a shape memory tubular body comprising a first end, a second end, and an axial length therebetween, the first end having an end opening, the second end attached to the second tubular member,

wherein at least part of the shape memory tubular body is compressed within the central lumen of the first tubular shaft in a first delivery configuration,

wherein the shape memory tubular body is transformable to a second configuration in which the first end is radially expanded while the second end and a majority of the shape memory tubular body remains radially compressed within the central lumen of the first tubular shaft and the second end is positioned proximal to the first end and the shape memory tubular body has a first expanded axial length,

wherein the shape memory tubular body is transformable to a third configuration via movement of the first tubular shaft with respect to the second tubular shaft in which the shape memory tubular body has a second expanded axial length greater than the first expanded axial length, wherein a width of the shape memory tubular body along its second expanded axial length is substantially the same as a width of the shape memory tubular body along its first expanded axial length.

Imperative Care v. Inari Medical
US Patent 12,016,580
Imperative Care Ex. 1002

INARI_020379

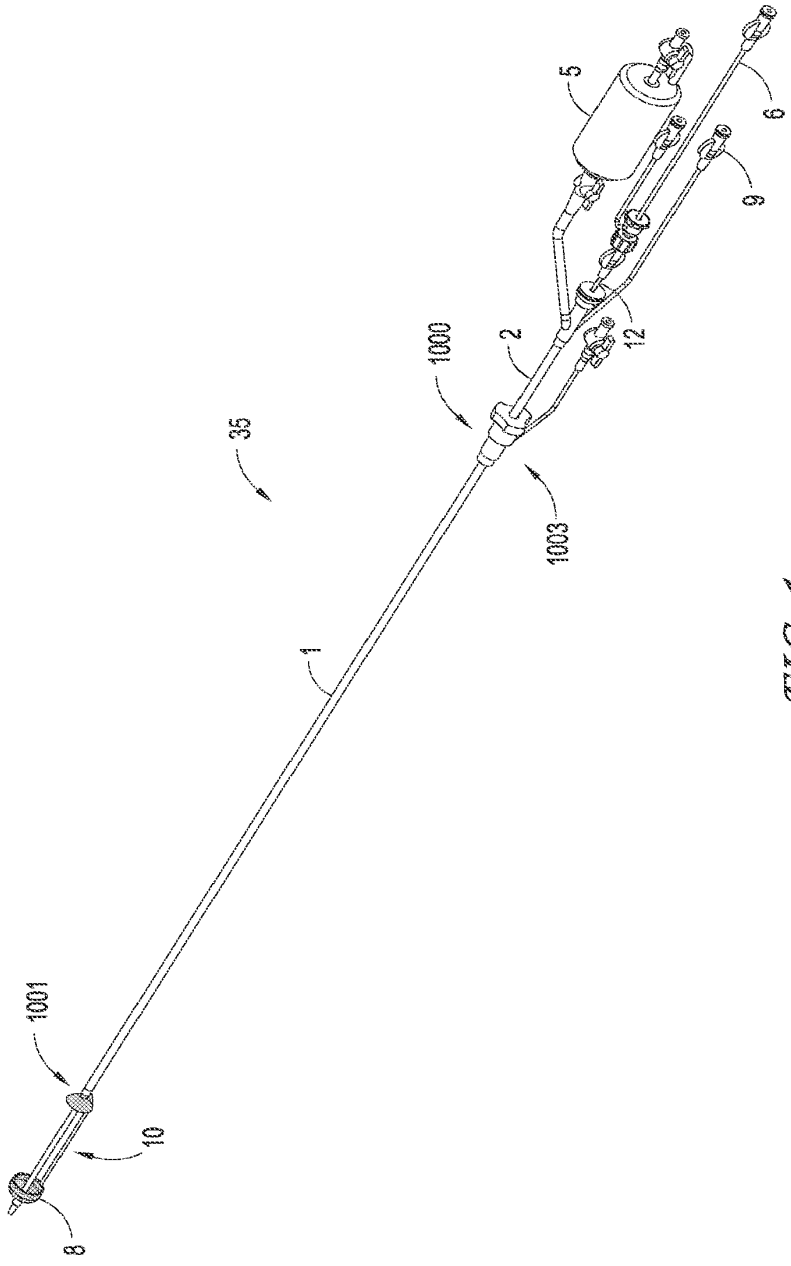


FIG. 1

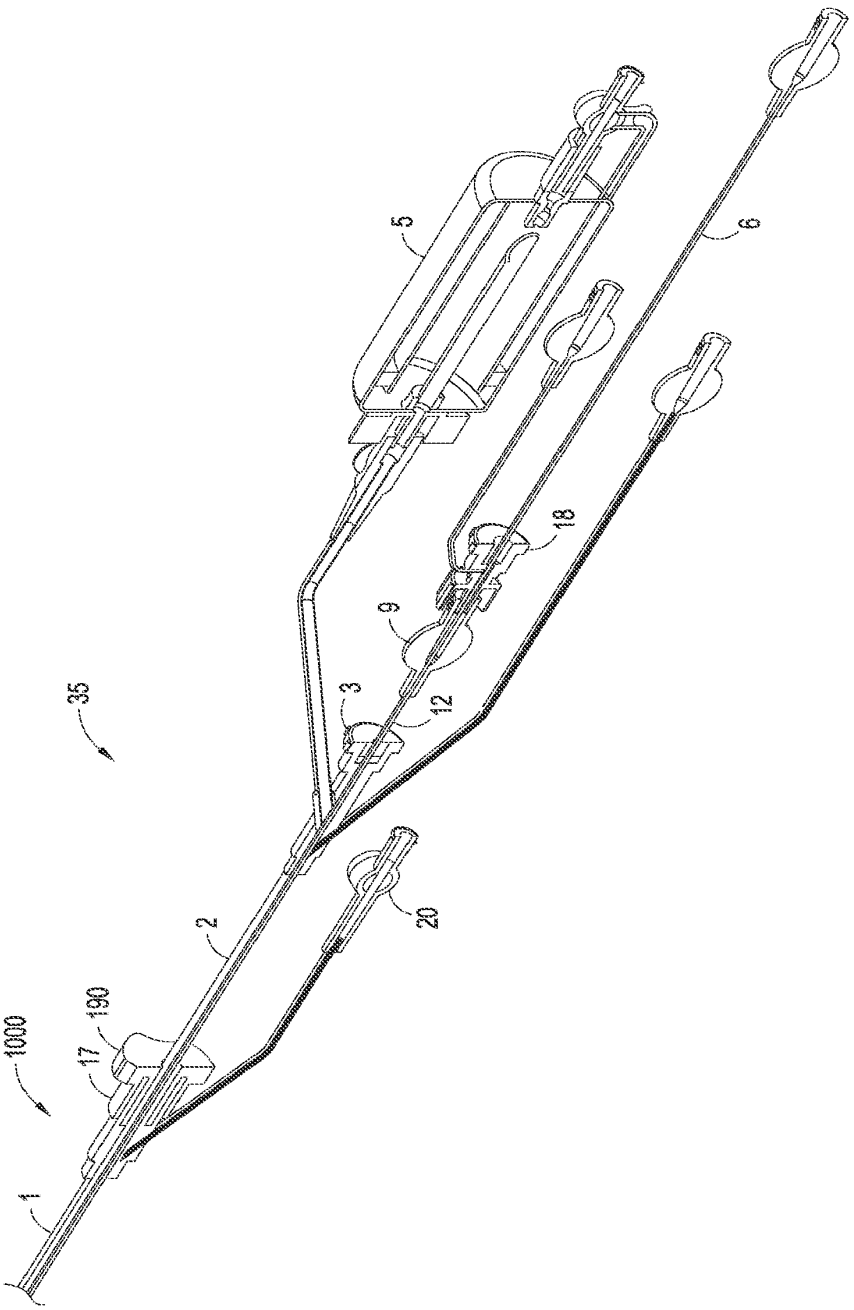


FIG. 2

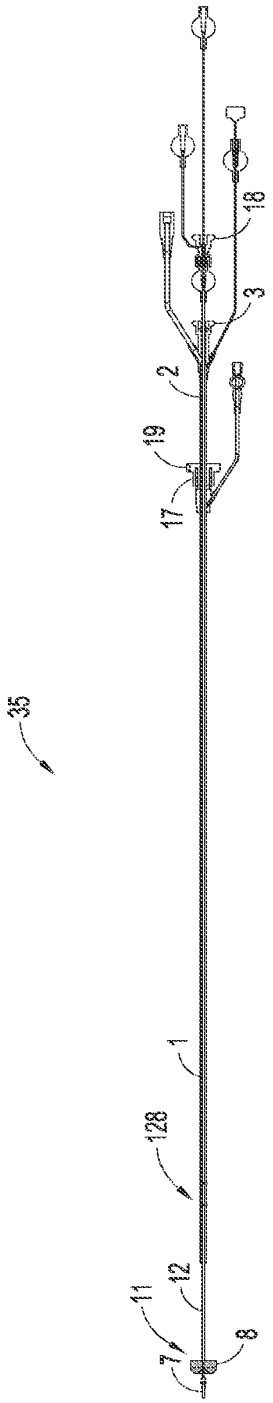


FIG. 3

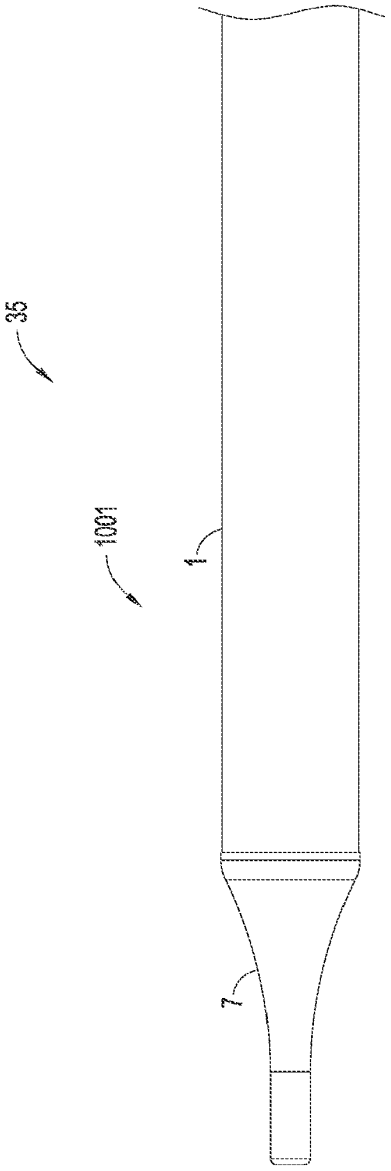


FIG. 4

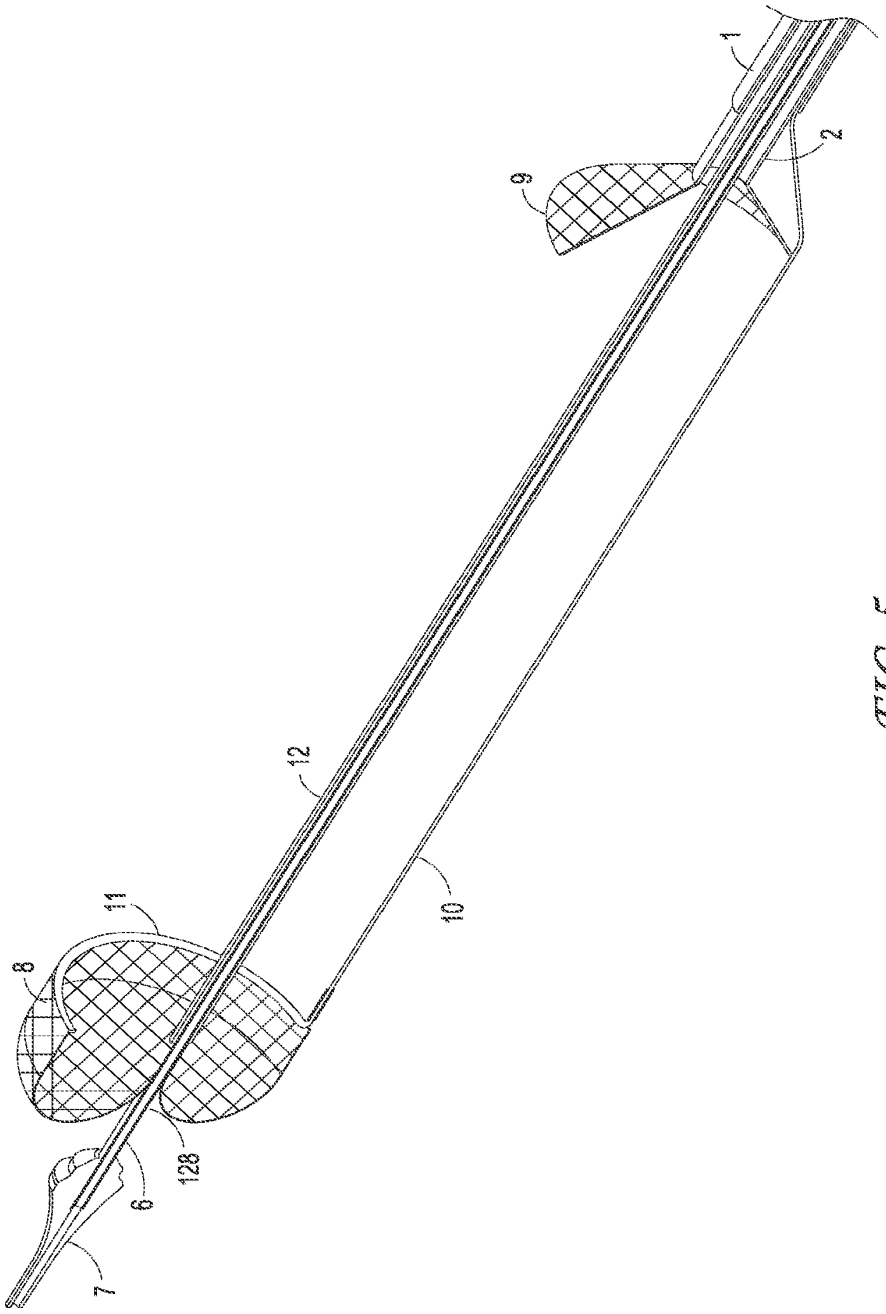


FIG. 5

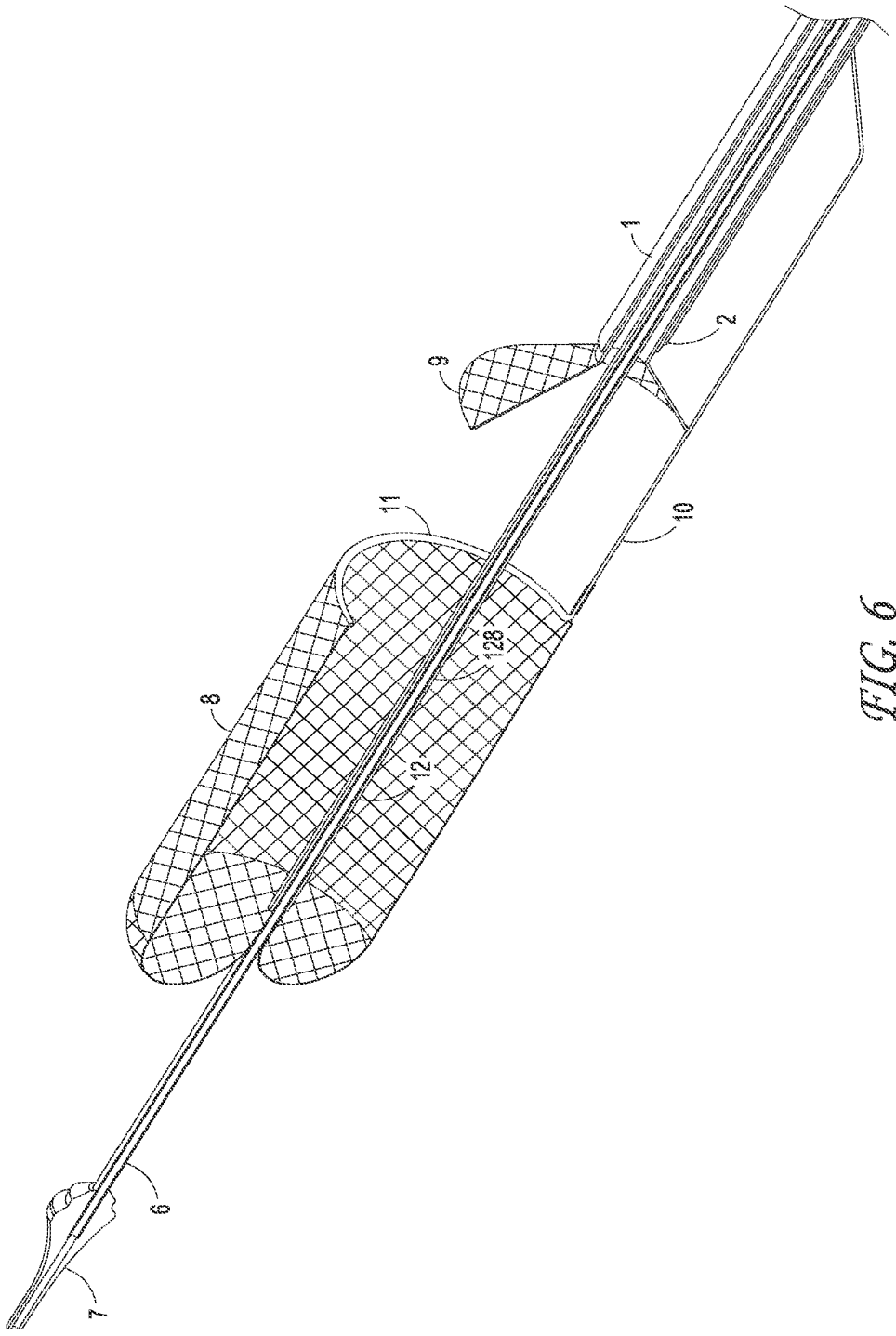


FIG. 6

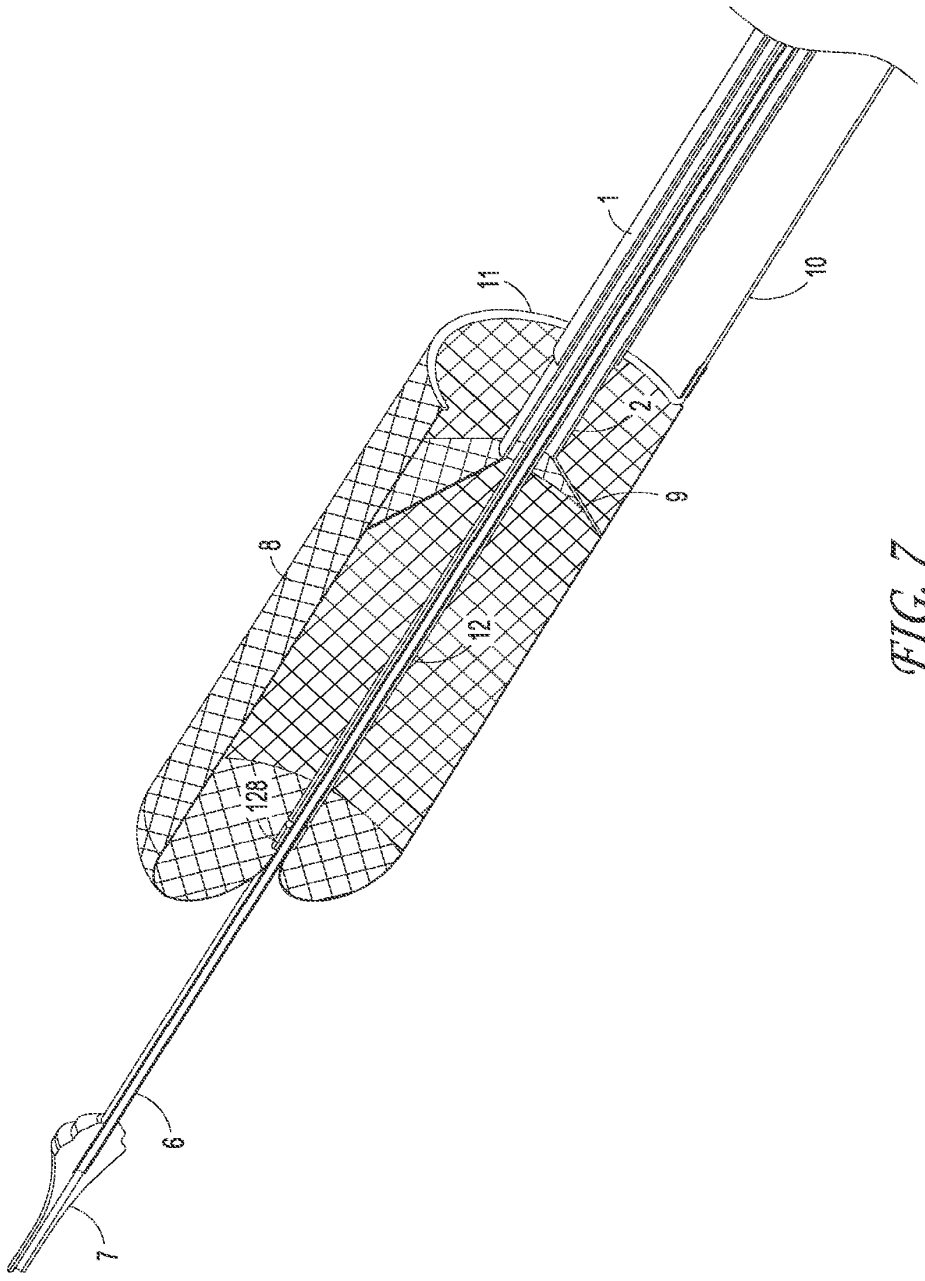


FIG. 7

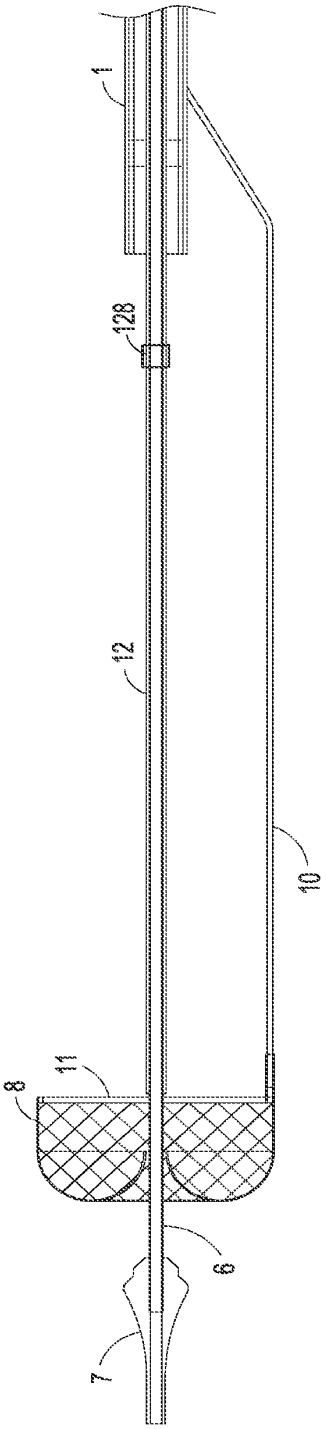


FIG. 8

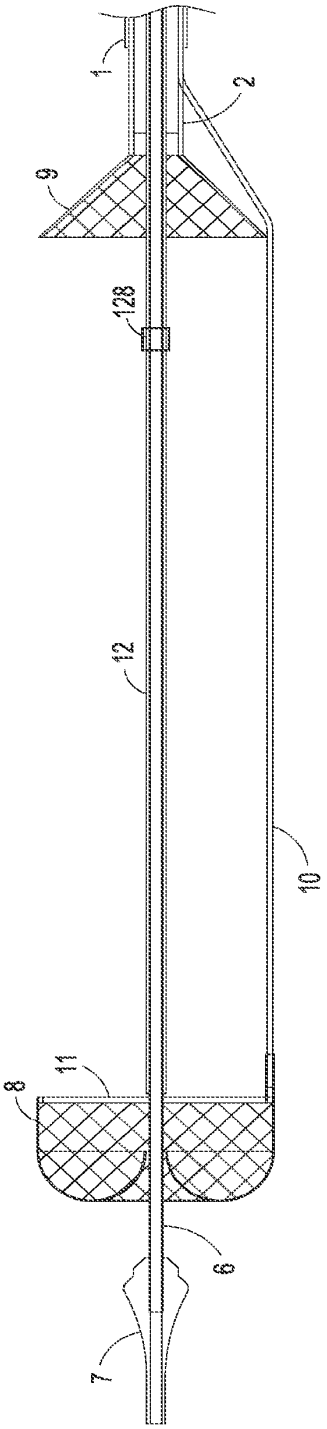


FIG. 9

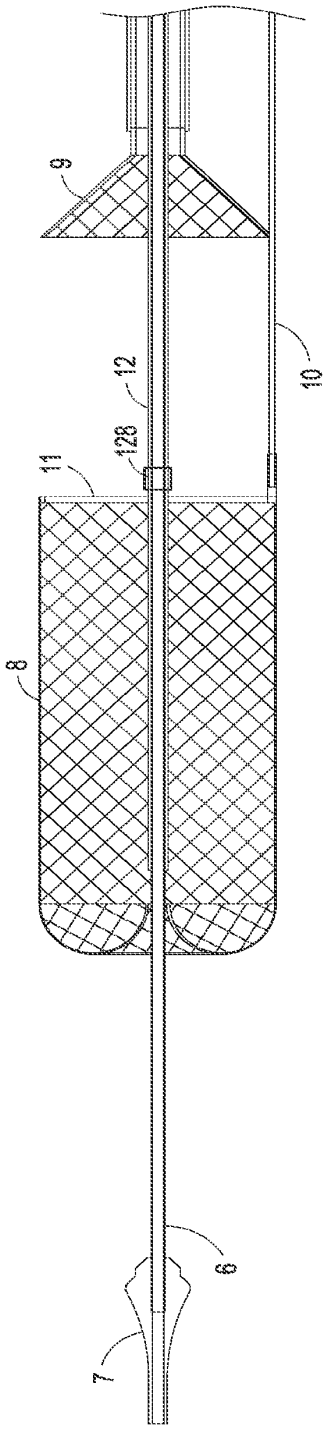


FIG. 10

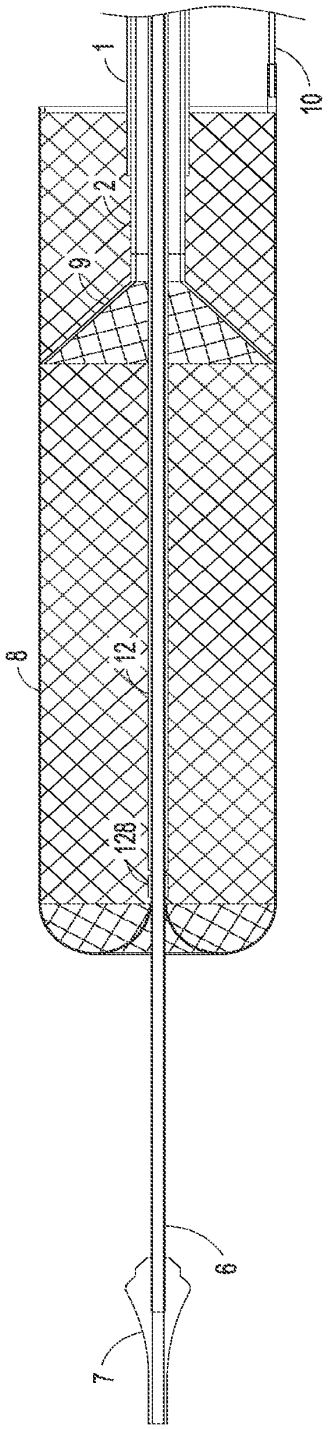


FIG. 11

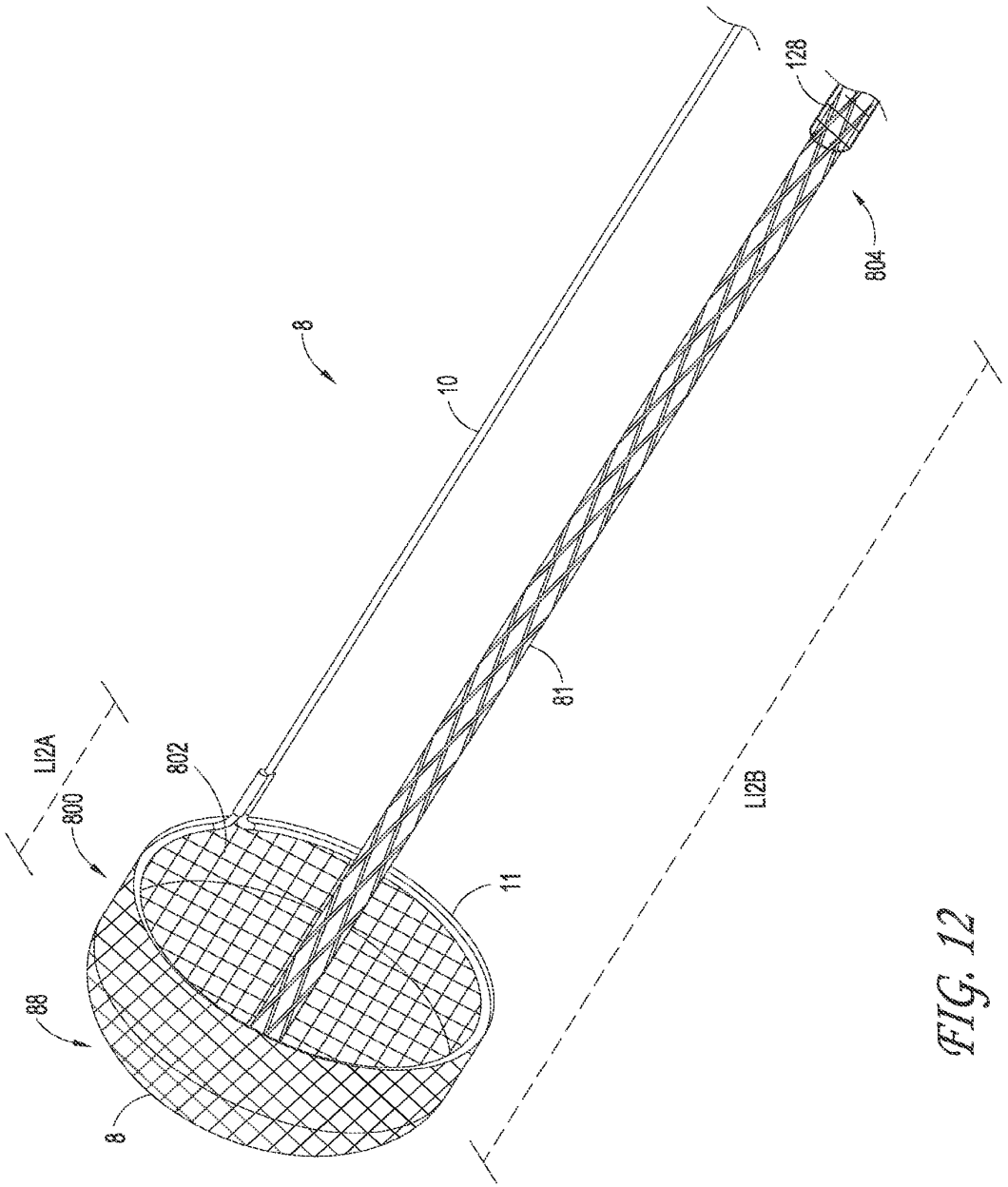


FIG. 12

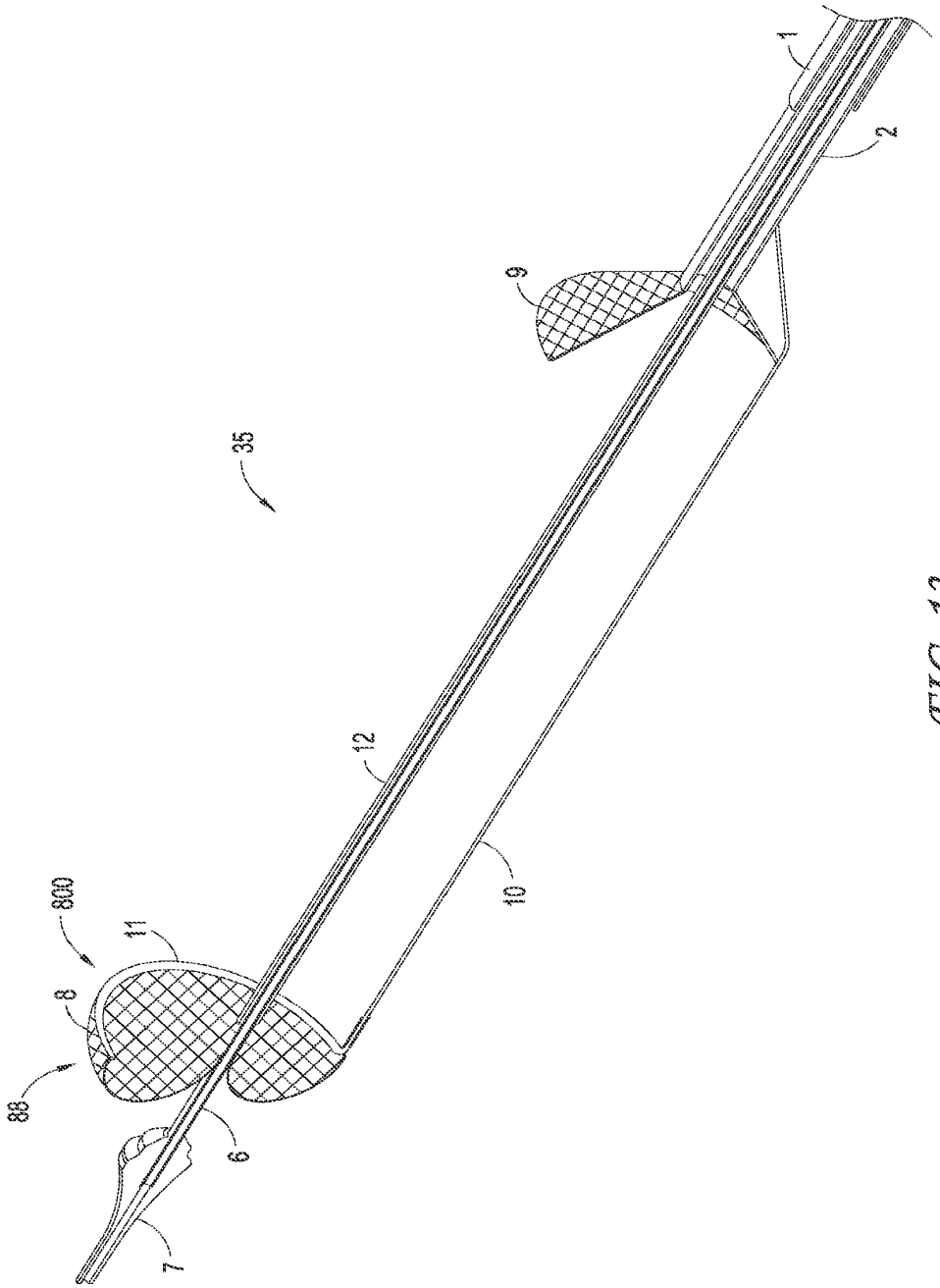


FIG. 13

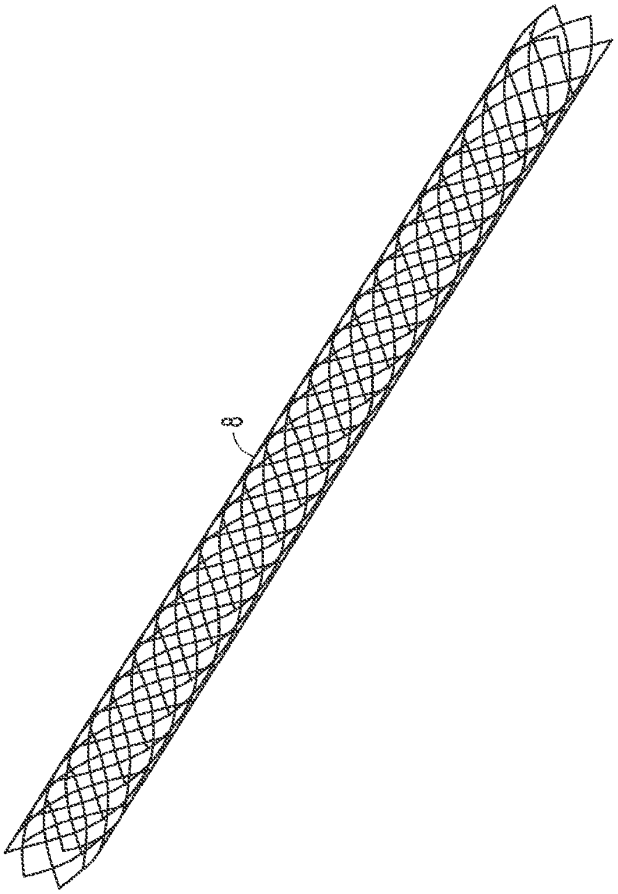


FIG. 14

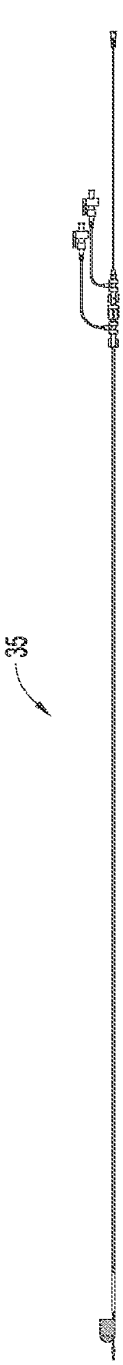


FIG. 15A

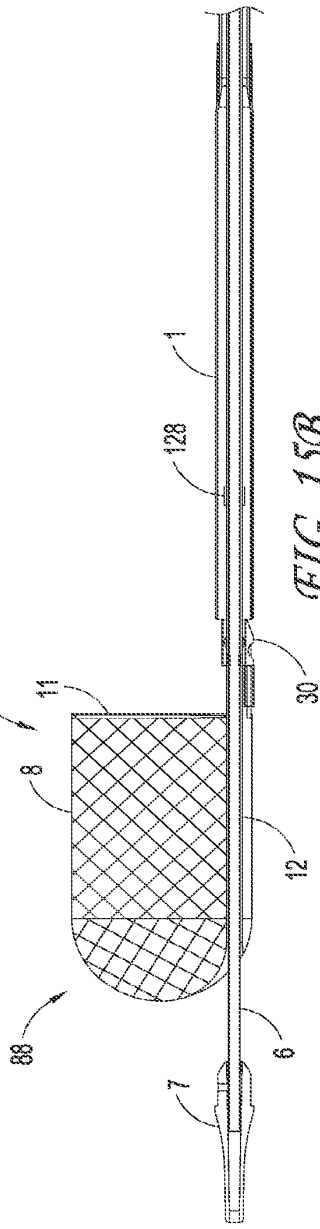


FIG. 15B

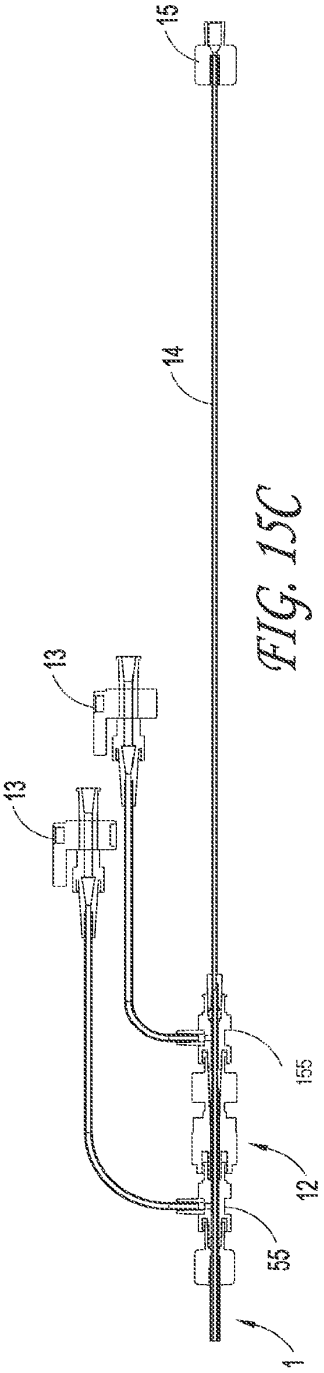


FIG. 15C

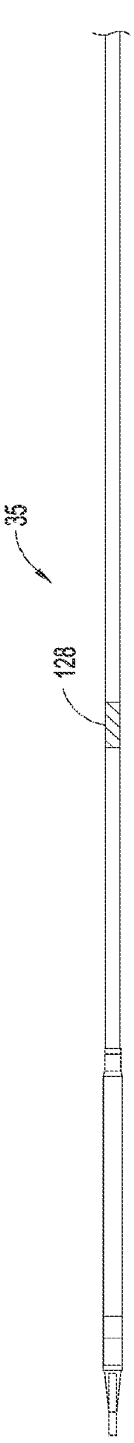


FIG. 16A

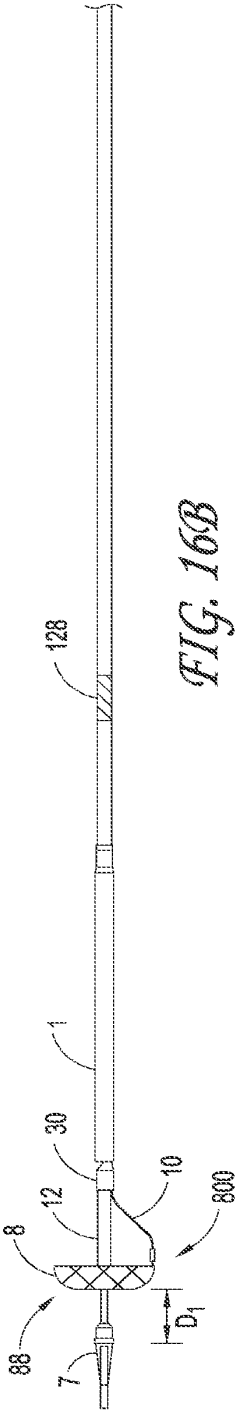


FIG. 16B

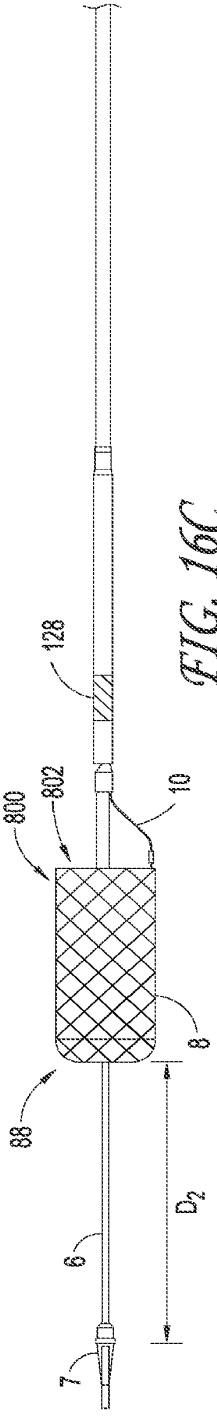


FIG. 16C

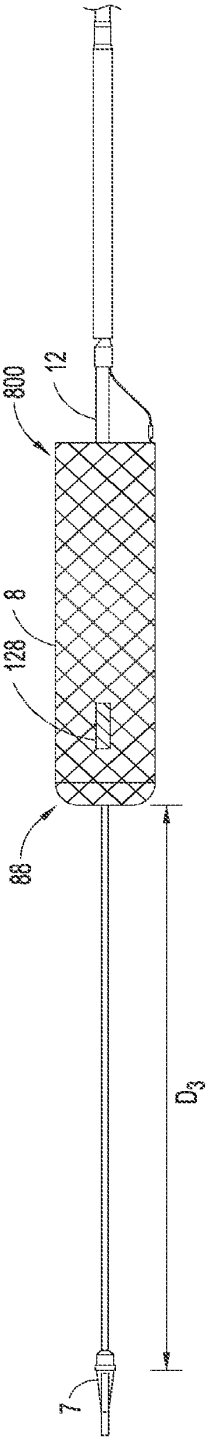
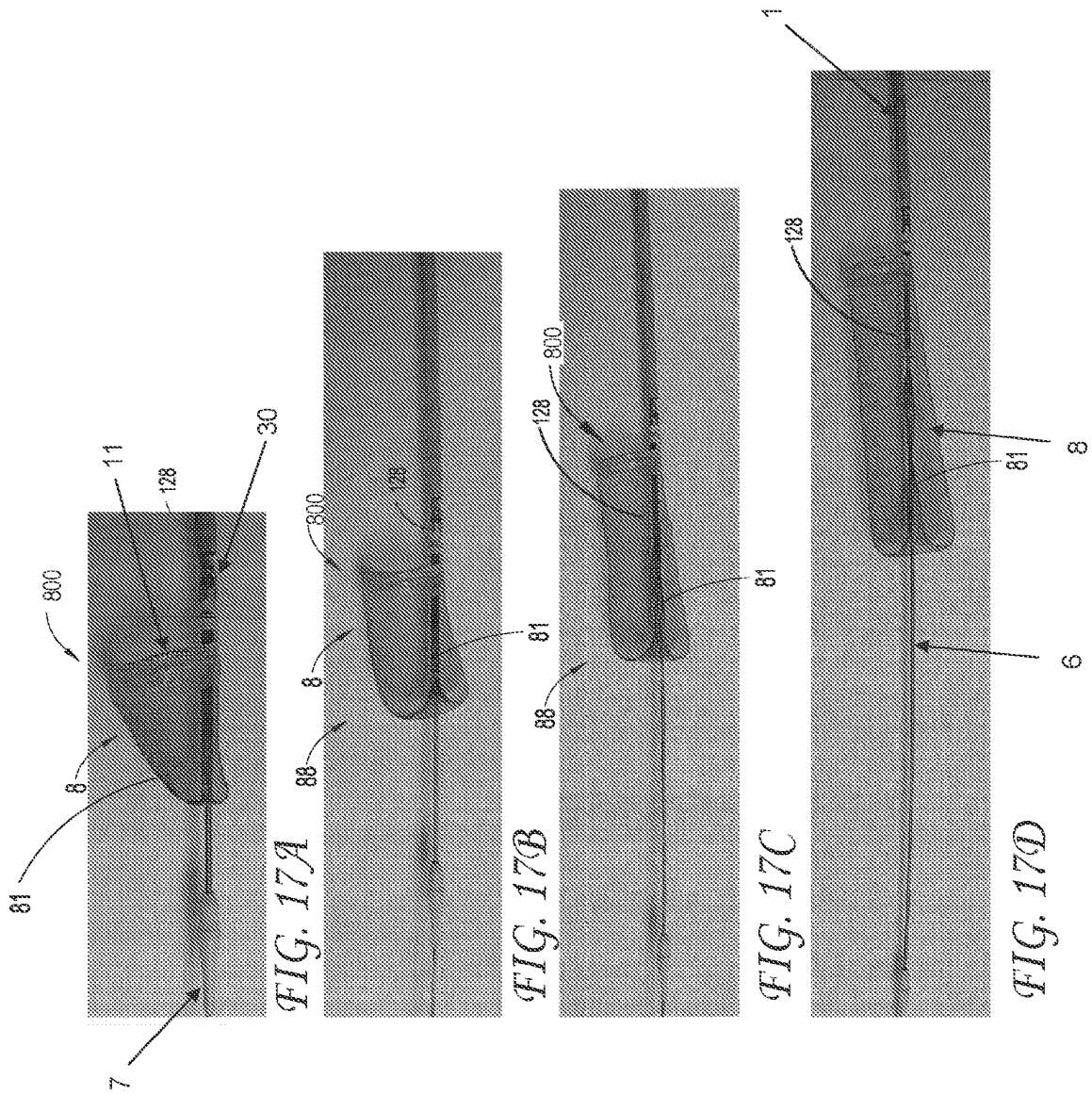


FIG. 16D


800
11
128
30
8
81
7
FIG. 17A
800
128
8
81
88
FIG. 17B
800
128
81
88
FIG. 17C
1
128
8
81
6
FIG. 17D

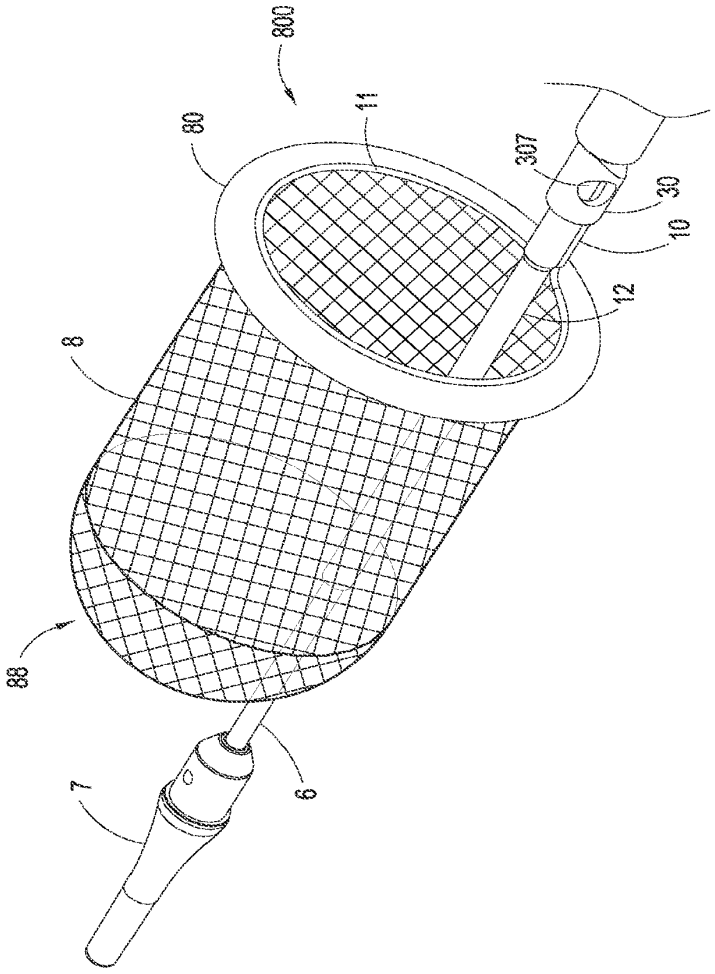


FIG. 18A

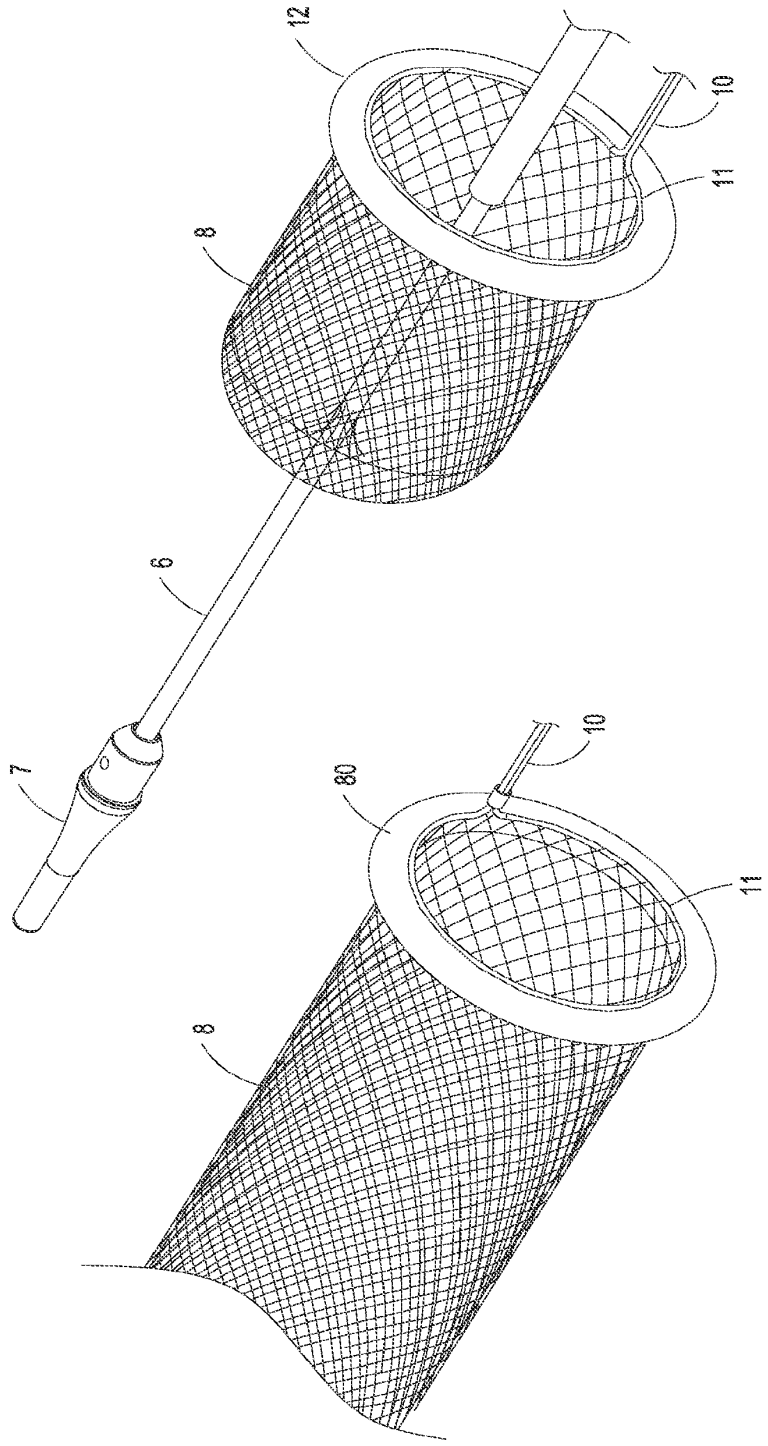


FIG. 18B

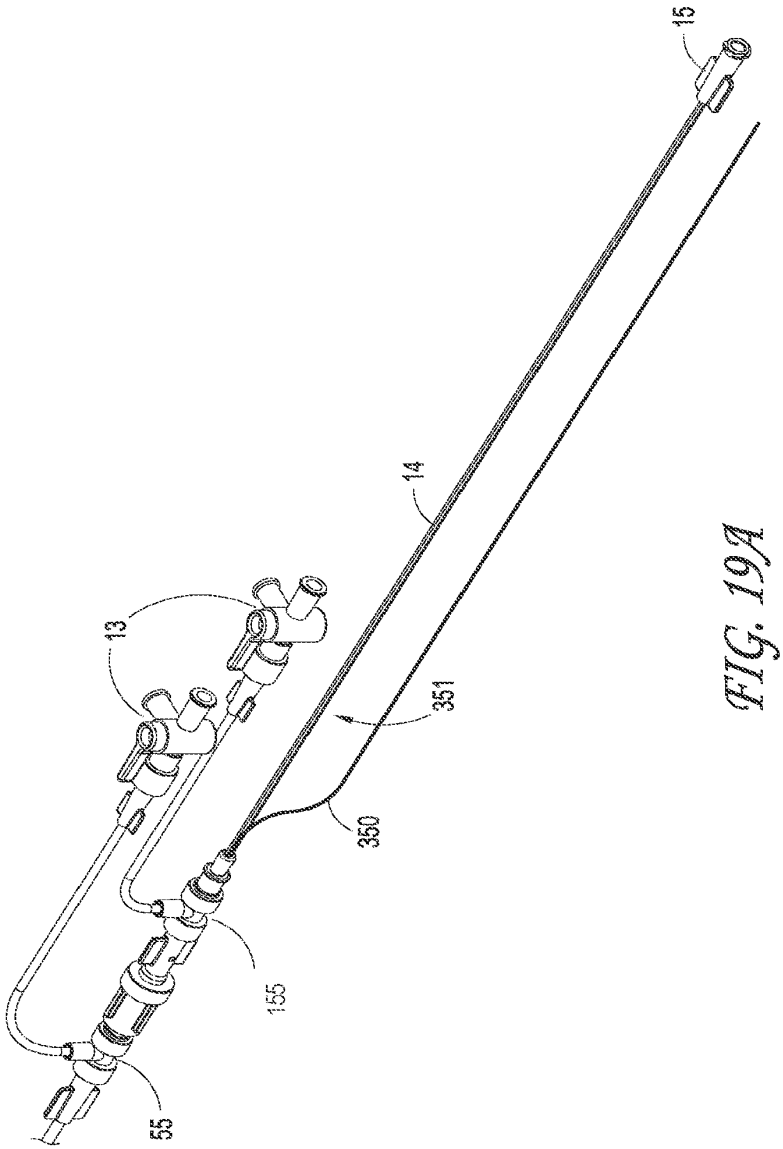


FIG. 19A

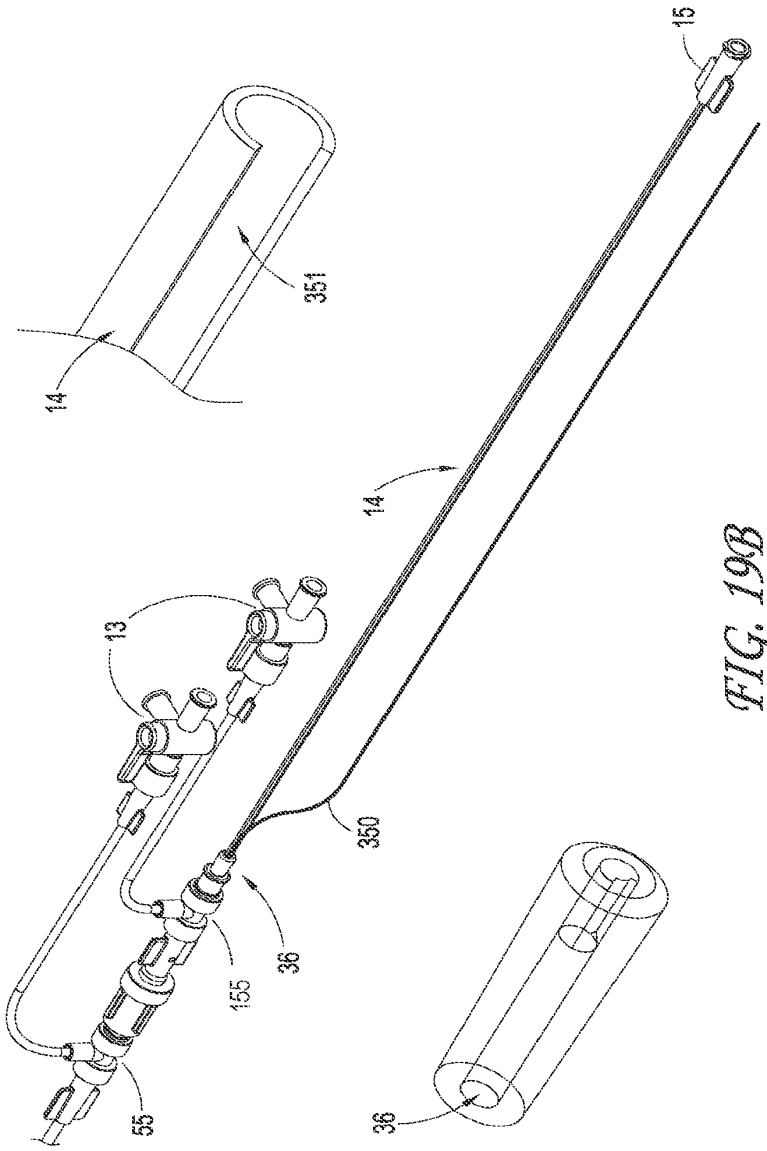


FIG. 19B

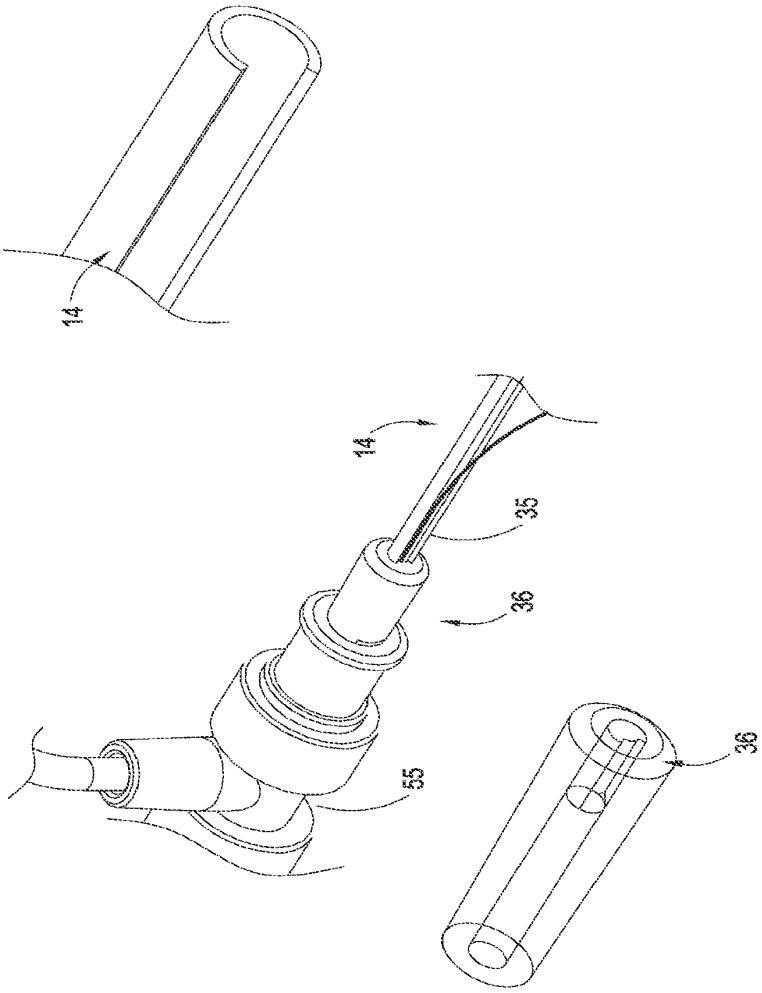


FIG. 19C

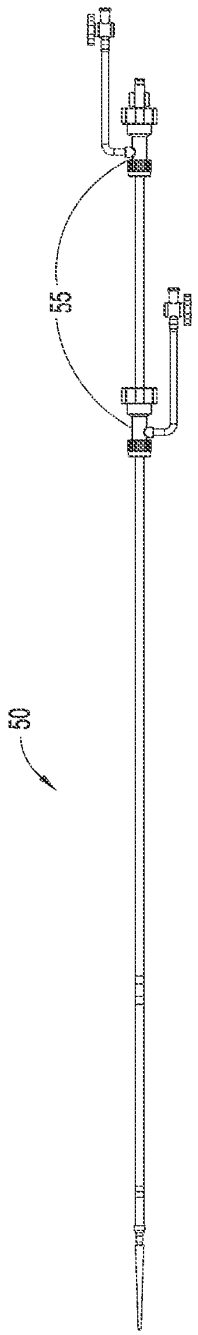


FIG. 20A

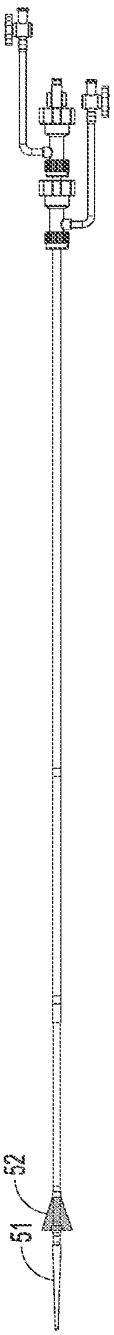


FIG. 20B

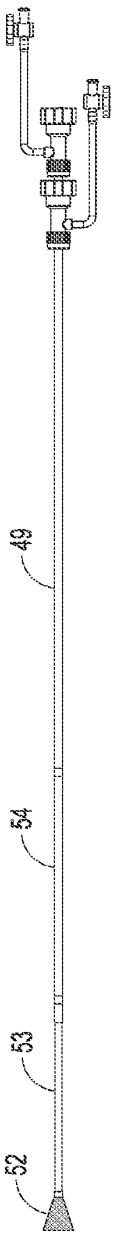


FIG. 20C

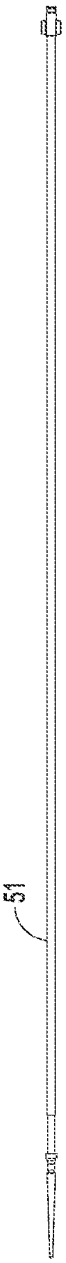


FIG. 20D

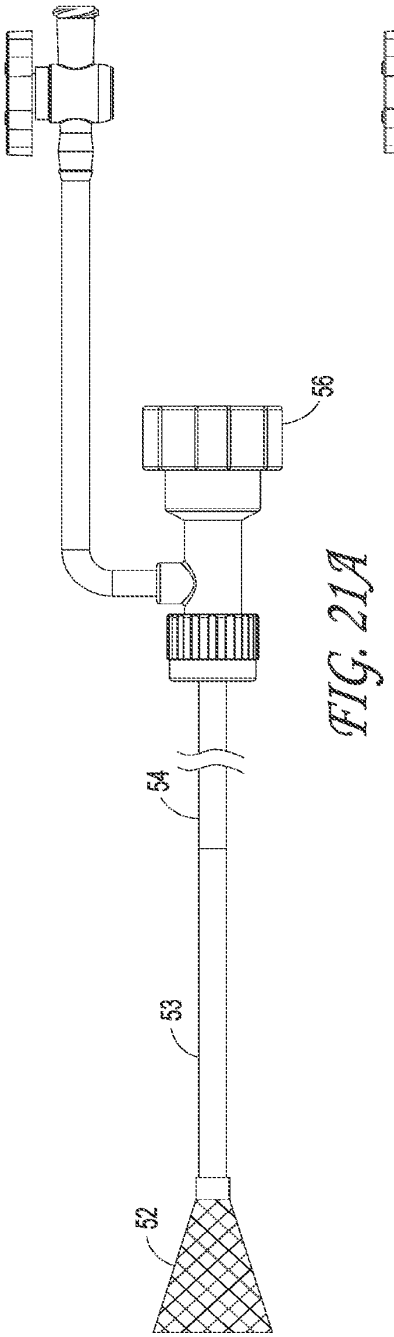


FIG. 21A

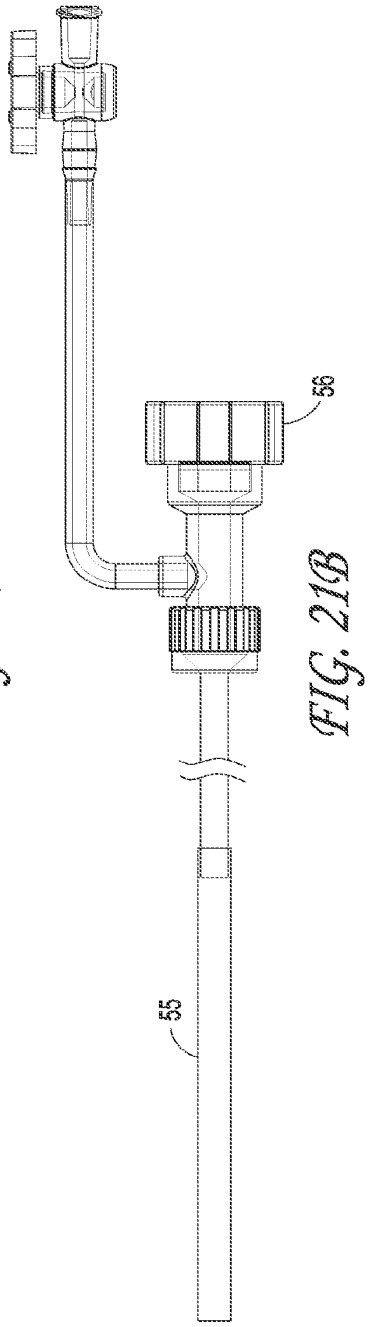


FIG. 21B

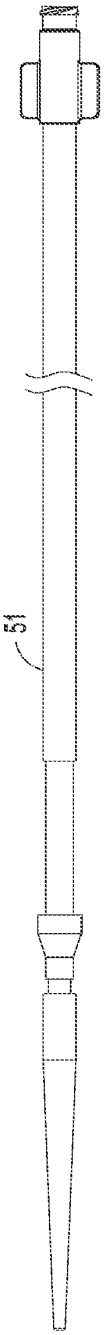


FIG. 21C

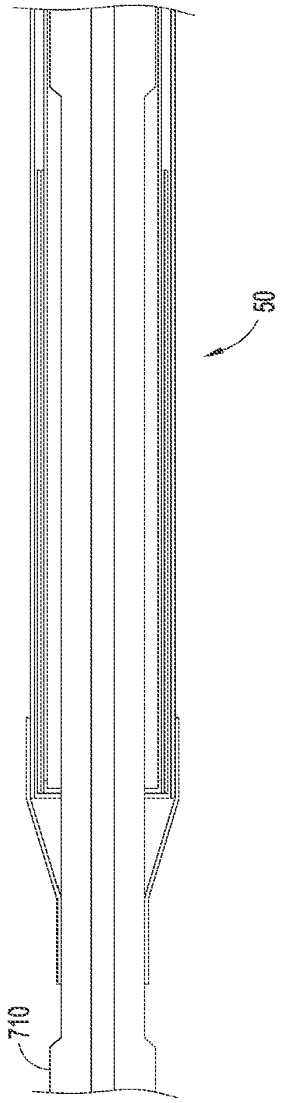


FIG. 21D

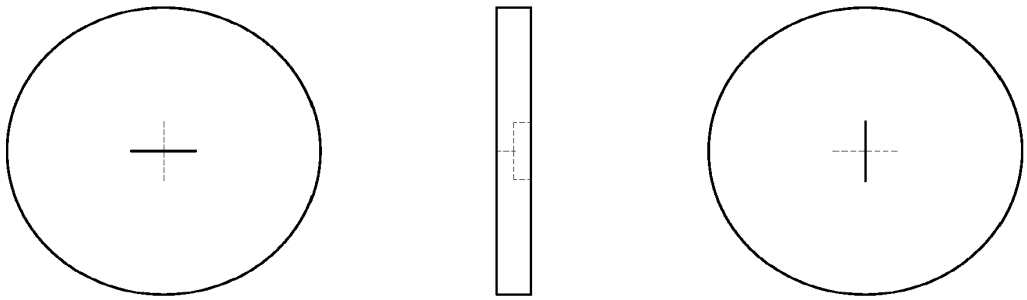


FIG. 21E

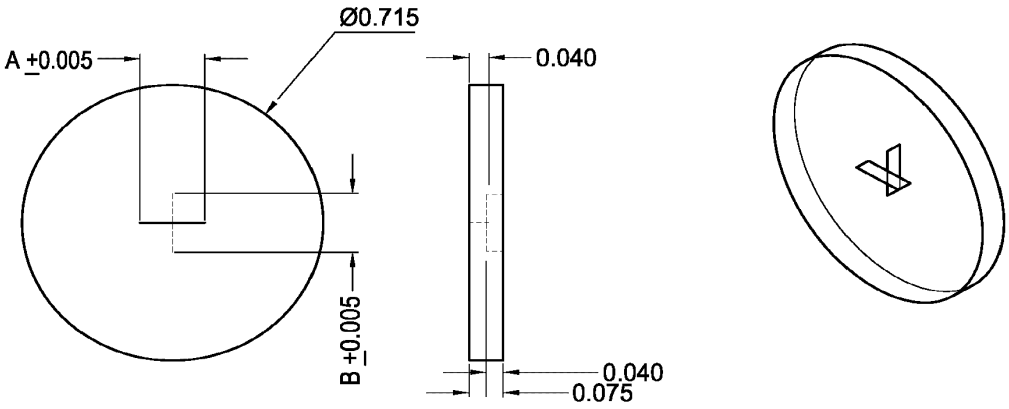


FIG. 21F

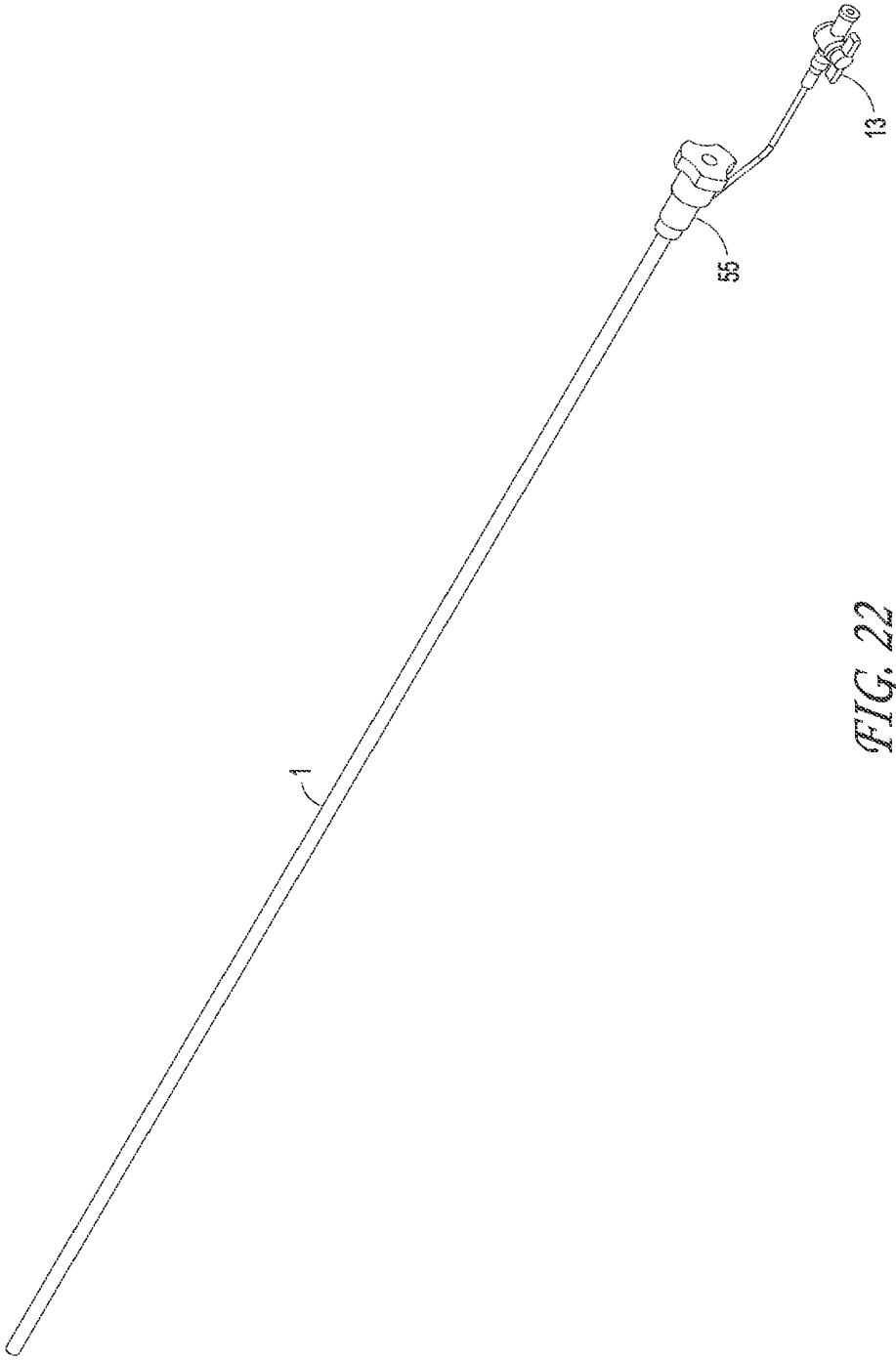


FIG. 22

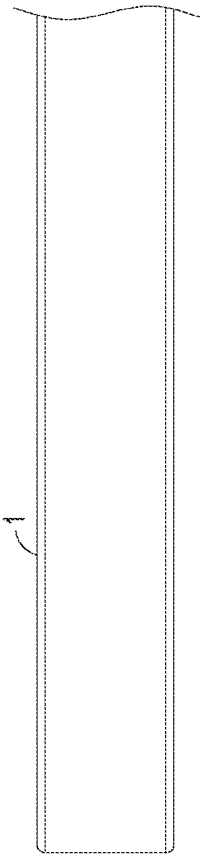


FIG. 23

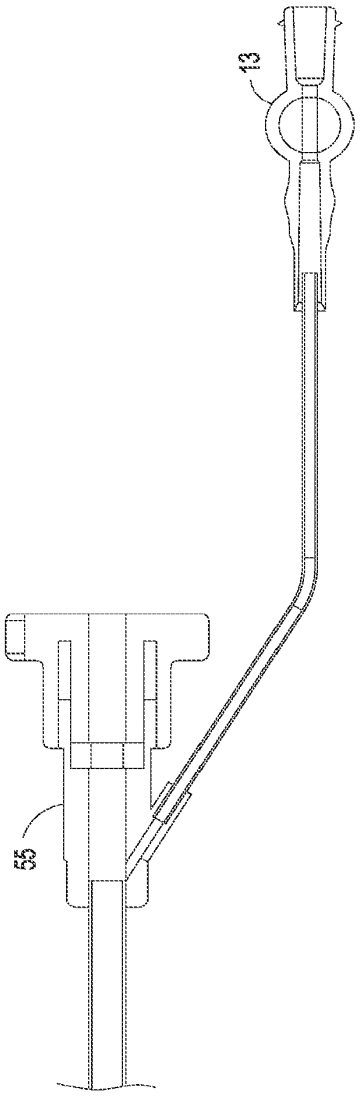


FIG. 24

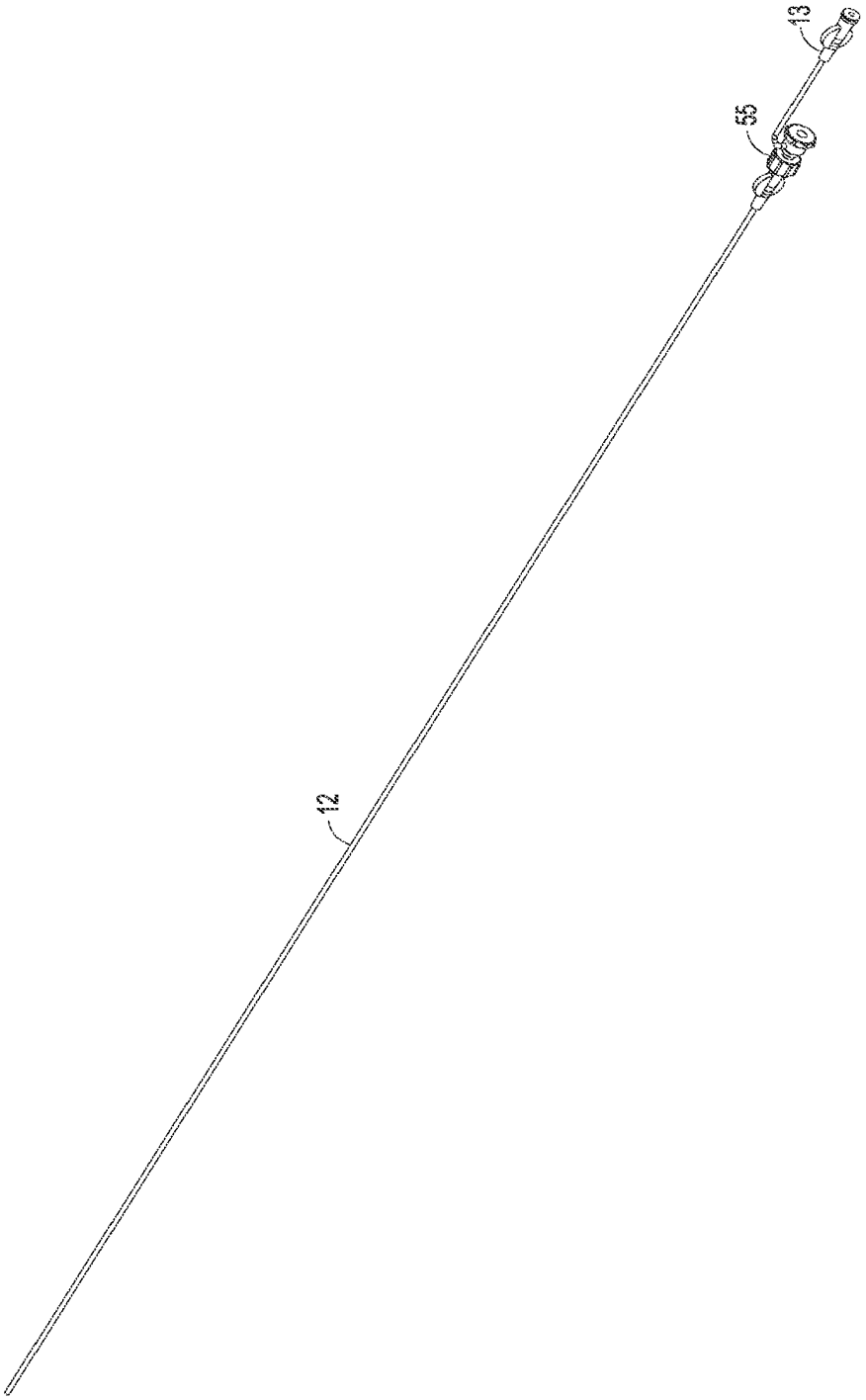


FIG. 25

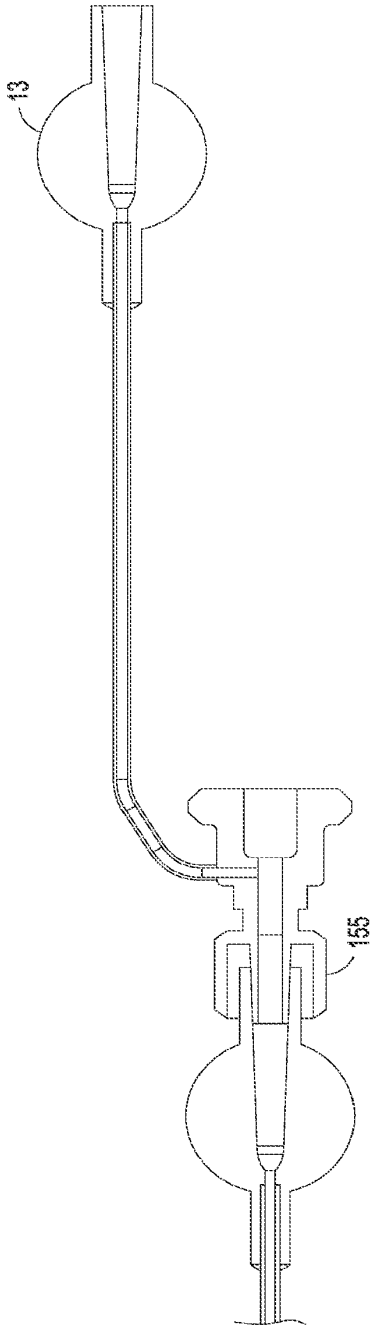


FIG. 26

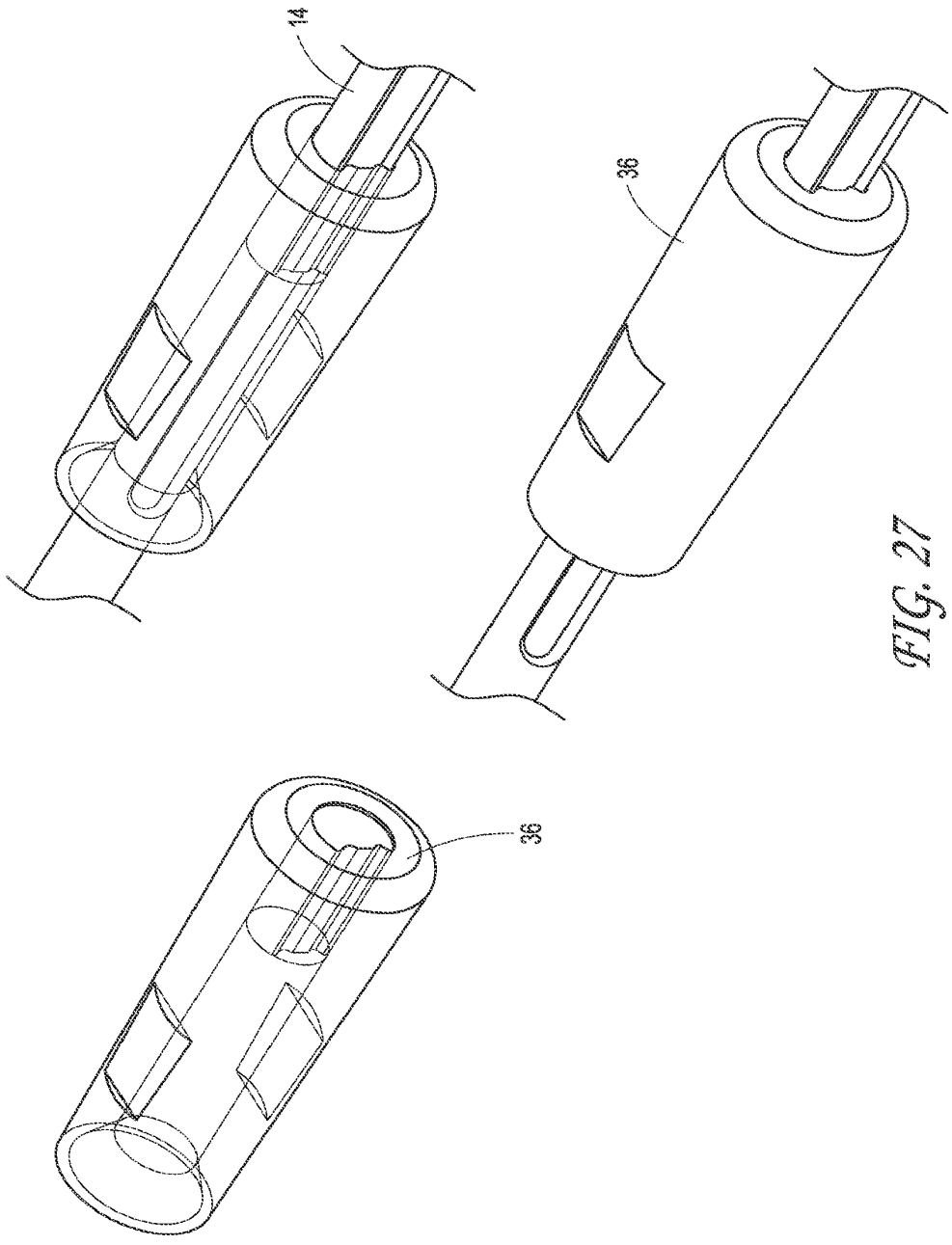


FIG. 27

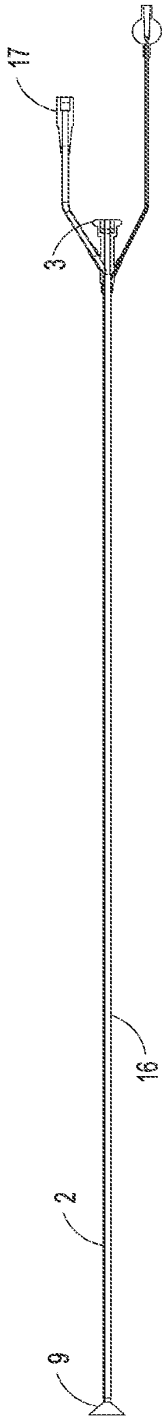


FIG. 28

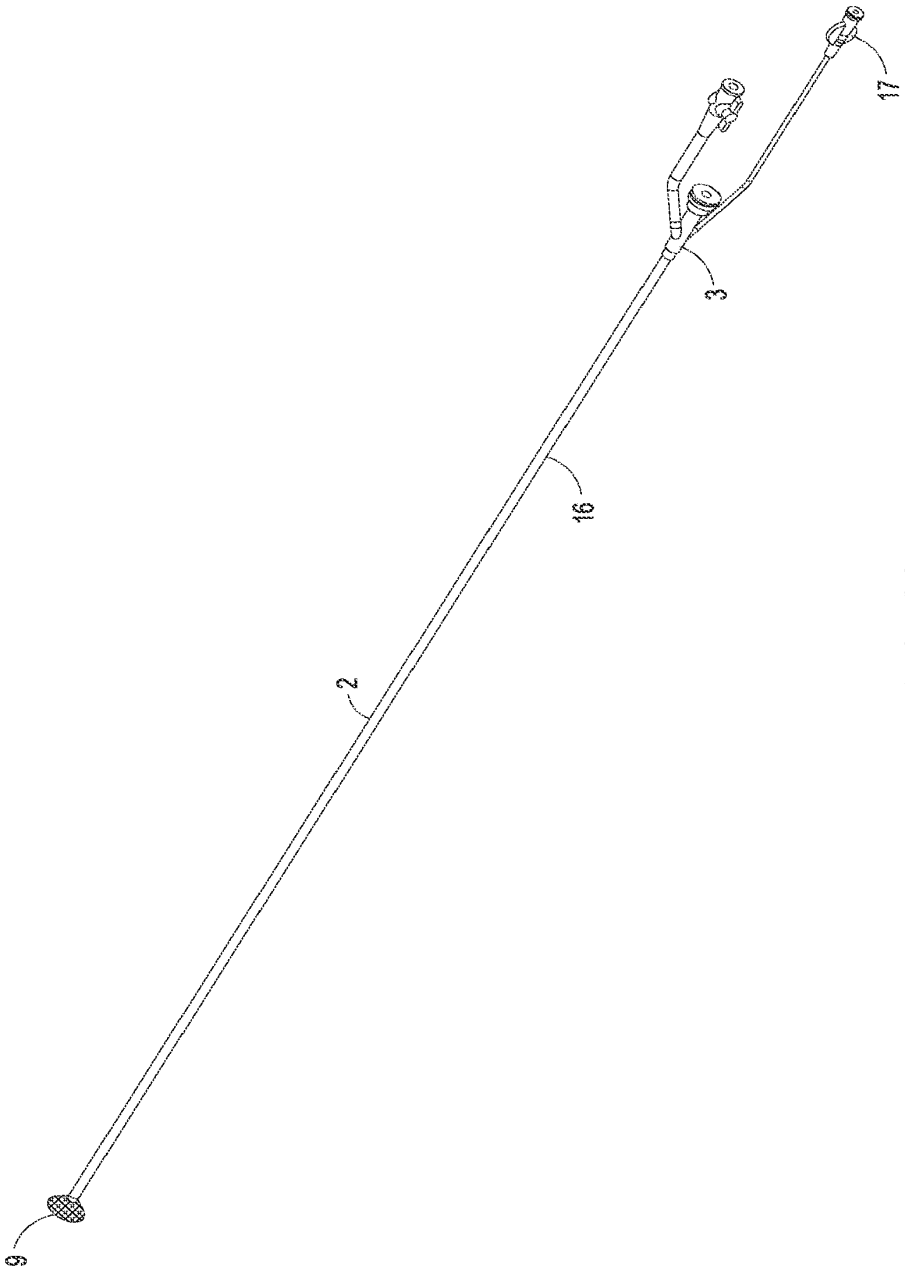


FIG. 29

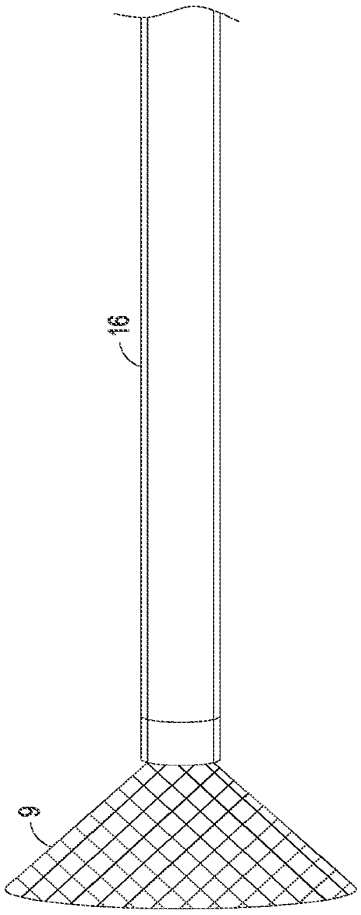


FIG. 30

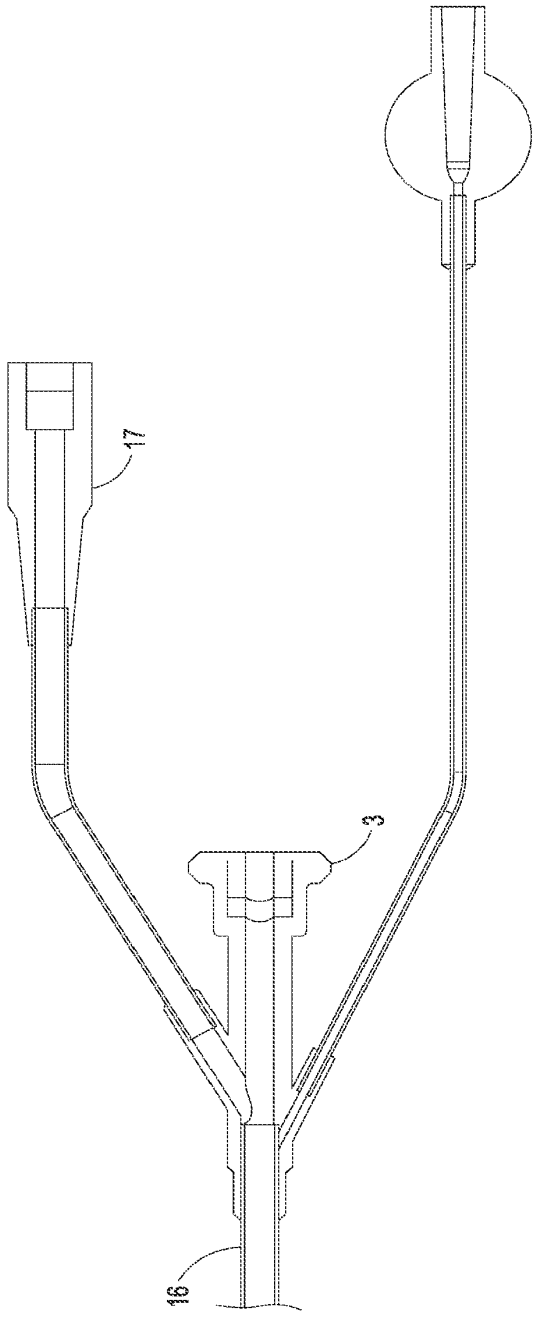


FIG. 31

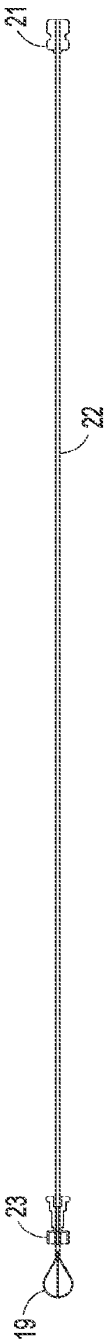


FIG. 32

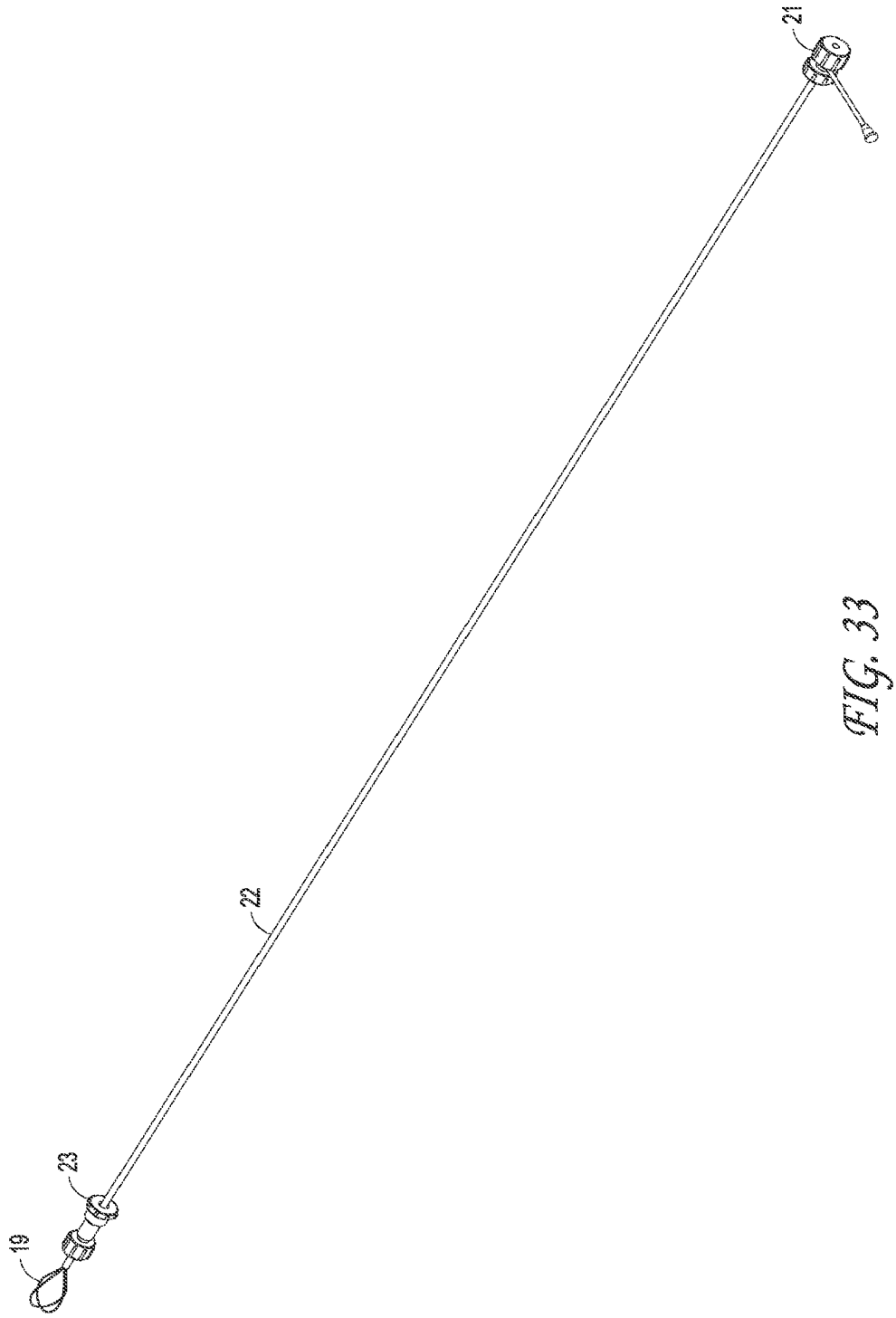


FIG. 33

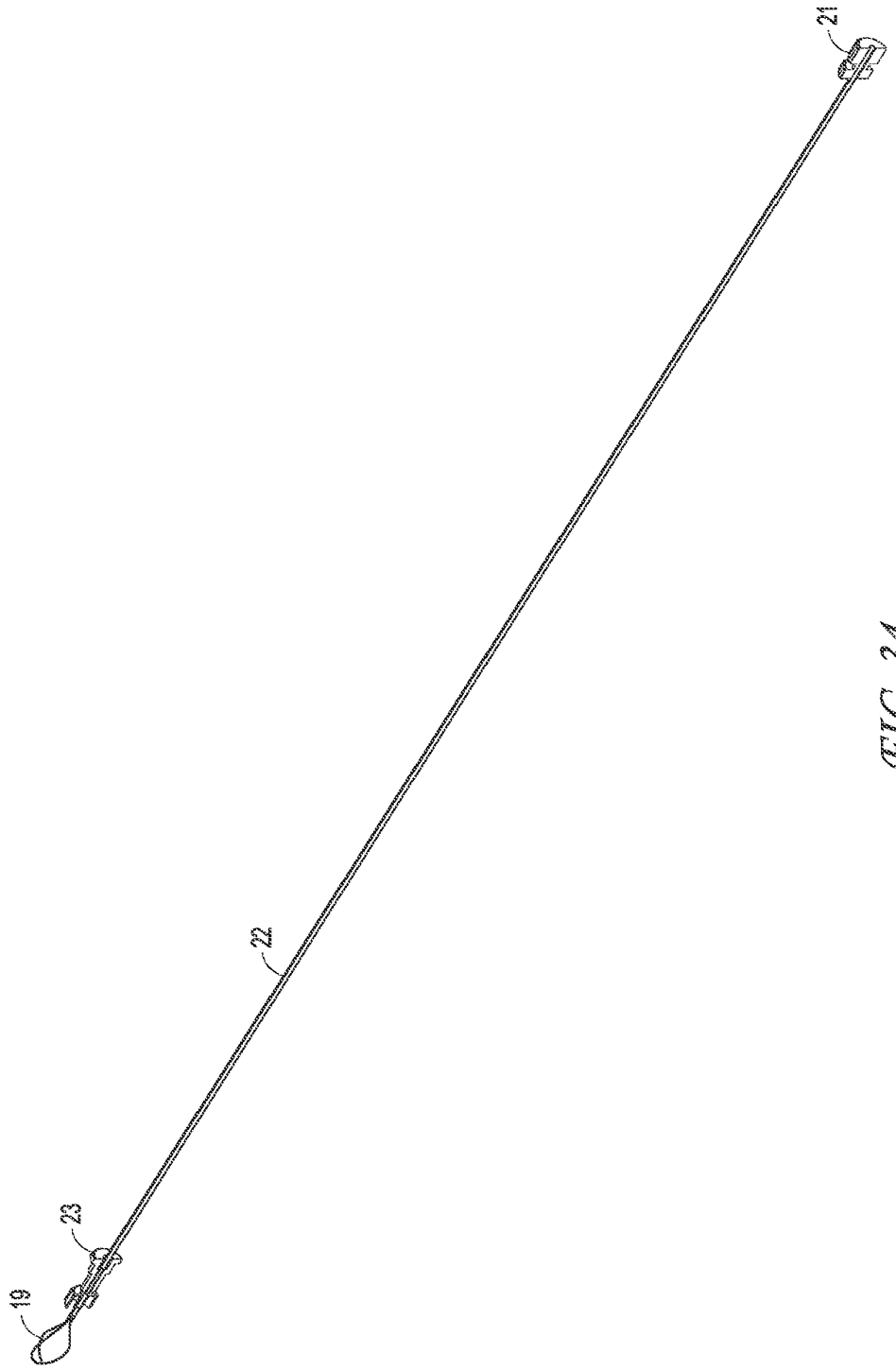


FIG. 34

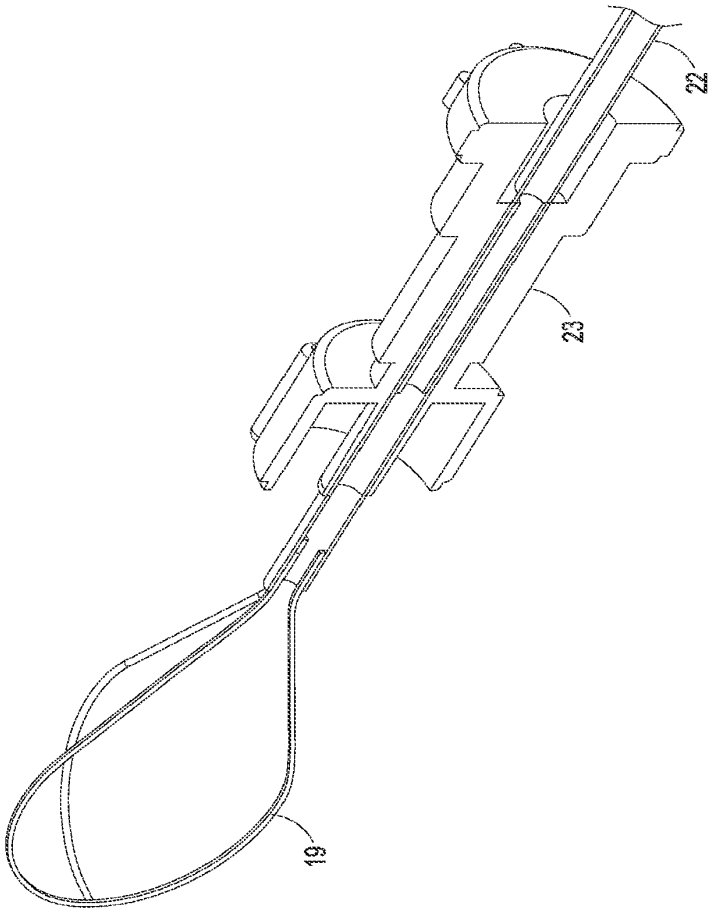


FIG. 35

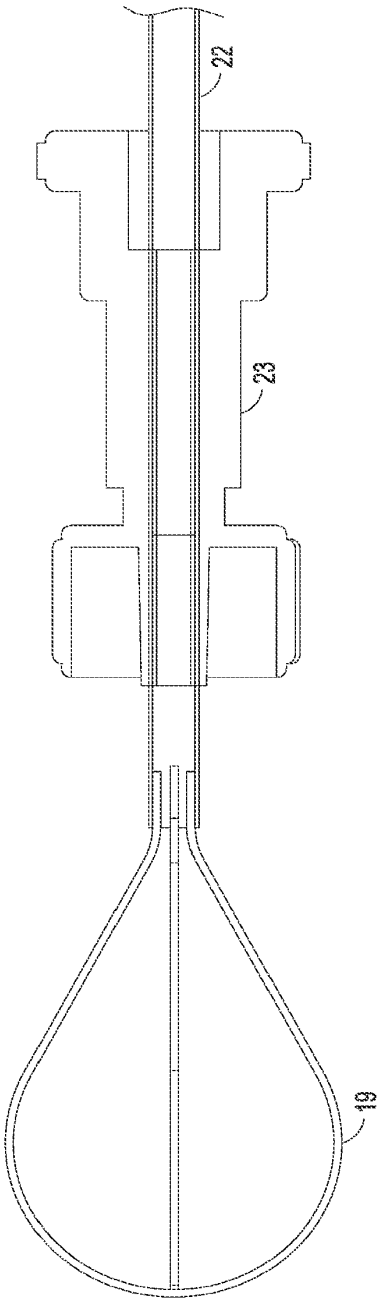


FIG. 36

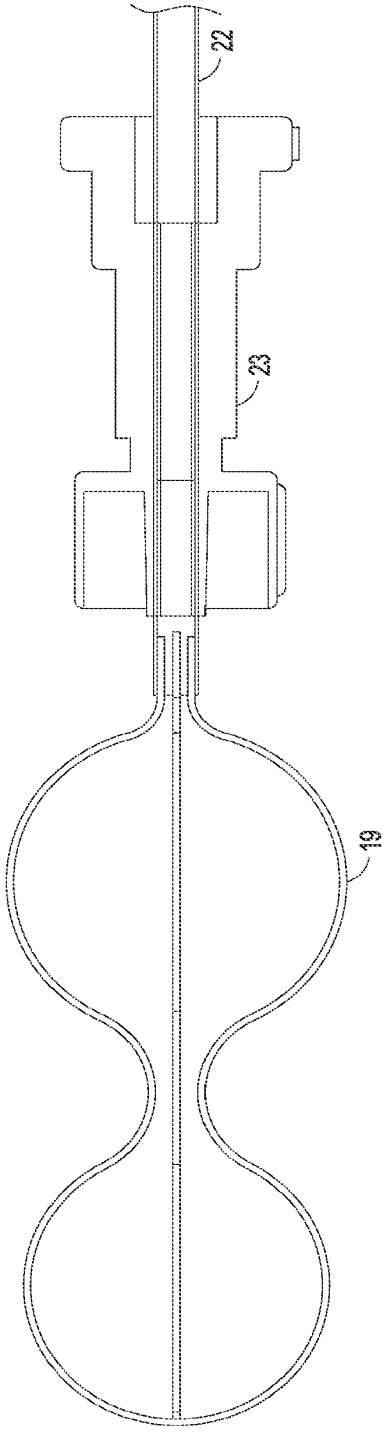


FIG. 37

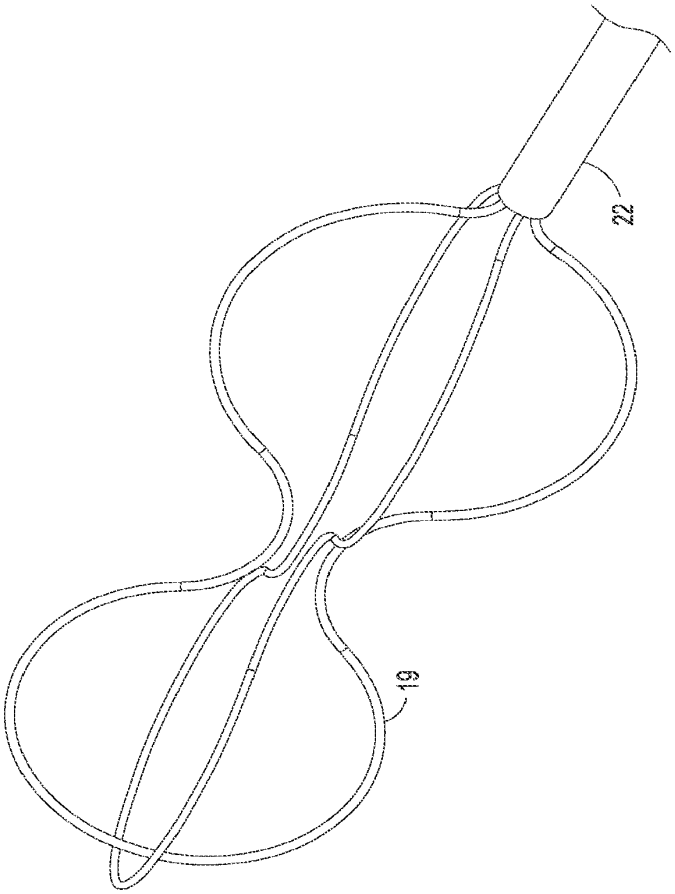


FIG. 38

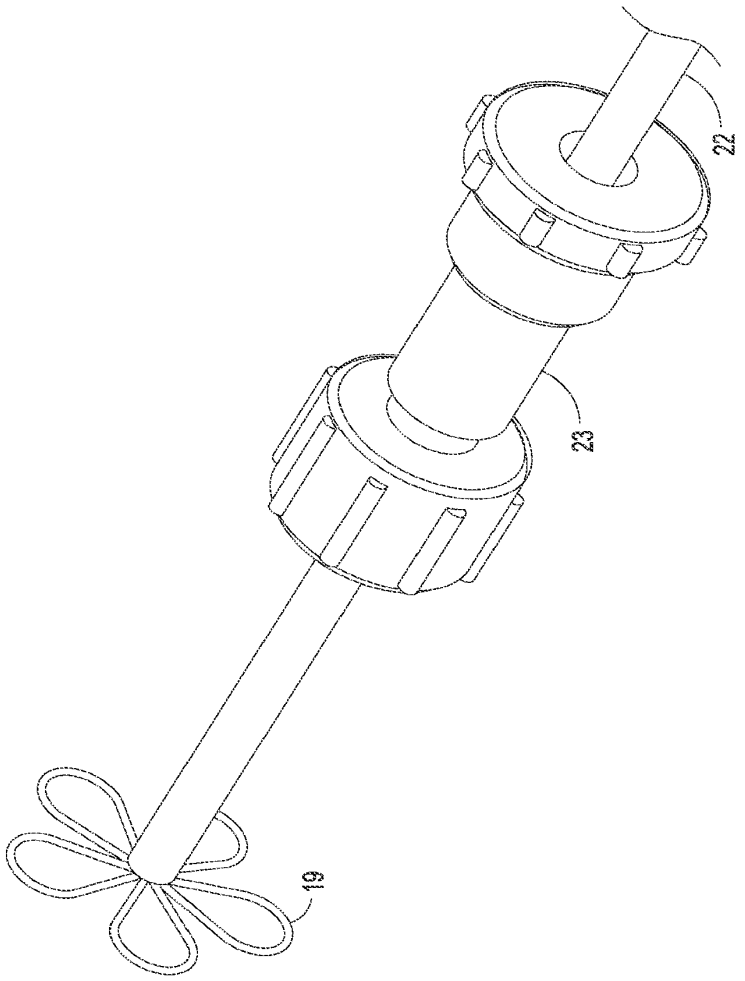


FIG. 39

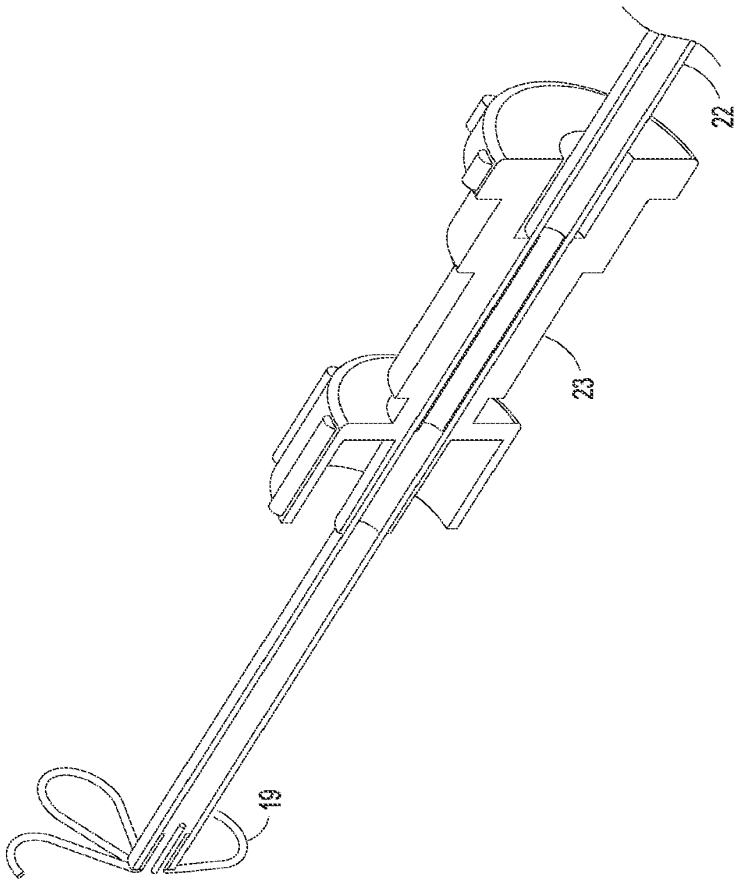


FIG. 40

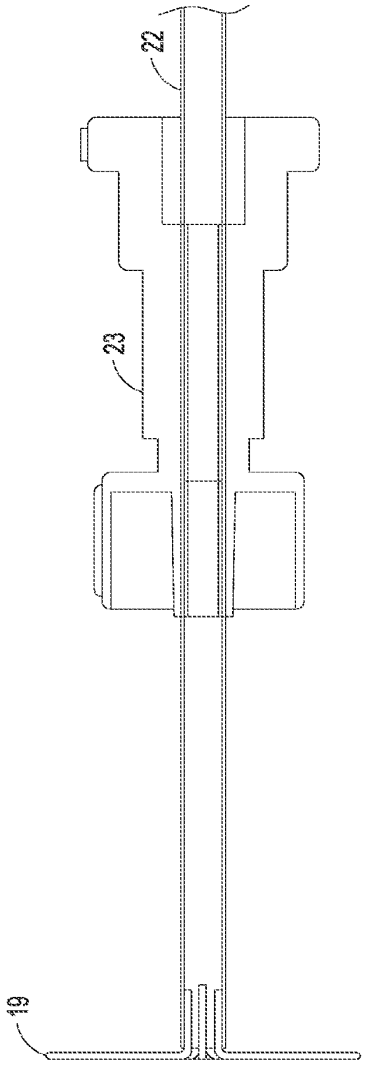


FIG. 41

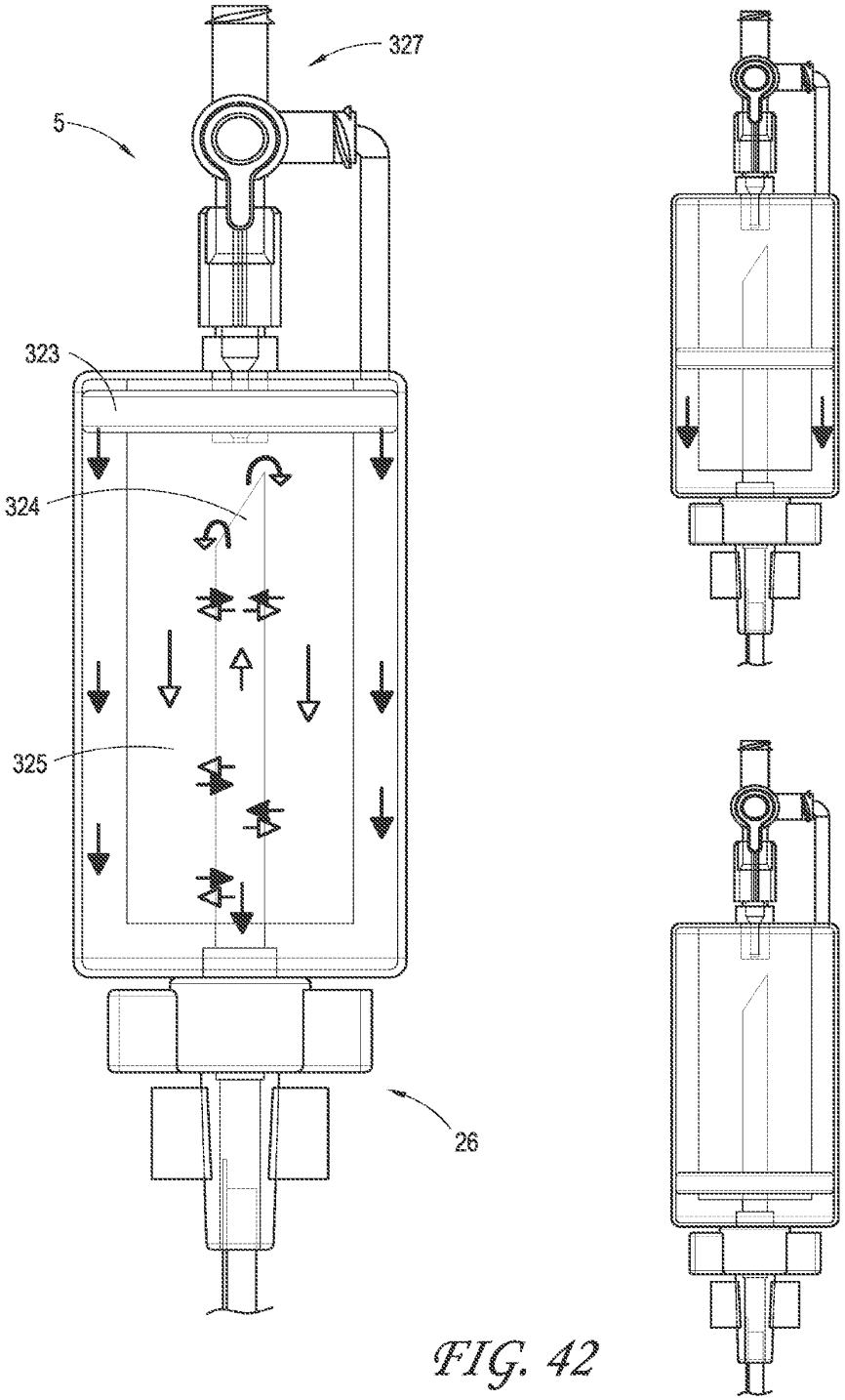


FIG. 42

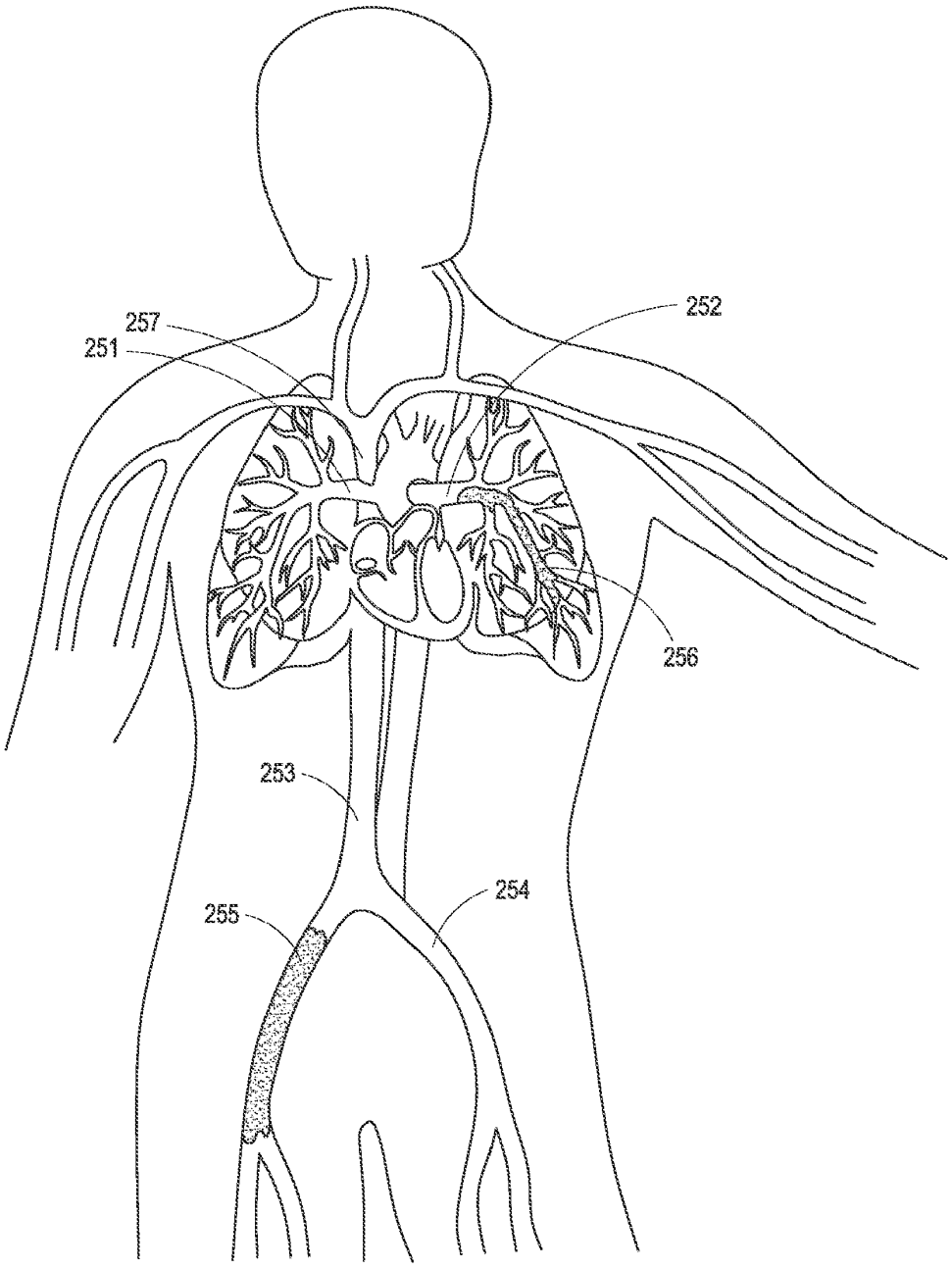


FIG. 43

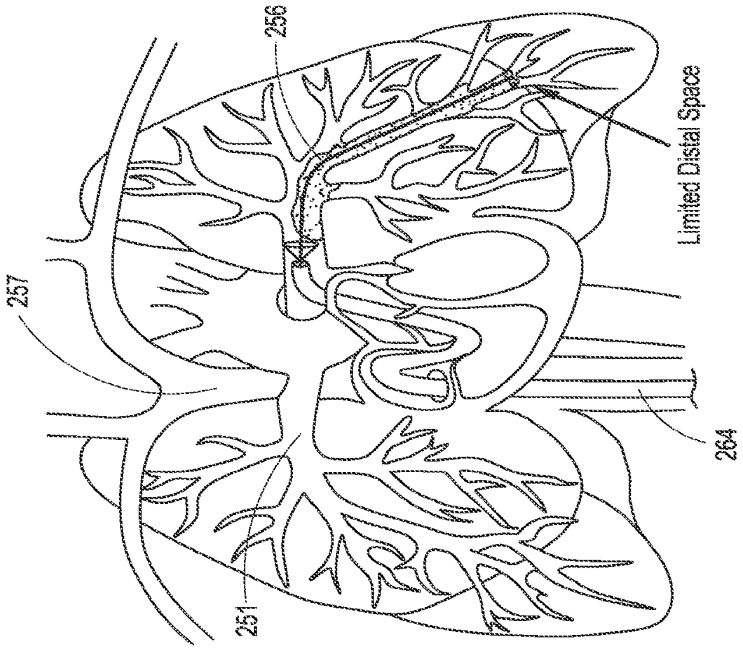


FIG. 44B

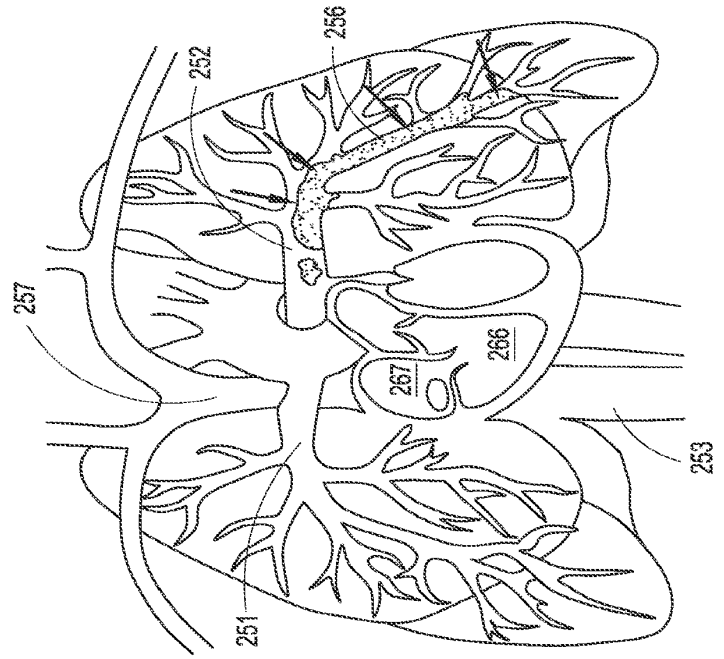


FIG. 44A

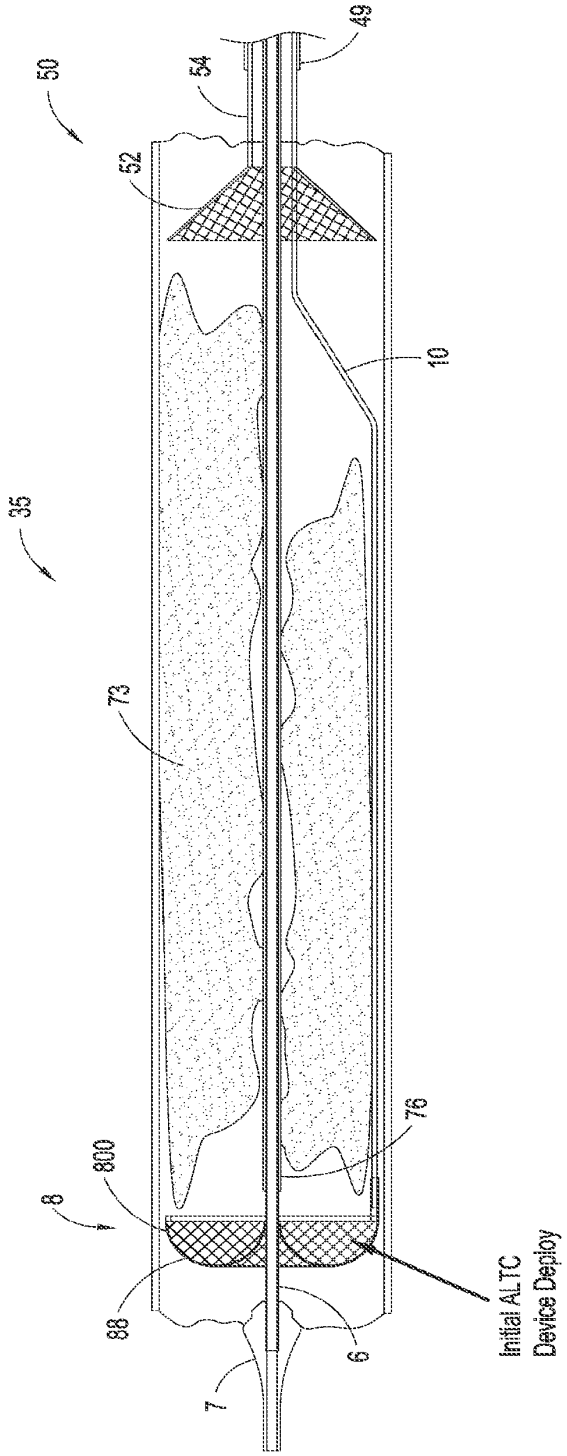


FIG. 45

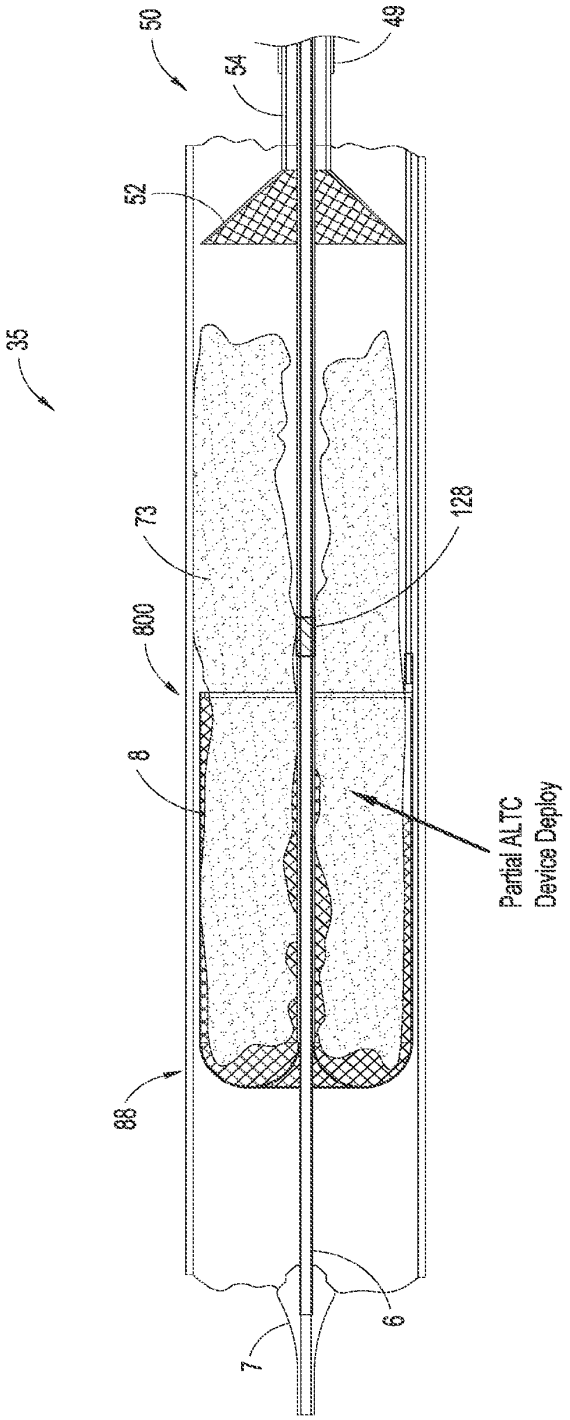


FIG. 46

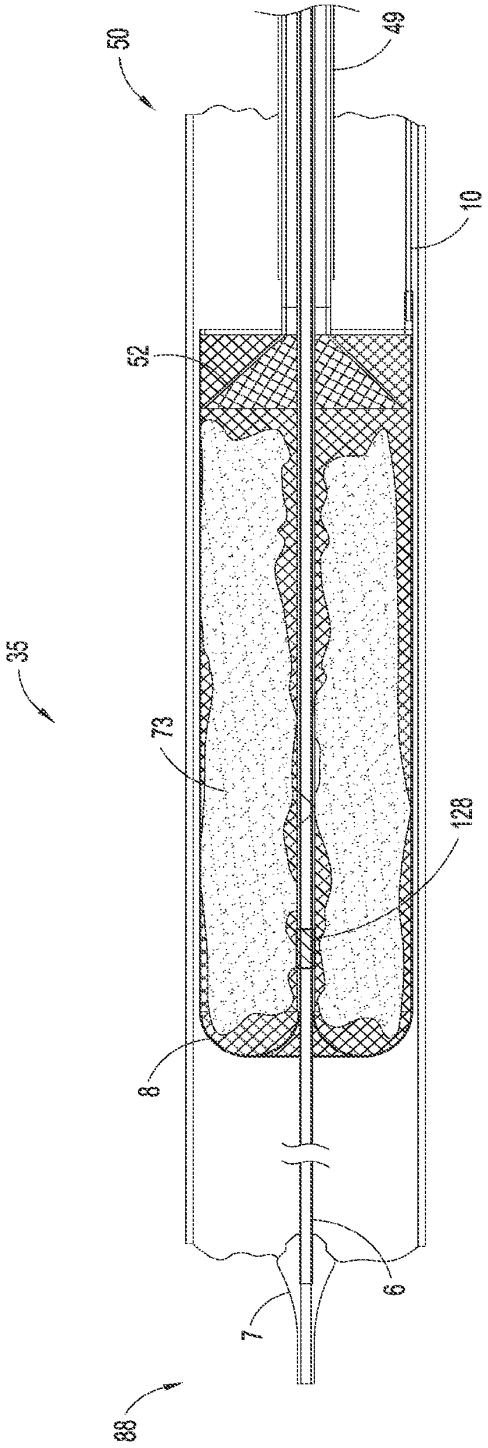


FIG. 47

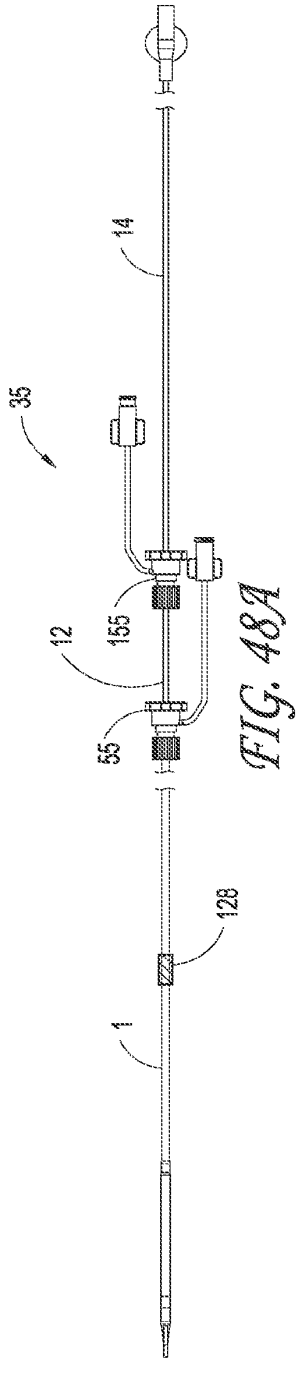


FIG. 48A

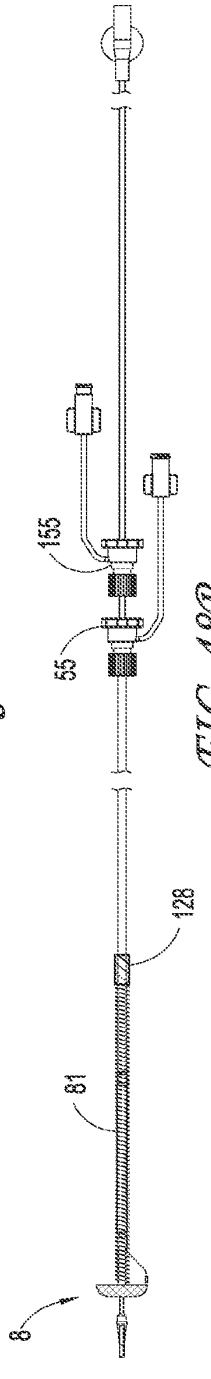


FIG. 48B

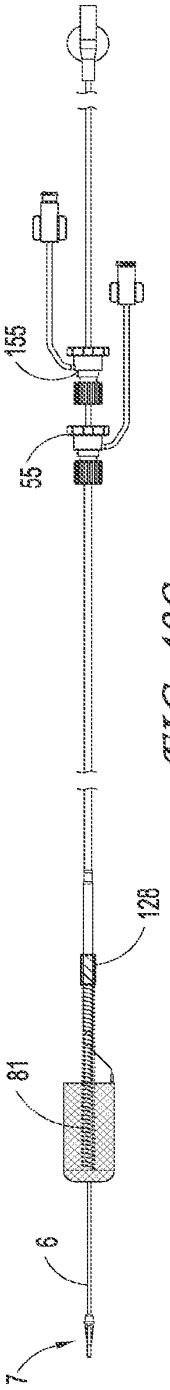


FIG. 48C

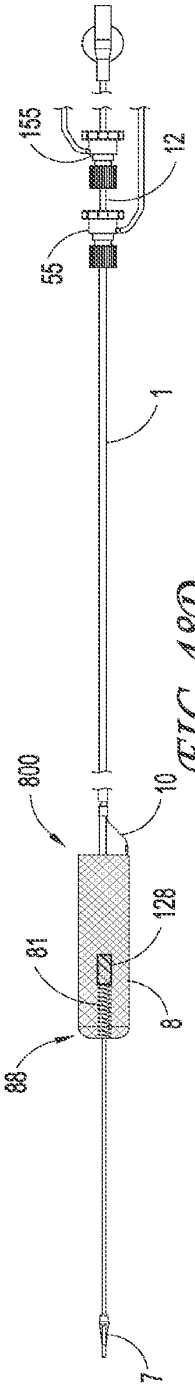


FIG. 48D

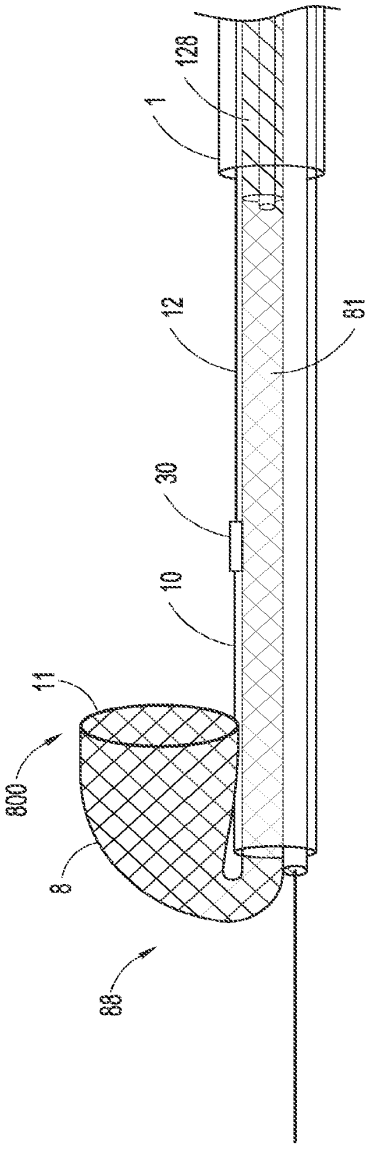


FIG. 49A

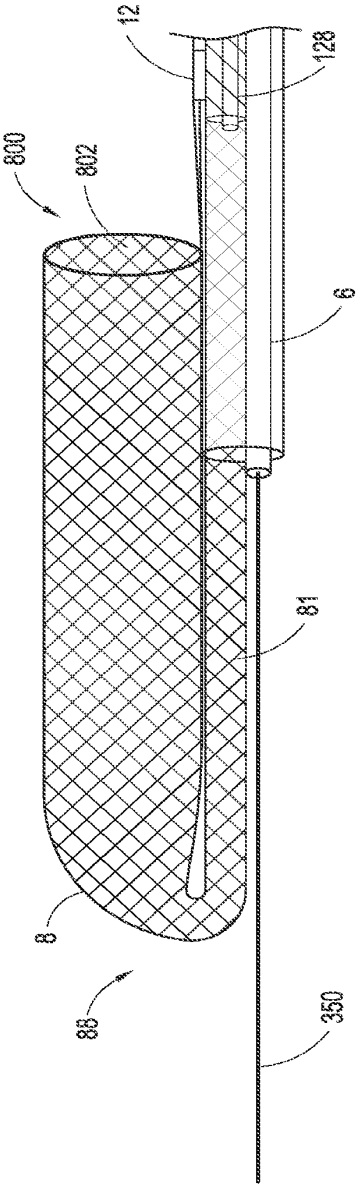


FIG. 49B

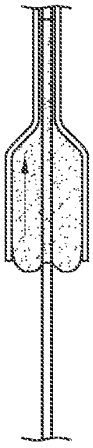


FIG. 50E

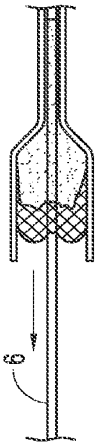


FIG. 50F

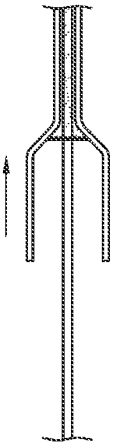


FIG. 50G

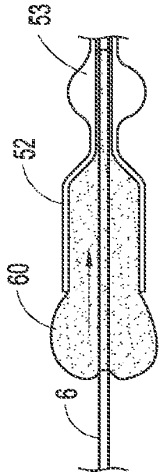


FIG. 50A

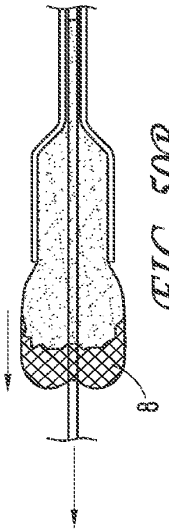


FIG. 50B

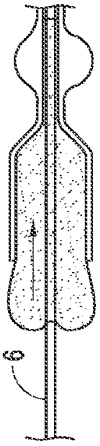


FIG. 50C

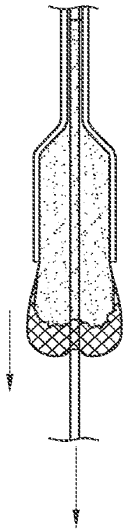


FIG. 50D

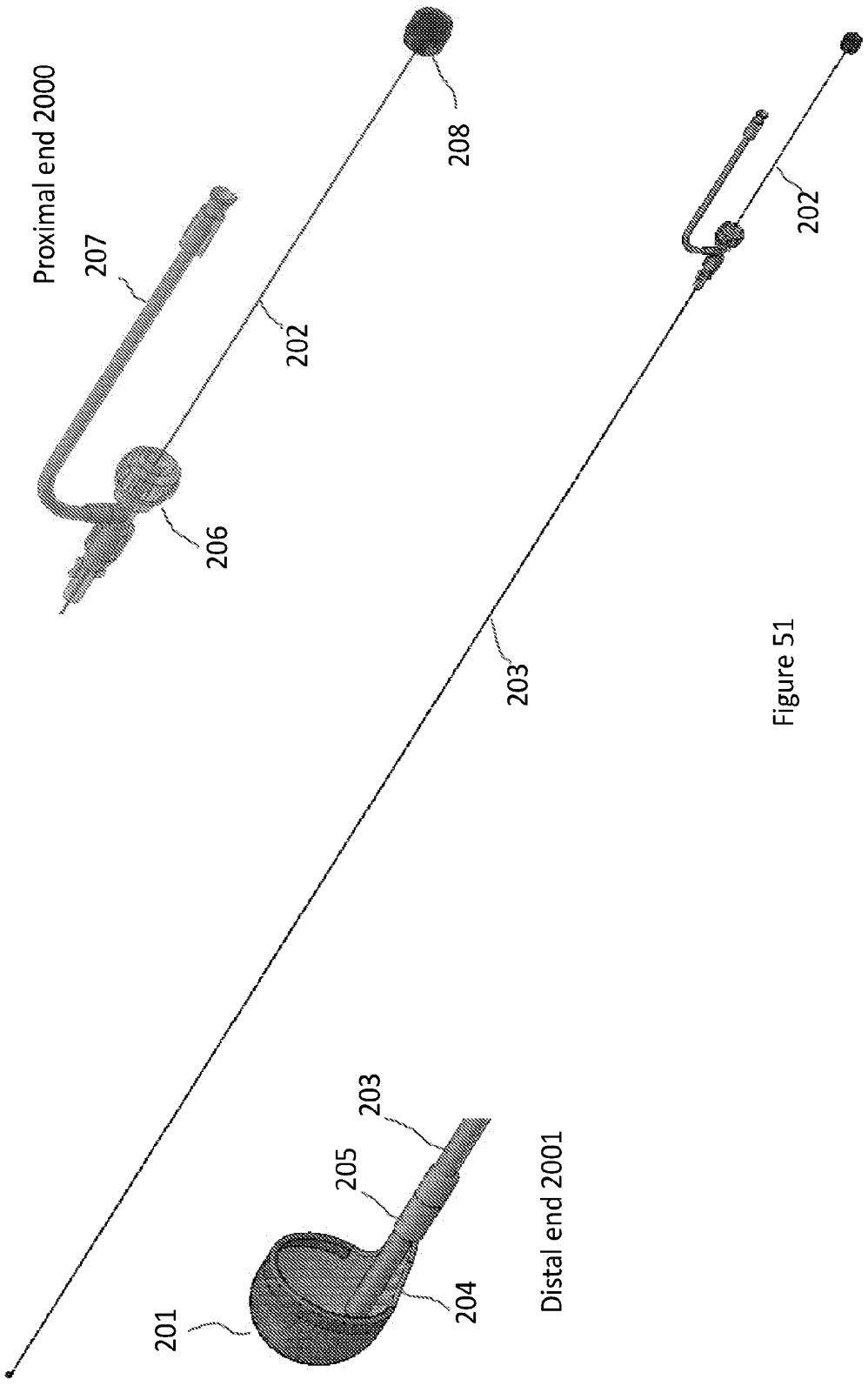

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Figure 51

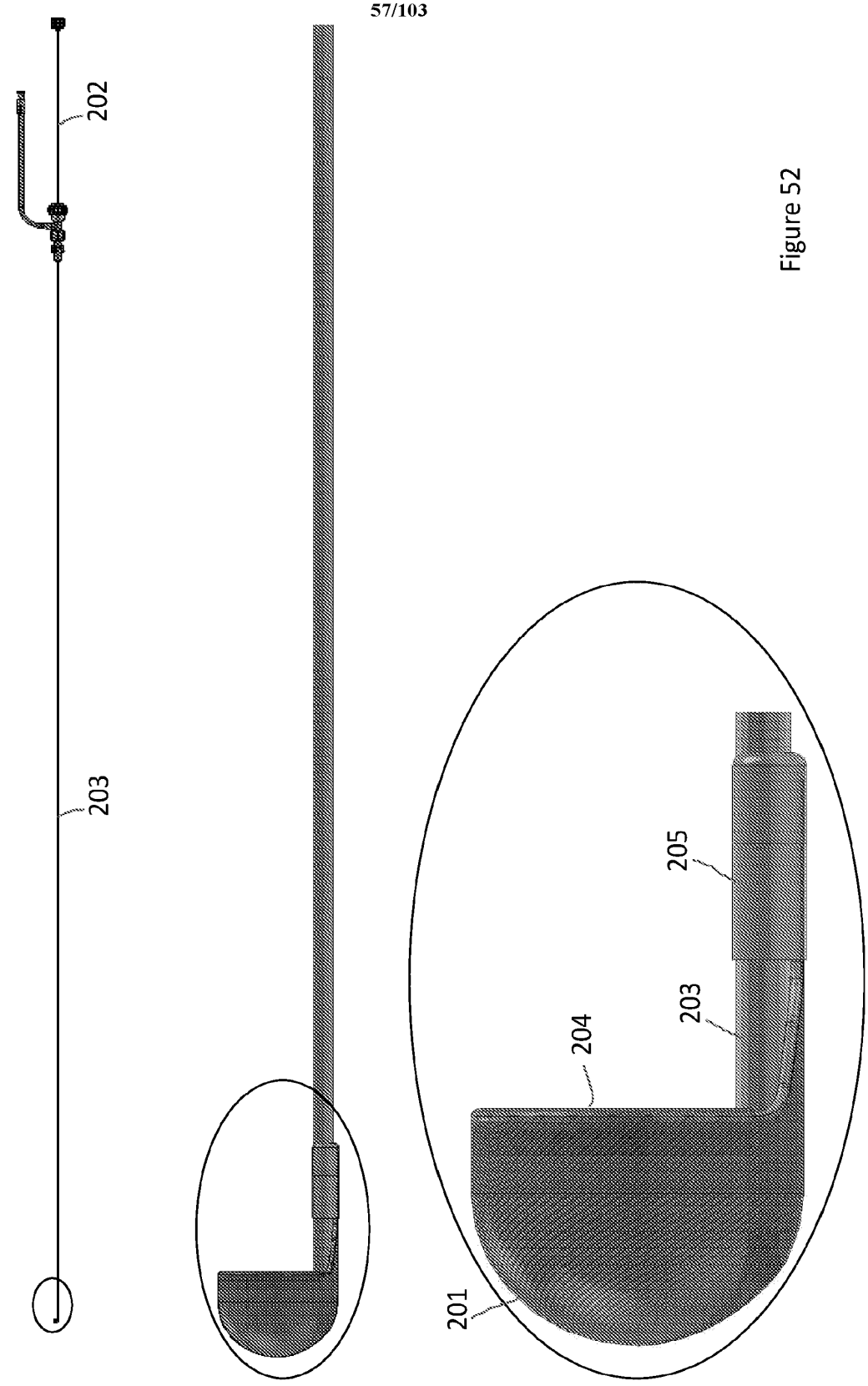


Figure 52

Figure 53

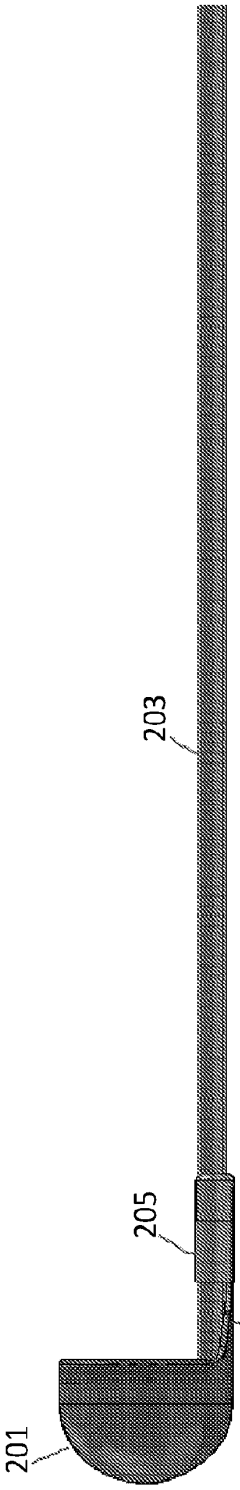


Figure 54

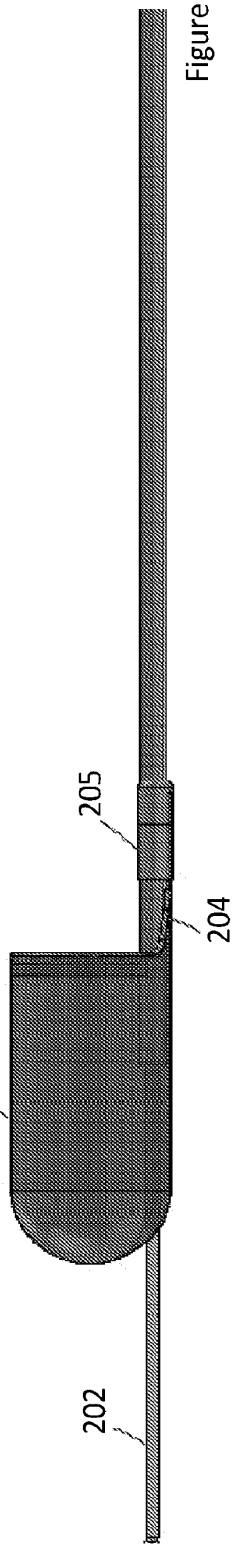
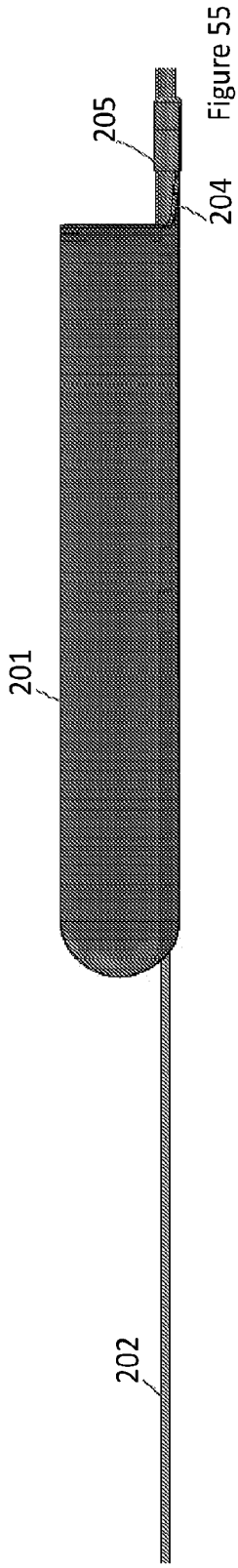


Figure 55



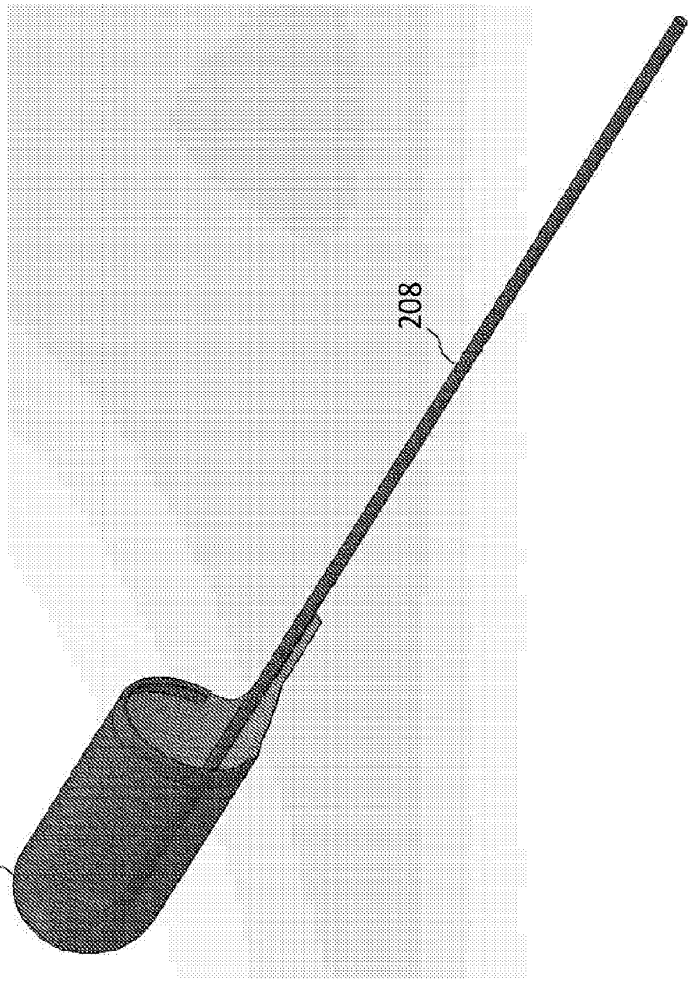


Figure 57

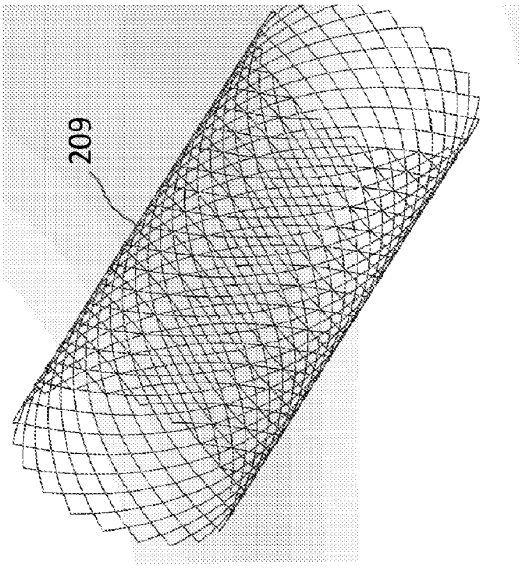


Figure 56

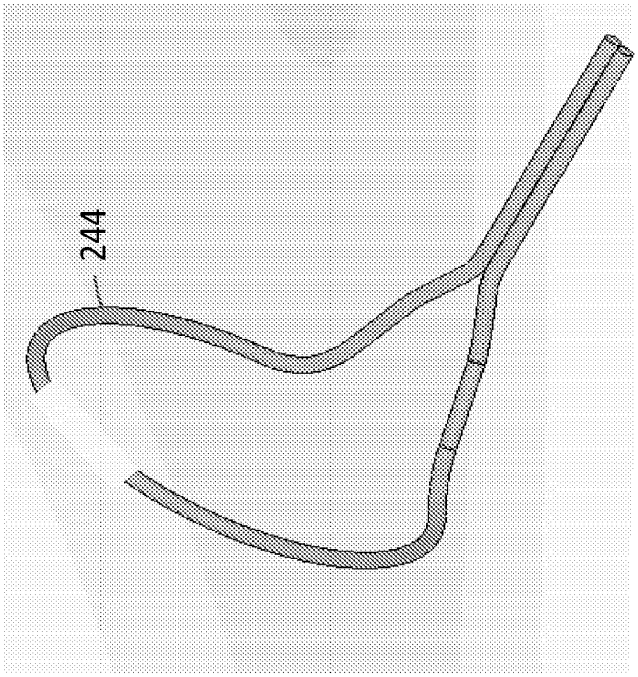


Figure 58B

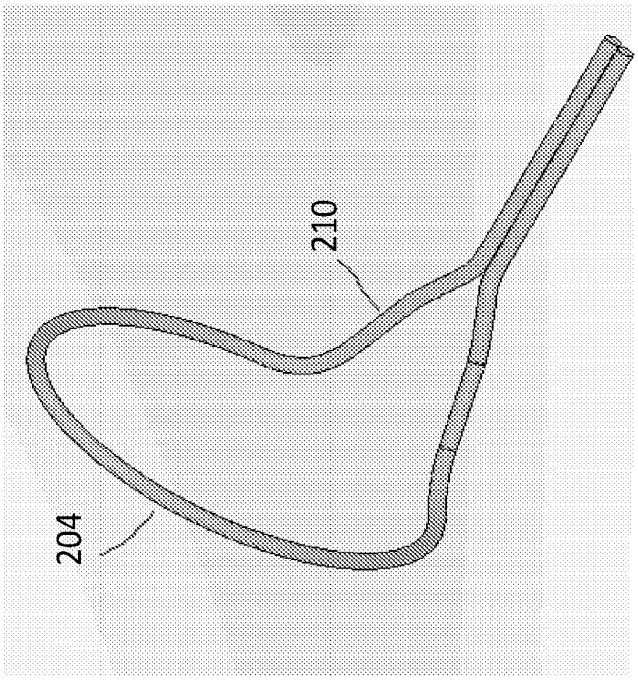


Figure 58A

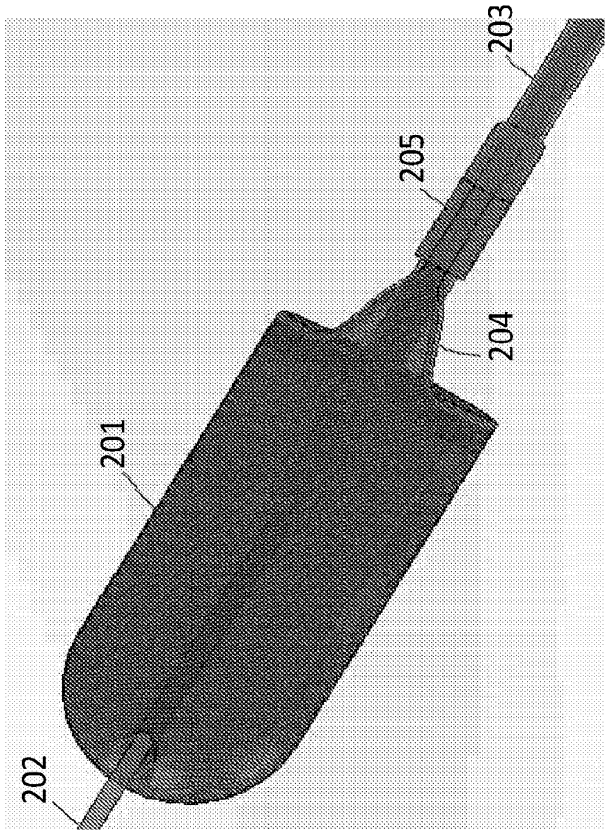


Figure 60

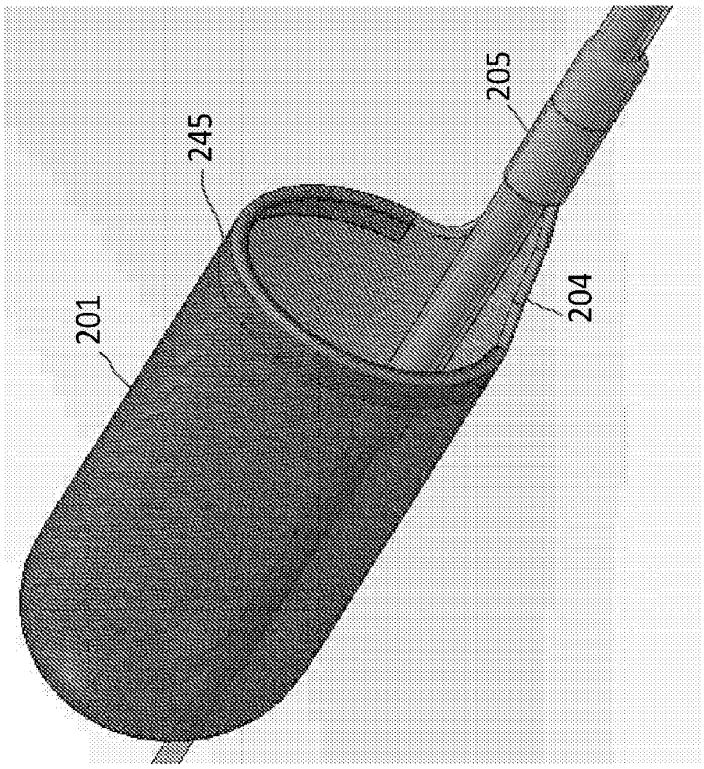
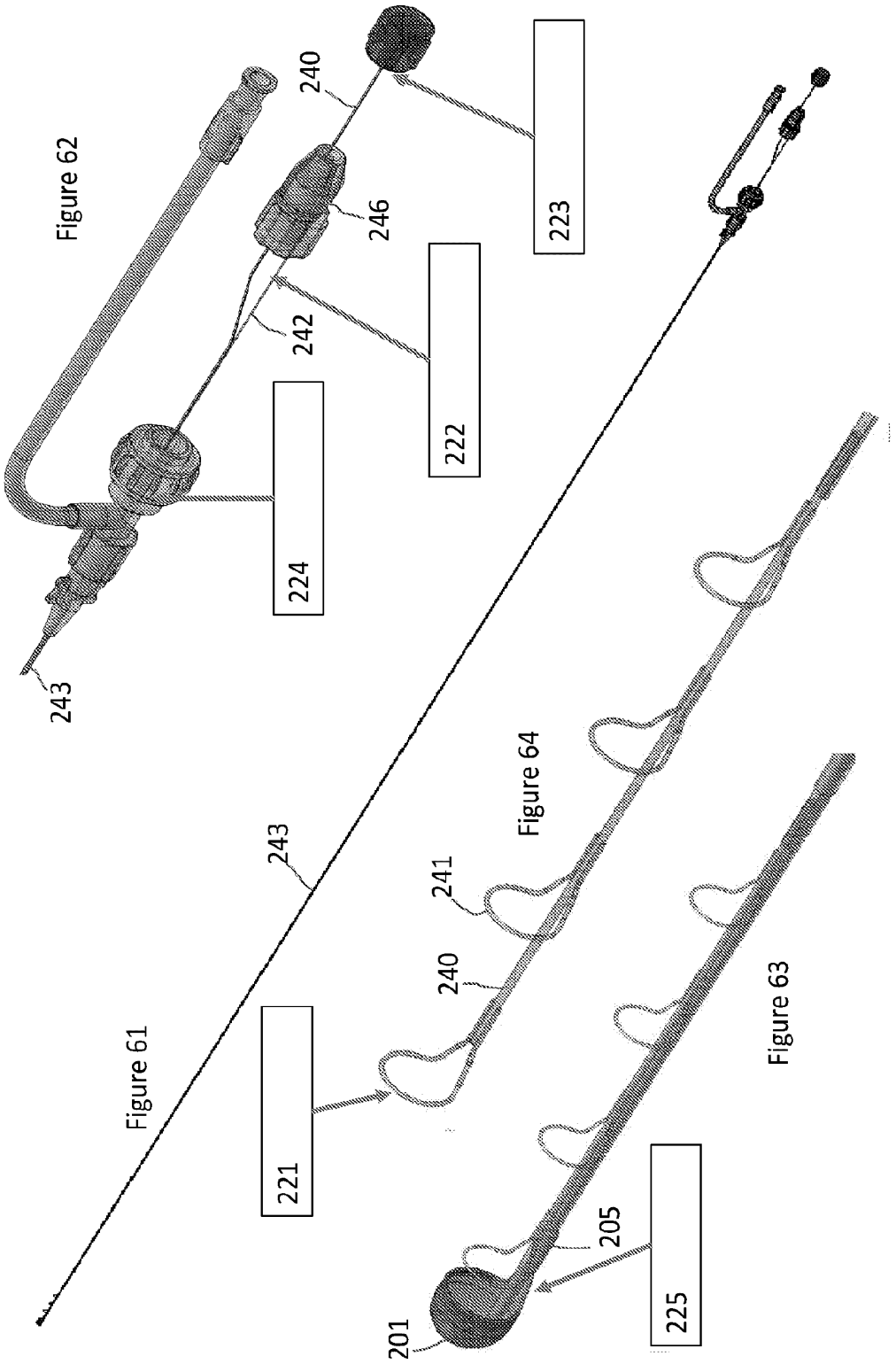


Figure 59


Figure 62
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Figure 64
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Figure 61
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Figure 63
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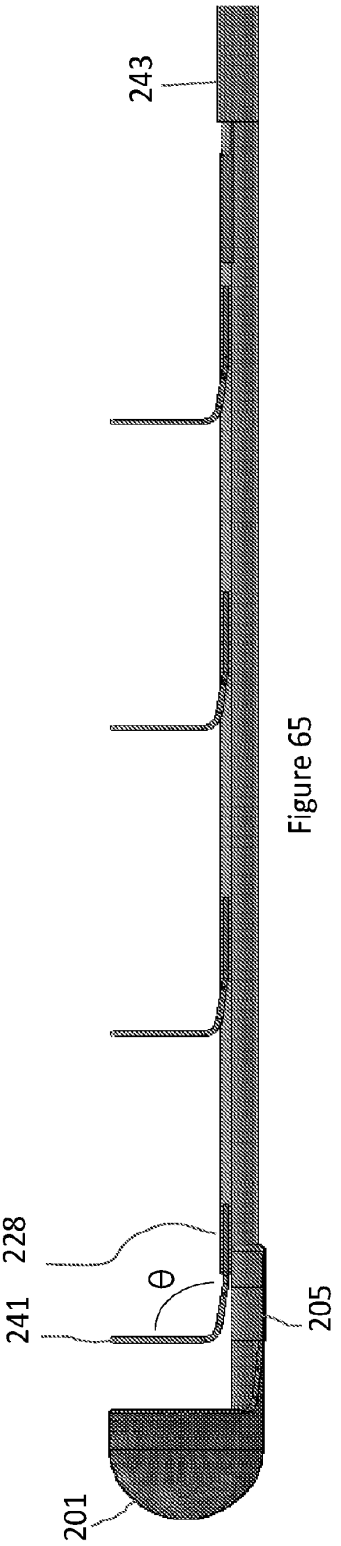


Figure 65

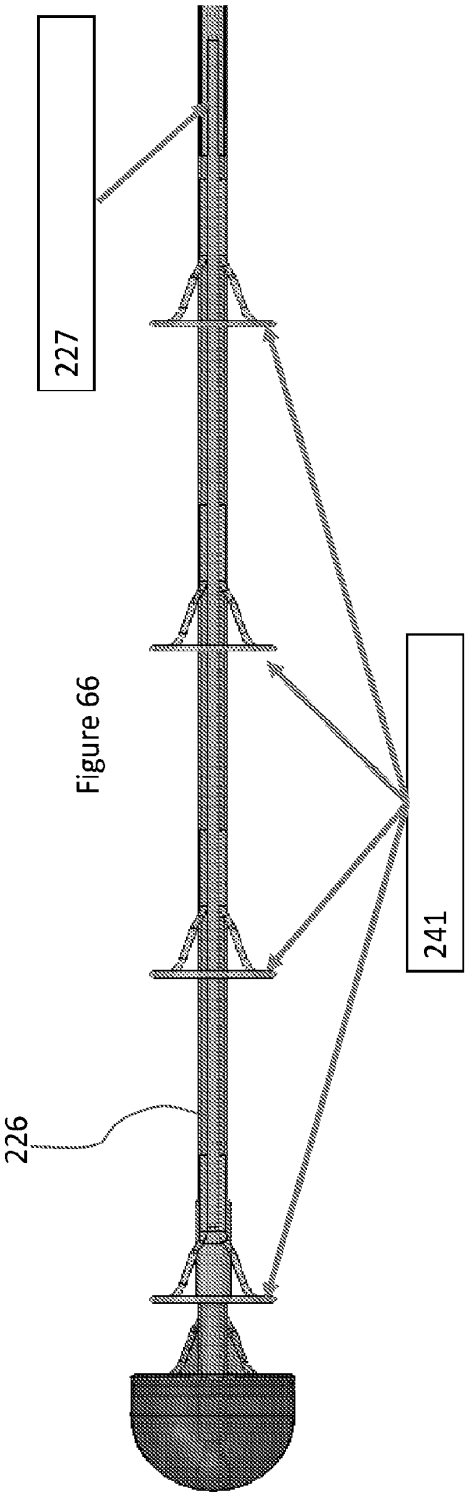


Figure 66

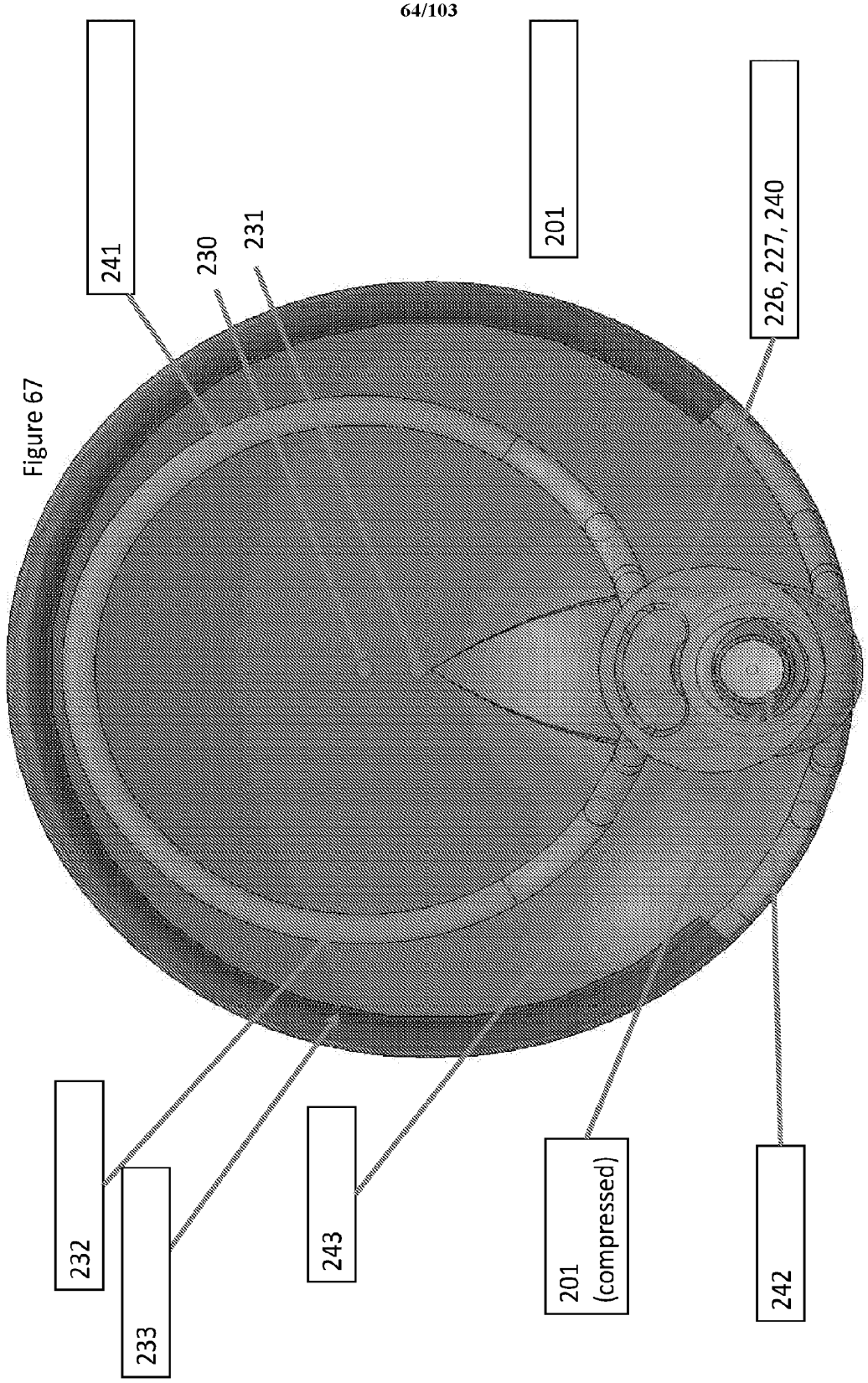


Figure 67

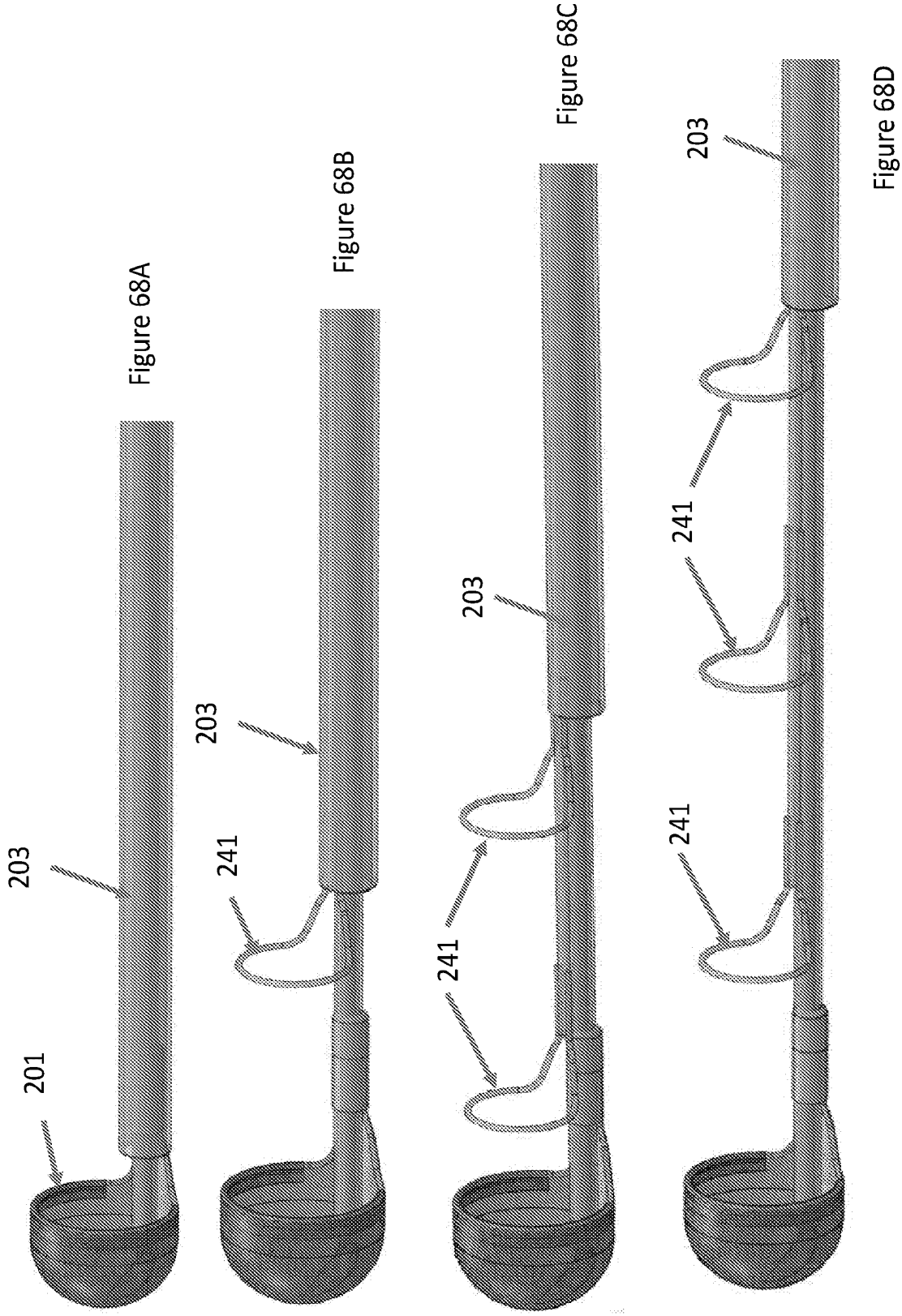

Figure 68A
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Figure 68B
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Figure 68C
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Figure 68D
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Figure 69A

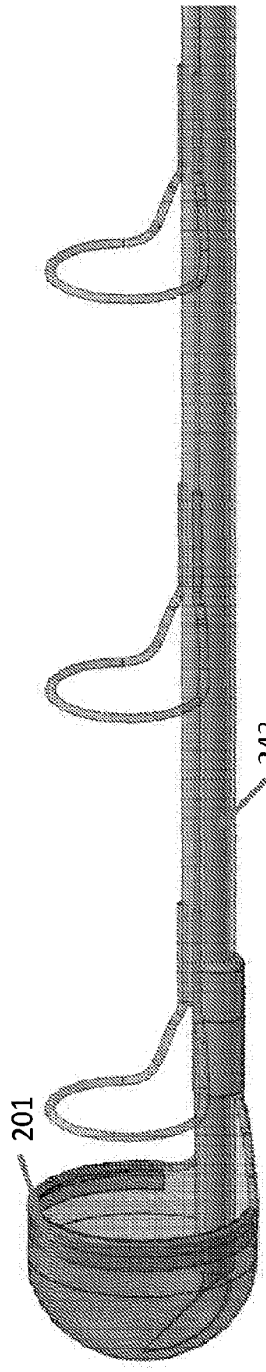


Figure 69B

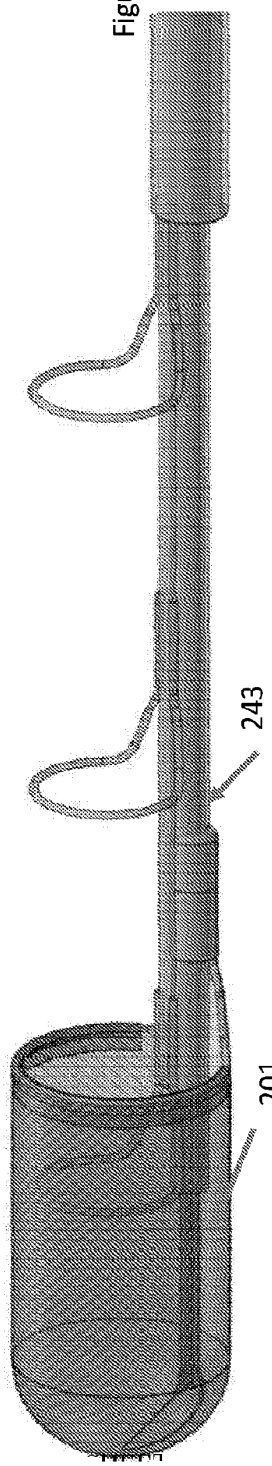
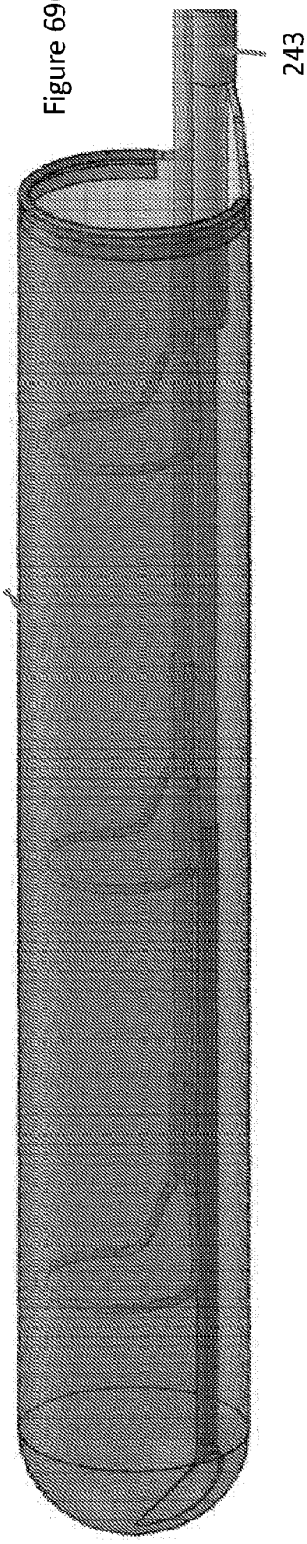


Figure 69C



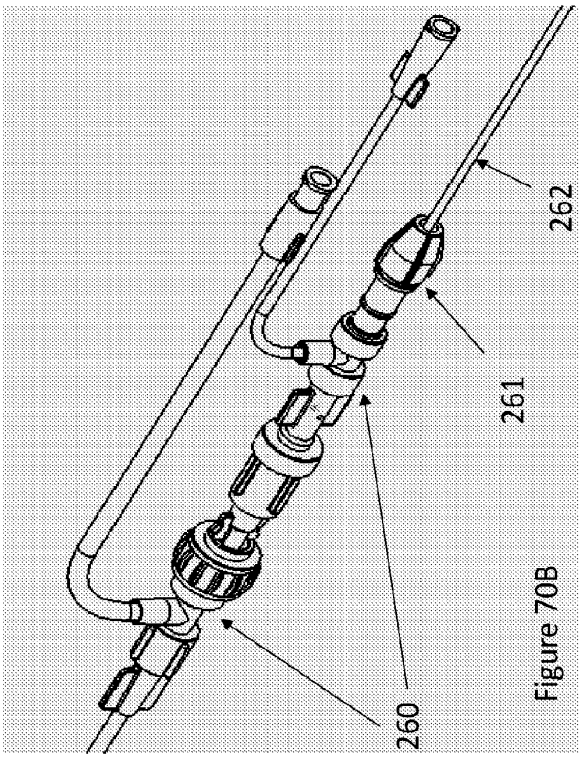


Figure 70B

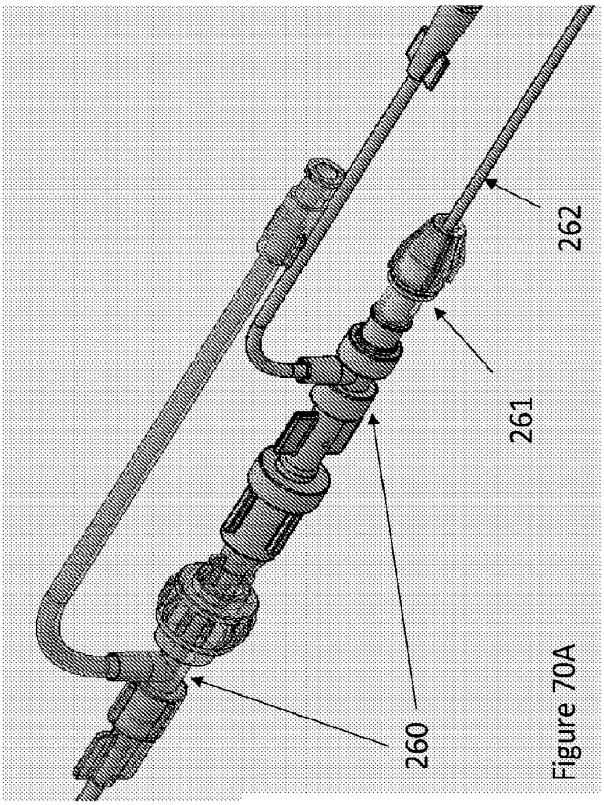


Figure 70A

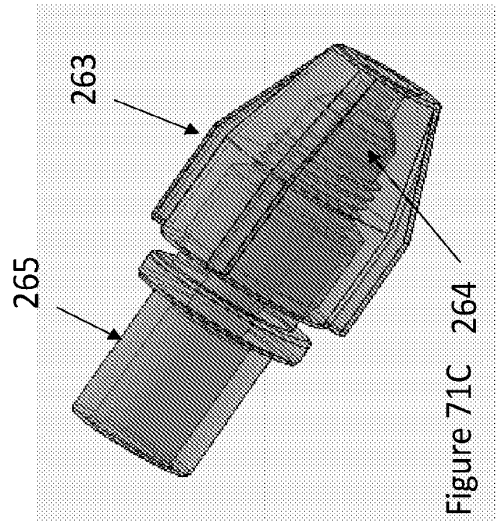


Figure 71C

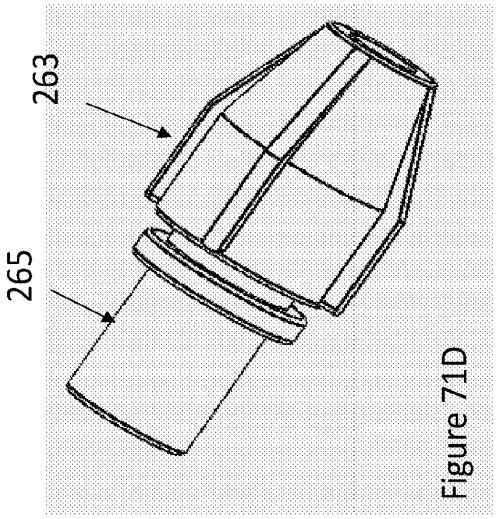


Figure 71D

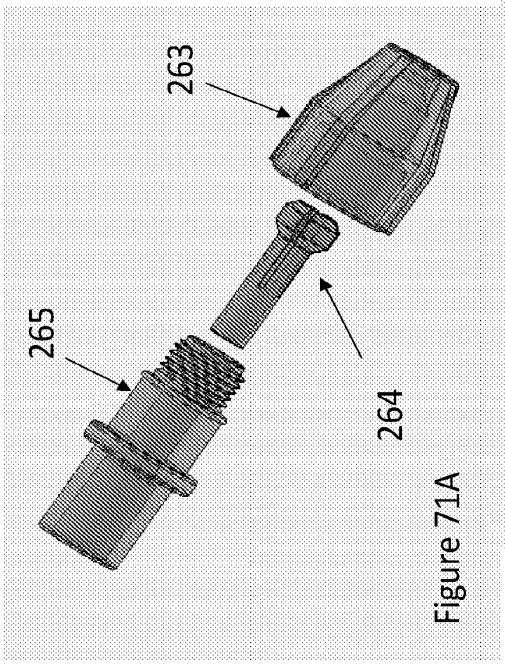


Figure 71A

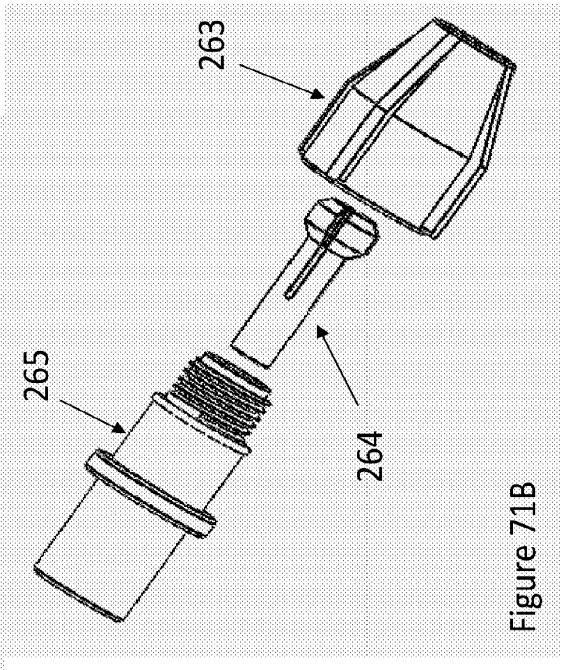


Figure 71B

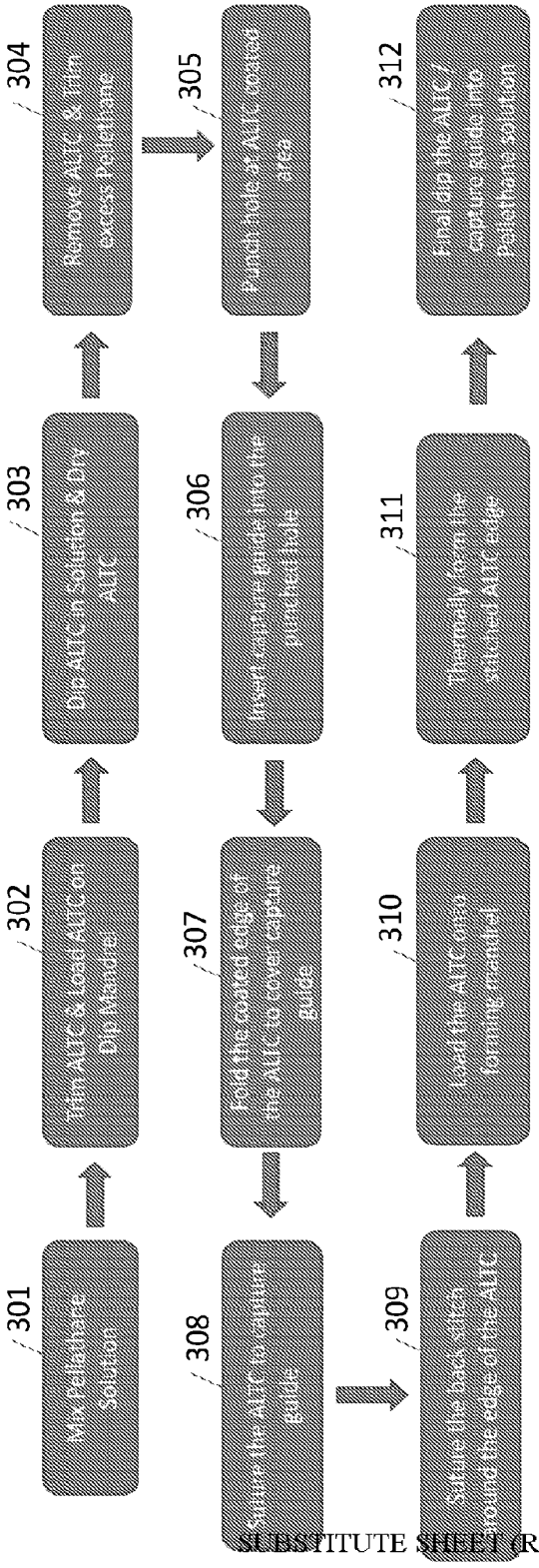


Figure 72

SUBSTITUTE SHEET (RULE 26)

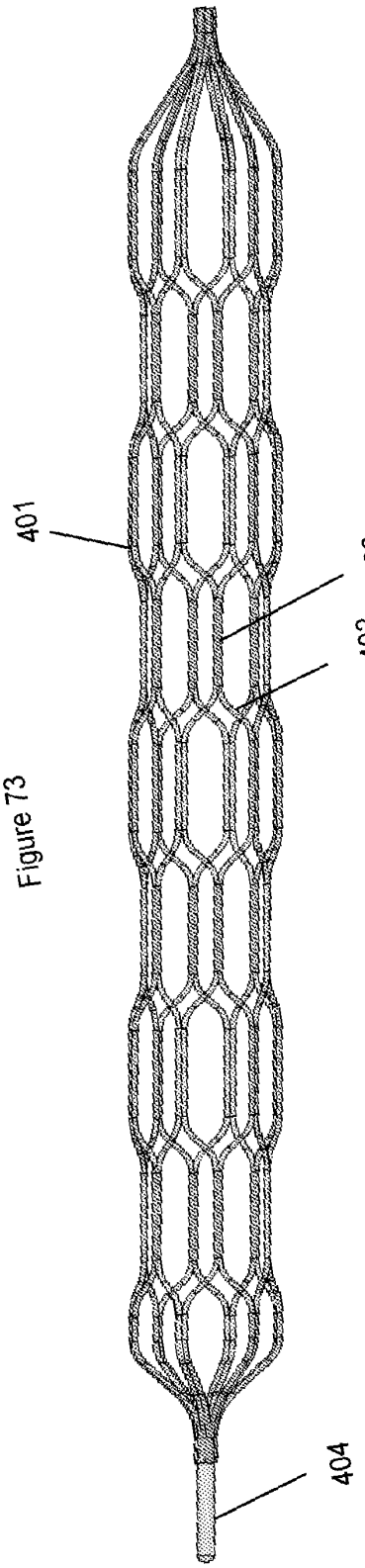


Figure 73

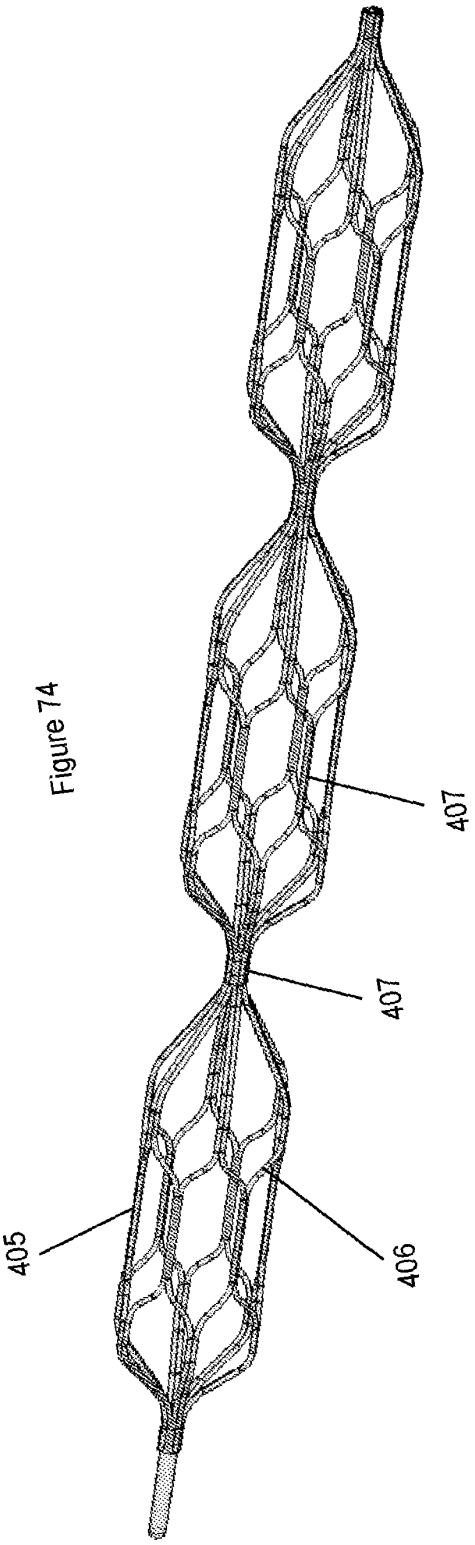


Figure 74

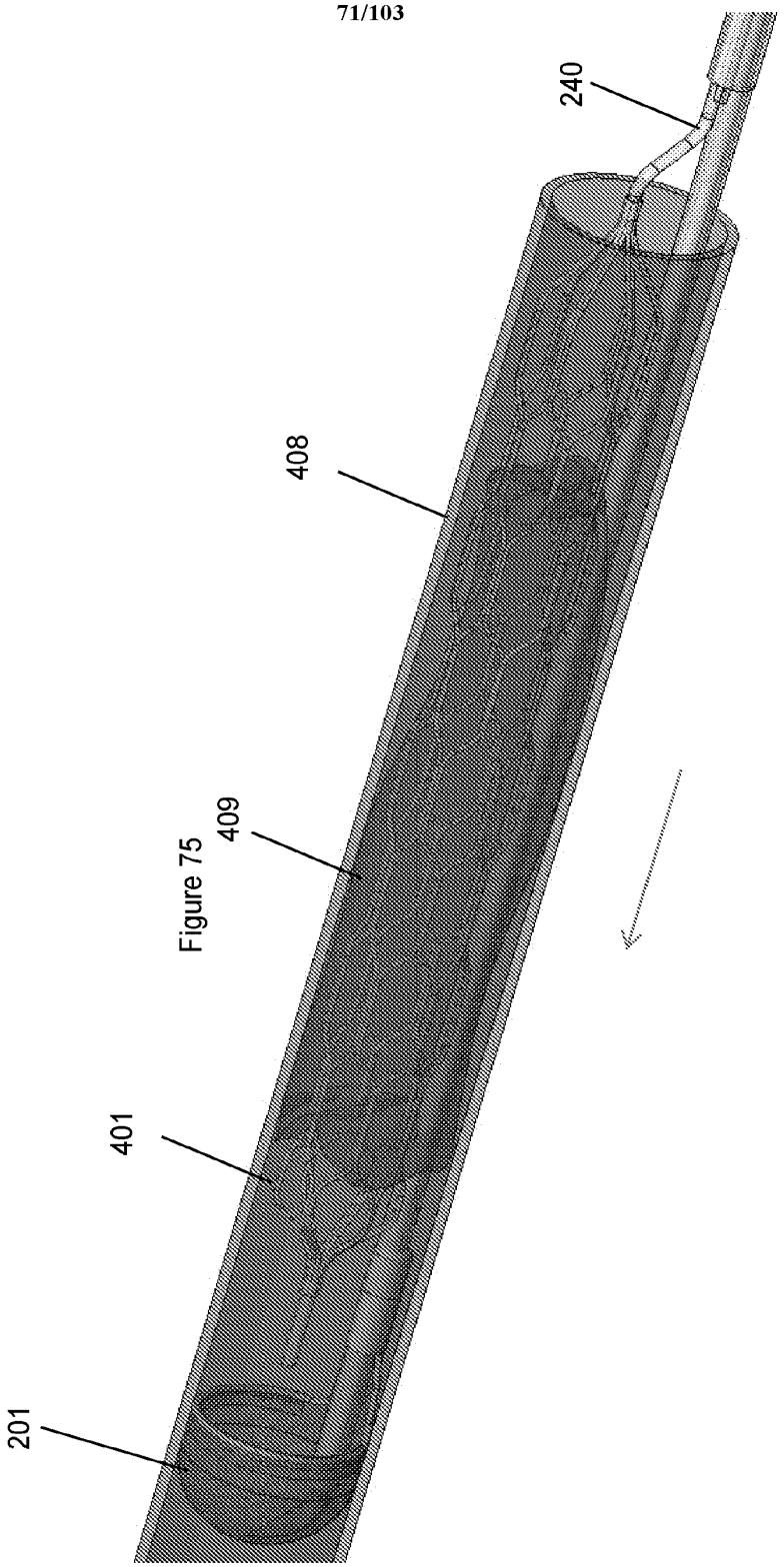


Figure 75

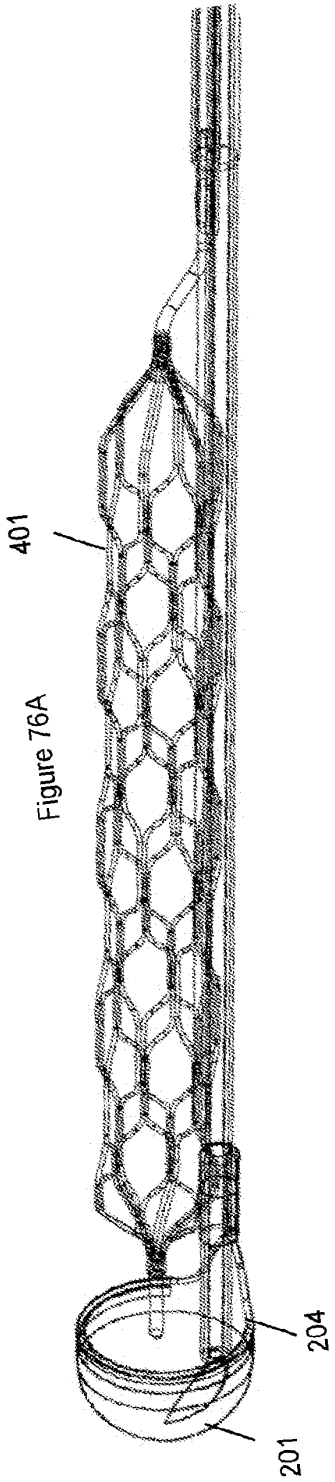


Figure 76A

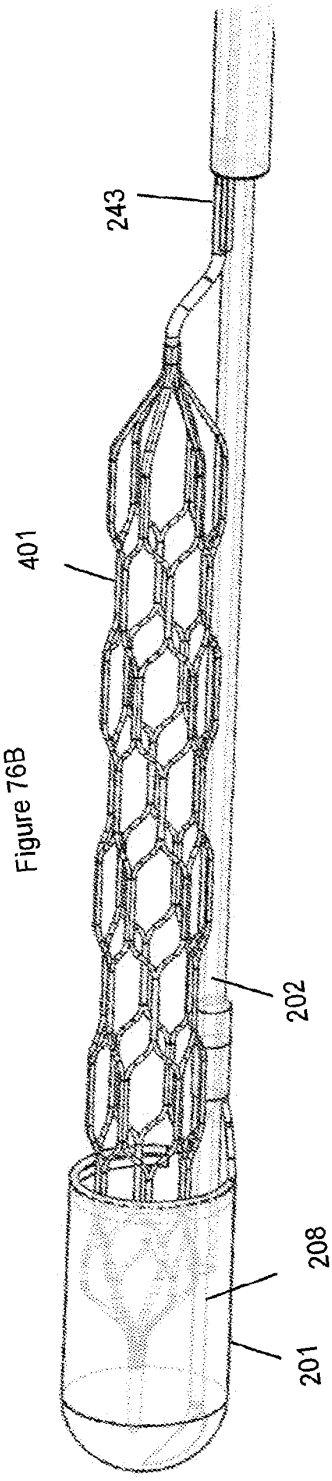


Figure 76B

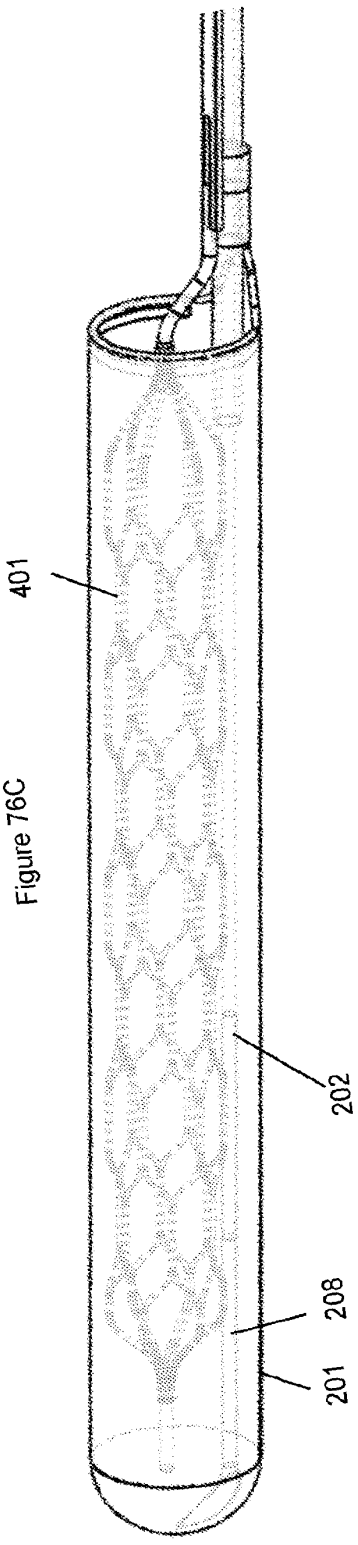


Figure 76C

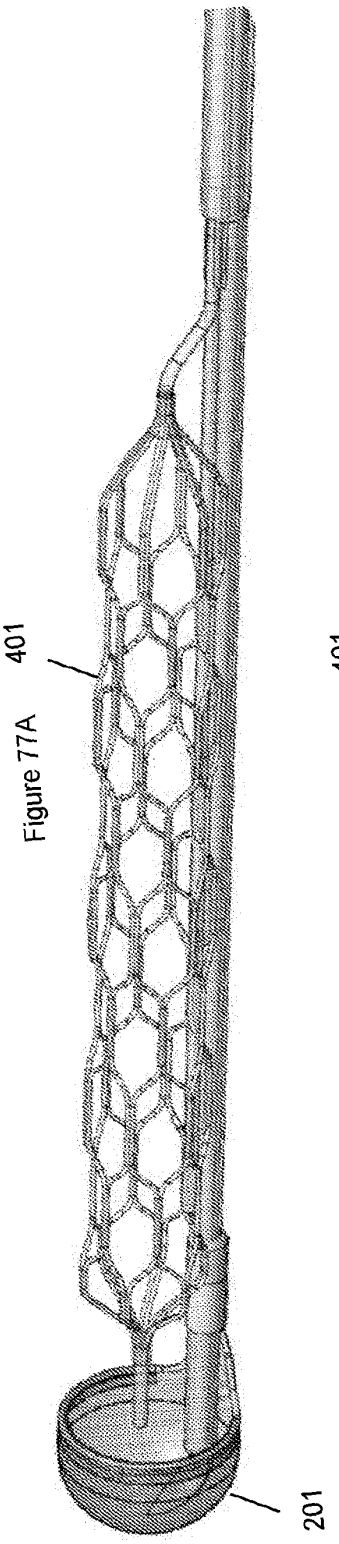


Figure 77A

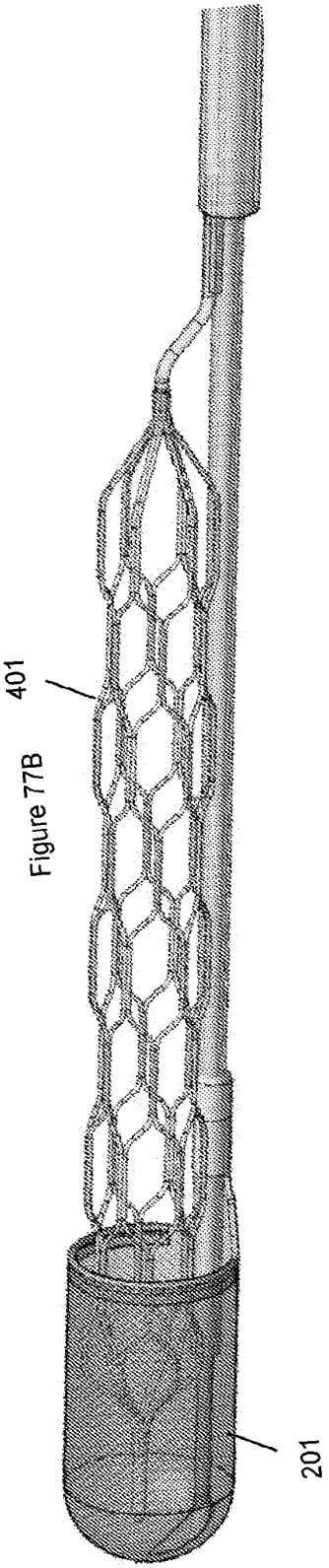


Figure 77B

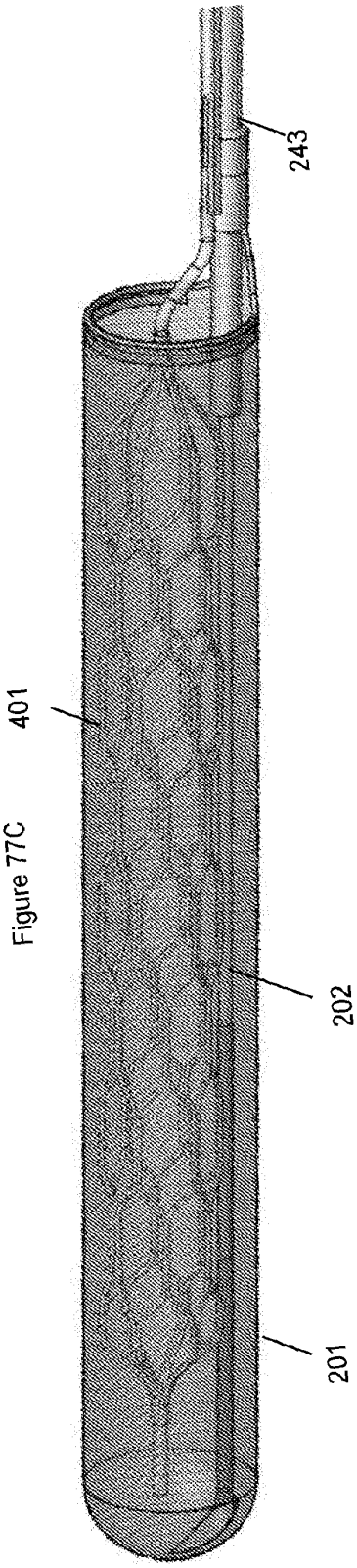


Figure 77C

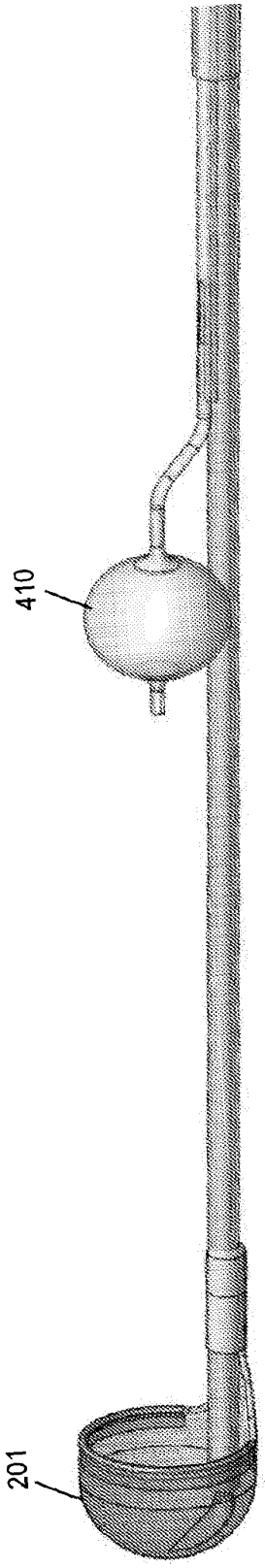


Figure 78

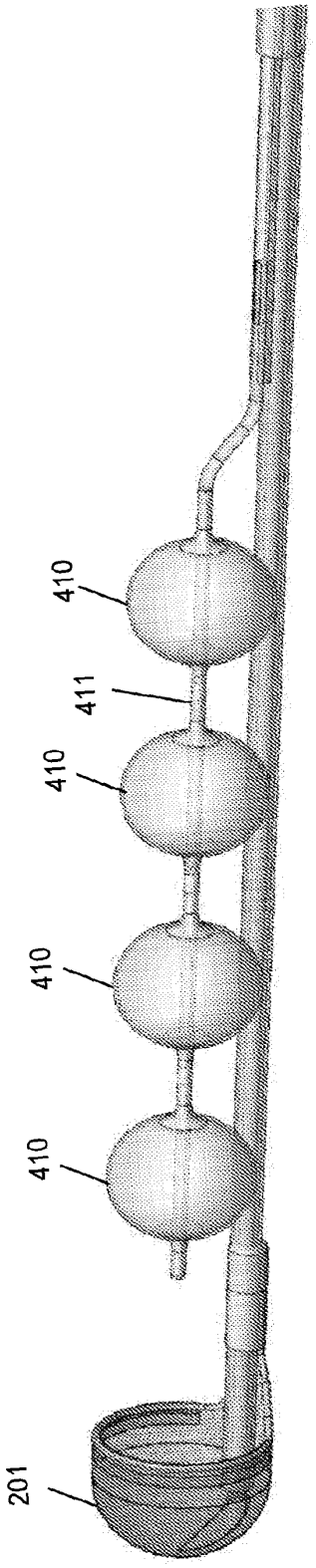


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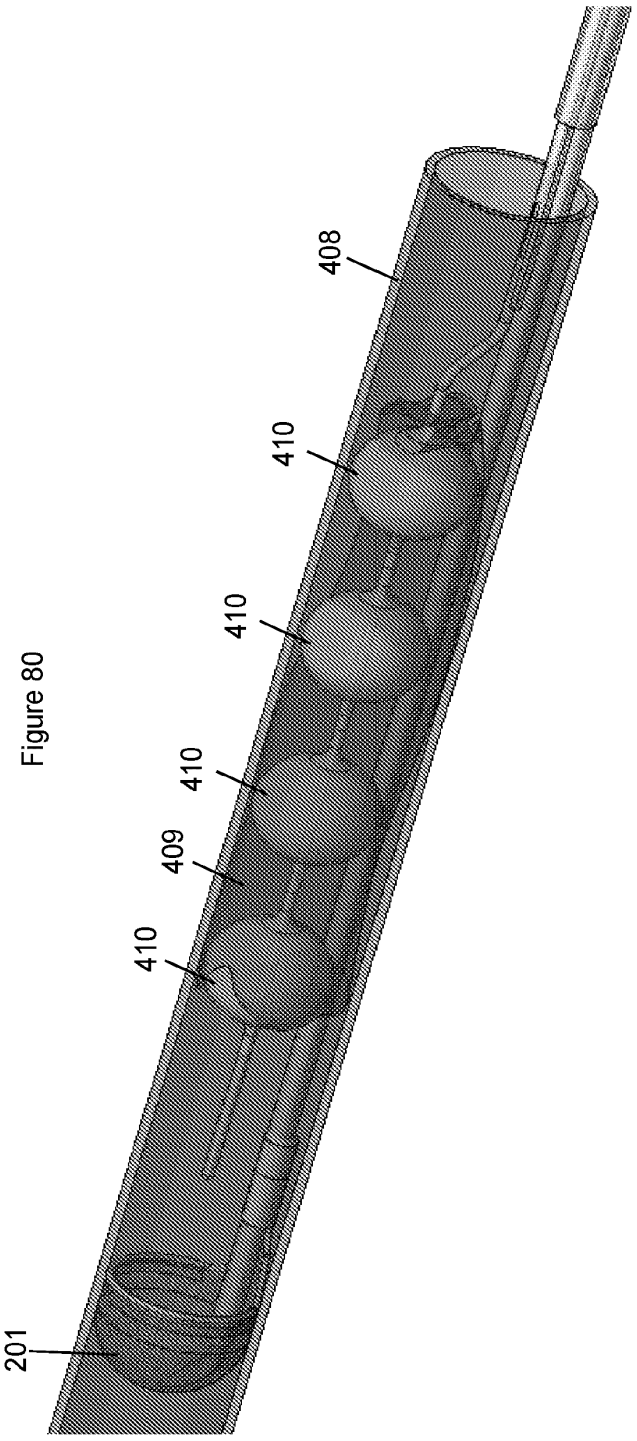


Figure 80

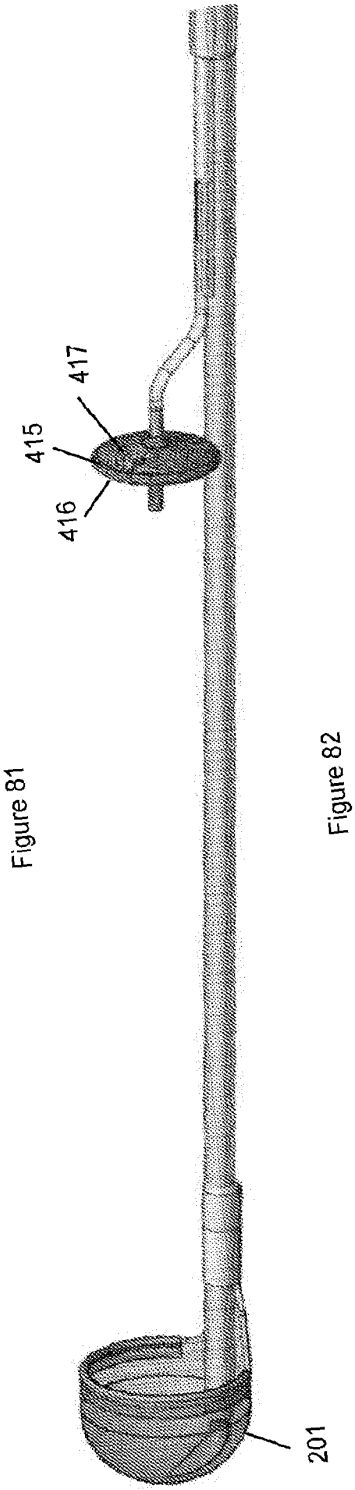


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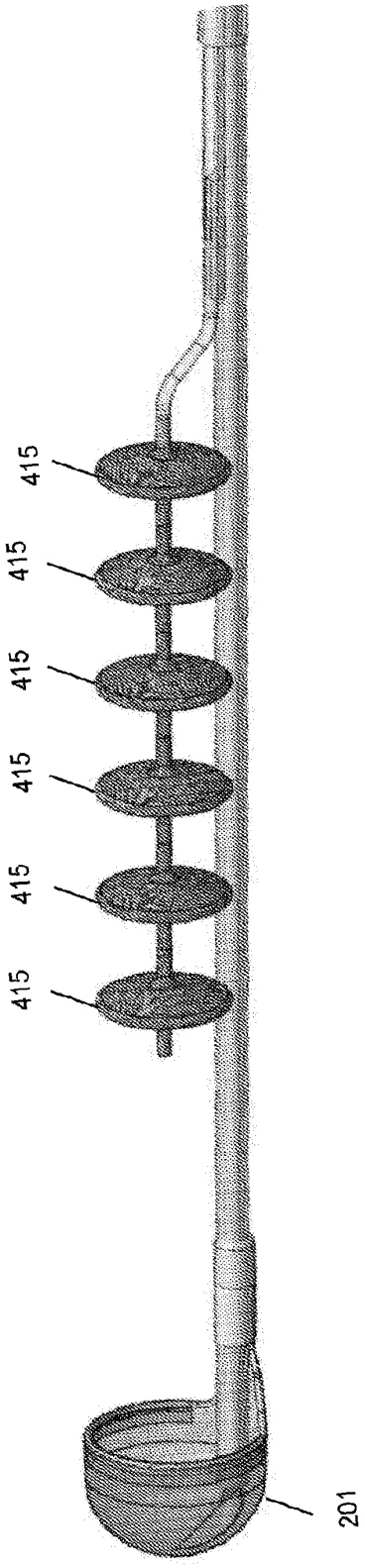


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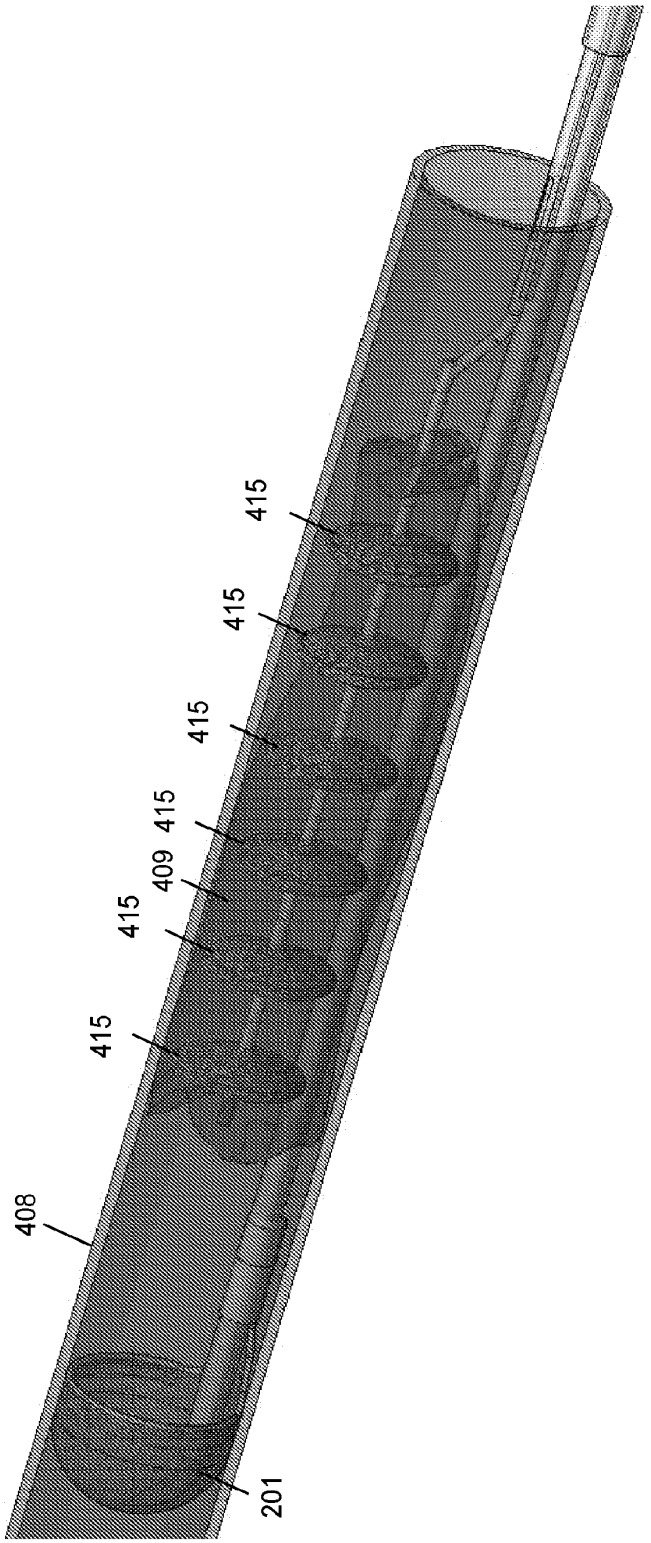


Figure 83

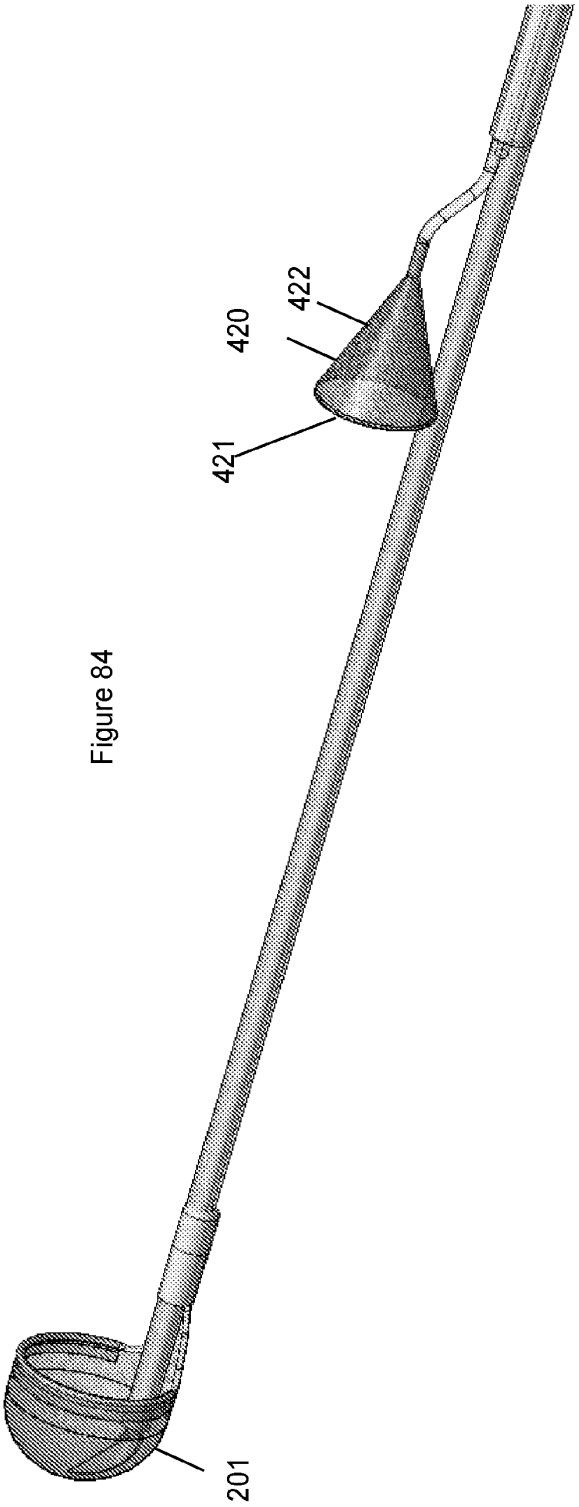


Figure 84

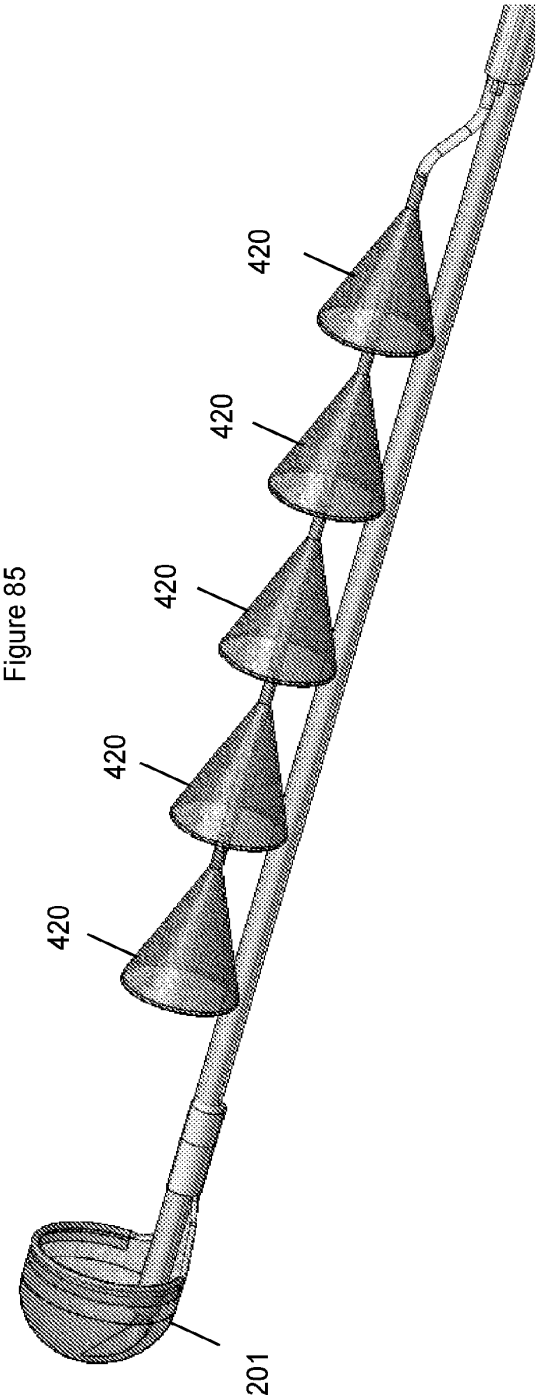


Figure 85

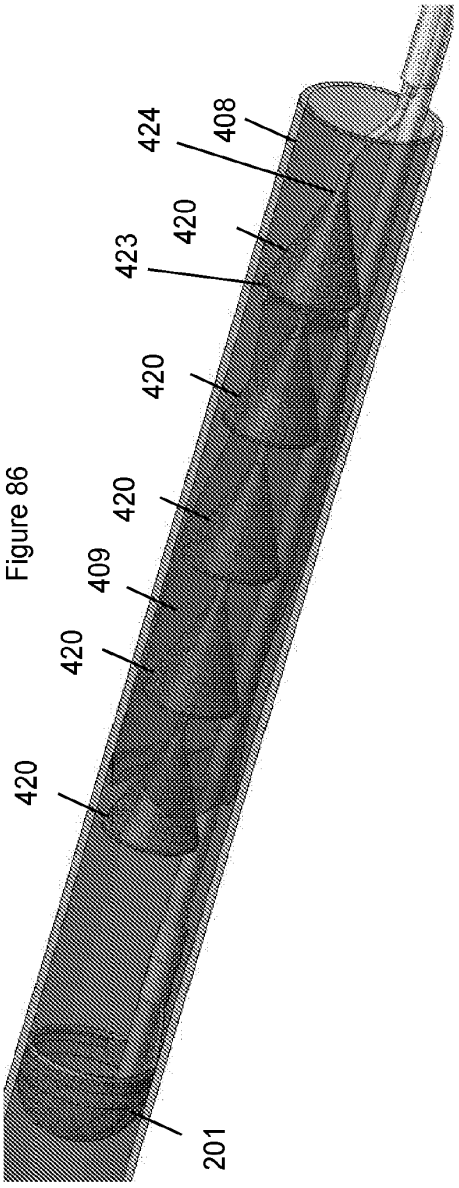


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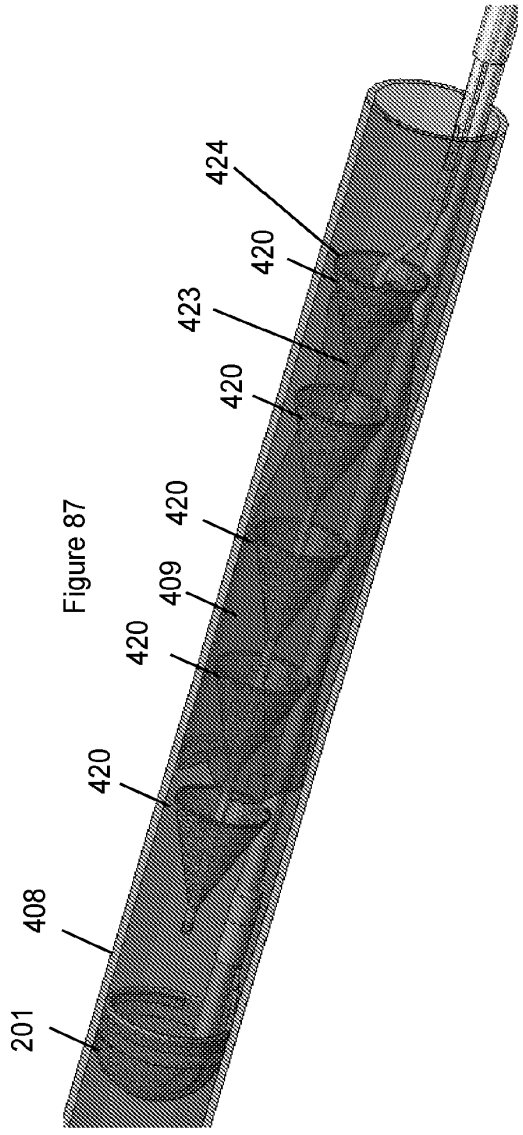


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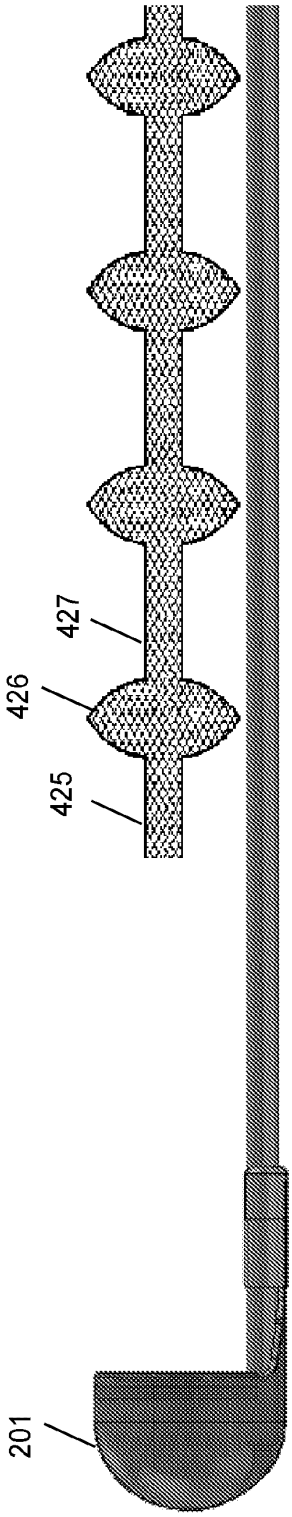


Figure 88A

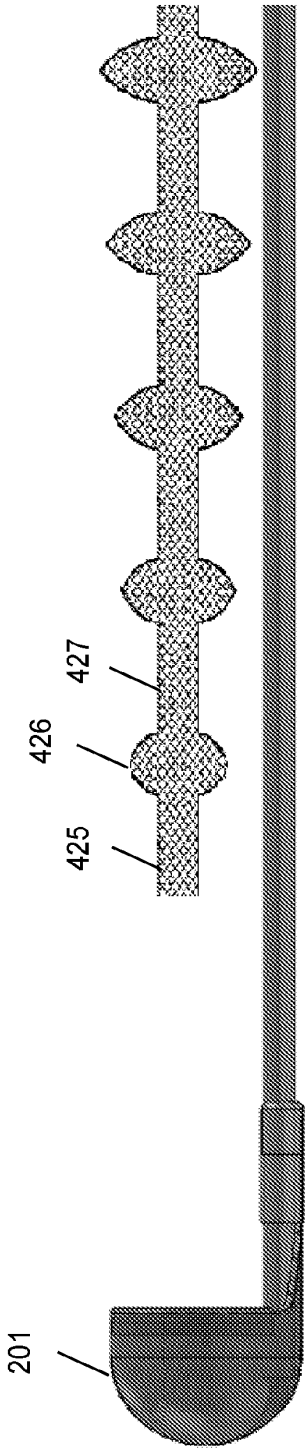


Figure 88B

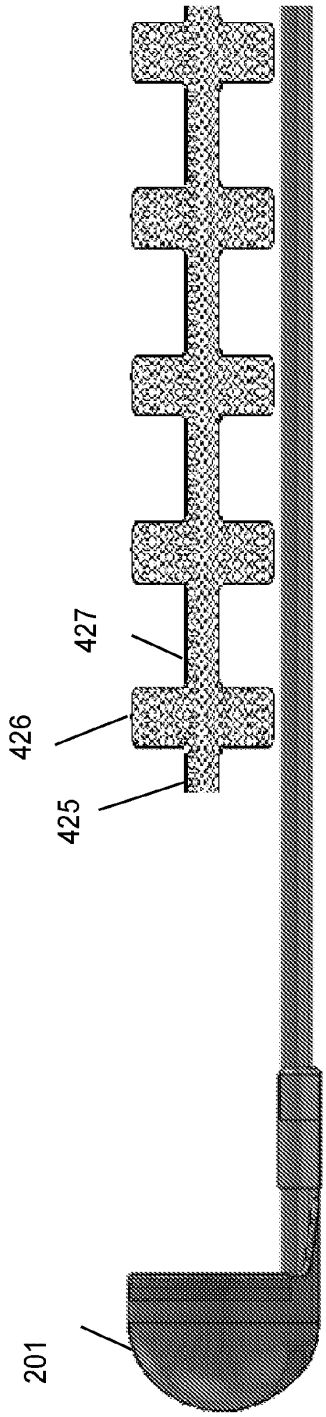


Figure 88C

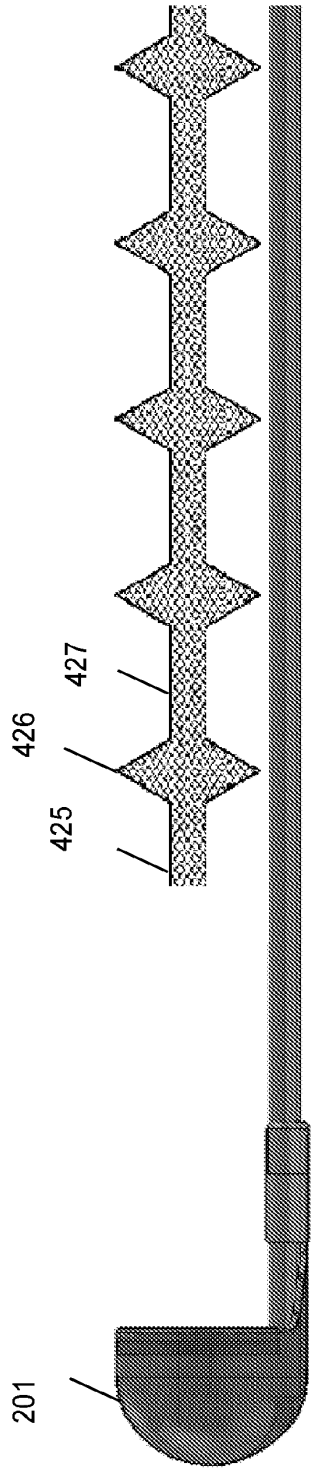


Figure 88D

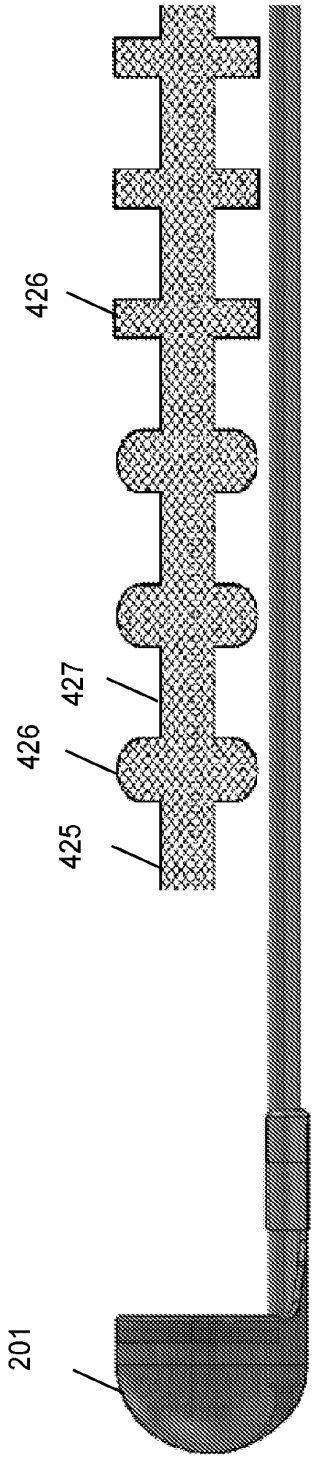


Figure 88E

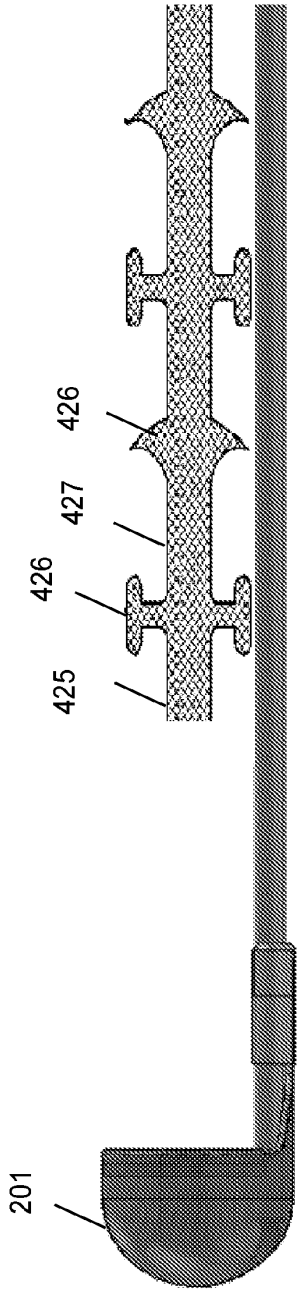


Figure 88F

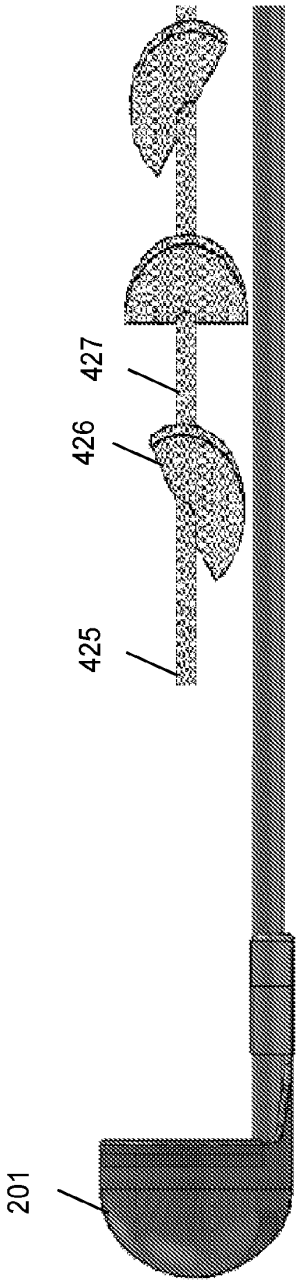


Figure 88G

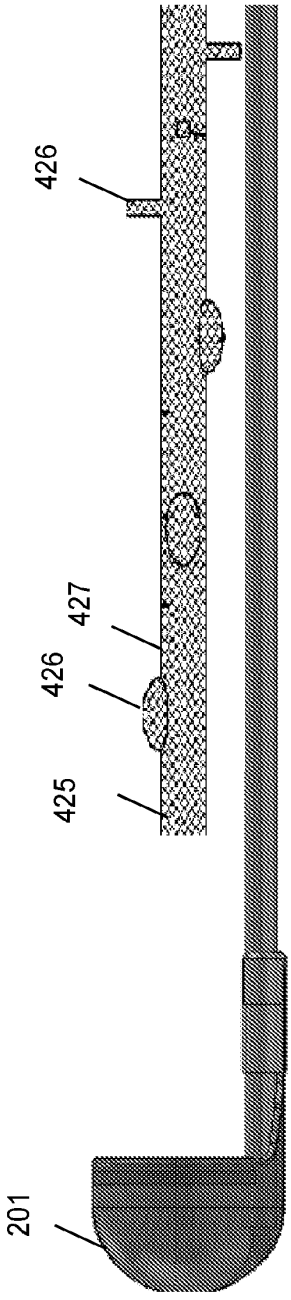


Figure 88H

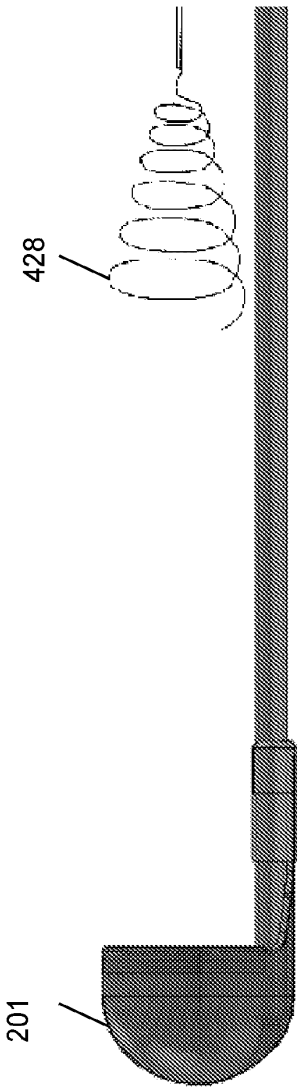


Figure 88I

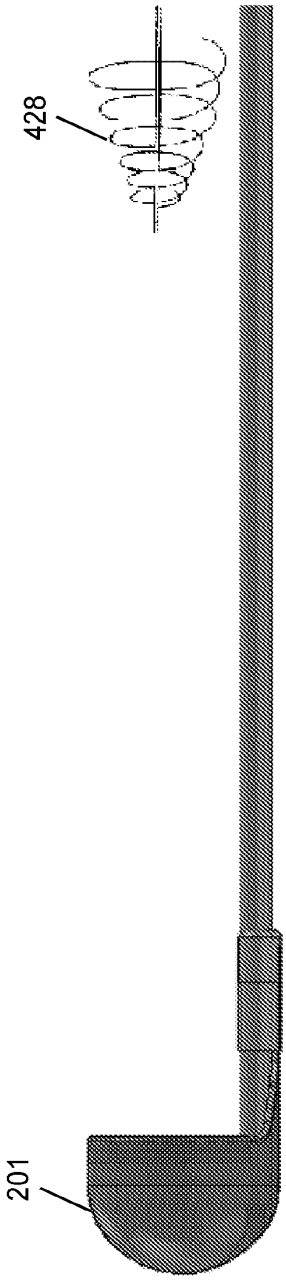


Figure 88J

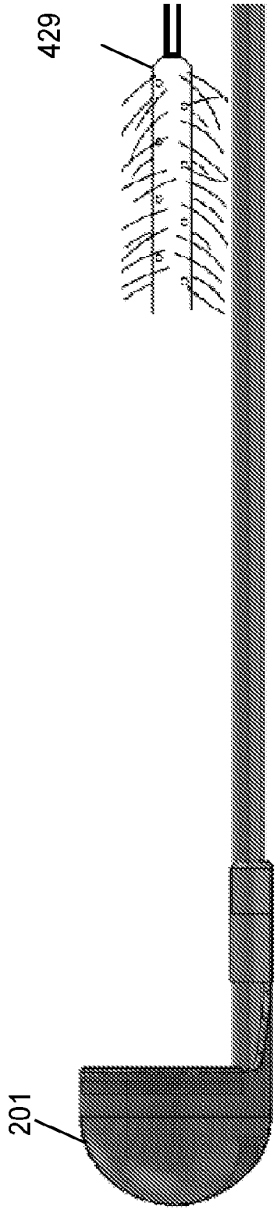


Figure 88K

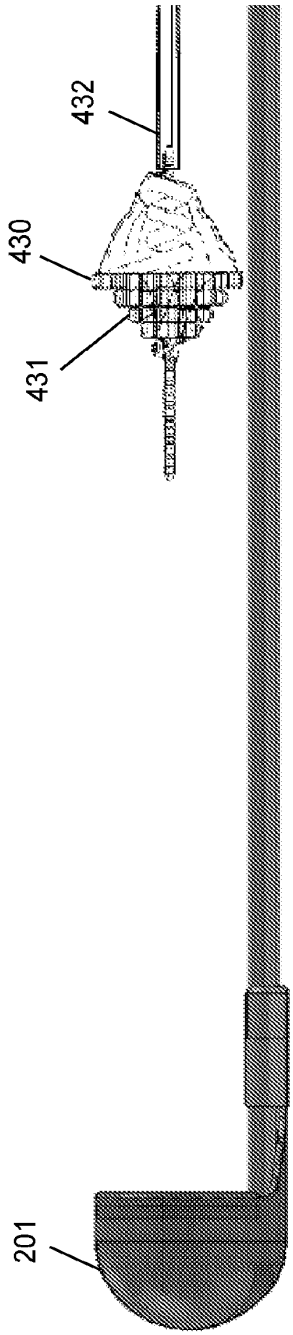


Figure 88L

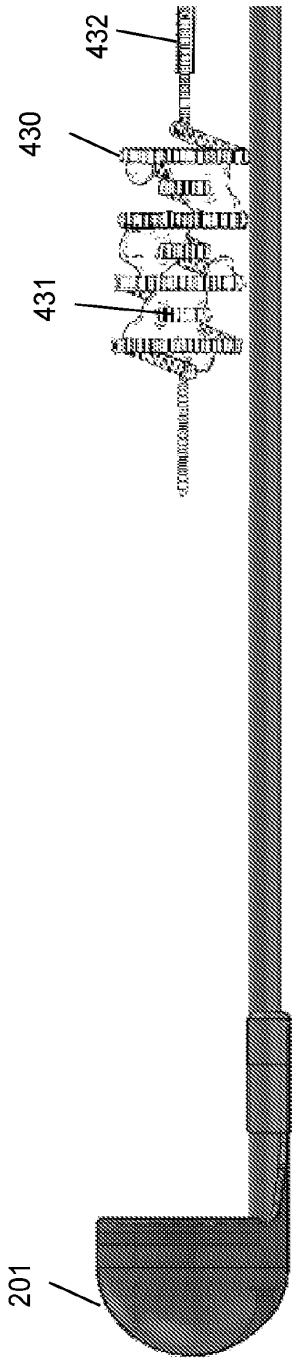


Figure 88M

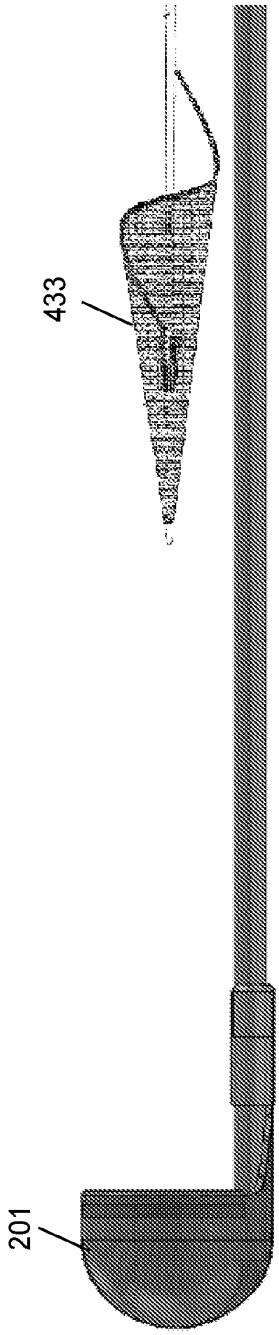


Figure 88N

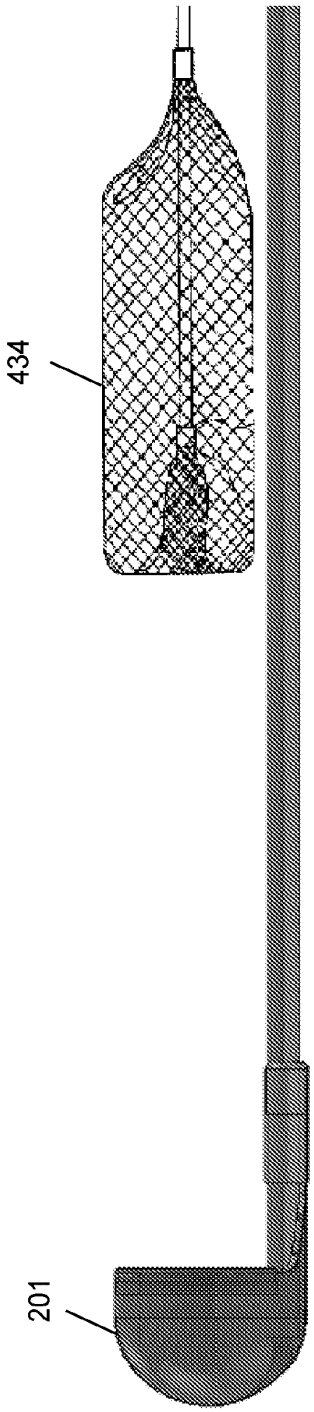


Figure 88O

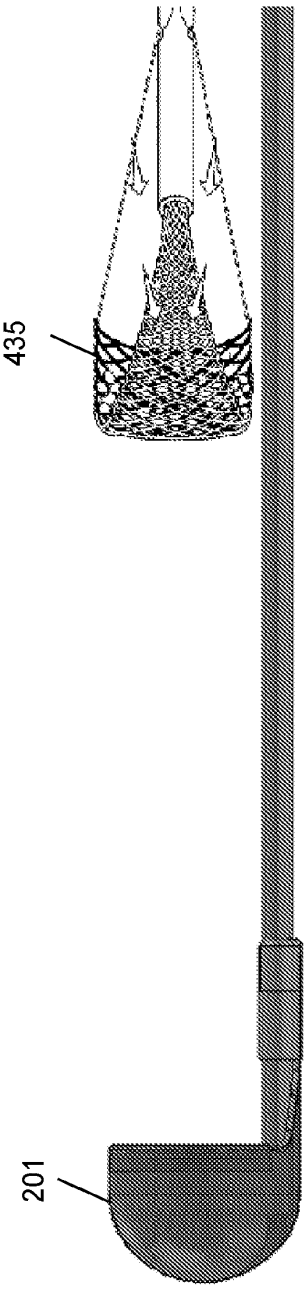


Figure 88P

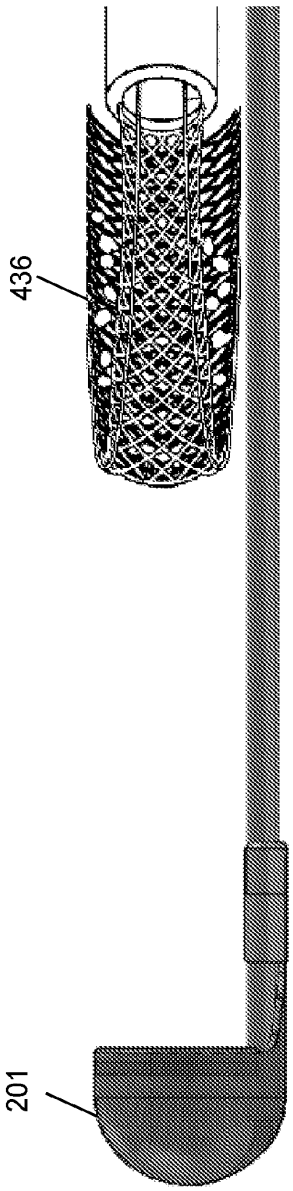


Figure 88Q

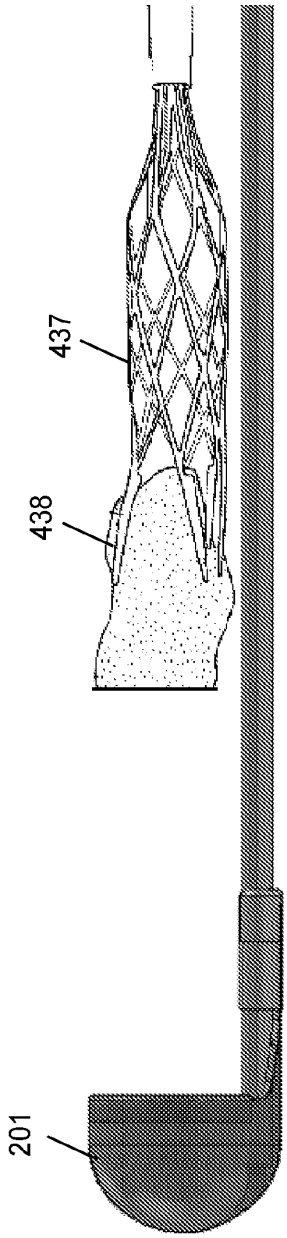


Figure 88R

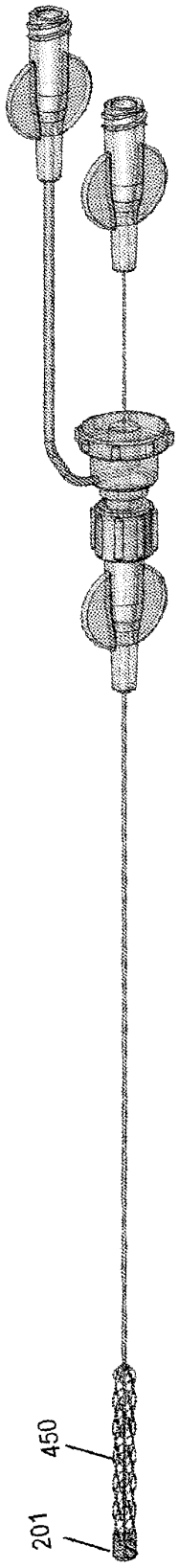


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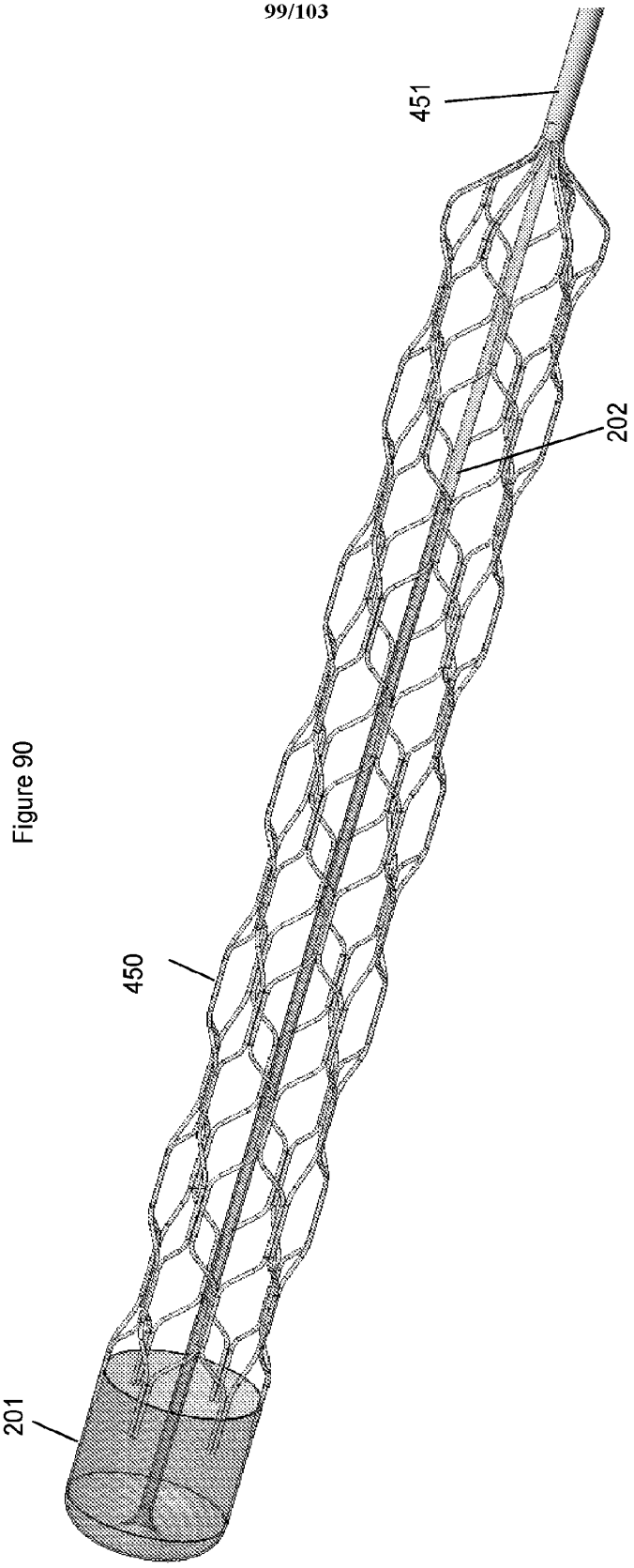


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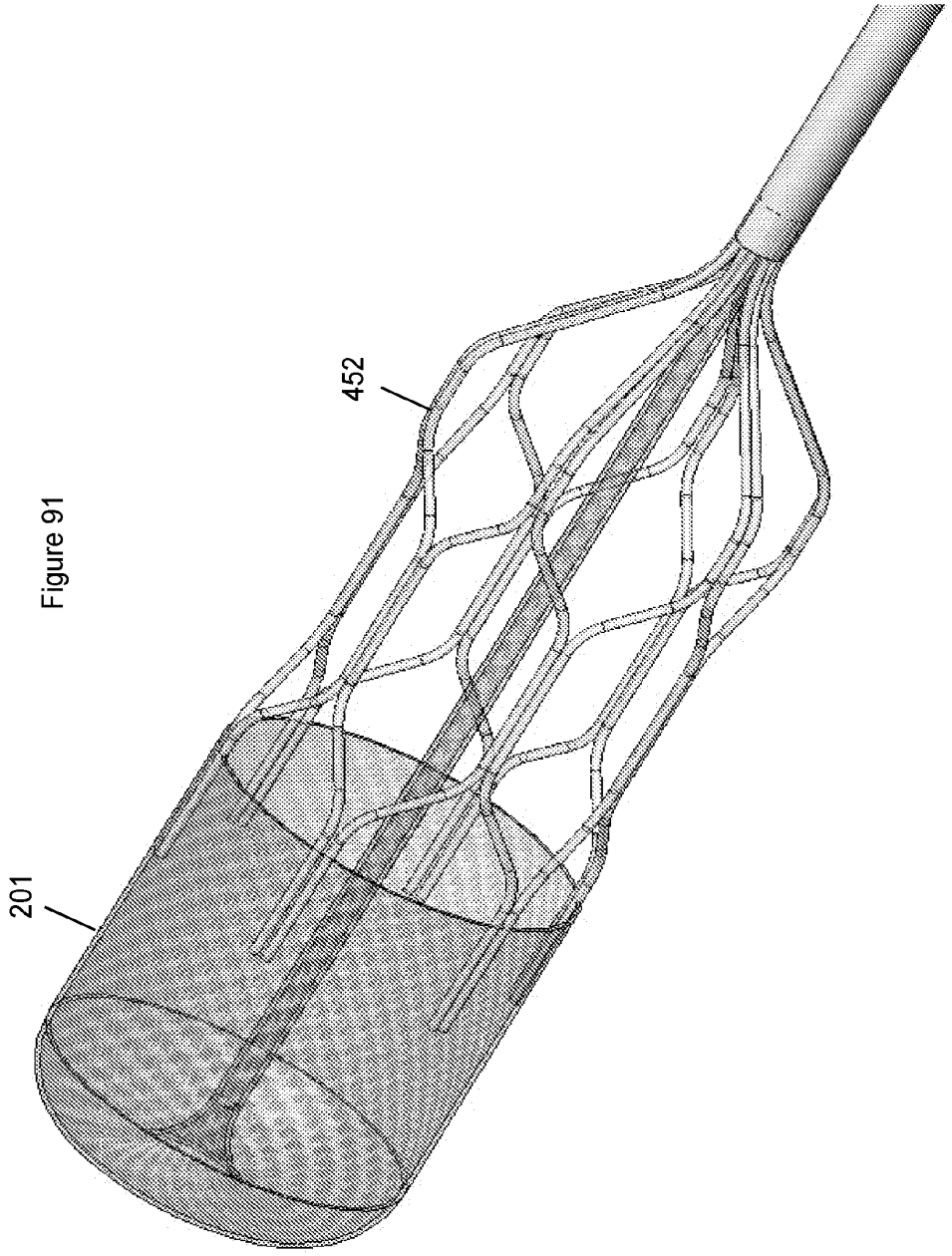


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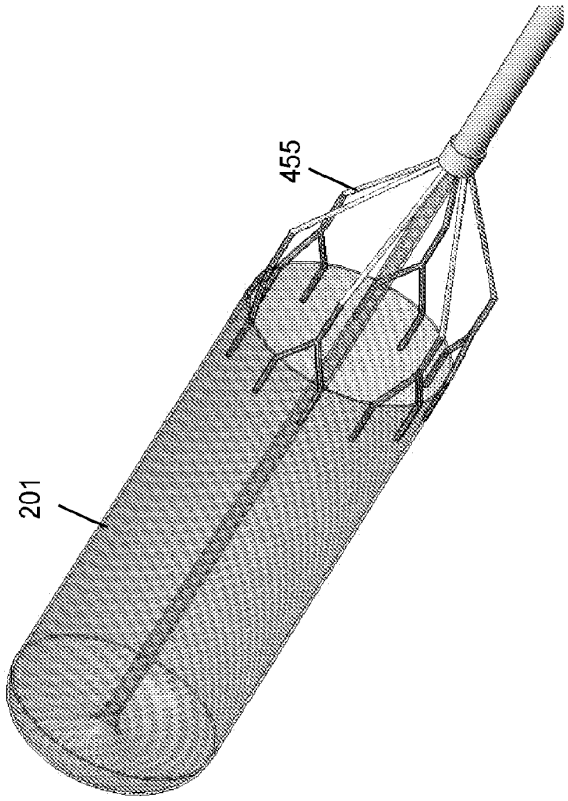


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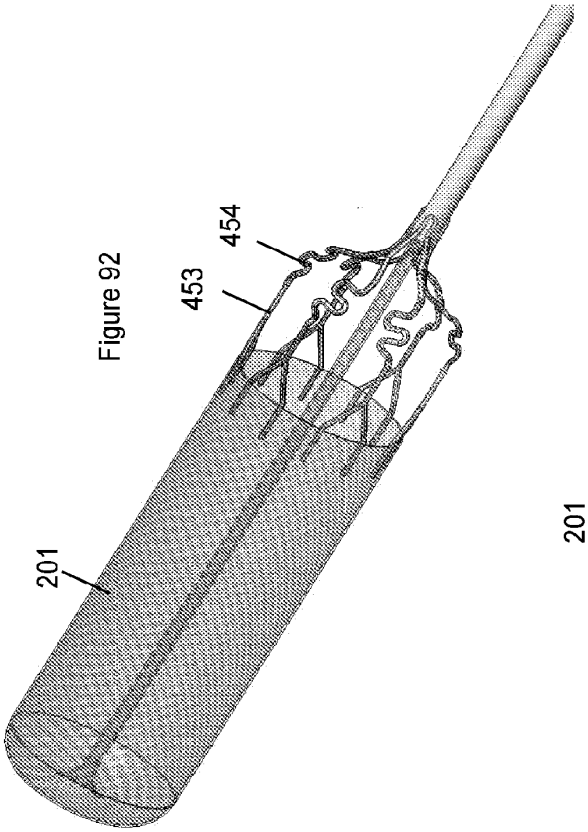


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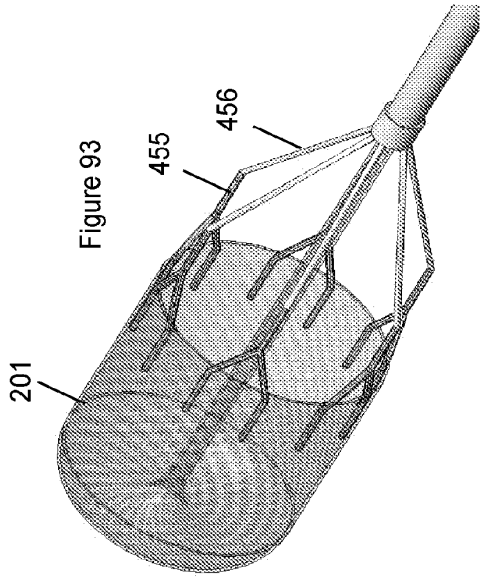


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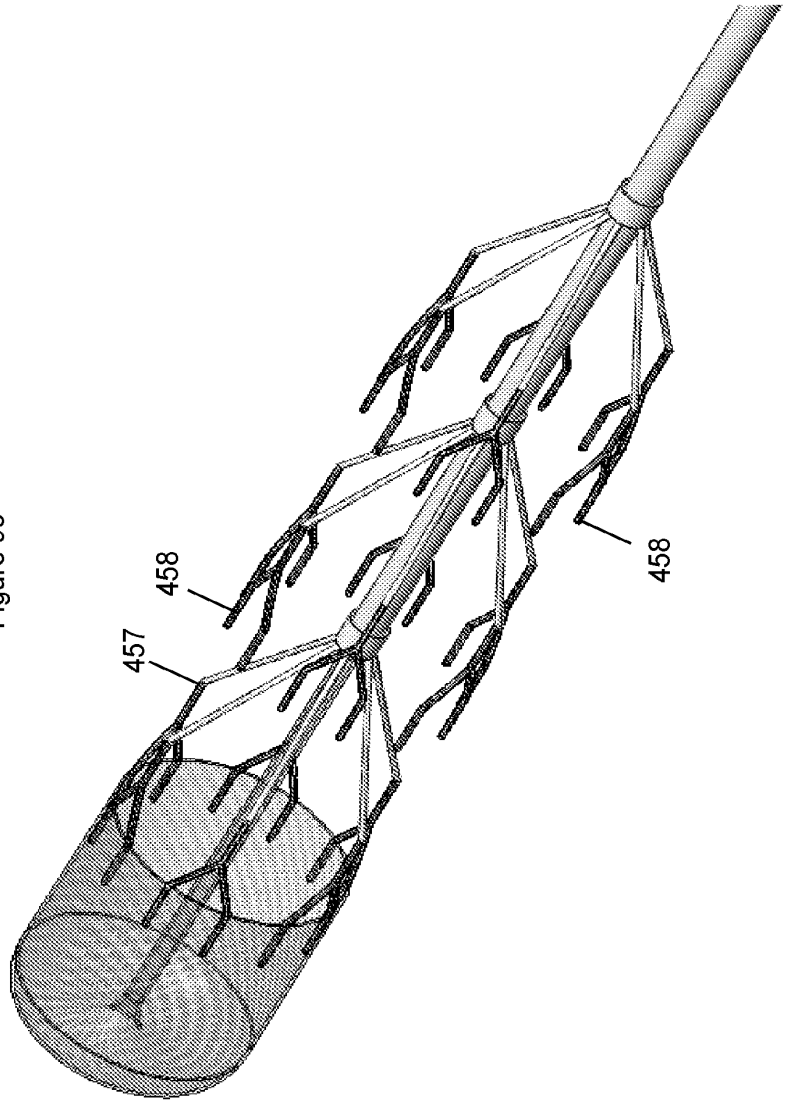


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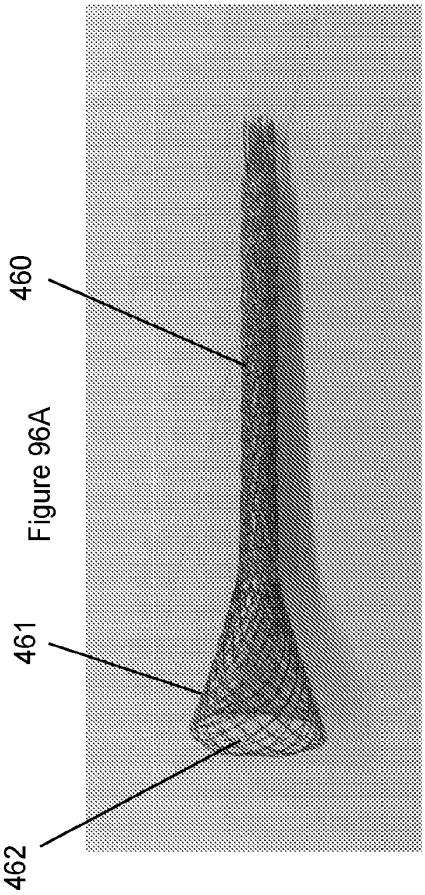


Figure 96A

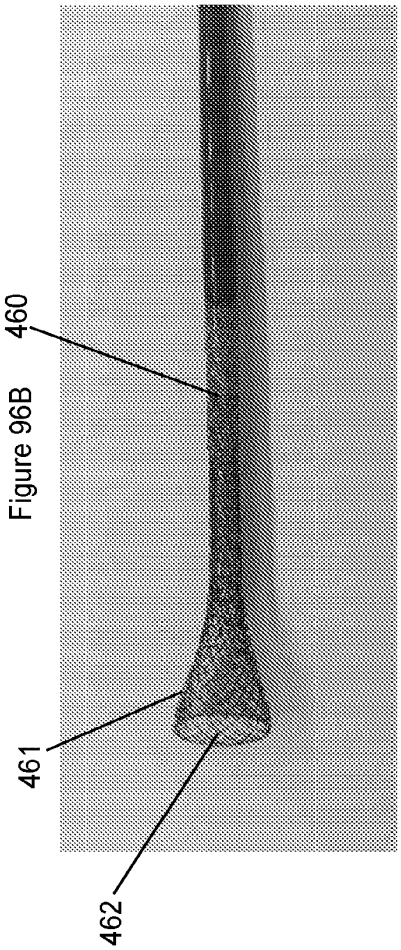


Figure 96B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 2018/016976

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/22 *(2006.01)*

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 17/00, 17/22, 17/221, A61F 2/01

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

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

PatSearch (RUPTO internal), Esp@cenet, PAJ, USPTO, Information Retrieval System of FIPS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y A	US 8968330 B2 (INCEPTUS MEDICAL LLC) 03.03.2015, fig. 6E-7B, 9A-9H, col. 3, line 57 - col. 7, line 39	1-4, 6, 7, 9-18, 20, 44 5, 8, 9 21-43
Y	US 5868708 A (APPLIED MEDICAL RESOURCES CORPORATION) 09.02.1999, fig. 1, 5, 7, 9-11, col. 6, line 10 - col. 9, line 65	5, 8
Y	US 6221006 B1 (ARTEMIS MEDICAL INC.) 24.04.2001, col. 8, lines 32-37, col. 9, lines 19-26	19
A	US 2011/0125181 A1 (EAMON BRADY et al.) 26.05.2011	1-44

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

☐ See patent family annex.

* Special categories of cited documents:

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

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

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 April 2018 (27.04.2018)	24 May 2018 (24.05.2018)
Name and mailing address of the ISA/RU: Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37	Authorized officer Y. Leonova Telephone No. (495)531-64-81

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

(25) Filing Language: English

(26) Publication Language: English

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

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

(72) Inventors: **GREENHALGH, E., Skott**; 1426 Rose Glen Road, Gladwyne, Pennsylvania 19035 (US). **WALLACE, Michael, P.**; 5849 Corte Margarita, Pleasanton, California 94566 (US). **GARABEDIAN, Robert**; 1691 Notre Dame Drive, Mountain View, California 94040 (US).

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

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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

Published:
— *with international search report (Art. 21(3))*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) Title: PRE-LOADED INVERTING TRACTOR THROMBECTOMY APPARATUSES AND METHODS

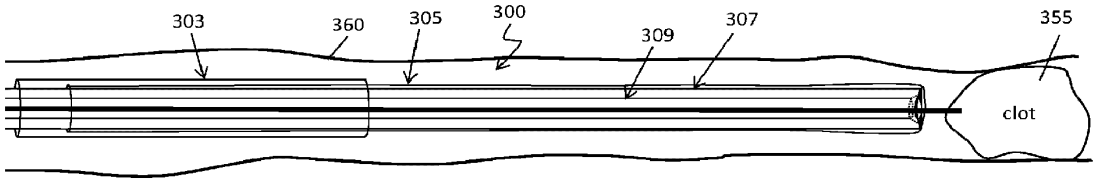


FIG. 3A

(57) Abstract: Mechanical thrombectomy apparatuses including an inverting, rolling conveyor region ("tractor") at the distal end that are configured to grab and remove thrombus material. In particular, described herein are mechanical thrombectomy apparatuses that are adapted to prevent premature deployment of the tractor, e.g., by including a tractor hold (e.g., a housing, a lock, a clamp, etc.) or the like to secure the outer end of the tractor against and/or relative to the elongate inversion support.

WO 2017/189550 A1

PRE-LOADED INVERTING TRACTOR THROMBECTOMY APPARATUSES AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

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

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

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

INCORPORATION BY REFERENCE

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

FIELD

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

BACKGROUND

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

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

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

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

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

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

SUMMARY OF THE DISCLOSURE

[00011] Described herein are mechanical thrombectomy apparatuses (devices, methods, systems, etc.) that include a distal inverting tube of highly flexible material, referred to herein as a tractor, that is pulled to continuously invert over a distal opening, such as the distal end of a catheter or annulus, in a rolling manner. This rolling can be used, alone or on conjunction with a vacuum or mechanical thrombus (e.g., "clot") grabber, to grab, capture and remove a clot from a vessel. As mentioned, the tractor may be formed of a material having many openings and may therefore be flexible, and loose, and may be biased so as to flare open within the vessel when deployed. Prior to positioning the apparatus for grabbing the clot, it may be particularly desirable to prevent the tractor from deploying (e.g., sliding axially axially, expanding, etc.) so as to allow accurate tracking within the body as well as to ensure reliable operation of the device. Thus, it may be helpful to pin or hold the tractor, and particularly the end of the tractor that has not been inverted (e.g., within a catheter and/or within the tractor itself) prior to deployment. However, holding or and/or retaining the tractor prior to deployment must be properly balanced. If too much force is required to deploy the tractor, the force may cause the apparatus to kink, collapse, and/or jam. If the tractor can be deployed with too little force may deploy prematurely. Further, since the apparatus is likely to be used in highly tortious vessels of the body, including arteries such as the internal carotid artery, it must be retained in a manner that does not inhibit overall flexibility of the device, or trigger premature release when navigating through the vessels.

[00012] In general, an inverting tractor apparatus may include a tractor (e.g., tractor region, tractor portion, etc.) comprising a flexible tube of material that inverts as it rolls over itself at a distal end. The inverting/rolling portion may be performed over an annulus that may be separately maneuvered relative to the tractor; the annual may be part of a catheter (e.g., the distal end of a catheter) or may be attached to a wire or other element having sufficient column strength to prevent the annulus (distal opening) over which the tractor is inverting from being collapsed or pulled proximally as the tractor is rolled.

[00013] In operation, the tractor inverts and may roll back into itself. When an outer catheter is used, the tractor may be drawn into the catheter. The annulus about which the tractor inverts at the distal end region of the apparatus is supported by a structure (e.g., rod, hypotube, catheter) that typically is more rigid (has a much larger column strength) than the tractor. Thus, as the tractor rolls, it produces a conveyor-like motion as a formerly outward-facing tractor region rolls around to become an inward-facing region within the lumen of the tractor and/or within the lumen of the catheter. This conveyor or rolling motion may draw a clot (or other object) from a vessel into the catheter.

[00014] The mechanical thrombectomy apparatuses described herein include pre-loaded inverting tractor thrombectomy apparatuses (e.g., devices, systems, etc.). These apparatuses may be configured to prevent premature release of the tractor. Any of these apparatuses may include, for example, a tractor hold that prevents the end of the tractor that is "outside" of the inner lumen from sliding axially and inverting until deployment. The tractor hold may include a housing, and particularly a housing extends only a slight distance proximally (therefor preventing increasing the stiffness of the apparatus or otherwise inhibiting maneuverability/tracking). The tractor hold may include hydrophobic and/or hydrophilic surfaces, e.g., coatings, on the outside end region of the tractor and/or the outer portion of a catheter over which the tractor rolls; these hydrophobic/hydrophilic surfaces may be arranged in a pattern. Any of the tractor holds described herein may include a releasable attachment, such as an adhesive, a mechanical attachment such as a clamp or interference region or the like. Any of the tractor holds may include a pair of engaging portions, such as a stop or hold (e.g., a tractor hold or stop element on the catheter) and a lock (e.g., a tractor lock, such as a ring on the end region of the tractor).

[00015] As mentioned, any of these apparatuses may include an inverting annuls that may be part of an elongate member having sufficient column strength to resist collapsing or deflecting when the tractor is pulled proximally through the annuls to roll over and invert. The annulus may be the distal end of a catheter, or a portion of a catheter, or it may be a ring or cylindrical region to which an elongate support (e.g., wire, rod, hypotube, or any combination of these, including concentric or sequential arrangements). The annulus is typically a ring-shaped opening (the opening of which may be any shape, including but not limited to round, oval, triangular, square, rectangular, etc.), over which the tractor is inverted, and this annulus is typically connected to an elongate supporting member. The annulus may be integral with the elongate supporting member. The annulus and elongate support member may together be referred to as an elongate inversion support. As mentioned this elongate

inversion support may generically be referred to herein as a catheter, which may include a tube, rod, hypotube, wire, shaft, etc. having an annuls or distal end opening over which the tractor is inverted so that the tractor rolls over the distal end opening (annulus) when an end of the tractor that is more radially positioned in the apparatus is pulled proximally. Also described herein are a variety of elongate inversion supports (e.g., catheters), as the shape (e.g., outer diameter) of the inverting support may affect the retention of the tractor prior to deployment.

[00016] For example, described herein are mechanical thrombectomy apparatuses for removing a clot from a vessel that include: an elongate inversion support (e.g., a catheter) having a proximal end and a distal end and a distal annulus (e.g., distal end opening); a tractor comprising a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter; a puller coupled to first end of the tractor, wherein the puller extends within the catheter to the proximal end of the catheter; and a tractor hold attached to an outer diameter of the catheter proximal to the distal end of the catheter, wherein the tractor hold secures a second end of the tractor that extends over the distal end of the catheter until a force greater than a threshold force is applied by pulling the first of the tractor proximally within the catheter. Any of these apparatuses may include a guidewire lumen extending through the catheter, the puller and the tractor, and configured to pass a guidewire.

[00017] In any of these variations, the tractor hold may be a housing. The housing may be a cylinder that is pinned or closed on one (e.g., the proximal) end, leaving an annular opening for the outermost end of the tractor.

[00018] The tractor hold may not extend to the proximal end of the catheter. For example, the tractor hold may extend proximally along the catheter for less than 10 cm (e.g. for less than 9 cm less than 8 cm, less than 7 cm, less than 6 cm, less than 5 cm, etc.).

[00019] In any of these variations, the tractor hold may compress the tractor against the catheter. Typically, the threshold force for the tractor hold is determined by the force required to deploy the tractor within the lumen, which may depend upon the length of the apparatus, the diameter of the tractor and/or catheter, and the materials of the tractor and elongate inversion support (e.g., catheter). For example, the tractor hold may be configured to hold the second end of the tractor until the threshold force is applied, wherein the threshold force is between 50 g force and 2000 g force (e.g., between 50 g of force and 1700 g of force,

between 50 g of force and 1500 g of force, between 40 g of force and 1000 g of force, between 50 g of force and 500 g of force, between 100g of force and 500 g of force, between 200 g of force and 500 g of force, between 250 g of force and 500 g of force, between 50 g of force and 450 g of force, between 100 g of force and 450 g of force, between 100 g of force and 400 g of force, between 200 g of force and 400 g of force, etc.). The range of force appropriate to the threshold force may be important in proper functioning of the apparatus, particularly when the force is applied by pulling proximally on the puller and/or tractor; too little force for the threshold and the tractor will prematurely deploy; too much force and the apparatus will jam (e.g., by kinking the elongate inversion support).

[00020] In any of the variations described herein, the tractor may be biased to collapse and/or expand. For example, the tractor may be biased to collapse over the catheter outer diameter (e.g., the outer diameter of the elongate inversion support, including the distal end of the catheter); such tractors may also be biased to expand after inverting (e.g., within the catheter) over the distal end opening of the elongate inversion support. This arrangement may cause the tractor to form a distal-facing region that flares, trumpet-like, towards a clot distal to the device, which may help in capturing the clot and also may prevent jamming of the tractor. Alternatively or additionally, some or all of the tractor regions may be configured to expand over the outer diameter of the elongate inversion support.

[00021] The proximal end of the tractor hold may be attached to the catheter. The tractor hold may be fixed, fused, or integrally formed with the catheter.

[00022] In any of these variations, the catheter (elongate inversion support) may include comprises a larger outer diameter region and a smaller outer diameter region that is proximal to the larger outer diameter region; the annulus (distal end opening) may be at the distal end of the elongate inversion support. The the tractor hold may secure the tractor at one or more of: over the smaller outer diameter region, and between the larger outer diameter region and the smaller outer diameter region. The outer diameter of the tractor hold may be flush with the larger outer diameter region. The tractor hold may reside in a narrowing (necked) region of the catheter to avoid forming a larger-diameter region. Any of these elongate inversion supports (e.g., catheters) having regions of different diameter may have a gradual (angled) or rapid (e.g., stepped) transition between the larger outer diameter and the smaller outer diameter.

[00023] The tractor hold may comprise one or more of: a polyether block amide, a polyolefin, a polyethylene, a polypropylene, a polyethylene terephthalate (PET), and a Polytetrafluoroethylene (PTFE).

[00024] The apparatus may include a tractor lock on the second end of the tractor, wherein the tractor lock engages with the tractor hold to secure the tractor lock on a proximal side of the tractor hold until the threshold force is applied by pulling the first of the tractor proximally within the catheter. For example, the tractor lock may be a ring affixed to the end region of the tractor. The tractor lock may be a band configured to slide over the outer diameter of the catheter. The tractor hold may be a projection extending from the outer diameter of the catheter. Either or both the tractor lock and tractor hold may be elastic (e.g., compliant, rubbery, etc.) so that pulling above the threshold deployment force may cause the tractor tractor lock to release from the tractor hold.

[00025] For example, described herein are mechanical thrombectomy apparatuses for removing a clot from a vessel, the apparatus comprising: a catheter having a proximal end and a distal end and a distal end opening, wherein the catheter comprises a larger outer diameter region and a smaller outer diameter region that is proximal to the larger outer diameter region; a tractor comprising a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter; a puller coupled to first end of the tractor, wherein the puller extends within the catheter to the proximal end of the catheter; and a tractor hold on an outer diameter of the catheter proximal to the distal end of the catheter, wherein the tractor hold secures a second end of the tractor that extends over the distal end of the catheter until a force greater than a threshold force is applied by pulling the first of the tractor proximally within the catheter, further wherein the tractor hold secures the tractor at one or more of: over the smaller outer diameter region, and between the larger outer diameter region and the smaller outer diameter region.

[00026] Also described herein are methods of removing a clot using a mechanical thrombectomy apparatus. These methods may include: positioning a distal end of the mechanical thrombectomy apparatus adjacent to a clot within a vessel, wherein the mechanical thrombectomy apparatus includes a tractor region that extends along a distal region of a catheter and inverts over a distal end of the catheter so that a first end of the tractor extends proximally within the catheter; disengaging a second end of the tractor from a tractor hold that secures the second end of the tractor to an outer diameter of the catheter by applying a first force that is greater than a threshold force (threshold deployment force) to the first end of the tractor; pulling the distal end of the tractor proximally within the catheter to

roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter; and drawing the clot into the catheter with the inverting tractor.

[00027] Disengaging the second end of the tractor from the tractor hold may include disengaging the second end of the tractor from a tractor hold that is attached to an outer diameter of the catheter. For example, disengaging the second end of the tractor from the tractor hold may comprise disengaging the second end of the tractor from a tractor hold that extends proximally along the catheter for less than 10 cm.

[00028] Disengaging the second end of the tractor from the tractor hold may include disengaging the second end of the tractor from a tractor hold that is open at a distal-facing end; a proximal end of the tractor hold may be attached to the outer diameter of the catheter. Disengaging the second end of the tractor from the tractor hold may include disengaging the second end of the tractor from a tractor hold that secures the second end of the tractor over a smaller outer diameter region of the catheter that is distal to a larger outer diameter region of the catheter.

[00029] Disengaging the second end of the tractor from the tractor hold may comprise disengaging the second end of the tractor from a tractor hold that secures the second end of the tractor between a larger outer diameter region of the catheter and a larger outer diameter region of the catheter, wherein the larger diameter outer region is distal to the smaller outer diameter region. Disengaging the second end of the tractor from the tractor hold may comprise disengaging a tractor hold from a tractor lock, wherein the tractor lock is on the second end of the tractor. Disengaging the second end of the tractor from the tractor hold may include compressing either or both the tractor hold and a tractor lock on the second end of the tractor so that the tractor lock moves from a position proximal to the tractor hold to a position that is distal to the tractor hold.

[00030] As mentioned, the deployment threshold may be between 0.5 N and 50 N. For example, disengaging the second end of the tractor from the tractor hold may comprise pulling the first end of the tractor with the first force wherein the threshold force is between 1 N and 20 N.

[00031] In any of the apparatuses described herein the puller to which the tractor is coupled may be configured to extend from the distal end of the apparatus further than the tractor. In any of these apparatuses, the puller may be a tube (inner catheter, hypotube, etc.), and may be inserted into the clot, or may be used to draw a vacuum, apply an agent (e.g., anticoagulant, etc.) or the like. For example, described herein are mechanical thrombectomy apparatuses for removing a clot from a vessel that include: a catheter having a proximal end

and a distal end and a distal end opening; a tractor comprising a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter; a puller having a proximal end and a distal end, wherein the first end of the tractor is coupled to the puller at a region that is proximal to the distal end, further wherein the puller extends within the catheter to the proximal end of the catheter. Any of these apparatuses may include a guidewire lumen extending through the catheter, the puller and the tractor, and configured to pass a guidewire.

[00032] For example, the apparatus may further include a stop between the distal end of the puller and the distal end opening. For example, the apparatus may include a stop on the puller between the distal end of the puller and the first end of the tractor, wherein first end of the tractor is coupled to a sliding ring configured to slide over the puller until it engages the stop. Any of these apparatuses may include a 2 mm or greater distance between the distal end of the puller and the region of the puller to which the first end of the tractor is coupled.

[00033] As mentioned, the proximal end of the puller may be configured to couple to a vacuum source. For example, the proximal end of the puller may include a valve, e.g., a Tuohy-Borst valve/rotating hemostasis valve (RHV).

BRIEF DESCRIPTION OF THE DRAWINGS

[00034] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00035] FIGS. 1A-1H illustrate an example of an apparatus for mechanically removing an object such as a clot form a body region. FIG. 1A shows an example of an elongate inversion support portion of an apparatus, configured as a catheter portion. For example, at least the distal end of the elongate inversion support may be configured as a catheter. FIG. 1B shows an enlarged view of a distal end (opening) of the catheter of the elongate inversion support of FIG. 1A, showing the aperture formed by the distal end opening; FIG. 1C shows an example of a distal tractor region of a flexible tube (tractor tube) extending from a puller (the puller in this example is configured as a catheter. The tractor is shown in a first (e.g., un-inverted) configuration) and may be biased open, e.g., by heat setting, to have an outer

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

[00036] FIG. 1I illustrates an alternative variation of a tractor and puller. In FIG. 1I, the tractor is shown attached to the distal end of a tapered or narrow puller; the distal end region is tapered, and includes a radiopaque marker at or near the attachment site to the tractor; the tractor may be knitted, braided, woven, etc. Thus, in some variations the distal end region of the puller may have a greater flexibility than the proximal end of the puller. The puller may be hollow (e.g., a catheter or hypotube) or solid (e.g., like a wire).

[00037] FIGS. 2A-2C illustrate a mechanical thrombectomy apparatus deploying prematurely within a vessel.

[00038] FIGS. 3A-3C illustrate a method of operating a mechanical thrombectomy apparatus that includes a tractor hold to prevent premature deployment.

[00039] FIGS. 4A-4C illustrate examples of mechanical thrombectomy apparatuses including a tractor hold that secures the tractor to the outer diameter of the catheter until release.

[00040] FIGS. 5A-5C illustrate examples of mechanical thrombectomy apparatus including a tractor hold as described herein.

[00041] FIG. 6A illustrates a catheter for a mechanical thrombectomy apparatus with an outer diameter that steps up from a first proximal outer diameter to a second, larger distal

outer diameter. FIGS. 6B-6D illustrate the catheter of FIG. 6A as part of different mechanical thrombectomy apparatuses having tractor holds that secure the tractor to the catheter.

[00042] FIG. 7A-7L illustrate examples of different elongate inversion supports for mechanical thrombectomy apparatuses. FIGS. 7A-7B illustrate a catheter portion of an elongate inversion support having both different diameters (e.g., a larger-diameter distal catheter connected to a smaller-diameter proximal region extending longitudinally in the proximal-to-distal axis), and a plurality of openings (e.g., cut-out regions, holes, etc.). FIGS. 7C-7D illustrate a catheter of an elongate inversion support having a plurality of opening formed therethrough. FIGS. 7E-7F illustrate another variation of a catheter of an elongate inversion support having a distal catheter region and an elongate support member formed by skive cutting the catheter. FIGS. 7G-7H illustrate another variation of an elongate inversion support having a distal catheter region and an elongate support member extending from the catheter region. FIGS. 7I-7J illustrate another variation of an elongate inversion support having a plurality or openings along the distal-to-proximal length. FIGS. 7K-7L illustrate another variation of an elongate inversion support having a minimal catheter region at the distal end forming a distal end opening that is connected to an elongate support (e.g., wire, tube, bar, rod, etc.).

[00043] FIGS. 8A-8D illustrate another example of an elongate inversion support that may be used as part of a mechanical thrombectomy apparatus. FIG. 8A shows the elongate inversion support. FIG. 8B shows a variation of the elongate inversion support of FIG. 8A including guide rings for the puller and tractor. FIG. 8C shows the elongate inversion support of FIG. 8B with the tractor and puller attached. FIG. 8D shows a mechanical thrombectomy apparatuses including that shown in FIG. 8C with an additional outer catheter.

[00044] FIGS. 9A-9C illustrate mechanical thrombectomy apparatuses, including apparatuses having pullers that may extend distally of the catheter (FIGS. 9B and 9C).

[00045] FIGS. 10A-10C illustrate an example of a mechanical thrombectomy apparatuses having a tractor hold configured to engage a tractor lock on the tractor.

[00046] FIG. 11A illustrates a method for removing clot using an intermediate catheter (e.g., sleeve) and a vacuum, in which a mechanical thrombectomy apparatus is extended from a distal end of the intermediate catheter to remove a clot.

[00047] FIG. 11B illustrates a method for removing clot using an intermediate catheter (e.g., sleeve) and a vacuum, in which a mechanical thrombectomy apparatus removes a clot that has been drawn into the distal end of the intermediate catheter.

[00048] FIGS. 12A-12C illustrates an example of the operation of a mechanical thrombectomy apparatus with an expandable distal end region (e.g., expandable distal end opening in the elongate inversion support.

DETAILED DESCRIPTION

[00049] In general, described herein are mechanical thrombectomy apparatuses having an inverting tractor region and an elongate inversion support having a distal annulus over which the tractor rolls and inverts over itself. Any of these apparatuses, and methods of using them, may be configured to prevent premature deployment of the tractor. The elongate inversion support may be a catheter having a distal end opening. The tractor may comprise a flexible tube that may be formed of a sheet having openings, or may be a woven, braided, knitted, etc. material such as a fiber. The tractor may extend longitudinally within the elongate inversion support and may and double back (e.g., invert) over the annulus of the elongate inversion support (e.g., the distal end of a catheter) so that it extends along the midline of the apparatus; when the elongate inversion support is a catheter, the tractor may extend within the catheter lumen. The tractor may connect to an inner puller that is typically coupled to an end of the tractor (which may be referred to as the inner end or the distal end) that can be pulled proximally to pull and invert the tractor over the distal end so that it rolls over the distal end, which may capture a clot. The apparatus may include a guidewire lumen extending through the catheter, tractor and/or tractor puller.

[00050] In general, a mechanical thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an elongate inversion support having a distal end and a distal annulus, and a flexible tractor assembly at least partially inverted and configured to roll and invert over the distal annulus of the elongate inversion support.

[00051] In many of the examples described herein, the elongate inversion support is a catheter (or a portion of a catheter at the distal end) and the annulus is formed by the distal end opening of the catheter; the tractor extends within the catheter and doubles back over the distal end of the catheter to extend over the outer diameter of the catheter at the distal end of the catheter, although it may extend proximal for any appropriate distance (including between 1-30 cm, between 2-20 cm, greater than 1 cm, 2 cm, 3 cm, 4 cm, 5 cm, 6 cm, 7 cm cm, 8 cm, 9 cm, 10 cm, 11 cm, 12 cm, 15 cm, 20 cm, etc.). The end of the tractor within the catheter may be coupled to a pusher (e.g., at a proximate pusher region connected to the distal or inner end of the tractor). The tubular tractor may include an elongate lumen that is configured to allow passage of a guidewire. The tubular tractor may also be configured to slide along the

long axis within the catheter lumen and invert over the distal end opening of the catheter when the proximal end region is pulled proximally. The tractor may be referred to herein as a tractor assembly, tractor portion, tractor tube, or simply a tractor, and is typically positioned and longitudinally slideable within the catheter, and arranged so a portion of the tractor (sometimes referred to as the "distal tractor region" or "distal-facing" tractor region) doubles back over itself.

[00052] For example, FIG. 1A shows one variation of a catheter that may form part of the apparatuses described herein. In this example, the catheter 100 includes a distal end region 103 that includes a distal end 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal tip (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing harness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00053] For example, FIG. 1A shows one variation of a catheter of an elongate inversion support that may form part of the apparatuses described herein. In this example, the elongate inversion support includes a catheter 100 having a distal end region 103 that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing harness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00054] In FIG. 1A, the elongate inversion support is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of of compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include a elongate inversion support that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like (as will be described in greater detail below in reference to FIGS. 7A-8D) or may be skived. Thus, any of the apparatuses and methods described herein may be adapted for use with an elongate inversion support that is not limited to catheters, including elongate inversion supports that include a portion of a catheter, or that include a ring or other structure forming the annulus at the distal end. In FIG. 1A the catheter 100 of the elongate inversion support may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00055] In some variations the distal end 105 of the elongate inversion support is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in some variations the distal tip (end) may be curved or radiused 109 as shown in FIG. 1B, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[00056] FIG. 1C shows an example of a flexible tractor 144 coupled to a puller 146. In this example to form a pullable tractor assembly 140, the tractor is shown integrated with the puller, forming the assembly. In FIG. 1C, the tractor is a tube of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The tractor is shown extended from the puller in a first configuration. It may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 144 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The puller 146 may typically be a less-expandable (or non-expandable) structure (tube, puller, etc.). In the example shown in FIG. 1C, the tractor 144 is configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first

configuration to a radial diameter that is between 1.1 and 10 times the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained, as shown in FIG. 1D. In FIG. 1D, the tractor of FIG. 1C is shown in an expanded, relaxed, configuration. Thus the expandable tractor may be biased to expand open. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00057] In FIGS. 1C and 1D the tractor and puller have two portions, a tractor 144 and a less expandable (or non-expandable) proximal portion comprising the puller 146. The puller may be a separate region, such as a wire, catheter or hypotube, which is connected to an end region of the tractor (e.g., a flexible mesh, woven, braided, etc.), e.g., the distal end or near the distal end. The inverting region of the tractor, where it rolls and inverts over the distal end opening of the catheter may be referred to as the distal-facing region of the tractor, which may actively grab clot when rolling.

[00058] In FIG. 1E, the flexible tractor of FIG. 1C is shown with the tractor doubled back over itself an over the the distal end of the catheter of the elongate inversion support 101. The distal end region is collapsed down, e.g., onto the puller and the elongate inversion support, and may be held collapsed. In this example a tractor hold 188 may be used to hold the tractor collapsed down onto the outer diameter of the elongate inversion support. However, in an unconstrained or deployed configuration, as shown in FIG. 1F, the tractor in this second configuration (e.g., the portion that is inverted over the distal end of the catheter) has an outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. Thus, the tractor 144 may be biased so that it has a relaxed expanded configuration in the first configuration (as shown in FIG. 1C) that is greater than the inner diameter (ID) of the catheter of the elongate inversion support portion of the apparatus and the relaxed expanded configuration of the second configuration (shown in FIG. 1F) inverted over the catheter has an OD that is greater than the OD of the catheter. The tractor is expandable and may be coupled to the puller. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to a push/pull wire or catheter.

[00059] FIGS. 1G and 1H illustrate the removal of a clot using an apparatus such as the apparatus assembled from the components of FIGS. 1A and 1E. In this example the apparatus is configured as a thrombectomy apparatus including a catheter of an elongate inversion support 101 and a flexible tractor that extends over the distal end region of the catheter and doubles-over itself at the distal end of the catheter to invert so that the external

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

[00060] These apparatuses may be highly flexible, both before actuating and during operation. For example, in general, the flexible tractor may not increase the stiffness/flexibility of the catheter, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortious vessels of the neurovasculature. Described herein are flexible tractor tube portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[00061] In any of the apparatuses described herein, in which the tractor is at least partially inverted over the distal end of the catheter so that the tractor extends on the outer surface of the catheter, the tractor may be releasably coupled to the outer diameter of the catheter to

allow the apparatus to be inserted through a body, including through tortious vessels in the body, prior to being deployed to remove a clot or other element from the vessel. The tractor may be a braided, woven or knit material tube of material that is inverted over the distal end of the catheter; alternatively the tractor may be formed of a sheet of material that include openings therethrough.

[00062] Any of the apparatuses described herein may be adapted to prevent premature deployment of the tractor, e.g., by including a tractor hold (e.g., a housing, a lock, a clamp, etc.) or the like to secure the outer end of the tractor against and/or relative to the elongate inversion support. For example, a tractor hold may secure the outer end of the tractor against a catheter into which the tractor inverts when pulled proximally by the puller.

[00063] An example of premature deployment is shown in FIGS. 2A-2C. For example, in FIG. 2A, the tractor 200 is guided over a guidewire 205 to a clot 255 (alternatively, the apparatus may be delivered without using a guidewire). In this example, the apparatus includes a tractor 203 that extends over and into a catheter 210. The inner end of the tractor is connected to a puller 207 (shown in this example as an inner catheter). The outer end 211 of the catheter is loose and is shown slightly expanded over the catheter outer diameter. As the apparatus is advanced distally towards the clot, shown in FIG. 2B, the tractor is, by virtue of being deployed, driven into the catheter prematurely, shortening the length of the tractor that is outside of the catheter and available to roll for capture of the clot. Further, the loose outer end of the tractor may interfere with accurate positioning of the apparatus. FIG. 2C illustrates the premature deployment compromising the rolling of the tractor 315. Once the tractor is prematurely deployed, moving it back and forth in the vessel to position it may result in the tractor, which may contact the vessel wall when deployed, folding or tangling, as shown in FIG. 2C.

[00064] In general, the apparatuses described herein are configured to prevent premature movement of the tractor on an outside, e.g., outer diameter, of the catheter during catheter access to a target location.

[00065] Any of the variations described herein may include a tractor hold that includes a sticky, tacky, gummy, or adhesive material on the tractor or between the tractor and the catheter over a portion of the tractor that is held against the outer diameter of the catheter. For example, as illustrated in FIGS. 4A-4C, the apparatus may include a sticky substance, like silicone, impregnated on the end of the tractor that is wrapped over the catheter (e.g., the outer end of the tractor, which may be referred to as the proximal-most most end of tractor). The sticky material may impregnated over a small portion of the tractor (e.g., local regions at

or near the proximal end and/or discrete regions, or patterns including spots, bands, etc. along the length of the outer portion of the tractor. The presence of the sticky regions may prevent premature slipping of the tractor (e.g., braid, woven, etc.) with respect to the catheter. For example, a silicone impregnated braid may sit on or over a section of the catheter that is not coated with a hydrophilic coating before the tractor is pulled around distal end opening of the catheter, which may help prevent the tractor from prematurely slipping off or over the catheter. As mentioned, a sticky (e.g., tacky, adhesive, gummy, etc.) region may be present on the entire tractor, on just an inside surface of the tractor (e.g., the surface that faces the catheter when applied over the outer diameter of the catheter), on both inner and outer surface of the tractor, and/or in discrete locations (including patterns) of the portion of the tractor outside of the catheter. For example, the apparatus may include a plurality of regions of sticky material arranged over the length of the proximal end of the tractor. In some variations the sticky material is arranged in a pattern. The material applied may be referred to as sticky with respect to the catheter (e.g., causing temporary and/or releasable attachment between the catheter and the tractor). In some variations, the sticky material may be coated or applied to the outer diameter of the catheter. When arranged in a pattern (e.g., on the tractor and/or OD of the catheter), the pattern of sticky material locations on the tractor (and/or catheter) may be arranged in multiple, non-contiguous locations along the length or the tractor. Patterns may include stripes, spirals, rings, spots, etc.

[00066] Alternatively or additionally, the tractor may be temporarily secured to the outside of the catheter through other methods to provide a temporary attachment of the tractor to the catheter outer diameter (OD). For example, a temporary attachment may be presented between the tractor and the catheter OD such that, when axial tension if applied to the tractor, e.g., by the user pulling the tractor to pull the tractor around catheter tip, the temporary attachment (e.g., a temporary bond, temporary securement, etc.) between the tractor and the catheter OD may be released, allowing the braid to slide relative to the catheter. Alternatively or in addition to the use of a sticky material between the tractor and the catheter, temporary attachments between the tractor and the OD of catheter may include: hydrophilic coatings on the tractor and/or catheter, and/or spot (including micro-spot) boding between the catheter and the tractor.

[00067] For example a hydrophilic surface on the tractor (e.g., inner face of the tractor) and/or catheter OD may be applied as a coating. The tractor may be pre-assembled onto the catheter and a hydrophilic/hydrophobic surface may provide a temporary attachment between the catheter and the tractor. A layer of hydrophilic coating (or two adjacent layers) may

secure the tractor to the catheter OD, and may help the apparatus track through a body vessel/lumen to the target location, after which the tractor may be deployed by pulling to separate the surfaces of the tractor and catheter OD, and to allow the tractor to roll over the distal end opening freely so that it may engage with a clot and draw it into the apparatus. In some variations, a hydrophilic coating may be separately applied to the tractor and/or the catheter. For example, the catheter OD and tractor may be separately coated with a hydrophilic coating and then assembled. When the apparatus is assembled (e.g., with the tractor over catheter distal end region, inverted and within the catheter), the coating on both subassemblies (e.g., tractor and catheter) may cold flow together. When the assembly is wetted in the body during catheter access and when approaching the target clot to be removed, the user may pull the tractor proximally (by pulling on the puller attached to the inner end of the tractor) which may slide the tractor with respect to the catheter OD, disengaging the tractor hold.

[00068] Alternatively the tractor hold can be formed by spot- or selectively bonding the tractor to the catheter OD. A spot or micro-bond may be adequate to prevent premature sliding of the tractor relative to the catheter OD during catheter access. For example, a spot bond or a plurality of micro-bonds can be created, e.g., by heat bonding (melting) or applying adhesive to attach the tractor to the catheter OD. The micro bonds can be placed circumferentially at several locations along the length of the braid, continuously along the braid/catheter contact length or in any other pattern, as discussed above.

[00069] FIG. 4A illustrates an example of a thermoplastic polyurethane (TPU) 404 that may be used to temporarily secure the tractor 406 to the outer diameter of the catheter; once in position, the distal end of the catheter (internal to the catheter) may be pulled proximally to break the material (in this example, pellathane) and release the tractor so that it may be rolled distally over the catheter to draw a clot into the catheter. In this example, the frangible (e.g., breakable) material is coated over a region on the catheter and/or tractor (shown here as a braided tractor) that does not include a hydrophilic coating). For example, the frangible material may be applied over a region that is masked (uncoated) from hydrophilic coating.

[00070] In FIGS. 4B and 4C, examples of mechanical thrombectomy apparatuses 400, 400' are shown, each having an outer catheter 409, and a tractor that extends over the distal end region of the catheter, and inverts over the distal end opening (annulus 411) of the catheter, and into the catheter where it connects to a puller 407. In FIG. 4B, the tractor is releasably adhered to the outer diameter of the catheter by a sticky (e.g., hydrophilic) region 414 that engages the outer end of the tractor to a region on the outer diameter of the catheter.

Thus, in order to pull the tractor proximally within the catheter and therefore roll the tractor over and into the distal end opening as described above (and shown, e.g., in FIG. 3C), an initial deployment force threshold (e.g., between 0.5 N and 50 N) may be required. Once the force is applied and the tractor is deployed to axially move distally over the outer surface, roll, invert and into the catheter, the force required to continue rolling may be substantially (e.g., the deployment force threshold may be 1.1x, 1.2x, 1.5x, 1.7x, 2x, 3x, 4x, 5x, 10x, or more the force required to roll the apparatus).

[00071] Similarly, in FIG. 4C, the apparatus may include a plurality of spot attachments 424 at the outer end of the tractor. As mentioned, there spots may be an adhesive attached into (e.g., into the mesh, etc.) of the tractor, or between the tractor and the outer diameter of the catheter. In both FIGS. 4B and 4C, the tractor may be held slightly in tension over the distal end region of the catheter, preventing the tractor from deploying and expanding, including expanding at the distal tip region (forming the trumpet-shaped opening such as shown in FIGS. 2A-2B).

[00072] Alternatively or additionally, any of the apparatuses described herein may include a tractor hold that is configured as a housing or garage for holding the outer end of the tractor, as shown in FIGS. 3A-3C and FIGS. 5A-5C. In these examples the tractor hold extends only partially down the catheter, which may prevent the hold from increasing the flexibility and maneuverability of the apparatus in the lumen. FIGS. 3A-3C illustrate the method of use of a variation of a mechanical thrombectomy apparatus 300 including a tractor hold 303. In this example, the tractor hold is positioned over the catheter, as shown in FIG. 3A, and holds the outer end of the tractor 305 against the outer diameter of the catheter 307. The tractor is connected to the puller 309. The tractor hold may be attached to the catheter (e.g., at a proximal end of the hold) or it may be applied over the catheter (e.g., shrink-wrapped over the catheter and the outer end of the tractor. The apparatus 300 may be guided over a guidewire 319, as shown, or it may be directed to the clot 355 within the vessel 360 without the use of a guidewire.

[00073] Once the distal end of the apparatus is near the clot, as shown in FIG. 3A, a force greater than a deployment threshold force (e.g., the force required to pull the tractor out of the tractor hold 303, leaving the tractor hold behind, and allowing the tractor to roll 382 over the distal end opening of the catheter, as illustrated in FIG. 3C. The apparatus may be advanced distally while pulling the inner end of the tractor proximally with the puller to invert and roll the tractor into the catheter. The tractor may then grab a clot and pull it into the catheter, as shown.

[00074] Similarly, in FIGS. 5A-5C, the apparatus 500 includes a tractor 503 coupled to a puller 507 at an inner end that is within a catheter 509. In this example, the outer end 504 of the tractor is pinned against the outer diameter of the catheter by a tractor hold 501 configured as a garage or housing. The housing may hold the end of the tractor lightly or it may secure it against the catheter more tightly, depending on the desired deployment threshold. In FIG. 5A, the tractor hold is secured to the outer diameter of the catheter by a weld or welds 505. Similarly in FIGS. 5B and 5C the tractor hold is secured by either being shrunk-fit to the outer diameter at the proximal end 515, or by an adhesive or glue 525, respectively.

[00075] In all of the examples shown in FIGS. 3A-3C and 5A-5C, the tractor hold extends only slightly down the length of the catheter, e.g., a few cm (e.g., less than 10 cm, less than 9 cm, less than 8 cm, less than 7 cm, less than 6 cm, less than 5 cm, less than 4 cm, less than 3 cm, etc.).

[00076] In any of the variations described herein, the elongate inversion support may have a different outer diameter along its axial (longitudinal) length. For example, although the catheter shown in FIG. 1A has a uniform diameter along its length, other apparatuses may include a catheter having a larger diameter at the distal end region than at more proximal regions, as shown in FIGS. 6A-8C. For example, in FIG. 6A, the elongate inversion support is a catheter having a larger outer diameter at the distal end than at the proximal end. The transition between the two regions is a step 605. The annular region (distal end opening 607) therefore has the same, larger, outer diameter as the distal end region. FIGS. 6B-6C, illustrates examples in which a tractor is held over the outer diameter and may be secured by a tractor hold. In general, particularly where the tractor is configured to contract down onto the tractor, simply having the transition, and particularly a rapid (including step) transition between a region of larger diameter and a region of smaller diameter, as shown in FIG. 6A, may help secure the tractor over the catheter. In FIG. 6B, the same catheter shown in FIG. 6A has had a tractor 603 attached so that it extends along the distal outer diameter region, inverts over the distal end opening 607, and into the catheter inner lumen, where it is connected to or integral with a puller 609. In FIG. 6B, the outer end of the tractor is held in place with a tractor hold 613; in this example, the tractor hold 613 is one or more arms that hold the tractor against the smaller inner diameter immediately adjacent to the step up to the larger diameter region of the catheter.

[00077] In FIG. 6B, the tractor hold is a narrower catheter 623 that extends proximally; the tractor is held between the distal opening of the tractor hold and the step up to the larger

diameter catheter 601. The outer surfaces of the tractor hold and the catheter 601 may be flush, e.g., having the same height. In FIG. 6B, if the tractor hold extends proximally far enough (e.g., to or beyond the end of the catheter) it may be actively disengaged, reducing or eliminating the deployment threshold force.

[00078] FIG. 6D shows another example of a tractor lock 633, similar to that shown in FIG. 6C, only extending partially proximally down the catheter. In any of these variations the tractor hold may be fixed to the outer diameter or it may be movable (e.g., slideable) relative to the outer diameter of the catheter.

[00079] FIGS. 7A-7L illustrate different variations of catheters that may be used as part of any of the apparatuses described herein. For example, FIG. 7A shows an example of a catheter 700 having a larger-diameter distal end region that also includes a plurality of openings, slots, holes, windows, slits, etc. 709. These openings may provide for delivery of fluid (including drugs) to the site of use, and/or removal of material, e.g., the application of vacuum through the apparatus, particularly useful when used with an intermediate catheter into which the apparatus (e.g., an elongate inversion support, a puller and tractor) is inserted, as will be described in greater detail below. FIG. 7B shows the apparatus of FIG. 7A with an attached puller and tractor.

[00080] FIGS. 7C and 7D illustrate another variation of a catheter that may be used as part of any of the apparatuses described herein, including, as here, catheters that have a plurality of cut-out regions. Similarly, FIGS. 7E and 7F show an example including a catheter having a large proximal skive region, leaving the majority of the outer diameter much smaller than at the distal end region, as shown. In addition, the distal end of the catheter may include openings, slots, cut-out regions, etc. 725. FIG. 7F shows the catheter of FIG. 7E with a tractor 714 coupled on an inner end to a puller 713. The puller is still pulled within the lumen of the catheter. A similar example is shown in FIGS. 7G and 7H, however instead of being skived, the elongate inversion support includes a distal portion formed of a catheter having cut-out regions 725 that is coupled to a rod, pole, wire or (as shown) a hypotube. This hypotube may be used as a guidewire lumen and/or as a channel for a stiffening or support member that may, once the device is positioned, enhance the column strength to allow pulling of the tractor proximally when inverting the tractor to roll.

[00081] FIGS. 7I and 7J illustrate an example of a catheter (FIG. 7I) and an apparatus including the catheter (7J) in which the sides of the catheter have been slotted, which may provide enhanced flexibility while maintaining column strength. An apparatus including the catheter of FIG. 7I is shown in FIG. 7J, also including a tractor and puller.

[00082] FIG. 7K is an example of an elongate inversion support in which the distal end is a cylinder 716, formed, for example, from a very small portion of a catheter. The distal end opening (annulus 707) may be used to invert the tractor, as shown in FIG. 7L. The elongate shaft 717 of the elongate inversion support may be a rod, tube, wire, etc. as described above. An additional outer catheter 726 may be included in any of these apparatuses, as shown in the exemplary apparatus shown in FIG. 7L, which includes the elongate inversion support of FIG. 7K.

[00083] FIGS. 8A-8D also illustrate another example of an elongate inversion support having a distal annulus or aperture 743, shown in this example a ring (e.g., toroid ring) bonded to a hypotube 746 (which may alternatively be a rod, wire, small-diameter catheter, etc.); as mentioned above, a stiffening member may be inserted into the elongate body of the elongate inversion support prior to or during pulling of the tractor proximally through the distal annulus. FIG.8B shows a similar variations of the elongate inversion support of FIG. 8A, only with a plurality of guides 750 extending down the length of the support into which the tractor puller and/or tractor may be held, as illustrated in FIG. 8C. In this example, the tractor 810 extends over the elongate inversion support and can be pulled proximally by the tractor puller 812. Although the tractor puller is shown as a catheter, in any of the apparatuses described herein, the tractor puller may instead be a wire, hypotube, etc. as mentioned above. FIG. 8D is an apparatus similar to that shown in FIG. 8C with the addition of an outer catheter 809.

RELEASABLE LOCK

[00084] In some variations, the tractor hold and distal end region of the catheter to which it is applied over may be configured as (or may include) a releasable lock, in addition to or instead of the tractor holds described above (e.g., a sticky materials, frangible release, housing, etc.). For example, the catheter may include a tractor hold comprising a friction lock (e.g., bump, protrusion, enlarged diameter, region, O-ring, etc.) on the outer diameter of the catheter that engages with a locking region (e.g., construction, inward-pointing bump, sticky coating, etc.) on the outer (e.g., proximal) end region of the tractor. The locking region on the outer end portion of the tractor may be proximally beyond the locking region (e.g., friction bump) on the catheter, so that the catheter locking region may be initially held beneath the tractor. When force is applied (e.g., deployment force applied by the user) to pull the tractor region proximally from the inside of the tractor, the force may overcome the locking engagement between the tractor locking region (e.g., constriction, inwardly-facing

protrusion, etc.) and the locking catheter locking region (e.g., friction bump, radial enlargement, O-ring, etc.) and the tractor may be released roll distally over the catheter. See FIGS. 10A-10C for an example of this arrangement. Note that this releasable lock may be used in combination with any of the features described above. In FIG. 10A-10C, the tractor 1007 includes a tractor lock 1006 at the outer end of the tractor. FIG. 10A shows just the tractor and puller 1003. The mechanical thrombectomy apparatus 1000 shown in FIG. 10B also includes a catheter 1011, and the catheter includes a tractor hold 1009. The tractor hold engages with the tractor lock; in FIG. 10B, the tractor hold is a protrusion that holds the tractor lock on the tractor on a proximal side of the tractor hold, until sufficient force is applied above the deployment threshold to deploy the tractor by pulling the tractor lock distally over the tractor hold, allowing the tractor 1007 to deploy and/or expanded, and be rolled over the distal end opening of the catheter, to capture a clot.

[00085] In any of these variations, but particularly the locking variations described herein, the tractor region may be held in tension, although tension is not necessary. Alternatively or additionally, a second outer cover or catheter may be used, or may be absent.

APPARATUSES HAVING DISTAL-EXTENDING PULLERS

[00086] In any of the variations described herein, the puller may extend more distally than the tractor in the apparatus. For example, a pre-assembled apparatus having the distal end of a tractor puller (e.g., catheter, hypotube, wire, etc.) that extends more distally beyond the catheter(s) or the rest of the apparatus may be used to help capture the clot. As mentioned above, any of these variations may include the use of a vacuum, e.g., for aspirating the clot. The vacuum may be applied through the puller. It may be easier to grab onto a clot when using aspiration to initiate the grabbing.

[00087] For example, FIG. 9A illustrates an example of a mechanical thrombectomy apparatus similar to that described above. The tractor 903 is connected to a puller 905 and the tractor extends along the outer diameter 901 of the catheter. In some variations, the tractor may be infused, bonded or laminated with a stiffening element in part to make it less likely that the tractor collapses in diameter when the dozer catheter is pulled and allows for vacuum applied to the applied to the proximal end of the tractor puller 905 to exert force/vacuum on the clot via the distal end of the assembly, as shown in FIGS. 9B and 9C.

[00088] In FIG. 9B, the tractor is coupled to a portion of the tractor puller 905 that is proximal 921 to a distal end of the puller. Thus, as the puller is extended distally, the tip may

extend past the distal end of the catheter, prior to inverting the tractor. FIG. 9B also shows an (optional) tractor hold 917

[00089] In FIG. 9C, the apparatus includes a stop element attached at or near the distal end of the puller 905. A sliding ring 911 on the tractor may be used to allow the puller to slide distally without pulling on the tractor; only when the puller is withdrawn proximally far enough that the stop 909 engages with the sliding ring 911 does the puller pull the tractor proximally, and invert the tractor over the distal end opening of the catheter, rolling the tractor an pulling in any clot material, which may be aided by the application of vacuum 914 through the puller. Thus, this arrangement may allow the user to extend the tractor puller distally at lengths beyond the distal end of the catheter without pulling the tractor distally.

[00090] In any of the variations described herein, including those shown in FIGS. 9A-9C, the apparatus may be coupled to a valve 923 for connection to a vacuum source 914. The vacuum may be connected to the elongate inversion support (e.g., catheter) and/or to the puller, as shown in FIGS. 9A-9C.

[00091] Any of the apparatus variations described herein may include a lubricous coatings such as hydrophilic coatings applied on the OD &/or ID of the tractor, on any and all sections, and/or on the outer or inner diameter of the elongate inversion support (e.g., catheter).

[00092] In general, the apparatuses described herein may allow delivery of a guidewire and/or a smaller catheter through the outer catheter and tractor, which may be useful for both guidewire operation (for clot access) and also for applying optional vacuum. In addition, the tractors described herein may have minimal to no collapsing when they are inverted inside the outer catheter when under axial tension, which may prevent jamming on the catheter distal tip and may reduce the amount and/or volume of clot that can be extracted. Further, any of the tractors described herein may have adequate coarseness to grab the clot, yet still roll smoothly around the distal annulus. Typically, the tractor does not adversely affect catheter tracking, as it may be extremely flexible and slippery.

[00093] As just discussed above, the pre-loaded tractors described herein may not slide with respect to the OD of catheter during vessel access. The tractor may only slide on the OD of catheter when the user pulls the tractor puller.

[00094] In general, the user may advance the elongate inversion support (e.g., catheter) forward while holding the tractor puller fixed, thereby enveloping clot in place rather than pulling clot to catheter. Further, the tractor may be biased (e.g., heat-shaped) to a preferred configuration to help grab clot effectively and roll nicely around the catheter tip. In general,

the distal end of the catheter (tip) may be stiffer than the catheter section just proximal to the tip (to allow rolling of dozer around tip). The tip may include a lubricious coating. The catheter tip may have a radius of > 0.00025", > 0.00035", > 0.0004", > 0.0004", > 0.00025", or < 0.0005" to allow rolling of tractor more easily. For example, the catheter tip hardness may be greater than >72D, and/or may be formed of a polymeric material such as PTFE, nylon, PEEK, stainless steel, etc.

[00095] In some variations, the distal region (e.g., distal 5 cm, 10 cm, etc.) of the catheter allows for tracking through 1/8" diameter radius and also has a limited axial compress to <10% of the distal catheter length during axial compression loads of, e.g., 100g, 200g, and 300g, etc. when pulling in the dozer and grabbing clot.

[00096] As mentioned above, any of these apparatuses may allow for the delivery of guidewire and/or smaller catheter through aspiration catheter. In general, the tractor may be configured to have a Poisson ratio <1.5 (e.g., <1.2, <1.1, etc.) when under tension (this helps prevent the tractor from jamming on catheter tip).

[00097] In any of the variations described herein, the tractor and/or catheter may be radiopaque. For example, a band or region may be radiopaque. The entire tractor may be radiopaque, e.g., NiTi wire filled with PT or Tantalum (DFT wire) may be used to form the tractor. Alternatively, the proximal and/or distal end of the tractor may have radiopaque markers.

[00098] The apparatuses described herein may be used to remove materials such as clots, including to prevent or treat stroke. For example, the apparatuses described herein may be used to track up through the siphon of the carotid artery, which is typically highly tortious. When pulled, the tractor may roll around the catheter distal end without locking up, while still grabbing clot. As mentioned, any of these apparatuses may also work in combination with a vacuum. The use of a vacuum may be unnecessary, but may be beneficial, particularly when initially engaging the clot with the tractor region and/or the distal end of the catheter. Any of the apparatuses described herein may also be configured to grab a clot in a large variety of vessels, including those ranging from 1.5 mm to 3.5 mm, even when the catheter has approximately the same outer diameter as the inner diameter of the vessel, or where the catheter is otherwise corked in the vessel.

APPARATUSES ADAPTED FOR USE WITH ASPIRATION

[00099] As mentioned, any of the apparatuses described herein may be adapted for use with a vacuum to apply suction (e.g. aspiration) to assist in clot removal. Although the

device may be used without the use of aspiration, in some instances clot removal may be aided by the use of the mechanical atherectomy apparatuses described herein. Furthermore, traditional techniques for removing a clot using aspiration (e.g., using a simple flexible catheter, commonly referred to as an intermediate catheter) may be improved by the use of the mechanical atherectomy apparatuses described herein. Use of aspiration alone often results in clogging of the intermediate (aspiration) catheter and may therefore have trouble removing the entire clot, particularly in the tortious vessels. Any of the apparatuses described herein may be used with an intermediate catheter, and may be adapted for use with vacuum clot removal technique, including being adapted to permit vacuum to be applied while the apparatus is within the lumen of the intermediate catheter, so that aspiration may still be applied from the distal end of the intermediate catheter and/or the apparatus, as well as permitting aspiration to be applied while the apparatus is extended distally from the intermediate catheter. The applied vacuum may aid in initially gasping or grabbing the thrombus. The vacuum may be applied from the distal end of the apparatus and/or of an intermediate or outer catheter or sleeve that is used with the apparatuses (e.g., elongate inversion support and inverting tractor). Also described herein are apparatuses that are adapted for use with a vacuum, including for use with an intermediate or outer catheter through which the apparatus may be delivered to the clot. The apparatus may grab clot from within the outer catheter, or it may be extended distally out of the intermediate or outer catheter. For example, FIGS. 7A-8D, described above and in additional detail below, are examples of elongate inversion supports that may be used in any of the apparatuses described; these elongate inversion supports may be particularly well suited to applying aspiration from the intermediate catheter.

[000100] FIG. 11A shows an example of a configuration in which an outer/intermediate catheter or sleeve that is highly flexible may be maneuvered, for example with a guidewire, to a distal end of the device. Thus, the intermediate catheter may be maneuvered near, or adjacent to, the thrombus. As in any of these methods of use described herein, imaging (such as fluoroscopy, contrast imaging, etc.) may be used. Once in positioned, the guidewire may be removed or left in place, and the apparatus including the elongate inversion support and inverting tractor may be extended within the intermediate catheter/sleeve. In FIG. 11A, the intermediate catheter 4104 is shown positioned within the vessel 4109 distally. As with any of the illustrations here, in the vessel maybe highly tortious and branching, although for convenience it is shown as straight in the figures. The apparatus 4100 is extended distally through the intermediate catheter, and extends out of the distal opening of the intermediate

catheter to grab the clot 4111, as shown. The puller 4105 may thus be drawn proximally (to the left in the figure) to pull the tractor 4103 from over the catheter portion of the elongate inversion support 4113, so that it inverts and rolls into the lumen of the elongate inversion support, capturing and drawing the clot in with it. The clot may be compressed.

[000101] Thus, this configuration may be referred to as a vessel cleaner. In addition to the rolling of the tractor to grab and pull the clot, the clot may be pulled by a vacuum applied from one or both of the intermediate catheter 4121 and/or the elongate inversion support 4123. Vacuum may be applied, e.g., within the intermediate catheter, before the apparatus is positioned distally (or even within the intermediate catheter at all) or after it has been extended distally from the intermediate catheter. This configuration shown in FIG. 11A may introduce the tractor through outer catheter to the face of clot. As mentioned, the mechanical thrombectomy apparatus may be extended distally from the intermediate catheter either by pushing it out distally and/or by pulling back the intermediate catheter to deploy all or part of the tractor into vessel, as shown. If vacuum is applied through the catheter, the catheter forming the elongate inversion support may be jacketed or sealed to allow aspiration through this catheter.

[000102] Optionally pull vacuum through outer and/or inner and/or puller. As mentioned, thereafter the tractor may be pulled proximally relative to the the elongate inversion support to pull the clot. The intermediate catheter may then be advanced distally and/or the mechanical thrombectomy apparatus may be withdrawn proximally to remove the apparatus once the clot has been removed. Thereafter an angiogram may be taken to confirm that the clot has been removed.

[000103] Alternatively, in FIG. 11B, a clot may be removed using the intermediate catheter to draw a vacuum with the mechanical thrombectomy apparatus within the lumen (e.g., near the distal end, but not extending fully from the distal end) of the intermediate catheter. As described for FIG. 11A, in FIG. 11B the intermediate catheter may be inserted into the vessel (e.g., using a guidewire) so that the distal end is positioned near the clot. Suction may be used to draw the clot into the intermediate catheter either before the mechanical thrombectomy device is inserted or after it has been inserted.

[000104] In FIG. 11B, the elongate inversion support 4113' is particularly well suited for use with a vacuum applied through the intermediate catheter 4104 surrounding the apparatus. For example, in FIG. 11B, the elongate inversion support 4113' include a distal catheter region 4125 that extends just a few cm from the distal end opening in which the clot is drawn. The elongate inversion support then tapers down to an elongate support, which may be

formed by a wire, hypotube or skived region. This configuration may prevent the catheter from blocking the lumen of the intermediate catheter and and therefore increasing the resistance of the vacuum before it can reach the open distal end and apply suction to drawn the clot. Alternatively or additionally, the outer diameter of the catheter portion of the elongate inversion support may be sized to allow more of the vacuum to pass. For example, the apparatus may be sized such that there is at least about 0.002 inches or greater (e.g., 0.003, 0.004, 0.005, 0.006, etc., inches) between the outer diameter of the catheter and the inner diameter of the intermediate catheter ("outer catheter"). This may also permit unimpeded rolling of the tractor over the distal end opening of the elongate inversion support.

[000105] In operation, the method of removing clot such as shown in FIG. 11B may include pulling at least the tip of a clot into the intermediate catheter through the use of a vacuum 4121. Typically the clot may clog within the intermediate catheter; the mechanical thrombectomy apparatuses described herein may be used to remove the clot from within the intermediate catheter. For example, while maintaining vacuum, the mechanical thrombectomy apparatus may be inserted (or it may be preloaded in intermediate catheter as mentioned) and the tractor puller 4105 may be pulled to pull the clot out of the intermediate catheter and the vessel, compress and/or macerate it and pull it into the apparatus and therefore the intermediate catheter, where it can be withdrawn proximally, e.g., by removing the mechanical thrombectomy apparatus. As mentioned, an angiogram may be taken through intermediate catheter (e.g., leaving it in place in case the mechanical thrombectomy apparatus needs to be re-inserted and used to remove more clot) to confirm clot has been removed.

[000106] As mentioned, a full catheter such as shown in FIG. 11A may block or prevent the vacuum from reaching the distal end of the intermediate vessel. Therefore it may be beneficial to adapt the mechanical thrombectomy apparatus so that it can be used with vacuum within an intermediate catheter or sleeve, as shown in FIG. 11B. This may be achieved as mentioned above, by minimizing the larger-diameter catheter portion of the elongate inversion support forming the distal end opening over which the tractor inverts. Returning now to FIGS. 7A-8D, in FIG. 7A, the elongate inversion support 700 has a distal catheter portion 701 having a larger diameter than the more proximal region 703, and also includes a plurality of openings, holes, gaps, cut-out regions, slots, etc. 709 that may allow the flow of vacuum through the elongate inversion support more easily. The elongate inversion support shown also includes a distal end 707 into which a tractor 711 inverts, as shown in FIG. 7B. IN FIG. 7B, the elongate inversion support is shown transparent so that the puller 713 and tractor within the elongate inversion support is visible.

[000107] Similarly, in FIGS. 7B and 7C, the entire length of the elongate inversion support includes a plurality of cut-out regions 713 which may increase the ability to allow the flow of a vacuum or other fluid within the apparatus, but may still allow the elongate inversion support to provide column strength to resist collapsing up to at least 500 g of compressive longitudinal force applied by, e.g., pulling on the tractor. Similarly, the elongate inversion support of FIGS. 7E and 7F show a skived catheter that also includes openings 709 along its length. The puller and tractor 412 are shown within the elongate inversion support in FIG. 7F. FIGS. 7G and 7H illustrate an example in which rather than a skived portion of the catheter, the distal catheter region of the elongate inversion support is formed by a wire, bar, tube, 721 etc., that is attached to the catheter at the distal end. The catheter may also optionally include openings 709. The elongate inversion support of FIGS. 7I and 7J includes openings 709' along all or much of its length (particularly near the distal end region) as shown.

[000108] Finally, the variation of the elongate inversion support shown in FIG. 7K includes a minimal catheter portion (cylinder 716) that is connected to a wire, bar, tube, hypotube, skived region, etc. 717.

[000109] FIGS. 8A-8D illustrate the operation of a similar minimal elongate inversion support 800. In this example, the apparatus includes a distal aperture 743 bonded securely to a wire, bar, tube, hypotube, skived region, etc. 746 forming an elongate support. The elongate support may be hollow (e.g., may include a lumen for a guidewire) or solid. The elongate support may also include one or more additional support guides 750 as shown in FIG. 8B. These supports may help contain the puller and/or tractor within the elongate inversion support. Any of the elongate inversion supports described herein may include additional support guides. The elongate inversion support of FIG. 8B is shown with a tractor 711 and puller 713 in FIG. 8C. As mentioned, this variation may be particularly well suited for use with an intermediate (e.g., "outer") catheter, sleeve, or the like 809, as shown in FIG. 8D.

EXPANDABLE DISTAL ENDS

[000110] Any of the mechanical thrombectomy apparatuses described herein may include an elongate inversion support having a distal end that is expandable from a smaller diameter aperture (e.g., distal end opening) to a larger-diameter aperture. This expansion may be performed by pulling the clot within the catheter. For example, FIGS. 12A-12C illustrates the operation of an example of an elongate inversion support configured as a catheter having

an expandable distal end. In this variation the catheter distal end 4401 may include slots or slits 4403 formed or cut, e.g., by laser-cutting, in the distal end of the catheter of the elongate inversion support. The apparatus may be operated as described above, positioning near (e.g., against or adjacent to) a clot, and pulling proximally on the puller to draw the tractor 4405 into the catheter, as shown in FIG. 12B. Although the apparatuses described herein may generally compress a clot greatly, compression may be made easier and/or more efficient by providing a more gradual decrease in radial diameter. As shown in FIG. 12B, when the tractor is rolled over the distal end opening and inverted, the clot maybe drawn in along with the tractor. As the large clot 4413 is brought into the distal end opening, the distal end opening may expand and open along the slots or slits 4403, as shown in FIG. 12C, so that the distal end opening flares out. In some variations an elastic sleeve, gasket, ring or cover (not shown in FIG. 12A-12C) may be included at least partially covering the distal end to prevent the edge from catching the tractor. For example, and elastic or stretchable layer may cover the cut distal end so that the distal end may be opened to form an outward flare. In FIG. 12C the outward-flared distal end is shown forming a funnel-shape into which the clot may be pulled. This funnel-shaped opening may help compress the clot so that it may be drawn into the mechanical thrombectomy apparatus.

[000111] In some variations the elongate inversion support may be configured to have, or to assume, a funnel-shape at the distal-facing end. The distal-facing end may always have a funnel-shaped mouth at the distal end opening, or the distal end opening may be configured to assume a funnel shape, as shown in FIGS. 12A-12C. In some variations the distal end of the elongate inversion support is configured to be elastic in a radial directly, but maintain stiffness along the proximal-to-distal axis (in compressive load). For example, the distal end of the elongate inversion support may be configured with strands or rods extending in the proximal-to-distal axis that have a high compressive load strength, but which may separate from each other to enlarge the distal end opening; for example they may be connected by rings in which more distal rings are more elastic/stretchable than more proximal rings.

[000112] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present.

In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[000113] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[000114] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[000115] Although the terms “first” and “second” may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[000116] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising" means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term "comprising" will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

[000117] In general, any of the apparatuses and methods described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may alternatively be exclusive, and may be expressed as "consisting of" or alternatively "consisting essentially of" the various components, steps, sub-components or sub-steps.

[000118] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or "approximately," even if the term does not expressly appear. The phrase "about" or "approximately" may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For example, if the value "10" is disclosed, then "about 10" is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that "less than or equal to" the value, "greater than or equal to the value" and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value "X" is disclosed the "less than or equal to X" as well as "greater than or equal to X" (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point "10" and a particular data point "15" are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[000119] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[000120] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

What is claimed is:

1. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:
    a catheter having a proximal end and a distal end and a distal end opening;
    a tractor comprising a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter;
    a puller coupled to the first end of the tractor, wherein the puller extends within the catheter to the proximal end of the catheter; and
    a tractor hold attached to an outer diameter of the catheter proximal to the distal end of the catheter, wherein the tractor hold secures a second end of the tractor to an outside surface of the catheter until a force greater than a threshold force is applied by pulling the first of the tractor proximally within the catheter
    wherein the threshold force is between 50 g of force and 500 g of force.

2. The apparatus of claim 1, further comprising a guidewire lumen extending through the catheter, the puller and the tractor, and configured to pass a guidewire.

3. The apparatus of claim 1, further wherein the tractor hold does not extend to the proximal end of the catheter.

4. The apparatus of claim 1, wherein the tractor hold extends proximally along the catheter for less than 10 cm.

5. The apparatus of claim 1, wherein the tractor hold compresses the tractor against the catheter.

6. The apparatus of claim 1, wherein the tractor hold is configured to hold the second end of the tractor until the threshold force is applied, wherein the threshold force is between 200 g of force and 500 g of force.

7. The apparatus of claim 1, wherein tractor is biased to expand beyond an outer diameter of the distal end of the catheter in a first relaxed configuration, further wherein the tractor is biased to expand to a second relaxed configuration having an outer diameter that is greater than an inner diameter of the distal end of the catheter, wherein the tractor converts between the first configuration and the second configuration by inverting.

8. The apparatus of claim 1, wherein a proximal end of the tractor hold is attached to the catheter.

9. The apparatus of claim 1, wherein the catheter comprises a larger outer diameter region and a smaller outer diameter region that is proximal to the larger outer diameter region, further wherein the tractor hold secures the tractor at one or more of: over the smaller outer diameter region, and between the larger outer diameter region and the smaller outer diameter region.

10. The apparatus of claim 9, wherein an outer diameter of the tractor hold is flush with the larger outer diameter region.

11. The apparatus of claim 9, further comprising a stepped transition between the larger outer diameter and the smaller outer diameter.

12. The apparatus of claim 1, wherein the tractor hold comprises one or more of: a polyether block amide, a polyolefin, a polyethylene, a polypropylene, a polyethylene terephthalate (PET), and a Polytetrafluoroethylene (PTFE).

13. The apparatus of claim 1, further comprising a tractor lock on the second end of the tractor, wherein the tractor lock engages with the tractor hold to secure the tractor lock on a proximal side of the tractor hold until the threshold force is applied by pulling the first of the tractor proximally within the catheter.

14. The apparatus of claim 13, wherein the tractor lock comprises a band configured to slide over the outer diameter of the catheter.

15. The apparatus of claim 13, wherein the tractor hold comprises a projection extending from the outer diameter of the catheter.

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

a catheter having a proximal end and a distal end and a distal end opening, wherein the catheter comprises a larger outer diameter region and a smaller outer diameter region that is proximal to the larger outer diameter region;

a tractor comprising a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter;

a puller coupled to first end of the tractor, wherein the puller extends within the catheter to the proximal end of the catheter; and

a tractor hold on an outer diameter of the catheter proximal to the distal end of the catheter, wherein the tractor hold secures a second end of the tractor that extends over the distal end of the catheter until a force greater than a threshold force is applied by pulling the first of the tractor proximally within the catheter, further wherein the tractor hold secures the tractor at one or more of: over the smaller outer diameter region, and between the larger outer diameter region and the smaller outer diameter region.

17. A method of removing a clot using a mechanical thrombectomy apparatus, the method comprising:

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

disengaging a second end of the tractor from a tractor hold that secures the second end of the tractor to an outer diameter of the catheter by applying a first force that is greater than a threshold force to the first end of the tractor;

pulling the distal end of the tractor proximally within the catheter to roll the tractor over the distal end of the catheter so that the tractor inverts over the distal end of the catheter; and

drawing the clot into the catheter with the inverting tractor.

18. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises disengaging the second end of the tractor from a tractor hold attached to an outer diameter of the catheter.

19. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises disengaging the second end of the tractor from a tractor hold that extends proximally along the catheter for less than 10 cm.

20. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises disengaging the second end of the tractor from a tractor hold that is open at a distal-facing end and wherein a proximal end of the tractor hold is attached to the outer diameter of the catheter.

21. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises disengaging the second end of the tractor from a tractor hold that secures the second end of the tractor over a smaller outer diameter region of the catheter that is distal to a larger outer diameter region of the catheter.

22. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises disengaging the second end of the tractor from a tractor hold that secures the second end of the tractor between a larger outer diameter region of the catheter and a larger outer diameter region of the catheter, wherein the larger diameter outer region is distal to the smaller outer diameter region.

23. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises disengaging a tractor hold from a tractor lock, wherein the tractor lock is on the second end of the tractor.

24. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises compressing either or both the tractor hold and a tractor lock on the second end of the tractor so that the tractor lock moves from a position proximal to the tractor hold to a position that is distal to the tractor hold.

25. The method of claim 17, wherein disengaging the second end of the tractor from the tractor hold comprises pulling the first end of the tractor with the first force wherein the threshold force is between 50 g of force and 500 g of force.

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

a catheter having a proximal end and a distal end and a distal end opening;

a tractor comprising a flexible tube that extends within the catheter, inverts over the distal end opening of the catheter and extends over the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter;

a puller having a proximal end and a distal end, wherein the first end of the tractor is coupled to the puller at a region that is proximal to the distal end, further wherein the puller extends within the catheter to the proximal end of the catheter;

a guidewire lumen extending through the catheter, the puller and the tractor, and configured to pass a guidewire.

27. The apparatus of claim 26, further comprising a stop between the distal end of the puller and the distal end opening.

28. The apparatus of claim 26, further comprising a stop on the puller between the distal end of the puller and the first end of the tractor, wherein first end of the tractor is coupled to a sliding ring configured to slide over the puller until it engages the stop.

29. The apparatus of claim 26, wherein there is 2 mm or greater distance between the distal end of the puller and the region of the puller to which the first end of the tractor is coupled.

30. The apparatus of claim 26, wherein the proximal end of the puller is configured to couple to a vacuum source.

31. The apparatus of claim 26, wherein the proximal end of the puller comprises a Tuohy-Borst valve/rotating hemostasis valve (RHV).

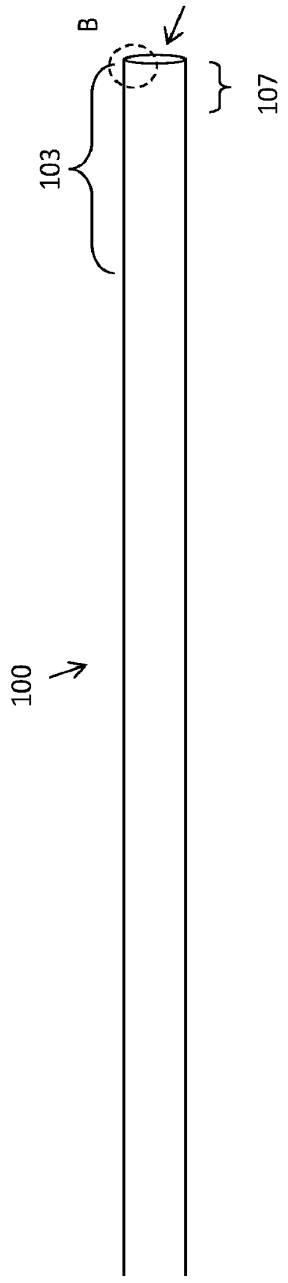


FIG. 1A

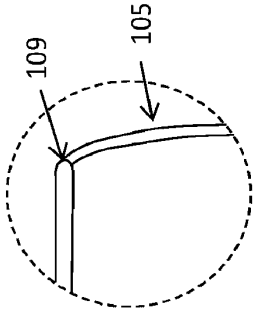


FIG. 1B

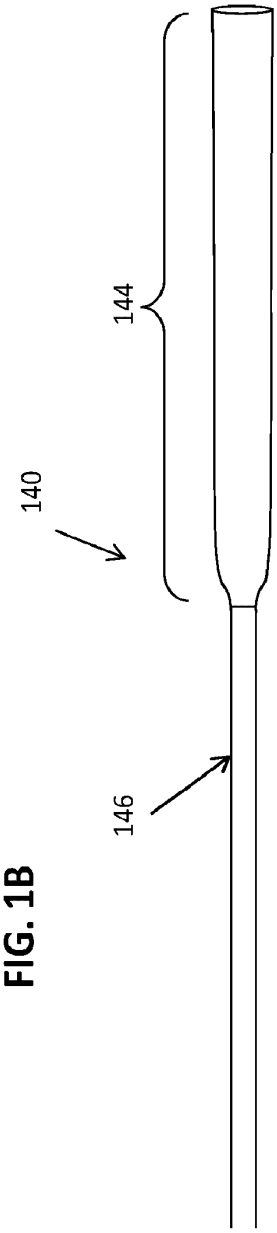


FIG. 1C

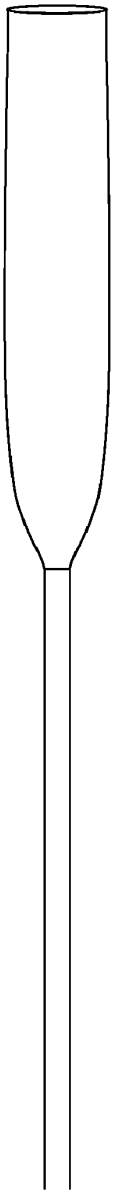


FIG. 1D

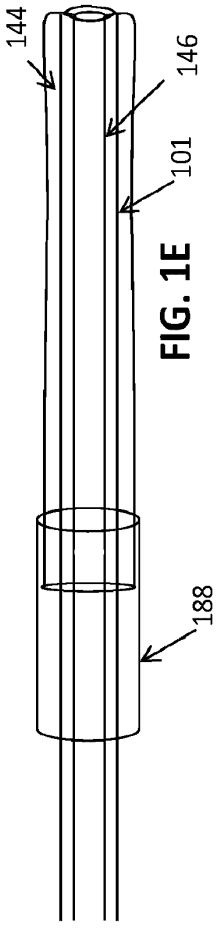


FIG. 1E

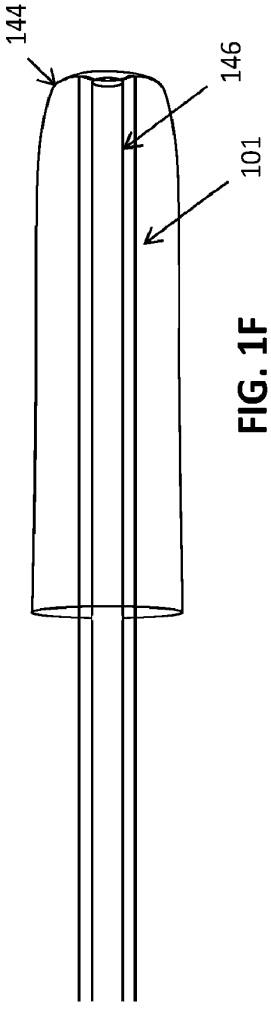


FIG. 1F

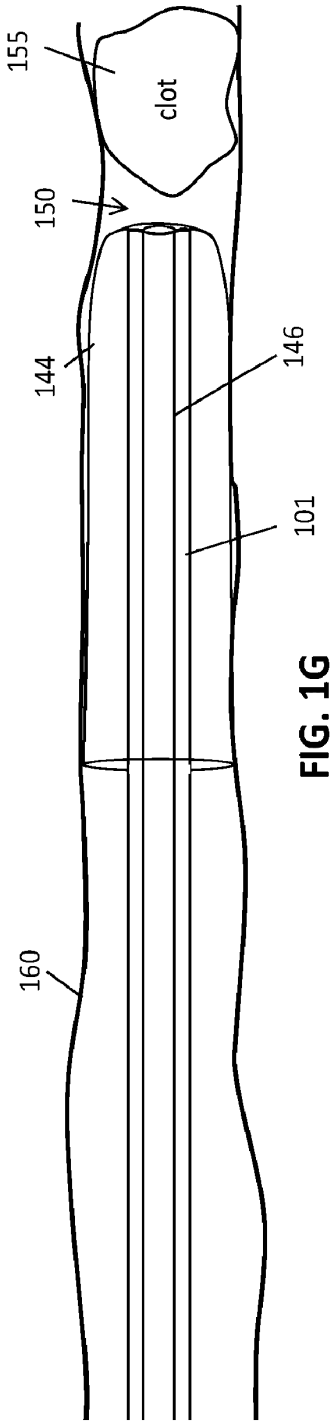


FIG. 1G

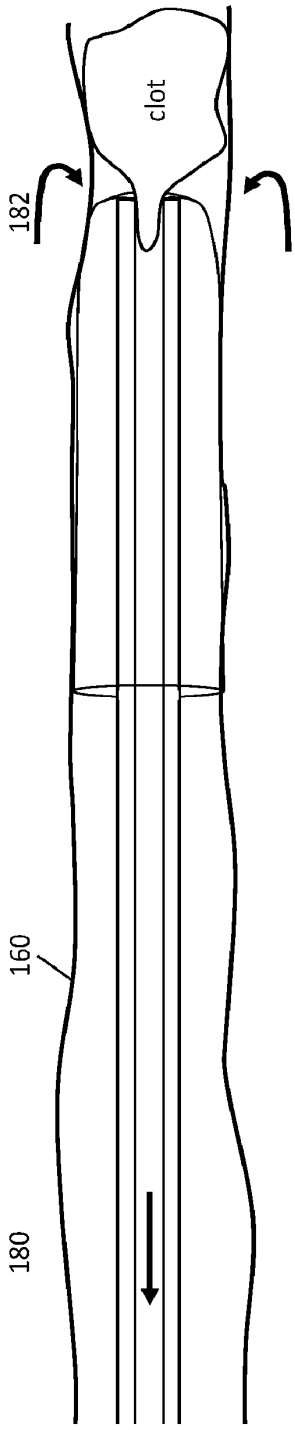


FIG. 1H

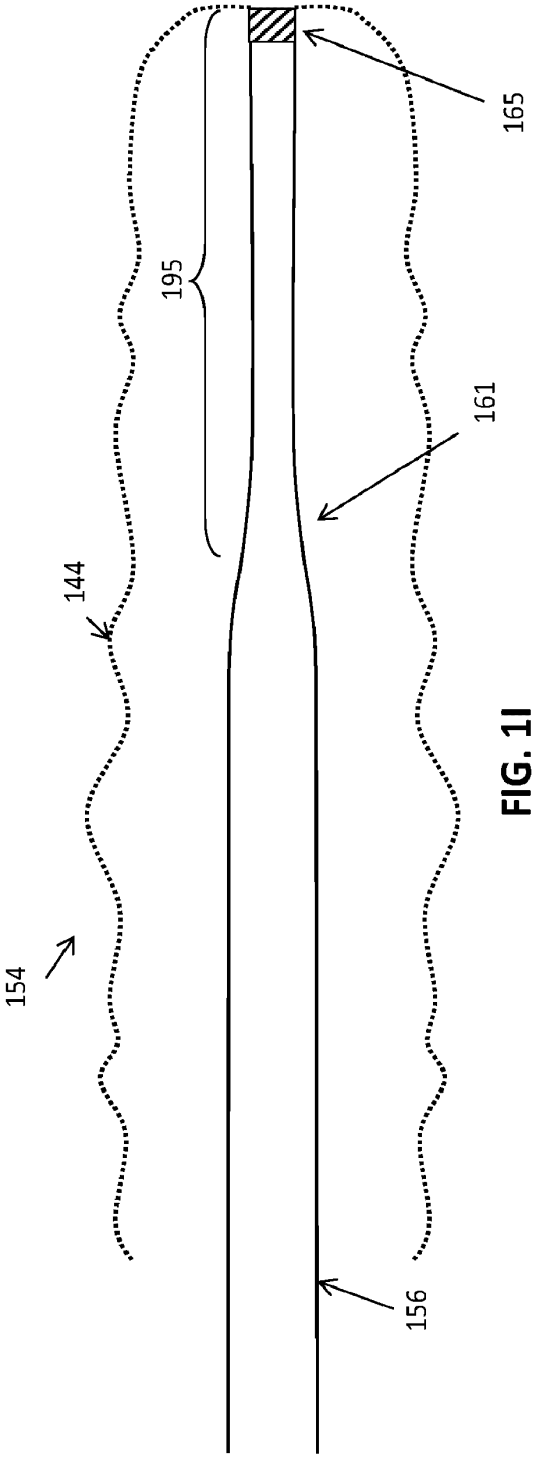


FIG. 1I

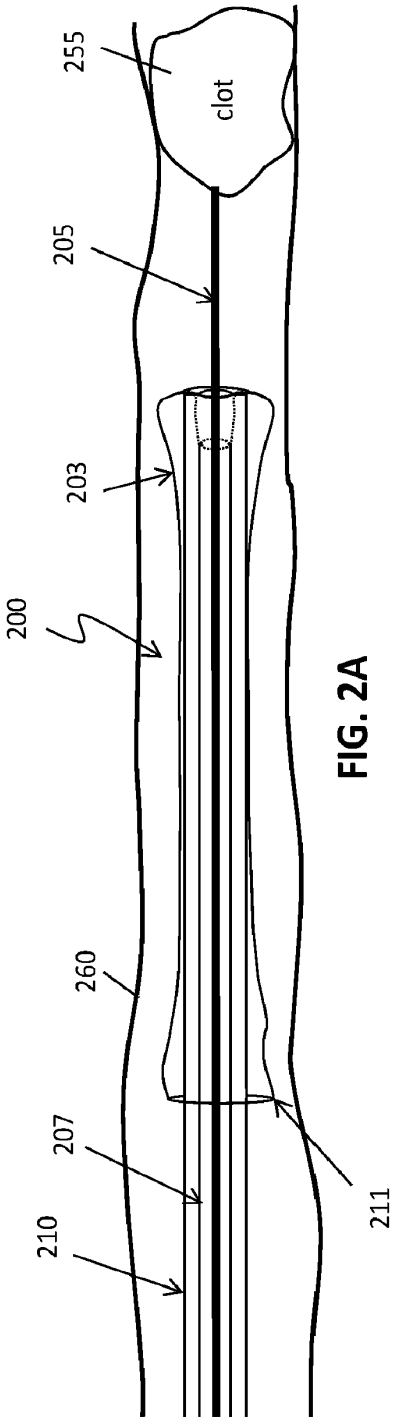


FIG. 2A

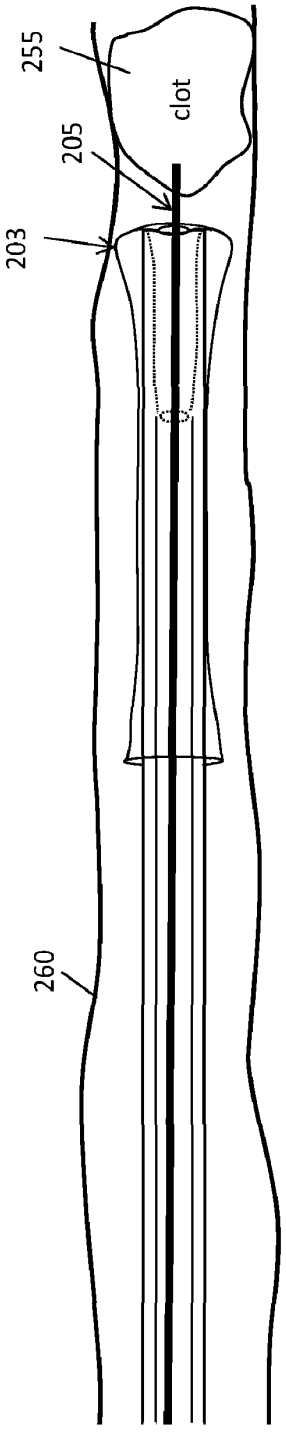


FIG. 2B

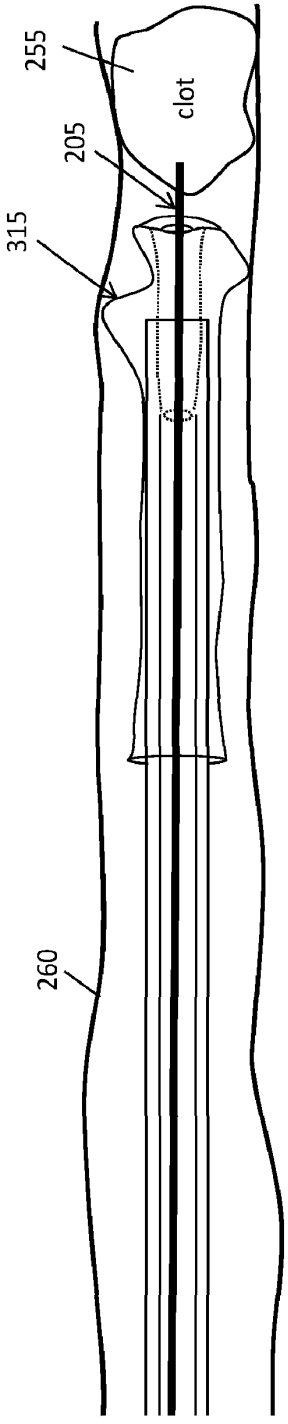


FIG. 2C

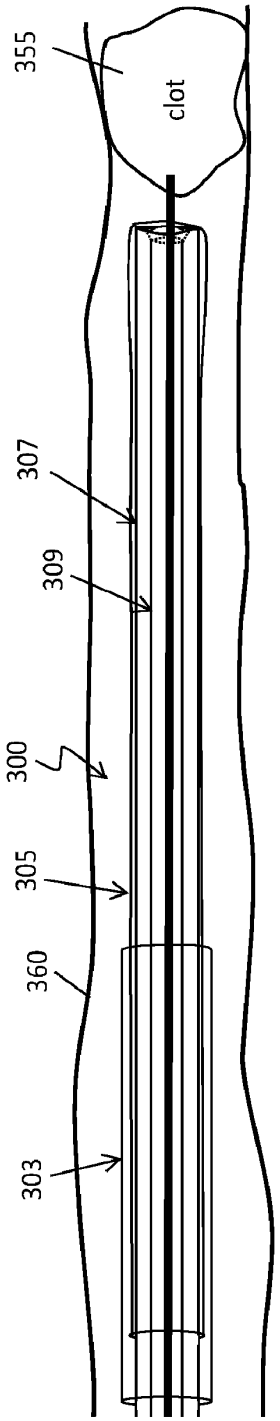


FIG. 3A

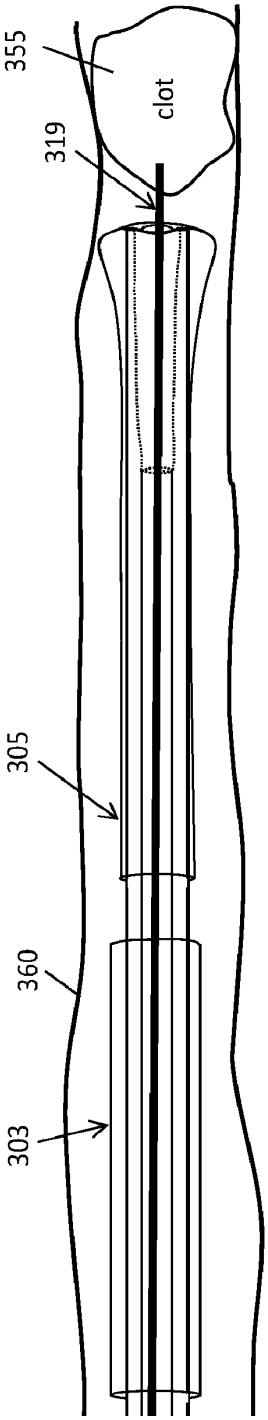


FIG. 3B

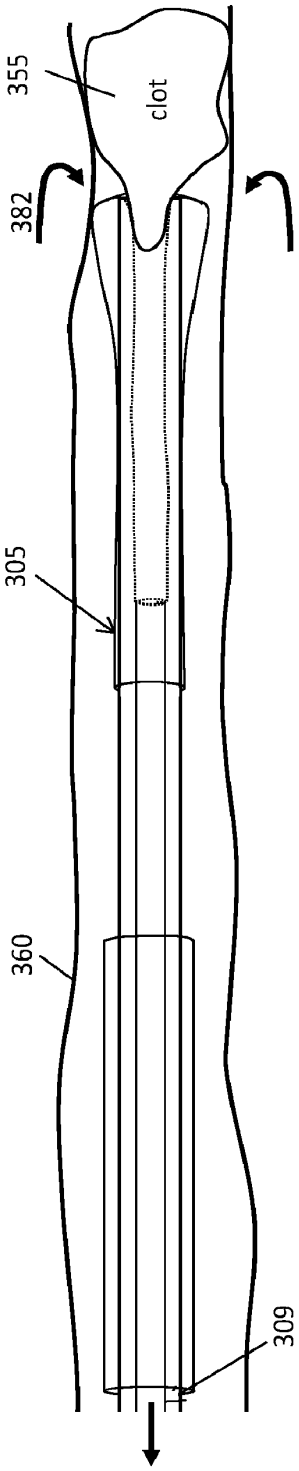


FIG. 3C

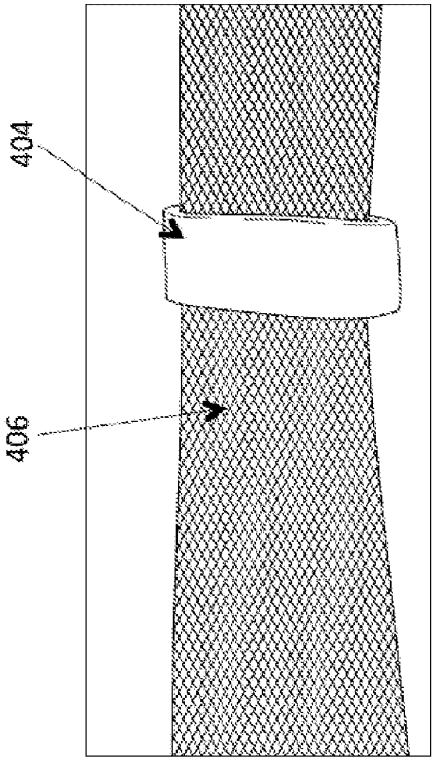


FIG. 4A

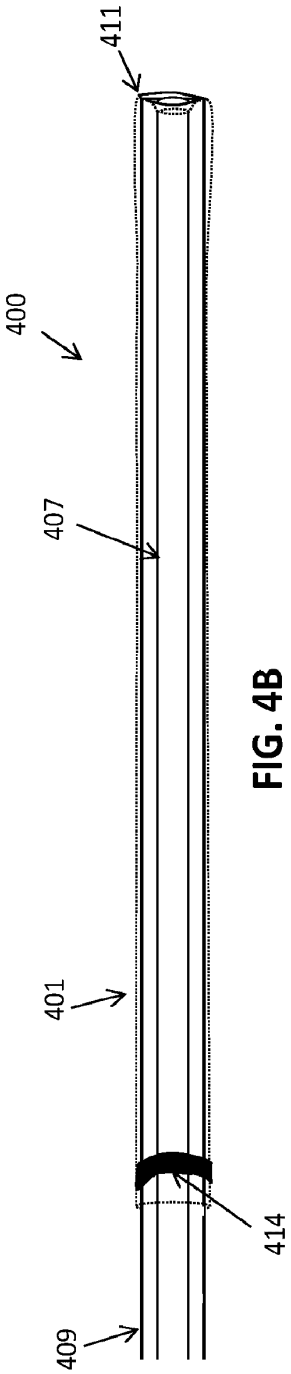


FIG. 4B

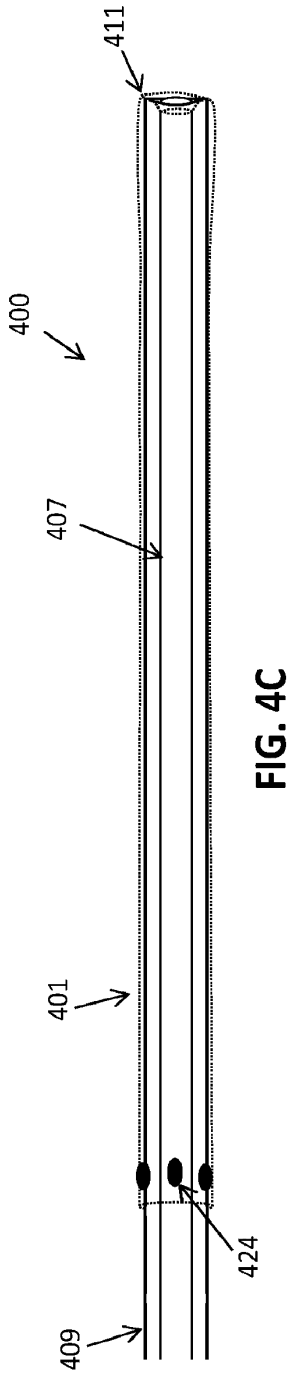


FIG. 4C

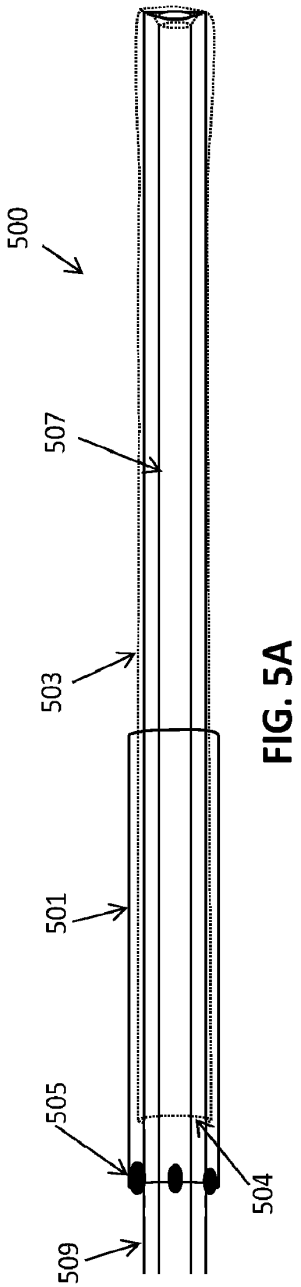


FIG. 5A

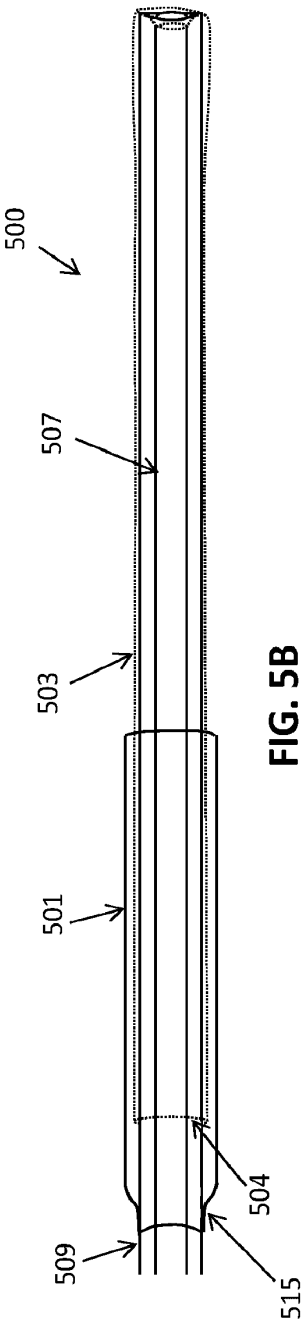


FIG. 5B

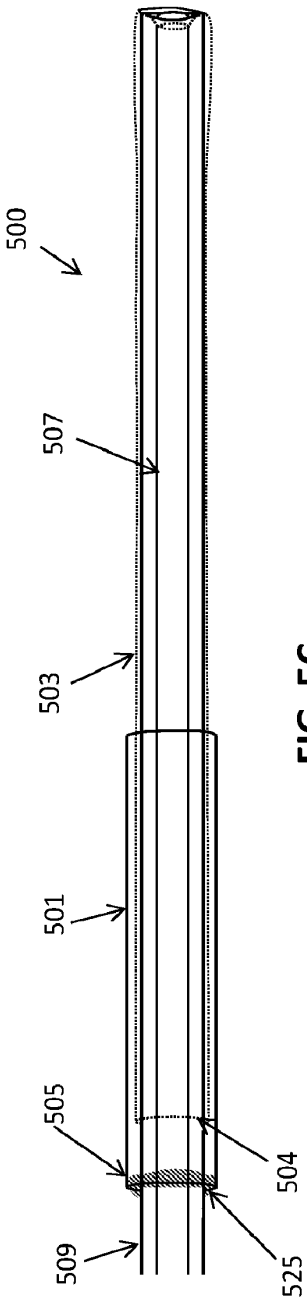


FIG. 5C

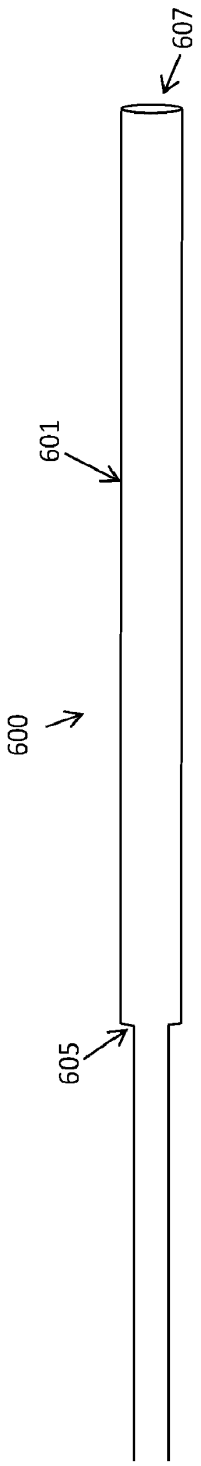


FIG. 6A

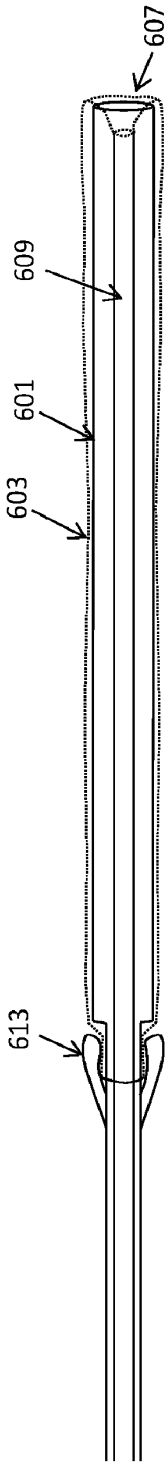


FIG. 6B

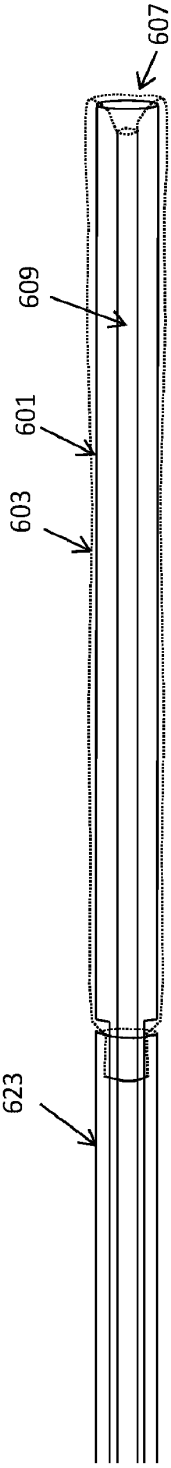


FIG. 6C

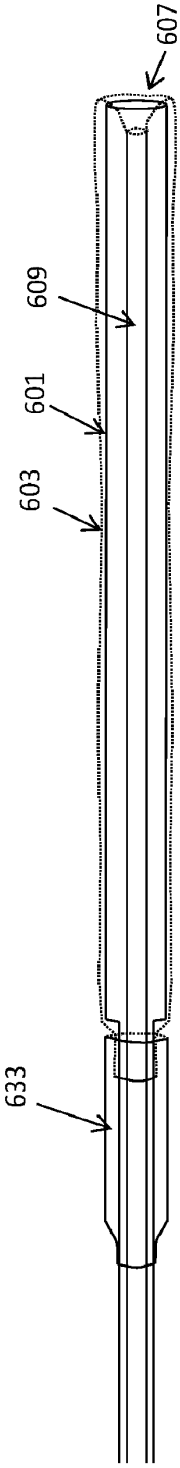


FIG. 6D

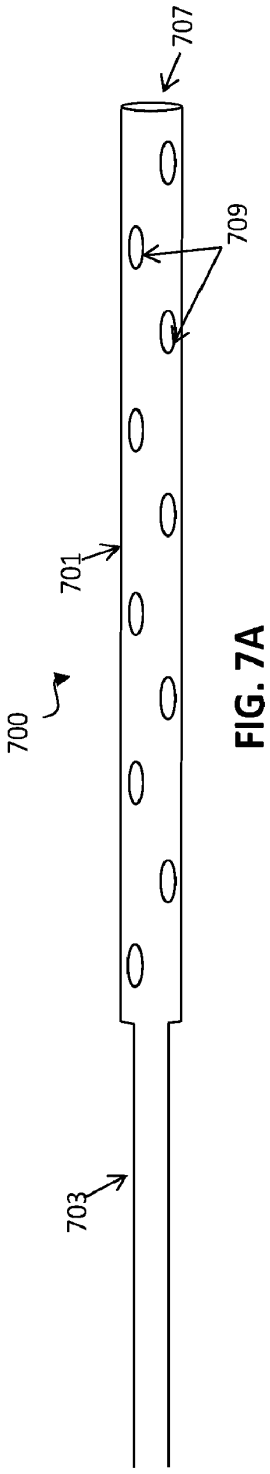


FIG. 7A

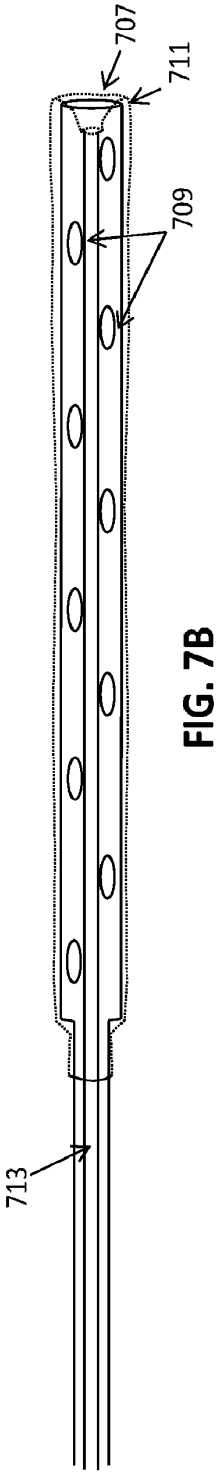


FIG. 7B

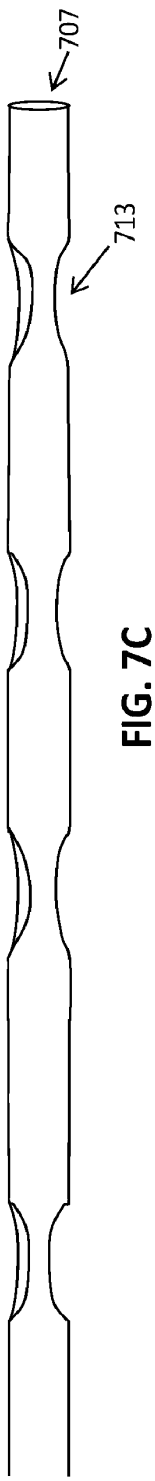


FIG. 7C

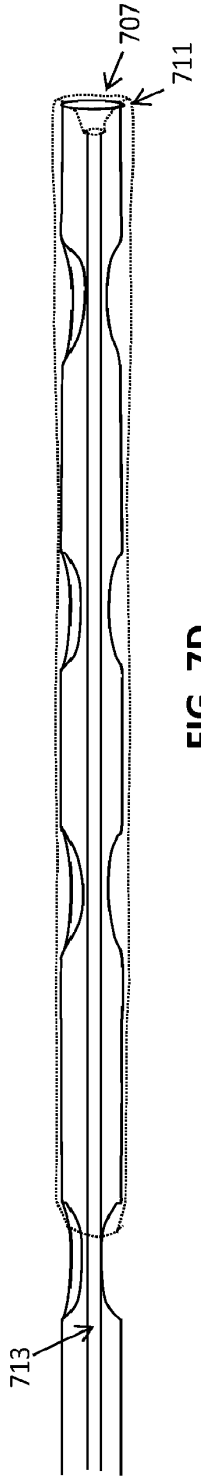


FIG. 7D

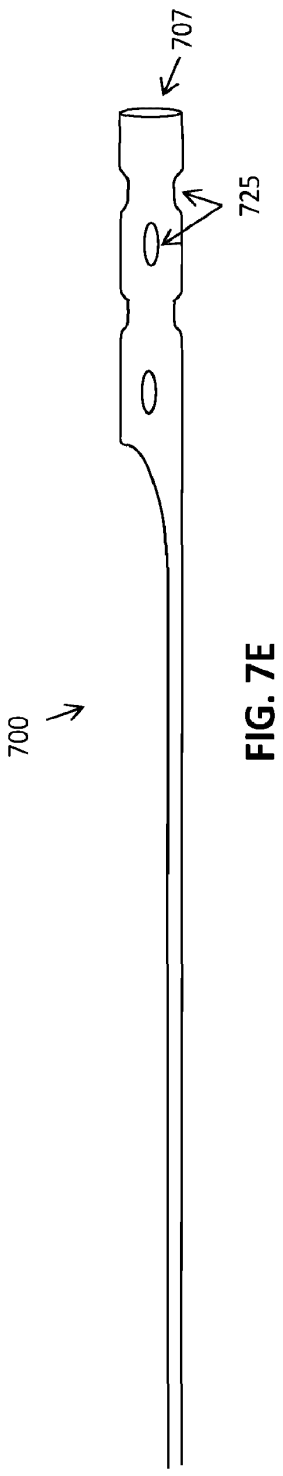


FIG. 7E

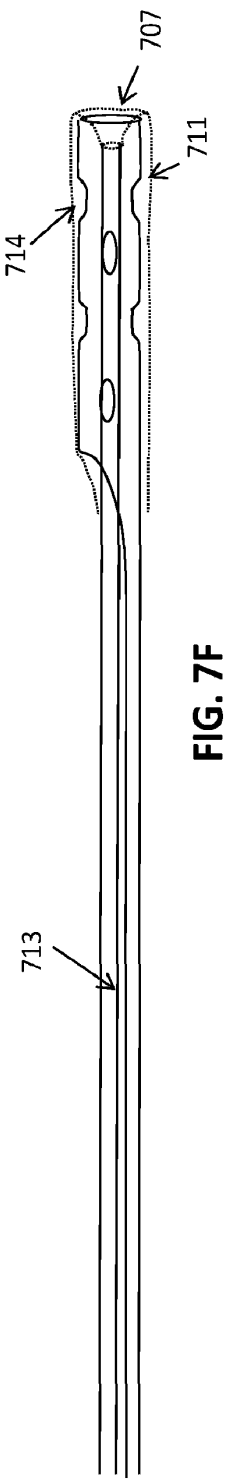


FIG. 7F

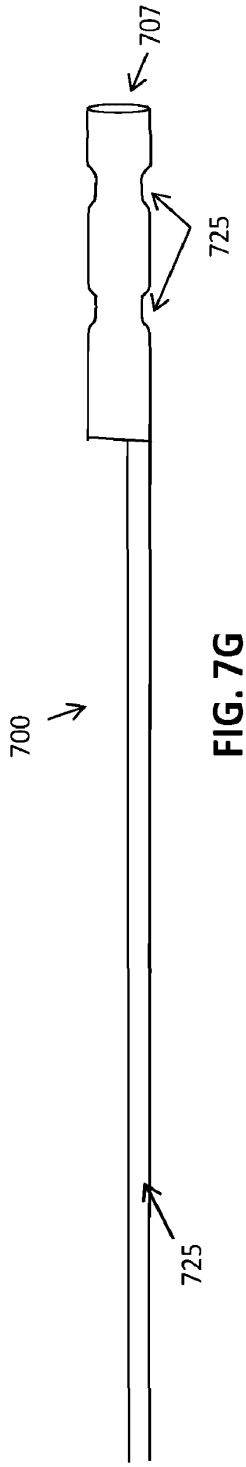


FIG. 7G

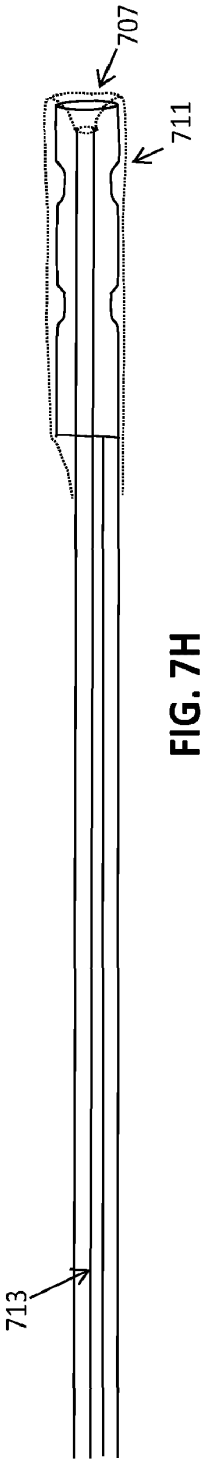


FIG. 7H

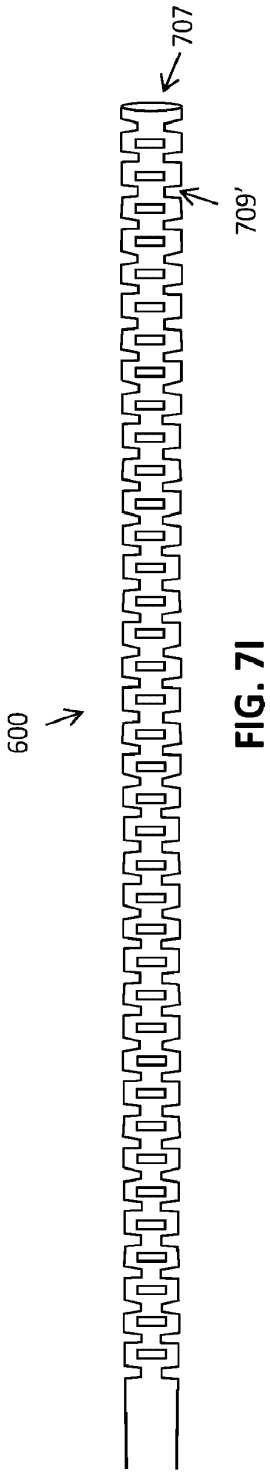


FIG. 7I

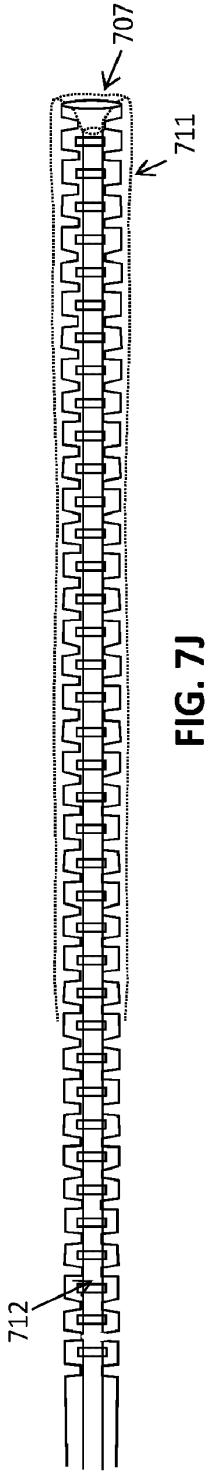


FIG. 7J

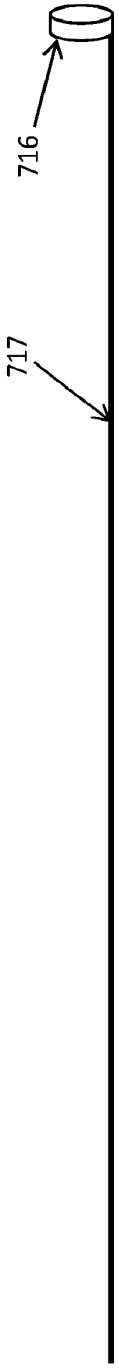


FIG. 7K

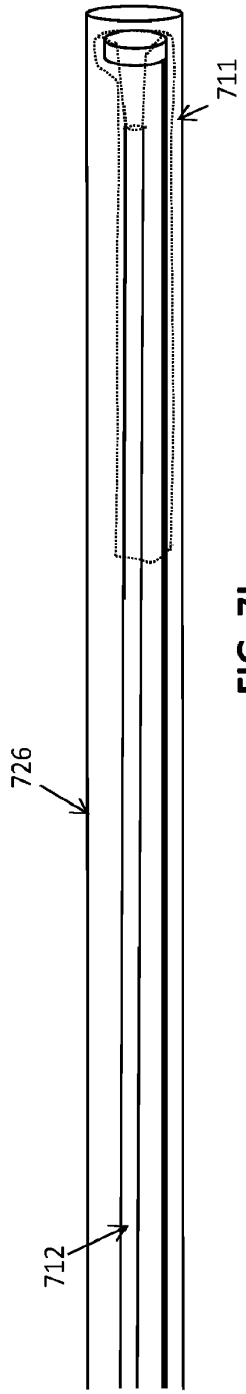


FIG. 7L

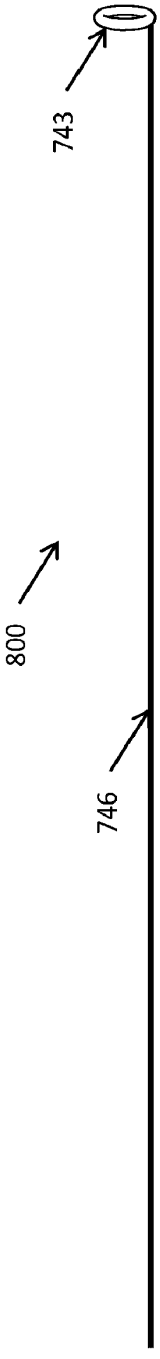


FIG. 8A

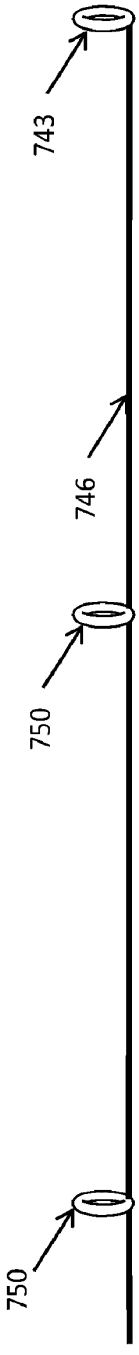


FIG. 8B

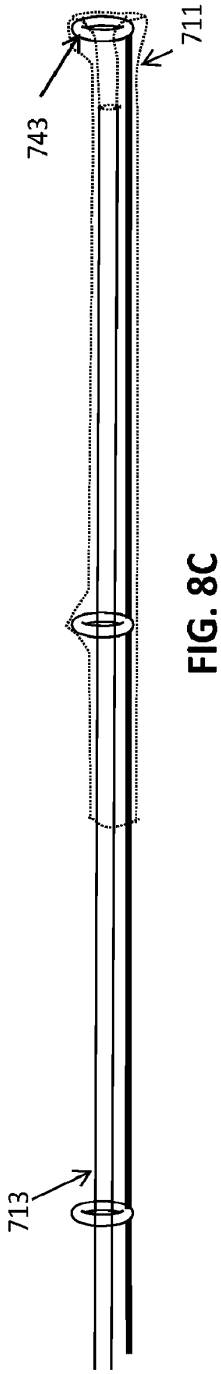


FIG. 8C

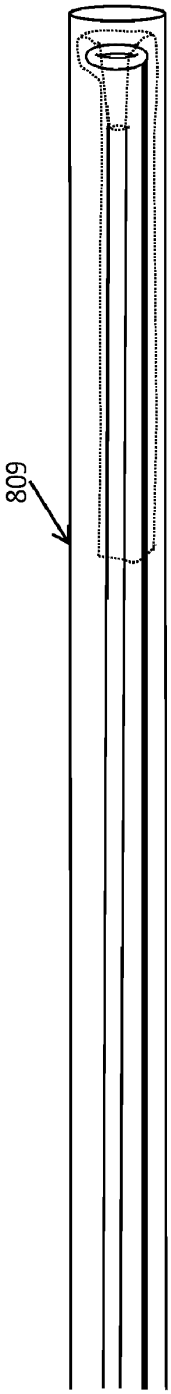


FIG. 8D

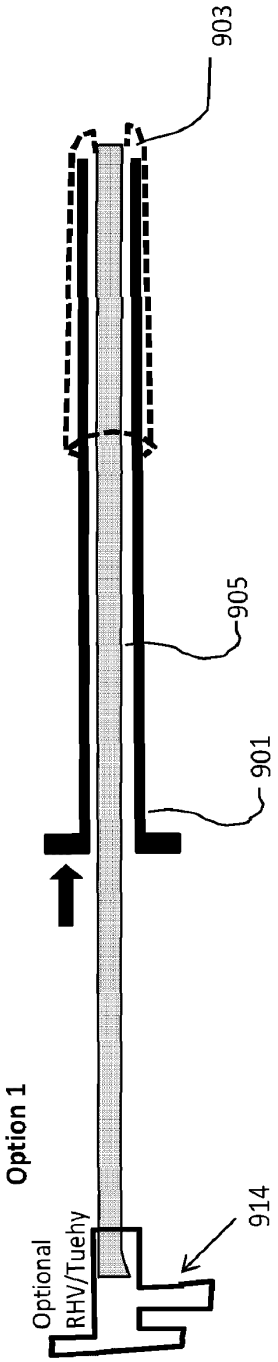


FIG. 9A

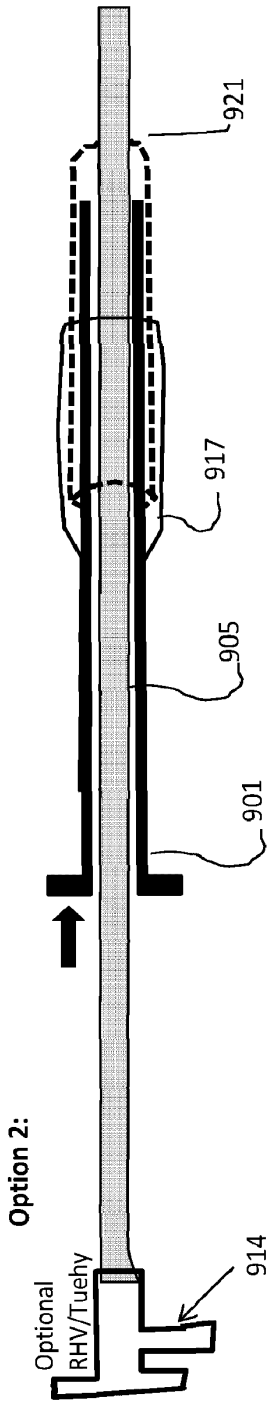


FIG. 9B

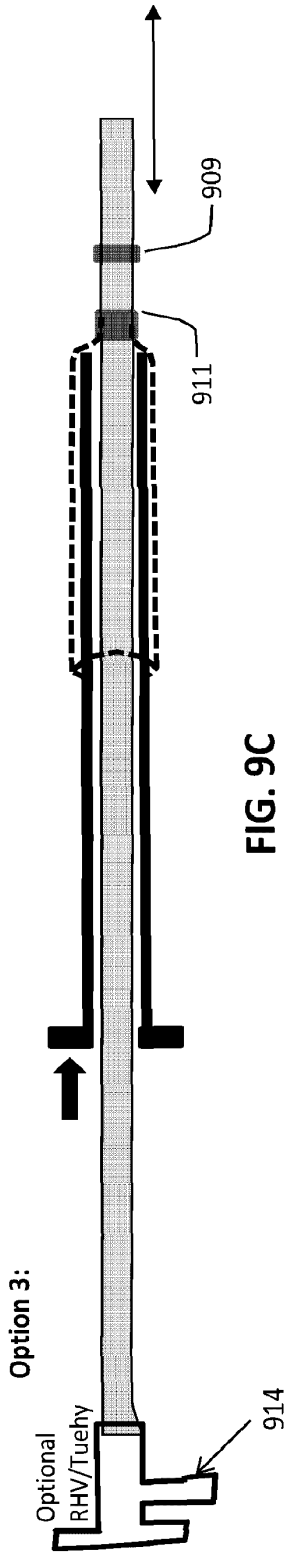


FIG. 9C

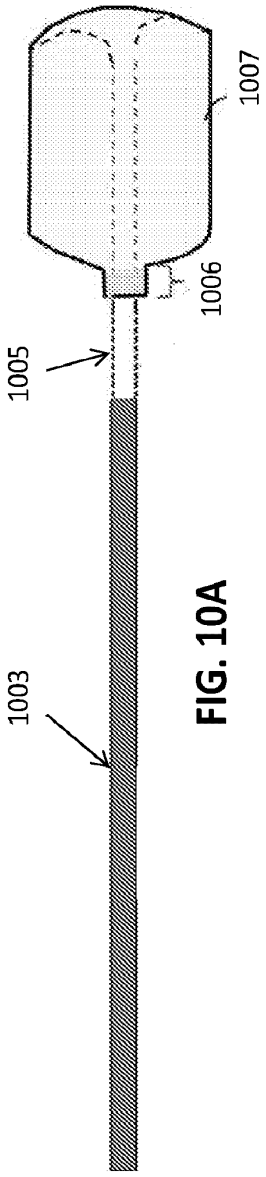


FIG. 10A

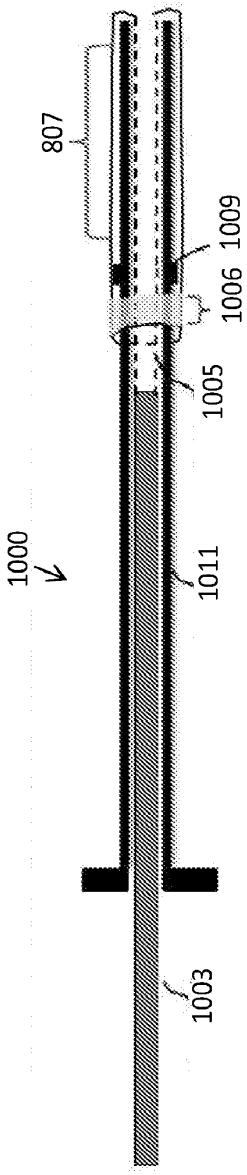


FIG. 10B

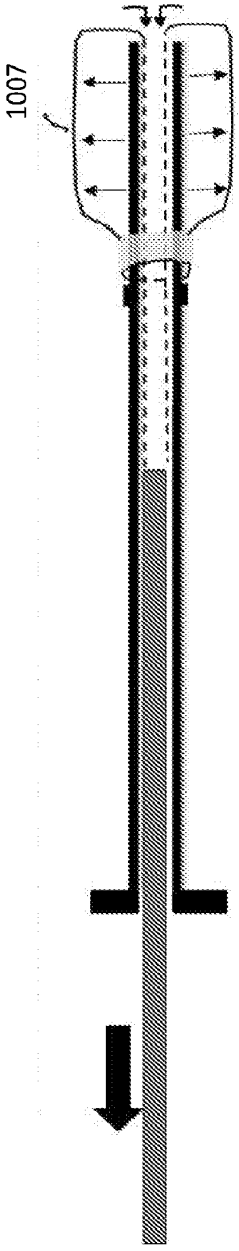


FIG. 10C

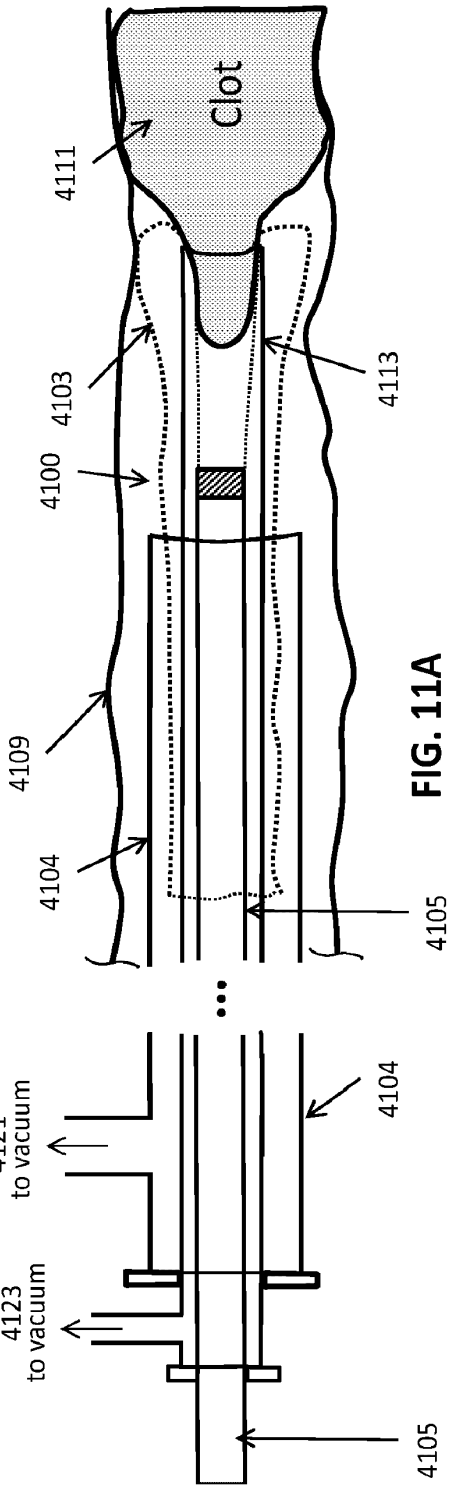


FIG. 11A

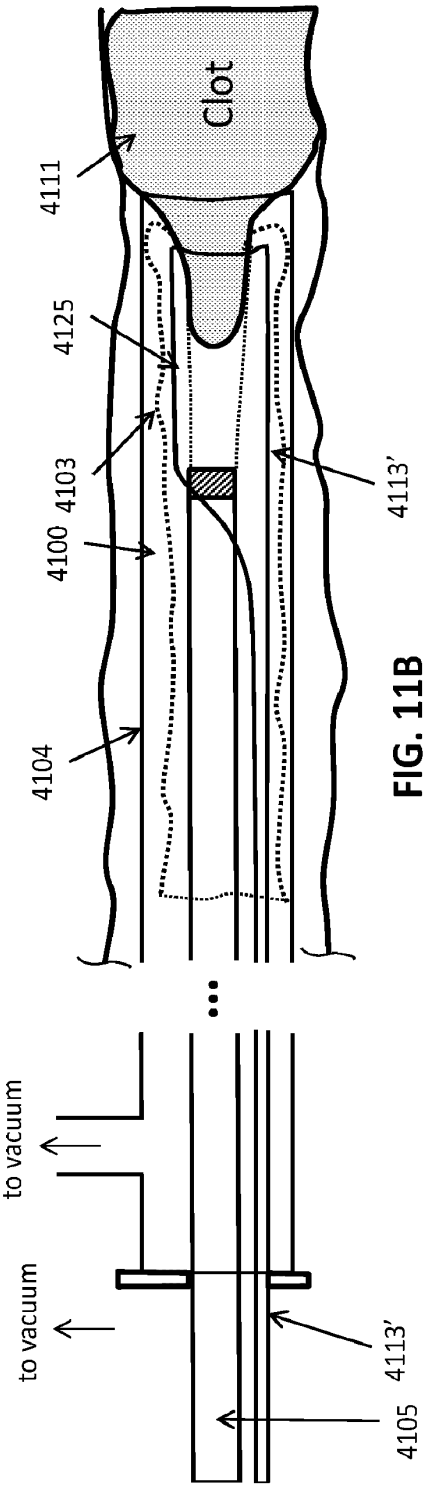


FIG. 11B

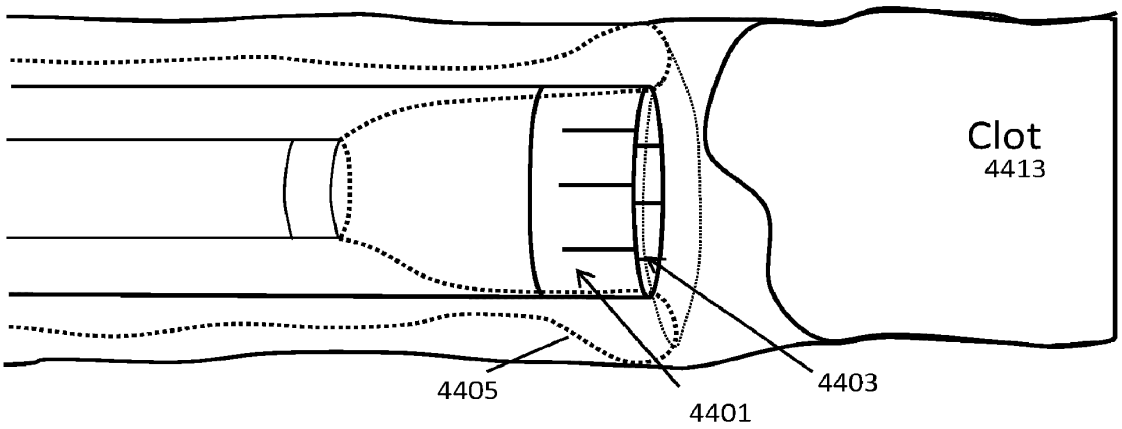


FIG. 12A

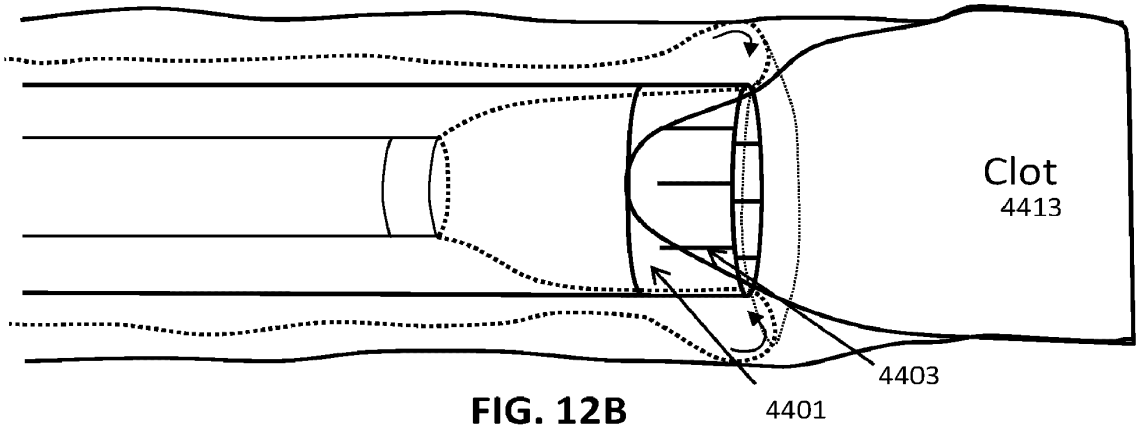


FIG. 12B

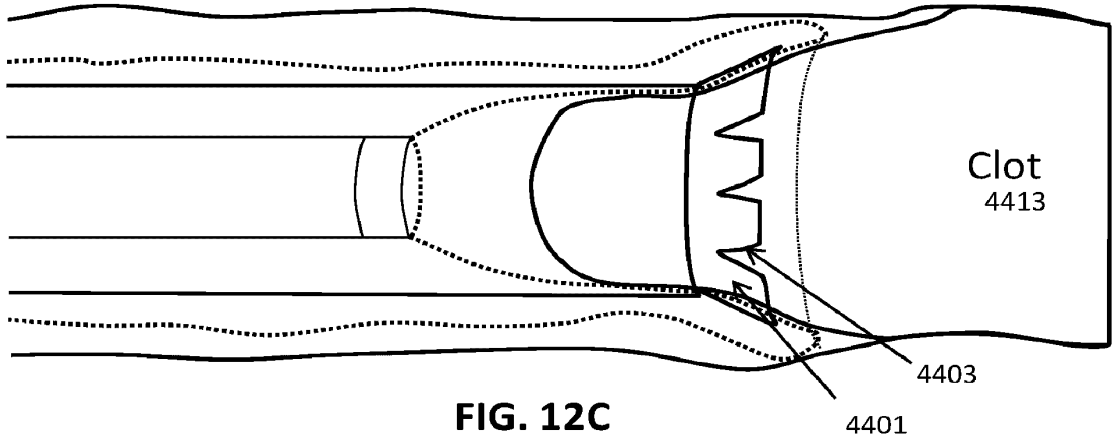


FIG. 12C

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

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

B. FIELDS SEARCHED

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

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; figures page 8, line 12 - page 11, line 16	1,16
A	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19) paragraphs [0152], [0153], [0167] - [0170]; figures 10, 13B	1,16

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

* Special categories of cited documents :

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

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

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 June 2017	29/08/2017

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

1

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

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

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

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

2. ☒ Claims Nos.: 17-25
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

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

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

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

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

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

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

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-16

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-16

A mechanical thrombectomy apparatus comprising: a catheter, a tractor, a puller and a tractor hold to secure an end of the tractor to an outside surface of the catheter until a force greater than a threshold force is applied by pulling the tractor proximally within the catheter.

---

2. claims: 26-31

A mechanical thrombectomy apparatus comprising: a catheter, a tractor, a puller and a guide wire lumen extending through the catheter, the puller and the tractor, and configured to pass a guide wire.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 17-25

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

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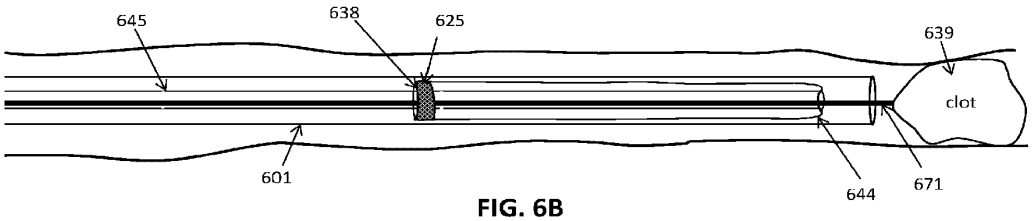


FIG. 6B

(57) Abstract: Rolling tractor tube mechanical thrombectomy apparatuses that may be deployed from out of a catheter *in situ* are described herein. These apparatuses may be delivered out of a catheter from a collapsed delivery configuration within the catheter to a deployed configuration out of the catheter, in which the same catheter is re-inserted between a tubular tractor and an elongate puller. In particular, any of these methods and apparatuses may be adapted to work with a tractor tube having an open end that is biased open, including using an annular bias.

WO 2017/210487 A1

INVERTING THROMBECTOMY APPARATUSES

FIELD

[0001] The apparatuses described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses.

BACKGROUND

[0002] Many vascular problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery. It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue, such as blood clots, from within a patient's vasculature may improve patient conditions and quality of life.

[0003] When a thrombus forms, it may effectively stop the flow of blood through the zone of formation. If the thrombus extends across the interior diameter of an artery, it may cut off the flow of blood through the artery. If one of the coronary arteries is 100% thrombosed, the flow of blood is stopped in that artery, resulting in a shortage of oxygen carrying red blood cells, e.g., to supply the muscle (myocardium) of the heart wall. Such a thrombosis is unnecessary to prevent loss of blood but can be undesirably triggered within an artery by damage to the arterial wall from atherosclerotic disease. Thus, the underlying disease of atherosclerosis may not cause acute oxygen deficiency (ischemia) but can trigger acute ischemia via induced thrombosis. Similarly, thrombosis of one of the carotid arteries can lead to stroke because of insufficient oxygen supply to vital nerve centers in the cranium. Oxygen deficiency reduces or prohibits muscular activity, can cause chest pain (angina pectoris), and can lead to death of myocardium which permanently disables the heart to some extent. If the myocardial cell death is extensive, the heart will be unable to pump sufficient blood to supply the body's life sustaining needs. The extent of ischemia is affected by many factors, including the existence of collateral blood vessels and flow which can provide the necessary oxygen.

[0004] Clinical data indicates that clot removal may be beneficial or even necessary to improve outcomes. For example, in the peripheral vasculature, inventions and procedures can reduce the need for an amputation by 80 percent. The ultimate goal of any modality to treat these conditions of the arterial or venous system is to remove the blockage or restore patency, quickly, safely, and cost effectively. This may be achieved by thrombus dissolution, fragmentation, thrombus aspiration or a combination of these methods.

[0005] Mechanical thrombectomy devices may be particularly advantageous. Depending on the size, location and extent of a clot, it may also be particularly advantageous to mechanical retrieve and break apart the clot in a manner that is both safe and effective. There is a definite need for a thrombectomy device, and particularly a mechanical thrombectomy device that can be more effective in removing tissue such as clots from within a body. Described herein are apparatuses (devices, systems and kit) and illustrative methods of using them that may address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[0006] Described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and illustrative methods of using and making them. These apparatuses may be configured for reliable operation in particular in narrow regions of the body, including peripheral vascular and neurovascular regions. Typically, the mechanical thrombectomy apparatuses described herein are inverting tractor thrombectomy apparatuses that includes a tractor (e.g., tractor region, tractor portion, etc.) comprising a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support. The elongate inversion support typically comprises a catheter having a distal end opening into which the tractor inverts. The flexible tractor inverts and rolls back into itself and may be drawn into the elongate inversion support in a conveyor-like motion; the outward-facing region rolls around to become an inward-facing region, e.g., within the lumen of the elongate inversion support. The rolling motion may thus draw a clot or other object within a vessel into the elongate inversion support.

[0007] The apparatus may be deployed from a collapsed configuration using an in situ deployment, wherein the tractor is folded over an elongate puller/pusher member (which may be a hollow tube, wire or the like), and is collapsed down into a compact form for positioning within the vessel. Once the distal end of the tractor is in position within the vessel, the tractor may be expanded open and the distal end of the catheter over which the tractor is to be rolled or inverted is advanced distally between the tractor and the puller/pusher member, so the

distal end opening of the catheter is positioned distally and the tractor can roll over the distal end and invert when the puller/pusher is pulled proximally.

[0008] In practice, it is beneficial to provide a tractor that is able to be radially compacted to a large degree (e.g., to less than 0.7x the diameter, 0.6x the diameter, 0.5x the diameter, 0.4x the diameter, 0.3x the diameter 0.2x the diameter, 0.1x the diameter, etc.) while still maintaining high degree of flexibility for ease in rolling and inverting over the distal end. Further, the tractor may be advantageously biased so that it has an outer diameter when collapsed into the catheter (after being rolled and inverted into the catheter) that is greater than 0.7x the inner diameter of the catheter (e.g., greater than 0.7x, 0.75x, 0.8x, 0.85x, 0.9x, 0.95x, etc.). In some variations, it may be particularly beneficial if the outer diameter of the portion of the tractor that extends along the outer diameter of the catheter is biased to have an inner diameter that is between 1.1x and 2x the outer diameter of the catheter (e.g., between 1.1x and 1.9x, between 1.1x and 1.8x, between 1.1x and 1.7x, between 1.1x and 1.6x, between 1.1x and 1.5x, etc.).

[0009] Unfortunately, when performing an in situ deployment, it has proven particularly difficult to provide a tractor having an open end region into which the distal end of the catheter may be easily, reliably and robustly inserted between the expanded tractor and the inner puller/puller, particularly when the apparatus is deployed within a curved, bent, or tortious portion of the body. If the catheter distal end does not clearly and cleanly enter between the outer end of the tractor and the puller/pusher, it may get caught on the tractor and may prevent successful operation.

[00010] Described herein are apparatuses for improving and enhancing deployment, and particularly in situ deployment, of the apparatus so that the distal end (tip) of the catheter can be deployed distally between the free tractor end and a puller/pusher to which the other end of the tractor is attached and inverted.

[00011] For example, described herein are mechanical thrombectomy apparatuses to be used for removing a clot from a vessel. Any of these apparatuses may include an annular bias that holds the flexible tractor tube open so that an elongate inversion support catheter can be inserted through the annular bias and between the flexible tractor tube and the elongate puller/pusher ("elongate puller") to prepare the apparatus for rolling the flexible tractor tube over the distal end opening of the elongate inversion support catheter, even where the flexible tractor tube is expanding from a collapsed configuration within the elongate inversion support catheter.

[00012] For example, an apparatus as described herein may include: an elongate inversion support catheter having a distal end and a distal end opening; an elongate puller extending within the elongate inversion support catheter; a flexible tractor tube having a free first end and a second end that is attached to a distal end region of the elongate puller, wherein the flexible tractor tube is inverted over the elongate puller and is held within the elongate inversion support catheter in a collapsed first configuration; and an annular bias around the free first end of the flexible tractor tube, wherein the flexible tractor tube is configured to be extended from the distal end opening of the elongate inversion support catheter and to expand into an expanded second configuration, wherein the annular bias has a diameter that is larger than an outer diameter of the elongate inversion support catheter in the expanded second configuration (e.g., between 1.1 and 10 times the OD of the elongate inversion support catheter in the expanded second configuration, between 1.1x and 10x, etc.).

[00013] For example, a mechanical thrombectomy apparatus for removing a clot from a vessel may include: an elongate inversion support catheter having a distal end and a distal end opening; an elongate puller extending within the elongate inversion support catheter, wherein the elongate puller comprises a central lumen; a flexible tractor tube having a free first end and a second end that is attached to a distal end region of the elongate puller, wherein the flexible tractor tube comprises a woven, braided, mesh or knitted material and is inverted over the elongate puller and is held within the elongate inversion support catheter in a collapsed first configuration; further wherein the flexible tractor tube is biased to expand to between 1.1 and 4 times an outer diameter of the elongate inversion support catheter in an un-inverted configuration and is further biased to expand to greater than 0.5x an inner diameter of the elongate inversion support catheter in an inverted configuration; and an annular bias around the free first end of the flexible tractor tube, wherein the flexible tractor tube is configured to be extended from the distal end opening of the elongate inversion support catheter and to expand into an expanded second configuration, wherein the annular bias has a diameter that is larger than (e.g., greater than 1.1 times, etc.) the outer diameter of the elongate inversion support catheter in the expanded second configuration so that the elongate inversion support catheter may be pushed through the annular bias and between the flexible tractor tube and an outer diameter of the elongate puller.

[00014] The annular bias may be any appropriate bias, including a ring, a stent (e.g., a stent having a zig-zag strut pattem), a lobed bias, etc. The annular bias may be attached the free, open end of the flexible tractor tube. The annual bias may be attached by stitching,

adhesive, etc. Alternatively or additionally, the annular bias may be formed by shape-setting the open end of the flexible tractor tube.

[00015] In particular, the flexible tractor tube may be biased to expand to between 1.1 and 4 times the outer diameter of the elongate inversion support catheter in an un-inverted configuration and may further be biased to expand to greater than 0.5x an inner diameter of the elongate inversion support catheter in an inverted configuration.

[00016] The elongate inversion support catheter may be configured to be pushed through the annular bias and between the flexible tractor tube and an outer diameter of the elongate puller when the flexible tractor tube is in the expanded second configuration.

[00017] In general, the flexible tractor tube may comprise a woven, braided, mesh or knitted material. For example, the flexible tractor tube may be a knitted material. The flexible tractor tube is typically formed of a soft material that may readily roll over the distal open end of the elongate inversion support catheter. For example, the flexible tractor tube may be sufficiently soft such that without support, it collapses radially under an axial compression of less than 200g of force. The flexible tractor tube may comprise steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, or a fabric.

[00018] Any of these apparatuses may be configured for use with a guidewire. For example, any of these apparatuses may be configured to include a guidewire lumen extending through the elongate puller that is configured to pass a guidewire.

[00019] Although any appropriate elongate inversion support catheter may be used, in particular, the elongate inversion support catheter may have a harness profile such that this distal end is generally soft, until the very distal end, which may be harder than the more proximal region (e.g., the distal most 5 mm, distal most 4 mm, distal most 3 mm, distal-most 2 mm, distal most 1mm, etc. has a hardness that is greater than the region immediately proximal, which otherwise gradually becomes softer along the distal length). For example, the material hardness of the elongate inversion support catheter may generally decrease over the distal end of the catheter until the distal end opening, wherein the distal end opening may have a material hardness that is greater than a material hardness of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile.

[00020] The elongate puller may comprise a hypotube. The flexible tractor tube may be any appropriate length. For example, the flexible tractor tube may be between 3 cm to 50 cm long.

[00021] The elongate inversion support catheter of the any of the apparatuses described herein may be or may include (particularly at its distal end) any appropriate catheter, e.g., a

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

[00022] The flexible tractor tube may be referred to as simply a tractor or as a tractor region , and may be configured to prevent jamming, while still able to efficiently "grab" a clot from within a vessel. For example, described herein are mechanical thrombectomy apparatuses that may be configured to grab or grasp a clot as it is mechanically drawn into the apparatus for removal. Although suction may be used in addition to the mechanical grabbing of the clot, in some variations suction is not used.

[00023] The flexible tractor tube may include projections that extend from the tractor region, particularly or exclusively as it bends around during inverting (e.g., at the distal end of the device). These projections may remain flat or non-extending when the tractor is held in parallel with the elongate inversion support. Alternatively, the projections may extend at all times. In general, the tractor may be formed of a woven materials, knitted material, or laser-cut sheet of material. The knitted and/or woven materials may be fibrous materials (including natural fibers, synthetics fibers, etc.), polymeric materials, or the like. For example, the material (e.g., strands) forming the woven or knitted material may be one or more of: monofilament polymer, multifilament polymer, NiTi filament, NiTi tube with radiopaque metallic center, Cobalt chromium alloy filament, Cobalt chromium alloy tube with radiopaque metallic center, Nylon, Polyester, Polyethylene terephthalate, and Polypropylene. The sheets of material (e.g. a solid sheet of material) formed into the tractor region may be one or more of: polymeric material (e.g., PTFE), silicone materials, polyurethanes, shape memory alloys, stainless steels, etc. The sheets may be extruded, glued, or the like. The sheets may be cut to form pores and/or projections. For example, the sheets may include one or more laser-cut projections. Any of these apparatuses may be coated with a hydrophilic and/or hydrophobic coating, and/or may include pores. The tractor may have a

porosity of greater than >60% (greater than 70%, greater than 75%, greater than 80%, greater than 85%, etc., between 60-95, 65-95, 70-95%, etc.).

[00024] In any of the apparatuses described herein, the elongate inversion support catheter may be adapted to enhance rolling of the tractor region (inverting) over the distal end. For example, in any of the apparatuses described herein, the catheter may be configured so that the material hardness of the catheter decreases over the distal end of the catheter until the distal end opening, wherein the distal end opening has a material hardness that is greater than a material hardness of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile. The catheter distal end may be stiffer because it is thicker (e.g., it may be formed by inverting the distal end of the catheter back over itself, and/or it may be formed of a stiffer material than the adjacent more proximal region (including by including a reinforcing material).

[00025] In any of the apparatuses described herein, the flexible tractor tube may include one or more coatings from the group of: a lubricious coating, a metal coating, a heparin coating, an adhesive coating, and a drug coating. In particular the tractor may include a uniform or non-uniform lubricious (e.g., hydrophilic) coating.

[00026] As mentioned, any of these apparatuses may include a puller, e.g., an elongate puller coupled to a distal end of the tractor. Any of these apparatuses may include an elongate puller within the catheter coupled to a distal end of the tractor. The elongate puller may comprise a hypotube having an inner lumen that is continuous with the guidewire lumen though the flexible tube.

[00027] In general, the tractor may be any appropriate length. For example, the tractor may be between 3 to 100 cm long (e.g., between 3 and 50 cm, between 3 and 40 cm, between 3 and 30 cm, between 3 and 20 cm, between 10 and 100 cm, between 10 and 50 cm, between 20 and 100 cm, between 20 and 50 cm, etc.).

[00028] In any of these apparatuses, the apparatus may be configured so that the tractor may be inverted and rolled into the catheter by applying less than 300 grams of force (e.g., less than 400 g of force, less than 300 g of force, less than 200 g of force, less than 100 g of force, less than 90 g of force, less 80 g of force, less than 70 g of force, less than 60 g of force, less than 50 g of force, less than 10 g of force, etc.) to a distal end of the flexible tube, e.g., by pulling the elongate puller. For example, as mentioned above, the apparatus may include a hydrophilic coating, a lubricant on the catheter and/or tractor, a sleeve between the tractor and catheter, etc. This force required to retract the tractor into the catheter typically refers to the force required to roll the tractor over the distal end of the tractor.

[00029] Any of the apparatuses described herein may be configured so that the tractor is highly soft, and therefore rolls around the distal end of the catheter forming the elongate inversion support easily without jamming and/or requiring a large force to roll the tractor over the distal end opening of the catheter. In particular, tractors having a low axial compression strength, that would, but for the elongate inversion support, typically buckle, have been found to prevent jamming of the elongate inversion support as the tractor inverts. In particular, unsupported tractors (e.g., tractor that are not rolling over a catheter supported annular opening) that are configured to collapse radially under an axial compression of less than about 500g of force (e.g., less than: about 500g force, about 400g force, about 300g force, about 200g force, about 150 g force, about 100 g force, about 50 g force, etc.) may be particularly helpful in preventing jamming. For most knitted, woven, and braided tractors, including those described herein, when the tractor is configured to withstand greater that this amount of axial compression force, the tractor may jam, and/or may require excessive force to invert. Thus, in any of the apparatuses and methods described herein, the tractor maybe sufficiently soft such that without support from the catheter, the tractor collapses radially under an axial compression of less than 200g of force when inverting (and may instead buckle).

[00030] Further, in any of the apparatuses described herein, the tractor may be biased to expand to greater than the outer diameter of the catheter in a second configuration (that is inverted relative to the first configuration) where the tractor is extending over the outer diameter of the catheter. The same tractor may be biased to expand to greater than the inner diameter of the catheter of the elongate inversion support in the first (e.g., un-inverted), configuration where the tractor is within the catheter of the elongate inversion support. Thus, in relaxed configuration, prior to assembling with the elongate inversion support, the tractor may be oversized compared to the catheter of the elongate inversion support; the portion of the tractor that extends within the catheter of the elongate inversion support, referred to as "un-inverted," may have an inner diameter that is greater than the inner diameter of the catheter, which may tend to drive the tractor toward the walls of the inner diameter of the catheter without collapsing down into the catheter. Further, the inner diameter of the tractor in the "inverted" configuration, e.g., the configuration of the portion that is doubled back over and along the catheter of the elongate inversion support, may be greater than the outer diameter of the catheter of the elongate inversion support. This arrangement may prevent jamming and an increased resistance between the tractor and the outside of the catheter of the elongate inversion support. The catheter may be biased to expand in both the inverted and

un-inverted configurations by, e.g., heat setting. The tractor may be inverted to transition between the first and second configurations by rolling over the distal end of the catheter; the terms "inverted" and "un-inverted" are therefore relative terms.

[00031] The annular bias may be biased to have an expanded, open configuration that has a slightly larger (e.g., greater than 5%, greater than 10%, greater than 15%, greater than 20%, greater than 25%, etc., larger than the expanded diameter of the flexible tractor tube. In addition, the annular bias may be relatively "stiffer" than the open (free) end of the flexible tractor tube, to prevent buckling, collapse, etc. In some variations, the annular bias has a smooth and/or curved edge to prevent getting caught on the elongate inversion support catheter when it is inserted into the annular bias.

BRIEF DESCRIPTION OF THE DRAWINGS

[00032] The novel features of embodiments of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00033] FIGS. 1A-1H illustrate an example of an apparatus for mechanically removing an object such as a clot form a body region. FIG. 1A shows an example of an elongate inversion support catheter portion of an apparatus. At least the distal end of the elongate inversion support is configured as a catheter. FIG. 1B shows an enlarged view of a partial section of a distal end (opening) of the catheter of the elongate inversion support of FIG. 1A, showing the aperture formed by the distal end opening; FIG. 1C shows an example of a flexible tractor tube attached over a puller (the puller in this example is configured as a catheter). The tractor is shown in a first configuration. In some variations, the flexible tractor tube may be biased open, e.g., by heat setting, to have an outer diameter that is greater than the inner diameter of the catheter of the elongate inversion support, as shown in FIG. 1D. FIG. 1D shows the same distal tractor region of FIG. 1C with the expandable first end region expanded. This first configuration may be compressed down into the elongate inversion support and the distal end inverted over the catheter portion of the elongate inversion support, as shown in FIG. 1E. In FIG. 1E, the assembled mechanical thrombectomy apparatus includes an elongate inversion support catheter having a distal end and a distal end opening; the elongate puller extends within the elongate inversion support catheter and a flexible tractor tube is connected at one end to the elongate puller. The flexible tractor tube and puller may be extended through the

elongate inversion support catheter, including extended out of the distal end (e.g., by pulling the elongate inversion support catheter proximally and/or by pushing the elongate puller distally). The flexible tractor tube may initially be held in a collapsed first configuration (as shown in FIG. 1E) for positioning within a vessel; it may be deployed and expanded, as shown in FIG. 1F, with the elongate inversion support catheter positioned between the flexible tractor tube and the elongate puller. The flexible tractor tube may be biased so that in the second configuration (inverted over the distal end of the catheter), the tractor has a 'relaxed' outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support.

[00034] FIGS. 1G and 1H illustrate the use of the an apparatus such as the one shown in FIGS. 1E and 1F to remove a clot by drawing the flexible tractor tube proximally and/or advancing the catheter distally towards the clot so that the expandable first end region inverts as it is drawn into the distal end of the catheter, pulling the clot into the catheter.

[00035] FIG. 1I illustrates an alternative variation of a tractor and puller. In FIG. 1I, the tractor is shown attached to the distal end of a tapered or narrow puller; the distal end region is tapered, and includes a radiopaque marker at or near the attachment site to the tractor; the tractor may be knitted, braided, woven, etc. Thus, in some variations the distal end region of the puller may have a greater flexibility than the proximal end of the puller. The puller may be hollow (e.g., a catheter or hypotube) or solid (e.g., like a wire).

[00036] FIGS. 2A -2F illustrate an exemplary (in situ) method of deploying a mechanical thrombectomy apparatus designed in accordance with the disclosed embodiments. In FIG. 2A the elongate inversion support catheter (either alone or with a guidewire) is positioned within the vessel, near a clot. In some variations the flexible tractor tube and elongate puller may already be positioned within the elongate inversion support catheter, e.g., near the distal end, or it may be moved into position thereafter, as shown in FIG. 2B. In FIG. 2C, the flexible tractor tube is deployed out of the elongate inversion support catheter and allowed to expand. Thereafter, the elongate inversion support catheter is moved distally between the flexible tractor tube and the elongate puller, as shown in FIG. 2D. Once the elongate inversion support catheter is positioned distally between the flexible tractor tube and elongate puller, as shown in FIG. 2E, the flexible tractor tube may be rolled and inverted into the elongate inversion support catheter, as shown in FIG. 2F. In this example, the inverting flexible tractor tube is shown grabbing a clot may as it is inverted into the elongate inversion support catheter. The flexible tractor tube extends from the distal end opening of the elongate inversion support catheter and expands into an expanded second configuration; the flexible

tractor tube is biased to expand to between 1.1 and 4 times an outer diameter of the elongate inversion support catheter in an un-inverted configuration (e.g., FIG. 2D) and is further biased to expand to greater than 0.5x an inner diameter of the elongate inversion support catheter in an inverted configuration (when drawn into the catheter as shown in FIG. 2F).

[00037] FIGS. 3A-3B illustrate a first variation of an apparatus having an elongate puller with a stepped outer diameter into which the flexible tractor tube may be compressed. This configuration may provide improved mobility within the elongate inversion support catheter. This variation may also be readily adapted for application to a vacuum through the hollow elongate puller. In FIG. 3A the flexible tractor tube is collapsed. In FIG. 3B the flexible tractor tube is expanded, as shown.

[00038] FIGS. 4A-4C illustrate deployment of the elongate puller with a stepped outer diameter shown in FIGS. 3A-3B. In FIG. 4A the elongate puller is positioned at the distal end of the elongate inversion support catheter, and extended from the distal end opening of the catheter until the collapsed flexible tractor tube is expanded at least slightly, as shown in FIG. 4B. An annular bias, described in greater detail below, may be used in this variation as well. As shown in FIG. 4C, the elongate inversion support catheter may then be positioned between the flexible tractor tube and the elongate puller, so that the elongate inversion support catheter can support the flexible tractor tube until it can be pulled proximally by pulling the elongate puller to invert into the elongate inversion support catheter.

[00039] FIG. 5A-5F illustrate the use of the apparatus of FIG. 3A-3B, including an annular bias, to remove a thrombus (clot) from within a vessel. In FIG. 5A the elongate inversion support catheter is positioned near the clot in the vessel. The elongate pusher to which a flexible tractor tube is attached at a first end, with an annular bias on an open, free second end, is extended distally through the catheter and out of the distal end of the elongate inversion support catheter, as shown in FIG. 5B. In FIG. 5C, the annular bias holds the free end of the flexible tractor tube open. In some variations the flexible tractor tube is biased to expand to diameter that is slightly greater than the outer diameter of the catheter (e.g., greater than 1.1x the outer diameter of the elongate inversion support catheter), however the annular bias may be open even slightly more, and may be more rigid when expanded open, as shown. The elongate inversion support catheter may then be inserted distally through the annular bias and between the flexible tractor tube and the elongate puller, as shown in FIGS. 5D-5E. A vacuum may be applied through the elongate puller and/or elongate inversion support catheter, as shown in FIG. 5E. In FIG. 5F, withdrawing the elongate puller proximally (with or without a vacuum) to roll the flexible tractor over the distal end of the

elongate inversion support catheter so that it inverts into the elongate inversion support catheter may draw the clot into the elongate inversion support catheter, as shown.

[00040] FIGS. 6A-6F illustrate another variation of an apparatus including an annular bias on an open, free, end of the flexible tractor tube. In FIG. 6A, the elongate inversion support catheter is positioned, shown here with the optional use of a guidewire, within the lumen of the vessel. In FIG. 6B, the elongate puller and flexible tractor tube are positioned distally within the elongate inversion support catheter, also over the guidewire; the flexible tractor tube is attached at one end of the flexible tractor tube, with the other end of the flexible tractor tube attached to an annular bias at a free (loose) end. The guidewire may be removed or left in position when deploying the flexible tractor tube from the distal end of the elongate inversion support catheter. In FIG. 6C, the distal end of the puller including the entire flexible tractor tube is extended distally from the elongate inversion support catheter and the annular bias expands to a diameter that is greater than the outer diameter of the elongate inversion support catheter. In FIG. 6D and 6E, the elongate inversion support catheter is advanced distally within the annular bias and between the flexible tractor tube and the elongate puller, so that the elongate inversion support catheter may support the flexible tractor tube as it is pulled proximally by the elongate puller to invert over the distal end opening of the elongate inversion support catheter. The apparatus may be advanced (e.g., while pulling the elongate puller proximally) to grab and remove a clot from the vessel, as shown in FIG. 6E.

[00041] FIGS. 7A-7D illustrate four variations of annular biases that may be used to support the expanded open (free) end of the flexible tractor tube in any of the variations described herein. The vertical columns illustrate an expanded end view, an expanded side view, a collapsed end view (e.g., within the elongate inversion support catheter) and a side view shown attached to a flexible tractor tube, respectively, from left to right. In FIG. 7A, a ring-shaped annular bias is shown. In FIG. 7B the annular bias is a member having lobes or petals, which may predictably collapse when compressed (e.g., see the collapsed end view). In FIG. 7C the annular bias is a stent-like structure having a plurality of zig-zagging struts (members).

[00042] FIGS. 8A-8C illustrate an example of an apparatus including a flexible tractor tube having a stent-like annular bias (formed of a loop of a sinusoidally arranged strut(s) having a 0.002" thickness attached to the open end of a 144 end 0.00075" NiTi braid flexible tractor tube). FIGS. 8A sows the expanded annular bias, shown attached to the flexible

tractor tube in FIG. 8B. The flexible tractor tube with the annular bias of FIG. 8A is shown attached to an elongate puller in FIG. 8C.

[00043] FIG. 9A shows another example of a flexible tractor tube (144 end 0.00075" NiTi) having an annular bias. FIG. 9B shows the open end of the flexile tractor tube rolling over the open distal end of the elongate inversion support catheter. FIG. 9C shows a schematic of the stent-like annular bias including lead-in arms that may help it roll over the elongate inversion support catheter.

[00044] FIG. 10 illustrates an example of a flexible tractor tube that is heat-set at the open end to have an inverted shape to allow for ease of insertion of the elongate inversion support catheter. In FIG. 10, the open (loose) end of the flexible tractor tube folds back under itself which may help guide the elongate inversion support catheter into the space between the flexible tractor tube and the elongate puller. In this example, the flexible tractor tube may not require an additional annular bias.

DETAILED DESCRIPTION

[00045] In general, described herein are mechanical thrombectomy apparatuses having an inverting flexible tractor tube that is configured to be deployed in situ (e.g., within a catheter) without jamming. Any of these apparatuses may include an elongate elongate inversion support catheter over which the flexible tractor tube inverts at the distal end. In the deployment configuration, the flexible tractor tube may comprise a flexible tube that doubles back (e.g., inverts) over the distal end opening of the elongate inverting support catheter so that the tractor tube extends into the opening of the elongate inverting support catheter when the tractor tube is pulled proximally. The tractor tube may be attached at one end to an elongate puller. Pulling the elongate puller proximally will roll and invert the tractor over the distal end opening of the elongate inverting support catheter which may capture a clot and pull it into the elongate inversion support catheter.

[00046] Any of the apparatuses may include a coating (e.g., hydrophilic, lubricious coating, etc.) or the like to enhance the sliding and inverting of the tractor over the distal end. Further, any of these apparatuses may include one or more projections that are configured to enhance grabbing and/or maceration of a clot.

[00047] In general, a mechanical thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an elongate inversion support catheter having a distal end and a distal annulus (distal end opening), and a flexible tractor assembly

including a flexible tractor tube coupled to an elongate puller. The flexible tractor tube is configured to roll and invert over the distal end opening of the elongate inverting support catheter.

[00048] In many of the examples described herein, the tractor assembly is configured to extend within the elongate inversion support catheter when deployed. Any of these apparatuses may switch between a delivery configuration, e.g., in which the entire tractor assembly may be held within the elongate inversion support catheter prior to deployment, and a deployed configuration, e.g., in which the elongate inversion support catheter is positioned between the flexible tractor tube and the elongate pusher to support the flexible tractor tube as it is pulled into the elongate inversion support catheter distal end opening to roll and invert into the elongate inversion support catheter. In particular, the apparatuses may be configured so that the transition between the delivery configuration and the deployed configuration is robust. For example, as will be described in greater detail herein, any of the apparatuses described herein may include an annular bias that enhances the ability of the elongate inversion support catheter to be inserted between the flexible tractor tube and the elongate puller.

[00049] FIGS. 1A to 1I illustrate various components of a mechanical thrombectomy apparatus that may include any of the features described herein. For example, FIG. 1A shows a catheter (e.g., an elongate inversion support catheter) that may form part of the apparatuses described herein. In this example, the elongate inversion support catheter includes a catheter body 100 having a distal end region 103 that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing harness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00050] In FIG. 1A, the elongate inversion support catheter is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled

over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of of compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include an elongate inversion support catheter that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like. In FIG. 1A the catheter 100 of the elongate inversion support catheter may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00051] In some variations the distal end 105 of the elongate inversion support is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in some variations the distal tip (end) may be curved or radiused 109 as shown in FIG. 1B, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[00052] FIG. 1C shows an example of a flexible tractor tube 144 coupled to an elongate puller 146, forming a pullable tractor assembly 140. In this example, the tractor tube is shown integrated with the puller and extending back over the puller, forming the assembly. The opposite end of the flexible tractor tube 147 is open and free (e.g., not connected to the puller or catheter). As will be described in greater detail below, this open, free, end may be adapted to be expanded and held open, e.g., by shape setting back on itself and/or by including an annular bias, to enhance deployment and positioning of the catheter between the flexible tractor tube and the puller. In FIG. 1C, the tractor tube is formed of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The tractor is shown extended from the puller in a first configuration. It may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 144 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The puller 146 may typically be a less-expandable (or non-expandable) structure (tube, puller, etc.). For example, the tractor 144 may be configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first

configuration to a radial diameter that is between 1.1 and 10 times (e.g., between 1.1x and 5x, between 1.1x and 4x, etc.) the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained. In FIG. 1D, the tractor tube has a larger expanded diameter than the variation shown in FIG. 1C in a relaxed configuration. In any of these variations, the expandable tractor may be biased to expand open. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00053] In FIGS. 1C and 1D the tractor and puller have two portions, a tractor tube 144 and a less expandable (or non-expandable) proximal portion comprising the elongate puller 146. The puller may be a separate region, such as a wire, catheter or hypotube, which is connected to an end region of the tractor (e.g., a flexible mesh, woven, braided, etc.), e.g., the distal end or near the distal end. The inverting region of the tractor, where it rolls and inverts over the distal end opening of the catheter may be referred to as the distal-facing region of the tractor, which may actively grab clot when rolling.

[00054] In FIG. 1E, the tractor assembly (flexible tractor tube 144 and puller 146 of FIG. 1D) are shown within an elongate inversion support catheter 100. The tractor is collapsed down 101, e.g., onto the puller, and may be held collapsed within the elongate inversion support catheter. Thus, FIG. 1E shows the pre-deployment (e.g., delivery) configuration. The tractor assembly may be axially movable (slidable) within the catheter so that it can be positioned within the catheter and within the vessel.

[00055] FIG. 1F shows a fully deployed apparatus. In FIG. 1F, the tractor tube is in an unconstrained or deployed configuration, and the elongate inversion support catheter is positioned between the tractor tube and the puller so that the tractor tube can be pulled proximally by pulling on the puller and rolling the tractor tube into the elongate inversion support catheter so that it inverts. In FIG. 1F, the tractor in this deployed configuration (e.g., the portion that is inverted over the distal end of the catheter) has an outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. Thus, the tractor 144 may be biased so that it has a relaxed expanded configuration with a diameter that is greater than the outer diameter (OD) of the elongate inversion support catheter; in addition, as will be described in relation to FIGS. 1G and 1H, below, the tractor tube may also be configured (e.g., by heat setting, etc.) so that when the tractor tube is inverted and pulled into the elongate inversion support catheter, the outer diameter of the inverted tractor tube has an outer diameter that is greater than 0.5x (e.g., greater than 0.6x, greater than 0.7x, greater than 0.75x, greater than 0.8x, greater than 0.9x, greater than 1x, etc.) the inner diameter (ID) of the

elongate inversion support catheter. This combination of an un-inverted diameter of the tractor tube of greater than the diameter of the OD of the elongate inversion support catheter and an inverted diameter of the tractor tube of greater than 0.7x the ID of the elongate inversion support catheter is surprisingly helpful for preventing jamming of the apparatus, both when deploying the apparatus and when rolling the tractor over the distal end opening of the elongate inversion support catheter to grab a clot. The tractor may be expandable and may be coupled to the puller as shown. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to elongate puller (e.g., a push/pull wire or catheter).

[00056] FIGS. 1G and 1H illustrate the removal of a clot using an apparatus such as the apparatus components of FIGS. 1A and 1E. The apparatus 10 is shown in a deployed state. In this example the thrombectomy apparatus 10 is configured as a thrombectomy apparatus including an elongate inversion support catheter 100 and a flexible tractor tube 144 that extends over the distal end region of the catheter and doubles-over itself at the distal end of the catheter to invert so that the external tractor end region is continuous with an inner, less-expandable (in this example, less-expandable includes non-expandable) second distal end region 146 (puller) that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The pusher/puller member that may be a rod or other member that is continuous with the distal end region of the tractor. In FIG. 1G the apparatus is shown positioned and deployed within the vessel 160 near a clot 155. The clot may be drawn into the catheter by pulling the tractor 140 proximally into the catheter 101, as indicated by the arrow 180 showing pulling of the inner portion of the flexible tractor (e.g., using a handle, not shown) resulting in rolling the tractor over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled into the catheter, shown by arrows 182. The end of the tractor outside of the catheter may be "loose" relative to the outer wall of the catheter. FIG. 1I illustrates another example of a tractor assembly 154 including a tractor tube 144 that is coupled to a puller 156. The puller in this example is tapered (having tapering region 161) and may therefore have a different flexibility of the distal end region than the proximal end region. For example the proximal end region may be less flexible than the narrower-diameter distal end region 195 to which the tractor is coupled. The assembly includes a radiopaque marker 165. The tractor may be attached to the puller by any appropriate means. For example, the tractor may be crimped, glued, fused, or otherwise attached to the puller, typically permanently.

[00057] In general the mechanical thrombectomy apparatuses described herein may be highly flexible, both before actuating and during operation. For example, the flexible tractor may not increase the stiffness/flexibility of the catheter of the elongate inversion support, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortious vessels of the neurovasculature. Described herein are flexible tractor tube portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[00058] The tractors may be woven, braided and/or knitted materials. For woven and braided materials, which may include a plurality of fibers that are woven or braided to form the inverting tube, these structures may be tuned to prevent jamming and/or to reduce the force necessary to pull the tractor and invert over the catheter tip. For example, the mechanical atherectomy apparatus may include a braid-type tractor that can roll freely around the tip of catheter even in a tortuous anatomy and when grabbing clot by tuning one or more of the braid structure; minimizing the braid angle; including a hydrophilic coating on the distal aspect of the catheter outer diameter (OD) or the inner diameter (ID) of the braid (e.g., tractor); including a radiused wall on the catheter; and/or increasing the stiffness of the distal tip region relative to adjacent proximal regions.

[00059] As mentioned, the tractor (e.g., braided, woven, knitted, etc.) may be configured to collapse down into the inner diameter (ID) of the catheter as little as possible. For example the tractor may collapse to an ID that is greater than, equal to, or within 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter inner diameter (ID)/Catheter Tip OD, since, when the tractor is being pulled around catheter tip it may create axial tension on the tractor (e.g., braid, knit, etc.) that can inadvertently cause the tractor to jam on the catheter tip. When tractor is pulled around catheter tip, the tractor is being pulled in the axial orientation creating axial tension on tractor structure as the tractor is being pulled through the catheter ID. By having the tractor elements jam at an ID greater than or equal to 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter ID (or in some variations, OD), when being axially tensioned, the tractor is less likely to grab/synch down onto the catheter tip, helping the braid roll around

the catheter tip with less axial force applied by the user. If less axial force is required by the user to pull the tractor structure around the tip then the catheter tip is less likely to buckle or deflect when retracting the tractor. It may be advantageous to minimize the chance the catheter tip will buckle. The tractor can be tuned to "jam" at a specific ID by controlling any of the following variables and in any combination: selecting a specific number of braid ends, selecting the size/diameter of the braid ends; selecting the braid material (e.g., multifilament or monofilament); heat setting the bias on the braid (e.g., braid diameter); and selecting a braid pattern, e.g., 1x2, 1x1 or any other pattern.

[00060] The braid angle may be minimized to prevent locking up of the rolling of the tractor over the catheter end opening. Typically, the lower the braid angle (e.g., 45 degrees or less, 40 degrees or less, 35 degrees or less, 30 degrees or less, 25 degrees or less, 20 degrees or less, etc.) the less likely it is to have the braid cross over points catch on the catheter tip.

[00061] In any of the variations described herein, the catheter and/or a surface of the tractor may be coated to enhance rolling over the distal end region of the catheter. It may be helpful to have a hydrophilic coating on the distal aspect of the catheter OD or the ID of the tractor so the tractor can more easily side over the catheters distal end and around the tip of the catheter when pulled through the inside of the catheter.

[00062] The radius wall of the catheter tip may be chosen/set to within a range that allows sliding. For example, it may be helpful for the tip of the catheter to have the largest radius possible but at least 0.0025" radius wall on the catheter, ideally approximately 0.005" radius wall.

[00063] The stiffness of the distal of the catheter may be sufficiently stiff to prevent collapse as the tractor is pulled; it may also be lubricious (e.g., by a coating or material property). The distal most section of the catheter tip (e.g., the last 5mm) may be fabricated of a material which is stiff enough and lubricious enough so the distal tip of the catheter does not collapse or buckle inward ward when the braid structure is rolling around the catheter tip. Thus, the distal tip may have a stiffness that is greater than the more proximal region at the distal end of the catheter.

[00064] It may be helpful or desirable to have pores in the tractor. A lack of gaps or small pore size may limit the ability of the braid to grab clot. Alternatively or additionally, it may be desirable to form a braid structure with texture. One example is to braid two or more different diameter braid ends into the same structure: the difference in braid end diameters

will help form a texture to the braid structures outer surface, aiding the grabbing of the clot when rolling the braid-dozer around the catheter tip.

[00065] As an alternative (or in addition) the tractor may be configured to lock so it does not compress in diameter during axial load by adding a coating, laminate or adhesive to the braid at a desired diameter. Adding a thin coating, laminate or adhesive can inhibit the braid elements from sliding with respect to each other, thereby locking the braid to a specific diameter. The coating can be applied while leaving the majority of the pores and pore area substantially open. Examples of thin coatings include urethanes and silicones with and without hydrophilic coatings and hydrophilic coatings with no tie layer.

[00066] Reducing the sliding friction of tractor to outer catheter wall, improving tractor to tip rolling, and/or enhancing tractor to inner catheter sliding may also be achieved by including a sliding skin or sleeve. For example, a thin (e.g., ultrathin) sleeve may be used. The sleeve would be made from low friction polymer (PET, PE, PP, PTFE, ePTFE, pebax, urethanes) by braiding, knitting, weaving, extrusion, melt blown, melt spinning, etc. The sleeve could be made from laser slotted tubing, chemical etching, micro machining. The sleeve could be also coated with a lubricious coating such as a hydrophilic coating. Lubricious coatings can be located on the outside and/or inside surfaces. The sleeve may be placed between the dozer element and the catheter wall and attached to the puller element. The sleeve may be less than 0.002" thick, ideally, less than 0.001" wall thickness. The sleeve may decouple the tractor clot grabbing system from the catheter wall, tip rolling and inner catheter dragging friction. The sleeve could be totally free from the tractor, connected to the tractor in discrete locations or connected fully to the tractor. This may allow the tractor to be designed to grab clot (larger wires: 0.001" to 0.002" for neuro, and 0.002" to 0.007" for other applications) and the skin to minimized in thickness and structure to reduce friction and skin bending stiffness.

[00067] In some variations, the tractor region may be formed of with a mixed or hybrid structure, combining one or more of interwoven or knitted braid polymer filaments with metallic filaments. The mixed structure (hybrid structure) may leverage both metallic elements interwoven with low friction polymer elements. The metallic filaments may create stiffness elements that may grip/grab a clot. The polymer filaments may aid in grabbing clot but may provide surface friction reduction to the outer catheter wall, the catheter tip and the inner catheter wall once around the tip.

[00068] Any of the apparatuses described herein may include a tractor having a hydrophilic/lubricous coating on the inside surface, e.g., for braided/knitted tractors, on the

inside surface (contacting the outer and inner diameter of the catheter) of the braid/knit, which is in contact with the outside of the catheter. Examples of lubricous coatings include hydrophilic coatings (e.g.,. hydrogels) and hydrophobic coatings (e.g., fluorine coating such as PTFE & FEP, parylene, silicone, siloxane (silicone additive) added to various polymers including pebax to make any material more lubricious, Polyethylene, polypropylene, FEP)

[00069] As mentioned above, any of these apparatuses may include a distal tip that is less rigid (e.g., 'softer') than the more proximal regions of the distal tip. This may be achieved by having a structural supporting member reinforcing the distal tip, or by modifying the material forming the distal tip.

[00070] Any of the tractors described herein may include a marker or makers (e.g., radiopaque markers, such as gold, Pt, etc.).

[00071] For purposes of illustration and to better understand the disclosed apparatuses, FIGS. 2A-2F illustrate an in situ method of deploying a mechanical thrombectomy apparatus constructed according to embodiments of the present invention. In FIG. 2A the elongate inversion support catheter 201 is positioned within the vessel, near a clot 239, e.g., by moving the elongate inversion support catheter distally 210 towards the clot. The elongate inversion support catheter may be positioned with a guidewire (not shown), or without a guidewire. The tractor assembly portion of the apparatus, e.g., a flexible tractor tube 244 and elongate puller 245 may be positioned with the catheter, or it may be moved through the catheter once it is in position within the vessel. In FIG. 2B, the tractor assembly 240 is positioned within the elongate inversion support catheter near the distal end. Once it is in an approximate location (e.g., near the clot 239), the flexible tractor tube 244 may be extended 212 from the distal end of the elongate inversion support catheter, as shown in FIG. 2C. The flexible tractor tube may be deployed out of the elongate inversion support catheter by pulling 214 the elongate inversion support catheter proximally and/or pushing the flexible tractor tube distally; once out of the elongate inversion support catheter, the flexible tractor tube is allowed to expand into a second (expanded configuration) outside of the elongate inversion support catheter. As mentioned, the flexible tractor tube may be biased so that in this un-inverted configuration the diameter of the flexible tractor tube is between 1.1x and 5x the OD of the elongate inversion support catheter (e.g., typically between 1.1x and 3x the OD of the elongate inversion support catheter, etc.). The elongate inversion support catheter may then be moved back distally, between the flexible tractor tube 244 and the elongate puller 245, as shown in FIG. 2D.

[00072] In practice, the catheter must fit into the open (free) end of the flexible tractor portion. The apparatus may be modified, e.g., by including an annular bias at or near the open end of the flexible tractor portion. Alternatively or additionally, the open end may be biased (e.g., heat set, shape set, etc.) to invert over or under itself.

[00073] In FIG. 2E, once the elongate inversion support catheter is positioned distally between the flexible tractor tube and elongate puller, the flexible tractor tube may be rolled and inverted 266 into the elongate inversion support catheter, as shown in FIG. 2F. In this example, the elongate puller 245 may be pulled through the elongate inversion support catheter proximally 218 to pull the flexible tractor tube proximally into the elongate inversion support catheter. In FIG. 2F, the rolling tractor is shown grabbing the clot 239, and inverting into the elongate inversion support catheter while pulling the clot into the elongate inversion support catheter. The flexible tractor tube in this example is biased to expand to between 1.1 and 4 times an outer diameter of the elongate inversion support catheter in an un-inverted configuration (e.g., FIG. 2D) and is further biased to expand to greater than 0.5x an inner diameter of the elongate inversion support catheter in an inverted configuration (when drawn into the catheter as shown in FIG. 2F).

[00074] FIGS. 3A-3B illustrate another example of a tractor assembly including a flexible tractor tube 344 attached at one end to an elongate puller 345. In this example, similar to FIG. 1I, the elongate puller has a stepped profile. The narrower-diameter region formed in the elongate puller by the stepped profile may allow the flexible tractor tube of the tractor assembly 334 to be compressed with a smaller profile within the elongate inversion support catheter. In FIG. 3A the flexible tractor tube 344 is shown collapsed (compressed) against the elongate puller. This configuration may provide improved mobility within the elongate inversion support catheter. This variation may also be readily adapted for application to a vacuum through the hollow elongate puller. In FIG. 3A the flexible tractor tube is shown as compressed or collapsed. FIG. 3B shows the flexible tractor tube in an expanded configuration. In this example, the flexible tractor tube 244 is expanded outward from the puller. The tractor tube may be biased (e.g., heat set, shape set, etc.) in this configuration. Alternatively or additionally, the apparatus may be compressed and held within an elongate inversion support catheter.

[00075] FIGS. 4A-4C illustrate deployment of the elongate puller with a stepped outer diameter, such as the variation shown in FIGS. 3A-3B, from a delivery configuration to a deployed configuration. In FIG. 4A the elongate puller 445 is positioned at the distal end of the elongate inversion support catheter 401; the flexible tractor tube 444 is attached at one

end to the puller. In FIG. 4B, the flexible tractor tube 444 is extended from the distal end opening of the elongate inversion support catheter and expanded 449 at least slightly. In this example, the elongate inversion support catheter 401 may be withdrawn proximally 410. An annular bias, described in greater detail below, may be used in this variation as well, to hold the free, open end 433 of the tractor tube 444 open. As shown in FIG. 4C, the elongate inversion support catheter 401 may then be positioned 412 between the flexible tractor tube 444 and the elongate puller 445, so that the elongate inversion support catheter 401 can support the flexible tractor tube a the distal end so that it can roll and invert into the elongate inversion support catheter, e.g., by pulling the elongate puller to invert into the elongate inversion support catheter.

[00076] FIG. 5A-5F illustrate the use of the apparatus of FIGS. 3A-3B, including an annular bias, to remove a thrombus (clot) from within a vessel. In FIG. 5A the elongate inversion support catheter 501 is positioned near a clot 539 in the vessel 550. The elongate pusher 545, to which a flexible tractor tube 544 is attached, forming a tractor assembly, may be positioned in the elongate inversion support catheter at the distal end. In FIG. 5B the elongate pusher is attached to the first end of the tractor tube 544 at a first end, with an annular bias open and unsecured (e.g., free) at the second end. The second, open or free end 533 may include one or more annular biases 525 that may is extended distally through the catheter and out of the distal end of the elongate inversion support catheter 501, as shown in FIG. 5B. In FIG. 5C, the annular bias 525 holds the free end 533 of the flexible tractor tube open. Alternatively or additionally, the flexible tractor tube may be biased to expand to diameter that is slightly greater than the outer diameter of the catheter 501 (e.g., greater than 1.1x the outer diameter of the elongate inversion support catheter), however the annular bias 525 may be open even slightly more, and may be stiffer (e.g., more rigid) when expanded open, as shown in FIG., 5C. The elongate inversion support catheter 501 may then be inserted distally through the annular bias 525 and between the flexible tractor tube 544 and the elongate puller 545, as shown in FIGS. 5D-5E. The entire apparatus may be advanced distally 552, either before or while rolling the tractor into the elongate inversion support catheter 501. A vacuum 560 (optional) may be applied through the elongate puller 544 and/or elongate inversion support catheter and/or the puller may be drawn proximally 554, as shown in FIG. 5E. In FIG. 5F, withdrawing 556 the elongate puller proximally (with or without a vacuum) to roll the flexible tractor over the distal end of the elongate inversion support catheter so that it inverts into the elongate inversion support catheter may draw the clot into the elongate inversion support catheter, as shown.

[00077] The variations shown in FIGS. 3A-3B, 4A-4C and 5A-5F having a stepped outer diameter in the puller may maximize the inner diameter of the tractor assembly, which may aid in aspiration (mechanical or by vacuum). In any of these variations, a vacuum can be applied to the apparatus (e.g., the tractor assembly) and/or the elongate inversion support catheter. In some variations the OD of the puller along at least part of its length (e.g., proximal to the free end of the tractor tube) may be approximately the same as the ID of the elongate inversion support catheter. This may aid in forming a seal such that vacuum applied through the elongate puller may be maintained the distal end of the elongate inversion support catheter and/or puller, which may help in grabbing the clot.

[00078] FIGS. 6A-6F illustrate another variation of an apparatus including an annular bias 625 on an open, free, end 638 of the flexible tractor tube 644. In FIG. 6A, the elongate inversion support catheter 601 is positioned in the vessel. In FIG. 6A, a guidewire 671 is shown. The catheter may be advanced over the guidewire, to approach the clot 639. In FIG. 6B, the elongate puller 645 and flexible tractor tube 644 are positioned distally within the elongate inversion support catheter 601, also over the guidewire 671. The tractor assembly includes the flexible tractor tube 644 attached at one end to the elongate puller 645, with the other end of the flexible tractor tube open and free (e.g., not attached to the puller or catheter), but coupled to an annular bias 625. The guidewire 671 may be removed or left in position when deploying the flexible tractor tube from the distal end of the elongate inversion support catheter. In FIG. 6C, the tractor assembly, including the distal end of the elongate puller 645 and the entire flexible tractor tube 644 is extended distally from the elongate inversion support catheter 601. The annular bias 625 expands 674 to a diameter that is greater than the outer diameter of the elongate inversion support catheter 601 (e.g., greater than 1.1x the diameter of the elongate inversion support catheter). The annular bias may also act to stiffen or otherwise stabilize this end region of the tractor tube (which may be on or near the open end of the tractor tube) so that the elongate inversion support catheter 601 can be inserted through the annular bias, as shown in FIG. 6D.

[00079] In FIG. 6D and 6E, the elongate inversion support catheter 601 is advanced distally 671 within the annular bias and between the flexible tractor tube 644 and the elongate puller 645, so that the elongate inversion support catheter can support the flexible tractor tube 644 as it is pulled 678 proximally by the elongate puller 645 to roll 663 and invert over the distal end opening of the elongate inversion support catheter (as shown in FIG. 6F). The apparatus may be advanced (e.g., while pulling the elongate puller proximally) to grab and remove a clot 639 from the vessel, as shown in FIG. 6E.

[00080] In any of these variations, the annular bias may be configured to keep the free end of the tractor tube open when deployed. The annular bias may be welded braided, bonded, glued and/or integral to the tractor tube. The annular bias may be attached to an outside, an inside or both (e.g., may be folded over the open end of the tractor tube, or may be attached on either side of the tractor tube.

[00081] FIGS. 7A-7D illustrate four variations of annular biases that may be used to support the expanded open (free) end of the flexible tractor tube in any of the variations described herein. For example, FIG. 7A shows an annular bias forming a circular loop in the expanded end view. The loop may be formed of a shape memory material, such as Nitinol, or a polymeric material. The loop may be orthogonal to the braid or weave of the tractor tube, which may aid in compressing when rolling over the distal end opening of the elongate inversion support catheter. In some variations the annular bias may be heat set to an irregular circular shape to aid in folding or may include buckling points around the perimeter of the annular bias. In the side view shown of the annular bias of FIG. 7A the annular bias is angled relative to the long axis of the tractor tube; alternatively, the annular bias may be attached perpendicular to the long axis (similar to FIG. 7B.

[00082] In any of the variations described herein, the annular bias may be configured to include one or more predetermined collapse/expansion locations about which the annular bias is configured to collapse or expand as it transitions between an expanded and a collapsed configuration. For example, the predetermined locations may be defined by the one or more lobes or vertices forming the annular bias. FIG. 7B shows an example in which the annular bias includes folds or bends that may control the collapsed configuration. In this example, the annular bias has lobes or petals, which may predictably collapse when compressed (e.g., see the collapsed end view). The annular bias may be shaped to compress into a small diameter as the tractor tube rolls around the tip of the elongate inversion support catheter. The u-shaped features (lobes, petals, etc.) at noon, 3 o'clock, 6 o'clock, and 9 o'clock are one example. Other examples include the use of fewer (e.g., 2 lobes, 3 lobes) or more (e.g., 5 lobes, 6 lobes, etc.).

[00083] In general, the annular bias has a stiffness that is greater than the stiffness of the flexible tractor tube (e.g., greater than 1.5x the stiffness, greater than 2x the stiffness, etc.).

[00084] In FIG. 7C the annular bias is a stent-like structure having a plurality of zig-zagging struts (members). The stent-like annular bias may easily invert when rolling around the catheter tip. The length of the zig-zags may be limited to < about 5-10 mm. In some variation multiple rows of zig-zags may be used.

[00085] FIG. 7D shows an example of an annular bias that is funnel-shaped. In operation, this structure may both help the insertion of the elongate inversion support catheter between the tractor tube and the elongate puller, and may also help with inverting the end of the tractor tube and pulling it into the elongate inversion support catheter.

[00086] An example of a stent-like annular bias is shown in FIGS. 8A-8C. In this example the annular bias is formed of a sinusoidally arranged loop of wire (though multiple wires/struts may be used) having a 0.002" thickness, which is attached to the open end region of a 144 end 0.00075" NiTi braid flexible tractor tube. FIGS. 8A shows the expanded annular bias 803, shown attached to a flexible tractor tube 801 in FIG. 8B. The flexible tractor tube 801 with the annular bias 803 of FIG. 8A is shown attached to an elongate puller 805 in FIG. 8C. In the example shown in FIG. 8, the annular bias is attached near the open (free) end of the tractor tube at the distal end region, but is slightly distal to the end. In some variations the annular bias is attached at the very end (or edge) of the open end of the flexible tractor tube.

[00087] Any of the annular biases described herein may also be configured to enhance rolling of the distal end of the apparatus over the tip of the elongate inversion support catheter. For example, FIG. 9A shows another example of a flexible tractor tube (144 end 0.00075" NiTi) having an annular bias, being rolled 961 into the elongate inversion support catheter by pulling proximally on the tractor tube. In FIG. 9B the open end of the flexile tractor tube (with an attached sent-like annular bias 903) is shown rolling over the open distal end of the elongate inversion support catheter. In order to enhance this rolling, in some variations, the annular bias may also include one or more extension (e.g., lead in arms) that may extend along the long axis (length) of the flexible tractor tube. A schematic of this configuration is shown in FIG. 9C. In FIG. 9C the stent-like annular bias includes lead-in arms that may help it roll over the elongate inversion support catheter. The lead-in arms may help the annular bias to roll around the catheter tip and into the ID of the elongate inversion support catheter. One or more (e.g., 1, 2, 3, 4, 5, 6, 7, 8, etc.) lead-in arms may be used; these lead in arms may be all the same length of different lengths.

[00088] FIG. 10 illustrates an example of a flexible tractor tube 1001 that is heat-set at the open end to have an inverted shape 1003 to allow for ease of insertion of the elongate inversion support catheter. In FIG. 10, the open (loose) end of the flexible tractor tube folds back under itself which may help guide the elongate inversion support catheter into the space between the flexible tractor tube 1001 and the elongate puller 1005. In this example, the flexible tractor tube may not require an additional annular bias.

[00089] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[00090] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[00091] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[00092] Although the terms "first" and "second" may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[00093] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising" means various components can be co-jointly employed in the claimed articles (e.g., compositions and apparatuses including devices and systems). For example, the term "comprising" will be understood to imply the inclusion of any stated elements but not the exclusion of any other elements.

[00094] In general, any of the apparatuses described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may alternatively be exclusive, and may be expressed as "consisting of" or alternatively "consisting essentially of" the various components, steps, sub-components or sub-steps.

[00095] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or "approximately," even if the term does not expressly appear. The phrase "about" or "approximately" may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For example, if the value "10" is disclosed, then "about 10" is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that "less than or equal to" the value, "greater than or equal to the value" and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value "X" is disclosed the "less than or equal to X" as well as "greater than or equal to X" (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a

number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point "10" and a particular data point "15" are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[00096] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[00097] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

1. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:
   an elongate inversion support catheter having a distal end and a distal end opening;
   an elongate puller extending within the elongate inversion support catheter;
   a flexible tractor tube having a free first end and a second end that is coupled to a distal end region of the elongate puller, wherein the flexible tractor tube is inverted over the elongate puller and is held within the elongate inversion support catheter in a collapsed first configuration; and
   an annular bias disposed at least partially around the free first end of the flexible tractor tube,
   wherein the flexible tractor tube is configured to be extended from the distal end opening of the elongate inversion support catheter and to expand into an expanded second configuration, and
   wherein the annular bias has a diameter that is larger than an outer diameter of the elongate inversion support catheter when the flexible tractor tube is in the expanded second configuration.

2. The apparatus of claim 1, wherein the annular bias comprises a ring.

3. The apparatus of claim 1, wherein the annular bias comprises a stent having a zig-zag strut pattern.

4. The apparatus of any of claims 1-3, wherein the annular bias has a diameter that is between 1.1x and 5x of the outer diameter of the elongate inversion support catheter when the flexible tractor tube is in the expanded second configuration.

5. The apparatus of any of claims 1-4, wherein the annular bias comprises a plurality of pre-determined collapse locations about which the annular bias is configured to collapse or expand.

6. The apparatus of any of claims 1-4, wherein the annular bias comprises a plurality of lobes, wherein the plurality of lobes comprise a respective plurality of collapse locations on the annular bias.

7. The apparatus of any of claims 1-6, wherein the annular bias is coupled to one or more of an inner side and an outer side of the flexible tractor tube.

8. The apparatus of any of claims 1-7, wherein the annular bias comprises a plurality of lead-in arms oriented along a long axis of the flexible tractor tube.

9. The apparatus of any of claims 1-8, further wherein the flexible tractor tube in an un-inverted configuration is biased to expand to between 1.1 and 4 times an outer diameter of the elongate inversion support catheter and wherein the flexible tractor tube is further biased in an inverted configuration to expand to greater than 0.5x an inner diameter of the elongate inversion support catheter.

10. The apparatus of any of claims 1-9, wherein the elongate inversion support catheter is configured to be pushed through the annular bias and between the flexible tractor tube and an outer wall of the elongate puller when the flexible tractor tube is in the expanded second configuration.

11. The apparatus of any of claims 1-10, wherein the flexible tractor tube comprises a woven, braided, mesh or knitted material.

12. The apparatus of any of claims 1-11, wherein the flexible tractor tube is sufficiently soft so as to collapse radially under an axial compression of less than 200g of force.

13. The apparatus of any of claims 1-12, further comprising a guidewire lumen extending through the elongate puller, the guidewire lumen being configured to allow passage of a guidewire therethrough.

14. The apparatus of claim 11, wherein the flexible tractor tube is knitted.

15. The apparatus of any of claims 1-14, wherein the flexible tractor tube comprises one or more of steel, polyester, nylon, expanded Polytetrafluoroethylene (ePTFE), Nitinol, and a fabric.

16. The apparatus of any of claims 1-15, wherein a material hardness of the elongate inversion support catheter decreases along a length of the distal end thereof, wherein the distal end opening has a material hardness that is greater than a material hardness

of a region immediately proximal to the distal end, and wherein the distal end opening has a rounded lip profile.

17. The apparatus of any of claims 1-15, wherein the elongate puller comprises a hypotube.

18. The apparatus of any of claims 1-17, wherein the flexible tractor tube has a length between 3 cm to 50 cm.

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

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

an elongate puller extending within the elongate inversion support catheter, wherein the elongate puller comprises a central lumen;

a flexible tractor tube having a free first end and a second end that is coupled to a distal end region of the elongate puller, wherein the flexible tractor tube comprises a woven, braided, mesh and/or knitted material, is inverted over the elongate puller, and is held within the elongate inversion support catheter in a collapsed first configuration, and wherein the flexible tractor tube is biased in an un-inverted configuration to expand to between 1.1 and 4 times an outer diameter of the elongate inversion support catheter in and is further biased in an inverted configuration to expand to greater than 0.5x an inner diameter of the elongate inversion support catheter; and

an annular bias disposed at least partially around the free first end of the flexible tractor tube, wherein the flexible tractor tube is configured to be extended from the distal end opening of the elongate inversion support catheter and to expand into an expanded second configuration, wherein the annular bias has a diameter that is larger than an outer diameter of the elongate inversion support catheter in the expanded second configuration so that the elongate inversion support catheter may be pushed through the annular bias and between the flexible tractor tube and an outer wall of the elongate puller.

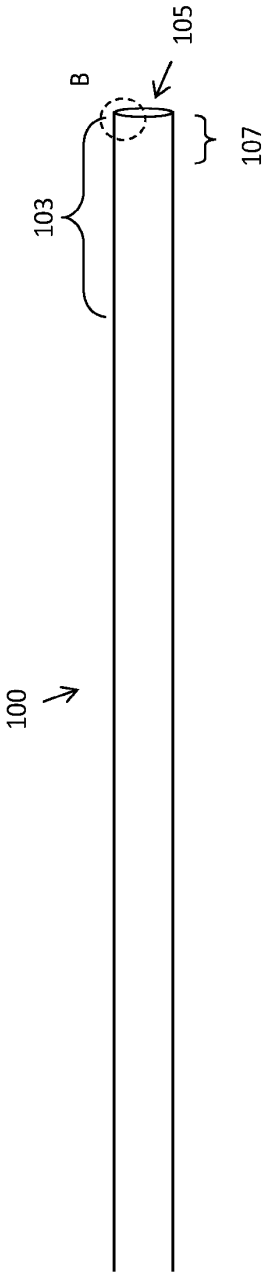


FIG. 1A

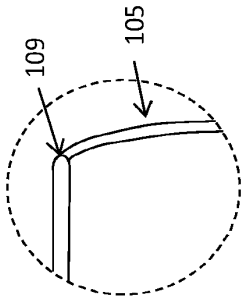


FIG. 1B

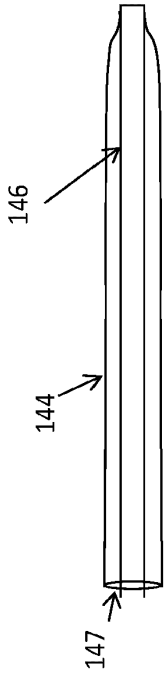


FIG. 1C

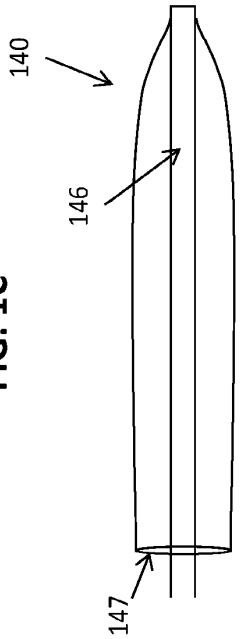


FIG. 1D

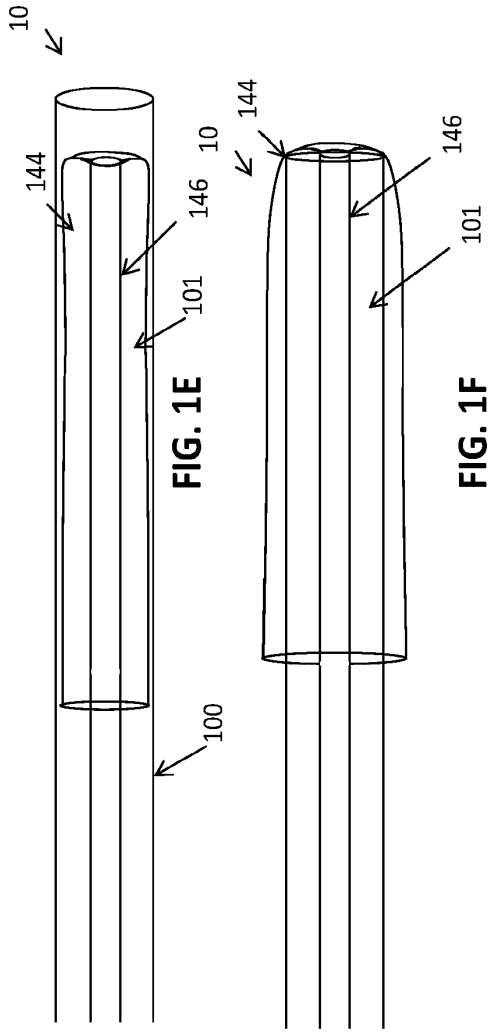


FIG. 1E

FIG. 1F

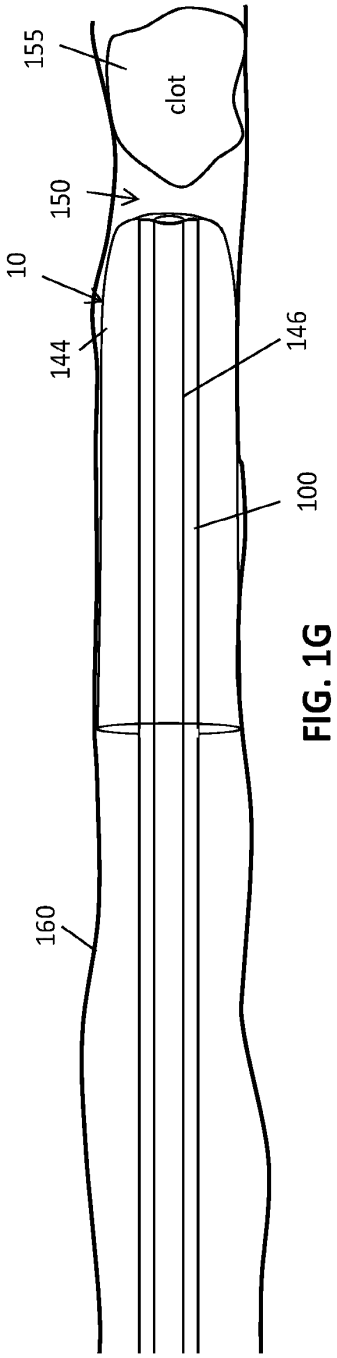


FIG. 1G

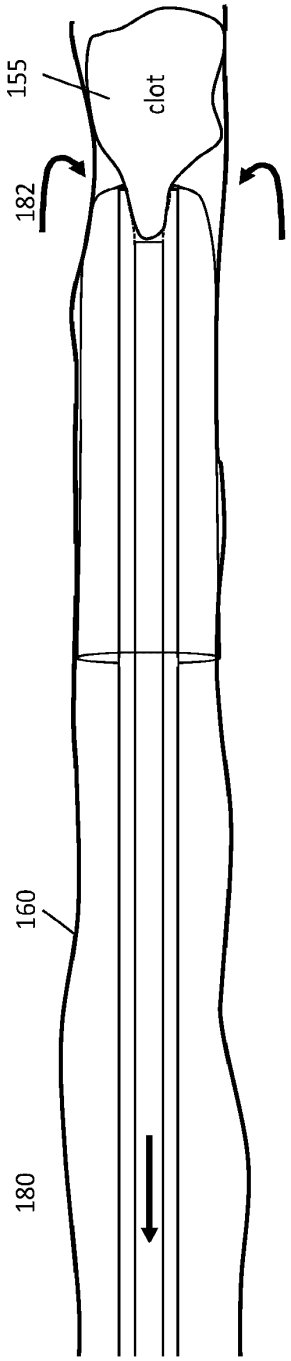


FIG. 1H

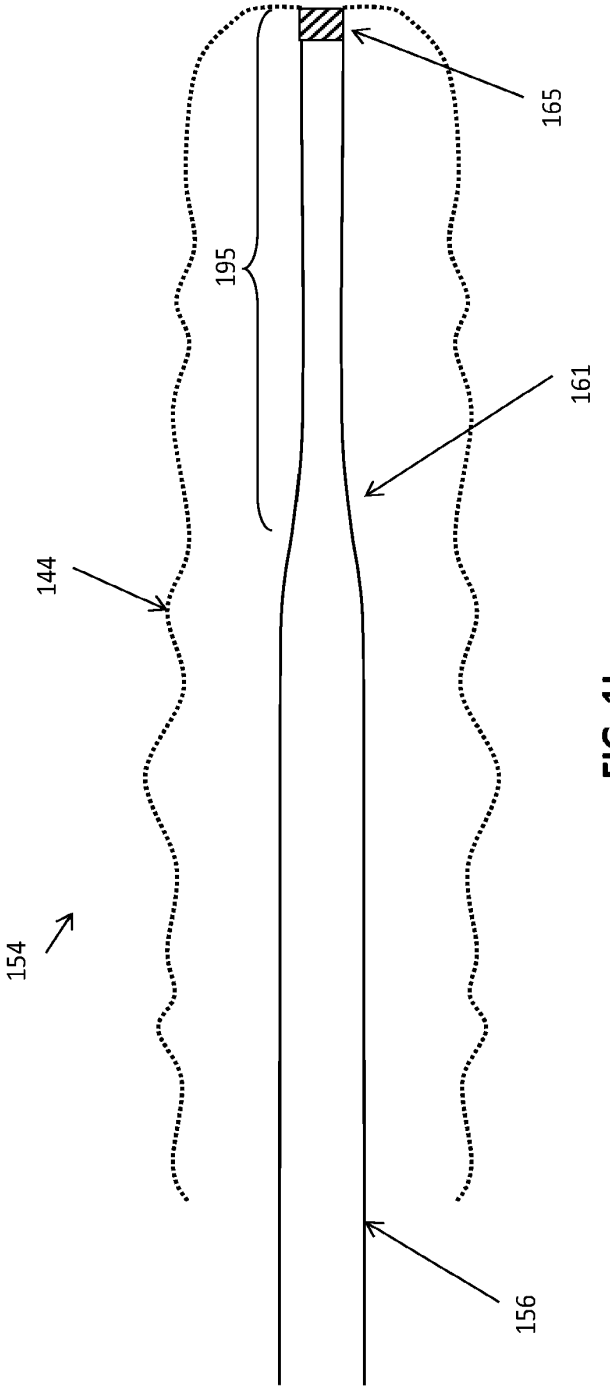


FIG. 1I

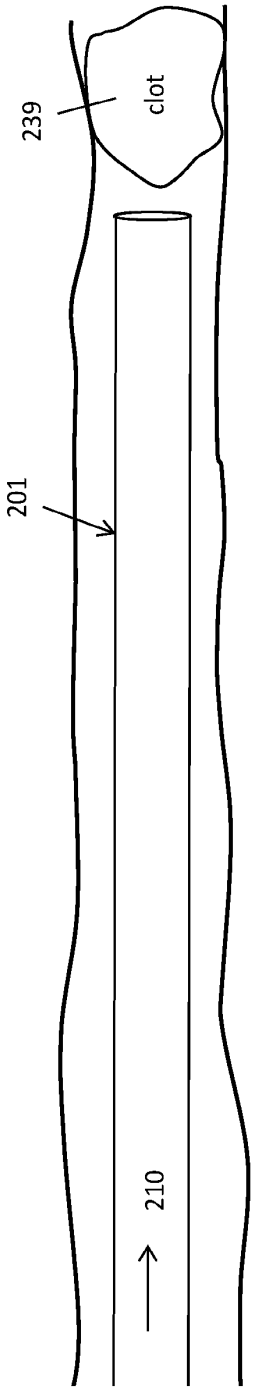


FIG. 2A

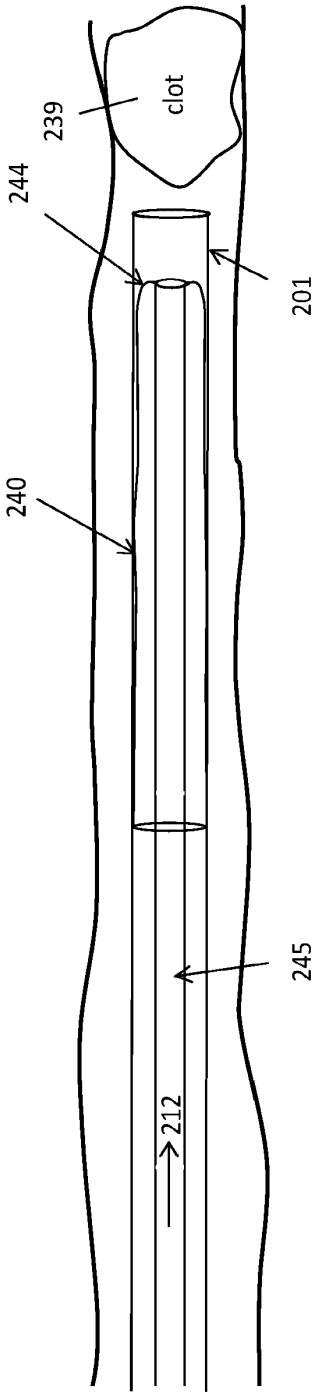


FIG. 2B

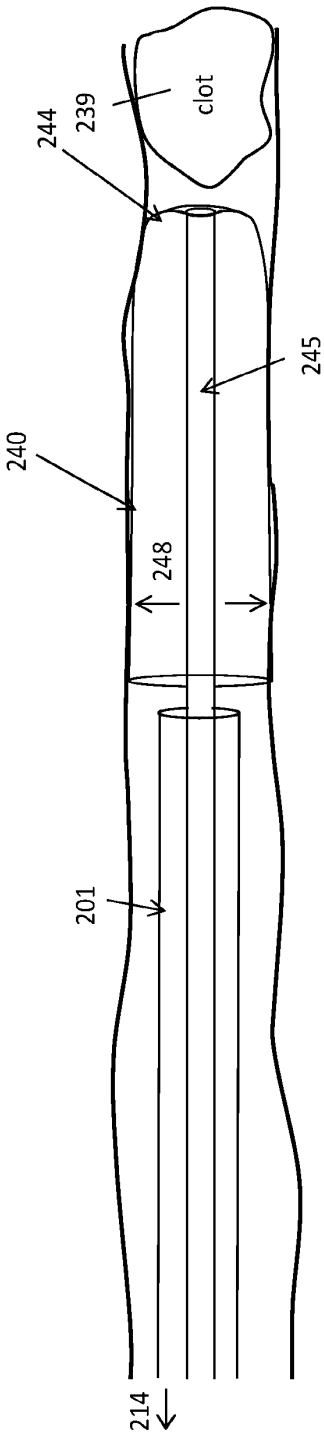


FIG. 2C

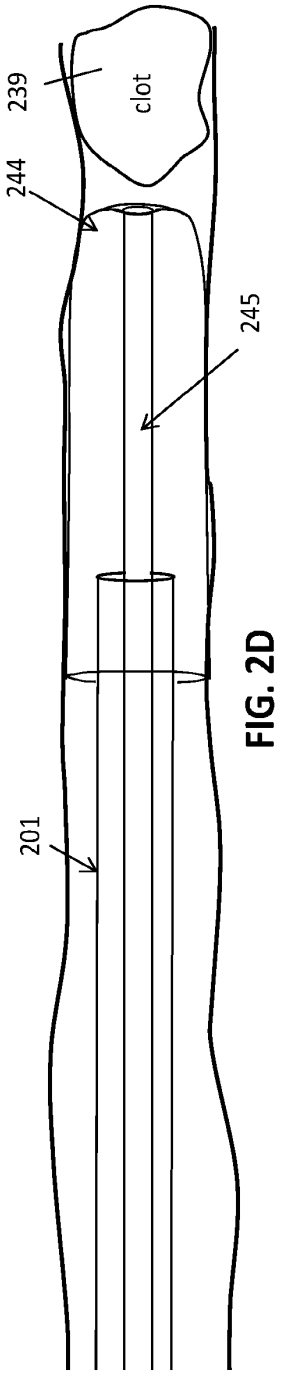


FIG. 2D

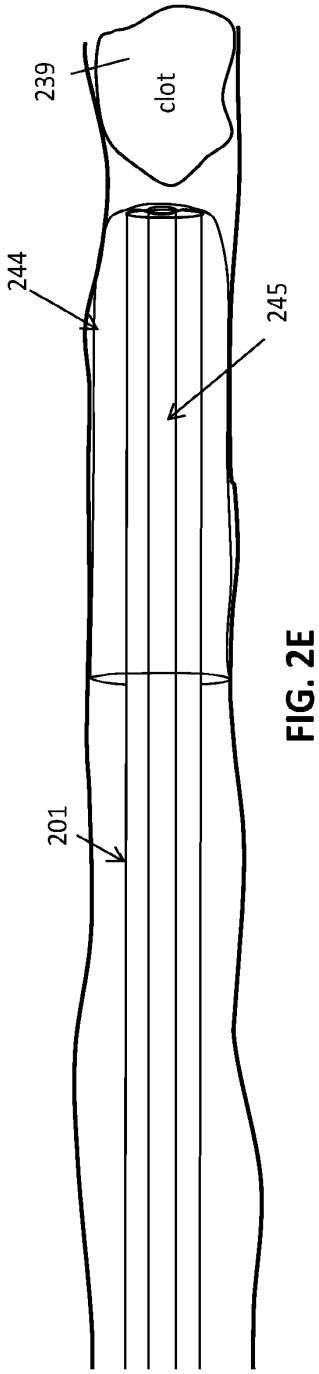


FIG. 2E

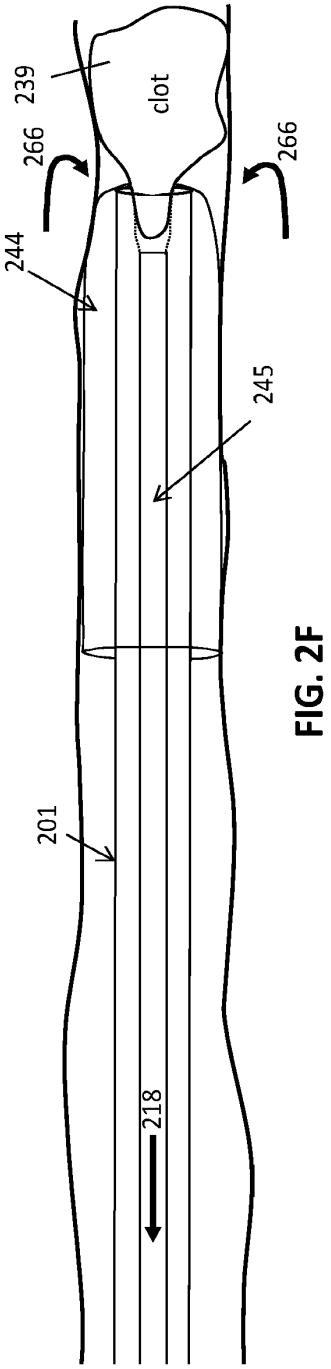


FIG. 2F

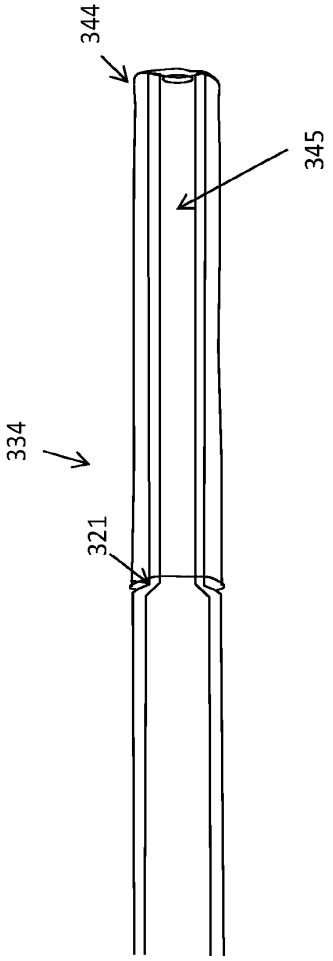


FIG. 3A

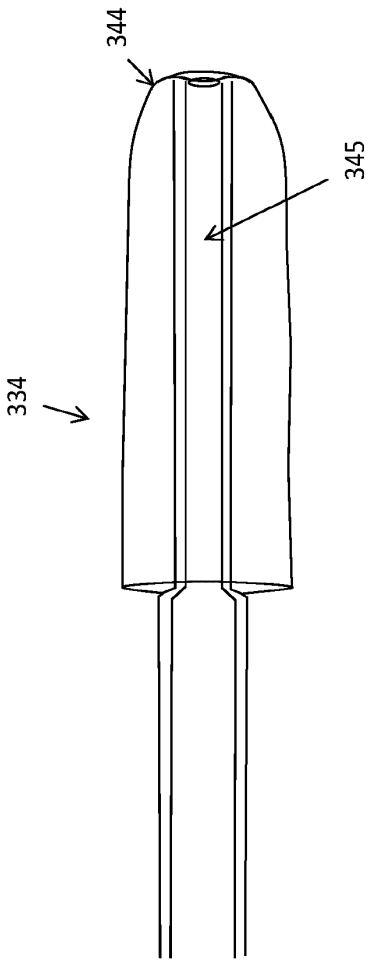


FIG. 3B

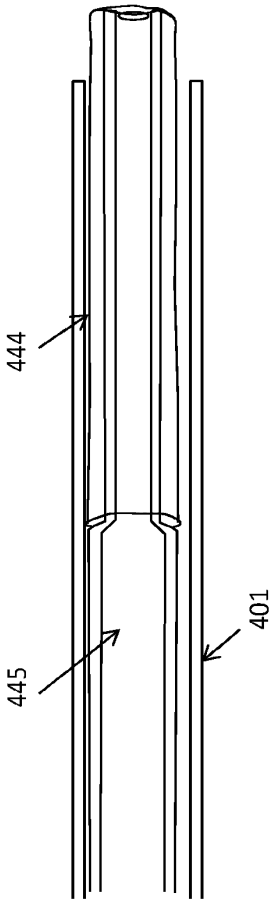


FIG. 4A

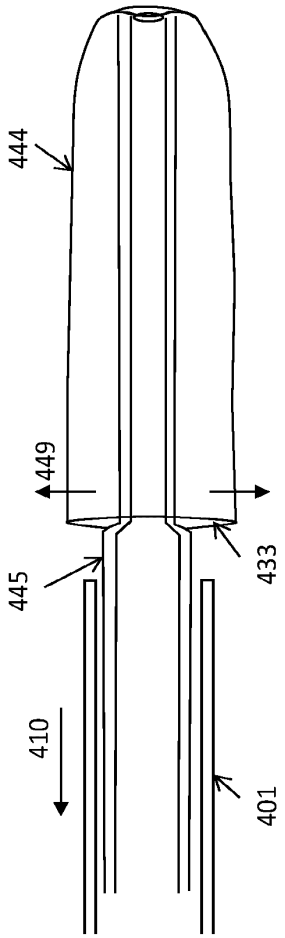


FIG. 4B

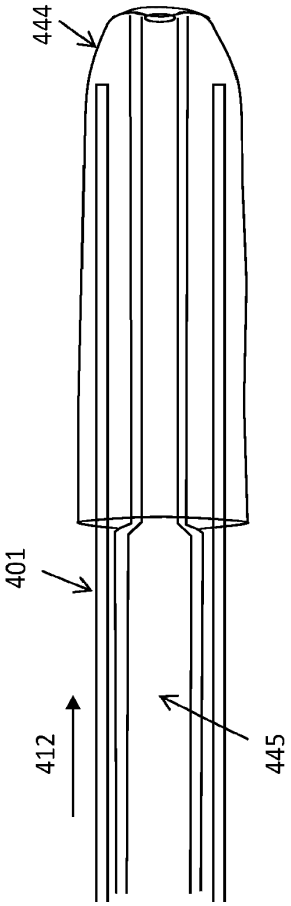


FIG. 4C

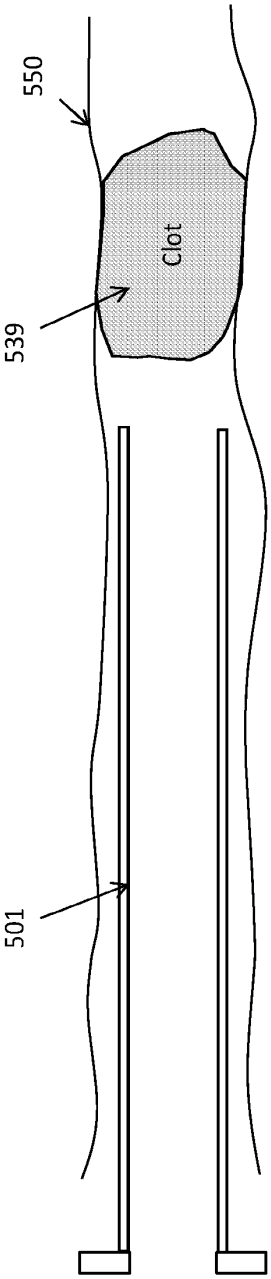


FIG. 5A

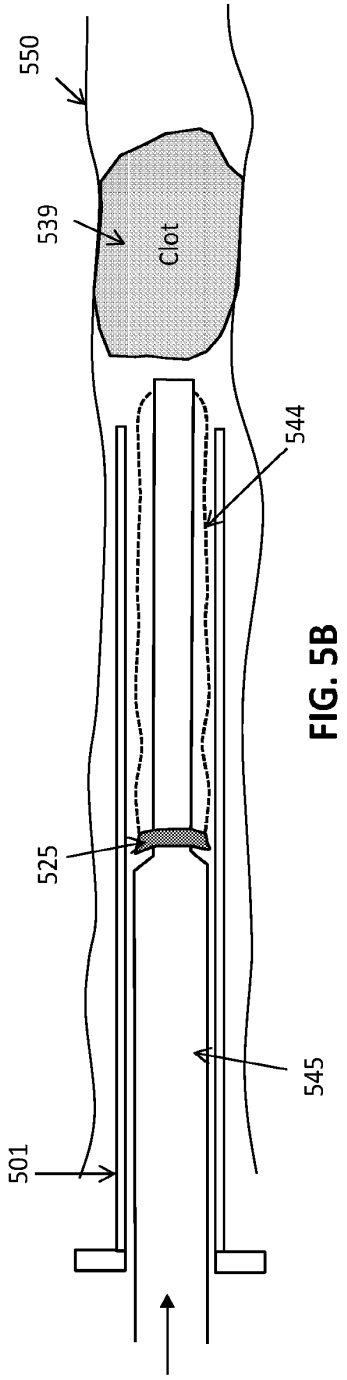


FIG. 5B

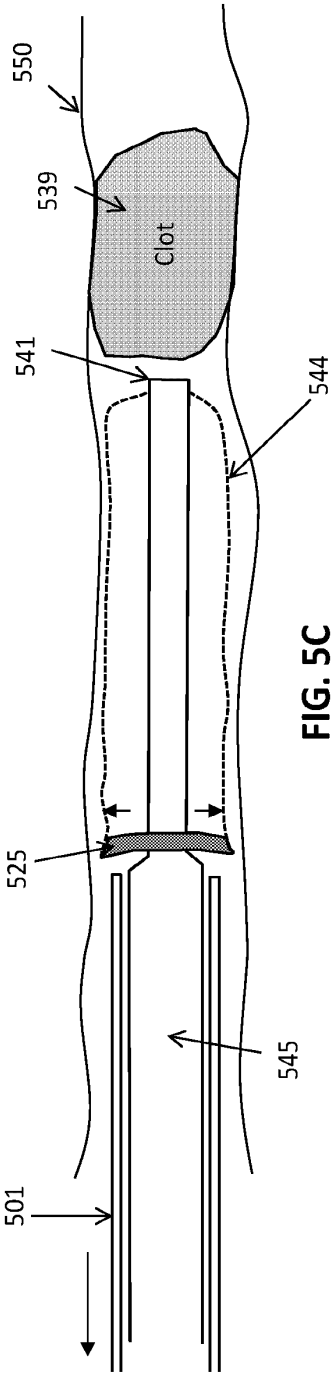


FIG. 5C

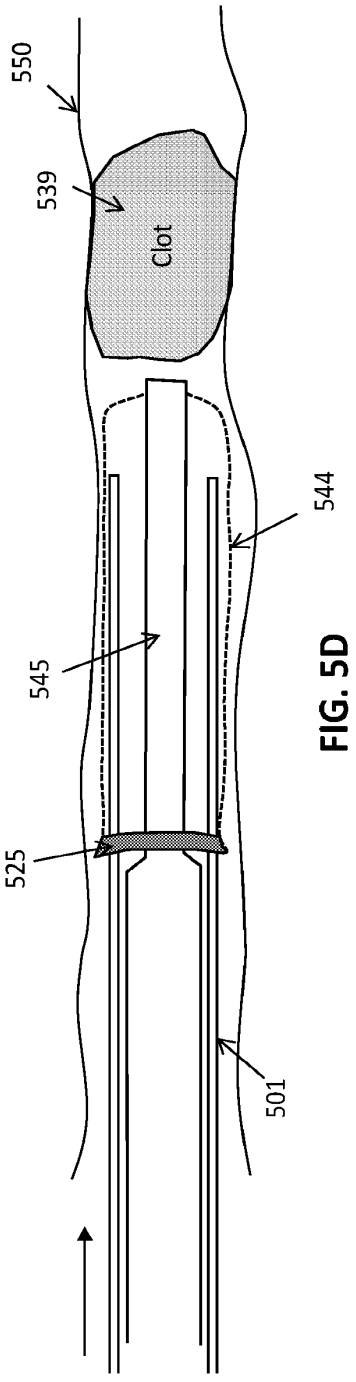


FIG. 5D

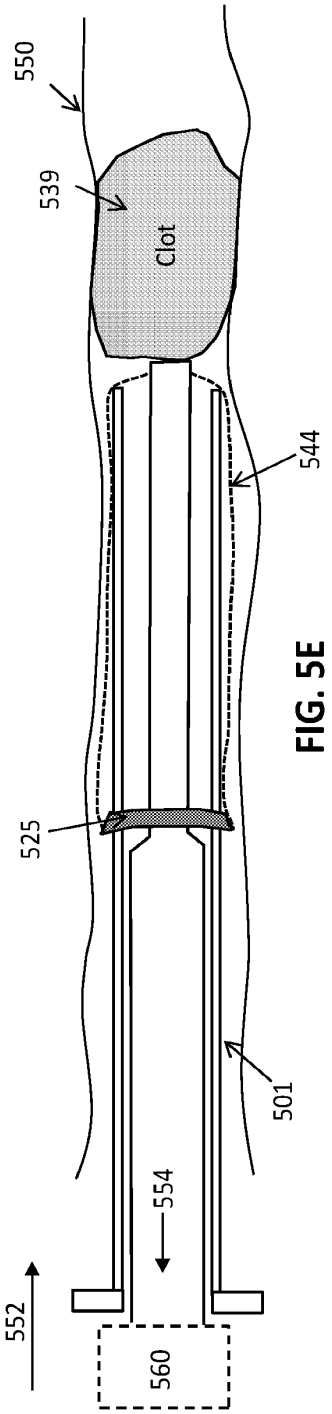


FIG. 5E

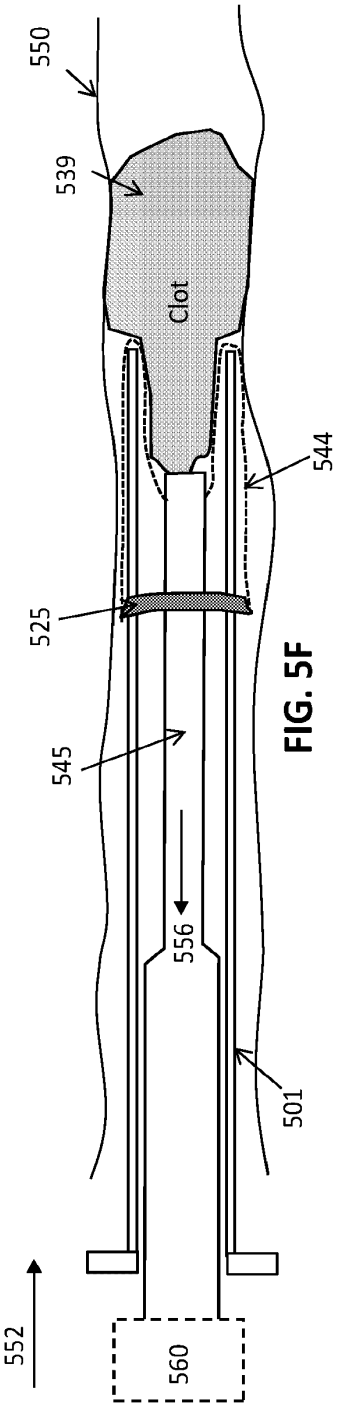


FIG. 5F

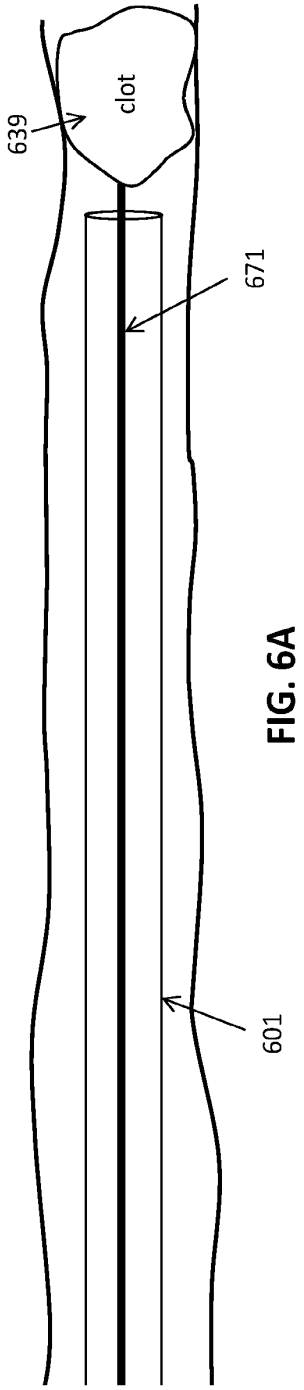


FIG. 6A

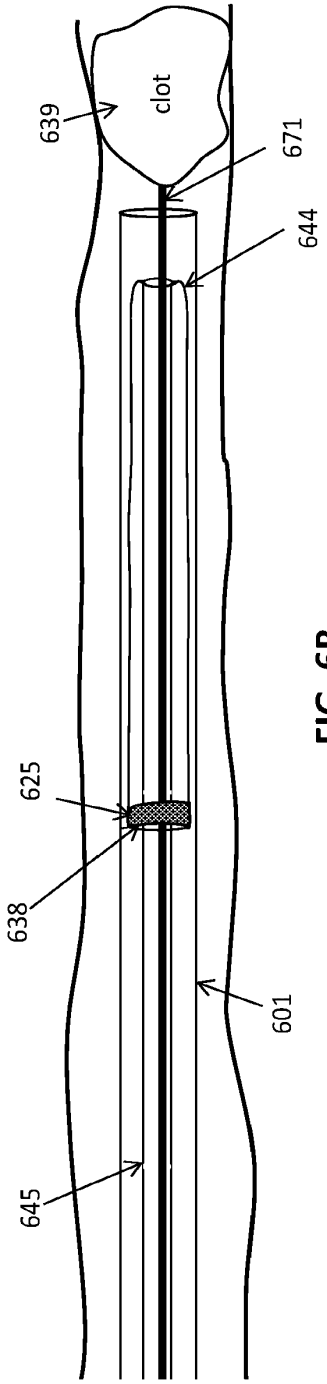


FIG. 6B

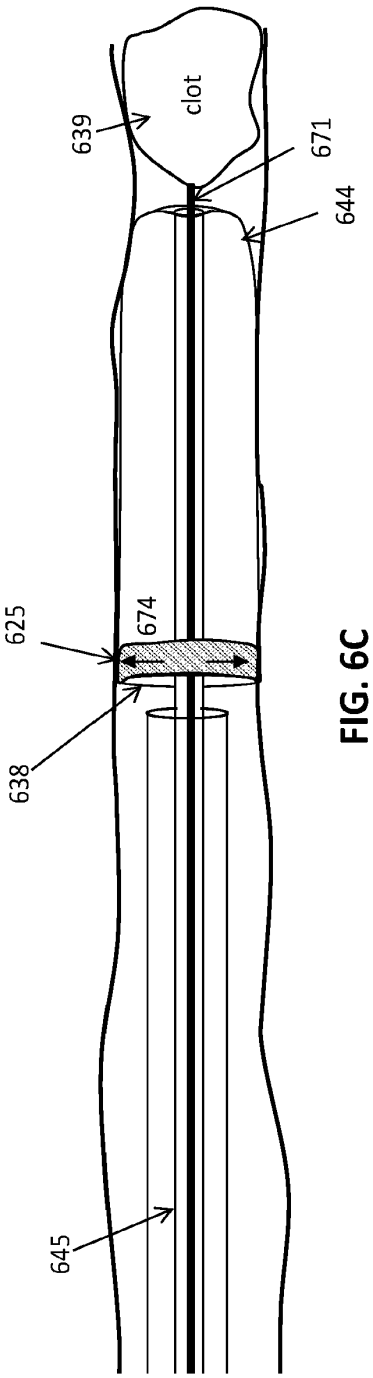


FIG. 6C

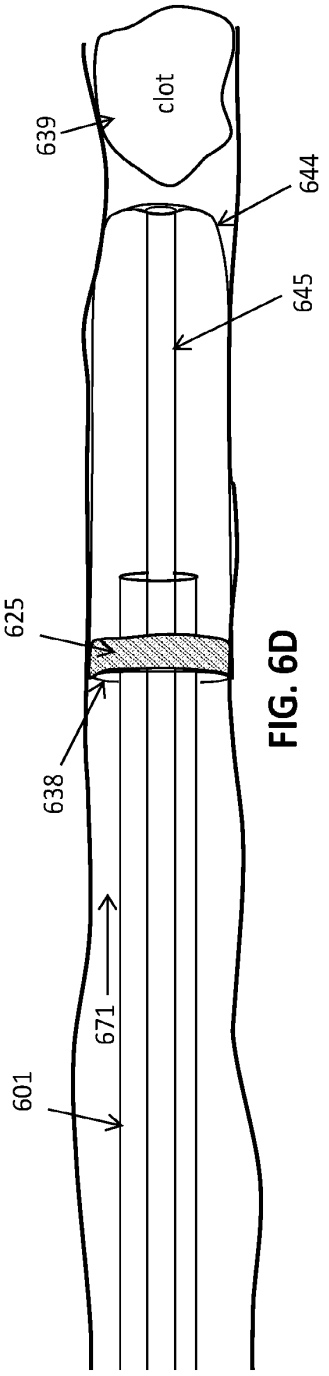


FIG. 6D

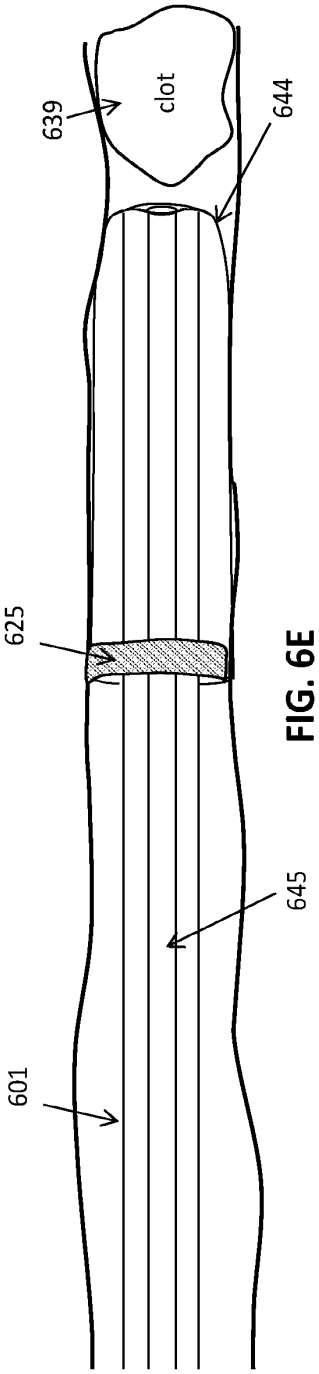


FIG. 6E

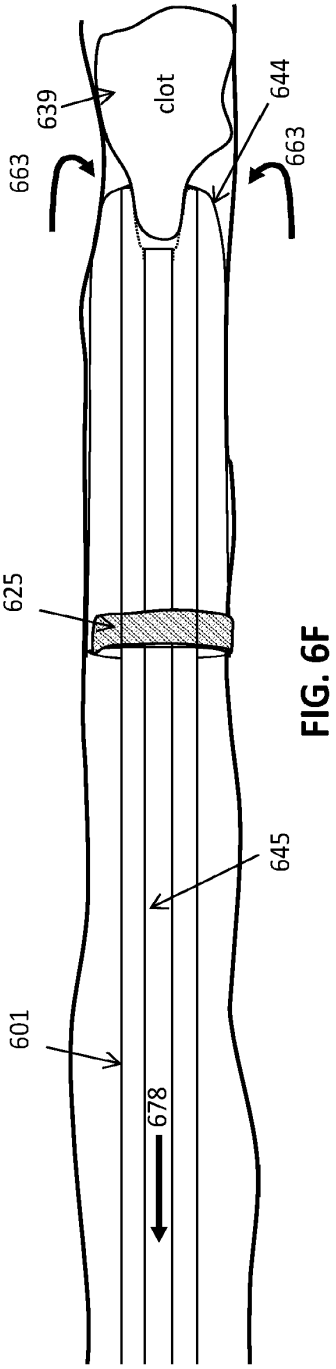


FIG. 6F

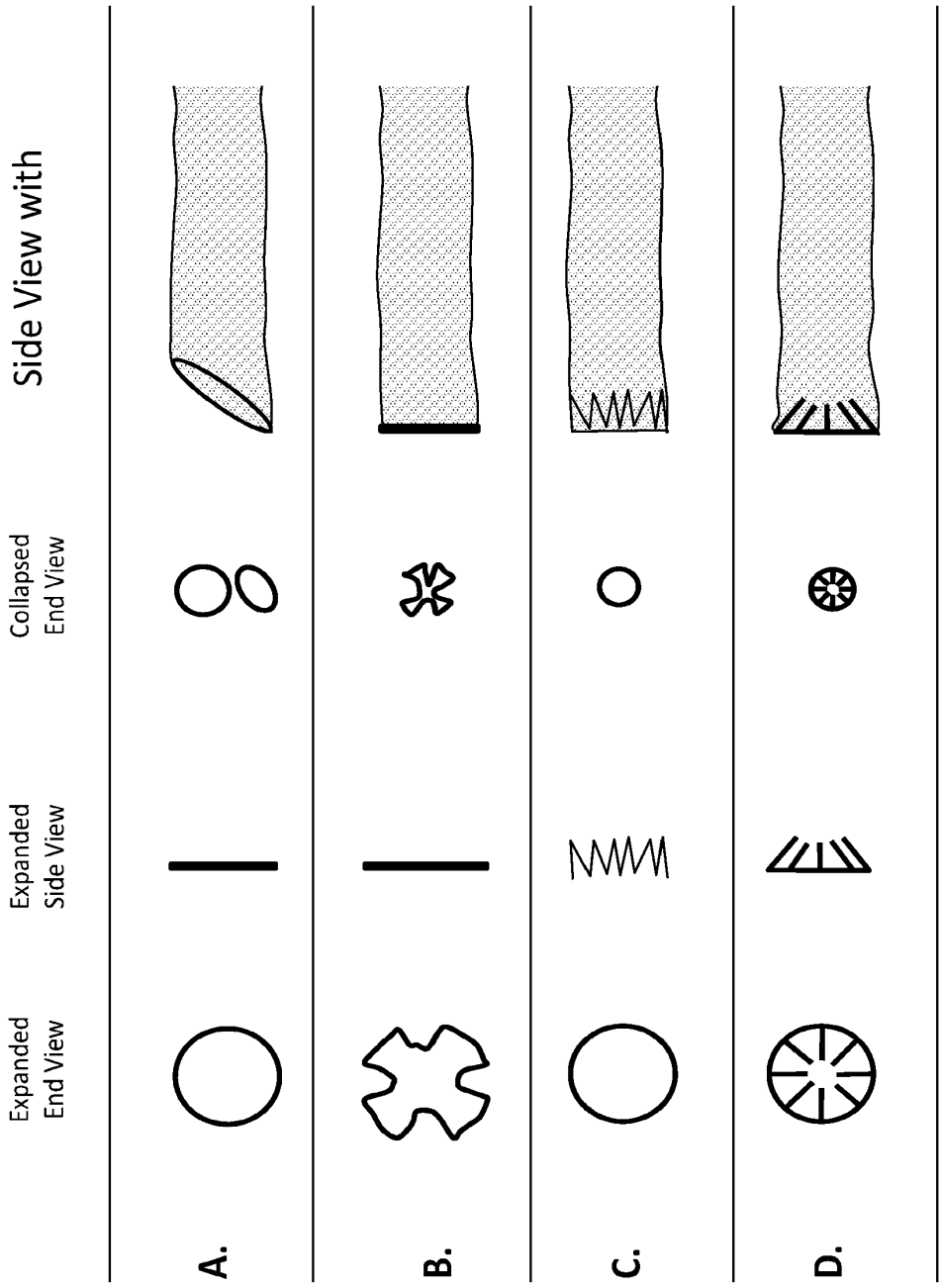

Expanded End View
Expanded Side View
Collapsed End View
Side View with
A.
B.
C.
D.

FIG. 7

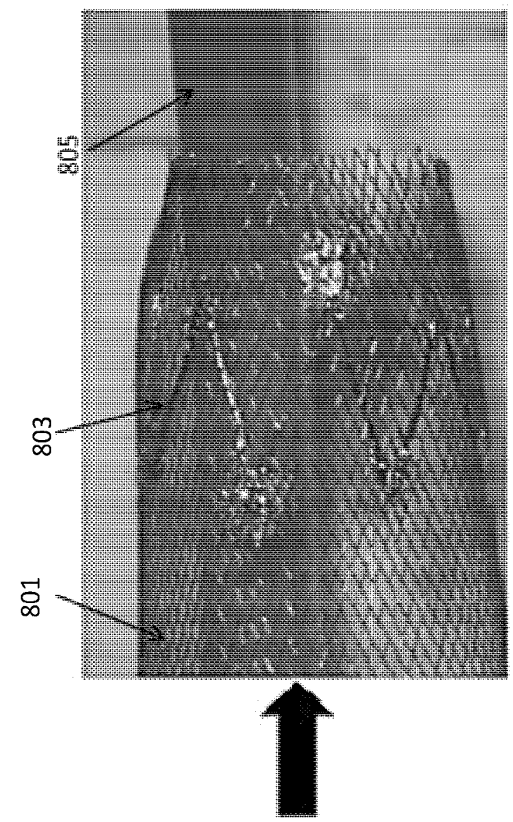


FIG. 8B

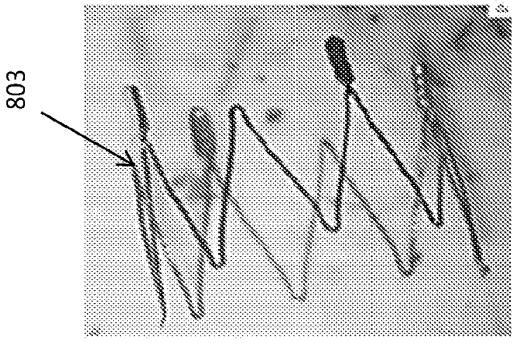


FIG. 8A

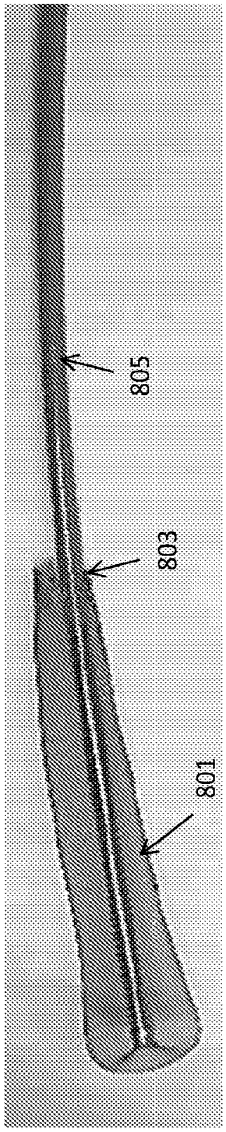


FIG. 8C

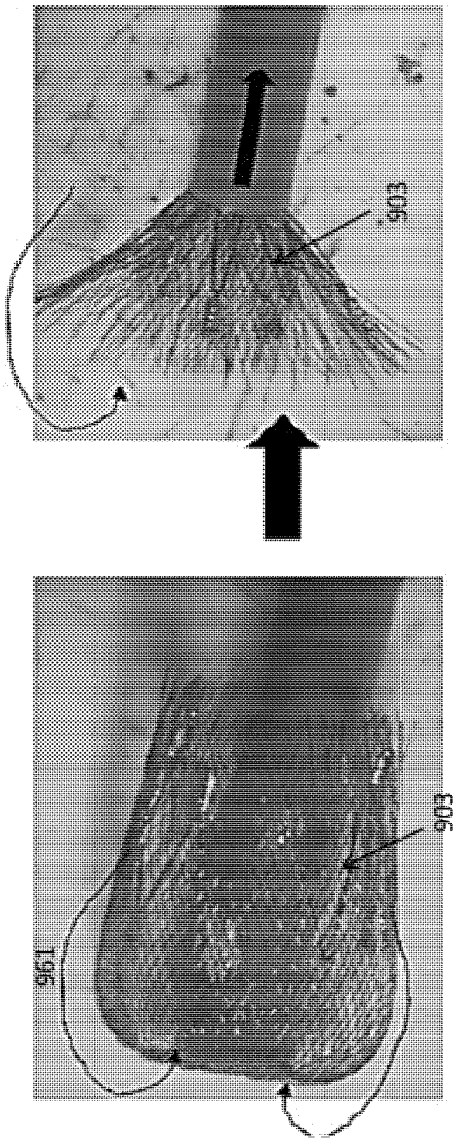


FIG. 9B

FIG. 9A

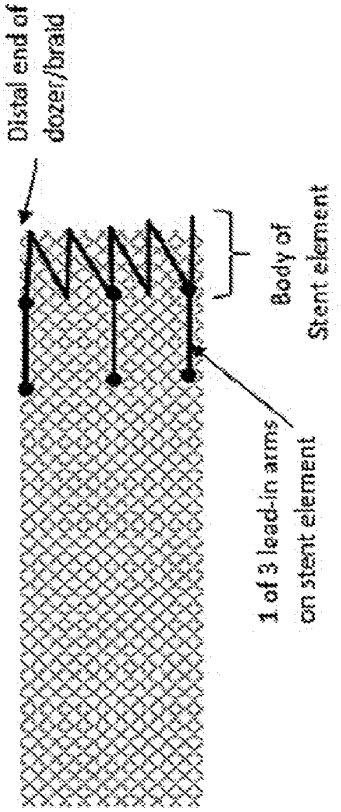


FIG. 9C

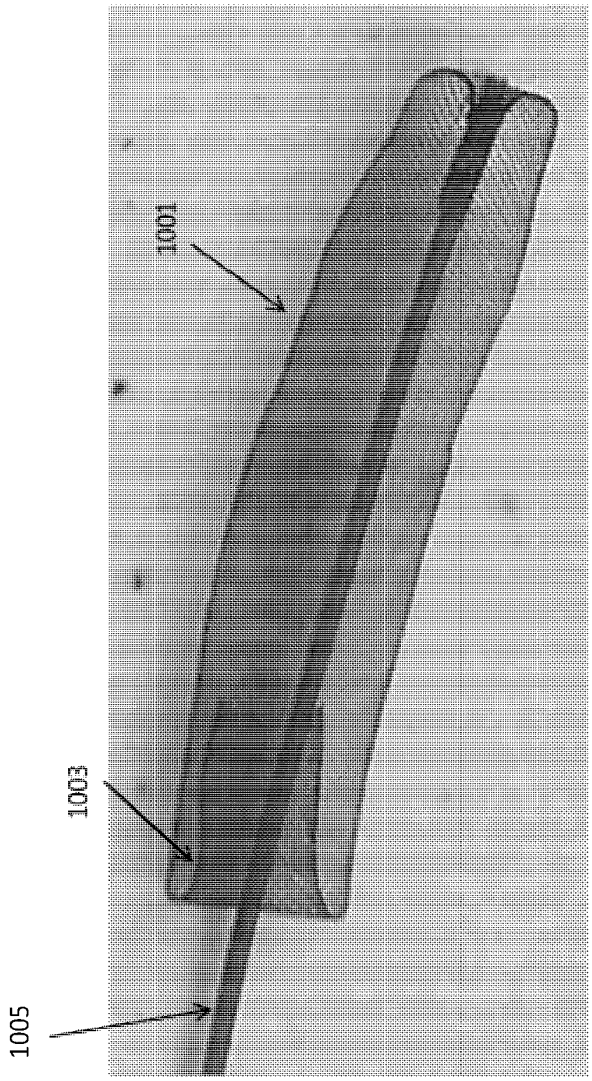


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/035543

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; figures page 8, line 12 - page 11, line 5	1-19
Y	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19) paragraphs [0152], [0153], [0167] - [0170]; figures 10, 13B	1-19
X,P	WO 2017/058280 A1 (GW MEDICAL LLC) 6 April 2017 (2017-04-06) the whole document	1-7,9-19

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

☒ See patent family annex.

* Special categories of cited documents :

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

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

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 August 2017	14/08/2017

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

1

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2017/035543

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2498349 A	17-07-2013	EP 2802275 A1	19-11-2014
		GB 2498349 A	17-07-2013
		US 2015005781 A1	01-01-2015
		WO 2013106146 A1	18-07-2013
WO 2012009675 A2	19-01-2012	US 2014005712 A1	02-01-2014
		WO 2012009675 A2	19-01-2012
WO 2017058280 A1	06-04-2017	US 9463035 B1	11-10-2016
		US 2017086864 A1	30-03-2017
		WO 2017058280 A1	06-04-2017

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

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

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

RECEIVED
PATENT DOCKETING

OCT 04 2021

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)

	Date of mailing *(day/month/year)* SEP 28 2021
Applicant's or agent's file reference 111552-8026WO00	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 21/35965	International filing date *(day/month/year)* 04 June 2021 (04.06.2021)
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
111552-8026WO00		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 21/35965	04 June 2021 (04.06.2021)	05 June 2020 (05.06.2020)
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 2 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. 10C

☒ 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 21/35965

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 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

OCT 04 2021

PERKINS COIE LLP

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	SEP 28 2021

Applicant's or agent's file reference	FOR FURTHER ACTION
111552-8026WO00	See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 21/35965	04 June 2021 (04.06.2021)	05 June 2020 (05.06.2020)

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

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

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	6 August 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 21/35965

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 21/35965

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	11-12, 18	YES
	Claims	1-10, 13-17, 19-20	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	None	NO

2 Citations and explanations.

Claims 1-10, 13-17, 19-20 lack novelty under PCT Article 33(2) as being anticipated by US 5,011,488 A to Ginsburg.

As per claim 1, Ginsburg discloses a funnel catheter assembly, comprising:
an outer shaft defining a lumen (12, Fig. 1 - outer shaft with a lumen);
an inner shaft extending through the lumen and having a proximal portion and a distal portion (14 Fig. 1 - inner shaft extending through 12 lumen having a proximal and distal end);
an expandable funnel coupled to the distal portion of the inner shaft (30, Fig. 1 - expandable funnel 30 coupled to distal portion of inner shaft); and
a control assembly (22, 40, Fig. 1) 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 (Fig. 2A - funnel is constrained within 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 (Fig. 2C - funnel is outside the lumen of the outer shaft such funnel can expand).

As per claim 2, Ginsburg discloses the funnel catheter assembly of claim 1 wherein the control assembly (22, 40, Fig. 1) is coupled to the outer shaft and configured to move the outer shaft relative to the inner shaft (Fig. 1; Col 5, ln 44-46 - see how control assembly is coupled to outer shaft and is capable of being used to move outer shaft relative to inner shaft).

As per claim 3, Ginsburg discloses 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 (24, Fig. 1 - proximal housing movement).

As per claim 4, Ginsburg discloses the funnel catheter assembly of claim 3 wherein the actuator is a slider (Col 5, ln 44-46 - pressure applied to actuator 24 provides axial sliding motion of the outer tube and inner tube).

As per claim 5, Ginsburg discloses the funnel catheter assembly of claim 1 wherein the funnel (30, Fig. 1) includes a proximal portion and a distal portion (Fig. 1 - funnel end connected to inner shaft 14 is proximal and distal is opposite end), and wherein the proximal portion of the funnel is coupled to the distal portion of the inner shaft (Fig. 1 - proximal portion of funnel is coupled to distal portion of inner shaft).

As per claim 6, Ginsburg discloses the funnel catheter of claim 5 wherein the distal portion of the funnel is coupled to the outer shaft (Fig. 1, Fig. 2C - when funnel 30 is retracted, distal portion of funnel is coupled to outer shaft).

As per claim 7, Ginsburg discloses the funnel catheter assembly of claim 1, further comprising a sealable hub (46, Fig. 1 - sealing member used to seal the proximal end tube) and a side port (48, Fig. 1 - aspiration port), wherein the side port (48, Fig. 1 - aspiration port) is rotatably coupled (Col 4, ln 61-66 - inner and outer tube can rotate thus the side port is rotatably coupled) between the control assembly (22, 40 Fig. 1) and the sealable hub (46, Fig. 1 - sealing open proximal end of tube).

-*-Continued in Supplemental Box-*-

Supplemental Box

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

As per claim 8, Ginsburg discloses a funnel catheter assembly, comprising:
an outer shaft defining an outer lumen (12, Fig. 1 - outer shaft with a lumen);
an inner shaft extending through the outer lumen and having a proximal portion and a distal portion (14 Fig. 1 - inner shaft extending through 12 lumen having a proximal and distal end);
an expandable funnel coupled to the distal portion of the inner shaft (30, Fig. 1 - expandable funnel 30 coupled to distal portion of inner shaft); and
a control assembly (22, 40, Fig. 1) 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 (22, 40, Fig. 1 - both 22 and 40 are used to move the outer shaft between the first and second position) wherein in the first position, the outer shaft is positioned at least partially over the funnel to radially constrain the funnel (Fig. 2C - outer shaft is position 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 (Fig. 2A - outer shaft is retracted to allow the funnel to expand).

As per claim 9, Ginsburg discloses the funnel catheter assembly of claim 8 wherein the control assembly includes a housing (22, Fig. 1) and an actuation member (40, Fig. 1), wherein the actuation member is coupled to a proximal portion of the outer shaft (40, Fig. 1 - actuation member is couple to proximal portion of outer shaft), and wherein the actuation member is slidable along the housing to move the outer shaft between the first and second positions (Fig. 1 -

As per claim 10, Ginsburg discloses the funnel catheter assembly of claim 8 wherein the funnel is configured to self expand (Col 6, ln 13-30 - spring elements can be used to allow the funnel to self-expand).

As per claim 13, Ginsburg discloses the funnel catheter assembly of claim 8 wherein the inner shaft defines an inner lumen sized to receive a dilator (70, Fig. 5C - inflatable balloon to come into contact with inside wall of blood vessel).

As per claim 14, Ginsburg discloses 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 (14 Fig. 1), an outer shaft (12, Fig. 1), and a funnel (30, Fig. 1) of the funnel catheter assembly into the vasculature of the patient (Fig. 5A; Col 6, ln 39-40 - assembly is introduced into vasculature of patient);
advancing the inner shaft (14 Fig. 1), the outer shaft (12, Fig. 1), and the funnel (30, Fig. 1) together to a deployment position within the vasculature of the patient (Col 6, ln 48-50 - system is positioned so it lies just outside region of stenosis), wherein the funnel is sheathed within a lumen of the outer shaft during the advancement (Fig. 5A - funnel is sheathed within a lumen during advancement);
moving the outer shaft relative to the inner shaft to unsheathe the funnel and permit the funnel to expand to an expanded position (Col 6, ln 48-60 - outer shaft is moved relative to inner shaft to unsheathe funnel to allow funnel to expand);
maintaining the funnel in the expanded position during at least a portion of the intravascular procedure (Fig. 5C-5E - funnel is maintained in expanded position during a portion of the 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 (Col 7, ln 4-12 - outer shaft is moved relative to inner to sheath the funnel); and
withdrawing the funnel catheter assembly from the patient (Col 7, ln 12-15 - assembly is removed from patient).

As per claim 15, Ginsburg discloses the method of claim 14 wherein the funnel is self-expandable (30, Fig. 1 - expandable funnel 30 coupled to distal portion of inner shaft), 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 (Col 6, ln 49-60 - outer shaft is moved relative to inner shaft to allow funnel to self-expand).

As per claim 16, Ginsburg discloses 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 (24, Fig. 1; Col 5, ln 44-46 -outer shaft is moved relative to inner shaft to unsheathe the funnel by moving a slider 24 which is coupled to proximal portion of outer shaft).

As per claim 17, Ginsburg discloses 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 (Col 4, ln 61-68 - inner and outer shaft are free to rotate in respect to each other).

As per claim 19, Ginsburg discloses the method of claim 14 wherein,
inserting the inner shaft (14 Fig. 1), the outer shaft (12, Fig. 1), and the funnel (30, Fig. 1) 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 (Fig. 5A; Col 6, ln 39-40 - assembly is introduced into vasculature of patient); and
advancing the inner shaft (14 Fig. 1), the outer shaft (12, Fig. 1), and the funnel (30, Fig. 1) further includes advancing the inner shaft (14 Fig. 1), the outer shaft (12, Fig. 1), and the funnel (30, Fig. 1), and the dilator (70, Fig. 5C - inflatable balloon to come into contact with inside wall of blood vessel) together to the deployment position (Col 6, ln 48-50 - system is positioned so it lies just outside region of stenosis).

-*-Continued in next Supplemental Box-*-

Supplemental Box

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

As per claim 20, Ginsburg discloses 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 (Col 6, ln 48-60 - outer shaft is moved relative to inner shaft to unsheathe funnel to allow funnel to expand), 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 (Col 7, ln 4-12 - outer shaft is moved relative to inner to sheath the funnel).

Claims 8, 11-12 lack novelty under PCT Article 33(2) as being anticipated by US 5,800,457 to Gelbfish.

As per claim 8, Gelbfish discloses a funnel catheter assembly, comprising:
an outer shaft defining an outer lumen (26, Fig. 2 - outer shaft with outer lumen);
an inner shaft extending through the outer lumen and having a proximal portion and a distal portion (12, Fig. 3D - inner shaft extending through outer lumen 26 and having a proximal and distal portion);
an expandable funnel coupled to the distal portion of the inner shaft (18, Fig. 3D - expandable funnel coupled to distal portion of inner shaft 12); and
a control assembly operably coupled to the proximal portion of the outer shaft (22, Fig. 2; Col 7, ln 11-15 - control unit 22 includes and is coupled to proximal portion of outer shaft 26) and configured to move the outer shaft between a first position and a second position (Col 7, ln 9-15 - outer member 26 is slide over inner shaft 12),
wherein
in the first position, the outer shaft is positioned at least partially over the funnel to radially constrain the funnel (Fig. 3A - outer shaft is positioned over the funnel to 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 (Fig. 3B - outer shaft is retracted such the funnel can radially expand).

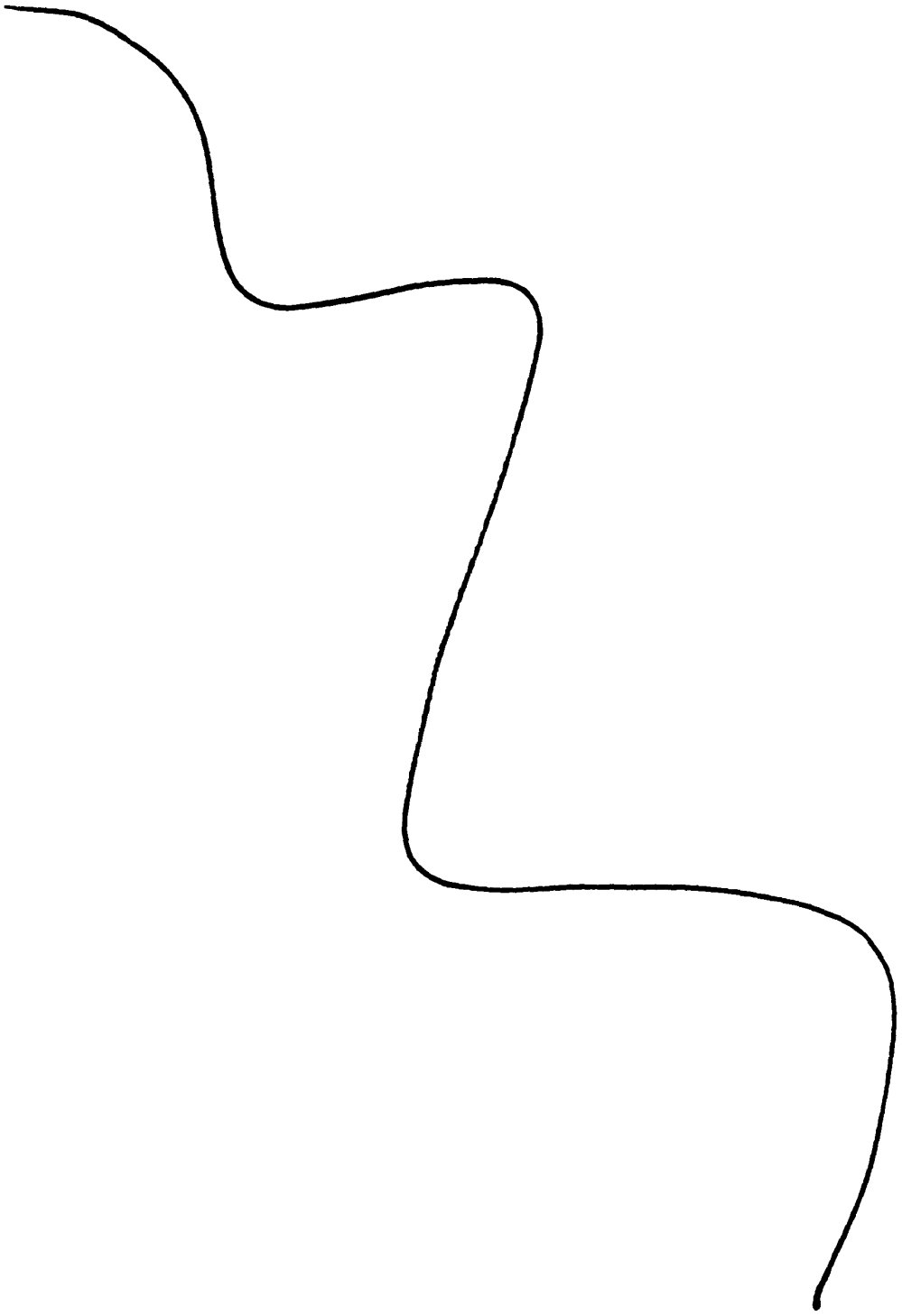
As per claim 11, Gelbfish discloses the funnel catheter assembly of claim 8 wherein the funnel is non-self expanding (Col 7, ln 25-30 - rod 30 is connected to shaft 12 to deploy the funnel), wherein the funnel is further coupled to a distal portion of the outer shaft (Fig. 3A - outer shaft 26 is coupled to funnel when unexpanded), and wherein movement of the outer shaft from the first position to the second position is configured to expand the funnel (Fig. 3B - outer shaft is move to second position to expand the funnel).

As per claim 12, Gelbfish discloses 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 (Fig. 3D; Col 8, ln 3-10 - distal portion of funnel is couple to distal portion of outer shaft through tether 42, 44 which traverses an aperture in the outer shaft).

Claims 18 lack an inventive step under PCT Article 33(3) as being obvious over Ginsburg in view of WO 2009/082513 A1 to Tex Medical (hereinafter 'Tex').

As per claim 18, Ginsburg discloses the method of claim 14 but is silent wherein the funnel is non-self-expanding, and wherein the method further comprises actuating the funnel to expand to the expanded position. Tex discloses the method of the funnel (20, Fig. 3A-B) wherein the funnel is coupled to a distal portion of the outer shaft (para [0042] - coupled at one end to distal end 11 of cannula 10) wherein the funnel is non-self expanding (para [0042] - in order to expand funnel 20 cannula 10 may include a balloon 33 position within cannula 10, in addition to an attachment mechanism such as string 34 connecting the balloon to the funnel, wherein when the balloon 33 is inflated it will pull on the string 34 thus deploying the funnel into an open position). Accordingly, it would have been obvious to a person of ordinary skill in the art to utilize Tex's non-self expanding funnel system with Ginsburg's funnel catheter assembly to allow for more control over the funnel deployment through controlled inflation of the balloon.

Claims 1-20 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.



INARL 020603

SEARCH HISTORY

Application Number	PCT/US 21/35965
Search Conducted By	JEF
Search Approved By	SCL

CPC/IPC Classifications Searched	CPC - A61M 2025/1045, A61B 17/22, A61B 17/221, A61B 2217/005, A61M 2025/109 IPC(8) - A61B 17/00, A61B 17/22, A61B 17/3207, A61M 25/10, A61M 1/00 (2021.01)
Date Conducted	06 August 2021 (06.08.2021)

Documentation Searched	CPC - Y10S 55/35, B01D 53/261 IPC(8) - A42B 3/28, A62B 18/00, A62B 23/00, B01D 45/00, A62B 7/00, F24F 1/04 (2021.01)
Search Terms Used	Intra, Intravascular, Treat, Treatment, Funnel, Catheter, Thrombi, Thrombus, Thrombosis, ClotTriver, Invari Medical, Adjustable, Percutaneous, Shaft, Blood, Clot
Date Conducted	06 August 2021 (06.08.2021)

Electronic Database Searched	PatBase
Files Searched	Full-text: AU BE BR CA CH CN DE DK EP ES FI FR GB IN JP KR SE TH TW US WO Bibliographic: (Europe) AT BA BE BG CH CS CY CZ DD DK EE ES FI GE GR HR HU IE IS IT LT LU LV MC MD MT NL NO PL PT RO RS SE SI SK SM TR UA YU (Asia) EA GC HK ID IL IN KZ MN MY PH RU SG SU TH TJ TW UZ VN (North America) CA CR CU DO GT HN MX NI PA SV TT (South America) AR BR CL CO EC PE UY (Australasia) AU NZ (Africa) AP DZ EG KE MA MW OA ZA ZM ZW
Date Conducted	06 August 2021 (06.08.2021)

Search Logic:

Search 1: PN=(US5102415 or US10898212) (Results 2)
Search 2: IC=(A61B17/00 or A61B17/22 or A61B17/3207 or A61M25/10 or A61M1/00) (Results 152615)
Search 3: CPC=(A61M2025/1045 or A61B17/22 or A61B17/221 or A61B2217/005 or A61M2025/109) (Results 7069)
Search 4: 2 or 3 (Results 153968)
Search 5: 4 and ft=(funnel) (Results 3521)

Search 6:	5 and ft=(thromb*) (Results 674)
Search 7:	6 and ft=(inner near outer) (Results 400)
Search 8:	7 and ft=(blood) (Results 388)
Search 9:	8 and ft=(inner near shaft) (Results 127)
Search 10:	9 and ft=(expand) (Results 117)
Search 11:	10 and ft=(mov*) (Results 114)
Search 12:	11 and ft=(expand* near funnel) (Results 32)
Search 13:	12 and Ft=(non* near self near expand*) (Results 2)
Search 14:	PN=(WO2004093966) (Results 1)
Search 15:	CTA 14 (Results 1656)
Search 16:	Ft=(funnel near catheter) (Results 750)
Search 17:	16 and ft=(outer or inner) (Results 560)
Search 18:	17 and ft=(expand) (Results 213)
Search 19:	18 and ft=(tether) (Results 27)
Search 20:	18 and ft=(self) (Results 142)
Search 21:	20 and ft=(blood) (Results 124)
Search 22:	21 and ft=(vessel) (Results 106)

Electronic Database Searched	Google
Files Searched	Scholar (Articles excluding patents)
Date Conducted	06 August 2021 (06.08.2021)

Search Logic:

Intravascular Treatment Funnel Catheter
10,000,000

Funnel Catheter Assembly
11,400,000

Thrombi Extraction Catheter
8,820,000

Thrombus Aspiration Catheter
7,160,000

Thrombus Funnel Catheter
7,800,000

Thrombosis Catheter
12,700,000

Thrombosis Funnel Catheter
10,900,000

ClotTriver Inari Medical

5,170

Catheter with Funnel End
13,200,000

Catheter adjustable Funnel Inner Shaft
14,900,000

Catheter Adjustable Funnel Inner Shaft Blood Clot
11,600,000

Percutaneous Funnel Catheter
12,300,000

Electronic Database Searched	Google
Files Searched	Patents (US Patents/Published Applications, EPO publications, International, China, Germany, Canada)
Date Conducted	06 August 2021 (06.08.2021)

Search Logic:

Funnel Catheter Blood Clot
12,760

Percutaneous Funnel Catheter
11,569

Catheter Adjustable Funnel Inner Shaft Blood Clot
1,374

Thrombus Adjustable Funnel Catheter
3,652

Funnel Aspiration Catheters
7,210

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

MAR 2 2 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 111552-8027WO00	Date of mailing *(day/month/year)* MAR 16 2022 **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 21/58793	International filing date *(day/month/year)* 10 November 2021 (10.11.2021)
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
111552-8027WO00		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 21/58793	10 November 2021 (10.11.2021)	10 November 2020 (10.11.2020)
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 3 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. 1C

   ☒ 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 21/58793

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 17/03; A61B 17/04 (2022.01)

CPC - A61B 17/04; A61B 2017/0496; A61B 17/03; A61B 17/56; A61B 17/0467; A61B 17/8869; A61B 17/0482; A61B 17/0469

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 5,376,101 A (GREEN et al.) 27 December 1994 (27.12.1994); entire document, especially col 6 ln 56 to col 7 ln 17, and Fig. 15-18.	1, 5-7 -- 2-4
Y	US 5,192,274 A (BIERMAN) 9 March 1993 (09.03.1993); especially col 2 ln 21-54, and Fig. 1-2.	2-3
Y	US 2013/0116708 A1 (ZINITI et al.) 9 May 2013 (09.05.2013); especially para [0090], and Fig. 18A-B.	4
A	US 2004/0260344 A1 (LYONS et al.) 23 December 2004 (23.12.2004); 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
2 March 2022	MAR 16 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

INARI_020609

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/US 21/58793

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

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of when the first through-hole and the second through-hole receive the suture and the actuator is in the second position, the actuator and the housing cooperate to permit the suture to move relative to the housing, not required by the claims of Group II-III.

The invention of Group II includes the special technical feature of a biasing member operably coupled between the actuator and the housing, not required by the claims of Group I or II.

The invention of Group III includes the special technical feature of adjusting a tension of the suture to a desired tension, not required by the claims of Group I-II.

COMMON TECHNICAL FEATURES

Groups I-III share the common technical feature of a suture tensioning device.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 8,888,791 B2 (JARAMILLO et al.) (hereinafter Jaramillo), which discloses a suture tensioning device (100; Fig. 1; col 5 ln 40-62).

Groups I-II share the common technical feature of a device for tensioning a suture, comprising:
a housing having a first through-hole; and
an actuator coupled to the housing and having a second through-hole,
wherein the actuator is movable relative to the housing from a first position to a second position.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by Jaramillo, which discloses a device for tensioning a suture (Fig. 9; col 7 ln 41-51), comprising:
a housing (upper housing of 900; Fig. 9; col 7 ln 41-51) having a first through-hole (902; Fig. 9; col 7 ln 41-51); and
an actuator (903, unlabeled semicircular half adjacent 903; Fig. 9; col 7 ln 41-51) coupled to the housing and having a second through-hole (901; Fig. 9; col 7 ln 41-51),
wherein the actuator is movable relative to the housing from a first position (903 adjacent and flush with housing of 900; Fig. 9; col 7 ln 41-51) to a second position (position of Fig. 9 with 903 deployed rotated outward; Fig. 9; col 7 ln 41-51).

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

MAR 22 2022

PERKINS COIE LLP

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	MAR 16 2022
Applicant's or agent's file reference 111552-8027WO00	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 21/58793	10 November 2021 (10.11.2021)	10 November 2020 (10.11.2020)

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

IPC - A61B 17/03; A61B 17/04 (2022.01)

CPC - A61B 17/04; A61B 2017/0496; A61B 17/03; A61B 17/56; A61B 17/0467; A61B 17/8869; A61B 17/0482; A61B 17/0469

Applicant INARI MEDICAL, INC.

1. This opinion contains indications relating to the following items:

- [x] 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
- [x] Box No. IV Lack of unity of invention
- [x] 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 March 2022	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 21/58793

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 21/58793

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 1-7 directed to a device for tensioning a suture, having a housing with a first through-hole and an actuator with a second through-hole.

Group II: Claims 8-14 directed to a suture tensioning device, having a housing, an actutator, and a biasing member.

Group III: Claims 15-20 directed to a method of tensioning a suture.

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 when the first through-hole and the second through-hole receive the suture and the actuator is in the second position, the actuator and the housing cooperate to permit the suture to move relative to the housing, not required by the claims of Group II-III.

The invention of Group II includes the special technical feature of a biasing member operably coupled between the actuator and the housing, not required by the claims of Group I or II.

The invention of Group III includes the special technical feature of adjusting a tension of the suture to a desired tension, not required by the claims of Group I-II.

COMMON TECHNICAL FEATURES

Groups I-III share the common technical feature of a suture tensioning device.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 8,888,791 B2 (JARAMILLO et al.) (hereinafter Jaramillo), which discloses a suture tensioning device (100; Fig. 1; col 5 ln 40-62).

Groups I-II share the common technical feature of a device for tensioning a suture, comprising:
a housing having a first through-hole; and
an actuator coupled to the housing and having a second through-hole,
wherein the actuator is movable relative to the housing from a first position to a second position.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by Jaramillo, which discloses a device for tensioning a suture (Fig. 9; col 7 ln 41-51), comprising:
a housing (upper housing of 900; Fig. 9; col 7 ln 41-51) having a first through-hole (902; Fig. 9; col 7 ln 41-51); and
an actuator (903, unlabeled semicircular half adjacent 903; Fig. 9; col 7 ln 41-51) coupled to the housing and having a second through-hole (901; Fig. 9; col 7 ln 41-51),
wherein the actuator is movable relative to the housing from a first position (903 adjacent and flush with housing of 900; Fig. 9; col 7 ln 41-51) to a second position (position of Fig. 9 with 903 deployed rotated outward; Fig. 9; col 7 ln 41-51).

-*- See Supplemental Box -*-

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. 1-7

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/58793

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	2-4	YES
	Claims	1, 5-7	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-7	NO
Industrial applicability (IA)	Claims	1-7	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1 and 5-7 lack novelty under PCT Article 33(2) as being anticipated by US 5,376,101 A (GREEN et al.) (hereinafter Green).

As pertaining to claim 1, Green teaches a device for tensioning a suture (Fig. 15-18; col 6 ln 56 to col 7 ln 17), comprising:
a housing (510; Fig. 15-18; col 6 ln 56-62) having a first through-hole (511; Fig. 15-18; col 6 ln 56-62); and
an actuator (520; Fig. 15-18; col 6 ln 56-62) coupled to the housing and having a second through-hole (passageway 526; Fig. 15-18; col 6 ln 63 to col 7 ln 13),
wherein the actuator is movable relative to the housing from a first position (position of 520 relative to 510 in Fig. 17; col 7 ln 4-12) to a second position (position of 520 relative to 510 in Fig. 16; col 6 ln 63 to col 7 ln 3),
wherein the first through-hole and the second through-hole are configured to receive a suture therethrough (10; Fig. 15-18; col 7 ln 1-3), and wherein-
when the first through-hole and the second through-hole receive the suture and the actuator is in the first position, the actuator and the housing cooperate to inhibit the suture from moving relative to the housing (receipt of 10 through 511, hole through 520, secured in Fig. 17; col 7 ln 4-17); and
when the first through-hole and the second through-hole receive the suture and the actuator is in the second position, the actuator and the housing cooperate to permit the suture to move relative to the housing (receipt of 10 through 511, hole through 520, adjustable in Fig. 16; col 6 ln 63 to col 7 ln 3).

As pertaining to claim 5, Green teaches the device of claim 1 wherein the first through-hole and the second through-hole are axially offset in the first position (position of 520 and 526 offset relative to 510 and 511 in Fig. 17; col 7 ln 4-12), and wherein the first through-hole and the second through-hole are axially aligned in the second position (position of 520 and 526 aligned relative to 510 and 511 in Fig. 16; col 6 ln 63 to col 7 ln 3).

As pertaining to claim 6, Green teaches the device of claim 5 wherein the housing and actuator engage the suture in the first position to clamp the suture relative to the housing (clamping of 10 with respect to 510 by 520 action; Fig. 16-17; col 6 ln 63 to col 7 ln 17).

As pertaining to claim 7, Green teaches the device of claim 1 wherein the first through-hole and the second through-hole are aligned along an axis in the second position (position of 520 and 526 aligned relative to 510 and 511 in Fig. 16; col 6 ln 63 to col 7 ln 3), and wherein the actuator is movable from the first position to the second position in a direction generally orthogonal to the axis (movement of 520 orthogonal to axis of 511; Fig. 16-17; col 6 ln 63 to col 7 ln 3).

Claims 2-3 lack an inventive step under PCT Article 33(3) as being obvious over Green in view of US 5,192,274 A to BIERMAN (hereinafter Bierman).

As pertaining to claim 2, Green teaches the device of claim 1, but is silent wherein further comprising a flexible pad coupled to the housing.
However, Bierman teaches a device (Fig. 1-2; col 2 ln 21-54), comprising:
a housing (12; Fig. 1-2; 2 ln 29-42); and
a flexible pad coupled to the housing (22; Fig. 1-2; col 2 ln 50-53, col 1 ln 22-24).
Accordingly, it would have been obvious to a person having ordinary skill in the art to have employed the pad of Bierman upon the device of Green, in order to safely and removably secure the device to a patient's skin.

As pertaining to claim 3, Green in view of Bierman teaches the device of claim 2 and Bierman further discloses wherein the flexible pad is configured to be placed against skin of a patient and to conform to the skin of the patient (flexible pad 22 applied upon skin of patient; Fig. 1-2; col 2 ln 50-53, col 1 ln 22-24).

-*- See Supplemental Box -*-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/58793

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
-*- Box IV.2 - Explanations where unity of invention is lacking -*-

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.

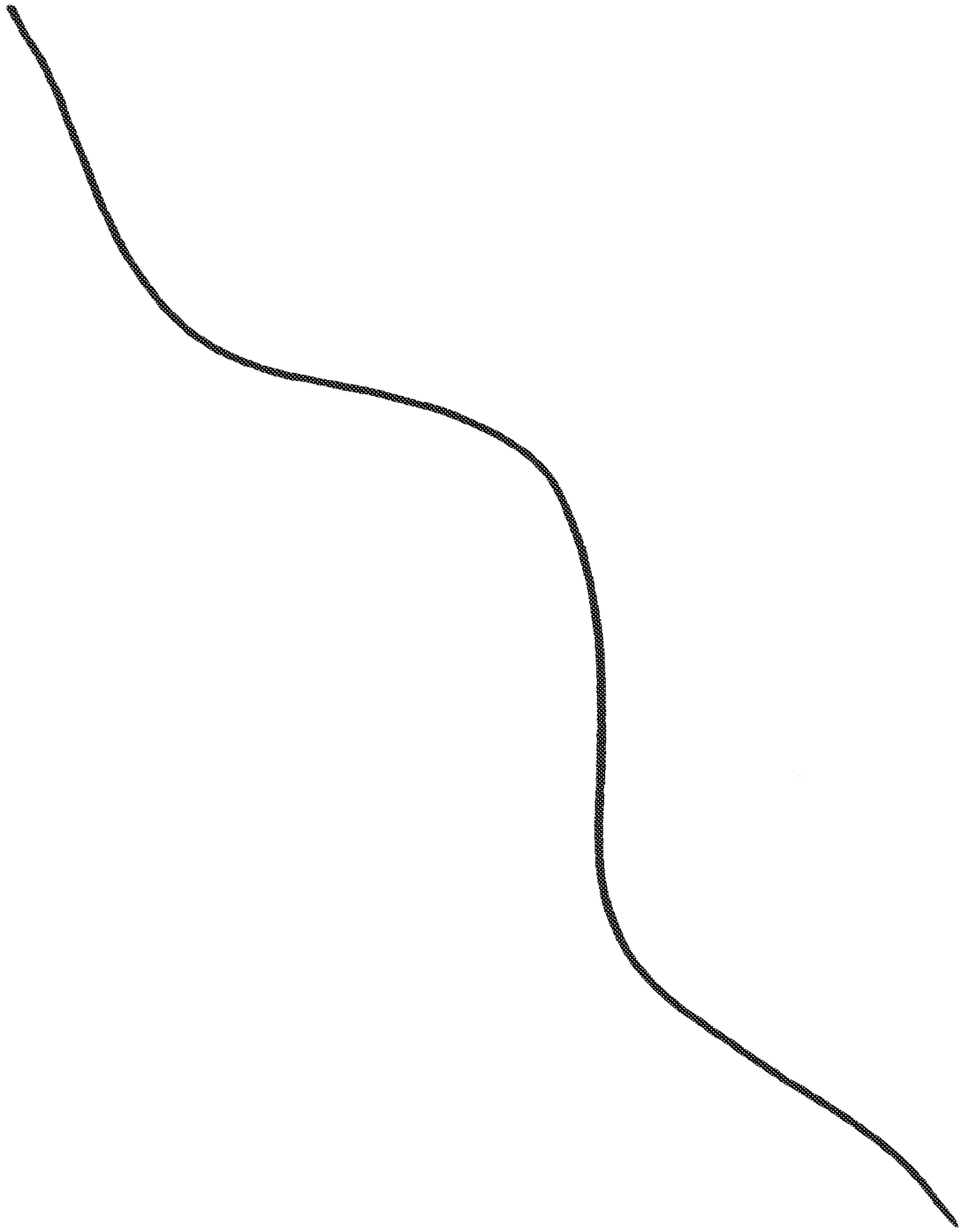
Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

-*- Box V.2 - Citations and explanations -*-

Claim 4 lacks an inventive step under PCT Article 33(3) as being obvious over Green in view of US 2013/0116708 A1 to ZINITI et al. (hereinafter Ziniti).

As pertaining to claim 4, Green teaches the device of claim 1 but is silent wherein further comprising a biasing member operably coupled between the actuator and the housing, wherein the biasing member is configured to bias the actuator to the first position.
However, Ziniti further discloses a device (Fig. 18A-B; para [0090]), comprising:
a biasing member operably coupled between the actuator and the housing (spring 612; Fig. 18A-B; para [0093]),
wherein the biasing member is configured to bias the actuator to the first position (spring 612 capable of being disposed to bias actuator; Fig. 18A-B; para [0093]).
Accordingly, it would have been obvious to a person having ordinary skill in the art to have employed the biasing member of Ziniti upon the device of Green, in order to aid in user deployment of the device.

Claims 1-7 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.



Application Number	PCT/US 21/58793
Search Conducted By	SBF
Search Approved By	SCL

CPC/IPC Classifications Searched	IPC(8) A61B 17/03; A61B 17/04 (2022.01) CPC A61B 17/04; A61B 2017/0496; A61B 17/03; A61B 17/56; A61B 17/0467; A61B 17/8869; A61B 17/0482; A61B 17/0469
Date Conducted	25 February-2 March 2022 (25.02.-02.03.2022)

Documentation Searched	IPC(8) A61B 17/03; A61B 17/04 (2022.01) CPC A61B 17/04; A61B 2017/0496; A61B 17/03; A61B 17/56; A61B 17/0467; A61B 17/8869; A61B 17/0482; A61B 17/0469 (keyword limited; terms below)
Search Terms Used	Suture tensioner inari medical flowstasis retention large bore through holes lock retainer misalign tighten adjust gap aperture align line up slot friction clamp clutch thread cable cord increment ratchet button actuator spring load stop restrain
Date Conducted	25 February-2 March 2022 (25.02.-02.03.2022)

Electronic Database Searched	PatBase
Files Searched	Full-text: AU BE BR CA CH CN DE DK EP ES FI FR GB IN JP KR SE TH TW US WO Bibliographic: (European) AT BA BE BG CH CS CY CZ DD DK EE ES FI GE GR HR HU IE IS IT LT LU LV MC MD MT NL NO PL PT RO RS SE SI SK SM TR UA YU (Asia) EA GC HK ID IL IN KZ MN MY PH RU SG SU TH TJ TW UZ VN (North America) CA CR CU DO GT HN MX NI PA SV TT (South America) AR BR CL CO EC PE UY (Australasia) AU NZ (Africa) AP DZ EG KE MA MW OA ZA ZM ZW
Date Conducted	25 February-2 March 2022 (25.02.-02.03.2022)
Search Logic:	

25 February-
Search 1: pa=(inari medical*) (Results 12)
Search 2: inv=(macias jacqueline* or enright paige* or tu thomas*) (Results 16)
Search 3: 1 or 2 (Results 26)
Search 4: pn=(US8888791) (Results 1)
Search 5: 3 and ft=(suture* near tension*) (Results 0)
Search 6: ctf 4 or ctb 4 (Results 165)
Search 7: 6 and ft=(suture* near (tension* or tighten* or adjust*)) (Results 100)
Search 8: 7 not (4 or 3) (Results 99)
Search 9: cpc=(A61B2017/0496*) (Results 1269)
Search 10: 9 and ft=((hole* or gap* or aperture*) near (align* or (line up*))) (Results 176)
Search 11: 10 not (7 or 4 or 3) (Results 173)

28 February-
Search 12: pn=(US20040260344A1) (Results 1)
Search 13: ctf 12 or ctb 12 (Results 193)
Search 14: 13 and ft=(suture* near (tension* or tighten* or adjust*)) (Results 105)
Search 15: 14 not (12 or 10 or 7 or 4 or 3) (Results 99)
Search 16: pn=(jp2018000843) (Results 1)
Search 17: ctf 16 or ctb 16 (Results 4)
Search 18: cpc=(A61B17/8869*) (Results 409)
Search 19: 18 and ft=((hole* or gap* or aperture* or slot*) near (align* or (line up*) or misalign* or friction*)) (Results 89)
Search 20: 19 not (17 or 16 or 14 or 12 or 10 or 7 or 4 or 3) (Results 79)
Search 21: 13 and ft=((hole* or gap* or aperture*) near (align* or (line up*))) (Results 25)
Search 22: pn=(us5376101) (Results 1)
Search 23: ctf 22 or ctb 22 (Results 308)
Search 24: 23 and ft=((hole* or gap* or aperture* or slot*) near (align* or (line up*) or misalign* or friction*)) (Results 78)
Search 25: 24 not (22 or 21 or 19 or 17 or 16 or 14 or 12 or 10 or 7 or 4 or 3) (Results 57)

2 March-
Search 26: ic=(A61B17/03* OR A61B17/04*) (Results 44372)
Search 27: cpc=(A61B17/03* OR A61B17/04* OR A61B17/56* OR A61B17/0467* OR A61B17/8869* OR A61B17/0482* OR A61B17/0469* OR A61B2017/0496*) (Results 45941)
Search 28: 26 or 27 (Results 76570)
Search 29: 28 and ft=((hole* or gap* or aperture* or slot*) near (align* or (line up*) or misalign* or friction* or clamp* or clutch*)) (Results 9859)
Search 30: 29 and ft=((suture* or thread* or cable* or cord*) near (tension* or tighten* or increment* or ratchet*)) (Results 1998)
Search 31: 30 and ft=(button* or actuator* or (spring* near load*)) (Results 1019)
Search 32: 31 and ft=(spring*) (Results 873)
Search 33: 32 and ft=(suture* near (lock* or stop* or restrain*)) (Results 238)
Search 34: 33 not (24 or 22 or 21 or 19 or 17 or 16 or 14 or 12 or 10 or 7 or 4 or 3) (Results 156)
Search 35: ft=(suture* near (tension* or tighten*)) (Results 6198)
Search 36: 35 and ft=((hole* or gap* or aperture* or slot* or groove*) near (align* or (line up*) or misalign* or friction*)) (Results 1081)
Search 37: 36 and ft=(suture* near (lock* or stop* or restrain*)) (Results 452)
Search 38: 37 and ft=(spring*) (Results 317)
Search 39: 38 and ft=(spring* near (load* or actuat*)) (Results 154)
Search 40: 39 not (33 or 24 or 22 or 21 or 19 or 17 or 16 or 14 or 12 or 10 or 7 or 4 or 3) (Results 20)

Electronic Database Searched	Google
Files Searched	Google Patents
Date Conducted	25 February-2 March 2022 (25.02.-02.03.2022)
Search Logic:	

Suture tensioning through holes
About 12,200 results

Suture tensioning through holes ratchet
About 4,700 results

Suture tensioning through holes lock
About 12,000 results

Suture retainer lock hole misalign
About 6,350 results

Electronic Database Searched	Google
Files Searched	Google Web
Date Conducted	25 February-2 March 2022 (25.02.-02.03.2022)
Search Logic:	

Suture tensioner
About results

Suture tensioner inari medical
About results

Flowstasis suture retention
About results

Large bore suture retention

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62/345,152	03 June 2016 (03.06.2016)	US
62/357,677	01 July 2016 (01.07.2016)	US

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

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

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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

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

(54) Title: CLOT-ENGULFING MECHANICAL THROMBECTOMY APPARATUSES

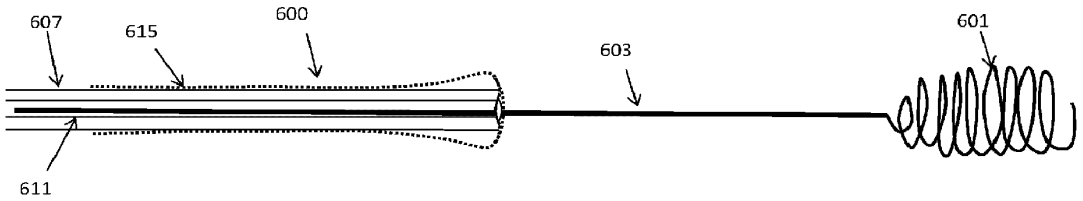


FIG. 6I

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

WO 2017/189615 A1

CLOT-ENGULFING MECHANICAL THROMBECTOMY APPARATUSES

CROSS REFERENCE TO RELATED APPLICATIONS

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

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

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

INCORPORATION BY REFERENCE

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

FIELD

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

BACKGROUND

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

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

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

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

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

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

SUMMARY OF THE DISCLOSURE

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BRIEF DESCRIPTION OF THE DRAWINGS

[00044] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

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

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

[00046] FIG. 1I illustrates an alternative variation of a tractor and puller. In FIG. 1I, the tractor is shown attached to the distal end of a tapered or narrow puller; the distal end region is tapered, and includes a radiopaque marker at or near the attachment site to the tractor; the tractor may be knitted, braided, woven, etc. Thus, in some variations the distal end region of the puller may have a greater flexibility than the proximal end of the puller. The puller may be hollow (e.g., a catheter or hypotube) or solid (e.g., like a wire).

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

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

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

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

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

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

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

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

DETAILED DESCRIPTION

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

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

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

[00057] For example, FIG. 1A shows one variation of a catheter that may form part of the apparatuses described herein. In this example, the catheter 100 includes a distal end region 103 that includes a distal end 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal tip (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing harness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

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

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

[00060] In some variations the distal end 105 of the elongate inversion support is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in some variations

the distal tip (end) may be curved or radiused 109 as shown in FIG. 1B, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[00083] FIG. 6I illustrates an example of a mechanical thrombectomy system for removing a clot from within a vessel. In FIG. 6I, the apparatus (e.g., system) includes an elongate inversion support comprising a catheter 607 having a distal end and a distal end opening, a tractor 615 comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of

the tractor is pulled proximally within the catheter. The system also includes a puller 611 connected to the first end of the tractor that extends proximally within the catheter. The system also includes a clot engaging member 601 on the distal end of an elongate manipulator 603. The elongate member is shown passing through a lumen extending continuously through the puller and the tractor and configured to pass the expandable elongate manipulator. This system may be used to remove a clot.

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

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

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

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

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

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

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

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

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

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

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

[00093] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features

or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[00094] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[00095] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[00096] Although the terms “first” and “second” may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[00097] Throughout this specification and the claims which follow, unless the context requires otherwise, the word “comprise”, and variations such as “comprises” and

"comprising" means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term "comprising" will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

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

[00099] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or "approximately," even if the term does not expressly appear. The phrase "about" or "approximately" may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For example, if the value "10" is disclosed, then "about 10" is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that "less than or equal to" the value, "greater than or equal to the value" and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value "X" is disclosed the "less than or equal to X" as well as "greater than or equal to X" (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point "10" and a particular data point "15" are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[000100] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the

invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

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

CLAIMS

What is claimed is:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

a tractor comprising a flexible tube that extends distally in an un-inverted configuration within the catheter, inverts over the distal end opening of the catheter and extends proximally in an inverted configuration along the distal end of the catheter, wherein the tractor is configured to invert by rolling over the distal end opening of the catheter when a first end of the tractor is pulled proximally within the catheter;

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

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

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

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

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

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

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

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

withdrawing the tractor and clot proximally from the vessel.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

withdrawing the tractor and clot proximally from the vessel.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

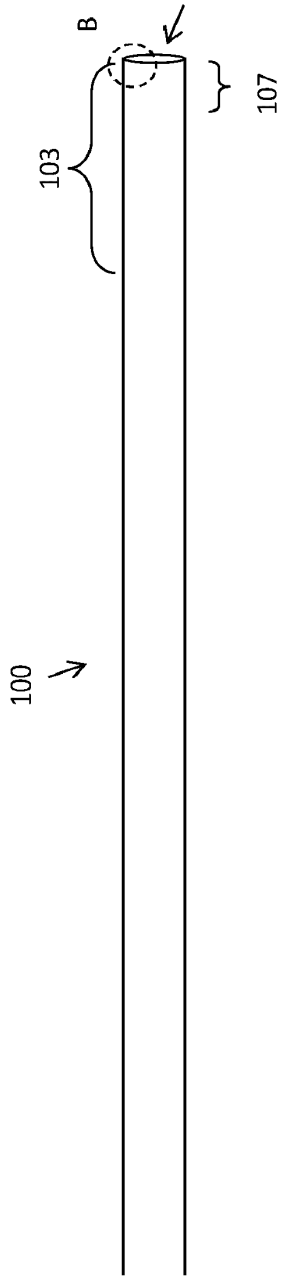


FIG. 1A

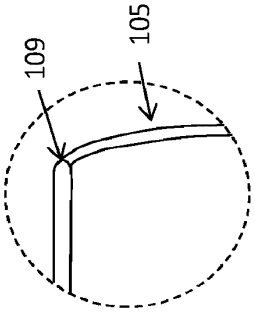


FIG. 1B

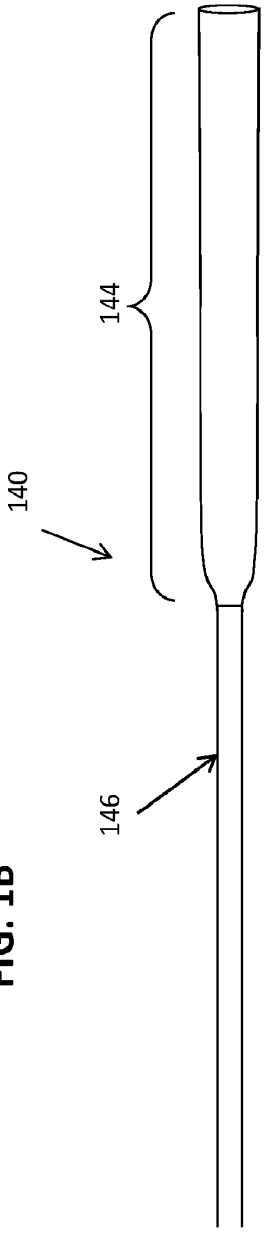


FIG. 1C

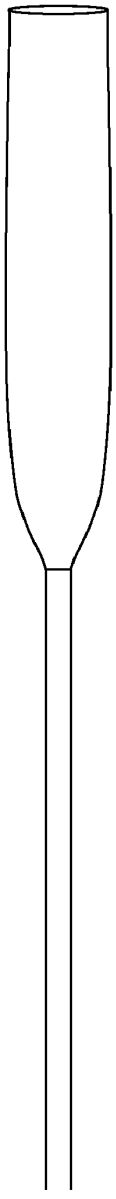


FIG. 1D

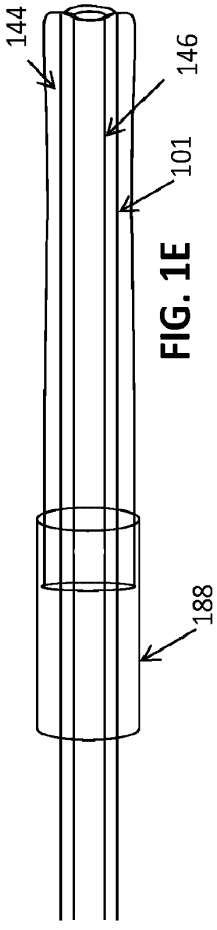


FIG. 1E

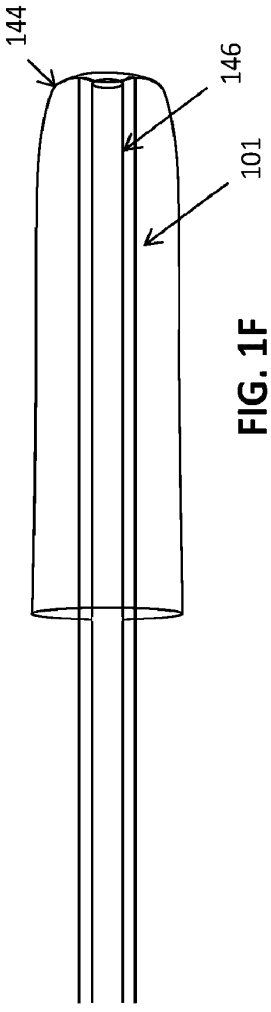


FIG. 1F

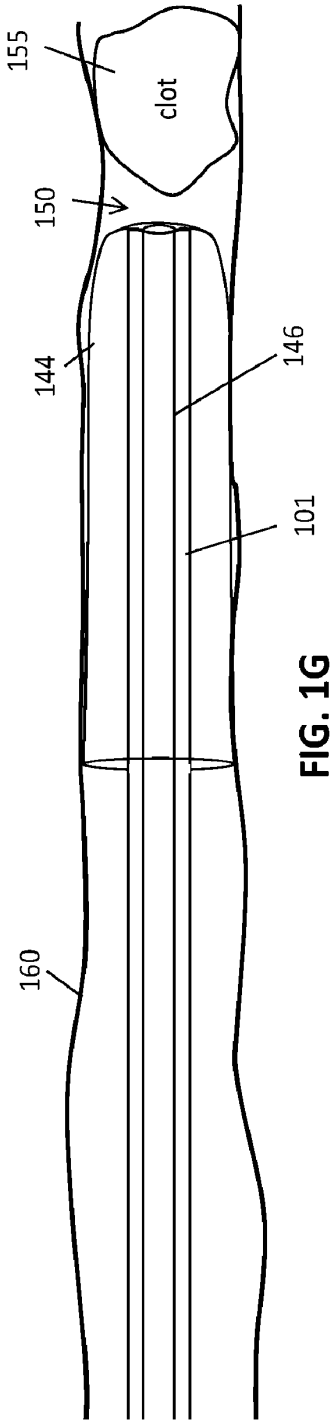


FIG. 1G

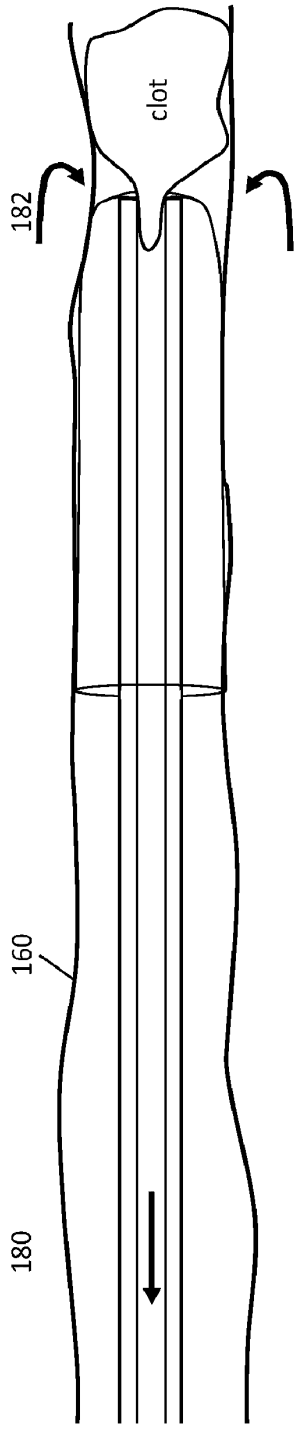


FIG. 1H

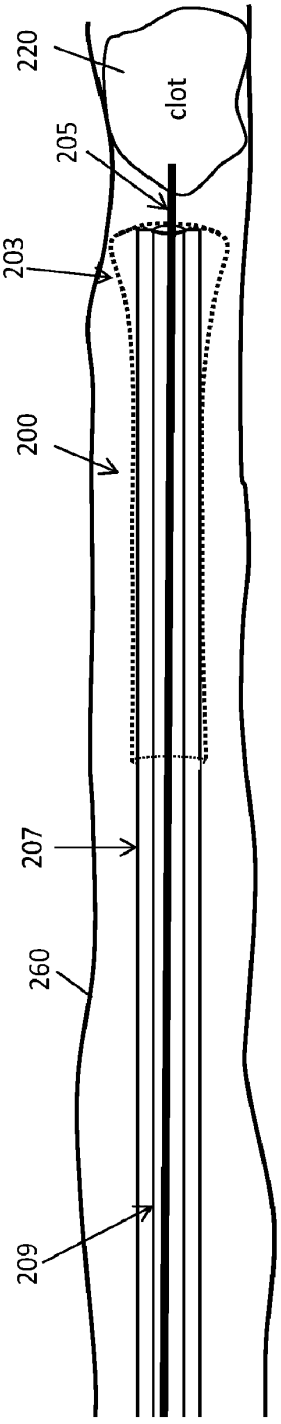


FIG. 2A

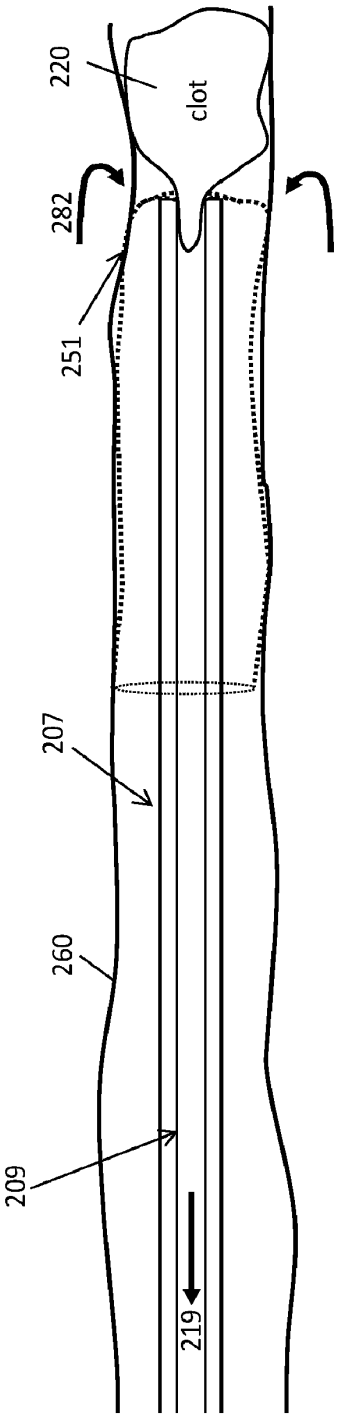


FIG. 2B

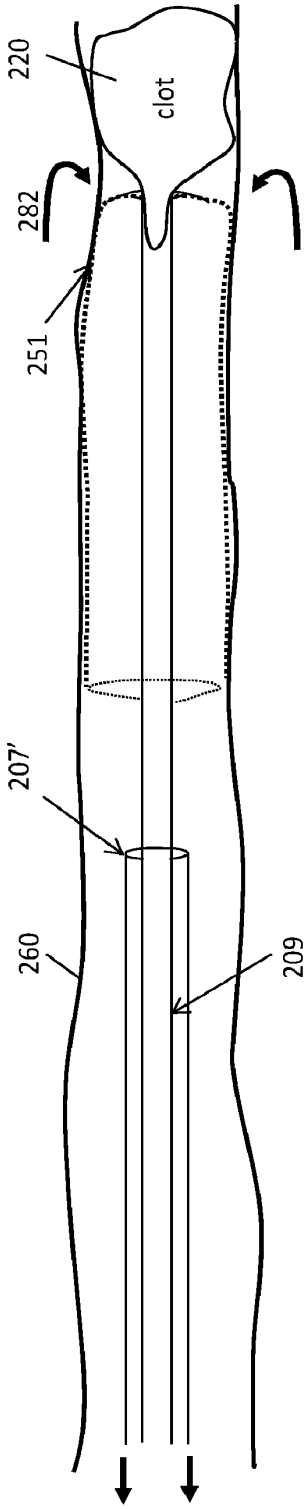


FIG. 2C

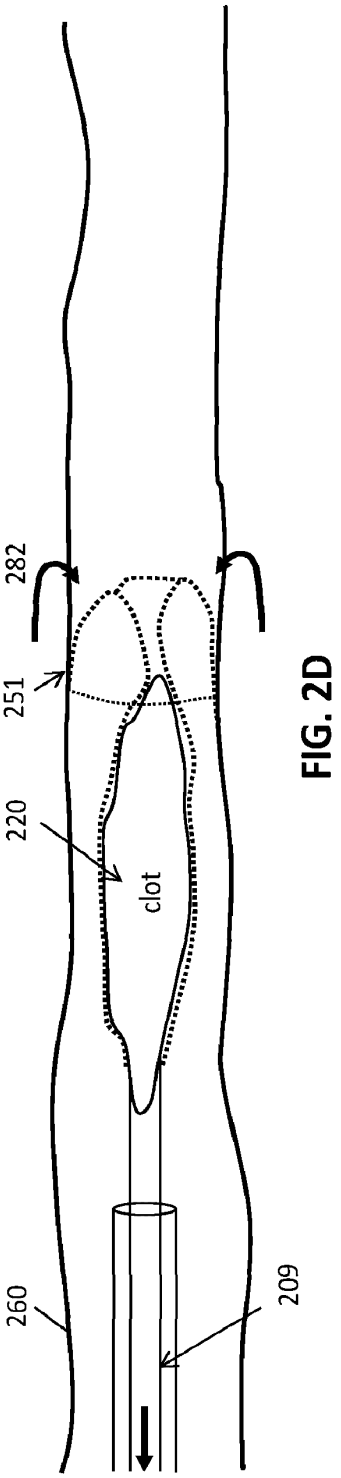


FIG. 2D

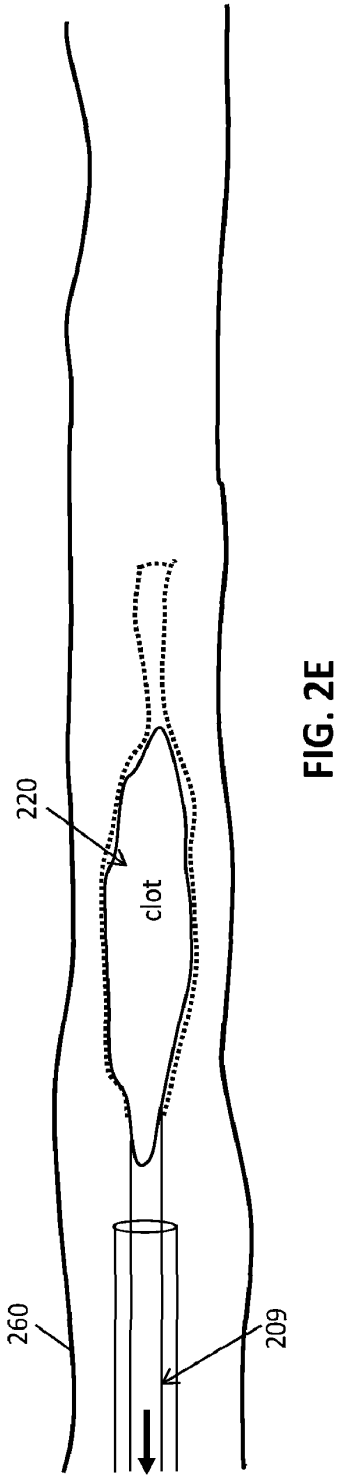


FIG. 2E

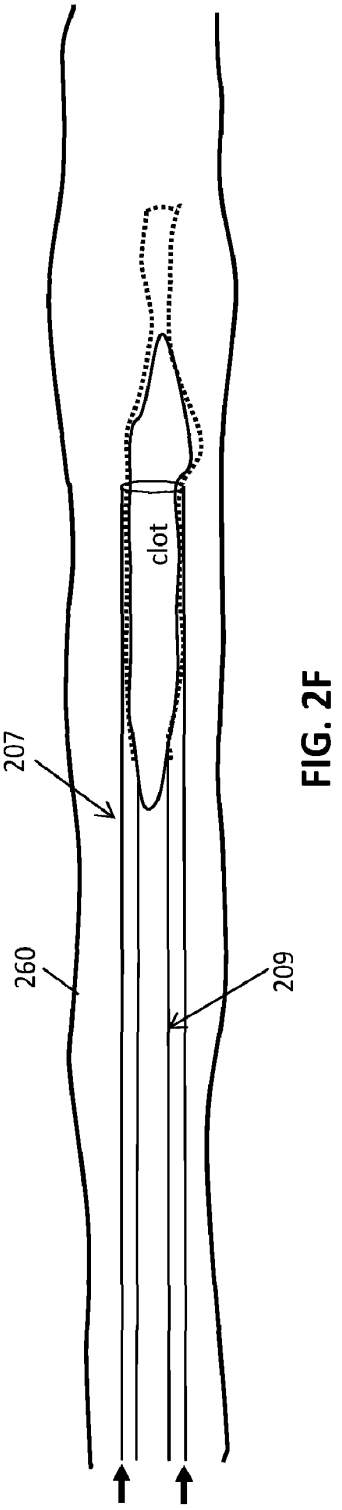


FIG. 2F

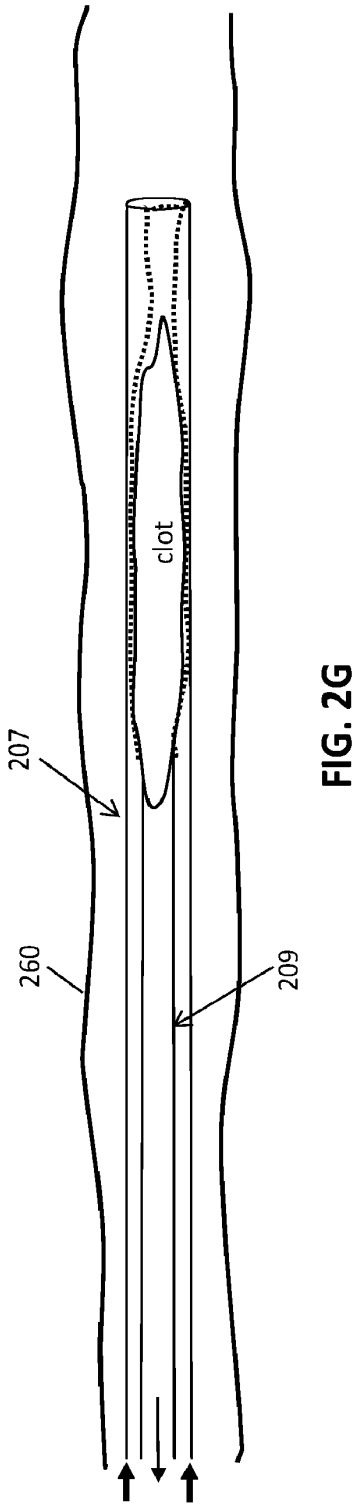


FIG. 2G

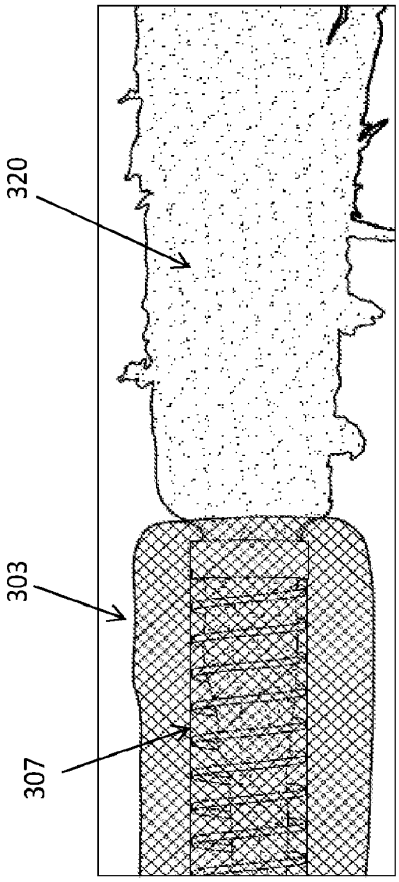


FIG. 3A

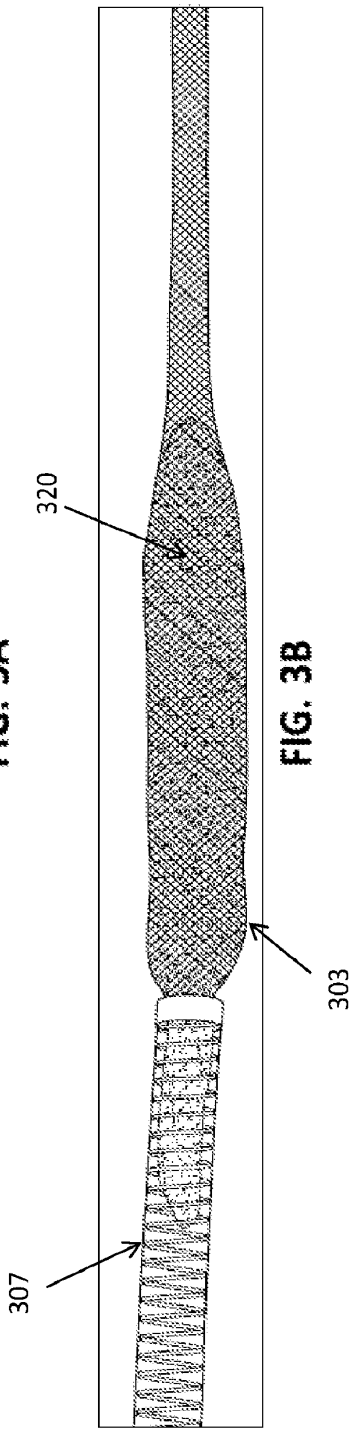


FIG. 3B

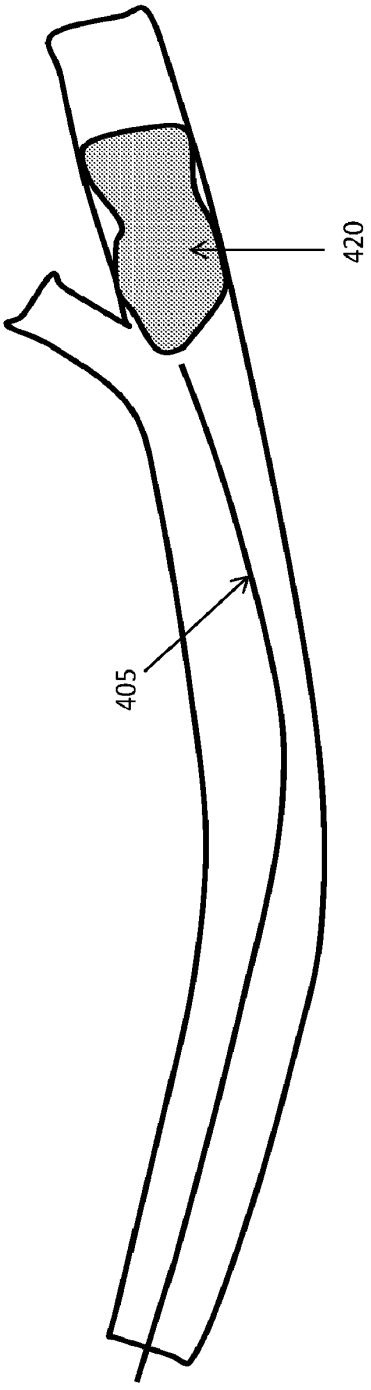


FIG. 4A

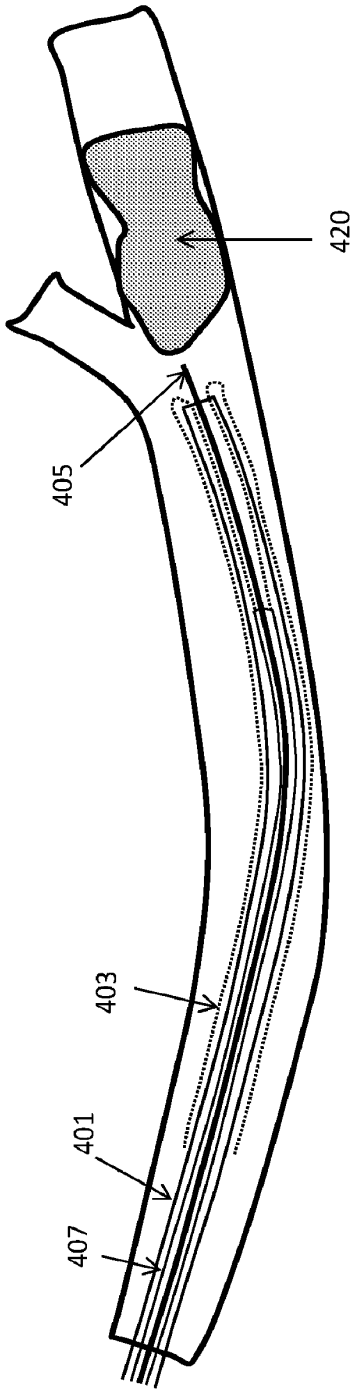


FIG. 4B

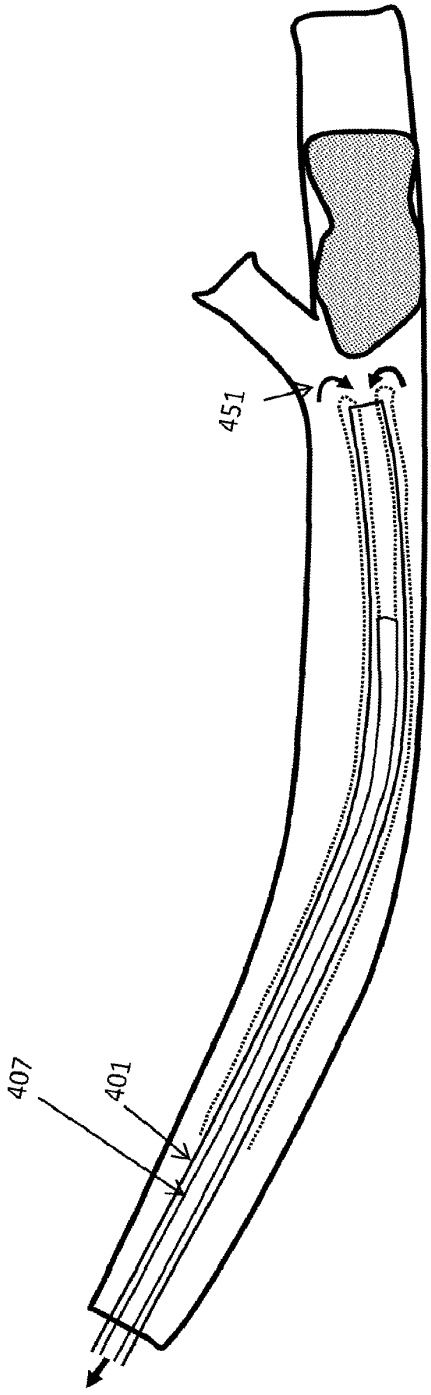


FIG. 4C

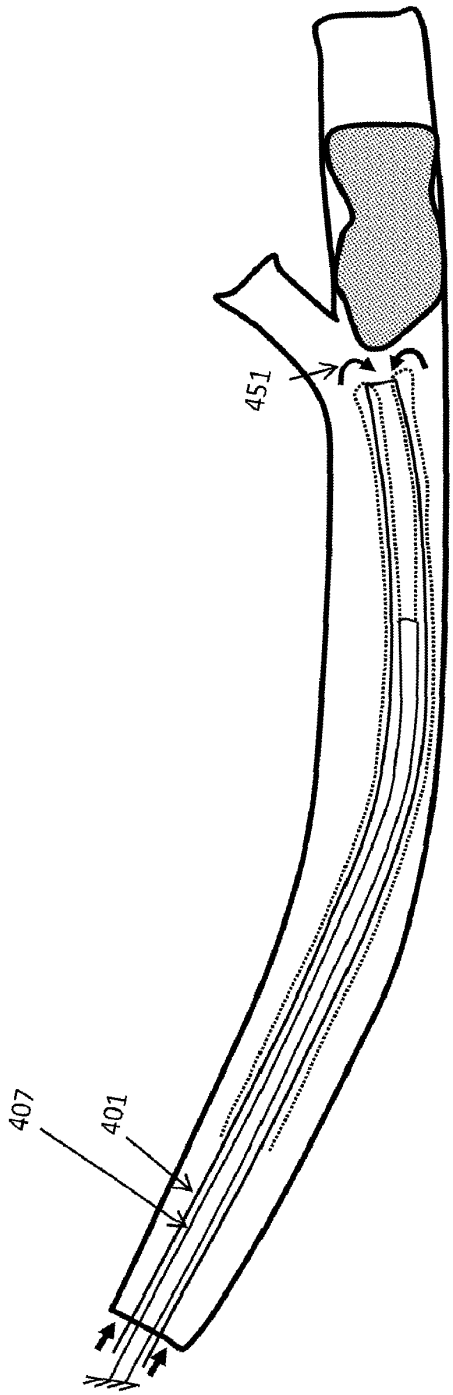


FIG. 4D

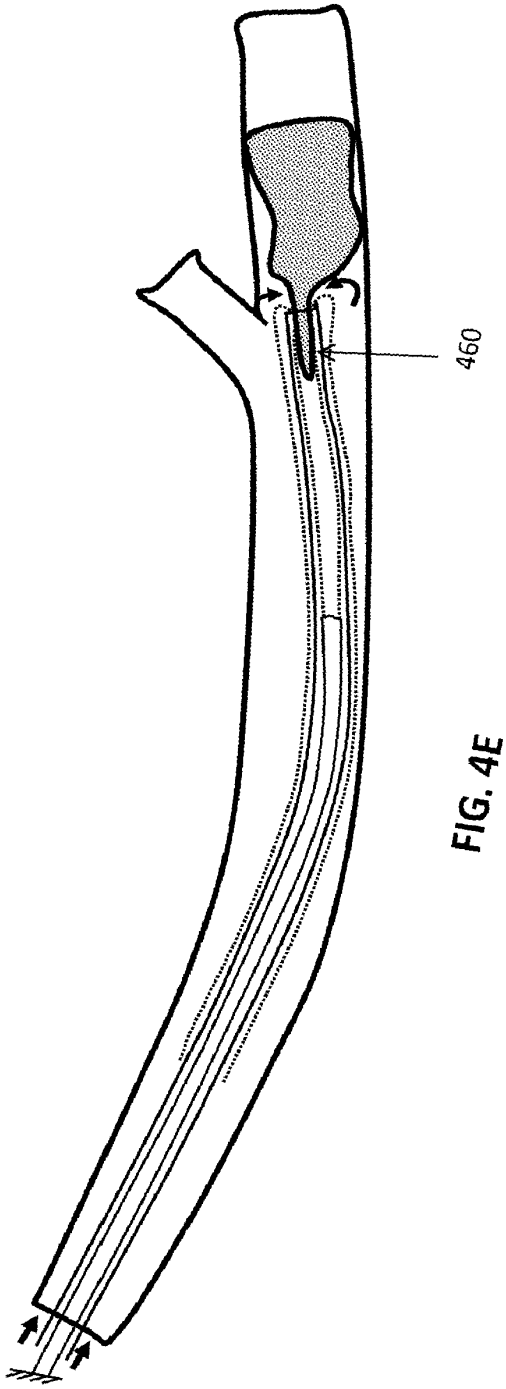


FIG. 4E

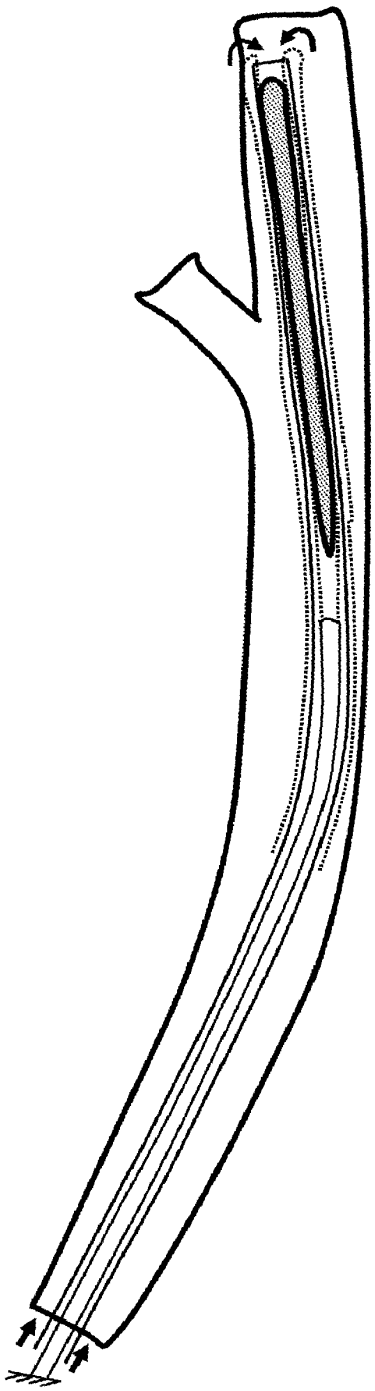


FIG. 4F

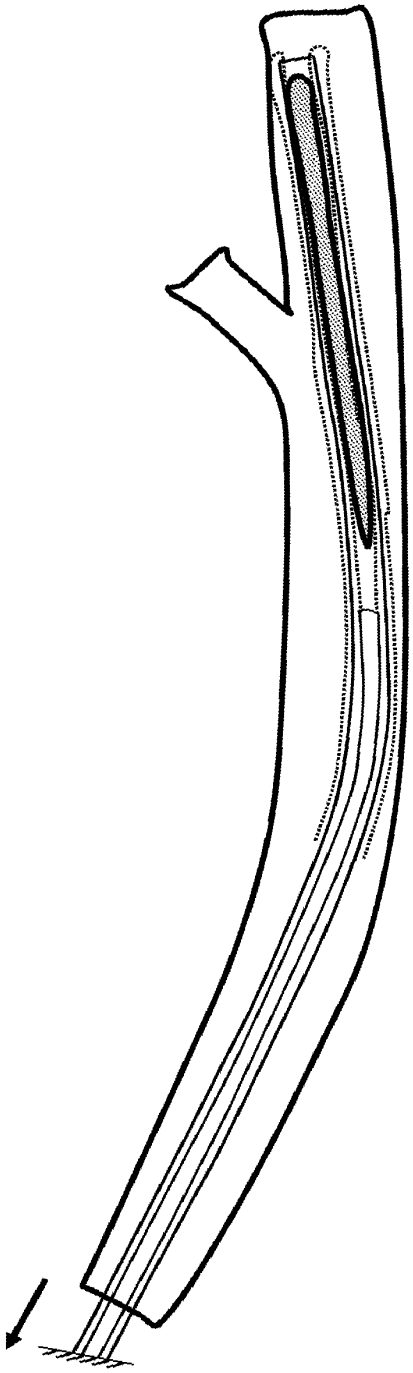


FIG. 4G

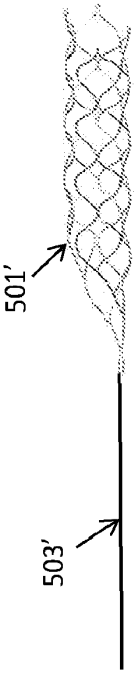


FIG. 5B

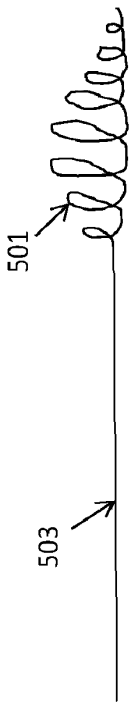


FIG. 5A

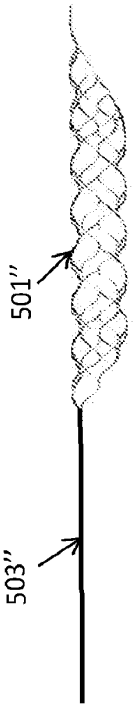


FIG. 5C

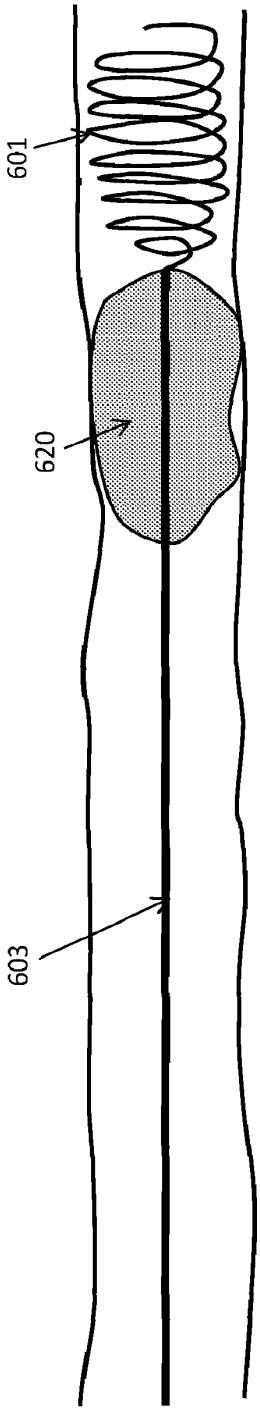


FIG. 6A

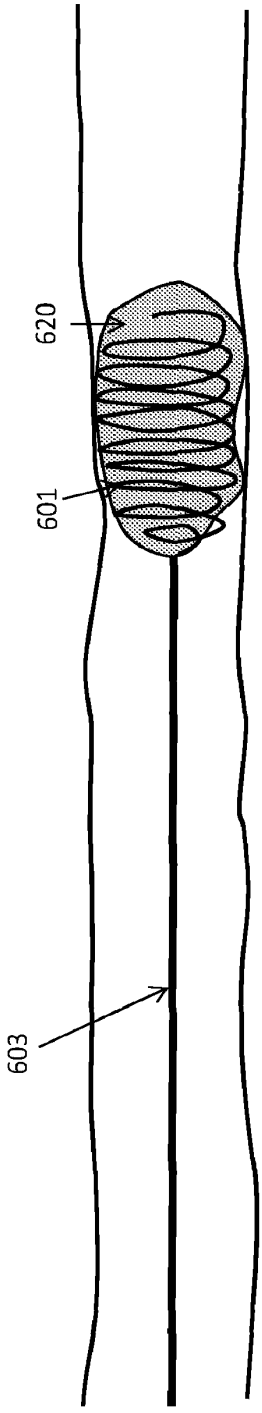


FIG. 6B

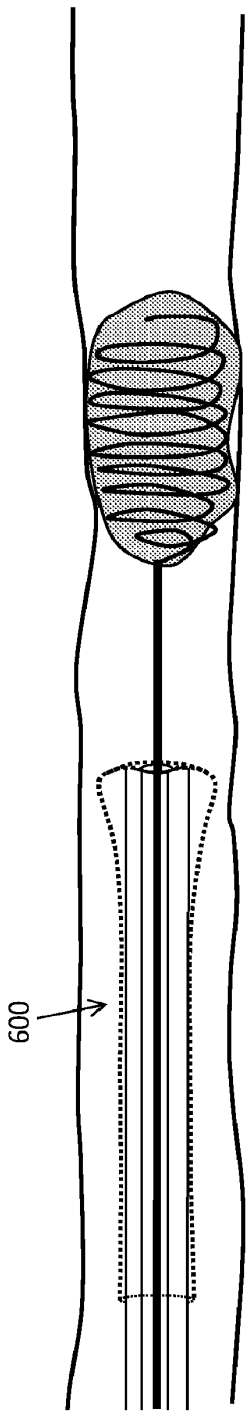


FIG. 6C

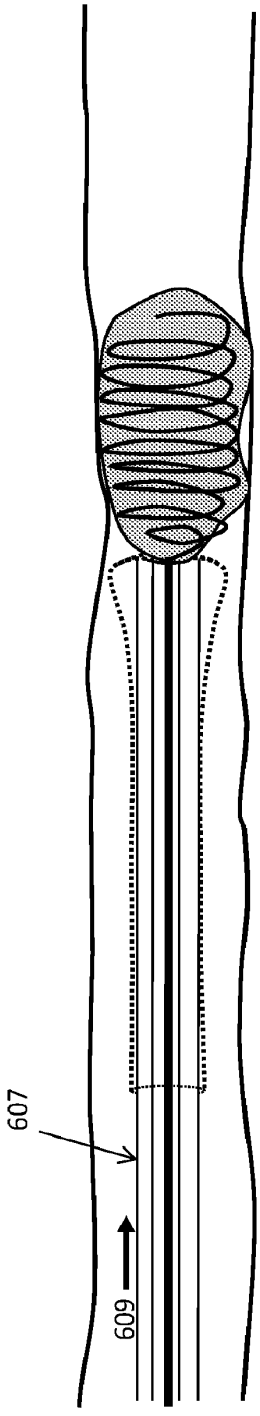


FIG. 6D

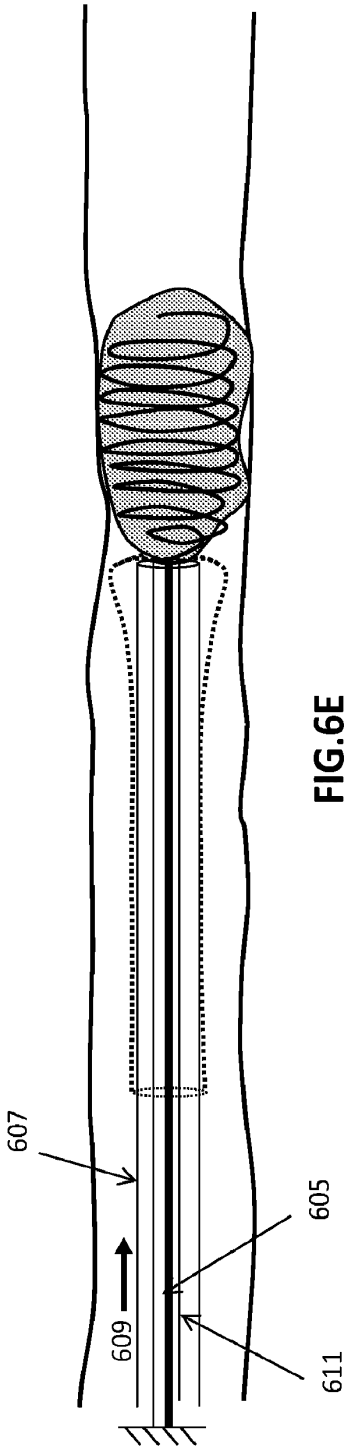


FIG.6E

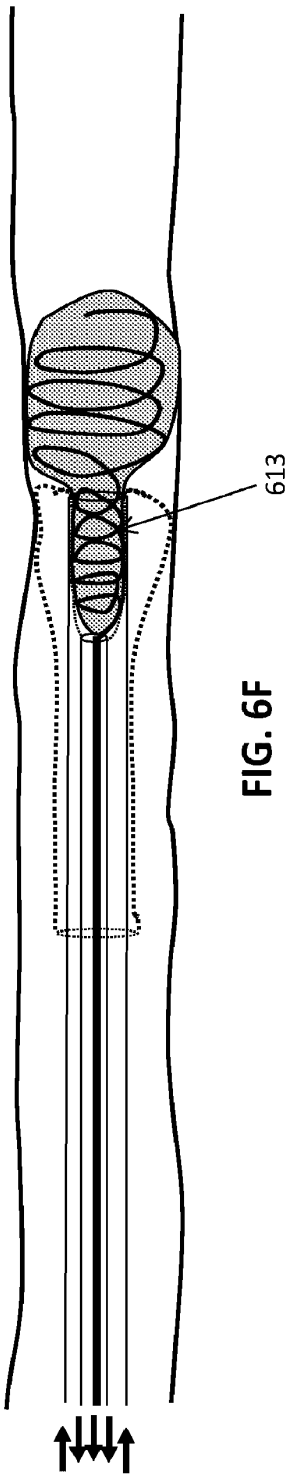


FIG. 6F

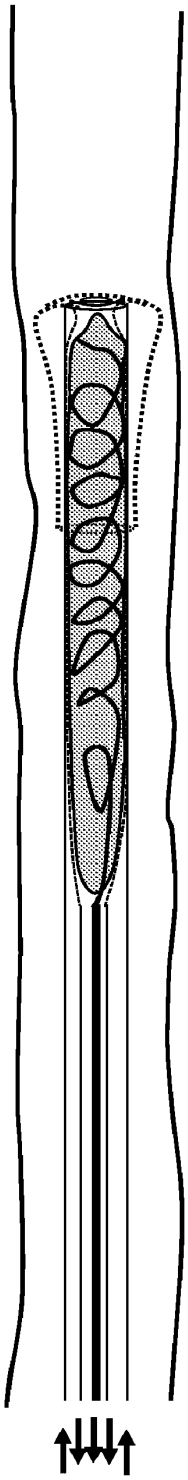


FIG. 6G

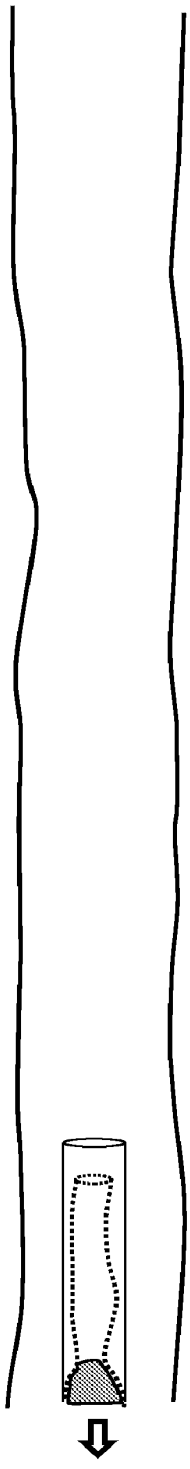


FIG. 6H

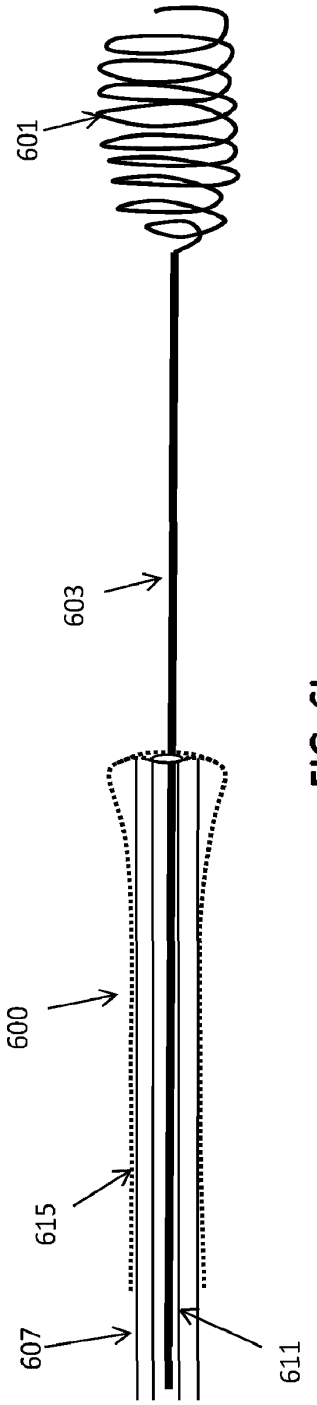


FIG. 6I

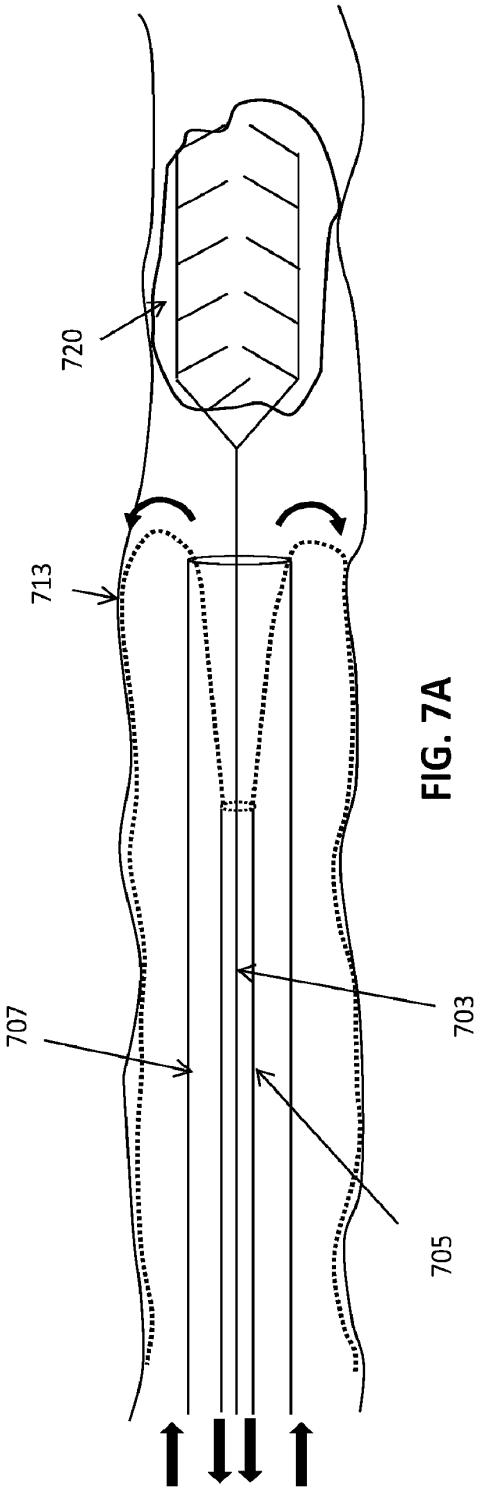


FIG. 7A

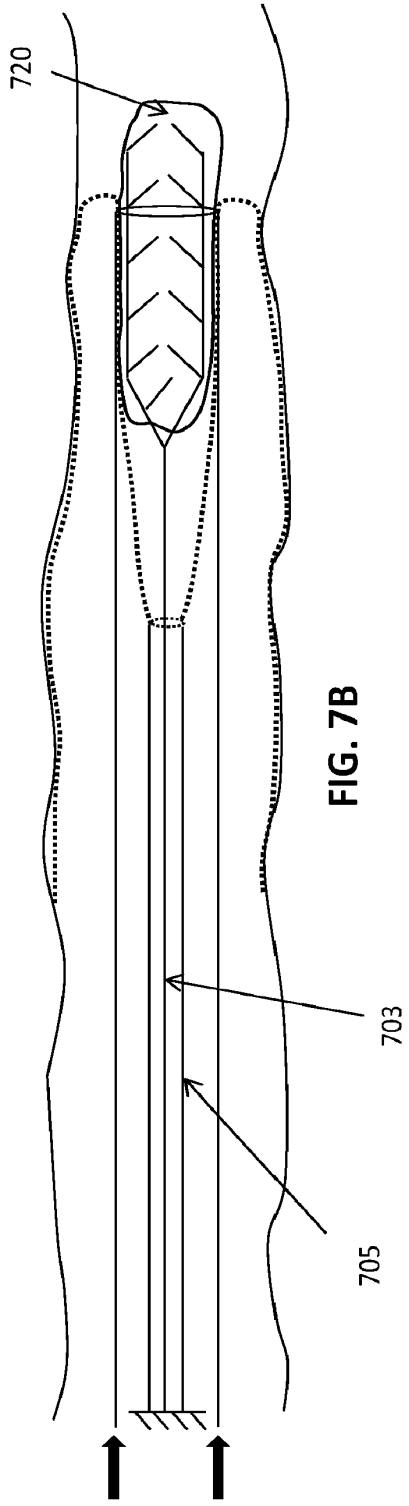


FIG. 7B

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

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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

"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)

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 June 2017	07/07/2017

Name and mailing address of the ISA/	Authorized officer
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1

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

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2012/049652 A1 (ENDOGROWTH (PROPRIETARY) LIMITED) 19 April 2012 (2012-04-19) figures	1,15
A	US 4 243 040 A (BEECHER) 6 January 1981 (1981-01-06) figures	1,15
X,P	WO 2017/058280 A1 (GW MEDICAL LLC) 6 April 2017 (2017-04-06) the whole document	1-15

1

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

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

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

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

2. ☒ Claims Nos.: 16-41
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

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

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

This International Searching Authority found multiple inventions in this international application, as follows:

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

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

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

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

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 16-41

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

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

(54) Title: INVERTING THROMBECTOMY APPARATUSES AND METHODS

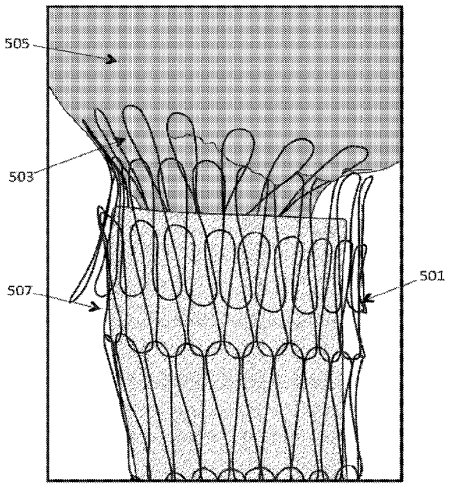


FIG. 5

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

[Continued on next page]

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Published:
— *with international search report (Art. 21(3))*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

INVERTING THROMBECTOMY APPARATUSES AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

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

INCORPORATION BY REFERENCE

[0002] All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

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

BACKGROUND

[0004] Many vascular problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery. It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue, such as blood clots, from within a patient's vasculature may improve patient conditions and quality of life.

[0005] When a thrombus forms, it may effectively stop the flow of blood through the zone of formation. If the thrombus extends across the interior diameter of an artery, it may cut off the flow of blood through the artery. If one of the coronary arteries is 100% thrombosed, the flow of blood is stopped in that artery, resulting in a shortage of oxygen

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

[0006] Clinical data indicates that clot removal may be beneficial or even necessary to improve outcomes. For example, in the peripheral vasculature, interventions and procedures can reduce the need for an amputation by as much as 80 percent. The ultimate goal of any modality to treat these conditions of the arterial or venous system is to remove the blockage or restore patency, quickly, safely, and cost effectively. This may be achieved by thrombus dissolution, fragmentation, thrombus aspiration or a combination of these methods.

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

SUMMARY OF THE DISCLOSURE

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

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

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

[00010] The elongate inversion support typically comprises a catheter having a distal end opening into which the tractor inverts. The flexible tractor inverts and rolls back into itself and may be drawn into the elongate inversion support in a conveyor-like motion; the outward-facing region rolls around to become an inward-facing region, e.g., within the lumen of the elongate inversion support. The rolling motion may thus draw a clot or other object within a vessel into the elongate inversion support.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BRIEF DESCRIPTION OF THE DRAWINGS

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

[00028] FIGS. 1A-1H illustrate an example of an apparatus for mechanically removing an object such as a clot form a body region. FIG. 1A shows an example of an elongate inversion support catheter portion of an apparatus. At least the distal end of the elongate inversion support is configured as a catheter. FIG. 1B shows an enlarged view of a partial section of a distal end (opening) of the catheter of the elongate inversion support of FIG. 1A, showing the aperture formed by the distal end opening; FIG. 1C shows an example of a flexible tractor tube attached over a puller (the puller in this example is configured as a catheter). The tractor

is shown in a first configuration. In some variations, the flexible tractor tube may be biased open, e.g., by heat setting, to have an outer diameter that is greater than the inner diameter of the catheter of the elongate inversion support, as shown in FIG. 1D. FIG. 1D shows the same distal tractor region of FIG. 1C with the expandable first end region expanded. This first configuration may be compressed down into the elongate inversion support and the distal end inverted over the catheter portion of the elongate inversion support, as shown in FIG. 1E. In FIG. 1E, the assembled mechanical thrombectomy apparatus includes an elongate inversion support catheter having a distal end and a distal end opening; the elongate puller extends within the elongate inversion support catheter and a flexible tractor tube is connected at one end to the elongate puller. The flexible tractor tube and puller may be extended through the elongate inversion support catheter, including extended out of the distal end (e.g., by pulling the elongate inversion support catheter proximally and/or by pushing the elongate puller distally). The flexible tractor tube may initially be held in a collapsed first configuration (as shown in FIG. 1E) for positioning within a vessel; it may be deployed and expanded, as shown in FIG. 1F, with the elongate inversion support catheter positioned between the flexible tractor tube and the elongate puller. The flexible tractor tube may be biased so that in the second configuration (inverted over the distal end of the catheter), the tractor has a 'relaxed' outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support.

[00029] FIGS. 1G and 1H illustrate the use of an apparatus such as the one shown in FIGS. 1E and 1F to remove a clot by drawing the flexible tractor tube proximally and/or advancing the catheter distally towards the clot so that the expandable first end region inverts as it is drawn into the distal end of the catheter, pulling the clot into the catheter.

[00030] FIG. 1I illustrates an alternative variation of a tractor and puller. In FIG. 1I, the tractor is shown attached to the distal end of a tapered or narrow puller; the distal end region is tapered, and includes a radiopaque marker at or near the attachment site to the tractor; the tractor may be knitted, braided, woven, etc. Thus, in some variations the distal end region of the puller may have a greater flexibility than the proximal end of the puller. The puller may be hollow (e.g., a catheter or hypotube) or solid (e.g., like a wire).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DETAILED DESCRIPTION

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

[00067] In general, a mechanical thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an elongate inversion support catheter having a distal end and a distal annulus (distal end opening), and a flexible tractor assembly including a flexible tractor tube coupled to an elongate puller. The flexible tractor tube is configured to roll and invert over the distal end opening of the elongate inverting support catheter.

[00068] In many of the examples disclosed and described herein, the tractor assembly is configured to extend within the elongate inversion support catheter when deployed. Any of these apparatuses may switch between a delivery configuration, e.g., in which the entire tractor assembly may be held within the elongate inversion support catheter prior to deployment, and a deployed configuration, e.g., in which the elongate inversion support catheter is positioned between the flexible tractor tube and the elongate pusher to support the flexible tractor tube as it is pulled into the elongate inversion support catheter distal end opening to roll and invert into the elongate inversion support catheter. In particular, the methods and apparatuses may be configured so that the transition between the delivery configuration and the deployed configuration is robust. For example, as will be described in greater detail herein, any of the apparatuses and methods disclosed and described herein may include an annular bias that enhances the ability of the elongate inversion support catheter to be inserted between the flexible tractor tube and the elongate puller.

[00069] FIGS. 1A to 1I illustrate various components of a mechanical thrombectomy apparatus that may include any of the features disclosed and described herein. For example, FIG. 1A shows a catheter (e.g., an elongate inversion support catheter) that may form part of the apparatuses disclosed and described herein. In this example, the elongate inversion support catheter includes a catheter body 100 having a distal end region 103 that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing harness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x)

has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00070] In FIG. 1A, the elongate inversion support catheter is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses disclosed and described herein may include an elongate inversion support catheter that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like. In FIG. 1A the catheter 100 of the elongate inversion support catheter may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00071] In some variations the distal end 105 of the elongate inversion support is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in some variations the distal tip (end) may be curved or radiused 109 as shown in FIG. 1B, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[00072] FIG. 1C shows an example of a flexible tractor tube 144 coupled to an elongate puller 146, forming a pullable tractor assembly 140. In this example, the tractor tube is shown integrated with the puller and extending back over the puller, forming the assembly. The opposite end of the flexible tractor tube 147 is open and free (e.g., not connected to the puller or catheter). As will be described in greater detail below, this open, free, end may be adapted to be expanded and held open, e.g., by shape setting back on itself and/or by including an annular bias, to enhance deployment and positioning of the catheter between the flexible tractor tube and the puller. In FIG. 1C, the tractor tube is formed of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The tractor is shown extended from the puller in a first configuration. It may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 144 may be sufficiently soft and

flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The puller 146 may typically be a less-expandable (or non-expandable) structure (tube, puller, etc.). For example, the tractor 144 may be configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first configuration to a radial diameter that is between 1.1 and 10 times (e.g., between 1.1x and 5x, between 1.1x and 4x, etc.) the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained. In FIG. 1D, the tractor tube has a larger expanded diameter than the variation shown in FIG. 1C in a relaxed configuration. In any of these variations, the expandable tractor may be biased to expand open. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00073] In FIGS. 1C and 1D the tractor and puller have two portions, a tractor tube 144 and a less expandable (or non-expandable) proximal portion comprising the elongate puller 146. The puller may be a separate region, such as a wire, catheter or hypotube, which is connected to an end region of the tractor (e.g., a flexible mesh, woven, braided, etc.), e.g., the distal end or near the distal end. The inverting region of the tractor, where it rolls and inverts over the distal end opening of the catheter may be referred to as the distal-facing region of the tractor, which may actively grab clot when rolling.

[00074] In FIG. 1E, the tractor assembly (flexible tractor tube 144 and puller 146 of FIG. 1D) are shown within an elongate inversion support catheter 100. The tractor is collapsed down 101, e.g., onto the puller, and may be held collapsed within the elongate inversion support catheter. Thus, FIG. 1E shows the pre-deployment (e.g., delivery) configuration. The tractor assembly may be axially movable (slidable) within the catheter so that it can be positioned within the catheter and within the vessel.

[00075] FIG. 1F shows a fully deployed apparatus. In FIG. 1F, the tractor tube is in an unconstrained or deployed configuration, and the elongate inversion support catheter is positioned between the tractor tube and the puller so that the tractor tube can be pulled proximally by pulling on the puller and rolling the tractor tube into the elongate inversion support catheter so that it inverts. In FIG. 1F, the tractor in this deployed configuration (e.g., the portion that is inverted over the distal end of the catheter) has an outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. Thus, the tractor 144 may be biased so that it has a relaxed expanded configuration with a diameter that is greater than the outer diameter (OD) of the elongate inversion support catheter; in addition, as will be described in relation to FIGS. 1G and 1H, below, the tractor tube may also be

configured (e.g., by heat setting, etc.) so that when the tractor tube is inverted and pulled into the elongate inversion support catheter, the outer diameter of the inverted tractor tube has an outer diameter that is greater than 0.5x (e.g., greater than 0.6x, greater than 0.7x, greater than 0.75x, greater than 0.8x, greater than 0.9x, greater than 1x, etc.) the inner diameter (ID) of the elongate inversion support catheter. This combination of an un-inverted diameter of the tractor tube of greater than the diameter of the OD of the elongate inversion support catheter and an inverted diameter of the tractor tube of greater than 0.7x the ID of the elongate inversion support catheter is surprisingly helpful for preventing jamming of the apparatus, both when deploying the apparatus and when rolling the tractor over the distal end opening of the elongate inversion support catheter to grab a clot. The tractor may be expandable and may be coupled to the puller as shown. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to elongate puller (e.g., a push/pull wire or catheter).

[00076] FIGS. 1G and 1H illustrate the removal of a clot using an apparatus such as the apparatus components of FIGS. 1A and 1E. The apparatus 10 is shown in a deployed state. In this example the thrombectomy apparatus 10 is configured as a thrombectomy apparatus including an elongate inversion support catheter 100 and a flexible tractor tube 144 that extends over the distal end region of the catheter and doubles-over itself at the distal end of the catheter to invert so that the external tractor end region is continuous with an inner, less-expandable (in this example, less-expandable includes non-expandable) second distal end region 146 (puller) that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The pusher/puller member that may be a rod or other member that is continuous with the distal end region of the tractor. In FIG. 1G the apparatus is shown positioned and deployed within the vessel 160 near a clot 155. The clot may be drawn into the catheter by pulling the tractor 140 proximally into the catheter 101, as indicated by the arrow 180 showing pulling of the inner portion of the flexible tractor (e.g., using a handle, not shown) resulting in rolling the tractor over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled into the catheter, shown by arrows 182. The end of the tractor outside of the catheter may be "loose" relative to the outer wall of the catheter. FIG. 1I illustrates another example of a tractor assembly 154 including a tractor tube 144 that is coupled to a puller 156. The puller in this example is tapered (having tapering region 161) and may therefore have a different flexibility of the distal end region than the proximal end region. For example, the proximal end region may be less flexible than the narrower-diameter distal end region 195 to which the tractor is

coupled. The assembly includes a radiopaque marker 165. The tractor may be attached to the puller by any appropriate means. For example, the tractor may be crimped, glued, fused, or otherwise attached to the puller, typically permanently.

[00077] In general, the mechanical thrombectomy apparatuses disclosed and described herein may be highly flexible, both before actuating and during operation. For example, the flexible tractor may not increase the stiffness/flexibility of the catheter of the elongate inversion support, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortious vessels of the neuro-vasculature. Disclosed and described herein are flexible tractor tube portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, disclosed and described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[00078] The tractors may be woven, braided and/or knitted materials. For woven and braided materials, which may include a plurality of fibers that are woven or braided to form the inverting tube, these structures may be tuned to prevent jamming and/or to reduce the force necessary to pull the tractor and invert over the catheter tip. For example, the mechanical atherectomy apparatus may include a braid-type tractor that can roll freely around the tip of catheter even in a tortuous anatomy and when grabbing clot by tuning one or more of the braid structure; minimizing the braid angle; including a hydrophilic coating on the distal aspect of the catheter outer diameter (OD) or the inner diameter (ID) of the braid (e.g., tractor); including a radiused wall on the catheter; and/or increasing the stiffness of the distal tip region relative to adjacent proximal regions. Altematively, it may be advantages to have a hydrophilic coating on 1, 3,5,10, or 15 cm of the distal ID or the entire catheter ID. This may even enhance aspiration of the clot without a tractor element.

[00079] As mentioned, the tractor (e.g., braided, woven, knitted, etc.) may be configured to collapse down into the inner diameter (ID) of the catheter as little as possible. For example, the tractor may collapse to an ID that is greater than, equal to, or within 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter inner diameter (ID)/Catheter Tip OD, since, when the tractor is being pulled around catheter tip it may create axial tension on the tractor (e.g., braid, knit, etc.) that can inadvertently cause the tractor to jam on the catheter tip. When

tractor is pulled around catheter tip, the tractor is being pulled in the axial orientation creating axial tension on tractor structure as the tractor is being pulled through the catheter ID. By having the tractor elements jam at an ID greater than or equal to 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter ID (or in some variations, OD), when being axially tensioned, the tractor is less likely to grab/synch down onto the catheter tip, helping the braid roll around the catheter tip with less axial force applied by the user. If less axial force is required by the user to pull the tractor structure around the tip then the catheter tip is less likely to buckle or deflect when retracting the tractor. It may be advantageous to minimize the chance the catheter tip will buckle. The tractor can be tuned to "jam" at a specific ID by controlling any of the following variables and in any combination: selecting a specific number of braid ends, selecting the size/diameter of the braid ends; selecting the braid material (e.g., multifilament or monofilament); heat setting the bias on the braid (e.g., braid diameter); and selecting a braid pattern, e.g., 1x2, 1x1 or any other pattern.

[00080] The braid angle may be minimized to prevent locking up of the rolling of the tractor over the catheter end opening. Typically, the lower the braid angle (e.g., 45 degrees or less, 40 degrees or less, 35 degrees or less, 30 degrees or less, 25 degrees or less, 20 degrees or less, etc.) the less likely it is to have the braid cross over points catch on the catheter tip.

[00081] In any of the variations disclosed and described herein, the catheter and/or a surface of the tractor may be coated to enhance rolling over the distal end region of the catheter. It may be helpful to have a hydrophilic coating on the distal aspect of the catheter OD or the ID of the tractor so the tractor can more easily side over the catheters distal end and around the tip of the catheter when pulled through the inside of the catheter.

[00082] The radius wall of the catheter tip may be chosen/set to within a range that allows sliding. For example, it may be helpful for the tip of the catheter to have the largest radius possible but at least 0.0025" radius wall on the catheter, ideally approximately 0.005" radius wall.

[00083] The stiffness of the distal of the catheter may be sufficiently stiff to prevent collapse as the tractor is pulled; it may also be lubricious (e.g., by a coating or material property). The distal most section of the catheter tip (e.g., the last 5mm) may be fabricated of a material which is stiff enough and lubricious enough so the distal tip of the catheter does not collapse or buckle inward ward when the braid structure is rolling around the catheter tip. Thus, the distal tip may have a stiffness that is greater than the more proximal region at the distal end of the catheter.

[00084] It may be helpful or desirable to have pores in the tractor. A lack of gaps or small pore size may limit the ability of the braid to grab clot. Alternatively, or additionally, it may be desirable to form a braid structure with texture. One example is to braid two or more different diameter braid ends into the same structure: the difference in braid end diameters will help form a texture to the braid structures outer surface, aiding the grabbing of the clot when rolling the braid-dozer around the catheter tip.

[00085] As an alternative (or in addition) the tractor may be configured to lock so it does not compress in diameter during axial load by adding a coating, laminate or adhesive to the braid at a desired diameter. Adding a thin coating, laminate or adhesive can inhibit the braid elements from sliding with respect to each other, thereby locking the braid to a specific diameter. The coating can be applied while leaving the majority of the pores and pore area substantially open. Examples of thin coatings include urethanes and silicones with and without hydrophilic coatings and hydrophilic coatings with no tie layer.

[00086] Reducing the sliding friction of tractor to outer catheter wall, improving tractor to tip rolling, and/or enhancing tractor to inner catheter sliding may also be achieved by including a sliding skin or sleeve. For example, a thin (e.g., ultrathin) sleeve may be used. The sleeve would be made from low friction polymer (e.g., PET, PE, PP, PTFE, ePTFE, pebax, urethanes) by braiding, knitting, weaving, extrusion, melt blown, melt spinning, etc. The sleeve could be made from laser slotted tubing, chemical etching, micro machining. The sleeve could be also coated with a lubricious coating such as a hydrophilic coating. Lubricious coatings can be located on the outside and/or inside surfaces. The sleeve may be placed between the dozer element and the catheter wall and attached to the puller element. The sleeve may be less than 0.002" thick, ideally, less than 0.001" wall thickness. The sleeve may decouple the tractor clot grabbing system from the catheter wall, tip rolling and inner catheter dragging friction. The sleeve could be totally free from the tractor, connected to the tractor in discrete locations or connected fully to the tractor. This may allow the tractor to be designed to grab clot (larger wires: 0.001" to 0.002" for neuro, and 0.002" to 0.007" for other applications) and the skin to minimized in thickness and structure to reduce friction and skin bending stiffness.

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

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

[00088] In some variations, the tractor region may be formed of with a mixed or hybrid structure, combining one or more of interwoven or knitted braid polymer filaments with metallic filaments. The mixed structure (hybrid structure) may leverage both metallic elements interwoven with low friction polymer elements. The metallic filaments may create stiffness elements that may grip/grab a clot. The polymer filaments may aid in grabbing clot but may provide surface friction reduction to the outer catheter wall, the catheter tip and the inner catheter wall once around the tip.

[00089] Any of the apparatuses disclosed and described herein may include a tractor having a hydrophilic/lubricous coating on the inside surface, e.g., for braided/knitted tractors, on the inside surface (contacting the outer and inner diameter of the catheter) of the braid/knit, which is in contact with the outside of the catheter. Examples of lubricous coatings include hydrophilic coatings (e.g., hydrogels) and hydrophobic coatings (e.g., fluorine coating such as PTFE & FEP, parylene, silicone, siloxane (silicone additive) added to various polymers including pebax to make any material more lubricious, Polyethylene, polypropylene, FEP)

[00090] As mentioned above, any of these apparatuses may include a distal tip that is less rigid (e.g., 'softer') than the more proximal regions of the distal tip. This may be achieved by having a structural supporting member reinforcing the distal tip, or by modifying the material forming the distal tip.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

INVERSION SUPPORT CATHETERS

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

[000117] The inversion support catheter may be configured so that it does not collapse (e.g., buckle) when 500 g or less of of compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force), particularly when the apparatus is configured for neurovascular applications. For peripheral vascular applications, the elongate inversion support catheter may be selected or configured to withstand at least 1500 g of

compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In addition, the inversion support catheters disclosed and described herein may be configured so that they do not foreshorten substantially when the tractor tube is pulled over the distal end (e.g., do not foreshorten by more than 2%, 3%, 4%, 5%, 6%, 7%, 8%, 9%, 10%, etc.).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[000148] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[000149] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the various inventions disclosed and described herein. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the term "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[000150] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially

relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[000151] Although the terms "first" and "second" may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed herein could be termed a second feature/element, and similarly, a second feature/element discussed herein could be termed a first feature/element without departing from the teachings of the disclosed and described embodiments.

[000152] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising" means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term "comprising" will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

[000153] In general, any of the apparatuses and methods disclosed and described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may alternatively be exclusive and may be expressed as "consisting of" or alternatively "consisting essentially of" the various components, steps, sub-components or sub-steps.

[000154] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or "approximately," even if the term does not expressly appear. The phrase "about" or "approximately" may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value unless the context indicates otherwise. For example, if the value "10" is disclosed, then "about 10" is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that "less than or equal to" the value, "greater than or equal to the value" and possible ranges between values are also disclosed, as appropriately

understood by the skilled artisan. For example, if the value "X" is disclosed the "less than or equal to X" as well as "greater than or equal to X" (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point "10" and a particular data point "15" are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[000155] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the disclosed inventions, which are defined by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the inventions as they are set forth in the claims.

[000156] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, as many are, in fact, disclosed. Thus, although specific embodiments have been illustrated and disclosed and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of the various embodiments disclosed and described herein, as well as further embodiments not specifically disclosed and/or described herein, will be apparent to those of skill in the art upon reviewing the above description in conjunction with the accompanying drawings.

CLAIMS

What is claimed is:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

an elongate inversion support catheter having a distal end and a tapered or rounded distal end opening;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

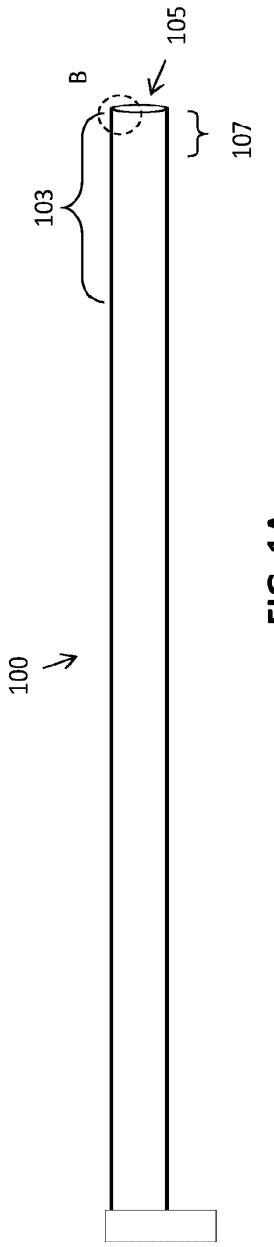


FIG. 1A

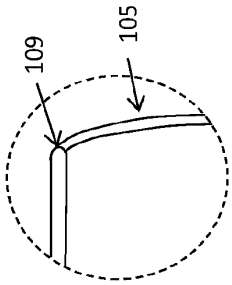


FIG. 1B

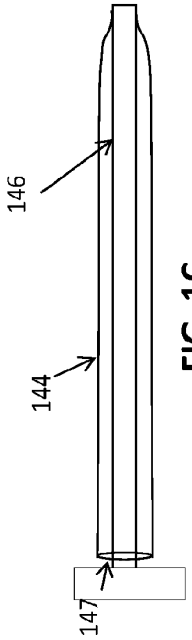


FIG. 1C

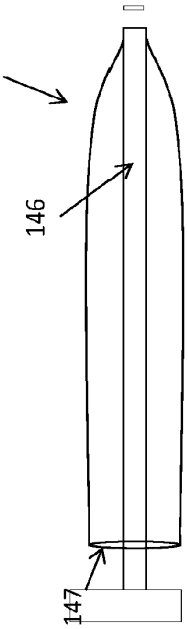


FIG. 1D

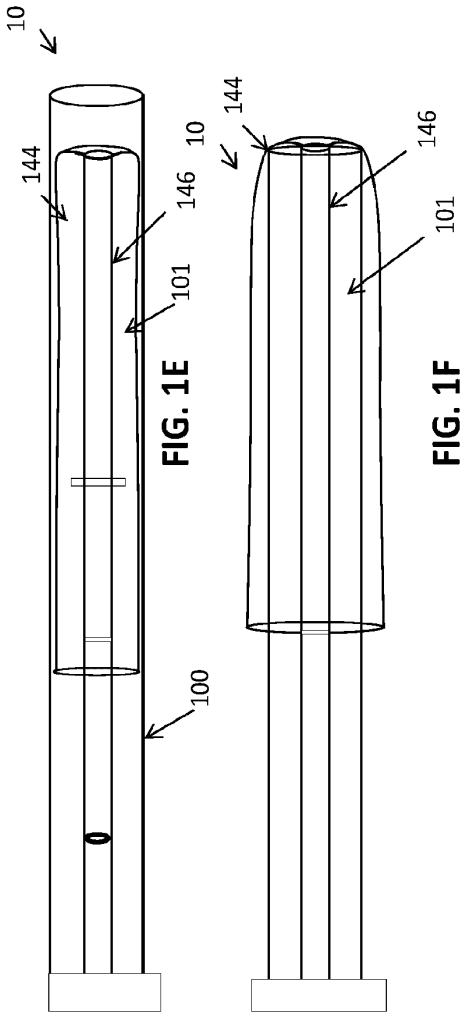


FIG. 1E

FIG. 1F

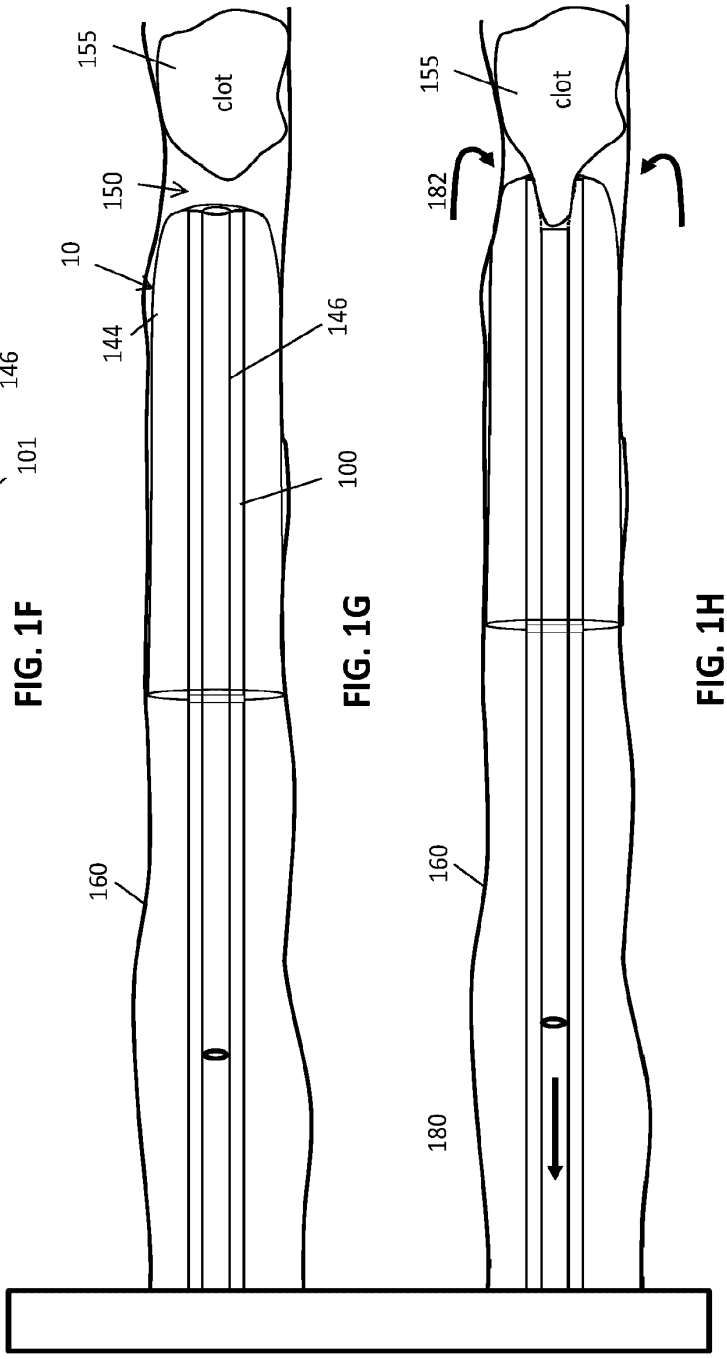


FIG. 1G

FIG. 1H

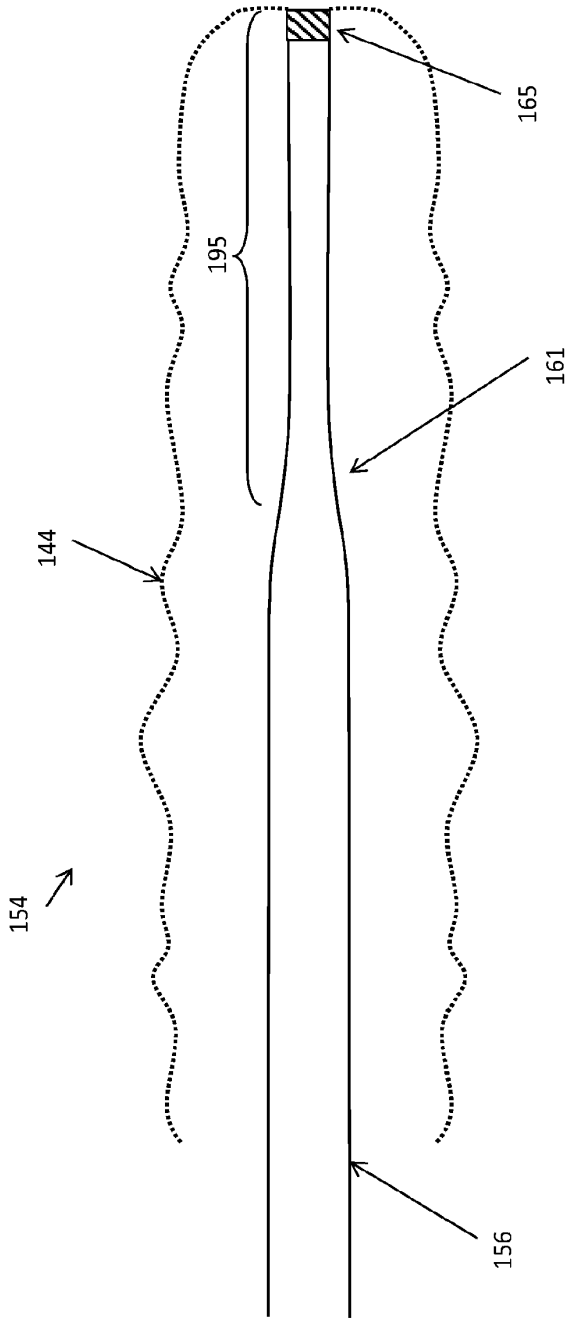


FIG. 1I

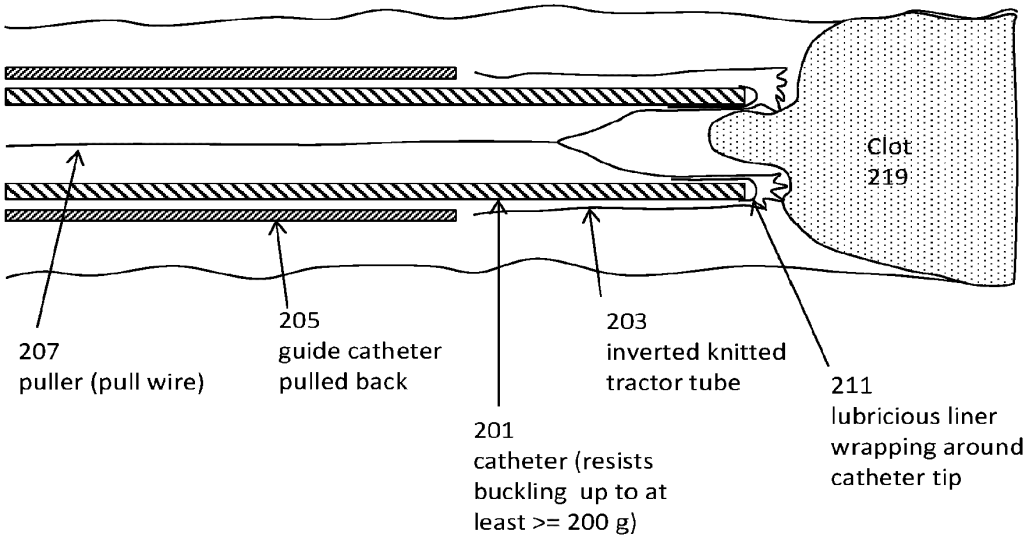

Clot
219
207
puller (pull wire)
205
guide catheter
pulled back
201
catheter (resists
buckling up to at
least >= 200 g)
203
inverted knitted
tractor tube
211
lubricious liner
wrapping around
catheter tip

FIG. 2A

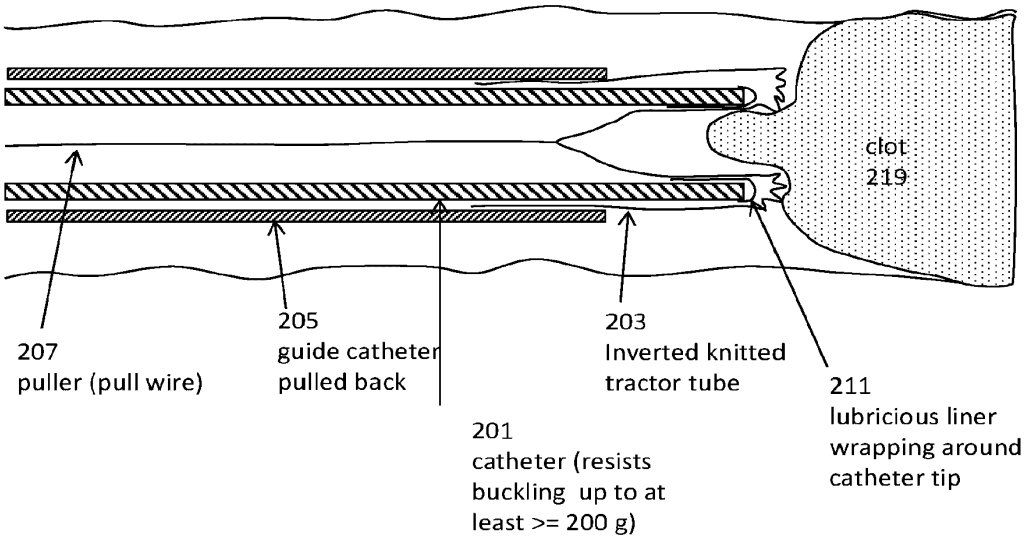

clot
219
207
puller (pull wire)
205
guide catheter
pulled back
201
catheter (resists
buckling up to at
least >= 200 g)
203
Inverted knitted
tractor tube
211
lubricious liner
wrapping around
catheter tip

FIG. 2B

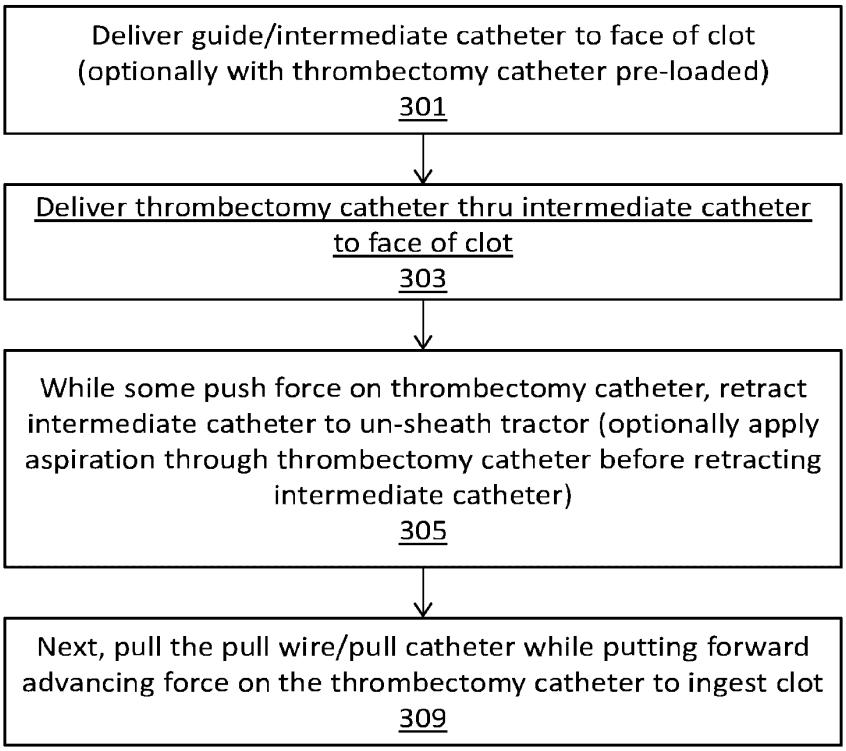

Deliver guide/intermediate catheter to face of clot (optionally with thrombectomy catheter pre-loaded)
301
Deliver thrombectomy catheter thru intermediate catheter to face of clot
303
While some push force on thrombectomy catheter, retract intermediate catheter to un-sheath tractor (optionally apply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

FIG. 3

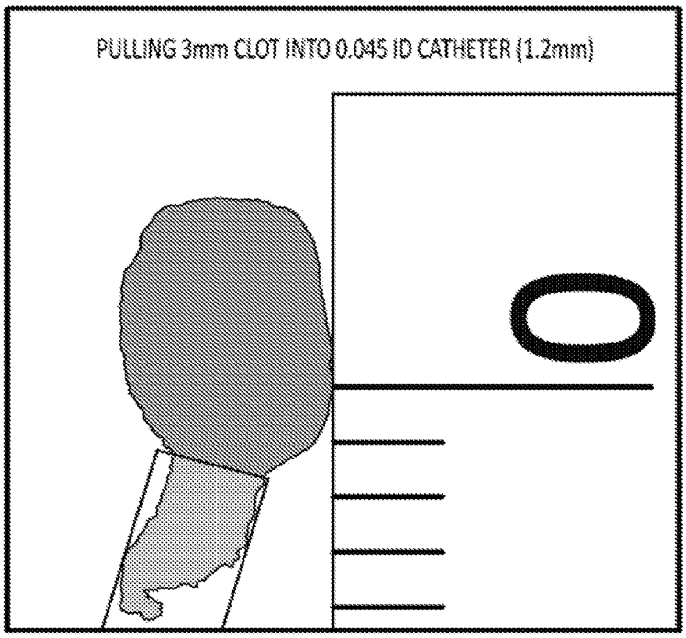


FIG. 4A

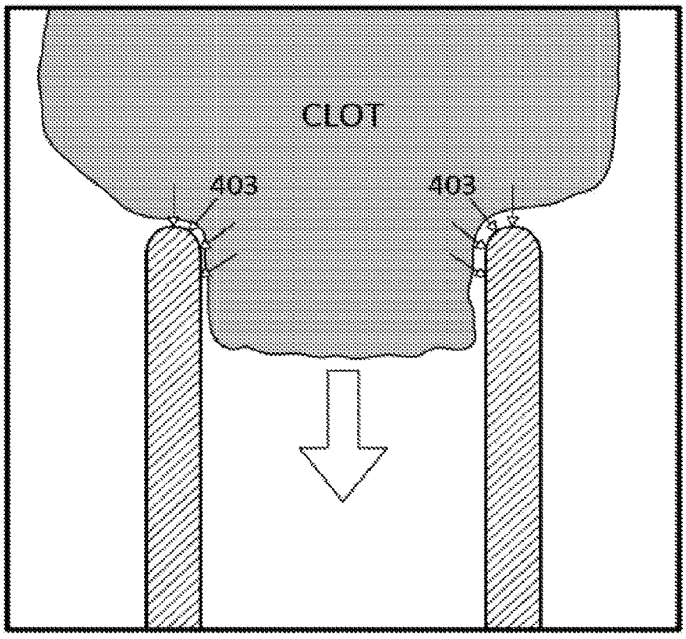


FIG. 4B

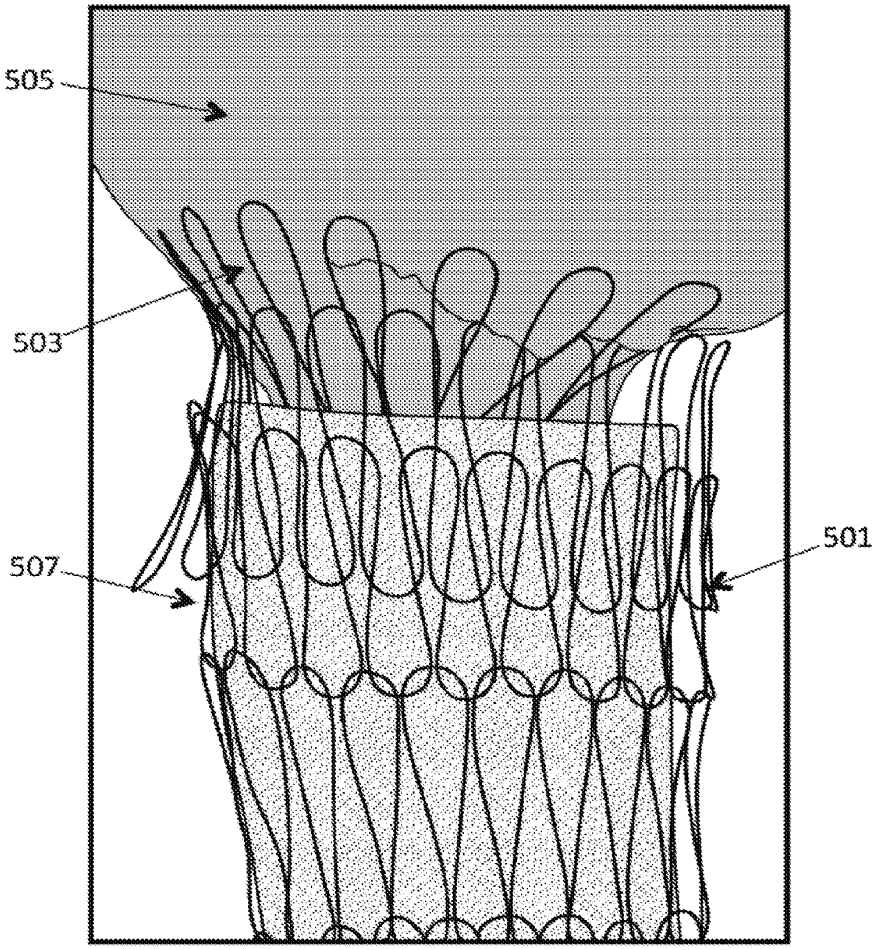


FIG. 5

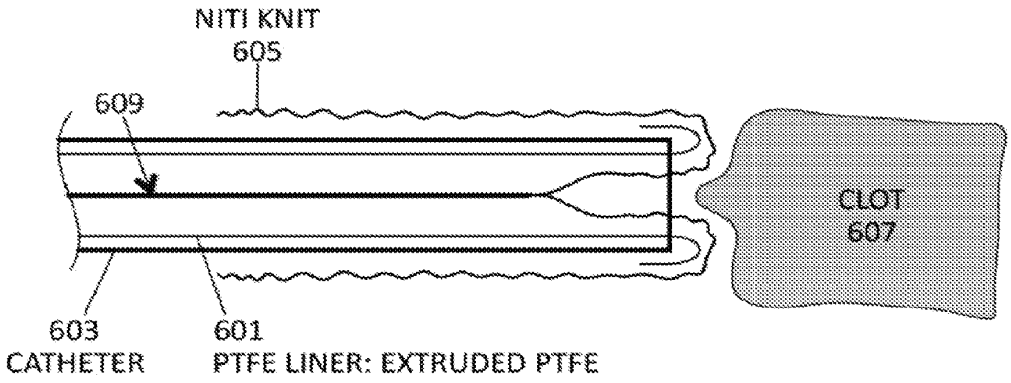

NITI KNIT
605
609
CLOT
607
603
CATHETER
601
PTFE LINER: EXTRUDED PTFE

FIG. 6A

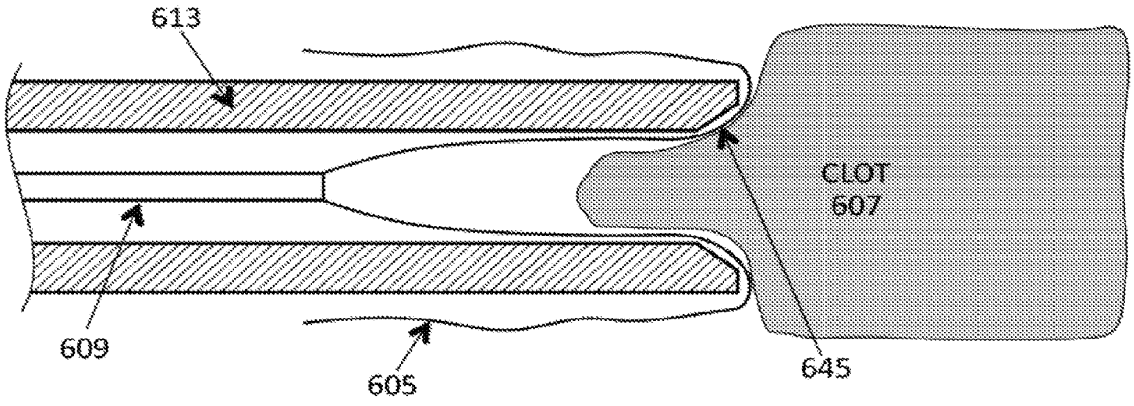

613
CLOT
607
609
605
645

FIG. 6B

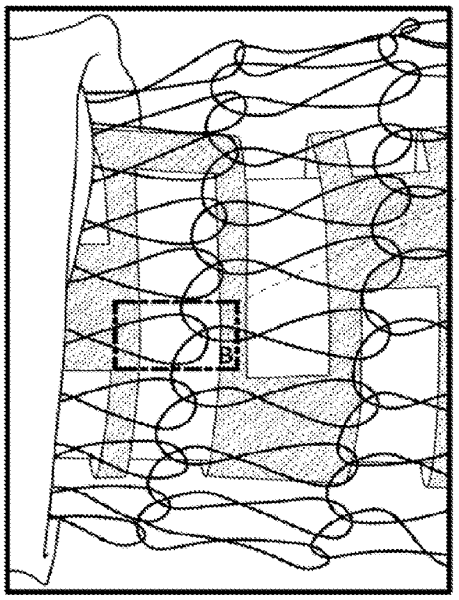


FIG. 7A

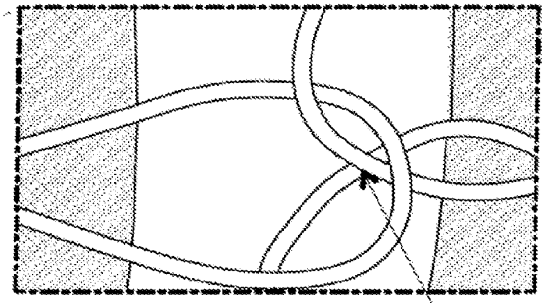


FIG. 7B

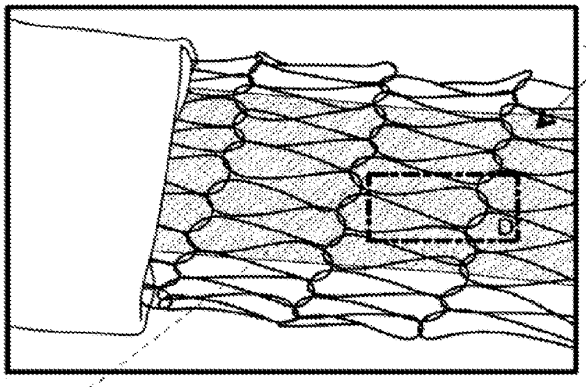


FIG. 7C

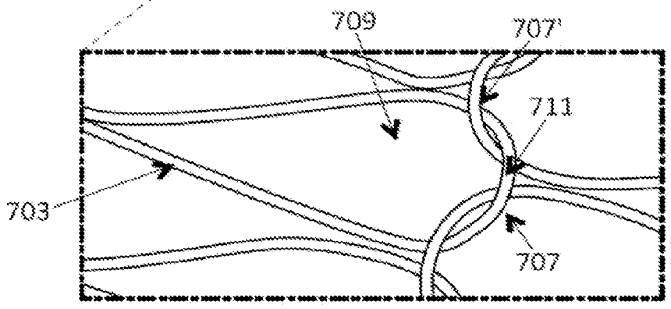


FIG. 7D

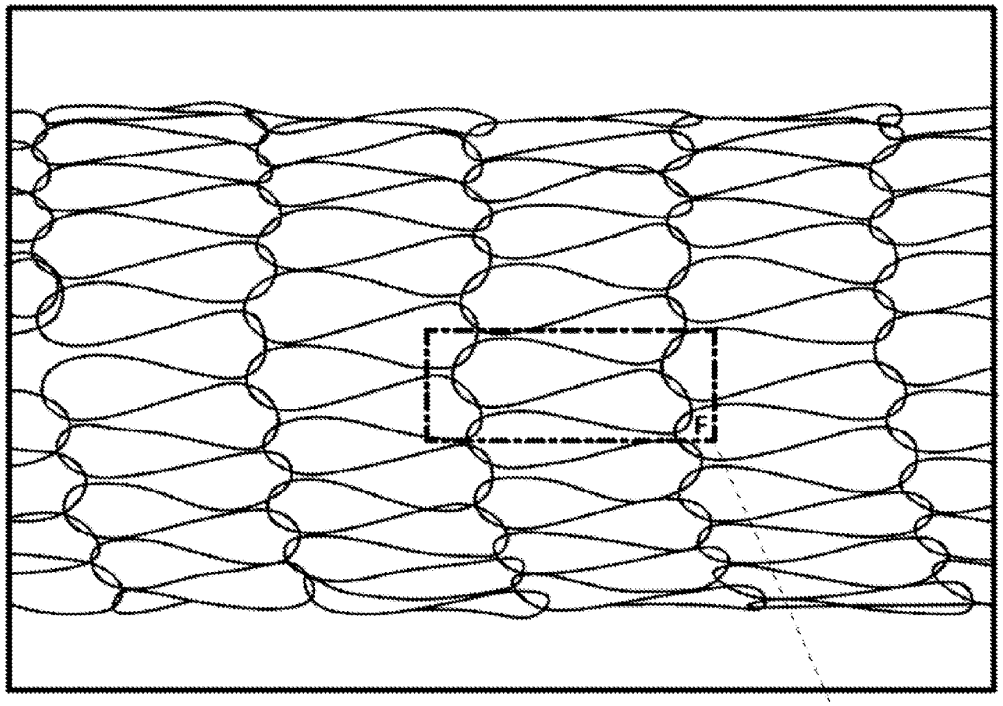


FIG. 7E

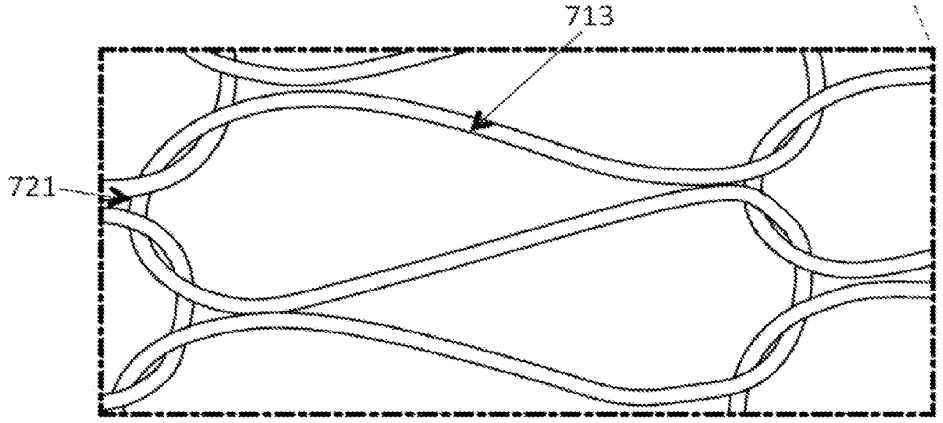


FIG. 7F

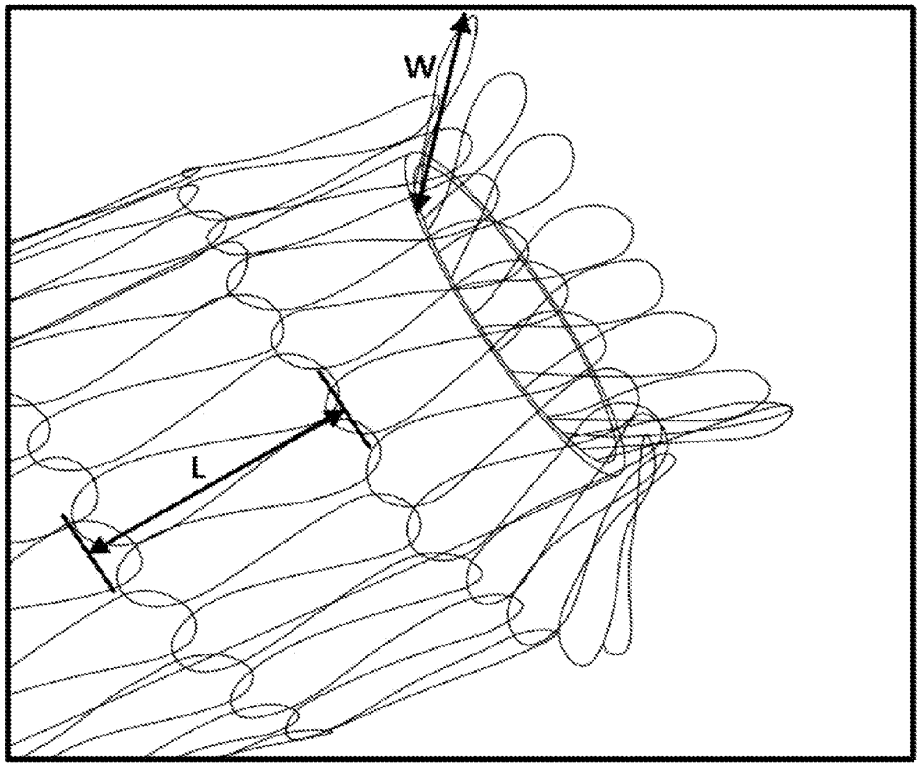


FIG. 8A

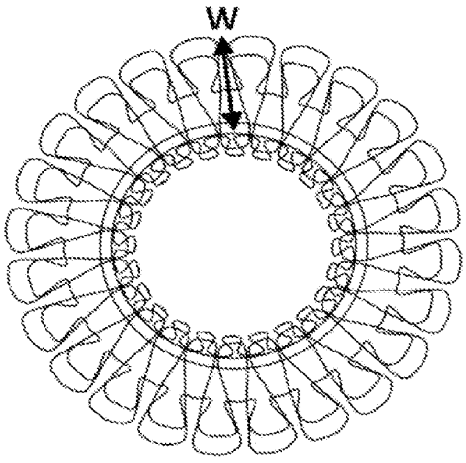


FIG. 8B

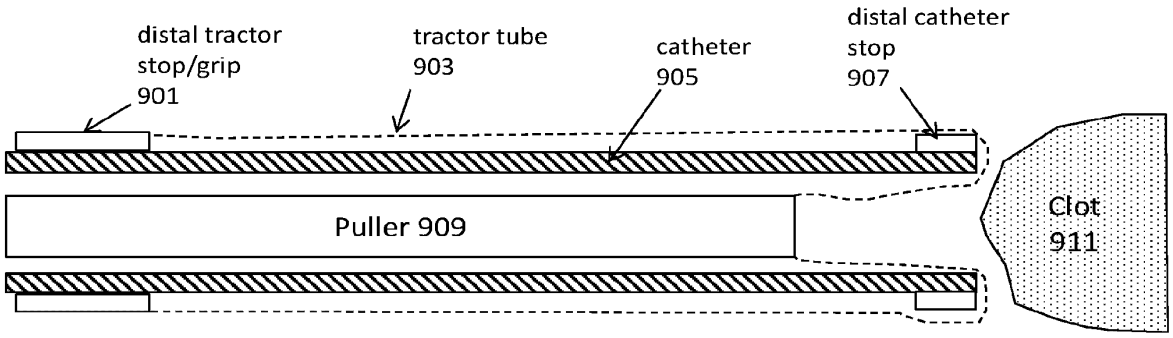


FIG. 9A

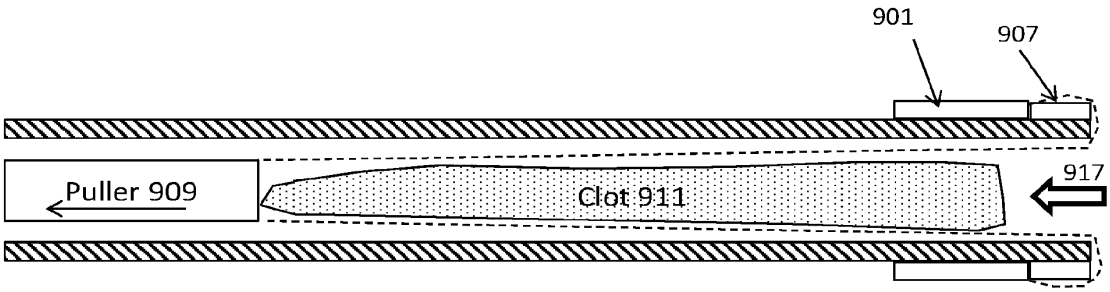


FIG. 9B

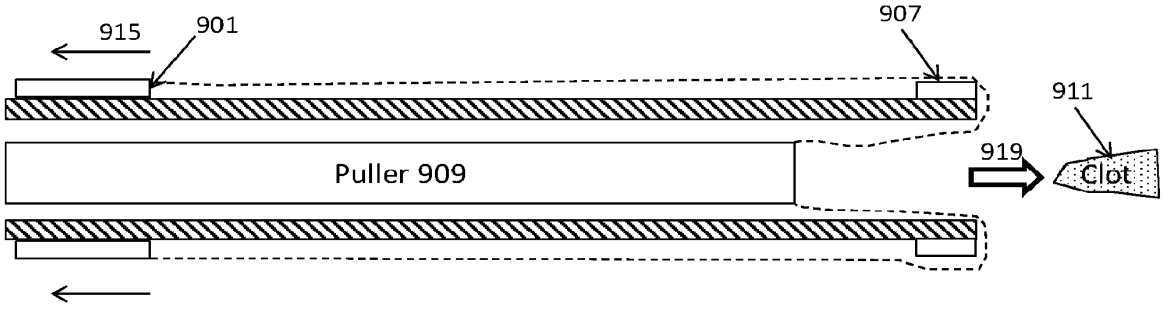


FIG. 9C

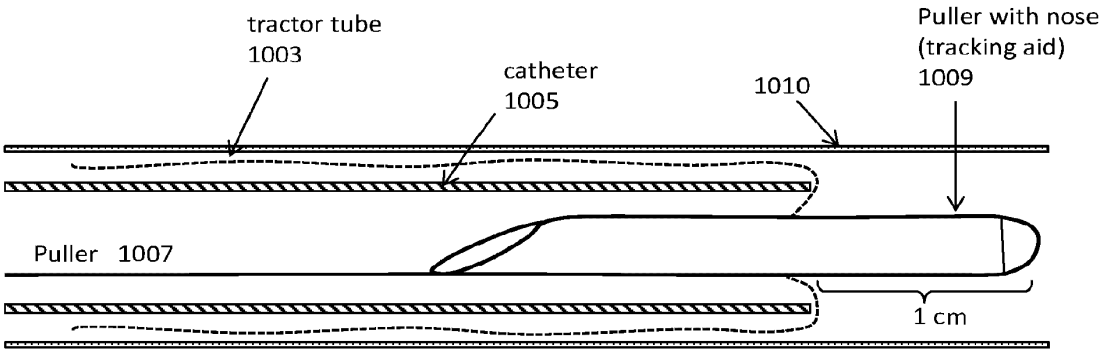


FIG. 10A

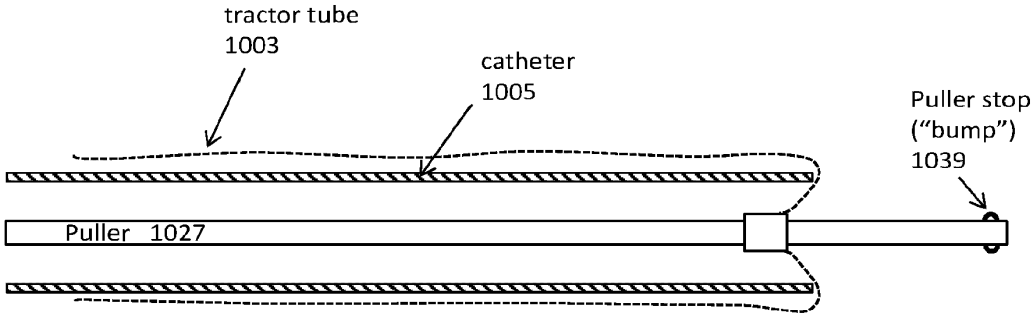


FIG. 10B

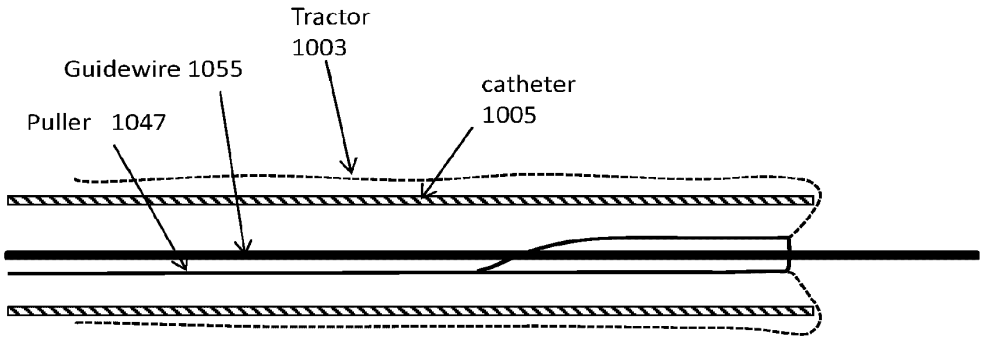


FIG. 10C

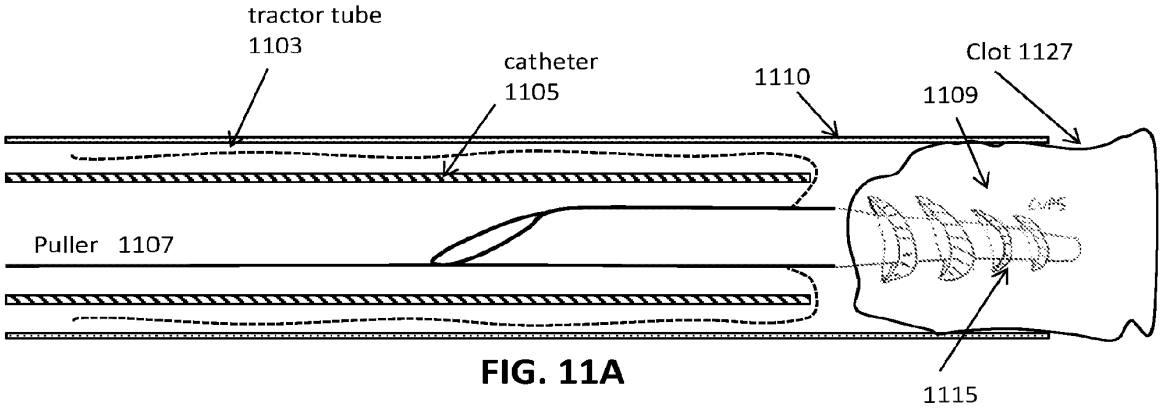


FIG. 11A

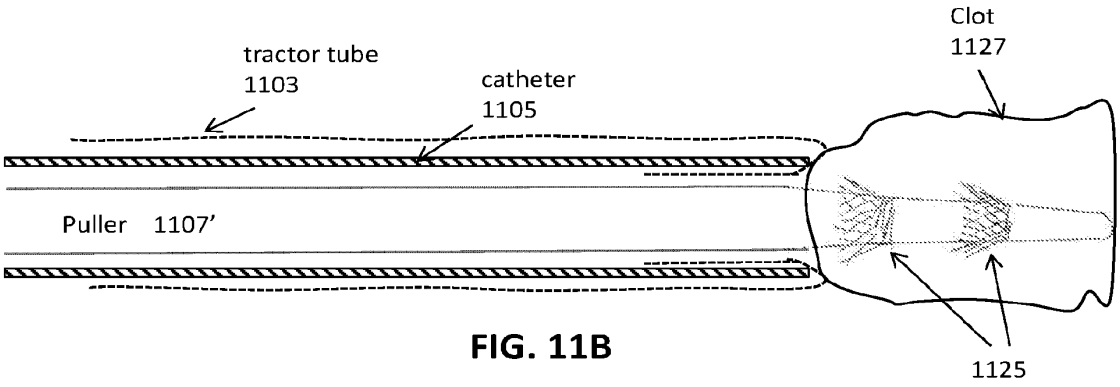


FIG. 11B

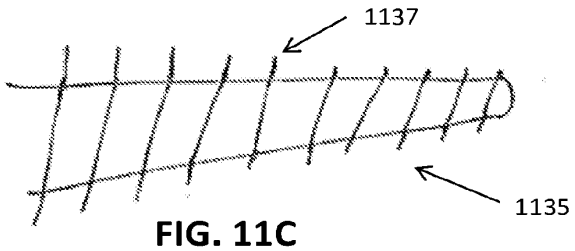


FIG. 11C

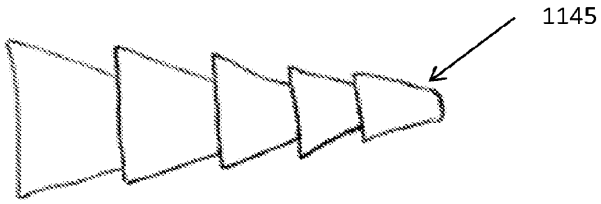


FIG. 11D

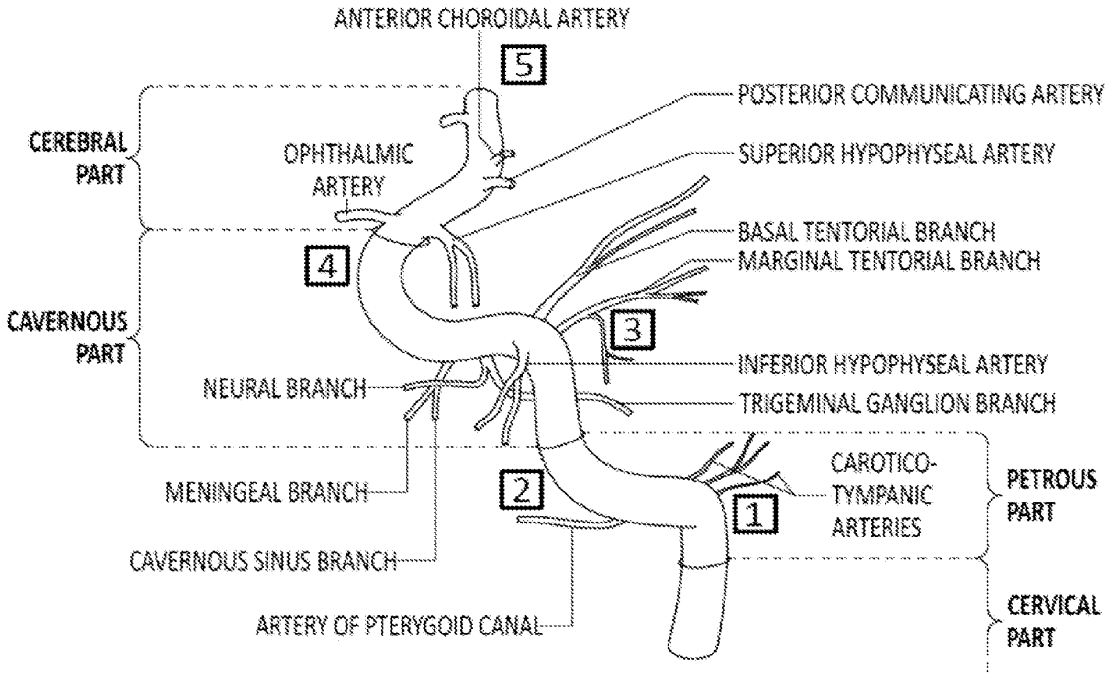


FIG. 12



FIG. 13A

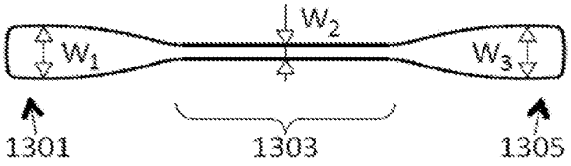


FIG. 13B

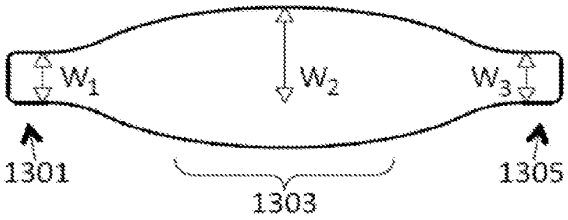


FIG. 13C

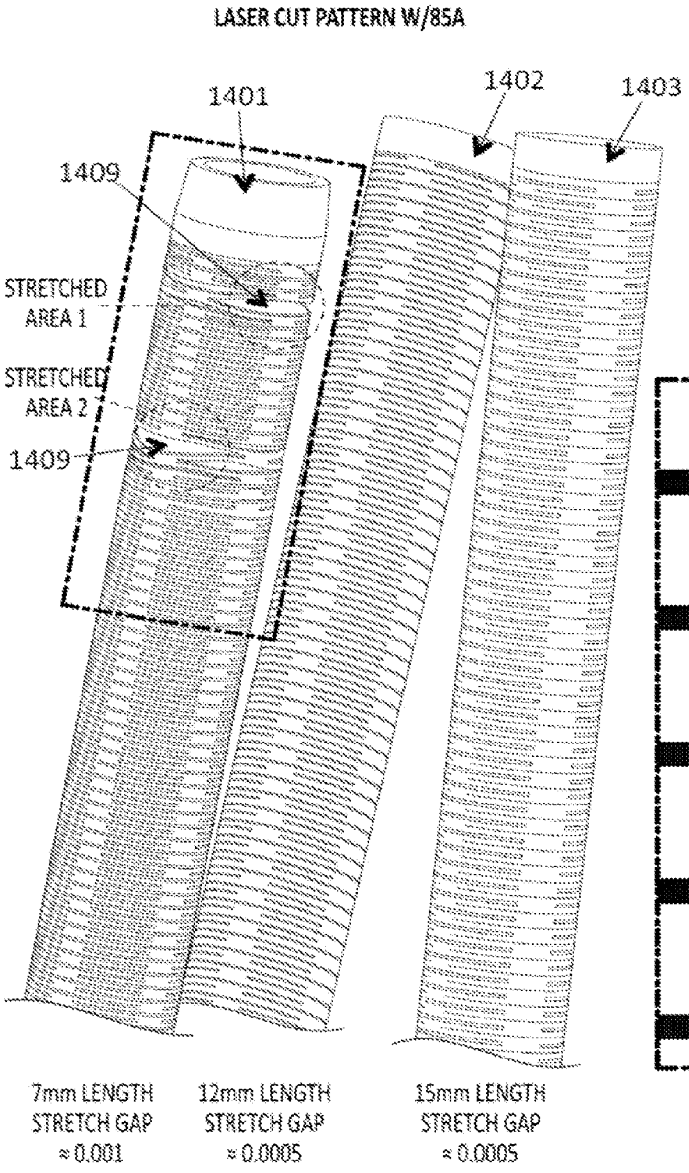


FIG. 14A

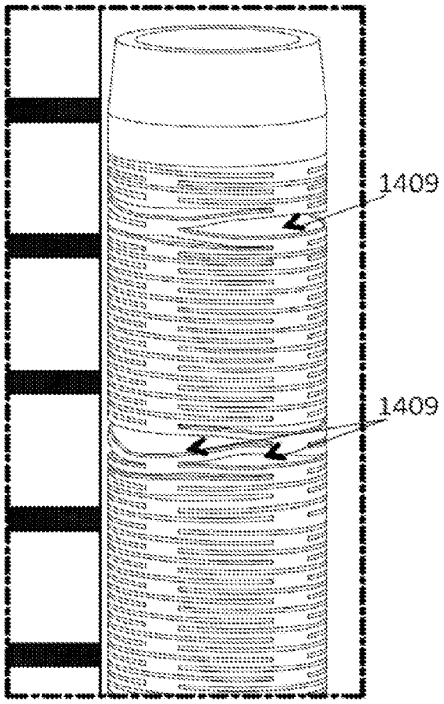


FIG. 14B

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

FIG. 14C

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

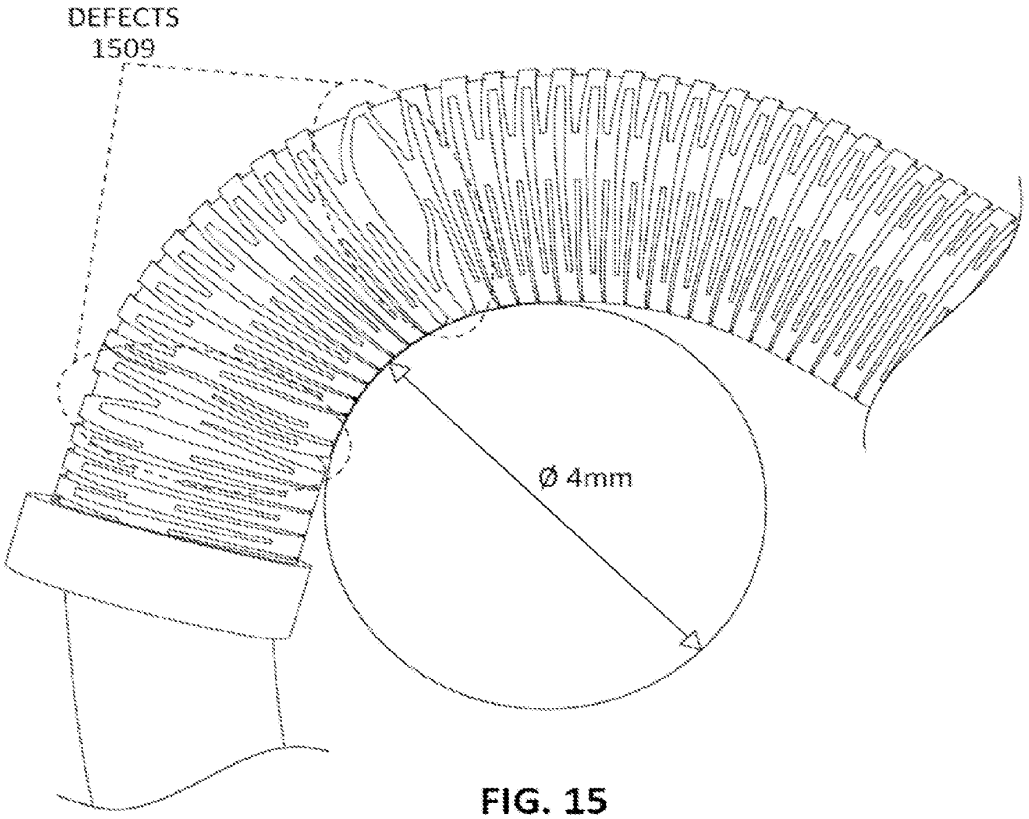


FIG. 15

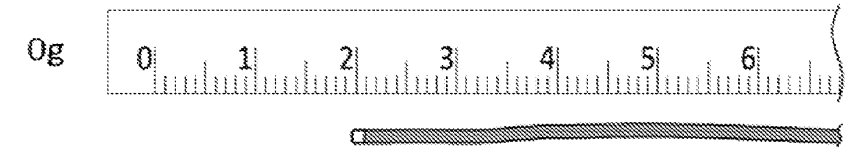


FIG. 16A

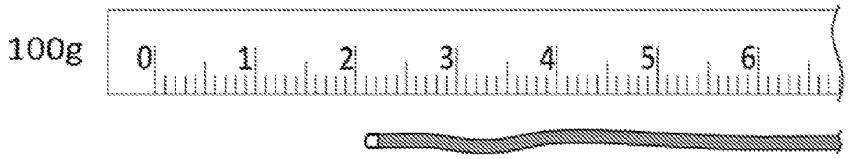


FIG. 16B

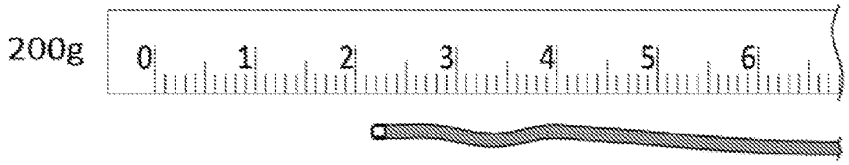


FIG. 16C

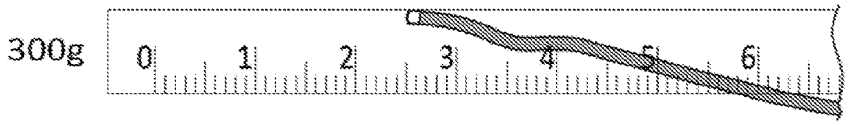


FIG. 16D

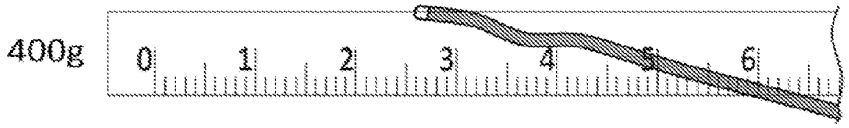


FIG. 16E

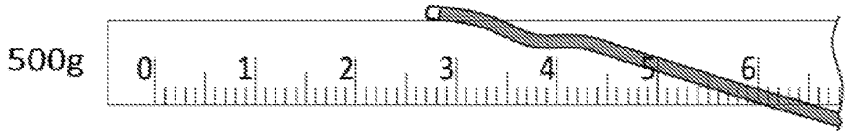


FIG. 16F

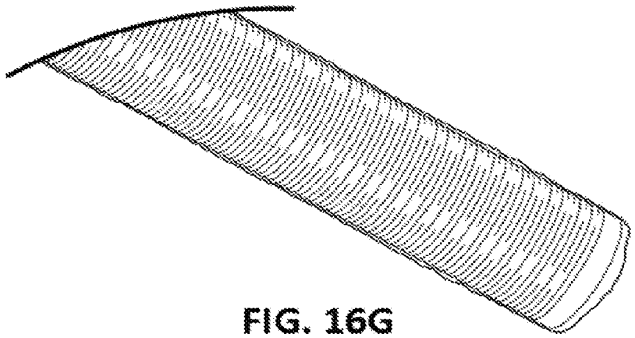


FIG. 16G

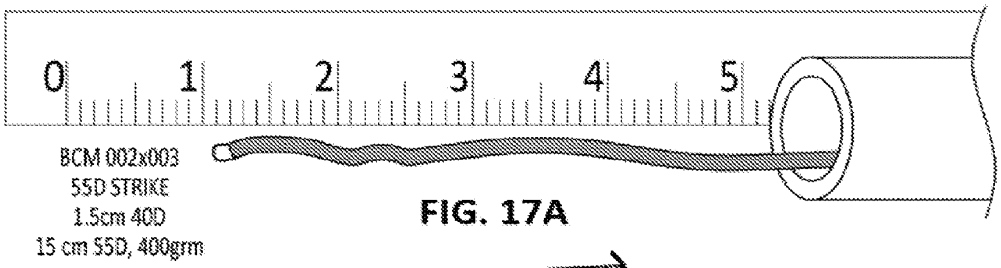


FIG. 17A

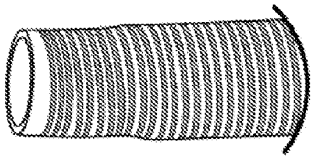


FIG. 17B

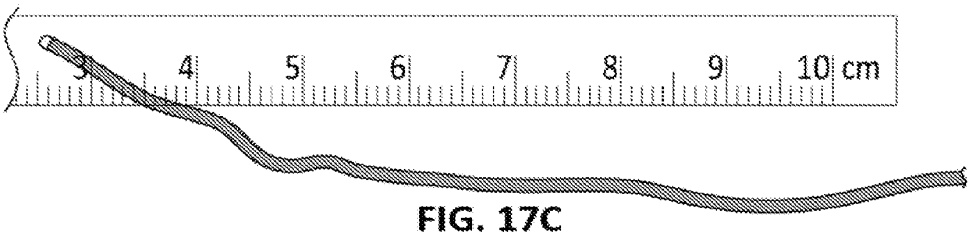


FIG. 17C

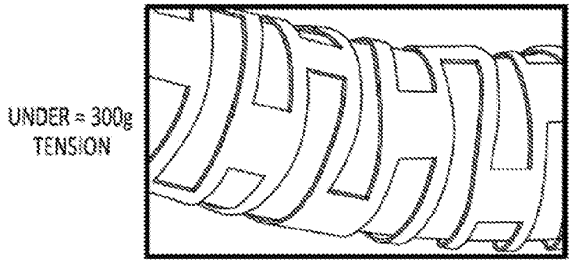


FIG. 17D

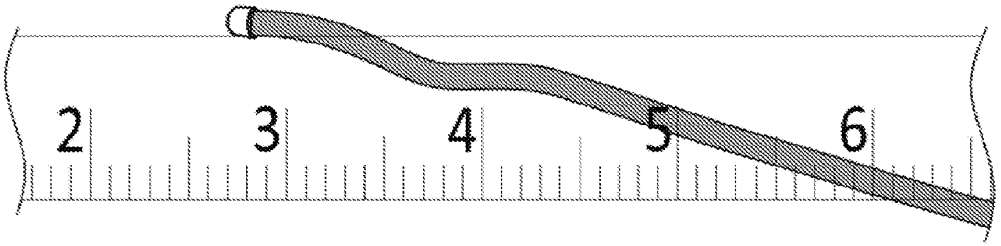


FIG. 17E

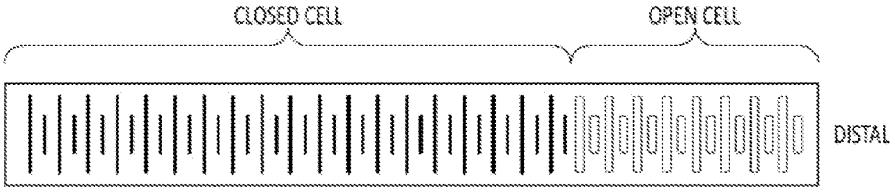


FIG. 18A



FIG. 18B

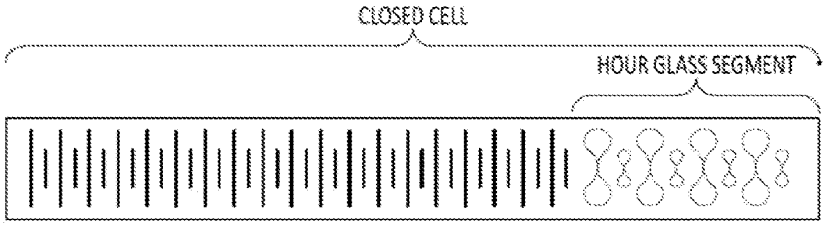


FIG. 18C

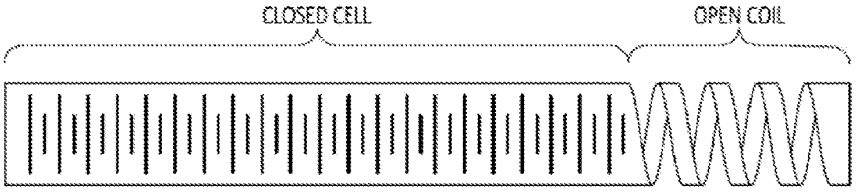


FIG. 18D

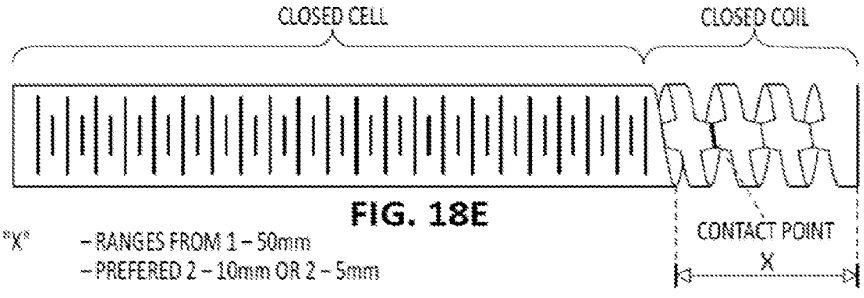
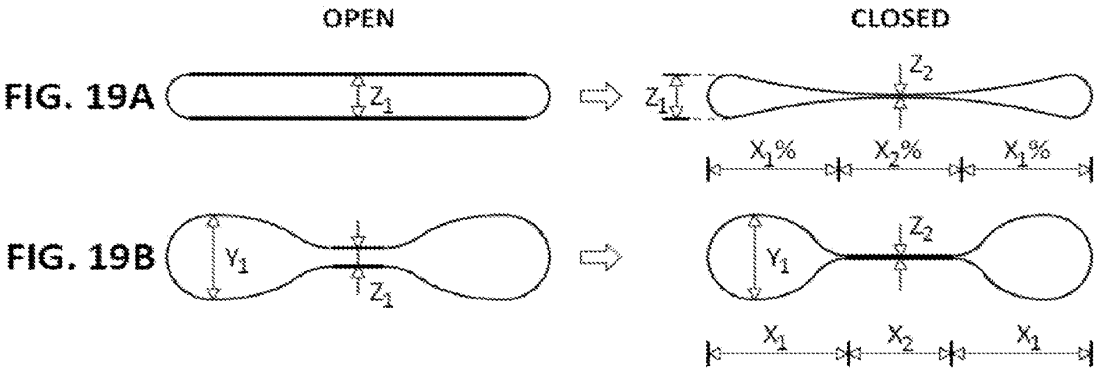


FIG. 18E

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



A DESIGN	
– "CLOSED CELL"	• $5\% X_1 \leq X_2\% \leq 95\% X_1$ • $\emptyset \leq Z_2\% \leq 95\% Z_1$ ex Z_1 = .001" Z_2 = .0001"
– "OPEN CELL"	• $.0005" \leq Z_1 \leq .010"$ ex Z_1 = .001"
B DESIGN	
– "CLOSED CELL"	• $5\% X_1 \leq X_2\% \leq 95\% X_1$ • $\emptyset \leq Z_2\% \leq 90\% Z_1$
– "OPEN CELL"	• $.0005" \leq Y_1 \leq .010"$ • $10\% Y_1 \leq Z_1 \leq 500 Y_1$ • $5\% X_1 \leq X_2 \leq 95\% X_1$

FIG. 19C

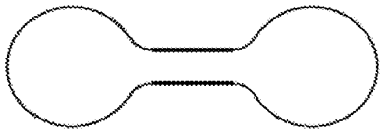


FIG. 20A

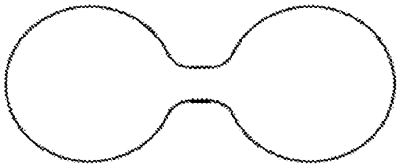


FIG. 20B

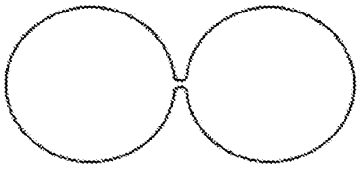


FIG. 20C

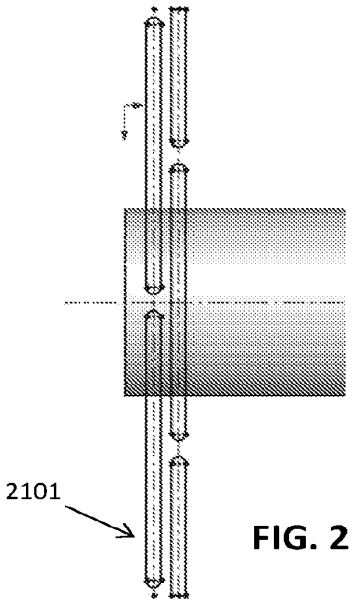


FIG. 21A

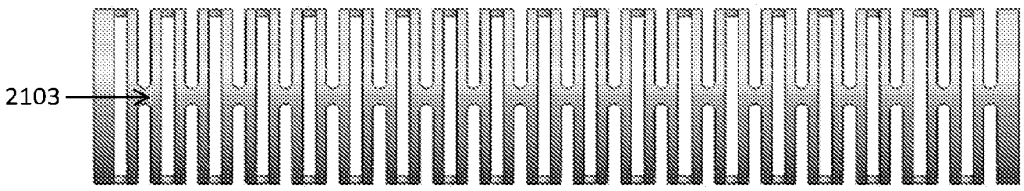


FIG. 21B

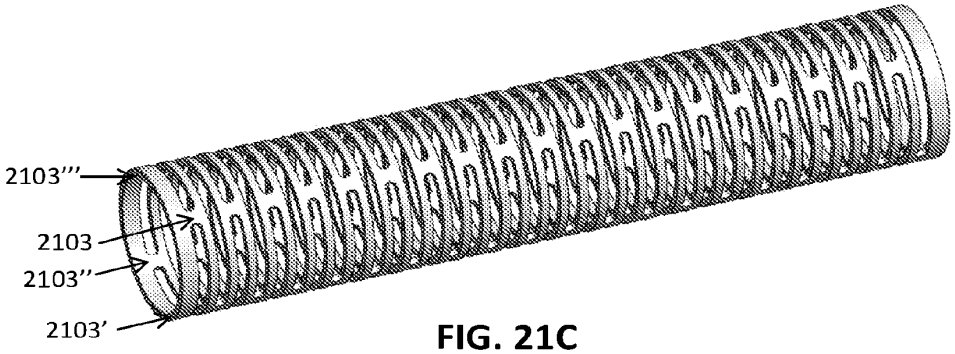


FIG. 21C

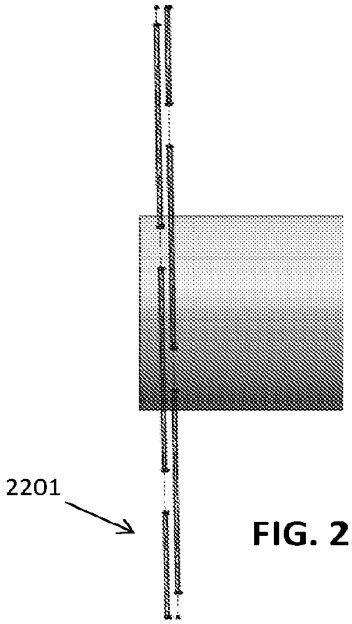


FIG. 22A

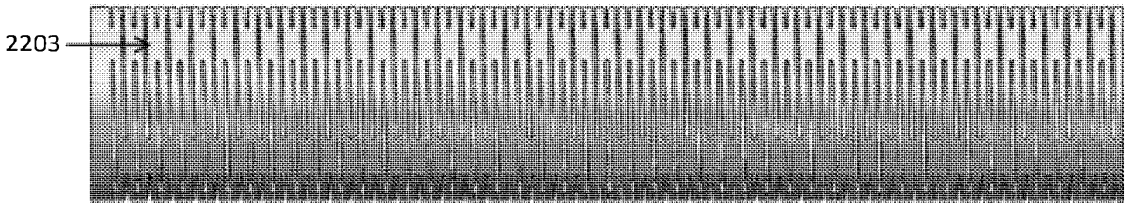


FIG. 22B

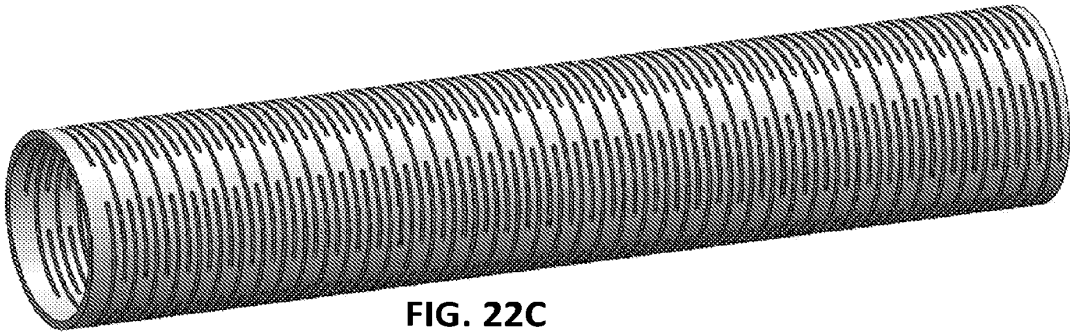


FIG. 22C

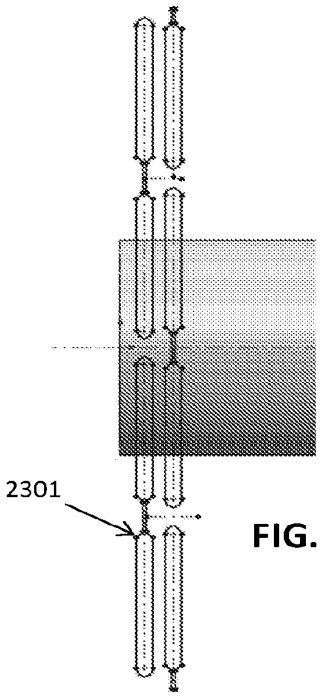


FIG. 23A

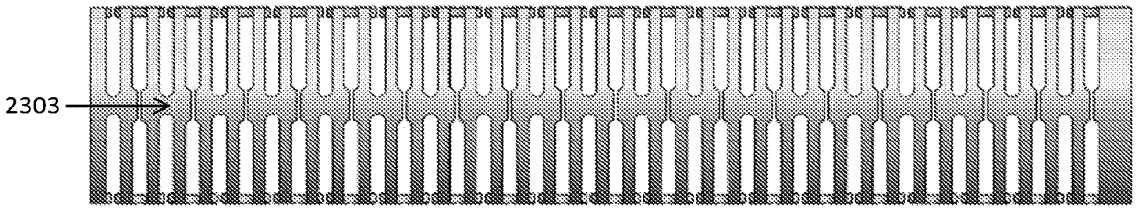


FIG. 23B

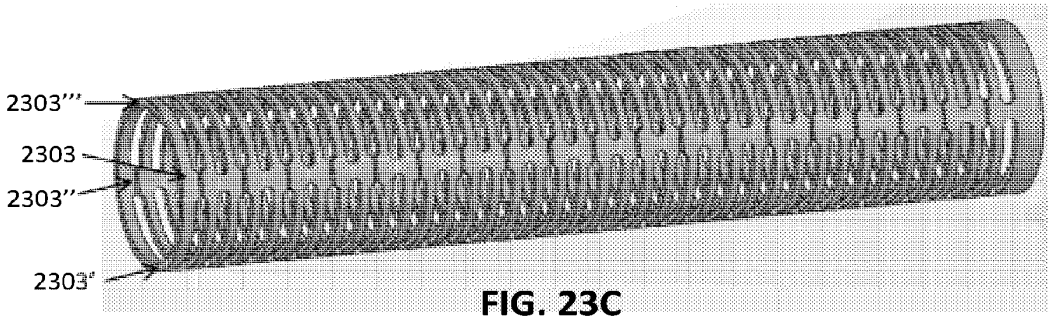


FIG. 23C

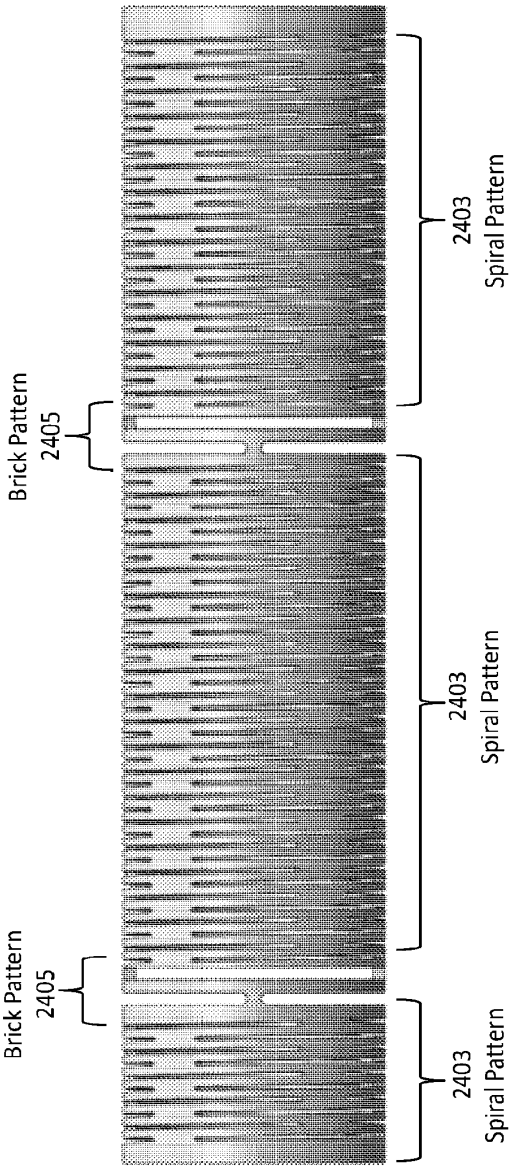


FIG. 24A

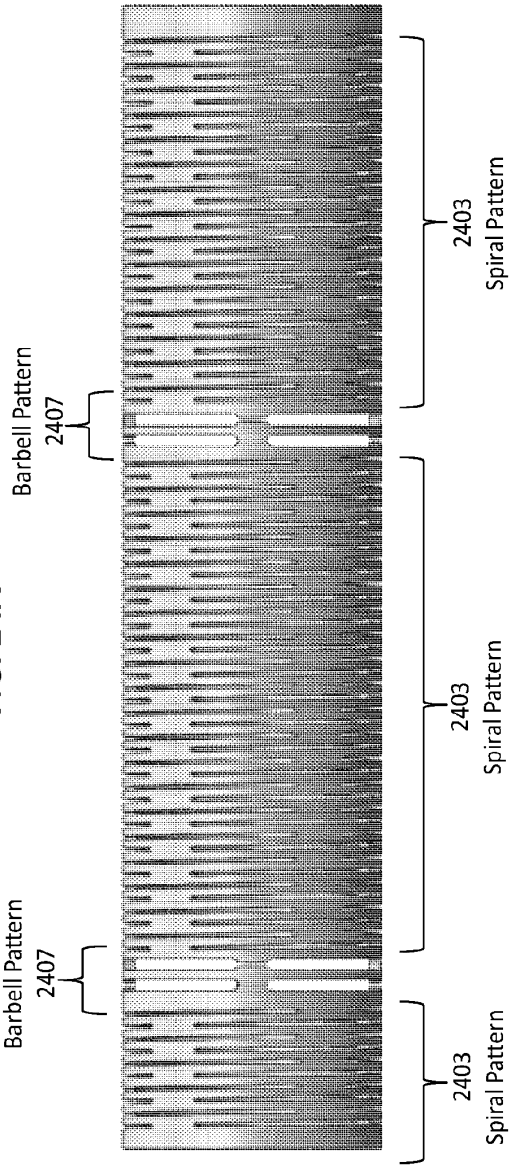


FIG. 24B

-3541-

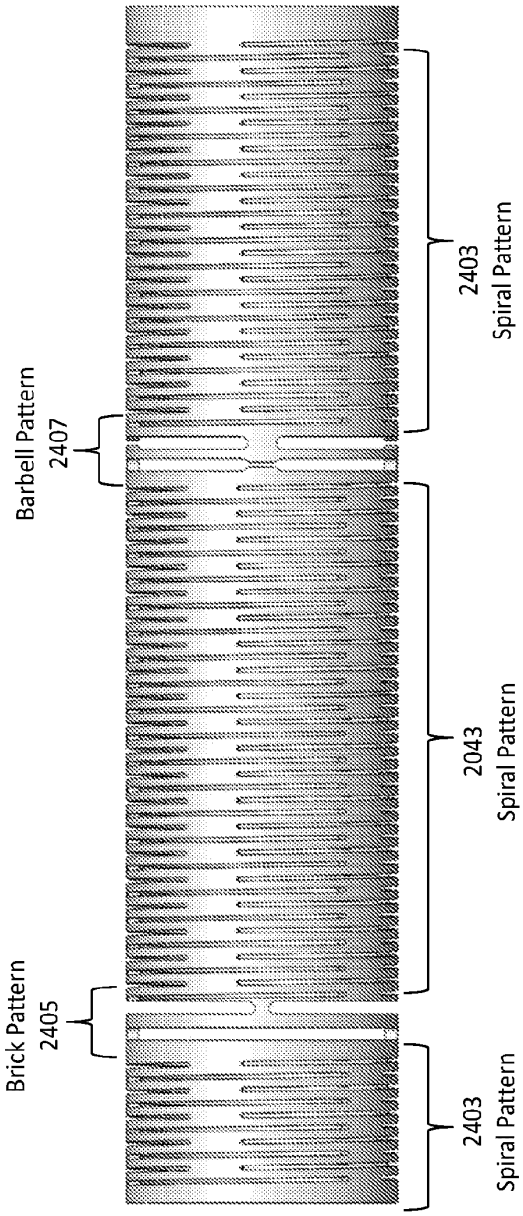

Barbell Pattern
2407
2403
Spiral Pattern
2043
Spiral Pattern
Brick Pattern
2405
2403
Spiral Pattern

FIG. 24C

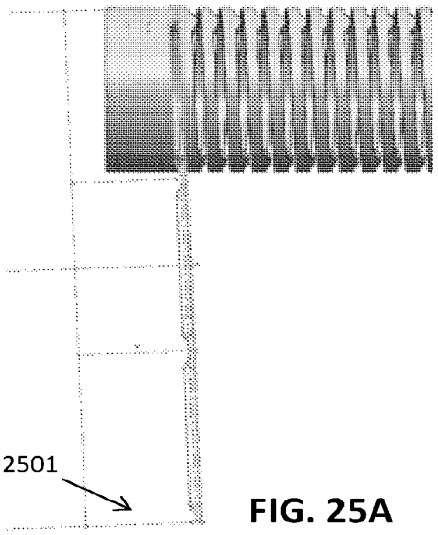


FIG. 25A

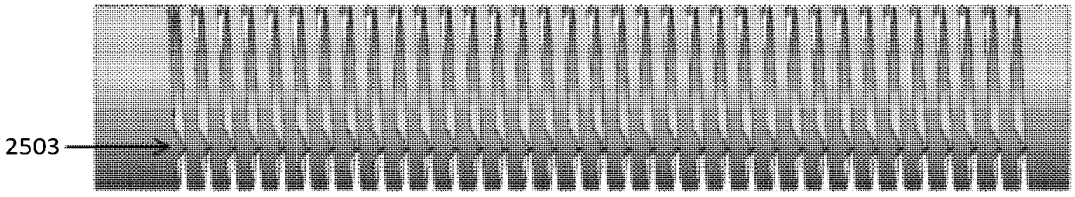


FIG. 25B

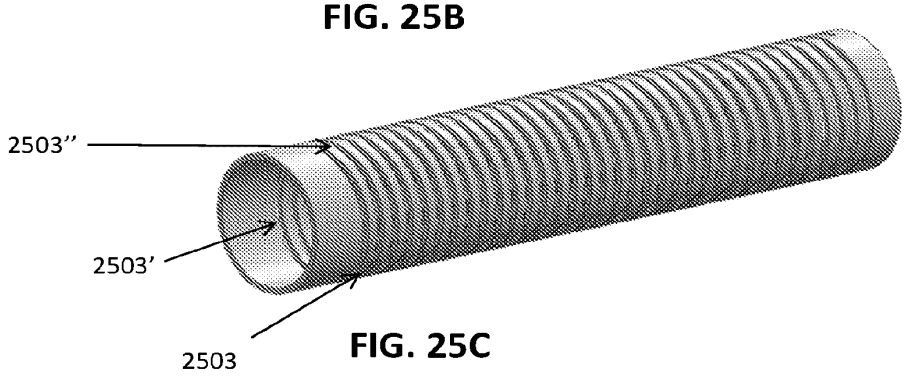


FIG. 25C

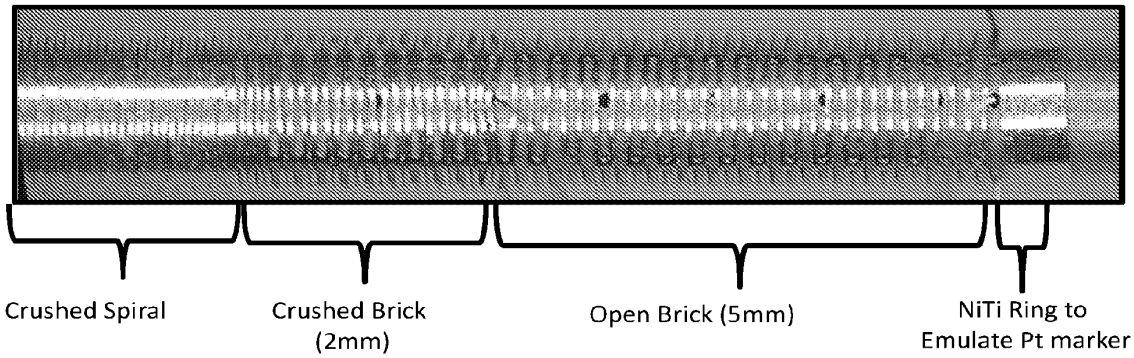

Crushed Spiral
Crushed Brick (2mm)
Open Brick (5mm)
NiTi Ring to Emulate Pt marker

FIG. 26

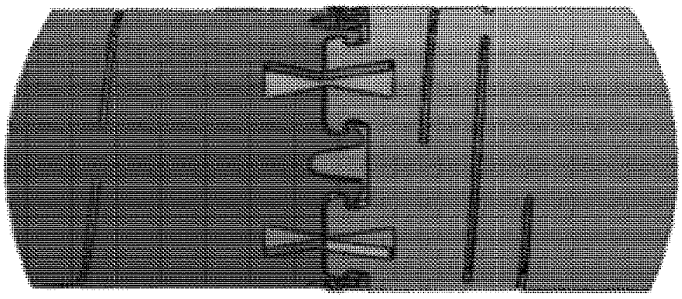


FIG. 27

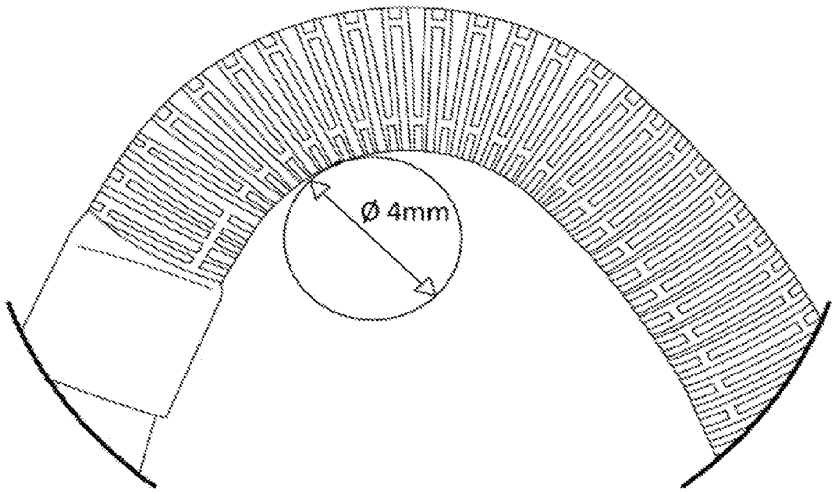


FIG. 28

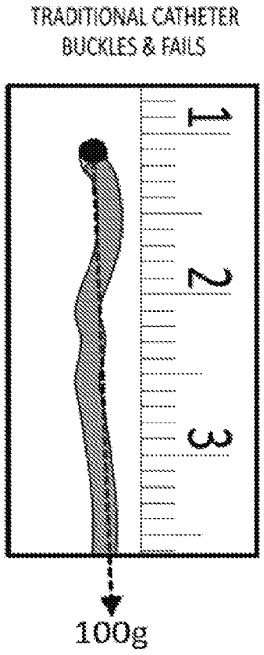


FIG. 29A

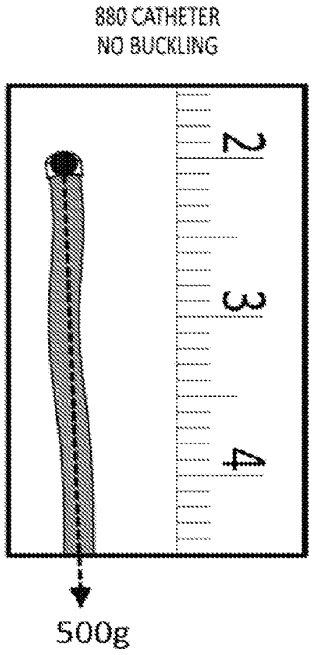


FIG. 29B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/040937

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

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

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

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

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

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

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

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

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

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

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

Remark on Protest

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

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

☒ No protest accompanied the payment of additional search fees.

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/040937

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

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

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

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 October 2018	14/11/2018

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

2

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

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2016/074627 A1 (COTTONE ROBERT J [US]) 17 March 2016 (2016-03-17) paragraph [0095] - paragraph [0100]; figures 7A-8D	11-22
A	AU 2015 210 338 A1 (SHIFAMED HOLDINGS LLC) 27 August 2015 (2015-08-27) paragraph [0087] - paragraph [0092]; figures 3-7b	11-22
A	US 2005/177132 A1 (LENTZ DAVID J [US] ET AL) 11 August 2005 (2005-08-11) paragraph [0027]; figures 1-7	11,22

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2018/040937

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

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

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-10

   Thrombectomy apparatus having knitted tractor tube.

   ---

2. claims: 11-22

   Thrombectomy apparatus having slotted inversion support catheter.

   ---

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
16 May 2019 (16.05.2019)

WIPO | PCT

(10) International Publication Number
WO 2019/094456 A1

(51) International Patent Classification:
A61B 17/221 (2006.01) *A61M 1/00* (2006.01)
A61B 17/34 (2006.01)

(21) International Application Number:
PCT/US2018/059607

(22) International Filing Date:
07 November 2018 (07.11.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/583,803 09 November 2017 (09.11.2017) US
62/664,822 30 April 2018 (30.04.2018) US

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

(72) Inventors: **WALLACE, Michael, P.**; 5849 Corte Margarita, Pleasanton, California 94566 (US). **GARABEDIAN, Robert**; 1691 Notre Dame Drive, Mountain View, California 94040 (US). **LEGUIDLEGUID, Roy**; 33018 Korbel Ct., Union City, California 94587 (US). **GREENHALGH, E., Skott**; 1426 Rose Glen Road, Gladwyne, Pennsylvania 19035 (US).

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

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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

Published:
— *with international search report (Art. 21(3))*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) Title: INVERTING THROMBECTOMY APPARATUSES HAVING ENHANCED TRACKING

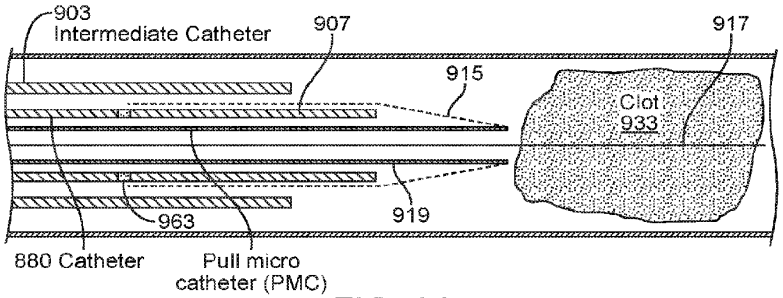


FIG. 9A

(57) Abstract: Mechanical thrombectomy apparatuses, and particularly knitted rolling tube mechanical thrombectomy apparatuses configured to have improved tracking for delivery through tortious vessels are described herein.

WO 2019/094456 A1

INVERTING THROMBECTOMY APPARATUSES HAVING ENHANCED TRACKING

FIELD

[0001] The apparatuses and methods described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses and methods.

BACKGROUND

[0002] Many vascular problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery. It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue, such as blood clots, from within a patient's vasculature may improve patient quality of life.

[0003] Mechanical thrombectomy devices may be particularly advantageous. There is a definite need for thrombectomy devices, and particularly a mechanical thrombectomy devices that can be easily and accurately delivered through the, often tortious, anatomy in the peripheral and central vasculature, then reliably deployed to remove clot material. Described herein are apparatuses (devices, systems and kit) and methods of using them that may address the needs and problems discussed above.

SUMMARY

[0004] Described herein are inverting tractor mechanical thrombectomy apparatuses (devices, systems, etc.) and methods of using and making them.

[0005] In particular, described herein are inverting tractor mechanical thrombectomy apparatuses that are configured to have improved tracking within even the most tortious vessels of the anatomy. These inverting tractor mechanical thrombectomy apparatuses may be referred to herein as mechanical thrombectomy apparatuses. The method and apparatuses described herein may include the use of a deliver catheter (e.g., "intermediate catheter") that

is pre-loaded with the mechanical thrombectomy apparatus in a specific arrangement that provides enhances tracking, and methods of using them to reach, and remove, clot.

[0006] Also described herein are adaptations to mechanical thrombectomy apparatuses that allow them to remove particularly large clots without breaking or disrupting the clot, even if the rolling tractor portion of the mechanical thrombectomy apparatus is not able to pull additional clot into the apparatus.

[0007] Typically, the mechanical thrombectomy apparatuses described herein are inverting thrombectomy apparatuses (also referred to herein as inverting tractor thrombectomy apparatuses and inverting tube thrombectomy apparatuses) that include a flexible tube (e.g., tractor tube, tractor region, tractor portion, etc.) and an elongate inversion support catheter. The tractor tube generally comprises a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support. The flexible tube may be formed of a knitted material, and may be configured (e.g., sized, oriented, etc.) to roll smoothly over the distal end opening of the elongate inversion support catheter.

[0008] The flexible tube may be configured so that it is doubly biased, in order to prevent jamming and to grab and compress relatively large clots as it rolls and inverts into the elongate inversion support catheter at the distal end opening of the elongate inversion support catheter; the flexible tube may be biased so that it has an expanded (e.g., relaxed) un-inverted configuration having an outer diameter that is approximately the same or slightly larger than the inner diameter of the elongate inversion support catheter, which may be referred to as a second configuration of the flexible tube. The flexible tube may also be further biased so that it has an expanded (e.g., relaxed) inverted configuration (which may be referred to as a first configuration) having an inner and outer diameter that is larger than the outer diameter of the elongate inversion support catheter. The inner diameter in this first configuration may be greater than 1.2x (e.g., between 1.2x and 10x, between 1.2x and 8x, between 1.2x and 6x, between 1.2x and 5x, between 1.2x and 3x, etc.) the outer diameter of the inversion support catheter. Thus, when the flexible tube is placed in and over the distal end of the inversion support catheter, a first (inner) portion of the tractor tube is within the distal end of the elongate inversion support catheter in the un-inverted configuration and it is biased to expand towards (and in some configuration against) the inner diameter of the inversion support catheter; the region of the flexible tube that is inverted over the distal end opening of the inversion support catheter and extends proximally down the outside of the inversion support catheter is in an inverted configuration in which the inner diameter of the flexible tube is biased to be larger than the outer diameter of the inversion support catheter. This double-

biased configuration may be a result of the weave pattern (e.g., knitting), and/or a shape setting of the material forming the tractor tube, which may be a shape memory material. As a result, the inverting portion of the flexible tube, where it rolls and inverts over itself at the distal end of the inversion support catheter may be prevented from collapsing on itself as the tractor tube is rolled and pulled into the inversion support catheter. In some variations this configuration may also result in a somewhat flattened (e.g., and in some cases "trumpet shaped") distal end face that is rolling over the distal end opening of the elongate inversion support catheter. The trumpet-shaped distal end may have a teardrop-shaped cross-section. In some variations, the distal end face of the flexible tube may be T-shaped.

[0009] Also described herein are variations in which the first configuration of the flexible tube on the outside of the inversion support catheter (which may be referred to herein as an elongate inversion support catheter) maybe flush or nearly flush with the outer diameter of the inversion support catheter, e.g., within 50%, 40%, 30%, 20%, etc. of the outer diameter of the inversion support catheter.

[00010] The flexible tube may be coupled to a puller that is within the lumen of the inversion support. The puller may be a wire, filament, rod or more preferably a catheter or tube (and may be referred to herein as a pull micro catheter or "PMC" for convenience). A guidewire may be passed through the flexible tube, and therefore through the inversion support and the tractor tube. As will be described herein, this may be used for positioning.

[00011] The inversion support catheter may be configured as a catheter having a distal end opening into which the tractor inverts. The flexible tube may invert and rolls back into itself and may be drawn into the inversion support in a conveyor-like motion; the outward-facing region rolls around to become an inward-facing region, e.g., within the lumen of the inversion support catheter. The rolling motion may thus draw a clot or other object within a vessel into the inversion support. The inversion support catheter may be shaped or configured to have a sufficient column strength to withstand the compressive pulling force of the flexible tube as it is drawn (and rolled, inverting) into the distal end of the inversion support catheter. The inversion support catheter may be slotted (e.g., may include a plurality of slots or openings) to provide increased flexibility as well as column strength. However, as will be described herein, many inversion support catheters may become less flexible (e.g., more rigid) when a compressive force is applied to the flexible tube, either as a result of pulling the flexible tube proximally, either from within the inversion support catheter, or from the outside of the inversion support catheter as the flexible tube brushes against the vessel and/or a delivery catheter when being driven distally towards a clot.

[00012] Thus, described herein are mechanical inverting thrombectomy apparatuses that are adapted to enhance tracking as the apparatus is positioned within the vessel by pushing it distally away from an insertion point into the body to the site of the thrombus. These apparatuses and methods may include pre-loading the apparatus within an intermediate catheter in a particular configuration allowing it to track more easily, as well as variations in which the flexible tube is held within the inversion support catheter and deployed near the clot. Finally, described herein are apparatus in which the flexible tube (e.g., mesh, weave, knit) to limit or prevent the application of a compressive force on the inversion support catheter that may otherwise reduce flexibility and maneuverability of the inversion support catheter.

[00013] Also described herein are apparatuses for removing extensive clots, even when the flexible tube portion of the apparatus has been completely inverted, without breaking the clot and risking release of the clot back into the bloodstream where it could cause further harm.

[00014] For example, described herein are apparatuses that use one or more vacuum sources that may be applied either or both when initially contacting a clot and/or when removing the clot after being completely or partially engulfed by the flexible tube (tractor) portion of the apparatuses described herein. For example, the inverting tube apparatus (e.g., a mechanical thrombectomy apparatus) is configured to be inserted through a vessel such as a blood vessel, artery, etc., until a distal end, or a distal-most end, of the inverting tube apparatus is proximate to a clot. The clot may be immediately adjacent to the end of the apparatus, or it may be within a few cm (e.g., within 1 cm, within 2 cm, within 3 cm, within 4 cm, etc.). This may be detected by visualization, such as fluoroscopy. Thus, the apparatuses described herein may include one or more markers for visualization. Contrast may be used to visualize the clot and/or may be released from the apparatus. The apparatus may be deployed in a pre-loaded/pre-assembled configuration, as will be described in more detail below.

[00015] The flexible tube may be knitted and/or the apparatus may be configured with the opening into the vacuum lumen (e.g., through the puller catheter) at the distal-most end of the device, so that the flexible tube extends behind (proximal) the distal-facing end of the puller catheter. For example, the method of removing a clot from a vessel may include: advancing an inverting tube apparatus through a vessel until a distal end of the inverting tube apparatus is proximate to a clot, wherein the inverting tube apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller catheter within a lumen of the elongate support catheter, and a knitted tube having a first end coupled at a distal end region of the puller catheter, wherein knitted tube inverts over a distal

end of the inversion support catheter and extends proximally between the intermediate catheter and the inversion support catheter, further wherein the knitted tube comprises a filament that is knitted to form a plurality of interlocking loop stitches; advancing the puller catheter distally so that a distal face of puller catheter extends distally from the inverting tube apparatus further than the knitted tube; applying a vacuum through the puller catheter to engage the clot with the distal face of the puller catheter; and pulling the puller catheter proximally to roll the knitted tube over a distal end of the inversion support catheter so that the knitted tube inverts over the distal end of the inversion support catheter, captures the clot, and pulls the clot proximally into the inversion support catheter.

[00016] A large clot may be a clot that is typically longer than the capacity of the apparatus to hold within the flexible tube. This is described in greater detail herein, but may be, e.g., a 12:1 ratio (where, for every 12 cm of, e.g., woven, flexible tube, 1 cm of length of clot may be contained within the woven flexible tube). In general, large clots may have a large diameter and/or a long length. Longer clots may include clots having a length that is about 0.5 m or longer (e.g., about 1 cm or longer, about 2 cm or longer, about 3 cm or longer, about 4 cm or longer, about 5 cm or longer, etc.).

[00017] With respect to removing larger clots, the second end may reach the distal end of the inversion support catheter while a portion of the clot extends distally from the inversion support catheter so that at least a portion of the clot extends out of the flexible tube. The second end of the flexible tube may be prevented (stopped) from inverting over the end of the inversion support catheter, or it may be inverted and flipped (e.g., by advancing the intermediate catheter) in a non-traumatic way that prevents or limits the risk of breaking/tearing/disrupting the clot.

[00018] In any of these variations, suction may be applied through the inverting tube apparatus (e.g., through the intermediate catheter and/or the inversion support catheter) when withdrawing the inversion support catheter and puller with the clot attached proximally into the intermediate catheter.

[00019] The second end of the flexible tube may comprise a cuff that is less flexible that a region of the tube adjacent to the cuff. As will be described in more detail below, the cuff may be formed as a material attached to or applied onto/over the end of the flexible tube. For example, the second end of the flexible tube may comprise a cuff formed of a polymeric material applied onto/over the knitted tube. The cuff may be slit or cut (e.g., all or partially along its length) to provide some flexibility when pulling over or around the end of the tube. For example, the cuff may include longitudinal slits along its length. The cuff may have a

durometer that is greater than the durometer of the flexible tube (e.g., knitted tube). The cuff, in some variations, is thicker than the flexible tube. In any of the variations described herein, the cuff may be radiopaque (e.g., by including a radiopaque material, such as platinum) on or within the cuff.

[00020] As mentioned, the apparatus may be configured so that the end (e.g., the second end) of the flexible tube may be prevented from inverting and rolling over the distal end of the inversion support catheter by simply pulling proximally on the puller. Thus, in any of these variations, the intermediate catheter may be configured to push the cuff over the distal end of the inversion support catheter when the intermediate catheter is advanced distally past the cuff

[00021] Specifically described herein are apparatuses using flexible knitted tubes (tractors) as part of any of the mechanical thrombectomy apparatuses described herein. For example, the knitted flexible tubes may be configured to have stitch lengths that assist in capturing of clot within the vessel, even where the vessel has a larger inner diameter than the outer diameter of the flexible tube in an expanded configuration outside of the inversion support catheter. In particular, apparatuses in which the stich length is within a range of lengths that may be set by the dimension of the vessel (e.g., blood vessel, artery, peripheral vessel, etc.) and/or the outer diameter of the inversion support catheter. For example, a stitch length may be between about 0.5mm and 10 mm and/or may be selected based on the dimension of the vessel into which the apparatus is to be operated to remove a clot.

[00022] For example, described herein are method of removing a clot from a vessel having an inner diameter (ID), the method comprising: advancing an inverting tube apparatus through the vessel until a distal end of the inverting tube apparatus is proximate to a clot, wherein the inverting tube apparatus comprises an intermediate catheter, an inversion support catheter within a lumen of the intermediate catheter, a puller within a lumen of the support catheter, and a knitted tube having a first end coupled at a distal end region of the puller and a second end, wherein the knitted tube extends between the intermediate catheter and the inversion support catheter; further wherein the knitted tube comprises a filament knitted to form a plurality of interlocking loop stitches, wherein each loop stitch has a stitch length that is between the difference of 25% of the ID and one half the outer diameter (OD) of the inversion support catheter and 65% of the ID and one half of the OD of the inversion support catheter; pulling the puller proximally to roll the knitted tube over the distal end of the inversion support catheter so that the knitted tube inverts over a distal end of the inversion

support catheter driving the loop stitches outward, captures the clot, and pulls the clot proximally into the inversion support catheter.

[00023] Any of these methods may be used in particular with apparatuses in which the flexible tube is configured to remain relative snug on the inversion support catheter (e.g., within 50% (e.g., 40%, 30%, 25%, 20%, 15%, 10%, etc.) of the outer diameter of the inversion support catheter in the expanded (unconstrained) first configuration. In general, these apparatuses may expand at or near the distal-facing ends of the flexible tube, where the tube is inverting over itself, but may not be expanded at more proximal regions. This may form the T-shaped, Y-shaped, and/or trumpet-shaped distal end faces of the flexible tubes described herein. For example, in some variations, the knitted tube extends over the inversion support catheter with an inner diameter that is within 20% of the OD the inversion support catheter.

[00024] The second end of the knitted tube may comprise a cuff that is less flexible that a region of the knitted tube adjacent to the cuff, as described above and further herein. Alternatively, or additionally, the knitted tube may be shape-set to have a narrower region at the second end region (near the second end) of the flexible tube.

[00025] As mentioned above, in general, each loop stitch may have a stitch length that is between the difference of 25% of the ID and one half the outer diameter (OD) of the inversion support catheter and 65% of the ID and one half of the OD of the inversion support catheter. For example, each loop stitch may have a stitch length that is between the difference of 30% of the ID and one half the OD of the inversion support catheter and 60% of the ID and one half of the OD of the inversion support catheter (e.g., between the difference of 35% of the ID and one half the OD of the inversion support catheter and 50% of the ID and one half of the OD of the inversion support catheter, between the difference of 40% of the ID and one half the OD of the inversion support catheter and 45% of the ID and one half of the OD of the inversion support catheter, between the difference of 25% of the ID and one half the OD of the inversion support catheter and 45% of the ID and one half of the OD of the inversion support catheter, etc.). The stitch length may refer to the longitudinal (in the proximal-to-distal axis, which may curve or bend) of the knitted tube. The knitted tube may be formed of one or more filaments (or filament bundles) that are knitted into the tube to form interlocking links (loop stitches). The filament material may be relatively stiff, such as a wire, e.g., Nitinol wire, that when knitted has a material flexibility. The knit may be coated with a material (e.g., a lubricious material, etc.). Examples of knits are illustrated in, e.g.,

U.S. app. no. 15/496,570, filed on 4/25/2017 ("Anti-Jamming and Macerating Thrombectomy Apparatuses and methods"), previously incorporated by reference in its entirety.

[00026] For example, an inverting tube apparatus for removing a clot from a vessel may include: an intermediate catheter; an inversion support catheter within a lumen of the intermediate catheter; a puller within a lumen of the elongate support catheter; and a knitted tube extending over the inversion support catheter, the knitted tube having a first end coupled at a distal end region of the puller and a second end that is free, wherein the knitted tube is configure to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the knitted tube rolls and inverts over a distal end of the inversion support catheter; further wherein the knitted tube comprises a filament knitted to form a plurality of interlocking loop stitches, wherein each loop stitch has a stitch length that is between 0.5mm and 10mm.

[00027] As mentioned, the knitted tube may extend over the inversion support catheter with an inner diameter that is within 20% (e.g., within about 10%, 15%, 20%, 25%, 30%, 40%, etc.) of the outer diameter of the inversion support catheter (e.g., relatively snugly to or against the inversion support catheter). The second end of the knitted tube may comprise a cuff that is less flexible that a region of the knitted tube adjacent to the cuff.

[00028] Any of the methods and apparatuses described herein may include an expanded flexible tube portion that expands outward less than the diameter of the vessel over much (e.g., greater than about 50%, about 60%, about 70%, about 75%, about 80%, about 90%, etc.) of its length while having an expanded second end region that has a much smaller diameter near this second end region (e.g., having a diameter that is within about 10%, 15%, 20%, 25%, 30%, 40%, etc. of the inversion support catheter. This configuration may allow even larger-diameter clots (e.g., from the peripheral vasculature) to be engulfed and safely removed with apparatuses having a much narrower diameter than the vessels in which the clots are located.

[00029] For example, described herein are inverting tube apparatus for removing a clot from a vessel, the apparatus comprising: an inversion support catheter; a puller within a lumen of the inversion support catheter; and a knitted tube extending over the inversion support catheter in a first configuration, the knitted tube having a first end coupled to a distal end region of the puller, and a second end that is free to move relative to the inserting support catheter, wherein the knitted tube is configure to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the knitted tube rolls and inverts over a distal end of the inversion support catheter into a second configuration within the inversion

support catheter; further wherein the knitted tube in the first configuration has an expanded outer diameter that is between 0.5 mm and 12 mm for a first region of the knitted tube that is adjacent to the first end, and the knitted tube in the second configuration has an inner diameter that is greater than 30% of an inner diameter of the inversion support catheter, and wherein a second region of the knitted tube adjacent to the second end has an expanded outer diameter that is less than the expanded outer diameter of the region of the knitted tube adjacent to the first end and within 20% of an outer diameter of the inversion support catheter.

[00030] As mentioned, the knitted tube in the first configuration may have an expanded outer diameter (unconstrained) that is between 0.5 mm and 12 mm; in some variations this expanded outer diameter is between 0.5 mm and 15 mm, e.g., between about 0.5 mm and about 14 mm, between about 0.5mm and about 13 mm, between about 0.5 mm and about 11 mm, between about 0.5 mm and about 10 mm, between about 0.5 mm and about 9 mm, between about 0.5 mm and about 8 mm, between about 3 mm and about 15 mm, between about 4 mm and about 15 mm, between about 5 mm and about 15 mm, between about 3 mm and about 12 mm, between about 4 mm and about 12 mm, between about 5 mm and about 12 mm, between about 3 mm and about 10 mm, between about 4 mm and about 10 mm, between about 5 mm and about 10 mm, etc.

[00031] Any of the apparatuses described herein may include a cuff at the second end, wherein the cuff has a stiffness that is greater than a region of the knitted tube adjacent to the cuff. Alternatively, or additionally, any of these apparatuses may include a stop configured to limit the travel of the knitted tube so that the second end does not roll and invert over the distal end of the inversion support catheter.

[00032] The knitted tube may be shape set so that the first configuration has the outer diameter between, e.g., 0.5mm and 10 mm for the region of the kitted tube adjacent to the first end, and the knitted tube in the second configuration has an inner diameter that is greater than, e.g., about 30 % (e.g., about 40%, about 50%, about 60%, etc.) of the inner diameter of the inversion support catheter.

[00033] The first region of the kitted tube (having the larger expanded diameter) may be any appropriate length (e.g., at least about 0.5 cm, about 1 cm, about 2 cm, about 3 cm, about 4 cm, about 5 cm, about 6 cm, about 7 cm, about 8 cm, about 9 cm, about 10 cm, etc.). Similarly, the second region (having the narrower expanded diameter) may be any appropriate length (e.g., at least about 0.5 cm, about 1 cm, about 2 cm, about 3 cm, about 4 cm, about 5 cm, etc.).

[00034] The knitted tube may comprise a filament knitted to form a plurality of interlocking loop stitches, wherein each loop stitch has a stitch length that is between a predetermined range (e.g., between about 0.5mm and 8 mm, about 0.5 to 10 mm, about 0.5 mm to 12 mm, about 0.5 to 14 mm, etc.). This may permit, for example, at a region of the knitted tube that is inverting from the first configuration to the second configuration, a sub-set of the plurality of loop stitches forming the knitted tube may extend proud from the long axis of the knitted tube by between 0.5 mm and 10 mm (e.g., between about 0.3 mm and about 8 mm, between about 0.5 mm and about 8 mm, between about 0.5 mm and about 7 mm, between about 0.5 mm and about 6 mm, greater than about 1 mm, greater than about 2 mm, greater than about 3 mm, greater than about 4 mm, greater than about 5 mm, etc.) as the knitted tube inverts.

[00035] Any of these apparatuses may include an intermediate catheter having a lumen as described herein. The inversion support catheter may be within the lumen of the intermediate support catheter and may be extended distally from the intermediate catheter to deploy the knitted tube so that the flexible tube may expand into the first configuration.

[00036] As mentioned, described herein are methods for removing a clot from a vessel a larger diameter (and therefore a larger clot diameter) than even the expanded flexible tube of the apparatus. For example, described herein are methods of removing a clot from a vessel having an inner diameter (ID) comprising: advancing an inverting tube apparatus through the vessel until a distal end of the inverting tube apparatus is proximate to a clot, wherein the inverting tube apparatus comprises an inversion support catheter, a puller within a lumen of the support catheter, and a knitted tube having a first end coupled to a distal end region of the puller, and a second end that is free to move relative to the inserting support catheter, wherein the knitted tube comprises a filament knitted to form a plurality of interlocking loop stitches, wherein each loop stitch has a stitch length; expanding the knitted tube to a first configuration along an outer surface of the inverting tube catheter to an outer diameter that between 10% and 80% of an inner diameter of the vessel for a first region of the knitted tube that is adjacent to the first end, wherein the knitted tube has a second configuration within the inverting tube catheter having an inner diameter that is greater than 30% of an inner diameter of the inversion support catheter, and wherein a second region of the knitted tube adjacent to the second end has an expanded outer diameter that is less than the expanded outer diameter of the first configuration; pulling the puller proximally within the inversion support catheter to roll the knitted tube over the distal end of the inversion support catheter so that the knitted tube inverts over a distal end of the inversion support catheter, driving the loop stitches

outward from the kitted tube by between 0.5 and 10 mm; capturing the clot with the knitted tube; and pulling the clot proximally into the inversion support catheter.

[00037] Expanding of the flexible tube (e.g., knitted tube) may comprise exposing the knitted tube from out of an intermediate catheter, wherein the inversion support catheter is within a lumen of the intermediate support catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[00038] The features and aspects of the various embodiments of the disclosed inventions are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00039] FIG. 1A illustrates one example of a delivery catheter ("intermediate catheter" or I.C.) that may be used with a mechanical thrombectomy apparatus as described herein.

[00040] FIGS. 1B-1C2 illustrate components of a mechanical (e.g., inverting tractor) thrombectomy apparatus; FIG. 1B shows an example of an elongate inversion support catheter that is configured to include a plurality of slots (shown here as transverse slots) arranged along the catheter in order to enhance flexibility of the elongate inversion support catheter while providing sufficient column strength to resist buckling as the tractor tube is drawn proximally to invert. The slot 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 tractor tube inverted (e.g., in an inverted configuration) over a puller; in FIG. 1C1 the puller is a puller catheter (PMC) while in FIG. 1C2 the puller is a guidewire. The tractor tube is shown schematically and may be a knitted, woven, or braided material.

[00041] FIGS. 2A-2C illustrate the operation of an inverting tractor mechanical thrombectomy apparatus as described above. FIG. 2A shows the assembled apparatus in which the tractor tube is coupled to the puller and within the elongate inversion catheter with the tractor tube inverting over the distal end of the elongate inversion catheter. FIG. 2B shows the apparatus of FIG. 2A delivered within a vessel near a clot. FIG. 2C shows the operation of the apparatus to withdraw the clot by pulling proximally on the tractor tube from within the elongate inversion support catheter so that the tractor tube is pulled to roll over and evert from the inverted configuration on the outside of the distal end of the elongate inversion support catheter into the un-inverted configuration within the elongate inversion support catheter, pulling the clot with it.

[00042] FIG. 2D illustrates an example of a tortious path that the inverting tractor mechanical thrombectomy apparatus may have to navigate in order to reach the clot.

[00043] FIG. 3A is an example of a preloaded assembly of an inverting tractor mechanical thrombectomy apparatus within an intermediate catheter that may be used as described in order to deliver an inverting tractor mechanical thrombectomy apparatus though a tortious vessel to a deployment location. In this example, the elongate inversion support catheter is held within the intermediate catheter (and may be locked in position) until deployed, while the pusher (e.g., PMC) and tractor are partially extending distally. A guidewire may also be used. FIG. 3B show a prototype assembly (pre-assembled) similar to that shown in FIG. 3A.

[00044] FIG. 4A is another example of a preloaded assembly of an inverting tractor mechanical thrombectomy apparatus within an intermediate catheter that may be used as described in order to deliver an inverting tractor mechanical thrombectomy apparatus though a tortious vessel to a deployment location. In this example, the elongate inversion support catheter is extended from the intermediate catheter, and extends distally along with the puller (PCM). FIG. 4B show a prototype assembly (pre-assembled) similar to that shown in FIG. 4A. FIG. 4C shows an example of a preloaded assembly such as the one shown in FIG. 4A and 4B navigating through a model of a tortious vessel. FIG. 4D is another example of a prototype pre-assembled assembly (inverting tractor mechanical thrombectomy apparatus) such as the one shown in FIG. 4A.

[00045] FIG. 5A is another example of a preloaded assembly of an inverting tractor mechanical thrombectomy apparatus within an intermediate catheter that may be used to deliver an inverting tractor mechanical thrombectomy apparatus though a tortious vessel to a deployment location. In this example, the elongate inversion support catheter, and the tractor tube are held within the intermediate catheter, and the distal end (extending beyond the attachment to the tractor tube) of the puller extends distally. FIG. 5B show a prototype assembly (pre-assembled) similar to that shown in FIG. 5A.

[00046] FIG. 6 is an example of a non-over-the-wire variation of an inverting tractor mechanical thrombectomy apparatus in which the puller is a guidewire, similar to the variation shown in FIG. 2C2.

[00047] FIGS. 7A-7C illustrate one example of an inverting tractor mechanical thrombectomy apparatus in which the apparatus is configured for delivery of the tractor tube within the elongate inversion support catheter so that it may later be deployed (as illustrated in FIGS. 7A-7C) to move the tractor tube portion so that it is inverted over the elongate inversion support catheter distal end.

[00048] FIGS. 8A-8C illustrate another method of deploying an inverting tractor mechanical thrombectomy apparatus (where the apparatus is configured for delivery of the tractor tube within the elongate inversion support catheter) so that the tractor tube portion is inverted over the elongate inversion support catheter distal end when at the deployment region near the clot. In both FIGS. 7A-7C and 8A-8C, withdrawing the tractor tube into the elongate inversion support catheter may prevent it from applying a compressive force on the elongate inversion support catheter as it is deployed through the vessel, either with an intermediate catheter or without an intermediate catheter.

[00049] FIGS. 9A-9K illustrate one method of delivering and deploying an inverting tractor mechanical thrombectomy apparatus pre-loaded into an intermediate catheter such as the one shown in FIGS. 3A-3B. Similar methods may be employed to deliver the pre-loaded variations shown in FIGS. 4A and 5A.

[00050] FIGS. 10A-10D illustrate another example of a method of delivering and deploying an inverting tractor mechanical thrombectomy apparatus pre-loaded into an intermediate catheter such as the one shown in FIGS. 3A-3B.

[00051] FIGS. 11A-11C illustrate a method of using an inverting tractor mechanical thrombectomy apparatus to remove clot after the tractor tube portion of the inverting tractor mechanical thrombectomy apparatus has been completely withdrawn into the elongate inversion support catheter.

[00052] FIG. 12A illustrates an inverting tractor mechanical thrombectomy apparatus configured to prevent the tractor tube from retracting fully into the elongate inversion support catheter. In FIG. 12A the tractor tube has a distal end region that is non-compliant and configured so that it cannot invert over the distal end of the elongate inversion support catheter.

[00053] FIG. 12B shows an example of a cuff on the distal end of an inverted flexible tube.

[00054] FIGS. 13A shows a knitted tractor tube extending in an inverted configuration over the outside of a distal end of an elongate inversion support catheter. FIG. 13B shows the knitted tractor of FIG. 13A applying compressive force to the elongate inversion support catheter when the apparatus is advanced distally. FIG. 13C illustrates an inverting tractor mechanical thrombectomy apparatus configured to hold the kitted tractor tube in a compressed state (in which the transversely arranged, or approximately transversely arranged loops forming the knit overlap over more than 20% or their longitudinal length).

[00055] FIGS. 14A-14D illustrate examples of inverting tractor mechanical thrombectomy apparatuses (e.g., elongate inversion support catheter portions) including a stop that is configured to hold the knitted tractor tube in a compressed configuration. In FIG. 14 a polymer strop is shown. In FIG. 14B a Nitinol braid stop has exposed filaments ("fingers") that prevent proximal sliding of the tractor tube. FIG. 14C shows another example of a Nitinol braid stop has exposed filaments ("fingers") that prevent proximal sliding of the tractor tube. FIG. 14D shows a Nitinol knit segment configured as a stop to prevent proximal sliding of the tractor tube during delivery.

[00056] FIGS. 15A-15G illustrate examples of finger-like stop elements similar to those shown in FIGS. 14B-14C. The distally-directed prongs, filaments or fingers of the stops shown may be placed anywhere along the length of the outer surface of the elongate inversion support catheter to prevent compression of the knitted tractor tube during delivery and deployment.

[00057] FIGS. 15H is another example of a stop on the outer surface of and elongate inversion support catheter having distally-facing prongs that prevent proximal movement of a woven tractor tube, in order to prevent compressive forces on the elongate inversion support catheter.

[00058] FIGS. 16A and 16B illustrate examples of annular housings ("garages") for the tractor tube on the outer surface of an elongate inversion support catheter that may also maintain the tractor tube in a compressed configuration on an outer surface of the apparatus, preventing it from applying compressive force on the distal end of the elongate inversion support catheter. In FIG. 16A, a 48-end braid forms an annular garage for holding the end of the tractor tube so that it remains in a compressed configuration along the outer surface of the elongate inversion support catheter. In FIG. 16B, the apparatus includes a 10 mm long braided region (similar to that shown in FIG. 15A, housing the end of the knitted tractor tube and preventing it from extending proximally and applying compressive forces on the distal end of the elongate inversion support catheter.

[00059] FIG. 17 is an example of one variations of an elongate inversion support catheter having a high column strength in compression, but a high flexibility when not under compression. In FIG. 17, the elongate inversion support catheter includes a plurality of slots or cut-our regions arranged approximately transverse to the elongate length (e.g., long axis). Any of these devices may also include a marker (e.g., platinum, or other radiopaque material) allowing visualization of the distal end region of the elongate inversion support catheter.

[00060] FIGS. 18A-18J illustrate a method of removing a clot from a vessel as described herein, in which a vacuum (suction) may be applied through the puller to make and confirm initial contact with the clot. In FIG. 18A, the apparatus is distally advanced over a guidewire adjacent to the clot. The apparatus may initially be in a tracking configuration as shown and discussed, in which the outer (inversion support) catheter is retracted into the lumen of the intermediate catheter while the puller (puller catheter) with the attached flexible tube extending proximally from the distal end, is tracked over the guidewire. In FIG. 18B, the apparatus is changed to a clot-grabbing configuration in which the inversion support catheter is extended towards the distal end of the apparatus, though still proximal to the puller distal end. The intermediate catheter may also optionally be withdrawn proximally, as shown in FIG. 18C, which in some variations (not shown in FIG. 18A-18J) may allow the flexible tube to expand outwards. FIG. 18C1 shows an example of a prototype device corresponding to FIG. 18C. Once in position, suction may be applied through the puller catheter, as shown in FIG. 18D. This focal suction may be applied while advancing the apparatus distally to engage the clot, as shown in FIG. 18E. The guidewire may be left in place or optionally removed (as shown in FIGS. 18D-18E). Once engaged with the clot at the distal end of the puller, which may be detected by observing the flow and/or pressure through the puller from the suction, the puller may be drawn proximally and/or the inversion support catheter may be moved distally so that the flexible tube rolls over the distal end opening of the inversion support catheter. In FIG. 18F approximately 30% of the clot has been drawn into the inversion support catheter by rolling the flexible tube; in FIG. 18G, more, but not all (e.g., approximately 70%) of the clot has been ingested, though a substantial amount of clot remains outside of the inversion support catheter and flexible tube. The vacuum may be left on, or it may be turned off while pulling the puller proximally to engulf/grab the clot. Heavy arrows indicate movement of the components of the apparatus, such as the intermediate catheter, which may be advanced distally, the inversion support catheter, which may also be advanced distally, and the puller, which may be withdrawn proximally. These motions may be coordinated by the handle (not shown) and/or performed manually by the user. Once the flexible tube has reached the distal end of the inversion support catheter, it may stop or be stopped, to prevent it from rolling over the distal end. In FIG. 18A-18J the second end of the flexible tube includes a cuff that may prevent the flexible tube from rolling over the distal end when pulling proximally on the puller, as shown in FIG. 18H. In FIG. 18I, the intermediate catheter is shown advancing distally beyond the cuff and distal end of the intermediate support catheter, which inverts the cuff over and against the clot without breaking or

disrupting the clot. A vacuum (suction) through the intermediate catheter is also shown being applied (by the small arrows). As shown in FIG. 18J, the flexible tube, puller and inversion support catheter are then drawn proximally into the intermediate catheter along with the un-engulfed portion of the clot, either by driving the intermediate catheter distally over them, and/or by pulling the inversion support catheter (which may be pulled with the puller) proximally.

[00061] FIG. 19 illustrates an example of a mechanical thrombectomy apparatus having a knitted flexible tube that is configured to operate even in larger-dimeter vessels (having proportionally larger-diameter clots) by configuring the stitch length of the knitted tube to help grab larger-diameter clots.

[00062] FIG. 20A illustrates a larger-dimeter clot (e.g., shown in the top as a 15 mm OD, 5 cm long clot) that was captured using a narrower-diameter mechanical thrombectomy apparatus having a knitted flexible tube portion (shown having an expanded outer diameter of 5 cm with an 8F inversion support catheter). The removed clot is shown on the bottom above the ruler.

[00063] FIG. 20B shows a side view of a distal end region of a similar mechanical thrombectomy apparatus having a knitted flexible tube that inverts into a 3 mm inversion support catheter. The knitted flexible tube has a 6 mm expanded first configuration, but may remove clots having an outer diameter much larger (e.g., a 15 mm outer diameter clot, as shown in FIG. 20A).

[00064] FIG. 21A illustrates and example of a relationship between the length of flexible tube required for a mechanical thrombectomy apparatus as described herein in order to completely engulf ("eat") a clot having an outer diameter of 15 mm and a length of 5 cm. In this example, the flexible tube is a knitted or woven tube formed of heat-set 0.01 inch NiTi wire.

[00065] FIG. 21B shows example of the distal ends of mechanical thrombectomy apparatus tested in FIG. 21A, showing variations with 8 mm expanded outer diameter, 5 mm expanded outer diameter, and 3 mm outer diameter, as well as an 8 French (8F) inversion support catheter.

[00066] FIG. 22A shows another example of a cuff that may be at the second end of a flexible tube of a mechanical thrombectomy apparatus. In FIG. 22A, the cuff includes a plurality of slits that may engage with the intermediate catheter (IC) when it is driven distally past the cuff to drive the cuff to invert over the distal end of an inversion support catheter, as shown in FIG. 18I, controllable preventing inversion when pulling the puller, but allowing

inversion without disrupting the clot when advancing the intermediate catheter, as illustrated in FIG. 22B, showing inversion of the cuff after driving the intermediate catheter distally.

[00067] FIGS. 23A-23B illustrate example of the proximal end of a mechanical thrombectomy apparatus, showing the components of the apparatus (e.g., guidewire, inner/inversion support catheter, puller, and intermediate catheter). FIG. 23B shows another example, of a proximal end of the mechanical thrombectomy apparatus showing manual controls, including vacuum attachment ports, for the different regions.

[00068] FIGS. 24A-24B illustrate another example of a set of proximal end controls for a mechanical thrombectomy apparatus. In FIG. 24A the apparatus control region is shown in a first puller position (prior to pulling the clot in). In FIG. 24B the apparatus control region is shown after pulling the clot (showing the puller hub extended proximally).

[00069] FIG. 25 illustrate an example of a mechanical thrombectomy apparatus in which the flexible tube is configured to cut tissue as it rolls into the inversion support catheter. In this example, the flexible tube is a knitted tube that includes sharp cutting edges that may be used to cut through tissue.

[00070] FIGS. 26A-26B illustrate two exemplary side perspective views of mechanical thrombectomy apparatuses. In FIG. 26A, similar to that shown in FIGS. 18A-18J, the apparatus include a flexible (e.g., knitted) tube that is attached at the first end to a puller catheter and is configured to expand within the inversion support catheter to an outer diameter that is greater than 40% (shown here, it's greater than 90%) of the inner diameter of the inversion support catheter, driving the region of the flexible tube within the inversion support catheter against the walls, even when unloaded by clot. The other region (un-inverted) of the flexible tube along the outer diameter of inversion support catheter is shown as snug with the inversion support catheter in the un-constrained configuration. This results in the Y-shaped distal profile, for the inverting flexible tube, which may help grab even larger diameter clots.

[00071] FIG. 26B illustrates another example of a mechanical thrombectomy apparatus in which the expanded outer profile of the flexible tube is expanded beyond the outer diameter of the inversion support catheter near the first end where it attaches to the puller, but the second end, that is freely sliding over the inversion support catheter, has a much smaller (nearly snug) expanded diameter. This region may also or alternatively include a cuff as described herein.

[00072] FIGS. 27A-27C illustrate operation of a mechanical thrombectomy apparatus having a cuff on one end of the flexible tube.

[00073] FIGS. 28A-28C illustrate one example of a mechanical thrombectomy apparatus that includes a cuff retainer that may aid in re-sheathing the apparatus into an intermediate catheter.

[00074] FIGS. 29A-29C illustrate another example of a mechanical thrombectomy apparatus that includes a cuff retainer.

[00075] FIGS. 30A-30C illustrate another example of a mechanical thrombectomy apparatus that includes a cuff retainer.

[00076] FIGS. 31A-31C illustrate another example of a mechanical thrombectomy apparatus that includes a cuff retainer (configured as a stop).

[00077] FIGS. 32A-32F illustrate examples of mechanical thrombectomy apparatus including a cuff that is adapted at the proximal-facing end to aid in re-sheathing into an intermediate catheter. FIGS. 32A-32C illustrate cuffs having a tapered proximal end region. FIGS. 32D and 32E illustrate cuffs having angled proximal-facing sides. FIG. 32F is an example of a cuff having a proximal stent-like region.

[00078] FIGS. 33A-33E illustrate one example of a re-loading mechanical thrombectomy apparatus in which a single-use sub-assembly (including the puller, cuff and flexible tube) can be withdrawn and a new sub-assembly inserted.

[00079] FIGS. 34A-34C illustrate operation of a re-usable/reloadable mechanical thrombectomy apparatus.

[00080] FIG. 35 schematically illustrates one example of an ejection apparatus that may be used to assist in ejecting captured clot material and/or reloading of a mechanical thrombectomy apparatus.

DETAILED DESCRIPTION

[00081] In general, described herein are inverting tractor mechanical thrombectomy apparatus having a tractor tube, configured as an inverting flexible tractor tube that may be pulled proximally to invert over and into the distal end of an elongate inversion support catheter. An end of the tractor tube may be coupled to a puller (e.g., pull wire, pull catheter, etc.) to provide the proximal pulling force. In particular, described herein are apparatuses and methods of using them that improve or enhance tracking of the apparatus from a patient insertion side (e.g., a femoral region or elsewhere) though a tortious vessel, to a deployment site where the apparatus may be deployed to mechanically remove a clot by rolling the tractor tube into the elongate inversion support catheter and grabbing the clot.

[00082] In general, the apparatus may be adapted to improve tracking by preventing stiffening or loss of flexibility of the elongate inversion support catheter that may otherwise occur when the tractor tube, which may extend along a substantial distance proximally from the distal open end of the elongate inversion support catheter, applies a compressive force on the elongate inversion support catheter. This may occur, for example, when the apparatus is deployed through the vessel and/or through an intermediate catheter. Although the outer surface of the elongate inversion support catheter, and/or the outer surface of the tractor tube may be lubricated to reduce friction, the distal movement of the apparatus may still result in a drag force on and portion of the tractor tube that is on the outside surface of the elongate inversion support catheter. The resulting drag force is transferred to the distal end of the elongate inversion support catheter, resulting in a compressive force on the elongate inversion support catheter. An example of this is illustrated in FIG. 13B, described in greater detail below.

[00083] This issue may be exacerbated when the apparatus includes an elongate inversion support catheter that is configured to have both a high column strength (resisting compression) and an increased flexibility, e.g., by including one or more cut-outs, slots, etc. arranged down the length of the elongate inversion support catheter. For example, metal tubes (e.g., Nitinol tubes, etc.) having transversely arranged slots cut into them along the length of the elongate inversion support catheter may have a high column strength, while remaining sufficiently flexible (at least in an unloaded/un-tensioned configuration).

[00084] In general, an inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an elongate inversion support catheter (such as those mentioned above), having a distal end and a distal annulus (distal end opening), and a flexible tractor assembly including a flexible tractor tube coupled to an elongate puller within the elongate inversion support catheter. The flexible tractor tube is configured to roll and invert over the distal end opening of the elongate inversion support catheter. Knitted tractor tubes are of particular interested and described herein, although it should be understood that other tractor tubes, e.g., woven, braided, etc., may be used.

[00085] Tracking of any of the inverting tractor mechanical thrombectomy apparatus described herein may include an intermediate catheter (I.C.) as a delivery catheter along with a guidewire. For example, FIG. 1A illustrates an example of a typical intermediate catheter 101 that may be used. Note that in some variations, as will be illustrated below, an intermediate catheter is not needed or used and the inverting tractor mechanical

thrombectomy apparatus may be delivered to the deployment site near the clot to be removed without the need for an intermediate catheter.

[00086] FIG. 1B illustrates one example of an elongate inversion support catheter. In this example, the elongate inversion support catheter 103 is formed of a normally high column-strength material (such as a metal, e.g. Nitinol) having a number of openings (e.g., cut-out regions) or slots along the length to provide enhanced flexibility. The distal end of the elongate inversion support catheter is open 105. Either the entire length or a portion of the length may be cut/slotted as described. The elongate inversion support catheter includes a catheter body having a distal end region that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm,05 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing harness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00087] In FIG. 1B, the elongate inversion support catheter is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of of compressive force is applied (e.g., able to withstand at least about 500g, at least about 700 g, at least about 600 g, at least about 500 g, at least about 400 g, at least about 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include an elongate inversion support catheter that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like. In FIG. 1B the catheter 103 of the elongate inversion support catheter may be any appropriate

type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00088] In some variations the distal end 105 of the elongate inversion support catheter is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in some variations the distal tip (end) may be curved or radiused, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[00089] FIG. 1C1 shows an example of a flexible tractor tube 111 coupled to an elongate puller 113, forming a pullable tractor assembly 140. In this example, the tractor tube 111 is shown integrated with the puller 113 and extending back over the puller. The puller in this example is a catheter (e.g. a micro catheter, also referred to herein as a PMC or pull micro catheter). In this example, the opposite end of the flexible tractor tube 111 is open and free (e.g., not connected to the puller or catheter, e.g. elongate inversion support catheter). As will be described in greater detail below, this open, free, end may be adapted to be expanded and held open, e.g., by shape setting back on itself and/or by including an annular bias, to enhance deployment and positioning of the catheter between the flexible tractor tube and the puller. In FIGS. 1C1 and 1C2, the tractor tube is formed of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The tractor 111 is shown extended from the puller in a first configuration. It may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 111 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The tractor 111 may be configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first configuration to a radial diameter that is between 1.1 and 10 times (e.g., between 1.1x and 5x, between 1.1x and 4x, etc.) the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained. In FIG. 1C2, the tractor tube 111 is shown coupled to a guidewire (non-hollow structure) 115. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00090] FIG. 2A illustrates an example of an inverting tractor mechanical thrombectomy apparatus 200 deployed. In FIG. 2B the inverting tractor mechanical thrombectomy apparatus is shown deployed near a clot 209. In the deployed configuration the puller 201 (shown here as a puller micro catheter) is held within the elongate inversion support catheter so that the

flexile tractor tube 203 extends from the end of the puller and expands toward the inner radius of the elongate inversion support catheter 207; at the distal end opening of the elongate inversion support catheter the tractor tube inverts over itself and extends proximally in an inverted configuration over the distal end of the elongate inversion support catheter. As shown in FIG. 2C, by pulling the puller proximally, the tractor tube rolls and everts over the distal end opening of the elongate inversion support catheter, drawing the adjacent clot into the elongate inversion support catheter, as shown.

[00091] FIG. 2A the elongate inversion support catheter is positioned between the tractor tube and the puller so that the tractor tube can be pulled proximally by pulling on the puller and rolling the tractor tube into the elongate inversion support catheter so that it inverts. The portion of the tractor tube that is inverted over the distal end of the elongate inversion support catheter has an outer diameter that is greater than the outer diameter of the elongate inversion support catheter. The tractor is biased so that it has a relaxed expanded configuration with a diameter that is greater than the outer diameter (OD) of the elongate inversion support catheter; in addition, the tractor tube may also be configured (e.g., by heat setting, etc.) so that when the tractor tube is everted and rolled over the distal end opening into the elongate inversion support catheter, the outer diameter of the tractor tube within the elongate inversion support catheter has an outer diameter that is greater than the inner diameter of the elongate inversion support catheter (e.g., greater than 0.1x, 0.5x 0.6x, 0.7x, 0.75x, 0.8x, 0.9x, 1x, etc. the inner diameter, ID, of the elongate inversion support catheter. This combination of an un-inverted diameter of the tractor tube of greater than the diameter of the OD of the elongate inversion support catheter and an inverted diameter of the tractor tube of greater than 0.7x the ID of the elongate inversion support catheter is surprisingly helpful for preventing jamming of the apparatus, both when deploying the apparatus and when rolling the tractor over the distal end opening of the elongate inversion support catheter to grab a clot. The tractor may be expandable and may be coupled to the puller as shown. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to elongate puller (e.g., a push/pull wire or catheter).

[00092] In FIG. 2C the clot may be drawn into the elongate inversion support catheter by pulling the tractor proximally into the distal end of the elongate inversion support catheter, as indicated by the arrows 211, 211' showing pulling of the inner portion of the flexible tractor, resulting in rolling the tractor over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled into the catheter, shown

by arrows. The end of the tractor outside of the catheter may be "loose" relative to the outer wall of the catheter.

[00093] In general the mechanical thrombectomy apparatuses described herein may be highly flexible, both before actuating and during operation. For example, the flexible tractor may not increase the stiffness/flexibility of the catheter of the elongate inversion support, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortious vessels of the neurovasculature. Described herein are flexible tractor tube portions that increase the stiffness of the last "y" cm (e.g., the distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[00094] The tractors may be woven, braided and/or knitted materials. For woven and braided materials, which may include a plurality of fibers that are woven or braided to form the inverting tube, these structures may be tuned to prevent jamming and/or to reduce the force necessary to pull the tractor and invert over the catheter tip. For example, the mechanical atherectomy apparatus may include a braid-type tractor that can roll freely around the tip of catheter even in a tortuous anatomy and when grabbing clot by tuning one or more of the braid structure; minimizing the braid angle; including a hydrophilic coating on the distal aspect of the catheter outer diameter (OD) or the inner diameter (ID) of the braid (e.g., tractor); including a radiused wall on the catheter; and/or increasing the stiffness of the distal tip region relative to adjacent proximal regions. Alternatively, it may be advantages to have a hydrophilic coating on 1, 3, 5, 10, or 15 cm of the distal ID or the entire catheter ID. This may even enhance aspiration of the clot without a tractor element.

[00095] As mentioned, the tractor (e.g., braided, woven, knitted, etc.) may be configured to collapse down into the inner diameter (ID) of the catheter as little as possible. For example the tractor may collapse to an ID that is greater than, equal to, or within 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter inner diameter (ID)/Catheter Tip OD, since, when the tractor is being pulled around catheter tip it may create axial tension on the tractor (e.g., braid, knit, etc.) that can inadvertently cause the tractor to jam on the catheter tip. When tractor is pulled around catheter tip, the tractor is being pulled in the axial orientation creating

axial tension on tractor structure as the tractor is being pulled through the catheter ID. By having the tractor elements jam at an ID greater than or equal to 90%, 85%, 75%, 70%, 65%, 60%, or 50% of the catheter ID (or in some variations, OD), when being axially tensioned, the tractor is less likely to grab/synch down onto the catheter tip, helping the braid roll around the catheter tip with less axial force applied by the user. If less axial force is required by the user to pull the tractor structure around the tip then the catheter tip is less likely to buckle or deflect when retracting the tractor. It may be advantageous to minimize the chance the catheter tip will buckle. The tractor can be tuned to "jam" at a specific ID by controlling any of the following variables and in any combination: selecting a specific number of braid ends, selecting the size/diameter of the braid ends; selecting the braid material (e.g., multifilament or monofilament); heat setting the bias on the braid (e.g., braid diameter); and selecting a braid pattern, e.g., 1x2, 1x1 or any other pattern.

[00096] The braid angle may be minimized to prevent locking up of the rolling of the tractor over the catheter end opening. Typically, the lower the braid angle (e.g., 45 degrees or less, 40 degrees or less, 35 degrees or less, 30 degrees or less, 25 degrees or less, 20 degrees or less, etc.) the less likely it is to have the braid cross over points catch on the catheter tip.

[00097] In any of the variations described herein, the catheter and/or a surface of the tractor may be coated to enhance rolling over the distal end region of the catheter. It may be helpful to have a hydrophilic coating on the distal aspect of the catheter OD or the ID of the tractor so the tractor can more easily side over the catheters distal end and around the tip of the catheter when pulled through the inside of the catheter.

[00098] The radius wall of the catheter tip may be chosen/set to within a range that allows sliding. For example, it may be helpful for the tip of the catheter to have the largest radius possible but at least 0.025" radius wall on the catheter, ideally approximately 0.05" radius wall.

[00099] The stiffness of the distal of the elongate inversion support catheter may be sufficiently stiff to prevent collapse as the tractor is pulled; it may also be lubricious (e.g., by a coating or material property). The distal most section of the elongate inversion support catheter tip (e.g., the last 5mm) may be fabricated of a material which is stiff enough and lubricious enough so the distal tip of the catheter does not collapse or buckle inward ward when the braid structure is rolling around the catheter tip. Thus, the distal tip may have a stiffness that is greater than the more proximal region at the distal end of the catheter.

[000100] It may be helpful or desirable to have pores in the tractor. A lack of gaps or small pore size may limit the ability of the braid to grab clot. Alternatively or additionally, it may

be desirable to form a braid structure with texture. One example is to braid two or more different diameter braid ends into the same structure: the difference in braid end diameters will help form a texture to the braid structures outer surface, aiding the grabbing of the clot when rolling the braid-dozer around the catheter tip.

[000101] As an alternative (or in addition) the tractor may be configured to lock so it does not compress in diameter during axial load by adding a coating, laminate or adhesive to the braid at a desired diameter. Adding a thin coating, laminate or adhesive can inhibit the braid elements from sliding with respect to each other, thereby locking the braid to a specific diameter. The coating can be applied while leaving the majority of the pores and pore area substantially open. Examples of thin coatings include urethanes and silicones with and without hydrophilic coatings and hydrophilic coatings with no tie layer.

[000102] As mentioned above, any of the apparatuses described herein may be configured to provide enhance delivery of the apparatus though the tortious anatomy of the vessels in order to deploy the apparatuses near the clot. For example, FIG. 2D illustrates an example of a tortious path 250 that may be navigated by the apparatuses (including in particular the apparatuses that are pre-loaded into an intermediate/delivery catheter).

[000103] PRELOADED APPARATUSES

[000104] One solution to the problem with tracking of the inverting mechanical thrombectomy apparatuses such as those described herein, and particularly those having a high flexibility, high column strength elongate inversion support catheter (which may stiffen when placed under even relatively small compressive forces from their distal end by the tractor tube) is to preload the inverting mechanical thrombectomy apparatuses within an intermediate catheter so that a portion of the inverting mechanical thrombectomy apparatus is protected within the body of the intermediate catheter, while the rest of the intermediate catheter portion is advanced over and/or along (with) a guidewire. For example, FIG. 3A illustrate one example of a pre-loaded inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy. In this example, the apparatus may include an intermediate catheter 303 having a distal end 305. The intermediate catheter (I.C.) may be considered part of the inverting mechanical thrombectomy apparatus, although in other variations it may be considered a separate component that is used with the inverting mechanical thrombectomy apparatus. The apparatus also includes an elongate inversion support catheter 307 (also referred to as push catheter "880 Device" in FIG. 3) within the lumen of the intermediate catheter. The elongate inversion support catheter 307 has a distal end 311 and a distal end opening. The apparatus

also includes a puller 319 extending distally within the elongate inversion support catheter and a flexible tractor tube 315 extending proximally from a distal end region of the puller. The puller extends from the distal end of the intermediate catheter and the distal end opening of the elongate inversion support catheter.

[000105] In the pre-assembled configuration shown in FIG. 3A, the elongate inversion support catheter is held within the lumen of the intermediate catheter so that the distal end opening of the elongate inversion support catheter is proximal to the distal end opening of the intermediate catheter by a first distance 325. This distance may be between about 1mm and about 10 cm (e.g., between about 2 mm and about 10 mm, between about 2 mm and about 20 mm, between about 2mm and about 30 mm, etc.). The elongate inversion support catheter may be fixed in position relative to the intermediate catheter, so that as the two catheters move together, until released. For example, the proximal ends of the intermediate catheter and the elongate inversion support catheter may be removably coupled.

[000106] The tractor tube in the pre-assembled apparatus of FIG. 3 extends between the elongate inversion support catheter and the intermediate catheter for some second distance along the length 323 of the elongate inversion support catheter. Securing the end of the tractor tube between the I.C. and the distal end of the elongate inversion support catheter may help both hold it in place, so that it may be held in compression, as will be described in greater detail below, which may also help prevent it from applying compressive force to the distal end of the elongate inversion support catheter. For example, the second length 323 may be between about 1 mm and about 50 cm (e.g., between about 5 cm and about 10 cm, between about 1 cm and about 20 cm, between about 1 cm and about 10 cm, between about 2 cm and about 20 cm, between about 2 cm and about 10 cm, etc.).

[000107] The portion of the tractor tube 315 and puller 319 (e.g., pull micro catheter, or pmc) in this pre-loaded example may extend distally and ride over the guidewire 317. The tractor tube and puller may also be longitudinally fixed relative to the intermediate catheter 303 (e.g., by releasably locking, e.g., at the distal end region) or they may be somewhat longitudinally slideable (and, in some variations, prevented from exceeding a range of, e.g., between about 1 mm and 20 cm from the distal end opening 305 of the intermediate catheter 303.

[000108] In practice, the portion 327 of the tractor tube 315 that extends outside of the intermediate catheter 303 may be between about 1 mm and about 20 cm (e.g., between about 1 cm and about 7cm, between about 1 cm and about 10 cm, between about 1 cm and about 15 cm, between about 2 cm and about 10 cm, between about 2 cm and about 7 cm, etc.). As

mentioned, this distance may be fixed (e.g., by fixing the puller with respect to the push catheter and/or I.C.), or variable. In any of these variations, the puller may extend some distance 329 beyond the distal attachment site for the flexible tractor tube, or the tractor tube may be attached at the distal end of the puller. The distance from the attachment site of the tractor tube and the distal end of the puller may be between about 0 mm and about 10 cm, for example (e.g., between about 1 mm and about 10 cm, between about 1 mm and about 5 cm, etc.).

[000109] In variations in which the pre-loaded apparatus is configured with the puller (and therefore the tractor tube) and/or the elongate inversion support catheter fixed relative to the intermediate catheter for delivery of the apparatus to the clot (e.g., adjacent to the clot), once in the deployment location, the elongate inversion support catheter and/or puller may be unlocked so that they may move independently of the intermediate catheter. In some variations, the elongate inversion support catheter may be unlocked first, so that it can be advanced distally into the tractor tube and over the puller; once the distal end of the elongate inversion support catheter is near the attachment site for the tractor tube on the puller, the puller may be also be released (manually or automatically).

[000110] FIG. 3B illustrates another example of a pre-loaded apparatus (pre-loaded inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy). In FIG 3B, the tractor tube is a knit 355 that is bonded to the puller near a distal end region, described in FIG. 3A. The distal end region of the puller (pmc) 337 extends from the intermediate catheter 343. The opposite end 345 of the tractor tube, approximately 1 cm) is held between the intermediate catheter and the elongate inversion support catheter 341, which is entirely within the intermediate catheter. Exemplary dimensions are shown by the ruler above the prototype device.

[000111] Another variation of a pre-loaded inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy is shown in FIGS. 4A-4D. In FIG. 4A, the apparatus contains the same elements shown in FIG. 3A, but they are arranged and interact in a different manner. For example, the pre-loaded apparatus includes an intermediate catheter 403 with an open distal end 405, an inner elongate inversion support catheter 307, a tractor tube 415 and a puller 419. In FIG. 4A, he tractor tube is connected to a distal end region of the puller (e.g., within a fixed distance 425 of the distal end of the puller, e.g., between about 0mm and 10 cm (e.g., about 1 mm to about 10 mm, etc.) as in the example in FIG. 3A. The opposite end of the tractor tube is held between the intermediate catheter 403 and the elongate inversion support catheter 407, as in

FIG. 3A. For example, between about 1 mm and about 50 cm of tractor tube (e.g., between about 5 cm and about 10 cm, between about 1 cm and about 12 cm, etc.) may be between the intermediate catheter and the elongate inversion support catheter; the tractor tube may be held loosely, or it may be held so that the distal end of the tractor tube on the outside of the elongate inversion support catheter is compressed, it from being pulled distally by friction from the vessel walls, resulting in compressive forces on the distal end of the elongate inversion support catheter.

[000112] In FIG. 4A, the elongate inversion support catheter is secured in position relative to the puller so that the distal end opening of the elongate inversion support catheter is near the attachment site for the tractor tube on the puller. For example, the distance between the elongate inversion support catheter distal end opening and the attachment site for the tractor tube 429 may be between about 0 mm and about 10 cm (e.g., between about 0 mm and about 1 mm, between about 0 mm and about 2 mm, between about 1 mm and about 5 mm, between about 1 mm and about 3 mm, etc.). As discussed above for FIG. 3A, the puller, elongate inversion support catheter and intermediate catheter may be releasably locked together so that they move together. The portion of the puller from the attachment site of the tractor tube to the distal end of the puller 425 may, as described for FIG. 3A, above, be between about 0 mm and about 10 cm (e.g., between about 0 mm and about 7 mm, between about 0 mm and about 5mm, etc.).

[000113] In operation, the pre-assembled apparatus shown in FIG. 4A may advance distally (e.g., over a guidewire) towards a clot in a vessel with the slightly more flexible distal end portion consisting of a distal portion of the puller, tractor and elongate inversion support catheter extending distally from the distal opening of the intermediate catheter by a distance 427 that may be, for example,, between about 1 cm and 20 cm (e.g., between about 2 cm and about 7 cm, between about 1 cm and 10 cm, between about 2 cm and about 7.5 cm, etc.). This presents a more flexible distal end region that tapers slightly over the guidewire, allowing the apparatus to navigate tortious vessels, including those having branches. Once the distal end of the apparatus is within the deployment region, near (e.g., adjacent to) the clot to be removed, the apparatus may be deployed by removing the coupling between the intermediate catheter, puller and elongate inversion support catheter, and allowing the intermediate catheter to be withdrawn at least slightly, and for the elongate inversion support catheter to be advanced while withdrawing the tractor tube proximally to roll the tractor tube so that it everts over the distal end opening of the elongate inversion support catheter.

[000114] FIG. 4B illustrates an example of distal end of a prototype pre-assembled apparatus similar to that shown in FIG. 4A. In FIG. 4B the apparatus is shown over a guidewire 417 with the elongate inversion support catheter 407 near the attachment site 433 for the tractor tube onto the distal end region of the puller; a distal end region of the puller 431 extends from the tractor tube attachment site to the distal end opening of the puller.

[000115] FIG. 4C illustrates tracing of an apparatus 460 such as the one shown in FIG. 4B through a tortious model of a blood vessel 455; the flexible distal end leads the device in tracking and navigating through the vessel. FIG. 4D illustrates another example of a distal end region of a pre-loaded inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel, also showing exemplary dimensions. In FIG. 4D, the apparatus is threaded over a movable guidewire 417, and shows a knitted tractor tube 415' that is attached to the distal end region of a puller 419; an elongate inversion support catheter 407' is between the tractor and the puller, as mentioned above. This is pre-loaded into an intermediate catheter 403'.

[000116] Another example of a pre-loaded inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy. In FIG. 5A, unlike the variations shown in FIG. 3A and 4A, both the elongate inversion support catheter 507 and the tractor tube 515 are held (e.g., releasably locked) within the intermediate catheter 503. This may prevent the tractor tube from pushing against the vessel wall during tracking, and therefore prevent compressive force on the elongate inversion support catheter that may otherwise result in it stiffening. In this example, a portion 509 of the puller 519 may extend distally out of the intermediate catheter, e.g., between about 0 mm to about 30 cm (e.g., between about 0.5 cm to about 20 cm, between about 1 cm to about 15 cm, between about 1 cm to about 10 cm, between about 1 cm and about 5 cm, etc.). The attachment site of the tractor tube to the puller may be at or near the distal opening of the intermediate catheter, or it may be offset by some predetermined distance 507 (or within a range of distances, e.g., between about 0 mm to about 10 cm, such as between about 1 cm to about 8 cm, between about 0 cm to about 2 cm, etc.). Similarly, the elongate inversion support catheter may be preloaded near the attachment site for the tractor tube to the puller (e.g., with a distance 505 of between about 0 mm to about 20 cm, preferably between about 0 mm and 10 mm). The entire length of the tractor tube 503 may be any appropriate length, e.g., between about 1 cm and about 60 cm (e.g., between about 5 cm and about 30cm, between about 5 cm and about 10 cm, etc.).

[000117] In operation, the apparatus shown in FIG. 5A may be deployed over a guidewire (with the component parts all removably secured together, e.g., at a proximal handle) and advanced distally until it is near the clot. In any of these examples, the guidewire may penetrate the clot or it may stop short of the clot. Thereafter, the intermediate catheter may be withdrawn proximally and/or the elongate inversion support catheter advanced distally so that the tractor tube is everted from over the distal end opening of the elongate inversion support catheter and into the elongate inversion support catheter. Pulling the puller proximally may continue to roll the tractor tube, while advancing the elongate inversion support catheter to pull the clot into the elongate inversion support catheter as the tractor tube everts.

[000118] FIG. 5B illustrates another example of the pre-loaded inverting tractor mechanical thrombectomy apparatus shown in FIG. 5A. IN this example, only the distal end of the puller 519' (referred to herein as the pull micro catheter or PMC), while the tractor tube attached more proximally to the PMC remains in the intermediate catheter (I.C.) 503'. In this example, the puller 519' rides over the guidewire 517, and has a length that is about 2 and 5 cm.

[000119] The examples shown in FIGS. 3A-5B shown above include a puller that is configured as a puller micro catheter than may be driven over a guidewire. Any of the variations described herein may instead by configured so that the puller is a guidewire, as shown in the example in FIG. 6. In this example the puller 619 is a guidewire and the tractor tube 615 is attached at one end to the puller. IN this example, the tractor is attached to the distal end of the puller, but it may be attached more proximally, as described above. The elongate inversion support catheter 607 is interposed between the puller and the tractor tube, and may be extended distally so that the tractor tube rolls over the distal end opening of the elongate inversion support catheter when pulling the puller to capture and remove a clot. In the variations shown in FIG. 6, the puller does not necessarily need to be a movable (i.e., longitudinally slideable) pull wire, but may be a fixed wire.

[000120] As an alternative to the pre-assembled configurations described in FIGS. 3A-5B described above, any of the apparatuses described herein may also or alternatively be configured to be deployed through an intermediate catheter that is first deployed (e.g., using a guidewire and one or more internal catheters), and left in place; the inverting tractor mechanical thrombectomy apparatus may then be delivered through the intermediate catheter.

[000121] Some variations an inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy are configured for delivery and deployment to remove a clot without needing an intermediate catheter. For example, in some variations all, or most of, the tractor tube is withdrawn into

the elongate inversion support catheter portion of the apparatus. Thus, the outer surface of the apparatus is the outer surface of the elongate inversion support catheter, which may be smooth, and/or lubricated, and therefore less likely than the tractor tube to provoke a compressive force on the distal end region that would otherwise stiffen the elongate inversion support catheter and prevent it from navigating a tortious vessel. For example, FIGS. 7A-7C show a first example of an inverting tractor mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy that is configured to deliver the apparatus to the deployment site near the clot with the tractor withdrawn nearly fully into the elongate inversion support catheter.

[000122] In FIG. 7A, the inverting tractor mechanical thrombectomy apparatus does not include (or require) the use of an intermediate catheter, though one may be used with it (not shown). The apparatus includes an outer elongate inversion support catheter 707 that includes a stop 704 at or near the distal end. This stop 704 may be a lip, flange, protrusion, or the like, and may provide a larger diameter region that engages with a complimentary stop 816 on the end of the tractor tube 715. The opposite end of the tractor tube is connected to a puller (puller micro catheter 719) similar to the variations described above. When delivered to the clot region of a vessel the puller is withdrawn (preferably loosely, to avoid compressive forces on the elongate inversion support catheter), so that the tractor tube is withdrawn into the elongate inversion support catheter except for small portion at the distal end that is prevented from rolling into the elongate inversion support catheter by the stop on the tractor tube engaging with the stop on the elongate inversion support catheter. The apparatus may be driven over a guidewire 717, as shown, until it is proximate to the clot. FIGS. 7B and 7C illustrate a two-step method for deploying the apparatus that may be used. In This example, the apparatus may be deployed by advancing the puller distally (e.g., "pushing" the puller 775), as shown in FIG. 7B. Thus, the tractor portion will be inverted over itself, ahead of the distal end of the elongate inversion support catheter. Thereafter, as shown in FIG. 7C, the elongate inversion support catheter may be advanced distally into the pocket 777 formed by the inverted tractor tube. The apparatus is then ready for the puller to be pulled proximally to roll the tractor tube back into the elongate inversion support catheter so that it may capture a clot, and may therefore be positioned against or adjacent to the clot.

[000123] FIGS. 8A-8C show an alternative method of deploying the apparatus shown in FIG. 7A. FIG. 8A is similar to FIG. 7A, showing delivery of the apparatus to the clot over a guidewire 717. The apparatus includes the tractor tube 715 and elongate inversion support catheter 707, which include a stop on one or both of the elongate inversion support catheter

and/or tractor tube to engage the distal end of the elongate inversion support catheter with the end of the tractor tube. The apparatus may be delivered with the tractor tube retracted so that it does not tension the elongate inversion support catheter. As shown in FIGS. 8B and 8C, once near the clot, the tractor tube may be repositioned outside of the elongate inversion support catheter so that it can be rolled and used to capture a clot. In FIG. 8B, the elongate inversion support catheter is pulled proximately 851; since the distal end of the elongate inversion support catheter is engaged with the tractor tube to prevent it from sliding off of the end of the elongate inversion support catheter, when the elongate inversion support catheter is pulled proximally while holding the puller in place (or advancing it distally), the tractor tube will extend out of the elongate inversion support catheter and invert, as shown. Thereafter, as shown in FIG. 8C, the elongate inversion support catheter may be advanced distally between the fold formed by the inverted tractor tube, and the entire apparatus advanced distally back to the clot 833, a shown. Once proximate the clot, the puller may be pulled proximally to capture the clot and remove it.

[000124] FIGS. 9A-9K illustrate one method of removing a clot using a preloaded assembly of an inverting tractor mechanical thrombectomy apparatus within an intermediate catheter, such as the variation shown in FIG. 3A. In general, a method of using any of the preloaded assemblies of inverting tractor mechanical thrombectomy apparatuses described herein (e.g., in FIGS. 3A-5B), may be delivered over a wire, through a guide catheter (or a sheath or balloon guide catheter) to a clot fact, e.g., proximate the clot. The tractor tube may then be aligned so that it warps around and over the distal end of the elongate inversion support catheter and rolls into (everts) the elongate inversion support catheter. Once in positioned (against the face of the clot), the elongate inversion support catheter may be pushed distally while pulling proximally on the puller to ingest the clot, until the full length of the tractor tube is pulled proximally and rolled into the elongate inversion support catheter, unless the apparatus includes a stop to prevent it from entering the elongate inversion support catheter. Aspiration may be applied through the elongate inversion support catheter and/or the puller (when a puller micro catheter is used) to ensure that the clot remains in contact with the distal end of the elongate inversion support catheter and tractor. The intermediate catheter may then be advanced to the distal end of the elongate inversion support catheter (and aspiration may be applied through the intermediate catheter. The elongate inversion support catheter may be withdrawn proximally through the intermediate catheter while applying aspiration, which may both ease retraction of the apparatus within the intermediate catheter and may remove any residual clot portions.

[000125] For example, in FIG. 9A, the apparatus has been delivered to the region adjacent to the clot and deployed out of the intermediate catheter 903. The elongate inversion support catheter 907 and puller 919 are advanced together distally to the clot 933 face over a guidewire 917. The elongate inversion support catheter includes a marking 963 that is visible under, for example, fluoroscopy or other imaging modality. In FIGS. 9A-9K this marking on the elongate inversion support catheter is a band. In FIG. 9B, the elongate inversion support catheter is advanced distally while simultaneously or sequentially pulling the puller proximally so that the tractor tube is rolled over the distal end opening of the elongate inversion support catheter and extends slightly within the elongate inversion support catheter (shown biased against the inner diameter of the elongate inversion support catheter). The tractor extending out of the elongate inversion support catheter is pushed against the clot face. In FIG. 9B, the guidewire has been left in place; alternatively, as shown in FIG. 9C, the guidewire may be removed. Alternatively, or additionally, the intermediate catheter 903 may be withdrawn proximally, which may fully unsheathe the tractor, including the distal end of the tractor. This may permit the tractor tube to roll freely over the distal end of the elongate inversion support catheter. The intermediate catheter may be locked to the elongate inversion support catheter, so that the two catheters move together wile drawing the puller proximally to roll the tractor tube over the elongate inversion support catheter, as shown in FIG. 9D. In this example, aspiration (e.g., vacuum) may also be applied, e.g., from within the puller and/or elongate inversion support catheter, which may help the rolling tractor to engage with the apparatus, even before rolling the tractor into the elongate inversion support catheter by withdrawing the puller proximally.

[000126] As shown in FIG. 9E, the puller 919 (PMC) may be drawn proximally while the elongate inversion support catheter 907 is advanced towards/into the clot. As previously mentioned, the intermediate catheter 903 may optionally be advanced with the elongate inversion support catheter (e.g., the two may be coupled together for this portion of the method. This step may be continued to ingest the clot. FIG. 9F shows the clot 30% ingested while still rolling the tractor tube into the elongate inversion support catheter (e.g., by pulling on the puller and/or pushing on the elongate inversion support catheter). FIG. 9G shows the clot 80% ingested and rolling into the elongate inversion support catheter. By FIG. 9H, the tractor tube has been fully withdrawn into the elongate inversion support catheter. In this example, the marker 963 on the elongate inversion support catheter aligns with either a marker on the puller or the puller itself (if it is visible under imaging). FIG. 17 shows another example of an elongate inversion support catheter (slotted 1709 to have a high column

strength and high flexibility) in which the distal end region 1707 is marked with a platinum material to make it visible when imaging (e.g., with fluoroscopy). In FIGS. 9A-9H, the entire clot (100%) is captured by the tractor tube within the elongate inversion support catheter once the entire tractor tube has been rolled into the elongate inversion support catheter. However, this is not necessarily the case, as will be described below, in some variations additional clot may be drawn into the elongate inversion support catheter and/or the intermediate catheter by applying a combination of mechanical action (e.g., pulling the clot with the portion captured by the tractor and suction. For example, FIG. 9I shows the (optional) use of aspiration through the intermediate catheter (and in some cases, the elongate inversion support catheter). The aspiration may be left on while withdrawing the apparatus proximally, as shown in FIG. 9J. As mentioned, this may remove any remaining clot. Alternatively, or additionally a second apparatus may be installed through the intermediate catheter and delivered to the deployment site (with the intermediate catheter left in position. Finally, as shown in FIG. 9K, an angiogram may be performed through the intermediate catheter to confirm that the vessel is opened. If not, additional procedures (e.g., another preloaded assembly of an inverting tractor mechanical thrombectomy apparatus may be inserted and used to remove clot) may be performed.

[000127] In general, when deploying any of the inverting tractor mechanical thrombectomy apparatuses described herein, and in particular, the pre-loaded inverting tractor mechanical thrombectomy apparatuses, the deployment may include the general steps described below. These steps may be customized as indicated herein. First, obtaining access with sheath to the patient's common carotid or ICA. Inject contrast through the sheath to image the vessel. Before, during or shortly after, on the back table (e.g., where the proximal end of the mechanical thrombectomy apparatus is held/prepared), flush the intermediate catheter (I.C.) and connect it to a first rotating hemostatic valve (RHV A), then introduce the elongate inversion support catheter ("880 Device"), puller and tractor through RHV A, e.g., using a peel-away sheath. The elongate inversion support catheter may then be positioned relative to the I.C., e.g., within about 1 cm proximal to the tip of the I.C., as shown in FIG. 3A, and locked in position relative to the I.C. RHV A may then be tightened. A second RHV (e.g., RHV B) may be coupled to the pusher and flushed, and RHV A may be flushed as well. Flush lines may be connected. A guide wire may be loaded through the apparatus. The puller may be locked in position (e.g., as shown in FIG. 3A, extending approximately 1 cm or more from the distal end opening of the I.C.) for tracking.

[000128] The apparatus may then be tracked to the desired location (e.g., near the clot). Once in position, the apparatus may be used to perform the thrombectomy. For example, RHV A and B may be loosened. The coupling between the elongate inversion support catheter and the I.C. may be released, as may any coupling between the puller and the I.C. and/or elongate inversion support catheter. The elongate inversion support catheter may be advanced over the puller until its distal end meets the distal connection between the tractor tube and the puller. The I.C. may be pulled back to unsheathe the tractor tube. The elongate inversion support catheter and I.C. may again be locked in position relative to each other. RHV A may be tightened, and the elongate inversion support catheter may be advanced to the clot face (possible with aspiration through the puller). With a slight pressure forward (distally) on the pusher (and/or I.C.), the puller may be pulled slowing proximally to ingest the clot. Alignment markers on the elongate inversion support catheter and the tractor (e.g., a region at the end of the tractor tube on the outside of the elongate inversion support catheter, or a region of the puller) may be monitored to indicate when the tractor tube is completely inverted into the elongate inversion support catheter, and the user may stop pulling proximally on the puller. RHV A may be loosened and the IC may be advanced, with aspiration, over the elongate inversion support catheter, which may remove any excess clot or pieces of clot. The elongate inversion support catheter, puller and tractor may then be withdrawn proximally through the I.C. The I.C. may remain in position and contrast applied to again image through the vessel and a TICI score determined.

[000129] Another example of the operation of a pre-loaded assembly of an inverting tractor mechanical thrombectomy apparatus is shown in FIGS. 10A-10D. For example, in FIG. 10A, the pre-assembled apparatus is similar to that shown in FIG. 3A, above. The apparatus includes an intermediate catheter 1003 that entirely houses the elongate inversion support catheter 1007 during the tracking through the tortious vessel 1081. A puller (pull micro catheter 1019) passes through the elongate inversion support catheter, and include a tractor tube (shown as a knit tractor tube 1015) extends from an attachment site 1008 approximately 2 mm proximal to the distal end of the puller. The opposite end of the tractor tube is held between the elongate inversion support catheter and the intermediate catheter (within the intermediate catheter). In FIG. 10A, the guidewire 1017 has been inserted distally to and through a clot 1033, and the pre-loaded assembly of the inverting tractor mechanical thrombectomy apparatus is locked (e.g., so that the puller extends distally a predetermined distance and the elongate inversion support catheter is locked relative to the intermediate catheter) and advanced distally over the guide wire until it reaches the clot face.

[000130] In FIG. 10B, the puller distal end is adjacent to the clot face, and the puller may be locked in position (e.g., at the handle) while the elongate inversion support catheter is unlocked from the intermediate catheter and advanced distally over the puller and between the gap formed by the tractor tube. In this example, as the elongate inversion support catheter is advanced distally, the tractor tube may compress to a compressed/jammed state, particularly when a knit material is used, before the elongate inversion support catheter slides within its inner diameter. In FIG. 10C, the elongate inversion support catheter is advanced distally 1068 over the puller (and under the tractor tube) until the distal end of the elongate inversion support catheter is aligned with the clot, as shown. Finally, as shown in FIG. 10D, the puller may be pulled proximally 1091 while the elongate inversion support catheter is pushed distally 1093 to roll the tractor into the elongate inversion support catheter and capture the clot 1033.

[000131] As discussed above, in some variations the tractor tube may be completely rolled into the elongate inversion support catheter before a clot has been completely removed. In such cases, it may be helpful to ensure that the clot is not ripped or fragmented during the process. In order to prevent this, the apparatus may be adapted to limit the movement of the puller and/or the tractor, in addition to (or instead of) using the vacuum and intermediate catheter, as described above. FIGS. 11A-11C illustrate an example in which the clot is too long for the tractor tube apparatus to fully engulf. In FIG. 11A, similar to FIG. 9H, the clot has been captured by the tractor tube 915, which is shown fully retracted into the elongate inversion support catheter 907. The user may detect that the tractor tube has been fully retracted because either the puller 919 maybe limited to prevent it moving further proximally when the tractor tube is fully retracted into the elongate inversion support catheter. Alternatively, or additionally, the tractor tube may include a first marker 963 that may align with a marker on the puller 965 when the tractor tube is fully retracted, as shown in FIG. 11A. Unlike FIG. 9H, however, in this example, the clot has not been fully captured, and some of it remains outside of the tractor and elongate inversion support catheter.

[000132] If the clot is not fully captured by the apparatus, there is a risk that continuing to pull on the clot may disrupt it, e.g., cutting it into fragments. To avoid this, the apparatus may be configured to prevent the user from continuing to apply force to the clot once the tractor has been fully deployed. As mentioned, the user may be instructed to stop drawing the puller proximally once one or more markers indicate that the tractor tube has been retracted to a predetermined position. In particular, it may be beneficial to prevent the tractor tube from fully inverting over the tractor tube, as described in FIG. 12A, below.

[000133] In some variations, the apparatus may include a stop (e.g., in a handle region) preventing or limiting the puller to prevent it from extending beyond a predefined limit. For example, the limiter or puller stop may be configured as a physical stop on the puller portion of a handle that limits the travel of the puller.

[000134] FIGS. 11B-11C illustrate a method for handling this situation without tearing (and risk harming the patient). In FIG. 11B the elongate inversion support catheter is stopped from advancing any further distally, and instead the intermediate catheter may be advanced distally (with or without aspiration through the intermediate catheter). In FIG. 11C, the clot, including the portion outside of the elongate inversion support catheter, has been fully captured within the intermediate catheter, as shown.

[000135] FIG. 12A illustrates another example of a configuration of the apparatus (and in particular the tractor tube) in which the distal end of the tractor tube is configured with a non-compliant material 1205 (e.g., a cuff) so that it cannot flip or roll over the distal end of the elongate inversion support catheter. This may prevent the user from pulling the tractor all the way around the catheter. In some variations, the cuff is configured to permit the tractor tube to flip over the distal end of the elongate inversion support catheter. For example, a cuff on the outer end of the tractor tube may include one or more slits (e.g., between one and 20 slits or slots) extending along its length configured to permit it to flip and invert, but providing an increase in the stiffness of the tractor tube. In any of these variations, the cuff on the outer end of the tractor tube may include a marker (e.g., radiopaque material); for example, the cuff may be a polymer including a platinum or other radiopaque material suspended in it. FIG. 12B illustrates an example of a cuff 1205' at one end of a flexible tube ('tractor') 1207 that has been inverted over the inversion support catheter 1209.

[000136] As mentioned above, any of these apparatuses may include one or more features that may be used to improve tracking, and in particular, by preventing the elongate inversion support catheter from stiffening. This may be a problem with the high column-strength, highly flexible elongate inversion support catheters that include one or more slot or cut-out regions along their length. One feature that may be included, discussed above, is the use of configurations in which the tractor tube, and particularly knitted tractor tubes, are delivered in a compressed state, rather than a stretched state. As mentioned above, pinning one end of the tractor tube in the intermediate catheter may be configured to do this in some of the preloaded configurations described above. FIGS. 13A-16B illustrate other variations. For example, FIG. 13A shows a knitted tractor tube 1315 over an elongate inversion support catheter 1307 that is stretched. The woven links are connected end-to-end (forming a helical winding pattern

around the elongate inversion support catheter). FIG. 13B illustrates the resulting compressive load on the catheter tip in this configuration; friction loads on the knit during tracking may pull on the distal end of the elongate inversion support catheter, causing it to stiffen in compression. However, such compressive loads may be lessened or eliminated by using a woven material held in a compressed configuration, as shown in FIG. 13C. In this example, the interlocking loops forming the weave are overlapping in a compressed state.

[000137] This compressed state may be maintained by pinning, securing or holding one or more ends or lengths of the tractor tube in place when the tractor tube is compressed. Any appropriate mechanism for holding the compression may be used. For example, the apparatus may include a stop or lock to engage with one or more regions of the tractor tube and hold it in a compressed configuration during tracking. FIGS. 14A-14D illustrate variations of structures (stops) that may be used to hold the woven tractor tube on the outside of the elongate inversion support catheter in a longitudinally compressed state. In FIG. 14A, the elongate inversion support catheter includes a polymeric lip, ridge or rim (stop) 1401 that may secure one end of the woven tractor tube against the elongate inversion support catheter with the tractor tube in compression. Distal force may be applied to pull the tractor tube out of the stop (not shown). FIG. 14B shows a Nitinol (NiTi) braid 1403 that holds the knitted tractor tube in compression along the length of the elongate inversion support catheter. FIGS. 14C shows a similar NiTi braids with exposed ends that engage with the knit of the tractor. FIG. 14D a NiTi knit segment also includes projections that engage with the knit, as shown.

[000138] FIGS. 14A-14G show similar finger-like elements that may be used to engage with the knit (the loops formed by the knit) of the tractor. In FIG. 15A. the loose ends of the woven material form short "fingers" that are exposed and engage with the knitted tractor, as shown in FIG. 15B. In FIG. 15C, as similar construction having longer "fingers" of loose ends is shown, and FIG. 15D shows the fingers engaging with the knitted tractor tube. FIG. 15E shows "fingers" formed by the loose ends of the weave located approximately 1 cm from the tip of the elongate inversion support catheter, and FIG. 15F shows these elements engaging the knitted tractor tube. FIG. 15G is another example of a set of fingers formed of projecting metal wires that may be used to removably hold the tractor tube against the elongate inversion support catheter in compression. FIG. 15H shows an example of a variation formed by a metal wire having very long "fingers", engaged with a knitted tractor tube, holding it in compression.

[000139] Alternatively, or additionally, any of these apparatuses may include a housing or garage that may be used to hold the knitted tractor tube in compression. For example, FIG.

16A and 16B illustrate one example of this configuration, in which a housing ('garage') region 1602 formed of a 48-end braided material, is used to hold the knitted tractor tube 1604 in a compressed state at one of its ends on the elongate inversion support catheter. FIG. 16B shows a similar example of a elongate inversion support catheter having a 10 mm long 'garage' region made of a braided material 1608.

REMOVAL OF LARGE CLOTS

[000140] Any of the mechanical thrombectomy apparatuses described herein may be adapted to remove large clots. In general, a large clot may be large in either or both diameter (outer diameter) and length, and may be large relative to the mechanical thrombectomy apparatus. For example, the clot may have a diameter that is larger than the diameter of the apparatus (e.g., larger than the expanded diameter of the flexible tube which captures the clot). Thus, the apparatus may be configured to capture and compress the clot so that it may be withdrawn from the lumen of the vessel, into the lumen of the intermediate catheter and/or inversion support catheter. The apparatus may also be configured to capture and remove clots that are longer than the ability of the flexible tube to hold.

[000141] In general, FIGS. 18A-18J show a method of removing a clot 1815 from a vessel 1815 as described herein, in which a vacuum (suction) may be applied through the puller to make and confirm initial contact with the clot. For example, FIGS. 18A-18B illustrate an example of an apparatus that is preloaded and configured to both track to the clot and to remove the large-diameter clot 1815. For example, in FIG. 18A, the apparatus (mechanical thrombectomy apparatus or inverting tube apparatus) includes an intermediate catheter (IC) 1801, an inversion support catheter ("outer catheter") 1803 within a lumen of the intermediate catheter, a puller (shown as a puller catheter) 1805 within a lumen of the inversion support catheter, and a flexible tube (e.g., knit tube) 1809 extending over the inversion support catheter. The flexile tube has a first end 1826 coupled at a distal end region of the puller and a second end 1824 comprising a cuff 1825 that is less flexible that a region of the flexible tube adjacent to the cuff, wherein the flexible tube is configure to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the flexible tube rolls and inverts over a distal end of the inversion support catheter 1823. The apparatus is shown over a guidewire 1807. In this example, multiple regions include markers that may be visualized, e.g., under fluoroscopy. For example, the end of the inversion support catheter includes a marker 1823, as does the distal end of the puller 1826. The puller may

also include an intermediate marker 1821, shown aligned with the cuff 1825; the cuff also includes a marker. The assembly is shown within the vessel 1813.

[000142] The apparatus may be distally advanced over the guidewire and positioned adjacent to the clot 1815. The apparatus may initially be pre-loaded in a tracking configuration, in which the outer (inversion support) catheter 1803 is retracted into the lumen of the intermediate catheter 1801 while the puller (puller catheter 1805) with the attached flexible tube 1809 extending proximally from the distal end 1826, is moved distally to track over the guidewire. In FIG. 18B, the apparatus is adjusted into a clot-grabbing configuration in which the inversion support catheter 1803 is extended distally towards the distal end of the apparatus, although it is still positioned proximal to the puller distal end 1827. The intermediate catheter 1801 may also optionally be withdrawn proximally, as shown in FIG. 18C, which in some variations may allow the flexible tube to expand outwards (see, e.g., FIG. 26B).

[000143] FIG. 18C1 shows an example of a prototype device corresponding to the apparatus configured as shown in FIG. 18C. In this example the flexible tube is a woven flexible tube 1809 that is shown extending distally from the distal end face 1827 of the puller. The puller is shown over a guidewire 1807.

[000144] Once the apparatus is in position near the clot, suction may be applied through the puller catheter, as shown in FIG. 18D. This focal suction (aspiration) 1840 may be applied while advancing the apparatus distally to engage the clot, as shown in FIG. 18E. In some variations, the guidewire is left in place (not shown) or it may be optionally removed (as shown in FIGS. 18D-18E). Once the distal-facing end of the puller is engaged with the clot, as shown in FIG. 18E, connection to the clot may be detected by observing the flow and/or pressure through the puller from the suction 1840'. Thereafter, the puller may be drawn proximally and/or the inversion support catheter may be moved distally so that the flexible tube rolls over the distal end opening of the inversion support catheter (these motions are shown by the large arrows). In FIG. 18F, approximately 30% of the clot has been drawn into the inversion support catheter by rolling 1866 the flexible tube. In FIG. 18G, more, but not all (e.g., approximately 70%) of the clot has been ingested, though a substantial amount of clot remains outside of the inversion support catheter and flexible tube. The vacuum may be left on, or it may be turned off while pulling the puller proximally to engulf/grab the clot. Heavy arrows indicate movement of the components of the apparatus, such as the intermediate catheter, which may be advanced distally, the inversion support catheter, which may also be advanced distally, and the puller, which may be withdrawn proximally. These motions may

be coordinated by the handle (not shown) and/or performed manually by the user. Once the flexible tube has reached the distal end of the inversion support catheter, it may stop or be stopped, to prevent it from rolling over the distal end. Rolling of the second end of the flexible tube over the inversion support catheter distal end may cut or break the clot off, which may be highly undesirable, as it may potentially release the clot, resulting in complications, and/or may require additional removal steps.

[000145] In FIG. 18A-18J the second end of the flexible tube includes a cuff 1825 that may prevent the flexible tube from rolling over the distal end when pulling proximally on the puller, as shown in FIG. 18H. In FIG. 18I, the intermediate catheter is shown advancing distally beyond the cuff and the distal end of the intermediate support catheter. In this configuration (as also described in FIGS. 22A-22B) the motion of the intermediate catheter 1801 may invert the cuff 1825 over the distal end of the inversion support catheter 1803 and against the clot 1815 without breaking or disrupting the clot. A vacuum (suction) may be applied through the intermediate catheter is also shown in FIG. 18I (by the small arrows). In FIG. 18J, the flexible tube, puller and inversion support catheter are then drawn proximally into the intermediate catheter along with the un-engulfed portion of the clot, either by driving the intermediate catheter distally over them, and/or by pulling the inversion support catheter (which may be pulled with the puller) proximally.

[000146] Thus, in the example shown in FIGS. 18A-18J, a larger clot, both in diameter and in length, may be removed by the apparatus.

[000147] FIG. 19 illustrates another example of an apparatus that is configured or adapted to have a smaller diameter (outer diameter) than the vessel and the clot but may be capable of grabbing and removing larger clots (e.g., clots having an outer diameter that are more than 1.5x, more than 2x, more than 2.5x, etc.) the outer diameter of the flexible tube capturing the clot.

[000148] In FIG. 19, the apparatus includes a flexible tube that is configured as a knit tube. In this example the region of the knit tube 1901 on the outside of the inversion support catheter 1903 hugs the outer diameter (OD) of the inversion support catheter. In order to maximize the ingesting efficiency/power of the knit when used to capture larger clots, the stich length of the knit may be tuned to the diameter of the vessel in which the apparatus is to be used. For example, in general, the stitch length 1905 is the lateral extent of a loop formed by the knit. In general, the outer diameter 1909 of the inversion support catheter may be known, and the inner diameter of the vessel (which may be equivalent to the outer diameter of the clot) may also be known or approximated (e.g. from fluoroscopy). Thus, the user, such

as a surgeon or physician, may select the appropriate flexible tube (e.g., knit) based on the selected size. For example, in FIG. 19, twice the knit or stich length (knit/stich length) plus the outer diameter of the inversion support catheter may be approximately equal to the ~Vessel ID in order to maximize power/efficiency when grabbing and/or removing clot. The woven stitches may act as fingers or extensions that swing around the distal end opening of the inversion support catheter 1907, as shown in FIG. 19. Thus, for vessel inner diameters of between set ranges, the knit/stitch length may be determined. In general, the knitted tube may comprise a filament knitted to form a plurality of interlocking loop stitches, wherein each loop stitch has a stitch length that is between the difference of 25% of the ID and one half the outer diameter (OD) of the inversion support catheter and 65% of the ID and one half of the OD of the inversion support catheter. For example, twice the knit/stitch length plus the inversion support catheter OD may be equal to a range of vessel inner diameters (IDs), such as between about 90%-110% of the vessel ID, between about 80-100% of the vessel ID, between about 60-100% of the vessel ID, between about 50-100% of the Vessel ID, between about 30-100% of the vessel ID, between about 20-100% of the vessel ID, between about 10-100% of the vessel ID, and/or between about 50-130% of the vessel ID.

[000149] In practice for most neurovascular and/or peripheral vascular applications, the knit/stitch length may be between about 0.5 mm and about 10 mm (e.g., about 0.5 mm, between about 0.1 to 0.5mm, about 1. mm, between about 0.5 – 1. mm, about 1.5mm, between about 1. -1.5mm, about 2. mm, between about 1.5 – 2. mm, about 2.5 mm, between about 2. - 2.5 mm, about 3. mm, between about 3. – 3.5 mm, between about 0.5mm – 10mm (e.g., by any 0.5 mm increment), etc.

[000150] In general, the apparatuses described herein may compress a clot. For example, FIG. 20A illustrates an example of a clot 2005 shown within the bottle on the top of the figure that is 5 cm long and has an outer diameter of about 15 mm. A portion of an inverting mechanical thrombectomy apparatus is shown in the middle of FIG. 20A, showing an inverting support catheter that is an 8 French (8F) catheter 2003 over which a flexible tube, formed of a knit material 2001, has been arranged, including coupling to one end of a puller (not shown). The flexible (knitted) tube in this example is biased to expand in an uploaded state to an outer diameter than is much greater than the outer diameter of the inverting support catheter. This apparatus was used to remove the clot 2005, which resulted in compressing the clot 2007, as shown in FIG. 20A, bottom.

[000151] Another example of an apparatus for removing clot is shown in FIG. 20B, showing a 10 mm diameter clot 2005' being grabbed and engulfed by a flexible tube 2001'

having an expanded outer diameter of 5 mm extending over a 3 mm outer diameter inversion support catheter.

[000152] In general, the amount of clot that may be contained (e.g., "eaten") by the rolling and inverting devices described herein in a single pass may be a function of the diameter of the clot, the length of the flexible tube, the structure of the flexible tube (e.g., woven, knitted, etc.) and most importantly, the expanded outer diameter of the flexible tube. For example, FIG.S 21A and 21B illustrate the relationship. In FIG. 21A, the graph shows the length of the flexible tube (e.g., length of the woven tube, L, needed to fully engulf a clot of 15 mm diameter and 5 cm length. In general, the results show that for compressible clots, the length of the flexible tube necessary to fully engulf a 5 cm length of 15 mm diameter clot (depending on the type of clot, including its compressibility) may be between about 6. mm and about 60 mm. Thus, as a rough rule of thumb, as much as a 12:1 ratio of flexible tube to clot may be necessary at this exemplary dimension of a clot. FIG. 21 B illustrates example of different apparatuses 2105 used to generate the data shown in FIG. 21A.

[000153] In general, the knit expands to a larger diameter than the outer diameter of the catheter once the apparatus is delivered to a clot site when the vessel ID is much larger than the catheter OD. Furthermore, the flexible tube (e.g., knit tube) may expand to a larger diameter than the catheter once it is delivered to clot site, particularly when the vessel ID is much larger than the catheter OD. This is illustrated, e.g., in FIG. 20B. Typically, to maximize the efficiency/power of the flexible tube to ingest a clot, when the catheter is much smaller than the vessel ID/clot OD, it may be helpful to have an expanded outer diameter of the flexible tube such that it is at least 10% (e.g., at least 20%, 30%, 40%, 50%, 60%, 70%, 80%, etc. of the Vessel ID, or any range between any two of these percentages). For example, it may be preferable for the expanded flexible tube to have at least 30% of the vessel ID. Further, as mentioned above, the expanded diameter of the flexible tube may be at least about 30%, 50%, 100%, 150%, 200%, 250%, 300%, 400%, 500%, 600%, etc. of the catheter OD (or any range between any of these two percentages).

[000154] As shown in FIG. 19, and discussed above, the extension of the loop stiches in flexible tubes that are knitted (forming "fingers" on the knit, or protrusion that roll and extend beyond the expanded OD of the rest of the flexible tube) may further help grab and remove clot. These extensions for an apparatus such as shown in FIG. 19 (or 26A) may be between about 0.5mm – 10mm (e.g., between any two value in this range, typically by 0.5 mm increments, including any range between any such increments).

[000155] FIGS. 22A and 22B illustrate an example of a cuff as discussed above. In the example shown in FIGS. 22A and 22B, the cuff 2201 is made of (or includes) a radiopaque polymer filling the cuff at the second end of knit tube. This may allow it to be seen under fluoroscopy, and may also prevent unraveling of the knitted tube. In FIG. 22A, the cuff includes a plurality of lateral slits 2205 (e.g., four are shown, though 3, 4, 5, 6, 7 or more slits may be used). These slits may allow the cuff to flip over inversion support catheter, e.g., when driven by an intermediate catheter 2203, as shown in FIG. 22B. In this example, the cuff may be formed of a polymer such (e.g., as Pebax 45D + 80% tungsten filled). The cuff may have a wall thickness of less than about 0.025 inches when laminated on knit, and may have a length of between 1 and 3 loop stitches (e.g., about 1.5 knit stitches long).

[000156] FIGS. 23A-23B and 24A-24B illustrate examples of a proximal end of a mechanical thrombectomy apparatus, showing components of the apparatus (e.g., guidewire 2305, inner/inversion support catheter 2307, puller 2309, and intermediate catheter 2311. FIG. 23B shows another example, of a proximal end of the mechanical thrombectomy apparatus showing manual controls, including vacuum attachment ports (RHVs) 2317, 2319, for the different regions, as well as the puller hub 2321 at the proximal end.

[000157] FIGS. 24A-24B illustrate another example of a set of proximal end controls for a mechanical thrombectomy apparatus. In FIG. 24A the apparatus control region is shown in a first puller position (prior to pulling the clot in), and includes the inner (e.g., puller) rotating hemostat valve (RHV) 2417, outer (intermediate catheter) rotating hemostat valve (RHV) 2419, as well as the puller hub 2421. One or more stop elements 2423, 2423' may be included on the puller to prevent it from pulling and completely inverting the flexible tube over the distal end of the inversion support catheter, as described above; flush ports 2432, 2433 are also shown. In FIG. 24B the apparatus control region is shown after pulling the clot (showing the puller hub extended proximally).

[000158] FIG. 25 illustrate an example of a mechanical thrombectomy apparatus in which the flexible tube 2505 is configured to cut tissue as it rolls into the inversion support catheter. In this example, the flexible tube is a knitted tube that includes sharp cutting edges that may be used to cut through tissue. The apparatus may be used over a guidewire to prevent the cutter from dissecting the vessel wall.

[000159] FIGS. 26A-26B illustrate two exemplary side perspective views of mechanical thrombectomy apparatuses. In FIG. 26A, similar to that shown in FIGS. 18A-18J, the apparatus include a flexible (e.g., knitted) tube 2601 that is attached at the first end to a puller catheter 2603 and is configured to expand within the inversion support catheter to an outer

diameter that is greater than 40% (shown here as greater than 90%) of the inner diameter of the inversion support catheter 2605, driving the region of the flexible tube within the inversion support catheter against the walls, even when unloaded by clot. The other region (un-inverted) of the flexible tube along the outer diameter of inversion support catheter is shown as snug with the inversion support catheter in the un-constrained configuration. This results in the Y-shaped distal profile 2609, for the inverting flexible tube, which may help grab even larger diameter clots.

[000160] FIG. 26B illustrates another example of a mechanical thrombectomy apparatus in which the expanded outer profile of the flexible tube 2601' is expanded beyond the outer diameter of the inversion support catheter 2605 near the first end where it attaches to the puller 2603, but the second end 2621, that is freely sliding over the inversion support catheter, has a much smaller (nearly snug) expanded diameter. This region may also or alternatively include a cuff as described herein.

Re-sheathing the tractor

[000161] Any of the inverting tube apparatuses described herein may be configured so that the inverting tube apparatus may be retracted (e.g., re-sheathed) into an intermediate catheter. In particular, any of the inverting tube apparatuses that include a cuff at one end (e.g., at the distal end) of the inverting flexible tube may be re-sheathed into the intermediate catheter after deployment, including after capturing all or a portion of a clot. FIGS. 27A-27C illustrates operation of an inverting tube apparatus having a cuff on one end of the flexible tube. As shown in FIG. 27A, the inverting tube apparatus includes an inversion support catheter 2707, a puller 2705 within a lumen of the inversion support catheter, and a flexible tube 2709 extending over the inversion support catheter that is coupled at a first (e.g., proximal) end to the puller, and is configured to roll and invert over the open distal end of the flexible inversion support catheter. In some examples, the flexile tube 2709 may be a woven or knit material. A second end (e.g., distal) end of the flexible tube 2709 may include a cuff 2711 that is less flexible that the region of the flexible tube adjacent 2715 to the cuff. In FIG. 27A, the apparatus is shown in a deployed or partially deployed configuration, in which the flexible tube 2709 and inversion support catheter has been extended out of the distal end of an intermediate catheter 2713, also referred to as a sheath). As discussed above, the apparatus may be delivered to the clot and deployed from out of the intermediate support catheter, including using a guidewire (not shown).

[000162] As shown in FIG. 27B, the flexible tube 2709 is configure to be pulled proximally into the inversion support catheter 2707 by pulling 2715 the puller 2705 proximally so that the flexible tube rolls 2719 and inverts over a distal end of the inversion support catheter; the cuff 2711 may slide along the outside surface of the inversion support catheter. As the device is deployed, the distal end 2714 of the cuff 2711 extends further from the distal end 2715 of the intermediate catheter (sheath 2713), which may have a distal end face that faces the deployed cuff 2711, se

[000163] At any point, either before or after flexible tube has completely, or mostly completely, withdrawn and inverted into the inversion support catheter, the apparatus, and in particular the inversion support catheter, flexible tube, cuff, and any captured clot material, may be withdrawn or re-sheathed back into the intermediate catheter 2713. However, in some cases, including (but not limited to) variations having a cuff 2711 at the second (e.g., distal) end of the flexible and inverting tube 2709 may make it difficult to re-insert the cuff back into the intermediate catheter, as illustrated in FIG. 27C.

[000164] In FIG. 27C, the distal face or end 2717 of the intermediate catheter 2713 is shown catching on the distal end 2714 of the cuff 2711 when attempting to re-sheath the sub-assembly including the cuff 2711, flexible tube 2709 and inversion support catheter 2707 back into the intermediate catheter 2713. Although in some variations this may be desirable, as it may help push the cuff and end of the flexible inverting tube off of the end of the inversion support catheter (which it may further envelop and/or cut the clot, as described above in relation to FIGS. 18H-18I), in some variations it may be desired to leave the cuff 2711 on an outside of the inversion support catheter 2707. In this case, as shown in FIG. 27C, if the distal end 2717 of the intermediate catheter 2713 catches on the end face 2714 of the cuff 2711, the cuff may be driven forward, towards the end of the inversion support catheter, as shown. In FIG. 17C, this is shown also driving 2725 the flexible inverting tube 2709 towards the end of the inversion support catheter.

[000165] To avoid this, the apparatus may be configured to include one or more **cuff retainers** that hold the cuff level and/or limit its movement so that it may slide into the intermediate catheter. FIGS. 28A-28C, 29A-29C, 30A-30C, and 312A-31C all describe cuff retainers that may be used.

[000166] For example, FIGS. 28A-28C illustrate an example of an inverting tube apparatus that includes a cuff at one end of the inverting flexible tube and a cuff retainer, in which the cuff ad flexible tube over the inversion support catheter may be re-sheathed into the intermediate catheter after deployment. The cuff retainer may facilitate the re-sheathing of

the cuff and flexible tube into the distal end of the intermediate catheter by applying a force to hold the cuff in a fixed position on the outside of the inversion support catheter. In some variations, the cuff retainer may also or alternatively hold the face of the cuff level relative to the distal end of the intermediate catheter.

[000167] In FIG. 28A, the inverting tube apparatuses include a cuff 2811 on the end of an inverting flexible tube 2809 that inverts into the inversion support catheter 2807. A puller (or pusher) 2805 may slide within the inversion support catheter and is attached to the flexible tube 2809. The puller (or pusher) in any of these examples may be a catheter and may pass a guidewire. The cuff retainer in this example is one or more leashes or tether 2835 (e.g., a filament, wire, strand, cable, etc.) that is connected at one or more points on the cuff and one or more locations on the outer surface (or through the outer surface) of the inversion support catheter. The cuff retainer shown is helically arranged over the inversion support catheter so that it may be unwound or unspooled as the puller/pusher pulls and inverts the flexible tube into the inversion support catheter. The cuff retainer may be elastic. In some variations the cuff retainer may include multiple tethers that are spaced circumferentially around the cuff (e.g., spaced equal distances apart).

[000168] The inverting flexible tube sub-assembly (cuff, inverting flexible tube, and inversion support catheter) may be re-sheathed into the intermediate catheter 2813 after the puller has pulled the flexible tube into the inversing support catheter, so that the cuff has slid over the inverting support catheter to a predetermined position 2833 towards the distal end of the inversion support catheter, as shown in FIG. 28B.

[000169] Once the cuff retainer 2835 is engaged and applying force against the cuff to hold it in position relative to the inversion support catheter, the intermediate catheter 2813 maybe be slid distally 2850 over the distal end of the cuff and/or the sub-assembly including the cuff may be drawn proximally back in to the intermediate catheter. This is illustrated in FIG. 28C.

[000170] In the variation shown in FIGS. 29A-29C, the cuff retainer 2935 is configured as one or more leashes or tethers 2935 (e.g., filaments, wires, strands, cables, etc.) that is/are attached to a cuff 2911. However, in this example, the cuff retainer passes through an opening 2941 in the inversion support catheter 2907 and attaches to the puller (or pusher) 2905. Thus, as the puller 2905 is drawn proximally to pull and invert the flexible tube 2909 into the inversion support catheter 2905, the cuff retainer 2935 is also drawn with the flexible tube. This configuration may coordinate the movement of the puller with the movement of the cuff, as illustrated in FIGS. 29B and 29C. In FIG.29B. As shown in FIG. 29B the cuff retainer also limits the axial movement of the cuff along the outside of the inversion support

catheter. Thus, by pulling the puller/pusher 2905 proximally, the cuff retainer may apply a force holding the cuff in position so that, as shown in FIG. 29C, the intermediate catheter (sheath 2913) may be advanced distally 2971 and over the cuff and outer portion of the flexible tube 2909. This configuration may also be useful in reloading the flexible tube, as (not shown) force applied to pull the cuff proximally (by pulling/pushing the cuff proximally on the inversion support catheter) may be transmitted to the puller through the cuff retainer (e.g., the one or more filaments, so that force is applied to both ends of the flexible tube to reload the device and also eject any clot within the flexible tube and inversion support catheter.

[000171] FIGS. 30A-30C illustrate another example of an apparatus including a cuff and a cuff retainer 3035, 3035' in which the cuff retainer includes a pair of leashes or tethers 3035, 3035' (e.g., filaments, wires, strands, cables, etc.) that are attached to the cuff 3011 and extend proximally through the intermediate catheter 3013 all the way to a proximal end of the device where they may be used to apply force (e.g., tension) to the cuff. In FIG. 30B, the puller 3005 has been withdrawn proximally 3072 to cause the flexible tube 3009 (attached to the puller) to roll and invert over the distal end of the inversion support tube 3007. By securing and/or pulling on the cuff retainer 3035, 3035', and in some variations also securing and/or pulling on the puller 3005, the cuff may be held in a fixed location while the intermediate catheter 3013 is driven distally 3074, as shown in FIG. 30C. In this example, the cuff retainer (e.g., tethers) may be made of a metallic (e.g., stainless steel, elgiloy, Nitinol, etc.) or polymeric material. As mentioned, in use, the cuff retainer may be locked down or free to move (e.g., slide) and may be manipulated by the user near the hub of the inversion support catheter or elsewhere on the proximal end of the apparatus.

[000172] In some variations, the cuff retainer may be used to pull back the tractor to eject clot after use. For example, the apparatus (e.g., the sup-portion including the cuff, the flexible tube and the puller) may be reloaded on the inversion support catheter and/or material such as a clot captured in the apparatus may be ejected by pulling the cuff proximally (and in some variations pushing the puller/pusher 3005 distally).

[000173] Although the cuff retainer shown in FIGS. 30A-30C is shown as one or more tethers, in some examples, the cuff retainer is a tubular structure, which may be knitted, woven, solid, etc.

[000174] In some variations the cuff retainer is a cuff stop near or on a distal region of the inversion support catheter. For example, in FIG. 31A the cuff retainer is configured as a cuff stop that is formed as a collar attached to the distal end region of the inversion support

catheter. In FIG. 31A, the cuff 3111 connected to an end of the flexible tube 3109 slides freely along the inversion support catheter 3105, so that when the puller/pusher 3105 within the inversion support catheter is drawn proximally 3172 (a shown in FIG. 31B), the cuff may be pulled distally while the flexible tube rolls and inverts over the distal end of the inversion support catheter. In FIG. 31B, the cuff is stopped from moving distally by the cuff retainer 3137 (cuff stop). The intermediate catheter (sheath 3113) may then be moved distally over the cuff and any portion of the flexible tube 3109 that is external to the inversion support catheter to re-sheath the apparatus, as shown in FIG. 31C. Alternatively, or additionally, the inversion support catheter, cuff, flexible tube and puller may be drawn proximally into the intermediate catheter. In some variations, a combination of both movements may be used. The puller may be pulled or held so that the cuff is held against the cuff retainer while re-sheathing or alternatively the intermediate catheter (sheath) may drive the cuff against the cuff retainer.

[000175] In FIGS. 31C the cuff retainer is a stop that is fixed to the outside of the inversion support catheter. Any stop that may engage with the outer distal-facing edge of the cuff and the inversion support catheter may be used. For example, the cuff retainer may be a cuff stop that is a bump, ridge, button, protrusion, band, ring, lip, or the like. One or more (e.g., two, three, etc.) discrete regions arranged around the outside of the inversion support catheter may be used. The cuff retainer may made of any appropriate material, e.g., a polymer or metallic structure, and may be a solid element or a braid or knit structure.

[000176] In addition to these mechanical cuff retainers (cuff stops), electrical and/or magnetic cuff retainers may be used. For example, the cuff retainer may be a magnetic or paramagnetic material that interacts with cuff (which may include a magnetic or parametric material) to limit movement of the cuff distally.

[000177] Any of the cuffs described herein may also include one or more tapered or shaped ends that also help re-sheath the apparatus. For example, in some variations, the proximal end of the cuff may be tapered towards the inversion support catheter.

[000178] FIGS. 32A-32C illustrate examples of tapered cuffs that may be used. In FIG. 32A, the apparatus includes a cuff 3211 that has a skived or tapered proximal end 3242. The cuff is attached at the other end to the flexible tube 3209 which inverts and rolls over the inversion support catheter 3207 when pulled by the puller 3205 from within the inversion support catheter. The sub-assembly including the inversion support catheter, flexible (inverting) tube, and the cuff is shown in a deployed configuration extending from outside of the intermediate catheter 3213. The tapered cuff may aid in re-sheathing the sub-assembly,

including the cuff, back into the intermediate catheter. A tapered cuff may be used with or without a cuff retainer, including any of those described above.

[000179] FIG. 32B is another example of a tapered cuff 3211 that includes a proximal tapered region 3245'. In this example, the tapered region includes serrations that may allow some flexibility of the narrowed proximal end so that it is still free to slide on the inversion support catheter. The serrations may be configured as one or more slots, slits or cut-out regions in the tapered region. The serrations may be limited to the tapered region.

[000180] FIG. 32C is another example of a tapered cuff 3211 having a crown-like tapered region 3255 comprising a number of larger cut-out regions, similar to the serrations of the tapered region in FIG. 22B. In FIG. 32C the tapered region may include tapered fingers or projections that may be triangular, square/rectangular, curved and/or sinuous and/or irregularly shaped tapered extensions. In some variations, the tapered region is crenelated.

[000181] The tapered regions of the cuff may extend over a portion of the cuff, e.g., between 5%-50% of the length of the cuff in the long-axis of the inversion support catheter (e.g., between 10% and 50%, between 15% and 50%, between 10% and 40%, etc.). The cuff may be any appropriate length, e.g., between 0.5 mm and 30 mm, between 1 mm and 20 mm, between 2 mm and 20 mm, greater than 2 mm, greater than 3 mm, greater than 4 mm, greater than 5 mm, greater than 6 mm, etc.).

[000182] FIGS. 32D and 32E illustrate cuffs having tapered regions that are angled on the proximal-facing sides. Thus, the proximal-facing side of the cuff is angled relative to the body of the cuff and the inversion support catheter. In FIG. 32D the cuff 3211 has an angled proximal side 3265, but the distal-facing side of the cuff is flat (e.g., perpendicular to the long axis of the inversion support catheter over which it may slide. FIG. 32E shows a cuff 3211'''' that is similar to the variation shown in FIG. 32D but is also angled on the distal-facing side. The angled proximal-facing side may be tapered (and/or may include tapered cut-out regions/perforations). Cuffs having angled proximal faces may also be used with a cuff retainer. The angled proximal face may be formed by cutting the cuff at an angle. Any appropriate angle may be used, e.g., between 5 degrees and 60 degrees (e.g., between 10 degrees and 50 degrees, between 15 degrees and 45 degrees, etc.), measured as the acute angle formed between the proximal-facing side and the sidewall of the cuff.

[000183] FIG. 32F illustrates a cuff 3211 having a proximal-facing stent like structure 3275 that is low-profile and may also help with re-sheathing. Any of the tapered and/or angled cuffs may also include a proximally-extending stent-like structure. The stent-like structure may include wires, filaments, ribbons, etc. extending from the proximal edge. These sent-like

structures may be flattened toward the inversion support catheter 3207 outer surface. A stent-like structure may also be referred to as a low-profile scaffolding, and may extend completely or partially around the perimeter of the cuff.

[000184] Any of the apparatuses described herein may also be configured to be re-loadable. For example, FIGS. 33A-33D illustrate one example of a re-loading apparatus in which a single-use subassembly including a cuff 3311 (configured as a split cuff), a flexible tube 3309, and an inner puller 3305, is loaded onto the inversion support catheter 3307, and partially deployed out of the intermediate catheter (sheath 3313). The sub-assembly, which may be referred to as an inverting flexible tube sub-assembly is removable from the inversion support catheter, and may be removed from the inversion support catheter out of the intermediate catheter after removing all or part of a clot; the intermediate catheter (sheath) may then be left in place while the intermediate catheter and inverting flexible tube sub-assembly may be removed from the vessel proximally. Once withdrawn, the sub-assembly may be removed from the inversion support catheter and a new sub-assembly may be loaded onto the inversion support catheter and inserted back through the intermediate catheter to remove additional clot material. This is illustrated in FIGS. 33A-33E.

[000185] In FIG. 33A, the apparatus is shown partially deployed, with the inversion support catheter 3307 extending out of the sheath 3313, and the flexible tube 3309 connected at one end to a split cuff 3311 and at the other end to a puller (e.g., puller assembly, including a puller wire 3305 and a puller catheter segment 3306). The cuff may be slid over the inversion support catheter distally as the puller is drawn proximally (e.g., by pulling on the puller end 3356). Pulling the puller proximally causes the flexible tube to roll and invert over the distal end of the inversion support catheter. In FIG. 33A, a guidewire 3341 may be used, and passes through the catheter segment 3306 of the puller. As described in greater detail above, this may draw a clot into the inversion support catheter. Once the cuff reaches the distal end of the inversion support catheter, as shown in FIG. 33B, the cuff may split apparat and roll and invert 3372 over the distal end of the inversion support catheter as well, into the inversion support catheter. As shown in FIG. 33C, the entire sub-assembly (e.g., the puller, flexible tube 3309 and split cuff 3311 may then be housed within the inversion support catheter 3307, and withdrawn proximally out of the sheath 3313. For example, the proximal end of the inversion support catheter may include a handle or grip 3361, allowing it to be advanced and/or withdrawn from outside of the patient. The entire sub-assembly and/or inversion support catheter may be removed proximally out of the patient.

[000186] Once removed, the inverting flexible tube sub-assembly may then be removed, along with captured clot, from the inversion support catheter, and either a new inversion support-catheter pre-loaded with an inverting flexible tube sub-assembly may then be inserted into the sheath and back into the vessel to capture any additional clot material, or the same inversion support catheter may be re-loaded with a new inverting flexible tube sub-assembly, as shown in FIGS. 33D and alternative variation in FIG. 33E.

[000187] In FIG. 33D, a new inverting flexible tube sub-assembly 3360, including the puller (puller assembly including pull wire 3305 and pull catheter 3306), flexible tube 3309 and cuff 3311, is loaded 3374 into the distal end of the inversion support catheter 3307. The variation shown in FIG. 33E is similar to that shown in FIG. 33D, but the cuff 3311' is un-inverted, and therefore loads on the outer surface of the inversion support catheter. As the loaded inversion support catheter is driven back through the sheath, the flexible tube 3309 and cuff may be driven proximally, so that it prepared to be withdrawn proximally by the puller to capture clot by the time it reaches the distal end region of the sheath.

[000188] In any of these variations, a guidewire may be use to insert and guide insertion of the inverting flexible tube sub-assembly and/or inversion support catheter to the clot material.

[000189] The steps of capturing clot, withdrawing the sub-assembly proximally and reloading anew sub-assembly, as illustrated in FIGS. 33A-33E, may be repeated as necessary to remove more clot material.

[000190] Alternatively, as mentioned above, any of the apparatuses described herein may be configured to reusing inverting flexible tube sub-assembly and other portions of the apparatus. For example, the apparatus may be deployed to a clot, and used to remove at least a portion of the clot, and the clot, captured by the flexible tube, may be withdrawn out of the vessel, and ejected from the flexible tube, and the flexible tube (e.g., the inverting flexible tube sub-assembly including the flexible tube) reloaded, reinserted and used to remove additional clot. An example of this is illustrated in FIGS. 34A-34C.

[000191] In FIG. 34A, a portion of clot 3490 has been captured by an apparatus. The apparatus may include an inversion support catheter 3407, a puller 3405, a flexible tube 3409 and a cuff 3411. In this example, the puller includes a proximal handle region 3465 and the inversion support catheter includes a proximal handle region 3467. The apparatus has been withdrawn from out of the patient after grabbing the clot material in FIG. 34A. The clot material may then be ejected from the apparatus, as shown in FIG. 34B. In this example, the clot material is ejected by pulling the cuff proximally 3472 and/or by pushing the puller distally 3474. In some variations, the clot may be ejected by both pushing the puller distally

and by pulling the cuff proximally. For example, in some variations it may be beneficial to use an ejection apparatus 3522, as shown schematically in FIG. 35, to coordinate the relative motion of the puller 3505 (or puller assembly) and the inversion support catheter 3507, while drawing the cuff 3511 proximally. The ejection apparatus 3522 couples to both the puller proximal handle 3565 and the inversion support catheter proximal handle 3567 and moves the two handles 3565 and 3567 closer to each other 3572, as shown by the arrows. Force may also be provided (manually or automatically) to move the cuff 3511 proximally to eject the clot material 3590 from the flexible tube 3509. For example, the ejection apparatus may be a mechanical apparatus including one or more springs (e.g., extension springs) to assist in ejecting the clot material.

[000192] Once the clot is ejected, as shown in FIG. 34C, the apparatus is prepared for re-insertion, and may be inserted back into the patient (e.g., through an intermediate catheter with or without a guidewire) to remove additional clot material. An additional cover or sheath may be used to re-introduce the apparatus through the intermediate catheter.

CLAIMS

1. An inverting tube apparatus for removing a clot from a vessel, the apparatus comprising:

an inversion support catheter;

a puller within a lumen of the inversion support catheter; and

a flexible tube extending over a distal end of the inversion support catheter, the flexile tube having a first end coupled at a distal end region of the puller and a second end comprising a cuff that is less flexible that a region of the flexible tube adjacent to the cuff, wherein the flexible tube is configure to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the flexible tube rolls and inverts over a distal end of the inversion support catheter.

2. The apparatus of claim 1, wherein the cuff comprises one or more slits along its length extending in a proximal-to-distal direction.

3. The apparatus of claim 1 or 2, wherein the cuff comprises a polymeric material.

4. The apparatus of any of claims 1-3, further comprising a cuff retainer configured to prevent the cuff from extending over the distal end of the inversion support catheter.

5. The apparatus of claim 4, wherein the cuff retainer comprises one or more filaments coupling the cuff to the inversion support catheter.

6. The apparatus of claim 4, wherein the cuff retainer comprises a mechanical stop on the inversion support catheter.

7. The apparatus of claim 4, wherein the cuff retainer comprises one or more filament connecting the cuff to the puller through a lateral opening in the inversion support catheter.

8. The apparatus of claim 4, wherein a proximal-facing end of the cuff is tapered.

9. The apparatus of claim 4, wherein a proximal-facing end of the cuff comprises a low-profile scaffolding extending at least partially around the perimeter of the cuff.

10. The apparatus of any of claims 1-9, further comprising a first proximal port configured to couple with a vacuum source to apply vacuum through the puller.

11. The apparatus of any of claims 1-9, further comprising a second proximal port configured to couple with a vacuum source to apply vacuum between the intermediate catheter and the inversion support catheter.

12. The apparatus of any of claims 1-11, wherein the intermediate catheter is configured to push the cuff over the distal end of the inversion support catheter when the intermediate catheter is advanced distally past the cuff.

13. The apparatus of any of claims 1-12, wherein the flexible tube comprises a knit.

14. The apparatus of any of claims 1-13, wherein the cuff is radiopaque.

15. An inverting tube apparatus for removing a clot from a vessel, the apparatus comprising:

an inversion support catheter;

a puller within a lumen of the inversion support catheter; and

a flexible tube extending over a distal end of the inversion support catheter, the flexile tube having a first end coupled at a distal end region of the puller and a second end comprising a cuff that is less flexible that a region of the flexible tube adjacent to the cuff, wherein the flexible tube is configure to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the flexible tube rolls and inverts over a distal end of the inversion support catheter, and wherein the cuff is tapered at the proximal facing end.

16. An inverting tube apparatus for removing a clot from a vessel, the apparatus comprising:

an intermediate catheter;

an inversion support catheter within a lumen of the intermediate catheter;

a puller within a lumen of the inversion support catheter; and

a knitted tube extending over the inversion support catheter, the knitted tube having a first end coupled at a distal end region of the puller and a second end that is free,

wherein the knitted tube is configured to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the knitted tube rolls and inverts over a distal end of the inversion support catheter,

wherein the knitted tube comprises a filament knitted to form a plurality of interlocking loop stitches, and

wherein each loop stitch has a stitch length that is between 0.5mm and 10mm.

17. The apparatus of claim 16, wherein the knitted tube extends over the inversion support catheter with an inner diameter that is within 20% of the outer diameter of the inversion support catheter.

18. The apparatus of claim 16 or 17, wherein the second end of the knitted tube comprises a cuff that is less flexible that a region of the knitted tube adjacent to the cuff.

19. An inverting tube apparatus for removing a clot from a vessel, the apparatus comprising:

an inversion support catheter;

a puller within a lumen of the inversion support catheter; and

a knitted tube extending over the inversion support catheter in a first configuration, the knitted tube having a first end coupled to a distal end region of the puller, and a second end that is free to move relative to the inserting support catheter, wherein the knitted tube is configure to be pulled proximally into the inversion support catheter by pulling the puller proximally so that the knitted tube rolls and inverts over a distal end of the inversion support catheter into a second configuration within the inversion support catheter;

further wherein the knitted tube in the first configuration has an expanded outer diameter that is between 0.5 mm and 12 mm for a first region of the knitted tube that is adjacent to the first end, and the knitted tube in the second configuration has an inner diameter that is greater than 30% of an inner diameter of the inversion support catheter, and wherein a second region of the knitted tube adjacent to the second end has an expanded outer diameter that is less than the expanded outer diameter of the region of the knitted tube adjacent to the first end and within 20% of an outer diameter of the inversion support catheter.

20. The apparatus of claim 19, further comprising a cuff at the second end, wherein the cuff has a stiffness that is greater than a region of the knitted tube adjacent to the cuff.

21. The apparatus of claim 19 or 20, further comprising a stop configured to limit the travel of the knitted tube so that the second end does not roll and invert over the distal end of the inversion support catheter.

22. The apparatus of any of claims 19-21, wherein the knitted tube is shape set so that the first configuration has the outer diameter between 0.5 mm and 10 mm for the region of the kitted tube adjacent to the first end, and the knitted tube in the second configuration has an inner diameter that is greater than 60% of the inner diameter of the inversion support catheter.

23. The apparatus of any of claims 19-22, wherein the first region of the kitted tube is at least 2 cm long.

24. The apparatus of any of claims 19-23, wherein the second region is at least 1 cm long.

25. The apparatus of any of claims 19-24, wherein the knitted tube comprises a filament knitted to form a plurality of interlocking loop stitches, wherein each loop stitch has a stitch length that is between 0.5 mm and 10 mm.

26. The apparatus of claim 25, wherein, at a region of the knitted tube that is inverting from the first configuration to the second configuration, a sub-set of the plurality of loop stitches forming the knitted tube extend proud from the long axis of the knitted tube by between 0.5 mm and 10 mm.

27. The apparatus of any of claims 19-26, further comprising an intermediate catheter having a lumen, wherein the inversion support catheter is within the lumen of the intermediate support catheter and may be extended distally from the intermediate catheter to deploy the knitted tube so that the knitted tube may expand into the first configuration.

28. The apparatus of any of claims 19-27, wherein the puller comprises a puller catheter.

29. A pre-loaded inverting mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy, the apparatus comprising:

an intermediate catheter having a distal end;

an inversion support catheter within a lumen of the intermediate catheter, the inversion support catheter having a distal end and a distal end opening;

a puller extending within the inversion support catheter; and

a flexible tube extending proximally from a distal end region of the puller so that a distal-facing face of the puller extends distally beyond the flexible tube,

wherein the puller extends from the distal end of the intermediate catheter and the distal end opening of the inversion support catheter; and wherein the distal end opening of the inversion support is held within the lumen of the intermediate catheter, and wherein the flexible tube extends between the inversion support catheter and the intermediate catheter.

30. The apparatus of claim 29, wherein the inversion support catheter comprises a plurality of slots or cut-out regions along its length to enhance flexibility while maintaining column strength such that the inversion support catheter is able to withstand at least about 500g of compressive force.

31. The apparatus of claim 29 or 30, wherein the flexible tube comprises a knitted tube.

32. The apparatus of claim 29, wherein the inversion support catheter comprises a plurality of slits or openings around the perimeter of the inversion support catheter and down the length of the inversion support catheter.

33. The apparatus of claim 29, wherein the inversion support catheter is removably secured to the intermediate catheter so that the intermediate support catheter and the intermediate catheter move relative to each other.

24. The apparatus of any of claims 19-23, further comprising a guidewire within the puller.

25. The apparatus of any of claims 19-23, wherein puller comprises a micro catheter.

26. The apparatus of any of claims 19-23, wherein the puller comprises a guidewire.

27. A pre-loaded inverting mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy, the apparatus comprising:

an intermediate catheter having a distal end;

an inversion support catheter extending distally from a lumen of the intermediate catheter, the inversion support catheter having a distal end and a distal end opening;

a puller extending distally within the inversion support catheter; and

a flexible tube extending proximally from a distal end region of the puller and between the intermediate catheter and the inversion support catheter,

wherein the puller extends from the distal end of the intermediate catheter and the distal end opening of the inversion support catheter; and wherein the distal end opening of the inversion support is held within the lumen of the intermediate catheter, and wherein the flexible tube extends between the inversion support catheter and the intermediate catheter, and

wherein the puller and inversion support catheter are releasably held together so that they move together while advancing distally within a vessel lumen.

28. The apparatus of claim 27, wherein the inversion support catheter comprises a plurality of slots or cut-out regions along its length to enhance flexibility while maintaining column strength such that the inversion support catheter is able to withstand at least about 500g of compressive force.

29. The apparatus of claim 27 or 28, wherein the tractor tube comprises a knitted tube.

30. The apparatus of claim 27, wherein the inversion support catheter comprises a plurality of slits or openings around the perimeter of the inversion support catheter and down the length of the inversion support catheter.

31. The apparatus of any of claims 27-30, further comprising a guidewire within the puller.

32. The apparatus of any of claims 27-30, wherein puller comprises a micro catheter.

33. The apparatus of any of claims 27-30, wherein the puller comprises a guidewire.

34. An inverting mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy, the apparatus comprising:

an inversion support catheter extending distally, the inversion support catheter having a distal end and a distal end opening, the inversion support catheter comprising a plurality of slots or cut-out regions along its length to enhance flexibility while maintaining column strength such that the inversion support catheter is able to withstand at least about 500g of compressive force;

a puller extending distally within the inversion support catheter; and

a flexible tube extending proximally from a distal end region of the puller,

wherein the flexible tube comprises a knitted material that is held in compression along an outside region of the inversion support catheter and inverts over the distal end opening of the inversion support catheter and couples to the puller, and

wherein pulling the puller proximally causes the flexible tube to roll from the outside region of the inversion support catheter, over the distal end opening and invert into the inversion support catheter.

34. A pre-loaded inverting mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy, the apparatus comprising:

an intermediate catheter having a distal end;

an inversion support catheter extending distally from a lumen of the intermediate catheter, the inversion support catheter having a distal end and a distal end opening;

a puller extending distally within the inversion support catheter; and

a flexible tube extending proximally from a distal end region of the puller and between the intermediate catheter and the inversion support catheter,

wherein the puller extends from the distal end of the intermediate catheter and the distal end opening of the inversion support catheter; and wherein the distal end opening of the inversion support is held within the lumen of the intermediate catheter, and wherein the flexible tube extends between the inversion support catheter and the intermediate catheter, and

wherein the puller and inversion support catheter are releasably held together so that they move together while advancing distally within a vessel lumen.

35. The apparatus of claim 34, wherein the inversion support catheter comprises a plurality of slots or cut-out regions along its length to enhance flexibility while maintaining column strength such that the inversion support catheter is able to withstand at least about 500g of compressive force.

36. The apparatus of claim 33 or 34, wherein the tractor tube comprises a knitted tube.

37. The apparatus of claim 27, wherein the inversion support catheter comprises a plurality of slits or openings around the perimeter of the inversion support catheter and down the length of the inversion support catheter.

38. The apparatus of any of claims 34-37, further comprising a guidewire within the puller.

39. The apparatus of any of claims 34-37, wherein puller comprises a micro catheter.

40. The apparatus of any of claims 34-37, wherein the puller comprises a guidewire.

41. An inverting mechanical thrombectomy apparatus for removing a clot from a vessel configured to be delivered through a tortious anatomy, the apparatus comprising:

an inversion support catheter extending distally, the inversion support catheter having a distal end and a distal end opening, the inversion support catheter comprising a plurality of slots or cut-out regions along its length to enhance flexibility while maintaining column strength such that the inversion support catheter is able to withstand at least about 500g of compressive force;

a puller extending distally within the inversion support catheter; and

a flexible tube extending proximally from a distal end region of the puller,

wherein the flexible tube comprises a knitted material that is held in compression along an outside region of the inversion support catheter and inverts over the distal end opening of the inversion support catheter and couples to the puller, and

wherein pulling the puller proximally causes the flexible tube to roll from the outside region of the inversion support catheter, over the distal end opening and invert into the inversion support catheter.

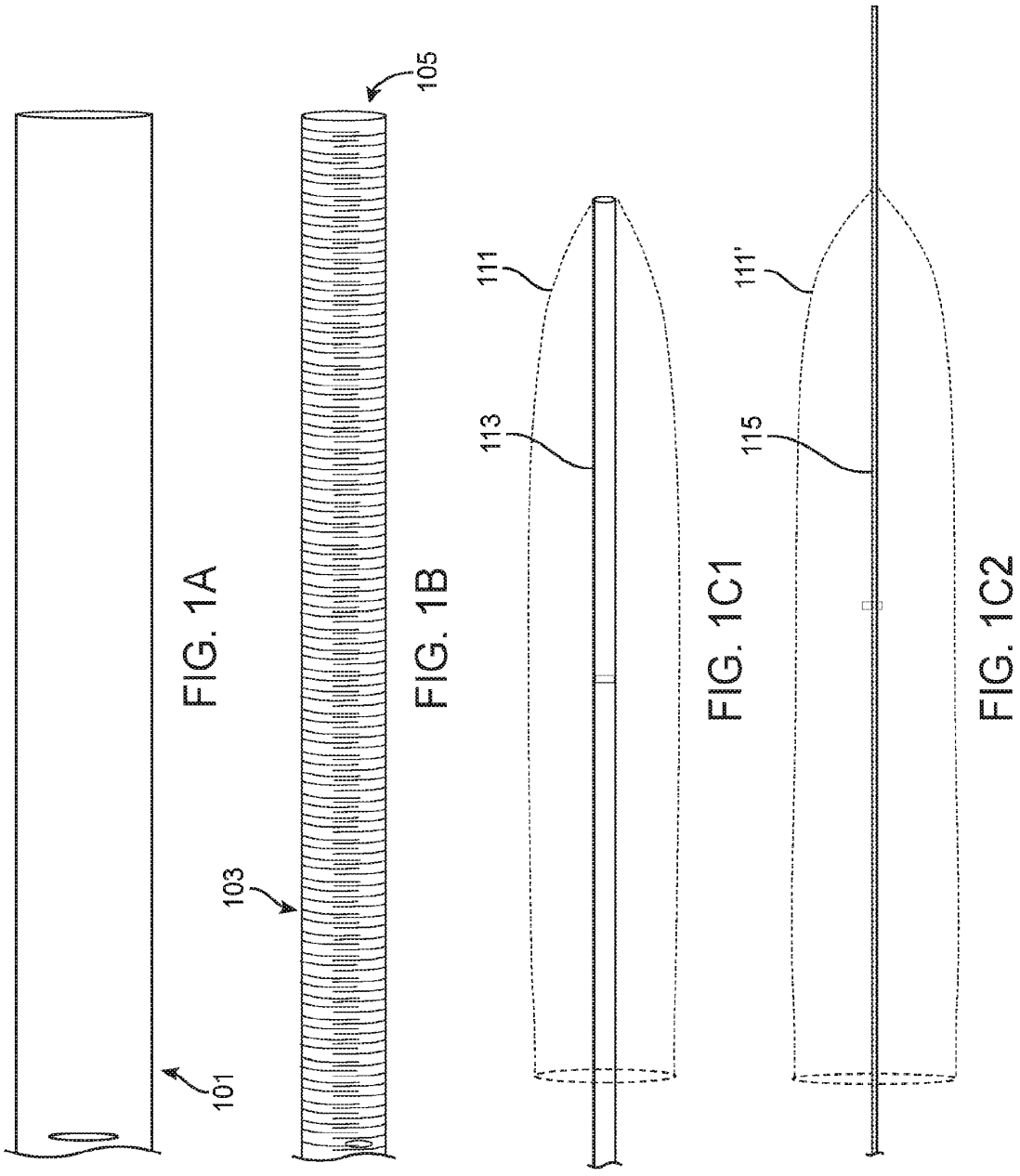


FIG. 1A

FIG. 1B

FIG. 1C1

FIG. 1C2

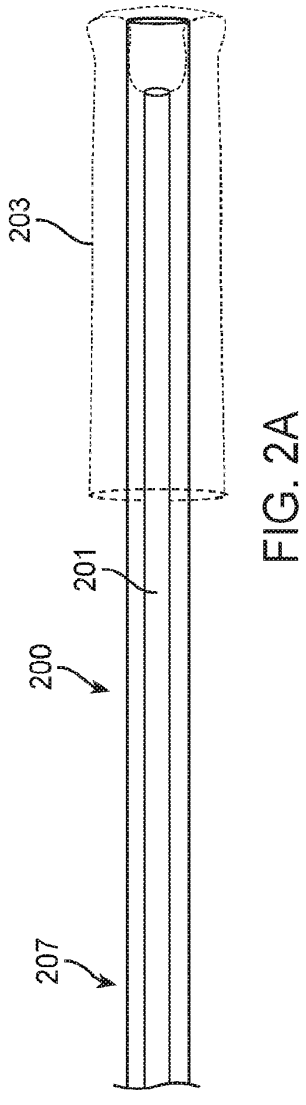


FIG. 2A

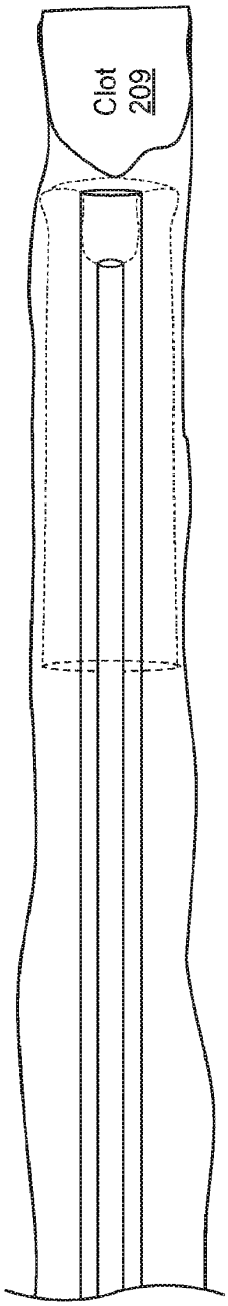


FIG. 2B

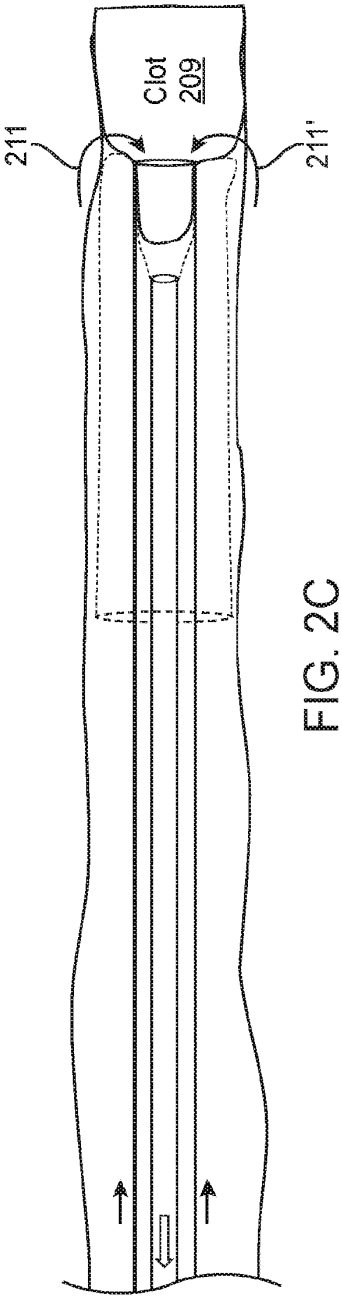


FIG. 2C

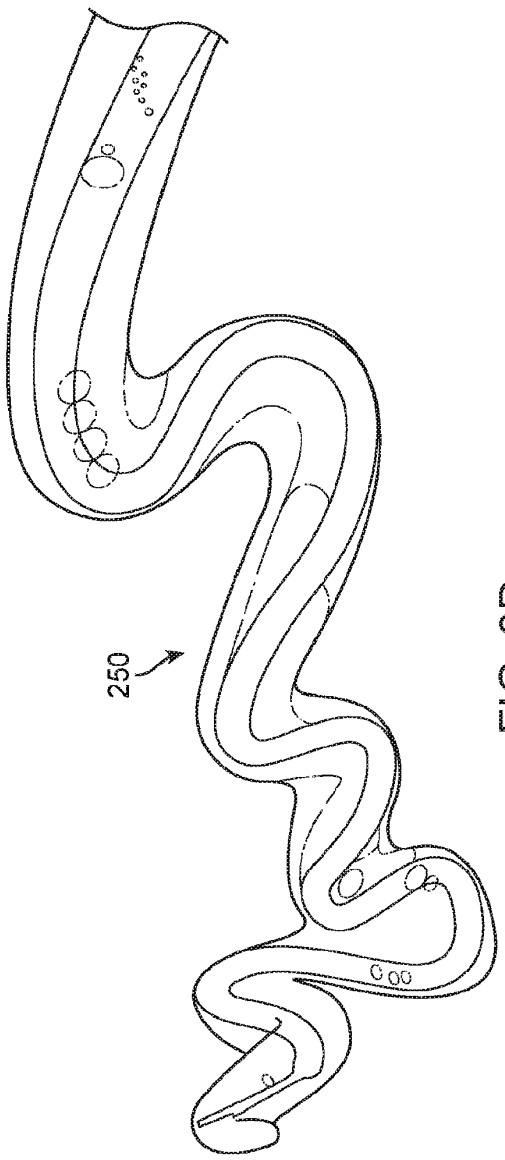


FIG. 2D

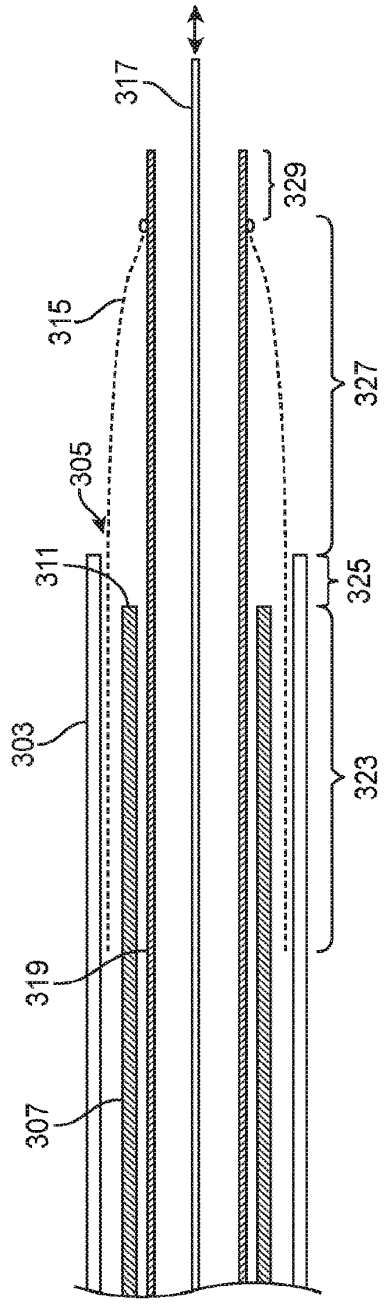

317
315
305
311
303
319
307
329
327
325
323

FIG. 3A

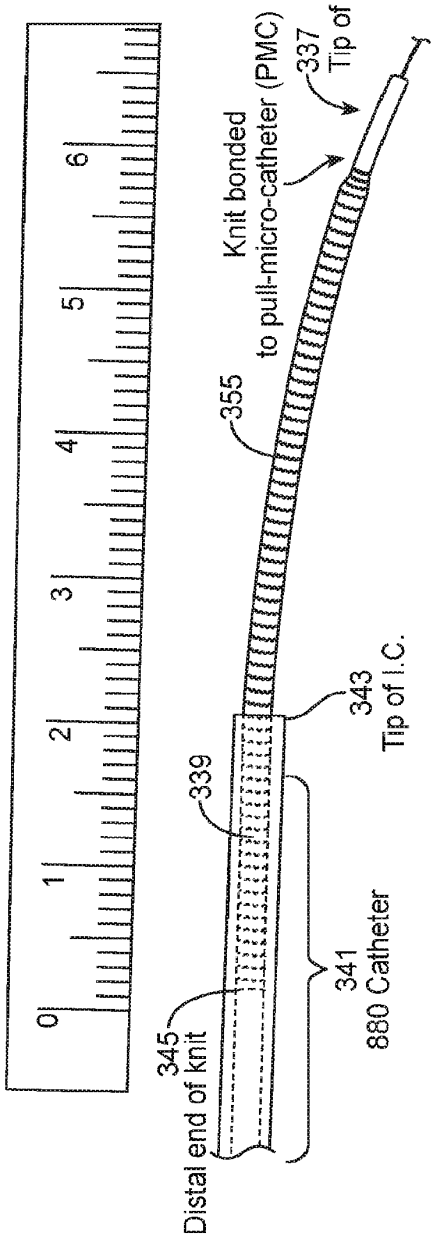

0
1
2
3
4
5
6
Knit bonded
to pull-micro-catheter (PMC)
337
Tip of PMC
355
343
Tip of I.C.
339
345
Distal end of knit
341
880 Catheter

FIG. 3B

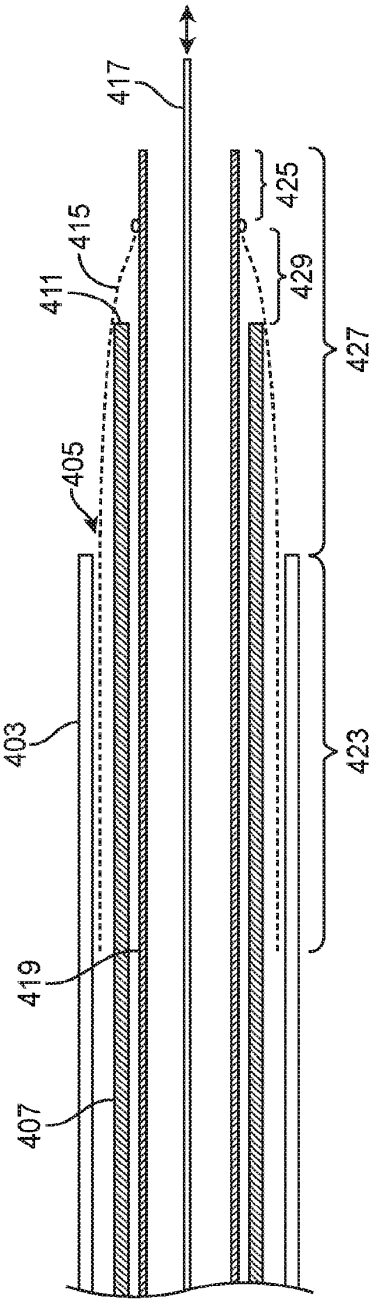


FIG. 4A

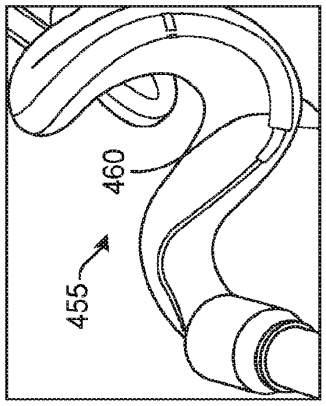


FIG. 4C

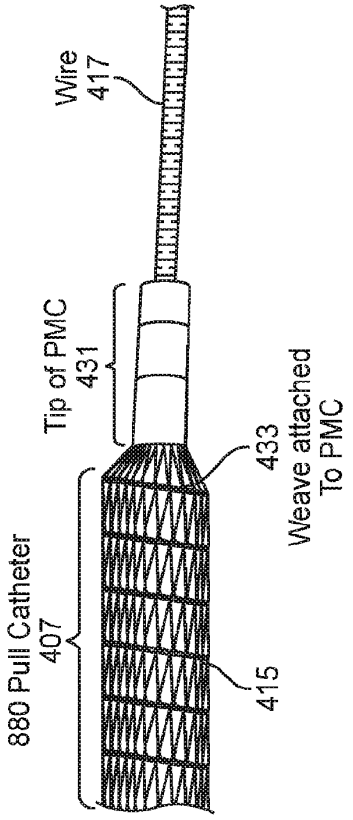


FIG. 4B

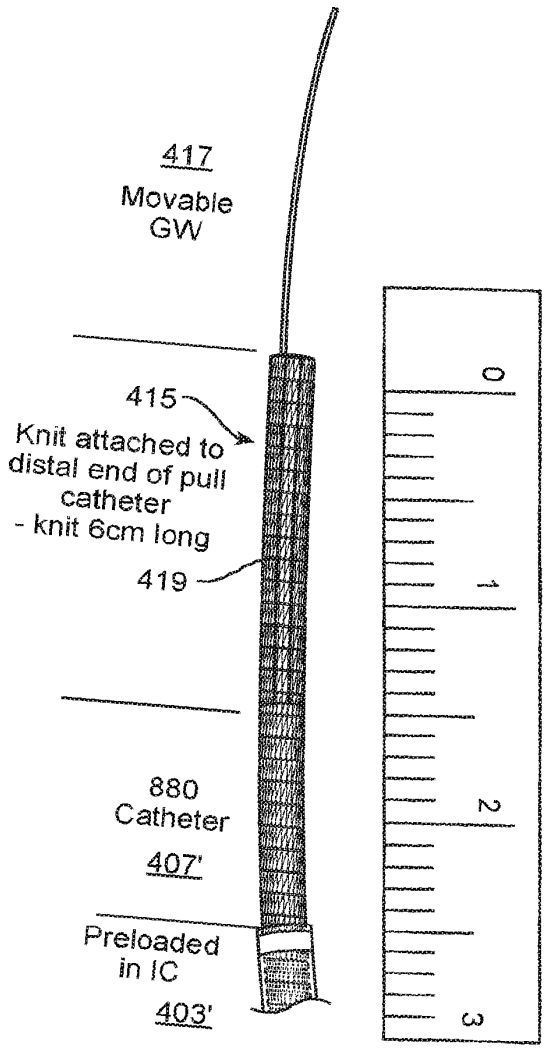

417
Movable
GW
415
Knit attached to
distal end of pull
catheter
- knit 6cm long
419
880
Catheter
407'
Preloaded
in IC
403'
0
1
2
3

FIG. 4D

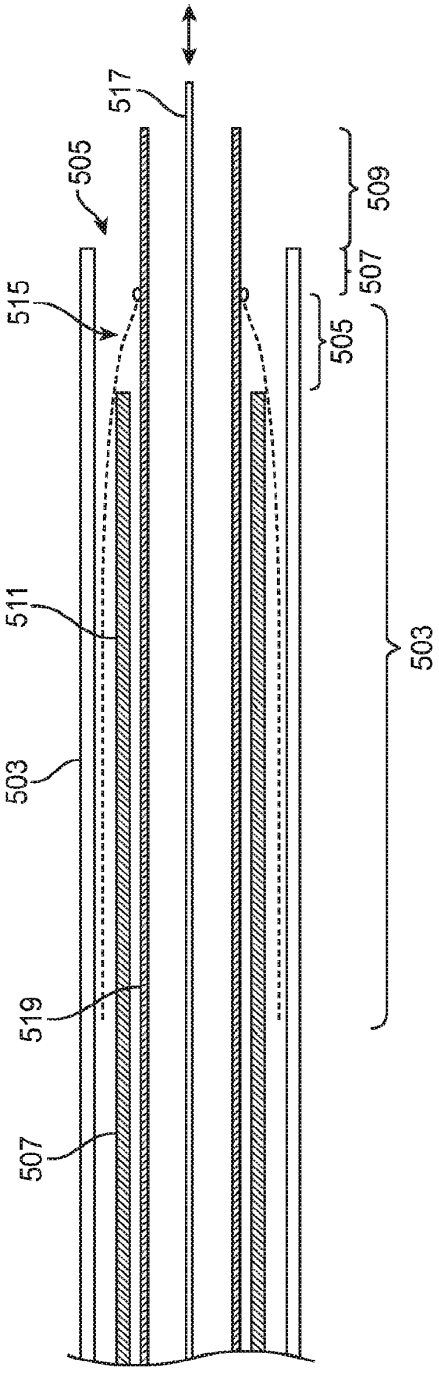

517
505
509
515
507
505
511
503
503
519
507

FIG. 5A

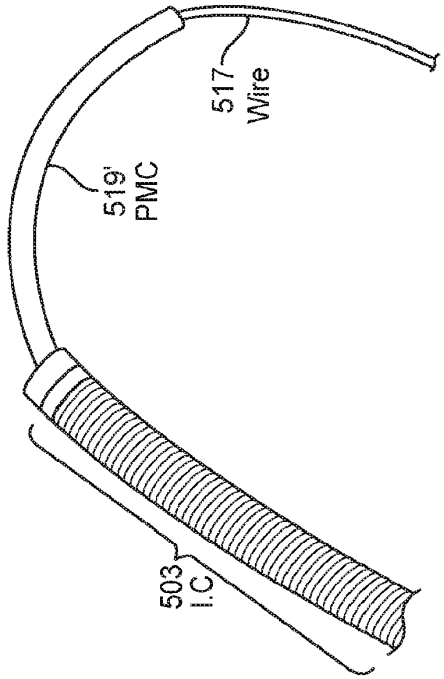

517
Wire
519'
PMC
503
I.C

FIG. 5B

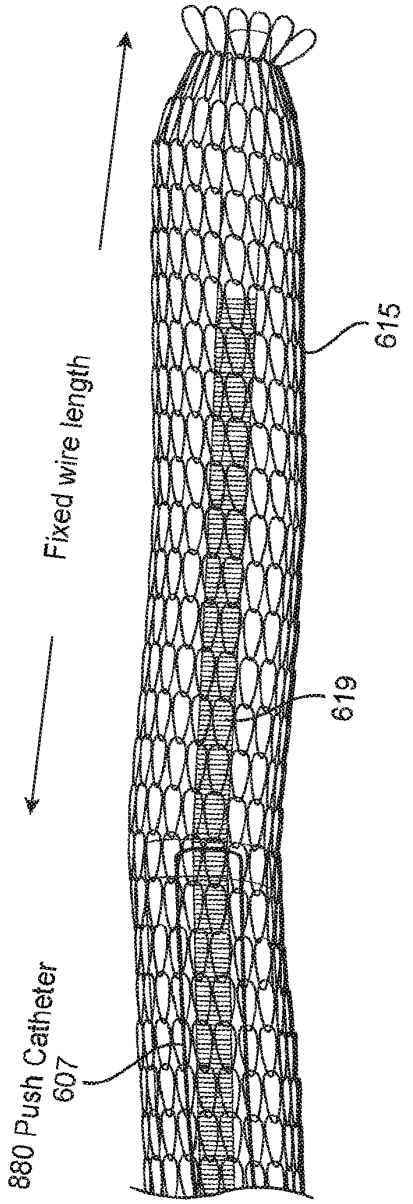


FIG. 6

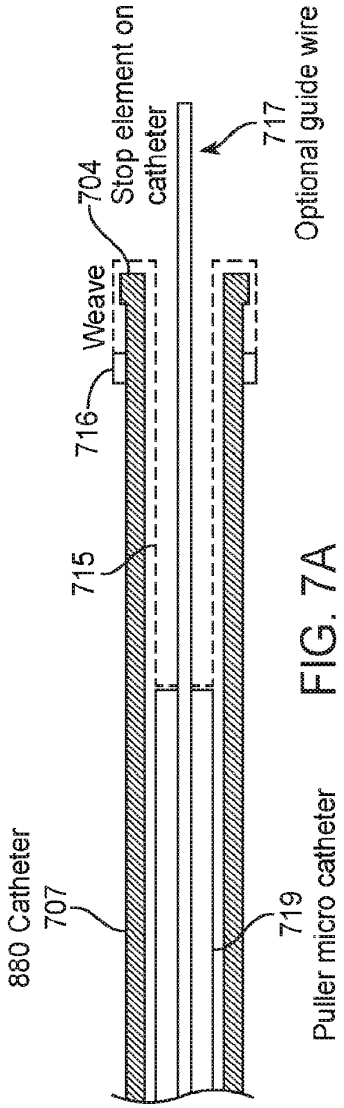


FIG. 7A

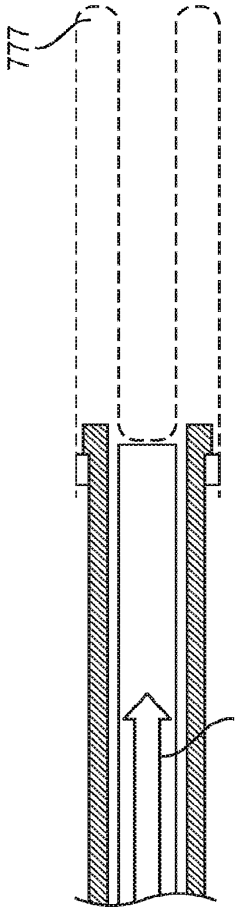


FIG. 7B

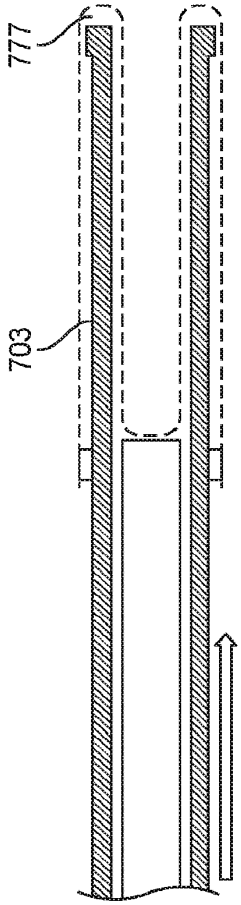
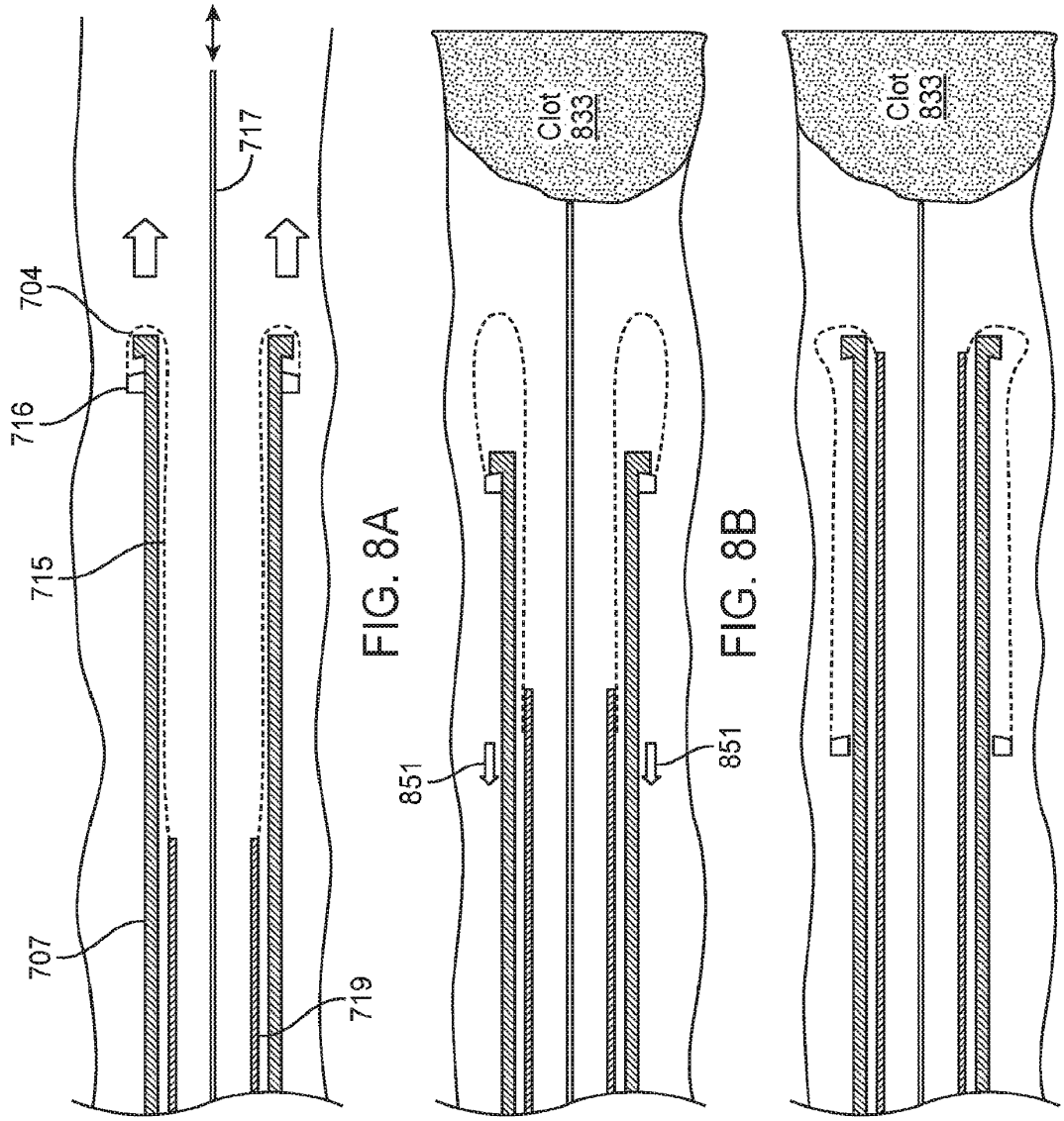


FIG. 7C


704
716
715
707
717
719
FIG. 8A
Clot
833
851
851
FIG. 8B
Clot
833
FIG. 8C

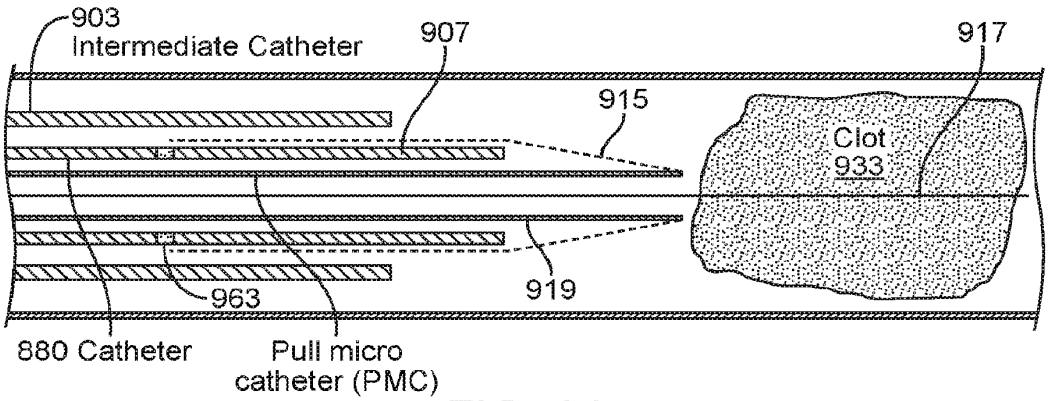


FIG. 9A

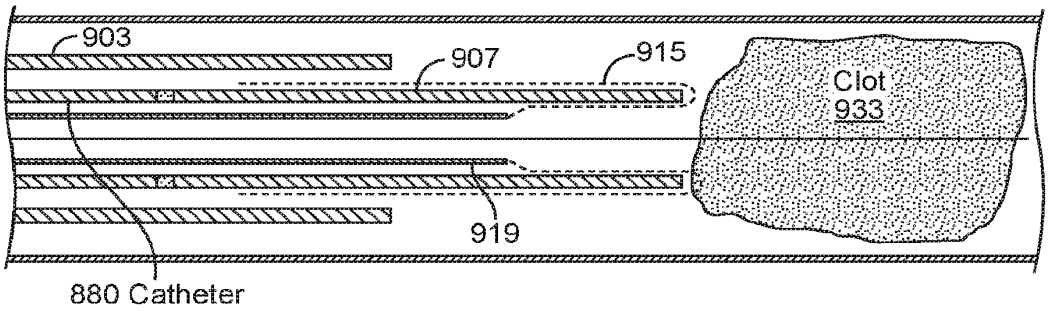


FIG. 9B

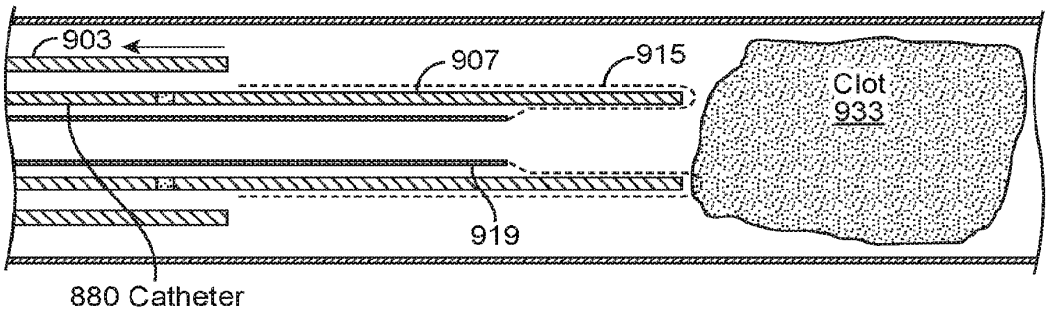


FIG. 9C

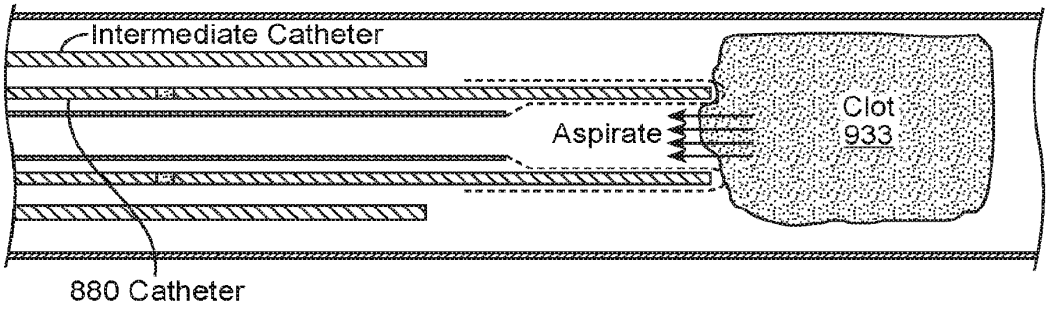


FIG. 9D

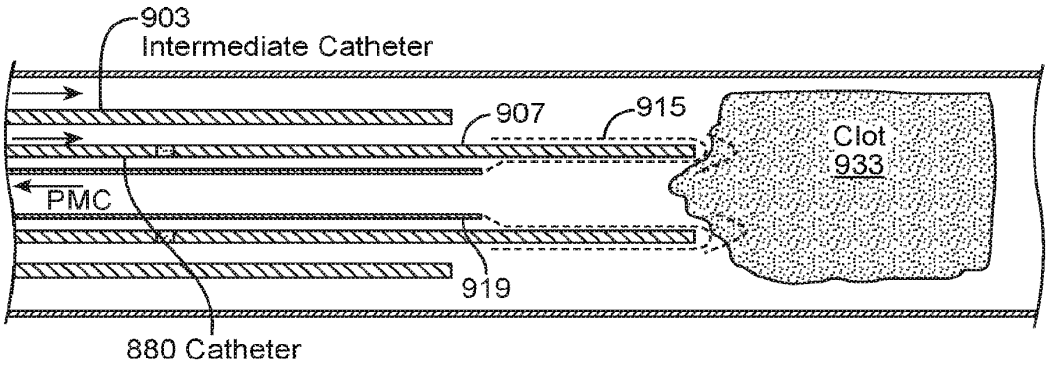


FIG. 9E

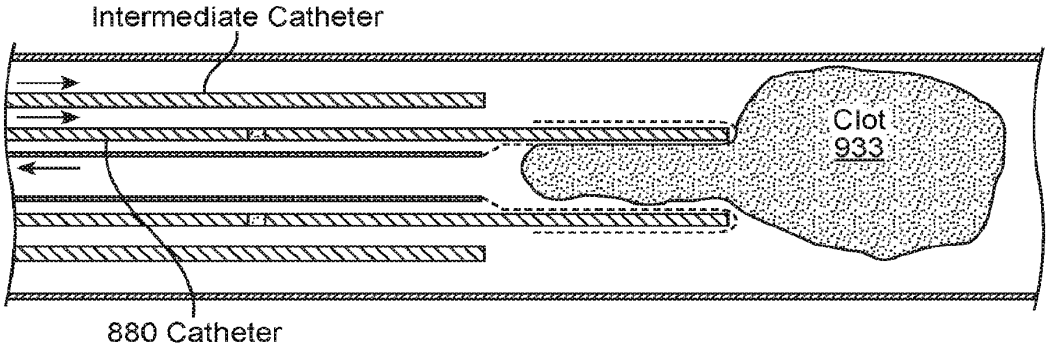


FIG. 9F

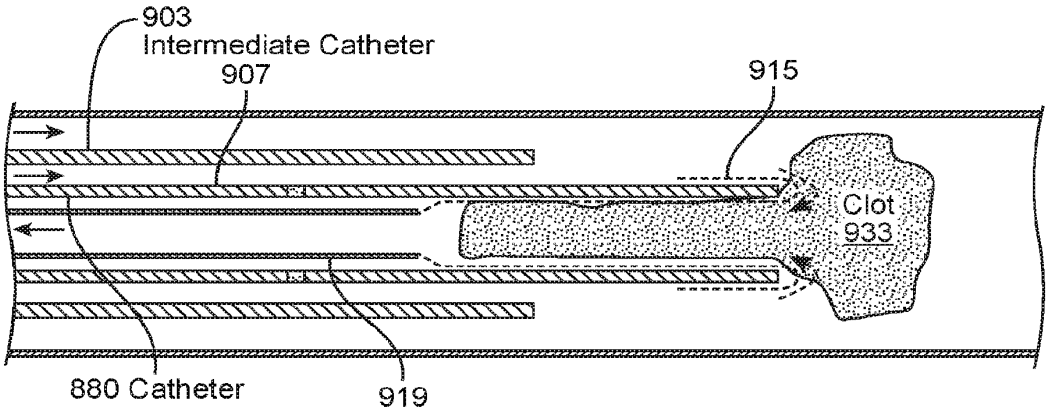


FIG. 9G

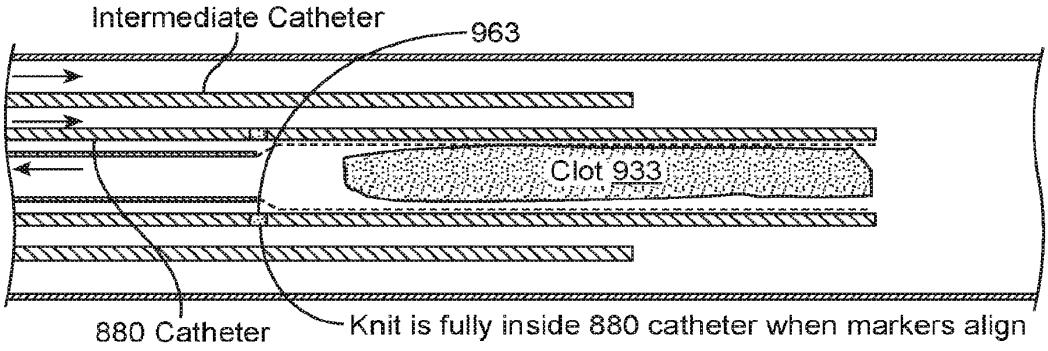


FIG. 9H

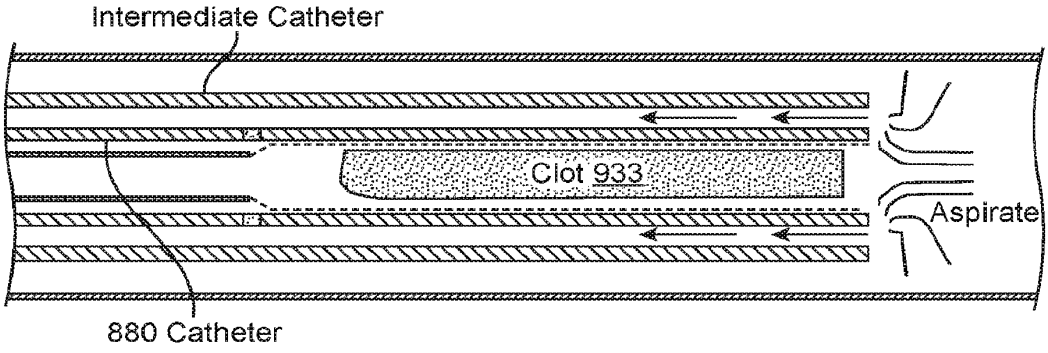


FIG. 9I

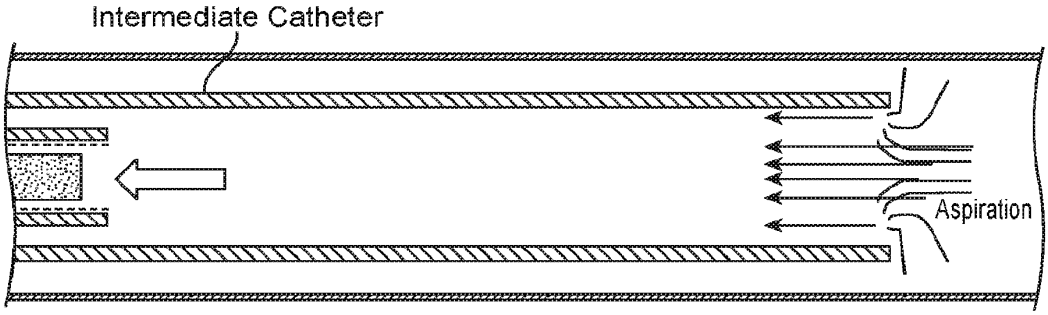

Intermediate Catheter
Aspiration

FIG. 9J

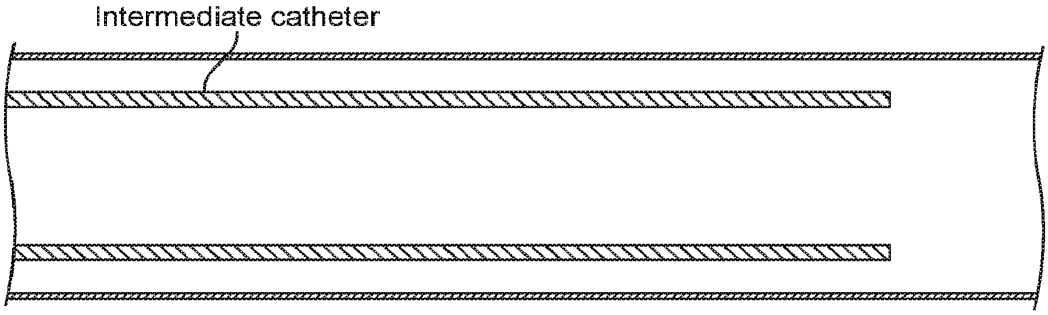

Intermediate catheter

FIG. 9K

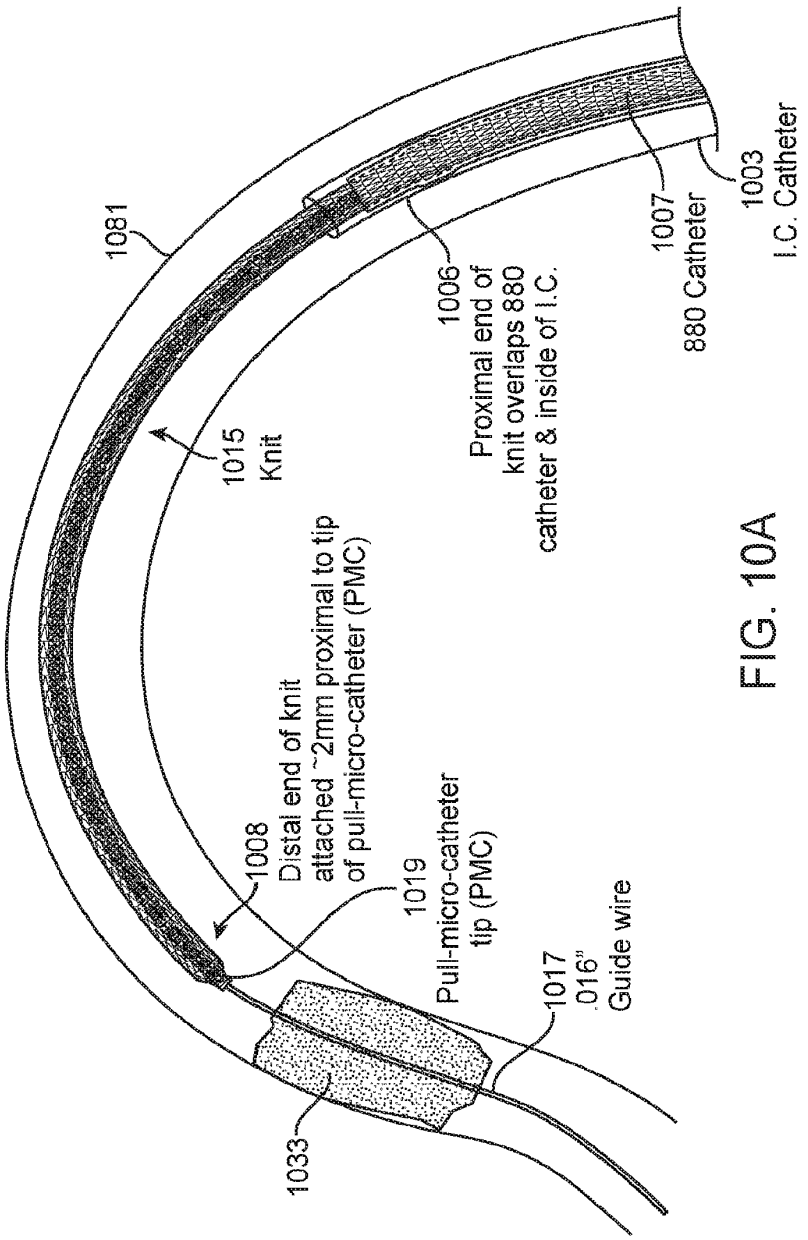

1081
1015
Knit
1008
Distal end of knit
attached ~2mm proximal to tip
of pull-micro-catheter (PMC)
1019
Pull-micro-catheter
tip (PMC)
1017
.016"
Guide wire
1033
1006
Proximal end of
knit overlaps 880
catheter & inside of I.C.
1007
880 Catheter
1003
I.C. Catheter

FIG. 10A

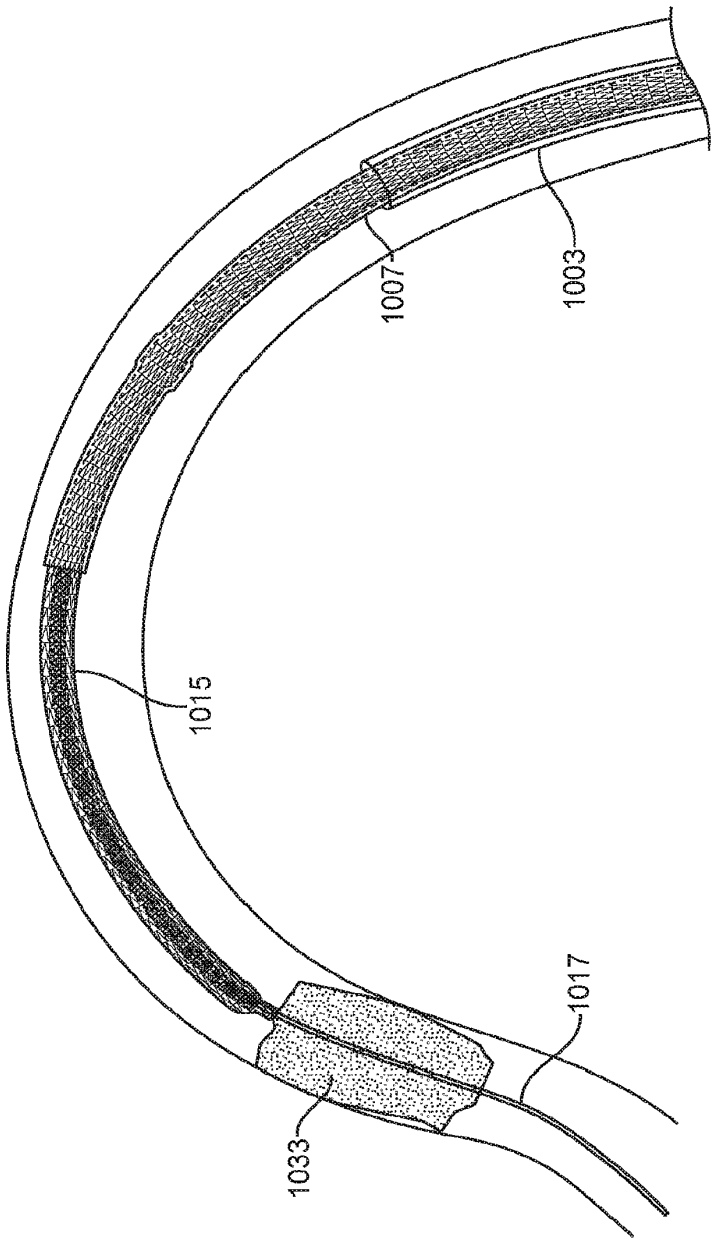


FIG. 10B

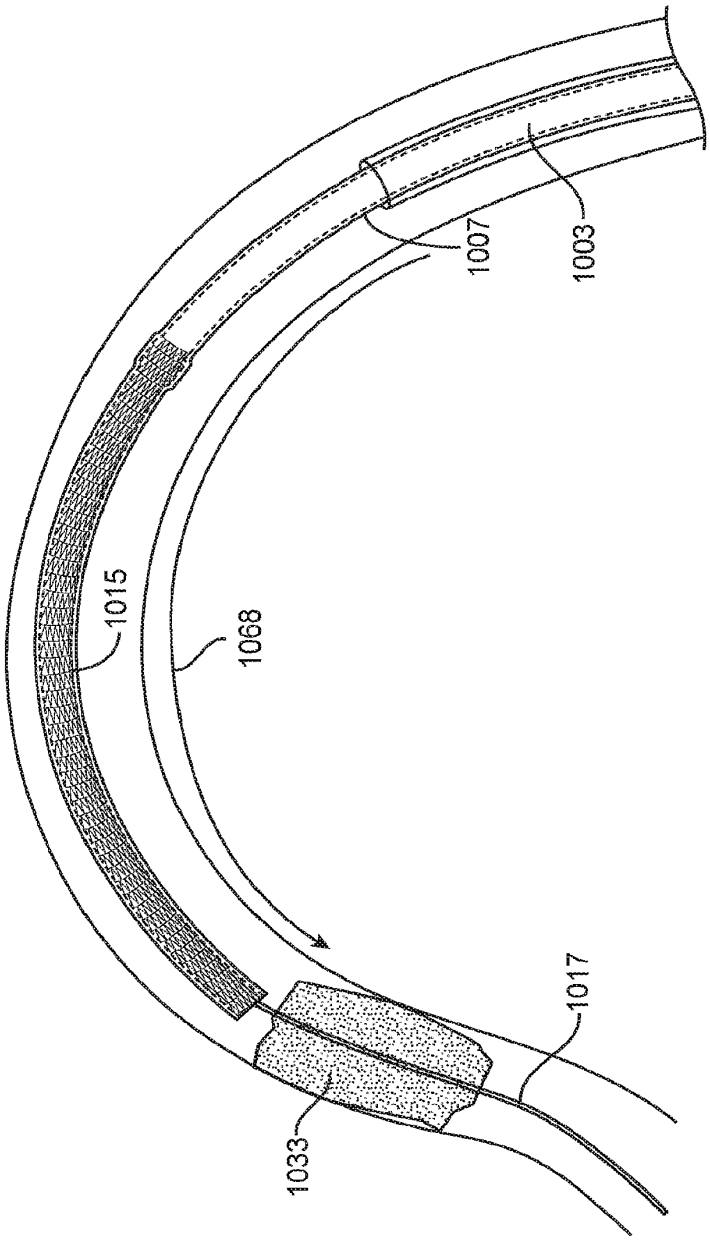


FIG. 10C

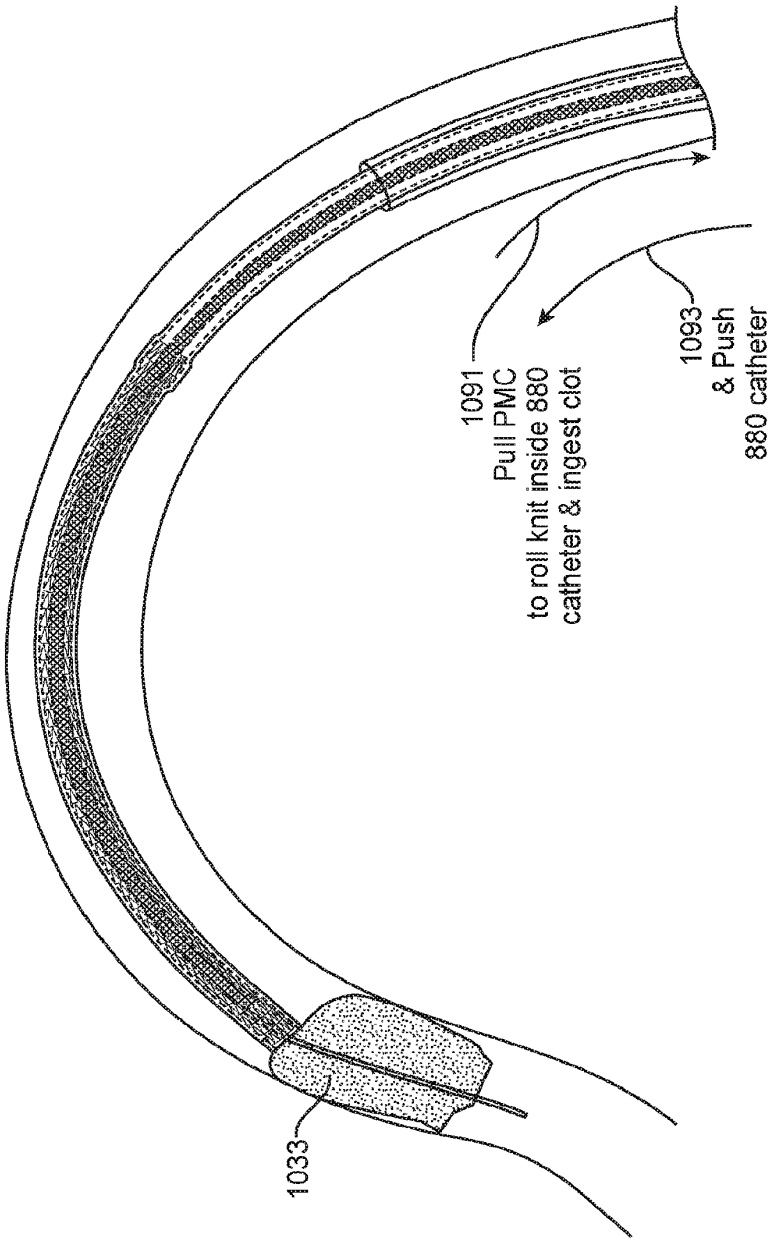

1091
Pull PMC
to roll knit inside 880
catheter & ingest clot
1093
& Push
880 catheter
1033

FIG. 10D

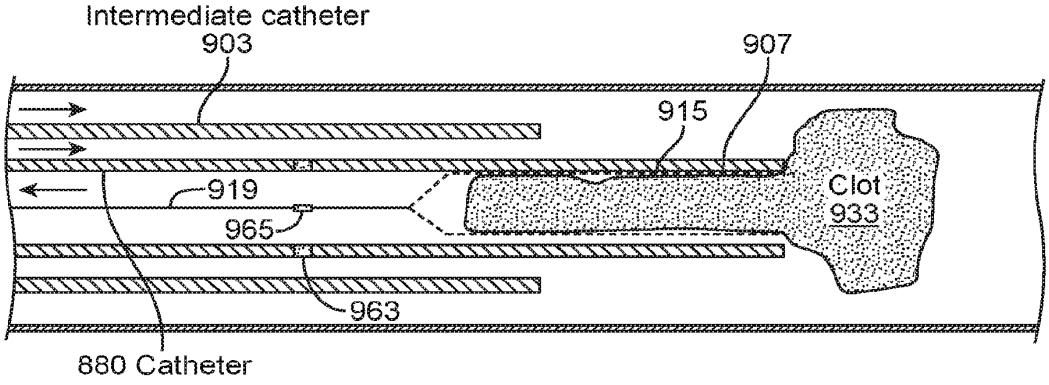


FIG. 11A

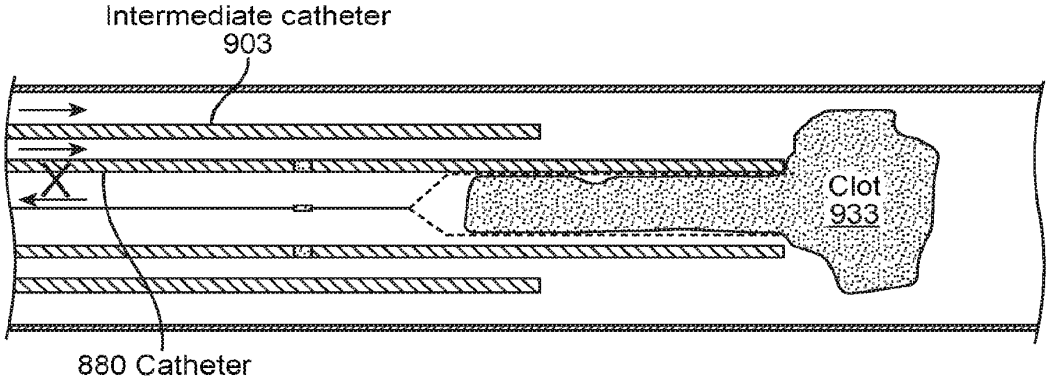


FIG. 11B

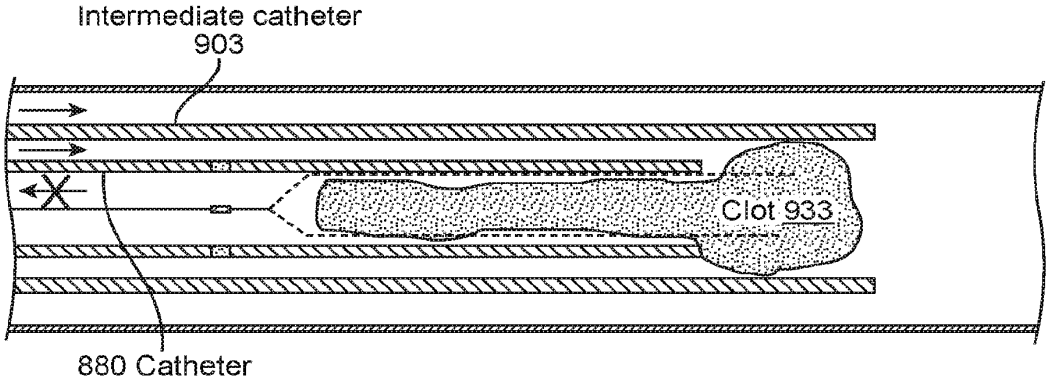


FIG. 11C

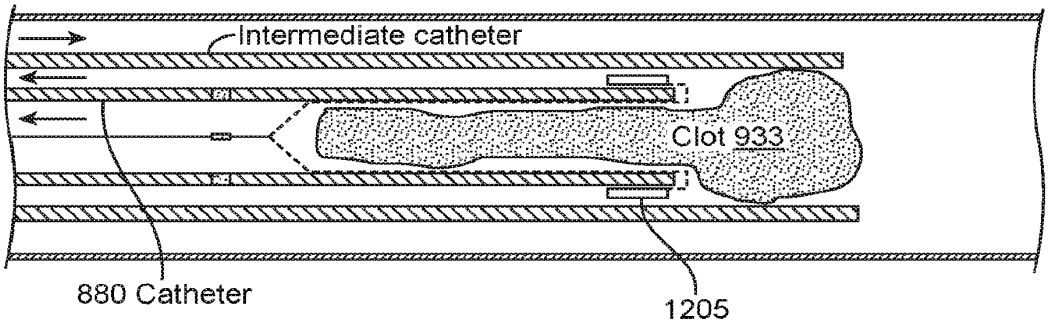


FIG. 12A

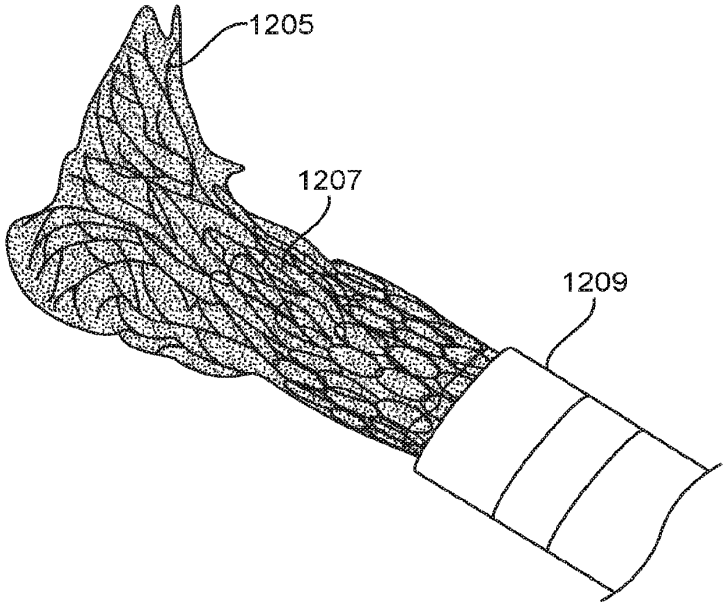


FIG. 12B

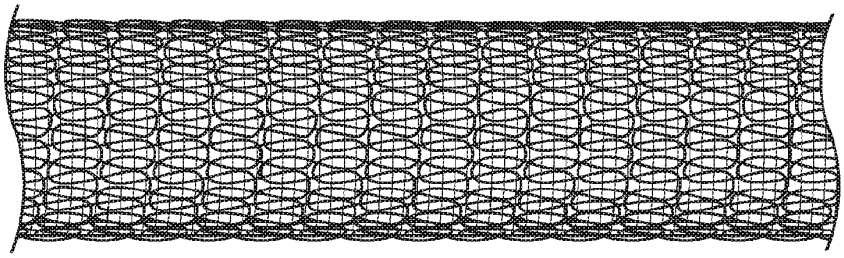


FIG. 13C

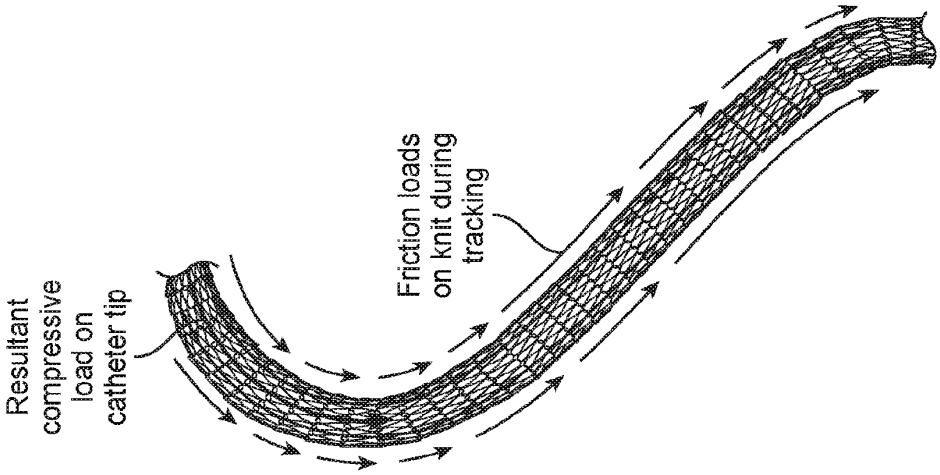


FIG. 13B

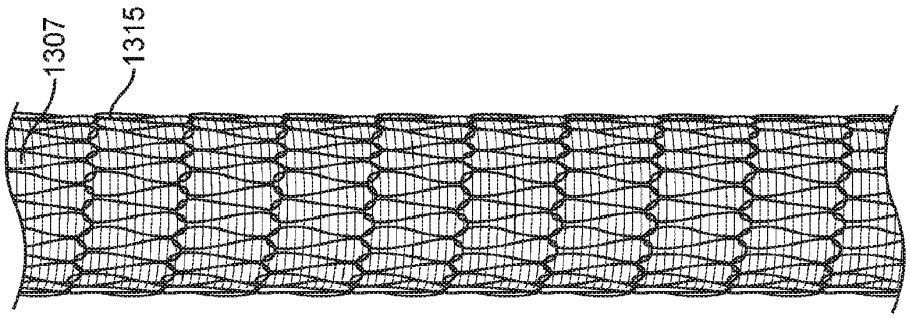
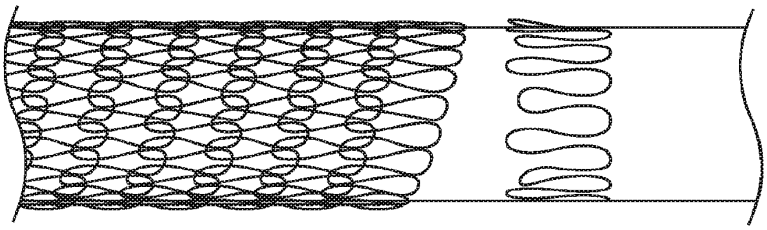
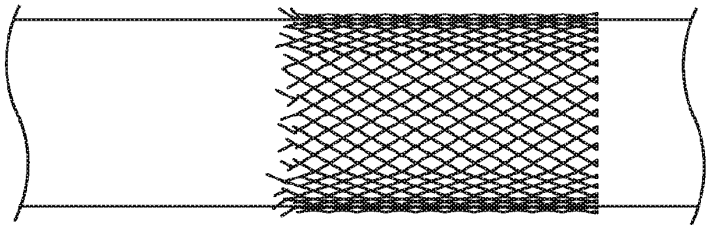


FIG. 13A



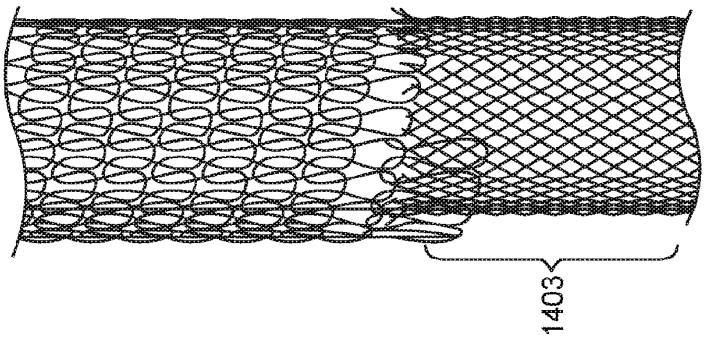
NiTi knit segment as a stop element

FIG. 14D



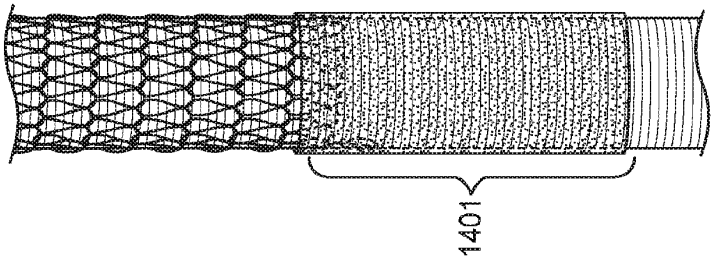
NiTi braid with exposed fingers

FIG. 14C



NiTi braid with exposed fingers

FIG. 14B



Polymer stop

FIG. 14A

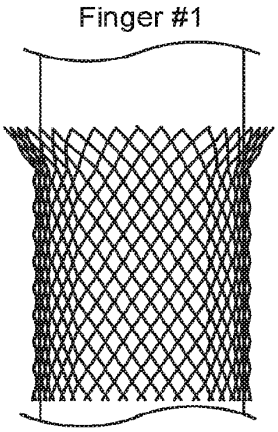


FIG. 15A

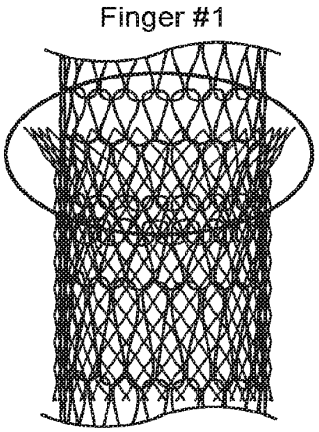


FIG. 15B

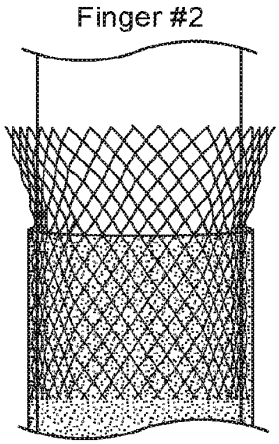


FIG. 15C

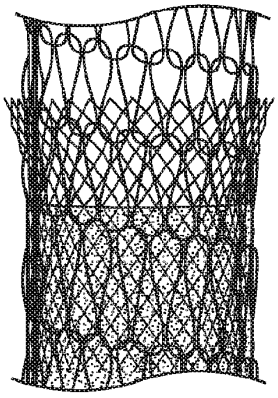


FIG. 15D

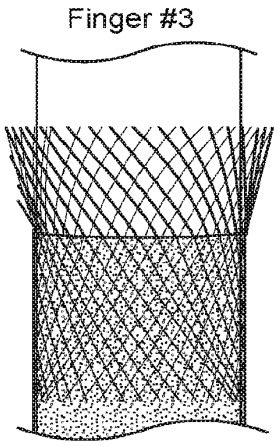


FIG. 15E

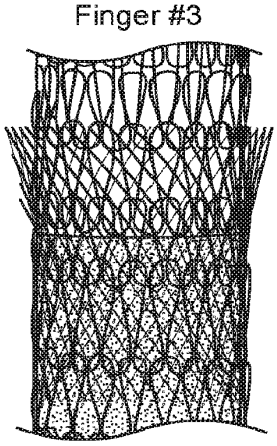


FIG. 15F

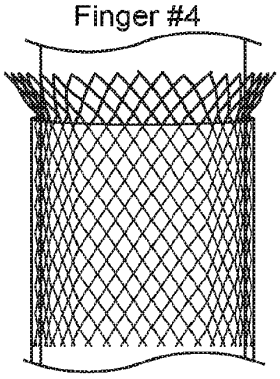


FIG. 15G

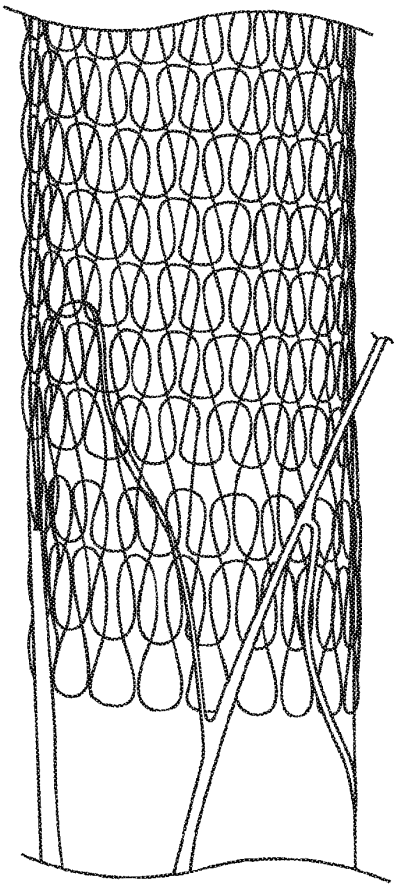


FIG. 15H

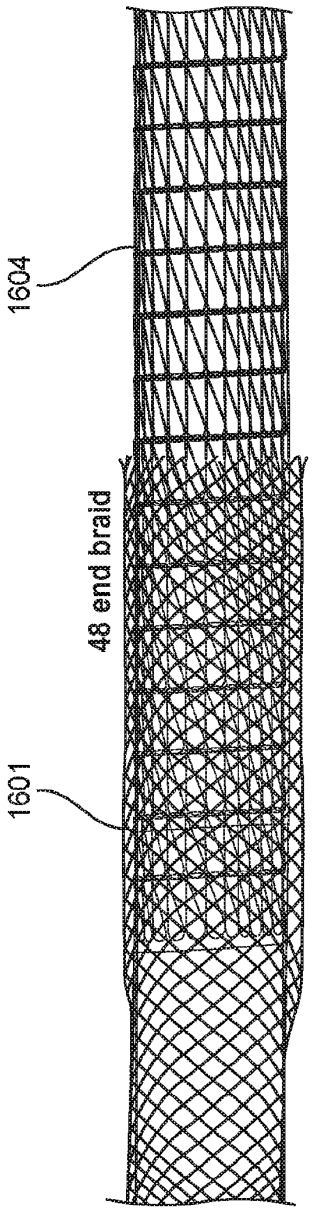


FIG. 16A

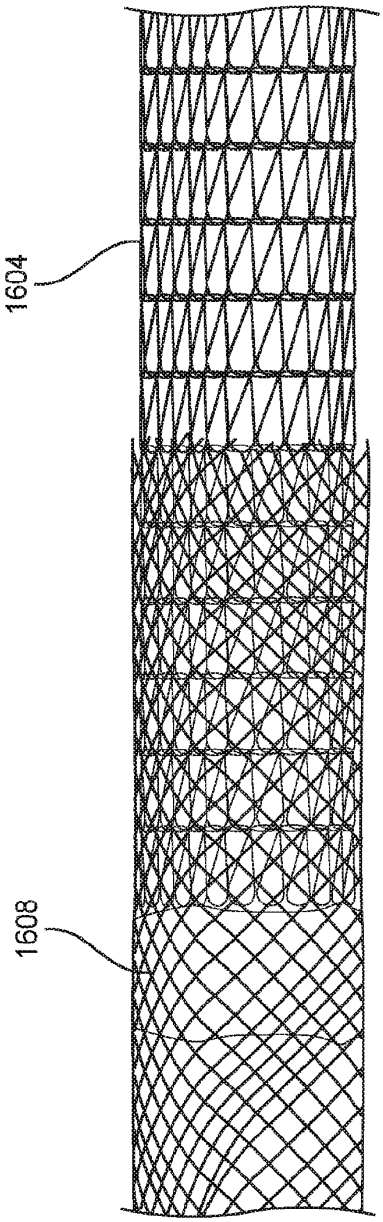


FIG. 16B

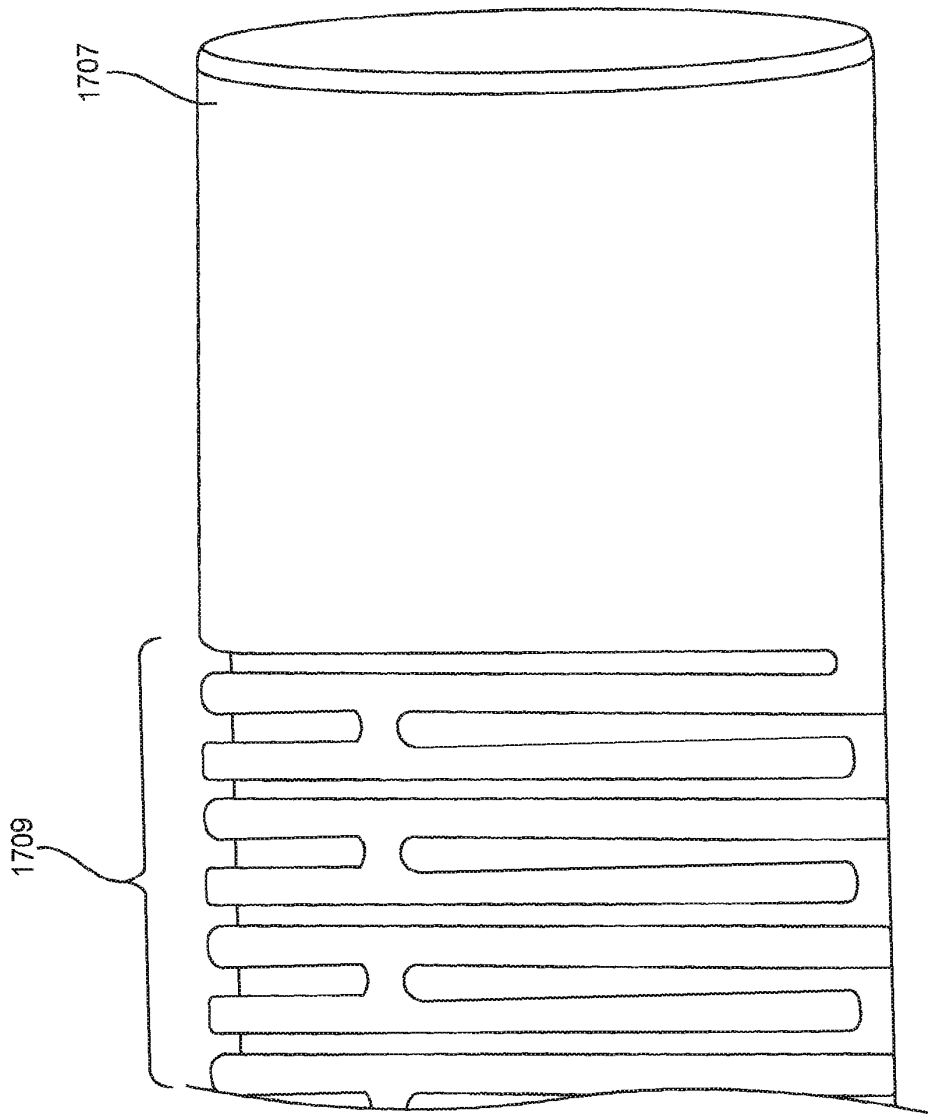


FIG. 17

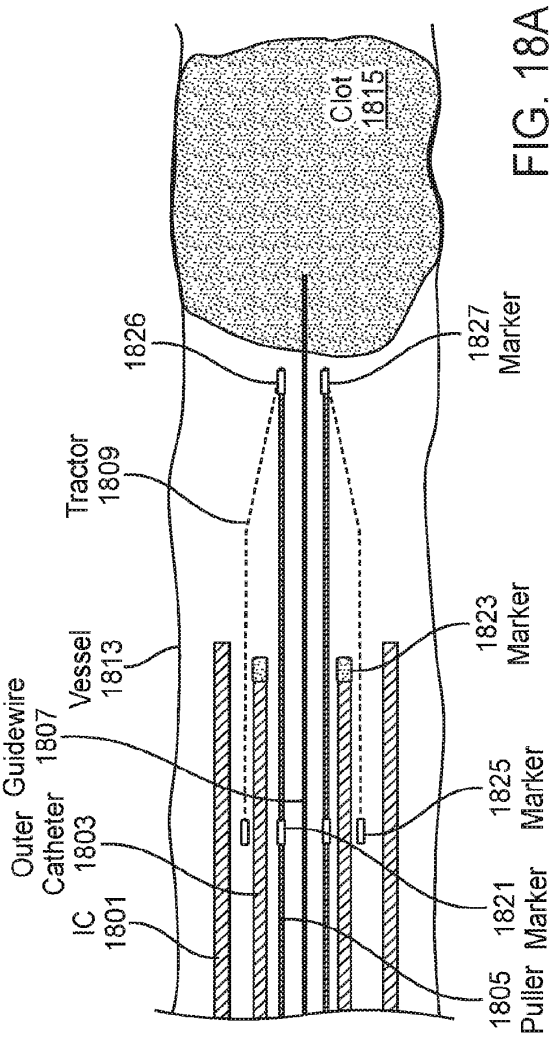


FIG. 18A

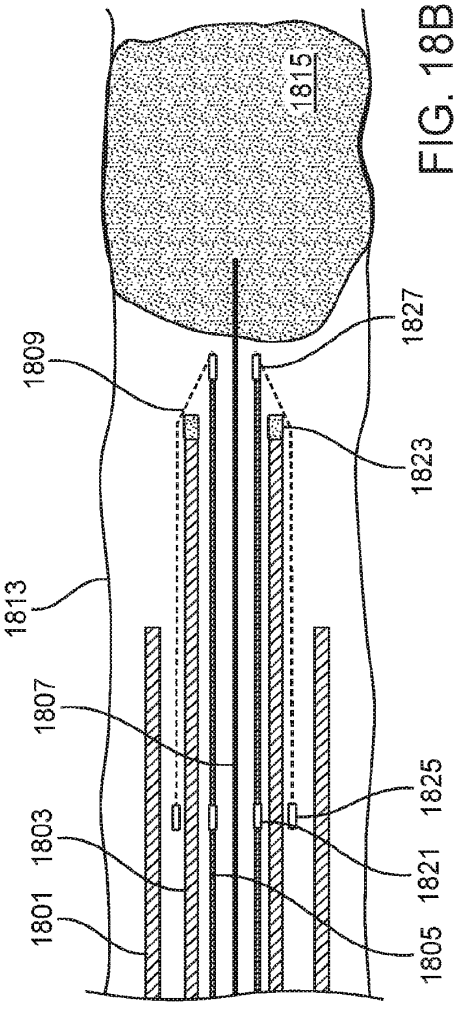


FIG. 18B

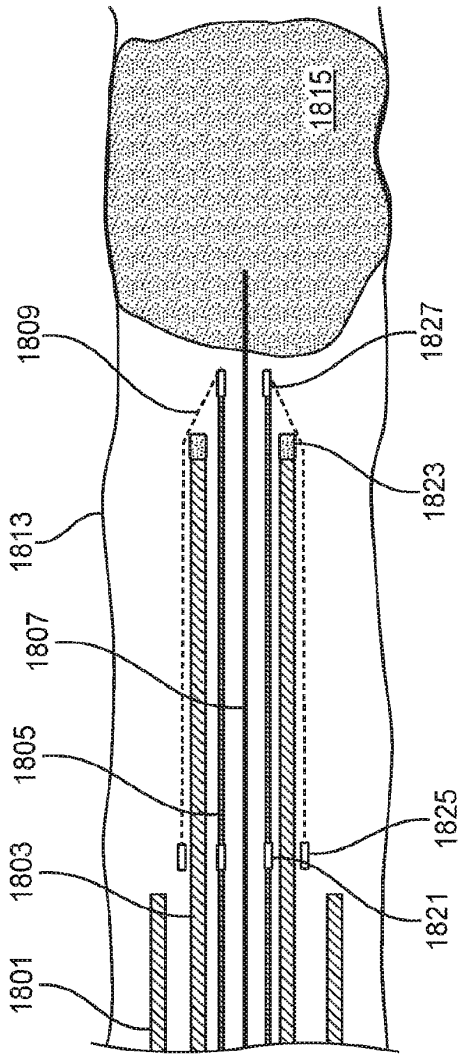


FIG. 18C

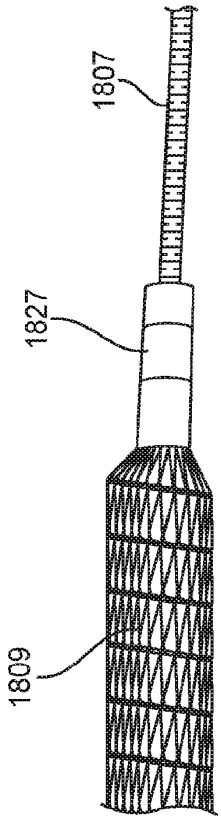


FIG. 18C1

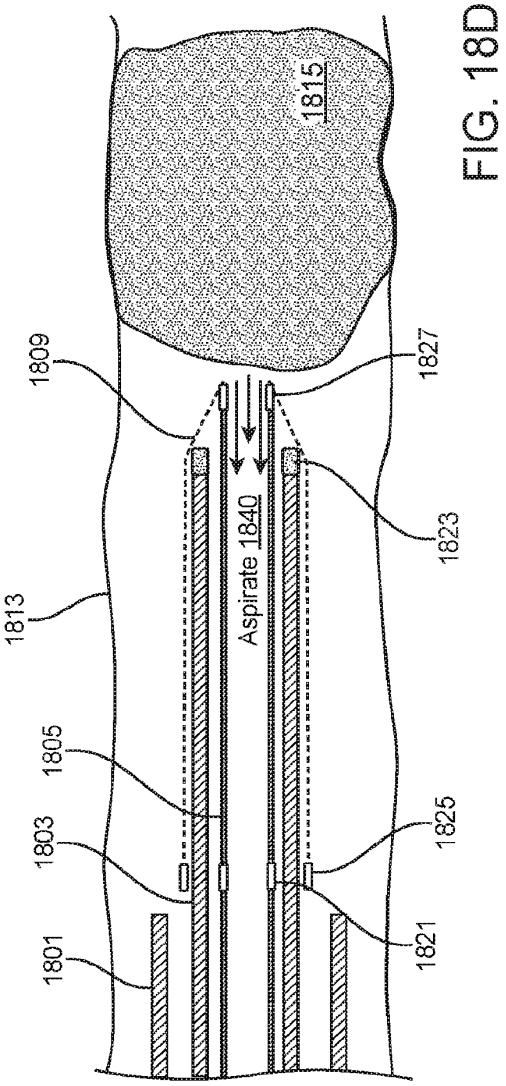


FIG. 18D

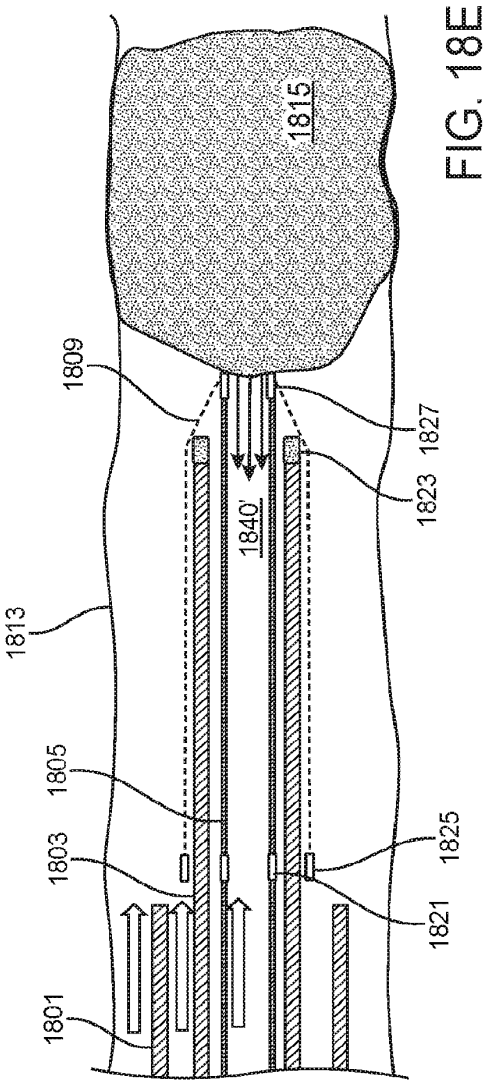


FIG. 18E

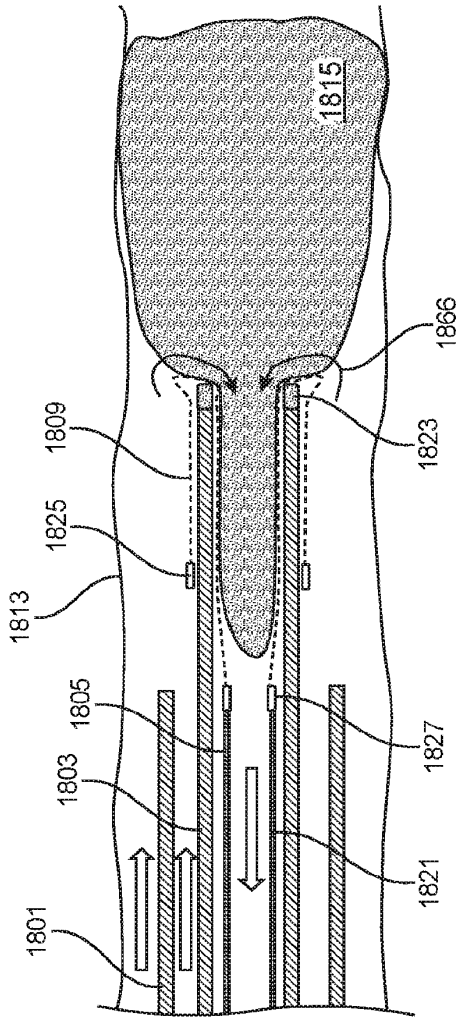


FIG. 18F

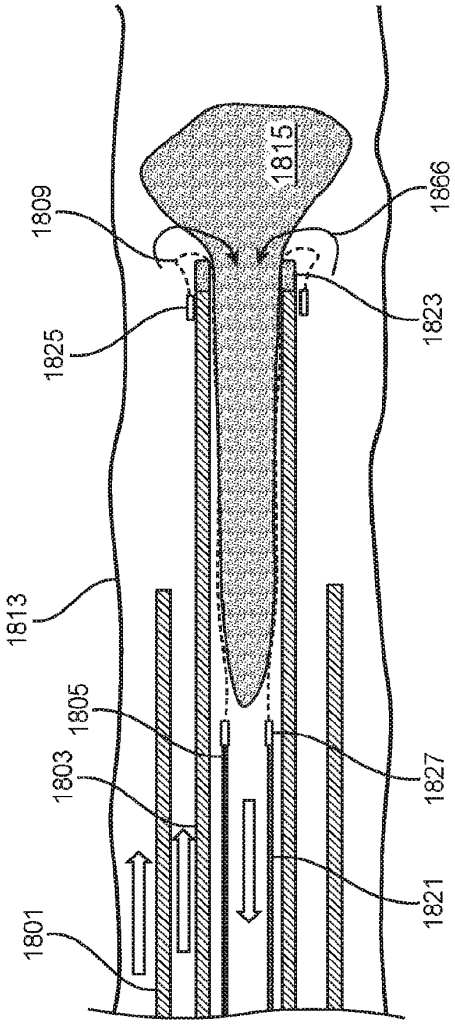


FIG. 18G

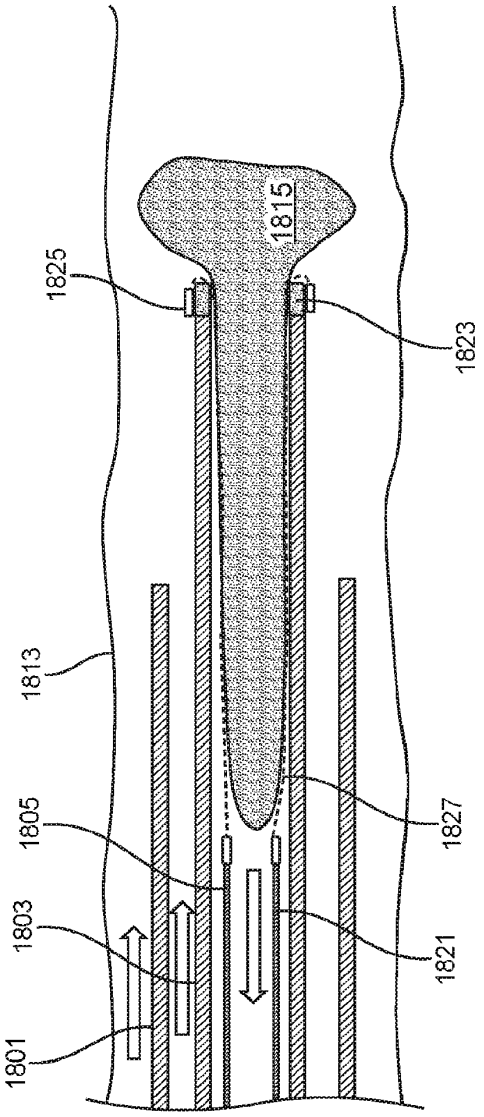


FIG. 18H

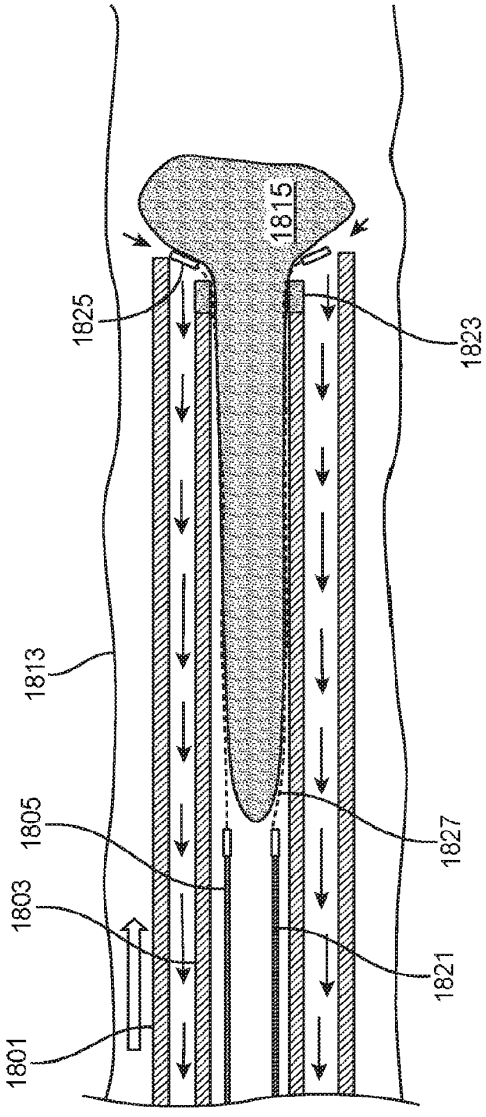


FIG. 18I

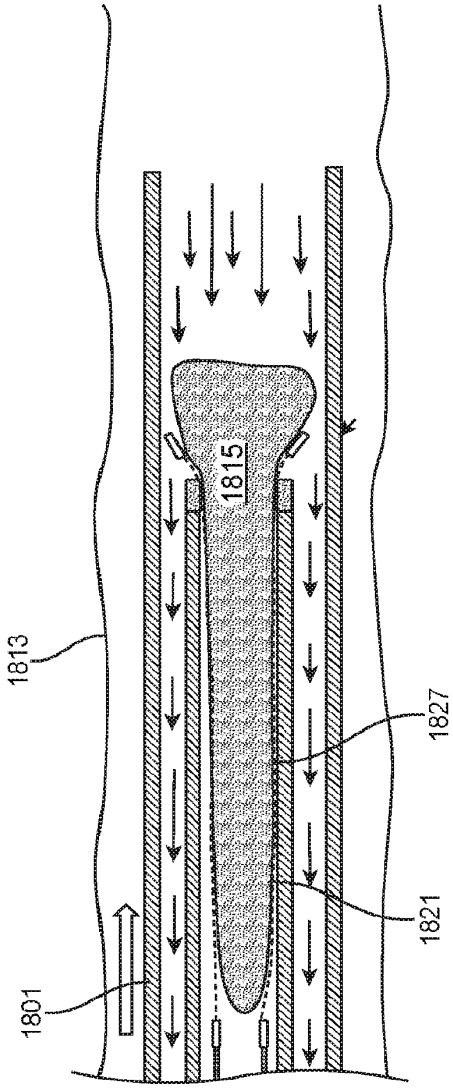


FIG. 18J

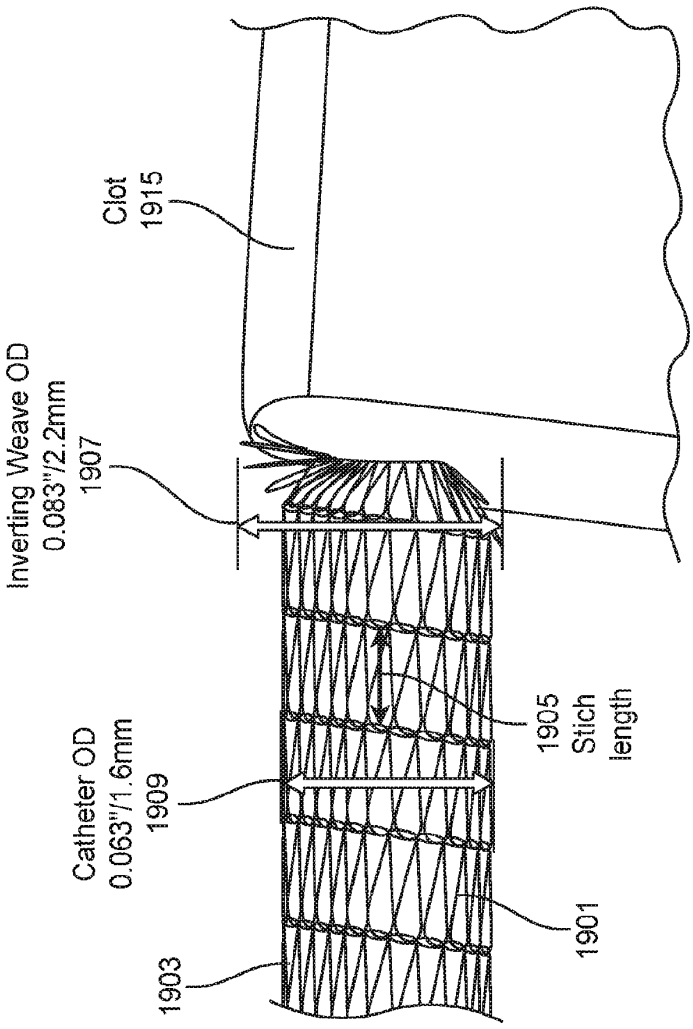

Clot
1915
Inverting Weave OD
0.083"/2.2mm
1907
1905
Stich
length
Catheter OD
0.063"/1.6mm
1909
1901
1903

FIG. 19

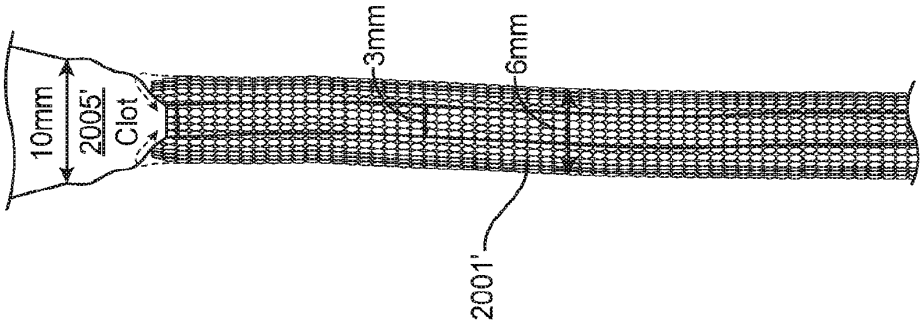


FIG. 20B

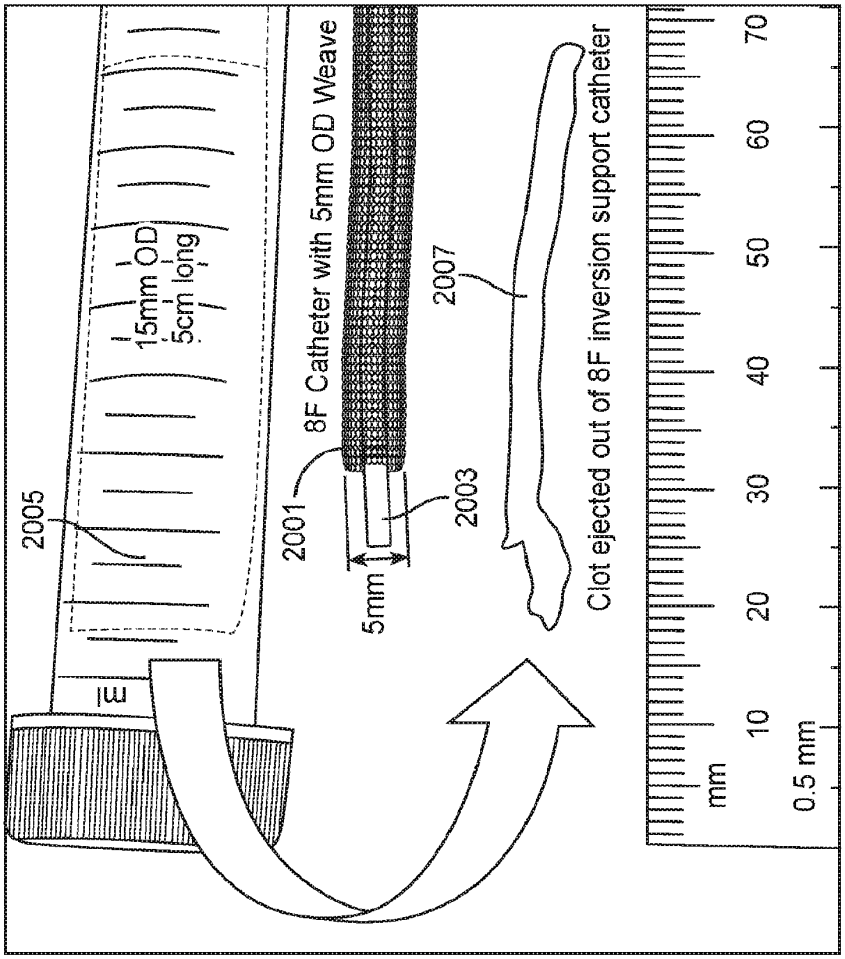


FIG. 20A

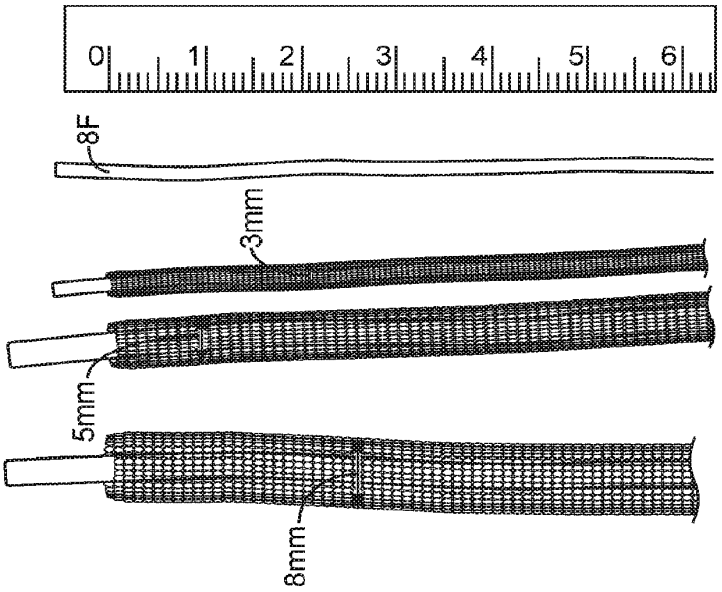


FIG. 21B

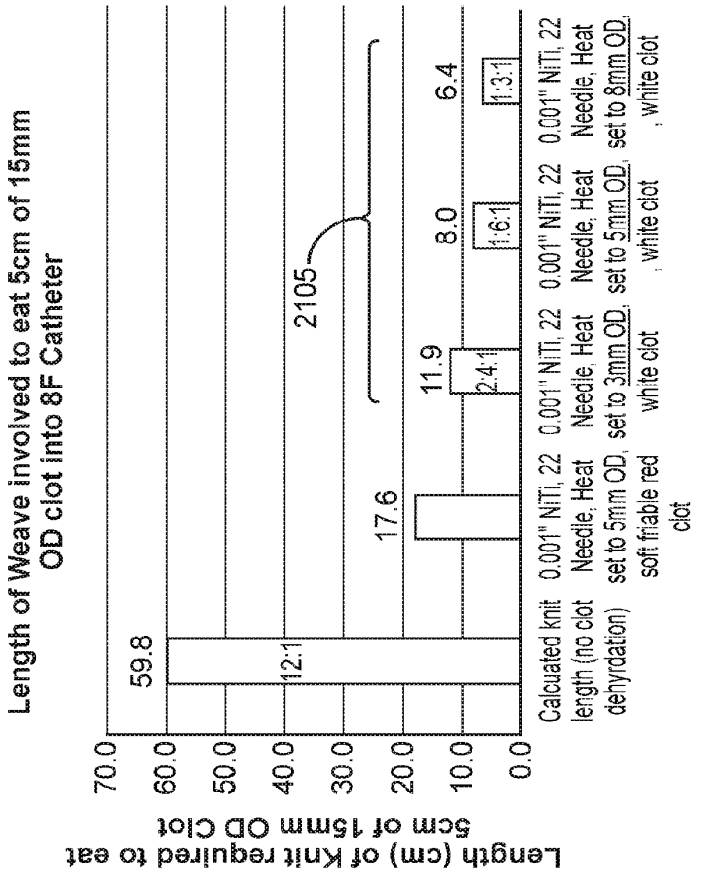


FIG. 21A

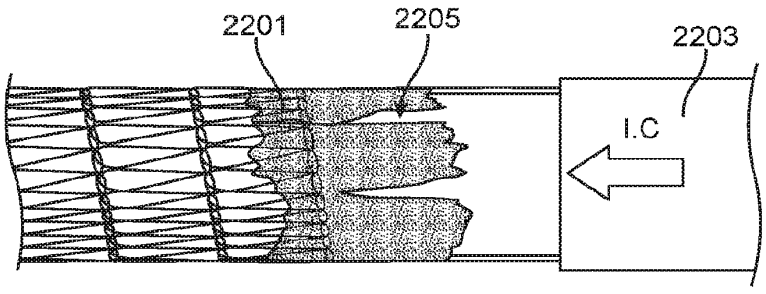


FIG. 22A

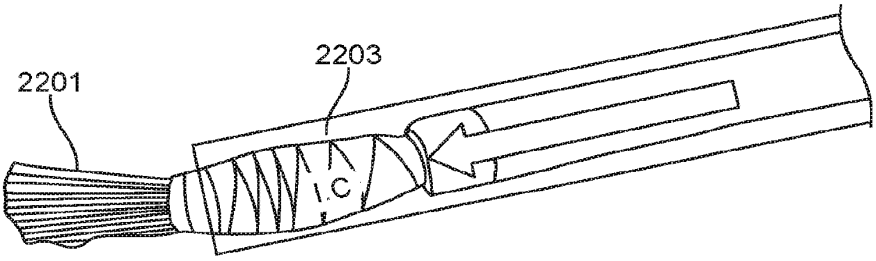


FIG. 22B

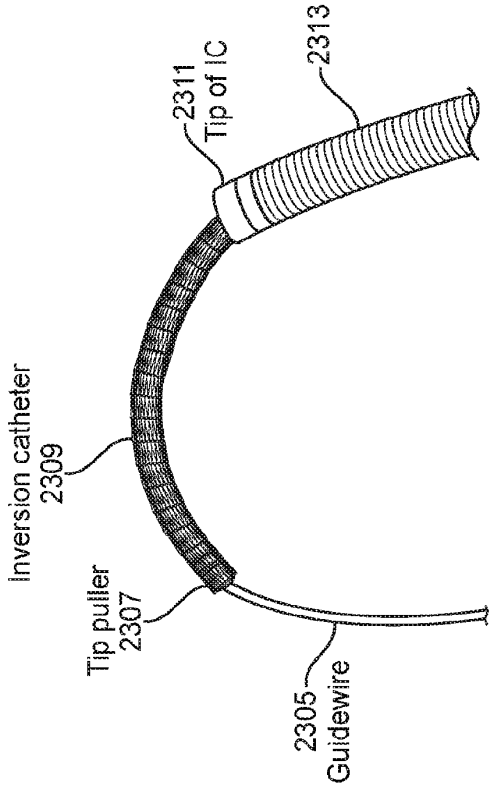


FIG. 23A

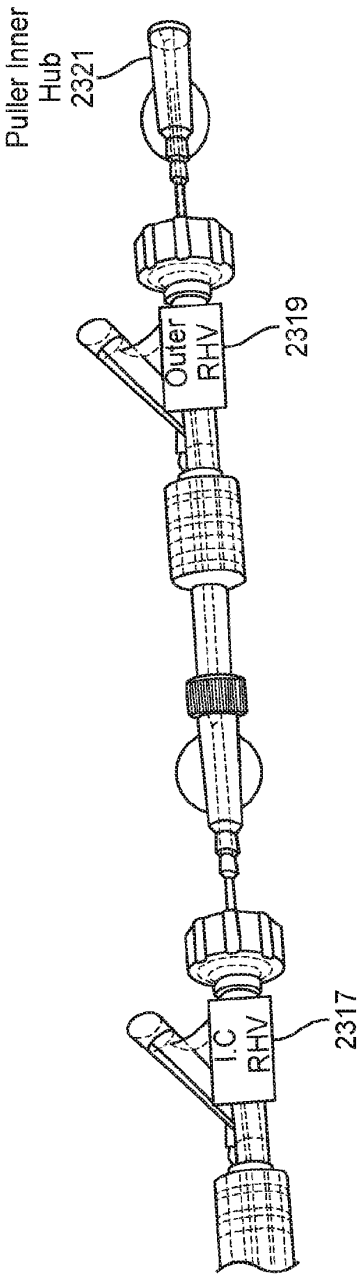


FIG. 23B

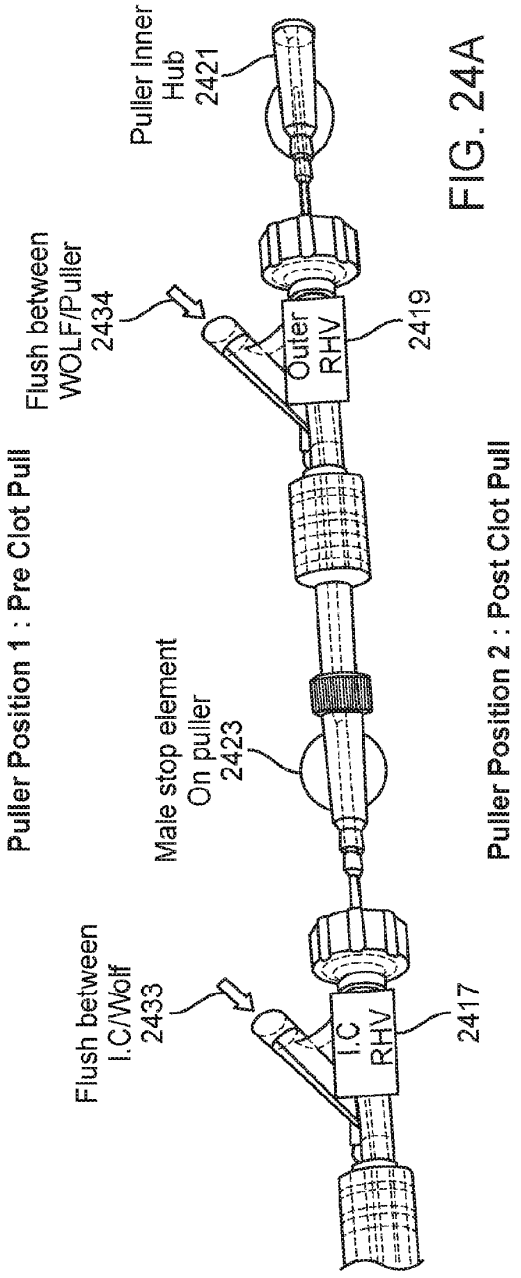


FIG. 24A

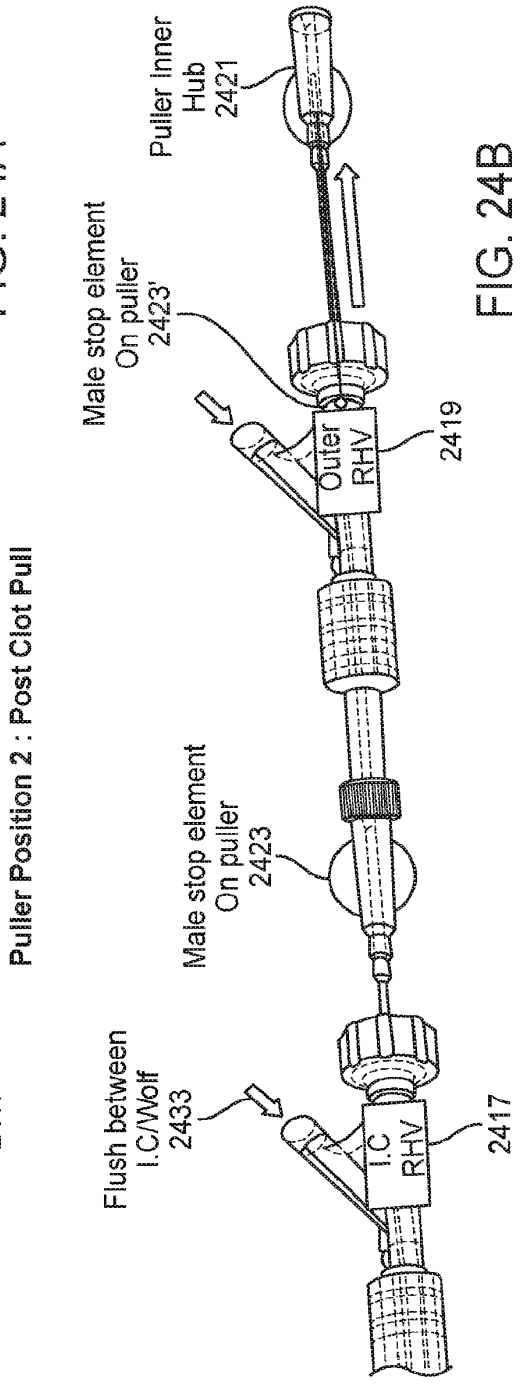


FIG. 24B

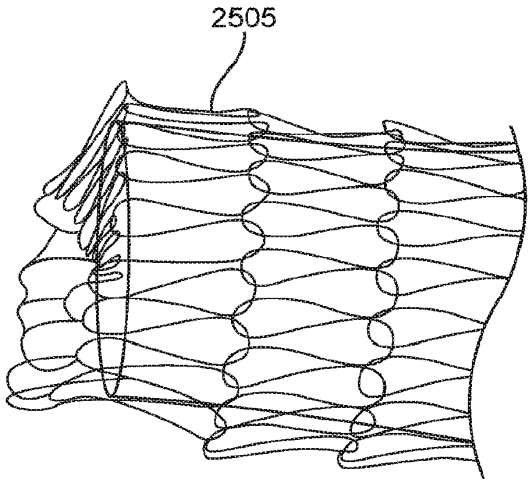


FIG. 25

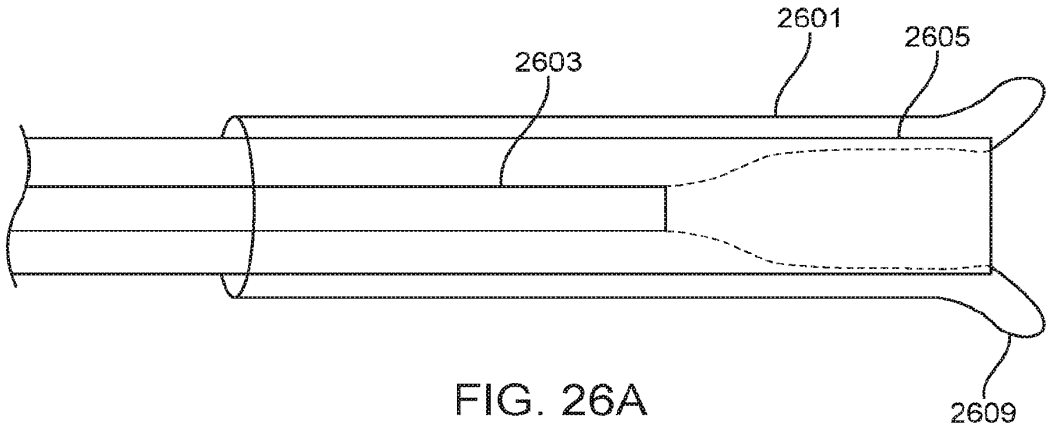


FIG. 26A

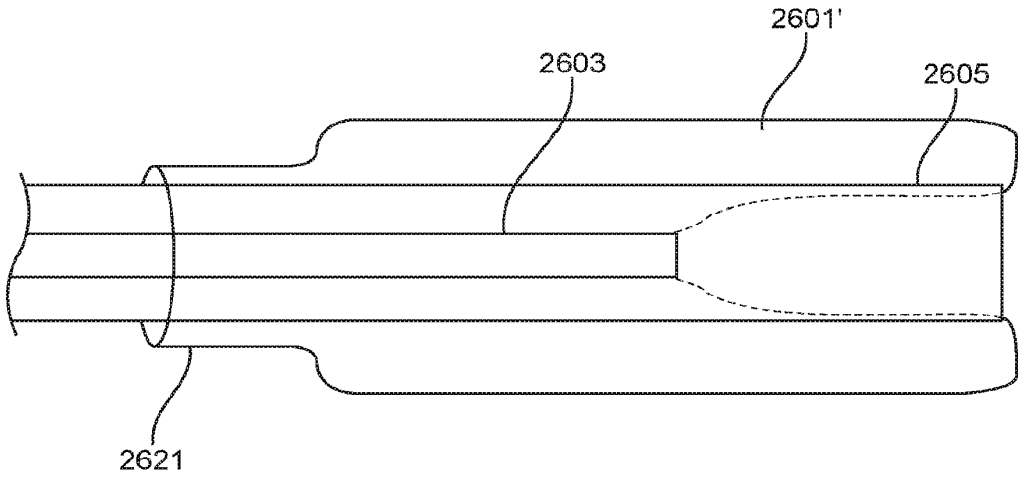


FIG. 26B

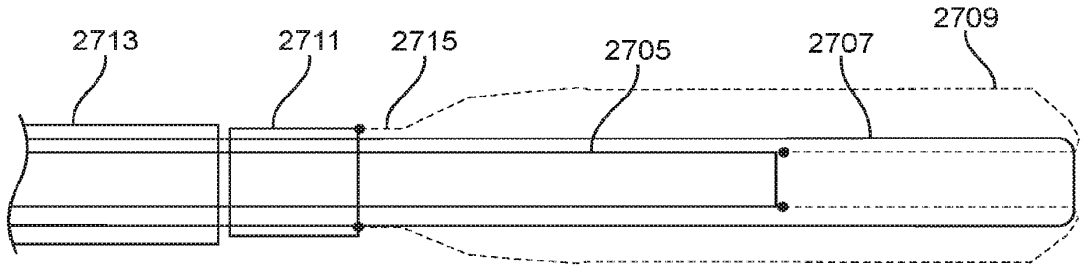


FIG. 27A

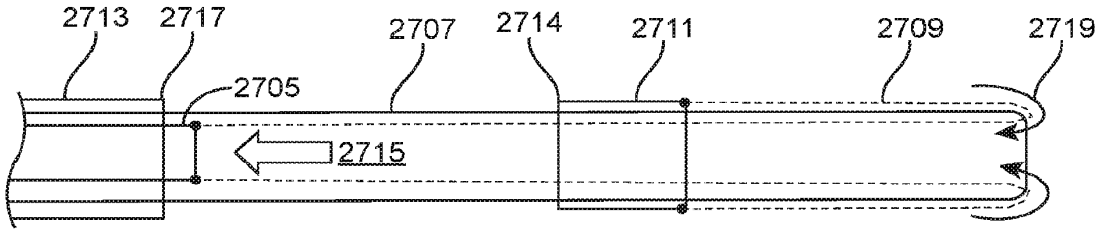


FIG. 27B

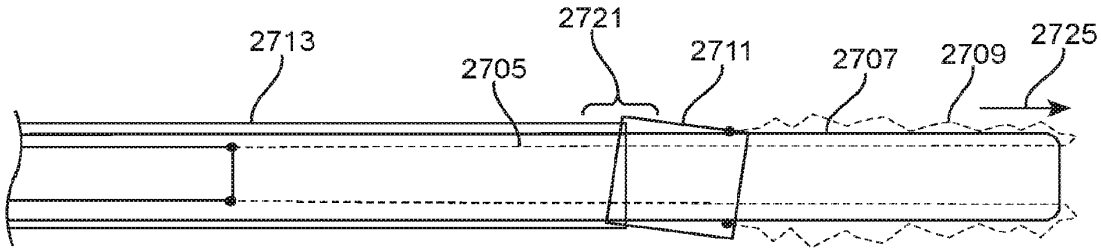


FIG. 27C

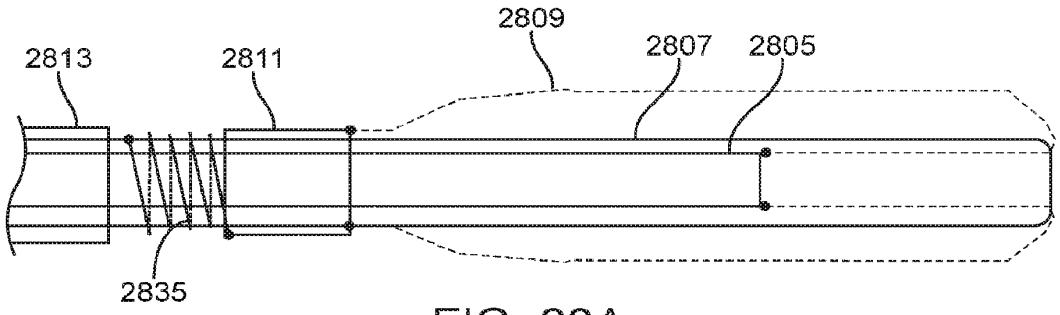


FIG. 28A

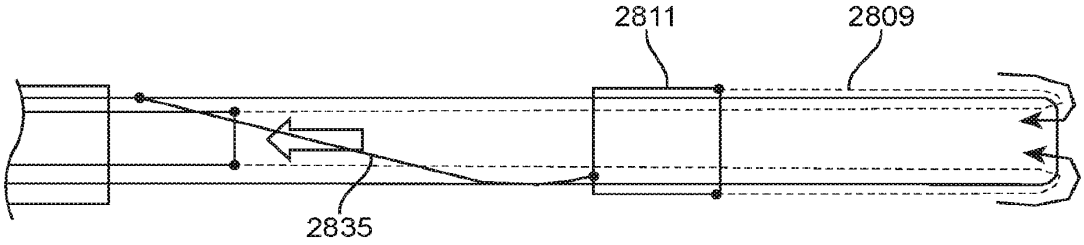


FIG. 28B

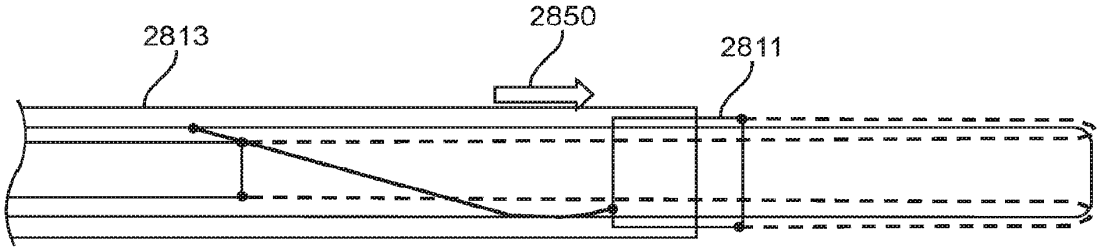


FIG. 28C

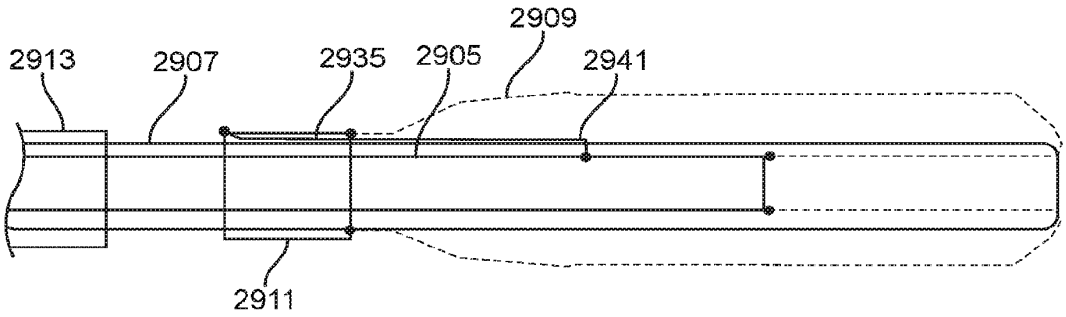


FIG. 29A

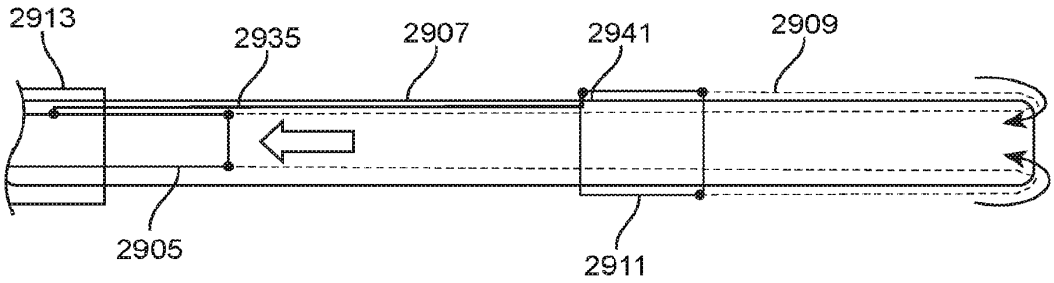


FIG. 29B

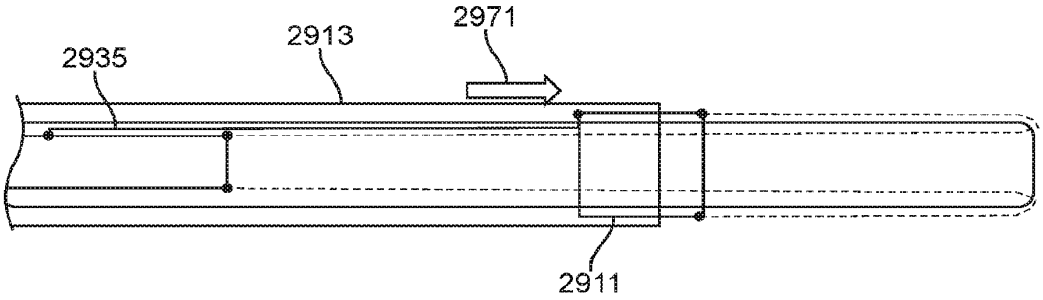


FIG. 29C

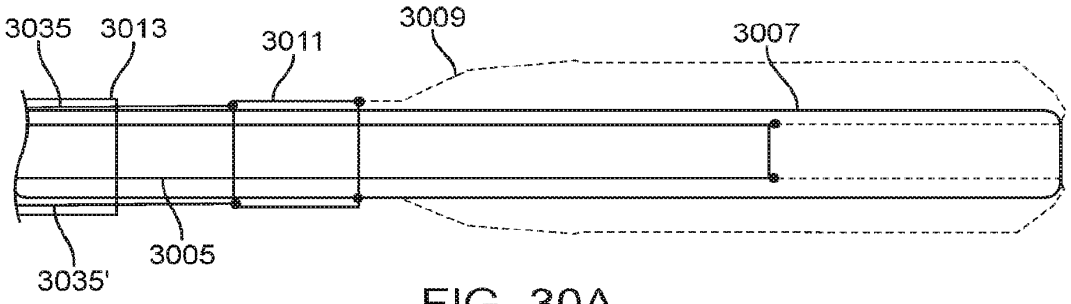


FIG. 30A

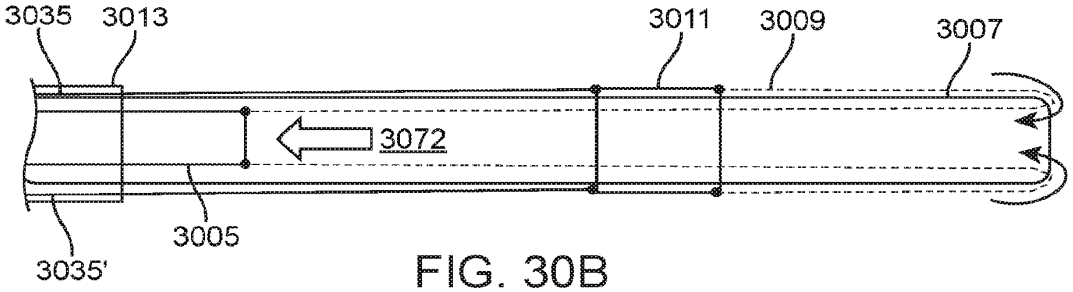


FIG. 30B

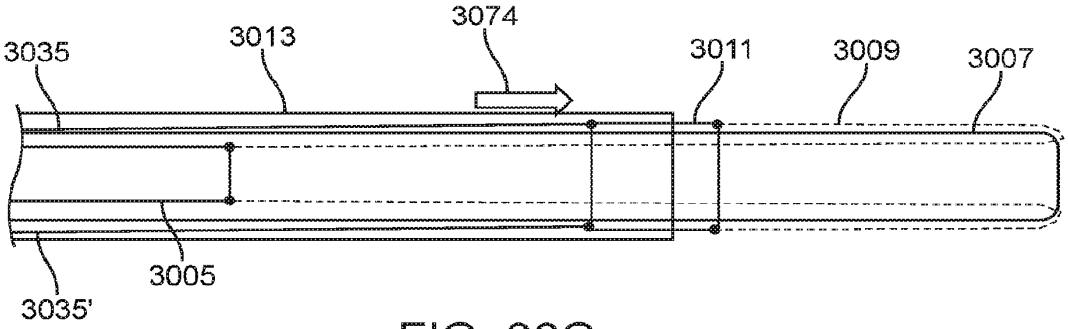


FIG. 30C

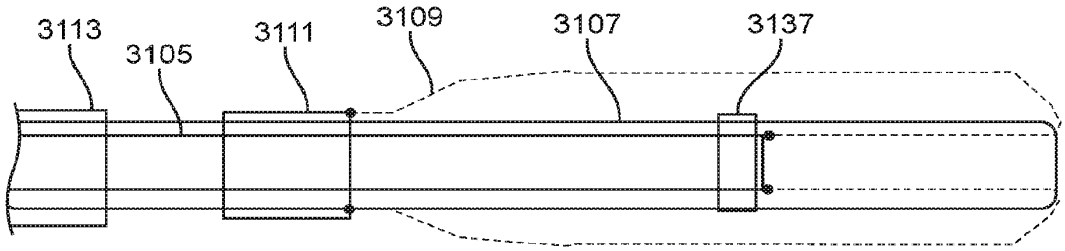


FIG. 31A

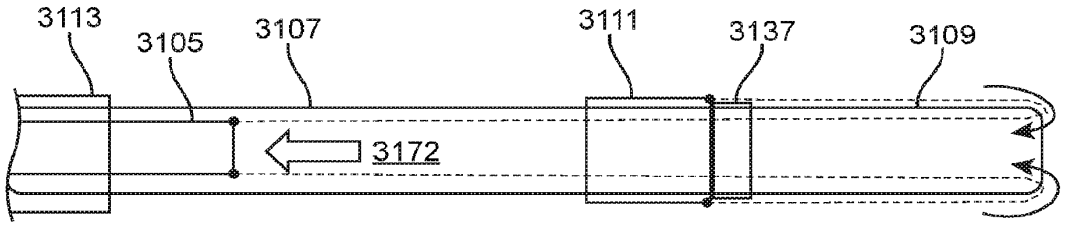


FIG. 31B

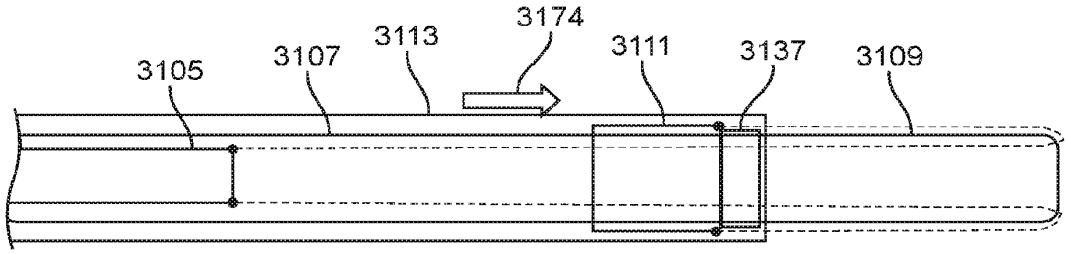


FIG. 31C

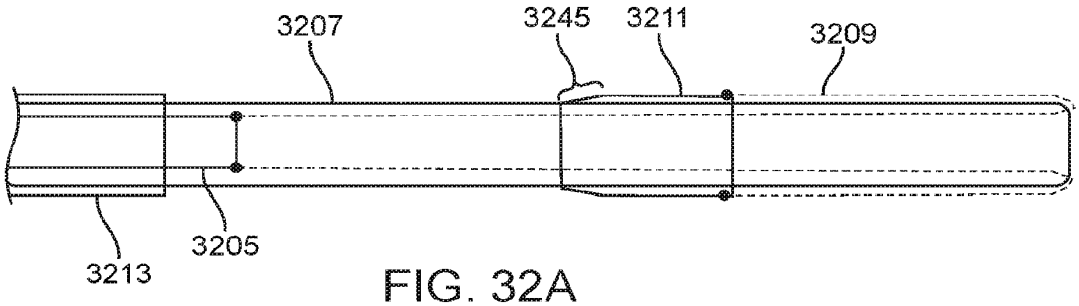


FIG. 32A

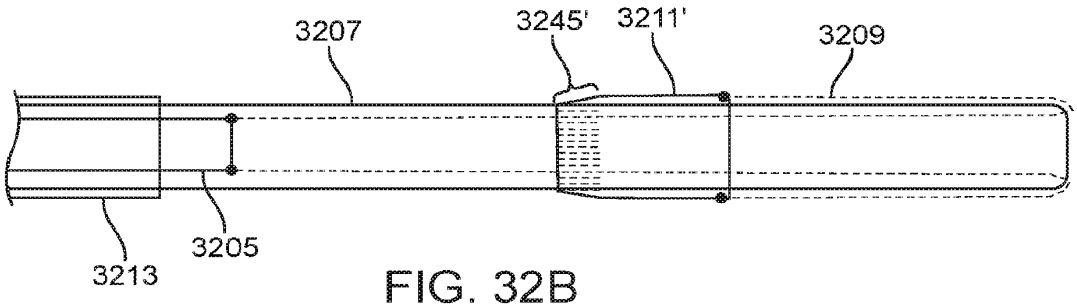


FIG. 32B

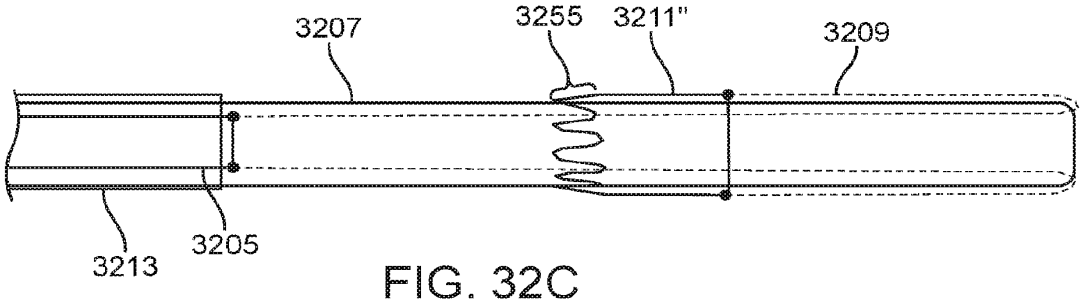


FIG. 32C

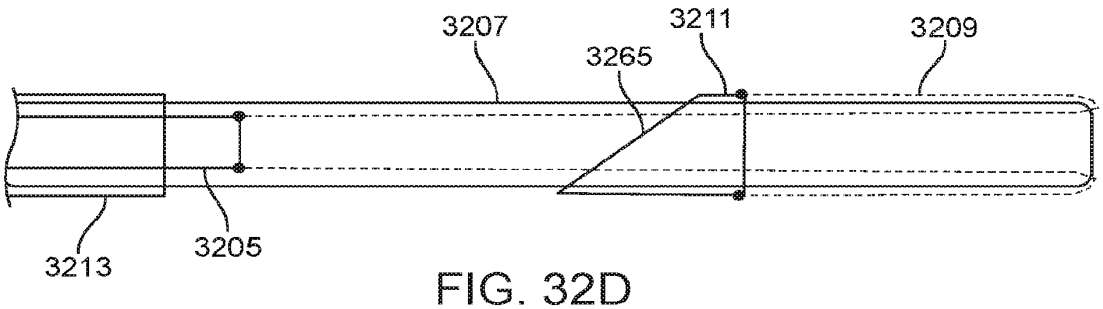


FIG. 32D

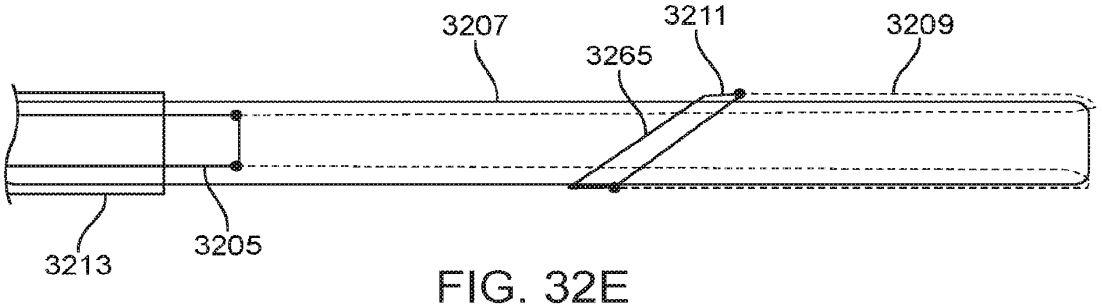


FIG. 32E

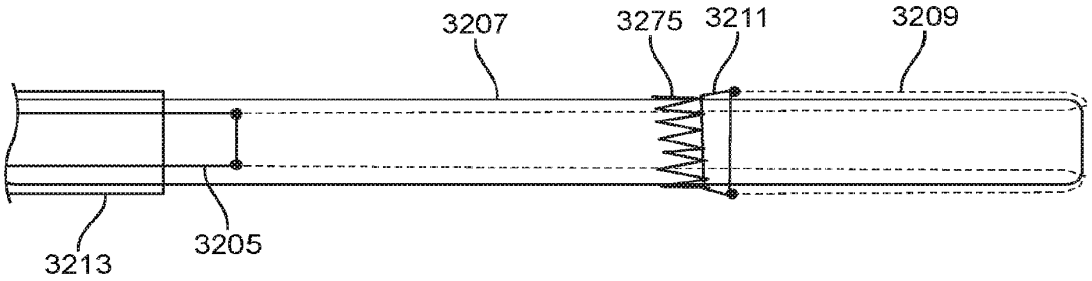


FIG. 32F

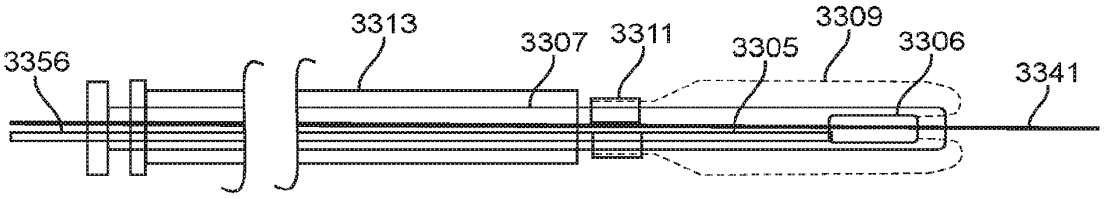


FIG. 33A

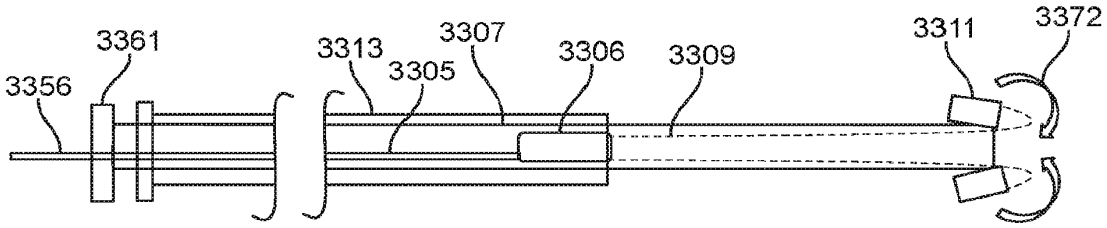


FIG. 33B

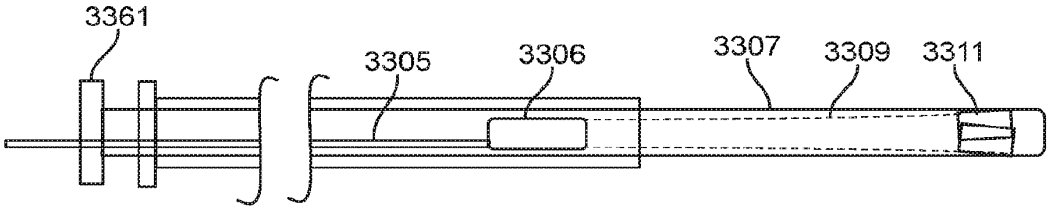


FIG. 33C

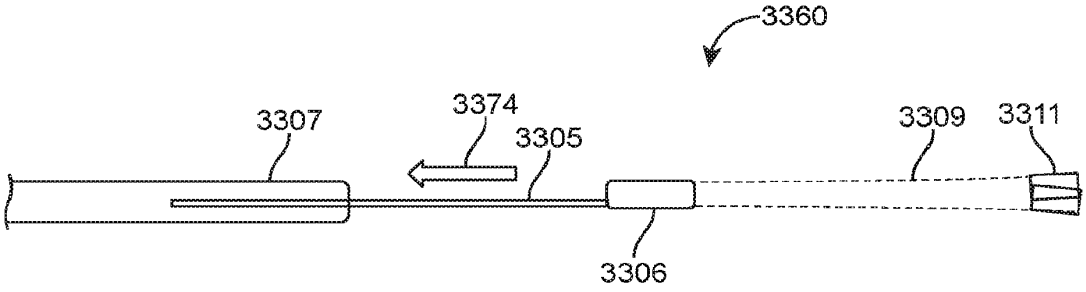


FIG. 33D

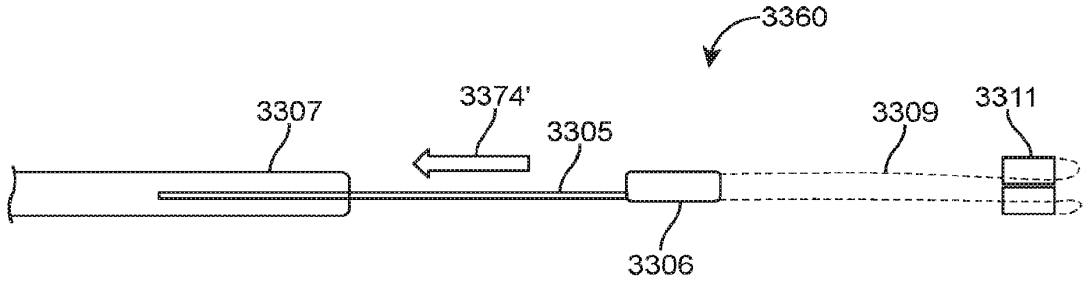


FIG. 33E

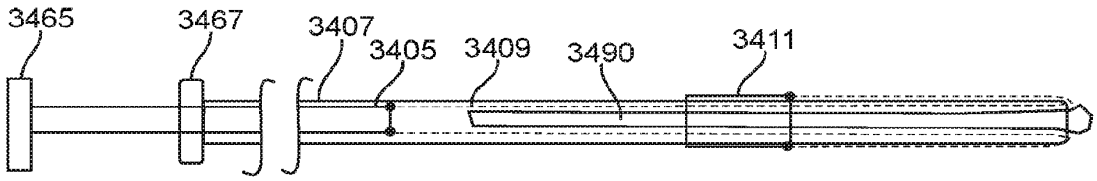


FIG. 34A

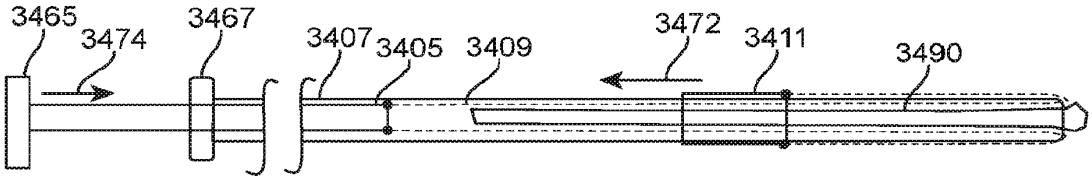


FIG. 34B

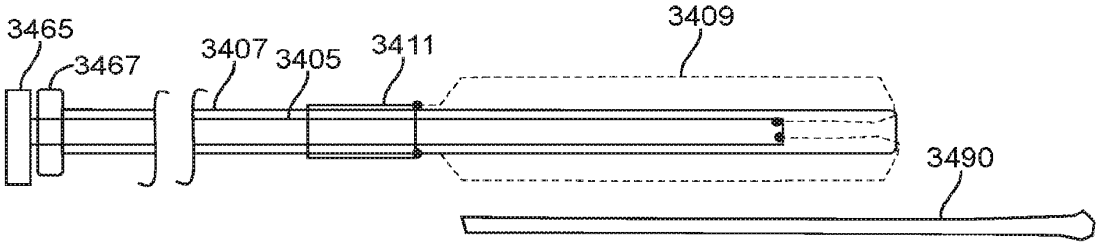


FIG. 34C

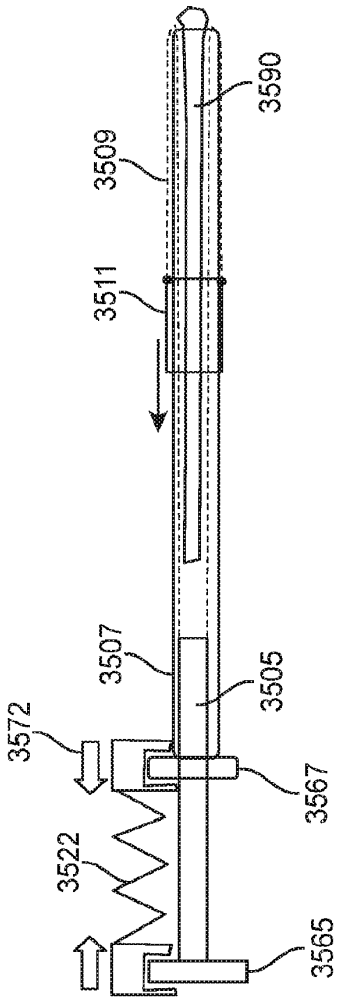


FIG. 35

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/059607

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/221 A61B17/34 A61M1/00
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61M

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2017/189550 A1 (STRYKER CORP [US]) 2 November 2017 (2017-11-02)	1-9, 11-15, 29-41
Y	abstract	19-28
A	paragraphs [0033], [0035] - [0036], [0049] - [0109]; figures 1-12	16-18

X	WO 2017/058280 A1 (GW MEDICAL LLC [US]) 6 April 2017 (2017-04-06)	1-18, 29-40
Y	abstract	19-28
	paragraphs [0014], [0015], [0043] - [0071], [0087], [0116] - [0171], [0190]; figures 1-38	

	-/--	

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

[X] See patent family annex.

* Special categories of cited documents :

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

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

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 March 2019	28/03/2019

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Ioanovici, T

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

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 2017/303948 A1 (WALLACE MICHAEL P [US] ET AL) 26 October 2017 (2017-10-26) abstract paragraphs [0058] - [0064], [0116] - [0148], [0159] - [0217]; figures 1-44	1-15,41 16-40
A	WO 2012/009675 A2 (LAZARUS EFFECT INC [US]; MARTIN BRIAN B [US]) 19 January 2012 (2012-01-19) abstract paragraphs [0167] - [0171]; figures 1-22	1-41
A	US 2005/085849 A1 (SEPETKA IVAN [US] ET AL) 21 April 2005 (2005-04-21) abstract paragraph [0083]; figures 5-46	1-41
X,P	WO 2017/210487 A1 (STRYKER CORP [US]) 7 December 2017 (2017-12-07) abstract paragraphs [0011] - [0017], [0020] - [0031], [0035] - [0088]; figures 1-10	1-4, 8-10, 13-15
X,P	WO 2018/049317 A1 (STRYKER CORP [US]) 15 March 2018 (2018-03-15) abstract paragraphs [0012], [0021] - [0036], [0054] - [0055], [0087] - [0134]; figures 1-28	1,3,4,8, 10,12, 13,15, 29-40
A	US 2011/160763 A1 (FERRERA DAVID A [US] ET AL) 30 June 2011 (2011-06-30) abstract paragraphs [0134], [0244] - [0246]; figures 2-60	1-41
A	US 2012/083868 A1 (SHRIVASTAVA SANJAY [US] ET AL) 5 April 2012 (2012-04-05) abstract paragraph [0052]; figures 1-10	1-41
A	WO 2012/049652 A1 (ENDOGROWTH PROPRIETARY LTD [ZA]; SMITH JAMES [ZA]) 19 April 2012 (2012-04-19) abstract page 9 - page 17; figures 1-14	1-41
A	US 2014/155980 A1 (TURJMAN ALEXIS [US] ET AL) 5 June 2014 (2014-06-05) abstract paragraphs [0257] - [0265]; figure 41	1-41

-/--

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/059607

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2017/189591 A1 (STRYKER CORP [US]) 2 November 2017 (2017-11-02) abstract paragraph [0044]; figures 1-9	1-41

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/059607

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

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

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

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

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

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

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

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

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

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

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

Remark on Protest

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

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

☒ No protest accompanied the payment of additional search fees.

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: 1-15, 41

Inverting tube aparatus for removing a clot from a vessel comprising an inversion support catheter, a puller and a flexible inverting tube with a cuff at the second end

1.1. claim: 41

Inverting mechanical thrombectomy aparatus for removing a clot from a vessel comprising an inversion support catheter with a plurality of slots or cut-outs for enhancing flexibility, a puller and a flexible knitted inverting tube

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2. claims: 16, 18

Inverting tube aparatus for removing a clot from a vessel comprising an intermediate catheter, an inversion support catheter, a puller and a knitted inverting tube with filament knitted to form a plurality of interlocking loop stitched having a length between 0,5 and 10 mm

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3. claims: 17, 19-28

Inverting tube aparatus for removing a clot from a vessel comprising an inversion support catheter, a puller and a knitted inverting tube having a first and a second configuration, the knitted tube having an expanded outer diameter of 0,5-12 mm for the first region adjacent the first end in the first configuration, an inner diameter grater than 30% of an inner diameter of the inversion support catheter in the second configuration, and a second region of the knitted tube adjacent the second end has an expanded outer diameter less than the expanded outer diameter of the knitted tube region adjacent the first end and within 20% of an outer diameter of the inversion support catheter.

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4. claims: 29-40

Pre-loaded inverting mechanical thrombectomy aparatus for removing a clot from a vessel comprising an intermediate catheter, an inversion support catheter, a puller and a flexible inverting tube extending between the inversion support catheter and the intermediate catheter, wherein the puller and the inversion support catheter are releasabl held together.

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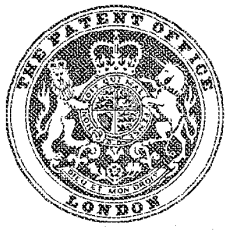
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1588072

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(54) EXTRACTING DEVICE FOR REMOVING OBJECTS FROM HUMAN BODY PASSAGES

(71) I, WILLIAM HOWARD BEECHER, a citizen of the United States of America of 292 Boyd Avenue, Elmhurst, Illinois 60126, United States of America, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to an extracting device for removing kidney stones or other objects from the urinary tract or other passages of the human body, some of which, such as blood vessels, may be reached through incisions.

An object of the present invention is to provide a new and improved extracting device which can easily be inserted into the ureters or other narrow passages of the human body, and will be capable of removing kidney stones and other objects in a highly effective and efficient manner.

A further object is to provide such a new and improved extracting device which will be capable of removing kidney stones and other similar objects from narrow passages of the human body, without scratching or otherwise injuring the walls of the passages.

According to the present invention there is provided an extracting device comprising an outer flexible tube the distal end of which is insertable into a body passage, an inner flexible tube slideably received within the outer tube for free longitudinal sliding movement with the distal end of the inner tube normally projecting beyond the distal end of the outer tube, the inner and outer tubes having clearance space therebetween for carrying fluid under pressure, a thin, tubular, highly distendable and limp sleeve having its proximal end portion connected to the distal end of the outer tube, the sleeve having a distal end portion which is inverted and is connected to the distal end of the inner tube for insertion into the body passage, the sleeve being otherwise free to expand upon inflation, the tubular sleeve having first and second tubular surfaces on opposite sides of the sleeve,the first surface facing inwardly at the proximal end portion of the sleeve, the inverted distal end portion of the sleeve being turned inside out with the second surface facing inwardly, the sleeve being inflatable by fluid transmitted along said clearance space to dilate the body passage, the sleeve when inflated having an annular flaring portion bulging beyond the distal end of the inner tube and curved convexly in longitudinal section for sealing engagement with a foreign object in the body passage, the annular flaring curved portion being soft, pliable and capable of conforming to the shape of the foreign object to effect a seal therewith, the inner tube being operative to transmit suction for capturing and holding the foreign object in sealing engagement with the annular flaring portion of the sleeve, and means for retracting the inner tube relative to the outer tube while the suction pulls the foreign object within the confines of the sleeve and the sleeve is progressively turned inside out around the foreign object to envelop the foreign object for removal with the tubes.

The sleeve may be inflatable by compressed air or some other fluid transmitted along the clearance space between the outer and inner tubes. The inflation of the sleeve dilates the body passage, so as to loosen any kidney stone or the like which may be lodged in the passage. A pressure source and a control valve are preferably connected to the free end of the outer tube, for selectively supplying fluid pressure thereto so as to inflate the sleeve.

A vacuum source and a vacuum control valve are preferably connected to the free end of the inner tube, for selectively providing a vacuum or suction within the inner tube, to suck the kidney stone against the end of the inflated sleeve, so as to capture the kidney stone. The inner tube is then retracted relative to the outer tube, so that the kidney stone will be pulled into the confines of the sleeve. Simultaneously, the sleeve is preferably deflated so that the sleeve will enfold the kidney stone. The outer and inner tubes may then be withdrawn from the body passage, so as to remove the kidney stone or other object. The sleeve surrounds the kidney stone and

INARI_020879

prevents it from scratching or otherwise injuring the inner walls of the body passage.

The flexible inner and outer tubes are preferably made of a resinous plastics material, such as polyethylene, for example. An X-ray contrast medium is preferably incorporated into or coated upon the material of the outer or inner tube, so that an X-ray fluoroscope may be used to assist in inserting the outer tube into the ureter or other body passage. Alternatively, the probe formed by the outer and inner tubes can be rendered visible on an X-ray fluoroscope by inserting a flexible metal wire within the inner tube. Alternatively, a fiber optic device can be used for observing and guiding the probe during insertion.

The inflatable sleeve is preferably made of a thin elastic latex rubber material or the like.

A manipulator is preferably connected to the free ends of the outer and inner tubes, so that the operator can easily advance and retract the inner tube, relative to the outer tube, with the thumb and fingers of one hand. The other hand may then be employed to operate the control valves which regulate the air pressure and the suction.

The inflatable sleeve preferably has first and second reduced end portions which are stretched around and secured to the outer and inner tubes. The second end portion is reentrant in that it extends into the sleeve, so that the inflated sleeve will project endwise beyond the end of the inner tube. In this way, the inflated sleeve will be capable of forming a seal with the kidney stone or other object to be removed.

One or more auxiliary tubes may be inserted through the inner tube to provide auxiliary communication with the body passage. The auxiliary tubes may be employed to supply various medications. The auxiliary tubes may also be employed to withdraw mucus or other fluids from the body passage. An auxiliary tube having a plurality of tube elements or bores may be employed if desired.

Alternately, one or more auxiliary tubes may be inserted into the body passage along with the outer tube.

While the extracting device is particularly well adapted for removing kidney stone from the urinary tract, the extracting device may also be employed for removing gallstones, by inserting the extracting device through a drainage tube which has been installed during gallbladder surgery. The extracting device may also be employed to remove foreign objects from the respiratory tract or the esophagus. In addition, the extracting device may be employed to remove blood clots, foreign materials or foreign bodies from blood vessels, by inserting the extracting device through an incision into the blood vessel.

The invention will now be described by way of example with reference to the accompanying drawings, in which:

Fig. 1 is an elevational view of an extracting device to be described as an illustrative embodiment of the present invention, the view being partly in longitudinal section.

Fig. 2 is a fragmentary longitudinal section of the extracting device, showing the inflatable sleeve in a changed position.

Fig. 3 is a fragmentary elevation of the manipulator for the extracting device, the view being taken generally as indicated by the line 3—3 in Fig. 1.

Fig. 4 is a fragmentary perspective view showing the inflatable sleeve on the insertable end of the extracting device.

Fig. 5 is a fragmentary perspective view, showing the manipulator for the extracting device.

Fig. 6(a) is a fragmentary enlarged longitudinal section of the extracting device, the view being partly diagrammatic.

Fig. 6(b) is a fragmentary section corresponding to a portion of Fig. 6(a) and showing a modified construction.

Fig. 6(c) is a fragmentary section corresponding to a portion of Fig. 6(a) and showing a modified construction with a sliding seal used with a snare, wire or one or more auxiliary tubes, to permit full use of the device with the snare, wire or one or more auxiliary tubes in place.

Figs. 7(a)—(g) are a series of fragmentary sections showing successive steps in a procedure whereby the extracting device may be used to capture and enfold a kidney stone or some other object in a human body passage.

Figs. 8(a)—(e) are a series of fragmentary sections showing successive steps in a procedure for advancing the insertable portion of the extracting device through a narrow body passage.

Fig. 9(a) is a fragmentary section showing the insertable portion of the extracting device, as employed in conjunction with an auxiliary tube adapted to be inserted into the body passage along with the extracting device.

Fig. 9(b) is a view similar to Fig. 9(a), but showing the extracting device in conjunction with two auxiliary tubes.

Fig. 9(c) is a view similar to Fig. 9(a), but showing the extracting device in conjunction with an auxiliary tube having three tube elements affording three individual passages.

Figs. 10(a)—(f) are a series of diagramatic sections showing several alternative constructions of the inflatable sleeve.

Figs. 11(a)—(f) are fragmentary longitudinal sections showing the insertable portion of the extracting device in conjunction with a snare to assist in capturing a kidney stone or other object, the views showing successive

INARI_020880

steps of a procedure for capturing and enfolding the object.

Fig. 12 is an enlarged fragmentary section showing the insertable portion of the extracting device in conjunction with a stiffening wire or auxiliary tube, inserted through the inner tube of the extracting device.

Fig. 13 is a fragmentary enlarged longitudinal section showing the extracting device in conjunction with a plurality of auxiliary tubes, inserted through the inner tube of the extracting device.

Fig. 14(a) is a fragmentary enlarged section of the insertable portion of the extracting device in conjunction with an auxiliary tube having a plurality of tube elements to afford a plurality of individual passages, the tube being inserted through the inner tube of the extracting device.

Fig. 14(b) is a fragmentary cross section of the auxiliary tube shown in Fig. 14(a).

As just indicated, Figs. 1---6 illustrate an extracting device 20 comprising an outer flexible tube or sheath 22 capable of being inserted into a narrow passage of the human body, such as one of the ureters. The outer tube 22 is sufficiently long to be inserted through the urethra and the bladder into one of the ureters, and along such ureter as far as possible toward the corresponding kidney. The diameter of the outer tube 22 is such as to fit snugly but comfortably into one of the ureters. The inflatable sleeve 28 can be made in various sizes to accommodate various sized objects to be removed. The inner tube 24 and the outer tube 22 can be sized accordingly. The outer tube 22 may be made of a resinous plastics material, such as polyethylene, for example. The tube 22 is sufficiently flexible to conform to the shape of the body passage, while being sufficiently stiff to provide for insertion of the tube without causing it to collapse.

The outer tube 22 may be inserted into one of the ureters with the aid of an auxiliary device such as a cystoscope and an X-ray system having a fluoroscope. Thus, the insertable portion of the extracting device 20 should preferably incorporate a material which is sufficiently opaque to X-rays to be visible on the fluoroscope. For this purpose, an X-ray contrast medium may be incorporated into the plastics material of the outer tube 22 or may be coated thereon. Alternately, a flexible metal wire may be inserted within the extracting device 20, as will be discussed below in greater detail. The wire is visible on the X-ray fluoroscope and also may serve to stiffen the insertable portion of the extracting device 20, so that it will be easier to insert. Alternately, a fiber optic device can be used for observing and guiding the probe during insertion.

As shown in Fig. 6, an inner flexible tube 24 is telescopically received within the outer tube 22, with an annular clearance space 26 therebetween for transmitting air or some other fluid under pressure. The inner tube 24 is freely slidable within the outer tube 22. As in the case of the outer tube 22, the inner tube 24 is preferably made of a resinous plastics material, such as polyethylene, for example. If desired, an X-ray contrast material may be incorporated into the material of the inner tube 24, or may be coated thereon so that the inner tube will be visible on an X-ray fluoroscope. Alternately, a fiber optic device can be used for observing and guiding the probe during insertion. In addition to serving as a conduit for air or some other fluid, the inner tube may be inserted more easily into the body passage by the operator, without causing the outer tube 22 to collapse.

An inflatable sleeve or dilator 28 is connected between the insertable end of the outer tube 22 and the corresponding end of the inner tube 24. The sleeve 28 is thin, highly flexible and limp, and also is preferably elastic so as to be capable of stretching when inflated with compressed air or some other fluid. The sleeve 28 is preferably made of thin latex rubber or some other similar material. The thin rubber material may be similar to that employed for surgical rubber gloves and other thin rubber objects. A thin resinous plastics film material can also be used.

The thin flexible sleeve 28 has one end portion 28*a* which is stretched around and secured to the insertable end of the outer tube 22, as by means of a suitable cement or adhesive. The sleeve 28 has a second end portion 28*b* which is stretched around the insertable end of the inner tube 24 and is secured thereto, as by means of a suitable cement or adhesive. Any other suitable means, such as a tieing ring or collar, may be employed to secure the ends of the sleeve 28 to the ends of the tubes 22 and 24.

As shown in Figs. 6(a) and 10(a), the end portion 28*b* of the flexible sleeve 28 is reentrant, in that end portion 28*b* extends into the sleeve 28. With this construction, the sleeve 28 projects beyond the end of the inner tube 22, particularly when the sleeve 28 is inflated, as shown, for example, in Fig. 7(b).

As shown in Fig. 6(a), the extracting device 20 preferably includes a system or means 30 for supplying air or some other fluid under pressure to the clearance space 26 between the outer and inner tubes 22 and 24, so as to inflate the thin flexible sleeve 28. The system 30 also preferably includes means for producing suction or a vacuum in the inner tube 24 to assist in capturing the kidney stone or other object which is to be removed from the body passage.

As shown in Fig. 6, the free end of the outer tube 22 is provided with a connector or fitting 32 to which a flexible hose 32*a* or the

INARI_020881

like may be connected, the hose being represented diagramatically by a solid line. Similarly, the inner tube 24 is provided with a connector or fitting 34 to which a hose 34*a* or the like may be connected. As shown, the hoses 32*a* and 34*a* extend radially or at right angles to the outer and inner tubes 22 and 24. The inner tube 24 extends through an annular seal 36 mounted in an opening 38 in the fitting 32, such opening being coaxial with the outer tube 22.

The illustrated system 30 of Fig. 6 for selectively producing air pressure incorporates an air compressor 40 which supplies compressed air to a pressure line 42 to which a pressure gauge 44 may be connected. A pressure regulator 46 and a combination flow control valve and meter 46*a* are preferably connected between the high pressure line 42 and a low pressure line 48 to which another pressure gauge 50 may be connected. A storage tank 52 may also be connected to the low pressure line 48, if desired.

In this embodiment, a filter 54 and a control valve 56 are connected between the low pressure line 48 and the hose or conduit 32*a* which is connected to the end fitting 32 on the outer tube 22. The illustrated control valve 56 is of a three-way type, adapted to connect the interior of the outer tube 22 to either the pressure line 48 or a vent line 58 leading to the atmosphere. In the position of the valve 56 shown in Fig. 6(a), the outer tube 22 is connected to the vent line 58 by an internal passage 60 within the valve 56. It will be apparent that the valve 56 may be shifted to a position in which the internal passage 60 establishes a connection between the pressure line 48 and the interior of the tube 22. The pressure regulator 46 and the flow control valve and meter 46*a* may be adjustable so that the air pressure in the low pressure line 48 may be varied, as desired.

In the system 30*a* of Fig. 6(a), a combined compressor and vacuum pump 40*a* supplies vacuum to an output vacuum line 62, to which a vacuum gauge 64 may be connected. It will be realized that the compressor and the vacuum pump may be provided as two separate units, if desired. In this embodiment, a vacuum regulator 66 and a combustion flow control valve and meter 66*a* are connected between the vacuum line 62 and a regulated vacuum line 68 to which another vacuum gauge 70 may be connected. A storage tank 72 may also be connected to the vacuum line 68 if desired.

A filter 74 and a vacuum control valve 76 are preferably connected between the regulated vacuum line 68 and the hose 34*a* which leads to the fitting 34 on the end of the inner tube 24. The control valve 76 may be of the three-way type and is shown in a position in which the interior of the inner tube 24 is connected to a vent line 78 by an internal passage 80 within the valve 76. It will be evident that the valve 76 can be shifted into a position in which the regulated vacuum line 68 is connected to the interior of the inner tube 24. The vacuum regulator 66 and flow control valve 66*a* may be adjustable so that the vacuum in the line 68 may be varied, as desired.

In the system 30*a* of Fig. 6(a), the combined compressor and vacuum pump 40*a* supplies pressure to an auxiliary pressure supply system 81, illustrated as comprising a compressor output pressure line 81*a* to which a control valve 81*b* may be connected. It will be realized that the compressor and the vacuum pump may be provided as two separate units if desired. The illustrated control valve 81*b* is of a three-way type, adapted to connect the compressor output pressure line 81*a* to either a high pressure input line 81*c* or a vent line 81*d*, leading to the atmosphere. In the position of the valve 81*b* shown in Fig. 6(a), the compressor output pressure line 81*a* is connected to the high pressure input line 81*c*. It will be apparent that the valve 81*b* may be shifted to a position in which the compressor output pressure line 81*a* is connected to the vent 81*d*. A gauge 81*e* may be connected to the high pressure input line 81*c*. A pressure regulator 81*f* and a combination flow control valve and meter 81*g* are preferably connected between the high pressure input line 81*c* and a low pressure line 81*h* to which another pressure gauge 81*i* may be connected. A storage tank 81*j* may also be connected to the low pressure line 81*h* if desired. In this embodiment, a filter 81*k* is connected between the low pressure line 81*h* and a hose or conduit 81*m* which is connected to the auxiliary tube or tubes 130 and 132, to be described in connection with Figs. 9(a)—(d) and Figs. 12 to 14.

Fig. 6(b) shows a modified construction of the fitting 34 having an axial opening 82 through which an auxiliary tube, a snare or a stiffening wire may be inserted into the inner tube 24. A plug 84 may be provided to close the opening 82 when not in use.

Fig. 6(c) shows another modified construction in which the plug 84 of Fig. 6(b) is replaced by a sliding seal or bushing 85 through which the auxiliary tube, snare or stiffening wire 130 may be inserted into the inner tube 24. The seal is inserted into the opening 82 in the fitting 32. The plug 84 may be used to close the opening 82 when the seal 85 is not in use.

As shown in Figs. 1 to 5, a manipulator 90 is preferably connected to the free ends of the outer and inner tubes 22 and 24, to make it easy to advance and retract the inner tube 24 relative to the outer tube 22. By using the manipulator 90, the operator can advance and retract the inner tube 24 with the thumb

INARI_020882

and fingers of one hand, so that the other hand can be used to operate the pressure and vacuum control valves 56 and 76 of Fig. 6.

As illustrated in Figs. 1 to 5, the manipulator 90 comprises a first member 92 which is telescopically slidable within a second member 94. The members 92 and 94 are connected to the outer and inner tubes 22 and 24, respectively. More specifically, the fitting or connector 32 on the free end of the outer tube 22 is mounted in the member 92, while the end fitting or connector 34 on the free end of the inner tube 24 is mounted in the member 94.

Finger and thumb rings are preferably provided on the telescopically slidable members 92 and 94. As shown, a thumb ring 96 is connected to the member 92 by means of a plunger rod 98. A swivel joint 100 is provided between the thumb ring 96 and the plunger rod 98, so that the thumb ring can be turned to an angle which is comfortable and convenient. The illustrated thumb ring 96 is made from a strip of sheet metal and can be bent to adjust the size of the thumb ring, as desired by the operator.

As shown, the member 94 is fitted with a pair of finger rings 102 which are also bent from a strip of sheet metal, so that the size of the rings 102 can easily be adjusted to suit the needs of the operator. The finger rings 102 are swingably mounted on the body member 94. For this purpose, the finger rings 102 are provided with a mounting member 104 having a pair of arms 106 which are swingably connected to the body member 94 by diametrically opposite pivots 108.

In the illustrated manipulator 90, two stop nuts 110 are mounted on the plunger rod 98, which is threaded to receive the stop nuts. It will be seen that the stop nuts 110 may be adjusted to limit the extent to which the plunger rod 98 may be depressed through the mounting member 104, which is apertured to provide a passage for the rod 98. In effect, the stop nuts 110 thereby provide an adjustment of the extent to which the inner tube 24 may be retracted relative to the outer tube 22.

The operation of the extracting device 10 is illustrated in Figs. 7 and 8, which should be taken in conjunction with Figs. 1—6. The unit comprising the outer flexible tube 22, the inner flexible tube 24 and the inflatable sleeve 28 constitutes a probe 120 which can readily be inserted into the urinary tract of the human body for removing kidney stones. The diameter of the outer tube 22 is such as to fit snugly but easily into the urethra and either of the ureters. Specifically, the probe 120 is properly lubricated and is inserted through the urethra into the bladder, and then through the bladder into one of the ureters. An X-ray fluoroscope and a cystoscope may be employed advantageously to assist in inserting the probe 120 into either urethra. In order that the probe 120 may be clearly visible on the X-ray fluoroscope, the probe preferably incorporates an X-ray contrast material which is relatively opaque to X-rays. Such material may be incorporated into the plastics material of either the outer tube 22 or the inner tube 24, or both. Alternatively, the X-ray contrast material may comprise a thin coating of a metal, such as gold, silver or aluminium. Another alternative is to insert a thin flexible metal wire into the inner tube 24, while the probe 120 is being inserted. The wire has the additional advantage of stiffening the probe 120. After the probe has been inserted, the wire can be removed. Alternately, a fiber optic device can be used for observing and guiding the probe during insertion.

Figs. 7(a)—(g) show steps 1—7 of a procedure for capturing and removing a kidney stone 122 or some other similar object, which may be lodged in one of the ureters. As shown in Fig. 7(a), the probe 120 is inserted until it is close to the kidney stone 122. The sleeve 28 is then inflated, as shown in Fig. 7(b), by supplying compressed air through the clearance space 26 between the tubes 22 and 24. The compressed air is supplied by operating the compressed air control valve 56 to the position in which it transmits compressed air from the pressure line 48 to the fitting 32 on the free end of the outer tube 22.

The inflation of the sleeve 28 dilates the ureter to some extent, so as to dislodge or loosen the kidney stone 122. Suction is then applied to the inner tube 24, so as to suck the kidney stone 122 toward the end of the inner tube 24 and into engagement with the projecting end of the inflated sleeve 28, as shown in Fig. 7(c). The end of the thin rubber sleeve 28 forms a seal with the kidney stone 122, so that it is securely held against the end of the probe by the suction.

The inner tube 24 is then gradually retracted, while the sleeve 28 is simultaneously and gradually deflated, as shown in Figs. 7(c)—(g), so that the kidney stone 122 is pulled within the confines of the sleeve 28. It will be seen that the deflated sleeve 28 enfolds the kidney stone 122, as shown to best advantage in Fig. 7(g), so that the sleeve 28 is interposed between the kidney stone 122 and the inner walls of the ureter.

The suction is applied to the inner tube 24 by operating the suction control valve 76 of Fig. 6, so that it establishes communication between the vacuum line 68 and the end fitting 34 on the inner tube 24. The suction is maintained while the probe 120 is withdrawn from the urinary tract. The kidney stone 122 remains a captive within the confines of the sleeve 28, so that the kidney stone is removed from the urinary tract. During the removal of the probe 120, the sleeve 28 prevents the

INARI_020883

kidney stone 122 from scratching or otherwise injuring the inner walls of the urinary tract.

Fig. 8 illustrates a procedure for using the inflatable sleeve 28 to assist in the insertion of the probe 120 into a narrow passage such as a ureter. In Fig. 8(a), the probe 120 has been inserted as far as possible with the sleeve 28 deflated. The sleeve 28 is then inflated, as shown in Fig. 8(b), so as to dilate the passage. Next, the sleeve 28 is again deflated, as shown in Fig. 8(c), and the outer tube 22 is immediately advanced, as shown in Fig. 8(d), while some of the dilation persists. The advancing movement of the outer tube 22 causes the sleeve 28 to collapse.

The inner tube 24 is then advanced within the outer tube 22, as shown in Fig. 8(e), so that the sleeve 28 is no longer collapsed. It will be seen that Fig. 8(e) is the same as Fig. 8(a), except that the probe 120 has been advanced. If further advancing movement is needed, the successive steps of Figs. 8(a)—(e) are repeated. This may be done several times until the probe 120 has been fully inserted to the desired position in the ureter or other body passage.

In some cases, it may be desirable to insert an auxiliary tube 130, along with the probe 120, as shown in Fig. 9(a). The auxiliary tube 130 provides auxiliary communication with the ureter or other body passage and may be employed to convey various fluids to or from the body passage. For example, the auxiliary tube may be emplyed to carry air into the body passage, beyond the probe 120, so as to obviate or lessen the tendency of the suction, applied by the probe 120, to cause partial collapse of the walls of the body passage. When the auxiliary tube 130 is supplied with compressed air from the combination vacuum pump-compressor 40*a* of Fig.6(a), the throughput of the closed system will provide the same amount of compressed air (volume measured as free air at atmospheric pressure) as the amount of air evacuated by the vacuum side of the pump (volume measured as free air at atmospheric pressure). The auxiliary tube 130 may also be employed to introduce a lubricating fluid into the body passage. A fluid medication can also be introduced into the body passage through the auxiliary tube 130. It is also possible to use the auxiliary tube 130 to withdraw mucus or other body fluids from the body passage.

As shown in Fig. 9(b), two or more auxiliary tubes 130 may be inserted into the body passage along with the probe 120, two such auxiliary tubes being shown in this view.

Fig. 9(c) shows a modified auxiliary tube 132 having a plurality of tube elements forming a plurality of individual auxiliary passages. As shown to best advantage in the cross section of Fig. 9(d), the auxiliary tube 132 has three tube elements 132*a*, *b* and *c*, which may be employed for simultaneously handling different fluids.

The auxiliary tubes 130 and 132 are preferably made of a flexible resinous plastics material, such as polyethylene, for example. The triple tube 132 may be formed by extrusion of the plastics material.

Fig. 12 shows a modified arrangement in which the auxiliary tube 130 is inserted through the inner tube 24 of the probe 120. The auxiliary tube 130 may be inserted into the tube 24 through the sliding seal 85 of Fig. 6(c). As shown in Fig. 13, two or more of the auxiliary tubes 130 may be inserted through the inner tube 24, after being inserted into the tube through a suitable sliding seal.

Figs. 14(a) and (b) show that the triple auxiliary tube 132 may be inserted through the inner tube 24 after being inserted through a suitable sliding seal. In all cases, the auxiliary tubes 130 and 132 may be inserted along the inner tube 124 either before or after the probe 120 is inserted into the body passage. The auxiliary tubes 130 and 132 may be removed from the inner tube 24 without removing the probe 120 from the body passage. The plug 84 may then be inserted in the connector.

It may also be considered that Fig. 12 illustrated insertion of a flexible metal wire within the inner tube 24. The element 130 may be regarded as the wire. As previously indicated, the flexible wire may be employed to stiffen the tubes 22 and 24 of the probe 120, or to absorb X-rays so that the probe 120 will be clearly visible on an X-ray fluoroscope. Alternately, a fiber optic device can be used for observing and guiding the probe during insertion.

Fig. 10 illustrates various alternative shapes for the inflatable sleeve 28. In Fig. 10(a), the sleeve 28 has a cylindrical sidewall 138 and radial endwalls 140 and 142. In Fig. 10(b) the sleeve has a tapered or frusto-conical sidewall 138(a).

In Figs. 10(c), (d) and (e), the cylindrical sidewall 138 is employed, but the endwall 142 is modified. Thus, the sleeve of Fig. 10(c) has a re-entrant, tapered, frusto-conical endwall 142(a) which may be advantageous in some instances to assist in the enfolding of the kidney stone by the sleeve. In Fig. 10(d), the sleeve has a stepped endwall 142(b). In Fig. 10(e), the sleeve has a re-entrant endwall 142(c) which is concavely curved. This construction may be advantageous in some cases for capturing and enfolding kidney stones.

In Fig. 10(f), the inflatable seal or sleeve 28 has one or more holes 143 which may be either molded in or pierced. Air or fluid from the inflator supply will pass through the holes 143 so as to obviate or lessen the tendency of the suction applied by the probe 120 to cause partial collapse of the walls of

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the body passage. The various alternative shapes shown in Figs. 10(b), (c), (d) and (e) may also be provided with one or more holes 143.

Figs. 11(a)—(f) illustrate the successive steps of a procedure for using the probe 120 in conjunction with a snare 150 to assist in capturing and removing a foreign object, such as the illustrated kidney stone 122. The illustrated snare 150 comprises a capturing head or portion 154 and an operating portion or member 156, here shown as a flexible wire which is inserted through the inner tube 24, so as to be accessible to the operator at the free end of the probe 120. The wire 156 is freely slidable within the inner tube 24.

The capturing head 154 of the snare 150 may comprise a multitude of strands or filaments 158, made of a material such as tinsel, capable of entwining the kidney stone 122. The filaments 158 are in a form resembling a ball and are secured to the front end of the operating wire 156. The filaments 158 may be made of metal, a resinous plastics material, or any other suitable material.

In the procedure of Figs. 11(a)—(f), the probe 120 is inserted into the ureter, or some other body passage, until the capturing head 154 of the snare 150 is as close as possible to the kidney stone 122, as shown in Fig. 11(a). The sleeve 28 is then inflated, as shown in Fig. 11(b), by supplying air or some other fluid under pressure to the interior of the outer tube 22. The inflation of the sleeve 28 tends to dislodge or loosen the kidney stone 122 from the walls of the ureter.

As shown in Fig. 11(c), the snare 150 is then advanced by moving the operating wire 156 through the inner tube 24. As the capturing head 154 is advanced, the filaments 158 become entwined around the kidney stone 122, as will be evident from Fig. 11(c). As the snare 150 is advanced, suction is preferably applied to the interior of the inner tube, so that the suction assists in the capture of the kidney stone 122.

The snare 150 is then retracted by moving the operating wire 156 within the inner tube 24, so as to bring the capturing head 154 and the kidney stone 122 as close as possible to the end of the inner tube. Meanwhile, suction within the inner tube 22 is maintained. Then, the inner tube 22 is gradually retracted, as shown in Figs. 11(d)—(f), to draw the kidney stone 122 and the capturing head 154 of the snare 150 into the confines of the sleeve 28. Simultaneously, the sleeve 28 is gradually deflated, so that it will enfold the kidney stone 122 and the capturing head 154. The thin rubber sleeve 28 forms a seal with the kidney stone 122 and the capturing head 154, so that the suction effectively retains the kidney stone within the folds of the sleeve 28.

With the suction still maintained, the probe 120 may then be withdrawn from the body passage, to remove the kidney stone 122 or other object. The sleeve 28 is interposed between the kidney stone 122 and the walls of the body passage, so that neither the kidney stone nor the head 154 of the snare 150 will scratch or otherwise injure the walls of the body passage.

WHAT I CLAIM IS:—

1. An extracting device for insertion into a human body passage for removing foreign objects therefrom, said device comprising an outer flexible tube the distal end of which is insertable into a body passage, an inner flexible tube slideably received within the outer tube for free longitudinal sliding movement with the distal end of the inner tube normally projecting beyond the distal end of the outer tube, the inner and outer tubes having clearance space therebetween for carrying fluid under pressure, a thin, tubular, highly distendable and limp sleeve having its proximal end portion connected to the distal end of the outer tube, the sleeve having a distal end portion which is inverted and is connected to the distal end of the inner tube for insertion into the body passage, the sleeve being otherwise free to expand upon inflation, the tubular sleeve having first and second tubular surfaces on opposite sides of the sleeve, the first surface facing inwardly at the proximal end portion of the sleeve, the inverted distal end portion of the sleeve being turned inside out with the second surface facing inwardly, the sleeve being inflatable by fluid transmitted along said clearance space to dilate the body passage, the sleeve when inflated having an annular flaring portion bulging beyond the distal end of the inner tube and curved convexly in longitudinal section for sealing engagement with a foreign object in the body passage, the annular flaring curved portion being soft, pliable and capable of conforming to the shape of the foreign object to effect a seal therewith, the inner tube being operative to transmit suction for capturing and holding the foreign object in sealing engagement with the annular flaring portion of the sleeve, and means for retracting the inner tube relative to the outer tube while the suction pulls the foreign object within the confines of the sleeve and the sleeve is progressively turned inside out around the foreign object to envelop the foreign object for removal with the tubes.

2. A device according to Claim 1, in which the inner and outer tubes are made of a resinous plastics material.

3. A device according to Claim 1, in which the sleeve is made of rubber.

4. A device according to Claim 1, including manipulating means connected to the proximal ends of the tubes for advancing and retracting the inner tube relative to the outer

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tube.

5. A device according to Claim 4, wherein said manipulating means includes first and second telescopically movable members connected to the respective inner and outer tubes, the first and second members having finger receiving rings for use in manually moving the members.

6. A device according to Claim 1, including first means for selectively supplying fluid under pressure to the proximal end of the clearance space to inflate the sleeve.

7. A device according to Claim 1 or 6, including second means for selectively supplying suction to the proximal end of the inner tube.

8. A device according to Claim 1, in which the proximal and distal end portions of the sleeve are of reduced diameters relative to the intermediate portion of the sleeve and are secured to the distal ends of the inner and outer tubes.

9. A device according to Claim 8, wherein the reduced distal end portion of the sleeve extends within the sleeve for receiving the distal end of the inner tube whereby the sleeve projects beyond the distal end of the inner tube.

10. A device according to Claim 1, including at least one auxiliary tube slideable within the inner tube to afford auxiliary communication with the body passage.

11. A device according to Claim 10, wherein the auxiliary tube includes a plurality of individual tube elements.

12. A device according to Claim 1, including at least one auxiliary tube extending along the outside of the outer tube and insertable in said body passage along with the outer and inner tubes to afford auxiliary communication with the body passage.

13. A device according to Claim 12, in which the auxiliary tube has a plurality of individual tube elements.

14. A device according to Claim 1, including a stiffening member slideably receivable in the inner tube for stiffening the inner and outer tubes to facilitate the insertion of the outer tube into the body passage.

15. A device according to Claim 1, including a snare having an operating member slideable within the inner tube, said snare being operative to assist in capturing a foreign object in the body passage.

16. A device according to Claim 1, including a snare having a thin flexible wire-like operating member slideably received in the inner tube, said snare having a capturing portion secured to the operating member and including a plurality of filamemts disposed adjacent the sleeve to assist in capturing a foreign object.

17. An extracting device for insertion into a human body passage, substantially as hereinbefore described with reference to the accompanying drawings.

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FIG. 1

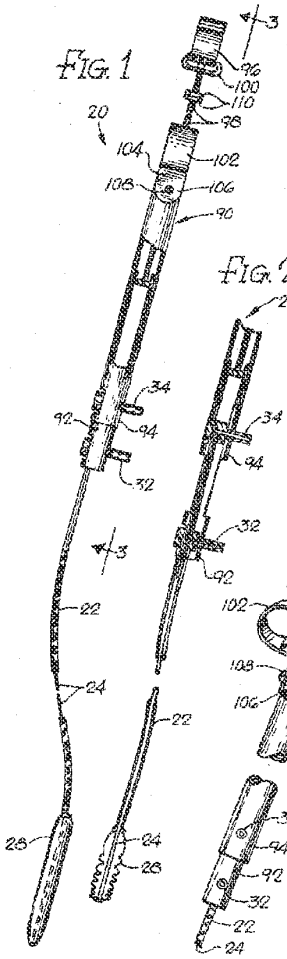


FIG. 2

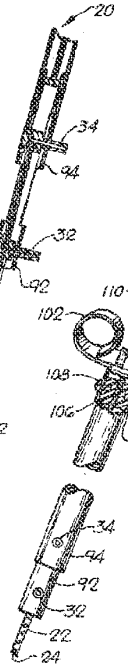


FIG. 3

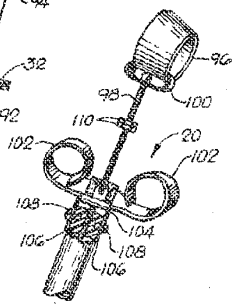


FIG. 5

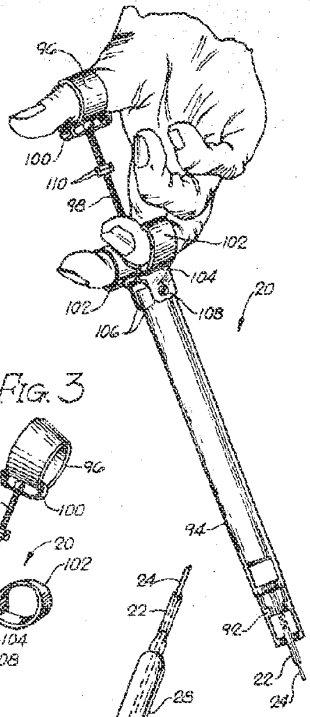
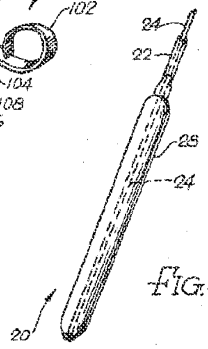
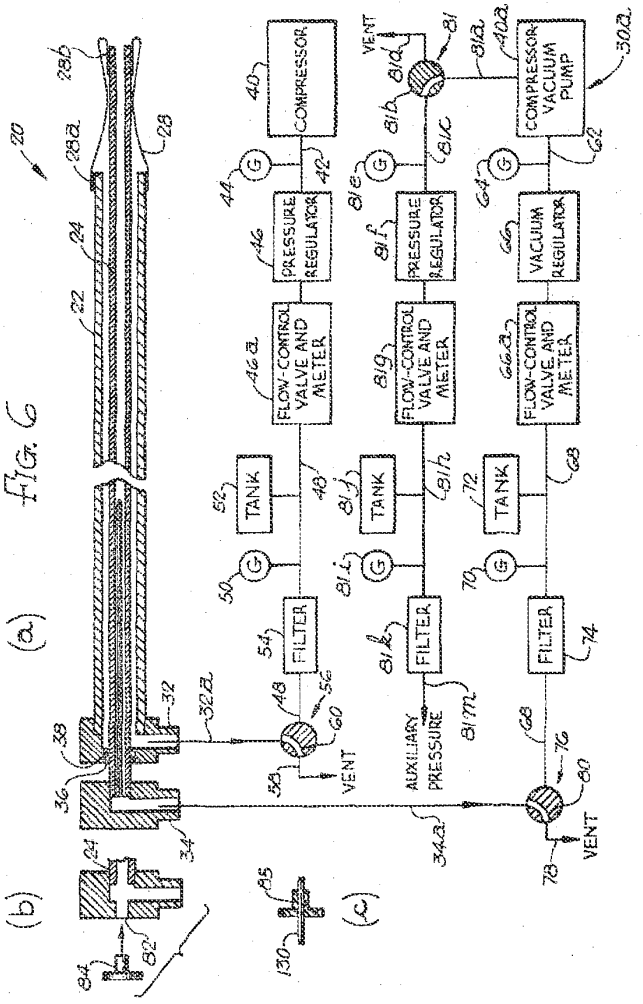


FIG. 4

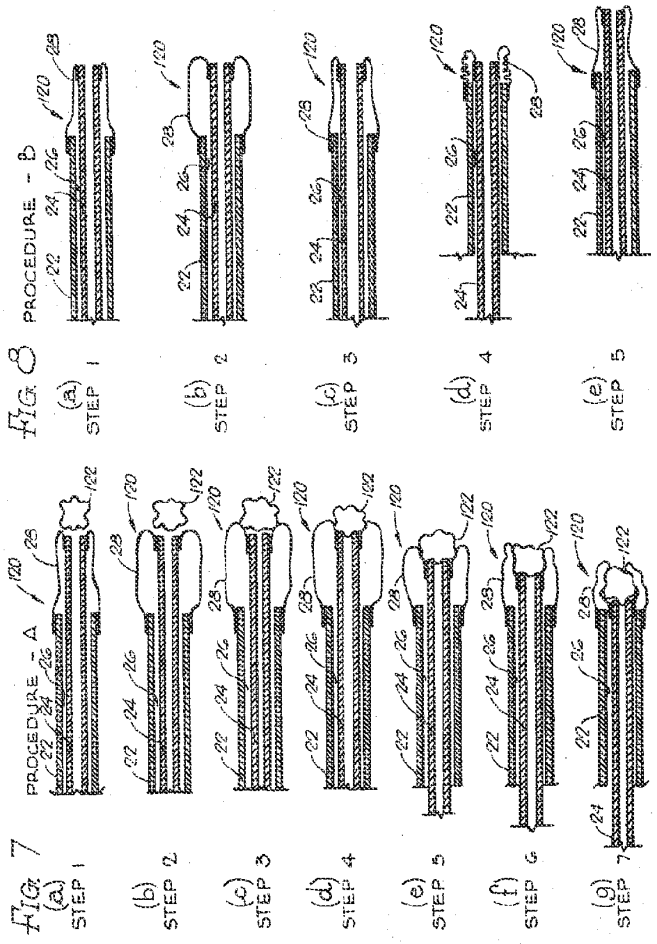


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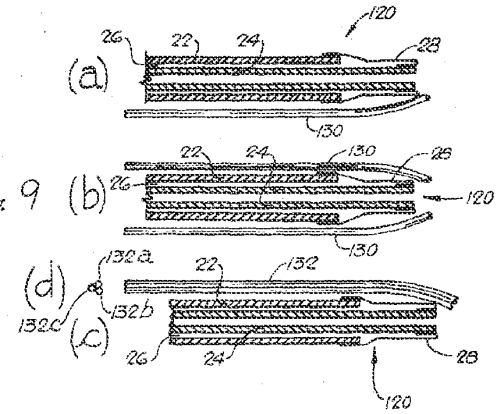

(a)
(b)
(c)
(d)
120
26
22
24
28
130
132
132a
132b
132c

FIG. 9

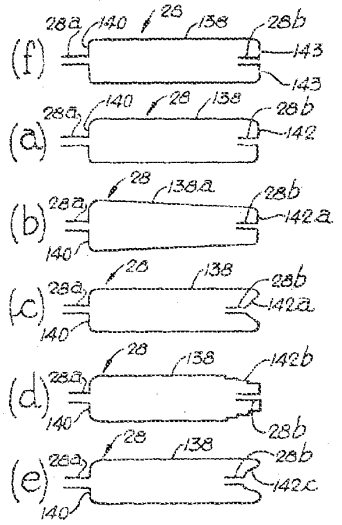

(f)
(a)
(b)
(c)
(d)
(e)
28
28a
28b
138
138a
140
142
142a
142b
142c
143

FIG. 10

FIG. 11

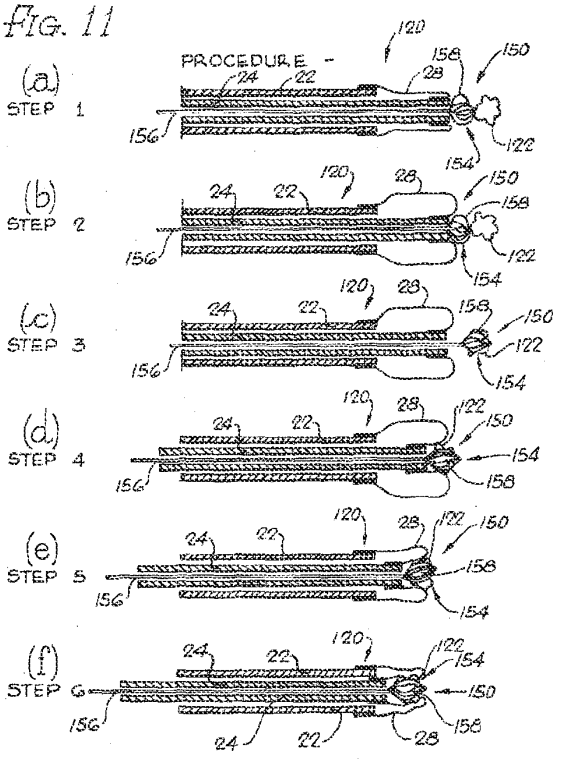

PROCEDURE -
(a) STEP 1
(b) STEP 2
(c) STEP 3
(d) STEP 4
(e) STEP 5
(f) STEP 6
120
158
150
28
24
22
156
154
122

FIG. 12

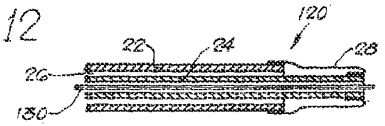


FIG. 13

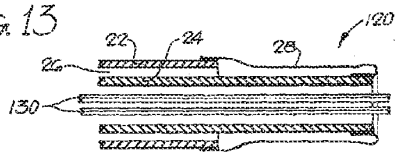
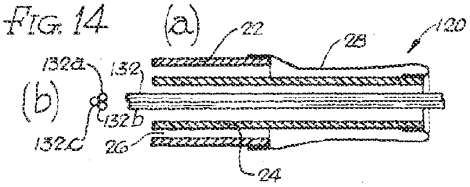


FIG. 14



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(54) **Title:** SYSTEMS AND METHODS FOR REMOVING UNDESIRABLE MATERIAL WITHIN A CIRCULATORY SYSTEM

(57) **Abstract:** A system for removing undesirable material from vessels and from chambers within the heart is provided. The system includes a suction cannula for removing the undesirable material from a site of interest within a patient. A filter device may be provided for capturing the undesirable material and removing it from the fluid flow. The system also includes pump for generating the necessary suction force through the suction cannula to dislodge the undesirable material from the site of interest and for generating a sufficient driving force to direct the fluid flow downstream within the system. The system further includes a reinfusion cannula for introducing fluid removed from the site of interest back into a patient. A method for removing undesirable material from vessels and from heart chambers is also provided.

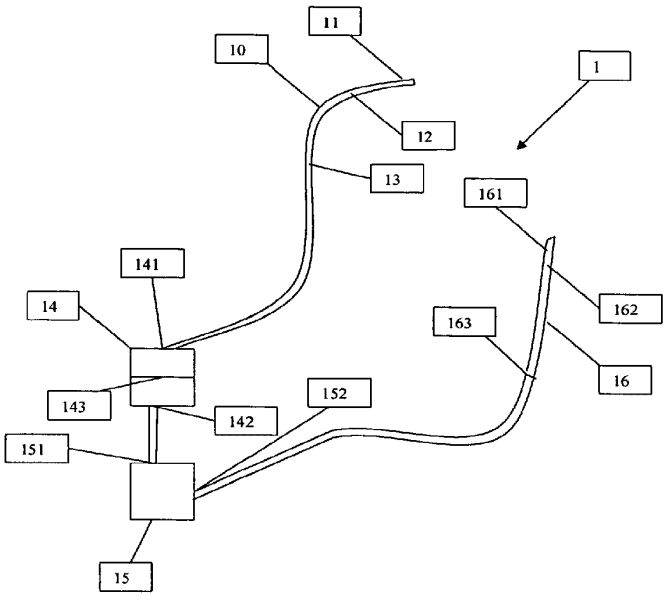


Fig. 1

WO 2009/082513 A1

SYSTEMS AND METHODS FOR REMOVING UNDESIRABLE MATERIAL WITHIN A CIRCULATORY SYSTEM

TECHNICAL FIELD

[0001] The present invention relates to systems and methods for removing undesirable materials from a site of interest within the circulatory system. More particularly, the present invention relates to systems and methods for removing substantially *en bloc* clots, thrombi, and emboli, among others, from within heart chambers, as well as medium to large vessels, while reinfusing fluid removed from the site of interest back into the patient to minimize fluid loss.

BACKGROUND ART

[0002] Many of the most common and deadly diseases afflicting mankind result from or in the presence of undesirable material, most notably blood clots, in the blood vessels and heart chambers. Examples of such diseases include myocardial infarction, stroke, pulmonary embolism, deep venous thrombosis, atrial fibrillation, infective endocarditis, etc. The treatment of some of these conditions, which involve smaller blood vessels, such as myocardial infarction and stroke, has been dramatically improved in recent years by targeted mechanical efforts to remove blood clots from the circulatory system. Other deadly conditions, which involve medium to large blood vessels or heart chambers, such as pulmonary embolism (1/2 million deaths per year) or deep venous thrombosis (2-3 million cases per year) have not benefited significantly from such an approach. Present treatment for such conditions with drugs or other interventions is not sufficiently effective. As a result, additional measures are needed to help save lives of patients suffering from these conditions.

[0003] The circulatory system can be disrupted by the presence of undesirable material, most commonly blood clots, but also tumor, infective vegetations, and foreign bodies, etc. Blood clots can arise spontaneously within the blood vessel or heart chamber (thrombosis) or be carried through the circulation from a remote site and lodge in a blood vessel (thromboemboli).

[0004] In the systemic circulation, this undesirable material can cause harm by obstructing a systemic artery or vein. Obstructing a systemic artery interferes with the

delivery of oxygen-rich blood to organs and tissues (arterial ischemia) and can ultimately lead to tissue death or infarction. Obstructing a systemic vein interferes with the drainage of oxygen-poor blood and fluid from organs and tissues (venous congestion) resulting in swelling (edema) and can occasionally lead to tissue infarction.

[0005] Many of the most common and deadly human diseases are caused by systemic arterial obstruction. The most common form of heart disease, such as myocardial infarction, results from thrombosis of a coronary artery following disruption of a cholesterol plaque. The most common causes of stroke include obstruction of a cerebral artery either from local thrombosis or thromboemboli, typically from the heart. Obstruction of the arteries to abdominal organs by thrombosis or thromboemboli can result in catastrophic organ injury, most commonly infarction of the small and large intestine. Obstruction of the arteries to the extremities by thrombosis or thromboemboli can result in gangrene.

[0006] In the systemic venous circulation, undesirable material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT arises most commonly when there is a propensity for stagnated blood (long-haul air travel, immobility) and clotting (cancer, recent surgery, especially orthopedic surgery). DVT causes harm by (1) obstructing drainage of venous blood from the legs leading to swelling, ulcers, pain and infection and (2) serving as a reservoir for blood clot to travel to other parts of the body including the heart, lungs (pulmonary embolism) and across a opening between the chambers of the heart (patent foramen ovale) to the brain (stroke), abdominal organs or extremities.

[0007] In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries, a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs and therefore the entire body, resulting in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting low blood oxygen and build up of blood carbon dioxide. If the obstruction is further downstream, it can

cut off the blood flow to a smaller portion of the lung, resulting in death of lung tissue or pulmonary infarction.

[0008] The presence of the undesirable material within the heart chambers can cause harm by obstructing flow or by serving as a reservoir for emboli to other organs in the body. The most common site for obstruction within the heart is in the heart valves. Infective vegetations, a condition known as endocarditis, can cause partial obstruction to flow across a valve before destroying the valve. Patients with prosthetic valves, especially mechanical valves, are particularly prone to valve thrombosis and obstruction. The heart chambers are the most common source of emboli (cardioemboli) to the systemic circulation, including stroke. Emboli tend to arise from areas that are prone to stagnation of blood flow under pathologic conditions. The left atrial appendage in patients with atrial fibrillation is prone to thrombosis, as well as the left ventricular apex in patients with acute myocardial infarction or dilated cardiomyopathy. Infected vegetations or thrombi on the heart valves are also common sources of emboli. Undesirable material such as blood clots and infected vegetations can reside in the chambers of the right heart (atrium and ventricle), often associated with prosthetic material such as pacemaker leads or long-term indwelling catheters.

[0009] The most effective treatment for conditions resulting from the presence of blood clots or other undesirable materials within the circulation is, of course, to stabilize or eliminate the material before it has embolized. Alternatively, if obstruction to flow has already occurred but before the obstruction has caused permanent harm (infarction, shock, death), the material can be eliminated by utilizing biologic or mechanical means.

[00010] Biologic treatments involve the delivery of agents to the material, which either dissolve the material or, at a minimum, stabilize it until the body can eliminate it. In the case of infective vegetations, antimicrobial agents can, over time, decrease the chances of embolization. In the case of blood clots, the agents include 1) anticoagulant agents (heparin, warfarin, etc.) which prevent propagation of blood clots; and 2) more potent thrombolytic agents (streptokinase, urokinase, tPA, etc,) which actively dissolve clots. The agents are usually delivered systemically, i.e., into a peripheral or central vein and allowed to circulate throughout the body.

Thrombolytic agents can also be delivered through a catheter directly to the blood clot which can increase its effectiveness by increasing local concentrations but this does not completely eliminate the absorption into systemic circulation throughout the body.

[00011] Thrombolytic agents have been shown to increase survival in patients with hemodynamically significant pulmonary embolism as documented by echocardiographic evidence of right ventricular strain. The use of thrombolytic agents is the standard of care in this subgroup of patients with a high 20-25% early mortality. They are commonly used in to dissolve clots in other blood vessels including arteries to heart, abdominal organs and extremities.

[00012] There are two primary disadvantages to thrombolytic agents. First, every cell in the body is exposed to the agent which can lead to serious and often life threatening bleeding complications in remote areas such as the brain and stomach. The risk of major bleeding complications can be as high as 25% and the risk of often fatal bleeding into the brain can go up to 3%. Second, blood clots undergo a process called organization where the soft gel-like red/purple clot is transformed into a firmer, whitish clot by the cross-linking of proteins such as fibrin. Organized clots are much less amenable to treatment with thrombolytic agents. Thromboemboli, such as pulmonary emboli, can contain a significant amount of organized clot since the thrombus frequently developed at its original site (e.g., the deep veins of the legs) over a long period of time prior to embolizing to the remote site (e.g., the lungs).

[00013] Mechanical treatments involve the direct manipulation of the material to eliminate the obstruction. This can involve aspiration, maceration, and compression against the vessel wall, or other types of manipulation. The distinct advantage of mechanical treatment is that it directly attacks the offending material and eliminates the vascular obstruction independent of the specific content of the offending material. Mechanical treatments, if feasible, can usually prove to be superior to biologic treatments for vascular obstruction. Procedural success rates tend to be higher. The best example of this advantage is in the treatment of acute myocardial infarction. Although thrombolytic therapy has had a major impact on the management of patient with myocardial infarction, this option is now relegated to a distant second choice. The clear standard of care today for an acute myocardial infarction is an emergency percutaneous coronary intervention during which the coronary artery obstruction is

relieved by aspiration, maceration or balloon compression of the offending thrombus. This mechanical approach has been shown to decrease the amount of damaged heart tissue and improve survival relative to the thrombolytic biological approach.

[00014] Mechanical treatment, however, has played a limited role in the removal of blood clots found in larger blood vessels such as pulmonary arteries and heart chambers. Surgical pulmonary embolectomy involves opening the pulmonary artery and removing the offending clot under direct vision. This operation has been performed for nearly 100 years, but did not become practical until the introduction of the heart lung machine. Even then, it was generally relegated to a salvage procedure in moribund patients in whom all other options had been exhausted because of the inherent danger in the surgery and the recovery period. While surgical pulmonary embolectomy is very effective in completely evacuating pulmonary emboli whether soft-fresh and firm-organized clot, it is an invasive procedure.

[00015] Recent data has shown that the early outcomes with surgical pulmonary embolectomy are excellent, at least as good as thrombolytic treatment, as long as the procedure is performed in a timely fashion before the patient becomes very ill or suffers a cardiac arrest. The long term outcomes of patients surviving surgical pulmonary embolectomy have always been very good. Although these data have generated a renewed interest in performing surgical pulmonary embolectomy, its use remains limited because of the invasiveness of the procedure. Although minimally invasive approaches have been described, the standard procedure requires a 20-25cm incision through the sternal bone and placing the patient on cardiopulmonary bypass (the heart-lung machine).

[00016] Catheter-based removal of blood clots from larger blood vessels (e.g., pulmonary arteries) and heart chambers has had limited success, at least compared to smaller blood vessels (e.g., coronary arteries). Catheter pulmonary embolectomy, where the pulmonary emboli are removed percutaneously using one of several techniques, has been around for nearly 30 years but few patients currently receive these therapies. These techniques can be subdivided into three categories. With fragmentation thrombectomy, the clot is broken into smaller pieces, most of which migrate further downstream, decreasing the central obstruction but resulting in a "no-reflow" phenomenon. It is sometimes used in combination with thrombolytics which

preclude their use as an alternative to thrombolytics. With the rheolytic thrombectomy, high velocity saline jets create a Venturi effect and draw the fragments of the clot into the catheter. Finally the aspiration techniques draw the clot into a catheter via suction. With a Greenfield embolectomy, the catheter with the attached clot is repeatedly drawn out of the vein. All of these techniques rely on catheters which are small compared to the size of the clots and blood vessels. Their limited success is likely related to their inability to achieve a complete en-bloc removal of the material without fragmentation.

[00017] The experience with catheter-based treatment of deep venous thrombus has also had limited success. The operator must use relatively small catheters to remove or break up large amounts of well embedded clot. This procedure is therefore time-consuming, inefficient and ultimately not very effective in removal of the whole clot.

[00018] It is clear that all of the therapeutic options available to patients with clot or other undesirable material in medium or large blood vessels, such as those with pulmonary embolism, have serious limitations. Anticoagulation only limits propagation of clot, it does not remove it. Thrombolytic therapy is not targeted, carries a real risk of major bleeding, and is not very effective in firm/organized clots. Catheter embolectomy uses technology developed for small blood vessels, does not scale well to material residing in medium and large vessels or heart chambers, and thus is not very effective. Surgical embolectomy is highly effective but highly invasive. There is a real need for a direct mechanical treatment that is as effective as surgical embolectomy but can be performed using endovascular techniques.

[00019] Current efforts to apply existing catheter embolectomy technologies to medium to large blood vessels and heart chambers encounter at least two obstacles: fragmentation and excessive blood loss. Techniques which depend on fragmentation of the material tend to be inefficient and ineffective in medium to large blood vessels and heart chambers because the flow of blood will carry a significant portion of the fragmented material away before it can be captured in the catheter. On the other hand, techniques which depend on aspiration of undesirable material will result in excessive blood loss as the size of the catheter increases.

[00020] A need therefore exists for a system and method to endovascularly remove undesirable material residing in medium to large blood vessels and heart chambers with minimal fragmentation and without excessive blood loss.

SUMMARY OF THE INVENTION

[00021] The present invention relates generally to systems and methods for removing undesirable material residing in vessels, such as blood vessels, or within chambers of the heart. More specifically, the subject invention relates to systems and methods for using a cannula to remove substantially *en bloc*, from a site of obstruction or interest, an undesirable material, such as blood clots, embolisms and thromboembolisms, without significant fragmentation and without excessive fluid loss. In addition, the systems and methods of the present invention may simultaneously reinfuse aspirated (i.e., removed) and filtered fluid, such as blood, back into the patient on a substantially continuous basis to minimize any occurrences of fluid loss and/or shock. The subject invention may be particularly useful, but may not be limited to, the removal of blood clots, tumors, infective vegetations and foreign bodies from medium to large blood vessels and heart chambers.

[00022] In one embodiment, a system for removing an undesirable material from within a vessel is provided. The system includes a first cannula having a distal end and an opposing proximal end. The distal end of the first cannula, in an embodiment, may include or may be deployable to a diameter relatively larger than that of the proximal end. The first cannula may be designed for maneuvering within the vessel to a site of interest, such that an undesirable material can be captured substantially *en bloc* through the distal end and removed along the first cannula away from the site. The system may also include a pump, in fluid communication with the proximal end of the first cannula, so as to provide a sufficient suction force for removing the undesirable material from the site of interest. The system may further include a second cannula in fluid communication with the pump, so that fluid removed from the site of interest by the first cannula can be directed along the second cannula and reinfused through a distal end of the second cannula. In one embodiment, the distal end of the second cannula may be situated in spaced relation to the distal end of the first cannula. The system may also be provided with a filter device positioned in fluid

communication with the first cannula. The filter device, in an embodiment, may act to entrap or capture the undesirable material and remove it from the fluid flow. The system may further be provided with a reservoir in fluid communication with the filter device. The reservoir may act to transiently collect fluid being directed from the filter device and to provide a source of fluid for reinfusion by the second cannula. A second filter may also be included in fluid communication between the pump and the second cannula, so as to remove, prior to reinfusion, any debris that may have escaped from the filter device from the fluid flow.

[00023] In another embodiment, there is provided a method for removing an undesirable material from within a vessel. The method includes initially maneuvering a first cannula having a distal end and an opposing proximal end to a site of interest within the vessel, such that the distal end of the first cannula is positioned adjacent the undesirable material. Next, a second cannula, in fluid communication with the first cannula, may be positioned such that its distal end can be situated in spaced relation to the distal end of the first cannula. Thereafter, a suction force may be provided through the distal end of the first cannula to the site of interest, so as to remove, through the distal end of the first cannula, the undesirable material substantially *en bloc* from the site of interest. Subsequently, any fluid removed along with the undesirable material may be reinfused, through the distal end of the second cannula, to a location in spaced relation from the distal end of the first cannula. The suction and reinfusion of blood can occur, in an embodiment, continuously for a desired duration to minimize fluid loss in the patient. Alternatively, the step of suctioning an undesirable material can occur at an intermittent pulse for a desired duration following reinfusion of the removed fluid.

[00024] In a further embodiment, an apparatus for removing an undesirable material from within a vessel is provided. The apparatus includes an elongated tube having a distal end through which an undesirable material can be captured, a pathway extending along the tube to provide a passage for transporting the undesirable material from the distal end, and a proximal end in opposing relations to the distal end through which the undesirable material can exit. The apparatus also includes a funnel situated at the distal end of the tube, and designed for deployment between an flared open position and a collapsed closed position, so as to better engage and capture the

undesirable material. The apparatus further includes a mechanism positioned about a distal portion of the tube, which mechanism, upon actuation, can deploy the funnel between the closed position and the open position. In one embodiment, the funnel includes a plurality of strips, with each strip being pivotally coupled at one end to the distal end of the tube. The funnel may also include a substantially impermeable membrane extending across a space between adjacent strips, such that the membrane, in connection with the strips define the shape of the funnel. The mechanism, in an embodiment, includes a balloon positioned circumferentially about the tube at a location proximal to the funnel, and an attachment mechanism provided with one end attached to the funnel and an opposite end attached to the balloon. By design, upon expansion of the balloon, the attachment mechanism can pull on the funnel to deploy it into a flared open position. The apparatus may also include a jacket positioned circumferentially about the distal end of the tube, and extending from the funnel to the balloon to protect the vessel from potential irritation that may be caused by the balloon and the strips defining the funnel. As the jacket may be attached to the funnel and the balloon, in one embodiment, the jacket may act as the mechanism for deploying the funnel into a flared open position upon expansion of the balloon.

BRIEF DESCRIPTION OF THE DRAWINGS

[00025] These and other features and advantages of the present invention will become more apparent from the following detailed descriptions taken in conjunction with the accompanying drawings wherein like reference characters denote corresponding parts throughout the several views.

[00026] Fig. 1 illustrates system for removing an undesirable material from within a vessel in accordance with one embodiment of the present invention.

[00027] Figs. 2A-H illustrate a distal end of a suction cannula in operation in connection with the system shown in Fig. 1.

[00028] Figs. 3A-B illustrate an alternate distal end of a suction cannula used in connection with the system shown in Fig. 1.

[00029] Figs. 4A-E illustrate a variety of cannulas for use in connection with the system shown in Fig. 1.

[00030] Fig. 5 illustrates a port through which another device may be introduced within a suction cannula used in connection with the system shown in Fig. 1.

[00031] Fig. 6 illustrates a system for removing an undesirable material from within a vessel in accordance with another embodiment of the present invention.

[00032] Fig. 7 illustrates a system of the present invention being deployed within a patient for removing an undesirable material from a site of interest.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

[00033] As noted above, existing catheter techniques may not be effective in removing undesirable material, such as clots, from medium and large size blood vessels or from heart chambers, because these catheters tend to be small relative to the material to be removed. As a result, the material often needs to be fragmented in order to fit within the catheter. However, with fragmentation, the chances of the fragments being carried away in the bloodstream increases, resulting in downstream obstruction. If the catheter is enlarged to accommodate the larger structure and material, such a catheter may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient.

[00034] The present invention overcomes the deficiencies of existing devices and techniques and can act to remove substantially *en bloc* (i.e., wholly or entirely) undesirable material, such as thrombi and emboli, from the vasculature, including medium to large size blood vessels, and from heart chambers. Vessels from which the undesirable material may be removed, in accordance with an embodiment of the present invention, include, for example, those within the pulmonary circulation (e.g., pulmonary arteries), systemic venous circulation (e.g., vena cavae, pelvic veins, leg veins, neck and arm veins) or arterial circulation (e.g., aorta or its large and medium branches). The heart chambers may be, for example, in the left heart (e.g., the left ventricular apex and left atrial appendage), right heart (e.g., right atrium and right ventricle), or on its valves. The present invention can also act to remove tumors, infective vegetations and other foreign.

[00035] Although reference is made to medium and large vessels, it should be appreciated that the systems and methods, hereinafter disclosed, can be scaled and adapted for use within smaller vessels within the body, if desired.

[00036] Referring now to Fig. 1, there is illustrated a system 1 for removing an undesirable material, substantially *en bloc*, from an obstruction site or site of interest within the vasculature, and for reinfusion of fluid removed (i.e., suctioned or aspirated) from the site of interest back into a patient, in order to minimize fluid loss within the patient. System 1, in an embodiment, may be provided with a first or suction cannula 10 for capturing and removing *en bloc* the undesirable material from the site of interest, such as that within a blood vessel or a heart chamber. Cannula 10, in an embodiment, may be an elongated tube and may include a distal end 11 through which the undesirable material can be captured and removed. Cannula 10 may also include a lumen or pathway 12 extending along a body portion of cannula 10. Pathway 12, in one embodiment, provides a passage along which the captured material and aspirated circulatory fluid, such as blood, that may be captured therewith may be transported and directed away from the site of interest. Cannula 10 may further include a proximal end 13 in opposing relations to the distal end 11, and through which the captured material may exit from the cannula 10.

[00037] Since cannula 10 may be designed for introduction into the vasculature, for instance, through a peripheral blood vessel, and may need to subsequently be maneuvered therealong to the site of interest, cannula 10, in an embodiment, may be made from a pliable material. In addition, as cannula 10 may be used to introduce a suction force to the site of interest for capturing the undesirable material, cannula 10 may be made from a sufficiently stiff material or may be reinforced with a sufficiently stiff material, so as not to collapse under a suction force. In one embodiment, cannula 10 may be constructed from a biocompatible material, such as polyvinyl chloride, polyethylene, polypropylene, polyurethane, Pebax®, silicone, or a combination thereof.

[00038] In certain instances, it may be desirable to maneuver cannula 10 to the site of interest using image guidance, for example, using fluoroscopy or echocardiography. In order to permit cannula 10 to be visualized, cannula 10, in an embodiment, may also include a radioopaque material or any material capable of being visualized.

[00039] To better engage and capture the undesirable material substantially *en bloc* and without significant fragmentation, the distal end 11 of cannula 10 may be designed to have a diameter that can be relatively larger than that of the proximal end

13. In one embodiment, as illustrated in Figs. 2A-D, distal end 11 of cannula 10 may be in the shape of a funnel 20, and may be provided with a diameter, for example, approximately at least three times that of pathway 12. Of course, depending on the surgical procedure being implemented, the ratio between the diameter of funnel 20 and pathway 12 can be varied, if so desired. Funnel 20, with its design, may be placed directly at a site of interest 23 to engage undesirable material 24 (Fig. 2C), or spatially away from the site of interest 23 to capture the undesirable material 24 (Fig. 2D). In a situation where the distal end 11 may be situated spatially away from the site of interest, by providing distal end 11 with funnel 20, a vortex effect may be generated during suctioning to better direct the undesirable material into the funnel 20. It is believed that fluid flowing into funnel 20 can often exhibit a laminar flow circumferentially along the interior surface of the funnel 20 to generate a vortex flow into the distal end 11 of suction cannula 10. Thus, in the presence of a vortex flow, such a flow can act to direct the undesirable material toward the distal end 11 to allow the material to subsequently be pulled into the distal end by suctioning.

[00040] To provide a funnel shaped distal end, cannula 10 may include, in an embodiment, a sheath 21 circumferentially situated about distal end 11 of cannula 10. Sheath 21, as illustrated, may be designed to slide toward as well as away from the distal end 11 of cannula 10. In that way, when the distal end 11 is positioned at the site of interest 23, and sheath 21 is retracted (i.e., slid away from the distal end 11), funnel 20 may be exposed and expanded into the desired shape in order to engage undesirable material 24. To collapse funnel 20, sheath 21 may be advanced toward the distal end 11 and over the funnel 20. Thereafter, cannula 10 may be maneuvered from the site of interest 23.

[00041] In order to enhance capture and removal of the undesirable material 24, looking now at Figs. 2E-G, cannula 10 may be designed to allow introduction of a catheter 25 with balloon 26 to the site of interest. In an example where the undesirable material 24 may be entrapped within funnel 20, catheter 25 with balloon 26 may be directed along the lumen or pathway 12 of cannula 10 and into funnel 20. Once catheter 25 has been advanced past the undesirable material 24 within funnel 20, balloon 26 may be inflated to a size sufficient to pull on the undesirable material entrapped within funnel 20. As balloon 26 is pulled down the funnel 20 towards

pathway 12, balloon 26 can dislodge the entrapped material and can eventually partially or substantially occlude a pathway 12, distal to the undesirable material 24, which in essence occludes the fluid communication between cannula 10 and the vessel. The suction force within pathway 12, as a result, can be enhanced to better remove the undesirable material. Similarly, as shown in Fig. 2H, in a situation where undesirable material 24 may be firmly lodged in the vessel at the site of interest 23 and the suction applied by cannula 10, spatially situated away from the site of interest 23, may insufficient to dislodge the undesirable material 24, catheter 25 and balloon 26 may be advanced past the distal end of cannula 10 and past the undesirable material 24 at the site of interest 23. Once past the undesirable material 24 the balloon 26 may be inflated and as balloon is withdrawn back towards the distal end 11 of cannula 10, it can dislodge the undesirable material and allow the suction to draw it into the distal end of cannula 10. Of course, this approach can also be applied when cannula 10 is situated directly at the site of interest 23 and the suction force may be insufficient to dislodge the undesirable material 24.

[00042] In another embodiment, looking now at Figs. 3A-B, funnel 20 located at distal end 11 of cannula 10 may be created by providing a plurality of independent strips 31, each coupled at one end to distal end 11 of cannula 10. In the embodiment shown in Fig. 3A, three strips 31 are illustrated. However, it should be appreciated that two or more strips 31 may be used, if so desired. Strips 31, in an embodiment, may be designed to pivot between a closed position, where strips 31 may be substantially adjacent one another, and an open position, where strips may be flared into a funnel 20, shown in Fig. 3A. To deploy strips 31, and thus funnel 20, between an open and closed position, cannula 10 may include a balloon 33 positioned circumferentially about cannula 10 and proximal to strips 31. In addition, an attachment mechanism, such as a string 34 or any similar mechanisms (e.g., rod, chain etc.), may be provided for each of the strips 31, with one end attached to one strip 31 and an opposite end attached to balloon 33. In this way, when balloon 33 is inflated and expands radially, balloon 33 may pull on each attachment mechanism 34, so as to deploy strips 31 into a flared open position. Balloon 33, in one embodiment, may be inflated through opening 37 through the use of any fluid, including water, air, or radioopaque contrast material. It should be noted that securing of the attachment mechanism to the strips

31 and balloon 33 can be accomplished using any methods or mechanisms known in the art. For instance, adhesives, knots, or soldering etc. may be used. Moreover, to the extent desired, strips 33 and balloon 31 may be designed to expand to a diameter larger than that of the vessel within which cannula 10 is being deployed. In that way, cannula 10 may be securely positioned at the site of interest for removal of the undesirable material substantially *en bloc*.

[00043] To better capture the undesirable material and direct it into the cannula 10, a membrane 35 may be placed across a space between adjacent strips 31 when the strips 31 are in the open position. In one embodiment, a continuous membrane 35 may be used to circumferentially stretch across each of the space between adjacent strips 31. Membrane 35 may also act to enhance suction at the site of interest, as it can cover up any open space between the strips 31. To that end, membrane 35, in an embodiment, may be made from a non-permeable material. It should be appreciated that membrane 35 and strips 31, as illustrated, together define funnel 20 at distal end 11 of cannula 10.

[00044] Furthermore, to protect the vessel from irritation or damage that may be caused by the presence of balloon 33 and/or strips 31, jacket 36, as shown in Fig. 3B, may be provided circumferentially about the distal 11 of cannula 10. In an embodiment, jacket 36 may extend substantially from a tip of each strip 31 to balloon 33. Jacket 36, however, can be affixed anywhere along each strip 31, if necessary. Since jacket 36 attaches at one end to strips 31 and at an opposite end to balloon 33, jacket 36, in an embodiment, may be used instead of attachment mechanism 34 to deploy strips 31 into an open position when balloon 33 is expanded. Of course, jacket 36 may also be used in conjunction with attachment mechanism 34 to deploy strips 31 into an open position. Furthermore, in one embodiment, jacket 36 may be lengthened, so that the end connected to strips 31 may instead be pulled over strips 31, into funnel 20, and attached substantially to a base of each strips 31 (i.e., base of funnel 20). With such a design, membrane 35 may not be necessary, as jacket 36 may serve the purpose of membrane 35 to cover the space between each of strips 31. In such an embodiment, at least that portion of jacket 36 extending over strips 31 and into the base funnel 20 can be impermeable.

[00045] In certain instances, balloon 33 may act to enhance the suction force being applied at the site of interest when removing the undesirable material. For instance, when cannula 10 is deployed downstream of the undesirable material, rather than substantially adjacent to the undesirable material, within a vessel having a venous circulation (i.e., flow toward the heart), balloon 33, when expanded radially, can substantially occlude the vessel, such that collateral fluid flow within the vessel can be minimized, thereby increasing the suction force that can be applied to the undesirable material. Additionally, the occlusion of such a vessel by balloon 33 can better direct the material being removed into the funnel 20 and prevent the material from being carried by the flow of blood past the funnel.

[00046] Alternatively, when cannula 10 is deployed upstream of the undesirable material within a vessel having an arterial circulation (i.e., flow away from the heart), rather than substantially adjacent to the undesirable material, balloon 33, when expanded radially, can substantially occlude the vessel, such that pressure being exerted on the downstream material by the fluid flow can be lessened. By lessening the pressure on the material to be removed, the suction force being applied at the site of interest can act to remove the material more easily.

[00047] As suction cannula 10 may be made from a pliable material, in order to efficiently direct it along a vessel to the site of interest, cannula 10 may be reinforced with wire or other material to optimize maneuverability within the vessel without kinking. Referring now to Fig. 4A, suction cannula 10 may, in addition to pathway 12, be provided with one or more additional pathway or lumen 41. In this multi-lumen design, pathway 12 may act, as noted above, to provide a passage along which the captured material may be transported and directed away from the site of interest. Lumen 41, on the other hand, can provide a passage along which a fluid can be directed to inflate balloon 33 through opening 37 (Figs. 3A-B). In certain embodiments, lumen 41 may also be used to accommodate other devices, such as other catheters or surgical instruments, for use in connection with a variety of purposes. For example, a device may be inserted and advanced along lumen 41 through the distal end 11 of suction cannula 10 to dislodge the undesirable material. An angiography catheter can be inserted and advanced along lumen 41 through the distal end 11 of suction cannula 10 to perform an angiogram to confirm the location

of the undesirable material or confirm that it has been successfully removed. A balloon embolectomy catheter can be inserted along lumen 41 toward the distal end 11 of suction cannula 10 to remove any material which may have clogged the cannula or past the any undesirable material firmly lodged in the vessel to draw it into the cannula. Although illustrated with such a multi-lumen design, any other multi-lumen design may be possible.

[00048] To introduce other devices, such as catheter 25 with balloon 26, into lumen 41 or pathway 12, cannula 10 may be provided with a port 51, as shown in Fig. 5, located at the proximal end 13 of cannula 10. It should be appreciated that in the embodiment where cannula 10 has only pathway 12 (i.e., single lumen cannula), port 51 may similarly be provided at the proximal end 13 of cannula 10 to allow the introduction of other devices into pathway 12.

[00049] Cannula 10 of the present invention may be of any sufficient size, so long as it can be accommodated within a predetermined vessel, such as a medium to large size blood vessel. The size of cannula 10 may also be determined by the size of the undesirable material to be removed, so long as the undesirable material can be removed substantially *en bloc* without significant fragmentation. In one embodiment, suction cannula 10 may be designed to remove at least 10 cm^3 of undesirable material substantially *en bloc*. Of course, cannula 10 can be scaled and adapted for use within smaller vessels in the body and for removing a relatively smaller volume or amount undesirable material, if so desired.

[00050] Looking again at Fig. 1, system 1 can also include filter device 14 in fluid communication with the proximal end 13 of cannula 10. Filter device 14, in one embodiment, may include an inlet 141 through which fluid removed from the site of interest along with the captured undesirable material can be directed from cannula 10. Filter device 14 may also include an outlet 142 through which filtered fluid from within device 14 may be directed downstream of system 1. To prevent the undesirable material captured from the site of interest from moving downstream of system 1, filter device 14 may further include a permeable sheet 143 positioned within the fluid flow between the inlet 141 and the outlet 142.

[00051] Permeable sheet 143, in an embodiment, may include a plurality of pores sufficiently sized, so as to permit fluid from the site of interest to flow therethrough,

while preventing any undesirable material captured from the site of interest from moving downstream of system 1. Examples of permeable sheet 143 includes coarse netting, fine netting, a screen, a porous filter, a combination thereof, or any other suitable filter material capable of permitting fluid to flow through while impeding movement of the captured undesirable material. It should be noted that, rather than just one, a plurality of permeable sheets 143 may be used. Alternatively, one permeable sheet 143 may be folded to provide multiple surfaces, similar to an accordion, for use in connection with filter device 14. By using a plurality of permeable sheets 143 or by folding sheet 143, the number of filtration surfaces through which the fluid must flow increases to enhance filtration and further minimize any occurrence of any undesirable material from moving downstream of system 1.

[00052] Although a permeable sheet 143 is described, it should be appreciated that filter device 14 may be of provided with any design capable of entrapping the undesirable material, while allowing fluid to move therethrough. To that end, filter device 14 may include a mechanical trap to remove the undesirable material from the fluid flow. Such a mechanical trap may be any trap known in the art and may be used with or without permeable sheet 143.

[00053] Still looking at Fig. 1, system 1 may also be provided with a pump 15 designed to generate negative pressure, so as to create a necessary suction force through cannula 10 to pull any undesirable material from the site of interest. In one embodiment, pump 15 may include an intake port 151 in fluid communication with outlet 142 of filter device 14. Intake port 151, as illustrated, may be designed to receive filtered fluid from filter device 14. Pump 15 may also be designed to generate the positive pressure, so as to create a necessary driving force to direct fluid through exit port 152 and downstream of system 1 for reinfusion of fluid removed from the site of interest back into the body. In an embodiment, the suction force and the drive force may be generated by pump 15 simultaneously and may take place continuously or intermittently for a set duration. Pump 15, as it should be appreciated, may be any commercially available pump, including those for medical applications and those capable of pumping fluids, such as blood. Examples of such a pump includes a kinetic pump, such as a centrifugal pump, and an active displacement pump, such as a rollerhead pump.

[00054] In an alternate embodiment, an independent vacuum device (not shown), may be provided for generating the necessary suction force at the site of interest, while a pump 15 may act to generate the necessary driving force for reinfusion purposes. In such an embodiment, pump 15 may be in fluid communication with the filter device 14, while the vacuum device may be in fluid communication with suction cannula 10 upstream to the filter device 14. The independent pump 15 and vacuum device may operate intermittently for a set duration, and if desired, either the vacuum device or pump 15 may operate continuously, while the other operates intermittently.

[00055] Downstream of pump 15, system 1 may further include a second or reinfusion cannula 16 in fluid communication with the exit port 152 of pump 15. Reinfusion cannula 16, in an embodiment, may be designed to permit filtered fluid, directed from filter device 14 by way of pump 15, to be reinfused back into a patient at a desired site. To that end, reinfusion cannula 16 may be designed for placement within the same or different vessel within which suction cannula 10 may be located.

[00056] Reinfusion cannula 16, in one embodiment, may be an elongated tube and includes a distal end 161 through which cleansed or filtered fluid can be reinfused back into the body. In an embodiment, distal end 161 of reinfusion cannula 16 may be designed so that it can be situated in spaced relation to the distal end 11 of the suction cannula 10 when system 1 is in operation. Reinfusion cannula 16 may also include a lumen or pathway 162 extending along its body portion to provide a passage along which the filtered fluid, such as blood, may be transported to a reinfusion site. Reinfusion cannula 16 may further include a proximal end 163 in opposing relations to the distal end 161, and through which the filtered fluid from pump 15 may enter into the cannula 16.

[00057] Furthermore, similar to suction cannula 10, since reinfusion cannula 16 may be designed for introduction into the vasculature, and may need to be maneuvered therealong, reinfusion cannula 16, in one embodiment, may be made from a pliable material. In one embodiment, reinfusion cannula 16 may be constructed from a biocompatible material, such as polyvinyl chloride, polyethylene, polypropylene, polyurethane, Pebax®, silicone, or a combination thereof. In certain instances, it may be desirable to maneuver reinfusion cannula 16 to the reinfusion site using image guidance, for example, using fluoroscopy or echocardiography. To permit reinfusion

cannula 16 to be visualized, reinfusion cannula 16, in an embodiment, may also be made to include a radioopaque material.

[00058] Since reinfusion cannula 16 may be made from a pliable material, in order to efficiently direct it along a vessel to the reinfusion site, reinfusion cannula 16 may be reinforced to optimize maneuverability within the vessel without kinking. Moreover as shown in Fig. 4B, reinfusion cannula 16 may be provided with one or more additional lumens. With a multi-lumen design, lumen 162, as noted above, may act to provide a passage along which the filtered fluid may be transported and directed to the reinfusion site. Lumen 42, on the other hand, can provide a passage through which a guide wire can be inserted to assist in the guiding the reinfusion cannula 16 to the reinfusion site, or through which other instruments and devices may be inserted for various surgical procedures. With such a multi-lumen design, reinfusion cannula 16 can serve as an introducer sheath by providing lumen 42 through which these instruments can pass, while filtered blood can be reinfused through lumen 162. Although illustrated with such a multi-lumen design, any other multi-lumen design may be possible.

[00059] Although illustrated as a separate component from suction cannula 10, in certain embodiments, the reinfusion cannula 16 may be designed to be substantially integral with suction cannula 10. In one embodiment, as illustrated in Fig. 4C, reinfusion cannula 16 may be incorporated as part of a double or multi- lumen introducer sheath 43 for insertion into the same vessel within which the suction cannula 10 may be situated. In particular, suction cannula 10 may be inserted and maneuvered through one lumen 44 of sheath 43, while reinfusion cannula 16 may be in fluid communication with lumen 45 of sheath 43. In such an embodiment, lumen 45 may include a distal end 451 in spaced relations to the distal end 11 of cannula 10, so that cleansed or filtered fluid may be introduced to the reinfusion site away from the site of interest where the distal end 11 of cannula 10 may be positioned.

[00060] Alternatively, as illustrated in Fig. 4D, reinfusion cannula 16 may be incorporated as part of a double or multi- lumen introducer sheath 43 where the reinfusion cannula 16 and the suction cannula 10 may be concentrically aligned along a shared axis A. In the embodiment shown in Fig. 4D, reinfusion cannula 16 may have a diameter that can be relatively larger than that of suction cannula 10. To that

end, reinfusion cannula 16 can accommodate suction cannula 10 within pathway 162 of the reinfusion cannula 16, and allow suction cannula 10 to extend from within pathway 162, such that the distal end 11 of suction cannula 10 may be positioned in spaced relations relative to the distal end 161 of reinfusion cannula 16. The spaced relations between distal end 161 and distal end 11 allows filtered fluid to be introduced to the reinfusion site away from the site of interest, where the removal of the undesirable material may be occurring.

[00061] In another embodiment, reinfusion cannula 16 and suction cannula 10 can be integrated into a single multi-lumen suction-reinfusion cannula 46, as shown in Fig. 4E. In the embodiment shown in Fig. 4E, multi-lumen cannula 46 may include a distal suction port 461 through which undesirable material from the site of interest can be removed, and a proximal reinfusion port 462 through which cleansed or filtered fluid may be reinfused back into the body. The spaced relations between the suction port 461 and reinfusion port 462 allows filtered fluid to be introduced to the reinfusion site away from the site of interest where the removal of the undesirable material may be occurring.

[00062] In an embodiment, the size of the reinfusion cannula, whether independent from the suction cannula, part of a multi-lumen introducer sheath, part of a multi-lumen combined suction-reinfusion cannula, or in concentric alignment with the suction cannula, may be designed so that it can handle a relatively rapid reinfusion of large volumes of fluid by pump 15.

[00063] With reference now to Fig. 6, system 1 may also include a reservoir 61. Reservoir 61, in one embodiment, may be situated in fluid communication between filter device 14 and pump 15, and may act to transiently collect fluid filtered from the site of interest, prior to the filtered fluid being directed into reinfusion cannula 16. By providing a place to transiently collect fluid, reservoir 61 can allow the rate of suctioning (i.e., draining, aspirating) to be separated from rate of reinfusing. Typically, the rate of reinfusion occurs at substantially the same rate of suctioning, as the volume of fluid suctioned from the site of interest gets immediately directed along the system 1 and introduced right back to the reinfusion site in a patient. However, the availability of a volume of transiently collected fluid in reservoir 61 now provides a source from which the amount or volume of fluid being reinfused back into the

patient can be adjusted, for example, to be less than that being suctioned from the site of interest, as well as the rate at which fluid can be reinfused back into the patient, for example, at a relatively slower rate in comparison to the rate of suctioning. Of course, if so desired or necessary, the reinfusion rate and volume can be adjusted to be higher, relative to the rate and volume of suction.

[00064] In accordance with one embodiment of the present invention, reservoir 61 may be a closed or an open container, and may be made from a biocompatible material. In an embodiment where reservoir 61 may be a closed container, system 1, likewise, will be a closed system. As a result, pump 15 may be used as both a suction source and a driving force to move fluid from the site of interest to the reinfusion site. In such an embodiment, pump 15 can generate a suction force independently of or alternately with a driving force to allow reservoir 61 collect filtered fluid from filter device 14. In one embodiment, pump 15 may be provided with a gauge in order to measure a rate of flow of the fluid being reinfused.

[00065] Alternatively, where reservoir 61 may be an open container, reservoir 61, in such an embodiment, may be designed to accommodate both a volume of fluid, typically at the bottom of reservoir 61, and a volume of air, typically at the top of reservoir 61, to provide an air-fluid interface within reservoir 61. As a result, using pump 15 in fluid communication with reservoir 61 may not provide the needed driving force and/or suction force to adequately remove the undesirable material and to subsequent reinfuse fluid back into a patient. To address this, system 1, in an embodiment, may include a separate and independent vacuum source, in fluid communication with the volume of air at the top of reservoir 61, for providing the necessary suction force from the top area of reservoir 61 where air exists, through filter device 14, through the distal end 11 of cannula 10, and to the site of interest. A port provided above the fluid level within reservoir 61 may be provided to allow the independent vacuum source to be in fluid communication with the volume of air within reservoir 61. Pump 15, on the other hand, may be in fluid communication with the volume of fluid within reservoir 61, and may act to generate the necessary driving force for reinfusion purposes.

[00066] It should be appreciated that although shown as separate components, to the extent desired, reservoir 61 and filter device 14 may be combined as a single unit.

[00067] Still referring to Fig. 6, system 1 may further include a second filter device 62 positioned in fluid communication between pump 15 and reinfusion cannula 16. Second filter device 62 may act to remove any debris or material (e.g., ranging from smaller than microscopic in size to relatively larger) that may have escaped and moved downstream from filter device 14, so that the fluid may be substantially cleansed prior to reinfusion. In an embodiment, second filter device 62 may include a porous membrane 63 whose pores may be measurably smaller than that in filter device 14, but still capable of allowing fluid to flow therethrough.

[00068] Since fluid such as blood needs to be filtered through system 1, it should be noted that system 1 and its components may be made from a biocompatible material to minimize any adverse reaction when fluid removed from the site of interest gets reinfused back into the body.

[00069] In operation, system 1 of the present invention may be introduced into the vasculature, preferably through a peripheral blood vessel, to remove undesirable material, such as a clot, emboli, or thrombi, substantially *en bloc* and without significant fragmentation, and subsequently reinfusing fluid removed from the site of interest back into a patient. In particular, system 1 and its components disclosed above can collectively form a substantially closed circuit through which fluid and an undesirable material from a site of interest can be removed by suction, cleared of the undesirable material, filtered to remove any additional debris, and actively introduced back into a patient at a reinfusion site.

[00070] With reference now to Fig. 7, there is shown one embodiment of the system of the present invention being utilized for removal of an undesirable material within a patient 700. System 70, as illustrated, includes a suction cannula 71, filter device 72, pump 73, second filter device 74 and reinfusion cannula 75. It should be appreciated that depending on the procedure and to the extent desired, system 70 may not need all of the components shown, or may need other components in addition to those shown.

[00071] In general the method of the present invention, in one embodiment, includes, initially accessing a first blood vessel 701 either by surgical dissection or percutaneously with, for instance, a needle and guide wire. The first blood vessel through which suction cannula 71 may be inserted into patient 700 can be, in an embodiment, any blood vessel that can be accessed percutaneously or by surgical

dissection such as femoral vein, femoral artery or jugular vein. Next, suction cannula 71 may be inserted into the first blood vessel 701 over the guide wire, and advanced toward a site of interest 702, for instance, in a second vessel or a heart chamber 703 where an undesirable material 706 may be residing. The second blood vessel or heart chamber, in an embodiment, can be the main pulmonary artery, branch pulmonary arteries, inferior vena cavae, superior vena cavae, deep veins of the pelvic, legs, arms or neck, aorta, or any other medium to large blood vessel for which the use of a cannula is suitable for removing undesirable material without causing undesirable damage to the blood vessel. In addition, the advancement of suction cannula 71 may be gauged or documented by fluoroscopic angiography, echocardiography or other suitable imaging modality.

[00072] In the case of pulmonary embolism, the suction cannula 71 may normally be introduced through the femoral, jugular or subclavian vein. Alternatively, the suction cannula 71 may be introduced, if desired, directly into the cardiac chambers using a minimally invasive surgical or endoscopic, thoracoscopic, or pericardioscopic approach.

[00073] Thereafter, a third blood vessel 704 may be accessed either by surgical dissection or percutaneously with, for example, a needle and guide wire. Subsequently, reinfusion cannula 75 may be inserted into the third blood vessel 703 using an open or over the guide wire technique. The third blood vessel through which the reinfusion cannula 75 may be inserted, in one embodiment, can be any large vein, such as the femoral vein or jugular vein. Reinfusion cannula 75 may then be advanced toward a reinfusion site, for example, within a fourth blood vessel 705. The fourth blood vessel, in one embodiment, can be the femoral vein, iliac vein, inferior vena cava, superior vena cava or right atrium.

[00074] Once reinfusion cannula 75 is in place and components of system 70 have connected, pump 73 may be activated, and suction cannula 71 may then be placed against and in substantial engagement with the undesirable material 706 at the site of interest 702 for removal by suctioning through the suction cannula 71. The undesirable material 706 and circulatory fluid removed from the site of interest 702 may thereafter be directed along suction cannula 71 into filter device 72 where the undesirable material 706 can be entrapped and removed from the fluid flow. The

resulting filtered fluid may next be directed downstream by way of pump 73 into the second filter device 74, where any debris or material (e.g., ranging from smaller than microscopic in size to relatively larger) that may have escaped and moved downstream from filter device 74 can be further captured and removed from the fluid flow prior to reinfusion. The resulting cleansed fluid may then be directed into the reinfusion cannula 75 and introduced back into the patient 700.

[00075] It should be appreciated that in certain instances, prior to connecting the suction cannula 71 and the reinfusion cannula 75, system 70 may need to be primed with fluid to minimize or eliminate any air and/or air bubbles from the system prior to the initiation of suction and reinfusion. To that end, the suction cannula 71 and reinfusion cannula 75 can be primed separately with fluid or by allowing blood to backfill the cannulae after insertion. The remaining components of the system 70 including all tubing, the filter device 72, the pump 73 and any other components of system 70 may also need to be primed with fluid prior to connecting them to the cannulae. In one embodiment, this can be achieved by temporarily connecting these components in fluid communication with other as a closed circuit and infusing fluid through a port, similar to port 51 in Fig. 5, while providing another port through which air can be displaced. Once these components have been fully primed with fluid, the circuit can be detached and connected to the primed suction cannula 71 and reinfusion cannula 75 in the appropriate configuration. Examples of a priming fluid include crystalloid, colloid, autologous or heterologous blood, among others.

[00076] During operation, pump 73, in one embodiment, may remain activated so that suction and continuous reinfusion of blood can occur continuously for a desired duration or until the removal of the undesirable material has been confirmed, for instance, by visualizing the captured undesirable material in the filter device 72. Alternatively pump 73 can be activated intermittently in short pulses, either automatically or manually by an operator (e.g., surgeon, nurse or any operating room attendant), for a desired duration or until the removal of the undesirable material has been confirmed by visualization of the material within filter device 72.

[00077] It should be appreciated that since suction cannula 71 may be deployed within any vessel within patient 700, depending on the procedure, in addition to being placed substantially directly against the undesirable material at the site of interest, suction

cannula 71 may be deployed at a location distant from the site of interest where direct engagement with the undesirable material may not be possible or desired.

[00078] In a situation where the suction cannula 71 is positioned within a vessel exhibiting a venous flow and at a distant location from the undesirable material, it may be desirable to place the distal end of suction cannula 71 downstream of the undesirable material, so that the fluid flow can push the undesirable material from the site of interest into suction cannula 71 during suction. To the extent there may be some difficulties with suctioning the undesirable material from its location, if necessary, a catheter may be deployed through suction cannula 71 and to the site of interest, where the undesirable material may be dislodged location for subsequent removal.

[00079] On the other hand, when suction cannula 71 is positioned within a vessel exhibiting arterial flow and at a distant location from the undesirable material, it may be necessary to place the distal end of suction cannula 71 upstream of the undesirable material for the purposes of removal, even though the undesirable material must move against the fluid flow in order to enter into the suction cannula 71. In such a situation, since the fluid flow in the vessel tends to exert a pressure against the undesirable material at the site of interest, and thus may make the undesirable material difficult to remove, suction cannula 71 may include a flow occlusion mechanism, similar to balloon 33 shown in Fig. 3. When expanded radially, the mechanism can substantially occlude the vessel, such that pressure being exerted on the downstream material by the fluid flow can be lessened. By lessening the pressure on the undesirable material to be removed, the suction force being applied at the site of interest can act to remove the material more easily. Again, if necessary, a catheter may be deployed through suction cannula 71 and to the site of interest, where the undesirable material may be dislodged or drawn back into the cannula to facilitate its removal.

[00080] The method of the present invention may also utilize a fluid reservoir, similar to reservoir 61 shown in Fig. 6, in connection with system 70. Such a reservoir may be placed in fluid communication between filter device 72 and pump 73. The reservoir, in an embodiment, may be an independent reservoir or may be integrated with filter device 72 as a single unit, similar to that shown in Fig. 7. By utilizing a

reservoir, a volume of transiently collected fluid may be used to independently control the rate or volume of suctioning (i.e., draining, aspirating) and/or the rate or volume of reinfusion.

[00081] In an embodiment where the reservoir may be an open container, it should be appreciated that system 70 may not be a substantially closed system. As a result, rather than utilizing a pump that can generate both a suction and a driving force for a closed system, an independent vacuum device 76 may be employed to generate the necessary suction force, from the top of the reservoir where a volume of air exists, for removal of the undesirable material, while independent pump 73 may be employed to generate the necessary driving force, from the bottom of the reservoir where a volume of aspirated fluid exists, for reinfusion.

[00082] The method of the present invention may also utilize a suction cannula 71 with a deployable funnel tip, similar to funnel 20 in Fig. 2 or in Fig. 3. In such an embodiment, the funnel may be deployed after suction cannula 71 has been positioned adjacent the site of interest. Thereafter, once the suction force has been activated, the funnel may be advanced to engage the undesirable material for removal. The funnel may remain deployed while the suction force is activated, and through multiple cycles, if necessary, until the undesirable material can be removed. Subsequently, the funnel may be retracted in order to reposition or remove suction cannula 71.

[00083] The method of the present invention may further utilize reinfusion cannula 75 that has been incorporated into an introducer sheath, such as sheath 43 as a multi-lumen cannula (Fig. 4C) or as one which concentrically aligns the suction cannula and reinfusion cannula (Fig. 4D). In this embodiment, the sheath/reinfusion cannula 75 may initially be inserted into a first blood vessel. Suction cannula 71 may then be inserted into the introducer lumen of the sheath/reinfusion cannula 75, and the assembly advanced together to a site of interest in a second blood vessel or heart chamber.

[00084] The method of the present invention may also further utilize a combined multi-lumen suction/reinfusion cannula, similar to cannula 46 shown in Fig. 4E. In such an embodiment, the combined suction/reinfusion cannula may initially be inserted into a first blood vessel to a location where its distal suction lumen can be placed adjacent the site of interest within a second blood vessel, while its proximal

located reinfusion lumen can be positioned at an appropriately spaced location from the suction lumen.

[00085] The method of the present invention may, in an embodiment, be employed to remove a plurality of undesirable materials, for instance, within the same vessel or its branches, from multiple vessels within the same vascular bed (e.g. left and right pulmonary arteries), from different vascular beds (e.g. pulmonary artery and iliofemoral veins), or a combination thereof. In such an embodiment, after the first undesirable material has been removed, the suction force may be deactivated. The next undesirable material to be removed may then be located, for example, using an appropriate imaging modality. Suction cannula 71 may thereafter be advanced to the location of this second undesirable material, and the suction force reactivated as above until this second undesirable material may be removed. The cycle may be repeated until each undesirable material at the various identified locations has been removed. Once all undesirable material has been removed, an appropriate procedure to prevent the development of or migration of new material, such as placement of an inferior vena cava filter, may be performed.

[00086] The method of the present invention may also be employed in combination with a balloon embolectomy catheter or other devices suitable for dislodging clots or other undesirable material from a cannula or a vessel. For example, should an undesirable material be lodged within suction cannula 71, a balloon catheter can be inserted through, for instance, a side port, similar to port 51 in Fig. 5, of suction cannula 71 and advanced past the lodged undesirable material. The balloon catheter may subsequently be inflated distal to the undesirable material. Once inflated, the suction force may be activated and the inflated catheter withdrawn along the suction cannula 71 to dislodge the undesirable material its location of obstruction. In a situation where the undesirable material may be adherent to a vessel wall, or for some other reason cannot be dislodged by simply applying suction to the site of interest, the balloon catheter can be inserted through the side port of suction cannula 71, advanced past a distal end of cannula 71, and past the adherent undesirable material. The balloon catheter may then be inflated distal to the undesirable material. Once inflated, the suction force may be activated and the inflated catheter withdrawn along the

suction cannula 71. As it is withdrawn, the balloon catheter can act to drag the undesirable material into suction cannula 71.

[00087] The method of the present invention may further be employed in combination with a distal protection device (not shown), such as a netting device, designed to be positioned downstream of the undesirable material, when removal may be performed within a vessel having arterial flow. In particular, with suction cannula 71 positioned upstream of the undesirable material, the netting device may be inserted through a side port in suction cannula 71, advanced past the undesirable material to a downstream location. The netting device may then be deployed to an open position approximating the diameter of the vessel. The deployed netting device may then act to entrap any material that may be dislodged from the site of interest and pushed downstream by the fluid flow. In the absence of the netting device, a dislodged material may be pushed downstream and may be lodged in a more life threatening location.

[00088] It is evident from the above description that the systems, including the various components, and methods of the present invention can act to remove clots and other types of undesirable material from the circulation, particularly from medium to larger vessels and heart chambers. Important to achieving this includes the ability of the operator to perform substantially *en bloc* removal of the undesirable material without significant fragmentation from the site of interest. Such a protocol may only be achieved previously with invasive, open surgery. In addition, by providing a system with components to permit aspirated fluid from the site of interest to be reinfused back to the patient, the system of the present invention allows a sufficiently and relatively large suction cannula to be employed for the removal of a relatively large undesirable material 15 in substantially one piece, without fragmentation. Furthermore, by providing a definitive mechanical treatment to the problem, the systems and methods of the present invention provide an attractive alternative to treatments, such as thrombolysis, which may not be an option or may be ineffective for many patients, and which may carry a significant risk of major complications. As such, the systems and methods of the *p*resent invention now provide a significant contribution to the field of cardiovascular medicine and surgery, particularly thromboembolic disease.

[00089] Although references have been made in connection with surgical protocols, it should be appreciated that the systems and methods of the present invention may be adapted for use in connection with non-surgical protocols, and in connection with any vessel capable of permitting fluid flow therethrough and capable of being obstructed. For instance, the system of the present invention may be adapted for use in connection with clearing obstructed oil pipelines, water pipes, and air ducts, among others.

[00090] While the present invention has been described with reference to certain embodiments thereof, it should be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the invention. In addition, many modifications may be made to adapt to a particular situation, indication, material and composition of matter, process step or steps, without departing from the spirit and scope of the present invention. All such modifications are intended to be within the scope of the claims appended hereto.

What is claimed is:

1. A system for removing an undesirable material from within a vessel, the system comprising:

a first cannula having a distal end and an opposing proximal end, the first cannula designed for maneuvering within a vessel to a site of interest, such that the undesirable material can be captured substantially *en bloc* through the distal end and removed along the first cannula away from the site;

a pump, in fluid communication with the proximal end of the first cannula, to provide a sufficient suction force for removing the undesirable material from the site of interest; and

a second cannula in fluid communication with the pump and being designed to have its distal end situated in spaced relation to the distal end of the first cannula, such that fluid removed from the site of interest by the first cannula can be directed along the second cannula and reinfused through the distal end of the second cannula.

2. A system as set forth in claim 1, wherein the first cannula is designed to remove the undesirable material from one of a medium size blood vessel, a large size blood vessel, or a heart chamber.

3. A system as set forth in claim 1, wherein the first cannula is designed to remove the undesirable material without substantial fragmentation.

4. A system as set forth in claim 1, wherein the distal end of the first cannula includes a diameter that is relatively larger than that of the proximal end of the first cannula.

5. A system as set forth in claim 4, wherein the distal end of the first cannula can occlude fluid flow adjacent the site of interest in order to enhance the suction force applied to the undesirable material.

6. A system as set forth in claim 1, wherein the distal end of the first cannula is deployable to expand from a first diameter to a relatively larger second diameter.

7. A system as set forth in claim 6, wherein the distal end of the first cannula is funnel shape.

8. A system as set forth in claim 6, wherein the distal end of the first cannula includes a mechanism for substantially occluding fluid flow adjacent the site of interest, in order to enhance suction force being applied to the undesirable material.

9. A system as set forth in claim 1, wherein the first cannula is made from a radioopaque material to permit visualization of the cannula for image guidance purposes.

10. A system as set forth in claim 1, wherein the first cannula is made from a material sufficiently pliable to permit maneuvering of the cannula within the vessel.

11. A system as set forth in claim 1, wherein the first cannula is made from a material sufficiently strong, so as to not collapse under suction.

12. A system as set forth in claim 1, wherein the first cannula is reinforced with to prevent kinking.

13. A system as set forth in claim 1, wherein the first cannula is constructed of a material including one of polyvinyl chloride, polyethylene, polypropylene, polyurethane, Pebax®, silicone, or a combination thereof.

14. A system as set forth in claim 1, wherein the first cannula includes a side port to permit introduction of other instruments or devices into the first cannula.

15. A system as set forth in claim 1, wherein the first cannula includes multiple lumens.

16. A system as set forth in claim 1, wherein the pump can simultaneously generate a negative pressure to create a suction force necessary to pull the undesirable material into the first cannula and a positive pressure to create a driving force necessary to reinfuse fluid through the second cannula.

17. A system as set forth in claim 1, wherein the pump can intermittently generate one of a negative pressure to create a suction force necessary to pull the undesirable material into the first cannula and a positive pressure to create a driving force necessary to reinfuse fluid through the second cannula.

18. A system as set forth in claim 1, wherein the second cannula is made from a material sufficiently pliable to permit maneuvering of the cannula within a vessel.

19. A system as set forth in claim 1, wherein the second cannula includes a side port to permit introduction of other instruments or devices into the second cannula.

20. A system as set forth in claim 1, wherein the second cannula includes multiple lumens.

21. A system as set forth in claim 1, wherein the second cannula and the first cannula are integral in an assembly and include respective distal ends that are in spaced relation relative to one another.

22. A system as set forth in claim 1, wherein the second cannula is integrated as part of an introducer sheath through which the first cannula can be advanced such that the respective distal ends of the second cannula and the first cannula are in spaced relation relative to one another.

23. A system as set forth in claim 1, further including a filter device in fluid communication with the first cannula for entrapping the undesirable material as it exits from the first cannula and removing it from the fluid flow.

24. A system as set forth in claim 23, wherein the filter device includes a permeable sheet capable of permitting fluid directed from the first cannula to flow therethrough, while impeding the undesirable material from flowing downstream within the system.

25. A system as set forth in claim 1, further including a reservoir in fluid communication with the filter device for collecting fluid being directed from the filter device and providing a source of fluid for reinfusion by the second cannula.

26. A system as set forth in claim 1, further including a reservoir and a filter device as an integral unit.

27. A system as set forth in claim 1, further including a second filter positioned in fluid communication between the pump and the second cannula for removing undesirable debris from the fluid flow prior to reinfusion by the second cannula.

28. A system as set forth in claim 1, wherein the undesirable material captured from the site of interest includes one of a clot, a thrombus, an embolus, a tumor, an infective vegetation, and a foreign body.

29. A system as set forth in claim 1, wherein the fluid removed from the site of interest includes blood.

30. A method for removing an undesirable material from within a vessel, the method comprising:

maneuvering a first cannula having a distal end and an opposing proximal end to a site of interest within a vessel in a patient, such that the distal end of the first cannula is positioned adjacent the undesirable material;

positioning a second cannula, in fluid communication with the first cannula, such that its distal end is situated in spaced relation to the distal end of the first cannula;

providing a suction force, through the distal end of the first cannula, to the site of interest, so as to remove the undesirable material *en bloc* from the site of interest through the distal end of the first cannula; and

reinfusing, through the distal end of the second cannula, any fluid removed along with the undesirable material to a location in spaced relation from the distal end of the first cannula.

31. A method as set forth in claim 30, wherein, in the step of maneuvering, the vessel includes one of a medium size blood vessel, a large size blood vessel, or a heart chamber.

32. A method as set forth in claim 30, wherein, in the step of maneuvering, the distal end of the first cannula includes a diameter that is relatively larger than that of the proximal end of the first cannula.

33. A method as set forth in claim 30, wherein the step of maneuvering includes substantially occluding fluid flow within the vessel adjacent the distal end of the first cannula, so as to enhance the suction force applied to the undesirable material.

34. A method as set forth in claim 33, wherein the step of occluding occurs within a vessel exhibiting venous circulation.

35. A method as set forth in claim 33, wherein the step of occluding occurs within a vessel exhibiting arterial circulation.

36. A method as set forth in claim 30, wherein the step of maneuvering includes expanding, at the site of interest, the distal end of the first cannula from a first diameter to a relatively larger second diameter.

37. A method as set forth in claim 30, wherein the step of positioning includes one of placing the distal end of the second cannula within the same vessel as that of the distal end of the first cannula, placing the distal end of the second cannula within a different vessel as that of the distal end of the first cannula, or placing the distal end of the second cannula in spaced relation to the distal end of the first cannula.

38. A method as set forth in claim 30, wherein the step of providing includes generating the suction force and a driving force for reinfusion from one source.

39. A method as set forth in claim 30, wherein the step of providing includes generating the suction force and a driving force for reinfusion from different sources.

40. A method as set forth in claim 30, wherein the step of providing includes removing the undesirable material without substantial fragmentation.

41. A method as set forth in claim 30, wherein the step of providing includes removing at least 10 cm^3 of the undesirable material without substantial fragmentation.

42. A method as set forth in claim 30, wherein the step of providing includes entrapping, downstream of the proximal end of the first cannula and towards a source for the suction force, the undesirable material so as to remove it from the fluid flow.

43. A method as set forth in claim 42, wherein in the step of entrapping includes permitting fluid flow to continue into the second cannula, while impeding movement of the undesirable material toward the second cannula.

44. A method as set forth in claim 42, further including capturing undesirable debris downstream of the entrapped undesirable material but before to the second cannula, so as to remove the debris from the fluid flow prior to reinfusing.

45. A method as set forth in claim 30, wherein the step of reinfusing includes collecting fluid directed from the proximal end of the first cannula and using the collected fluid as a source of fluid for reinfusion.

46. A method as set forth in claim 30, wherein prior to providing a suction force, the method includes priming the circuit with fluid to minimize presence unwanted air being introduced into the patient.

47. A method as set forth in claim 30, wherein the undesirable material being removed from the site of interest includes one of a clot, a thrombus, an embolus, a tumor, an infective vegetation, and a foreign body.

48. A method as set forth in claim 30, wherein, in the step of reinfusing, the fluid removed from the site of interest includes blood.

49. A method as set forth in claim 30, wherein the step of reinfusing includes introducing a sufficient amount of fluid back into the patient, so as to minimize fluid loss in the patient.

50. A method for removing an undesirable material from within a vessel, the method comprising:

identifying in a patient a site of interest within a vessel having an undesirable material to be removed therefrom;

maneuvering to the site of interest a pathway along which the undesirable material can be directed away from the site of interest;

applying a suction force through the pathway to the site of interest, such that a fluid flow is created into the pathway and that the undesirable material is pulled into the pathway and away from the site of interest;

entrapping the undesirable material after it has exited the pathway, so as to remove the material from the fluid flow; and

introducing the fluid flow back into the patient at a location in spaced relation to the site of interest, so as to minimize fluid loss in the patient.

51. An apparatus for removing an undesirable material from within a vessel, the apparatus comprising:

an elongated tube having a distal end through which an undesirable material can be captured, a pathway extending along the tube to provide a passage for transporting the undesirable material from the distal end, and a proximal end in opposing relations to the distal end through which the undesirable material can exit;

a funnel situated at the distal end of the tube, and designed for deployment between a collapsed closed position and an flared open position, so as to better engage and capture the undesirable material; and

a mechanism positioned about a distal portion of the tube, the mechanism, upon actuation, can deploy the funnel between the closed position and the open position.

52. An apparatus as set forth in claim 51, wherein the tube is made from a material sufficiently pliable to permit maneuvering of the cannula within the vessel.

53. An apparatus as set forth in claim 51, wherein the tube is made from a material sufficiently strong, so as to not collapse under suction.

54. An apparatus as set forth in claim 1, wherein the tube includes a side port to permit introduction of other instruments or devices into the first cannula.

55. An apparatus as set forth in claim 51, wherein the tube includes multiple lumens.

56. An apparatus as set forth in claim 51, wherein the funnel includes a plurality of strips, each pivotally coupled at one end to the distal end of the tube.

57. An apparatus as set forth in claim 56, wherein the funnel includes a substantially impermeable membrane extending across a space between adjacent strips.

58. An apparatus as set forth in claim 51, wherein the mechanism comprises:

a balloon positioned circumferentially about the tube at a location proximal to the funnel; and

an attachment mechanism attached at one end to the funnel and at an opposite end to the balloon, so that upon expansion of the balloon, the mechanism can pull on the funnel to deploy it into a flared open position.

59. An apparatus as set forth in claim 58, wherein the balloon is designed to also occlude the vessel within which the apparatus is situated upon expansion of the balloon.

60. An apparatus as set forth in claim 58, wherein the attachment mechanism includes one of a string, a rod, a chain, or other similar mechanisms.

61. An apparatus as set forth in claim 58, further including a jacket provided circumferentially about the distal end of the tube, and extending from the funnel to the balloon.

62. An apparatus as set forth in claim 61, wherein the jacket acts as the mechanism for deploying the funnel into a flared open position upon expansion of the balloon.

63. An apparatus as set forth in claim 61, wherein the jacket extends into the funnel and is attached to a base of the funnel, so as to act as a membrane defining the funnel.

64. An apparatus as set forth in claim 51, wherein the mechanism includes a sheath designed to slide toward and away from the distal end of the tube.

65. An apparatus as set forth in claim 64, wherein the sheath, when actuated to slide away from the distal end tube, exposes the funnel to permit the funnel to be deployed into the flared open position.

66. An apparatus as set forth in claim 64, wherein the sheath, when actuated to slide toward the distal end of the tube, covers up the funnel to permit the funnel to be deployed into a collapsed closed position.

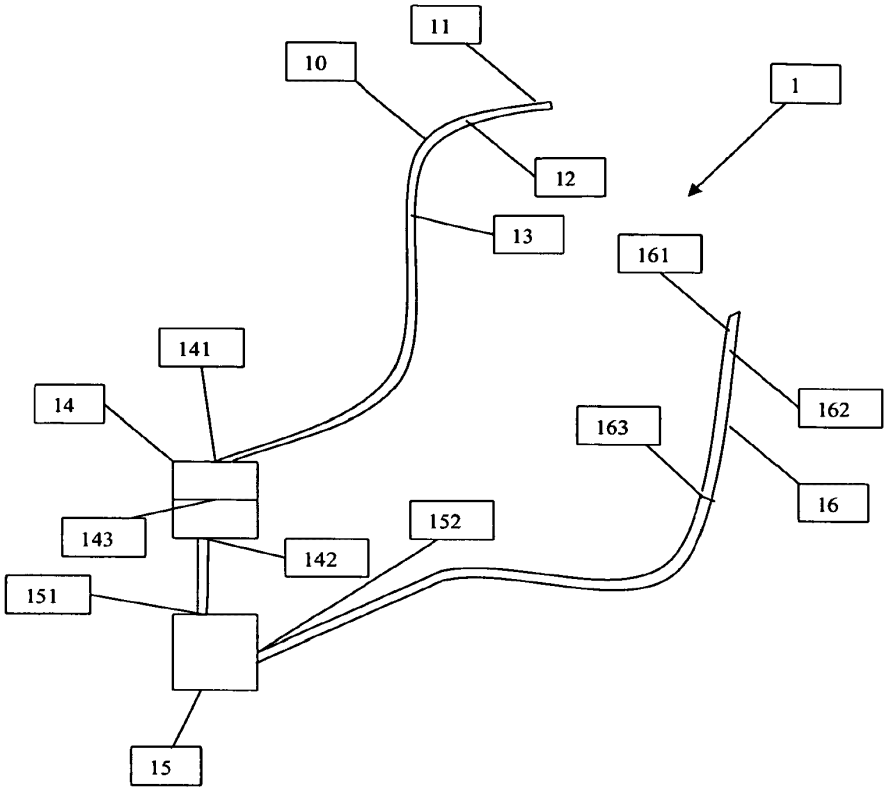


Fig. 1

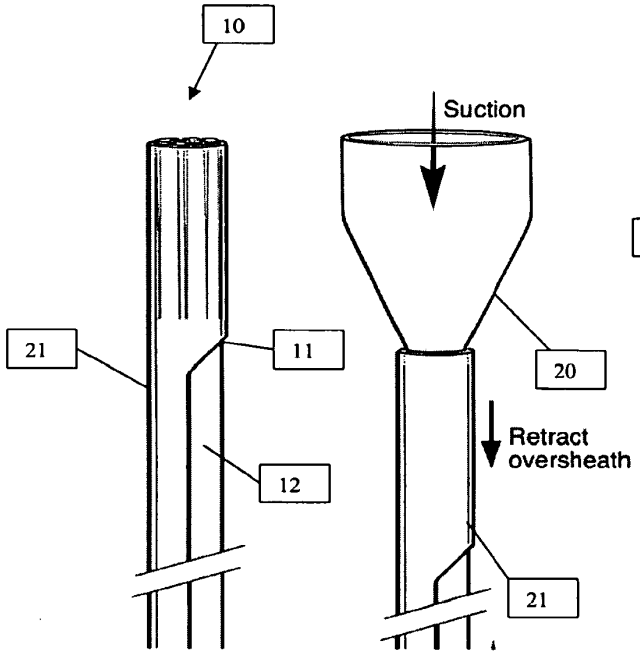


Fig. 2A

Fig. 2B

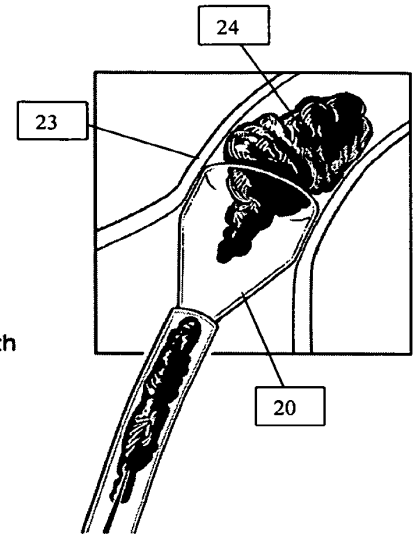


Fig. 2C

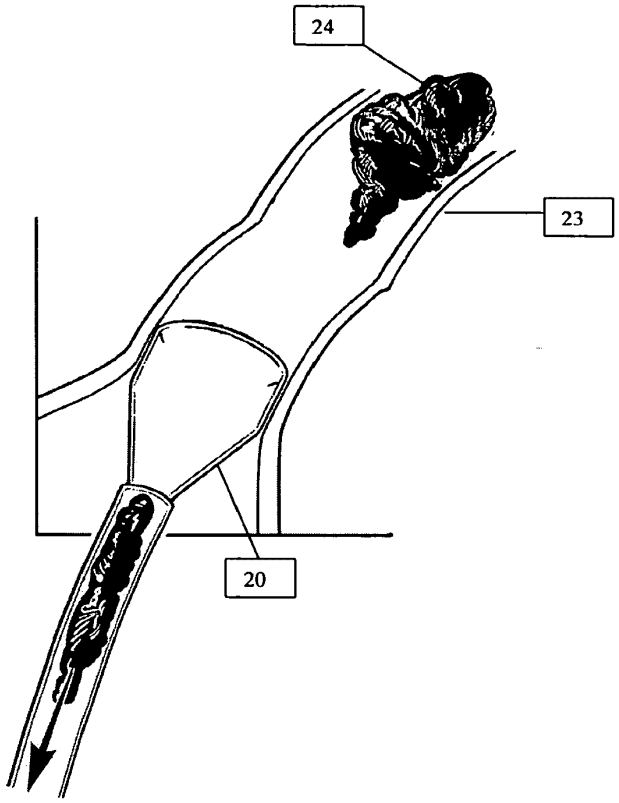


Fig. 2D

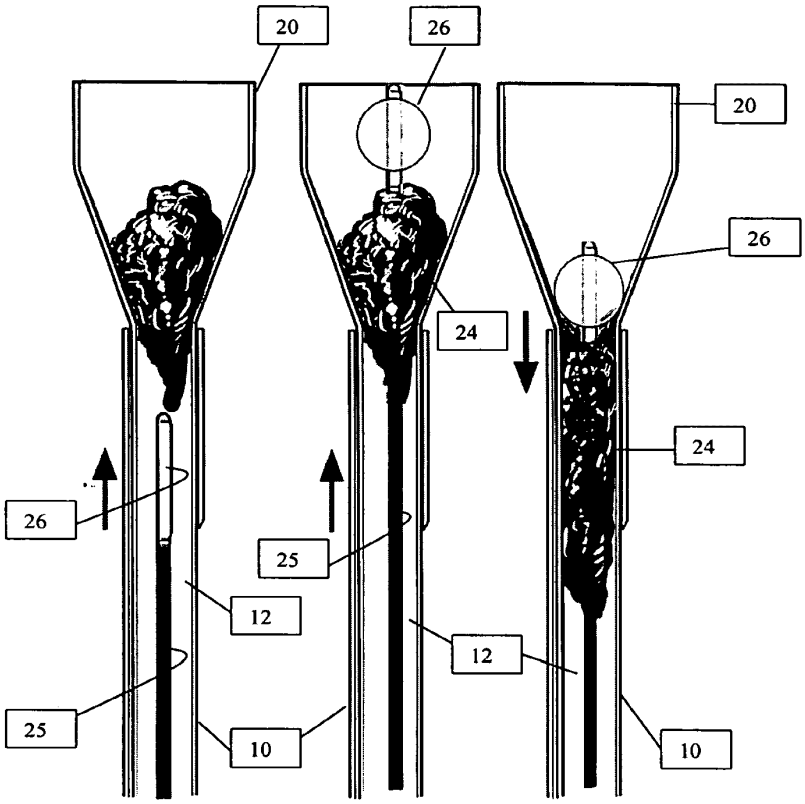


Fig. 2E Fig. 2F Fig. 2G

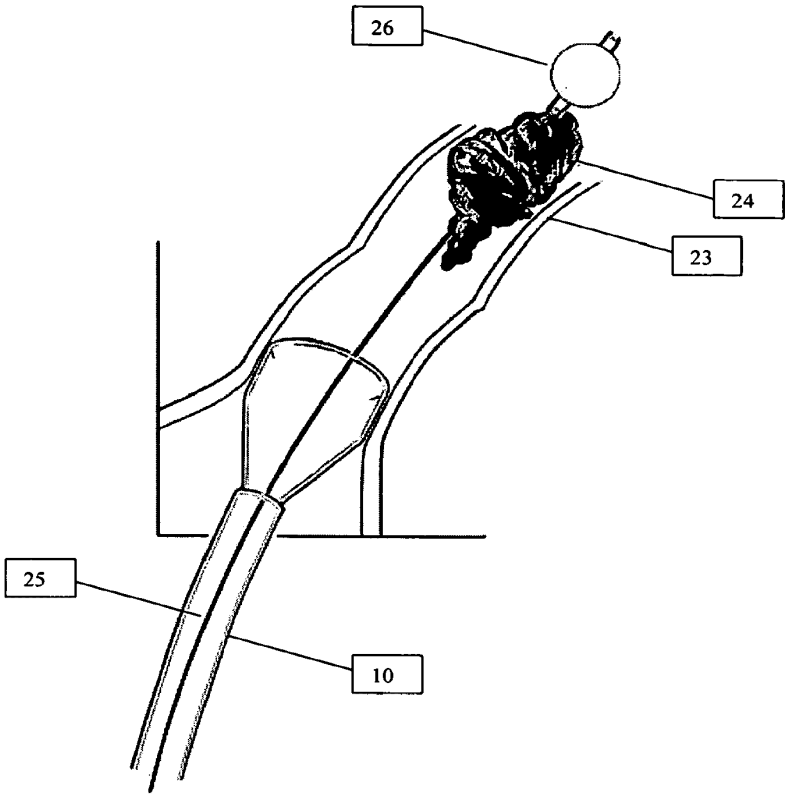


Fig. 2H

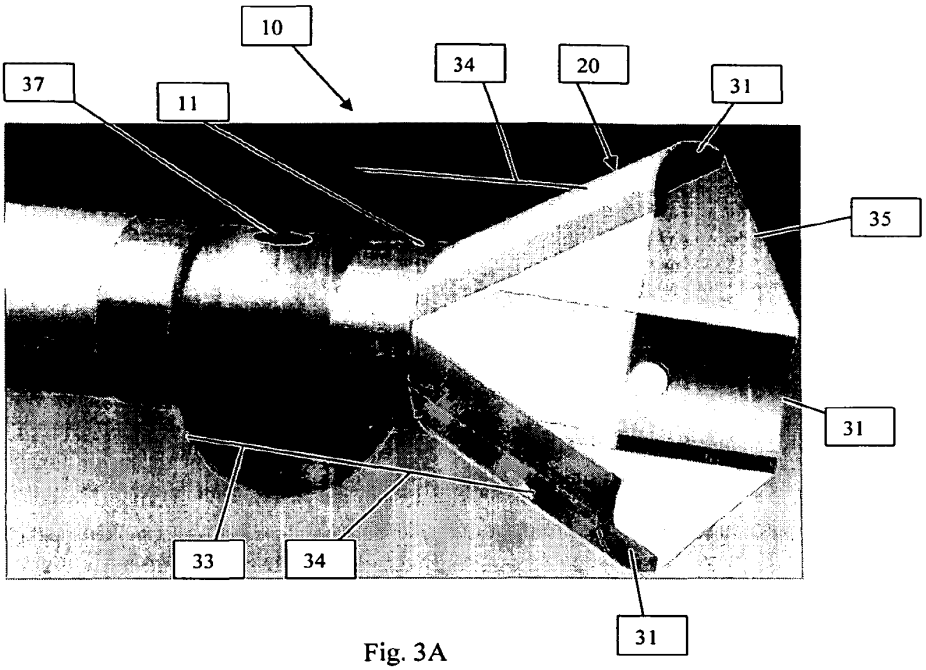


Fig. 3A

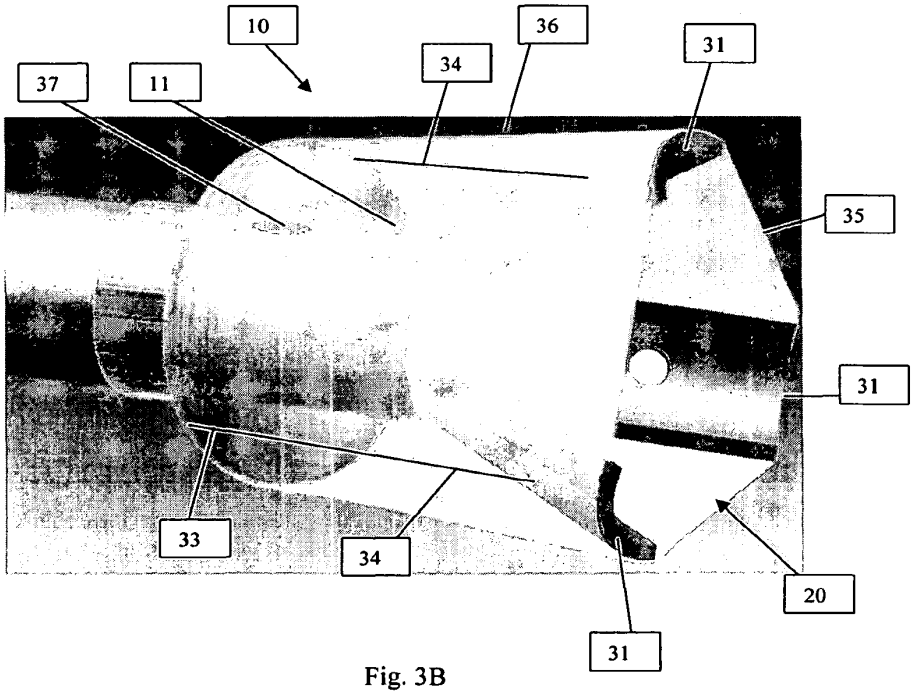


Fig. 3B

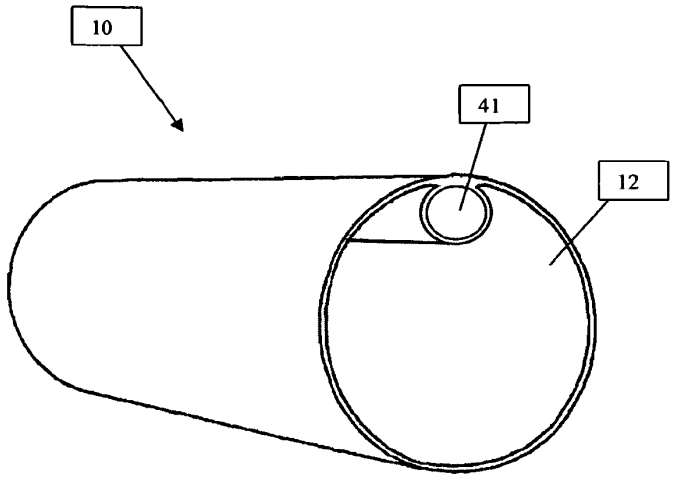


Fig. 4A

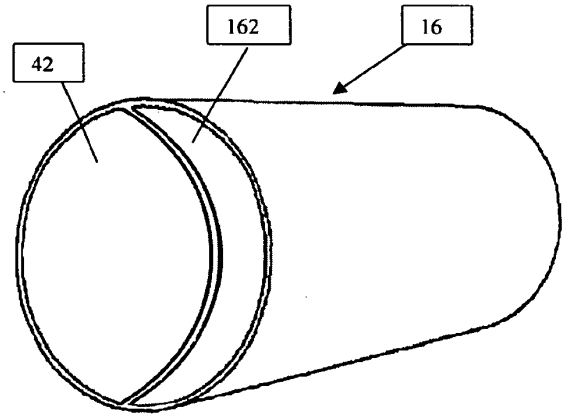


Fig. 4B

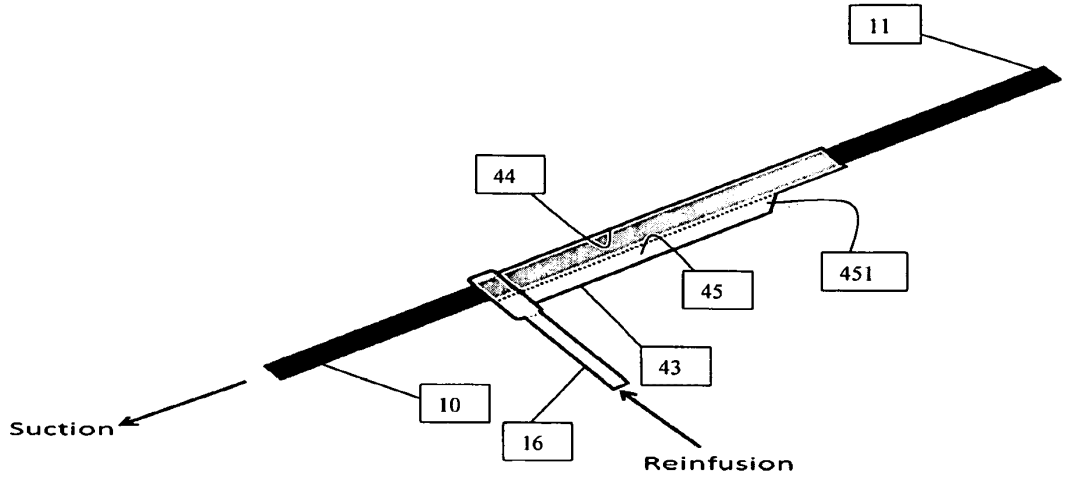

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Suction
Reinfusion

Fig. 4C

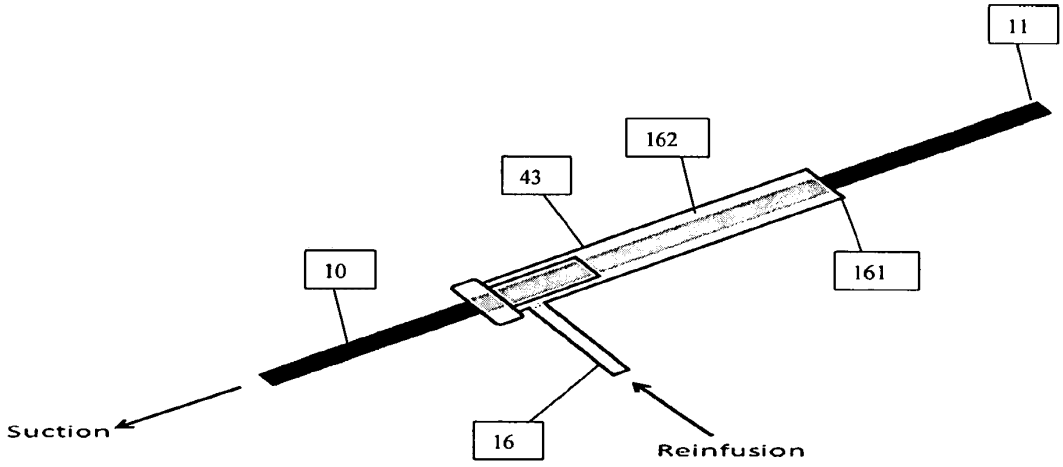

11
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Suction
Reinfusion

Fig. 4D

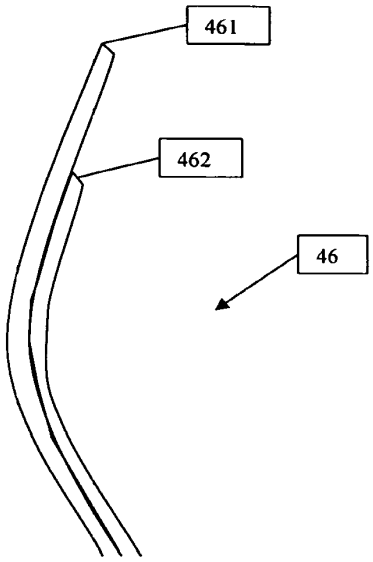


Fig. 4E

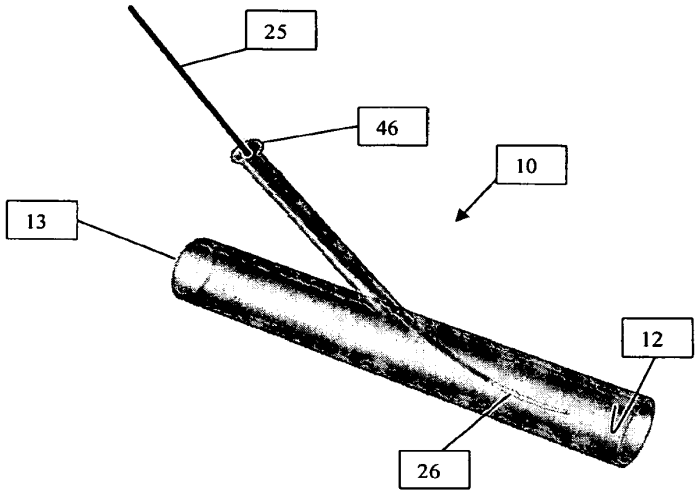


Fig. 5

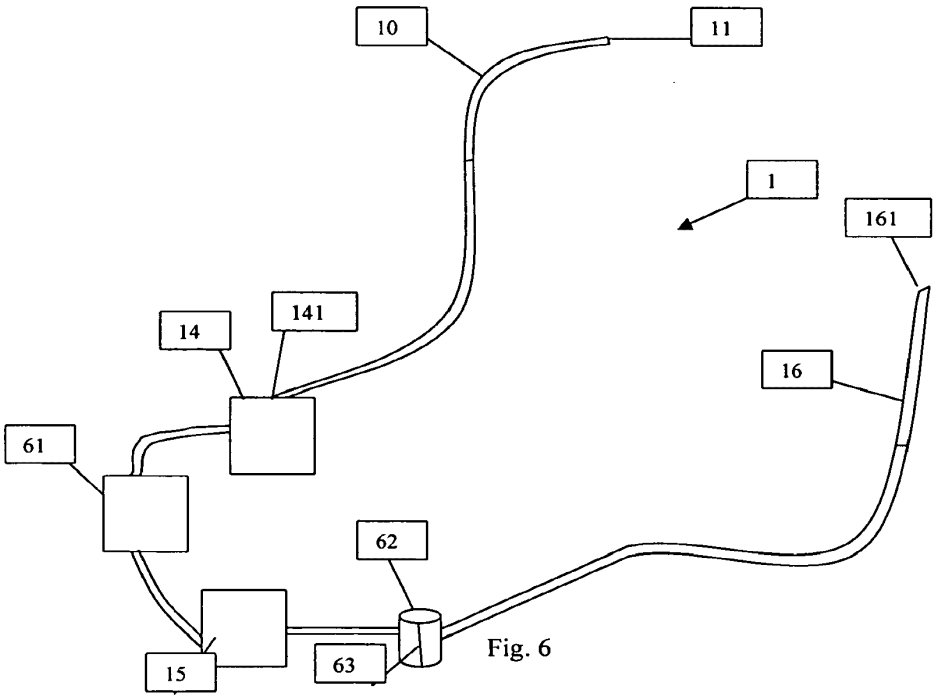


Fig. 6

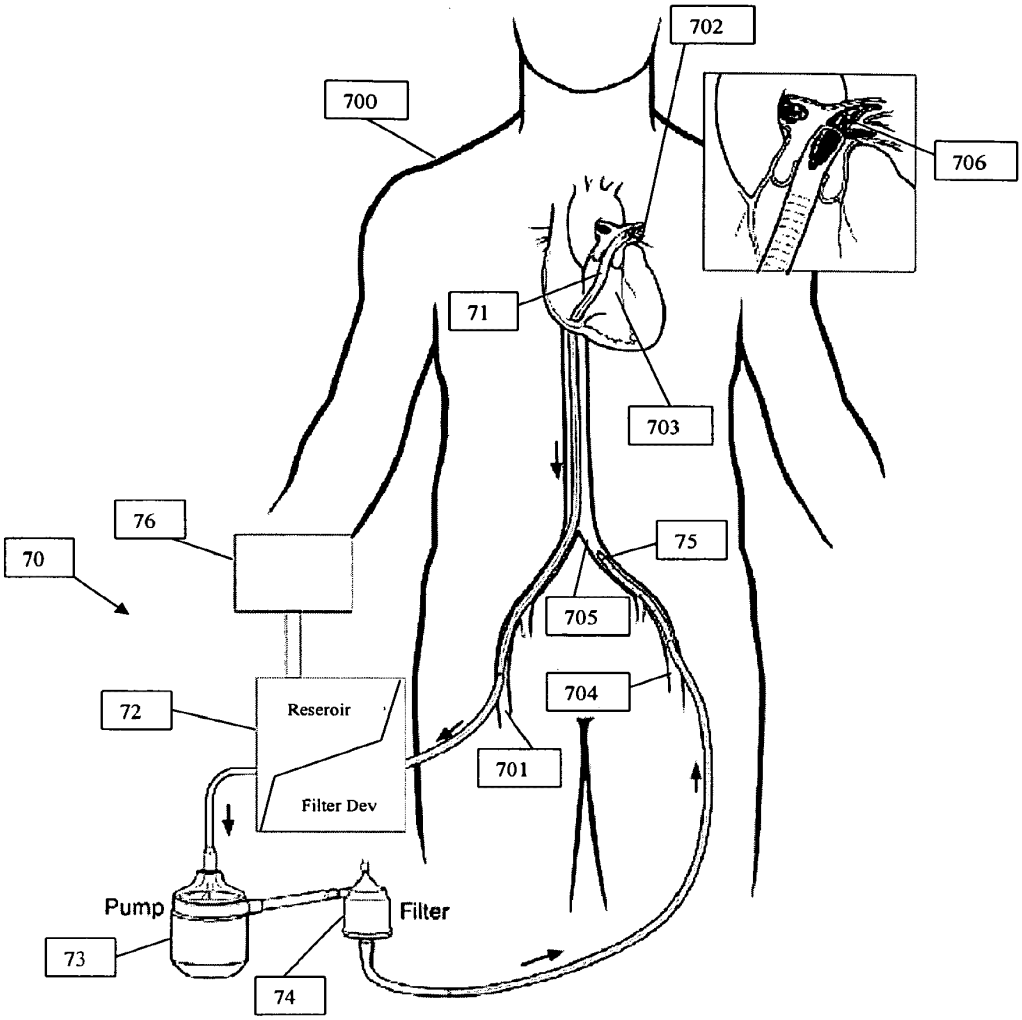

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Reseroir
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Filter Dev
Pump
Filter
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Fig. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/72352

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 37/00 (2008.04)
USPC - 604/5.01
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC: 604/5.01

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 604/5.01, 5.04, 6.09, 6.11, 6.16

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST (PGPB,USPT,USOC,EPAB,JPAB), Freepatentsonline, Google Scholar
Search Terms: clot removal, suction, reinfusion, filter, balloon, occlude, reservoir, pump, vein, artery, heart, vacuum

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 6,719,717 B1 (Johnson et al.) 13 April 2004 (13.04.2004), entire document especially FIG. 2F, col. 1, line 51-54, 57 and 65-67; col. 2, line 6-7,19-34, 36-38, 43-45 and 48-54; col. 3, line 23-39, 42-45, 48-56, 61-64 and 66-67; col. 4, line 8-10 and 57-59; col. 5, line 10-18, 30-36, 48-52, 56-58 and 63-67; col. 6, line 2-5, 18-20 and 59-67 and col. 7, line 1-3	1-4, 6-7, 10-11, 14-21, 23-26, 28-32, 36-45, 47-55 and 64-66 --- 5, 8-9, 12-13, 22, 27, 33-35, 46 and 56-63
Y	US 5,188,618 A (Thomas) 23 February 1993 (23.02.1993), especially col. 3, line 22-25	5, 8 and 33-35
Y	US 5,158,533 A (Strauss et al.) 27 October 1992 (27.10.1992), especially col. 3, line 24-26, col. 4, line 23-25 and col. 8, line 53-66	12 and 46
Y	US 2001/0049486 A1 (Evans et al.) 06 December 2001 (06.12.2001), especially para [0012], [0031] and [0035]	22, 27 and 37
Y	US 2002/0165574 A1 (Reesemann et al.) 07 November 2002 (07.11.2007), especially para [0106], [0114], [0133], [0152] and [0156]	9, 13, 56-57
Y	US 2003/0093112 A1 (Addis) 15 May 2003 (15.05.2003), especially Fig. 4, para [0012], [0028] and [0029]	58-63
Y	US 6,905490 B2 (Parodi) 14 June 2005 (14.06.2005), especially Fig. 3C and col. 7, line 30-42	62-63

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
20 October 2008 (20.10.2008)	04 NOV 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2007)

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Notice

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DESCRIPTION JPH07323090A

[0001]

13 INDUSTRIAL APPLICABILITY The present invention relates to a medical tube suitably used for manufacturing a catheter such as a catheter for vasodilation and a catheter for endovascular treatment diagnosis.

[0002]

19 BACKGROUND ART The catheter has been an instrument used for draining and injecting body fluids and drugs from body cavities or tubular organs.

21 In recent years, catheters have become more sophisticated, and for example, angioplasty catheters used for percutaneous transluminal angioplasty (PTA) that dilates narrowed parts of blood vessels, urinary conduction and bladder temperature measurement. A urine-guided balloon catheter with a temperature sensor that can be performed at the same time, a thermodilution catheter that is placed inside the heart and used to measure heart rate output, and a drug used in intraarterial infusion therapy, etc., is injected into the target site for treatment. Catheter for drug injection treatment, catheter for angioplasty for injecting contrast agent for angioplasty, cyanoacrylate, ethylene-vinyl alcohol copolymer for aneurysms and arteriovenous malformations found in cerebral blood vessels, etc. Applications include liquid embolization substances such as dimethylsulfoxide solutions, granular embolization substances such as polyvinyl alcohol resin granules, and embolization catheters used for embolization in which an embolization member such as a coil is injected. Various applications other than the above have been attempted for these catheters.

[0003]

37 Until now, heart and brain surgery required large-scale surgery that required thoracotomy,

craniotomy, etc., and the key to success or failure of surgery was whether or not the postoperative recovery was good rather than the surgery itself. ..

40 The above-mentioned procedure using a catheter enables diagnosis and treatment with low physical aggression without incising the human body such as thoracotomy, laparotomy, and craniotomy. In addition, since it does not require major surgery, for example, the patient's intraoperative and postoperative pain is reduced, postoperative early recovery / early rehabilitation, less physical damage, less mental burden, and financial burden. It has advantages such as mitigation. In the future, diagnosis and treatment methods using catheters are expected to develop further.

[0004]

50 The medical tube, which is the main body of the high-performance catheter as described above, is required to have high flexibility and a wall thickness as thin as possible.

52 That is, it is desired that the outer diameter of the tube is as small as possible and the inner hole through which the fluid flows is made as large as possible in order to improve the insertability into the body. However, reducing the wall thickness conflicts with making it difficult to easily collapse. Generally, a tube with a thin wall is easy to break (poor kink resistance), easy to crush (weak to external pressure applied from the outside of the tube, that is, insufficient pressure resistance on the outside), and easy to burst (inside the tube). It is known that it is vulnerable to external pressure applied from, that is, its inner pressure resistance is insufficient).

[0005]

63 On the other hand, catheters used by inserting into body cavities or tubular organs are required to have operability so that they can be inserted quickly and reliably even when applied to a vasculature with a thin and complicated pattern. To.

66 In order to have high operability, it is necessary to satisfy the following points. The first is that the pushing force of the operator for inserting into the blood vessel can be reliably transmitted from the proximal end side to the distal end side of the catheter, that is, it has a so-called pushing property. The second is that the rotational force applied on the proximal end side of the catheter can be reliably transmitted to the distal end side, that is, it has so-called torque transmissibility. Third, it is possible to proceed smoothly in a curved blood vessel along a pre-inserted guide wire without damaging the inner wall of the blood vessel, so-called followability (hereinafter, "following to the guide wire" or simply "following"). "). Fourth, as mentioned above, the catheter tip reaches the target location, and even after the guide wire is pulled out, the catheter does not bend at the curved or bent part of the blood vessel, so-called kink resistance. To have.

[0006]

80 From such a demand, a medical tube using a reinforcing material has been proposed.

81 For example, Japanese Patent Application Laid-Open No. 58-38565 and Japanese Patent Application Laid-Open No. 60-126170 disclose a so-called "enhanced type" medical tube having a blade or a coil and a method for manufacturing the same. In these tubes, a reinforcing body is embedded in the resin in order to impart rigidity to the tubes. As a result, these tubes are very hard and have excellent pressure resistance, but thin-walled ones have the disadvantage of being easily broken. Examples of applications of reinforced tubes to catheters include US Pat. No. 4,516,972, International Application WO88 / 06465, Epoxy 3-54592, Epoxy 4-670, and Epoxy 4-44553. There are Japanese Patent Laid-Open No. 4-44554, Japanese Patent Application Laid-Open No. 2-191465, etc., but the main purpose is to give the catheter rigidity. Is manufactured by impregnating with a resin, and has the above-mentioned problems.

[0007]

95 For the purpose of improving the torque transmission, pushability and flexibility of the catheter, a catheter in which a flexible coating is placed on a vine winding spring body or a coil is available in US Pat. No. 4,351,341 and Special Table 3-50189. It is described in Japanese Patent Publication No. 4-792272, Japanese Patent Publication No. 2-172474, International Application No. WO 93/05842, etc., because these are merely a single coil coated with an outer sheath. In addition, although it has excellent kink resistance, it has the disadvantage that the wall surface must be thickened in order to have pressure resistance from the inside.

103 Further, in this tube, since the coil is exposed in the lumen of the catheter, the guide wire is easily caught by the coil. Further, in the catheter for embolization, there is a possibility that a granular embolic substance or an expansion member such as a coil may be caught in the gap of the coil and clogged due to the opening of the gap between the strands, especially when the tube is bent. It requires careful operation.

[0008]

111 Japanese Patent Publication No. 3-29669 has an example in which a torque cable composed of multi-layer coils wound in opposite directions is applied to a catheter, but this also does not have an inner sheath and has the above-mentioned problem. Have.

114 Japanese Patent Application Laid-Open No. 53-21910 and JP-A-5-15585 propose a spirally curved core material in which the inner and outer surfaces are covered with flexible inner and outer pipes by forming gaps. ing. These are structures that only cover the inside and outside of a single spiral tubular coil with a large gap, and although they are excellent in flexibility, they have insufficient inner and outer pressure resistance, torque transmission, and pushability, so they have a large diameter. Although it is sufficient as a guide tube and a flexible tube for a heart-lung machine, it has been virtually impossible to use it as a main body tube of a small-diameter catheter that is used by inserting it into the body cavity or the

central side of a tubular organ.

[0009]

126 INDUSTRIAL APPLICABILITY The present invention has been made in view of the above problems, and satisfies the properties required for a tube constituting a catheter applicable to various body cavities, that is, flexibility and flexibility. It is an object of the present invention to provide an unprecedented medical tube having excellent kink resistance, thin wall thickness, excellent torque transmission and pushability, and excellent inner and outer pressure resistance.

132 Another object of the present invention is to provide a medical tube through which a guide wire can be satisfactorily inserted without being caught on the inner surface of the catheter. Furthermore, it is an object of the present invention to obtain a medical tube particularly suitable for constructing a small-diameter catheter applied in a fine body cavity, such as a catheter for vasodilation and a catheter for cerebrovascular embolization.

[0010]

140 SOLUTION: Such an object is solved by the present invention of the following (1) to (13).

141 (1) A medical tube having a flexible tubular body having an open tip and a proximal end and a reinforcing body arranged inside the tubular body, the reinforcing body having at least a part thereof. , A coil layer composed of a first coil and a second coil provided substantially coaxially with the first coil and wound in the direction opposite to the first coil. Is arranged so that the width of the gap between the pitches of the first and second coils can be freely displaced over a predetermined length from the tip end to the base end, and the curvature of the tubular body is formed. A medical tube characterized by being configured to be flexibly curved without being restricted by the tubular body.

[0011]

152 (2) The medical tube according to (1) above, wherein the coil layer is substantially in close contact with the tubular body.

[0012]

157 (3) The medical tube according to (1) or (2) above, wherein the first and second coils are provided in close contact with each other.

[0013]

162 (4) The medical tube according to any one of (1) to (3) above, wherein the first and second coils are each wound in close contact winding.

[0014]

167 (5) The medical tube according to any one of (1) to (4) above, wherein the first and second coils are flat plate coils.

[0015]

172 (6) The coil layer further has one or more coils provided substantially coaxially with the first and second coils, and all the coils of the coil layer have a free width of the gap between pitches. The medical tube according to any one of (1) to (5), which is provided so as to be displaced to.

[0016]

179 (7) The medical tube according to (6), wherein all the coils in the coil layer are configured by winding adjacent coils in opposite directions.

[0017]

184 (8) A medical tube having a flexible inner layer, a reinforcing layer adhered to the outside of the inner layer, and a flexible outer layer adhered to the outside of the reinforcing layer, wherein the reinforcement is provided. The body, at least in part thereof, is provided substantially coaxially with the first coil and the first coil, wound in the direction opposite to the first coil, and substantially around the first coil. It is composed of a coil layer composed of a second coil that is not fixed, and the coil layer extends from the tip thereof toward the proximal end for a predetermined length, and is a gap between the pitches of the first and second coils. Almost all of the widths of the inner layer are arranged so as to be freely displaceable, and are configured to be flexibly curved with the curvature of the inner layer and the outer layer without being restricted by the inner layer and the outer layer. A medical tube featuring.

[0018]

198 (9) The above-mentioned (1) to (8), wherein the vicinity of the tip of the medical tube is made of a flexible material and has the most flexible tip portion on which the coil layer is not arranged. Medical tube.

[0019]

204 （10） A catheter for cerebrovascular embolization, comprising a tube body inserted into a body cavity, wherein the tube body is composed of the medical tube according to any one of

(1) to (9) above.

[0020]

(11) It has a tube body inserted into a body cavity, at least one lumen formed in the tube body, and an extension body provided at the tip of the tube body and having an internal space communicating with the lumen. A catheter for vasodilation, wherein the tube body is composed of the medical tube according to any one of (1) to (9).

[0021]

(12) An inner tube having a first lumen with an open tip, and an inner tube provided coaxially with the inner tube and having a tip at a position recessed by a predetermined length from the tip of the inner tube, and an outer surface of the inner tube. It has an outer tube forming a second lumen between them, a tip portion and a proximal end portion, the proximal end portion is attached to the outer tube, the distal end portion is attached to the inner tube, and the proximal end portion is attached. A contractionable or foldable extension that communicates with the second lumen in the vicinity, a first opening that communicates with the first lumen provided at the base end of the inner tube, and the outer tube. A balloon catheter having a second opening that communicates with the second lumen provided at the proximal end, wherein at least one of the inner tube and the outer tube is any of the above (1) to (9). A vasodilator catheter characterized by being composed of the medical tubing described in the above.

[0022]

(13) It is composed of the catheter for cerebrovascular embolization described in (10) above, a guide wire composed of a metal elastic core material, a plastic coating material coated on the surface thereof, and a hydrophilic lubricating layer fixed to the surface of the coating material. Catheter device.

[0023]

(14) It is composed of the catheter for vasodilation according to the above (11) or (12), a metal elastic core material, a plastic coating material coated on the surface thereof, and a hydrophilic lubricating layer fixed to the surface of the coating material. A catheter instrument consisting of a guide wire that can be inserted into a tube.

[0024]

In the medical tube of the present invention, at least a part of the reinforcing body is composed of the coil layer described above, and due to the configuration, at least the tip

portion is flexible, can be freely bent in all directions, and has kink resistance. ..

249 The coil body or the vine winding body having a spring property is rich in flexibility because the gap between the pitches can be freely widened and narrowed (freely displaceable).

251 It is preferable that the flexible tubular body or the flexible inner and outer layers are in close contact with the coil layer, but the coil layer may be adhered to the tubular body or the inner layer and the outer layer, or the gap may be formed. Embedding so as to be buried impairs the flexibility of the coil layer.

255 Therefore, it is preferable that the coil layer does not substantially adhere and is not embedded over a predetermined length from the tip end to the base end.

[0025]

260 The medical tube of the present invention has a structure in which the coil layer is arranged inside a flexible tubular body, that is, a structure in which the coil layer is arranged between the flexible inner layer and the outer layer, so that the wall of the tube is formed. It can be made thin and has high pressure resistance.

264 It is not possible to flow a liquid or the like only with a coil layer having a gap between winding pitches, but by providing a tubular body or an inner layer and an outer layer that cover the inside and outside of the coil layer, a fluid, a guide wire, or the above-mentioned embolic substance can be provided. Etc. to facilitate passage.

268 The pressure resistance of these tubular bodies or the inner and outer layers to the pressure applied from the opposite side to the coil is improved because they are supported from the back side by the coil.

271 This pressure resistance increases as the gap between pitches becomes smaller, that is, the coil winding becomes denser, and it does not depend on the wall thickness or material of the tubular body or the inner layer and the outer layer.

274 Therefore, even if the entire medical tube is thinned, the pressure resistance is not affected.

[0026]

278 Hereinafter, the configuration of the present invention will be described in detail with reference to the drawings.

280 1 is a plan view showing a configuration example of the medical tube of the present invention, FIG. 2 is a partially broken enlarged perspective view of the vicinity of the tip of the medical tube shown in FIG. 1, and FIG. 3 is a medical tube shown in FIG. A partially enlarged cross-sectional view showing the configuration of the tube, FIG. 4 is an enlarged cross-sectional view taken along the line I-I of FIG.

285 Hereinafter, the right side in FIGS. 1 to 3 is referred to as a "tip" and the left side is referred to as a "base end".

[0027]

290 The medical tube 1 shown in FIG. 1 is composed of a flexible tubular body 2.

291 The tubular body 2 is composed of a base portion 11 or a main body portion 11 and a tip portion 12 in order from the base end, and a lumen 14 is formed inside from the base end to the tip end.

294 In the illustrated example, the tip end side of the base portion 11 is formed with a tapered portion 13 whose inner diameter and outer diameter gradually decrease in a tapered shape from the base end side toward the tip end, whereby the tip end portion 12 is larger than the base portion 11. It has a small diameter.

298 In this way, by making the diameter of the medical tube 1 smaller at the tip portion 12 than at the base portion 11, the tip end side can be made relatively flexible and the base end side can be made relatively hard, and the pushability and the guide wire can be obtained. Followability can be improved.

302 Further, by making the inner diameter of the base portion 11 wider than that of the tip portion 12, the guide wire inserted in the tube 1 becomes easy to move smoothly, and the operability of the guide wire is improved.

305 In the present invention, the inner diameter and the outer diameter of the medical tube 1 are not limited to the above configurations, and may be substantially constant over the entire length of the tube 1, for example.

[0028]

311 As shown in FIG. 2, the tubular body 2 is composed of an inner layer 21 and an outer layer 22.

313 The inner layer 21 and the outer layer 22 are made of a thin-walled tube made of a flexible synthetic resin, are arranged substantially coaxially, extend from the base end to the tip end of the medical tube 1, and extend from the tip end and the base end. They are joined over a predetermined length by, for example, bonding or fusion.

317 Then, the space inside the inner layer 21 forms the lumen 14.

318 Further, the inner layer 21 and the outer layer 22 form the tapered portion 13 by gradually reducing the inner diameter and the outer diameter from the base end to the tip end in a predetermined length between the tip end and the base end. ..

321 Further, on the tip side of the tapered portion, the inner layer 21 and the outer layer 22 have substantially constant inner and outer diameters, respectively, and constitute the tip portion 12. Further, even on the proximal end side of this portion, the inner layer 21 and the outer layer 22 have substantially constant inner and outer diameters, respectively, and the tapered portion is also included to form the base portion 11.

[0029]

329 The constituent material of the tubular body 2, in other words, the constituent materials of the inner layer 21 and the outer layer 22 may be any material having a certain degree of flexibility, for example, polyethylene, polypropylene, polybutene, polymethylpentene,

polybutadiene, polyisoprene, and the like. Elastomers such as propylene-butene copolymers and ethylene-propylene copolymers, modified polyethylenes, modified polyolefins such as modified polypropylenes, fluororesins such as soft polyvinyl chloride and polytetrafluoroethylene, ethylene-vinyl acetate copolymers, polyesters. , Polyamite, polyacetal, polyurethane and other flexible resins, olefin-based elastomers, urethane-based elastomers, ester-based elastomers, polyvinyl chloride-based elastomers, polyamide-based elastomers, styrene-based elastomers and other elastomers, silicone rubber, Examples thereof include elastomers such as latex rubbers and natural rubbers, and blends of these materials.

341 Further, the resin and the elastomer are preferably thermoplastic, and if it is thermoplastic, the medical tube 1 can be easily manufactured.

[0030]

346 The inner layer 21 and the outer layer 22 do not necessarily have to be made of the same material, and further, an X-ray impermeable substance, a plasticizer, a pigment, or the like may be mixed with these materials.

349 In particular, as the constituent material of the inner layer 21, polyethylene, polypropylene, and fluororesin are particularly preferable from the viewpoints of ease of molding, ease of insertion into the coil layer 4, which will be described later, and chemical resistance.

[0031]

355 Further, since the outer layer 22 can easily coat the coil layer 4 described later, it is preferable to form the outer layer 22 with a solvent-swellable resin tube or a heat-shrinkable resin tube.

358 Examples of the solvent-swellable resin include the modified polyolefin, ethylene-vinyl acetate copolymer, polyamide elastomer, polyester elastomer, polyurethane and the like. In particular, from the viewpoint of adhesion and fusion with the inner layer 21, modified polyolefin is preferable, and among the modified polyolefin, modified polyethylene containing polyethylene as a main component is preferable. As the modified polyethylene, an adhesive resin made of ethylene and a copolymer made of, for example, acrylate, maleic anhydride, or the like as a raw material has a particularly preferable property. The tube made of this resin quickly swells with a solvent such as THF, the inner and outer diameters of the tube expands, and the outer layer 22 is surely restored to its original shape by removing the solvent by air drying or the like. If it is configured, it can be easily and surely coated and adhered to the coil layer 3 described later. Further, as the heat-shrinkable resin, a resin tube such as an electron beam-crosslinked polyolefin, crosslinked silicon, or a shape memory resin can be preferably used. Since these tubes can be contracted by heat, by forming the outer layer 22 with these tubes, the coil layer 3 described later can be easily inserted and adhered.

[0032]

375 As shown in FIGS. 2 to 4, a coil layer 3 having a role as a reinforcing body for reinforcing the strength of the medical tube 1 is arranged inside the tubular body 2, that is, between the inner layer 21 and the outer layer 22. Has been done.

378 In other words, the coil layer 3 which has a role as a reinforcing body for reinforcing the strength of the medical tube 1 is adhered to the outside of the inner layer 21, and the outer layer 22 is adhered to the outside of the coil layer 3. ing. The coil layer 3 shown in FIG. 2 is provided substantially coaxially with the first coil 31 wound on the outer peripheral surface of the inner layer 21 and the first coil 31, and is in close contact with the first coil 31. It is composed of a coil 31 of 1 and a second coil 32 that is wound in the opposite direction. The coil layer 3 has a long tube-like shape, and its outer peripheral surface and inner peripheral surface are arranged in the tube 1 in a state of being in contact with the tubular body 2, in other words, the inner layer 21 and the outer layer 22.

[0033]

390 A cutting-edge portion 16 in which the coil layer 3 is not arranged is formed near the tip of the tube 1.

392 The coil layer 3 extends in the proximal direction from a position slightly retracted from the tips of the tubular body 2, that is, the inner layer 21 and the outer layer 22, and the tip side of the coil layer 3 is the most composed of the inner layer 21 and the outer layer 22. It is a tip portion 16. Since the coil layer 3 is not arranged, the cutting edge portion 16 is more flexible than the portion on the proximal end side of the cutting edge portion 16. Therefore, when the tube 1 is inserted into a blood vessel, the irritation given to the blood vessel can be reduced. Further, since the coil layer 3 does not protrude from the tubular body 2, that is, the tips of the inner layer 21 and the outer layer 22, there is no possibility that the protruding portion will damage the body cavity or the tubular organ when inserted into the body cavity or the tubular organ. preferable. The length of the cutting edge portion 16, that is, the distance from the tip of the coil layer 3 to the tips of the tubular body 2 or the inner layer 21 and the outer layer 22 is preferably about 10 mm or less, more preferably 0.5 to 5 mm. Degree.

[0034]

408 The position of the coil layer 3 in the medical tube 1 is not particularly limited, but it is preferable that the coil layer 3 extends from the base end of the medical tube 1 to the vicinity of the tip end of the tube 1.

411 By arranging the coil layer 3 over the entire length of the tube 1 in this way, the torque and the pushing force applied to the base 11 can be satisfactorily transmitted to the vicinity of the tip of the tube 1 via the coil layer 3. In the illustrated example, in the vicinity of the base end of the tube 1, the coil layer 3 has a base end at a position slightly separated from the base ends of the tubular body 2, that is, the inner layer 21 and the outer layer 22, and the

medical tube 1 has a base end. The structure is such that the coil layer 3 is provided over almost the entire length.

[0035]

421 Then, in the medical tube 1, even if a pressure higher than that of the inner layer 21, that is, the lumen 14, is applied to the inner layer 21, the inner layer 21 is supported from the opposite side by the first coil 31, and is related to the thickness of the inner layer 21. However, it exhibits higher pressure resistance than the case of the inner layer 21 alone.

425 Further, even if a higher pressure is applied to the outer layer 22 than the outside of the outer layer 22, the outer layer 22 is supported from the opposite side by the second coil 32, and the outer layer 22 is supported from the opposite side regardless of the thickness of the outer layer 22 as compared with the case of the outer layer 22 alone. Demonstrates high pressure resistance. Therefore, the medical tube 1 has excellent pressure resistance inside and outside, and even if a pressure higher than the inside or the outside of the tube 1 is applied to the tube 1, the tube 1 is unlikely to be crushed or burst.

[0036]

435 In order to exert such an action satisfactorily, it is preferable that the coil layer 3 is in close contact with the tubular body 2 or the inner layer 21 and the outer layer 22.

437 In other words, the first coil 31 is preferably in close contact with the tubular body 2 or the inner layer 21, and the second coil 32 is preferably in close contact with the tubular body 2 or the outer layer 22. The first coil layer 31 and the second coil layer 32 may be in close contact with the inner layer 21 or the outer layer 22 over the entire length thereof, but at least a part thereof, for example, the tip portion 12 is predetermined. It may be in close contact over the length. Further, by bringing the first coil layer 31 and the second coil layer 32 into close contact with the inner layer 21 or the outer layer 22, the wall thickness of the medical tube 1 can be reduced, so that the diameter of the tube 1 can be reduced satisfactorily. be able to. Further, due to the close contact, the torque and the pushing force at the base 11 of the medical tube 1 can be reliably transmitted to the vicinity of the tip of the tube 1.

[0037]

451 In the illustrated example, the first coil 31 and the second coil 32 have an inner diameter and an outer diameter gradually decreasing from the proximal end to the distal end over a predetermined length between the tip and the proximal end, and the tapered portion. It constitutes 13.

455 Further, on the tip side of the tapered portion, the inner and outer diameters of the coils 31 and 32 are substantially constant, respectively, and constitute the tip portion 12. Further, even on the proximal end side of this portion, the inner diameter and the outer diameter of

the coils 31 and 32 are substantially constant, respectively, and the base portion 11 includes the tapered portion.

[0038]

463 As shown in FIG. 3, the first coil 31 is a medical tube in which a bundle 31A in which five flat wire wires 31a, 31b, 31c, 31d to 31e having a rectangular cross-sectional shape are bundled together. It is configured by winding right-handed toward the tip of 1.

466 Further, the second coil 32 is a bundle 32A in which five flat wire wires 32a, 32b, 32c, 32d to 32e having a rectangular cross-sectional shape as described above are bundled into a medical tube 1 The coil is wound in the direction opposite to that of the first coil 31, that is, left-handed, toward the tip of the coil.

[0039]

473 For these strands 31a to e and strands 32a to e, it is preferable that the width x of the gap between the strands in the bundles 31A and 32A described above is close to zero, respectively.

476 The closer the width x is to zero, the more the strands 31a to e or the strands 32a to e are in close contact with each other, which is advantageous for supporting the inner layer 21 and the outer layer 22. In other words, the larger the width x, the higher the possibility that the inner layer 21 and the outer layer 22 will fall into the gap between the strands 31a to e and the strands 32a to e, resulting in minute tearing.

[0040]

484 Further, in the first coil 31 and the second coil 32, the width of the gap between the pitches (in the illustrated example, the width of the gap between the pitches of the bundles 31A and 32A) y is the strands 31a to e and, respectively. It is preferably smaller than the width z of the strands 32a to e, more preferably about 30% or less of the width z, and more preferably closer to zero, that is, the coils 31 and 32 are tightly wound. ..

489 By doing so, it is possible to prevent the wires 31a to e of the coil 31 from jumping out of the gap of the coil 32, and it is possible to prevent the wires 32a to e of the coil 32 from falling into the gap of the coil 31. The thickness t of the first coil 31 and the second coil 32 is preferably about 0.005 to 0.1 mm, more preferably about 0.005 to 0.05 mm, respectively.

[0041]

496 The cross-sectional shapes of the first coil 31 and the second coil 32 are not limited to the rectangle shown in the figure, and may be, for example, a circle, an ellipse, a triangle, a square, a parallelogram, a polygon of a pentagon or more, and the like. May be good.

499 However, it is preferable that the coils 31 and 32 are flat plate coils in which the strands 31a

to 31a to 32a to e form a flat plate. By using a flat plate coil, the thickness of the coil layer 3 can be effectively reduced, and the coils 31 and 32 can be easily wound in close contact with each other. Further, it is preferable that the first coil 31 and the second coil 32 are in close contact with each other. By bringing the medical tube 1 into close contact, the wall thickness of the medical tube 1 can be reduced, so that the diameter of the tube can be reduced, and the torque and pushing force applied to the base 11 of the medical tube 1 are applied to the tube via the coils 31 and 32. It is possible to reliably convey to the vicinity of the tip of 1.

[0042]

510 Then, the coil layer 3 has a predetermined length from its tip toward the proximal end (in other words, in the distal end side portion of the coil layer 3) between the pitches of the first coil 31 and the second coil 32. Almost all of the width y of the gap is arranged so as to be freely displaceable, and is configured to be able to flexibly bend without being restricted by the tubular body 2 (inner layer 21 and outer layer 22).

515 As a result, the coil layer 3 can freely widen or narrow the width y of almost the entire gap between the pitches, and can be bent very flexibly without hindering the bending of the tubular body 2.

[0043]

521 Specifically, the first coil 31 is embedded so as to extend at least a predetermined length from its tip toward the proximal end, not to be fixed to the inner layer 21, and to fill almost all the gaps between the pitches. It has not been.

524 Almost all of the gaps between the pitches are voids because the material such as resin and the adhesive constituting the inner layer 21 do not substantially flow into the gaps. Similarly, the second coil 32 is also embedded so that it is not fixed to the outer layer 22 and fills almost all the gaps between the pitches, at least for a predetermined length from the tip end toward the base end. No material such as resin or an adhesive constituting the outer layer 22 has substantially flowed into almost all of the gaps between the pitches, resulting in voids. In the first and second coils 31 and 32 configured in this way, almost the entire width y of the gap between the pitches can be freely widened or narrowed due to the curvature of the inner layer 21 and the outer layer 22, which is extremely high. Can be flexibly curved.

[0044]

536 In the present invention, "the width of the gap between the pitches of the coil can be freely displaced" means that the width y of the gap between the pitches freely widens and narrows without substantially impairing the original flexibility of the coil. It is possible (displaceable).

[0045]

542 In the coil layer 3, it is preferable that the entire gap between pitches can be freely displaced in the tip side portion, but if the flexible curvature of this portion is not substantially hindered, the coil layer 3 may be part of the coil layer 3. For example, an adhesive, a resin material, or the like may flow into the gap to form a region that cannot be freely displaced.

546 Such a region has a length sufficiently shorter than the total length of the distal end side portion of the coil layer 3 (for example, 10% or less of the total length of the distal end side portion).

549 It should be noted that this region may be dispersedly provided at two or more locations on the tip end side portion of the coil layer 3, but it is preferably provided at one location, and in the case of two or more locations, the regions are as close as possible. Is preferable.

[0046]

555 Further, as shown in the figure, when the coil layer 3 is provided up to the vicinity of the base end of the tubular body 2, the adhesive is impregnated over a certain length on the base side of the coil layer 3 in order to improve the pushability of the catheter. , May be hard.

558 In this case, if the entire coil layer 3 is impregnated with the adhesive, the flexibility of the coil layer 3 is lost. Therefore, it is decided to impregnate only the base side of the medical tube 1, specifically, the medical tube 1. From the base end, it is preferable to impregnate the total length of the medical tube 1 over a length of about 5 to 50%, more preferably about 10 to 40%, still more preferably about 20 to 30%.

[0047]

566 The medical tube 1 configured in this way is highly flexible and has appropriate rigidity.

567 Further, a lubricant such as silicone oil may be applied between the coil layer 3 and the inner layer 21 and the outer layer 22 in order to improve the sliding of the coil layer 3. By doing so, the coil layer 3 can be bent more flexibly without being caught by the inner layer 21 and the outer layer 22.

[0048]

574 Examples of the constituent materials of the strands 31a to e and the strands 32a to e constituting the first coil 31 and the second coil 32 include metal materials such as stainless steel, tungsten, aluminum, Ni—Ti alloy, and brass. Highly rigid resins such as polytetrafluoroethylene (Teflon), polyvinyl chloride, polyamide, polyethylene terephthalate, polysulfone, polycarbonate, polyarylate, polyacetal, polyphenylene sulfide, polyetherketone, polyetheretherketone, polyimide, polyamideimide, etc. Materials, PAN-based, pitch-based, naphthalene-based, carbon fibers and carbon fibers such as their prepregs, ceramics, etc. can be used, but materials with high safety for medical use are preferable, and in particular, shaping and quenching is possible. Stainless steel such as SUS304 is preferable.

[0049]

586 From such a constituent material, the strands 31a to 32a to 32a to e are formed by appropriately selecting dimensions such as wall thickness and width, and these are wound at a predetermined pitch to form the coil shown in FIG. 2. Layer 3 is obtained.

589 In the production of the coil layer 3, for example, the strands 31a to e are spirally wound (in the illustrated example, in the right-handed direction toward the tip) along the rod-shaped core material, and then the strands 32a to e are wound. Is wound in the direction opposite to the strands 31a to e (in the illustrated example, in the left-handed direction toward the tip), and then the core material is removed.

[0050]

597 The dimensions of the medical tube 1 vary depending on the application, but the length is 200 to 2000 mm, preferably 1000 to 2000 mm, and the outer diameter is 0.35 to 4.3 mm, preferably 0.40 to 2.00 mm. The inner diameter is 0.25 to 4.00 mm, preferably 0.30 to 1.80 mm.

601 Further, the thickness (thickness) of the tube wall of the medical tube 1 is preferably thin, but when the wall thickness of the tube 1 is T and the inner diameter of the tube 1 is S, this wall thickness T is the inner diameter S. The value divided by (thickness inner diameter ratio) is preferably in the range of T / S = 0.05 to 0.50, and more preferably 0.07 to 0.326.

605 When this value is less than 0.05, the wall thickness T becomes too thin with respect to the inner diameter S, and the strength of the medical tube 1 is significantly reduced. On the other hand, if it exceeds 0.50, the wall thickness T and the outer diameter of the tube accompanying it increase too much, which is not preferable.

[0051]

612 In the illustrated example, the first coil 31 is right-handed and the second coil 32 is left-handed, each of which is configured as a set of five strands, but in the present invention, the coils 31 and 32 are right-handed. The order of left-handed winding and the number of strands to be bundled are free, and the above-mentioned width x and width y may differ depending on the part of the medical tube 1.

617 For example, by increasing the width x or the width y toward the tip, in other words, reducing the width x or the width y toward the base end, the closer the coils 31 and 32 are to the tip, the more flexible the bending becomes. Moreover, the closer it is to the base end, the more difficult it is to bend, and it is possible to obtain a medical tube having good flexibility near the tip end and excellent torque transmission and pushability. Further, the width z of the first coil 31 and the second coil 32 may be constant over the entire length of the medical tube 1 or may differ depending on the site. For example, by making the width z smaller toward the tip, in other words, increasing the width z toward the base end, the closer the coils 31 and 32 are to the tip, the easier it is to bend, and the closer it is to the base end, the more difficult it

is to bend. It is possible to obtain a medical tube having good flexibility near the tip and excellent torque transmission and pushing property.

[0052]

631 FIG. 5 is a partially broken enlarged perspective view showing the vicinity of the tip portion of another configuration example of the medical tube of the present invention.

633 The same configurations as those shown in FIGS. 1 to 4 are designated by the same reference numerals and the description thereof will be omitted.

[0053]

638 The medical tube 10 shown in FIG. 5 has almost the same configuration as the medical tube 1, but has a tip soft tip 15 made of a highly flexible material, and the tip 15 and the coil layer 3 are formed. It differs in that the tip 160 is configured from the portion near the tip of the unarranged tubular body 2 (inner layer 21 and outer layer 22).

642 The tip 15 is formed in a short tubular shape, and is bonded to the tubular body 2, in other words, the tips of the inner layer 21 and the outer layer 22 by adhesion or the like so that the lumen thereof communicates with the lumen 14. With this configuration, the cutting-edge portion 160 of the medical tube 10 has higher flexibility than the portion in which the coil layer 3 is arranged, so that a stimulus given to the blood vessel or the like when inserted into the blood vessel or the like is given. Can be reduced.

[0054]

651 As the constituent material of the advanced soft chip 15, it suffices to have flexibility, and for example, polyurethane, vinyl chloride-urethane copolymer, silicone RTV rubber and the like can be used.

654 The length of the chip 15 is 0.5 to 30 mm, preferably about 2 to 15 mm.

[0055]

658 Although the configuration example in which the coil layers form a two-layer structure has been described above, in the present invention, the coil layer may have a structure of three or more layers in which three or more coils are arranged substantially coaxially.

661 In this case, it is preferable that the adjacent coils are wound in opposite directions in each coil. Further, the coil layers in the present invention do not have to have the same number of layers over the entire length thereof. It may be provided in some places.

[0056]

667 Further, in the illustrated example, the coil layer 3 is arranged over almost the entire area of

the medical tube 1 and is formed so as to reinforce the medical tube 1 over almost the entire area. However, in the medical tube of the present invention, a part thereof. In the above, a reinforcing body other than the coil layer, for example, a tube or a tube body made of a member having high rigidity may be arranged, and such a body and the coil layer may be combined to form a reinforcing body.

673 However, by forming the reinforcing body only with the coil layer and forming the medical tube with a material having relatively high flexibility (flexibility) except for this coil layer, appropriate flexibility and rigidity (hardness) are obtained. With), good kink resistance, excellent torque transmission and push-in performance, and by using a guide wire, it can be inserted into the body cavity well following this guide wire, and it also has excellent pressure resistance. You can get a medical tube.

[0057]

682 Further, in the present invention, the coil layer is not limited to the one arranged over the entire length of the medical tube, for example, a configuration in which the coil layer 3 is not arranged in the middle of the medical tube 1 or the tip portion of the tube 1. The coil layer 3 may be arranged only on the twelve.

686 However, if the coil layer is arranged over almost the entire length of the medical tube, the torque and pushing force applied at the base 11 can be satisfactorily transmitted to the vicinity of the tip of the medical tube via the coil layer.

[0058]

692 Further, in the present invention, it is preferable that the outer surface of the tubular body 2 or the outer layer 22 is covered with a hydrophilic (or water-soluble) polymer substance (not shown).

695 As a result, when the outer surface of the tubular body 2 or the outer layer 22 comes into contact with blood, physiological saline, or the like, the coefficient of friction is reduced to impart lubricity, and the slidability of the medical tube 1 is further improved. As a result, pushability, followability, and kink resistance are further improved. Further, when the inner surface of the inner layer 21 is also lubricated with the hydrophilic polymer substance, silicone oil, oil or fat, etc., the guide wire inserted in the tube 1 becomes easy to move in the tube 1, and the guide wire can be operated. Sex improves.

[0059]

705 Examples of the hydrophilic polymer substance include the following natural or synthetic polymer substances or derivatives thereof.

707 <Natural polymer substance> 1) Starch-based examples: carboxymethyl starch, dialdehyde starch 2) Cellulose-based examples: CMC (carboxymethyl cellulose), MC (methyl cellulose), HEC (hydroxyethyl cellulose), HPC (hydroxypropyl cellulose) 3) Tannin, starch-based

examples: tannin, nignin Examples: alginic acid, gum arabic, guar gum, tragant gum, tamarint species 5) Protein examples: gelatin, casein, glue, collagen

[0060]

715 <Synthetic water-soluble polymer> Example: Polyvinyl alcohol 2) Polyethylene oxide-based Example: Polyethylene oxide, Polyethylene glycol 3) Acrylic acid-based Example: Polyacrylic acid sodium 4) Anhydrous maleic acid-based Example: Methyl vinyl ether Anhydrous maleic acid copolymer 5) phthalic acid-based example: polyhydroxyethyl phthalic acid ester 6) water-soluble polyester example: polydimethyllol propionic acid ester 7) ketone aldehyde resin example: methylisopropylketoneformaldehyde resin 8) acrylamide-based example: polyacrylamide, polydimethylacrylamide 9) Polyvinylpyrrolidone-based 10) Polyamine-based Example: Polyethyleneimine 11) Polyelectron Example: Polystyrenesulfonate Example: Water-soluble nylon, P (GMA-DMAA) block copolymer (poly (glycidyl methacrylate-dimethylacrylamide) block copolymer)

[0061]

728 Among these, in particular, a cellulose-based polymer substance (for example, hydroxypropyl cellulose), a polyethylene oxide-based polymer substance (polyethylene glycol), and a maleic anhydride-based polymer substance (for example, a methylvinyl ether anhydrous maleic acid copolymer). Such as maleic anhydride copolymers), acrylamide-based polymer substances (eg, polyacrylamide), water-soluble nylons (eg, AQ-nylon P-70 manufactured by Toray Co., Ltd.), polyglycidyl methacrylate-dimethylacrylamide copolymers. , It is preferable because a low friction coefficient can be stably obtained.

735 Among them, in particular, the polyglycidyl methacrylate-dimethylacrylamide copolymer, which is a block copolymer composed of a hydrophilic compound block and a hydrophobic compound block, is lubricated because the hydrophilic compound (polydimethylacrylamide) is a water-swellable compound. Since it has excellent properties and has a hydrophilic / hydrophobic microdomain structure, antithrombotic properties can also be expected.

[0062]

743 Further, the derivative of the polymer substance is not limited to a water-soluble substance, and as long as the water-soluble polymer substance has the basic composition, there is no particular limitation, and even an insolubilized polymer substance can be used as a molecular chain. It suffices as long as it has a degree of freedom and contains water.

747 For example, esterified products, salts, amidated products, anhydrides, halides, etherified products, hydrolysates, acetal products, formal products, and alkylols obtained by condensation, addition, substitution, oxidation, reduction reaction, etc. of the above polymer substances. Diazonium group, azide group, isocyanate group, acid chloride group, acid anhydride group, iminocarbonate ester group, amino group, carboxyl group, Cross-linked

products with substances having two or more epoxy groups, hydroxyl groups, aldehyde groups, reactive functional groups; copolymers with vinyl compounds, acrylic acids, methacrylic acid, diene compounds, maleic anhydride and the like can be mentioned.

[0063]

758 In order to fix the coating layer of such a hydrophilic polymer substance to the outer surface of the tubular body 2 or the outer layer 22, it is preferable to covalently bond with the reactive functional group present or introduced on the surface. ..

761 This makes it possible to obtain a long-lasting lubricious surface.

762 The reactive functional group existing or introduced in or on the surface of the tubular body 2 or the outer layer 22 may be any group as long as it reacts with the polymer substance and is bonded or crosslinked to fix it. , Azido group, isocyanate group, acid chloride group, acid anhydride group, iminocarbonate ester group, amino group, carboxyl group, epoxy group, hydroxyl group, aldehyde group and the like, and in particular, isocyanate group, amino group, epoxy group and aldehyde. Groups are suitable.

[0064]

771 The average molecular weight of the hydrophilic polymer substance is not particularly limited, but is preferably about 3 to 5 million.

773 As a result, a lubricating layer having high lubricity, an appropriate thickness, and an appropriate degree of swelling when water is contained can be obtained. The thickness of the lubricating layer made of such a hydrophilic polymer is not particularly limited, but is preferably about 0.1 to 100 μm, particularly preferably about 1 to 30 μm. The composition and coating method of the hydrophilic polymer substance are described in, for example, JP-A-53-106778, US Pat. No. 4,300,309, JP-A-60-259269, and Japanese Patent Application Laid-Open No. 1-33181. You can apply something like that.

[0065]

783 Further, in the present invention, it is preferable to apply a treatment for imparting higher biocompatibility to the outer surface of the tubular body 2 or the outer layer 22.

785 As biocompatibility, antithrombotic property is required, and various known methods can be mentioned for imparting antithrombotic property. However, it is preferable to fix heparin on the outer surface by coating with a heparin solution or heparin bonding. Further, if a thrombolytic agent is mixed with the constituent material of the tubular body 2 or the outer layer 22 and extruded to form a tube, the thrombolytic agent is gradually released when inserted into a blood vessel and used, which is preferable. ..

[0066]

794 FIG. 6 is a plan view showing a configuration example of the catheter for cerebrovascular embolization of the present invention.

796 Hereinafter, the catheter for cerebrovascular treatment of the present invention will be described with reference to the drawings. The same components as those of the configuration examples shown in FIGS. 1 to 4 are designated by the same reference numerals and the description thereof will be omitted. The cerebrovascular treatment catheter 4 of the present invention includes the medical tube 1 shown in FIGS. 1 to 4, the reinforcing tube 41 mounted around the outer periphery of the vicinity of the base end of the tube 1, the medical tube 1 and the reinforcing tube. It is composed of a hub 42 mounted near the base end of 41, a tip soft tip 43 joined to the tip of a medical tube 1, and a contrast marker 44.

[0067]

807 The reinforcing tube 41 is, for example, a heat-shrinkable tube 51 having a heat-shrinkable inner diameter slightly smaller than the outer diameter near the base end of the tube 1. It can be easily attached by fitting it in the vicinity of the base end of No. 1 and heating (for example, applying hot air) to shrink it.

811 Further, the hub 42 has a lumen communicating with the lumen 14 of the tube 1 and an opening communicating the lumen 14 with the outside, and has an injection port for a chemical solution, an embolic substance, etc. into the lumen 14 and a guide wire. It functions as an insertion port and also functions as a grip when operating the cerebrovascular treatment catheter 4.

[0068]

819 The tip soft chip 43 is made of a highly flexible material similar to the chip 15 described above.

821 The tip 43 is formed in the shape of a short cylinder, and is fixed and joined to the tip of the tube 1 by adhesion or the like so that the lumen thereof communicates with the lumen 14 of the tube 1. Further, the contrast marker 44 is configured by winding a platinum wire rod around the outer surface of the chip 53 in a coil shape. The marker 44 may be embedded in the tubular body 2, between the inner layer 21 and the outer layer 22, or in the tip soft tip 43. With such a structure, the tip 44 does not protrude to the outer surface of the catheter, so that a step is formed. Is not formed and irritation to blood vessels is reduced. The length of the chip 43 is about 0.5 to 30 mm, preferably about 2 to 15 mm.

[0069]

832 Since the cerebrovascular embolization catheter 4 is composed of the medical tube 1 as a tube body to be inserted into the cerebrovascular vessel, it is flexible and rich in kink resistance.

835 In addition, the pressure resistance on the inside and the pressure resistance on the outside

are also very excellent, it is hard to be crushed even if the wall thickness is thin, and it can be inserted well along the guide wire even in a blood vessel that branches and bends finely and complicatedly. It is difficult to rupture even if a high pressure is applied to the inside of the catheter 4 by pouring a large amount of a highly viscous contrast medium or embolic substance.

[0070]

844 The dimensions of the cerebral vascular embolization catheter 4 are about 1000 to 2000 mm in length, preferably about 1300 to 1700 mm, and the outer diameter is about 0.3 to 3 mm, preferably about 0.4 to 1.0 mm. The inner diameter is about 0.20 to 0.70 mm, preferably about 0.3 to 0.7 mm, and the wall thickness is about 0.04 to 0.15 mm, preferably about 0.06 to 0.1 mm.

[0071]

852 Further, in the cerebrovascular embolization catheter 4, the outer surface of the portion to be inserted into the blood vessel, that is, the outer surface of the tip soft tip 44 and the medical tube 1, is coated with a lubricating polymer substance and biocompatibility treatment is performed. Is preferable.

856 The coating of the lubricating polymer substance and the biocompatibility treatment can be performed in the same manner as described above.

858 The coating of the lubricating polymer substance and the biocompatibility treatment may be performed at the stage of manufacturing the medical tube 1 or after assembling the cerebrovascular embolization catheter 4.

[0072]

864 Further, in the cerebrovascular embolization catheter 4, in a part of the medical tube 1, an adhesive, a resin material or the like may be allowed to flow into the gap between the pitches of the coil layer 3 to regulate the displacement of the gap. ..

867 In particular, when the portion extending from the base end of the tube 1 to the predetermined length is made in this way, the hardness from the base end of the tube 1 to the predetermined length is increased, and the torque transmissibility and the pushing property of the catheter 4 can be further improved. In order to obtain the catheter 4 having such a configuration, for example, the gap may be impregnated with an adhesive or the like at the stage where the coil layer 3 is formed, or after the medical tube 1 is manufactured, the hub 42 is tubed. It is also possible to impregnate the base end of the tube 1 with an adhesive by utilizing the capillary phenomenon before attaching to 1.

[0073]

878 Next, the method and operation of the above-mentioned cerebrovascular embolization catheter 4 will be described.

880 First, a guiding catheter (not shown) having a lumen through which the catheter 4 can be inserted is inserted and indwelled from the femoral artery to the internal carotid artery, the external carotid artery, or the vertebral artery via the aorta. The inner surface of the guiding catheter has a hydrophilic coating. Next, a guide wire composed of a metal elastic core material, a plastic coating material coated on the surface thereof, and a hydrophilic lubricating layer fixed to the surface of the coating material, or a metal elastic core material and the tip of the core material are provided. A catheter 4 in which a guide wire composed of a obtained X-ray contrast-enhanced coil and a fluorine-based coating material coated on the surface of the core material is inserted and set is placed along the lumen of the guiding catheter of the guiding catheter. It protrudes from the tip and is inserted to the target blood vessel together with the above guide wire. When the blood vessel branches on the way, the guide wire is preceded so that it can be selectively inserted into the target blood vessel, and then the catheter is pushed in. If it is difficult to insert along the guide wire, rotate the hand of the catheter and push it in while transmitting the rotation to the tip of the catheter to advance to the target blood vessel. The cerebral aneurysm existing in the target blood vessel is confirmed from the upstream side under fluoroscopy with a contrast medium of a catheter. When the target site is reached, the tip 11 of the catheter 4 is inserted into the cerebral aneurysm, the guide wire is removed, and then an embolic substance such as a liquid, granular, or microcoil is introduced. When the introduction is completed, the guiding catheter and the catheter 4 are removed from the body, hemostasis is performed, and the procedure is completed.

[0074]

904 Since the catheter 4 of the present invention is configured with the medical tube 1 of the present invention as a member, it is highly flexible and kink-resistant, and even a fine and complicated blood vessel of a cerebral aneurysm can be satisfactorily used. It can be inserted and has good followability to the guide wire, and even complicatedly curved and bent blood vessels can easily proceed along the guide wire without kinking.

909 In addition, it has excellent torque transmission and pushability, making it a catheter with good operability, and also has excellent pressure resistance on the inside and outside, so it is hard to collapse even without a guide wire in a fine and complicated blood vessel. There is little risk of bursting even if liquid or granular embolic material is poured.

[0075]

916 The catheter for cerebrovascular embolization of the present invention is not limited to the configuration shown in the figure. A cutting-edge portion that is more flexible than the portion in which the coil layer 3 that serves as a reinforcing body is arranged may be formed.

919 Even in such a configuration, since the cutting edge portion is composed of a flexible inner

layer 21 and an outer layer 22, it is very flexible, and therefore, when it is inserted into a body cavity such as a blood vessel, there is little irritation to the body cavity. It is also possible to prevent damage to the inner wall of the body cavity, and obtain a catheter that can be inserted quickly and with certain selectivity even in a body cavity having a fine and complicated pattern such as a cerebral blood vessel. Further, in this case, the contrast marker may be embedded and arranged between the inner layer 21 and the outer layer 22 at the most advanced portion.

[0076]

930 7 is a plan view showing a configuration example of the vasodilator catheter of the present invention, and FIG. 8 is a vertical cross-sectional view showing the tip of the vasodilator catheter shown in FIG. 7.

933 Hereinafter, the vasodilator catheter of the present invention will be described with reference to the drawings. The same components as those of the configuration examples shown in FIGS. 1 to 4 are designated by the same reference numerals and the description thereof will be omitted. The vasodilator catheter 5 shown in FIGS. 7 and 8 is provided at the tube body 50 inserted into the body cavity, at least one lumen 511 formed in the tube body 50, and the tip of the tube body 50. It has an expansion body 53 having an internal space communicating with the lumen 511, and the tube body 50 is composed of the medical tube 1 shown in FIGS. 1 to 4.

[0077]

944 Specifically, the catheter 5 is a so-called double lumen coaxial type guide wire movable (over the wire type) vasodilator catheter, and the tube body 50 is composed of an inner tube 51 and an outer tube 52. Has been done.

947 An inner pipe 51 having a first lumen 511 having an open tip and an inner pipe 51 provided coaxially with the inner pipe 51 and having a tip at a position retracted by a predetermined length from the tip of the inner pipe 51. It has an outer pipe 52 forming a second lumen 521, a tip portion 531 and a base end portion 532, the base end portion 532 is attached to the outer pipe 52, and the tip portion 531 is an inner pipe 51. A contractionable or foldable expansion body 53 that is attached to and communicates with the second lumen 521 near the proximal end portion 532, and a first that communicates with the first lumen 511 provided at the proximal end portion of the inner tube 51. Has an opening 581 and a second opening 591 communicating with a second lumen 521 provided at the base end of the outer tube 52. At least one of the inner tube 51 and the outer tube 52 is composed of the above-mentioned medical tube of the present invention.

[0078]

961 In the illustrated example, the inner tube 51 is configured using the medical tube 1 shown in

FIGS. 1 to 4, and as shown in FIG. 8, the flexible tubular body 2 and the tubular body 2 It has a coil layer 3 which has a role as a reinforcing body arranged inside.

964 The tubular body 2 is composed of a flexible inner layer 21 and a flexible outer layer 22, in other words, the inner tube 51 is adhered to the flexible inner layer 21 and the outer side of the inner layer 21. It has a structure having a coil layer 3 having a role as a reinforcing layer and a flexible outer layer 22 adhered to the outside of the coil layer 3. The coil layer 3 is composed of a first coil 31 and a second coil that is wound in the direction opposite to that of the first coil 31. The coil layer 3 is arranged so that the gap between the pitches of the first and second coils 31 and 32 can be freely displaced over a predetermined length from the tip end to the base end, and the tubular body 2 is curved. As a result, it can be flexibly curved without being restricted by the tubular body 2.

[0079]

976 The inner tube 51 has a first lumen 511 with an open tip.

977 The first lumen 511 is a lumen for inserting a guide wire, and communicates with a first opening 581 forming a guide wire port provided in the branch hub 57 described later. The inner pipe 51 has an outer diameter of 0.40 to 2.50 mm, preferably 0.55 to 2.40 mm, and an inner diameter of 0.25 to 2.35 mm, preferably 0.30 to 1.80 mm. ..

[0080]

984 The outer pipe 52 has an inner pipe 51 inserted therein and is provided coaxially with the inner pipe 51, and the tip thereof is provided at a position slightly retracted from the tip of the inner pipe 51.

987 A second lumen 521 is formed by the inner surface of the outer pipe 52 and the outer surface of the inner pipe 51. By forming in this way, the cross-sectional area of the second lumen 521 can be made large, and the lumen having a sufficient volume can be obtained. The second lumen 521 communicates with the extension 53 at its tip and at its proximal end, and the proximal end of the second lumen 521 is a fluid (eg, angiographic agent) for expanding the extension 53. Communicates with a second opening 591 of the branch hub 57 forming an injection port for injecting the fluid. The outer tube 52 has an outer diameter of 0.70 to 4.30 mm, preferably 0.75 to 4.00 mm, and an inner diameter of 0.70 to 3.80 mm, preferably 0.80 to 3.00 mm. ..

[0081]

999 The constituent material of the outer tube 52 may be any material having a certain degree of flexibility, for example, polyolefins such as polyethylene, polypropylene, polybutene, and ethylene-propylene copolymer, polyvinyl chloride, and ethylene-vinyl acetate copolymer weight. Thermoplastic resins such as coalesced, polyurethane and polyester, polyamide elastomers, polyester elastomers, silicone rubbers, polytetrafluoroethylene and the like can

be used, preferably the above-mentioned thermoplastic resins, and more preferably polyolefins.

[0082]

1009 The expansion body 53 is contractable, and in a non-expandable state, it can be folded around the outer periphery of the inner tube 51.

1011 The dilated body 53 is foldable and has a substantially cylindrical portion 533 having at least a substantially cylindrical shape and having substantially the same diameter so that the narrowed portion of the blood vessel can be easily dilated.

1014 The above-mentioned substantially cylindrical portion does not have to be a perfect cylinder, and may be a polygonal columnar portion. The base end portion 532 of the extended body 53 is liquid-tightly fixed to the tip end portion of the outer tube 52 by adhesion or heat fusion, and the tip end portion 531 is the tip end of the inner tube 51 as shown in FIG. It is directly adhered to the part in a liquid-tight manner. The extended body 53 forms an internal space 534 between the inner surface of the extended body 53 and the outer surface of the inner tube 51. The internal space 534 communicates with the second lumen 521 at the base end portion 532 on the entire circumference thereof. In this way, since the second lumen 521 having a relatively large volume is communicated with the base end of the expansion body 53, the expansion fluid can be injected from the second lumen 521 into the internal space 534 of the expansion body 53. It's easy. The constituent material of the extended body 53 is preferably one having a certain degree of flexibility, for example, polyolefins such as polyethylene, polypropylene and ethylene-propylene copolymer, polyvinyl chloride, ethylene-vinyl acetate copolymer, polyurethane and the like. Thermoplastic resin, polyamide elastomer, silicone rubber, latex rubber, polyethylene terephthalate, polyester, polyamide, polyphenylene sulfide and the like can be used. Preferred is polyphenylene sulfide.

[0083]

1034 Further, the extended body 53 has a tapered portion from the distal end side and the proximal end side of the substantially cylindrical portion 533 to the distal end portion 531 and the proximal end portion 532 fixed to the inner pipe 51 and the outer pipe 52. There is.

1038 As for the size of the extended body 53, the outer diameter of the substantially cylindrical portion 533 when expanded is 1.00 to 35.00 mm, preferably 1.50 to 30.00 mm, and the length is 10.00 to 80. It is 0.00 mm, preferably 15.00 to 75.00 mm, and the total length of the extension 53 is 15.00 to 120.00 mm, preferably 20.00 to 100.00 mm.

[0084]

1045 Further, a marker 54 made of an X-ray opaque material (for example, gold, platinum or an

alloy thereof) is provided on the outer surface of the inner tube 51 at a position between the tip end portion 531 and the base end portion 532. Has been done.

1048 This marker 54 makes it possible to easily confirm the position of the extended body 53 under fluoroscopy. As the form of the marker 54, it is preferable to crimp the ring formed of the above metal to the outer surface of the inner tube 51. This makes it possible to obtain a clear X-ray contrast image.

[0085]

1055 Further, a tip soft tip 55 is fixed and joined to the tip of the inner tube 52 as the most advanced portion of the inner tube 52.

1057 The tip soft tip 55 is formed in the shape of a short cylinder, and is fixed and joined to the tip of the inner tube 51 by adhesion or fusion so that its lumen communicates with the first lumen 511. By providing the tip 55, the possibility of damaging the blood vessel at the tip of the catheter 5 can be reduced. As the constituent material of the chip 55, it suffices to have flexibility, and for example, polyurethane, silicone RTV rubber, vinyl chloride-urethane copolymer, styrene-based elastomer and the like can be used. The length of the chip 55 is 0.5 to 5 mm, preferably about 0.5 to 3 mm.

[0086]

1067 Further, the catheter 5 shown in FIGS. 7 and 8 has a reinforcing tube 56 and a branch hub 57.

1069 In the illustrated example, the reinforcing tube 56 is attached around the outer periphery of the outer tube 52 near the base end. The reinforcing tube 56 is, for example, a tube 56 having heat shrinkage, formed so that the inner diameter after heat shrinkage is slightly smaller than the outer diameter near the base end of the outer pipe 52, and has heat shrinkage. Can be easily attached by fitting the outer tube 52 in the vicinity of the base end and heating (for example, applying hot air) to shrink the outer tube 52. The reinforcing tube is not limited to the above, and for example, the inner tube 51 may be provided with the same tube as the reinforcing tube 56.

[0087]

1080 The branch hub 57 has a first opening 581 that communicates with the first lumen 511 to form a guide wire port, and communicates with the inner tube hub 58 fixed to the inner tube 51 and the second lumen 521. It has a second opening 591 forming an injection port, and is composed of an outer pipe hub 59 fixed to the outer pipe 52.

1084 The inner tube hub 58 and the outer tube hub 59 are fixed to each other. As a constituent material of the branch hub 574, a thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate, and a methacrylate-butylene-styrene copolymer can be preferably used. Further, the branch hub 57 may not be provided, and a tube having a port member

forming an opening at the base end may be attached to each of the first lumen 511 and the second lumen 521 in a liquid-tight manner.

[0088]

1093 Next, the method and operation of the vasodilator catheter 5 will be described by taking as an example the case of treating a stenosis generated in a coronary artery blood vessel.

1095 First, before inserting the catheter 5 into the blood vessel, the air in the dilator 53 and the second lumen 521 is removed as much as possible and replaced with a liquid such as a contrast medium. At this time, the extended body 53 is kept in a contracted or folded state. Next, a sheath is placed in the patient's blood vessel by, for example, the Seldinger method, and then a guiding catheter is inserted into the blood vessel through the lumen of the sheath and placed at the entrance of the coronary artery. It is preferable that the inner surface of the guiding catheter has a hydrophilic coating. Next, a guide wire composed of a metal elastic core material, a plastic coating material coated on the surface thereof, and a hydrophilic lubricating layer fixed to the surface of the coating material, or a metal elastic core material and the tip of the core material. A guide wire composed of the provided X-ray contrast-enhanced coil and the fluorine-based coating material coated on the surface of the core material is inserted into the first lumen 511, and the catheter 5 is inserted from the lumen of the guiding catheter. Insert into a blood vessel. Subsequently, the position of the marker 54 is visually recognized under fluoroscopy, and while confirming the positions of the catheter 5 and the tip of the guide wire, the guide wire is advanced to advance the catheter 5, and the catheter 5 is inserted to the stenosis and expanded. The body 53 is positioned within the stenosis.

[0089]

1115 After that, an injector with a pressure gauge is connected to the second opening 581 forming the injection port of the catheter 5, an angiographic agent is injected so as to be about several to ten and several atmospheres, and the dilator 63 is inflated. The lesion, the atheroma, is compressed and the stenosis is dilated.

1119 Then, the contrast medium is injected from the contrast medium injection port provided in the connector of the guiding catheter, and the peripheral blood flow is confirmed by X-ray imaging. When the blood flow is improved, the catheter 5 and the guide wire are removed, and then the guiding catheter is removed to complete the procedure.

[0090]

1126 Since the catheter 5 of the present invention is configured with the medical tube 1 of the present invention as a member, it is highly flexible and resistant to kink, and can be satisfactorily inserted into a relatively thin blood vessel such as a coronary artery. The followability to the guide wire is also good, and even a complicatedly curved or bent blood

vessel can easily proceed along the guide wire without kinking.

1131 In addition, it has excellent torque transmission and pushability, making it a catheter with good operability. Furthermore, it has excellent pressure resistance on the inside and outside, and even if an expansion fluid is poured into the internal space 534 of the expansion body 53 at high pressure. It is unlikely to collapse or burst. Further, even if a contrast medium is poured into the first lumen 511 during the operation, it is unlikely to be crushed or ruptured and can be safely handled.

[0091]

1140 In the illustrated example, the inner tube 51 is made of the medical tube 1, but the present invention is not limited to this, and the outer tube 52 may be made of the medical tube 1 or the inner tube. Both the 51 and the outer tube 52 may be composed of the medical tube 1.

1143 Further, the medical tube of the present invention constituting the inner tube 51 and the outer tube 52 is not limited to the illustrated medical tube 1, and is shown in FIG. 5, for example, in place of the medical tube 1 described above. A medical tube 10 may be used.

[0092]

1149 Further, in the illustrated example, a double lumen coaxial type guide wire movable (over-the-wire type) vasodilator catheter has been described, but the present invention is not limited to this, and the US patent 4,771,778 is not limited thereto. The so-called on-the-wire type vasodilator catheter in which the dilator is directly fixed to the guide wire described in the specification, etc., and the catheter described in the US patents 4,748,982, etc. are used for the blood vessel. It can also be applied to a so-called monorail type vasodilator catheter in which the guide wire can be replaced while it is inserted, and the medical tube of the present invention may be used for such a type of catheter tube.

[0093]

1160 The medical tube, the cerebral vascular treatment catheter, and the vasodilator catheter in the present invention have been described above, but the present invention is not limited to this, and for example, a vascular catheter such as a contrast catheter, a guiding catheter, and a drug injection are used. It may be applied to a catheter, a devascularization catheter for open heart surgery, an endoscopic catheter, a laparoscopic catheter, a thoracic laparoscopic catheter and the like.

[0094]

1169 Hereinafter, the present invention will be described in more detail based on specific examples.

1171 [Example 1] Using linear low-density polyethylene (manufactured by Mitsui Nisseki Polymer

Co., Ltd., trade name: Ultozex, grade 4570) as a raw material, an inner diameter of 0.47 mm and an outer diameter of 0.52 mm are obtained by ordinary extrusion molding. I got a tube.

1174 By pulling down the die from this tube, a molded body of the inner layer 21 was manufactured as a two-stage different diameter tube having an inner diameter of 0.41 mm and an outer diameter of 0.45 mm.

1177 The obtained inner layer 21 had a total length of 1700 mm, a small diameter tip portion of 800 mm, and a base length of 900 mm.

[0095]

1182 On the other hand, using a modified polyethylene resin (manufactured by Atchem, trade name Bondine, grade TX-8030) as a raw material, the take-up speed is changed in the middle of extrusion molding to manufacture a molded body of an outer layer 22 having a different diameter between the tip portion and the base portion. bottom.

1186 The total length of the outer layer 22 is 1700 mm, and the length of the tip portion having a small diameter is 750 mm. The length of the tapered portion was 50 mm, and the length of the base including the tapered portion was 950 mm. The inner diameter of the tip portion was 0.50 mm and the outer diameter was 0.56 mm, the tapered portion was smoothly changed, and the inner diameter of the base portion was 0.56 mm and the outer diameter was 0.63 mm.

[0096]

1195 Further, strands 31a to e made of stainless steel (SUS304), having a plate thickness t of 0.010 mm and a plate width z of 0.120 mm were prepared, and the strands 31a to e were combined into a bundle 31A. The first coil 31 was manufactured by winding the strands 31a to e right-handed on core materials having different diameters at the tip and the base in a state where the strands 31a to e were in close contact with each other without any gap.

1200 The gap y between the pitches of the coils 31 was 0.02 mm.

[0097]

1204 Subsequently, the strands 32a to e configured in the same manner as the strands 31a to e are prepared, the strands 32a to e are made into a bundle 32A as a set of five, and the strands 32a to e are brought into close contact with each other without a gap. In this state, the core material and the first coil 31 were overlapped and wound counterclockwise to produce a second coil 32.

1209 The gap y between the pitches of the coil 32 was set to 0.02 mm as in the coil 31.

[0098]

1213 Then, the core material was extracted to manufacture a coil layer 3 having a different

diameter between the tip portion and the base portion.

1215 The obtained coil layer 3 has an inner diameter of 0.47 mm, an outer diameter of 0.51 mm, a length of 730 mm, and a tapered portion having a length of 50 mm, and has a smooth diameter. It was changing. The inner diameter of the base was 0.53 mm, the outer diameter was 0.57 mm, and the length was 820 mm including the tapered portion.

[0099]

1222 The coil layer 32 was inserted into the outer layer 22 swollen in a THF solvent, the outer layer 22 was air-dried, and then the inner layer 21 was inserted into the coil layer 3.

1224 Then, these coil layers 3, the inner layer 21 and the outer layer 22 were heat-treated in an oven at 60 ° C. for 16 hours. By this heat treatment, the residual stress of the inner layer 21 was removed, the inner diameter and the outer diameter of the inner layer 21 were increased, and the inner layer 21 and the coil layer 3 were in close contact with each other. Further, both end portions of the inner layer 21 and the outer layer 22 were fused and fused at a position 1 mm ahead of the tip end and the base end of the coil layer 3 to obtain the medical tube 1 of the present invention shown in FIGS. 1 to 4. The obtained medical tube 1 has a total length of 1500 mm, an inner diameter of the tip portion 12 of 0.43 mm, an outer diameter of 0.57 mm, and a length of 730 mm, and the tapered portion 13 has a length of 50 mm and a smooth diameter. It had changed to. The inner diameter of the base 11 was 0.48 mm, the outer diameter was 0.64 mm, and the length was 770 mm.

[0100]

1238 [Comparative Example 1] High-density polyethylene (manufactured by Mitsubishi Yuka Co., Ltd., trade name Mitsubishi Polyeth-HD, grade EY40H) is molded by ordinary extrusion molding and has an inner diameter of 0.43 mm and an outer diameter of 0.57 mm. A tube of Comparative Example 1 having the same dimensions as the tip portion 12 of Example 1 was manufactured.

[0101]

1246 [Comparative Example 2] A reinforced tube having an inner diameter of 0.43 mm and an outer diameter of 0.57 mm reinforced with a metal braid and having the same dimensions as the tip portion 12 of the embodiment according to the method described in Japanese Patent Publication No. 4-670. Manufactured.

1250 Specifically, high-density polyethylene (manufactured by Mitsubishi Yuka Co., Ltd., trade name Mitsubishi Polyeth-HD, grade JY20) was coated on a copper wire having an outer diameter of 0.43 mm to a thickness of 15 μm using a cross molding machine. ..

1253 A 20 μm stainless steel (SUS304) blade wire is wound around a copper wire in a mesh pattern using a braider device (manufactured by Nagata Seiki Co., Ltd., model number STM-II), and then the same resin is melt-coated using a coating die. , The above blade wire was

buried. Then, the copper wire used for the core was stretched, stretched, and removed to prepare a tube of Comparative Example 3.

[0102]

1261 [Comparative Example 3] A tube of Comparative Example 2 composed of a coil layer 3 and an outer layer 22 was produced in the same manner as in Example 1 except that the inner layer 21 of Example 1 was not provided.

1264 Experiments 1 to 4 shown below were carried out for Examples 1 and Comparative Examples 1 to 3 to compare the mechanical strengths.

[0103]

1269 [Experiment 1] The flexural modulus and bending stress of the tips 12 of Example 1 and the tubes of Comparative Examples 1 to 3 were measured by a three-point bending test.

1271 The flexural modulus was used as a comparison of tube hardness, and the bending stress was used as a comparison of tube flexibility. The three-point bending test was performed by cutting the tip portion 21 of Example 1 and the tubes of Comparative Examples 1 and 2 to 20 mm each, using the jig 20 shown in FIG. 9, and referring to the bending test of JIS K7203. .. The test was carried out using an AUTOGRAPH AGS-100A manufactured by Shimadzu Corporation at a test speed of 1 mm / min at room temperature.

[0104]

1280 Two support rods 62 having a diameter of 2 mm were placed on the sample table 61 of the jig 6 shown in FIG. 9, and the tip portion 21 of Example 1 cut to a fixed size was placed and supported on the support rod 62.

1283 The distance between the support rods 62 (distance between fulcrums) was 10 mm. In this state, a pusher 64 having a fulcrum ball 63 having a diameter of 2 mm is connected to a load cell (not shown) of the testing machine, and the pusher 64 is moved in the direction of the arrow in the figure to perform a three-point bending test. rice field. The same test as above was performed on the tubes of Comparative Examples 1 to 3.

[0105]

1291 By the above bending test, the stress strain curve shown in FIG. 10 was obtained.

1292 The initial slope in this stress-strain curve is defined as the bending stress W, and this bending stress W represents the force required to simply bend each sample by 1 mm. bottom. The results are shown in Table 1 below.

[0106]

1298 [Experiment 2] The inner pressure resistance test shown below was performed on the tip portion 12 of Example 1 and the tubes of Comparative Examples 1 to 3 to evaluate the pressure resistance to pressure from the inside.

1301 As shown in FIG. 11, the tip of the tip portion 12 of Example 1 was sealed with an epoxy resin 71, and the connector 72 was connected to the base end. These were placed in a hot water bath at 37 ° C., and nitrogen gas was sent from the injection port 73 of the connector 72 to the inside of the tip portion 12 using a nitrogen gas cylinder, and the pressure was applied at a rate of 1.0 kg / cm2 per minute. By visually observing the bubbles generated in the water, the pressure value at which the leak or rupture occurred was measured. In addition, the same measurements as above were performed for the tubes of Comparative Examples 1 to 3. The results are shown in Table 1 below.

[0107]

1312 [Experiment 3] The outer pressure resistance test shown below was performed on the tip portion 12 of Example 1 and the tubes of Comparative Examples 1 to 3 to evaluate the pressure resistance against crushing from the outside.

1315 As shown in FIG. 12, the tip portion 12 of Example 1 was covered with a metallic sheath 82 having an injection port 81, and the tip 83 and the base end 84 of the sheath 82 were sealed with epoxy resin, respectively. At this time, the tip portion 12 was made longer than the total length of the sheath 82 and protruded from the tip end 83 and the base end 84. In this state, the whole was placed in a hot water bath at 37 ° C. The lumen 85 composed of the tip portion 12 and the sheath 82 was pressurized with nitrogen gas, and the outside of the tip portion 12 was pressurized by 1.0 kg / cm2.

[0108]

1325 At the time when the pressurization was started, a straight core rod 86 made of stainless steel (SUS304) was passed through the inner lumen 14 of the tip portion 12, and the passability of the core rod 86 was confirmed.

1328 The outer diameter of the core rod 86 was set to 0.38 mm, which is 0.05 mm smaller than the inner diameter of the tip portion 12. The pressure value when the lumen 14 was crushed by the deformation of the tip portion 12 due to pressurization and the core rod became immobile was obtained, and the crush resistance due to the pressure from the outside was evaluated. In addition, the pressure value at the time of leakage or rupture was also obtained by visually observing the bubbles generated in the water, but in most cases, the occurrence of crushing occurred earlier. In addition, the same measurements as above were performed for the tubes of Comparative Examples 1 to 3. The results are shown in Table 1 below.

[0109]

1340 [Experiment 4] The kinkability test shown below was performed on the tips 12 of Example 1 and the tubes of Comparative Examples 1 to 3 using the device 9 shown in FIG.

1342 The kink resistance test was performed using an autograph (AUTOGRAPH AGS-100A manufactured by Shimadzu Corporation) at a test speed of 10 mm / min. At room temperature. As shown in FIG. 13, core rods 91 are inserted into both ends of the tip portion 12 of the first embodiment cut to 65 mm, the space between the two core rods 91 is set to 25 mm, and the gap between the core rod 91 and the tip portion 12 is set. Was filled with epoxy resin. Both ends of the tip portion 12 into which the core rod 91 is inserted are sandwiched between chucks 92, and the chuck 92 on the upper side is lowered at a constant speed to narrow the interval. The moving distance of the chuck 92 on the upper side at this time was measured. It can be said that the smaller this measured value is, the worse the kink resistance is. In addition, the same measurements as above were performed for the tubes of Comparative Examples 1 to 3. The results are shown in Table 1 below.

[0110]

1357 [Experiment 5] The tip portion 12 of Example 1 and the tubes of Comparative Examples 1 to 3 were subjected to the tensile test shown below, the breaking strength and the breaking elongation were measured, and the strength of the tubes was compared.

1360 The tensile test was performed using an autograph (AUTOGRAPH AGS-100A manufactured by Shimadzu Corporation) at a test speed of 100 mm / min. At room temperature, and the breaking strength and breaking elongation were determined. In this test, using the same equipment as in Experiment 4, the chuck 92 was widened between the two chucks 92 at a constant speed, contrary to Experiment 4, and the chuck 92 when the tip portion 12 of Example 1 was broken. The distance traveled was measured. The same measurement was performed on the tubes of Comparative Examples 1 to 3. The results are shown in Table 1 below.

[0112]

1371 As shown in Table 1 above, from the measured values of flexural modulus, the hardness of the tube is the hardest in the reinforced tube of Comparative Example 2, and it is composed only of a flexible resin material, and has the same dimensions. It can be said that the tube of Example 1 is more flexible than the tube of Comparative Example 1.

1375 Further, it can be seen from the measured values of bending stress that the tube of Example 1 is more flexible than that of Comparative Examples 1 and 2. Furthermore, it is clear from the measured values of kink resistance that the tube of Example 1 is less likely to cause kink and is excellent in flexibility. From the above, it is understood that the medical tube of the present invention is excellent in flexibility and kink resistance.

[0113]

1383 Regarding the inner and outer pressure resistance, from the measured values shown in Table 1, the tube of Example 1 is superior to the tube of Comparative Example 1 in both inner pressure resistance and outer pressure resistance. Understand.

1386 Further, the tube of Comparative Example 2 is excellent in pressure resistance, but is a hard tube as described above. Further, comparing Example 1 and Comparative Example 3, Example 1 in which the inner layer 21 is provided inside the coil layer 3 has an inner pressure resistance as compared with Comparative Example 3 in which the inner layer 21 is not provided inside the coil layer 3. It has been shown that the sex is significantly improved. That is, it can be seen that the pressure resistance is remarkably improved by forming the structure in which the flexible layer is covered with the coil layer. Conventionally, for tubes of the same inner and outer diameters, the pressure resistance depends on the hardness of the material of the tube. Therefore, it was conventionally thought that the pressure resistance would be lost if the tube was softened. It is understood that the medical tube of the present invention satisfies both the flexibility and pressure resistance of the tube.

[0114]

1401 Further, from the results of the tensile test of the tube, it is shown that the tube of Example 1 is superior in strength to the tube of Comparative Examples 1 and 2.

1403 Further, the tube of Comparative Example 2 has a remarkably low breaking elongation, and such a tube tends to break suddenly, so that it is not preferable for safety as a tube used by inserting it into a body cavity. From the above, it is understood that the medical tube of the present invention has both satisfactory flexibility, pressure resistance and strength.

[0115]

1410 When the tubes of Example 1 and Comparative Examples 1 and 2 were bent at right angles and the presence or absence of kink was observed, the tubes of Example 1 maintained the inner holes and did not break, but Comparative Examples 1 to 2. The tube 2 was broken and the inner hole was crushed.

[0116]

1417 [Example 2] The medical tube 10 shown in FIG. 5 was manufactured.

1418 The chip 15 was manufactured using polyurethane.

1419 When the same test as above was performed on this tube 10, the flexibility, pressure resistance and strength were all excellent as in Example 1. Further, the tip of this tube 10 was very flexible as compared with Example 1.

[0117]

1425 [Example 3] Using the medical tube 1 of Example 1 as a member, a catheter 4 for cerebrovascular embolization shown in FIG. 6 was manufactured.

1427 Specifically, after cutting the medical tube 1 of Example 1 to a fixed size with an excimer laser, the tube 1 is provided with a reinforcing tube 41 (material: polyethylene resin) and a hub 42 (material: nylon 12 resin).), The tip soft tip 43 (material; polyurethane), and the contrast marker 44 made of a platinum coil were attached using a urethane adhesive. The marker 44 was wrapped around the outer surface of the chip 43, and a urethane adhesive was applied on the marker 44 so that the outer surface of the catheter 4 was smooth.

[0118]

1436 The catheter 4 is a catheter having a taper of 1.7 Fr at the tip and 1.9 Fr at the base, the total length of the catheter is 1500 mm, and the effective length of the catheter (length excluding the hub and the reinforcing tube) is 1400 mm.

1439 At the time of assembly, a cyanoacrylate-based instant adhesive was impregnated into the gap between the first and second coils 31 and 32 on the proximal end side of the medical tube 1 by utilizing the capillary phenomenon. The instant adhesive penetrated to about 1/3 of the base 11 of the medical tube 1, and the portion became hard. Further, the tip portion 12 having a small diameter was coated with a P (GMA-DMAA) block copolymer which is a hydrophilic polymer substance, and a surface treatment having lubricity when wet was performed.

[0119]

1449 When cerebral vascular treatment (cerebral artery embolization) for embolizing a cerebral aneurysm was performed using this catheter 4, the bending followability and torque controllability for a winding blood vessel were very good, and the catheter operability was improved. It was excellent.

[0120]

1456 [Example 4] The vasodilator catheter 5 shown in FIG. 7 was manufactured using the multilayer medical tube 1 of Example 1 as a member.

1458 Specifically, the medical tube 1 of Example 1 is cut to a fixed size, and this is used as an inner tube 51, which is made of an outer tube 52 (material: polypropylene resin), an expansion body 53 (material: polycarbonate sulfide resin), and platinum. The contrast marker 54, the tip soft tip 55 made of polyurethane, the reinforcing tube 56 (material: polyethylene resin), the inner tube hub 58 (material: polycarbonate resin), and the outer tube hub 59 (material: polycarbonate resin) were attached.

1464 The entire obtained catheter 5 was a tapered catheter with an outer diameter of 2.7 Fr (outer diameter of about 0.9 mm), and the total length of the catheter was 1550 mm and the

effective length of the catheter was 1350 mm.

[0121]

1470 When the PTCA procedure was performed using this catheter 5, the catheter was excellent in flexion followability, stenosis passage, pushability, and guide wire mobility, and the catheter was easy to operate.

1473 In addition, during the PTCA procedure, a contrast medium with high viscosity was used as the expansion fluid of the expansion body 53, and the pressurizing pressure of the expansion body 53 was increased to 16 kg / cm2, but the inner tube 51 was not crushed or ruptured at all. I couldn't.

[0122]

1480 INDUSTRIAL APPLICABILITY As described above, the medical tube of the present invention is rich in flexibility and kink resistance, has good torque transmissibility and push-in property, and is also excellent in pressure resistance on the inside and outside. ..

1483 Therefore, it can be suitably used as a member of a catheter having excellent operability, and is particularly effective as a member of a small-diameter catheter used by inserting it into a body cavity having a small diameter. Therefore, it is possible to provide a catheter useful for, for example, angioplasty, drug infusion therapy, angiography, and embolization therapy.

[0123]

1491 In addition, the catheter for cerebrovascular embolization of the present invention composed of the above-mentioned medical tube is rich in flexibility and kink resistance, has good torque transmissibility and push-in property, and has inner and outer pressure resistance. Are better.

1495 Therefore, it has excellent operability, can reach the target site of the fine and complicated cerebral blood vessels along the guide wire well, minimizes damage to the tubular tissue and organs of the human body, and is safe. Very expensive.

[0124]

1501 Further, the vasodilator catheter of the present invention composed of the above-mentioned medical tube is rich in flexibility and kink resistance, has good torque transmissibility and push-in property, and has excellent inner and outer pressure resistance. There is.

1504 Therefore, it has excellent operability, can reach the target member well along the guide wire, and can minimize damage to the tubular tissue and organs of the human body. In addition, there is very little risk of explosion even if a high pressure is applied when expanding the expanded body, and the safety is very high.

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

(19) World Intellectual Property Organization
International Bureau

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

PCT

(10) International Publication Number
WO 2010/002549 A3

(51) International Patent Classification:
A61B 17/50 (2006.01) *A61M 1/00* (2006.01)
A61B 17/22 (2006.01)

(21) International Application Number:
PCT/US2009/046659

(22) International Filing Date:
8 June 2009 (08.06.2009)

(25) Filing Language: English

(26) Publication Language: English

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61/059,796 8 June 2008 (08.06.2008) US
61/210,596 19 March 2009 (19.03.2009) US

(71) Applicant *(for all designated States except US)*: **HOTSPUR TECHNOLOGIES, INC** [US/US]; 880 Maude Avenue, Suite A, Mountain View, CA 94043 (US).

(72) Inventors; and

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

(74) Agent: **ENGLISH, William, A.**; Vista IP Law Group LLP, 2040 Main Street, 9th Floor, Irvine, CA 92614 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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

Published:

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

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(88) Date of publication of the international search report:
25 March 2010

(54) Title: APPARATUS AND METHODS FOR REMOVING OBSTRUCTIVE MATERIAL FROM BODY LUMENS

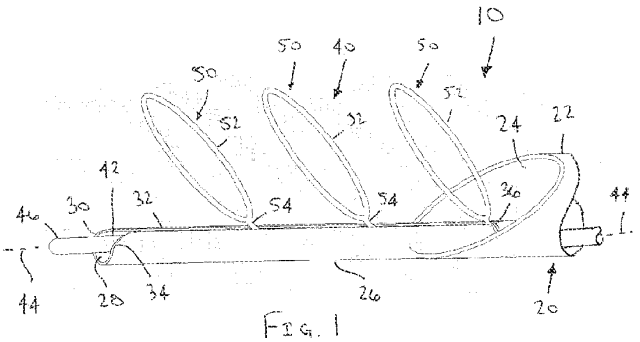


Fig. 1

(57) Abstract: An apparatus is provided for removing material within a body lumen that includes a catheter including a proximal end, a distal end for introduction into a body lumen, and an aspiration lumen extending therebetween; a guide member extending from the distal end and terminating in a distal tip, the guide member comprising a track adjacent a track lumen extending from the distal tip into the aspiration lumen; and an obstruction clearing device deployable from the guide member and retractable along the track. In addition or alternatively, the apparatus includes a cutting head reciprocable within the aspiration lumen adjacent the distal end for macerating material being aspirated into the aspiration lumen.

WO 2010/002549 A3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/046659

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/50(2006.01)i, A61B 17/22(2006.01)i, A61M 1/00(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC : A61B 17/22, A61B 17/50, A61M 1/00

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

- Korean Utility models and applications for Utility models since 1975
- Japanese Utility models and applications for Utility models since 1975

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

eKOMPASS(KIPO internal) & keywords : "blood", "lumen", "cutting" and "clear"

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 05843103 A (EDWARD I. WULFMAN) 01 Dec. 1998 See Column 2, line 66 - Column 5, line 25; Claims 1-4; Figs. 1, and 6-9.	21 - 24
A	The whole documents.	1 - 10, 25 - 30
A	US 06547754 B1 (MICHAEL EVANS et al.) 15 Apr. 2003 The whole documents.	1 - 10, 21 - 30
A	US 2005-038383 A1 (GREGORY S. KELLEY et al.) 17 Feb. 2005 The whole documents.	1 - 10, 21 - 30

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

☒ See patent family annex.

* Special categories of cited documents:

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

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

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of 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 2010 (25.01.2010)	**27 JANUARY 2010 (27.01.2010)**
Name and mailing address of the ISA/KR Korean Intellectual Property Office Government Complex-Daejeon, 139 Seonsa-ro, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer YANG, Seong Ji Telephone No. 82-42-481-5624

Form PCT/ISA/210 (second sheet) (July 2008)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/046659

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.: 11 - 20and 31
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 11-20 and 31 pertain to methods for treatment of a patient by surgery, and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT.

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

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

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

This International Searching Authority found multiple inventions in this international application, as follows:

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

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

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

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

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2009/046659

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 05843103 A	01.12.1998	CA 2282276 A1	11.09.1998
		EP 1011483 A4	28.06.2000
		EP 1011483 A1	28.06.2000
		JP 2001-513692 A	04.09.2001
		WO 1998-038926 A1	11.09.1998
US 06547754 B1	15.04.2003	US 05380273 A	10.01.1995
		US 05498236 A	12.03.1996
		US 05713848 A	03.02.1998
		US 06287271 B1	11.09.2001
		US 06506782 B1	21.01.2003
		US 06936025 B1	30.08.2005
		US 2003-0083608 A1	01.05.2003
		WO 1996-039955 A1	19.12.1996
US 2005-038383 A1	17.02.2005	None	

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

MAR 28 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: 111552-8028WO00	Date of mailing (day/month/year): MAR 22 2022
International application No.: PCT/US 21/59718	FOR FURTHER ACTION: See paragraphs 1 and 4 below
Applicant: INARI MEDICAL, INC.	International filing date (day/month/year): 17 November 2021 (17.11.2021)

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	Authorized officer: Keri Rodriquez
Facsimile No. 571-273-8300	Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/220 (revised January 2020)

INARI_020984

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
111552-0028WO00	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 21/59718	17 November 2021 (17.11.2021)	18 November 2020 (18.11.2020)

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. 7C

☒ as suggested by the applicant.

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

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

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/59718

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

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

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

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

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

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

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

Group I: Claims 1-14 directed to an aspiration catheter.

Group II: Claims 15-20 directed to a method of removing clot material from a blood vessel.

^-Continued in Supplemental Box-^

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

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

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

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-14

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/59716

A. CLASSIFICATION OF SUBJECT MATTER
IPC - A61M 25/00; A61B 17/22 (2022.01)
CPC - A61M 25/0041; A61M 25/0045

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
Y	CN 110652645 A (Shanghai Warbey Medical Technology Co Ltd) 07 January 2020 (07.01.2020), entire document, especially	1-14
Y	US 2006/0074401 A1 (Ross) 06 April 2006 (06.04.2006), entire document, especially	1-14
A	US 2016/0151605 A1 (GMEDIX, INC.) 02 June 2016 (02.06.2016), entire document	1-14
A	US 2013/0197454 A1 (Terumo Kabushiki Kaisha) 01 August 2013 (01.08.2013), entire document	1-14

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

* Special categories of cited documents
"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
03 March 2022	MAR 22 2022
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

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

INARI_020987

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/59718

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

The invention of Group II includes the special technical feature of positioning a distal tip of the aspiration catheter proximate the clot material; activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter, not required in Group I.

The inventions of Groups I-II share the technical features of an aspiration catheter, comprising: a distal portion and a proximal portion, wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion. Specifically, Groups I and II are related as an apparatus (Group I) and methods for using the apparatus (Group II). The apparatus is known in prior art as shown in CN 110652645 A to Shanghai Wanhey Medical Technology Co Ltd (hereinafter "Shanghai"). Therefore, Groups I and II lack unity since the shared technical features do not represent a contribution over Shanghai.

Shanghai discloses of an aspiration catheter (Fig 1A-1B; para [0093]-[0099], para [0115] further teaches wherein the catheter can be used for aspiration), comprising: a distal portion (left half of 10; Fig 1A-1B; para [0093]) and a proximal portion (right half of 10; Fig 1A-1B; para [0093]), wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion (Fig 1A-1B; para [0075]; Shanghai teaches wherein the distal region of the aspiration catheter has good flexibility wherein the flexibility of the distal end of the catheter allows for a distal end of the braid of wires within the distal end of the catheter taught by Shanghai to be flexible and deflectable with respect to the longitudinal axis of the proximal portion taught by Shanghai).

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

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

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (day/month/year)	MAR 22 2022

Applicant's or agent's file reference	FOR FURTHER ACTION
111552-8028WO00	See paragraph 2 below

International application No.	International filing date (day month year)	Priority date (day month year)
PCT/US 21/59718	17 November 2021 (17.11.2021)	18 November 2020 (18.11.2020)

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

IPC - A61M 25/00; A61B 17/22 (2022.01)

CPC - A61M 25/0041; A61M 25/0045

Applicant: INARI MEDICAL, INC.

1. This opinion contains indications relating to the following items:

- [X] 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
- [X] Box No. IV Lack of unity of invention
- [X] 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
- [X] 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	03 March 2022	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 21/59718

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(i)).

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 21/59718

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 examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-14 directed to an aspiration catheter.

Group II: Claims 15-20 directed to a method of removing clot material from a blood vessel.

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

The invention of Group II includes the special technical feature of positioning a distal tip of the aspiration catheter proximate the clot material; activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter, not required in Group I.

The inventions of Groups I-II share the technical features of an aspiration catheter, comprising: a distal portion and a proximal portion, wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion. Specifically, Groups I and II are related as an apparatus (Group I) and methods for using the apparatus (Group II). The apparatus is known in prior art as shown in CN 110652645 A to Shanghai Wathery Medical Technology Co Ltd (hereinafter "Shanghai"). Therefore, Groups I and II lack unity since the shared technical features do not represent a contribution over Shanghai.

Shanghai discloses of an aspiration catheter (Fig 1A-1B; para [0093]-[0099]; para [0115] further teaches wherein the catheter can be used for aspiration), comprising: a distal portion (left half of 10; Fig 1A-1B; para [0093]) and a proximal portion (right half of 10; Fig 1A-1B; para [0093]), wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion (Fig 1A-1B; para [0076]; Shanghai teaches wherein the distal region of the aspiration catheter has good flexibility wherein the flexibility of the distal end of the catheter allows for a distal end of the braid of wires within the distal end of the catheter taught by Shanghai to be flexible and deflectable with respect to the longitudinal axis of the proximal portion taught by Shanghai).

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

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

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. 1-14.

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

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/59718

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1 Statement

Novelty (N)	Claims	1-14	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-14	NO
Industrial applicability (IA)	Claims	1-14	YES
	Claims	None	NO

2 Citations and explanations:
Claims 1-7 lack an inventive step under PCT Article 33(3) as being obvious over CN 110859645 A to Shanghai Wanbey Medical Technology Co Ltd (hereinafter "Shanghai") in view of US 2008/0074401 A1 to Ross.

As per claim 1, Shanghai teaches an aspiration catheter (Fig 1A-1B; para [0003]-[0009]; para [0115] further teaches wherein the catheter can be used for aspiration), comprising:
an inner liner (20; Fig 1A-1B; para [0093]) defining a lumen (21; Fig 1A-1B; para [0093]) and having a proximal region (right half of 20; Fig 1A-1B; para [0093]) and a distal region (left half of 20; Fig 1A-1B; para [0093]);
a braid of wires over the inner liner (40; Fig 1A-1B; para [0093]), [wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained];
a wire coiled over at least a portion of the distal region of the inner liner (30; Fig 1A-1B; para [0093], [0099]); and
an outer sheath over the braid of wires (Box VIII), the wire, and the inner liner (50; Fig 1A-1B; para [0093]).
While Shanghai teaches wherein the distal region of the aspiration catheter has good flexibility (Fig 1A-1B; para [0076]; the flexibility of the distal end of the catheter allows for a distal end of the braid of wires within the distal end of the catheter taught by Shanghai to be flexible and deflectable), Shanghai does not specifically teach wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained. However, Ross teaches a similar catheter (Fig 1-2; para [0024]-[0034]) comprising a braid of wires (2A; Fig 1-2; para [0027]; reinforcing material 24 is taught to be formed of a braid made of metallic filaments) over an inner liner (22; Fig 1-2; para [0027]) wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the catheter is unconstrained (Fig 1-2; para [0026]-[0026], [0035]; Ross teaches wherein the elongate shaft 16, including the reinforcing material 24 can be bent depending on the desired application - see Fig 6 further showing a configuration of the catheter that is formed to a bent configuration at the distal tip of the catheter). Accordingly, it would have been obvious to one of ordinary skill in the art to have employed deflectable portion taught by Ross with the aspiration catheter taught by Shanghai, in order to allow for improved navigation of tortuous vessels (para [0006]-[0010]).

As per claim 2, Shanghai in view of Ross teach the aspiration catheter of claim 1, and Ross further teaches wherein the wires in the deflectable portion of the braid of wires (Box VIII) is pre-shaped to deflect away from the longitudinal axis (Fig 1-2; para [0032]-[0035]; the catheter is taught to be formed as shown in Fig 6 by constraining the catheter in a desired curvature of position and then heating the shaft to shrink the shrink tubing 28, such that the reinforcing material 24 is pre-shaped in the curved configuration).

As per claim 3, Shanghai in view of Ross teach the aspiration catheter of claim 1, and Ross further teaches wherein the deflectable portion of the braid of wires (Box VIII) is configured to deflect away from the longitudinal axis to have a bend angle of between about 165-195 degrees (Box VIII) when the aspiration catheter is unconstrained (Fig 1-2; para [0032]-[0035]; the catheter is taught to be formed as shown in Fig 6 by constraining the catheter in a desired curvature of position and then heating the shaft to shrink the shrink tubing 28, such that the reinforcing material 24 is pre-shaped in the curved configuration - Fig 6 further shows the bend angle to be almost exactly 180 degrees at the distal end, such that the bend angle is reasonably considered to be between 165-195 degrees).

As per claim 4, Shanghai in view of Ross teach the aspiration catheter of claim 1, and Ross further teaches wherein the deflectable portion of the braid of wires (Box VIII) is configured to deflect away from the longitudinal axis to have a bend angle [of about 270 degrees] when the aspiration catheter is unconstrained (Fig 1-2; para [0032]-[0035]; the catheter is taught to be formed as shown in Fig 6 by constraining the catheter in a desired curvature of position and then heating the shaft to shrink the shrink tubing 28, such that the reinforcing material 24 is pre-shaped in the curved configuration). While Ross teaches wherein the catheter can have a bent shape depending on the desired application (para [0025]), Ross does not specifically teach a bend angle of about 270 degrees. However, it is well known that optimizing size, shape and angle is of the ordinary skill in the art. Accordingly, it would have been obvious to one of ordinary skill in the art to have arrived at a bend angle of about 270 degrees, in order to allow for improved navigation of tortuous vessels.

-*-Continued in Supplemental Box-*-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/59718

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-4 and 8-10: The term "the braid" is confusing and lacks proper antecedent basis. The term "the braid" appears to be referring to the braid of wires previously referred to. For purposes of this opinion, the term "the braid" has been interpreted as "the braid of wires."

Claim 3: The recitation "between about between about 165-195 degrees" appears to be a typographical error that is inconsistent with known grammatical standards and has been interpreted to be "between about 165-195 degrees."

Claim 4: The recitation "between about 270 degrees" appears to be a typographical error that is inconsistent with known grammatical standards and has been interpreted to be "about 270 degrees."

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/59718

Supplemental Box

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

As per claim 6, Shanghai in view of Ross teach the aspiration catheter of claim 1. While Shanghai teaches wherein the aspiration catheter can be used as a neurovascular catheter (para [0007]-[0008]), Shanghai does not specifically teach wherein the lumen has a diameter of 20 French or greater. However, it is well known in the art that routine experimentation and various engineering design choices could have been made to have arrived at wherein the lumen has a diameter of 20 French or greater (Note: providing a larger diameter allows for aspiration of larger vessels, such as the aorta, which help provide oxygenated blood to the brain and spinal cord). Accordingly, it would have been obvious to one of ordinary skill in the art to have arrived at wherein the lumen has a diameter of 20 French or greater, in order to allow for use in larger blood vessels.

As per claim 6, Shanghai in view of Ross teach the aspiration catheter of claim 1. While Shanghai teaches wherein the aspiration catheter can be used as a neurovascular catheter (para [0007]-[0008]), Shanghai does not specifically teach wherein the lumen has a diameter of 24 French or greater. However, it is well known in the art that routine experimentation and various engineering design choices could have been made to have arrived at wherein the lumen has a diameter of 24 French or greater (Note: providing a larger diameter allows for aspiration of larger vessels, such as the aorta, which help provide oxygenated blood to the brain and spinal cord). Accordingly, it would have been obvious to one of ordinary skill in the art to have arrived at wherein the lumen has a diameter of 24 French or greater, in order to allow for use in larger blood vessels.

As per claim 7, Shanghai in view of Ross teach the aspiration catheter of claim 1 wherein the inner liner is formed from polytetrafluoroethylene material (Fig 1A-1B; para [0097]), and wherein the outer sheath is formed from a thermoplastic elastomer material (Fig 1A-1B; para [0110]; the outer layer 50 is taught to be made of Pebax).

Claims 1 and 8-14 lack an inventive step under PCT Article 33(3) as being obvious over Shanghai in view of Ross (second treatment)

As per claim 1, Shanghai teaches an aspiration catheter (Fig 1A-1B; para [0093]-[0099]; para [0115] further teaches wherein the catheter can be used for aspiration), comprising:
an inner liner (20; Fig 1A-1B; para [0093]) defining a lumen (21; Fig 1A-1B; para [0093]) and having a proximal region (right half of 20; Fig 1A-1B; para [0093]) and a distal region (left half of 20; Fig 1A-1B; para [0093]);
a braid of wires over the inner liner (40; Fig 1A-1B; para [0093]), [wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained];
a wire coiled over at least a portion of the distal region of the inner liner (30; Fig 1A-1B; para [0093], [0099]); and
an outer sheath over the braid of wires (Box VIII), the wire, and the inner liner (50; Fig 4; para [0111]; Shanghai teaches an outer layer 50, which can be reasonably considered to be used with the catheter 10 shown in Fig 1A-1B).
While Shanghai teaches wherein the distal region of the aspiration catheter has good flexibility (Fig 1A-1B; para [0076]; the flexibility of the distal end of the catheter allows for a distal end of the braid of wires within the distal end of the catheter taught by Shanghai to be flexible and deflectable), Shanghai does not specifically teach wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained. However, Ross teaches a similar catheter (Fig 1-2; para [0024]-[0034]) comprising a braid of wires (24, Fig 1-2, para [0027]; reinforcing material 24 is taught to be formed of a braid made of metallic filaments) over an inner liner (22; Fig 1-2; para [0027]) wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the catheter is unconstrained (Fig 1-2; para [0025]-[0026], [0035]; Ross teaches wherein the elongate shaft 16, including the reinforcing material 24 can be bent depending on the desired application - see Fig 8 further showing a configuration of the catheter that is formed to a bent configuration at the distal tip of the catheter). Accordingly, it would have been obvious to one of ordinary skill in the art to have employed deflectable portion taught by Ross with the aspiration catheter taught by Shanghai, in order to allow for improved navigation of tortuous vessels (para [0006]-[0010]).

As per claim 8, Shanghai in view of Ross teach the aspiration catheter of claim 1 wherein the outer sheath has a first hardness over the proximal region (Fig 4; para [0111]; the proximal region of outer layer 50 is taught to comprise a material with about a 75D shore hardness), and wherein the outer sheath has a second hardness over the distal region of the inner liner that is less than the first hardness (Fig 4; para [0111]; the distal part of the outer layer 50 is taught to comprise an ultra-low hardness material, which has a hardness of about 60A shore hardness).

-*-Continued in next Supplemental Box-*-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/59718

Supplemental Box

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

As per claim 9, Shanghai teaches an aspiration catheter (Fig 1A-1B, 4; para [0080]-[0088]; [0111]-[0112]; para [0115] further teaches wherein the catheter can be used for aspiration), comprising:
a proximal region defining a longitudinal axis (region of 10 comprising proximal part of outer layer 50; Fig 1A-1B, 4; para [0093]-[0099]; [0111]-[0112]; the outer layer 50 is taught to comprise three parts, including a proximal part, positioned at the proximal end of the catheter body 10);
an intermediate region extending from the proximal region (region of 10 comprising transition section of outer layer 50; Fig 1A-1B, 4; para [0093]-[0099]; [0111]-[0112]; the outer layer 50 is taught to comprise three parts, including a transition section extending from the proximal part of the proximal end of the catheter body 10);
a distal region extending from the intermediate region (region of 10 comprising distal part of outer layer 50; Fig 1A-1B, 4; para [0093]-[0099]; [0111]-[0112]; the outer layer 50 is taught to comprise three parts, including a distal part, positioned at the distal end of the catheter body 10);
an inner liner (30; Fig 1A-1B; para [0093]) defining a lumen (21; Fig 1A-1B; para [0093]) and extending through the proximal region, the intermediate region and the distal region (Fig 1A-1B; para [0093]-[0099]);
a braid of wires extending over the inner liner and through the proximal region, the intermediate region and the distal region (40; Fig 1A-1B; para [0093]), [wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained];
a wire coiled in the distal region (30; Fig 1A-1B; para [0093], [0096]); and
an outer sheath extending over the braid of wires (Box VIII), the wire, and the inner liner and through the proximal region, the intermediate region, and the distal region (50; Fig 4; para [0111]-[0112]; Shanghai teaches an outer layer 50, which can be reasonably considered to be used with the catheter 10 shown in Fig 1A-1B).
While Shanghai teaches wherein the distal region of the aspiration catheter has good flexibility (Fig 1A-1B; para [0078]; the flexibility of the distal end of the catheter allows for a distal end of the braid of wires within the distal end of the catheter taught by Shanghai to be flexible and deflectable), Shanghai does not specifically teach wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained. However, Ross teaches a similar catheter (Fig 1-2; para [0024]-[0034]) comprising a braid of wires (24; Fig 1-2; para [0027]; reinforcing material 24 is taught to be formed of a braid made of metallic filaments) over an inner liner (22; Fig 1-2; para [0027]) wherein a deflectable portion of the braid of wires (Box VIII) over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the catheter is unconstrained (Fig 1-2; para [0025]-[0026], [0035]; Ross teaches wherein the elongate shaft 16, including the reinforcing material 24 can be bent depending on the desired application - see Fig 6 further showing a configuration of the catheter that is formed to a bent configuration at the distal tip of the catheter). Accordingly, it would have been obvious to one of ordinary skill in the art to have employed deflectable portion taught by Ross with the aspiration catheter taught by Shanghai, in order to allow for improved navigation of tortuous vessels (para [0006]-[0010]).

As per claim 10, Shanghai in view of Ross teach the aspiration catheter of claim 1, and Ross further teaches wherein the deflectable portion of the braid of wires (Box VIII) is configured to deflect away from the longitudinal axis to have a bend angle of between about 165-195 degrees (Box VIII) when the aspiration catheter is unconstrained (Fig 1-2; para [0032]-[0035]; the catheter is taught to be formed as shown in Fig 6 by constraining the catheter in a desired curvature of position and then heating the shaft to shrink the shrink tubing 28, such that the reinforcing material 24 is pre shaped in the curved configuration - Fig 6 further shows the bend angle to be almost exactly 180 degrees at the distal end, such that the bend angle is reasonably considered to be between 165-195 degrees).

As per claim 11, Shanghai in view of Ross teach the aspiration catheter of claim 9 wherein the outer sheath has (a) a first hardness in the proximal region of between about 55D-75D (Fig 4; para [0111]; Shanghai teaches wherein the proximal part of outer layer 50 has a shore hardness of about 75D), (b) a second hardness in the intermediate region of between about 30D-60D (Fig 4; para [0111]; Shanghai teaches wherein the transition section has a shore hardness of between 30D-63D allowing for a shore hardness of 63D to make up the transition section), and (c) a third hardness in the distal region (of between about 30D-40D (Fig 4; para [0111]; Shanghai teaches wherein the distal part has a shore hardness of about 60A). While Shanghai teaches wherein a third hardness is less than the first hardness and the second hardness (Fig 4; para [0111]), Shanghai does not specifically teach between about 30D-40D. However, it is well known in the art that routine experimentation and various engineering design choices could have been made to have arrived at between about 30D-40D. Accordingly, it would have been obvious to one of ordinary skill in the art to have arrived at between about 30D-40D, in order to provide improved structural integrity in the distal region of the aspiration catheter.

As per claim 12, Shanghai in view of Ross teach the aspiration catheter of claim 9 wherein the outer sheath (a) has a first hardness in the proximal region (Fig 4; para [0111]; Shanghai teaches wherein the proximal part of outer layer 50 has a shore hardness of about 75D), (b) a second hardness in the intermediate region less than the first hardness (Fig 4; para [0111]; Shanghai teaches wherein the transition section has a shore hardness of between 30D-63D), and (c) a third hardness in the distal region less than the second hardness (Fig 4; para [0111]; Shanghai teaches wherein the distal part has a shore hardness of about 60A).

As per claim 13, Shanghai in view of Ross teach the aspiration catheter of claim 12 wherein (a) the proximal region has a first length (Fig 4; para [0112]; the proximal part is taught to have a length of 1000-1200mm), (b) the intermediate region has a second length less than the first length (Fig 4; para [0112]; the transition section is taught to have a length of 10-50mm), and (c) the distal region has a third length greater than the second length and less than the first length (Fig 4; para [0112]; the distal part is taught to comprise a length of 100-200mm).

-*-Continued in next Supplemental Box-*-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/59718

Supplemental Box

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

As per claim 14, Shanghai in view of Ross teach the aspiration catheter of claim 13. While Shanghai teaches wherein the overall length of the catheter body can be easily modified to suit specific applications, Shanghai does not specifically teach wherein the first length is between about 20.0- 28.0 inches, the second length is between about 2.0-3.0 inches, and the third length is between about 11.00-15.00 inches. However, it is well known that optimizing size, shape and angle is of the ordinary skill in the art. Accordingly, it would have been obvious to one of ordinary skill in the art to have optimized the size of the first length, the second length and the third length to have arrived at wherein the first length is between about 20.0- 28.0 inches, the second length is between about 2.0-3.0 inches, and the third length is between about 11.00-15.00 inches. Accordingly, it would have been obvious to one of ordinary skill in the art to have arrived at wherein the first length is between about 20.0- 28.0 inches, the second length is between about 2.0-3.0 inches, and the third length is between about 11.00-15.00 inches, in order to improve navigation of the aspiration catheter within blood vessels.

Claims 1-14 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

(19)中华人民共和国国家知识产权局

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US 7285126 B2,2007.10.23,说明书第11栏第2段至第13栏第4段,图10-14.
US 2004/0006361 A1,2004.01.08,全文.
US 2002/0010487 A1,2002.01.24,全文.
审查员 王婷婷

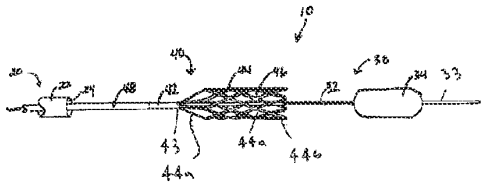
权利要求书1页 说明书13页 附图14页

(54)发明名称

流动恢复系统

(57)摘要

提供了用于移除体腔内的阻塞性物质的装置和方法。所述装置包括从套管可部署的剥离器装置，剥离器装置包括由轴承载且位于约束管内的可扩展笼。该轴相对于约束管可移动，以在体腔内部署和扩展笼，使得笼的开放端被定向为朝向阻塞性物质。笼前进以捕获物质或者通过在物质之外扩展并被收回的可扩展部件将物质引入笼中。笼撤回到约束管内以径向向内地压缩笼。穿过笼中的孔延伸的物质通过约束管的锋利的边缘被削切。然后通过套管从体腔抽吸更小的、被削切的颗粒。



CN 102186427 B

1. 一种用于从体腔移除阻塞性物质的系统，包括：

外部管状部件，包括近端、被确定尺寸以被引入体腔的远端、以及在所述近端与所述远端之间延伸的腔；

阻塞装置，能够从所述管状部件被部署至将要被移除的阻塞性物质之外的位置，所述阻塞装置包括位于其远端上的可扩展部件；以及

剥离器装置，包括在轴的远端上承载的可扩展笼和约束管，所述约束管用于使所述笼保持在收缩形态以允许所述剥离器装置通过管状部件腔被引入到所述体腔中，所述笼在体腔内能够从所述约束管的远端被部署并且能够扩展至扩展形态，所述笼包括与处于所述扩展形态的笼的内部连通的开放端，以将阻塞性物质捕获到所述笼的内部，

其中，所述笼包括管状结构，所述管状结构包括在所述笼的开放端和闭合端之间延伸的壁，所述笼包括在所述开放端与所述闭合端之间延伸的多个支杆，由此在所述壁中限定了多个孔，

所述多个支杆包括通常在所述笼的开放端和闭合端之间轴向延伸的第一组支杆，以及在所述第一组支杆的相邻支杆之间不连续延伸的第二组支杆，从而限定网状壁结构，

所述第一组支杆具有比所述第二组支杆更大的刚性，使得所述笼关于其纵轴在第一方向的旋转引起所述笼径向扩展。

2. 如权利要求 1 所述的系统，其中，所述阻塞装置能够相对于所述剥离器装置移动，使得扩展的可扩展部件将置于所述可扩展部件与所述笼之间的阻塞性物质引导至所述笼的开放端内，以将所述物质捕获到所述笼的内部。

3. 如权利要求 1 所述的系统，其中，所述笼能够在体腔内扩展之后缩回到所述约束管中，使得所述笼的闭合端可滑动地与所述约束管的远端接合并且使得所述笼向所述收缩形态被压缩。

4. 如权利要求 3 所述的系统，其中，所述笼包括管状结构，所述管状结构包括在所述笼的开放端和闭合端之间延伸的壁，所述壁包括限定了期望孔隙尺寸的多个孔，从而当随着所述笼缩回到所述约束管中，所述笼可滑动地与所述约束管的远端接合时，由所述笼捕获的通过所述孔延伸的阻塞性物质通过所述约束管的远端而与所述笼分离。

5. 如权利要求 4 所述的系统，进一步包括真空源，所述真空源连接至所述管状部件的腔，以将与所述笼分离的阻塞性物质抽吸到所述管状部件的腔中。

6. 如权利要求 1 所述的系统，其中，所述剥离器装置的轴包括在其近端和远端之间延伸的腔，以在该腔中可滑动地接纳所述阻塞装置，所述可扩展部件处于收缩形态。

7. 如权利要求 1 所述的系统，进一步包括从所述笼的开放端向远侧延伸的多个远末端。

INARI_020998

流动恢复系统

[0001] 相关申请

[0002] 本申请要求共同未决的 2008 年 9 月 22 日提交的第 61/099,171 号美国临时专利申请、2009 年 1 月 9 日提交的第 61/143,603 号美国临时申请和 2009 年 2 月 12 日提交的第 61/152,227 号美国临时专利申请的优先权，其全部公开通过引用明确并入本文。

技术领域

[0003] 本发明通常涉及用于处理患者体腔（例如，管状移植物 (tubulargraft)、主动脉 - 静脉瘘 (aorto-venous fistula)、血管等）内的阻塞性物质（例如，血栓，器官狭窄）和 / 或不期望物质的装置。更具体地，本发明涉及用于移除或以其它方式捕获体腔内的血栓或其它阻塞性物质的装置，以及制造和使用这种装置的方法。

背景技术

[0004] 患者脉管系统内的血管或其它体腔内的流动可能由于各种原因而变得缩窄或最终中断。例如，炎症和 / 或细胞增殖可能导致血管逐渐变窄。此外，这种变窄或血管内的其它流动问题可能导致血栓的形成。

[0005] 移除粘附至血管壁的不期望物质（例如，血栓）的一种方法可涉及使装置（例如，Fogarty（福格蒂）栓子清除气囊）前进至附着的阻塞性物质之外的一点，将装置扩展至血管内部的尺寸，然后撤回扩展的装置，以将附着的物质清扫出血管。虽然这种方法经常是成功的，但是也存在一些情况：附着的物质没有脱离血管壁，并且甚至在多次通过后仍然留在血管内。

[0006] 移除附着的物质的另一种方法是推进可以刮擦附着的物质的表面或与附着的物质缠绕在一起的旋转结构，从而迫使附着的物质脱离血管壁。Arrow Treratola 装置具有若干径向向外扩展以接触血管壁的螺 旋线。通过连接至装置的机头中电动机的驱动轴使这些线高速旋转。在操作过程中，当 Treratola 装置前进时，它摩擦血管的内壁。一旦与附着的物质接合 (engage)，装置刮擦该物质的内表面，而且在许多情况下，装置可冲破附着的物质与血管壁之间的界面。在这种情况下，附着的物质可从血管壁脱落，并且缠绕在 Treratola 装置的螺旋线上。

[0007] 虽然这可解决从血管壁移除附着的物质的直接目标，但是往往很难从血管本身移除物质，因为 Treratola 装置没有提供任何方法来解开 (unwind) 或抽吸物质。当 Treratola 装置从血管移除时，它通常通过紧贴的孔，例如导引器套管。任何缠绕在 Treratola 装置上的物质在该 Treratola 装置进入套管时被推落，因此这些物质仍然留在血管中。

[0008] 因此，从主动脉 - 静脉瘘、血管或其它体腔中移除物质的装置和方法是有用的。

发明内容

[0009] 本发明涉及处理患者体腔（例如管状移植物、主动脉 - 静脉瘘、血管等）的装置。更具体地，本发明涉及用于移除或以其它方式捕获体腔内的血栓或其它阻塞性物质的装

INARI_020999

置，以及制造和使用这种装置的方法。

[0010] 根据一个实施方式，提供了用于从体腔移除阻塞性物质的系统。所述系统包括外部管状部件，其包括近端、远端、以及在近端与远端之间延伸的腔。任选地，环形可扩展阻塞部件可设置在外部管状部件远端上。该系统还包括剥离器装置，其可插入通过腔并且包括细长轴、连接至细长轴远端的可扩展笼、以及包括具有锋利的边缘的远端开口的约束管，其中，轴和笼相对于约束管轴向可移动。可选地，约束管固定地连接至外部管状部件的内表面，或者约束管可独立于外部管状部件可移动。

[0011] 笼可包括多个孔，并且约束管的远端锋利的边缘被配置为当将笼撤回到约束管时削切通过孔突出的阻塞性物质。任选地，笼的内表面可包括多个向内突出的倒钩。笼可包括远端伸出结构和/或厚支杆以及与厚支杆连接在一起的薄支杆。任选地，一根或多根控制线可连接至 笼的远端伸出结构，其中，控制线可被配置为当笼处于扩展形态时，将伸出结构一起拉向闭合形态。任选地，驱动轴可操作地连接至笼，以使笼在通过体腔前进期间旋转，或者该系统可包括促动器从而手动地旋转笼。在示例性实施方式中，所述远端伸出结构可具有平滑边缘、具有沟槽的边缘或蜿蜒的边缘。

[0012] 在示例性实施方式中，系统可进一步包括具有可扩展处理元件的细长处理部件，可扩展处理元件选择性地可扩展以当笼处于扩展形态时将体腔内的阻塞性物质引入到笼中。细长处理部件可插入通过穿过剥离器装置轴中的腔。可选地，细长处理部件可插入通过邻近剥离器装置轴的外部管状部件腔。任选地，在这个可选实施方式中，笼可包括细长处理部件可通过的不间断的路径或其它开口。

[0013] 根据另一实施方式，提供了用于从体腔移除阻塞性物质的方法，包括将外部管状部件引入到体腔内，外部管状部件包括腔和远端开口。可通过管状部件腔将剥离器装置引入到体腔内。在示例性实施方式中，剥离器装置包括细长轴，连接至细长轴远端的可扩展笼，以及具有远端开口的约束管。通过使细长轴相对于约束管向远侧前进可将可扩展笼部署在约束管远端开口的外部，并且使其在体腔内扩展。可将阻塞性物质捕获到笼内，然后将笼向近侧撤回到约束管中。当笼收缩时，通过笼中的孔突出的物质可被削切，例如，通过约束管远端开口的锋利的边缘被削切。附加地或者可选地，可将削切的物质抽吸到外部管状部件远端开口中。任选地，方法还可包括在外部管状部件远端上扩展阻塞部件，例如以防止阻塞性物质紧邻地经过外部管状部件的远端。

[0014] 在示例性实施方式中，所述方法还可包括将将包括远端可扩展处理元件的细长处理部件引导通过外部管状部件腔并引入到体腔中，使得处于收缩形态的可扩展处理元件位于阻塞性物质的远侧，并且笼被定位在阻塞性物质的近侧。可扩展处理元件可以被扩展并且将可扩展处理元件向近侧朝向可扩展笼撤回，使得阻塞性物质被撤到笼的开放端内。

[0015] 在另一示例性实施方式中，所述方法还可包括使可扩展笼朝向阻塞性物质前进并且在推进期间使笼旋转，直至阻塞性物质缠绕在笼的 远端部。笼的旋转可引起所述阻塞性物质与血管壁分离，并且笼可撤回到约束管中。所述撤回步骤可从笼远端部释放阻塞性物质和/或将阻塞性物质撤到约束管中。任选地，笼可一次或多次地重新部署、扩展和/或撤回，例如以分离阻塞性物质和/或将阻塞性物质撤到笼中。

[0016] 根据另一实施方式，提供了用于从体腔移除阻塞性物质的装置，包括：外部管状部件，包括近端、被确定尺寸以被引入体腔的远端、以及在近端与远端之间延伸的腔；细长轴，

INARI_021000

包括近端和远端并且在管状部件腔内轴向可移动；以及可扩展的剥离器笼，包括附接至轴的远端的第一端和第二自由端。当笼被置于管状部件腔内时笼可从收缩形态扩展，当笼从管状部件腔被部署时笼可从扩展形态扩展。

[0017] 在一个实施方式中，笼包括管状结构，管状结构包括在第一端与第二端之间延伸的壁，第二端限定了与处于扩展形态的笼的内部连通的开口，以将阻塞性物质捕获到笼的内部。壁可包括多个支杆 / 孔，使得当笼在将阻塞性物质捕获到笼内之后撤回到管状部件腔时，管状部件的远端可滑动地与笼的壁接合，或者以其它方式分离由笼捕获的穿过孔延伸的阻塞性物质，并且将笼压缩回到收缩形态。

[0018] 根据又一实施方式，提供了用于从体腔移除阻塞性物质的系统，包括：外部管状部件，包括近端、被确定尺寸以被引入体腔的远端、以及在近端与远端之间延伸的腔；阻塞装置，从管状部件可被部署至将要被移除的阻塞性物质之外的位置，阻塞装置包括位于其远端上的可扩展部件；以及剥离器装置。剥离器装置可包括轴的远端上承载的可扩展笼以及用于使笼保持在收缩形态的约束管，例如以允许将剥离器装置通过管状部件引入体腔中。笼可从约束管的远端可部署并且在体腔内可扩展至扩展形态。在一个实施方式中，笼可包括与处于扩展形态的笼的内部连通的开放端，以将阻塞性物质捕获到笼的内部。

[0019] 考虑下面结合附图的描述，本发明的其它方面和特征将会变得显而易见。

附图说明

[0020] 应理解的是，图中所示的示例性装置不必按照比例绘制，主要用于强调而非说明所示实施方式的各个方面和特征。

[0021] 图 1 是包括从进入套管可部署的剥离器装置和闭塞装置的流动恢复系统的示例性实施方式的侧视图；

[0022] 图 2A 是可包含在图 1 的系统中的进入套管的截面侧视图，该图包括位于进入套管的远端上的可扩展部件；

[0023] 图 2B 是可包含在图 1 的系统中的进入套管的可选实施方式的截面侧视图，该图包括位于进入套管的远端上的可扩展部件；

[0024] 图 3 是可包含在图 1 的系统中的剥离器装置的笼的内表面的细部；

[0025] 图 4A 和图 4B 是可包含在图 1 的系统的剥离器装置中的约束管的示例性实施方式的截面侧视图；

[0026] 图 5 是进入装置的可选实施方式的截面侧视图，该进入装置包括可包含在图 1 系统中的整合的约束管；

[0027] 图 6 是包括从进入套管可部署的剥离器装置和闭塞装置的流动恢复系统的另一示例性实施方式的侧视图；

[0028] 图 7 至图 10 示出了患者身体内体腔的截面视图，其示出了移除体腔内阻塞性物质的方法；

[0029] 图 11A 和图 11B 分别是处于扩展形态和收缩形态的剥离器装置的另一示例性实施方式的透视图；

[0030] 图 12A 是可以并入图 11A 和图 11B 的剥离器装置笼的平面样式的俯视图；

[0031] 图 12B 是图 12A 的平面样式的一部分的细部；

INARI_021001

[0032] 图 13 是图 11A 和图 11B 中所示的剥离器装置笼沿方向 A 旋转的详细透视图；

[0033] 图 14A 和图 14B 是剥离器装置笼的另一示例性实施方式的截面图，该剥离器装置包括控制线，分别用于在开放结构与闭合结构之间引导笼的远端；

[0034] 图 14C 是图 14A 和图 14B 的剥离器装置笼的可选示例性实施方式的截面图，该剥离器装置包括控制线以及围绕控制线的套管，以在开放结构与闭合结构之间引导笼；

[0035] 图 15A 至图 15C 是可设置在剥离器装置笼（如图 11A 和图 11B 中所示的笼）上的远末端的可选实施方式的侧视图；以及

[0036] 图 16A 至图 16H 是患者身体内体腔的截面视图，其示出了移除体腔内阻塞性物质的另一方法。

具体实施方式

[0037] 转到附图，图 1 示出了用于处理体腔的装置 10 的示例性实施方式，装置 10 例如用于从体腔（诸如血管、主动脉 - 静脉瘘、管状移植物等）内移除血栓、血块、物体、碎片和 / 或其它不期望的或阻塞性物质。通常，装置 10 包括外部进入套管或其它管状部件 20、以及任选地阻塞装置 30 和剥离器 (macerator) 装置 40，它们一起可提供流动恢复系统，例如以从患者身体的体腔内移除阻塞性物质。另外，这种系统可包括一个或多个未示出的附加部件，例如，一根或多根导引线 (guidewire)、注射器或膨胀介质和 / 或真空的其它源等。

[0038] 套管 20 可以是细长的管状体（例如，导引器或手术 (procedure) 套管），包括近端（未示出）、被确定尺寸以被引入体腔内的远端 22、以及在近端与远端 22 之间延伸的腔 24。套管 20 可被配置为经皮置于体腔内，例如包括圆的或其它基本上无损伤的末端，从而便于推入到患者身体内的体腔内和 / 或沿着患者身体内的体腔前进。

[0039] 套管 20 可具有沿着其长度基本均匀的结构，或可选地，该结构可以是变化的。例如，套管 20 的近端部可以是基本刚性或半刚性的以通过推动或以其它方式操纵近端来方便装置 10 的前进。附加地或可选地，套管 20 的远端部可以是柔性的，例如以便于折弯和 / 或在弯曲的解剖结构中前进而不存在扭结或弯曲变形的高风险。在示例性实施方式中，形成套管 20 的材料可以是诸如金属、塑料（例如 PEEK、GrilamedL25 等）、或复合材料。套管 20 的长度可约在 5cm 至 130cm 之间，外径约在 1.6 毫米至 2.0 毫米之间，腔 24 的直径可约在 1.4 毫米与 1.8 毫米之间。

[0040] 任选地，套管 20 可在近端（未示出）上包括握柄或套筒 (hub)。如下进一步描述，握柄可成形为便于握住或操纵装置 10 或装置 10 的单独部件。另外，握柄可包括与例如围绕剥离器装置 40 和 / 或阻塞装 置 30 的腔 24 连通的端口，例如以将流体注入腔 24 和 / 或从腔 24 抽吸物质。如下进一步描述，例如，注射器、真空管线等可连接至端口，以抽吸容纳在套管 20 的腔 24 内和 / 或在体腔内邻近远端 22 放置的阻塞性物质。

[0041] 任选地，套管 20 可包括由远端 22 承载的可扩展 (expandable) 部件或其它阻塞元件，例如以在体腔内固定套管 20 和 / 或密封体腔以防止在手术期间流体流过远端 22。例如，图 2A 示出了体腔 50 内的套管 20'，该套管 20' 包括位于其远端 22' 上的可扩展部件 26'。如果需要，可扩展部件 26' 可以是柔性气囊（例如由柔性材料制成，其可根据运送到气囊 26' 中的膨胀介质的量成比例地弹性扩展）、半柔性气囊或非柔性气囊（例如 PTA 气囊）。在这个实施方式中，套管 20' 可包括从套管 20' 的近端延伸到远端 22' 且与气囊 26' 的内

INARI_021002

部连通的膨胀腔（未示出）。诸如具有盐溶液或其它流体的注射器等的膨胀介质和/或真空的源（未示出）可连接至套管 20' 的近端，以经由膨胀腔将膨胀介质运送到气囊 26' 中和/或从气囊 26' 中抽吸流体，例如，以便于在手术后使气囊收缩。可选地，可扩展部件 26' 可以是以机械或其它方式可扩展的，例如，包括可扩展框架、或者在膜（未示出）内或以其它方式连接至膜（未示出）的其它结构。

[0042] 可扩展部件 26' 可从低轮廓、收缩形态（例如，抵靠套管 20' 的外表面布置以便于套管 20' 的引入）扩展，并且可从高轮廓、扩展形态扩展，例如以与其内引入套管 20' 的体腔 50 的内表面接合或以其它方式接触。在扩展形态中，可扩展部件 26' 可在体腔 50 内提供基本的流体密封，例如以防止沿着体腔 50 的大量生理流动，否则其可能允许松散物质的颗粒移动经过套管 20 进入患者身体的其它部位，在那里颗粒可能造成伤害。附加地或可选地，可扩展部件 26' 还可基本上固定和/或稳定体腔 50 内的套管，例如，以防止在处理过程中体腔 50 内的套管 20' 因疏忽而移动。

[0043] 在使用过程中，在套管 20' 被引入时，可扩展部件 26' 可保持低轮廓形态，然后一旦套管 20' 被定位在正被处理的体腔 50 内，则可扩展部件 26' 扩展至高轮廓形态。当阻塞性物质从体腔 50 经由套管 20' 或 装置 10 的其它部件移除时，可扩展部件 26' 可保持扩展状态，如下进一步描述。一旦体腔 50 被充分处理，则可扩展部件 26' 可收缩以恢复体腔 50 内的生理流动。

[0044] 在图 2B 中所示的可替换实施方式中，可提供包括可扩展部件 26" 的进入套管 20"，可扩展部件 26" 延伸到套管 20" 的远端 22" 之外以为套管 20" 提供可扩展的远末端。因此，可扩展部件 26" 可提供从增大的远末端向套管 20" 的腔 24" 的圆锥形过渡或其它过渡，例如，如果需要，可在可扩展部件 26" 的远末端内或邻近可扩展部件 26" 的远末端执行阻塞性物质的剥离。在剥离期间，阻塞性物质的颗粒可在套管 20" 的腔 24" 内或者邻近套管 20" 的腔 24" 释放。在 2009 年 8 月 8 日提交的第 PCT/US09/53237 号申请中可得到进入套管 20" 和/或可扩展部件 26" 的更多信息，该申请的全部公开通过引用明确并入本文。

[0045] 回到图 1，阻塞装置 30 通常包括轴或其它细长部件 32，其包括近端（未示出）和远端 33，远端 33 被确定尺寸以被引导例如经由腔 24 穿过套管 20，并且在远端 33 上承载有可扩展的阻塞或处理部件 34。通常，阻塞部件 34 从收缩形态（未示出）（例如，其尺寸适合被引导通过套管 20 的腔 24）扩展，并从扩展形态（图 1 所示）扩展，以与体腔的壁接合或以其它方式接触，其中阻塞部件 34 在体腔内扩展。在示例性实施方式中，阻塞部件 34 可以是可扩展成基本上球形或圆筒形的气囊，例如柔性气囊、半柔性气囊或非柔性气囊。在这个实施方式中，轴 32 可包括与阻塞部件 34 的内部连通的膨胀腔（未示出），例如，以选择性地扩展和收缩阻塞部件 34。任选地，阻塞部件 34 可包括芯线和/或螺旋结构（未示出），例如使得阻塞部件可在扩展形态中采用螺旋形。在 2009 年 7 月 2 日提交的第 12/497,135 号共同未决申请中公开了可用于阻塞部件 30 的示例性装置，该申请的全部公开通过引用明确地并入本文。可选地，如果需要，阻塞部件 34 可包括框架或其它机械上可扩展的结构（未示出）。

[0046] 继续参照图 1，剥离器装置 40 通常包括轴或其它细长部件 42，其包括近端（未示出）和远端 43、以及在远端 43 上承载的可扩展笼 44，远端 43 被确定尺寸以适配于套管 20 的腔 24 内。任选地，如下进一步 描述，轴 42 可包括腔或其它轨道（未示出），以可滑动地

INARI_021003

容纳通过该腔或其它轨道的阻塞部件 30。附加地或可选地，如下进一步描述，轴 42 可包括一个或多个附加腔（未示出），例如用于接收导引线或其它轨（也未示出），一个或多个促动器线或线缆（也未示出）等。

[0047] 如图所示，笼 44 是开放的或多孔的可扩展结构，其包括连接至轴 42 的闭合的近端或第一端 44a 以及开放的远端或第二端 44b，例如，以在笼 44 内容纳接收的阻塞性物质，如下进一步描述。通常，笼 44 包括在第一端 44a 与第二端 44b 之间和 / 或围绕笼 44 的外周延伸的多个支杆 (struts)44a，由此例如至少邻近第一端 44a 限定了包括多个孔 46 的圆筒形外壁或其它管状外壁。支杆 44a 和 / 或孔 46 可被确定尺寸以适应笼 44 的扩展和 / 或收缩，和 / 或限定期望的孔隙尺寸，一旦比期望孔隙尺寸大的颗粒被捕获到笼 44 内，则该期望的孔隙尺寸防止该颗粒逃脱，如下进一步描述。

[0048] 笼 44 从例如适于低轮廓、收缩形态（未示出）（以适于被引导通过套管 20）和高轮廓、扩展形态（图 1 所示）扩展，在高轮廓、扩展形态中，笼 44 径向向外扩展，例如以接触的体腔的壁，其中笼 44 在体腔内被部署 (deploy) 和 / 或扩展。任选地，如图 3 所示，笼 44 可包括从支杆 44a 径向向内突出的多个倒钩或其它特征 41，例如以与被捕获到笼 44 内的阻塞性物质接合和 / 或对其提供附加的牵引力，如下进一步描述。

[0049] 笼 44 可由例如能够在收缩形态与扩展形态之间弹性或塑性地变化一次或多次的多种材料形成。例如，笼 44 可由弹性或超弹性材料形成，例如金属（如不锈钢、镍钛合金等）、塑料或复合材料。在示例性实施方式中，笼 44 可由管形成，该管的一个或多个部分通过激光切割、蚀刻、机械切割等被移除以限定支杆 44a 和 / 或孔 46。可选地，笼 44 可由片形成，该片的一个或多个部分也通过激光切割、蚀刻、机械切割、冲压等被移除以限定支杆 44a 和 / 或孔 46，该片可例如通过焊接、钎焊、用粘接剂粘合、熔化等将片的边缘附接在一起以卷成管状形状。

[0050] 然后，例如通过绕着闭合端 44a 压接、粘接剂粘合、熔接、缠绕轴环、线或其它材料等，绕着轴 42 的远端 43 基本上永久地附接闭合 端 44a，从可使笼 44 附接至轴 42。因此，闭合端 43 可固定在收缩形态，而笼 44 的其余部分可自由地从收缩形态扩展至扩展形态。在示例性实施方式中，笼 44 可由超弹性材料形成，该超弹性材料可被加热处理以将扩展形态设计到笼 44 中，并且允许笼 44 被弹性压缩并保持在收缩形态。

[0051] 因此，在图 1 所示的实施方式中，笼 44 可以是自扩展结构，例如，径向向内弹性地可压缩至收缩形态，而偏移 (bias) 以向扩展形态扩展。可选地，笼 44 可例如通过剥离器装置 40 近端上连接至笼 44 的促动器（未示出）进行机械地扩展和收缩。

[0052] 为了将自扩展笼 44 维持在收缩形态，例如在被引导通过套管 20 期间或者从套管 20 被部署之前，剥离器装置 40 可包括绕着轴 42 可滑动地布置的约束管 48。约束管 48 可以是细长的管状体，包括近端（未示出）、远端 48a、以及在近端与远端 48a 之间延伸的腔 49，腔 49 被确定尺寸以接收轴 42 和处于收缩形态的笼 44。可选地，可围绕笼 44 设置其它可移动的约束件，以将笼 44 维持在收缩形态，直至期望在体腔内部署笼 44 并使其扩展，其它可移动的约束件例如为围绕笼 44 缠绕的一根或多根可移除的线、撕开的套等（未示出）。

[0053] 约束管 48 的远端 48a 可被确定尺寸以可滑动地布置在套管 20 内，例如，以容纳剥离器装置 40 被引导通过套管 20 的腔 24。约束管 48、轴 42 和笼 44 可轴向地相对彼此移动，例如，以允许笼 44 被收回到约束管 48 内和 / 或从约束管 48 被部署。因此，例如在通过套

INARI_021004

管 20 将笼 44 引入体腔期间，约束管 48 可将笼 44 维持在收缩形态，并允许笼 44 从约束管 48 被部署，使得笼 44 呈现扩展形态。

[0054] 轴 42 和 / 或约束管 48 的近端（未示出）可延伸或以其它方式连接至套管 20 的近端，并且可从套管 20 的近端被驱动。例如，套管 20 可在其近端上包括握柄或套筒（未示出），该握柄或套筒可包括一个或多个促动器以从套管 20 的远端 22 推动剥离器装置 40，和 / 或使笼 44 从约束管 48 被部署以及用约束管 48 包覆笼 44。轴 42 和 / 或约束管 48 可延伸到握柄内，或者在轴 42 和 / 或约束管 48 与握柄上的一个或多个促动器之间可连接有一个或多个线缆、线、杆、或其它促动器元件（未 示出）。

[0055] 例如，第一促动器（例如滑动器、按钮、转盘等）可设置在握柄（未示出）上，以相对于套管 20 推动和 / 或收回整个剥离器装置 40，例如以使笼 44 从套管 20 的远端 22 被部署但仍然被约束管 48 所包覆。然后例如另一滑动器、按钮、转盘等（也未示出）的第二促动器可被激活，以例如通过相对于约束管 48 推动轴 42 和笼 44 或者在基本上不移动笼 44 的情况下收回约束管 48，从而露出笼 44。在上面通过引用并入的第 12/497,135 号申请中公开了可设置在装置 10 上的示例性握柄和 / 或促动器。

[0056] 可选地，套管 20 和剥离器装置 40 可以是结构上分离的装置，并且剥离器装置 40 可例如经由套管 20 近端的端口或其它开口被引入到套管 20 中。例如，握柄或套筒（未示出）可设置在套管 20 的近端上，握柄或套筒包括与腔 24 连通的端口（未示出），在腔 24 中可容纳剥离器装置 40 和 / 或其它装置的引入。任选地，端口可包括一个或多个密封件（例如止血密封件），在其内可容纳接收的剥离器装置 40，并且提供基本地流体密封以防止体液从腔 24 漏出。在这个可选实施方式中，剥离器装置 40 本身可包括位于其近端上的握柄或套筒（未示出），该握柄或套筒包含一个或多个促动器（也未示出）以与上文所述的促动器相似的方式相对于约束管 48 操纵轴 42 和笼。

[0057] 任选地，以类似方式，阻塞装置 30 可连接至套管 20 和 / 或剥离器装置 40，例如用装置 10 的握柄上的一个或多个促动器（未示出）来部署和 / 或撤回阻塞装置 30。可选地，阻塞装置 30 可以是与套管 20 和 / 或剥离器装置 40 分离的装置，并且剥离器装置 40 可包括用于接收阻塞装置 20 的端口，例如与上述端口相似。

[0058] 任选地，如图 4A 和图 4B 所示，约束管 48 可被配置以便于移除由笼 44 捕获的过量物质。例如，约束管 48 的远端 48a 可包括滑动或以其它方式与笼支杆 44a 相互作用的一个或多个特征，例如以当笼 44 在将阻塞性物质捕获到笼 44 内之后撤回到约束管 48 中时，切除延伸到笼孔 46 外的过量物质。因此，当笼 44 进入约束管 48 并且向收缩形态压缩时，约束管 48 的远端 48a 上的特征可削切或以其它方式切除突 出到笼孔 46 外的过量物质。

[0059] 在图 4A 中所示的示例性实施方式中，约束管 48 的远端 48a 可包括围绕与腔 49 连通的远端开口 43 延伸的锋利的边缘 47，锋利的边缘 47 适于削切可能通过笼 44 的孔 46 突出的过量的阻塞性物质。在图 4A 中所示的示例性实施方式中，锋利的边缘 47 可以是单地 (single-ground) 边缘，例如在撤回期间，锋利的边缘 47 可沿着笼 44 的外表面削切以切割或以其它方式分离通过孔 46 延伸的阻塞性物质。可选地，如图 4B 所示，约束管 48' 可被设置为包括围绕远端开口 43' 延伸的双地 (double-ground) 边缘 47'。双地锋利的边缘 47' 可以以与单地边缘 47 类似的方式切割过量的阻塞性物质，但是由于笼进入约束管 48' 的腔 49'，所以双地锋利的边缘 47' 更加抗损。例如，由于切割边缘 47' 的直径稍稍大于约束管

INARI_021005

48' 的腔 49' 本身的直径，所以在笼 44 的撤回期间，切割边缘 47' 可以不接触笼 44 的外表面，而是与笼 44 保持微小的间隔。

[0060] 在图 5 中所示的可选实施方式中，可以省略图 4A 和图 4B 中示出的约束管 48，套管 60 可用于在笼 44 被引入期间将笼 44（未示出）约束在收缩形态和 / 或在笼 44 的撤回期间移除过量物质。与前面的实施方式类似，套管 60 包括近端（未示出）、远端 62、以及在近端与远端 62 之间延伸的腔 64。与前面的实施方式不同，套管 60 包括并入到远端 64（例如在腔 64 内）中的约束管 48"。约束管 48"可以是相对短的管状体，其在腔 64 中以短距离延伸并且包括围绕远端开口 43" 的露出且锋利的边缘 47"，例如单地或双地边缘，与前面的实施方式类似。约束管 48"可以基本上永久地附接在腔 64 内或例如通过用粘接剂粘合、干涉配合 (interference fit)、熔接、声波焊接等的其它方式连接至远端 62，从而提供从远端开口 43" 到腔 64 的过渡。

[0061] 在使用过程中，笼 44 可从腔 64 被推进并且离开远端开口 43"，于是笼 44 可自由地向扩展形态扩展。在将不期望物质捕获到笼 44 内之后（如本文的其它地方进一步描述），笼 44 可通过远端开口 43" 撤回到套管 60 中，于是当笼 44 收缩时，穿过笼 44 的孔 46 延伸的过量阻塞性物质可通过锋利的边缘 47" 被切割或以其它方式分离。

[0062] 在其它可选的实施方式中，图 1 所示的套管 20 可用于在引入和 / 或撤回期间约束笼 44，并且约束管 48 完全可以省略。与前面的实施方式不同，然而，当笼 44 撤回到套管 20 时，由于套管 20 与被引导通过套管 20 的约束管 48 相比直径相对较大，所以笼 44 可以不收缩成较小的尺寸。在这个可选的实施方式中，在笼 44 撤回到套管 20 之后，阻塞性物质的一部分可能留在笼 44 中。换句话说，剥离器装置笼 44 可用于在不切除过量阻塞性物质的情况下捕捉并移除阻塞性物质。可选地，套管 20 本身可包括锋利的远端边缘（未示出），或者锋利的末端可附接到套管 20 的远端 22（也未示出），例如以在笼 44 的撤回期间切割过量的阻塞性物质，而笼 44 内的阻塞性物质被撤回到套管 20 中笼 44 内。

[0063] 进一步参照图 1，在示出的实施方式中，剥离器装置 40 的轴 42 包括腔以可滑动地接收阻塞装置 30 的轴 32，例如，使得剥离器装置 40 和阻塞装置 30 具有同心、相对彼此伸缩的布置。可选地，如图 6 所示，可以设置装置 10'，其中，剥离器装置 40 和阻塞装置 30 被设置为相对于外套管 20 并排布置。在这个可替换的实施方式中，套管 20、阻塞装置 30 和剥离器装置 40 可以以与上述实施方式类似的方式构造。任选地，剥离器装置 40 可包括笼 44，笼 44 包括由笼 44 的支杆 44a 限定的不间断路径 45，该不间断路径 45 沿着笼 44 的至少一部分轴向地延伸，以容纳穿过笼 44 的阻塞装置 30，并且允许笼 44 基本上完全闭合到收缩形态。

[0064] 在这个实施方式中，阻塞装置 30 和剥离器装置 40 可被接纳在套管 20 的共同腔 24 中，如图 6 所示。可选地，套管 20 可包括彼此相邻布置的分离的腔（未示出），每个腔用于接收阻塞装置 30 和剥离器装置 40 中的一个。除此以外，装置 10' 的结构和操作可以与参照图 1 的装置 10 所描述的结构和操作相似。

[0065] 转到图 7 至图 10，示出了在体腔 50 内移除物质（例如血栓或其它阻塞性物质 52）的示例性方法。体腔 50 可以是例如在相邻动脉与静脉之间连通的患者胳膊内的血管、主动脉 - 静脉瘘、管状移植物、异种移植物等。可选地，本文所述的装置和方法可用于处理患者身体内 的其它位置，例如患者的脉管系统或其它体腔。虽然结合图 7 至图 10 示出并描述

INARI_021006

-3800-

了图 1 所示的装置 10，但是应该意识到的是，本文所述方法可以使用本文所述的任意装置和系统来执行。

[0066] 通常，该方法可涉及捕获扩展的阻塞部件 34 与扩展的笼 44 之间的血栓或其它阻塞性物质，例如，使得该物质可由笼 44 捕获，碎成更小颗粒，在笼 44 内被移除，和 / 或通过套管 20 从体腔 50 抽出。最初，如图 7 所示，套管 20 可例如通过常规方法从进入位置经皮引入到体腔 50 中，并且被操纵以在体腔 50 内定位套管 20 的远端 22，邻近阻塞性物质 52 并且与其间隔。任选地，如果套管 20 包括位于远端 22 上的可扩展部件，例如如图 2A 或 2B 所示的气囊 26、26'，那么在远端 22 被置于体腔 50 内的期望位置之后，可扩展部件（未示出）可以在任意时间扩展，例如以防止套管 20 的随后移动和 / 或基本上密封体腔 50 以防止流体紧邻套管 20 流过。

[0067] 附加地或可选地，例如在将套管 20 的远端 22 引入到体腔 50 中之后的任何时间，可将抽吸应用于套管 20 的腔 24。例如，注射器或真空管线可连接到套管 20 的近端，并且被激活以将基本持续的真空应用到腔 24 以将体腔 50 内的松散物质拉到腔 24 中。

[0068] 然后将阻塞装置 30 从套管 20 引入到体腔 50 中，并且使处于低轮廓结构（未示出）的阻塞部件 34 前进穿过物质 52。例如，阻塞装置 30 可被加载到套管 20 的腔 24 中并且经过套管 20 的长度进入到体腔 50 中，或者阻塞装置 30 可在手术和仅在从套管 20 被部署之前被整合到或预加载到套管 20 中。可选地，阻塞装置 30 的远末端可充分小和 / 或尖锐以自由地穿过物质 52，和 / 或可以是圆的或其它基本上无创伤的以沿着体腔 50 的壁经过物质 52。一旦阻塞部件 34 被定位在物质 52 之外的远侧，那么阻塞部件 34 被扩展到如图 7 所示的高轮廓状态。

[0069] 接下来，参照图 8，剥离器装置 40 可从套管 20 被部署，例如在阻塞装置 30 的轴 32 的上方或邻近阻塞装置 30 的轴 32。可推进剥离器装置 40 直至笼 44（在约束管 48 内维持在收缩形态）布置在物质 52 的与扩展的阻塞部件 34 相反的近侧或者与扩展的阻塞部件 34 相反地邻近物质 52。因此，阻塞性物质 52 的一侧可被阻塞部件 34 限制，并 且其另一侧被剥离器装置 40 限制。一旦笼 44 在体腔 50 内被定位，笼 44 就可在体腔 50 内扩展，例如通过使笼从约束管 48 被部署，于是笼 44 可如图 8 所示弹性径向向外扩展以接触体腔的壁。

[0070] 转向图 9，然后阻塞装置 30 可向近侧朝向笼 44 被收回，以朝向剥离器装置笼 44 拉动体腔 50 内的物质 52 并使其进入剥离器装置笼 44，如图所示。可选地，笼 44 可朝向阻塞装置 30 前进以将物质 52 捕获到笼 44 中，通过阻塞部件 34 防止物质 52 离开笼向远侧移动。如上所述，如果笼 44 包括例如如图 3 所示的倒钩 41，那么倒钩 41 可部分刺入或以其它方式与被捕获到笼 44 内的物质 52 接合，例如以防止物质 52 相对于笼 44 移动。

[0071] 任选地，阻塞装置 30 和 / 或剥离器装置 40 可包括锁定机构，例如一个或多个协作制动装置、凸片或其它特征（未示出），当阻塞装置 30 已经被放置在距笼 44 预定距离的位置处（例如如图 9 所示，基本上邻近笼 44 使得阻塞装置 30 基本上封住笼 44 内的阻塞性物质 52）时，锁定机构可基本上相对于笼 44 固定阻塞装置 30。可选地，锁定机构可设置在装置 10 的近端上，例如在握柄（未示出）上，该锁定机构可被锁定和解锁以选择性地相对于笼 44 固定阻塞装置 30。随着锁定机构的接合，阻塞装置 30 可以不被引导向远侧远离笼 44，例如使得阻塞装置 30 的随后运动与笼 44 的运动连接在一起。

[0072] 转向图 10，然后剥离器装置笼 44 和扩展的阻塞部件 34 可向近侧朝向套管 20 被引

INARI_021007

导，例如，直至笼 44 进入约束管 48。如果在此之前没有应用真空，那么真空源可被激活以将体腔 50 内释放的物质抽吸到套管 24 的腔 24 中，如图所示。当笼 44 被拉回到约束管 48 时，笼 44 可径向向内被压缩，由此迫使物质 52 的一个或多个部分穿过笼 44 的孔 46。通过孔 46 露出的物质 52 的一个或多个部分可被削切，例如通过约束管 48 的锋利的远端边缘 47、47'（未示出，见图 4A 和图 4B）被削切，以在体腔 50 内使物质 52 碎成很多更小的颗粒 53。松散颗粒 53 可以从体腔 50 例如通过抽吸穿过套管腔 24 被移除，如图所示。注意的是，减小的颗粒尺寸可随着笼 44 中孔 46 的尺寸而变化。因此，可选择笼孔 46 的尺寸，以将物质 52 的颗粒尺寸减小至所需的最大横 截面，例如使得减小的直径的颗粒 53 可以可靠地通过套管 20 被移除，而基本上不存在堵塞套管腔 24 的风险。

[0073] 在一个实施方式中，当笼 44 撤回到约束管 48 中（在约束管 48 中笼 44 的内部空间最小）时，笼 44 可被压缩至收缩形态，从而通过笼 44 的孔 46 挤压基本上所有被捕获的物质 52。然后将挤压和 / 或削切的颗粒 53 抽吸到套管 20 的腔 24 中。可选地，笼 44 可在收缩形态中具有充足的内部空间，使得当笼 44 完全撤回到约束管 48 中时，至少一些被捕获的物质可留在笼 44 内。

[0074] 随着笼 44 完全撤回到约束管 48 中，剥离器装置 40 和阻塞装置 30 可撤回到套管 20 中，并且装置 10 从患者身体被移除。可选地，阻塞装置 30 可被收缩并且使阻塞装置 30 前进穿过体腔 50 内阻塞性物质的另一部分（未示出）。在这个可选实施方式中，然后可例如通过重复上述步骤重新部署剥离器装置 40 以捕获并移除物质。可选地，如果需要，整个装置 10 可被引入到另一体腔（未示出）内，并且阻塞装置 30 和剥离器装置 40 被重新部署以捕获和 / 或移除患者身体的其它区域中的阻塞性物质。

[0075] 一旦足够的物质已经被移除，那么阻塞装置 30 的阻塞部件 34 可被收缩，并且阻塞装置 30 可撤回到剥离器装置 40 中，或者如果剥离器装置 40 已经撤回到套管 20 中，那么阻塞装置 30 可撤回到套管 20 中。套管 20 内的抽吸可以是不连续的，套管 20 上的可扩展部件可被收缩（如果设置在套管 20 上），并且套管 20 可从体腔 50 撤出。

[0076] 转向图 11A 至图 13，示出了剥离器笼 144 的另一实施方式，其可包括在本文所描述的任意装置和 / 或系统中。通常，剥离器笼 144 包括闭合的近端或第一端 144a 和开放的远端或第二端 144b，与前面的笼 44 相似。笼 144 可包括在第一端 144a 与第二端 144b 之间和 / 或绕着笼 144 的外周延伸的多个支杆 116、118，由此限定了包括多个孔 146 的圆筒形外壁或其它管状外壁，与前面的笼 44 相似。

[0077] 笼 144 的闭合端 144a 可包括轴环 (collar) 部分 141，其可附接至剥离器装置轴 42（未示出，见例如图 1），而笼 144 开放的远端 143 可包括多个向远侧伸出的元件或远末端 112。例如，图 11A 示出了处 于扩展形态的笼 144，其中，例如由于轴环部分 141 附接至轴（未示出）所以轴环部分 141 保持被压缩，并且笼 144 限定了从闭合端 144a 向开放端 144b 延伸的基本上连续的直径。图 11B 示出了处于压缩形态的笼 144，例如其中，笼 144 可被约束或以其它方式压缩在轴的周围和 / 或在约束管（也未示出）内。

[0078] 与图 1 的笼 44 不同，如在图 12A 和图 12B 中最佳见到的，笼 144 包括至少两种不同类型的支杆 116，118。例如，笼 144 可包括多个较厚的支杆 116，其沿着笼 144 的长度基本连续地延伸，例如在第一端 144a 与第二端 144b 之间的第一螺旋结构中。此外，笼 144 可包括多个较薄的支杆 118，其可与相邻的厚支杆 116 连接在一起。如图所示，与厚支杆 116

INARI_021008

不同，薄支杆 118 不是基本连续的，而是可以不连续模式螺旋地和 / 或圆周地围绕笼 44 延伸。任选地，薄支杆 118 还可具有弯曲或其它特征，例如相对变薄或穿孔的部分，这允许薄支杆 118 与厚支杆 116 相比相对容易弯曲。孔 146 可由厚支杆 116 与薄支杆 118 之间的间隔限定，从而限定了笼 144 所需的孔隙尺寸。可通过与前面所述的材料和方法相似的材料和方法来形成笼 144。

[0079] 笼 144 的开放端 144b 上的远末端 112 可以为笼 144 提供基本无损伤的远端，例如以防止刺穿其内部署有笼 144 的体腔的壁或对其造成其它伤害。附加地或可选地，远末端 112 可以足够的柔韧以允许远末端 112 在使用过程中螺旋地扭转和 / 或彼此互锁。图 15A 至图 15C 示出了远末端的可选结构，可在笼 144 上设置远末端，例如以便于与体腔内的阻塞性物质接合和 / 或移除体腔内的阻塞性物质。例如，图 15A 示出了远末端 112a 的示例性实施方式，远末端 112a 包括具有平滑前缘 125 的基本直的结构。

[0080] 可选地，图 15B 示出了远末端 112b 的另一示例性实施方式，远末端 112b 包括沿着远末端 112b 的长度间隔分布的一系列槽或凹口 126，例如其可允许远末端 112b 互相缠绕和 / 或与捕获的或通过远末端 112b 以其它方式接合的阻塞性物质缠绕，以便于移除，如下面参照图 16A 至 16H 的进一步描述。例如，当笼 144 旋转时，远末端 112b 和阻塞性物质可缠绕在一起，例如使得其它远末端 112b 和 / 或阻塞性物 质的一个或多个部分可进入槽 126，并且远末端 112b 彼此互锁。图 15C 示出了远末端 112c 的又一示例性实施方式，远末端 112c 包括蜿蜒的样式 (pattern)127。在这个实施方式中，蜿蜒的样式 127 的内弯部 128 可提供使远末端 112c 和 / 或阻塞性物质可缠绕在一起的多个区域，例如与图 15A 的远末端 112a 中所示的提供平滑边缘 125 相比。

[0081] 图 11A 至图 13 中所示的笼 144 的一个优势是，笼 144 可便于部署笼 144 和 / 或使笼 144 前进进入或穿过体腔内的阻塞性物质。与此相反，图 1 中所示的笼 44 一旦在体腔内被部署则通常保持静止，例如，而阻塞装置 40 被收回以将阻塞性物质收到笼 44 中。例如，图 11A 至图 13 的笼 144 可便于将物质 52 拉到笼 144 的开放端 144a 内和 / 或使阻塞性物质与体腔 50 的壁分离。

[0082] 在向远侧前进过程中，笼 144 可例如通过手动或通过连接到装置 10 的握柄（未示出）中的电动机的驱动轴（见例如图 1）同时前进和旋转。这可导致在笼 144 前进时，笼 144 的远末端 112 沿着体腔 50 的内壁例如以螺旋方式行进。当遇到血栓或其它阻塞性物质时，远末端 112 可在物质 52 与体腔 50 的壁之间穿过，从而将物质 50 定位在笼 144 内。

[0083] 笼 144 的远末端 112 可便于分离物质和 / 或将物质捕获到笼 144 内。例如远末端 112 的边缘可提供这样的笼 144 的远侧前缘，即其不是基本光滑的圆柱体，而是限定了起伏的表面。因此，当笼 144 旋转时，笼 144 的远末端 112 可通过重复与物质 52 接触而起到锯的作用，这可增加物质 52 从体腔 50 的壁脱落和 / 或被捕获到笼 144 内的机会。为了进一步确保笼 144 的前缘在不期望物质与体腔 50 的壁之间穿过，远末端 112 和 / 或支杆 116、118 的边缘还可起到沿着体腔 50 的壁削切的刀片的作用以将附着的物质拉到笼 144 中。因此，支杆 116、118 可切割或以其它方式分离体腔 50 与阻塞性物质 52 之间的界面。

[0084] 远末端 112 可被形成使得它们基本符合笼 144 的圆柱形形状，例如虽然可选地远末端 112 可径向向外偏移，但是限定了与扩展的笼 144 的其余部分类似的直径，例如以确保远末端 112 在体腔 50 的壁与阻塞性物质 52 之间穿过和 / 或加强远末端 112 与体腔 50 的

INARI_021009

壁的接合。可选 地，远末端 112 可偏移以径向向内延伸，例如相对于装置 10 的中心纵轴横向地向内延伸，例如以防止伤害体腔 50 壁的高风险。

[0085] 此外，支杆 116、118 的不同厚度和 / 或形状可提供这样的笼 144，根据笼 40 的旋转方向，笼 144 以不同方式响应。例如，图 13 中的箭头“A”表示笼 144 旋转的第一方向。如果在这个旋转期间笼 144 与体腔 50 壁（未示出）接触的部分中遇到阻力，那么可能发生扭曲。由于厚支杆 116 具有较高的抗弯曲性而薄支杆 118 容易弯曲，所以扭曲可能不会折弯厚支杆 116，但是可能导致薄支杆 118 弯曲成以在相邻的支杆 116、118 之间限定更大的角度，并且使笼 144 径向向外扩展。这可增加剥离器笼 144（例如，厚支杆 116 的前缘）与体腔 50 的壁之间的接触力，从而可增加从体腔 50 的壁移除阻塞性物质并且将阻塞性物质捕获到笼 144 内的机会。可选地，厚支杆 116 的前缘可包括锋利的边缘或其它特征，这可增强切割或与体腔 50 内附着的物质的其它接合。

[0086] 如果笼 144 在与“A”相反的第二方向旋转，那么由于薄支杆 118 的低断裂强度，扭曲可能导致薄支杆 118 弯曲以减小相邻的支杆 116、118 之间的角度，并且笼 144 可能不会以与第一方向类似的方式径向向外扩展。关于旋转方向的这种各向异性可能是有用的，因为笼 144 可在“A”方向前进和旋转以与阻塞性物质接合并使附着的阻塞性物质与血管壁分离，例如，使物质进入笼 144。扭曲还可引起笼 144 向外扩展以更好地附着或接合血管壁。如果笼 144 遇到过多的阻力，那么笼 144 可沿第二方向旋转，例如以释放阻力而不引起径向扩展。根据薄支杆 118 与厚支杆 116 之间的刚度差，笼 144 在第二方向的旋转还可引起笼 144 径向地收缩以进一步便于释放。

[0087] 转向图 14A 至图 14C，示出了可扩展笼 144 的又一个实施方式，其可包括选择性地打开和 / 或闭合笼 144 的开放远端 143 的促动机构。例如，通过例如使用连接至每个远末端 112 的控制元件（例如，一个或多个线或细丝 114）径向向内收缩远末端 112，可基本上闭合笼 144 的开放远端 143。可选地，单一控制元件（未示出）可穿过每个远末端 112，例如圆周地且连续地穿过多个远末端中的孔（未示出），使得 控制元件上的向近侧的拉力可使远末端 122 折弯或以其它方式径向向内引导远末端 122。任选地，如果需要，可提供锁定机构（未示出）以将远末端 122 固定在闭合的方向。可选地，远末端 122 可彼此互锁，例如如上所述，以将远末端 122 固定在闭合的方向。

[0088] 图 14A 示出了远端 143 开放，笼 144 处于扩展形态，例如控制元件 114 松弛并且远末端 112 偏移至基本上轴向开放的结构。图 14B 示出了远末端 112 弯曲或以其它方式向内朝向闭合形态被引导，例如在向近侧的拉力被施加到控制元件 114 之后。远末端 112 的结构通过提供例如变薄的支杆宽度、变薄的支杆厚度、穿孔部分等（未示出）的一个或多个优选的弯曲特征可有助于这种弯曲，以提供远末端 112 的铰接区域。在可选实施方式中，如图 14C 所示，管状部件 113 可在控制元件 114 上前进以引起远末端 112 径向向内弯曲。

[0089] 图 14B 和图 14C 中所示的闭合结构可允许被捕获到笼 144 内的阻塞性物质被基本上保留在其内，例如，不需要本文其它地方所述的可扩展的阻塞部件 34。在这些可选实施方式中，笼 144 可简单地撤回到约束管或者进入套管（未示出）中，从而径向向内压缩笼 144。当笼被压缩（例如如上所述被抽吸）时，随着远末端 112 的闭合，所捕获的物质不会简单地从笼 144 的远端 143 逃脱，而是保留在笼 144 内通过孔 146 突出（在图 14B 和 14C 中未示出）。可选地，所捕获的物质可以也如上所述随着笼 144 撤回到约束管或套管中。

INARI_021010

[0090] 转向图 16A 至图 16H，示出了另一示例性方法，例如通过图 11A 至图 13 所示的笼 144 从血管或其它体腔 150 内移除阻塞性物质。与前述实施方式相似，可经由进入套管和 / 或约束管 148 将笼 144 引入体腔 150。如图 16A 所示，笼 144 已经在体腔 150 内被部署和扩展，使得开放的远端 143 邻近待移除的阻塞性物质 152 布置。一旦笼 144 完全扩展，笼 144 就可在体腔内朝向阻塞性物质 152 前进和旋转。

[0091] 转向图 16B，笼 144 的远端 143 可与物质 152 接合，例如使得远末端 112 在一定程度上在物质 152 与体腔 152 的壁之间穿过，但是当它们与物质 152 缠绕在一起时还可以自由变形。任选地，在笼 144 前进之前，阻塞装置（未示出）可被引导通过物质 152 并且阻塞部件在 物质 152 之外扩展。因此，在笼 144 前进时，阻塞部件可防止物质 152 远离笼 144 向远侧移动。

[0092] 另外参照图 16C，当笼 144 进一步旋转时，远末端 112 可至少部分地绕着物质 152 缠绕或者绕着彼此缠绕，由此在笼 144 与物质 152 之间产生机械接合。然后可将笼 144 的进一步旋转传递至物质 152，这样可引起物质 152 扭转和 / 或以其它方式脱离体腔 150 的壁。在缠绕和进一步旋转之后，被缠绕的物质 152 可完全从体腔 150 的壁移除，如图 16D 所示。

[0093] 如图 16E 所示，与前述实施方式类似，然后可将笼 144 撤回到进入套管和 / 或约束管 148，从而将笼 144 径向向内地压缩至收缩形态。由于笼 144 的远末端 112 基本上是直的并且在它们的远端上是自由的（即，笼 144 在其远端上是开放端并且未附接至芯线），所以当笼 144 撤回到进入套管 20 时，远末端 112 可松开并且物质 152 被释放。因此，如图所示，分离的物质 152 可在体腔 50 内保持松驰。

[0094] 此后，如图 16F 所示，笼 144 可从约束管 148 或套管被重新部署，并且再次通过邻近松散物质 152 布置的开放端 143 扩展。然后例如通过阻塞装置 134 将物质 152 拉入笼 144 的开放端 143，阻塞装置 134 可以是之前在物质 152 之外部署的相同装置，或者是在重新部署笼 144 之前或之后被引入到体腔 150 中且位于物质 152 之外的不同装置。

[0095] 参照图 16G，然后将其内具有捕获的物质 152 的笼 144 撤回到套管 20 或约束管（未示出）中，与前面的实施方式类似。如本文其它地方所讨论的，当笼 144 被压缩时，通过笼 144 的孔 146 突出的任何物质都可被削切或以其它方式分离，例如以确保笼 144 不会在套管 20 的末端被卡住。如图 16H 所示，笼 144 可完全撤回到套管 20 中，并且物质 152 的任何剩余松散颗粒可通过套管腔被抽吸，与前面的实施方式类似。例如，如上所述，可通过套管 20 随时将真空应用到体腔 150 内以抽吸体腔 150 内的松散颗粒，例如当笼 144 使物质与体腔 150 的壁分离时或者在其之后被释放的。这些步骤中的任意步骤都可根据需要重复多次，以移除任何剩余物质。

[0096] 应理解，对于具体实施方式来说，文中的任何实施方式所示的元 件或部件都是示例性的，并且可用于或结合至文中所公开的其它实施方式。

[0097] 虽然本发明可以进行各种修改、和替换形式，但其具体实施例已在附图中示出并在文中详细描述。然而，应理解，本发明并不限制于所公开的具体形式或方法，相反，本发明包括落入所附权利要求范围内的所有修改、等同和替代。

INARI_021011

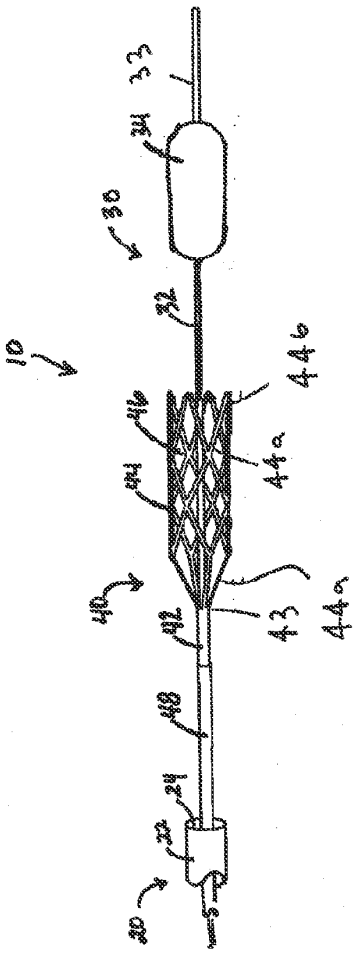

10
22
34
30
32
46
46a
44a
44b
40
42
43
44c
48
24
22
20
50

图 1

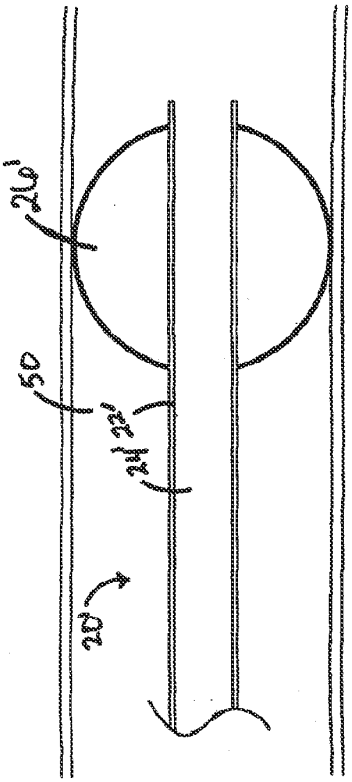

20'
50
24'
22'
20'

图 2A

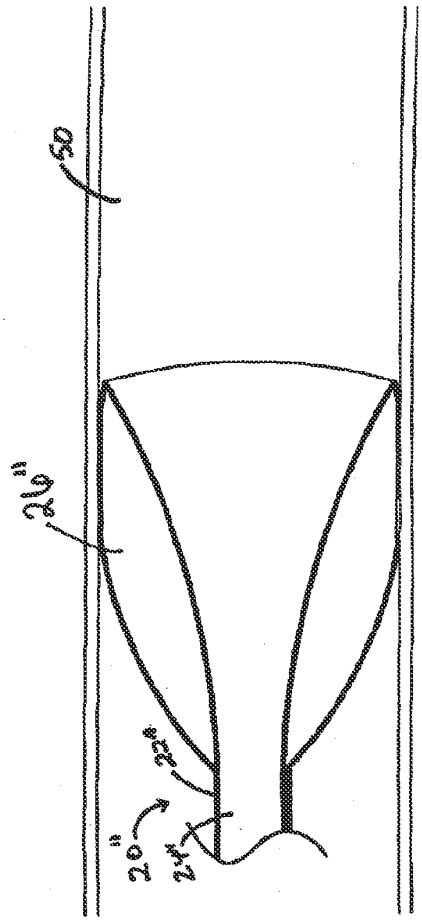


图 2B

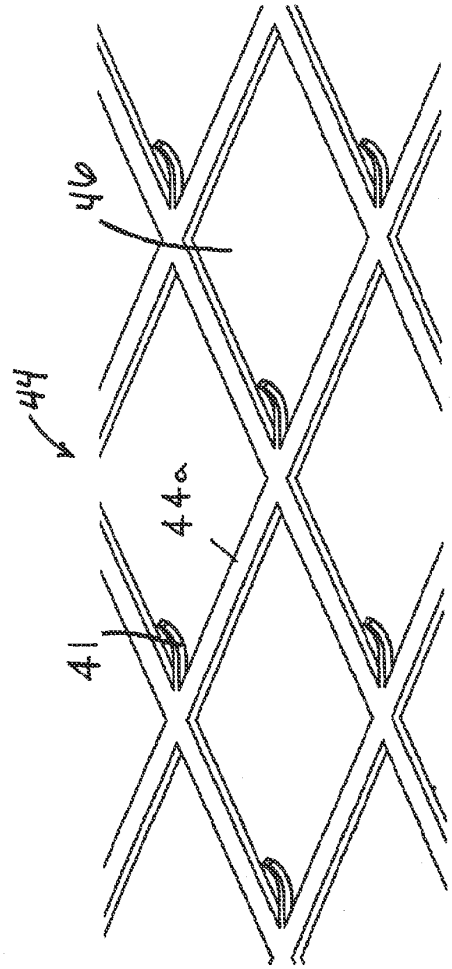


图 3

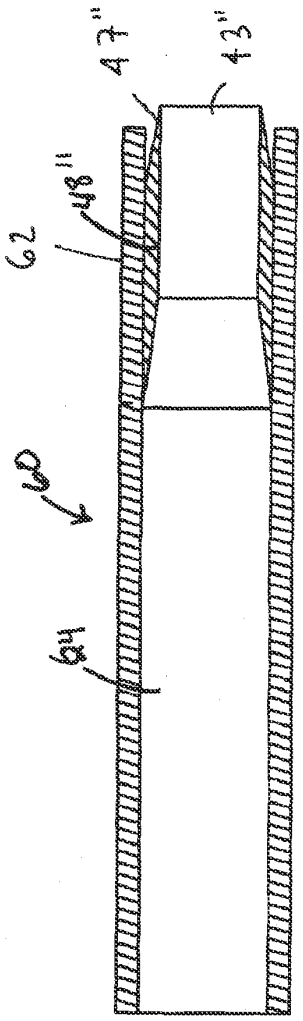


图 5

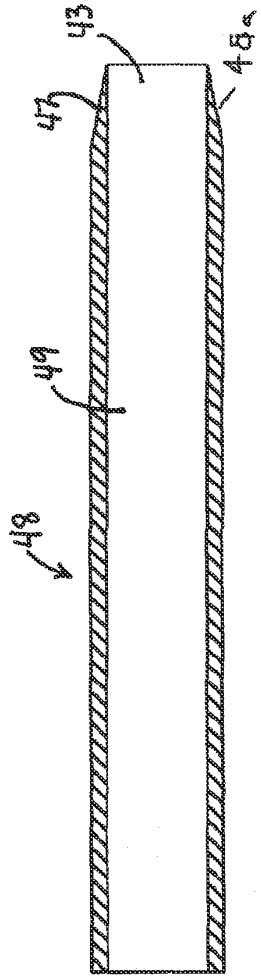


图 4A

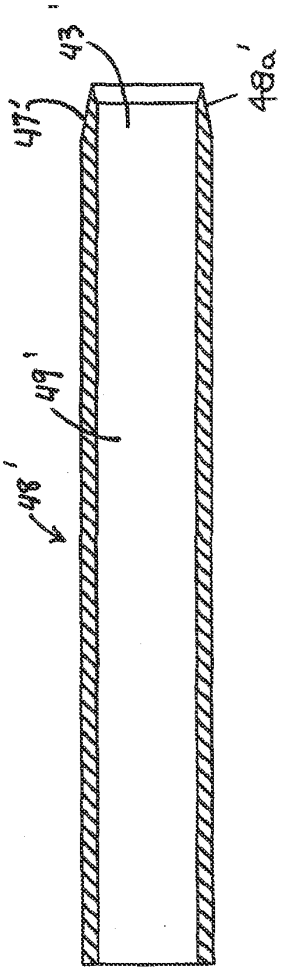


图 4B

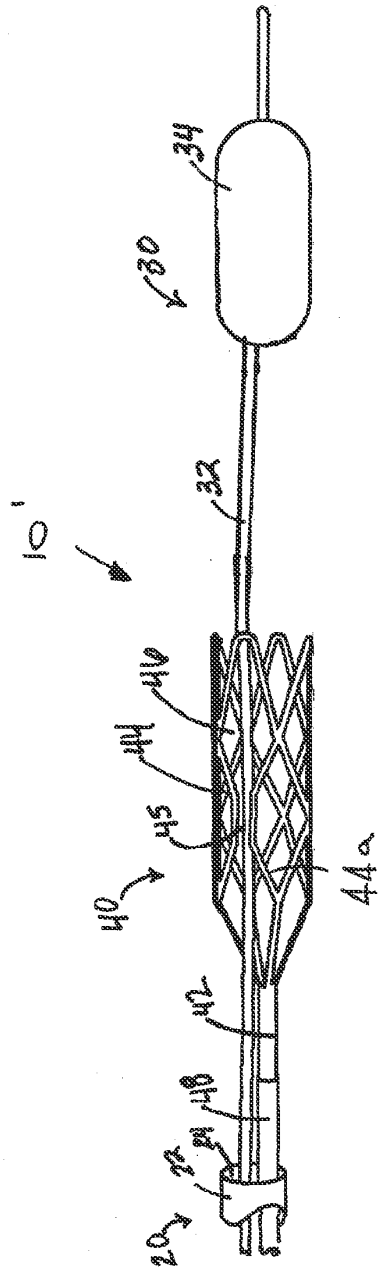


图 6

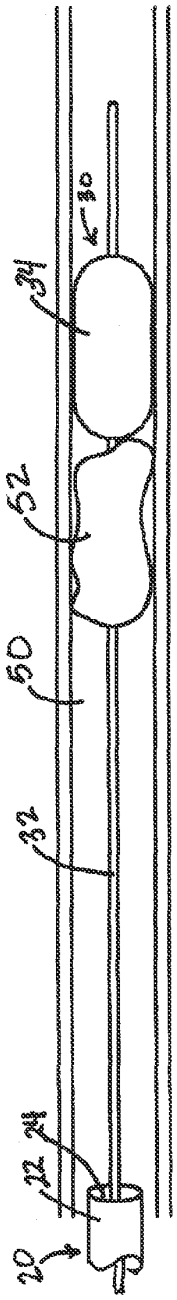


图 7

INARI_021015

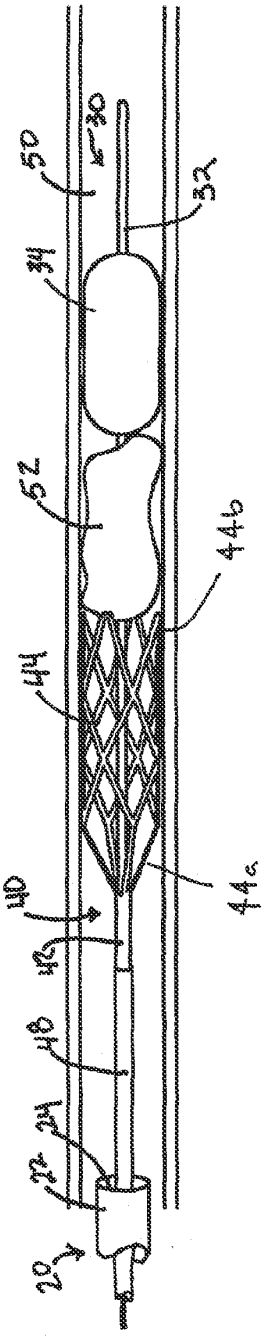


图 8

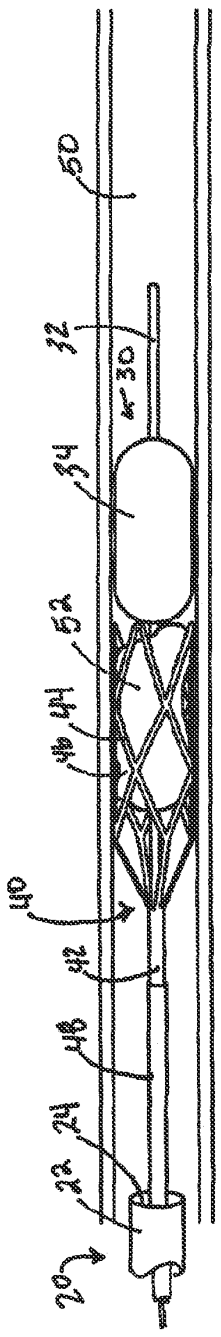


图 9

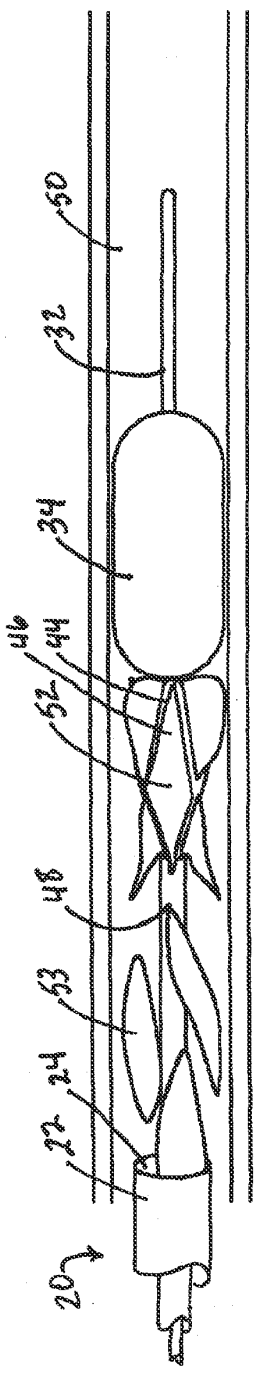


图 10

INARI_021016

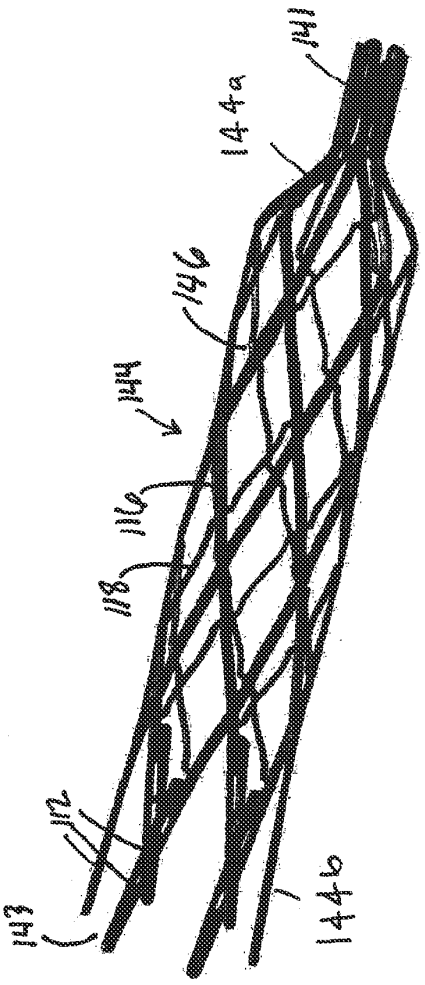

141
144a
146
144
116
118
112
143
144b

图 11A

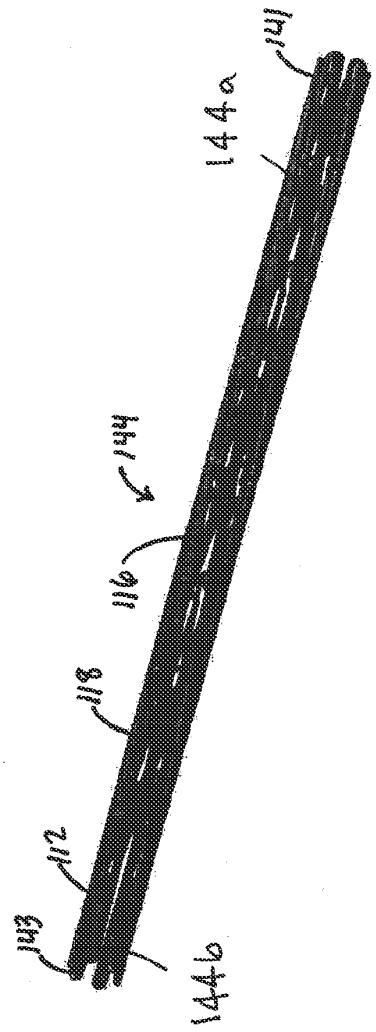

141
144a
144
116
118
112
143
144b

图 11B

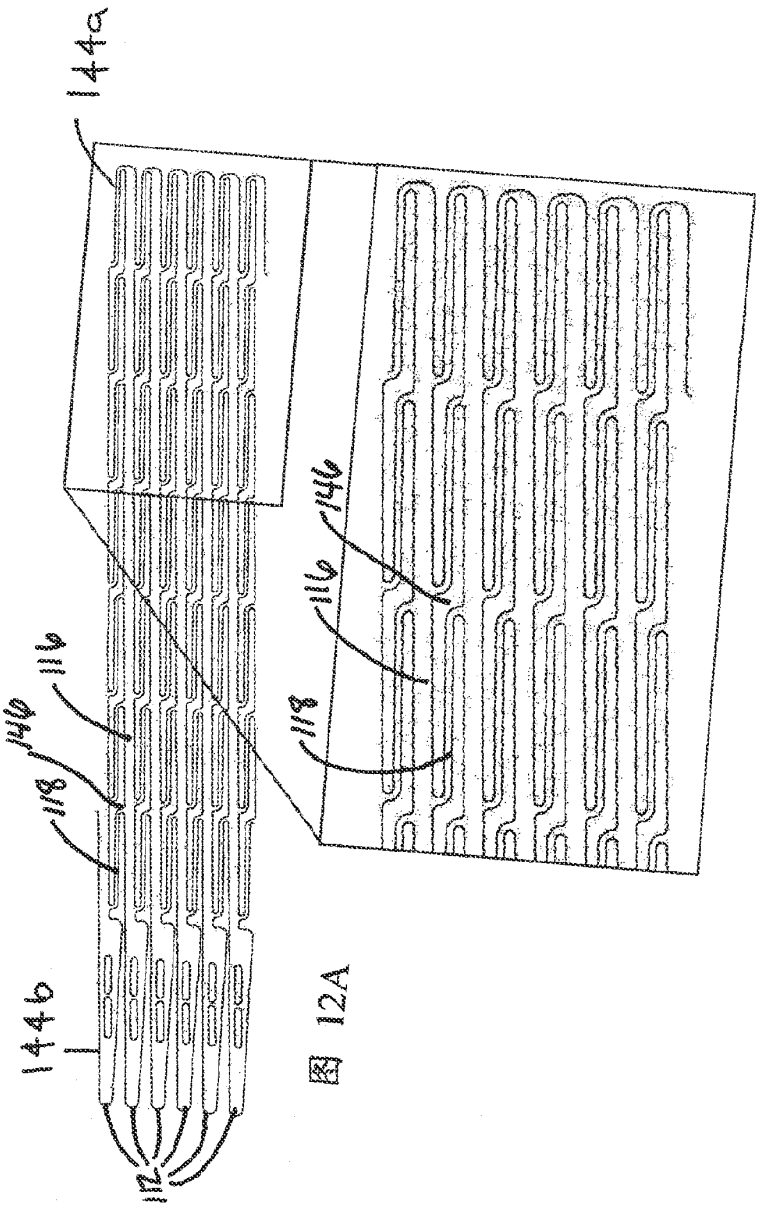


图 12A

图 12B

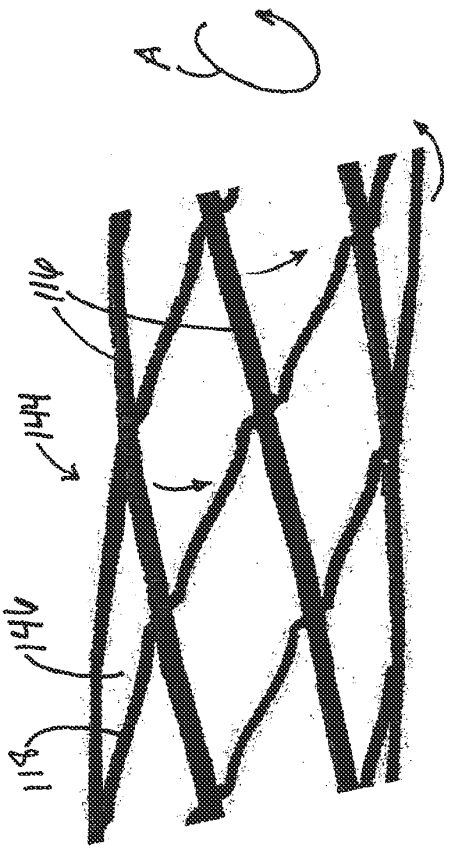


图 13

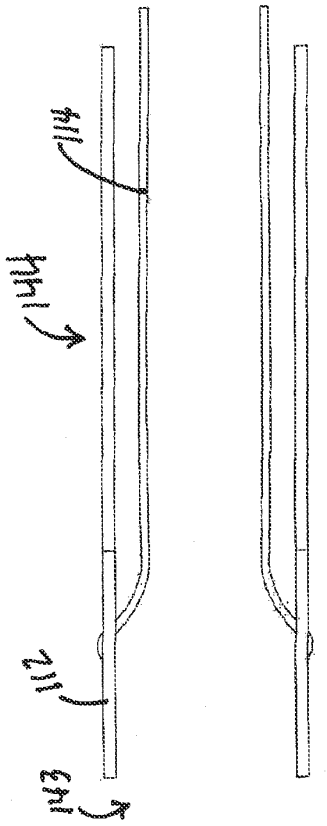


图 14A

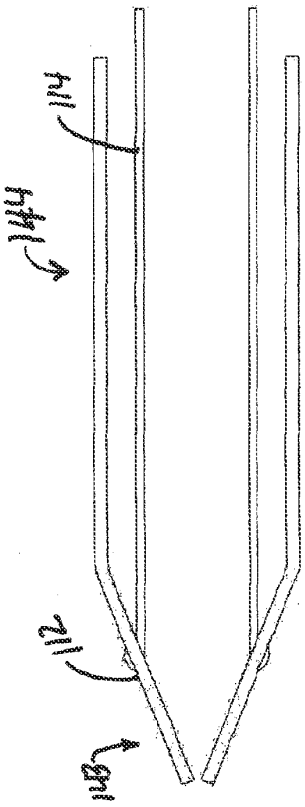


图 14B

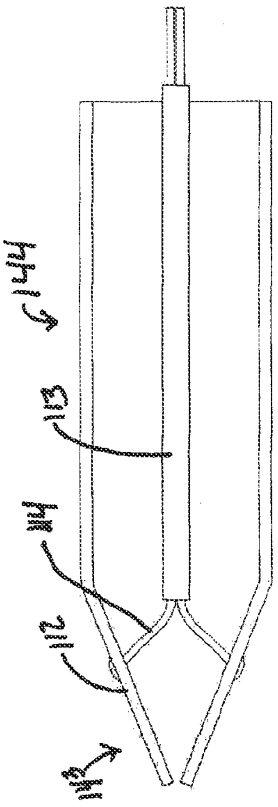


图 14C

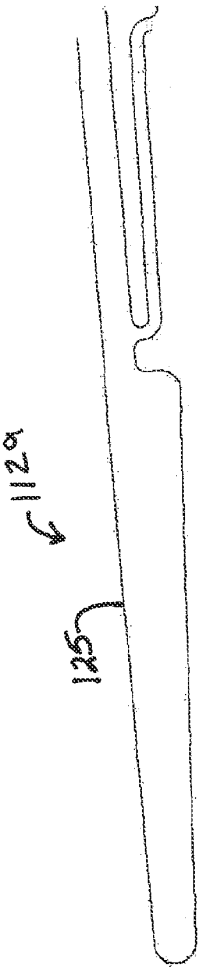


图 15A

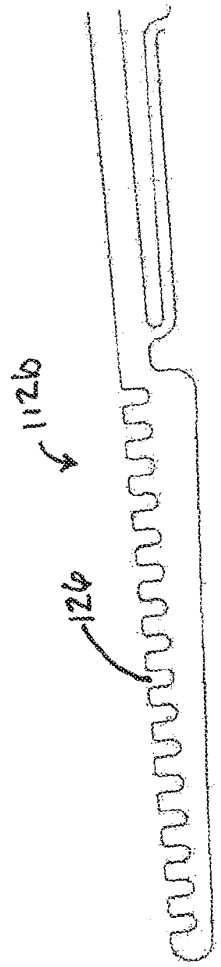


图 15B

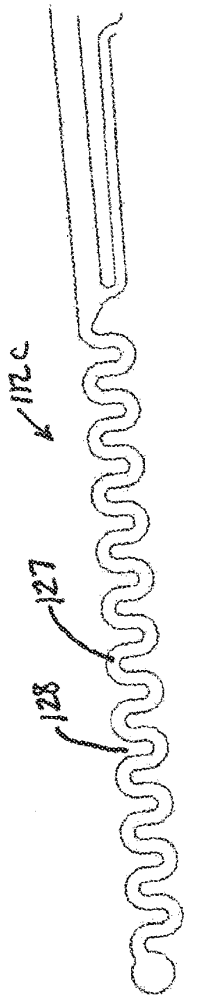


图 15C

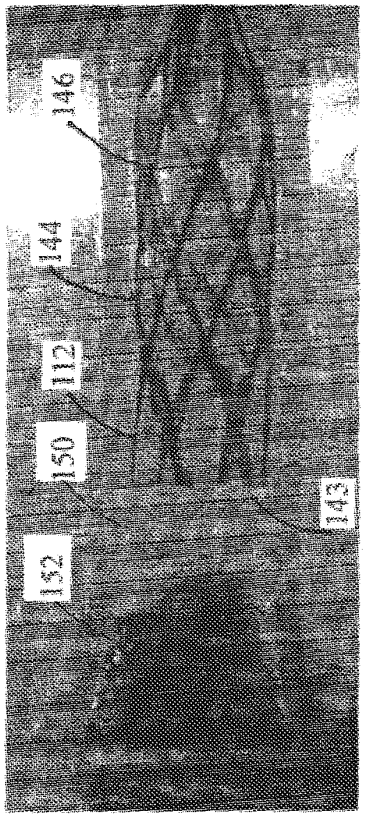


图 16A

INARI_02102

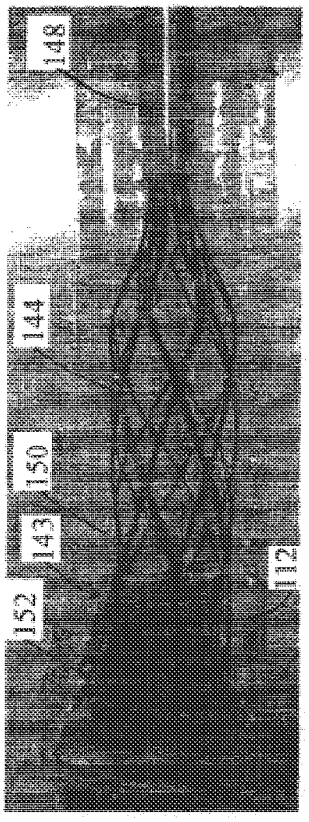


图 16B

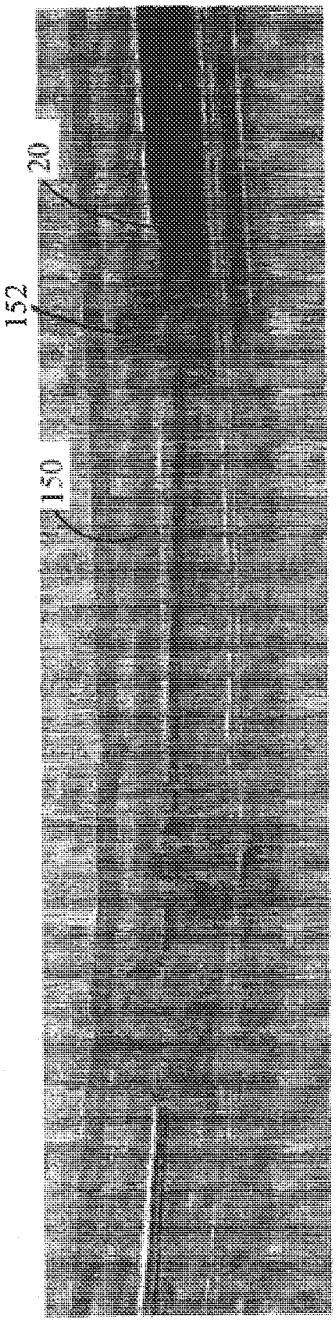


图 16E

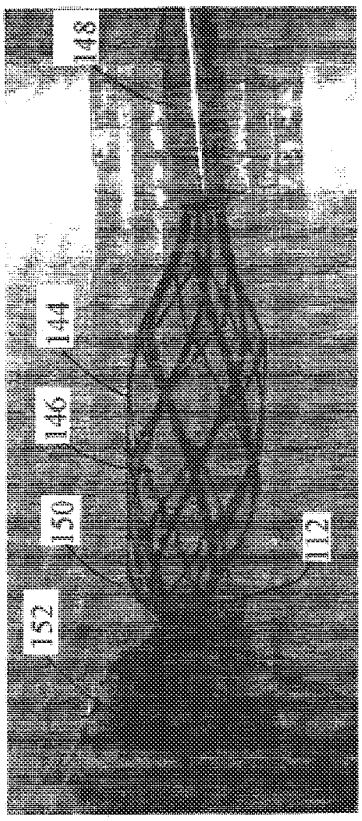


图 16C

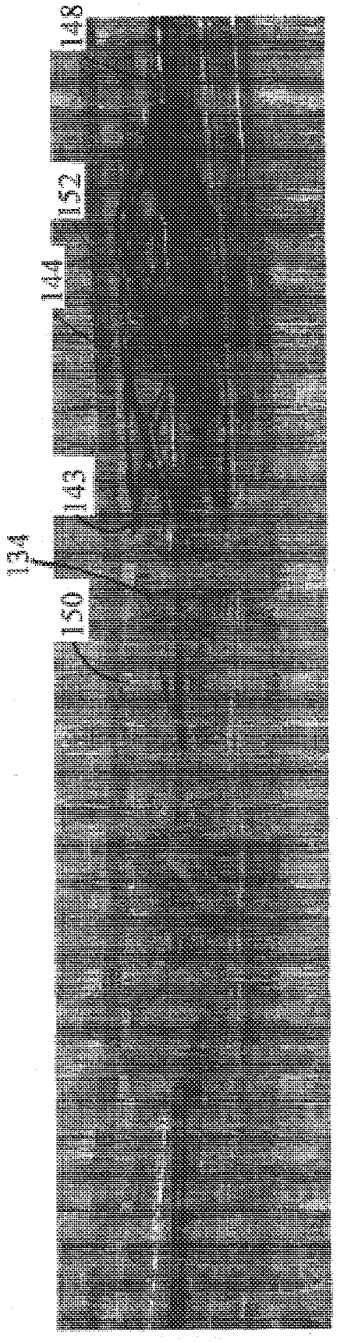


图 16F

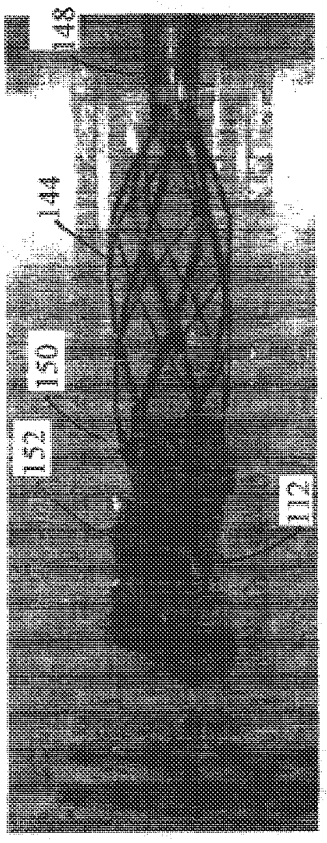


图 16D

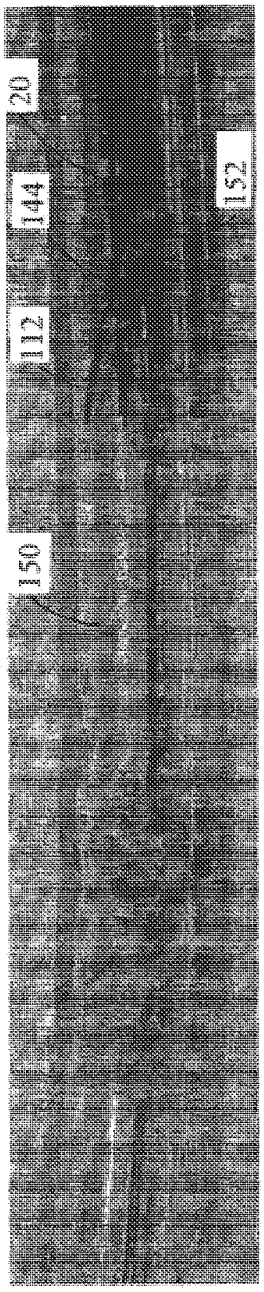


图 16G

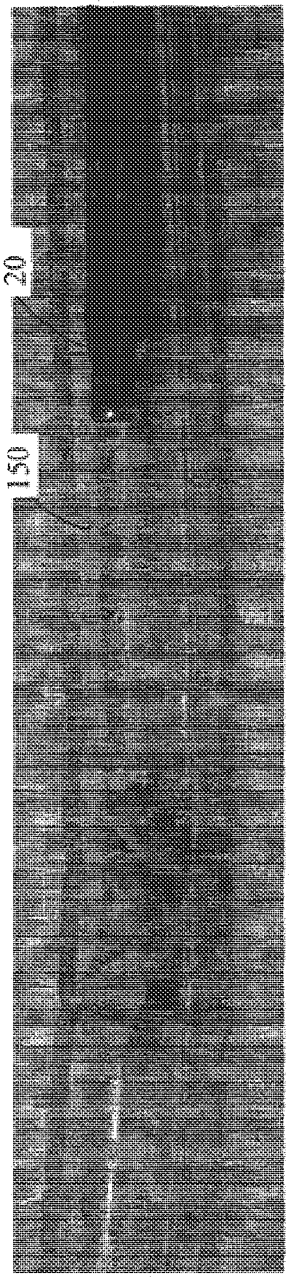


图 16H

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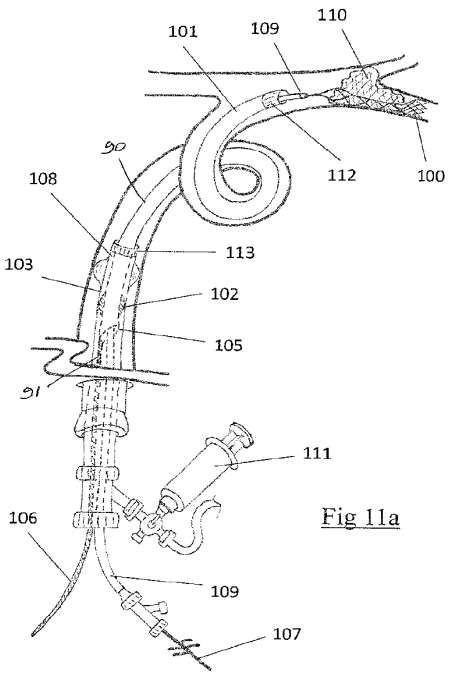


Fig 11a

(57) Abstract: A catheter 101 provides a proximal seal 102 against a guide catheter inner lumen 103 so that aspiration may be applied through a guide catheter 108 and thus take advantage of the large proximal lumen. The catheter 101 is a rapid exchange (RX) catheter with an exit port 105 that defines a transfer port for aspiration and provides a deliverability advantage of minimal frictional engagement with the guide catheter 108 proximal of the exit port 105. Aspiration can be applied to the lumen of the guide catheter 108 and is directed to and effective at the tip of the Rx aspiration catheter 101 due to the presence of flow a restrictor or seal 102 between the outer surface of the Rx aspiration catheter 101 and the inner guide catheter 108. This seals the lumen between the outside of the Rx aspiration catheter 101 and the inner surface of the guide catheter 03 and prevents backflow of blood into the tip of guide catheter 108 reducing the effectiveness of the aspiration. An expansile tip 112 of the Rx catheter 101 facilitates aspiration and retrieval of the clot 110 by expanding under load. The expansile tip 112 can also partially or fully occlude the vessel providing flow arrest and thereby improving aspiration effectiveness.

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DEVICES FOR REMOVAL OF ACUTE BLOCKAGES FROM BLOOD VESSELS

Field of the Invention

This invention relates to devices intended for removing acute blockages from blood vessels. Acute obstructions may include clot, misplaced devices, migrated devices, large emboli and the like. Thromboembolism occurs when part or all of a thrombus breaks away from the blood vessel wall. This clot (now called an embolus) is then carried in the direction of blood flow. An ischemic stroke may result if the clot lodges in the cerebral vasculature. A pulmonary embolism may result if the clot originates in the venous system or in the right side of the heart and lodges in a pulmonary artery or branch thereof. Clots may also develop and block vessels locally without being released in the form of an embolus - this mechanism is common in the formation of coronary blockages. The invention is particularly suited to removing clot from cerebral arteries in patients suffering acute ischemic stroke (AIS), from coronary native or graft vessels in patients suffering from myocardial infarction (MI), and from pulmonary arteries in patients suffering from pulmonary embolism (PE) and from other peripheral arterial and venous vessels in which clot is causing an occlusion.

Summary of Invention

According to the invention there is provided a catheter for assisting in the retrieval of a clot from a vessel comprising a distal end and a proximal end, a distal segment and a proximal segment and a lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment and a flow restrictor located on the outer surface of the catheter distal of the transfer port.

In one case the catheter is an aspiration catheter for aspirating a clot.

In one embodiment the flow restrictor is actuatable between engaged and disengaged configuration. The catheter may comprise an actuator for selectively engaging and/or disengaging the flow restrictor.

In one case the flow restrictor comprises a framework and a membrane coupled to the framework, the framework being movable by the actuator between an expanded configuration and a retracted configuration.

The aspiration catheter may comprise a proximal flow restrictor proximate the proximal end of the distal segment and a distal flow restrictor spaced distally from the proximal flow restrictor.

In one case the distal end of the catheter comprises a mouth for reception of clot. The mouth may be defined by an expansile tip.

In one embodiment the distal segment includes a hinge adjacent to the distal mouth. The hinge may be defined by a region of the distal segment which is configured to have lateral flexibility.

In one case the mouth has an expanded configuration and a retracted configuration. The catheter may comprise a control member for controlling the movement of the mouth between the expanded and retracted configurations.

In one embodiment the mouth comprises a number of segments and the control member is configured to move at least some of the segments. The control member may comprise a draw string or the like.

In another aspect the invention provides a catheter for aspirating a clot in a vessel comprising a distal end and a proximal end, a distal segment and a proximal segment and a lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment wherein the distal end of the catheter comprises a mouth for reception of clot. The mouth may be defined by an expansile tip. In one case the catheter has a flow restrictor located on the outer surface of the catheter distal of the transfer port.

Also provided is a system for treating an occlusion in a vessel the system comprising:-
a first catheter and a second catheter;
the first catheter comprising a proximal end, a distal end and a lumen extending between the proximal end and the distal end, the lumen of the first catheter further comprising a proximal segment and a distal segment;
the second catheter comprising a distal end and a proximal end, a distal segment and a proximal segment, and a lumen, said lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment;
the first catheter being configured to facilitate aspiration through the lumen;

the transfer port being configured to transmit aspiration in the proximal lumen of the first catheter into the lumen of the distal segment of the second catheter and the distal end of the second catheter being configured to receive clot into at least a portion of the lumen of the second catheter.

In one embodiment the system further comprises a flow restrictor between the first catheter and the distal segment of the second catheter, distal of the transfer port. The flow restrictor may be located on the inner surface of the first catheter. Alternatively or additionally the flow restrictor is located on the outer surface of the second catheter.

In one embodiment there is a proximal flow restrictor proximate the proximal end of the distal segment of the second catheter and a distal flow restrictor spaced distally from the proximal flow restrictor.

In one case the distal end of the second catheter comprises a mouth for reception of clot. The mouth may be defined by an expansile tip.

In one embodiment the transfer port comprises a rapid exchange port.

In one case the first catheter is a guide catheter. The second catheter may be an intermediate catheter.

The system may also include a microcatheter which is adapted to be advanced through the first catheter and the second catheter. The system may further comprise a clot engaging device for delivery from the microcatheter.

Also provided is a method of removing a clot from a vessel, the method comprising:-
providing a guide catheter and an intermediate catheter, the intermediate catheter having a distal mouth and being configured such that it is advancable within the lumen of the guide catheter;
inserting the guide catheter into a first vessel proximal of an occlusion;
advancing the intermediate catheter through the lumen of the guide catheter until the tip of the intermediate catheter extends distal of the guide catheter into a second vessel adjacent to the occlusion;

applying aspiration to the proximal end of the guide catheter;
the intermediate catheter being configured to direct said aspiration through the distal lumen of the intermediate catheter to aspirate the clot into the mouth of said intermediate catheter.

The aspiration catheter may comprise a distal end, a proximal end, a distal segment, a proximal segment and a lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment.

In one embodiment the method comprises restricting flow between the outside surface of the intermediate catheter and the inside surface of the guide catheter.

In one embodiment the method comprises the step, before or after aspiration, of delivering a microcatheter to the occlusion and deploying a clot capture device from the microcatheter. The method may comprise advancing the microcatheter to the clot, deploying a clot capture device from the microcatheter, retracting the microcatheter to a location proximal of a transport port at the proximal end of a distal segment of the aspiration catheter.

In a further aspect the invention provides method of removing an occlusion from a vessel comprising:-
providing a first aspiration catheter and a second aspiration catheter, the second aspiration catheter extending distal of the first aspiration catheter and further comprising a transfer lumen proximal of the distal end of the first aspiration catheter;
inserting the first catheter into a first vessel proximal of the occlusion;
advancing the second catheter through the lumen of the first catheter until the tip of the second catheter extends distal of the first catheter into a second vessel and is substantially opposing the occlusion; and
aspirating through the proximal lumen of the first catheter so as to urge the clot into the distal lumen of the second catheter.

The method may comprise restricting flow between the outside surface of the second catheter and the inside surface of the first catheter.

The method may comprise the step, before or after aspiration, of delivering a microcatheter to the occlusion and deploying a clot capture device from the microcatheter. In one case the

method as comprises the step, prior to aspiration, of retracting the microcatheter to a location proximal of the transfer port.

In one embodiment the first aspiration catheter is a guide catheter. In one case the second aspiration catheter is an intermediate catheter.

In one aspect the invention provides a clot receptor device. In one case the device is a catheter which may include rapid exchange features. In one embodiment the device provides a self-expanding aspiration catheter with flow-arrest.

The aspiration assist device has a distal end which expands to seal against the vessel proximal of the clot and provides a large open mouth to receive clot easily without risk of dislodging the clot from the thrombectomy device (if used).

The inner rapid exchange expandable device is delivered through an outer catheter, which may be a conventional intermediate or aspiration catheter or a distal access catheter (DAC). In one case it is a tailored catheter with an extremely trackable distal section for ease of access. This outer catheter trackability is possible because the distal section does not require much axial stiffness, as neither clot not thrombectomy device are retracted directly into it.

The rapid exchange (RX) expanding device may be supplied within the outer catheter (about 15cm proximal of the distal end) and both are delivered together over a microcatheter (or wire) until the outer catheter tip approaches the clot. The inner RX expanding device is advanced to the distal end of the outer, and the outer is then retracted to deploy the self expanding RX device.

The Rx device seals against the vessel wall and against the inner lumen of the outer catheter to allow highly effective aspiration, and its distal end expands to provide a large opening and reception space to receive the target clot and thrombectomy device (if used).

In another similar embodiment the self expanding aspiration catheter has a full length tubular proximal shaft, rather than a rapid exchange shaft, so that it does not require a proximal seal and aspiration can be applied by applying a vacuum force to its proximal hub.

The invention also provides a rapid exchange aspiration catheter.

The catheter provides a proximal seal against guide catheter inner lumen so that aspiration may be applied through the guide taking advantage of the large proximal lumen.

The catheter having deliverability advantages of minimal frictional engagement with guide or microcatheter proximal of exit port.

Retracting the microcatheter just proximal of exit port (rather than completely removing it) creates a large aspiration advantage.

Also provided is a removable microcatheter hub that enables physician to advance a DAC over the microcatheter after the microcatheter (and thrombectomy device) are already in position (as bail, out for example).

Brief Description of the Drawings

Figs. 1 and 2 illustrate a clot receptor device and system according to the invention;
Figs. 3 to 9 illustrate various alternative clot receptors;
Figs. 10 and 11 illustrate a rapid exchange aspiration catheter according to the invention;
Figs. 12 and 13 illustrate various proximal and distal seals;
Figs. 14 to 37 illustrate various alternative distal ends and expansile tips of a clot collector device of the invention;
Fig. 38 illustrates an alternative rapid exchange configuration
Figs. 39 to 46 illustrate a removable microcatheter hub according to the invention;
Figs. 47 to 51 illustrate the creation of the distal segment with a continuous and smooth stiffness profile;
Figs. 52 to 55 illustrate a dual lumen aspiration catheter according to the invention;
Figs. 56 to 59 illustrate a clot receptor device and system according to the invention;
Fig. 60 illustrates a clot receptor device according to the invention;
Figs. 61a-c illustrate a clot receptor device and system according to the invention:
Fig. 62 illustrates a portion of a clot receptor device and system according to the invention;
Fig. 63 illustrates a clot receptor device according to the invention;
Figs. 64a-d illustrate an expansile tip of a clot collector device of the invention and
Fig. 65 illustrates a rapid exchange aspiration catheter according to the invention.

Detailed Description of the Drawings

Fig. 1 illustrates a clot receptor device 2 of this invention being used in the retrieval of a clot 1 from the blood vessel of a patient. The clot receptor device 2 comprises an elongate proximal shaft 13 and a tubular expansile distal section 4. The proximal end 5 of the expansile distal section 4 is configured to seal against the inner lumen of a distal section 6 of a catheter 7 through which it is advanced, while the distal end 8 of the expansile distal section is configured to seal against the wall of the blood vessel. The proximal seal against the lumen of the intermediate catheter 7 enables an aspiration force (such as a vacuum or a negative pressure differential, as may be induced by retracting a syringe plunger or through a vacuum pump) to be transmitted through the intermediate catheter 7 to the clot receptor device 2 and thus to the clot. The low profile proximal shaft 13 of the clot receptor device 2 minimizes the space occupied within the intermediate catheter 7, maximising the effectiveness of the transmission of this vacuum / aspiration force to and trough the clot receptor 2. The seal at the proximal end of the clot receptor 2 may be provided by the expansile body of the clot receptor 2 opposing the lumen of the intermediate catheter 7. Other embodiments of this seal include a soft cuff of a foam or fibre construction, or polymer leafs or leaflets, or a balloon cuff, or a stent-like construction with a membrane cover, or combinations of these or other designs

The distal end 8 of the expansile distal section 4 is configured to open to a larger diameter than the proximal end, typically at least 50% larger, and in some embodiments up to 500% larger or more, depending on the relative size of the target blood vessel and the lumen of the catheter 7 through which the device is advanced. The large open mouth of the distal end 8 of the clot receptor 2 provides an easy path for retraction of clot into its interior space, and once within this space the clot can be safely retrieved from the patient. In one embodiment the inner lumen of the clot receptor device 2 has a profiled surface (like a sharkskin, or backward facing teeth) which allows clot to slide easily into the device, but resist the clot from escaping back out of the device.

Figs 2a to 2f illustrate a typical method of use of such a device and system. The method may include at least some of the following steps: Accessing an arterial blood vessel of a patient using conventional means such as an introducer 10 and guide catheter or sheath 11, advancing a microcatheter 12 up to and across a target occlusive clot with the aid of a guidewire 17, removing the guidewire 17 and advancing a mechanical thrombectomy device 15 such as a stent-retriever through the microcatheter 12 to the target clot 1, retracting the microcatheter 12 at least a few cm to deploy a mechanical thrombectomy device 15 within the clot 1, advancing an

intermediate catheter 7 containing the clot receptor device 2 up to a position just proximal of the clot 1 (or within the clot, or considerably proximal of the clot if vessel disease or tortuosity makes access difficult), advancing the clot receptor device 2 up the distal end of the intermediate catheter 7 (or up to and out of the catheter and into or over the clot), retracting the intermediate catheter 7 a short distance to deploy the clot receptor device 2, aspirating through the intermediate catheter 7 using a syringe or pump to suck blood and the target clot into the clot receptor device 2, withdrawing the mechanical thrombectomy device 15 into the clot receptor 2 while continuing to aspirate, withdrawing the clot receptor device 2 and its contents at least partially into the lumen of the intermediate catheter 7, withdrawing the intermediate catheter 7, clot receptor device 2, clot and mechanical thrombectomy device 15 through the guide or sheath 11 and out of the patient.

Many variants of this method are possible.

For example it may be desirable to withdraw the clot 1 and mechanical thrombectomy device 15 through the clot receptor 2, intermediate catheter 7 and guide 11 and out of the patient while leaving the intermediate catheter 7 and clot receptor 2 in place. This allows the physician to retain a protective seal in the vessel to prevent the escape of any clot particles that may be dislodged, and also preserves a means of quick and easy access back to the target site with a microcatheter and thrombectomy device in case additional passes are needed to completely clear the vessel.

Another method variant involves removing the clot receptor device 2 and thrombectomy device 15 together through the intermediate catheter 7, leaving the intermediate catheter 7 in place for easy re-access to the target site.

Yet another method variant involves using the clot receptor device 2 as the primary clot retrieval tool, without the aid of a mechanical thrombectomy device such as a stent-retriever. The clot receptor 2 is configured to expand and seal against the vessel wall adjacent the proximal end of the clot, thus aspirating through the intermediate catheter 7 and clot receptor 2 provides a highly effective suction force to draw the clot into the clot receptor 2. If the clot passes through the clot receptor 2 and into the intermediate catheter 7 it may be aspirated through the intermediate catheter 7 and right out of the patient. If the clot is too large or too firm to pass through the clot receptor 2 then the clot receptor 2 may be withdrawn into the intermediate catheter 7. Because

the clot receptor 2 has a smooth and funnel shaped exterior it can be easily retracted into the intermediate catheter 7 even when containing a bulky and/or firm clot.

The distal end 8 of the clot receptor device 2 is intended to open up upon exiting the catheter through which it is delivered to provide a large open mouth approximately equal in size to the inner diameter of the vessel in which it is located and provide a seal against this vessel or significant flow restriction such that when a suction force is applied through the clot receptor 2 this force causes blood and clot distal of the receptor 2 to flow into the receptor 2 rather than blood proximal of the receptor 2. This flow occurs because the pressure inside the clot receptor 2 is lower than that outside (distal and proximal) of the clot receptor 2. If the seal were not present two flow paths into the clot receptor 2 would exist and the less restricted proximal flow path would dominate, reducing the effectiveness of the clot retraction.

In order to adequately seal against the vessel wall the clot receptor 2 should have either a) a high radial force or hoop strength so that the pressure gradient created by the application of suction/aspiration does not collapse the clot receptor or create a flow path past it or b) a seal construction such that the presence of a pressure gradient across the clot receptor 2 serves to tighten the seal rather than reduce it. The geometry and construction of the clot receptor sealing end should be such that it can conform well to the vessel wall, which may be not be effectively circular (such as when close to bifurcations for example, or when inclined at an angle to the vessel wall).

Thus one embodiment of the distal portion of a clot receptor may comprise a self-expanding frame with a relatively non-porous cover, such that the cover prevents any significant passage of blood through the wall of the clot receptor, and the self expanding frame has sufficient radial or hoop strength to resist the pressure gradient created by the application of suction/aspiration. The cover may be a polymeric membrane, or may be a woven or braided or knitted structure. In one embodiment the membrane is a polymer membrane, preferably with a high elastic strain limit and a low modulus to permit its expansion by a low radial force frame structure. A preferred membrane is a polyurethane membrane, which might be extruded or blow moulded or ideally dip coated directly onto the frame. The membrane may be coated with a low friction coating such as a hydrophobic silicone or a hydrophilic material. In one embodiment the membrane is a hydrophilic material itself, comprising a hydrogel with sufficient thickness and modulus to retain its structure under the force of aspiration. Other suitable materials for this cover include PTFE,

ETFE and PFA. Materials such as PET, UHMWPE, PET and PEN would be particularly suitable for use in the making of a cover that is woven, braided, knitted or otherwise formed from fibres

Another embodiment of the distal portion of a clot receptor may comprise a combination of a self-expanding frame with a relatively non-porous membrane cover, and a plurality of flexible leaflets or vanes disposed around its outer circumference in a manner similar to that of a leaflet valve. In yet other embodiments the additional seal provided by these flexible leaflets is instead provided by an outer cuff, and this outer cuff may comprise a compressible material such as a foam or a hydrogel or a fibre bundle or a shaped polymer.

In yet another embodiment the expansion of the distal end of the clot receptor may be actuatable by the user, by retraction of a pull wire within the device shaft for example, or by inflation of a balloon cuff.

Some of the various embodiments of the distal end of the clot receptor are illustrated in Figs. 3 to 9.

Fig. 3 depicts one embodiment of the distal end of the clot receptor comprising a stent-like self-expanding frame 25 with an outer membrane covering 27. A proximal shaft 21 is connected to the frame and membrane at a proximal entry port 20. The proximal end 24 of the expansile section is configured to gently appose the wall of a catheter through which it is delivered, while the distal end 23 is configured to expand and appose the vessel wall, creating a large opening 22 into the internal reception space. The frame structure 25 is in one embodiment a Nitinol structure laser cut from a tube or sheet, and in another embodiment is a wire structure, wound or braided from Nitinol or stainless steel or other such biocompatible metallic material as are commonly used in the construction of stents or snares. The membrane 27 may comprise a lip 26 which is folded over and wrapped inside the frame 25.

Figs 4 and 5 depict a typical embodiment of the distal end of the clot receptor. Fig. 4 shows a clot receptor 30 housed in an outer intermediate catheter 31, positioned in a vessel 32. The distal end 35 of the clot receptor is folded to wrap it into a suitable profile to fit into the lumen of the intermediate catheter 31. Fig. 5 shows the deployed clot receptor upon retraction of the intermediate catheter 31, such that distal end 35 has expanded and is contacting the vessel wall 32, and proximal end 34 is sealing against the inner lumen of the intermediate catheter 31. In

another embodiment the distal end 35 expands to a smaller diameter than that of the vessel, but a larger diameter than that of the intermediate catheter.

The intermediate catheter inner lumen may be as small as 0.75mm or as large as 2.0mm, but is preferably between 1.0mm and 1.7mm. The clot receptor distal end may be configured to expand to a diameter equal to or slightly larger than the target vessel in order to provide a seal, or to a diameter slightly smaller than the target vessel in cases where a low profile, deliverable device is a higher priority than a perfect seal. In one embodiment configured for use in middle cerebral arteries of the brain, the clot receptor distal end is configured to expand to a diameter of between 2mm and 4mm. In another embodiment such as might be used in the internal carotid artery, the clot receptor distal end is configured to expand to a diameter of between 4mm and 7mm.

Figs 6a and 6b illustrate the collapsed (for delivery) and expanded forms of the distal end of a clot receptor 40 of this invention. In this case the mechanism of collapse for delivery through an intermediate catheter is a creasing and folding mechanism, similar to that used to wrap angioplasty balloons. The material of the distal expansile end 42 is configured into pleats or folds 41 to wrap it efficiently into delivery form.

Figs 7a and 7b illustrate the collapsed (for delivery) and expanded forms of the distal end of a clot receptor 50 of this invention. In this case the mechanism of collapse for delivery through an intermediate catheter is a rolling mechanism, with an unrolling mechanism taking place for expansion. The distal expansile end 52 exists in its minimum strain state when fully expanded as shown in Fig. 7b. It is configured with a seam 51 running from its distal most end to a point distal of its proximal end. The seam allows the self-expanding clot receptor to be rolled up like a cigarette paper to assume a lower profile shape for delivery.

Figs 8a and 8b illustrate the collapsed (for delivery) and expanded forms of a frame 60 of the distal end of a clot receptor of this invention. This frame may be formed from Nitinol or another material with a sufficient elastic strain limit such that this limit is not exceeded when the device is collapsed for delivery through an intermediate catheter. In one embodiment the frame is laser cut from a Nitinol tube or sheet, and comprises struts 61 connected at crowns 62. The distal end of the frame comprises terminal crowns 63, which may be formed with atraumatic ends of a higher radius of curvature than that used for the more proximal crowns. The frame may be covered with a polymeric membrane as described earlier.

Fig. 9 illustrates the expanded form of a frame 70 of the distal end of a clot receptor of this invention, which is similar to frame 60 of Fig. 8 but is formed from wires 73 rather than cut from a tube or sheet. One advantage of such a structure is that non superelastic materials (such as SS, MP35N or other materials commonly used in the manufacture of balloon expandable stents) can be used in its construction. This is because a much lower strain is induced in the frame in moving from its expanded to collapsed state, because the wires are free to move and slide relative to one another, even at crossover points 72. The wires form crowns 71 of a large and gentle radius at the distal end of the frame, rendering the tip of the device atraumatic to a blood vessel.

Referring to Figs. 10 and 11 there is illustrated an aspiration catheter 101 according to the invention. In Fig. 11a the aspiration catheter 101 is illustrated as part of a clot retrieval system for retrieval of a clot 110. The clot retrieval system further comprises a clot engaging device 100, a microcatheter 109 through which the clot engaging device is delivered and a guide catheter 108 through which the aspiration catheter 100 and microcatheter 109 are delivered. The aspiration catheter 101 comprises a distal segment 90 and a proximal segment 91. The distal segment 90 comprises a distal end provided with a distal tip 112 and a proximal end provided by a transfer port 105. A lumen of the distal segment 90 extends proximal of the distal end 112 and terminates at the transfer port 105. The proximal segment 91 extends from the distal segment 90 and in this case is provided by a proximal shaft 106. A flow restrictor 102 is located on the outer surface of the aspiration catheter 101 distal of the transfer port 105. The aspiration catheter 101 provides a proximal seal 102 against a guide catheter inner lumen 103 so that aspiration may be applied through the guide catheter 108 and thus take advantage of a large proximal lumen.

Fig.10 shows a simplified view of a distal region of the system, illustrating more clearly how the aspiration catheter flow restrictor 102 interacts with the inner lumen of the guide catheter 108. The guide catheter 108 may also have a flow restrictor component such as the inflatable balloon portion 104 shown in this illustration.

The aspiration catheter 101 is a rapid exchange (RX) catheter in which the exit port 105 defines a transfer port for aspiration and provides a deliverability advantage of minimal frictional engagement with the guide catheter 108 proximal of the exit port 105.

In some cases a microcatheter 109 may be provided through which a clot capture device 100 is delivered. Retracting the microcatheter 109 just proximal of the exit port 105 (rather than completely removing it) creates large aspiration advantage.

In one case the microcatheter 109 and the Rx aspiration catheter 101 are introduced together into the guide catheter 108.

The guide wire and microcatheter 109 are then advanced across the clot 110. The guidewire can be removed and a clot retrieval device such as a stent retriever device 100 is introduced.

Using the microcatheter 109 for support, the Rx aspiration catheter 101 can be forwarded to a position proximal to the clot 110 by pushing the proximal shaft 106 or handle into the guide catheter 108. The stentriever device 100 can be deployed by retracting the micro catheter 109.

The Rx aspiration catheter 101 can then be forwarded to contact the clot 110 or be positioned just proximal to or at the proximal face of the clot 110. The microcatheter 109 can then be retracted sufficiently to be proximal of the Rx port 105 of the Rx aspiration catheter 101. This facilitates an increased lumen for aspiration without the necessity of removing the microcatheter 109 fully from the intermediate / aspiration catheter.

Aspiration can be applied to the lumen of the guide catheter 108 with a manual syringe 111 or vacuum pump. This aspiration is directed to and effective at the distal tip 12 of the Rx aspiration catheter 101 due to the presence of the flow restrictor or seal 102 between the outer surface of the Rx aspiration catheter 101 and the inner guide catheter 108. This seals the lumen between the outside of the Rx aspiration catheter 101 and the inner lumen 103 of the guide catheter 108 and prevents backflow of blood into the tip of the guide catheter 108 which would reduce the effectiveness of the aspiration. The seal 102 may not need to stop flow in the lumen completely but needs to restrict flow sufficiently so as not to have a significant effect on aspiration performance. This seal 102 can be generated in a number of ways such as those described in Figs 12 to 13l. In some cases the seal 102 is located on the inside surface of the guide catheter 108 and/or on the outside surface of the aspiration catheter 101.

The Rx aspiration catheter 101 is constructed of a proximal handle (not shown) to facilitate grip and a proximal shaft 106 constructed from a wire or tube formed preferably from Nitinol,

stainless steel, PEEK or some other similar material. An additional seal may be provided on a proximal haemostasis valve to assist in sealing against the proximal shaft 106. The material of the shaft 106 has high compressive and tensile strength and may have a low friction coating or jacket to minimise insertion and retraction forces. The low friction coating or jacket could be formed from PTFE, HDPE or a similar material.

The Rx exit port 105 on the aspiration catheter 101 can facilitate forwarding a microcatheter 109 through the port 105 and through the distal section 90 of the Rx catheter 101 prior to insertion into the guide catheter 108. The Rx exit port 105 may be formed in a funnel shape to make it easier to forward a microcatheter 109 into the port even in position in the guide catheter 108. The port 105 may be formed from a moulded component or from the tubing of the distal section 90 of the catheter 101.

The distal section of the Rx aspiration catheter 101 has good push and trackability characteristics to allow it to be forwarded to the target location. Therefore it may be constructed of one or more materials to give a reducing stiffness profile along the length. A braided wire or coil wire construction or combination of both may be used to improve compressive strength and track ability. Linear wire supports running parallel to the tube axis may also be used.

A top layer of low friction material may be applied to the distal section of the catheter 101 or alternatively a hydrophilic coating or silicon oil coating may be applied to the surface. The inner lining of the distal section of the catheter 101 consists of PTFE or similar low friction material to minimise insertion and retraction forces.

The seal 102 on the outer surface of the Rx aspiration catheter 101 distal section 90 prevents or significantly reduces blood flow travelling from the guide catheter distal tip 113 to the Rx port 105 of the Rx aspiration catheter 101 as shown in Fig. 12a. Various embodiments of proximal seals 102 are illustrated in Figs. 12 to 13l.

In another embodiment of the device shown in Fig. 12b an additional seal 114 is provided on the distal end of the catheter 101 to seal between the Rx catheter and the target vessel. This seal 114 is spaced distally from the proximal flow restrictor 102 and occludes blood flow in the vessel and improves aspiration effectiveness without the need for a balloon guide catheter. The seal 114 can be constructed in a similar manner to those shown in Figs 12a to 13l.

The seal 102 can be formed from an outer sleeve on the catheter which may be smooth or have a grooved or profiled surface 116 as shown in Fig. 13a. Fig. 13j shows a profiled surface with a spiral groove 125. The seal could also be formed from one or more moulded rings with a sealing lip or "O" ring profile 117 as shown in Fig. 13b. It could also be formed from an inflatable balloon 115 which is inflated by injecting saline through a lumen in the shaft and catheter as shown in Figs 12a, 12b and 13g.

In another embodiment illustrated in Fig. 13d the seal 102 can be constructed of fibres in a brush / bristle configuration 119 or from a fibre mesh 123 formed of PET fibres or similar material as shown in Fig. 13h. Similarly the seal could be formed of a sponge material 121 which is compressed when inserted into the lumen of the guide catheter 108 as shown in Fig. 13f.

In a further embodiment the seal 102 could be provided by a body 124 formed from a hydrophilic 124 or similar material which swells and increases in diameter when in contact with saline or blood. The seal 102 may also be formed by having a close tolerance clearance fit between the outer diameter of the distal end of the Rx aspiration catheter 101 and the inner diameter of the guide catheter 103. In another embodiment, the seal 102 is formed from a lip 118 or membrane 120 which restricts flow particularly in one direction as shown in Figs 13c and 13e.

In another embodiment of the seal 102 shown in Figs 13k and 13l, the occlusion between the Rx aspiration catheter 101 and the guide catheter 108 is achieved through longitudinal compression of the aspiration catheter 101. This can be achieved by having an expansile section 127 which increases in diameter when the catheter is under compression. The compression can be a result of retrieving clot 110 and the stentriever device 100 into the tip 112 or may be manually actuated through a pull wire 126. This pull wire 126 may run through a separate lumen from the proximal end of the device as shown in the cross sectional view A-A in Fig. 13l.

The clot 110 and stentriever type device 100 can be fully or partially retrieved into the Rx aspiration catheter 101 as controlled by the physician and depending on the resistance felt by the user or clot obstruction of the lumen as indicated by an increase in vacuum / loss of suction. The expansile tip 112 of the Rx aspiration catheter 101 facilitates aspiration and retrieval of the clot 110 and stentriever device 100 by expanding under load to reduce the retraction force and lessen the risk of scraping clot off the surface of the stentriever device 100. The expansile tip

112 can also partially or fully occlude the vessel providing flow arrest improving aspiration effectiveness.

The expansile tip 112 can be formed in a number of ways and various embodiments are shown in Figs 14 to 37.

In one embodiment the expansile tip 112 can be formed from a co-extrusion of materials with different properties such as a soft expansile polymer 131 co-extruded with a higher modulus polymer 130 to provide longitudinal support. A fully expansile ring 132 could then be connected to this tip as shown in Fig. 14. The tip 112 may also include one or multiple metallic wire supports 133 as shown in Figs 15 and 24. In another embodiment shown in Fig. 18 the tip has a skived profile to increase contact area with the clot during retrieval or aspiration. The tip may be formed with holes 134 or perforations 137 to allow it to split and change shape when a device 100 and clot 110 is retracted into the tip as shown in Figs 16 and 17. These features can be combined with tip constructions containing materials of different durometers such as shown in Figs 16, 17, 18, 21 and 25. In these embodiments the tip materials 143, 136, 146, 151, 164 have a lower durometer and are more expansile than the support materials 135, 144, 145, 150, 165. These support materials may be embedded within the wall of the tubing or may be on the inner or outer surface. They may also be formed in a spline, coil, stripe, 'U' shape or other configuration to provide longitudinal support to the expansile material to prevent it collapsing or buckling under compressive load, such as occurs during retrieval of a clot or stentriever device, or during insertion through a guide or access catheter. Fig. 19 shows another embodiment where multiple holes 139 produce a lattice or framework in the tip. Single or multiple protrusions or "teeth" 141 may also be applied to the inner surface 142 at the distal tip to improve grip on the clot as shown in Fig. 20.

The expansile tip may be pre shaped to form a flared profile (Fig. 22a) or a tapered profile as shown in Fig. 22b. Alternatively the tip shape may be a combination of these profiles such as bulbous or 'pear' shaped as shown in Fig. 23a to 23d. In the configuration shown in Fig. 23a the tip 160 has an increased diameter larger than the proximal catheter diameter 161 which then tapers to a reduced diameter 162 for ease of insertion. In the configuration shown in Fig. 23b the tip 166 has an increased diameter larger than the proximal catheter diameter 161 which then tapers to a reduced diameter 167, however the reduced diameter 167 is still larger than the proximal catheter diameter 161. This tip configuration provides benefits of improved aspiration

effectiveness and reduced retrieval force but also low insertion force and trackability benefits due to the distal tip radius or taper 167. The tip radius 167 also prevents the tip snagging on a bifurcation on insertion, such as at the ostium of the ophthalmic artery in the internal carotid artery. Fig. 23c shows how the tip 160 elongates during insertion through a guide or access catheter 108, while Fig. 23d shows the tip 160 expanding to accommodate the retrieval of a clot 110 and stentriever device 100. The profiled tips can also be constructed using multiple materials of varying durometer and expansile characteristics.

The expansile tip 112 could also be profiled and contain one or more slot cuts 170 to facilitate expansion as shown in Figs 26, 29 and 30. Other embodiments of profiled tips to facilitate expansion and retrieval of the clot 110 and stentriever device 100 are shown in Figs 27 and 28.

In another embodiment of the Rx aspiration catheter tip 112 shown in Fig. 31, the distal end of the tip has a collar 171 which tracks closely over the guidewire. This helps direct the catheter over the guidewire to the target location reducing the risk of snagging. The tip configuration shown in Fig. 32 has a flattened section 173 which contains a large number of aspiration pores 174, and aspiration windows 172. This design potentially increases the contact area with the clot improving grip where the catheter is used without a stentriever device. Fig. 33 shows an end view of Fig. 32 with the arrows indicating the direction of blood flow.

Referring to Figs. 34 to 35 there is illustrated a catheter with an expandable distal end 180, which is expanded by means of a lifebelt shaped annular balloon 181 at or adjacent its distal end. The balloon is inflated by injecting a fluid through an inflation lumen 182 running from the proximal to distal end of the device. The distal end of the catheter has a ring of petals 183 which act as a seal or occluder to limit the volume of blood flowing from proximal of the tip into the catheter, when aspirating through the catheter. The petals 183 may be formed from a polymeric material. Fig. 34a shows the tip in the collapsed configuration and Fig. 34b shows the tip when the annular balloon 181 is inflated. Fig. 35 shows an additional embodiment where the catheter has an Rx construction with the inflation lumen 182 running through the shaft to the proximal end of the device.

In another embodiment of the catheter tip 112, shown in Figs 36a and 36b, the tip 184 is constructed so that it can invert as the stentriever device 100 and clot 110 are retrieved into the

catheter. This can reduce the retraction force and constrain the clot so fragments are not released during the retrieval process. Fig. 36b shows the tip after inversion.

Referring to Figs. 37a and 37b there is illustrated a clot retrieval catheter with a self-expanding distal tip 190 that is constrained by a tapered cap 191 for ease of deliver and atraumatic access to a target site. The cap component 191 can be retracted to allow the catheter mouth 192 to expand, creating a large opening to accept clot or other material into its lumen. The cap component 191 has a distal end whose outer diameter is ideally lower than that of the catheter shaft immediately proximal of the cap, and an inner lumen sized to enable the device to be advanced over a thrombectomy device shaft and microcatheter. The cap component 191 may also comprise a guide tube 193 to aid the device in moving smoothly over a thrombectomy device shaft or microcatheter.

In another embodiment of the device shown in Fig. 38 the distal section of the catheter 194 is shortened so that distance X is typically between 5 and 50 mm long. This device can be forwarded over the shaft of the stentriever device 100 to the target location to facilitate partial or full retrieval of the stentriever 100 into the expansile tip 112. In this embodiment the distal section 194 is forwarded out of the guide catheter 108 and does not translate aspiration to the distal tip 112, but has improved trackability and access performance to reach the target vessels due to reduced friction and pushability of the wire shaft. The short length distal section 194 and tip 112 are connected to a shaft 106 constructed from a wire or tube formed preferably from Nitinol, stainless steel, PEEK or some other similar material. The shaft material has high compressive and tensile strength and has a low friction coating or jacket to minimise insertion and retraction forces. The expansile tip 112 can be constructed in a similar manner to those shown in Figs 14 to 37.

The Rx aspiration catheter 101, microcatheter 109, stentriever device 100 and clot 110 can be retracted as a unit back to the tip of the guide catheter 113 and then fully into the guide catheter 108. The guide or access catheter 108 may also have an expansile tip 113 to facilitate retraction of the devices and clot, with a reduced force and lower risk of dislodging the clot from the devices. This expansile tip 113 on the guide catheter may be constructed in a similar manner to those shown in Figs 14 to 37. Likewise the expansile tip 112 construction and seal 102 construction shown in Figs 12 to 37 may also be applied to a standard length intermediate or aspiration catheter.

The Rx aspiration catheter 101, microcatheter 109, stentriever device 100 and clot 110 can then be retrieved from the guide catheter 108 and removed fully from the patient.

Referring to Figs. 39 to 46 there is illustrated a removable microcatheter hub according to the invention. The removable hub enables a physician to advance an intermediate or access catheter over the microcatheter after the microcatheter (and thrombectomy device) are already in position (as bail out for example). It is not possible with a standard microcatheter to forward an intermediate or access catheter over the proximal end as the fixed hub is in the way, therefore the standard microcatheter has to be removed to introduce an intermediate catheter.

Use of a microcatheter with a removable hub that facilitates the use of an extension wire facilitates improved control on the microcatheter position as the intermediate catheter is introduced.

In Figs. 39 to 46 the following numerals are used:

300 detachable hub
301 microcatheter shaft
302 strain relief element extending from microcatheter hub
303 internal connector (see Figs. 42/43 for detail)
304 end of microcatheter shaft which has detached
305 extendable shaft for intermediate catheter exchange
306 internal thread on microcatheter hub
307 microcatheter connector
308 O-ring seal
309 external thread on microcatheter connector
310 bond
311 closed end to prevent outbleed
312 bond
313a extension wire
313b extension wire housing
314 laser cut hypotube which acts as a core reinforcement for microcatheter
315 stiff proximal shaft so that it can be gripped and pulled/twisted during microcatheter removal

316 compressible O-ring which locks the microcatheter into recess incorporated into moulded catheter hub
317 detachable hub
318 extension tube
319 spring clip – e.g. stainless steel or Nitinol
320 injection moulded hub

D1 0.021 inch ID approx.
D2 0.029 inch OD approx.
D3 0.039 inch OD approx.
D4 0.045 inch OD approx.

Fig. 39 shows the microcatheter hub 300 assembled with the microcatheter shaft 301. Fig. 40 shows the microcatheter shaft after detachment and Fig. 41 shows the mating end of the extendable shaft 305. By connecting the extendable shaft 305 to the microcatheter shaft 301 the working length of the catheter is increased to facilitate forwarding an intermediate or access catheter over the microcatheter while maintaining positional control. The extendable shaft 305 can then be removed and the detachable hub reconnected to the microcatheter.

Fig. 42 illustrates the construction of the microcatheter connector 307 and detachable hub 300. The detachable hub 300 can be screwed onto the microcatheter connector 307 due to thread 309 on the connector and the mating thread 306 on the hub. 'O' ring 308 prevents any blood loss or air ingress between the connector 307 and the hub 300 when tightened.

Fig. 43 shows a section view of an embodiment of the extendable shaft 305 which utilises an extension wire 313a and extension wire hub 313b. The extension wire 313a and hub 313b are shown screwed onto the microcatheter shaft 301and connector 307.

Figs 44 to 46 show another embodiment of a detachable hub where the microcatheter shaft 301 is connected to the detachable hub 317 by a compressible 'O' ring 316. The 'O' ring 316 sits in a groove on the moulded hub 320 which is connected to the microcatheter shaft 301. The 'O' ring is compressed by rotating part of the housing 321 on the detachable hub 317. The extension tube 318 can be pushed over the moulded hub 320 on the microcatheter shaft 301 after the hub 317

has been removed. The extension tube 318 is then held in position by the spring clip 319 engaging with the groove on the moulded hub 320.

Figs. 47 to 50 illustrate a method of manufacture of a large diameter aspiration catheter. The aspiration catheter is highly trackable so that it can be navigated to tortuous/distal cerebrovascular location.

Fig. 47 is a graph of lateral stiffness with distance from the tip.

Fig. 48 illustrated a conventional diagram in which different tubular segments 200, 201, 202, 203, 204 are of different materials. The segments are used to create a stepped material stiffness profile (gradually increasing modulus/share hardness).

Fig. 49 illustrates a distal segment according to the invention in which a smooth stiffness profile is created by blending elements 205, 206 of different modulus. For example, tapered tubes 205, 206 (Figs. 50, 51) may be placed on a mandrel overlapping each other and use heat to cause them to melt and flow into each other. The resultant tube may then be applied to a threaded or spiral wire or unreinforced base, or use as a stand-alone catheter.

Referring to Figs. 52 to 55 there is illustrated a dual lumen aspiration catheter to aid with aspiration and prevent the lumen of the catheter getting blocked with clot.

Lumen A – a smaller diameter lumen can be used to retrieve the device into and cause the clot to shear off. The distal end of *Lumen A* could be flush with or recessed from the distal tip of *Lumen B*.

Lumen B – the larger lumen would have aspiration constantly applied to it, to aspirate the clot that is sheared off the device when it is retrieved into the smaller lumen (*Lumen A*).

The smaller lumen A may have an inner diameter to facilitate the introduction of a microcatheter through the lumen. The microcatheter can then be inserted through this lumen and across the clot as per standard procedure. The stentriever device can then be deployed across the clot. Retrieving the stentriever and clot into the catheter causes the clot to be sheared off the stentriever within the aspiration catheter. This configuration prevents the clot snagging on the

struts of the stentriever device and blocking the aspiration lumen. The larger diameter lumen may have a diameter of about 0.058 inch and may have aspiration applied to it to aspirate the clot as the device is being retrieved into the smaller diameter lumen.

One clot receptor catheter tip according to the invention the clot receptor tip is expanded by means of a balloon, which may be attached to the shaft of a thrombectomy device, or to a microcatheter, or may be integral to the clot receptor catheter itself.

One embodiment of such a device is shown in these Figs 56 to 59. The device comprises a thrombectomy device 400 with an inflation lumen 402 extending from the proximal end of the shaft to a balloon 401 at the distal end of the shaft, and an clot receptor catheter 404 with a flexible expandable distal section 405. The thrombectomy device 400 is expanded in the clot 403. Either the thrombectomy device and clot are then retrieved towards the clot receptor catheter 404 or the clot receptor catheter is advanced towards the thrombectomy device. The balloon 401 at the distal end of the device is positioned so that the distal end is in line with the distal end of an intermediate catheter. The balloon is expanded to plastically deform 406 the distal end of the clot receptor catheter and then deflated. The resultant open mouth 407 of the clot receptor catheter allows the entire device and clot to be retrieved into the intermediate catheter. This prevents loss of clot on retrieval into a small lumen of a conventional intermediate catheter. The expansile distal portion 405 of the clot receptor catheter may be formed of a polymeric material with a low modulus and a high elongation strain to break of greater than 100%, and ideally greater than 300%. It may also comprise a support structure of a metallic material such as stainless steel which can be plastically deformed by the balloon and can then retain its deformed shape with sufficient integrity to accept the thrombectomy device and clot.

The balloon expandable tip of the invention can be applied to any catheter – standard or rapid exchange, and can be used with or without a thrombectomy device to aid in the aspiration and/or retrieval of clot from blood vessels.

Fig. 60 illustrates an RX clot removal catheter 500. This device 500 is very similar in design and in use to that shown in figs 11a-d, except that the element 504 is an actuatable flow restrictor or seal, which can be selectively engaged or disengaged by the operator. The catheter 500 comprises a proximal elongate shaft 501 and a distal generally tubular portion 502. The distal portion 502 comprises reinforcement member 507 and a polymeric cover member 510, and

extends from an entry/exit port 517 to a distal clot reception tip 503. The cover member 510 may comprise multiple layers and segments. A low friction inner layer may be employed as a lining for the lumen of the tubular section, a highly compliant membrane 506 may be employed to cover the actuatable flow restrictor / seal region, and a low modulus polymer may be employed to cover the main tubular body. The distal end or tip 503 may comprise any of the designs shown elsewhere in this document. In a preferred embodiment the tip 503 is connected to the distal end of the tubular portion 502 by a hinge element 511. This hinge element may simply be a short region of the tubular section configured to have a high degree of lateral flexibility relative to the rest of the tubular section. This flexibility may be achieved by having a short region of the tubular section without any reinforcement element 507, or alternatively the reinforcement at that region could be a highly flexible reinforcement such as a generally spiral metallic coil.

The actuatable flow restrictor or seal 504 comprises a framework 508, with a membrane covering 506. The framework 508 is at least partially collapsible by retraction of actuation member 512, which runs through proximal elongate shaft 501 and is connected at its proximal end to slider element 514, which is in turn slidably constrained within handle 513, and coupled to spring element 515. Proximal elongate shaft 501 may comprise a tube of stainless steel, Nitinol or other metallic or high modulus polymeric material, and may contain a liner in order to provide a low friction internal surface against which the actuation member 512 may slide. The shaft 501 may be tapered or may be slotted in order to provide a smooth transition in stiffness over its length. In the embodiment shown a portion of the shaft material has been removed from the distal portion 516 of shaft 501 in order to provide an exit port for actuation member 512 and to provide a connection member to the proximal end of tubular portion 502. This distal portion 516 may also be flattened, which may assist in creating a similar curvature to that of the tubular portion 502 so that the two portions can be smoothly joined together by welding, soldering, bonding or other appropriate method of fixation. The main body of the shaft may also have an oval or somewhat flattened profile, as this may be beneficial in allowing the user to seal a haemostasis valve around the shaft and a microcatheter when the two are side by side in the guide/sheath as shown previously in Fig. 11a.

The reinforcement member 507 may be formed from a metal (such as stainless steel or Nitinol or MP35N or other suitable alloy) or from a high modulus polymer material. In one embodiment (as shown) the reinforcent is formed from a tube from which sections 509 have been cut away to add lateral flexibility while maintaining column and hoop strength.

In the catheter illustrated in Fig. 60 the actuatable seal 504 is located adjacent to the proximal end of the distal tubular section, where it also forms the exit/entry port to the proximal end of the distal tubular section 502, but it could be positioned more distally in other variants of the invention. Once the catheter has been advanced to a position proximal of or adjacent the target clot the seal can be actuated to effect a seal between the proximal portion of the tubular section of the RX clot removal catheter and the inner lumen of the guide catheter. A vacuum force can then be applied to the proximal end of the guide catheter using a syringe or pump. This vacuum force will create a low pressure region inside the guide catheter which will extend (via the seal) into the distal tubular portion of the RX clot removal catheter. This low pressure will create a pressure gradient at the tip of RX clot removal catheter which will encourage the flow of clot into the catheter.

In some scenarios, such as when retrieving a firm clot with a high fibrin content, it may not be possible to aspirate the clot fully into and through the RX clot removal catheter, and the clot may become lodged at the tip of the catheter. In such a case it may be necessary to remove the RX clot removal catheter with the clot through the guide catheter and out of the patient. It may be desirable to create reverse flow in the cerebral vasculature during this retrieval process in order to prevent the escape and distal migration of any fragments of the clot being retrieved. This can be done by disengaging the RX clot removal catheter seal so that the low pressure zone is redirected into the distal lumen of the guide catheter. Thus pressure gradient between the blood in the cerebral vasculature and the fluid within the guide catheter lumen causes a flow of the blood from the high pressure region to the low pressure region. The seal as shown can also serve to create a guiding feature to assist the advancement of another device into the tubular distal section of the clot removal catheter. This might be advantageous if for example the catheter was used as a primary clot debulking tool - so that it was advanced to a target clot and aspiration was applied to it through the guide catheter to remove the occlusive clot but was not successful in removing all of the clot. In this case a microcatheter (and guidewire if desired) could be advanced through the RX clot removal catheter and across the remaining clot so that a thrombectomy device could then be advanced through the microcatheter. The thrombectomy device and remaining clot could then be withdrawn into the RX clot removal catheter (under aspiration if desired) to complete the recanalisation of the patient's vessel.

Figures 61a – 61c illustrate a method of use of the RX clot removal catheter 500. This catheter can be used in a similar manner and for a similar purpose to catheter 101 illustrated previously in figures 10 and 11, except that the seal / flow restrictor of catheter 500 can be selectively activated or deactivated by the user. The catheter can be used as the primary clot retrieval device as shown in figures 61a-c, or as an adjunctive device as shown in figures 11a-d. Fig. 61a shows the catheter 500 advanced through a guide catheter 550 towards a target clot 555 located in blood vessel 554. In this case the catheter 550 has an external flow restrictor in the form of a balloon at its distal end.

The method of use of such a system could entail: Accessing the patient's vasculature using standard methods, advancing a guiding catheter or sheath 550 to a region proximal of the target occlusive clot 555, advancing the RX clot removal catheter 500 through the guide/sheath to a location proximal or adjacent to or within the target clot as shown in Fig. 61a (which may be achieved with the aid of a microcatheter and/or guidewire and/or thrombectomy device), activating the proximal flow restrictor/seal 504 of the catheter 500 to connect the lumens of the two catheters, inflating the external balloon (if present and if desired) at the end of the guide/sheath, aspirating using a syringe 556 or vacuum pump (not shown) through the a connector 551 attached to the proximal end of the guide/sheath 550 so that a pressure gradient is created which sucks blood and clot into the mouth 503 of the Rx clot removal catheter 500 and through the catheter 500 and the guide/sheath 550 and into the syringe as shown in Fig. 61b. If any clot remains caught in the end of the catheter tip 503 (as may happen if the clot has a significant organized fibrin component such as may occur in clots originating from a heart valve or an atrial appendage for example) it may be necessary to withdraw the catheter 500 and the trapped clot 555 together through guide/sheath 550 and out of the patient as shown in Fig. 61c. In such a scenario the flow restrictor/seal 504 may be de-activated so as to enable a vacuum force applied by the syringe to the guide/sheath to be transmitted to the distal end 553 of the guide/sheath and thus create flow reversal and draw blood and any clot fragments 557 back into the tip of the guide/sheath as the captured clot is retracted.

Fig. 62 depicts another system of this invention which functions in a similar manner to the previously described Rx catheter systems, but in this case the flow restrictor or seal between the inside of the guide/sheath 600 and the outside of the Rx catheter 603 is created by a sealing element 602 attached to the inside of the guide/sheath 600. This sealing element 602 may

comprise an inflatable balloon, similar to the external flow restricting balloon 601 shown on the outside of the guide/sheath.

Fig. 63 depicts another system of this invention in which an Rx clot retrieval catheter 650 has two flow restrictor / seal elements 651 and 652. The more proximal restrictor 651 is used to restrict flow between the Rx catheter 650 and the guide catheter 655 within which it is positioned, while the more distal restrictor 652 is used to create a flow restriction within vessel 656. The combination of these two flow restrictors means that a vacuum or negative pressure can be applied to the proximal end of guide catheter 655 and transmitted to the distal end of Rx catheter 650 in such a way that any blood aspirated into the mouth of Rx catheter 650 is not supplied from the body of blood proximal to seal 652 in vessel 656.

This system enables a physician to use a standard guide or sheath to rapidly create an access path to the region of the target occlusion, and then use the Rx catheter 650 to quickly access and aspirate the target clot from the vessel. This system provides a major advantage in the speed and ease with which a physician will be able to access and retrieve the clot. The provision of the distal vessel seal 652 on the Rx catheter rather than on the guide or sheath means that this seal can be placed more distally in the vasculature, past the petris portion of the carotid vasculature when used in the ICA for example, which means less likelihood of vessel collapse when a suction force is applied, and less likelihood of vessel spasm.

In a preferred embodiment the flow restrictors / seals are actuatable and are formed from compliant balloons, which are inflated via a hollow shaft 657 by means of a syringe or inflator 653 applied to handle 654 of the Rx catheter 650. In other embodiments the proximal flow restrictor may be passive (i.e. it cannot be selectively activated or inactivated) as shown in several other designs in this disclosure. In yet other embodiments the distal seal may be actuated by means of an actuating member rather than an inflation lumen.

Most of the Rx (rapid exchange) catheters disclosed herein share some common features and geometry. Taking catheter 500 of Fig. 60 as an example: They have a distal generally tubular portion 502 comprising an inner lumen which starts with an opening or entry/exit port 517 and ends in a distal tip or mouth 503 into which clot is received. They have a proximal elongate shaft 501 which is connected at its distal end to the entry/exit port 517 and at its proximal end in some embodiments to a handle 513. The preferred geometry of these catheters depends on the target

clot location. For clots located in the anterior or posterior cerebral anatomy the distal tubular portion 502 is preferably greater than 10cm (so that it can extend from within the distal end of a guide/sheath which may be located in an internal carotid artery or a vertebral artery, right up to the proximal face of a target clot), and less than 40cm so that the minimum possible length of tubular portion 502 is located within the lumen of the guide/sheath, thus maximising the internal volume of the combined guide/Rx catheter system for optimum aspiration efficacy).

The optimal internal and external diameters of the Rx catheter depends very much on the site of the target clot and the size of the guide catheter or sheath through which the catheter is to be advanced. In the case of retrieval of occlusive clots from cerebral vessels the likely vessel diameters range from approximately 1.5mm up to 6mm, with 3mm being a very typical diameter. Guide catheters / sheaths used in these scenarios have typically an internal diameter of between 0.060" and 0.095", so that a suitable system might consist of a guide catheter with an internal diameter of 0.078" and an Rx clot retrieval catheter whose distal tubular section has an outside diameter of 0.070" and an inside diameter of 0.062". Such a system provides a very significant benefit in terms of flow resistance over an equivalently sized conventional combination of a guide and intermediate/aspiration (not rapid exchange) catheter. In particular the effective proximal lumen of the system of this invention is that of the guide catheter (0.078"), while the effective proximal lumen of the conventional system would be that of the intermediate/aspiration catheter (0.062"). This results in a significantly lower flow restriction in the Rx system of the invention, which means that for a given vacuum / suction force applied to the proximal end of the system, a much greater flow will be created through the system of this invention. While a conventional (not rapid exchange) intermediate/aspiration catheter may be stepped in diameter to maximise its proximal internal diameter, this proximal internal diameter must always be significantly smaller than the guide/sheath in which it is positioned. This is not the case in the system of this invention.

Yet another embodiment of this invention is shown in Figures 64a-d, which depict a distal end configuration which could be employed with any of the clot retrieval catheters previously shown. The catheter distal end 700 has an integrated control member 701, which forms a loop 704 at the tip where it is connected to tip members 703 so that it acts like a draw string when pulled. The tip may comprise relatively stiff members 703 interspersed with relatively compliant members 702, so that the tip has both axial stiffness (to permit effective operation of the drawstring mechanism) and radial compliance (to allow expansion and contraction of the tip).

Therefore when actuated by pulling as shown in Fig. 64b, the control member causes the tip of the catheter to reduce in diameter. This can improve the ability of the catheter to track through tortuousity and across obstacles such as the origin of the ophthalmic artery.

Similarly when the control member is pushed forward it can cause or allow the catheter tip to expand forming a funnel shape as shown in Fig. 64c. This can improve the ability of the catheter to aspirate clots and also act as a flow restrictor in the vessel.

In use the control member may be pulled back during insertion of the catheter to improve accessibility. It can then be forwarded to increase the diameter of the tip and aspirate the occlusion.

If the occlusion or blood clot can only be partially aspirated, then the tip diameter can be reduced again by pulling the control member, causing the clot to be trapped as shown in Fig. 64d, reducing the risk of the clot travelling to a new territory during retraction of the catheter and improving dislodgement.

The flaps 703 of the catheter tip are not rigidly connected to the integrated control member 701 but form a loop which can slide over the control member. The control member distal end 706 may also be fixed to the inner surface of the catheter.

Referring to Fig. 65 there is illustrated an aspiration catheter 801 according to this invention in use in a thrombectomy procedure. The catheter 801 is similar to catheter 101 of Figs 10 and 11 and provides a proximal seal 802 against a guide catheter inner lumen 803 so that aspiration applied by syringe 811 (or a pump or by other means) through guide catheter 808 (via a rotating haemostasis valve (RHV) 814) can be transferred through to the distal end 812 of the aspiration catheter. Thrombectomy device 800 is shown deployed within clot 810, having been delivered through microcatheter 809 by means of proximal shaft 807. The method of use of the system illustrated is very similar to that described in Figs 11a-d, except that in this embodiment the proximal end 815 of the microcatheter 809 and proximal end 806 of Rx aspiration catheter 801 are positioned within separate branches of a rotating hemostasis valve (RHV) 813. This configuration provides significant ease of use advantages over the configuration described in Fig. 11. In particular the RHV 813 can be more easily sealed around the proximal shaft 806 of the

aspiration catheter to prevent any air ingress (or fluid leakage) during aspiration. In addition the user has better control over the aspiration catheter 801, microcatheter 809 and thrombectomy device 800 relative to the guide catheter 808, and can use RHVs 813 and 814 to lock and hold the aspiration catheter or microcatheter independently of each other.

One embodiment of the method of use of such a system could consist of the following steps: Accessing an arterial blood vessel of a patient using conventional means such as an introducer and guide catheter 808 and/or sheath, advancing Rx aspiration catheter 801 through a first branch of RHV 813 attached to proximal end of guide catheter 808, advancing a microcatheter 809 through a second branch of RHV 813 and through the aspiration catheter 801 and guide catheter 808 up to and across a target occlusive clot 810 with or without the aid of a guidewire, removing the guidewire (if used) and advancing a mechanical thrombectomy device 800 such as a stent-retriever through the microcatheter 809 to the target clot 810, retracting the microcatheter 809 at least a few cm to deploy a mechanical thrombectomy device 800 within the clot 810, advancing the aspiration catheter 801 up to a position just proximal of the clot 810 (or within the clot, or considerably proximal of the clot if vessel disease or tortuosity makes access difficult), optionally creating flow arrest by inflating the balloon of the guide catheter 808 (if used, or by other means), aspirating through the aspiration catheter 801 using a syringe 811 or pump connected to the guide catheter 808 while withdrawing the mechanical thrombectomy device 800 towards and into the distal mouth 812 of the aspiration catheter 801, withdrawing the clot 810, mechanical thrombectomy device 800 and microcatheter 809 through the aspiration catheter 801 and guide catheter 808 and out of the patient while continuing to aspirate.

A possible variant of the final step of the above method could involve removing the aspiration catheter along with the clot 810, mechanical thrombectomy device 800 and microcatheter 809. This variant is useful if a large and/or firm clot is encountered which the physician cannot (or does not wish to) fully withdraw into the mouth of the aspiration catheter. In such a situation the RHV 813 must be removed once the exit port 805 of the aspiration catheter 801 reaches the RHV 813.

Another method of use of such an Rx aspiration catheter system is to retrieve clot using aspiration without the use of a thrombectomy device. The rapid exchange shaft of this invention provides great advantages in terms of speed, deliverability, ease of use and aspiration lumen. A microcatheter or other similar catheter and guidewire nay be used to provide support to assist in

tracking the aspiration catheter to the target site in a similar manner to that illustrated in either Fig. 65 or Figs 11a-d.

It will be apparent from the foregoing description that while particular embodiments of the present invention have been illustrated and described, various modifications can be made without departing from the spirit and scope of the invention. For example, while the embodiments described herein refer to particular features, the invention includes embodiments having different combinations of features. The invention also includes embodiments that do not include all of the specific features described.

The invention is not limited to the embodiments hereinbefore described which may be varied in construction and detail.

Claims

1. A catheter for assisting in the retrieval of a clot from a vessel comprising a distal end and a proximal end, a distal segment and a proximal segment and a lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment and a flow restrictor located on the outer surface of the catheter distal of the transfer port.

2. A catheter as claimed in claim 1 wherein the flow restrictor is actuatable between engaged and disengaged configuration.

3. A catheter as claimed in claim 2 comprising an actuator for selectively engaging and/or disengaging the flow restrictor.

4. A catheter as claimed in claim 2 or 3 wherein the flow restrictor comprises a framework and a membrane coupled to the framework, the framework being movable by the actuator between an expanded configuration and a retracted configuration.

5. A catheter as claimed in any of claims 1 to 4 comprising a proximal flow restrictor distal of the proximal end of the distal segment and a distal flow restrictor spaced distally from the proximal flow restrictor.

6. A catheter as claimed in any of claims 1 to 5 wherein the distal end of the catheter comprises a mouth for reception of clot.

7. A catheter as claimed in claim 6 wherein the mouth is defined by an expansile tip.

8. A catheter as claimed in claim 6 or 7 wherein the distal segment includes a hinge adjacent to the distal mouth.

9. A catheter as claimed in claim 8 wherein the hinge is defined by a region of the distal segment which is configured to have lateral flexibility.

10. A catheter as claimed in any of claims 6 to 9 wherein the mouth has an expanded configuration and a retracted configuration.

11. A catheter as claimed in claim 10 comprising a control member for controlling the movement of the mouth between the expanded and retracted configurations.

12. A catheter as claimed in claim 11 wherein the mouth comprises a number of segments and the control member is configured to move at least some of the segments.

13. A catheter as claimed in claim 12 wherein the control member comprises a drawstring.

14. A catheter for aspirating a clot in a vessel comprising a distal end and a proximal end, a distal segment and a proximal segment and a lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment wherein the distal end of the catheter comprises a mouth for reception of clot.

15. A catheter as claimed in claim 13 having a flow restrictor located on the outer surface of the catheter distal of the transfer port.

16. A catheter as claimed in claim 15 wherein the mouth is defined by an expansile tip.

17. A catheter as claimed in claim 15 or 16 wherein the distal segment includes a hinge adjacent to the distal mouth.

18. A catheter as claimed in claim 17 wherein the hinge is defined by a region of the distal segment which is configured to have lateral flexibility.

19. A catheter as claimed in any of claims 15 to 18 wherein the mouth has an expanded configuration and a retracted configuration.

20. A catheter as claimed in claim 19 comprising a control member for controlling the movement of the mouth between the expanded and retracted configurations.

21. A catheter as claimed in claim 20 wherein the mouth comprises a number of segments and the control member is configured to move at least some of the segments.

22. A catheter as claimed in claim 21 wherein the control member comprises a draw string.

23. A catheter as claimed in any of claims 1 to 22 wherein the catheter is an aspiration catheter for aspirating a clot.

24. A system for treating an occlusion in a vessel the system comprising:-

a first catheter and a second catheter;

the first catheter comprising a proximal end, a distal end and a lumen extending between the proximal end and the distal end, the lumen of the first catheter further comprising a proximal segment and a distal segment;

the second catheter comprising a distal end and a proximal end, a distal segment and a proximal segment, and a lumen, said lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment;

the first catheter being configured to facilitate aspiration through the lumen;

the transfer port being configured to transmit aspiration in the proximal lumen of the first catheter into the lumen of the distal segment of the second catheter and the distal end of the second catheter being configured to receive clot into at least a portion of the lumen of the second catheter.

25. A system as claimed in claim 24 wherein the second catheter is a catheter as claimed in any of claims 1 to 23.

26. A system as claimed in claim 24 further comprising a flow restrictor between the first catheter and the distal segment of the second catheter, distal of the transfer port.

27. A system as claimed in claim 26 wherein the flow restrictor is located on the inner surface of the first catheter.

28. A system as claimed in claim 26 or 27 wherein the flow restrictor is located on the outer surface of the second catheter.

29. A system as claimed in any of claims 26 to 28 comprising a proximal flow restrictor distal of the proximal end of the distal segment of the second catheter and a distal flow restrictor spaced distally from the proximal flow restrictor.

30. A system as claimed in any of claims 24 to 29 wherein the distal end of the second catheter comprises a mouth for reception of clot.

31. A system as claimed in claim 30 wherein the mouth is defined by an expansile tip.

32. A system as claimed in any of claims 24 to 31 wherein the transfer port comprises a rapid exchange port.

33. A system as claimed in any of claims 24 to 32 wherein the first catheter is a guide catheter.

34. A system as claimed in any of claims 24 to 33 wherein the second catheter is an intermediate catheter.

35. A system as claimed in any of claims 24 to 34 further comprising a microcatheter which is adapted to be advanced through the first catheter and the second catheter.

36. A system as claimed in claim 35 further comprising a clot engaging device for delivery from the microcatheter.

37. A system as claimed in claim 33 wherein the guide catheter is mounted in a proximal rotating haemostasis valve through which aspiration is applied.

38. A system as claimed in claim 35 or 36 wherein a proximal end of the microcatheter and a proximal end of the aspiration catheter are locatable within separate branches of a proximal rotating haemostasis valve.

39. A method of removing a clot from a vessel, the method comprising:-
providing a guide catheter and an intermediate catheter, the intermediate catheter having a distal mouth and being configured such that it is advancable within the lumen of the guide catheter;
inserting the guide catheter into a first vessel proximal of an occlusion;
advancing the intermediate catheter through the lumen of the guide catheter until the tip of the intermediate catheter extends distal of the guide catheter into a second vessel adjacent to the occlusion;
applying aspiration to the proximal end of the guide catheter;
the intermediate catheter being configured to direct said aspiration through the distal lumen of the intermediate catheter to aspirate the clot into the mouth of said intermediate catheter.

40. A method as claimed in claim 39 wherein the aspiration catheter comprises a distal end, a proximal end, a distal segment, a proximal segment and a lumen extending proximal of the distal end and terminating at a transfer port at the proximal end of the distal segment.

41. A method as claimed in claim 39 or 40 comprising restricting flow between the outside surface of the intermediate catheter and the inside surface of the guide catheter.

42. A method as claimed in any of claims 39 to 41 comprising the step, before or after aspiration, of delivering a microcatheter to the occlusion and deploying a clot capture device from the microcatheter.

43. A method as claimed in claim 42 comprising advancing the microcatheter to the clot, deploying a clot capture device from the microcatheter, retracting the microcatheter to a location proximal of a transport port at the proximal end of a distal segment of the aspiration catheter.

44. A method of removing an occlusion from a vessel comprising:-

providing a first aspiration catheter and a second aspiration catheter, the second aspiration catheter extending distal of the first aspiration catheter and further comprising a transfer lumen proximal of the distal end of the first aspiration catheter;

inserting the first catheter into a first vessel proximal of the occlusion;

advancing the second catheter through the lumen of the first catheter until the tip of the second catheter extends distal of the first catheter into a second vessel and is substantially opposing the occlusion; and

aspirating through the proximal lumen of the first catheter so as to urge the clot into the distal lumen of the second catheter.

45. A method as claimed in claim 44 comprising restricting flow between the outside surface of the second catheter and the inside surface of the first catheter.

46. A method as claimed in claim 44 or 45 comprising the step, before or after aspiration, of delivering a microcatheter to the occlusion and deploying a clot capture device from the microcatheter.

47. A method as claimed in claim 46 comprising the step, prior to aspiration, of retracting the microcatheter to a location proximal of the transfer port.

48. A method as claimed in any of claims 44 to 47 wherein the first aspiration catheter is a guide catheter.

49. A method as claimed in any of claims 44 to 48 wherein the second aspiration catheter is an intermediate catheter.

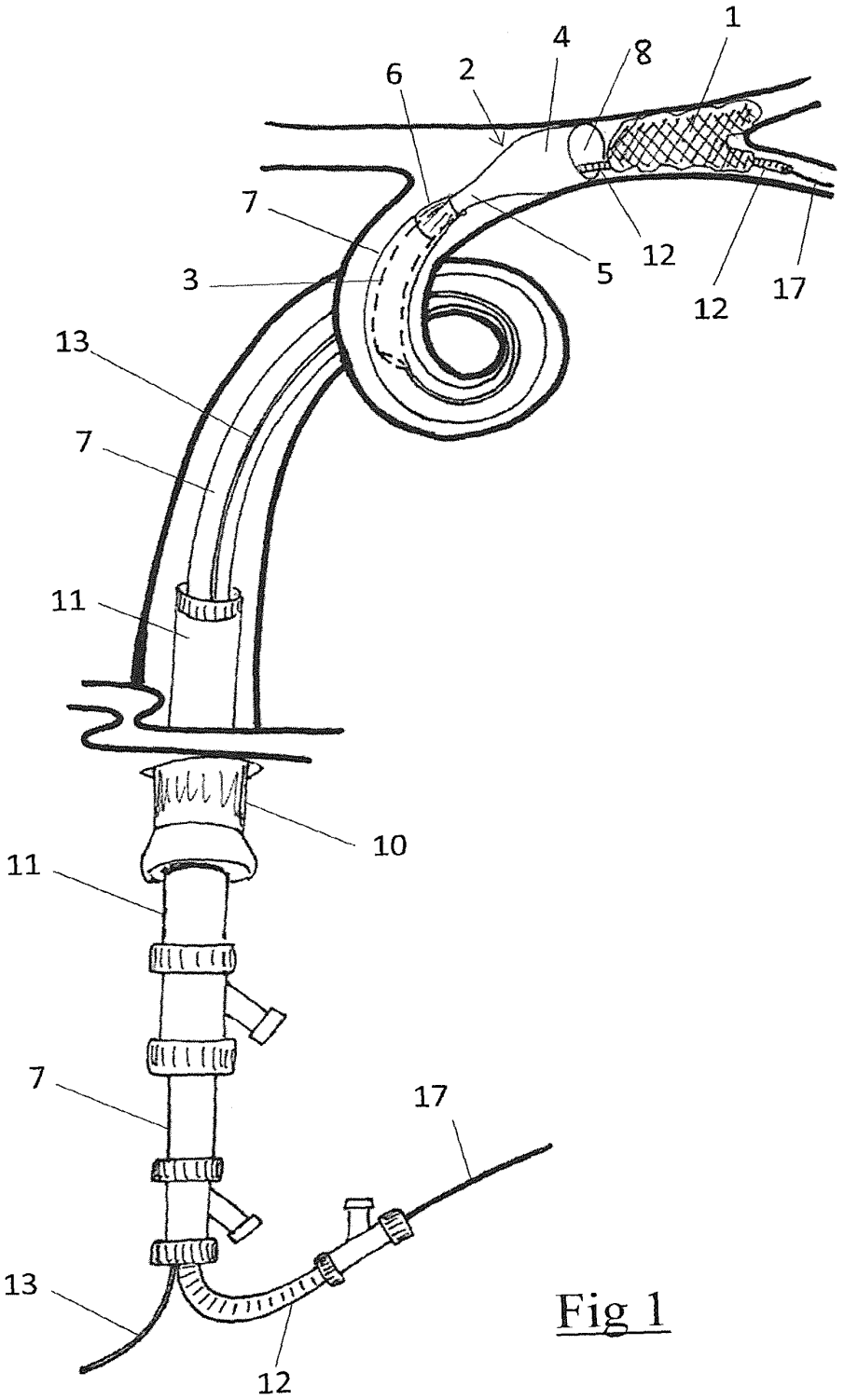


Fig 1

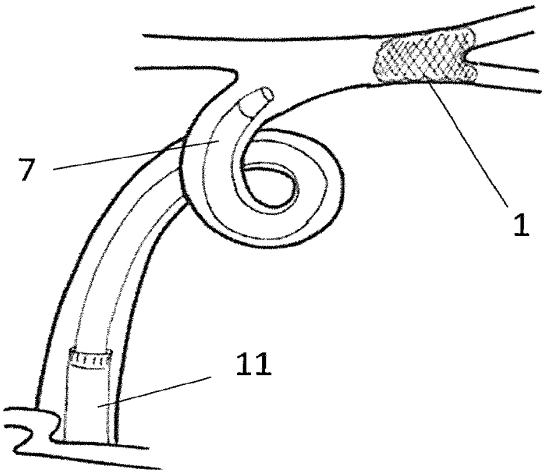


Fig 2a

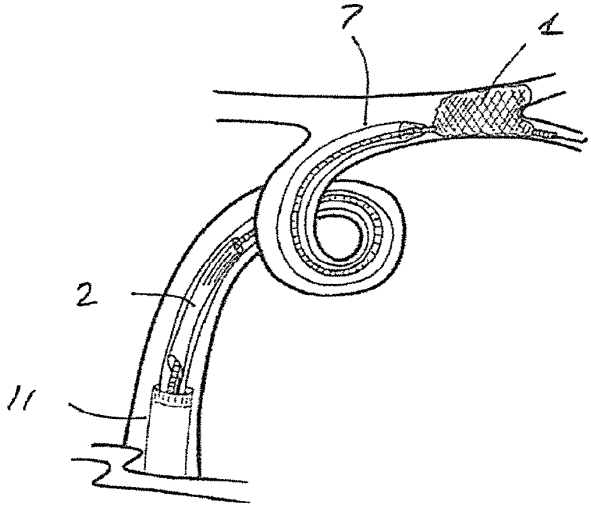


Fig 2b

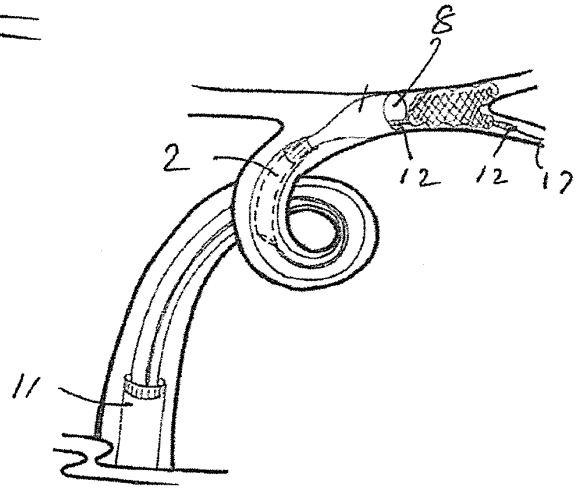


Fig 2c

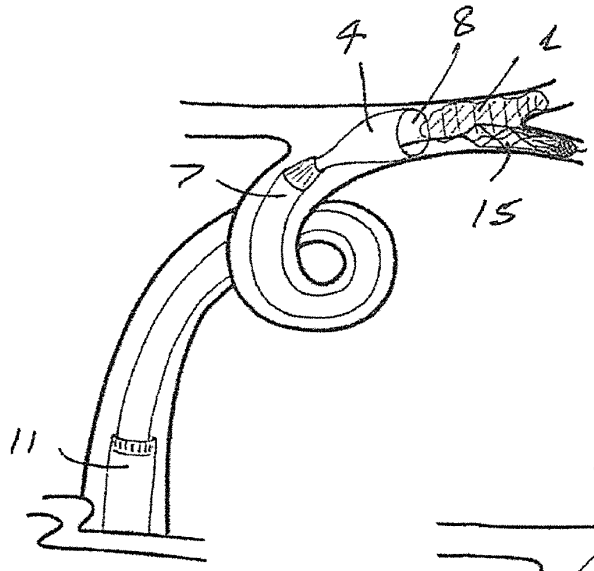


Fig 2d

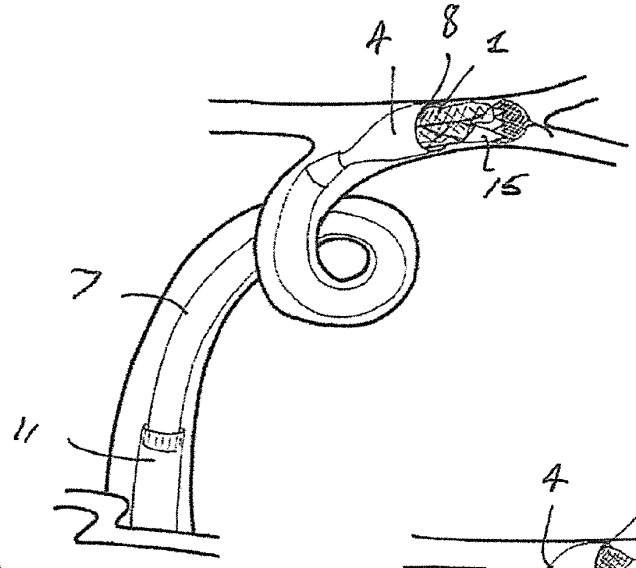


Fig 2e

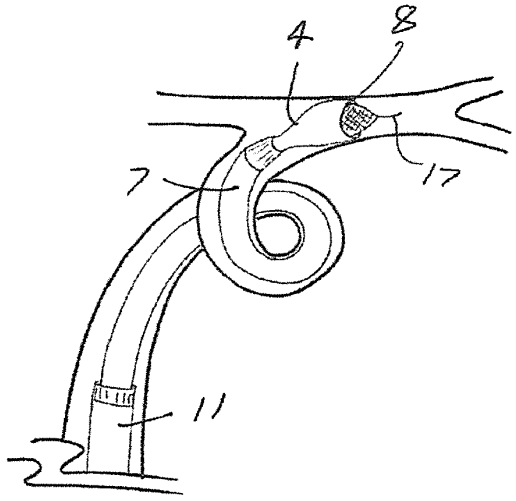


Fig 2f

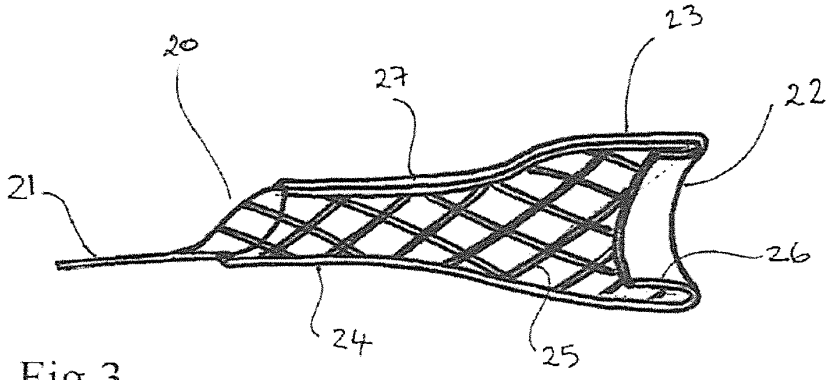


Fig 3

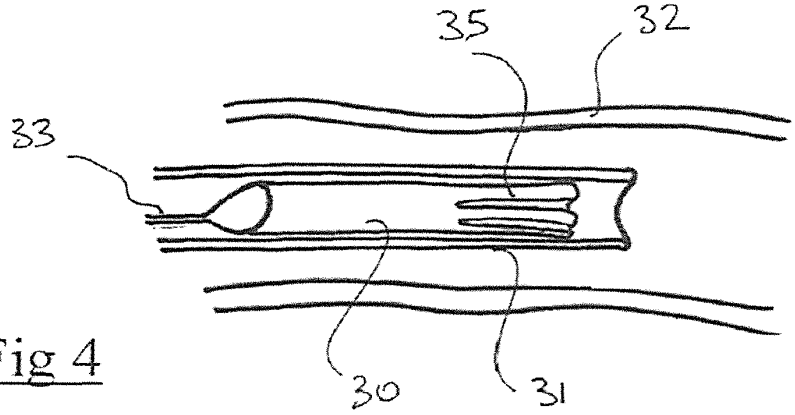


Fig 4

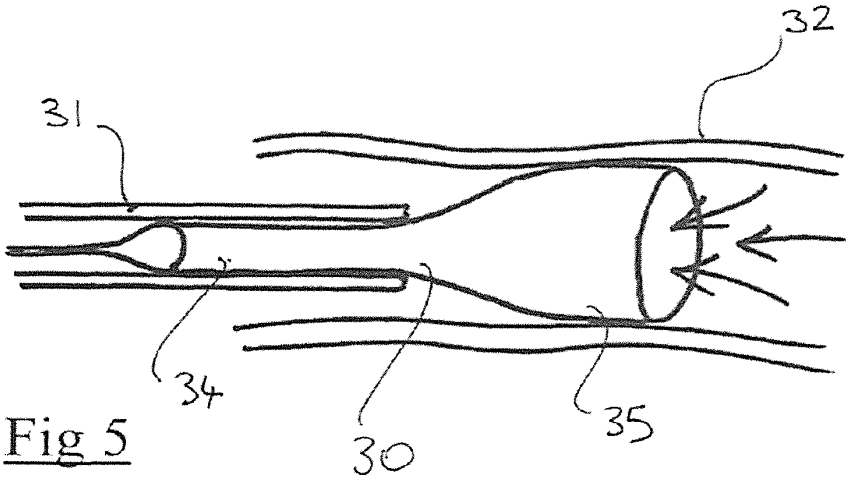


Fig 5

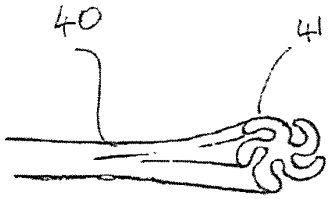


Fig 6a

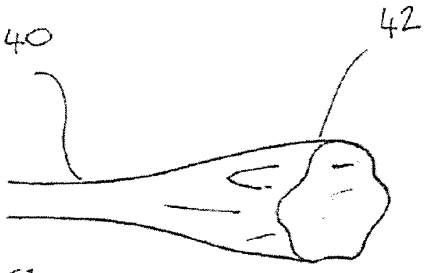


Fig 6b

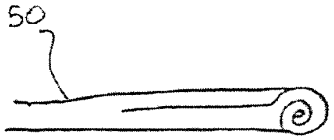


Fig 7a

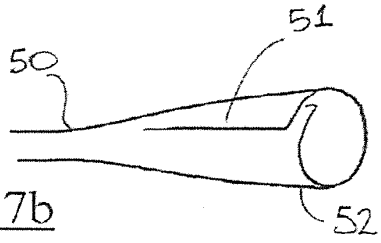


Fig 7b



Fig 8a

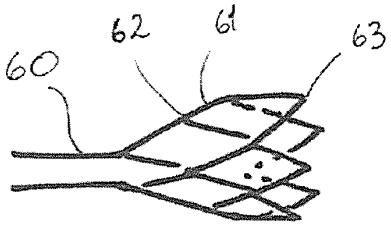


Fig 8b

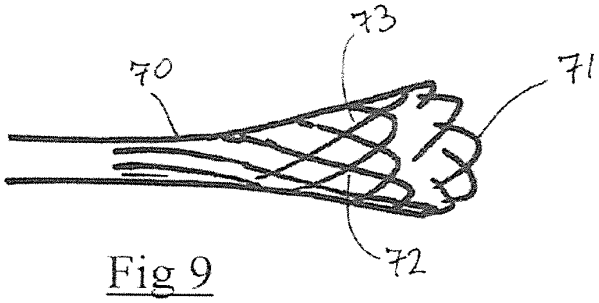


Fig 9

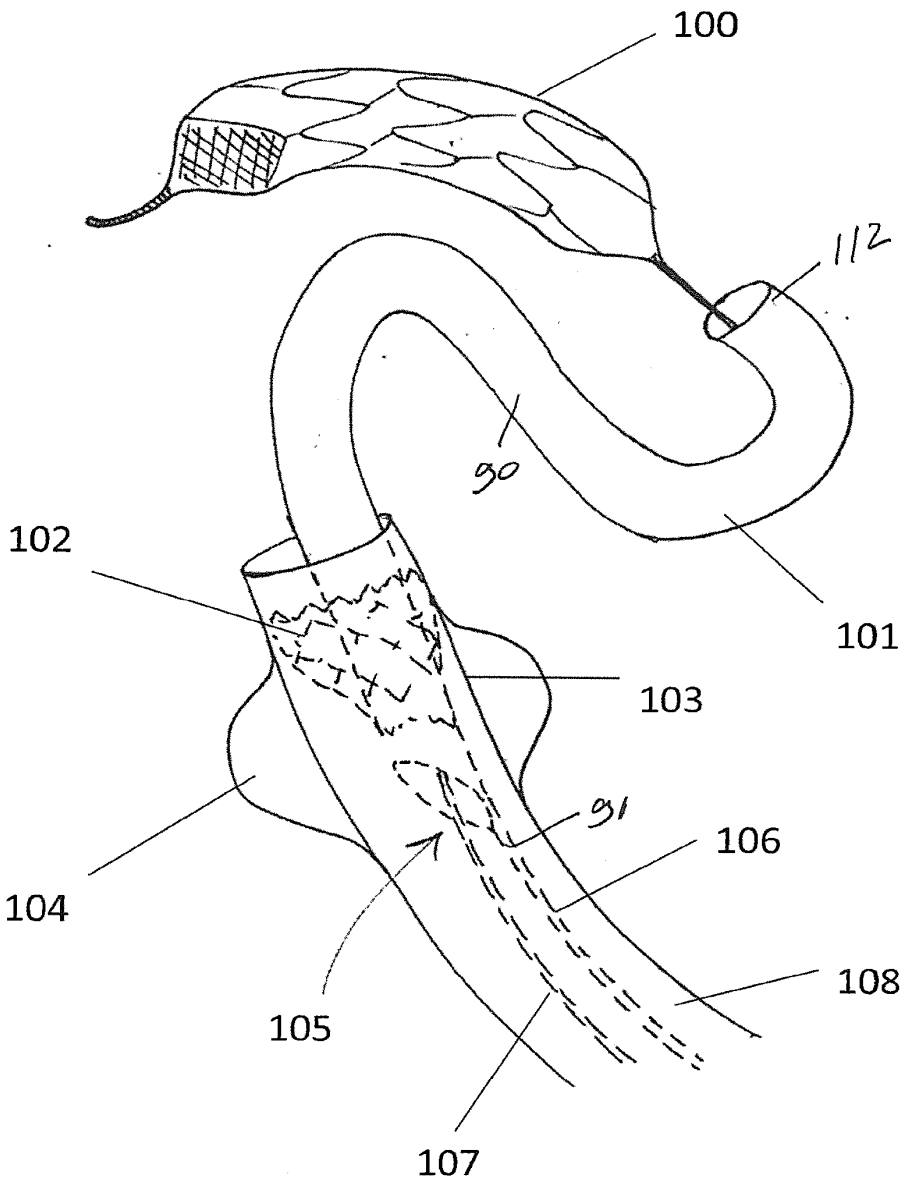


Fig 10

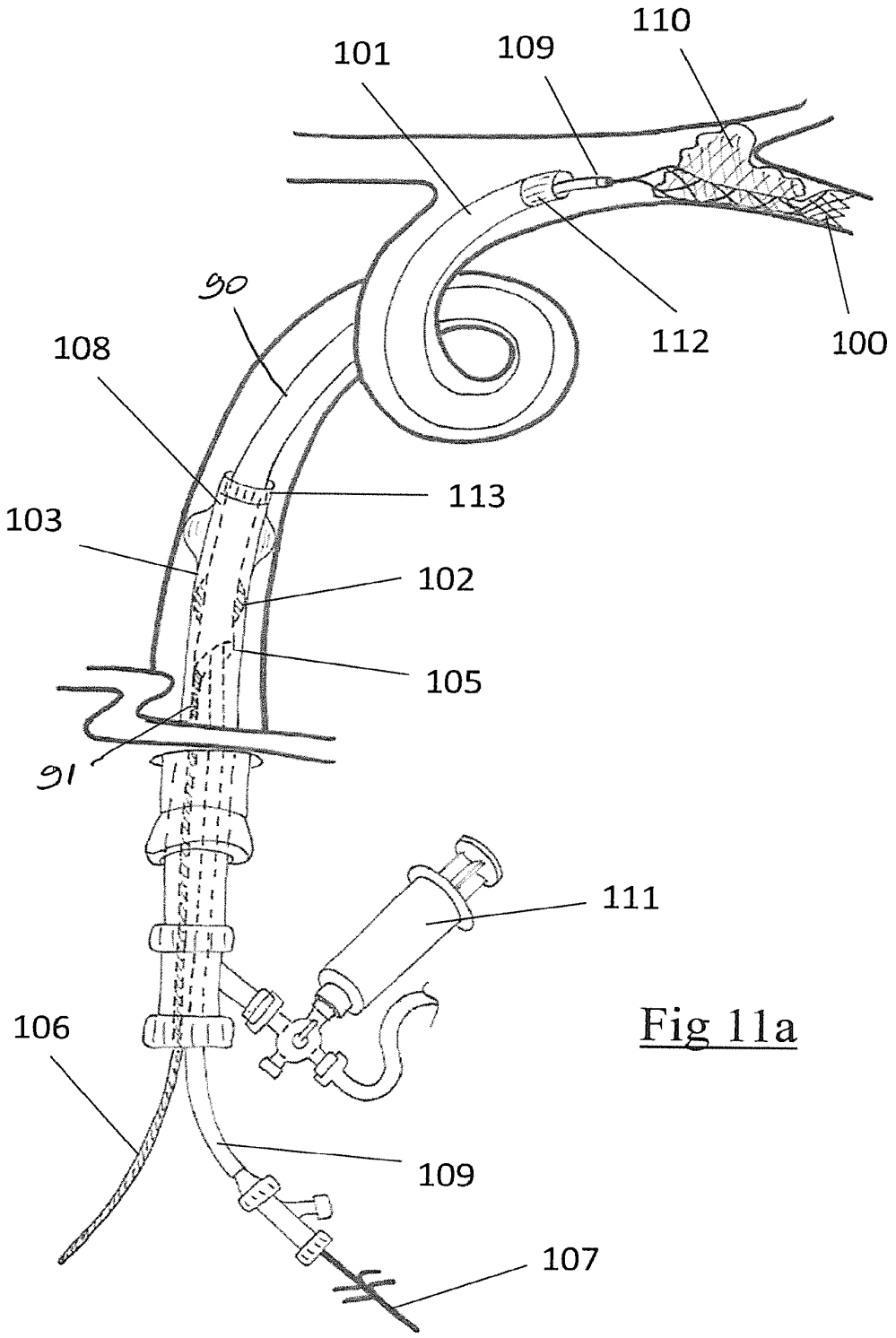


Fig 11a

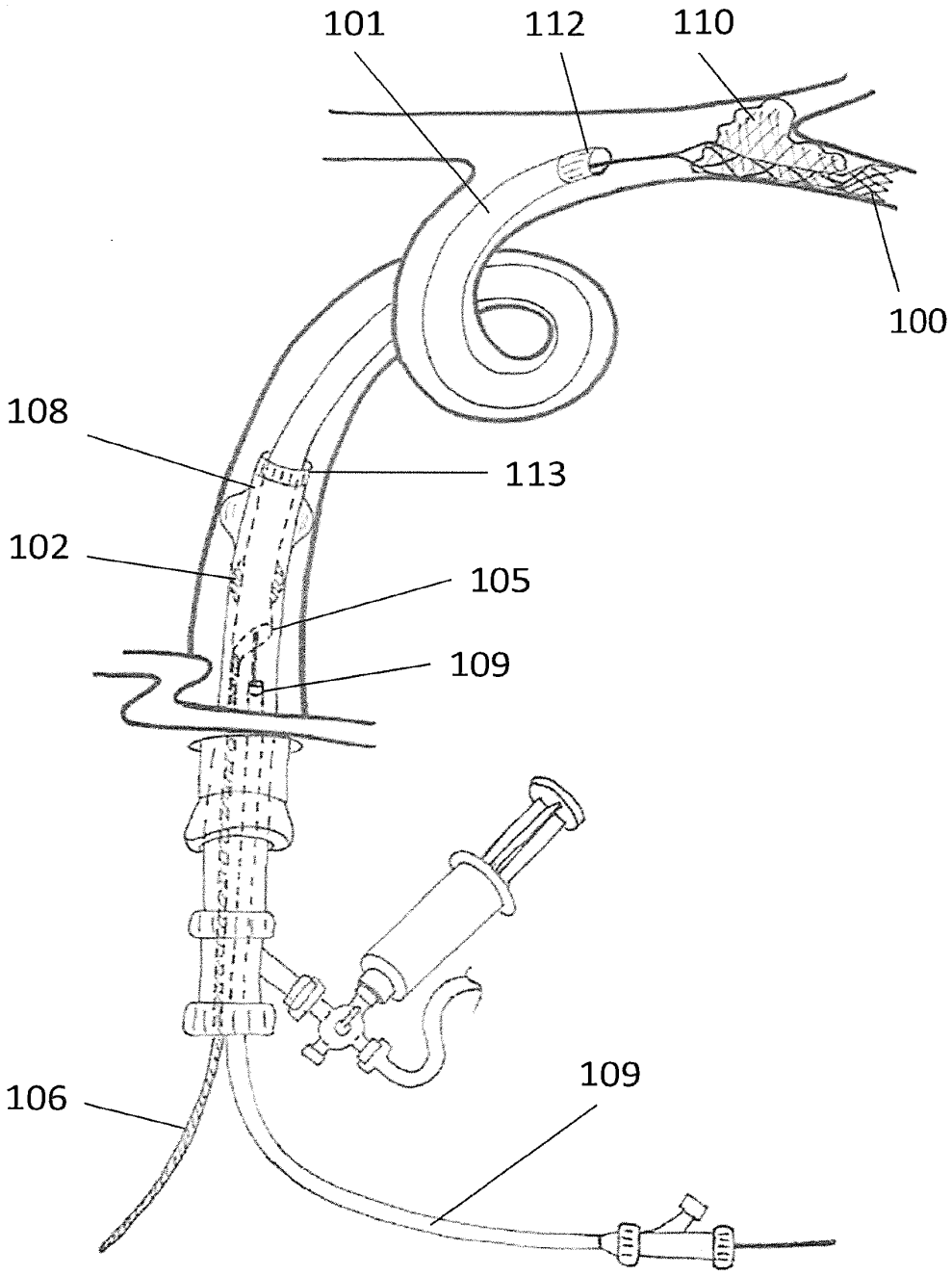


Fig 11b

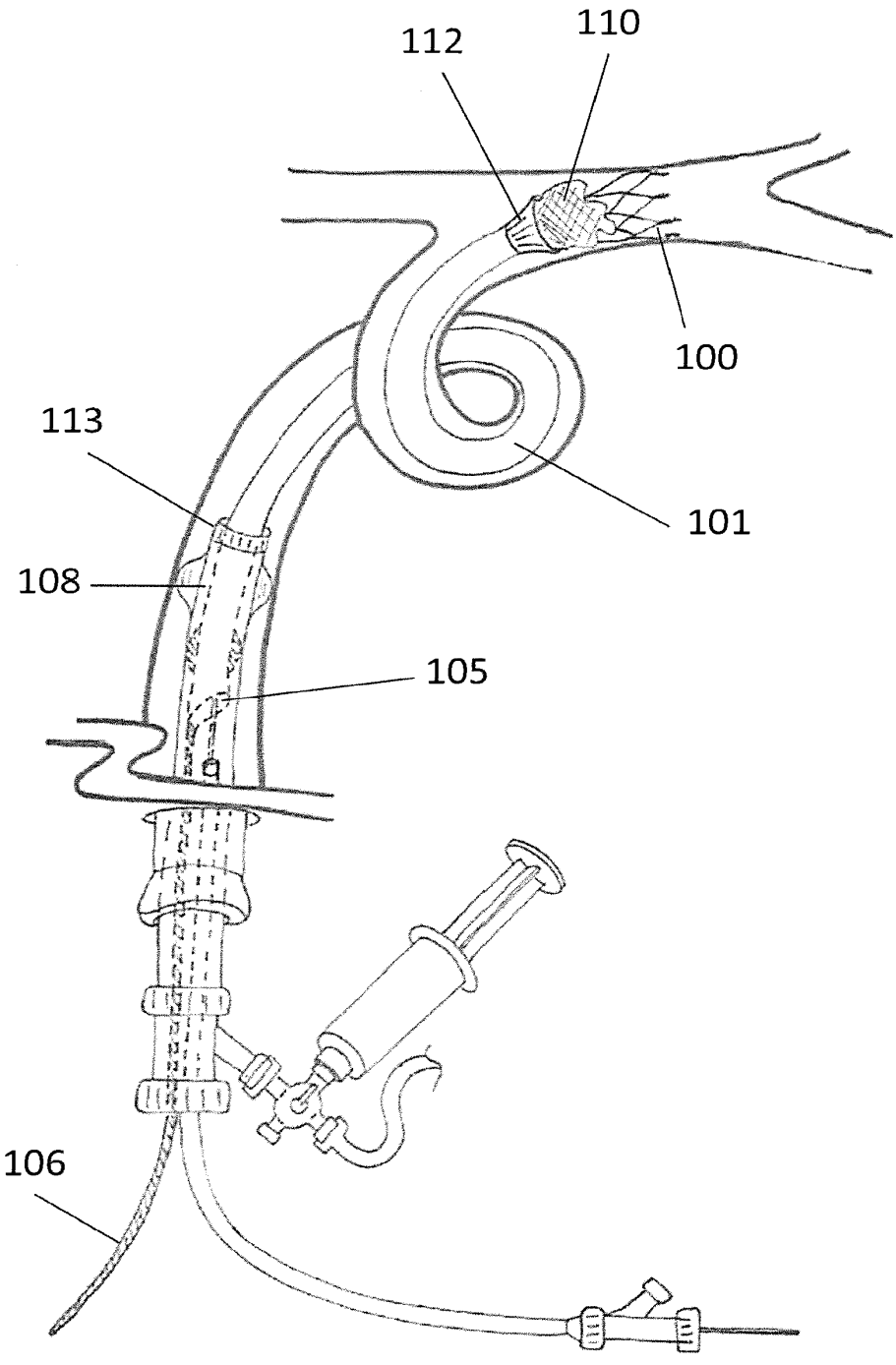


Fig 11c

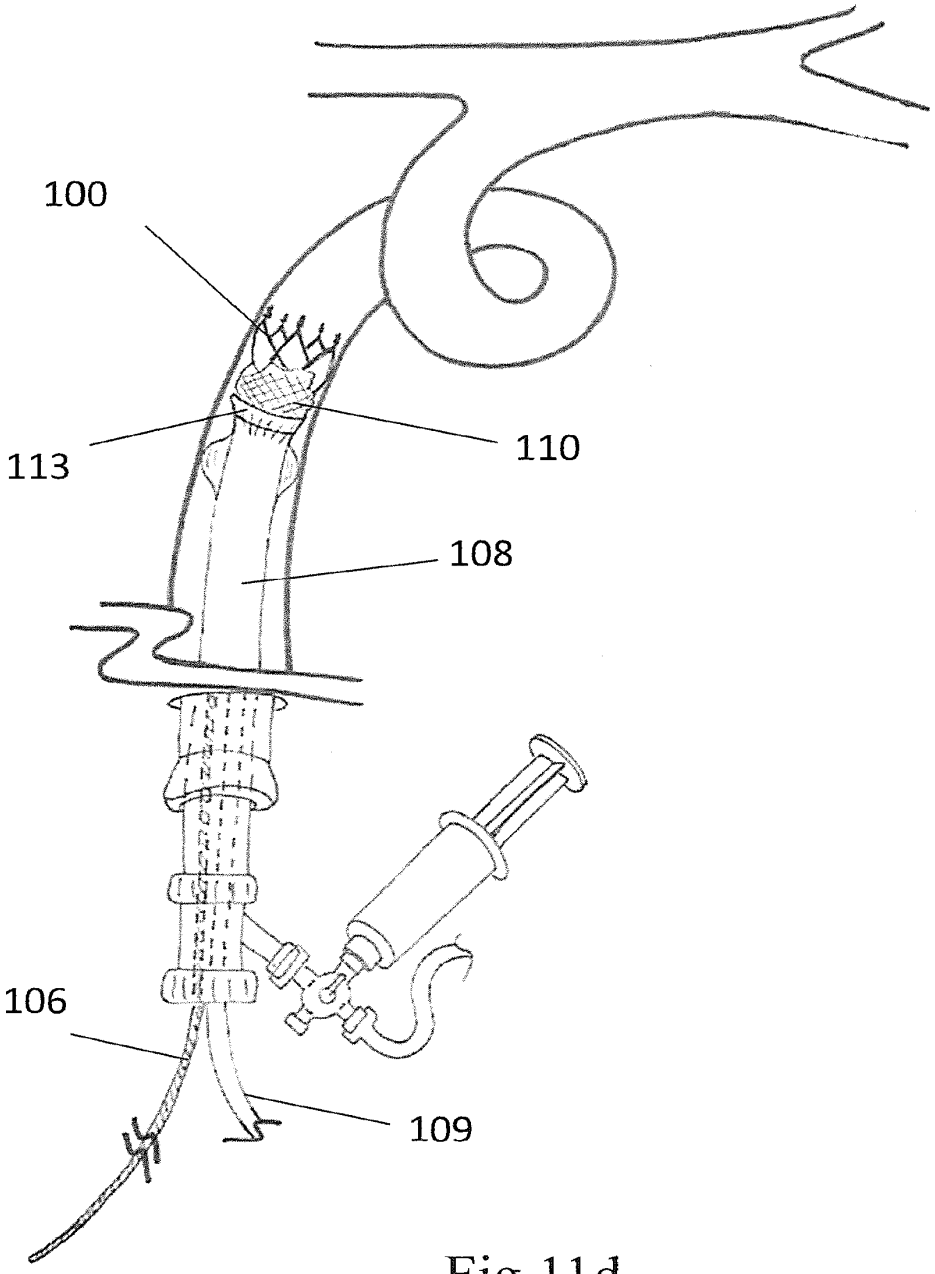


Fig 11d

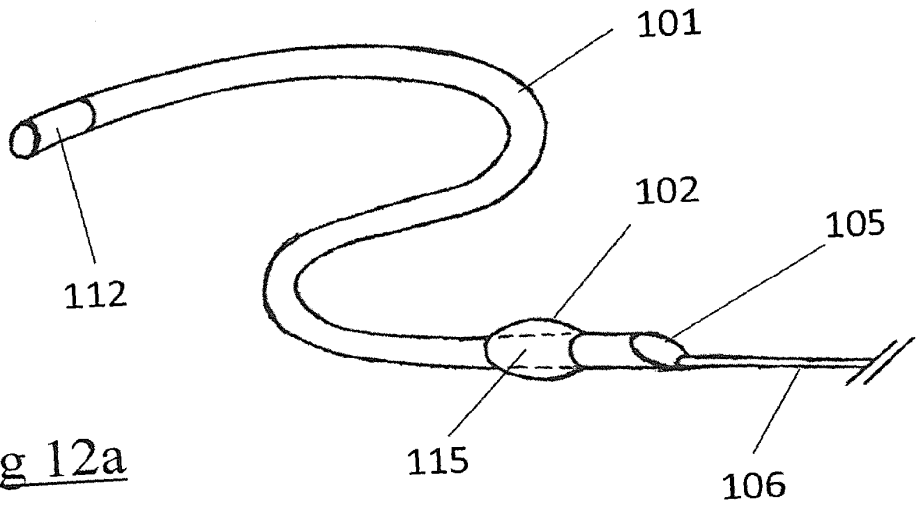


Fig 12a

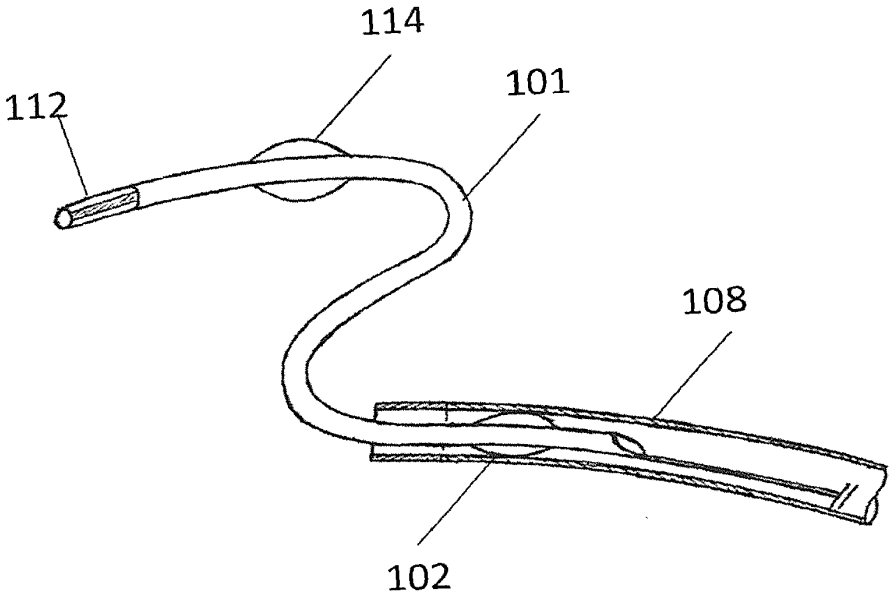


Fig 12b

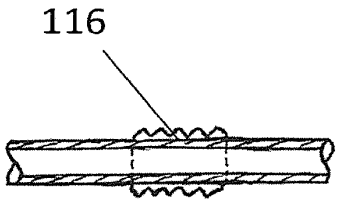


Fig 13a

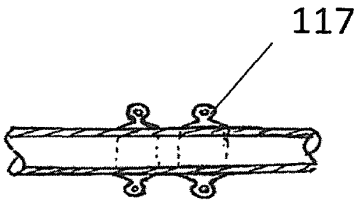


Fig 13b

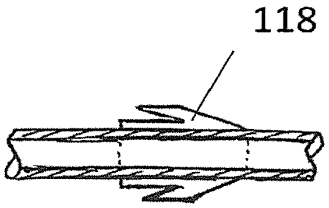


Fig 13c

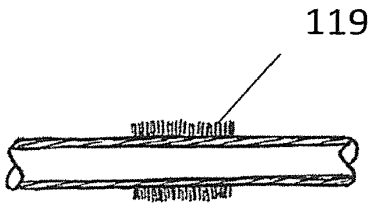


Fig 13d

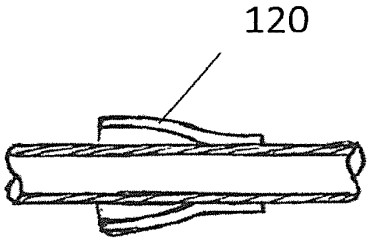


Fig 13e

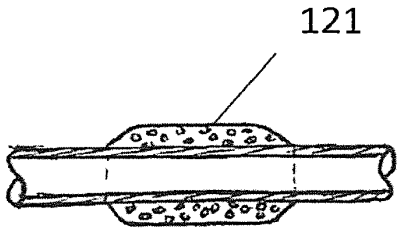


Fig 13f

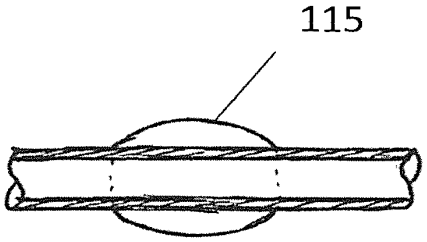


Fig 13g

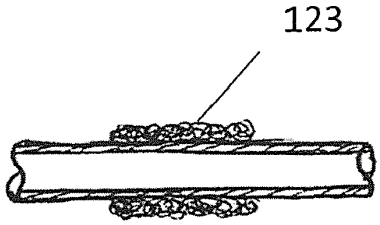


Fig 13h

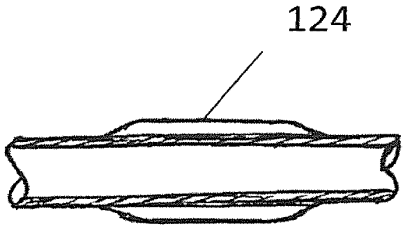


Fig 13i

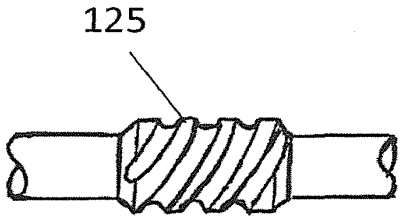


Fig 13j

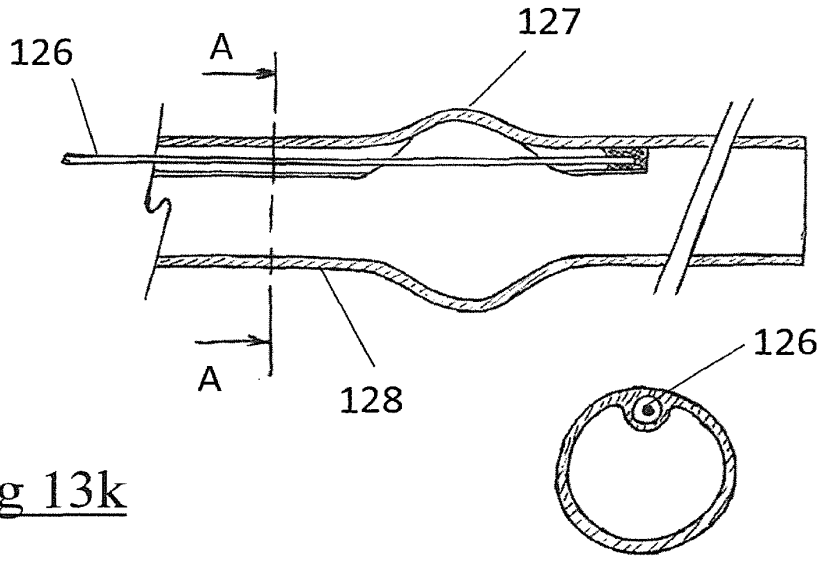


Fig 13k

Fig 13L

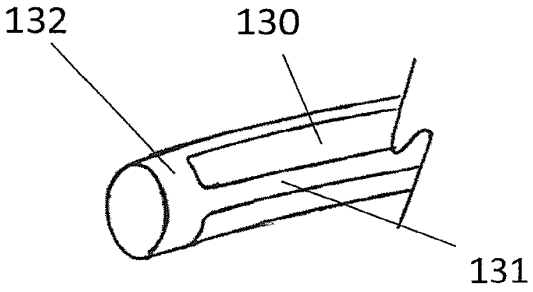


Fig 14

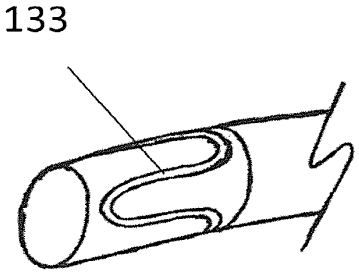


Fig 15

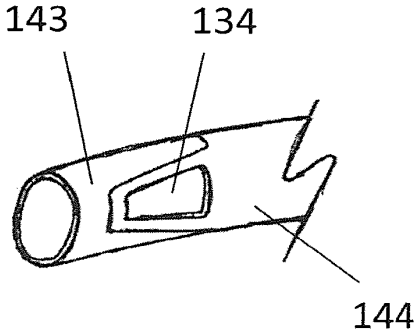


Fig 16

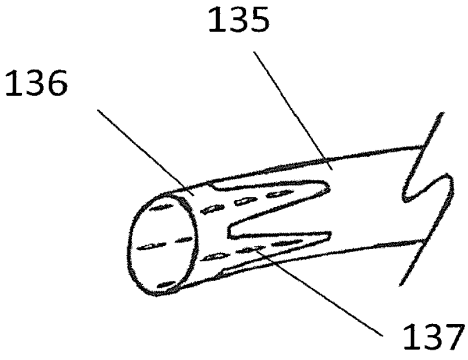


Fig 17

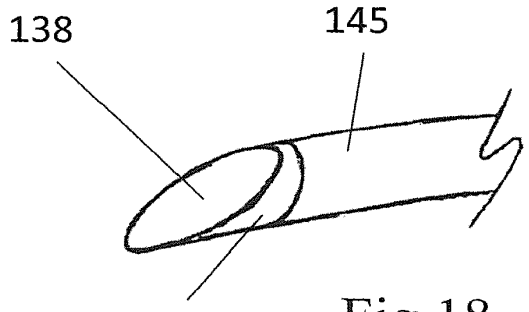


Fig 18

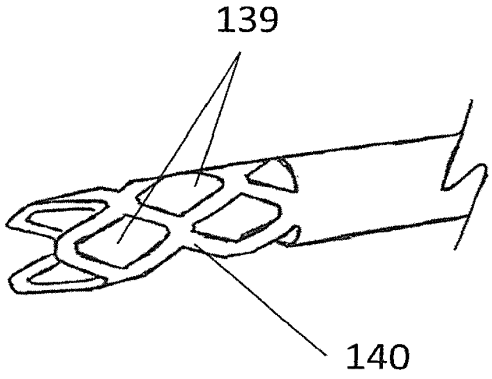


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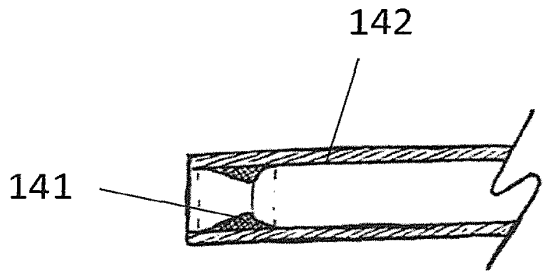


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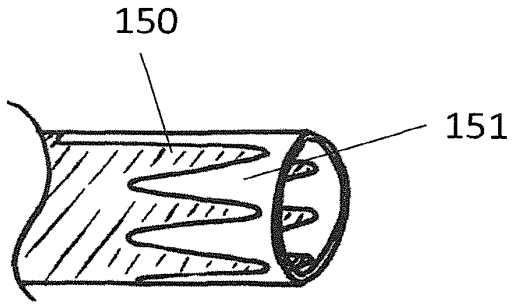


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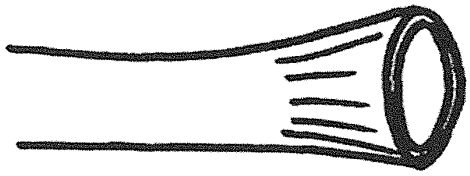


Fig 22a



Fig 22b

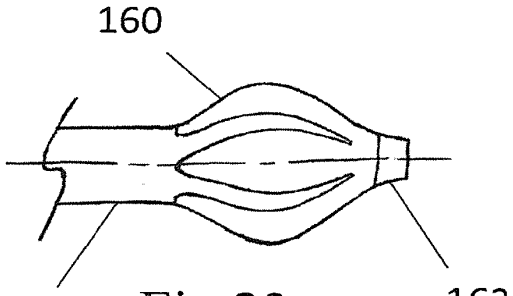


Fig 23a

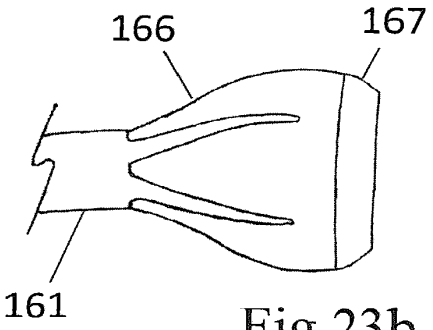


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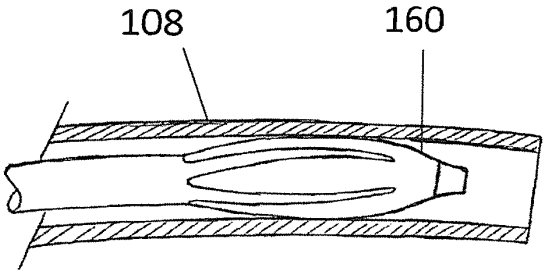


Fig 23c

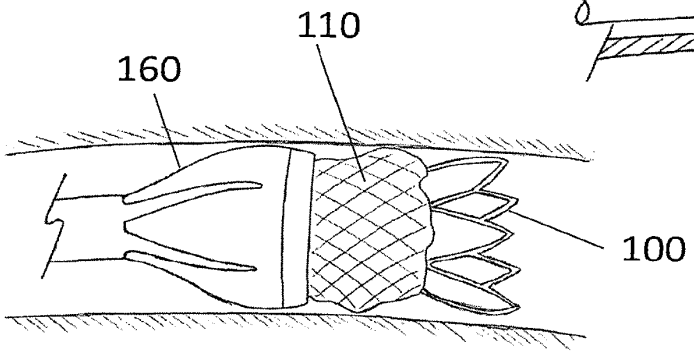


Fig 23d

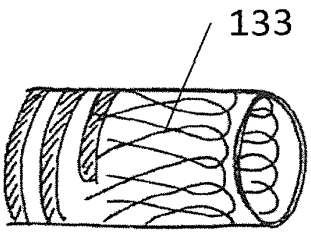


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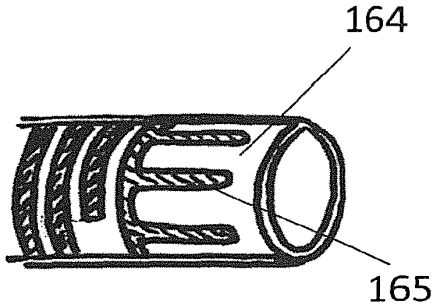


Fig 25



Fig 26

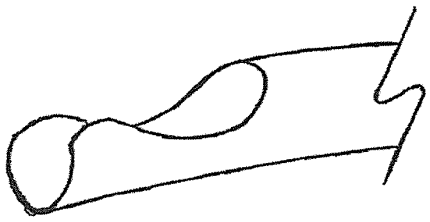


Fig 28



Fig 27

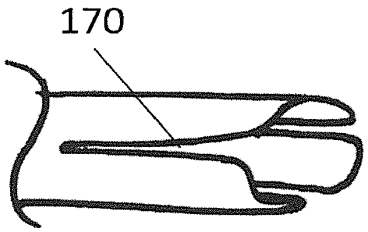


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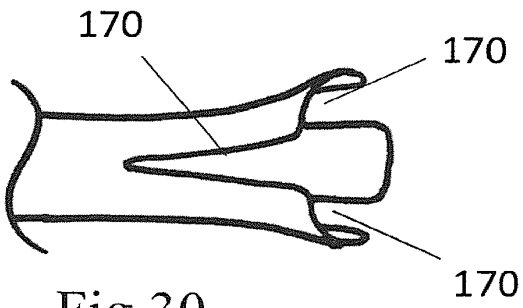


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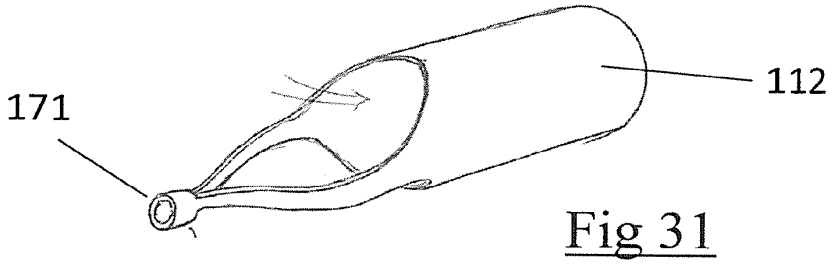


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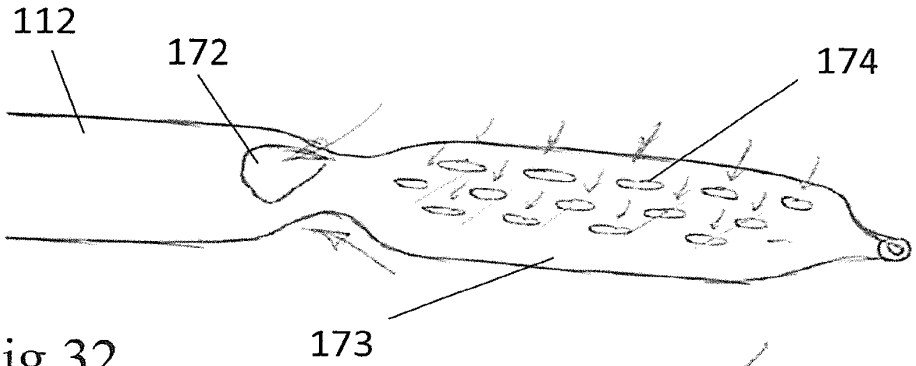


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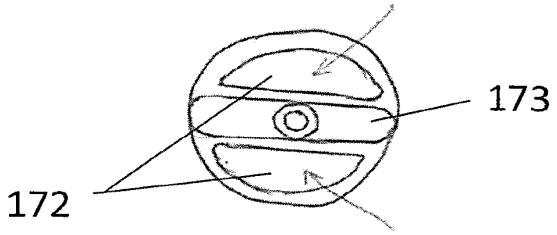


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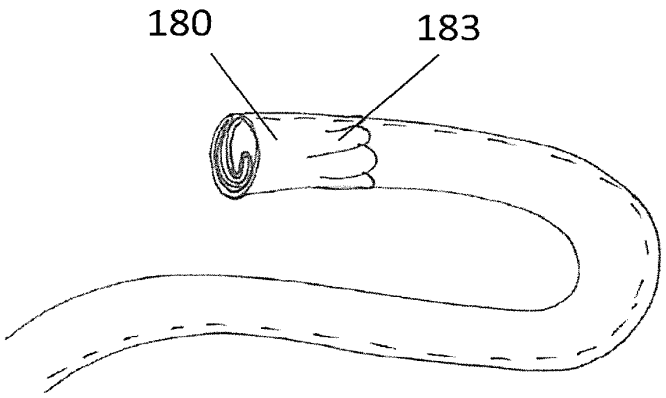


Fig 34a

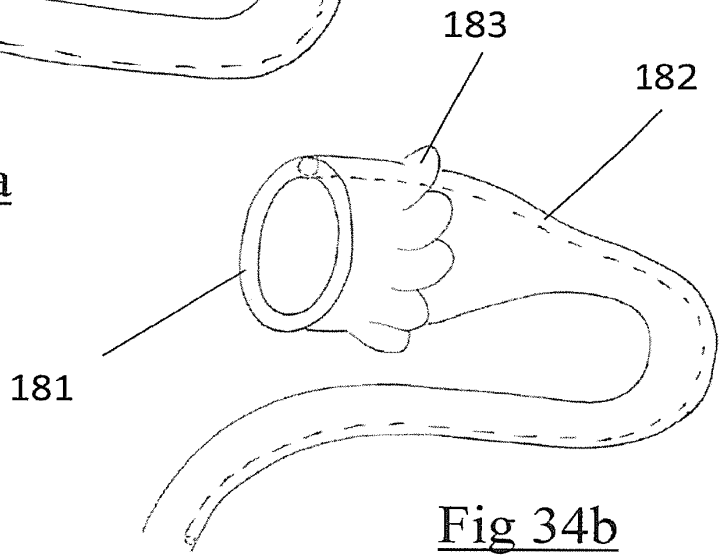


Fig 34b

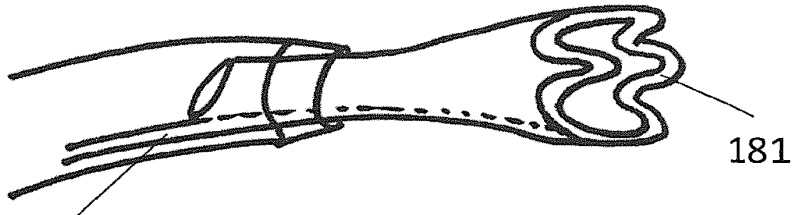


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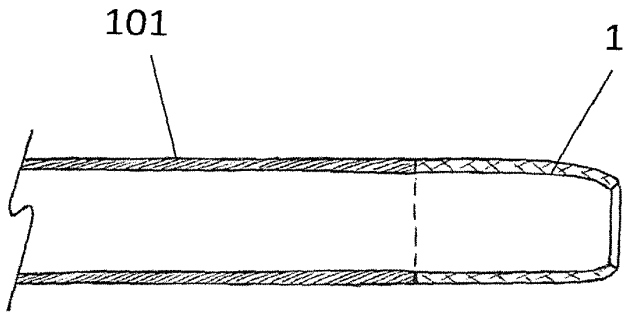


Fig 36a

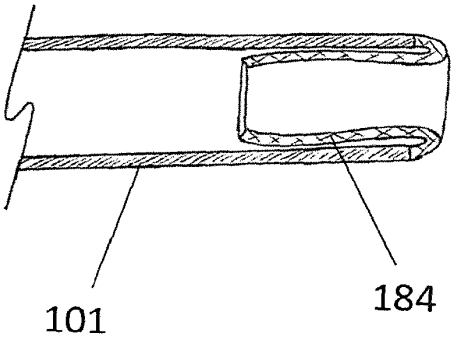


Fig 36b

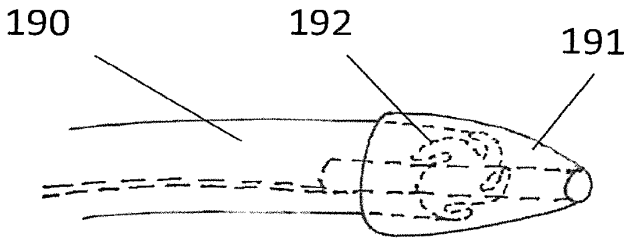


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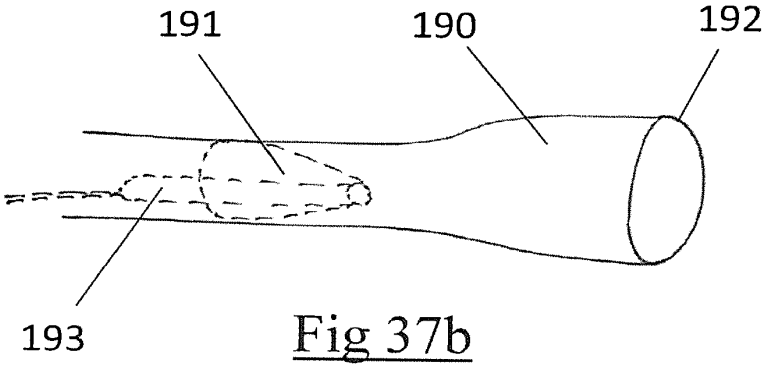


Fig 37b

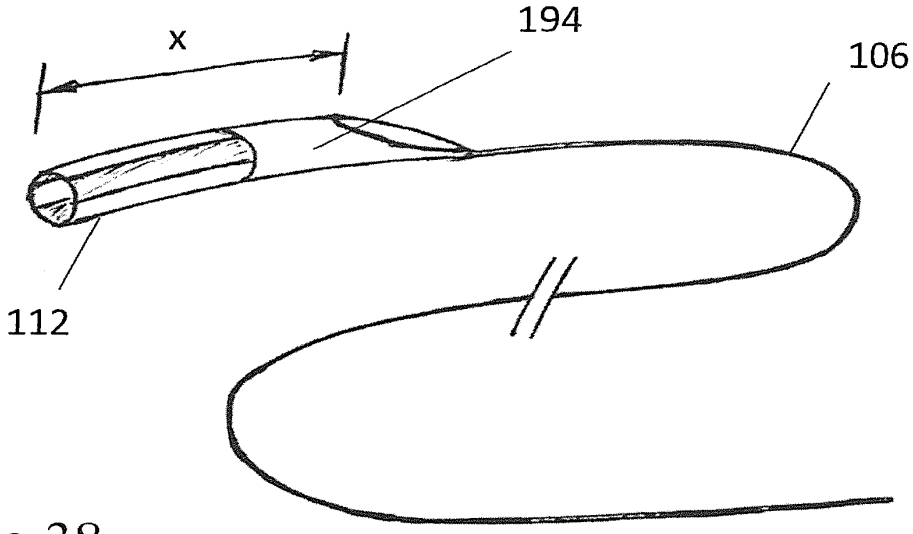


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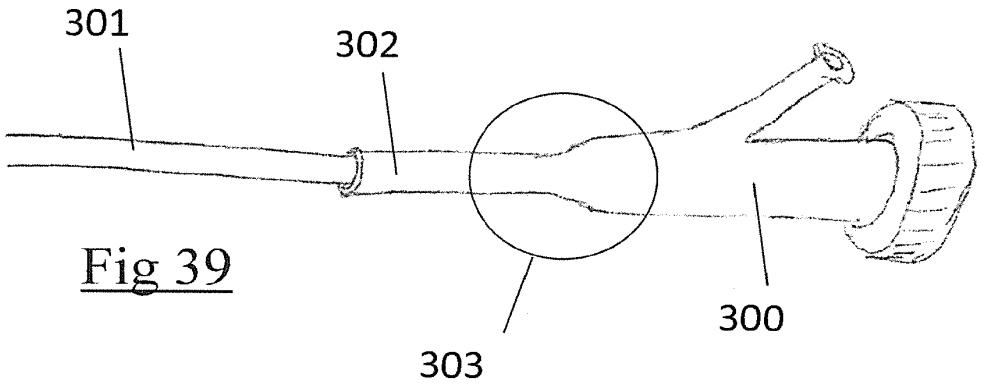


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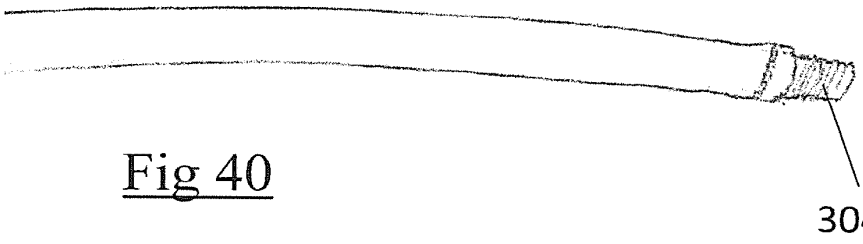


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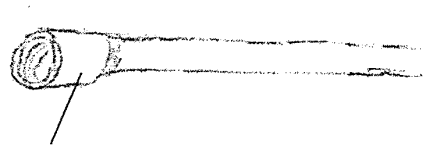


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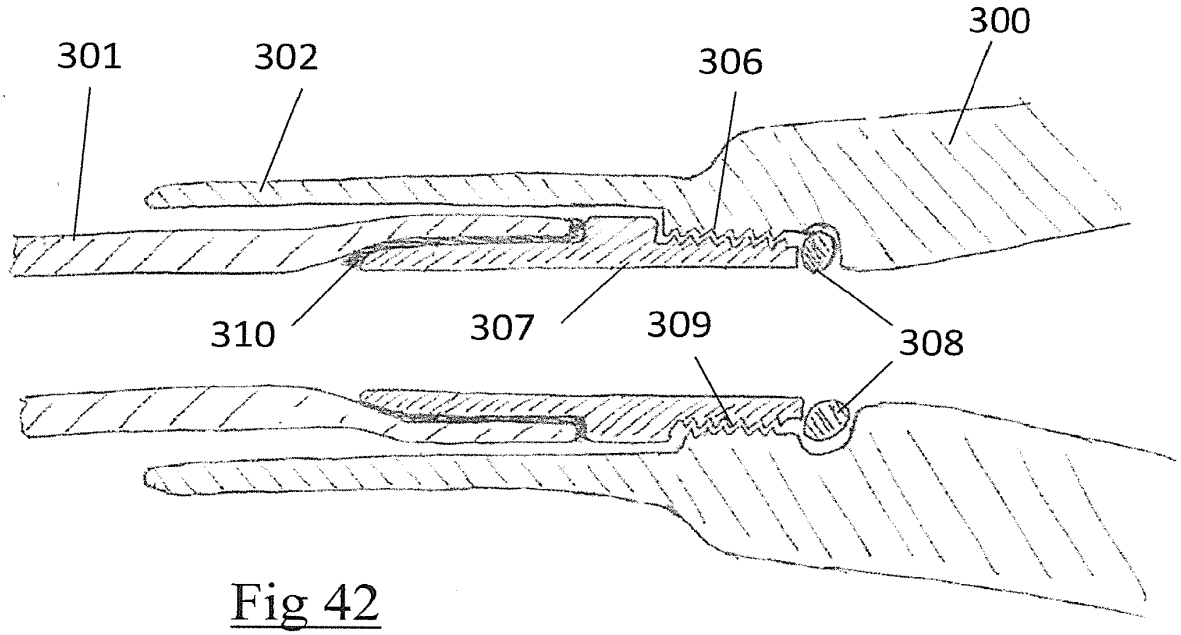


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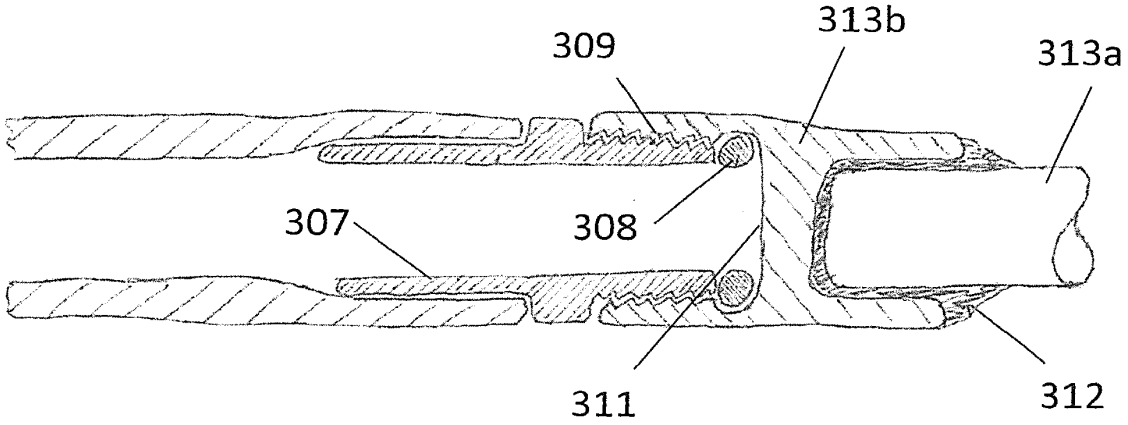


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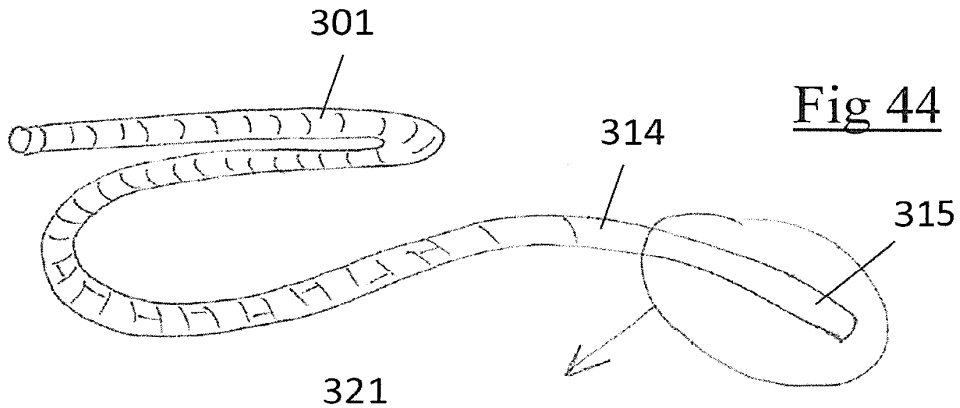


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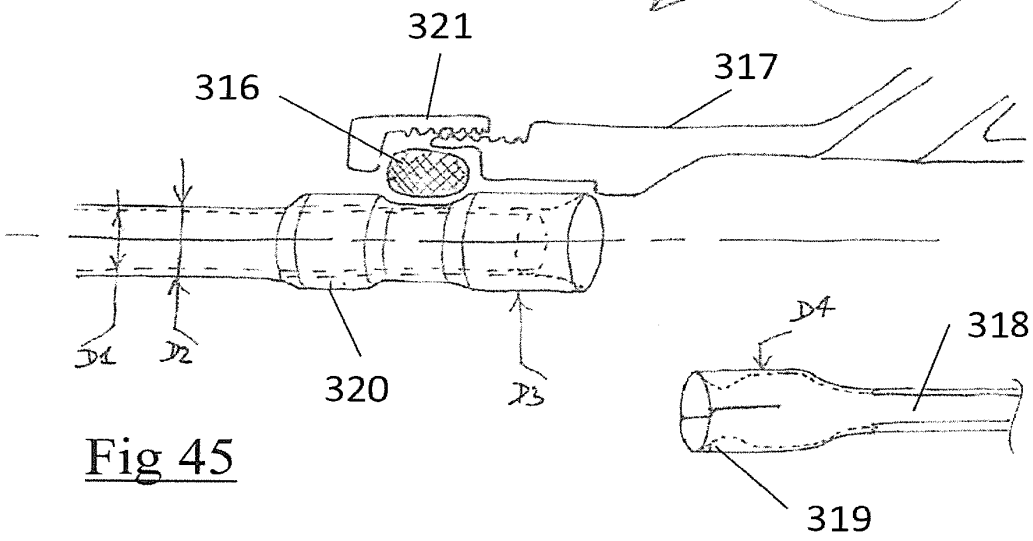


Fig 45

Fig 46

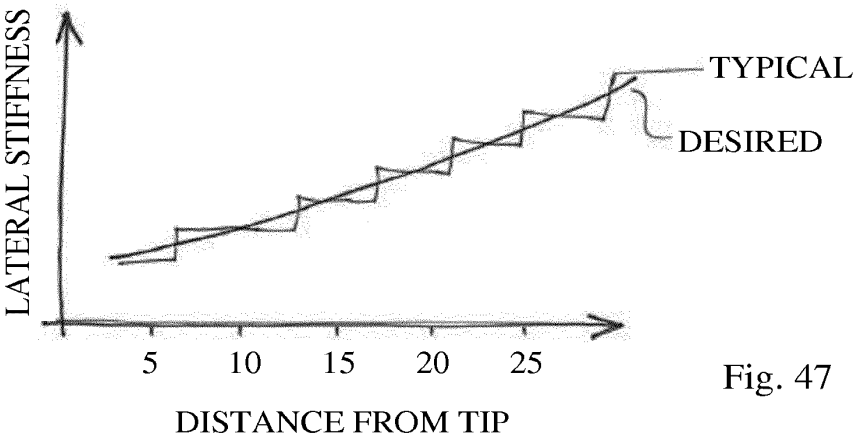


Fig. 47

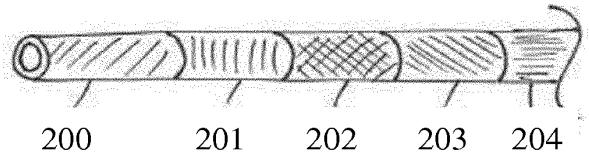


Fig. 48

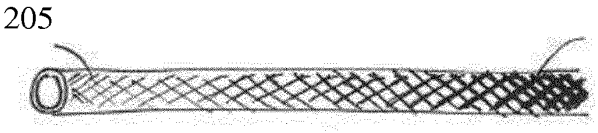


Fig. 49



Fig. 50

Fig. 51

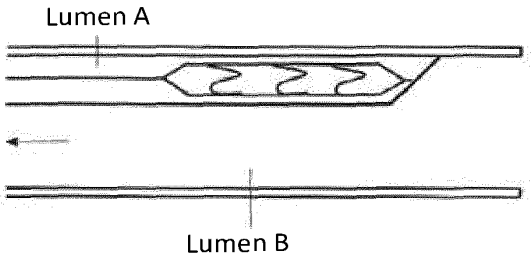


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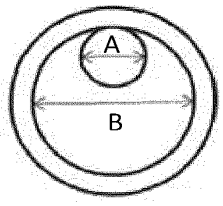


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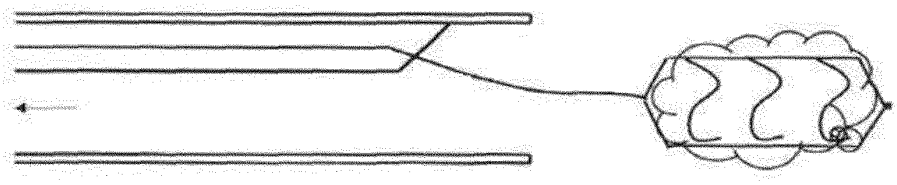


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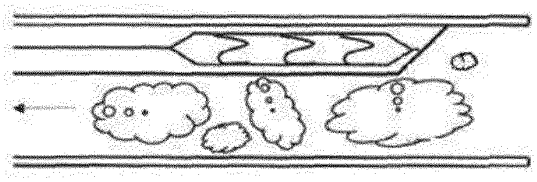


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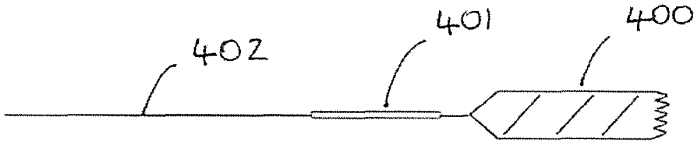


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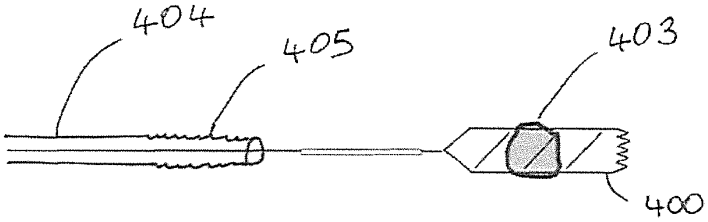


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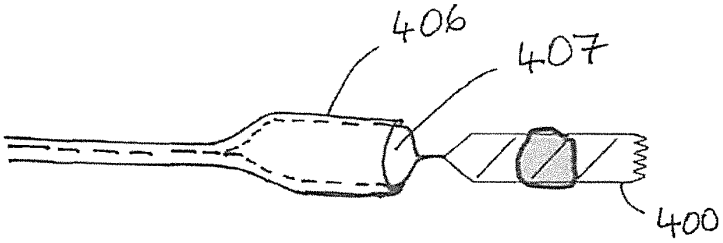


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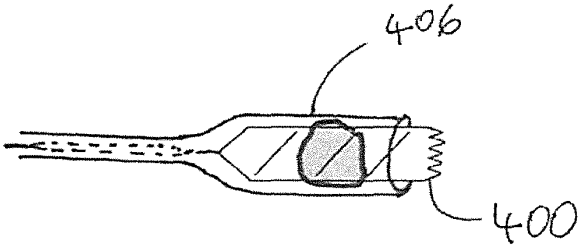


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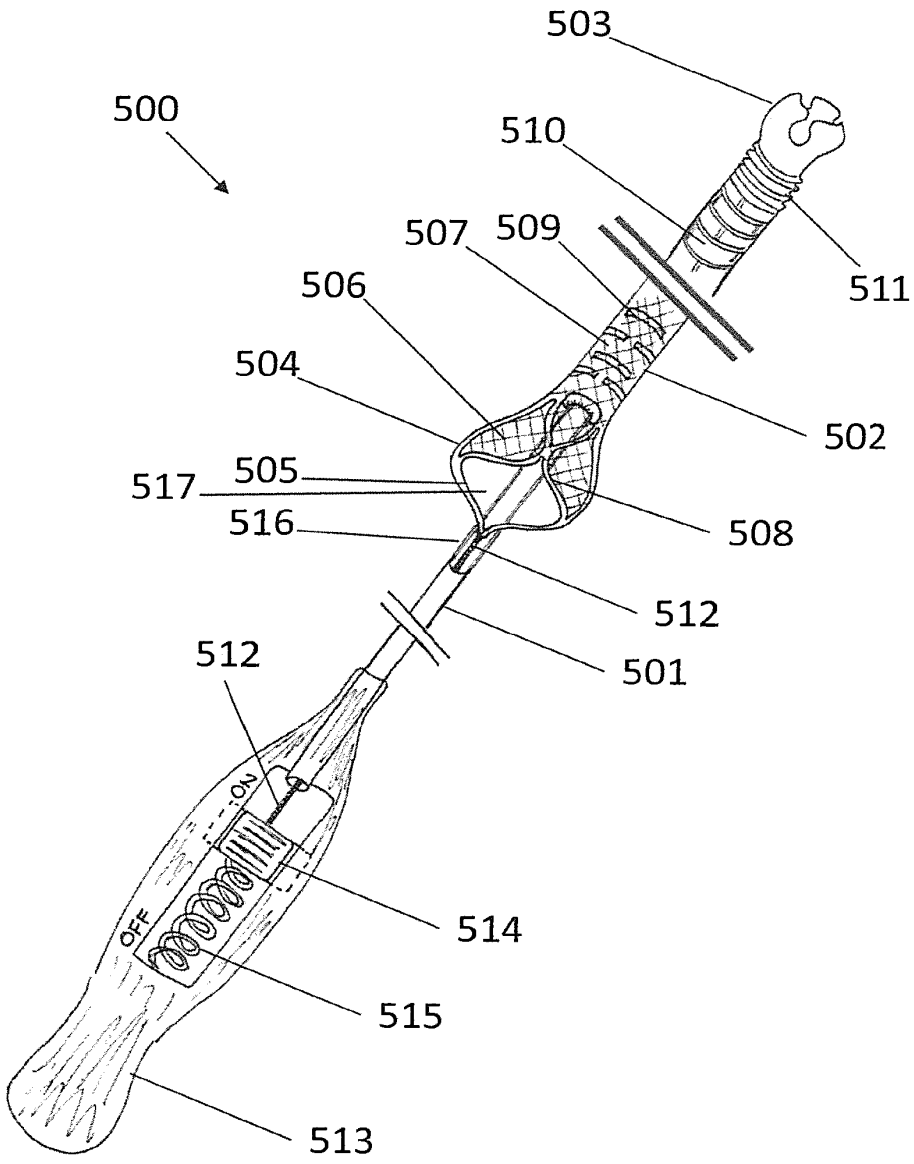

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Fig 60

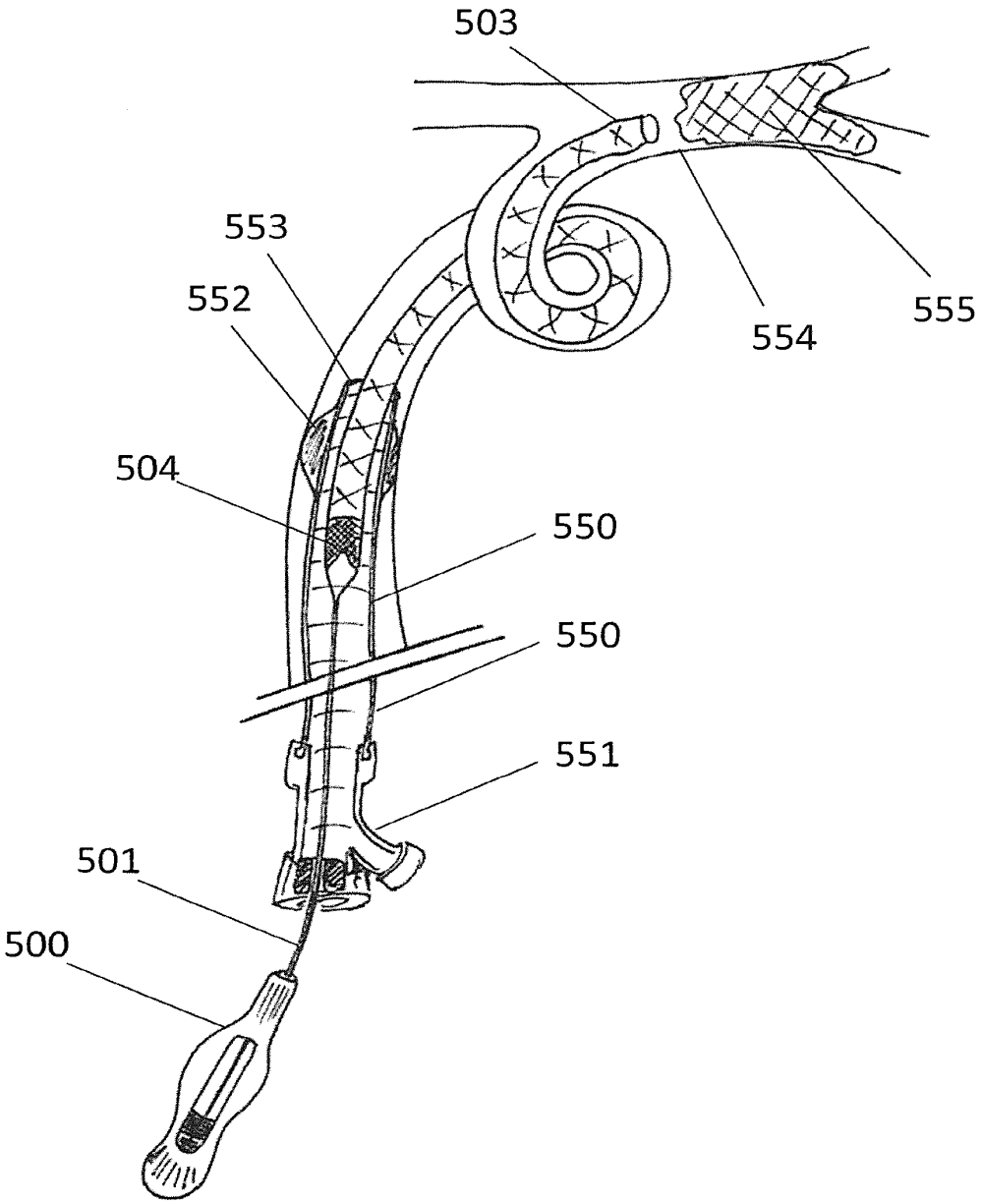


Fig 61a

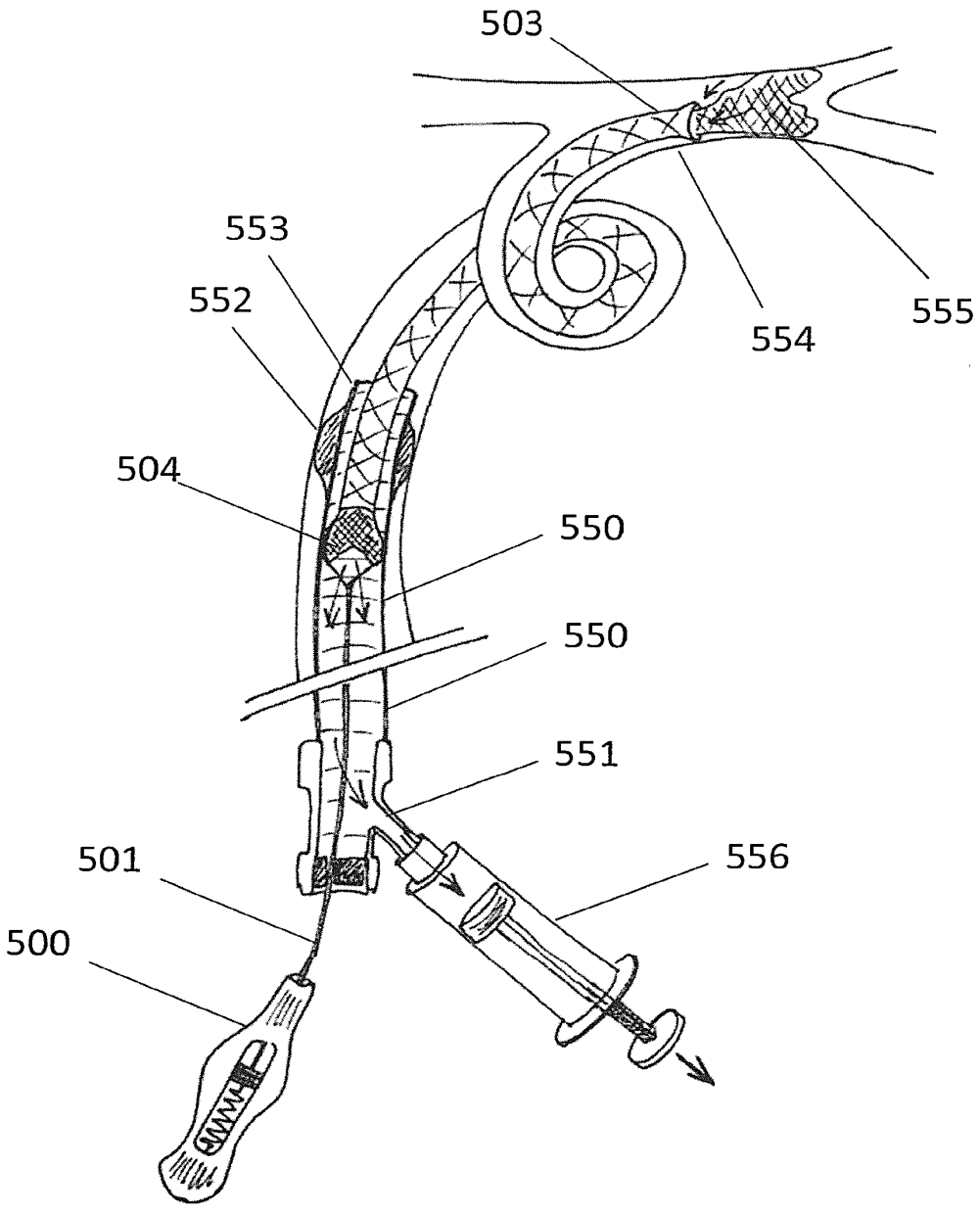


Fig 61b

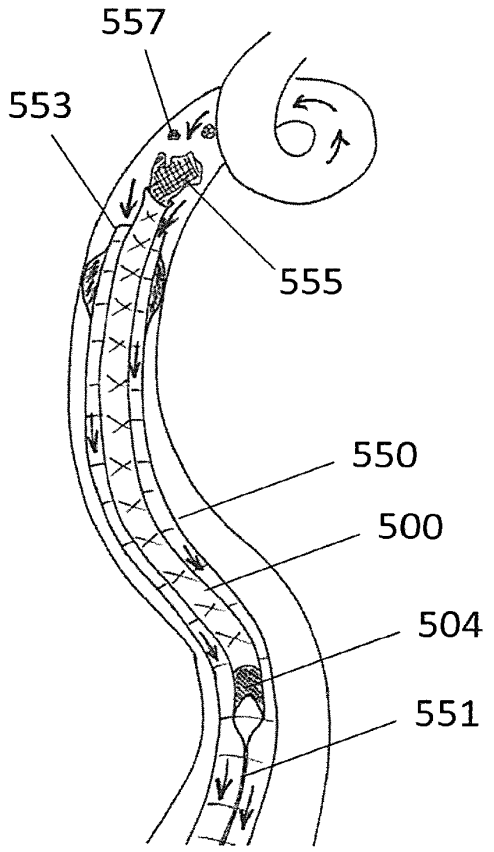


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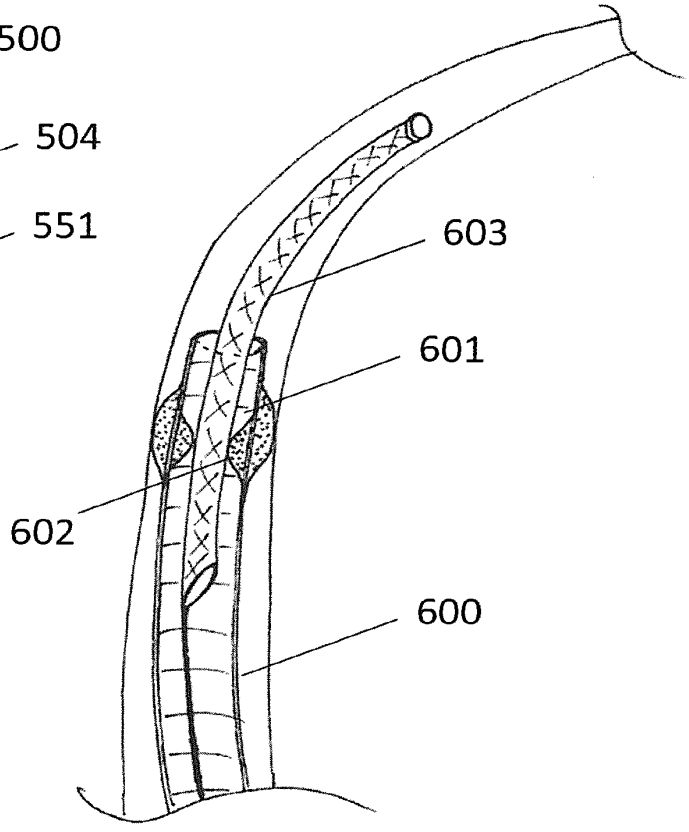


Fig 62

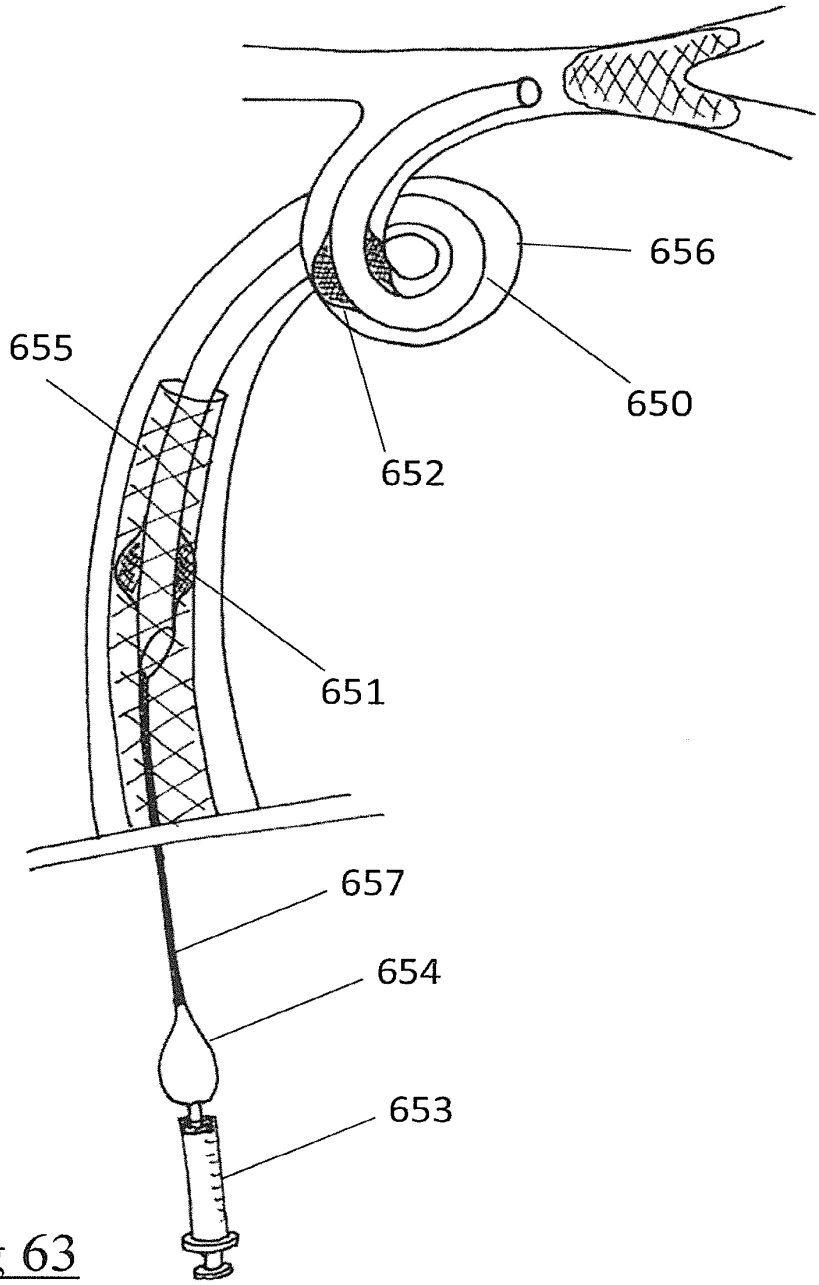


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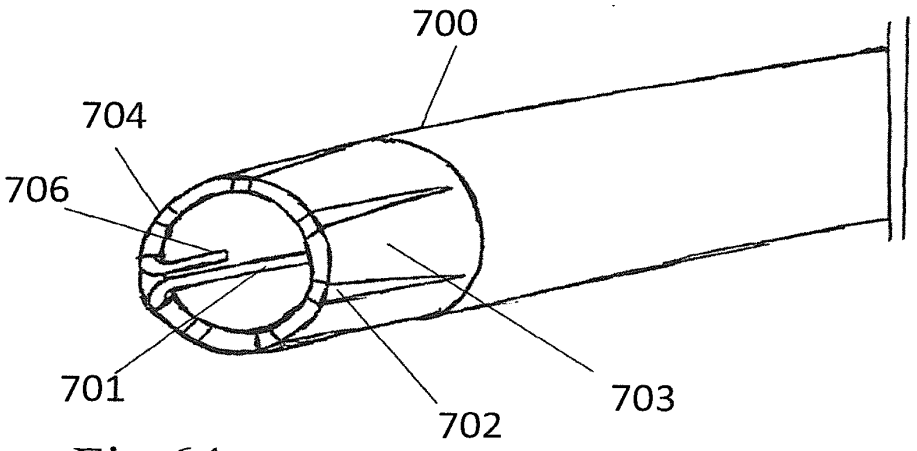


Fig 64a

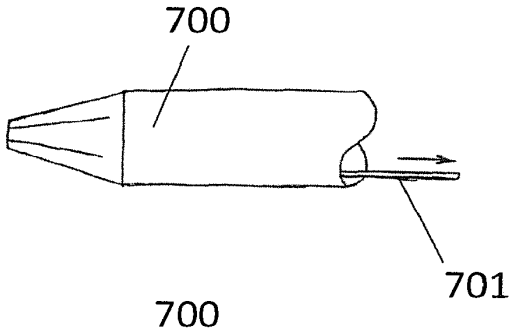


Fig 64b

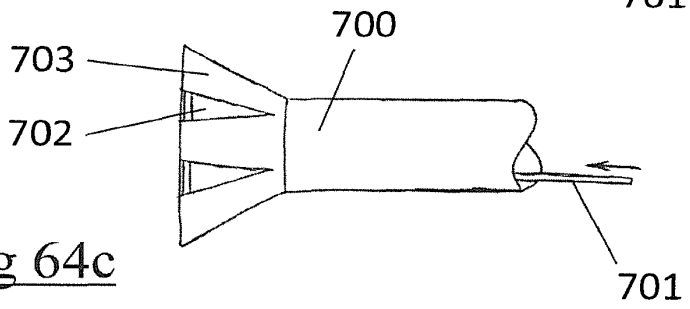


Fig 64c

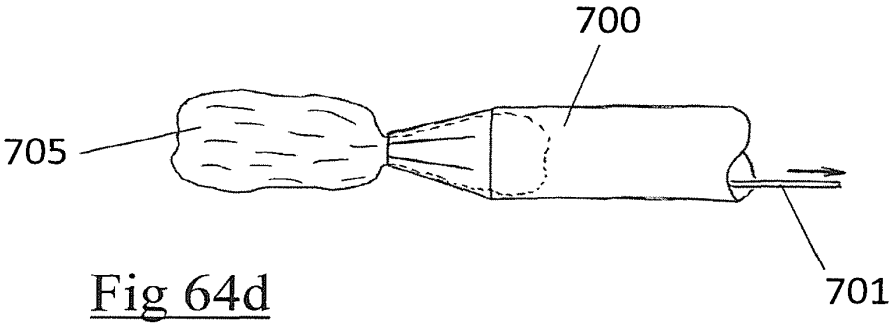


Fig 64d

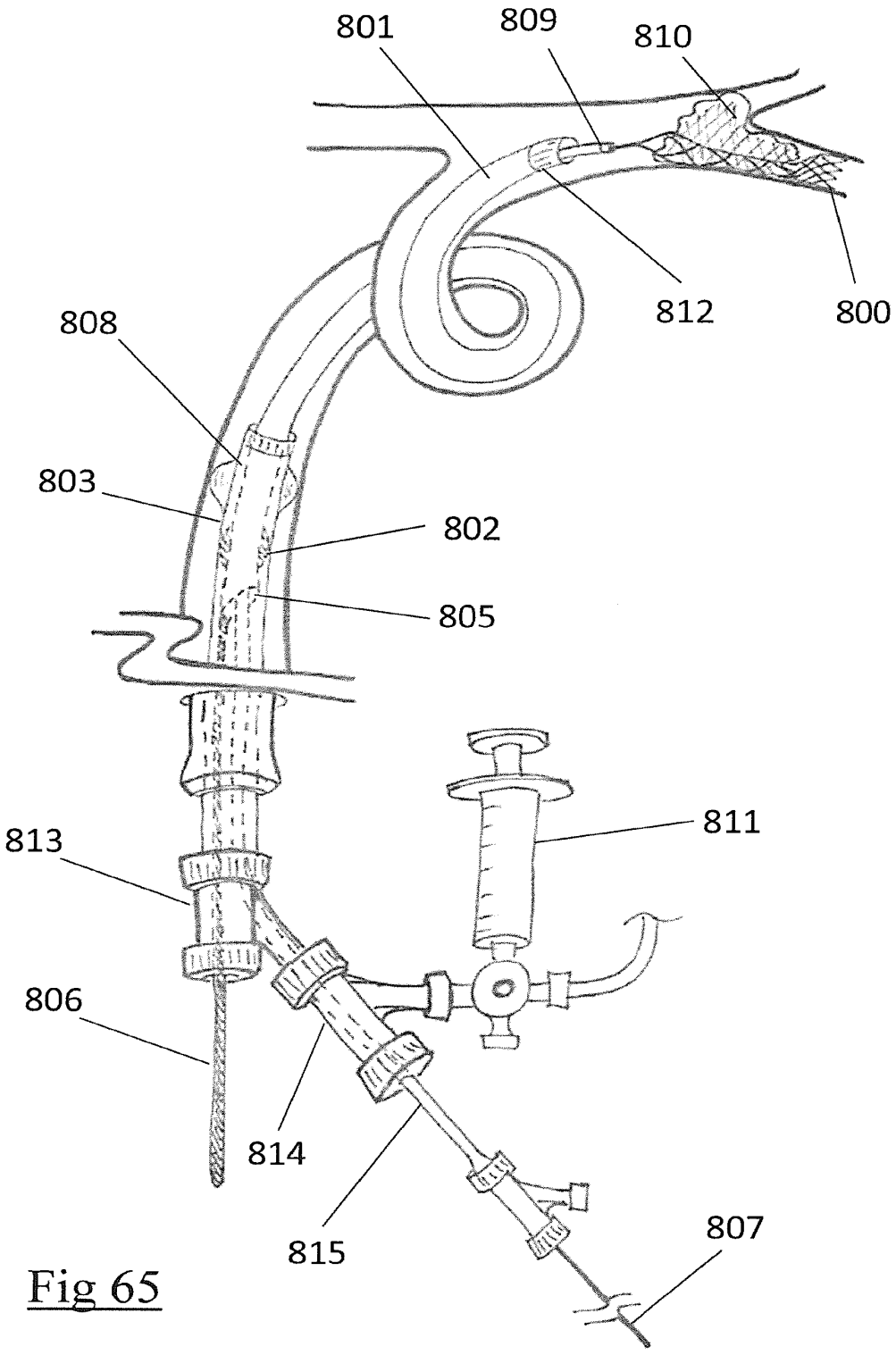


Fig 65

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2015/063104

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 8 057 497 B1 (RAJU SESHADRI [US] ET AL) 15 November 2011 (2011-11-15)	1-7, 10-12, 14-16, 19-21, 23-34, 36-38
Y	column 4, lines 17,18, 29-64; figures 2,2a,6 page 5, lines 33-40 page 7, lines 61-67	8,9,13, 17,18, 22,35

Y	US 5 769 871 A (MERS KELLY WILLIAM C [US] ET AL) 23 June 1998 (1998-06-23) column 4, line 64 - column 5, line 13; figures 1-3	8,9,13, 17,18, 22,35

	-/--	

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

[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

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Date of the actual completion of the international search	Date of mailing of the international search report
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2

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A	WO 99/56801 A2 (MICROVENTION INC [US]) 11 November 1999 (1999-11-11) page 21, line 22 - page 23, line 5; figure 6	1-38

2

INTERNATIONAL SEARCH REPORT

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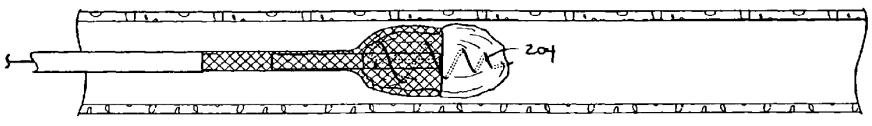
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(54) Title: SYSTEMS, METHODS AND DEVICES FOR REMOVING OBSTRUCTIONS FROM A BLOOD VESSEL



(57) Abstract: A system for removing an obstruction from a blood vessel includes an obstruction engaging element and an expandable capture element. The capture element preferably has a flexible cover and an expandable support structure. The engaging element engages the obstruction and moves the obstruction into the capture element. The capture element protects the obstruction when the obstruction is moved into the catheter.

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SYSTEMS, METHODS AND DEVICES FOR REMOVING OBSTRUCTIONS FROM A BLOOD VESSEL

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation in part of Serial No. 09/756,476, filed January 8, 2001, which is a continuation-in-part of Application Serial No. 09/605,143, filed June 29, 2000, entitled, "Methods and Devices for Removing an Obstruction From a Blood Vessel," by inventors Sepetka, et al., the full disclosures of which are incorporated herein by reference for all purposes.

BACKGROUND OF THE INVENTION

The present invention is directed to methods and devices for removing obstructions from blood vessels. The device may be used to retrieve and remove clots and other biological obstructions. The device may also be used to retrieve embolic coils and the like which have been misplaced or have migrated to an undesirable location.

One such obstruction removal device is disclosed in U.S. Patent No. 5,895,398 which is hereby incorporated by reference. The device has an expandable engaging member which is introduced into the blood vessel to engage the obstruction for removal.

The present invention is also directed to devices, systems and methods which use an expandable capture element when removing obstructions from a blood vessel. One such system for removing obstructions in a blood vessel is described in U.S. Patent No. 5,102,415 to Guenther et al. The system described in U.S. Patent No. 5,102,415 has a balloon catheter and a catheter having an expandable tip which receives the obstruction. The balloon catheter is passed through the obstruction while the balloon is deflated. The balloon is then inflated and the tip of the catheter is expanded. The balloon is then moved proximally so that the obstruction is pulled into the expanded tip of the catheter. A problem with the system of U.S. Patent No. 5,102,415 is that the interaction between the balloon catheter and the leading edge of the catheter may tend to shear off portions of the obstruction. This can cause obvious problems when working in sensitive vascular areas.

The present invention is directed to additional devices and methods for removing obstructions in a blood vessel.

SUMMARY OF THE INVENTION

In accordance with the present invention, device and methods for removing obstructions are provided. In a first aspect of the invention, an obstruction removal device is provided which has an obstruction engaging element extending from an insertion element. The engaging element is movable from a collapsed position to an expanded position. The engaging element forms coils having varying diameter wherein the coils at a distal portion are larger than coils at an intermediate portion. The distal portion forms a relatively closed structure which prevents the obstruction, or any part thereof, from migrating downstream. The distal portion is expanded distal to the obstruction while the proximal portion engages and holds the obstruction.

In another aspect of the present invention, another obstruction removal device is provided which has at least one closed loop and preferably two closed loops. The closed loop provides an advantage when advanced through a catheter or sheath in that the closed loop produces opposing radial forces on the catheter or sheath through which the loop is advanced. In this manner, the obstruction removal device can be advanced more easily through the catheter or sheath to prevent binding or kinking of the device during advancement. In a preferred embodiment, the obstruction removal device has two loops of varying diameter with the distal loop having a larger diameter. Each of the loops lie in a plane with the planes of the two loops preferably being perpendicular to one another.

In another aspect of the invention, another obstruction removal device is provided which has wound sections formed by one or more filaments which are separated by sections substantially free of the filaments. The intermittent wound sections provide discrete portions where the obstruction can be engaged. In an embodiment, the wound sections can slide on the core element to provide flexibility when advancing the obstruction removal device. The wound sections and sections free of filament are preferably about 1-5 mm long. The obstruction removal device preferably has at least three wound sections and more preferably at least five wound sections.

In still another aspect of the invention, another obstruction removal device is provided which has alternating large and small diameter portions. In a preferred embodiment, the obstruction removal device has at least four large diameter sections and three smaller diameter portions. The alternating large and small diameter portions may help to engage certain types of obstructions and can also help to prevent parts of the obstruction from breaking off and migrating downstream.

Any of the obstruction removal devices described herein may also be used with a source of power coupled to the obstruction removal device for use as described below. The source of power may simply produce a positive or negative charge or may be an RF energy source. The source of power may be used to help the obstruction removal device penetrate and engage the obstruction and may also be used to adhere the obstruction to the obstruction removal device as will be described. In a preferred embodiment, a negative charge is provided when advancing the obstruction removal device into the obstruction and a positive charge, or RF energy, is supplied to adhere the device to the obstruction.

The devices of the present invention may be manufactured in any suitable manner. In another aspect of the present invention, the obstruction removal device has a core element surrounded by a sheath. A strand, preferably about four strands, are positioned between the core element and the tube. The strand and the tube prevent any part of the obstruction removal device from breaking free should the core element fail. The strand and tube will hold the obstruction removal device together even if the core element breaks. The sheath is preferably flexible so that the sheath can undergo much larger deflections than the core element.

The obstruction removal devices of the present invention may also be advanced through a guide catheter having a flow restricting element which is preferably a balloon but may be any other suitable structure. The flow restricting element is expanded to reduce blood flow through the obstructed vessel to minimize the likelihood that the obstruction will migrate downstream.

In another aspect of the invention, a system is provided which has an expandable capture element and an obstruction engaging device which together work to remove an obstruction from a blood vessel. The capture element is advanced through the patient in a collapsed position and is expanded when at the desired location. The obstruction engaging device preferably has one or more filaments which provide a relatively flexible interaction between the engaging device and the capture element. This provides advantages over the use of a balloon catheter as described in greater detail below. The obstruction engaging device preferably has 1-4 filaments and more preferably 1-2 filaments. Of course, the obstruction engaging device may have more filaments without departing from various aspects of the invention and, in fact, the device may form a filter which further helps to prevent portions of the obstruction from being carried downstream.

The capture element is preferably naturally biased toward the expanded position although the capture element may also be manually actuated as described below. The capture element has a support structure with a flexible cover attached thereto. The support structure preferably has a closed loop which opens the distal end of the cover. The loop is preferably integrally formed and has a number of integrally formed hinges which deflect when the loop is expanded and collapsed. The hinges are preferably V-shaped although other shapes may be used. A plurality of struts extend proximally from the loop.

The capture element may also be expanded by the user so that the user may select the appropriate time for expansion of the capture element. In this manner, the user may advance the capture element to a suitable location for expansion. The user may also collapse the capture element before withdrawing the capture element into a catheter. The capture element has an actuator for opening and closing the capture element. The actuator may have a control arm and a stable arm although any suitable actuator may be used. The control arm is manipulated to expand and contract a loop at the distal end of the capture element. Alternatively, the actuator may be a tube which cinches the loop closed. In a specific embodiment, the capture element may also evert when moving to the expanded position.

The device of the present invention may be used in various different locations and for various different purposes. In one embodiment, the device may be used in connection with a guide catheter. When used with the guide catheter, the device may be expanded to slow or even stop blood flow when performing other procedures downstream of the guide catheter such as removing a clot or placing a stent.

Alternatively, the device may be passed through a conventional guide catheter so that the device may be introduced further into the vasculature. In this system, the capture element passes through the guide catheter. The obstruction engaging device is then used to engage the obstruction and move the obstruction into the capture element.

The present invention is also directed to methods and devices for removing an obstruction where the obstruction engaging element has a shape which traps the obstruction. In one aspect, the element extends proximally and then distally to ensnare the obstruction. The element may have such a shape naturally or may be moved into this shape by manipulating the element. For example, the element may be rotated in one or both directions to ensnare the obstruction. The element may have a portion which prolapses to capture the element as the element is manipulated.

In still another aspect of the invention, the capture element inverts when the obstruction is moved into the capture element. The obstruction is preferably engaged with an engaging element having a filament which ensnares the obstruction. The obstruction engaging element may be independent from the capture element or may be connected to the engaging element. The capture element inverts upon application of a compressive force to the inverting portion or upon any other suitable actuation force. The capture element preferably inverts when the compressive force is applied by either the obstruction or the engaging element.

The present invention is also directed to actuators for medical devices. In a first aspect, an actuator is provided which has an outer member and a plurality of fingers extending from the outer member. The fingers form an end that can be opened and closed by bending and straightening the fingers. The fingers may be bent by moving an inner member coupled to the fingers or by tensioning or releasing tension on a filament. The medical devices described above may be used for any suitable purpose including capture or containment of obstructions. For this purpose, the fingers or frame may be covered with the cover that forms an enclosure to hold the obstruction.

In another aspect, the medical device may have a frame that extends from inner and outer members. The frame forms an end that also opens and closes. The frame has a first set of connectors coupled to the outer member and a second set of connectors coupled to the inner member. The inner and outer members are movable relative to one another to open and close the end. The frame may be an integral structure with the structure being deformed when the end opens and closes. In still another aspect, the frame may be made of a shape memory material which regains either the closed or open position when heated or cooled. For example, the frame may be heated using electrical energy or other suitable source to actuate the frame.

These and other advantages of the invention will become apparent from the following description, drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a system for removing an obstruction.

Figure 2 shows the obstruction removal device in a collapsed condition.

Figure 3 shows the obstruction removal device with a distal portion of the obstruction removal device expanded.

Figure 4 shows the obstruction removal device with a proximal portion expanded to engage an obstruction.

Figure 5 shows another obstruction removal device.

Figure 6 shows yet another obstruction removal device.

Figure 7 shows still another obstruction removal device.

Figure 8 is an end view of the obstruction removal device of Figure 7.

Figure 9 is an exploded view showing a method of constructing an obstruction removal device.

Fig. 10 shows another system for removing an obstruction from a blood vessel.

Fig. 11 shows a capture element in an expanded position with an obstruction engaging element engaging an obstruction

Fig. 12 shows the obstruction moved into the capture element with the obstruction engaging element.

Fig. 13 shows the capture element collapsed and contained within a catheter.

Fig. 14 shows an alternative structure for the capture element.

Fig. 15 shows another capture element.

Fig. 16 shows a distal end of the capture element of Fig. 15.

Fig. 17 shows the support structure for the capture element of Figs. 15 and 16.

Fig. 18 shows the capture element collapsed around the obstruction prior to withdrawal.

Fig. 19 shows the capture element contained within the catheter in an inverted position when collapsed.

Fig. 20 shows another support structure for the capture element with the support structure in an expanded position.

Fig. 21 shows the support structure of Fig. 20 in a collapsed position.

Fig. 22 shows still another support structure for the capture element.

Fig. 23 shows another capture element having a support structure which bows outward to preferentially close the distal end.

Fig. 24 shows the capture element of Fig. 23 with an obstruction contained within the capture element.

Fig. 25 shows another capture element.

Fig. 26 shows yet another capture element in an expanded position.

Fig. 27 shows the capture element of Fig. 26 in a collapsed position.

Fig. 28 shows another device for capturing an obstruction.

Fig. 29 shows the capture device of Fig. 28 advanced at least partially into engagement with the obstruction.

Fig. 30 shows an obstruction engaging element advanced through the capture element.

Fig. 31 shows the element engaging the obstruction.

Fig. 32 shows the obstruction partially contained within the capture element.

Fig. 33 shows the obstruction completely contained within an inverted portion of the capture element.

Fig. 34 shows still another device for capturing an obstruction.

Fig. 35 shows the element engaging the obstruction.

Fig. 36 shows the inverting portion beginning to invert to capture the obstruction.

Fig. 37 shows the obstruction partially contained within the capture element.

Fig. 38A shows the obstruction completely contained within the capture element.

Fig. 38B shows the inverting portion contained within another catheter such as the guide catheter for removal from the patient.

Fig. 39 shows the distal end of the device of Figs. 34-38 with the engaging element expanded.

Fig. 40 shows the distal end of the device of Figs. 34-38 with the engaging element collapsed.

Fig. 41A shows an actuator for a medical device having which has a deformable frame being used as an obstruction capture device.

Fig. 41B shows the capture device with an obstruction contained therein.

Fig. 42A shows the actuator of Fig. 40 with the distal end closed.

Fig. 42B shows the capture device withdrawn into another catheter.

Figs. 43A-D show the frame coupled to inner and outer members.

Fig. 44 shows another actuator having a frame made of a shape memory material.

Fig. 45 shows the actuator of Fig. 43 with the distal end closed.

Fig. 46 shows still another actuator for a medical device.

Fig. 47 shows the actuator of Fig. 46 with a plurality of fingers in a closed position.

Fig. 48 shows an alternate embodiment of the medical device of Figs. 45 and 46.

Fig. 49 shows the medical device of Fig. 48 with the fingers in a closed position.

Fig. 50 shows the actuator of Figs. 46-49 used to capture or remove an obstruction.

Fig. 51 shows the actuator of Figs. 46-49 with the distal end closed to capture the obstruction.

Fig. 52 shows another obstruction engaging element.

Fig. 53 shows the obstruction engaging element of Fig. 52 with the element engaging an obstruction.

Fig. 54 shows the obstruction engaging element of Figs. 52 and 53 with the element having a prolapsed portion.

Fig. 55 shows another obstruction engaging element in an expanded position.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to Figs. 1-4, a system 2 for removing an obstruction is shown. A guide catheter 4 is advanced to a location proximal to an obstruction. When accessing the cerebral vasculature, for example, the guide catheter 4 is often positioned in the carotid or vertebral artery. Of course, the guide catheter 4 may not be necessary or may be positioned in any other suitable location depending upon the location of the obstruction. The guide catheter 4 preferably has a flow restricting element 6 which restricts or even stops blood flow through the vessel as described below. The flow restricting element 6 is preferably a balloon 5 coupled to a source of inflation fluid 7 which is used to inflate the balloon 5.

An obstruction removing device 8 is advanced through the guide catheter 4 to the obstruction. A microcatheter 10 may also be positioned within the guide catheter 4 to deliver the obstruction removing device 8 further into the vasculature. The obstruction removing device may be advanced by itself through the microcatheter 10 or may be contained within a sheath 12 which is advanced through the microcatheter 10. A source power 14 may also be coupled to the obstruction removal device 8 for use in the manner explained below.

The power source 14 may simply produce a positive or negative charge or may be an RF or other suitable power source.

The obstruction removing device 8 has an engaging element 16 extending from an insertion element 18. The engaging element 16 is movable from a collapsed position (Fig. 2) to an expanded position (Figs. 3 and 4). When the engaging element 16 is contained within the sheath 12 or microcatheter 10, the engaging element 16 is in a relatively straight configuration. The engaging element 16 has a distal portion 20, which forms a relatively closed structure, which can catch or trap the obstruction, or any part thereof, to prevent migration of the obstruction or part thereof. The engaging element 16 has a proximal portion 22 which is formed with smaller coils than the distal portion 20. The proximal portion 22 engages the obstruction as described below.

The engaging element 16 preferably has a number of markers 23, 25, 27 which provide an indication as to how much of the engaging element 16 extends from the sheath 12 or microcatheter 10. For example, markers 23, 25, 27 may indicate when the engaging element 16 is ½, ¾ or fully exposed. In this manner, the user may quickly advance the engaging element engaging element 16 through the sheath 12 or microcatheter 10 without inadvertently exposing and advancing the engaging element 16 out of the sheath 12 or microcatheter. The markers 23, 25, 27 can also be used to provide a controlled diameter of the engaging element 16 since the diameter of the engaging element 16 is known for the various positions corresponding to the markers 23, 25, 27. The markers 23, 25, 27 may also be used to size the vessel in which the engaging element 16 is positioned by observing when the engaging element 16 engages the vessel walls and determining the size of the engaging element 16 using the markers 23, 25, 27.

The insertion element 18 is preferably made of a superelastic material or stainless steel having a diameter of 0.004 to 0.038 inch and preferably about 0.010 inch. Although the insertion element 18 is preferably a solid, elongate element, the insertion element 18 may take any other suitable structure such as a hollow tube. The engaging element 16 is preferably made of a superelastic material, such as nitinol, and has a diameter of 0.005-0.018 inch, more preferably 0.005-0.010 inch and most preferably about 0.008 inch. The engaging element 16 has a rounded, atraumatic tip 24 to prevent damage to the vessel and facilitate advancement through the vessel, microcatheter 10 and/or sheath 12. A radiopaque wire 26, such as platinum ribbon 28 having a width of 0.004 inch and a thickness of 0.002 inch, is preferably wrapped around the engaging element 16 to improve radiopacity.

The device 8 is preferably self-expanding but may also be expanded with an actuator 29. The actuator 29 is preferably a thin filament which is tensioned to move the device 8 to the expanded position. An advantage of the invention is that the filament 29 extends through the same lumen as the device 8 thereby minimizing the overall size of the device. It is understood that throughout discussion of the devices and methods herein that any of the devices may be expanded using the actuator 29 rather than being self-expanding without departing from the scope of various aspects of the invention.

The device 8 may also include a cover 9 which extends between adjacent coils. The cover 9 may be a number of individual strands 11 which extend between the coils or may be an elastic membrane which covers the coils. The strands 11 are preferably elastic to stretch when the device 8 is expanded.

Use of the obstruction removing device 8 is now described. The guide catheter 4 is introduced into the patient and delivered proximal to the target vessel such as to the carotid or vertebral artery. The microcatheter 10 is then advanced through the guide catheter 4 further into the vasculature to a position proximal to, within or distal to the obstruction. The obstruction removal device 8 is then advanced through the microcatheter 10 either by itself or pre-loaded within the sheath 12. The obstruction removal device 8 is then advanced to the obstruction. Before advancing the obstruction removal device 8 further, the flow restricting element 6 on the guide catheter 4 is expanded to reduce and even stop flow through the vessel. Stopping flow in the vessel may help prevent the obstruction, or any parts thereof, from migrating downstream. Reducing flow through the vessel may also reduce the likelihood that the obstruction is disrupted by a combination of flow and the obstruction removal device 8.

The obstruction removal device 8 is then placed into the obstruction and preferably through the obstruction. The engaging element 16 is then advanced out of the microcatheter 10 or sheath 12 to permit the distal portion 20 of the engaging element 16 to expand at a location beyond the obstruction. In this manner, the relatively closed distal portion 20 prevents the obstruction, or any part thereof, from migrating downstream. The proximal portion 22 is then advanced out of the sheath 12 or microcatheter 10 so that the smaller coils of the proximal portion 22 engage the obstruction as shown in Fig. 4.

Referring to Fig. 5, another obstruction removal device 8A is shown wherein the same or similar reference numbers refer to the same or similar structure. The obstruction removal device 8A has a first section 30 with larger diameter coils than a second section 32.

A third section 34 also has larger coils than the second section 32 with the second section 32 positioned between the first and third sections 30, 34. The obstruction removal device 8A may have a number of alternating small and large sections 30, 32, 34 which can enhance the ability of the obstruction removal device 8A to engage various obstructions. In the preferred embodiment of Fig. 5, the obstruction removal device 8A has four large sections 32, 34 with relatively large coils and three sections 30 having smaller coils.

The obstruction removal device 8A may be used in any suitable manner to engage the obstruction. For example, the microcatheter 10 or sheath 12 may be advanced through the obstruction and then retracted to expose the obstruction removal device 8A. The obstruction removal device 8A is then retracted into the obstruction to engage the obstruction. The obstruction removal device 8A may be rotated when moved into the obstruction to take advantage of the generally helical shape of the obstruction removal device. The obstruction removal device 8A may also be used to engage the obstruction by simply retracting the microcatheter 10 or sheath 12 with the obstruction removal device 8A expanding within the obstruction. Finally, the engaging element 16A may be exposed and expanded proximal to the obstruction and then advanced into the obstruction. When advancing the obstruction removal device 8A into the obstruction, the user may also twist the obstruction removal device 8A to take advantage of the generally helical shape. The alternating large and small sections 30, 32, 34 enhance the ability of the engaging element 16A to engage varying shapes and sizes of obstructions.

Referring to Fig. 6, still another obstruction removal device 8B is shown wherein the same or similar reference numbers refer to the same or similar structure. The obstruction removal device 8B has the insertion element 18 with an engaging element 16B extending therefrom. The engaging element 16B forms a helical coil 38 with a generally frustoconical shape, however, the engaging element 16B may take any other shape without departing from the scope of the invention including any shape disclosed in this application or any patent incorporated by reference herein.

A filament 40, preferably a radiopaque filament, is wrapped around the engaging element 16B. The filament 40 is wrapped somewhat loosely around the engaging element 16B so that the filament 40 provides additional surface area to engage the obstruction. The filament 40 forms a wound section 42, and more preferably at least five wound sections 42, which are separated by substantially exposed sections 44 of the engaging element 16B. The wound and exposed sections 42, 44 may be 1-5 mm long. Stated another

way, the wound and exposed sections 42, 44 are at least 1 mm, more preferably at least 3 mm long, and no more than 8 mm long. The wound sections 42 may be formed by a single filament 40 which extends continuously between the wound sections 42 or may be formed by independent filaments 40 at each wound section 42 which are attached to the engaging element 16B.

The wound sections 40 may be movable along the engaging element 16B to provide flexibility when advancing the obstruction removal device 8B through small and tortuous vessels. The movable wound sections 40 may also allow different parts of the obstruction removal device 8B to grip different parts of the obstruction to hold the obstruction together or engage different parts of the obstruction. The obstruction removal device 8B is used in substantially the same manner as the other obstruction removal devices described herein. The obstruction removal device 8B has a handle 41 with a lead screw 43 which engages threads 55. The handle 41 is rotated to advance and retract the engaging element 16B.

Referring to Fig. 7, still another obstruction removal device 8C is shown wherein the same or similar reference numbers refer to the same or similar structure. The obstruction removal device 8C has an engaging element 16C , which forms a first closed loop 50, and a second closed loop 52. The first loop 50 is preferably somewhat larger than the second closed loop 52 with the first loop 50 having a diameter of about 1.5-8.0 mm and the second loop 52 having a diameter of about 1.5-6.0 mm. A tip 54 extends from the first loop 50 for a distance of about 5 mm. A radiopaque element 56, such as platinum ribbon, is preferably wrapped around the loops 50, 52 to improve radiopacity and to enhance the ability of the engaging element 16C to hold the obstruction. The radiopaque element 56 also may provide advantages when engaging an obstruction in a manner similar to the obstruction removal devices described above with reference to Fig. 6.

An advantage of the obstruction removal device 8C is that the loops 50, 52 exert substantially equal and opposing forces on the sheath 12 or microcatheter 10 through which the obstruction removal device 8C is advanced. In this manner, kinking or binding of the obstruction removal device 8C during advancement can be minimized or reduced altogether. Referring to the end view of Fig. 8, the first and second loops 50, 52 preferably lie in first and second planes 58, 60, respectively, which are preferably perpendicular to one another.

Another method of aiding mechanical capture of an obstruction is to coat the

device and elements of the present invention with a material 61 which helps to adhere the obstruction, and in particular thrombus, to the device or element. The material 61 is preferably fibrin but may be any other suitable material. Use of the material 61 may be incorporated into any of the devices described herein or other suitable device such as the devices shown in Figs. 2-8, 22 or 30.

Referring to Fig. 9, an exploded view of a construction of the obstruction removal device 8, 8A, 8B, 8C is shown. A tube 62, which is preferably a thermoplastic polymer such as polyester or urethane is positioned over a core element 64. As mentioned above, the core element 64 is preferably a superelastic or stainless steel element at either the insertion element 18 or the engaging element 16 (Figs. 2-7). A reinforcing strand 66 is trapped between the tube 62 and the core element 64 to reinforce the obstruction removal device. The strand 66 is preferably small and has a diameter or thickness of less than 0.005 inch, more preferably less than 0.0001 inch, so that the overall size of the obstruction removal device is not increased significantly with use of the strand 66. The strand 66 may be made of any suitable material including VECTRAN made by Celanese Acetate LLP or DACRON or KEVLAR which are both manufactured by Dupont. VECTRAN is a thermoplastic multifilament yarn spun from a liquid crystal polymer.

The strand 66 provides a degree of safety in that the strand 66 and tube 62 together prevent any part of the obstruction removal device from breaking free from the rest of the device. The tube 62 will resist breaking since it is more flexible than the core element 64 and can undergo larger deflections and displacements without breaking. In a preferred embodiment, 2-8 strands 66, preferably about 4 strands 66, are used. The overall size of the device is also relatively small with the outer diameter of the resulting structure being no more than 0.020 inch and more preferably no more than 0.012 inch.

The power source 14 may be also be used with any of the obstruction removal devices in the following manner, however, the methods and devices of the present invention may, of course, be practiced without the power source 14. As mentioned above, the power source 14 may simply produce a charge at the engaging element 16 or may be a source of RF energy. In one particular method of the present invention, the power source 14 produces a negative charge while advancing the engaging element 16 through the obstruction. The negative charge may aid in passing the engaging element 16 through the obstruction and may help to dissolve part of the obstruction. The power supply is then changed to produce a positive charge to adhere the obstruction to the engaging element 16. Alternatively, the

power source 14 may be an RF energy source, which delivers RF to the engaging element 16 which also adheres the obstruction to the engaging element 16 and may help provide a controlled penetration into the obstruction. The obstruction is then removed by moving the obstruction into the guide catheter 4, which is then withdrawn to remove the obstruction. Use of the power source 14 is particularly useful when the obstruction is a biologic structure such as a clot.

Referring to Figs. 10-14, another system 100 for removing an obstruction is shown. The system 100 is particularly useful for removing clots and thrombus from blood vessels but may also be used to remove other obstructions such as embolic coils and the like. The system 100 includes an expandable capture element 102 and an obstruction engaging device 106 which work together to capture the obstruction. The obstruction engaging device 106 engages the obstruction and moves the obstruction into the capture element 102 as described below. After the obstruction has been captured, the capture element 102 may then be used in various ways for ultimate removal of the obstruction. The capture element 102 may be advanced through the guide catheter 4 or through another catheter 107 which is advanced through the guide catheter 4. As will be explained below, the capture element 102 is preferably advanced over the obstruction engaging device 106.

The obstruction engaging device 106 may be any of the engaging or removal devices described herein or any other suitable device. Various aspects of the invention preferably include one or more features of the obstruction removing devices described herein and all aspects, features, dimensions, and characteristics of the obstruction removing and engaging devices described herein are incorporated here. It is understood that the term obstruction removal device and obstruction engaging device are interchangeable. The obstruction engaging device 106 may be contained within the sheath 12 or may be advanced by itself through the guide catheter 4 and/or catheter 107.

The engaging device 106 may have one or more filaments 108, preferably 1-4 and more preferably 1-2 filaments, which engage the obstruction. The filament 108 forms a relatively small, flexible interaction between the engaging device 106, capture element 102 and obstruction which provides advantages over the prior art method of using a balloon catheter. The filament 108 may deflect and displace to accommodate the geometry and orientation of the obstruction when the obstruction enters the capture element 102. The interaction between the balloon catheter and the expandable catheter of the prior art tends to shear off portions of the obstruction due to the relatively rigid interaction between the balloon

catheter and expanded catheter. The filament 108 also has a relatively small size which further enhances the flexibility of the obstruction engaging device 108. The filament 108 may also form one or more loops 110 which further serve to create a soft, flexible interaction between the obstruction engaging device 106 and capture element 102. The filaments 108 may also form a filter which further prevents the obstruction or portions thereof from travelling downstream.

The capture element 102 preferably has a support structure 112 with a flexible cover 114 attached thereto. The support structure 112 is preferably self-expanding although the support structure 112 may also be selectively expanded by the user as explained below. The support structure 112 preferably has a loop 116 having integrally formed hinges 117. The hinges 117 are preferably formed by V-shaped interconnecting elements 120 although other shapes, such as U-shaped, may be used. The loop 116 is preferably formed as an integral structure with the loop 116 being formed from a tube of material which is cut, etched, treated or otherwise formed into the loop 116 with hinges 117. The loop is preferably made of a superelastic material although any suitable material may be used.

Struts 122 extend proximally from the loop 116. The struts 122 do not intersect and generally form a cone 124 when expanded. The struts 122 are coupled to a lumen 121 which receives the engaging device 106 so that the capture element 102 can be advanced over the engaging device 106 as described below. Referring also to Fig. 14, the struts 122 may also be coupled together at a hub 126 at the proximal end. The hub 126 has a lumen 127 which receives the engaging device 106. A shaft 128 extends from the hub 126 and is used to manipulate the capture element 102. The struts 122 are preferably made of a superelastic material or stainless steel and are attached to the closed loop 116 by soldering, welding, glue or any other suitable attachment method. The struts 122 may also be integrally formed with the loop 116. Of course, the supporting structure 112 may be made of any other suitable material and may be formed in any other suitable manner. The struts 122 may also be bowed outward so that the distal end of the device is preferentially closed before the entire device has been withdrawn as shown in Figs. 23 and 24.

The cover 114 is preferably attached to the support structure 112 with glue, thread, suture or any other suitable method. The cover 114 preferably lies over the support structure 112 but may also be contained within the support structure 112. The cover 114 is relatively long to ensure that the entire obstruction is captured. The cover 114 is preferably at least three times, more preferably at least five times, and most preferably at least seven times

larger than the maximum expanded diameter of the support structure 112 or cover 114. Of course, the capture element 102 may have any other suitable dimensions depending upon the particular application. The cover 114 is preferably made of ePTFE but may be made of any other suitable material. The cover 114 may also be a mesh-like structure, or any other suitable expandable structure which can contain the obstruction and parts thereof, without departing from the scope of the invention.

Various methods of the present invention are now described. The methods are described in connection with system 100 of Figs. 10-14 but may be practiced with other suitable devices and systems. The present invention is well-suited for use in the cerebral vasculature and a cerebral application is described, however, the invention may be practiced in other vascular locations as well.

The guide catheter 4 is advanced to a suitable location. The obstruction engaging device 106 is then advanced through the guide catheter 4. Referring to Figs 11 and 12, the obstruction engaging device 106 is then used to engage the obstruction in any manner described herein. For example, the sheath 10 (see Fig. 10) may be advanced through the obstruction and then retracted so that a proximal portion 111 of the device 106 is contained within the obstruction. The device 106 is then moved proximally, and is preferably twisted, so that the loops 110 engage the obstruction. In the specific embodiment of Figs. 11-14, the device 106 ensnares the obstruction with the loops 110 when twisted and moved proximally.

The capture element 102 is then advanced over the engaging device 106. The capture element 102 may be advanced through the guide catheter 4 or may be advanced through the catheter 107 which is advanced through the guide catheter 4 further into the cerebral vasculature. The capture element 102 is then moved out the catheter 107 or guide catheter 4 so that the capture element 102 expands. The obstruction is then moved into the capture element 102 with the device 106 as shown in Fig. 13. When the obstruction is contained within the capture element 102, the capture element 102 is then withdrawn into the catheter 107 or guide catheter 4 as shown in Fig. 14. The catheter 107 and/or guide catheter 4 are then withdrawn from the patient thereby withdrawing the obstruction.

It may be desirable to reduce or even stop blood flow through the blood vessel during the procedure to reduce flow forces on the obstruction when manipulating the obstruction. Reducing flow in the vessel may also prevent some parts of the obstruction from breaking off and flowing downstream before entering the capture element 102. Referring again to Figs. 10 and 22, blood flow may be reduced by inflating a balloon 131 on the guide

catheter 4 or the catheter 107. The balloon 131 is inflated using a suitable source of inflation fluid 133. Alternatively, the capture element 102 itself may also be used to reduce blood flow through the vessel. The capture element 102 naturally impedes blood flow since it expands within the blood vessel. The capture element 102 may also be designed to only partially occlude the vessel so that some blood flow is provided to the area downstream from the capture element 102. The device 102 may be modified to include a second loop130 extending between the struts 122 to enhance the ability of the device 102 to occlude the vessel. The loop 130 preferably has the features of the loop 116. Although it is preferred to reduce or even stop flow in the vessel, the invention may also be practiced without reducing blood flow.

The devices and methods of the present invention may also be practiced with a source of vacuum 135 providing suction during capture of the obstruction. The source of vacuum 135 may be activated during engagement of the obstruction with the device 106, movement of the obstruction into the capture element 102, and/or withdrawal of the capture element 102 into the catheter 107 or guide catheter 4. The source of vacuum 135 is coupled to the guide catheter, 4, catheter 107 and lumen 121 for these purposes.

Referring to Figs. 10 and 15-17, another capture element 132 for removing an obstruction is shown wherein the same or similar reference numbers refer to the same or similar structure. The capture element 132 is selectively expandable by the user which provides various advantages described below. The cover 114 is attached to a catheter 134 near or at the distal end 135. The catheter 134 may be the guide catheter 4 or the catheter 107 in the system 100 described above. An expandable and collapsible loop 136 is attached to the distal end of the cover 114 to expand and collapse the distal end of the cover 114. The loop 136 is expanded and collapsed by manipulating an actuator 138 which includes a control arm 140 and a stable arm 142. The control arm 140 extends and slides through an eyelet 144 when expanding and collapsing the loop 136. The stable arm 142 extends from the loop 136 at or near the eyelet 144 to stabilize the loop 136 when moving the control arm 140. The cover 114 is attached to the loop 136 using any suitable method. For example, the distal end may be inverted to create a fold 141 which surrounds the loop 136.

Another advantage of the capture element 132 is that the capture element 132 may be selectively expanded and contracted by the user. The capture element 132 may be fully or partially collapsed to trap the obstruction prior to withdrawal of the capture element 132 into the catheter 107 or guide catheter 4 as shown in Fig. 18. In fact, the capture element

132 may be withdrawn by itself by simply closing the distal end and withdrawing the capture element 132. In this manner, the capture element 132 protects the obstruction during withdrawal and prevents the obstruction from escaping. This provides obvious advantages over the system of Guenther described above.

Referring to Figs. 10 and 19, still another capture element 150 is shown in which the same or similar reference numbers refer to the same or similar structure. The capture element 150 has the cover 114 and the actuator 138 which includes the stable arm 142, control arm 140, and loop 136 although other actuating structures may be used. The capture element 150 is contained within the catheter 107 or the guide catheter 4 during introduction and is then everted out of the catheter 107 or catheter 4 when deployed. The capture element 150 may be used in substantially the same manner as the other capture elements described herein and in particular the capture element 132 of Figs 15-17. The capture element 150 may also be used to further collapse the cover 114 since the actuator 138 may be used to close the distal end with the cover 114 deployed. After the obstruction is contained within the capture element 150, the capture element 150 is withdrawn into the catheter 107 or catheter 4. Although it is preferred to withdraw the capture element 150 into the catheter 4 or catheter 107, the capture element 150 may be collapsed and then inverted back into the catheter 4, 107 thereby trapping the obstruction in the catheter 4, 107 itself.

Referring to Figs. 20 and 21, the distal end of yet another capture element 152 is shown in which the same or similar reference numbers refer to the same or similar structure. The capture element 152 has a self-expanding support structure 154 with an expandable loop 156 at the distal end. The loop 156 has a tube 158 which receives a wire 160 at both ends. The slidable connection between the tube 158 and wire 160 permits the loop 156 to contract and expand between the positions of Figs. 20 and 21. Struts 162 extend from the loop which engage the catheter to collapse the loop 156. The cover 114 is attached to the loop 156 by any suitable method. The capture element 152 is used in any manner described herein. The capture element 152 is used in any manner described herein and those methods are incorporated here.

Referring to Fig. 25, still another device 170 is shown wherein the same or similar reference numbers refer to the same or similar structure. The device 170 is similar to the device of Fig. 15 in that the device 170 may be selectively expanded and collapsed by the user. The device 170 has a collar 172, which may also be a continuous sheath or tube, which slides over the catheter 107 or sheath 12. The engaging device 106 passes through the

catheter 107 or sheath 12 (Fig. 10) and is used in the manner described herein. A 174 wire, or other elongate member, is coupled to the collar 172 for advancing and manipulating the collar 172.

The cover 114 is coupled to a loop 176 which is selectively expanded by the user as now explained. The loop 176 is manipulated with the actuator 138 which may be any suitable mechanism. The actuator 138 has a wire 139 passing through an actuator tube 178 and may also include the stable arm 142. The wire 139 is coupled to the loop so that movement of the wire 139 opens and closes the loop 176. The actuator tube 178 may be simply advanced to cinch the loop 176 closed. The loop 176 is preferably naturally biased toward the open position and is held closed by the tube 178.

The device 170 is used in substantially the same manner as the other devices described herein and discussion of those methods are specifically incorporated here. The device 170 may be advanced by itself through the vasculature with the tube 178 holding the loop 176 in the closed position. The cover 114 is advanced by manipulating the tube 178, wire 139 and wire 174. The cover 114 is advanced over the catheter 107 or sheath 12 and the tube 178 is retracted to permit the loop 176 to expand. The obstruction is then introduced into the cover 114 and the cover 114 is then closed by advancing the tube 178 to cinch the loop 176 closed. The actuator 138 may also be manipulated to open or close the loop 176 together with the tube 178 or independently of the tube 178.

Referring to Figs. 26 and 27, still another device 180 is shown wherein the same or similar reference numbers refer to the same or similar structure. The device 180 has the cover 114 and a loop 182 coupled to the distal end of the cover 114. Stabilizing struts 184 extend from an end 186 of a tubular body 188 to the loop 182. Actuating arms 190 extend through the body 188 and are also attached to the loop 182. The arms 190 are manipulated to move the loop 182 between the collapsed and expanded positions of Figs. 26 and 27. The engaging device 106 passes through the body 188 and may be delivered through the catheter 107 or sheath 12. The device 180 is used in substantially the same manner as the device of Fig. 15 and discussion of those methods are incorporated here.

Referring to Figs. 28-33, another capture element 200 is shown for capturing an obstruction. The capture element 200 has an inverting portion 202 that inverts to entrap the obstruction. The capture element 200 is then withdrawn into the guide catheter 4 (Fig. 1) for removal of the obstruction from the patient.

Referring to Fig. 31, the engaging element 204 is shown engaging the obstruction. The element 204 may be any suitable element such as the obstruction engaging elements and removal devices described herein. The element 204 passes through a lumen 205 in the capture element 200. The engaging element 204 may be advanced through the capture element 200 by itself or may be contained within the microcatheter 10 or sheath 12 (Figs. 1 and 2) which is advanced through the capture element 200.

The capture element 200 has a distal portion 207 which is flexible and which may be partially contained, engaged or otherwise in contact with the obstruction as shown in Fig. 29. The distal portion 207 may also invert but preferably does not invert. The distal portion 207 necks-down at a distal end 209 to a size smaller than the guidewire GW so that the capture element 200 is advanced together with the guidewire. Of course, the capture element 200 may also be advanced by itself after introduction of the guidewire and may be contained within or advanced over another catheter without departing from the invention.

The element 204 engages the obstruction in any suitable manner. The inverting portion 202 is then inverted by applying a compressive force to the inverting portion 202. The compressive force is applied by moving the capture element 200 relative to the engaging element 204 which causes the element 200 and/or obstruction to compress the inverting portion. Continued relative movement moves the obstruction into the inverted capture element 200 as shown in Figs. 32 and 33 to capture the obstruction. The capture element 200 is then moved into the guide catheter 4 (Fig. 1) for removal from the patient. The capture element 200 may be made of any suitable materials. For example, the distal portion 207 may be made of any suitable polymeric material such as those described herein and the inverting portion 202 may be made of a braided or woven material or fabric made of fibers or filaments of nitinol, stainless steel, polymer or other material.

Referring to Figs. 34-40, another capture element 210 for removing an obstruction is shown wherein the same or similar reference numbers refer to the same or similar structure. The capture element 210 also has an inverting portion 212 connected to an end 213 of a delivery element 214 which may be a hollow tube, sheath or catheter. The distal end of the capture element 210 has a collar 214 attached to a proximal end 216 of an engaging element 218. A distal end 220 of the obstruction engaging element 218 is attached to an inner element 222 such as a wire, mandrel or guidewire. The collar 214 slides over the inner element 222 so that when the inner element 222 and delivery element 214 are movable relative to one another. Relative movement between the inner element 222 and delivery

element 214 moves the obstruction engaging element 218 between the expanede and collapsed positions (Figs. 39 and 40) and also can collapse the capture element 210. The engaging element 218 is similar to the other elements and devices described herein in that the element has a filament 224 which is tensioned to collapse the filament 224. The filament 224 forms coils 226 around the inner element 222.

The capture element 210 and obstruction engaging element 218 are advanced through the patient in either the sheath 12 or microcatheter 10 (Figs. 1 and 2). The capture element 210 and obstruction engaging element 218 are then positioned distal to the obstruction and the obstruction is engaged with the element 218. The capture element 210 and engaging element 218 are then moved relative to one another to invert the capture element 210 as described above.

Referring to Figs. 41-43, another aspect of the present invention is shown which provides an actuator 228 for a medical device 230. The actuator 228 may be used for actuating any medical device and a specific example is a capture element or an obstruction removal device. The medical device 230 has a frame 232, an outer member 234 and an inner member 236 positioned within the outer member 234. The frame 232 extends distally from the inner and outer members 236, 234.

The frame 232 has a distal end 238 which moves between the open (Figs. 41A and B) and closed (Figs. 42A and B) positions. The frame 232 has a first set of connectors 240 coupled to the outer member 234 and a second set of connectors 242 coupled to the inner member 236. The inner and outer members 236, 234 are moved relative to one another so that the frame 232 is deformed to open and close the distal end between the positions of Figs. 41A and B and 42A and B. The inner and outer members 236, 234 are preferably tubes but may be any other suitable structure that permits longitudinal movement of the connectors 240, 242 in the manner described. The connectors 240, 242 extend longitudinally to a ring 241 formed of V-shaped elements 243. The connectors 240 attached to the inner member 236 are coupled to intersections 245 of the ring 241 and the other connectors 240 are attached to the other intersections 247 of the ring. Stated another way, the connectors 240, 242 are attached at spaced apart positions on the ring with one connector 240 between each pair of connectors 242. The frame 232 is preferably integrally formed in a manner similar to a stent. For example, the frame 232 may be formed by removing material from a tube to provide the frame structure.

A cover 233 may be provided over or under the frame 232 so that the frame 232 acts as an actuator 244 to open and close the cover 233. The cover 233 may be used in the same manner as any of the capture elements described herein. To this end, any of the obstruction engaging elements described herein may be used with the device to trap and remove obstructions.

Referring to Figs. 44 and 45, still another medical device 250 is shown which is similar to the medical device 230 of Figs. 41-43. The medical device also has a frame 252 having a distal end 254 which opens and closes. The frame 252 is made of a shape memory material which either recovers the open or closed position when heated. The shape memory material may be heated in any suitable manner including use of a heated fluid or by applying electrical energy which heats the frame 252 to cause the frame to assume the recovered shape. Fig. 45 shows the frame 252 assuming the collapsed shape upon application of electrical energy from an energy source 253. The cover 233 may also be provided so that the frame acts as an actuator for still another capture device. Figs. 45 show the medical device 250 being used to capture an obstruction. The device 250 is then withdrawn into the guide catheter or other suitable catheter for removal of the obstruction.

Referring to Figs. 46-51, still another actuator for a medical device 256 is shown. The characteristics of the medical device 256 may be used to form any device. The medical device 256 has a plurality of longitudinally extending fingers 258. The fingers 258 are normally in a relatively straight configuration. The fingers 258 are bent inward so that a distal end 260 closes (Fig. 47). The fingers 258 may be attached to the cover 233 to open and close the cover 233 with the fingers 258. The fingers 258 are preferably bent by tensioning flexible, elongate members 262. The elongate members 262 may be attached to an inner member 264 (Figs. 46 and 47) or an outer member 265 (Figs. 48 and 49). Any of the obstruction engaging elements may be used with the medical device to remove an obstruction in any manner described herein. For example, Figs. 50 and 51 show the medical device 256 being used to capture or remove an obstruction. The device 256 may be used to capture or engage the obstruction by itself or in cooperation with any a suitable engaging element 257.

Referring to Figs. 52-55, another obstruction engaging element 270 is shown. The obstruction engaging element 270 includes a filament 272 which forms windings or coils 274. The windings 274 may take any suitable shape such as helical. The obstruction engaging element 270 is advanced to an obstruction in any manner described herein. For example, the obstruction engaging element 270 may be contained within the sheath 12 or

catheter 10 (Figs. 1 and 2) and advanced through the obstruction. The obstruction engaging element 270 is then advanced out of the sheath 12 or catheter 10 (Figs. 1 and 2) to permit the obstruction engaging element 270 to expand.

When the element initially expands, the coils 274 do not overlap when viewed along a longitudinal axis L. The element 270 is then engaged by manipulating the element 270. After the obstruction has been engaged, the element 270 is rotated which tends to open the coils 274. This causes one or more proximal coils 274 to prolapse over other coils to ensnare the obstruction. Stated another way, the element 270 initially extends distally in a relatively continuous manner. After rotating the element 270, the element extends distally, then proximally, then distally again. Stated yet another way, the coils are manipulated so that they appear to overlap when viewed along the longitudinal axis L. The prolapsed or overlapping coils 274 may provide an even more secure engagement to the obstruction. The element 274 may also be formed to have the overlapping or prolapsed sections when in the natural, unbiased and expanded position as shown in Figs. 54.

While the above is a description of the preferred embodiments of the invention, various alternatives, substitutions and modifications may be made without departing from the scope thereof, which is defined by the following claims. Thus, the preferred embodiments should not be taken as limiting the scope of the invention. For example, although all of the obstruction removal devices described herein are self-expanding structures, the obstruction removal devices may also have actuating mechanisms for moving the engaging element between the expanded and collapsed positions. Furthermore, the present invention is directed to a number of separate inventions and each of these inventions may be claimed independently of one another. Each feature, aspect and advantage of the invention may be claimed independent of one another without departing from the scope of the invention. For example, use of the power source 14 is independent of the using the intermittent wound sections 42 but may be used with any of the devices and methods described herein. As a further example, any engaging device, even a balloon, may be used with some of the inventive aspects of the capture element and any capture element may be used with inventive aspects of the engaging device.

The obstruction engaging element may be used in any manner described herein and all such methods, devices and systems form part of the present invention. It can be appreciated that various aspects of each of the obstruction engaging elements may be practiced with various aspects of the capture element and, thus, all such combinations are, of

course, contemplated whether or not all such combinations are specifically identified herein. Finally, the devices of the present invention may also be used in connection with simply controlling blood flow through an area and not necessarily with removal of an obstruction. Thus, it is understood that various aspects of the present invention are not limited to removal of obstructions. Thus, the invention does not include a single essential feature, aspect or advantage and the invention should not be limited as such.

WHAT IS CLAIMED IS:

1. A method of removing an obstruction, comprising the steps of:

providing an obstruction removing device, the obstruction removing device having an element movable from a collapsed position to an expanded position, the element being contained within a lumen in a delivery device in the collapsed position;

advancing the delivery device through the patient's vascular system to an obstruction in a vessel;

expanding at least part of the engaging element toward the expanded position;

coupling the engaging element to a supply of power;

moving the engaging element into contact with the obstruction; and

supplying power to the element when the engaging element is in contact with the obstruction.

2. A method of constructing an obstruction removing device, comprising the steps of:

providing an elongate element;

positioning at least one strand against the elongate element; and

positioning a tube over the fiber to trap the fiber.

3. An obstruction removal device, comprising:

an insertion element having an expandable element extending from the insertion element;

at least one strand extending along at least the expandable element; and

a tube of material which traps the at least one strand.

4. The device of claim 2, wherein:

the strand has a diameter of less than 0.005 inch.

5. The device of claim 4, wherein:

the strand is a thermoplastic multifilament yarn spun from a liquid crystal polymer.

6. The device of claim 2, wherein:

the elongate element being made of superelastic material.

7. The device of claim 2, wherein:
the elongate element having a diameter of 0.005-0.018 inch.

8. The device of claim 2, wherein:
the elongate element being biased toward an expanded position.

9. The device of claim 2, wherein:
the elongate element has an diameter of 0.005-0.010 inch.

10. A kit for removing an obstruction in a blood vessel, comprising:
an obstruction removing device having an elongate insertion element and an expandable obstruction engaging element extending from the elongate insertion element; and
a catheter having an expandable balloon mounted thereto, the catheter having at least one lumen sized to receive the obstruction removal device.

11. A method of removing an obstruction in a blood vessel, comprising the steps of:
providing an obstruction removal device and a guide catheter, the obstruction removing device having an elongate insertion element and an expandable obstruction engaging element extending from the elongate insertion element, the guide catheter having a flow restricting element mounted thereto, the delivery catheter having at least one lumen sized to receive the obstruction removal device;
advancing the obstruction removal device through the guide catheter to an obstruction in a blood vessel;
expanding the flow restricting element to at least reduce blood flow in the blood vessel;
engaging the obstruction with the obstruction removal device while the flow restricting element is expanded; and
removing the obstruction.

12. An obstruction removal device, comprising:
an elongate element extending from an insertion element, the elongate element being movable from a collapse position to an expanded position, the elongate element

forming helical coils having varying diameter, wherein the coils at a distal portion are larger than the coils at an intermediate portion.

13. The device of claim 12, wherein:

the elongate element has a proximal portion which has coils which are larger than the coils at the intermediate portion.

14. A method of removing an obstruction from a patient, comprising the steps of:

providing an obstruction removal device, the obstruction removal device having an engaging element extending from an insertion element, the engaging element being movable from a collapsed condition to an expanded condition, the engaging element having a proximal portion and a distal portion;

passing the obstruction removal device through an obstruction in a vessel with the engaging element in the collapsed position;

expanding the distal portion at a location distal to the obstruction so that the distal portion forms a trap to prevent the obstruction from traveling downstream; and

engaging the obstruction with the proximal portion of the obstruction removal device after the expanding step.

15. An obstruction removal device, comprising:

an elongate insertion element; and

an obstruction engaging element extending from the insertion element, the obstruction removing element being movable from a collapsed position to an expanded position, the obstruction removing device forming at least one closed loop in the expanded position, the closed loop exerting substantially equal and opposing radial forces when collapsed.

16. The device of claim 15, wherein:

the obstruction engaging element forms at least two loops in the expanded position, a first loop lying in a first plane when expanded and a second loop lying in a second plane when expanded.

17. The device of claim 16, wherein:

the first plane is substantially perpendicular to the first plane.

18. The device of claim 16, wherein:

the first loop is larger than the second loop, the first loop being positioned distal to the second loop.

19. The device of claim 15, wherein:

the engaging element is formed by a core element and a filament wrapped around the core element.

20. An obstruction removal device, comprising:

an elongate insertion element; and

an obstruction engaging element movable from a collapsed position to an expanded condition, the engaging element having at least two wound sections having a filament wound around a core element, the wound sections being separated by a section substantially free of the filament.

21. The device of claim 20, wherein:

the section which is substantially free of the filament is at least 1 mm long.

22. The device of claim 20, wherein:

the section which is substantially free of the filament is at least 3 mm long.

23. The device of claim 20, wherein:

the section which is substantially free of the filament is no more than 6 mm long.

24. An obstruction removing device, comprising:

an elongate insertion element; and

an obstruction engaging element movable from a collapsed position to an expanded condition, the engaging element having a first section, a second section, and a third section, the second section being positioned between the first and third sections, the second section forming coils having a smaller diameter than coils formed by the first and third sections.

25. The device of claim 24, wherein:

the obstruction engaging element has a fourth section and a fifth section, the fourth section being positioned between the third and fifth sections, the fourth section forming coils having a smaller diameter than coils formed by the third and fifth sections.

26. A system for removing an obstruction from a blood vessel, comprising:

a catheter having a lumen;

an expandable capture element which is contained within the lumen of the catheter, the capture element being slidable within the lumen of the catheter between a collapsed position contained within the lumen and an expanded position in which the capture element is positioned outside the lumen; and

an obstruction engaging device having a filament, the filament being movable from a collapsed position to an expanded position, the obstruction engaging element passing through the catheter.

27. The system of claim 26, wherein:

the expandable capture element is naturally biased toward the expanded position when positioned outside the lumen.

28. The system of claim 26, wherein:

the expandable capture element has a support structure with a flexible cover attached to the support structure.

29. The system of claim 28, wherein:

the self-expanding support structure has a closed loop having integrally formed hinges.

30 . The system of claim 29, wherein:

the hinges are V-shaped interconnecting elements.

31 . The system of claim 28, wherein:

the support structure has a plurality of longitudinal struts extending from the loop.

32. The system of claim 26, wherein:

the capture element has an expandable loop at the distal end.

33. The system of claim 32, wherein:
the loop is formed by an eyelet with a control arm extending through the eyelet.

34. The system of claim 26, wherein:
the capture element has a flexible cover, the cover having a length which is at least three times an expanded diameter of the capture element.

35. The system of claim 34, wherein:
the length of the cover is at least five times the expanded diameter of the capture element.

36. The system of claim 26, wherein:
the engaging device has 1-4 filaments.

37. A method of removing an obstruction from a blood vessel comprising the steps of:
providing a catheter, an obstruction engaging device and an expandable capture element, the capture element being contained within a lumen of the catheter in a collapsed position, the capture element moving to an expanded position when positioned outside the lumen, the obstruction engaging device having a filament which is movable from a collapsed position to an expanded position;
introducing the catheter into a blood vessel of a patient;
engaging an obstruction with the filament;
expanding the capture element; and
moving the obstruction into the capture element with the engaging device after the engaging and expanding steps.

38. A system for removing an obstruction from a blood vessel, comprising:
a catheter having a lumen;
an expandable capture element contained within the lumen of the catheter, the capture element being in a collapsed position when contained within the lumen and being in an expanded position when positioned outside the lumen, the expandable capture element

having a support structure forming a closed loop having a plurality of integrally formed hinges; and

an obstruction engaging device which extends through the expandable capture element, the engaging device having a collapsed shape and an expanded shape.

39. The system of claim 38, wherein:

the capture element has a flexible cover attached to the support structure, the cover having a distal end which is positioned at the loop so that the loop opens the distal end of the cover.

40. The system of claim 38, wherein:

the support structure has a plurality of longitudinal struts which extend proximally from the loop.

41. The system of claim 40, wherein:

the struts do not intersect and form a form a conical shape when the capture element is in the expanded.

42. The system of claim 38, wherein:

the loop has integrally formed hinges.

43. The system of claim 42, wherein:

the hinges are formed by V-shaped elements.

44. The system of claim 38, wherein:

the obstruction engaging device has a filament configured to penetrate and engage an obstruction.

45. A system for removing an obstruction from a blood vessel, comprising:

a catheter having a lumen;

an expandable capture element which is contained within the lumen of the catheter, the capture element being slidable within the lumen of the catheter, the capture element having an actuator for manually expanding and contracting the capture element; and

an obstruction engaging device which passes through the capture element.

46. The system of claim 45, wherein:

the obstruction engaging devices includes a filament for engaging the obstruction.

47. The system of claim 45, wherein:
the actuator has a control arm and a stable arm, the control arm being manipulated to expand and collapse the capture element.

48. The system of claim 45, wherein:
the actuator has a loop and a control arm which is manipulated to open and close the loop.

49. The system of claim 45, wherein:
the capture element everts when moving outside the lumen.

50. The system of claim 45, wherein:
the actuator includes a tube and a wire extending through the tube.

51. The system of claim 45, wherein:
the actuator includes at least two wires.

52. The system of claim 51, wherein:
the actuator includes first and second stabilizing wires and at least one actuating wire.

53. A catheter for capturing an obstruction, comprising:
a catheter having a lumen;
a capture element positioned in the lumen of the catheter, the capture element being expandable, the capture element having an expandable support structure and a cover attached to the support structure, the cover having a length which is at least three times a diameter of the support structure in the expanded position.

54. The catheter of claim 53, wherein:
the cover has a length which is at least five times a diameter of the support structure in the expanded position.

55. A device for removing an obstruction from a blood vessel, comprising:

an expandable loop which is movable from a collapsed position to an expanded position;

a cover coupled to the loop, the distal end of the cover being moving from a closed position to an open position when the loop moves from the collapsed to expanded positions; and

a tube having an actuator extending therethrough, the actuator being coupled to the loop so that relative movement between the tube and the actuator causes the loop to move between the expanded and collapsed positions.

56. The device of claim 55, wherein:

the tube is positioned outside the cover.

57. The device of claim 55, further comprising:

a catheter passing through the cover; and

an obstruction engaging device passing through the catheter.

58. A device for removing an obstruction from a blood vessel, comprising:

a tube;

a support structure movable between a collapsed position and an expanded position, the support structure extending through the tube and being naturally biased toward the expanded position, wherein the support structure expands when moved out of the distal end of the tube and is in the collapsed position when contained within the tube, the support structure being bowed outward;

a cover coupled to the structure, the cover moving from a closed position to an open position when the loop moves from the collapsed position to the expanded position.

59. A method of removing an obstruction from a blood vessel, comprising the steps of:

providing a obstruction engaging element having a collapsed position and an expanded position, the obstruction engaging element having at least one filament, the filament being in a substantially straight configuration when collapsed;

advancing the obstruction engaging element through a patient's vascular system to an obstruction with the obstruction engaging element in the collapsed position; and

engaging the obstruction with the obstruction engaging element, the filament engaging the obstruction with a shape which extends from a proximal end toward a distal end, turns back toward the proximal end and again turns back and extends toward the distal end.

60. A device for removing an obstruction from a blood vessel, comprising:

a delivery element having a lumen; and

an obstruction engaging element positioned in the lumen, the obstruction engaging element having a filament which has a collapsed position and an expanded position, the filament being in a substantially straight configuration when collapsed within the lumen of the delivery element, the filament being movable to a shape which extends from a proximal end toward a distal end, turns back toward the proximal end and again turns back and extends toward the distal end.

61. The device of claim 60, wherein:

the filament is naturally biased into the shape.

62. The device of claim 60, wherein:

the distal end of the filament is a free end and the obstruction engaging element has only one filament.

63. The device of claim 60, wherein:

the obstruction engaging element forms the shape by manipulating the obstruction engaging element.

64. The device of claim 63, wherein:

the obstruction engaging element is rotated to form the shape.

65. The device of claim 64, wherein:

the obstruction engaging element is rotated so that coils prolapse over other coils.

66. A method of removing an obstruction from a blood vessel, comprising the steps of:

providing a obstruction engaging element having a collapsed position and an expanded position, the obstruction engaging element having at least one filament which is coated with fibrin;

advancing the obstruction engaging element through a patient's vascular system to an obstruction with the obstruction engaging element in the collapsed position;

positioning the obstruction engaging element to engage the obstruction; and

removing the obstruction with the obstruction engaging element.

67. A device for removing an obstruction from a blood vessel, comprising:

a delivery element having a lumen; and

a obstruction engaging element having a collapsed position and an expanded position, the obstruction engaging element having at least one filament which is coated with fibrin, the obstruction engaging element being contained within the lumen of the delivery element.

68. The device of claim 67,

the obstruction engaging element is in a substantially straightened configuration when collapsed.

69. The device of claim 67, wherein:

the obstruction engaging element has a filament.

70. The device of claim 67, wherein:

the obstruction engaging element has only one filament which extends to a free end.

71. A method of removing an obstruction from a blood vessel, comprising the steps of:

providing a capture element and an obstruction engaging element;

moving the obstruction with the obstruction engaging element into the capture element, wherein the capture element has an inverting portion which inverts when the obstruction is moved into the capture element; and

removing the obstruction from the patient.

72. A device for removing an obstruction from a blood vessel, comprising:

a capture element having an inverting portion which inverts to capture an obstruction, the inverting portion inverting upon application of a compressive force to the inverting portion.

73. The device of claim 72, further comprising:
an obstruction engaging element extending through the capture element.

74. The device of claim 72, wherein:
the obstruction engaging element has a filament which is manipulated to ensnare the obstruction.

75. The device of claim 72, wherein:
the filament extends through the capture element.

76 . The device of claim 72, wherein:
the obstruction engaging element is movable relative to the capture element.

77. The device of claim 76, wherein:
the obstruction engaging element is movable relative to the capture element to invert the capture element.

78. The device of claim 76, wherein:
the obstruction engaging element is coupled to the capture element.

79. The device of claim 78, wherein:
the obstruction engaging element is wound around a central wire with a distal end of the obstruction engaging element attached to the central wire.

80. The device of claim 78, wherein:
the obstruction engaging element is connected to the capture element.

81. The device of claim 78, wherein:
the obstruction engaging element contacts the capture element to invert the capture element.

82. The device of claim 72, wherein:
the inverting portion is a braided structure.

83. A medical device, comprising:

an outer member;

a plurality of fingers extending distally from the outer member, the plurality of fingers forming an end, the end being movable between an open position to a closed position, the plurality of fingers being bent when moving from the open position to the closed position.

84. The medical device of claim 83, further comprising:

an inner member positioned in the outer member;

the plurality of fingers being moved between the open and closed positions by relative movement of the inner and outer members.

85. The medical device of claim 83, wherein:

each of the plurality of fingers has a flexible actuator attached thereto, wherein the actuator is manipulated to move the fingers between the open and closed positions.

86. The medical device of claim 83, further comprising:

a sheath positioned to cover at least one of an inner and outer surface of the frame.

87. The medical device of claim 83, further comprising:

an obstruction engaging element extending through the outer member.

88. The medical device of claim 39, wherein:

the fingers are independent from one another and extend independently from the outer member

89. A medical device, comprising:

an outer member;

an inner member positioned within the outer member;

a frame extending distally from the inner and outer members, the frame having an end which is movable from an open position to a closed position, the frame having a first set of connectors coupled to the outer member and a second set of connectors coupled to the inner member;

wherein the inner and outer members are movable relative to one another to move the open end between the open and closed positions.

90. The medical device of claim 89, further comprising:
a cover positioned to cover at least one of an inner and outer surface of the frame.

91. The medical device of claim 89, further comprising:
an obstruction engaging element extending through the inner member.

92. The medical device of claim 89, wherein:
the frame is integrally formed.

93. The medical device of claim 89, wherein:
the frame has a ring at the distal end.

94. The medical device of claim 89, wherein:
the ring is formed by v-shaped elements.

95. The medical device of claim 89, wherein:
the first set of connectors and second set of connectors are connected to the ring at space-apart locations one after the other.

96. A medical device, comprising:
an outer member;
a frame extending distally from the outer member, the frame having an end which is movable from an open position to a closed position;
wherein the frame moves between the open and closed positions by applying electrical energy to the frame.

97. The medical device of claim 94, further comprising:
a cover positioned to cover at least one of an inner and outer surface of the frame.

98. The medical device of claim 94, further comprising:
an obstruction engaging element extending through the inner member.

99. The medical device of claim 94, wherein:
the frame is integrally formed.

100. The medical device of claim 94, wherein:
the frame comprises a shape-memory material, wherein application of the electrical energy causes the shape-memory material to change shape

101. The medical device of claim 98, wherein:
the frame moves to the closed position upon application of the electrical energy.

102. A method for removing an obstruction from a blood vessel using the devices of claims 83-98.

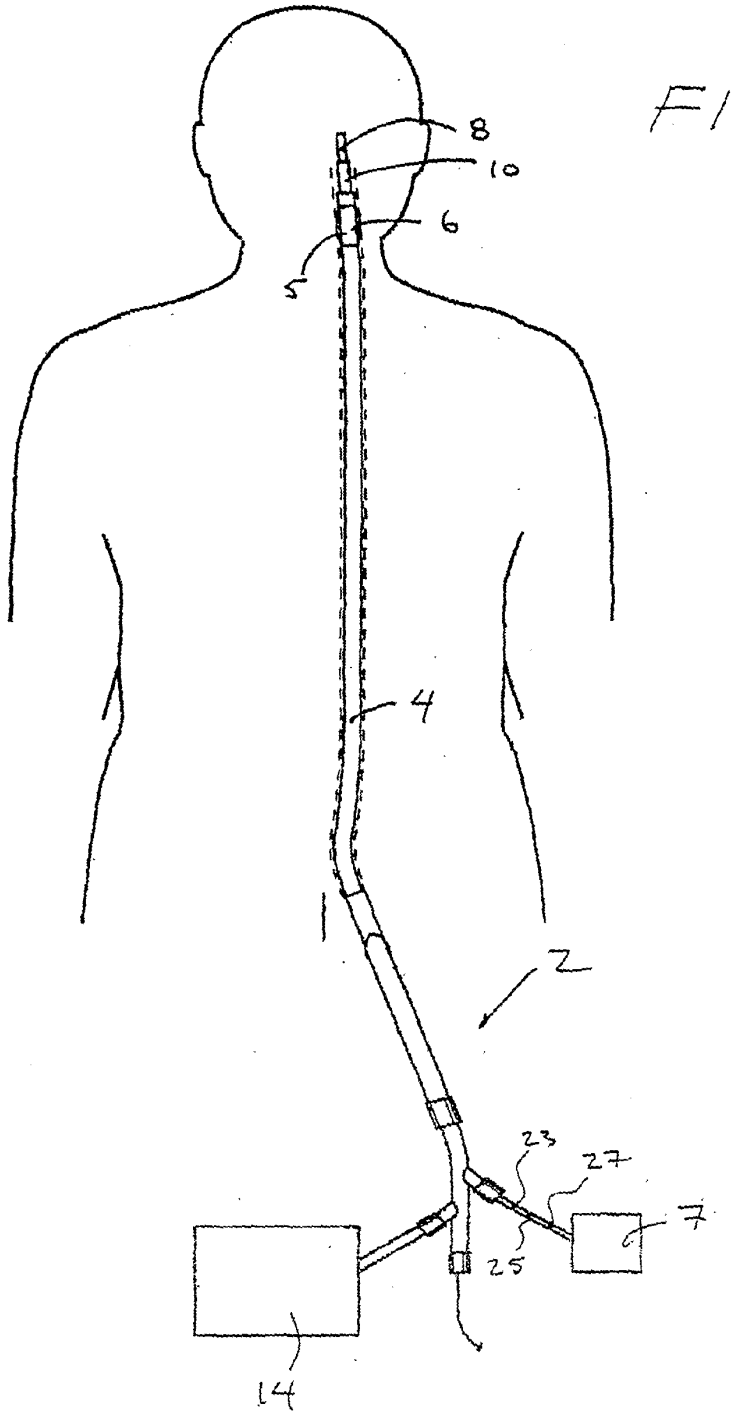


FIG. 1

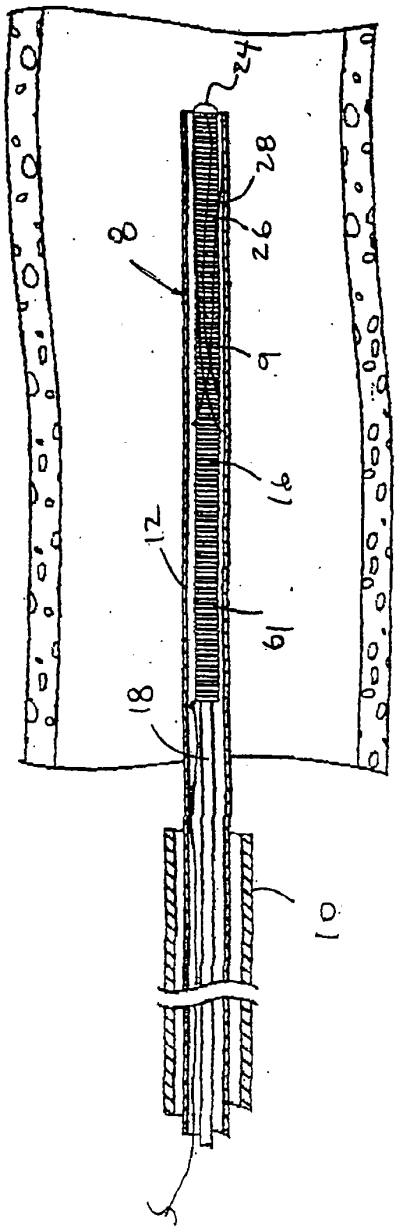


FIG. 2

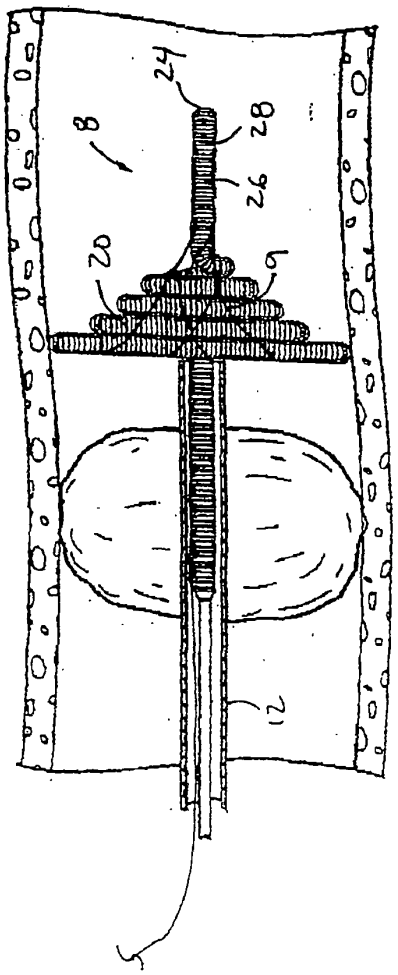


FIG. 3

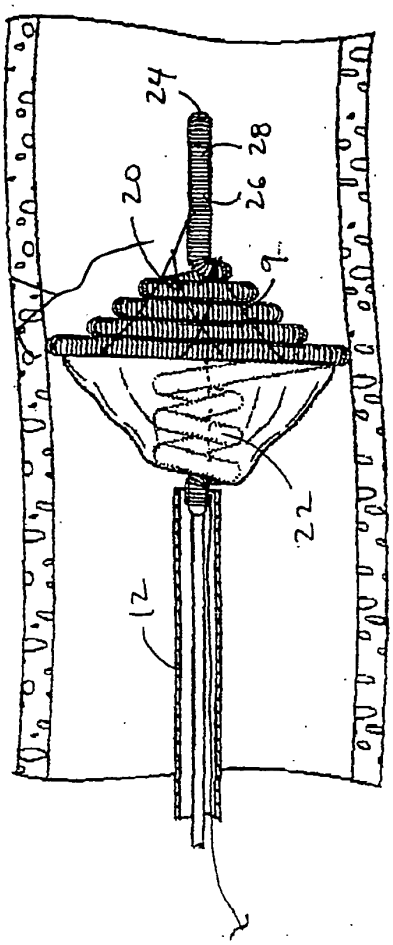


FIG. 4

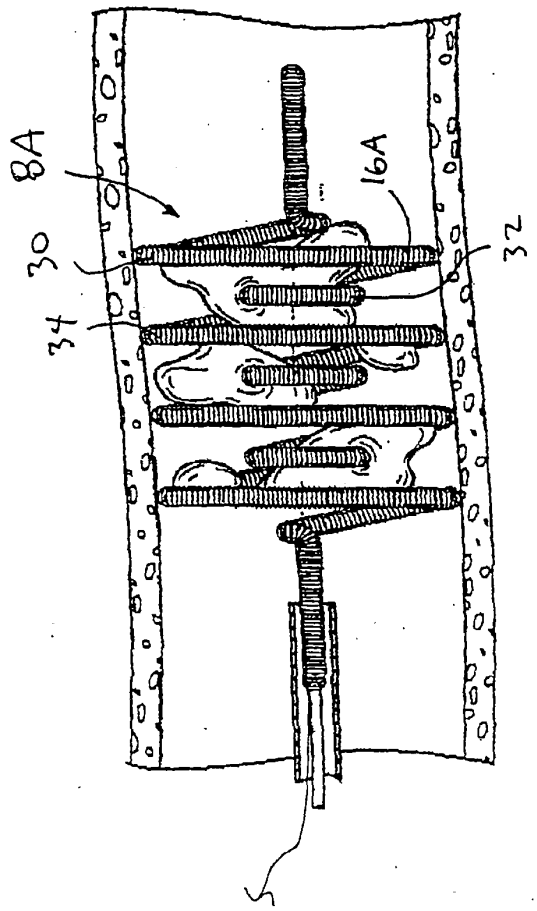


FIG. 5

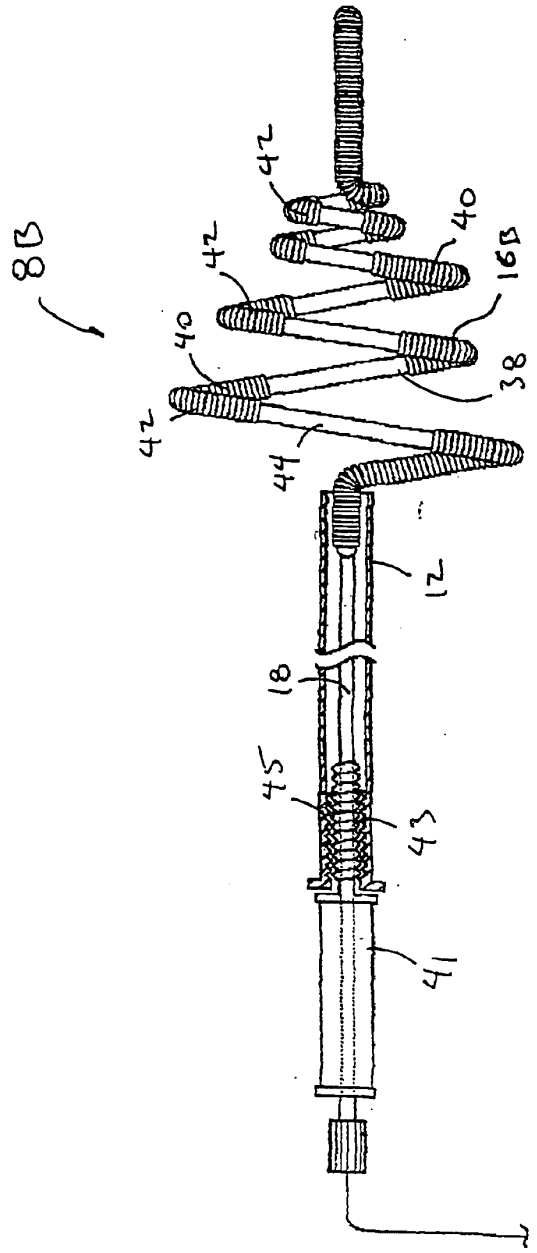


FIG. 6

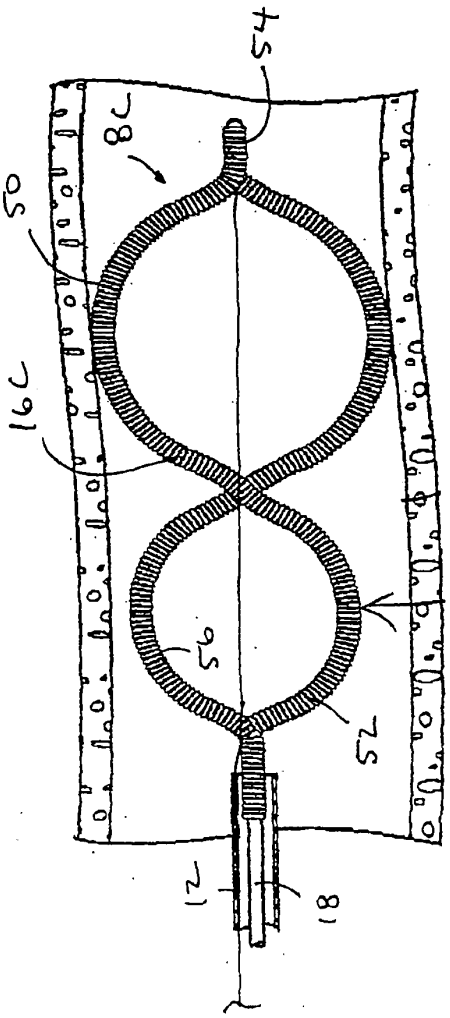


FIG. 7

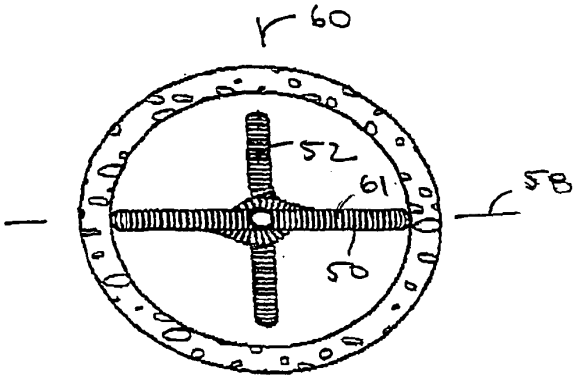


FIG. 8

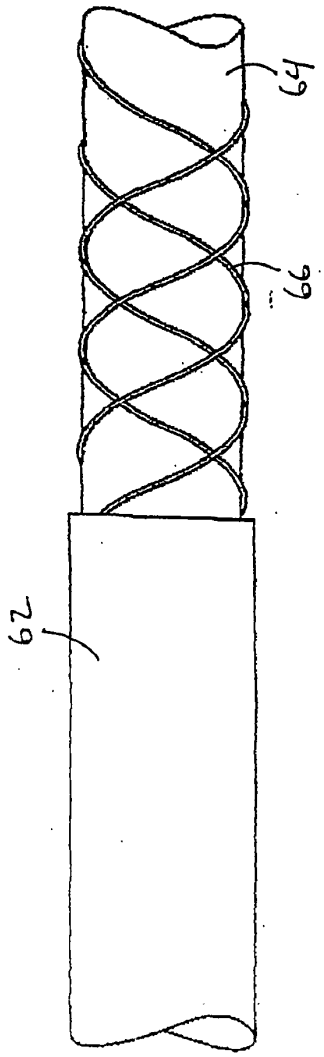


FIG. 9

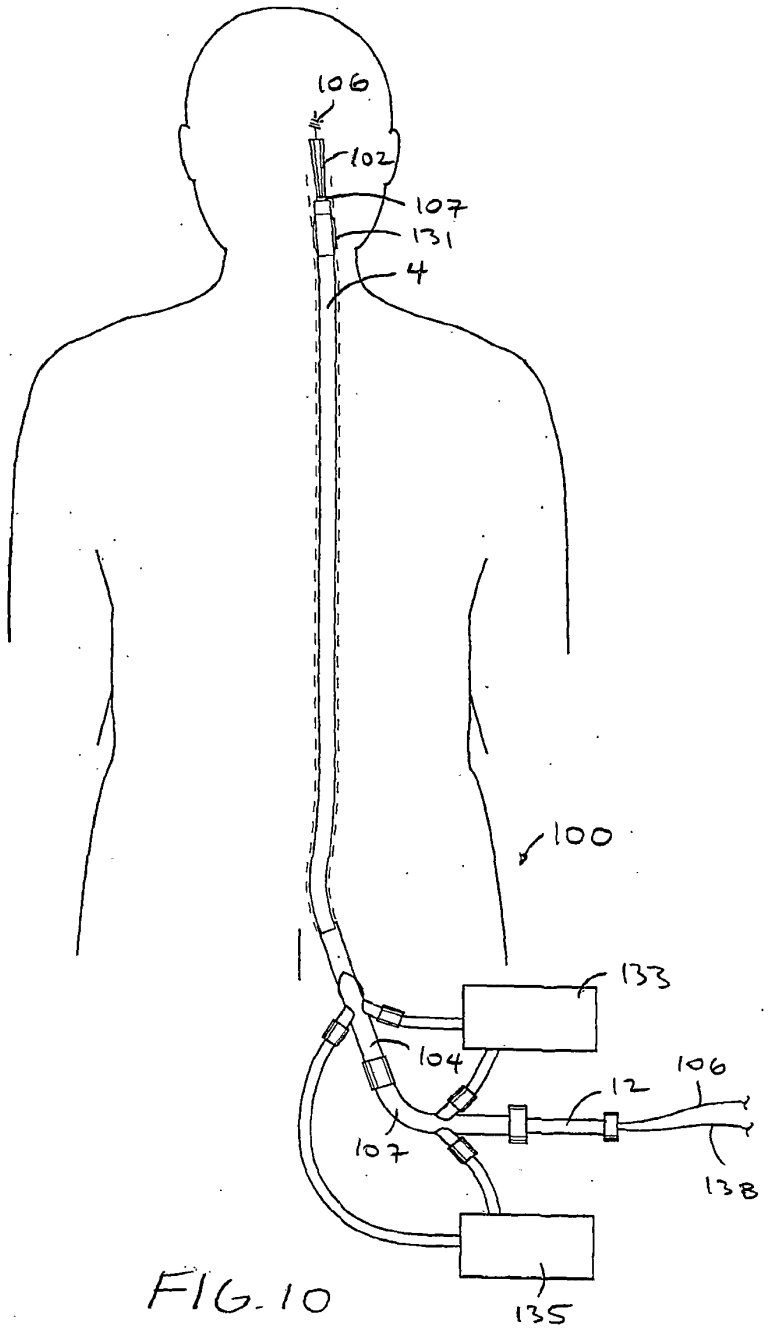


FIG. 10

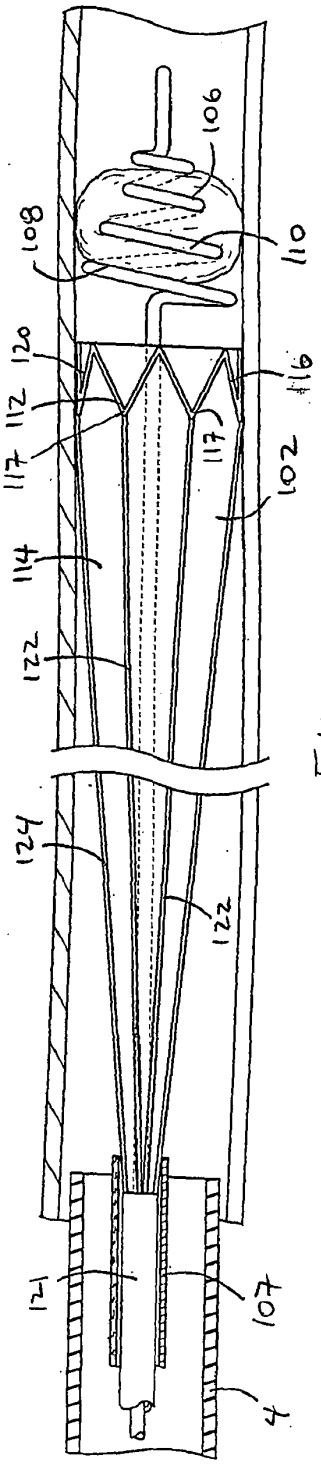

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FIG. 11

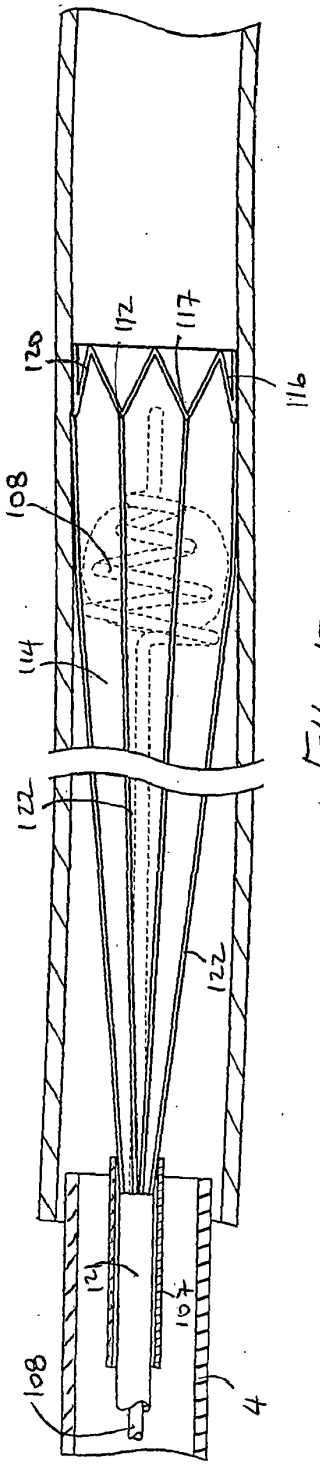

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FIG. 12

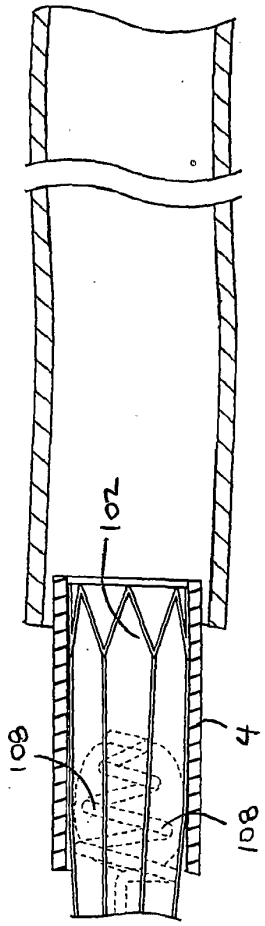


FIG. 13

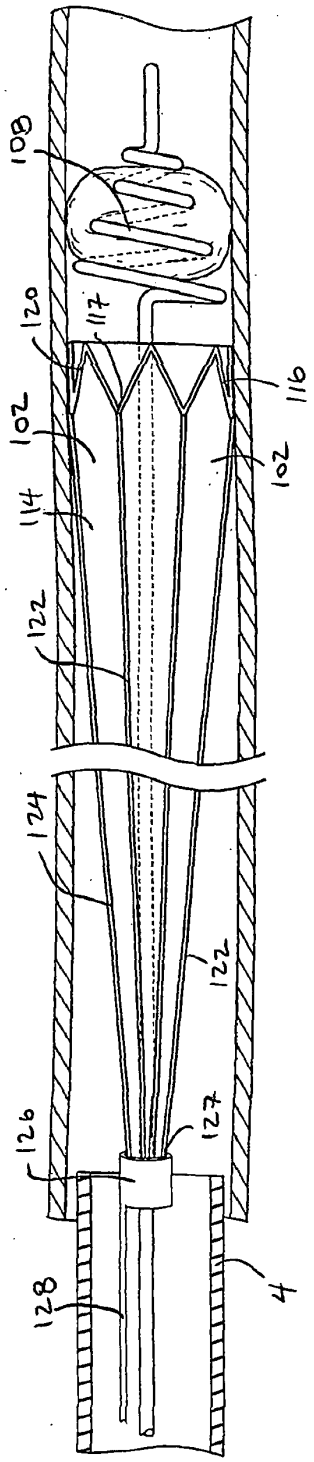


FIG. 14

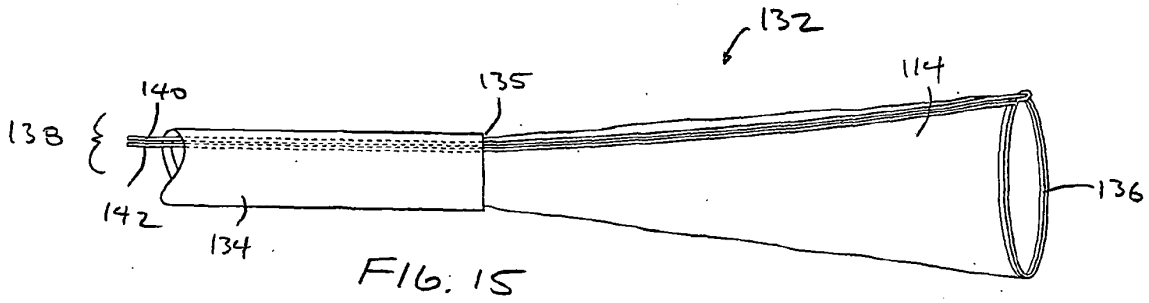


FIG. 15

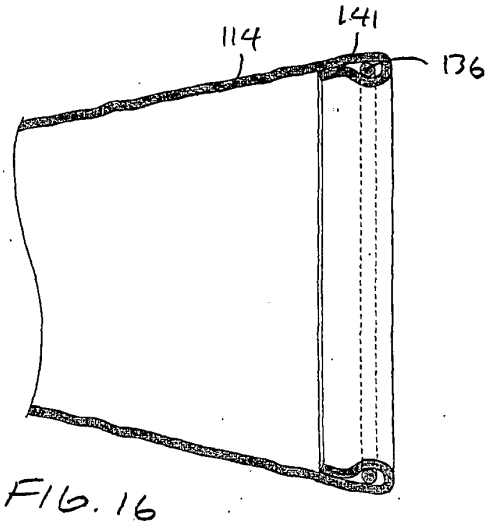


FIG. 16

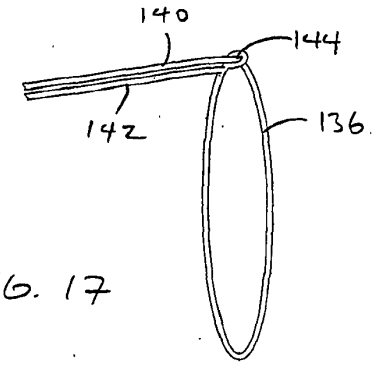


FIG. 17

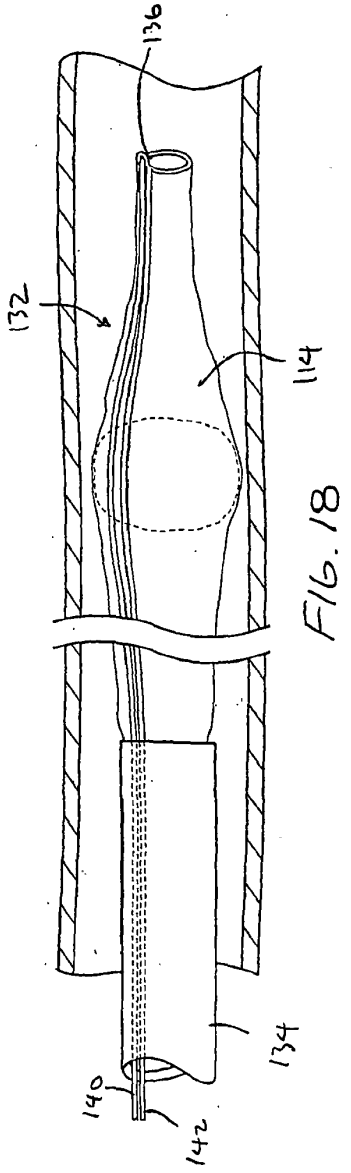


FIG. 18

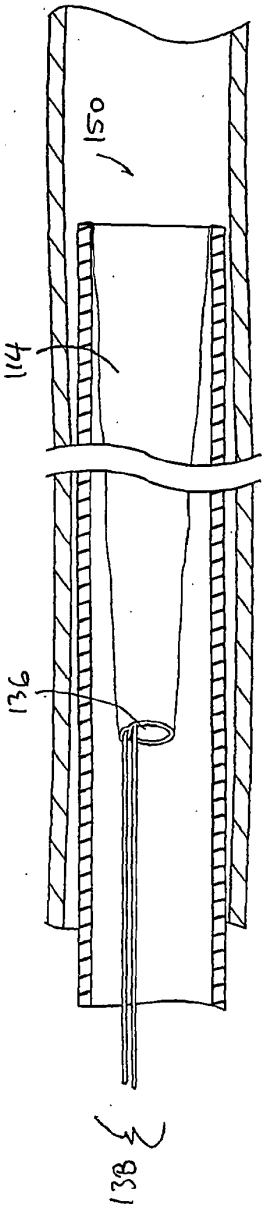


FIG. 19

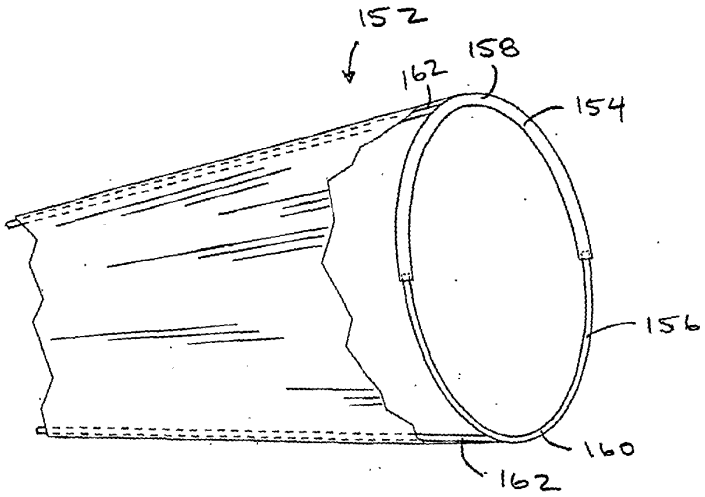


FIG. 20

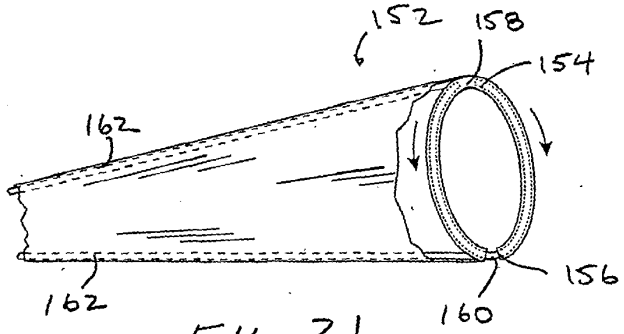


FIG. 21

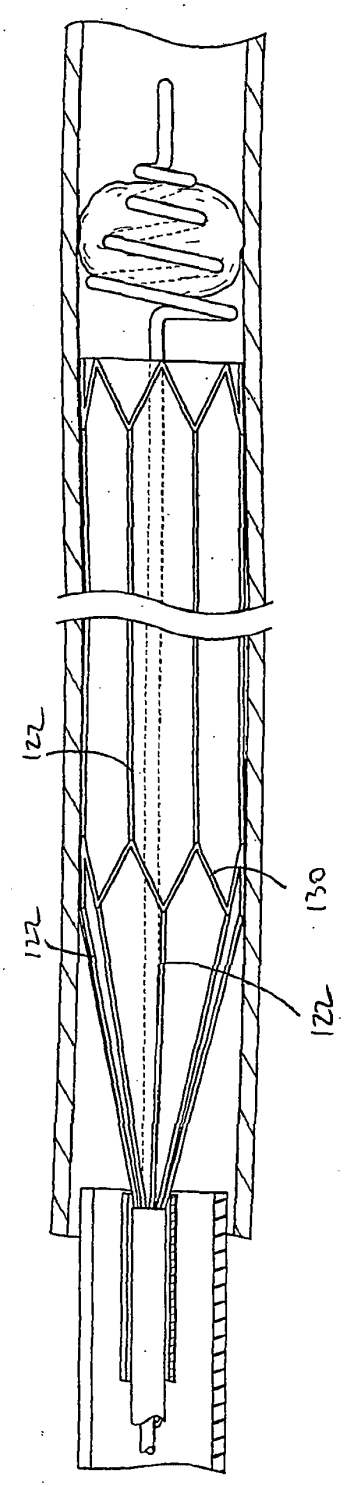


FIG. 22

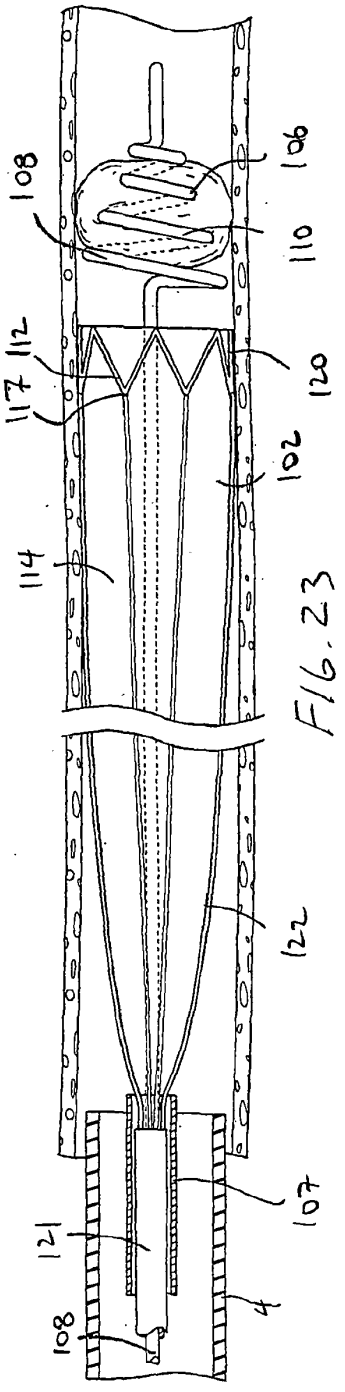

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FIG. 23

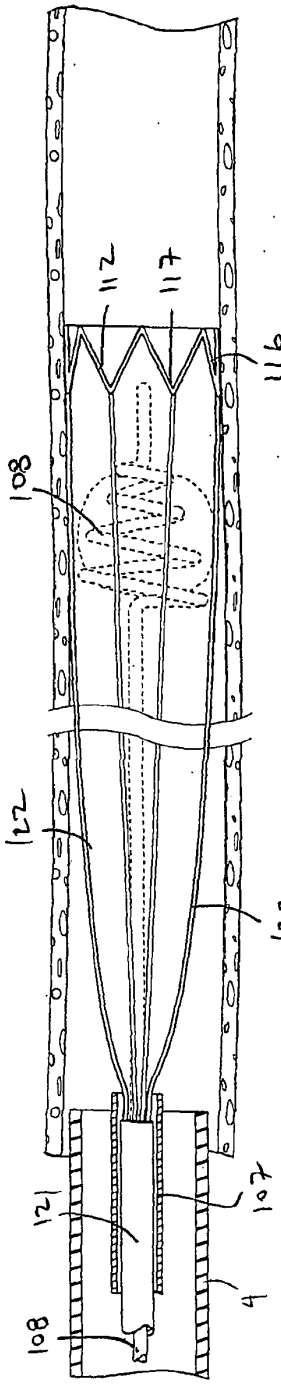

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FIG. 24

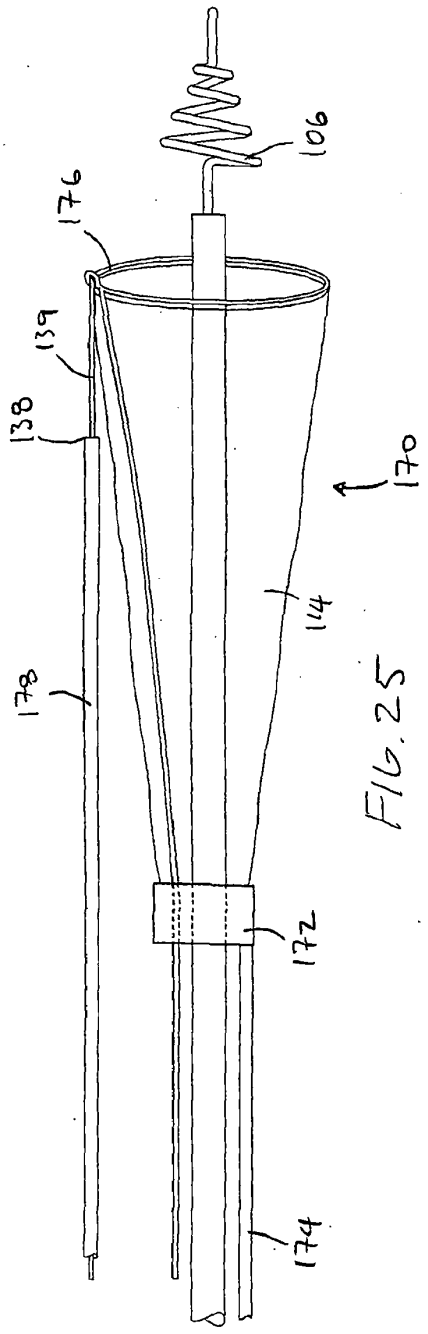


FIG. 25

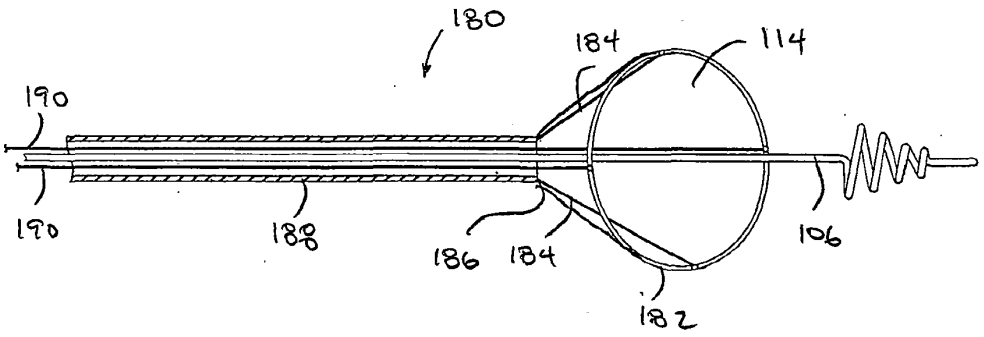

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FIG. 26

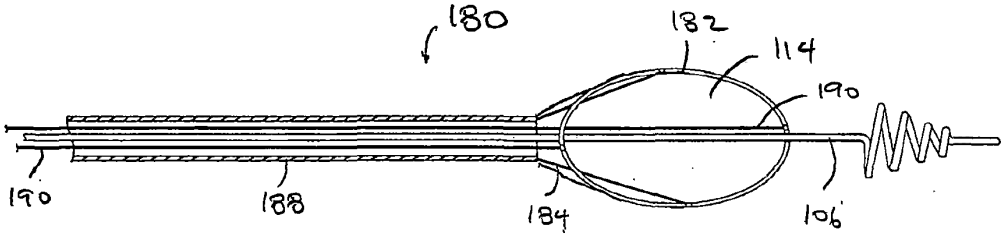

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FIG. 27

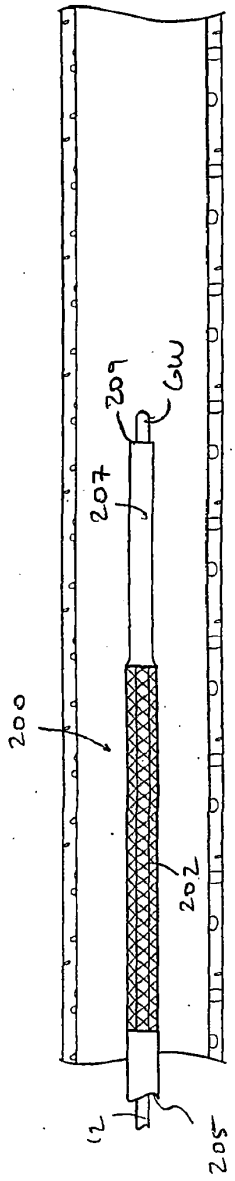


FIG 28

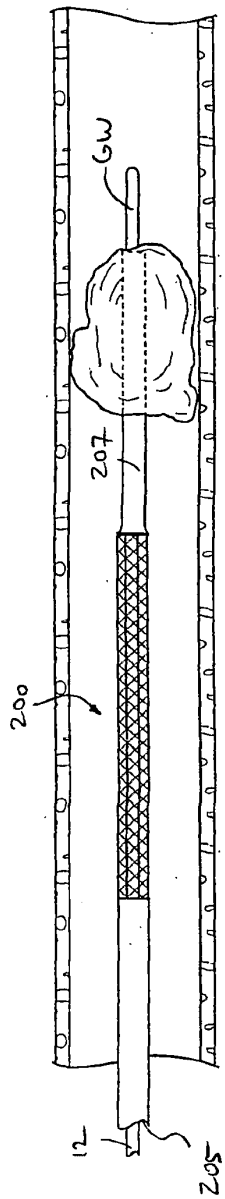


FIG 29

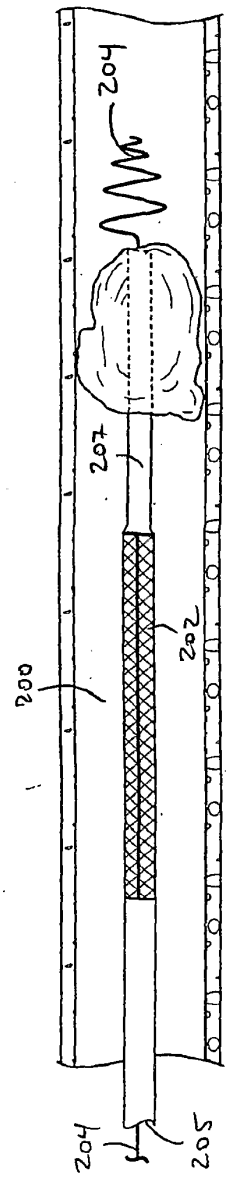


FIG 30

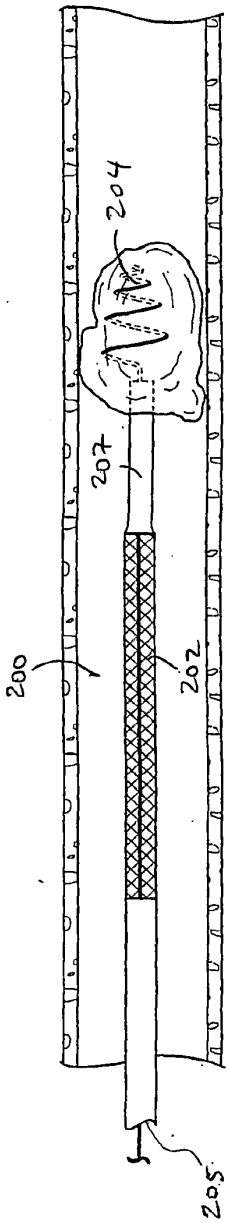


FIG 31

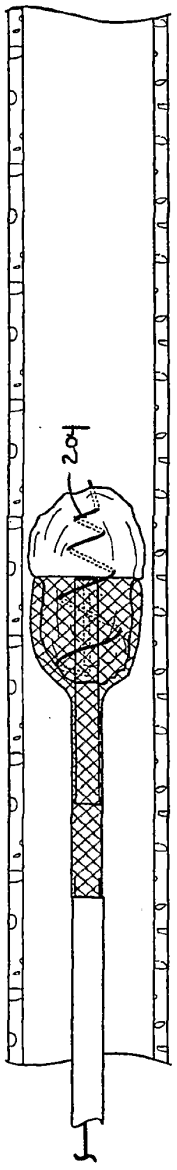


FIG 32

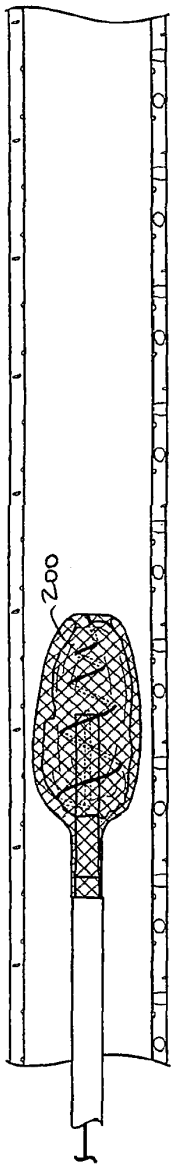


FIG 33

FIG 34

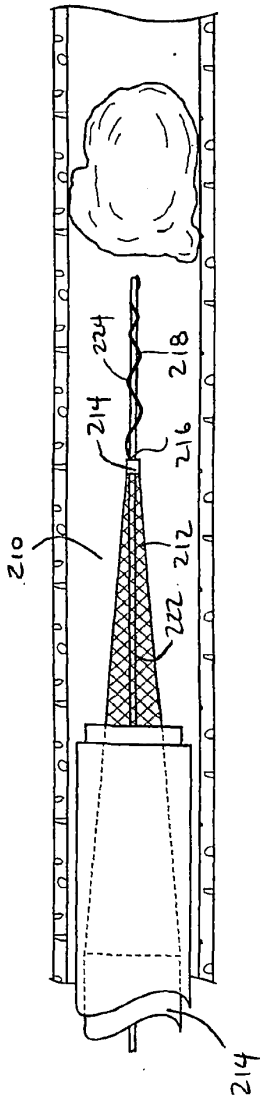


FIG 35

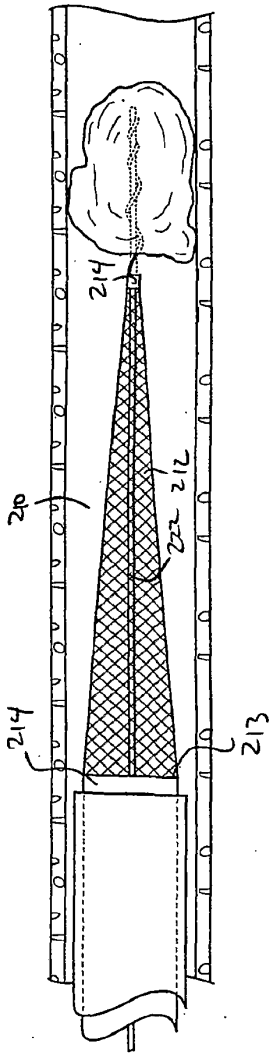


FIG 36

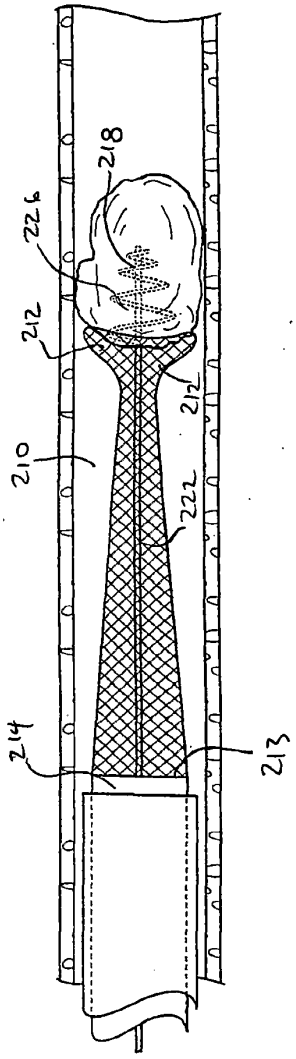


FIG 37

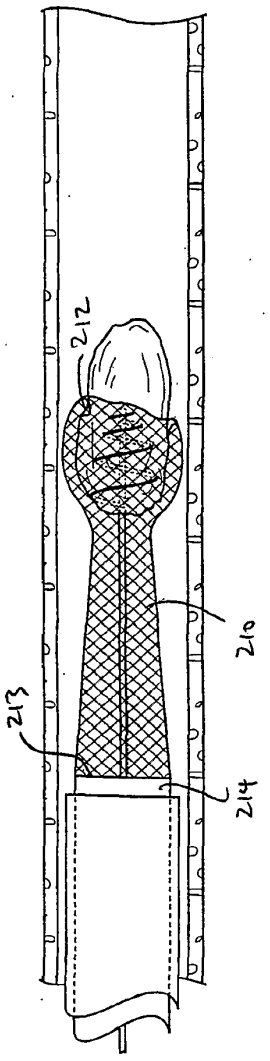


FIG 38A

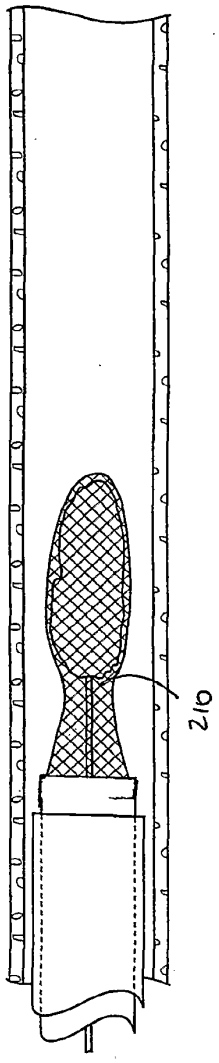
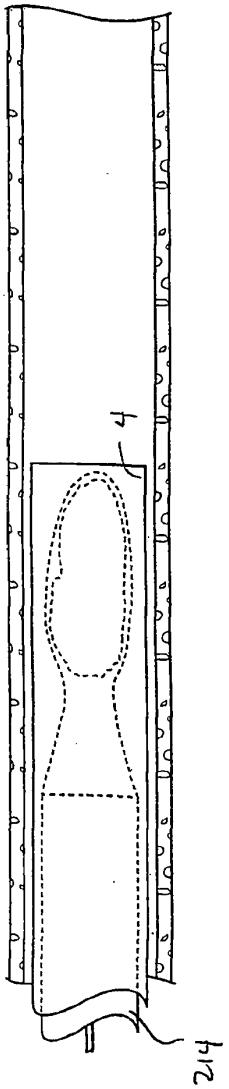


FIG. 38B



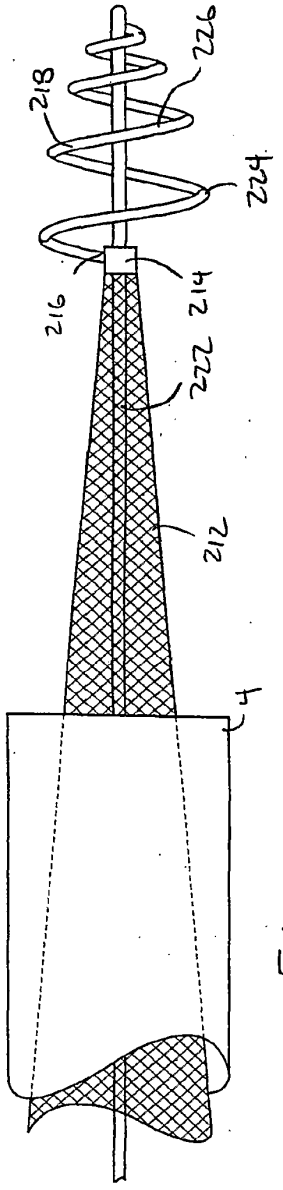


FIG 39

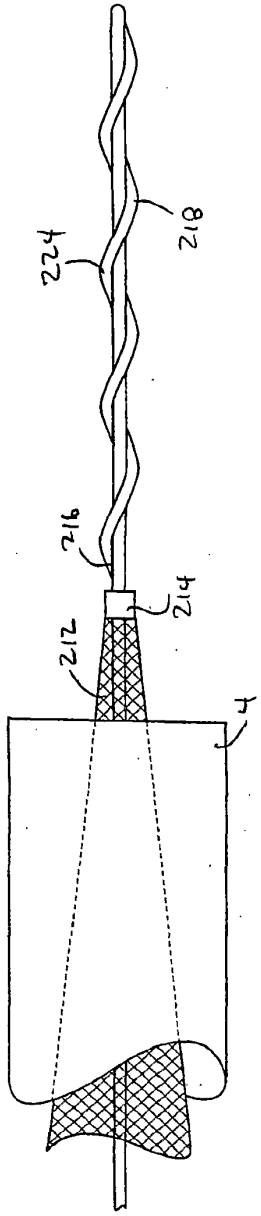


FIG 40

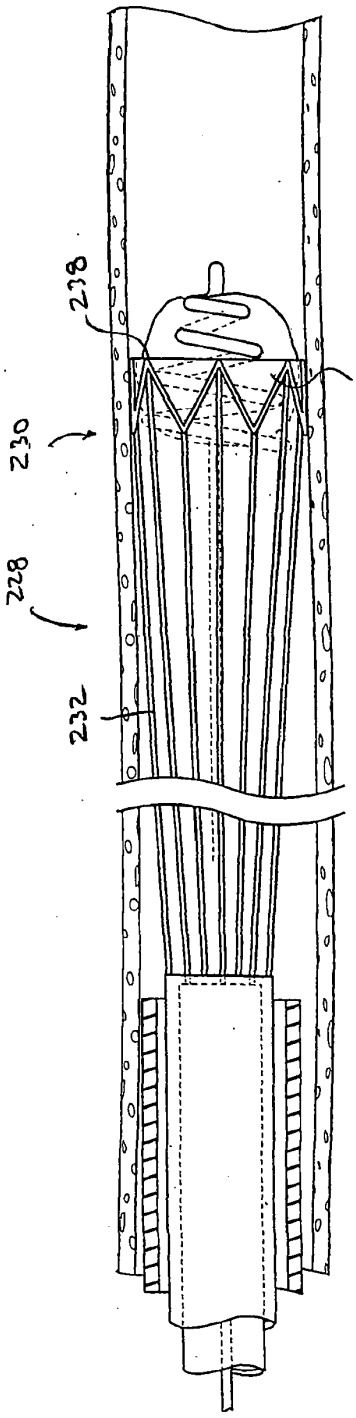


FIG 41A

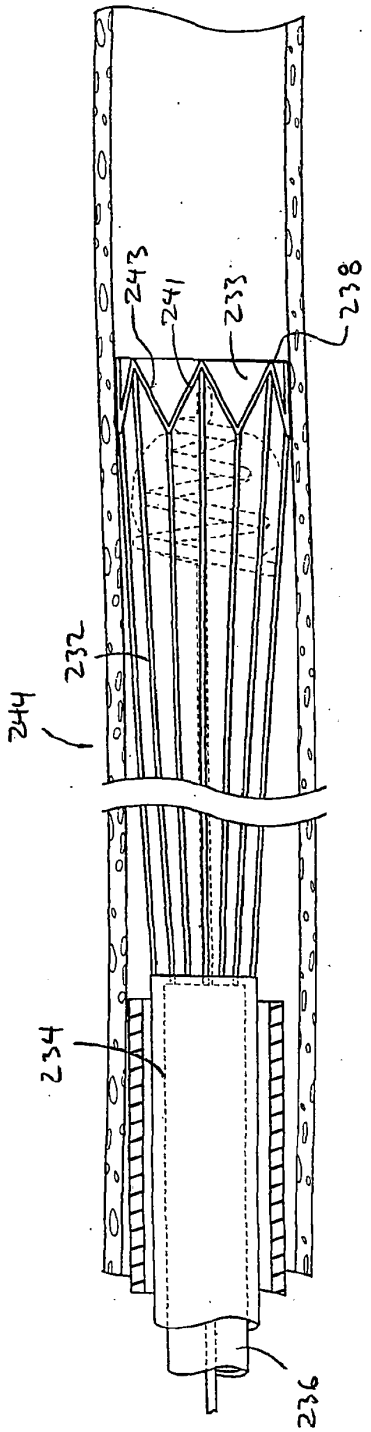


FIG. 41B

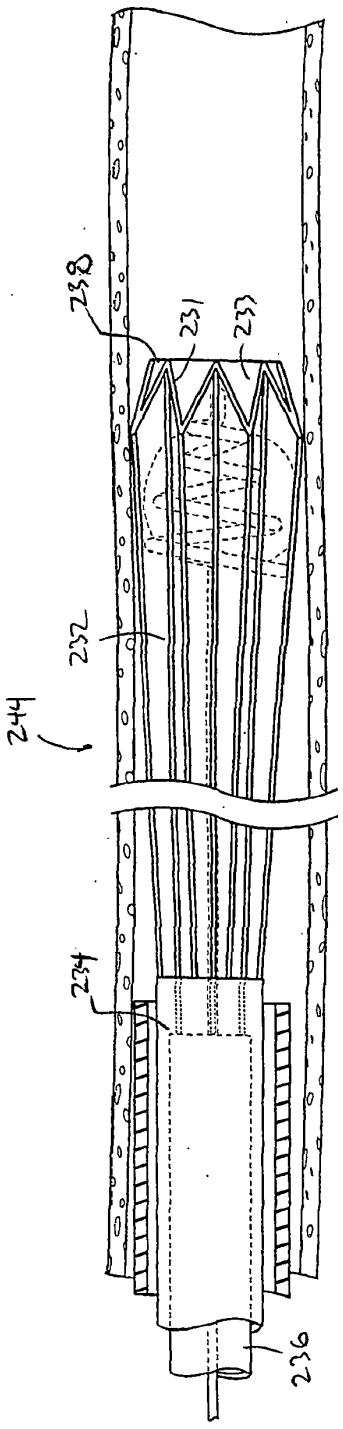


FIG 42A

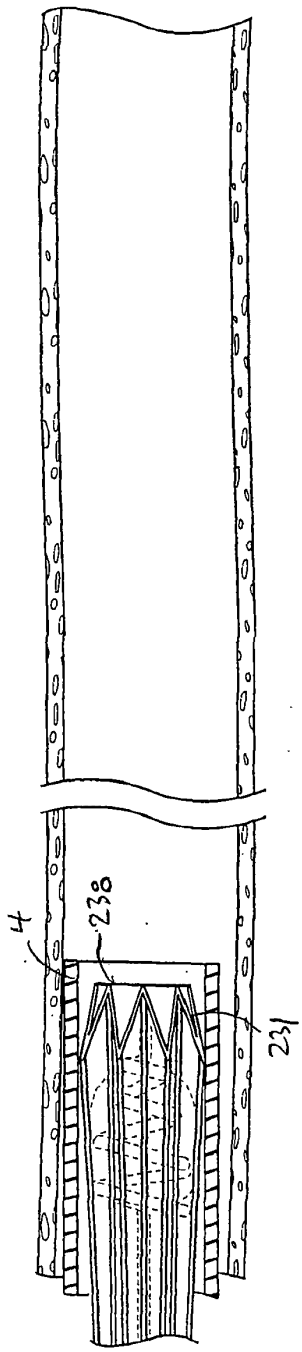


FIG 42B

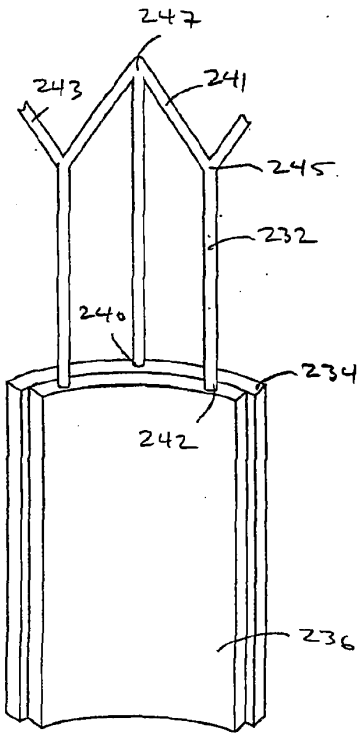


FIG 43A

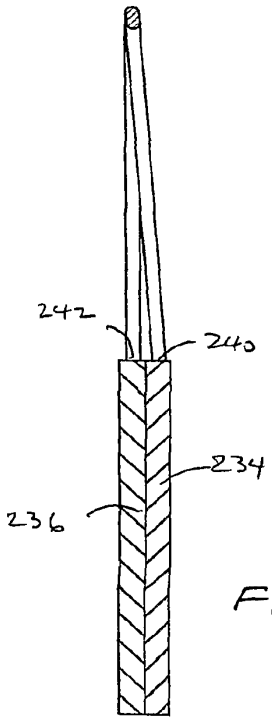


FIG 43C

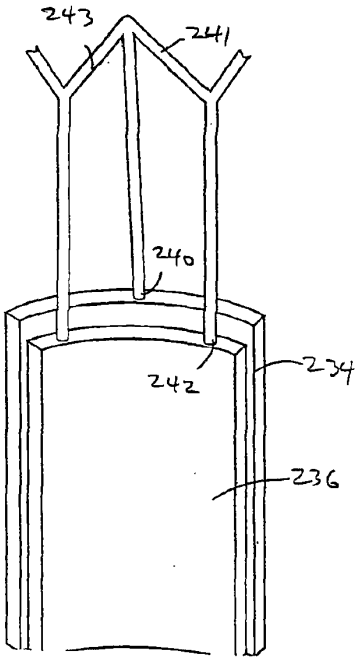


FIG 43B

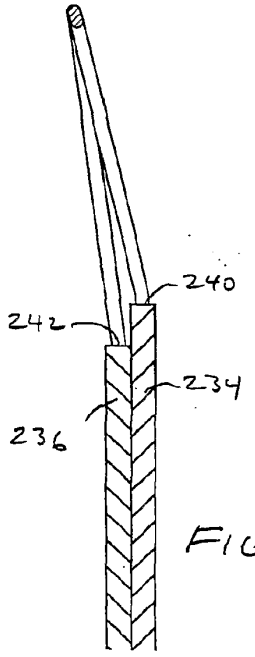


FIG 43D

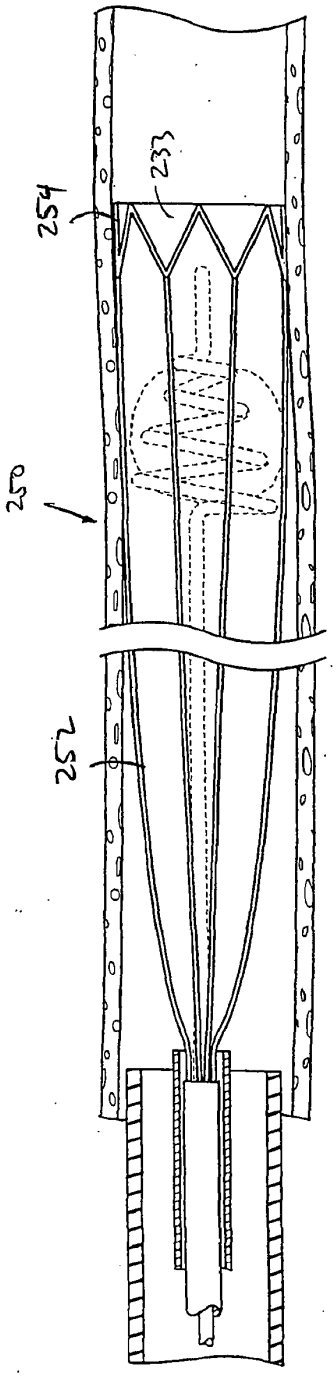


FIG 44

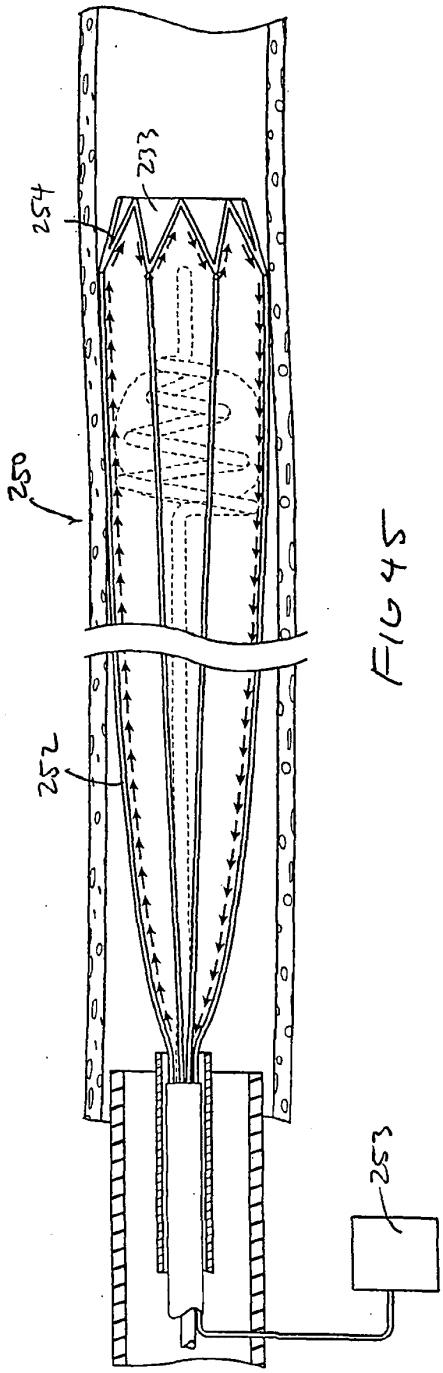


FIG 45

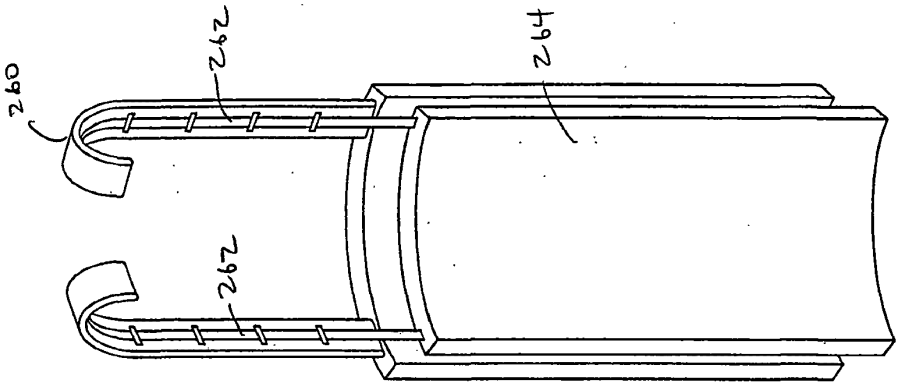


FIG. 47

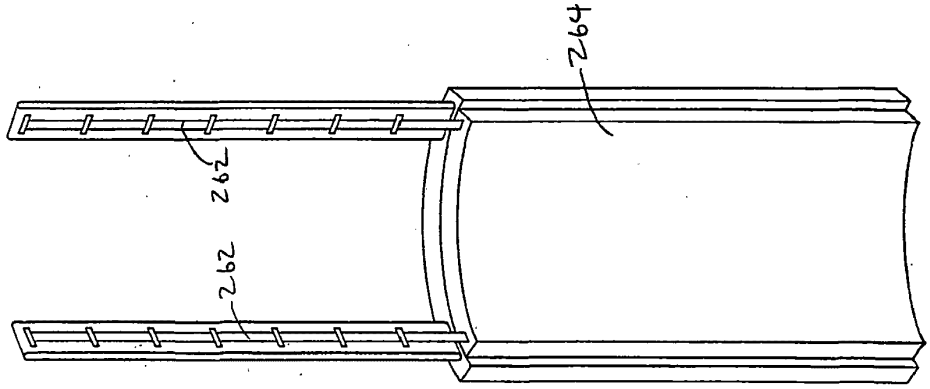


FIG 46

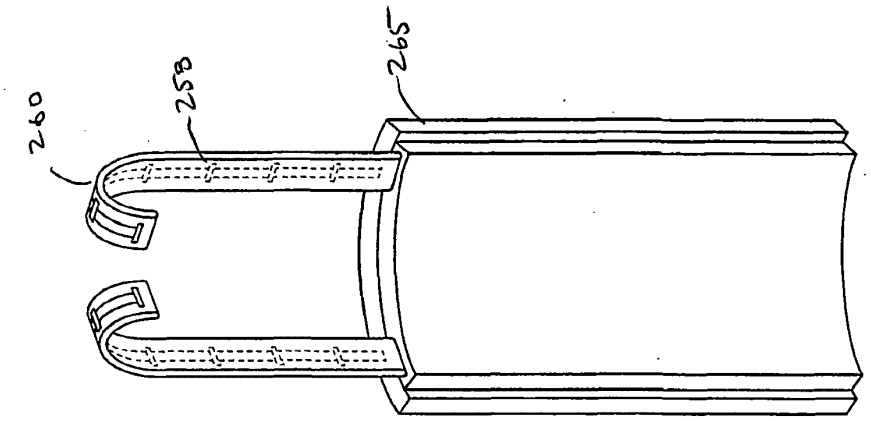


FIG 49

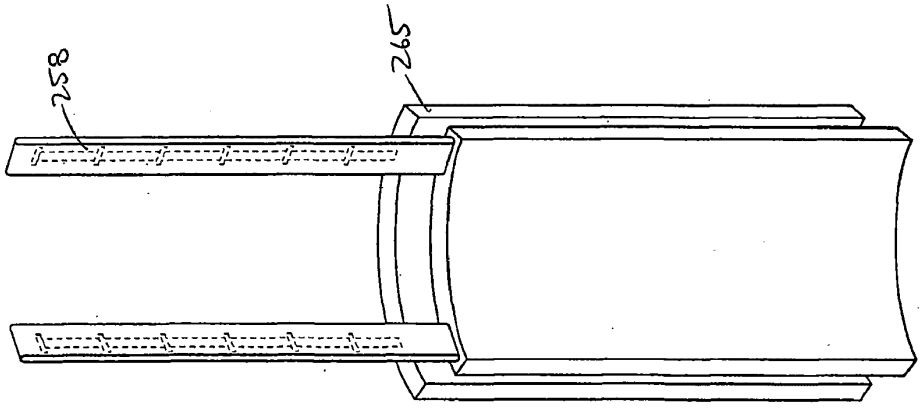


FIG 48

FIG. 50

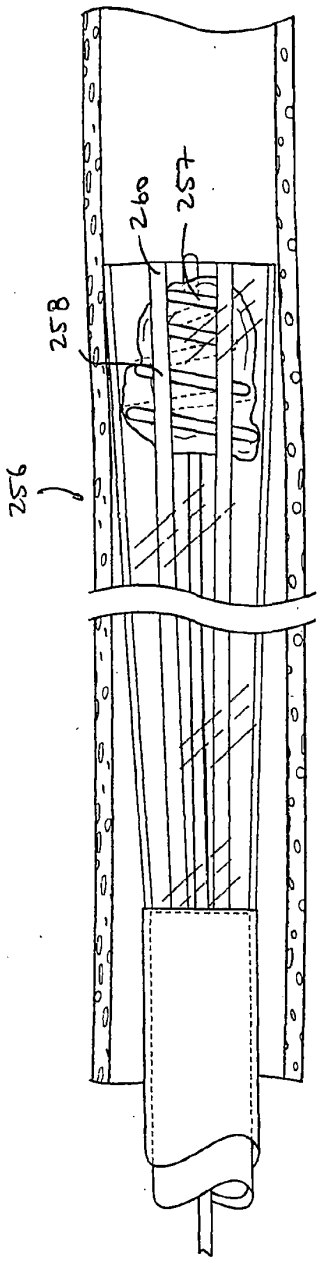


FIG. 51

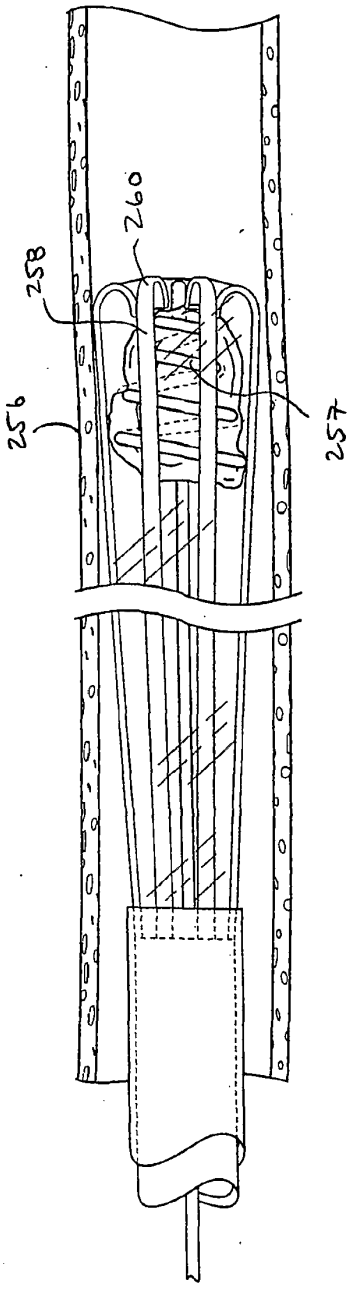


FIG. 52

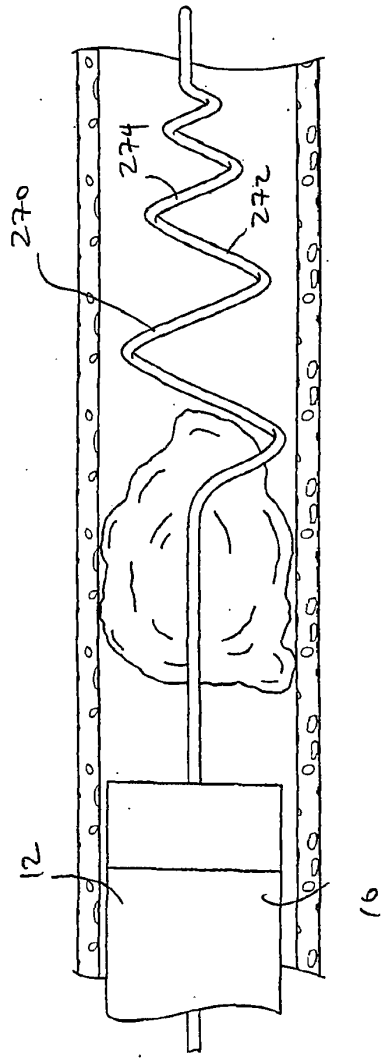


FIG. 53

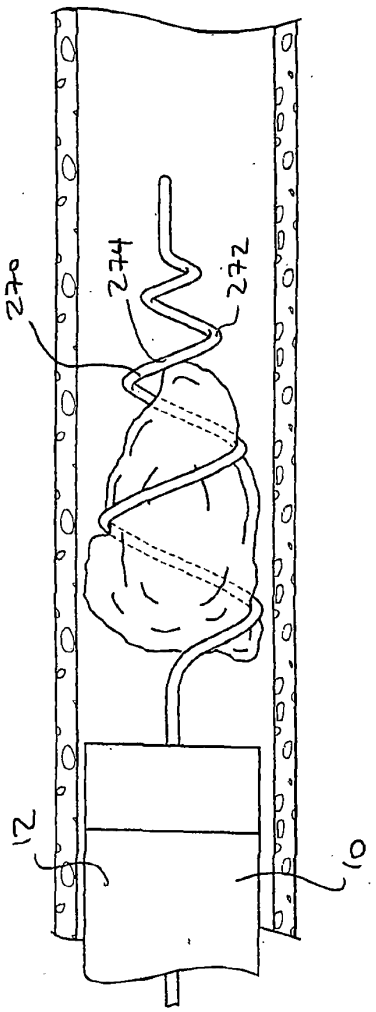


FIG. 54

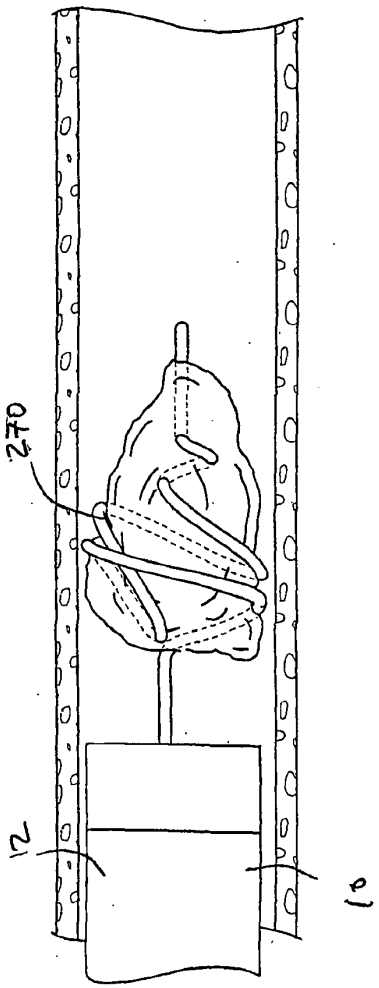
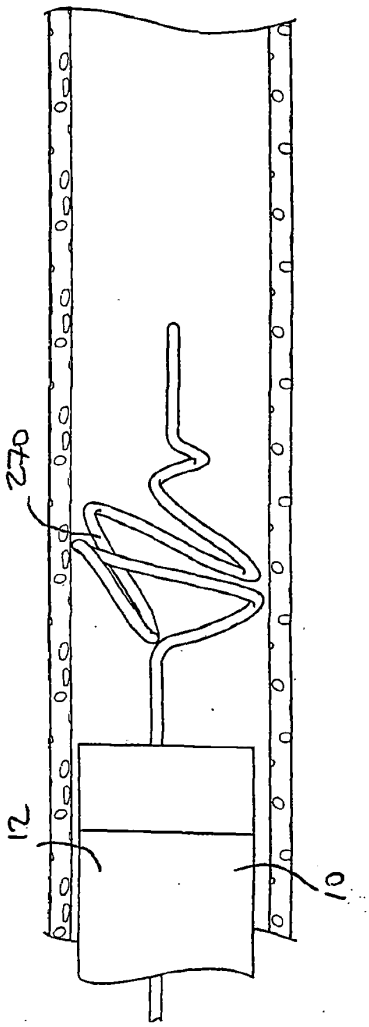


FIG. 55



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GB 2498349 B

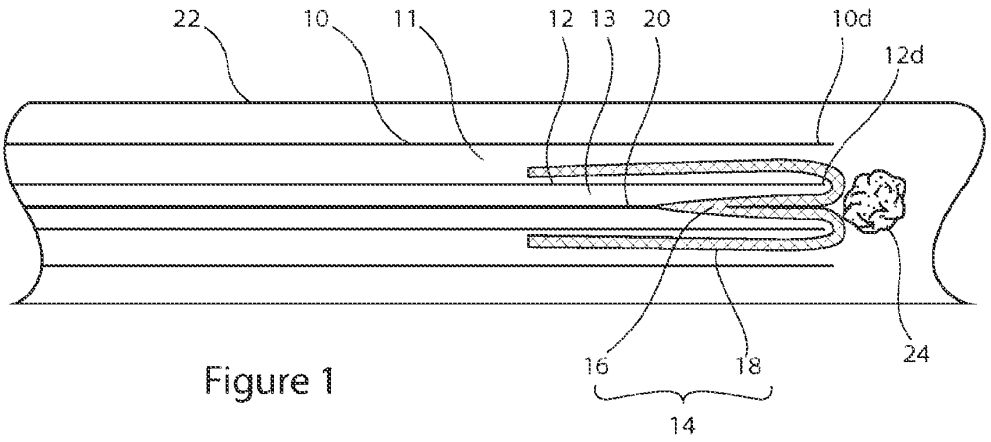


Figure 1

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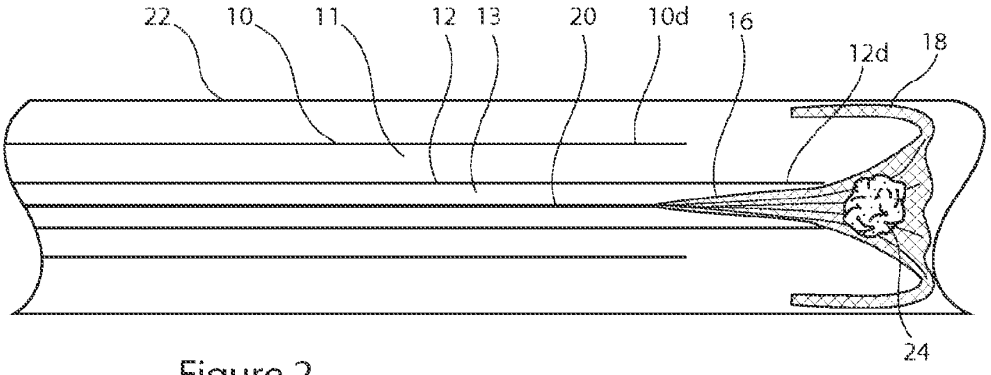


Figure 2

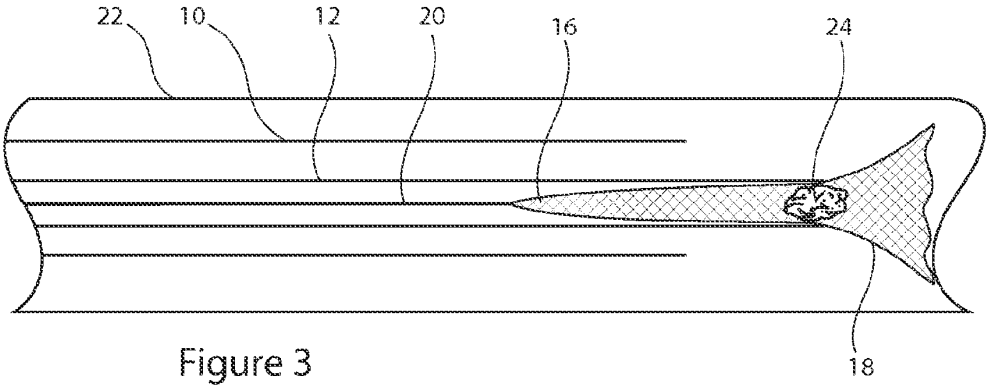


Figure 3

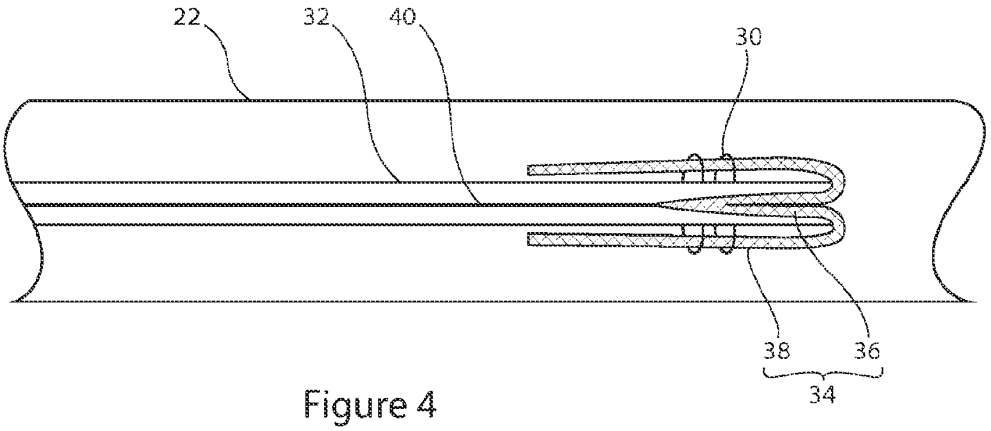


Figure 4

06 02 13

OBJECT CAPTURE DEVICE

Description

Technical Field

The present invention relates to an object capture device as well as to a method of capturing objects from a body lumen, particularly for the capture of thrombi in a patient's vasculature.

Background Art

It is known that material may form or build up in vessels of the circulatory system; such material may seriously compromise the health of the patient. For example, thrombi or blood clots may form and may partially or completely occlude a blood vessel, decreasing or even completely cutting off blood flow through the vessel. The thrombus may adhere to the vessel wall or may be dislodged, becoming free floating in the vessel. A free floating thrombus, also known as an embolus, may travel along a vessel and eventually cause a blockage in a distant part of the body, such as the heart or the brain, with potentially lethal consequences.

Various devices are known for capturing and removing thrombi and other objects from a patient's blood system. Such devices typically involve the use of a plurality of different tools which are deployed in different stages of the capture and removal procedure. For example, a first medical device may be introduced to break the thrombus into pieces so as to prevent it from blocking a vessel. However, breaking the thrombus into pieces can be harmful to the patient as dislodged parts may travel through the circulatory system and eventually block another vessel elsewhere. In order to avoid this, blocking and/or suction means are required to ensure that the dislodged parts are safely collected. For example, a filter may be positioned distal of the thrombus so as to catch the dislodged parts after the thrombus has been broken up by the first medical device. The material trapped by the filter can remain in place until removed using yet further apparatus

such as an aspirator. Various prior art thrombus capturing devices are disclosed in US2010/0249815, US 7,621,870, US 2007/0149996 and US 7,780,696.

Disclosure of the Invention

The present invention seeks to provide an improved object capture device and method, particularly for removing objects such as thrombi from a patient's vasculature.

The preferred embodiment provides a single tool for capturing and removing thrombi. This tool can be used in a single stage, thus facilitating the medical procedure quickly and easily. There is also disclosed a method for capturing and removing thrombi. In particular the invention provides a mechanism for pulling a thrombus away from a vessel wall. The device comprises an object collecting member, hereinafter referred to as a basket.

According to an aspect of the present invention there is provided a medical device for collecting objects from a body vessel, including: a catheter provided with a proximal end, a distal end and a lumen therethrough; an elongate basket provided with a closed first end and an open second end; and an actuator connected to the closed first end of the basket and extending through the lumen of the catheter to the proximal end of the catheter; wherein the catheter and the basket are movable relative to one another between a first configuration in which the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over the first end of the basket, and a second configuration in which the first end of the basket is withdrawn into the catheter and the everted second end is at least partially inverted; and wherein, the medical device is operable so as to relatively move the catheter and the basket from said first configuration to said second configuration, said movement in use causing objects in a body vessel to be drawn into the basket.

The second end may be constrained in the first position and free from attachment or constraint in the second position.

The actuator may be, for example, a wire, rod or cable, hereinafter referred to as a wire.

In the second configuration at least part of the second end of the basket may be withdrawn into the catheter.

Also described is a medical device for collecting objects from a body vessel, including: a catheter provided with a proximal end, a distal end and a lumen therethrough; an elongate basket provided with a first end and a second end; and an actuator connected to the first end of the basket and extending through the lumen of the catheter to the proximal end of the catheter; wherein the catheter and the basket are movable relative to one another between a first configuration in which the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over the first end of the basket, the second end being constrained in position, and a second configuration in which the first end is withdrawn into the catheter and the everted second end is at least partially inverted, the second end being free from constraint; and wherein, the medical device is operable so as to release the second end from constraint, and move the catheter and the basket from said first configuration to said second configuration, said movement in use causing objects in a body vessel to be drawn into the basket.

20 06 12

The basket may be provided with a closed first end and an open second end. By providing a basket having a closed first end, the basket is able to pull, as if sucking, an object such as a thrombus into the basket.

Preferably the basket is made of spring steel, or shape memory material such as, for example, Nitinol, hereinafter referred to as shape memory material. Where the remembered shape is a generally tubular basket, on release of the second end of the basket the basket may spring radially outwardly and distally of the catheter to surround a thrombus. By providing a rolling basket which rolls outwardly during its deployment so as to position itself between a thrombus and the vessel wall in which the thrombus lies, the basket may surround

the thrombus such that when the basket is withdrawn into the catheter the thrombus is withdrawn into the basket.

The everted portion of the basket may scrape against the vessel wall thus dragging any plaque or thrombus adhered thereto into the basket as the basket is reverted or inverted by withdrawal of the member into the catheter. As the basket is withdrawn into the catheter a pulling or suction effect is created, pulling an end of the thrombus or other object or material into the basket and pulling the rest of the thrombus through the vessel towards the catheter so that it too can be captured by the basket. The pulling or suction effect may be best achieved when the basket is positioned up against the object in the vessel before pulling the basket into the catheter.

The actuator may be actuatable so as to draw the basket into the catheter and so move the catheter and the basket from said first configuration to said second configuration. The medical device may be operable so as to advance the catheter over the basket and so move the catheter and the basket from said first configuration to said second configuration. The medical device may be operable so as to advance the catheter over the basket and so as to draw the basket into the catheter. Thus the basket may be withdrawn into the catheter and the catheter may be advanced over the basket at the same time. In use the movement between the catheter and the basket may cause objects in a body lumen to be drawn into the basket.

In the second configuration the first end and substantially the whole of the second end of the basket may be withdrawn into the catheter. If the thombus is appropriately sized, the basket containing the thrombus may be withdrawn through the catheter lumen and out of the patient.

The thombus may be broken down in the patient's lumen by a lytic agent, before being removed from the patient. The lytic agent may be delivered to the site of the thrombus through the catheter lumen, or through a lumen external to the catheter, for example though a lumen in an outer sheath.

The basket can, in the first configuration, have a first end inside the catheter and second end everted over the distal end of the catheter. In the first

configuration the second end of the basket may extend radially out of the catheter and be everted over the first end of the basket and over the distal end of the catheter.

The basket may be made from wire or filamentary material. The basket may be made from braided material such as braided wire. The braiding of the basket may be tight. In other words the wires may be packed closely together, such that the spaces between the wires, if any, are small. The wires may be tightly braided so as to prevent bodily fluid such as blood from passing through the basket. For example the basket may be similar to that found in a flow diverter. The basket may have an impermeable covering to prevent fluid from passing through the basket.

The basket may be constructed so as to allow fluid to pass through the closed first end of the basket. For example the basket may comprise apertures through which fluid can pass. However, the closed first end of the basket may prevent captured objects, such as fibres from a thrombus, from passing through.

The basket may be sized so as to collect a substantially entire thrombus or other object or material. Thombi can be very large. As such the second end of the basket may be, for example from approximately 10 mm to 200mm in length.

The medical device may comprise an outer catheter, also known as an outer sheath. The outer sheath may be provided with a proximal and a distal end and a lumen therethrough. The catheter may be disposed within the lumen of the outer catheter, thereby to be configured as an inner catheter. An annular space may be provided between the inner and the outer catheters. Where an outer catheter is provided, the second end of the basket may be located in the annular space between the inner and outer catheters in the first configuration, so as to constrain the second end during delivery.

The inner and outer catheters may be moveable relative to one another so as to release the second end of the basket from between the outer catheter and the inner catheter. The second end of the basket may be free from constraint in the second configuration. The second end of the basket may be free from attachment in both the first and second configurations.

The second end may be attached to the catheter in the first configuration. Such attachment may be with ties. The ties may be releasable using a trigger wire, for example.

Where the basket is made of shape memory material, releasing the second end may allow the basket to assume its memory shape.

Also described is a method of collecting objects from a body vessel, including: providing a medical device comprising a catheter provided with proximal end, a distal end and a lumen therethrough, and an elongate basket provided with a closed first end and an open second end; and an actuator connected to the closed first end of the basket and extending through the lumen of the catheter to the proximal end of the catheter; wherein the catheter and the basket are moveable relative to one another between a first configuration and a second configuration, wherein in the first configuration the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over the first end of the basket, and in the second configuration the first end of the basket is withdrawn into the catheter and the everted second end is at least partially inverted; inserting the medical device into a body vessel; and operating the medical device so as to move the catheter and the basket from said first configuration to said second configuration thereby causing objects in a body vessel to be drawn into the basket.

20 06 12

The method may comprise the step of withdrawing the medical device from the body lumen, the medical device containing objects from the body vessel. In particular the basket may contain objects from the body vessel. The object containing portion of the basket may be contained within the catheter.

Where the medical device comprises an outer sheath, and where the second of the basket is held between the sheath and the inner catheter, the method may comprise the step of withdrawing the outer sheath so as to release the basket. After operating the medical device so as to capture a thrombus or other object or material in the basket, the method may comprise advancing the outer

sheath distally relative to the catheter and basket, such that the outer sheath surrounds an object containing portion of the basket, before removing the device from the patient's lumen. In this case the object containing portion of the basket may be contained within the outer sheath. Where the second end of the basket is held in the first position by ties, for example, the method may comprise the step of releasing the ties so as to release the basket.

The device described may be in the first configuration whilst tracking through the vasculature. On reaching a location proximate to the thrombus or other object, the site of interest, the device may be activated so as to move to the second configuration.

Also described is a method of collecting objects from a body vessel, including: providing a medical device for collecting objects from a body vessel, the medical device including: a catheter provided with a proximal end, a distal end and a lumen therethrough; an elongate basket provided with a first end and a second end; and a wire connected to the basket and extending through the lumen of the catheter to the proximal end of the catheter; wherein the catheter and the basket are movable relative to one another between a first configuration in which the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over the first end of the basket, the second end being constrained in position, and a second configuration in which the first end is withdrawn into the catheter and the second end is at least partially inverted, the second end being free from constraint; inserting the medical device into a body vessel; and operating the medical device so as to release the second end from constraint, and so as to move the catheter and the basket from said first configuration to said second configuration, such that an object in a body vessel is drawn into the basket.

20 06 12

Brief Description of the Drawings

Embodiments of the present invention are described below, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 shows an embodiment of a medical device for collecting objects from a body lumen, the medical device comprising a catheter and a basket arranged in a first configuration;

Figure 2 shows the medical device of Figure 1 after the outer sheath has been withdrawn from around the basket;

Figure 3 shows the medical device of Figures 1 and 2, the catheter and the basket arranged in the second configuration; and

Figure 4 shows another embodiment of a medical device for collecting objects from a body lumen.

Description of the Preferred Embodiments

Referring to Figure 1, there is shown in schematic form an embodiment of a medical device for collecting objects from a body lumen 22. The medical device is shown inside a patient's vessel 22; within which there is also a thrombus 24. The medical device comprises an outer catheter 10 disposed concentrically around an inner catheter 12, and an object collecting member 14, hereafter called a basket 14.

The inner 12 and outer 10 catheters are in the form of elongate tubes having proximal (not shown) and distal 10d,12d ends. In use the distal ends 10d,12d of the catheters are positioned proximate the thrombus or object or material to be removed and the proximal ends are outside of the patient. The outer catheter 10 comprises a lumen in which the inner catheter 12 is disposed. The catheters are arranged such that an annular gap 11 is provided between the inner 12 and outer 10 catheters. The inner catheter 12 also comprises a lumen 13, into which the basket 14 may be withdrawn.

The basket comprises a first end portion 16 and a second end portion 18. The first end portion 16 of the basket 14 is connected to an actuator wire 20. The wire 20 is disposed inside the lumen of the inner catheter 12 and extends through the lumen to an actuating portion of the medical device which in use is external to the patient's body. The first end portion 16 of the basket 14 is, in a first configuration, housed within the lumen of the inner catheter 12. The basket

14 extends, from the first end portion 16, out of the end of the inner catheter 12 and is everted so as to extend backwardly over itself around the inner catheter and inside the outer catheter 10 such that the second end portion 18 of the basket 14 is housed in the annular gap 11 between the inner catheter 12 and the outer catheter 10.

In this case the distal ends of the catheters are aligned with one another and are positioned such that the basket abuts the thrombus 24. The basket surrounds part of the thrombus when it is moved up against the thrombus, giving it a grip on the thrombus and thus aiding withdrawal/pulling of the thrombus into the basket when the device is used.

The basket 14 comprises a braided wire basket made of shape memory material, or of spring steel, for example. Such a basket may be flexible so as to fit around thrombi of various shapes and sizes, and so as to be able to be withdrawn into the narrow lumen of the inner catheter. The braiding of the basket is tight, such that the spaces between the wires, if any, are small. It is not necessary for the basket to allow blood or other fluid to pass through it. The thrombus removal process may be carried out very quickly and as such preventing blood flow through the vessel whilst the procedure is carried out does not harm the patient.

Figure 2 shows the medical device of Figure 1 after the outer catheter 10 has been withdrawn relative to the inner catheter 12. The outer catheter is provided so as to cover the basket and prevent it from springing open during introduction of the device. Once the outer catheter has been withdrawn the second end portion 18 of the basket 14 is no longer constricted and is able to spring open outwardly. The basket opens until it comes into contact with the internal walls of the vessel, scraping along the sides of the lumen so as to surround the thrombus 24. The second end portion 18 of the basket 14 remains everted, backwards over itself, and contacts the sides of the vessel 22.

Figure 3 shows the medical device of Figures 1 and 2 in a second configuration, in which the first end portion 16 of the basket 14 and part of the second end portion 18 are withdrawn into the inner catheter 12 such that the basket 14, and the thrombus 24 inside it, is substantially contained within the

inner lumen 12. The basket 14 can be from 10 to 200mm long, depending on the length and size of the material/thrombus to be captured. The basket 14 is designed to be long enough to trap the entirety of the thrombus. In particular, the everted second portion 18 of the basket 14 is designed to be long enough to trap the entirety of the thrombus. In one mode movement of the basket 14, from the first configuration shown in Figure 1 to the second configuration shown in Figure 3, is actuated by pulling on the actuating element 20. By pulling back on the actuating element 20 the second end portion 18, the open end of the basket, is pulled into the distal end 12d of the inner catheter 12. This action causes the second end portion 18 of the basket to roll inwardly, thus drawing, as if pulling or sucking, the thrombus into the closing basket. The thrombus is thus trapped bit-by-bit in the basket and withdrawn into the inner catheter 12. As a result of the relative movement between the inner catheter 12 and the basket 14 from the first configuration to the second configuration the thrombus 24 is thus drawn into the inner catheter 12, inside the basket 14.

Where the thrombus is small enough to be withdrawn through the lumen of the inner catheter continued retraction of the actuating element 20 allows withdrawal of the basket, in which the thrombus is held, through the lumen 13 of the inner catheter 12. The basket 14 containing the thrombus 24 may thus be completely removed from the patient's vessel through the lumen 13 of the inner catheter 12. As such this embodiment provides a single tool which is used in a single stage to remove the thrombus from a patient's vessel.

Where the thrombus is too large to be pulled into the lumen of the inner catheter, the outer catheter or sheath may be advanced over the thrombus. In this manner the thrombus can be held within the basket and also within the outer catheter so that it can then be removed from the patient.

In some instances, instead of pulling back on the actuator wire 20, the inner catheter 12 may be advanced over the basket 14. This movement from the first configuration to the second configuration will have the same effect of withdrawing the basket 14 into the inner catheter 12.

The apparatus may be operated by advancing the inner catheter 12 over the basket 14 as the actuator wire 20 is basket 14 withdrawn into the catheter 12. A combination of the two movements may be performed together so that as the basket 14 is withdrawn in the catheter 12 the catheter is also advanced over the basket.

Figure 4 shows another embodiment of a medical device for collecting objects from a body vessel. The medical device comprises an inner catheter 32, and a basket 34 having first 36 and second 38 end portions.

In this device ties 30 are provided to secure the second end portion 38 of the basket 34 in its everted position around the outside of the inner catheter 32. In this embodiment the outer catheter is not required to secure the basket 34 in its first configuration. Trigger wires (not shown) may be used to release the ties 30 so as to enable the basket to open outwardly as a result of its shape memory characteristics, and to be withdrawn into the inner catheter 32. An outer catheter (not shown) may be provided for use in delivery of the medical device to a location adjacent a thrombus inside a vessel.

It is to be understood that the different features of the various embodiments described herein can be combined together; as such the features described in the dependent claims may be combined with the embodiments described in each of the independent claims.

20 06 12

CLAIMS

1. A medical device for collecting objects from a body vessel, including:

a catheter provided with a proximal end, a distal end and a lumen therethrough;

an elongate basket provided with a closed first end and an open second end; and

an actuator connected to the closed first end of the basket and extending through the lumen of the catheter to the proximal end of the catheter;

wherein the catheter and the basket are movable relative to one another between a first configuration in which the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over at least part of the first end of the basket, and a second configuration in which the first end is withdrawn into the catheter and the everted second end is at least partially inverted; and

wherein, the medical device is operable so as to move the catheter and the basket from said first configuration to said second configuration, said movement in use causing objects in a body vessel to be drawn into the basket.

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2. A medical device according to claim 1, wherein the basket is made of shape memory material.

3. A medical device according to claim 1, wherein the basket is made of wire or filamentary material.

4. A medical device according to claim 3, wherein the basket is made of braided wire or filamentary material.

5. A medical device according to claim 4, wherein the wire or filamentary material is tightly braided so as to prevent fluid from passing through the basket.

6. A medical device according to claim 5, wherein the basket has an impermeable covering.

7. A medical device according to claim 1, wherein the actuator is a wire.

8. A medical device according to claim 1, wherein the basket comprises apertures sized to allow fluid to pass through the closed first end of the basket but prevent the captured objects from passing therethrough.

9. A medical device according to claim 1, wherein the actuator is actuatable so as to draw the basket into the catheter and so move the catheter and the basket from said first configuration to said second configuration.

20 06 12

10. A medical device according to claim 1 wherein, the medical device is operable so as to advance the catheter over the basket and so move the catheter and the basket from said first configuration to said second configuration.

11. A medical device according to claim 1, wherein in the second configuration the first end and substantially the whole of the second end of the basket may be withdrawn into the catheter.

12. A medical device according to claim 1 wherein the basket is from 10 to 200mm in length.

13. A medical device according to claim 1 wherein the second end is constrained in the first position and free from constraint in the second position.

14. A medical device according to claim 1 comprising an outer sheath provided with a proximal and a distal end and a lumen therethrough, wherein the catheter is disposed within the lumen of the outer sheath, thereby to be configured as an inner catheter, an annular space being provided between the inner catheter and the outer

sheath, and wherein in said first configuration the second end of the basket is located in the annular space between the inner catheter and outer sheath.

15. A medical device according to claim 14 wherein the second end of the basket is free from attachment and wherein the inner catheter and outer sheath are moveable relative to one another so as to release the second end of the basket from between the outer sheath and the inner catheter.

16. A medical device according to claim 13 wherein, the medical device is operable so as to release the second end from constraint.

17. A medical device according to claim 16, wherein the basket is made of shape memory material, said material having a memory shape, and wherein releasing the second end portion allows the basket to assume its memory shape.

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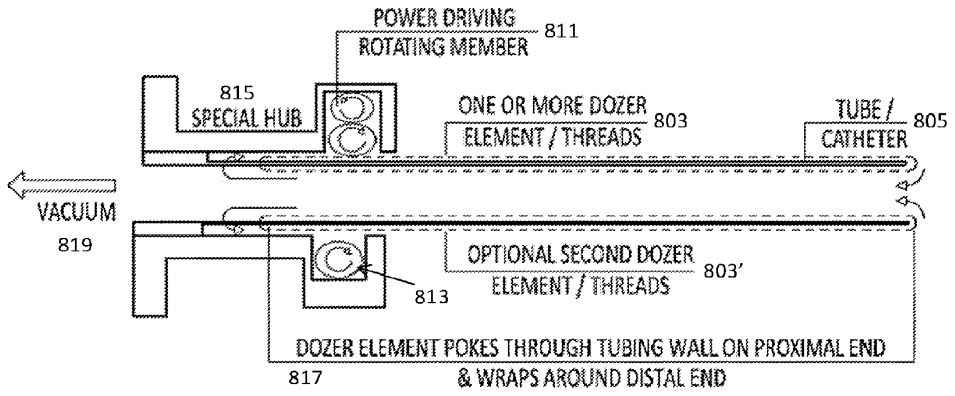


FIG. 8A

(57) Abstract: Mechanical thrombectomy apparatuses (devices, systems, etc.) are configured for being positioned within a vessel and used to remove a thrombus, e.g., clot, from within a vessel. One such system includes an inverting tractor thrombectomy apparatus having a tractor comprising a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support by extending the tractor region and/or a puller coupled to the tractor distally beyond the end of the catheter.

WO 2017/189591 A1

INVERTING MECHANICAL THROMBECTOMY APPARATUSES AND METHODS OF USE IN THE VASCULATURE

FIELD

[0001] The apparatuses and methods described herein relate to inverting mechanical thrombectomy apparatuses and methods of their use.

BACKGROUND

[0002] It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue from within a vasculature, such as blood clots, may improve patient conditions and quality of life.

[0003] Many vascular system problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery.

[0004] When a thrombus forms, it may effectively stop the flow of blood through the zone of formation. If the thrombus extends across the interior diameter of an artery, it may cut off the flow of blood through the artery. If one of the coronary arteries is 100% thrombosed, the flow of blood is stopped in that artery, resulting in a shortage of oxygen carrying red blood cells, e.g., to supply the muscle (myocardium) of the heart wall. Such a thrombosis is unnecessary to prevent loss of blood but can be undesirably triggered within an artery by damage to the arterial wall from atherosclerotic disease. Thus, the underlying disease of atherosclerosis may not cause acute oxygen deficiency (ischemia) but can trigger acute ischemia via induced thrombosis. Similarly, thrombosis of one of the carotid arteries can lead to stroke because of insufficient oxygen supply to vital nerve centers in the cranium. Oxygen deficiency reduces or prohibits muscular activity, can cause chest pain (angina pectoris), and can lead to death of myocardium which permanently disables the heart to some extent. If the myocardial cell death is extensive, the heart will be unable to pump sufficient blood to supply the body's life sustaining needs. The extent of ischemia is affected by many factors, including the existence of collateral blood vessels and flow which can provide the necessary oxygen.

[0005] Clinical data indicates that clot removal may be beneficial or even necessary to improve outcomes. For example, in the peripheral vasculature, inventions and procedures can reduce the need for an amputation by 80 percent. The ultimate goal of any modality to treat these conditions of the arterial or venous system is to remove the blockage or restore patency, quickly, safely, and cost effectively. This may be achieved by thrombus dissolution, fragmentation, thrombus aspiration or a combination of these methods.

[0006] Mechanical thrombectomy devices may be particularly advantageous. Depending on the size, location and extent of a clot, it may also be particularly advantageous to mechanical retrieve and break apart the clot in a manner that is both safe and effective. There is a definite need for a thrombectomy device, and particularly a mechanical thrombectomy device that can be more effective in removing tissue such as clots from within a body. Described herein are apparatuses (devices, systems and kit) and methods of using them that may address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[0007] Described herein are mechanical thrombectomy apparatuses (devices, systems, etc.) and methods for using them to remove a thrombus, e.g., clot, from within a vessel. These mechanical thrombectomy apparatuses may be inverting tractor thrombectomy apparatuses. Typically, the mechanical thrombectomy apparatuses described herein are inverting tractor thrombectomy apparatuses that includes a tractor (e.g., tractor region, tractor portion, etc.) comprising a flexible tube of material that inverts over itself as it rolls over a distal end opening of an elongate inversion support. The elongate inversion support typically comprises a catheter having a distal end opening into which the tractor inverts. The flexible tractor inverts and rolls back into itself and may be drawn into the elongate inversion support in a conveyor-like motion; the outward-facing region rolls around to become an inward-facing region, e.g., within the lumen of the elongate inversion support. The rolling motion may thus draw a clot or other object within a vessel into the elongate inversion support.

[0008] Before these apparatuses can remove a clot from a vessel, however, they must be positioned within the vessel adjacent to the clot to be removed. As described herein, the inverting tractor thrombectomy apparatuses described herein may be accurately positioned either with our without the use of a guidewire or guide sleeve within a vessel by taking advantage of the rolling motion of tractor at the distal end of the apparatus. The arrangement of the tractor, elongate inversion support (e.g. which may be or may include a catheter) and the puller connected to the tractor may be used to easily and accurately position the apparatus

adjacent a clot and remove the clot in a manner that may be both easier and more efficient than other methods.

[0009] Further described herein are systems and methods for advancing an inverting tractor thrombectomy apparatus forward in the vasculature. These systems and methods may use use the rolling motion of the tractor to move through the vasculature including over/around clot.

[00010] For example, described herein are systems and methods for removing a clot from a vessel using a mechanical thrombectomy apparatus. The mechanical thrombectomy apparatus may include an elongate inversion support (comprising or consisting of a catheter) that extends in a long axis from a proximal end to a distal end, a puller extending distally within the elongate inversion support (e.g. catheter) and a flexible and tubular tractor, wherein the tractor is coupled to a distal end region of the puller and further wherein the tractor is inverted over a distal end opening of the catheter so that the tractor extends proximally over the catheter. Illustrative methods using the apparatus may include: advancing the puller distally within the elongate inversion support (e.g., catheter) and within the vessel towards a clot, so that the tractor extends from the puller distally beyond the distal end opening of the catheter, forming a gap between the tractor and the distal end opening of the catheter; advancing the catheter distally over the puller and into the gap; and drawing the clot into the catheter with the tractor by pulling the tractor proximally within the catheter so that the tractor rolls and inverts over the distal end opening of the catheter.

[00011] Further illustrative methods include repeating the advancing steps one or more times. For example the method may include: advancing the puller distally within the elongate inversion support (e.g., catheter) and within the vessel towards a clot, so that the tractor extends from the puller distally beyond the distal end opening of the catheter, forming a gap between the tractor and the distal end opening of the catheter; advancing the catheter distally over the puller and into the gap; repeating the advance steps until the distal end opening of the catheter is adjacent to the clot; and drawing the clot into the catheter with the tractor by pulling the tractor proximally within the catheter so that the tractor rolls and inverts over the distal end opening of the catheter.

[00012] These illustrative methods for advancing the clot pulling apparatus may therefore be described as "inchworm" type advancement, as the tractor is extended from within the catheter to distally extend in the vessel, then the catheter may follow the tractor distally. In any of these methods, the tractor may be 'reset' back into the catheter (as it may otherwise be left deployed out of the catheter along vessel), by pulling it back into the catheter. For

example, the tractor may be pulled back into the catheter by pulling proximally on the puller once the catheter distal end opening is positioned against the distal-facing tractor (the region doubling-back or inverting over itself) so that the tractor can roll over the distal end opening. Resetting or repositioning the tractor in this manner may require that the apparatus be configured to prevent jamming (e.g., "anti-jamming"), including one or more of: having a lubricious and/or smooth tip, having a tip region that is more rigid than the more proximal regions of the tip, and/or having a tractor that is biased to have a first relaxed configuration that has an outer diameter that is greater than the inner diameter of the catheter and a second relaxed configuration that has an inner diameter that is greater than the outer diameter of the catheter, where the tractor converts between the first and second configurations by inverting over itself (e.g., over the distal end opening of a catheter). These configurations may prevent the tractor for buckling when pushed out of the distal end opening or when pulled back into the distal end opening of the catheter.

[00013] The repeated steps of inching forward by extending the tractor distally (e.g., pushing the puller coupled to the tractor distally, including distally out of the distal opening of the catheter), then advancing the catheter into the gap formed by the folded-over tractor, e.g., the gap between the distal end opening of the catheter and the tractor, may also include resetting the tractor by pulling the tractor back into the catheter once the distal end of the catheter has been advanced. The steps of advancing the tractor distally from the distal- end of the catheter and advancing the catheter behind the tractor (and optionally pulling the tractor back into the catheter by pulling proximally while holding the catheter fixed (or advancing it distally) may be repeated until the apparatus is adjacent to the clot; thereafter the clot can be removed as discussed above, by pulling the puller proximally to draw the tractor into the catheter.

[00014] In general, drawing the clot into the catheter may include advancing the catheter distally while pulling the pusher proximally. Further, the apparatus may be advanced distally (or retracted proximally) without the use of a guidewire or guide catheter. For example, advancing the puller distally may comprise advancing the puller without using a guidewire extending distal to the puller. Advancing the puller may comprise extending the distal end of the puller out of the distal end opening of the catheter. Alternatively the puller may remain in the catheter when advanced distally.

[00015] The tractor may be any appropriate tractor, including a woven, braided, or knitted tractor, or a tractor formed of a solid sheet of material (e.g., that may be cut or perforated). For example, advancing the puller may comprise extending the tractor distally within the

vessel, further wherein the tractor comprises a woven flexible and tubular tractor. Advancing the puller may comprise extending the tractor distally within the vessel, further wherein the tractor comprises a knitted tractor.

[00016] The systems described herein include a puller and tractor having a lumen (e.g., central lumen) through which a guidewire may be advanced. For example, advancing the puller may comprise extending the tractor distally within the vessel, further wherein the puller comprises a central lumen configured to pass a guidewire therethrough.

[00017] Further, the systems and methods described herein may be used (and performed) in any vessel within the body, including peripheral and neurovascular vessels. For example, these systems and methods may be used (performed) within an internal carotid artery (e.g., advancing the puller may comprise advancing the puller within an internal carotid artery).

[00018] Also described herein are systems including a mechanical thrombectomy apparatus that may be positioned within a vessel for removing a clot from within the vessel, in which the mechanical thrombectomy apparatus includes a puller within a first catheter that is within a second catheter, wherein the puller and second catheter are connected by a flexible and tubular tractor. For purposes of illustration, a method using such system may comprise: advancing the puller distally through the first catheter and the second catheter and within the vessel towards a clot, so that the flexible and tubular tractor extends from the puller beyond a distal end opening of the first catheter and beyond a distal end opening of the second catheter; advancing the outer catheter distally through the vessel by one or more of: holding the position of the first catheter within the vessel and pulling the puller proximally within the first catheter; or moving the first catheter distally relative to the puller; and drawing the clot into the first catheter with the flexible and tubular tractor by pulling the flexible and tubular tractor proximally within the first catheter so that the flexible and tubular tractor rolls and inverts over the distal end opening of the catheter. Any of these methods may also include repeating the advancing steps until the clot is adjacent to the distal end of the puller.

[00019] Drawing the clot into the catheter may further include advancing the first catheter distally while pulling the pusher proximally. Advancing the puller distally may include advancing the puller without using a guidewire extending distal to the puller. Advancing the puller may include extending the flexible and tubular tractor distally within the vessel further wherein the flexible and tubular tractor comprises a woven flexible and tubular tractor. Alternatively, advancing the puller may include extending the flexible and tubular tractor distally within the vessel further wherein the flexible and tubular tractor comprises a knitted flexible and tubular tractor.

[00020] Advancing the puller may comprise extending the flexible and tubular tractor distally within the vessel further wherein the puller has a central lumen configured to pass a guidewire therethrough, and drawing the clot into the first catheter may comprise uncoupling the flexible and tubular tractor from the second catheter.

[00021] Also described herein are mechanical thrombectomy apparatus for removing a clot from a vessel that include a motorized or motor-driven tractor. For example described herein are apparatuses including: a flexible catheter having a distal end and a distal end opening; a tractor comprising a flexible belt that extends within the catheter, inverts over the distal end opening of the catheter and extends along the outer diameter of the catheter; a power drive at a proximal end of the flexible catheter configured to drive the tractor around the catheter so that it inverts over the distal end opening of the catheter; and a guidewire lumen through the catheter and the tractor configured to pass a guidewire.

[00022] The flexible belt may comprise a flexible tube. In some variations, the tractor comprises a plurality of flexible belts that each extend within the catheter, invert over the distal end opening of the catheter and extend along the outer diameter of the catheter.

[00023] The the power drive may be configured to engage with the flexible belt on an outer surface of the catheter. The power drive may comprise an annular ring surrounding the catheter and the tractor.

[00024] Any of these apparatuses may include an outer catheter configured to enclose the flexible catheter and tractor, wherein the flexible catheter and tractor may be inserted through the body within the outer catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[00025] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[00026] FIGS. 1A-1H illustrate an example of a mechanical thrombectomy apparatus for mechanically removing an object such as a clot form a body region. FIG. 1A shows an example of an elongate inversion support portion of an apparatus, configured as a catheter. For example, at least the distal end of the elongate inversion support may be configured as a catheter. FIG. 1B shows an enlarged view of a distal end (opening) of the catheter of the elongate inversion support of FIG. 1A, showing the aperture formed by the distal end

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

[00027] FIG. 1I illustrates an alternative variation of a tractor and puller. In FIG. 1I, the tractor is shown attached to the distal end of a tapered or narrow puller; the distal end region is tapered, and includes a radiopaque marker at or near the attachment site to the tractor; the tractor may be knitted, braided, woven, etc. Thus, in some variations the distal end region of the puller may have a greater flexibility than the proximal end of the puller. The puller may be hollow (e.g., a catheter or hypotube) or solid (e.g., like a wire).

[00028] FIGS. 2A-2E illustrate a method of positioning a mechanical thrombectomy apparatus within a vessel and/or removing a clot from a vessel using the mechanical thrombectomy apparatus. In FIGS. 2A-2E the apparatus is shown inching distally within the vessel towards the clot using the tractor, so that the clot may be captured and removed by the tractor. In FIGS. 2A-2E the apparatus is advanced distally without the use of a guidewire.

[00029] FIGS. 3A-3D illustrate a method of positioning a mechanical thrombectomy apparatus within a vessel and/or removing a clot from a vessel using the mechanical thrombectomy apparatus similar to that shown in FIGS. 2A-2E only using a guidewire.

[00030] FIGS. 4A-4D illustrate a method of positioning a mechanical thrombectomy apparatus within a vessel and/or removing a clot from a vessel using the mechanical thrombectomy apparatus in which the distal end of the puller, to which one end of the tractor is attached, is extended distally from the catheter.

[00031] FIGS. 5A-5C illustrate a method of positioning a mechanical thrombectomy apparatus within a vessel and/or removing a clot from a vessel using the mechanical thrombectomy apparatus similar to that shown in FIGS. 4A-4D but include the use of a guidewire.

[00032] FIGS. 6A-6B illustrates another method of positioning a mechanical thrombectomy apparatus within a vessel and/or removing a clot from a vessel using the mechanical thrombectomy apparatus, in which the apparatus include a tractor that is connected (attached) to both the pusher and an outer catheter or element.

[00033] FIG. 7 illustrates one region (e.g., the internal carotid artery) in which the apparatuses and methods described herein may be used.

[00034] FIG. 8A-8B illustrate an example of a mechanical thrombectomy apparatus for removing a clot from a vessel that include a motorized or motor-driven tractor. FIG. 8A shows the apparatus in a side view, schematically illustrating the internal components. FIG. 8B is an example of a catheter and tractor(s) that may be used with an apparatus such as the one shown in FIG. 8A.

[00035] FIGS. 9A-9B illustrate a method of operating a mechanical thrombectomy apparatus for removing a clot from a vessel that include a motorized or motor-driven tractor, such as the one shown in FIGS. 8A-8B. FIG. 9C illustrates a motorized or motor-driven (e.g., "power driven) continuous tractor that is loaded into a larger catheter (e.g., an intermediate catheter).

DETAILED DESCRIPTION

[00036] Described herein are mechanical thrombectomy apparatuses, including manually drive and power-driven apparatuses, and methods of using them. In particular, described herein are methods of positioning these apparatuses within a vessel and/or removing clot with them that may include extending the tractor region and/or the puller distally of the distal end of the apparatus to assist in advancing the apparatus distally.

[00037] Any of the mechanical thrombectomy apparatuses described herein may have an inverting tractor that is configured to prevent jamming and grab a blood clot. These

apparatuses may include an elongate elongate inversion support support that supports an annulus over which the tractor inverts at the distal end. The tractor may comprise a flexible tube that doubles back over (e.g., inverts) over the distal end of the elongate inverting support (e.g., a catheter) so that it extends into the annuls opening of the elongate inverting support and an inner puller coupled to the inner end of the tractor that the tractor can be pulled proximally to pull and invert the tractor over the annulus at the distal end of the elongate inverting support to roll and capture a clot. The apparatus may include a guidewire lumen extending through the elongate inverting support, and/or tractor puller that is configured to pass a guidewire.

[00038] The apparatuses described herein may be adapted to prevent jamming, e.g., by including a coating (e.g., hydrophilic, lubricious coating, etc.) or the like to enhance the sliding and inverting of the tractor over the distal end. Further, any of these apparatuses may include one or more projections that are configured to enhance grabbing and/or maceration of a clot. Grabbing of a clot may be particularly, but not exclusively, helpful when the tractor is lubricious. Although lubricious tractors may may resist jamming and require less force to operate, e.g., inverting over the distal end of the catheter, it may be more difficult to initially grab or grasp clot when the tractor is more lubricious. It may also be particularly helpful to include projections that are retracted along the length of the tractor adjacent to the outer diameter of the elongate inverting support (e.g., catheter), for example, when positioning the apparatus within a vessel, but extend the projections outward from the tractor when rolling and inverting to grab a clot.

[00039] In general, a mechanical thrombectomy apparatus for removing a clot from a vessel may be a system, assembly or device including an elongate inversion support having a distal end and a distal annulus, and a flexible tractor assembly at least partially inverted and configured to roll and invert over the distal annulus of the elongate inverting support.

[00040] In many of the examples described herein, the elongate inversion support is a catheter (or a portion of a catheter at the distal end) and the annulus is formed by the distal end opening of the catheter; the tractor extends within the catheter and doubles back over the distal end of the catheter to extend over the outer diameter of the catheter at the distal end of the catheter, although it may extend proximal for any appropriate distance (including between 1-30 cm, between 2-20 cm, greater than 1 cm, 2 cm, 3 cm, 4 cm, 5 cm, 6 cm, 7 cm cm, 8 cm, 9 cm, 10 cm, 11 cm, 12 cm, 15 cm, 20 cm, etc.). The end of the tractor within the catheter may be coupled to a puller (e.g., at a proximate puller region connected to the distal or inner end of the tractor). The tubular tractor may include an elongate lumen that is configured to

allow passage of a guidewire. The tubular tractor may also be configured to slide along the long axis within the catheter lumen and invert over the distal end opening of the catheter when the proximal end region is pulled proximally. The tractor may be referred to herein as a tractor assembly, tractor portion, tractor tube, or simply a tractor, and is typically positioned and longitudinally slideable within the catheter, and arranged so a portion of the tractor (sometimes referred to as the "distal tractor region" or "distal-facing" tractor region) doubles back over itself.

[00041] For example, FIG. 1A shows one variation of a catheter of an elongate inversion support that may form part of the apparatuses described herein. In this example, the elongate inversion support includes a catheter 100 having a distal end region 103 that includes a distal end opening 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal-most end region (distal end 105, including the distal end opening) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region of the catheter (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing harness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[00042] In FIG. 1A, the elongate inversion support is an elongate hollow catheter having a column strength that is sufficient to prevent buckling when the catheter is pulled over the distal annulus (distal end opening). Thus, the elongate inversion support may be configured so that it does not collapse (e.g., buckle) when 500 g or less of of compressive force is applied (e.g., at least about 700 g, 600 g, 500 g, 400 g, 300 g, etc. of compressive force) for neurovascular applications. For peripheral vascular applications the elongate inversion support may be selected or configured to withstand at least 1500 g of compressive force (e.g., at least about 2000 g, 1900 g, 1800 g, 1700 g, 1600 g, 1500 g, 1400 g, etc. of compressive force). In general, any of the apparatuses described herein may include a elongate inversion support that is not a full-length catheter, but may include a portion of a catheter, typically at the distal end, connected to a rod, wire, hypotube, or the like (as will be described in greater detail below in reference to FIGS. 42A-43D) or may be skived. Thus, any of the apparatuses and methods described herein may be adapted for use with an elongate inversion support that

is not limited to catheters, including elongate inversion supports that include a portion of a catheter, or that include a ring or other structure forming the annulus at the distal end. In FIG. 1A the catheter 100 of the elongate inversion support may be any appropriate type of catheter or portion of a catheter, including microcatheters appropriate for neurovascular use.

[00043] In some variations the distal end 105 of the elongate inversion support is adapted so that the tractor may slide or roll and invert over the distal end of the catheter without being caught (binding, jamming) or without substantial friction. For example, in some variations the distal tip (end) may be curved or radiused 109 as shown in FIG. 1B, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter).

[00044] FIG. 1C shows an example of a flexible tractor 144 coupled to a puller 146. In this example to form a pullable tractor assembly 140, the tractor is shown integrated with the puller, forming the assembly. In FIG. 1C, the tractor is a tube of material (e.g., wove, knitted, braided, etc.) that is flexible and elongate. The tractor is shown extended from the puller in a first configuration. It may be particularly beneficial if the relaxed outer diameter of the flexible tractor in this first configuration has a greater outer diameter than the outer diameter of the catheter of the elongate inversion support into which the tractor will be positioned prior to inverting. The flexible and tubular tractor 144 may be sufficiently soft and flexible (e.g., having a low collapse strength) so as to easily roll and fold over the distal aperture of the elongate inversion support. The puller 146 may typically be a less-expandable (or non-expandable) structure (tube, puller, etc.). In the example shown in FIG. 1C, the tractor 144 is configured, e.g., by shape-setting (heat setting, etc.), to expand in the relaxed first configuration to a radial diameter that is between 1.1 and 10 times the diameter of the inner diameter of the catheter of the elongate inversion support when unconstrained, as shown in FIG. 1D. In FIG. 1D, the tractor of FIG. 1C is shown in an expanded, relaxed, configuration. Thus the expandable tractor may be biased to expand open. The tractor may be formed of a mesh, braided, woven, knitted, or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[00045] In FIGS. 1C and 1D the tractor and puller have two portions, a tractor 144 and a less expandable (or non-expandable) proximal portion comprising the puller 146. The puller may be a separate region, such as a wire, catheter or hypotube, which is connected to an end region of the tractor (e.g., a flexible mesh, woven, braided, etc.), e.g., the distal end or near the distal end. The inverting region of the tractor, where it rolls and inverts over the distal end opening of the catheter may be referred to as the distal-facing region of the tractor, which may actively grab clot when rolling.

[00046] In FIG. 1E, the flexible tractor of FIG. 1C is shown with the tractor doubled back over itself an over the the distal end of the catheter of the elongate inversion support 101. The distal end region is collapsed down, e.g., onto the puller and the elongate inversion support, and may be held collapsed. In this example a tractor hold 188 may be used to hold the tractor collapsed down onto the outer diameter of the elongate inversion support. However, in an unconstrained or deployed configuration, as shown in FIG. 1F, the tractor in this second configuration (e.g., the portion that is inverted over the distal end of the catheter) has an outer diameter that is greater than the outer diameter of the catheter of the elongate inversion support. Thus, the tractor 144 may be biased so that it has a relaxed expanded configuration in the first configuration (as shown in FIG. 1C) that is greater than the inner diameter (ID) of the catheter of the elongate inversion support portion of the apparatus and the relaxed expanded configuration of the second configuration (shown in FIG. 1F) inverted over the catheter has an OD that is greater than the OD of the catheter. The tractor is expandable and may be coupled to the puller. In some variations the flexible tractor and the puller may comprise the same material but the tractor may be more flexible and/or expandable, or may be connected to a push/pull wire or catheter.

[00047] FIGS. 1G and 1H illustrate the removal of a clot using an apparatus such as the apparatus assembled from the components of FIGS. 1A and 1E. In this example the apparatus is configured as a thrombectomy apparatus including a catheter of an elongate inversion support 101 and a flexible tractor that extends over the distal end region of the catheter and doubles-over itself at the distal end of the catheter to invert so that the external tractor end region is continuous with an inner less-expandable (in this example, less-expandable includes non-expandable) second distal end region 146 (puller) that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The pusher/puller member that may be a rod or other member that is continuous with the distal end region of the tractor. In FIG. 1G the apparatus is shown positioned and deployed within the vessel 160 near a clot 155. The clot may be drawn into the catheter by pulling the tractor 140 proximally into the catheter 101, as indicated by the arrow 180 showing pulling of the inner portion of the flexible tractor (e.g., using a handle, not shown) resulting in rolling the tractor over the end opening of the catheter and into the catheter distal end and inverting the expandable distal end region so that it is pulled into the catheter, shown by arrows 182. The end of the tractor outside of the catheter may be "loose" relative to the outer wall of the catheter. FIG. 1I illustrates another example of a tractor assembly 154 including a tractor 144 that is coupled to a puller 156. The puller in this example is tapered (having tapering region

161) and may therefore have a different flexibility of the distal end region than the proximal end region. For example the proximal end region may be less flexible than the narrower-diameter distal end region 195 to which the tractor is coupled. The assembly includes a radiopaque marker 165. The tractor may be attached to the puller by any appropriate means. For example, the tractor may be crimped, glued, fused, or otherwise attached to the puller, typically permanently.

[00048] In general the mechanical thrombectomy apparatuses described herein may be highly flexible, both before actuating and during operation. For example, the flexible tractor may not increase the stiffness/flexibility of the catheter of the elongate inversion support, and particularly the distal end region of the catheter too much, to avoid impacting maneuverability, particularly within tortious vessels of the neurovasculature. Described herein are flexible tractor tube portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5 cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

ILLUSTRATIVE METHODS OF ADVANCING AN INVERTING TRACTOR APPARATUS

[00049] For purposes of better understanding the mechanical thrombectomy systems and apparatuses disclosed herein, various methods of their use will now be described. In one such method, a mechanical thrombectomy apparatus is be advanced distally within a vessel and may grab and engulf a clot that is located distally by using the tractor to extend distally ahead of the apparatus, and in some cases pull (e.g., against the vessel walls) to guide or draw the catheter distally forward. This method of advancement may be referred to as "inchworm" or 'worm-like" motion within the vessel. For example, FIGS. 2A-2E illustrate a first method of advancing a mechanical thrombectomy apparatus and/or removing a clot from a vessel using the mechanical thrombectomy apparatus. In this example, the apparatus includes a catheter 205 extending proximally to distally, a puller 207 (shown as a thin tube or hypotube, though it may be a wire or rod, as mentioned above), extending distally within the catheter and a flexible and tubular tractor 209. The tractor is coupled to a distal end region of the puller 217

and the tractor is inverted over a distal end opening of the catheter 219 so that the tractor extends proximally over the outside (outer diameter) of the catheter. In operation, the apparatus may be advanced distally (e.g., towards a clot 213) in a vessel 211, as shown in FIGS. 2B-2D. In FIG. 2B, the puller is pushed distally 220 (shown by arrows on the left) to advanced distally within the catheter and within the vessel towards a clot, so that the tractor extends from the puller distally beyond the distal end opening of the catheter 218, forming a gap 219 between the tractor and the distal end opening of the catheter. This gap is an annular, distal-facing cavity (e.g. pouch) formed in the tractor, and into which the distal end opening of the catheter may be advanced, as shown in FIG. 2C. In FIG. 2C, the catheter is advanced distally over the puller and into the gap. Following this step, the tractor is extended further outside of the catheter, and is in contact with the walls of the vessel 211, through it does not have to be. The outer diameter of the expanded tractor maybe narrower than the vessel inner diameter (ID) or it may be greater than then ID of the vessel (and may therefore touch against them.

[00050] When advancing the catheter distally 222 (shown in arrows on left) and into the gap, the puller may be held in position relative to the catheter. In variations in which the tractor contacts the outer diameter of the vessel, this contact may hold the tractor in place against the vessel wall.

[00051] The steps of FIGS. 2B and 2C may be repeated multiple times to continue to advance the apparatus distally, however, in some variations it may be beneficial to retract or reset the tractor back into the catheter, e.g., by withdrawing the puller proximally to pull the tractor back into the catheter. This is illustrated in FIG. 2D. In this example, the puller 207 is withdrawn proximally 224 (arrows on left), so that the tractor coupled to the puller 217 is pulled back into the catheter after inverting over the distal end opening of the catheter. It may be beneficial to perform this step after the catheter has been extended distally fully, e.g., until it pushes distally against the back of the inverting (bent-over) region, as shown in FIG. 2D. One the tractor has been sufficiently retracted, the steps shown in FIGS. 2B-2C may be repeated, as shown in FIG. 2E, until the distal end opening of the catheter is adjacent to the clot. After positioning next to the clot (and in some cases adjacent to it), vacuum may be applied to pull the clot into contact with the apparatus, and/or the device may be advanced by pushing the catheter distally while pulling the puller proximally to roll and invert the tractor into the catheter (see., e.g., FIG. 1H).

[00052] The method of advancing the apparatus described in FIGS. 2A-2E above may be particularly helpful in advancing the apparatus within a vessel even without the use of a

guidewire or equivalent (e.g., guide catheter). However this method may also be used with a guidewire, as illustrated in FIGS. 3A-3D. In this example, the apparatus 300 is otherwise the same as shown in FIGS. 2A-2E, but may include or be used with a guidewire 355. In general, the same steps may be performed as discussed above. Alternatively, before or after a cycle of inching forward as describe in FIGS. 2A-2E, the apparatus may be slid distally along the guidewire toward the clot. Thus, in some variations, this method may be used to help navigate the apparatus within congested or tortious regions where advancing by sliding may not be as effective.

[00053] Another method of advancing an apparatus distally using the tractor is illustrated in FIGS. 4A-4D. This method is also similar to that shown in FIGS. 2A-2E and 3A-3C above, but may extend the tractor portion even further distally using the pusher, so that the pusher extends past the distal end of the apparatus, out of the catheter. In contrast, in FIGS. 2A-2E, the pusher remains substantially within the catheter, thus smaller 'steps' may be taken by the device.

[00054] In FIG. 4A, the apparatus is similar to that discussed above, including a puller 407 that is connected at a distal end region 417 to a tractor 403. The tractor is inverted over the distal end opening of a catheter 405. The apparatus may be advanced within a vessel 411 towards a clot 413, as shown in FIG. 4B, by advancing the inner puller 407 distally 420 so that the puller distal end (and attached tractor) extends distally from the catheter distal end opening. The tractor may tent, forming a gap 419 or pouch between the distal end of the catheter and the distal face of the tractor (distal-facing end). In this example, the gap 419 is formed between the distal end of the catheter and the end of the puller. Thereafter, as shown in FIG. 4C, the catheter may be advanced distally 422 within the gap of the tractor. In both this example and the example shown in FIGS. 2A-2E, the puller and tractor may be advanced distal of the catheter distally while the outer portion of the tractor remains over the catheter, e.g. the second end of the tractor 414 that is shown extended over the outer diameter of the catheter remain proximal to the distal end of the catheter. Once positioned near the clot 413, the tractor may be rolled into the catheter by pulling proximally on the puller and (optionally) advancing the apparatus distally by pushing the catheter distally.

[00055] If the distal end of the apparatus (e.g., the distal-facing, inverting tractor) is not adjacent to the clot 413, the steps above can be repeated, either with or without retracting the tractor into the catheter (e.g., by pulling proximally on the puller). FIG. 4D illustrates an example of retracting the tractor into the catheter by pulling proximally on the puller 424.

[00056] FIGS. 5A-5C illustrate the method of FIGS. 4A-4C with a guidewire 515. The apparatus may be the same (e.g., may include a puller 507 coupled at a distal end 517 to a flexible tractor 503 that is inverted over the distal end opening of a catheter 505 and extending along the outer surface of the catheter). The steps may be the same as discussed above, including advancing the tractor and puller distally by pushing the puller distally 520 towards a clot 513, as shown in FIG. 5B. The catheter may then be advanced (by sliding over the guidewire) as shown in FIG. 5C into the gap or pouch formed by the tractor 519. Once positioned near the clot 513, the tractor may be rolled into the catheter by pulling proximally on the puller and (optionally) advancing the apparatus distally by pushing the catheter distally.

[00057] FIGS. 6A-6B illustrate another method for advancing an apparatus distally, in which both ends of the tractor 603 are coupled to axially movable elements. For example, in FIG. 6A the first end of the tractor 603 is coupled to a puller 607 within the catheter 605. In addition, the second end of the tractor is shown coupled to an outer axially movable member (second or outer catheter 619). This tri-axial system may be used to inchworm the apparatus distally by alternately holding and pulling on the various pullers and catheters. For example, in FIG. 6A, the tip of the apparatus may be advanced distally toward a clot by holding the catheter fixed, allowing the puller to float (e.g., not constraining it) and pulling the outer catheter proximally 640. As a result, the outer portion of the flexible tractor may be pulled proximally, pulling the puller and opposite end of the tractor distally, as shown in FIG. 6B. Thereafter, the puller may be held in place, the outer catheter may be free to move axially, and the catheter may be advanced distally into the gap formed by the tractor, which may drive the tractor distally (e.g., back to the configuration shown in FIG. 6A) and pull the outer catheter distally. These steps may be repeated as necessary. In some variations the outer catheter may be removably attached to the tractor, and the tractor may be pulled proximally to separate from the outer catheter.

[00058] A guidewire may also be used with this method. In this example, tip advancement of the apparatus may take advantage of the outer (e.g., guide) catheter stiffness (e.g., bending and column stiffness) to aid in catheter tip advancement. This may be particularly helpful in neurovascular regions, such as shown in FIG. 7.

[00059] FIG. 7 illustrate the uses of the methods described herein to advance the apparatus 701 within a neurovascular structure such as the internal carotid segment in the head. For example, the distal tip of the apparatus may be positioned at the distal tip of the internal carotid segment; once positioned, an advancement method such as one of those described

herein may be used drive the apparatus distally forward towards the clot. Such a method may create a pushing force forward from the internal carotid artery without sacrificing the trackability of the apparatus or the small outer diameter of the apparatus.

[00060] The apparatuses described herein may also be used to advance other apparatuses (including catheters and tubes). For example, any of these apparatuses and methods may be used in reverse (e.g. pulling proximally on an outer portion of the catheter) to pull an apparatus within the lumen of the tractor distally for delivery at an internal vessel site.

[00061] Thus, to advance a tool (e.g., a tube, etc.) into the patient, a tractor inserted into the body (which may be advanced as descried herein, even for use without performing a thrombectomy or in addition to a thrombectomy) may be pulled from the outside of the catheter proximally (e.g., with an overtube or pull wire) to invert the tractor in the opposite direction from out of the catheter. As the tractor on the OD of the catheter is pulled proximally, it may advance a tool (e.g., tube) inside the apparatus to the target location in the patient. This mechanism could be used in a variety of applications including; passing mature clot or vessel lesion, placing an intubation system (e.g., in a throat), providing rectal or vaginal access, performing NOTES surgery, inserting a tool such as a trocar, inserting a scope into a body region (e.g., gastrointestinal region, colon, blood vessel lumen, etc.), inserting a robotic tool, crossing a calcified vessel, etc. Other applications of the apparatuses and methods of removing and/or placing material using the apparatuses described herein may include include removal of tissue, such as gall bladder removal and removal of fat (liposuction). For example a cutting or ablative tool may be passed down the middle of the apparatus, through the catheter, the puller and the tractor, and extended from the distal end, where it may be used to cut tissue that may then be pulled out of the body using the tractor by pulling the tractor proximally within the catheter. Note that this method may be used to remove both the tool and/or the cut tissue. Thus, despite referring to these apparatuses as mechanical mechanical thrombectomy apparatuses herein, any of these devices may be adapted for uses not limited to thrombectomy, and may alternatively be referred to as mechanical tractor apparatuses.

[00062] Also described herein are powered mechanical thrombectomy apparatuses in which the tractor may be driven by a driver such as an electrical motor. For example, FIG. 8A illustrates an example of a power driven tractor in a mechanical thrombectomy apparatus. The apparatus may drive the tractor continuously in a loop, thus the tractor may be configured as a closed loop, belt or toroid of material that extends around a catheter. The power drive may run the apparatus in either the forward or reverse directions. In FIG. 8A,

the tractor comprises a plurality of belts 803 that extend around and through the catheter 805. A drive motor 811 drives rotation of the belts. In FIG. 8A the drive motor drives a ring 813 that can therefor drive multiple belts forming the tractor or in some variations, a single torus that passes over the supporting catheter. The catheter may include holes or openings 817 into which the belts forming the tractor may reside. The belts extend along the length of the catheter 805. In this example, a hub 815 holds the proximal end of the catheter and holds the belts against the drive motor and/or drive ring that is driven by the drive motor, and may also connect to a vacuum 819.

[00063] FIG. 8B shows an enlarged view of a catheter and tractor that may be used with the apparatus shown in FIG. 8A. FIG. 8B shows the catheter 805 including a plurality of belts 803, 803' forming the tractor. The belts pass through an opening in the catheter at the proximal end, but roll over the distal end of the catheter, and extend along the outer and inner longitudinal axis.

[00064] FIGS. 9A-9B illustrates an example of operation of a power driven mechanical thrombectomy apparatus configured to grab a clot. In FIG. 9A, the apparatus 900 is similar to that shown in FIG. 8A, above, including a plurality of belts 903, 903' forming the tractor, and an internal catheter 905; the bests rotate down the length of the catheter. Note that the catheter may be rigid or flexible. The catheter may include channels, and/or notches or other guide along its length for guiding and/or enclosing the belts at various portions. In FIG. 9A, the apparatus is positioned adjacent to a clot 924. The clot may initially be grabbed using aspiration (e.g., vacuum). In FIG. 9B, the apparatus may is shown after grabbing the clot, and compressing it within the catheter.

[00065] Note that the power-driven mechanical thrombectomy apparatuses shown in FIGS. 9A and 9B do not include a puller, as the motor may act like a puller. In some variations a separate puller may be used.

[00066] As mentioned above, any of the apparatuses described herein may be used with an additional outer catheter, including the powered apparatuses described herein. For example, FIG. 9C illustrates an example of a powered apparatus 900 used with an intermediate catheter having a larger OD than the powered mechanical thrombectomy apparatus. In this example, the length of the apparatus is slightly greater or almost equal to the length of the intermediate catheter 930, so that just the distal end region of the apparatus, including the inverting tractor (belts) is accessible and/or sticks out 933 of the intermediate catheter. Alternatively, the apparatus may be retracted into the outer (intermediate) catheter slightly, or may extend substantially from the end of the outer catheter.

[00067] Any of the methods (including user interfaces) described herein may be implemented as software, hardware or firmware, and may be described as a non-transitory computer-readable storage medium storing a set of instructions capable of being executed by a processor (e.g., computer, tablet, smartphone, etc.), that when executed by the processor causes the processor to control perform any of the steps, including but not limited to: displaying, communicating with the user, analyzing, modifying parameters (including timing, frequency, intensity, etc.), determining, alerting, or the like.

[00068] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[00069] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[00070] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For

example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[00071] Although the terms "first" and "second" may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[00072] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising" means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term "comprising" will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

[00073] In general, any of the apparatuses and methods described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may alternatively be exclusive, and may be expressed as "consisting of" or alternatively "consisting essentially of" the various components, steps, sub-components or sub-steps.

[00074] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or "approximately," even if the term does not expressly appear. The phrase "about" or "approximately" may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For

example, if the value "10" is disclosed, then "about 10" is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that "less than or equal to" the value, "greater than or equal to the value" and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value "X" is disclosed the "less than or equal to X" as well as "greater than or equal to X" (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point "10" and a particular data point "15" are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[00075] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[00076] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the

above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

What is claimed is:

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

a flexible catheter having a distal end and a distal end opening;

a tractor comprising a flexible belt that extends within the catheter, inverts over the distal end opening of the catheter and extends along the outer diameter of the catheter;

a power drive at a proximal end of the flexible catheter configured to drive the tractor around the catheter so that it inverts over the distal end opening of the catheter; and

a guidewire lumen through the catheter and the tractor configured to pass a guidewire.

2. The apparatus of claim 1, wherein the flexible belt comprises a flexible tube.

3. The apparatus of claim 1, wherein the tractor comprises a plurality of flexible belts that each extend within the catheter, invert over the distal end opening of the catheter and extend along the outer diameter of the catheter.

4. The apparatus of claim 1, wherein the power drive is configured to engage with the flexible belt on an outer surface of the catheter.

5. The apparatus of claim 1, wherein the power drive comprises an annular ring surrounding the catheter and the tractor.

6. The apparatus of claim 1, further comprising an outer catheter configured to enclose the flexible catheter and tractor, wherein the flexible catheter and tractor may be inserted through the body within the outer catheter.

7. A method of removing a clot from a vessel using a mechanical thrombectomy apparatus including a catheter extending from a proximal end to a distal end, a puller extending distally within the catheter and a flexible and tubular tractor, wherein the tractor is coupled to a distal end region of the puller and further wherein the tractor is inverted over a distal end opening of the catheter so that the tractor extends proximally over the catheter, the method comprising:

advancing the puller distally within the catheter and within the vessel towards a clot, so that the tractor extends from the puller distally beyond the distal end opening of the catheter, forming a gap between the tractor and the distal end opening of the catheter;

advancing the catheter distally over the puller and into the gap;

repeating the advance steps until the distal end opening of the catheter is adjacent to the clot; and

drawing the clot into the catheter with the tractor by pulling the tractor proximally within the catheter so that the tractor rolls and inverts over the distal end opening of the catheter.

8. The method of claim 7, wherein repeating further comprises comprising pulling the pusher proximally within the catheter to invert a portion of the tractor over the distal end opening of the catheter.

9. The method of claim 7, wherein drawing the clot into the catheter further comprises advancing the catheter distally while pulling the pusher proximally.

10. The method of claim 7, wherein advancing the puller distally comprises advancing the puller without using a guidewire extending distal to the puller.

11. The method of claim 7, wherein advancing the puller comprises extending the distal end of the puller out of the distal end opening of the catheter.

12. The method of claim 7, wherein advancing the puller comprises extending the tractor distally within the vessel, further wherein the tractor comprises a woven flexible and tubular tractor.

13. The method of claim 7, wherein advancing the puller comprises extending the tractor distally within the vessel, further wherein the tractor comprises a knitted tractor.

14. The method of claim 7, wherein advancing the puller comprises extending the tractor distally within the vessel, further wherein the puller comprises a central lumen configured to pass a guidewire therethrough.

15. The method of claim 7, wherein advancing the puller comprises advancing the puller within an internal carotid artery.

16. A method of removing a clot from a vessel using a mechanical thrombectomy apparatus having a puller within a first catheter that is within a second catheter, wherein the puller and second catheter are connected by a flexible and tubular tractor, the method comprising:

advancing the puller distally through the first catheter and the second catheter and within the vessel towards a clot, so that the flexible and tubular tractor extends from the puller beyond a distal end opening of the first catheter and beyond a distal end opening of the second catheter;

advancing the outer catheter distally through the vessel by one or more of: holding the position of the first catheter within the vessel and pulling the puller proximally within the first catheter; or moving the first catheter distally relative to the puller; and

drawing the clot into the first catheter with the flexible and tubular tractor by pulling the flexible and tubular tractor proximally within the first catheter so that the flexible and tubular tractor rolls and inverts over the distal end opening of the catheter.

17. The method of claim 16, further comprising repeating the advancing steps until the clot is adjacent to the distal end of the puller.

18. The method of claim 16, wherein drawing the clot into the catheter further comprises advancing the first catheter distally while pulling the pusher proximally.

19. The method of claim 16, wherein advancing the puller distally comprises advancing the puller without using a guidewire extending distal to the puller.

20. The method of claim 16, wherein advancing the puller comprises extending the flexible and tubular tractor distally within the vessel further wherein the flexible and tubular tractor comprises a woven flexible and tubular tractor.

21. The method of claim 16, wherein advancing the puller comprises extending the flexible and tubular tractor distally within the vessel further wherein the flexible and tubular tractor comprises a knitted flexible and tubular tractor.

22. The method of claim 16, wherein advancing the puller comprises extending the flexible and tubular tractor distally within the vessel further wherein the puller has a central lumen configured to pass a guidewire therethrough.

23. The method of claim 16, wherein advancing the puller comprises advancing the puller within an internal carotid artery.

24. The method of claim 16, wherein drawing the clot into the first catheter comprises uncoupling the flexible and tubular tractor from the second catheter.

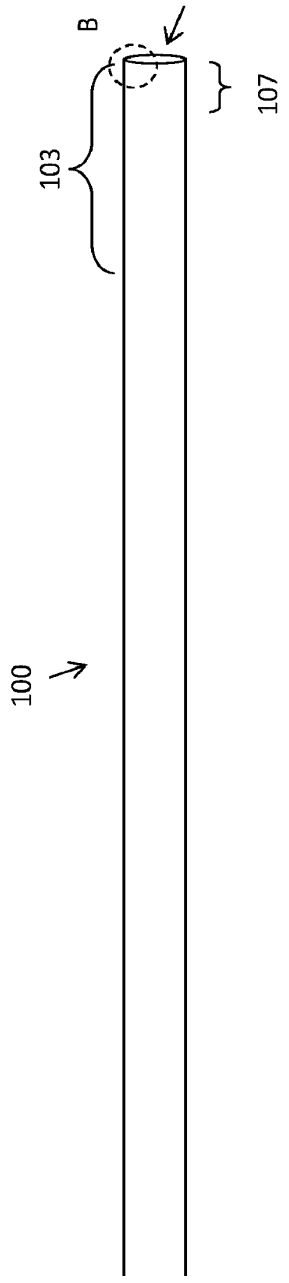


FIG. 1A

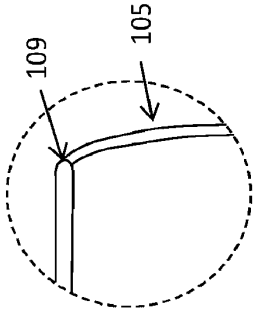


FIG. 1B

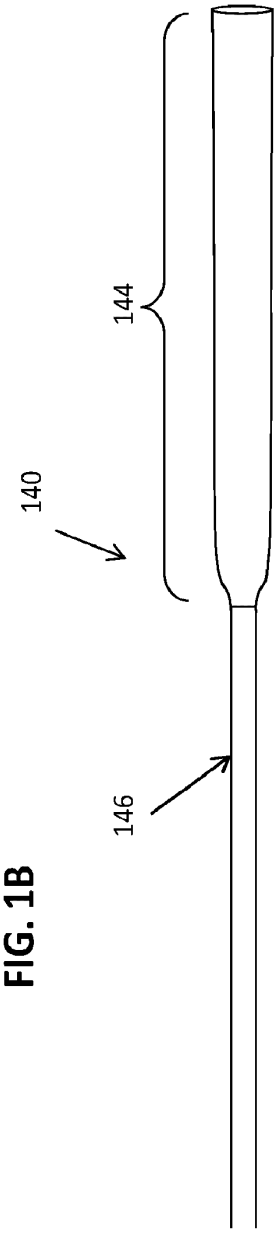


FIG. 1C

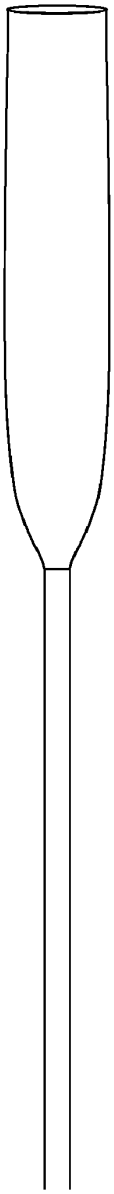


FIG. 1D

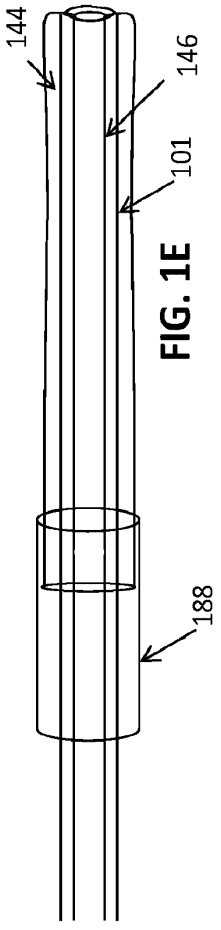


FIG. 1E

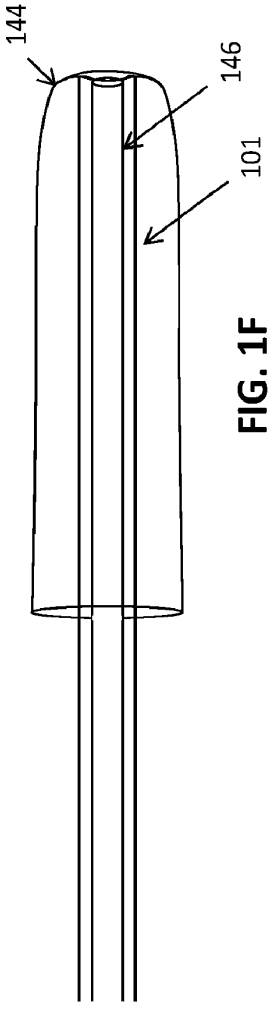


FIG. 1F

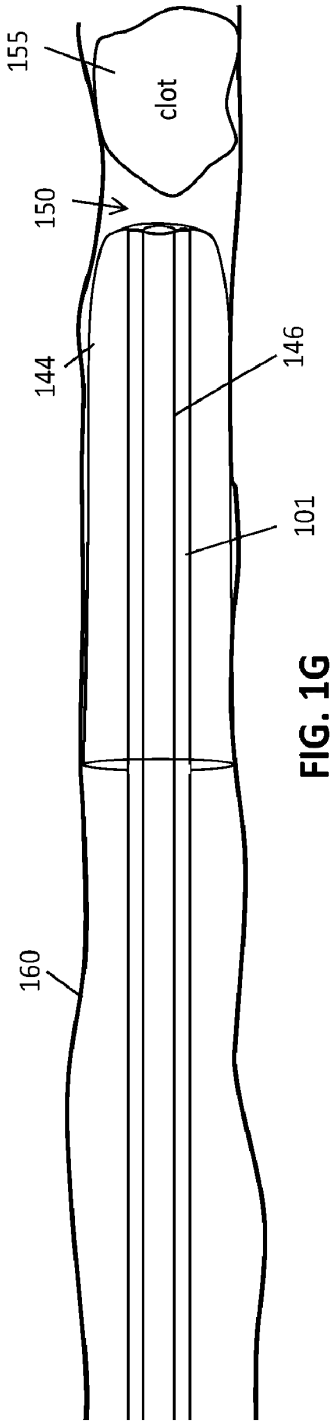


FIG. 1G

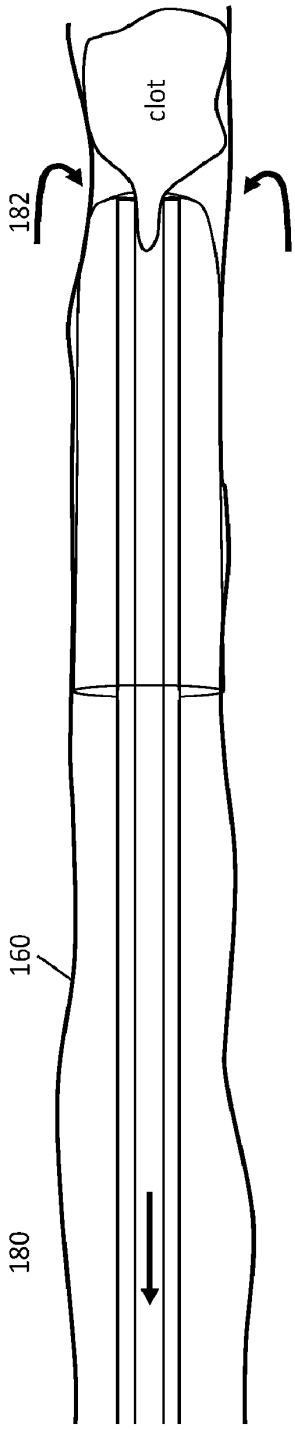


FIG. 1H

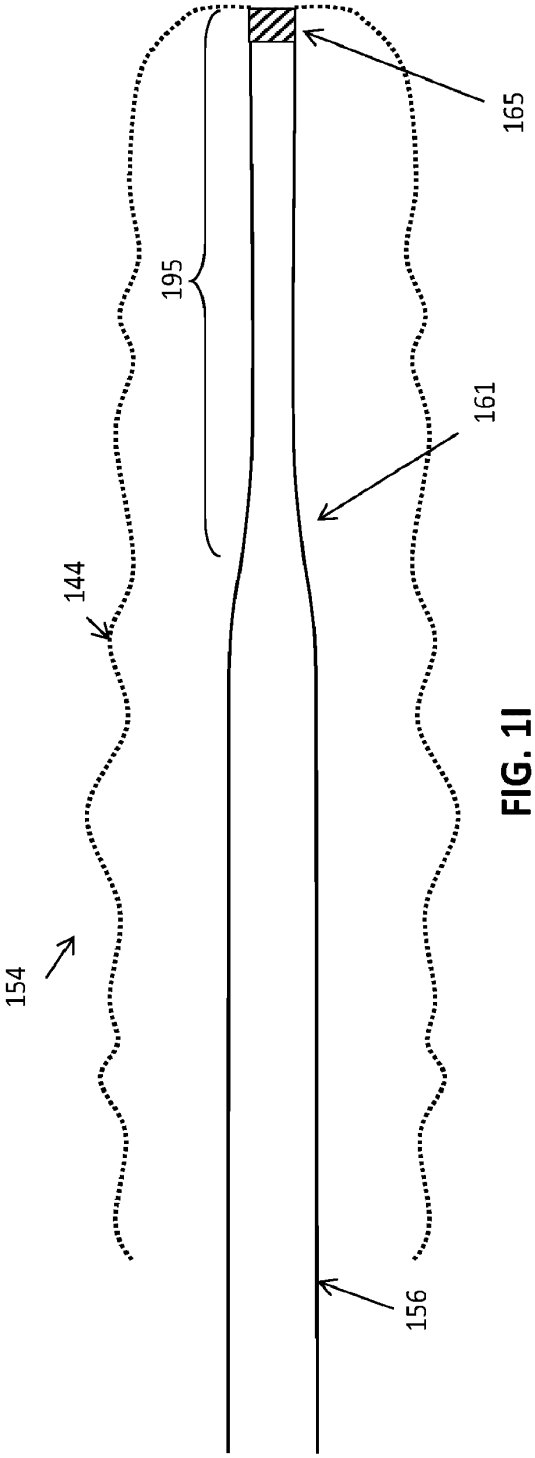


FIG. 1I

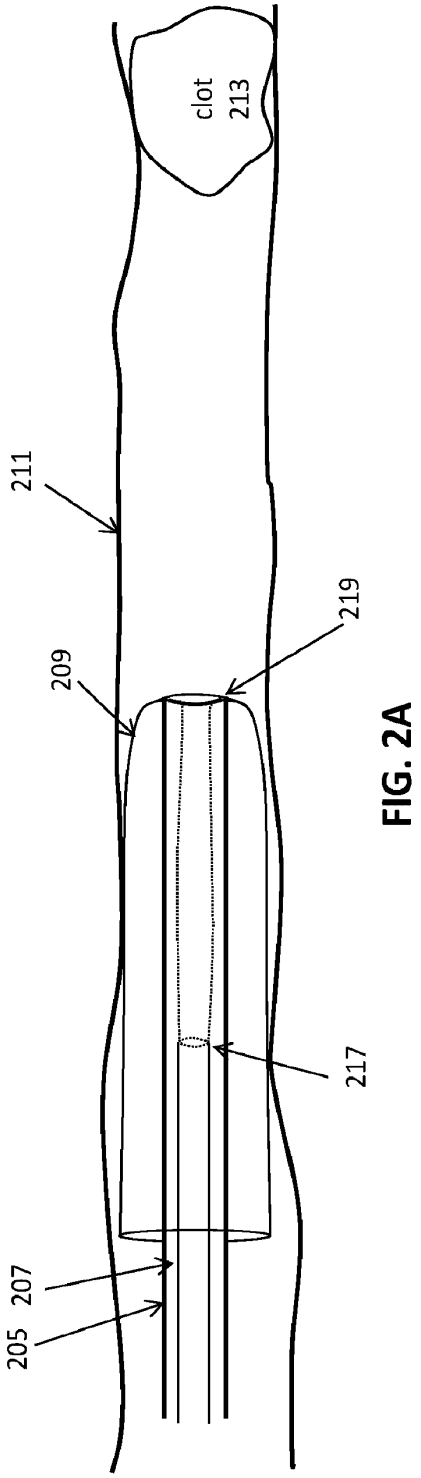


FIG. 2A

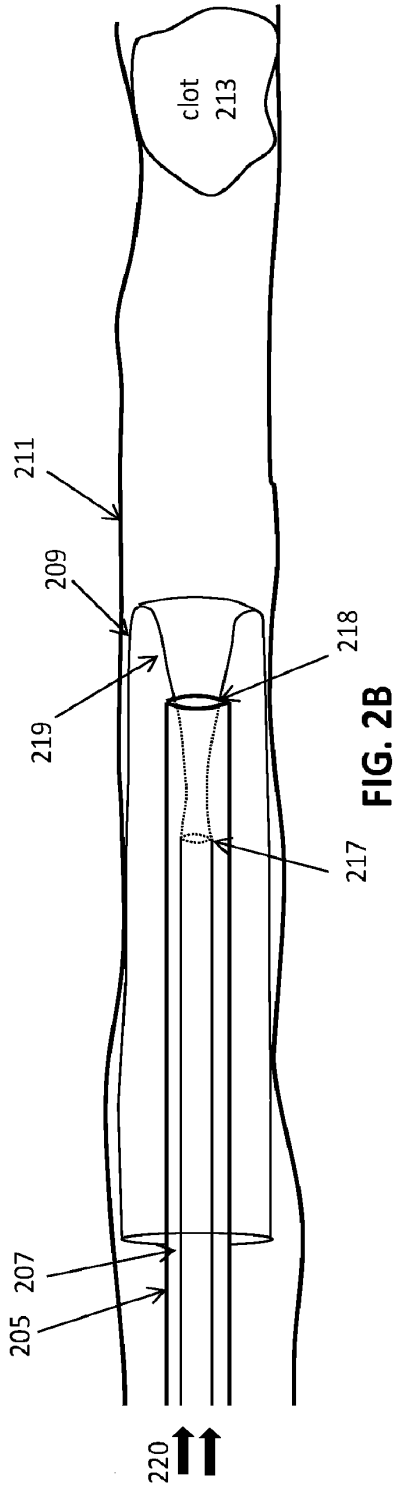


FIG. 2B

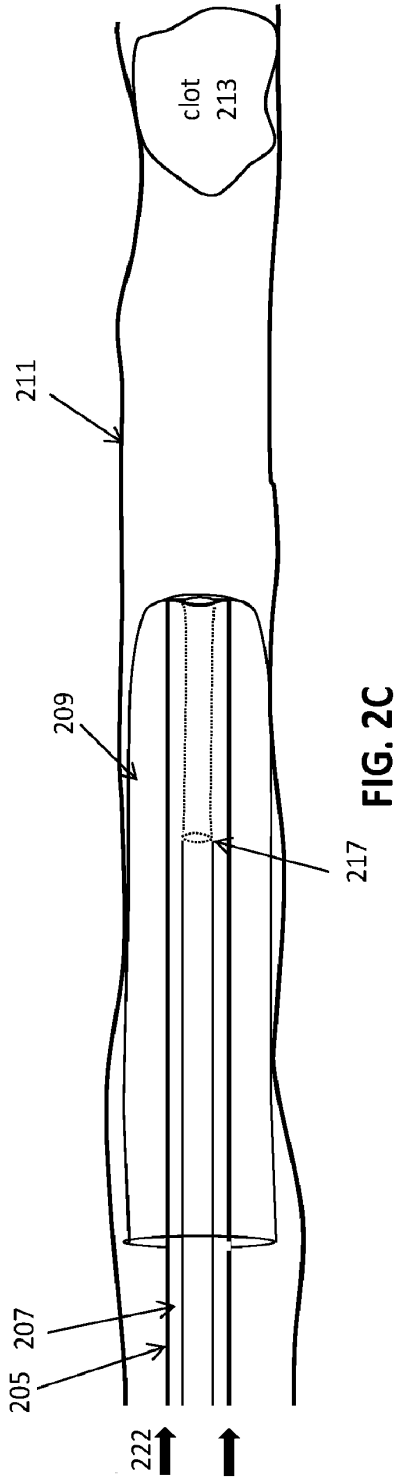


FIG. 2C

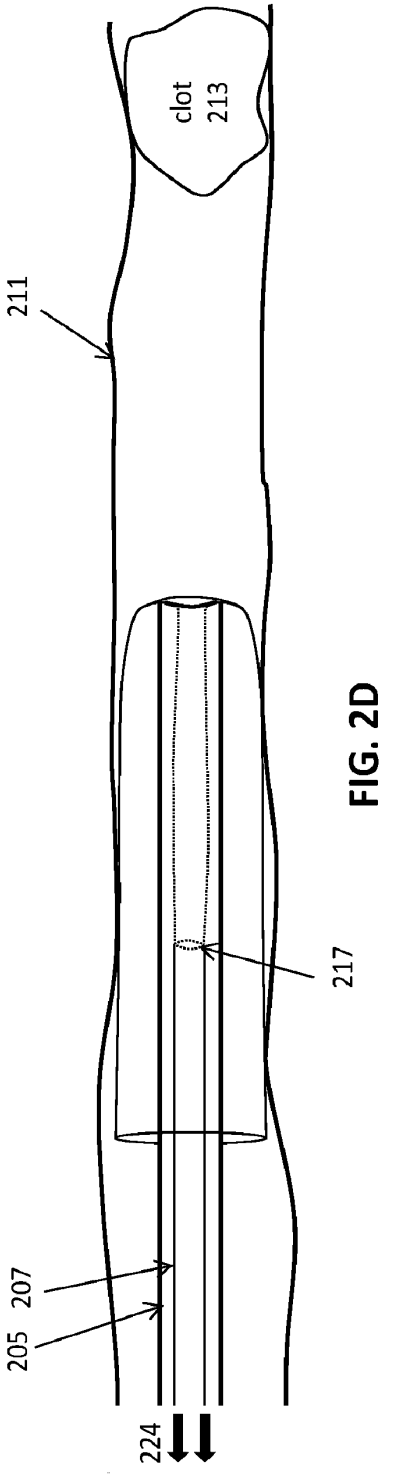


FIG. 2D

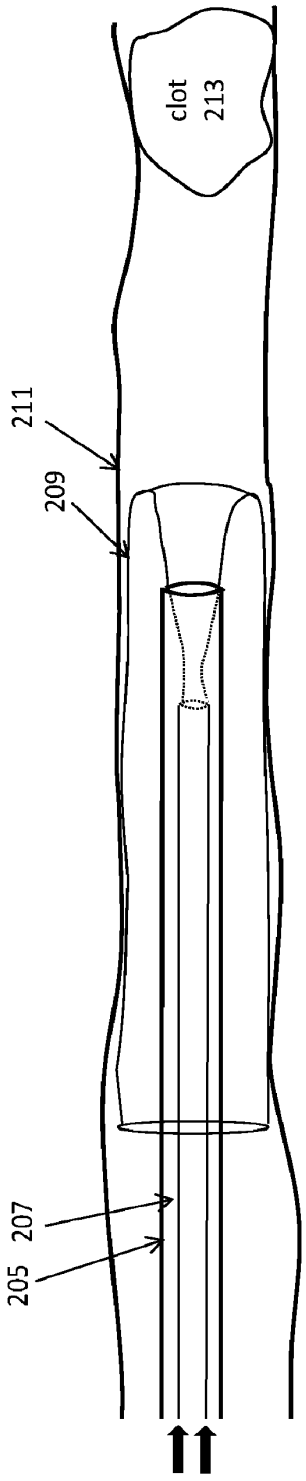


FIG. 2E

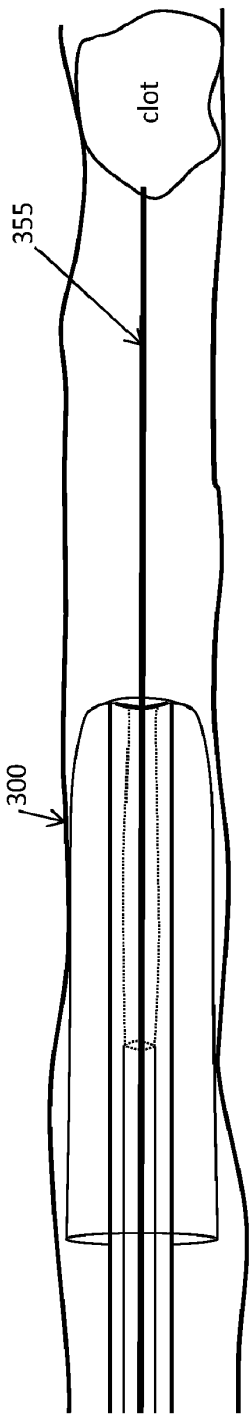


FIG. 3A

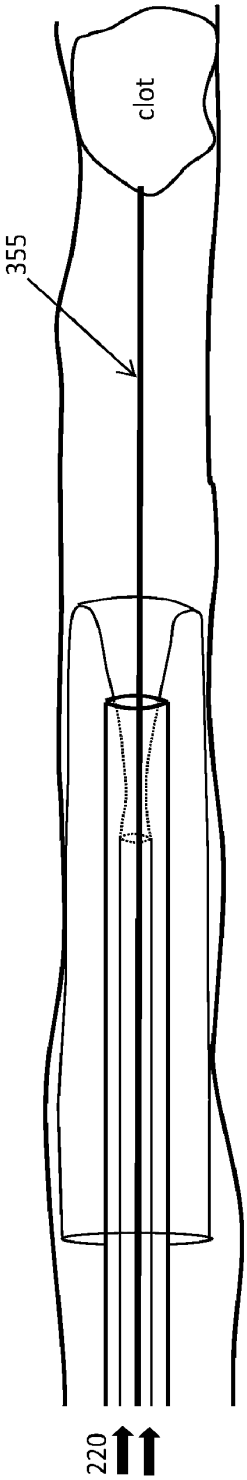


FIG. 3B

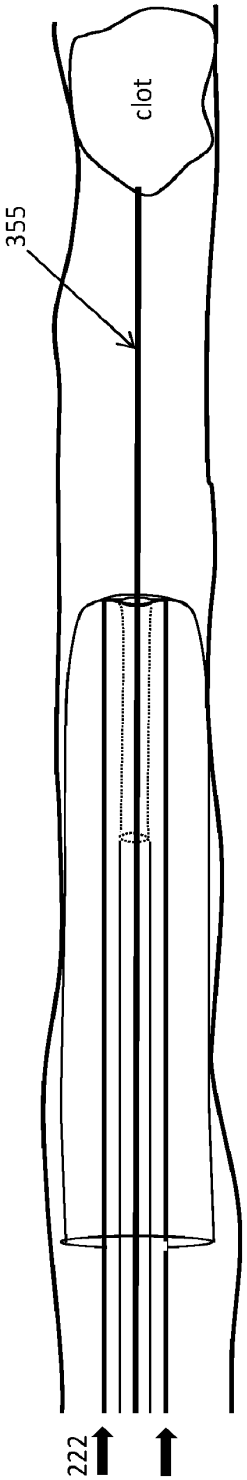


FIG. 3C

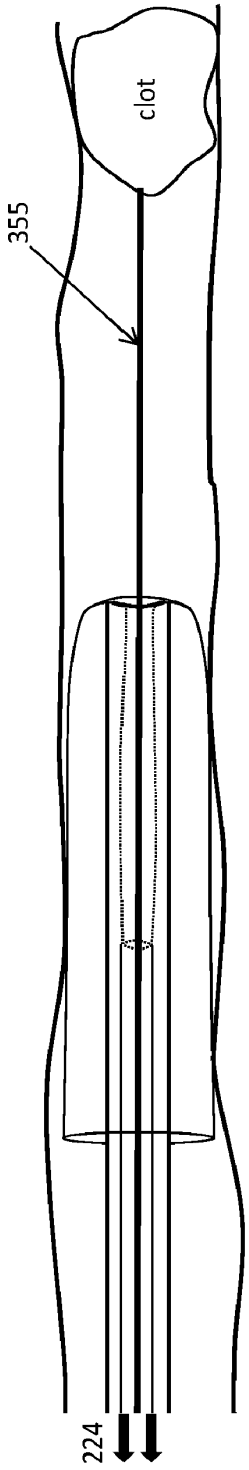


FIG. 3D

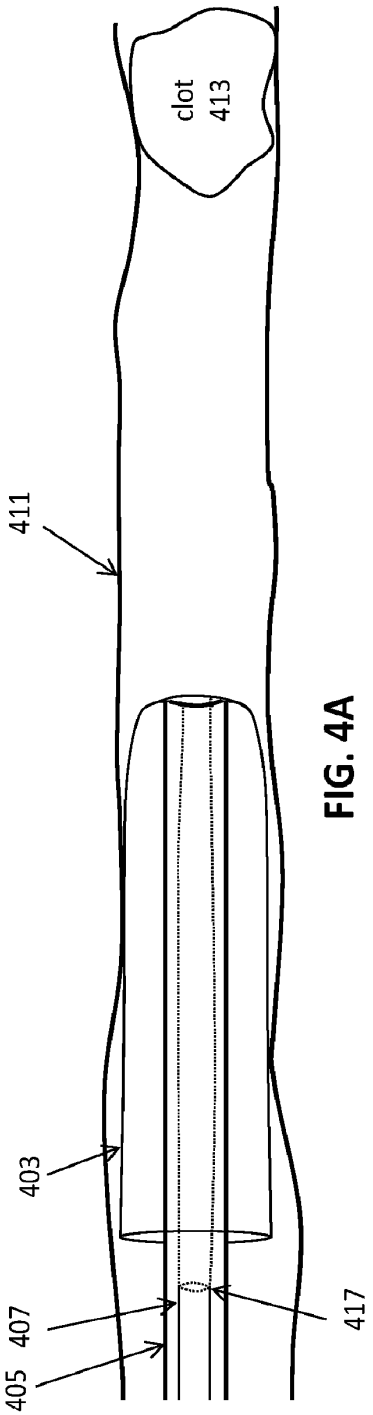


FIG. 4A

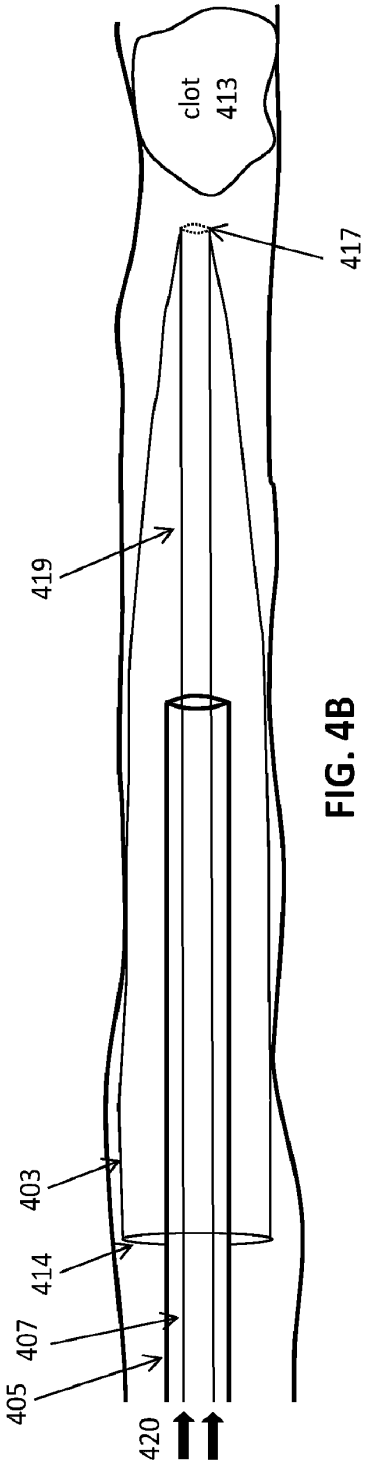


FIG. 4B

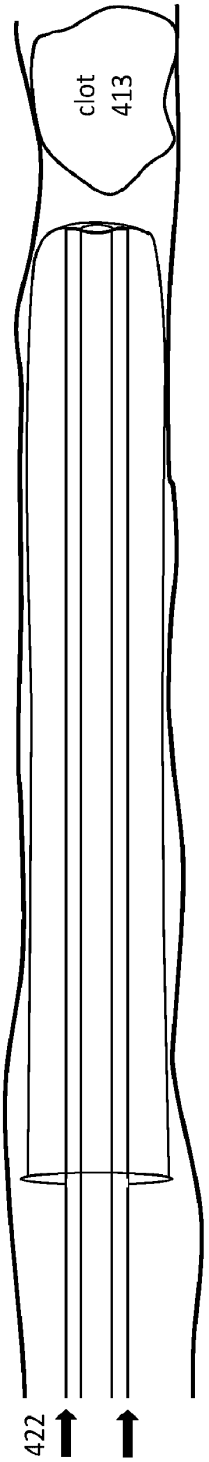


FIG. 4C

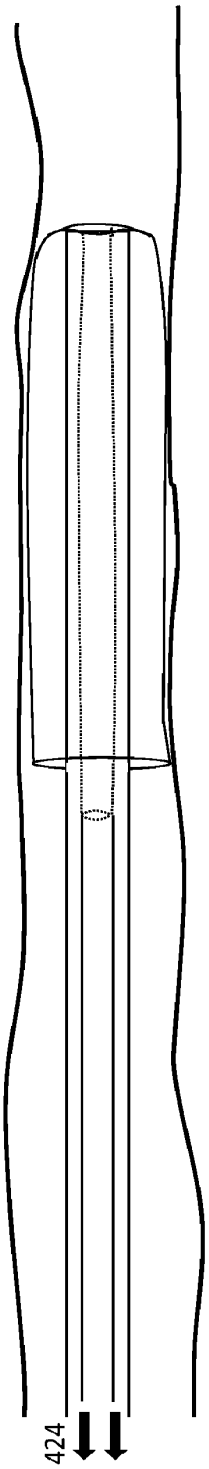


FIG. 4D

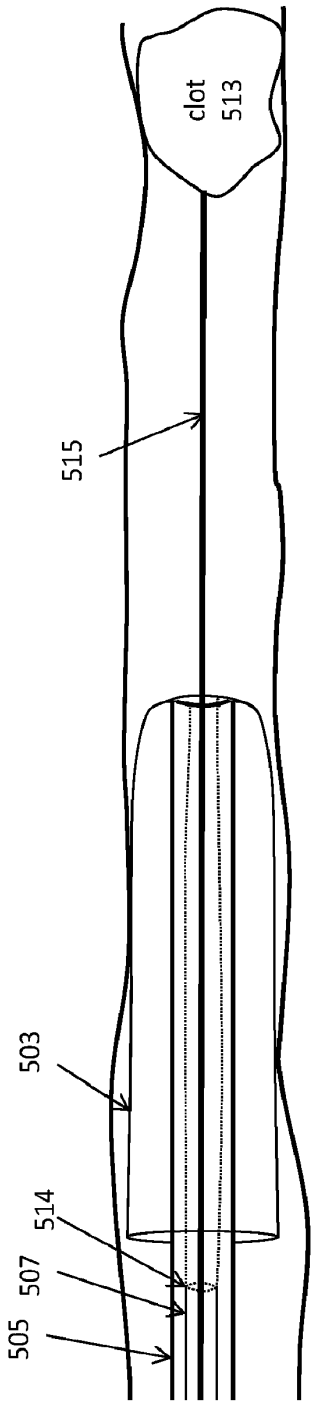


FIG. 5A

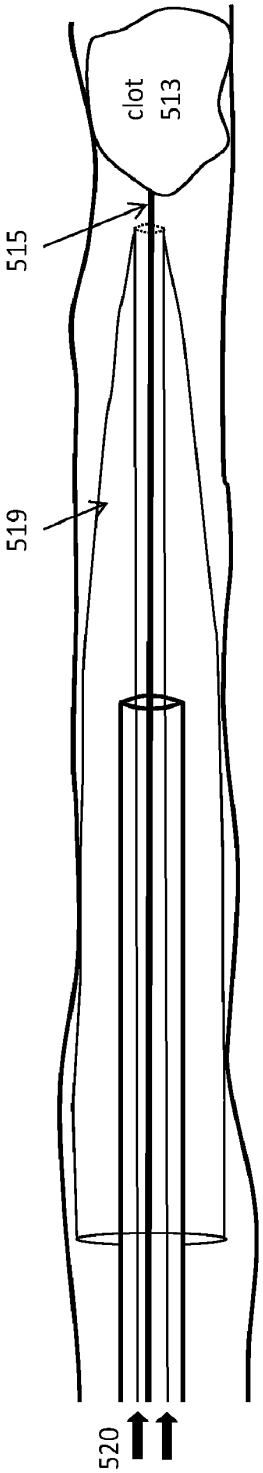


FIG. 5B

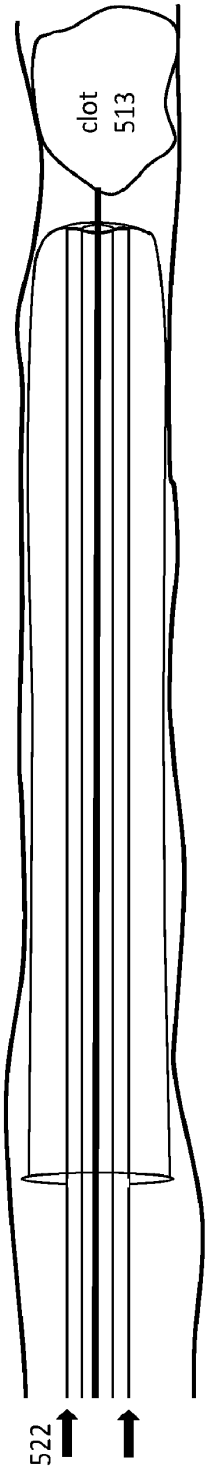


FIG. 5C

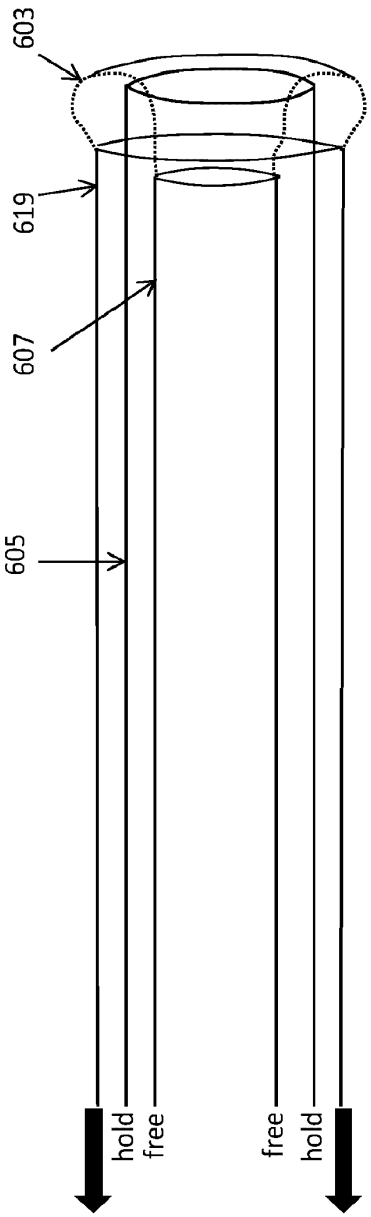


FIG. 6A

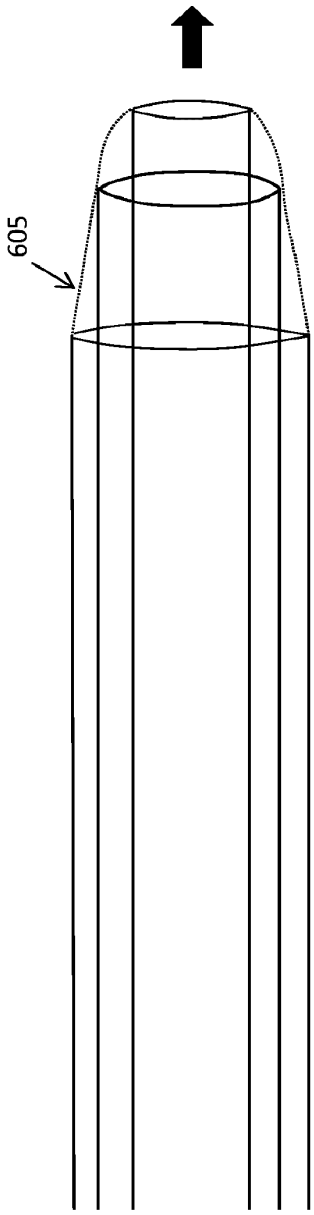


FIG. 6B

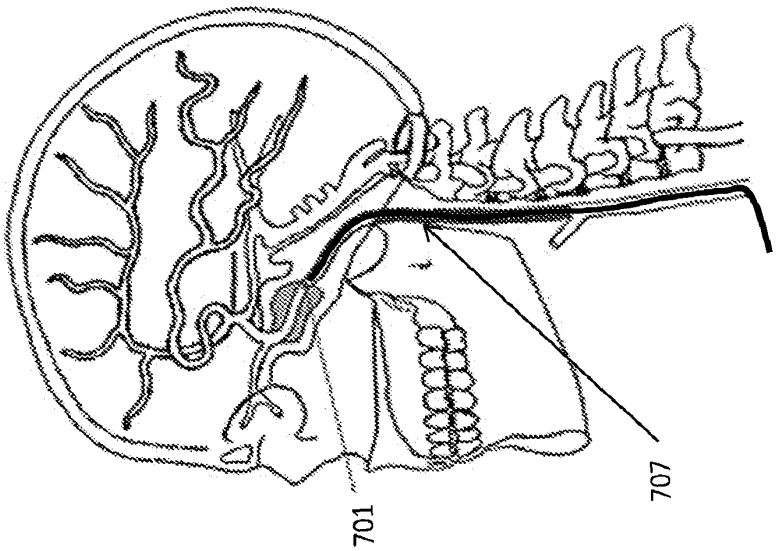


FIG. 7

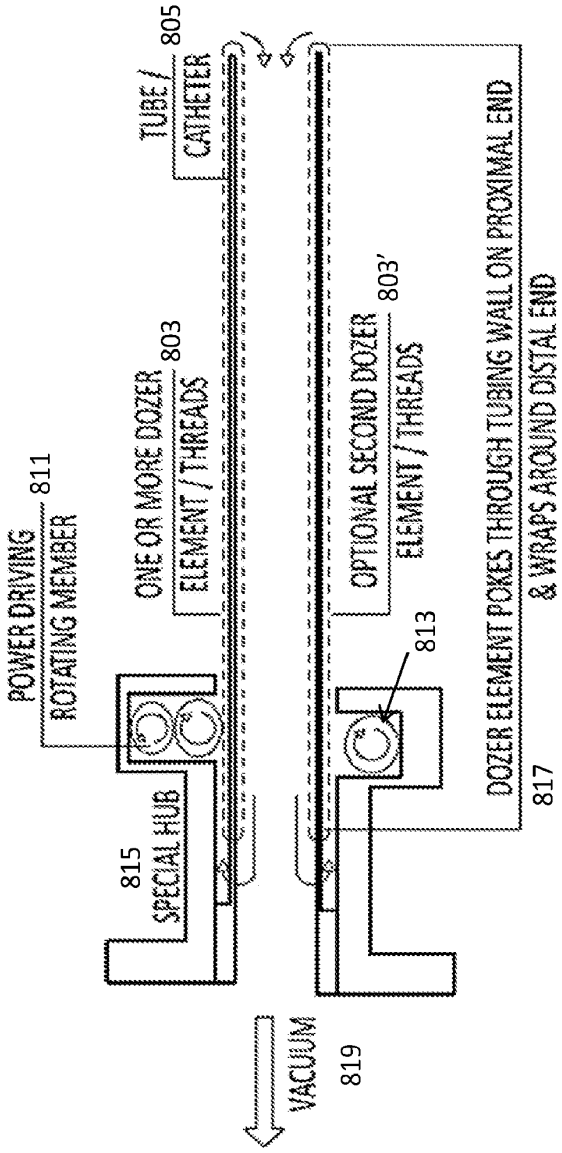

POWER DRIVING
ROTATING MEMBER
811
ONE OR MORE DOZER
ELEMENT / THREADS
803
TUBE /
CATHETER
805
OPTIONAL SECOND DOZER
ELEMENT / THREADS
803'
813
DOZER ELEMENT POKES THROUGH TUBING WALL ON PROXIMAL END
& WRAPS AROUND DISTAL END
817
815
SPECIAL HUB
VACUUM
819

FIG. 8A

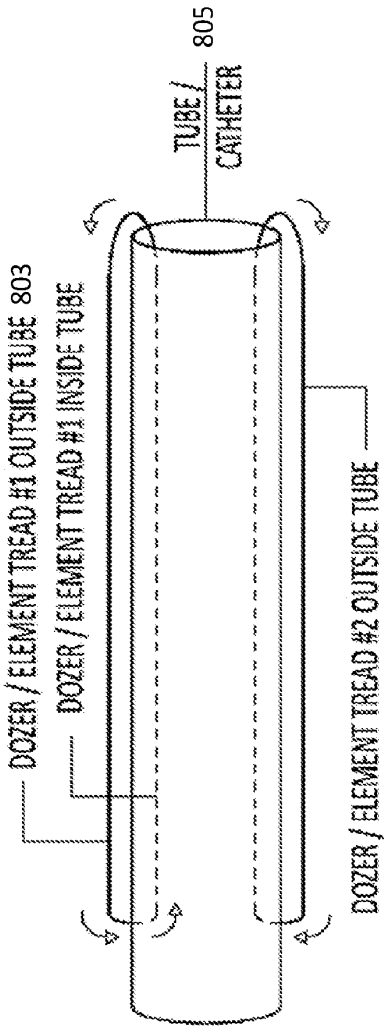

TUBE /
CATHETER
805
DOZER / ELEMENT TREAD #1 OUTSIDE TUBE 803
DOZER / ELEMENT TREAD #1 INSIDE TUBE
DOZER / ELEMENT TREAD #2 OUTSIDE TUBE
803'

FIG. 8B

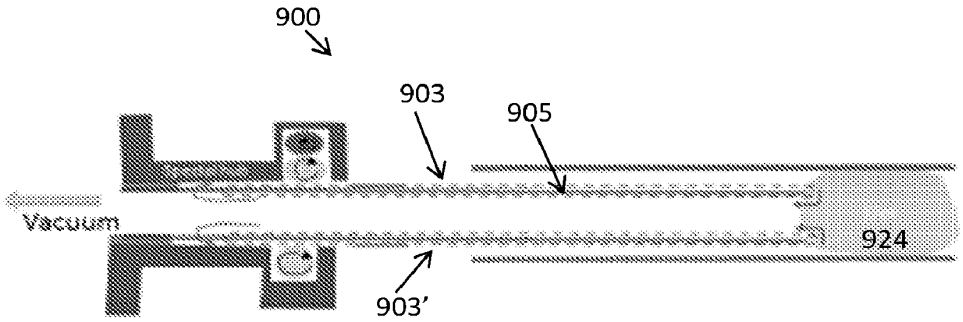


FIG. 9A

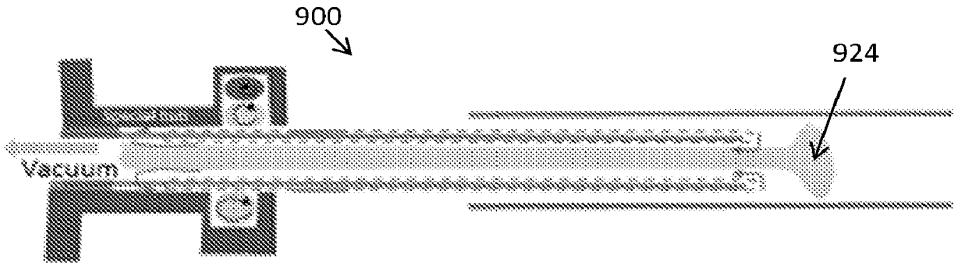


FIG. 9B

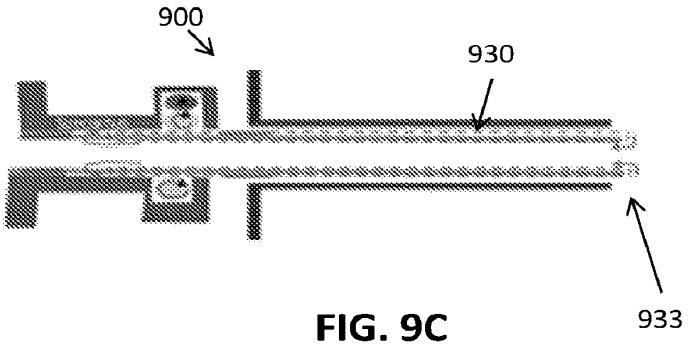


FIG. 9C

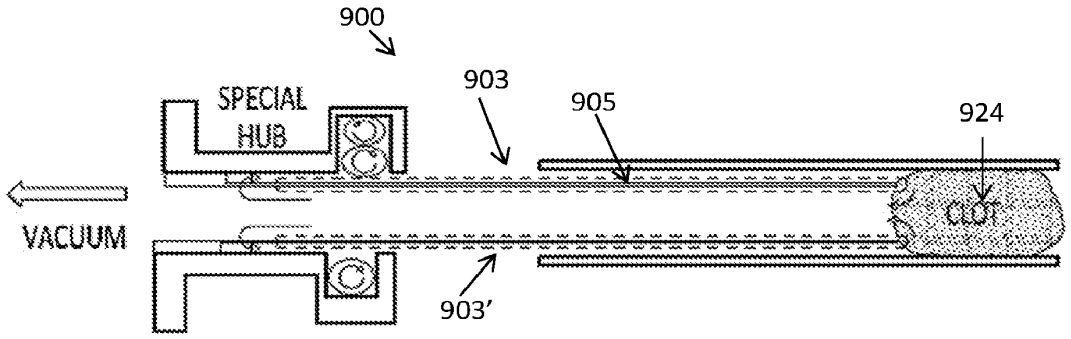


FIG. 9A

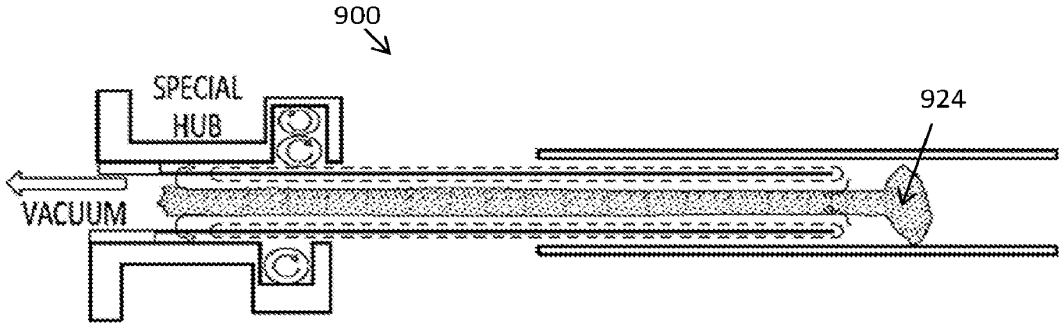


FIG. 9B

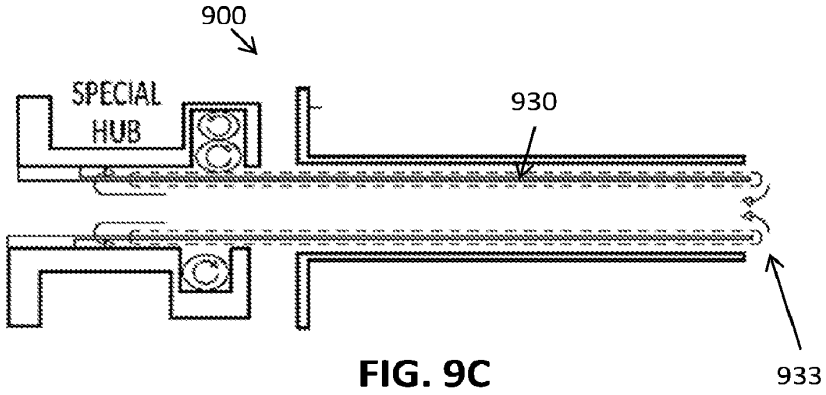


FIG. 9C

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2012/009675 A2 (LAZARUS EFFECT, INC.) 19 January 2012 (2012-01-19) paragraphs [0152], [0153], [0167] - [0170]; figures 10, 13B	1
A	GB 2 498 349 A (COOK MEDICAL TECHNOLOGIES LLC) 17 July 2013 (2013-07-17) abstract; figures page 8, line 12 - page 11, line 16	1
A	US 2013/096571 A1 (MASSICOTTE ET AL.) 18 April 2013 (2013-04-18) abstract; figures	1
A	US 2006/089533 A1 (ZIEGLER ET AL.) 27 April 2006 (2006-04-27) figures	1

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

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

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

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 June 2017	07/07/2017

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

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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	WO 00/32118 A1 (ATROPOS LIMITED) 8 June 2000 (2000-06-08) figures -----	1
A,P	WO 2017/058280 A1 (GW MEDICAL LLC) 6 April 2017 (2017-04-06) the whole document -----	1

1

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/029440

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

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

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

2. ☒ Claims Nos.: 7-24
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

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

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

This International Searching Authority found multiple inventions in this international application, as follows:

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

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

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

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

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 7-24

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2017/029440

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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(54) **Title:** RETRIEVAL SYSTEMS AND METHODS FOR USE THEREOF

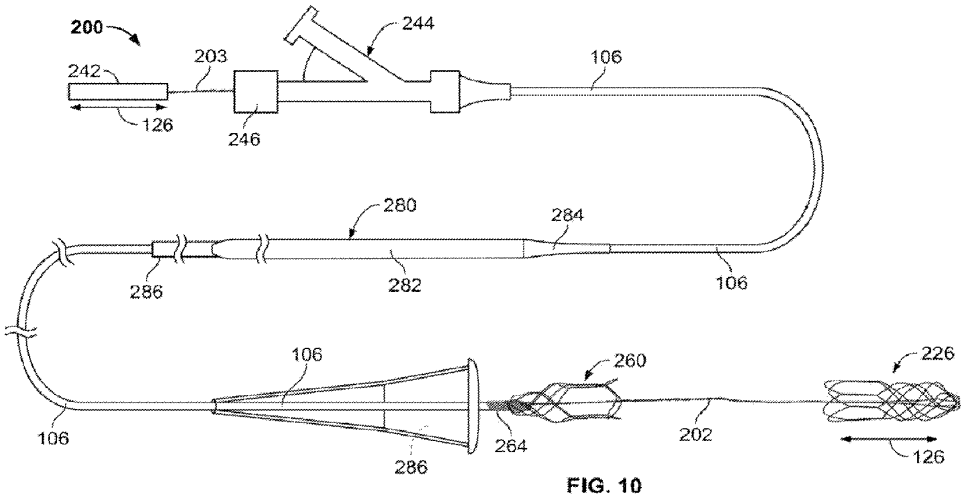


FIG. 10

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

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RETRIEVAL SYSTEMS AND METHODS FOR USE THEREOF

RELATED APPLICATIONS

[0001] This application is a non-provisional application of U.S. Provisional Application No. 61/016,651 filed on December 26, 2007, the entirety of which is incorporated by reference herein.

FIELD OF THE INVENTION

[0002] The devices described herein are intended to retrieve obstructions from the body. In a first variation, the devices are constructed in wire form where the wires diverge from a main bundle to form a variety of shapes that form a composite device. The benefit of such a diverging wire construction is that the composite complex device can be of a "joint-less" construction. Such devices have applicability through out the body, including clearing of blockages within body lumens, such as the vasculature, by providing a capturing portion that can envelop the obstruction to address the frictional resistance between the obstruction and body lumen prior to attempting to translate and/or mobilize the obstruction within the body lumen. In addition, the devices described below include features that prevent unwanted and premature mobilization of the obstruction when removing the obstruction through tortuous anatomy.

BACKGROUND OF THE INVENTION

[0003] Many medical device applications require advancement of device in a reduced profile to a remote site within the body, where on reaching a target site the device assumes or is deployed into a relatively larger profile. Applications in the cerebral vasculature are one such example of medical procedures where a catheter advances from a remote part of the body (typically a leg) through the vasculature and into the cerebral region of the vasculature to deploy a device. Accordingly, the deployed devices must be capable of achieving a larger profile while being able to fit within a small catheter or microcatheter. In addition, the degree to which a physician is limited in accessing remote regions of the cerebral vasculature is directly related to the limited ability of the device to constrain into a reduced profile for delivery.

[0004] Treatment of ischemic stroke is one such area where a need remains to deliver a device in a reduced profile and deploy the device to ultimately remove a blockage in an artery leading to the brain. Left untreated, the blockage causes a lack of supply of oxygen and nutrients to the brain tissue. The brain relies on its arteries to supply oxygenated blood from the heart and lungs. The blood returning from the brain carries carbon dioxide and cellular waste. Blockages that interfere with this supply eventually cause the brain tissue to stop functioning. If the disruption in supply occurs for a sufficient amount of time, the continued lack of nutrients and oxygen causes irreversible cell death (infarction). Accordingly, immediate medical treatment of an ischemic stroke is critical for the recovery of a patient.

[0005] Naturally, areas outside of ischemic stroke applications can also benefit from improved devices. Such improved devices can assume a profile for ultimate delivery to remote regions of the body and can remove obstructions. There also remains a need for devices and systems that can safely remove the obstruction from the body once they are secured within the device at the target site. Furthermore, there remains a need for such devices that are able to safely removed once deployed distally to the obstructions in the even that the obstructions is unable to be retrieved.

[0006] Accordingly, a need remains for devices that can assume deployed configurations and are fabricated to eliminate or reduce the number of joints and/or connection points in the device.

SUMMARY OF THE INVENTION

[0007] The examples discussed herein show the inventive device in a form that is suitable to retrieve obstructions or clots within the vasculature. The term obstructions may include blood clot, plaque, cholesterol, thrombus, naturally occurring foreign bodies (i.e., a part of the body that is lodged within the lumen), a non-naturally occurring foreign body (i.e., a portion of a medical device or other non-naturally occurring substance lodged within the lumen.) However, the devices are not limited to such applications and can apply to any number of medical applications where elimination or reduction of the number of connection points is desired.

[0008] One variation of the device includes a medical device for removing an obstruction from a blood vessel, the medical device comprises a main bundle comprising a group of wires having a first end and a second end, a capturing portion formed by the group of wires and having a translating surface adjacent to a capturing surface, the translating surface having an open proximal end and the capturing surface having a permeable distal end, where the capturing portion is formed from the group of wires such that the group of wires diverges from the second end of the main bundle to form the permeable distal end, the group of wires extend back in a proximal direction to form the capturing surface, the translating surface, and open proximal end about the main bundle; and where the translating surface and capturing surface are configured so that a translating surface axial strength is greater than a capturing surface axial strength, wherein application of a tensile force on the main bundle causes axial compression of the capturing surface without causing axial compression and deformation of the translating surface sufficient to deform the translating surface as the capturing portion engages the obstruction.

[0009] The medical device can include a capturing surface that is configured to generate a spring force against the translating surface when a proximal force applied by the main bundle of wires compresses the capturing surface against the translating surface when encountering resistance from the obstruction, where the capturing surface is configured to have a sufficient axial stiffness to direct the spring force and proximal force to the open proximal end as the open proximal end engages the obstruction where the capturing surface is also sufficiently flexible to conform to a shape of the vessel.

[0010] In another variation, the capturing section is configured so that when the open proximal end of the translating section engages resistance equal to or greater than a threshold force, proximal movement of the leading wire inverts the capturing section within the translating section and reduces a size of the capturing section to enable the capturing section to re-enter a catheter.

[0011] In those variation of the device that are navigated in tortuous anatomy (such as the cerebral vasculature), the device can include a main bundle joined to a proximal bundle, where the proximal bundle comprises a stiffness greater than the main bundle and where the main bundle extends for at least a predetermined range

from the permeable distal end to allow navigation of a distal portion of the medical device within the cerebral vasculature.

[0012] Another variation of the device includes a retrieval device for removing an obstruction from a body lumen, the system comprising at least one leading wire; a retrieval body comprising a translating section adjacent to a capturing section, the translating section having an open proximal end and the capturing section having a permeable distal end, where the leading wire is extends to a portion of the capturing section to permit articulation of the open proximal end relative to the leading wire; and where the translating section and capturing section are configured so that a translating section axial strength is greater than a capturing section axial strength, wherein application of a tensile force on the leading wire causes axial compression of the capturing surface without causing axial deformation of the translating surface when the retrieval body engages the obstruction.

[0013] Variations of the retrieval system can also include a sheath having a hub located at a proximal end, a proximal capture portion affixed to a distal end of the sheath, at least one leading wire extending through the sheath, where a distal section of the leading wire comprises a distal stiffness and where a proximal section of the leading wire comprises a proximal stiffness, where the proximal stiffness is greater than the distal stiffness, a distal capturing portion at the distal end of the leading wire, the distal capturing portion being axially moveable relative to the proximal capture portion, and an insertion tool slidably located over the sheath, the insertion tool comprising a gripping region affixed to a rigid section, where compression of the gripping portion creates a frictional fit between the insertion tool such that when the insertion tool is coupled to the catheter, compression of the gripping portion and axial movement of the insertion tool advances the sheath within the catheter.

[0014] In one variation of the devices described herein, the device comprises a main bundle or group of wires that diverge to form a device having various shapes but few or no connections points or joints (where fabrication of such a construction is referred to as "jointless"). Clearly, the inventive devices described herein are not limited to such a jointless construction. Additional variation includes one or more leading wires that are attached to a capturing portion as described below.

[0015] In another variation, the device includes a main bundle comprising one or a group of wires. The device also includes a capturing portion formed by the wires or wire of the main bundle. The capturing portion includes a cavity or space that is able to surround the obstruction. Accordingly, the capturing portion includes an open proximal end, a permeable distal end, and a capturing surface extending therebetween. The permeable distal end should be sufficiently permeable to allow blood to flow but have sufficient surface area to prevent escape of the obstruction or to prevent particles such as pieces of clot or emboli that would otherwise cause a complication if such pieces migrate through the body. In some variations of the device, the capturing portion is formed from the group of wires such that the group of wires diverges from the second end of the main bundle to form the permeable distal end, the group of wires extend back in a proximal direction to form the capturing surface and open proximal end about the main bundle. Although some closing of the open proximal end can occur, it will not be sufficient to interfere with the obstruction as the capturing portion moves over the obstruction. In some variations, the permeable end may be the distal end or be towards the distal end (meaning anywhere past a proximal end). The terms distal and proximal are relative to the physician (e.g., the distal end is the farthest end from the catheter/physician).

[0016] The devices of the present invention typically include a main bundle from which the wires extend. In most case, the main bundle extends for a length sufficient to withdraw the device from a body of a patient. Accordingly, in such cases, the main bundle shall extend through the length of a catheter. In alternate constructions, the main bundle may be affixed to a single wire or member. In such cases, a main bundle does not extend from the capturing portion to the exterior of the patient. Instead, a single wire extends to the operator interface of the device where the wire is affixed to a main bundle.

[0017] Devices of the present invention can incorporate any number of wires of different characteristics including, but not limited to, materials, shapes, sizes and/or diameters. Clearly, the number of permutations of device configurations is significant. Providing devices with such a composite construction allows for the manipulation of the device's properties to suite the intended application.

[0018] In an additional variation, the surface of the capturing portion can include a wire frame structure, a mesh, a single wound wire, a film, a membrane, a polymer

covering, and a plurality of crossing wires or a heterogeneous mixing of these. In additional variations, a section of the capturing portion can include wires, while another section of the capturing portion can include a film. Clearly, any number of permutations is within the scope of this disclosure. In any case, the capturing surface should prevent the obstruction from escaping as the device is removed from the body. Clearly, the capturing surface can comprise any number of shapes or configurations.

[0019] As noted herein, the joint-less construction improves the flexibility and strength of the device by eliminating joints, connection points, or other attachment points. In addition, the joint-less construction improves the ability of the device to be delivered through a small microcatheter. As a result, the device and microcatheter are able to access remote regions of the vasculature.

[0020] The devices may be fabricated to be self-expanding upon deployment from a catheter. Alternatively, the devices can be constructed from shape-memory alloys such that they automatically deploy upon reaching a pre-determined transition temperature.

[0021] The devices of the present invention may also include features to prevent migration of the obstruction as the capturing portion encapsulates the obstruction. For example, a proximal foot (such as region of increased surface area) can be located on or in the catheter. In another variation, an additional capture portion is located on the catheter where the proximal end of this capture is a mesh, a single wound wire, a film, a membrane, a polymer covering, or a plurality of crossing wires affixed to or in the catheter. Accordingly, the capturing portions both envelope or surround the obstruction as they are moved together. As noted below, additional variations may allow for temporarily locking of the two capturing portions together for increase effectiveness in removing the obstruction from the body.

[0022] The capturing portions disclosed herein can include mechanical features that assist in removal of the obstruction. These features can be hooks, fibers, barb, or any such structure. Any portion of the capturing portion or even the device can have such hooks, fibers, or barbs that grip into the obstruction as the device surrounds the obstruction. It will be important that such features prevent the obstruction from sliding proximally but do not hinder the ability of the practitioner to remove the device from the body.

[0023] The operation of the devices and method described herein secure the obstruction, overcome the friction forces acting on the obstruction, and then remove the obstruction from the anatomy without losing or fractionating the obstruction. In a first variation, the inventive method includes advancing a catheter distal to the obstruction, deploying a first capturing portion distal of the obstruction, where the first capturing portion comprises a translating surface and a capturing surface, the translating surface having an open proximal end and the capturing surface having a permeable distal end, and at least one leading wire affixed to the capturing surface and extending through the capturing portion and through the catheter, where the translating surface and capturing surface are configured so that a translating surface axial strength is greater than that of a capturing surface axial strength, proximally moving the leading wire to compress the capturing surface without compressing the translating surface such that the translating surface gradually advances over the obstruction, and removing the obstruction and first capturing portion from the blood vessel

[0024] Additional variations of the method include (1) passing a catheter distally to the obstruction by passing either through the obstruction and/or between the obstruction and the vascular wall; (2) deploying a first capturing portion distally to the obstruction and the catheter is withdrawn proximal to the obstruction; (3) the capturing portion is then translated over the obstruction by withdrawing the main bundle. Since the main bundle is affixed to a distal end of the capturing portion, misalignment between the bundle and the capturing portion does not cause distortion of the open proximal end. Since the open proximal end remains expanded against the lumen wall, the capturing portion can then be advanced over the obstruction.

[0025] The method and systems may also include the use of an additional capturing portion having an open distal end. This configuration allows the first capturing portion and second capturing portion to envelop or ensnare the obstruction from both the proximal and distal sides. Additional variations even allow for temporarily locking the two capturing portions together. Such a feature increases the ability to remove the obstruction from the body

[0026] It should be noted that reference to surrounding, capturing or securing the obstruction includes partially and/or fully surrounding, engulfing, encapsulating,

and/or securing the obstruction. In any case, a portion of the device engages the obstruction prior to translation of the obstruction within the lumen.

[0027] It should be noted that in some variations of the invention, all or some of the device can be designed to increase their ability to adhere to the obstruction. For example, the wires may be coupled to an energy source (e.g., RF, ultrasonic, or thermal energy) to "weld" to the obstruction. Application of energy to the device can allow the surrounding portion to deform into the obstruction and "embed" within the obstruction. Alternatively, the device can impart a positive charge to the obstruction to partially liquefy the obstruction sufficiently to allow for easier removal. In another variation, a negative charge could be applied to further build thrombus and nest the device for better pulling force. The wires can be made stickier by use of a hydrophilic substance(s), or by chemicals that would generate a chemical bond to the surface of the obstruction. Alternatively, the filaments may reduce the temperature of the obstruction to congeal or adhere to the obstruction.

[0028] Additional variations of the invention include a reentry device for withdrawing an object into a distal end of a sheath, the reentry device comprising a elongate member having a distal portion and a lumen extending therethrough, a plurality of first tines arranged circumferentially at the distal portion, the plurality of first tines each having a distal end forming a first discontinuous funnel where the distal end of each first tine is spaced from the distal end of an adjacent first tine, wherein the first discontinuous funnel is collapsible upon withdrawal into the distal end of the sheath, a second funnel spaced proximal to the first funnel, where the second funnel is collapsible upon withdrawal into the distal end of the sheath, and wherein a distal perimeter of the first discontinuous funnel shape is distal to a distal perimeter of the second funnel.

[0029] In an additional variation, the second funnel comprises a plurality of second tines arranged circumferentially at the distal portion, the plurality of second tines each having a distal end forming a second discontinuous funnel shape where the distal end of each second tine is spaced from the distal end of an adjacent second tine.

[0030] Another example of a reentry device includes an elongate member having a distal portion and a lumen extending therethrough, the elongate member sized to slidably fit within the sheath, a first slotted funnel comprising a plurality of first tines each having free ends discontinuous with free ends of adjacent first tines, where the first

slotted funnel is collapsible upon withdrawal into the distal end of the sheath; and a second funnel located proximal to the free ends of the first tines.

[0031] The reentry device can also comprises a retrieval system for withdrawing an object into a distal end of a sheath. The term sheath, when used with a reentry device, is intended to include any tube, introducer, sheath, or access device. Typically, when the retrieval device is used with neurovascular retrieval devices, the sheath will be a femoral access sheath or device. Regardless, the reentry device includes a first elongate member having a distal portion and a lumen extending therethrough, a second elongate shaft extending through the first elongate member, a flexible layer having a first end inverted on a distal end of the second elongate shaft and a second end affixed to an exterior of the first elongated shaft, where decreasing a distance between the distal end of the second elongate shaft and the exterior of the first elongated member causes the flexible material to form a funnel when the flexible layer further inverts about the second elongate shaft.

[0032] Additional devices and methods for treating ischemic stroke are discussed in commonly assigned U.S. Patent application nos.: 11/671,450 filed February 5, 2007; 11/684,521 filed March 9, 2007; 11/684,535 filed March 9, 2007; 11/684,541 filed March 9, 2007; 11/684,546 filed March 9, 2007; 11/684,982 filed March 12, 2007, 11/736,526 filed April 17, 2007, 11/736,537 filed April 17, 2007, and 11/825,975 filed September 10, 2007; the entirety of each of which is incorporated by reference. The principles of the invention as discussed herein may be applied to the above referenced cases to produce devices useful in treating ischemic stroke. In other words, the wire-shaped construction of devices according to present invention may assume the shapes disclosed in the above-referenced cases when such a combination is not inconsistent with the features described herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] Each of the following figures diagrammatically illustrates aspects of the invention. Variation of the invention from the aspects shown in the figures is contemplated.

[0034] Fig. 1A illustrates an example of a device according to the present invention when used in a system for removing obstructions from body lumens.

[0035] Fig. 1B illustrates a first example of an obstruction removal medical device.

[0036] Fig. 1C illustrates the obstruction removal device articulating relative to leading wires (or a main bundle) without deforming an open end of the capturing portion.

[0037] Figs. 2A to 2E show a capturing portion for use with systems described herein where the capturing portion has sections of varying axial strengths. Such features can optionally be designed to provide a spring force when a section of the capturing portion is compressed and/or staged inversion of the capturing portion so that it can be removed through an immovable obstruction.

[0038] Fig. 3A illustrates a first variation of the device having a joint-less construction of a capturing portion that articulates about a main bundle of wires.

[0039] Figs. 3B to 3H illustrate various constructions of capturing portions for use in the present invention.

[0040] Fig. 4A illustrates a variation of a capturing portion having a main bundle that extends beyond a certain distance to provide a device having an extremely flexible distal region and a relatively stiff proximal region with a strong joint region that will be sufficiently spaced from tortuous anatomy during use of the device.

[0041] Fig. 4B illustrates a main bundle having a curved or shaped portion.

[0042] Figs. 4C to 4E illustrate wires of different constructions within a main bundle.

[0043] Fig. 5A illustrates am example of a proximal foot located on a catheter of the present system.

[0044] Fig. 5B illustrates a distal and a proximal capturing portion located on a system under the present invention.

[0045] Figs. 5C to 5E illustrate an overview of a variation of a delivery system employing a proximal and distal capturing portion.

[0046] Figs. 5F illustrates compression or collapsing of a proximal capturing portion about an obstruction prior to translation of the obstruction in the vessel.

[0047] Figs. 6A to 6B illustrate an example of traversing an obstruction with a sheath to deploy a distal capturing portion.

[0048] Figs. 7A to 7C illustrates a condition where a section of the capturing portion deflects to provide a spring force that gradually drives a traversing section along the obstruction.

[0049] Figs. 7D to 7G illustrate staged inversion of the distal capturing portion to allow removal of the device from an immovable clot.

[0050] Fig. 8A illustrates closure of the proximal opening of a capturing portion without the benefit of articulation of the capturing portion about a leading wire.

[0051] Fig. 8B illustrates, conceptually, one benefit of articulation of a capturing portion about a leading wire or main bundle of wires.

[0052] Figs. 8C to 8D illustrate a proximal capturing portion and a distal capturing portion approaching an obstruction.

[0053] 8F illustrates a device after securing an obstruction between proximal and distal capturing sections.

[0054] Fig. 9 illustrates a main bundle as including an increased surface area or medial foot that is used to dislodge or loosen the obstruction from a wall of the body passage.

[0055] Fig. 10 illustrates a variation of a proximal and distal end of a retrieval device.

[0056] Figs. 11A to 11C illustrate a variation of a funnel catheter useful for retrieving objects from vessels or body lumens.

[0057] Fig. 12A shows an example of a retrieval device getting caught on a guide sheath.

[0058] Figs. 12B to 12C provide illustrative examples of funnel catheter used for removal of an obstruction.

[0059] Fig. 13A to 13G illustrates another variation of a funnel catheter using a mesh or layer of material to form a funnel.

[0060] Figs. 14A to 14D illustrate additional concepts to prevent or minimize flaring of the distal capture portion so that it may be withdrawn into a guide sheath.

DETAILED DESCRIPTION

[0061] It is understood that the examples below discuss uses in the cerebral vasculature (namely the arteries). However, unless specifically noted, variations of the device and method are not limited to use in the cerebral vasculature. Instead, the invention may have applicability in various parts of the body. Moreover, the invention may be used in various procedures where the benefits of the method and/or device are desired.

[0062] Fig. 1A illustrates a system **10** for removing obstructions from body lumens as described herein. In the illustrated example, this variation of the system **10** is suited for removal of an obstruction in the cerebral vasculature. Typically, the system **10** includes a catheter **12** microcatheter, sheath, guide-catheter, or simple tube/sheath configuration for delivery of the obstruction removal device to the target anatomy. The catheter should be sufficient to deliver the device as discussed below. The catheter **12** may optionally include an inflatable balloon **18** for temporarily blocking blood flow or for expanding the vessel to release the obstruction.

[0063] It is noted that any number of catheters or microcatheters maybe used to locate the catheter/microcatheter **12** carrying the obstruction removal device **200** at the desired target site. Such techniques are well understood standard interventional catheterization techniques. Furthermore, the catheter **12** may be coupled to auxiliary or support components **14**, **16** (e.g., energy controllers, power supplies, actuators for movement of the device(s), vacuum sources, inflation sources, sources for therapeutic substances, pressure monitoring, flow monitoring, various bio-chemical sensors, bio-chemical substance, etc.) Again, such components are within the scope of the system **10** described herein.

[0064] In addition, devices of the present invention may be packaged in kits including the components discussed above along with guiding catheters, various devices that assist in the stabilization or removal of the obstruction (e.g., proximal-assist devices that holds the proximal end of the obstruction in place preventing it from straying during removal or assisting in the removal of the obstruction), balloon-tipped guide catheters, dilators, etc.

[0065] Fig. 1B illustrates a first example of an obstruction removal medical device according to the features described herein. As shown, the device **200** generally includes capturing portion **226** comprising a translating section/surface **222** and a capturing section/surface **224**. In the illustrated variation, the translating section **222** shown comprises a wire framework. However, any number of configurations is within the scope of this disclosure. In many variations of the device, the translating section **222** provides a low friction surface so that it translates over the obstruction without significantly moving the obstruction. This permits the capturing portion **226** to envelop or surround the obstruction prior to attempting to move the obstruction within the body lumen. As noted herein, the translating

section **222** attempts to reduce the outward radial force applied by the obstruction against the wall of the lumen during movement of the obstruction within the lumen.

[0066] Fig. 1B illustrates a distal section of the capturing portion **226** that serves as a capturing section/surface **232**. The capturing section **232** has an increased frictional surface (in this variation illustrated by the crossing **204** wires) so that it can capture and ultimately remove the obstruction. The frictional surface of the capturing section **232** can also be described as an increased coverage density. In essence, as the frictional surface of capturing section **232** coverage density increases, there is a greater "device" surface area to interact with the obstruction. In some variations the capturing section **232** increases in frictional surface between the translating section **234** and the end of the device **200**.

[0067] As shown, the device **200** includes a main bundle **202** comprising a group of individual leading wires **204**. In this variation, the bundle of leading wires **204** is surrounded by a coil or coiled wire **205**. The coiled wire **205** can comprise a single leading wire that joins the device **202**. Alternatively, the coiled wire **205** can extend terminate or wrap back prior to forming the capture portion **226**. Moreover, the coiled wire **205** can extend throughout a length the main bundle **202**, or along one or more segments of the main bundle **202**.

[0068] While the example shows the group consisting of four individual leading wires **204**, the bundle **202** can have any number of leading wires. In various examples 2, 4, or 8 wires were used to construct the device. In certain variations, the number of wires in the main bundle loop around from the capturing portion. For example, if 2 leading wires are used to construct the device, then when constructing the main bundle **202** 2 wires are set to extend distally towards the capturing portion, where the 2 wires are then shaped to form the capturing portion. Eventually, the wires then loop back to extend proximally away from the capturing portion. Therefore, the 2 wires are doubled in the main bundle to create 4 separate wires in the main bundle.

[0069] The individual wires **204** themselves may be comprised of a number of different "micro" filaments, wires, or a single type of wire. Variations of the wires **204** are discussed in detail below; however, the wires **204** can be strands, filaments, or any similar structure that is able to be joined to form the device. The bundle **202** may be braided, wrapped, twisted, or joined in any manner such that

they do not separate or become unbundled except where desired. For example, wires in any section of the device **200** can be bonded together (e.g., with epoxy, a polymeric coating, weld, solder, and/or adhesive, etc.) to prevent the wires from separating during deformation of the device as it deploys or removes the obstruction. In addition, the main bundle **202** can incorporate any number of features to assist in orienting the device **200** within the body passage. For example, the main bundle **202** can include a pre-set bend that would bias the capturing portion **226** in a desired orientation upon deployment as discussed below.

[0070] As also discussed below, variations of the present device **200** include capturing portions **226** where the translating section **234** provides a greater axial strength than an axial strength of the capturing section **232**. The axial strength (e.g., column strength) determines whether the respective section of the capturing portion **226** compresses when the device **200** encounters resistance from an object and as a proximal or pulling force is applied through the main bundle or leading wire **202**. In use, the translating section **234** resists axial compression and deformation so that it can locate about the obstruction. While the nature of moving the translating section will place the structure in a state of compression, there will be no visible deformation or deflection that prevents the translating section from advancing across an obstruction.

[0071] There are a number of approaches to adjust the axial strength of a capturing section **232** as well as the entire structure. In a first example, the manner in which the leading wire is wound to form the respective surface **232**, **234** impact the respective axial strength. As shown, the traversing section **234** comprises a series of wrapped wires extending in an axial direction. This axial alignment causes the wires to oppose axial forces and thus increases the axial strength of the traversing section **234** relative to the capturing section **232**. In the latter section, the wires **232** extend in a helical direction about the section **232**. Thus there is less resistance to an axial load when compared to the traversing section **234**.

[0072] Alternatively, or in combination, additional techniques can produce a device **200** with a capturing portion **226** that has sections of varying axial strength. In one example, the wire diameter can be adjusted to produce the desired column strength. Generally, for a given construction, a larger diameter wire increases the column strength of the section. In addition, larger diameter leading wires can

terminate at the translating section **234** to permit smaller diameter wires to form the capturing section **232**. In another example, the leading wire **204** composition can be selected to produce the desired axial strength. For example, drawn filled tube (DFT) wire has 30% platinum 70% nitenol. Decreasing the amount of platinum and increasing the nitenol increases the wire strength and results in higher column strength. In yet another example, the respective section, or the entire capturing portion **226**, can be processed to produce the desired axial strength. For example, changing the annealing profile (e.g., temp, time) affects the wire strength, and therefore the axial strength.

[0073] Variations of devices **200** described herein can have capturing portions with alternate configurations than those shown in above. The capturing portion **226** can include constructional designs such as a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, a film, a membrane, a polymer covering, , or a plurality of crossing wires. In variations of the device, the capturing portion **226** is sufficiently permeable to allow blood or other fluid flow therethrough. As noted above, capturing portion **226** may be any structure that covers, encapsulates, engulfs, and/or ensnares the obstruction either fully or partially. Accordingly, although the capturing portion **226** is illustrated as a filter/bag, the wires may diverge to form a coil, helical shape, other mesh structure, or any other structure that defines a space that can be translated over the obstruction to ultimately remove the obstruction **2**.

[0074] The capturing portion **226** can include an open proximal end **228**, a permeable distal end **230** and a capturing surface **232** located therebetween. The capturing surface **232** of the capturing portion **226** defines a volume, cavity, or space that is able to cover, encapsulate, envelop, engulf, ensnare and/or surround the obstruction. Generally, the term traversing wire or filament refers to the section of leading wire **204** that forms the traversing surface **238**. Generally, the traversing wires form the capturing surface **238** and then form the open proximal end **228**. As discussed herein and illustrated below, the open proximal end **228** expands within the lumen, typically to the lumen walls, so that the obstruction enters the open proximal end **228** as the bundle **202** (or leading wire) translates the device **200** proximally.

[0075] The permeable distal end **230** is typically sufficiently porous so that fluid or blood may flow through. However, the end **230** is sufficiently closed (or has an

increased surface area) so that the obstruction should not escape through the distal end **230** of the device **200**. This construction typically causes the the obstruction to become ensnared within the capturing portion **226** and prevented from passing through by the permeable distal end **230**.

[0076] As shown in Fig. 1C, an important feature of the present devices **200** is that the main bundle **202** and capturing portion **226** can articulate relative to one another without interfering with the size or profile of the open proximal end **228**. This feature is described more fully below. As shown, the main bundle **202** extends through the open proximal end **228** and through at least a the traversing section **234**capturing portion **226**.

[0077] Fig. 1C illustrates a condition where the main bundle **202** and capturing portion **226** articulate relative to one-another. Because the main bundle **202** joins the capturing section **232** at a distance from the open proximal end **228** movement of the main bundle **202** relative to an axis **236** of the capturing portion **226** does not reduce a profile of the open proximal end **228**. If the main bundle **202** were affixed or connected to the open proximal end **228**, then any movement of the bundle **202** away from the capturing portion's axis **236** would exert a force on the open end. This force, in turn, would cause the open end to narrow or deform. By doing so, the open end would not be able to uniformly expand against the lumen wall to capture the obstruction.

[0078] Turning now to the construction of the device **200**, as shown above, the main bundle or a leading wire **202** extends beyond the open proximal end **228** and forms the capturing portion. In one variation, the construction of the device relies on converging/diverging wires to form continuous shapes so that the device is completely joint or connection free. However, as noted herein, the leading wire or main bundle **202** can be affixed to a structure that forms the capturing portion via an attachment point, joint, or junction. In addition, the structures forming the capturing portion can be fabricated from such processes as laser cutting of tubes, etching, metal injection molding, or any other such process.

[0079] The devices of the present invention can also include additional features to aid in removal of obstructions. For example, as shown in Figs. 1B to 1C, the open proximal end **228** can include one or more petals or flanges **238** extending radially outward. The flanges **238** allow device **200** to have a flared structure at the open proximal end **228**. In one example, the capturing portion **226** can be slightly

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

[0080] In additional variations, the main bundle can diverge to form the capturing portion in multiple locations so long as the capturing portion's ability to articulate is not sacrificed. For example, the main bundle can diverge in several locations along the capturing surface (not shown).

[0081] Figs. 1B to 1C also shows an integrally formed reinforcement ring **240** located along the length of the capturing surface **232** (i.e., on the traversing wires). The reinforcement ring **240** can be a separate or discrete ring located on or in the capturing surface **232**. Alternatively, or in combination, the reinforcement ring **240** can be a ring shape that is integrally formed through arrangement of the wires **204** (as show in Figs. 1B to 1C). The reinforcement ring **240** assists in expanding the device when deployed in the body lumen and/or prevents the device (e.g., the open proximal end) from collapsing as the device moves within the lumen to secure the obstruction. The reinforcement ring **240** can comprise a single wire, or a twisted pair of wires. Alternatively, the rings do not need to extend entirely circumferentially around the capturing surface. Instead, a reinforcement portion may extend between adjacent traversing wires but does not necessarily extend around the circumference of the capturing section. As noted herein, reinforcement portions may extend between adjacent traversing wires in multiple locations.

[0082] Figs. 2A to 2E show several benefits of varying axial strengths of the different sections of a capture portion **226**. As shown in Fig. 2A, when the physician retrieves the capturing portion **226** by pulling on the leading wire or main bundle **202** (as shown by arrow **120**), the entire capturing portion **226** translates as shown by arrow **122**. However, when the device **200** encounters resistance (as schematically shown by force arrows **124**) the lesser axial strength of the capturing section **232** causes axial deformation or compression of the capturing section **232** (as shown by Fig. 2B). In certain variations, the capturing section **232**

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

[0083] Fig. 2C shows an additional safety benefit given the varying axial strengths of the different sections of a capture portion **226**. In the event the capturing portion **226** encounters an excessive degree or threshold of force (as denoted by arrows **124**), the reduced axial strength of the capturing section **232** can invert within the translating section **234**. As shown, the permeable distal end **230** of the capturing section **232** inverts and is pulled by the main bundle **202** within the translating section **234** and reduces in size. As shown in Fig. 2D, continued pulling on the main bundle **202** causes eventual inversion of the translating section **234** so that the capturing section **232** extends through the translating section **234** and the permeable distal end **230** is now proximal to the translating section **234**. Continuing to apply move the main bundle **202** in a proximal direction **120** inverts the capturing portion **226** as shown in Fig. 2E. As shown, the translating section **234** is now distal to the capturing section **232**. This causes a reduction in the size of the capturing portion through inversion of the capturing portion **226**. This feature permits withdrawal of the capturing portion **226** within a delivery sheath **106** or through an immobile obstruction (as discussed below). As shown below, the ability to sequentially invert the capturing portion **226** and reduce its diameter enables retrieval of the device if deployed distal to atherosclerotic plaque or an immobile object where continued pulling against the object could cause damage or tearing of the body passage or vessel wall. It was found that retrieval devices that are not constructed with regions of varying axial strength, spring function, or staged inversion can often flatten or expand in diameter when attempting to retrieve the device though an immobile or stubborn obstruction.

[0084] Fig. 3A illustrates an additional variation of a capturing portions **226** according to the present disclosure. In Fig. 3A, the main bundle **202** and the group of wires **204** branch or diverge at the permeable distal end **230** to form the capturing portion **226**. In additional variations, the main bundle **202** can branch or

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

[0085] Fig. 3B illustrates a variation having an integrated reinforcement ring **240**. Typically, the reinforcement ring **240** provides radial strength to the capturing portion **226** to prevent collapse or deformation that would otherwise interfere with enveloping the obstruction. A reinforcement ring **240** may allow for use of wires that would otherwise provide unacceptable radial strength. For example, the reinforcement ring **240** may permit use of smaller diameter wires thereby allowing the device **200** to compress to a smaller diameter during delivery via a catheter.

[0086] In addition to the reinforcement ring **240**, Fig. 3B includes an open proximal end **228** having a number of petals/flanges **238**. In this variation, although the flanges **238** intersect one another, they are independently moveable.

[0087] Fig. 3C shows a variation of a device **200** where the capturing portion **226** includes flanges **238** that are interwoven or connected with adjacent flanges **238**. (Variations include bonding or otherwise joining the adjacent flanges together.) This feature provides the flanges **238** with a higher radial strength that reduces the likelihood that the flanges **238** bend or distort when moving in the body lumen or removing the obstruction.

[0088] Figs. 3D to 3E illustrate additional variations of devices having capturing portions **226** that have a basket type configuration. As shown, the capturing portions **226** and surface **232** comprise a denser mesh of traversing wires that ultimately lead to the traversing section **234** that terminates in flanges **238** at the open proximal end **228**. In such variations, a first portion of the traversing surface **232**that is adjacent to the open proximal end has a low coverage density relative to the remaining portion of the capturing surface having a higher coverage density that eventually forms the permeable distal end **230**. This construction lowers the lowering frictional resistance of the first portion of the capturing surface when

moving over or against the obstruction but allows the remaining portion of the capturing surface to encapsulate and secure the obstruction.

[0089] As shown in Fig. 3E, the wires diverge from the main bundle towards the distal end of the capturing portion **226** to form the permeable distal end **230**. The permeable distal end **230** can actually have the same configuration as the capturing surface **232**. In other words, the permeable distal end can simply be an extension of the capturing surface that extends over the distal end of the capturing portion.

[0090] Naturally, the divergence of the wires can occur over a length of the capturing portion **226** rather than immediately at the distal end. For example, as show in Fig. 3D, the wires diverge towards a mid-section of the capturing portion and ultimately form the permeable distal end **230**.

[0091] Fig. 3F illustrates a variation of a device **200** having multiple reinforcement rings **240**. As noted above, the reinforcement rings provide additional radial strength to the capturing portion **226** as the device **200** moves within the body lumen and prevents distortion of the capturing portion **226**. However, as noted above, the device will be fabricated to provide varying regions of axial strength to allow for either the spring effect or the staged inversion discussed above. In any case, the rings **240** do not need to extend around an entire circumference of a device, variations include any number of supports that extend between adjacent traversing wires.

[0092] Fig. 3G illustrates another variation of a device **200** having a leading wire **202** extending to a distal end **230** of a capturing portion **226**. In this variation the capturing portion **226** is fabricated from a stent-type structure. As noted above, it is within the scope of this disclosure to use any type of similar structure such as a laser cut tube, a chemically etched or photo etched tube, a polymer or metal injection molded structure, a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, a film, a membrane, a polymer covering, or a plurality of crossing wires as the capturing portion **226** so long as the device can be compressed to a small size for delivery and expand after traversing the obstruction. The illustrated variation also shows a covering **270** located on the distal end **230** of the capturing portion **226**. The length of the polymeric covering **270** can vary across the capturing portion **226** to prevent the obstruction from escaping as the device is translated over the obstruction. Furthermore, the covering **270** can be polymeric or a wire mesh. However, typically the covering has sufficient porosity

to allow blood to flow through the device **200**. In this variation, the flanges **238** form the translating surface.

[0093] Fig. 3H illustrates another feature for use with system described herein. In this variation, the system includes a proximal capturing portion **260** located on an exterior of a delivery sheath **106**. The main bundle **202** extends through the sheath **106** to a distal capturing portion (not shown). As discussed below, the proximal capturing portion **260** can be similar to the distal capturing portions **226** described herein with the exception that the distal end **262** of the proximal capturing portion is open while the proximal end **264** of the proximal capturing portion is closed. Furthermore, the proximal capturing portion **260** articulates with respect to the sheath **106** much in the same manner as the distal capturing portion **226** articulates relative to the main bundle **202**. In this variation, the proximal end **264** of the proximal capturing portion **260** is tapered or has a smaller profile than the remaining proximal capturing portion **260**. Such a feature may be useful to improve the deliverability of the device to the intended site as well as to maneuver around any obstructions within the body passage. In addition, as noted below, the proximal capturing portion **260** can be compressed about the obstruction to improve the ability of the system to remove the obstruction. The construction of the proximal capturing portion **260** can optionally include variations having regions of differing axial strength, or sections capable of generating spring force. Typically, since the proximal capturing portion **260** is not advanced distal to the obstruction, the need for staged inversion is not necessary. Accordingly, any number of capturing designs can be incorporated for the proximal capturing portion.

[0094] In some variations, the leading wire can extend to the proximal end of the system for manipulation by the physician. However, it is often the case that the characteristics of the device must vary along its length. For example, when the device is intended for use in remote tortuous anatomy, the proximal section of the device is desirably stiffer (to advance the distal portion of the device to the target anatomy). However, the distal section of the device must have properties that make it suitable for the tortuous anatomy. In the case where devices are used in the cerebral vasculature, the distal section must be extremely flexible, while the proximal section should be stiff. In many cases, different material properties are

required. A problem then arises in attempting to join different materials especially in the joining region.

[0095] Conventional joining methods include soldering, welding, gluing, thermal junctions, etc. These joining methods produce an area having an increase in the stiffness of the device. For example, if two wires are to be laser welded together, then the section where they are joined has an overlap which yields greater stiffness than the rest of the wire. This increased area of stiffness is often balanced against the strength of the joined segment. If the joined region is too long, the strength will be sufficient but the increase in stiffness often prevents navigation through the tortuous anatomy. IF the joined region is too short, then the device can navigate through the anatomy but the bond is weaker and a risk of failure increases.

[0096] Fig. 4A illustrates another variation of an improvement for use with the devices described herein especially for use in tortuous anatomy such as the cerebral vasculature. In this example, the capturing portion **226** is show with a number of leading wires **204** extending proximally. To provide the desired characteristics, the leading wires **204** are joined in region **196** to wires **198** having a structure that is suitable for the proximal anatomy (e.g., the wires are larger in diameter or stiffer). To enable use of the device **200** in the cerebral anatomy without compromising bond strength characteristics or flexibility of the device **200**, the leading wires extend a pre-determined region so that the bond region **196** is placed out of the tortuous anatomy. Since the cerebral vasculature is approximately 30 centimeters in length, the leading wires **204** can extend for a length **195** of at least a predetermined length so that it remains very flexible when navigating the cerebral vasculature or other tortuous anatomy. In one example the length was 20 centimeters (but can be 30 or more centimeters). By deliberately extending the leading wires **204** by length **194**, the length of the bond region **196** can be chosen to accommodate the proximal anatomy (where a greater stiffness of the bond region **196** can be accommodated). The length of the bond region **196** can vary depending on the application (e.g., from 2 to20 cm for a device intended for cerebral the cerebral vasculature). However, the bond can extend along the entire proximal section of leading wire.

[0097] Fig. 4B illustrates an addition aspect of for use with devices described herein where the main bundle **202** has a curved or bend portion **252**. This pre-set

shape assists in orienting the capturing portion **226** within the body passage since the bend will cause the device to bias against a wall of the body passage.

[0098] Fig. 4C and 4D show cross sectional views taken along the line A-A in Fig. 4B. As shown, the wire form construction described herein allows for a number of configurations depending on the particular application. For example, the individual wires **204** (as discussed herein) may themselves comprise a bundle of smaller wires or filaments. In addition, the wires can be selected from materials such as stainless steel, titanium, platinum, gold, iridium, tantalum, Nitinol, alloys, and/or polymeric strands. In addition, the wires used in a device may comprise a heterogeneous structure by using combinations of wires of different materials to produce a device having the particular desired properties. For example, one or more wires in the device may comprise a shape memory or superelastic alloy to impart predetermined shapes or resiliency to the device. In some variations, the mechanical properties of select wires can be altered. In such a case, the select wires can be treated to alter properties including: brittleness, ductility, elasticity, hardness, malleability, plasticity, strength, and toughness.

[0099] The device may include a number of radiopaque wires, such as gold and platinum for improved visibility under fluoroscopic imaging. In other words, any combination of materials may be incorporated into the device. In addition to the materials, the size of the wires may vary as needed. For example, the diameters of the wires may be the same or may vary as needed.

[0100] In addition, the individual wires may have cross-sectional shapes ranging from circular, oval, d-shaped, rectangular shape, etc. Fig. 4C illustrates one possible variation in which a number of circular wires **204** are included with a d-shaped wire 205. Moreover, the device is not limited to having wires having the same cross-sectional shape or size. Instead, the device can have wires having different cross-sectional shapes. For example, as shown in Fig. 4D, one or more wires **205** can have a different cross-sectional shape or size than a reminder of the wires **204**. Clearly, any number of variations is within the scope of this disclosure.

[0101] To illustrate one such example, a device can have 8-12 wires made of .003" round superelastic material (e.g., nitinol). The device may additionally have 2-4 wires made from .002" platinum for fluoroscopy. Of the 8-12 nitinol wires, 1-4 of these wires can be made of a larger diameter or different cross-section to increase the overall strength of the device. Finally, a couple of polymer fibers can

be added where the fibers have a desired surface property for clot adherence, etc. Such a combination of wires provides a composite device with properties not conventionally possible in view of other formation means (such as laser cutting or etching the shape from a tube or joining materials with welds, etc.). Clearly, any number of permutations is possible given the principles of the invention.

[0102] In another example, the device may be fabricated from wires formed from a polymeric material or composite blend of polymeric materials. The polymeric composite can be selected such that it is very floppy until it is exposed to either the body fluids and or some other delivered activator that causes the polymer to further polymerize or stiffen for strength. Various coatings could protect the polymer from further polymerizing before the device is properly placed. The coatings could provide a specific duration for placement (e.g., 5 minutes) after which the covering degrades or is activated with an agent (that doesn't affect the surrounding tissues) allowing the device to increase in stiffness so that it doesn't stretch as the thrombus is pulled out. For example, shape memory polymers would allow the device to increase in stiffness.

[0103] In another variation, one or more of the wires used in the device may comprise a Drawn Filled Tube (DFT) such as those provided by Fort Wayne Metals, Fort Wayne, Indiana. As shown in Fig. 4E, such a DFT wire 252 comprises a first material or shell 208 over a second material 210 having properties different from the outer shell. While a variety of materials can be used, one variation under the present devices includes a DFT wire having a superelastic (e.g., Nitinol) outer tube with a radiopaque material within the super-elastic outer shell. For example, the radiopaque material can include any commercially used radiopaque material, including but not limited to platinum, iridium, gold, tantalum, or similar alloy. One benefit of making a capturing portion from the DFT wire noted above, is that rather than having one or more markers over the capturing portion, the entire capturing portion can be fabricated from a super-elastic material while, at the same time, the super-elastic capturing portion is made radiopaque given the core of radiopaque material within the super-elastic shell. Clearly, any composite DFT wire 252 can be incorporated into the system and capturing portions described herein.

[0104] Fig. 5A shows a working end of a variation of a system **10** for removing an obstruction from a body lumen. In this variation, the system **10** includes a main

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

[0105] The size of the proximal foot **256** can be adjusted depending on the target site anatomy. For example, a larger surface area can be employed if the target site is within a bifurcation of the body passage. The size of the proximal foot **256** can also be adjustable during the procedure. For example, in the case of a petal/flange **258** configuration, the petals **258** can assume a larger size to initially stabilize the obstruction and then reduce in size to allow the obstruction to be completely engulfed by capturing section **226**.

[0106] The proximal foot **256** can extend from an interior of the catheter **102**, such as from within the internal lumen of the catheter, or from an additional lumen within a wall of the catheter. Alternatively, the proximal foot **256** can be permanently affixed to the catheter **102**. In such a case, a separate catheter (without a proximal foot) can be employed to traverse the obstruction for deployment of the device distally to the obstruction. Once the device is deployed, the catheters can be exchanged to provide the proximal foot. In an additional variation, the proximal foot **256** can be affixed to a delivery sheath (as described below) and be collapsed within the catheter, where advancement out of the catheter expands the proximal foot **256** so that it may function as described above.

[0107] In an additional variation, a proximal capturing portion (as shown in Fig. 3H) can be used with a foot **256** that is located about the main bundle **202**. Such a variation may or may not include a distal capturing portion. Accordingly, the construction of the proximal capturing portion (as described herein to include

sections of varying axial strength) can be used to perform a push and relax technique (similar to that of the pull and relax technique described herein).

[0108] Fig. 5B illustrates another variation of the system **10** where the system includes a proximal capturing portion **260** located on an exterior of a delivery sheath **106**. Naturally, the proximal capturing portion **260** could also be affixed to an exterior of a micro-catheter. The proximal capturing portion **260** is similar to the capturing portions **226** described herein with the exception that the distal end **262** of the proximal capturing portion is open while the proximal end **264** of the proximal capturing portion is closed. The proximal capturing portion can also optionally be configured to have regions of varying axial strength, spring rate, and various other features associated with the distal capturing portion **226**. In the illustrated variation, the capturing portion **226** and main bundle **202** move relative to the proximal capturing portion **260** to capture an obstruction. Furthermore, the proximal capturing portion **260** articulates with respect to the sheath **106** much in the same manner as the distal capturing portion **226** articulates relative to the main bundle **202**. As shown, the petals **238** on the open ends **228** and **262** can interact to nest once the capturing portions **226** and **260** are moved sufficiently close to one another. The outward force caused by the retained obstruction provides a frictional interaction between adjacent petals/flanges **238** to maintain the nesting.

[0109] Variations of the device include additional structures, such as springs, hooks, barbs, etc, to cause the open ends 228 and 262 to interlock. As noted above, a separate catheter can be used to initially deploy the capturing portion **226** beyond the obstruction. Although the capturing portions shown have the same configuration, the capturing portions **226** and **260** used in any given system do not have to match in size, shape, and configuration. For example, the proximal capturing portion can be impermeable to flow while the distal capturing portion allows flow. In another example, one basket may be undersized relative to the other to improve nesting.

[0110] In any case, the construction of the system **10** shown in Fig. 5B includes open ends **228** and **262** of capturing portions **226** and **260** that are unconnected. Accordingly, as the capturing portions **226** and **260** move towards one another as a result of the main bundle **202** translating relative to the delivery sheath **106** the open ends are free to articulate around the main bundle **202** and delivery sheath **106** respectively to remain expanded against the lumen wall.

[0111] Figs. 5C to 5E illustrate a variation of a system for delivery of the capturing portions **226** and **260**. Fig. 5C shows the proximal **260** capturing portion affixed to a delivery sheath **106**. In alternate variations, the proximal capturing portion **260** can be replaced with a proximal foot (not shown). As noted above, the main bundle or leading wires **202** extends through the delivery sheath **106** and connects to the distal capturing portion **226** beyond the opening **228** of the distal capturing portion **200**. The main bundle or leading wire **202** extends through the proximal capturing portion **260**. This allows the free ends of the capturing portions **228** and **262** to remain relatively unattached so that they can articulate and conform to the curvature of the vessels (as discussed below). The capturing portions **226** and **260**, main bundle **202** and delivery sheath **106** extend through a microcatheter **102**.

[0112] Fig. 5D illustrates a state of deployment after the microcatheter **102** traverses the obstruction (not shown). Once the microcatheter **102** is distal to the obstruction, the distal capturing portion **226** deploys from the end of the microcatheter **102**. As noted herein, the capturing portions can self-expand or can expand upon actuation by the physician. In any case, the distal capturing portion **226** should be sufficiently collapsible to remain within the microcatheter **102** for deployment distal to an obstruction. To deploy the distal capturing portion **200** from the catheter **102**, the main bundle **202** can translate to push the distal capturing portion **226** to eject it from the catheter **102**. Alternatively, the microcatheter **102** can be withdrawn from the distal capturing portion **226**.

[0113] Fig. 5E illustrates the deployment state after the catheter **102** is withdrawn proximal to the obstruction (not shown) and after the proximal capture portion **260** is delivered from the microcatheter **102**. As noted above, the proximal capture portion **260** can be affixed to an exterior of the catheter, in which case the catheter may be either de-sheathed or exchanged. Alternatively, and as shown, the proximal capturing portion **260** is affixed to a delivery sheath **106** and is fabricated to collapse within the microcatheter for ultimate deployment, whereby translating the sheath **106** delivers the proximal portion **260** from the microcatheter.

[0114] Fig. 5F shows another aspect of the system **10** where the proximal end **264** of the proximal capturing portion **260** is collapsed or compressed about an obstruction **2** prior to translation of the obstruction **2** within the vessel. In this illustration, the proximal capturing portion **260** is compressible by advancing the catheter **102** over the closed proximal end **264** of the capturing portion **260**. In

such a case, the proximal capturing portion **260** is slidable within and relative to the catheter **102.** Naturally, variations may include compressing the proximal end **264** during translation of the obstruction **2**. In either case, the proximal capturing portion **260** can be compressed in a number of different ways. For instance, the proximal basket can be compressed using a catheter **102**(as shown), or the delivery sheath **106**, or any other number of mechanisms (not illustrated).

[0115] As shown, the proximal end **264** can be compressed using a sheath **106** and/or catheter **102** However, other means of compressing may be employed (e.g., a loop structure, a tube over the sheath, a draw-string configuration, etc.) In use, once the distal capturing portion **226** is deployed distally to the obstruction **2** and the catheter **102** is withdrawn proximal to the obstruction **2**, the proximal capturing portion **260** is deployed. As the proximal capturing portion **260** partially (or totally) engulfs the obstruction **2**, the physician can collapse or compress the proximal capturing portion **260** to better secure the obstruction within the system **10**.

[0116] It is noted that any number of shapes, configurations, as well as any number of joined wires may be contemplated to form devices under the present disclosure. However, variations of the invention include selecting a number of wires to produce specific structural properties to the device. For example, the devices can have any number of wires where the limit is determined by the ability to produce a device of a sufficiently small size to access the area containing the obstruction. However, in some cases, it may be desired that wires are chosen to impart specified characteristics. For example, in the illustrated variation, the main bundle may comprise any number of wires that do not diverge to form subsequent shapes in the device. In other words, not all of the wires forming a section are required to diverge to form an adjacent section. Instead, these non-diverging wires may simply "loop" back away from the device. In an additional variation, one or more wires may diverge to form a particular portion of the capturing portion (e.g., the closed end, traversing wires, etc.). Then the wires can loop back to converge again with the main bundle.

[0117] Figs. 6A to 6E show one example of the deployment of a variation of a device according to the present invention about an obstruction in a vessel. The figures are intended to demonstrate the initial placement of the device immediately prior to removal of the obstruction.

[0118] Fig. 6A illustrates an obstruction **2** lodged within a body lumen or vessel **6**. In the case where the vessel is a cerebral artery, the obstruction may result in an ischemic stroke. Using standard interventional catheterization techniques, a microcatheter **102** and guidewire **104** traverse the obstruction. The microcatheter **102** may be advanced through the obstruction **2**. Alternatively, the microcatheter **102** may "push" aside the obstruction and is advanced around the obstruction. In any case, the microcatheter **102** travels from the near end **3** (or proximal side) of the obstruction **2** to the far end **4** (or distal side) of the obstruction **2**. It is noted that the catheter **102** may be centered or off-center with respect to the obstruction **2**. Furthermore, the device may or may not be used with a guidewire to navigate to the site and traverse the obstruction.

[0119] Some variations of the device may be placed without an accompanying guidewire. Moreover, the structures discussed herein may be directly incorporated into a guidewire assembly where deployment may require a sheath or other covering to release the components from constraint.

[0120] Fig. 6B illustrates deployment of a capturing portion **226** and main bundle **202** of the device **200** from within the microcatheter **102** distal to the obstruction **2**. Accordingly, in most variations, the capturing portion **226** is designed to fit within the catheter **102** for delivery and expand upon deployment. Alternatively, the device may be actuated to assume the desired shape (e.g., upon reaching a transition temperature where one or more wires comprise a shape memory alloy). As shown, the capturing portion **226** includes a traversing section **234** and a capturing section **232**. In some procedures the traversing section **234** engulfs the obstruction **2** with little or no complication as the main bundle **202**, catheter **102**, or sheath **106** pulls the capturing portion **226** in a proximal direction.

[0121] However, as discussed above, there may be some procedures where the distal capturing portion **226** is deployed distal to an obstruction **2** that is deposited within the vessel or lumen such that a steady translation of the capturing portion **226** will not engulf the obstruction **2**. Figs. 7A to 7G illustrate some examples of such a situation. As shown in Fig. 7A, a sheath **106** might be able to traverse the obstruction **2** to deploy the distal capturing portion **226** in preparation for engulfing the obstruction **2**. Fig. 7B illustrates a condition where the traversing section **234** engages the obstruction **2** but is unable to easily or fully engulf the obstruction **2**. However, in those variations where the capturing portion **226** includes regions

having different axial strength (as discussed above), continued pulling of the main bundle **202** in a proximal direction **120** causes the capturing section **234** to compress. When the capturing section **234** is constructed to function as spring, the deformation of the capturing section **232** stores energy from the proximal movement of the main bundle **202**. This storing of energy allows the physician to relax the pulling force **120** on the main bundle **202**. Fig. 7C shows a compressed capturing section **234**. The energy stored in the capturing section **232** gradually drives the open proximal end **228** of the translating section **234** over or along the obstruction **2**. The physician can apply this "pull and relax" technique repeatedly until the obstruction is sufficiently captured by the capturing portion **226**. In some variations, the capturing section **234** remains compressed as the obstruction **2** finally breaks loose and removed.

[0122] Fig. 7D represents the situation where a distal capturing portion distal to an object **2** that is significantly embedded within a vessel or body lumen. In such cases, the force required to remove the obstruction **2** may damage the vessel or lumen. Such obstructions include atherosclerotic plaque or other immobile objects. As shown, when the distal capturing portion **226** is pulled once the proximal force **120** reaches a threshold value (as determined by the construction of the capturing portion **226**) the capturing portion **226** undergoes a staged inversion as the permeable end **230** enters the traversing section **232**. In this variation, the permeable end **230** actually enters the obstruction **2**. The construction of the capturing portion **226** prevents flattening or expanding in diameter, where such movements would prevent removal of the capturing portion. Again, if the force applied by the capturing portion **226** breaks the obstruction **2** free. The obstruction **2** can be removed even though a part of the capturing portion **226** is within the obstruction **2** as shown in Fig. 2D.

[0123] Fig. 7E shows advanced inversion of the capturing portion **226** as the capturing section **234** is now proximal to the traversing section **232**. The traversing section **232** may be deformed upon inversion but will taper towards the capturing section **234** as the capturing section **234** passes through the obstruction **2** (typically via an opening that was previously created by advancement of a sheath **106** through or around the obstruction **2**).

[0124] Fig. 7F shows the capturing portion **226** nearly passing through the obstruction **2** so that it may be removed from the body. As shown in Fig. 7G, the

capturing portion **226** is now fully inverted and is in a state where it can re-enter a catheter for removal from the patient.

[0125] The construction described herein that allows for staged inversion of the capturing portion **2** provides a significant safety feature. A physician must undertake additional surgical intervention to remove any retrieval device that has become lodged distally to an immobile obstruction. The ability of staged inversion allows the physician to invert and remove the capturing portion **226** if application of a predetermined or threshold force is exceeded by proximal displacement of the device. This feature reduces the need for additional surgical intervention to remove a retrieval device that would otherwise become lodged or separated as a result of excessive forces being applied.

[0126] Figs. 8A to 8B illustrate an additional benefit of affixing a leading wire or bundle of wires **202** beyond a proximal opening **228** of a capturing portion **226**. Fig. 5A illustrates a basket type structure **90** where a wire **202** is affixed to a proximal end **92**. As shown, as the leading wire **202** pulls the basket **90** through tortuous anatomy **6**, the force component pulling away from an axis of the device **90** causes the proximal open end **92** to constrict or reduce in size. As shown, as the proximal end **92** approaches the obstruction **2** the perimeter of the end is not placed against the walls of the body passage **6**. As a result, the constricted opening **92** places an increased axial force on the obstruction **2** as the basket **90** translates over the obstruction **2** (because the proximal end **92** pushes against the obstruction rather than sliding around it), making encapsulation of the obstruction more difficult and possible leading to vascular damage.

[0127] Fig. 8B shows a device **200** according to the principles disclosed herein. The leading wire **202** is affixed to the distal end **230** of the capturing portion **226**. As the main bundle 202 is pulled through the curved vascular path, the capturing portion **226** pivots or articulates about the bundle 202 and remains aligned with the axis of the vessel. As a result any misalignment between the leading wire **202** and an axis of the capturing portion **226** does not affect the open proximal end **228**. As noted above, some closing of the open proximal end may occur, though it will not be sufficient to interfere with the obstruction as the capturing portion moves over the obstruction. Such a configuration allows the perimeter of the open proximal end **228** to remain against the wall of the passage **6**. As shown, because the open

proximal end **228** is not constricted, the open proximal end **228** is better suited to slide around the obstruction for eventual removal.

[0128] Fig. 8C shows withdrawal of the microcatheter **102** to the proximal side **3** of the obstruction **2** and deployment of a proximal capturing portion **260** (in alternate variations, a proximal foot can be used or the capturing portion **226** alone can be used). Again, the catheter **102** can be exchanged for a catheter **102** having a proximal capturing portion **260**. Alternatively, and as shown in the accompanying figures, the proximal capturing portion **260** can be affixed to a delivery sheath **106** that is fed through the microcatheter **102**.

[0129] As also shown in the figure, the main bundle **202** and capturing portions become misaligned due to the tortuousity of the anatomy. However, because the capturing portions **226** and **260** are able to pivot or articulate relative to the main bundle **202** and catheter **102** or sheath **106**, the open ends are able to remain against the lumen wall. In conventional devices where the open end is attached to either a wire or catheter, when the wire or catheter bends in the anatomy, the forces exerted on the open ends deform or distort the end to assume a reduced profile. Accordingly, the physician may have difficulty in removing an obstruction if the profile of the open end becomes reduced in size. Closing of the open end can also result in vascular damage if the physician applies too much force in translating the device.

[0130] Fig. 8D shows movement of the capturing portions **226** and **260** adjacent to the obstruction **2**. The proximal capturing portion **260** can remain stationary or may be advanced relative to the distal capturing portion **226**. Regardless, the physician is able to ensnare the obstruction **2** within the cavities defined by the capturing portions **226** and **260**. Fig. 8E illustrates the system as the two capturing portions are drawn together. For purposes of clarity, the obstruction is not shown. Upon sufficient advancement of the capturing portion **226** and proximal capturing portion **260** relative to one-another, flanges **238** on the respective open ends can interlock. This feature provides added safety in removing the device as the obstruction is encapsulated between the two nested portions.

[0131] Fig. 8F illustrates a device **200** after securing an obstruction between a proximal **260** and distal **226** capturing sections. As shown, the captured obstruction **2** is held between capturing portions **226** and **260** where the flanges **238** nest within one-another to "lock" the capturing portions together. In some

variations of the device, one of the capturing portions can be undersized relative to the other. This configuration allows for the undersized capturing portion to become further compressed as the devices are pulled together. The compression of the capturing surface then serves to further compress the obstruction **2** captured within the device.

[0132] The capturing portions described herein can include coverings or wrappings so long as the other features of the device are not impaired. Such coverings can be located on both capturing portions **226** and **260**, only one or more capturing portions. The covering can include a strand or fiber wrapped or woven about the section, a polymer film, or a dipped polymer coating such as silicone, urethane, etc. The coating on either capturing portion can be solid or porous. In the latter case, blood can continue to flow through the coating. In one variation, the proximal capturing portion **260** could employ a solid covering while the distal capturing portion **200** could include a porous covering. In such a case, blood or other fluid flow could be temporarily halted by the presence of the solid covering to assist in removal of the obstruction.

[0133] Fig. 9 illustrates a variation of the system where the main bundle **202** includes a medial foot **274**. The construction of the medial foot **274** can be similar to that of the proximal foot discussed above (e.g., wires looped into a petal configuration.) However, the medial foot includes a surface area or diameter larger than a diameter of the main bundle. In any case, the increased surface area of the medial foot **274** provides an increased resistance to the obstruction **2** as the distal capturing portion **200** and main bundle **202** are pulled in a proximal direction towards an obstruction **2**. The medial foot **274** engages the obstruction **2** to partially displace or loosen the obstruction from the walls of the body passage. The medial foot **274** can be slidably located on the main bundle such that after a threshold force, the medial foot moves within the distal capturing portion **200**. The main bundle **202** can include any number of medial feet **274**.

[0134] Although the illustrated variation shown above comprise open-ended, circular, looped or partial loop shape cross sectional areas, variations of the capturing portions can include any number of shapes. For example, such a shape can include a circle, an arcuate shape, a partial circular shape, a loop, an oval, a square, a rectangle, a polygon, an overlapping loop, a pair of semi-circles, etc.) The various shapes may be heat set to be either self-expanding (i.e., superelastic)

or the use of shape memory alloys can allow for the device to assume the particular shape upon reaching a desired transition temperature.

[0135] The exemplary shapes discussed above permit the shaped section to adjust in diameter in response to placement in varying diameters of body lumens. It is noted that a device may have different shaped sections on different ends of the device.

[0136] While many different shapes are contemplated to be within the scope of this disclosure, the shapes will depend upon the ultimate application of the device. As noted herein, the illustrated examples have particular applicability in retrieving obstructions from the vasculature. Accordingly, for these applications the shaped sections should form a shape so that they can expand against a vessel wall without causing trauma to the vessel. For example, upon release from the catheter, the shaped section can assume their resting shape and expand within the vessel. The resting shape can be constructed to have a size slightly greater than that of the vessel. Sizing the device relative to the target vessel may assist in placing the parts of the device against a vessel.

[0137] In an additional aspect, the shaped sections may be designed to have an unconstrained shape that is larger than the intended target vessel or simply different than a cross sectional profile of the intended vessel (i.e., not circular or tubular, but e.g., linear or other different shape). In such an example, as the shaped section is released from the delivery catheter, the shape section attempts to return to the unconstrained shape. In those variations where the unconstrained shape is different from the circular profile of the vessel, the leading wire assumes a shape that accommodates the vessel but is more rigid and stable since its unconstrained shape is entirely different from that of the vessel. In other words, the shaped section continually exerts an outward force on the vessel.

[0138] In yet another aspect, the shaped sections shown herein may not necessarily lie in the same plane. Instead, they can be axially spaced by an offset. One benefit of constructing the device to have non-planar shaped section is that the configuration might allow for delivery of the device through a smaller microcatheter because the shaped sections do not interfere with one another when collapsed to fit within the microcatheter.

[0139] Another aspect applicable to all variations of the devices is to configure the devices (whether the traversing filament or the surrounding portion) for better

adherence to the obstruction. One such mode includes the use of coatings that bond to certain clots (or other materials causing the obstruction.) For example, the wires may be coated with a hydrogel or adhesive that bonds to a thrombus. Accordingly, as the device secures about a clot, the combination of the additive and the mechanical structure of the device may improve the effectiveness of the device in removing the obstruction. Coatings may also be combined with the capturing portions or catheter to improve the ability of the device to encapsulate and remove the obstruction (e.g., a hydrophilic coating).

[0140] Such improvements may also be mechanical or structural. Any portion of the capturing portion can have hooks, fibers, or barbs that grip into the obstruction as the device surrounds the obstruction. The hooks, fibers, or barbs **154** can be incorporated into any portion of the device. However, it will be important that such features do not hinder the ability of the practitioner to remove the device from the body.

[0141] In addition to additives, the device can be coupled to an RF or other power source (such as **14** or **16** in Fig. 1A), to allow current, ultrasound or RF energy to transmit through the device and induce clotting or cause additional coagulation of a clot or other the obstruction.

[0142] The methods described herein may also include treating the obstruction prior to attempting to remove the obstruction. Such a treatment can include applying a chemical or pharmaceutical agent with the goal of making the occlusion shrink or to make it more rigid for easier removal. Such agents include, but are not limited to chemotherapy drugs, or solutions, a mild formalin, or aldehyde solution.

[0143] As for other details of the present invention, materials and manufacturing techniques may be employed as within the level of those with skill in the relevant art. The same may hold true with respect to method-based aspects of the invention in terms of additional acts that are commonly or logically employed. In addition, though the invention has been described in reference to several examples, optionally incorporating various features, the invention is not to be limited to that which is described or indicated as contemplated with respect to each variation of the invention.

[0144] Fig. 10 illustrates one variation of a retrieval device **200** including a distal capture portion **226** coupled to one or more leading wires in the form of a main bundle **202**. The main bundle extends through a sheath **106** that includes a

proximal capture portion **260**. The configuration of the retrieval device **200** can incorporate the proximal and distal capture portions discussed herein as well as various other configurations discussed in the commonly assigned patent applications noted above. In addition, the relative sizes of the various components shown in Fig. 10 and discussed below are for illustrative purposes only.

[0145] An end **264** of the proximal capture portion **260** is affixed to a distal end of the sheath **106**. However, as noted above, other variations are within the scope of the disclosure. The main bundle **202** can optionally terminate at a handle **242**. As noted above, in certain variations, the main bundle is joined to a stiffer wire or stiffer bundle of wires. This allows the device **200** to have a very flexible distal section with a relatively stiffer proximal section. Fig. 4A above, discusses placement of a joint at a location spaced from the distal section of the device so as to increase a bond strength but not impair the distal section's flexibility. In any case, the device **200** can have a proximal bundle **203** that comprises either the exposed wires or a covering/tube over the wires. In certain variations, the bundle or wire **202**, **203** can be encapsulated with a coating.

[0146] The proximal end of the sheath **106** includes a sheath handle **244**. As discussed herein, axial movement of the bundle **202** or proximal bundle **203** (typically at the handle **242**) results in movement **126**, or translation of the bundle within the sheath **106**. This action moves the distal capture portion **226** (as shown by arrows **126**). In certain variations, the device **200** is loaded into a microcatheter (not shown but discussed above) that is delivered to the site of the obstruction and crosses the obstruction.

[0147] In some variations, the sheath hub **244** includes one or more locking hubs **246**. Where actuation (either axial or rotational) of the locking hub **246** locks the main bundle **202** relative to the sheath handle **244** and sheath **106**. It follows that such locking action also locks the distal capture portion **226** relative to the proximal capture portion **260**. A variety of methods can be employed to increase a frictional interference between the locking hub **246** and the proximal bundle **203**. As a result, when a physician determines a length of an obstruction, the physician can set a spacing between the capturing portions **226** **260** by locking the proximal bundle **203** relative to the sheath hub **244**. Accordingly, the proximal bundle **203** can include any type of incremental markings to allow the physician to readily determine a spacing of the capturing portions. As illustrated, the sheath hub **244**

can include additional injection ports to deliver fluid or other substances through the sheath **106**.

[0148] As noted above, the device **200** can be used with micro-catheter. In those variations it is important that the device **200** is loaded without damaging the distal bundle **202**, capture portions **226 260**, and/or sheath **106**. As a result, the device **200** can include an optional funnel **286** that reduces the proximal capture portion **260** (and /or the distal capture portion **226**) for loading within the microcatheter and/or sheath **106**.

[0149] Another variation of the device **200** includes an insertion tool **280** slidably affixed to the sheath **280**. Because variations of the device **200** can be extremely flexible, the insertion tool **280** can be used to provide column strength to the sheath **106**, bundle **202** or other components as the device **200** is pushed into the microcatheter. The insertion tool comprises a rigid section **282** and a frictional coupler **284**. The rigid section **282** has a column strength that supports the device **200** to prevent buckling. The frictional coupler **284** can be a flexible material that allows an operator to squeeze or grip the coupler **284** to create a temporary frictional interface between the loading tool **280** and the device **200** (typically the sheath **106**). Such an action allows axial advancement of the device **200** as the loading tool **280** is advanced into the microcatheter. Once the rigid section **282** is fully inserted into the microcatheter, the operator releases the frictional coupler **284** and can withdraw the loading tool **280** from the catheter without withdrawing the device **200**. The insertion tool **280** can also include an optional loading tube **286** slidably coupled to the rigid section **282**. When used, the funnel **286** can withdraw the proximal and distal capturing portion **226 260** within the loading tube **286**. The loading tube **286** then couples to a microcatheter allowing the capturing portions to advance therein as the rigid section **282** and frictional coupler **284** advance the device **200** relative to the loading tube **286**.

[0150] Fig. 11A illustrates a funnel catheter **300** useful for retrieving objects from vessels or body lumens. Typically, when a physician captures an obstruction in various retrieval devices, the device and the obstruction are easily removed from the body by withdrawing the device and obstruction into a sheath, guide catheter or introducer ("guide catheter"). However, in some circumstances, a physician has difficulty withdrawing the obstruction loaded device within a sheath, guide catheter or introducer. Specifically, one or more components of the retrieval

device might become caught on an edge of the guide catheter. The concern may still remain even when using a guide catheter having an increased diameter (such as when the retrieval device catches on one edge of the guide catheter tip). Moreover, large guide catheters are difficult to advance within various parts of the anatomy. As a result, the obstruction loaded device must travel further. Movement of the obstruction loaded device within the body creates the risk that the obstruction will detach or break apart and cause additional adverse consequences.

[0151] The funnel catheter **300** includes a first and second slotted funnels **330, 340** located at the distal end of an inner shaft **302.** Each funnel **330 340** comprises a number of extensions or tines **332 342**. The inner shaft **302** can be cut to produce the first tines **332**. Alternatively, the first tines **332** can be affixed to a portion of the inner shaft **302**. The second slotted funnel **340** is offset in both a proximal and rotational position relative to the first slotted funnel **330**. The purpose of this dual offset is discussed in detail below. As shown, the second funnel **340** can be a slotted tube that is affixed over the inner shaft **302**. In an alternate variation, a plurality of second tines **342** can be located about the inner shaft **302** to form a second slotted funnel **340**. As shown in Fig. 11B, the tines **332 342** can be configured to expand outward (if not restrained) via use of a coil or other spring-type means. Alternatively, they can be actuated to expand outward. However, in most cases, the tines **332 342** can expand passively upon entry of the retrieval device **200**. The expansion of one or both funnels assists in receiving the retrieval device. In additional configurations, one or more funnels can be designed so that they remain in a cylindrical shape rather than expand outwards (as shown in Fig. 11C). Variations of the funnel catheter **300** can include configurations having one or more funnels, or configurations where the tines spaced or adjacent (or a combination thereof).

[0152] Fig. 11C also illustrates the dual offset nature of the dual funnel catheter **300**. The first offset is a linear offset **316** such that the distal ends of the first tines **332** or funnel **330** extends beyond a distal end of the second tines **342** or second funnel **340**. The second offset comprises a rotational offset (denoted by rotational angle **A**). For example, the illustrated rotational offset **A** is 45 degrees. However, the rotational offset can vary depending on the particular application. In most variations, the rotational offset **A** will place the second tines **342** over the gaps or spaces between the first tines **332**. The number of tines can vary depending on the

application. Variations of the funnel catheter can include discontinuous funnels with two or more tines.

[0153] Turning back to Fig. 11A, the funnel catheter **300** can optionally include any number of medical fittings or components. As shown, the catheter **300** includes a hemostasis valve or hub **306** at the proximal end. The hemostasis valve **306** can include a fluid side port **308** for delivery of fluid through the catheter **300**. The catheter **300** can also include one or more radiopaque markers **310** so that the location of the funnel or funnels **330 340** can be identified via non-invasive imaging (e.g., under fluoroscopy). The funnel catheter **300** can also optionally include one or more markers **312**. Such markers are useful to inform a physician (who is only able to view the proximal end of the device **300**) of the distance to the first or second funnel. As a result, the physician will be able to determine whether the funnels are advanced out of the guide catheter. Fig. 11A also shows the funnel catheter **300** as including a loading tool **314**. The loading tool **314** can be advanced over the funnels **330 340** to compress the funnel when loading into a guide catheter or other sheath.

[0154] Figs. 12A to 12C provide an illustrative example where use of a funnel catheter **300** aids in removal of an obstruction **2** loaded within a retrieval device **200**.

[0155] As shown in Fig. 12A, attempting to remove the obstruction **2** when engulfed in the retrieval device **200** creates a risk that one or more portions of the device **200** become caught on the guide sheath or access catheter **108**. In some cases, the physician can simply engage the device **200** against the distal end of the guide sheath **108** and withdraw until the obstruction **6** and device **200** are located in an acceptable area of the body or withdrawn entirely from the body. For example, in certain situations, the obstruction **6** and device **200** can be withdrawn with the guide sheath **108** until all components reach a high flow, non-critical locations (e.g., the groin area). In the case of a clot, a clot dissolving substance (TPA) can then be applied to dissolve and remove the clot. Alternatively, the physician can attempt to aspirate through the guide sheath **108** in an attempt to draw the entire retrieval device **200** and obstruction **2** within the guide sheath **108**. In yet another variation, the physician can advance fibers or guide wires out through the guide sheath **108**, then withdraw the obstruction **2**/retrieval device **200** and attempt to use the fibers or guide wires as a moveable surface to capture the

device **200**. Furthermore, the physician can attempt to use a variety of existing devices (e.g., the FastCath provided by Genesis Medical Inc., the Merci Retriever provided by Concentric Medical Inc., or any commercially available snare or distal protection device) to remove the engulfed obstruction **2** from the body.

[0156] In some variations, the capturing portions discussed above can be constructed to improve their ability to be withdrawn into a guide sheath. For example, increasing the number of petals or flanges on the traversing sections increases the probability that the distal flanges nest within the proximal capturing portion. Alternatively, or in combination, the petals **238** on the distal capturing portion can be staggered in length or position to ease insertion into the proximal capturing portion. In another variation, the petals **238** shape or curvature can be adjusted so that they do not flare outward.

[0157] Fig. 12B shows a distal end of a funnel catheter **300** as it receives an obstruction **2** loaded retrieval device **200**. As shown, the tines **332** of the first funnel **330** receive the device **200**. The tines **332** minimize the likelihood that the device **200** becomes caught. The limited surface area of the tine **332** (combined with the rounded tines **332 342**) produces a tendency for the device **200** to deflect away from the tines as it is withdrawn into the funnels. The second funnel **340**(being rotationally offset from the first funnel **330** provides coverage over the spaces between the first tines **332** thereby assisting in nesting of the device **200** within the funnels. Ultimately, the device **200** and obstruction **2** are withdrawn into a guide sheath **108** and removed from the body.

[0158] Figs. 12 C to 12D show additional variations of funnel catheter **300**. Fig. 12C shows a single funnel **330** having a plurality of tines **332**. Fig. 12D illustrates a dual funnel catheter **300** having a discontinuous first funnel **230** and a second funnel **346**. The second funnel **346** can be a continuous funnel so long as it is able to retract within the guide sheath **108**. As shown, the second funnel **346** can include a single slit **348** that allows the funnel to compress within the guide sheath **108**. In addition, the variation of Fig. 12D can be used without the first discontinuous funnel **330**. Accordingly, as the retrieval device **200** and clot **2** approach the funnel **346** and enters the funnel, further withdrawing the retrieval device **200** causes squeezing of the retrieval device **200** and obstruction **2**. In yet another variation, the funnel **346** can incorporate a drawstring to compress the funnel **346** once the retrieval device **200** and obstruction are located therein.

[0159] Fig. 13A to 13B illustrates another variation of a funnel catheter **350** suited to remove a retrieval device **200** from the body. As shown in Fig. 13A, the funnel catheter **350** includes a first shaft **352** and a second shaft **354** slidably located therein. A mesh **370** is fused to each shaft **352 354** at a distal location **362 364**. Accordingly, relative movement of the shafts **352 354** (either the first shaft **352** can be pushed or the second shaft **354** can be pulled) creates a funnel shape **372** as the mesh portion affixed to the second shaft **354** is inverted within the remainder of the mesh **370**. It is noted that in some variations of the system, the mesh funnel funnels are combined with the tine based funnels described above. Such that one funnel comprises the tines while the other comprises the mesh structure described herein.

[0160] In another variation, a third distally located capture portion (similar to a distal capture portion) can be used to draw the retrieval device within a guide sheath. In such a variation, the third capture portion can be a larger distal capture portion and when the retrieval device engulfs an obstruction, the third basket portion can be proximally withdrawn to capture the retrieval device and obstruction.

[0161] As illustrated in Fig. 13B, as the retrieval device **200** and obstruction **2** approach the funnel catheter **350**, the distal attachment points **362 364** of the shafts **352 354** are moved together to invert the mesh **370** and form a funnel **372**. The retrieval device **200** can then be withdrawn into the funnel. This design allows for the retrieval device **200** to be fully withdrawn into the catheter **350** while the funnel **372** is expanded. Alternatively, the funnel **372** can be used to compress the retrieval device **200** and obstruction **2** prior to withdrawal into the catheter **350**.

[0162] The mesh **370** can include any medically acceptable material such as a nitenol braid. Furthermore, the mesh allows for flow through the vessel or lumen while expanded. However, additional variations of the device can include a solid layer of material substituted for the mesh.

[0163] Figs. 13C to 13E illustrate another variation of a funnel catheter **350** suited to remove a retrieval device **200** from the body. As shown in Fig. 13C, the funnel catheter **350** includes a first shaft **352** and a second shaft **354** slidably located therein. A mesh **370** is joined only the rear shaft **354** at a distal location **362**. The end of the mesh **370** is free at the distal end of the device **350**. The mesh **370** is sized at a distal end **371** to neck down. Accordingly, as the distal shaft moves

rearward, the mesh **370** is unsupported. The necked section **371** of the mesh allows for distal advancement of the device **200** through the neck portion **371**. However, as shown by Fig. 13D, rearward movement of the device **200** causes engagement with the neck portion **371**. Further rearward movement of the device **200** causes the unsupported mesh **370** to form a funnel shape **372** as shown in Fig. 13E. The funnel shape allows for the retrieval device **200** to be fully withdrawn into the catheter **350** while the funnel **372** is expanded. Alternatively, the funnel **372** can be used to compress the retrieval device **200** and obstruction **2** prior to withdrawal into the catheter **350**. To compress the funnel, the device **200** can be advanced out of the funnel and away from the mesh **370**. Next, the distal shaft **352** can be advanced through the neck portion **371** of the mesh **370** to receive the device **200**. In another variation, the device **350** can include a single shaft **354** where the mesh **370** can extend beyond the shaft **354**. The mesh can be heat set to assume a funnel shape upon the application of a current or as it reaches body temperature. In another variation, the mesh **370** can comprise a super-elastic material that assumes the shape shown in Fig. 13E when released from a constraining member.

[0164] Figs. 13F to 13G illustrate yet another variation a funnel catheter **350** suited to remove a retrieval device **200** from the body. In this variation, the funnel catheter **350** includes a single shaft **354** having a mesh **370** is fused to a distal location **364**. The mesh **370** is free at a proximal side. The mesh is also pre-formed to assume a funnel shape as shown in Fig. 13G. Accordingly, upon delivery the mesh **370** can be constrained (e.g., via a sheath, or other removable restraint). Once the restraint is removed, the mesh **370** expands to form a funnel **372**.

[0165] Figs. 14A to 14D illustrate additional concepts for use with various retrieval devices **200**. Fig. 14A illustrates a distal capturing portion **226** and a proximal capturing portion **260** where the proximal capturing portion includes a covering **212** (e.g., a polymeric covering or a wire or fiber wound about the flanges **238**). The covering **212** prevents the flanges **238** of the distal capturing portion **226** from flaring outside of the proximal capturing portion **260**.

[0166] Fig. 14B illustrates a variation of a reentry sleeve where tines **332** of the reentry sleeve **302** include protrusions **214** on an inner surface. The protrusions **214** cause the tines **332** to splay out as the retrieval device **200** is withdrawn within

the tines **332**. As the reentry sleeve **302** is withdrawn in a guide catheter (as discussed above) the protrusions serve to compress the retrieval device **200** even further.

[0167] Fig. 14C and 14D illustrate variations of a wire or fiber **218** affixed to the flanges **238** of a distal capturing portion **226** to assist in compressing the flanges **238** prior to entry within a guide sheath. As shown in Fig. 14C the fiber **218** can be affixed to a suture ring **216**. As the fiber **218** is pulled, the suture ring **216** compresses the flanges **238** to prevent outward flaring. In Fig. 14D, one or more fibers **218** are affixed to one or more flanges **238**. Once the obstruction is captured, the fibers can be pulled to draw the flanges **238** closed.

[0168] Various changes may be made to the invention described and equivalents (whether recited herein or not included for the sake of some brevity) may be substituted without departing from the true spirit and scope of the invention. Also, any optional feature of the inventive variations may be set forth and claimed independently, or in combination with any one or more of the features described herein. Accordingly, the invention contemplates combinations of various aspects of the embodiments or combinations of the embodiments themselves, where possible. Reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in the appended claims, the singular forms "a," "and," "said," and "the" include plural references unless the context clearly dictates otherwise.

[0169] It is important to note that where possible, aspects of the various described embodiments, or the embodiments themselves can be combined. Where such combinations are intended to be within the scope of this disclosure.

CLAIMS

We claim:

1. A medical device for removing an obstruction from a blood vessel, the medical device comprising:

a main bundle comprising a group of wires having a first end and a second end;

a capturing portion formed by the group of wires and having a translating surface adjacent to a capturing surface, the translating surface having an open proximal end and the capturing surface having a permeable distal end;

where the capturing portion is formed from the group of wires such that the group of wires diverges from the second end of the main bundle to form the permeable distal end, the group of wires extend back in a proximal direction to form the capturing surface, the translating surface, and open proximal end about the main bundle; and

where the translating surface and capturing surface are configured so that a translating surface axial strength is greater than a capturing surface axial strength, wherein application of a tensile force on the main bundle causes axial compression of the capturing surface without causing axial compression and deformation of the translating surface sufficient to deform the translating surface as the capturing portion engages the obstruction.

2. The medical device of claim 1, where the capturing portion is formed such that articulation of the capturing portion relative to the main bundle does not cause the open proximal end to reduce in size.

3. The medical device of claim 1, where the capturing surface is configured to generate a spring force against the translating surface when a proximal force applied by the main bundle of wires compresses the capturing surface against the translating surface when encountering resistance from the obstruction, where the capturing surface is configured to have a sufficient axial stiffness to direct the spring force and proximal force to the open proximal end as the open proximal end engages the obstruction where the capturing surface is also sufficiently flexible to conform to a shape of the vessel.

4. The medical device of claim 1, where the capturing section is configured so that when the open proximal end of the translating section engages resistance equal to or greater than a threshold force, proximal movement of the main bundle inverts the capturing section within the translating section and reduces a size of the capturing section.

5. The medical device of claim 4, where the capturing section and traversing section are configured to invert upon continued proximal movement of the main bundle such that the traversing surface moves distally to the capturing surface.

6. The medical device of claim 1, where the main bundle is joined to a proximal bundle, where the proximal bundle comprises a stiffness greater than the main bundle and where the main bundle extends for a pre-determined distance from the permeable distal end to allow navigation of a distal portion of the medical device within the cerebral vasculature.

7. The medical device of claim 6, where the pre-determined distance is at least 20 cm.

8. The medical device of claim 1, where the capturing surface has an increased frictional resistance as compared to the translating surface, such that the capturing surface engages the obstruction for removal of the obstruction.

9. The medical device of claim 1, where the open proximal end further comprises a plurality of flanges extending from the translating surface.

10. The medical device of claim 9, where the flanges extend radially away from an axis of the capturing portion.

11. The medical device of claim 1, where the capturing portion is self-expandable.

12. The medical device of claim 1, where at least a portion of the capturing surface comprises a structure selected from the group consisting of a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, and a plurality of crossing wires or a combination thereof.

13. The medical device of claim 1, where the main bundle of wires includes at least a first wire and a second wire where the first and second wire each have different characteristics.

14. The medical device of claim 13, where the characteristics are selected from a group consisting of material, cross-sectional shape, and cross-sectional size.

15. The medical device of claim 1, where the main bundle of wires includes at least one shape memory alloy wire.

16. The medical device of claim 1, where the main bundle of wires includes at least one wire selected from the group consisting of a superelastic wire, a polymeric wire, or a metal alloy.

17. The medical device of claim 16, where the metal alloy comprises an alloy selected from the group consisting of stainless steel, titanium, platinum, gold, iridium, tantalum, nitinol, and combinations thereof.

18. The medical device of claim 1, further comprising at least one radiopaque material located on the capturing portion.

19. The medical device of claim 1, where the individual wires in the group of wires each comprise a bundle of smaller wires.

20. The medical device of claim 1, where the individual wire comprises a super-elastic outer shell and an inner core of a radiopaque material.

21. The medical device of claim 20, where the inner core comprises a material selected from a group consisting of platinum, iridium, gold, and tantalum.

22. The medical device of claim 1, where the capturing portion is jointless.

23. The medical device of claim 1, where at least one of the wires from the main bundle returns to the main bundle after forming at least a part of the capturing portion.

24. The medical device of claim 1, where each of the wires from the main bundle returns to the main bundle after forming a part of the capturing portion.

25. The medical device of claim 1, where the main bundle is surrounded by a coil or coiled wire.

26. A retrieval device for removing an obstruction from a body lumen, the retrieval device comprising:

at least one leading wire;

a retrieval body comprising a translating section adjacent to a capturing section, the translating section having an open proximal end and the capturing section having a permeable distal end, where the leading wire extends to a portion of the capturing section to permit articulation of the open proximal end relative to the leading wire; and

where the translating section and capturing section are configured so that a translating section axial strength is greater than a capturing section axial strength, wherein application of a tensile force on the leading wire causes axial compression of the capturing surface without causing axial deformation of the translating surface when the retrieval body engages the obstruction.

27. The retrieval device of claim 26, where the retrieval body is formed such that articulation of the retrieval body relative to the leading wire occurs without narrowing of the open proximal end during articulation.

28. The retrieval device of claim 26, where the capturing section is configured to generate a spring force against the translating section when a proximal force applied by the leading wire compresses the capturing section against the translating section when encountering resistance from the obstruction, where the capturing section is configured to have a sufficient axial stiffness to direct the spring force and proximal force to the open proximal end as the open proximal end engages the obstruction, where the capturing section is also sufficiently flexible to conform to a shape of the body lumen.

29. The retrieval device of claim 26, where the capturing section is configured so that when the open proximal end of the translating section engages resistance equal to or greater than a threshold force, proximal movement of the leading wire inverts the capturing section within the translating section and reduces a size of the capturing section.

30. The retrieval device of claim 29, where the capturing section and traversing section are configured to invert upon continued proximal movement of the leading wire such that the traversing section moves distally to the capturing section.

31. The retrieval device of claim 26, where the at least one leading wire is joined to at least one proximal leading wire, where the proximal leading wire comprises a stiffness greater than the leading wire and where the leading wire extends for a pre-determined distance from the permeable distal end to allow navigation of a distal portion of the retrieval device within the cerebral vasculature.

32. The retrieval device of claim 31, where the pre-determined distance is at least 20 cm.

33. The retrieval device of claim 26, where the leading wire is surrounded by a coil or coiled wire.

34. The retrieval device of claim 26, where the leading wire extends to the permeable distal end.

35. The retrieval device of claim 26, where the capturing portion comprises a structure selected from a group consisting of a laser cut tube, an etched tube, an injection molded structure.

36. The retrieval device of claim 36, where the at least one leading wire is attached to the capturing portion via a joint or junction.

37. The retrieval device of claim 26, where the translating section has a low coverage density relative to the capturing section, thereby lowering frictional resistance of the first portion of the capturing surface when moving over the obstruction.

38. The retrieval device of claim 37, where the at least one leading wire comprises a super-elastic outer shell and an inner core of a radiopaque material.

39. The retrieval device of claim 38, where the inner core comprises a material selected from a group consisting of platinum, iridium, gold, tantalum, alloys or mixtures thereof.

40. The retrieval device of claim 38, where leading wire is continuous with and forms the capturing portion.

41. The retrieval device of claim 26, where the at least one leading wire comprises a group of wires forming a main bundle and where the group of wires forms the capturing portion such that the group of wires diverges from a second end of the main bundle to form the permeable distal end, the group of wires continue to extend to form both the capturing surface and open end.

42. The retrieval device of claim 26, where the at least one leading wire comprises a group of wires forming a main bundle and where the group of wires forms, the capturing portion such that the group of wires diverges from a second end of the main bundle to form the capturing surface, the group of wires continues to extend to form both the permeable distal end and open proximal end.

43. The retrieval device of claim 26, where the at least one leading wire comprises a group of wires forming a main bundle and where at least one individual wire has a cross-sectional shape selected from the group consisting of a circle, an oval, a rectangular shape, a polygon, and a D-shape.

44. The retrieval device of claim 26, where the retrieval body is jointless.

45. The retrieval device of claim 26, where at least a portion of the capturing section comprises a structure selected from the group consisting of a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, a plurality of crossing wires, and a combination thereof.

46. The retrieval device of claim 26, where the open proximal end of the translating section further comprises a plurality of flanges extending from the capturing portion

47. The retrieval device of claim 26, where the retrieval body is self-expandable and compresses to fit within a lumen of a catheter.

48. The retrieval device of claim 26, further comprising at least one radiopaque material located on the capturing section.

49. The retrieval device of claim 26, where the leading wire comprise a bundle of smaller wires.

50. The retrieval device of claim 26, where the leading wire comprises a group of wires that diverges towards the permeable distal end of the capturing section.

51. The retrieval device of claim 26, further comprising a proximal capturing portion where the retrieval body is moveable relative to the proximal capturing portion, where the proximal capturing portion comprises an open distal end and a proximal end, where the leading wire extends through the open distal end of the proximal capturing portion, and is moveable relative to the proximal capturing portion such that a distance between the distal open end of the proximal capturing portion and the proximal open end of the retrieval body can be changed.

52. The retrieval device of claim 51, where the proximal end of the proximal capturing portion is permeable.

53. The retrieval device of claim 51, where the proximal end of the proximal capturing portion is non-permeable.

54. The retrieval device of claim 51, further comprising a first plurality of flanges located on the proximal open end of the distal capturing portion and a second plurality of flanges located on the distal open end of the proximal capturing portion, where the first and second plurality of flanges can removably engage each other.

55. The retrieval device of claim 51, where the proximal capturing portion and retrieval body are rotatable relative to each other.

56. The retrieval device of claim 51, where the proximal end of the proximal capturing portion is connected about the leading wire such that the leading wire is moveable therethrough.

57. The retrieval device of claim 51, further comprising a sheath extending over the leading wire, where the proximal end of the proximal capturing portion is affixed to the sheath.

58. The retrieval device of claim 51, where the proximal capturing portion comprises a structure selected from a group consisting of a laser cut tube, an etched tube, an injection molded structure.

59. The retrieval device of claim 58, where the at least one leading wire is attached to the proximal capturing portion via a joint or junction

60. The retrieval device of claim 51, where the proximal capturing portion has a coverage density that increases from the open distal end to the proximal end.

61. The retrieval device of claim 51, where the proximal capturing portion is formed from a wire comprising super-elastic outer shell and an inner core of a radiopaque material.

62. The retrieval device of claim 61, where the inner core comprises a material selected from a group consisting of platinum, iridium, gold, and tantalum or combination thereof.

63. The retrieval device of claim 51, where the proximal capturing portion is jointless.

64. The retrieval device of claim 51, where at least a portion of a surface of the proximal capturing portion comprises a structure selected from the group consisting of a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, a plurality of crossing wires, and a combination thereof.

65. A method of removing an obstruction from a blood vessel, the method comprising:

advancing a catheter distal to the obstruction;

deploying a first capturing portion distal of the obstruction, where the first capturing portion comprises a translating surface and a capturing surface, the translating surface having an open proximal end and the capturing surface having a permeable distal end, and at least one leading wire affixed to the capturing surface and extending through the capturing portion and through the catheter, where the translating surface and capturing surface are configured so that a translating surface axial strength is greater than that of a capturing surface axial strength;

proximally moving the leading wire to compress the capturing surface without compressing the translating surface sufficient to cause axial deformation of the translating surface such that the translating surface gradually advances over the obstruction; and

removing the obstruction and first capturing portion from the blood vessel.

66. The method of claim 65, where pulling on the leading wire causes the capturing surface to apply a spring force against the translating surface such that the open proximal end advances along the obstruction.

67. The method of claim 65, where applying a threshold force on the leading wire while the open proximal end engages the obstruction causes the capturing surface to invert within the capturing portion.

68. The method of claim 67, where applying the threshold force comprises continuing to apply the threshold force to withdraw the capturing surface into the catheter distal end.

69. The method of claim 67, where applying the threshold force comprises continuing to apply the threshold force to invert the capturing portion such that the capturing surface is proximal to the translating surface.

70. The method of claim 65, where pulling on the leading wire to apply the force to the capturing surface comprises applying the force to the permeable distal end.

71. The method of claim 65, where pulling on the leading wire to apply the force to the capturing surface comprises applying the force to the capture surface.

72. The method of claim 65, further comprising a second capturing portion having an open distal end and a proximal end attached axially moveable relative to the first capturing portion, such that moving the first capturing portion over the obstruction causes the open proximal end of the first capturing portion to move towards the open distal end of the second capturing portion to surround the obstruction.

73. The method of claim 72, where the proximal end of the second capturing portion is non-permeable and temporarily occludes or interrupts flow.

74. The method of claim 72, where the proximal end of the second capturing portion is permeable and permits flow during removal of the obstruction.

75. The method of claim 72, further comprising continuing to move the first capturing portion towards the second capturing portion such that the open proximal end and the open distal end can removably engage each other.

76. The method of claim 72, further comprising compressing the second capturing portion about the obstruction to further secure the obstruction.

77. A reentry device for withdrawing an object into a distal end of a sheath, the reentry device comprising:

a elongate member having a distal portion and a lumen extending therethrough; and

a plurality of first tines arranged circumferentially at the distal portion, the plurality of first tines each having a distal end forming a first discontinuous funnel where the distal end of each first tine is spaced from the distal end of an adjacent first tine, wherein the first discontinuous funnel is collapsible upon withdrawal into the distal end of the sheath..

78. The reentry device of claim 77, further comprising:

a second funnel spaced proximal to the first funnel, where the second funnel is collapsible upon withdrawal into the distal end of the sheath; and

wherein a distal perimeter of the first discontinuous funnel shape is distal to a distal perimeter of the second funnel.

79. The reentry device of claim 78, where the second funnel comprises a plurality of second tines arranged circumferentially at the distal portion, the plurality of second tines each having a distal end forming a second discontinuous funnel shape where the distal end of each second tine is spaced from the distal end of an adjacent second tine.

80. The reentry device of claim 79, further comprising at least one protrusion on an inner surface of at least the first or second tine.

81. The reentry device of claim 78, where the second funnel comprises a continuous funnel.

82. The reentry device of claim 77, further comprising a second funnel, where the second funnel comprises a flexible layer.

83. The reentry device of claim 82, where the flexible layer comprises a mesh braid.

84. The reentry device of claim 83, where the mesh braid comprises a Nitinol braid.

85. The reentry device of claim 77, where the second funnel comprises a tapered split tube.

86. A reentry device for withdrawing an object into a distal end of a sheath, the reentry device comprising:

an elongate member having a distal portion and a lumen extending therethrough, the elongate member sized to slidably fit within the sheath;

a first slotted funnel comprising a plurality of first tines each having free ends discontinuous with free ends of adjacent first tines, where the first slotted funnel is collapsible upon withdrawal into the distal end of the sheath; and

a second funnel located proximal to the free ends of the first tines.

87. The reentry device of claim 86, where the second funnel comprises a second slotted funnel comprising a plurality of second tines each having free ends discontinuous with free ends of adjacent second tines, where the first slotted funnel is collapsible upon withdrawal into the distal end of the sheath.

88. The reentry device of claim 87, where the free ends of the second tines are located proximally to the free ends of the first tines relative to the elongate member and where the first and second tines are rotationally offset.

89. The reentry device of claim 86, where the second funnel comprises a second continous funnel, where the second continuous funnel is collapsible upon withdrawal into the distal end of the sheath.

90. The reentry device of claim 86, where the second funnel comprises a tapered split tube.

91. The reentry device of claim 86, where the second funnel comprises a flexible layer.

92. The reentry device of claim 91 where the flexible layer comprises a mesh braid.

93. The reentry device of claim 92, where the mesh braid comprises a Nitinol braid.

94. A retrieval system for withdrawing an object into a distal end of a sheath, the retrieval system comprising:

an elongate member having a distal portion and a lumen extending therethrough; a flexible layer having a portion affixed to the elongate member, where a first end of the flexible layer is configured to form a funnel at the distal portion of the elongate member;

a retrieval device advanceable through the elongate member for engaging the object, where proximal movement of the retrieval device into the flexible causes the flexible layer to engage the retrieval device to assist the retrieval device securing the object to the sheath.

95. The retrieval system of claim 94, where the elongate member comprises a first shaft and a second shaft, where the first and shaft are in telescoping engagement, where a first end of the flexible layer is affixed to the first shaft and a second end of the flexible member is affixed to the second shaft, where moving the first and second shaft to decrease a distance between ends of the flexible member causes the flexible material to form a funnel when the flexible layer further inverts about the second elongate shaft.

96. The retrieval system of claim 94, where the flexible layer is affixed to the elongate member at a single location.

97. The retrieval system of claim 96, where the flexible member is affixed to the elongate member at a distal location, and where the flexible member has a pre-determined funnel shape such that when unrestrained the flexible member forms the funnel shape about the distal end of the elongate member.

98. The retrieval system of claim 96, where the flexible member is affixed to the elongate member at a proximal location, and where the flexible member extends beyond the distal end of the elongate member.

99. The retrieval system of claim 98, where proximal movement of the retrieval device engages he flexible member causing the flexible member to form a funnel shape.

100. The retrieval system of claim 98, where the flexible member has a pre-determined funnel shape such that the flexible member assumes a funnel shape when un-restrained.

101. The retrieval system of claim 94, where the flexible layer comprises a mesh braid.

102. The retrieval system of claim 101, where the mesh braid comprises a Nitinol braid.

103. The retrieval system of claim 94, where the flexible layer comprises a flexible layer of material.

104. The retrieval system of claim 94, further comprising:

a retrieval sheath extending through the second elongate member having a proximal capture portion affixed to a distal end;

at least one leading wire extending through the retrieval sheath, where a distal section of the leading wire comprises a distal stiffness and where a proximal section of the leading wire comprises a proximal stiffness, where the proximal stiffness is greater than the distal stiffness; and

a distal capturing portion at the distal end of the leading wire, the distal capturing portion being axially moveable relative to the proximal capture portion.

105. The retrieval system of claim 104, where the distal section of the leading wire extends proximally for a pre-determined distance from the distal capturing portion to allow navigation of a distal section of the leading wire within the cerebral vasculature.

106. The retrieval system of claim 105, where the pre-determined distance is at least 20 cm.

107. A system for removing a object within a body, the system device comprising:

a sheath having a sheath distal end and a sheath lumen extending therethrough; a reentry device slidably located in the sheath lumen and being advanceable out of the sheath distal end, the reentry device comprising an elongate member having a first slotted funnel and a second slotted funnel, the elongate member having a distal portion and a lumen extending therethrough and being sized to slidably fit within the sheath,

the first slotted funnel and the second slotted funnel each respectively comprising a plurality of first and second tines, each of the tines having a free end discontinuous with the free ends of an adjacent tines, where a distal end of the second slotted funnel is proximal to a distal end of the first slotted funnel and where the first and second tines are rotationally offset such that upon withdrawal into the sheath, the second tines cover a portion off a space between adjacent first tines.

108. The system of claim 107, further comprising a capturing section slidably advanceable through the elongate member.

109. A retrieval system for use with a catheter, the system comprising:

a retrieval sheath;

a proximal capture portion affixed to a distal end of the retrieval sheath;

at least one leading wire extending through the retrieval sheath, where a distal section of the leading wire comprises a distal stiffness and where a proximal section of the leading wire comprises a proximal stiffness, where the proximal stiffness is greater than the distal stiffness; and

a distal capturing portion at the distal end of the leading wire, the distal capturing portion being axially moveable relative to the proximal capture portion.

110. The retrieval system of claim 109, an insertion tool slidably located over the retrieval sheath, the insertion tool comprising a gripping region affixed to a rigid section, where compression of the gripping portion creates a frictional fit between the insertion tool such that when the insertion tool is coupled to the retrieval sheath, compression of the gripping portion and axial movement of the insertion tool advances the retrieval sheath within the catheter.

111. The retrieval system of claim 109, where distal section of the leading wire is joined to the proximal section of the leading wire at a bond region, where the bond region is located a pre-determined distance from distal capture portion to allow navigation of a distal section of the system within the cerebral vasculature.

112. The retrieval system of claim 111, where the pre-determined distance is at least 20 cm.

113. The retrieval system of claim 109, further comprising a funnel slidably located on the sheath, where movement of the proximal capture portion and distal capture portion within the funnel causes the proximal and distal capture portions to compress.

114. The retrieval system of claim 109, where the insertion tool comprises a loading tube such that the proximal capture portion and distal capture portion can compress within the loading tube.

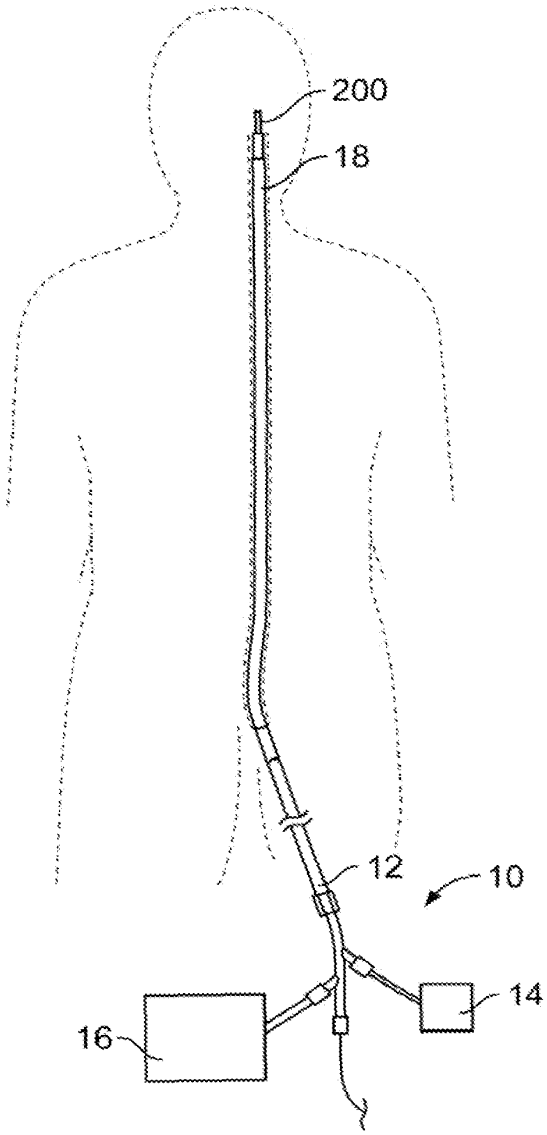


FIG. 1A

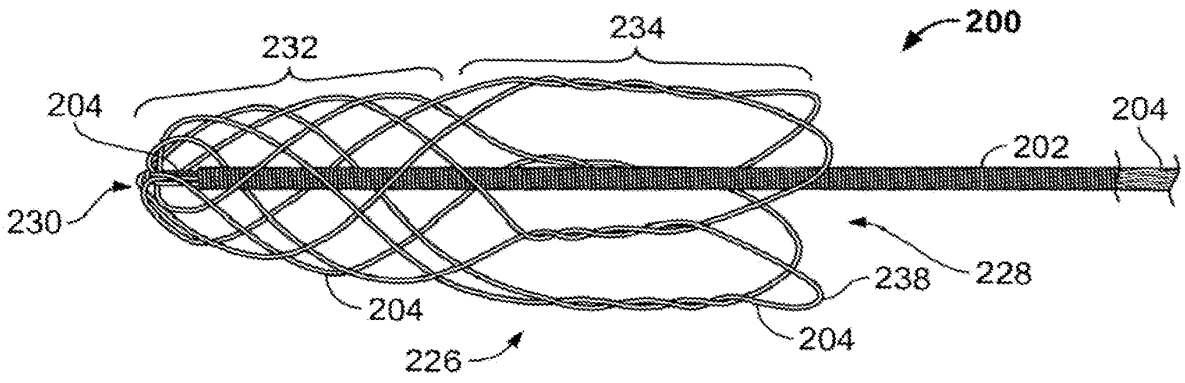

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FIG. 1B

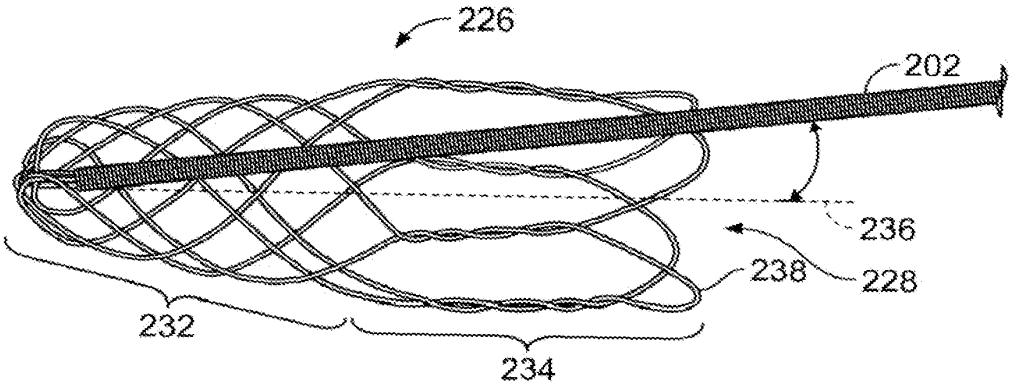

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FIG. 1C

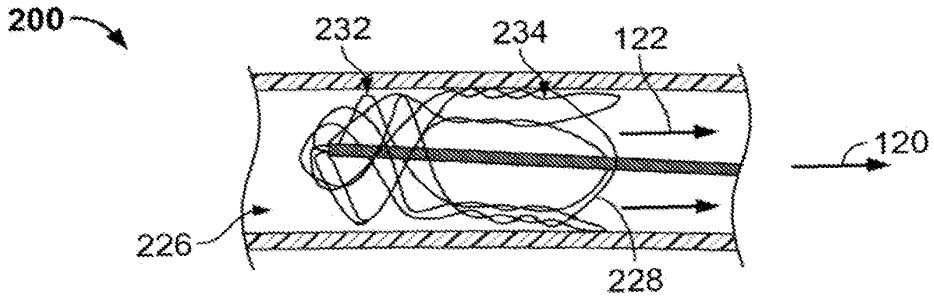


FIG. 2A

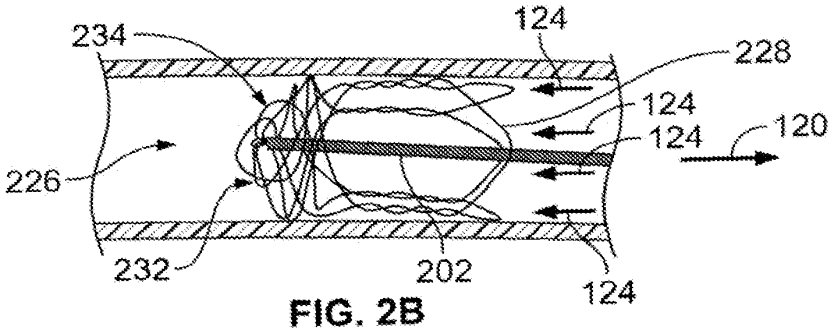


FIG. 2B

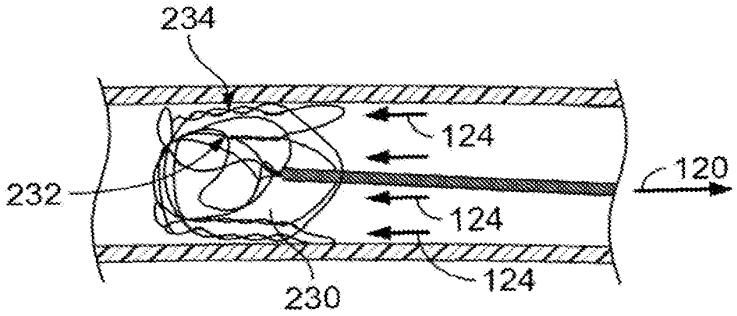


FIG. 2C

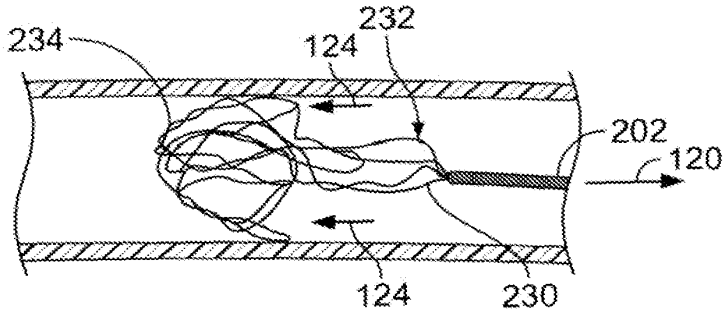


FIG. 2D

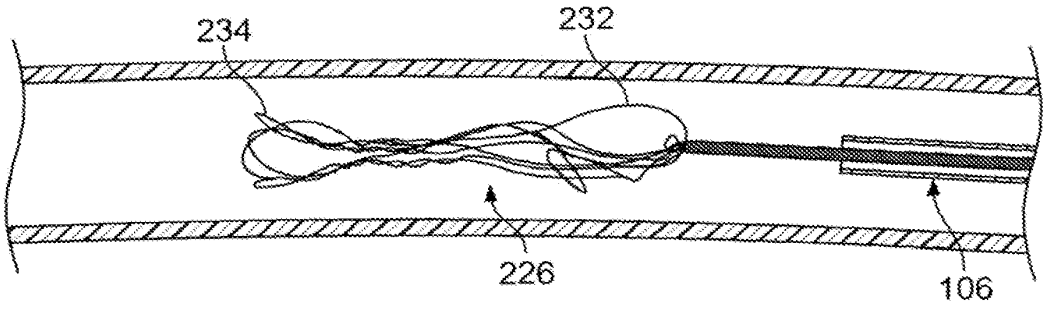


FIG. 2E

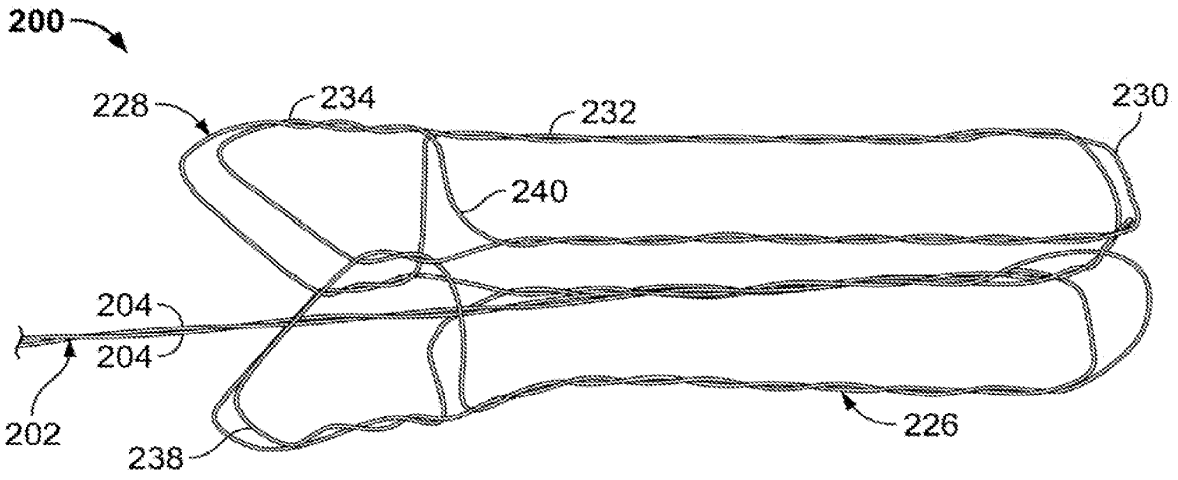

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FIG. 3A

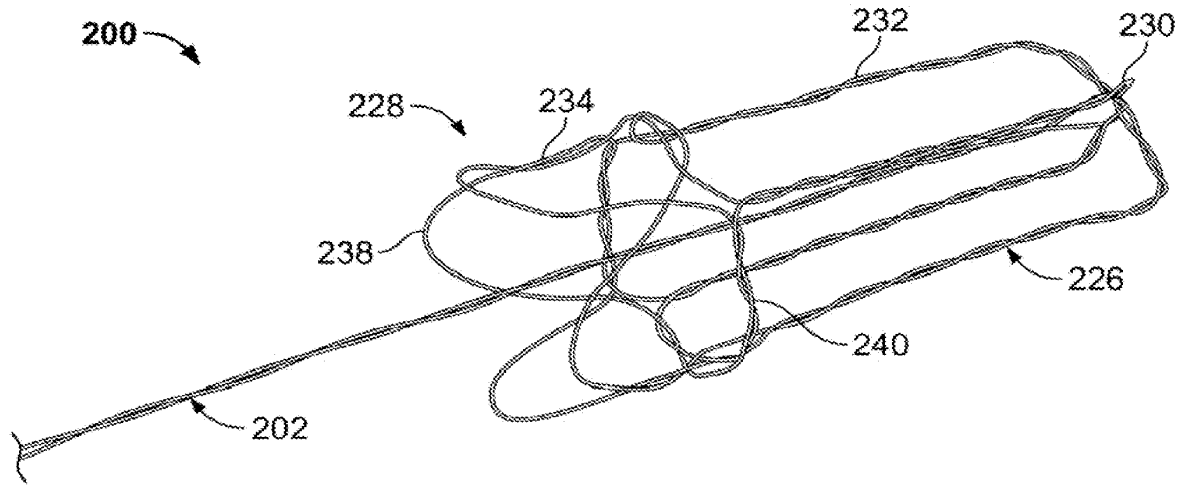

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FIG. 3B

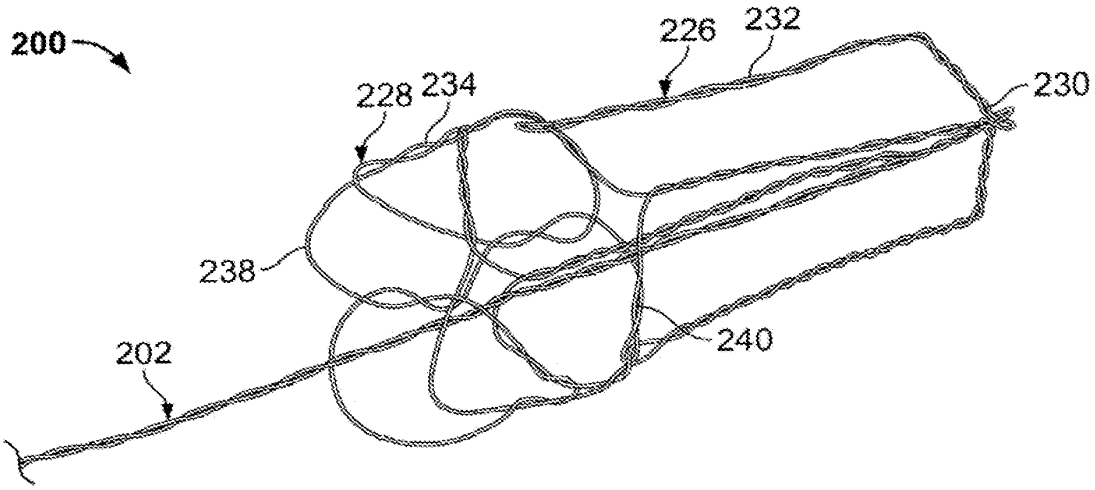


FIG. 3C

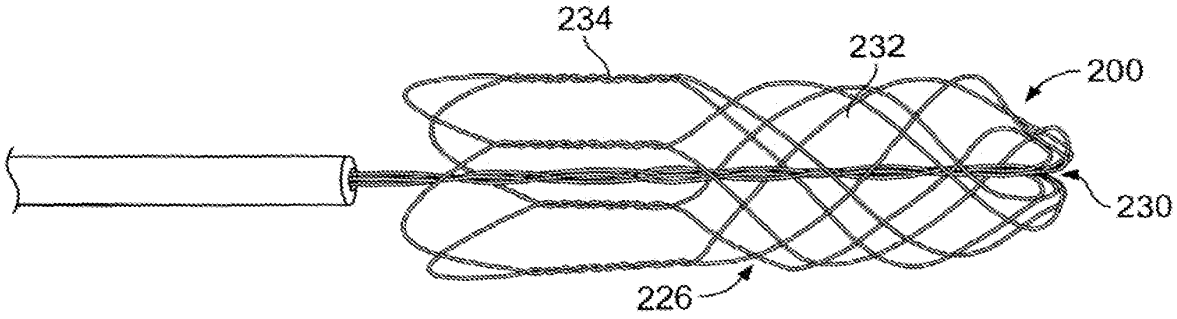


FIG. 3D

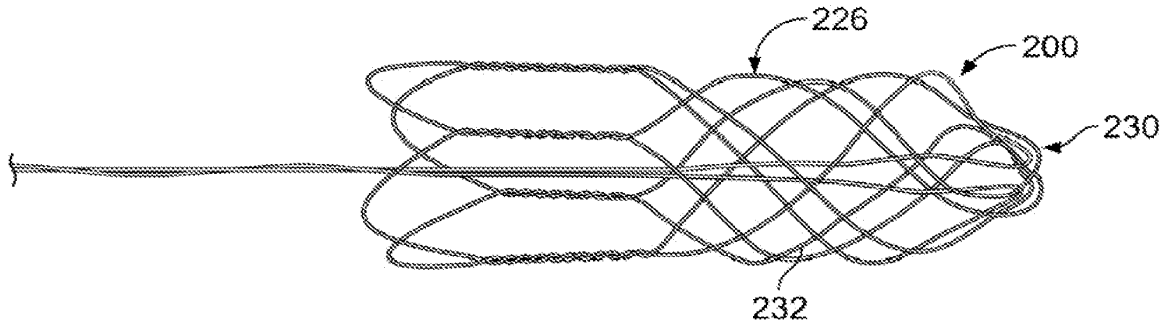


FIG. 3E

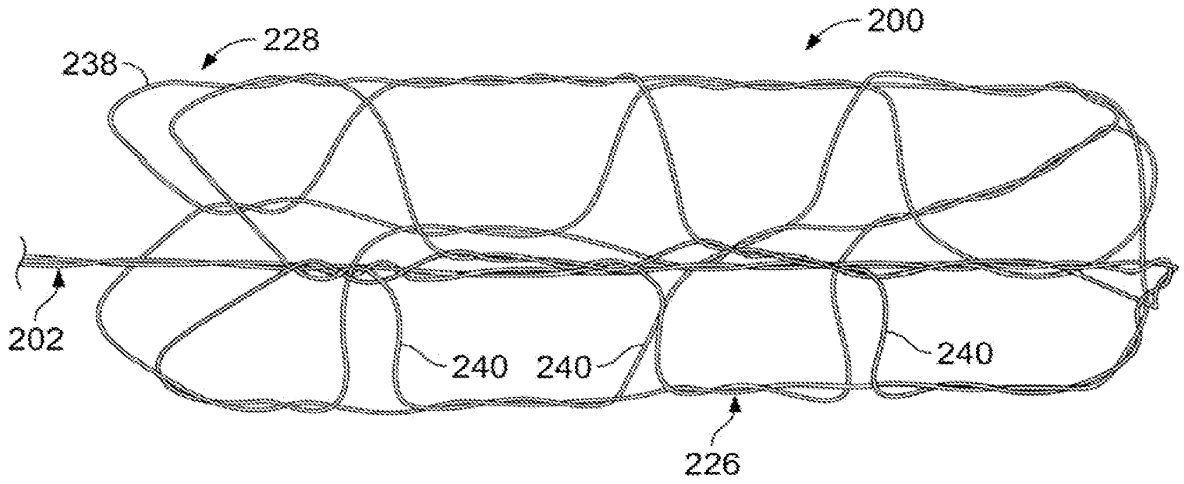


FIG. 3F

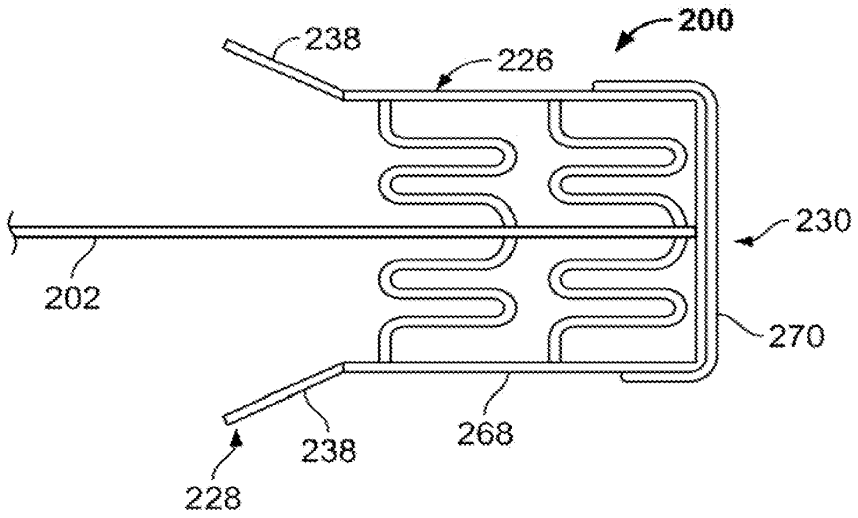


FIG. 3G

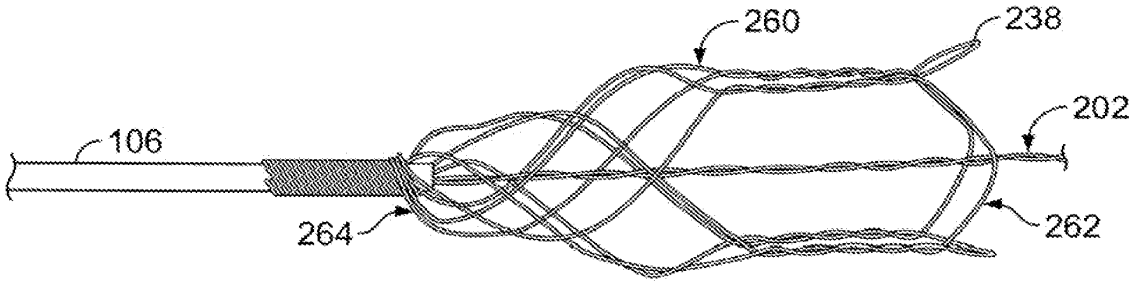


FIG. 3H

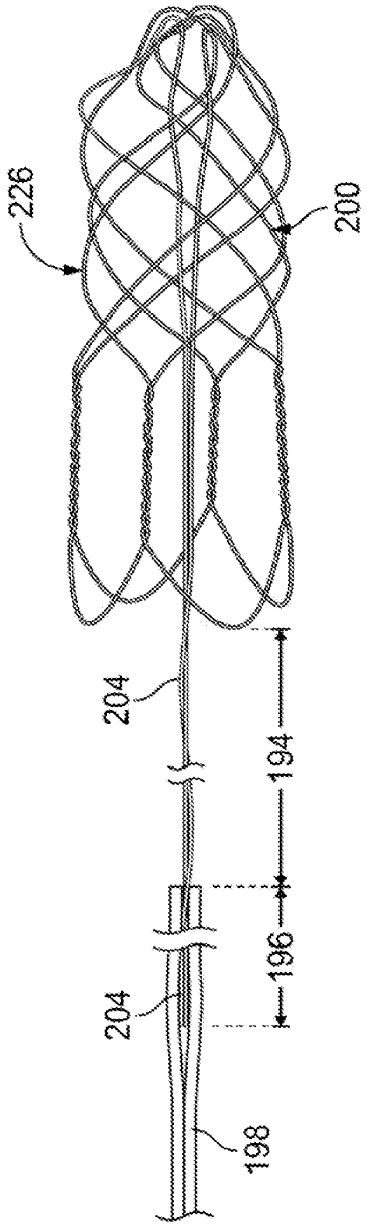


FIG. 4A

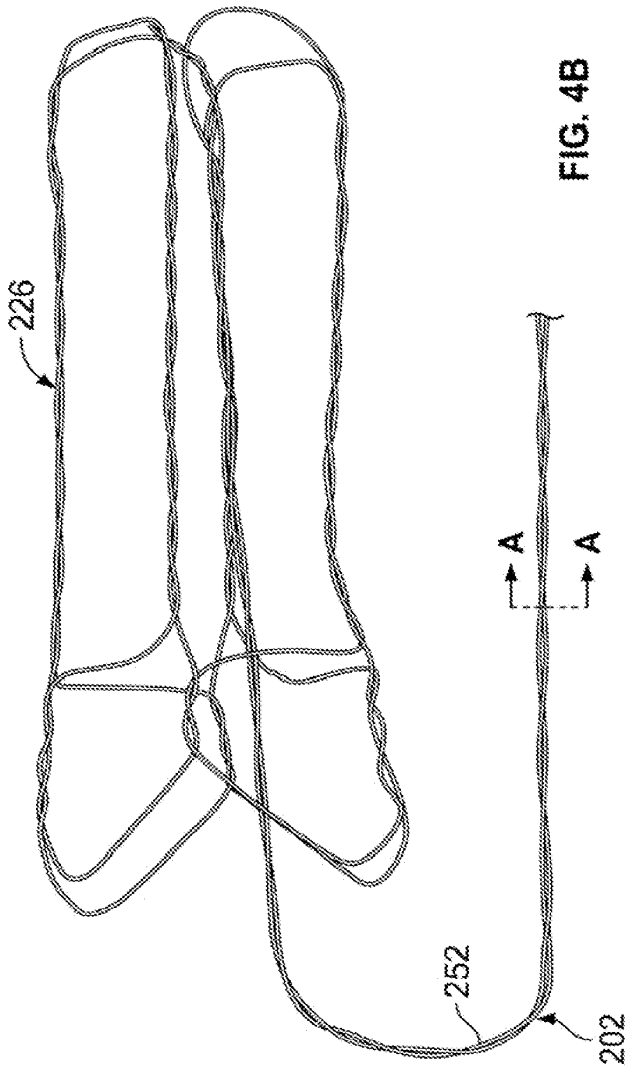


FIG. 4B

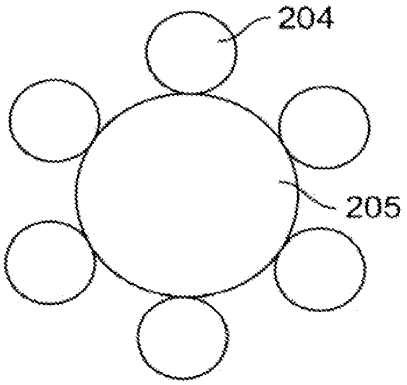


FIG. 4C

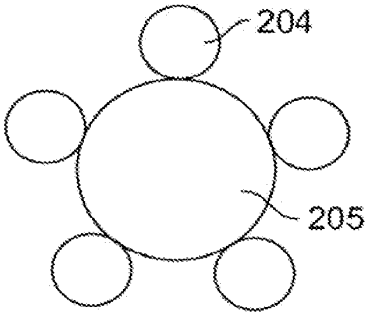


FIG. 4D

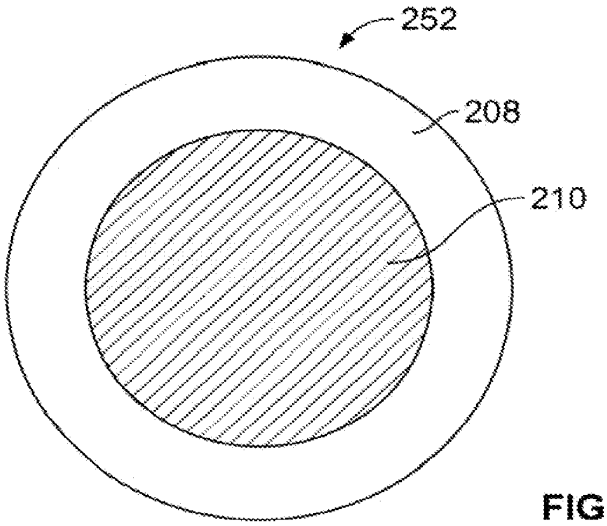


FIG. 4E

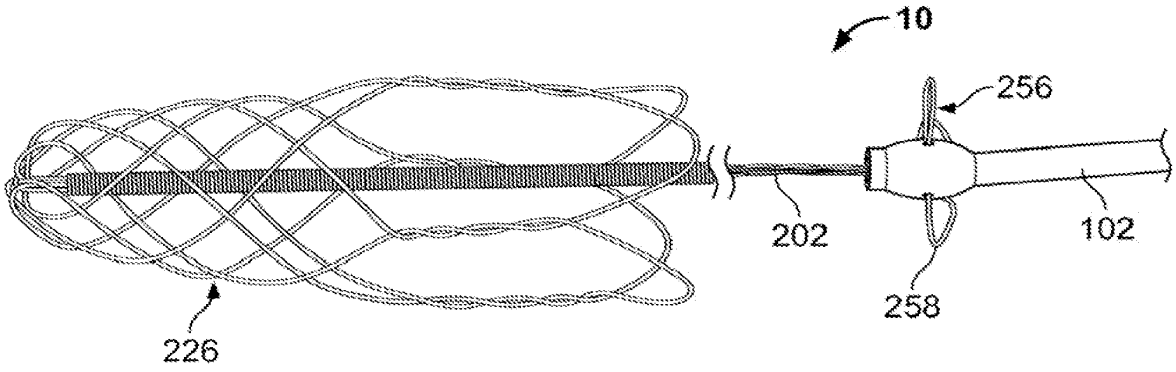


FIG. 5A

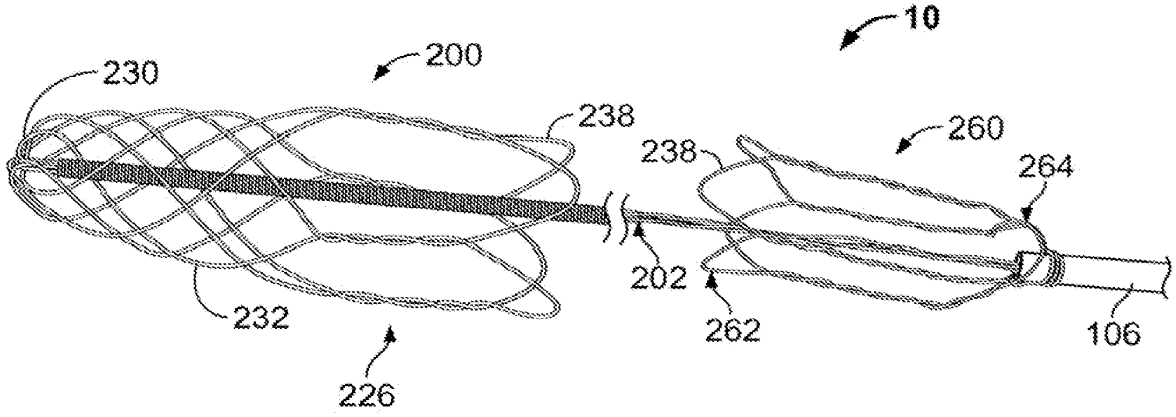


FIG. 5B

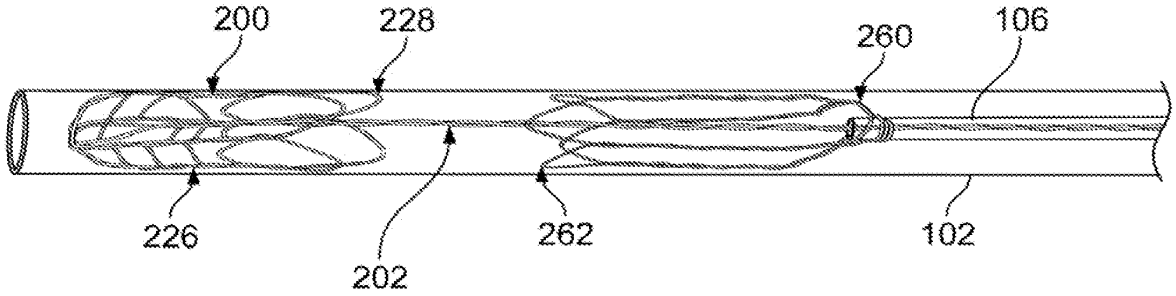


FIG. 5C

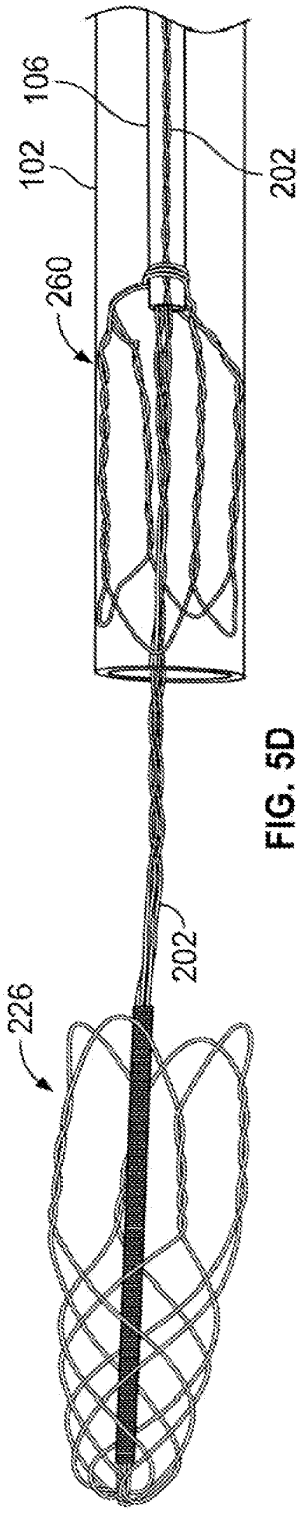


FIG. 5D

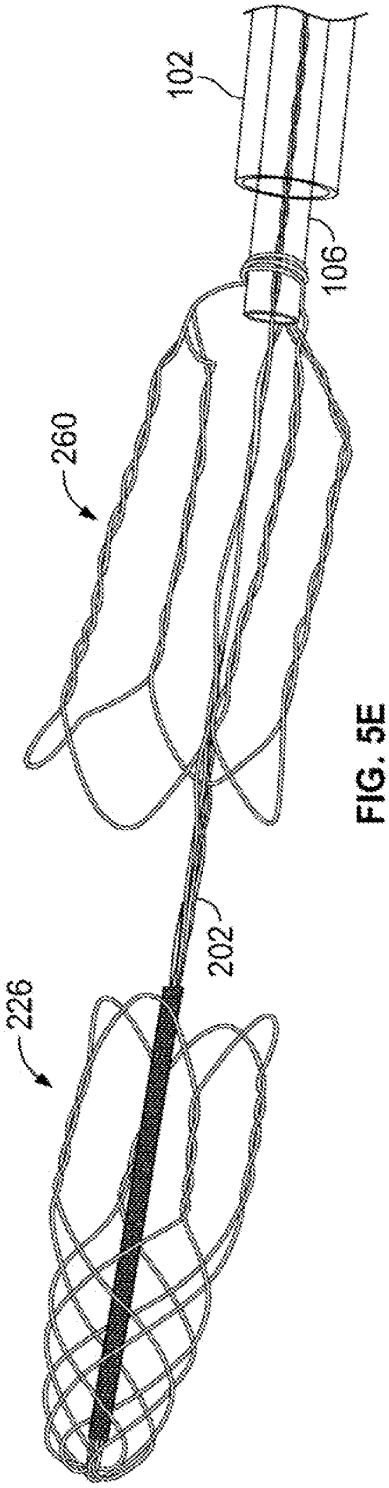


FIG. 5E

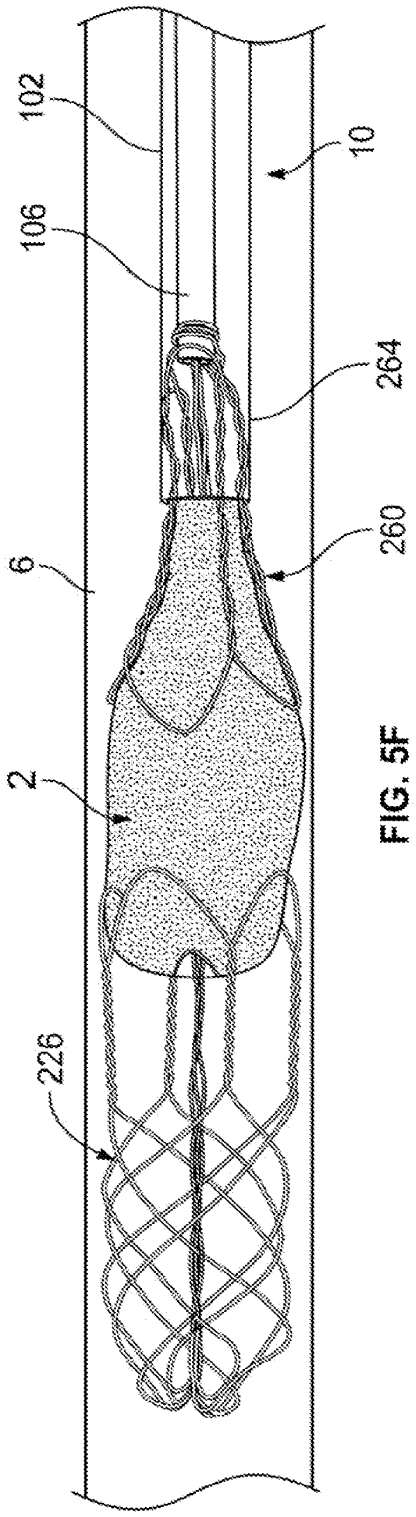


FIG. 5F

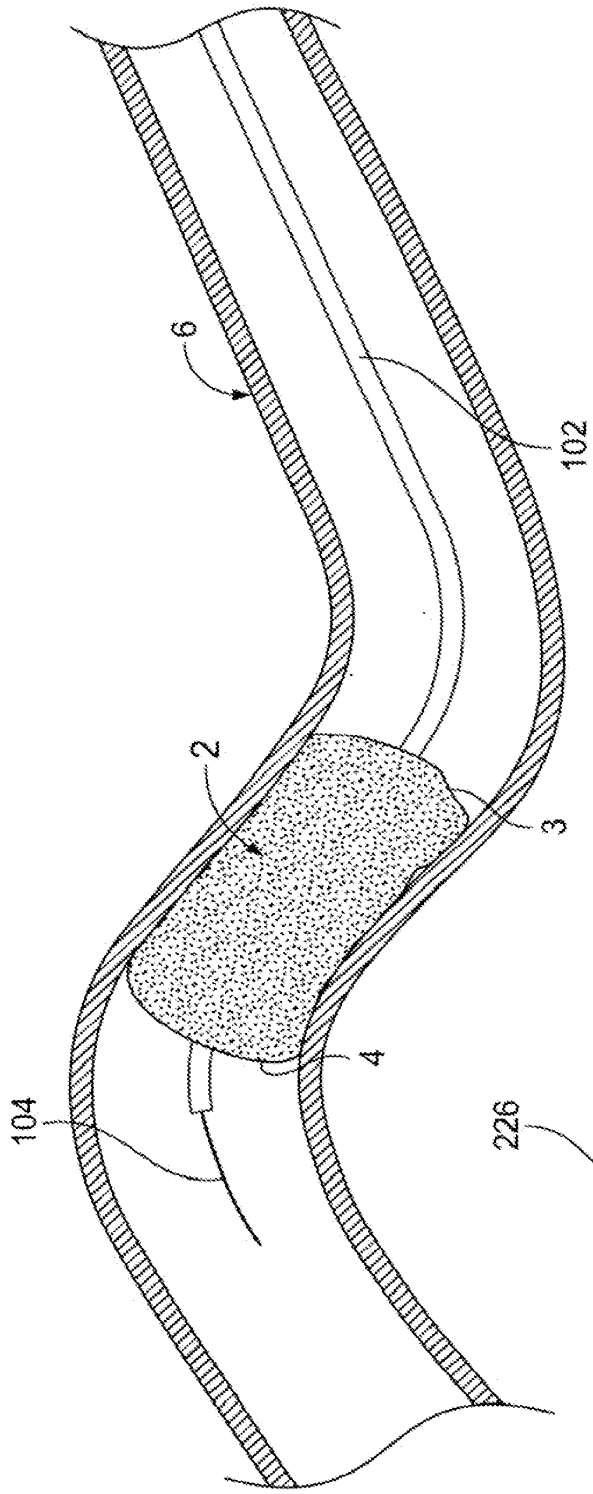


FIG. 6A

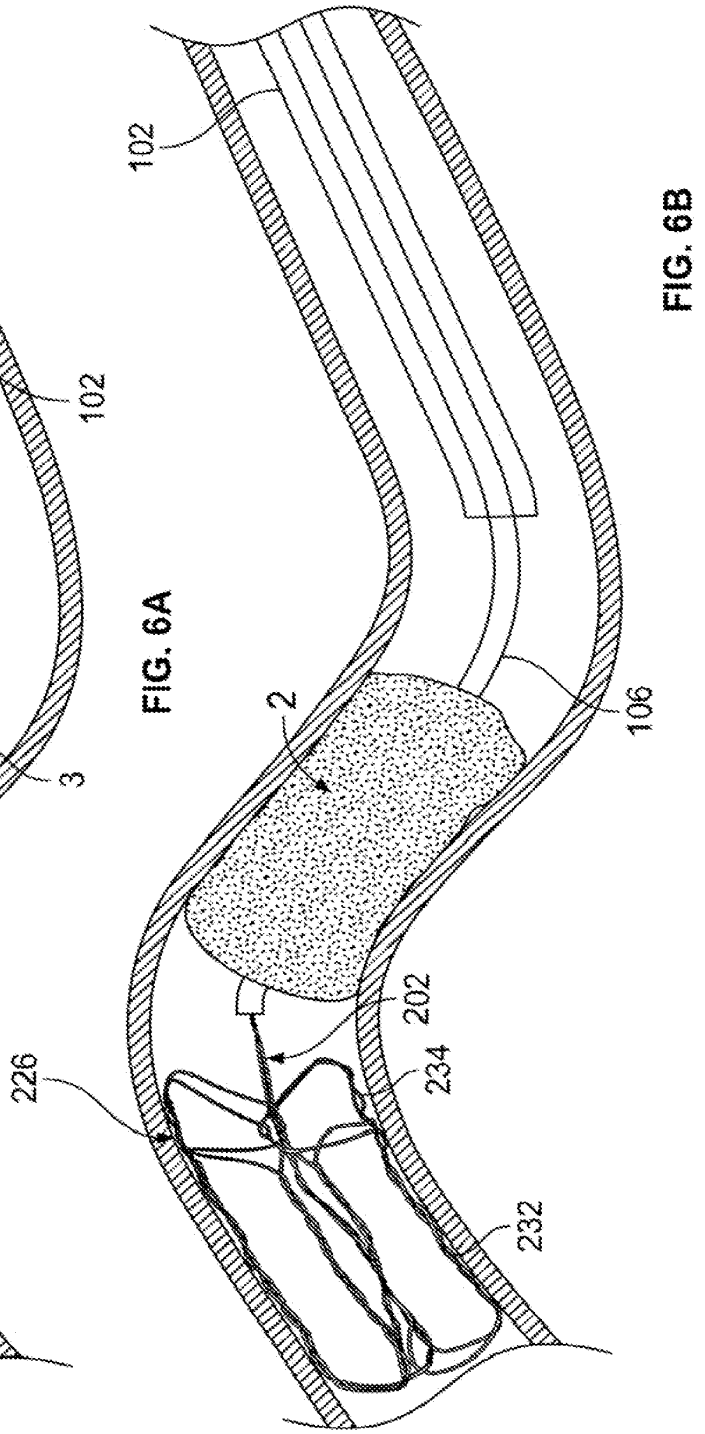


FIG. 6B

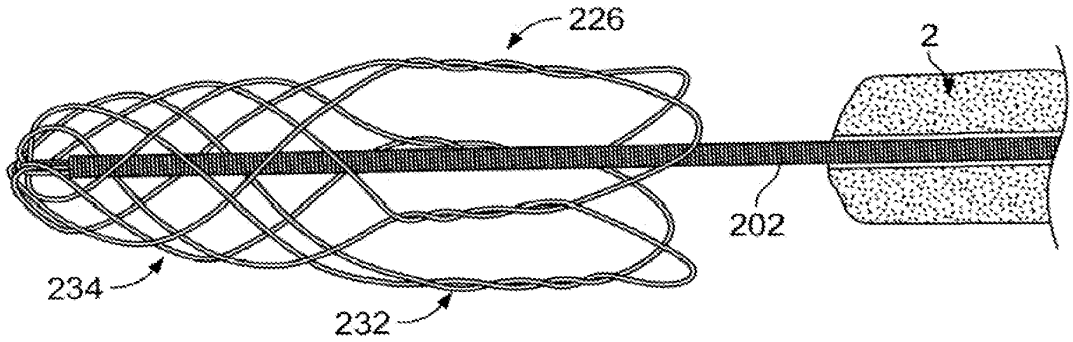


FIG. 7A

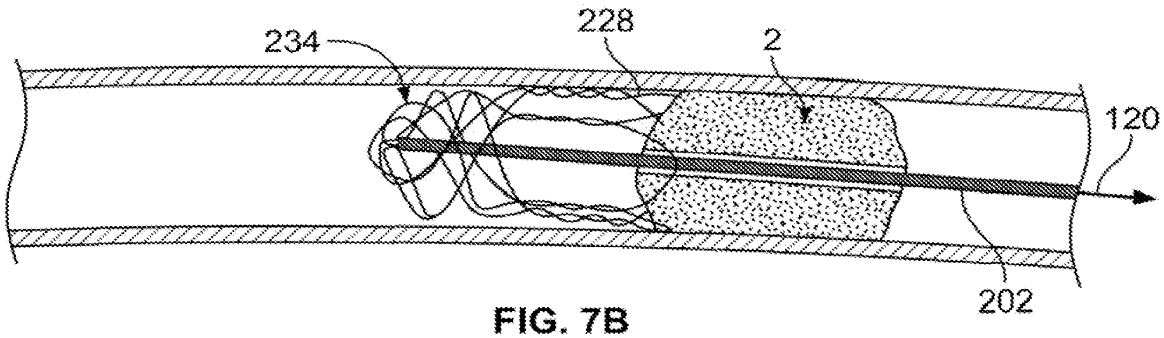


FIG. 7B

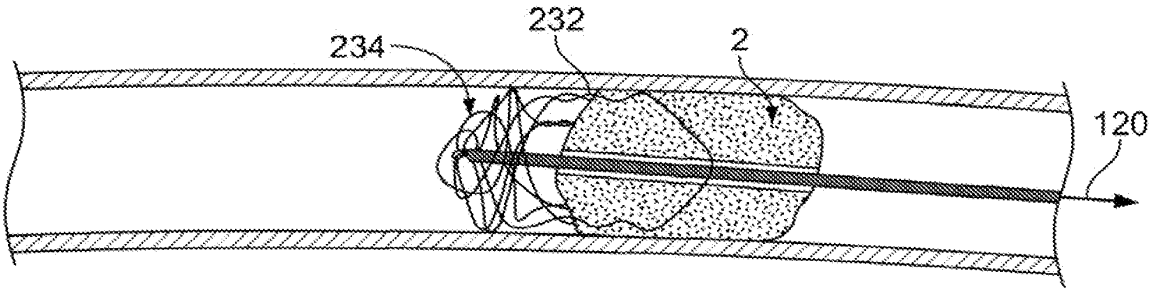


FIG. 7C

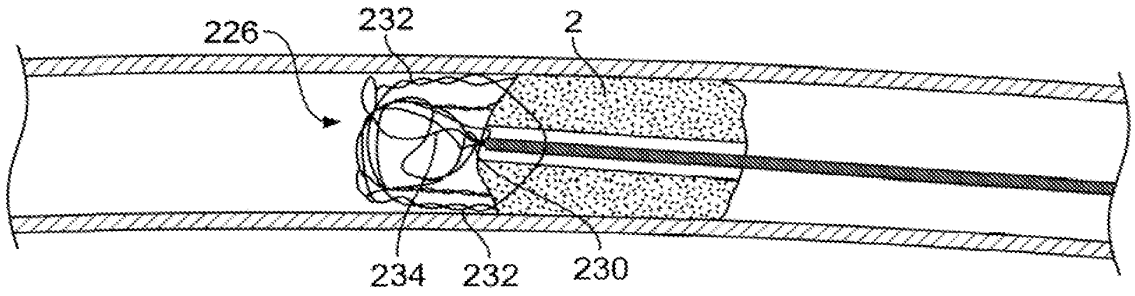


FIG. 7D

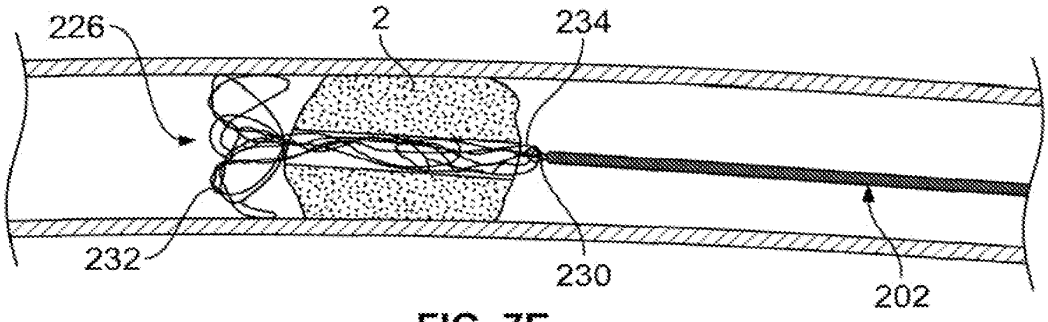


FIG. 7E

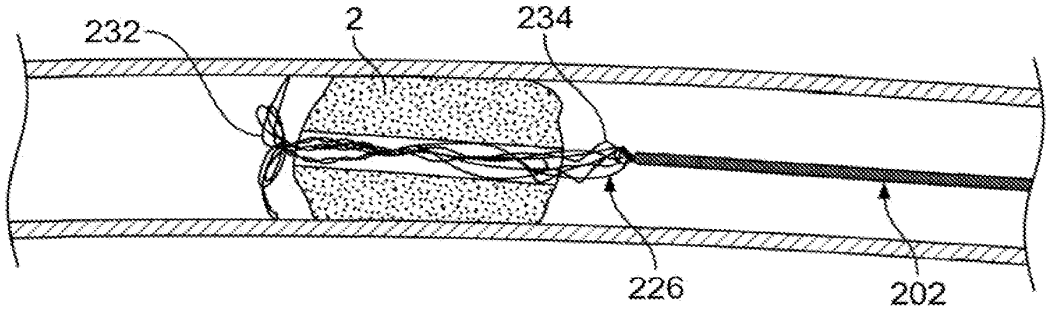


FIG. 7F

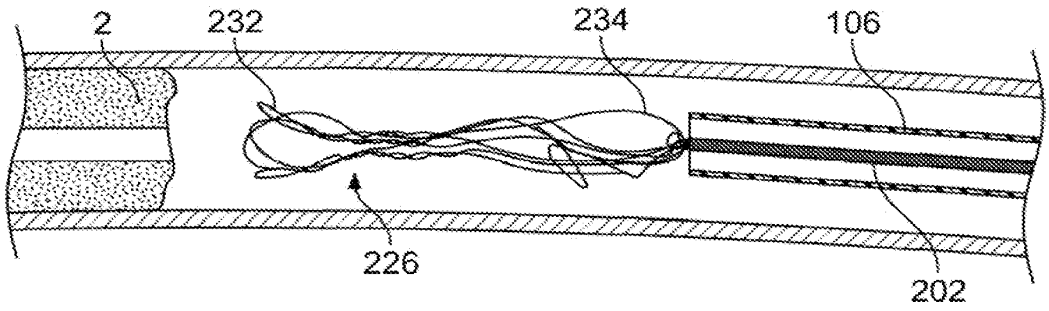


FIG. 7G

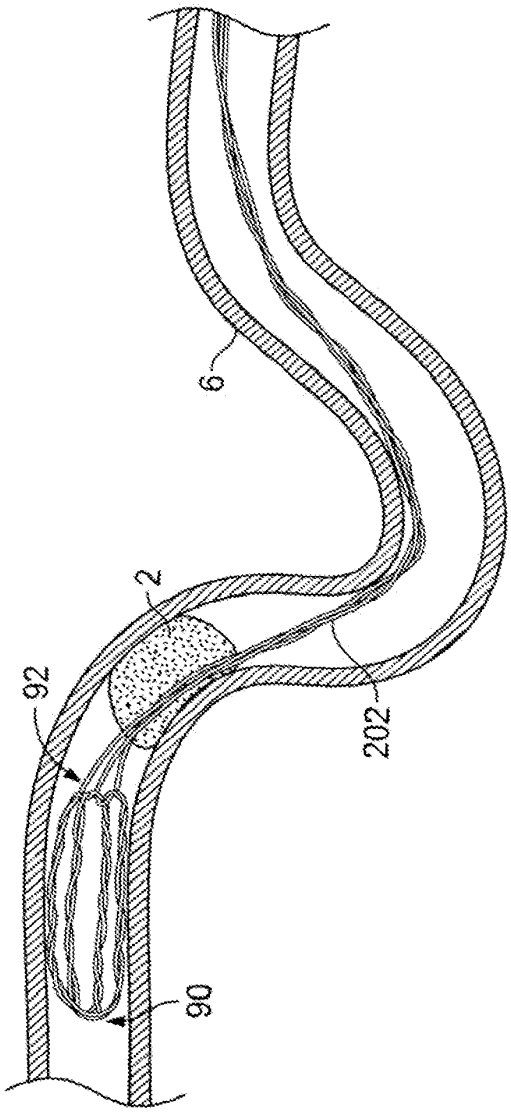


FIG. 8A

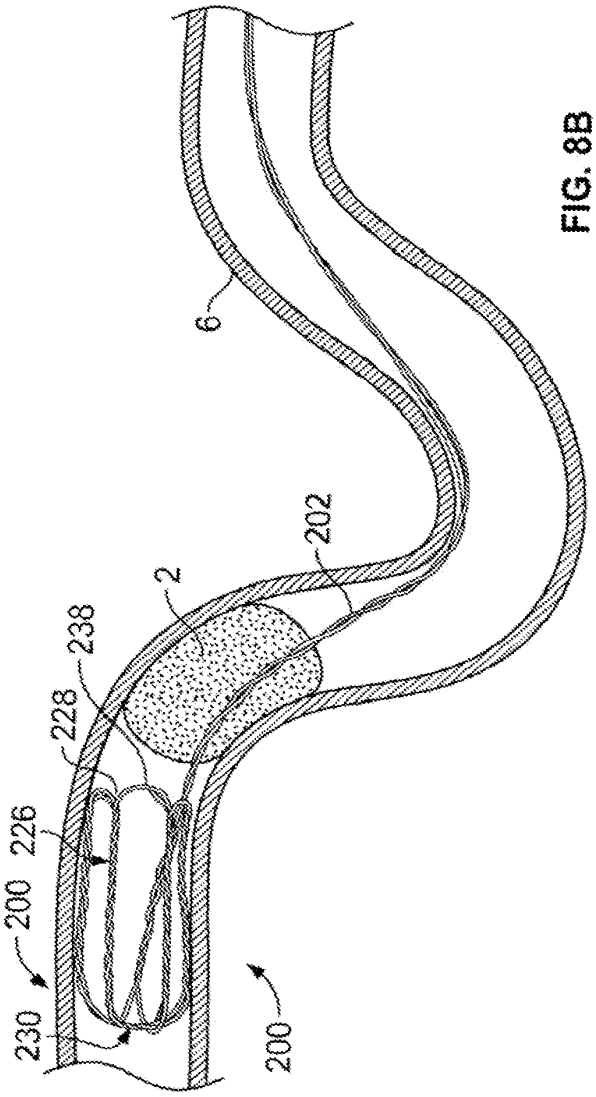


FIG. 8B

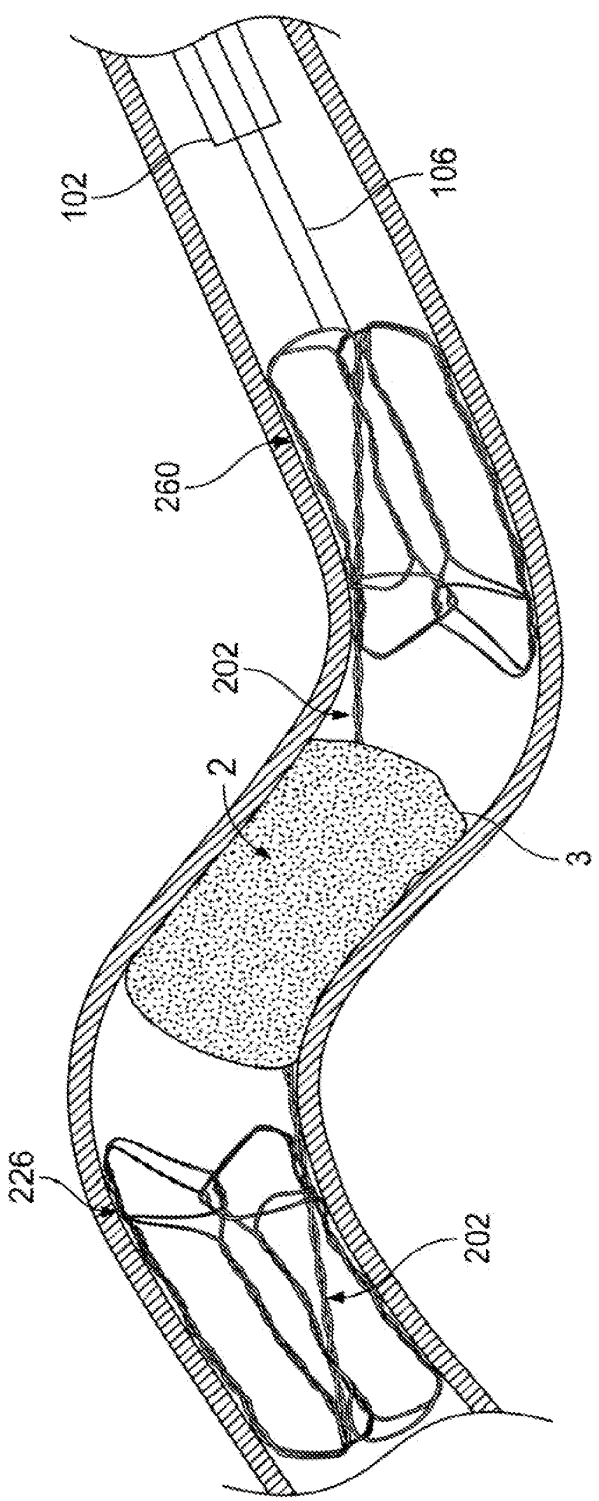


FIG. 8C

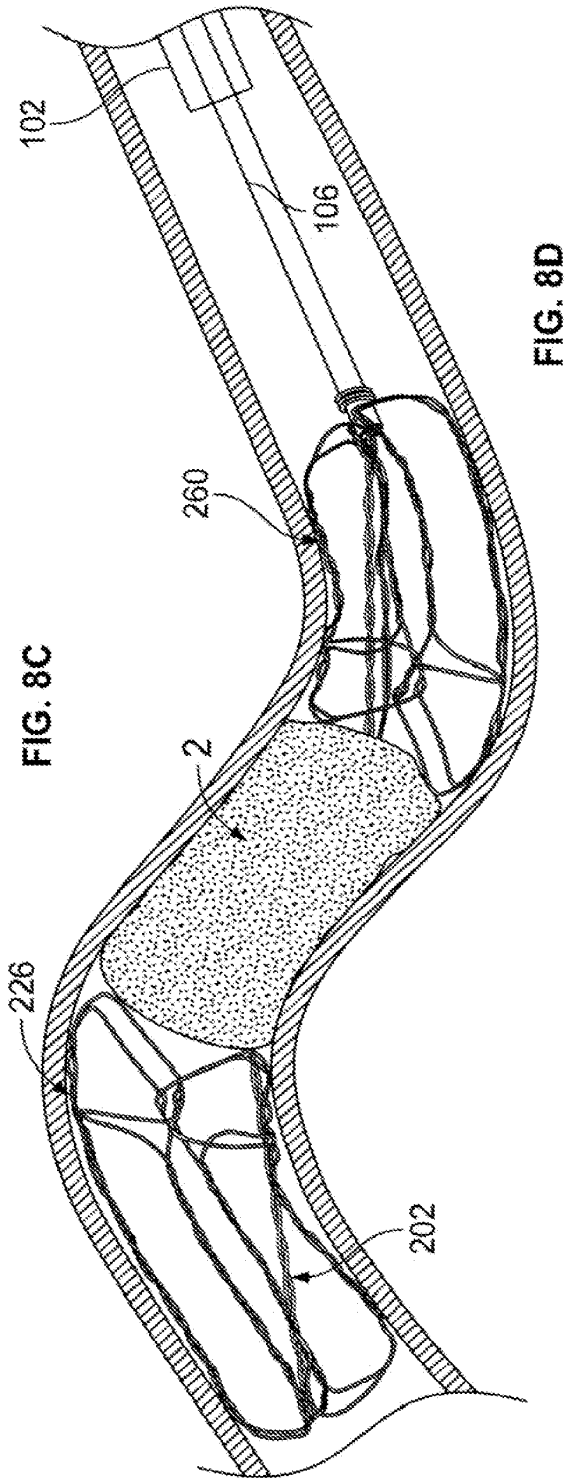


FIG. 8D

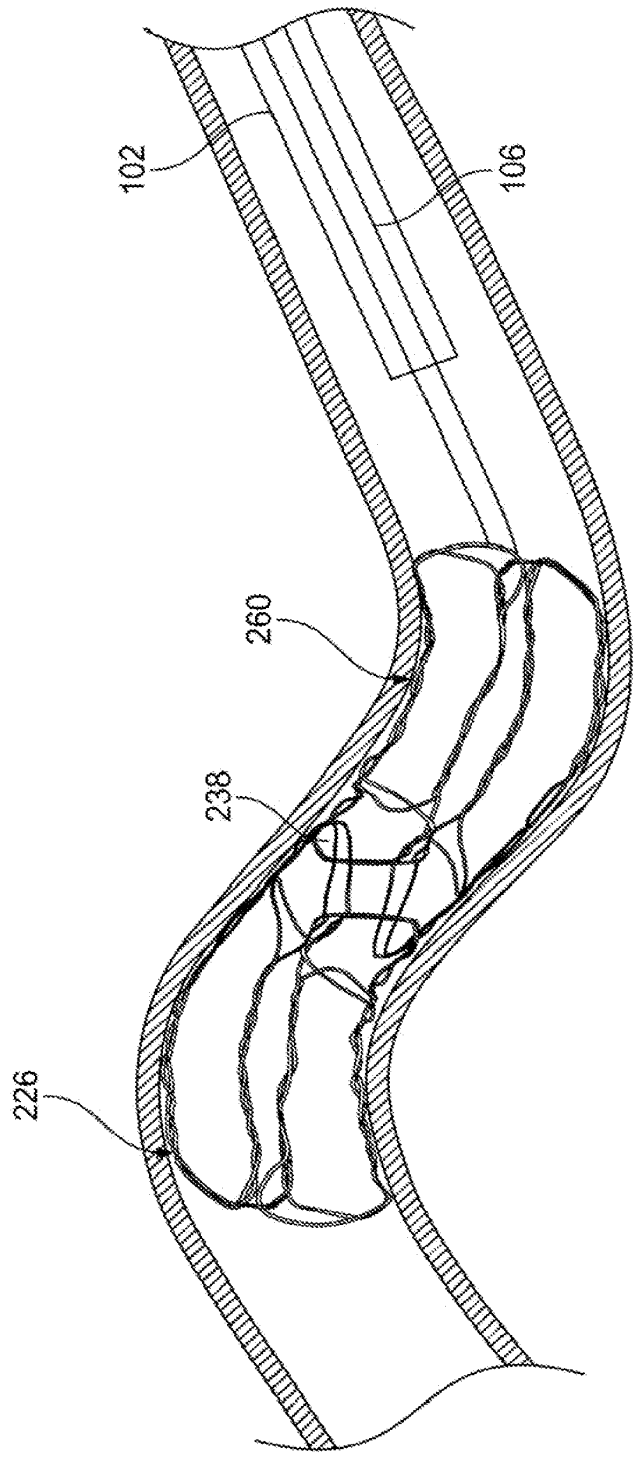


FIG. 8E

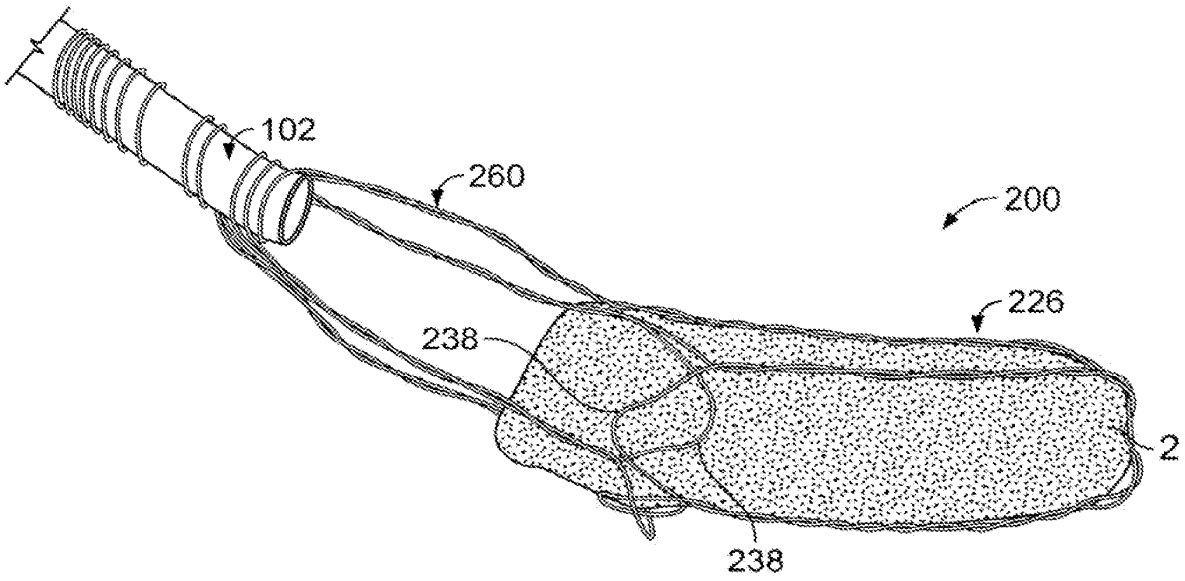


FIG. 8F

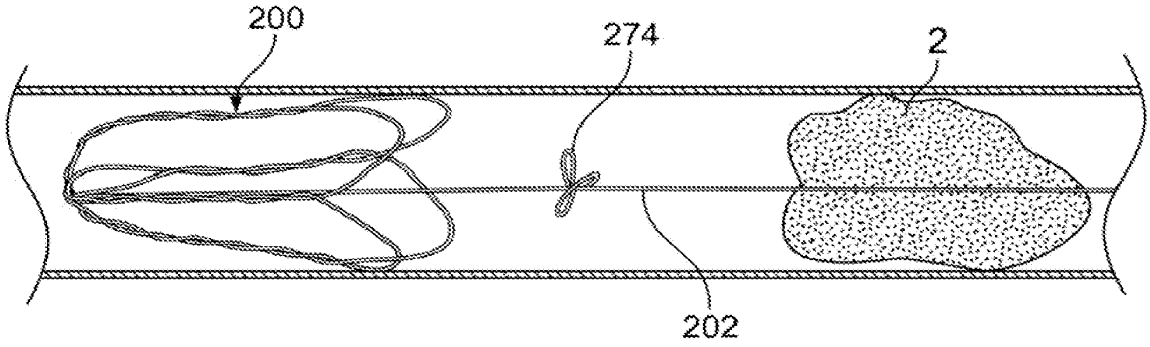


FIG. 9

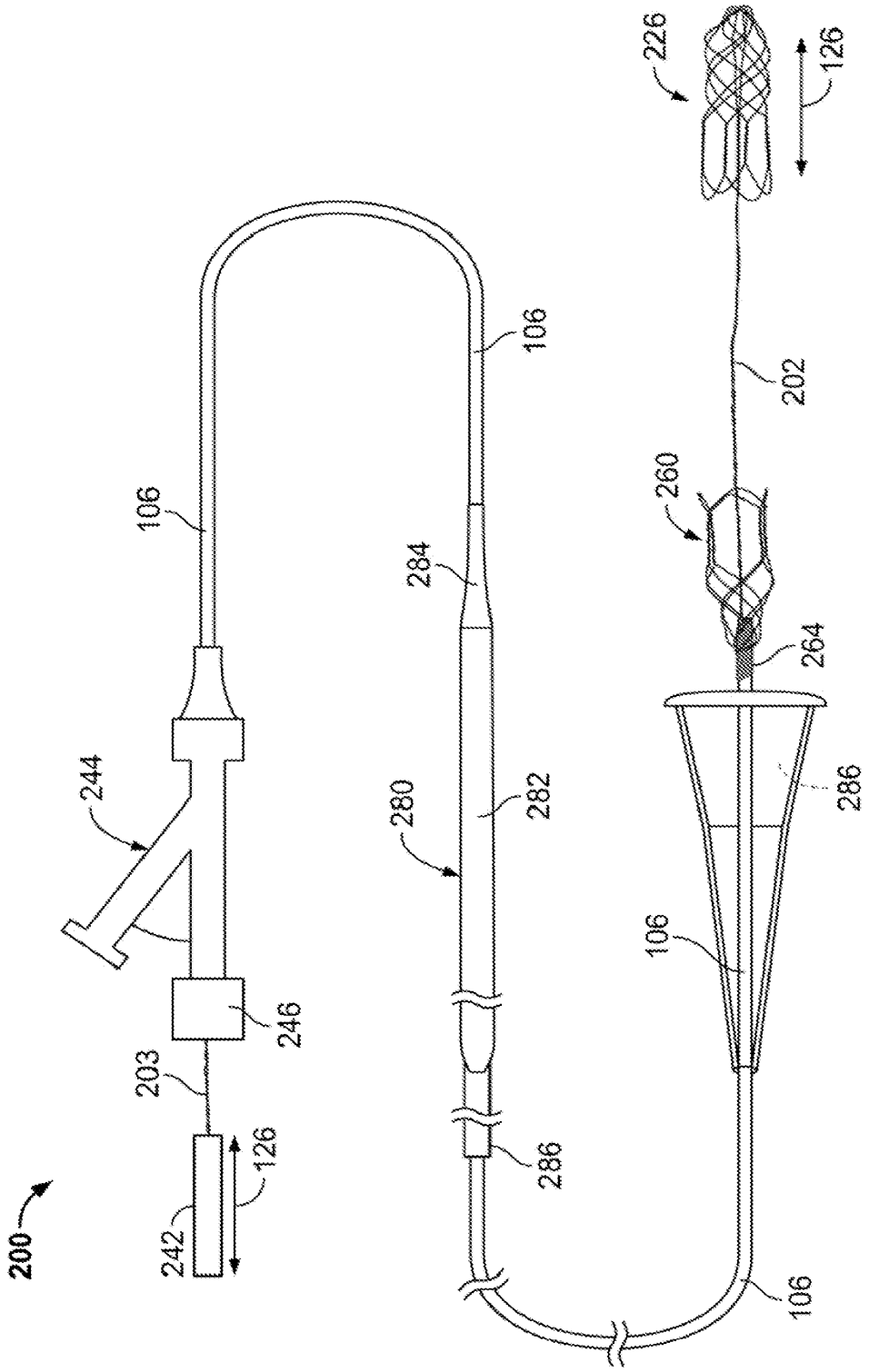

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FIG. 10

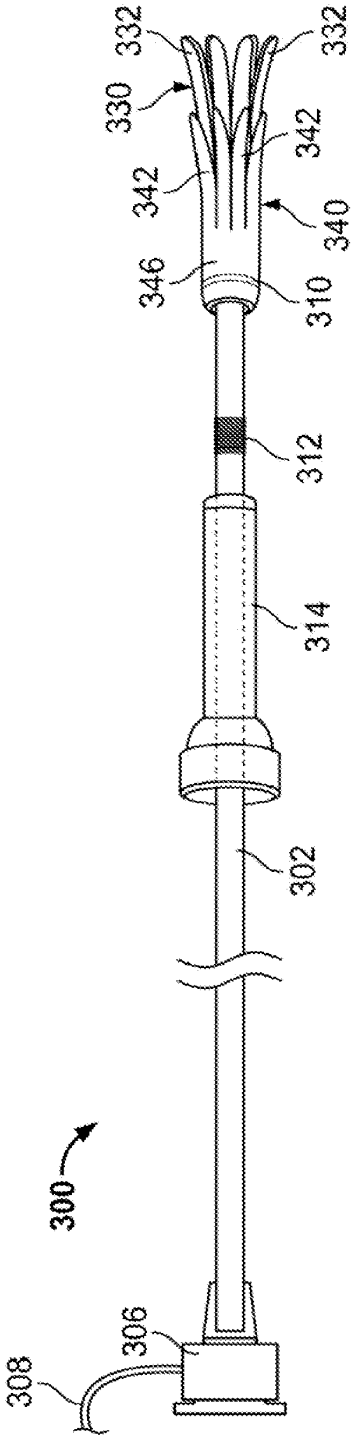


FIG. 11A

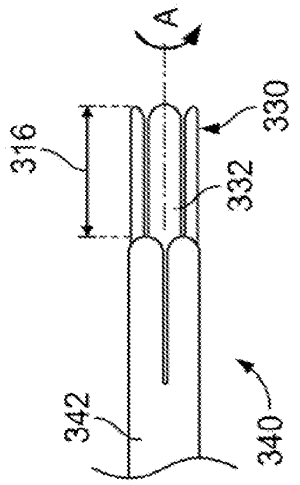


FIG. 11C

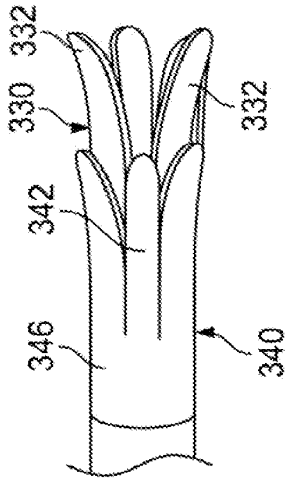


FIG. 11B

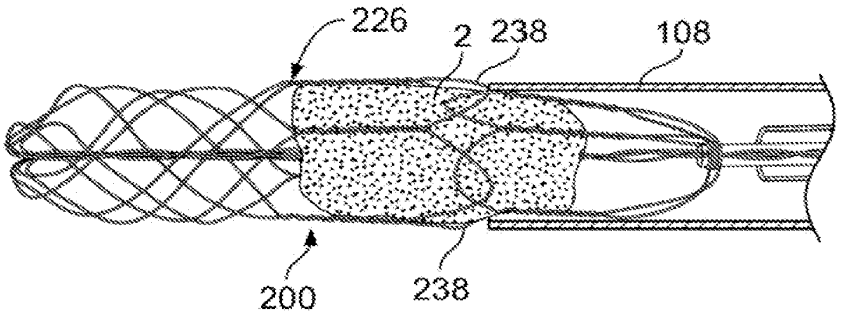


FIG. 12A

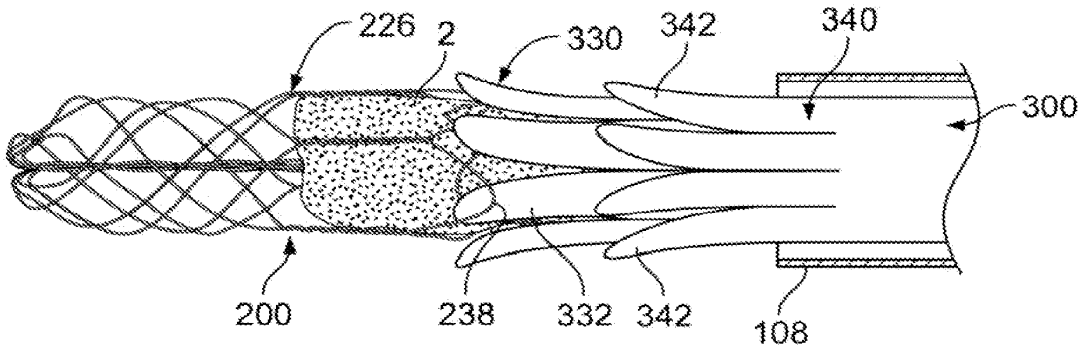


FIG. 12B

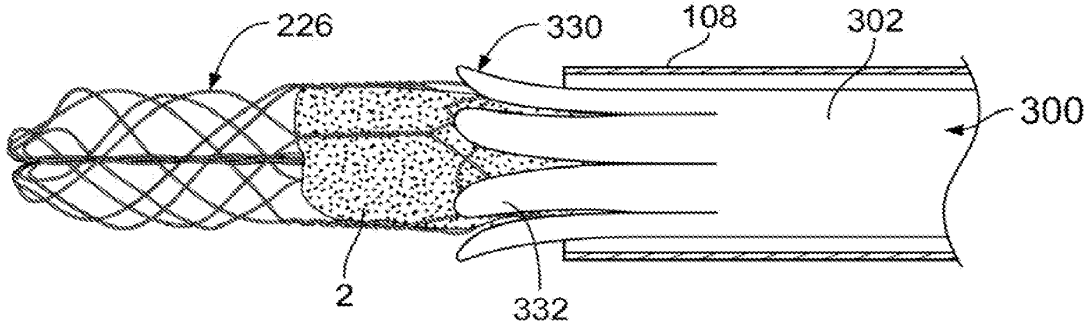


FIG. 12C

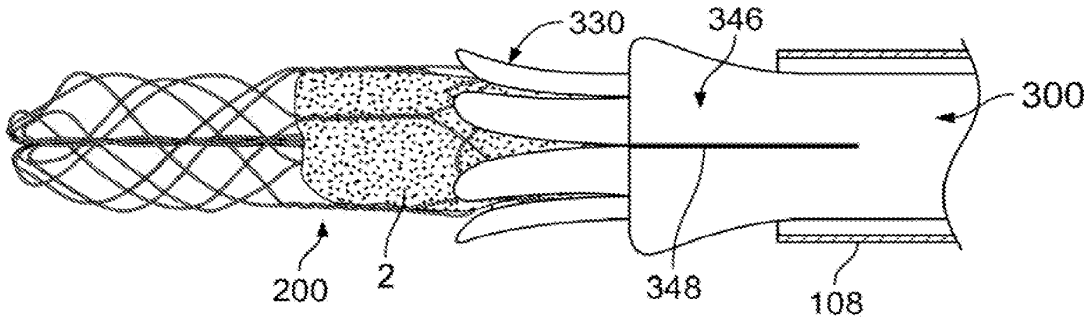


FIG. 12D

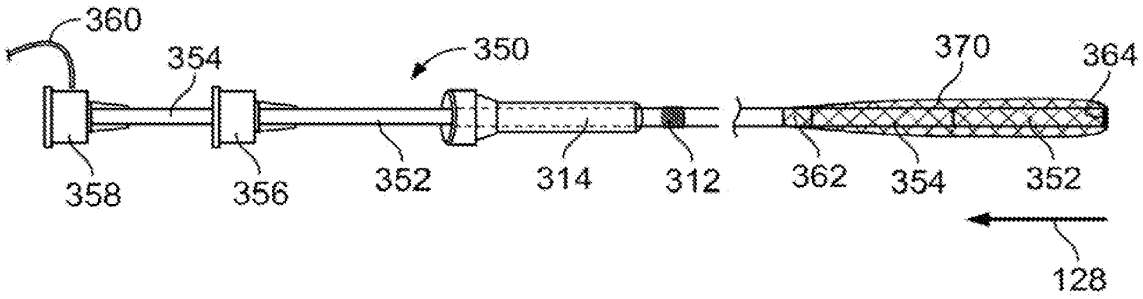


FIG. 13A

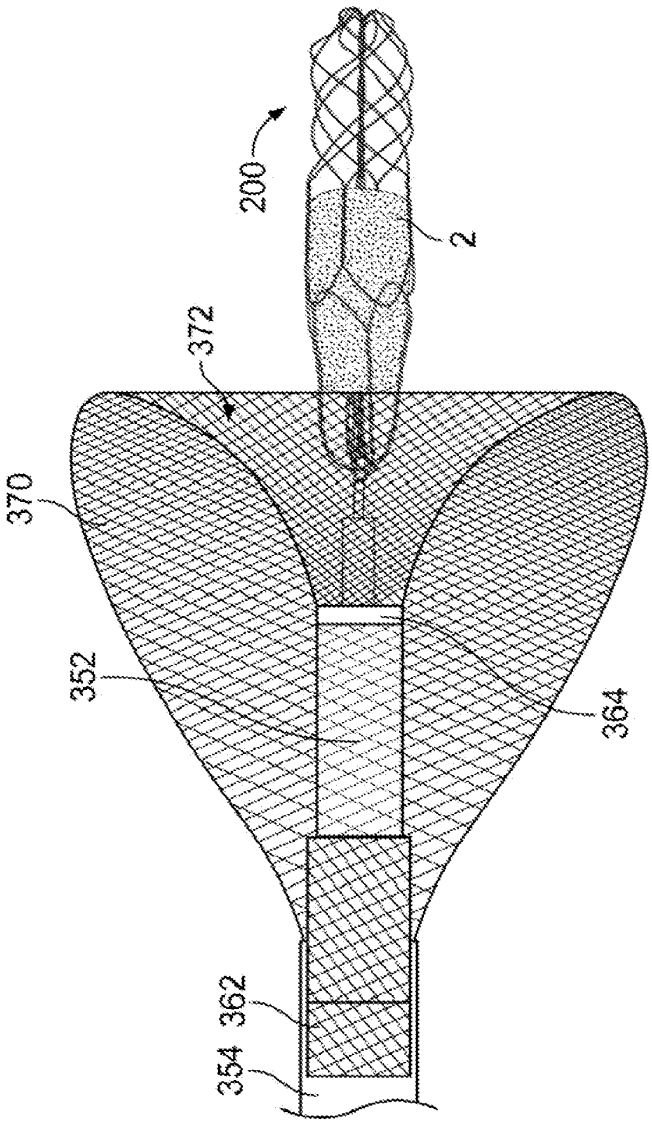


FIG. 13B

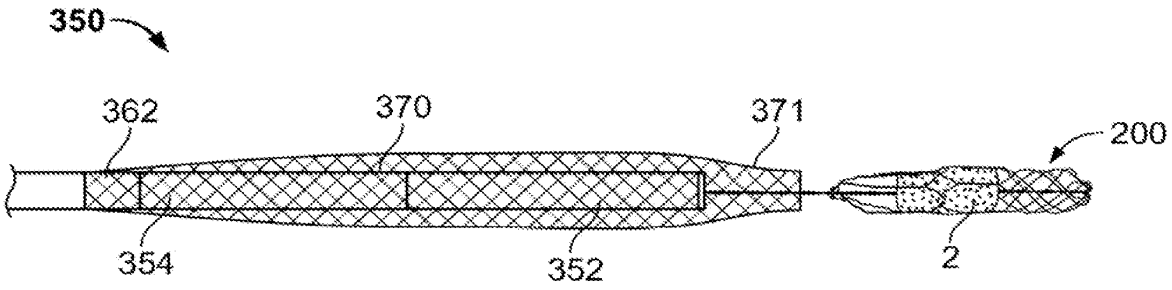


FIG. 13C

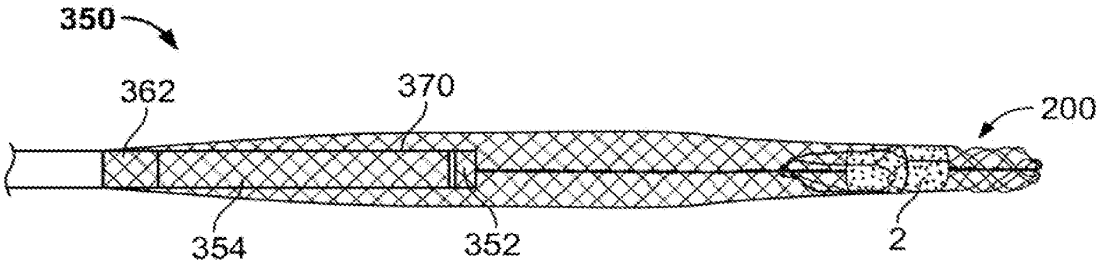


FIG. 13D

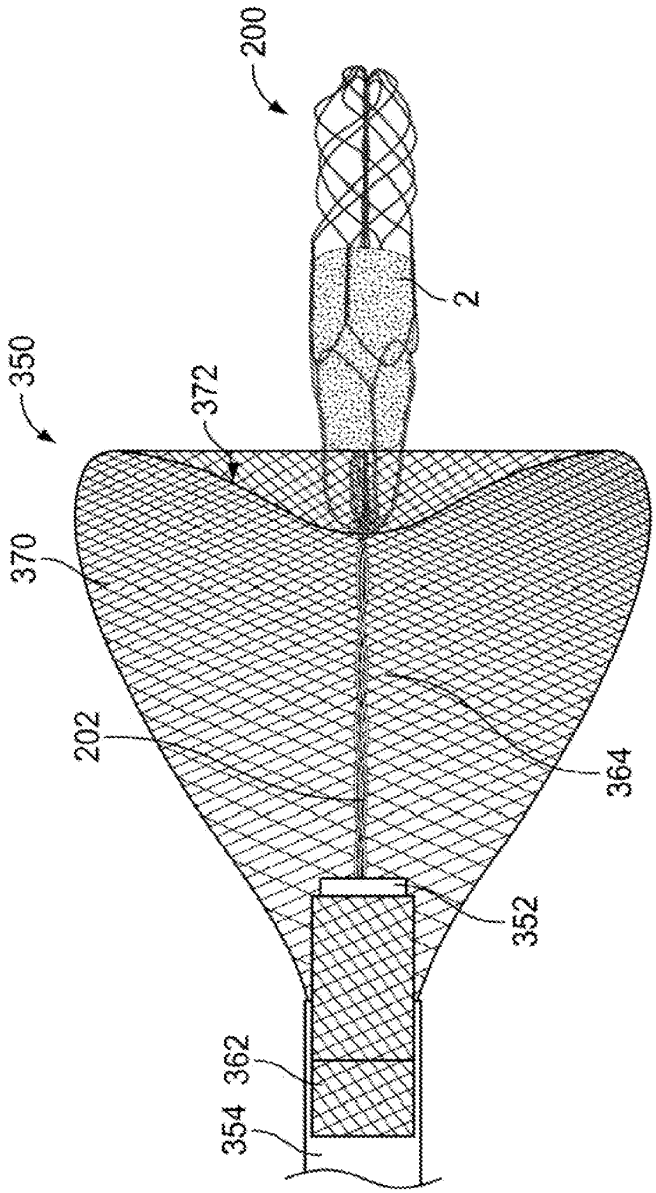


FIG. 13E

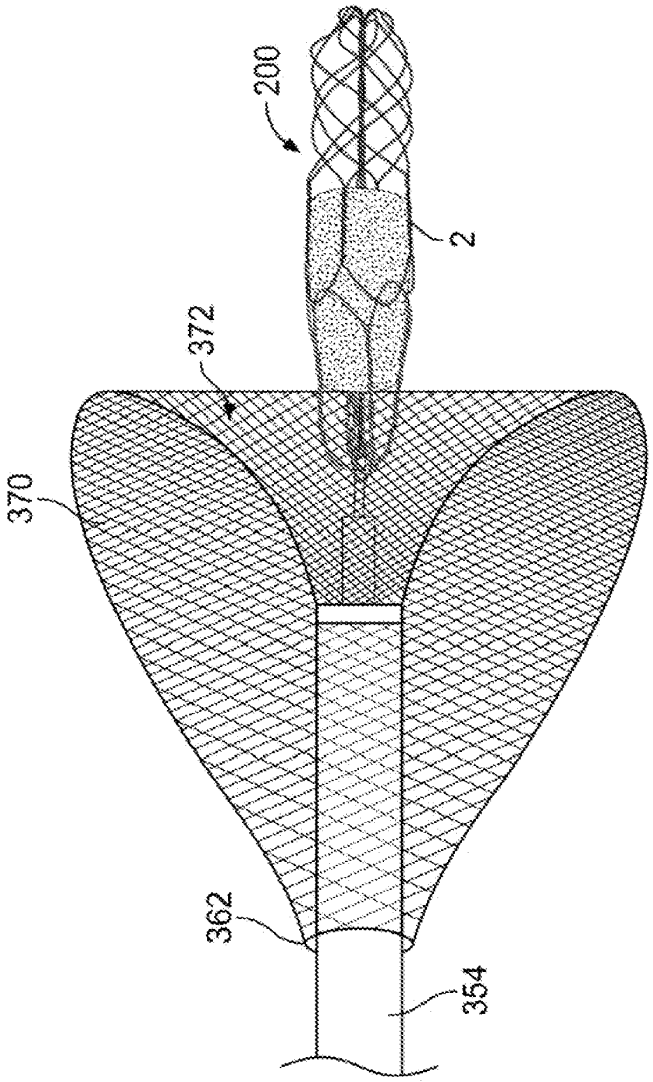


FIG. 13G

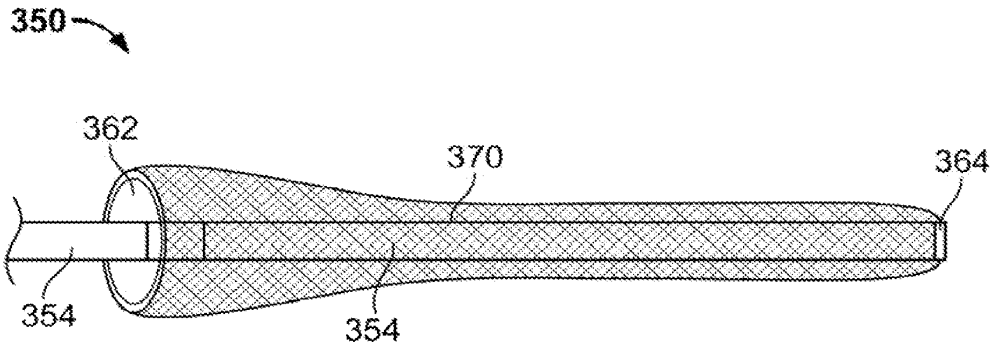


FIG. 13F

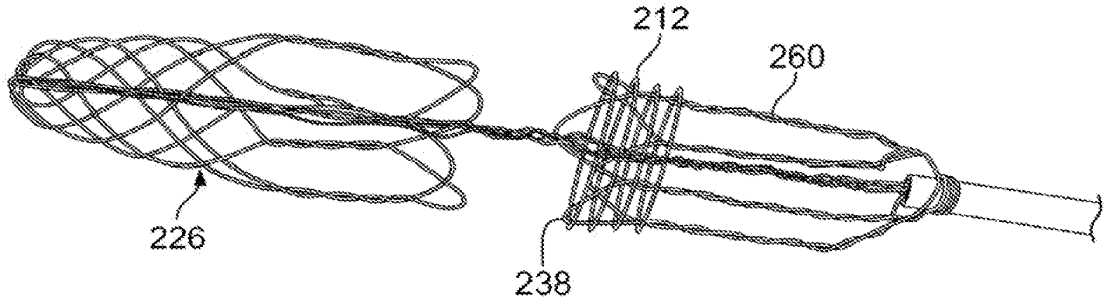


FIG. 14A

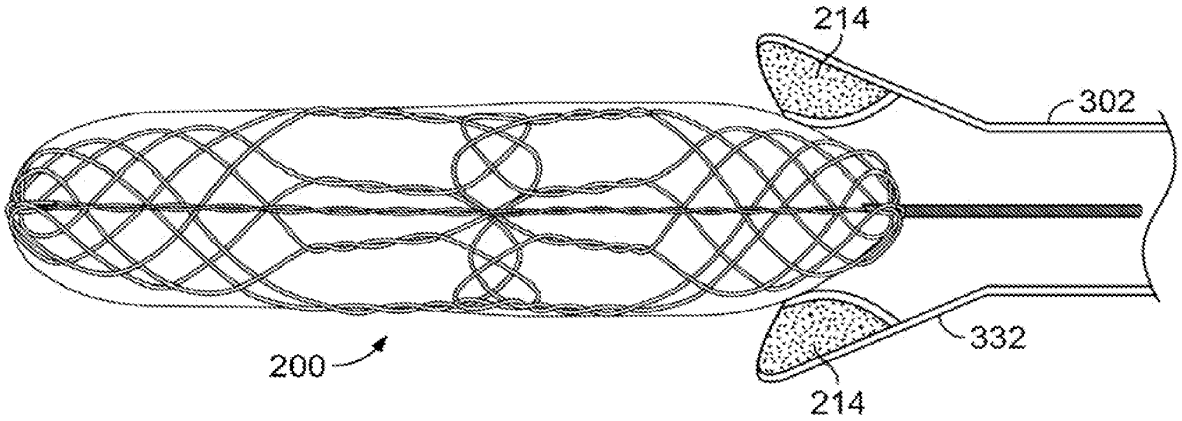


FIG. 14B

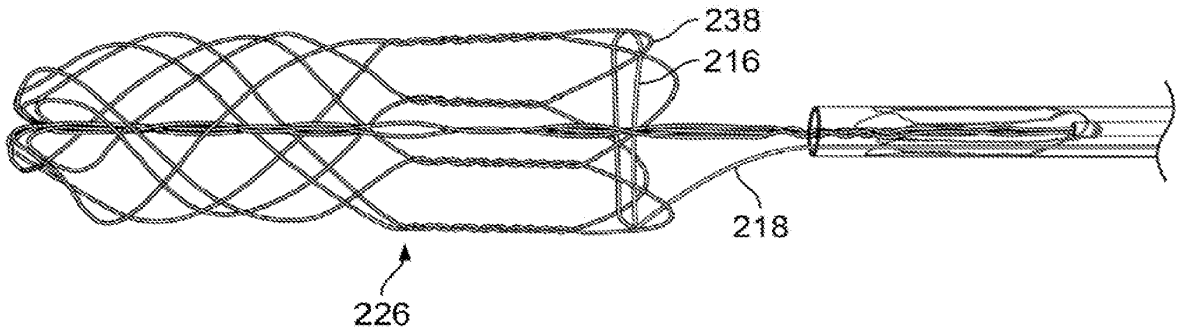


FIG. 14C

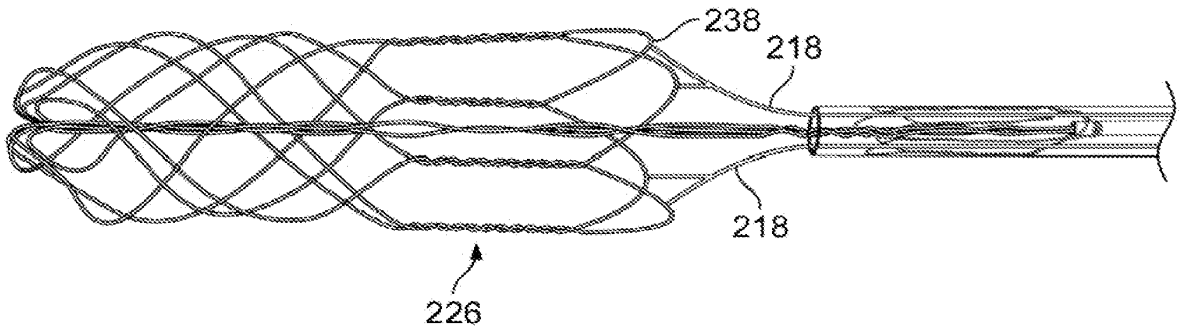


FIG. 14D

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/88371

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/22 (2009.01)
USPC - 606/200
According to International Patent Classification (IPC) or to both national classification and IPC

B FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
606/200

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
A61B 17/221 (2009.01)
606/127, 159

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest, Google
Search Terms Used: obstruction, blood vessel,lumen, wire, capture, removal, catheter, retrieval device, friction,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2006/0009784 A1 (Behl et al.) 12 January 2006 (12.01.2006), abstract, para [0009], [0013]-[0014], [0029]-[0030]	1-76, 109-114
Y	US 2007/0225749 A1 (MARTIN et al.) 27 September 2007 (27.09.2007), para [0014]-[0017], [0044], [0082], [0096]-[0098]	1-76, 109-114
Y	US 2005/0090857 A1 (Kusleika et al.) 28 April 2005 (28.04.2005), para [0035] .Fig.4B, para [0066], [0073], [0089]. Fig 8.	18, 20-21, 38-40, 48, 51-64, 66-69, 72-76, 109-114
Y	US 2005/0004594 A1 (Nool et al.) 6 January 2005 (6.01.2005), para [0042], [0077]	53, 73
Y	US 6,221,006 B1 (Dubrul et al.) 24 April 2001 (24.04.2001), Col 16, ln 41-42.	7, 32, 111-112

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

* Special categories of cited documents:
"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
5 April 2009 (05. 04. 2009)	16 APR 2009
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/88371

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

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

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

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

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

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

This International Searching Authority found multiple inventions in this international application, as follows:
In order for more that one invention to be examined, the appropriate examination fees must be paid.
There are considered to be 2 inventions as follows:

Group I: claims 1-76 and 109-114 characterized by the axial strength of the capture wire
Group II: claims 77-108 characterized by a funnel

Groups I and II share the technical feature of a retrieval sheath. This generic feature does not avoid the prior art, as evinced by US 2005/0090857 A1 to KUSLEIKA et al which teaches a common example of such a sheath (para [0046]).

The inventions listed above do not relate to a single general inventive concept under PCT rule 13.1 because, under PCT Rule 13.2 the inventions lack the same or corresponding special technical features. Neither of these technical features is common to the other group nor do they correspond to a special technical feature in the other groups.

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

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

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

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
claims 1-76 and 109-114

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2007)

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A61M 5/32 (2006.01) *A61M 5/00* (2006.01)

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(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,

(54) Title: MEDICAMENT FILLING SYSTEM

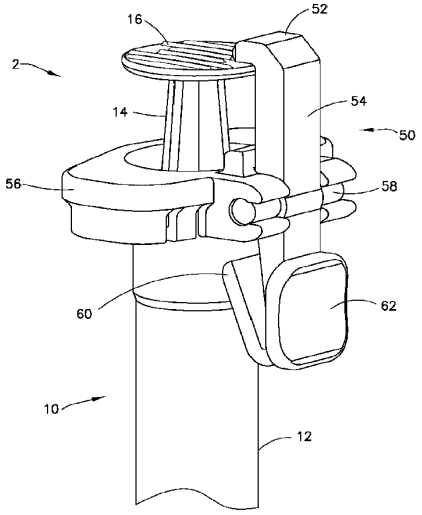


FIG. 1

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

[Continued on next page]

WO 2021/067134 A1

TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

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

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

MEDICAMENT FILLING SYSTEM

RELATED APPLICATION

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

FIELD OF THE INVENTION

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

BACKGROUND OF THE INVENTION

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

SUMMARY OF THE INVENTION

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

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

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

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

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

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

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

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

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

BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CLAIMS

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

a syringe, including:

a barrel configured to carry the medicament;

a plunger that communicates with the barrel; and

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

a locking assembly disposed around the barrel;

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

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

3. The syringe assembly of claim 1, wherein:

the locking assembly includes:

a hook configured to engage the plunger head; and

a depressible button and spring member connected to the hook,

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

4. The syringe assembly of claim 3, wherein:

the locking assembly further includes:

a base engaged to the barrel;

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

a shaft that connects the arm to the base.

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

6. The syringe assembly of claim 4, wherein:

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

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

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

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

7. The syringe assembly of claim 3, wherein:

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

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

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

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

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

a syringe, including:

a barrel configured to carry a medicament; and

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

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

a notch disposed in each axial rib; and

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

11. The syringe assembly of claim 10, wherein:

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

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

12. The syringe assembly of claim 11, wherein:

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

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

13. The syringe assembly of claim 12, wherein:

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

the arm extends upward from the base; and

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

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

a vial adapter comprising:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

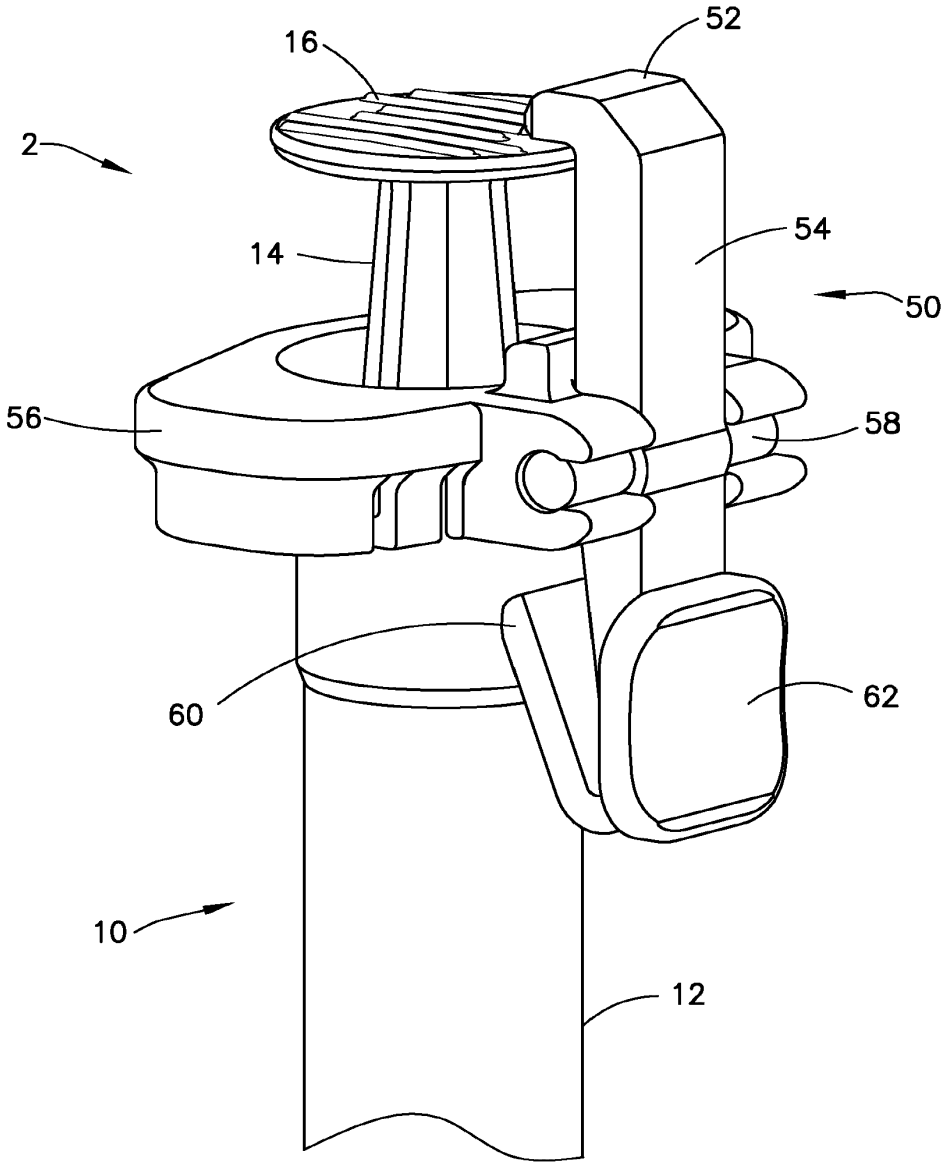


FIG. 1

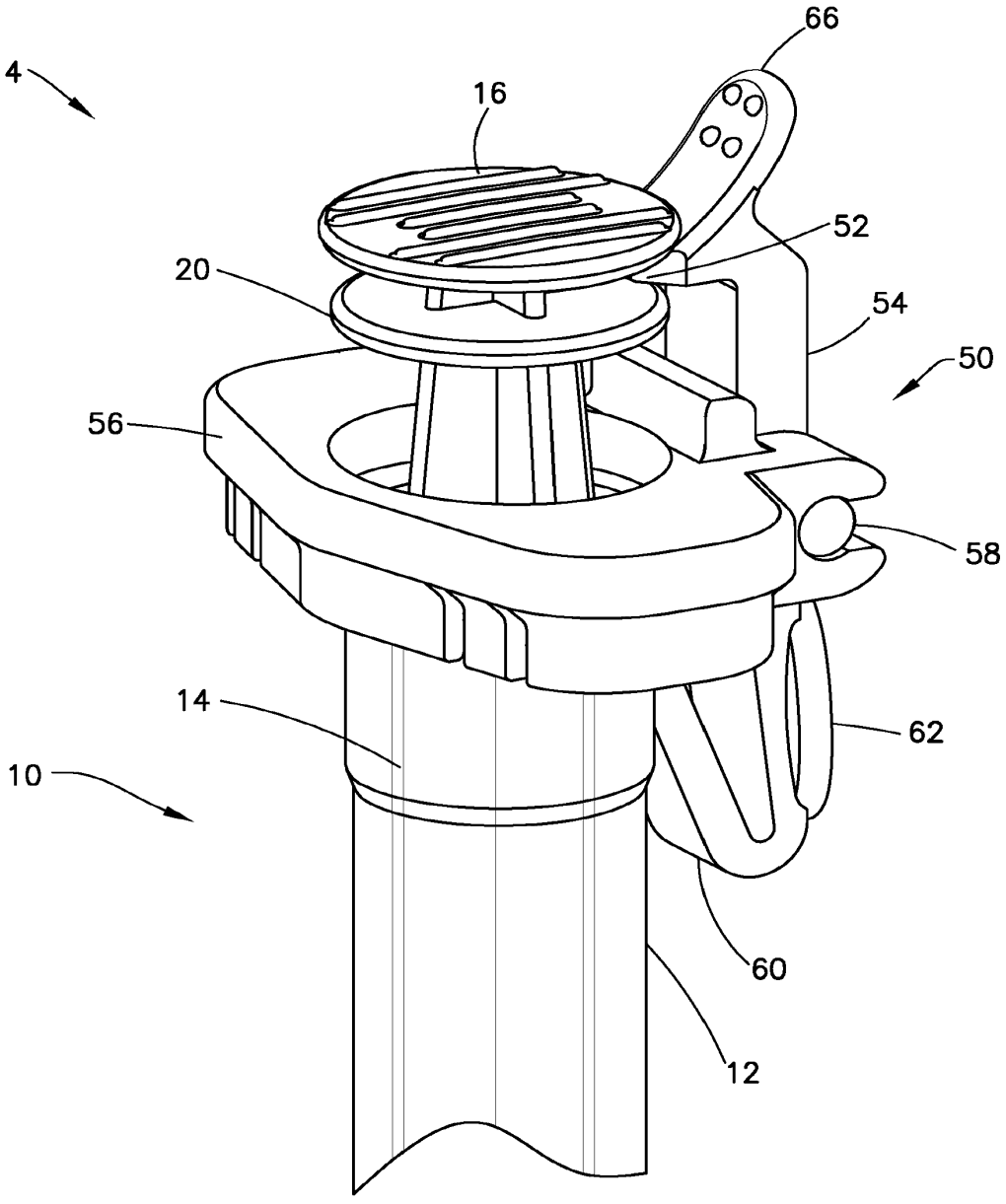


FIG.2

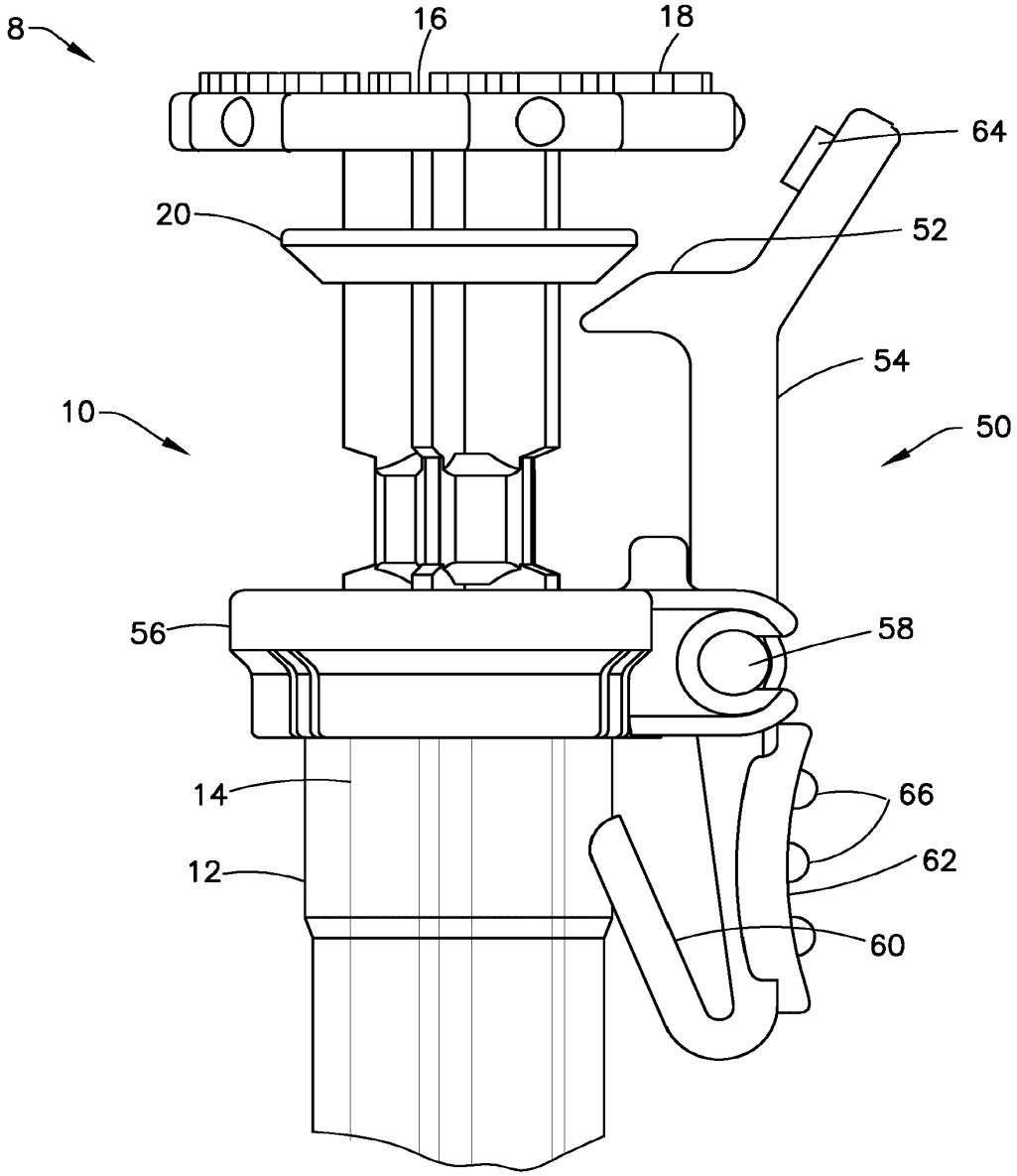


FIG.3

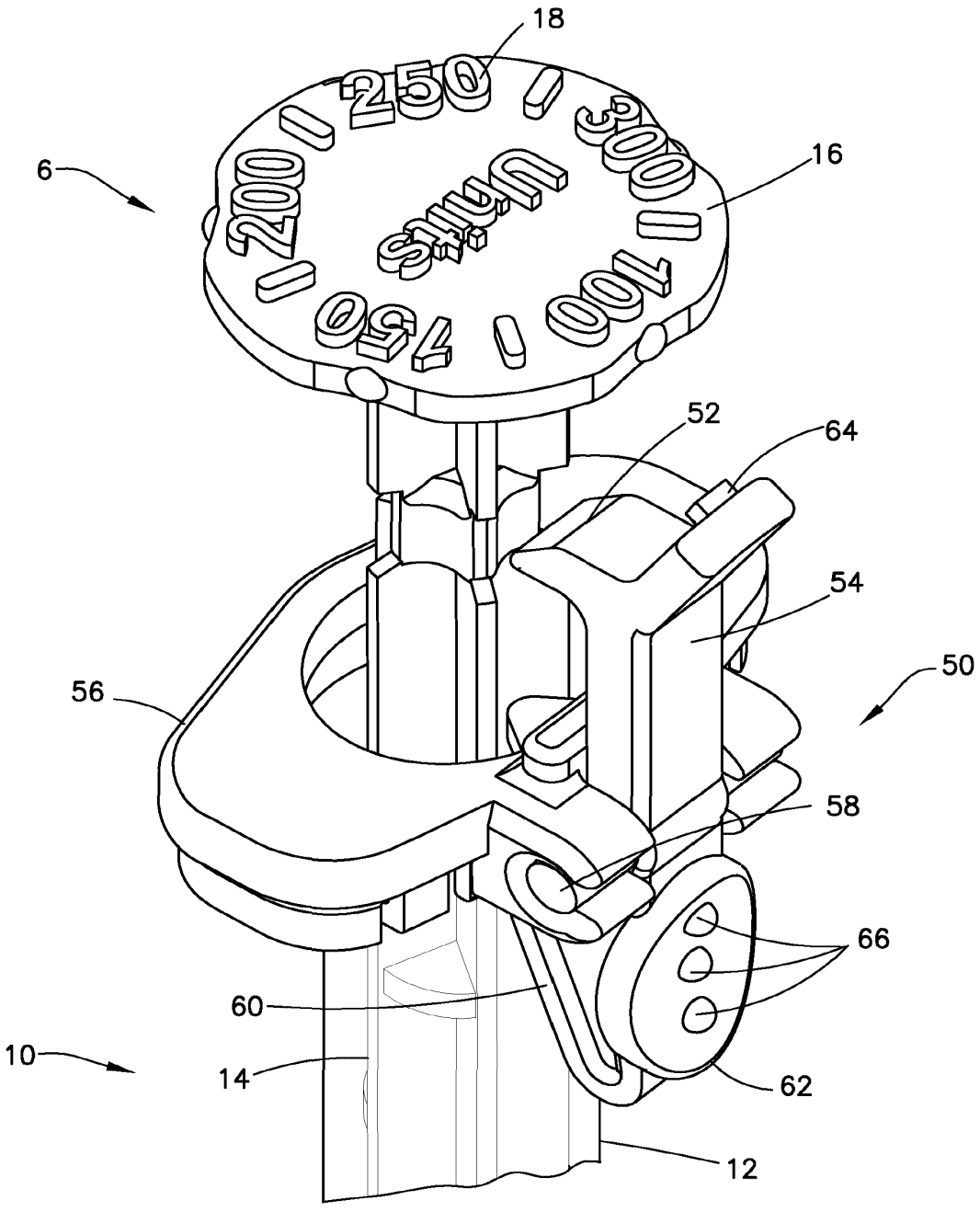


FIG.4

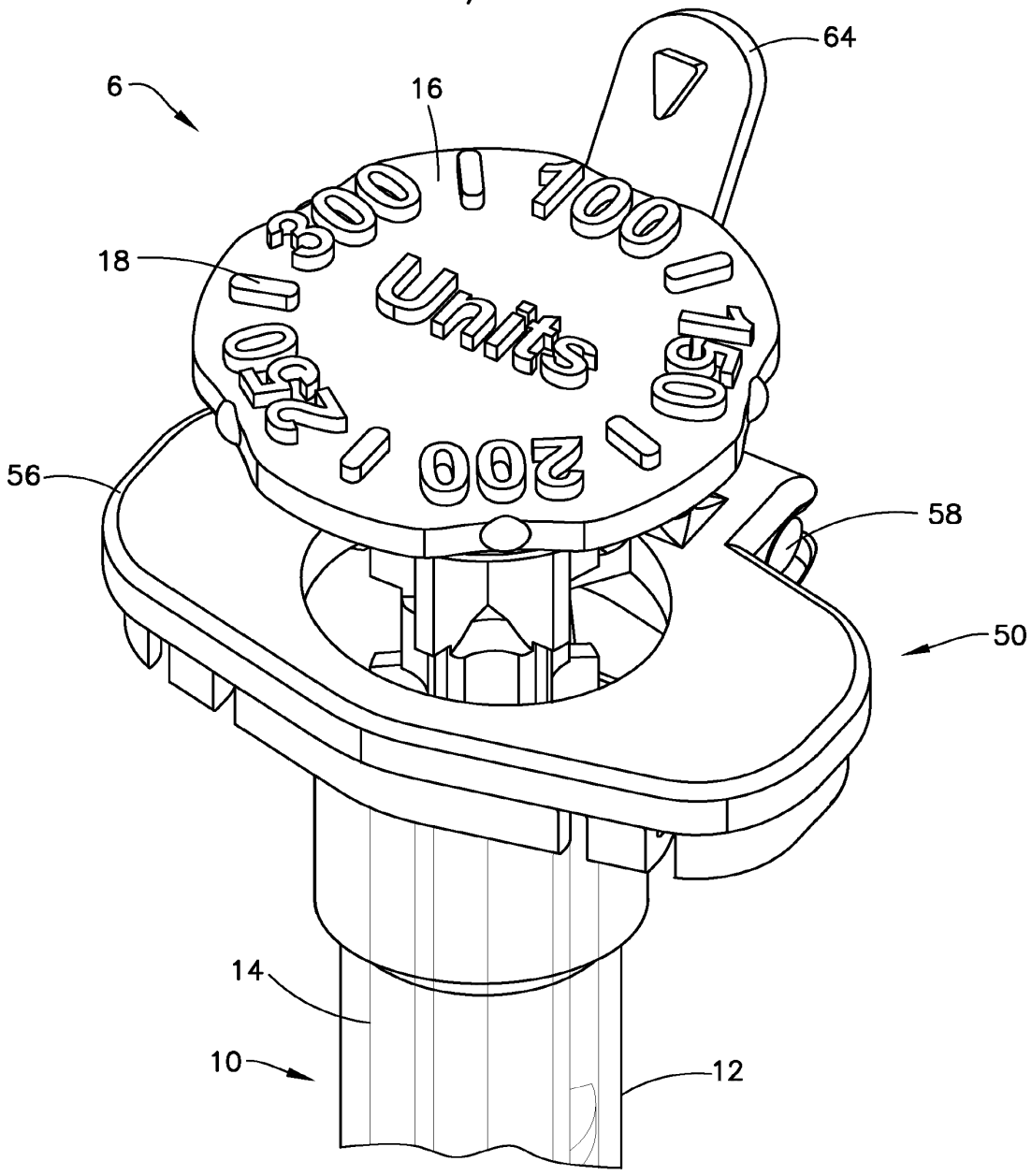


FIG.5

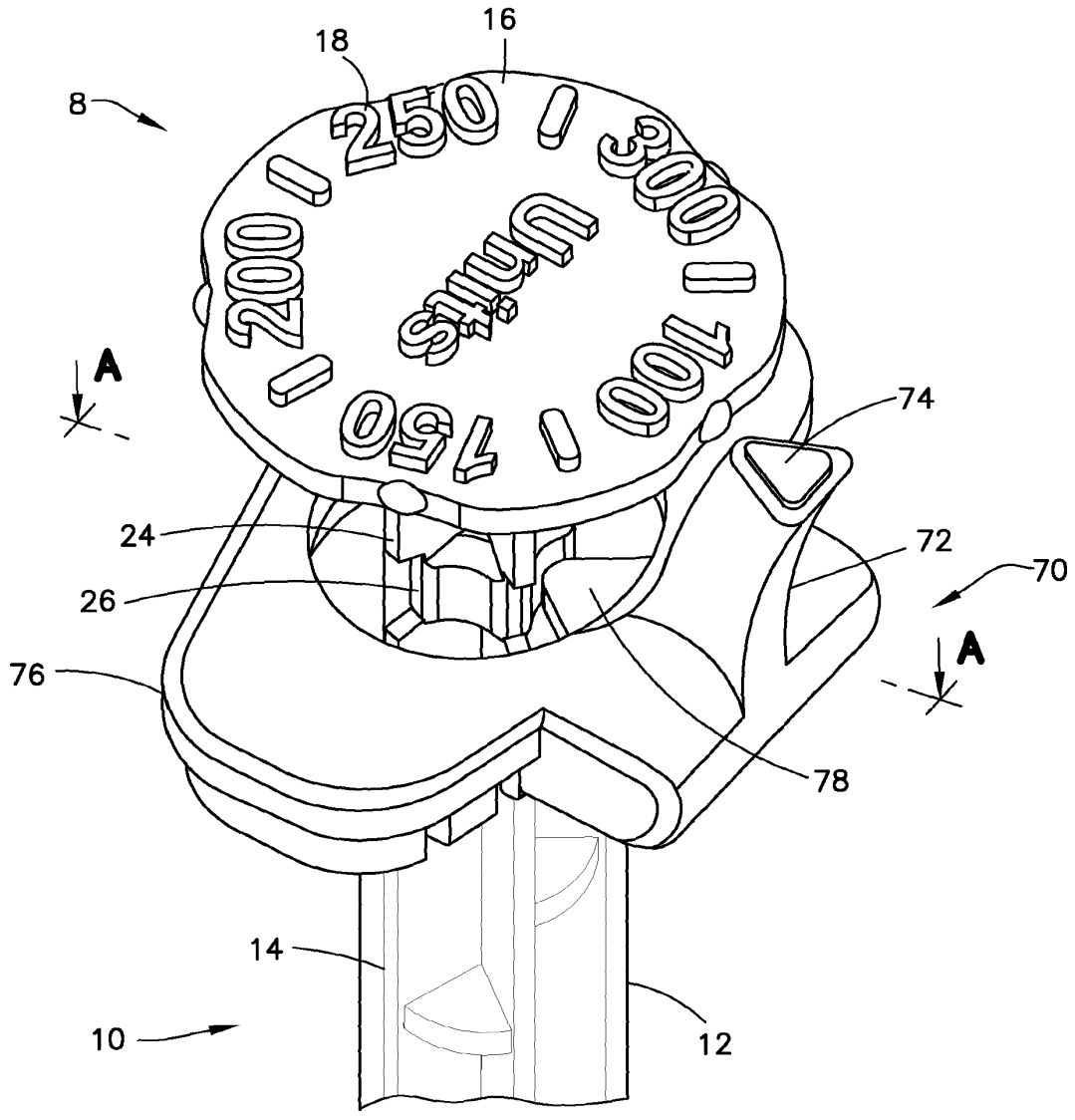


FIG.6

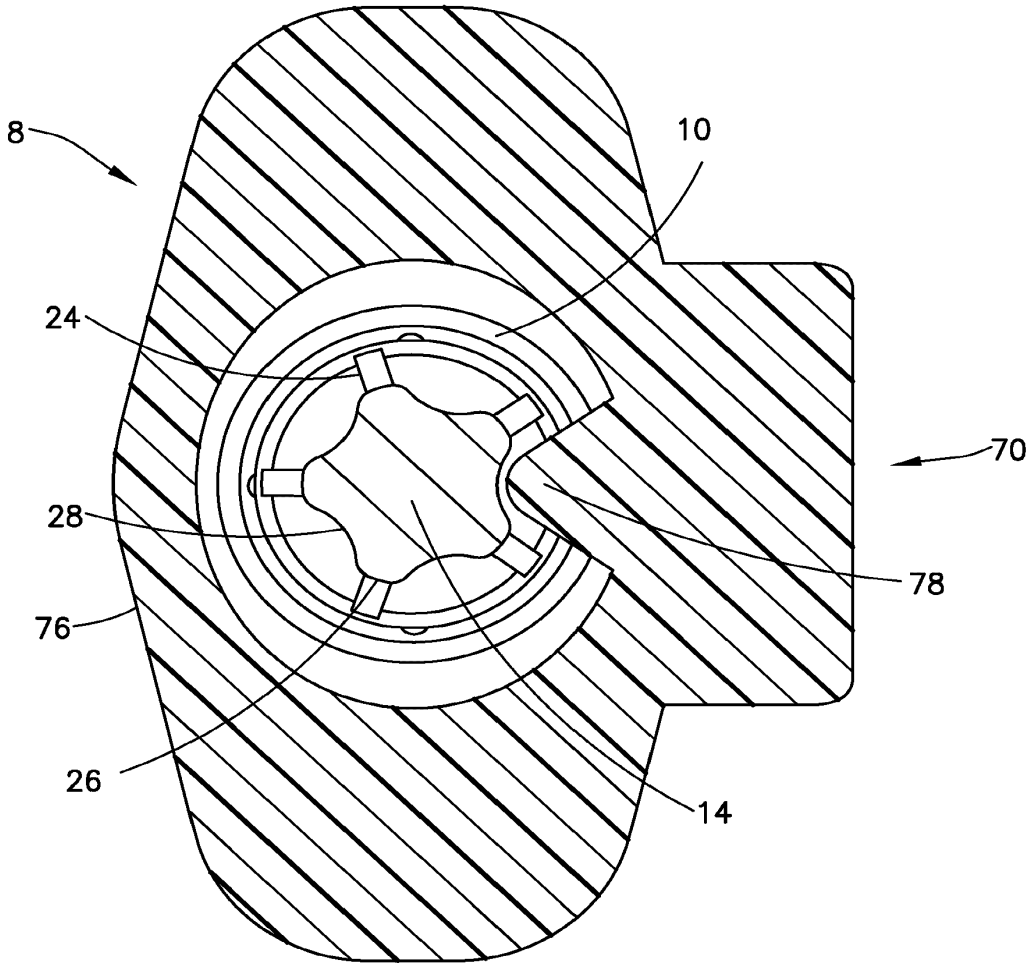


FIG.7

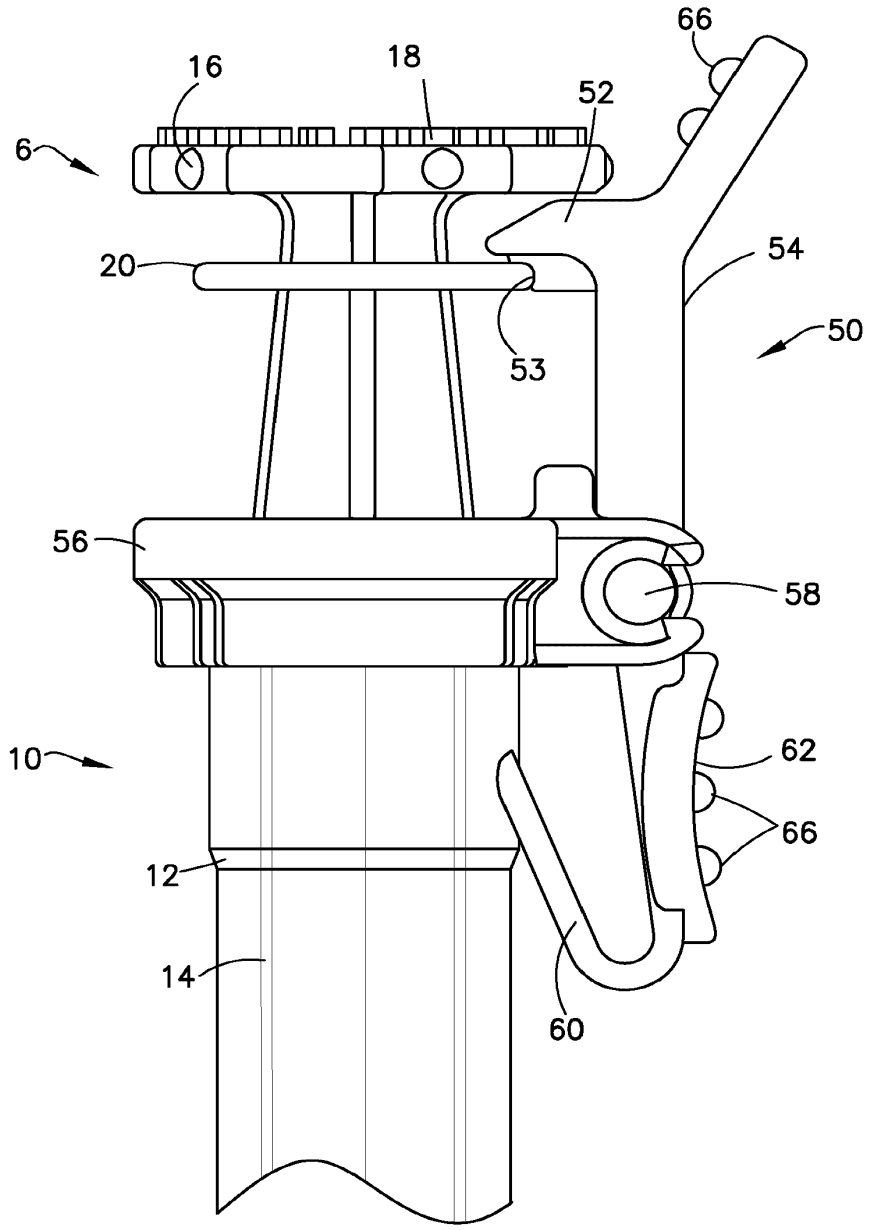


FIG.8

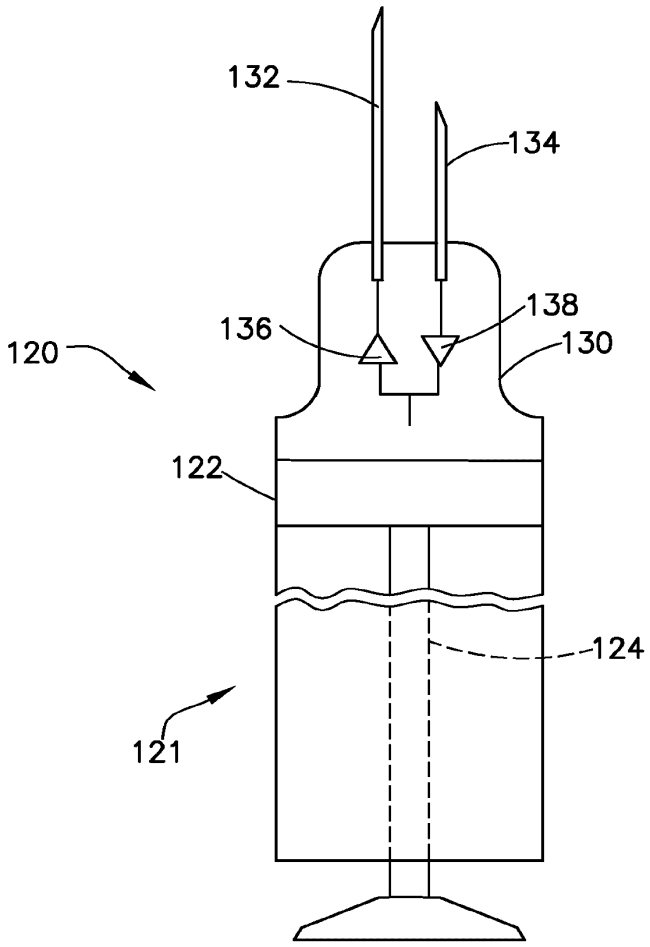


FIG.9

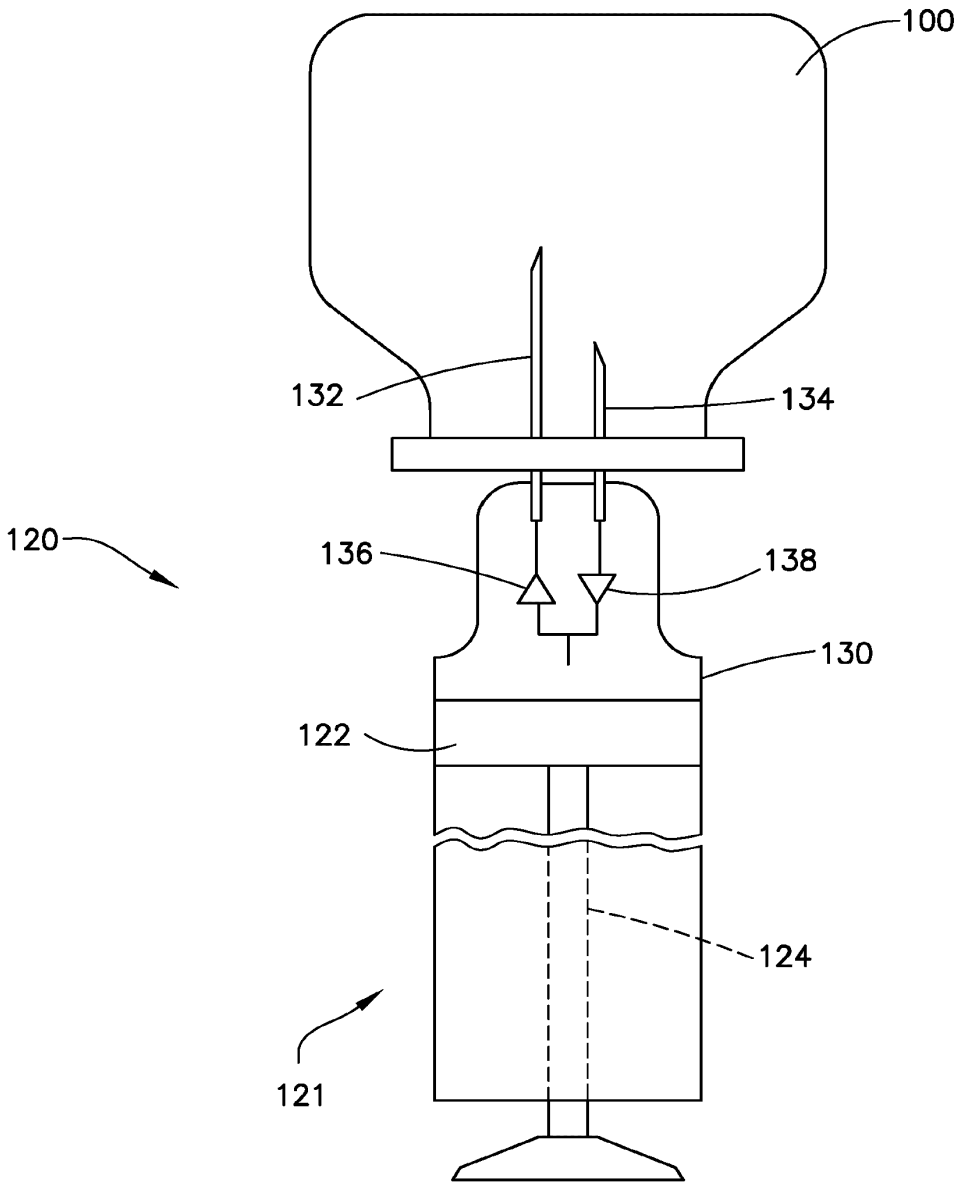


FIG.10

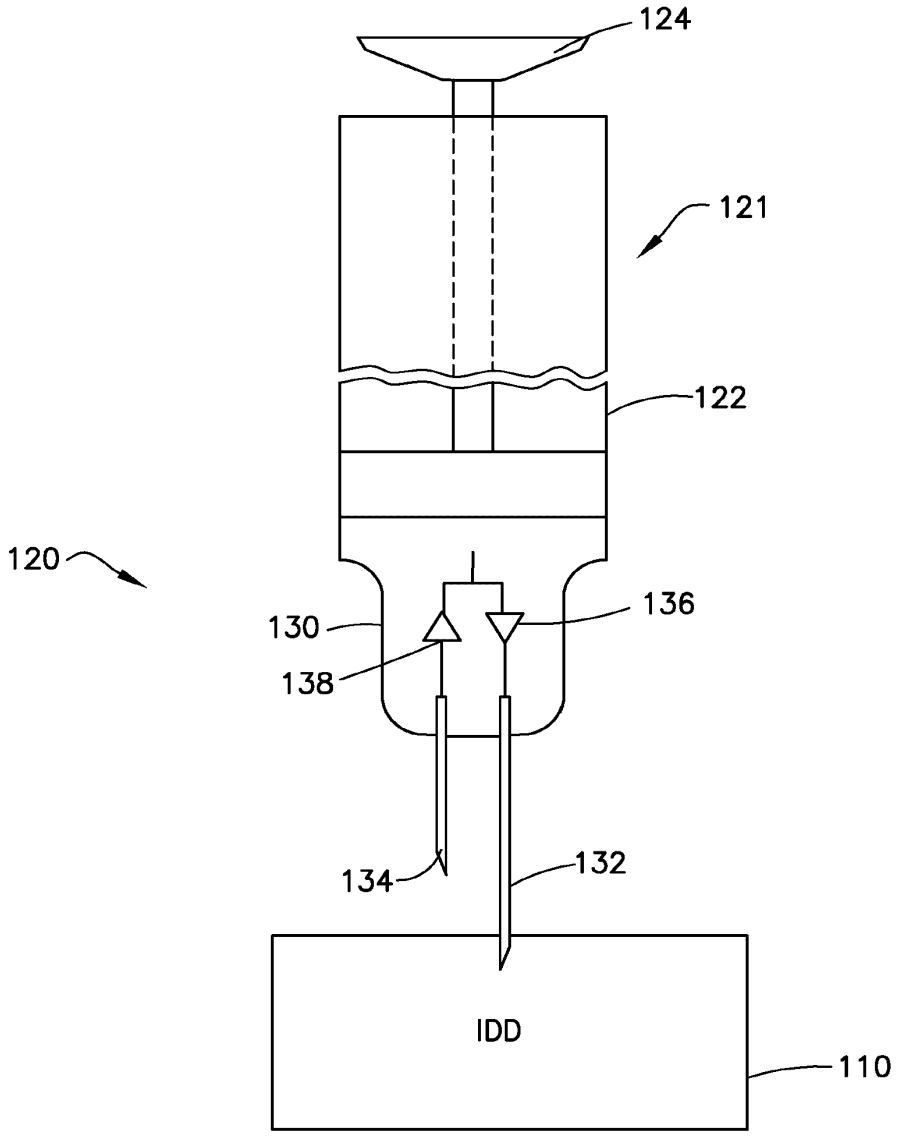


FIG.11

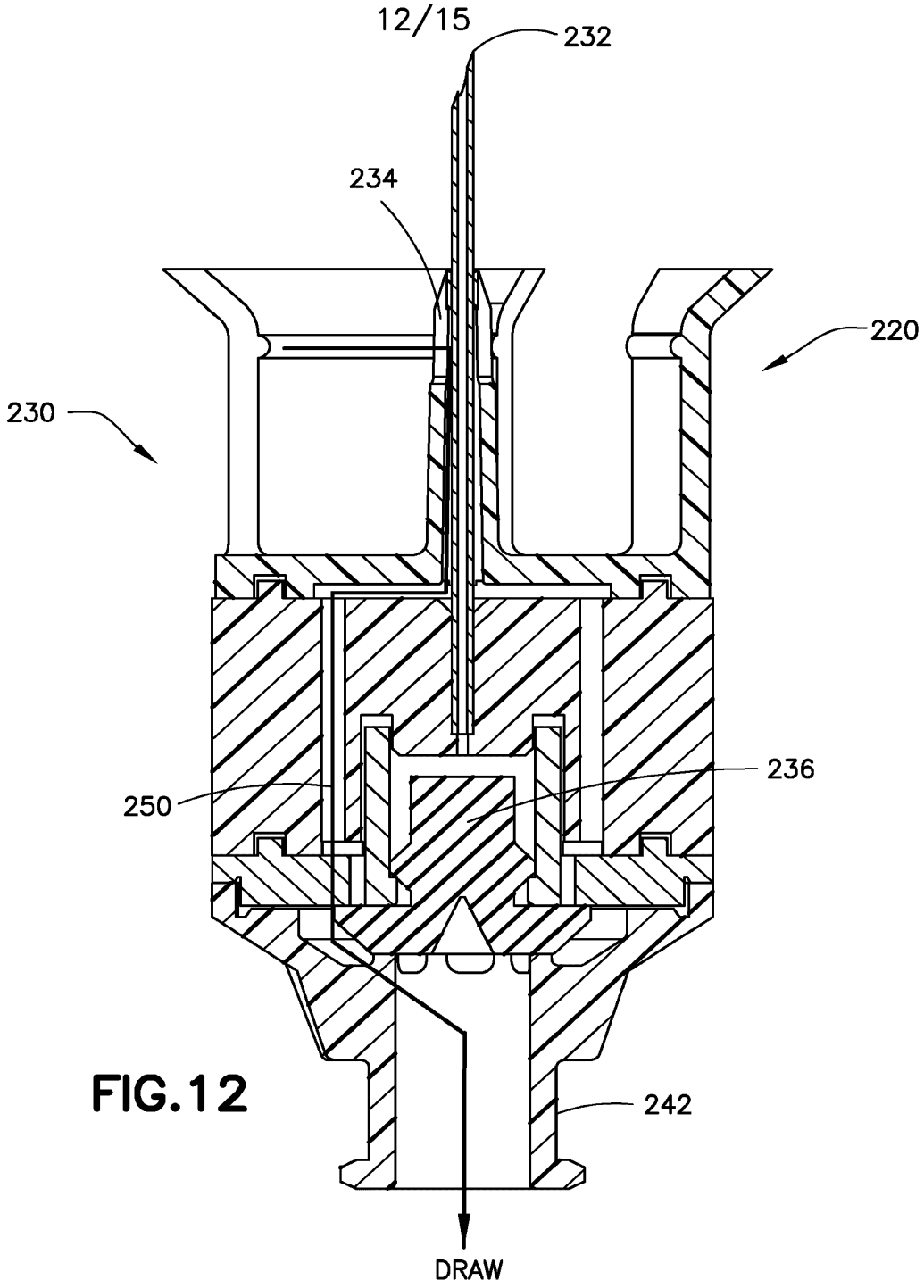


FIG.12

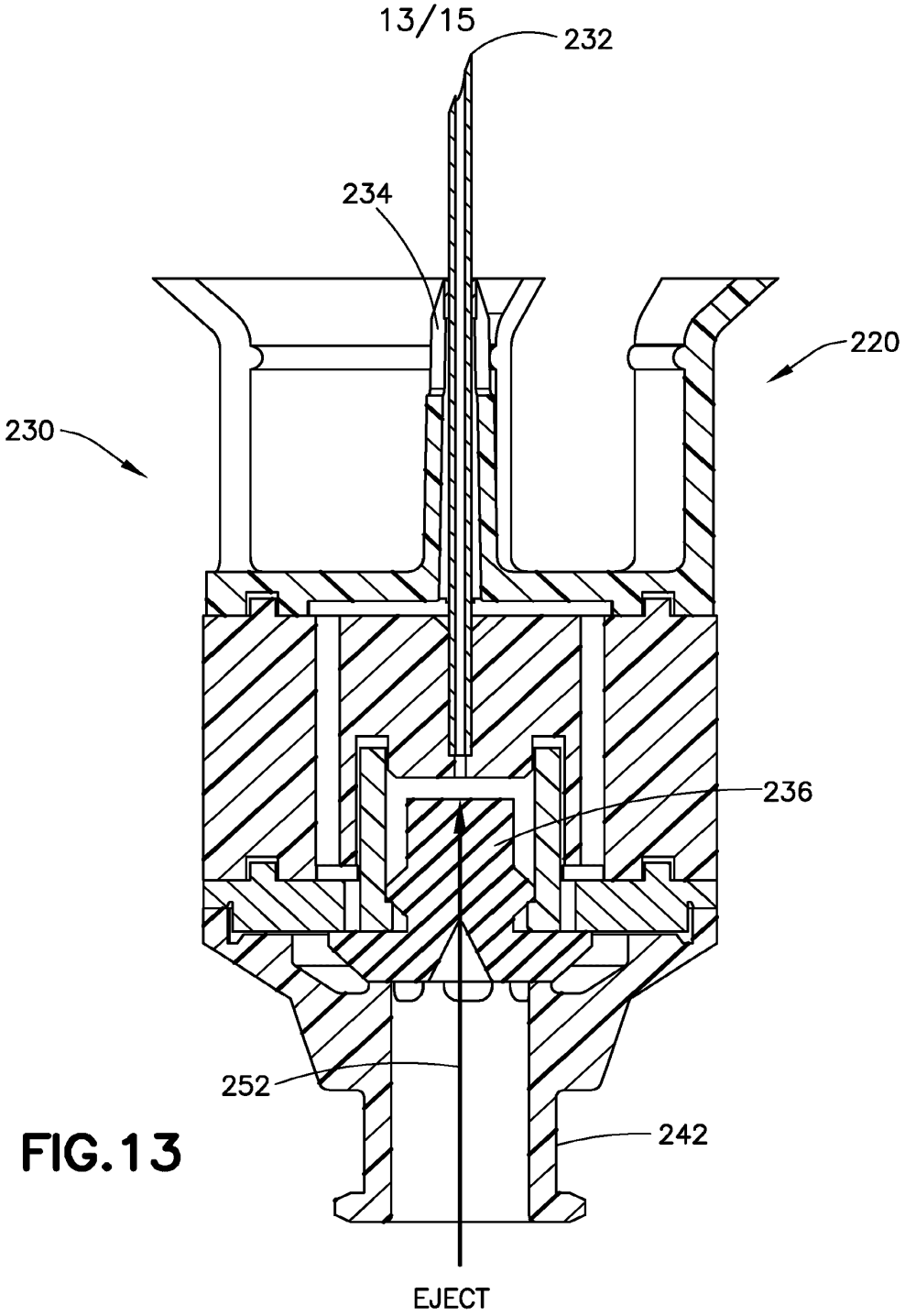


FIG. 13

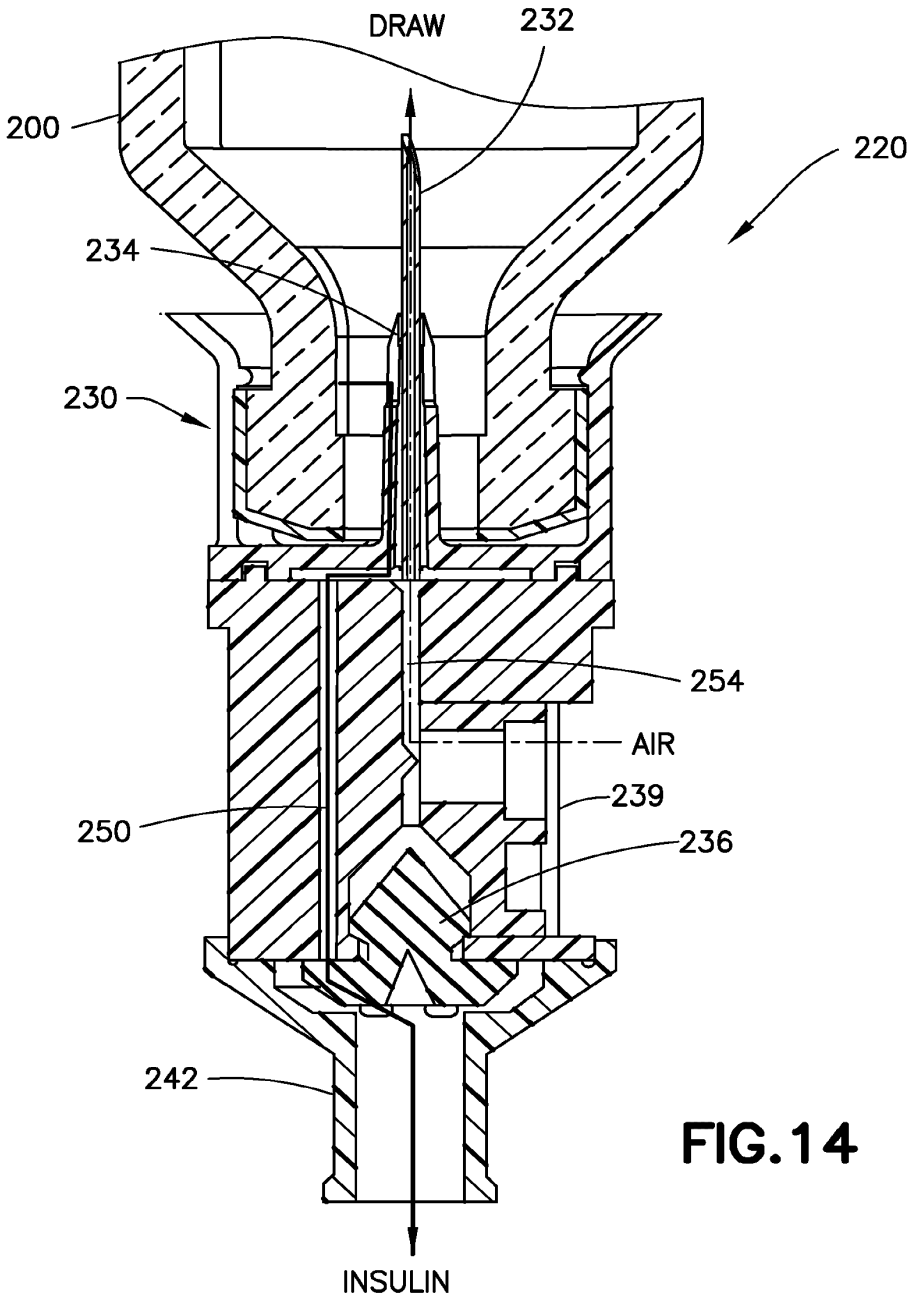


FIG.14

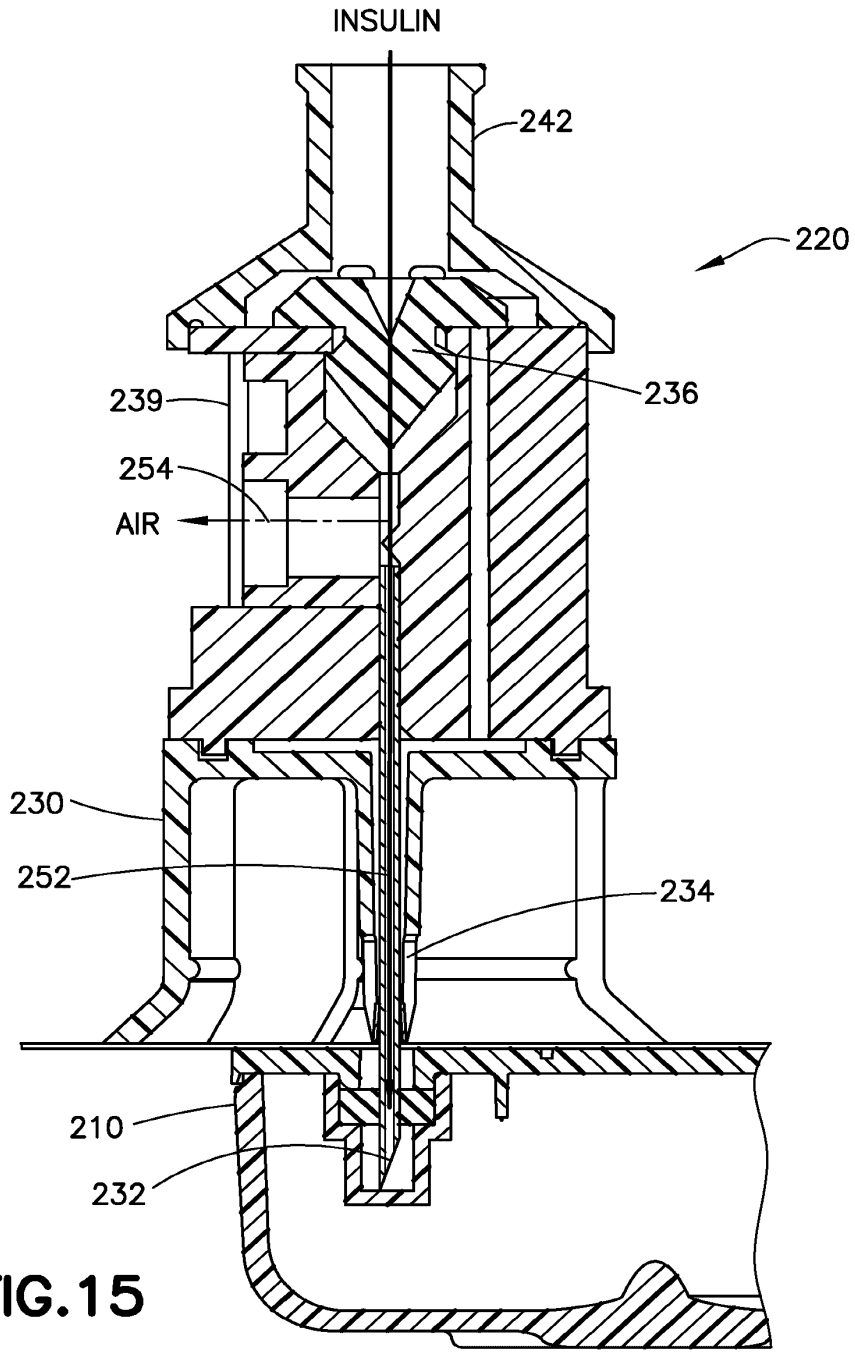


FIG.15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 20/52760

A. CLASSIFICATION OF SUBJECT MATTER

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

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y -- A	US 5,830,152 A (TAO) 3 November 1998 (03.11.1998); entire document, especially col 6 ln 14-51, and Fig. 1-2.	1 -- 2 -- 3-9
X -- A	WO 99/07421 A1 (GENESIS INDUSTRIES INCORPORATED) 18 February 1999 (18.02.1999); entire document, especially pg 6 ln 19 to pg 7 ln 12, and Fig. 1-2.	10 -- 11-13
X -- A	US 2010/0276034 A1 (GONNELLI et al.) 4 November 2010 (04.11.2010); entire document, especially para [0063], and Fig. 17.	14-17 -- 18-21
Y	US 4,498,904 A (TURNER et al.) 12 February 1985 (12.02.1985); especially col 3 ln 45-65, and Fig. 1-4.	2
A	US 2010/0084041 A1 (FEHR et al.) 8 April 2010 (08.04.2010); entire document.	1-21
A	US 2014/0018770 A1 (SUTKIN) 16 January 2014 (16.01.2014); entire document.	1-21

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
13 January 2021	17 FEB 2021
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Lee Young Telephone No. PCT Helpdesk: 571-272-4300

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 20/52760

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

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

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

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

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

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

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

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

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

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

-*- See Supplemental Box -*-

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

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

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

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

Remark on Protest

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

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

☒ No protest accompanied the payment of additional search fees.

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

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

SPECIAL TECHNICAL FEATURES

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

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

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

COMMON TECHNICAL FEATURES

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

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

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

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

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WIPO | PCT

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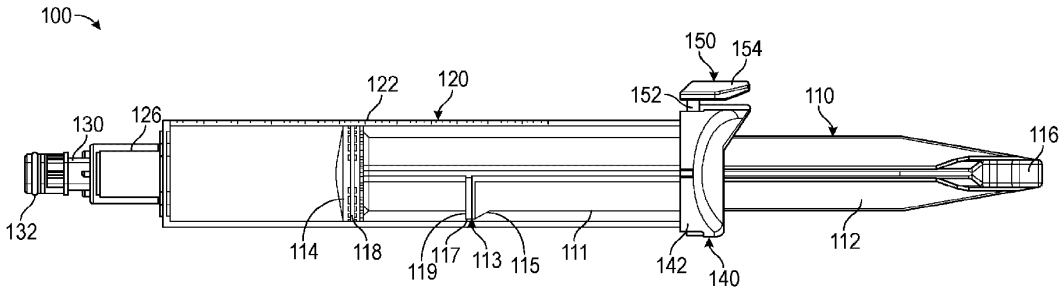


FIG. 1B

(57) Abstract: Automatically-locking syringes are disclosed herein. A syringe in accordance with embodiments of the present technology can include (i) a barrel, (ii) a plunger slidably positioned within the barrel, and (iii) a lock plate coupled to the barrel. The plunger also extends through an opening in the lock plate, and a biasing member is configured to bias the lock plate to a locking position. When the plunger is moved from a depressed position to a withdrawn position, the lock feature engages the lock plate to drive the lock plate away from the locking position to thereby permit the lock feature to pass through the opening in the lock plate. After the lock feature passes through the opening, the biasing member drives the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.

[Continued on next page]

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AUTOMATICALLY-LOCKING VACUUM SYRINGES, AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/061,902, filed August 6, 2020, and titled "AUTOMATICALLY-LOCKING VACUUM SYRINGES, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology relates generally to systems, methods, and devices for the intravascular treatment of emboli and/or thrombi within a blood vessel of a human patient. In particular, some embodiments of the present technology relate to automatically-locking syringes for generating and releasing stored vacuum pressure to aspirate clot material from a blood vessel.

BACKGROUND

[0003] Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

[0004] When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. However, infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can accordingly lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

[0005] In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT commonly occurs where there is a propensity for stagnated blood (e.g., long distance air travel, immobility) and clotting (e.g., cancer, recent surgery such as orthopedic surgery,). DVT can obstruct drainage of venous blood from the legs leading to swelling, ulcers, pain and infection. DVT can also create a reservoir in which blood clots can collect and then travel to other parts of the body including the heart, lungs, brain (stroke), abdominal organs, and/or extremities.

[0006] In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs, and therefore the entire body. This can result in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting in low blood oxygen and buildup of blood carbon dioxide.

[0007] There are many existing techniques to reestablish blood flow through an occluded vessel. Embolectomies, for example, are a surgical technique involving incising a blood vessel and placing a balloon-tipped device (such as the Fogarty catheter) at the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to withdraw the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Although such surgical techniques have been useful, exposing a patient to surgery may be traumatic and best avoided when possible. Additionally, the use of a Fogarty catheter may be problematic due to the possible risk of damaging the interior lining of the vessel as the catheter is being withdrawn.

[0008] Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating vessel stenosis, but it is generally not effective for treating acute thromboembolisms as none of the occlusive material is removed and restenosis regularly occurs after dilation. Another percutaneous technique involves placing a catheter near the clot and infusing streptokinase, urokinase, or other thrombolytic agents to dissolve the clot. Unfortunately, thrombolysis typically takes hours to days to be successful. Additionally, thrombolytic agents can cause hemorrhaging, and in many patients the thrombolytic agents cannot be used at all.

[0009] Various devices exist for performing a thrombectomy or removing other foreign material. However, such devices have been found to have structures which are either highly complex, cause trauma to the treatment vessel, or lack the ability to be appropriately fixed against the vessel. Furthermore, many of the devices have highly complex structures that lead to manufacturing and quality control difficulties as well as delivery issues when passing through

tortuous or small diameter catheters. Less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all the clot material.

[0010] Thus, there exists a need for improved systems and methods for embolic extraction.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0012] Figures 1A and 1B are an exploded isometric view and a side view, respectively, of a vacuum-pressure locking syringe in accordance with embodiments of the present technology.

[0013] Figures 2A and 2B are isometric views of the syringe of Figures 1A and 1B in a depressed position and a withdrawn position, respectively, in accordance with embodiments of the present technology.

[0014] Figure 3A is a side view, and Figures 3B and 3C are enlarged side views, of the syringe illustrating the steps of locking a plunger of the syringe to a lock member of the syringe in accordance with embodiments of the present technology.

[0015] Figure 4 is an enlarged isometric view of a portion of the syringe in accordance with additional embodiments of the present technology.

[0016] Figures 5A and 5B are an isometric view and a side view, respectively, of a syringe in a withdrawn position in accordance with additional embodiments of the present technology.

[0017] Figure 5C is an isometric of the syringe of Figures 5A and 5B in a depressed position in accordance with embodiments of the present technology.

[0018] Figure 6A is a side view of a vacuum-pressure locking syringe in accordance with additional embodiments of the present technology.

[0019] Figures 6B and 6C are enlarged side views of a locking mechanism of the syringe of Figure 6A in a first position and a second position, respectively, in accordance with embodiments of the present technology.

[0020] Figure 7 is a partially schematic side view of a clot treatment or clot removal system incorporating the syringe of Figures 1A–4, the syringe of Figures 5A–5C, and/or the syringe of Figures 6A–6C in accordance with embodiments of the present technology.

[0021] Figures 8A and 8B are enlarged, partially-schematic side views of a vacuum indicator of the clot removal system of Figure 7 in a vacuum-off position and a vacuum-on position, respectively, in accordance with embodiments of the present technology.

[0022] Figure 9 is a perspective view of a vacuum indicator in a vacuum-off position in accordance with additional embodiments of the present technology.

[0023] Figures 10A and 10B are perspective views of a vacuum indicator in a vacuum-off position and a vacuum-on position, respectively, in accordance with additional embodiments of the present technology.

[0024] Figure 11 is a side-view of the syringe of Figures 1A and 1B including a vacuum indicator in accordance with embodiments of the present technology.

[0025] Figures 12A and 12B are perspective views of a syringe including a vacuum indicator in accordance with additional embodiments of the present technology.

[0026] Figures 13A–13C are side views of a vacuum indicator in a vacuum-off position, a partial-vacuum position, and a full-vacuum position, respectively, in accordance with additional embodiments of the present technology.

[0027] Figures 14A and 14B are an isometric view and a top view of a syringe in accordance with additional embodiments of the present technology.

[0028] Figures 14C and 14D are enlarged side views of a vacuum indicator of the syringe of Figures 14A and 14B in a "vacuum-off" and a "vacuum-on" position, respectively, in accordance with embodiments of the present technology.

[0029] Figures 14E and 14F are enlarged partially transparent side views of the vacuum indicator of Figures 14A–14D in the vacuum-off and the vacuum-on position, respectively, in accordance with embodiments of the present technology.

[0030] Figure 14G is an enlarged side cross-sectional view of the vacuum indicator of Figures 14A–14F in the vacuum-off position in accordance with embodiments of the present technology.

[0031] Figures 15A and 15B are an isometric view and a side view of a syringe in accordance with additional embodiments of the present technology.

[0032] Figures 15C and 15D are enlarged side views of a vacuum indicator of the syringe of Figures 15A and 15B in a "vacuum-off" and a "vacuum-on" position, respectively, in accordance with embodiments of the present technology.

[0033] Figures 15E and 15F are enlarged partially transparent side views of the vacuum indicator of Figures 15A–15D in the vacuum-off and the vacuum-on position, respectively, in accordance with embodiments of the present technology.

[0034] Figure 15G is an enlarged side cross-sectional view of the vacuum indicator of Figures 15A–15F in the vacuum-off position in accordance with embodiments of the present technology.

[0035] Figure 16 is an enlarged side cross-sectional view of the vacuum indicator of Figures 15A–15G further including a biasing member in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0036] The present technology is generally directed to automatically-locking syringes, such as for use in clot removal systems for aspirating clot material from a blood vessel of a human patient. In some embodiments, an automatically-locking syringe can include (i) a barrel, (ii) a lock plate coupled to the barrel, and (iii) a plunger slidably positioned within the barrel and having a lock feature configured to engage the lock plate. The plunger also extends through an opening in the lock plate, and a biasing member is configured to bias the lock plate toward a locking position. When the plunger is moved through the barrel from a depressed position to a withdrawn position, the lock feature is configured to engage the lock plate to drive the lock plate away from the locking position to thereby permit the lock feature to pass through the opening in the lock plate. When the lock feature passes through the opening, the biasing member is configured to bias the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position. Accordingly, in one aspect of the present technology, the plunger is automatically locked in position via engagement of the lock plate with the lock feature when the plunger is withdrawn a selected distance.

[0037] In additional embodiments, an automatically-locking syringe can include (i) a barrel having a flange, (ii) a plunger slidably positioned within the barrel, and (iii) at least one lock

member coupled to the plunger. The lock member can include a body and a first arm hingedly coupled to the body. The first arm is configured to be biased at least partially outwardly away from a longitudinal axis of the plunger to a locking position. When the plunger is in a withdrawn position, the first arm can engage the flange of the barrel to inhibit movement of the plunger through the barrel from the withdrawn position to a depressed position. The syringe can further include an actuator that is movable between a first position and a second position. The actuator can include a second arm configured to engage the first arm in the second position to drive the first arm inwardly toward the longitudinal axis and away from the locking position. Accordingly, when the plunger is withdrawn, moving the actuator from the first position to the second position can drive the first arm radially inward away from the locking position to permit movement of the plunger through the barrel from the withdrawn position to the depressed position.

[0038] Specific details of several embodiments of the present technology are described herein with reference to Figures 1A–16. The present technology, however, may be practiced without some of these specific details. In some instances, well-known structures and techniques often associated with the disclosed syringes, clot removal systems, and the like have not been shown in detail so as not to obscure the present technology. The terminology used in the description presented below is intended to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain specific embodiments of the disclosure. Certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

[0039] The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be arbitrarily enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles, and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles, and features without departing from the spirit or scope of the present technology.

[0040] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to use in a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

[0041] The headings provided herein are for convenience only and should not be construed as limiting the subject matter disclosed.

I. Selected Embodiments of Vacuum-Pressure Locking Syringes

[0042] Figures 1A and 1B are an exploded isometric view and a side view, respectively, of a vacuum-pressure locking syringe ("syringe 100") in accordance with embodiments of the present technology. The syringe 100 is in a partially-withdrawn position in Figure 1B. Referring to Figures 1A and 1B together, the syringe 100 includes a plunger 110 slidably positioned within a barrel 120. The barrel 120 is shown as partially transparent in Figure 1B for clarity. The barrel 120 can include a barrel portion 122 (e.g., a cylindrical portion) extending between a flange 124 and a tip 126. In some embodiments, the barrel portion 122 can have a volume of about 60 cc or greater than 60 cc. The tip 126 is configured to be releasably or permanently coupled to an adaptor 130 (shown as partially transparent in Figures 1A and 1B). In some embodiments, the tip 126 can define a bore 128 having a size of about 26 French or greater. In the illustrated embodiment, the adaptor 130 is a Toomey-tip adaptor having a sealing member 132 (e.g., an O-ring) extending around an exterior surface thereof for sealingly engaging (e.g., connecting to) a Toomey fitting or Toomey adaptor. In other embodiments, the adaptor 130 can be omitted and the tip 126 of the barrel 120 can be directly coupled to another device or system (not shown), and/or the tip 126 can be another type of tip such as, for example, a Luer lock, Lock slip, and/or needle.

[0043] In the illustrated embodiment, the plunger 110 includes a shaft 112 extending between a flange 114 and a grip portion 116. The grip portion 116 is configured to be grasped by a user for withdrawing (e.g., retracting, pulling) and/or depressing (e.g., advancing, pushing) the plunger 110 through the barrel 120 during operation of the syringe 100. The plunger 110 can include a sealing member 118 positioned around the flange 114 and configured to sealingly engage an interior surface of the barrel portion 122 to define a sealed volume (e.g., of negative/vacuum

pressure) within the barrel 120. The various components of the syringe 100 can comprise metal, plastic, and/or other suitable materials.

[0044] As best seen in Figure 1B, the shaft 112 of the plunger 110 includes a lower edge or surface 111 and a lock feature 113 extending/protruding from the lower surface 111. In the illustrated embodiment, the lock feature 113 includes (i) a ramp portion 115, (ii) a plateau portion 117 extending from the ramp portion 115, and (iii) a stop surface 119 extending from the plateau portion 117. The ramp portion 115 can extend/slope at angle relative to the lower surface 111 in a direction (i) away from the lower surface 111 and (ii) toward the flange 114 of the plunger 110. The plateau portion 117 can extend away from the ramp portion 115 in a direction toward the flange 114 and generally parallel to the lower surface 111. The stop surface 119 can extend away from the plateau portion 117 in a direction generally perpendicular to the plateau portion 117 and the lower surface 111. In some embodiments, the lock feature 113 can be a tab, flat face, half disc, and/or other feature extending from the lower surface 111 of the shaft 112.

[0045] In the illustrated embodiment, the syringe 100 further includes a base 140 and a lock member 150 operably coupled to the base 140. In some embodiments, the base 140 can be coupled to the flange 124 of the barrel 120. Accordingly, the base 140 can couple the lock member 150 to the barrel 120. The base 140 can include a body 142 having an opening 143 extending therethrough and configured to slidably receive the shaft 112 of the plunger 110. The lock member 150 can include a lock plate 152 coupled to a button portion 154. The lock plate 152 can include an opening 153 (i) extending therethrough, (ii) defined by an edge portion 156, and (iii) configured to slidably receive the shaft 112 of the plunger 110. In some embodiments, the lock member 150 can be movably coupled to the base 140 via, for example, a biasing member (e.g., an arm 358 illustrated in Figures 3B and 3C, springs 460 illustrated in Figure 4, and/or another type of biasing member). As described in greater detail below with reference to Figures 3A–4, the lock plate 152 is configured to engage the lock feature 113 of the plunger 110 when the plunger 110 is withdrawn to a selected position to lock the plunger 110 in the selected position. The selected position can correspond to a pre-selected vacuum volume of the barrel 120. The button portion 154 is actuatable (e.g., depressible) by a user to release the lock plate 152 from the lock feature 113 to release the plunger 110 to, for example, permit the plunger 110 to move through the barrel 120 to expel any contents (e.g., bodily fluids such as blood and clot material) collected in the barrel 120 from the tip 126.

[0046] Figures 2A and 2B are isometric views of the syringe 100 in a depressed position (e.g., a first position, an emptied positioned, zero-vacuum position) and a withdrawn position (e.g., a second position, a vacuum-storage position, a vacuum-generation position, full-vacuum position), respectively, in accordance with embodiments of the present technology. The barrel 120 is shown as partially transparent in Figures 2A and 2B for clarity. Referring to Figures 2A and 2B together, in general, a user can move the syringe 100 from the depressed position to the withdrawn position by pulling the grip portion 116 of the plunger 110 in the direction of arrow A (Figure 2A) relative to the barrel 120 to withdraw the plunger 110 through the barrel 120, the base 140, and the lock member 150. In some embodiments, withdrawing the plunger 110 can charge a vacuum (e.g., generate negative pressure) within the barrel 120. Moreover, the lock plate 152 of the lock member 150 can engage the lock feature 113 (obscured in Figure 2B) of the plunger 110 when the plunger 110 is withdrawn past the lock plate 152 to automatically lock the plunger 110 in the withdrawn position. To move the syringe 100 from the withdrawn position to the depressed position, the user can (i) actuate the button portion 154 of the lock member 150 (e.g., depress the button portion 154 in the direction of arrow B in Figure 2B) to disengage the lock plate 152 from the lock feature 113 to unlock the plunger 110 from the lock member 150 and then (ii) push the plunger 110 in the direction of arrow C (Figure 2B) relative to the barrel 120.

[0047] Figure 3A is a side view, and Figures 3B and 3C are enlarged side views, of the syringe 100 illustrating the process of locking the plunger 110 to the lock member 150 in accordance with embodiments of the present technology. The syringe 100 is in a partially-withdrawn position in Figures 3A and 3B. More specifically, Figures 3A and 3B illustrate the syringe 100 as the lock feature 113 passes through the opening 153 (Figure 1A) in the lock member 150 during withdrawal of the plunger 110 from the depressed position to the withdrawn position. Figure 3C illustrates the syringe 100 after the lock feature 113 has been withdrawn through the opening 153 past the lock plate 152. The barrel 120 is shown as partially transparent in Figures 3A–3C, and the base 140 is shown as partially transparent in Figures 3B and 3C for clarity.

[0048] Referring to first to Figures 3B and 3C together, the lock member 150 further includes an arm 358 (e.g., a biasing member) operably coupling the lock member 150 to the base 140. In the illustrated embodiment, for example, the arm 358 projects away from (e.g., perpendicular) to the lock plate 152 and presses against (e.g., engages, attaches to) the base 140. The arm 358 can be a spring arm, living hinge, lever arm, or other member that is (i) hingedly/movably coupled to the lock member 150 and (ii) configured to bias the lock plate 152

upward to a locking position (e.g., a first position) as shown in Figures 3C and 1B (e.g., in an upward direction indicated by arrow D in Figure 3C). As the lock feature 113 is withdrawn past the lock plate 152, the lock feature 113 can engage the lock plate 152 and drive the lock plate 152 against the biasing force of the arm 358 away from the locking position (e.g., toward a second position) as shown in Figure 3B (e.g., in a downward direction indicated by arrow E in Figure 3B).

[0049] More specifically, referring to Figures 3A and 3B together, as the plunger 110 is withdrawn toward the lock member 150 in the direction of the arrow A, the ramp portion 115 of the lock feature 113 first engages the edge portion 156 (Figure 1A) of the lock plate 152 at a first side 357a of the lock plate 152 opposite a second side 357b. As the plunger is withdrawn farther, the angled ramp portion 115 drives the lock plate 152 (and the button portion 154) downward in the direction of the arrow E against the biasing force of the arm 358 (e.g., away from the locking position) until the lock plate 152 reaches the plateau portion 117 of the lock feature 113. That is, the ramp portion 115 of the lock feature 113 translates the longitudinal force of the plunger 110 into radial movement of the lock plate 152. Continued withdrawal of the plunger 110 slides the lock plate 152 over/against the plateau portion 117 until the lock feature 113 reaches the stop surface 119. Referring to Figure 3C, when the lock plate 152 passes the end of the plateau portion 117, the arm 358 can drive the lock plate 152 upward in the direction of arrow D to the locking position. The plunger 110 is then inhibited from moving/advancing past the lock plate 152 toward the depressed position (e.g., in the direction of the arrow C shown in Figure 2B). Specifically, the second side 357b of the lock plate 152 can engage/contact the stop surface 119 of the lock feature 113 to inhibit advancement of the plunger 110. In other embodiments, the lock feature 113 and/or the lock plate 152 can have different configurations/arrangements that facilitate locking of the plunger 110 in the withdrawn position. For example, in some embodiments the plateau portion 117 of the lock feature 113 can be omitted.

[0050] To unlock the plunger 110 from the lock member 150, the user can actuate the button portion 154 of the lock member 150 by, for example, pressing the button portion 154 downward in the direction of arrow E. The movement of the button portion 154 drives the lock plate 152 downward relative to the lock feature 113 until the edge portion 156 (Figure 1A) of the lock plate 152 fully passes the stop surface 119 of lock feature 113, thereby permitting movement of the lock feature 113 through the opening 153 (Figure 1A) of the lock plate 152. The user can then advance the plunger 110 through the barrel 120 to expel any contents collected in the barrel 120.

[0051] Accordingly, in one aspect of the present technology, the plunger 110 is automatically locked in position—via the lock plate 152 and lock feature 113—when the plunger 110 is withdrawn a selected distance. In contrast, many conventional locking syringes require the user to rotate the plunger relative to the barrel to facilitate locking of the plunger. Such rotation can be difficult when the syringe has a large volume—for example, 60 cc or greater—and thus requires a relatively significant retraction force to withdraw the plunger. Therefore, the syringe 100 of the present technology has improved usability compared to conventional locking syringes, especially during procedures that require multiple withdrawals of the plunger 110 over the course of the procedure. In some embodiments, the lock member 150 and the lock feature 113 can be configured (e.g., shaped, positioned) such that the syringe 100 automatically locks at a selected position corresponding to a selected volume of the barrel 120. In some embodiments, the selected volume can be about 60 cc or greater.

[0052] In another aspect of the present technology, the syringe 100 is lockable at only a single position. This can be particularly useful where the syringe 100 is used in procedures in which a single operational volume is preselected/desired, such as during a clot removal procedure that includes aspirating clot material from a vessel, as described in greater detail below with reference to Figure 6.

[0053] Figure 4 is an enlarged isometric view of a portion of the syringe 100 in accordance with additional embodiments of the present technology. The barrel 120 is shown as partially transparent in Figure 4 for clarity. In the illustrated embodiment, the lock plate 152 of the lock member 150 is operably coupled to the base 140 via a pair of springs 460 (only one of the springs 460 is visible in Figure 4). The springs 460 are configured to bias the lock plate 152 to the first position shown in Figures 4 and 1B, and can replace or supplement the arm 358 described in detail above with reference to Figures 3A–3C. More particularly, each of the springs 460 can be a compression spring operably coupled between a first spring mount 462 of the lock plate 152 and a second spring mount 464 of the body 142 of the base 140. In a similar manner as described in detail above with reference to Figures 3A–3C, (i) the lock feature 113 can engage the lock plate 152 and drive the lock plate 152 against the biasing force of the springs 460 during withdrawal of the plunger 110, and (ii) the springs 460 can drive the lock plate 152 upward after the lock feature 113 passes through the lock plate 152 to automatically lock the plunger 110 in the withdrawn position.

[0054] Figures 5A–5C are an isometric view, a side view, and another isometric view, respectively, of a syringe 500 in accordance with additional embodiments of the present technology. The syringe 500 is in a withdrawn/retracted position in Figures 5A and 5B, and in a depressed/advanced position in Figure 5C. Referring to Figures 5A–5C together, the syringe 500 can include several features generally similar or identical to the syringe 100 described in detail above with reference to Figures 1A–4. In the illustrated embodiment, for example, the syringe 500 includes a plunger 510 configured to be slidably positioned within a barrel 520. The barrel 520 is shown as partially transparent in Figures 5A–5C for clarity. The barrel 520 can include a barrel portion 522 extending between a flange 524 and a tip 526. In some embodiments, the tip 526 is configured to be releasably or permanently coupled to an adaptor 530 (e.g., a Toomey tip adaptor; shown as partially transparent in Figures 5A–5C). The plunger 510 can include a shaft 512 extending between a flange 514 and a grip portion 516. The plunger 510 can include a sealing member 518 positioned around the flange 514 and configured to sealingly engage an interior surface of the barrel portion 522 to define a sealed volume (e.g., of negative/vacuum pressure) within the barrel 520.

[0055] In the illustrated embodiment, the syringe 500 further includes a pair of lock members 570 (identified individually as a first lock member 570a and a second lock member 570b) operably coupled to an actuator 580. In some embodiments, the shaft 512 of the plunger 510 includes a spline 511 (e.g., a wall portion), and the lock members 570 can be positioned on opposite sides of the spline 511. The lock members 570 can each include a body 572 and an arm 574 hingedly/movably attached to the body 572. The arms 574 can be spring arms, living hinges, lever arms, or other members configured to be biased outwardly away from a longitudinal axis L (Figure 5A) of the syringe 500. The bodies 572 can each include a first end portion 573 and a second end portion 575 opposite the first end portion 573, and can each include/define an elongate opening 576 extending between the first and second end portions 573, 575. The lock members 570 can be formed of plastic, metal, and/or other suitable materials and can be single integral parts (e.g., injected molded parts) or can be formed of discrete parts coupled together.

[0056] In the illustrated embodiment, the actuator 580 includes a push portion 582 and a pair of elongate arms 584 (identified individually as a first arm 584a and a second arm 584b) extending away from the push portion 582. In some embodiments, the push portion 582 is slidably coupled to the spline 511 of the shaft 512 and configured to slide at least partially between (i) a first position in which the push portion 582 abuts and/or is adjacent to the grip portion 516 of the

plunger 510 and (ii) a second position in which the push portion 582 abuts and/or is adjacent to the second end portions 575 of the arms 574. The plunger 580 is shown in the second position in Figures 5A–5C. The first arm 584a can extend at least partially through the opening 576 in the first body 570a, and the second arm 584b can extend at least partially through the opening 576 in the second body 570b. In some embodiments, the arms 584 are slidably positioned within the openings 576 such that movement of the push portion 582 between the first and second positions advances/retracts the arms 584 through the openings 576. In some embodiments, in the first position, the arms 584 of the actuator 580 do not extend over the arms 574 of the lock members 570. In the second position, the arms 584 of the actuator 580 can extend over/around all or a portion of the arms 574 of the lock members 570 to move (e.g., pinch) the arms 574 inwardly toward the longitudinal axis L—counter to the biasing force of the arms 574 (e.g., in the direction of arrows F in Figure 5B). The actuator 580 can be formed of plastic, metal, and/or other suitable materials and can be a single integral part or can be formed of discrete parts coupled together.

[0057] In the withdrawn position shown in Figures 5A and 5B, the arms 574 of the lock members 570 are biased outwardly such that end portions of the arms 574 engage the flange 524 of the barrel 520. Accordingly, the arms 574 inhibit/lock the plunger 110 from advancing farther into the barrel 520 toward the depressed position. To unlock the plunger 510, a user can push the push portion 582 of the actuator to move the push portion 582 at least partially from the first position to the second position (e.g., toward the barrel 520 and the lock members 570). The movement of the push portion 582 drives the arms 584 through the openings 576 in the bodies 572 and over/around the arms 574 of the lock members 570 to move the arms 574 inward toward the longitudinal axis L and out of engagement with the flange 524. The user can then advance the plunger 510 toward the depressed position (Figure 5C) to expel any contents collected in the barrel 520.

[0058] To subsequently withdraw the plunger 510 from the depressed position to the retracted position, the user can first move the actuator 580 to the first position to free the arms 574 of the lock members 570 from the arms 584 of the actuator 580. Accordingly, the arms 574 of the lock members 570 can return to their outwardly-biased position and, in some embodiments, can contact an inner surface of the barrel portion 522. Then, as the plunger 510 is withdrawn through the barrel 520, the arms 574 of the of lock members 570 can spring (i) outward as they are withdrawn from the barrel 520 (e.g., after they past the flange 524) and (ii) into engagement with the flange 524. Accordingly, in one aspect of the present technology, the plunger 510 is

automatically locked in position—via the arms 574 of the lock members 570—when the plunger 510 is withdrawn a selected distance.

[0059] In some embodiments, the lock members 570 can be configured (e.g., shaped, positioned) such that the syringe 500 automatically locks at a selected position corresponding to a selected volume of the barrel 520. In some embodiments, the selected volume can be about 60 cc or greater. In some embodiments, the syringe 500 can include only one of the lock members 570, or more than two of the lock members 570.

[0060] Figure 6A is a side view of a vacuum-pressure locking syringe ("syringe 600") in accordance with additional embodiments of the present technology. The syringe 600 is in a depressed position in Figure 6A. The syringe 600 can include several features generally similar or identical to the syringe 100 described in detail above with reference to Figures 1A–3C. In the illustrated embodiment, for example, the syringe 600 includes a plunger 610 slidably positioned within a barrel 620. The barrel 620 is shown as partially transparent in Figure 6A for clarity. The syringe 600 further includes a base 640 and a lock member 650 operably coupled to the base 640. The lock member 650 includes a lock plate 652 coupled to a button portion 654. The plunger 610 includes a lower edge or surface 611 including a plurality of lock features 613 extending/protruding from the lower surface 611. Each of the lock features 613 can include (i) a ramp portion 615, (ii) a plateau portion 617 extending from the ramp portion 115, and (iii) a stop surface 619 extending from the plateau portion 617.

[0061] When the plunger 610 is withdrawn through the barrel 620, the lock features 613 are configured to engage the lock plate 652 to automatically lock the plunger 110 in a withdrawn position corresponding to the position of the lock feature 613. More specifically, a user can withdraw the plunger 610 to a desired location/volume and the lock feature 613 nearest the lock plate 652 can engage the lock plate 652 to automatically lock the plunger 610 in position. To move the syringe 600 from the withdrawn position to the depressed position, the user can (i) actuate the button portion 654 of the lock member 650 to disengage the lock plate 652 from the lock feature 613 to unlock the plunger 610 from the lock member 650 and then (ii) push the plunger 610 relative to the barrel 620. In one aspect of the present technology, the syringe 600 includes multiple ones of the lock features 613 that permit the syringe 600 to be automatically locked at multiple different positions. In the illustrated embodiment, the plunger 610 includes 12 locking features while, in other embodiments, the syringe 600 can include any number of lock

features 613 to facilitate locking of the syringe 600 at any desired position/volume. Moreover, the location of the lock features 613 can be selected to provide refined volume and vacuum control.

[0062] In the illustrated embodiment, the syringe 600 further includes a locking mechanism 690 that is actuatable to enable/disable the auto-locking functionality of the syringe 600. More specifically, Figures 6B and 6C are enlarged side views of the locking mechanism 690 of the syringe 600 in a first position and a second position, respectively, in accordance with embodiments of the present technology. Referring to Figures 6B and 6C together, the locking mechanism 690 can include a pin 692 operably coupled to the base 650 via a biasing member 694. In the illustrated embodiment, the pin 692 includes a head portion 693 and an engagement portion 695. The biasing member 694 can be operably coupled between the head portion 693 and the base 640, and the engagement portion 695 can at least partially extend through a channel 696 in the base 640. The lock member 650 can include an opening 698 configured to receive the engagement portion 695 of the pin 692 in the first position shown in Figure 6B.

[0063] In the first position shown in Figure 6B, the biasing member 694 (e.g., a tension spring) biases the lock pin 692 toward the lock member 650 such that the engagement portion 695 is positioned in the opening 698. Referring to Figures 6A and 6B together, in the first position the lock member 650 is partially depressed such that the lock features 613 are free to slide past the lock plate 652 without engaging the lock plate 652. Accordingly, the plunger 610 can be withdrawn/depressed through the barrel 620 without the lock features 613 automatically locking the syringe 600—and thus the syringe 600 functions similar to a conventional syringe when the locking mechanism 690 is in the first position. To enable to the auto-locking functionality of the syringe 600, a user can pull the pin 692 (e.g., the head portion 693) away from the lock member 650 (e.g., against the biasing force of the biasing member 694) to withdraw the engagement portion 695 from the opening 698 and disengage the engagement portion 695 from the lock member 650. Accordingly, in the second position, the lock member 650 is operable to engage the lock features 613 to auto-lock the syringe 600 (e.g., the lock member 650 can be biased towards as described with reference to Figures 3A–4). In other embodiments, the pin 692 can be operably coupled to the lock member 650 and configured to engage the base 640. In some embodiments, the syringe 100 and/or the syringe 500 described in detail with reference to Figures 1A–5C can include an identical or similar locking mechanism for enabling/disabling the autolocking functionality.

II. Selected Embodiments of Clot Treatment Systems

[0064] Figure 7 is a partially schematic side view of a clot treatment or clot removal system comprising an aspiration assembly 700 ("assembly 700") incorporating the syringe 100, the syringe 500, and/or the syringe 600 in accordance with embodiments of the present technology. In the illustrated embodiment, the assembly 700 includes a catheter subsystem 710 fluidly coupled to a tubing subsystem 720. In general, the assembly 700 (i) can include features generally similar or identical to those of the aspiration assemblies described in detail in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety, and/or (ii) can be used to treat/remove clot material from a patient (e.g., a human patient) using any of the methods described in detail therein.

[0065] In the illustrated embodiment, the catheter subsystem 710 includes a catheter 702 (e.g., an aspiration catheter) comprising an elongated shaft defining a lumen 704 and having a distal portion 703 and a proximal portion 705. The catheter subsystem 710 further includes a valve 706 that can be integral with or coupled to the proximal portion 705 of the catheter 702. In some embodiments, the valve is a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in the proximal direction through the valve 706 as various components such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and so on are inserted through the valve 706 to be delivered through the catheter 702 to a treatment site in a blood vessel. The valve 706 includes a branch or side port 708 configured to fluidly couple the lumen 704 of the catheter 702 to the tubing subsystem 720. In some embodiments, the valve 706 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety.

[0066] The tubing subsystem 720 fluidly couples the catheter subsystem 710 to the syringe 100, the syringe 500, and/or the syringe 600 (collectively the "syringe 100/500/600"). More specifically, the tubing subsystem 720 can include one or more tubing sections 724 (individually labeled as a first tubing section 724a and a second tubing section 724b), at least one fluid control device 726 (e.g., a valve), and at least one connector 728 (e.g., a Toomey tip connector) for fluidly coupling the tubing subsystem 720 to the syringe 100/500/600 and/or other suitable components. More specifically, in the illustrated embodiment the fluid control device 726 is a stopcock that is

fluidly coupled to (i) the side port 708 of the valve 706 via the first tubing section 724a and (ii) the connector 728 via the second tubing section 724b.

[0067] The fluid control device 726 is externally operable by a user to regulate the flow of fluid therethrough and, specifically, from the lumen 704 of the catheter 702 to the syringe 100/500. In some embodiments, the connector 728 is a quick-release connector (e.g., a quick disconnect fitting) that enables rapid coupling/decoupling of the catheter 702 and the fluid control device 726 to/from the syringe 100/500/600.

[0068] With reference to Figures 1A–7 together, the syringe 100/500/600 is configured to generate (e.g., form, create, charge, build-up) a vacuum (e.g., negative relative pressure) and store the vacuum for subsequent application to the catheter subsystem 710. For example, during operation of the assembly 700, a user can first close the fluid control device 726 before (i) withdrawing the plunger 110 of the syringe 100 until the plunger 110 automatically locks to build up vacuum pressure within the barrel 120 of the syringe 100, (ii) withdrawing the plunger 510 of the syringe 500 until the plunger 510 automatically locks to build up vacuum pressure within the barrel 520 of the syringe 500, and/or (iii) withdrawing the plunger 610 of the syringe 600 until the plunger 610 automatically locks at a location corresponding to one of the lock features 613. In this manner, a vacuum is charged within the syringe 100/500/600 (e.g., a negative pressure is maintained) before the syringe 100/500/600 is fluidly connected to the catheter subsystem 710. To aspirate the lumen 704 of the catheter 702, the user can open the fluid control device 726 to fluidly connect the syringe 100/500/600 to the catheter subsystem 710 and thereby apply or release the vacuum stored in the syringe 100/500/600 to the lumen 704 of the catheter 702.

[0069] Opening of the fluid control device 726 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing subsystem 720 and the catheter 702, thereby generating a suction pulse throughout the catheter 702. In particular, the suction is applied at the distal portion 703 of the catheter 702. In one aspect of the present technology, pre-charging or storing the vacuum in the syringe 100/500/600 before applying the vacuum to the lumen 704 of the catheter 702 is expected to generate greater suction forces and corresponding fluid flow velocities at and/or near the distal portion 703 of the catheter 702 compared to simply activating the syringe 100/500/600 while it is fluidly connected to the catheter 702. When the distal portion 703 is intravascularly positioned near clot material within a patient (e.g., a human patient), the suction forces generated by application of the stored vacuum can be used to aspirate or otherwise remove clot material from within a blood vessel of the patient.

III. Selected Embodiments of Vacuum Indicators

[0070] Referring to Figure 7, in some embodiments the assembly 700 can include a vacuum indicator 730 (shown schematically) operably coupled to the tubing subsystem 720. As described in greater detail below with reference to Figures 8A and 8B, the vacuum indicator 730 can provide an indication, such as a visual indication, of whether the assembly 700 is under vacuum pressure. In the illustrated embodiment, the vacuum indicator 730 is operably coupled to the tubing subsystem 720 between the fluid control device 726 and the valve 706 (e.g., to the first tubing section 724a, between separate portions of the first tubing section 724a). In other embodiments, the vacuum indicator 730 can be operably coupled to the tubing subsystem 720 between the fluid control device 726 and the connector 728 (e.g., to the second tubing section 724b, between separate portions of the second tubing section 724b).

[0071] Figures 8A and 8B are enlarged, partially-schematic side views of the vacuum indicator 730 in a vacuum-off position and a vacuum-on position, respectively, in accordance with embodiments of the present technology. Referring to Figures 8A and 8B together, the vacuum indicator 730 includes a body 832 and a flexible member 834 operably coupled to the body 832. The flexible member 834 is shown as partially transparent in Figures 8A and 8B for clarity. In some embodiments, the body 832 is an integral or one-piece member of plastic, metal, or another suitably rigid material. The body 832 can include a first connector portion 836a (e.g., a first barb), a second connector portion 836b (e.g., a second barb), and a central portion 838 extending between the first and second connector portions 836a, b. The body 832 can further define a lumen 837 extending therethrough between the first and second connector portions 836a, b. The first connector portion 836a can be coupled to a first tube 825a and the second connector portion 836b can be coupled to a second tube 825b. In some embodiments, the first and second tubes 825a, b can together form the first tubing section 724a (Figure 7) such that the vacuum indicator 730 is fluidly coupled between the fluid control device 726 and the valve 706.

[0072] In the illustrated embodiment, the central portion 838 of the body 832 includes/defines (i) a recess 840 extending circumferentially thereabout (ii) and an opening 842 positioned in the recess 840 and extending through the central portion 838 to the lumen 837. In some embodiments, the recess 840 can have a different shape and/or can extend only partially around the central portion 838, and/or the body 832 can include more than one of the openings 842 positioned in the recess 840. The flexible member 834 can be a thin compliant tube that is positioned over the recess 840 and the opening 842. In some embodiments, opposing end portions

of the flexible member 834 are secured to the body 832 via a first attachment member 844a and a second attachment member 844b. The first and second attachment members 844a, b can comprise adhesives, welds, fasteners, collars, or other components that mechanically secure the flexible member 834 over the recess 840 such that the flexible member 834 forms a seal over the recess 840. In some embodiments, the flexible member 834 can have a thickness of between about 0.005 inch to about 0.100 inch.

[0073] With additional reference to Figure 7, when the assembly 700 is not under vacuum, the flexible member 834 is positioned over the recess 840 in a relaxed state such that the flexible member 834 has a generally cylindrical shape as shown in Figure 8A. When a vacuum is generated in the assembly 700, the vacuum is applied to the flexible member 834 via the opening 842 and pulls/sucks the flexible member 834 into the recess 840 as shown in Figure 8B. The deformation of the flexible member 834 provides a visual indication to a user of the assembly 700 that the assembly 700 is under vacuum. When the vacuum is released, the flexible member 834 returns/rebounds to the vacuum-off position shown in Figure 8A to provide a visual indication that the assembly 700 is not under vacuum.

[0074] In some embodiments, the thickness of the flexible member 834, the size of the opening 842, and/or the number of openings 842 can be selected such that the flexible member 834 deforms to the vacuum-on position (Figure 8B) and returns to the vacuum-off position (Figure 8A) at a selected level of vacuum. For example, making the flexible member 834 thinner will cause it to indent under less vacuum while making the flexible member 834 thicker will require more vacuum to indent. Likewise, a thinner flexible member 834 will be less likely to rebound to the vacuum-off position (Figure 8A) and therefore require more pressure (e.g., positive pressure) to rebound, while a thicker flexible member 834 will rebound with little to no pressure.

[0075] In some embodiments, the vacuum indicator 730 can include a housing 846 (shown schematically) at least partially surrounding the flexible member 834. The housing 846 can be formed of a rigid material (e.g., plastic, metal) and can be coupled to the body 832. In some embodiments, the housing 846 is configured to inhibit or even prevent excessive deformation of the flexible member 834 when the assembly 700 is under positive pressure. For example, when positive pressure is applied to the assembly 700, the flexible member 834 can flex outwardly away from the body 832 and contact the housing 846. The housing 846 can therefore inhibit the flexible member 834 from flexing further outwardly, which could damage or rupture the flexible member 834.

[0076] In some aspects of the present technology, the vacuum indicator 730 can aid the user during a clot removal procedure on a patient using the assembly 700. Sometimes, for example, after applying the vacuum stored in the syringe 100/500/600 to the lumen 704 of the catheter 702, clot material can at least partially clog the distal portion 703 of the catheter 702—causing the assembly 700 to cavitate. In such instances, it is often desirable to remove the assembly 700 from the patient to thereby remove the clot material clogging and/or attached to the distal portion 703 of the catheter 702. However, user error and/or leakage of the assembly 700 (e.g., out of the valve 706) can dissipate the vacuum in the assembly 700, thereby releasing and/or decreasing the force holding the clot material to the catheter 702. The vacuum indicator 730 can provide a fast and easy visual indication to the user of whether the assembly 700 is maintaining vacuum. Thus, based on the position of the vacuum indicator 730, the user can determine how to proceed with the procedure—for example, whether to continue withdrawing the assembly 700 from the patient.

[0077] In some aspects of the present technology, the vacuum indicator 730 is a passive device that adds no or very little volume to the flow path of the assembly 700. Adding volume to the flow path of the assembly 700 can reduce the amount of aspirational force that can be generated at the distal portion 703 of the catheter 702. Accordingly, the vacuum indicator 730 can provide an indication of vacuum (e.g., on or off) without negatively affecting the clot removal capabilities of the assembly 700. In contrast, for example, a vacuum gauge coupled along the flow path of the assembly 702 would increase the volume thereof and reduce the aspirational force of the assembly 700. Moreover, the recess 840 can have a relatively small volume such that the vacuum indicator 730 is not prone to clogging during use of the assembly 700 (e.g., clogging with blood clots during a thrombectomy procedure using the assembly 700). In contrast, a vacuum gauge or similar mechanism would be more prone to clogging, possibly rendering them non-functional.

[0078] Figure 9 is a perspective view of a vacuum indicator 930 in a vacuum-off position in accordance with additional embodiments of the present technology. The vacuum indicator 930 can include some features, functions, and/or advantages that are generally similar or identical to the vacuum indicator 730 described in detail above with reference to Figures 8A and 8B. For example, in the illustrated embodiment the vacuum indicator 930 includes a body 932 and a flexible member 934 operably coupled to the body 932. The flexible member 934 is shown as partially transparent in Figure 9 for clarity. The body 932 can include a first connector portion 936a (e.g., a first barb), a second connector portion 936b (e.g., a second barb), and a central portion 938 extending between the first and second connector portions 936a, b. The body 932 can further

define a lumen 937 extending therethrough between the first and second connector portions 936a, b. The first and second connector portions 936a, b can be coupled to, for example, various tubes of the first tubing section 724a and/or the second tubing section 724b (Figure 7).

[0079] In the illustrated embodiment, the central portion 938 of the body 932 includes/defines a plurality of longitudinal openings 950 extending through the central portion 938 to the lumen 937. In some embodiments, the openings 950 can be equally spaced about the body 932. In other embodiments, the central portion 938 can include more or fewer of the openings 950 and/or the openings 950 can be positioned differently about the central portion 938. The flexible member 934 can be a thin compliant tube that is sealingly secured to the body 932 over the openings 950 via a first attachment member 944a and a second attachment member 944b.

[0080] With additional reference to Figure 7, when the assembly 700 is not under vacuum, the flexible member 934 is positioned over the openings 950 in a relaxed state such that the flexible member 934 has a generally cylindrical shape as shown in Figure 9. When a vacuum is generated in the assembly 700, the vacuum is applied to the flexible member 934 via the openings 950 and pulls the flexible member 934 at least partially into one or more of the openings 950. The deformation of the flexible member 934 provides a visual indication to a user of the assembly 700 that the assembly 700 is under vacuum. When the vacuum is released, the flexible member 934 can return to the position vacuum-off shown in Figure 9 to provide a visual indication that the assembly 700 is not under vacuum. In some embodiments, the vacuum indicator 930 can include a housing (not shown) at least partially surrounding the flexible member 934 and configured to inhibit or even prevent excessive deformation of the flexible member 934 when the assembly 700 is under positive pressure.

[0081] Figures 10A and 10B are perspective views of a vacuum indicator 1030 in a vacuum-off position and a vacuum-on position, respectively, in accordance with additional embodiments of the present technology. The vacuum indicator 1030 can include some features, functions, and/or advantages that are generally similar or identical to the vacuum indicator 730 and/or the vacuum indicator 930 described in detail above with reference to Figures 8A–9. For example, referring to Figures 10A and 10B together, the vacuum indicator 930 includes a flexible member 934 fluidly coupled to a tube 1025. In some embodiments, the tube 925 is a portion of the first tubing section 724a or the second tubing section 724b (Figure 7).

[0082] In the illustrated embodiment, however, the flexible member 1034 is directly attached to the tube 1025 over a hole or opening 1027 (obscured in Figure 10A and shown

schematically) in the tube 1025. In some embodiments, opposing end portions of the flexible member 1034 are secured to the tube 1029 via a first attachment member 1044a and a second attachment member 1044b. The first and second attachment members 1044a, b can be clamps, collars, or other mechanical components that mechanically secure the flexible member 1034 over the opening 1027 such that the flexible member 1034 forms a seal over the opening 1027. The first and second attachment members 1044a, b can be secured to the tube 1025 via compression, adhesives, fasteners, and/or other suitable means of connection. In some embodiments, the opening 1027 can have a diameter of about 0.100 inch to about 0.300 inch.

[0083] With additional reference to Figure 7, when the assembly 700 is not under vacuum, the flexible member 1034 is positioned over the opening 1027 in a relaxed state such that the flexible member 1034 has a generally cylindrical shape as shown in Figure 10A. When a vacuum is generated in the assembly 700, the vacuum is applied to the flexible member 1034 via the opening 1027 and pulls the flexible member 1034 into the opening 1027 as shown in Figure 10B. The deformation of the flexible member 1034 provides a visual indication to a user of the assembly 700 that the assembly is under vacuum. When the vacuum is released, the flexible member 1034 returns to the vacuum-off position shown in Figure 10A to provide a visual indication that the assembly 700 is not under vacuum.

[0084] In some embodiments, a syringe configured in accordance with the present technology can include a vacuum indicator integrated therewith. For example, Figure 11 is a side-view of the syringe 100 of Figures 1A and 1B including a vacuum indicator 1130 formed in the adaptor 130 in accordance with embodiments of the present technology. In the illustrated embodiment, the vacuum indicator 1130 includes a flexible member 1134 sealingly positioned over an opening 1152 in the adaptor 130. The flexible member 1134 can be formed from a compliant material, such as silicone, and can have a dome-like shape in a vacuum-off position shown in Figure 11. With additional reference to Figure 7, when the syringe 100 is coupled to the system 700 (e.g., to the connector 728) and the plunger 110 is drawn to pull a vacuum in the barrel 120, the vacuum is applied to the flexible member 1134 via the opening 1152 and pulls the flexible member 1134 into/toward the opening 1152. For example, the flexible member 1134 can invert when the assembly 700 is under vacuum. The inversion/deformation of the flexible member 1134 provides a visual indication to a user of the assembly 700 that the assembly 700 is under vacuum. When the vacuum is released, the flexible member 1134 can passively return to the vacuum-off

position shown in Figure 11 to provide a visual indication that the assembly 700 is not under vacuum.

[0085] Figures 12A and 12B are perspective views of a syringe 1200 including a vacuum indicator 1230 in accordance with additional embodiments of the present technology. The syringe 1200 is in a withdrawn position in Figure 12B. Referring to Figures 12A and 12B together, the syringe 1200 includes a plunger 1210 slidably positioned within a barrel 1220. The barrel 1220 is shown as partially transparent in Figure 1B for clarity. The plunger 1210 includes a flange 1214 configured to sealingly engage an inner surface of the barrel 1220 to define a sealed volume 1217 (Figure 12B: e.g., of negative/vacuum pressure) within the barrel 1220.

[0086] In the illustrated embodiment, the vacuum indicator 1230 includes a housing 1260 (shown as partially transparent in Figures 12A and 12B) coupled to the plunger 110 and defining a lumen 1262. The flange 1214 can include a through-hole 1264 fluidly coupling the lumen 1262 of the housing 1260 to the sealed volume 1217 within the barrel 1220. The vacuum indicator 1230 can further include an indication member 1266 slidably positioned within the lumen 1262. The indication member 1266 can be an elongate member and, in some embodiments, can have a color (e.g., a relatively bright color) that contrasts with a color of the housing 1260. In some embodiments, the indication member 1266 is configured to sealingly engage the housing 1260. For example, the housing 1260 can include one or more sealing members (e.g., O-rings; not shown) on an inner surface thereof and/or the indication member 1266 can include one or more sealing members (e.g. O-rings; not shown) on an outer surface thereof to provide a dynamic seal between the housing 1260 and the indication member 1266. In the illustrated embodiment, the indication member 1266 is operably coupled to the flange 1214 via a biasing member 1268 that extends through the lumen 1262. The biasing member 1268 (e.g., a compression spring) is configured to bias the indication member 1266 through the lumen 1262 in a direction away from the flange 1214 (e.g., as indicated by arrow F in Figure 12A).

[0087] With additional reference to Figure 7, when the syringe 1200 is coupled to the system 700 (e.g., to the connector 728) and the plunger 1210 is drawn to pull a vacuum in the sealed volume 1217 of the barrel 1220, the vacuum is applied to the indication member 1266 via the through-hole 1264 in the flange 1214 and the lumen 1262 of the housing 1260. The vacuum pulls the indication member 1266 through the lumen 1262 against the biasing force of the biasing member 1268 as indicated by arrow G in Figure 12B. The positioning of the indication member 1266 relative to the housing 1260 can provide a visual indication to a user of the assembly 700

that the assembly 700 is under vacuum. In some embodiments, for example, when the plunger 1210 is fully withdrawn, the indication member 1266 can be positioned entirely within the lumen 1262 and thus obscured by the housing 1260 as shown in Figure 12B. When the vacuum is released, the biasing member 1268 drives the indication member 1266 through the lumen 1262 in the direction of arrow F at least partially outside the housing 1260 (e.g., as shown in Figure 12A) to provide a visual indication that the assembly 700 is not under vacuum. In some aspects of the present technology, the position of the indication member 1266 relative to the housing 1260 can provide an indication of a varying level of vacuum in the assembly 700 (e.g., in contrast to a binary on/off indication).

[0088] In some embodiments, the plunger 1210 includes a grip portion 1216 configured to engage the indication member 1266, as shown in Figure 12A, to inhibit further movement of the indication member 1266 in the direction of arrow F when the assembly 700 is under positive pressure. In some embodiments, any of the vacuum-pressure locking syringes 100/500/600 described in detail above with reference to Figures 1A–6C can include the vacuum indicator 1230.

[0089] Figures 13A–13C are side views of a vacuum indication device or vacuum indicator 1330 in a vacuum-off position, a partial-vacuum position, and a full-vacuum position, respectively, in accordance with additional embodiments of the present technology. Referring to Figures 13A–13C together, the vacuum indicator 1330 includes a sealing indicator 1370 slidably positioned within a barrel 1320. The barrel 1320 includes a cap 1371 (e.g., a sealed cap), and a tip 1326 (e.g., a Luer connector) that can be directly coupled to another device or system, such as the fluid control device 726 (e.g., stopcock) of Figure 7, as shown in Figures 13B and 13C.

[0090] In some embodiments, the sealing indicator 1370 is configured to sealingly engage the barrel 1320 to define a first volume or chamber 1372 and a second volume or chamber 1374 within the barrel 1320. For example, the sealing indicator 1370 can include one or more sealing members (e.g. O-rings; not shown) on an outer surface thereof to provide a dynamic seal between the barrel 1320 and the sealing indicator 1370. In some embodiments, the one or more sealing members can engage the barrel 1320 with low friction to facilitate sliding movement of the sealing indicator 1370 within the barrel 1320. The first chamber 1372 can be a sealed volume with no outlet, while the second chamber 1374 can be open to the tip 1326.

[0091] With additional reference to Figure 7, when the assembly 700 is not under vacuum pressure, the sealing indicator 1370 can be positioned near an upper portion of the barrel 1320 proximate the cap 1371. When the syringe 100/500/600 is used to generate a vacuum in the

assembly 700, vacuum pressure is generated in the second chamber 1374. The vacuum pressure in the second chamber 1374 pulls the sealing indicator 1370 downward toward the tip 1326 of the barrel 1320 as shown in Figure 13B. As the sealing indicator 1370 moves downward away from the cap 1371, the volume of the first chamber 1372 increases, thereby generating vacuum pressure in the first chamber 1372. The vacuum pressure generated in the first chamber 1372 provides a resistive force that acts against the vacuum force in the second chamber 1374 to urge the sealing indicator 1370 upward toward the cap 1371. The vacuum force in second chamber 1374 must overcome the resistive vacuum force in first chamber 1372 to cause the sealing indicator 1370 to travel downward through the barrel 1320. In some embodiments, the vacuum indicator 1370 is configured (e.g., shaped, sized) such that the sealing indicator 1370 abuts the tip 1326 of the barrel 1320 in the full-vacuum position, as shown in Figure 13C, to indicate that a maxium vacuum level has been generated in the assembly 700. If vacuum force dissipates or is lost in the assembly 700, the resitive vacuum force in the first chamber 1372 can return the sealing indicator 1370 toward the vacuum-off position shown in Figure 13A.

[0092] In general, the opposing vacuum forces in the first and second volumes 1372, 1374, along with the friction forces between the barrel 1320 and the sealing indicator 1370, dictate the travel speed and location of the sealing indicator 1370 along the barrel 1320. In some aspects of the present technology, the vacuum indicator 1330 can provide a continuous resolution of the vacuum level at higher vacuum levels (e.g., greater than 25 inHg). That is, the position of the sealing indicator 1370 in the barrel 1320 can indicate a specific level of vacuum in the assembly 700.

[0093] Figures 14A and 14B are an isometric view and a top view of a syringe 1400 in accordance with additional embodiments of the present technology. The syringe 1400 is in a depressed/advanced position in Figures 14A and 14B. Referring to Figures 14A and 14B together, the syringe 1400 can include several features generally similar or identical to the syringe 100 described in detail above with reference to Figures 1A–4, and can be coupled to the assembly 700 of Figure 7 for use in a clot removal procedure. In the illustrated embodiment, for example, the syringe 1400 includes a plunger 1410 configured to be slidably positioned within a barrel 1420. The barrel 1420 is shown as partially transparent in Figures 14A and 14B for clarity. The barrel 1420 can include a barrel portion 1422 and a tip 1426. The plunger 1410 can include a shaft 1412 and a grip portion 1416. The syringe 1400 further includes a base 1440 and a lock member 1450 having a lock plate 1452 (obscured in Figure 14B and partially obscured in Figure 14A) and a

button portion 1454. The lock member 1450 is configured to automatically engage the base 1440 when the plunger 1410 is withdrawn to automatically lock the plunger 1410 in a withdrawn position, as described in detail above. The button portion 1454 can be actuatable (e.g., depressible) by a user to release the lock plate 1452 from the base 1440 to release the plunger 1410 to, for example, permit the plunger 1410 to move through the barrel 1420 to expel any contents (e.g., bodily fluids such as blood and clot material) collected in the barrel 1420 from the tip 1426. In the illustrated embodiment, however, the button portion 1454 extends generally parallel to the grip portion 1416 of the plunger 1410.

[0094] Moreover, in the illustrated embodiment the syringe 1400 further includes a vacuum indicator 1430 formed in and/or coupled to the tip 1426. Figures 14C and 14D are enlarged side views of the vacuum indicator 1430 in a "vacuum-off" and a "vacuum-on" position, respectively, in accordance with embodiments of the present technology. Figures 14E and 14F are enlarged partially transparent side views of the vacuum indicator 1430 in the vacuum-off and the vacuum-on position, respectively, in accordance with embodiments of the present technology. Figure 14G is an enlarged side cross-sectional view of the vacuum indicator in the vacuum-off position in accordance with embodiments of the present technology. Referring to Figures 14E–14G together, the vacuum indicator 1430 can include a flexible member 1434 (e.g., a diaphragm, a rolling diaphragm) sealingly positioned over an opening 1461 in the tip 1426. The flexible member 1434 can be formed from a compliant material, such as silicone.

[0095] Referring to Figures 14C–14G together, in the illustrated embodiment the vacuum indicator 1430 further includes (i) a non-transparent (e.g., opaque) bonnet or base 1435 positioned around and/or coupled to the flexible member 1434, (ii) a transparent tube 1437 coupled to and extending from the base 1435, and (iii) a non-transparent cap 1439 coupled to and positioned above the tube 1437. The base 1435, the tube 1437, and/or the cap 1439 can be integrally formed or can be separate components coupled together. The vacuum indicator 1430 can further include an indicator 1460 movably positioned within the tube 1437 and the cap 1439. The indicator 1460 can include a first indicator region 1462 and a second indicator region 1464 each having at last one different visual characteristic (e.g., color, pattern, size, thickness, shape) from one another. For example, in some embodiments the first indicator region 1462 can be a first color (e.g., red) while the second indicator region 1464 can be a different second color (e.g., green). In some embodiments, a first end portion of the indicator 1460 (e.g., a lower end of the first indicator region 1462) can be coupled to the flexible member 1434 and a second end portion of the indicator

1460 (e.g., an upper end of the second indicator region 1464) can be coupled to the cap 1439 via a biasing member 1466 (Figures 14F and 14G), such as a spring. As best seen in Figure 14G, in some embodiments the biasing member 1466 can extend at least partially through an internal channel 1469 of the indicator 1460.

[0096] When the tip 1426 of the syringe 1400 is not under vacuum, the vacuum indicator 1430 is in the vacuum-off position in which the biasing member 1466 biases the indicator 1460 toward the cap 1439 such that the first indicator region 1462 is positioned adjacent the transparent tube 1437—and thus visible to the user—as shown in Figures 14C and 14E. At the same time, the second indicator region 1464 is obscured by the non-transparent cap 1439 in the vacuum-off position. When the tip 1426 of the syringe 1400 is under vacuum, the vacuum indicator 1430 is in the vacuum-on position in which the vacuum pulls the flexible member 1434 into/toward the opening 1461, thereby pulling the indicator 1460 toward the opening 1461 against the biasing force of the biasing member 1466 such that the second indicator region 1464 is positioned adjacent the transparent tube 1437—and thus visible to the user—as shown in Figures 14D and 14F. At the same time, the first indicator region 1462 is obscured by the non-transparent base 1435 in the vacuum-on position. In this manner, the first and second indicator regions 1462, 1464 are configured to provide a visual indication to the user of whether the syringe 1400 (and the coupled assembly 700 of Figure 7) is under vacuum or not.

[0097] Figures 15A and 15B are an isometric view and a side view of a syringe 1500 in accordance with additional embodiments of the present technology. The syringe 1500 is in a depressed/advanced position in Figures 15A and 15B. Referring to Figures 15A and 15B together, in some embodiments the syringe 1500 can be generally identical to the syringe 1400 described in detail above with reference to Figures 14A and 14B (e.g., including the plunger 1410, the barrel 1420, the 1426, the base 1440, and the lock member 1450). In the illustrated embodiment however, the syringe 1500 includes a different vacuum indicator 1530 formed in and/or coupled to the tip 1426.

[0098] Figures 15C and 15D are enlarged side views of the vacuum indicator 1530 in a "vacuum-off" and a "vacuum-on" position, respectively, in accordance with embodiments of the present technology. Figures 15E and 15F are enlarged partially transparent side views of the vacuum indicator 1530 in the vacuum-off and the vacuum-on position, respectively, in accordance with embodiments of the present technology. Figure 15G is an enlarged side cross-sectional view of the vacuum indicator in the vacuum-off position in accordance with embodiments of the present

technology. The vacuum indicator 1530 can include several features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the vacuum indicator 1430 described in detail above with reference to Figures 14C–14G, and can operate in a generally similar or identical manner to the vacuum indicator 1430.

[0099] For example, referring to Figures 15E–15G together, the vacuum indicator 1530 can include a flexible member 1534 (e.g., a diaphragm, a rolling diaphragm) sealingly positioned over the opening 1461 in the tip 1426. The flexible member 1534 can be biased to a first (e.g., preconvoluted) position in the vacuum-off position and can be pulled downward toward the opening 1461 to a second position in the vacuum-on position. Referring to Figures 15C–15G together, the vacuum indicator 1530 can further include (i) a non-transparent (e.g., opaque) base 1535 positioned around and/or coupled to the flexible member 1534, (ii) a transparent tube 1537 coupled to and extending from the base 1535, and (iii) a non-transparent cap 1539 coupled to and positioned above the tube 1537. The base 1535, the tube 1537, and/or the cap 1539 can be integrally formed or can be separate components coupled together. The vacuum indicator 1530 further includes an indicator 1560 positioned within the tube 1537 and the cap 1539. In the illustrated embodiment, the indicator 1560 includes a first indicator region or portion 1562 and a second indicator region or portion 1564 each having at last one different visual characteristic from one another. For example, in some embodiments the first indicator portion 1562 can be a first color (e.g., red) while the second indicator portion 1564 can be a different second color (e.g., green). In some embodiments, the second indicator portion 1564 is at least partially nested within the first indicator portion 1562 in the vacuum-off position (e.g., as best seen in Figure 15G). The first indicator portion 1562 (e.g., a lower end portion thereof) can be coupled to the flexible member 1534 while the second indicator portion 1564 (e.g., an upper end portion thereof) can be coupled to the cap 1539.

[0100] When the tip 1426 of the syringe 1500 is not under vacuum, the vacuum indicator 1530 is in the vacuum-off position in which the flexible member 1534 is in the first position and biases the first indicator portion 1562 upward toward the cap 1539 such that the second indicator portion 1564 is positioned adjacent the transparent tube 1537—and thus visible to the user—as shown in Figures 15C and 15E. At the same time, the first indicator portion 1562 at least partially surrounds the second indicator portion 1564 such that the second indicator portion 1564 is obscured and not visible to the user in the vacuum-off position. When the tip 1426 of the syringe 1500 is under vacuum, the vacuum indicator 1530 is in the vacuum-on position in which the

vacuum pulls the flexible member 1534 into/toward the opening 1461, thereby pulling the first indicator portion 1562 downward away from the cap 1539 and the second indicator portion 1564 such that the second indicator portion 1564 is visible through the transparent tube 1537, as shown in Figures 15D and 15F. At the same time, the first indicator portion 1562 is obscured by the non-transparent base 1535 in the vacuum-on position. In this manner, the first and second indicator portions 1562, 1564 are configured to provide a visual indication to the user of whether the syringe 1500 (and the coupled assembly 700 of Figure 7) is under vacuum or not.

[0101] In some embodiments, alternatively to or in addition to using the flexible member 1534 to bias the first indicator portion 1562 to the vacuum-off position, the vacuum indicator 1530 can include a biasing member configured to bias the first indicator portion 1562 to the vacuum-off position. Figure 16, for example, is an enlarged side cross-sectional view of the vacuum indicator 1530 further including a biasing member 1666, such as a spring, operably coupled between the cap 1539 and the first indicator portion 1562 in accordance with embodiments of the present technology. In the illustrated embodiment, the biasing member 1666 has an upper end portion 1667 coupled to the cap 1539 (e.g., a spring-mount thereof) and a lower end portion 1668 coupled to the first indicator portion 1562 (e.g., a spring mount thereof). In some embodiments the biasing member 1666 can extend at least partially through an internal channel 1669 of the second indicator portion 1564. When the tip 1426 of the syringe 1500 is not under vacuum, the biasing member 1666 can bias the first indicator portion 1562 toward the cap 1539 to the vacuum-off position. When the tip 1426 of the syringe 1500 is under vacuum, the flexible member 1534 can pull the first indicator portion 1562 toward the opening 1461 against the biasing force of the biasing member 1666 to the vacuum-on position.

IV. Further Examples

[0102] The following examples are illustrative of several embodiments of the present technology:

1. An automatically-locking syringe, comprising:

a barrel;

a plunger slidably positioned within the barrel, wherein the plunger is movable between a depressed position and a withdrawn position, and wherein the plunger includes a lock feature; and

a lock plate coupled to the barrel and having an opening extending therethrough, wherein the plunger is slidably positioned in the opening, wherein the lock plate includes a biasing member configured to bias the lock plate to a locking position, and wherein—

when the plunger is moved from the depressed position to the withdrawn position, the lock feature is configured to engage the lock plate to drive the lock plate to a position away from the locking position to thereby permit the lock feature to pass through the opening, and

after the lock feature passes through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.

2. The syringe of example 1 wherein the lock feature includes a stop surface extending generally perpendicular to a longitudinal axis of the syringe, and wherein the lock plate is configured to engage the stop surface when (a) the lock plate is in the locking position and (b) the plunger is in the withdrawn position.

3. The syringe of example 1 or example 2, further comprising a button coupled to the lock plate, wherein the button is actuatable to move the lock plate away from the locking position to permit movement of the plunger from the withdrawn position to the depressed position.

4. The syringe of any one of examples 1–3 wherein the biasing member includes at least one of a spring and a living hinge.

5. The syringe of any one of examples 1–3 wherein the biasing member is an arm hingedly coupled to the locking plate.

6. The syringe of any one of examples 1–5 wherein the lock feature is one of a plurality of lock features positioned along a longitudinal axis of the plunger.

7. The syringe of example 6 wherein—

when the plunger is moved from the depressed position to the withdrawn position, individual ones of the lock features are configured to sequentially engage the lock

plate to drive the lock plate to the position away from the locking position to thereby permit the lock feature to pass through the opening, and

after the individual ones of the lock features sequentially pass through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.

8. The syringe of example 6 or example 7, further comprising a locking mechanism configured to engage the lock plate to lock the lock plate in the position away from the locking position.

9. The syringe of any one of examples 1–8 wherein the barrel has a volume of about 60 cc or greater.

10. An automatically-locking syringe, comprising:

a barrel including a flange;

a plunger slidably positioned within the barrel, wherein the plunger is aligned along a longitudinal axis, and wherein the plunger is movable along the longitudinal axis between a depressed position and a withdrawn position;

a lock member coupled to the plunger, wherein the lock member includes a body and a first arm hingedly coupled to the body, and wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position; and

an actuator including a second arm, wherein the actuator is movable between a first position and a second position, and wherein the second arm is configured to engage the first arm in the second position to drive the first arm inwardly toward the longitudinal axis away from the locking position.

11. The syringe of example 10 wherein the first arm is configured to engage the flange of the barrel to inhibit movement of the plunger from the withdrawn position to the depressed position when (a) the actuator is in the first position and (b) the plunger is in the withdrawn position.

12. The syringe of example 10 or example 11 wherein the lock member includes a third arm hingedly coupled to the body, wherein the third arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position, wherein the actuator includes a fourth arm, and wherein the fourth arm is configured to engage the third arm in the second position to drive the third arm inwardly toward the longitudinal axis away from the locking position.

13. The syringe of example 12 wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis in a first direction, and wherein the third arm is configured to be biased at least partially outwardly away from the longitudinal axis in a second direction opposite the first direction.

14. The syringe of example 12 or example 13 wherein the first arm and the third arm have an identical size and shape, and wherein the second arm and the fourth arm have an identical size and shape.

15. The syringe of any one of examples 12–14 wherein the third arm is configured to engage the flange of the barrel to inhibit movement of the plunger from the withdrawn position to the depressed position when (a) the actuator is in the first position and (b) the plunger is in the withdrawn position.

16. A clot treatment system, comprising:

a catheter;

a pressure source configured to generate vacuum pressure; and

a tubing subsystem configured to fluidly connect the catheter to the pressure source, wherein the tubing subsystem includes a vacuum indicator configured to provide an indication that the catheter is under vacuum pressure.

17. The clot treatment system of example 16 wherein the tubing subsystem includes an aperture, wherein the vacuum indicator includes a flexible member positioned over the aperture, and wherein the flexible member is configured to deform about the opening when the catheter is under vacuum pressure to provide the indication that the catheter is under vacuum pressure.

18. The clot treatment system of example 17 wherein the vacuum indicator includes a housing positioned around the flexible member and configured to inhibit excessive deformation of the flexible member when the catheter is under positive pressure.

19. The clot treatment device of any one of examples 16–18, wherein the pressure source is an automatically-locking syringe.

20. The clot treatment device of claim 16 wherein—

the tubing subsystem includes a valve, a first tubing section, a fluid control device, and a second tubing subsystem,

the valve fluidly connects the catheter to the first tubing section,

the first tubing section is fluidly connected between the valve and the fluid control device,

the second tubing system fluidly connects the fluid control device to the pressure source, and

the vacuum indicator is fluidly connected between the valve and the fluid control device.

21. A syringe, comprising:

a barrel having a tip, wherein the tip includes an opening;

a plunger movable through the barrel to generate vacuum pressure within the barrel; and

a vacuum indicator positioned over the opening in the tip, wherein the vacuum indicator includes a transparent tube and an indicator movably positioned within the tube, wherein the indicator includes a first region having a first visual characteristic and a second region having a second visual characteristic different than the first visual characteristic, and wherein—

when the barrel is not under vacuum pressure, the first region is configured to be positioned adjacent the tube; and

when the barrel is under vacuum pressure, the second region is configured to be positioned adjacent the tube.

22. The syringe of example 21 wherein the vacuum indicator further includes an opaque cap over the tube, wherein the indicator is movably positioned within the cap and the tube, and wherein—

when the barrel is not under vacuum pressure, the second region is configured to be positioned adjacent the cap; and

when the barrel is under vacuum pressure, the first region is configured to be positioned adjacent the cap.

23. The syringe of example 22 wherein the vacuum indicator further includes a biasing member coupled between the indicator and the cap, wherein the biasing member is configured to bias the indicator to position the first region adjacent the tube when the barrel is not under vacuum pressure.

24. The syringe of any one of examples 21–23 wherein the vacuum indicator further includes a flexible member positioned over the opening in the tip and coupled to the indicator.

25. The syringe of example 24 wherein the flexible member is configured to deform about the opening when the catheter is under vacuum pressure.

26. The syringe of example 24 or example 25 wherein the vacuum indicator further includes an opaque cap over the tube, wherein the first portion of the indicator is coupled to the flexible member, and wherein the second portion of the indicator is coupled to the cap.

27. The syringe of any one of examples 21–26 wherein the vacuum indicator further includes a flexible member positioned over the opening in the tip and a biasing member, wherein the first portion of the indicator is coupled to the biasing member, and wherein the second portion of the indicator is coupled to the flexible member.

28. The syringe of any one of examples 21–27 wherein the first and second portions of the indicator are movable relative to one another, and wherein the second indicator is at least partially nested within the second indicator.

V. Conclusion

[0103] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0104] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0105] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. An automatically-locking syringe, comprising:

a barrel;

a plunger slidably positioned within the barrel, wherein the plunger is movable between a depressed position and a withdrawn position, and wherein the plunger includes a lock feature; and

a lock plate coupled to the barrel and having an opening extending therethrough, wherein the plunger is slidably positioned in the opening, wherein the lock plate includes a biasing member configured to bias the lock plate to a locking position, and wherein—

when the plunger is moved from the depressed position to the withdrawn position, the lock feature is configured to engage the lock plate to drive the lock plate to a position away from the locking position to thereby permit the lock feature to pass through the opening, and

after the lock feature passes through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.

2. The syringe of claim 1 wherein the lock feature includes a stop surface extending generally perpendicular to a longitudinal axis of the syringe, and wherein the lock plate is configured to engage the stop surface when (a) the lock plate is in the locking position and (b) the plunger is in the withdrawn position.

3. The syringe of claim 1, further comprising a button coupled to the lock plate, wherein the button is actuatable to move the lock plate away from the locking position to permit movement of the plunger from the withdrawn position to the depressed position.

4. The syringe of claim 1 wherein the biasing member includes at least one of a spring and a living hinge.

5. The syringe of claim 1 wherein the biasing member is an arm hingedly coupled to the locking plate.

6. The syringe of claim 1 wherein the lock feature is one of a plurality of lock features positioned along a longitudinal axis of the plunger.

7. The syringe of claim 6 wherein—

when the plunger is moved from the depressed position to the withdrawn position, individual ones of the lock features are configured to sequentially engage the lock plate to drive the lock plate to the position away from the locking position to thereby permit the lock feature to pass through the opening, and

after the individual ones of the lock features sequentially pass through the opening, the biasing member is configured to drive the lock plate to the locking position to inhibit movement of the plunger from the withdrawn position to the depressed position.

8. The syringe of claim 6, further comprising a locking mechanism configured to engage the lock plate to lock the lock plate in the position away from the locking position.

9. The syringe of claim 1 wherein the barrel has a volume of about 60 cc or greater.

10. An automatically-locking syringe, comprising:

a barrel including a flange;

a plunger slidably positioned within the barrel, wherein the plunger is aligned along a longitudinal axis, and wherein the plunger is movable along the longitudinal axis between a depressed position and a withdrawn position;

a lock member coupled to the plunger, wherein the lock member includes a body and a first arm hingedly coupled to the body, and wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position; and

an actuator including a second arm, wherein the actuator is movable between a first position and a second position, and wherein the second arm is configured to engage

the first arm in the second position to drive the first arm inwardly toward the longitudinal axis away from the locking position.

11. The syringe of claim 10 wherein the first arm is configured to engage the flange of the barrel to inhibit movement of the plunger from the withdrawn position to the depressed position when (a) the actuator is in the first position and (b) the plunger is in the withdrawn position.

12. The syringe of claim 10 wherein the lock member includes a third arm hingedly coupled to the body, wherein the third arm is configured to be biased at least partially outwardly away from the longitudinal axis of the plunger to a locking position, wherein the actuator includes a fourth arm, and wherein the fourth arm is configured to engage the third arm in the second position to drive the third arm inwardly toward the longitudinal axis away from the locking position.

13. The syringe of claim 12 wherein the first arm is configured to be biased at least partially outwardly away from the longitudinal axis in a first direction, and wherein the third arm is configured to be biased at least partially outwardly away from the longitudinal axis in a second direction opposite the first direction.

14. The syringe of claim 12 wherein the first arm and the third arm have an identical size and shape, and wherein the second arm and the fourth arm have an identical size and shape.

15. The syringe of claim 12 wherein the third arm is configured to engage the flange of the barrel to inhibit movement of the plunger from the withdrawn position to the depressed position when (a) the actuator is in the first position and (b) the plunger is in the withdrawn position.

16. A clot treatment system, comprising:

a catheter;

a pressure source configured to generate vacuum pressure; and

a tubing subsystem configured to fluidly connect the catheter to the pressure source, wherein the tubing subsystem includes a vacuum indicator configured to provide an indication that the catheter is under vacuum pressure.

17. The clot treatment system of claim 16 wherein the tubing subsystem includes an aperture, wherein the vacuum indicator includes a flexible member positioned over the aperture, and wherein the flexible member is configured to deform about the opening when the catheter is under vacuum pressure to provide the indication that the catheter is under vacuum pressure.

18. The clot treatment system of claim 17 wherein the vacuum indicator includes a housing positioned around the flexible member and configured to inhibit excessive deformation of the flexible member when the catheter is under positive pressure.

19. The clot treatment device of claim 16, wherein the pressure source is an automatically-locking syringe.

20. The clot treatment device of claim 16 wherein—

the tubing subsystem includes a valve, a first tubing section, a fluid control device, and a second tubing subsystem,

the valve fluidly connects the catheter to the first tubing section,

the first tubing section is fluidly connected between the valve and the fluid control device,

the second tubing system fluidly connects the fluid control device to the pressure source, and

the vacuum indicator is fluidly connected between the valve and the fluid control device.

21. A syringe, comprising:

a barrel having a tip, wherein the tip includes an opening;

a plunger movable through the barrel to generate vacuum pressure within the barrel; and

a vacuum indicator positioned over the opening in the tip, wherein the vacuum indicator includes a transparent tube and an indicator movably positioned within the tube, wherein the indicator includes a first portion having a first visual characteristic and a second portion having a second visual characteristic different than the first visual characteristic, and wherein—

when the barrel is not under vacuum pressure, the first portion is configured to be positioned adjacent the tube; and

when the barrel is under vacuum pressure, the second portion is configured to be positioned adjacent the tube.

22. The syringe of claim 21 wherein the vacuum indicator further includes an opaque cap over the tube, wherein the indicator is movably positioned within the cap and the tube, and wherein—

when the barrel is not under vacuum pressure, the second portion is configured to be positioned adjacent the cap; and

when the barrel is under vacuum pressure, the first portion is configured to be positioned adjacent the cap.

23. The syringe of claim 22 wherein the vacuum indicator further includes a biasing member coupled between the indicator and the cap, wherein the biasing member is configured to bias the indicator to position the first portion adjacent the tube when the barrel is not under vacuum pressure.

24. The syringe of claim 21 wherein the vacuum indicator further includes a flexible member positioned over the opening in the tip and coupled to the indicator.

25. The syringe of claim 24 wherein the flexible member is configured to deform about the opening when the catheter is under vacuum pressure.

26. The syringe of claim 24 wherein the vacuum indicator further includes an opaque cap over the tube, wherein the first portion of the indicator is coupled to the flexible member, and wherein the second portion of the indicator is coupled to the cap.

27. The syringe of claim 21 wherein the vacuum indicator further includes a flexible member positioned over the opening in the tip and a biasing member, wherein the first portion of the indicator is coupled to the biasing member, and wherein the second portion of the indicator is coupled to the flexible member.

28. The syringe of claim 21 wherein the first and second portions of the indicator are movable relative to one another, and wherein the second indicator is at least partially nested within the second indicator.

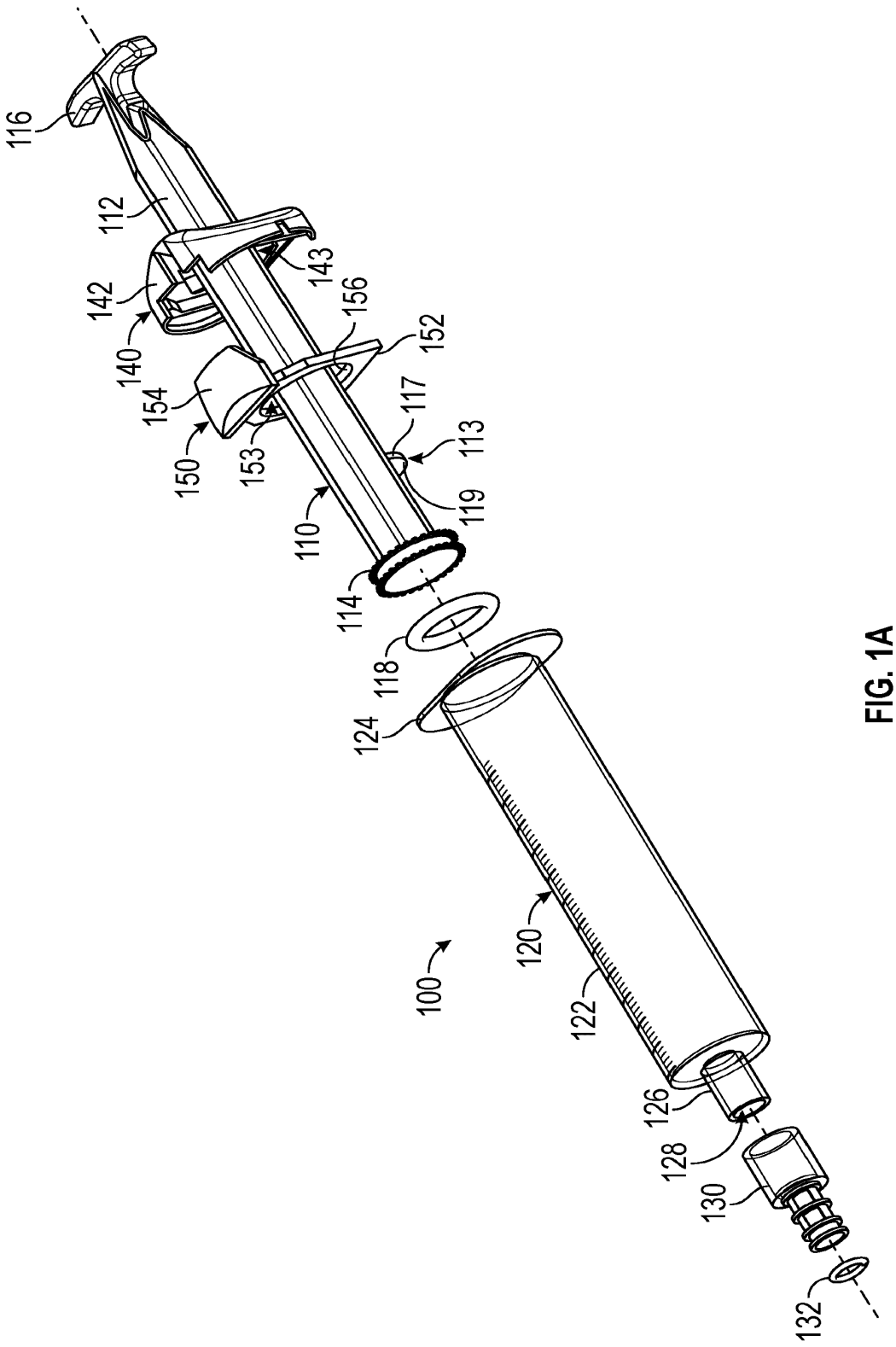

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FIG. 1A

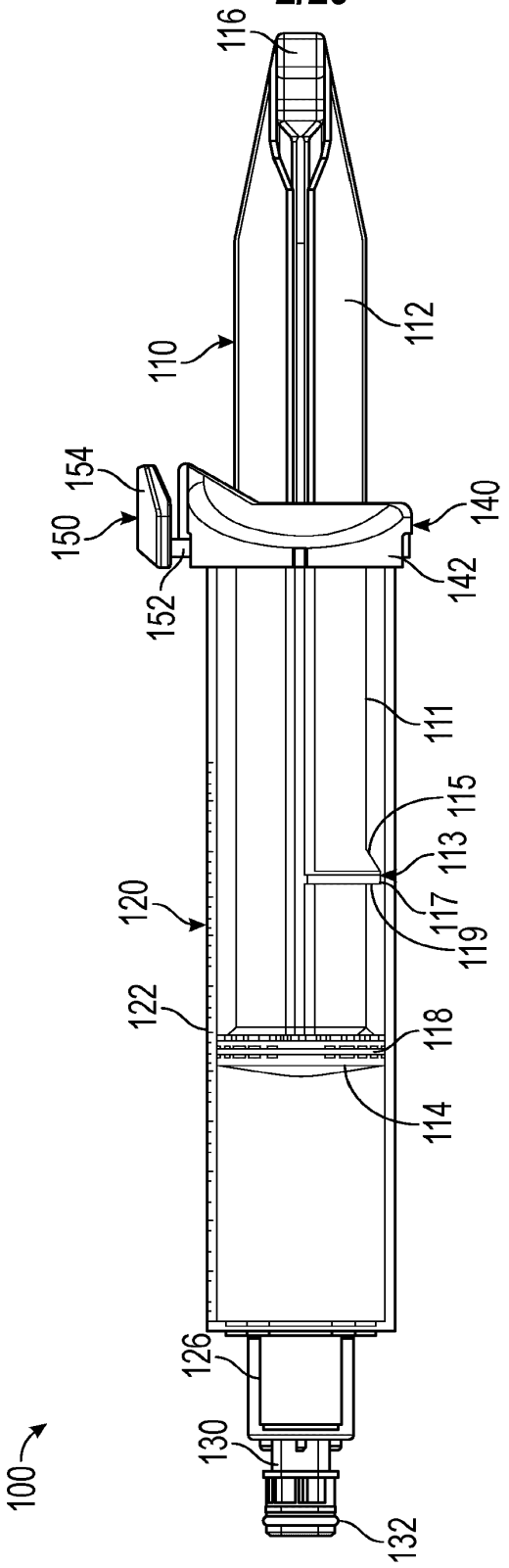

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FIG. 1B

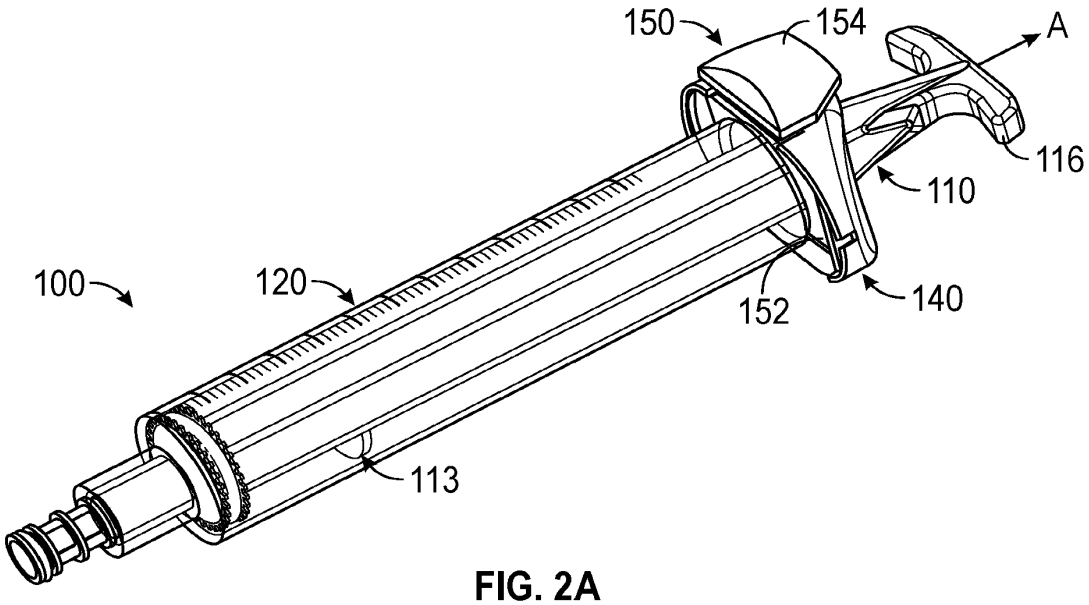

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FIG. 2A

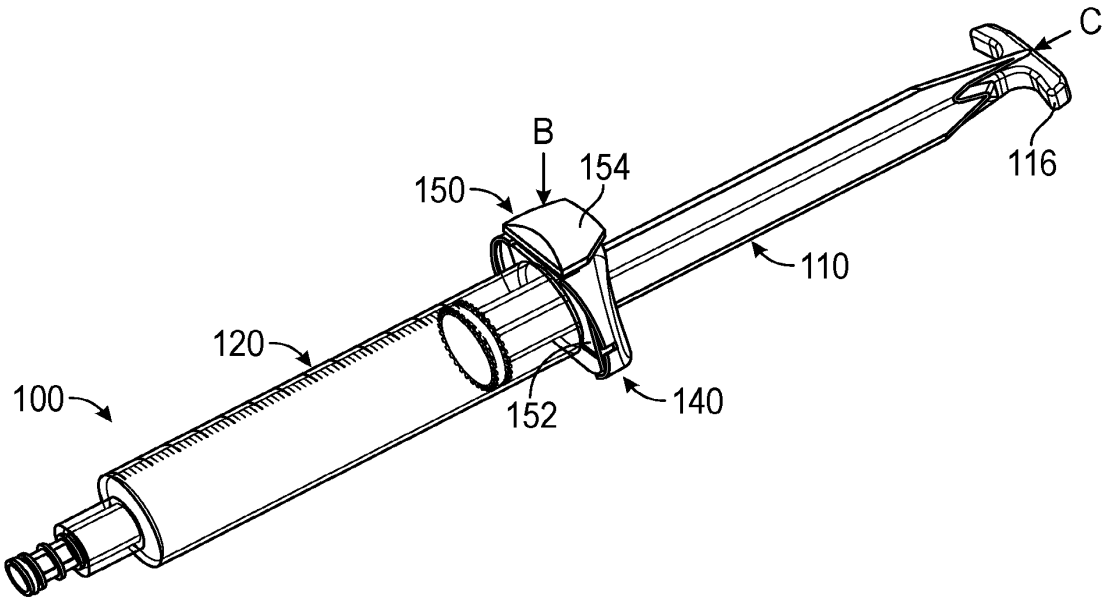

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140

FIG. 2B

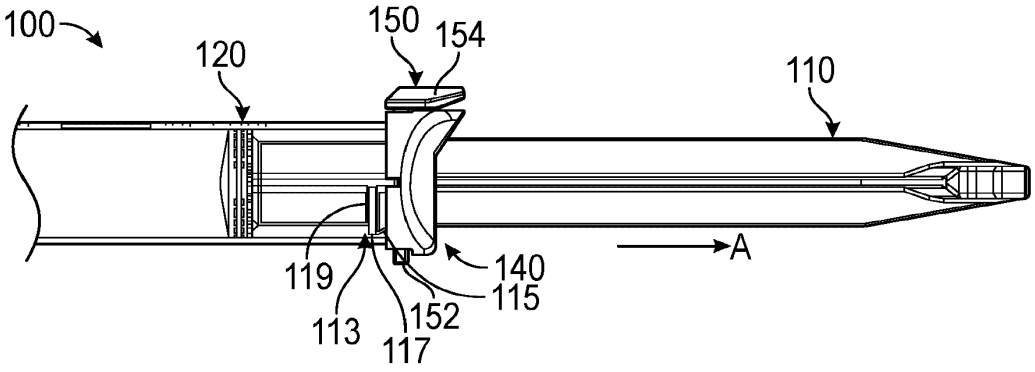

100
120
150
154
110
A
140
115
119
113
152
117

FIG. 3A

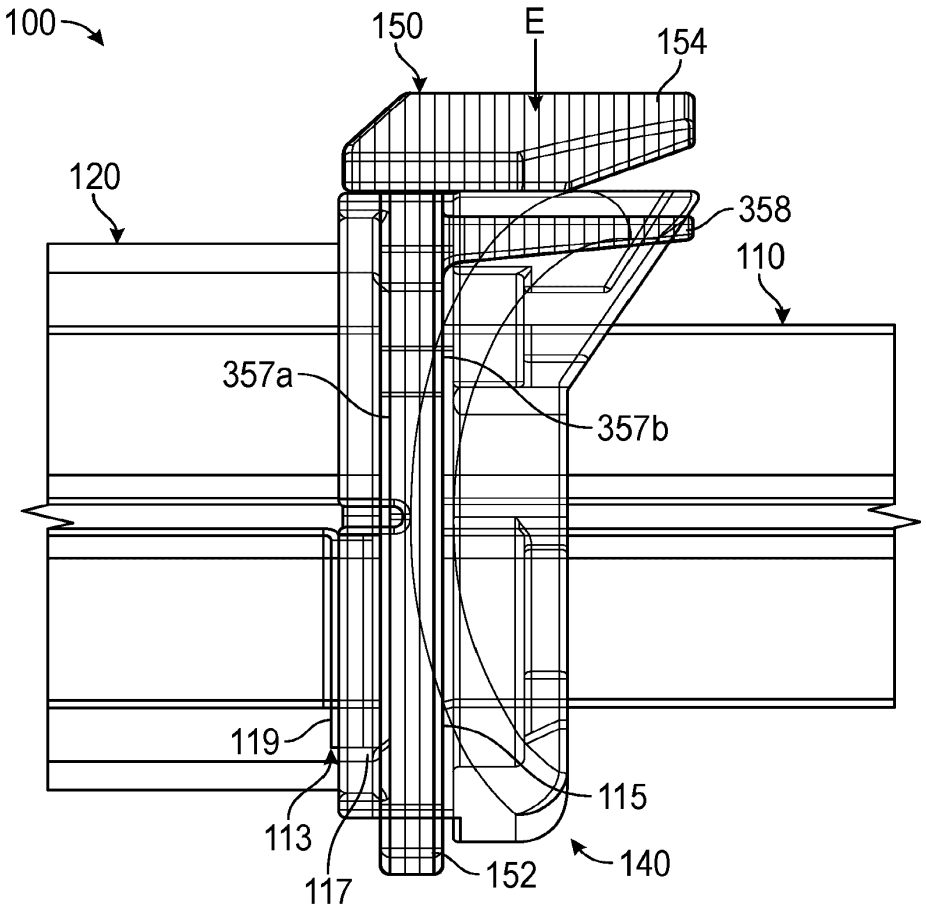

100
150
E
154
120
358
110
357a
357b
119
115
113
140
152
117

FIG. 3B

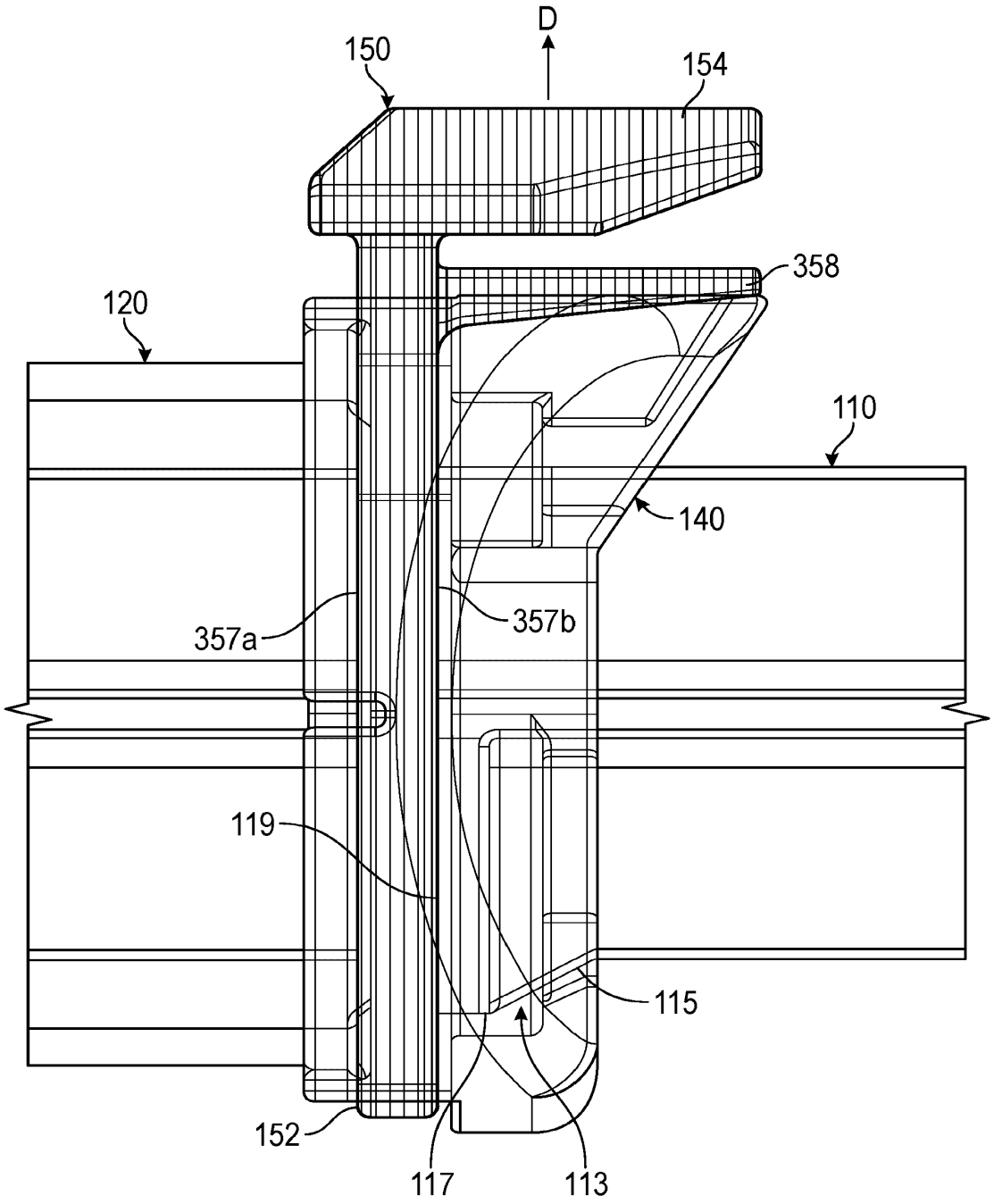


FIG. 3C