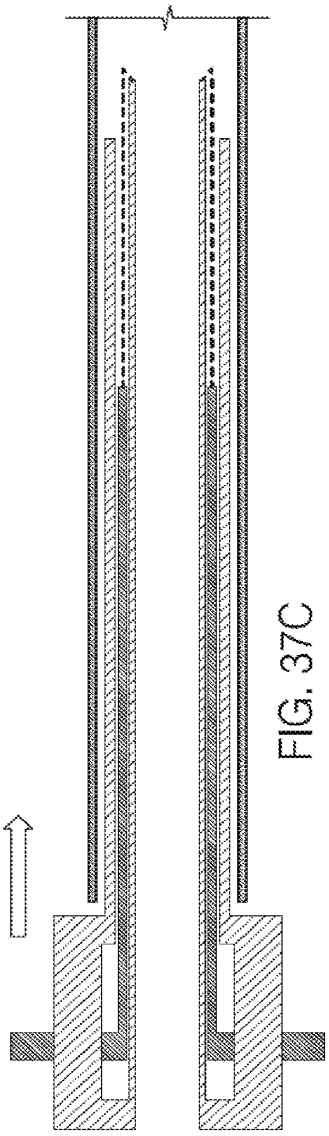


FIG. 37C

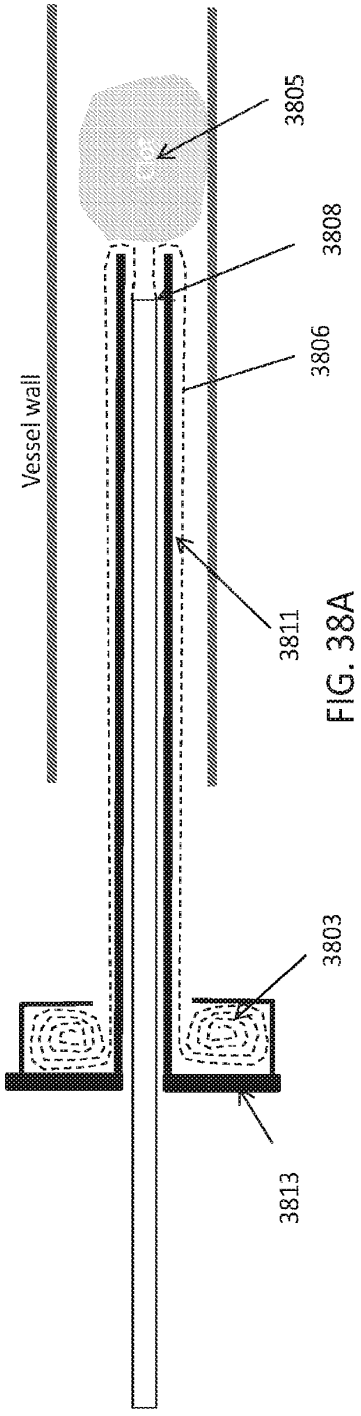


FIG. 38A

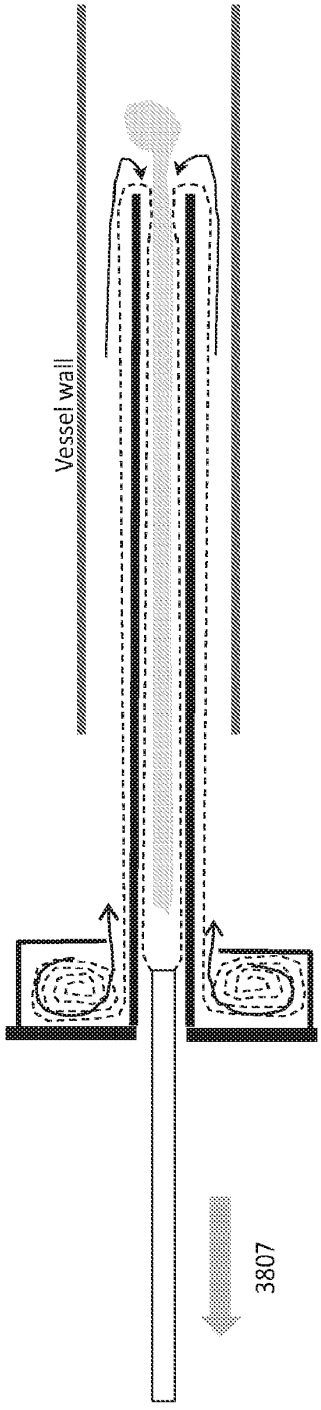


FIG. 38B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/17982

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/01 (2016.01)
CPC - A61B 17/221, A61F 2/01, A61B 2017/22038, A61B 2017/22079, A61B 2017/22081
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61F 2/01 (2016.01)
CPC - A61B 17/221, A61F 2/01, A61B 2017/22038, A61B 2017/22079, A61B 2017/22081

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
(CPC) 606/200, 159, 127; (CPC) A61B 2017/221*; A61F 2/013, 2002/01*
(Search term limited; see below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest (PGPB, USPT, EPAB, JPAB); Google; PatBase (All);
Search Terms: thrombectomy, embolectomy, remov*, captur*, thromb*, clot*, emboli*, plaque*, invert*, inversion, evert*, intussuscept*, mesh, net, basket, smooth*, round*, edge, tip, end, stiff*, reinforc*, snag*, expand*,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y -- A	US 2015/0005781 A1 (LUND-CLAUSEN et al.) 01 January 2015 (01.01.2015) Entire document, especially Abstract, para[0003], para[0036]- para0042] and FIGS. 1-3.	1-2 5-20, 23-28, 30-34 --- 3-4, 21-22, 29, 35-39, 74-76, 79-80 --- 77
Y -- A	US 2010/0249815 A1 (JANTZEN et al.) 30 September 2010 (30.09.2010) Entire document, especially Abstract, para[0029] and FIGS. 1-4.	3-4, 21-22, 29, 35-39, 74-76, 79-80 --- 77
Y	US 2006/0293696 A1 (FAHEY et al.) 28 December 2006 (28.12.2006) Entire document, especially Abstract, para[0018], para[0125]- para[0126].	36, 75
A	US 2013/0317589 A1 (MARTIN et al.) 28 November 2013 (28.11.2013) Entire document.	1-39, 74-77, 79-80
A	US 2010/0030256 A1 (DUBRUL et al.) 04 February 2010 (04.02.2010) Entire document.	1-39, 74-77, 79-80
A	US 2003/0083693 A1 (DANIEL et al.) 01 May 2003 (01.05.2003) Entire document.	1-39, 74-77, 79-80
A	US 2007/0149996 A1 (COUGHLIN) 28 June 2007 (28.06.2007) Entire document.	1-39, 74-77, 79-80
A	US 2007/0112374 A1 (PAUL et al.) 17 May 2007 (17.05.2007) Entire document.	1-39, 74-77, 79-80

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 April 2016	06 MAY 2016
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/17982

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 40-73, 78
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

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

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

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

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (January 2015)

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 April 2021 (22.04.2021)

WIPO | PCT

(10) International Publication Number
WO 2021/076954 A1

(51) International Patent Classification:
A61B 17/14 (2006.01) *A61F 2/01* (2006.01)
A61B 17/22 (2006.01) *A61M 25/01* (2006.01)
A61B 17/32 (2006.01) *A61M 25/08* (2006.01)

(21) International Application Number:
PCT/US2020/056067

(22) International Filing Date:
16 October 2020 (16.10.2020)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/916,044 16 October 2019 (16.10.2019) US

(71) Applicant: **INARI MEDICAL, INC.** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US).

(72) Inventor: **DINH, James Quang**; 9 Parker, Suite #100, Irvine, California 92618 (US).

(74) Agent: **WILLIAMS, Matthew S.** et al.; PERKINS COIE LLP, P.O. Box 1247, Seattle, Washington 98111-1247 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,

(54) Title: SYSTEMS, DEVICES, AND METHODS FOR TREATING VASCULAR OCCLUSIONS

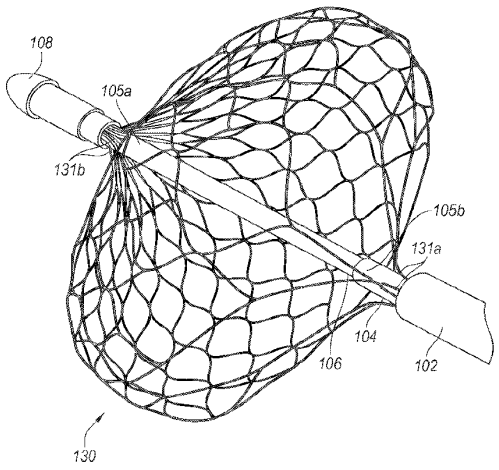


Fig. 1C

(57) Abstract: Systems and methods for the intravascular treatment of clot material within a blood vessel of a human patient are disclosed herein. A device in accordance with embodiments of the present technology can include, for example, a plurality of interconnected struts forming a unitary structure having a proximal portion and a distal portion. The struts can form a plurality of first cells in the proximal portion and a plurality of second cells, smaller than the first cells, in the distal portion. The device can be pulled against clot material within a blood vessel to engage, disrupt, and/or capture the clot material.

[Continued on next page]

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MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

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

SYSTEMS, DEVICES, AND METHODS FOR TREATING VASCULAR OCCLUSIONS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 62/916,044, filed October 16, 2019, and titled "SYSTEMS, DEVICES, AND METHODS FOR TREATING VASCULAR OCCLUSIONS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology relates generally to systems, devices, and methods for the intravascular treatment of colt material (e.g., emboli and/or thrombi) within a blood vessel of a human patient. In particular, some embodiments of the present technology relate to expandable devices for engaging and removing clot material.

BACKGROUND

[0003] Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

[0004] When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. However, infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can accordingly lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

[0005] In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT commonly occurs where there is a propensity for stagnated blood (e.g., long distance air travel, immobility, etc.) and clotting (e.g., cancer, recent surgery, such as orthopedic surgery, etc.). DVT can obstruct drainage of venous blood from the legs leading to swelling, ulcers, pain and infection. DVT can also create a reservoir in which blood

clots can collect and then travel to other parts of the body including the heart, lungs, brain (stroke), abdominal organs, and/or extremities.

[0006] In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs, and therefore the entire body. This can result in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting in low blood oxygen and buildup of blood carbon dioxide.

[0007] There are many existing techniques to reestablish blood flow through an occluded vessel. Embolectomies, for example, are a surgical technique involving incising a blood vessel and placing a balloon-tipped device (such as the Fogarty catheter) at the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to withdraw the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Although such surgical techniques have been useful, exposing a patient to surgery may be traumatic and best avoided when possible. Additionally, the use of a Fogarty catheter may be problematic due to the possible risk of damaging the interior lining of the vessel as the catheter is being withdrawn.

[0008] Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating vessel stenosis, but it is generally not effective for treating acute thromboembolisms as none of the occlusive material is removed and restenosis regularly occurs after dilation. Another percutaneous technique involves placing a catheter near the clot and infusing streptokinase, urokinase, or other thrombolytic agents to dissolve the clot. Unfortunately, thrombolysis typically takes hours to days to be successful. Additionally, thrombolytic agents can cause hemorrhage, and in many patients the thrombolytic agents cannot be used at all.

[0009] Various devices exist for performing a thrombectomy or removing other foreign material. However, such devices have been found to have structures which are either highly complex, cause trauma to the treatment vessel, or lack the ability to be appropriately fixed against

the vessel. Furthermore, many of the devices have highly complex structures that lead to manufacturing and quality control difficulties as well as delivery issues when passing through tortuous or small diameter catheters. Less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all of the clot material.

[0010] Thus, there exists a need for improved systems and methods for embolic extraction.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0012] Figures 1A and 1B are side views of a clot treatment system in a pre-deployed configuration and a deployed configuration, respectively, configured in accordance with embodiments of the present technology.

[0013] Figure 1C is an enlarged perspective view of a distal portion of the clot treatment system shown in Figure 1B configured in accordance with an embodiment of the present technology.

[0014] Figures 2A–2C are a side view, a proximally-facing perspective view, and a distally-facing perspective view, respectively, of a clot treatment device of the clot treatment system of Figures 1A–1C configured in accordance with embodiments of the present technology.

[0015] Figure 3 is a flow diagram of a process or method for operating the clot treatment system to remove clot material from within a blood vessel of a human patient in accordance with an embodiment of the present technology.

[0016] Figures 4A–4F are schematic illustrations of a distal portion of the clot treatment system during a procedure to remove clot material from a blood vessel of a human patient in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0017] The present technology is generally directed to systems, devices, and methods for removing clot material from a blood vessel of a human patient. In some embodiments, a clot removal system can include a delivery catheter and a clot treatment device. The clot treatment device can include a plurality of interconnected struts forming a unitary structure that is movable

between a compressed configuration and an expanded configuration. In the expanded configuration, the unitary structure can include (i) a proximal connection region, (ii) a proximal conical region extending from the proximal connection region, (iii) a cylindrical region extending from the proximal conical region, (iv) a distal conical region extending from the cylindrical region, and (v) a distal connection region extending from the distal conical region. In some embodiments, a first portion of the struts form first cells in the proximal conical region, and a second portion of the struts form second cells in the distal conical region that are smaller than the first cells.

[0018] In some embodiments, the system further includes a handle configured to be gripped by an operator, and a first shaft coupled between the handle and the proximal connection region of the clot treatment device. The clot treatment device can be maintained in the compressed configuration within a lumen of the delivery catheter and near a distal terminus of the delivery catheter. To move the clot treatment device to the expanded configuration, the operator can move the handle to advance the first shaft to thereby advance the clot treatment device past the distal terminus and out of the lumen of the delivery catheter. When the clot treatment device is no longer constrained by the delivery catheter, the clot treatment device can expand (e.g., self-expand) to the expanded configuration. In some embodiments, the system further includes a second shaft extending at least partially through the first shaft and coupled to the distal connection region of the clot treatment device. Relative movement between the first and second shafts can allow the clot treatment device to lengthen/shorten and to correspondingly radially expand/compress.

[0019] During a procedure to remove clot material from a blood vessel of a human patient, the clot treatment device can be expanded distal of the clot material within the blood vessel, and then retracted proximally into the clot material to capture/disrupt the clot material. In one aspect of the present technology, the larger first cells of the clot treatment device are configured to receive the clot material therethrough as the clot treatment device is pulled against the clot material, and the smaller second cells of the clot treatment device are configured to retain the clot material within the clot treatment device. In another aspect of the present technology, the clot treatment device has sufficient radial stiffness (e.g., at the cylindrical region) to inhibit the clot treatment device from slipping (e.g., not engaging) the clot material when the clot treatment device is pulled against the clot material. Accordingly, the clot treatment device can be used to capture/disrupt adhered, organized, and/or chronic clots that would otherwise be difficult to remove.

[0020] Although many of the embodiments are described below with respect to systems, devices, and methods for treating a pulmonary embolism, other applications and other embodiments in addition to those described herein are within the scope of the technology (e.g., intravascular procedures other than the treatment of emboli, intravascular procedures for treating cerebral embolism, intravascular procedures for treating deep vein thrombosis (DVT), etc.). Additionally, several other embodiments of the technology can have different configurations, states, components, or procedures than those described herein. Moreover, it will be appreciated that specific elements, substructures, advantages, uses, and/or other features of the embodiments described with reference to Figures 1–4F can be suitably interchanged, substituted or otherwise configured with one another in accordance with additional embodiments of the present technology. Furthermore, suitable elements of the embodiments described with reference to Figures 1–4F can be used as standalone and/or self-contained devices. A person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described below with reference to Figures 1–4F.

[0021] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," etc. are not meant to limit the referenced component to use in a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems and devices of the present technology can be used in any orientation suitable to the user.

[0022] Figures 1A and 1B are side views of a clot treatment or clot removal system 100 ("system 100") configured in accordance with embodiments of the present technology. The system 100 is in a constrained/pre-deployment configuration in Figure 1A, and the system 100 is in an expanded/deployed configuration in Figure 1B. Referring to Figures 1A and 1B together, in the illustrated embodiment the system 100 includes a delivery catheter 102 (e.g., a tube, a shaft, etc.; which can also be referred to herein as an outer shaft) defining a lumen and having a proximal end portion 103a and a distal end portion 103b. The proximal end portion 103a of the delivery catheter 102 is coupled to a hub 110, such as a sealable hub, valve, etc. The lumen of the delivery catheter 102 can be fluidly coupled to a port assembly 112 via the hub 110.

[0023] In the illustrated embodiment, the port assembly 112 includes a fluid control device 114 fluidly coupled between (i) a port connector 116 (e.g., a Luer connector/fitting) and (ii) a tubing section 118 coupled to the hub 110 (e.g., to a branch or side port of the hub 110). The fluid control device 114 is actuatable to fluidly connect the lumen of the delivery catheter 102 to the port connector 116. In the illustrated embodiment, the fluid control device 114 is a stopcock while, in other embodiments, the fluid control device 114 can be a clamp, valve, and/or other suitable fluid control device. During a clot removal procedure using the system 100, various components (e.g., syringes, vacuum sources, etc.) can be coupled to the port connector 116 to remove fluid from and/or inject fluid into the lumen of the delivery catheter 102. For example, in some embodiments a syringe or other pressure source can be coupled to the port connector 116 and used to draw a vacuum while the fluid control device 114 is closed, and the fluid control device 114 can then be opened to instantaneously or nearly instantaneously apply the vacuum to the lumen of the delivery catheter 102 (e.g., to generate suction at the distal portion 103b for removing clot material). In other embodiments, a constant vacuum source (e.g., a pump) can be coupled to the port assembly 112 to provide constant aspiration of the lumen of the delivery catheter 102. In some embodiments, flushing fluid (e.g., saline) can be injected through the port assembly 112 to flush the lumen of the delivery catheter 102.

[0024] In the illustrated embodiment, the system 100 further includes an intermediate shaft 104 (e.g., a catheter, tube, etc.) extending at least partially through the lumen of the delivery catheter 102 and defining a lumen, and an inner shaft 106 (e.g., a catheter, tube, etc.) extending at least partially through the lumen of the intermediate shaft 104. Accordingly, in some embodiments the delivery catheter 102, the intermediate shaft 104, and the inner shaft 106 are coaxially aligned/arranged. The system 100 further includes a clot treatment device 130 coupled to the intermediate shaft 104 and the inner shaft 106. The delivery catheter 102, the intermediate shaft 104, the inner shaft 106, and the clot treatment device 130 can collectively be referred to as a treatment portion 111 (e.g., an insertion portion) of the system 100. As described in greater detail below with reference to Figures 3–4F, the treatment portion 111 is configured to be inserted through a guide catheter to position the clot treatment device 130 at a treatment site during a clot removal procedure.

[0025] As described in greater detail below with reference to Figures 2A–2C, the clot treatment device 130 can be a self-expanding unitary structure comprising a plurality of interconnected struts. In the pre-deployment configuration shown in Figure 1A, the clot treatment device 130 is constrained within the delivery catheter 102 and thus obscured. In the

deployed configuration shown in Figure 1B, the clot treatment device 130 extends past the distal end portion 103b of the delivery catheter 102 (e.g., a distal terminus of the delivery catheter 102) and is radially expanded.

[0026] Figure 1C is an enlarged perspective view of a distal portion of the system 100 shown in Figure 1B configured in accordance with an embodiment of the present technology. In the illustrated embodiment, the intermediate shaft 104 includes a distal end portion 105b coupled to a proximal portion 131a of the clot treatment device 130. In some embodiments, the proximal portion 131a of the clot treatment device 130 includes a plurality of struts that are gathered together and secured to the distal end portion 105b of the intermediate shaft 104. For example, the struts at the proximal portion 131a of the clot treatment device 130 can be secured to the outer surface of the intermediate shaft 104 via adhesives, fasteners, a hub or other device, etc. The inner shaft 106 includes a distal end portion 107 coupled to a distal portion 131b of the clot treatment device 130. In some embodiments, the distal portion 131b of the clot treatment device 130 includes a plurality of struts that are gathered together and secured to the distal end portion 107 of the inner shaft 106 via a friction fit, pressure fit, etc., between the inner shaft 106 and a distal tip 108 (e.g., an atraumatic tip). In other embodiments, the struts at the distal portion 131b of the clot treatment device 130 can be secured to the outer surface of the inner shaft 106 via adhesives, fasteners, a hub or other device, etc.

[0027] Referring again to Figures 1A and 1B together, the intermediate shaft 104 includes a proximal end portion 105a coupled to the handle 120 (e.g., to a distal portion of the handle 120) to operably couple the handle 120 to the clot treatment device 130. Accordingly, the intermediate shaft 104 extends between and operably couples the handle 120 and the clot treatment device 130. In some embodiments, a proximal end portion of the inner shaft 106 (obscured in Figures 1A and 1B) is not coupled to any portion of the system 100 and floats within the lumen of the intermediate shaft 104. In one aspect of the present technology, this arrangement allows the inner shaft 106 to move relative to the intermediate shaft 104 in response to external forces on the clot treatment device 130, thereby allowing the clot treatment device 130 to elongate/shorten longitudinally and to correspondingly radially compress/expand. In other embodiments, the proximal end portion of the inner shaft 106 can be coupled to an actuation mechanism 122 (shown in dashed lines in Figures 1A and 1B) of the handle 120. The actuation mechanism 122 can be configured to drive the inner shaft 106 proximally and/or distally to shorten and/or elongate, respectively, the clot treatment device 130. More specifically, in some embodiments distal movement of the actuation mechanism 122 relative to

the handle 120 can move the inner shaft 106 distally relative to the intermediate shaft 104 to lengthen and radially compress the clot treatment device 130, while proximal movement of the actuation mechanism 122 relative to the handle 120 can move the inner shaft 106 proximally relative to the intermediate shaft 104 to shorten and radially expand the clot treatment device 130.

[0028] In the illustrated embodiment, the handle 120 further includes a proximal hub 124, such as a Luer hub, configured to receive a guidewire (not shown) therethrough. The handle 120, the inner shaft 106, and the tip 108 can together define a lumen for receiving the guidewire therethrough. In some embodiments, the guidewire can have a diameter of about 0.035 inch, about 0.018 inch, less than about 0.1 inch, less than about 0.05 inch, etc. In some embodiments, the handle 120 further includes a lock feature 126 such as, for example, a spinlock or a push-in-and-turn lock. The lock feature 126 is configured to selectively engage (e.g., lockingly engage) with a mating feature 115 of the hub 110. Locking the handle 120 to the hub 110 via the lock feature 126 and the mating feature 115 secures the position of the intermediate shaft 104 relative to the delivery catheter 102. In the illustrated embodiment, the intermediate shaft 104 is longer than the delivery catheter 102 such that a portion of the intermediate shaft 104 and the clot treatment device 130 extend distally from the distal end portion 103b of the delivery catheter 102 when the handle 120 is lockingly engaged with the hub 110.

[0029] To deploy the clot treatment device 130 from the pre-deployment configuration (Figure 1A) to the deployed configuration (Figure 1B), an operator can move the handle 120 distally toward the hub 110 and/or can move the hub 110 toward the handle 120. This movement advances the intermediate shaft 104 distally through the delivery catheter 102 and pushes the clot treatment device 130 distally out of the delivery catheter 102. The clot treatment device 130 can self-expand as it is released from the lumen of the delivery catheter 102. When the handle 120 abuts the hub 110, the operator can actuate the lock feature 126 to secure the position of the intermediate shaft 104 relative to the delivery catheter 102 to, for example, maintain the clot treatment device 130 in the deployed configuration.

[0030] In some embodiments, proximal movement of the handle 120 and/or distal movement of the hub 110 (e.g., from the position shown in Figure 1B to the position shown in Figure 1A) can retract the clot treatment device 130 back into the delivery catheter 102. That is, in some embodiments the clot treatment device 130 can be resheathed within the delivery catheter 102. In such embodiments, the clot treatment device 130 can be repeatedly expanded

and then retracted and compressed into the delivery catheter 102. In some embodiments, the tip 108 is configured (e.g., sized and shaped) to abut the distal end portion 103b of the delivery catheter 102 in the pre-deployment configuration (Figure 1A). This can inhibit or even prevent the clot treatment device 130 from being pulled fully through the delivery catheter 102 and, in some embodiments, can substantially seal the lumen of the delivery catheter 102. In other embodiments, the tip 108 is sized and shaped to allow the tip 108—and thus the entire clot treatment device 130—to be retracted through the delivery catheter 102.

[0031] Figures 2A–2C are a side view, a proximally-facing perspective view, and a distally-facing perspective view, respectively, of the clot treatment device 130 in the expanded configuration in accordance with embodiments of the present technology. Referring to Figures 2A–2C together, the clot treatment device 130 comprises a plurality of struts 240 that together define a plurality of first cells 250 (e.g., interstices, pores, openings, etc.) and a plurality of second cells 252. The struts 240 can have a variety of shapes and sizes and, in some embodiments, the struts 240 can have a thickness and/or diameter between about 0.0125–0.150 inch, between about 0.075–0.125 inch, between about 0.090–0.150 inch, and/or other dimensions. In general, the struts 240 together form a unitary structure that is configured to engage, capture, disrupt, and/or separate a portion of a thrombus (e.g., a vascular thrombus) from a blood vessel containing the thrombus.

[0032] In the illustrated embodiment, (i) the first cells 250 generally face proximally while the second cells 252 generally face distally, and (ii) the first cells 250 are larger than the second cells 252. As best seen in Figure 2A, the clot treatment device 130 includes (i) a first region 242 including the proximal portion 131a, (ii) a second region 243 distal of the first region 242, (iii) a third (e.g., central) region 244 distal of the second region 243, (iv) a fourth region 245 distal of the third region 244, and (v) a fifth region 246 distal of the fourth region 245 and including the distal portion 131b. In the illustrated embodiment, the struts 240 are gathered together (e.g. positioned proximate one another) at the first and fifth regions 242, 246 to facilitate their connection to the intermediate and inner shafts 104, 106, respectively, as shown in Figure 1C. The second region 243 can have a generally conical shape that tapers (e.g., radially narrows) in the proximal direction. Similarly, the fourth region 245 can have a generally conical shape that tapers in the distal direction. The third region 244 can have a generally tubular/cylindrical shape including, for example a generally flat outer strut surface/boundary 248. Moreover, in the illustrated embodiment the first and second regions 242, 243 have fewer of the struts 240 than the fourth and fifth regions 245, 246 to thereby define the larger first cells 250. Conversely, the

fourth and fifth regions 245, 246 have more of the struts 240 than the first and second regions 242, 243 to thereby define the smaller second cells 252. The third region 244 can be a transition region in which the number of the struts 240 increases in the proximal direction (e.g., toward the fourth region 245) such that some of the first cells 250 abut some of the second cells 252 in the third region 244. In other embodiments, the first cells 250 can be formed only in the second region 243, can occupy the entire third region 244, can extend into the fourth region 245, etc.

[0033] In some embodiments, the clot treatment device 130 is made from a shape memory material such as a shape memory alloy and/or a shape memory polymer. For example, the clot treatment device 130 can comprise nitinol and/or a nitinol alloy. Similarly, the clot treatment device 130 can be made using a variety of techniques including welding, laser welding, cutting, laser cutting, expanding, etc. For example, in some embodiments the clot treatment device 130 can first be laser cut from a piece of nitinol (e.g., a nitinol tube), and then further shaped using a heat setting process such that the clot treatment device 130 has the illustrated shape in the expanded configuration. For example, as is known in the art of heat setting nitinol structures, a fixture, mandrel, or mold may be used to hold the clot treatment device 130 in its desired configuration, and then the clot treatment device 130 can be subjected to an appropriate heat treatment such that the struts 240 of the clot treatment device 130 assume or are otherwise shape-set to the outer contour of the mandrel or mold. The heat setting process may be performed in an oven or fluidized bed, as is well-known. Therefore, the heat setting process can impart a desired shape, geometry, bend, curve, serration, scallop, void, hole, etc., in the super-elastic and/or shape memory material or materials used to form the clot treatment device 130. Accordingly, the clot treatment device 130 may be radially constrained without plastic deformation and will self-expand on release of the radial constraint.

[0034] In general, the size of the clot treatment device 130 can be selected based on the size (e.g., diameter) of the blood vessel from which thrombus is to be extracted. In some embodiments, in a fully-expanded configuration unconstrained within a vessel, the clot treatment device 130 can have a length L (Figure 2A) of between about 0.025–1.50 inches, between about 0.70–1.15 inches, etc. In some embodiments, in the fully-expanded position unconstrained within a vessel, the clot treatment device 130 can have a maximum diameter D (Figure 2A; e.g., at the third region 244) of between about 0.025–1.5 inches, between about 0.71–1.34 inches, etc.

[0035] The clot treatment device 130 is configured (e.g., shaped, sized, angled, formed, etc.) to engage, disrupt, and/or capture clot material from within a blood vessel when the clot

treatment device 130 is retracted through/against the clot material in the expanded configuration. For example, as described in greater detail below with reference to Figures 3–4F, the clot treatment device 130 can be withdrawn proximally through/against the clot material. In one aspect of the present technology, the larger first cells 250 are configured to receive the clot material therethrough as the clot treatment device 130 is pulled against the clot material, and the smaller second cells 252 (and associated struts 240) are configured to retain the clot material within the clot treatment device 130. In another aspect of the present technology, the clot treatment device 130 has sufficient radial stiffness (e.g., at the third region 244) to inhibit the clot treatment device 130 from slipping (e.g., not engaging) the clot material when the clot treatment device 130 is pulled against the clot material. Accordingly, the clot treatment device 130 can be used to capture/disrupt adhered, organized, and/or chronic clots. In some embodiments, portions of the struts 240 (e.g., at the second region 243) can be sharpened and/or can include a cutting element (e.g., a knife or knife edge) attached thereto or otherwise integrated with to further facilitate disruption/cutting of the clot material.

[0036] Figure 3 is a flow diagram of a process or method 360 for operating the system 100 to remove clot material from within a blood vessel (e.g., a pulmonary blood vessel) of a patient (e.g., a human patient) in accordance with an embodiment the present technology. Figures 4A–4F are schematic illustrations of a distal portion of the system 100 inserted through a guide catheter 470 during a procedure to remove clot material PE from a blood vessel BV of a patient in accordance with embodiments of the present technology. Although some features of the method 360 are described in the context of the embodiments shown in Figures 4A–4F for the sake of illustration, one skilled in the art will readily understand that the method 360 can be carried out using other suitable systems and/or devices described herein.

[0037] With reference to Figures 3 and 4A, at block 361, the method 360 can include positioning a distal portion 471 of the guide catheter 470 proximate to the clot material PE within the blood vessel BV (e.g., at a treatment site). In the illustrated embodiment, a distal terminus of the guide catheter 470 is positioned proximate to a proximal portion of the clot material PE. However, in other embodiments the distal terminus of the guide catheter 470 can be positioned at least partially within the clot material PE, or the distal terminus of the guide catheter 470 can be positioned distal of the clot material PE. Access to the blood vessel BV can be achieved through the patient's vasculature, for example, via the femoral vein. In some embodiments, such as when the blood vessel BV is a pulmonary blood vessel, an introducer (e.g., a Y-connector with a hemostasis valve; not shown) is connected to the guide catheter 470 and can be partially

inserted into the femoral vein. A guidewire 472 can be guided into the femoral vein through the introducer and navigated through the right atrium, the tricuspid valve, the right ventricle, the pulmonary valve, and into the main pulmonary artery. Depending on the location of the clot material PE, the guidewire 472 can be guided to one or more of the branches of the right pulmonary artery and/or the left pulmonary artery. In some embodiments, the guidewire 472 can be extended entirely or partially through the clot material PE. In other embodiments, the guidewire 472 can be extended to a location just proximal of the clot material PE. After positioning the guidewire 472, the guide catheter 470 can be placed over the guidewire 472 and advanced to the position proximate to the clot material PE as illustrated in Figure 4A.

[0038] In some embodiments, a pressure source can be coupled to the guide catheter 470 and used to aspirate the lumen of the guide catheter 470 to, for example, generate suction (e.g., as indicated by arrows A) to suck/draw all or a portion of the clot material PE into the guide catheter 470. For example, in some embodiments a vacuum can be pre-charged (e.g., in a syringe fluidly coupled to the lumen of the guide catheter 470) and the vacuum can be applied to the lumen of the guide catheter 470 to instantaneously or nearly instantaneously generate suction at the distal portion 471 of the guide catheter 470 (e.g., to generate a suction pulse at the distal portion 471 of the guide catheter 470). Specific details of such methods and associated devices are disclosed in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety.

[0039] However, even where suction is applied to remove/dislodge the clot material PE from the blood vessel BV, the suction may not be enough to dislodge/disrupt all the clot material PE. For example, many chronic (e.g., organized) clots can strongly adhere to the walls of the blood vessel BV—making it difficult to remove them. In one aspect of the present technology, the system 100 can be inserted through the guide catheter 470 before, during, and/or after suction is applied via the guide catheter 470 to engage, disrupt, and/or capture the clot material PE—even where the clot material PE is strongly adhered within the blood vessel BV.

[0040] For example, with reference to Figures 3 and 4B, at block 362, the method 360 can include advancing the clot treatment device 130 (compressed within the delivery catheter 102 and thus obscured in Figure 4B) through the guide catheter 470 to proximate the clot material PE. More specifically, the treatment portion 111 of the system 100 can be advanced through the guide catheter 470 in the compressed pre-deployment configuration until the tip 108 is positioned

(i) distal of the distal portion 471 of the guide catheter 470 and (ii) distal of the clot material PE within the blood vessel BV. In other embodiments, the tip 108 can be positioned within the clot material PE. In some embodiments, the treatment portion 111 can be advanced over the guidewire 472 while, in other embodiments, the guidewire 472 can be omitted.

[0041] With reference to Figures 3 and 4C, at block 363, the method 360 can include moving the clot treatment device 130 from the compressed pre-deployment configuration to the expanded deployed configuration such that the clot treatment device 130 is expanded distal and/or partially within the clot material PE. For example, as described in detail above with reference to Figures 1A and 1B, an operator of the system 100 can advance the handle 120 distally toward the hub 110 and/or retract the hub 110 toward the handle 120 to move the intermediate shaft 104 relative to the delivery catheter 102 to advance the clot treatment device 130 out of the delivery catheter 102, thereby allowing the clot treatment device 130 to expand (e.g., self-expand) within the blood vessel BV. In the illustrated embodiment, the clot treatment device 130 (e.g., the outer strut surface 248 of the third region 244) contacts (e.g., engages, apposes, etc.) the wall of the blood vessel BV. In some embodiments, the clot treatment device 130 is oversized relative to the blood vessel BV such that the clot treatment device 130 exerts a radially outward force on the wall of the blood vessel BV. In other embodiments, the clot treatment device 130 can be sized such that it does not contact the walls of the blood vessel BV.

[0042] With reference to Figures 3 and 4D, at block 364, the method 360 can include retracting the clot treatment device 130 proximally (e.g., in the direction of arrow B) into/toward the clot material PE. More specifically, with reference to Figures 1A and 1B, the operator can pull the entire system 100 proximally (e.g., by gripping the hub 110) to retract the treatment portion 111 through the lumen of the guide catheter 470. As the clot treatment device 130 is retracted, the clot treatment device 130 engages the clot material PE to capture/disrupt the clot material PE. For example, the clot material PE can enter through the first cells 250 (Figures 2A–2C) and be retained within the clot treatment device 130 by the smaller second cells 252 (Figures 2A–2C). In one aspect of the present technology, the clot treatment device 130 can shear the clot material PE from the wall of the blood vessel BV even where the clot material PE is strongly adhered to the wall of the blood vessel BV.

[0043] In some embodiments, where the inner shaft 106 floats within the lumen of the intermediate shaft 104, the length L (Figure 2A) of the clot treatment device 130 can increase as the clot treatment device 130 is pulled into/against the clot material PE and the intermediate shaft

104 moves proximally relative to the inner shaft 106. In other embodiments, where the system 100 includes the actuation mechanism 122, the operator can actuate the actuation mechanism 122 to increase the longitudinal and/or radial stiffness of the clot treatment device 130 by locking or substantially locking the relative position of the intermediate and inner shafts 104, 106.

[0044] With reference to Figures 3 and 4E, at block 365, the method 360 can include retracting the clot treatment device 130 and the captured clot material PE into the lumen of the guide catheter 470. In some embodiments, the clot treatment device 130 can be fully removed from the guide catheter 470. In some embodiments, if any of the clot material PE remains in the blood vessel BV, the clot treatment device 130 can be cleaned and blocks 362–365 can be repeated to capture the remaining clot material PE. Alternatively, a new clot treatment device 130 can be reinserted through the guide catheter 470 to capture the remaining clot material PE. In some embodiments, the clot treatment device 130 can break apart the clot material PE without necessarily capturing the clot material PE and, after or during retraction of the clot treatment device 130, aspiration can be applied to the guide catheter 470 to suck the remaining clot material PE into the guide catheter 470. Finally, with reference to Figures 3 and 4F, at block 366, the method 360 can include removing the guide catheter 470 from the blood vessel BV and from the patient after a sufficient portion of the clot material is removed from the patient.

[0045] Several aspects of the present technology are set forth in the following additional examples:

1. A clot treatment system, comprising:

an outer catheter defining a lumen;

an inner catheter positioned at least partially in the lumen of the outer catheter; and

a clot treatment device including a plurality of interconnected struts forming a unitary structure movable between a compressed configuration and an expanded configuration, wherein in the expanded configuration the unitary structure includes—

a proximal connection region coupled to the outer catheter;

a proximal conical region extending from the proximal connection region, wherein a first portion of the struts form first cells in the proximal conical region;

a cylindrical region extending from the proximal conical region;

a distal conical region extending from the cylindrical region, wherein a second portion of the struts from second cells in the distal conical region, and wherein the second cells are smaller than the first cells; and

a distal connection region extending from the distal conical region and coupled to the inner catheter.

2. The clot treatment system of example 1 wherein the inner catheter has (a) a distal end portion coupled to the distal connection region of the clot treatment device and (b) a proximal end portion configured to float within the lumen of the outer catheter.

3. The clot treatment system of example 1 or example 2 wherein the inner and outer catheters are configured to receive a guidewire therethrough.

4. The clot treatment system of any one of examples 1–3, further comprising a handle coupled to a proximal end portion of the outer catheter, wherein the handle includes an actuation mechanism coupled to a proximal end portion of the inner catheter, and wherein actuation of the actuation mechanism is configured to translate the inner catheter relative to the outer catheter to longitudinally compress or longitudinally elongate the clot treatment device.

5. The clot treatment system of any one of examples 1–4, further comprising:

a delivery catheter defining a lumen; and

a handle coupled to a proximal end portion of the outer catheter and movable between a first position and a second position relative to the delivery catheter, wherein—

in the first position, the clot treatment device is constrained within the lumen of the delivery catheter in the compressed configuration, and

in the second position, the clot treatment device is positioned distal of the lumen in the expanded configuration.

6. The clot treatment system of example 5, further comprising a hub coupled to a proximal end portion of the delivery catheter, wherein the handle includes a lock feature configured to secure the handle to the hub in the second position.

7. The clot treatment system of example 5 or example 6 wherein the handle, the delivery catheter, the outer catheter, and the inner catheter are configured to receive a guidewire therethrough.

8. The clot treatment system of any one of examples 1–7 wherein, in the expanded configuration, the cylindrical region has a diameter of between about 0.71 inch to about 1.34 inches.

9. The clot treatment system of any one of examples 1–8 wherein the struts of the clot treatment device are configured to self-expand from the compressed configuration to the expanded configuration when unconstrained.

10. The clot treatment system of any one of examples 1–9 wherein the struts of the clot treatment device include a shape memory material.

11. The clot treatment system of any one of examples 1–10 wherein the unitary structure includes (a) a first number of the struts in the proximal conical region and (b) a second number of the struts in the distal conical region that is greater than the first number of struts.

12. A method of clot removal, the method comprising:

positioning a distal portion of a guide catheter proximate to clot material within a blood vessel of a human patient;

advancing a clot treatment device through the guide catheter to proximate the clot material;

expanding the clot treatment within the blood vessel distal of the clot material, wherein the clot treatment device includes a plurality of interconnected struts forming a unitary structure having a proximal portion and a distal portion, wherein the struts form a plurality of first cells in the proximal portion and a plurality of second cells in the distal portion, and wherein the first cells are larger than the second cells;

generating suction at the distal portion of the guide catheter; and

proximally retracting the clot treatment device through the clot material.

13. The method of example 12 wherein advancing the clot treatment device through the guide catheter includes advancing the clot treatment device over a guidewire.

14. The method of example 12 or example 13 wherein the proximal portion of the unitary structure is coupled to an outer catheter extending at least partially through the guide catheter, and wherein the distal portion of the unitary structure is coupled to an inner catheter extending at least partially through the outer catheter.

15. The method of example 14 wherein advancing the clot treatment device through the guide catheter includes advancing the clot treatment device over a guidewire extending through the guide, outer, and inner catheters.

16. The method of any one of examples 12–15 wherein generating suction at the distal portion of the guide catheter includes generating suction, before proximally retracting the clot treatment device, to aspirate a first portion of the clot material into the guide catheter.

17. The method of example 16 wherein proximally retracting the clot treatment device includes proximally retracting the clot treatment device through a second portion of the clot material remaining in the blood vessel to capture the second portion of the clot material.

18. The method of any one of examples 12–17 wherein proximally retracting the clot treatment device through the clot material includes capturing at least a portion of the clot material, and wherein the method further comprises retracting the clot treatment device and the captured clot material into the guide catheter.

19. A clot treatment system, comprising:

an outer shaft defining a lumen;

an inner shaft positioned at least partially in the lumen of the outer shaft; and

a plurality of interconnected struts forming a unitary structure having a proximal portion and a distal portion, wherein the proximal portion is coupled to the outer shaft, wherein the distal portion is coupled to the inner shaft, and wherein the struts form a plurality of first cells in the proximal portion and a plurality of second

cells in the distal portion, and wherein the first cells are larger than the second cells.

20. The clot treatment system of example 12 wherein the outer shaft and the inner shaft are configured to receive a guidewire therethrough.

21. A clot treatment device, comprising:

a plurality of interconnected struts forming a unitary structure movable between a compressed configuration and an expanded configuration, wherein in the expanded configuration the unitary structure includes—

a proximal connection region;

a proximal conical region extending from the proximal connection region, wherein a first portion of the struts form first cells in the proximal conical region;

a cylindrical region extending from the proximal conical region;

a distal conical region extending from the cylindrical region, wherein a second portion of the struts from second cells in the distal conical region, and wherein the second cells are smaller than the first cells; and

a distal connection region extending from the distal conical region.

22. The clot treatment device of example 21, further comprising:

a first shaft coupled to the proximal connection region and defining a lumen; and

a second shaft coupled to the distal connection region and extending at least partially through the lumen of the first shaft.

23. The clot treatment device of example 21 or example 22 wherein the second shaft has (a) a distal end portion coupled to the distal connection region and (b) a proximal end portion configured to float within the lumen of the first shaft.

24. The clot treatment device of any one of examples 21–23 wherein the struts are configured to self-expand from the compressed configuration to the expanded configuration when unconstrained.

25. The clot treatment device of any one of examples 21–24 wherein the struts are made from a shape memory material.

26. A clot treatment device, comprising:

a plurality of interconnected struts forming a unitary structure having a proximal portion and a distal portion, wherein the struts form a plurality of first cells in the proximal portion and a plurality of second cells in the distal portion, and wherein the first cells are larger than the second cells.

[0046] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0047] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0048] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the

technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A clot treatment system, comprising:

an outer catheter defining a lumen;

an inner catheter positioned at least partially in the lumen of the outer catheter; and

a clot treatment device including a plurality of interconnected struts forming a unitary structure movable between a compressed configuration and an expanded configuration, wherein in the expanded configuration the unitary structure includes—

a proximal connection region coupled to the outer catheter;

a proximal conical region extending from the proximal connection region, wherein a first portion of the struts form first cells in the proximal conical region;

a cylindrical region extending from the proximal conical region;

a distal conical region extending from the cylindrical region, wherein a second portion of the struts from second cells in the distal conical region, and wherein the second cells are smaller than the first cells; and

a distal connection region extending from the distal conical region and coupled to the inner catheter.

2. The clot treatment system of claim 1 wherein the inner catheter has (a) a distal end portion coupled to the distal connection region of the clot treatment device and (b) a proximal end portion configured to float within the lumen of the outer catheter.

3. The clot treatment system of claim 1 wherein the inner and outer catheters are configured to receive a guidewire therethrough.

4. The clot treatment system of claim 1, further comprising a handle coupled to a proximal end portion of the outer catheter, wherein the handle includes an actuation mechanism coupled to a proximal end portion of the inner catheter, and wherein actuation of the actuation

mechanism is configured to translate the inner catheter relative to the outer catheter to longitudinally compress or longitudinally elongate the clot treatment device.

5. The clot treatment system of claim 1, further comprising:

a delivery catheter defining a lumen; and

a handle coupled to a proximal end portion of the outer catheter and movable between a first position and a second position relative to the delivery catheter, wherein—

in the first position, the clot treatment device is constrained within the lumen of the delivery catheter in the compressed configuration, and

in the second position, the clot treatment device is positioned distal of the lumen in the expanded configuration.

6. The clot treatment system of claim 5, further comprising a hub coupled to a proximal end portion of the delivery catheter, wherein the handle includes a lock feature configured to secure the handle to the hub in the second position.

7. The clot treatment system of claim 5 wherein the handle, the delivery catheter, the outer catheter, and the inner catheter are configured to receive a guidewire therethrough.

8. The clot treatment system of claim 1 wherein, in the expanded configuration, the cylindrical region has a diameter of between about 0.71 inch to about 1.34 inches.

9. The clot treatment system of claim 1 wherein the struts of the clot treatment device are configured to self-expand from the compressed configuration to the expanded configuration when unconstrained.

10. The clot treatment system of claim 1 wherein the struts of the clot treatment device include a shape memory material.

11. The clot treatment system of claim 1 wherein the unitary structure includes (a) a first number of the struts in the proximal conical region and (b) a second number of the struts in the distal conical region that is greater than the first number of struts.

12. A method of clot removal, the method comprising:

positioning a distal portion of a guide catheter proximate to clot material within a blood vessel of a human patient;

advancing a clot treatment device through the guide catheter to proximate the clot material;

expanding the clot treatment within the blood vessel distal of the clot material, wherein the clot treatment device includes a plurality of interconnected struts forming a unitary structure having a proximal portion and a distal portion, wherein the struts form a plurality of first cells in the proximal portion and a plurality of second cells in the distal portion, and wherein the first cells are larger than the second cells;

generating suction at the distal portion of the guide catheter; and

proximally retracting the clot treatment device through the clot material.

13. The method of claim 12 wherein advancing the clot treatment device through the guide catheter includes advancing the clot treatment device over a guidewire.

14. The method of claim 12 wherein the proximal portion of the unitary structure is coupled to an outer catheter extending at least partially through the guide catheter, and wherein the distal portion of the unitary structure is coupled to an inner catheter extending at least partially through the outer catheter.

15. The method of claim 14 wherein advancing the clot treatment device through the guide catheter includes advancing the clot treatment device over a guidewire extending through the guide, outer, and inner catheters.

16. The method of claim 12 wherein generating suction at the distal portion of the guide catheter includes generating suction, before proximally retracting the clot treatment device, to aspirate a first portion of the clot material into the guide catheter.

17. The method of claim 16 wherein proximally retracting the clot treatment device includes proximally retracting the clot treatment device through a second portion of the clot material remaining in the blood vessel to capture the second portion of the clot material.

18. The method of claim 12 wherein proximally retracting the clot treatment device through the clot material includes capturing at least a portion of the clot material, and wherein the method further comprises retracting the clot treatment device and the captured clot material into the guide catheter.

19. A clot treatment system, comprising:

an outer shaft defining a lumen;

an inner shaft positioned at least partially in the lumen of the outer shaft; and

a plurality of interconnected struts forming a unitary structure having a proximal portion and a distal portion, wherein the proximal portion is coupled to the outer shaft, wherein the distal portion is coupled to the inner shaft, and wherein the struts form a plurality of first cells in the proximal portion and a plurality of second cells in the distal portion, and wherein the first cells are larger than the second cells.

20. The clot treatment system of claim 12 wherein the outer shaft and the inner shaft are configured to receive a guidewire therethrough.

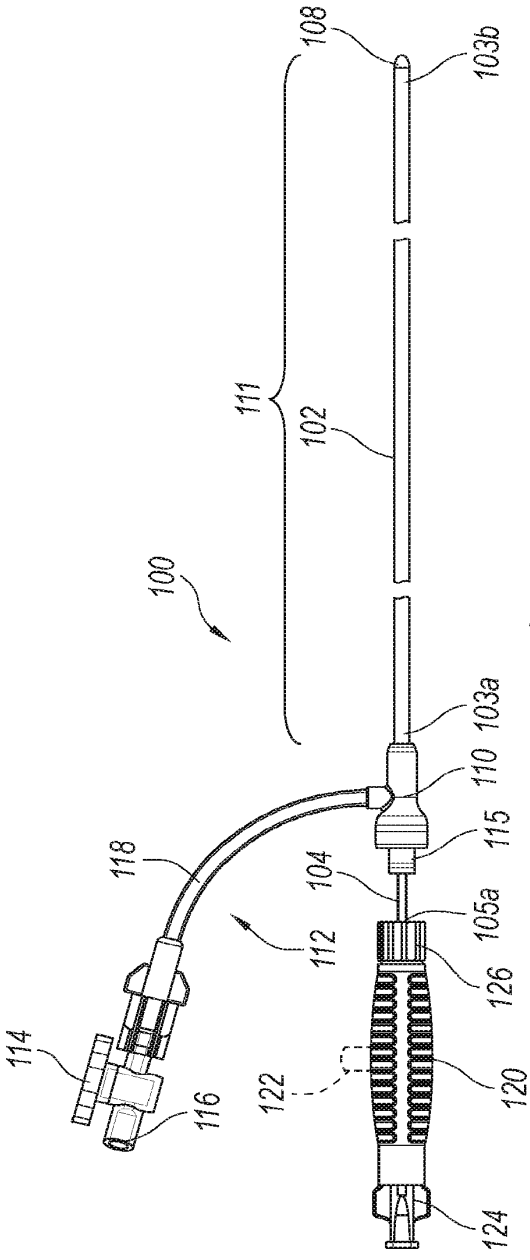

Fig. 1A

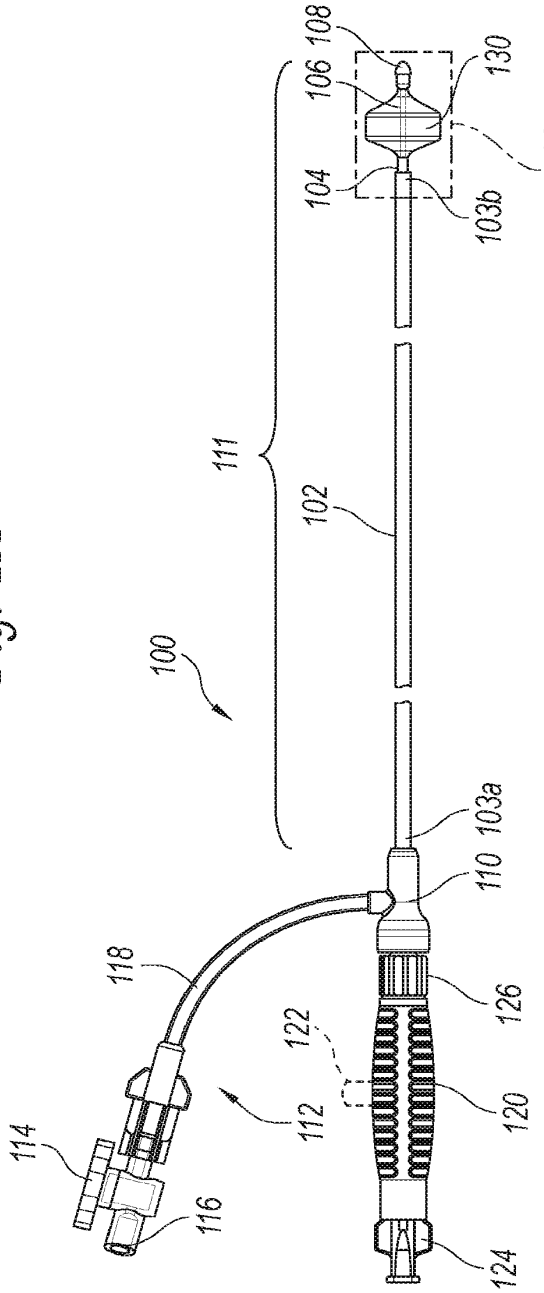

Fig. 1B

Fig. 1C

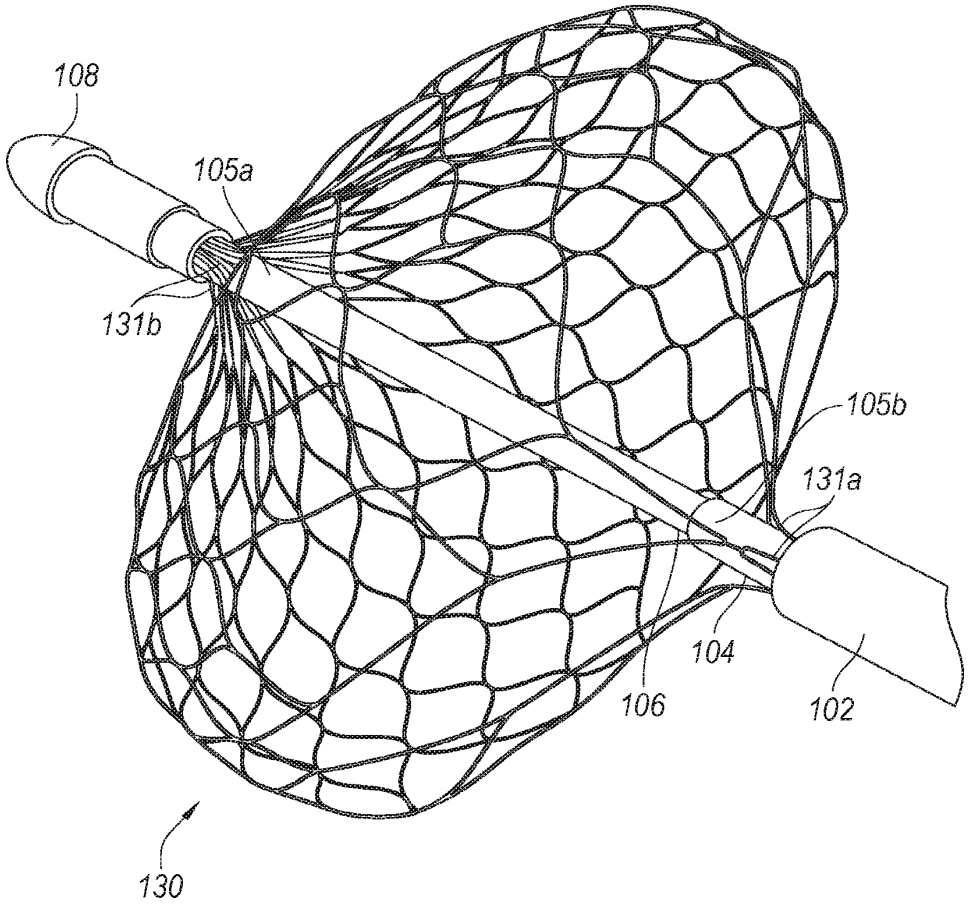

Fig. 1C

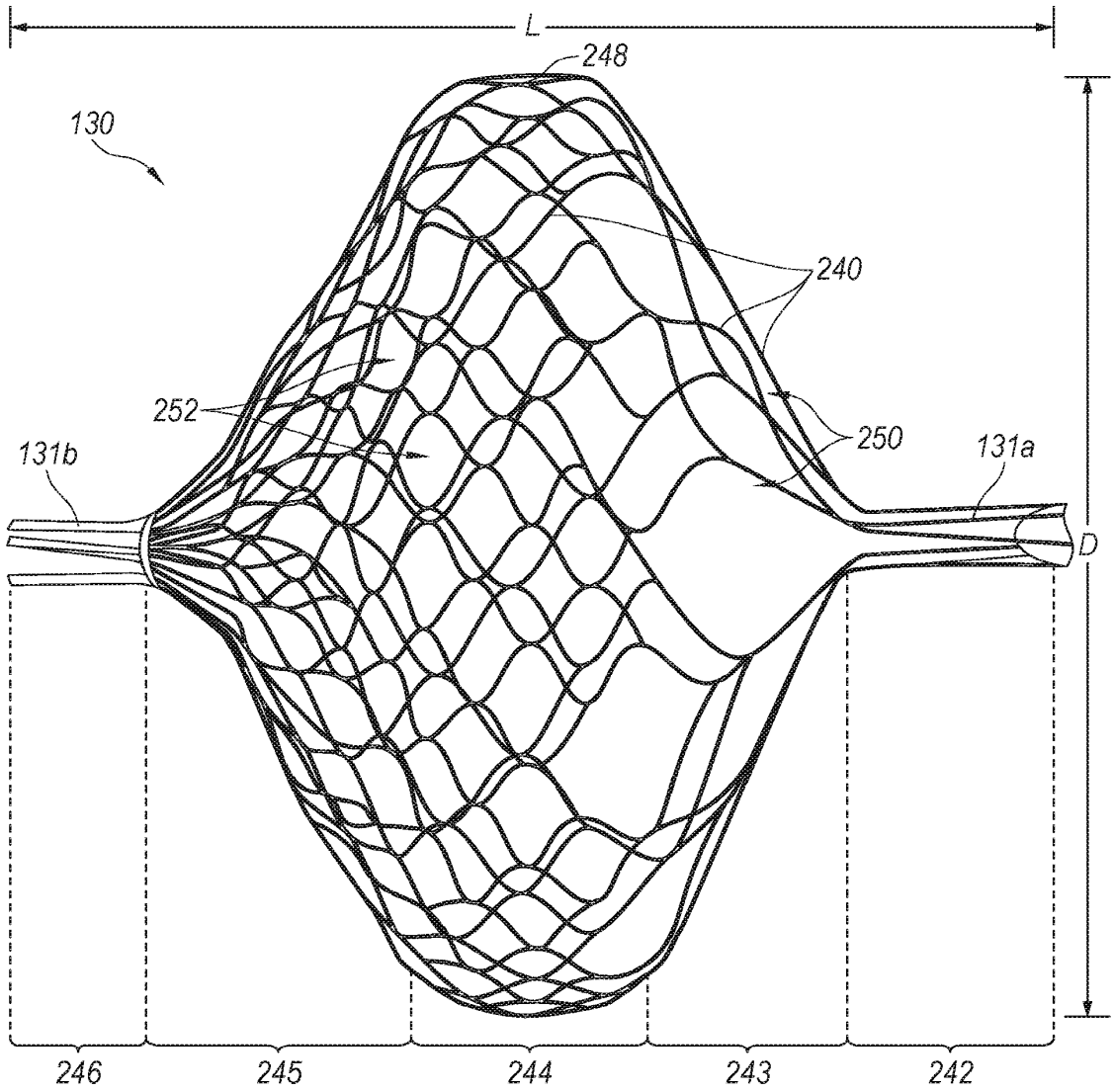

Fig. 2A

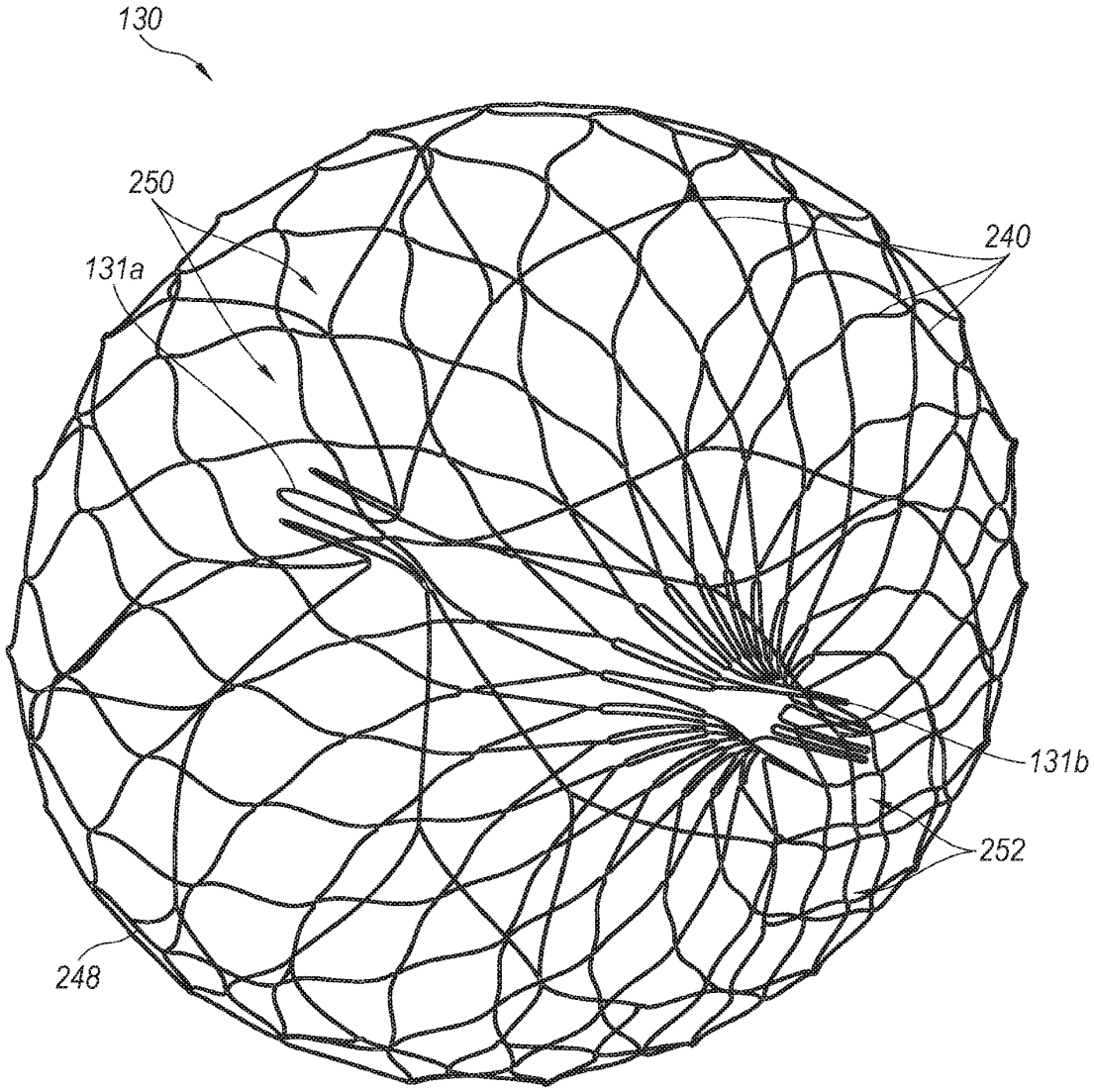

Fig. 2B

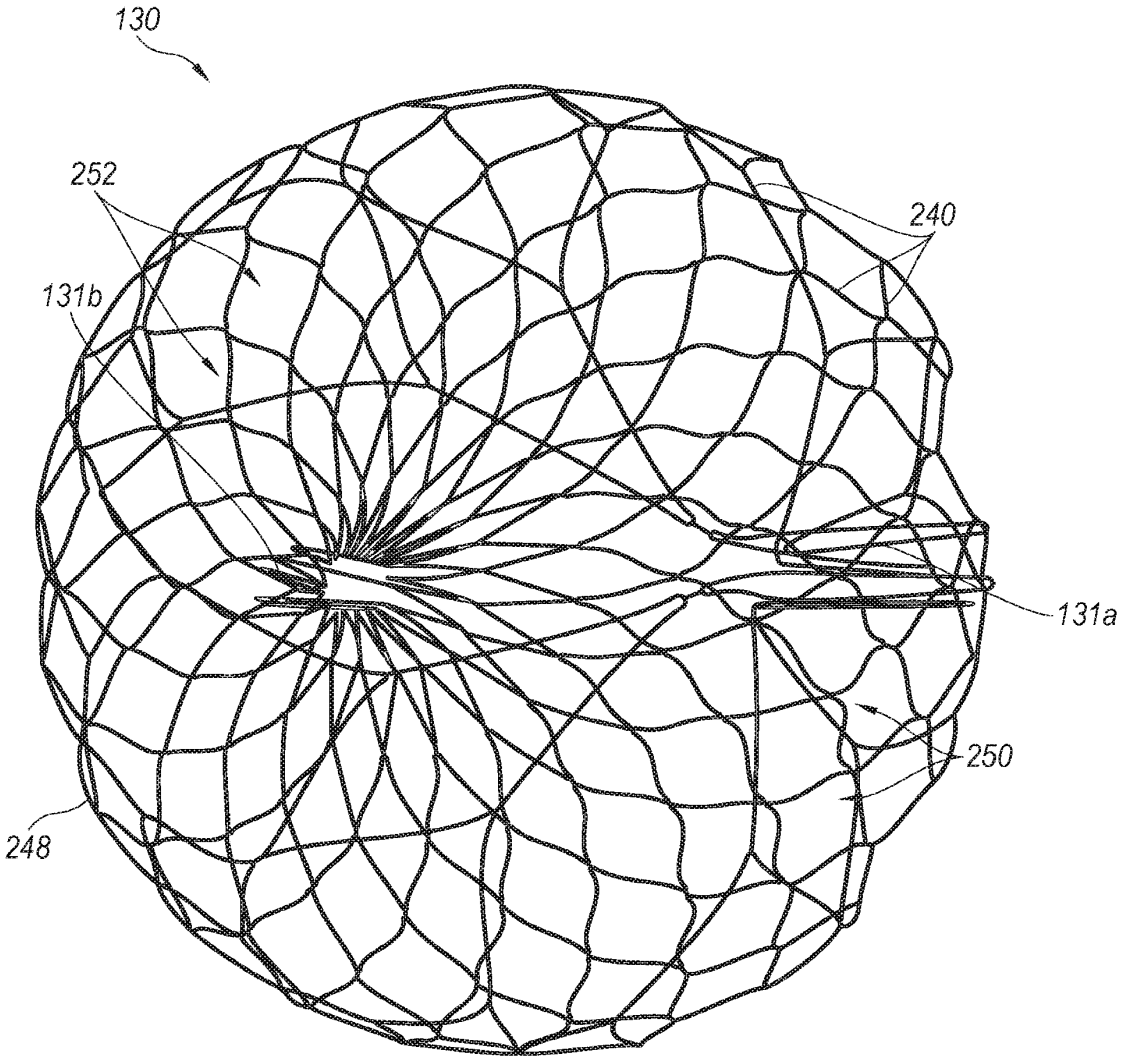

Fig. 2C

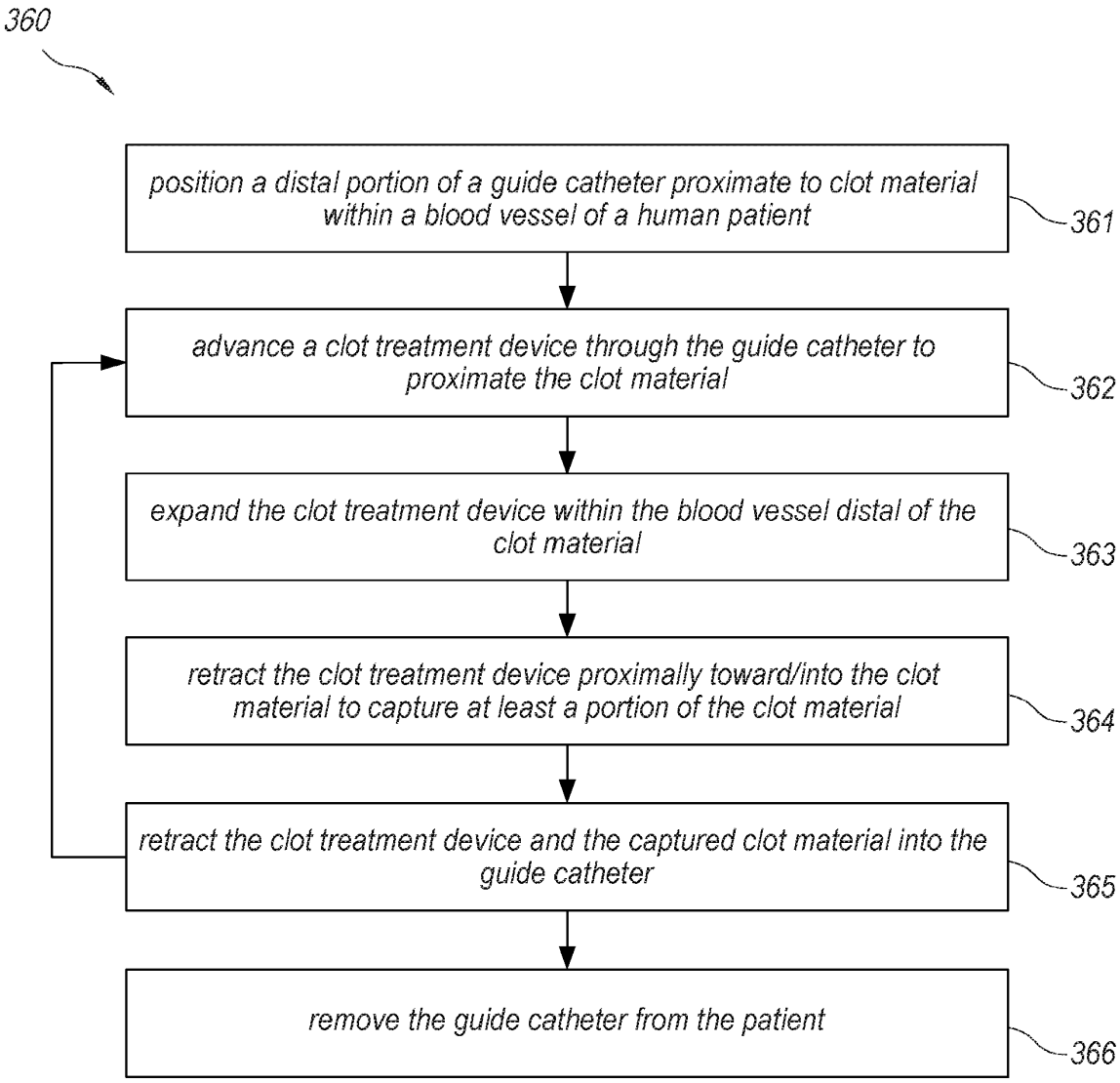
360
position a distal portion of a guide catheter proximate to clot material within a blood vessel of a human patient
361
advance a clot treatment device through the guide catheter to proximate the clot material
362
expand the clot treatment device within the blood vessel distal of the clot material
363
retract the clot treatment device proximally toward/into the clot material to capture at least a portion of the clot material
364
retract the clot treatment device and the captured clot material into the guide catheter
365
remove the guide catheter from the patient
366

Fig. 3

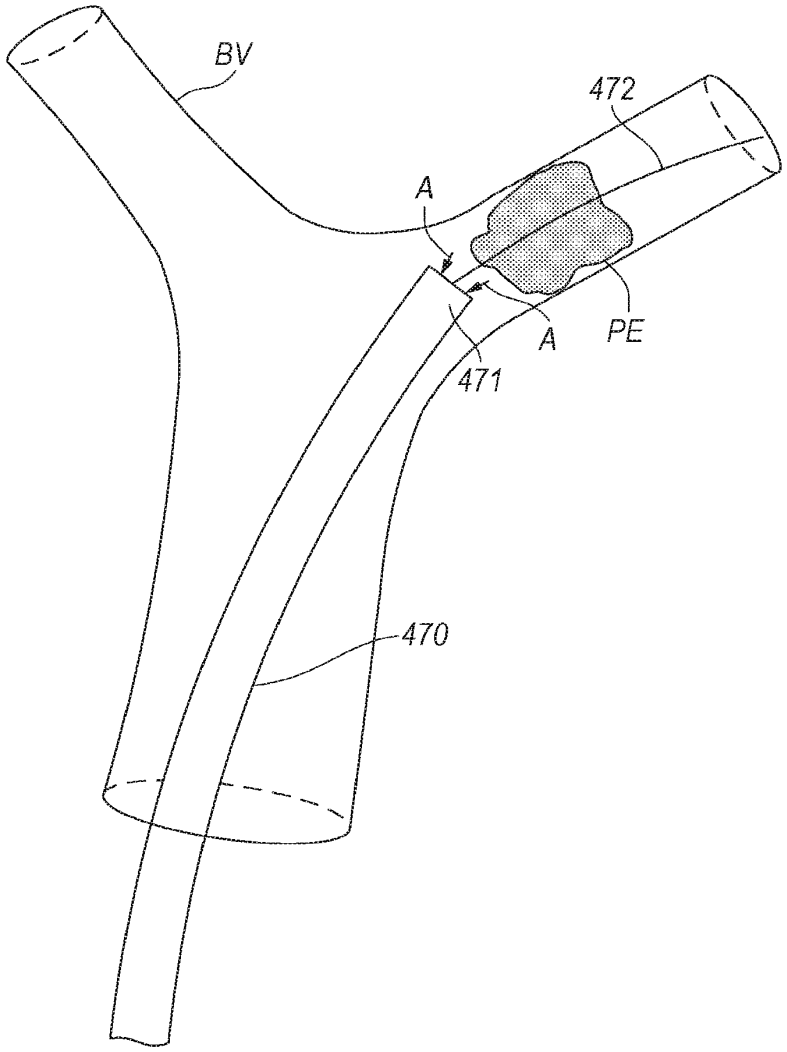

Fig. 4A

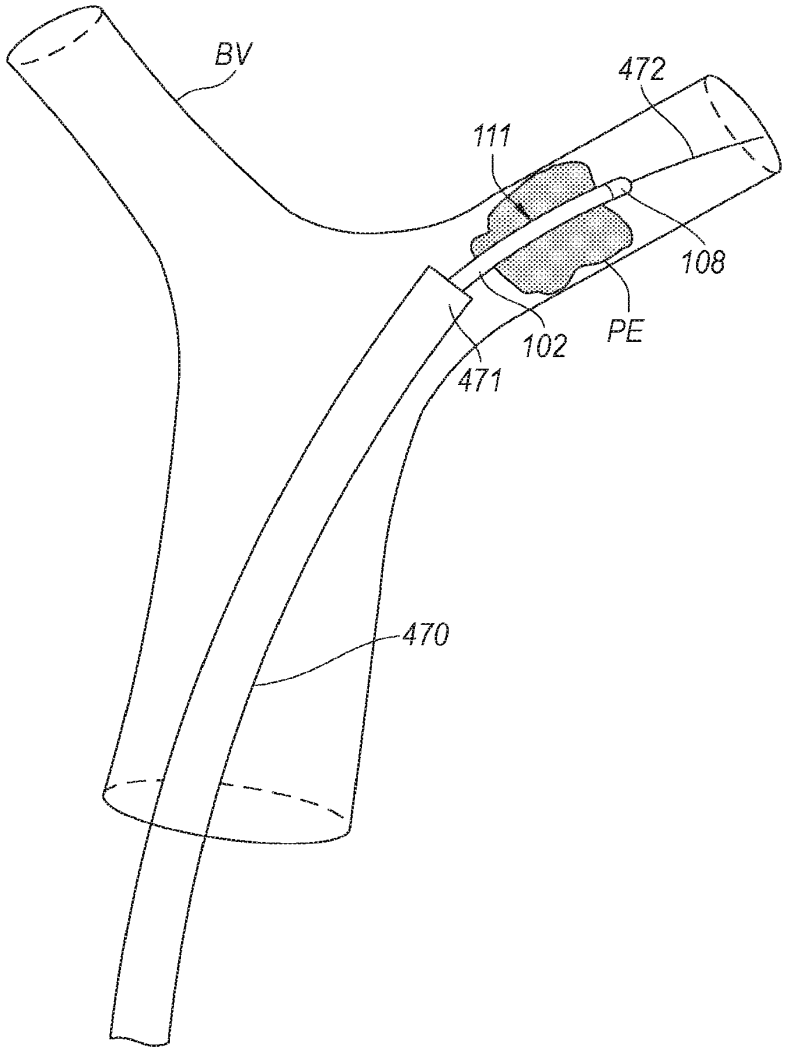

Fig. 4B

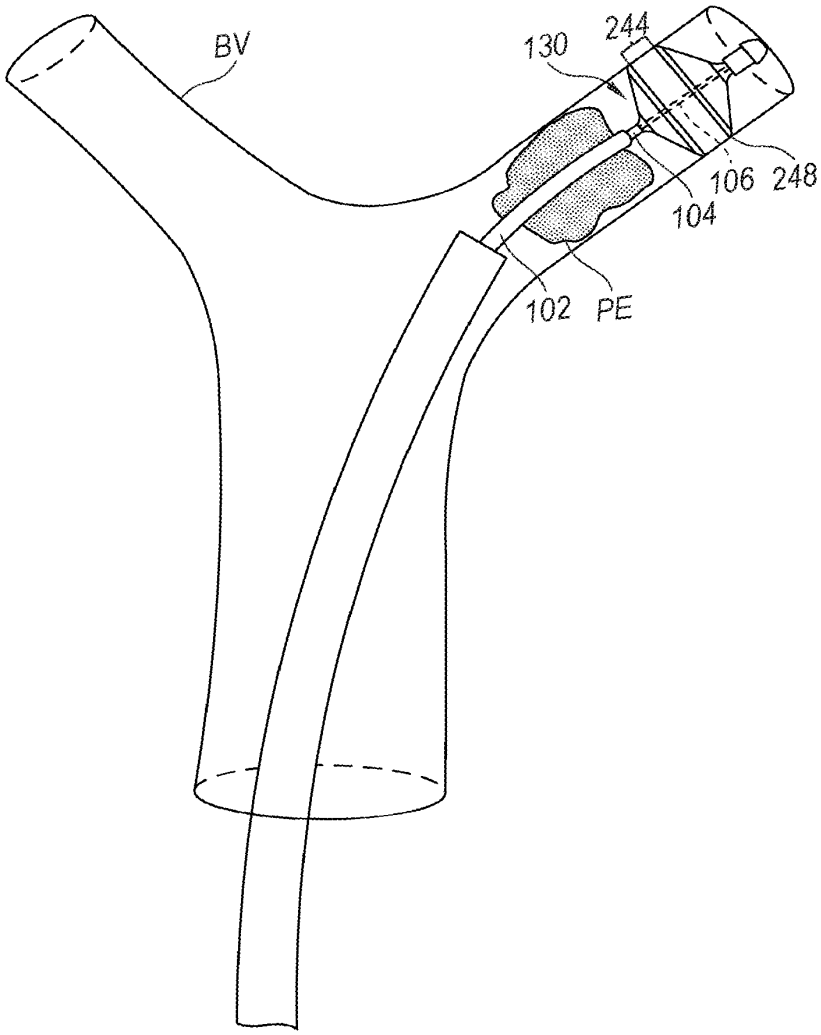

Fig. 4C

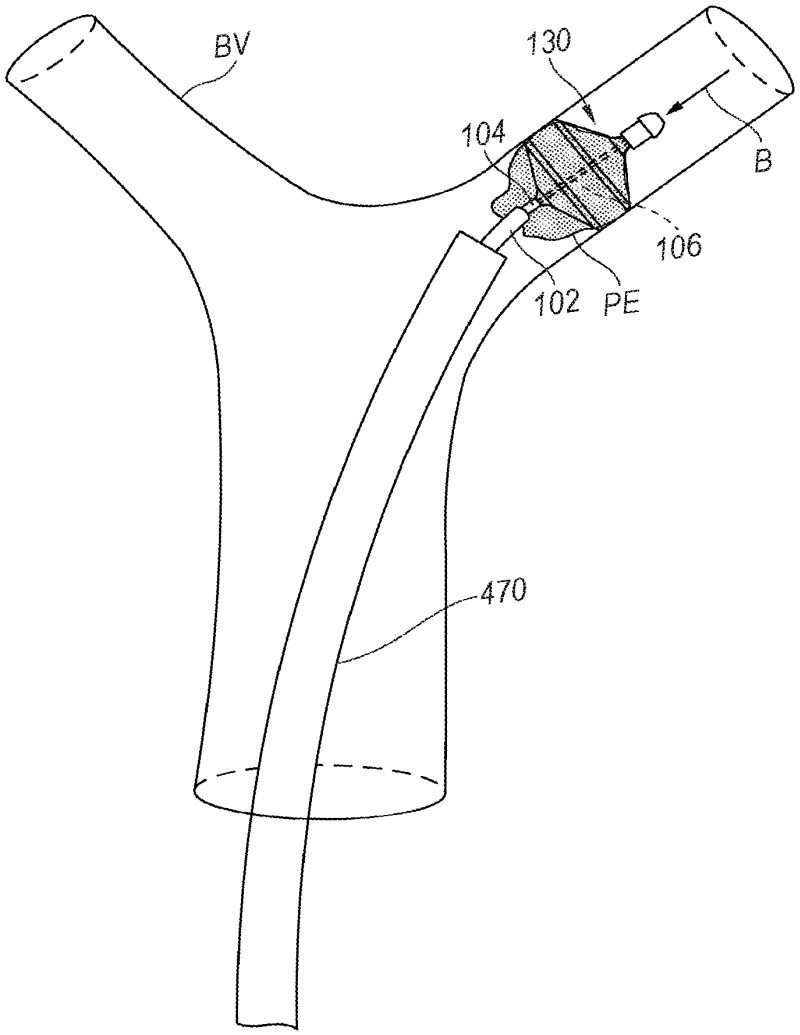

Fig. 4D

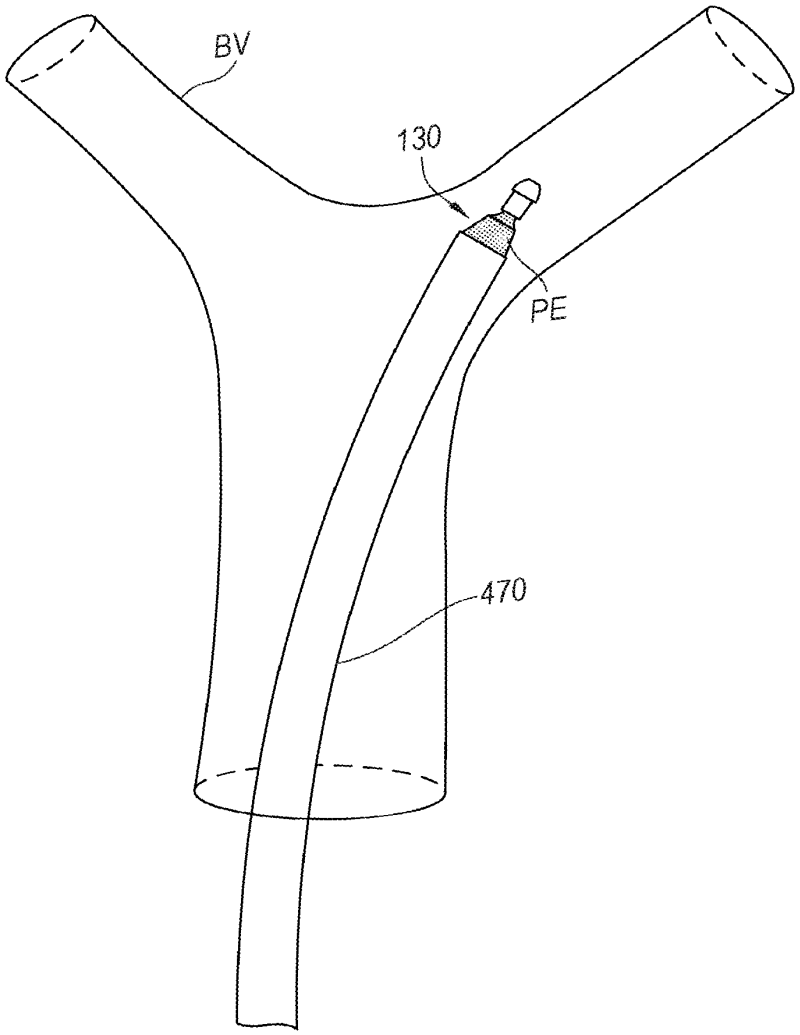

Fig. 4E

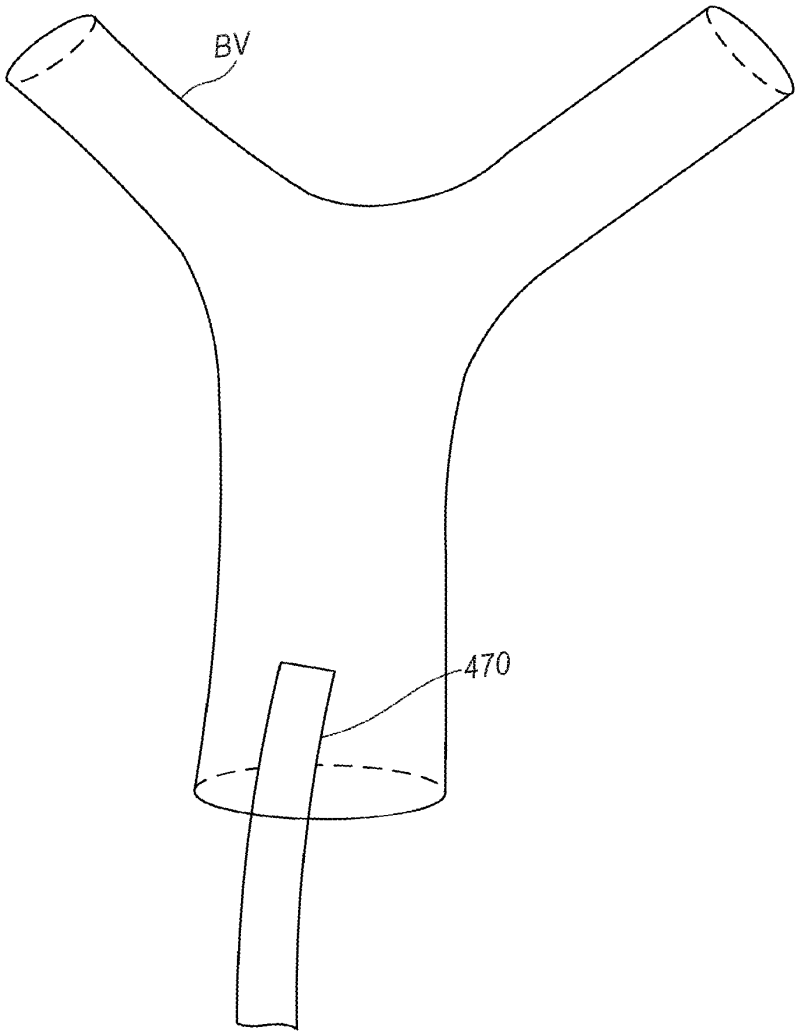

Fig. 4F

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 20/56067

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 17/14; A61B 17/22; A61B 17/32; A61F 2/01; A61M 25/01; A61M 25/08 (2020.01)

CPC - A61B 17/14; A61B 17/22; A61B 17/32; A61F 2/01; A61M 25/01; A61M 25/08; A61M 25/09; A61B 17/221; A61B 17/3205; A61B 17/3207

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2019/0046219 A1 (INARI MEDICAL, INC.) 14 February 2019 (14.02.2019); entire document, especially para [0196]-[0201], and Fig. 29-34D.	1-20
A	US 2019/0000492 A1 (NEURAVI LIMITED) 3 January 2019 (03.01.2019); entire document.	1-20
A	US 2014/0371779 A1 (NEURAVI LIMITED) 18 December 2014 (18.12.2014); entire document.	1-20
A	US 2018/0064454 A1 (NEUROVASC TECHNOLOGIES, INC.) 8 March 2018 (08.03.2018); entire document.	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 December 2020	22 JAN 2021
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Lee Young Telephone No. PCT Helpdesk: 571-272-4300

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(74) Agent: **MCLEAN, Craig**; Novartis Pharma AG, Patent Department, CH-4002 Basel (CH).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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

Declarations under Rule 4.17:

[Continued on next page]

(54) **Title**: SYRINGE

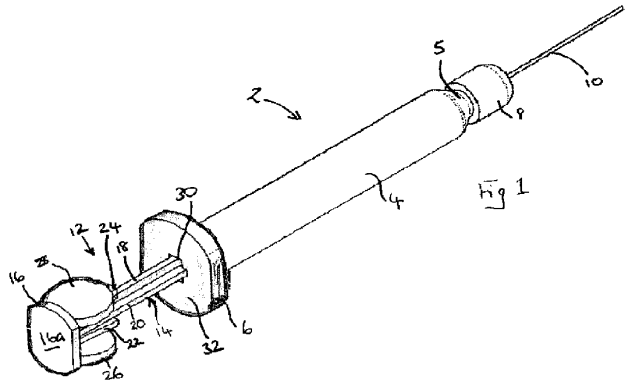


Fig 1

(57) **Abstract**: A syringe (2) including a barrel (4) with discharge end (5) defining a discharge passage, plunger (12) being adapted to move axially within the barrel and capable of displacing fluid from the chamber through the discharge end; the plunger includes a control arm (22, 24) including a first releasable stop element and a second non-releasable stop element, the first and second stops are both axially spaced from the rear end of the plunger, the control arm has a first configuration in which the first stop element is axially aligned with a stop surface (32) defined by a part of the barrel (4), the first stop element is adapted to limit the axial movement of the plunger; and a second configuration in which the first stop element is disposed out of alignment with the stop surface and the second stop element is axially aligned with the stop surface, the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element.

WO 2011/073176 A1

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

Published:

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

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

Syringe

The present invention relates to a syringe and, in particular, to a syringe adapted to permit priming, followed by dosing of a pre-determined dose.

It is often desirable to deliver a relatively small volume of fluid from a syringe in a method that is both accurate and reproducible. Typically, syringes containing fluids are first primed, to ensure that no air or other gas is present in the syringe and then a second, delivery (dosage) step is performed to deliver the required volume of fluid. However, it is difficult to deliver accurately a relatively small volume of fluid during the delivery step using a conventional syringe.

WO01/62319, US3,934,586 and WO03/004080 all describe dual stage syringes, but none of them addresses the issue of delivering accurately and reproducibly a relatively small volume of a fluid.

According to a first aspect of the present invention, there is provided a syringe for dispensing a fluid, the syringe including a barrel including a discharge end defining a discharge passage, and a plunger disposed within the barrel, the plunger being adapted to move axially within the barrel such that the plunger and discharge end define a variable volume chamber within the barrel and the plunger is capable of displacing fluid from the chamber through the discharge end; wherein the plunger includes a control arm which includes a first releasable stop element and a second non-releasable stop element, wherein the first and second stops are both axially spaced from the rear end of the plunger and wherein the control arm has a first configuration in which the first stop element is axially aligned with a stop surface defined by a part of the barrel, whereby the first stop element is adapted to limit the axial movement of the plunger, and a second configuration in which the first stop element is disposed out of alignment with the stop surface and the second stop element is axially aligned with the stop surface, whereby the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element.

By having a first, releasable stop, a priming stroke can be defined in which the plunger is moved from a start position to the first stop. The first stop can then be removed or by-passed by moving the control arm from the first configuration to the second configuration. When the first stop is removed, by disposing it out of alignment with the stop surface, the syringe may

be used to deliver a dose of fluid contained therein by further movement of the plunger from the first to the second stop. The spacing between the first and second stops corresponds to a fixed dose for a given internal diameter of the barrel. Thus, the second stop element is disposed rearwardly from the first stop element and the spacing between the first and second stop elements defines the dosing stroke of the plunger.

Locating the first and second stops on a control arm and spacing both of the stops from the end of the plunger means that it is possible to achieve accurate and reproducible dosing of relatively small doses of the fluid by controlling the spacing between the stops. This is because the second stop is well defined. In the art, the second stop is often defined by a plunger button engaging or contacting the barrel body. However, this opens up the possibility that the user does not fully displace the plunger, resulting in an underdose being delivered. Additionally or alternatively, there is the possibility of foreign material becoming lodged at the rear of the barrel, which would prevent complete displacement of the plunger to the second stop. This would also result in an underdose being delivered. For doses having relatively small volumes, it is important that the dosing stroke is well defined.

In an embodiment of the invention as defined anywhere herein, the control arm is resiliently deformable, wherein the first configuration represents a rest or non-deflected position, and the second configuration represents a deflected position. In such an arrangement, the control arm must be urged from the first configuration to the second configuration in order to remove or release the first stop.

The plunger may include a retaining element to retain the control arm in the second configuration. For example, this might include an axially slidable collar or sleeve carried by the plunger or a two-part clip, wherein one part of the clip is carried by the control arm and the other part of the clip is carried by the plunger. In this arrangement, the syringe may be used one-handed, as the control arm does not need to be manually retained in the second configuration and the retaining element prevents the accidental return of the control arm to the first configuration from the second configuration and the consequent re-engagement of the first stop.

In a further embodiment of the invention as defined anywhere herein, the plunger includes a shaft connected at one end to a piston disposed in use within the barrel and connected at the other end to a push button, and the control arm is hingedly coupled to the shaft. This

arrangement provides a control arm which is relatively straightforward to engineer and is intuitive for a user to operate.

The barrel may include a collar comprising a collar body which defines therethrough a shaft guide channel, wherein the shaft of the plunger is slidably retained within the guide channel. The collar body may further define the stop surface.

The guide channel may be adapted to receive therein the first stop element when the control arm is in the second configuration.

In order to maintain the first stop element aligned with the stop surface, for example during the priming step, the shaft of the plunger may include an orientation controlling element which is adapted to maintain the axial orientation of the plunger shaft relative to the guide channel. This ensures that the plunger remains in the desired axial orientation until the priming step is complete and the first stop element of the plunger has engaged the stop surface.

In an embodiment of the invention as defined anywhere herein, the orientation controlling element includes a spline (a longitudinally extending rib) carried by the plunger shaft which is located in use within a spline channel defined through the collar.

The interaction of the spline carried by the plunger shaft with the spline channel prevents unwanted movement, e.g. rotation, of the plunger relative to the barrel.

The skilled person will appreciate that the plunger may include more than one spline, wherein the splines are circumferentially offset from each other.

In such an embodiment, the barrel and/or collar typically includes corresponding spline channels for each spline.

A common arrangement for plungers is to include a cruciform-shaped shaft. Thus, in an embodiment of the invention as defined anywhere herein, the plunger shaft has a cruciform cross sectional configuration. In such an embodiment, the collar body may define a guide channel having complimentary cruciform shape.

In embodiments where the spline channel is adapted to receive therein the first stop element when the control arm is in the second configuration, one or more of the splines may include a longitudinal notch which is capable of receiving therein at least a part of the control arm. Thus, the first stop element of the control arm may have a cross-section which is smaller than or congruent with the cross section of the notch formed within the respective spline, wherein the first stop element extends laterally outwards from the spline in the first configuration of the control arm and is axially aligned with the spline in the second configuration of the control arm. In other words, the first stop element may be contained within the notch in the second configuration of the control arm.

Of course, the first stop element may extend beyond the notch defined by the spline in embodiments where the spline channel is adapted to receive therein the first stop element, i.e. in addition to the spline itself.

The first stop element may be a forward facing end wall of the control arm.

The second stop element may extend outwardly from the first stop element. In such embodiments, the second stop element may be carried by the control arm and is spaced rearwardly from the first stop element to define a dosing stroke which is the spacing between the first and second stop elements.

The second stop element may be defined by an edge portion of a control button which defines a substantially planar button surface. In such an embodiment, it is clear to a user how to operate the syringe: the syringe is primed by urging the plunger forwards until the first stop engages or contacts the stop surface. The control button is then pressed, which moves the control arm from the first to the second configuration, whereupon the first stop element is disengaged from (moved out of alignment with) the stop surface. The plunger is then again urged forwards until the second, non-releasable, stop element engages or contacts the stop surface, at which point the dose stroke is complete.

In an embodiment of the invention as defined anywhere herein, the plunger includes a pair of opposed control arms. By having two or more control arms, the possibility of the first stop element accidentally and/or unintentionally being disposed out of axial alignment with the stop surface is significantly reduced.

According to a second aspect of the invention, there is provided a plunger assembly for use with a syringe barrel, the assembly including a collar adapted to engage one end of the barrel; and a plunger including a piston adapted to be located within the barrel, an elongate shaft extending from the piston and a push button at the end of the shaft opposite to the piston, wherein the elongate shaft is slidably retained within the collar, and wherein the plunger shaft includes a control arm which includes a first releasable stop element and a second non-releasable stop element, wherein the first and second stops are both axially spaced from the push button and wherein the control arm has a first configuration in which the first stop element is axially aligned with a stop surface defined by the collar, whereby the first stop element is adapted to limit the axial movement of the plunger, and a second configuration in which the first stop element is disposed out of alignment with the stop surface and the second stop element is axially aligned with the stop surface, whereby the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element.

The additional features described and defined herein in connection with the first aspect of the invention may apply equally to the second aspect of the invention. Thus, the second aspect of the invention may include any, some or all of the additional features described hereinabove.

According to a third aspect of the invention, there is provided a syringe kit including a syringe barrel and a plunger assembly according to the second aspect of the invention.

According to a fourth aspect of the invention, there is provided a pre-filled syringe for dispensing a fluid, the syringe including a barrel including a discharge end defining a discharge passage, the barrel containing therein a medicament in fluid form; and a plunger disposed within the barrel, the plunger being adapted to move axially within the barrel such that the plunger and discharge end define a variable volume chamber within the barrel and the plunger is capable of displacing fluid from the chamber through the discharge end; wherein the plunger includes a control arm which includes a first releasable stop element and a second non-releasable stop element, wherein the first and second stops are both axially spaced from the rear end of the plunger and wherein the control arm has a first configuration in which the first stop element is axially aligned with a stop surface defined by a part of the barrel, whereby the first stop element is adapted to limit the axial movement of the plunger, and a second configuration in which the first stop element is disposed out of alignment with

the stop surface and the second stop element is axially aligned with the stop surface, whereby the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element.

The additional features described and defined herein in connection with the first aspect of the invention may apply equally to the fourth aspect of the invention. Thus, the fourth aspect of the invention may include any, some or all of the additional features described hereinabove.

As used herein, the term "forward" means towards the discharge end of the syringe and the term "rearward" means away from the discharge end of the syringe.

The skilled person will appreciate that the features specified above in connection with embodiments of the invention may be combined with each other and any of the aspects of the invention as defined. Thus, the present invention includes within its scope an aspect of the invention combined with two or more of the features described anywhere herein as optional features. All such combinations of features described herein are considered to be made available to the skilled person.

Embodiments of the invention will now be described in detail, by way of example only, with reference to the accompanying drawings in which:

Figure 1 is a perspective view of a syringe according to a first embodiment of the invention;
Figure 2 is side elevational view of the syringe shown in Figure 1;
Figure 3 is a plan view from above of the plunger assembly of the syringe shown in Figure 1;
Figure 4 is a perspective view of a syringe according to a second embodiment of the invention; and
Figure 5 is a side elevational view of the syringe shown in Figure 4.

For the avoidance of doubt, the skilled person will appreciate that in this specification, the terms "up", "down", "front", "rear", "upper", "lower", "width", etc. refer to the orientation of the components as found in the syringe when installed for normal use as shown in the Figures.

A syringe 2 according to a first embodiment of the invention is shown in Figures 1, 2 and 3. The syringe 2 includes a barrel 4 defining a cylinder therein. Located at the rear of the barrel 4 is a collar 6 and at the opposite end, i.e. the front, of the barrel 4 is a discharge end 5

which defines therein a discharge passage. Secured to the discharge end 5 is a connecting collar 8 of a hypodermic needle 10.

The skilled person will appreciate that the hypodermic needle connecting collar 8 may be a simple friction fit with the discharge end 5 of the barrel 4 or it may be a locking collar, such as a Luer-Lok collar. The connection of hypodermic needles to syringe barrels is well known in the art and will not be described in detail herein.

The syringe 2 further includes a plunger assembly 12. The plunger assembly 12 consists of a plunger shaft 14 which terminates at its rearward end in a push button 16 and terminates at its forward end in a piston (not shown) located within the cylinder defined by the barrel 4. The plunger shaft 14 is slidably retained within the collar 6.

The push button 16 defines a rearward facing push button surface 16a which is substantially planar.

The plunger shaft 14 is cruciform in cross-section and defines a pair of opposed vertical splines 18 and a pair of opposed horizontal splines 20.

Included in the plunger assembly 12 is a pair of opposed control arms 22, 24 hingedly connected to the plunger shaft 14 adjacent to the push button 16. Figure 2 shows the control arms 22, 24 in a first configuration in which the distal ends of the control arms 22, 24 are laterally spaced from the plunger shaft 14. The forward facing end surfaces of the control arms 22, 24 define the first stop elements.

The width of each of the control arms 22, 24 is slightly greater than the width of the corresponding vertical spline 18, and the height of each of the control arms 22, 24 is slightly less than the corresponding vertical spline 18.

The collar 6 includes a body which defines therein a plunger shaft guide channel in the form of a cruciform aperture 30 substantially about the longitudinal axis of the barrel 4. Each of the four arms of the cruciform-shaped aperture 30 has a height which is slightly greater than the height of the corresponding spline 18, 20. The width of the horizontal arms is similarly slightly greater than the width of the corresponding horizontal splines 20. However, the width of the

vertical arms of the cruciform aperture 30 is such that they are slightly wider than the width of the corresponding control arms 22, 24.

The body of the collar 6 about the cruciform aperture 30 defines a stop surface.

The vertical splines 18 each define a notch 40 which is sized to accommodate the corresponding control arm 22, 24 in their second configuration in which the control arms 22, 24 are arranged axially within the corresponding vertical spline 18. Thus, each notch 40 is substantially equal in length to the corresponding control arm 22, 24 and the depth of each notch 40 is substantially identical to the height of the corresponding control arm 22, 24.

The front facing wall of each of the control arms 22, 24 includes a recess (not shown) which is configured to receive therein a corresponding protrusion (not shown) which extends outwards from the rear facing wall of each of the vertical splines 18.

Extending outwardly from the control arms 22, 24 are respective control buttons 26, 28 in the form of short cylindrical bodies. The forward facing side wall portion of each control button 26, 28 defines a respective second stop element.

In use, the barrel 4 includes a medicament in fluid form and the plunger is disposed in a start position in which the first stop elements defined by the forward facing walls of the control arms 22, 24 are spaced from the stop surface defined by the body of the collar 6. The control arms 22, 24 are in their rest position, as shown in Figure 2.

A user initiates a priming step to remove any gas or dead volume from within the barrel by urging the plunger forward via the rearward facing push button surface 16a. This causes the piston within the barrel 4 to move forward, expelling the unwanted gas and priming the syringe. The priming stroke is continued until the forward facing end walls of the control arms 22, 24 engage the stop surface defined by the body of the collar 6.

Once the priming step is complete, the user exerts a force on each of the two control buttons 26, 28 which urges them towards each other. This causes the control arms 22, 24 to be located within the corresponding notch 40 of the respective vertical spline 18 and for the forward facing end walls of the control arms 22, 24 to become axially aligned with the vertical arms of the cruciform aperture 30. Thus, in this second configuration of the control arms 22,

24, the forward facing end walls of the control arms 22, 24 are no longer axially aligned with the stop surface defined by the body of the collar 6 and are capable of being received into the vertical arms of the cruciform aperture 30.

When the control arms 22, 24 are fully located within the corresponding notch 40, the protrusions extending from the rearward facing end wall portions of the vertical splines 18 engage with the respective recesses formed in the forward facing end walls of the control arms 22, 24 such that the control arms 22, 24 are releasably retained in the second configuration.

Once the control arms 22, 24 are in their second configuration, the hypodermic needle 10 is inserted into or through the skin of a patient and the dose stroke is commenced. The dose stroke is defined by the short distance between the forward facing end walls of the control arms 22, 24 and the forward facing side walls of the cylindrical-shaped control buttons 26, 28. At the end of the dose stroke, the forward facing side walls of the cylindrical-shaped control buttons 26, 28 engage the stop surface defined by the body of the collar 6.

The skilled person will appreciate that the actual dose delivered by the syringe during the dose stroke is a function of the internal diameter of the barrel 4 and the spacing between the first stop elements (the forward facing end walls of the control arms 22, 24) and the second stops (the forward facing side walls of the cylindrical-shaped control buttons 26, 28). The delivery dose can be varied by varying one or both of these physical properties.

A second embodiment of the invention is shown in Figures 4 and 5.

A syringe 102 according to the second embodiment of the invention includes a barrel 104 defining a cylinder therein. Located at the rear of the barrel 104 is a collar 106 and at the opposite end, i.e. the front, of the barrel 104 is a discharge end 105 which defines therein a discharge passage. Secured to the discharge end 105 is a connecting collar 108 of a hypodermic needle 110.

The syringe 102 further includes a plunger assembly 112. The plunger assembly 112 consists of a plunger shaft 114 which terminates at its forward end in a piston (not shown) located within the cylinder defined by the barrel 4. The plunger shaft 114 is slidably retained within the collar 106.

A push button 116 is slidably coupled to a rear end portion of the plunger shaft 114 and defines a rearward facing push button surface 116a which is substantially planar. A cylindrical sleeve 150 extends forward from the push button 116 and overlies a portion of the plunger shaft 114. The push button 116 and associated sleeve 150 can move axially relative to the plunger shaft 114 within fixed limits.

The plunger shaft 114 is cruciform in cross-section and defines a pair of opposed vertical splines 118 and a pair of opposed horizontal splines 120.

Included in the plunger assembly 112 is a pair of opposed control arms 122, 124 hingedly connected to the plunger shaft 114 adjacent to the push button 116. A proximal portion of the control arms 122, 124 adjacent to the push button 116 is disposed within the sleeve 150.

Figure 5 shows the control arms 122, 124 in a first configuration in which the distal ends of the control arms 122, 124 are spaced from the plunger shaft 114. The hinged arrangement of the control arms 122, 124 is such that they are biased towards this first configuration and they provide a resistive force against movement towards each other.

The forward facing end surfaces of the control arms 122, 124 define the first stop elements.

The width of each of the control arms 122, 124 is substantially the same as the width of the corresponding vertical spline 118, and the height of each of the control arms 122, 124 is slightly less than the corresponding vertical spline 118.

The collar 106 includes a body which defines therein a plunger shaft guide channel in the form of a cruciform aperture 130 substantially about the longitudinal axis of the barrel 104. Each of the four arms of the cruciform-shaped aperture 130 has a height which is slightly greater than the height of the corresponding spline 118, 120 and a width which is similarly slightly greater than the width of the corresponding splines 118, 120.

The body of the collar 106 about the cruciform aperture 130 defines a stop surface.

The vertical splines 118 each define a notch 140 which is sized to accommodate the corresponding control arm 122, 124 in their second configuration in which the control arms

122, 124 are arranged axially within the corresponding vertical spline 118. Thus, each notch 140 is substantially equal in length to the corresponding control arm 122, 124 and the depth of each notch 140 is substantially identical to the height of the corresponding control arm 122, 124.

Extending outwardly from the control arms 122, 124 are respective lugs 126, 128 in the form of triangular-shaped wedges. The forward facing wall of each of the lugs 126, 128 defines a respective second stop element.

In use, the barrel 4 includes a medicament in fluid form and the plunger is disposed in a start position in which the first stop elements defined by the forward facing walls of the control arms 22, 24 are spaced from the stop surface defined by the body of the collar 6. The control arms 22, 24 are in their rest position, as shown in Figure 2.

A user initiates a priming step to remove any gas or dead volume from within the barrel by urging the plunger forward via the rearward facing push button surface 116a. As the frictional forces between the piston and the cylinder defined within the barrel 104 and between the plunger shaft 114 and the cruciform aperture 130 are less than the resistive forces exerted by the control arms 122, 124, the force exerted by the user on the push button 116 causes the piston within the barrel 104 to move forward, expelling the unwanted gas and priming the syringe 102. The priming stroke is continued until the forward facing end walls of the control arms 122, 124 engage the stop surface defined by the body of the collar 106.

When the forward facing end walls of the control arms 122, 124 engage the stop surface defined by the body of the collar 106, further movement of the plunger shaft forward is prevented.

At this point, the hypodermic needle 110 is inserted into or through the skin of a patient and the dose stroke initiated.

To initiate the dose stroke, the user continues to apply force to rearward facing surface 116a of the push button 116. As the plunger shaft 114 is prevented from moving forward by the forward facing end walls of the control arms 122, 124 contacting the stop surface, the force is directed through the sleeve 150 to the control arms 122, 124. This force overcomes the resistive force of the control arms 122, 124 and urges them towards each other until they

become axially aligned with the vertical splines 118 and contained within the respective notches 140. At this point the forward facing end walls of the control arms 122, 124 no longer contact the stop surface defined by the body of the collar 106 and the control arms 122, 124 are capable of entering the respective arms of the cruciform aperture 130.

When the forward facing end walls of the control arms 122, 124 disengage from the stop surface, the plunger shaft and the attached piston can continue to move forward for the dose stroke until the outwardly extending lugs 126, 128 contact the stop surface, at which point the dose step is complete.

Example 1

Tests of the first embodiment syringe described above were carried out as follows:

Test Apparatus

The syringe plunger and collar were assembled to a sample 1ml syringe barrel. A needle was fitted to the discharge end of the syringe barrel.

Preparation and Measurement

The syringe was filled with a nominal volume of RO/DI water, held vertically and tapped to release air bubbles, and primed to the first stop. A clean Eppendorf Tube was tared on an analytical balance. The control buttons were urged towards each other to release the first stops and to permit dosing, and the plunger depressed to the second stop, discharging the dose into the vial.

The vial was then closed and weighed.

The test was repeated, re-using the syringe, but taking a clean vial each time.

Calculation

Dose mass was calculated from the difference in weight of the vial.
Dose volume was calculated from the mass by dividing by density.
Density = 998.022kg/m^3 at lab conditions of 21°C and 42%RH

Apparatus

Sartorius ME235S-OCE analytical balance (5 decimal places / 1g)

300 µl Eppendorf Tubes

Syringe Device as described above

Results

Table 1

	mean	Standard deviation	lowest	highest
Mass (g)	0.0520	0.0032	0.0474	0.0584
Volume (µl)	52.11	3.21	47.52	58.52

The results from N = 10 measurements

The dose delivered by the prototype in the tests is in the range 53.02 ± 5.5µl i.e. 47.52 to 58.52µl.

The syringe delivered a well controlled dose, within a tolerance of ± 5.5µl, which is within the tolerance of ± 7.5µl associated with the acceptance limits.

Claims

1. A syringe for dispensing a fluid, the syringe including a barrel including a discharge end defining a discharge passage, and a plunger disposed within the barrel, the plunger being adapted to move axially within the barrel such that the plunger and discharge end define a variable volume chamber within the barrel and the plunger is capable of displacing fluid from the chamber through the discharge end; wherein the plunger includes a control arm including a first releasable stop element and a second non-releasable stop element, wherein the first and second stops are both axially spaced from the rear end of the plunger and wherein the control arm has a first configuration in which the first stop element is axially aligned with a stop surface defined by a part of the barrel, whereby the first stop element is adapted to limit the axial movement of the plunger; and a second configuration in which the first stop element is disposed out of alignment with the stop surface and the second stop element is axially aligned with the stop surface, whereby the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element, the control arm is resiliently deformable and the first configuration represents a rest or non-deflected position, and the second configuration represents a deflected position.

2. A syringe according to Claim 1, wherein the plunger includes a retaining element to retain the control arm in the second configuration.

3. A syringe according to Claim 2, wherein the retaining element is selected from an axially slidable sleeve and a two-part clip, wherein one part of the clip is carried by the control arm and the other part of the clip is carried by the plunger.

4. A syringe according to any preceding claim, wherein the plunger includes a shaft connected at one end to a piston disposed in use within the barrel and connected at the other end to a push button, and the control arm is hingedly coupled to the shaft.

5. A syringe according to Claim 4, wherein the barrel includes a collar comprising a collar body which defines therethrough a shaft guide channel, wherein the shaft of the plunger is slidably retained within the guide channel, and wherein the collar body defines the stop surface.

6. A syringe according to Claim 5, wherein the guide channel is adapted to receive therein the first stop element when the control arm is in the second configuration.

7. A syringe according to Claim 5 or 6, wherein the shaft of the plunger includes an orientation controlling element which is adapted to maintain substantially fixed the axial orientation of the plunger shaft relative to the guide channel.

8. A syringe according to Claim 7, wherein the plunger shaft has a cruciform cross-sectional configuration and the collar body defines a guide channel having a complimentary cruciform shape.

9. A syringe according to any preceding claim, wherein the first stop element includes a forward facing end wall of the control arm.

10. A syringe according to any preceding claim, where the second stop element is a projection from the control arm which extends outwardly from the first stop element and is spaced rearwardly from the first stop element.

11. A syringe according to Claim 10, wherein the second stop element is defined by a forward facing wall portion of a cylindrical control button carried by the control arm.

12. A syringe according to any preceding claim, which includes a pair of opposed control arms.

13. A plunger assembly for use with a syringe barrel, the assembly including a collar adapted to engage one end of the barrel; and a plunger including a piston adapted to be located within the barrel, an elongate shaft extending from the piston and a push button at the end of the shaft opposite to the piston, wherein the elongate shaft is slidably retained within the collar, and wherein the plunger shaft includes a control arm including a first releasable stop element and a second non-releasable stop element, wherein the first and second stops are both axially spaced from the push button and wherein the control arm has a first configuration in which the first stop element is axially aligned with a stop surface defined by the collar, whereby the first stop element is adapted to limit the axial movement of the plunger, and a second

configuration in which the first stop element is disposed out of alignment with the stop surface and the second stop element is axially aligned with the stop surface, whereby the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element.

14. A pre-filled syringe for dispensing a fluid, the syringe including a barrel including a discharge end defining a discharge passage, the barrel containing therein a medicament in fluid form; and a plunger disposed within the barrel, the plunger being adapted to move axially within the barrel such that the plunger and discharge end define a variable volume chamber within the barrel and the plunger is capable of displacing fluid from the chamber through the discharge end; wherein the plunger includes a control arm including a first releasable stop element and a second non-releasable stop element, wherein the first and second stops are both axially spaced from the rear end of the plunger and wherein the control arm has a first configuration in which the first stop element is axially aligned with a stop surface defined by a part of the barrel, whereby the first stop element is adapted to limit the axial movement of the plunger, and a second configuration in which the first stop element is disposed out of alignment with the stop surface and the second stop element is axially aligned with the stop surface, whereby the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element.

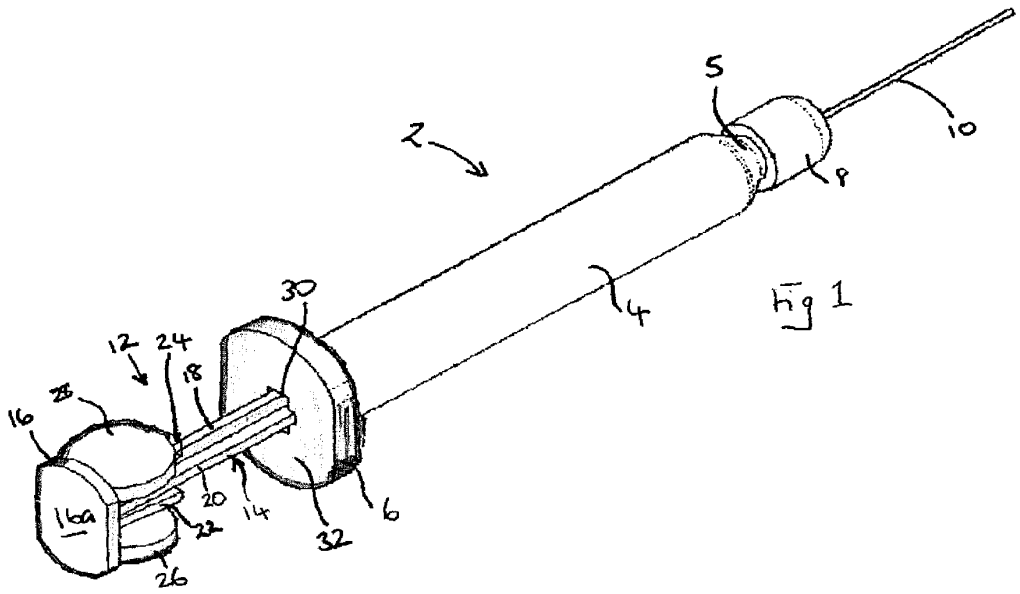


Fig 1

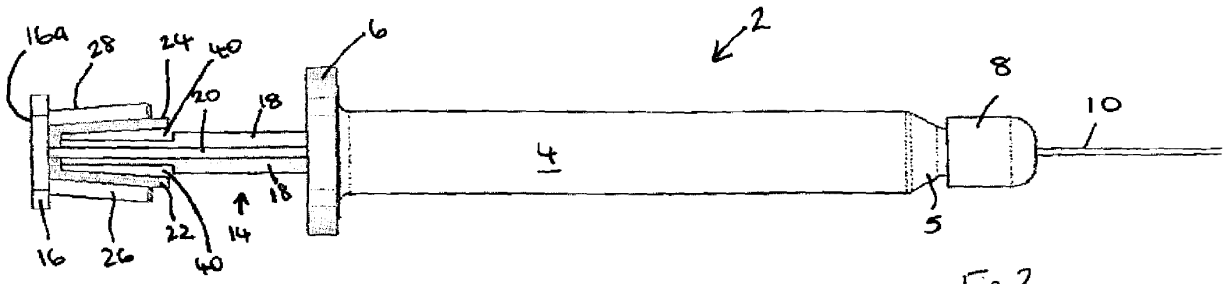


Fig 2

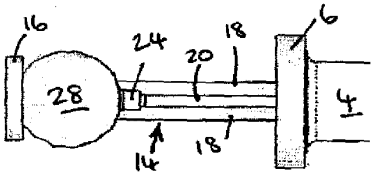
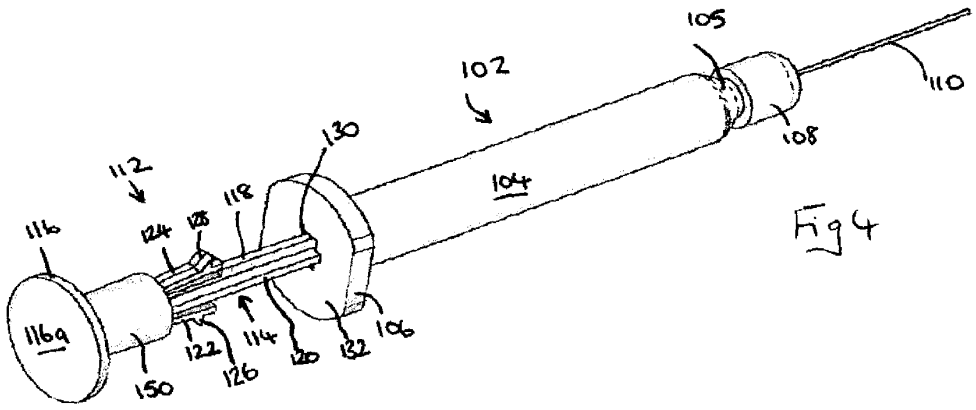


Fig 3


105
102
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130
112
104
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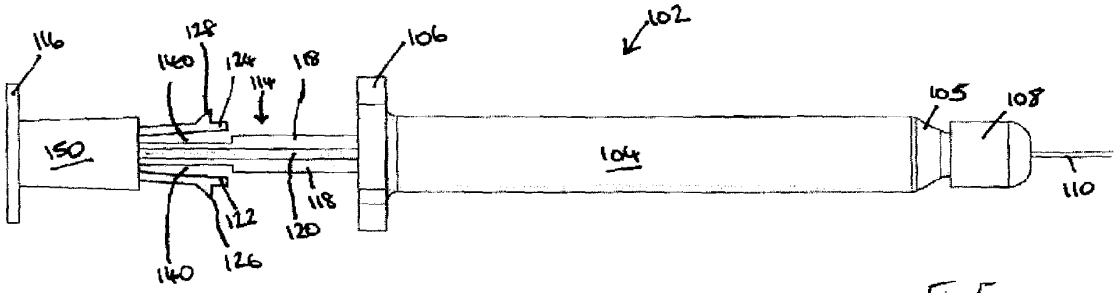
116
124
128
116a
122
114
120
132
106
126
150

Fig 4


116
128
140
124
114
118
106
102
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108
150
104
110
122
120
118
140
126

Fig 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2010/069597

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/315
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/004080 A1 (AKZO NOBEL NV [NL]; RIKKEN JOHANNES MATHIAS GERARD [NL]; NICKOLSON VIC) 16 January 2003 (2003-01-16) cited in the application	14
Y	page 4, line 5 - page 6, line 9	1,9,13
A	figures 1, 2A-2D	2-4

A	WO 01/62319 A2 (ABBOTT LAB [US]) 30 August 2001 (2001-08-30) page 12, line 12 - line 16 page 17, line 7 - line 27 figures 1B,1C,7A,7B	1,4-8

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 May 2011	31/05/2011

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Sedy, Radim

2

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	FR 2 627 087 A1 (PLANCON J [FR]; SEBBIN LABORATOIRES [FR]) 18 August 1989 (1989-08-18) page 3, line 28 - page 4, line 2 page 5, line 9 - line 13 figures 1, 4	1,9
A	EP 0 911 046 A2 (TAKEDA CHEMICAL INDUSTRIES LTD [JP]) 28 April 1999 (1999-04-28) paragraph [0006]; figure 19	2,4
Y	GB 1 230 522 A (TASMAN VACCINE LAB LTD) 5 May 1971 (1971-05-05)	13
A	page 2, line 21 - line 27 figures 1, 4	5,7,8

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2010/069597

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 03004080 A1	16-01-2003	NONE	
WO 0162319 A2	30-08-2001	AT 297769 T	15-07-2005
		AU 4158401 A	03-09-2001
		AU 2001241584 B2	14-04-2005
		CA 2400937 A1	30-08-2001
		DE 60111501 D1	21-07-2005
		DE 60111501 T2	18-05-2006
		EP 1257310 A2	20-11-2002
		ES 2243459 T3	01-12-2005
		JP 2004500201 T	08-01-2004
		US 2005004530 A1	06-01-2005
FR 2627087 A1	18-08-1989	NONE	
EP 0911046 A2	28-04-1999	AT 284723 T	15-01-2005
		CA 2246985 A1	16-03-1999
		DE 69828135 D1	20-01-2005
		DE 69828135 T2	03-11-2005
		JP 3968445 B2	29-08-2007
		JP 11076405 A	23-03-1999
		US 6371941 B1	16-04-2002
GB 1230522 A	05-05-1971	AU 455834 A	
		FR 2024089 A5	21-08-1970
		NL 6908371 A	04-12-1970

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(54) Title: AXIAL LENGTHENING THROMBUS CAPTURE SYSTEM

(57) Abstract: Systems and methods can remove material of interest, including blood clots, from a body region, including but not limited to the circulatory system for the treatment of pulmonary embolism (PE), deep vein thrombosis (DVT), cerebrovascular embolism, and other vascular occlusions.

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AXIAL LENGTHENING THROMBUS CAPTURE SYSTEM

PRIORITY CLAIM

[0001] Any and all applications for which a foreign or domestic priority claim is identified in the Application Data Sheet as filed with the present application. This application claims the benefit under 35 U.S.C. § 120 as continuation of U.S. nonprovisional application no. 15/604531, filed May 24, 2017, which is a continuation-in-part application of U.S. Pat. App. No. 15/428,076 filed on February 8, 2017, which is a continuation-in-part application of U.S. Pat. App. No. 15/230,109 filed on August 5, 2016, which claims the benefit under 35 U.S.C. § 119(e) as a nonprovisional application of each of U.S. Provisional App. Nos. 62/202,074 filed on August 6, 2015, 62/273,418 filed on December 30, 2015, and 62/345,863 filed on June 6, 2016. Each of the aforementioned priority applications is hereby incorporated by reference in their entireties.

BACKGROUND

Field of the Invention

[0002] The invention relates to, in some aspects, systems and methods to remove materials of interest, including blood clots, from a body region, including but not limited to the circulatory system for the treatment of pulmonary embolism (PE), deep vein thrombosis (DVT), cerebrovascular embolism, and other vascular occlusions.

Description of the Related Art

[0003] It is understood that undesirable materials such as blood clots (which could be referred to as thrombi, thromboemboli, or emboli herein) in the blood vessels may partially or completely occlude blood vessels in areas of the coronary, cerebrovascular, pulmonary, peripheral venous, and peripheral arterial circulation resulting in myocardial infarction, stroke, pulmonary embolism, deep vein thrombosis, and infarction of an extremity respectively.

[0004] Various therapies and devices are known to either dissolve, debulk and/or aspirate the thromboemboli. For instance, anticoagulant agents such as heparin and warfarin help stabilize blood clots and prevent further forming of clots while thrombolytic agents such

as urokinase, streptokinase, and tPA assist in dissolving blood clots. These agents can be delivered via systemic infusion or catheter-based infusion to the intended location. While thrombolytic agents can be effective in dissolving blood clots, they require a long time duration in order for the agents to dissolve the blood clots; thus patients may need to remain in the hospital intensive care unit (ICU) during thrombolytic infusion. Relatively long lengths of stay can increase healthcare costs significantly. A major limitation for these thrombolytic agents is that they can potentially cause intracranial, gastrointestinal, retroperitoneal, and pericardial bleeding, among other sites, which can be often life-threatening and cause significant morbidity and mortality risks.

[0005] Mechanical debulking and/or aspiration devices can be used to remove the obstruction. These mechanical techniques can either macerate, aspirate, or a combination thereof in order to remove the blood clots. An advantage of mechanical therapy is that it can remove thrombus directly from the blockage area and immediately eliminates the obstruction and may be superior to thrombolytic agents in some cases. However, current mechanical therapies have some major limitations. There is minimal to no flow during the procedure thus there is little time before patients may become hemodynamically instable. The debris removed from mechanical treatment can travel distally creating additional embolization. The small size devices are unable to remove large amount of blood clots in short time periods thus patients may become hemodynamically instable.

[0006] Catheter-based removal of blood clots from larger blood vessels (e.g., pulmonary arteries) have had limited success compared to smaller blood vessels (e.g., coronary arteries). Catheter pulmonary embolectomy is where pulmonary emboli are removed percutaneously using several techniques. Fragmentation thrombectomy breaks blood clots into smaller pieces, most of which travel further downstream, resulting in distal embolization. It is sometimes used in combination with thrombolytics. With the rheolytic thrombectomy, high velocity saline jets create a Venturi effect and draw the fragments of the clot into the catheter. This method poses risk of hemolysis. Finally the aspiration techniques draw the clot into a catheter via suction. All of these techniques rely on the catheter used to remove the clots from blood vessels. The users use small catheters to remove or break up large amounts of blood clot. This procedure is therefore time-consuming and inefficient. Once the blood clots are broken into small pieces, the debris can migrate distally and create

unwanted emboli. Rheolytic therapy poses the risk of hemolysis. Additionally, the ability to suction is limited due the small catheter size suctioning large emboli. These limitations cause in some cases unnecessary duress to the user and risk to the patient.

[0007] Catheter-based removal of blood clots in general also has a major limitation when distal working space within a body lumen is limited. Conventional devices may require full axial and/or radial deployment and expansion to be functional, and as such flexibility to use such devices for a variety of clinical situations involving differing clot or other material sizes to be removed can be very limited. Therefore, conditions where there is limited distal space of blood vessels can render these conventional devices ineffective.

[0008] It is evident that all of the therapeutic options available to patients with blood clots or other undesirable material in blood vessels and other body lumens have limitations. Anticoagulation only limits propagation of clots but does not actively remove it. Thrombolytic therapy poses a risk of major bleeding. Catheter embolectomy is not effective to manage removal of material in large vessels. Additionally, these devices require distal space to fully deploy to be functional thus ineffective in tight distal spaces. Surgical embolectomy can be highly effective but highly invasive, and has a high rate of morbidity and mortality. There is a need for a direct mechanical treatment that is as or more effective as surgical embolectomy removing large blood clots but can be performed using endovascular techniques and restore immediate blood flow, and cause a lower incidence of complications.

SUMMARY

[0009] In some embodiments, disclosed herein is a capture system for selected materials within a body. The capture system can include a capture assembly configured to isolate unwanted material, e.g., a blood clot that can include a shape memory body such as made of, for example, a mesh material and having a distal end connected to a capture guide having a distal opening. The shape memory body can further include a proximal end connected to a first shaft, and a tubular sidewall between the proximal end and the distal end. The capture assembly can be configured to expand the capture guide and the distal opening end when the shape memory body proximal end is compressed in the delivery system. The shape memory body can be movable from a first configuration having a first axial length and a second configuration having a second axial length. The shape memory body can be

configured to roll out, invert, evert, and/or variably lengthen proximally or distally from the first configuration to the second configuration. The second axial length can be different from the first axial length. The width of the capture assembly can, in some cases not substantially change from the first configuration to the second configuration. The capture system can also include a control line configured to independently move the capture assembly from the first configuration to the second configuration. The first shaft can extend within the longitudinal axis of the capture assembly.

[0010] In some embodiments, disclosed herein is a material, e.g., a clot capture system. The system can include a first, outer tubular shaft comprising a central lumen, the first outer tubular shaft comprising a proximal portion and a distal portion, the distal portion more radially expandable than the proximal portion. The system can also include a second tubular shaft configured to be positioned within the central lumen of the first shaft. The system can also include a third tubular shaft configured to be positioned within a central lumen of the second shaft. The shape memory tubular body can include a first end, a second end, and an axial length therebetween, the first end having a proximal-facing opening and a ring-shaped capture guide attached to a circumference of the proximal-facing opening, the capture guide operably attached to the second tubular shaft, the second end attached to an outer wall of the third tubular shaft. The shape memory tubular body can be compressed within the central lumen of the second tubular shaft in a first delivery configuration. The shape memory tubular body can be transformable to a second configuration in which the first end and the capture guide is radially expanded up to a dynamic fold point, but the second end and a segment of the shape memory tubular body extends in a different direction, such as proximally past the dynamic fold point, and remains radially compressed within the central lumen of the second tubular shaft and the second end is positioned proximal to the first end and the shape memory tubular mesh body has a first expanded axial length. The shape memory tubular body can be transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, and a width of the shape memory tubular shaft along its second expanded axial length is the same or substantially the same as a width of the shape memory tubular shaft along its first expanded axial length. The first tubular shaft can be configured to be reversibly coupled with respect to the second tubular shaft in the delivery configuration and axially

movable with respect to the third tubular shaft in the second configuration. In some embodiments, the second expanded axial length is about or at least about, for example, 105%, 110%, 115%, 120%, 125%, 130%, 150%, 200%, 250%, 300%, 350%, 400%, 450%, 500%, or more of the first axial length. The capture system of Claim 1, wherein the shape memory body can be porous, semi-permeable, and non-porous, and include nitinol braided, woven, or non-woven mesh, or nitinol wire. In some embodiments, the tubular body is coated with a hydrophilic or hydrophobic agent, or noncoated, and may not include a shape memory metal or material. In some embodiments, the tubular mesh body is configured to invert, evert, or roll out with respect to the first, second, and/or third shaft. The system can also include a control line extending proximally from the capture guide, either terminating on a sleeve on one of the shafts or extending proximally to the proximal end of the system. In some embodiments, the system includes a suction element configured to operably connect with the proximal opening of the shape memory tubular body. The system can also include a mechanical thrombectomy element, such as a macerator. The system can also include a filter collection chamber configured to collect and filter blood obtained from the suction element.

[0011] The system can further include an expanding guide catheter configured to receive the capture assembly in the form of a kit. The expanding guide element can include an open funnel distal tip, that can be porous in some embodiments to allow flow around the funnel distal tip.

[0012] In some embodiments, disclosed herein is a material, such as a clot capture system that can include a first, outer tubular shaft comprising a central lumen; a second tubular shaft configured to be positioned within the central lumen of the first shaft, the second tubular shaft comprising a proximal portion and a distal portion, the distal portion more radially expandable than the proximal portion; a third tubular shaft configured to be positioned within a central lumen of the second shaft; a tubular mesh comprising a first end, a second end, and an axial length therebetween, the first end having a proximal-facing opening and a ring-shaped capture guide attached to a circumference of the proximal-facing opening, the capture guide operably attached to the second tubular shaft, the second end attached to an outer wall of the third tubular shaft. The tubular mesh can be compressed within the central lumen of the second tubular shaft in a delivery configuration. The tubular mesh can also be transformable to a second configuration in which the first end and the

capture guide is radially expanded but the second end and a portion, such as a minority, half, or a majority of the tubular mesh remains radially compressed within the central lumen of the second tubular shaft and the second end is positioned proximal to the first end and the tubular mesh has a first expanded axial length. The tubular mesh can be transformable to a third configuration in which the tubular mesh has a second expanded axial length greater than the first expanded axial length, wherein a width of the tubular mesh along its second expanded axial length is substantially the same as a width of the tubular mesh along its first expanded axial length, wherein the third tubular shaft extends distally through the proximal end opening as well as the second axial expanded length of the shape memory tubular body. In some embodiments, the tubular mesh is not under tension or substantially under tension in the second configuration or the third configuration defining an axial working range of the tubular mesh.

[0013] In some embodiments, a material, such as a clot capture system includes a first, outer tubular shaft comprising a central lumen; a second tubular shaft configured to be positioned within the central lumen of the first shaft, the second tubular shaft comprising a proximal portion and a distal portion, the distal portion more radially expandable than the proximal portion; a third tubular shaft configured to be positioned within a central lumen of the second shaft; a tubular body that may include shape memory materials that includes a first end, a second end, and an axial length therebetween, the first end having a proximal-facing opening and a ring-shaped capture guide attached to a circumference of the proximal-facing opening, the capture guide operably attached to the second tubular shaft via a sleeve circumscribing a portion of the second tubular shaft, the second end attached to an outer wall of the third tubular shaft. The shape memory tubular body can be compressed within the central lumen of the second tubular shaft in a delivery configuration. The shape memory tubular body can be transformable to a second configuration by axial movement of the second tubular shaft with respect to the first tubular shaft, in which the first end and the capture guide is radially expanded but the second end and a segment of the shape memory tubular body remains radially compressed within the central lumen of the second tubular shaft and the second end is positioned proximal to the first end and the shape memory tubular mesh body has a first expanded axial length. The shape memory tubular body can be transformable to a third configuration by movement of the second tubular shaft with respect

to the third tubular shaft, in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein a width of the shape memory tubular shaft along its second expanded axial length is substantially the same as a width of the shape memory tubular shaft along its first expanded axial length, wherein the third tubular shaft extends distally through the proximal end opening as well as the second axial expanded length of the shape memory tubular body. The shape memory tubular body can, in some cases, be transformable to a fourth configuration by movement of the second tubular shaft with respect to the third tubular shaft. The shape memory tubular body can have a third expanded axial length greater than the second expanded axial length, wherein a width of the shape memory tubular shaft along its third expanded axial length is less than the width of the shape memory tubular shaft along its second expanded axial length. The clot capture system can also include a sleeve that includes a metal or polymer, and the sleeve can be partially or fully radiopaque or radiolucent under fluoroscopy or other imaging.

[0014] Also disclosed herein is a method of performing a thrombectomy. The method can include, for example, accessing the interior of a blood vessel; advancing a thrombus capture device comprising a capture assembly through the blood vessel; positioning the thrombus capture device such that a distal end of the device is distal to the thrombus; actuating the capture assembly to isolate the thrombus within the capture device, wherein the capture assembly is movable from a first configuration having a first axial length and a second configuration having a second axial length, the second axial length being different from the first axial length, wherein the width of the capture assembly does not substantially change from the first configuration to the second configuration; and suctioning, macerating, and/or mechanically removing the thrombus.

[0015] In some embodiments, a method of performing a thrombectomy can include, for example, accessing the interior of a blood vessel; advancing an expanding guiding catheter through the blood vessel; positioning the expanding guiding catheter such that a distal end of the device is proximal to a thrombus; retracting the expanding guide catheter outer member to expand a funnel tip and exposing an expandable inner member; advancing a thrombus capture device comprising a capture assembly through the expanding guide catheter; positioning the thrombus capture device such that a distal end of the device is distal to or within the thrombus; and actuating the capture assembly to isolate the thrombus

within the capture device. The capture assembly can be movable from a first configuration having a first axial length and a second configuration having a second axial length, the second axial length being different from the first axial length. The width of the capture assembly may not substantially change from the first configuration to the second configuration. The method can also include retracting the capture assembly with the thrombus into an expanding guide catheter funnel tip and expandable inner body. The method can also include axially lengthening the thrombus capture device distally and retracting the thrombus into the funnel tip of the expanding guide catheter. The method can further include radially shortening the thrombus capture device to compress the thrombus and promote removal of the thrombus.

[0016] In some embodiments, disclosed herein is a clot capture system that can include a capture assembly configured to isolate a blood clot. The system can include a shape memory body that has a distal end connected to a capture guide comprising a distal or proximal opening. The shape memory body can also include a proximal end connected to a first shaft, and a sidewall between the proximal end and the distal end. The capture guide and the distal zone of the shape memory body opening end can also be fully or partially recaptured inside the outer sheath. The capture assembly can be configured to radially expand the capture guide and a distal zone of the shape memory body opening end while the shape memory body proximal end remains compressed in the delivery configuration. The capture assembly can be movable from a first configuration having a first axial length to a second configuration having a second axial length. The shape memory body can be configured to roll out, invert, evert, and/or variably lengthen proximally from the first configuration to the second configuration. The second axial length can be different from the first axial length. The width of the capture assembly can in some cases not substantially change from the first configuration to the second configuration.

[0017] Also disclosed herein is a capture assembly configured to isolate a blood clot including a shape memory body including a proximal end and a distal end connected to a capture guide including a distal opening, a proximal end connected to a shaft, and a sidewall between the proximal end and the distal end. The capture assembly can be configured to expand the capture guide and the distal shape memory body opening end while the shape memory body proximal end is compressed in the delivery configuration between a first shaft

and a second shaft, and movable from a first configuration having a first axial length and a second configuration having a second axial length. The shape memory body can be configured to roll out/unroll, invert, evert, and/or variably lengthen proximally from the first configuration to the second configuration. The second axial length can be different from the first axial length. In some cases, the width of the capture assembly does not substantially change from the first configuration to the second configuration. Furthermore, the shape memory body can be fully or partially recaptured inside the outer sheath once deployed. The system can also include a sleeve coupled a control line connected to the second shaft configured to move the capture assembly from the first configuration to the second configuration. The first shaft and the second shaft can be off-axis with respect to the capture assembly.

[0018] Also disclosed herein is a method of performing a thrombectomy. The method can include any number of the following: accessing the interior of a blood vessel; advancing a thrombus capture device comprising a capture assembly through the blood vessel; positioning the thrombus capture device such that a distal end of the device is distal to the thrombus; actuating the capture assembly to isolate the thrombus within the capture device, wherein the capture assembly is movable from a first configuration having a first axial length and a second configuration having a second axial length, the second axial length being different from the first axial length, wherein the width of the capture assembly does not substantially change from the first configuration to the second configuration; and suctioning the thrombus.

[0019] In some embodiments, the methods can include any number of the following: accessing the interior of a blood vessel; advancing an expanding guiding catheter through the blood vessel; positioning the expanding guiding catheter such that a distal end of the device is proximal to a thrombus; retracting the expanding guide catheter outer member to expand a funnel tip and exposing an expandable inner member; advancing a thrombus capture device comprising a capture assembly through the expanding guide catheter; positioning the thrombus capture device such that a distal end of the device is distal to or within the thrombus; actuating the capture assembly to isolate the thrombus within the capture device, wherein the capture assembly is movable from a first configuration having a first axial length and a second configuration having a second axial length, the second axial

length being different from the first axial length wherein the width of the capture assembly does not substantially change from the first configuration to the second configuration; and retracting the thrombus into an expanding guide catheter funnel tip and expandable inner body. In some embodiments, the capture guide is first recaptured into the outer sheath of the delivery catheter and then retract into the expanding guide catheter funnel tip and expandable inner body.

[0020] In some embodiments, disclosed herein is a clot capture system. The system can include a first tubular member comprising a central lumen. The system can include a second tubular member. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an end opening, the second end attached to the second tubular member. In some embodiments, at least part of the shape memory tubular body is compressed within the central lumen of the first tubular shaft in a first delivery configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end is radially expanded while the second end and a majority of the shape memory tubular body remains radially compressed within the central lumen of the first tubular shaft and the second end is positioned proximal to the first end and the shape memory tubular body has a first expanded axial length. In some embodiments, the shape memory tubular body is transformable to a third configuration via movement of the first tubular shaft with respect to the second tubular shaft in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein a width of the shape memory tubular body along its second expanded axial length is substantially the same as a width of the shape memory tubular body along its first expanded axial length.

[0021] The system can include a capture guide attached to the first end opening. In some embodiments, the capture guide at least partially circumscribes the first end opening. In some embodiments, the capture guide fully partially circumscribes the first end opening. The system can include an expandable cover element circumscribing the capture guide. In some embodiments, the expandable cover element is inflatable. The system can include a control line extending proximally from the capture guide. The system can include a sleeve attached to the first tubular shaft and the first end opening of the shape memory tubular body. In some embodiments, the shape memory tubular body is configured to invert, evert, or roll

out with respect to the first tubular shaft or the second tubular shaft. In some embodiments, the end opening of the shape memory tubular body is proximal-facing. In some embodiments, the shape memory tubular body comprises a mesh. In some embodiments, the shape memory tubular body is configured to allow fluid flow therethrough. In some embodiments, the second tubular member comprises a central lumen. The system can include an expanding guide element configured to receive the capture assembly. In some embodiments, the expanding guide element comprises an open funnel distal tip. In some embodiments, the open funnel distal tip is porous to allow flow. In some embodiments, the shape memory tubular body has a maximal length of between about 0.5cm and about 125cm. In some embodiments, the shape memory tubular body is transformable to a fourth configuration wherein the shape memory tubular body has a third axial expanded length greater than the second axial expanded length, wherein a width of the shape memory tubular body along its third expanded axial length is less than the width of the shape memory tubular body along its second expanded axial length.

[0022] In some embodiments, disclosed herein is a system for capturing material of interest within a body lumen. The system can include a first tubular member comprising a central lumen. The system can include a second tubular member. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an end opening, the second end attached to an outer wall of the second tubular member. In some embodiments, the shape memory tubular body is compressed within the central lumen of the first tubular shaft in a first delivery configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end opening and a first segment of the shape memory tubular body extending axially in a first direction from the first end opening is radially expanded to a fold point, while a second segment of the shape memory tubular body extends axially from the fold point to the second end of the shape memory tubular body in a second direction opposite the first direction, the second segment relatively radially compressed with respect to the first segment, the second end positioned proximal to the first end. In some embodiments, the shape memory tubular body is transformable to a third configuration via movement of the first tubular shaft with respect to the second tubular shaft in which the axial length of the first segment increases by a first amount, the shape memory tubular body has a second expanded

axial length greater than the first expanded axial length, wherein a width of the shape memory tubular body along its second expanded axial length is substantially the same as a width of the shape memory tubular body along its first expanded axial length.

[0023] In some embodiments, disclosed herein is a clot capture system. The system can include a first tubular member comprising a central lumen. The system can include a second tubular member. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an end opening, the second end attached to an outer wall of the second tubular member. In some embodiments, the shape memory tubular body is compressed within the central lumen of the first tubular shaft in a first delivery configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end opening and a first segment of the shape memory tubular body extending axially in a first direction from the first end opening is radially expanded to a fold point, while a second segment of the shape memory tubular body extends axially from the fold point in a second direction opposite the first direction to the second end, the second segment radially compressed with respect to the first segment, the second end positioned proximal to the first end. In some embodiments, the shape memory tubular body is transformable to a third configuration via movement of the first tubular shaft with respect to the second tubular shaft in which the axial length of the first segment increases by a first amount, the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein a width of the shape memory tubular body along its second expanded axial length is substantially the same as a width of the shape memory tubular body along its first expanded axial length.

[0024] In some embodiments, disclosed herein is a clot capture system. The system can include an outer sheath comprising a central lumen. The system can include a dual lumen shaft configured to be positioned within the central lumen of the outer sheath. The system can include an inner pusher configured to be positioned within a first lumen of the dual lumen shaft. The system can include an anchor pusher configured to be positioned within a second lumen of the dual lumen shaft. The system can include an anchor coupled to the anchor pusher. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening and a

capture guide attached to a portion of the opening. In some embodiments, the shape memory tubular body and the anchor are compressed in a first configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains radially compressed within the lumen of the dual lumen shaft and the shape memory tubular body has a first expanded axial length with a first cross-section, wherein the first cross-section is substantially similar to the cross-section of the capture guide. In some embodiments, the shape memory tubular body is transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein the shape memory tubular body encapsulates the anchor in the third configuration.

[0025] The system can include, for example, one, two, or more anchors. The anchors can have any desired configuration to stabilize or associate with a clot to facilitate removal, including a J-hook shape in some cases. The anchors can penetrate a clot or other material to be captured in some embodiments, or do not penetrate but rather circumscribe or otherwise stabilize or reversibly secure at least a portion of the clot or other material to be captured. In some embodiments, the anchors have a central longitudinal axis that is coaxial. The system can include three anchors, or more. In some embodiments, the cross-section of the anchor is round, ovoid, square, rectangular, or another cross section. In some embodiments, the anchor comprises nitinol. In some embodiments, the anchor forms an angle with the anchor pusher, wherein the angle is approximately 90 degrees. In some embodiments, the anchor forms an angle with the anchor pusher, wherein the angle is approximately 45 degrees. In some embodiments, the anchor forms an angle with the anchor pusher, wherein the angle is between 5 degrees and 135 degrees. In some embodiments, the diameter of the anchor is less than the diameter of the shape memory tubular body when radially expanded. In some embodiments, a portion of the anchor pusher is crescent shaped. In some embodiments, the capture guide comprises nitinol. In some embodiments, the capture guide comprises a central longitudinal axis and wherein the dual lumen shaft is offset from the central longitudinal axis. In some embodiments, the second end of the shape memory tubular body is coupled to the inner pusher. In some embodiments, the capture guide

forms a continuous loop. In some embodiments, the capture guide forms a non-continuous loop.

[0026] In some embodiments, disclosed herein is a clot capture system. The system can include an inner pusher. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening and a capture guide attached to at least a portion of the opening, the second end coupled to the inner pusher. In some embodiments, the shape memory tubular body and the capture guide are compressed in a first configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains radially compressed and the shape memory tubular body has a first expanded axial length with a first cross-section, wherein the first cross-section is substantially similar to the cross-section of the capture guide. In some embodiments, the shape memory tubular body is transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length. In some embodiments, the capture guide forms a continuous loop. In some embodiments, the capture guide forms a non-continuous loop.

[0027] Also disclosed herein is a method of using a clot capture system. The method can include any number of the following: positioning a system near a blood clot in the first configuration; transforming the shape memory tubular body to the second configuration; and transforming the shape memory tubular body to the third configuration to encapsulate the clot. The system can include an inner pusher. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening and a capture guide attached to at least a portion of the opening, the second end coupled to the inner pusher. In some embodiments, the shape memory tubular body and the capture guide are compressed in a first configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains radially compressed and the shape memory tubular body has a first expanded axial length with a first cross-section, wherein the first cross-section is substantially similar to the cross-section of the

capture guide. In some embodiments, the shape memory tubular body is transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length. In some embodiments, the blood clot is within the CNS.

[0028] Also disclosed herein is a method of using a clot capture system. The method can include any number of the following: positioning a system near a blood clot; transforming the shape memory tubular body to the second configuration; expanding the anchor; and transforming the shape memory tubular body to the third configuration to encapsulate the anchor. The system can include an outer sheath comprising a central lumen. The system can include a dual lumen shaft configured to be positioned within the central lumen of the outer sheath. The system can include an inner pusher configured to be positioned within a first lumen of the dual lumen shaft. The system can include an anchor pusher configured to be positioned within a second lumen of the dual lumen shaft. The system can include an anchor coupled to the anchor pusher. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening and a capture guide attached to a portion of the opening. In some embodiments, the shape memory tubular body and the anchor are compressed in a first configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains radially compressed within the lumen of the dual lumen shaft and the shape memory tubular body has a first expanded axial length with a first cross-section, wherein the first cross-section is substantially similar to the cross-section of the capture guide. In some embodiments, the shape memory tubular body is transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein the shape memory tubular body encapsulates the anchor in the third configuration. In some embodiments, deploying the anchor comprises securing the anchor within the clot. In some embodiments, transforming the shape memory tubular body to the third configuration to encapsulate the anchor further comprises encapsulating the clot. In some embodiments, the blood clot is a neurological blood clot.

[0029] In some embodiments, disclosed herein is a clot capture system. The system can include a first tubular member comprising a central lumen. The system can include a second tubular member. The system can include a plurality of axially spaced-apart anchors extending radially outwardly from the first tubular member or the second tubular member. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an end opening, the second end attached to the second tubular member. In some embodiments, at least part of the shape memory tubular body is compressed within the central lumen of the first tubular shaft in a first delivery configuration. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end is radially expanded while the second end and a majority of the shape memory tubular body remains radially compressed within the central lumen of the first tubular shaft and the second end is positioned proximal to the first end and the shape memory tubular body has a first expanded axial length. In some embodiments, the shape memory tubular body is transformable to a third configuration via movement of the first tubular shaft with respect to the second tubular shaft in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein a width of the shape memory tubular body along its second expanded axial length is substantially the same as a width of the shape memory tubular body along its first expanded axial length.

[0030] In some embodiments, disclosed herein is a clot capture system. The system can include an anchor. The system can include a tubular body comprising a first end, a second end, and an axial length therebetween. The first end can have an opening. The tubular body and the anchor can be compressed in a delivery configuration. The tubular body and the anchor can be transformable to a deployed configuration in which the anchor and the shape memory tubular body first end are expanded but the shape memory tubular body second end and a majority of the shape memory tubular body remains compressed and the tubular body has a first expanded axial length. The shape memory tubular body can transformable to a capture configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length. The shape memory tubular body can encapsulate the anchor, or a portion thereof, in the capture configuration. In some embodiments, the system can include two or more anchors. In some embodiments, the

two anchors have a central longitudinal axis that is coaxial. In some embodiments, the anchor is a stent like structure. In some embodiments, the anchor is a balloon. In some embodiments, the anchor is a disk. In some embodiments, the anchor comprises nitinol. In some embodiments, the anchor comprises a spherical balloon. In some embodiments, the anchor is configured to entangle a clot. In some embodiments, the anchor is coupled to the shape memory tubular body. In some embodiments, the anchor is a funnel. In some embodiments, the anchor is tapered from the distal end to the proximal end of the anchor. In some embodiments, the shape memory tubular body comprises a central longitudinal axis and wherein the anchor is offset from the central longitudinal axis. In some embodiments, the second end of the shape memory tubular body is coupled to an inner pusher.

[0031] In some embodiments, disclosed herein is a clot capture system. The system can include an anchor. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween. The first end can have an opening. The shape memory tubular body and the anchor can be configured to be compressed during delivery. The first end of the shape memory tubular body and the anchor can be configured to be expanded while the second end and a majority of the shape memory tubular body remains compressed. The shape memory tubular body can have a first expanded axial length with a first cross-section. The shape memory tubular body can be configured to be axially lengthened. In some embodiments, the system can include a pusher, wherein the second end of the shape memory tubular body is coupled to the pusher. In some embodiments, the anchor and the shape memory tubular body are fixed together.

[0032] In some embodiments, disclosed herein is a method of using a clot capture system. The method can include positioning any clot capture system disclosed herein near a blood clot. The method can include expanding the shape memory tubular body and the anchor. The method can include axially lengthening the shape memory tubular body to encapsulate the clot. In some embodiments, the blood clot is within the central nervous system.

[0033] In some embodiments, disclosed herein is a method of using a clot capture. The method can include positioning any clot capture system disclosed herein near a blood clot. The method can include transforming the shape memory tubular body and the

anchor to the deployed configuration. The method can include transforming the shape memory tubular body and the anchor to the capture configuration to encapsulate the anchor.

[0034] In some embodiments, disclosed herein is a clot capture system. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains compressed within the first lumen of the dual lumen shaft and the shape memory tubular body has a first expanded axial length with a first cross-section. In some embodiments, the first cross-section is substantially similar to a cross-section of the capture guide. In some embodiments, the cross-section of the shape memory tubular body is round. In some embodiments, the anchor forms an angle with the anchor pusher when expanded, wherein the angle is approximately 90 degrees. In some embodiments, the anchor forms an angle with the anchor pusher when expanded, wherein the angle is approximately 45 degrees. In some embodiments, the anchor forms an angle with the anchor pusher when expanded, wherein the angle is approximately 5 degrees. In some embodiments, wherein a diameter of the anchor is less than a diameter of the shape memory tubular body when expanded. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains compressed and the shape memory tubular body has a first expanded axial length with a first cross-section. In some embodiments, the first cross-section is substantially similar to a cross-section of the capture guide. In some embodiments, the shape memory tubular body is transformable to a second configuration in which the first end is radially expanded while the second end and a majority of the shape memory tubular body remains compressed within the central lumen of the first tubular member and the second end is positioned proximal to the first end and the shape memory tubular body has a first expanded axial length. In some embodiments, a width of the shape memory tubular body along the second expanded axial length is substantially the same as a width of the shape memory tubular body along the first expanded axial length. In some embodiments, disclosed herein is a method of using a clot capture system. The method can include transforming the shape memory tubular body to the third configuration to encapsulate the blood clot. In some embodiments, the blood clot is within the central nervous system. In some embodiments, expanding the anchor

comprises securing the anchor within the blood clot. In some embodiments, transforming the shape memory tubular body to the third configuration to encapsulate the anchor further comprises encapsulating the blood clot.

[0035] In some embodiments, disclosed herein is a clot capture system. The system can include a shaft. The system can include a plurality of axially spaced-apart anchors comprising a reduced configuration and an expanded configuration. In some embodiments, the plurality of axially spaced-apart anchors extend radially outward from the shaft in the expanded configuration. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween. In some embodiments, the first end can include an opening. In some embodiments, the shape memory tubular body can be compressed in a compressed configuration. In some embodiments, the shape memory tubular body can be transformable to a first expanded configuration in which the first end is expanded. In some embodiments, the second end and a portion of the shape memory tubular body can be compressed in the first expanded configuration. In some embodiments, the shape memory tubular body can have a first expanded axial length in the first expanded configuration. In some embodiments, the shape memory tubular body can be transformable to a second expanded configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length. In some embodiments, the shape memory tubular body circumscribes the plurality of axially spaced-apart anchors in the second expanded configuration. In some embodiments, the plurality of axially spaced-apart anchors comprise three or more anchors. In some embodiments, the plurality of axially spaced-apart anchors are coaxial. In some embodiments, the plurality of axially spaced-apart anchors comprise nitinol. In some embodiments, an anchor of the plurality of axially spaced-apart anchors forms an angle with an anchor pusher when expanded, wherein the angle is approximately 90 degrees. In some embodiments, an anchor of the plurality of axially spaced-apart anchors forms an angle with an anchor pusher when expanded, wherein the angle is approximately 45 degrees. In some embodiments, a cross-section of an anchor of the plurality of axially spaced-apart anchors is less than a cross-section of the first end of the shape memory tubular body when expanded. In some embodiments, the plurality of axially spaced-apart anchors are coupled to an anchor pusher. In some embodiments, the second end of the shape memory tubular body is coupled to an inner pusher.

[0036] In some embodiments, disclosed herein is clot capture system. The system can include a shaft. The system can include an anchor comprising a reduced configuration and an expanded configuration. In some embodiments, the anchor extends outward from the shaft in the expanded configuration. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, In some embodiments, the first end can have an opening. In some embodiments, the shape memory tubular body can be compressed in a compressed configuration. In some embodiments, the shape memory tubular body can be transformable to a first expanded configuration wherein the first end is expanded. In some embodiments, the second end and a portion of the shape memory tubular body can be compressed in the first expanded configuration. In some embodiments, the shape memory tubular body can have a first expanded axial length. In some embodiments, the shape memory tubular body can be transformable to a second expanded configuration in which the shape memory tubular body has a second expanded axial length. In some embodiments, the second expanded axial length is greater than the first expanded axial length. In some embodiments, the first cross-section is round. In some embodiments, the anchor forms an angle with an anchor pusher when expanded, wherein the angle is between 5 degrees and 135 degrees. In some embodiments, the system can include a second anchor. In some embodiments, the anchors are coaxial. In some embodiments, the second end of the shape memory tubular body is coupled to an inner pusher.

[0037] In some embodiments, disclosed herein is clot capture system. The system can include a shaft. The system can include an anchor configured to expand outwardly from the shaft. The system can include a shape memory tubular body comprising a first end, a second end, and an axial length therebetween. In some embodiments, the first end can have an opening. In some embodiments, the shape memory tubular body can be compressed in a compressed configuration. In some embodiments, the shape memory tubular body can be transformable to a first expanded configuration wherein the first end is expanded while the second end and a portion of the shape memory tubular body remains compressed. In some embodiments, the shape memory tubular body can have a first expanded axial length in the first expanded configuration. In some embodiments, the shape memory tubular body can be transformable to a second expanded configuration wherein the shape memory tubular body has a second expanded axial length greater than the first expanded axial length. In some

embodiments, the shape memory tubular body surrounds the anchor in the second expanded configuration. In some embodiments, the system can include a second anchor. In some embodiments, the anchors are spaced axially apart along the longitudinal axis of the shaft. In some embodiments, the anchor is configured to entangle a clot. In some embodiments, a cross-section of the anchor is less than a cross-section of the first end of the shape memory tubular body when expanded.

[0038] In some embodiments, the shape memory tubular body can have a first expanded axial length in the first expanded configuration extending from the first end to a fold. In some embodiments, the fold forms the distal end of the shape memory tubular body in the first expanded configuration. In some embodiments, the first end and the second end are proximal to the distal end in the first expanded configuration. In some embodiments, the shape memory tubular body can circumscribes at least one anchor of the plurality of axially spaced-apart anchors in the second expanded configuration. In some embodiments, an anchor of the plurality of axially spaced-apart anchors forms an angle with an anchor pusher when the anchor is expanded, wherein the angle is approximately 90 degrees. In some embodiments, an anchor of the plurality of axially spaced-apart anchors forms an angle with an anchor pusher when the anchor is expanded, wherein the angle is approximately 45 degrees. In some embodiments, a cross-section of each of the plurality of axially spaced-apart anchors is less than a cross-section of the first end of the shape memory tubular body when the plurality of axially spaced-apart anchors and the first end of the shape memory tubular body are expanded. In some embodiments, the shape memory tubular body comprises a distal end in the first expanded configuration. In some embodiments, the first end and the second end are proximal to the distal end in the first expanded configuration. In some embodiments, a cross-section of the shape memory tubular body is round when the shape memory tubular body is expanded. In some embodiments, the anchor forms an angle with an anchor pusher when the anchor is expanded, wherein the angle is between 5 degrees and 135 degrees. In some embodiments, the first anchor and the second anchor are coaxial. In some embodiments, an anchor can be configured to expand. In some embodiments, the shape memory tubular body comprises a dynamic fold point between the first end and the second end in the first expanded configuration. In some embodiments, the first end and the second end are proximal to the dynamic fold point in the first expanded configuration. In some

embodiments wherein the first anchor and the second anchor are spaced axially apart along the longitudinal axis of a shaft. In some embodiments, a cross-section of the anchor is less than a cross-section of the first end of the shape memory tubular body when the anchor and the first end are expanded.

[0039] In some embodiments, the shape memory tubular body and the at least one anchor can be transformable to a second configuration in which the at least one anchor and the first end of the shape memory tubular body are expanded but the second end of the shape memory tubular body and a portion of the shape memory tubular body remains compressed such that the second end is positioned proximal to the first end and the first end overlaps with the portion of the shape memory tubular body that remains compressed. In some embodiments, the first end overlaps with the portion of the shape memory tubular body that remains compressed. In some embodiments, the shape memory tubular body can be transformable to a configuration in which the opening is expanded and a first segment of the shape memory body extending axially in a first direction from the opening is expanded to a fold point, the first segment having a first expanded axial length, and a second segment of the shape memory body extending axially from the fold point to the second end of the shape memory body in a second direction opposite the first direction such that the second segment of the shape memory tubular body extends at least partially within the first segment of the shape memory tubular body. In some embodiments, the second segment is relatively compressed with respect to the first segment. In some embodiments, the second end positioned proximal to the first end. In some embodiments, the second segment of the shape memory tubular body extends at least partially within the first segment of the shape memory tubular body.

BRIEF DESCRIPTION OF THE FIGURES

[0040] Figure 1 illustrates examples of a catheter system, and various possible elements that can be included in a material capture system, according to some embodiments of the invention.

[0041] Figure 2 illustrates a close-up view of the thrombus capture systems of Figures 1 and 2.

[0042] Figure 3 illustrates an axially-lengthening thrombus capture (ALTC) system in the initial deployment configuration with the ALTC device expanded, according to some embodiments of the invention.

[0043] Figure 4 illustrates a close up view of the ALTC system distal segment position in the delivery configuration indicating the outer sheath and nose tip, according to some embodiments of the invention.

[0044] Figure 5 illustrates the distal end of an axial lengthening thrombus capture device at the initial deployment position, according to some embodiments of the invention.

[0045] Figure 6 illustrates the axial lengthen thrombus capture device retracting proximally to deploy and lengthen, according to some embodiments of the invention.

[0046] Figure 7 illustrates the axial lengthen thrombus capture device is fully deployed and the funnel tip of the guide catheter is positioned within the ALTC device, according to some embodiments of the invention.

[0047] Figures 8 and 9 illustrate different views of the initial deployment position of the ALTC Device and the funnel tip of the suction catheter, according to some embodiments of the invention.

[0048] Figure 10 illustrates the partially deployed ALTC Device, according to some embodiments of the invention.

[0049] Figure 11 illustrates an ALTC device deployed configuration where the funnel tip of the suction catheter is positioned inside the ALTC device, according to some embodiments of the invention.

[0050] Figure 12 illustrates the Axial Lengthening Thrombus Capture (ALTC) assembly wherein the distal end of the ALTC device is in the expanded (deployed) configuration and is fixed to the thrombus capture guide and capture pullwire, according to some embodiments of the invention. For purpose of illustration, the proximal end is in a collapsed configuration and extends proximally.

[0051] Figure 13 illustrates the axial lengthening thrombus capture device in the initial deployed configuration, according to some embodiments of the invention.

[0052] Figure 14 illustrates the thrombus capture element of the ALTC device that can include a stent or braided mesh, according to some embodiments of the invention.

[0053] Figures 15A-C illustrate an embodiment of the ALTC system, a distal portion of the ALTC System and a proximal portion of the ALTC System respectively.

[0054] Figure 16A illustrates another embodiment of the axial lengthening thrombus capture device in the delivery configuration, according to some embodiments of the invention.

[0055] Figure 16B illustrates the axial lengthening thrombus capture device in the initial deployed configuration wherein the outer sheath is retracted to expanded the axial lengthen thrombus capture device. The loop is coupled to the sleeve wherein it is coupled to the capture catheter shaft, according to some embodiments of the invention.

[0056] Figure 16C illustrates the axial lengthening thrombus capture device retracting proximally and lengthening, according to some embodiments of the invention.

[0057] Figure 16D illustrates the lengthening of the axial lengthening thrombus capture device and in some cases at full deployment, according to some embodiments of the invention.

[0058] Figures 17A-D illustrate different configurations of the ALTC device, according to some embodiments of the invention.

[0059] Figures 18A-B illustrate an embodiment of a distal portion of the axially-lengthening thrombus capture system with a cover element radially outward of, and partially or completely circumscribing the capture guide of the ALTC device, which can be in the shape of a ring as illustrated.

[0060] Figures 19A-C illustrates an embodiment of an axially-lengthening thrombus capture system, configured to allow the guidewire to distally exit the system prior to exiting the luer port at the proximal end of the system.

[0061] Figure 20A illustrates the expanding guide catheter system in the delivery configuration, according to some embodiments of the invention.

[0062] Figure 20B illustrates the expanding guide catheter system wherein the funnel tip is in deployed position and the obturator is positioned in the expanding guide catheter lumen, according to some embodiments of the invention.

[0063] Figure 20C illustrates the expanding guide catheter having a funnel tip, expanding distal segment and non-expanding proximal segment, according to some embodiments of the invention.

[0064] Figure 20D illustrates an obturator, according to some embodiments of the invention.

[0065] Figures 21A-C illustrate the expanding guide catheter system including the expanding guide catheter, outer cover and obturator, according to some embodiments of the invention.

[0066] Figure 21D illustrates an embodiment wherein a cover tip encapsulates the distal end of the outer cover of the expanding guide catheter system, according to some embodiments of the invention. Figures 21E-F illustrate an embodiment of a hemostasis valve for use within a hemostasis guide catheter system.

[0067] Figure 22 illustrates the outer sheath assembly of the capture device, according to some embodiments of the invention.

[0068] Figures 23 and 24 illustrate the distal end and proximal end of the outer sheath assembly respectively.

[0069] Figure 25 illustrates the capture catheter assembly, according to some embodiments of the invention.

[0070] Figure 26 illustrates the proximal end of the capture catheter, according to some embodiments of the invention.

[0071] Figure 27 illustrates an embodiment of a key cap feature to enable an anti-rotation of the hypotube pusher.

[0072] Figures 28 and 29 illustrates the suction catheter that can include a funnel tip, catheter shaft, and connector with seal, according to some embodiments of the invention.

[0073] Figure 30 illustrates the distal end of the suction catheter indicating the funnel tip and catheter shaft, according to some embodiments of the invention.

[0074] Figure 31 illustrates the proximal end of the suction catheter indicating the connector with seal and ports for use with filter chamber and access to flush catheter lumen, according to some embodiments of the invention.

[0075] Figures 32–41 illustrate different macerator designs and shapes, according to some embodiments of the invention.

[0076] Figure 42 illustrates a filter collection chamber that can include an inflow port to connect to a syringe, an outflow port to connect to the suction catheter, a plunger, a

filter to filter blood clot or debris and retain in the chamber and a chamber to collect blood clot or debris, according to some embodiments of the invention.

[0077] Figure 43 illustrates a blood clot lodging in the left side of pulmonary system, according to some embodiments of the invention.

[0078] Figure 44A and 44B illustrate blood clots residing in the left side pulmonary system and the capture device respectively, according to some embodiments of the invention.

[0079] Figure 45 illustrates the initial deployment configuration of the axial lengthening thrombus capture device positioned distal to the thrombus occluded area and a funnel tip positioned proximal to the thrombus occlusion, according to some embodiments of the invention.

[0080] Figure 46 illustrates the axial lengthening thrombus capture device lengthening proximally to capture the thrombus, according to some embodiments of the invention.

[0081] Figure 47 illustrates the axial lengthening thrombus capture device completely capturing the thrombus, and a funnel tip is inside the axial lengthening thrombus capture device.

[0082] Figure 48A illustrates the delivery configuration of the capture catheter device, according to some embodiments of the invention.

[0083] Figure 48B illustrates the initial deployment position of the axial lengthening thrombus capture device, according to some embodiments of the invention.

[0084] Figure 48C illustrates the lengthening of the axial lengthening thrombus capture device, according to some embodiments of the invention.

[0085] Figure 48D illustrate the final deployment of the axial lengthening thrombus capture device, according to some embodiments of the invention.

[0086] Figures 49A and 49B illustrate another embodiment of the axial lengthening thrombus capture device wherein the guidewire lumen and capture catheter is offset to the longitudinal axis of the axial lengthening thrombus capture device, according to some embodiments of the invention.

[0087] Figures 50A – 50G illustrate an embodiment of the retrieval of thrombus into the expanding guide catheter wherein the ALTC device lengthens distally and creates

additional space and the thrombus is redistributed and enable better retrieval into the expanding guide catheter. The funnel tip and expanding section of the expanding guide catheter also facilitate the ease of thrombus retrieval.

[0088] Figure 51 illustrates an embodiment of a system for removing blood clots.

[0089] Figure 52 illustrates the distal end of the capture device of the system of Figure 51 in the deployed configuration.

[0090] Figure 53 illustrates the distal end of the capture device of the system of Figure 51 in an initial deployed configuration.

[0091] Figure 54 illustrates the distal end of the capture device of the system of Figure 51 in a second configuration.

[0092] Figure 55 illustrates the distal end of the capture device of the system of Figure 51 in a third configuration.

[0093] Figure 56 illustrates an embodiment of the basket mesh element of the system of Figure 51. The basket mesh element can made of metallic materials such as Nitinol. The mesh element can be braided or laser cut.

[0094] Figure 57 illustrates an embodiment of a capture device element of the system of Figure 51.

[0095] Figures 58A- 58B illustrate embodiments of an expandable loop element of the system of Figure 51.

[0096] Figure 59 illustrates a view of a capture device opening for a system for neuro thrombus.

[0097] Figure 60 illustrates another view of a capture device opening of Figure 59.

[0098] Figure 61 illustrates an embodiment of a system.

[0099] Figure 62 illustrates a distal end of the capture device system of the system of Figure 61.

[0100] Figure 63 illustrates a proximal end of the system of Figure 61.

[0101] Figure 64 illustrates an anchor assembly of the system of Figure 61.

[0102] Figure 65 illustrates a side view of a distal end of the capture device and anchors of the system of Figure 61.

[0103] Figure 66 illustrates a top view of a distal end of the capture device and anchors of the system of Figure 61.

[0104] Figure 67 illustrates a front view of a distal end of the capture device of the system of Figure 61.

[0105] Figure 68A illustrates the capture device of the system of Figure 61 in an initial deployed configuration.

[0106] Figure 68B illustrates the capture device and first anchor release of the system of Figure 61 when the outer sheath retracts proximally.

[0107] Figure 68C illustrates the capture device, first anchor, and second anchor release of the system of Figure 61 when the outer sheath is retracted.

[0108] Figure 68D illustrates the capture device, first anchor, second anchor, and third anchor release of the system of Figure 61 when the outer sheath is retracted.

[0109] Figure 69A illustrates the capture device of the system of Figure 61 in an initial deployed configuration and the anchors are fully released.

[0110] Figure 69B illustrates the capture device of the system of Figure 61 lengthened proximally to encapsulate the first anchor.

[0111] Figure 69C illustrates the capture device of the system of Figure 61 lengthened proximally to encapsulate the anchors.

[0112] Figures 70A and 70B illustrate views of an embodiment of a pusher lock system.

[0113] Figures 71A-71D illustrate views of a pusher lock of the pusher lock system of Figure 70A.

[0114] Figure 72 illustrates a method of assembly an ALTC device to a capture guide.

[0115] Figure 73 illustrates an embodiment of an anchor.

[0116] Figure 74 illustrates an embodiment of an anchor.

[0117] Figure 75 illustrates a distal end of a capture device system including the anchor in a vessel of Figure 73.

[0118] Figure 76A illustrates the capture device of the system of Figure 75 in an initial deployed configuration and the anchor is fully expanded.

[0119] Figure 76B illustrates the capture device of the system of Figure 75 lengthened proximally to encapsulate a portion of the anchor.

[0120] Figure 76C illustrates the capture device of the system of Figure 75 lengthened proximally to encapsulate the anchor.

[0121] Figure 77A illustrates the capture device of the system of Figure 75 in an initial deployed configuration and the anchor is fully expanded.

[0122] Figure 77B illustrates the capture device of the system of Figure 75 lengthened proximally to encapsulate a portion of the anchor.

[0123] Figure 77C illustrates the capture device of the system of Figure 75 lengthened proximally to encapsulate the anchor.

[0124] Figure 78 illustrates a distal end of a capture device system including an embodiment of an anchor.

[0125] Figure 79 illustrates a distal end of a capture device system including an embodiment of an anchor.

[0126] Figure 80 illustrates the capture device system in a vessel of Figure 79.

[0127] Figure 81 illustrates a distal end of a capture device system including an embodiment of an anchor.

[0128] Figure 82 illustrates a distal end of a capture device system including an embodiment of an anchor.

[0129] Figure 83 illustrates the capture device system in a vessel of Figure 82.

[0130] Figure 84 illustrates a distal end of a capture device system including an embodiment of an anchor.

[0131] Figure 85 illustrates a distal end of a capture device system including an embodiment of an anchor.

[0132] Figure 86 illustrates the capture device system in a vessel of Figure 85.

[0133] Figure 87 illustrates a capture device system in a vessel.

[0134] Figures 88A-88R illustrate embodiments of an anchor.

[0135] Figure 89 illustrates an embodiment of a system designed for removing a blood clot.

[0136] Figure 90 illustrates a distal end of the system of Figure 89.

[0137] Figure 91 illustrates a distal end of a system including an embodiment of an anchor.

[0138] Figure 92 illustrates a distal end of a system including an embodiment of an anchor.

[0139] Figure 93 illustrates a distal end of a system including an embodiment of an anchor.

[0140] Figure 94 illustrates the capture device of the system of Figure 93 lengthened proximally to encapsulate the anchor.

[0141] Figure 95 illustrates a distal end of a system including an embodiment of an anchor.

[0142] Figures 96A-96B illustrate an embodiment of an expandable guide catheter.

DETAILED DESCRIPTION

[0143] The present invention provides, in some embodiments, systems and methods that can be delivered percutaneously in a body to retrieve and removal materials including blood clots, stones/calculi, and/or foreign materials in a body lumen, including a blood vessel, such as an arterial vessel or a venous vessel within the circulatory system. The present invention can, in some embodiments, also apply to nonvascular areas to treat, for example, gallstones, kidney stones, common bile duct stones, and the like.

[0144] Systems can be delivered percutaneously, via a cut-down approach, a thoracoscopic approach, or via other approaches, for example, using a catheter system 35, of which a perspective view of an embodiment is shown in Figure 1. Figure 1 also illustrates examples of various possible elements that can be included in a material capture system, according to some embodiments of the invention. As illustrated in Figure 1, included in some embodiments are any number of, such as one, two, or more of the following components: a first tubular member, such as an outer sheath 1, a second tubular member, such as a capture catheter 12, a third tubular member, such as a guidewire tube 6 an axial lengthening thrombus capture device 8, a suction catheter 2, and a filter collection chamber 5. The outer sheath 1 can, in some embodiments, be an elongate tubular member with a central lumen therethrough, and have a proximal end 1000 and a distal end 1001. The distal end 1001 of the

outer sheath 1 can be operably connected to a capture device (e.g., tubular mesh 8), which can be movably axially with respect to the outer sheath 1. In some embodiments, the outer sheath 1 has a relatively rigid proximal portion and a distal portion that is more flexible than the relatively rigid proximal portion, which can be advantageous to flexibly expand if necessary to accommodate the passage of large clots and/or other materials. The proximal end 1000 of the outer sheath 1 can connect to a proximal hub 1003 that may include any number of: the suction catheter 2, capture catheter 12, guidewire tube 6, and filter collection chamber 5. Non-limiting examples of other optional elements that can be included in the system (not shown in Figure 1) include a macerator tool (described elsewhere herein) and a discrete expanding guide catheter (described elsewhere herein. In some embodiments, the outer sheath 1 has a lumen configured to house the suction catheter 2, which in turn has a lumen configured to house the capture catheter 4, which in turn has a lumen configured to house the guidewire tube/guidewire lumen assembly 6 and the axial lengthening thrombus capture device (ALTC device) 8, which in turn has a lumen configured to house a guidewire (not shown) therethrough. An ALTC device as defined herein can include any structure, such as a net-like structure for example, configured to capture materials within a body location and axially lengthen and shorten through a working range, with or without radially shortening in width or diameter throughout that working range depending on the desired clinical result. In some embodiments, the outer sheath 1 has an inner diameter configured to house the capture catheter 12 coaxially therein, and the capture catheter 12, which in turn has a lumen configured to house the guidewire tube 6 and the body of the ALTC device 8. The ALTC device 8 can in some embodiments including a mesh net-like structure with a proximal-facing opening at one end that can be made of a shape memory metal or polymer, a non-shape memory metal such as stainless steel, or another non-shape memory fabric, embodiments of which are described in detail elsewhere herein. In some embodiments, conventional net-like structures such as used in IVC and other embolic filters can be utilized with systems and methods herein. In some embodiments, a thrombus capture device can be configured in some embodiments to axially lengthen throughout a working range, with or without radially shortening the device throughout the working range.

[0145] Figure 2 illustrates a close-up view of the proximal end 1000 of the thrombus capture systems of Figure 1. Illustrated is outer sheath 1 configured to, in some

embodiments, house suction catheter 2 therethrough. Also illustrated is the proximal end of the outer sheath 1 which can terminate in a connector 17 and hemostasis seal 190, of which another tube, such as the suction catheter 2 (and/or capture catheter 4) can be inserted coaxially into. The proximal end of the suction catheter 2 can also include a connector 3 having a seal, and a lumen of which the capture catheter 12 can be inserted into. The capture catheter 4 can also include a connector with a seal 18 at its proximal end. The guidewire tube 6 with a lumen to house a guidewire therethrough can be configured to fit coaxially within the capture catheter shaft 12. Also illustrated is an optional filter collection chamber 5 with a lumen fluidly connected to a lumen of the suction catheter 2. A proximal hub 17 is also illustrated, as well as a flush port 20. In some embodiments, suction is not required (and as such a suction catheter 2 is not included in the system), and the clot or other materials can be captured either mechanically, hydraulically and/or maceration via the ALTC device 8.

[0146] Figure 3 illustrates an axially-lengthening thrombus capture system 35 in the initial deployment configuration with the ALTC device 8 radially expanded, according to some embodiments of the invention. Also illustrated is nose tip 7 distal to the ALTC device 8. Relative axial movement of the outer tube 1 with respect to capture catheter 4 can allow for transformation of a first end (e.g., an expanded proximal end with a proximal-facing opening, or distal or laterally facing opening in other embodiments) of the ALTC device 8 from a radially compressed to a radially expanded configuration. In some embodiments, the proximal end opening of the ALTC device 8 includes a capture guide 11 that takes the form of, in some embodiments, a radially expandable shape memory partial or full ring-like annular structure that expands once free of the sidewall of the outer tube 1 along with a portion of the ALTC device mesh 8 attached to the capture guide 11. In the illustrated configuration, however, a significant portion of the surface area and/or the axial length of the mesh of the ALTC device remains in a compressed configuration within the lumen of the capture catheter 4, as the other end of the ALTC device mesh 8 is still operably attached, such as fixed to the outer diameter sidewall of the guidewire catheter 6.

[0147] Figure 4 illustrates a close up view of the distal end of the ALTC catheter system 35 in the delivery configuration including the distal end 1001 of the outer sheath 1 and nose tip 7, which can be atraumatic and tapered as shown, according to some embodiments of the invention.

[0148] The ALTC Device 8 can function to retrieve and capture materials such as thromboemboli. The capture catheter 4 is shown, along with the ALTC Device 8, capture catheter shaft body 12, pull wire 10, and thrombus capture guide 11.

[0149] As illustrated in Figures 5-9 for example, a thrombus capture guide 11 can attach to a portion, such as an open end of the ALTC Device 8 and one, two, or more capture pull wires 10 where the capture pull wires are positioned inside the side lumen of the suction catheter 2 or outside of the lumen in other embodiments, and extends proximally. The distal end of the capture pullwire 10 can be connected to the proximal end of the ALTC device 8 at the capture guide 11 as illustrated. The capture pullwire 10 can extend proximally through the length of the outer sheath 1, and the proximal end of the pullwire 10 can be pushed or pulled allow a user to control, such as adjust the axial length of the ALTC device 8, for example when axially elongating the ALTC device in a proximal direction. In some embodiments, the capture pullwire 10 and the capture guide 11 are the only elements attached to the proximal end of the ALTC device 8. In some embodiments, the capture pullwire 10 and the capture guide 11 can be made into a single component such as a Loop. In some other embodiments, the capture guide and the proximal end of the ALTC device is sutured in place using silk or polymeric filaments such as Ultra-High Molecular Weight polyethylene, Nylon, PET, PTFE. In some embodiments, the open end of the ALTC device is covered with a low durometer film or coating and is then folded over the capture guide 11 and suture to secure the assembly. In another embodiment, the open end of the ALTC device 8, capture guide 11 and sutured assembly is coated with a low durometer polymeric materials. Another method to secure the wire ends is to apply polymeric fabric either on the outer or inner surface of the tubular structure and secure via suturing in place with suture filaments. The fabric can be at least one piece initially wrapped either on the inner or outer surface of the tubular structure and then folded over to the opposite side to secure and protect with wire ends. The two sides of the fabric can secured to the tubular structure using suture filament. Other means of securing the fabric to the tubular structure such as thermal bonding, press, lamination, chemicals, mechanical securement, and lasers can be used in some embodiments. The closed end of the ALTC device can be attached to an outer surface of the guidewire tube 6, which in turn can be positioned within a lumen of the capture catheter shaft 12. As such, axial elongation of the ALTC device in a distal direction can be achieved by, for

example, movement of the guidewire tube 6 and pullwire 10 distally with respect to the capture catheter shaft 12. The axial elongation of the ALTC device in a proximal direction can be achieved by, for example, movement of the capture pullwire and capture catheter shaft proximally. The Thrombus Capture Guide 11 can be formed, for example, from metallic, shape memory, or other appropriate materials. In some embodiment, the thrombus capture guide 11 can include a loop configuration and be formed from nitinol shape memory wire of various geometries such as round, oval, elliptical, flat, and the like. The thrombus capture guide 11 can be formed of different shapes such as a circular loop, oval loop, z-shape, etc. In some embodiment, the loop 11 can be shaped set either into coils, multiple full circles, full circle or partial circles where the ends of the wire formed into two legs. The partial circle can be from, for example, 180 degrees to 359 degrees or 220 degrees to 359 degrees. The legs can be configured to be off-axis to the loop such that it can be right angle, acute or obtuse angle relative to the loop. It can be arcuate and form a partial or full ring as illustrated, and can circumscribe or otherwise form an outer diameter, and define the proximal-most end of the ALTC Device 8. The thrombus capture guide 11 can in some embodiments include a single loop or multiple loops positioned along the length of the ALTC Device 8 and not necessarily be present or have the entire guide 11 at the proximal-facing end opening end of the ALTC device 8. In some embodiments, the thrombus capture guide 11 does not include a loop. The ALTC Device tubular structure can be configured to be compressed and positioned within the Capture Catheter Shaft 12 lumen during introduction into the vascular system where the Capture Catheter Shaft 12 is configured to be positioned coaxially within and extend through the tubular structure and thrombus capture guide 11.

[0150] As illustrated in Figure 5, the Axial Lengthening Thrombus Capture Device (ALTC Device) 8 can be in some embodiments a generally tubular net-like mesh structure that is collapsible, expandable and configured to axially lengthen or shorten, such as within a working range, while maintaining or substantially maintaining its diameter within the working range to retrieve and capture foreign or otherwise unwanted materials within the body, including the vascular system such as blood clots, thrombus and/or foreign materials.

[0151] As shown, for example, in Figure 6, it can also be possible to lengthen the ALTC Device 8 in an appropriate direction, such as distally, by pushing the capture catheter 12 relative to the guidewire shaft 6, thereby allowing additional reserve radially compressed

length of the tubular mesh 8 to radially expand out of the confines of the lumen of the capture catheter 12 to axially lengthen the Thrombus Capture Device 8 and maintain its constant or substantially constant diameter through a working range. The other end of the ALTC device 8 at its radially compressed end can be fixed to the outer sidewall of the guidewire tube 6. A combination technique of, for example, manipulating the Capture Pull wire 10 attached to the Capture Catheter shaft 12 movement (Figure 6) can position the ALTC device at a desired location within the body lumen, and movement of the guidewire catheter 6 axially with respect to the capture catheter shaft 12 will also axially lengthen or shorten the ALTC Device 8 while maintaining its diameter through a working range. When the ALTC Device 8 is in the deployed (expanded) configuration, the ALTC Device 8 can also be stretched beyond the working range to an extended axial length to reduce its diameter.

[0152] Figure 7 illustrates the axial lengthening thrombus capture device 8 is fully deployed such that the attachment site 128 of the ALTC device 8 on the guidewire lumen 6 outer diameter is distal to the distal end of the capture catheter shaft 12 and the funnel tip 9 of the suction catheter is positioned within the ALTC, according to some embodiments of the invention.

[0153] Figures 8 and 9 illustrate different views of the initial deployment position of the ALTC Device 8 and the funnel tip of the optional suction catheter 2, according to some embodiments of the invention.

[0154] Figure 10 illustrates the partially deployed ALTC Device, according to some embodiments of the invention, where the ALTC device 8 is axially lengthened while maintaining its width normal to the axial direction.

[0155] Figure 11 illustrates an ALTC device deployed configuration where the funnel tip of the suction catheter is positioned inside the ALTC device, according to some embodiments of the invention.

[0156] As illustrated, a Guidewire Lumen Assembly 6 can include a nose tip 7, shaft, lumen, and a proximal connector and port where a guidewire can be inserted therethrough. The central lumen can have a distal opening in some embodiments The guidewire tube 6 can be used to navigate and track over the guidewire in the vascular system. The guidewire tube 6 can extend coaxially within the lumen of the catheter shaft 12. A nose tip 7 can form or otherwise connect to the distal end of the guidewire tube 6 6 shaft to aid

tracking the system through the vascular system, and can be atraumatic in some embodiments. The guidewire tube 6 can be made of polymeric materials such as, and not limited to Polyimide, Nylon, Polyurethane, Pebax, Polyethylene, PET, PTFE or ePTFE. The guidewire tube 6 can have, in some embodiments, radiopaque markers along its length for use to indicate the location of the ALTC Device, initial deployment, partial deployment, final deployment, the percent of length deployed and/or any combination thereof.

[0157] Figure 12 illustrates the Axial Lengthening Thrombus Capture (ALTC) assembly 8 without the outer sheath, capture catheter 4, or guidewire catheter 6 present for clarity. As illustrated, end 800 with proximal-facing opening 802 of the ALTC device 8 is in the expanded (deployed) configuration and is fixed to the thrombus capture guide 11 and capture pullwire 10, according to some embodiments of the invention. For purpose of illustration, a reserve portion of unexpanded mesh 81 including end 804 is in a collapsed configuration and extends proximally toward attachment site 128.

[0158] In some embodiments, the tubular mesh structure 8 can axially lengthen or shorten without reducing or substantially reducing its diameter through a working length/axial range because the radially expanded portion of the tubular mesh structure is subject to none or minimal tension as it elongates or shortens axially through that axial working range. Not to be limited by theory, this can be accomplished at least in part because the tubular mesh structure can elongate axially throughout the working range by unrolling, everting, or otherwise expanding or transforming a radially compressed reserve segment of tubular mesh, such as unexpanded mesh 81. As such, an expanded "end" opposite the end of the radially expanded device with the capture guide and proximal end opening, such as dynamic fold point 88 of the radially expanded portion of the tubular mesh 8 may not be the absolute end of the tubular mesh fixed to a tubular shaft at zone 128, but rather an intermediate dynamic fold point 88 that is not fixed at that point to a tubular shaft, and as such not under any, or not substantially under any tension. The radially compressed reserve segment of tubular mesh 81 thus extends back in a different or the opposite direction (e.g., proximally in some cases) and ends at the terminal fixation point to the tubular shaft (e.g., at location 128). If it has not exceeded the working length of the expanded tubular shaft, the distance between the dynamic fold point 88 and the distal end of the entire catheter system

(e.g., the nose tip) can increase as the radially expanded portion of the tubular mesh 8 lengthens, and the radially compressed reserve segment is used up.

[0159] Once the compressed reserve segment 81 of tubular mesh 8 is nearly or completely expanded to, or almost to its actual end at 128 and the tubular mesh 8 is axially elongated beyond its working length range, further axial elongation can start to exert significantly increased tension on the fully axially expanded tubular mesh structure 8, causing it to assume a configuration in which it radially contracts as it further axially lengthens.

[0160] A tubular net-like structure with one open end as disclosed above and elsewhere herein can be highly advantageous as a relatively small axial segment of the tubular mesh can be radially expanded and be fully functional to capture emboli and/or other materials in tight working environments, such as in obstructed body lumens with limited space to maneuver distal to the treatment location of interest. If it is desired that a greater axial length of radially expanded tubular mesh is required, such as to capture a relatively long length thromboemboli, the compressed reserve segment of tubular mesh can be unrolled, everted or otherwise expanded or transformed to a specific axial length as desired. Having a compressed reserve segment that can be stored along the length of the catheter system in a compact manner can be very advantageous in providing a long effective capture length tubular mesh without requiring the entire capture system to have a long fixed length as would be required in conventional filters/nets, which can be fixed at both ends and thus are functional and fully radially expanded when the first end is spaced apart from the second end at a single specific axial distance.

[0161] As illustrated in Figure 12, some or most of the axial length of the ALTC device, e.g., the tubular mesh structure 8 remains radially compressed as part of the reserve segment between the outer diameter of the guidewire catheter 6 and the inner diameter of the shaft 12 of the capture catheter (distance between of which is length L12B), with the radially expanded portion of the tubular mesh structure 8 being defined along the axial length between proximal end 800 with proximal-facing opening 802 and the dynamic fold point 88 (distance between of which is length L12A), the sum of L12A and L12B amounting to the absolute length of the tubular mesh 8. In this initial configuration, the length L12B of the

radially compressed reserve segment 81 can be about, or at least about 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, or more of the absolute length of the tubular mesh 8.

[0162] Figure 13 illustrates the axial lengthening thrombus capture device 35 in the initial deployed configuration, according to some embodiments of the invention, with the radially expanded segment of the mesh 8 between end 800 and dynamic fold point 88 and the reserve compressed segment (not shown) extending axially proximally past end 800 to fixation point 128 on the outer surface of the guidewire shaft (not shown). Figure 14 illustrates the thrombus capture element 15 of the ALTC device that can include a stent, braided, woven, laser cut, or other mesh such as a net-like structure, according to some embodiments of the invention. The tubular mesh structure need not necessarily be porous, and can be covered by nonporous or other layers. The ALTC Device tubular mesh structure 8 can be made of any suitable polymeric materials such as but not limited to polyethylene terephthalate (PET), polyethylene (PE) polypropylene (PP), nylon, silk, UHMWPE, PTFE, Kevlar, cotton, and/or metallic materials including superelastic material, nitinol, stainless steel, cobalt-chromium-nickel-molybdenum-iron alloy, or cobalt-chrome alloy, Chronichrome, or Elgiloy. The tubular structure can be braided, extruded, woven, knitted, laser cut, dip, film cast from a polymeric and/or metallic flat sheet, metallic filaments, polymeric filament or fabric in some embodiments. The tubular structure can be film cast with laser cut holes in some embodiments. The tubular structure can also be braided from polymeric and/or metallic filaments or any combination thereof. In some cases, the tubular structure can be made of nitinol wire mesh having multiple wire strands. Furthermore, the tubular structure can include at least one wire strand made of high radiopaque material such as tantalum, platinum, gold or nitinol drawn filler tube with a platinum core to enable viewing the tubular structure under fluoroscopy. In some embodiments, the tubular structure can include one, two, or more radiopaque markers. Depending of the diameter of the ALTC device, the number of wire strands can range from, for example, 1 to 576 wire strands. The ALTC Device can have 2, 4, 144, 288, or another number of wire strands in some embodiments. In some embodiment, the ALTC device is configured to have one wire strand. The wire strand diameter can range from, for example, .0002" up to .015". In some embodiments, the wire strand diameter is about 0.001". The tubular structure can be impermeable in some sections, permeable in other sections and/or a combination thereof. The

tubular structure can be non-coated, or coated with one, two, or more anti-thrombogenic agents such as heparin to prevent clotting, or other therapeutic agents. The tubular structure can also be coated with a hydrophilic or hydrophobic agent. The tubular structure can have different pore sizes to assist with capturing small emboli or larger pore sizes to allow perfusion or blood flow. The tubular structure can have uniform pore sizes through the entire length or a combination of different pore sizes along its entire length. For example, when utilized as a cerebral protection filter, the ALTC device pore size can be sufficiently large to capture clinical relevant emboli size as small as, for example, about 200, 175, 150, 125, 100, 75, 50 microns or less while maintaining perfusion or blood flow. During retrieval, the ALTC device 8 can be repositioned to a particular section of the tubular structure that has smaller pore size and retrieve the blood clots/thrombus. In some embodiments, the ALTC device can deploy and enmesh within the blood clot to capture the blood clot in, for example, the neurovascular system. During retrieval, the ALTC device can lengthen sufficiently beyond the captured thrombus to create a protection filter distal to the captured thrombus. This can be clinically beneficial to prevent thrombus from dislodging during retrieval and thereby prevent secondary stroke. The ALTC Device tubular structure **8** proximal end can, in some embodiments, attach to the guidewire tube **6** outer surface, such as near attachment site 128. In some embodiments the proximal end of the ALTC Device tubular structure can be wrapped and sutured with polymeric filaments and encapsulated with low durometer polymeric material to fixably secure the wire ends to the shaft, such as the guidewire lumen assembly. Other means of attachment to secure the wire ends such as mechanically, thermally or chemically bonding the polymer to secure the wire ends can be used. In another embodiment, the ALTC Device proximal end can be fixed to the outer surface of the guidewire shaft using adhesive and is sandwiched between the outer surface of the guidewire shaft and cover tubes.

[0163] Figures 15A-C illustrate another embodiment of a clot capture system, a distal portion of the ALTC System and a proximal portion of the ALTC System respectively. Figure 15A schematically illustrates the catheter system 35, while Figure 15B shows the distal nose tip 7 operably connected to the distal end of the guidewire shaft 6 that includes a lumen for a guidewire to pass therethrough. One end of the ALTC device 8 can be fixably attached to the guidewire shaft 6 at one or more locations 128 and the other end 800 that

includes proximal or distal-facing opening 802 is attached to capture guide 11, such as in the form of a loop 11, and it is movable axially distally and proximally via capture guide 11 Loop can include, for example, one, two, or more linear segments that extend proximally from the loop 11 onto the capture catheter shaft 12, which are in turn secured proximally to the capture catheter shaft 12 by a the sleeve 30. The sleeve 30 in some embodiments can be present instead of the pullwire(s) extending proximally all the way through the device. This can in some cases be advantageous ergonomically and allow for more streamlined control at the proximal end for a user. . The axially expanded length of the tubular mesh 8 is shown extending from end 800 to dynamic fold point 88, with the reserve length of compressed tubular mesh (not shown) running proximally along the outer sidewall of the guidewire shaft 6 to its end at fixation point 128. Figure 15C illustrates an embodiment of the proximal end of the system, including one or more flush ports 13, hub 55 of the outer sheath 1, hub 155 of the capture catheter 12, and hypotube pusher 14, and proximal-most hub 15 with a lumen configured to slide a guidewire therethrough. The hypotube pusher 14 can in some embodiments be coextensive with, such as welded or otherwise attached to the third tubular member (e.g., the guidewire tube 6), and when manipulated by an operator effect axial movement of the guidewire tube 6 in a proximal or distal direction. In some embodiments, there can be an integral guidewire tube 6 from the proximal most hub 15 to the distal nose tip 7. The third tubular member 14 can be configured to be placed within a lumen of a second tubular member (e.g., capture catheter shaft 12), such as at its proximal end at hub 155. The second tubular member can be configured to be placed within a lumen of a first tubular member (e.g., outer sheath 1), such as its proximal end at hub 55. In some embodiments, hub 55 and hub 155 can include complementary threads or other reversible locking features to allow for the outer sheath 1 to be reversibly coupled to the capture catheter 12 to allow for axial movement of the two tubular members in concert with each other. Uncoupling the hubs 55, 155 can allow for axial movement of the capture catheter 12 with respect to the outer sheath 1 and vice versa.

[0164] Still referring to Figures 15A-C, in some embodiments as illustrated, if a sleeve 30 is present, no separate pullwire extends from the capture guide 11 proximally to the proximal end of the system. In some such embodiments, axial movement of the capture catheter shaft 12 proximally with respect to the guidewire tube shaft 6 facilitates radial

expansion of at least a portion of the ALTC device 8 and positioning of the ALTC device 8 within a body lumen. Axial lengthening and/or shortening of the ALTC device 8 in some embodiments can be effectuated by movement of the guidewire tube 6 (of which the other end of the ALTC device not attached to the capture catheter 12 via sleeve 30 is attached to, such as at attachment site 128) with respect to the capture catheter 12 and/or movement of the capture catheter 12 with respect to the guidewire tube 6.

[0165] Figure 16A illustrates another embodiment of a distal portion of the axial lengthening thrombus capture device 35 in the delivery configuration, according to some embodiments of the invention.

[0166] Figure 16B illustrates the axial lengthening thrombus capture device in the initial deployed configuration wherein the outer sheath 1 is retracted, e.g., proximally to radially expand an end that includes the proximal-facing opening 802 of the axial lengthen thrombus capture device (e.g., tubular mesh 8) to dynamic fold point 88 which serves as the effective expanded distal end of the tubular mesh 8. The capture guide 11 and associated terminal wires 10 are operably coupled to the sleeve 30, and the sleeve 30 is coupled to the outer wall of the capture catheter shaft 12, according to some embodiments of the invention. The compressed reserve length segment (not shown) of the tubular mesh, such as about or at least about 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90% or more of the absolute axial length of the ALTC device 8 (e.g., tubular mesh) taking into account folds remains inverted, rolled up, and/or otherwise radially compressed and circumscribed by the inner sidewall of the capture catheter shaft 12, up to the point where the other end of the ALTC device 8 is attached on an outer diameter of the guidewire tube 6 at attachment site 128. As illustrated, the dynamic fold point 88 varies along the length of the tubular mesh 8 depending on the length of the compressed reserve length segment that is expanded. The dynamic fold point 88 "floats" and is not directly attached to the guidewire shaft 6 nor the capture catheter shaft 12, and as such moves axially proximally when the expanded segment of the tubular mesh 8 axially lengthens.

[0167] As such, when the guidewire shaft 6 with distal nose tip 7 is maintained in a constant position, axial elongation of the expanded tubular mesh 8 results in an increase in the axial distance D between the distal nose tip 7 and the dynamic fold point 88, so distance D3 is greater than D2, which is in turn greater than D1. Furthermore, as shown in Figure 16B

the first end 800 of the tubular mesh is distal to the unexpanded end of the tubular mesh (at location 128) fixed to the outer sidewall of the guidewire tube 6, but moves closer proximally in Figure 16C and becomes proximal to the unexpanded end of the tubular mesh at Figure 16D while the dynamic fold point 88 moves proximally but is still slightly distal to the unexpanded distal end of the tubular mesh 8 in Figure 16D, where the expanded axial length is even greater, or in some cases at its maximum working length. As noted, the diameter/width of the expanded tubular mesh remains constant or relatively constant between Figures 16A-D. Upon exhaustion of the compressed reserve segment which has transformed into expanded tubular mesh, continued axial expansion can result in increased tensile forces on the tubular mesh, resulting in a configuration in which radial contraction begins to occur.

[0168] Figures 17A-D illustrate different configurations of the ALTC device, according to some embodiments of the invention. During delivery, the capture guide 11 (e.g., ring-shaped in some embodiments) connected to the expanded end 800 of the tubular mesh 8 can be configured to collapse within the outer sheath 1 lumen during introduction into the vascular system and is configured to radially expand first when the outer sheath 1 retracts proximally while the length of reserve tubular mesh structure 81 of the ALTC device 8 extending proximally from the dynamic fold point 88 to fixation point 128 on the guidewire shaft 6 remains compressed in the capture catheter shaft 12 lumen. The dynamic fold point 88 serves as the effective expanded distal end of the tubular mesh 8. Upon further retracting the thrombus capture guide 11 via pulling the Capture Pull Wire 10 (or sleeve 30 as shown) and capture catheter shaft 12 proximally, the portion of the ALTC Device 8 tubular structure that is compressed within the Capture Catheter Shaft 12 lumen expands and can transform via, e.g., roll out proximally, inversion, and/or eversion, and axially lengthening the ALTC Device 8. Advance of the Capture Catheter Shaft 12 distally can collapse at least a portion of the ALTC Device 8 tubular structure into the Capture Catheter Shaft 12 lumen, as previously shown in Figures 7 - 9. The ALTC Device's ability to expand, roll out, axially lengthen and maintaining a substantially constant diameter through a working range creates a cavity (or pocket) within the sidewall of the radially expanded segment of the ALTC Device 8 to retrieve and capture foreign materials such as, for example, blood clots/thrombus. In another embodiment a sleeve **30** (Figures 16A-D and 17A-D) can be used to couple, such as permanently, the Capture Pull Wire **10** to a portion of the Capture Catheter shaft **12** to enable

both components to operate together. Coupling the Capture Pull Wire 10 and the Capture Catheter shaft 12 can allow the user to manage the capture device more efficiently and easily. In another embodiment, the capture guide 11 takes the form of a loop and can attach to the Sleeve 30, which is coupled to the Capture Catheter Shaft 12.

[0169] Figures 18A-B illustrate an embodiment of a distal portion of the axially-lengthening thrombus capture system with a cover element 80 radially outward of, and partially or completely circumscribing the capture catheter shaft 12 or loop 11 of the ALTC device, which can be in the shape of a ring as illustrated. In some embodiments, the cover element 80 can function to protect one or more of the capture guide, ALTC device, and the luminal wall of the lumen being treated. The ring 80 can also be configured to provide a seal against the luminal wall, e.g., of the vessel, to prevent leakage or migration or embolization of unwanted material around the tubular mesh 8. In some embodiments, the cover 80 can also include a skirt portion. The cover 80 can be axially and/or radially expandable, such as an inflatable balloon, a soft polymer, a gel, a foam, a textile fabric, shape memory, and/or include other materials. If the cover 80 is expandable, it can be configured to reversibly contract to allow for fluid flow around the cover 80 once the procedure is completed. Also as illustrated is sleeve 30 serving to attach the capture guide 11 connected to one or more wires 10. Sleeve 30 can include one or more apertures 307 that serve as relatively radiolucent markers, and/or the sleeve 30 could be made of a radiopaque material in some embodiments. Also as illustrated, the capture catheter 12 as well as guidewire tube 6 can extend through the tubular mesh 6 from first end 800 through dynamic fold point 88. The reserve segment of compressed tubular mesh is not shown for clarity.

[0170] Figures 19A-C illustrate an embodiment of an axially-lengthening thrombus capture system, configured to allow the guidewire 350 to distally exit the system prior to exiting the luer/proximal-most port 15 at the proximal end of the system. The guidewire's proximal end can exit the system through an aperture or slot 351 in the sidewall once it passes the reversibly couplable hemostasis seals 55, 155 of the outer sheath 1 assembly and the capture catheter 12 respectively. In some embodiments, the guidewire 350 is configured to exit sideways, that is laterally. In some embodiments, a keyed cap 36 is positioned distal to the hemostasis seals 55, 155, which is in turn proximal to a shaft 14, which can serve as a hypotube pusher connected to or coextensive with the guidewire tube

and be made of metal in some embodiments. The shaft 34 can include a sidewall groove 351 fully or partially axially from the port 15 to the hub 155 and/or one, two, or more discrete slots as illustrated.

[0171] Such embodiments can be advantageous, for example, to utilize a shorter length guidewire needed when the delivery system overall length increases. In some embodiments, when the ALTC capture device increase in length, the hypotube is also lengthened to accommodate thus increase the distance for user to manage the guidewire and system. The side guidewire feature can minimize the distance resulting in better handling, and the proximal end of the guidewire 350 need not necessarily extend past the proximal end of the entire system, such as at port 15. As such, the guidewire as part of the system can advantageously have a total length in some embodiments that is the same as, or even less than the axial length of the entire material capture system from proximal port 15 to distal nose tip 7, which may otherwise not be possible.

[0172] The guidewire 350 can be located near the hemostasis seals 55, 155 area during the procedure, and as such the entire procedure/operation can be done with the user not needing to look down to see where the components are located. As such, the user can hold the hemostasis seals 55, 155 housing in one hand while at the same time manipulating the guidewire 350 and hypotube pusher 14 with the other hand in the general area without substantially moving away from the area. The users can hold and maneuver the hypotube pusher 14 or hold and maneuver the guidewire 350 or hold both the hypotube pusher 14 and guidewire 350 at the same time. In some embodiments, the inner diameter of the shaft 14 with groove can be generally larger than the guidewire 350 that allows the guidewire 350 to exit laterally. The keyed cap 36 with a boss profile can mate to the groove of the metal shaft 14 to prevent the metal shaft 14 from rotating and still allow the shaft 34 to slide back and forth axially.

[0173] In some embodiments, an Expanding Guide Catheter 50 (shown in Figures 20-21 for example) is a discrete catheter that can be utilized together with the clot capture system, and functions to assist in retrieving the ALTC Device 8 (and associated catheter system 35) and capture blood clots and other undesired materials. In some embodiments, the Expanding Guide Catheter 50 can include a first tubular member, such as an outer sheath 49 with a proximal end, a distal end, a lumen extending from the proximal end and the distal

end, and a port on the proximal end, which can be coaxial as illustrated or offset from the longitudinal axis of the outer sheath 49. A second tubular member, such as inner catheter 54 can have a proximal end, a distal end, and a lumen extending from the proximal end to the distal end and can be configured to be placed within the lumen of the outer sheath 49. The inner catheter 54 can also have a proximal port, a removable obturator 51 positionable in the inner catheter lumen, distal expandable funnel tip 52, expandable shaft section 53 proximal to the funnel tip 52, an inner shaft 54, and connectors with seal 55. The obturator 51 can be used to aid in inserting and navigating the Expanding Guide Catheter 50 in the vascular system. The obturator 51 can be made of polymeric materials such as Polyethylene, Nylon, Pebax, Polyurethane, PET or PTFE for example. The obturator 51 can have a tapered distal end in some embodiments to aid in introducing the Expanding Guide Catheter 50 in the vasculature or other body lumen. Alternatively, other embodiments of the obturator 51 includes an expandable member such as a balloon operably connected to the distal end. Expansion of the expandable member, such as inflating the balloon can create a smooth tip transition. The balloon can be made of polymeric materials such Nylon, Polyurethane, PET, etc. Inflating the balloon can also secure the balloon obturator to the guide catheter such that when applying axial load proximally to the obturator shaft will articulate the tip of guiding catheter. The funnel tip 52, illustrated for example in Figures 20B-C, can include a distal funnel-like segment, and be adjacent to an expandable proximal segment 53 wherein it is connected to a more proximal portion of the inner shaft 54. The funnel tip 52 can be, in some embodiments, made of either polymeric and/or metallic materials. It can be either tubular in shape, woven or braided. The braid configurations can be, in some cases, 1x1 or 1x2 or 2x1 or 2x2 or any combination thereof. The picks per inch (PPI) can range from, in some embodiments, 5 to 60. The number can be, in some embodiments, from one wire filament up to 288 wire filaments. The wire shape can be, e.g., round, flat, oval, rectangular or square. The wire diameter can be, e.g., from .0005" up to .015". The flat wire thickness can be, e.g., from .0005" up to .010" and the wire width can be, e.g., from .001" up to .030". The funnel tip 52 distal segment can have various shapes or configurations to allow better retrieving the blood clots or thrombus. In some embodiments, the funnel tip 52 distal segment has a large open end where it contacts the vessel wall when expanded and transitions to smaller opening proximal segment 53. The distal segment open end can range from, in some embodiments,

about 5 mm to about 80 mm in diameter. The funnel tip distal segment 52 also has, in some embodiments, openings or holes (perforations) along the side to allow blood flow. The funnel distal segment 52 can have either one layer of braid or multiple layers. In some embodiments, the funnel distal segment has two layers. In some one layer embodiments, the most distal open end of the funnel does not have the wire end terminate or exposed such that the wire ends are located at the proximal end of the funnel assembly. The funnel tip proximal segment 53 can be configured such that it is capable of expanding and receive the ALTC device and captured blood clots or thrombus. The proximal segment 53 can be configured to expand to receive object that is larger than its inner diameter and recovery after passage. The proximal segment 53 can include a PTFE inner layer and compliance and/or low durometer polymeric materials such as Polyurethane, Silicone, Tecoflex, Pebax 25D and/or 35D or braid and/or non-braided such as Pebax/Propel/BaSO4 outer layer. The proximal segment 53 can also include other lower durometer polymeric materials. The composite funnel tip and proximal segment can be laminated via dipped coat, spray or reflow process or any combination thereof. The braid materials can be either metallic and/or polymer and/or combination thereof. The braid configurations can be, e.g., 1x1 or 1x2 or 2x1 or 2x2 or any combination thereof. The picks per inch (PPI) can range from, for example, 5 to 60. The number can be, e.g., from one wire filament up to 288 wire filaments. The wire cross-sectional shape can be, for example, round, flat, oval, rectangular or square. The wire diameter can be, e.g., from .0005" up to .015". The flat wire thickness can be, e.g., from .0005" up to .010" and the wire width can be, e.g., from .001" up to .030". In some embodiments, an advantageous feature is the ability to expand and contract without buckling under compression. The inner diameter can range from, e.g., 2F to 30F. In some embodiments, the inner diameter can range from, e.g., 6F to 18F. The expanded length section can be up to the entire catheter length. In some embodiments, the length is about 20cm. The funnel distal 52 and proximal segment 53 can also be made as one component wherein the braid configuration is continuous. Coupled to or continuous with the funnel tip proximal segment 53, the inner shaft 54 can be made from materials such as and not limited to Nylon, Polyurethane, Pebax, Polyethylene, PET, PTFE, or ePTFE. The inner shaft 54 can be braided or non-braided. The outer shaft 49 can function to slide over and collapses the funnel tip and provide support during introduction into the vasculature. The outer shaft 49

retracts to deploy the funnel tip. The outer shaft 49 can be made of polymeric materials such as Nylon, Polyurethane, Pebax, Polyethylene, PET, PTFE, ePTFE, FEP or combination thereof. The outer shaft 49 diameter can range from, e.g., 4F to 34F. The outer shaft 49 inner diameter can range from, for example, 3F to 32F. In some embodiments, the inner diameter has substantially the same throughout the lumen shaft. In some embodiments, the inner diameter at the distal end is larger than the proximal end inner diameter. The change in inner diameter can be in one location, two or more locations. The outer diameter is substantially the same throughout the entire length of the outer sheath shaft. In some embodiments, the outer shaft 49 is about 22F or smaller in diameter. The outer shaft 49 can include a radiopaque marker at the distal end or radiopaque filler along its shaft length for visibility under fluoroscopy. In some embodiment, the outer shaft can be deflectable (via, for example, one, two, or more pullwires on the distal end) at various locations and multiple deflectable directions along the shaft length to accommodate various tortuous paths such as entry into the right atrium, right ventricle, main pulmonary artery, and left and right pulmonary artery for pulmonary embolism applications.

[0174] Still referring to Figures 20A-20D, in some embodiments the expanding guide catheter 50 can be utilized to retrieve blood clots or thrombus. The expanding guide catheter 50 and obturator 51 can be introduced over a wire into the vasculature and advanced near the treatment area. The obturator 51 is removed. The outer member 49 of the expanding guide catheter is retracted proximally to expand the funnel tip 52 and the expandable section 53 of the guide catheter 50. In some embodiments, the guide outer shaft 49 is inserted into the vessel together with the obturator 51 and the obturator 51 is removed once the outer shaft 49 is in a desired position. The inner guide member can include the funnel tip 52, proximal segment 53 and the inner shaft 54 is then inserted into the outer shaft 49 up to the distal tip of the outer shaft 49. The outer shaft 49 can then be retracted (or the inner shaft 54 advanced) to expand and deploy the distal funnel 52 and the proximal segment 53. The capture catheter system 35 is inserted over the wire and through the lumen of the expanding inner guide member 54. Once the ALTC Device 8 is deployed and captures the blood clots, the ALTC Device 8 is retracted along with the captured blood clots into the funnel tip 52 and expanding guide inner member 53, (shown later in Figure 50). When high resistance is encountered at the funnel tip due to the large blood clot position at the tip, the guidewire lumen can

advances distally to lengthen the ALTC Device. Lengthening the ALTC device can create additional space within the ALTC device such that the blood clot volume is redistributed thereby reduces the large blood clots pooled at the tip of expanding guide catheter. The expanding guide catheter distal section also allows larger clots to be captured due to its expandability increasing the lumen size. Continuing to retract the ALTC device will retrieve additional captured blood clots inside the expanding guide catheter. Repeated lengthening of the ALTC during the procedure will continue to redistribute the clot and retrieve inside the Expanding Guide Catheter, advantageously allowing for improved thrombus processing and redistribution. In some embodiments, a kit can include a capture catheter system 35 as described herein and configured to be reversibly placed within, and move axially with respect to an inner lumen of a discrete expanding guide catheter system 50 as described herein.

[0175] Figure 21D illustrates an embodiment wherein a cover tip 710 encapsulates the distal end of the outer cover of the expanding guide catheter system, according to some embodiments of the invention. In some embodiments, a guide catheter is part of a hemostasis guide system that can includes one or more obturators, an inner shaft member, an outer shaft member, and a hemostasis valve disposed within a housing of the system. The inner shaft member can include a non-expandable braided proximal segment, a distal expandable segment and a braided funnel distal end which can be as described elsewhere herein. The inner shaft member can be positioned within the lumen of the outer shaft member. The outer shaft member can have, for example, a braided polymeric configuration with a flexible kink resistance distal segment. The inner shaft and outer shaft member can be attached to the housing body. The housing body can be, for example, at a proximal end of the guide catheter system. The hemostasis valve can be disposed within the housing body. The hemostasis valve can be in some embodiments a flexible disc-like valve. The hemostasis valve can be configured to provide hemostasis and prevent leakage, such as with nothing inside. In some embodiments, the system can be configured for use with a 0.035" guidewire, 5Fr catheter, and include sizes between about 12F and about 17F, such as about 12F, 16F, or 17F. The hemostasis valve can include two surfaces, an upper surface and a lower surface. The upper surface and lower surface can be opposing surfaces in some embodiments. The upper surface can include a slit extending partially across the upper surface and a depth into the valve without protruding all the way through the thickness of the

lower surface. The lower surface can include a slit extending across the lower surface and a depth into the valve without protruding all the way through the thickness of the upper surface. In some embodiments, the valve has a diameter of between about 0.50" and about 1.00", such as about 0.5", 0.6", 0.7", 0.8", 0.9", or 1.0". In some embodiments, the valve has a thickness of between about 0.050" and about .0100", such as about 0.075". In some embodiments, the slits can have a depth/thickness of between about 0.020" and about 0.060", such as about 0.040". The midpoint of a slit can be in some cases at or proximate the center of the surface of the disc. The upper slit and the lower slits can intersect at, for example, a point location within the valve. The slits can extend beyond the intersection point by a desired distance, such as between about .001" and about .010" or approximately .005" beyond the intersection point. In some embodiments, the arrangement of the slits along the valve permits insertion and removal of shafts therethrough while preventing leakage of blood or air back across the valve. The upper and lower slits can have long axes that intersect at an angle. The angle could be in some embodiments between about 45 degrees and about 135 degrees, or about 45, 60, 75, or 90 degrees in some cases.

[0176] Figures 22-24 illustrate the outer sheath assembly 1 of the capture device, according to some embodiments of the invention. The outer sheath 1 can function to contain, protect, and deliver the Axial Lengthening Thrombus Capture Device (tubular mesh 8 (not shown) to the desired anatomical location, such as in a radially compressed configuration. As shown in Figure 22, the Outer Sheath 1 can include a soft atraumatic distal tip, a shaft body that can be tubular in some embodiments, an interior channel/lumen configured to house and reversibly couple at its proximal end a second tubular member, such as a capture catheter as described elsewhere herein, and a proximal connector with a seal 55 and flush tube/port 13. The Outer Sheath 1 can be made from suitable medical grade materials, including but not limited to Nylon, Polyurethane, Pebax, Polyethylene, PET, PTFE, ePTFE, PEEK, PEBAX/Propell and polypropylene. The polymeric materials can include radiopaque materials such as, for example, barium sulfate, bismuth subcarbonate or bismuth trioxide to enable viewing under fluoroscopy. The radiopaque materials can form one, two, or more discrete marker elements in some embodiments, such as at the distal tip, and/or spaced apart at regular or irregular intervals along the length of the outer sheath 1. The outer diameter of the outer sheath 1 can range from, for example, 3F to 30F. The inner diameter of the outer

sheath 1 can range from, for example, 2F to 28F. In some embodiments, the inner diameter is substantially constant throughout the interior channel, e.g., the lumen shaft. In some embodiments, the inner diameter at the distal end is about or at least about 10%, 20%, 30%, 40%, 50%, or more than the proximal end. The change in inner diameter can be, for example, stepwise or gradual in one location or two or more locations. The outer diameter can be substantially the same the entire length of the catheter, in some embodiments. The outer sheath 1 working length can be, in some cases, from about 10cm to about 150cm. In some embodiment, the Outer Sheath 1 working length is about 135cm in some embodiments. The Outer Sheath 1 shaft can be braided or non-braided. In some embodiments, the Outer Sheath 1 shaft can be deflectable (via, for example, one, two, or more pullwires on the distal end) at various locations and multiple deflectable directions along the shaft length to accommodate various tortuous paths such as entry into a left or right heart atrium, heart ventricle, main pulmonary artery, and left and right pulmonary artery for pulmonary embolism applications, or a vein such as the great saphenous vein, superficial femoral, common femoral, SVC, IVC, or other upper or lower extremity, visceral, or other superficial or deep veins for deep venous thrombosis removal applications. The distal end of the shaft of the outer sheath 1 can be configured to deflect up to 360 degrees in some cases. Additionally, the distal tip of the Outer Sheath 1 can be configured to deflect or bias toward or away from the vessel wall. The distal tip of the outer sheath 1 can include one, two, or more radiopaque markers to indicate tip location. Alternatively, the distal tip can include radiopaque materials such as, for example, Barium Sulfate, Bismuth Subcarbonate or Bismuth Trioxide. Figure 23 and 24 illustrate the distal end and proximal end of the outer sheath assembly respectively. As shown in Figure 26, the proximal end of the outer sheath 1 connects to the outer sheath connector 55 with seal and coupler to a capture catheter connector, and flush port 13.

[0177] Figure 25 illustrates the capture catheter assembly 12, according to some embodiments of the invention, showing catheter shaft 12 and outer sheath 1. Figure 26 illustrates the proximal end of the capture catheter, according to some embodiments of the invention, showing a connector with seal 155 operably connected to a flush port 13.

[0178] Figure 27 illustrates an embodiment of a key cap 36 feature to prevent or inhibit rotation of the hypotube pusher 14. As illustrated, the key cap 36 can be a tubular member with a lumen to fit the hypotube pusher 14 therethrough. The lumen is non-circular

in some embodiments, and/or have a non-circular zone, or otherwise configured to prevent or limit rotation. In some embodiments, the lumen includes teeth or other projections into the lumen as shown to prevent undesired rotation of the hypotube pusher. In some embodiments, the lumen or a portion thereof has a square, rectangular, triangular, oval, pentagonal, hexagonal, or other non-circular geometry, and configured to limit rotation.

[0179] In some embodiments, as illustrated in Figures 28-29 for example, an optional suction catheter 2 can function to aspirate thrombus within the ALTC Device 8. The suction catheter 2 can include in some embodiments a distal funnel tip 9, elongate shaft body 16, and proximal connector with seal 3. Figure 30 illustrates a close-up view of the funnel tip 9 which can be attached at the suction catheter shaft 16 distal end to aid in retrieving the thrombus and allow efficient suction. The funnel tip 9 can be made of, for example either polymeric and/or metallic materials. It can be tubular in shape, woven or braided, in some embodiments. Funnel tip 9 can be in various configurations to allow better retrieval and suction. In some embodiments, the funnel tip 9 has a funnel shape with a first, larger distal diameter, a transition section, and a second, smaller proximal diameter as illustrated. The suction catheter shaft 16 creates a pathway for the aspirated thrombus to travel proximally and exit the body and in some embodiments into the optional filter collection chamber. The shaft can be of various diameters, lengths and/or geometries to aid in the removal of materials such as blood clots. The suction catheter shaft can be made from suitable materials such as and not limited to Nylon, Polyurethane, Pebax, Polyethylene, PET, PTFE, ePTFE, PEEK, and polypropylene. In some embodiments, the suction catheter Shaft distal end is expandable so to accommodate large amount of blood clots. The suction catheter 2 can attach to the proximal end of filter collection chamber 5 to enable thrombus aspiration (or removal). In some embodiments, the suction catheter shaft 16 is deflectable at one, two, or more locations along the shaft length to accommodate various tortuous paths such as entry into the right atrium, right ventricle, main pulmonary artery, and left and right pulmonary artery. A proximal flush port 13 is also illustrated.

[0180] In some embodiments, a mechanical thrombectomy tool such as macerator 19 shown in Figures 32-41 for example, can function to disrupt and break up the thrombus within the ALTC Device 8. The macerator 20 can include a disruptor 19, shaft 22 and proximal connector with seal 21. Adjustable Touhy knob 23 distally is also shown just

proximal to disruptor 19. The disruptor 19 can be attached to the distal end of the shaft 22. The macerator 20 can have various end effector tip configurations as illustrated in Figures 35-41 depending on the desired clinical result to break up the thrombus within the ALTC Device 8, including a bulbous shape (Figure 36), proximal and distal bulbs with a narrow waist (Figure 37), a plurality of proximal and distal bulbs with a narrow waist each offset by an angle, such as about 90 degrees (Figure 38), a flower petal design with petals radiating radially outwardly from a central hub (Figure 39), a hemi-petal design (Figure 40), or a substantially linear design orthogonal from the longitudinal axis of the shaft 22 (Figure 41). The disruptor 19 collapses during insertion through the suction catheter 2 system and expands once exiting the catheter. The disruptor 19 can be made of, for example, metallic materials such as stainless steel, Nitinol, cobalt chrome, etc. The macerator can be activated either by manual rotation, manipulation and/or a motorized handle.

[0181] To macerate the thrombus, the macerator 19 is inserted through the suction catheter 2 and position within the ALTC Device 8. A manual technique applies to the luer connector 21 of the macerator 19 by rotating the luer connector 21 causing the disruptor 20 to rotate thereby breaking up the thrombus. Alternatively, the macerator 19 can be used with a motorized handle (not shown). Traversing the disruptor 20 axially through the entire length of the ALTC device 8 can aid in breaking up the thrombus.

[0182] The filter collection chamber 5 (Figure 42) can function to suction and collect the blood clots. The filter collection chamber 5 can include, for example, a collection chamber 325, filter 324, plunger 323, inflow port 327 and outflow port 326. The filter collection chamber 5 can have an outflow port 326 attaching to the suction catheter 2 connector and an inflow port 327 where a syringe or a similar device can attach for aspiration. The collection chamber 325 has a filter system 324 residing inside the chamber 325 to allow filtering the blood and thrombus. The chamber 325 also has a plunger 323 for use in injecting fluid such as saline to fill the chamber 325 and push filtered blood back into the vasculature. The plunger 323 can serve as a seal on one side of the chamber.

[0183] To aspirate the thrombus from the system, the suction catheter 2 is attached to the filter collection chamber 5 (Figure 42). A large syringe attaches to the proximal end of the filter collection chamber 5. Applying suction using the syringe causes the thrombus and blood clots to migrate into the filter collection chamber 5. Once all the

thrombus is contained within the chamber 5, close stopcock, detach the syringe and fill with saline and reattach the syringe to the filter collection chamber 5. Alternatively, an extension tube and external saline filled syringe can be used to fill saline into the suction syringe. Injecting via the syringe will push saline into the chamber 325 causing the plunger 323 to push the blood back into the vasculature. The chamber 325 will return the blood and leave the thrombus inside the chamber 325. Alternatively, the filter collection chamber 5 can be detached without returning filtered blood to the system. Once the thrombus is removed, retract the suction catheter 2 inside the outer sheath 1. Retract the ALTC Device 8 into the outer sheath 1 and remove the entire system from the body.

[0184] Catheter systems as described herein can be utilized for a variety of indications depending on the desired clinical result. In some embodiments, the use is not limited to venous systems and can apply to other arterial, venous, or nonvascular areas such as neurovascular, peripheral vascular, cardiovascular, temporary embolic protection device for a cardiovascular procedure such as valve replacement, carotid protection, pulmonary protection during deep vein thrombectomy or embolectomy), or retrieval of an implant, medical device, or other material.

[0185] Figure 43 illustrates a blood clot lodging in the left side of the pulmonary system. Shown is the right pulmonary artery 251, left pulmonary artery 252, inferior vena cava 253, left iliac artery 254, right iliac artery 255, a pulmonary embolus 256 in the left pulmonary artery 252 distally, and the superior vena cava 257.

[0186] Figure 44A and 44B illustrate blood clots residing in the left side pulmonary system and the capture device respectively, according to some embodiments of the invention. In addition to the anatomical features illustrated in Figure 43, also shown is the guide catheter 264, right ventricle 266, and right atrium 267. As shown in Figure 44B, capture devices as described and illustrated herein can advantageously be utilized when there is very limited distal space, as the device is functional throughout a wide working axial range as discussed elsewhere herein.

[0187] Figures 45-47 illustrate capture of a thrombus within a vessel, according to some embodiments. Figure 45 illustrates the initial deployed configuration of the axial lengthening thrombus capture device (e.g., tubular mesh) 8 with end 800, dynamic fold point 88, and reserve radially compressed segment (not shown) terminating proximally at point

128 where the radially compressed segment is fixably attached to the outer sidewall of the guidewire lumen 6 is shown. The expanded segment of the tubular mesh 8 is positioned distal to the thrombus 73 occluded area and the expanding guide catheter 50 including distal funnel tip 52 with proximal expandable section, inner catheter 54 and outer catheter 49, or in some embodiments suction catheter funnel tip positioned proximal to the thrombus occlusion 73, according to some embodiments of the invention. In some embodiments, expanding guide catheter 50 as described elsewhere herein or a suction catheter can be utilized depending on if suction is desired. Also shown proximally is inner sheath 54 and outer sheath 49 of expanding guide catheter 50. Actuation of capture pullwire 10 alone or with capture catheter 12 such as axially in an appropriate direction (or capture catheter coupled to the outer sheath (not shown) in embodiments with a sleeve as previously described) can result in axial lengthening or shortening of the ALTC device 8 depending on the desired clinical result. Figure 46 illustrates the axial lengthening tubular mesh 8 expandable segment lengthening proximally to capture the thrombus, according to some embodiments of the invention, with the associated radially compressed segment shortening reciprocally. Figure 47 illustrates the axial lengthening thrombus capture device completely capturing the thrombus, and the expanding guide catheter funnel tip or alternatively the suction catheter funnel tip is inside the axial lengthening thrombus capture device. Subsequent suction via the suction catheter 2 in embodiments where suction is utilized can be performed to remove the blood clot or thrombus. The ALTC Device can lengthen to have a maximal length that covers the entire length of catheter system from, e.g., about 0.5cm to about 125cm. In some embodiments, the ALTC device may lengthen to about or at least about 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 20, or more centimeters. Depending on vessel diameter, the outer diameter of the ALTC device can range from, in some embodiments, about 1 millimeter up to about 80 millimeters. For example, large vessels such as the inferior vena cava, superior vena cava, descending, and ascending aorta, the diameter can range up to about 60, 70, 80, 90, 100 millimeters or more. Small vessels in the neurovascular system can be, for example, as small as about or less than about 5, 4.5, 4, 4.5, 3, 2.5, 2, 1.5, 1, 0.5, or less millimeters in diameter. The diameter of the ALTC device can achieve the similar effect of reducing or stretching the ALTC device diameter. In some embodiments, suction is not utilized or required, and the ALTC device envelops the clot, which can be mechanically pulled back into the capture

catheter. In some embodiments, the ALTC device can be utilized to treat, for example, a clot in the carotid or cerebral arterial or venous circulation. The vessels to be treated could include, for example, the Circle of Willis, left or right common carotid or internal carotid arteries, anterior cerebral arteries, anterior communicating arteries, middle cerebral artery, posterior communicating arteries, carotid siphon, basilar arteries, vertebral arteries, or ophthalmic arteries for example, or any branches thereof. In some embodiments, the ALTC device can be utilized to treat, for example, a femoral vein, a brachial vein, a pulmonary vein, a breast vein, a cerebral vein, a brain sinus vein, a renal vein, a portal vein, a jugular vein, or another vein.

[0188] Figure 48A illustrates another delivery configuration of the clot capture system 35 that can include features as previously described, according to some embodiments of the invention. Figure 48B illustrates the initial deployment position of the axial lengthening thrombus capture device, according to some embodiments of the invention, and reversible coupling of the hub 55 of the capture catheter 155 to the hub 55 of the outer sheath. Figure 48C illustrates the further lengthening of the expanded segment of the axial lengthening thrombus capture device, according to some embodiments of the invention, with reciprocal shortening of the reserve compressed segment 81. As illustrated, the guidewire tube 6 with nose tip 7 is maintained in position while the capture catheter reversibly coupled to the outer sheath can be withdrawn proximally. Figure 48D illustrate the final deployment of the axial lengthening thrombus capture device at its maximal working length, according to some embodiments of the invention.

[0189] In some embodiments, systems and devices as disclosed herein can involve a general percutaneous technique, a cut-down procedure, or minimally invasive technique such as transapical, thoracoscopic, laparoscopic, or other techniques, for example, and not limited to transfemoral, transradial and/or internal jugular venous access. The technique can also apply to the arterial system, including neurovascular, cardiovascular, and peripheral vascular applications, as well as for use as an embolic protection device such as for a cardiovascular procedure such as valve replacement or repair for example. In some embodiments, a thrombectomy system can be delivered downstream of the aortic root, such as prior to the aortic arch, and a variable-length shape memory mesh structure such as an ALTC device with an open proximal end and closed distal end expanded prior to the index

cardiovascular procedure, to capture downstream emboli, calcifications, or other debris. In some embodiments, the system can be deployed to prevent embolization during a deep vein thrombectomy or pulmonary embolectomy, for example. In another embodiment, the system can be deployed to prevent embolization or retrieval during acute ischemic stroke. Systems and methods as disclosed herein can also be utilized in non-vascular anatomy such as the biliary tree to capture gallstones, common bile duct stones, and pancreatic duct stones, for example, in the ureters or bladder to capture kidney stones, or in the fallopian tubes to capture ova or other materials, or in the gastrointestinal tract such as the esophagus, stomach, duodenum, jejunum, ileum, or colon to capture, for example, foreign bodies. Described herein are some embodiments of using the venous system to access the pulmonary artery to treat pulmonary embolism. The technique can also apply to other areas of the vasculature. Initial puncture to access the femoral vein. A short access guidewire is inserted into the femoral vein. Next, an appropriate 5F or 6F introducer sheath is inserted. The guidewire is exchanged for a 180cm, 260cm or 300cm guidewire and advance pass the inferior vena cava, right atrium, right ventricle and the pulmonary artery to access the occluded treatment area. A longer length introducer/guiding catheter may be necessary to cross the tricuspid and pulmonary valve. Once the guidewire passes through the occluded treatment area, the 5F or 6F introducer sheath is exchanged for a long guiding catheter and position proximally near the occluded area. The catheter system 35 is inserted over the wire and through the guiding catheter and advance distally to the occluded area. The catheter system 35 can also utilize the outer sheath deflectable features to navigate through the vasculature without the use of a guiding catheter. Next, the catheter system's nose tip 7 passes through the occluded treatment area and positioned distal to the occluded treatment area. The Outer Sheath 1 is retracted to deploy the thrombus capture guide 11. The outer sheath 1 is retracted past the thrombus and positioned proximal to the thrombus (occluded area). The Suction Catheter 2 advances distally outside the Outer Sheath 1 and positions proximally to the occluded area, if suction is utilized.

[0190] To retrieve and capture materials such as blood clots or thrombus, the Thrombus Capture Guide 11 retracts by pulling the Capture Pullwire 10 proximally while push/pull Capture Catheter 12 to axially lengthen the ALTC Device 8 over the thrombus without substantially decreasing the device diameter. As needed, advancing the Capture

Catheter shaft 12 distally while pulling the Capture Pullwire will allow the ALTC Device 8 to axially lengthen to capture the thrombus. Furthermore, the expandable Funnel Tip 9 of the Suction Catheter 2 (or the funnel tip of the expanding guide catheter) can be positioned at the proximal end of the occluded area to support and minimized thrombus movement. This maneuver continues until all thrombus is inside the ALTC Device 8. Once the thrombus is completely within the ALTC Device 8, pulling the ALTC Device 8 away from the occluded area can restore immediate blood flow while containing the thrombus inside the ALTC Device 8.

[0191] In some embodiments, the capture catheter shaft 12 and the guidewire tube 6 are configured to be positioned side-by-side adjacent (e.g., offset and not coaxial, and not passing within the opening 802 or other radially expanded portion of the tubular mesh 6) to the ALTC Device 8 and capture guide (shown, for example, in Figures 49A and 49B). Also illustrated is the dynamic fold point 88, reserve radially compressed segment 81 and compressed end at 128 fixed to the outer wall of the guidewire tube 6.

[0192] Figures 50A – 50G illustrate the retrieval of thrombus into the expanding guide catheter wherein the ALTC device lengthens distally and creates additional space and the thrombus is redistributed and enable better retrieval into the expanding guide catheter. The funnel tip 52 and expanding section 53 of the expanding guide catheter also facilitate the ease of thrombus retrieval. For example, when the ALTC Device (e.g., tubular mesh 8) captures the blood clot inside, the ALTC Device 8 can advantageously stretch axially and compress radially beyond its working length (e.g., when the reserve radially compressed segment has been completely expanded, and/or by distal advance of the guidewire tube 6), effectively squeezing the blood clot radially to decrease its diameter/width. Fresh blood clots are typically soft and deformable. Applying axial stretching to the ALTC device can squeeze out the fluid that is within the blood clot, thereby reducing the size of blood clot and allowing blood clots to be removed from the vascular system more easily. The ability of the ALTC Device to lengthen dynamically also provides another clinically effective way to remove the large clot burden by redistributing the volume of blood clot or thrombus, as shown, for example, in Figure 50A – 50G. For example, with respect to current interventional devices such as filters and baskets, when blood clots or thrombus is collected and retrieved into a catheter such as a guiding catheter or sheath, the blood clot or thrombus can gather together

or pooled at base of the filter or basket into a large "ball-like" shape and prevent the large "ball-like" thrombus to enter the lumen of the guiding catheter or sheath. A similar effect can occur when aspiration/suction is attempted using a smaller inner diameter guide catheter. However, the ALTC device can lengthen serially from the distal end to create additional length and space within the ALTC Device (as shown, for example, in Figures 50B, 50D, and 50F). By lengthening the ALTC Device's distal end, the blood clot or thrombus is redistributed within the ALTC device thereby reducing the ball-like size of the blood clot, thrombus, or other material for better retrievable inside the guiding catheter lumen (Figures 50C, 50E, 50G). These steps can be repeated for about or at least about 2, 3, 4, 5, or more cycles until all the blood clot and thrombus is retrieved in the catheter in a compacted form. Furthermore, the use of an expanding guide catheter with an expandable distal section in concert with the ALTC device can allow more efficient blood clot or thrombus removal, as illustrated, for example, in Figures 50A and 50C. The effectiveness of the ALTC Device 8 can be further demonstrated in an extreme vascular condition where there is minimal to no distal space available for conventional thrombectomy catheters to fully axially expand in order to be functional. The distal space beyond the distal end of the thrombectomy system can be in some cases less than about 3cm, 2cm, 1cm, 5mm, or less. In other words, the ALTC Device 8 can be delivered in a first, radially compressed configuration, and compressed by the outer sheath. Upon removal of the outer sheath, the ALTC Device 8 can transform into a radially expanded configuration and configured to capture thromboemboli even though the device may be in an axially compressed configuration. The ALTC Device 8 can then be axially expanded, such as, for example, at least about 1.25x, 1.5x, 2x, 2.5x, 3x, 3.5x, 4x, 4.5x, 5x, 5.5x, 6x, 6.5x, 7x, 8x, 9x, 10x, or more with respect to its fully functional axially compressed length while still maintaining a constant or substantially constant radially expanded diameter through a working range, such as between about 1cm and about 50cm, between about 1cm and about 20cm, between about 1cm and about 10cm, between about 1cm and about 5cm, or between about 1cm and about 3cm in some embodiments. In some embodiments, the ALTC device 8 has an open proximal end during delivery, and/or throughout its working axial length. The Thrombus Capture Guide 11 can advantageously deploy initially in the tight space while the ALTC device body remains inside the Capture Catheter shaft 12. Subsequently, the Thrombus Capture Guide retracts proximally to begin

deploying the ALTC Device 8. The potential axially expanded length of the ALTC Device 8 is not necessarily limited and in some embodiments could extend to the entire length of the catheter system. The ALTC Device 8 can be collapsed and contained within the Capture Catheter shaft 12 and Outer Sheath 1 during introduction into the vasculature and expands when the Outer Sheath 1 retracts proximally to deploy the ALTC Device 8. The Capture Catheter shaft 12 can be made from suitable materials such as and not limit to Nylon, Polyurethane, Pebax, Polyethylene, PET, PTFE, ePTFE, PEEK, polypropylene. It is also advantageous and possible in some embodiments that the Capture Catheter shaft 12 is deflectable at various locations and multiple deflectable directions along the shaft length to accommodate various tortuous paths such as entry into the right atrium, right ventricle, main pulmonary artery, left and right pulmonary artery as previously described.

[0193] A perspective view of another embodiment of a capture system is shown in Figure 51. Figure 51 also illustrates non-limiting examples of various possible elements that can be included in a material capture system, according to some embodiments of the invention. As illustrated in Figure 51, included in some embodiments are any number of, such as one, two, or more of the following components: a thrombus capturing device or ALTC device 201 having any of the features described herein, e.g., a pusher wire or inner pusher 202, a first tubular member such as an outer sheath 203, a loop or capture guide 204, and a coupler 205. The ALTC device 201 can attach to the capture guide 204. In some embodiments, the capture guide 204 comprises a metallic material, such as Nitinol. The capture guide 204 can be in the form of, for example, a loop, as shown, or any closed shape including an oval, ellipse, or polygon. The capture guide 204 can be in the form of an open shape such as any linear or non-linear segment. The ALTC device 201 and the capture guide 204 can be coupled such as being sutured together. The ALTC device 201 and the capture guide 204 can be encapsulated in a low durometer polymeric material. The capture guide 204 can be coupled to the outer sheath 203 via the coupler 205. The proximal end of the ALTC device 201 (not shown) can be coupled to the inner pusher 202.

[0194] The outer sheath 203 can, in some embodiments, be an elongate tubular member with a central lumen therethrough, and have a proximal end 2000 and a distal end 2001, both shown in Figure 51. The distal end 2001 of the outer sheath 203 can be operably connected to a capture device (e.g., tubular mesh as described herein), which can be movably

axially with respect to the outer sheath 203. The proximal end 2000 can include any number of, such as one, two, or more of the following components: a hemostasis assembly 206, a flush port 207, and a collapsed segment 208. The outer sheath 203 extends proximally and can be coupled to the hemostasis assembly 206. The inner pusher 202 extends proximally and can be coupled to a luer. In some embodiments, the inner pusher 202 can have a lumen to allow passage of a guidewire. In some embodiments, the inner pusher 202 is a solid shaft.

[0195] Figure 52 shows the distal end 2001 of the ALTC device 201 in a deployed configuration. In some embodiments, the ALTC device 201 in the initial deployed configuration has a low profile. A portion of the ALTC device 201 is extended while the remaining length of the ALTC device 201 is collapsed and contained within the outer sheath 203 as previously described. In some methods of use, the ALTC device 201 can be collapsed and tracked through a sheath or guide catheter (not shown) to the intended treatment area. In some embodiments, the guide catheter can be retracted proximally to initially deploy the ALTC device 201 and the capture guide 204. For instance, the retraction of the guide catheter can cause the capture guide 204 to expand. The capture guide 204 can include a compressed or constrained configuration while within the guide catheter. During the initial deployment, the capture guide 204 is released from a constrained position to a neutral position. In the neutral position, the capture guide 204 creates a perimeter for the ALTC device 201. In the case of a loop or other circular configuration, the capture guide 204 can create a constant diameter. In the case of other shapes or configurations, the capture guide 204 can create a constant cross-section. Alternatively or in combination, in other methods of use, the ALTC device 201 can be advanced distally from the guide catheter to deploy the ALTC device 201.

[0196] In some cases, only a small fractional portion of the ALTC device 201, such as less than about 50%, 45%, 40%, 35%, 30%, 25%, 20%, 15%, 10%, 5%, or less of the axial length of the device can be initially deployed and fully functional. The small portion can correspond to an amount of the ALTC device 201 which allows the capture guide 204 to assume the neutral position. During the deployment of the capture guide 204, a length of the ALTC device 201 can be retained within the outer sheath 203. The ALTC device 201 can follow a curve from the capture guide 204 to the outer sheath 203. Retracting the outer sheath 203 can lengthen the ALTC device 201 while maintaining a constant diameter or cross-section provided by the capture guide 204.

[0197] Figure 53 illustrates an embodiment of an ALTC device 201 in the initially deployed configuration. As illustrated in Figure 53, the ALTC device 201 can be in some embodiments a generally tubular structure, and in some cases a net-like mesh structure that is collapsible within the outer sheath 203. The ALTC device 201 is expandable to the diameter or cross-section provided by the capture guide 204. The ALTC device 201 can be axially lengthened or shortened, such as within a working range, by releasing the ALTC device 201 from the outer sheath 203. The ALTC device 201 can be axially lengthened or shortened while maintaining or substantially maintaining the diameter or cross-section provided by the capture guide 204. The ALTC device 201 can be deployed to form a generally tubular or cylindrical shape of varying axial lengths. The ALTC device 201 can be axially lengthened or shortened to retrieve and capture foreign or otherwise unwanted materials within the body, including the vascular system such as blood clots, thrombus and/or foreign materials. In some embodiments, an outer sheath is not present and a loader can be utilized to prepare the ALTC device 201 for delivery in a low crossing-profile configuration.

[0198] As shown, for example, in Figures 54 and 55, the ALTC device 201 can be axially lengthened. Figure 54 illustrates the ALTC device 201 in a second configuration. The ALTC device 201 is in the second configuration wherein the deployed and expanded ALTC device 201 is longer than the initial deployed configuration in the axial direction. The remaining collapsed ALTC device 201 length resides inside the outer sheath 203 and is shorter than the initial deployed configuration. The outer sheath 203 can be retracted to axially lengthen the ALTC device 201. As the outer sheath 203 is retracted, the capture guide 204 is retracted since the capture guide 204 is coupled to the outer sheath 203 via the coupler 205. As the capture guide 204 is retracted, the ALTC device 201 is advance from the collapsed portion 208 to the expanded portion. The outer sheath 203 can be retracted proximally to axially lengthen the ALTC device 201. Alternatively or in combination, in other methods of use, the capture guide 204 can be retracted to axially lengthen the ALTC device 201, such as be retracting the outer sheath 203. The diameter or cross-section of the ALTC device 201 can remain constant or substantially constant between the initial deployed configuration and the second configuration.

[0199] Alternatively or in combination, in other methods of use, the inner pusher 202 is advanced distally to advance the proximal end of the ALTC device 201. As described

herein, the proximal end of the ALTC device 201 is coupled to the inner pusher 202. In the second configuration, the inner pusher 202 is advanced distally to release a portion of ALTC device 201 from the outer sheath 203.

[0200] Figure 55 illustrates an embodiment of an ALTC device 201 in a third configuration. The ALTC device 201 is in the third configuration wherein the deployed and expanded ALTC device 201 is longer than the second configuration in the axial direction. The remaining collapsed ALTC device 201 length resides inside the outer sheath 203 and is shorter than the second configuration. The outer sheath 203 can be retracted proximally to axially lengthen the ALTC device 201. The diameter or cross-section of the ALTC device 201 can remain constant or substantially constant between the second configuration and the third configuration. Alternatively or in combination, in other methods of use, in the third configuration, the inner pusher 202 is advanced distally to a greater extent. In the third configuration, the inner pusher 202 is advanced distally to release a longer portion of ALTC device 201 from the outer sheath 203.

[0201] Figure 56 illustrates an embodiment of the material capture, e.g., basket mesh element 209. The basket mesh element 209 can be a component of the ALTC device 201. The basket mesh element 209 can be a structural mesh that provides an appropriate shape as described herein. The basket mesh element 209 can comprise Nitinol or other materials. The basket element can be braided, weave, wireform or laser cut. The basket mesh element 209 can include a first end that couples to the capture guide 204. The basket mesh element 209 can be coupled to the capture guide 204 via a suture or other mechanical means including welding, clips, flanges, adhesive, lamination, etc. The basket mesh element 209 and the capture guide 204 can be encapsulated within a low durometer polymeric material. The second end of the basket mesh element 209 can be coupled to the inner pusher 202. The second end can be folded inward to couple to the inner pusher 202. The second end can be inverted to couple to the inner pusher 202. The second end 202 can form a tube within a tube configuration of the ALTC device 201.

[0202] Figure 57 illustrates an embodiment of the ALTC device 201. The ALTC device 201 has an expanded portion when the ALTC device 201 is deployed (e.g., initial deployed configuration, second configuration, third configuration, etc.). The expanded portion has a constant diameter or cross-section as described herein. The expanded portion,

or a portion thereof, is coupled to the capture guide 204. The expanded portion is coupled to the outer sheath 203 via the capture guide 204 and the coupler 205. The ALTC device 201 has a collapsed portion 208. The collapsed portion 208 can reside within the lumen of the outer sheath 203. The collapsed portion 208 can be retained within the outer sheath 203 when the expanded portion is in the deployed configuration. The collapsed portion 208, or a portion thereof, can be coupled to the inner pusher 202. The collapsed portion 208 is everted as shown. During axial lengthening of the ALTC device 201, a portion of the collapsed portion 208 can roll-out at a distal region to transition between the collapsed portion 208 and the expanded portion.

[0203] Figures 58A and 58B illustrate embodiments of the capture guide 204. Figure 58A illustrates the capture guide 204. Figure 58B illustrates the capture guide 244, which can include any of the features of capture guide 204. The capture guide 204 can form a continuous shape. The capture guide 204 can include leg elements 210. The leg elements 210 can transition the capture guide 204 from an axial direction to a perimeter shape. The perimeter shape can be circular as shown in Figure 58A. The capture guide 204 can form a continuous loop. The capture guide 244 can include a non-continuous perimeter. As shown in Figure 58B, the capture guide 244 can include a non-continuous loop. The capture guide 204, 244 can be made of a metallic material. In some embodiments, the capture guide 204, 244 is formed of a shape-memory material. In some embodiments, the capture guide 204, 244 is formed from Nitinol. The capture guide 204, 244 can be formed of a spring-like material such as a metal. The capture guide 204, 244 can be circular, elliptical, semi-circular, or any combination thereof. The capture guide 204, 244 can include a pre-shaped curve. The pre-shaped curve can be formed during the manufacturing of the capture guide 204, 244. The pre-shaped curve can be a neutral or expanded shape of the capture guide 204, 244. Upon release of a constraint, the capture guide 204, 244 will assume the pre-shaped curve. The capture guide 204, 244 can have any curved shape. The capture guide 204, 244 can have a single radius of curvature or multiple portions having different radii of curvature. The capture guide 204, 244 can be considered spring loaded based in part of the material and the shape of the capture guide 204, 244. In some embodiments, the anchors can include non-continuous shapes, such as hooks with sharp or atraumatic segments or tips in some cases.

[0204] The capture guide 204, 244 can have two or more leg elements 210. The leg elements 210 can be adjacent or adjoining within the guide catheter during delivery. The leg elements 210 can be relatively parallel or side-by-side during delivery in the collapsed configuration. The collapsed leg elements 210 can define a different diameter or cross-section as compared to the fully expanded or neutral configuration of the capture guide 204, 244. In some embodiments, the collapsed leg elements 210 enable the capture guide 204, 244 to have a smaller diameter or cross-section while collapsed within the guide catheter. For example, when the capture guide 204, 244 is fully expanded, the circular portion of the capture guide 204, 244 defines a diameter. For non-circular capture guide 204, 244, the capture guide 204, 244 can define a cross-section when fully expanded. Upon collapsing the leg elements 210, the circular portion of the capture guide 204, 244 defines a diameter that is smaller than the previous expanded configuration. The capture guide 204 can comprise one segment as shown in Figure 58A with two ends that form a continuous loop configuration. The capture guide 244 can comprise multiple segments as shown in Figure 58B and form a non-continuous loop.

[0205] During expansion, the leg elements 210 can bias the capture guide 204, 244 outward to assume the neutral configuration of the capture guide 204, 244. The leg elements 210 can be positioned at an angle relative to each other in the neutral configuration of the capture guide 204, 244. The leg elements 210 can include one or more bends to facilitate folding of the capture guide 204, 244. The one or more bends can enable the capture guide 204, 244 to fold in a low profile configuration along the longitudinal axis of the guide catheter.

[0206] Figure 59 shows one aspect of the opening of the ALTC device 201. The end of the ALTC device 201, or a portion thereof, attaches to the capture guide 204. While the capture guide 204 is shown in Figure 59, any capture guide or feature thereof can be coupled to the end of the ALTC device 201. The end of the ALTC device 201 and the capture guide 204 form an assembly. The assembly can be encapsulated within a low durometer polymeric material to form a polymeric coating or ring 245. The polymeric coating can encapsulate the assembly completely or a portion thereof. In the illustrated embodiment, the polymeric coating encapsulates a portion of the end of the ALTC device 201 and the capture guide 204. The polymeric coating can encapsulate the rounded portion of

the capture guide 204 having a constant or substantially constant diameter. The polymeric coating can encapsulate the entire ALTC device 201, or any portion thereof. The area where the polymeric coating is void/not present can allow for easy movement. For instance, the area between the leg elements can be void. The void area can facilitate collapse of the capture guide 204. In some embodiments, the polymeric coating can be selectively applied. In some embodiments, the polymeric coating can form a ring or a portion of a ring. The polymeric coating can be applied to the outside of the material capture element, e.g., basket mesh element 208. The polymeric coating can be applied to the inside of the basket mesh element 208. The polymeric coating can be applied to the entire basket mesh element 208 to encapsulate the basket mesh element 208.

[0207] Figure 60 shows one aspect of the opening of the ALTC device 201. The ALTC device 201 can include a central, longitudinal axis. The outer sheath 203 can include a longitudinal axis. The inner pusher 202 can extend along the longitudinal axis of the outer sheath 203. The central, longitudinal axis of the ALTC device 201 can be offset from the longitudinal axis of the outer sheath 203. The central, longitudinal axis of the ALTC device 201 can be offset from the longitudinal axis of the inner pusher 202. The capture guide 204 can define the offset. For instance, the central, longitudinal axis of the ALTC device 201 can include the central point of the circle created by the capture guide 204. The central point of the capture guide 204 can be offset from the outer sheath 203. As described herein, the end of the ALTC device 201 is coupled to the inner pusher 202. The ALTC device 201 axially lengthens by releasing a portion of the ALTC device 201 from the outer sheath 203. The ALTC device 201 that is released follows a portion of the inner pusher 202 as shown in Figure 59. The released portion of the ALTC device 201 curves outward and assumes the diameter of the capture guide 204. The ALTC device 201 can form an everted shape with a portion of the ALTC device 201 collapsed near the inner pusher 202 and a portion of the ALTC device 201 expanded to the diameter or cross-section of the capture guide 204. In some embodiments, the shape of the ALTC device 201 can resemble a tube within a tube. In some embodiments, the ALTC device 201 can be considered telescoping.

[0208] A perspective view of another system is shown in Figure 61. Figure 62 shows the proximal end of the system and Figure 63 shows the distal end of the system. Figure 64 shows a subassembly of the system. Figures 61-64 also illustrates non-limiting

examples of various possible elements that can be included in a material capture system, according to some embodiments of the invention. As illustrated in Figure 61, included in some embodiments are any number of, such as one, two, or more of the following components: an anchor assembly 221, a corewire and basket assembly 222, an anchor and pusher assembly 223, a proximal catheter assembly 224, and a distal catheter assembly 225. The anchor assembly 221 can include about or at least about one, two, three, four, five, or more anchors 241 configured to secure a clot. The anchor and pusher assembly 223 includes one or more anchors 241 and the anchor pusher 240. The anchors can be coupled to the pusher as described herein. The corewire and basket assembly 222 can include a corewire 242 and the ALTC device 201. The proximal catheter assembly 224 can include a shaft with one, two, or more lumens, e.g., the dual lumen shaft 243. Figure 61 illustrates a dual lumen shaft 243 of the system. The dual lumen shaft 243 can be attached to the hemostasis housing 206 described herein. The dual lumen shaft 243 can be coupled to the capture guide 204 via the coupling 205. The illustrated embodiment shows a dual lumen shaft, but other configurations are contemplated. In some embodiments, the shaft has a single lumen. In some embodiments, the shaft is a multi-lumen shaft. The shaft can have about or more than about one lumen, two lumens, three lumens, four lumens, five lumens, six lumens, seven lumens, etc. In some embodiments, the anchor 241 is a single loop. In some embodiments, the anchor 241 is a continuous loop. In some embodiments, the anchor 241 has a closed perimeter. In some embodiments, the anchor 241 has an open perimeter. In some embodiments, the anchor 241 forms a circular shape. In some embodiments, the anchor 241 forms an oval. In some embodiments, the anchor 241 forms any round, closed shape.

[0209] Figure 62 illustrates the proximal end of the system including the corewire and basket assembly 222, the anchor and pusher assembly 223, and the proximal catheter assembly 224. The corewire and basket assembly 222 and the anchor and pusher assembly 223 can reside in separate lumens of the dual lumen shaft 243. The system can include the corewire 242. The corewire 242 can include any of the features or function as the inner pusher 202. The corewire 242 can be coupled to a pusher lock 246. The anchor pusher 240 can extend through the pusher lock 246. The pusher lock 246 can be movable along the shaft of the anchor pusher 240. In some embodiments, the pusher lock 246 can limit the expansion of the anchors 241. In some embodiments, the pusher lock 246 can provide a tactile response

when the anchors 241 are deployed by abutting the anchor and pusher assembly 223 with the pusher lock 246.

[0210] Figure 63 illustrates the distal catheter assembly 225. The distal catheter assembly 225 can include any of the features described herein. The distal catheter assembly 225 can include the ALTC device 201. The distal catheter assembly 225 can include the coupler 205 between the outer shaft 203 and the capture guide 204.

[0211] Figure 64 illustrates the anchor assembly 221. The anchor assembly 221 can comprise one or more anchors 241. The anchor assembly 221 can comprise about or at least about one anchor, two anchors, three anchors, four anchors, five anchors, six anchors, seven anchors, eight anchors, nine anchors, ten anchors, or more than ten anchors 241. The illustrated embodiment shows three anchors, but other configurations are contemplated. The anchor assembly 221 can include the anchor pusher 240. The anchor pusher 240 can include an elongate member comprising a shaft. The anchor pusher 240 can be extended proximally within the dual lumen shaft 243. The anchor pusher 240, or a portion thereof, can pass proximally through the proximal catheter assembly 224. The anchor pusher 240, or a portion thereof, can pass proximally through the pusher lock 246. The anchor pusher 240, or a portion thereof, can be connected to the luer hub. The anchor assembly 221 can be contained in the dual lumen shaft 243. The one or more anchors 241 can be coupled at a distal end of the anchor pusher 240. The one or more anchors 241 can be one anchor or a plurality of anchors 241. The anchors can be connected to the anchor pusher 240 in series, and regularly or irregularly spaced apart. In some embodiment, the diameter of the anchor 241 when expanded is smaller than the diameter of the capture guide 204 when expanded. In some embodiment, the diameter of the anchor 241 when expanded is smaller than the ALTC device 201 when expanded. The anchor 241 can be designed to fit within the ALTC device 201 when the ALTC device 201 is expanded. In some embodiments, the anchors can form symmetric or asymmetric loop shapes to circumscribe and stabilize a portion of the clot. In some embodiments, the anchors can be an mesh or braided element. In some embodiments, the anchor can be a balloon. In some embodiment, there can be a combination of braided mesh and balloon. In some embodiments, the anchors 241 can have a portion that extend radially outwardly from the elongate member in which they are attached.

[0212] Figure 65 illustrates a side view of the distal end of the ALTC device 201 and the anchors 241. The anchors 241 can include or be similar to any of the features of capture guide 204, 244 described herein. Each anchor 241 can form a continuous shape, or a discontinuous shape in other embodiments. Each anchor 241 can include leg elements 228. The leg elements 228 can transition the anchor 241 from an axial direction to a perimeter shape. The perimeter shape can be circular as shown in Figure 64. The anchor 241 can form a continuous loop. The anchor 241 can include a non-continuous perimeter such as a non-continuous loop. The anchor 241 can be made of a metallic material. In some embodiments, the anchor 241 is formed of a shape-memory metal such as Nitinol. The anchor 241 can be circular, elliptical, semi-circular, or any combination thereof. Each anchor 241 can include a pre-shaped curve. Two or more anchors 241 can have the same pre-shaped curve. Two or more anchors 241 can have a different pre-shaped curve. The pre-shaped curve can be formed during the manufacturing of the anchors 241. The pre-shaped curve can be a neutral or expanded shape of the anchors 241. Upon release of a constraint, the anchors 241 can assume the pre-shaped curve. The pre-shaped curve of the anchors 241 can be similar to the pre-shaped curve of the capture guide 204. The anchors 241 can have a different radius of curvature from the capture guide 204. As described herein, the anchors 241 can have a smaller diameter than the capture guide 204. Alternatively, the anchors can have the same or larger diameter than the capture guide. In some embodiments, the anchors include barbed elements to attach to a clot. In some embodiments, the anchors are atraumatic and do not include any barbed or other sharp surfaces.

[0213] The anchor 241 can have two or more leg elements 228. The leg elements 228 can be adjacent or adjoining within the guide catheter during delivery, and relatively parallel to the . The leg elements 228 can be relatively parallel or side-by-side during delivery in the collapsed configuration. The collapsed leg elements 228 can define a different diameter or cross-section as compared to the fully expanded or neutral configuration of the anchor 241. In some embodiments, the collapsed leg elements 228 allow the anchor 241 to have a smaller diameter or cross-section while collapsed within the guide catheter. For example, when the anchor 241 is fully expanded, the circular portion of the anchor 241 defines a diameter. For non-circular anchors 241, the anchor 241 can define a cross-section when fully expanded. Upon collapsing the leg elements, the circular portion of the anchor

241 defines a diameter that is smaller than the previous expanded configuration. The anchor 241 can comprise one segment as shown in Figure 64 that forms a continuous loop configuration. The anchor 241 can comprise multiple segments similar to capture guide 244 shown in Figure 58B. The anchors 241 have a outwardly curving shape relative to the two or more leg elements 228.

[0214] The anchor 241 can include an expanded position as shown in Figure 65. In the case of a shape memory material the expanded position can be a neutral position of the material. The anchor 241 can be configured to fold or bend during delivery. The anchor 241 can assume a low-profile configuration during delivery. The expanded anchor 241 can have any shape including round, circular, elliptical, etc. The anchors 241 expand to their pre-formed shape upon removal of a constraint, such as outer sheath 203, delivery catheter, or other constraining structure.

[0215] The expanded position of an anchor 241 can be defined by angle theta θ. In some embodiments, the angle theta is measured from the leg element 228 to the circular portion of the anchor 241. In some embodiments, the angle theta is measured from the horizontal to the vertical extension of the anchor 241. In some embodiments, the angle theta is measured from the dual lumen shaft 243 to the expanded portion of the anchor 241. In some embodiments, the angle theta determines the vertical or substantially vertical orientation of the anchor 241. Each anchor 241 of a plurality of anchors 241 can have the same angle theta. If the anchors 241 are arranged in a series, the angle theta can be uniformly the same. Two or more anchors 241 can have the same angle theta, or angles that are within about 30, 25, 20, 15, 10, 5, 4, 3, 2, 1, or less degrees of each other.

[0216] Each anchor 241 of a plurality of anchors 241 can have a different angle theta. Two or more anchors 241 can have the different angle theta. If the anchors 241 are arranged in a series, the series of anchors 241 can also have different variations in the angle theta. For example, the first anchor 241 can have a first angle theta such as about or at least about 45 degrees, such as between about 0 and 90 degrees, between about 15 and 75 degrees, or between about 30 and 60 degrees in some cases. The next or immediately adjacent anchor 241 can have a second angle theta such as 135 degrees. The next or immediately adjacent anchor 241 can have a third angle theta such as 45 degrees. The series can continue to

alternate between 45 degrees and 135 degrees or other desired angles. In some embodiments, the series of anchors can have different diameter.

[0217] In some embodiments, two or more anchors 241 can form a mirror image. In some embodiments, two or more anchors 241, 241 can extend from the dual lumen shaft 243 such that the circular portion of one anchor 241 substantially projects onto the circular portion of the other anchor 241. In some embodiments, two or more anchors 241 can be identical or substantially identical in orientation. In some embodiments, two or more anchors 241 can be coaxial. In some embodiments, two or more anchors 241 have different orientations relative to the dual lumen shaft 243. In some embodiments, two or more anchors 241 are not coaxial. In some embodiments, a first anchor 241 has a first axis extending through the circular portion of the first anchor 241 and the second anchor 241 has a second axis extending through the circular portion of the second anchor 241. In some embodiments, the first axis and the second axis can be skewed. In some embodiments, the first axis and the second axis are perpendicular. In some embodiments, the first axis and the second axis are parallel. In some embodiments, the first axis and the second axis are coaxial.

[0218] In some embodiments, the angle theta can range from 5 degrees to 175 degrees. Examples of the angle theta include 5 degrees, 10 degrees, 15 degrees, 20 degrees, 25 degrees, 30 degrees, 35 degrees, 40 degrees, 45 degrees, 50 degrees, 55 degrees, 60 degrees, 65 degrees, 70 degrees, 75 degrees, 80 degrees, 85 degrees, 90 degrees, 95 degrees, 100 degrees, 105 degrees, 110 degrees, 115 degrees, 120 degrees, 125 degrees, 130 degrees, 135 degrees, 140 degrees, 145 degrees, 150 degrees, 155 degrees, 160 degrees, 165 degrees, 170 degrees, 175 degrees, etc., and ranges incorporating any two of the aforementioned values. Examples of the angle theta can be in the range of 0-20 degrees, 20-40 degrees, 40-60 degrees, 60-80 degrees, 80-100 degrees, 100-120 degrees, 120-140 degrees, 140-160 degrees, 160-180 degrees, etc. In some embodiments, the angle theta can be approximately 90 degrees. In such embodiment, the anchor 241 can be approximately vertical relative to the dual lumen shaft 243. In some embodiments, the angle theta can be approximately 45 degrees. In such embodiment, the anchor 241 can form an acute angle relative to the dual lumen shaft 243. In some embodiments, the angle theta can be approximately 135 degrees. In such embodiment, the anchor 241 can form an obtuse angle relative to the dual lumen shaft 243.

[0219] The anchor and pusher assembly 223, or a portion thereof, can be moved within the dual lumen shaft 243. In some embodiments, the anchor and pusher assembly 223 can be moved coaxially within a lumen of the dual lumen shaft 243. The anchor and pusher assembly 223 can be moved independently from the corewire and basket assembly 222. In some embodiments, the anchor and pusher assembly 223 can be moved simultaneously with the corewire and basket assembly 222. In some embodiments, the anchor and pusher assembly 223 can be advanced distally or proximally relative to the dual lumen shaft 243. In some embodiments, the anchor and pusher assembly 223 does not impact the movement of the ALTC device 201. The one or more anchors 241 can be moved independently of the ALTC device 201. As described herein, the one or more anchors 241 can be moved relative to a stationary ALTC device 201. As described herein, the ALTC device 201 can be moved relative to a stationary anchor 241.

[0220] Figure 66 illustrates a top view of the distal end of the ALTC device 201 and the anchors 241. The one or more anchors 241 can be coupled to a distal pusher 226. In some embodiments, the leg extensions 228 of the anchors 241 are coupled to the distal pusher 226. In some embodiments, the angle theta is measured from the distal pusher 226 to the expanded portion of the anchor 241. In the illustrated embodiment, each anchor 241 is coupled to the distal pusher 226. The movement of the distal pusher 226 causes simultaneous movement of all anchors 241 coupled thereto. In alternative embodiments, two or more distal pushers 226 are provided. Each of the two or more distal pushers 226 controls the movement of one or more anchors 241. The two or more distal pushers 226 can move independently such that two or more anchors 241 can move independently. Other configurations are contemplated. The distal pusher 226 can be coupled to a crescent pusher 227. In some embodiments, the crescent pusher 227 can provide rigidity to the distal pusher 226. The distal pusher 226 and the crescent pusher 227 can be affixed via welding, adhesive, mechanical interference, etc.

[0221] Figure 67 illustrates a front view of the distal end of the ALTC device 201 and the anchors 241. The dual lumen shaft 243 is shown in cross section. In some embodiments, the dual lumen shaft 243 provides a lumen for the anchor and pusher assembly 223 and a lumen for the corewire and basket assembly 222. The two lumens can be separated

such that movement of one assembly does not impact the movement of the other assembly. Other configurations are contemplated.

[0222] The corewire and basket assembly 222 includes the corewire 242. The corewire 242 is shown disposed in one lumen of the dual lumen shaft 243. The corewire 242 can include any of the feature or functions of the inner pusher 202 described herein. The compressed basket or compressed ALTC device 201 is disposed in the same lumen of the dual lumen shaft 243 as the corewire 242. The compressed ALTC device 201 can have any of the features or function as the collapsed segment 208 described herein. The outer shaft of the dual lumen shaft 243 is shown.

[0223] The anchor and pusher assembly 223 can include the distal pusher 226 and the crescent pusher 227 described herein. The crescent pusher 227 can be coupled to the anchor pusher 240, described herein. In some embodiments, the distal pusher 226, the crescent pusher 227, and the anchor pusher 240 are integrally or monolithically formed. In some embodiments, the distal pusher 226 is a portion of the anchor pusher 240. The crescent shape of the crescent pusher 227 may prevent rotation of the crescent pusher 227 within the dual lumen shaft 243. The crescent pusher 227 is shown a lumen of the dual lumen shaft 243.

[0224] The anchors 241 can be coupled to the anchor pusher 240, such that movement of the anchor pusher 240 causes movement of the one or more anchors 241. The anchors 241 can be coupled to the distal pusher 226, such that movement of the distal pusher 226 causes movement of the one or more anchors 241. In some embodiments, the anchors 241 can be welded to the distal pusher 226. The anchors 241 are arranged such that the anchors 241 are coaxial along central longitudinal axis 230. As shown in the illustrated embodiment, only one anchor is visible from the front view due to the coaxial nature of the anchors 241.

[0225] The ALTC device 201 is expanded as shown in Figure 67. The outer diameter 232 of the anchor 241 can be smaller than the inner diameter 233 of the basket or ALTC device 201 in order for the ALTC device 201 to capture the anchors 241. The ALTC device 201 can capture one or more anchors depending on the axial length of the ALTC device 201. The axial length of the ALTC device 201 is adjustable based on the release of the ALTC device 201 from the dual lumen shaft 243. As a longer portion of the ALTC device 201 is released, the ALTC device 201 axially lengthens. As described herein, the ALTC

device 201 remains at a constant diameter or cross-section as the ALTC device 201 lengthens. The capture guide 204 maintains the shape of the expanded ALTC device 201 as the ALTC device 201 axially lengthens. The capture guide 204 is smaller in diameter than the outer diameter 232 of the anchor 241.

[0226] The capture guide 204 can function as a centering device to center the system within the vessel. The capture guide 204 can be a similar diameter or cross-sectional shape as the vessel. In some methods of use, the capture guide 204 is smaller than the diameter of the blood vessel when the capture guide 204 is expanded. In some methods of use, the capture guide 204 is approximately equal to the diameter of the blood vessel when the capture guide 204 is expanded. In some methods of use, the ALTC device 201 is smaller than the diameter of the blood vessel when the ALTC device 201 is expanded. In some methods of use, the ALTC device 201 is approximately equal to the diameter of the blood vessel when the ALTC device 201 is expanded. In some methods of use, the ALTC device 201 contacts the vessel wall of the blood vessel. In some methods of use, the ALTC device 201 does not contact the vessel wall.

[0227] The capture guide 204 can include the central longitudinal axis 231. In some embodiments, the dual lumen shaft 243 can be offset from the central longitudinal axis 231. In some embodiments, the dual lumen shaft 243 can be coaxial with the central longitudinal axis 231 (not shown). The anchor 241 can include the central longitudinal axis 230. In some embodiments, the dual lumen shaft 243 can be offset from the central longitudinal axis 230. In some embodiments, the dual lumen shaft 243 can be coaxial with the central longitudinal axis 230 (not shown). In some embodiments, the central longitudinal axis 230 of the anchor 241 can be offset from the central longitudinal axis 231 of the capture guide 204. In some embodiments, the central longitudinal axis 230 of the anchor 241 can be coaxial with the central longitudinal axis 231 of the capture guide 204 (not shown). In some embodiments, the dual lumen shaft 243 can be positioned near an edge of the capture guide 203. Other configurations are contemplated.

[0228] Figures 68A-69C illustrate capture of a clot within a vessel, according to some embodiments. Figure 68A illustrates the ALTC device 201 in the initially deployed configuration. As illustrated in Figure 68A, the ALTC device 201 can be in some embodiments a generally semi-spherical mesh structure when initially deployed. The mesh

structure is initially collapsible within a guide catheter or outer sheath 203. The guide catheter delivers the ALTC device 201 to the desired location within the body of the patient. The capture guide 204 is released from the constrained condition within the guide catheter or outer sheath 203. The capture guide 204 expands to have a cross-sectional shape. In some embodiments, the capture guide expands to a round or circular shape.

[0229] The ALTC device 201 is expandable to the diameter or cross-section provided by the capture guide 204. In some methods of use the ALTC device 201 is expanded by removal of a constraint. The ALTC device 201 can be released from a guide catheter. The guide catheter can be retracted to allow the capture guide 204 to expand. In some methods of use, the ALTC device 201 can be released from within the dual lumen shaft 243 by retraction of the dual lumen shaft. As described herein, one end portion of the ALTC device 201 is coupled to the capture guide 204. The ALTC device 201 can include a tubular mesh with a distal end. The ALTC device 201 can include a dynamic fold point as described herein such that the tubular mesh becomes everted upon release from the dual lumen shaft 243. The ALTC device 201 can include a reserve radially compressed segment within the dual lumen shaft terminating proximally at a point coupled to the inner pusher 202. In some methods of use, the expanded segment of the ALTC device 201 is positioned distal to the blood clot. The outer sheath 203 is positioned proximally, within, or adjacent to the blood clot.

[0230] Figure 68B shows the ALTC device 201 in the initially deployed configuration. As described herein, the corewire and basket assembly and the anchor and pusher assembly can be independently actuated. The first anchor 241 can be released when the outer sheath 203 retracts proximally. The first anchor 241 can include a shape memory material such that the first anchor 241 assumes an expanded configuration. The first anchor 241 can expand such that the first anchor 241 is defined by the angle theta. The first anchor 241 expands from a low profile configuration to an expanded configuration. The low profile configuration can enable the anchor 241 to reside within the outer sheath 203 during delivery. In some additionally or alternative methods of use, the first anchor 241 can be released when the anchor pusher 240 advances distally.

[0231] The released anchor can be firmly secured to the clot. In some methods of use, the first anchor 241 can become entangled in the clot. In some methods of use, the first

anchor 241 can reside against the clot. In some methods of use, the first anchor 241 can be designed to push the clot. In some methods of use, the first anchor 241 can be designed to perform a sweeping motion through the clot. The sweeping motion can be over an arc of the angle theta, or a portion thereof. The sweeping motion can break the clot, or a portion thereof.

[0232] Figure 68C shows the ALTC device 201 in the initially deployed configuration. The second anchor 241 can be released when the outer sheath 203 retracts proximally. In some methods of use, the second anchor 241 can be released when the anchor pusher 240 advances distally. The second anchor 241 can include a shape memory material such that the second anchor 241 assumes an expanded configuration. The second anchor 241 can expand such that the second anchor 241 is defined by the angle theta. As described herein, the first anchor 241 and the second anchor 241 can have the same or different orientation for the angle theta.

[0233] Figure 68D shows the ALTC device 201 in the initially deployed configuration. In some methods of use, the third anchor 241 can be released when the outer sheath 203 retracts proximally. In additional or alternative embodiments, the third anchor 241 can be released when the anchor pusher 240 is advanced distally. The third anchor 241 can include a shape memory material such that the third anchor assumes an expanded configuration. The third anchor 241 can expand such that the third anchor 241 is defined by the angle theta. As described herein, the first anchor 241, the second anchor 241 and the third anchor 241 can have the same or different orientation for the angle theta.

[0234] The first anchor 241, the second anchor 241 and the third anchor 241 can be designed to be secured to the clot. The arrangement of the anchors 241 can be designed to facilitate engagement with the clot. For instance, the number of anchors, the spacing of the anchors, the cross-section dimension of the anchors, the shape of the anchors, the orientation of the anchors relative to the anchor pusher, the angle theta, the shape of the leg extension, the rapidness of the shape memory material to assume the neutral shape, the stiffness of the material, as well as other factors can be optimized to facilitate engagement of the anchors 241 with the clot.

[0235] The ALTC device 201 and the anchors 241 can retract proximally to remove the clot. In some methods of use, the ALTC device 201 can catch emboli or debris

that dislodges during removal of the clot. In some methods of use, the ALTC device 201 is positioned downstream in a vessel to catch debris. The curved distal end of the ALTC device 201 can function as a net. In some methods of use, the anchors 241 can disrupt the clot to enable easier removal of the clot. In some methods of use, the sweeping motion of deploying the anchors 241 can break apart the clot.

[0236] Figures 69A-69C illustrates the axial lengthening sequence of the ALTC device 201, according to some embodiments. The dual lumen sheath 243 can be retracted to axially lengthen the ALTC device 201. As the dual lumen sheath 243 is retracted, the capture guide 204 is retracted since the capture guide 204 is coupled to the dual lumen sheath 243 via the coupler 205. As the capture guide 204 is retracted, the collapsed portion 208 becomes the expanded portion. The dual lumen sheath 243 can be retracted proximally to axially lengthen the ALTC device 201. Alternatively or in combination, in other methods of use, the capture guide 204 can be retracted to axially lengthen the ALTC device 201, such as be retracting the dual lumen sheath 243. The diameter or cross-section of the ALTC device 201 remains constant between the initial deployed configuration shown in Figure 69A and the expanded configurations shown in 69B and 69C. In additional or alternative methods of use, the corewire 242 can be actuated to axially lengthen the ALTC device 201. The corewire 242 can be positioned within the dual lumen shaft 243. Actuation of the corewire 242 such as axially in the appropriate direction will release the constrained portion of the ALTC device 201. The movement of the corewire 242 can result in axial lengthening or shortening of the ALTC device 201.

[0237] Figure 69A illustrates the system after deployment of the anchors 241. In some methods of use, the anchors 241 are deployed before axial lengthening of the ALTC device 201. In some methods of use, one or more steps of releasing an anchor and axially lengthening can occur in any order. In some methods of use, the first anchor is deployed and then the ALTC device 201 is axially lengthened to cover the first anchor. In some methods of use, the first and second anchors are deployed before the ALTC device 201 is axially lengthened to cover the first anchor or the second anchor. In some methods of use, the first, second, and third anchors are deployed before the ALTC device 201 is axially lengthened to cover the first anchor, the second anchor, or the third anchor. In some embodiments, two or more steps can occur simultaneously. In some methods of use, the first anchor is deployed

and the ALTC device 201 is axially lengthened to cover the first anchor simultaneously. In some methods of use, the first and second anchor are deployed and the ALTC device 201 is axially lengthened to cover either the first anchor or the second anchor simultaneously. In some methods of use, the first, second, and third anchors are deployed and the ALTC device 201 is axially lengthened to cover the first anchor, the second anchor, or the third anchor simultaneously.

[0238] Figure 69B illustrates the axial lengthening of the expanded portion of the ALTC device 201. The ALTC device 201 is lengthening proximally to capture the clot secured by the first anchor 241. The compressed or constrained segment of the ALTC device 201 is shortening within the dual lumen shaft 243 reciprocally. The dual lumen sheath 243 can be retracted to axially lengthen the ALTC device 201, as described herein. The ALTC device 201 can encapsulate the first anchor 241. The first anchor 241 can be sized to fit within the ALTC device 201 once the ALTC device 201 is axially lengthened.

[0239] Figure 69C illustrates the axial lengthening of the expanded portion of the ALTC device 201. The ALTC device 201 is lengthening proximally to capture the clot secured by the first anchor 241, the second anchor 241, and the third anchor 241. The compressed or constrained segment of the ALTC device 201 is shortening within the dual lumen shaft 243 reciprocally. Figure 69C illustrates the axial lengthening ALTC device 201 is sufficient to completely capture the clot. The ALTC device 201 and the anchors 241 can retract proximally to remove the clot.

[0240] The ALTC device 201 can be axially lengthened, such as within a working range, by releasing the ALTC device 201 from the sheath, which can have one, two, or more lumens in the sheath 243. The ALTC device 201 can be axially lengthened or shortened while maintaining or substantially maintaining the diameter or cross-section provided by the capture guide 204. The ALTC device 201 can be axially lengthened or shortened to retrieve and capture foreign or otherwise unwanted materials within the body, including the neurovascular system such as blood clots, thrombus and/or foreign materials.

[0241] The ALTC device 201 described herein can be sized to fit within a vessel of the neurovascular system, including any vessel noted elsewhere herein. As one example, the ALTC device 201 can be used to treat arteries, veins, and non-vascular lumens or regions. In some embodiments, the device can be configured to treat cerebral venous sinus thrombosis

and cavernous sinus thrombosis. A thrombus, commonly called a clot, is the product of blood coagulation due to aggregated platelets and red blood cells connected by a fibrin protein to block a blood vessel. The thrombus can travel (embolize), such as propagating toward the heart, lungs or other organs. The removal of thrombus can reduce the risk of a stroke, myocardial infarction, and/or pulmonary embolisms. The ALTC device 201 can lengthen to have a maximal length that covers the entire length of anchors 241, e.g., from about 0.01 mm to about 100 mm. Depending on vessel diameter, the outer diameter of the ALTC device 201 can range from, in some embodiments, from about 0.01 millimeter up to about 10 millimeters. The diameter of the ALTC device can achieve the similar effect of reducing or stretching the ALTC device diameter. In some embodiments, suction is not utilized or required, and the ALTC device envelops the clot, which can be mechanically pulled back into the capture catheter. In some embodiments, the mechanical thrombectomy systems and methods as disclosed herein can be used in combination with, and/or coated with a therapeutic agent such as, for example, one or more anti-thrombotic or anti-platelet agents such as heparin, hirudin, warfarin, dabigatran, and/or enoxaparin; tPA, streptokinase, or urokinase, an anti-proliferative agent such as paclitaxel (Taxol), rapamycin (Sirolimus), zotarolimus, or tacrolimus; and the like depending on the desired clinical result.

[0242] Figures 70A and 70B illustrate views of an embodiment of a pusher lock system. The pusher lock system can be utilized with any of the system described herein. Figure 70A also illustrates non-limiting examples of various possible elements that can be included in a material capture system, according to some embodiments of the invention. As illustrated in Figure 70A, included in some embodiments are any number of, such as one, two, or more of the following components: a hemostasis seal 260, a pusher lock 261, and a pusher 262. The hemostasis seal 260 can include a plurality of seals at spaced apart locations in the pusher lock system. The hemostasis seal 260 can be similar to the seals shown in Figure 21E and 21F. The pusher lock 261 can include any of the features of pusher lock 246 described herein. The pusher 262 can include any of the features of the inner pusher 202. The pusher 262 can include any of the features of the corewire 242 described herein. The pusher 262 can include any of the features of the anchor pusher 240 described herein.

[0243] Referring first to the system shown in Figures 70A-B, the pusher 262 can include any of the features of the inner pusher 202 described herein. The pusher 262 can

extend from the proximal end to the distal end. In some embodiments, the pusher extends from the nosetip of the catheter to the proximal end. In some embodiments, the pusher 262 is a single shaft. In some embodiments, the pusher 262 comprises one or more subcomponents. The pusher 262 can include an inner guidewire lumen shaft extending from the distal end toward the proximal end. The pusher 262 can include a pusher tube extending from the proximal end. The inner guidewire lumen shaft can be attached to a pusher tube to form a unitary structure. Other configurations are contemplated. The pusher 262 can comprise any material suitable to axially lengthen the ALTC device 201, as described herein. In some embodiments, the pusher 262 or a component thereof, comprises a metal such as stainless steel or titanium. In some embodiments, pusher tube can comprise stainless steel.

[0244] The pusher 262 can be positioned coaxially within a shaft. In some embodiments, the pusher 262 is placed within a middle shaft. The guidewire lumen shaft and the pusher tube assembly are positioned coaxially within the middle shaft. The pusher tube is extended beyond the middle shaft. The pusher tube can slide coaxially with respect to the middle shaft to either lengthen or shorten the ALTC device 201. During clinical use, if there is no locking mechanism for the pusher 262, the user can inadvertently actuate the pusher tube or the middle shaft prematurely, which will deploy the ALTC device 201. The pusher lock 261 helps to secure the pusher tube to the middle shaft during insertion of the catheter. The pusher lock 261 can be unlocked after unsheathing the ALTC device 201. The pusher lock 261 can be unlocked when the user is ready for lengthening the ALTC device 201.

[0245] In some alternative and additionally embodiments, the guidewire lumen shaft and the pusher tube assembly are positioned coaxially within the outer sheath 203. The pusher tube is extended beyond the outer sheath 203. The pusher tube can slide coaxially with respect to the outer sheath 203 to either lengthen or shorten the ALTC device 201. In some embodiments, the pusher tube extends beyond the outer sheath 203, as shown in Figure 51. During clinical use, if there is no locking mechanism for the pusher 252, the user can inadvertently actuate the pusher tube or the outer sheath 203 prematurely, which will deploy the ALTC device 201. The pusher lock 251 helps to secure the pusher tube to the outer sheath 203 during insertion of the catheter. The pusher lock 261 can be unlocked after unsheathing the ALTC device 201. The pusher lock 261 can be unlocked when the user is ready for lengthening the ALTC device 201.

[0246] Referring now to the system shown in Figure 62, the pusher 262 can include any of the features of the corewire 242 described herein. The pusher 262 can include any of the features of the anchor pusher 240 described herein. The pusher 262 can extend from the proximal end to the distal end. The pusher 262 can include an inner guidewire lumen shaft extending from the distal end toward the proximal end. The pusher 262 can include a pusher tube extending from the proximal end. Other configurations are contemplated.

[0247] The pusher 262 is positioned coaxially within a shaft. In some embodiments, the pusher 262 is placed within a middle shaft of the dual lumen shaft 243. The guidewire lumen shaft and the pusher tube assembly are positioned coaxially within the middle shaft. The pusher tube is extended beyond the middle shaft. The pusher tube can slide coaxially with respect to the middle shaft to either lengthen or shorten the ALTC device 201. During clinical use, if there is no locking mechanism for the pusher 262, the user can inadvertently actuate the pusher tube or the middle shaft of the dual lumen shaft 243 prematurely, which will deploy the ALTC device 201. The pusher lock 261 helps to secure the pusher tube to the middle shaft during insertion of the catheter. The pusher lock 261 can be unlocked after unsheathing the ALTC device 201. The pusher lock 261 can be unlocked when the user is ready for lengthening the ALTC device 201.

[0248] In some alternative or additional embodiments, the pusher 262 is placed within an upper shaft of the dual lumen shaft 243. The guidewire lumen shaft and the pusher tube assembly are positioned coaxially within the upper shaft. The pusher tube is extended beyond the upper shaft. The pusher tube can slide coaxially with respect to the upper shaft to deploy the anchors 241. During clinical use, if there is no locking mechanism for the pusher 262, the user can inadvertently actuate the pusher tube or the dual lumen shaft 243 prematurely, which will deploy the anchors 241. The pusher lock 261 helps to secure the pusher tube to the dual lumen shaft 243 after during insertion of the catheter. The pusher lock 261 can be unlocked after unsheathing the ALTC device 201. The pusher lock 261 can be unlocked after unsheathing the first anchor 241. The pusher lock 261 can be unlocked when the user is ready to deploy the anchors 241.

[0249] The method can include one or more of the following steps in any order. The delivery catheter can be prepared. The delivery catheter can be prepared at the bedside of

a patient. The delivery catheter can be prepared according to one or more instructions. In some methods of use, the pusher lock 261 can be locked in position. The pusher lock 261 can be locked in position on the pusher 262. In some embodiments, the pusher lock 261 is locked in position by rotating the lock cap 263. In some embodiments, the pusher lock 261 can be locked by rotating clockwise. In some embodiments, the pusher lock 261 can be locked by rotating counterclockwise.

[0250] In some methods of use, a guidewire is positioned within a patient. In some methods of use, the inner guidewire lumen shaft of the pusher 262 can be guided over the guidewire. In some methods of use, the pusher tube of the pusher 262 can be guided over the guidewire. In some methods of use, the system is advanced over the guidewire. In some methods of use, the delivery catheter is advanced to the intended area for treatment. In some methods of use, the delivery catheter is retracted. In some methods of use, the outer sheath 203 is retracted to deploy the ALTC device 201.

[0251] In some methods of use, the pusher lock 251 is unlocked. In some methods of use, the pusher lock 261 is unlocked by rotating the lock cap 263 counterclockwise. In some methods of use, the pusher lock 261 is unlocked by rotating the lock cap 263 in an opposite direction. Upon unlocking the pusher lock 261, the ALTC device 201 can be lengthened. In some methods of use, the ALTC device is lengthened by axially actuating the middle shaft. In some methods of use, the ALTC device is lengthened by axially actuating the pusher tube. In some methods of use, the ALTC device is lengthened by axially actuating the outer sheath. In some methods of use, the ALTC device is lengthened by axially actuating the dual lumen shaft. The pusher lock 261 can be used to affix the pusher tube to the middle shaft as needed.

[0252] Figures 71A-71D illustrate views of a pusher lock 261 of the pusher lock system of Figure 70A. As illustrated in Figure 71A-71D, included in some embodiments are any number of, such as one, two, or more of the following components: the lock cap 263, a collet 264, and a lock body 265. The lock cap 263 and the lock body can include mating threads. In the illustrated embodiment, the lock cap 263 includes female threads and the lock body 265 includes male threads. The collet 264 is disposed between the lock cap 263 and the lock body 265. The pusher 252, or a portion thereof, is designed to be placed within the collet 264. The pusher 252 can extend through an opening in the lock cap 263, through the collet

264, and through an opening in the lock body 265. The lock cap 263 also includes a ramped surface designed to interact with the collet. As the lock cap 262 is rotated, the collet 264 can be brought into engagement with the ramped surface. Further rotation can cause the collet to collapse or tighten onto the pusher 252. Other configurations are contemplated.

[0253] Figure 72 illustrates a flow chart of an embodiment of a method 300. In some embodiments, the method can assemble the end of the ALTC device 201 to the capture guide 204. The method can include one or more of the following steps, in any order. The step 301 can include mixing a thermoplastic and/or polyurethane, e.g., Pellethane solution. The solution is mixed using, e.g., a thermoplastic polyurethane, e.g., Pellethane and, e.g., a cyclic ester such as Tetrahydrofuran (THF). The mixture of Pellethane and Tetrahydrofuran (THF) ratio can range from, e.g., between about 1:1 and about 1:20 of Pellethane to THF. The ratio of Pellethane to Tetrahydrofuran can be, for example, about, at least about, or no more than about 1:1, 1:2, 1:3, 1:4, 1:5, 1:6, 1:7, 1:8, 1:9, 1:10, 1:11, 1:12, 1:13, 1:14, 1:15, 1:16, 1:17, 1:18, 1.19; 1:20, or ranges including any two of the aforementioned values. The step 302 can include trimming the ALTC device 201. The end of the ALTC device 201 can be squared trim. The step 302 can include loading the ALTC device 201 on the dipping mandrel. The dipping mandrel can be made of polymeric and/or metallic materials such as HDPE, PTFE, stainless steel, etc. The mandrel can be non-coated or coated to allow ease of manufacturing. The step 303 can include dipping the ALTC device 201 in the solution. The ALTC device mounted on a dipping mandrel is slowly dipped into the Pellethane/THF solution. The step 303 can include drying the ALTC device 201. The ALTC device 201 can hang to allow to dry, or dried using other mechanisms. The step 304 can involve removing the ALTC device 201. The step 304 can involve trimming the excess Pellethane. The dipped end of the ALTC device 201 can encapsulate and fix the wire ends of the basket mesh element 209 from movement. The dipped end can prevent the wire ends of the basket mesh element 209 from being exposed. The ALTC device 201 is removed from the dipping mandrel. The excess Pellethane is trimmed close to the edge of the ALTC device 201.

[0254] The step 305 can include punching or otherwise creating one or more apertures in the Pellethane coating. The dipped area of ALTC device 201 can be punched to create holes at predetermine location to allow placement of the capture guide. Other methods of making holes in the coating are contemplated. The step 306 can include inserting the

capture guide 204 into the punched hole. The capture guide 204 is inserted into the punched hole. The capture guide 204 can be woven through two or more holes. The capture guide can be threaded from one side of the ALTC device 201 to the other side of the ALTC device 201. The step 307 can include folding the edge of the ALTC device to cover the capture guide 204. The dipped coat edge of the ALTC device 201 is folded to cover the wire loop of the capture guide 204. The folding can protect and prevent the encapsulated wire ends of the basket mesh element 209 from protruding. The step 308 can include suturing the ALTC device 201 and the capture guide 204. The ALTC device 201 is sutured to the capture guide 204 using suture materials. Suture materials can include, for example, PET, PTFE, HMWPE, or other materials known in the art. The step 309 can include suturing around the edge of the ALTC device. The step 309 can include suture the back stitch around the edge.

[0255] The step 310 can include loading the ALTC device onto the forming mandrel. When the suturing is completed, the ALTC device 201 in then loaded onto the forming mandrel. The step 311 can include thermally forming the stitched ALTC edge. The step 311 can include thermally forming the stitched ALTC device edge using appropriate heating. The forming mandrel can be either polymeric or metallic materials such as PTFE, stainless steel, etc. The step 312 can include dipping the ALTC device and capture device. The ALTC device and capture device can be dipped in the Pellethane solution from step 301. The ALTC device and capture device can be dipped in another solution. The dipping process can include dipping the ALTC device 201 and capture guide 204 into the Pellethane/THF solution. The dipping can secure the assembly of the ALTC device 201 and capture device 204. The step 312 can include loading the assembly of the ALTC device 201 and capture device 204 onto the dipping mandrel. The dipping mandrel can be the same dipping mandrel of steps 302, 303. The dipping mandrel can be a different mandrel. The dipping mandrel for this step 312 can be made of polymeric and/or metallic materials such as HDPE, PTFE, stainless steel, etc. The mandrel for this step 312 can be non-coated or coated to allow ease of manufacturing. In some methods of use, a film or sheet of material can be used in addition or in place of one or more dipping steps. The film can be an extruded polymeric film. The sheet can be a sheet of low durometer polymer such as pellethane, polyurethane, tecothane, etc. The film or sheet can be used and place over the end of the ALTC device. In some methods of use, a film or sheet of material can be used in addition thermally forming the edge of the

ALTC device 201. The film or sheet can be thermally fused. The film or sheet can be laminated together. Other manufacturing methods are contemplated.

[0256] Figures 73-94 illustrate embodiments of anchors. The anchors described herein can be used in conjunction with, or in place of, anchors 241. The one or more anchors described herein can form an anchor assembly 221 described herein. The anchor assembly 221 can include about or at least about one, two, three, four, five, or more anchors configured to secure a clot. In some embodiments, two or more anchors of the anchor assembly 221 can be the same. In some embodiments, two or more anchors of the anchor assembly 221 can be different. In some embodiments, two or more anchors of the anchor assembly 221 can be selected from anchors described herein. In some embodiment, the diameter of the anchor when expanded is smaller than the ALTC device 201 when expanded. In some embodiment, the anchor can be designed to fit within the ALTC device 201 when the ALTC device 201 is expanded. In some embodiments, the anchor can be designed to substantially the same or larger than the ALTC device 201. In some embodiments, the distal end of the ALTC device 201 has a flexible, atraumatic extension forming the distal end of the system. In some embodiments, the distal end of the ALTC device 201 has an anchor. In some embodiments, the anchor can have any shape to entangle a portion of the clot. In some embodiments, the anchor can have any shape to stabilize a portion of the clot. In some embodiments, the anchor can have any shape to provide radial support to the clot. In some embodiments, the anchor can have any shape to provide axial support to the clot. In some embodiments, the anchor can have any shape to move a portion of the clot, such as distally toward the ALTC device 201 or proximally away from the ALTC device 201. In some embodiments, the anchor can rotate. In some embodiments, the anchor can move axial to break up the clot.

[0257] The systems described herein can include the guidewire lumen 6, which can advance distally to lengthen the ALTC device 201. Referring to Figure 5, the outer sheath 1 has an inner diameter configured to house the capture catheter 12 coaxially therein, and the capture catheter 12, which in turn has a lumen configured to house the guidewire tube 6 and the body of the ALTC device 8. The systems described herein can include the pusher 202 or corewire 242. Alternatively or in combination, in other methods of use, an end of the ALTC device 201 is coupled to the inner pusher 202. In the second configuration, the inner pusher 202 is advanced distally to release a portion of ALTC device 201 from a sheath.

As the inner pusher 202 is advanced distally, a portion of the collapsed portion 208 becomes the expanded portion of the ALTC device 201. As the inner pusher 202 is advanced distally, the ALTC device 201 is axially lengthened. In additional or alternative methods of use, the corewire 242 can be actuated to axially lengthen the ALTC device 201. The corewire 242 can be positioned within the dual lumen shaft 243. Actuation of the corewire 242 such as axially in the appropriate direction will release the constrained portion of the ALTC device 201. The movement of the corewire 242 can result in axial lengthening or shortening of the ALTC device 201. In some embodiments, the systems described herein can include a fixed guidewire. In some embodiments, the systems described herein can be advanced along a guidewire. In some embodiments, the systems described herein can slide along a guidewire. In some embodiments, the systems described herein can include a lumen configured to slide along a guidewire. In some embodiments, the guidewire is a shaft. In some embodiments, the guidewire has a lumen. In some embodiments, the guidewire is a needle. In some embodiments, the guidewire is solid. In some embodiments, the guidewire is flexible. In some embodiments, the guidewire functions to guide the system within the body of the patient. In some embodiments, the guidewire functions to deploy one or more components of the device.

[0258] The system can include a dual axial lengthening basket and anchor capture device as described here. The anchors can be any configuration such as stent-like, balloon, coils, loops, wire forms into various geometric shapes (not shown), etc. such as the embodiments described herein. In some methods of use, the anchors can function to secure the emboli, thrombus or debris and allow for removal. In some methods of use, the anchors can function to break up the emboli, thrombus or debris. In some embodiments, the ALTC device 201 and the one or more anchors move or translate together. In some embodiments, the ALTC device 201 and the one or more anchors move or translate independently or separately. In some embodiments, one or more anchors can move as a unit with another anchor. In some embodiments, one or more anchors can move independently or separately from another anchor.

[0259] Figure 73 illustrates an embodiment of an anchor 401. The anchor 401 can include any of the features of anchors described herein. In some embodiments, the anchor 401 can comprise symmetric loop shapes. In some embodiments, the anchor 401 can

comprise asymmetric loop shapes. In some embodiments, the anchor 401 can comprise polygonal shapes or generally polygonal shapes. In some embodiments, the anchor 401 comprises generally hexagonal shapes. In some embodiments, the anchor 401 has a constant diameter. In some embodiments, the anchor 401 has two or more diameters. In the illustrated embodiments, the anchor 401 has an alternating larger diameter and smaller diameter. In some embodiments, the smaller diameter is more than 50% of the larger diameter, the smaller diameter is more than 60% of the larger diameter, the smaller diameter is more than 70% of the larger diameter, the smaller diameter is more than 80% of the larger diameter, the smaller diameter is more than 90% of the larger diameter, the smaller diameter is approximately equal to the larger diameter, etc. It is also understood the anchor can have various length. For example, the anchor can have sufficient length such that the anchor is partially deploy to accommodate the length of the clot. Furthermore, the remainder of the anchor is compressed with the delivery catheter and can be lengthen and expand to accommodate longer length clot as needed.

[0260] In some embodiments, the anchor 401 can be a mesh, braid or other network of wire or thread. In some embodiments, the anchor 401 can have an interlaced structure. In some embodiments, the anchor 401 can be formed from parallel or axial wires or threads 402. The parallel or axial wires or threads can be coupled or otherwise connected at junctions 403. The junctions 403 can couple two or more wires or threads 402 together. In some embodiments, the junctions 403can be staggered to form the mesh structure. In some embodiments, the anchor 401 forms a helix. In some embodiments, the anchor 401 forms a double helix. In some embodiments, the anchor 401 forms a helical structure. In some embodiments, the anchor 401 forms an irregular mesh. In some embodiments, the anchor 401 forms a regular mesh. In some embodiments, the anchor 401 forms a fully connected structure. The anchor 401 can comprise a repeating or tessellating shape such as triangles, squares, or hexagons. The anchor can be laser-cut.

[0261] The anchor 401 can include an flexible tip 404. The flexible tip 404 can function as atraumatic soft tip. The opposite end of the anchor 401 is attached to the anchor pusher 240 and function in a similar manner described herein. The flexible tip 404 can be disposed within the outer sheath 203 described herein. The anchor pusher 240 can be disposed within the dual lumen shaft 243 described herein. The anchor pusher 240 can be

disposed within any lumen of any device, shaft or catheter described herein. The anchor can be offset to the ALTC device. The anchor can be coaxial to the ALTC device. The anchor pusher 240 and the anchor 401 can be coupled together such that movement of the anchor pusher 240 causes movement of the anchor 401. In some embodiments, the flexible tip 404, anchor 401 and the anchor pusher 240 is cannulated for an "over the wire" configuration. The anchor pusher 240 can be guided over a guidewire for placement of the anchor 401.

[0262] Figure 74 illustrates an embodiment of an anchor 405. The anchor 405 can include any of the features of anchors described herein, including anchor 401. In some embodiments, the anchor 405 can be a mesh, braid, laser cut or other network of wire or thread 406. In some embodiment, the anchor is made from one wire or thread. In some embodiments, the anchor 405 can be formed from parallel or axial wires or threads 406. The parallel or axial wires or threads can be coupled or otherwise connected at junctions 407. The junctions 407 can couple two or more wires or threads 406 together. In some embodiments, the junctions 407 can be staggered to form the mesh structure. In some embodiments, the junctions 407 can couple all of the wires or threads 406 together. In some embodiments, the junctions 407 can form a plurality of discrete subsections. In the illustrated embodiments, the anchor 405 can include three subsections formed from two junctions 407. Other configurations are contemplated (e.g., the anchor 405 includes two subsections formed from one junction 407, the anchor 405 can include four subsections formed from three junctions 407, the anchor 405 include five subsections formed from four junctions 407, etc.). In the illustrated embodiments, the anchor 405 has an alternating larger diameter and smaller diameter formed by the junctions 407. In some embodiments, the smaller diameter is less than 50% of the larger diameter, the smaller diameter is less than 40% of the larger diameter, the smaller diameter is less than 30% of the larger diameter, the smaller diameter is less than 20% of the larger diameter, the smaller diameter is less than 10% of the larger diameter, etc. It is also understood the anchor is not limited to metal only but other materials such as polymeric materials PTFE, PET, Nylon, Polyethylene, PEEK, Polypropylene, Polyimide.

[0263] Figure 75 illustrates a distal end of a capture device system including the anchor 401. The system can be placed within a vessel 408. The vessel can be any target vessel within the body of a patient. In some embodiments, the vessel is in the central nervous system or a coronary or peripheral vessel as described elsewhere herein. The system is placed

near an obstruction 409 or other source of debris or material. In some embodiments, the obstruction is a blood clot. In some embodiments, the obstruction is a neurological blood clot. In some embodiments, the obstruction is an emboli. In some embodiments, the obstruction is a foreign body.

[0264] Figure 75 illustrates the system with the anchor 401 and the ALTC device 201 deployed. In some methods of use, one or more steps of releasing an anchor 401 and axially lengthening can occur in any order. In some methods of use, the anchor 401 is deployed before axial lengthening of the ALTC device 201. In some embodiments, the anchor forms only a single loop. In some embodiments, the single loop functions in a similar manner to the anchor 401. In some methods of use, the anchor 401 is deployed by axial movement of the anchor pusher 240. The anchor pusher 240 can release the anchor 401 from a sheath such as dual lumen sheath 243 described herein. In some methods of use, the anchor 401 is deployed and then the ALTC device 201 is axially lengthened to cover the anchor 401. In some methods of use, the anchor 401 is deployed before the ALTC device 201 is axially lengthened to cover the anchor 401. In some methods of use, the anchor 401 is partially deployed before the ALTC device 201 is axially lengthened to cover the anchor 401. In some methods of use, the anchor 401 is not deployed before the ALTC device 201 is axially lengthened. In some methods of use, the anchor 401 is deployed after the ALTC device 201 is axially lengthened. In some methods of use, the anchor 401 is partially deployed after the ALTC device 201 is partially axially lengthened. In some methods of use, the anchor 401 is deployed and the ALTC device 201 is axially lengthened simultaneously. In some methods of use, the anchor 401 is deployed and the ALTC device 201 is axially lengthened independently. In some methods of use, the anchor 401 is fixed and the ALTC device 201 is axially lengthened. In some methods of use, the ALTC device 201 is fixed and the anchor 401 is deployed or expanded. In some methods of use, the anchor 401 is only deployed if covered by the ALTC device 201. In some methods of use, the anchor 401 is only deployed the ALTC device 201 provides distal protection. The anchors described herein can function in any manner described herein.

[0265] In some methods of use, the ALTC device 201 is positioned distally to the anchor 401. In some methods of use, the ALTC device 201 is positioned downstream in the direction of blood flow. The direction of blood flow is shown in Figure 75 by the red arrow.

In some methods of use, the ALTC device 201 is positioned distal to the obstruction or clot. In some methods of use, the ALTC device 201 is positioned to capture fragments of the obstruction. In some methods of use, the ALTC device 201 provides distal protection during clot removal. In some methods of use, alternatively, the ALTC device 201 is positioned proximally to the anchor 401. In some methods of use, the ALTC device 201 is positioned upstream to the anchor 401. In some methods of use, alternatively, two or more ALTC device 201 are utilized. In some methods of use, one ALTC device 201 is positioned distally and one ALTC device 201 is positioned proximally. In some methods of use, the two ALTC device 201 can move toward each other. In some methods of use, the two ALTC device 201 can meet at an intermediate location. The systems described herein can include one or more ALTC devices 201. The systems described herein can include one or more ALTC devices 201 positioned as described herein. In some embodiment, the anchor 401 can position distal to the ALTC device 201 (not shown).

[0266] In some methods of use, the anchor 401 is positioned distally to the ALTC device 201. In some methods of use, the anchor can function to block emboli. In some methods of use, the anchor 401 is positioned downstream in the direction of blood flow, or upstream in other embodiments. The direction of blood flow is shown in Figure 75 by the arrow. In some methods of use, the anchor 401 is positioned distal to the obstruction or clot. In some methods of use, the anchor 401 is positioned to capture fragments of the obstruction. In some methods of use, the ALTC device 201 is lengthened for clot removal. In some methods of use, alternatively, two or more the anchors 401 are utilized. In some methods of use, one, two, or more anchors 401 are positioned distally and one, two, or more anchors 401 are positioned proximally of the ALTC device 201. In some methods of use, the two anchors 401 can move toward each other. In some methods of use, the two anchors 401 can meet at an intermediate location. The systems described herein can include one, two, or more anchors 401. The systems described herein can include one, two, or more anchors 401 positioned as described herein.

[0267] In some embodiments, the anchor is deployed adjacent to the clot. In some embodiments, the anchor is deployed within the clot. In some embodiments, the anchor is deployed distal to the clot. In some embodiments, the anchor is deployed proximal to the clot. In some methods of use, the anchor 401 deploys within the obstruction or clot. In some

methods of use, the anchor 401 is positioned to entangle the obstruction. In some methods of use, the anchor 401 is positioned distally to the obstruction or downstream in the direction of blood flow. In some methods of use, the anchor 401 can move proximally through the obstruction. In some methods of use, the anchor 401 is positioned proximally to the obstruction or upstream in the direction of blood flow. In some methods of use, the anchor 401 can move distally through the obstruction. In the illustrated embodiment, the obstruction or clot can pass through the anchor 401. In the illustrated embodiment, the obstruction or clot can be caught in the anchor 401. In some methods of use, the anchor 401 moves after deployment. For instance, the anchor 401 can move distally therefore moving the obstruction distally. The anchor 401 can move proximally therefore moving the obstruction proximally. In some embodiments, the anchor 401 can rotate. After deployment of the anchor 401, the obstruction and the anchor 401 can move together as a unit. After deployment of the anchor 401, the obstruction, the anchor 401, and the ALTC device 201 can move together as a unit. In some methods of use, the anchor 401 moves after axially lengthening of the ALTC device 201. In some methods of use, the anchor 401 moves before axially lengthening of the ALTC device 201.

[0268] Figures 76A-76C illustrates the axial lengthening sequence of the ALTC device 201, according to some embodiments. The ALTC device 201 can be lengthened in any manner described herein. In some methods of use, the ALTC device 201 can be lengthened by retraction of a constraining member such as a sheath. As the sheath is retracted, the capture guide 204 is expanded. After the capture guide 204 is expanded, a portion of the ALTC device 201 is expanded. In some methods of use, the sheath dual lumen sheath 243 can be retracted to axially lengthen the ALTC device 201. In some embodiments, for the dual lumen sheath 243 in some cases, there may be no outer sheath required to constrain the device. In some embodiments, the dual lumen sheath 243 constrains the ALTC device 201. In some embodiments, the dual lumen sheath 243 constrains the anchors. In some embodiments, the dual lumen sheath 243 is loaded with the ALTC device 201. In some embodiments, the dual lumen sheath 243 is loaded with the one or more anchor. In some embodiments, the ALTC device 201 and the one or more anchor are loaded in a single lumen of a single lumen sheath. In some embodiments, the ALTC device 201 and the one or more anchor are loaded in a single lumen of a dual lumen sheath. In some embodiments, the ALTC

device 201 and the one or more anchor are loaded in separate lumens of a sheath. In some embodiments, the ALTC device 201 and the one or more anchor are advanced from a single lumen of a single lumen sheath. In some embodiments, the ALTC device 201 and the one or more anchors are advanced from a single lumen of a dual lumen sheath. In some embodiments, the ALTC device 201 and the one or more anchors are advanced from separate lumens of a sheath. In some embodiments, the device would be loaded in a sheath/guide/microcatheter in advance. Effectively, in some cases the guide/microcatheter can be used as a sheath.

[0269] In some embodiments, the ALTC device 201 maintains the diameter of the capture guide 204. In some methods of use, the ALTC device 201 can be lengthened by extension of a member such as a pusher 202 or corewire 242. Alternatively or in combination, in other methods of use, the inner pusher 202 is advanced distally to advance an end of the ALTC device 201. As described herein, an end of the ALTC device 201 is coupled to the inner pusher 202. In the second configuration, the inner pusher 202 is advanced distally to release a portion of ALTC device 201 from a sheath. As the inner pusher 202 is advanced distally, a portion of the collapsed portion 208 becomes the expanded portion of the ALTC device 201. As the inner pusher 202 is advanced distally, the ALTC device 201 is axially lengthened.

[0270] Figure 76A illustrates the system after deployment of the anchor 401. In some methods of use, the anchor 401 is deployed before axial lengthening of the ALTC device 201. The capture guide 204 is expanded and a portion of the ALTC device 201 is expanded. Figure 76A illustrates the axial lengthen device or ALTC device 201 with an expandable anchor 401 positioned near the opening end of the ALTC device 201. In some embodiments, the expandable anchor 401 can be independently movable such that expandable anchor 401 can retract proximally or distally while the ALTC device 201 is stationary. In some embodiments, alternatively, the anchor 401 and the ALTC device 201 can move together as one unit. In some embodiments, the ALTC device 201 and the expandable anchor 401 are collapsed in the delivery configuration. In some embodiments, the ALTC device 201 and the expandable anchor 401 are expanded when deployed within the target vessel.

[0271] Figure 76B illustrates the axial lengthening of the expanded portion of the ALTC device 201. In some methods of use, the ALTC device 201 is lengthening proximally to encapsulate the anchor 401. In some methods of use, the anchor 401 has captured an obstruction or clot. In some methods of use, the ALTC device 201 is lengthening proximally to encapsulate the obstruction or clot. In some methods of use, the ALTC device 201 is lengthening proximally to encapsulate only a portion of the anchor 401. The collapsed portion 208 of the ALTC device 201 is shortened as the ALTC device 201 is axially lengthened. In some methods of use, the ALTC device 201 is not lengthened proximally to encapsulate a portion of the anchor 401. In some methods of use, the ALTC device 201 and the anchor 401 remain in the position shown in Figure 76A during clot removal.

[0272] Figure 76C illustrates the axial lengthening of the expanded portion of the ALTC device 201. The ALTC device 201 is lengthening proximally to capture the clot secured by the anchor 401. In some methods of use, the ALTC device 201 is lengthening proximally to circumscribe the entire anchor 401. The collapsed portion 208 of the ALTC device 201 is shortened as the ALTC device 201 is lengthened. For instance, collapsed portion 208 has a smaller axial length in Figure 76C than in Figure 76B. Figure 76C illustrates the axial lengthening ALTC device 201 is sufficient to completely capture the clot. In some methods of use, the ALTC device 201 and the anchor 401 can retract proximally to remove the clot. In some methods of use, the ALTC device 201 and the anchor 401 can retract proximally while the configuration shown in Figure 76A. In some methods of use, the ALTC device 201 and the anchors 401 can retract proximally while the ALTC device 201 does not circumscribe the entire anchor 401.

[0273] In Figure 76C, the deployed and expanded ALTC device 201 is longer, e.g., in length, than the deployed and expanded ALTC device 201 in Figure 76B. The collapsed portion 208 resides inside the outer sheath 203 or dual lumen shaft 243 and is shorter in Figure 76C than in Figure 76B. The diameter or cross-section of the ALTC device 201 can remain constant or substantially constant during axially lengthening. The diameter or cross-section of the ALTC device 201 can in some cases remain constant between the initial deployed configuration shown in Figure 76A and the expanded configurations shown in 76B and 76C. In some embodiments, two or more steps can occur simultaneously. In some

methods of use, the anchor 401 is partially deployed and the ALTC device 201 is axially lengthened to cover the anchor 401 simultaneously.

[0274] Figures 77A-77C illustrate additional views of the system. The anchor 405, or any of the anchors described herein, can be deployed in a similar manner as anchor 401. In some embodiments, the ALTC device 201 is axially lengthened with the expandable anchor 401 positioned near the opening end of the ALTC device 201. In some embodiments, the ALTC device 201 is extended over the expandable anchor 401. In some embodiments, the ALTC device 201 is positioned distal to the obstruction, clot, emboli, and/or foreign body for distal protection. In some embodiments, the ALTC device 201 is positioned distally or downstream in the direction of blood flow. In some embodiments, the expandable anchor 401 is deployed within the obstruction. In some embodiments, the ALTC device 201 retracts proximally over the expandable anchor 401 and the obstruction. In some embodiments, the obstruction is removed. In some embodiments, the ALTC device 201 is positioned distal to the obstruction for distal protection. In some embodiments, the expandable anchor 401 deploys within the obstruction and retracts to remove the obstruction while the ALTC device 201 remains in position. In some embodiments, the ALTC device 201 retracts subsequently to remove emboli. In some embodiments, the expandable anchor 401 and the ALTC device 201 retract as one unit to remove the obstruction. In some embodiments, the ALTC device 201 is retracted over the expandable anchor and obstruction and the entire device is removed.

[0275] Figure 78 illustrates another embodiment of an anchor 410. The anchor 410 can include any of the features of anchors described herein. In some embodiments, the anchor 410 can include a balloon. Balloon materials can be compliant, semi-compliant, or non-compliant. In some embodiments, the anchor 410 can comprise a spherical balloon. In some embodiments, the anchor 410 can comprise an oblong balloon. In some embodiments, the anchor 410 can include one or more shaped ends, including conical, square, spherical, tapered, etc. In some embodiments, the anchor 410 can includes a dog bone shaped with proximal and distal areas of increased diameter balloon or stepped balloon having two or more different diameters. In some embodiments, the anchor 410 can include an axially or radially offset balloon. In some embodiments, the anchor 410 can comprise any shape including a conical balloon, tapered balloon, stepped balloon, square balloon, polygonal balloon, etc. In some embodiment, the balloons can be in series or in parallel or

circumferentially or radially. Additional balloon shapes are disclosed in U.S. Patent Application No. 11/851,848, filed Sept. 7, 2007 and published July 23, 2013 as U.S. Patent No. 8491623 ("Vogel"), which is incorporated by reference in its entirety. In some embodiments, the anchor 410 has a diameter. In some embodiments, the anchor 410 has two or more diameters. In some embodiments, the smaller diameter is more than 50% of the larger diameter, the smaller diameter is more than 60% of the larger diameter, the smaller diameter is more than 70% of the larger diameter, the smaller diameter is more than 80% of the larger diameter, the smaller diameter is more than 90% of the larger diameter, the smaller diameter is approximately equal to the larger diameter, etc. In some embodiments, two or more anchors 410 have the same shape. For instance, two or more anchors 410 can be spherical. In some embodiments, two or more anchors 410 can be identical. In some embodiments, two or more anchors 410 have a different shape. For instance, the first anchor 410 can be spherical and the second anchor 410 can be oblong. In some embodiments, two or more anchors 410 have a different diameter or cross-section. Figure 78 illustrates the ALTC device 201 with a single balloon. In some embodiments, the balloon is independently movable relative to the ALTC device 201. In some embodiments, the balloon and ALTC device 201 can also retracted as one unit. Figure 79 for example illustrates balloons 410 are positioned in series. In some embodiment, the balloons can position side-by-side, in parallel, circumferentially, and/or radially. Further in some embodiments, the balloons' shape and diameter can be configured so that there are gaps between the balloons to allow potential blood flow.

[0276] In some embodiments, the anchor 410 can be inflated. In some embodiments, an inflation medium such as gas or liquid is supplied to the anchor 410. In some embodiments, the anchor 410 can be inflated to form a rigid body. In some embodiments, the anchor 410 can be inflated to transmit a force to the obstruction, such as force to compress or move the obstruction. In some embodiments, the anchor 410 can be deflated. The inflation medium can be removed from the anchor 410. In some embodiments, the anchor 410 has a rough or textured outer surface. In some methods of use, the anchor 410 becomes entangled with the obstruction or clot described herein. In some embodiments, the anchor 410 has a smooth outer surface. In some embodiments, the anchor 410 can compress the obstruction or clot thereby opening the blood vessel. The anchor 410 can apply a

compressive force on the obstruction during inflation of the anchor 410. In some embodiments, the anchor 410 can be self-deployed. In some embodiments, the anchor 410 can include a shape memory material to deploy the anchor 410.

[0277] Figure 79 illustrates an embodiment including a plurality of anchors, such as a first anchor 410, a second anchor 410, a third anchor 410, and a fourth anchor 410. The system can include one or more of the anchors 410. In the illustrated embodiment, the system includes four anchors 410 but other configurations are contemplated (e.g., two anchors, three anchors, five anchors, six anchors, seven anchors, eight anchors, nine anchors, ten anchors, etc.). In some embodiments, two or more anchors 410 are inflated simultaneously. For instance, the anchors 410 can be coupled such that fluid can flow between the anchors 410. In some embodiments, two or more anchors 410 are inflated independently. For instance, each anchor can be separately supplied fluid for inflation, or include a common inflation lumen. In some embodiments, two or more anchors 410 are inflated in series. In some embodiments, two or more anchors 410 are inflated in parallel. In some embodiments, two or more anchors 410 are deflated simultaneously. In some embodiments, two or more anchors 410 are deflated independently. In some embodiments, two or more anchors 410 are deflated in series. In some embodiments, two or more anchors 410 are deflated in parallel. The two or more anchors 410 can be coupled via an inflation lumen 411. The inflation lumen 411 can allow delivery of the fluid to inflate the anchors.

[0278] Figure 79 illustrates the ALTC device 201 with a series of balloons positioned near the opening end of the ALTC device 201. In some embodiments, the balloons are independently movable relative to the ALTC device 201. In some embodiments, the balloons and the ALTC device 201 can also retracted as one unit. In some embodiments, the balloons function as anchors as described herein to entangle the clot. In some embodiments, the balloons function to compress the clot to open the target vessel. Other functions for the balloons are contemplated. In some embodiments, the balloons have a uniform size and shape, but can be positioned adjacent each other in order of increasing or decreasing diameter, or have different shapes in some embodiments.

[0279] Figure 80 illustrates the system within the vessel 408 with the obstruction 408 after deployment of the anchors 410. In some methods of use, the anchors 410 are inflated before axial lengthening of the ALTC device 201. In some methods of use, one or

more steps of deploying or inflating anchors 410 and axially lengthening can occur in any order. In some methods of use, the anchors 410 are inflated and then the ALTC device 201 is axially lengthened to cover the anchors 410. In some methods of use, two or more anchors 410 can be inflated before the ALTC device 201 is axially lengthened. In some methods of use, the anchors 410 are fixed such that the anchors 410 need not be inflated. In some methods of use, one or more anchors 410 are deflated before the ALTC device 201 is axially lengthened. In some methods of use, one or more anchors 410 are inflated after the ALTC device 201 is axially lengthened. In some methods of use, the anchors 410 are inflated and the ALTC device 201 is axially lengthened simultaneously. In some methods of use, the anchors 410 are inflated and the ALTC device 201 is axially lengthened independently. In some methods of use, the anchors 410 are only inflated if covered by the ALTC device 201.

[0280] Figure 80 illustrates the ALTC device 201 positioned distal to the obstruction. Figure 80 illustrates the balloons expanding within the obstruction. In some embodiments, one or more anchors 410 are positioned distally to the obstruction before inflation. After inflation, the one or more distal anchors 410 can push the obstruction proximally. In some embodiments, one or more anchors 410 are positioned proximally to the obstruction before inflation. After inflation, the one or more distal anchors 410 can push the obstruction distally toward the ALTC device 201.

[0281] In some methods of use, the ALTC device 201 is positioned distally to the anchors 410. In some methods of use, the ALTC device 201 provides distal protection during clot removal, akin to a filter in some cases. In some methods of use, the anchors 410 inflate within the obstruction. In some methods of use, the anchors 410 are positioned to entangle the obstruction. In some methods of use, the anchors 410 move after deployment. In some methods of use, the anchors 410 move simultaneously. In some methods of use, the anchors 410 move independently, or all in concert in some cases. In some methods of use, the anchors 410 move distally therefore moving the obstruction distally. In some methods of use, the anchors 410 move toward the ALTC device 201. After deployment of the anchors 410, the obstruction and the anchors 410 can move together as a unit. In some methods of use, the anchors 410 move after axially lengthening of the ALTC device 201. In some methods of use, the anchors 410 move before axially lengthening of the ALTC device 201.

[0282] Figure 81 illustrates an embodiment of an anchor 415. The anchor 415 can include any of the features of anchors described herein. In some embodiments, the anchor 415 can comprise a disk. In some embodiments, the anchor 415 can be arcuate shaped such as round or circular, or ovoid. In some embodiments, the anchor 415 can have a constant or variable diameter. In some embodiments, the anchor 415 can be any shape, including a polygon, elliptical, etc. In some embodiments, the anchor 415 can be entirely flat or have flat surfaces. In some embodiments, the anchor 415 can be concave, convex, or another curved shaped. For instance, a first surface 416 of the anchor 415 can be concave and a second surface 417, opposite the first surface can be concave. For instance, a first surface 416 of the anchor 415 can be convex and a second surface 417, opposite the first surface can be convex. In some embodiments, the anchor 415 can have a smooth outer surface. In some embodiments, the anchor 415 can include a roughened or porous outer surface. The anchor can conform when contacting a surface such as a vessel wall.

[0283] In some embodiments, the anchor 415 can be deployed similar to anchor 241. In some embodiments, the anchor 415 can self-deploy. In some embodiments, the anchor 415 can include a shape memory material to deploy the anchor 415. In some embodiments, the anchor 415 can be inflated. In some embodiments, an inflation medium such as gas or liquid is supplied to the anchor 415. In some embodiments, the anchor 415 can be deflated. Figure 81 illustrates the ALTC device 201 with a single disk positioned proximal to the ALTC device 201. In some embodiments, the expandable disk is independently movable relative to the ALTC device 201. In some embodiments, the expandable disk and ALTC device 201 can also be retracted as one unit. In some embodiment, the anchor 415 is adjacent, side-by-side or offset to the ALTC device 201. In some embodiment, the anchor 415 is coaxial or in-line to the ALTC device.

[0284] Figure 82 illustrates an embodiment including a first anchor 415, a second anchor 415, a third anchor 415, a fourth anchor 415, a fifth anchor 415, and a sixth anchor 415. The system can include one, two, or more of the anchors 415. In the illustrated embodiment, the system includes six anchors 415 but other configurations are contemplated (e.g., about, at least about, or no more than about two anchors, three anchors, four anchors, five anchors, seven anchors, eight anchors, nine anchors, ten anchors, etc.). In some embodiments, the anchor 415 comprises a helix or helical structure. For instance, the first

anchor 415 can be joined with the second anchor 415 to form a helix. A helical anchor is disclosed, for example, in Figure 6A of PCT/IB2014/066389, filed Nov. 27, 2014 and published June 4, 2015 as WO 2015/079401 ("Yachia"), which is incorporated by reference in its entirety.

[0285] In some embodiments, two or more anchors 415 are deployed simultaneously. In some embodiments, two or more anchors 415 are deployed independently. For instance, the first anchor 415 and the second anchor 415 can be deployed independently. In some embodiments, two or more anchors 415 are deployed in series. For instance, the first anchor 415 can be deployed before the second anchor 415. In some embodiments, two or more anchors 415 are deployed in parallel. Figure 82 illustrates the ALTC device 201 with a series of expandable disks positioned proximal to the ALTC device 201. In some embodiments, the expandable disks are independently movable relative to the ALTC device 201. In some embodiments, the expandable disks and ALTC device 201 can also be retracted as one unit.

[0286] Figure 83 illustrates the system within the vessel 408 with the obstruction 409. In some methods of use, one or more steps of deploying or inflating anchors 415 and axially lengthening can occur in any order. In some methods of use, the anchors 415 are deployed before axial lengthening of the ALTC device 201. In some methods of use, one or more anchors 415 are deployed before the ALTC device 201 is axially lengthened to cover the anchors 410. In some methods of use, one or more anchors 415 are deployed after the ALTC device 201 is axially lengthened. In some methods of use, the anchors 415 are deployed and the ALTC device 201 is axially lengthened simultaneously. In some methods of use, the anchors 415 are only deployed if covered by the ALTC device 201. Figure 83 illustrates the ALTC device 201 positioned distal to the obstruction and the expandable disks deployed within the obstruction. The single disk embodiment shown in Figure 81 can be deployed within the obstruction in a similar manner. In some methods of use, the ALTC device 201 is positioned distally to the anchors 415. In some methods of use, the ALTC device 201 provides distal protection during clot removal. In some methods of use, the anchors 415 deploy within the obstruction or clot. In some methods of use, the anchors 415 move after deployment.

[0287] Figure 84 illustrates an embodiment of an anchor 420. The anchor 420 can include any of the features of anchors described herein. In some embodiments, the anchor 420 can comprise a funnel. In some embodiments, the anchor 420 can include a round or circular opening. In some embodiments, the anchor 420 can taper from a larger diameter or cross-section to a smaller diameter or cross-section. In some embodiments, the anchor 420 can taper along the length of the anchor 420. In some embodiments, the anchor 420 can be any generally conical shape. In some embodiments, the anchor 420 can include an inflection point. In some embodiments, the anchor 420 can include a radially outward flare. In some embodiments, the anchor 420, or a surface thereof, is concave. In some embodiments, the anchor 420, or a surface thereof, is convex. In some embodiments, the anchor 420 can have a smooth outer surface. In some embodiments, the anchor 420 can include a roughened or porous outer surface. In some embodiment, the anchor 420 is adjacent, side-by-side or offset to the ALTC device 201. In some embodiment, the anchor 420 is coaxial or in-line to the ALTC device.

[0288] In some embodiments, the anchor 420 is formed as a mesh or braid, laser cut or stent structure. The funnel shape of the anchor 420 can in some cases assist in retrieving and containing the obstruction or clot. In some embodiments, the anchor 420 comprises structural features to assist in the deployment of the funnel shape, such as to hold the rim 421 of the funnel shape open. In some embodiments, the anchor 420 can include struts comprising a shape memory or self-expanding material such as nitinol, or other stent structure, mesh, and/or webbing. In some embodiments, the anchor 420 can be deployed similar to anchor 241. In some embodiments, the anchor 420 can be self-deployed. In some embodiments, the anchor 420 can include a shape memory material to deploy the anchor 420. The anchor 420 can include a rim 421. The rim 421 can include any of the features of the capture guides described herein.

[0289] In some embodiments, the proximal end opening of the anchor 420 includes the rim 421 that takes the form of, in some embodiments, a radially expandable shape memory partial or full ring-like annular structure. The rim 421 expands once freed or released from a constraining member such as any sheath or tube described herein. In some embodiments, the rim 421 is coupled with a portion of a mesh, interlaced structure, or covering 422. In some other embodiments, the rim 421 and the proximal end of the covering

422 can be sutured in place using silk or polymeric filaments such as Ultra-High Molecular Weight polyethylene, Nylon, PET, PTFE. In some embodiments, the covering 422 comprises with a low durometer polymeric material.

[0290] The rim 421 and/or the covering 422 can be formed, for example, from metallic, shape memory, or other appropriate materials. In some embodiment, the rim 421 can include a loop configuration and be formed from nitinol shape memory wire of various geometries such as round, oval, elliptical, flat, and the like. The rim 421 can be formed of different shapes such as a circular loop, oval loop, z-shape, etc. In some embodiment, the rim 421 can be shaped set either into coils, multiple full circles, full circle or partial circles where the ends of the wire formed into two legs. The partial circle can be from, for example, 180 degrees to 359 degrees or 220 degrees to 359 degrees. The legs can be configured to be off-axis to the loop such that it can be right angle, acute or obtuse angle relative to the loop. It can be arcuate and form a partial or full ring as illustrated, and can circumscribe or otherwise form an outer diameter, and define the proximal-most end of the anchor 420. The anchor 420 can in some embodiments include a single loop or multiple loops positioned along the length of the covering 422. The anchor 420 can be configured to be compressed and positioned within a lumen of a shaft during introduction into the vascular system where the anchor 420 is configured to be positioned coaxially within the obstruction or clot. In some methods of use, the anchor 420 is configured to be deployed to entangle with the obstruction or clot.

[0291] Figure 84 illustrates the ALTC device 201 with an expandable funnel like anchor. In some embodiments, the funnel shaped anchor is positioned proximal to the ALTC device 201. In some embodiments, the funnel shaped anchor is independently movable relative to the ALTC device 201. In some embodiments, alternatively, the anchor and ALTC device 201 can move as one unit.

[0292] Figure 85 illustrates an embodiment including a plurality of anchors, such as a first anchor 420, a second anchor 420, a third anchor 420, a fourth anchor 420, and a fifth anchor 420. The system can include one or more of the anchors 420. In the illustrated embodiment, the system includes five anchors 420 but other configurations are contemplated (e.g., two anchors, three anchors, four anchors, six anchors, seven anchors, eight anchors, nine anchors, ten anchors, etc.). In some embodiments, two or more anchors 420 are deployed simultaneously. In some embodiments, two or more anchors 420 are deployed

independently. For instance, the first anchor 420 and the second anchor 420 can be deployed independently. In some embodiments, two or more anchors 420 are deployed in series. For instance, the first anchor 420 can be deployed before the second anchor 420. In some embodiments, two or more anchors 420 are deployed in parallel. Figure 85 illustrates the ALTC device 201 with expandable funnel like anchors. In some embodiments, the funnel shaped anchors are positioned proximal to the ALTC device 201. In some embodiments, the funnel shaped anchors are independently movable relative to the ALTC device 201. In some embodiments, alternatively, the anchors and ALTC device 201 can move as one unit.

[0293] Figure 86 illustrates the system within the blood vessel 408 and the obstruction 409. In some methods of use, one or more steps of deploying one or more anchors 420 and axially lengthening can occur in any order. In some methods of use, one or more anchors 420 are deployed before axial lengthening of the ALTC device 201. In some methods of use, the anchors 420 are deployed before the ALTC device 201 is axially lengthened to cover the anchors 420. In some methods of use, one or more anchors 420 are deployed after the ALTC device 201 is axially lengthened. In some methods of use, the anchors 420 are deployed and the ALTC device 201 is axially lengthened simultaneously. In some methods of use, the anchors 420 are deployed and the ALTC device 201 is axially lengthened independently. In some methods of use, the anchors 420 are only deployed if covered by the ALTC device 201. In some methods of use, the ALTC device 201 is positioned distally to the anchors 420. In some methods of use, the ALTC device 201 provides distal protection during clot removal. In some methods of use, the anchors 420 deploy within the obstruction or clot. In some methods of use, the anchors 420 move after deployment.

[0294] Figure 86 illustrates an embodiment in which the anchors 420 face forward. The anchors 420 can taper inward from a distal end 423 to a proximal end 424. The rim 421 of each anchor 420 can be located at the distal end 423 of each anchor 420. Figure 87 illustrates a system with anchors 420 deployed within a vessel 408 comprising an obstruction 409. Figure 87 illustrates an embodiment in which the anchors 420 face backward. The anchors 420 can taper inward from the proximal end 424 to a distal end 423. The rim 421 of each anchor 420 can be located at the proximal end 424 of each anchor 420. In some embodiments, the anchors 420 have a single configuration, e.g., all anchors 420 face

forward as shown in Figure 86, all anchors 420 face backward as shown in Figure 87. In some embodiments, two or more anchors 420 have a different configuration, e.g., the first anchor 420 faces forward and the second anchor 420 faces backward. In some embodiments, the anchor 420 can switch between facing forward and facing backward. In some embodiments, the anchors 420 can be configured to roll out, invert, evert, and/or variably lengthen proximally or distally between facing forward and facing backward. In some embodiments, one or more anchors 420 can be configured to switch between facing forward and facing backward. In some embodiments, one or more anchors 420 can be fixed as either facing forward or facing backward. Figures 86 and 87 illustrate the ALTC device 201 positioned distal to the obstruction. Figures 86 and 87 illustrate the expandable funnel shape anchors deployed within the obstruction.

[0295] The anchors described herein can have any shape. Other expandable shapes and/or geometric anchors are contemplated. In some embodiments, the anchor can be shaped as a coil. In some embodiments, the anchor can be shaped as a loop. In some embodiments, the anchor can be shaped as a clover. In some embodiments, one or more anchors are offset to the ALTC device 201. In some embodiments, the anchor can be coaxial to the ALTC device 201 wherein the anchors can be attached to the shaft of the ALTC device 201. In some embodiments, this configuration allows the anchor and the axial lengthen device move as one unit.

[0296] U.S. Patent Application No. 14/602,014, filed Jan. 21, 2015 and published Aug. 9, 2016 as U.S. Patent No. 9408620 ("Rosenbluth"); U.S. Patent Application No. 08/723,619, filed Oct. 20, 1996 and published Apr. 20, 1999 as U.S. Patent No. 5895398 ("Wensel"); U.S. Patent Application No. 08/968146, filed Nov. 12, 1997 and published Sept. 7, 1999 as U.S. Patent No. 5947985 ("Imran"); U.S. Patent Application No. 09/756476, filed Jan. 8, 2001 and published Dec. 16, 2003 as U.S. Patent No. 6663650 ("Sepetka"); U.S. Patent Application No. 09/789332, filed Feb. 20, 2001 and published Jan. 11, 2005 as U.S. Patent No. 6840950 ("Sanford"); U.S. Patent Application No. 12/581,960, filed Oct. 20, 2009 and published Jan. 10, 2012 as U.S. Patent No. 8092486 ("Berrada"); U.S. Patent Application No. 11/580,546, filed Oct. 13, 2006 and published Aug. 28, 2012 as U.S. Patent No. 8252017 ("Paul"); U.S. Patent Application No. 12/564892, filed Sept. 22, 2009 and

published Oct. 30, 2012 as U.S. Patent No. 8298252 ("Krolik") are all incorporated by reference herein in their entireties.

[0297] In some embodiments, the clot treatment device described by Rosenbluth et al. can be used in place of, or in combination with, the anchors described herein. Referring now to Figures 88A-88H, embodiments of an anchor 425 are disclosed. Referring to FIG. 88A, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by a cylindrical disk shape with a rounded triangular cross-section. Referring to FIG. 88B, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by a cylindrical disk shape with a rounded triangular cross-section wherein the diameter of the disk increases along the length of the anchor 425 thus forming a conical exterior extent. Referring to FIG. 88C, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by a cylindrical disk shape with a rectangular cross-section. Referring to FIG. 88D, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by a cylindrical disk shape with a linear (non-rounded) triangular cross-section. Referring to FIG. 88E, some of the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by a cylindrical disk shape with a rounded cross-section and others have a rectangular cross section. Referring to FIG. 88F, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 alternate between cylindrical disk shape with a T-shaped cross-section and a flare-shaped cross-section. Referring to FIG. 88G, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by a partial cylindrical disk shapes. Referring to FIG. 88H, the radially extending portions 426 between the generally cylindrical sections 427 of the anchor 425 are defined by tabs and bumps or protuberances arising from the cylindrical surface of the anchor 425. In some embodiments, the anchors described herein provide greater surface area along the anchor than an anchor that is uniformly cylindrical. In some methods of use, the increased surface area facilitates the treatment and/or retrieval of the obstruction or clot.

[0298] In some embodiments, the anchor 425 can have a generally cylindrical shape that, during use, provides a flow lumen for blood across a clot. The anchor 425 is not, however, limited to a generally cylindrical shape. For example, the shape can be generally

conical, generally concave or generally convex along its axis, so long as such shapes provide the aforesaid lumen for blood flow. In some embodiments, the anchor 425 also has a series of radially extending portions 426 which are separated by generally cylindrical portions 427. In some embodiments, the clot treatment device 425 can be porous so as to allow the flow of blood therethrough. In some embodiments, the anchor 425 is made from a mesh or braided material. The material can be a superelastic material such as nitinol or an alternative material such as cobalt chrome alloy. In some embodiments, the anchor 425 can be made from a wire lattice, wire braid or stent. In some embodiments, the anchor 425 can be self expanding.

[0299] In some embodiments, the anchor radially expands into the clot. In some methods of use, at least a portion of the anchor expands distal of the clot. As shown in some figures herein, at least one of the anchors of a plurality of anchors can be located distal to the clot upon expansion of the anchors. In some methods of use, upon expansion of the anchor, blood flowthrough the clot is restored. More specifically, the blood is now free to move through the mesh of the anchor and exit the anchor distal to the clot. As a result, the acute condition of blockage is corrected thus immediately improving the circulation of oxygenated blood in the patient. The expansion, inflation, or deployment of the anchors described herein can impinge or cut into the clot material. This entanglement can enhance the subsequent removal of the clot since portions of the clot collect between the radially extending portions 426; through the pores of the mesh forming the radially extending portions 426; along the longitudinal cylindrical sections 427 between the radially extending portions 426 of the anchor 425; and/or within the anchor 425 itself.

[0300] In some methods of use, the deployment of the anchor 425 results in an outwardly expanding generally cylindrical force being urged against an inner surface of the clot. In some methods of use, this force pushes the clot material outwardly and creates a lumen through which blood flow is restored. In some methods of use, the outwardly expanding generally cylindrical force can vary in magnitude along the axis of the anchor, due in part to the shape of the anchor. In some embodiments, the deployment of the anchor changes the angular orientation of the anchor with respect to the axis of the system. In some methods of use, this angular change or twisting can improve or enhances adherence of clot material to the anchor 425.

[0301] The clot treatment devices disclosed in Rosenbluth may be included in a system with the ALTC device 201 described herein. The ALTC device 201 can surround the clot treatment devices similar to the anchors described herein. After the clot treatment device has been expanded, the ALTC device 201 can be axially lengthened to capture the clot. In one embodiment, the clot treatment device and the ALTC device 201 are pulled back simultaneously in a proximal direction. This is followed by the entire system being withdrawn.

[0302] The clot and foreign body removal device of Wensel can be used in place of, or in combination with, the anchors described herein. Referring now to Figures 88I-88J, embodiments of the anchor 428 are disclosed. The anchor 428 can be a clot capture coil. In some embodiments, the coil is made from a flexible solid elastic or superelastic material which has shape memory, e.g., it can deform to a straight position and then return to a resting coil configuration. In some embodiments, the coil is made out of a solid nitinol wire with a diameter of, e.g., about 0.0005 inches to about 0.038 inches. Nitinol is preferred in some cases because of its superelasticity and its shape memory. However, other solid materials that are also elastic or superelastic and have shape memory could also be used such as some synthetic plastics, metallic alloys, and the like. The diameter of the coils can vary depending on the size of the vessel occluded. The diameter can range from about 1 mm for small vessels to about 30 mm for large vessels such as the pulmonary arteries or inferior vena cava. The length of the coil can also vary but typically ranges from about 3 to about 300 mm in the proximal to distal direction. Because the nitinol coil is superelastic, the coil can be extended to a completely straight configuration with the use of minimal force and then reform to its natural resting configuration when the force is removed. In some embodiments, the coil is made out of a solid biphasic material which changes shape upon heating or the passage of electric current. In some embodiments, the coil is cone-shaped.

[0303] In some embodiments, the anchors described herein can comprise a shape memory body. The anchor can comprise a single wire or multiple wires. The anchor can comprise one or more loops. The anchor can comprise one or more helices. In some embodiments, the loops and/or helices can have an increasing diameter from proximal to distal end of the anchor. In some embodiments, the loops and/or helices can have a

decreasing diameter from proximal to distal end of the anchor. In some embodiments, the loops and/or helices can have a variable diameter from proximal to distal end of the anchor.

[0304] The apparatus of Imran can be used in place of, or in combination with, the anchors described herein. Referring now to Figure 88K, an embodiment of the anchor 429 is disclosed. The anchor 429 can include a brush. The brush is formed on the distal extremity of the flexible elongate tubular member. The brush is comprised of a plurality of radially extending bristles formed of a suitable soft material such as Nylon with the brush having an outer diameter corresponding generally to the inner diameter of the lumen defined by the wall. The distal extremity is provided with a plurality of randomly disposed ports interposed between the bristles for supplying irrigation liquid to the brush. With irrigation liquid being supplied through the ports and aspiration taking place through the aspiration port, the brush can be rotated by rotating the proximal extremity of the therapeutic catheter. By moving the catheter back and forth, the bristles can come into engagement with the wall throughout the entire length of the chamber to remove the plaque in small particles. As the small particles are removed they can be aspirated from the chamber through the aspiration port.

[0305] The obstruction removal device of Sepetka can be used in place of, or in combination with, the anchors described herein. Referring now to Figures 88L-88M, the obstruction removing device 430 has an engaging element 431 extending from an insertion element 432. The engaging element 431 is movable from a collapsed position to an expanded position. When the engaging element 431 is contained within a sheath or other member, the engaging element 431 is in a relatively straight configuration. The engaging element 431 has a distal portion, which forms a relatively closed structure, which can catch or trap the obstruction, or any part thereof, to prevent migration of the obstruction or part thereof. The engaging element has a proximal portion which is formed with smaller coils than the distal portion. The proximal portion engages the obstruction as described below. The engaging element 431 preferably has a number of markers which provide an indication as to how much of the engaging element extends from the sheath. For example, markers may indicate when the engaging element 431 is ½, ¾ or fully exposed. In this manner, the user may quickly advance the engaging element 431 through the sheath without inadvertently exposing and advancing the engaging element 431 out of the sheath. The markers can also be used to

provide a controlled diameter of the engaging element 431 since the diameter of the engaging element is known for the various positions corresponding to the markers. The markers may also be used to size the vessel in which the engaging element 431 is positioned by observing when the engaging element 431 engages the vessel walls and determining the size of the engaging element 431 using the markers.

[0306] The engaging element 431 is preferably made of a superelastic material, such as nitinol, and has a diameter of, in some cases, about 0.005-0.018 inch, about 0.005-0.010 inch or about 0.008 inch. The engaging element 431 can have a rounded, atraumatic tip to prevent damage to the vessel and facilitate advancement through the vessel and/or sheath. A radiopaque wire, such as platinum ribbon having a width of 0.004 inch and a thickness of 0.002 inch, is preferably wrapped around the engaging element 431 to improve radiopacity. The device is preferably self-expanding but may also be expanded with an actuator. The actuator is preferably a thin filament which is tensioned to move the device to the expanded position. An advantage is that the filament extends through the same lumen as the device thereby minimizing the overall size of the device. It is understood that throughout discussion of the devices and methods herein that any of the anchors described herein may be expanded using the actuator rather than being self-expanding. The obstruction removal device shown in Figure 88M has a first section with larger diameter coils than a second section. A third section also has larger coils than the second section with the second section positioned between the first and third sections. The obstruction removal device may have a number of alternating small and large sections which can enhance the ability of the obstruction removal device to engage various obstructions. The obstruction removal device can have four large sections with relatively large coils and three sections having smaller coils, but other configurations are contemplated with different numbers of sections.

[0307] The expansion elements of Sanford can be used in place of, or in combination with, the anchors described herein. Referring now to Figures 88N, an anchor 433 is shown. The anchor 433 can include a helical expansion ring connected to the inlet of the anchor. Expansion ring has a proximal end and a distal end. The distal end can be fixed to guidewire. Alternately, the anchor could have resilient, expansion material embedded in its inlet. The anchor can include inclined "sail" at its inlet. The sail acts as an expansion mechanism to expand the anchor when exposed to blood flow. In some embodiments, the

anchor has its inlet coated with a hydrogel coating which swells upon contact with blood and acting to expand the inlet of filter.

[0308] The filter devices of Berrada can be used in place of, or in combination with, the anchors described herein. Referring now to Figures 88O, the anchor 434 can be an everting filter. Everting filter includes a flexible, mesh, filter body. The filter body may be formed of a plurality of wires or strands which can be used to form the mesh filter body through a variety of methods, for example, braiding, knitting, weaving, helically winding, and counterwinding. The mesh can be fused at some or all of the fiber or strand intersection points. The mesh can also be electrospun, and formed of sheet or film having holes formed by laser drilling, punching, dissolving components selectively, and the like. The strands can be formed of material such as wire, which can be metallic wire or polymeric wire. The wire may be substantially circular in cross section or may have any number of square, rectangular or irregular cross sectional profiles. The mesh is preferably self-expanding. The self-expanding mesh can be formed totally or in part from self-expanding Nitinol, Elgiloy, titanium, or stainless steel wires and the like, and combinations thereof. The self-expanding mesh can also be formed of engineering polymers, for example, liquid crystal polymer, PEEK, polyimide, polyester, and the like. A preferred mesh is formed of Nitinol wires, which can be heat set to the desired expanded shape. The mesh can preferably be heat set to a desired bias shape. Another mesh is highly elastic, and preformed by mechanical overstress to the desired expanded shape. The mesh is preferably made radiopaque by means of plating, core wires, tracer wires, or fillers that have good X-ray absorption characteristics compared to the human body. The mesh may be either partly or totally radiopaque.

[0309] The filter body may be seen to have a plurality of pores or openings between the filter body strands or wires. The pores have an average pore size over the filter body, where the individual pore sizes may vary depending upon the location over the filter body. The filter body also has a proximal opening formed in filter body proximal region. The filter body may also be considered to have an interior within the filter body and an exterior defined outside of the filter body. The everted shape of filter defines an everted cavity or concave region bounded by filter body everted surface region or cavity side walls and the filter body distal-most extent. It may be seen from inspection of Figure 88O that axially translating proximal ring relative to distal ring while holding the filter body diameter

consistent may change the degree of eversion of filter body. The filter material occupying distal-most region may therefore change with the degree of eversion of filter, with different locations of filter body being distal-most varying as a function of the degree of eversion. The length of a distal cavity will increase with increasing eversion.

[0310] The filter devices of Paul can be used in place of, or in combination with, the anchors described herein. Referring now to Figures 88P-88Q, the anchor 435 and anchor 436 are everted. The anchor 435 is everted to form a proximally facing concave geometry. The filter portion may be everted by moving the control wires proximally, thereby pulling the first end of the filter portion back over the rest of the filter portion. Further, the filter portion may also be made of a shape memory material such that the filter portion has two defined geometries. For example, the mesh material may be made of a shape memory alloy so that the mesh material is biased into a straight tubular geometry in a non-everting state at a first temperature. The first temperature being controlled, for example, by fluid flowing through the guiding member across the medical device. At a second temperature, such as the ambient temperature inside the vessel, the filter portion is biased into a proximally facing concave geometry. When the filter portion is biased into the proximally facing concave geometry, the filter portion everts causing the filter portion 1to expand against the inner wall of the vessel. While the medical device is expanded against the inner wall of the vessel, the filter portion serves to collect emboli that may break free from the stenosed area preventing such emboli from blocking smaller vessels downstream of the medical device. When everted, the first end of the filter portion is biased against the inner wall of the vessel forcing the fluid to flow through the proximally facing concave geometry formed by the filter portion. Therefore, emboli are trapped in the distal region of the proximally facing concave geometry. The medical device remains in this expanded state during the interventional procedure to capture any emboli that break free from the stenosis. After the interventional procedure is completed, the medical device may be removed. To trap the emboli in the filter portion, the control wires may be pulled further proximally drawing the filter portion against the guiding member.

[0311] For anchor 436, the control wires extend through the tubular geometry of the filter portion. Accordingly, the control wires form a frame structure along the length of the filter portion. The control wires may be made of a synthetic material, a stainless steel, or a shape memory alloy, such as Nitinol. The shape memory characteristics of the control wire

may be used to support the first end of the filter portion against the inner wall of the vessel. Supporting the filter portion against the wall of the vessel ensures that the fluid will flow through the proximally facing concave geometry formed by the everted filter portion, thereby causing emboli to be trapped by the medical device.

[0312] The cages of Krolik can be used in place of, or in combination with, the anchors described herein. Referring now to Figure 88R, the anchor 437 can include a macerator cage. Generally, the macerator cage includes a closed proximal or first end and an open distal or second end. The cage may include a plurality of struts extending between the first and second ends and/or around a periphery of the cage, thereby defining a cylindrical or other tubular outer wall including a plurality of apertures.

[0313] The open distal end of the cage may include a plurality of distally protruding elements or distal tips 438. The cage includes at least two different types of struts. For example, the cage may include a plurality of relatively thick struts that extend substantially continuously along a length of the cage e.g., in a first helical configuration between the first and second ends. In addition, the cage may include a plurality of relatively thin struts, which may connect adjacent thick struts together. As shown, the thin struts are not substantially continuous as are the thick struts, but may extend in a discontinuous pattern helically and/or circumferentially around the cage. Optionally, the thin struts may also have bends or other features, e.g., relatively thinned or perforated portions, that allow the struts to bend relatively easily compared to the thick struts. The apertures may be defined by the spaces between the thick struts and the thin struts, thereby defining a desired pore size for the cage.

[0314] The distal tips 438 on the open end may provide a substantially atraumatic distal end for the cage, e.g., to prevent puncture or other damage to a wall of a body lumen within which the cage is deployed. In addition or alternatively, the distal tips 438 may be sufficiently flexible to allow the distal tips to twist helically and/or interlock with one another during use. The distal tips 438 may facilitate engaging and/or removing obstructive material within a body lumen. Alternatively, the distal tip 438 can include a series of slots or indentations spaced apart along a length of the distal tip e.g., that may allow the distal tips to entangle with each other and/or with the obstructive material captured or otherwise engaged by the distal tips to facilitate removal. For example, when the cage is rotated, the distal tips

438 and obstructive material may be wound together, e.g., such that portions of other distal tips and/or obstructive material may enter the slots and the distal tips 438 become interlocked with one another.

[0315] During distal advancement, the cage may be concurrently advanced and rotated, e.g., manually or using a driveshaft. This may cause the distal tips 438 of the cage to track along the inside wall of the body lumen, e.g., in a helical manner as the cage is advanced. When thrombus or other obstructive material is encountered, the distal tips 438 may pass between the material and the wall of the body lumen, thereby positioning the material inside the cage. In some methods of use, the anchors described herein are rotated. In some methods of use, the anchors described herein are translated.

[0316] The distal tips 438 of the cage may facilitate separation and/or capture of material within the cage. For example, the edges of the distal tips may provide distal leading edges of the cage that are not a substantially smooth cylinder but define an undulating surface. Consequently, the distal tips 438 of the cage may act as a saw by repeatedly making contact with the material as the cage is rotated, which may increase the chance of material being dislodged from the wall of the body lumen and/or captured within the cage. To further ensure that the leading edge of the cage passes between the unwanted material and the wall of the body lumen, the distal tips 438 and/or edges of the struts may also act as blades shearing along the wall of the body lumen to draw adherent material into the cage. Thus, the struts may cut or otherwise separate the interface between the body lumen and the obstructive material.

[0317] The distal tips 438 may be formed such that they conform substantially to the cylindrical shape of the cage, e.g., defining a diameter similar to the rest of the expanded cage, although alternatively the distal tips 438 may be biased radially outwardly, e.g., to ensure that the distal tips 438 pass between the wall of the body lumen and the obstructive material and/or enhance engagement of the distal tips against the wall of the body lumen. Alternatively, the distal tips 438 may by biased to extend radially inwardly, e.g., laterally inwardly, relative to a central longitudinal axis of the apparatus, e.g., to prevent substantial risk of damage to the wall of the body lumen.

[0318] The systems described herein are intended for use in any size vessel. The systems can be deployed in vessels with a diameter about 10 μm, 20 μm, 30 μm, 40 μm, 50

μm, 60 μm, 70 μm, 80 μm, 90 μm, 100 μm, 200 μm, 300 μm, 400 μm, 500 μm, 600 μm, 700 μm, 800 μm, 900 μm, 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm, 15 mm, 16 mm, 17 mm, 18 mm, 19 mm, 20 mm, 21 mm, 22 mm, 23 mm, 24 mm, 25 mm, between 1 mm and 8 mm, between 10 μm, and 1 mm, between 100 μm and 1 mm, between 100 μm and 10 mm etc. The anchors can have a diameter or cross-section about 10 μm, 20 μm, 30 μm, 40 μm, 50 μm, 60 μm, 70 μm, 80 μm, 90 μm, 100 μm, 200 μm, 300 μm, 400 μm, 500 μm, 600 μm, 700 μm, 800 μm, 900 μm, 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm, 15 mm, 16 mm, 17 mm, 18 mm, 19 mm, 20 mm, 21 mm, 22 mm, 23 mm, 24 mm, 25 mm, less than 10 mm, less than 1 mm, less than 100 μm, less than 10 μm, etc. The ALTC device 201 can have a diameter or cross-section about 10 μm, 20 μm, 30 μm, 40 μm, 50 μm, 60 μm, 70 μm, 80 μm, 90 μm, 100 μm, 200 μm, 300 μm, 400 μm, 500 μm, 600 μm, 700 μm, 800 μm, 900 μm, 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm, 15 mm, 16 mm, 17 mm, 18 mm, 19 mm, 20 mm, 21 mm, 22 mm, 23 mm, 24 mm, 25 mm, less than 10 mm, less than 1 mm, less than 100 μm, less than 10 μm, etc., or ranges incorporating any two of the aforementioned values. It is contemplated that different sizes of the systems will be available for selection by the user based on the obstruction and the target vessel.

[0319] A perspective view of another embodiment of a capture system is shown in Figure 89. Figure 89 also illustrates non-limiting examples of various possible elements that can be included in a material capture system, according to some embodiments described herein. As illustrated in Figure 89, included in some embodiments are any number of, such as one, two, or more of the following components: a thrombus capturing device or ALTC device 201 having any of the features described herein, e.g., a pusher wire or inner pusher 202, a first tubular member such as an outer sheath (not shown), and an anchor such as any of the anchors described herein. Figure 89 illustrates an anchor 450. In some embodiments, the ALTC device 201 can attach to the anchor 450. In some embodiments, the anchor 450 functions as the capture guide 204 described herein. In some embodiments, the anchor 450 comprises a metallic material, such as Nitinol. The anchor 450 can be in the form of, for example, a loop, as shown, or any closed shape including an oval, ellipse, or polygon. The anchor 450 can be in the form of an open shape such as any linear or non-linear segment. The

ALTC device 201 and the anchor 450 can be coupled such as being sutured together. The ALTC device 201 and the anchor 450 can be encapsulated in a low durometer polymeric material. The anchor 450 can be coupled to the outer sheath 203. The proximal end of the ALTC device 201 can be coupled to an inner pusher 202 as described herein. The anchor 450 can have any of the features of anchors described herein, including anchor 401.

[0320] The anchor 450 can be connected to an anchor pusher 451. The anchor pusher 451 can, in some embodiments, be an elongate tubular member with a central lumen therethrough, and have a proximal end and a distal end, both shown in Figure 89. The distal end of the anchor pusher 451 can be operably connected to the anchor 450 (e.g., tubular mesh as described herein). In some embodiments, anchor 450 can be fixed or stationary with respect to the anchor pusher 451. In some embodiments, anchor 450 can be move axially with respect to the anchor pusher 451. The proximal end can include any number of, such as one, two, or more of the following components: a hemostasis assembly 206, a flush port 207, and a collapsed segment 208. The anchor pusher 451 extends proximally and can be coupled to the hemostasis assembly 206. The anchor pusher 451 extends proximally and can be coupled to a luer. In some embodiments, the anchor pusher 451 can have a lumen to allow passage of a guidewire. In some embodiments, the anchor pusher 451 is a solid shaft.

[0321] Figure 89 also shows the distal end of the ALTC device 201 in a deployed configuration. In some methods of use, a portion of the ALTC device 201 is axially extended while the remaining length of the ALTC device 201 is collapsed and contained within a sheath as previously described. In some methods of use, the ALTC device 201 can be collapsed and tracked through a sheath or guide catheter (not shown) to the intended treatment area. In some embodiments, the guide catheter can be retracted proximally to initially deploy the ALTC device 201 and the self expandable anchor 450. For instance, the retraction of the guide catheter can cause the anchor 450 to expand. The anchor 450 can include a compressed or constrained configuration while within the guide catheter. During the initial deployment, the anchor 450 is released from a constrained position to a neutral position. In the neutral position, the anchor 450 creates a perimeter for the ALTC device 201. In the case of a loop or other circular configuration, the anchor 450 can create a constant diameter. In the case of other shapes or configurations, the anchor 450 can create a constant

cross-section. Alternatively or in combination, in other methods of use, the ALTC device 201 can be advanced distally from the guide catheter to deploy the ALTC device 201.

[0322] In some cases, only a small fractional portion of the ALTC device 201, such as less than about 50%, 45%, 40%, 35%, 30%, 25%, 20%, 15%, 10%, 5%, or less of the axial length of the device can be initially deployed. The small portion can correspond to an amount of the ALTC device 201 which allows the anchor 450 to assume the neutral position. During the deployment of the anchor 450, a length of the ALTC device 201 can be retained within the outer sheath 203. The ALTC device 201 can follow a curve from the anchor 450 to the outer sheath 203. Retracting the outer sheath 203 can lengthen the ALTC device 201 while maintaining a constant diameter or cross-section provided by the anchor 450. In some embodiments, the proximal end of the ALTC device 201 is fixed relative to the anchor 450. In some embodiments, the ALTC device 201 can axially lengthen by releasing the compressed portion 208 as described herein. In some methods of use, the ALTC device 201 is axially lengthened. In some methods of use, the ALTC device 201 is not axially lengthened. The ALTC device 201 can serve as distal protection without further axially lengthening. In some embodiments, the ALTC device 201 is deployed before the anchor 450. In some embodiments, the ALTC device 201 is deployed after the anchor 450.

[0323] Figure 89 illustrates a system including a dual ALTC device 201 and anchor 450. The anchor functions to replace the nitinol. In some methods of use, the ALTC device 201 and the anchor 450 retract together. In some methods of use, the ALTC device 201 and the anchor 450 move as a unit. In some embodiments, the distal end consists of axial lengthen device wherein the opening end attaches to an expandable anchor. The ALTC device 201 comprises a proximal opening. In some embodiments, the capture guide 204 is replaced with an anchor, such as anchor 450. The proximal opening of the ALTC device 201 is coupled to the anchor 450 such that the ALTC device 201 and the anchor move together. In some embodiments, the distal end of the axial lengthen device is fixed to the pusher 202 that extends proximally. The ALTC device 201 can be coupled to the pusher 202. The pusher 202 can push the compressed portion 208 from the sheath 451 to cause axially lengthening of the ALTC device 201. The pusher 202 can extend to the proximal end of the system to be controlled by the user. In some embodiments, the proximal end of the expandable anchor attaches a pusher tube 451 extending proximally and attaches to a hemostasis housing. In

some embodiments, the proximal end of the anchor 450 is coupled to the anchor pusher 451. The anchor pusher 451 can extend proximally and attach to the hemostasis housing as described herein. The system can be designed for thrombectomy. The system can include a distal basket or ALTC device 201 and anchor 450. The anchor 450 can be made of wireform, laser cut or stent-like structure. The materials can be such as shape memory, stainless steel, Cobalt Chromium.

[0324] Figure 90 illustrates the distal end of the system of Figure 89. The system includes the ALTC device 201 and the expandable anchor 450. In some embodiments, the ALTC device 201 and the anchor 450 are fixed and move as one unit. In some embodiments, the distal end of the expandable anchor 450 attaches to the opening end of the ALTC device 201. In some embodiments, the proximal end of the anchor 450 attaches to the catheter shaft 451. In some embodiments, the distal end of the ALTC device 201 extends through the anchor 450. In some embodiments, the distal end of the ALTC device 201 extends through the anchor 450 centrally or along a longitudinal axis. In some embodiments, the distal end of the ALTC device 201 extends through the anchor 450 along an axis offset from the longitudinal axis of the anchor 450. The distal end of the ALTC device 201 can be the compressed portion 208 as described herein. In some embodiments, the distal end of the ALTC device 201 is coupled to a pusher wire 202. In some embodiments, the distal end of the ALTC device 201 is coupled to the pusher wire 202 or other device described herein.

[0325] In some embodiments, alternatively, the distal end of the expandable anchor 450 is separated from the opening end of the ALTC device 201. In some embodiments, the proximal end of the expandable anchor 450 attaches to distal end of catheter shaft. In some embodiments, the body of the ALTC device 201 extends through the anchor 450 centrally and attaches to the pusher 202. The pusher 202 can be contained within the pusher tube 451, sheath 203, dual lumen sheath 243 or other constraining member described herein. The anchor 450 can be designed to collapse within the pusher tube 451. The ALTC device 201 can be designed to collapse within the pusher tube 451. In some methods of use, the ALTC device 201 can be released from the pusher tube 451 by proximal movement of the pusher tube 451. In some methods of use, the anchor 450 can be released by proximal movement of the pusher tube 451. In some methods of use, the ALTC device 201

can be released from the pusher tube 451 by distal movement of the pusher 202. In some methods of use, the anchor 450 can be released by distal movement of the pusher 202.

[0326] Figure 91 illustrates another embodiment of a capture system, which can have any of the features described herein. The capture system includes an anchor 452. The anchor 452 can have any of the features of anchors described herein, including anchor 405. A portion of the anchor 452 can be contained within the pusher tube 451. In some embodiments, the ALTC device 201 can attach to the anchor 452 as described herein.

[0327] Figure 92 illustrates another embodiment of a capture system, which can have any of the features described herein. The capture system includes an anchor 453. In some embodiments, the ALTC device 201 can attach to the anchor 453 as described herein. In some embodiments, the anchor 453 is formed as a stent structure. The anchor 453 can includes a plurality of struts. Each strut can be connected to the ALTC device 201 at one or more locations. In the illustrated embodiment, each strut is connected to the ALTC device 201 at two locations but other configurations are contemplated (e.g., one location, three locations, four locations, five locations, a plurality of locations, etc.). In some embodiments, the struts can be equally spaced. In some embodiments, the struts are not equally spaced. In some embodiments, the struts can include a zig-zag pattern or bends 454. In some embodiments, the bends 454 can improve flexibility of the capture system. In some embodiments, the bends 454 can allow the capture system to turn. In some embodiments, the bends 454 can be located near a proximal end of the anchor 453. In some embodiments, the bends 454 can be located near a distal end of the anchor 453. In some embodiments, the struts of the anchor 453 assist in retrieving and containing the obstruction or clot. In some embodiments, the struts comprise a shape memory or self-expanding material such as nitinol. In some embodiments, the anchor 453 can be self-expanded.

[0328] Figures 93-94 illustrate another embodiment of a capture system, which can have any of the features described herein. The capture system includes anchor 455. In some embodiments, the struts 456 of the anchor 455 can be straight. In some embodiments, the struts 456 can include a straight portion. In some embodiments, the straight portion in near a proximal end of the anchor. Figures 93-94 illustrates the axial lengthening of the expanded portion of the ALTC device 201. The ALTC device 201 is lengthening proximally. The compressed or constrained segment of the ALTC device 201 is shortened within the

pusher tube 241. In some embodiments, the pusher tube 241 can be retracted to axially lengthen the ALTC device 201, as described herein. The ALTC device 201 and the anchor 455 can be retracted as a unit. Figure 93 illustrates the axial lengthening device and the expandable anchor in the initial configuration. Figure 94 illustrates the axial lengthening device and the expandable anchor wherein the axial lengthening device is lengthened.

[0329] Figure 95 illustrates another embodiment of a capture system, which can have any of the features described herein. The capture system includes an anchor 457. In some embodiments, a portion of the anchor 457 is connected to the ALTC device 201. The anchor 457 can include one or more distal tips 458. In some embodiments, one or more distal tips 458 are not connected to the ALTC device 201. The distal tips 458 can function as distal tips described herein.

[0330] The distal tips 458 may provide a substantially atraumatic distal end, e.g., to prevent puncture or other damage to a wall of a body lumen within which the anchor 457 is deployed. The distal tips 458 may facilitate engaging and/or removing obstructive material within a body lumen. Alternatively, the distal tips 458 can entangle with each other and/or with the obstructive material captured or otherwise engaged by the distal tips 458 to facilitate removal. The distal tips 458 may facilitate separation and/or capture of material. The distal tips 458of the anchor 457 may act as a saw by repeatedly making contact with the material, which may increase the chance of material being dislodged from the wall of the body lumen and/or captured within the anchor 457. To further ensure that the leading edge of the anchor 457 passes between the unwanted material and the wall of the body lumen, the distal tips 458 and/or edges may also act as blades shearing along the wall of the body lumen to draw adherent material into the anchor 457. Thus, the distal tips 458 may cut or otherwise separate the interface between the body lumen and the obstructive material. The distal tips 458 may be formed such that they conform substantially to the cylindrical shape of the ALTC device 201, e.g., defining a diameter similar to the rest of the ALTC device 201. In some embodiments, the distal tips 458 may be biased radially outwardly or biased to extend radially inwardly. Other configurations of the distal tips 458 are contemplated.

[0331] In some embodiments, the systems described herein comprise a fixed ALTC device 201. In some embodiments, the ALTC device 201 is inserted into the patient in the initial configuration. For instance, the capture guide 204 described herein can be fixed

such that the ALTC device 201 assumes the initial configuration. In some embodiments, the ALTC device 201 does not lengthen. In some embodiments, the axial length of the ALTC device 201 is fixed. In some embodiments, the anchor is fixed. In some embodiments, the anchor is inserted into the patient in the expanded or inflated configuration. In some embodiments, the anchor does not expand or inflate within the body of the patient. In some embodiments, the anchor has a fixed shape or configuration. In some embodiments, the system includes a clot buster or debulking at the front end. In some embodiments, the clot buster moves distally to break apart the clot. In some embodiments, the clot buster is a portion of the anchor. In some embodiments, the clot buster is separate device.

[0332] Figure 96A-96B illustrate an expandable guide catheter 460. The guide catheter 460 includes an expandable distal end, configured to be positioned away from a user, within a body of a patient. The guide catheter 460, or at least the distal end, can feature at least a dual braid layer including an outer layer and an inner layer. In some embodiments, the expandable guide catheter 460 can include a dual layer structure. In some embodiments, the expandable guide catheter 460 can include an outer braid layer 461. In some embodiments, the outer braid layer 461 is coated with a material such as one or more polymeric materials. In some embodiments, the expandable guide catheter 460 can include an inner braid layer 462. In some embodiments, the inner braid layer 462 is not coated with a polymeric material. In some embodiments, a portion of the inner braid layer 462 is not coated. In some embodiments, a distal portion of the inner braid layer 462 is not coated. In some embodiments, a length of the inner braid layer 462 is not coated. In some embodiments, the entire length of the inner braid layer 462 is not coated. In some embodiments, a portion of the outer braid layer 461 is coated. In some embodiments, a distal portion of the outer braid layer 461 is coated. In some embodiments, a length of the outer braid layer 461 is coated. In some embodiments, the entire length of the outer braid layer 461 is coated. In some embodiments, the outer braid layer 461 remains coated or encased with the polymer during the procedure.

[0333] In some embodiments, the outer braid layer 461 is coated with a polymer. The polymer can be any material including Pellethane, Silicone, Tecoflex, Tecothane, Latex, Pebax. The polymer can function akin to a slip layer. The polymer can facilitate the sliding of the catheter against a target vessel. In some embodiments, the inner braid layer 462 is not coated with a polymer, instead, retains the mesh-like structure as shown. The inner braid

layer 462 advantageously provides decreased surface area, decreased surface contact, and/or decreased friction relative to an object within the lumen of the catheter. For instance, the mesh-like structure of the inner braid layer 462 has less surface area to contact the object within the lumen than a solid, inner wall. The inner braid layer 462 allows for a retrieval catheter, one or more anchors, the obstruction, or the ALTC device 201 to more easily slide axially when withdrawn proximally through the lumen. In some methods of use described herein, the ALTC device 201 can be axially lengthened over one or more anchors before retraction into the guide catheter 406. In some methods of use described herein, the ALTC device 201 can be axially lengthened over an obstruction such as a clot before retraction into the guide catheter 406. In some methods of use described herein, the ALTC device 201 can provide distal protection as the ALTC device 201 is retracted into the guide catheter 460.

[0334] In some embodiments, the guide catheter 460 has a funnel shape at the distal end. In some embodiments, distal refers to the portion of the guide catheter 460, or component thereof, which is furthest from the user during use, while proximal refers to the portion of the guide catheter 460 or component thereof which is closest to the user. In some embodiments, the distal end of the guide catheter 460 is positioned within the body of the patient and the proximal end is outside the body of the patient.

[0335] In some embodiments, the expandable guide catheter 460 can include any of the features of the ALTC device 201 described herein. In some embodiments, the mesh can be made from metallic materials such as individual non-elastic wires. In some embodiments, the mesh can be made from elastic elements. In some embodiments, the mesh can be made from a combination of elastic and non-elastic wires. In some embodiments, the dual braid can be made of either polymeric or metallic materials. In some embodiments, the metallic materials can be Nitinol, stainless steel, steel, shape memory alloy, elastic alloy, Nickel Titanium alloy, etc. In some embodiments, the braid wire diameter can range from .0005" to .030", e.g., .0005", .001", .0015", .002", .0025", or .003", between .0005"-.0015", between .001"-.002", between .0015"-.0025", between .002"-.003" etc. Other configurations of braid wire diameter are contemplated. The braid wire can be woven in any pattern. In some embodiments, the guide catheter 460 can include at least one polymer layer. The at least one polymer layer can applied to any surface of the braid wire. The braid wire can include one or more woven patterns, for instance a first wave pattern in a first portion of the

guide catheter 460 and a second wave pattern in a second portion of the guide catheter 460. The woven pattern can be a typical over under pattern, e.g., two over, two under; one over, one under, etc. The woven paten can from a tubular braid. In some embodiments, the guide catheter 460 can include multiple layers of braid wire.

[0336] The braid wire can form a mesh. In some embodiments, the cross-section of the wire can be any shape including round, polygonal, elliptical, etc. The shape of the wire can be flat, square, ribbon, round, etc. In some embodiments, the total braid angle can range from 10 degrees to 170 degrees. In some embodiments, the total braid angle is 0 degrees, 10 degrees, 20 degrees, 30 degrees, 40 degrees, 50 degrees, 60 degrees, 70 degrees, 80 degrees, 90 degrees, 100 degrees, 110 degrees, 120 degrees, 130 degrees, 140 degrees, 150 degrees, 160 degrees, 170 degrees, 180 degrees, between 0-45 degrees, between 45-90 degrees, between 90-135 degrees, between 135-180 degrees, etc. In some embodiments, the braid density can range from 5 PPI to 60 PPI. In some embodiments, the braid density is less than 5 PPI, 5 PPI, 10 PPI, 15 PPI, 20 PPI, 25 PPI, 30 PPI, 35 PPI, 40 PPI, 45 PPI, 50 PPI, 55 PPI, 60 PPI, 65 PPI, 70 PPI, 75 PPI, 80 PPI, between 0-20 PPI, between 20-40 PPI, between 40-60 PPI, between 60-80 PPI, etc. In some embodiments, the inner diameter can range from 1F to 30F. In some embodiments, the inner diameter is less than 1F, 1F, 2F, 3F, 4F, 5F, 6F, 7F, 8F, 9F, 10F, 11F, 12F, 13F, 14F, 15F, 16F, 17F, 18F, 19F, 20F, 21F, 22F, 23F, 24F, 25F, 26F, 27F, 28F, 29F, 30F, 31F, 32F, 33F, 34F, 35F, between 0F-5F, between 5F-10F, between 15F-20F, between 20F-25F, between 25F-30F, between 30F-35F, etc. In some embodiments, the outer diameter can range from 2F up to 33F. In some embodiments, the outer diameter is less than 1F, 1F, 2F, 3F, 4F, 5F, 6F, 7F, 8F, 9F, 10F, 11F, 12F, 13F, 14F, 15F, 16F, 17F, 18F, 19F, 20F, 21F, 22F, 23F, 24F, 25F, 26F, 27F, 28F, 29F, 30F, 31F, 32F, 33F, 34F, 35F, between 0F-5F, between 5F-10F, between 15F-20F, between 20F-25F, between 25F-30F, between 30F-35F, etc.

[0337] In some embodiments, the expandable guide catheter 460 can include a shaft. In some embodiments, the expandable guide catheter 460 can include a shaft that expands under compression. In some embodiments, the expandable guide catheter 460 can include a shaft that lengthens under compression. In some embodiments, the expandable guide catheter 460 can include a shaft that expands upon release of a constraint. In some embodiments, the expandable guide catheter 460 can include a shaft that expands due to

temperature. In some embodiments, the expandable guide catheter 460 can include a shaft that expands to assume a neutral configuration.

[0338] In some embodiments, the expandable guide catheter 460 can include an inverted structure. In some embodiments, one end of the braid begins at the proximal end and extends to the distal end where it folds inward and extends back to the proximal end. In some embodiments, the dual braid extends from the proximal end to the distal end. In some embodiments, the braid at the distal end can be continuous. In some embodiments, the braid at the distal end can be discontinuous. In some embodiments, one end of the braid begins at the proximal end and extends to the distal end wherein it folds inward and extends back to the proximal region. In some embodiments, one end of the braid begins at the proximal end and extends to the distal end wherein it folds outward and extends back to the proximal region. The outer braid layer 461 and the inner braid layer 462 are concentric.

[0339] In some embodiments, the outer layer braid 461 is encapsulated with polymeric materials. In some embodiments, the polymer layer can have uniform wall thickness. In some embodiments, the polymer layer can have uniform density. In some embodiments, the polymer layer can have uniform wall thickness throughout the entire catheter length. In some embodiments, the polymer layer can have non-uniform wall thickness. In some embodiments, the proximal end of the catheter wall thickness is thicker than the wall thickness at the distal end. In some embodiments, the polymeric material can have the same softness (durometer) through the catheter length. In some embodiments, the polymeric material can have different or a variety of softness (durometer) through the catheter length. In some embodiments, the polymeric material is expandable. In some embodiments, the polymeric material is flexible. In some embodiments, the outer layer composite is expandable. In some embodiments, polymeric materials can be any elastomer materials such as Polyurethane, Pellethane, Silicone, Tecoflex, Tecothane, Latex, Pebax and/or combination thereof. In some embodiments, the polymer can be coupled to the braid material through any methods known in the art. In some embodiments, the polymer can be coated, molded, dipped or thermally fused onto the braid.

[0340] In some embodiments, the guide catheter 460 has a funnel shape at distal end. In some embodiments, the guide catheter outer braid is encapsulated from the proximal end to the distal end near the funnel. In some embodiments, the funnel outer and inner braid

layer is not encapsulated with polymer. In some embodiments, the funnel outer braid is encapsulated with polymer. In some embodiments, the inner braid layer can be encapsulated with polymer and the outer layer is not.

[0341] The guide catheter 460 can function as an access system. In some embodiments, the guide catheter 460 is introduced in a compressed diameter configuration. In some embodiments, after introduction, the guide catheter 460 may be radially expanded to accommodate passage of larger diameter surgical instruments therethrough such as ALTC device 201 and/or the anchors described herein.

[0342] The guide catheter 460 can be useful for forming and enlarging access area in target locations within a patient's body. In some embodiments, the guide catheter 460 is delivered in a small diameter configuration and expanded. In some embodiments, only a distal end or a funnel end is expanded. In some embodiments, the guide catheter 460 can change the size of the lumen that the guide catheter 460 is inserted into, such as enlarging a vessel by pressing against the vessel wall. The guide catheter 460 can include a polymeric coating that facilitates sliding contact with the vessel wall.

[0343] In some embodiments, passage of the ALTC device 201 through the guide catheter 460 can cause expansion of the guide catheter 460. In some embodiments, the collapsed ALTC device 201 can be sized to fit within the guide catheter 460. In some embodiments, the expanded ALTC device 201 can be sized to fit within the guide catheter 460. In some embodiments, the expanded ALTC device 201 can be retracted through the guide catheter 460. In some embodiments, the one or more expanded anchors can be retracted through the guide catheter 460. In some embodiments, the one or more expanded anchors can be sized to fit within the guide catheter 460. The uncoated inner braid layer 462 reduces sliding contact between the guide catheter 460 and any components passed therethrough.

[0344] In some embodiments, the guide catheter 460 can function as a variable sized cannula. In some embodiments, the guide catheter 460 can function as a tissue dilator. In some embodiments, the guide catheter 460 can change shape during axial compression of the braid. In some embodiments, axial shortening can cause radial expansion of the guide catheter 460. In some embodiments, the guide catheter 460 can be variably expanded based on the amount of compressive force. In some embodiments, the guide catheter 460 is self-

expanding. In some embodiments, the guide catheter 460 is expanded by a mechanism e.g., pull strings, release from a constraint, application of compressive force, application of tension, etc. In some embodiments, the guide catheter 460 is a shape memory material.

[0345] In some embodiments, the guide catheter 460 can facilitate the removal of a blockage within the vasculature of a patient. In some embodiments, the guide catheter 460 can surround the one or more anchors that are entangled in the clot. In some embodiments, the surface of the clot can slide easily within the guide catheter, due in part, to the inner surface of the guide catheter 460. In some embodiments, the guide catheter 460 can slide easily within the target vessel, due in part, to the outer surface of the guide catheter 460. In some embodiments, the guide catheter 460 can be collapsed after receiving the one or more anchors. In some embodiments, the guide catheter 460 can surround the ALTC device 201 which itself encapsulates the obstruction. In some embodiments, the outer surface of the ALTC device 201 can slide easily within the guide catheter, due in part, to the inner surface of the guide catheter 460. In some embodiments, the guide catheter 460 can be collapsed after receiving the ALTC device 201.

[0346] Systems and methods can be utilized or modified for use in connection with those described herein can be found, for example, in U.S. Patent Application No. 11/101,224, filed Apr. 7, 2005 and published July 2, 2013 as U.S. Patent No. 8475487 ("Bonnette"); U.S. Patent Application No. 12/738,702, filed Oct. 27, 2008 and published Oct. 21, 2010 as U.S. Patent Pub. No. 20100268264 ("Bonnette '264") are all incorporated by reference herein in their entireties.

[0347] In some methods of use, the ALTC device 201 is used in combination with a thrombectomy catheter, such as an AngioJet® thrombectomy device or potentially an aspiration catheter may be used to remove the embolic debris. In some methods of use, one or more anchors described herein is used in combination with a thrombectomy catheter or an aspiration catheter, such as an AngioJet® thrombectomy device. The use of the AngioJet®, a rheolytic cross stream thrombectomy catheter, can include an inherent ability to remove thrombus of larger diameter than the catheter's diameter. However, the disruptive strength of the device falls off with the radial distance from the catheter. Hence, at some radial distance the clot can be stronger than the disruptive force generated by the AngioJet® cross stream

flow patterns. In the case of organized thrombus, this radial distance from the catheter can be smaller than for softer thrombus.

[0348] Water jet thrombectomy procedures in general can be limited in ability in some cases. However, adding mechanical disruption such as by use of the anchors described herein can unexpectedly and synergistically improve water jet ablation. By combining mechanical agitation, e.g.,, abrasive intimate contact of thrombus by a flexible and expandable anchor component and an ALTC device 201, with a rheolytic thrombectomy catheter (AngioJet®), a variety of thrombus can be cleared than can be cleared by mechanical agitators or rheolytic cross stream thrombectomy catheters individually.

[0349] Another aspect and feature of some embodiments of the devices of the present disclosure is a device having the ability to capture large and small embolic debris. Another aspect and feature of the devices of the present disclosure is a device having the ability to temporarily capture debris which may later be removed by manual aspiration or by the use of an AngioJet® thrombectomy device and catheter or which may be treated by thrombolytics. Another aspect and feature of the devices of the present disclosure is a device having the ability to macerate debris to a clinically insignificant size (depending on the area of the body) or to a size which can be pharmacologically treated or removed by another device, such as an AngioJet® thrombectomy device and catheter. Another aspect and feature of the devices of the present disclosure is a device having the ability to macerate non-embolic debris, such as a stationary thrombus, by pulling the device through such an obstruction.

[0350] Systems and methods can be utilized or modified for use in connection with those described herein can be found, for example, in U.S. Patent Application No. 14/774,735, filed Mar. 17, 2014 and published Jan. 28, 2016 as U.S. Pub No. 20160022290 ("Johnson"); U.S. Patent Application No. 13/741,845, filed Jan. 15, 2013 and published Jan. 2, 2014 as U.S. Patent Pub. No. 20140005712 ("Martin") are all incorporated by reference herein in their entireties.

[0351] An intravascular ultrasound (IVUS) transducer disclosed in Johnson can be incorporated into the systems described herein. In some embodiments, an intravascular ultrasound (IVUS) transducer can be added to or incorporated into the delivery system and method. A pressure sensor can be used to measure the pressure at various positions within the vasculature, which can be used to determine blood flow, while the intravascular ultrasound

(IVUS) transducer can be used to measure fluid flow and/or provide imaging within the vessel. In some embodiments, the pressure sensor and/or IVUS transducer can be incorporated into the guidewire at one or more locations, such as the distal end or distal portion of a guidewire, as well as being incorporated into intermediate and proximal portions of the guidewire. The guidewire with the pressure sensor and/or the IVUS transducer can be used much like a normal guidewire to help navigate the delivery device through the vasculature, with the added benefit of providing pressure measurements and ultrasound imaging to help in the navigation, to visualize the device placement site, and to monitor and ensure proper device deployment. In some embodiments, the IVUS transducer generates image slices as it is advanced and retracted which can then be assembled together to form a three dimensional reconstruction of the vasculature and/or the device within the vasculature. In some embodiments, the guidewire with the pressure sensor and/or IVUS transducer can be fastened to a catheter in a similar manner to that described below for a catheter having a pressure sensor and/or IVUS transducer that is fastened to another catheter.

[0352] Use of the ultrasound imaging system can allow the operator to deliver the device without fluoroscopy or using less fluoroscopy, thereby reducing the radiation exposure to the patient, while allowing more accurate evaluation of the vasculature, aiding placement of the device and allowing confirmation that device placement was proper. The imaging can be used to aid in the deployment of the filters or other devices. The imaging can also be used to aid in the retrieval of the deployed devices by providing visualization of, for example, the retrieval features on the deployed device and of the retrieval features, such as loops on a snare, of the retrieval device. The vasculature and implant location can be imaged prior to deployment, after deployment and/or during deployment. The imaging can be used during the retrieval process. The imaging can be used to aid in positioning of the filter or device within the vasculature. The imaging can be used to image the deployment location and determine the appropriate sizing of the filter or other device. The imaging can be used to help estimate treatment duration.

[0353] Although imaging systems described above have been primarily described as ultrasound based, other imaging systems can be used instead or in addition. For example, the imaging system can be based on intravascular ultrasound (IVUS), Forward-Looking

IVUS (FLIVUS), optical coherence tomography (OCT), piezoelectric micro-machined ultrasound traducer (PMUT), and/or FACT.

[0354] Other components described by Martin can also be incorporated into the systems described herein. All or some of the device can be designed to increase their ability to adhere to the obstruction. For example, the wires may be coupled to an energy source (e.g., RF, ultrasonic, or thermal energy) to "weld" to the obstruction. Application of energy to the device can allow the surrounding portion to deform into the obstruction and "embed" within the obstruction. Alternatively, the device can impart a positive charge to the obstruction to partially liquefy the obstruction sufficiently to allow for easier removal. In another variation, a negative charge could be applied to further build thrombus and nest the device for better pulling force. The wires can be made stickier by use of a hydrophilic substance(s), or by chemicals that would generate a chemical bond to the surface of the obstruction. Alternatively, the filaments may reduce the temperature of the obstruction to congeal or adhere to the obstruction.

[0355] Another aspect applicable to variations of the devices can be to configure the devices (whether the traversing filament or the surrounding portion) for better adherence to the obstruction. One such mode includes the use of coatings that bond to certain clots (or other materials causing the obstruction.) For example, the wires may be coated with a hydrogel or adhesive that bonds to a thrombus. Accordingly, as the device secures about a clot, the combination of the additive and the mechanical structure of the device may improve the effectiveness of the device in removing the obstruction. Coatings may also be combined with the capturing portions or catheter to improve the ability of the device to encapsulate and remove the obstruction (e.g., a hydrophilic coating).

[0356] Such improvements may also be mechanical or structural. Any portion of the capturing portion can have hooks, fibers, or barbs that grip into the obstruction as the device surrounds the obstruction. The hooks, fibers, or barbs can be incorporated into any portion of the device. However, it will be important in some embodiments that such features do not hinder the ability of the practitioner to remove the device from the body.

[0357] In addition to additives, the device can be coupled to an RF, microwave, magnetic, thermal, cryo, or other power source, to allow electrical, current, ultrasound or RF

energy to transmit through the device and induce clotting or cause additional coagulation of a clot or other obstruction.

[0358] The methods described herein may also include treating the obstruction prior to attempting to remove the obstruction. Such a treatment can include applying a chemical or pharmaceutical agent with the goal of making the occlusion shrink or to make it more rigid for easier removal. Such agents include, but are not limited to chemotherapy drugs, or solutions, lytic agents such as tPA, urokinase, or streptokinase for example, an anticoagulant, a mild formalin, or aldehyde solution.

[0359] Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings. Therefore, it should be understood at this time that the inventions may be practiced otherwise than as specifically described herein. It is contemplated that various combinations or subcombinations of the specific features and aspects of the embodiments disclosed above may be made and still fall within one or more of the inventions. Further, the disclosure herein of any particular feature, aspect, method, property, characteristic, quality, attribute, element, or the like in connection with an embodiment can be used in all other embodiments set forth herein. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the disclosed inventions. Thus, it is intended that the scope of the present inventions herein disclosed should not be limited by the particular disclosed embodiments described above. Moreover, while the inventions are susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the inventions are not to be limited to the particular forms or methods disclosed, but to the contrary, the inventions are to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the various embodiments described. Any methods disclosed herein need not be performed in the order recited. The methods disclosed herein include certain actions taken by a practitioner; however, they can also include any third-party instruction of those actions, either expressly or by implication. For example, actions such as "inserting a catheter transfemorally" includes "instructing the insertion of a catheter transfemorally." The ranges disclosed herein also encompass any and all overlap, sub-ranges, and combinations thereof. Language such as "up to," "at least,"

"greater than," "less than," "between," and the like includes the number recited. Numbers preceded by a term such as "approximately", "about", and "substantially" as used herein include the recited numbers (e.g., about 10% = 10%), and also represent an amount close to the stated amount that still performs a desired function or achieves a desired result. For example, the terms "approximately", "about", and "substantially" may refer to an amount that is within less than 10% of, within less than 5% of, within less than 1% of, within less than 0.1% of, and within less than 0.01% of the stated amount.

WHAT IS CLAIMED IS:

1. A clot capture system, comprising:

an anchor,

a tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening,

wherein the tubular body and the anchor are compressed in a delivery configuration,

wherein the tubular body and the anchor are transformable to a deployed configuration in which the anchor and the shape memory tubular body first end are expanded but the shape memory tubular body second end and a majority of the shape memory tubular body remains compressed and the tubular body has a first expanded axial length,

wherein the shape memory tubular body is transformable to a capture configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein the shape memory tubular body encapsulates the anchor, or a portion thereof, in the capture configuration.

2. The clot capture system of Claim 1, further comprising two or more anchors.

3. The clot capture system of Claim 2, wherein the two anchors have a central longitudinal axis that is coaxial.

4. The clot capture system of Claim 1, wherein the anchor is a stent like structure.

5. The clot capture system of Claim 1, wherein the anchor is a balloon.

6. The clot capture system of Claim 1, wherein the anchor is a disk.

7. The clot capture system of Claim 1, wherein the anchor comprises nitinol.

8. The clot capture system of Claim 1, wherein the anchor comprises a spherical balloon.

9. The clot capture system of Claim 1, wherein the anchor is configured to entangle a clot.

10. The clot capture system of Claim 1, wherein the anchor is coupled to the shape memory tubular body.

11. The clot capture system of Claim 1, wherein the anchor is a funnel.

12. The clot capture system of Claim 1, wherein the anchor is tapered from the distal end to the proximal end of the anchor.

13. The clot capture system of Claim 1, wherein the shape memory tubular body comprises a central longitudinal axis and wherein the anchor is offset from the central longitudinal axis.

14. The clot capture system of Claim 1, wherein the second end of the shape memory tubular body is coupled to an inner pusher.

15. A clot capture system, comprising:

an anchor;

a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening,

wherein the shape memory tubular body and the anchor are configured to be compressed during delivery,

wherein the first end of the shape memory tubular body and the anchor are configured to be expanded while the second end and a majority of the shape memory tubular body remains compressed, wherein the shape memory tubular body has a first expanded axial length with a first cross-section,

wherein the shape memory tubular body is configured to be axially lengthened.

16. The clot capture system of Claim 15, further comprising a pusher, wherein the second end of the shape memory tubular body is coupled to the pusher.

17. The clot capture system of Claim 15, wherein the anchor and the shape memory tubular body are fixed together.

18. A method of using a clot capture system, comprising:

positioning the system of Claim 15 near a blood clot;

expanding the shape memory tubular body and the anchor; and

axially lengthening the shape memory tubular body to encapsulate the clot.

19. The method of Claim 18, wherein the blood clot is within the central nervous system.

20. A method of using a clot capture system, comprising:

positioning the system of Claim 1 near a blood clot;

transforming the shape memory tubular body and the anchor to the deployed configuration;

transforming the shape memory tubular body and the anchor to the capture configuration to encapsulate the anchor.

21. A clot capture system, comprising:

an outer sheath comprising a central lumen;

a dual lumen shaft configured to be positioned within the central lumen of the outer sheath;

an inner pusher configured to be positioned within a first lumen of the dual lumen shaft;

an anchor pusher configured to be positioned within a second lumen of the dual lumen shaft,

an anchor coupled to the anchor pusher,

a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening and a capture guide attached to a portion of the opening,

wherein the shape memory tubular body and the anchor are compressed in a first configuration,

wherein the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains radially compressed within the lumen of the dual lumen shaft and the shape memory tubular body has a first expanded axial length with a first cross-section, wherein the first cross-section is substantially similar to the cross-section of the capture guide,

wherein the shape memory tubular body is transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein the shape memory tubular body encapsulates the anchor in the third configuration.

22. The clot capture system of Claim 21, further comprising two anchors.

23. The clot capture system of Claim 22, wherein the two anchors have a central longitudinal axis that is coaxial.

24. The clot capture system of Claim 21, further comprising three anchors.

25. The clot capture system of Claim 21, wherein the cross-section is round.

26. The clot capture system of Claim 21, wherein the anchor comprises nitinol.

27. The clot capture system of Claim 21, wherein the anchor forms an angle with the anchor pusher, wherein the angle is approximately 90 degrees.

28. The clot capture system of Claim 21, wherein the anchor forms an angle with the anchor pusher, wherein the angle is approximately 45 degrees.

29. The clot capture system of Claim 21, wherein the anchor forms an angle with the anchor pusher, wherein the angle is between 5 degrees and 135 degrees.

30. The clot capture system of Claim 21, wherein the diameter of the anchor is less than the diameter of the shape memory tubular body when radially expanded.

31. The clot capture system of Claim 21, wherein a portion of the anchor pusher is crescent shaped.

32. The clot capture system of Claim 21, wherein the capture guide comprises nitinol.

33. The clot capture system of Claim 21, wherein the capture guide comprises a central longitudinal axis and wherein the dual lumen shaft is offset from the central longitudinal axis.

34. The clot capture system of Claim 21, wherein the second end of the shape memory tubular body is coupled to the inner pusher.

35. A clot capture system, comprising:

an inner pusher element;

a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an opening and a capture guide attached to at least a portion of the opening, the second end coupled to the inner pusher element,

wherein the shape memory tubular body and the capture guide are compressed in a first configuration,

wherein the shape memory tubular body is transformable to a second configuration in which the first end and the capture guide are radially expanded but the second end and a majority of the shape memory tubular body remains radially compressed and the shape memory tubular body has a first expanded axial length

with a first cross-section, wherein the first cross-section is substantially similar to the cross-section of the capture guide,

wherein the shape memory tubular body is transformable to a third configuration in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length.

36. The clot capture system of Claim 35, wherein the capture guide forms a continuous loop.

37. The clot capture system of Claim 35, wherein the capture guide forms a non-continuous loop.

38. A method of using a clot capture system, comprising:

positioning the system of Claim 35 near a blood clot in the first configuration;

transforming the shape memory tubular body to the second configuration; and

transforming the shape memory tubular body to the third configuration to encapsulate the clot.

39. The method of Claim 38, wherein the blood clot is within the CNS.

40. A method of using a clot capture system, comprising:

positioning the system of Claim 21 near a blood clot;

transforming the shape memory tubular body to the second configuration;

expanding the anchor; and

transforming the shape memory tubular body to the third configuration to encapsulate the anchor.

41. The method of Claim 40, wherein deploying the anchor comprises securing the anchor within the clot.

42. The method of Claim 40, wherein transforming the shape memory tubular body to the third configuration to encapsulate the anchor further comprises encapsulating the clot.

43. The method of Claim 40, wherein the blood clot is a neurological blood clot.

44. A clot capture system, comprising:

a first tubular member comprising a central lumen;

a second tubular member;

a plurality of axially spaced-apart anchors extending radially outwardly from the first tubular member or the second tubular member; and