CLAIMS

I/We claim:

1. A clot treatment system, comprising:

an outer catheter defining a lumen;

an inner catheter positioned at least partially in the lumen of the outer catheter; and

a clot treatment device including a plurality of interconnected struts forming a unitary structure movable between a compressed configuration and an expanded configuration, wherein in the expanded configuration the unitary structure includes—

a proximal connection region coupled to the outer catheter;

a proximal conical region extending from the proximal connection region, wherein a first portion of the struts form first cells in the proximal conical region;

a cylindrical region extending from the proximal conical region;

a distal conical region extending from the cylindrical region, wherein a second portion of the struts from second cells in the distal conical region, and wherein the second cells are smaller than the first cells; and

a distal connection region extending from the distal conical region and coupled to the inner catheter.

2. The clot treatment system of claim 1 wherein the inner catheter has (a) a distal end portion coupled to the distal connection region of the clot treatment device and (b) a proximal end portion configured to float within the lumen of the outer catheter.

3. The clot treatment system of claim 1 wherein the inner and outer catheters are configured to receive a guidewire therethrough.

4. The clot treatment system of claim 1, further comprising a handle coupled to a proximal end portion of the outer catheter, wherein the handle includes an actuation mechanism coupled to a proximal end portion of the inner catheter, and wherein actuation of the actuation

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[PART 3 OF 6]

mechanism is configured to translate the inner catheter relative to the outer catheter to longitudinally compress or longitudinally elongate the clot treatment device.

5. The clot treatment system of claim 1, further comprising:

a delivery catheter defining a lumen; and

a handle coupled to a proximal end portion of the outer catheter and movable between a first position and a second position relative to the delivery catheter, wherein—

in the first position, the clot treatment device is constrained within the lumen of the delivery catheter in the compressed configuration, and

in the second position, the clot treatment device is positioned distal of the lumen in the expanded configuration.

6. The clot treatment system of claim 5, further comprising a hub coupled to a proximal end portion of the delivery catheter, wherein the handle includes a lock feature configured to secure the handle to the hub in the second position.

7. The clot treatment system of claim 5 wherein the handle, the delivery catheter, the outer catheter, and the inner catheter are configured to receive a guidewire therethrough.

8. The clot treatment system of claim 1 wherein, in the expanded configuration, the cylindrical region has a diameter of between about 0.71 inch to about 1.34 inches.

9. The clot treatment system of claim 1 wherein the struts of the clot treatment device are configured to self-expand from the compressed configuration to the expanded configuration when unconstrained.

10. The clot treatment system of claim 1 wherein the struts of the clot treatment device include a shape memory material.

11. The clot treatment system of claim 1 wherein the unitary structure includes (a) a first number of the struts in the proximal conical region and (b) a second number of the struts in the distal conical region that is greater than the first number of struts.

12. A method of clot removal, the method comprising:

positioning a distal portion of a guide catheter proximate to clot material within a blood vessel of a human patient;

advancing a clot treatment device through the guide catheter to proximate the clot material;

expanding the clot treatment within the blood vessel distal of the clot material, wherein the clot treatment device includes a plurality of interconnected struts forming a unitary structure having a proximal portion and a distal portion, wherein the struts form a plurality of first cells in the proximal portion and a plurality of second cells in the distal portion, and wherein the first cells are larger than the second cells;

generating suction at the distal portion of the guide catheter; and

proximally retracting the clot treatment device through the clot material.

13. The method of claim 12 wherein advancing the clot treatment device through the guide catheter includes advancing the clot treatment device over a guidewire.

14. The method of claim 12 wherein the proximal portion of the unitary structure is coupled to an outer catheter extending at least partially through the guide catheter, and wherein the distal portion of the unitary structure is coupled to an inner catheter extending at least partially through the outer catheter.

15. The method of claim 14 wherein advancing the clot treatment device through the guide catheter includes advancing the clot treatment device over a guidewire extending through the guide, outer, and inner catheters.

16. The method of claim 12 wherein generating suction at the distal portion of the guide catheter includes generating suction, before proximally retracting the clot treatment device, to aspirate a first portion of the clot material into the guide catheter.

17. The method of claim 16 wherein proximally retracting the clot treatment device includes proximally retracting the clot treatment device through a second portion of the clot material remaining in the blood vessel to capture the second portion of the clot material.

18. The method of claim 12 wherein proximally retracting the clot treatment device through the clot material includes capturing at least a portion of the clot material, and wherein the method further comprises retracting the clot treatment device and the captured clot material into the guide catheter.

19. A clot treatment system, comprising:

an outer shaft defining a lumen;

an inner shaft positioned at least partially in the lumen of the outer shaft; and

a plurality of interconnected struts forming a unitary structure having a proximal portion and a distal portion, wherein the proximal portion is coupled to the outer shaft, wherein the distal portion is coupled to the inner shaft, and wherein the struts form a plurality of first cells in the proximal portion and a plurality of second cells in the distal portion, and wherein the first cells are larger than the second cells.

20. The clot treatment system of claim 12 wherein the outer shaft and the inner shaft are configured to receive a guidewire therethrough.

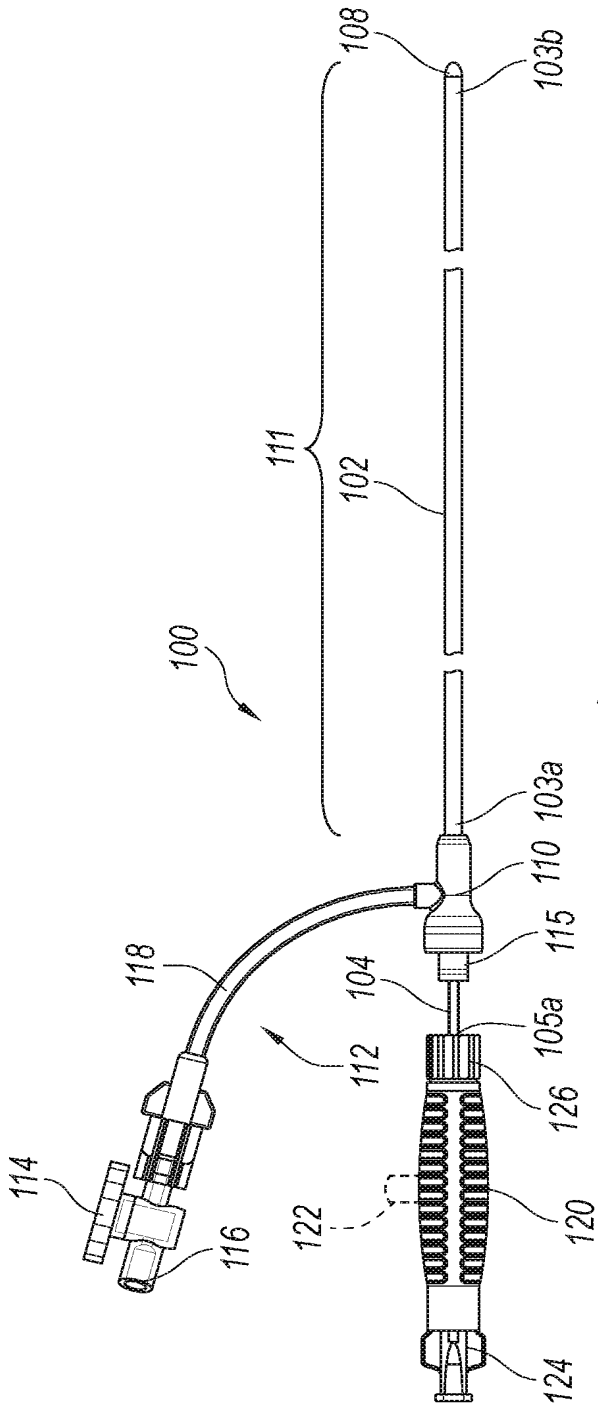


Fig. 1A

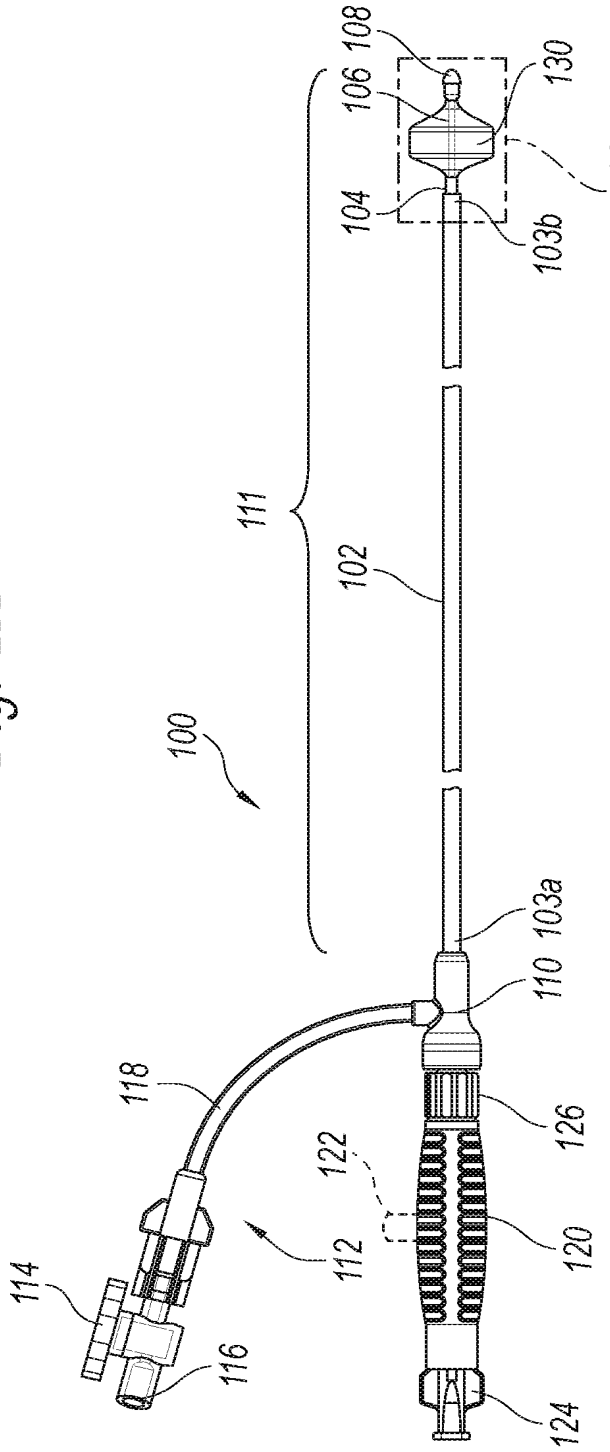


Fig. 1B

Fig. 1C

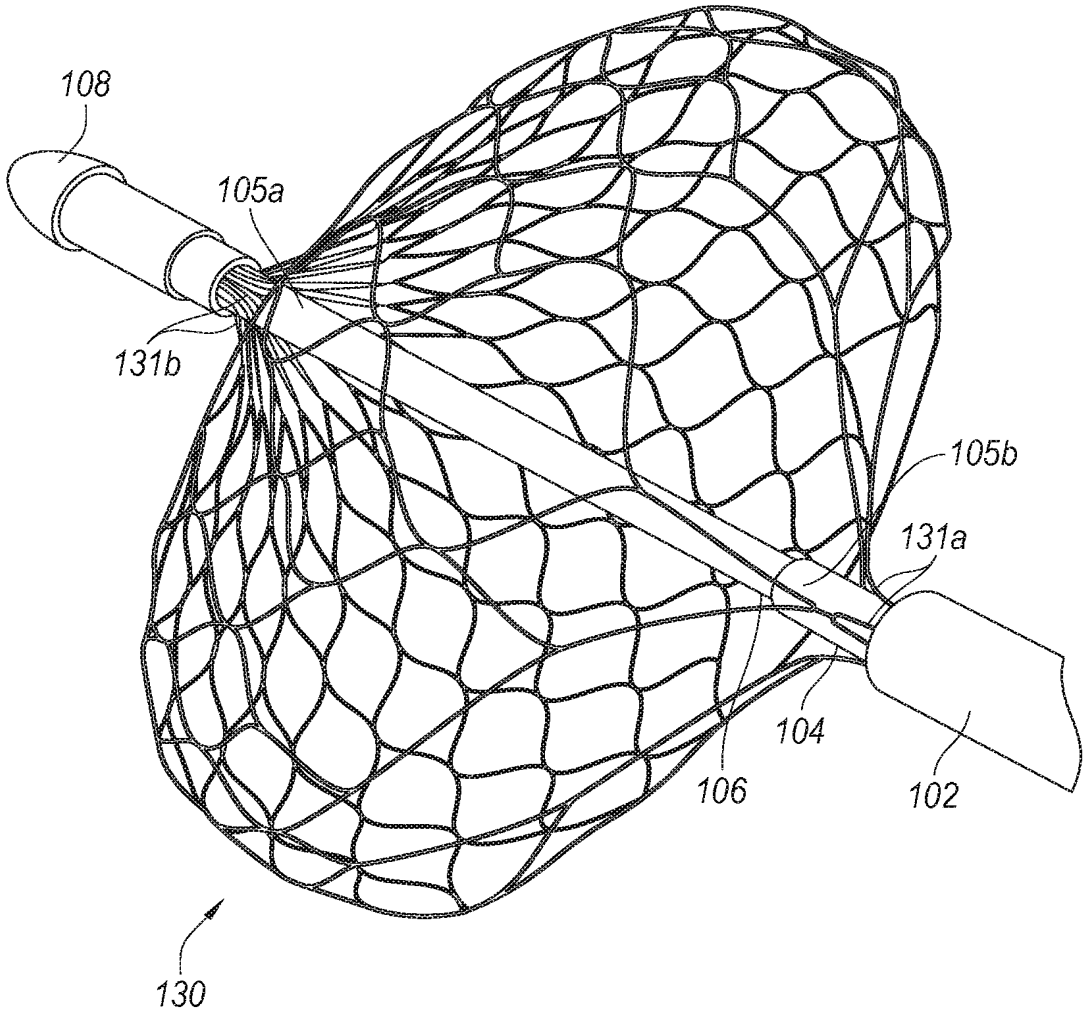


Fig. 1C

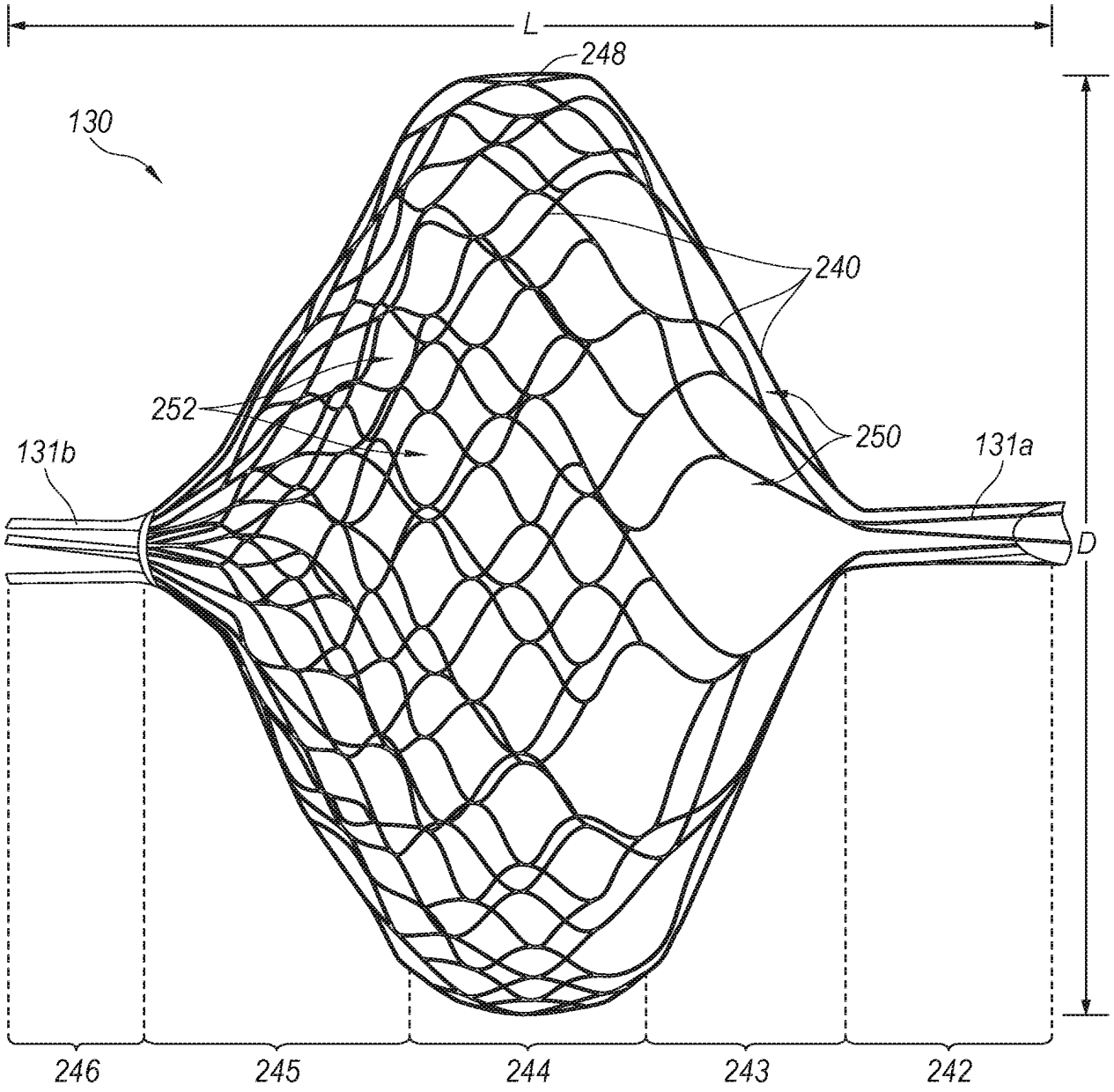


Fig. 2A

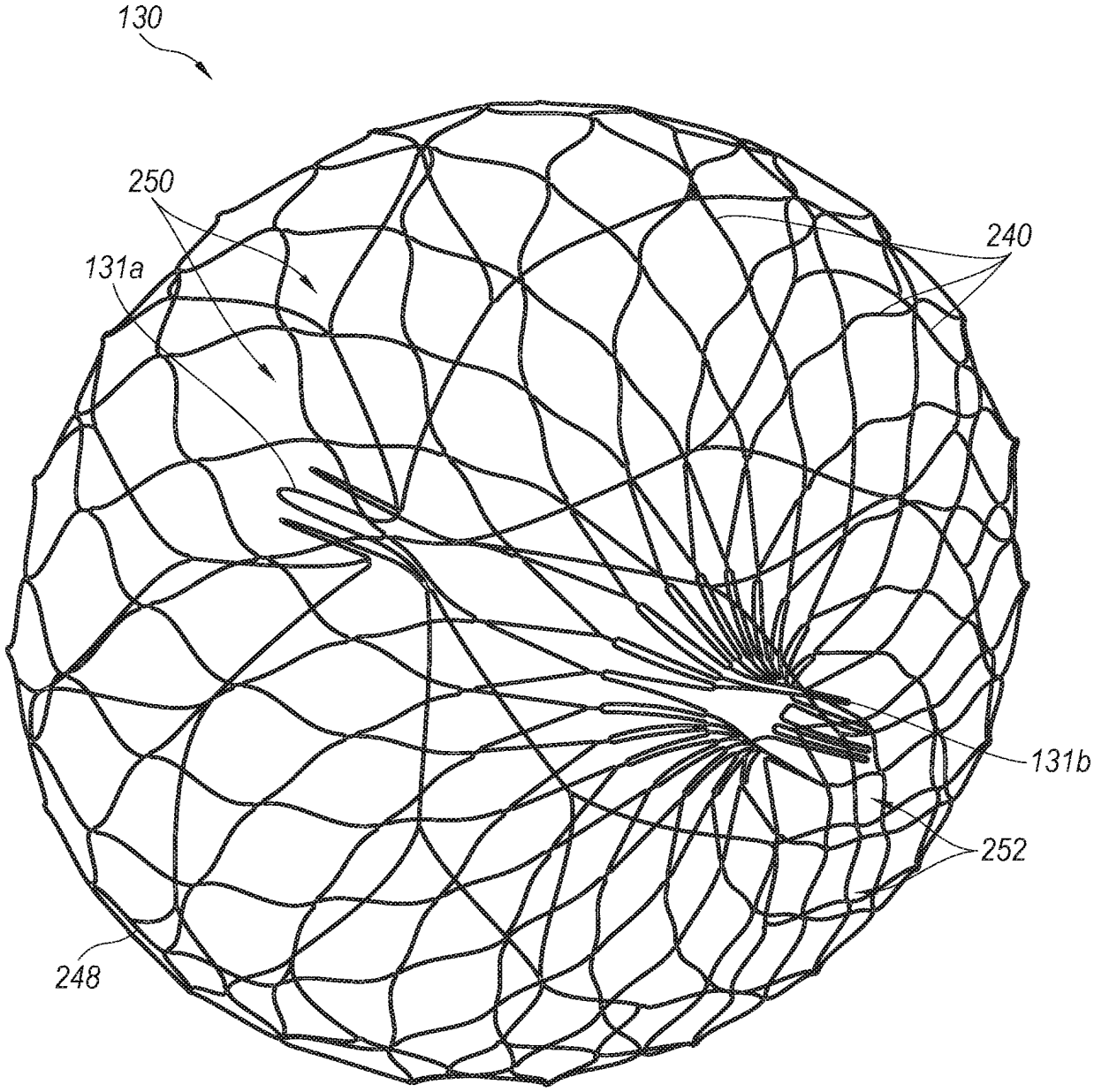


Fig. 2B

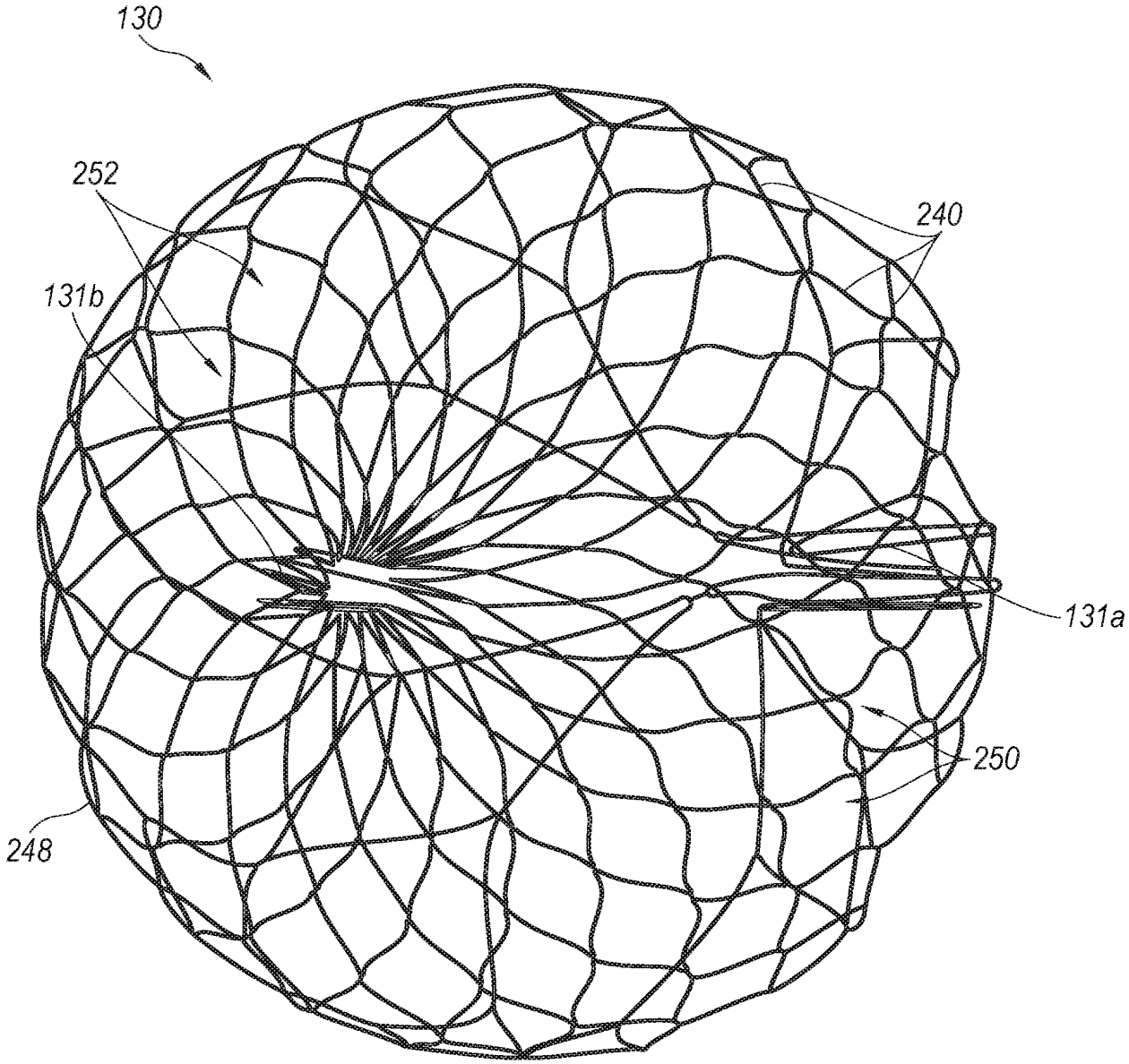


Fig. 2C

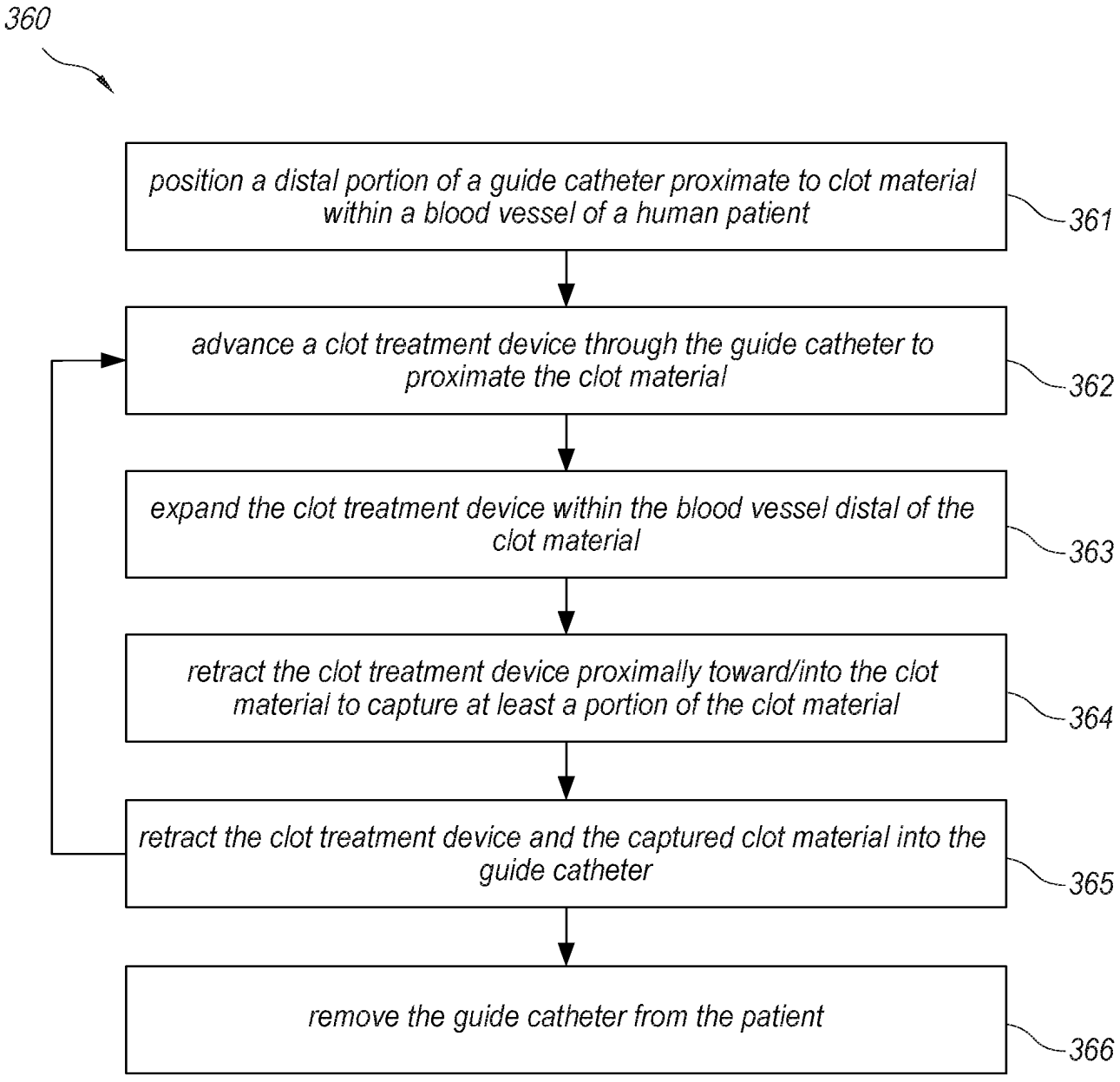

360
position a distal portion of a guide catheter proximate to clot material within a blood vessel of a human patient
361
advance a clot treatment device through the guide catheter to proximate the clot material
362
expand the clot treatment device within the blood vessel distal of the clot material
363
retract the clot treatment device proximally toward/into the clot material to capture at least a portion of the clot material
364
retract the clot treatment device and the captured clot material into the guide catheter
365
remove the guide catheter from the patient
366

Fig. 3

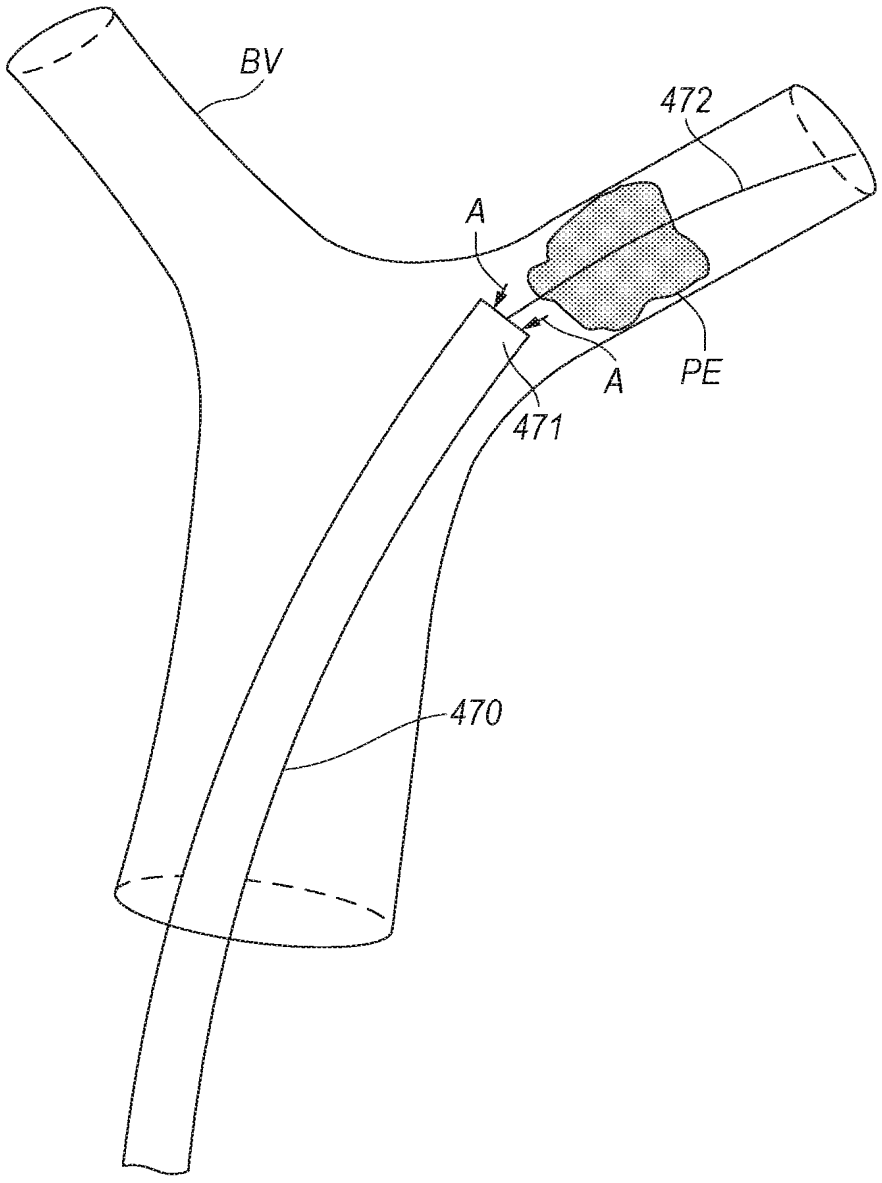


Fig. 4A

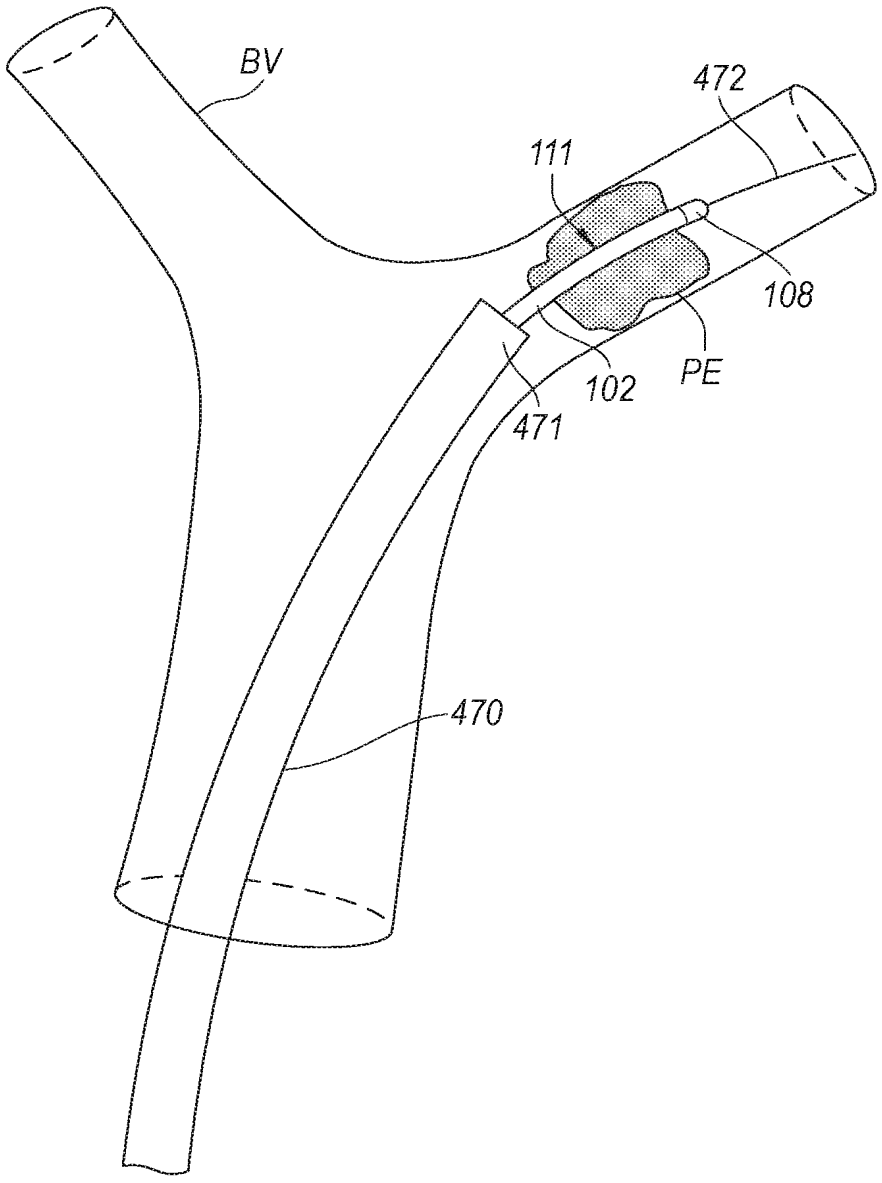


Fig. 4B

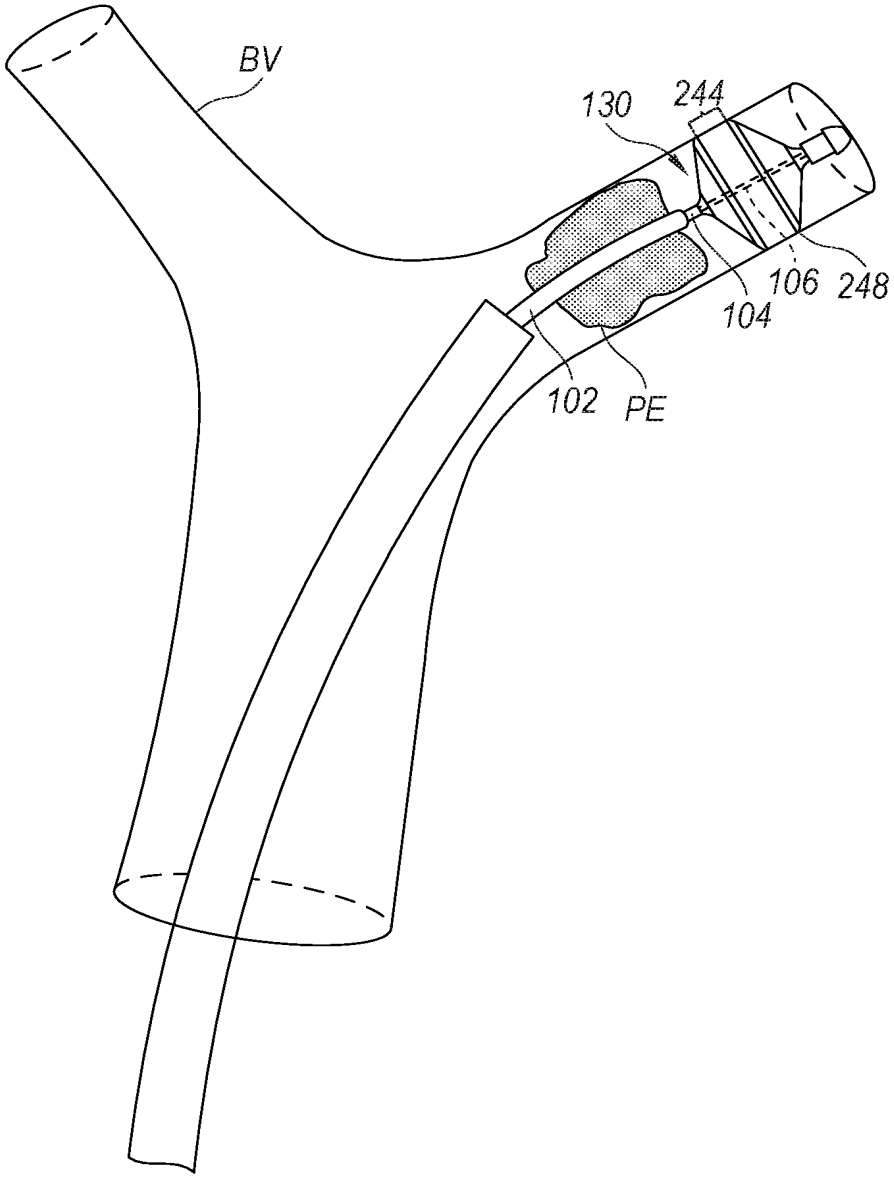


Fig. 4C

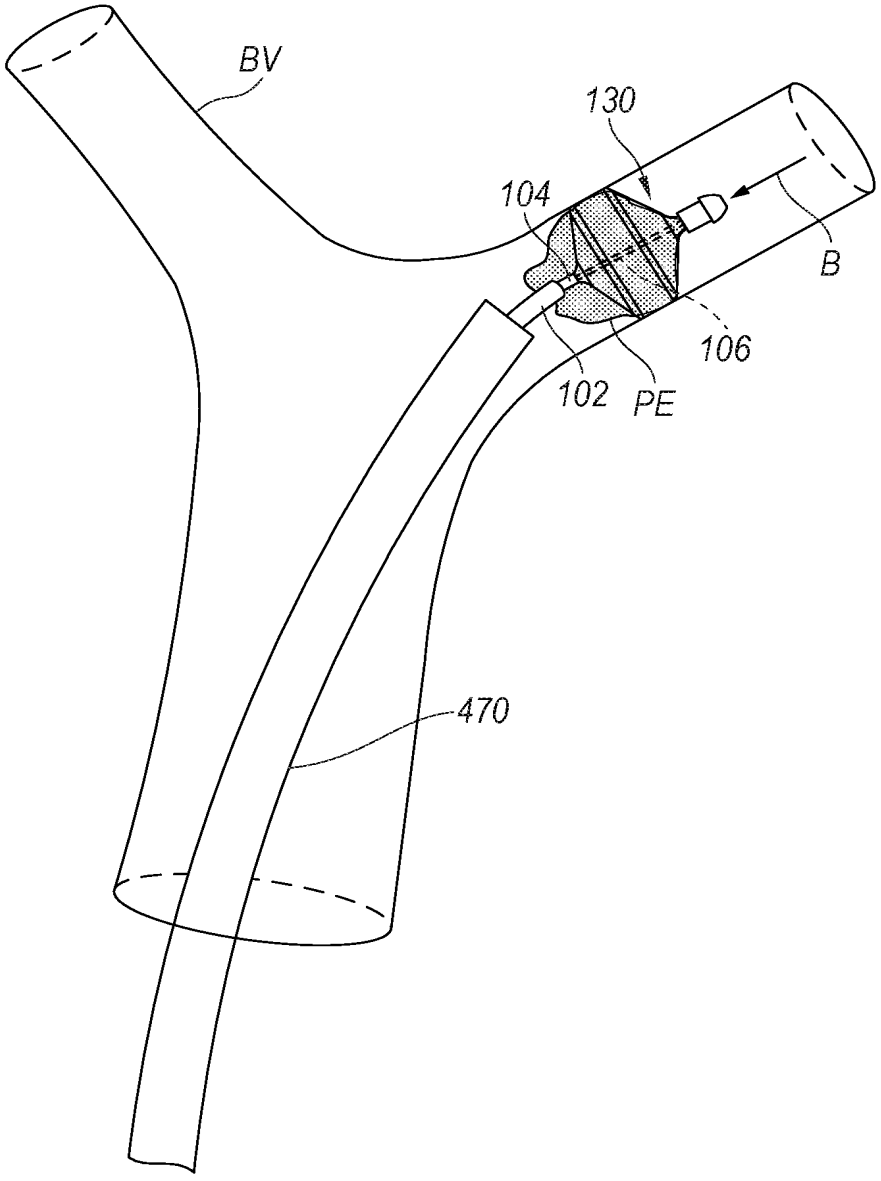


Fig. 4D

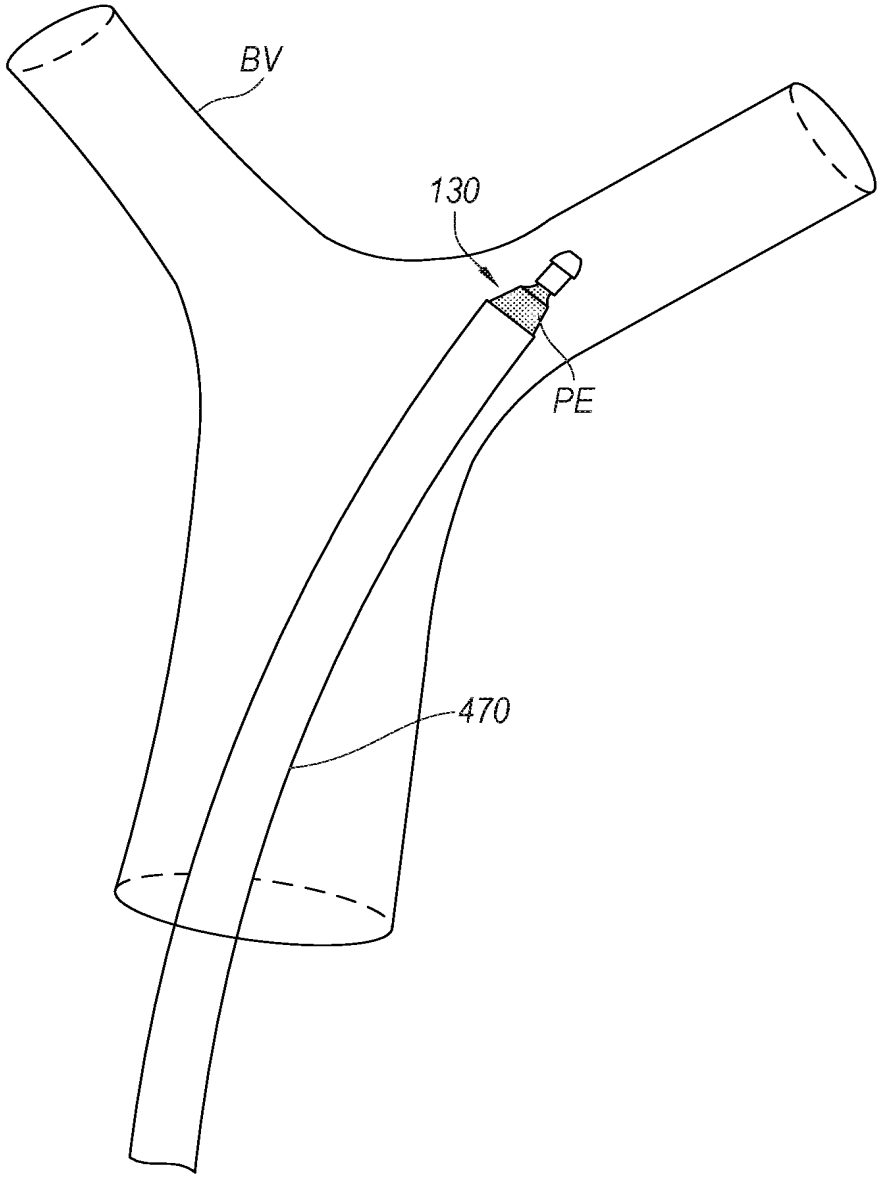


Fig. 4E

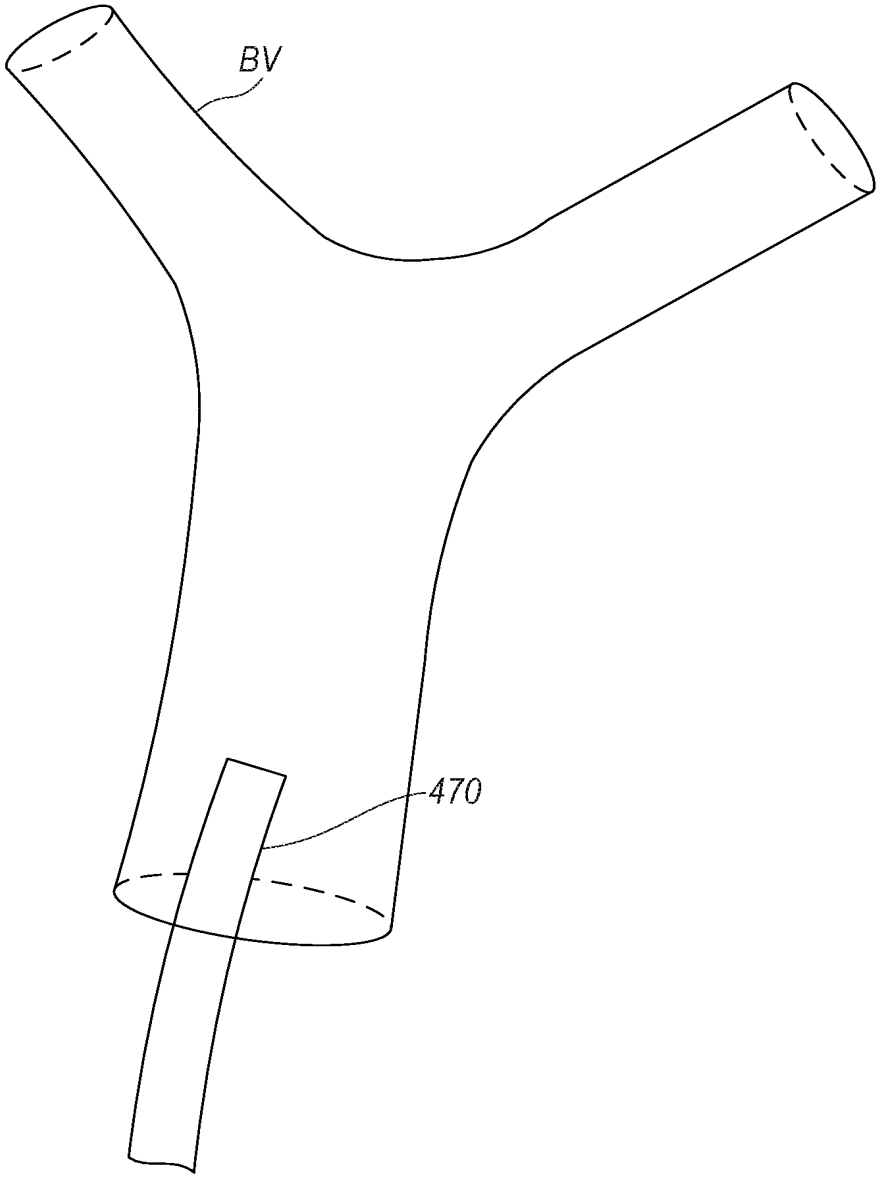


Fig. 4F

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 20/56067

A. CLASSIFICATION OF SUBJECT MATTER

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CPC - A61B 17/14; A61B 17/22; A61B 17/32; A61F 2/01; A61M 25/01; A61M 25/08; A61M 25/09; A61B 17/221; A61B 17/3205; A61B 17/3207

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2019/0046219 A1 (INARI MEDICAL, INC.) 14 February 2019 (14.02.2019); entire document, especially para [0196]-[0201], and Fig. 29-34D.	1-20
A	US 2019/0000492 A1 (NEURAVI LIMITED) 3 January 2019 (03.01.2019); entire document.	1-20
A	US 2014/0371779 A1 (NEURAVI LIMITED) 18 December 2014 (18.12.2014); entire document.	1-20
A	US 2018/0064454 A1 (NEUROVASC TECHNOLOGIES, INC.) 8 March 2018 (08.03.2018); entire document.	1-20

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
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"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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"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 December 2020	22 JAN 2021
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Lee Young Telephone No. PCT Helpdesk: 571-272-4300

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(71) Applicant: **INARI MEDICAL, INC.** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US).

(72) Inventor; and
(71) Applicant: **MACIAS, Jacqueline** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US).

(72) Inventors: **ENRIGHT, Paige Elizabeth**; 9 Parker, Suite #100, Irvine, California 92618 (US). **TU, Thomas M.**; 9 Parker, Suite #100, Irvine, California 92618 (US).

(74) Agent: **WILLIAMS, Matthew S.** et al.; Perkins Coie LLP, P.O. Box 1247, Seattle, Washington 98111-1247 (US).

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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:** DEVICES FOR ADJUSTABLY TENSIONING SUTURES, AND ASSOCIATED SYSTEMS AND METHODS

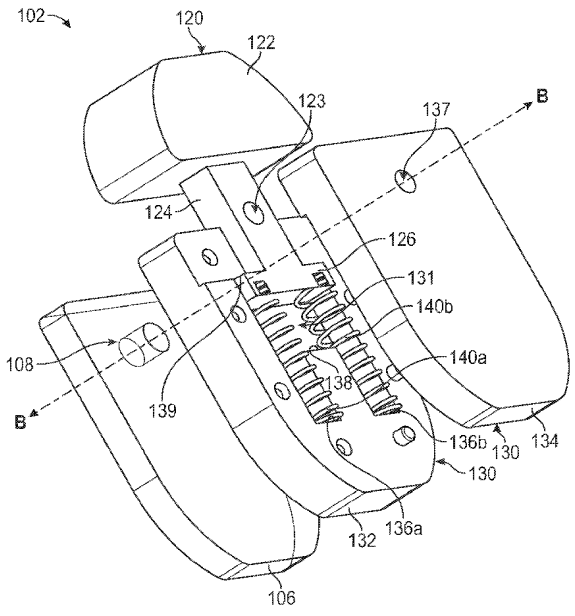


FIG. 1C

(57) **Abstract:** Disclosed herein are devices, systems, and methods for adjustably tensioning sutures, such as sutures used to close a catheter access site of a human patient. In some embodiments, a suture tensioning device includes a housing and an actuation member slidably coupled to the housing. The housing can include a first through-hole and a second through-hole at least partially aligned along an axis. The actuation member can include a third-through-hole. The suture tensioning device can further include a biasing member operably coupled between the actuation member and the housing. The biasing member can bias the actuation member to a first position in which the third through-hole is offset from the axis. The actuation member is movable to a second position in which the third through-hole is at least partially aligned with the first and second through-holes along the axis.

WO 2022/103848 A1

[Continued on next page]

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— *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))*

DEVICES FOR ADJUSTABLY TENSIONING SUTURES, AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/111,774, filed November 10, 2020, and titled "DEVICES FOR ADJUSTABLY TENSIONING SUTURES, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to systems, methods, and devices for adjustably tensioning sutures, such as sutures used to close a percutaneous catheter access site of a human patient.

BACKGROUND

[0003] Percutaneous medical procedures involve accessing the inner organs, tissue, and/or vasculature of a patient via a puncture in the skin of the patient. A percutaneous approach is commonly used in intravascular procedures such as angioplasty, stenting, clot removal, and so on. More specifically, many intravascular procedures include inserting a catheter and/or medical device into a blood vessel of a patient through an access site, such as a popliteal access site, an internal jugular access site, a femoral access site, or another venous or arterial access site. For example, an introducer assembly can be positioned in the blood vessel through the access site, and one or more medical instruments can be advanced through the introducer assembly for carrying out the intravascular procedure.

[0004] After such procedures, the access site must be closed to maintain hemostasis as the patient recovers. Common techniques for closing the access site include manual compression and suturing. However, it may be difficult to successfully close the access site and achieve hemostasis when the access site is large, such as for intravascular procedures utilizing large bore catheters. Additionally, the access site closure may be uncomfortable to the patient during recovery.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0006] Figures 1A and 1B are an isometric view and a partially-exploded isometric view, respectively, of a suture tensioning device in accordance with embodiments of the present technology.

[0007] Figures 1C and 1D are exploded top and bottom isometric views, respectively, of the tensioning assembly 102 in accordance with embodiments of the present technology.

[0008] Figure 1E is an exploded isometric view of a dressing assembly of the suture tensioning device in accordance with embodiments of the present technology.

[0009] Figure 2 is an isometric view of a threading tool for use with the suture tensioning device in accordance with embodiments of the present technology.

[0010] Figure 3 is a flow diagram of a process or method for operating the suture tensioning device in accordance with embodiments of the present technology.

[0011] Figures 4A and 4B are isometric views of the suture tensioning device illustrating threading of a suture therethrough in accordance with embodiments of the present technology.

[0012] Figure 5 is an enlarged side cross-sectional view of a suture positioned within the tensioning assembly of the suture tensioning device in accordance with embodiments of the present technology.

[0013] Figure 6 is an exploded isometric view of a tensioning assembly in accordance with additional embodiments of the present technology.

[0014] Figures 7A and 7B are an exploded isometric view and an isometric view, respectively, of a suture tensioning device in accordance with additional embodiments of the present technology.

[0015] Figure 8 is an exploded isometric view of a tensioning assembly in accordance with additional embodiments of the present technology.

[0016] Figure 9 is an exploded isometric view of a suture tensioning device in accordance with additional embodiments of the present technology.

[0017] Figures 10A and 10B are isometric views of a tensioning assembly in a first position and a second position, respectively, in accordance with additional embodiments of the present technology.

[0018] Figure 11 is an isometric view of a tensioning assembly in accordance with additional embodiments of the present technology.

[0019] Figure 12 is an exploded isometric view of a tensioning assembly in accordance with additional embodiments of the present technology.

[0020] Figures 13A and 13B are isometric views of a tensioning assembly in a first position and a second position, respectively, in accordance with additional embodiments of the present technology.

DETAILED DESCRIPTION

[0021] The present technology is generally directed to devices for adjustably tensioning sutures, such as sutures used to close a catheter access site of a human patient, and associated systems and methods. In some embodiments, a suture tensioning device includes a housing and an actuation member slidably coupled to the housing. The housing can include a first through-hole and a second through-hole at least partially aligned with one another along an axis. The actuation member can include a third-through-hole. The suture tensioning device can further include a biasing member operably coupled between the actuation member and the housing. The biasing member can exert a biasing force against the actuation member that holds the actuation member in a first position in which the third through-hole is offset from the axis and therefore not aligned with the first and second through-holes of the housing. The actuation member can be movable against the biasing force of the biasing member to a second position in which the third through-hole is at least partially aligned with the first and second through-holes along the axis.

[0022] In operation, a user can thread a suture through the first, second, and third through-holes when the actuation member is in the second position. The suture can be used to close a puncture in the patient, such as a catheter access site. After adjusting the tension in the suture to a desired tension, the user can release the actuation member to permit the biasing member to drive the actuation member to the first position. In the first position, the actuation member and/or the housing engage the suture to inhibit the suture from moving through the first, second, and third through-holes. Accordingly, the suture tensioning device can maintain the desired tension

in the suture. To adjust the tension in the suture, the user can actuate (e.g., depress) the actuation member against the biasing force of the biasing member to move the actuation member to the second position. The user can then adjust the tension in the suture to another desired tension, and then release the actuation member to lock the suture in position at the selected tension. Accordingly, in one aspect of the present technology the suture tensioning device allows the tension in the suture to be easily adjusted. For example, the user can increase the tension to better close the puncture and maintain hemostasis and/or decrease the tension to accommodate patient comfort.

[0023] Certain details are set forth in the following description and in Figures 1–13B to provide a thorough understanding of various embodiments of the present technology. In other instances, well-known structures, materials, operations, and/or systems often associated with intravascular procedures, percutaneous access sites, etc., are not shown or described in detail in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. Those of ordinary skill in the art will recognize, however, that the present technology can be practiced without one or more of the details set forth herein, and/or with other structures, methods, components, and so forth.

[0024] The terminology used below is to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain examples of embodiments of the technology. Indeed, certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

[0025] The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope unless expressly indicated. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles and features without departing from the present technology. In addition, those of ordinary skill in the art will appreciate that further

embodiments of the present technology can be practiced without several of the details described below.

[0026] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," etc., are not meant to limit the referenced component to 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.

[0027] Figures 1A and 1B are an isometric view and a partially-exploded isometric view, respectively, of a suture tensioning device 100 in accordance with embodiments of the present technology. Referring to Figures 1A and 1B together, the suture tensioning device 100 can include a tensioning assembly 102 (shown exploded in Figure 1B) configured to be coupled to a dressing assembly 104 via a pad 106. The dressing assembly 104 is configured to be positioned over an incision or puncture in a patient (e.g., a human patient), such as a percutaneous access site, and can be adhered to the patient (e.g., the skin of the patient) around the puncture. The tensioning assembly 102 is configured to receive and tension one or more sutures used to close the puncture. Figures 1C and 1D are exploded top and bottom isometric views, respectively, of the tensioning assembly 102 in accordance with embodiments of the present technology. The pad 106 is shown as partially transparent in Figures 1A–1D for clarity. Figure 1E is an exploded isometric view of the dressing assembly 104 in accordance with embodiments of the present technology.

[0028] Referring first to Figure 1E, in some embodiments the dressing assembly 104 includes a contact layer 110 and an adhesive portion 112 over and/or integrated with the contact layer 110. The contact layer 110 and the adhesive portion 112 are shown as partially transparent in Figure 1E for the sake of clarity. In the illustrated embodiment, the dressing assembly 104 has a generally elongate, oval-like shape while, in other embodiments, the dressing assembly 104 can have other shapes (e.g., rectangular, circular, rectilinear, polygonal, irregular). In some embodiments, the contact layer 110 includes and/or comprises an adhesive material (e.g., an acrylic and/or acrylate material) on its underside for releasably securing the dressing assembly 104 to a patient. In some embodiments, the contact layer 110 (e.g., an upper surface of the contact layer 110) can include a medical tape including, for example, a polyethylene material.

The adhesive portion 112 can comprise an acrylic, acrylate, or other suitable adhesive material. In the illustrated embodiment, the dressing assembly 104 includes a first removable protection layer 114a and a second removable protection layer 114b (collectively "protection layer 114") coupled to the contact layer 110 (e.g., a lower surface of the contact layer 110). The protection layer 114 can cover, seal, and/or protect the contact layer 110 and its adhesive before the dressing assembly 104 is used, and can be removed before placing the dressing assembly 104 on the patient. In some embodiments, the first removable protection layer 114a and the second removable protection layer 114b can be folded to facilitate their removal from the contact layer 110. In other embodiments, the dressing assembly 104 can include more or fewer layers and/or can include different materials. For example, the dressing assembly 104 can include multiple different layers laminated together.

[0029] In the illustrated embodiment, (i) the protection layer 114 includes/defines a first opening 111 (e.g., a through-hole or aperture formed between the first removable protection layer 114a and the second removable protection layer 114b), (ii) the contact layer 110 includes a second opening 113, and (iii) the adhesive portion 112 includes a third opening 115 (collectively "openings 111–115"). Referring to Figures 1A, 1B, and 1E together, the openings 111–115 are at least partially aligned to define a through-hole 118 extending entirely through the dressing assembly 104 between a first surface 117a (e.g., a lower surface) and a second surface 117b (e.g., an upper surface) thereof. The tensioning assembly 102 is configured to be secured to the adhesive portion 114 of the dressing assembly 104 over the through-hole 118. As described in greater detail below with reference to Figures 3–4B, one or more sutures can be threaded (e.g., routed, inserted) through the through-hole 118 to the tensioning assembly 102.

[0030] In operation of the suture tensioning device 100, the dressing assembly 104 can be placed against the skin of a patient with the protection layer 114 in place. After positioning the openings 111–115 over/at a desired location, such as an incision in the patient, an operator can peel back and remove the first removable protection layer 114a and the second removable protection layer 114a and then adhere the contact layer 110 to the patient.

[0031] Referring to Figures 1A–1D together, the tensioning assembly 102 can include an actuation member 120 movably (e.g., slidably) coupled to/within a housing 130 having a lower housing portion 132 and an upper housing portion 134. In the illustrated embodiment, the lower housing portion 132 and/or the upper housing portion 134 (e.g., either together or individually) define a channel 131 including a first biasing member mount 136a, a second biasing member

mount 136b, a first stop surface 138, and a second stop surface 139. The actuation member 120 can include (i) a press portion 122 extending at least partially outside the housing 130, (ii) an elongate portion 124 extending from the press portion 122 into the housing 130 past the second stop surface 139, and (iii) a flange or mount portion 126 extending from the elongate portion 124 and at least partially through the channel 131. A first biasing member 140a can be operably coupled between the first biasing member mount 136a and the mount portion 126 of the actuation member 120. Likewise, a second biasing member 140b can be operably coupled between the second biasing member mount 136b and the mount portion 126 of the actuation member 120.

[0032] The biasing members 140 are configured (e.g., shaped, sized, and/or positioned) to drive the actuation member 120 outward away from the first stop surface 138 in a direction indicated by arrow A in Figure 1A (e.g., in a horizontal or lateral direction). In some embodiments, the biasing members 140 are compression springs that extend through the channel 131 and that are directly attached to the biasing member mounts 136 and the mount portion 126 via an adhesive, fasteners (e.g., screws), welding, or another suitable attachment mechanism. In other embodiments, the tensioning assembly 102 can include more or fewer of the biasing members 140 (e.g., one, three, four or more) operably coupling the actuation member 120 to the housing 130. In some embodiments, the biasing members 140 can have a spring constant of between about 10–25 pounds per inch (e.g., between about 12–22 pounds per inch, between about 16–18 pounds per inch, about 17 pounds per inch, and so on).

[0033] In the illustrated embodiment, the lower housing portion 132 includes/defines a first through-hole 133 (Figure 1D), the elongate portion 124 of the actuation member 120 includes a second through-hole 123 (Figure 1C), and the upper housing portion 134 includes a third through-hole 137. The first through-hole 133 and the third through-hole 137 are at least partially aligned with one another (e.g., superimposed over one another) along an axis B shown in Figures 1C and 1D (e.g., a vertical axis).

[0034] The tensioning assembly 102 is in a first position (e.g., a lock position) in Figures 1A–1D in which the biasing members 140 bias the actuation member 120 outward in the direction of arrow A such that the mount portion 126 engages/contacts the second stop surface 139 of the lower housing portion 132. In the first position, the second through-hole 123 through the elongate portion 124 of the actuation member 120 is not aligned with the first and third through-holes 133, 137 of the housing 130. More specifically, the second through-hole 123 is positioned axially away from the axis B such that the second through-hole 123 is not

superimposed with the first and third through-holes 133, 137. In operation, the actuation member 120 can be actuated to move the tensioning assembly 102 from the first position to a second position (e.g., a release position; shown in Figure 4B) in which the second through-hole is aligned with the first and third through-holes 133, 137. More specifically, a user (e.g., a physician, nurse) can press the press portion 122 of the actuation member 120 to drive the actuation member 120 inward in the direction of arrow C shown in Figure 1B—against the biasing force of the biasing members 140—until the mount portion 126 engages the first stop surface 138 of the lower housing portion 132. In the second position, the second through-hole 123 is at least partially aligned with the first and third through-holes 133, 137 along the axis B. In some embodiments, the movement of the actuation member 120 in the direction of arrow C is generally orthogonal to the axis B.

[0035] Referring to Figures 1A–1E together, in some embodiments the pad 106 can be coupled to/between the lower housing portion 132 and the adhesive portion 114 of the dressing assembly 104 via an adhesive, fasteners, a snap-fit arrangement, and/or the like. In some embodiments, the pad 106 can be flexible and configured to conform to the skin of a patient during use of the suture tensioning device 100. For example, the pad 106 can be formed from a thermoplastic elastomer (TPE), rubber, silicone, and/or another flexible material. In some embodiments, the adhesive portion 114 of the dressing assembly 104, the pad 106, and the lower housing portion 132 of the housing 130 all have the same generally curved-rectangular planform shape. In other embodiments, the adhesive portion 114, the pad 106, and the lower housing portion 132 can have different shapes (e.g., rectangular, circular, rectilinear, polygonal, irregular) and/or different shapes than one another. In some embodiments, the pad 106 can be omitted and the lower housing portion 132 can be directly attached to the adhesive portion 114 of the dressing assembly 104.

[0036] In the illustrated embodiment, the pad 106 includes/defines a through-hole 108 that is aligned along the axis B with (i) the with the first and third through-holes 133, 137 of the tensioning assembly 102 and (ii) the through-hole 118 of the dressing assembly 104. Accordingly, when the tensioning assembly 102 is in the second position with the actuation member 120 pressed inward toward the housing 130, each of the through-holes 108, 118, 123, 133, and 137 are at least partially aligned to define a continuous path through the suture tensioning device 100 for receiving one or more sutures.

[0037] Figure 2 is an isometric view of a threading tool 250 for use with the suture tensioning device 100 in accordance with embodiments of the present technology. The threading tool 250 can include an elongate portion 252 and a loop portion 254 enclosing/defining an opening 256. In some embodiments, the elongate portion 252 and the loop portion 254 can be formed from a flexible material, such as a nylon monofilament. In some embodiments, the elongate portion 252 can be more rigid than the loop portion 254. For example, the elongate portion 252 can be formed of a different, more rigid material than the loop portion 254 and/or can be made thicker than the loop portion 254. As described in detail below with reference to Figures 4A and 4B, the threading tool 250 can be inserted and pulled through the tensioning assembly 102 when the tensioning assembly 102 is in the second position to pull/thread one or more sutures positioned in the opening 256 through the tensioning assembly 102.

[0038] Figure 3 is a flow diagram of a process or method 360 for operating the suture tensioning device 100 in accordance with embodiments of the present technology. Although some features of the method 360 are described in the context of the embodiments shown in Figures 1A–2 for the sake of illustration, one skilled in the art will readily understand that the method 360 can be carried out using other suitable systems and/or devices described herein—for example, using any of the suture tensioning devices described below with reference to Figures 6–13B.

[0039] At block 361, the method 360 includes threading one or more sutures through the suture tensioning device 100. The sutures can be used to close a puncture in a patient. Figures 4A and 4B, for example, are isometric views of the suture tensioning device 100 illustrating threading of a suture 470 therethrough before the dressing assembly 104 has been attached to the skin in accordance with embodiments of the present technology. In some embodiments, the sutures 470 have a U.S.P. size of between about #4-0 to #2. Referring first to Figure 4A, a user can insert/loop the suture 470 (e.g., end portions 472 of the suture 470) through the opening 256 of the threading tool 250. With the tensioning assembly 102 in the second position, the user can then insert the elongate portion 252 of the threading tool 250 through the through-holes in the dressing assembly 104, the pad 106, and the tensioning assembly 102. For example, the user can depress the actuation member 120 to maintain the tensioning assembly 102 in the second position. Then, referring to Figure 4B, the user can pull the threading tool 250 entirely through the through-holes in the suture tensioning device 100 to pull the suture 470 therethrough. In other embodiments, the user can thread the suture 470 through the suture tensioning device 100 without using the threading tool 250.

[0040] In some embodiments, the suture 470 can be threaded/tied in a figure eight around the puncture. In some embodiments, the suture 470 is not knotted (e.g., in a surgeon's knot) before being threaded through the suture tensioning device 100. The puncture can be an access site into the body of the patient used to carry out a percutaneous medical procedure, such as an intravascular procedure that includes inserting a catheter or medical device into a blood vessel of the patient through the access site. The access site can be a popliteal access site, an internal jugular access site, a femoral access site, or another venous or arterial access site. In some embodiments, the access site can be relatively large, such as those needed to facilitate intravascular procedures utilizing large bore catheters. In some embodiments, the access site can be used to facilitate any of the clot removal procedures described in detail in (i) U.S. Patent No. 9,700,332, filed September 16, 2016, and titled "INTRAVASCULAR TREATMENT OF VASCULAR OCCLUSION AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS," (ii) U.S. Patent No. 10,098,651, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," and/or (iii) U.S. Patent Application No. 16/536,185, titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," filed August 8, 2019, each of which is incorporated herein by reference in its entirety.

[0041] At block 362, the method 360 includes coupling the suture tensioning device 100 to the patient. For example, the user can remove the protection layer 116 from the dressing assembly 104 and press the lower layer 110 of the dressing assembly 104 against the skin of the patient around the puncture to adhere the dressing assembly 104 to the patient over/around the puncture. In some embodiments, the dressing assembly 104 can be coupled to the patient before the suture 470 is threaded through the tensioning assembly 102 and/or before the tensioning assembly 102 is coupled to the dressing assembly 104.

[0042] At block 363, the method 360 includes adjusting the suture 470 to have a desired/selected tension. For example, the user can continue depressing the actuation member 120 to move the tensioning assembly 102 to the second position, and then pull the suture 470 until a desired tension is achieved. The tension can be sufficient to close the puncture in the patient and maintain hemostasis at the puncture.

[0043] At block 364, the method 360 includes locking the suture 470 in the suture tensioning device 100 to maintain the desired tension in the suture 470. For example, after pulling the suture 470 to have the desired tension, the user can simply release the actuation

member 120 to allow the actuation member 120 to return to the first position from the second position, thereby preventing the suture 470 from moving within the tensioning assembly 102. More specifically, Figure 5 is an enlarged side cross-sectional view of the suture 470 positioned within the tensioning assembly 102 with the actuation member 120 in the first position in accordance with embodiments of the present technology.

[0044] Referring to Figures 1A–D and 5 together, releasing the actuation member 120 allows the biasing members 140 to drive the actuation member 120 away from the first stop surface 138 toward and/or into engagement with the second stop surface 139, thereby moving the second through-hole 123 out of alignment with the first and third through-holes 133, 137. As the actuation member 120 moves to the first position, a perimeter or edge 527 of the second through-hole 123 engages the suture 470 and pulls the suture 470 through the channel 131 within the housing 130 in the direction of the arrow A (Figure 1A). Thus, as shown in Figure 5, the suture 470 traverses through the tensioning assembly 102 along a serpentine path, and the friction/engagement between the suture 470 and the actuation member 120 and the housing 130 can lock/clamp the suture 470 in position—inhibiting or even preventing movement of the suture 470 through the housing 130. That is, the tensioning assembly 102 cinches the suture 470 in the first position to inhibit movement of the suture 470 therethrough.

[0045] At block 365, the method 360 optionally includes adjusting the tension of the suture 470. To adjust the tension, the user can depress the actuation member 120 to move the actuation member 120 against the biasing force of the biasing members 140 to the second position, and then advance or retract the suture 470 through the tensioning assembly 102 to decrease or increase the tension, respectively. For example, the user may wish to increase the tension of the suture 470 to increase the constriction force on the puncture to facilitate hemostasis. Conversely, the user may wish to decrease the tension of the suture 470 to accommodate the comfort of the patient. Accordingly, in one aspect of the present technology the suture tensioning device 100 permits the tension in the suture 470 to be simply adjusted by depressing/releasing the actuation member 120 and without disturbing the dressing assembly 104. In contrast, conventional techniques for closing punctures include knotting a suture used to close the puncture to maintain tension in the suture. However, knots prevent the tension in the suture from being easily adjusted—as the knot must be undone and then retied to adjust the tension.

[0046] At block 366, the method 360 includes removing the suture 470 from the suture tensioning device 100 and removing the suture tensioning device 100 from the patient. For

example, the user can depress the actuation member 120 to move the actuation member 120 to the second position, and then pull the tensioning assembly 102 and/or the dressing assembly 104 away from the patient to remove the suture 470 therefrom. In some embodiments, the tensioning assembly 102 can be decoupled from the dressing assembly 104 and removed from over the suture 470 while the dressing assembly 104 remains on the patient.

[0047] Figures 6–13B illustrate additional embodiments of suture tensioning devices and tensioning assemblies in accordance with the present technology. The suture tensioning devices described with reference to Figures 6–13B can include several features generally similar or identical to the features of one another and/or the features of the suture tensioning device 100 described in detail with reference to Figures 1A–5, and can be operated in and function in a generally similar or identical manner. Accordingly, the description of Figures 6–13B emphasizes the unique features of the various embodiments. However, one skilled in the art will appreciate that the various embodiments can be combined and/or modified. For example, each of the tensioning assemblies described with reference to Figures 6–13B can be coupled to a dressing assembly (e.g., the dressing assembly 104) and/or a flexible pad (e.g., the pad 106), even if not expressly shown.

[0048] Figure 6 is an exploded isometric view of a tensioning assembly 602 in accordance with additional embodiments of the present technology. In the illustrated embodiment, the tensioning assembly 602 includes an actuation member 620 operably coupled to a housing or base 630 via a first biasing member 640a and a second biasing member 640b. More specifically, the first biasing member 640a can be coupled in/between a first biasing member mount 629a on the actuation member 620 and a first channel 636a formed in the base 630. Similarly, the second biasing member 640b can be coupled in/between a second biasing member mount 629b on the actuation member 620 and a second channel 636b formed in the base 630. The base 630 can include a channel 631 configured to slidably receive an elongate portion 624 of the actuation member 620. The base 630 can further include a first through-hole 633 and a second through-hole 637 extending at least partially therethrough and providing access to the channel 631. The first and second through-holes 633, 637 can be at least partially aligned with one another (e.g., along an axis extending therethrough). The elongate portion 624 of the actuation member 620 can include a third through-hole 623.

[0049] The biasing members 640 are configured to bias the actuation member 620 away from the base 630 to a first position in which the third through-hole is not aligned with (e.g., is

offset from) the first and second through-holes 633, 637. A user can depress the actuation member 620 toward the base 630 against the biasing force of the biasing members 640 to drive the elongate portion 624 of the actuation member 620 through the channel 631 such that the third through-hole 623 is aligned with the first and second through-holes 633, 637. Accordingly, in operation the user can insert one or more sutures through the through-holes 623, 633, 637 when the tensioning assembly 602 is in the second position, and can then release the actuation member 620 to allow the tensioning assembly 602 to return to the first position. In the first position, the actuation member 620 and the base 630 can cinch the sutures (e.g., in the manner described with respect to Figure 5) to inhibit movement of the sutures through the tensioning assembly 602.

[0050] Figures 7A and 7B are an exploded isometric view and an isometric view, respectively, of a suture tensioning device 700 in accordance with additional embodiments of the present technology. Referring to Figures 7A and 7B together, the suture tensioning device 700 can include a tensioning assembly 702, a dressing assembly 704, and a pad 706 (e.g., a flexible pad). The pad 706 defines a through-hole 708 and is configured (e.g., sized and shaped) to be positioned in an aperture 719 in the dressing assembly 704. For example, the pad 706 can be directly coupled to the skin of a patient through the aperture 719.

[0051] In the illustrated embodiment, the tensioning assembly 702 includes a base portion 780 including/defining a channel 781 and configured to be positioned in the through-hole 708 of the pad 706. In other embodiments, the base portion 780 can be coupled to the pad 706 over the through-hole 708. The tensioning assembly 702 further includes a body portion 782 coupled to the base portion 780. The body portion 782 defines a channel 783 that is accessible via a pair of first through-holes 784 (a lower one of the first through-holes 784 is obscured in Figures 7A and 7B). The tensioning assembly 702 can further include an actuation member 786 having an elongate portion 785 rotatably positioned within the channel 783. The elongate portion 785 includes a second through-hole 787. The channel 781 of the base portion 780 and the first through-holes 784 of the body portion 782 are at least partially aligned along an axis extending therethrough. The actuation member 786 is rotatable to rotate the second through-hole 787 of the elongate portion 785 into and out of alignment with the first through-holes 784 and the channel 781.

[0052] In operation, a user can rotate the actuation member 786 such that the second through-hole 787 is aligned with the channel 781 and the first through-holes 784, and then thread one or more sutures through the channel 781, the lower one of the first through-holes 784, the

second through-hole 787, and the upper one of the first through-holes 784. Once the one or more sutures are threaded through the tensioning assembly 702, the actuation member 786 can be rotated to cinch the sutures to inhibit movement of the sutures through the tensioning assembly 702. In some embodiments, the sutures can be wound around the elongate portion 785 of the actuation member 786 to cinch the sutures via the friction between the sutures and the outer surface of the elongate portion 785. In some embodiments, the actuation member 786 can be rotated in a first direction (e.g., clockwise) to increase the tension in the sutures, and in a second direction (e.g., counterclockwise) to decrease the tension in the sutures. Accordingly, in one aspect of the technology the tensioning assembly 702 is actuatable to increase/decrease the tension in the sutures without requiring a user to manually pull/release the sutures through the tensioning assembly 702.

[0053] Figure 8 is an exploded isometric view of a tensioning assembly 802 in accordance with additional embodiments of the present technology. In the illustrated embodiment, the tensioning assembly 802 includes an actuation member 890 (e.g., a lever arm) rotatably coupled to a housing 892. More specifically, the housing 892 can include a base 893 and a sidewall 894 projecting from the base 893, and the actuation member 890 can be an elongate member extending through and supported by the sidewall 894 (e.g., extending through a pair of openings therein). The base 893 can include/define a first through-hole 895, and the actuation member 890 can include a second through-hole 896. In some embodiments, the tensioning assembly 802 can further include a cap 898 having a third through-hole 899 and configured to be coupled to the housing 892 opposite the base 893. When the cap 898 is coupled to the housing 892, the first and third through-holes 895, 899 can be at least partially aligned with one another. The actuation member 890 is rotatable to rotate the second through-hole 896 into and out of alignment with the first and third through-holes 895, 899.

[0054] In operation, a user can rotate the actuation member 890 such that the second through-hole 896 is aligned with the first and third through-holes 895, 899, and then thread one or more sutures through each of the through-holes. Once the one or more sutures are threaded through the tensioning assembly 802, the actuation member 890 can be rotated to wind the sutures around the actuation member 890 to cinch the sutures via the friction between the sutures and the outer surface of the actuation member 890. In some embodiments, the actuation member 890 can be rotated in a first direction (e.g., clockwise) to increase the tension in the sutures, and in a second direction (e.g., counterclockwise) to decrease the tension in the sutures. Accordingly, in one aspect of the technology the tensioning assembly 802 is actuatable to increase/decrease

the tension in the sutures without requiring a user to manually pull/release the sutures through the tensioning assembly 802.

[0055] Figure 9 is an exploded isometric view of a suture tensioning device 900 in accordance with additional embodiments of the present technology. In the illustrated embodiment, the suture tensioning device 900 includes a tensioning assembly 902 configured to be coupled to a dressing assembly 904. The dressing assembly 904 defines a through-hole 918 and can be applied to a patient over and/or proximate to a puncture in the skin of the patient. The tensioning assembly 902 includes a base portion 980 and a cap or lid portion 982 configured to releasably mate with and engage the base portion 980. More specifically, the base portion 980 can include/define an annular groove 983 configured (e.g., shaped, sized, and/or positioned) to receive a flange portion 986 of the lid portion 982. The lid portion 982 can be rotated by a user to rotate the flange portion 986 through the groove 983. In some embodiments, the lid portion 982 further includes a projection 987 extending radially outward from the flange portion 986 and configured to be positioned in a track 988 formed in the base portion 980 (e.g., in a sidewall of the base portion 980). Rotation of the lid portion 982 can bring the projection 987 into contact with end portions of the track 988, thereby limiting the rotation of the lid portion 982. That is, the track 988 can extend only partially around the base portion 980 such that the lid portion 982 is rotatable through an angle less than 360 degrees. In the illustrated embodiment, the base portion 980 includes a first through-hole 990 and the lid portion 982 includes a second through-hole 992 that can be rotated into and out of alignment with the first through-hole 990.

[0056] In operation, a user can rotate the lid portion 982 such that the second through-hole 992 is aligned with the first through-hole 990, and then thread one or more sutures through the through-hole 918 in the dressing assembly 904 and the first and second through-holes 992, 994. Once the one or more sutures are threaded through the tensioning assembly 902, the lid portion 982 can be rotated to cinch the sutures in the groove 983 between the flange portion 986 and the base portion 980 to inhibit movement of the sutures through the tensioning assembly 902. In some embodiments, the lid portion 982 can be rotated in a first direction (e.g., clockwise) to increase the tension in the sutures, and in a second direction (e.g., counterclockwise) to decrease the tension in the sutures. Accordingly, in one aspect of the technology the tensioning assembly 902 is actuatable to increase/decrease the tension in the sutures without requiring a user to manually pull/release the sutures through the tensioning assembly 902.

[0057] Figures 10A and 10B are isometric views of a tensioning assembly 1002 in a first position and a second position, respectively, in accordance with additional embodiments of the present technology. Referring to Figures 10A and 10B together, the tensioning assembly 1002 includes (i) a base 1080 defining a recess 1081 and (ii) a compressible member 1082 configured (e.g., shaped and sized) to be inserted into the recess 1081. In some embodiments, the compressible member 1082 can be formed from a material having a softer durometer than the base 1080. Accordingly, the compressible member 1082 can be pushed into the recess 1081 and snugly secured therein via a friction-fit or snap-fit arrangement. In the illustrated embodiment, the base 1080 defines a first through-hole 1084 and the compressible member 1082 defines a second through-hole 1086. In the first position, when the compressible member 1082 is positioned outside of the recess 1081, the second through-hole 1086 can have a first diameter D_1. In the second position, when the compressible member 1082 is compressed inside of the recess 1081, the second through-hole 1086 can have a second diameter D_2 that is smaller than the first diameter D_1. Moreover, the first and second through-holes 1084, 1086 can be at least generally aligned over one another in the second position.

[0058] In operation, a user can thread one or more sutures through the first and second through-holes 1084, 1086 when the tensioning assembly 1002 is in the first position. The user can then manually adjust the tension in the sutures before positioning (e.g., snapping) the compressible member 1082 into the recess 1081. The diameter D_2 of the second through-hole 1086 can be small enough that the compressible member 1082 cinches/grips the sutures in the second position to inhibit movement of the sutures through the tensioning assembly 1002. To adjust the tension in the sutures, the user can remove the compressible member 1082 from the recess 1081 and manually adjust the tension.

[0059] Figure 11 is an isometric view of a tensioning assembly 1102 in accordance with additional embodiments of the present technology. In the illustrated embodiment, the tensioning assembly 1102 includes a flexible tube 1180 and a clamp 1182 positioned around the flexible tube 1180. The flexible tube 1180 includes a first end portion 1183a, a second end portion 1183b, and a middle portion 1183c extending therebetween. The flexible tube 1180 can define a lumen 1185 extending between the first and second end portions 1183a, b. In some embodiments, a diameter of the lumen 1185 can vary. For example, in the illustrated embodiment the flexible tube 1180 is flared at the first and second end portions 1183a, b such that the diameter of the lumen 1185 is greater at and near the first and second end portions 1183a, b than at the middle portion 1183c. The clamp 1184 can include a first arm 1186a and a second

arm 1186b that are pivotally coupled together via, for example, a pin 1188. The clamp 1182 is in a first position in Figure 11 in which the arms 1186 are pivoted apart from each other. The arms 1186 can each include one or more mating/engagement features (not shown) such that the arms 1186 can be pivoted toward each other and coupled together in a second position (e.g., via a snap-fit arrangement). In the second position, the arms 1186 compress the flexible tube 1180. In the illustrated embodiment, the clamp 1182 is positioned around the middle portion 1183c of the flexible tube 1180. In some embodiments, the diameter of the flexible tube 1180 at the first and second end portions 1183a, b can be greater than a diameter of the clamp 1182 in the first position such that the clamp 1182 does not easily slide off the flexible tube 1180.

[0060] In operation, a user can thread one or more sutures through the lumen 1185 when the clamp 1182 is in the first position. The user can then manually adjust the tension in the sutures before moving the arms 1186 of the clamp 1182 to the second position to compress the flexible tube 1180 against/onto the sutures to cinch/grip the sutures to inhibit movement of the sutures through the tensioning assembly 1102. To adjust the tension in the sutures, the user can move the clamp 1182 to the first position illustrated in Figure 11 and manually adjust the tension.

[0061] Figure 12 is an exploded isometric view of a tensioning assembly 1202 in accordance with additional embodiments of the present technology. In the illustrated embodiment, the tensioning assembly 1202 includes a lower portion 1280, an upper portion 1282 coupled to the lower portion 1280 and defining a lumen 1283, and a flexible membrane 1284 positioned in the lumen 1283. The lower portion 1280 can include a first through-hole 1286, the flexible membrane 1284 can include a second through-hole 1288, and the upper portion 1282 can include a third through-hole (obscured in Figure 12). Each of the through-holes can be at least partially aligned with another. The upper portion 1282 can further include a port 1285 configured to operably/fluidly couple the flexible membrane 1284 with an external pressure source (e.g., a vacuum source such as a syringe). Applying negative pressure to the port 1285 can at least partially collapse the flexible membrane 1284.

[0062] Accordingly, in operation, a user can thread one or more sutures through the first through-hole 1286 in the lower portion 1280, the second through-hole 1288 in the flexible membrane 1284, and the third through-hole in the upper portion 1282 without applying negative pressure to the port 1285. The user can then manually adjust the tension in the sutures before applying negative pressure to the port 1285 to collapse the flexible membrane 1284 around the sutures to cinch/grip the sutures to inhibit movement of the sutures through the tensioning

assembly 1202. To adjust the tension in the sutures, the user can remove the negative pressure source and manually adjust the tension in the sutures.

[0063] Figures 13A and 13B are isometric views of a tensioning assembly 1302 in a first position and a second position, respectively, in accordance with additional embodiments of the present technology. Referring to Figures 13A and 13B together, the tensioning assembly 1302 includes an elongate flexible strap 1380 and a base 1390. In the illustrated embodiment, the base 1390 includes a first opening 1392 and a second opening 1394 extending therethrough between a first surface 1391 and a second surface 1393. The strap 1380 can include a tab portion 1382 and a ratchet surface 1384 including a plurality of ridges or ratchet portions 1386. In the illustrated embodiment, the strap 1380 is threaded through the first and second openings 1392, 1394 such that the ratchet surface 1384 faces radially-inward and the tab portion 1382 is positioned near and/or in the second opening 1394 and is accessible at the first surface 1391. In the first positioned shown in Figure 13A, the tab portion 1382 is separated from (e.g., disengaged from, decoupled from) the ratchet surface 1384. In the second position shown in Figure 13B, the tab portion 1382 engages the ratchet surface 1384.

[0064] In operation, with the tensioning assembly 1302 in the first position, a user can thread one or more sutures along the ratchet surface 1384 of the strap 1380 and through the first opening 1392 (e.g., in a direction from the first surface 1391 toward the second surface 1393). The user can then move the tensioning assembly 1302 to the second position by pressing the tab portion 1382 of the strap 1380 against the ratchet surface 1384 and the suture to secure the suture to the strap 1380 (e.g., against one or more of the ratchet portions 1386). In some embodiments, the user can then adjust the tensioning in the strap by pulling/pushing the strap 1380 through the base 1390, like a zip-tie, until a desired suture tension is reached. To remove the suture, the tensioning assembly 1302 can be returned to the first position and the suture removed from the first opening 1392.

[0065] In some embodiments, the tensioning assemblies described in detail herein can have other features and/or the features of the various embodiments can be combined. For example, any of the tensioning assemblies including a rotatable actuation member (e.g., the tensioning assembly 702, the tensioning assembly 802, the tensioning assembly 902, and so on) can utilize a slot rather than a hole for securing the suture to the actuation member. Specifically, for example, the elongate portion 785 of the actuation member 786 of the tensioning assembly 702 described in detail with respect to Figures 7A and 7B can include a slot extending at least

partially therethrough instead of the second through-hole 787. The slot can receive and secure the suture without requiring that the slot be fully aligned with the channel 781 of the base portion 780 or the first through-hole 784. Similarly, the second through-hole 896 of the actuation member 890 of the tensioning assembly 802 described in detail with respect to Figure 8 can be replaced with a slot, and so on. In some embodiments, the tensioning assemblies described in detail herein can have one or more locking features for inhibiting movement of the actuation members to, for example, maintain tension in a suture secured thereto/therein.

[0066] Several aspects of the present technology are set forth in the following examples:

1. 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, wherein the first through-hole and the second through-hole are configured to receive a suture therethrough, 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; 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.

2. The device of example 1, further comprising a flexible pad coupled to the housing.

3. The device of example 2 wherein the flexible pad is configured to be placed against skin of a patient and to conform to the skin of the patient.

4. The device of any one of examples 1–3 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.

5. The device of any one of examples 1–4 wherein the first through-hole and the second through-hole are axially offset in the first position, and wherein the first through-hole and the second through-hole are axially aligned in the second position.

6. The device of example 5 wherein the housing and actuator engage the suture in the first position to clamp the suture relative to the housing.

7. The device of any one of examples 1–6 wherein the first through-hole and the second through-hole are aligned along an axis in the second position, and wherein the actuator is movable from the first position to the second position in a direction generally orthogonal to the axis.

8. A suture tensioning device, comprising:

a housing having a first through-hole and a second through-hole, wherein the first and second through-holes are at least partially aligned along an axis;

an actuator slidably coupled to the housing, wherein the actuator includes a third through-hole; and

a biasing member operably coupled between the actuator and the housing, wherein the biasing member is configured to bias the actuator toward a first position in which the third through-hole is offset from the axis, and wherein the actuator is movable to a second position in which the third through-hole is at least partially aligned with the first and second through-holes along the axis.

9. The suture tensioning device of example 8 wherein the first, second, and third through-holes are configured to receive a suture therethrough, and wherein the actuator and the housing engage the suture when the actuator is in the first position to inhibit the suture from moving through the first, second, and third through-holes.

10. The suture tensioning device of example 8 or example 9 wherein the first, second, and third through-holes are configured to receive a suture therethrough, and wherein the actuator and the housing engage the suture when the actuator is in the first position to maintain a tension of the suture.

11. The suture tensioning device of any one of examples 8–10 wherein the biasing member is a first biasing member, wherein the suture tensioning device further comprises a second biasing member operably coupled between the actuator and the housing, and wherein the first and second biasing members are configured to bias the actuator to the first position.

12. The suture tensioning device of any one of examples 8–11, further comprising a flexible pad coupled to a lower portion of the housing, wherein the flexible pad includes a fourth through-hole aligned with the first and second through-holes along the axis, and wherein the flexible pad is configured to be placed against skin of a patient and to conform to the skin of the patient.

13. The suture tensioning device of any one of examples 8–12, further comprising a dressing assembly configured to be attached to skin of a patient around a puncture in the skin, wherein the housing is configured to be releasably coupled to the dressing assembly.

14. The suture tensioning device of any one of examples 8–14 wherein the actuator is movable from the first position to the second position in a direction generally orthogonal to the axis.

15. A method of tensioning a suture used to close a puncture in skin of a patient, the method comprising:

threading the suture through a suture tensioning device;

adjusting a tension of the suture to a desired tension; and

actuating the suture tensioning device to lock the suture in the suture tensioning device to maintain the desired tension.

16. The method of example 15 wherein actuating the suture tensioning device to lock the suture includes releasing an actuator of the suture tensioning device.

17. The method of example 16 wherein adjusting the tension of the suture includes pulling the suture while depressing the actuator.

18. The method of example 16 or example 17 wherein the method further comprises, after releasing the actuator to lock the suture, pulling the suture while depressing the actuator to adjust the tension in the suture from the desired tension to another desired tension.

19. The method of any one of examples 15–18 wherein the method further comprises adjusting the tension in the suture from the desired tension to another desired tension, wherein adjusting the tension in the suture to the other desired tension includes actuating the suture tensioning device to unlock the suture from the suture tensioning device.

20. The method of any one of examples 15–19 wherein the method further comprises positioning a flexible pad of the suture tensioning device against the skin of the patient.

[0067] 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.

[0068] 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.

[0069] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in

the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A 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, wherein the first through-hole and the second through-hole are configured to receive a suture therethrough, 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; 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.

2. The device of claim 1, further comprising a flexible pad coupled to the housing.

3. The device of claim 2 wherein the flexible pad is configured to be placed against skin of a patient and to conform to the skin of the patient.

4. The device of claim 1 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.

5. The device of claim 1 wherein the first through-hole and the second through-hole are axially offset in the first position, and wherein the first through-hole and the second through-hole are axially aligned in the second position.

6. 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.

7. The device of claim 1 wherein the first through-hole and the second through-hole are aligned along an axis in the second position, and wherein the actuator is movable from the first position to the second position in a direction generally orthogonal to the axis.

8. A suture tensioning device, comprising:

a housing having a first through-hole and a second through-hole, wherein the first and second through-holes are at least partially aligned along an axis;

an actuator slidably coupled to the housing, wherein the actuator includes a third through-hole; and

a biasing member operably coupled between the actuator and the housing, wherein the biasing member is configured to bias the actuator toward a first position in which the third through-hole is offset from the axis, and wherein the actuator is movable to a second position in which the third through-hole is at least partially aligned with the first and second through-holes along the axis.

9. The suture tensioning device of claim 8 wherein the first, second, and third through-holes are configured to receive a suture therethrough, and wherein the actuator and the housing engage the suture when the actuator is in the first position to inhibit the suture from moving through the first, second, and third through-holes.

10. The suture tensioning device of claim 8 wherein the first, second, and third through-holes are configured to receive a suture therethrough, and wherein the actuator and the housing engage the suture when the actuator is in the first position to maintain a tension of the suture.

11. The suture tensioning device of claim 8 wherein the biasing member is a first biasing member, wherein the suture tensioning device further comprises a second biasing member operably coupled between the actuator and the housing, and wherein the first and second biasing members are configured to bias the actuator to the first position.

12. The suture tensioning device of claim 8, further comprising a flexible pad coupled to a lower portion of the housing, wherein the flexible pad includes a fourth through-hole aligned

with the first and second through-holes along the axis, and wherein the flexible pad is configured to be placed against skin of a patient and to conform to the skin of the patient.

13. The suture tensioning device of claim 8, further comprising a dressing assembly configured to be attached to skin of a patient around a puncture in the skin, wherein the housing is configured to be releasably coupled to the dressing assembly.

14. The suture tensioning device of claim 8 wherein the actuator is movable from the first position to the second position in a direction generally orthogonal to the axis.

15. A method of tensioning a suture used to close a puncture in skin of a patient, the method comprising:

threading the suture through a suture tensioning device;

adjusting a tension of the suture to a desired tension; and

actuating the suture tensioning device to lock the suture in the suture tensioning device to maintain the desired tension.

16. The method of claim 15 wherein actuating the suture tensioning device to lock the suture includes releasing an actuator of the suture tensioning device.

17. The method of claim 16 wherein adjusting the tension of the suture includes pulling the suture while depressing the actuator.

18. The method of claim 16 wherein the method further comprises, after releasing the actuator to lock the suture, pulling the suture while depressing the actuator to adjust the tension in the suture from the desired tension to another desired tension.

19. The method of claim 15 wherein the method further comprises adjusting the tension in the suture from the desired tension to another desired tension, wherein adjusting the tension in the suture to the other desired tension includes actuating the suture tensioning device to unlock the suture from the suture tensioning device.

20. The method of claim 15 wherein the method further comprises positioning a flexible pad of the suture tensioning device against the skin of the patient.

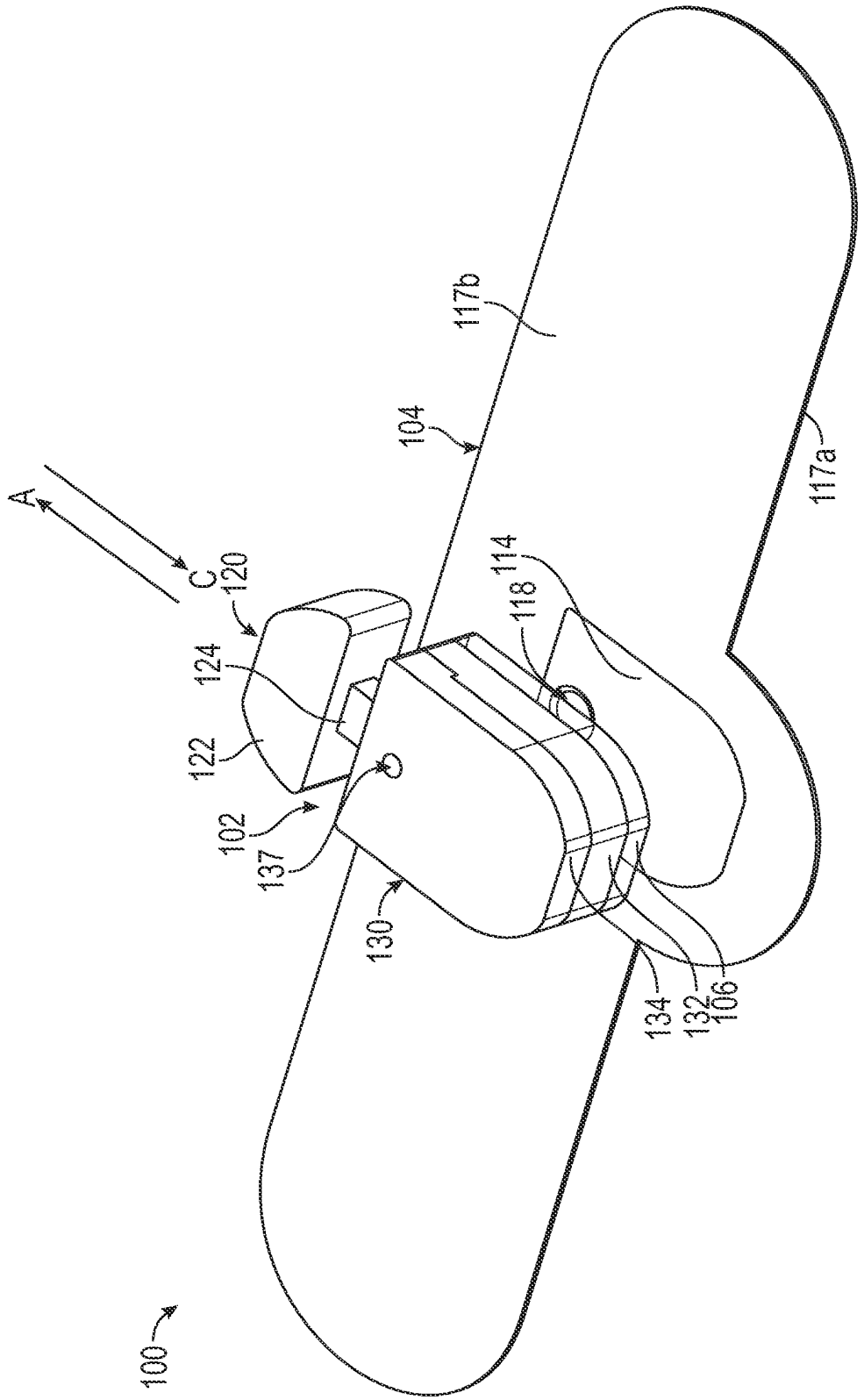


FIG. 1A

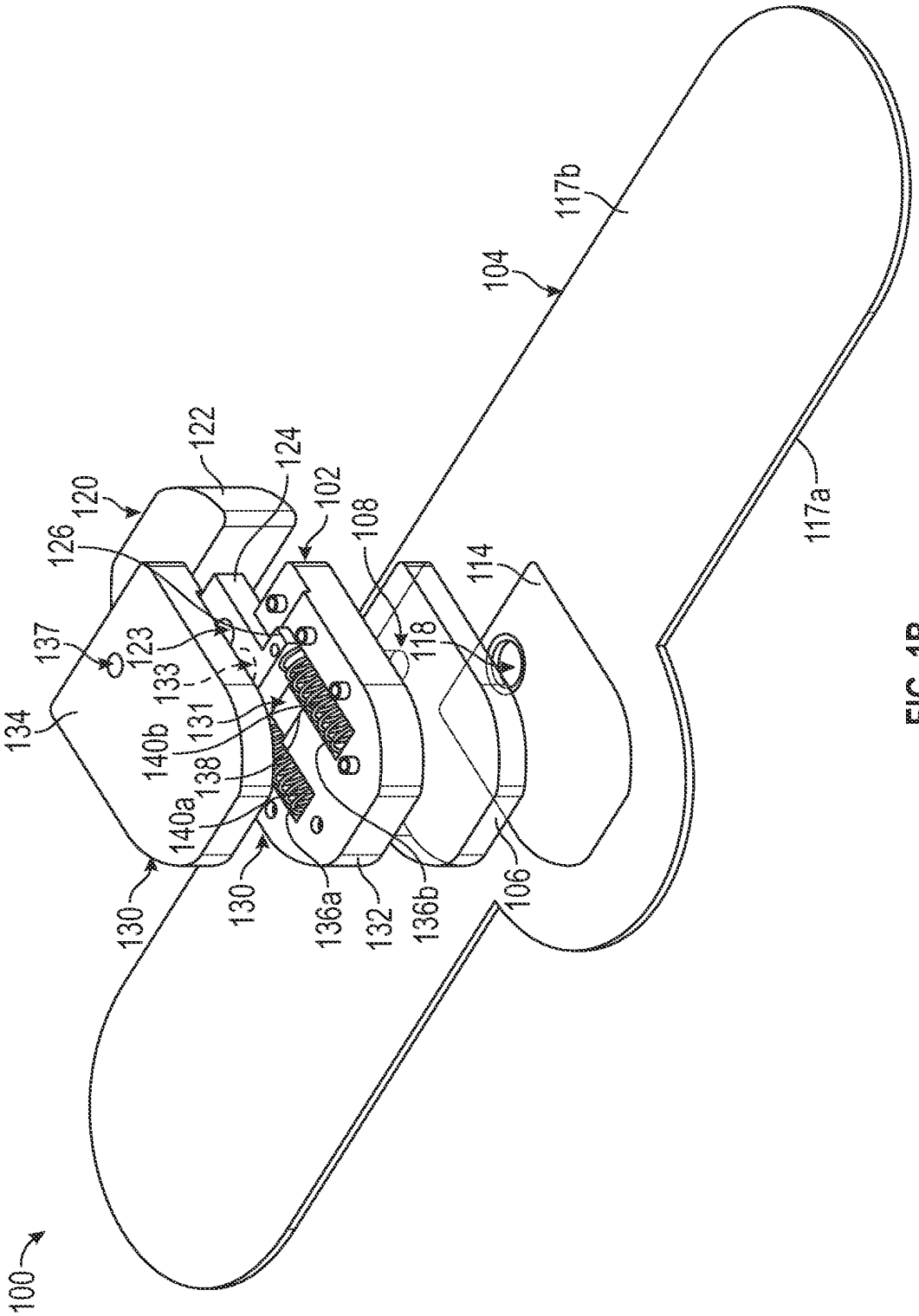

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136a
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136b
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FIG. 1B

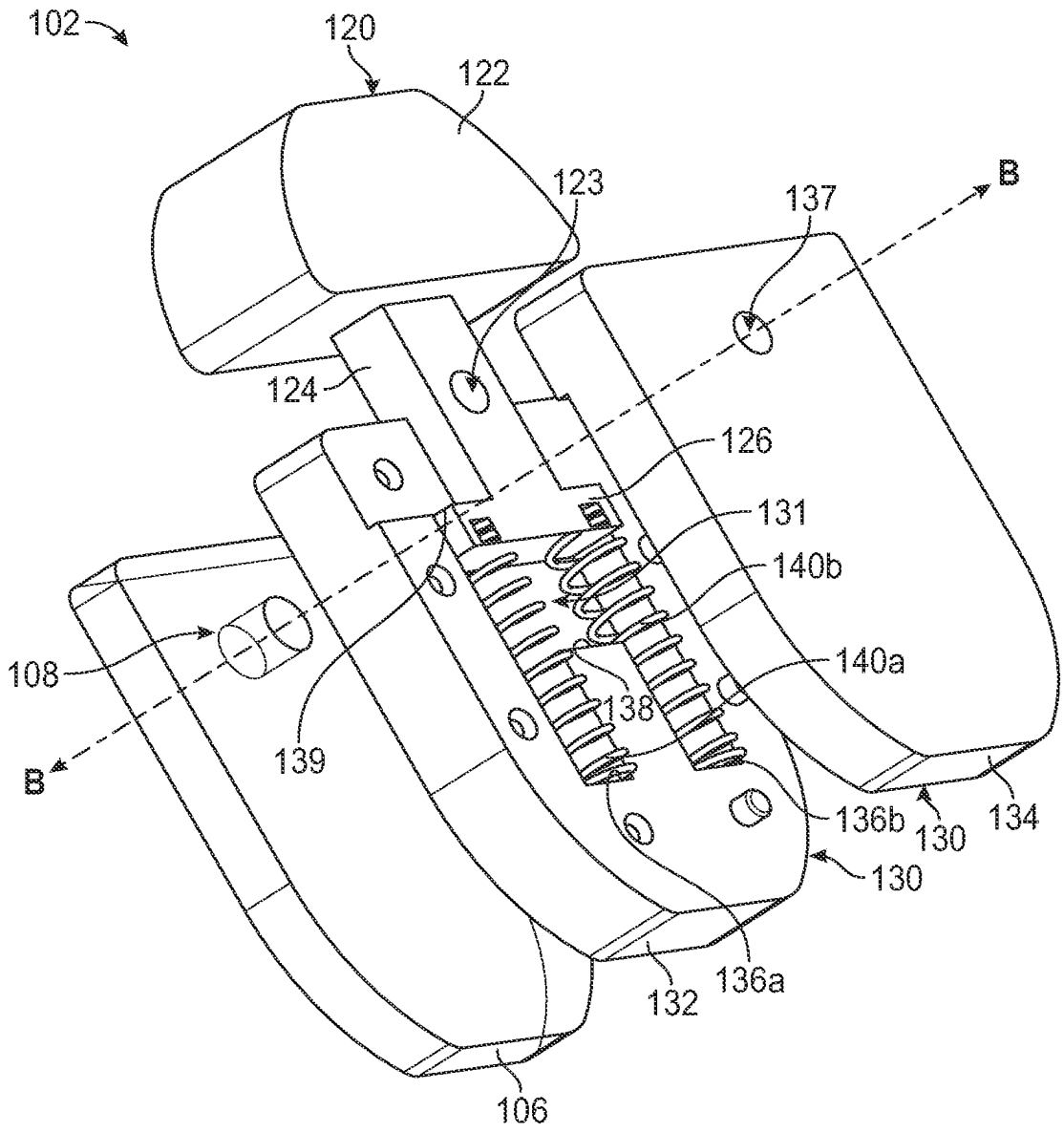

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136a
106

FIG. 1C

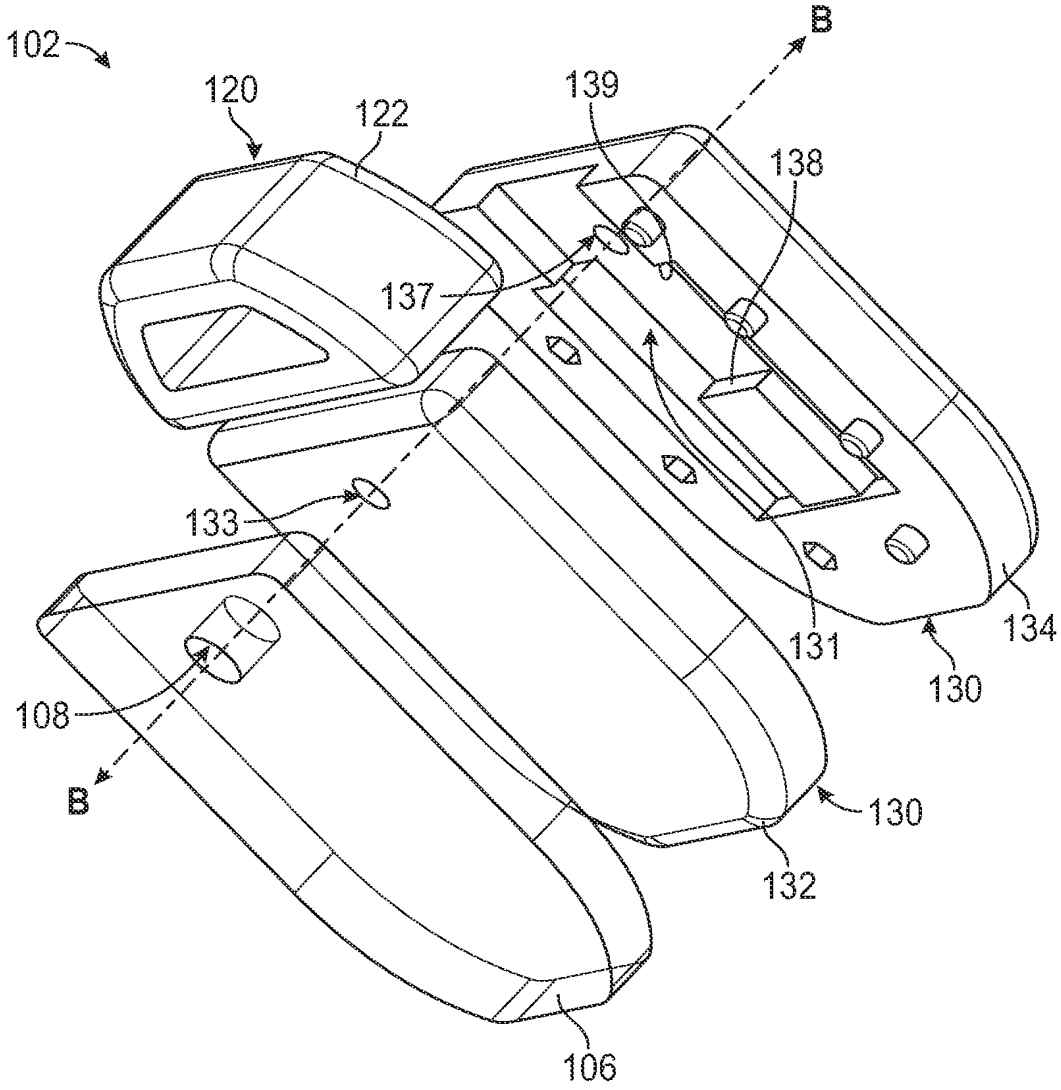


FIG. 1D

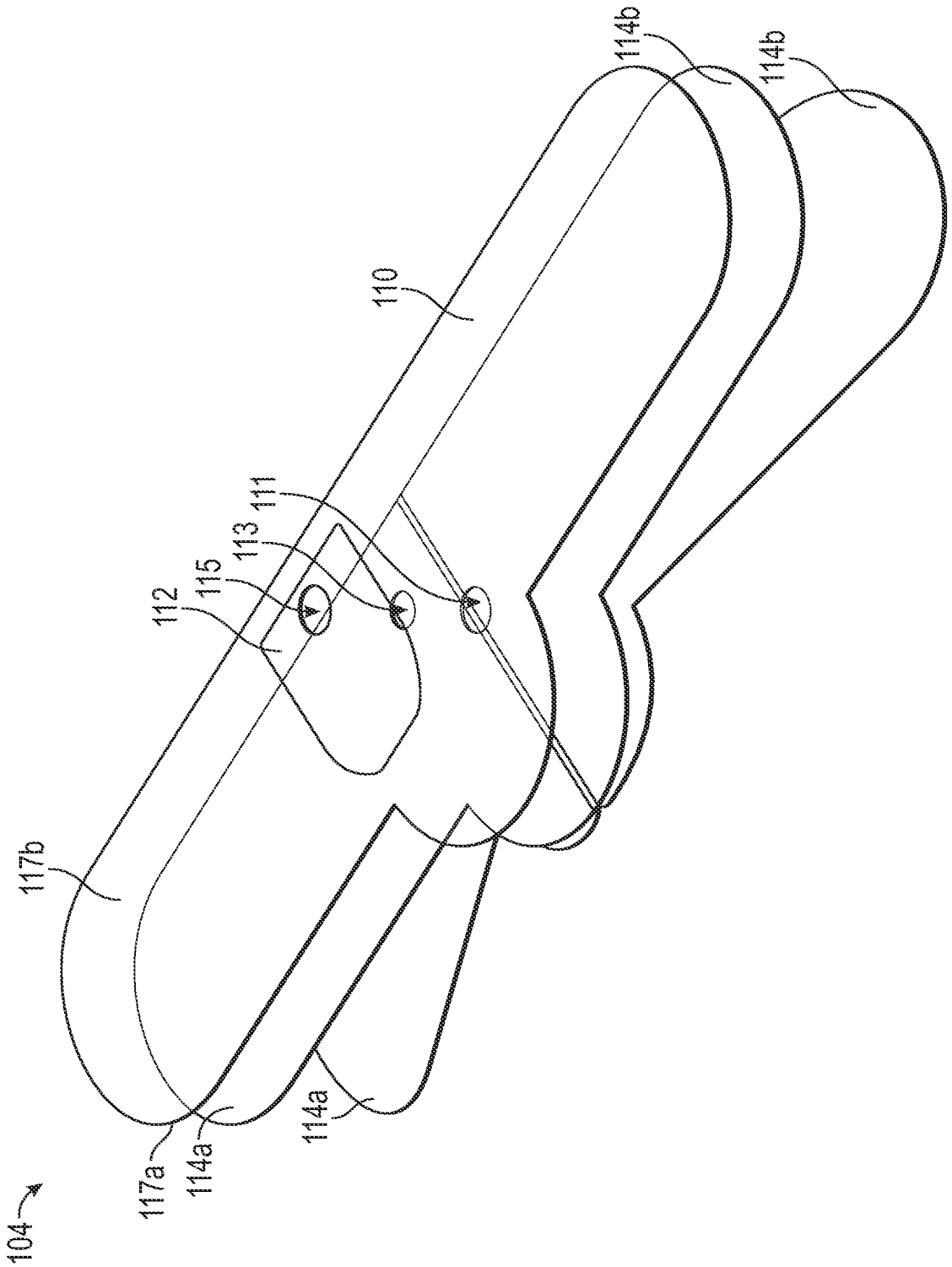


FIG. 1E

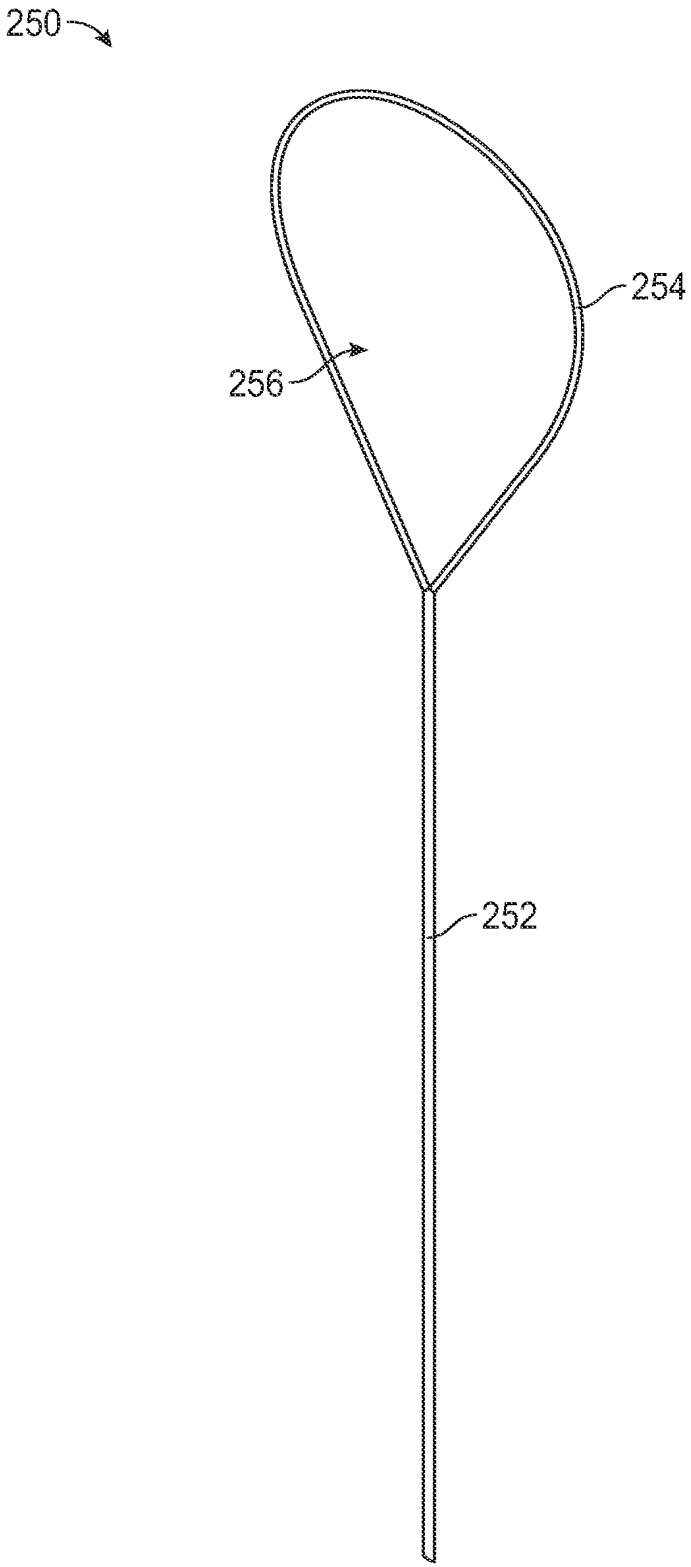


FIG. 2

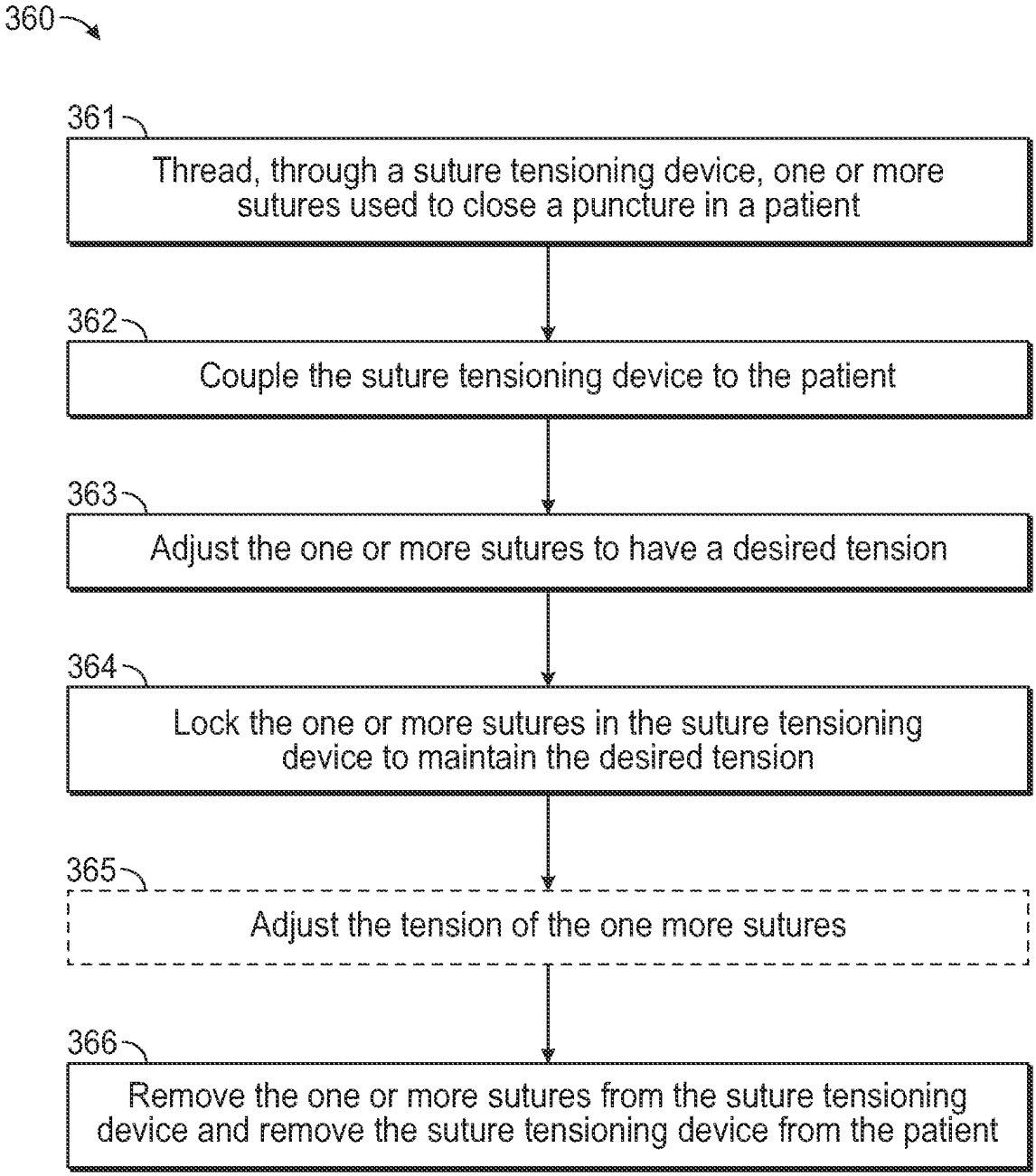

360
361
Thread, through a suture tensioning device, one or more sutures used to close a puncture in a patient
362
Couple the suture tensioning device to the patient
363
Adjust the one or more sutures to have a desired tension
364
Lock the one or more sutures in the suture tensioning device to maintain the desired tension
365
Adjust the tension of the one more sutures
366
Remove the one or more sutures from the suture tensioning device and remove the suture tensioning device from the patient

FIG. 3

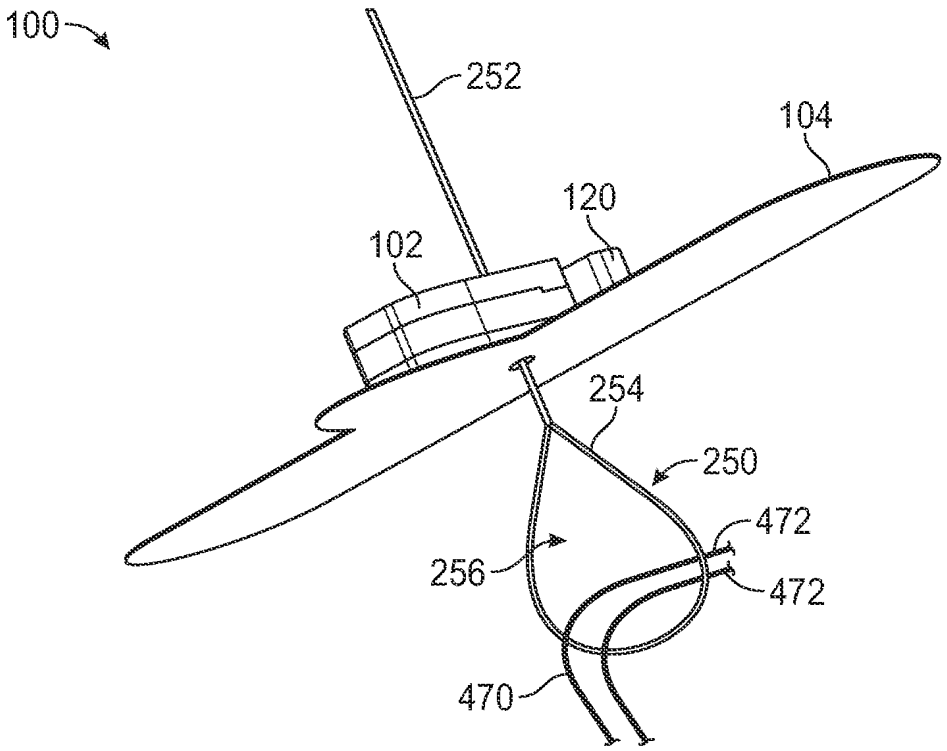

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FIG. 4A

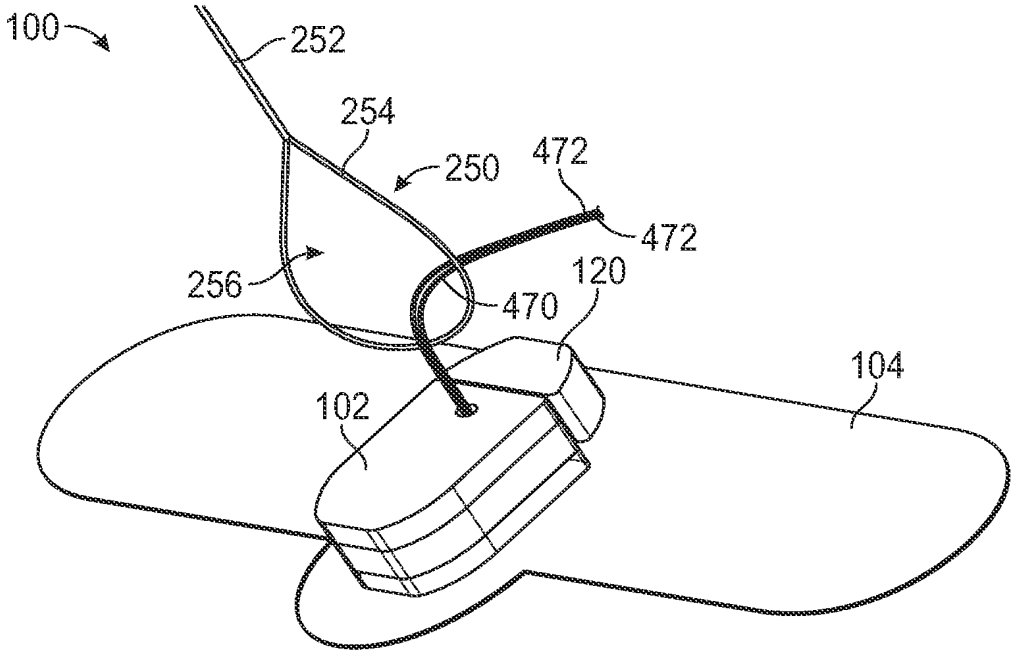

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FIG. 4B

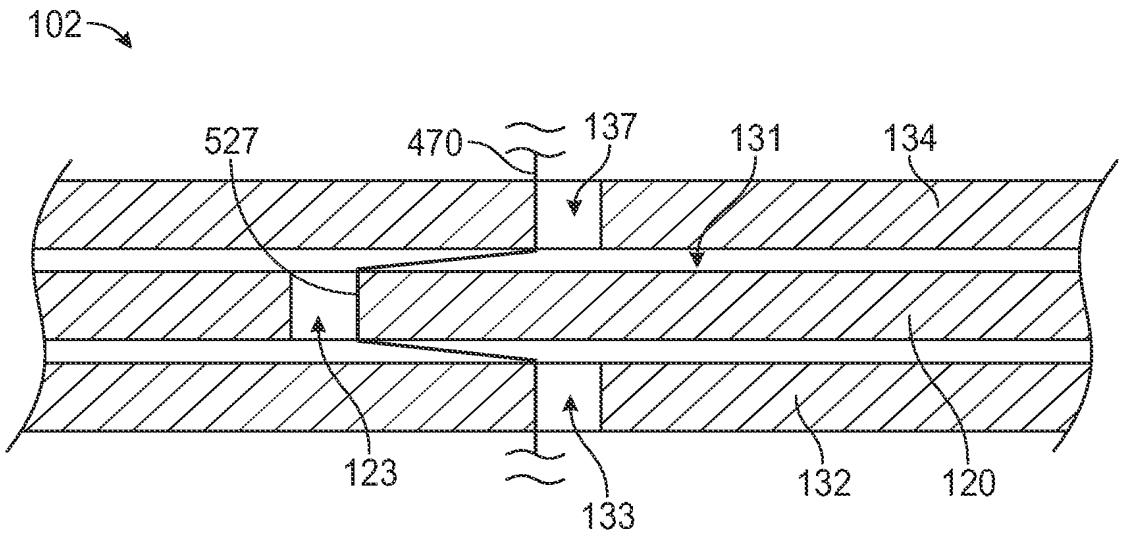

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FIG. 5

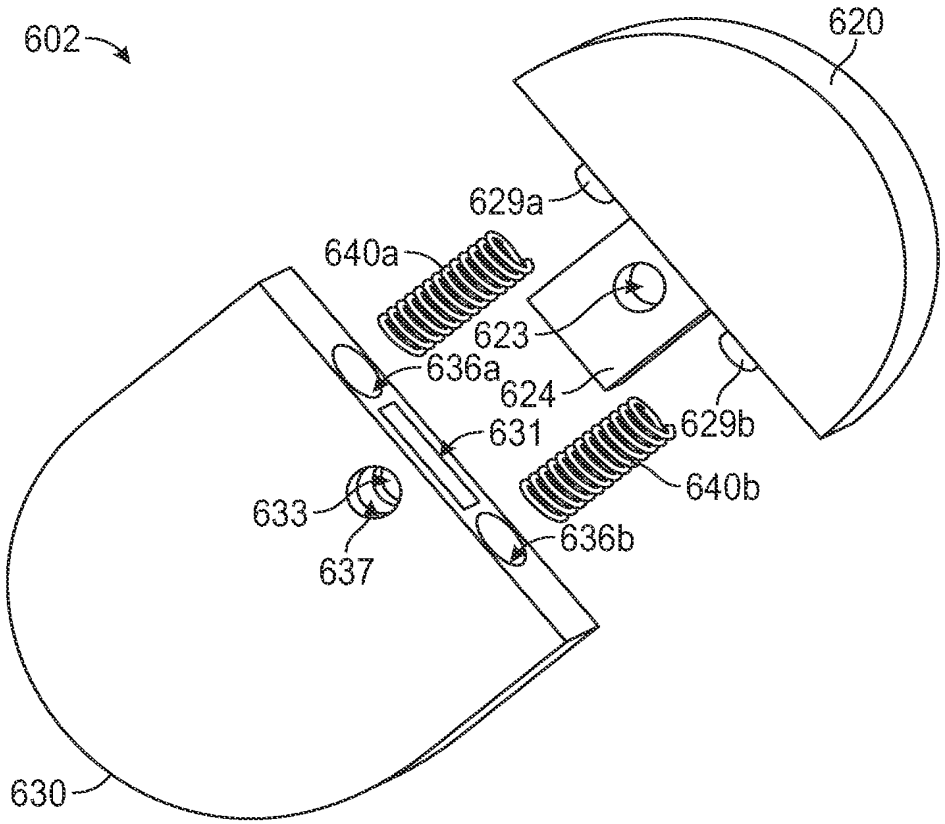

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629b
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637
636b
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FIG. 6

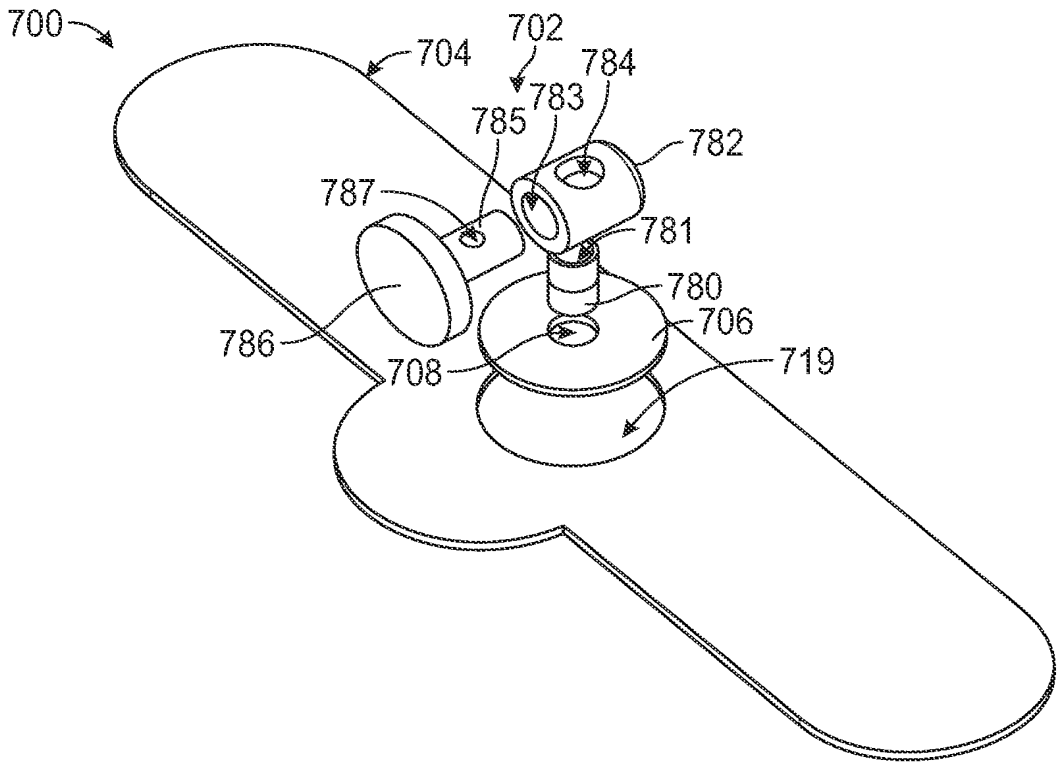

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FIG. 7A

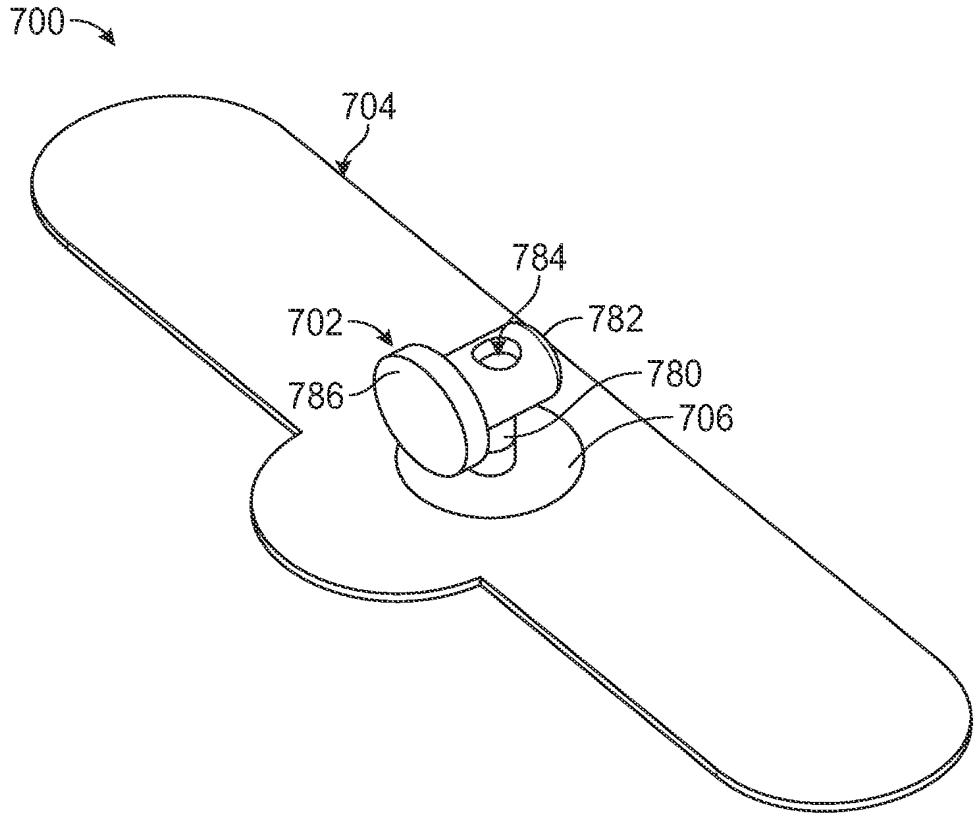

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FIG. 7B

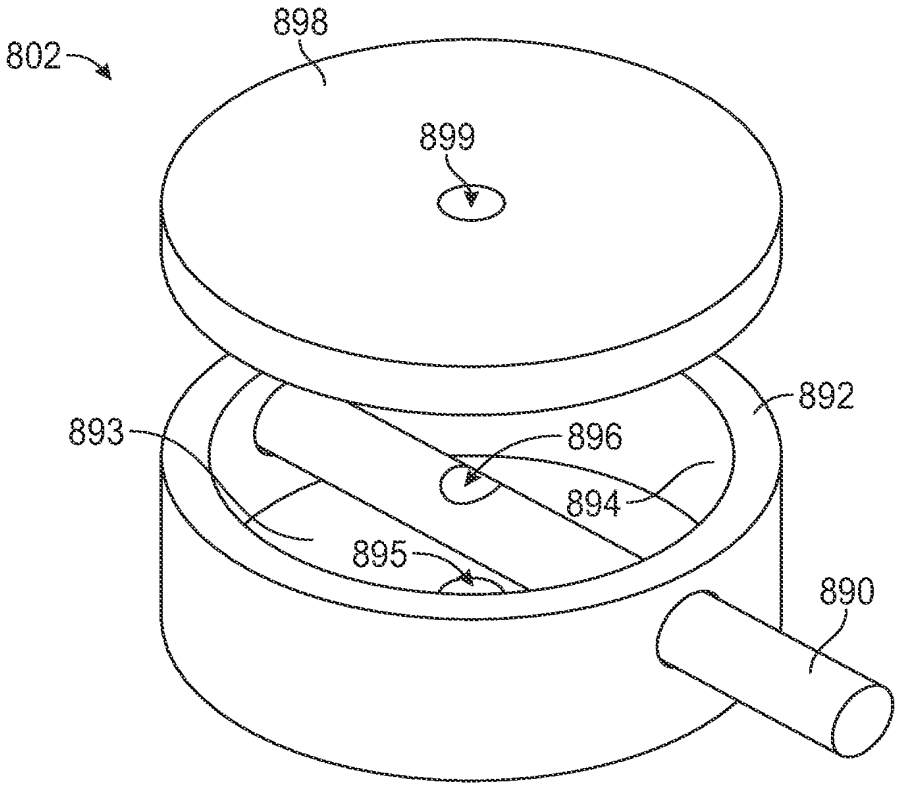

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FIG. 8

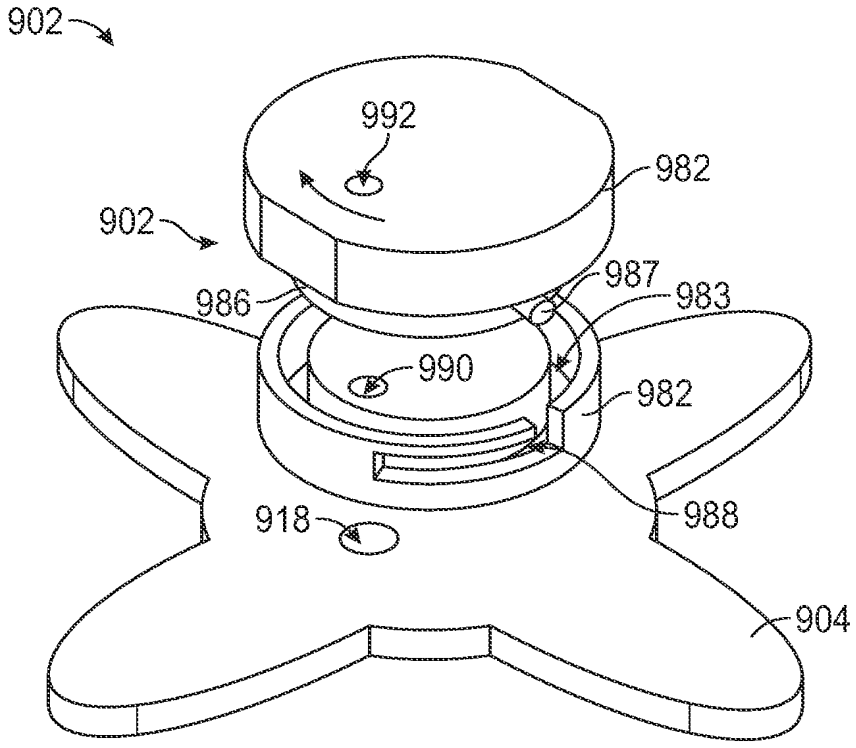

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FIG. 9

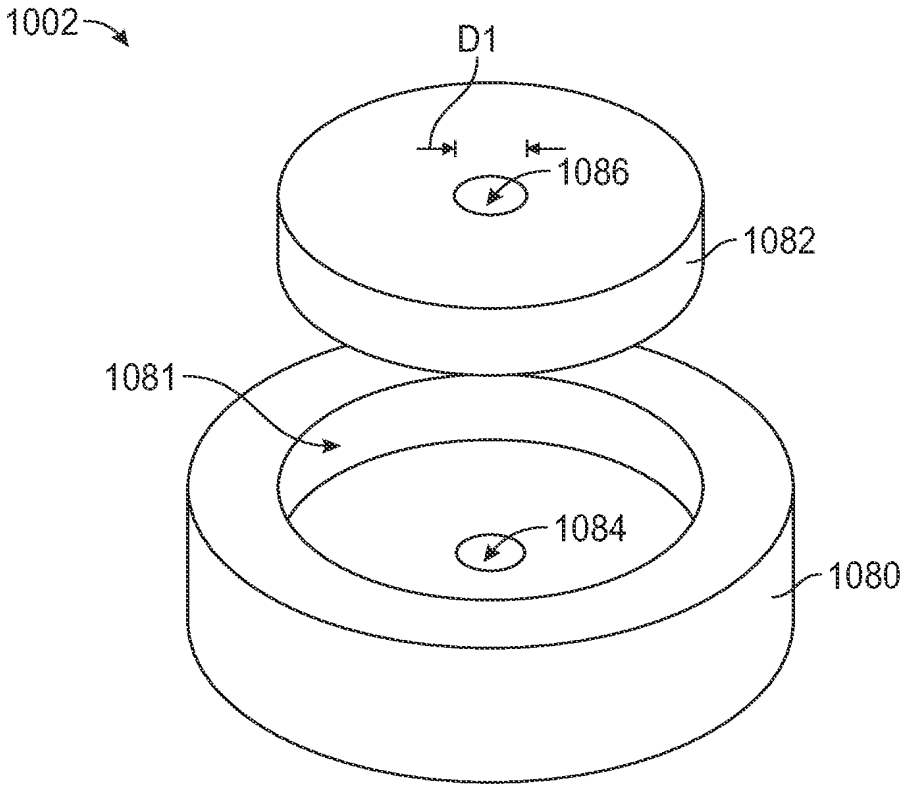


FIG. 10A

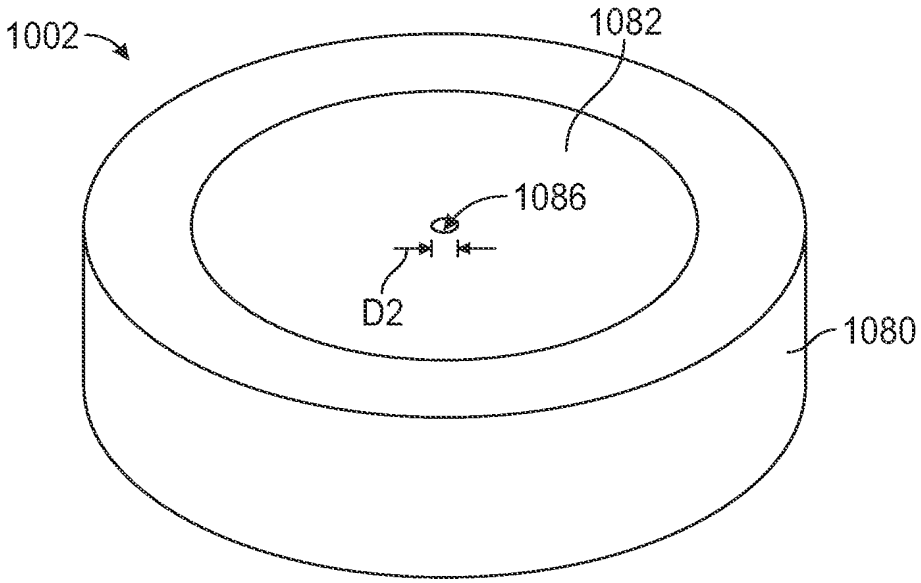


FIG. 10B

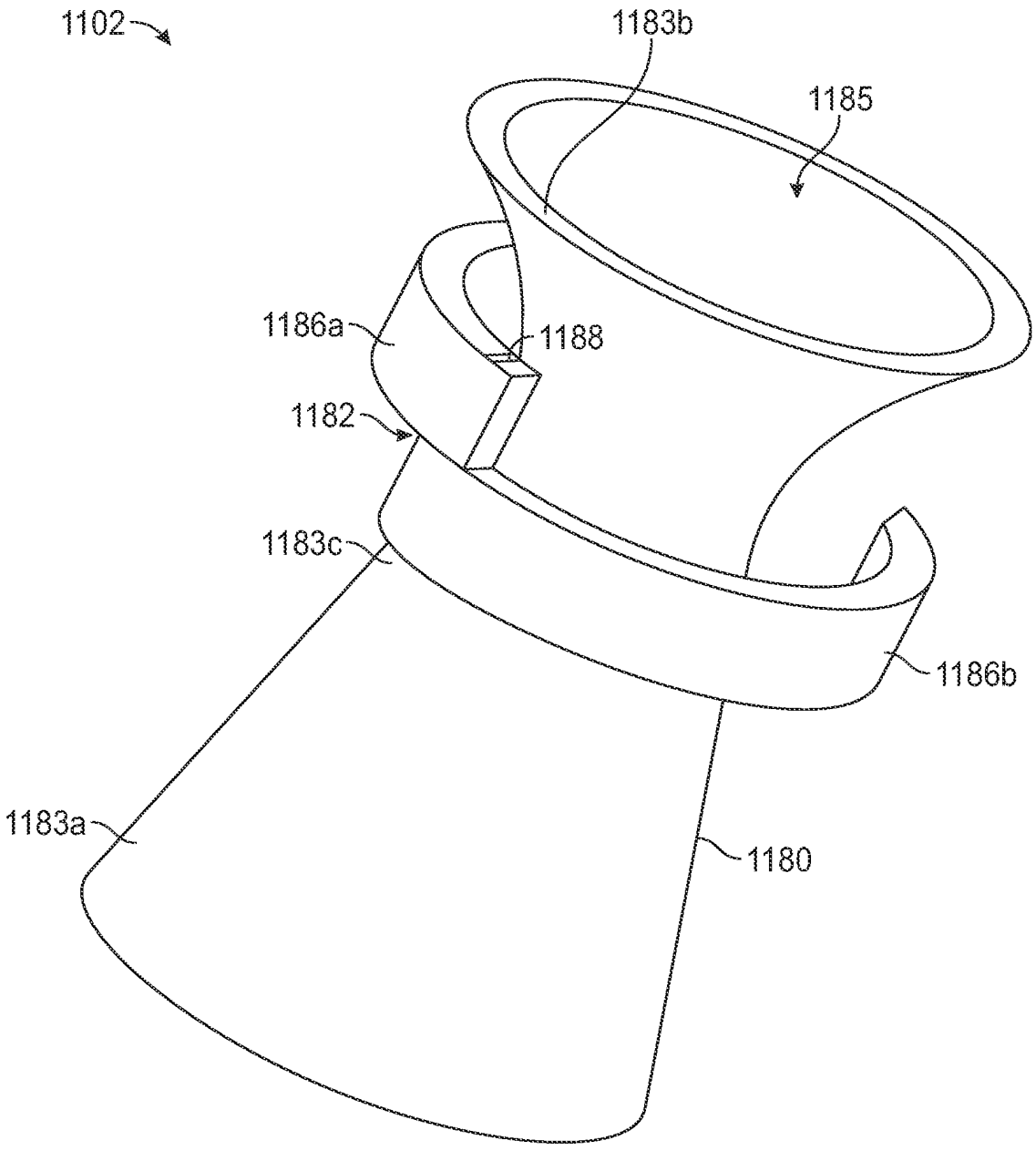


FIG. 11

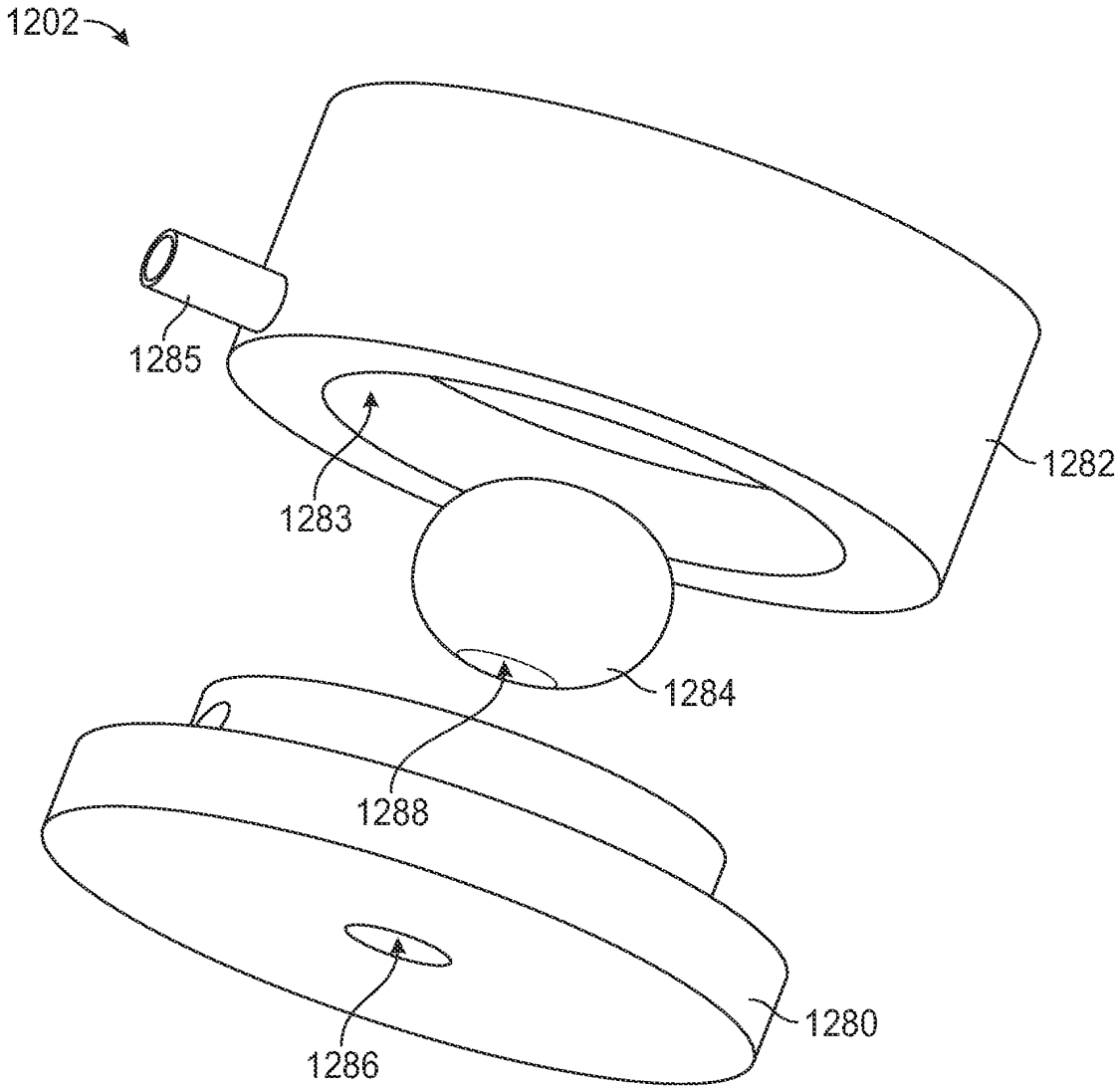


FIG. 12

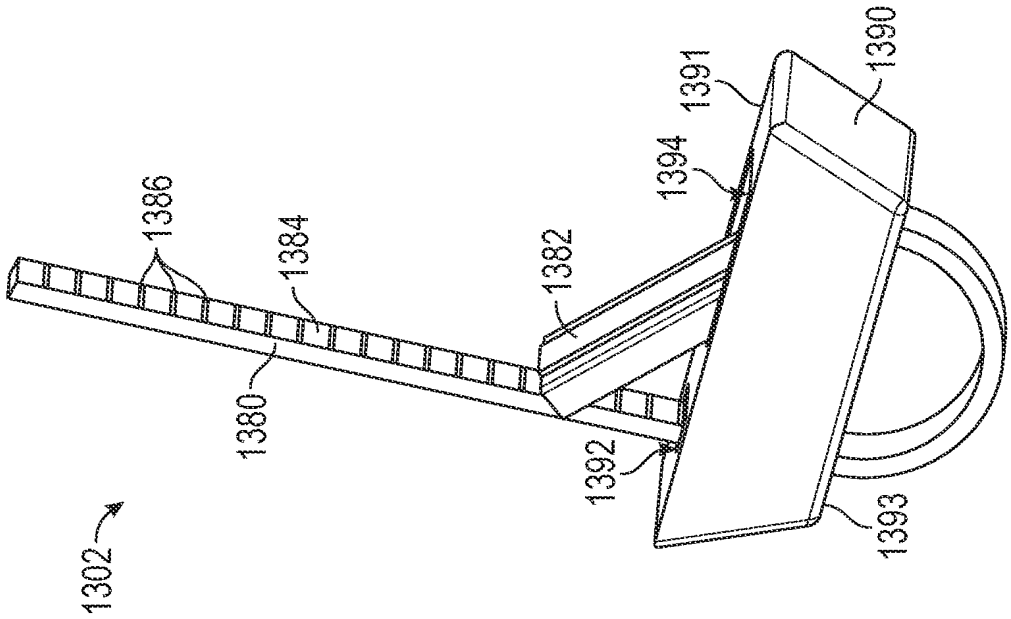


FIG. 13B

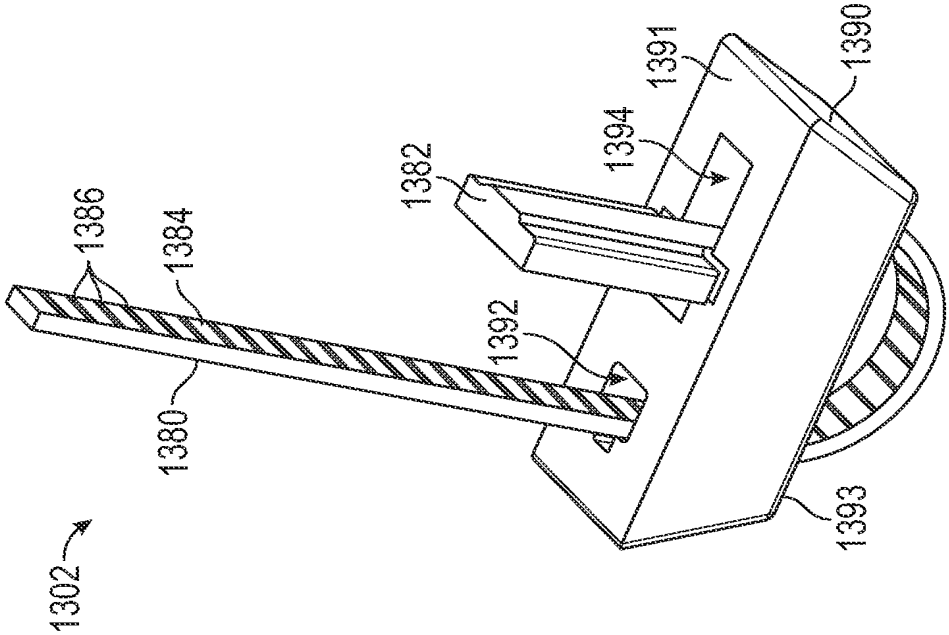


FIG. 13A

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

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

-*- 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

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PATENT DOCKETING

APR 21 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)

Applicant's or agent's file reference 111552-8020WO00	Date of mailing *(day/month/year)* APR 14 2021 **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US2020/065645	International filing date *(day/month/year)* 17 December 2020
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
   (Facsimile No.: +41 22 338 82 70)

   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, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/220 (revised January 2019)

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
111552-8020WO00		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/US2020/065645	17 December 2020	18 December 2019
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. 3A

   ☒ as suggested by the applicant.

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

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

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

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/065645

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

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

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

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

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

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

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

See extra sheet(s).

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

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

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

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

1-10

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/065645

A. CLASSIFICATION OF SUBJECT MATTER

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

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

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

see Search History document

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

see Search History document

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

see Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

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

* Special categories of cited documents:

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

"D" document cited by the applicant in the international application

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

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

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

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

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

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

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

"&" document member of the same patent family

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

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

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

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

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

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

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

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

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

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

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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

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APR 21 2021

PERKINS COIE LLP

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	APR 14 2021

Applicant's or agent's file reference	FOR FURTHER ACTION
111552-8020WO00	See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2020/065645	17 December 2020	18 December 2019

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

IPC(8) - A61B 17/221; A61B 17/22; A61B 17/3207; A61B 17/34; A61F 2/01; A61F 2/86 (2021.01)
CPC - A61B 17/221; A61B 17/320725; A61B 17/3415; A61B 2017/22041; A61B 2017/22094; A61B 2017/2212; A61B 2017/2215; A61B 2017/320741; A61F 2/011; A61F 2/013; A61F 2002/016; A61F 2002/018; A61F 2230/0069 (2021.02)

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, VA 22313-1450 Facsimile No. 571-273-8300	25 March 2021	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 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/US2020/065645

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/US2020/065645

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

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

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

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

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

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

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. 1-10

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

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2020/065645

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	YES
	Claims	1, 3-10	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-10	NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1 and 3-10 lack novelty under PCT Article 33(2) as being anticipated by Neuravi Limited (hereinafter Neuravi).

Regarding claim 1, Neuravi discloses a coring element for coring a vascular thrombus within a blood vessel of a patient (clot retrieval device for removing occlusive clot from a blood vessel, title; clot retrieval device 1, Fig. 1a), the coring element comprising: a unitary structure (outer member 2, Figs. 1a, 1g and 1h) having a first region (expandable member 26, Fig. 1h) adjacent to a proximal portion of the unitary structure (collar 12, Fig. 1g; The proximal end of the outer member may comprise of a collar 12, para. [0198]), wherein the first region includes a first mouth (first opening 22, Fig. 1g) configured to core the vascular thrombus (inlet openings 22 are provided in the outer member 2 these inlets 22 provide the primary movement freedom available to the clot and so the expansion of the outer member 2 urges the clot into the reception space 11. The outer member 2 has multiple inlet mouths 22 to accept the clot, para. [0198]); a second region distal of the first region (expandable member 27, Fig. 1h), wherein the second region is generally tubular (see Fig. 1g) and includes a first plurality of interconnected struts (struts 48 interconnected at junction 41, Fig. 1h); a third region distal of the second region (region between member 27 and member 28, Figs. 1g and 1h), wherein the third region includes a second mouth (second opening 22, Fig. 1g) configured to core the vascular thrombus (inlet openings 22 are provided in the outer member 2 these inlets 22 provide the primary movement freedom available to the clot and so the expansion of the outer member 2 urges the clot into the reception space 11. The outer member 2 has multiple inlet mouths 22 to accept the clot, para. [0198]); and a fourth region distal of the third region (expandable member 28, Fig. 1h), wherein the fourth region is generally tubular (see Fig. 1g) and includes a second plurality of interconnected struts (struts 23 that interconnect at eyelet junctions comprising radiopaque markers 25 as shown in Figs. 1g and 1h).

Regarding claim 3, Neuravi discloses the coring element of claim 1 and further discloses wherein the unitary structure extends along a longitudinal axis (central horizontal axis in Figs. 1g and 1h), and wherein the first region includes a pair of first curved struts that curve in opposite directions around the longitudinal axis and intersect at a pair of first junctions to define the first mouth (see Figs. 1a, 1g and 1h showing the member 26 including a pair of first curved struts 43 extending from member 26 in Fig. 1h towards member 27 in opposite directions, and intersect at a proximal end of struts 43 at junction points 46 to define first mouth 22).

Regarding claim 4, Neuravi discloses the coring element of claim 1 and further discloses wherein the unitary structure extends along a longitudinal axis (central horizontal axis in Figs. 1g and 1h), wherein the third region includes (a) a pair of upper curved struts that curve around the longitudinal axis and intersect each other at an upper junction (see Figs. 1a, 1g and 1h showing the third region including a first upper curved strut extending from member 28 in Fig. 1h towards member 27, a second upper curved strut 43 extending from member 27, the first and second upper curved struts intersecting at upper junction 41) and (b) a pair of lower curved struts that curve around the longitudinal axis and intersect each other at a lower junction, and wherein the lower and upper curved struts define the second mouth (see Figs. 1a, 1g and 1h showing the third region including a first lower curved strut extending from member 28 in Fig. 1h towards member 27, a second lower curved strut 43 extending from member 27, the first and second lower curved struts intersecting at lower junction 41, the lower and upper curved struts defining the second mouth 22).

Regarding claim 5, Neuravi discloses the coring element of claim 4 and further discloses wherein the lower and upper curved struts define (a) a first mouth portion opening in a first direction generally orthogonal to the longitudinal axis (see Fig. 1a showing the lower and upper curved struts of second mouth 22 having a first mouth portion opening in a first upward direction) and (b) a second mouth portion opening in a second direction generally orthogonal to the longitudinal axis, and wherein the first and second mouth portions define the second mouth (see Fig. 1a showing the lower and upper curved struts of second mouth 22 having a second mouth portion opening in a second downward direction, the first and second mouth portions defining second mouth 2).

Regarding claim 6, Neuravi discloses the coring element of claim 5 and further discloses wherein the first direction is generally opposite to the second direction (see Fig. 1a showing the first upward direction opposite to the second downward direction).

Regarding claim 7, Neuravi discloses the coring element of claim 1 and further discloses wherein the coring element is expandable from a compressed delivery configuration to an expanded deployed configuration (The outer member is configured to self-expand upon release from a restraining sheath (such as a microcatheter), para. [0198]).

Regarding claim 8, Neuravi discloses the coring element of claim 7 and further discloses wherein the coring element is configured to self-expand (The outer member is configured to self-expand upon release from a restraining sheath (such as a microcatheter), para. [0198]).

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Regarding claim 9, Neuravi discloses the coring element of claim 8 and further discloses wherein the coring element is made from a shape memory material (Both the inner and outer expandable members are desirably made from a material capable of recovering its shape automatically once released from a highly strained delivery configuration. A superelastic material such as Nitinol or an alloy of similar properties is particularly suitable, para. [0190]).

Regarding claim 10, Neuravi discloses the coring element of claim 1 and further discloses wherein the fourth region of the unitary structure is configured to be connected to a braided filament mesh structure (see Fig. 1a showing member 28 comprising a collar at junction point 9 for connecting to inner member 3; The distal end of the coil 18 on the inner tubular member 3 is bonded to the distal collar of the outer member 2 by adhesive, para. [0206]; the inner member comprises a braided structure, formed from one or more wires. The braided structure comprises a series of opposing spirals, with multiple overlap points where one wire crosses over another, para. [0226]).

Claim 2 lacks an inventive step under PCT Article 33(3) as being obvious over Neuravi Limited (hereinafter Neuravi).

Regarding claim 2, Neuravi discloses the coring element of claim 1 in a first embodiment but does not disclose in the first embodiment wherein the first mouth is radially offset from the second mouth.
However, Neuravi teaches in a second embodiment a coring element (outer expandable member shown in Figs. 21a and 21b; FIGS. 21a and 21b show an alternative embodiment of an outer expandable member such as part 2 of FIG. 1, para. [0245]) comprising a first mouth (large cell 973, Fig. 21a) and a second mouth (large cell 978, Fig. 21a), wherein the first mouth is radially offset from the second mouth (The large inlet window cells facilitate movement of the clot into the outer member and into the reception space between the outer member and inner tubular member, para. [0245]; The distribution of the large inlet windows and smaller cells is key to the performance of the device and in this configuration the large inlet windows and smaller scaffolded cells are generally alternated along the length of the device, para. [0246]).
Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the coring element of the first embodiment of Neuravi to include wherein the first mouth is radially offset from the second mouth, as taught by the second embodiment of Neuravi, for the purpose of providing means for engaging a clot by dislodging it from a patient's vessel with interconnected struts or scaffolds and means for collecting the clot into the coring element with large openings between the scaffolds and offset from each other large opening (Neuravi second embodiment, The large inlet window cells facilitate movement of the clot into the outer member and into the reception space between the outer member and inner tubular member. The smaller highly scaffolded cells engage with the clot and help dislodge the clot from the vessel. They also promote the movement of the clot from the highly scaffolded areas into the inlet windows of the device, para. [0245]).

Claims 1-10 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Search History:

Limited Classification Search

The Patent Analyst performed a limited classification search within the following US, IPC, CPC, ECLA, or F-Term classification areas:

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

IPC (8) Class/Subclass(es): A61B 17/221; A61B 17/22; A61B 17/3207; A61B 17/34; A61F 2/01; A61F 2/86 (2021.01)

U.S. Class/Subclass(es): 604/104; 604/164.05; 606/127; 606/159; 606/194; 606/198; 606/200

See Global Search Results.

Global Patent Literature Text Search

The Patent Analyst performed the following global text search, which was not limited by classification but may or may not have been limited by other criteria:

Minesoft PatBase: https//www.patbase.com

#	Search query	Results
1	PA=(INARI MEDICAL)	7
2	INV=((THRESS w2 John))	3
3	TAC=(vascular w3 thrombus)	116
4	3 and strut%	2
5	CPC=(A61B17/221 or A61B17/320725 or A61B2017/22094 or A61B2017/2212 or A61B2017/320741 or A61B2017/2215 or A61F2/011 or A61F2/013 or A61F2002/016 or A61B17/3415 or A61B2017/22041 or A61F2002/018 or A61F2230/0069)	8,713
6	5 and mouth*	239
7	6 and strut*	52
8	7 and (tubular* or cylind*)	33
9	8 and (strut* w10 (curv* or taper* or arch* or arc))	5
10	IC=(A61B17/22 or A61B17/221 or A61B17/3207 or A61B17/34 or A61F2/01 or A61F2/86)	46,593
11	10 and (mouth* or ((opening% or aperture% or hole%) w5 strut%))	1,007
12	11 and (strut* w10 (curv* or taper* or arch* or arc))	30
13	12 and (tubular* or cylind*)	20
14	UC=(606/127 or 606/159 or 604/104 or 604/164.05 or 606/194 or 606/198 or 606/200)	7,348
15	14 and (mouth* or ((opening% or aperture% or hole%) w5 strut%))	262

16	15 and (strut* w10 (curv* or taper* or arch* or arc))	22
17	16 and (tubular* or cylind*)	12

Google Patents: https://patents.google.com

#	Search query	Results
1	occlusive clot removing device comprising first and second mouth openings connected by a plurality of struts	1,496
2	mesh device comprising first and second openings for removing a blood vessel clot	40,948
3	a coring element for coring a vascular thrombus within a blood vessel of a patient	11,255
4	devices and methods for treating vascular occlusion	136,839

Computer Accessed Text Databases Searched

The Patent Analyst searched the following computer accessed text databases:

Google: https://www.google.com/

#	Search query	Results
1	devices and methods for treating vascular occlusion	9,200,000
2	a coring element for coring a vascular thrombus within a blood vessel of a patient	2,410,000
3	mesh device comprising first and second openings for removing a blood vessel clot	315,000
4	occlusive clot removing device comprising first and second mouth openings connected by a plurality of struts	36,800

Google Scholar: https://scholar.google.com/

#	Search query	Results
1	devices and methods for treating vascular occlusion	66,700
2	a coring element for coring a vascular thrombus within a blood vessel of a patient	1,950
3	mesh device comprising first and second openings for removing a blood vessel clot	11,700
4	occlusive clot removing device comprising first and second mouth openings connected by a plurality of struts	3

Date search was completed: 25 March 2021

EA/DD

Espacenet

Bibliographic data: JP2005230132 (A) — 2005-09-02

MEDICAL TREATMENT TOOL

Inventor(s): KATO TOMIHISA ± (KATO TOMIHISA)

Applicant(s): ASAHI INTECC CO LTD ± (ASAHI INTECC CO LTD)

Classification: **- international:** ***A61B1/00; A61B17/22; A61B17/221;*** (IPC1-7): A61B1/00; A61B17/22

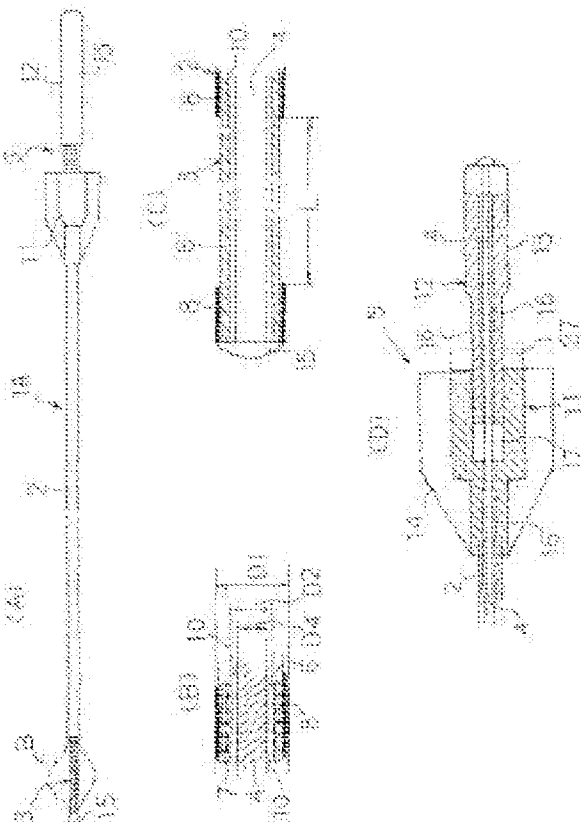
- cooperative:

Application number: JP20040040692 20040218

Priority number (s): JP20040040692 20040218

Abstract of JP2005230132 (A)

PROBLEM TO BE SOLVED: To provide a medical treatment tool to be inserted into a body cavity to highly efficiently perform foreign matter removal treatment in the body cavity by capturing and recovering foreign matters within the body cavity through an endoscope and thrombus removal treatment with high quality. ; SOLUTION: The medical treatment tool is characterized by such a structure that, in a flexible linear wire for which an operational core material 4 is freely slidably inserted into a main linear wire portion 2 of a hollow wire-stranded coil body 6 having a coating outer layer 8, both ends of the operational core material 4 are connected to a front end of the main linear wire portion 2 and a hand operation portion 5 at a rear end of the main linear wire portion 2. A diametrically expandable portion 3 composed of the hollow wire-stranded coil body in an exposed straight



form is provided near the distal end of the
main linear wire portion 2, and at least the diametrically expandable portion 3 is composed of the diametrically reduced hollow wire-stranded coil body 6. By the relative sliding of the operational core material 4 and the main linear wire portion 2 by the hand operation part 5, the diametrically expandable portion 3 freely forms a basket-like expanded configuration and a diametrically shrunken configuration from the basket-like expanded configuration. ; COPYRIGHT: (C)2005,JPO&NCIPI

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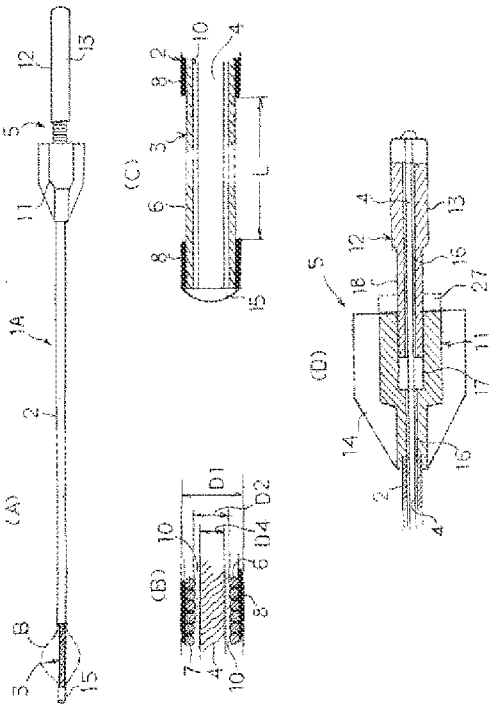
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(71)出願人　390030731
朝日インテック株式会社
愛知県名古屋市守山区脇田町１７０３番地
(74)代理人　100084526
弁理士　岡　賢美
(72)発明者　加藤　富久
愛知県名古屋市守山区脇田町１７０３番地
朝日インテック株式会社内

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4C061 GG15

(54)【発明の名称】医療用処置具

(57)【要約】
【課題】　体腔内に挿入して「内視鏡を介して体腔内の異物を捕獲回収する体腔内異物除去治療」や血栓除去治療が、高品質高能率にできる医療用処置具を提供する。
【解決手段】　被覆外層８を有する中空撚線コイル体６の主線条部２に操作用芯材４をスライド自在に貫挿した可撓性線条体にして、操作用芯材４の両端は主線条部２の前端と主線条部２の後端の手元操作部５に連結されると共に、主線条部２の先端近傍に露出ストレート形態の前記中空撚線コイル体から成る膨縮径部３を備え、少くとも膨縮径部３が縮径加工した中空撚線コイル体６から成り、手元操作部５による操作用芯材４と主線条部２の相対スライドによって、膨縮径部３のバスケット状膨径変体と該バスケット状膨径からの縮径変体を自在にした構造を特徴とする医療用処置具が特徴である。
【選択図】　図１



【特許請求の範囲】
【請求項1】
被覆外層を有する中空撚線コイル体の主線条部に操作用芯材をスライド自在に貫挿した可撓性線条体にして、前記操作用芯材の両端は前記主線条部の前端と該主線条部の後端の手元操作部に連結されると共に、前記主線条部の先端近傍に露出ストレート形態の前記中空撚線コイル体から成る膨縮径部を備え、少くとも前記膨縮径部が縮径加工した中空撚線コイル体から成り、前記手元操作部による前記操作用芯材と前記主線条部の相対スライドによって、前記膨縮径部のバスケット状膨径変体と該バスケット状膨径からの縮径変体を自在にした構造を特徴とする医療用処置具。
【請求項2】
中空撚線コイル体の主線条部に、操作用芯材をスライド自在に貫挿した可撓性線条体にして、前記操作用芯材の両端は前記主線条部の前端と該主線条部の後端の手元操作部に連結されると共に、前記主線条部の先端近傍に、自由状態においてバスケット状膨径形態の前記中空撚線コイル体から成る膨縮径部を備え、前記手元操作部の操作によって該膨縮径部の膨縮径変体を可能にした構造を特徴とする医療用処置
【請求項3】
膨縮径部が、縮径加工した中空撚線コイル体から成る請求項２に記載の医療用処置具。
【請求項4】
操作用芯材が、単線、または太線外周に細線を撚り合せて成る請求項２または請求項３のいずれかに記載の医療用処置具。
【請求項5】
手元操作部が、主線条部側と操作用芯材側の雌ねじ体と雄ねじ体の螺合機構、または、主線条部側と操作用芯材側の操作片の近接・離反スライド機構から成る請求項１～請求項４のいずれかに記載の医療用処置具。
【請求項6】
膨縮径部が、中空撚線コイル体の素線群の欠落ゾーンを備え、膨径状態においてスプーン形態を呈する請求項１～請求項５のいずれかに記載の医療用処置具。
【請求項7】
膨縮径部を構成する中空撚線コイル体のコイル素線が、剛線と柔軟線の組合せ形態から成る請求項１～請求項６のいずれかに記載の医療用処置具。
【請求項8】
膨縮径部の両側部位の中空撚線コイル体に、コイル素線群の結束固定手段を設けた請求項１～請求項７のいずれかに記載の医療用処置具。
【請求項9】
膨縮径部の膨径状態または縮径状態のセットロック手段を備えた請求項１～請求項８のいずれかに記載の医療用処置具。
【請求項10】
膨縮径部のコイル素線群の長さが、該コイル素線群の３６０°撚りスパンと概ね同一に設定された請求項１～請求項９のいずれかに記載の医療用処置具。
【請求項11】
手元操作部が、請求項５に記載の操作片の近接・離反スライド機構にして、該操作片がスライド作動側の雌操作片と固定側の雄操作片の組合せにして、かつ主線条部の後端が該雌操作片に連結され、操作用芯材の後端が該雄操作片に連結されて成る構造を特徴とする請求項２に記載の医療用処置具。

【発明の詳細な説明】
【技術分野】
【0001】
本発明は、体腔内に挿入して「内視鏡を介して体腔内の異物を捕獲回収する体腔内異物除去治療」や「血栓除去治療」等に用いる医療用処置具に関するものである。
【背景技術】

【0002】
体腔内異物の捕獲回収に用いる医療用処置具は、特許文献１・２に示される背景技術があり、特許文献１には（図８（Ａ）参照）長尺可撓性の樹脂製チューブのシース３０内に「進退自在の芯線の操作ワイヤ３１」を設けると共と、シース３０の先端部分に操作ワイヤ３１の進退操作によって膨縮変形できる「数本のバスケットワイヤ３２によって、予めかご状に成形したバスケット部３３」を設けた構造のものが示されており、そのバスケット部３３を膨大・縮径変化させることによって体腔内異物をバスケット部３３内に捕獲回収して体外に取り出す用法に成っている。
【0003】
そして、特許文献２には（図８（Ｂ）参照）金型成形・熱処理加工によって予め所定の湾曲形状に成したバスケットワイヤ３２から成るバスケット部３３がシース３０に内挿した操作ワイヤ３１の先端に突設した構造のものが示されており、操作ワイヤ３１の進退操作によってバスケット部３３の後半部分をシース３０内に引き込んだり押し出すことによってバスケット部３３を膨大・縮径させる構造を有し、体腔内異物を膨大形状のバスケット部３３に捕獲回収して体外に取り出す用法に成っている。
【0004】
【特許文献1】特開平９－１９４３９公報
【特許文献2】特開２００２－２５３５５８公報
【発明の開示】
【発明が解決しようとする課題】
【0005】
以上の背景技術の特許文献１のものは、操作ワイヤ３１の引き操作を解除するとバスケット部３３は最初の設定形状に縮径変化するものの、捕獲した体腔内異物の緊締保持ができないので保持力が弱い。そして、バスケット部３３は樹脂製シース３０との固定構造のためシース３０からの外れを生じたり、その固定部位が太くなるので内視鏡の細径化が困難にして患者の負担が大になる。
【0006】
そして、特許文献２のものは、操作ワイヤ３１を引き操作してバスケット部３３を樹脂製シース３０内に強制引き込みさせるので、そのシース３０の端部がバスケット部３３の縮径抵抗によって容易に膨径化（先太形状化）して、バスケット部３３の縮径緊締力を低下させるので、捕獲回収した体腔内異物の保持力の安定性に欠ける。
【0007】
さらに、特許文献１・２のバスケット部３３は操作ワイヤ３１を弦とする「単純な略弓形状」のバスケットワイヤ３２の集合から成る形態のため、バスケットワイヤ３２の隣接間隙が体腔内の抵触抵抗や捕獲異物の保持外力によって容易に過大過小変化して形状を崩す現象が避けられない。以上の背景技術のものは、体腔内異物の捕獲・収納作業がやりづらく、その上捕獲した異物を体腔内に落下させることがあり、当該治療性を妨げる難点があり、さらに、素線群を金型加工・熱処理加工によって所定形状に加工し、しかるのち、それを集合してシース３０との固定手段を施してバスケット部３２に成す工法が煩雑にして手数がかかり、かつ、美麗形状に成形し難い成形上の難点がある。
【0008】
本発明は、以上の背景技術の難点を解消する治療用処置具を提供するものである。
【課題を解決するための手段】
【0009】
以上の技術課題を解決する本発明の医療用処置具は「被覆外層を有する中空撚線コイル体の主線条部に操作用芯材をスライド自在に貫挿した可撓性線条体にして、前記操作用芯材の両端は前記主線条部の前端と該主線条部の後端の手元操作部に連結されると共に、前記主線条部の先端近傍に露出ストレート形態の前記中空撚線コイル体から成る膨縮径部を備え、少くとも前記膨縮径部が縮径加工した中空撚線コイル体から成り、前記手元操作部による前記操作用芯材と前記主線条部の相対スライドによって、前記膨縮径部のバスケッ

ト状膨径変体と該バスケット状膨径からの縮径変体を自在にした構造」の第１発明の医療用処置具と、

【0010】

「中空撚線コイル体の主線条部に、操作用芯材をスライド自在に貫挿した可撓性線条体にして、前記操作用芯材の両端は前記主線条部の前端と該主線条部の後端の手元操作部に連結されると共に、前記主線条部の先端近傍に、自由状態においてバスケット状膨径形態の前記中空撚線コイル体から成る膨縮径部を備え、前記手元操作部の操作によって該膨縮径部の膨縮径変体を可能にした構造」の第２発明の医療用処置具が特徴である。

【0011】

即ち、前記構成の第１発明の医療用処置具は、特開２００２－２７５７７４公報等に示される「多数のコイル素線を同一円周上に撚合構成した可撓性線状体の中空撚線コイル体」とその可撓性線状体に内挿した前記操作用芯材によって主要部を構成し、体腔内に挿入した後にその操作用芯材を「プル操作」することによって、該中空撚線コイル体の一部の「スエージング加工等によって強制縮径加工した部分の前記膨縮径部」を膨径弾性変体させて治療用バスケット部として機能させる思想を特徴とするものである。

【0012】

そして、前記第２発明の医療用処置具は、第１発明と同様な主要部の先端部分に設けた「自由状態で該中空撚線コイル体が成すバスケット状の膨縮径部」を前記操作用芯材のプッシュ操作（中空撚線コイル体との相対前方滑り操作）によってストレート状等に強制縮径変体可能に成し、その縮径状態で体腔内に挿入すると共に、体腔内で復元膨径状態にして、治療用バスケット部として機能させる思想を特徴とするものである。

【0013】

そして、以上の第１・第２発明の医療用処置具は、後述する特有作用効果のさらなる安定向上を図る技術意図から、前記手元操作部を「雌ねじ体と雄ねじ体の螺合機構」または「操作片の近接・離反スライド機構」に構成したり、前記操作用芯材が「単線または太線外周に細線を撚り合せた形態」前記中空撚線コイル体の撚り線が「剛線と柔軟線の組合せ形態」を採択する。

【0014】

さらに、前記膨縮径部が「コイル素線の欠落ゾーンを備え、膨径状態においてスプーン形態を呈し、体腔内異物の掬い取りスプーン部として機能させる形態」「膨縮径部の膨径状態・縮径状態のセットロック手段の付設」「膨縮径部の両端の中空撚線コイル体の固定手段の付設」「膨縮径部のコイル素線群の長さを、該コイル素線の３６０°撚りスパンと概ね同一に設定する形態」「前記操作片を相対スライド自在の雌操作片と雄操作片の組合せに成し、その雌操作片に主線条部の後端を連結する手元操作部形態」等の態様を必要に応じて採択する。

【発明の効果】

【0015】

前記第１発明の医療用処置具は、下記の特有の作用効果がある。即ち、体腔内異物の捕獲回収部として機能する膨縮径部が「被覆外層不存在の露出形態の中空撚線コイル体」によって構成され、かつ、その膨縮径部以外の「被覆外層存在の中空撚線コイル体」との連続一体化構造から成るので、その主線条部の中空部内の操作用芯材に加わるプル外力によって、ストレート状の該膨縮径部のコイル素線が素直に反応して弾性変位して「中間膨大・両端絞りのリブ集合バスケット形状に膨径変体」する。そして、そのプル外力が不存在になるとコイル素線それぞれの復元反力によって元のストレート状に自力復元して縮径変体作用する。なお、前記のプル外力のとき膨縮径部以外の主線条部の中空撚線コイル体は、被覆外層が存在しているので膨径変化するおそれがなく正常なストレート形状が維持される。

【0016】

そして、その膨径変体状態の中空撚線コイル体のコイル素線は、コイル巻きによる撚り角（リード角）に基づいて「拡径変体したバスケット形状の中心線の該操作用芯材に対し

てスパイラル状」を呈すると共に、コイル巻きによる加工応力を残留させたまま弾性変形しているので、外力による形状歪が極めて少く、そのスパイラル状のコイル素線群が輪郭するバスケット部は素線間間隙の崩れが少い極めて良好なバスケット形状にして、かつ体腔内の接触抵抗や「粘性度」によって容易に変形する恐れがなく、捕捉後の異物を落下させることなく捕捉力を高める応分のバスケット剛性を有する。

【0017】

さらに、そのバスケット部は操作用芯材を弦とする「スパイラル状のコイル素線の略弓形」の集合から成り、その弦の長さは前記の相対滑り度によって長短調整可能となるので、その弦長の調整セットによって「膨大径が大にして膨大スパンが少なる偏平形態バスケット部」「膨大径が少にして膨大スパンが大なる紡錘形態バスケット部」「この両者の中間形態」のセットが自在にして、その上、そのバスケット部の母体の膨縮径部は、主線条部の任意位置に設定できるので、体腔内治療部位の個有事情にマッチングしたバスケット部の多様形状パターンの設定が自在となる。以上の形状特性・形状変化性によって体腔内異物の捕獲がし易く、かつ、捕獲異物の落下トラブルが防止できる。

【0018】

即ち、例えば前記紡錘形バスケット部・中間形状バスケット部によって体腔内異物をバスケット部内に捕獲し、しかるのち、前記偏平形態に変形させることによって「操作用芯材の長軸方向とコイル素線との傾斜角が増大する」ことにより、異物との接触面積が増大してバスケット部内の捕獲異物を押え込みキャッチして落下させることなく的確な除去治療ができる。

【0019】

さらに、前記第１発明のものの中空撚線コイル体の少くとも前記膨縮径部は、公知のスエージング加工・ダイス加工による強制縮径加工が施されて、コイル体を構成する素線群は「断面形状が略扇形状を呈して相互面圧接した形態」にして剛性が大であり、その素線群によって形成されたバスケット部は捕獲した体腔内異物の保持力が前記背景技術のものより特段に大になる。そして、その強制縮径加工によって素線の剛性が向上するので、素線の細径化が可能になり、前記の異物捕獲作用が特段に向上すると共に、その細径化によって内視鏡用の細径化が可能になって患者の負担緩和ができる。

【0020】

さらに、本発明の治療用処置具は「被覆外層つき中空撚線コイル体と、その中空撚線コイル体に貫挿する操作用芯材」の２要素によって主要部が構成できるので、背景技術の「シース３０・操作ワイヤ３１・バスケットワイヤ３２」の３要素によって主要部を構成するものより構造簡素にして形成し易く、かつ機械的構造が安定する。

【0021】

詳しくは背景技術のものは、バスケットワイヤ３２に予め「曲りぐせ」加工と、その曲りぐせを保持させる熱処理加工が必要にして、その加工バスケットワイヤ３２を結束して整列配設する困難な成形加工が不可欠にしてバスケット部３３の成形性が極めて劣ると共に、その配設ミスを生ずるリスクが高く形状安定性に欠ける。しかし本発明のものは、中空撚線コイル体の被覆外層を必要長に単に剥離するのみで正確な膨縮径部が形成可能にして、その上剥離位置を変えるのみで、バスケット部の位置が自在に設定可能であり極めて成形簡素にして、かつ精確形状の膨縮径部が成形できる。

【0022】

一方、前記第２発明の医療用処置具は下記の特有の作用効果がある。即ち、前記第２発明のものは前記第１発明の膨縮径部を自由状態において設定し、体腔内挿入のときのみ該膨縮径部を強制縮径させる形態にして、体腔内患部において自由状態解放の膨径形態に成す形態相違のみであることから、その膨縮径部の膨径形態は「前記第１発明の体腔内で強制拡径変体させて保持するものより当然に形状安定性」が良好となり、前記第１発明の段落００１５～００２１に示す作用効果を「より安定向上する」ことができる。

【0023】

さらに、前記第１・第２発明の態様形態の前記スプーン形態のものは、スプーン形態の

膨縮径部を「例えば、手元操作部の回転操作によって回転操作してスプーン機能させて体腔内異物を掬い捕獲する」新たな効率的用法が可能になる。

【0024】

以上の特有作用によって本発明の医療用処置具は、体腔内異物の捕獲回収等の治療が極めて的確かつ迅速になる高実用性を有して当該治療性を特段に向上する。以上の主たる作用効果がある。

【発明を実施するための最良の形態】

【0025】

以下、前記第１・第２発明の好ましい実施例を説明する。

【実施例】

【0026】

まず、図１・図２を参照して第１発明１実施例の医療用処置具１Ａ（以下、単に処置具１Ａという）を説明する。即ち、細長可撓性の主線条部２の前端近傍に「体腔内異物の捕獲回収用のバスケット部Ｂを膨縮自在に成す膨縮径部３」を設けると共に、その主線条部２の後端に「膨縮径部３を膨縮径操作する手元操作部５」を備えた体腔内異物の捕獲回収治療用の処置具において、この実施例の主線条部２は「多数本の線材を撚合構成して中心芯材を抜き出し、または、多数本の線材を同一円周上に撚合構成して中心部分を長さ方向に貫通する中空部１０に成した中空撚線コイル体６」に樹脂質の被覆外層８を一体に設けた構造を有している。

【0027】

即ち、中空撚線コイル体６は（図２参照）細線材（０．１粍直径）を７本撚り合せたコイル素線７（直径＝０．３粍）を１０本撚り合せて中空コイル体（直径Ｄ５＝１．３粍）に成し、しかるのち、その中空コイル体を公知の「スエージング加工・ダイス引き加工」によって強制縮径（直径Ｄ６＝１．１粍）加工して、コイル素線７のそれぞれが横断面略扇形状にして、かつ、隣接相互の該略扇形側面が相互強圧接した形態に形成されている。さらに、その外周に被覆外層８を設けて「直径Ｄ１＝１．５粍・内径直径Ｄ２＝０．７粍の可撓性コイル体」に形成されている。

【0028】

なお、被覆外層８の樹脂質は熱可塑性樹脂（ポリアミド・ふっ素樹脂等）熱硬化性樹脂（フェノール樹脂・エポキシ樹脂等）のいずれでも良く、また、加工方法として押出成形・熱収縮チューブにより被覆外層８を設けても良い。そして、熱可塑性樹脂であればロックウエル硬度８０（Ｒスケール）以上の比較的硬度の高いものが好ましい。

【0029】

そして、この主線条部２の中空部１０には、前端を主線条部２の先端に連結し、かつ、後端を手元操作部５の雄ねじ体１２に連結した操作用芯材４がスライド移動自在に貫挿され、さらに、膨縮径部３は「主線条部２の被覆外層８のみを剥離して中空撚線コイル体６のストレート状の外周を、そのまま露出した構造」にして、主線条部２の先端近傍に長さＬに形成設定されている。なお、図中の１５は主線条部２の中空部１０の先端を閉じて操作用芯材４の前端を連結した先頭栓、１６は操作用芯材4の遊挿孔である。

【0030】

そして、手元操作部５は（図１（Ｄ）参照）「雌ねじ孔１７を有して主線条部２の後端に固着した筒状の雌ねじ体１１と、この雌ねじ体１１に螺合する雄ねじ部１８を棒状の把持部１３の前方に突設した雄ねじ体１２の組合せからなる螺合機構を有し、その雌ねじ体１１の外周に突設した把手フイン１４を指先で保持し、雄ねじ体１２を他の指先で回転操作すると、操作用芯材４にプル操作力が生じて、操作用芯材４が主線条部２の中空撚線コイル体６の中空部１０内をスライド移動して、前記構成要件の主線条部２と操作用芯材４の相対スライド操作ができる。

【0031】

なお、この実施例の操作用芯材４は（図２（Ｃ）参照）「直径０．１６粍の素線を７本セットにして、そのうち１本を芯線・他の６本を該芯線に撚合した公知の「１×７」の撚

り線にして直径Ｄ４＝約０．５粍」である。そして中空撚線コイル体６はコイル素線７と中心芯材を用いてロープ状に撚合構成した後、該中心芯材を抜き出して成形したり、または、その中心芯材を用いないで該撚合素線を同一円周上に撚合構成して成形する。

【0032】

そして、この実施例の手元操作部５は雌ねじ体１１・雄ねじ体１２の螺合機構にして、雄ねじ体１２を回転（右ねじのときは左回転・左ねじのときは右回転）して後退させて操作用芯材４をプル操作する構造であることから、操作用芯材４中空撚線コイル体６の撚り方向が下記のように設定されている。即ち、操作用芯材４の撚り線は、プル操作の回転方向によって「撚りが緊締方向となる」撚り方向（Ｓ撚り・Ｚ撚り）にして、かつ、中空撚線コイル体６のコイルの撚り方向が操作用芯材４の撚り線の撚り方向と同一にした撚り形態に設定されている。

【0033】

以上の図１実施例の処置具１Ａは（図３参照）先頭栓１５から体腔内に挿入して体腔内異物の捕獲回収治療を行うとき、手元操作部５を回転操作して「操作用芯材４を手元部側へプル操作して主線条部２内を後退スライド移動」させると、そのスライド移動によって先頭栓１５に手元側への引き寄せ外力を生じ、その外力の吸収クッション部として膨縮径部３が機能する。

【0034】

かくして（図３（Ａ）実線矢印参照）、その引き寄せ外力にバランスした膨径力が膨縮径部３に生じてコイル素線７のそれぞれが中高山状に外方へ弾性歪して「コイル素線７のそれぞれが適量間隔を有して輪郭リブ線となる「膨大径Ｄ１・膨大スパンＳ１のバスケット部Ｂ１」に膨大変形する。

【0035】

そして、その状態において手元操作部５を操作して、前記プル操作によるプル力を解消するとバスケット部Ｂ１はコイル素線７自体の復元収縮力と、操作用芯材４の前進操作力または主線条部２の後退力の支援によって、前記膨大変形状態のコイル素線７のそれぞれが、元位置または元位置近似に復帰して概ね元姿勢に縮径変形できる。

【0036】

そして、その治療において、膨径変形状態のバスケット部Ｂ１に体腔内異物を捕獲回収する。しかるのち、その収容異物の落下防止を図るために、手元操作部５を操作して操作用芯材４のプル量を調整して「膨大スパンＳ１・膨大径D1のバスケット部Ｂ１を膨大スパンＳ２・膨大径Ｄ２偏平形態のバスケット部Ｂ２」に変形して、該異物をコイル素線７によって挟着保持して体外に的確に回収する治療方法を必要に応じて実行する。なお、中空撚線コイル体６の前記の強制縮径加工は、必ずしも中空撚線コイル体６の全長ではなく、少くとも膨縮径部３の部位のみに施せば足りる。

【0037】

以上の実施例の処置具１Ａは前記の主たる作用効果が存在すると共に、下記の従たる作用効果がある。即ち、膨縮径部３の構成素線が略扇形異形断面であることから回収内包した体腔内異物のコイル素線７のコーナーによる粉砕機能があり、さらに、図３に示す膨径度の進行に比例して（図３（Ｃ）参照）「スパイラル状のコイル素線７が、操作用芯材４が成す中心線に対して直交方向の形態」を呈して図示矢印の捻り反転作用が生じ、これによってバスケット部Ｂ内の回収異物を強固に保持して落下させない特有作用がある。

【0038】

そして、操作用芯材４と中空撚線コイル体６が前記の撚り構成から成るので、プル操作による操作用芯材４の撚り線の弛緩がなくプル操作力の伝達性が良好に成ると共に（図３（Ｂ）参照）操作用芯材４のＴ１方向のプル操作回転の影響を受ける中空撚線コイル体６は、Ｔ２方向のコイル撚りを戻す作用力を受け、近傍に存在する膨縮径部３の膨径変体作用を支援する作用が存在し、さらに、バスケット部Ｂを構成する中空撚線コイル体６のコイル素線７がスパイラル捻回して、かつ、撚り線であることから、バスケット部Ｂを輪郭するコイル素線７が「ストレート線の同一膨大形態」のものより柔軟性が向上し、異物と

の接触表面積が増大する為、血管内の血栓・粘性の高い血餅等の捕捉回収が一段とし易くなると共に、血管壁等を傷つけることがない。以上の諸作用から、この実施例の処置具１Ａは体腔内異物の捕獲回収治療が極めて簡便かつ的確にして当該治療性を特段に向上することができる。

【0039】

次に、図４・図５を参照して第２発明１実施例の医療用処置具１Ｂ（以下、単に処置具１Ｂという）を説明する。即ち、前記の処置具１Ａと同様な「先端部分に膨縮径部３を設けた中空撚線コイル体６・操作用芯材４を貫挿した主線条部２・手元操作部５」から成る基本形態のものにおいて、この実施例のものの膨縮径部３は、中空撚線コイル体６のコイル素線７が自由状態において必要膨度を呈するバスケット膨径体（図３のＢ１程度）に塑性変形して設定されている。

【0040】

なお、この自由状態膨径の膨縮径部３は、例えば下記の工法によって成形する。即ち、主線状部２の被覆外層８を剥離した後、中空撚線コイル体６のコイル素線７を「スパイラル状の溝部を設けた膨隆形状の成形用芯金の該溝部」に嵌め込み、その成形用芯金を上下から押え付ける上下金型によって膨大成形し、しかるのち熱処理を施して該成形芯金から外して自由状態で所要の膨径形状を保持する形状に成形される。

【0041】

そして、手元操作部５の操作による操作用芯材４のプッシュ操作によって、操作用芯材４を前方へ押し出すことによって膨径形状の膨縮径部３を強制縮径変形させて「ストレート形態」または「体腔内挿入可能程度の微膨径形態」に自在にセット可能になると共に、操作用芯材４をプル操作することによって膨縮径部３のさらなる膨径変化（図３のＢ２程度）ができる。

【0042】

詳しくは、この実施例のものの手元操作部５は（図４（Ｄ）参照）、主線条部２の後端に連結固定した管体にして後端に指先係止孔２３を有する雄操作片２２と、この雄操作片２２の胴部を横断貫通して雄操作片２２の周壁に切設したスリット２５を介して雄操作片２２の長手方向にスライド移動自在に組合せ、かつ、両側に指先係止孔２３を設けた雌操作片２１によって前記の近接・離反スライド機構を構成しており、この雌操作片２１に操作用芯材４の後端が接続されている。

【0043】

そして、この指先係止孔２３に指先を入れて雌操作片２１を前方へプッシュ操作することによって、主線条部２と操作用芯材４を相対スライド移動させて、図３（Ａ）に示す点線矢印のように、予め膨径設定されている図示Ｂ１の膨縮径部３を「ストレート形態の膨縮径部３」に変形セットして体腔内挿入脱すると共に、体腔内の治療部位にセットした「ストレート形態の膨縮径部３」を、図示Ｂ１・Ｂ２のように任意膨径度にセットして、前記図１実施例と同様に体腔内治療を施す構造に設定されている。

【0044】

なお、この実施例の処置具１Ｂは、前記プッシュ操作のとき操作用芯材４の長手方向に圧縮力が加わるので（図４（Ｃ）参照）太線ＷＡまたは太線ＷＡを芯線にして細線ＷＢを撚合した撚合線の耐高挫屈性の操作用芯材４を用いると共に、雌操作片２１には芯材４の挫屈防止パイプＰ１が設けられている。そして、雄操作片２２の胴部には膨縮径部３の任意膨縮径度をセットロックする「セットロックねじ２７」が雄操作片２２の胴部に設けてある。以上の実施例の処置具１Ｂは前記の主たる作用効果がある。

【0045】

続いて、図５～図７を参照して第１・第２発明の他の実施例を説明する。即ち、まず図５（Ａ）は第２発明の他の実施形態が示してあり、図４に示すものと同様な「雌操作片２１と雄操作片２２との組合せ形態の手元操作部５」において、中空撚線コイル体６の後端が雌操作片２１に接続されると共に、操作用芯材４の後端が雄操作片２２に接続されている。そして、指先係止孔２３に指先を入れて雌操作片２１を雄操作片２２に対して引き寄

せる（プッシュ操作）ことによって、中空撚線コイル体６に後退力（操作用芯材４に対する相対的後退力）を付与し、その後退力によって膨縮径部３を任意縮径度に縮径変化させる膨縮径プロセスに構成されている。

【0046】

なお、この実施例のものにも、雌操作片２１を雄操作片２２へ引き寄せ操作したときの雄操作片２２近傍の操作用芯材４の座屈を防止する保護パイプＰ２が雄係止片２２に設定されている。この膨縮径プロセスのものは背景技術のものと同様な操作プロセスのため、術者が慣れた従来手技が適用できるメリットがある。

【0047】

一方、図５（Ｂ）は図１（Ｄ）に示す螺合機構の手元操作部５から成る処置具１Ｂの実施例が示してあり、主線条部２の後端が雌ねじ体１１の前端に接続され、操作用芯材４の後端が雄ねじ体１２の後端に連結されており、雄ねじ体１２を回転させることによって操作用芯材４をプッシュ操作してスライドさせ膨縮径部３を縮径変形させる。そして、必要に応じて逆にプル操作して膨径操作をするように成っている。

【0048】

そして、この実施例のものの雌ねじ体１１の前端には「前記のプッシュ操作によって生ずる応力から主線条部２を保護する保護パイプＰ３」が突設されている。

【0049】

次に図６は段落００１４に示す「スプーン形態の膨縮径部３」の実施例が示してあり、膨縮径部３を構成する中空撚線コイル体６のコイル素線７群のうち、数本のコイル素線７を欠落させた（この実施例のものは本来存在すべき１０本中３本欠落）素線欠落ゾーン２８が設けてあり、その欠落ゾーン２８以外のコイル素線７によって「膨径状態でスプーン状バスケット部となるスプーン形態膨縮径部３」に形成されている。

【0050】

この図６実施例のものは、そのスプーン形態の膨縮径部３を深底・浅底の任意のスプーン形状にして体腔内で回転操作等をすることによって、スプーン体として機能させて体腔内異物の掬い取りキャッチが可能になると共に、消化管・血管等の体腔分岐部分の通過がし易く（素線欠落ゾーン２８を利用して通過させる）医療用処置具の品質・性能が一段と向上する。なお、このスプーン形態のものは、スプーン機能するコイル素線７に大なる外力が加わるので図４（Ｃ）に例示する剛性形態のコイル素線７が好ましい。

【0051】

次に図７のものは膨縮径部３を構成する中空撚線コイル体６のコイル素線７の他の態様が示してあり、単線のコイル素線７Ｂと「１×７撚り線のコイル素線７Ａ」の剛線（７Ｂ）と柔軟線（７Ａ）の組合せに設定されており、図７（Ａ）は連続６本の７Ａと連続４本７Ｂの配列形態、図７（Ｂ）は７Ａ・７Ｂの交互配設形態に成っている。この図７実施形態のものは下記の特有作用がある。

【0052】

即ち、粘度の高い体内分泌物により、ワイヤ相互付着して拡径できないことがあるが、例えば隣接線に剛線を用いる場合、ワイヤ相互付着力に抗して拡径することができる。器官等の凹凸状の内壁状態により柔軟線のみのとき均等に拡径することは困難なことがあるが、剛線の存在により均等拡径できる。そして、柔軟線の屈曲変形部分より膨縮径部３の内部へ異物が入り込み易くなり捕捉し易くなる。膨縮径部の円筒状軸直交方向の剛性が異なるゾーンを設ける構造（図７（Ａ））により、器官・血管等の分岐位置において柔軟線７Ａ部分の一方向を易屈曲させることにより、所望の位置に処置具を導入することが容易となる。

【0053】

次に、以上の第１・第２発明の他の実施形態群を説明する。即ち、まず図示しないが本発明の他の実施例として、膨縮径部３の長さＬを、コイル素線７の３６０° 撚りワンピッチと概ね同一に設定する形態にすることがある。この形態のものは膨縮径部３が膨縮径変体したときバスケット部Ｂを構成輪部するコイル素線７が、膨縮径部３の中心線を３６０

〃捻回するスパイラル形態となるので、特に膨大径Ｄ２偏平形態のバスケット部Ｂ２において異物捕捉力を高めることができ、さらに、操作用芯材４をプル操作すると、スパイラル形態のコイル素線７群が相互に接触状態となって、前記の特有作用が一段と安定し向上する。

【0054】

さらに、処置具１Ａ・１Ｂは（図７（Ｃ）参照）膨縮径部３の両端に「コイル素線７群をコイル状のまま結束固定する結束リング体Ｓによる結束固定手段」または「コイル素線７群をコイル状のまま溶着固定する結束固定手段」から成るコイル素線７群の結束固定手段を必要に応じて施す。この結束固定手段を設けたものは、膨縮径部３の膨径変体のときバスケット部Ｂの両端のコイル素線７に生ずる「膨径変体に基づく応力」を該結束固定手段によって担持してコイル素線７の浮上りほぐれを防止作用するので、膨縮径部３・バスケット部Ｂの形状が安定して反復膨縮径変化させても形状崩れがなく膨縮径部３の前記特有作用が一段と安定して良好となる。

【0055】

なお、本発明の処置具１Ａ・１Ｂは前記の実施例に限定されず、例えば処置具１Ａに処置具１Ｂの前記実施例の手元操作部５を設定したり、処置具１Ｂに処置具１Ａの前記実施例の手元操作部５を設定する変化がある。そして、前記実施例で示した被覆外層８は、膨縮径部３の膨径応力が膨縮径部３以外の中空撚線コイル体６に及ぶのを防止するための保護被覆であることから、自由状態で膨径状に設定されている処置具１Ｂでは必ずしも必要ではない。

【0056】

そして、中空撚線コイル体６は当該分野の先行文献の特願２００２－３５８８５１に開示されている「捻回抵抗負荷の基に捻回形成すると共に、加工による残留応力除去の加熱処理を施した高度の回転追従性・真直性付与形態に形成されて成る中空撚線コイル体」「コイル素線７がオーステナイト系ステンレス鋼線から成る中空撚線コイル体」「形状記憶特性・超弾性特性を示すＮｉ－Ｔｉ合金線材を、コイル線の一部に、またはコイル線全体に用いた中空撚線コイル体」「膨縮径部３以外の部分の被覆外層８を本発明の特有作用を阻害しない範囲で部分的に省略した形態」「樹脂被覆に代るステンレス鋼管・銅管等の金属製管体の被覆外層形態」等を含む総ての形態の主線条部・中空撚線コイル体が構成要件となる。

【0057】

なお、前記実施例では「被覆外層８を剥離した露出形態の膨縮径部３」のみを説明したが、下記の形態にすることがある。即ち、被覆外層８を剥離した後の膨縮径部３に、ゴム質（天然ゴム・ウレタンゴム等）等の柔軟被覆を全部または一部に形成した「被覆付き膨縮径部構造」にして、例えばカテーテル等を併用して「その被覆つき膨縮径部」を膨大変体させて血管壁に摺接させながら、カテーテル管内へ体腔内異物を回収する治療手法等を可能にする形態にすることがある。

【産業上の利用可能性】

【0058】

本発明の医療用処置具は、前記の体腔内異物の捕獲回収治療用のみではなく「脈管内異物除去治療具」等として広く応用できる。

【図面の簡単な説明】

【0059】

【図1】第１発明１実施例の医療用処置具を示し、（Ａ）はその全体正面図、（Ｂ）（Ｃ）（Ｄ）はその要部拡大図

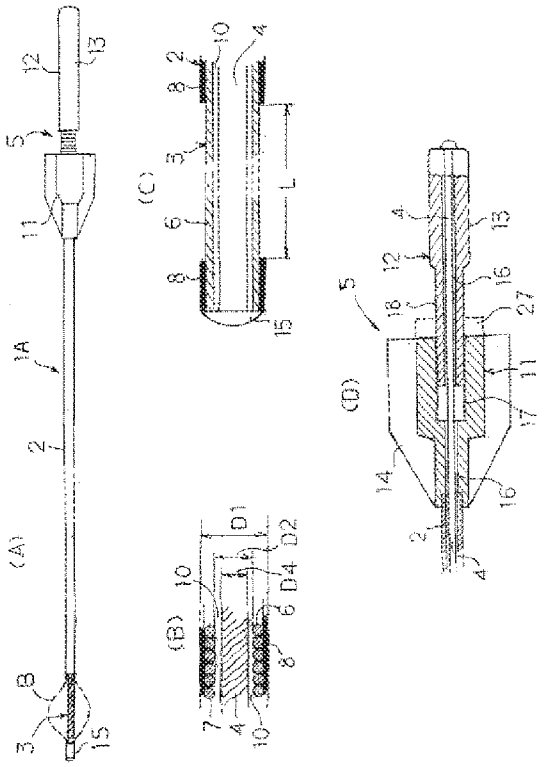
【図2】図１実施例の要部の構造を示し、（Ａ）は中空撚線コイル体の断面図、（Ｂ）は膨縮径部の正面図、（Ｃ）は操作用芯材の断面図

【図3】本発明の医療用処置具の作用状態を示し、（Ａ）（Ｂ）（Ｃ）ともその作用説明図

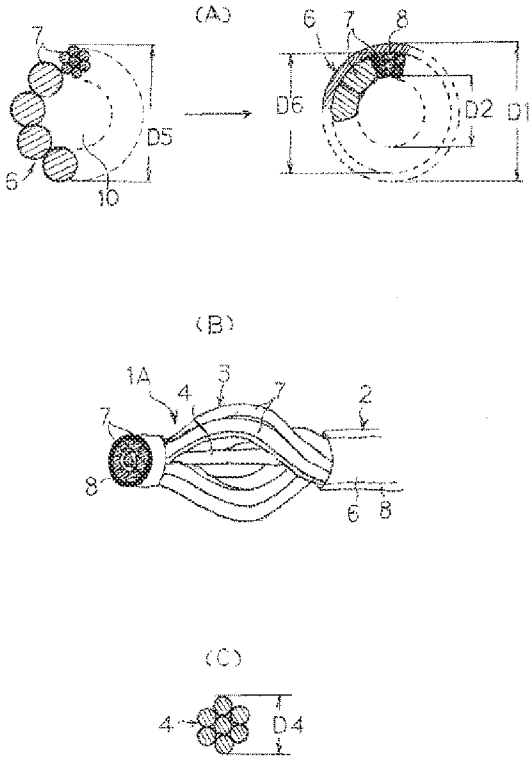
【図4】第２発明１実施例の医療用処置具を示し、（Ａ）はその全体正面図、（Ｂ）（Ｄ

）はその要部拡大図、（Ｃ）はその操作用芯材の断面図
【図5】第２発明の医療用処置具の他の実施例を示し、（Ａ）（Ｂ）ともその構造と作用を示す正面図
【図6】第１・第２発明の医療用処置具の他の実施例の膨縮径部を示し、（Ａ）はその正面図、（Ｂ）はその断面図
【図7】第１・第２発明の医療用処置具の他の実施例を示し、（Ａ）（Ｂ）は中空撚線コイル体の断面図、（Ｃ）は膨縮径部の正面図
【図8】背景技術の医療用処置具を示し（Ａ）（Ｂ）ともその要部正面図
【符号の説明】
【0060】
１Ａ　第１発明の医療用処置具
１Ｂ　第２発明の医療用処置具
２　主線条部
３　膨縮径部
４　操作用芯材
５　手元操作部
６　中空撚線コイル体
７　コイル素線
８　被覆外層
１０　中空撚線コイル体の中空部
１１　雌ねじ体
１２　雄ねじ体
１３　把持部
１７　雌ねじ孔
１８　雄ねじ部
２１　雌操作片
２２　雄操作片
２３　指先係止孔
２８　コイル素線欠落ゾーン
Ｂ　バスケット部
Ｄ　膨大径
Ｓ　膨大スパン

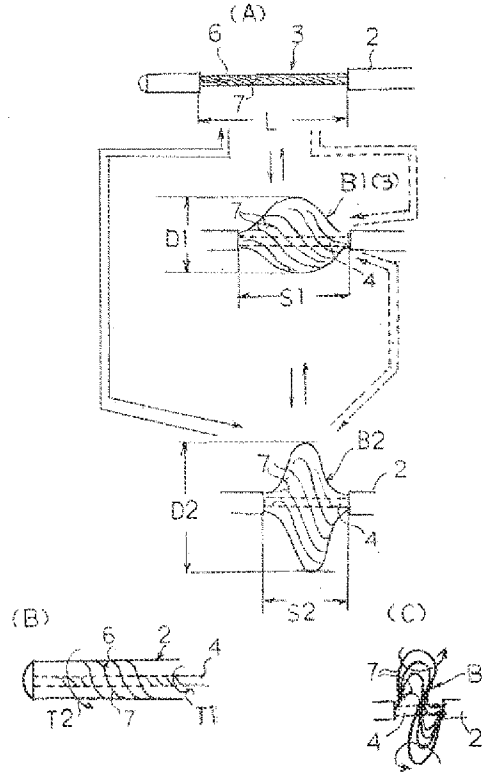
【図1】



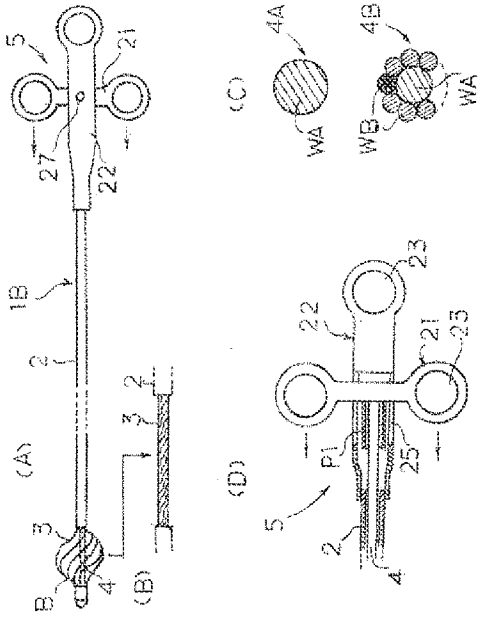
【図2】



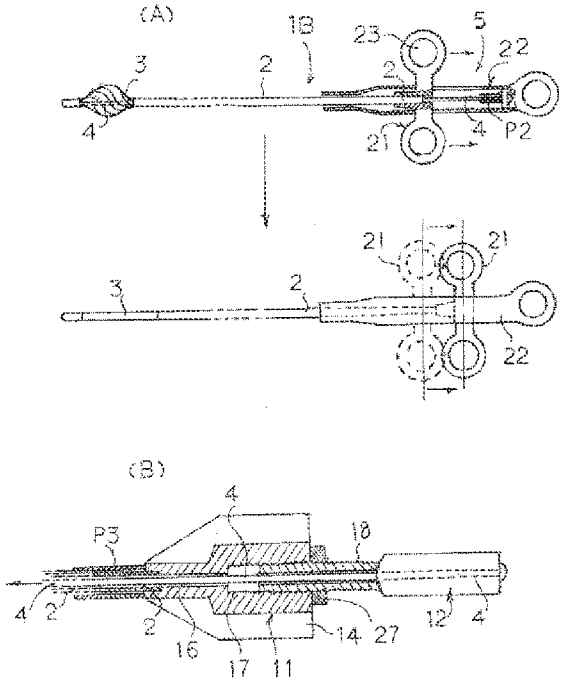
【図3】



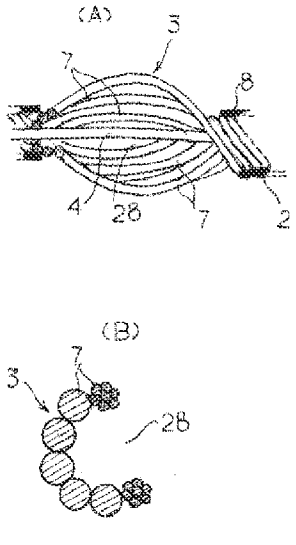
【図4】



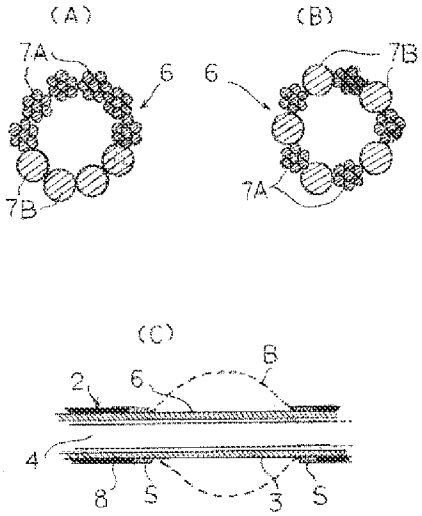
【図5】


(A)
1B
23
5
22
3
2
4
P2
21
(B)
4
P3
18
12
16
17
11
14
27

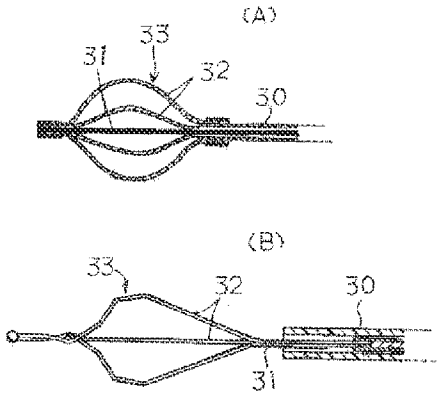
【図6】


(A)
3
7
8
4
28
2
(B)
3
28

【図7】


(A)
7A
6
7B
(B)
6
7B
7A
(C)
2
6
8
4
8
5
3
5

【図8】


(A)
31
33
32
30
(B)
33
32
30
31

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(71) Applicant *(for all designated States except US)*: **NEURAVI LIMITED** [IE/IE]; c/o Roger Lenfestey & Co., Town Park Centre, Tuam Road, Galway (IE).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BRADY, Eamon** [IE/IE]; Doon, Kilrickle, Loughrea, Co. Galway (IE). **RAZAVI, Mahmood** [US/US]; 14 Laurelwood, Irvine, CA 92620 (US). **VALE, David** [IE/IE]; 10 Crestwood, Coolough Road, Galway (IE). **O'SHAUGHNESSY, John** [IE/IE]; Furrymelia - East, Barna, Co. Galway (IE).

(74) Agents: **O'BRIEN, John, A.** et al.; c/o John A. O'Brien & Associates, 3rd Floor, Duncairn House, 14 Carysfort Avenue, Blackrock, County Dublin (IE).

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(54) **Title**: CLOT CAPTURE SYSTEMS AND ASSOCIATED METHODS

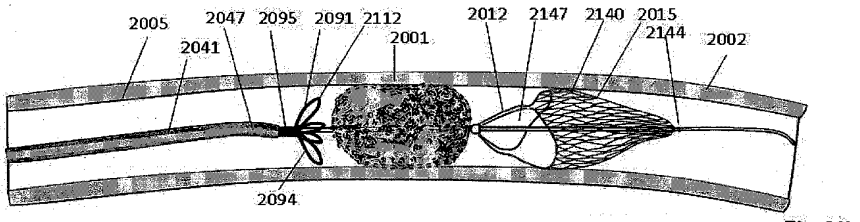


Fig. 80h

(57) **Abstract**: A clot capture system for disengaging a clot 2001 from a vessel wall 2002 and removing the clot 2001 from the vessel 202, comprises a clot capture device 2140 for placement on a distal side of a clot 2001. The clot capture device 2140 has a retracted delivery configuration and an expanded deployed configuration. The clot removal device has a proximal support frame 2012, and a distal fibre net 2130. The support frame 2012 has a retracted delivery configuration and an expanded deployed configuration. The proximal support frame 2012 in the expanded configuration defines a proximal inlet mouth for engaging a clot 2001 and a net 2130 for confining the clot 2001. An elongate member facilitates capture and/or withdrawal of a clot 2001 from a vessel 2002. The system also comprises a clot debonding device 2091 for placement on a proximal side of a clot 2001. The clot debonding device 2091 has a retracted delivery configuration and an expanded deployed configuration and comprises a clot engagement element 2112 which defines a distal abutment in the deployed configuration for urging a clot 2001 into the clot capture device 2140.

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"Clot Capture Systems and Associated Methods"

Introduction

The invention relates to devices, and methods of removing acute blockages from blood vessels. The invention especially relates to removing acute obstructions from blood vessels. Acute obstructions may include clot, misplaced devices, migrated devices, large emboli and the like. More particularly the invention relates to removing clot from cerebral arteries in patients suffering acute ischemic stroke.

Accessing the neurovascular bed is difficult with conventional technology as the target vessels are small in diameter, are remote relative to the site of insertion and are highly tortuous. Despite the fact that there are over 600,000 acute ischemic strokes in the US each year, clot retrieval devices are used to treat patients in less than <1% of cases. The reasons for this are that conventional technology is either too large in profile, lacks the deliverability to navigate tortuous vessels or is not effective at removing clot when delivered to the target site.

Statements of Invention

In accordance with the present invention, device and methods for removing obstructions are described. The invention provides designs and systems for removing clot and other obstructions from the neurovascular arteries and veins as well as other vascular beds.

In one case the invention provides endovascular capture devices which capture obstructive elements and retrieve them from the vessel. The devices of the invention may be used in vessels that are small, tortuous and easily ruptured.

The invention provides a means for removing acute blockages or obstructions from blood vessels. Acute obstructions may include clot, misplaced devices, migrated devices, large emboli and such like. The invention is especially directed at removing clot from cerebral arteries in patients suffering acute ischemic stroke.

The invention provides a clot retrieval device that can be delivered through a micro catheter. The device has sufficient structure to engage the clot. The device provides a means for debonding the clot from the vessel wall. The device further provides means to prevent the fragmentation of the clot and effectively retrieve the clot from the vessel.

There are significant challenges associated with retrieving clot from cerebral vessels including: navigation of the highly tortuous pathways that often exist in the distal internal carotid artery and cerebral arteries, collapsing a device into a profile compatible with the tiny microcatheters typically used in cerebral vessels, disengaging the target clot from the vessel wall without applying painful or harmful forces to the cerebral vessels, and retaining adequate clot retaining scaffolding features in an ultra low profile device to remove the captured clot without fragmentation.

This invention provides a therapeutic device which can be collapsed to a very low profile, and which has a flexible configuration suitable for navigation beyond the Petris portion of the internal carotid artery to restore blood flow by the capture and removal of target clots from the cerebral vasculature. Features and methods that enable disengagement and capture of the target clots which are substantially equivalent in size to the target vessel and to the opening of the clot retrieval device itself are also disclosed.

The invention further provides a device for removing an obstruction from a vessel comprising: an elongate member, a frame with one or more openings and a plurality of fibre segments wherein the elongate element has a proximal end, a distal end and an intermediate segment, and in use the proximal end extends exterior of the patient the intermediate segment extends through the vasculature of the patient to the target vessel and the distal end is positioned in the target vessel with the frame connected to the elongate member adjacent the distal end.

The obstruction to be removed may be clot, with removal of this clot providing the therapeutic benefit of restoring blood flow to the vessel.

The device may comprise a proximal support frame; and a distal fibre net, the support frame having a retracted delivery configuration and an expanded deployed configuration, the proximal support frame in the expanded configuration defining a proximal inlet mouth for engaging or embracing a clot and the net confining the clot; and an elongate member to facilitate capture and/or withdrawal of a clot from a vessel.

The frame may comprise a collapsed state for delivery through the vasculature to the vessel and an expanded state for removing the obstruction from the vessel. The expanded state the frame may comprise a hoop.

The frame may be cut from a metallic tube and the cut frame may comprise a one piece construction. This one piece frame may comprise at least one connector element and a hoop element, and may also comprise a collar.

The frame may be connected to the elongate member and the point of attachment to the elongate member may be spaced apart from the hoop.

The connector element may extend between the points of connection to both the elongate member and the hoop, and may be fixedly connected to the elongate member.

One or more connector elements may be fixed to the elongate member so as to allow rotation between the elongate member and the connector element, or said connector elements may be indirectly fixed to the elongate member.

One or more connector elements may be coupled to a collar and said collar fixed to said elongate member.

The frame may be made of one piece and comprise regions of low strain and regions of high strain, wherein the regions of high strain comprise curved segments to relieve said high strain.

The frame may have an 'as cut' state and an expanded state wherein in the 'as cut' state the frame has a pattern cut through its wall and said pattern defines the collar, one or more connectors, the hoop and the struts that define the hoop.

The frame expanded state may be achieved by expanding the hoop and connector elements to the desired shape for clot retrieval and heat setting the frame in the expanded such that the expanded shape is remembered by the frame and the frame is relaxed in the expanded state.

The connector element may be parallel to the axis of the tube in the as cut state, or may be at an angle to the axis of the metallic tube.

The struts that define the hoop may be parallel to the axis of the tube in the as cut state, or may comprise a helix which traces a pathway around the axis of the tube. Said helix may trace a pathway of not greater than 180 degrees around the axis of the tube.

The cross section of the tube may comprise four quadrants and the at least one first strut and the at least one second strut may be situated either in adjacent quadrants or in the same quadrant over at least a portion of their length in the as cut state.

The hoop may comprise at least one first strut and at least one second strut and said at least one first strut and said at least one second strut may meet at a junction element and said junction element may be at the end of said at least one first and second struts. The at least one first strut and the at least one second strut may be diametrically opposite when the frame is in the as cut state.

The cut pattern of the junction element may comprise a smooth inner curve and a smooth outer curve.

The at least one first strut and the at least one second strut and the junction element may comprise a common neutral axis of bending in the as cut configuration.

The shape defined by the neutral axis of the at least one first strut and at least one second strut may be substantially linear and the shape defined by the neutral axis of the junction element may be curved.

The radius of curvature of the neutral axis of the junction element may be greater when the junction element is in the expanded state than when the junction element is in the as cut state.

The frame may comprise a collar, one or more connector elements and a hoop, and said collar may be fixed to the elongate member. Said collar may be slidable relative to the elongate member, and said elongate member may comprise at least one stop to limit the translation of the collar.

The distal end of the elongate member may comprise a frame, or the elongate member may comprise a shaped section adjacent its distal end and said shaped section comprises the frame.

The elongate member may comprise a tube and the elongate member and the frame may be integral.

The elongate member may comprise a guidewire.

The bending stiffness of the elongate member may decrease along the length of the elongate member.

The elongate member may comprise a plurality of circumferential slots adjacent its distal end, said slots reducing the bending stiffness of the elongate member. The distance between said slots may vary along the length of the elongate member.

The elongate member may comprise at least one continuous helical slot adjacent the distal end of the elongate member to reduce the bending stiffness of the elongate member.

The bending stiffness of the elongate member may decrease gradually along the length of the distal segment of the elongate member. Also the diameter of the elongate member may be less in the distal segment than in the proximal segment.

The elongate member may comprise a solid wire, a wire with a coating, a wire and an outer tube, a wire and a outer coil, a tubular member and an inner core, a tubular member and an inner cable, or a tubular member and an inner tube.

The elongate member may be offset relative to the axis of the vessel when the frame is in the expanded configuration, or the elongate member may be substantially concentric with the axis of the vessel when the frame is expanded in the vessel, or the elongate member may be adjacent the wall of the vessel when the frame is in the expanded configuration in the vessel.

The frame may comprise a collapsed state for delivery through the vasculature to the vessel and an expanded state for removing the obstruction from the vessel. The expanded state of the frame may comprise a hoop.

The wire of the hoop may comprise a round wire, a square wire, a rectangular wire, an elliptical wire a flattened wire or a multifilament.

The elongate member may comprise a wire and the distal segment of said wire is formed into a hoop. The distal end of said wire may be fixed to the wire in order to close the hoop. The fixing of the wire distal end to the wire may comprise a weld joint, a solder joint, an adhesive joint, a bifilar joint, a coupling, a compression joint, a snap fit, or an interlock.

The hoop may comprise a single piece hoop cut from a metallic tube or from a metallic sheet.

The distal section of the elongate member may comprise a tube and said hoop may be integral with said tube.

The elongate member distal end may comprise a machined section. The elongate member distal end machined section may comprise a hoop.

The elongate member cross-section may comprise four quadrants and the hoop may comprise at least two struts, each extending from a separate quadrant. The first strut may extend from said first quadrant and said second strut extend from said third quadrant. The first and second struts may be diametrically opposite. The first strut may extend from said first quadrant and said

second strut may extend from said second quadrant. The first strut may extend from said first quadrant and said second strut may extend from said first quadrant.

The struts may comprise a plurality of net attachment features.

The hoop of the frame may be expanded by inserting a pin between the struts and heat treating the frame to set the shape. This pin diameter may be similar to the diameter of the target vessel.

The hoop may be cut from a large diameter tube, the diameter of which is similar to the diameter of the target vessel. Alternatively the hoop may be integral with the elongate member.

A plurality of connector elements may be attached to the hoop. This plurality of connector elements may be connected to the hoop at a series of spaced apart junction points around the circumference of the hoop and said spacings may be substantially equal.

In its expanded state the hoop may define an opening, and said opening may be elliptical or circular in shape, and may be similar in size to the cross-sectional area of the target vessel. The axis of the elongate member may pass through this opening created in the hoop in its expanded state.

The connector element may extend at least partially radially inward from the hoop and be connected to the collar, or the connector element may extend radially inward and proximally from the hoop and be connected to the collar, or the connector element may extend radially inward and distally from the hoop and be connected to the collar.

In the collapsed state the hoop may lie substantially parallel the elongate member, or may lie at an angle of approximately 90 degrees to the axis of the elongate member.

In the expanded state the hoop may make an angle of greater than 90 degrees to the axis of the elongate member, or may make an angle of less than 90 degrees to the axis of the elongate member. The angle between the hoop and the elongate member may be between 45 degrees and 135 degrees. The angle between the hoop and the elongate member may be between 60 degrees and 120 degrees. The angle between the hoop and the elongate member may be between 80 degrees and 100 degrees.

The hoop may comprise a number of struts wherein said struts are rectangular, square or circular in cross-section. The struts may be interconnected. These interconnections may be at the strut ends and said interconnections may comprise curved crown elements.

In the collapsed state said the curved crown elements may connect strut segments that are substantially parallel, or may connect strut segments that are angled relative to one another.

The hoop may comprise a plurality of curved segments. The plurality of curved segments of the hoop may be configured to from a single plane, or may be configured to form two planes with the curved segments interconnecting at a point of intersection of the planes.

The plurality of curved segments may comprise a plurality of struts and said plurality of struts may form a substantially circular hoop when viewed along the axis of the elongate member.

The frame may comprise at least two openings in the expanded state each opening defining an opening for the capture of clot. The two openings may comprise a circular shape.

Each opening may be defined by a strut section and a body strut section wherein the strut section comprises two radially projecting struts and the body strut section comprises a curved strut wherein the radius of curvature of said body strut section is substantially similar to the target vessel size for the device.

The body strut section may connect the ends of the two projecting radial struts. The two substantially parallel wires may be connected to each other at at least one end.

The elongate member may extend in use from the target vessel through the vasculature of the patient and further extend exterior of the patient.

The elongate member may comprise a distal end, said distal end may terminate adjacent the frame collar, or may terminate at the distal junction of the capture fibres. Or the distal end may terminate distal of said frame and net and comprise a soft atraumatic tip.

The elongate member may comprise an inner lumen said inner lumen may extend from the proximal end of the elongate member at least to an area adjacent the frame.

The elongate member may comprise an exit port, said exit port located in the distal region of the elongate member.

The elongate member may comprise an inner core and an outer tube. Said inner core may comprise a wire and said wire may comprise a tapered distal end. The inner core wire may comprise an atraumatic distal end.

The distal end of the inner core wire may be associated with the distal fibre junction. The fibre junction may be adjacent to the core wire. The fibre junction may be tethered to the core wire.

The fibre junction may be integral with the distal segment of the inner core, or may be moveable relative to the inner core, or may be moveable by the inner core.

The inner core may comprise a coil. This coil may be a radiopaque coil.

The frame may comprise at least one collar. The collars may be fixed relative to the elongate member, or the collars may be slidable relative to the elongate member.

The frame may comprise a first collar and a second collar. Said first collar may be fixed relative to the elongate member and said second collar may be slidable relative to said elongate member.

The collar may be integral with at least one first strut and the collar and first strut may comprise a collapsed state for delivery through the vasculature and an expanded state for capturing and removing said occlusive material.

The at least one integral collar strut may define an area of bending and said area of bending may comprise a relaxed state and a strained state wherein in the frame expanded state the area of bending is in the relaxed state and in the frame collapsed state the area of bending is in the strained state.

The frame may comprises at least one proximal connector strut and at least one distal connector strut where said at least one proximal connector strut is connected to the hoop at a point which is spaced apart from the point of connection of the at least one distal connector strut.

The cross-sectional dimensions of the connector struts may be different to the cross-sectional dimensions of the hoop struts.

The device may further comprise a third collar distal of previously mentioned first and second collars.

The frame may further comprise a formed collar wherein the collar comprises a C shaped section. This C shaped section may be formed by cutting a segment of the large diameter tube, and forming the tube section such that it's radius of curvature is greatly reduced and heat treating the section so as to permanently set the formed shape.

Any or all of these collars may comprise at least one longitudinal slot extending along at least a portion of the length of the collar, and / or at least one circumferential slot extending partially around the circumference of the collar.

The plurality of fibres may constitute a capture net, said net comprising a series of fibre segments arranged to create a three dimensional clot capture net. The net may be connected to the frame at a plurality of points or engagement features around the circumference of the frame.

The capture net may comprise a knitted, braided or crocheted structure, or may comprise a series of longitudinal fibre segments. This structure may comprise a tube. This tube may be cylindrical or conical in shape.

The net comprises an inner layer and an outer layer. The inner layer and the net outer layer may be integral

The net may be connected to the frame with a fibre. The net may partially encircle the frame.

The net may comprise a fibre junction wherein a plurality of fibre segments are connected. The capture net may comprise a series of fibre segments extending between the frame and this fibre junction. The fibre junction may be spaced apart from the frame and the fibre segments may define a basket for restraining clot that has been debonded from the vessel.

The clot capture system may have a capture net wherein the net comprises a proximal end and a distal end, the proximal end of the net being attached to the frame.The capture net may have a low density structure where the area ratio of the fibres to the capture net pores is <20%.

At least one of the plurality of high tensile fibres may have an ultimate tensile strength of at least 1500 MPa, or at least 2000 MPa, or at least 2500 MPa, or 3000 MPa or greater.

At least one of the plurality of high tensile fibres may comprise polymer fibers such as Ultra High Molecular Weight Polyethylene or Kevlar, or metal fibers such as 302 stainless steel, 304 stainless steel, other stainless steels, MP35N, L604, 35N LT, or Nitinol.

Wherein a metal fiber is used it may be cold worked to at least 50%.

An Ultra High Molecular Weight Polyethylene (UHMWPE) fiber may comprise a Dyneema, Celanese, Spectra or a Tekmilon fibre.

The frame may comprise a plurality of attachment points around its circumference, and the capture net may be secured to the frame at a plurality of points around the circumference of the frame.

The attachment features may be integral with the frame struts and comprise localised changes to the cross section of the struts. The localised change in cross section may comprise a hole in the

strut wherein the hole is circular, oblong, elliptical, curved and the hole may be in the centre of the strut or is offset. The hole may extend through the wall of the frame.

The localised change in cross section may comprise a notch, a recess, a depression, or a groove in the outer surface of the strut of the frame. The attachment points may comprise a plurality of such localised changes in cross section. The plurality of attachment points may be spaced equally around the circumference of the frame.

The plurality of attachment points may comprise holes in the struts and said holes may be less than 50 microns in diameter, or less than 30 microns in diameter, or less than 25 microns in diameter, or less than 20 microns in diameter.

The holes may not be fully cylindrical, but may be less than 50 microns in one dimension, or less than 30 microns in one dimension, or less than 25 microns in one dimension, or less than 20 microns in one dimension.

The frame and holes may be polished by a polishing process selected from sand blasting or electropolishing or chemical etching.

The device may further comprise a fibre junction where a plurality of fibre segment ends are connected. This fibre junction may comprise a knot, a weld, an adhesive joint, a site of attachment, a laminated junction, a coupling, a bonded joint or an assembly joint.

The device may further comprise a distal collar and said distal collar may comprise a junction for a number of fibres of the fibre net.

The distal collar may comprise a reception space and said reception space may be configured to restrain the ends of said fibre segments.

The distal collar reception space may comprise an annular space, said annular space sized to allow fibres to be received in the space.

The distal collar reception space may comprise at least one hole wherein said hole is sized to receive at least one fibre. The distal collar reception space may also comprise a plurality of holes, said plurality of holes being sized to receive one or more fibres.

The distal collar reception space may comprise a feature such as a hole, a groove or an annular space in the wall of the collar wherein said feature is sized to receive at least one fibre. This feature may also be located between the collar and the elongate member.

The device may comprise an expansion cable which may be connected to the frame and extend in use exterior of the patient.

The expansion cable may comprise a relaxed state and a tensioned state wherein in the relaxed state the expansion cable exerts no force on the frame and in the tensioned state the expansion cable exerts an expansion force on the frame. This expansion force may assist in the expansion of the frame.

The expansion cable in use may extend from exterior of the patient through a lumen in the elongate member, through an exit port located in the distal region of the elongate member and terminate at a point of connection with the frame.

The expansion cable may comprise a polymeric or metallic cable, and may be a monofilament or multifilament. The material of the expansion cable may be a polymer, such as a polyester, Ultra high molecular weight polyethylene, a fluoropolymer, a nylon, or Kevlar, or may be metallic such as a stainless steel or nitinol, or may be a mixture of the above or may possess similar properties to the above.

The frame may comprise an expanded configuration and a collapsed configuration and may be naturally biased towards the collapsed configuration and may further comprise a restraining system, which allows the frame to be stored in the collapsed state (during delivery) by interconnecting elements of the frame to one another.

The restraining system may comprise restraining one or more struts to each other.

The restraining system may comprise restraining a frame hoop in a collapsed state substantially parallel with the axis of the elongate member.

The elongate member may comprise an inner core extending distal of the collar of the frame, and the restraining system may comprise fixing the hoop to the inner core in a collapsed state.

The frame may comprise a supporting strut extending distally from the collar and substantially parallel to the axis of the collar, and the restraining system may comprise fixing the hoop to the supporting strut in a collapsed state.

The supporting strut may comprise an engagement feature allowing the supporting strut and the hoop and/or a connector element to be fastened to the supporting strut.

The device may further comprise a micro-delivery catheter comprising a reception space and a shaft. This reception space may extend proximally wherein the frame and net are configured to

be received in the reception space in the collapsed state for delivery to the site of occlusion. The reception space may comprise a tubular element.

The collar or collars of the frame may be mounted on a tubular member and the tubular member may be moveable relative to the guidewire. The tubular member may be connected to a control wire and said control wire may extend proximally to the user, allowing the user to move the frame relative to the guidewire, or the tubular member may extend proximally to the user, allowing the user to move the frame relative to the guidewire.

The frame of this invention may also compromise hinges and may comprise a plurality of struts with one or more hinges connecting at least a pair of said struts. The expansion of the frame from its collapsed state to its expanded state may comprise an articulation of one or more of these hinges. Said hinges may be configured to articulate without significant resistance.

The at least one pair of struts may comprise a first strut and a second strut and the first strut may comprise a first point wherein said first point is spaced apart from the hinge. The at least one hinge may be configured such that said first point is restricted to move through a segment of a substantially circular arc when said hinge is articulated. The at least one hinge may be configured such that said first point is restricted to move through a set of points defining a substantially spherical surface when said hinge is articulated.

The at least one hinge may each comprise a first strut and a second strut, the first and second struts comprising hinge attachment features and said first and second struts being coupled by a hinge coupling element.

The hinge attachment features may comprise a hole, a mounting, a loop, a cut profile or a formed shape.

The hinge coupling may comprise a monofilament fibre, a multifilament fibre, a pin, a loop, a C section, a ring, a tether, or an articulating coupling.

The hinge attachment feature may comprise a hole and the hinge coupling may comprise a fibre wherein said fibre is looped through the hole in said first and second struts so as to fix said struts to one another while allowing said struts to articulate in at least one direction.

The frame may comprise a hoop and at least one connector strut. This hoop may comprise a plurality of hoop struts. The at least one hinge may comprise a pair of hoop struts. The at least one hinge may comprise a hoop strut and a connector strut.

The frame may comprise a compound hinge wherein more than two struts are hinged relative to each other. The compound hinge may comprise three struts. The compound hinge may comprise two hoop struts and a connector strut.

The at least one connector strut may be connected to the elongate member. The connection between the connector strut and the elongate member may comprise a hinge. The connection between the connector strut and the elongate member may comprise a collar wherein said collar connects the connector strut to the elongate member.

The frame may comprise an arrangement of hinges and said hinges may comprise movement freedoms and movement constraints and said movement freedoms and movement constraints may be arranged such that the frame moves progressively between a collapsed state and an expanded state when activated and between an expanded state and a collapsed state when deactivated.

The frame may be expanded by advancing or retracting at least a part of the elongate member. The elongate member may be connected to at least one strut and advancing or retracting a portion of the elongate member may cause the articulation of the at least one hinge and the frame expands.

The elongate member may comprise a first portion and a second portion and the elongate member first portion may be connected to an at least one first strut and the elongate member second portion may be connected to at least one second strut and relative movement between the elongate member first portion and the elongate member second portion may cause expansion or collapse of the frame depending on the direction of relative motion.

The elongate member may comprise an inner shaft and an outer tubular member and said outer member may be slidable relative to said inner shaft. Movement of the outer tubular member relative to the inner shaft may cause the frame to expand and/or collapse.

Any of the frames disclosed herein may be expanded by the release of stored energy. Said stored energy may comprise the release of stored elastic energy wherein at least one element of the frame comprises an elastic component and said elastic component is restrained in a strained state during delivery. Upon removal of said constraint said elastic component relaxes to its unstrained state and in so doing the frame is expanded.

The elastic component may comprise a nitinol component, a shape memory component, an elastic component or a super-elastic component.

The elastic component may comprise a hoop strut, a connector strut, a connector or a combination of these elements or a junction between these elements.

This invention also comprises a clot debonding device which may be used in conjunction with the clot retrieval designs described herein. The clot debonding device is designed to assist in the removal of obstructions from a vessel by providing an abutment surface which may be used to appose one side of the obstruction so that a force may be applied to the other side of the obstruction without said force being transmitted to the vessel in which the obstruction is placed. It therefore enables a clot retrieval device or other similar device to more effectively engage and capture clot or other such vessel obstructions.

It will be appreciated that such a device also has applications beyond its use with the clot retrieval device described herein. Such a clot debonder may be effectively used to aid the disengagment and removal of vessel obstructions in conjunction with other clot retrieval devicesor thrombectomy devices or aspiration devices.

The invention further provides a clot capture system for disengaging a clot from a vessel wall and removing the clot from the vessel, the clot capture system comprising:- a clot capture device for placement on a distal side of a clot, the clot capture device having a retracted delivery configuration and an expanded deployed configuration; and a clot debonding device for placement on a proximal side of a clot, the clot debonding device having a retracted delivery configuration and an expanded deployed configuration and comprising a clot engagement element which defines a distal abutment in the deployed configuration for urging a clot into the clot capture device.

It will be understood that the above mentioned clot capture device may be any of the clot retrieval device embodiments previously described herein, and the clot capture system may comprise any combination of the permutations described below with those of the clot retrieval devices described above.

The abutment area of the clot debonding device may be configured to engage with the clot in its expanded configuration. The engagement of the abutment area with the clot may comprise a relative movement between the abutment area and the clot and said relative movement may at least partially disengage the clot from the vessel. The relative movement between the abutment area and the clot may comprise an axial movement or a rotational movement or a combination of both movements of the abutment area.

The clot retrieval device may be configured to engage the clot from a distal end and the clot debonding device may be configured to engage the clot from a proximal end. The clot debonding device may thus be configured to apply a debonding force to the clot to disengage the clot from the vessel, and the clot retrieval device may be configured to apply a reaction force to the clot wherein the reaction force is applied substantially in the opposite direction to the debonding force and the combination of said forces disengages the clot from the vessel wall.

The clot retrieval device may comprise an engagement element and a reception space said engagement element may be configured to engage the clot from a distal end and said reception space may be configured to receive said disengaged clot and to allow the removal of said clot from the vasculature.

The clot debonding device may be configured to at least partially protect the blood vessel from the forces of clot debonding.

The clot engagement element may extend substantially the width of the mouth of the capture device in the deployed configuration.

The clot debonding device is movable relative to the clot capture device in the deployed configuration.

The clot engagement element may have a longitudinal axis and the distal abutment may extend radially of the longitudinal axis. The longitudinal axis may be a substantially central axis and the distal abutment may extend radially outwardly of the substantially central axis, or the longitudinal axis may be an offset axis and the distal abutment may extend radially outwardly of the offset axis.

The engagement element may comprise an axially extending region and a radially extending region. The engagement element may further comprise a circumferential region extending from the radial region. The engagement element may also comprise a transition region between the axial region and the radial region.

The clot debonding device may comprise an axially extending collar.

The clot capture device may define an inlet mouth in the deployed configuration and the clot engagement element may extend substantially the width of the inlet mouth of the clot capture device.

The clot debonding device may be slidable relative to the clot capture device.

The clot debonding device may be rotatable relative to the clot capture device.

In the deployed configuration, the clot capture device may be located distal of the clot debonding device.

The clot capture device and the clot debonding device may be independently movable.

The clot capture system may comprise an elongate member. The clot capture system may comprise a first elongate member associated with the clot capture device. The clot capture system may comprise a second elongate member associated with the clot debonding device. The first elongate member may comprise a guidewire, and said guidewire may comprise a stop. This stop may comprise a distal stop.

The second elongate member may comprise a proximal shaft. The clot debonding device may be mounted to the proximal shaft. The clot bonding device may be fixedly mounted to the proximal shaft.

The clot capture system may comprise a delivery catheter for the clot capture device.

The system may further comprise a first access catheter and a second access catheter, the distal end of said first access catheter being placed in a proximal vessel and the distal end of said second access catheter being placed in a distal vessel wherein the second access catheter is delivered to said distal vessel through the lumen of said first access catheter. Said first access catheter may comprise a guide catheter or a guide sheath and said second access catheter may comprise a delivery catheter or a microcatheter, wherein the clot retrieval device is configured to be delivered through the second access catheter.

The clot debonding device may comprise a lumen extending from its distal end and a proximal shaft connected either directly or by a collar to the expandable engagement element. The clot debonding device may be configured as a rapid exchange catheter.

The distal end of the clot debonding device may comprise an abutment surface in the collapsed state for advancement of the clot retrieval basket through a catheter lumen.

The expandable engagement element may expand radially outward from a central axis and may comprise an inflatable element, a self expanding element, a shape memory element, a super elastic element, a remotely activated element, a coil or spring element.

The expandable engagement element may comprise a balloon, an inflatable cuff, a plurality of struts, a slotted section, a cell structure, a plurality of wire segments, a helical coil, a flare, a ring, a braided section, or a hoop.

The expandable engagement element may comprise a slotted tubular member, or a number of overlapping coaxial slotted tubular members. The slotted tubular members may be self

expanding or may be expanded by retraction of an actuation element connected to their distal end.

The expandable engagement element may comprise elements which expand into a generally helical configuration, such as a coiled element which at least partially uncoils to expand from one diameter to a second larger diameter.

The expandable engagement element may comprise a number of curved wire struts or segments, which may have points of inflection, and/or which may be configured to create closed or open cells, or a mixture of both.

The expandable engagement element of the clot debonder may be made from a shape memory alloy or a super elastic alloy such as Nitinol, or from another metal such as stainless steel, or from a polymer such as PEEK, Nylon, PE or Polyimide.

The expandable engagement element may comprise a plurality of struts or segments cut from a tube. Said struts or segments cut from a tube with slots that run substantially parallel to the longitudinal axis of the tube, or with slots that are not parallel to the longitudinal axis of the tube. Said struts or segments may overlap or may be non non-overlapping.

The engagement element may comprise a collapsed state wherein the engagement struts are aligned with the axis of the clot debonder and said plurality of struts comprise a tubular structure.

Said plurality of struts may be close packed in the delivery configuration.

In the expanded state the engagement element is preferably configured to transmit axial force of the user to the clot. The engagement element may comprise an engagement surface and said engagement surface may comprise a distally facing surface. In one embodiment the engagement surface comprises an annular surface. With this embodiment the engagement surface may have an outer diameter and an inner diameter. The outer diameter may be substantially the same or smaller than the diameter of the vessel. The outer diameter may be substantially the same or smaller than the diameter of the clot. The inner diameter may be substantially the same or larger than the diameter of the guidewire.

In one embodiment the engagement surface comprises a flared surface. In another embodiment the engagement surface comprises a plurality of struts said struts configured to apply pressure to the clot over a substantial portion of the cross-section of the vessel. In one embodiment the engagement surface is configured to apply an axial displacement to the entire body of the clot. The engagement surface of the clot debonding device may be configured to prevent clot fragmentation during debonding and capture.

In one embodiment the engagement element comprises a plurality of elongate struts. In the delivery configuration the elongate struts may be substantially aligned with the axis of the vessel. In the expanded configuration the struts may project radially outward from the axis of the clot debonder. In one embodiment the struts are interconnected. The struts may comprise regions of bending.

In one embodiment the struts of the engagement element comprise an outer ring member and a plurality of radial struts connected to said outer ring member. In another embodiment the strut arrangement of the engagement element comprises a plurality of cells. Each cell boundary may be defined by a strut. In another embodiment the engagement element comprises an outer ring member. The outer ring may comprise a plurality of struts configured in a circumferential ring. The engagement element may comprise an inner ring member. The inner ring member may be connected to or separate of the outer ring member. In one embodiment the outer ring member is connected to the collar by a plurality of radial struts. In one embodiment the outer ring member comprises a plurality of zig zag strut elements.

In one embodiment the struts are cut from a nitinol tube. The tube may comprise a cut pattern. The cut pattern may comprise a plurality of longitudinal slots and a plurality of struts. In one embodiment the cut pattern comprises a plurality of curved segments interconnecting said struts.

In another embodiment the engagement element comprises a plurality of wires. The wires may comprise a collapsed state and an expanded state. In the collapsed delivery state the wires may be substantially aligned with the axis of the vessel. In the expanded state the wires may project radially outwardly of the axis of the clot debonding device.

In the fully expanded state the engagement element may comprise an outer rim. The outer rim may comprise a plurality of curved segments.

In another embodiment the engagement element comprises a plurality of shaped wires. Each shaped wire may comprise a first wire end and a second wire end. The first wire ends and second wire ends may be fixed to a tubular member. The wire segment may comprise a first radial curve adjacent the collar and a second circumferential curve. The circumferential curve in the wire may comprise an atraumatic vessel interface.

In one embodiment the engagement element comprises an axial strut segment, a curved strut segment and a radial strut segment. With this embodiment the engagement element may be connected to a tubular member at the proximal end of the axial strut section. The struts of the axial segment may be oriented substantially parallel to the axis of the clot debonding device.

The engagement element may comprise an immediate segment distal of the axial segment. The intermediate segment may comprise the radial curve. The intermediate section may comprise most of the engagement surface. The intermediate section may provide a high area surface for the transmission of force to the clot.

The clot debonding element may be designed to transmit force over the entire surface of the clot. The clot debonding element may be configured to debond the clot in one piece. The clot debonder may be configured such that the clot does not snag on its surface. The clot debonder may be configured to push the clot into the opening of the clot capture basket.

The clot debonder engagement element may be configured such that upon withdrawal it disengages from the clot without snagging, or fragmenting the clot and without removing the clot from the capture basket.

The connection between the wire and the collar may be configured so as to orient the wire parallel to the axis of the clot debonding device. The connection between the collar and the wire may comprise a hole in the collar. Immediately distal of the collar the wire may comprise a curve. The wire may be radially curved so as to create an abutment surface. The body of the wire may be substantially radial relative to the axis of the clot debonder. The clot engagement element may comprise a plurality of radial wire segments configured to deliver and distribute pressure to one face of the clot. The wires may comprise a second curved segment. This second curved segment may define an outer rim of the clot engagement element. The curved segment may also present an atraumatic surface to the vessel. This second curved segment may be curved in the circumferential direction.

The clot engagement element may comprise radial and circumferential engagement elements and may transmit force to the clot in a manner similar to that of a piston.

In another embodiment the struts or wires of the engagement element comprise an articulation region. The engagement element may assume the expanded state by an articulation of the struts or wires about the articulation region.

The invention also provides a method for removing clot from a vessel involving a clot capture device that comprises a frame, a net and an elongate member such as a wire and is capable of being advanced through a microcatheter comprising the steps of: advancing a crossing guidewire through the vasculature and across the clot,advancing a microcatheter over the guidewire such

that the tip of the microcatheter is across the clot, removing the crossing guidewire from the microcatheter, advancing through the lumen of the microcatheter a collapsed clot capture device, deploying the clot capture device distal of the tip of the microcatheter, expanding the clot capture device distal of the microcatheter, retracting the clot capture device and engaging with the clot, applying a force to the clot over at least a portion of the outer circumference of the clot, applying shearing forces to the clot, disengaging the clot from the wall of the vessel, capturing the clot within the clot capture basket, removing the clot capture basket and the clot from the patient and taking a final angiogram of the recannalized vessel.

The step of removing the clot capture basket may comprise at least partially collapsing the basket and/or applying compressive forces to the clot.

The clot capture device may comprise a frame, a wire and a net wherein the frame is expandable and the net is attached to the frame and the frame is at least partially fixed to the guidewire.

The invention provides a further method for removing clot from a vessel involving a clot capture device that comprises a frame and a net and is capable of being advanced through a microcatheter and is further advancable relative to a guidewire comprising the steps of: advancing a guidewire through the vasculature and across the clot, advancing a microcatheter over the guidewire such that the tip of the microcatheter is across the clot, advancing the frame and net in a collapsed state over the guidewire, deploying the frame and net from the distal end of the microcatheter, expanding the frame and net distal of the clot, retracting the frame and net and engaging with the clot, applying a force to the clot over at least a portion of the outer circumference of the clot, applying shearing forces to the clot, disengaging the clot from the wall of the vessel, encircling at least a portion of the clot with the frame, restraining fragments of the clot with the net, removing the frame and net from the patient and taking a final angiogram of the recannalized vessel.

The clot capture device may comprise an advancement element and the step of advancing the frame and net over the guidewire may comprise advancing the advancement element parallel of and relative to the guidewire.

The invention provides a further method for removing clot from a vessel involving a clot capture device that comprises a frame, a net and an elongate wire and is capable of being advanced through a guide catheter comprising the steps of: advancing a guidewire through the vasculature and across the clot, advancing a guidecatheter into the target vessel and positioning the tip of the

guidecatheter proximal of the clot, advancing the clot capture device in a collapsed state through the guidecatheter, advancing the frame and net and the distal portion of the elongate wire across the clot, deploying the frame and net distal of the clot, expanding the frame and net distal of the clot, retracting the elongate wire with the frame and net attached, applying a force to the clot over at least a portion of the outer circumference of the clot, disengaging the clot from the wall of the vessel ,encircling at least a portion of the clot with the frame, restraining fragments of the clot with the net, removing the frame and net from the patient, taking a final angiogram of the recannalized vessel.

The invention also provides a further method for removing clot from a vessel involving a clot capture device that comprises a basket and a debonding element, the capture basket comprising a collapsed state for delivery through the vasculature and an expanded state for the capture of clot, the clot debonding element comprising a collapsed delivery state and an expanded state the method comprising the steps of: advancing a guidewire through the vasculature and across the clot, advancing a microcatheter over the guidewire such that the tip of the microcatheter is across the clot, advancing the basket through the microcatheter, deploying the basket from the distal end of the microcatheter, expanding the basket distal of the clot, retracting the microcatheter until the tip of the micro catheter is proximal of the clot, retracting the basket and engaging with the clot, advancing the clot debonder through the microcatheter, deploying the clot debonder proximal of the clot, advancing the clot debonder to engage with the clot from the proximal side, retracting the basket while holding the clot debonder steadfast, disengaging the clot from the wall of the vessel without applying force to the vessel wall distal of the occlusion, disengaging the clot from the wall of the vessel, encircling at least a portion of the clot with the frame, retracting the clot debonder, collapsing the clot debonder inside the lumen of the microcathater, restraining fragments of the clot with the basket, removing the basket and the clot from the patient and taking a final angiogram of the recannalized vessel.

The above methods may include applying a force to the clot over at least a portion of the outer circumference of the clot, and/or applying shearing forces to the clot and/or collapsing the clot debonder inside the lumen of the guidecatheter and/or expanding the clot debonder at the distal end of the microcatheter.

The step of expanding the clot debonder may comprise inflating the clot debonder, or inflating a sac at the distal end of the clot debonder.

The step of expanding the clot debonder may comprise removing an outer restraint from clot debonder and allowing the clot debonder to self-expand. The step of removing this restraint may comprise removing a pod from over the clot debonder.

The step of removing the restraint may comprise retracting the distal end of the microcatheter from over the clot debonder.

The invention further discloses a method for removing clot from a vessel comprising the steps of: providing a clot capture device comprising a basket and a debonding element, the capture basket comprising a collapsed state for delivery through the vasculature and an expanded state for the capture of clot, the clot debonding element comprising a collapsed delivery state and an expanded state; advancing the basket through the vasculature in the collapsed state; deploying the basket distal of the clot; advancing the clot debonder through the vasculature; deploying the clot debonder proximal of the clot; engaging the basket and/or the clot debonder with the clot; disengaging the clot from the wall of the vessel; capturing the clot in the basket; and removing the clot from the vasculature.

Brief Description of the Drawings

The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which: -

Fig. 1 shows a patient catheterized via femoral access with a clot retrieval device positioned in a cerebral vessel using the arterial system for its delivery;

Fig. 2 shows some of the anatomy of arteries above the aortic arch leading to the brain;

Fig. 3a shows part of the cerebral circulation with an obstructive clot positioned in the Anterior Cerebral Artery, distal of the Middle Cerebral Artery branch;

Fig. 3b shows a guidewire being placed across the obstructive clot;

Fig. 3c shows a micro-catheter with the clot retrieval device of the invention crossing the obstructive clot;

Fig. 3d shows the micro-catheter removed with the clot retrieval device placed distal of the obstructive clot;

Fig. 3e shows the clot retrieval device being advanced proximally and capturing the obstructive clot with a removal catheter advanced from the proximal side;

Fig. 3f shows the clot retrieval device, the captured occlusive clot and the removal catheter being removed from the vessel;

Fig. 3g shows the target vessel with the obstructive clot and devices completely removed;

Fig. 4a shows a target vessel with an occlusive clot;

Fig. 4b shows a guidewire with its distal tip across the obstructive clot;

Fig. 4c shows a micro-catheter advanced over the guidewire until its distal end is across the obstructive clot;

Fig. 4d shows the preplaced micro-catheter with its distal end across occlusive clot and a clot retrieval device being advanced through its inner lumen;

Fig. 4e shows clot retrieval device deployed distal of occlusive clot with the micro-catheter being withdrawn, the clot retrieval device being connected to a wire and the proximal end of the wire exiting the patient and being controlled by a physician;

Fig. 4f shows the clot retrieval device deployed distal of the occlusive clot;

Fig. 4g shows the clot retrieval device being advanced proximally and capturing the obstructive clot with a removal catheter advanced from the proximal side;

Fig. 4h shows the clot retrieval device, the captured occlusive clot and the removal catheter being removed from the vessel;

Fig. 4i shows the target vessel with the obstructive clot and devices completely removed;

Fig. 5a shows a target vessel with an occlusive clot;

Fig. 5b shows a micro delivery catheter with a clot retrieval device collapsed within a distal lumen of the micro delivery catheter, the micro delivery catheter being advanced

across the occlusive thrombus, the clot retrieval device having a guidewire that extends proximally and distally;

Fig. 5c shows the micro delivery catheter being removed with the clot retrieval device deployed in the target vessel distal of the occlusive clot with the guidewire extending across the lesion and proximal to the user;

Fig. 5d shows the clot retrieval device deployed in the target vessel distal of the occlusive clot with the guidewire extending across the lesion and proximal to the user;

Fig. 5e shows the clot retrieval device being advanced proximally and capturing the obstructive clot with a removal catheter advanced from the proximal side;

Fig. 5f shows the clot retrieval device, the captured occlusive clot and the removal catheter being removed from the vessel;

Fig. 5g shows the target vessel with the obstructive clot and devices completely removed;

Fig. 6 is a detailed view of the distal end of a clot retrieval device in its expanded clot capture state;

Fig. 7a shows a clot retrieval device in its expanded capture state;

Fig. 7b shows the clot retrieval device of Fig. 7a inside a micro delivery catheter in its collapsed delivery state;

Fig 8a shows a clot retrieval device frame constructed from a guidewire;

Fig 8b shows a clot retrieval device frame attached to a guidewire;

Fig 8c shows a clot retrieval device frame mounted between stops on a guidewire;

Fig 8d shows a clot retrieval device frame connected to a tubular element mounted proximal to a stop on a guidewire;

Fig 8e shows a clot retrieval device frame connected to a tubular element mounted a guidewire;

Fig 8f shows a clot retrieval device frame connected to a tubular element with an exit port and proximal shaft, mounted on a rapid exchange guidewire;

Fig 9a shows the frame of a clot retrieval device in the expanded state;

Fig 9b shows the frame of a clot retrieval device in the expanded state;

Fig 9c shows the frame of a clot retrieval device in the expanded state;

Fig 9d shows the frame of a clot retrieval device in the expanded state;

Fig 9e shows the frame of a clot retrieval device in the expanded state;

Fig 9f shows the frame of a clot retrieval device in the expanded state;

Fig 9g shows the frame of a clot retrieval device in the expanded state;

Fig 9h shows the frame of a clot retrieval device in the expanded state;

Fig 9i shows the frame of a clot retrieval device in the expanded state;

Fig. 10 shows a clot retrieval device in its expanded state;

Fig. 11a shows a clot retrieval device in its expanded capture state;

Fig. 11b shows the clot retrieval device of Fig. 11a inside a micro delivery catheter in its collapsed delivery state with the capture fibers removed (for illustration);

Fig. 11c shows the clot retrieval device of Fig. 11a inside a micro delivery catheter in its collapsed delivery state;

Fig. 12a shows a clot retrieval device in its expanded capture state without capture fibers being shown (for illustrative purposes);

Fig. 12b shows a clot retrieval device of Fig. 12a inside a micro delivery catheter in its collapsed delivery state with the capture fibers removed (for illustration);

Fig. 13 shows a clot retrieval device in its expanded state;

Fig 13a shows a view of a collar and strut arrangement for use with a number of frame designs of the invention;

Fig. 13b shows another view of a collar and strut arrangement for use with a number of frame designs on the invention;

Fig. 13c shows an end view of a collar and strut arrangement for use with a number of frame designs of the invention with the strut in its collapsed state;

Fig. 13d shows an end view of a collar and strut arrangement for use with a number of frame designs on the invention with the strut in its expanded state;

Fig. 14 shows a distal collar mounted on a guidewire with eyelets for fiber alignment and/or attachment;

Fig. 15 shows a distal collar with eyelets for fiber alignment and/or attachment;

Fig. 16 shows a distal collar mounted on a guidewire with eyelets for fiber alignment and/or attachment;

Fig. 17 shows a distal collar mounted on a guidewire with eyelets for fiber alignment and/or attachment;

Fig. 18 shows a clot retrieval device in the deployed configuration distal of an occlusive clot;

Fig. 19 shows a clot retrieval device being withdrawn proximally to capture a clot;

Fig. 20a shows a first side view of a strut of the hinged frame of a clot retrieval device;

Fig. 20b shows a second side view of a strut of the hinged frame of a clot retrieval device;

Fig. 20c shows a strut of the hinged frame of a clot retrieval device. The strut has a preset curved shape;

Fig. 20d shows the joining of the ends of two struts in the construction of a hinged frame;

Fig. 20e shows a hinged frame with four struts forming a ring and four support elements supporting the frame;

Fig. 20f shows four struts of a hinged support frame configured into a ring;

Fig. 20g shows how the hinged support frame can collapse about the X axis;

Fig. 20h shows how the hinged support frame can collapse about the Y axis;

Fig. 21 shows an enlarged view of a hinged support frame with eyelets for fiber attachment;

Fig. 22a shows a clot retrieval device with a hinged frame in the expanded configuration;

Fig. 22b shows a clot retrieval device with a hinged frame in the partially collapsed configuration

Fig. 22c shows a clot retrieval device with a hinged frame in the fully collapsed configuration;

Fig. 23a shows a clot retrieval device with a hinged frame in the expanded configuration;

Fig. 23b shows a clot retrieval device with a hinged frame in the partially collapsed configuration;

Fig. 23c shows a clot retrieval device with a hinged frame in the fully collapsed configuration;

Fig. 24a shows a clot retrieval device with a hinged frame in the fully expanded configuration;

Fig. 24b shows a clot retrieval device with a hinged frame in the partially collapsed configuration;

Fig. 24c shows a clot retrieval device with a hinged frame in the fully collapsed configuration;

Fig 25a shows a section of a strut of a clot retrieval device;

Fig 25b shows a section of a strut of a clot retrieval device;

Fig 25c shows a section of a strut of a clot retrieval device;

Fig 25d shows two sections of two adjacent struts of a clot retrieval device nesting together;

Fig. 26a shows an eyelet for capture fibre attachment to a strut;

Fig. 26b shows an eyelet for capture fibre attachment to a strut;

Fig. 26c shows an eyelet for capture fibre attachment to a strut;

Fig. 26d shows an eyelet in a strut section with a capture fibre in situ;

Fig. 26e shows an eyelet in a strut section with a capture fibre in situ;

Fig. 26f shows an eyelet in a strut section with a capture fibre in situ;

Fig. 27a shows a cross section of a strut with a capture fibre threaded through an eyelet;

Fig. 27b shows a strut with a capture fibre threaded through an eyelet;

Fig. 27c shows a cross section of a strut with a capture fibre threaded through an eyelet;

Fig. 27d shows a strut with a capture fibre threaded through an eyelet;

Fig. 28a shows a segment of a strut of a clot retrieval device;

Fig. 28b shows a cross section of a strut;

Fig. 28c shows a fixture for assembling capture fibres to struts;

Fig 29a shows two eyelets for capture fibre attachment to a strut;

Fig 29b shows an eyelet for capture fibre attachment to a strut;

Fig 29c shows an eyelet for capture fibre attachment to a strut;

Fig 29d shows a strut with curvature to define a capture fiber attachment location;

Fig 29e shows a strut with raised features to define a capture fiber attachment location;

Fig 29f shows a strut with recessed features to define a capture fiber attachment location;

Fig 29g shows a strut with recessed features to define a capture fiber attachment location;

Fig 29h shows a strut with bands to define a capture fiber attachment location;

Fig 29i shows a strut with coils to define a capture fiber attachment location;

Fig 30a shows a strut with a sleeve to create a capture fiber attachment location;

Fig 30b shows a strut with a coating to create a capture fiber attachment location;

Fig 30c shows a strut and a capture net with a connecting fiber joining the two;

Fig 30d shows a strut and a capture net with connecting rings joining the two;

Fig 30e shows a strut and a capture net with a connecting fiber joining the two;

Fig 31a shows a capture net of a woven or braided construction;

Fig 31b shows a capture net of a knitted construction;

Fig 31c shows a sectional side view of the capture net of fig31a or fig 31b inverted and mounted on a frame;

Fig 32a shows a monofilament capture fiber;

Fig 32b shows a multifilament twisted capture fiber;

Fig 32c shows a multifilament braided capture fiber;

Fig 32d shows a multifilament capture fiber with a cover sleeve;

Fig 32e shows a multilayer capture fiber;

Fig 33a shows a frame with a capture net with a porosity gradient;

Fig 33b shows a frame with a capture net with a porosity gradient;

Fig 33c shows a frame with capture fibers with a porosity gradient;

Fig 33d shows a frame with capture fibers with a stiffening fiber;

Fig. 34a shows a clot retrieval device in the fully expanded configuration;

Fig. 34b shows a clot retrieval device in the collapsed configuration inside a catheter;

Fig. 34c shows a ring and guidewire of a clot retrieval device;

Fig. 34d shows a ring and guidewire of a clot retrieval device;

Fig. 34e shows a portion of a guidewire of a clot retrieval device;

Fig. 34f shows a portion of a guidewire of a clot retrieval device;

Fig. 35a shows a vessel with an obstructive clot;

Fig. 35b shows a clot retrieval device crossing an obstructive clot;

Fig. 35c shows a clot retrieval device being deployed in a vessel;

Fig. 35d shows a clot retrieval device deployed in a vessel;

Fig. 35e shows a clot retrieval device fully expanded in a vessel;

Fig. 35f shows a clot retrieval device capturing an obstructive clot;

Fig. 35g shows a clot retrieval device being collapsed;

Fig. 35h shows a clot retrieval device partially collapsed;

Fig. 35i shows a clot retrieval device being removed from a vessel;

Fig. 36a shows a clot retrieval device in the expanded configuration;

Fig. 36b shows a clot retrieval device in the collapsed delivery configuration;

Fig. 37a shows a conventional guidewire;

Fig. 37b shows a portion of a guidewire modified to create a clot retrieval device;

Fig. 37c shows a clot retrieval device in the expanded state;

Fig 37d shows a clot retrieval device in the collapsed delivery configuration;

Fig 37e shows an end view of a clot retrieval device;

Fig 38a shows a portion of a guidewire modified to create a clot retrieval device;

Fig 38b shows a portion of a guidewire modified to create a clot retrieval device;

Fig 38c shows a cross sectional view of a guidewire modified to create a clot retrieval device;

Fig 39a shows an end view of a clot retrieval device;

Fig 39b shows a clot retrieval device in the expanded configuration;

Fig 39c shows a clot retrieval device in the collapsed delivery configuration;

Fig 40a shows an end view of a clot retrieval device;

Fig 40b shows a clot retrieval device in the expanded configuration;

Fig 41a shows an end view of a clot retrieval device;

Fig 41b shows a clot retrieval device in the expanded configuration;

Fig 42a shows an end view of a clot retrieval device;

Fig 42b shows a clot retrieval device in the expanded configuration;

Fig 43a shows a clot retrieval device in the expanded configuration;

Fig 44a shows an end view of a frame design of a clot retrieval device;

Fig 44b shows a view of a portion of frame of a clot retrieval device;

Fig 44c shows a clot retrieval device in the expanded configuration;

Fig 44d shows a clot retrieval device in the delivery configuration;

Fig 45a shows an end view of a frame design of clot retrieval device;

Fig 45b shows a view of a portion of frame of a clot retrieval device;

Fig 45c shows a clot retrieval device in the expanded configuration;

Fig 46 shows a clot retrieval device in the expanded configuration;

Fig. 47a shows a clot retrieval device in the expanded configuration;

Fig. 47b shows a clot retrieval device in the partially collapsed configuration;

Fig. 47c shows a clot retrieval device in the delivery configuration;

Fig 47d shows a view of a portion of frame section of a clot retrieval device;

Fig 48a shows a clot retrieval frame mounted on a guidewire;

Fig 48b shows the device of fig 48a and a delivery device housed in a microcatheter;

Fig 49a shows a clot retrieval device and a delivery catheter;

Fig 49b shows the device of fig 49a loaded within its delivery catheter;

Fig 50a shows a clot retrieval device;

Fig 50b shows the device of fig 50a loaded within a catheter;

Fig 50c shows the device of fig 50a partially withdrawn into a retrieval catheter;

Fig 51a shows a clot retrieval device positioned over a full length guidewire;

Fig 51b shows a clot retrieval device positioned over a rapid exchange length guidewire;

Fig. 52a shows a clot retrieval device;

Fig. 52b shows a guidewire of the clot retrieval device of fig 2a;

Fig. 53 shows another clot retrieval device;

Fig. 54 shows a frame cut from a hypotube for use as the frame of a clot retrieval device;

Fig. 55a shows another clot retrieval device delivered through a microcatheter;

Fig. 55b shows another clot retrieval device delivered through a microcatheter;

Fig. 56 shows a detailed view of the distal end of a clot retrieval device and a microcatheter delivery system;

Fig. 57 shows a detailed view of the distal end of another clot retrieval device and a microcatheter delivery and retrieval system;

Fig. 58a shows a detailed view of the distal end of another clot retrieval device and a microcatheter delivery and retrieval system;

Fig. 58b shows a detailed view of the clot retrieval device of Fig. 58a in another configuration;

Fig. 59a shows a guidewire with a step at the distal, the tip of the guidewire is placed in a vessel (not shown);

Fig. 59b shows a microcatheter being advanced over the guidewire;

Fig. 59c shows the clot retrieval device being delivered through the microcatheter and over the wire, a clot debonding device is also being advanced through the microcatheter;

Fig. 59d shows the clot retrieval device deployed from the distal end of the microcatheter and expanded in the vessel (not shown);

Fig. 59e shows the clot retrieval device deployed from the distal end of the microcatheter and the microcatheter advanced proximally;

Fig. 59f shows the clot debonding element deployed from the microcatheter;

Fig. 59g shows the clot debonding element retrieved back into the distal end of the microcatheter;

Fig. 59h shows the clot retrieval device collapsed back into the pod of the microcatheter;

Fig. 60 shows an end view of a clot debonding element;

Fig 61a shows a side view of an unexpanded clot debonding element;

Fig 61bshows a side view of the expanded clot debonding element from fig 61a;

Fig 61c shows an end view of the expanded clot debonding element from fig 61a;

Fig. 62a shows an end view of another clot debonding element;

Fig. 62b shows a side view of a clot debonding device;

Fig. 62c shows a side view of another clot debonding device;

Fig. 62d shows a side view of yet another clot debonding device;

Fig. 62e shows a side view of an alternative clot debonding device;

Fig 63a shows a side view of the end of an unexpanded clot debonding catheter;

Fig 63b shows a side view of the end of an expanded clot debonding catheter from fig 63a;

Fig 64a shows a side view of the end of an unexpanded clot debonding catheter;

Fig 64b shows a side view of the end of an expanded clot debonding catheter from fig 64a;

Fig 65a shows a side view of the end of an unexpanded clot debonding catheter;

Fig 65b shows a side view of the end of an expanded clot debonding catheter from fig 65a;

Fig 66a shows a side view of the end of an unexpanded clot debonding catheter;

Fig 66b shows a side view of the end of a partially expanded clot debonding catheter from fig 66a;

Fig 66c shows an end view of the expanded clot debonding catheter from fig 66a;

Fig 67a shows a side view of the end of an unexpanded clot debonding catheter;

Fig 67b shows an end view of the expanded clot debonding catheter from fig 67a;

Fig 68a shows a side view of the end of an unexpanded clot debonding catheter;

Fig 68b shows a side view of the end of a partially expanded clot debonding catheter from fig 68a;

Fig 68c shows an end view of the expanded clot debonding catheter from fig 68a;

Fig 69a shows the clot debonding catheter from fig 68a mounted over a microcatheter prior to deployment proximal to a clot and clot retrieval device;

Fig 69b shows the clot debonding catheter from fig 69a post deployment;

Fig. 70 shows a clot retrieval device in the deployed configuration distal of an occlusive clot;

Fig. 71 shows a collector device being used with a clot retrieval device;

Fig. 72 shows a collector device with deployed elements being used to advance clot into a clot retrieval device;

Fig. 73 shows the collector device in an advanced position with most of the clot inside the clot retrieval device;

Fig. 74 shows an alternative clot advancement device;

Fig. 75 shows a clot advancement device with two coil elements;

Fig. 76a shows a side view of another clot advancement device;

Fig. 76b shows an end view of the clot advancement device of Fig. 76a;

Fig. 77 shows another clot retrieval device with an integral clot debonding element;

Fig. 78a shows an artery or vein with an occlusive clot acutely lodged in the vessel, the occlusive clot reduces or prevents distal blood flow;

Fig. 78b shows the occlusive clot of Fig. 78a with platelets being activated at the site of occlusion;

Fig 78c shows bonds formed between the occlusive clot and the vessel wall;

Fig 79a shows a vein or artery with an occlusive clot lodged therein;

Fig. 79b shows an occlusive clot with the tip of a guidewire advanced across the occlusive clot;

Fig. 79c shows a microcatheter advanced over the guidewire such that its tip is distal of the occlusive clot;

Fig. 79d shows the microcatheter tip distal of the occlusive clot with the guidewire removed;

Fig. 79e shows a clot retrieval device being advanced through the lumen of the microcatheter;

Fig. 79f shows the clot retrieval device expanded with the microcatheter partially withdrawn;

Fig. 79g shows a clot debonding element advanced through the microcatheter and in the deployed state;

Fig. 79h shows the clot being engaged by both the clot retrieval device and the clot debonding element;

Fig. 79i shows the clot captured in the net of the clot retrieval device with the clot debonding element removed through the lumen of the microcatheter;

Fig. 79j shows the clot retrieval device with the frame partially collapsed and the clot captured in the net;

Fig. 79k shows the clot retrieval device, the microcatheter and the captured clot being removed from the vessel;

Fig. 79l shows the vessel recannalized;

Fig 80a shows a vein or artery with an occlusive clot lodged therein;

Fig. 80b shows an occlusive clot with the tip of a guidewire advanced across the occlusive clot;

Fig. 80c shows a microcatheter advanced over the guidewire such that its tip is distal of the occlusive clot;

Fig. 80d shows the microcatheter tip distal of the occlusive clot with the guidewire removed;

Fig. 80e shows a stepped guidewire advanced through the lumen of the microcatheter;

Fig. 80f shows a clot retrieval device being advanced through the lumen of the microcatheter and over the guidewire;

Fig. 80g shows the clot retrieval device expanded with the microcatheter partially withdrawn;

Fig. 80h shows a clot debonding element advanced through the microcatheter and in the deployed state;

Fig. 80i shows the clot being engaged by both the clot retrieval device and the clot debonding element;

Fig. 80j shows the clot captured in the net of the clot retrieval device with the clot debonding element removed through the lumen of the microcatheter;

Fig. 80k shows the clot retrieval device with the frame partially collapsed and the clot captured in the net;

Fig. 80l shows the clot retrieval device, the microcatheter and the captured clot being removed from the vessel; and

Fig. 80m shows the vessel recannalized.

Detailed Description

The present invention is related to an apparatus and methods for the removal of obstructions in vessels. More particularly the present invention relates to devices and methods for the removal of obstructive clot from cerebral vessels.

With reference to Fig 1 there is shown a schematic representation of the catheterization of a patient with a clot retrieval device 1 according to the invention. The patient is catheterized via the femoral artery with a catheter 2 in accordance with standard interventional technique.

Fig. 2 shows a schematic representation of some of the arteries supplying blood to the brain. The arteries shown are on the anterior circulation. Vessel 400 is the Aorta. Vessel 401 is the brachio-cephalic artery. Vessel 402 is the subclavian artery. Vessel 403 is the common carotid artery. Vessel 404 is the internal carotid artery. Vessel 405 is the external carotid artery. Vessel 406 is the middle cerebral artery. Vessel 407 is the anterio-cerebral artery. A catheter 2 is shown with its distal end in the common carotid artery. In the more detailed drawings of the invention the details of the access site will not be shown but in general access and delivery is in accordance with Fig 1 and/or Fig 2. It will be appreciated that the devices and methods disclosed in this invention relate to all of femoral access, radial access, direct stick access, carotid access even where only one variation is shown or described.

Now with reference to Fig. 3a to Fig. 3g a first method of using the devices of the invention is highlighted. Fig. 3a shows an obstructive clot 3 located on a cerebral vessel 4. The first step in treating this obstruction is to cross the obstruction 3 with a guidewire 5. The guidewire 5 is inserted into the arterial system through conventional techniques and is advanced to the obstruction. The tip of the guidewire 5 is advanced across the obstruction 3, Fig. 3b. A micro delivery catheter 6 can then be advanced over the guidewire 5 and across the obstructive clot 3. The clot retrieval device 1 is expanded in the target vessel distal of the clot 4. The micro delivery catheter is withdrawn until its tip is proximal of the occlusive clot. Alternatively it can be completely removed from the patient. The clot retrieval device is positioned at the distal end of guidewire 5 and is fixed thereto. The obstructive clot 3 is captured in the device by advancing the device proximally (Fig 3e). A removal catheter 7 is advanced over the guidewire 5 to assist in the removal of the clot 3. The removal catheter 7 may be a micro-catheter, a guide catheter, a sheath or a special recovery catheter. Aspiration may be employed through the lumen of the recovery catheter to assist in clot removal. Fig 3g shows the target vessel recannalised after the removal of the obstructive clot 3.

Fig. 3a shows part of the cerebral circulation with an obstructive clot 3 positioned in the Anterior Cerebral Artery 4, distal of the Middle Cerebral Artery branch.

Fig. 3b shows a Guidewire 5 being placed across the obstructive clot 3.

Fig. 3c shows a micro-catheter 6 with the clot retrieval device 1 of the invention crossing the obstructive clot 3.

Fig. 3d shows the micro-catheter removed with the clot retrieval device 1 placed distal of the obstructive clot 3.

Fig. 3e shows the clot retrieval device 1 being advanced proximally and capturing the obstructive clot 3 with a removal catheter 7 advanced from the proximal side.

Fig. 3f shows the clot retrieval device 1, the captured occlusive clot 3 and the removal catheter 7 being removed from the vessel.

Fig. 3g shows the target vessel 4 with the obstructive clot and devices completely removed.

With reference to Fig 4a to Fig 4i another method of employing the clot retrieval devices of this invention is described. With this method an access guidewire 15 is used to cross the obstructive clot 13. A micro catheter 16 is advanced over the access guidewire15 and across the clot 13. The access guidewire 15 is removed from the lumen of the micro-catheter 16. A clot retrieval device 11 is advanced through the lumen of the micro-catheter 16 in a collapsed state. It will be appreciated that the clot retrieval device was collapsed in order to access the proximal end of the lumen of the micro-catheter 16. The clot retrieval device 11 expands distal of the tip of the micro-catheter 16 and clot 13. The micro-catheter 16 is advanced proximally until its tip is proximal of the clot. Alternatively the micro-catheter 16 can be removed from the patient (as shown Fig. 4d). The clot retrieval device 11 is advanced proximally with the aid of guidewire 18 to capture the obstructive clot 13. The guidewire 18 of the clot retrieval device 11 extends proximally of the expanded section of the device 11 and allows the physician to control the clot retrieval device 11. A removal catheter 17 is advanced over the guidewire 18 to assist in the removal of the clot 13. The removal catheter 17 may be the same micro-catheter that was used to deliver the clot removal device or it may be different size micro-catheter, or a guide catheter, or a sheath or a balloon catheter or a special recovery catheter. The recovery catheter 17 may also be used by the physician to assist with the clot capture by preventing the clot 13 from migrating proximally. Aspiration may be employed through the lumen of the recovery catheter to assist in

clot removal. Fig 4i shows the target vessel recannalised after the removal of the obstructive clot 13.

Fig. 4a shows a target vessel 14 with an occlusive clot 13.

Fig. 4b shows a guidewire 15 with its distal tip across the obstructive clot 13.

Fig. 4c shows a micro-catheter 16 advanced over the guidewire 15 until its distal end is across the obstructive clot 13.

Fig. 4c shows the preplaced micro-catheter 16 with its distal end across occlusive clot 13 and a clot retrieval device 11 being advanced through its inner lumen, guidewire 18 having being removed from the microcatheter.

Fig. 4d shows clot retrieval device 11 deployed distal of occlusive clot 13 with the micro-catheter 16 being withdrawn. Clot retrieval device is connected to wire 18 and proximal end of wire 18 exits the patient and is controlled by the physician.

Fig. 4e shows the clot retrieval device 11 deployed distal of occlusive clot 13 with the micro-catheter being removed.

Fig. 4f shows the clot retrieval device 11 deployed distal of occlusive clot 13.

Fig. 4g shows the clot retrieval device 11 being advanced proximally and capturing the obstructive clot 13 with a removal catheter 17 advanced from the proximal side.

Fig. 4h shows the clot retrieval device 11, the captured occlusive clot 13 and the removal catheter 17 being removed from the vessel.

Fig. 4i shows the target vessel 14 with the obstructive clot 13 and devices completely removed.

Referring now to Fig. 5a to Fig 5g another method of employing the clot retrieval devices of this invention is described. With this method the obstructive clot 23 in target vessel 24 is crossed directly with a clot retrieval micro-delivery catheter 26. The clot retrieval micro delivery catheter 26 has a reception space at its distal end and the collapsed capture device 21 resides in this reception space during delivery. In one embodiment the distal end of the guidewire 28 of the clot retrieval device 21 extends distally of the micro-delivery catheter 26 and assists the device in crossing the occlusive clot 23. When the distal end of the micro-delivery catheter is across the

clot 23, the clot retrieval device 21 is deployed and the micro delivery catheter 26 advanced proximally.

The clot retrieval device 21 is advanced proximally with the aid of guidewire 28 to capture the obstructive clot 23. The guidewire 28 of the clot retrieval device 21 extends proximally of the expanded section of the device 21 and allows the physician to control the clot retrieval device 21. A removal catheter 27 is advanced over the guidewire 28 to assist in the removal of the clot 23. The removal removes the clot and capture device as described above.

Fig. 5a shows a target vessel 24 with an occlusive clot 23.

Fig. 5b shows a micro delivery catheter 26 with a clot retrieval device 21 collapsed within a distal lumen of the micro delivery catheter. The micro delivery catheter is advanced across the occlusive thrombus 23. The clot retrieval device 21 has a Guidewire 28 that extends proximally and distally.

Fig. 5c shows micro delivery catheter 26 being removed with the clot retrieval device 21 deployed in the target vessel 24 distal of the occlusive clot 23 with Guidewire 28 extending across the lesion and proximal to the user.

Fig. 5d shows the clot retrieval device 21 deployed in the target vessel 24 distal of the occlusive clot 23 with guidewire 28 extending across the lesion and proximal to the user.

Fig. 5e shows the clot retrieval device 21 being advanced proximally and capturing the obstructive clot 33 with a removal catheter 27 advanced from the proximal side.

Fig. 5f shows the clot retrieval device 21, the captured occlusive clot 23 and the removal catheter 27 being removed from the vessel.

Fig. 5g shows the target vessel 24 with the obstructive clot 23 and devices completely removed.

In one embodiment (not shown) the removal catheter comprises a balloon catheter wherein the guidewire lumen of the balloon catheter is larger than the guidewire diameter. The distal end of the balloon catheter lumen provides a reception space for a portion of the collapsed clot capture device. The balloon may be inflated during the clot capture step to prevent the clot from migrating proximally.

With reference to Fig. 6 an example of the clot retrieval device of this invention is shown. The device 31 comprises a frame 34, a proximal collar 33, a distal collar 36, capture fibers 35, and a guidewire 32. Frame 34 comprises a metallic elliptical hoop. The hoop 34 is subtended at an acute angle relative to the guidewire 32 in the expanded configuration. In the collapsed state the hoop 34 sits substantially parallel to the guidewire 32. The frame 34 further comprises eyelets 38 that allow for a low profile interconnection between the capture fibers 35 and the frame 34. The eyelets 38 are shown as circular eyelets positioned substantially in the center of the struts. Multiple eyelets are located around the frame. Corresponding eyelets 38 are located on distal collar 36. The capture fibers are looped through the eyelets either in a simple single loop or using multiple loops. Where two or more loops are employed the loops act like a knot and prevent fiber slippage. In the embodiment shown the capture fibers 35 are not interconnected with each other but form straight line connections between the frame and the distal collar. This configuration means that there are no knots or fiber overlaps in the entire capture net which improves the wrapping profile of the device. In one embodiment the fibres are looped through the eyelets of the collar and the eyelets of the frame and this avoids the need for knots thus reducing the profile. The eyelets 38 of the distal collar 36 are arranged around the circumference of the distal collar 36. In one embodiment the distal collar is fixed to the guidewire 32. In another embodiment the distal collar 36 is slidable relative to the guidewire 32. In another embodiment the distal collar is rotatable relative to the guidewire. The proximal collar and the frame are preferably connected. In one embodiment the proximal collar and the frame are integral. In another embodiment both the frame and collar are machined from a hypotube. In this embodiment the hypotube diameter corresponds to that of the collar and the frame is laser cut in a configuration that corresponds closely to the shape of the frame when it is collapsed for delivery. The proximal hypotube is mechanically connected to the wire. This mechanical connection allows the memory in the metal to act to generate an angle between the frame and the guidewire in its expanded state. In one embodiment the mechanical connection comprises a closely tolerance fit between the collar inner diameter and the wire. In another embodiment the collar is fixed to the wire. It may be fixed by gluing, welding, or other well known means. The tip 37 of guidewire 32 is soft and flexible to allow the delivery system (not shown) to steer through the anatomy.

With reference to Fig. 7a another clot capture device 41 of the invention is shown. This device employs a similar arrangement to the device of Fig. 6, however in this instance the capture fibers 45 are interconnected. It will be noted that the fibers 45 are connected in a series of interconnecting loops 49. These loops 49 can be crafted by hand and have the advantage of

avoiding the need for knots, bonds or other features that will significantly impact the profile of the device in the delivery configuration. The loops mean that the interconnected fibres can slide relative to one another and this allows the net to change its shape in response to an irregularly shaped clot. Alternatively the net may be knitted or braided so as to create a regular net structure. With both knitting and braiding it is also possible to create fibre interconnections without rigidly fixing the fibres at the cross over points. Attachment fibres are used to connect the net to the frame. In one case the proximal collar 43, distal collar 46 and guidewire 42 have similar features to those of fig 6.

The clot capture device of Fig 7a is shown in the delivery configuration in fig. 7b. The frame 44 lies substantially parallel to the guidewire 42 inside the lumen of delivery catheter 50. The delivery catheter 50 comprises a proximal shaft 51, a distal shaft 52 and a distal tip 53. The clot retrieval device sits inside a reception space at the distal end of the delivery catheter 50. The distal tip of the delivery catheter is preferably a soft tip material. The proximal end 51 of the delivery catheter 50 extends back to the user. In one embodiment the delivery catheter is a rapid exchange catheter.

In another embodiment the shaft 50 comprises a loading system. The distal tip 53 of the shaft 50 is engaged with the proximal end of a micro-catheter. The micro-catheter has had its distal end preplaced at a target treatment site. With the distal tip 53 engaged with the proximal end of the micro-catheter the clot retrieval element 41 is advanced into the lumen of the micro-catheter. When the proximal collar 43 has entered the micro-catheter the shaft 50 can be removed and the clot retrieval device 41 advanced through the micro catheter to the target location. It will be appreciated that the features of the loading system described with respect to the clot retrieval device 41 could be applied to other clot retrieval devices of the invention. It will also be appreciated that the method steps described can be applied with the methods described in Fig 3 to 5.

Figs 8a-f show a variety of frame mounting constructions that could be employed in the creation of a device similar to that described in Fig. 6. Fig. 8a shows a frame 501 constructed from a guidewire 502. Fig. 8b shows a frame 503 fixedly attached to guidewire 504 at proximal collar 505. Fig. 8c shows a frame 506 connected to a guidewire 507 in such a way that the collar 508 of the frame can translate and rotate along and around the guidewire between the two stops 509, which are fixedly attached to the guidewire, or an integral part of the guidewire. Fig 8d shows a frame 510 whose proximal end is attached to tube 511, which is slideably mounted on guidewire

513 proximal to stop 512. Fig 8e shows a frame 514 which is attached to tube 516, which is slideably mounted on guidewire 515 such that the tube and frame can be advanced or retracted over the guidewire and the guidewire can be moved or exchanged through the tube. Fig 8f shows a variant of the design shown in Fig 8e, in which frame 517 is attached to tube 518 and tube 518 is connected to a proximal shaft 519 at the guidewire exit port 520. Such a design would facilitate the deployment of the device over a shorter "rapid exchange" guidewire

In other embodiments alternative stop configurations to those shown in Fig. 8c may be employed, in order to facilitate and control movement of the clot retrieval device relative to the guidewire, and/or in order to control the manner in which force may be transmitted to the device during delivery, retrieval and general use. Some of these alternative configurations are shown in various figures throughout this document. It will also be understood that the many other frame designs disclosed in previous and subsequent figures, although illustrated in a certain configuration, may be configured in any of the other configurations depicted in Figs 8a-f.

Figs 9a-i show a variety of frame designs that could be employed in the creation of a clot capture device. Frame 550 in Fig 9a has a generally circular perimeter with which to appose the vessel wall, and two proximal arms which taper outward distally from a proximal terminus. Such a design could be constructed from wire or from a cut tube or by other means, and could be made from any of the materials described later as suitable for the manufacture of frame 64 in Fig 10a. Frame 551 in Fig 9b is similar to frame 550 except that the inner terminus of the proximal arms is positioned distal to the outer circumferential portion of the frame. Frame 552 in Fig 9c is similar to frame 550 except that the frame arms are of unequal lengths and/or angles, such that an offset is created between the centreline of the vessel and the proximal neck of the frame. Frame 553 in Fig 9d is similar to frame 550 except that the frame arms are of unequal lengths and/or angles, such that the circumferential portion of the frame is inclined at an angle relative to the centreline of the vessel. Frame 554 in Fig 9e is similar to frame 553 except that the frame has only one proximal arm. Frame 555 in Fig 9f is similar to frame 550 except that the frame has three proximal arms. Frame 556 in Fig 9g is similar to frame 550 except that the frame has four proximal arms. Frame 557 in Fig 9h is similar to frame 554 except that the frame has an additional arm that tapers distally inwards from the outer circumferential portion. Frame 558 in Fig 9i is similar to frame 501 of Fig 8a except that the frame is not constructed directly from the guidewire itself, but from a separate material.

Another clot retrieval device 61 is shown in Fig. 10a-e. The clot retrieval device 61 shown in fig. 10a comprises a frame 64, a guidewire 62, proximal collar 63, distal collar 66, support struts 60 and capture fibers 65. With this embodiment the frame 64 forms a three dimensional shape in its expanded configuration. The three dimensional shape is such that the outer surface of the frame in its expanded configuration can oppose the wall of a generally cylindrical vessel. The frame is preferably cut from a hypotube and is preferably metallic. Preferably the frame is nitinol, stainless steel, tantalum, MP35N, L604, a memory material, spring steel, or another high strength alloy. The frame comprises a number of segments 67. In a preferred embodiment the frame comprises pairs of segments. Each pair of segments are arranged at an angle and the angle of arrangement gets smaller as the frame is collapsed and increases as the frame is expanded. The pairs of segments are interconnected to from a 3D structure. In the embodiment shown two pairs of segments are shown. Three pairs of segments or more is also possible. The frame 64 is connected to the guidewire with support struts 60. In the embodiment shown the support struts 60 are attached to the frame 64 at its proximal end. The support struts 60 however are positioned underneath the frame 64 in the expanded configuration. This ensures that the frame 64 has maximum support when the guidewire 62 is being advanced proximally as the support struts 60 act generally to expand the frame. With this embodiment the frame is advanced proximally with a push force transmitted from the distal side. The force is transmitted along support struts 60 and has two components. One component acts to push the frame in the proximal direction while the other force acts to push the frame against the wall of the vessel. This makes it difficult for clot to escape around the outside of the frame 64. The support struts 60 are connected to the guidewire 62 through proximal collar 63. The support struts 60 may be connected to the frame in a number of ways. The support struts 60 may be laser cut from the same tube as the frame 67 and as such would be integral with the frame 67.

Fig 10b-e show a clot retrieval device 61 where the proximal collar 63, the support struts 60, and the frame are cut from a single piece of tubing which may be a hypotube. Fig 10b is similar to fig 10a except that the proximal collar, the support struts and the frame are a single component. In order to manufacture such a complex component the metal used may be elastic. In one embodiment spring steel or a nitinol alloy is used. Preferably nitinol is used to make the frame. Fig 10c shows an elevation of the one piece frame component 64 in the collapsed (as cut) configuration. The proximal collar 63 is simply a segment of the original hypotube and should be kept as short as possible. A pair of support struts 60 extends from proximal collar 63 and connects the proximal collar 63 with the struts 67 of the frame 64. The support struts 60 are positioned diametrically opposite (thus only one is visible in the elevation view). The interface

87 between the support struts 60 and the collar 63 is an area of high strain when the device is expanded. The wall thickness of the support struts 60 may be locally thinned to reduce strain in this area. At the distal end each support strut 60 bifurcates to form two struts 67 of frame 64. The two struts are of the same length and reconnect at their distal end. The bifurcation 85 is also an area of high strain during expansion and the stress is relieved in this area by reducing locally the width of the struts. The junction 86 at the distal end is another area of high stress during expansion and the stress is relieved in this area by locally reducing the width of the strut in the region of the junction 86. Fig 10d shows an end-view looking at the collar 63 end. Fig 10e shows a sectional view at a-a. This sectional view shows the arrangement of the four struts 67, and the cut gap 88 between the struts. The construction of junction area 86 where neighboring struts 67 are connected is further highlighted.

In another embodiment the support struts 60 may be separate components that are joined to the frame 67. The support struts 60 may be connected to the frame by a hinge. The resistance of the hinge to movement is much less than the resistance of the frame or support struts to bending movements. The hinge may be formed by an interconnection between the support strut 60 and the frame 64. In another embodiment a suture or fiber(s) is used to create the hinge. With this embodiment the flexibility of the suture/fiber allows the strut to move relative to the frame while their points of connection are relatively constrained.

The capture fibers 65 of this embodiment are of similar size to those described earlier. The capture fibers 65 are attached to the frame 64 and the distal collar 66 through eyelets 68. Preferably the fibers are highly oriented fibers. This high orientation results in fibers that are anisotropic and these fibers are particularly preferred. These fibers are very strong along the axis of the fiber and less strong in other directions. The distal collar 66 contains eyelets 68 through which the capture fibers are threaded. In one embodiment the distal collar 66 is fixed to the guidewire. In another embodiment the distal collar 66 is integral with the guidewire. In yet another embodiment the guidewire is a hypotube and the eyelet holes are made in the guidewire hypotube thus eliminating the need for a separate distal collar. In yet other embodiments the fibres are attached to a collar or directly to the guidewire or to each other by bonding, welding or other methods.

Yet another embodiment of the invention is shown in Fig.11a -11c. The clot retrieval device 71 comprises a frame 74, a guidewire 72, proximal collar 73, intermediate collar 70 a distal collar 76, support struts 79 and capture fibers 75. With this embodiment the frame comprises a hoop

subtended at an angle relative to the guidewire 72. The hoop is held relative to the wire by two support struts 79 a proximal collar 73 and an intermediate collar 70. In one embodiment the proximal collar is fixed and the distal collar slides on the guidewire. In another embodiment the distal collar is fixed and the proximal collar slides on the Guidewire. In yet another embodiment both collars are slidable on the guidewire and a stop or stops are used to enable a force to be applied through the guidewire to either collar, such as illustrated in figs 7, 48 and 50. Fig. 11b shows the clot retrieval device 71 in the collapsed crossing configuration. In this illustration the capture fibers 75 are not shown (for clarity). The support struts 79 are positioned distal and proximal of the frame in the collapsed configuration. The crossing catheter 80 is preferably a micro-catheter. Preferably the crossing catheter 80 is 2.3 French or less in its distal diameter 82. Preferably the crossing catheter 80 has a distal diameter 82 of 1.9 French or less. More preferably the crossing catheter 80 has a distal diameter 82 of 1.6 French or less. The tip 83 of the crossing catheter is preferably made of a soft material and has a smooth transition. Fig 11c shows the clot retrieval device 71 and the crossing catheter 80 of Fig 11b, with the exception that the capture fibers 75 are also shown. The diameter of the capture fibers 75 is so small as they exert only a minor influence on the profile.

Fig 12a and Fig. 12b show another embodiment of the invention. This embodiment is similar to that of Fig 11a-11c except that the frame 94 is circular rather than elliptical and the support struts 99 make an angle with the guidewire that is closer to a right angle. In the expanded position the proximal collar 93 and the intermediate collar 90 are adjacent each other. The support struts 99 are connected to the frame in a hinged configuration. This hinged configuration is important as the support strut moves through a large angle during device expansion. In one embodiment the support strut moves through an angle of greater than 60'. Preferably the support strut moves through an angle of at least 80'. More preferably the support strut moves through an angle of at least 90'. This large angle of movement has the effect of reducing the length of the device in the collapsed configuration and this shorter device is more deliverable.

For example: For a device with an expanded diameter of 3mm, changing the strut angle from 45' to 90' has the effect of shortening the device by 1.24mm. In the neurovascular territory where vessel diameters are small and vessel tortuousity is high this is a very significant reduction. In one embodiment the hinge comprises three elements, a strut element 99 a frame element 94 and a hinge element 104. The frame element 94 and the strut element 99 are connected with the hinge element 104. The hinge element allows the frame 94 and strut 99 to change angle relative to each other with little resistance. In one embodiment the hinge element is a pin. In another the hinge

element 104 is a fiber, a filament, a multifilament or a suture. In another embodiment the strut 99 and the frame 94 are connected and the hinge is integral of the connection. In another embodiment the hinge comprises a weakness in the structure at the area where the strut 99 and frame 94 meet. In another embodiment the hinge between the strut 99 and frame 94 is adjacent a hinge in the frame.

In one embodiment the intermediate collar is fixed to the wire. With this embodiment the intermediate collar 90 provides a movement stop to the proximal collar 93. This configuration provides a particularly stiff frame construction even for a low profile device. In another embodiment the proximal collar is fixed and the intermediate collar 90 can move axially. In one embodiment the proximal collar 93, intermediate collar 90 and distal collar are radiopaque. With this embodiment the collars are made from or coated with a material that absorbs X-Rays. Typically this involves using materials that have a high atomic mass. Materials with a concentration of gold, platinum, iridium, tungsten, and tantalum are especially suited. It will be appreciated that a variety of other metals, alloys or compounds could be employed. Such radiopaque features may be used in any of the devices described herein.

Fig 12b shows the clot retrieval device 91 in the delivery configuration. A crossing catheter 100 is used to constrain the device 91 in the collapsed state during delivery and crossing of the obstruction. The catheter has a proximal end 101 and a distal end 102. The guidewire extends proximally through a lumen of the crossing catheter 100 and exits at either the proximal end of the crossing catheter 100 or through an exit port in the wall of the crossing catheter 100. The capture fibers are arranged as previously described although they are not shown in Fig 12a or 12b.

Fig 13a shows the clot retrieval device of Fig 12 except that the capture fibers 95 are shown. Fig 13 also shows the collar arrangement whereby the intermediate collar 90 is fixed relative to guidewire 92 and the proximal collar 93 is slidable relative to guidewire 92. In another embodiment the proximal collar 93 and intermediate collar 90 are rotatable relative to guidewire 92. Fig 13 b to Fig 13e show views of the proximal collar, intermediate collar and support struts of Fig 12 and Fig 13. The collar 105 could be either a proximal collar or an intermediate collar. In the embodiments shown the strut 106 and collar 105 are integral. In one embodiment they are formed from a single piece of hypotube. Preferably the tube is nitinol and the shape of the strut 106 is set by heat treatment. Fig 13b and fig 13d show an arrangement where the strut is in the delivery configuration. This is also the pre-heat treatment configuration. The lumen 108 is sized

to fit over the guidewire of the earlier embodiments. Fig 13d and fig 13e show the collar 105 and strut 106 in the expanded configuration. The hole 107 allows for the creation of a hinge feature with the frame of earlier embodiments.

Some examples of intermediate or distal collars 131 associated with the clot retrieval devices of the invention are shown in Figs 14 to fig 17. Fig 14, fig.16 and fig 17 shows collar 131 with lumen 109 mounted on guidewire 112. The collar comprises eyelets 130 for attachment of capture fibers 115. In fig 14 the capture fibers form a knitted structure and are connected to the collar in a series of loops through the eyelets 130. In fig. 16 the capture fibers 115 are arranged in a weaved configuration and are attached to the eyelets through a series of loops. The capture fiber may be looped between one eyelet 130 and a neighboring eyelet or it may be looped through the eyelet and the body of the collar 131.

Fig 18 and fig 19 show the clot retrieval device 91 of fig 12 and fig 13 in use. The device 91 is shown deployed distal of obstructive clot 100. The device is advanced proximally in order to capture the clot as shown in Fig 19.

Now with reference to fig 20 through to fig 23 there is shown another clot retrieval device of the invention. This device is constructed from a series of sub-elements that work together through a series of hinge elements. For the purpose of describing the hinge features of this invention, hinges will be classified in terms of the number of axis of freedom available to the hinge. One axis of freedom shall mean that the hinge movement is limited to a single plane of movement. An example of a hinge with one axis of freedom is the human knee joint. Two axis of freedom shall mean that the hinge movement is limited to a two planes of movement and the two planes are normal to each other (X,Y). An example of a hinge with two axis of freedom is the human hip joint.

With reference to fig.20a-h there is shown a number of sub-elements to the frames of the clot retrieval devices of the invention. Fig 20a and fig 20b show a strut element 150 with curved ends 152 and a hinge hole 151 located concentric with curved ends. Curved ends 152 may be curved in one axis or two axes depending on whether the hinge has one axis of freedom or two axis of freedom. Fig 20c shows the strut 150 in a curved configuration. Fig 20d shows a schematic of the construction of a hinge between two struts 150. The end curves 152 of two struts are brought into contact and a hinge element 153 secures the strut ends 152 relative to each other. Since both ends are curved in two planes this configuration creates a hinge with two axis of freedom. In one embodiment the hinge element 153 is a ring element. In another embodiment the hinge element

153 is a fiber, monofilament, multifilament, a wire or a suture. Fig. 20d also shows eyelets 154 on the strut for attachment of capture fibers.

Fig 20e shows another hinge configuration of the clot retrieval devices of the invention whereby two struts or a strut and a support member are joined in a hinged configuration. The strut 150 has two curved ends 152 and each curved end 152 has two hinge holes 151. Each hinge hole is fastened to its neighboring hinge hole to create a hinge that has one axis of freedom. A frame 164 for a clot retrieval device is shown in fig.20f and fig 20g. The frame comprises four struts 150 configured in a circular arrangement. Each strut comprises curved ends 152 and hinge holes 151 adjacent said curved ends. The frame 164 is supported by support members. In one embodiment proximal support members 157 and distal support members 156 are employed. Proximal support members 157 are connected to the guidewire proximally. Distal support members 156 are connected to the guidewire distally. In one embodiment the proximal support member 157 and/or the distal support member 156 is connected to the guidewire 172 via a collar 155. In one embodiment the support member 156/157 is integral with the collar 155. In another embodiment the support member 156/157 is connected to the collar with a hinge arrangement. Preferably the hinge arrangement comprises a hinge with one axis of freedom. In one embodiment the support member 156/157 and the collar are integral and the hinge is made by thinning out the wall of the support member in the plane of bending adjacent the collar. Thinning the wall reduces plastic strain in the wall during hinging and allows large angles of movement. In one embodiment the support member 156/157 contacts the frame on its inner surface. In another embodiment the support member 157 contacts the frame intermediate the inner and outer surfaces.

Fig 20h shows the arrangement of a frame support 165. The frame support comprises a collar 155 and support members 157. The collar comprises an inner lumen 166 and an outer surface. The support members 157 comprise a curved end 158 and a hinge hole 151.

Fig 20h and fig 20i show how the hinges 167/168 allow the support frame to collapse. It will be noted that pairs of hinges facilitate most efficient collapse of the frame of the clot retrieval device. In the delivery configuration the curve of the struts 150 is straightened. This is illustrated in fig 20j where all of the hinges 168/167 are in the collapsed state and the struts 150 are straightened and lie substantially parallel to the axis of the guidewire 172.

Fig 21a-c shows the frame elements of fig. 20a-j assembled and mounted on a guidewire. Fig 21a shows the frame 164 of fig. 20j integrated with proximal and distal frame supports 165 of fig

20h. Fig 21b shows the frame 164 of fig 20j integrated with proximal and distal frame supports 165 of fig 20h and all of this mounted on guidewire 172. Fig 21c shows the clot retrieval device 175 assembled and in the collapsed configuration with capture fibers 171 included.

The hinges 167/168 associated with the body of frame 164 provide no bias for the frame. The hinges 167/168 thus provide no significant resistance to either expansion or collapse. The frame can thus be expanded from a collapsed state in one of the following ways.

In one embodiment the frame 164 is expanded and collapsed by movement of the more proximally located collar 155a relative to the more distal collar 155b. In one embodiment either the more proximally located collar 155a or the more distally located collar 155b is fixed to the guidewire 172. If the more distally located collar 155b is fixed longitudinally, then, advancing the more proximally located collar 155a distally expands the frame 164. In one embodiment movement of the collar 155a is achieved using a bumper catheter 173 as shown in Fig 21c. The bumper catheter 173 has an outside diameter, a lumen and a distal face. The bumper catheter 173 is advanced over the Guidewire 172 until its distal face is adjacent the proximal end of collar 155a. The bumper catheter is further advanced and engages with the collar 155a and causes collar 155a to advance distally. As collar 155a advances distally the frame 164 expands. With the frame 164 in the expanded state, and the bumper catheter 173 held in position the clot retrieval device 175 and bumper catheter 173 are advanced proximally to capture the clot. When the clot is captured the bumper catheter 173 is disengaged from the collar 155a. The clot retrieval device 175 is retrieved. This may be achieved using a retrieval catheter, a micro-catheter, a sheath or guide catheter or the lumen of another catheter. Alternatively the clot retrieval device 175 can be withdrawn proximally into the procedural catheter.

In another embodiment the bumper catheter is connected to the collar 155a. In this way advancing the bumper catheter distally causes the frame 164 of the clot retrieval device 175 to expand, while advancing the bumper catheter proximally causes the frame 164 to collapse. In another embodiment the bumper catheter 173 is detachably coupled to the clot retrieval device 175 through collar 155a.

In another embodiment the support members 157/156 of frame support 165 are biased to the expanded state. For delivery the frame 164 is stored inside the pod of a delivery catheter. Upon deployment distal and proximal frame supports 165 acts on hinge points 167/168 and cause these to move radially outward. As these move outward the frame 164 of the clot retrieval device expands. On full expansion the frame 164 assumes a 3 dimensional ring-like configuration. With

this embodiment, when the clot retrieval device 175 is deployed and the frame 164 is expanded the clot is captured by proximally advancing the clot retrieval device 175. After the clot is captured the clot retrieval device 175 is retrieved using a retrieval catheter, a micro-catheter, a sheath or guide catheter or the lumen of another catheter. Alternatively the clot retrieval device 175 can be withdrawn proximally into the procedural catheter.

A capture fiber collar 169 is located distal of the collars 155a/155b and this collar 169 provides an anchor site for the capture fibers distally. The capture fiber collar 169 may be fixed on the wire 172 or may be slidable and/or rotatable on the wire172. In a preferred embodiment the capture fiber collar 169 has a limited range of movement. The movement may be limited proximally by abutment with the collar 155b of the frame support 165, or it may be limited by a stop (not shown) on the Guidewire 172. The movement of the capture fiber collar 169 may be limited distally by the capture fibers or by a stop on the wire 172. In yet another embodiment the distal tip of the guidewire ends proximal of collar 169, and collar 169 is therefore not engaged with the guidewire, but still acts as a distal terminus for the capture fibers.

Fig 22 shows the frame 164 of the invention when viewed from the proximal end in its expanded configuration. The struts 150, the support members 157/156 and the collars 155a/155b/169 are preferably manufactured from a metal. Preferably the material is nitinol, stainless steel, MP35N, L604, Tantalum, a mixture of the above or another alloy with similar mechanical attributes. The optimum choice of materials is dependant on the design and operating mechanism of the frame. In the case of a self expanding frame as illustrated in figs 10a-d it will be advantageous to select a material which can recover from the high strains that may be induced in collapsing the frame for delivery through a small diameter catheter. Such strains will be design dependant, but selection of a superelastic material such as nitinol, which can recover from strains as high as 8%, will enable more compact geometries for areas 85 and 86 to be adopted. In the case of a frame that is expanded by an external force as described in relation to fig 21c, greater flexibility in material choice is made possible. In the case of hinged designs, as for example is shown in fig 22, still greater material choice is afforded, as significant strains are not induced in the hinged areas.

A frame 164 of a clot retrieval device of the invention is shown in fig 23a-23c at various levels of expansion. In fig 23a the frame 164 is shown in the fully expanded configuration. Struts 150 form a circular ring and these are supported by support members 157/156. The proximal collar 155a and support member 157 support the frame 164 at two opposing hinge points 168. The

more distally located collar 155b and support members 156 support the frame at the two remaining opposing hinge points 167. The frame 164 is shown in the partially collapsed state in fig. 28b. The proximal collar 155a has moved proximally relative to the more distally located collar 155b. In the partially collapsed (or expanded) configuration the struts form a zigzag pattern in three dimensions. The zigzag pattern is defined on a cylindrical surface in 3D space.

The frame 164 is shown in the fully collapsed state in fig 23c. The collar 155a has moved even more proximally and the strut 150 is substantially parallel to the axis of the guidewire 172.

Fig 24a-24c shows the device of fig 23 with the capture fibers 171 in place. It will be appreciated that other capture fiber arrangements described in this invention could be used with the frames 164 and clot retrieval devices of fig 20-28.

Fig 25a-d and fig 26a-f show more detailed views of aspects of the struts 150 of the frames 164. In one embodiment the struts are rectangular in cross-section 180. In another the cross-section 181 of the struts 150 is circular. In another embodiment the strut 150 comprises a number of eyelets 154 and the strut 150 comprises a thickened section 185 adjacent the eyelet 154. The eyelets 154 and thickened sections 185 are staggered on neighboring struts such that the struts stack more efficiently in the collapsed configuration. In one embodiment the eyelets 154 are circular. In another embodiment the eyelets 154 are centered on the neutral axis 195 of the strut 150. The neutral axis 195 of the strut 150 is defined as the portion of the strut that undergoes zero strain when the strut is loaded in bending. In another embodiment the eyelets 190 are elliptically shaped and the major axis of the elliptical eyelets 190 is substantially parallel with the neutral axis 195 of the strut 150. In another embodiment the eyelet 191 is elongated and the axis of elongation is approximately parallel to the neutral axis 195 of the strut 150. Capture fibers 192 are looped through eyelets 150. In one embodiment the capture fiber 192 makes a single loop through the eyelets 150. In another embodiment the capture fiber 193 makes a double loop through the eyelet 190. In another embodiment multiple capture fibers are looped through eyelets 191 or a single capture fiber 194 is looped multiple times.

The eyelets of this invention could be configured in a variety of shapes including elliptical, square, oblong, rectangular, polyhedral, or combinations or variations of the above. The eyelets are typically very small in diameter and are preferably processed by laser machining. The eyelets have a minor axis and a major axis. For the purpose of this invention the dimension of the minor axis is defined as the largest diameter of cylindrical pin guage (gage) that will fit into the eyelet without deforming the eyelet. Per this invention it is desired that the eyelet dimension be as small

as possible. Preferably the eyelet has a minor axis that is less than 100 micrometers. More preferably the eyelet has a minor axis that is less than 50 micrometers. More preferably the eyelet has a minor axis that is less than 30 micrometers. Most preferably the eyelet has a minor axis that is less than 20 micrometers. When the major axis of the eyelet is positioned on the neutral axis of the strut then it is the size of the minor axis that dictates the loss of mechanical properties of the strut. It is therefore an object of this invention to minimize the loss of mechanical integrity of the struts while allowing high strength fibers to be secured to the frame. In another embodiment the capture fiber has a flattened aspect. The fiber may be elliptical or flattened in cross section or the fiber may be multifilament fiber.

The capture fibers used with the clot capture devices of this invention have special properties. In order to deliver the capture device through a micro catheter the capture fibers are exceedingly small. Fibers with a diameter of less than 100 micrometers are desired. More preferably the diameter of the fibers is less than 50 micrometers. Even more preferably the diameter of the fiber is less than 30 micrometers. Most preferably the diameter of the fiber is less than 20 micrometers.

The capture fibers 35 of this invention are exceptionally strong in order to achieve the really low delivery profiles of the invention. Suitable fibers include Ultra High molecular weight polyethylene fibers, PET fibers, stainless steel fibers, MP35N fibers, PTFE fibers, Polypropylene fibers, nylon fibers, Kevlar fibers and PEEK fibers. More preferably the fibers are polymeric fibers. More preferably the fibers are Nylon, PET, Kevlar or UHMWPE. Most preferably the fibers are made from ultra high molecular weight polyethylene (UHMWPE) or Kevlar. UHMWPE has a very long molecular chain and can therefore have molecular weights from 3 million to as high as 10 million atomic units, as opposed to approximately 500,000 atomic units for standard HDPE. This gives it excellent abrasion resistance as well as strength, making it an excellent choice for a capture net fiber. An exemplary UHMWPE capture fiber is supplied by DSM Dyneema BV, Urmond, The Netherlands.

Tables 1and 2 below compare the properties of a range of material fibers. The strength of a specific fiber strand is proportional to ultimate tensile strength of its material and to the square of the fiber diameter. Therefore a big reduction in strength is caused by a relatively small reduction in diameter. For example with reference to table 1, reducing the diameter of a Dyneema UHMWPE fiber from 30 microns to 15 microns results in a four-fold decrease in fiber strength from 1.86N to 0.46N. For this reason while it is desirable for profile reasons to use a low fiber

diameter, it is also desirable to use a fiber with a high ultimate tensile strength. The fibers used are sufficiently strong to withstand the loads that will be experienced during device delivery and clot retrieval, and also to facilitate device manufacturability. Inadequate fiber strength in manual, automated or semi-automated assembly processes is likely to result in frequent breakages and low yields. Preferably an individual fiber strength will be greater than 0.25N. More preferably an individual fiber strength will be greater than 0.35N. Most preferably an individual fiber strength will be greater than 0.5N. While PET is generally considered a high strength polymer, particularly when highly oriented, it can be seen from Table 2 that to achieve a 0.5N fiber strength a PET fiber diameter of over 25 microns is required, while the same strength can be achieved with UHMWPE or Kevlar fibers in diameters of less than 20 microns.

Fiber material	Fiber diameter (microns)					UTS (Mpa)
	15.00	20.00	25.00	30.00	50.00	
UHMWPE - Dyneema	0.46	0.82	1.29	1.85	5.14	2620
UHMWPE - Celanese	0.23	0.41	0.64	0.92	2.55	1300
UHMWPE - Spectra 1000	0.51	0.90	1.41	2.03	5.64	2870
UHMWPE - Tekmilon	0.43	0.77	1.20	1.73	4.81	2450
PET	0.18	0.31	0.49	0.71	1.96	1000
Nylon	0.14	0.25	0.39	0.57	1.57	800
Kevlar	0.53	0.94	1.47	2.12	5.89	3000
302 SS (50%CW)	0.27	0.48	0.74	1.07	2.98	1516
302 SS (90%CW)	0.42	0.75	1.17	1.68	4.67	2378
MP35N (95%CW)	0.44	0.78	1.22	1.76	4.90	2495
35NLT (90%CW)	0.45	0.80	1.25	1.80	5.01	2551
L604 (50%CW)	0.40	0.70	1.10	1.58	4.40	2241
Nitinol	0.26	0.45	0.71	1.02	2.84	1448

Table 1 - Fiber Strengths (in Newtons) for specific fiber diameters

Fiber material	Fiber strength required (N)					UTS (Mpa)
	0.20	0.50	1.00	5.00	10.00	
UHMWPE - Dyneema	9.86	15.59	22.04	49.29	69.71	2620
UHMWPE - Celanese	14.00	22.13	31.30	69.98	98.97	1300
UHMWPE - Spectra 1000	9.42	14.89	21.06	47.10	66.61	2870
UHMWPE - Tekmilon	10.19	16.12	22.80	50.97	72.09	2450
PET	15.96	25.23	35.68	79.79	112.84	1000
Nylon	17.84	28.21	39.89	89.21	126.16	800
Kevlar	9.21	14.57	20.60	46.07	65.15	3000
302 SS (50%CW)	12.96	20.49	28.98	64.80	91.64	1516
302 SS (90%CW)	10.35	16.36	23.14	51.74	73.17	2378
MP35N (95%CW)	10.10	15.97	22.59	50.51	71.44	2495
35NLT (90%CW)	9.99	15.80	22.34	49.96	70.65	2551
L604 (50%CW)	10.66	16.85	23.84	53.30	75.38	2241
Nitinol	13.26	20.97	29.65	66.31	93.77	1448

Table 2 - Fiber diameters (in microns) for specific fiber strengths

While UHMWPE fibers are extremely strong they are difficult to bond. The present invention overcomes these difficulties by allowing one single fiber to be used to manufacture the entire capture net. Furthermore the arrangement of the frame eyelets and collar eyelets allows a single fiber to be threaded over and over. Single loops can be made through the eyelets or multiple loops can be made. Multiple loops can be used to terminate a fiber. A small drop of adhesive can be used to fix the end of the fibers in the eyelets. Even though it is difficult to bond to the surface of UHMWPE fibers the adhesive acts as a mechanical constraint that prevents the loops from unraveling. Further since the load is carried by multiple fibers and multiple loops it is dispersed.

In another embodiment the capture fiber is a multifilament fiber. In yet another embodiment the fiber is a flat fiber or an oblong fiber.

In one embodiment the eyelets are positioned on the neutral axis of the strut of the frame. The neutral axis is generally at the center of the strut and corresponds to the line or plane in the strut that sees zero strain when the strut is loaded in bending. The advantage of putting the eyelet on the neutral axis is that it reduced the weakening effect of the eyelet. Where the eyelet has a major and a minor axis it is preferred that the major axis is as close to the neutral axis of the strut as possible.

Fig 27a shows a cross-sectional view of a strut 150. The cross section shows an eyelet 197 and a capture fiber threaded through the eyelet. Fig 27b shows a plan view of the same strut 150, eyelet 197 and capture fiber 196 arrangement.

Fig 27c shows another arrangement of strut 150, eyelet 198 and capture fibers 199. This time the eyelet is offset relative to the neutral axis of the strut 150. The eyelet is positioned close to one wall of the strut. A relief section 200 is also shown. This relief section 200 is created by partially machining material in the area where the capture fiber lies. In the embodiment shown the relief section 200 is created on the outer surface of the device. This ensures that the capture fibers do not add to the profile of the device as they loop about the frame. A plan view of the strut 150, eyelet 198, capture fiber 199 and relief section 200 is shown in fig 27d. It will be noted that the capture fiber 199 loops around the strut section twice in this schematic.

It will be appreciated that the capture fibers of this invention and the eyelets of the invention are both very small and assembling both presents a challenge. Fig 28a shows a view of a segment of a strut 150 with eyelet 154. Fig 28b shows a cross sectional view of the strut 150 taken through eyelet 154 along section line a-a. Fig 28c shows a representation of a fixture device that allows the assembly of the capture fibers

In another embodiment the eyelet is positioned close to the edge of the strut. With this embodiment the strut may be thickened on the side opposite the eyelet to compensate for any weakening.

Figs 29a-i show additional eyelets and fiber path defining features to those previously described in figs 25-28. The purpose of these features is to provide points or areas of engagement between the frame and the fibers that help to define the configuration of the fiber or fibers. Frame 600 in Fig 29a has eyelets 601 and 602 similar to those described in frames 26a and 26b. Frame 603 in fig 29b has a circular offset eyelet 604. Frame 605 in fig 29c has an assymetrical offset eyelet 606. Frame 607 in fig 29d has an inflexion 608 which creates a feature to provide a preferential seat for fiber attachment. Fig 29e shows two variations of raised features 610 and 611, pairs of which may be used to define a fiber attachment point to the frame 609. Fig 29f shows recessed features 613 which may be used to define fiber attachment points to the frame 612. Fig 29g shows recessed features 615 which may be used to define fiber attachment points to the round wire of frame 614. Frame 616 in Fig 29h is similar to frame 614, except that its raised features are separate components, which in one embodiment are radiopaque marker bands, and in another embodiment are of other metallic or polymeric materials. Element 619 in fig 29i is wrapped

around frame 618 in such a way as to leave defined spaces 620 in which to attach fibers to the frame. In one embodiment element 619 is a radiopaque platinum wire, but in other embodiments may also be of other materials or in the shape of a coil. The recesses and raised areas illustrated may be created by a laser machining process, or by other mechanical, electrical or chemical means.

Now with reference to figs 30a-e there are shown various frame features which may assist the attachment of a distal fiber or fiber structure to a frame structure. Fig 30a illustrates a frame 650 with an external sleeve 651, which provides an attachment surface to which fibers may be more easily bonded or a higher friction surface on which fibers will slip less easily if tied in place. Attachment surface 651 may be a polymer sleeve, which may be placed prior to forming the frame shape and may also be bonded or heat shrunk into position. Alternatively the attachment surface may be a coating 652, as shown in fig 30b. Figs 30c-e describe variants in which connection elements are used to join distal fibers to a frame. These connection elements may be fibers also, and may be used with any of the frame designs disclosed elsewhere, particularly those with features as shown in figs 25-30. Fiber 655 in fig 30c is connected to frame 653 by connection element 654, which is itself wrapped around frame 653. Fiber 655 is shown connected to the eyelets of frame 656 by discrete connection elements 657 in fig 30d, and by a continuous connection element 658 in fig30e.

Figs 31a and 31c show two fiber configurations that may be employed to reduce the size of embolus that can pass through the fiber net. The weave or braid configuration 700 shown in fig 31a is constructed from multiple fibers, which is advantageous in that if one fiber breaks the integrity of the entire structure is not significantly affected; however this structure leaves multiple loose fiber ends 701 at each end. Fig 31b shows a design which deals with this challenge by folding the woven net around the frame 703 and joining the loose ends together at a distal junction 704. In another embodiment the woven net may be folded around a connecting element which is in turn connected to the frame, or may be connected to the frame in a similar fashion to that described in figs 30c-e. Fig 31c shows a knitted net 705, which can be formed from a single fiber, and thus does not have the disadvantage of multiple loose ends. Such a net may be joined to the frame in a multitude of ways, many of which have been previously described in figs 25-30.

Fig 32a-e illustrates a number of fibre types that may be employed in the construction of a fiber net. A monofilament fiber 750 is shown in fig 32a. A multifilament twisted fiber 751 is shown in

fig 32b. A multifilament braided fiber 752 is shown in fig 32c. A multifilament fiber with an outer sleeve 753 is shown in fig 32d. A multilayer fiber 754 is shown in fig 32e. Any of these fibers may be used to construct the net designs shown in figs 33a-d. Figs 33a and 33b show how a porosity gradient may be created with either a knitted 756 or braided 757 design, which may be advantageous in efficiently balancing wrapped profile and effective particle retention. Figs 33c and 33d show a clot retrieval device constructed with axial fibers 758, which also create a similar porosity gradient. Fig 33d illustrates a similar design to fig 33c, except that a stiffening element 759 is provided, which serves to control the wrapped configuration of the net during delivery and retrieval.

Now with reference to fig 34a-f there is shown a clot retrieval device 218 which comprises a frame assembly 225 and a catheter 211. The frame assembly 225 further comprises strut section 214 with eyelets 212, capture fibers 215, a fiber junction 217, an expansion cable 213, and a guidewire 210. The frame assembly 225 is shown in its expanded state in Fig 34a and in its delivery state in Fig 34b. The strut section 214 lies substantially parallel to the axis of the catheter 211 in the delivery configuration. The strut section 214 expands to a ring shape when it is not constrained. The strut section 214 is deployed from the catheter 211 by advancing the guidewire 210 relative to the catheter 211. In order to deliver the device 218 into very small vessels it is necessary that the profile (diameter) of the device is very small. In retrieving obstructive clots from the brain it is desired that the device can be delivered through a micro-catheter. Typical commercially available micro catheters have profiles of 1.2F to 1.9F (1F=0.333mm=0.013"). The inner lumen of a 1.9F micro-catheter is approximately 0.016" (0.41mm). In order for the clot retrieval device to fit into this space the cross-sectional area of the strut section needs to be very small. However in order to capture clot effectively larger strut sections are desired. The strut section 214 of fig 34 has a cross sectional area that can fit into a micro-catheter. The expansion cable 213 is a flexible yet strong cable and it is fastened to the strut section 214 at anchor point 223. The anchor point 223 is at the distal most portion of strut section 214. The other end of expansion cable 213 is fastened to the distal end 216 of catheter 211. The expansion cable is strong, flexible and very small in diameter. The cable may be manufactured from polymeric or metallic cable materials. Preferably the cable is made from polyester, nylon, olefin, fluoropolymer, stainless steel or other similar cables. The expansion cable may be monofilament or multifilament. PET, Nylon, UHMWPE, Kevlar and PEN fibers are especially preferred. When the strut section 214 is deployed it expands to form a ring. The strut section 214 is connected to the guidewire section 210 at the distal section 229 of guidewire. The strut section 214 and distal section 229 of guidewire are adapted such that the strut section

214 sits at an angle transverse to the axis of the vessel. In one embodiment the strut section 214 and/or/not the distal section of guidewire 210 have a preset shape that causes the strut section 214 to sit transverse to the axis of the vessel. In another embodiment the expansion cable 213 is tensioned by advancing the catheter 211 proximally relative to frame assembly 225. When the expansion cable is tensioned it causes the strut section 214 to move more transversely in the vessel. It will be appreciated that this mechanism allows the user to modify the shape of the strut section 214 as well as controlling the resistance of the strut section to collapse during clot capture. It will also be appreciated that this allows the device to be delivered through micro-catheters as the cross sectional area of the strut section can be reduced significantly. In another embodiment more than one expansion cable 213 is employed. With this embodiment the expansion cables are preferably attached to opposite sides of the strut section 214. Both cables are attached to the distal end of catheter 211 and both cables are tensioned by a proximal advancement of the catheter 211 relative to the frame assembly 225. With two cables the position of attachment 223 to the strut section can be varied. However some displacement relative to distal section 229 of guidewire is desired as this reduces the force required to bias the strut section 214.

In another embodiment the tensioning of the expansion cable 213 is controlled by a handle at the user end. The handle comprises means for locking to the guidewire, means for locking to the catheter 211 and a mechanism to control fine axial motion of the catheter 211 and guidewire 210. In one embodiment the fine axial motion is controlled by a helical mechanism such as a thread or coil. In another embodiment the fine axial motion is achieved with a gear arrangement such as a rack and pinion. In one embodiment the guidewire locking mechanism comprises a pin vice. In another embodiment the expansion cable is fastened to the proximal end of catheter 211. In another embodiment the expansion cable is releasably attached to the proximal end of catheter. In yet another embodiment the expansion cable 213 can be released from catheter 211 and catheter 211 can be removed from the guidewire 210 leaving the frame assembly and the expansion cable behind. With this embodiment the strut section can be activated directly by the user by tensioning the expansion cable. In another embodiment the expansion cable has a grip section attached to its proximal end.

In the embodiment shown in fig 34a-b the strut section 214 is shown delivered inside the distal end 216 of catheter 211. The catheter 211 with strut section 214 collapsed are delivered to the target location through a procedural catheter. The lumen at the distal end 216 of catheter 211 is sized to accommodate the frame assembly 225 in its collapsed state.

With reference to fig 34c-f there is shown some detailed embodiments of the frame assembly 225 of the invention. Fig 34c shows a frame assemble 225 comprising a strut section 214 and guidewire 210. The strut section 214 is ring shaped and is integral with the distal end 228 of guidewire 210. The guidewire 210 comprises a proximal section 226 and a distal section 228. The proximal and distal segments are joined at junction section 227. In one embodiment the proximal section at least partially comprises a tube and said tube engages with junction section 227 to connect the proximal 226 and distal 228 sections of the guidewire 210. The joint between the proximal 226 and distal 228 sections of the guidewire may be further reinforced by any of a variety of conventional joining techniques including screw joint, welding, soldering brazing, adhesive bonding, crimping, swaging or combinations of the above. The guidewire 210 extends from the strut section 214 back to the user in use and is thus much longer than depicted. The strut section 214 may be any of a variety of cross-sectional shapes including circular, elliptical, rectangular, square, polyhedral, and multifilament. Circular or rectangular are preferred. The strut section further comprises eyelets 212. The eyelets 212 are as described earlier in fig 30-33. The expansion cable 213 is connected to the strut section 214 at its distal end. An eyelet 223 may be used to effect cable attachment. The cross sectional area of the distal end of the guidewire 210 may be locally modified to improve the shaping of the frame by the expansion cables. The guidewire 210 may be flattened so as to create a directional bias for strut section 214 when expansion cable 213 is activated. A flattened cross section in this area has the effect of keeping the strut section 214 in plane during expansion. The strut section 214 of fig 34c may be cut from a hypotube. The shape may be cut from a small diameter tube and expanded or it may be cut directly from a large diameter tube.

Fig 34d shows an alternative construction of the frame assembly 225. The guidewire 210 and frame assembly 214 are manufactured from a single piece of wire. The strut section 214 forms a ring shape and comprises eyelets 212 and an expansion cable 213 attachment eyelet 223. The strut section 214 is made from a wire that is looped and joined to itself. The joint area 219 is at the distal end of guidewire 210. A smooth transition 224 is effected between the joint area 219 and the distal end of the guidewire 210. The distal portion 229 of the joint area 219 may be locally thinned or flattened to create a bias for strut section expansion. Fig 34e-f show segments of strut sections 214 of the invention wherein the strut sections 214 have either a circular or rectangular cross section.

The method of use of clot retrieval device 218 of fig.34a-f is highlighted in fig 35a-i. Fig 35a shows a vessel 220 and an obstructive clot 221. The clot retrieval device 218 is shown in its collapsed state crossing the obstructive clot 221. The distal tip 216 of catheter 211 is advanced across obstructive clot 221 with strut section collapsed inside the lumen of the catheter distal tip 216. The guidewire extends proximally and is operably moveable relative to catheter 211 to deploy the strut section 214. The strut section 214 is deployed by advancing catheter 211 proximally while holding the guidewire 210 fixed (fig 35c-d). The strut section assumes its remembered ring shape in the vessel. The clot retrieval device is advanced proximally until its strut section 214 is adjacent the obstructive clot 221. At this point the catheter 211 is advanced proximally relative to the guidewire 210 until the expansion cable 213 is tensioned (fig 35e). This step can be controlled with a handle mechanism at the proximal end as described elsewhere. Increasing the tension in expansion cable 213 changes the angle that the strut frame 214 makes relative to the axis of the vessel 220. This in effect changes the size of the capture opening of the clot retrieval device 218. As the capture opening increases the strut frame 214 achieves better apposition with the walls of the vessel 220. It will be appreciated that these features allow the user to achieve very efficient clot capture. However overly tensioning the expansion cable 213 is not desirable as this will induce trauma to the vessel. Rather the expansion cable 213 is tightened to the point where the strut section 214 has achieved apposition with the vessel and the catheter 211 is then locked relative to the guidewire at the user end. The clot retrieval device 218 is now advanced proximally to capture obstructive clot 221 (fig 35f). With the obstructive clot captured the lock between catheter 211 and guidewire 210 is released. The guidewire is advanced proximally relative to catheter 211 and at least the proximal portion of strut section is drawn into the lumen at the distal end 216 of catheter 211 (fig 35g-h). This step reduces the diameter of the strut section and makes removal of the clot 221 and clot retrieval device 218 easier. The clot retrieval device 218 and clot 221 are removed from the body (fig 35i).

In another embodiment the lumen at the distal end 216 of catheter 211 is sized only to accommodate guidewire 210. With this embodiment the strut section 214 cannot be collapsed inside catheter 211. Instead, the frame assembly 225 and catheter 211 are delivered through the lumen of a micro catheter. The tip of the micro-catheter is placed across the obstructive clot. The strut section 214 is collapsed and while restrained in the collapsed state the frame assembly 225 and catheter 211 are advanced into the proximal lumen of the micro-catheter. The clot retrieval device is advanced through the lumen of the micro-catheter and deployed distal of the tip of the micro-catheter. When the device is deployed the micro-catheter is advanced proximally. Subsequently the clot retrieval device is advanced until the strut section is adjacent the

obstructive clot. The catheter 211 is advanced proximally and expansion cable 213 is activated. When the frame section is expanded to the desired shape, the expansion cable 213 and catheter 211 are locked relative to guidewire 210. The clot retrieval device 218 is advanced proximally to capture the clot. The micro-catheter is again advanced until its distal tip engages with the strut section 214 of the clot retrieval device 218. The micro catheter is advanced further and partially collapses the strut section. The micro-catheter and clot retrieval device 218 are withdrawn from the vessel together.

Yet another embodiment is shown in Fig 36a-b. The clot retrieval device 218 is the same as the clot retrieval device of fig 35. However in the embodiment shown in fig 36 the lumen of catheter 211 accommodates a separate crossing guidewire 222. The crossing guidewire 222 runs parallel the guidewire 210 of the clot retrieval device. The crossing guidewire 222 may sit side by side with the collapsed clot retrieval device. Alternatively catheter 211 has a separate lumen for crossing guidewire 222. The crossing guidewire is free to move axially and rotationally relative the clot retrieval device. The crossing guidewire 222 is preferably a conventional guidewire and its tip can be shaped to access target vessels. This allows the crossing guidewire 222 to be used in conjunction with catheter 211 to access difficult to reach locations by advancing the crossing guidewire 222 relative to the catheter 211 and torqueing it as necessary to achieve access. When the tip section of crossing guidewire 222 has accessed a side branch the catheter 211 can be advanced over the crossing guidewire. When the clot retrieval device218 is delivered to the target location the crossing guidewire may be removed. Alternatively the crossing guidewire may be left in the target vessel.

Fig 36a shows a crossing guidewire 222 with its distal tip across the capture fibers 215 of clot retrieval device 218. The capture fibers are arranged in a fashion that a small diameter device can be pushed through the gaps in the capture fibers 215. The ability of low profile devices to cross the capture fibers allows other devices to be used with the clot retrieval device.

Another embodiment of the invention is shown in Fig 37a-e. Fig 37a shows a conventional guidewire 230. The guidewire comprises a proximal end 231, a distal end 232 and a tip 234. The tip 234 is flexible and atraumatic to vessels. Many of the features of the clot retrieval device 250 of this embodiment are achieved by modifying the area 233 adjacent the tip 234 of conventional Guidewires 230. With reference to fig 37b there is shown a guidewire 233 which has been modified proximal of the tip in order to create clot retrieval device 250. The guidewire 233 comprises an inner shaft 235 and an outer shaft 236. The inner shaft and the outer shaft are fixed

together. Proximal of the tip of the guidewire 230 the outer shaft 236 has substantially longitudinal cuts 238 so as to create strut elements 237. The strut elements 237 are cut so as to create ring elements 247. One or more ring elements may be created with strut elements 237. In the embodiment shown two ring elements 247 are created by cutting two pairs of strut elements 237 and connecting the strut elements 237 at their distal ends. In one embodiment the segment of the outer shaft 236 adjacent the tip 234 is made from an elastic, a super elastic or a shape memory material. Preferably said elastic material is nitinol or a spring steel. Most preferably the outer shaft 236 is made from nitinol. Fig 37c shows the clot retrieval device 250 in its expanded state. It can be seen that a number of elements have been added to the modified guidewire of fig 37b to create the clot retrieval device 250. The strut elements 237 have a collapsed state and an expanded state. Fig 37b shows the strut section 237 in it's as machined (laser cut) state. The strut section 237 is shown in its expanded state in fig 37c. In the expanded state the strut sections 237 form a capture frame 247. In the embodiment shown the capture frame 247 comprises two D-shaped elements. The capture frame comprises radial strut sections 246 and body strut sections 248. The body strut sections interface with the vessel wall in the expanded state and provide a line of apposition around the circumference of the vessel. The radial strut section 246 connects the body strut section to guidewire shaft 236. Eyelets 244 are provided on at least the body strut section 248 and capture fibers 241 are fixed to the capture frame 247 using said eyelets 244. The capture fibers 241 are fixed to collar 243 distally. Collar 243 is fixed to the distal portion of the guidewire. In another embodiment the distal eyelets are cut into the outer shaft 236 of the guidewire 230. This eliminates the need for collar 243 and reduces the distal profile of the device. When the strut section 237 is in the expanded state a recess area 240 is created in the wall of the guidewire. The integrity of the guidewire is maintained by the presence of connector elements 242. The connector element 242 is a portion of the outer shaft 236 that lies adjacent the recess area and connects the distal part 232 of the outer tube 236 with the proximal part 231 of the outer shaft 236. The connection between the proximal portion 231 and the distal portion 232 of the guidewire 230 is further reinforced with the inner shaft 235. In one embodiment the inner shaft 235 is fixed to the outer shaft 236. In one embodiment the connector element 242 is fixed to the inner shaft 235. When the strut section 237 is in the collapsed state it packs into the recess area 240. This keeps the delivery profile of the clot retrieval device 250 extremely low. Since the capture fibers are made from a highly oriented fiber such as Dyneema (UHMWPE), and since the recess space 240 is larger than the strut section the attachment of the capture fibers to the strut section 237 will not adversely impact the profile of the strut section 237 of the clot retrieval device 250 in the collapsed configuration.

The clot retrieval device 250 is shown in the delivery configuration in fig 37d. The delivery catheter 245 is of an extremely low profile. Preferably the delivery catheter is less than 2F (0.66mm). More preferably the delivery catheter profile is less than 1.9F. Even more preferably the delivery catheter is less than 1.6F.

Fig 37e shows an end view of the device 250 in the expanded state. The view is as seen from distal of the expanded strut section 237. The inner core 235 is visible with two connector elements 242 diagonally opposite. The strut section 237 is shown expanded to from capture frame 247. The capture frame 247 comprises a double-D shape. The capture frame 247 further comprises radial strut sections 246 and body strut sections 248. The strut sections 237 are provided with eyelets 238 for capture fiber attachment.

In yet another embodiment the clot retrieval device 250 is delivered to the target site without the need for a delivery catheter. With this embodiment the inner shaft 235 and the outer shaft 236 are moveable relative to each other. The strut section 237 is connected to the inner shaft 235 in the delivery configuration and said connection restrains the strut section 237 in the collapsed state. Upon reaching the target site relative movement of the inner shaft relative to the outer shaft releases the connection and allows the strut section 237 to expand. In one embodiment the connection comprises a tether that is attached to both the strut section 237 and the inner shaft 235. In the collapsed configuration the tether is under tension as it restrains the strut section 237. The inner shaft 235 is either advanced or rotated to relax the tension in the tether and this allows the strut section 237 to expand. In another embodiment an engagement between the inner shaft 235 and the strut section 237 retains the strut section 237 in the collapsed state. The inner shaft 235 is either rotated or advanced to disengage with the strut section 237 and this allows the strut section 237 to expand. The engagement may be a frictional engagement, a snap engagement, a clip engagement feature, a hook engagement or other similar engagements.

Now with reference to figs 38-39 there is shown another low profile clot retrieval device 280. Fig 38a-b shows modifications to guidewire 260 necessary to create clot retrieval device 280 of Fig 39a-b. The modified guidewire 260 comprises a tubular shaft 261 which has a proximal end 266 and a distal end, an outer surface and an inner lumen. The distal end of tubular shaft 261 comprises a strut section 267 and an expansion cable 265. The strut section is shown in the 'as cut' state in fig 38a-b. The strut section 267 comprises at least one pair of generally longitudinal struts 264 and a strut connection 268 at the distal end of longitudinal struts 264. Where the strut segment 267 comprises a single pair of longitudinal struts 264 then in the expanded

configuration the axis of the outer shaft adjacent the strut section 267 will be offset relative to the axis of the vessel (as shown in fig 39a-b). However where the strut segment 267 comprises two pairs (or more) of longitudinal struts 264 then in the expanded configuration the axis of the outer shaft adjacent the strut section 267 will be generally coaxial with the axis of the vessel. In one embodiment the strut connection is a short strut like element. In a preferred embodiment the strut connection 268 has a curved aspect. The curved aspect helps to distribute stress as the strut section is expanded to from a ring. Preferably the strut connection has an inner curve and an outer curve wherein the inner curve has a smaller radius than the outer curve. Preferably the difference in radius of the inner curve versus the outer curve is less than the width of the strut sections 267. Preferably the strut connection comprises a strain relief feature. In another embodiment the strut connection 268 comprises an element that is curved in at least two dimensions.

The expansion cable is attached to the frame section 267 at attachment point 269 and extends proximally to the user. The expansion cable 265 enters the lumen of the tubular shaft 261 at port 262 and extends through the lumen back to the user. The expansion cable can be tensioned by the user at the proximal end of the guidewire shaft 261. In one embodiment the expansion cable is attached to a fine adjustment mechanism at the user end. This allows the user to control the level of tension in the expansion cable 265 and thus the resistance of the strut section 267 to collapse during clot capture. The port 262 position along the tubular shaft 261 may be varied. In one embodiment the distal opening of the lumen of the tubular shaft 261 is used as the port 262.

In the embodiment shown in fig 38 the eyelets 270 are shown along the length of strut section 267. Eyelets may also be placed at the distal end of the tubular shaft 261. The eyelets 270 may be created in a variety of configurations as previously described. Likewise, the attachment of the capture fibers 279 is as described earlier.

In another embodiment the width of struts 264 is sufficiently great that an expansion cable is not needed in order for the strut section 267 to effectively capture the obstructive clot.

The clot retrieval device 280 is shown assembled and in the expanded state in fig 39a-b. The capture fibers and the distal collar 282 have been added to fig 38 and the strut section 267 has been expanded. The strut section 267 is preferably made from an elastic material, a super elastic material or a shape memory material. The strut section 267 forms a ring in the expanded state and the ring shaped strut section 267 apposes the vessel in the expanded state. In use the expanded strut section 267 is advanced proximally to capture the clot. The expansion fiber 265

is used to add stiffness to the frame and prevent its partial collapse during clot capture. The large open mouth of the strut section in the expanded state makes this embodiment an effective clot capture device. The capture fibers are terminated at a distal junction 281 with a collar as previously described. The distal collar comprises eyelets for capture fiber attachment. In another embodiment the distal junction 281 is formed by the joining of the distal ends of the capture fibers 280 to each other. In one embodiment a knot arrangement is used, in another embodiment the capture fibers are bonded or welded together.

In the embodiment shown in fig 39 the distal junction 281 is free to move proximally as it is not constrained relative to the guidewire 261. In another embodiment at least one of the capture fibers has a bias. Preferably said bias generally pushes the distal junction 281 distal of the strut section. Preferably the biased capture fiber is elastic, super elastic or shape memory. Preferably said biased capture fiber is metallic. Preferably said capture fiber is nitinol, or stainless steel.

Fig 39c shows the clot retrieval device 280 in the delivery configuration. The strut section 267 is shown in the collapsed configuration inside a pod 285 of delivery catheter 284. The guidewire shaft 261 extends proximally through the lumen of catheter 284. In one embodiment the catheter 284 and guidewire 261 are arranged in an over the wire fashion. In another embodiment the catheter 284 and guidewire 261 are arranged in a rapid exchange fashion. The catheter shaft is preferably made from a thin walled flexible material. Preferably the catheter is made from an olefin, nylon, a PEBAX, polyester, polyurethane or a fluoropolymer. The delivery catheter may be made from a combination of these materials. The catheter may be made with two or more layers and at least one of these layers comprise at least one of the above list of materials.

Fig 40a-b shows a clot retrieval device 290 that is very similar to the clot retrieval device 280 of fig 39. The clot retrieval device 290 has a first difference in that the distal junction is connected to strut tip 287. The strut tip is created during the machining of the strut section 267. The strut tip is formed from a portion of the wall of the tubular shaft 261 that lies between longitudinal struts 264. The strut tip is designed to be mechanically similar to the core of a guidewire tip. The strut tip tapers distally and has an atraumatic element 287 at its distal end. The strut tip 287 provides a site upon which the distal junction 281 can be connected. In the embodiment shown a collar is used as the distal junction 281 and the collar has limited movement relative to the strut tip 287. In one embodiment the collar is fixed relative to the strut tip. A second difference between the clot retrieval device 280 of fig 39 and clot retrieval device 290 of fig 40 is that the distal end of the tubular shaft 261 has machined slots 286 to improve the trackability of the

device. In one embodiment the slots run transverse to the axis of the tubular shaft and run only part of the circumference. In another embodiment pairs of transverse slots 286 are arranged on opposite sides of the tubular shaft 261. In another embodiment the slots 286 are arranged in a continuous helix along a portion of the distal end of the tubular shaft 261. In another embodiment the clot retrieval device comprises a supporting strut 288. The supporting strut 288 extends distally and substantially parallel of the axis of the tubular shaft 261 and comprises a restraining feature. The supporting strut 288 is configured to restrain the strut section 267 in the collapsed state during delivery. The restraining feature may comprise a tether arrangement, an interconnection between the supporting strut and the strut section 267, an interlock between the supporting strut and the strut section 267, or a coupling between the supporting strut 288 and the strut section 267. The restraining feature may be deactivated when the clot retrieval device 290 is at the site of the occlusion causing the strut section 267 to expand to its remembered expanded state. The deactivation may be brought about by means of a release cable, use of an inner core which may be advanced or retracted to free the strut section or advancement or retraction of an outer tubular member or a combination of these mechanisms. In another variant the restraining feature may be configured such that the strut section is firstly restrained to itself and secondly restrained to the supporting strut and that both restraints are decoupled either simultaneously or in series when the clot retrieval device 290 is at the site of occlusion. The clot retrieval device 290 is otherwise the same as clot retrieval device 280 and similar numbers shall have the same meaning for both devices.

The clot retrieval devices of fig 41-43 are very similar to the clot retrieval devices shown in fig 39 and fig 40. With Fig 41 the strut tip is cut substantially parallel to the longitudinal struts 264 of strut section 267. The longitudinal strut extends distal of the strut section and connects the tubular shaft proximally 261 with a distal segment of tubular shaft 291. The distal segment of the tubular shaft 291 is modified to make it atraumatic to vessels. The modification may comprise a spiral cut or slots as described previously. The distal tip 293 of the tubular shaft 291 is smooth soft and atraumatic. The distal junction 268 is connected to the distal shaft 291 as previously described.

Fig 42a-b shows an inner core 301 adapted to from a guidewire like tip to the clot retrieval device 300. The inner core has proximal diameter that allows it to fit inside the lumen of the tubular shaft 261. The inner core 301 may be fixed relative to outer shaft 261 or it may be moveable relative to outer shaft 261. The distal portion of the inner core tapers distally and has an atraumatic tip 302. The atraumatic tip 302 comprises a rounded tip 304 and a coil segment

303. The rounded tip 304, the distal tip of the inner core 301 and the coils are preferably fastened together. The distal junction 268 is positioned proximal of the distal end of the core wire. In one embodiment the distal junction comprises a collar with eyelets for capture fiber attachment. The proximal end of inner core may be terminated distal of port 262. Alternatively the inner core extends proximally but provides clearance for the expansion cable. In yet another embodiment the inner core 301 and the expansion cable 265 are connected proximal of port 262 and the inner core 301 movement is used to tension the expansion cable 265. In another embodiment the inner core 301 distal end is shapeable.

In another embodiment the clot retrieval devices of this invention are adopted for use as embolic protection devices. With this embodiment the delivery catheter is removed after deployment and the guidewire is employed to deliver treatment devices. A greater number of capture fibers are employed and the capture fibers are arranged so as to create distal pores of less than 200 microns.

Another embodiment of the invention is shown in fig 44-46 wherein the clot retrieval device comprises a guidewire 330, a clot capture ring 320, and capture fibers 333. With reference to fig 44a there is shown a clot capture ring 320 of clot retrieval device 350. The clot capture ring is characterized in that it is cut from a tube and formed. The strut section 321 is shown in its as cut configuration and provides strong vessel apposition. The strut section is attached to the guidewire with a collar element 322. The collar element is cut from the same tube as the strut section 321 but it is formed into a collar after cutting. The collar element 322 comprises at least one finger element 323. The finger element is formed into a tubular segment such that it can be attached to the guidewire. Preferably one or more finger elements wrap around the guidewire diameter and make a secure attachment. Multiple finger elements are preferred over one wide finger element to ensure the device is trackable while distributing forces to the guidewire. The collar element may be welded or bonded to the guidewire. Alternatively the collar element may be a force fit with the guidewire. Fig 44b shows a view of the collar element 322 and a portion of the strut section 321 in the as cut configuration. In this embodiment pairs of fingers 323 are located on either side of member 326. The collar element 322 is connected to the strut section by a connector element 325. The connector element 325 has a curved interface with the strut section 321. The connector element 325 is designed such that it distributes strain loads it has to endure during collapse and delivery. The curved interface helps to distribute the loads. Preferably the connector element comprises strain distributing features as described. The eyelets 327 are shown on the strut section and these function as previously described.

Fig 44c shows the clot retrieval device 350 in the expanded configuration mounted on guidewire 330. The guidewire comprises a shaft, a proximal end 331, a distal end 332 and a tip 329. The capture ring 320 is connected to the guidewire adjacent the distal end 332. The capture ring is secured to the guidewire 330 using collar element 322. Capture fibers 333 are attached to the strut section using eyelets 327 and are attached to the distal end of the guidewire at distal attachment point 328. Distal attachment point comprises at least one eyelet in the guidewire. The guidewire may be tubular in this area or at least one micro-hole may be drilled through the wall of the guidewire to create an attachment. Alternatively the capture fibers may be bonded or mechanically fastened to the guidewire.

The clot retrieval device 350 is shown in the collapsed configuration inside the distal lumen of delivery catheter 335 in fig 44d. The clot retrieval device is deployed by advancing the guidewire 330 relative to the delivery catheter 335.

Fig 45a-c shows a variation in the embodiments shown in fig 44. This time the connector element 340 is longer than previously described. This allows better strain relief to be achieved in the area of bending during collapse and it also allows the offset of the guidewire position to be controlled. In the embodiment shown the guidewire position is close to the strut frame but there is still a gap between the guidewire and the wall. This partial offset feature allows for a large capture opening.

Another variation of the embodiments described in fig 44-45 is shown in fig 46. This time an expansion cable 341 is employed to help frame expansion. The device is shown with the expansion cable in the tensioned configuration with the frame expanded into a ring. The expansion cable allows the angle of the ring to the vessel to be controlled by the user. In the embodiment shown the angle is greater than 90'. This makes the resistance of the frame to collapse very difficult during clot capture. The guidewire shaft has a port 342 and an inner lumen 343 through which the expansion cable runs. The proximal end of the expansion cable exits the lumen 343 at the proximal end of the guidewire 331.

With reference to fig 47a-d there is shown another clot retrieval device 360 which is constructed from a guidewire 364, capture fibers 365 and a fiber anchor 367. The guidewire comprises a proximal end 363, a distal end 368, a distal tip 369 and a frame section 361. The proximal end of the guidewire 363, comprises a tube section with an expansion cable 362 extending from the frame section 361 to a point proximal and external of the guidewire 364. The proximal end of

the guidewire 363, in use, is external of the patient. The expansion cable is attached to the distal end of the distal frame section 371. The distal tip 369 has an atraumatic tip to prevent vessel injury. The frame section 361 further comprises a distal frame section 371 and a proximal frame section 370. The frame section 361 has an expanded configuration and a collapsed configuration. In the collapsed configuration the frame section comprises an elongate element. In the expanded configuration the proximal frame section 370 and distal frame section 371 forms a ring that orients transverse to the axis of the vessel.

In a first embodiment the frame section 361 is a substantially elongate element in its relaxed state. When the expansion cable 362 is tensioned the shape of frame section 361 changes from its relaxed elongate state to its expanded ring configuration. This shape change is controlled by compression slots 375 in the tubular wall of the guidewire shaft 364. The compression slots 375 allow the shaft 364 to compress preferentially on one side and this allows the shaft to adopt a curved configuration. Where all the slots are on one side of the tube then the tube will bend into a simple curve when loaded in compression. Complex curves can be achieved by using multiple slots and moving the position of the slots around the axis of the tube. Fig 47d shows a section 364 of a guidewire shaft with slots designed to create both simple and complex curves. In the center of the slotted section all the slots 375 are in a line and this construction will allow for a simple curve when the shaft is compressed. At both the proximal and distal end of the section, the slot position changes as we move along the shaft. This creates a curve in two dimensions (Y & Z). In order to create the ring shown in fig 47a two complex curves ('a' in fig 47d) at either end of a simple curve ('b' in fig 47d) are required.

In another embodiment the frame section 361 is ring shaped in its relaxed state. In this configuration the device is collapsed for delivery using a delivery catheter 372. The collapsed device is stored in the lumen of the delivery catheter and advanced across the obstruction. It is deployed distal of the obstruction and opposes the vessel wall. The expansion cable may be employed in order to improve the stiffness of the device in the expanded configuration. Since the expansion cable effectively locks the distal end of the distal frame section 371 to the proximal end of the proximal frame section it greatly increases the resistance of the frame section to collapse.

In another embodiment two or more expansion cables are used. The first expansion cable is used as described above. The second expansion cable is attached to the frame section 361 between the distal frame section 371 and the proximal frame section 370. The expansion cable extends

proximally until it enters the lumen of the guidewire 364 proximal of the frame section through a port in the wall. This second expansion cable when tensioned prevents the frame from collapsing distally when capturing clot.

With each of these embodiments the capture fibers 365 are attached to the frame section 361 at the proximal end and to the fiber anchor 367 at the distal end. Preferably the capture fibers 365 are slidably attached to the fiber anchor 367. In one embodiment the capture fibers 365 are connected to the compression slots 375. In another embodiment the frame section 361 comprises eyelets as previously described and the capture fibers are attached to the eyelets. In either scenario the attachment points of the capture fibers 365 are spaced apart along the length of the frame section 361. Preferably the capture fibers 365 are evenly spaced apart along the frame section 361. The fiber anchor 367 at the distal end provides for secure fiber attachment to the distal shaft 368 while allowing the capture fibers 365 to slide at the fiber anchor. The ability of the fibers to slide is important in allowing the frame section to collapse efficiently. Fibers attached to the distal part of distal frame section 371 require very little slack in order to allow that portion of the frame to move from an expanded state to a collapsed state. However, fibers at the proximal end of the proximal section of the frame 370 require considerable slack in order to allow that portion of the frame to collapse unconstrained. In order to minimize the amount of capture fiber 365 slack it is preferred that fibers connected to the distal section of the distal frame section 371 be looped through the fiber anchor and connected back to the proximal end of the proximal frame section 370. By taking this approach throughout the frame the level of capture fiber slack can be minimized. It will be appreciated that in order to allow for this fiber slack to be distributed the fibers need to slide through the fiber anchor with ease. Preferably the size of the opening on the distal anchor for fiber attachment is a clearance fit for the capture fibers. In one embodiment the anchor 367 comprises a ring with an inner diameter. The inner diameter is larger than the diameter of the guidewire and one or more attachment legs 376 fix the ring relative to the guidewire.

Fig 48a shows a clot Retrieval device 800 in the expanded state. Fig 48b shows the same device loaded into a microcatheter 812 for delivery to the target site. Frame 804 is similar to frame 361 in fig 47a, but in this case is not formed from the guidewire. Frame 804 expands to a generally circular shape in end view, but elongates and twists into a longitudinal element when collapsed for delivery and retrieval as shown in fig 48b. The proximal 807 and distal 806 ends of the frame 804, are mounted to tubular elements 808 and 805 respectively. These elements are mounted on the guidewire 809, allowing rotation and translation of the frame relative to the guidewire. Stops

801, 802 and 803 are positioned on the guidewire to allow the user to apply a push or pull force to appropriate elements of the device to facilitate its advancement or withdrawal. Stop 803 prevents the frame from elongating during clot retrieval, and together with stop 802 acts against the frame during clot capture and retrieval. Stop 802 apposes element 805 during device advancement through and from a delivery microcatheter 812 as shown in fig 48b. Apposing the distal end of the frame in this way keeps the frame 804 in tension rather than compression as would be the case if force were applied to element 807 to facilitate advancement . Keeping the frame in tension reduces the lateral forces applied to the lumen of the microcatheter, and thus reduces the force required to advance the clot retrieval device through the microcatheter. In one embodiment of this design a delivery assist catheter 811, with proximal element 810, may be used to transmit a push force to stop 801, which in turn transmits a push force through the guidewire to stop 802 and thus to the distal end of the frame. This method of advancement eliminates the need for that element of the guidewire proximal of stop 801 to transmit push, and therefore permits the use of a more flexible wire. In another embodiment (not shown) stop 801 is not present and delivery assist catheter 811 is not required as push force can be transmitted through the guidewire to stop 802 and thus to the frame.

Figs 49a-b illustrate another clot retrieval device 850 similar to device 360 shown in fig 47a, but employing an additional tether element 853. Frame 851 is configured to tend to adopt a curved profile and appose the vessel wall when released from the constraints of the delivery microcatheter 854 shown in fig 49b. When placed in tension the tether element 853 provides additional integrity to the frame, and acts against the tendency of the frame to elongate when meeting resistance such as during clot capture. Once the target clot has been successfully captured the tether element may be relaxed so as to allow the frame to elongate again for ease of retrieval. Alternatively the tether element may be kept in tension to maintain the frame and capture net 852 in a more preferential configuration for retention of captured clot during retrieval from the body.

Figs 50a-c show another clot retrieval device 870 . Fig 50a shows the device in its deployed state. Frame 871 is connected to guidewire 875 by element 873, which allows the frame to rotate and translate relative to the guidewire. Distal capture net 872 is connected to frame 871 and is also connected at its distal end to collar 874. Fig 50b shows the device encapsulated in microcatheter 878 just prior to deployment from the microcatheter. To effect deployment the guidewire 875 on which the device is mounted is fitted with a stop 877, which apposes collar 874 when the microcatheter is retracted, preventing the clot retrieval device from retracting with

the catheter. This configuration also holds the capture net in tension, with the associated benefits described previously in relation to figs 48a and b. In the embodiment shown a second guidewire stop 876 is provided, which apposes proximal frame element 873 during retraction and retrieval of the device. Such a design allows the length of guidewire protruding distal to stop 877 to be limited or eliminated. In another embodiment (not shown) only one guidewire stop is provided which acts in both deployment and retrieval.

Fig 51a shows a clot retrieval device 890 configured in such a way that it may be used in conjunction with a variety of suitably sized guidewires 891. The device 890 has a shaft 892 which is sized to be able to advance or retract over guidewire 890. Fig 51b shows a similar device 894 mounted on a shaft 895 which has a guidewire exit port 896, so that the device may be used with any suitably sized short length guidewires.

Fig 52a shows a clot retrieval device 2010. The clot retrieval device 2010 comprises guidewire 2020 and a clot capture basket 2011. The clot capture basket comprises a frame 2012, and a net 2015. The clot retrieval device 2010 has an expanded state for engagement and capture of clots and a collapsed state for delivery through the vasculature. The frame 2012 comprises a collar 2023 for mounting the frame 2012 on the guidewire 2020, a hoop 2014 composed of struts 2009 and at least one connector element 2013 to connect the collar 2023 and the hoop 2014. Preferably the frame 2012 is made from a superelastic or shape memory material. The frame further comprises a bifurcation point 2022 where the connector 2013 splits to form two struts 2009. In this embodiment the connector 2013 has greater width than the struts 2009. In another embodiment the connector 2013 has greater width over most of its length than tha strut 2009 except in the region just proximal to the bifurcation. In this area the width of the connector 2013 is significantly reduced. This allows the connector 2013 to hinge at this point and so respond to vessel asymmetry or asymmetry in the guidewire access.

In one embodiment the clot capture basket 11is fixed to the guidewire. In another embodiment the clot capture basket 2011 is slidable on the guidewire 2020.

Fig 53 shows another clot retrieval device 2010 which is almost identical to the clot retrieval device of fig 2002 except that the connector comprises a pair of parallel struts 2025. The pair of parallel struts 2025 allows the connector to contribute strongly to the engagement force of the device while providing greater lateral flexibility. The capture basket 2011 further comprises a basket mounting tube 2019. The basket mounting tube 2019 extends from the proximal end of the basket 2011 to the distal end of the net 2015. The net is attached to the mounting tube 2019.

The mounting tube may be fixed relative to the collar 2023 or it may slide relative to the collar 2023. The distal end of mounting tube is configured to engage with the stop 2017.

Fig 54 shows a frame 2012 of Fig 52 as a sub-component. The frame 2014 comprises three segments; the proximal segment comprises a collar 2023 which is a short tube for mounting on the guidewire 2020, the intermediate segment comprises two connectors 2013 and the distal segment comprises a plurality of struts that form a hoop 2014. Ideally there are four struts that each form a quadrant of the hoop. The frame 2014 is preferably made from a super elastic or a shape memory alloy.

Fig 55 shows another clot retrieval device 2030, which is similar to the clot retrieval devices of Fig 52-54, and similar numerals are used to describe similar elements. The clot retrieval device is shown with a microcatheter 2031. The clot retrieval device is delivered through the lumen of a microcatheter and is moveable relative to the microcatheter 2031. The movement of the clot retrieval device 2030 relative to the microcatheter is effected by the movement element 2019. In one embodiment movement element 2019 comprises a tubular element which is slidable over the guidewire. The tubular element may be fixed to the collar 2023 of the capture basket 2011 and can thus control movement of the capture basket 2011 in both directions relative to the guidewire or the microcatheter. Alternatively the tubular element 2019 is separate fro the capture basket and advances the capture basket as a bumper tube. With this embodiment the bumper tube can advance the clot capture basket 2011 but can not withdraw the basket. In this embodiment the capture basket is withdrawn by engaging the step at the distal end of the guidewire.

Alternatively the movement element 2019 is a guidewire. With this embodiment the capture basket 2011 if fixed to the guidewire 2019 and thus movement of the capture basket is controlled by the guidewire. Forward and backward movement of the capture basket 2011 are controlled by the guidewire 2019.

Fig 56 shows another clot retrieval device 2040, which is similar to the clot retrieval devices of Fig 52-55, and similar numerals are used to describe similar elements. With this embodiment the capture basket 2011 is deployed from a reception space 2046 at the distal end 2047 of the microcatheter 2041. The guidewire 2020 is moveable relative to the capture basket 2011. The microcatheter is connected to the capture basket 2011 by a telescoping tube 2048 which is fixed the collar 2023. The telescoping tube 2048 further comprises a stop 2043 which engages with a microcatheter stop 2044 to prevent complete separation of the basket 2011 and the microcatheter 2041. A bumper tube (not shown) is used to deploy the capture basket 2011 from the reception

space 2046. The capture basket 2011 is removed at the end of the procedure by withdrawing the guidewire 2020 so as to engage the guidewire distal stop 2017 with the body tube 2021. This forces the telescoping tube 2048 and the capture basket back into the reception space for removal.

Fig 57 shows another clot retrieval device 2060, which is similar to the clot retrieval devices of Fig 52-56, and similar numerals are used to describe similar elements. With this embodiment a bumper tube 2048 is used to advance the clot capture basket 2011 over the guidewire. The bumper tube further comprises a rapid exchange feature. The bumper tube comprises a lumen with a proximal exit port 2061 from which the guidewire exits. A control element 2063 is connected to the proximal end of bumper tube 2048. The control element 2063 extends proximal of the microcatheter 2041 and out of the patient. The user controls the position of the clot capture basket 2011 using a control handle 2065 at the proximal end 2064 of the control element 2063.

Fig 58 shows another clot retrieval device 2080, which is similar to the clot retrieval devices of Fig 52-57, and similar numerals are used to describe similar elements. With this embodiment a tether 2042 extends between the collar 2023 of the capture basket 2011 and the microcatheter 2041. The tether 2042 has a relaxed configuration as shown in fig 58a and a taut configuration as shown in fig 58b. The proximal end of the tether 2042 extends proximally. In one embodiment the tether 2042 is controlled by the user. In another embodiment the proximal end of the tether 2042 is connected to the microcatheter. The tether 2042 allows the capture basket 2011 to move relative to the microcatheter within a certain limit.

Fig 59a-h shows the devices as described in Fig 52-58 and similar numerals are used to describe similar elements. Fig 59a-h also shows some of the methods of use of the clot retrieval devices described in the earlier drawings. These figures also disclose a clot debonding device 2091, which may be used in conjunction with the clot retrieval designs described herein. The clot debonding device is designed to assist in the removal of obstructions from a vessel by providing an abutment surface which may be used to appose one side of the obstruction so that a force may be applied to the other side of the obstruction without said force being transmitted to the vessel in which the obstruction is placed. It therefore enables a clot retrieval device or other similar device to more effectively engage and capture clot or other such vessel obstructions.

It will be appreciated that such a device also has applications beyond its use with the clot retrieval device described herein. Such a clot debonder may be effectively used to aid the

disengagment and removal of vessel obstructions in conjunction with other clot retrieval devices or with thrombectomy devices or aspiration devices.

Fig. 59a shows a guidewire 2020 with a step 2017 at its distal end. The tip of the guidewire is placed in a vessel (not shown) distal of an occlusive clot (not shown). In Fig. 59b a microcatheter 2041 is advanced over the guidewire 2020 until its tip is also distal of the occlusive clot. A clot retrieval basket 2011 is advanced through the lumen of the microcatheter 2041 in Fig. 59c. In Fig. 59c the clot capture basket 2011 is being advanced using the distal end of a clot debonding device 2091. The clot debonding device 2091 comprises an expandable engagement element 2093 at its distal end. The expandable engagement element 2093 has an expanded configuration for engaging with a clot and debonding the clot and a collapsed state for delivery through a microcatheter. The expandable engagement element 2093 comprises a number of struts or wire segments 2094. In one embodiment the clot debonding element is cut from a hypo tube and the struts are expanded to the desired expanded shape and heat treated to remember that shape. Preferably the expandable engagement element 2093 is made from a shape memory alloy, a super elastic alloy. In one embodiment the expandable engagement element 2093 is made of Nitinol. The clot debonding device 2091 comprises a lumen extending from its distal end. The expandable engagement element 2093 comprises a channel or a lumen in both the expanded and collapsed states. In one embodiment the struts or wires of the expandable engagement element 2093 assume a collapsed state which maintains a channel (or lumen) over the distal end of the expandable engagement element 2093. In another embodiment the expandable engagement element 2093 comprises a collar 2095 and said collar comprises a lumen.

The clot debonding device 2091 further comprises a proximal shaft 2096. The proximal shaft 2096 is connected to the expandable engagement element 2093 and facilitates advancing and withdrawing the expandable engagement element 2091. In one embodiment the proximal shaft is connected directly to the expandable engagement element 2093. In another embodiment the proximal shaft 2096 is connected to the collar 2095 which in turn is connected to the expandable engagement element 2093. In one embodiment the expandable engagement element is integral with the collar 2095. In another embodiment the expandable engagement element is integral with the proximal shaft 2096. The proximal shaft 2096 comprises a lumen 2099 which is connected with the lumen or channel of the expandable engagement element and extends proximally to an exit port 2100. In Fig 59 the exit port is shown at the proximal end of the shaft 2096. However, it will be appreciated that the exit port could be distal of the proximal end of the

shaft 2096. The exit port may be towards the distal end of the shaft 2096. In one embodiment the exit port comprises an opening in the sidewall of the shaft. In another embodiment the shaft 2096 comprises a construction of at least two elements. The distal element comprises a tubing with a lumen and the proximal end comprises a connector element to connect the user with the distal lumen.

In one embodiment (not shown) the clot capture basket is advanced with a bumper tube which is removed upon deployment. When the clot capture basket 2090 is deployed distal of the occlusive clot then the clot debonding device is advanced over the proximal section of the guidewire 2020 and through the lumen of the microcatheter 2041 and it is deployed proximal of the occlusive clot. With this embodiment the rest of the procedure is as described in Fig 59a-59h.

The clot debonding device 2091 comprises an engagement surface. The engagement surface is configured to engage with clot and comprises an expanded state and a collapsed state. The engagement surface is configured to achieve a low profile in the collapsed state and it is further configured to be highly trackable such that it can easily navigate the pathway to tortuous neurovascular vessels. In one embodiment the engagement surface comprises a substantially tubular structure for advancement through the vasculature in the collapsed state. Preferably in the collapsed state the tubular structure comprises a short tubular structure. The engagement surface in one embodiment comprises a cylindrical surface in the collapsed state.

In the expanded state the engagement surface is preferably configured for the transmission of force or pressure to the clot. The engagement surface may comprise an annular surface. With this embodiment the engagement surface has an outer diameter and an inner diameter. In one embodiment the outer diameter is sized to be similar to the diameter of the vessel or to the diameter of the clot and the inner diameter is similar in diameter to the dimensions of the guidewire 2020.

In one embodiment the engagement surface comprises a flared surface. In another embodiment the engagement surface comprises a plurality of struts said struts configured to apply pressure to the clot over a substantial portion of the cross-section of the vessel. In one embodiment the engagement surface of the clot debonding device is configured to apply an axial displacement to the entire body of the clot. Preferably the engagement surface of the clot debonding device is configured to displace the clot without fragmenting the clot.

In one embodiment the engagement surface comprises a plurality of elongate struts. In the delivery configuration the elongate struts are substantially aligned with the axis of the vessel while in the expanded configuration the struts project radially outward from the axis of the vessel. In one embodiment the struts are connected to each other. In one embodiment the struts of the engagement surface comprises an outer ring member and a plurality of radial struts connected to said outer ring member. In another embodiment the strut arrangement of the engagement surface comprises a plurality of cells. In another embodiment the engagement surface comprises an outer ring member and an inner ring member.

The inner ring member may be connected to or separate of the outer ring member. In one embodiment the outer ring member is connected to the collar 2095 by a plurality of radial struts. In one embodiment the outer ring member comprises a plurality of zig zag strut elements. In one embodiment the struts are cut from a tube and the tube comprises an 'as cut' configuration and an expanded configuration.

In another embodiment the engagement surface comprises a plurality of wires. The wires comprise a collapsed state and an expanded state and in the collapsed delivery state the wires are substantially aligned with the axis of the vessel. In the expanded state the wires project radially outwardly of the axis of the clot debonding device. In this or in any of the other embodiments the engagement surface may expand concentrically about its axis, or may take up an eccentric configuration.

Fig 59d shows the clot capture basket 2090 in its deployed state distal of the occlusive clot. The deployment is effected by advancing the clot debonding device 2091. The expandable engagement element 2093 abuts the collar 2023 of the basket 2090 and deploys the basket 2090. The expandable engagement element 2093 remains in the collapsed state at the distal end of the microcatheter 2041. The microcatheter 2041 is withdrawn until its distal end is proximal of the occlusive clot.

With reference to Fig 59e, the system further comprises a tether 2092 which limits the movement of the clot retrieval basket relative to either the microcatheter 2041 or the clot debonding device 2091. In the embodiment shown the tether 2092 is attached to the clot debonding device 2091. As the microcatheter 2041 is withdrawn the distance between the clot engagement device and the microcatheter 2041 increases until all the slack in the tether 2092 is removed.

With reference to Fig 59f, the tip of the microcatheter is proximal of the occlusive clot, the basket 2090 is deployed distal of the clot and the expandable engagement element 2093 is deployed. This is achieved by advancing the proximal shaft 2096 relative to the microcatheter 2041. Upon deployment the struts or wires 2094 of the expandable engagement element 2093 expanded to their remembered expanded state. The guidewire is now moved proximally until the step engages with the clot capture basket 2090 and then both the basket 2090 and guidewire 2020 move proximally until the basket frame 2012 engages with the distal side of the occlusive clot. At this point the clot debonding device is advanced until the expanded struts 2094 engage with the proximal side of the occlusive clot. With the occlusive clot engaged at both ends the clot debonding device is advanced while holding the capture basket 2090 steadfast. This breaks the bonds between the clot and the vessel without applying any force to the distal vessels. This arrangement ensures that most of the forces of clot debonding are contained in the segment of the vessel where the clot is adherent. This is usually a segment of a few millimetres and the forces applied are shear forces rather than tensile forces. It may be necessary to adjust the position of the basket 2090 during the debonding step to continue to keep vessel tensile forces very low.

It will be appreciated that in order to remove an occlusive clot from a vessel that two sets of forces need to be dealt with. Firstly there is a blood pressure drop that lodges the clot in the vessel. More importantly, the presence of an initial clot results in platelet activation and inflammation at the site. During the inflammatory response a complex series of reactions are occurring including the cross linking of blood soluble fibrinogen into fibrin (a blood insoluble macromolecule that is the main component of clot) and the formation of platelet bridges. These reactions result in the progressive formation of chemical bonds between the clot and the vessel wall. Over time the clot becomes more rigidly fixed or bonded at the site of occlusion. In order to break these bonds a force needs to be applied and as the inflammation process progresses these bonds become more difficult to break. Furthermore, where a mechanical force is applied to the clot there is automatically a reaction force which is equal in size but acting in the opposite direction. With conventional devices this force is absorbed by the vessel. It is an object of this invention to prevent significant force being applied to the vessel during clot debonding.

In another embodiment the clot debonding device 2091 is deployed in the clot and a first portion of the clot is debonded from the vessel wall. It will be appreciated that this step could be repeated until all the clot has been debonded and captured in the clot capture basket 2090.

In an alternative method both the clot capture basket 2090 and the clot debonding device 2091 are both engaged with the occlusive clot as described above. Then the clot capture basket 2090 is pulled proximally while the clot debonding device is held steadfast. Which ever method is employed one element (either the clot debonding device, or the clot capture basket) is held steadfast and this element absorbs the reaction forces of clot debonding and thus prevents force being transmitted to the vessel.

With reference to Fig. 59g, after the clot has been debonded and captured in the clot capture basket 2090 the clot debonding device 2091 can be collapsed. This is achieved by pulling the device proximally such that the microcatheter tip collapses the struts 2094 of the expandable engagement element 2093. As the clot debonding device 2091 is pulled proximally the tether 2092 becomes taut and the clot capture basket is also drawn proximally.

In Fig. 59h the clot debonding device is withdrawn to the point where at least a portion of the frame 2012 of the clot capture basket 2090 is inside the distal end of the microcatheter 2041. The clot debonding device 2091 and the clot capture basket 2090 can be withdrawn from the patient at this point. Because of the tether between the clot debonding device 2091 and the capture basket 2090 the clot capture basket 2090 can be removed without removing the Guidewire 2020. The guidewire 2020 is left behind (not shown) for a final angiogram before also being removed if no further intervention is required.

Figs 60a-b show end views of the clot debonding devices of this invention. The clot debonding element 2110 of fig 60a comprises a lumen 2113 sized to accommodate a guidewire, a plurality of struts or wires 2111 which have an expanded state and a collapsed state, and a tubular element 2095. In the expanded state the struts or wires 2095 project at least partially radially outward with respect to the tubular member. In the collapsed state the struts or wires 2095 assume a somewhat tubular configuration when collapsed inside a microcatheter. In the collapsed state the struts or wires are substantially aligned with the longitudinal axis of the microcatheter and comprise a channel or lumen that can accommodate a guidewire. The pattern of the expandable portion 2112 can be varied greatly. In the figures shown two patterns are shown. However it will be appreciated that a myriad of other patterns are possible. These patterns may comprise some of the following elements: Single struts, bifurcated struts, bifurcated wires, struts or wires with curved segments, curved struts or wires with points of inflection, struts or wires connected with tethers, struts or wires that are configured to create a closed cell, a combination of at least one open and one closed cell, closed cells with multiple curved segments, struts or wires

configured to create a cell with multiple curved segments, struts or wires configured to create a planar cell, and/or struts or wires configured to create a non-planar cell.

The pattern of the clot debonding element 2110 of fig 60a has overlapping wires. The use of crossing wires provides for better engagement with the clot. In this case the wires over lap to achieve the cross. However where the struts are cut from hypotube, junctions can be created without the need to cross the wires, as shown in the pattern in figs 62a-c.

Fig 60b shows a pattern with no cross overs. This pattern may be manufactured from a hypotube. In the fully expanded state the clot debonder may comprise an outer rim 2116. With the embodiment shown in fig 60a and 60b the outer rim 2116 comprises a plurality of curved segments. Each pair of radially projecting struts 2095 meet at their distal end and this region is characterised in that it comprises a curved atraumatic region. This curved region is preferably curved in the circumferential direction.

Figs 61 a-c show another clot debonder pattern 900 which features multiple longitudinal slots 902 which enable the distal end of tubular element 901 to expand radially outward to create an abutment surface as shown in side view in fig 61b and in end view in fig 61c. Tubular element 901 is preferentially cylindrical, and may be made from either a metallic or polymeric material, but preferentially metallic, and most preferentially nitinol.

In one embodiment the engagement surface comprises an axial strut segment 903, a curved strut segment 904 and a radial strut segment 905. With this embodiment the engagement surface 906 is connected to a tubular member 901 at its proximal end. The axial strut section 903 defines the point of connection between the engagement surface 906 and the tubular member 901. In the expanded configuration the struts of the axial segment 903 are oriented substantially parallel to the axis of the clot debonding device. However the axial segment 903 is preferably extremely short. Immediately distal of the axial segment 903 comprises the curved segment 904. In the expanded state this segment is curved such that the struts assume a radial configuration. The radial section 905 preferably comprises most of the engagement surface 906 and provides a high area surface for the transmission of force to the clot.

It will be appreciated that the clot debonding element is designed to transmit force over the entire surface of the clot and this ensures that the clot is debonded in one piece. The clot debonder is further configured such that the clot does not snag on its surface and it is further configured to push the clot into the opening of the clot capture basket.

The clot debonder engagement surface is configured such that upon withdrawal it disengages from the clot without snagging, or fragmenting the clot and without removing the clot from the capture basket.

In another embodiment the engagement surface 906 of fig 61a-c comprises a plurality of wires. With this embodiment the engagement surface 906 comprises an axial wire segment 903 which is connected to the collar 2095. Preferably the connection between the wire and the collar is configured so as to orient the wire parallel to the axis of the clot debonding device. While the connection point with the collar is aligned with the axis of the vessel the segment of the wire immediately distal of the collar (curved wire segment) comprises a curve in the expanded configuration. The wire is curved so as to orient the wire radially and create an abutment surface. The intermediate segment of the wire is distal of the curved segment and is characterised in that the wire is substantially radial relative to the axis of the clot debonder. This plurality of radial wire segments is configured to deliver and distribute pressure to one face of the clot. The distal segment of the wires comprises a second curved segment 908. This second curved segment 908 defines an outer rim 2116 of the clot engagement surface 906. The curved segment 908 also presents an atraumatic surface to the vessel. This second curved segment 908 is curved in the circumferential direction.

In one variation the engagement surface 906 comprises a plurality of first wires and a plurality of second wires and said first and second wires are connected at the distal most point. In the embodiment described above said first and second wires may be integral and may comprise a single formed wire. With this embodiment the wire engagement surface comprises a plurality of petal like engagement elements. Each petal comprises a radial clot engagement element and a circumferential clot engagement element. Because the engagement surface 906 comprises radial and circumferential engagement elements force is transmitted to the surface in a manner similar to that of a piston.

In another embodiment the struts or wires of the engagement surface 906 comprise an articulation region. With this embodiment the engagement surface 906 assumes the expanded state by an articulation of the struts or wires about the articulation region.

Fig 62a-e shows side views of a number of clot debonding devices. These devices could be employed with any of the clot retrieval devices described in Fig 52-59 or Fig 79-80. Fig 62a shows a colt debonding device 2126 wherein the device comprises an expandable portion 2112, a

collar 2095 connecting said expandable portion 2112 with the tubular member 2114. In use the tubular member 2114 extends from the site of occlusion proximally through the vasculature and extends outside the patient such that it can be manipulated by the user. The tubular member comprises a lumen 2113 extending over its entire length.

Fig 62b shows an alternative configuration of the clot debonding device 2115. This device also comprises an expandable section 2112, struts or wires 2111, a connecting collar 2095 and a tubular member 2114. In this case the tubular member 2114 is shorter than in fig 62a. In use the tubular member extends from the site of occlusion only partially through the vasculature. In this case the user controls clot engagement using the connector element 2117. The connector element 2117 if fixed to the tubular member 2114 at an attachment point 2119. The lumen 2113 of the tubular member 2114 is sized to accommodate a guidewire. This embodiment has the advantage of providing single user wire exchange (a rapid exchange feature).

Fig. 62c shows an alternative configuration which is similar to that of fig 62b except that no collar is employed. The tubular member 2114 is connected directly with the expandable section 2112. The proximal end of tubular member 2114 comprises an exit port 2120 to facilitate rapid exchange delivery. Fig 62d shows an alternative configuration which is similar to that of fig 62b except that no tubular member is employed. In this case the connector element 2117 is connected directly with the collar 2095.

Fig 62e shows yet another configuration which is similar to that of fig 62d except that no collar is employed. The connector element 2117 is connected directly with the expandable section 2112.

Figs 63, 64 and 65 show three designs of clot debonders that can alter the shape of their distal ends to create an abutment surface to facilitate capture of clot into a clot retrieval device. Fig 63a shows device 910 with an inflatable distal cuff 911, which is shown in the inflated state in fig 63b. Inflation may be with a liquid, such as saline or contrast media or a mix of the two, or may be with a gas such as carbon dioxide. The inflating media is injected from the proximal end of the device through a lumen (not shown) in the wall of tube 912.

Fig 64a shows device 920 with an expandable section 924, which is shown in the expanded state in fig 64b. The expandable section 924 is formed from wound or braided elements, which form a structure which tends to increase in diameter when compressed, and reduce in diameter when elongated. Expansion of this cuff is effected by advancement of outer member 921 relative to

inner member 922, which is connected to the distal end of the expandable section by means of distal cuff 923. Retraction of outer member 921 reverses the effect by elongating the expandable section and reducing it to its original diameter.

Fig 65a-b show a clot debonder 915 with an expansile distal cuff 916 of a similar design to that of device 920, but in which no actuation is required to effect the expansion. The expansile distal cuff is configured to preferentially adopt the expansile state depicted in fig 65b, and is held in the unexpanded state by the constraint provided by the lumen of the catheter (not shown) through which it is advanced to the target site.

Figs 66 and 67 show two examples of self-expanding clot debonders that expand upon advancement past the end of an outer constraining surface such as that of the lumen of a microcatheter 926. Debonder 925 is shown in the constrained state in fig 66a, in the partially expanded state in fig 66b, and in the fully expanded state in end view in fig 66c. Fig 67a and b show a similar design to fig 66, wherein an additional element is employed to create a greater abutment surface area and perimeter.

Figs 68a-c show views of another clot debonding device, which could be employed with any of the clot retrieval devices described herein. Fig 68a shows a side view of the debonder 950 in its unexpanded state. Fig 68b shows a side view of the debonder in a partially expanded state. Fig 68c shows an end view of the debonder in its fully expanded state. Device 950 contains multiple expandable portions 952, created by the addition of a plurality of longitudinal slots 953 to tubular member 954. An actuating element 951 is attached to the distal end of member 954, and runs within member 954 from the distal to the proximal end of the device. Retraction of the actuating element applies a compressive force to expandable portions 952 defined by slots 953. Controlled buckling of areas 956 is facilitated by the presence of crease lines 956. Tubular member 954 may be configured in a similar manner to member 954 in figs 62a or fig 62c, such that the debonder is used as an "over the wire" or "rapid exchange" device. In one embodiment the clot debonder lumen 955 is sized so that it may be advanced through a pre-placed access microcatheter to the target site. In another embodiment the clot debonder lumen 955 is sized so that it may be backloaded onto a microcatheter prior to insertion of the microcatheter, and can then be advanced over the microcatheter to the target site.

Figs 69a and 69b show the clot debonder 950 depicted in fig 68 in use in conjunction with a clot retrieval device 961 and microcatheter 963. Fig 69b shows the clot debonder advanced past the end of the microcatheter 963 and the actuator 951 retracted to expand the expandable distal area

952, which is shown in abutment with clot 962 just prior to retrieval of the clot into the clot retrieval device 961.

Figs 70-73 show the clot retrieval device of fig 12 and 13 being used in conjunction with clot retrieval assist device 119. With this embodiment the clot retrieval device 91 is delivered across the obstructive clot and deployed as previously described. The clot retrieval assist device is delivered over the proximal section of the guidewire 92 until its distal tip is proximal of the obstructive clot. The clot retrieval assist device comprises a catheter 116 with a lumen, an expandable element(s) 117 wherein the expandable element 117 comprises a wire frame 118 that defines an inner space 132. The wire frame 118 has a remembered expanded configuration and a collapsed delivery configuration. In one embodiment the wire frame 118 defines an inner space 132 that has a paddle like expanded shape. In another the wire frame defines a circular inner space 132. In another embodiment the wire frame 118 defines a kidney shaped inner space 132. With the clot retrieval assist device 91 proximal of the occlusive clot 103 the expandable element 117 is deployed. The size of the expanded element 117 is controlled by the degree of deployment. When the expandable element 117 is at least partially deployed it is advanced against the occlusive clot 103 and forces the clot 103 into the clot retrieval device 91. In another embodiment the clot retrieval assist device 119 is held stationary with its expandable element 117 in the at least partially expanded state and clot retrieval device 91 is advanced proximally to capture the occlusive clot 103.

In another embodiment the clot retrieval device comprises a frame 94 a proximal collar 93 and a distal collar 90 and two connector elements 99. The proximal 93 and distal 90 collars are associated with the guidewire 92 and the connectors 99 connect the proximal and distal collars to the Guidewire 92. At least one of said proximal and distal collars is slidable relative to the guidewire 92.

Fig 74 shows an alternative clot retrieval assist device 110. With this device 110 the expandable element 113 comprises a helical element and is attached to inner shaft 112. In the delivery configuration inner shaft 112 is retracted and both the inner shaft and expandable element 113 are housed inside the lumen of delivery catheter 111. With this embodiment advancement of the clot may be achieved by pushing as described with Fig 19 or alternatively by rotation. With the rotation embodiment the expandable element 113 is either deployed in the body of the occlusive clot 103 or it is advanced in its expanded state until it is in the body of the occlusive clot. The

inner shaft is rotated and the helical frame acts like an auger to move the occlusive clot into the clot retrieval device 91.

An alternative clot retrieval assist device 110 is shown in Fig 75. With this device the expandable element 113 comprises multiple coil elements. An inner helical element 115 and outer element 114 are both connected to inner shaft 112 and rotation of inner shaft 112 rotates both coil elements.

Yet another clot retrieval assist device 120 is shown in fig. 76a and fig. 76b. The clot retrieval device is delivered over the proximal end 127 of guidewire 92. The clot retrieval assist device comprises an inner shaft 122, an expandable element 123 and a delivery catheter (not shown). The expandable element 113 comprises a wire formed into a spiral. The spiral has a gradually increasing diameter. An inner coil of the spiral 124 has a smaller diameter than outer coil 125. In the expanded configuration the clot retrieval assist device 120 is advanced distally over the guidewire 92 and the expandable element 113 engages the obstructive clot 100 and forces the clot 100 into the clot retrieval device 91. Alternatively the clot retrieval device 91 may be advanced proximally while the clot retrieval assist device 120 remains stationary and limits the proximal movement of the clot 100 and thus forces the clot into the clot retrieval device 91.

An alternative clot retrieval system is shown in fig 77a-b. The clot retrieval system 2160 comprises a clot capture basket 2154 mounted on a guidewire 2162. The clot retrieval system 2160 further comprises a clot debonding element 2161 mounted on the guidewire 2162. The clot capture basket 2163 comprises a frame 2164 a collar 2168 mounted on the guidewire 2162 and at least one connector 2167 connecting the collar 2168 with the frame 2164. The frame 2164 comprises one or more pairs of struts 2166. In one embodiment the struts comprise a series of net attachment points 2175. The attachment points 2175 comprise a change in the cross section of the strut 2166 and provide a location for the attachment of a fibre of the net 2163 to the frame 2164. In one embodiment the attachment point 2175 comprises an eyelet. In another the point of attachment comprises a recess or a nick, or a reduction in the strut dimension.

The collar 2168 may be fixedly mounted on the guidewire 2162. In the embodiment shown the collar 2168 is rotationally mounted on the guidewire 2162. This is achieved by the use of a proximal stop 2170 and distal stop172 mounted on either side of the collar 2168. The capture net 2163 is connected to the guidewire distal of the collar 2168. In one embodiment a distal collar 2169 is employed to provide an attachment point between the net 2163 and the guidewire 2162.

The frame 2164 has a collapsed state and an expanded state and in the expanded state (shown) comprises a hoop 2165. The hoop 2165 allows the frame to effectively engage with the outer bonded surface of the clot. The hoop 2165 is created by constructing that portion of the frame with at least one pairs of struts 2166. The pairs of struts form segments of a hoop 2165 in the expanded state but lay adjacent each other and parallel to the guidewire in the collapsed state.

The clot debonding element comprises at least one strut 2173 and it also has an expanded configuration (shown) and a collapsed configuration. In the collapsed state the struts 2173 of the clot debonding element 2161 lie adjacent and substantially parallel to the guidewire 2162. The at least one strut 2173 comprises a strut distal end 2178 and a strut proximal end 2177. At least one of said distal 2178 and proximal 2177 strut ends is slidable relative to the guidewire 2162. Furthermore, at least one of said distal strut ends 2178 or proximal strut ends 2177 are restricted from rotational motion relative to the guidewire 2162. The ability of at least one strut end to slide relative to the guidewire provides a first means of allowing the clot debonding element to assume an expanded configuration when not constrained. On the other hand preventing at least one strut end from rotating relative to the guidewire 2162 allows torque transmitted from the proximal end of the guidewire to be applied to the occlusive clot 2001 and debond said clot from the vessel wall 2002.

In the collapsed state both the basket and the clot debonding element collapse inside a microcatheter 2041 (not shown) in a fashion similar to that described earlier.

It will be appreciated that the clot debonding element as described with reference to fig 77 could equally be employed with any of the baskets described in any of the other clot capture basket devices of the invention.

With reference to Fig 78 there is shown a schematic representation of a vessel with an acute occlusion with a piece of thrombus (clot). The clot may be embolic in origin or it may be thrombotic. Embolic occlusions of cerebral vessels are responsible for between 20% and 35% of all strokes. Embolic strokes are most frequently of cardiogenic origin with carotid and aortic disease also being major contributors. Thrombotic occlusions occur when thrombus forms in the vessel usually in response to underlying vascular disease. Thrombotic occlusions are responsible for between 45% and 50% of all strokes. The acute occlusion 2001 of Fig 78a is fixed in the vessel 2002 primarily by the forces of blood pressure acting on the proximal side and force fitting it in a tapered vessel 2002.

However, the presence of the clot causes an inflammatory response at the site and platelets 2003 in the area are activated (Fig. 78b). The inflammatory response results in the formation of more thrombus and bonds 2004 start to form between the occlusive thrombus 2001 and the vessel wall 2002. Over time the bonding forces between the clot and the vessel wall become more significant and make removal of the clot more difficult. Fig 78c shows a schematic representation of the occlusive clot 2001 after a time has passed with further thrombus deposited at the site and bonds 2004 formed between the clot 2001 and the vessel wall 2002.

Fig. 79a-I shows a method of using the devices of this invention. Fig 79a shows a vessel 2002 with an occlusive clot 2001. The vessel 2002 has a proximal end 2005 and a distal end. The procedure to treat the occlusion per this invention comprises firstly gaining access to the vasculature. This is carried out by conventional means (the Seldenger technique). A guide catheter is placed in a large vessel proximal of the occlusion (not shown). A procedural guidewire 2020 is advanced through the guide catheter or sheath and is advanced across the occlusive clot 2001 as in Fig 79b. When the guidewire 2020 is in place a microcatheter is advanced over the guidewire until the tip of the microcatheter is across the occlusion (fig 79c). As can be seen with reference to Fig. 79d the guidewire 2020 is now removed thus leaving the microcatheter 2041 in place with its tip 2047 across the occlusion 2001 and an empty lumen prepared for device advancement. With reference to Fig 79e, the clot retrieval device 2130 is advanced in its collapsed state through the lumen of the microcatheter 2041 until it is deployed out of the distal end of the microcatheter 2041. Upon deployment the frame 2012 of the clot retrieval device 2130 causes the basket to expands. In the embodiment described in Fig 79 e, the frame 2012 is attached to the wire. The frame may be fixedly attached to the guidewire or it may be rotationally attached to the guidewire or it may be attached such that it has at least some rotational and/or some translational freedom.

With reference to fig 79f, the microcatheter is withdrawn to the proximal side of the occlusion 2001 when the clot capture device 2130 is deployed. The clot capture device 2130 is manipulated to ensure that it is fully engaged with the vessel wall. The clot debonding device 2091 is now advanced through the lumen of the microcatheter and its distal end is advanced distal of the microcatheter tip 2047. When the distal portion of the clot debonding device exits the microcatheter 2041 the expandable segment 2112 expands to its remembered expanded state. In the expanded state the clot debonding device 2091 is advanced until it engages with the proximal portion of the clot 2001 (fig.79h). At this point the clot capture basket 2130 is

advanced proximally while the clot debonding device 2091 is held steadfast. This action breaks the bonds between the clot and the vessel and the clot 2001 is forced into the capture basket 2130. The clot debonding device 2091 can now be removed. This is achieved by withdrawing it back into the lumen of the microcatheter 2041. In its expanded state the clot debonding device has a conical aspect and this facilitates the retrieval of the device 2091 into the microcatheter 2041 (fig 79i). The clot debonding device 2091 can be fully withdrawn through the lumen of the microcatheter or it can be advanced a sufficient distance proximally to allow recovery of the clot capture basket 2130.

The clot capture basket recovery steps are described with reference to Fig 79j and 79k. The microcatheter distal end 2047 is engaged with the frame 2012 of the capture basket 2130. The guidewire is pulled proximally to force the proximal section of the frame 2012 into the lumen of the microcatheter. As the proximal section of the frame enters the microcatheter the frame struts 2009 collapse and the mouth of the basket closes. This allows the basket to be withdrawn from the vessel without the frame engaging with the vessel wall. The capture basket 2130, the microcatheter 2041 and the guidewire 2020 are removed together. The capture net 2015 scaffolds the clot during removal and prevents fragments from embolizing. The capture basket 2130, the microcatheter 2041 and the guidewire 2020 are withdrawn through the lumen of the guide catheter or sheath and removed from the patient. The net allows the clot to deform and change shape as it is pulled into the guide catheter or sheath without allowing particles or fragments to embolize.

Fig. 80a-m shows another method of using the devices of this invention. Fig 80a shows a vessel 2002 with an occlusive clot 2001. The vessel 2002 has a proximal end 2005 and a distal end. The procedure to treat the occlusion per this invention comprises firstly gaining access to the vasculature. This is carried out by conventional means (the Seldenger technique). A guide catheter is placed in a large vessel proximal of the occlusion (not shown). A procedural guidewire 2020 is advanced through the guide catheter or sheath and is advanced across the occlusive clot 2001 as in Fig 80b. When the guidewire 2020 is in place a microcatheter is advanced over the guidewire until the tip of the microcatheter is across the occlusion (fig 80c). As can be seen with reference to Fig. 80d the guidewire 2020 is removed thus leaving the microcatheter 2041 in place with its tip 2047 across the occlusion 2001 and an empty lumen prepared for device advancement. With reference to Fig 80e, a special clot retrieval guidewire 2142 is advanced through the microcatheter until its distal tip is distal of the microcatheter 2041. The clot retrieval guidewire 2142 has a stop 2144 at its distal end. The stop 2142 limits the

movement of the clot capture basket 2140 on the wire and prevents the clot capture device 2140 from sliding off the distal end of the guidewire 2142.

The clot retrieval device 2140 is advanced over the guidewire 2142 in its collapsed state through the lumen of the microcatheter 2041 until it is deployed out of the distal end of the microcatheter 2041. Upon deployment the frame 2012 of the clot retrieval device 2140 causes the basket to expand. In the embodiment described in Fig 80f, the capture basket 2140 is slidable on the clot capture guidewire 2142.

With reference to fig 80g, the microcatheter 2041 is withdrawn to the proximal side of the occlusion 2001 when the clot capture device 2140 is deployed. The clot capture device 2140 may be manipulated to ensure that it is fully engaged with the vessel wall 2002. The clot debonding device 2091 is now advanced through the lumen of the microcatheter 2041 and its distal end is advanced distal of the microcatheter tip 2047. When the distal portion of the clot debonding device 2091 exits the microcatheter 2041 the expandable segment 2112 expands to its remembered expanded state. In the expanded state the clot debonding device 2091 is advanced until it engages with the proximal portion of the clot 2001 (fig.80i). At this point the clot capture guidewire 2142 is advanced proximally until the stop 2144 engages with the capture basket 2140. In one embodiment the stop 2144 engages with either the collar 2023 of the capture basket 2140. In another the stop 2144 engages with a tube extending from the proximal end of the basket. Further withdrawal of the guidewire 2142 causes the clot capture basket 2140 to advance proximally. The guidewire 2142 is advanced proximally until the capture basket engages with the distal end of the occlusive clot 2001. With the clot debonding device 2091 held steadfast the basket is withdrawn proximally until the clot is debonded and enters the basket.

The clot debonding device 2091 can now be removed. This is achieved by withdrawing it back into the lumen of the microcatheter 2041. In its expanded state the clot debonding device has a conical aspect and this facilitates the retrieval of the device 2091 into the microcatheter 2041 (fig 80j). The clot debonding device 2091 can be fully withdrawn through the lumen of the microcatheter or it can be advanced a sufficient distance proximally to allow recovery of the clot capture basket 2130.

The clot capture basket recovery steps are described with reference to Fig 80k to 80m. The microcatheter distal end 2047 is engaged with the frame 2012 of the capture basket 2140. The guidewire is pulled proximally to force the proximal section of the frame 2012 into the lumen of the microcatheter 2041. As the proximal section of the frame enters the microcatheter the frame

struts 2009 collapse and the mouth of the basket closes. This allows the basket 2140 to be withdrawn from the vessel without the frame 2012 engaging with the vessel wall 2002. In this embodiment the capture basket 2140 and the microcatheter 2041 are removed together. The guidewire is left in the vessel until the very end of the procedure. This has the advantage of allowing the physician carry out final imaging steps prior to loosing access to the vessel. The capture net 2015 scaffolds the clot during removal and prevents fragments from embolizing. The capture basket 2140, the microcatheter 2041 and the clot 2001 are withdrawn through the lumen of the guide catheter or sheath and removed from the patient. The net allows the clot 2001 to deform and change shape as it is pulled into the guide catheter or sheath without allowing particles or fragments to embolize.

It will be appreciated that the various features illustrated and/or described herein may be used as appropriate with any of the devices, methods or systems described.

The invention is not limited to the embodiments hereinbefore described which may be varied in detail.

Claims

1. A clot capture system for disengaging a clot from a vessel wall and removing the clot from the vessel, the clot capture system comprising:-

a clot capture device for placement on a distal side of a clot, the clot capture device having a retracted delivery configuration and an expanded deployed configuration; and

a clot debonding device for placement on a proximal side of a clot, the clot debonding device having a retracted delivery configuration and an expanded deployed configuration and comprising a clot engagement element which defines a distal abutment in the deployed configuration for urging a clot into the clot capture device.

2. A clot capture system as claimed in claim 1 wherein the clot engagement element has a longitudinal axis and the distal abutment extends radially of the longitudinal axis.

3. A clot capture system as claimed in claim 2 wherein the longitudinal axis is a substantially central axis and the distal abutment extends radially outwardly of the substantially central axis.

4. A clot capture system as claimed in claim 2 wherein the longitudinal axis is an offset axis and the distal abutment extends radially of the offset axis.

5. A clot capture system as claimed in any of claims 1 to 4 wherein the engagement element comprises an axially extending region and a radially extending region.

6. A clot capture system as claimed in claim 5 wherein the engagement element further comprises a circumferential region extending from the radial region.

7. A clot capture system as claimed in claim 5 or 6 wherein the engagement element comprises a transition region between the axial region and the radial region.

8. A clot capture system as claimed in any of claims 1 to 7 wherein the clot debonding device comprises an axially extending collar.

9. A clot capture system as claimed in any of claims 1 to 8 wherein the clot capture device defines an inlet mouth in the deployed configuration and the clot engagement element extends substantially the width of the inlet mouth of the clot capture device.

10. A clot capture system as claimed in any of claims 1 to 9 wherein the clot debonding device is movable relative to the clot capture device in the deployed configuration.

11. A clot capture system as claimed in claim 10 wherein the clot debonding device is slidable relative to the clot capture device.

12. A clot capture system as claimed in claim 10 or 11 wherein the clot debonding device is rotatably relative to the clot capture device.

13. A clot capture system as claimed in any of claims 1 to 12 wherein the clot capture device and the clot debonding device are independently movable.

14. A clot capture system as claimed in any of claims 1 to 13 comprising an elongate member.

15. A clot capture system as claimed in any of claims 1 to 14 comprising a first elongate member associated with the clot capture device.

16. A clot capture system as claimed in any of claims 1 to 15 comprising a second elongate member associated with the clot debonding device.

17. A clot capture system as claimed in claim 15 wherein the first elongate member comprises a guidewire.

18. A clot capture system as claimed in claim 17 wherein the guidewire comprises a stop.

19. A clot capture system as claimed in claim 18 wherein the stop comprises a distal stop.

20. A clot capture system as claimed in claim 16 wherein the second elongate member comprises a proximal shaft.

21. A clot capture system as claimed in claim 20 wherein the clot debonding device is mounted to the proximal shaft.

22. A clot capture system as claimed in claim 21 wherein the clot bonding device is fixedly mounted to the proximal shaft.

23. A clot capture system as claimed in any of claims 1 to 22 comprising a delivery catheter for the clot capture device.

24. A clot capture system as claimed in any of claims 1 to 23 comprising a delivery catheter for the clot debonding device.

25. A capture system as claimed in any of claims 1 to 24 wherein the clot capture device comprises:-

a proximal support frame;

a distal fibre net; and

an elongate member to facilitate capture and/or withdrawal of a clot from a vessel.

26. A clot capture system as claimed in claim 25 wherein the net comprises a proximal end and a distal end, the proximal end of the net being attached to the frame.

27. A clot capture system as claimed in claim 26 wherein the frame comprises a plurality of attachment points for attachment of the net to the frame.

28. A clot capture system as claimed in claim 27 wherein the attachment points are substantially equispaced around the frame.

29. A clot capture system as claimed in any of claims 25 to 28 wherein the fibre net comprises at least one fibre having an ultimate tensile strength of at least 2000 MPa.

30. A clot capture system as claimed in any of claims 25 to 29 wherein the diameter of the fibre is less than 30 microns.

31. A clot capture system as claimed in any of claims 25 to 30 wherein the diameter of the fibre is less than 25 microns.

32. A clot capture system as claimed in any of claims 25 to 31 wherein the diameter of the fibre is less than 20 microns.

33. A clot capture system as claimed in any of claims 25 to 32 wherein the fibre is of ultra high molecular weight polyethylene.

34. A clot capture system as claimed in any of claims 25 to 32 wherein the fibre is of Kevlar.

35. A clot removal device for restoring blood flow to a vessel, the device comprising:-

a proximal support frame; and

a distal fibre net,

the support frame having a retracted delivery configuration and an expanded deployed configuration,

the proximal support frame in the expanded configuration defining a proximal inlet mouth for engaging a clot and the net confining the clot; and

an elongate member to facilitate capture and/or withdrawal of a clot from a vessel.

36. A clot removal device as claimed in claim 35 wherein the net comprises a proximal end and a distal end, the proximal end of the net being attached to the frame.

37. A clot removal device as claimed in claim 35 or 36 wherein the frame comprises a plurality of attachment points for attachment of the net to the frame.

38. A clot removal device as claimed in claim 37 wherein the attachment points are substantially equispaced around the frame.

39. A clot removal device as claimed in any of claims 35 to 38 wherein the fibre net comprises at least one fibre having ultimate tensile strength of at least 2000 MPa.

40. A clot capture device as claimed in any of claims 34 to 39 wherein the diameter of the fibre is less than 30 microns.

41. A lot capture device as claimed in any of claims 34 to 40 wherein the diameter of the fibre is less than 25 microns.

42. A clot capture device as claimed in any of claims 34 to 41 wherein the diameter of the fibre is less than 20 microns.

43. A clot capture device as claimed in any of claims 34 to 42 wherein the fibre is of ultra high molecular weight polyethylene.

44. A clot capture device as claimed in any of claims 34 to 42 wherein the fibre is of Kevlar.

45. A method for removing clot from a vessel comprising the steps of:

providing a clot capture device comprising a basket and a debonding element, the capture basket comprising a collapsed state for delivery through the vasculature and an expanded state for the capture of clot, the clot debonding element comprising a collapsed delivery state and an expanded state;

advancing the basket through the vasculature in the collapsed state;

deploying the basket distal of the clot;

advancing the clot debonder through the vasculature;

deploying the clot debonder proximal of the clot;

engaging the basket and/or the clot debonder with the clot;

disengaging the clot from the wall of the vessel;

capturing the clot in the basket; and

removing the clot from the vasculature.

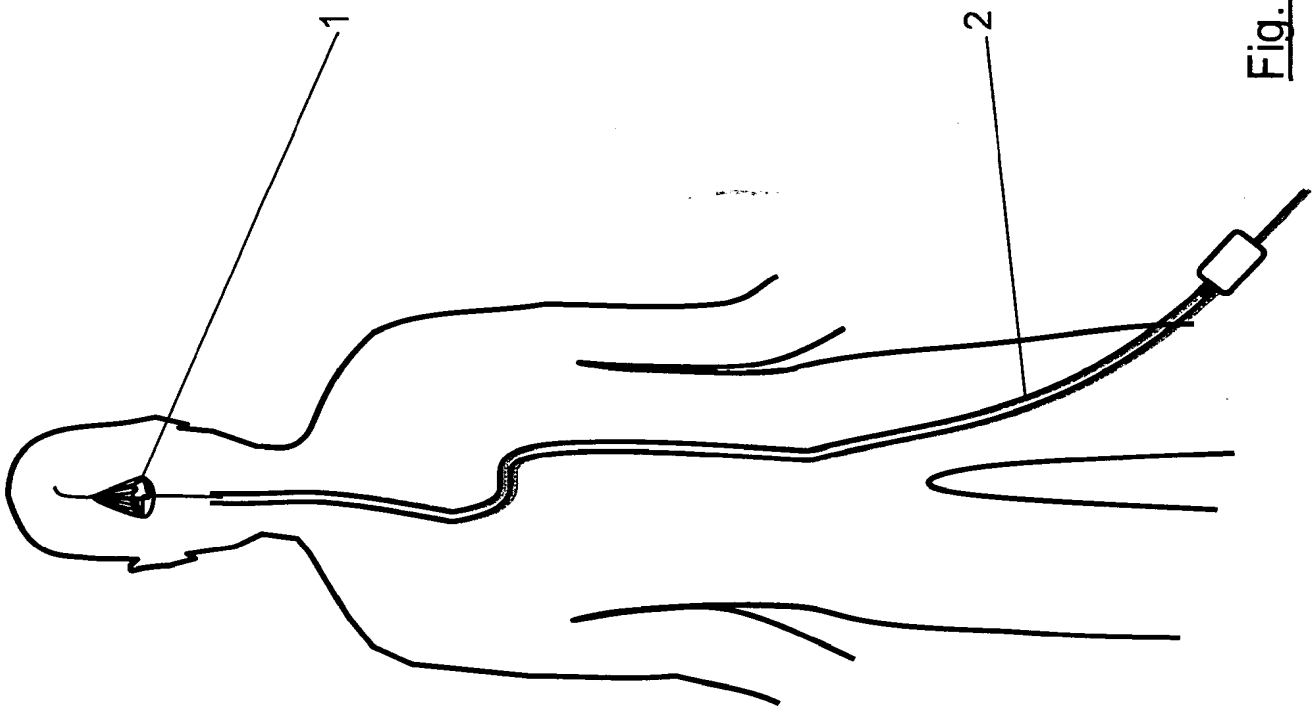


Fig. 1

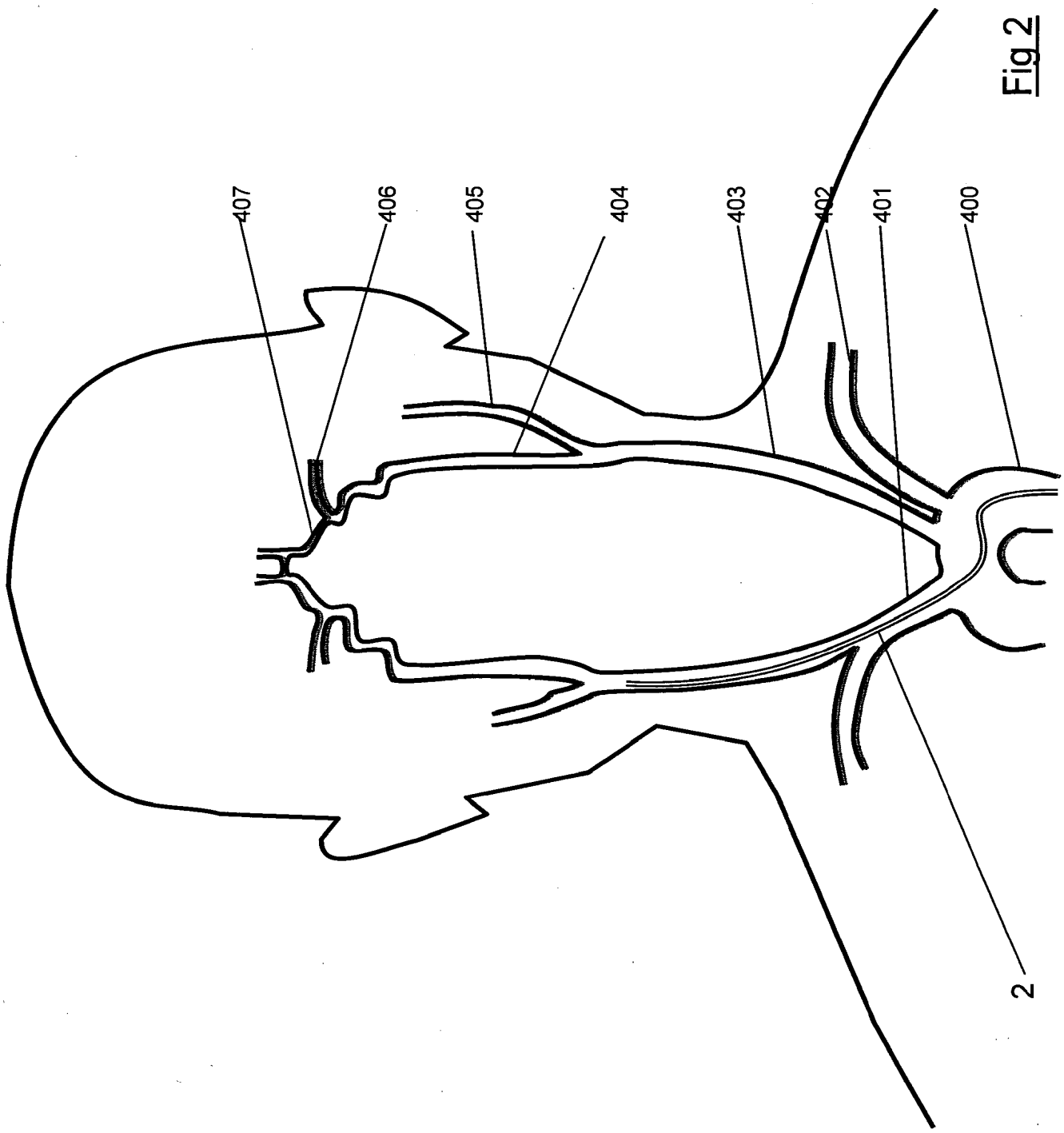
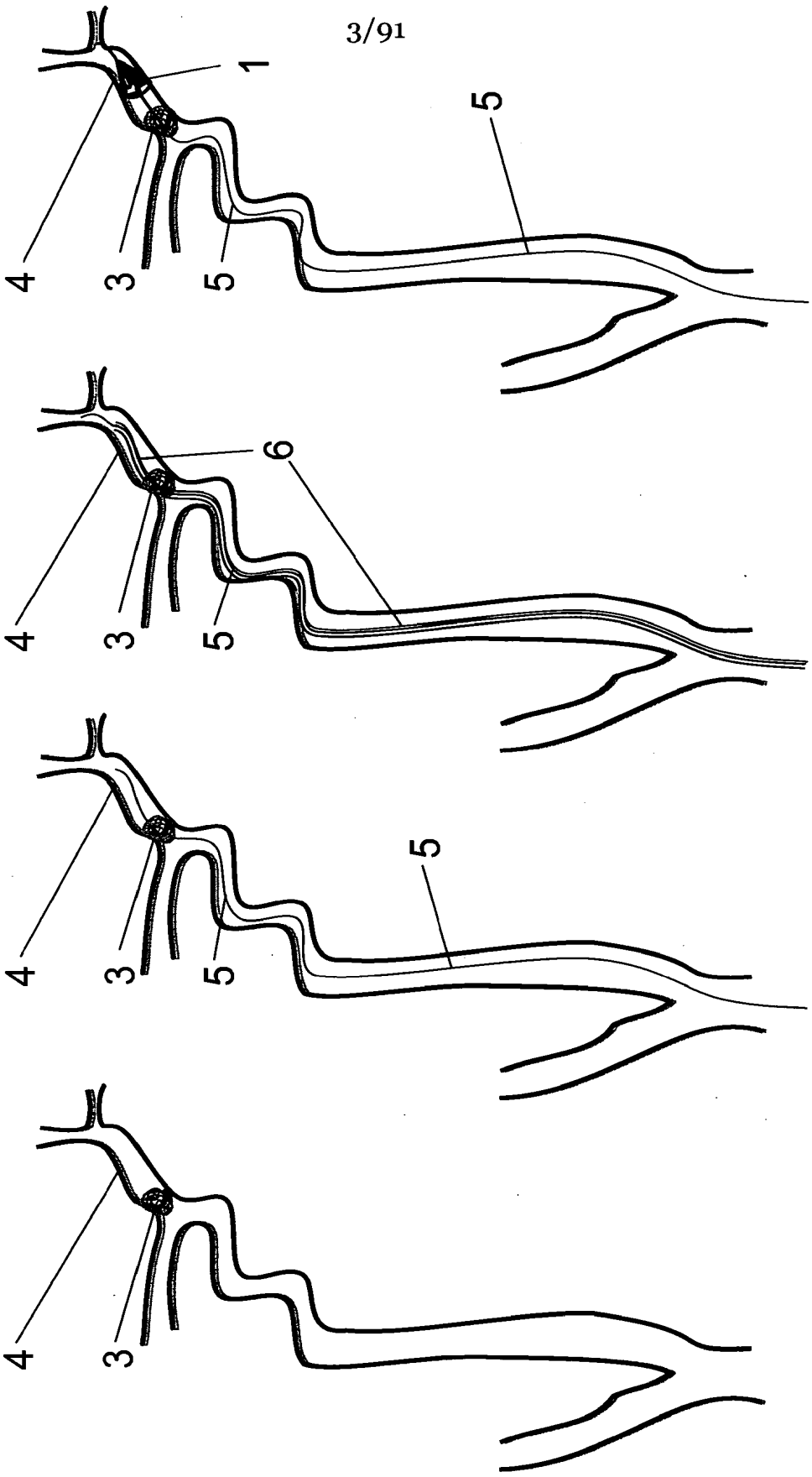


Fig 2


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Fig. 3.d
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Fig. 3c
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Fig. 3b
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Fig 3a

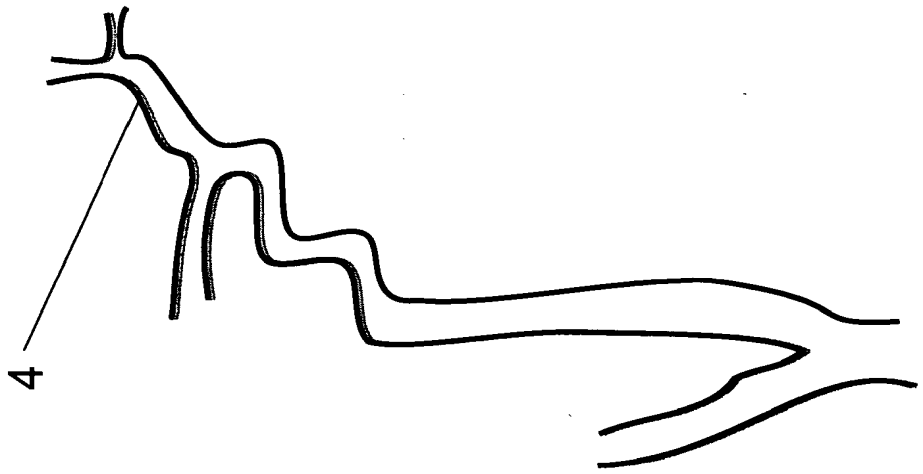


Fig. 3g

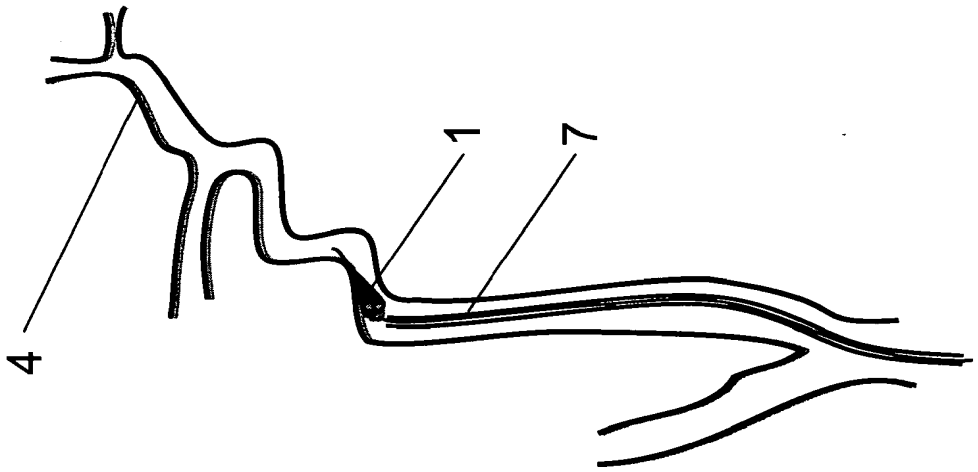


Fig. 3f

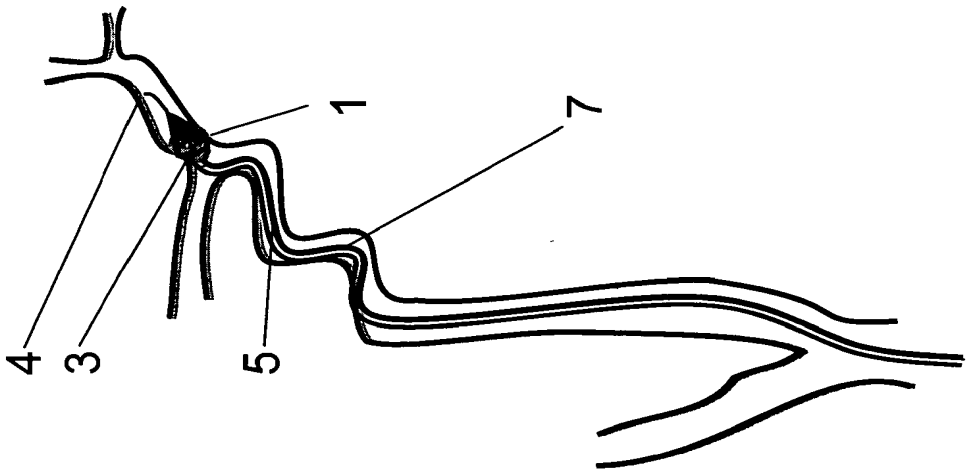


Fig 3e

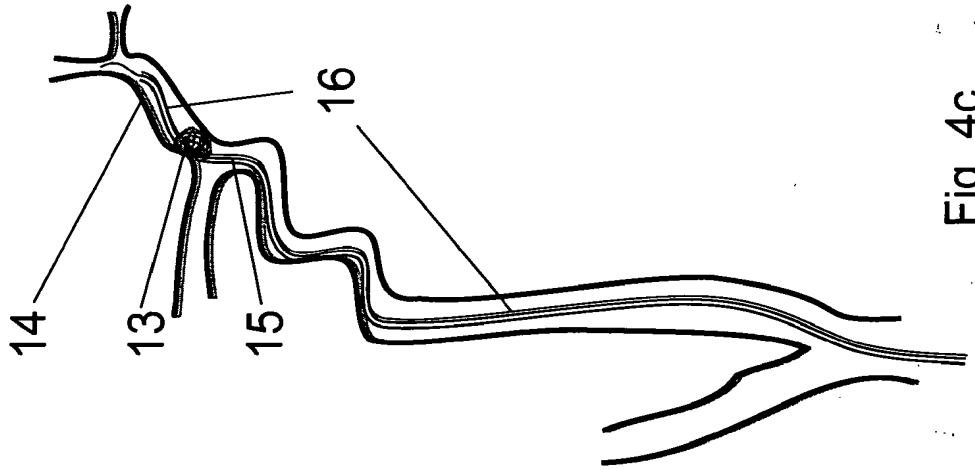


Fig. 4c

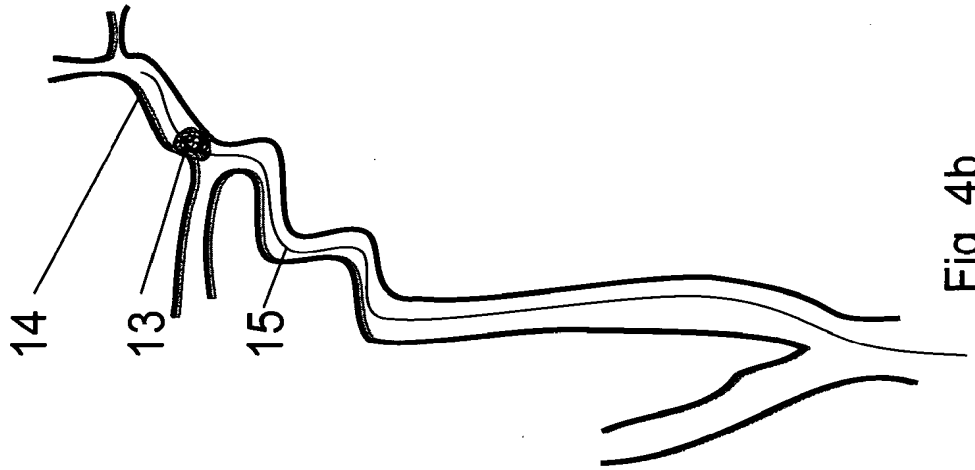


Fig. 4b

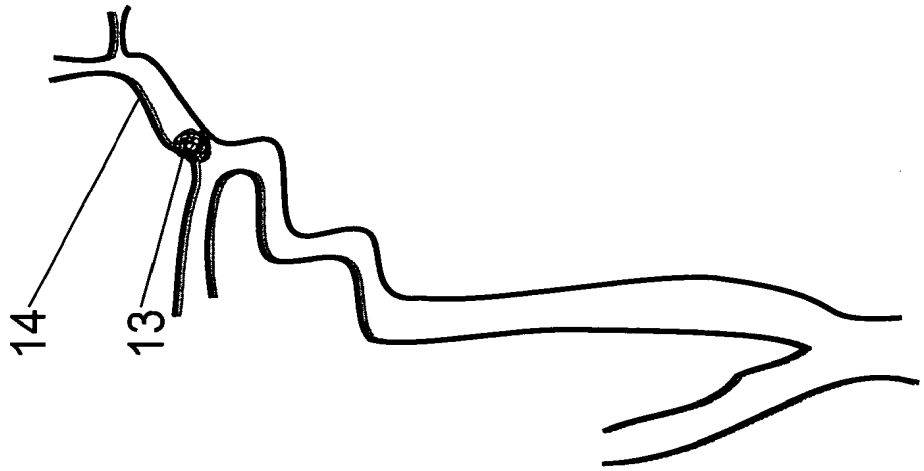


Fig 4a

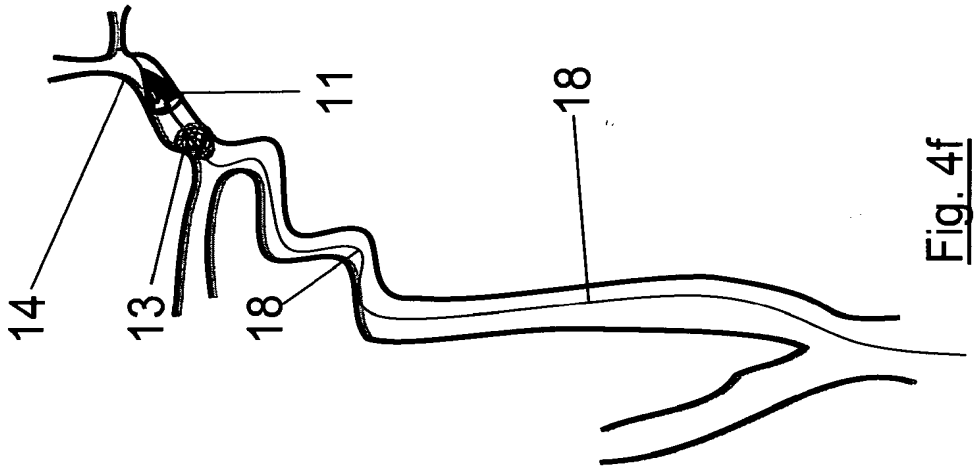


Fig. 4f

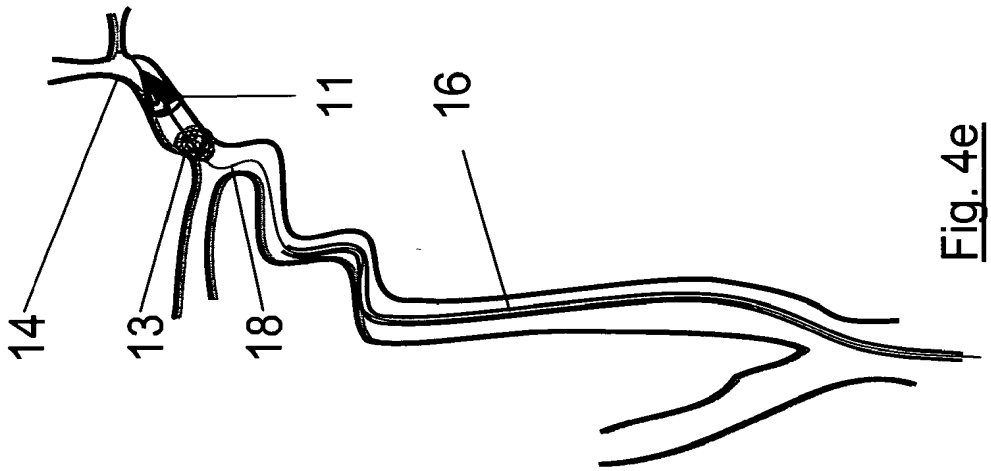


Fig. 4e

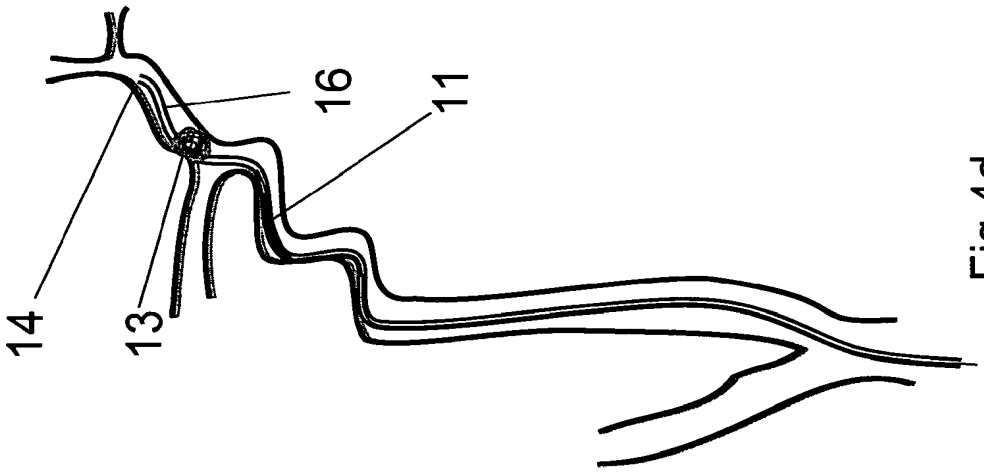


Fig 4d

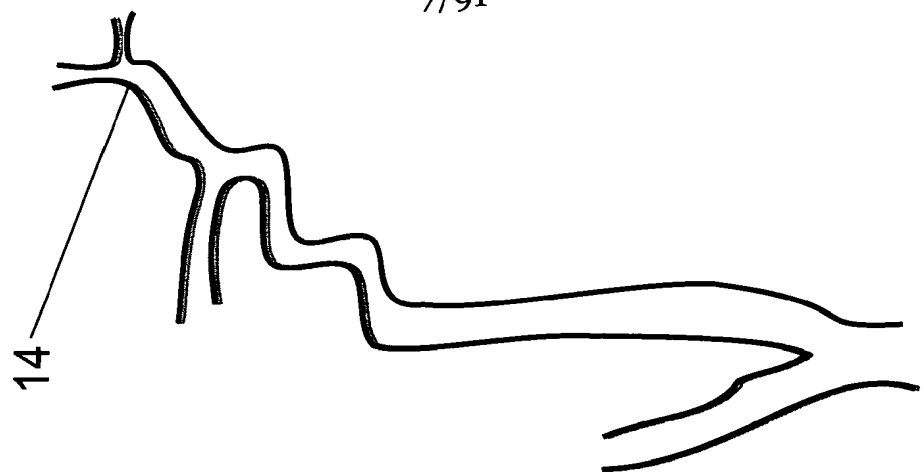


Fig. 4i

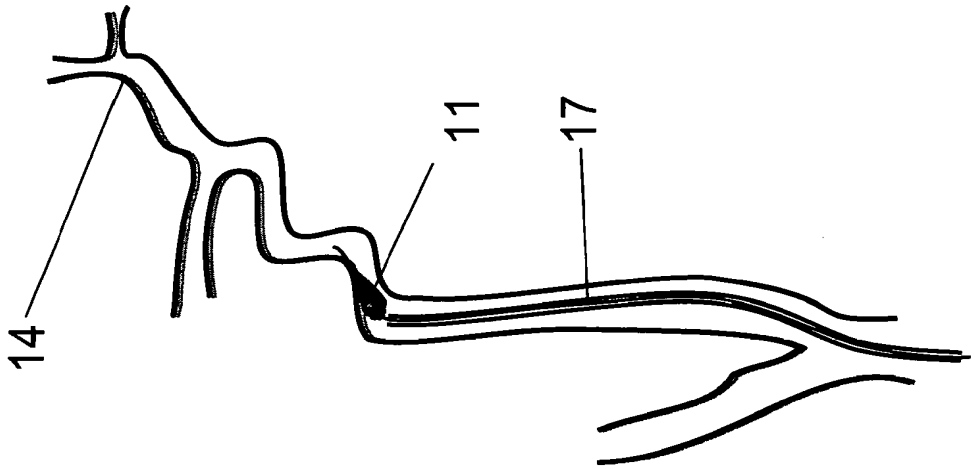


Fig. 4h

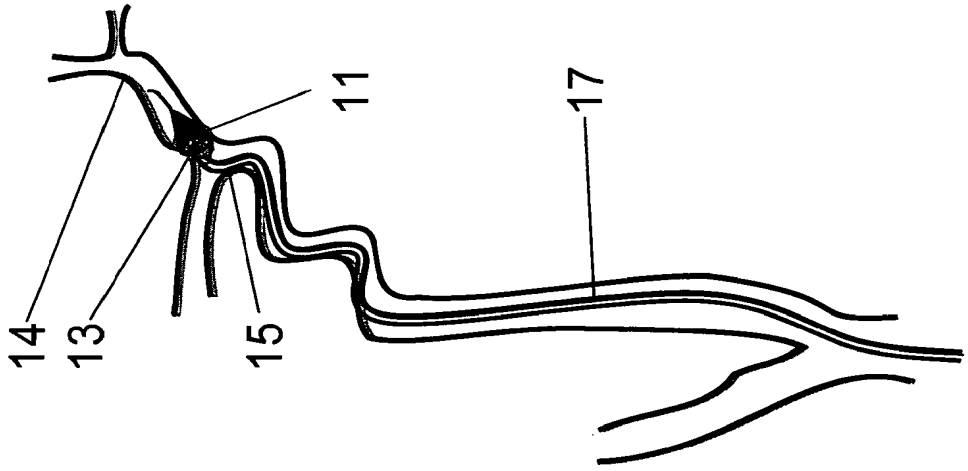
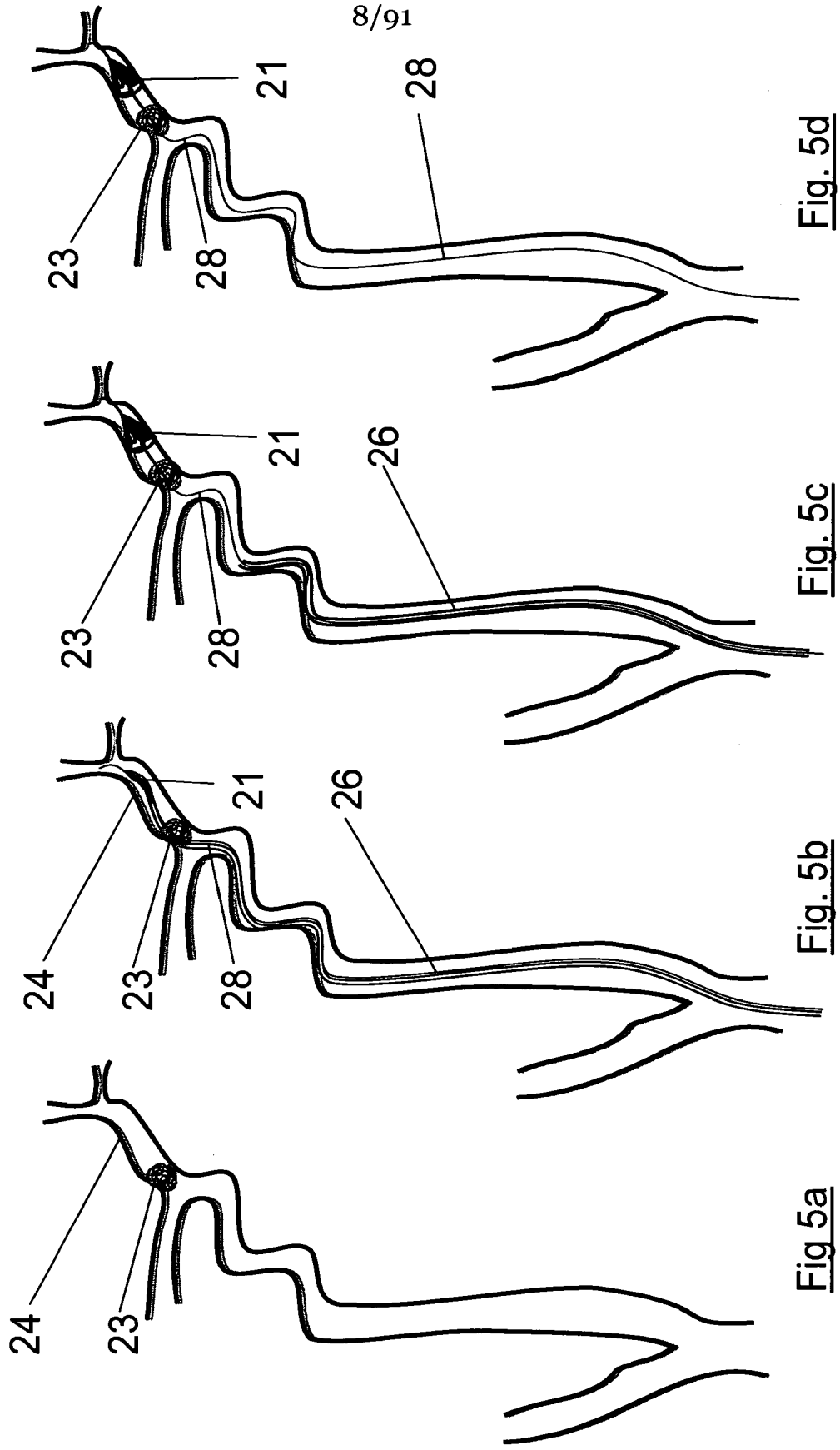


Fig 4g


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Fig. 5d
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Fig. 5c
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Fig. 5b
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Fig 5a

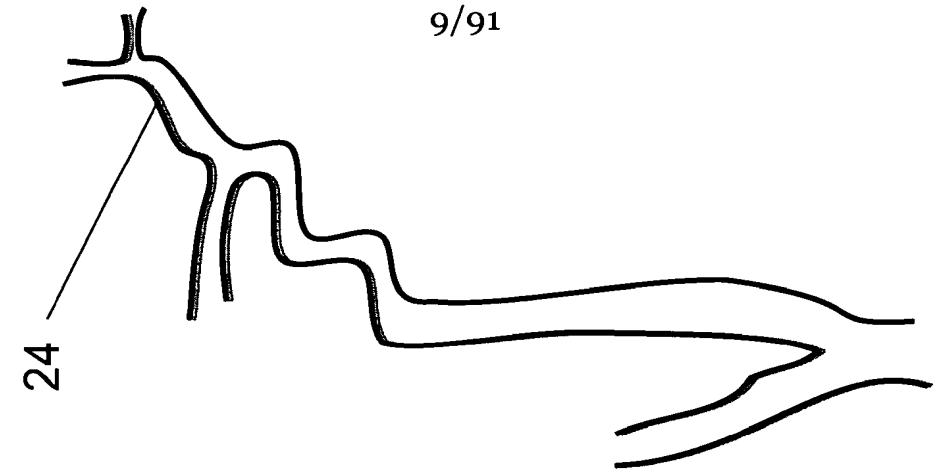


Fig. 5g

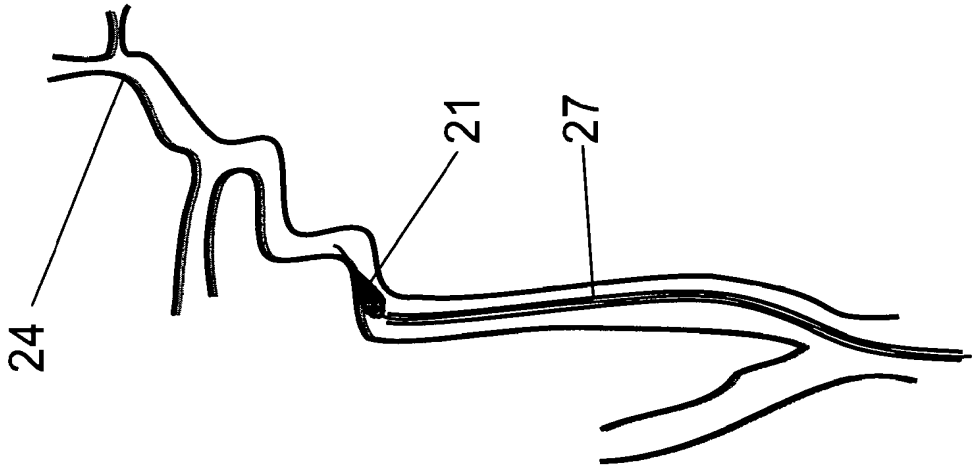


Fig. 5f

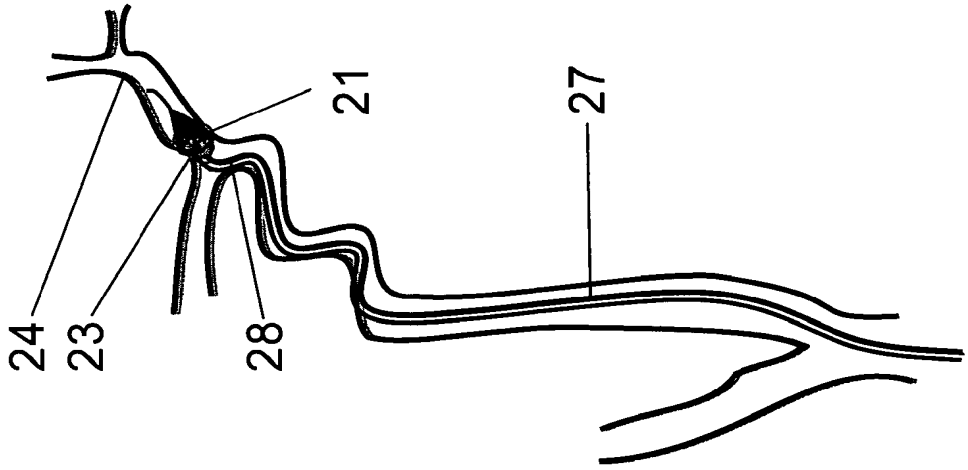


Fig 5e

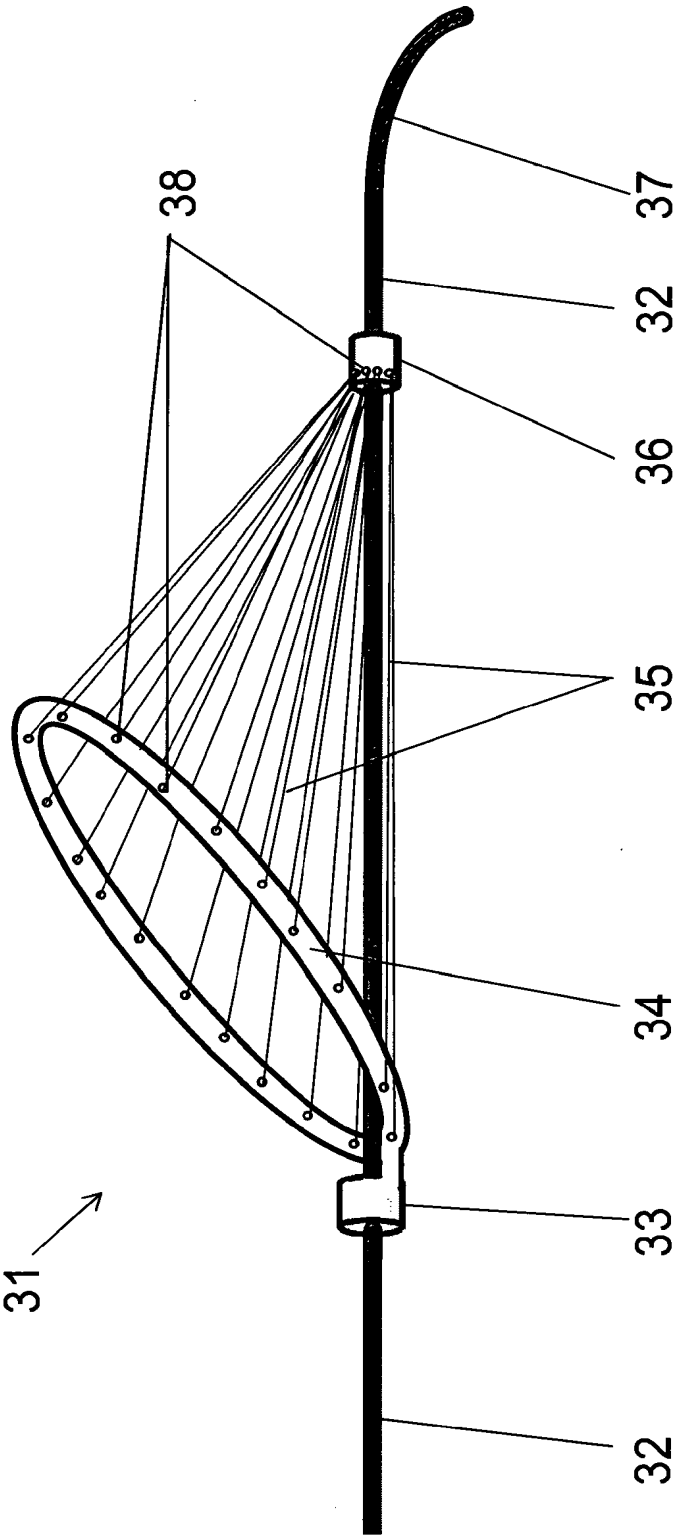
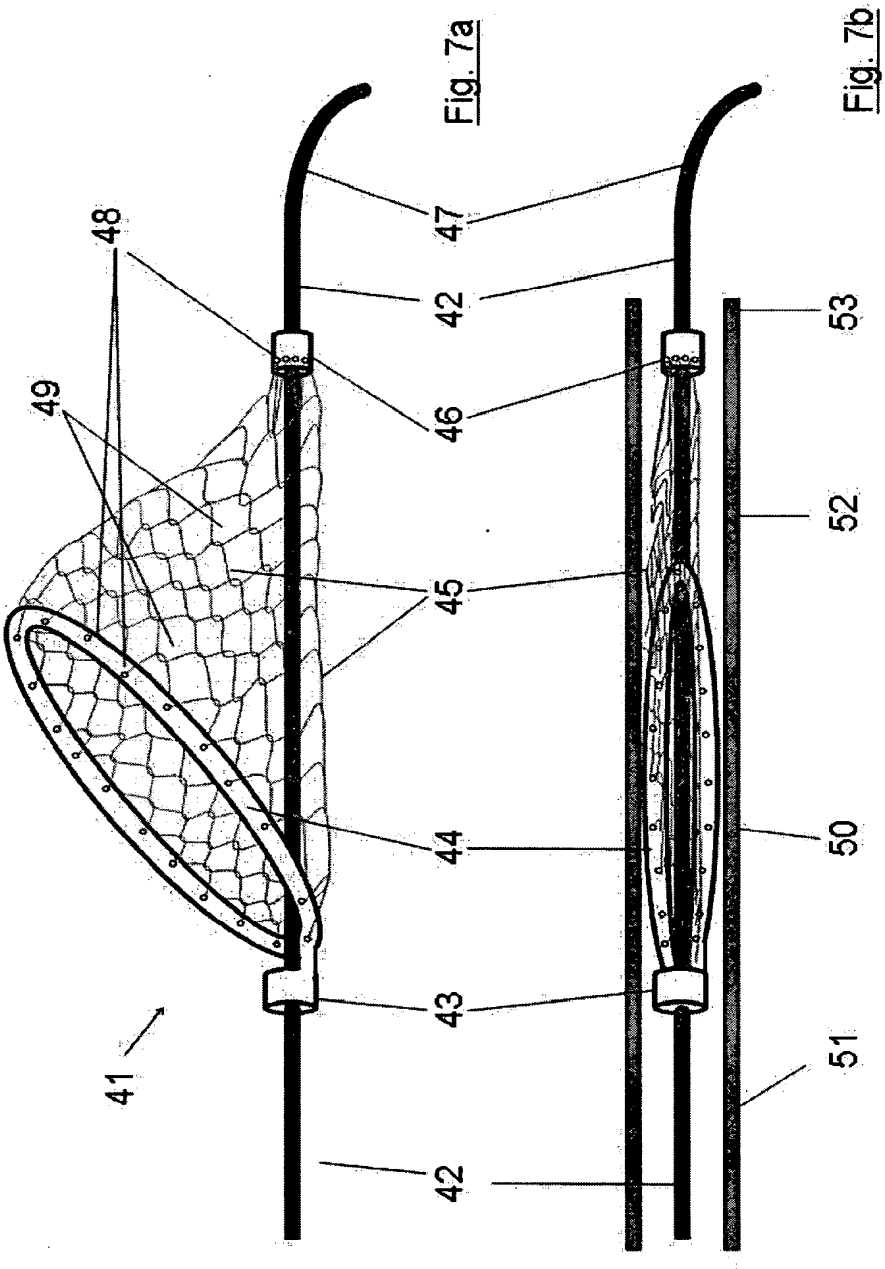


Fig. 6


Fig. 7a
Fig. 7b
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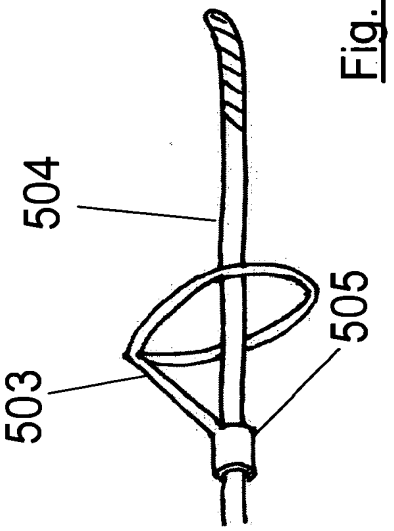


Fig. 8b

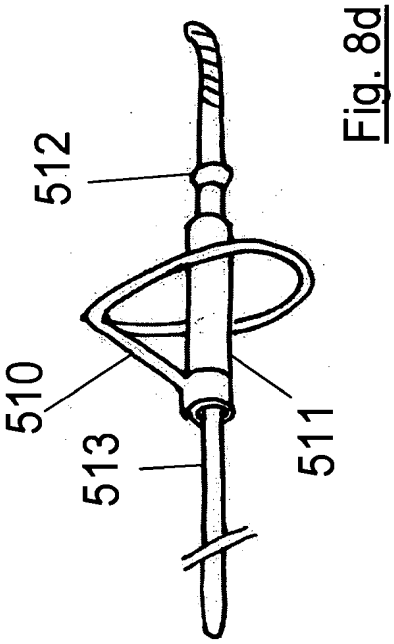


Fig. 8d

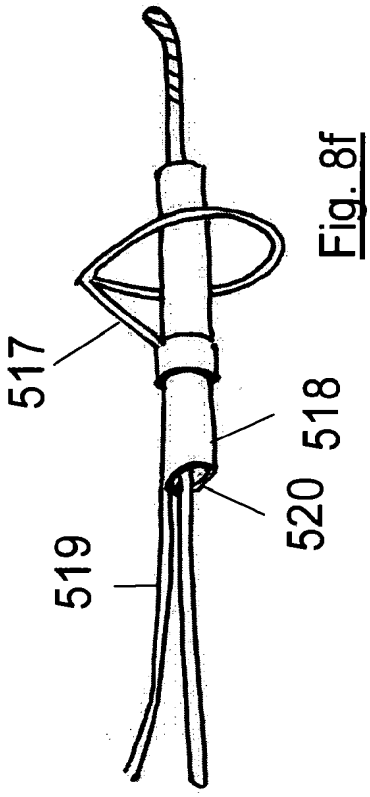


Fig. 8f

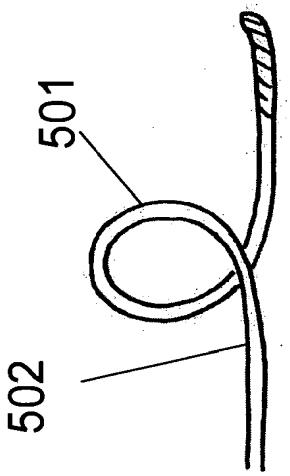


Fig. 8a

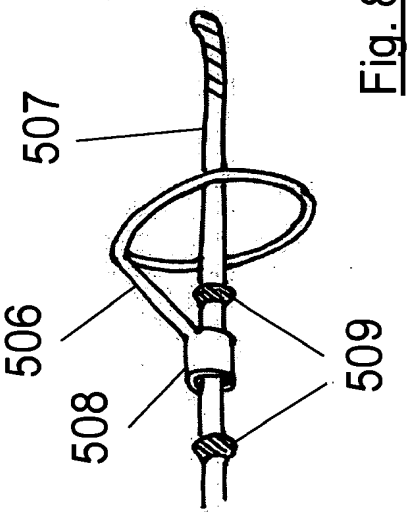


Fig. 8c

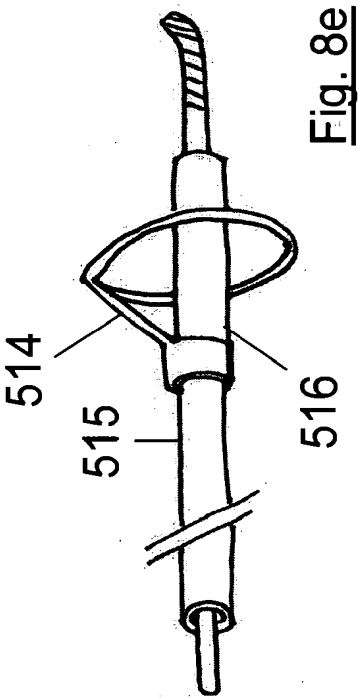


Fig. 8e

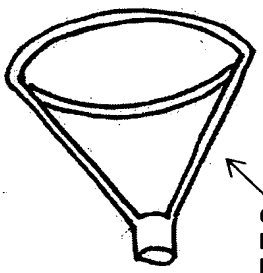


Fig. 9a

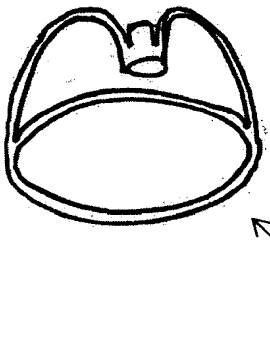


Fig. 9b

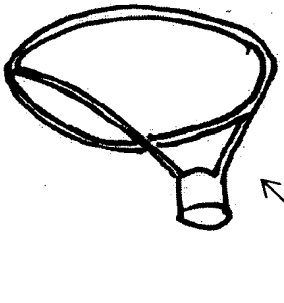


Fig. 9c

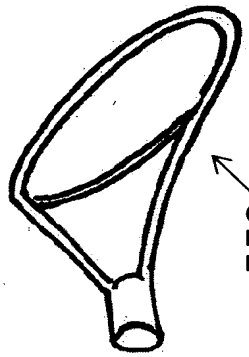


Fig. 9d

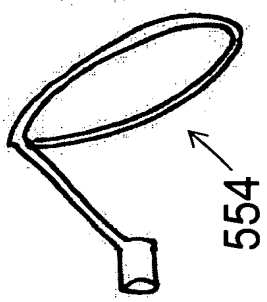


Fig. 9e

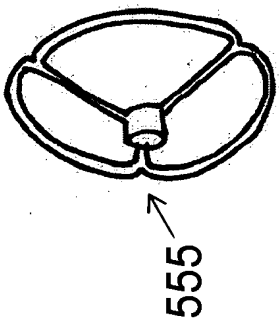


Fig. 9f

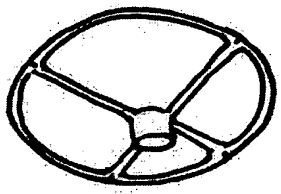


Fig. 9g

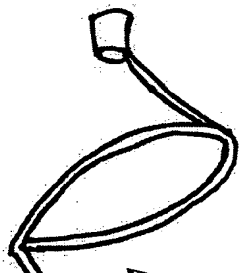


Fig. 9h

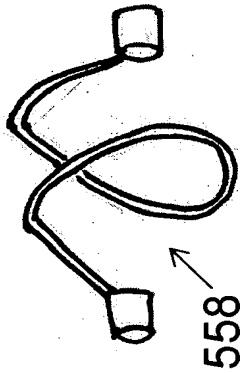


Fig. 9i

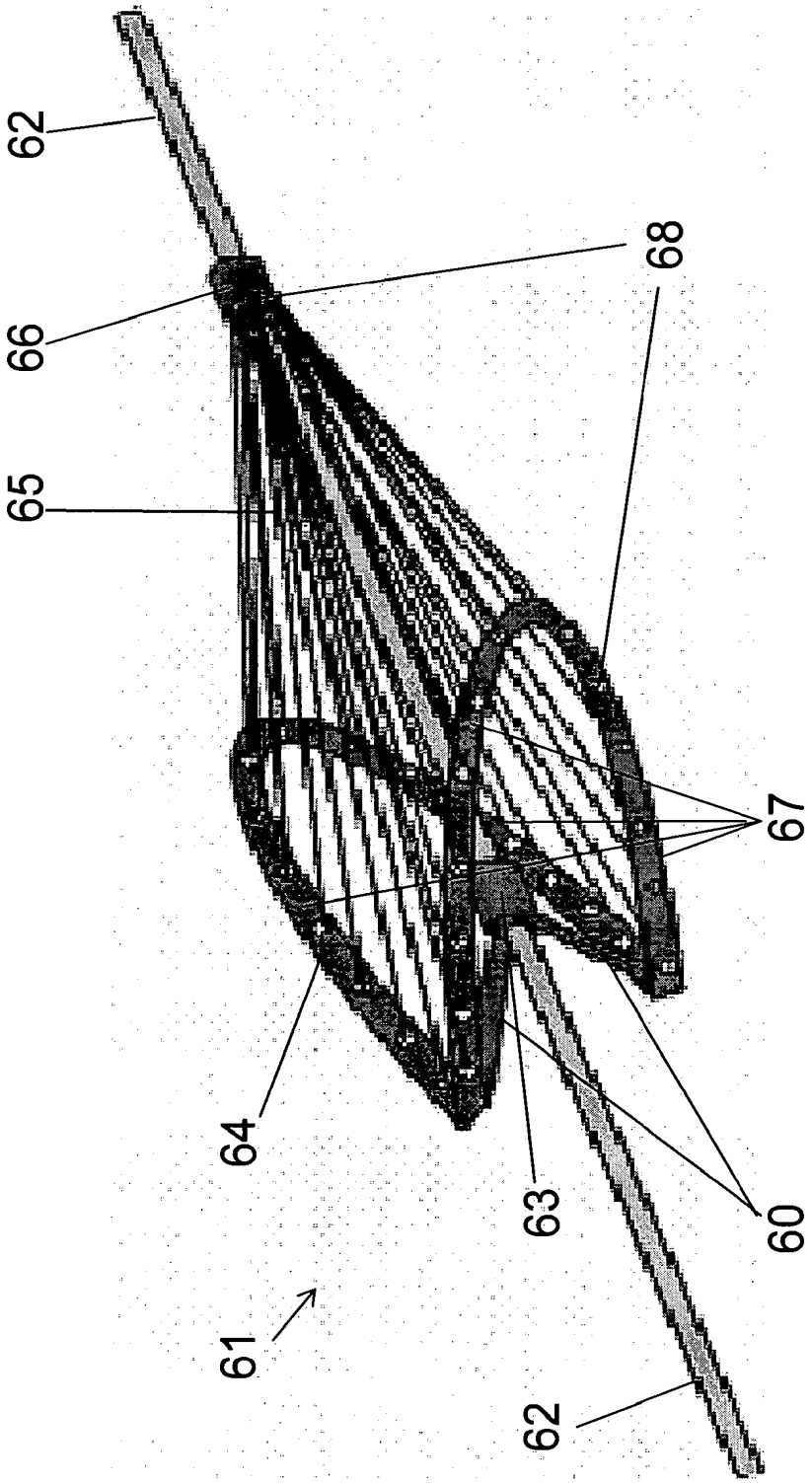


Fig. 10a

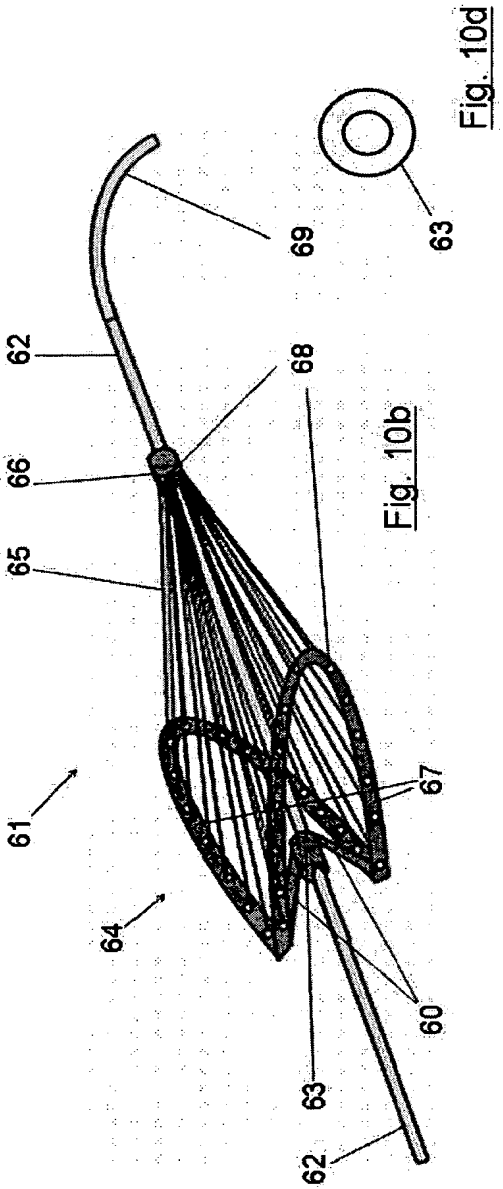


Fig. 10b

Fig. 10d

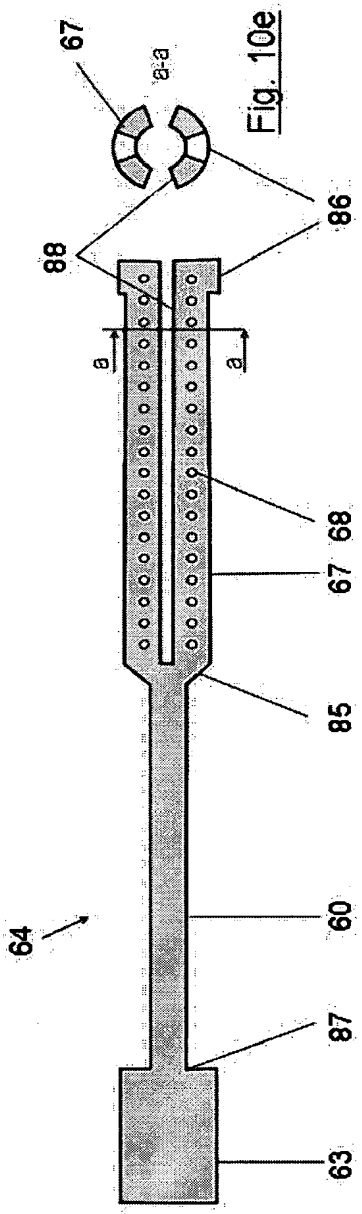
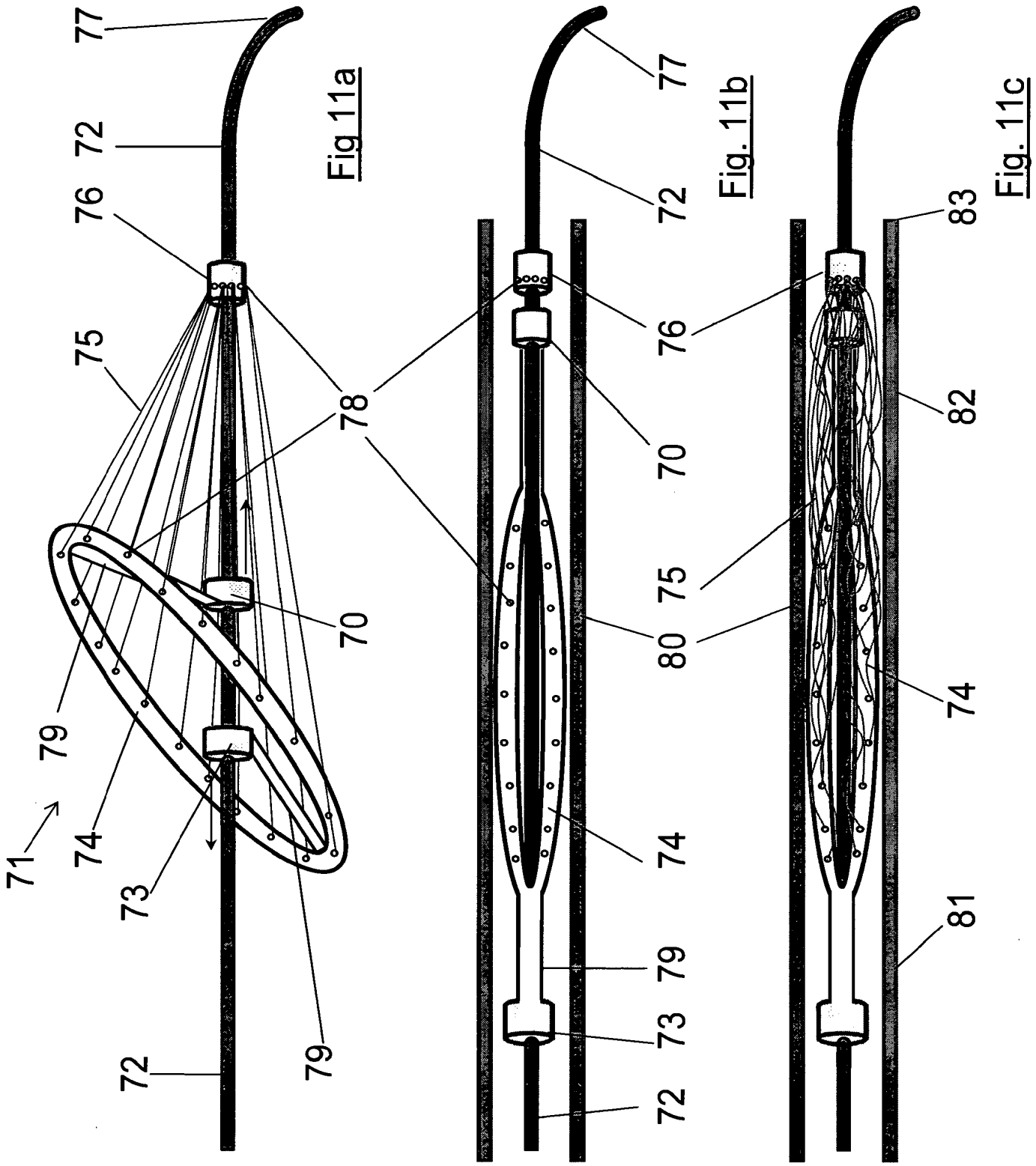


Fig. 10e

Fig. 10c


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Fig 11a
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Fig. 11b
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Fig. 11c

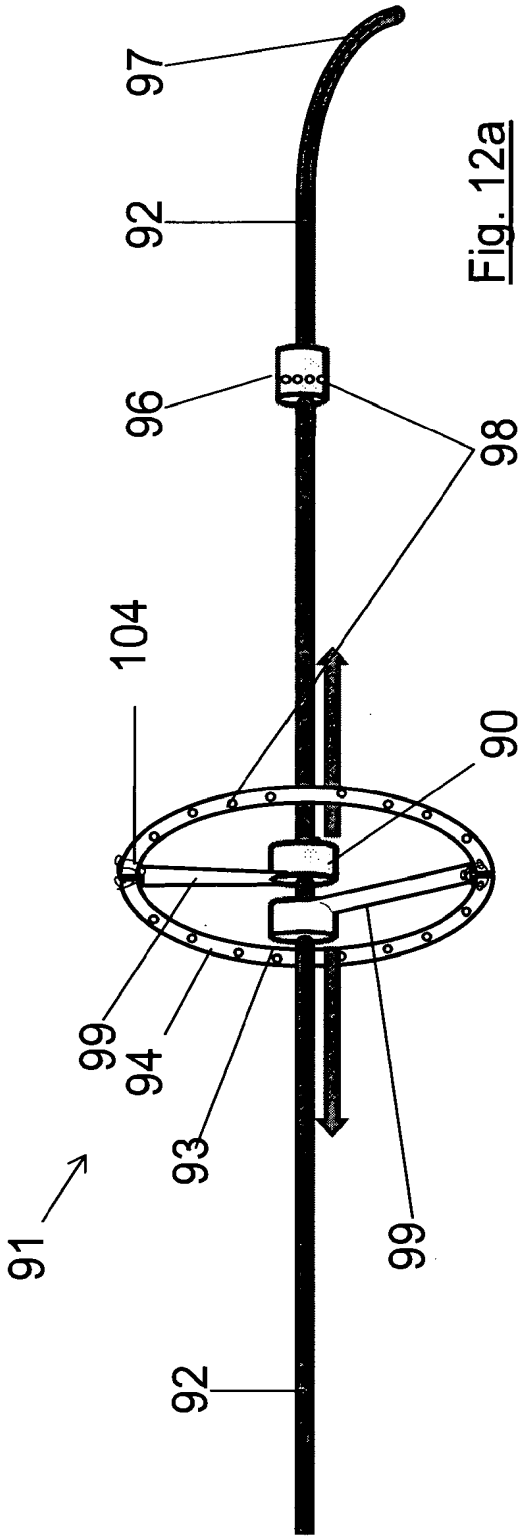


Fig. 12a

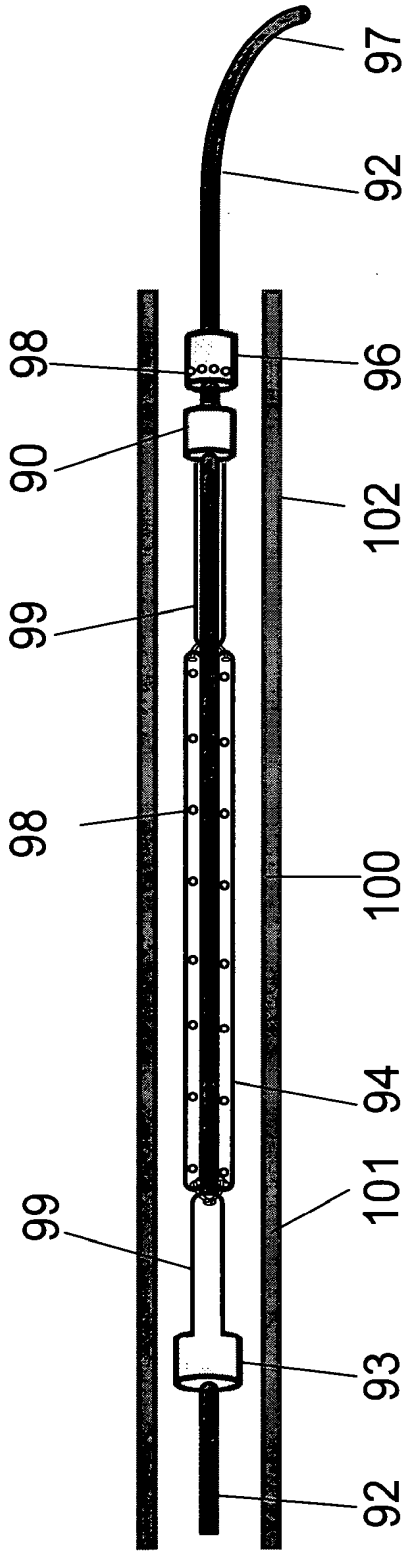


Fig. 12b

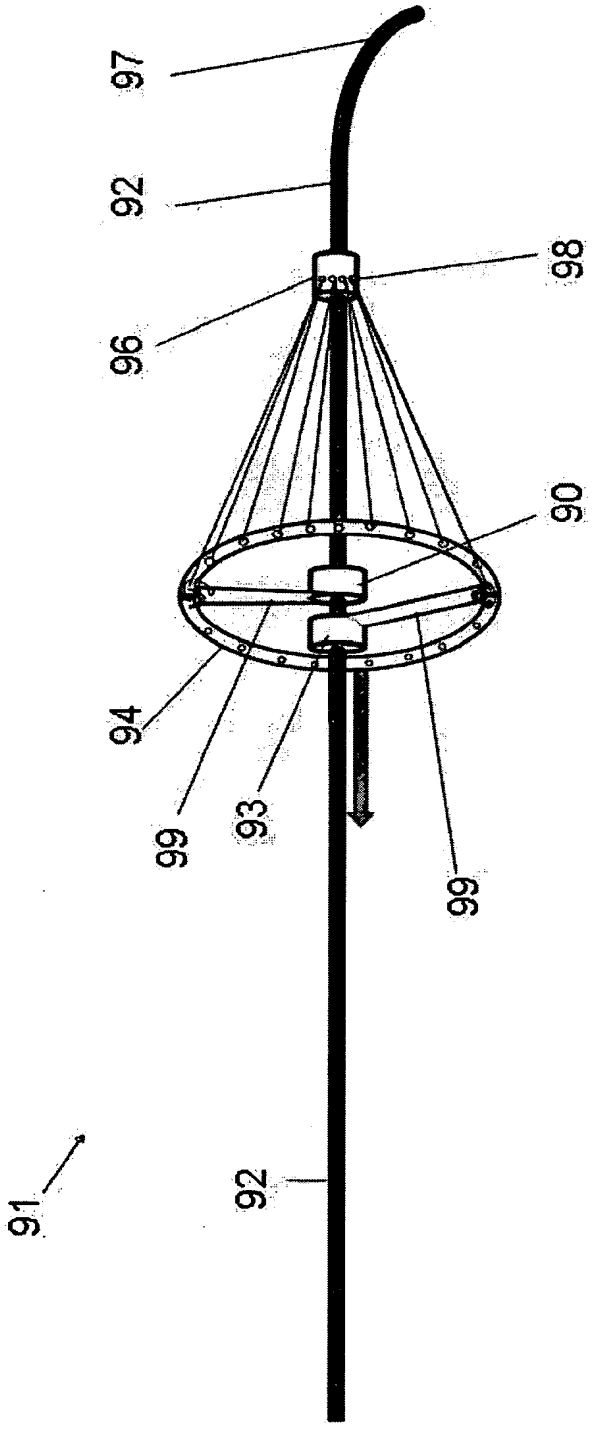


Fig. 13a

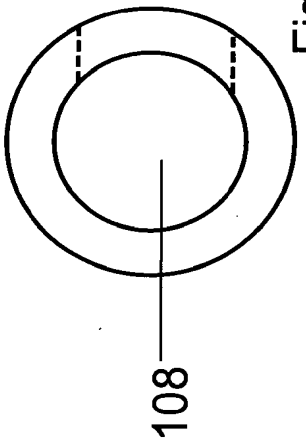


Fig. 13d

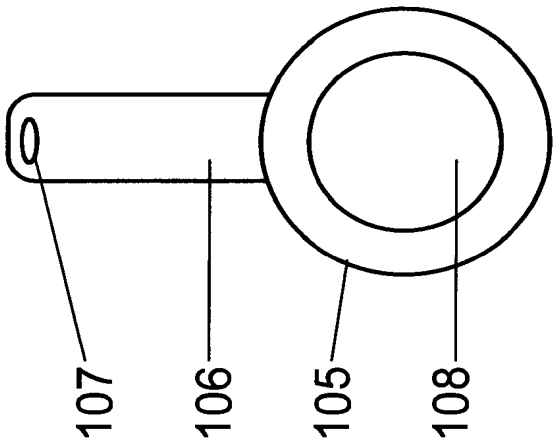


Fig. 13e

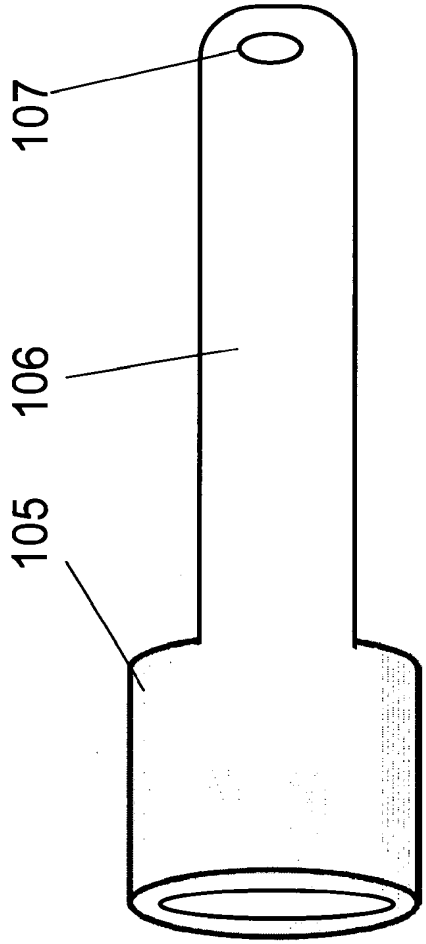


Fig. 13b

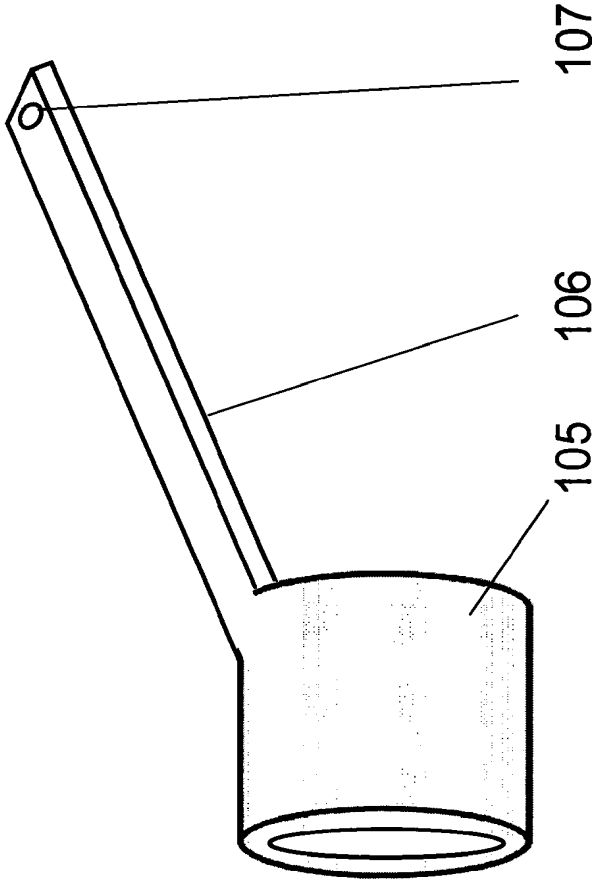


Fig. 13c

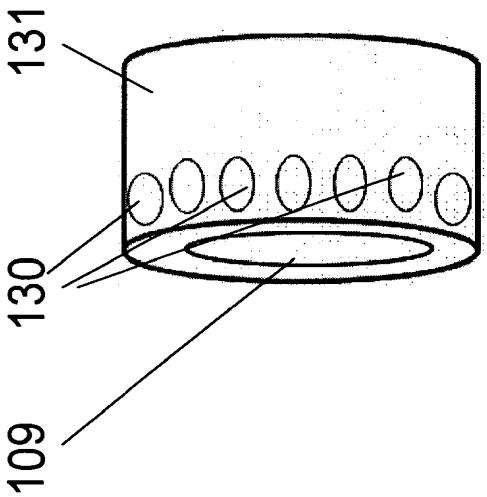


Fig. 15

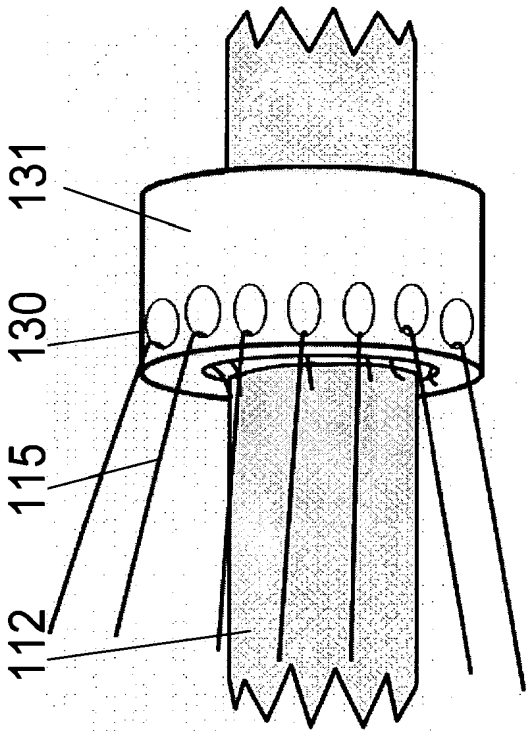


Fig. 17

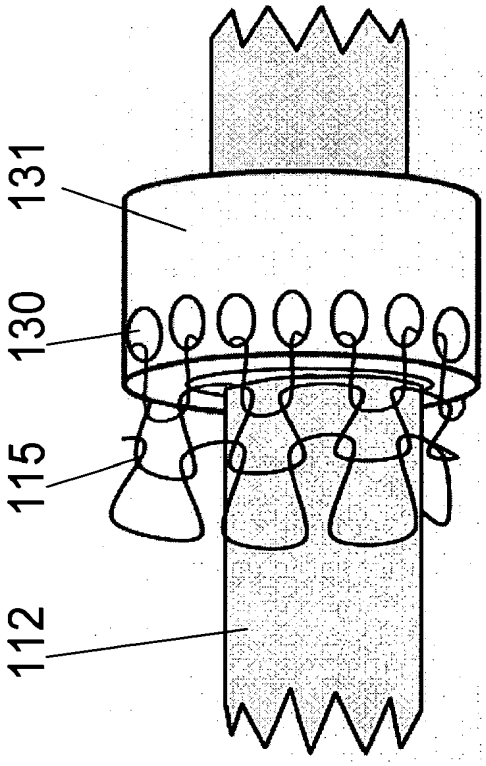


Fig. 14

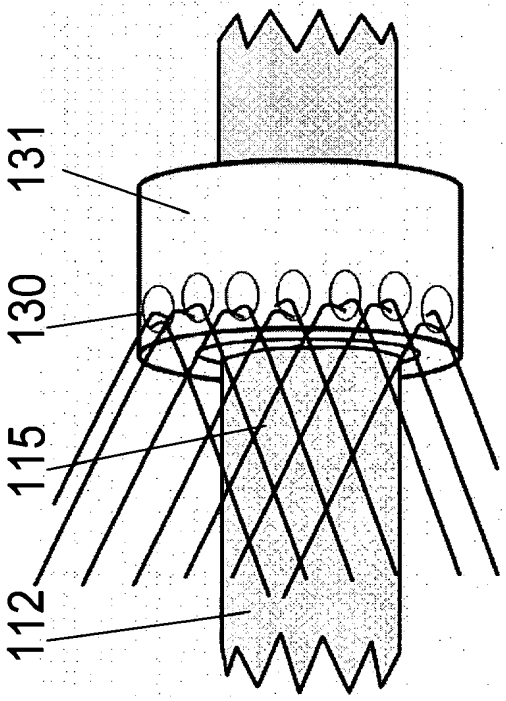


Fig. 16

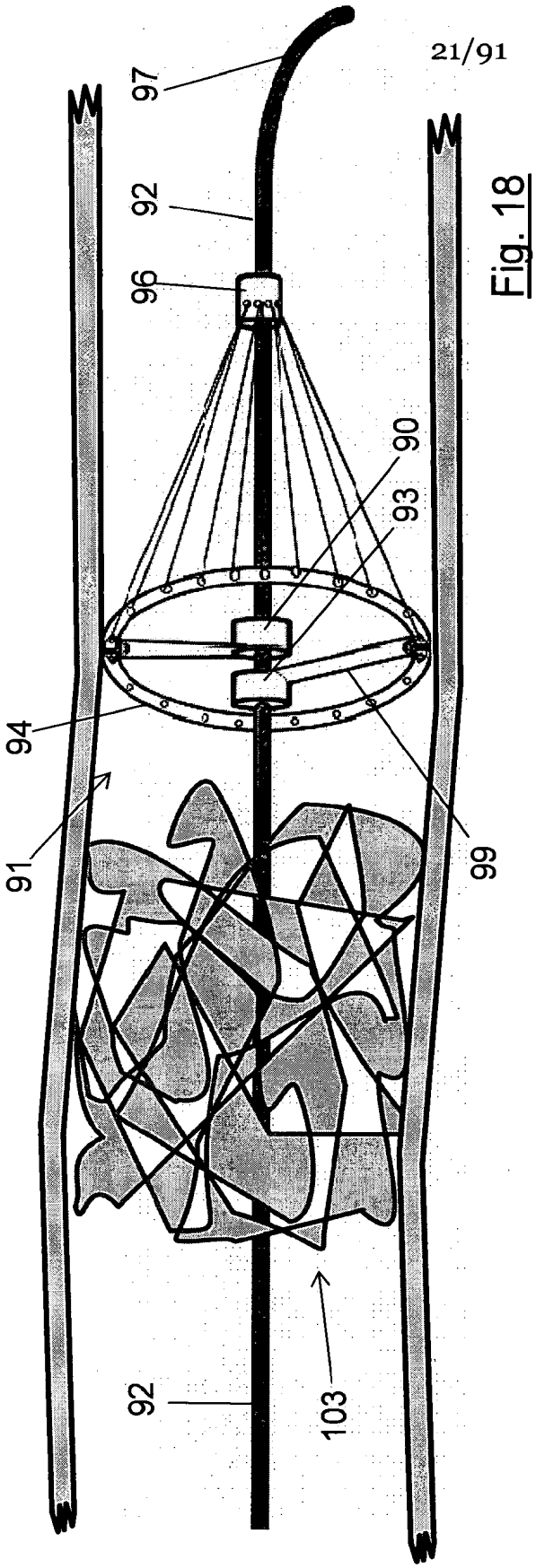


Fig. 18

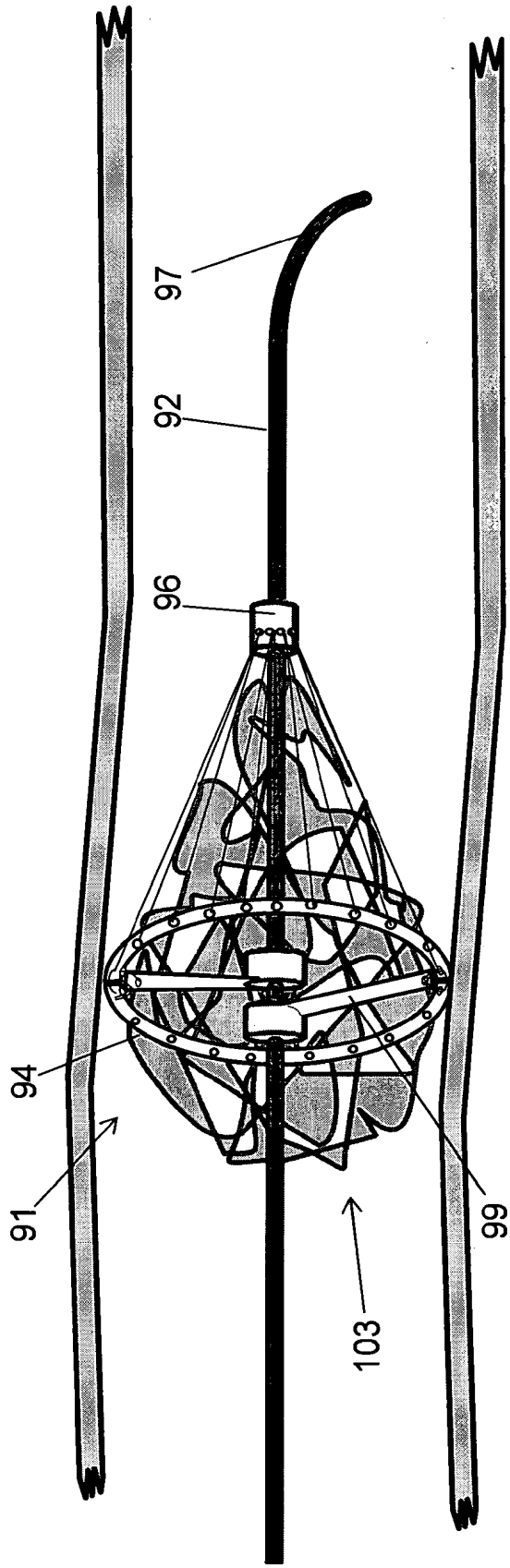


Fig. 19

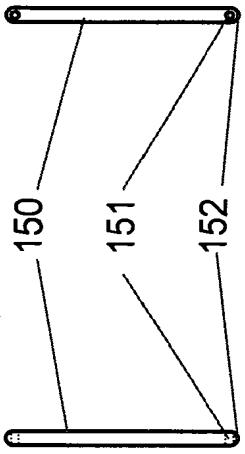


Fig. 20a

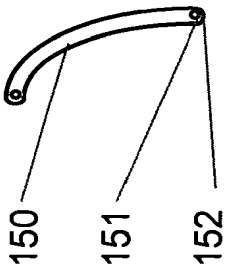


Fig. 20b

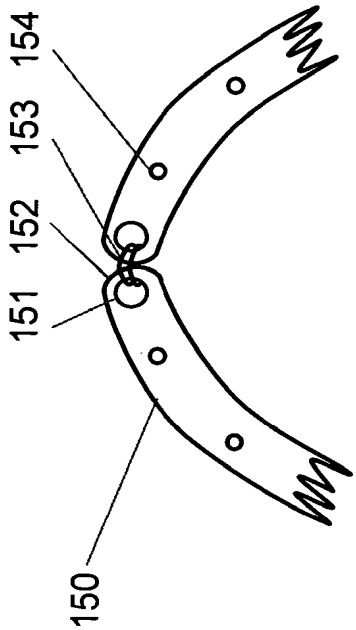


Fig. 20c

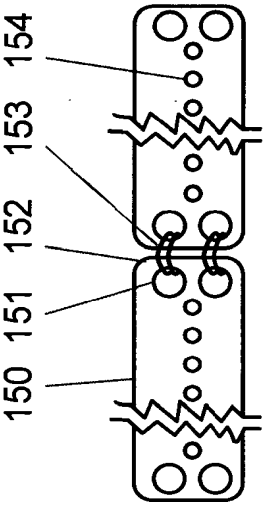


Fig. 20d

Fig. 20e

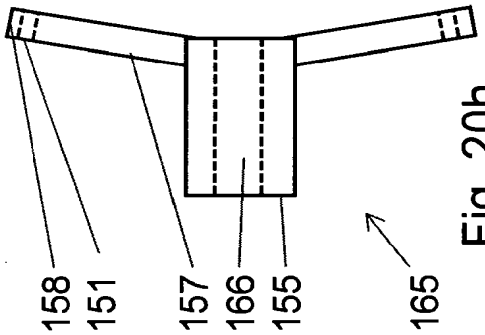


Fig. 20h

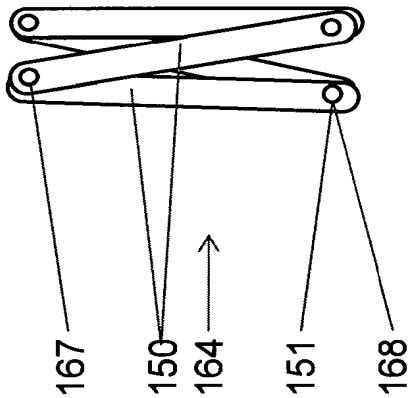


Fig. 20k

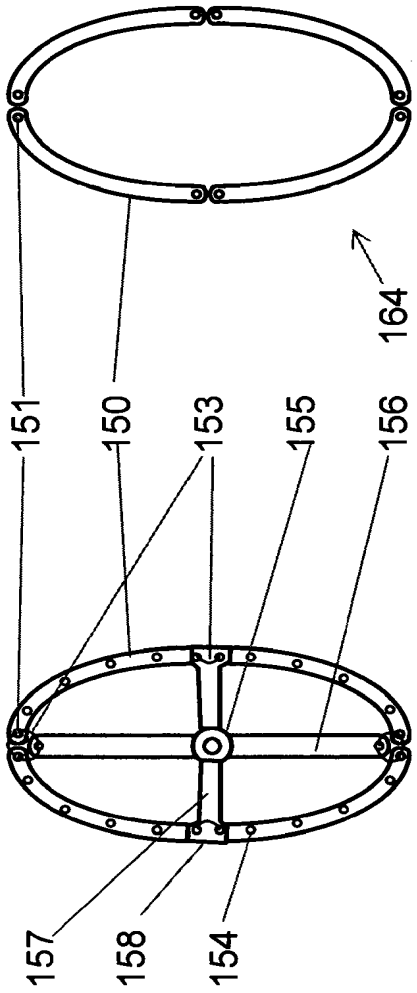


Fig. 20g

Fig. 20f

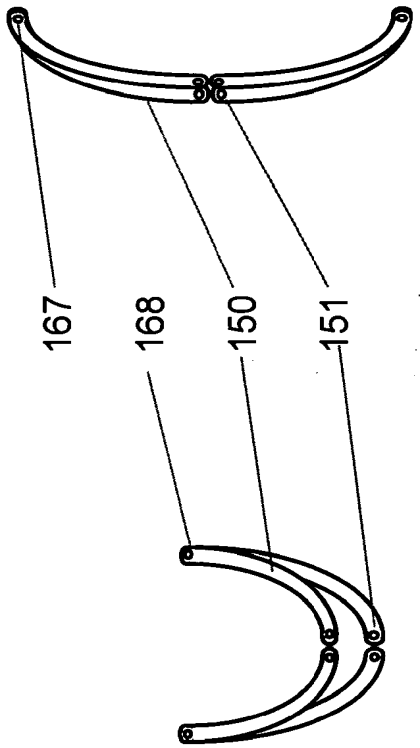


Fig. 20j

Fig. 20i

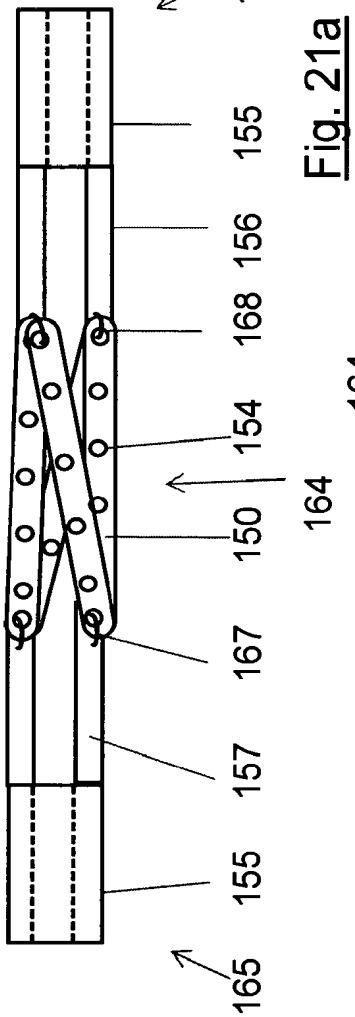


Fig. 21a

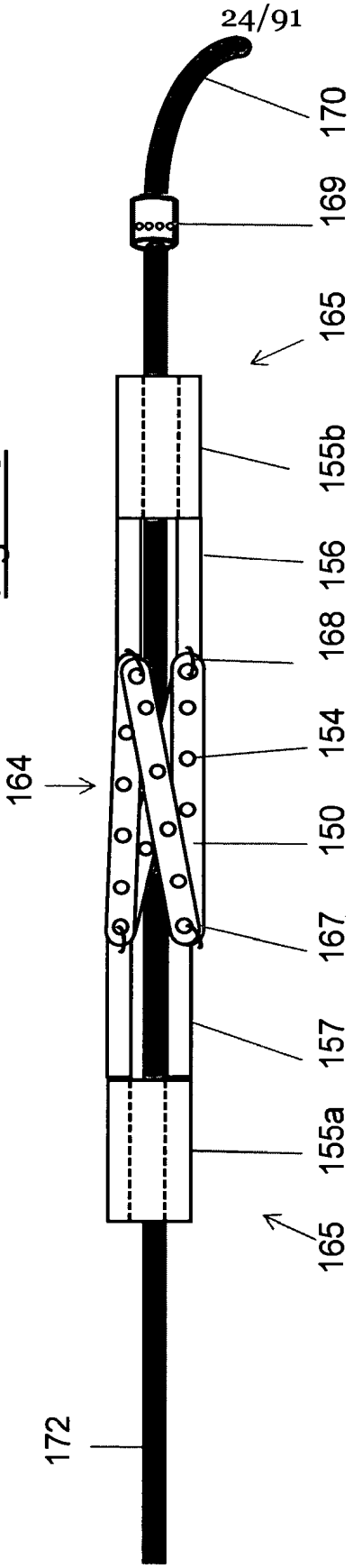


Fig. 21b

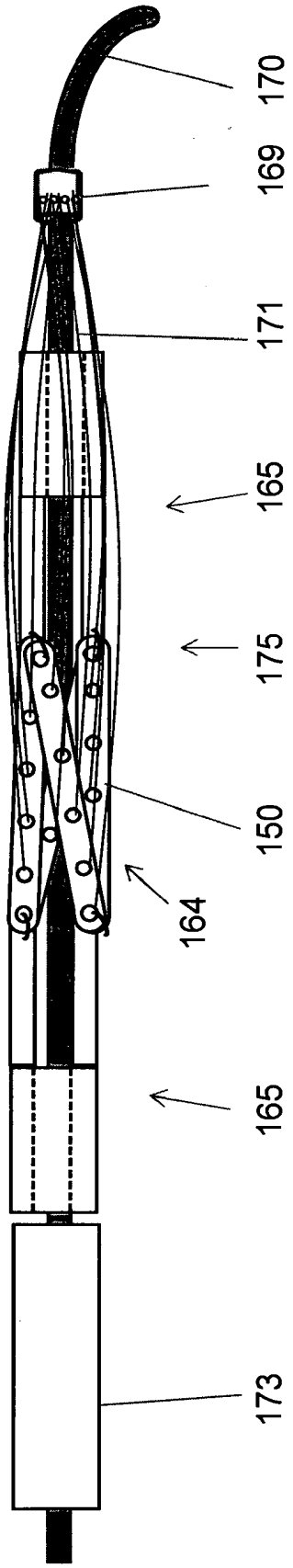


Fig. 21c

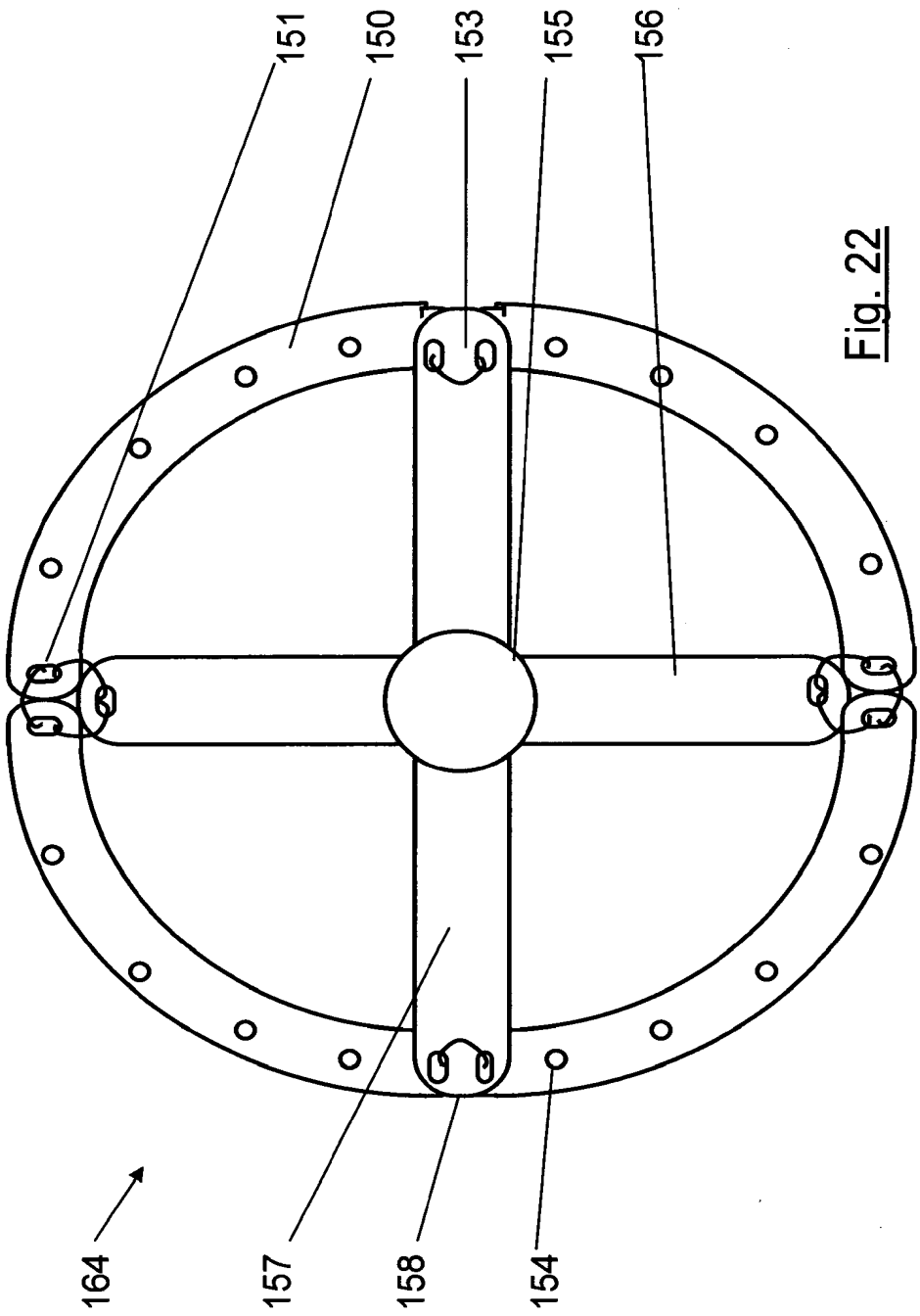


Fig. 22

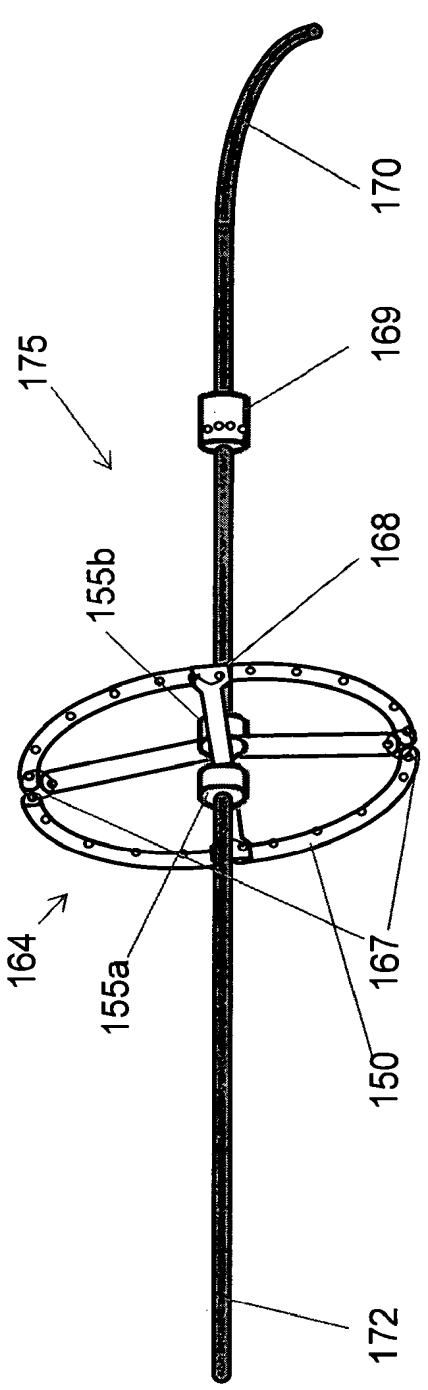


Fig. 23a

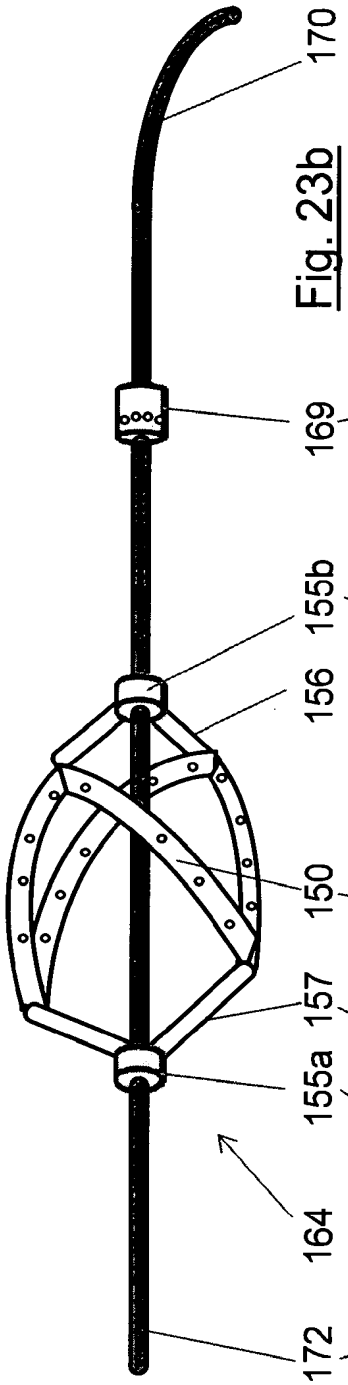


Fig. 23b

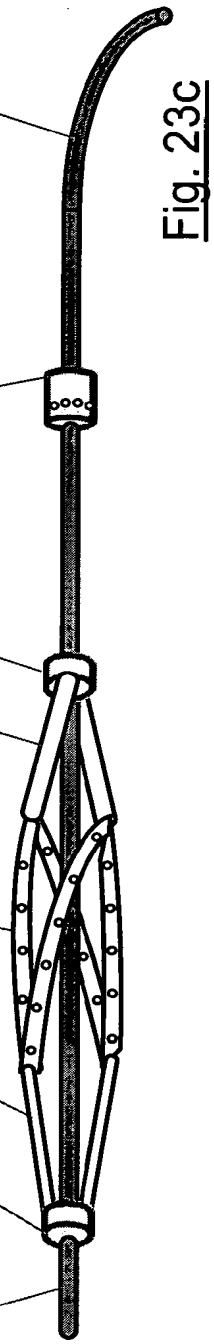


Fig. 23c

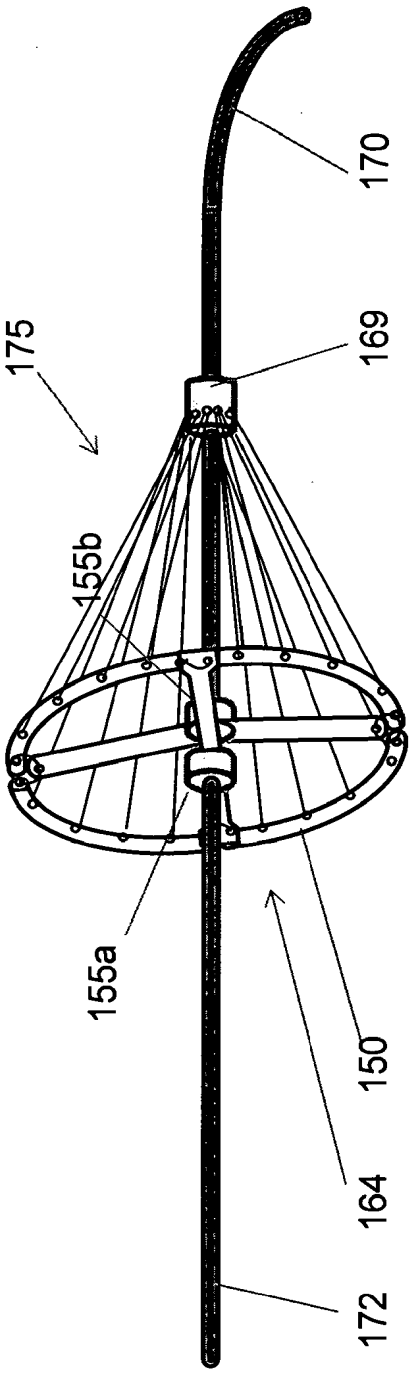


Fig. 24a

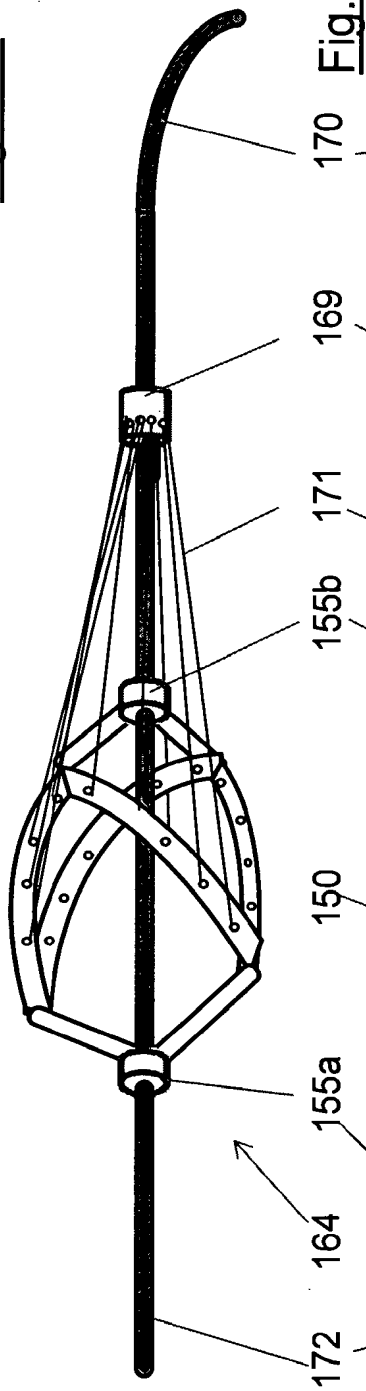


Fig. 24b



Fig. 24c

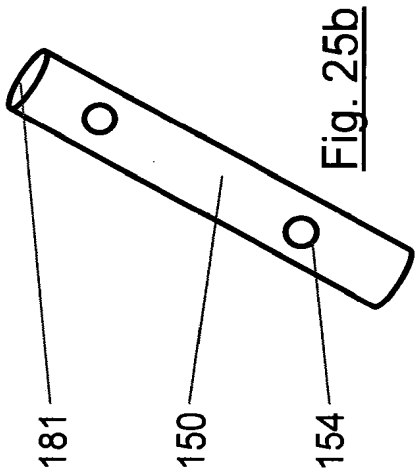


Fig. 25b

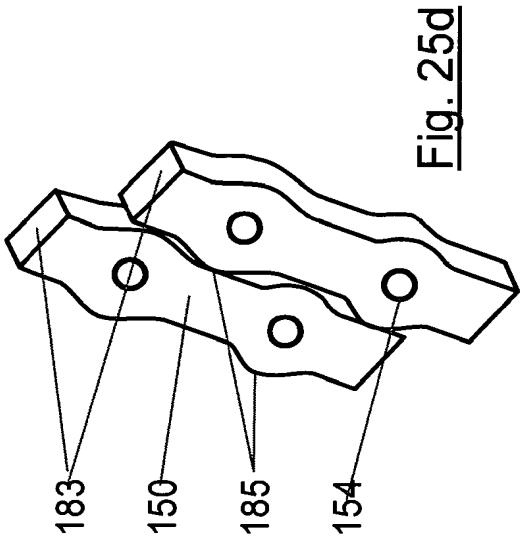


Fig. 25d

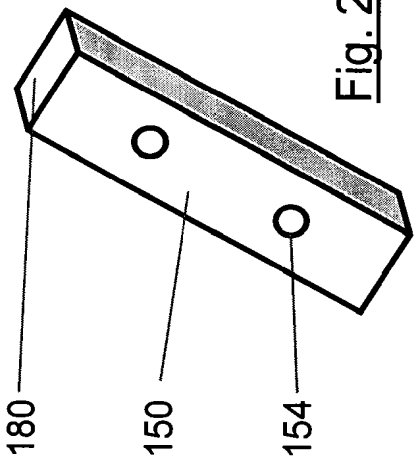


Fig. 25a

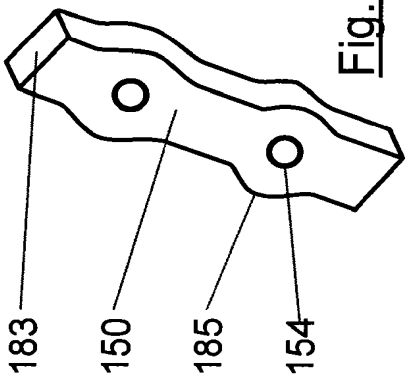


Fig. 25c

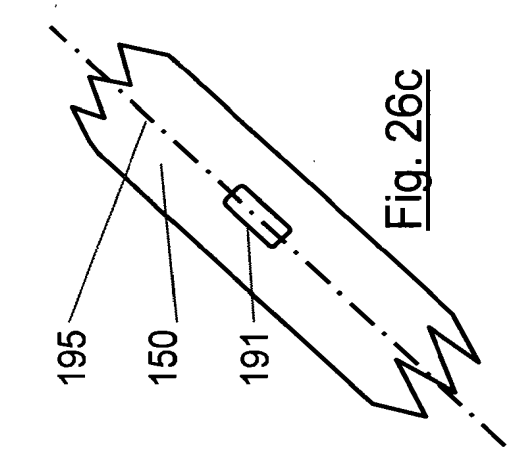


Fig. 26c

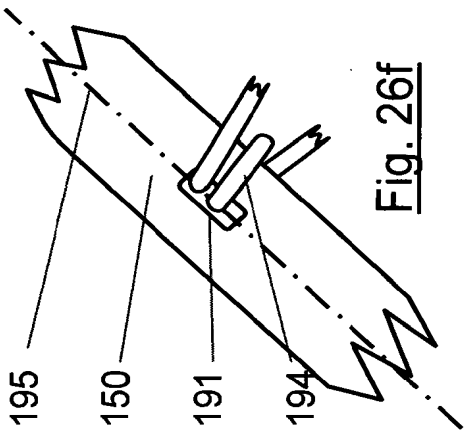


Fig. 26f

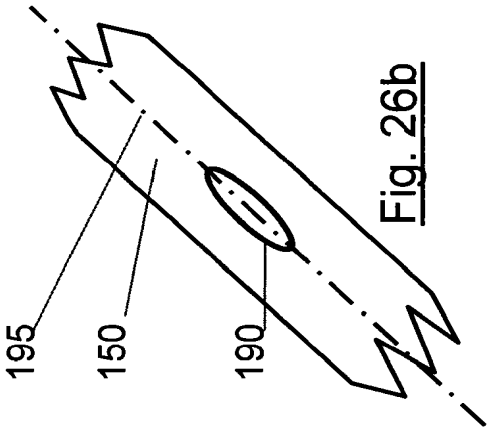


Fig. 26b

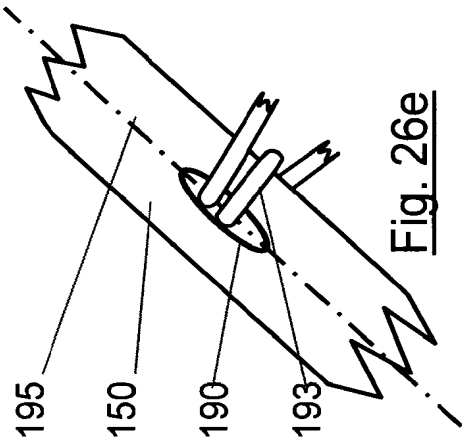


Fig. 26e

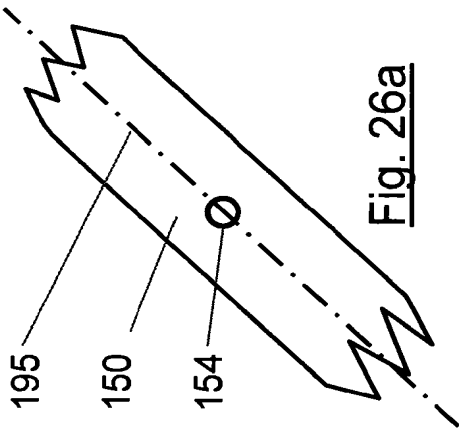


Fig. 26a

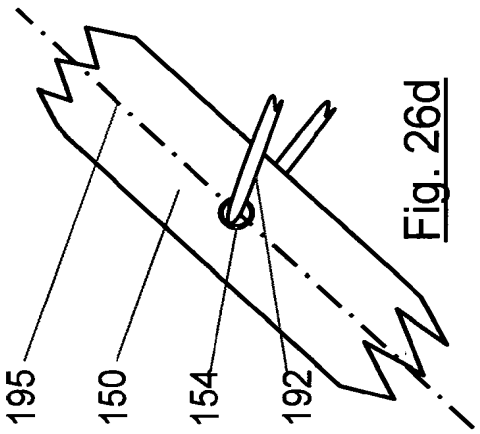


Fig. 26d

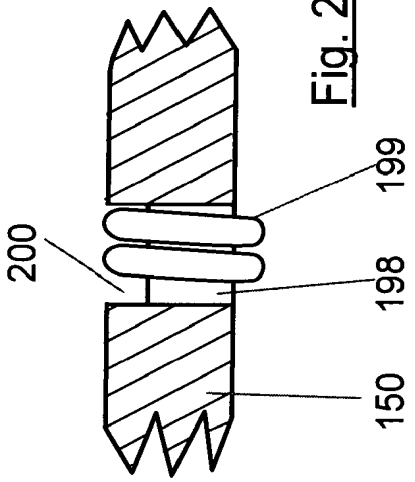


Fig. 27c

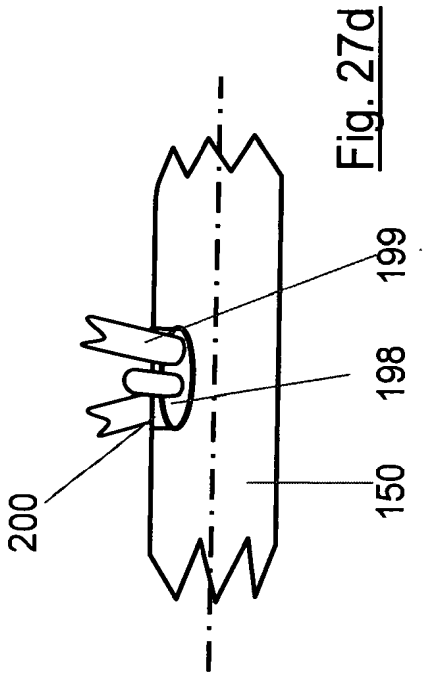


Fig. 27d

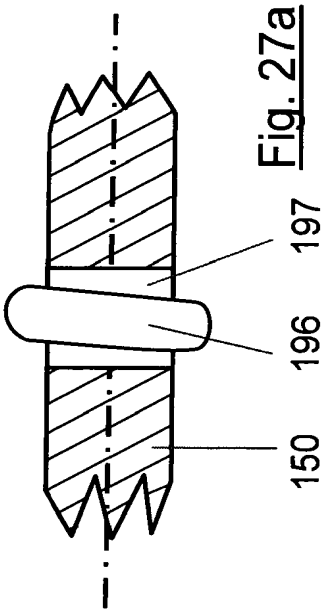


Fig. 27a

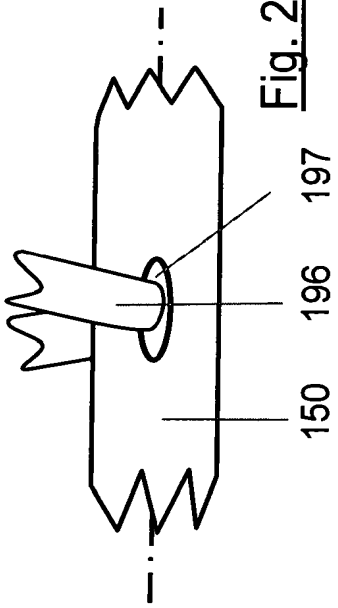


Fig. 27b

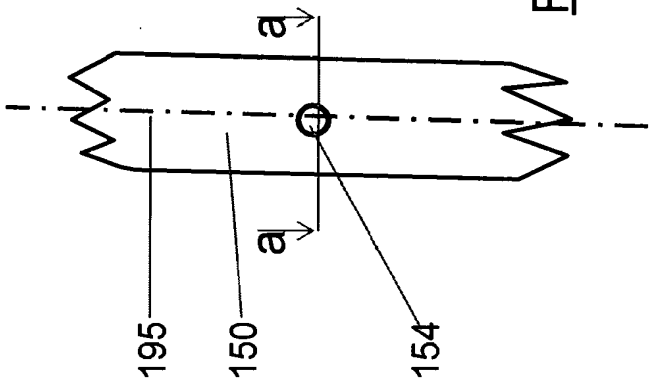


Fig. 28a



Section a-a

Fig. 28b

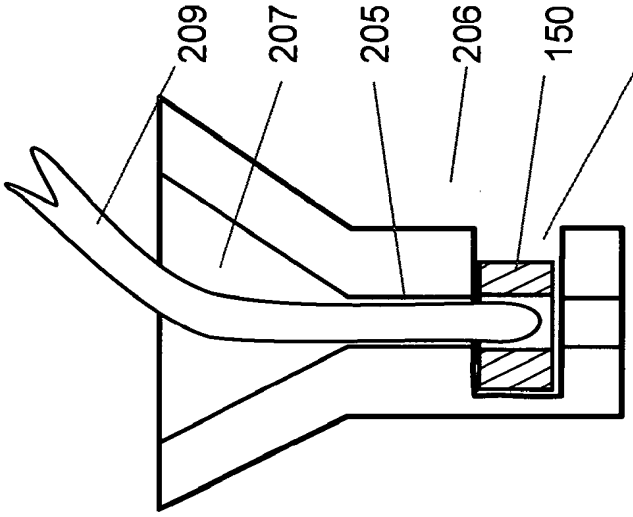


Fig. 28c

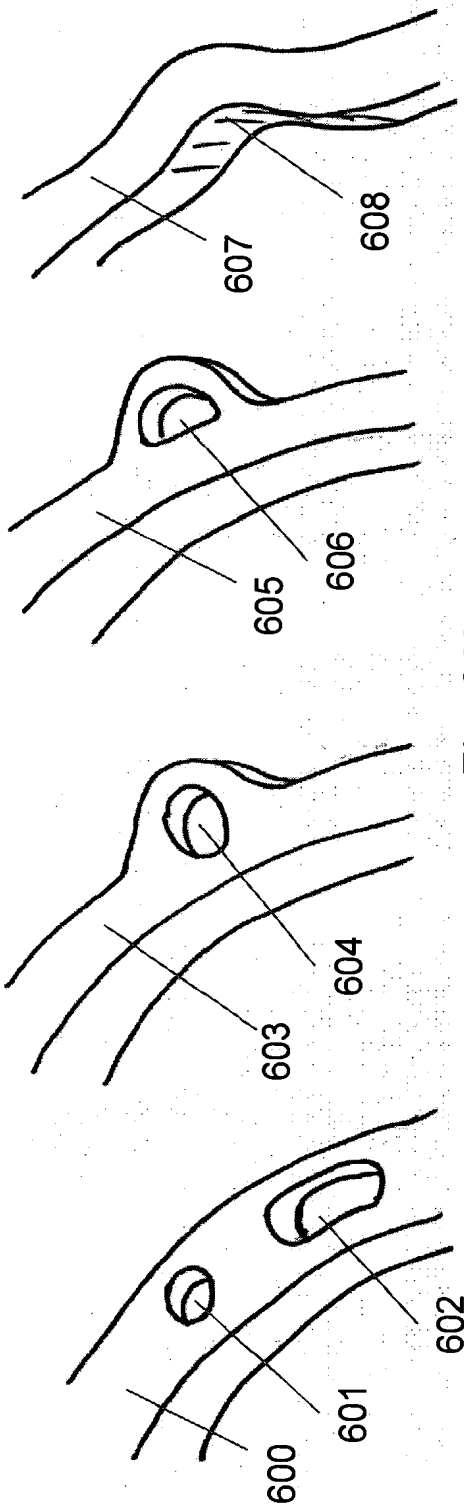


Fig. 29a

Fig. 29b

Fig. 29c

Fig. 29d



Fig. 29e

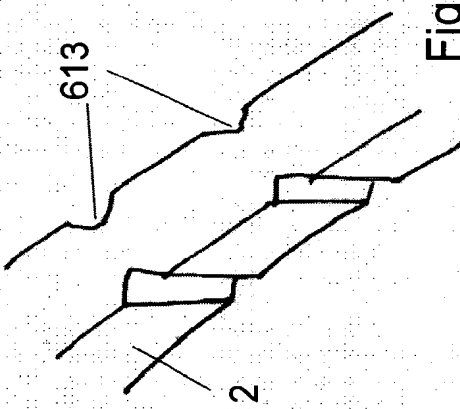


Fig. 29f

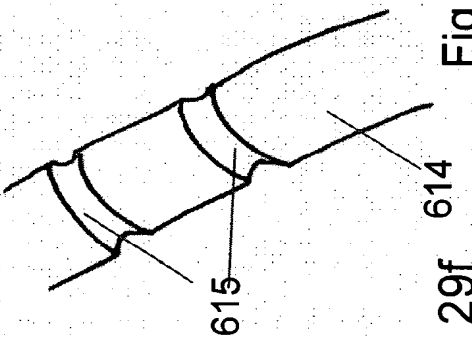


Fig. 29g

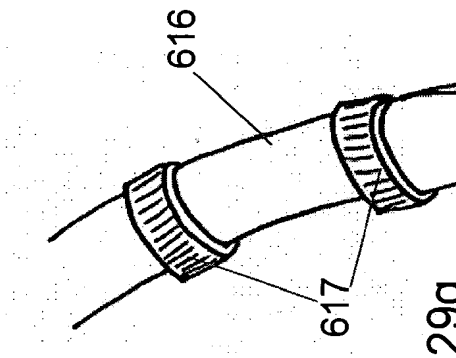


Fig. 29h

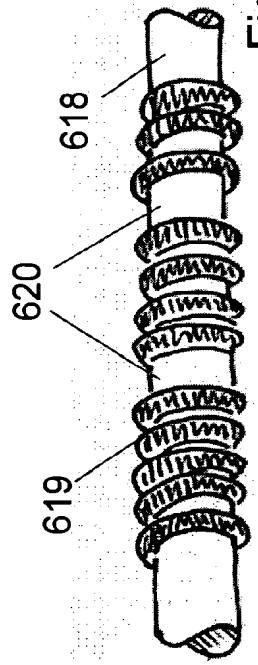


Fig. 29i

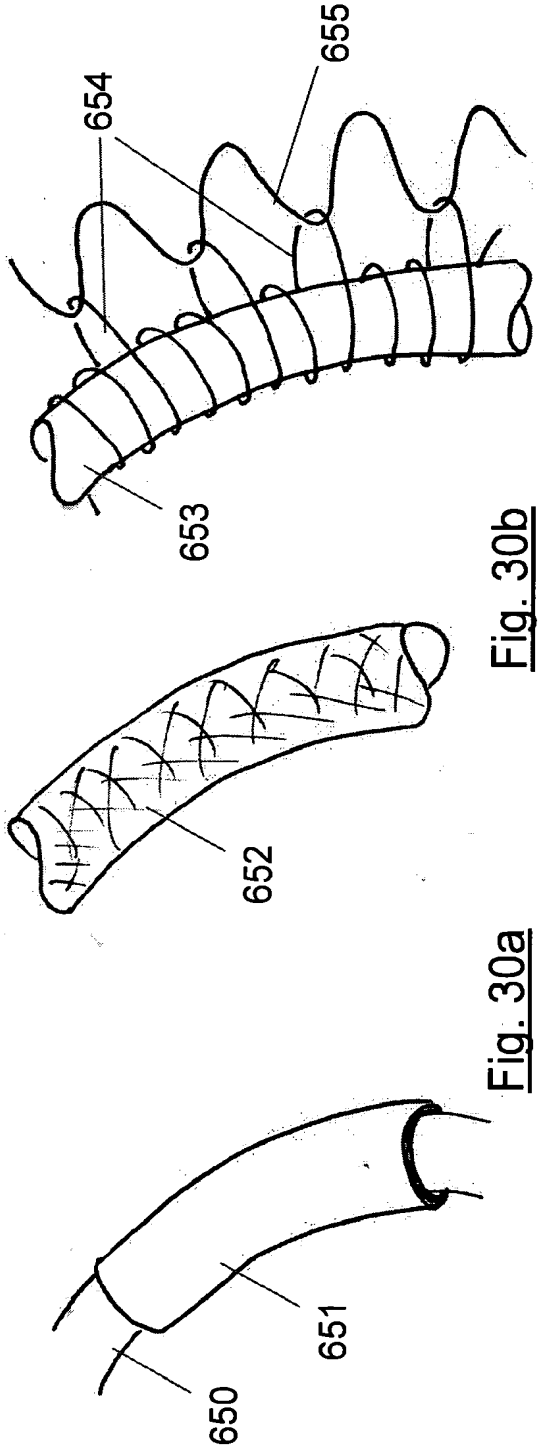


Fig. 30a

Fig. 30b

Fig. 30c

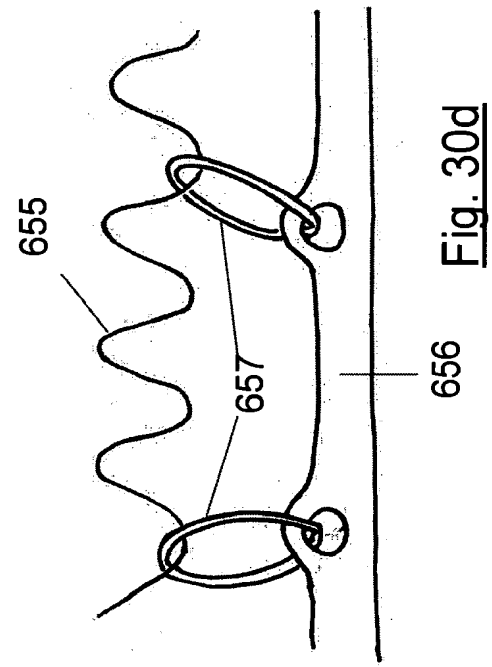


Fig. 30d

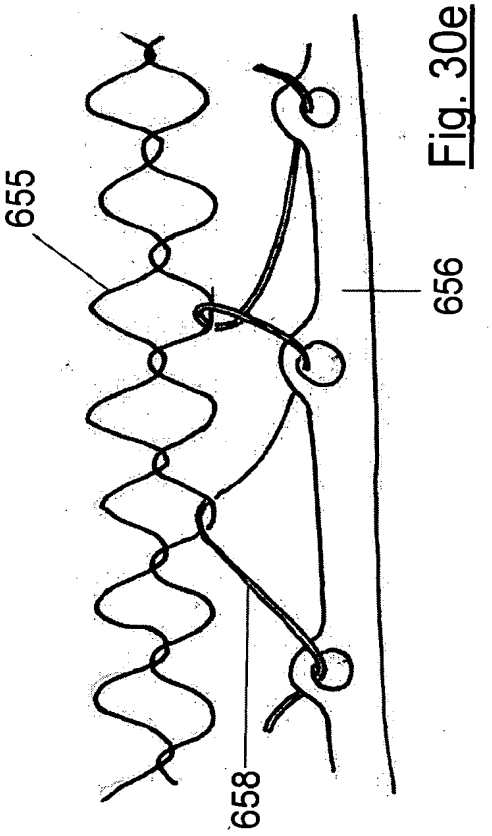


Fig. 30e

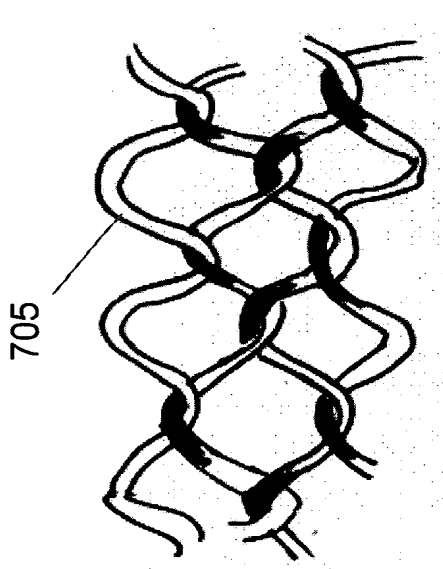


Fig. 31c

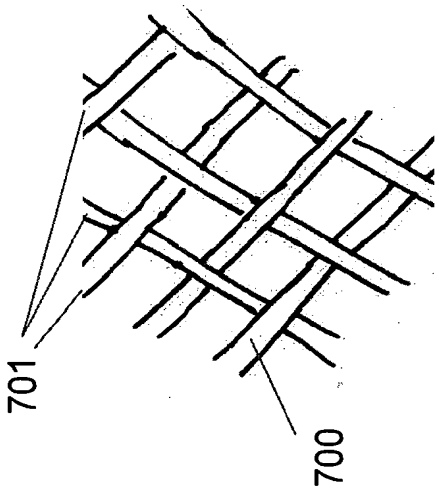


Fig. 31a

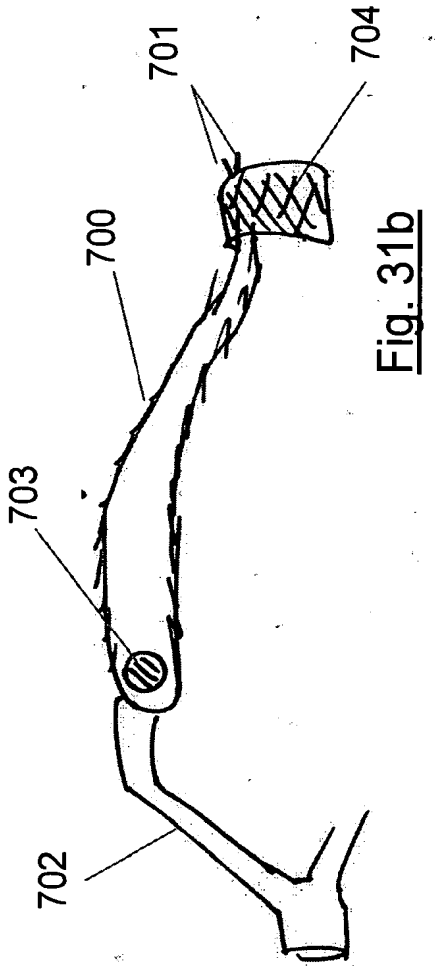


Fig. 31b

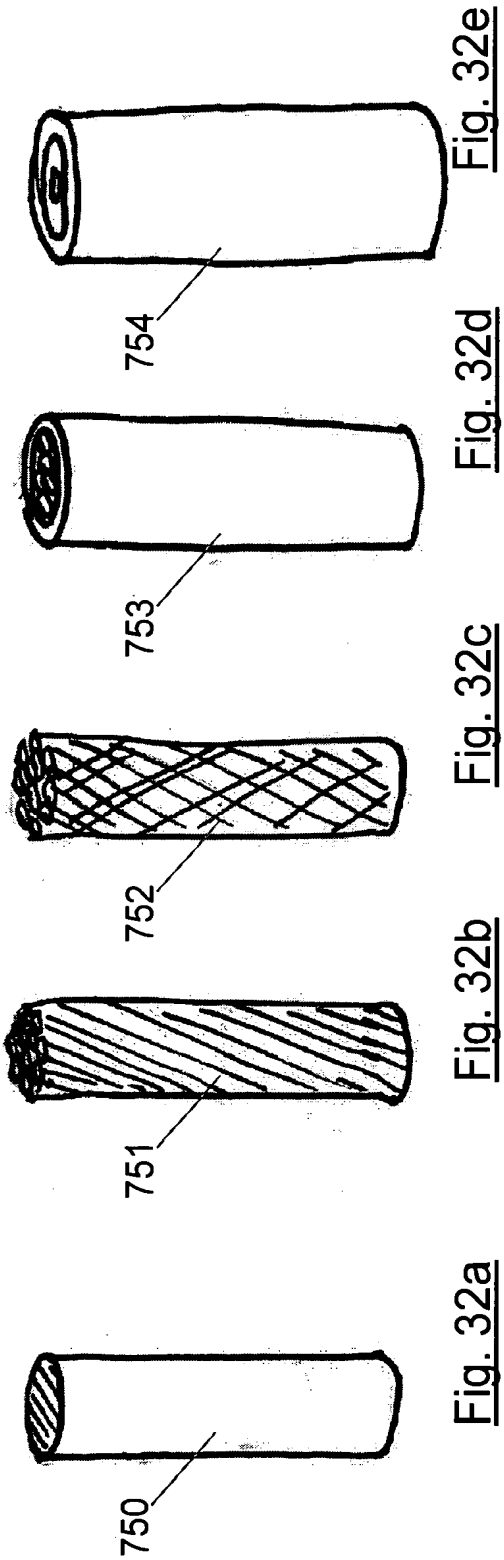


Fig. 32a Fig. 32b Fig. 32c Fig. 32d Fig. 32e

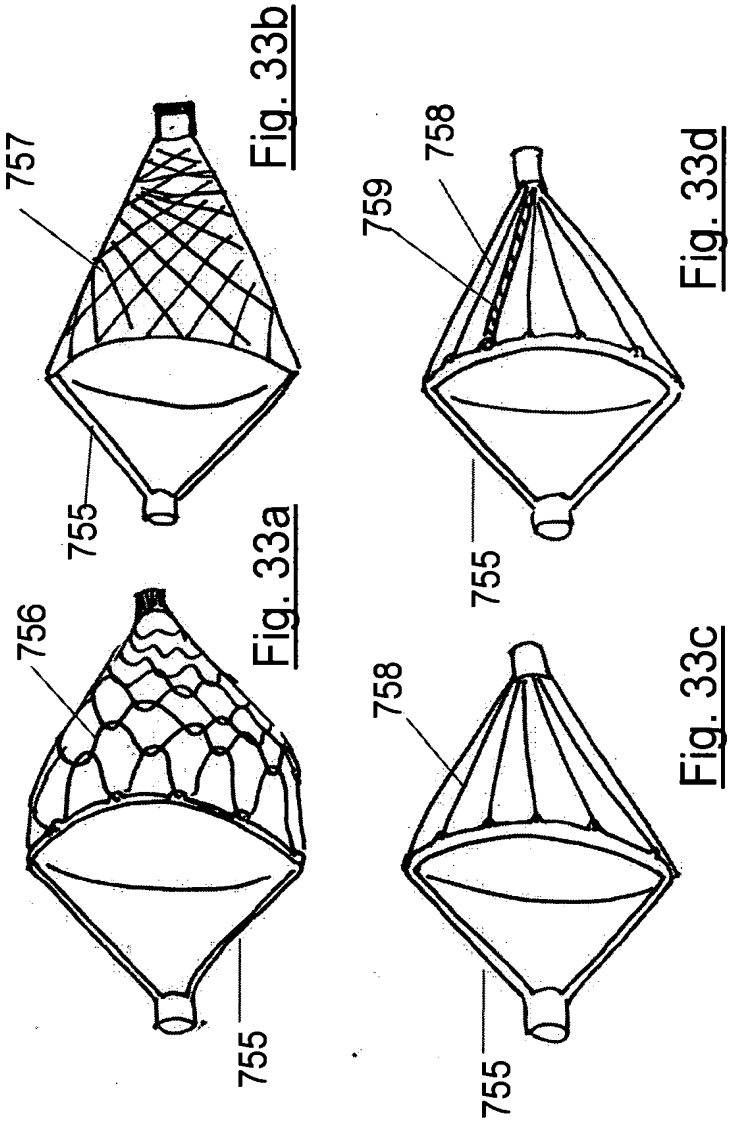


Fig. 33a Fig. 33b Fig. 33c Fig. 33d

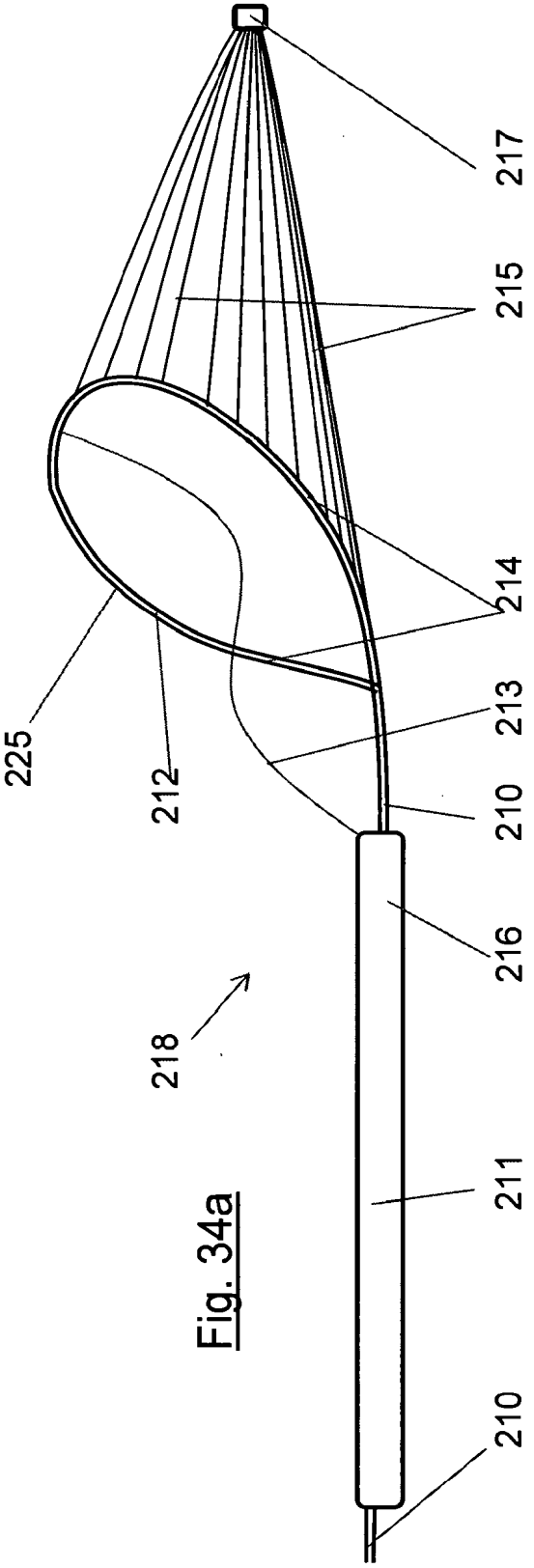


Fig. 34a

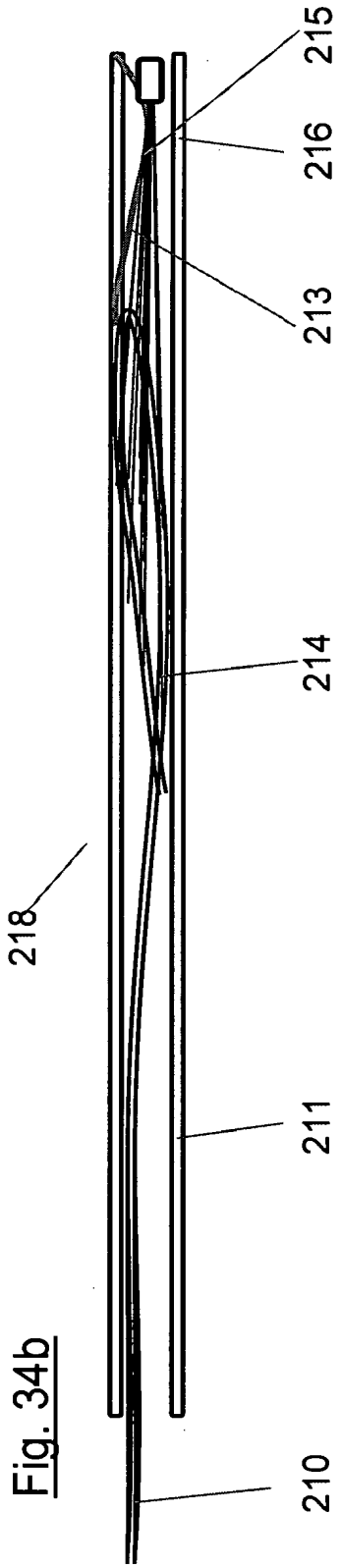


Fig. 34b

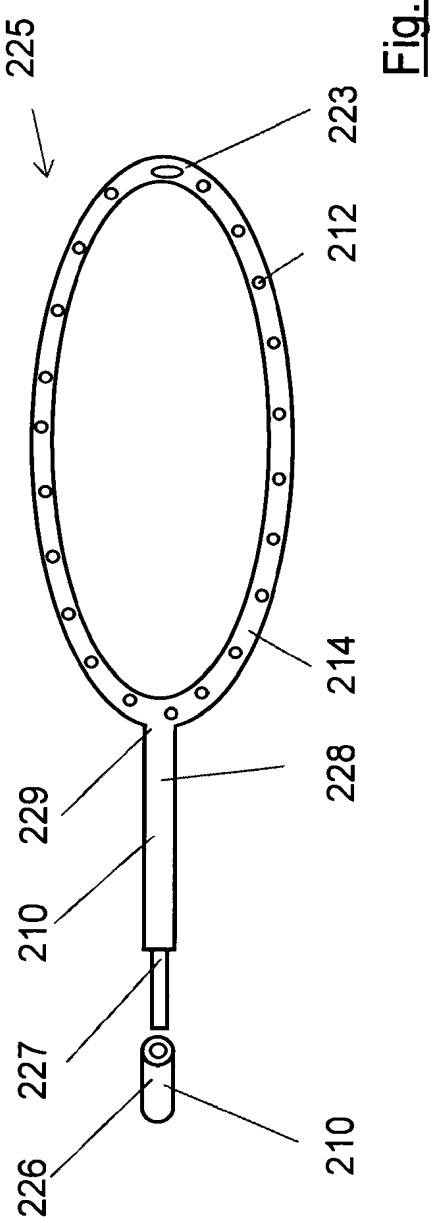


Fig. 34C

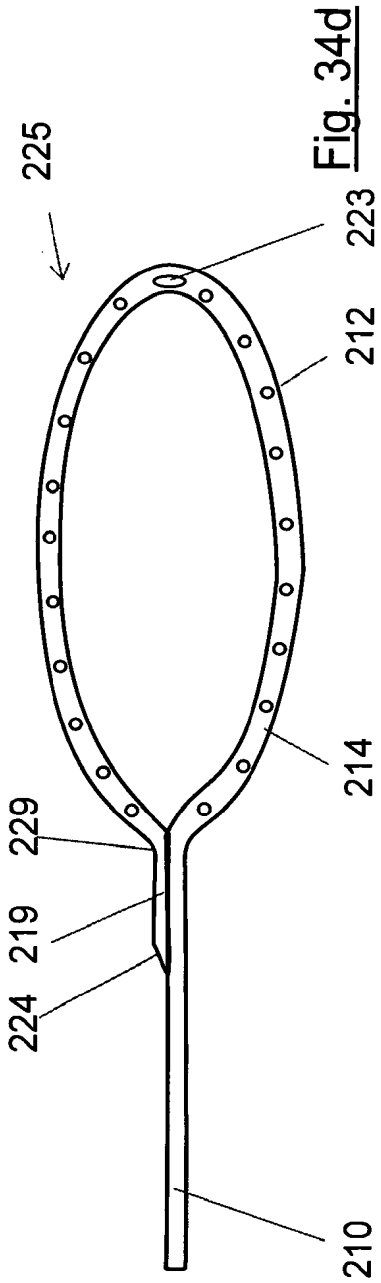


Fig. 34d



Fig. 34f



Fig. 34e

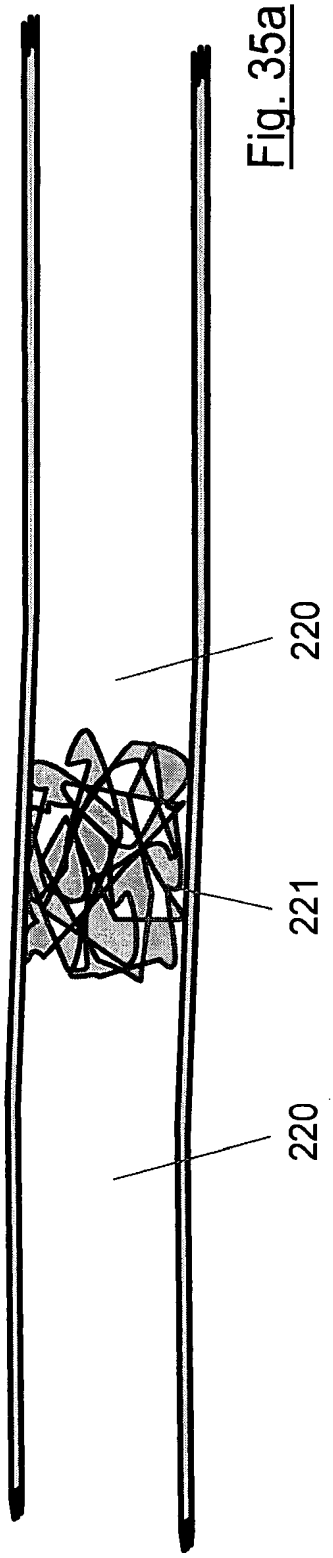


Fig. 35a

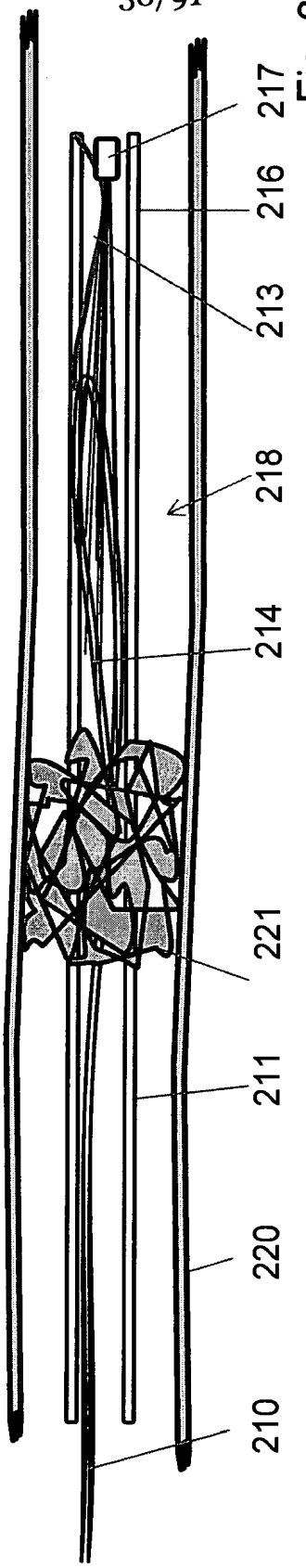


Fig. 35b

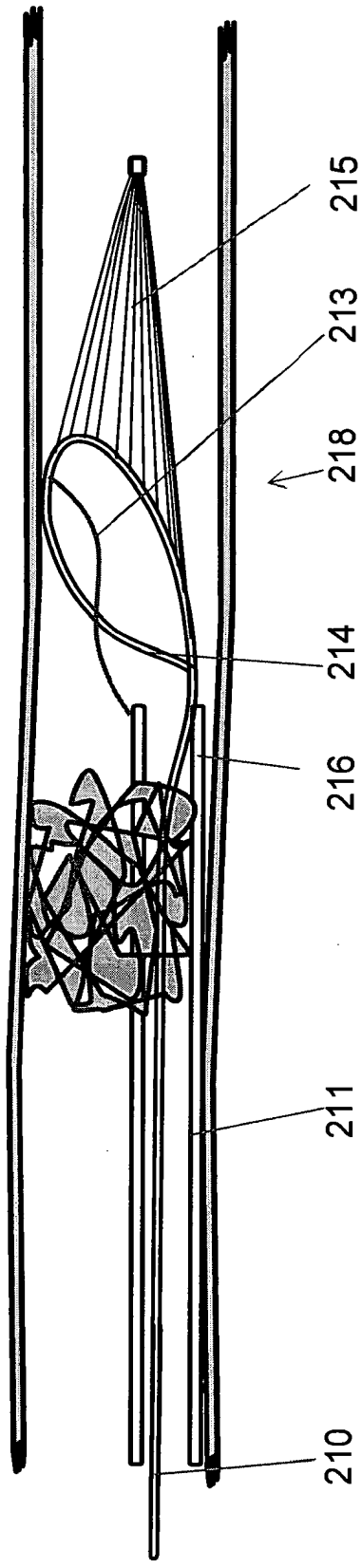


Fig. 35c

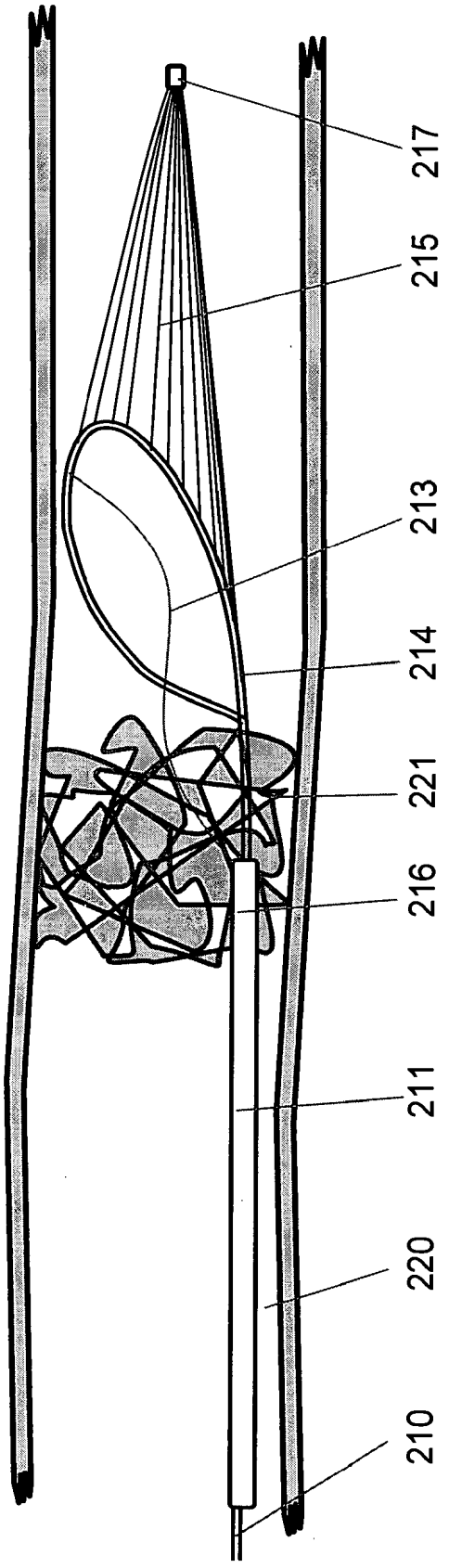


Fig. 35d

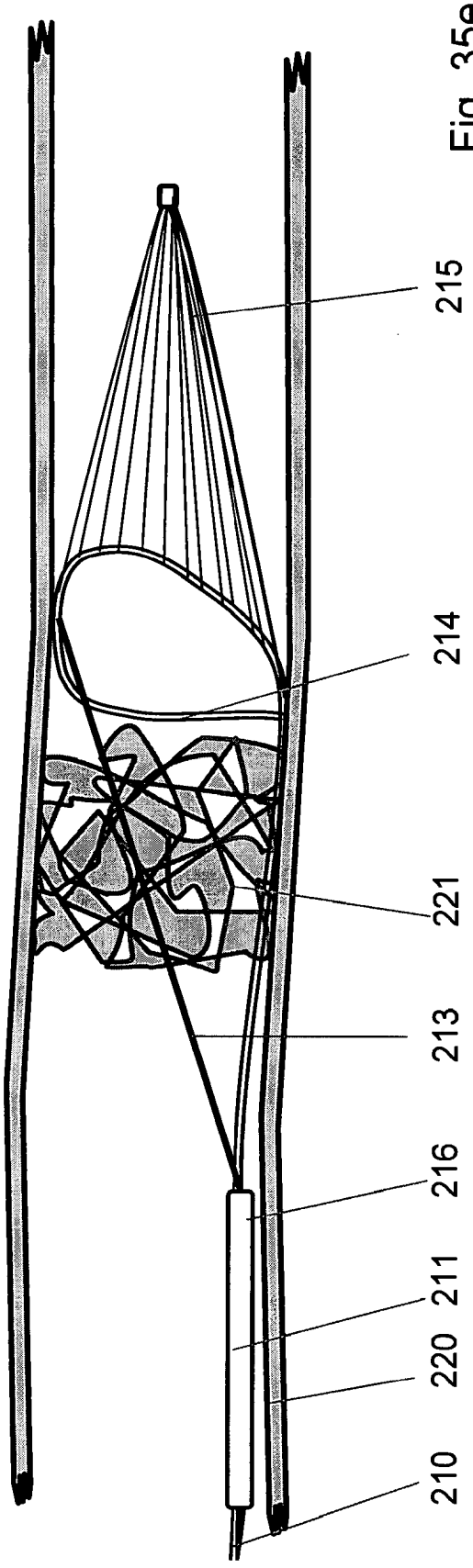


Fig. 35e

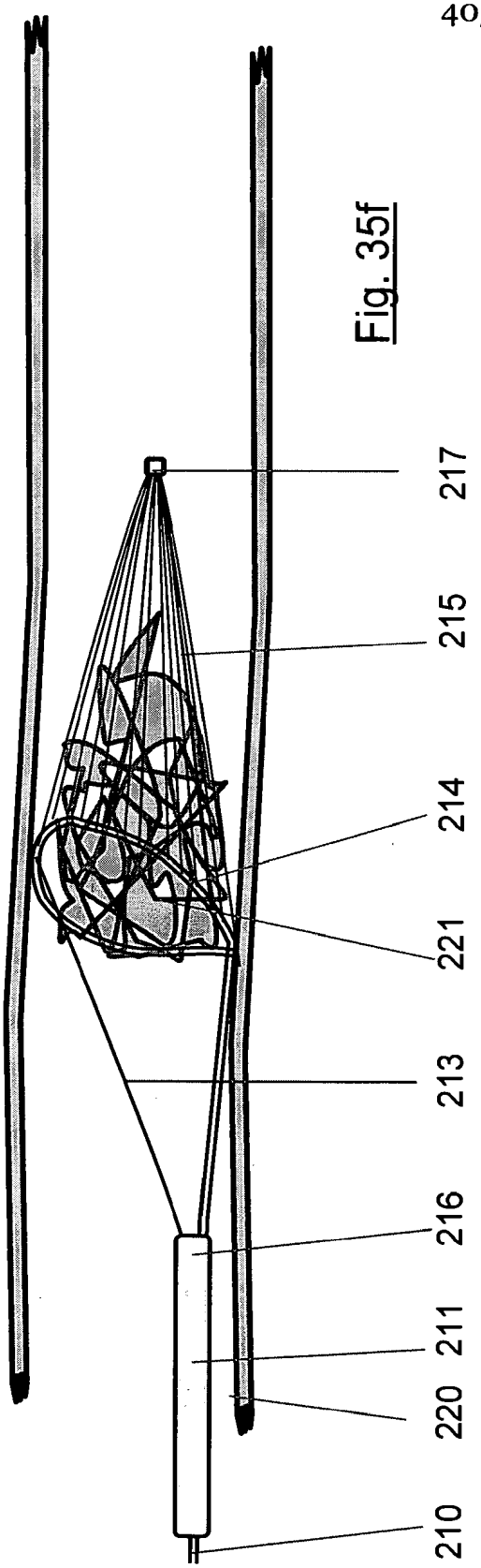


Fig. 35f

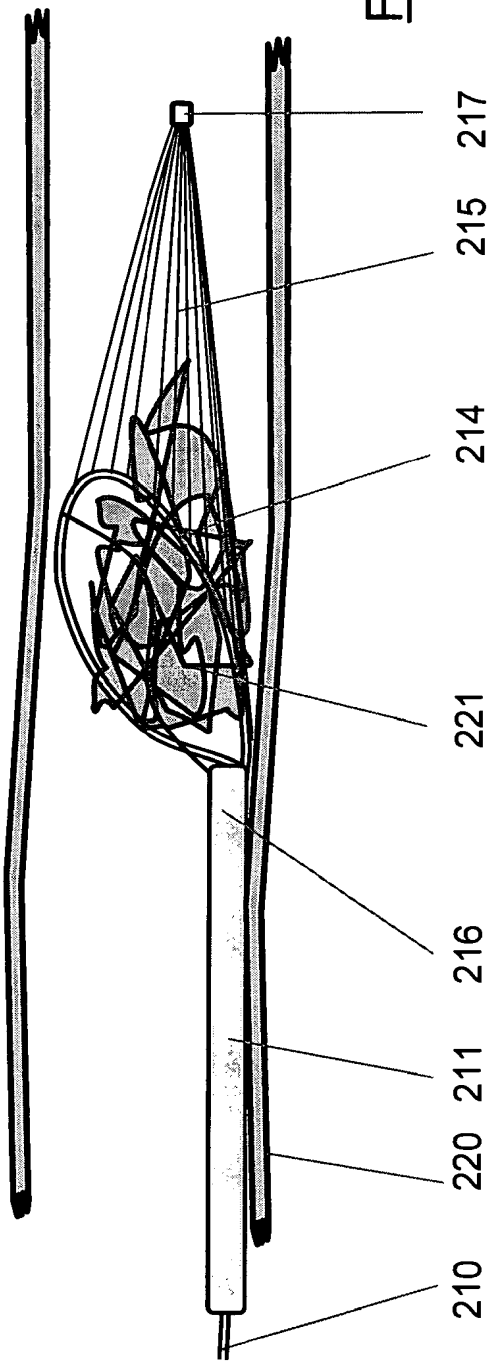


Fig. 35g

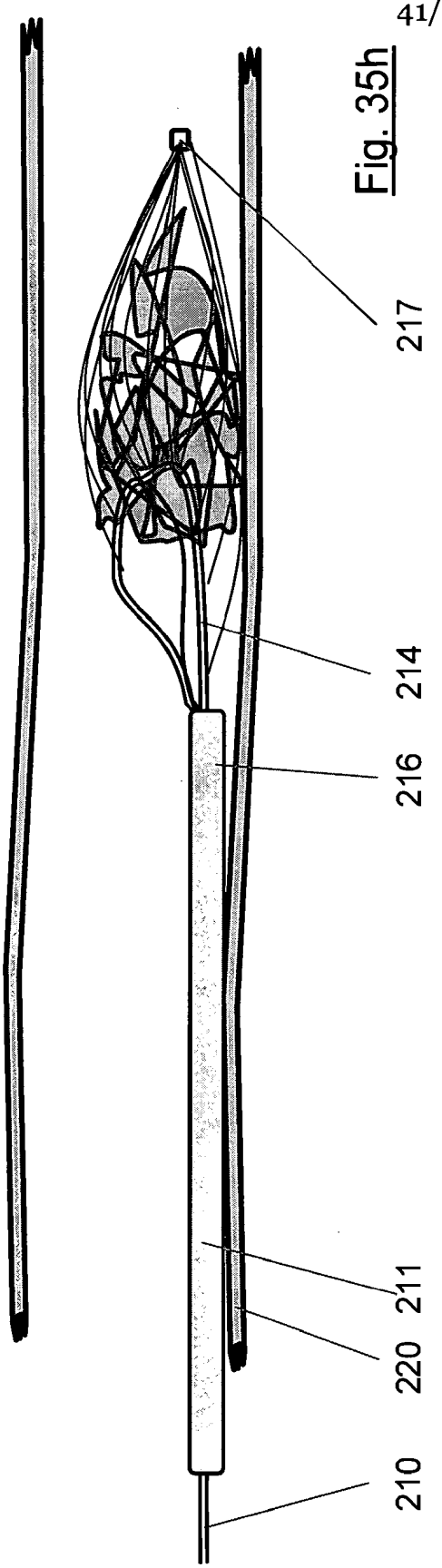


Fig. 35h

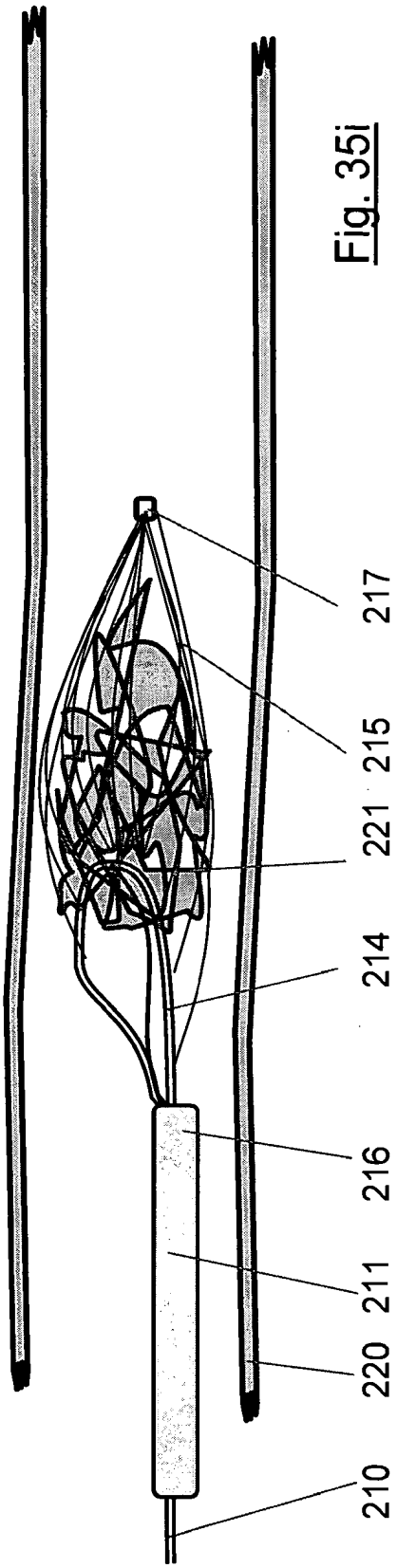


Fig. 35i

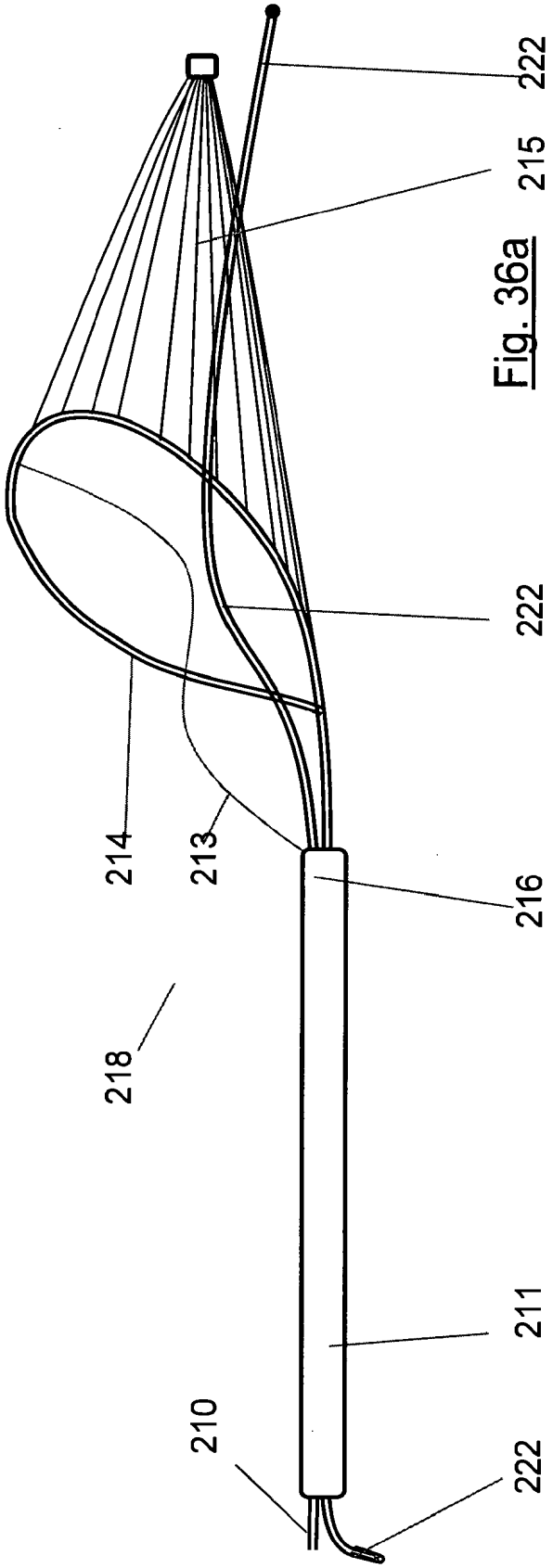


Fig. 36a

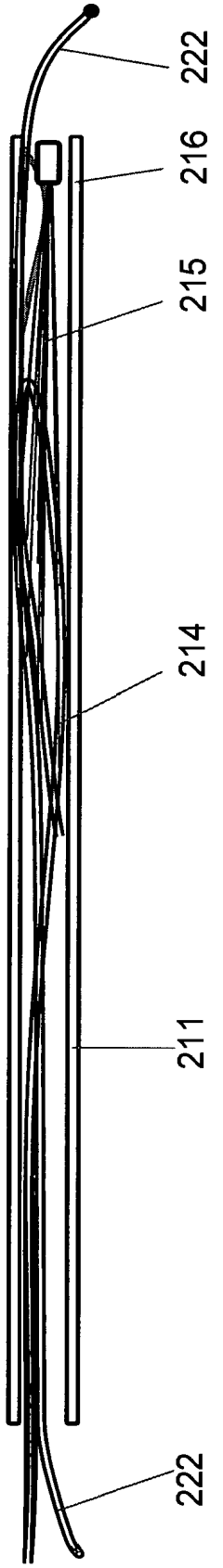


Fig. 36b

Fig. 37a

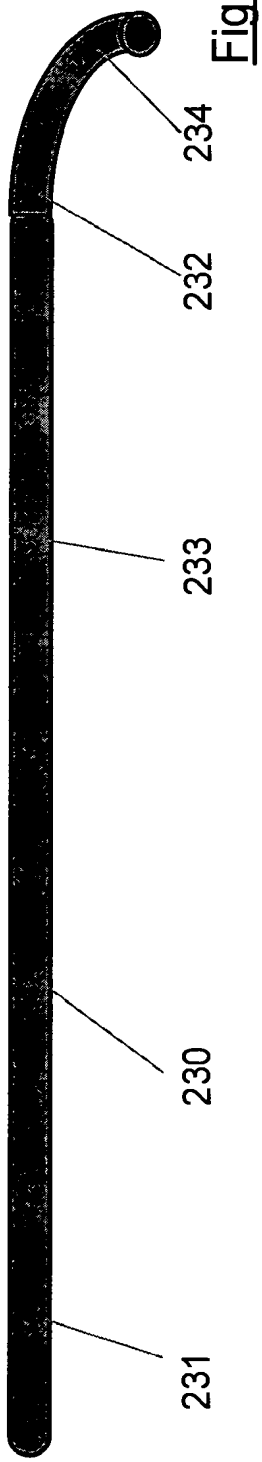


Fig. 37b

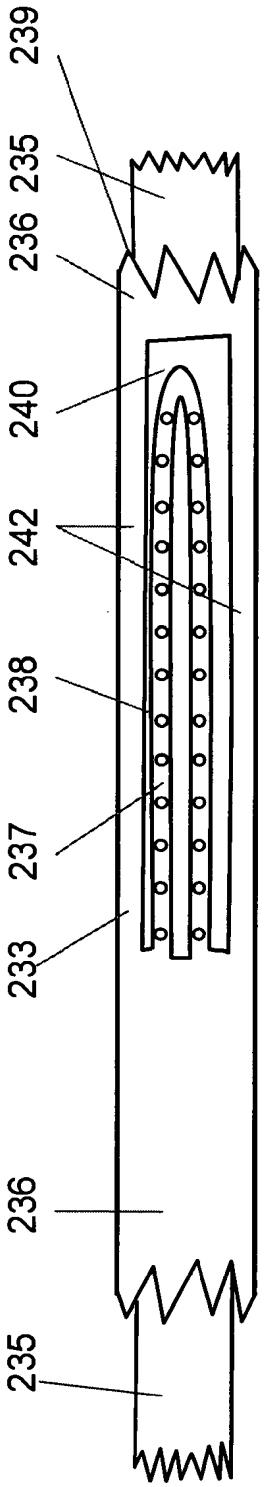
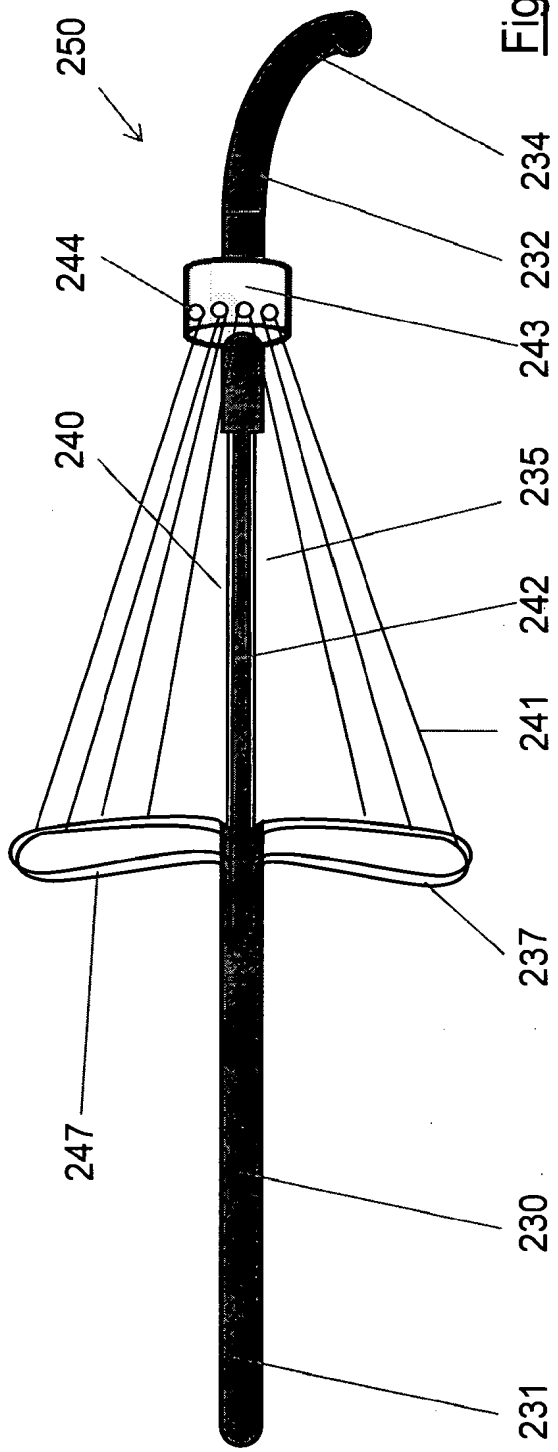


Fig. 37c



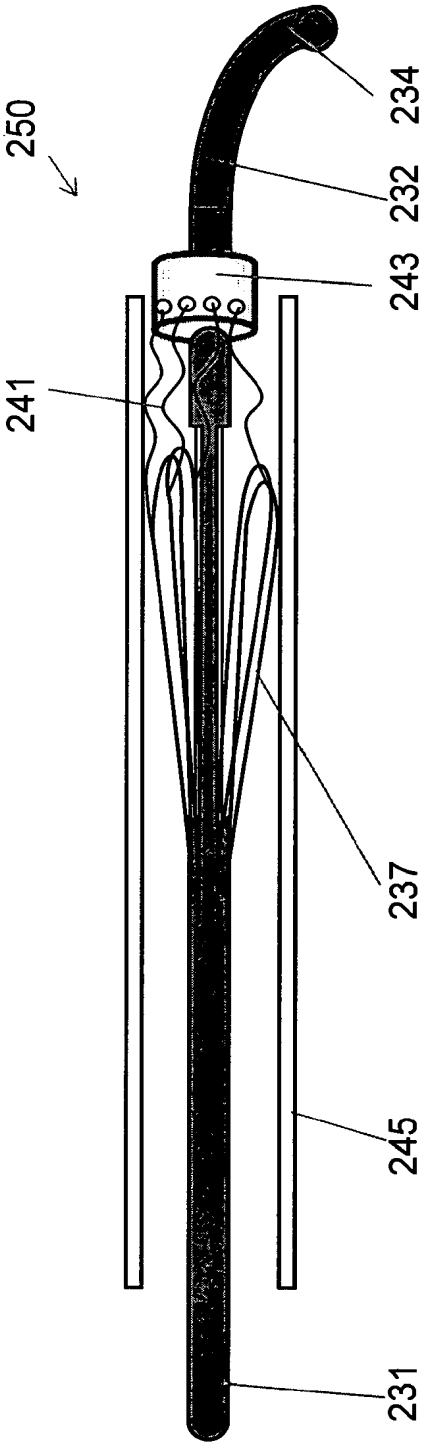


Fig. 37d

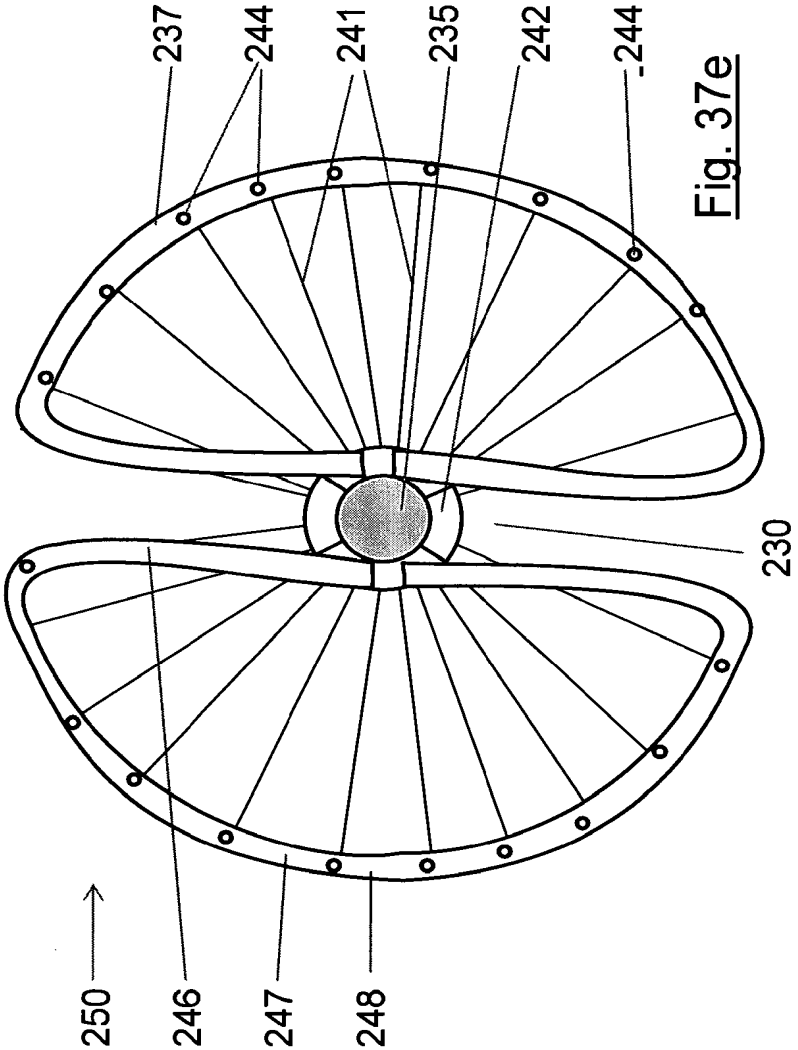


Fig. 37e

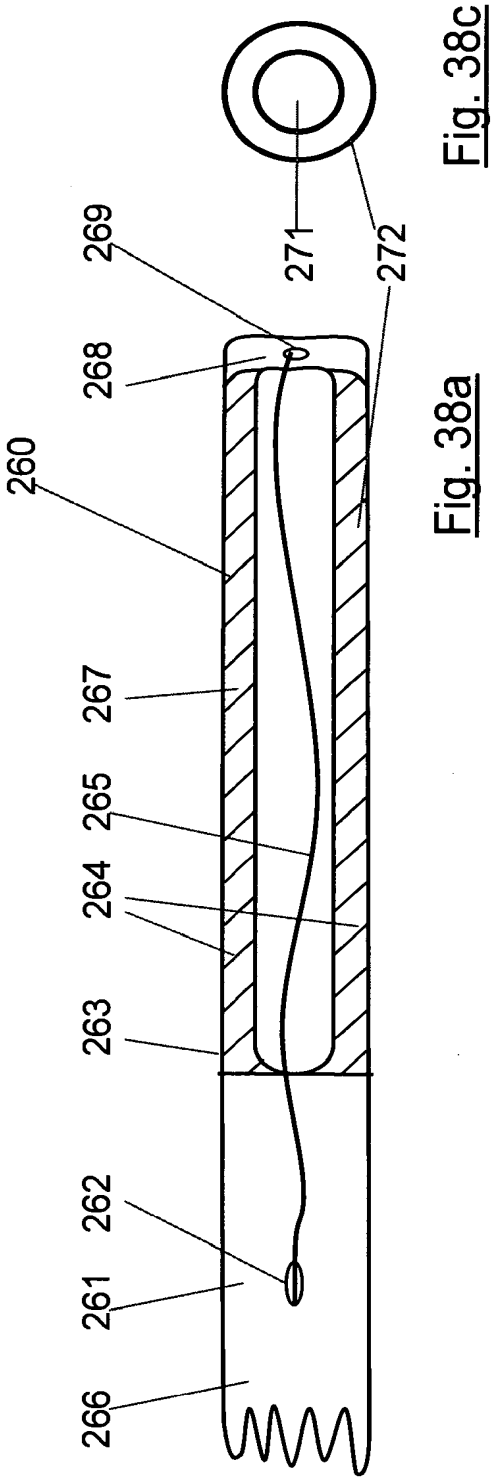


Fig. 38a

Fig. 38c

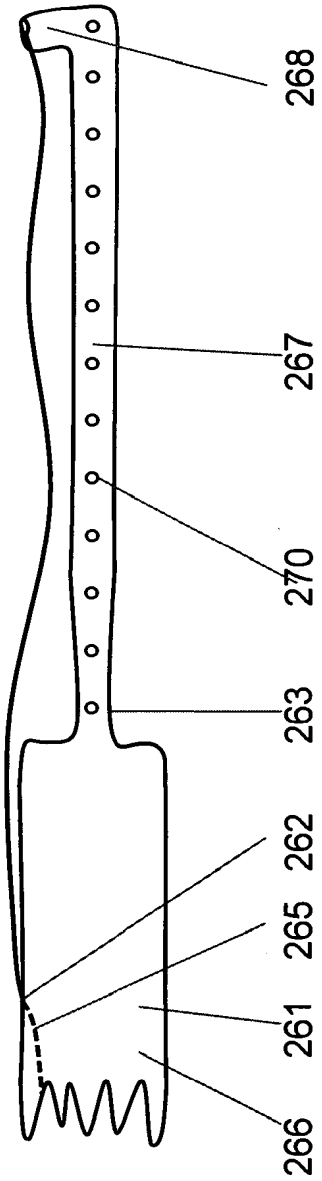


Fig. 38b

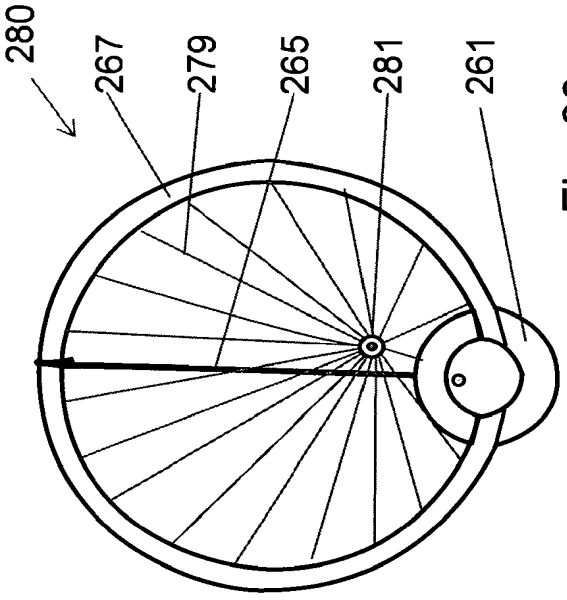


Fig. 39a

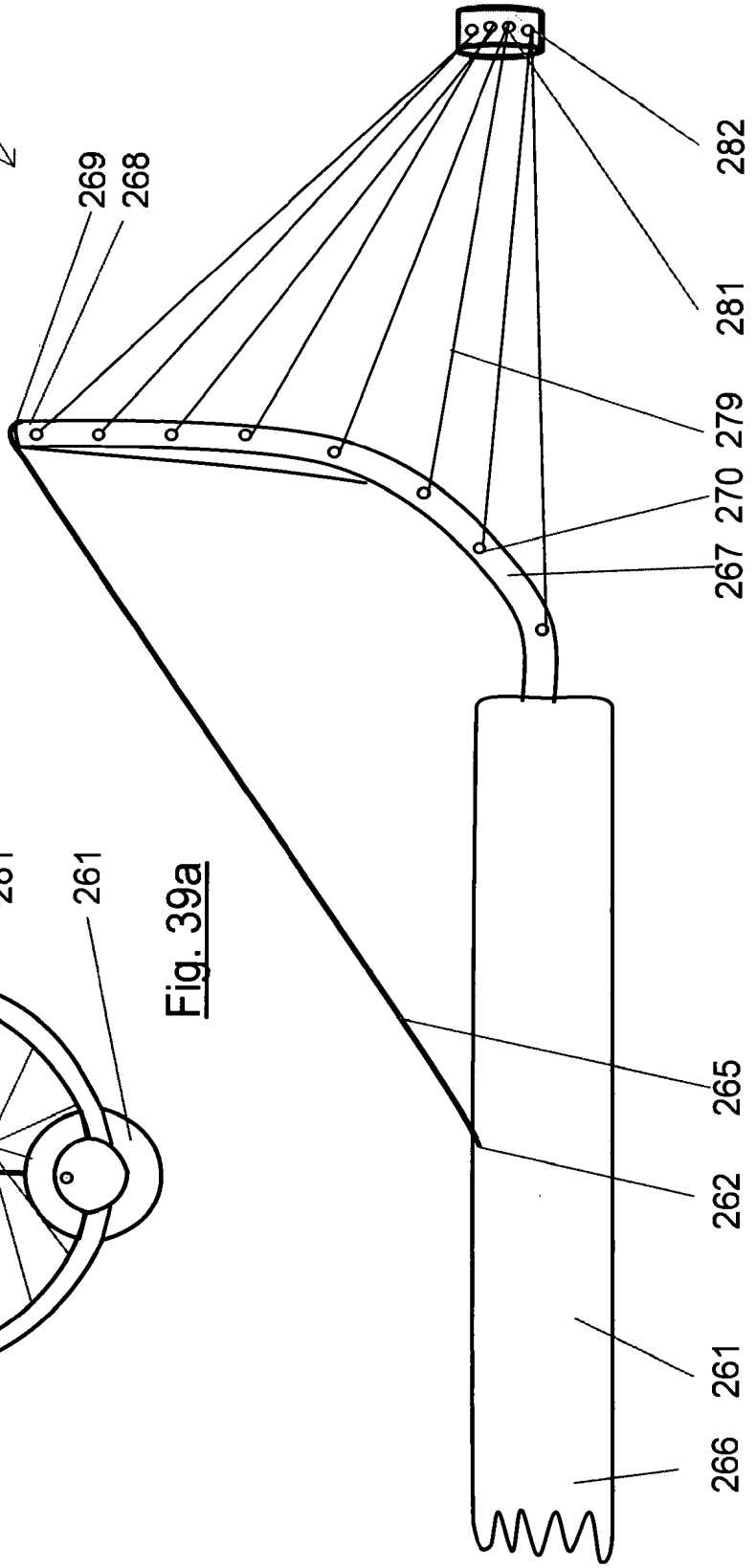


Fig. 39b

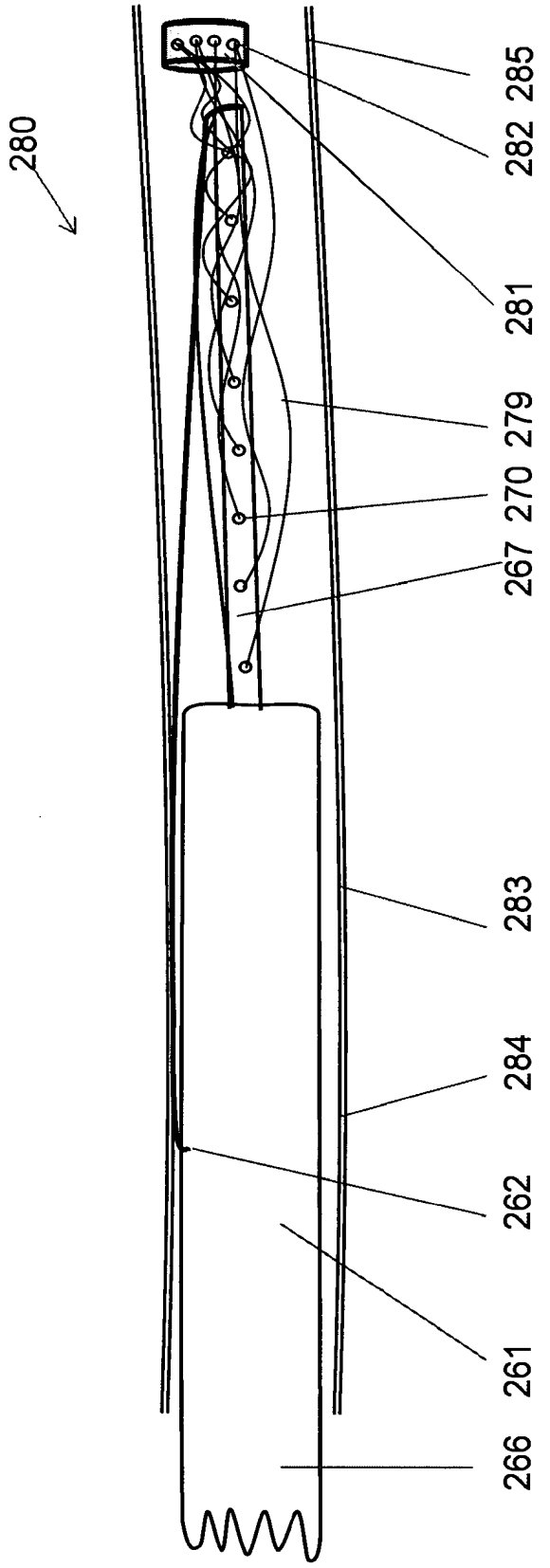


Fig. 39c

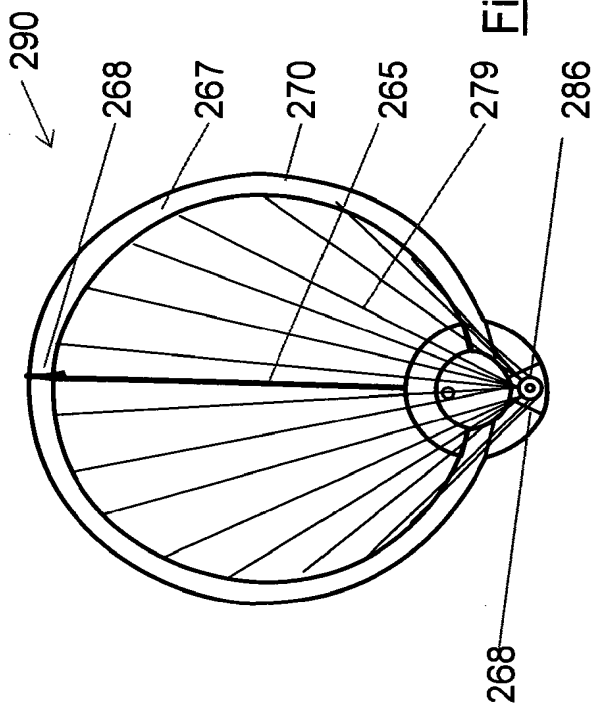


Fig. 40a

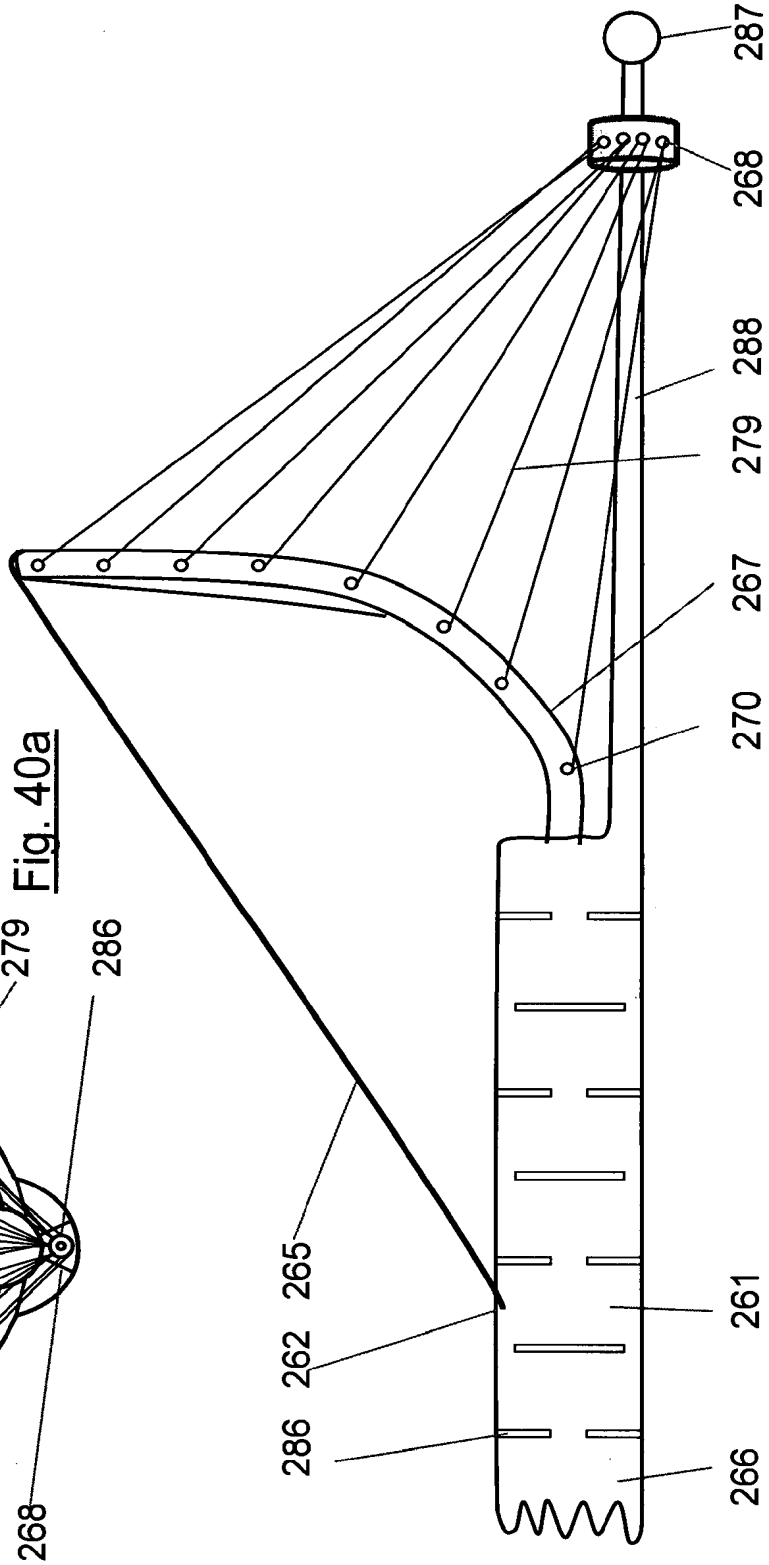


Fig. 40b

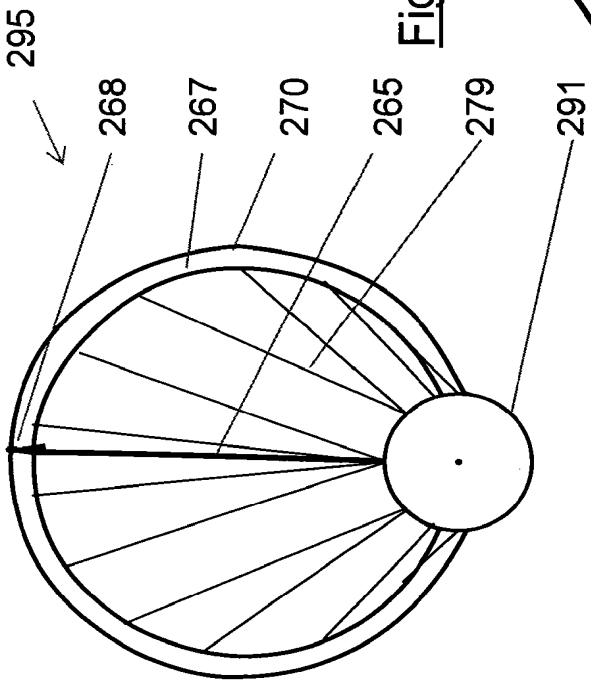


Fig. 41a

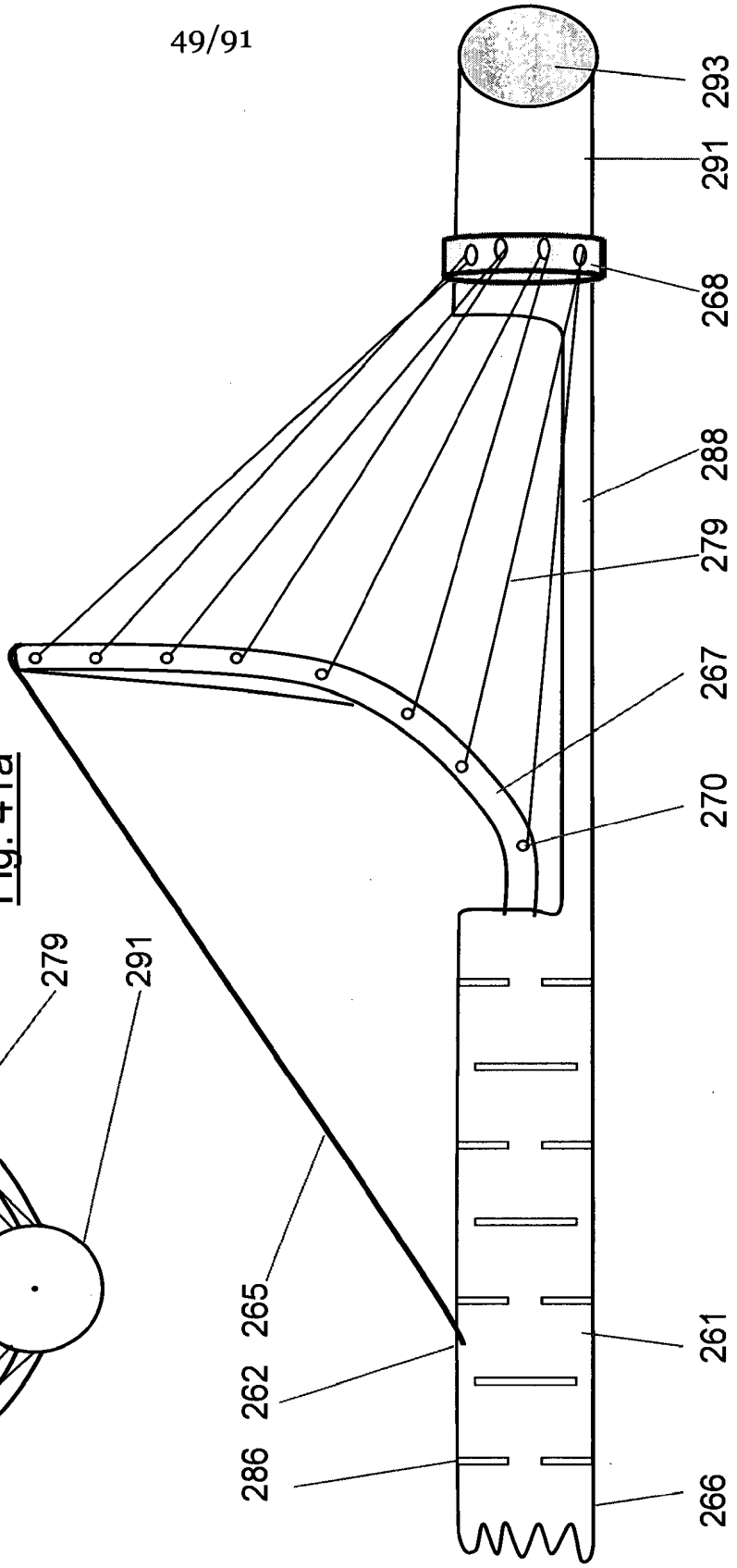


Fig. 41b

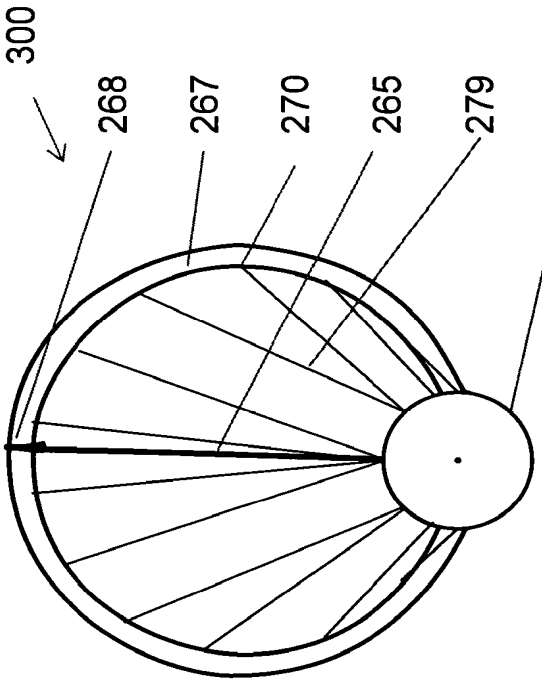


Fig. 42a

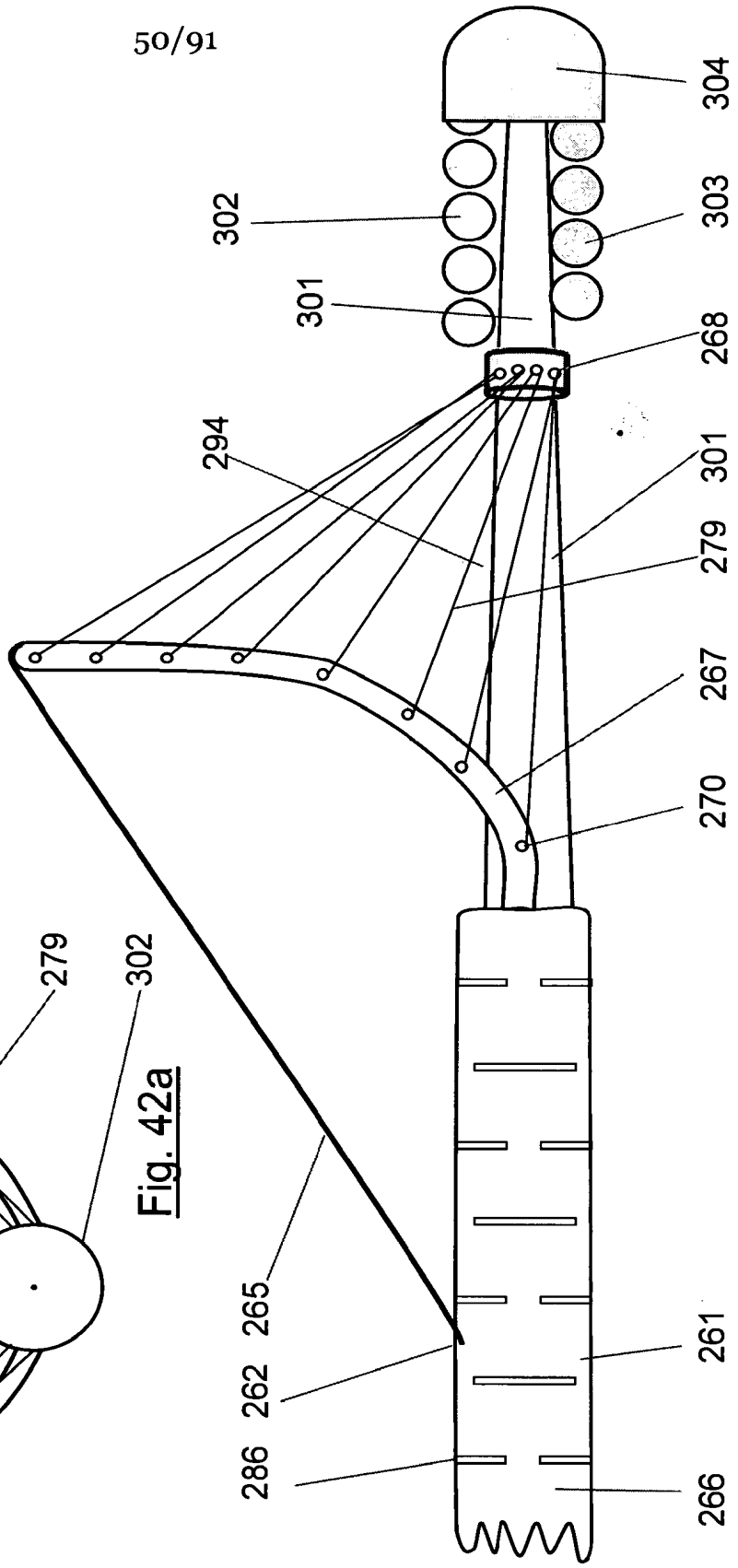


Fig. 42b

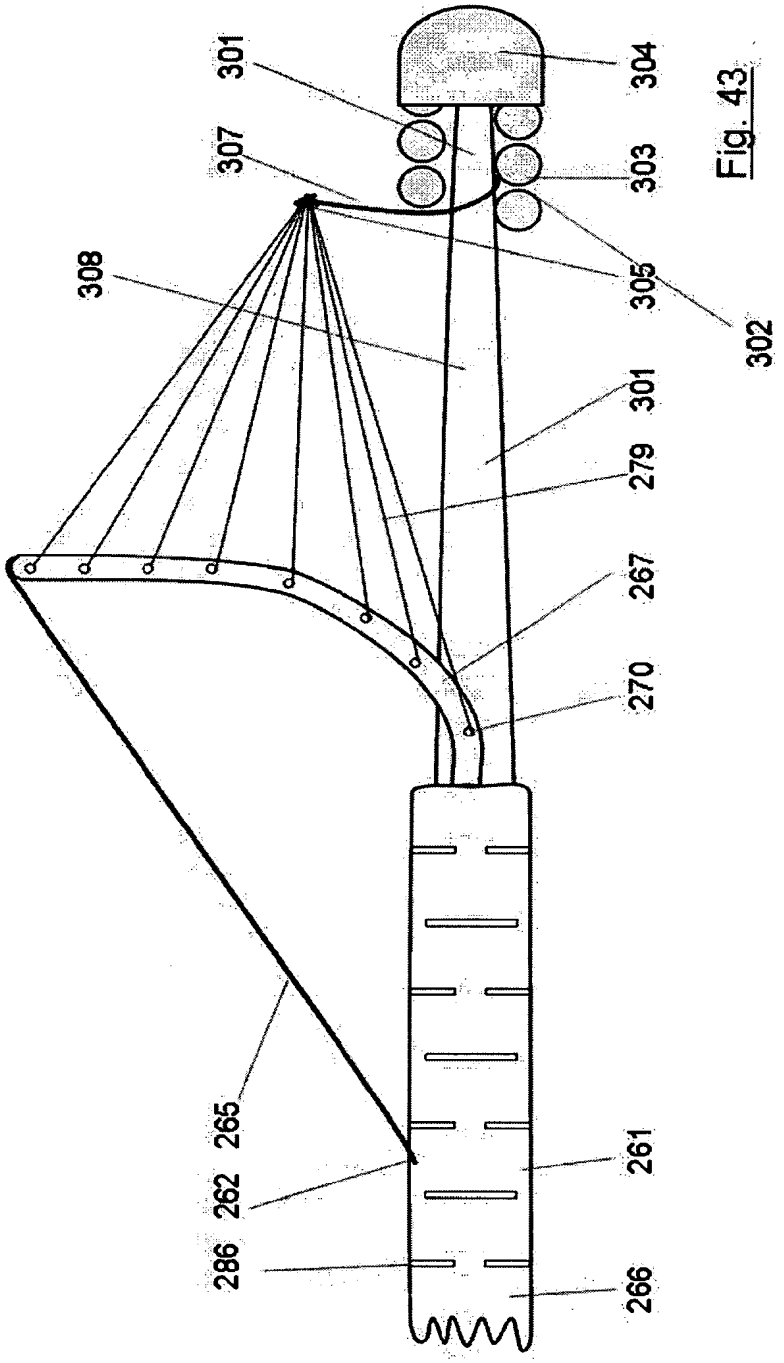


Fig. 43

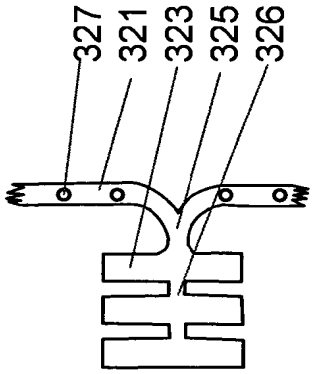


Fig. 44b

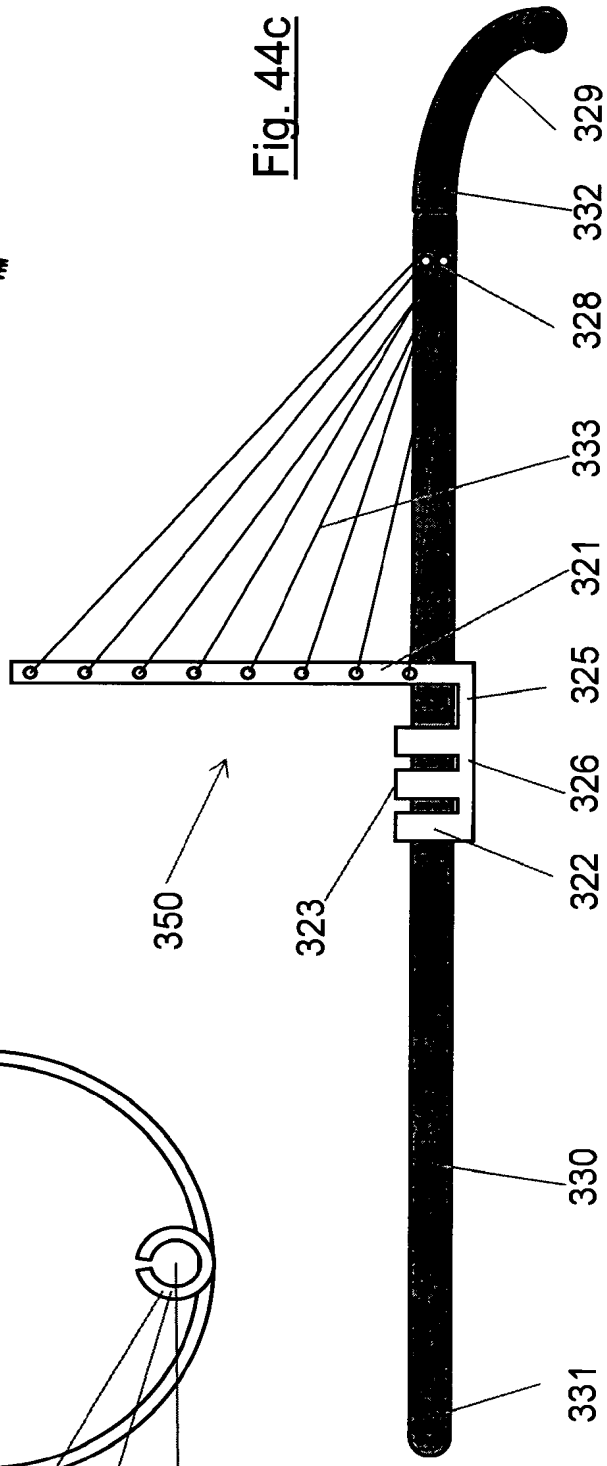


Fig. 44c

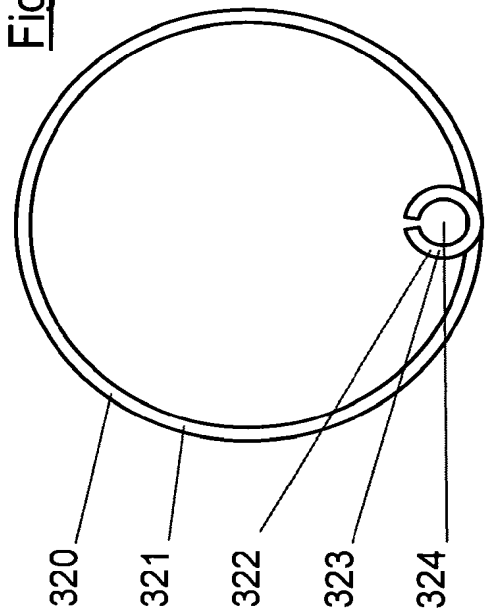


Fig. 44a

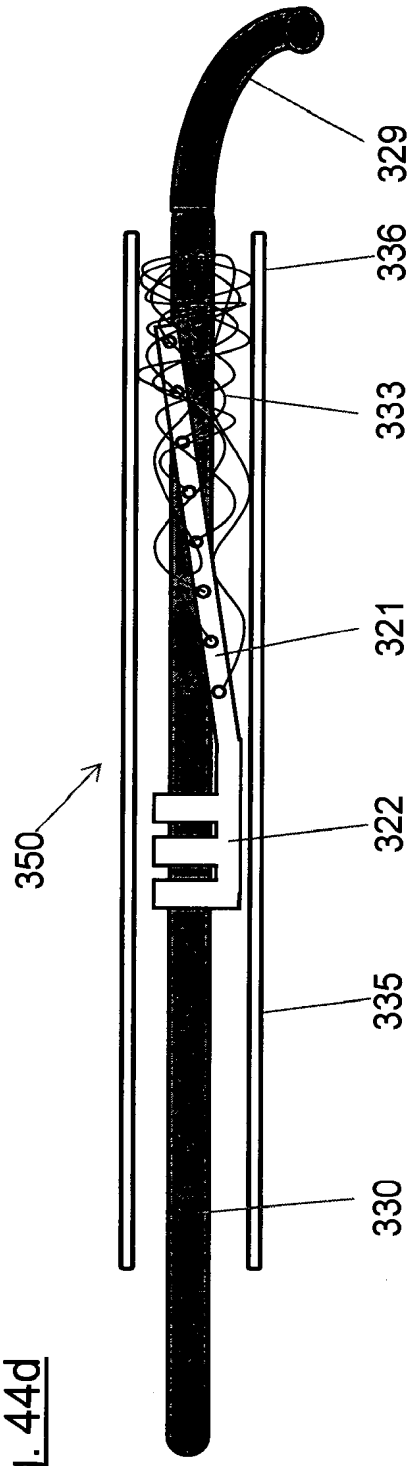


Fig. 44d

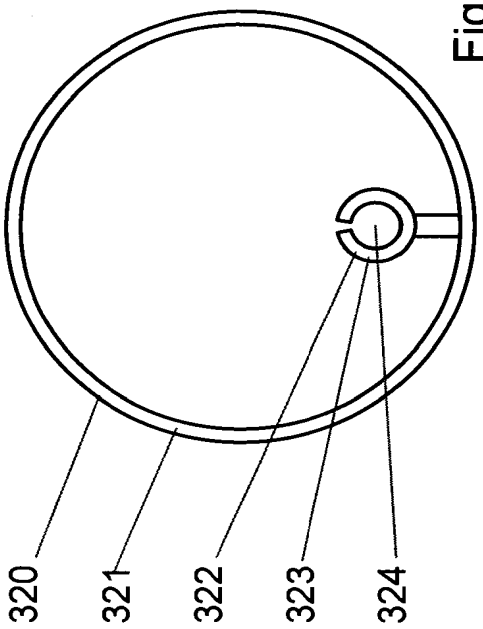


Fig. 45a

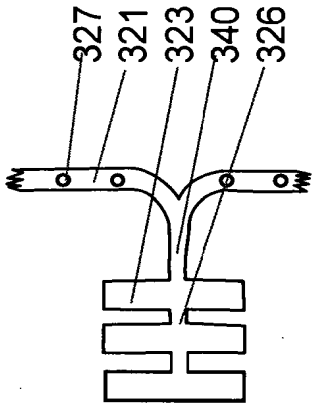


Fig. 45b

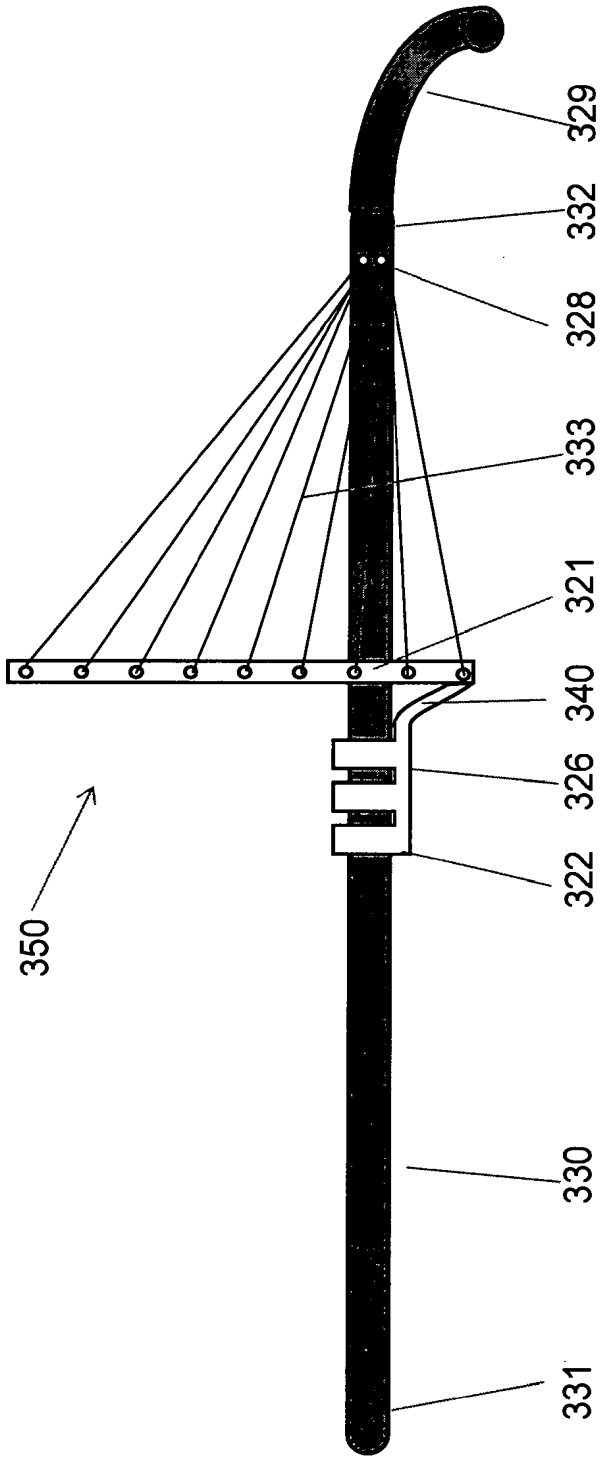


Fig. 45c

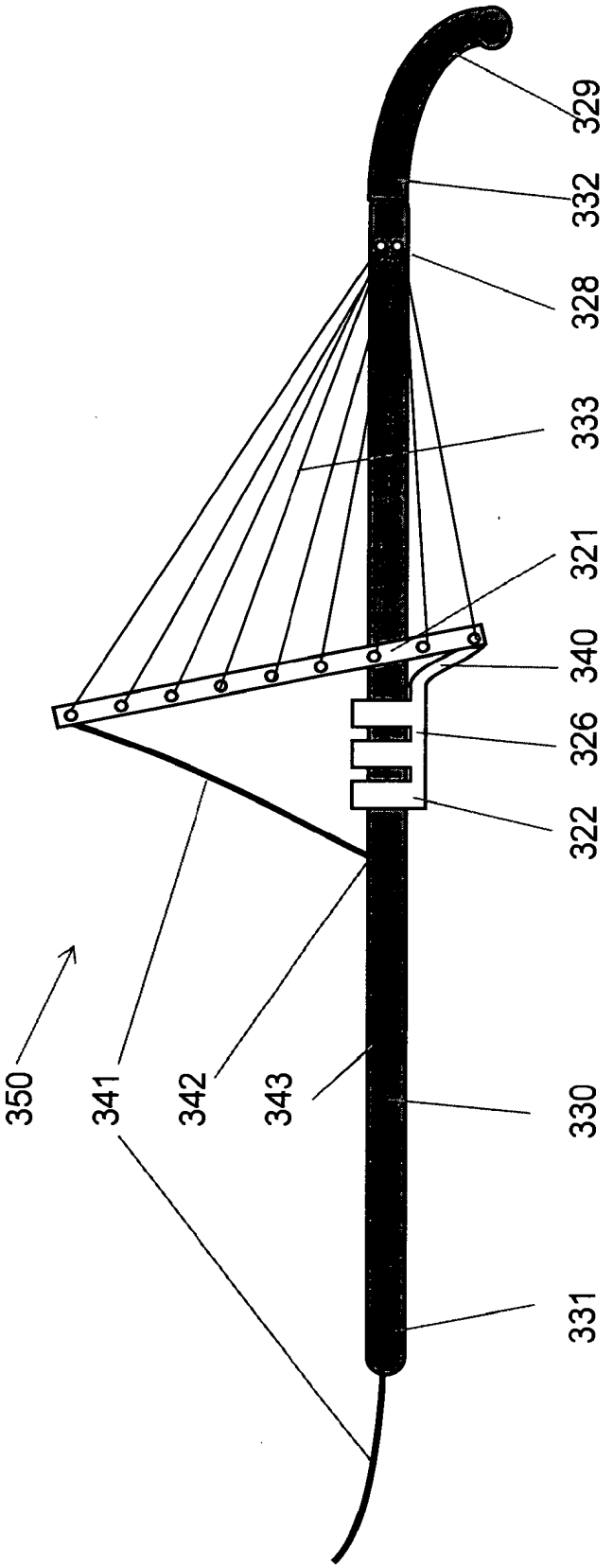
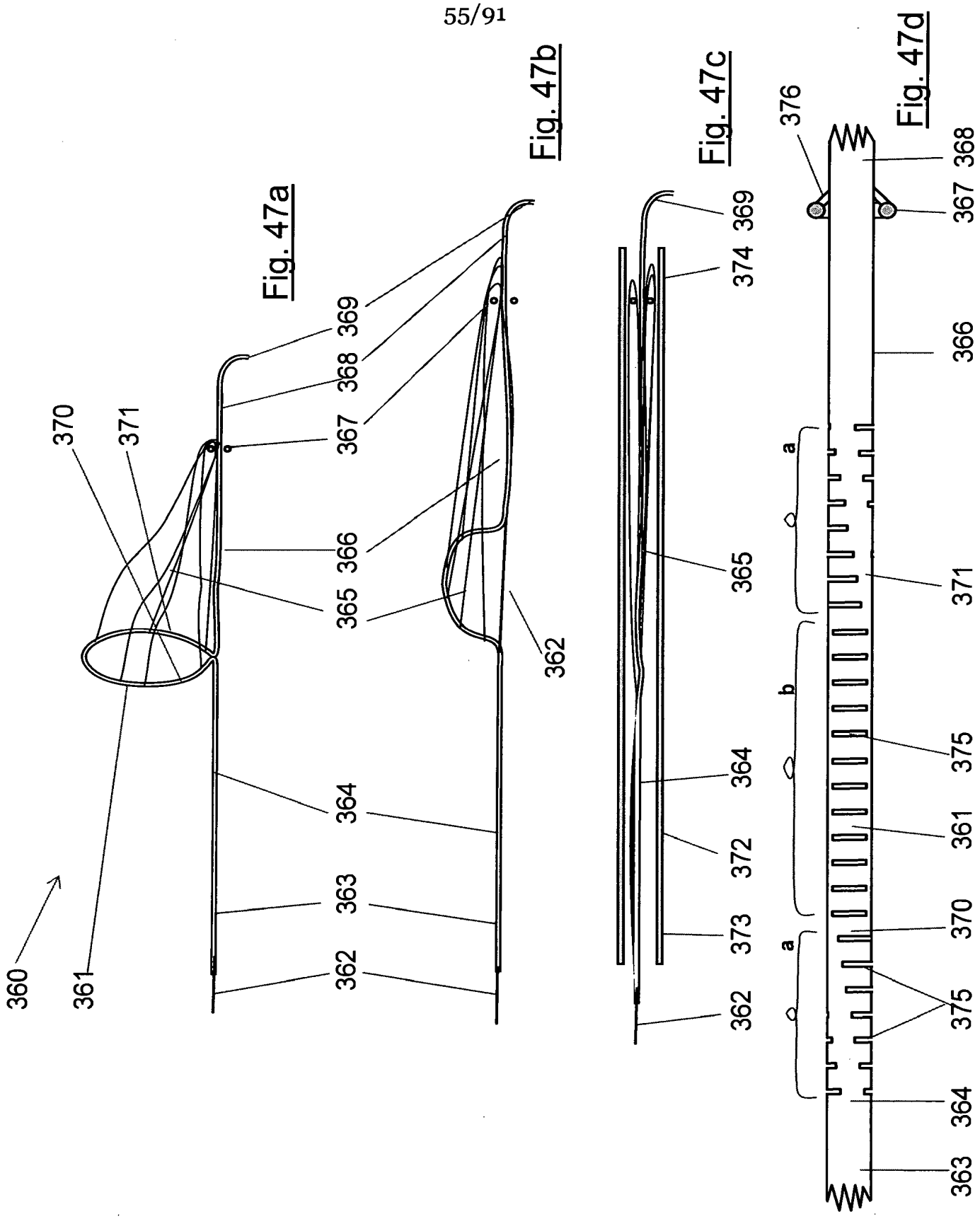


Fig. 46


Fig. 47a
Fig. 47b
Fig. 47c
Fig. 47d
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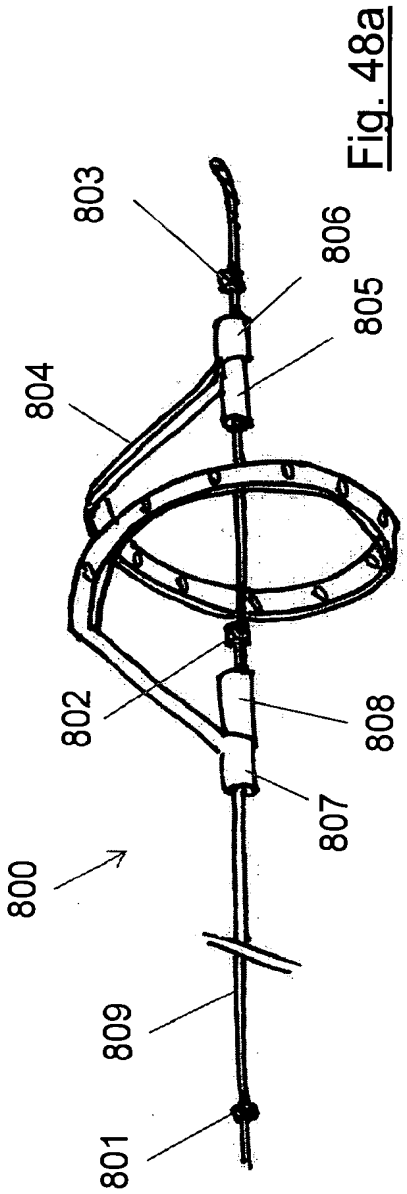


Fig. 48a

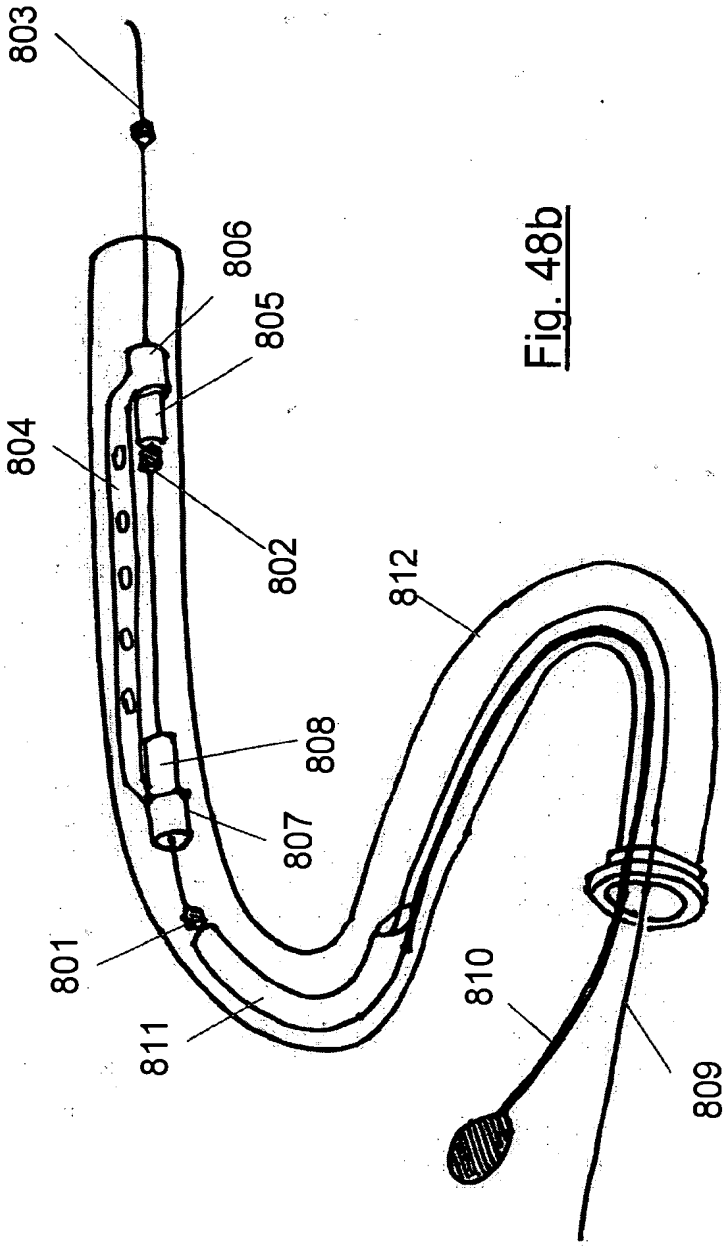


Fig. 48b

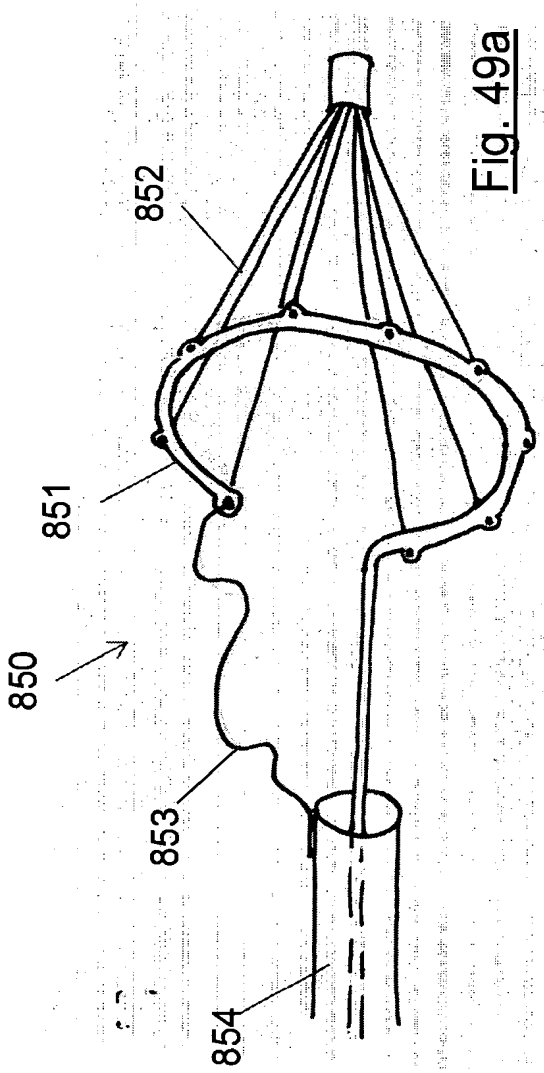


Fig. 49a

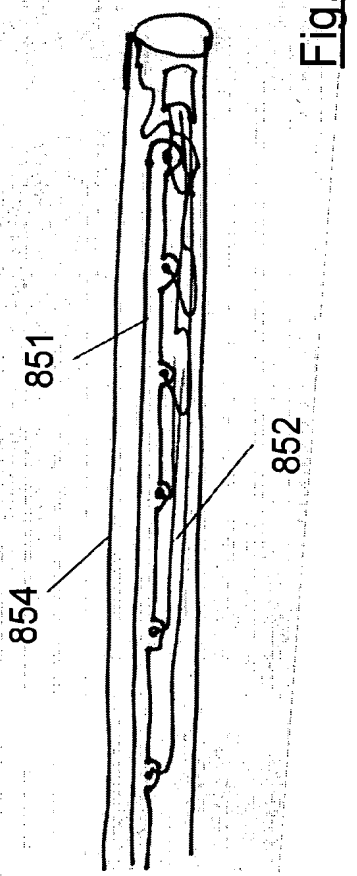
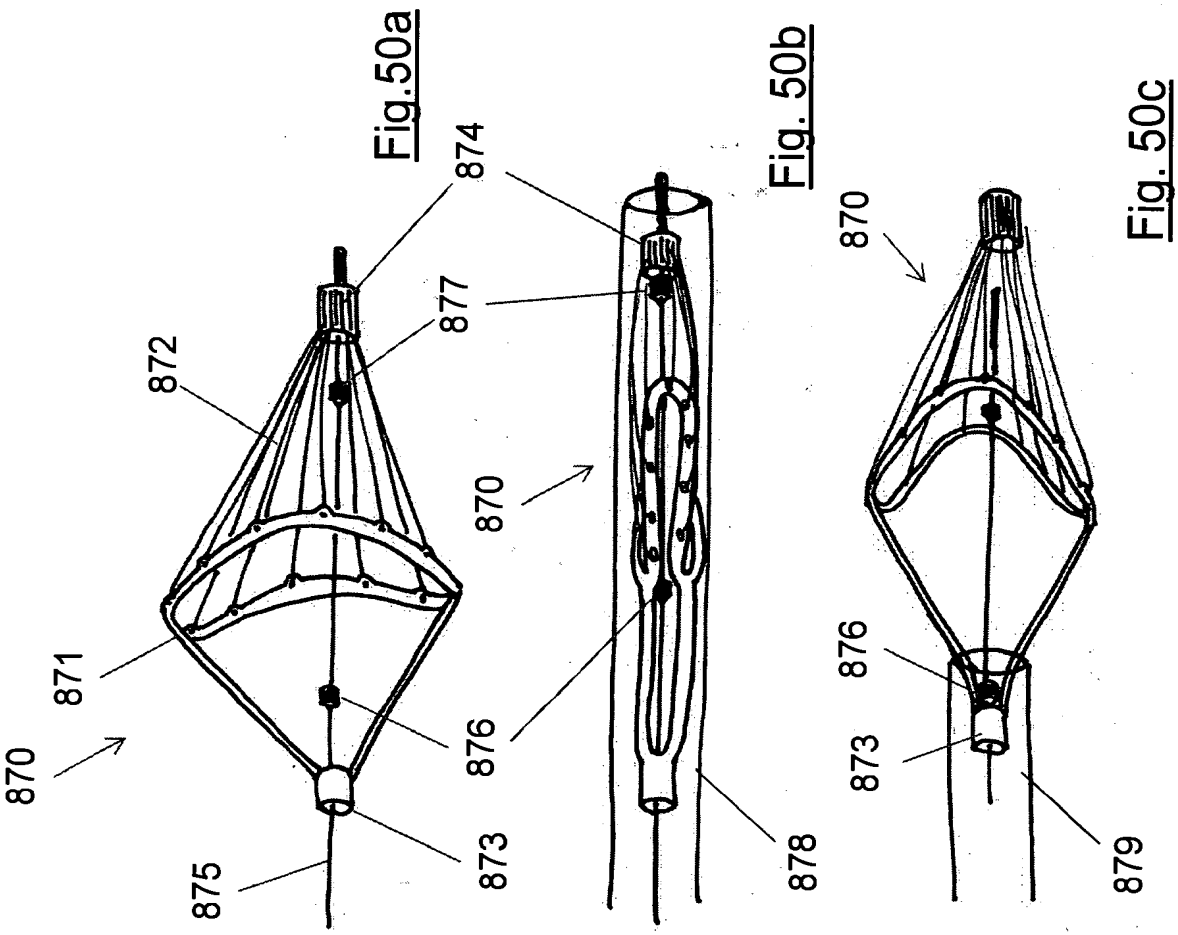


Fig. 49b


Fig.50a
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Fig. 50b
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Fig. 50c
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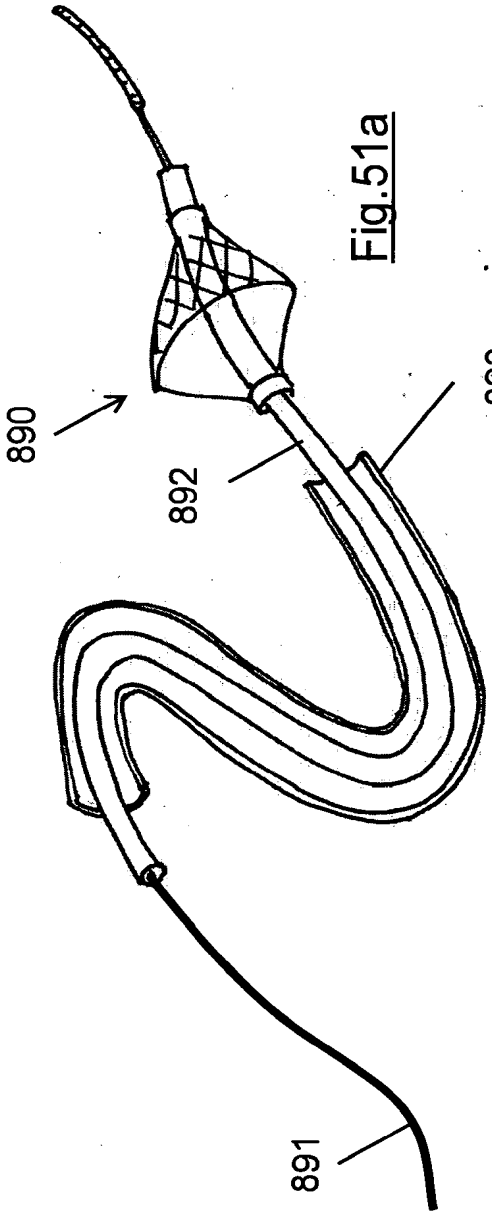


Fig.51a

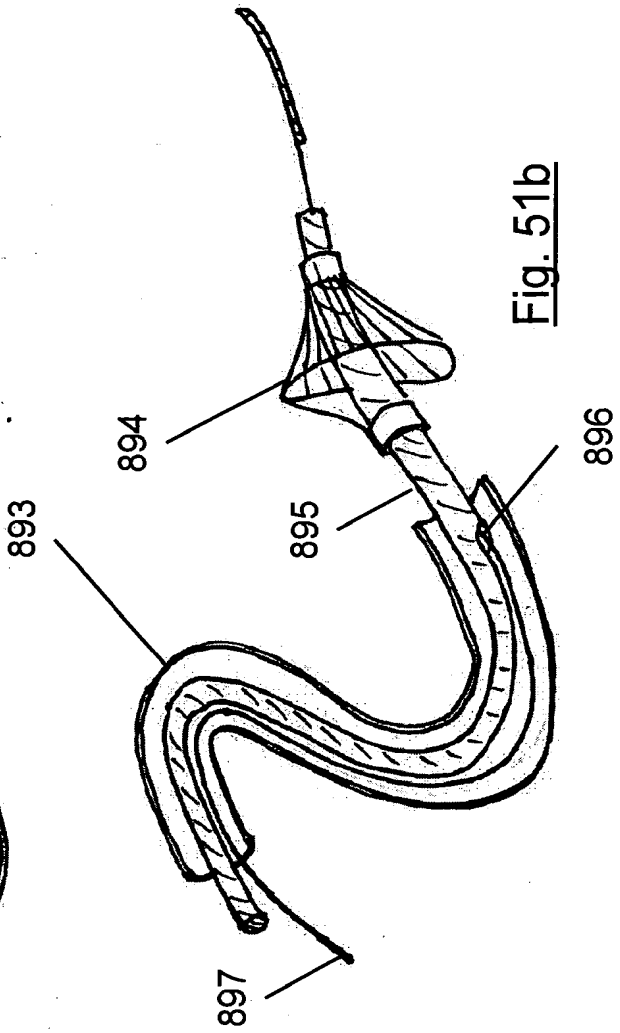


Fig. 51b

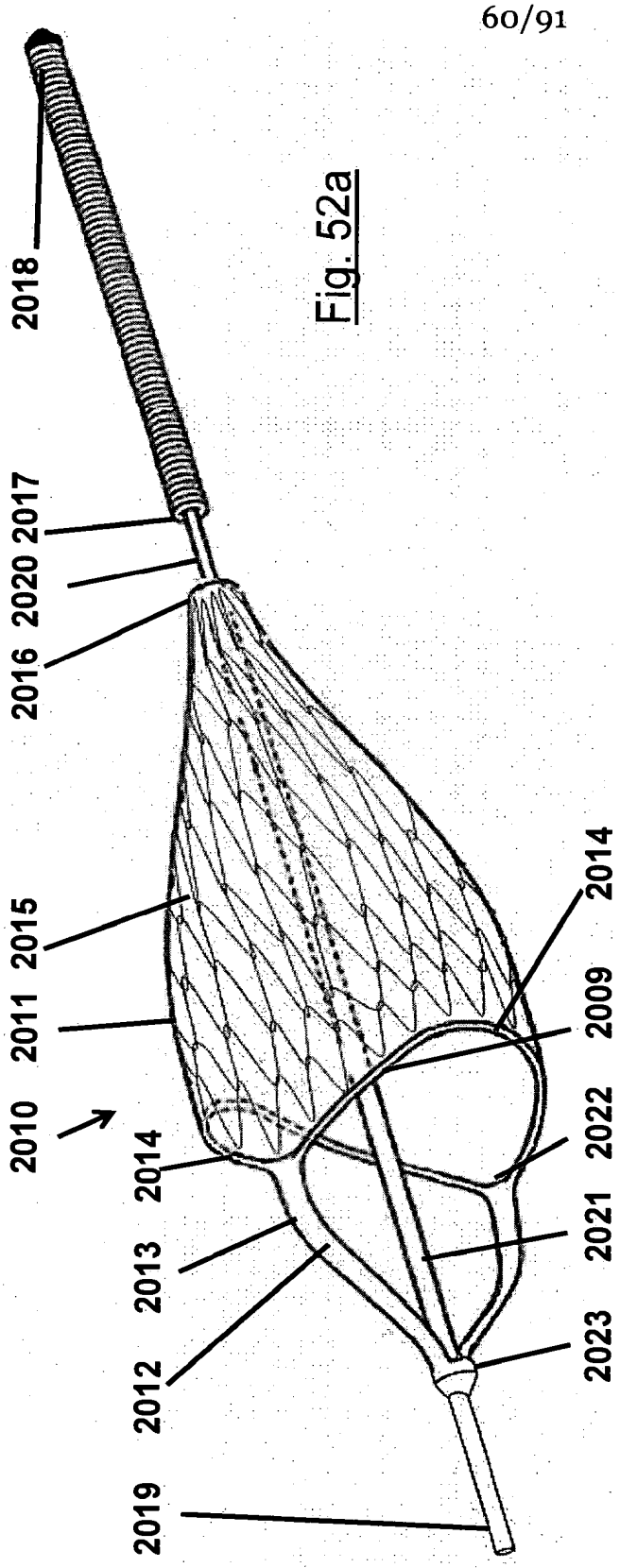


Fig. 52a

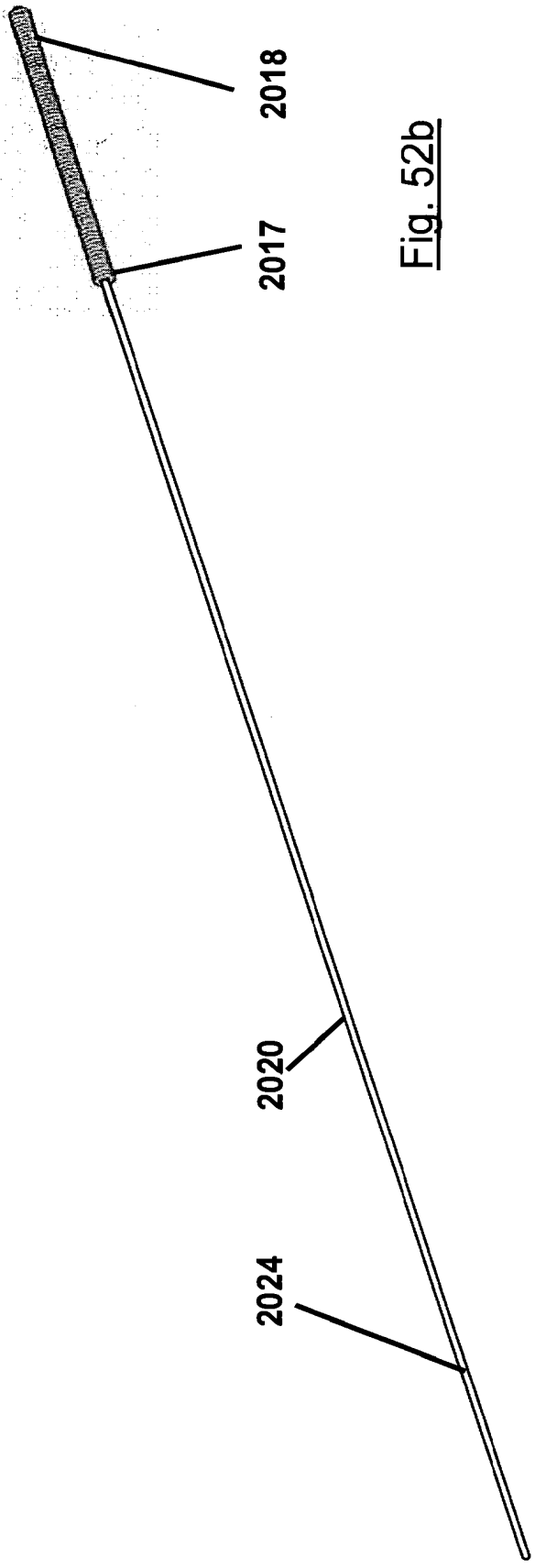


Fig. 52b

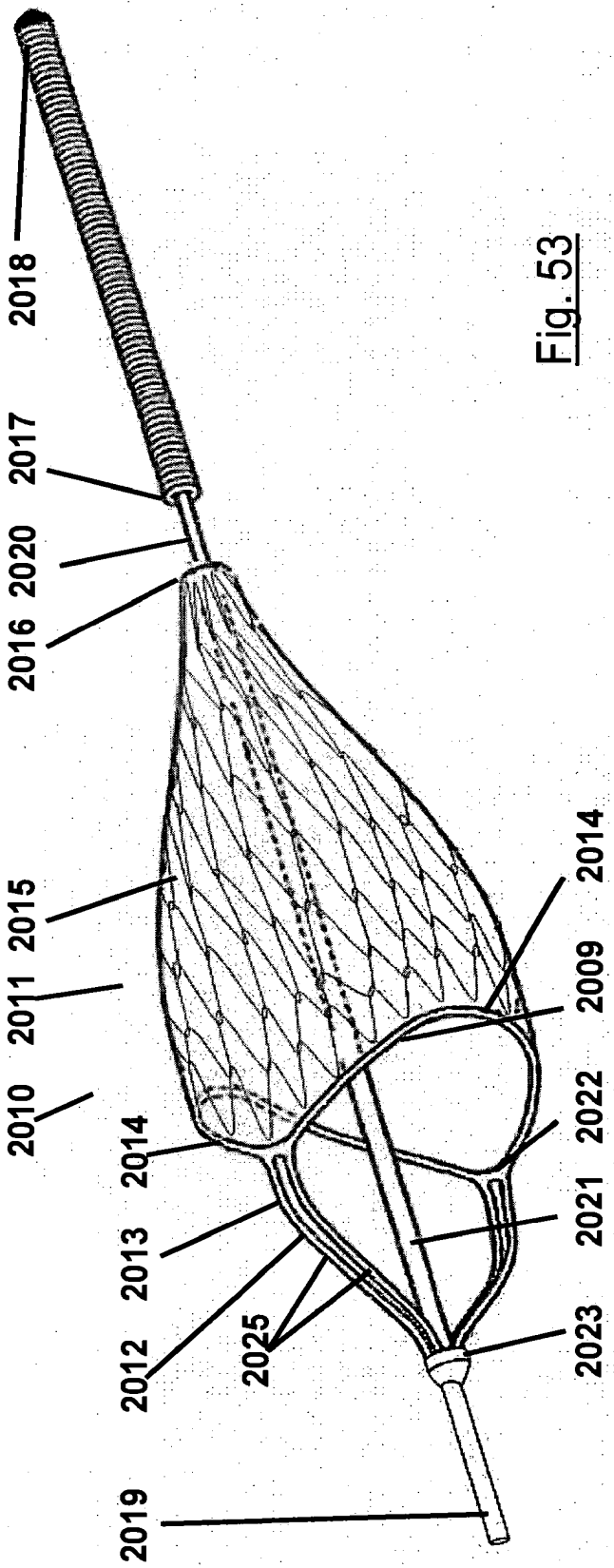

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Fig. 53

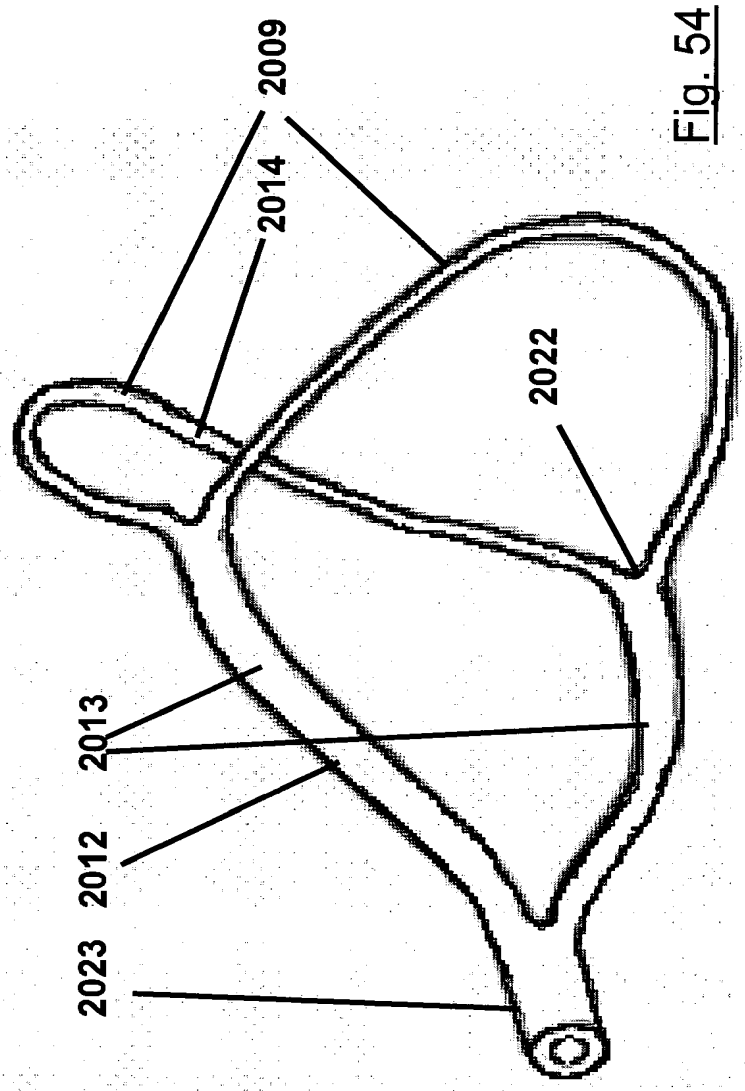


Fig. 54

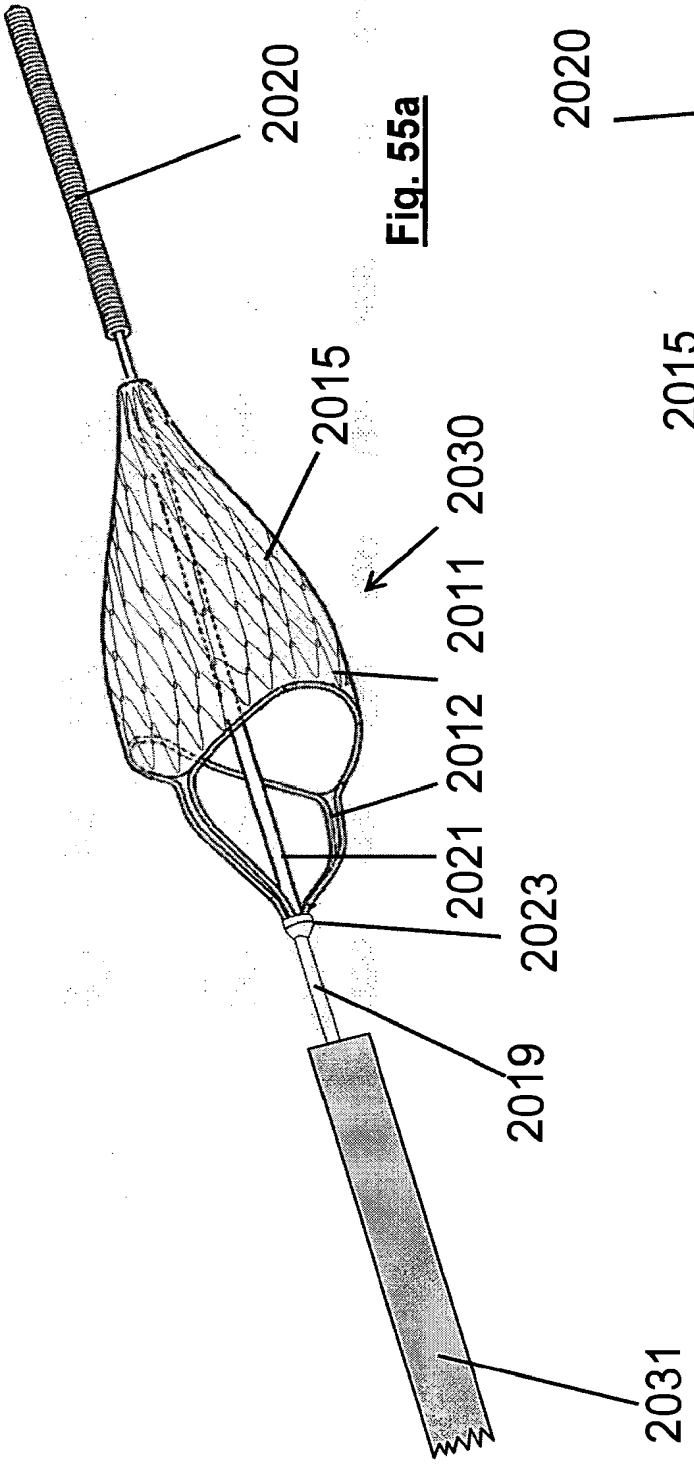


Fig. 55a

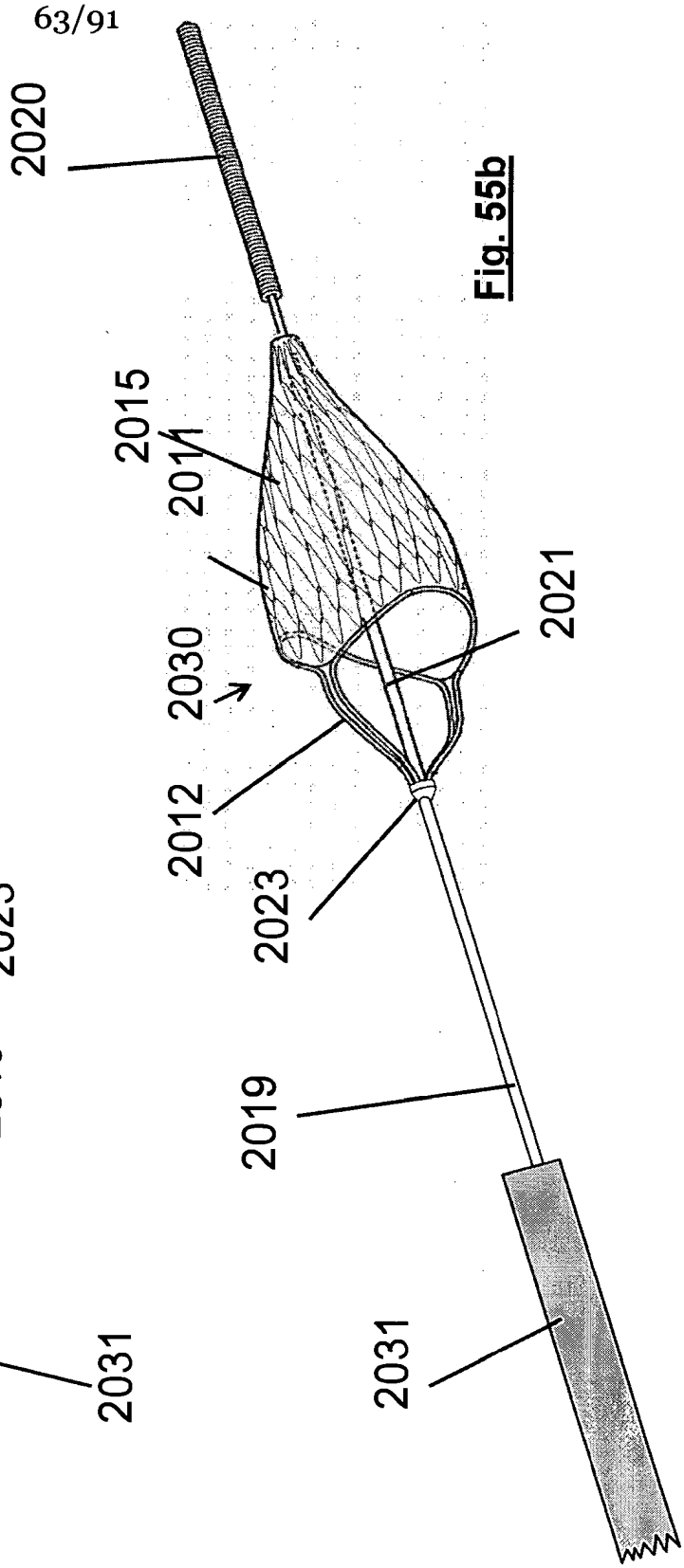


Fig. 55b

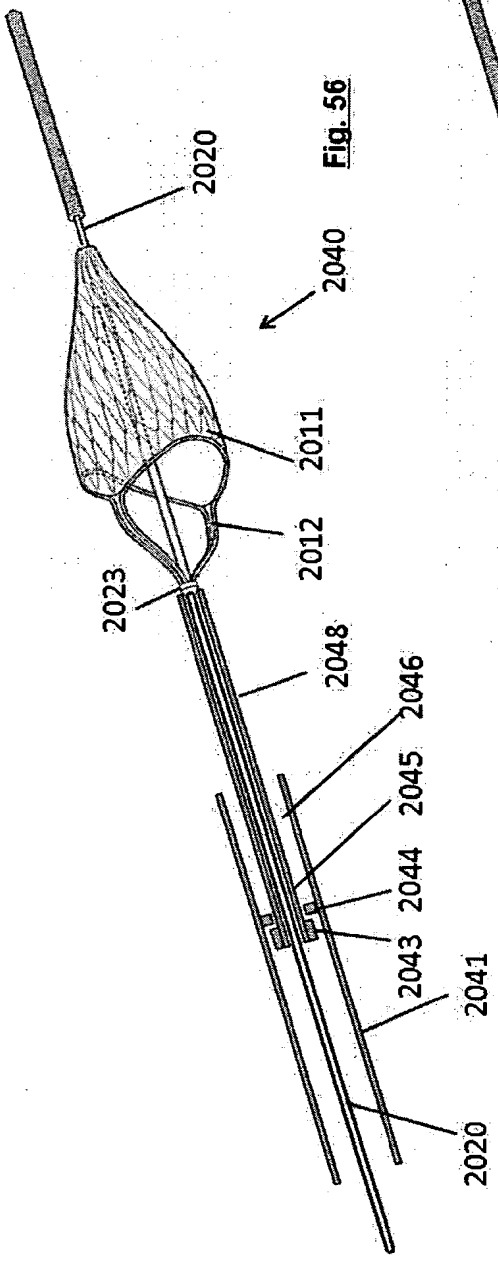

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2043
2041
2020

Fig. 56

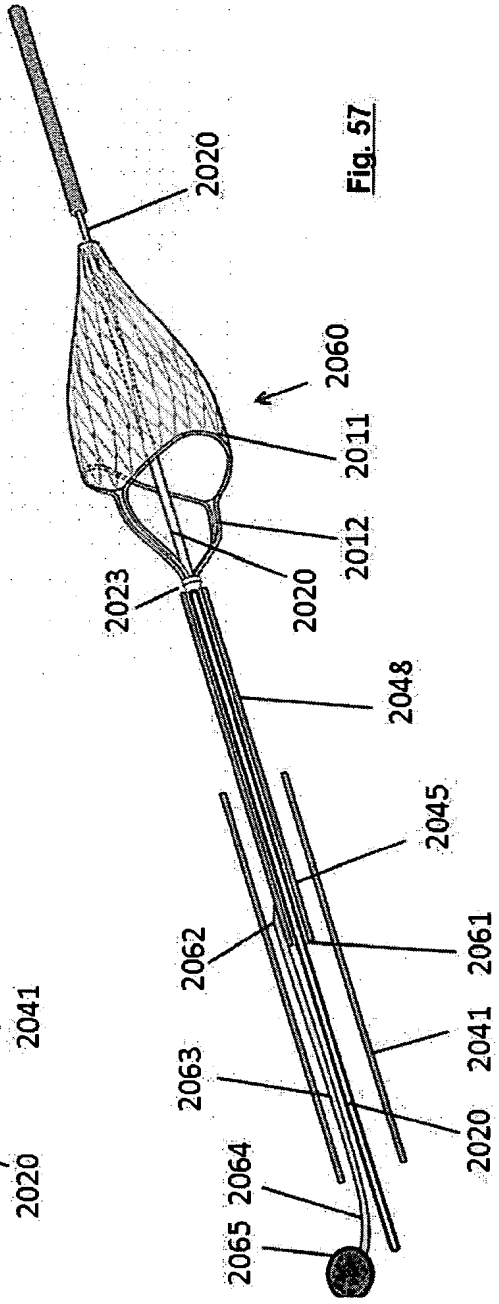

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Fig. 57

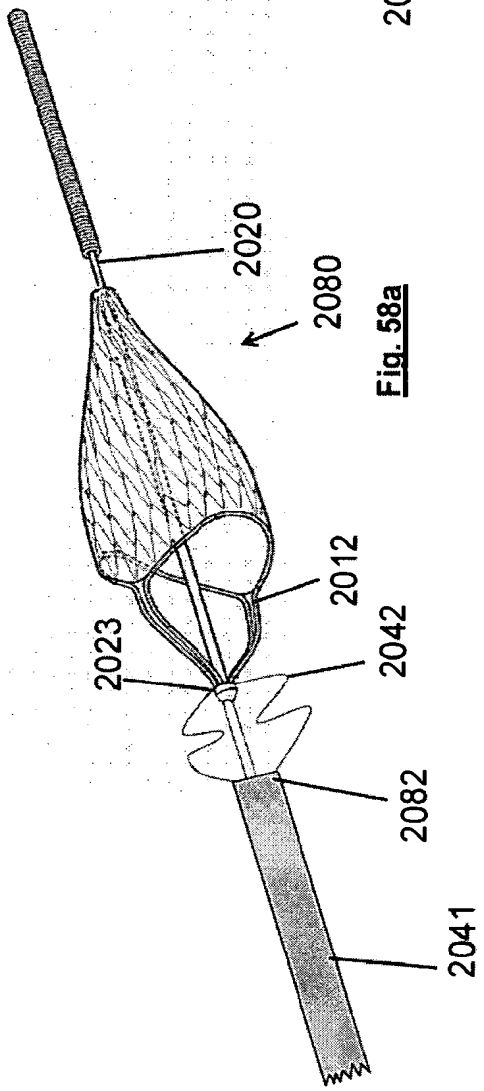


Fig. 58a

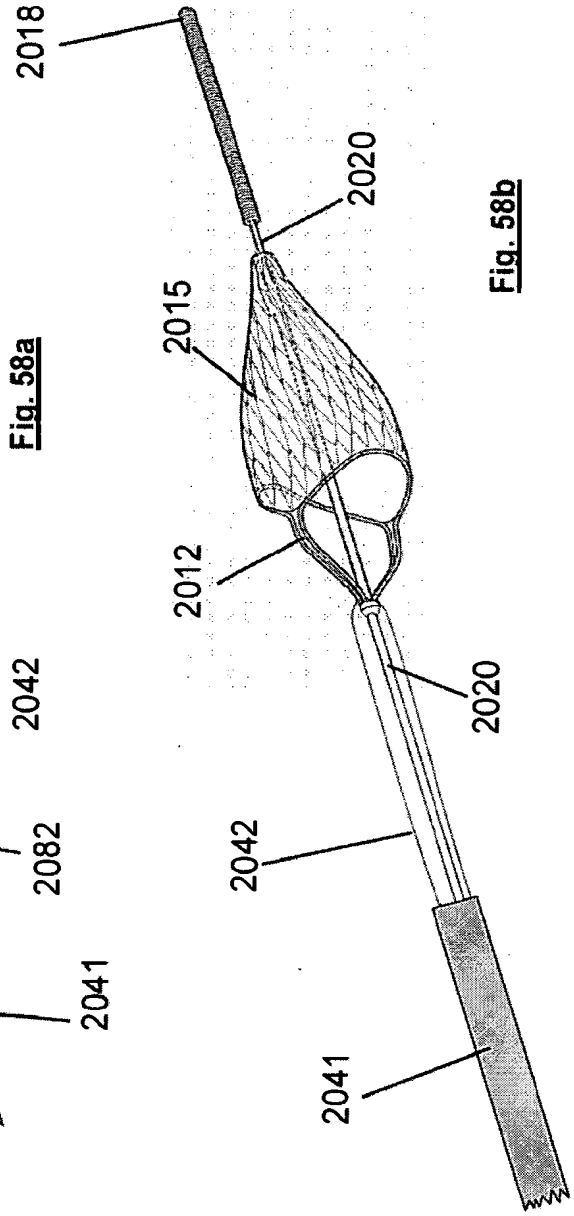


Fig. 58b

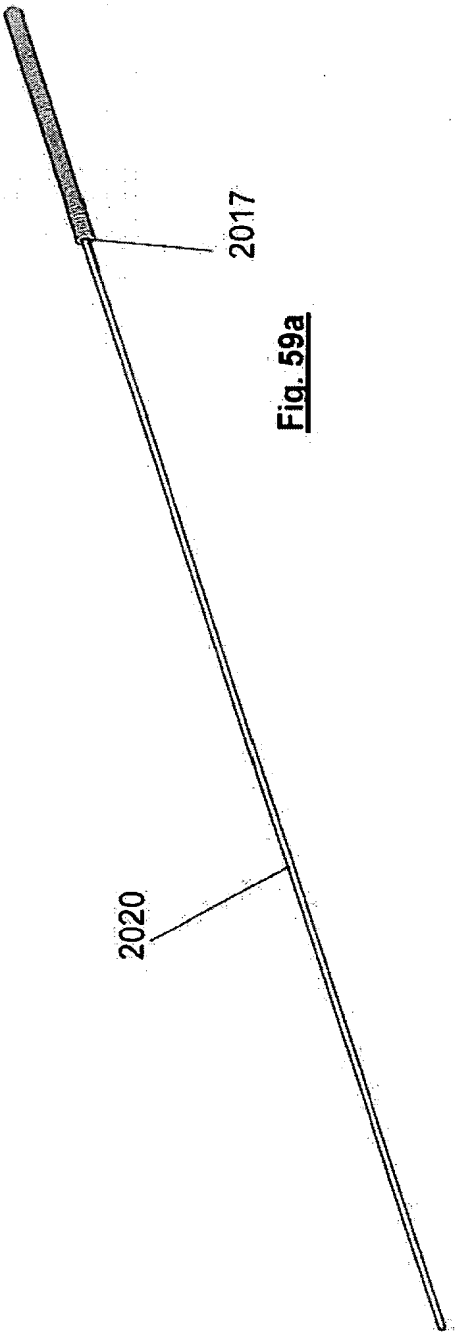


Fig. 59a

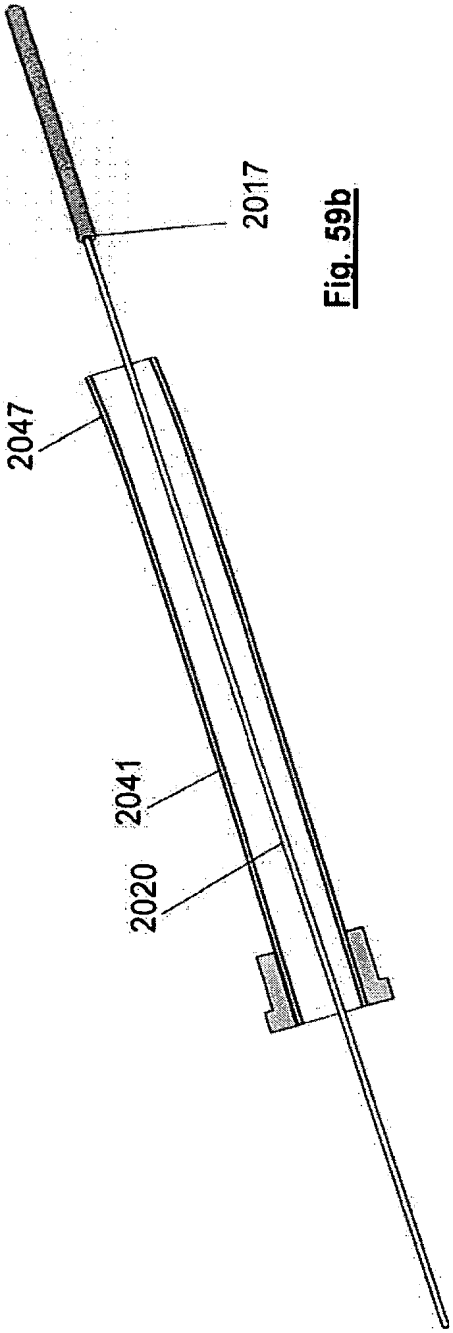


Fig. 59b

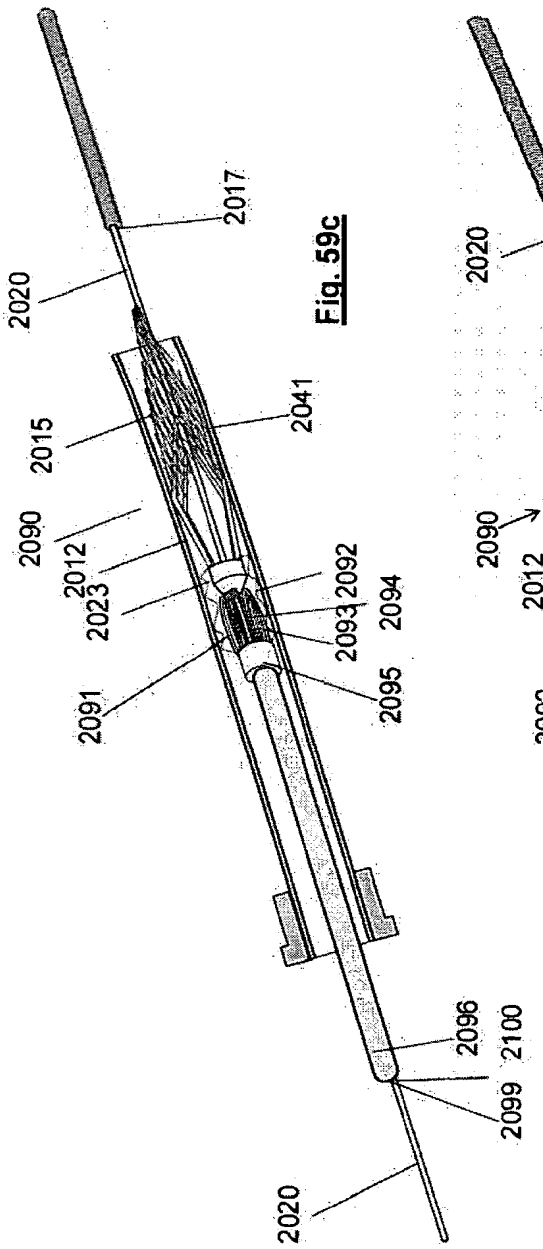


Fig. 59c

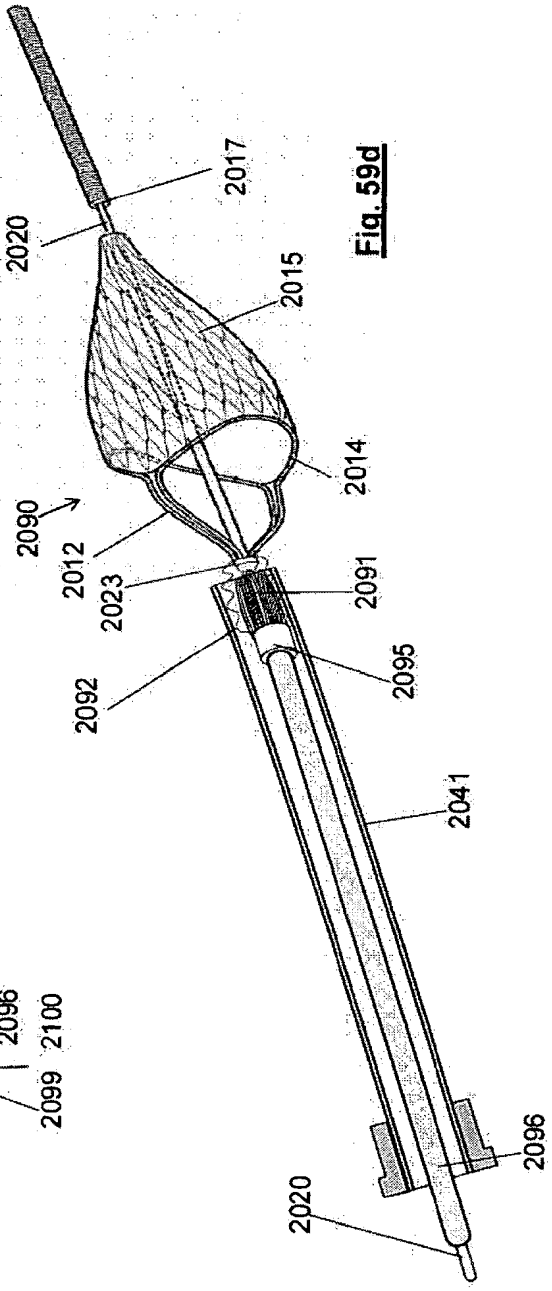


Fig. 59d

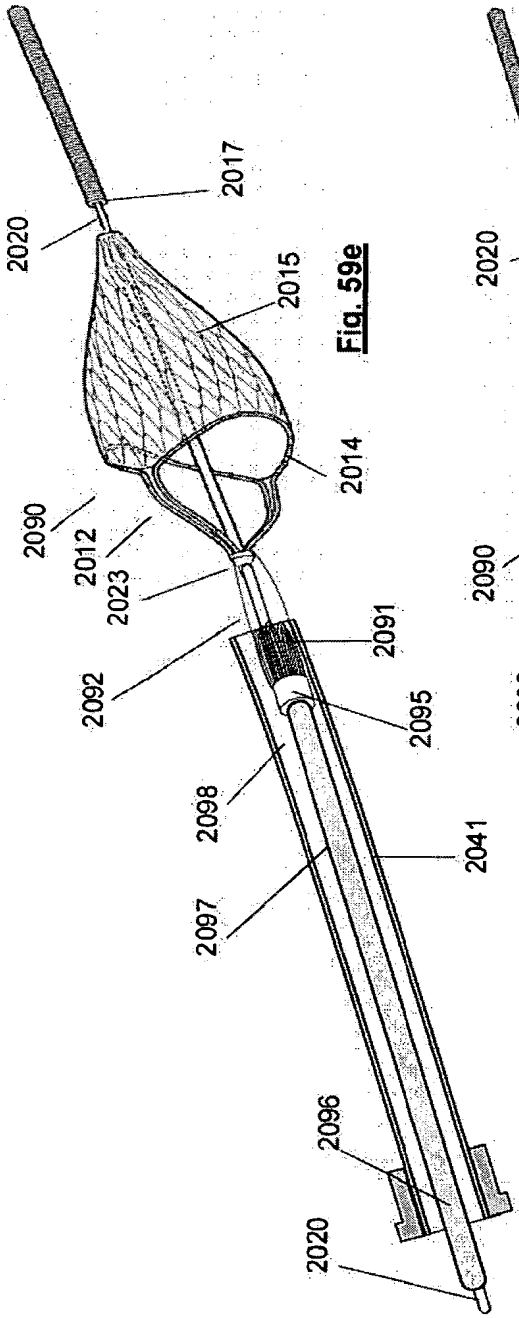


Fig. 59e

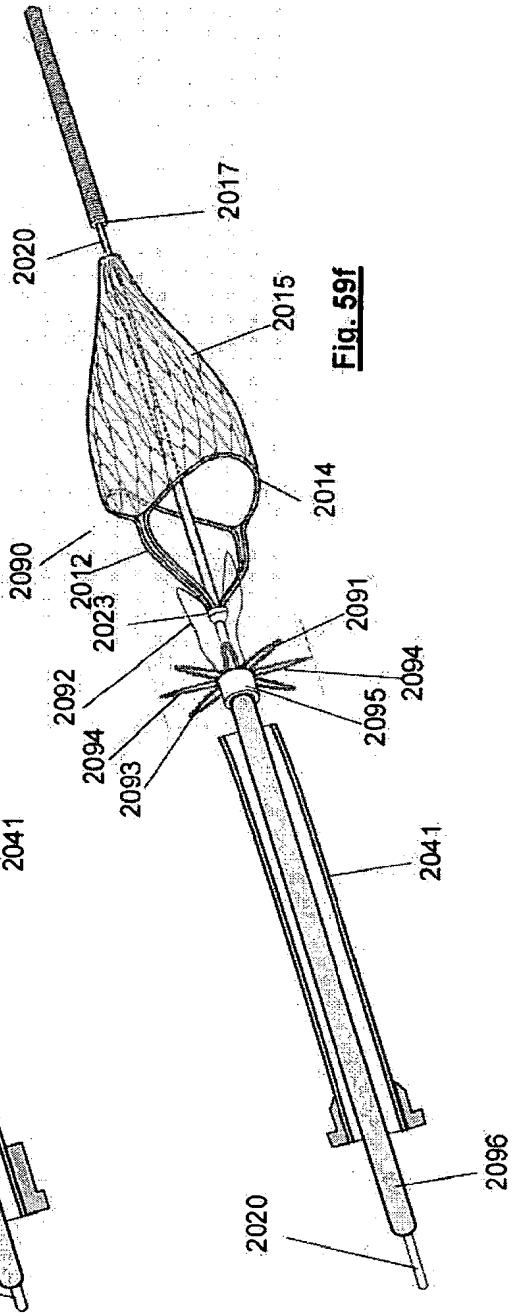


Fig. 59f

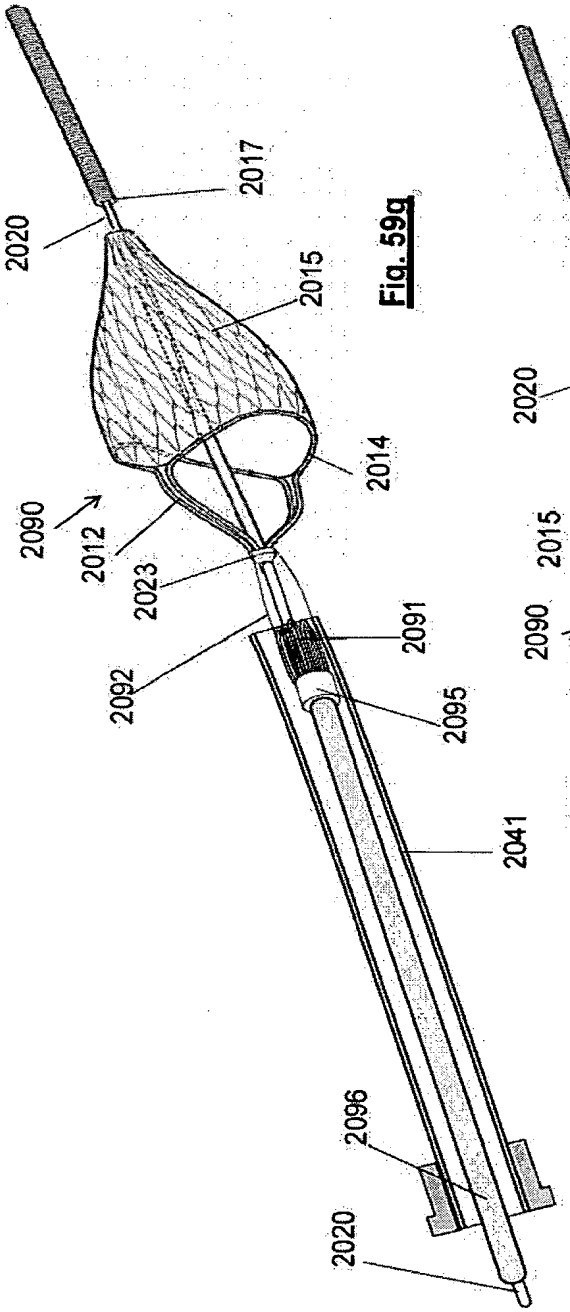


Fig. 59g

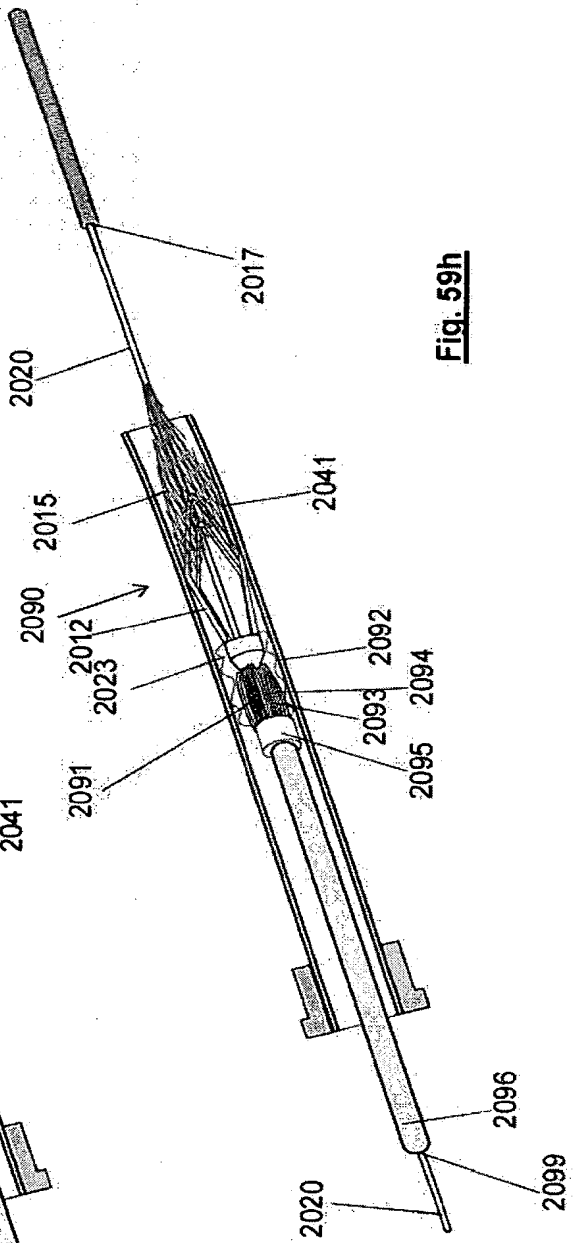


Fig. 59h

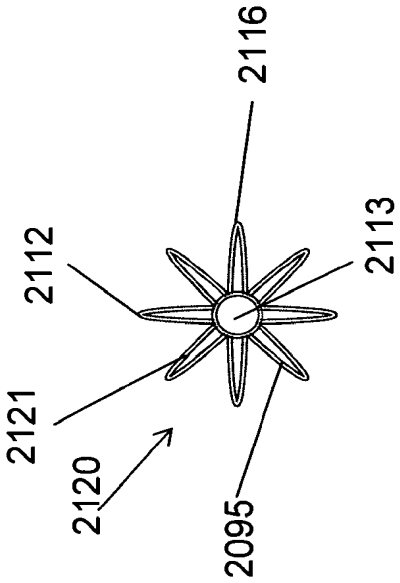


Fig. 60b

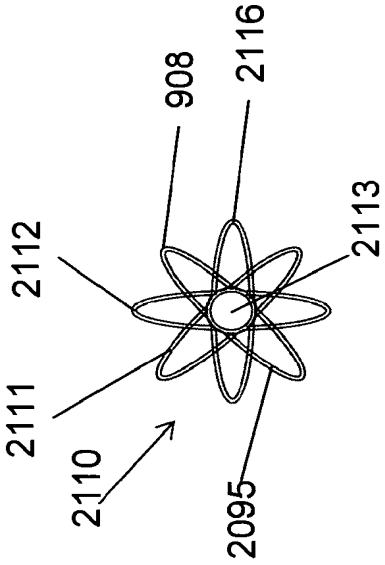


Fig. 60a

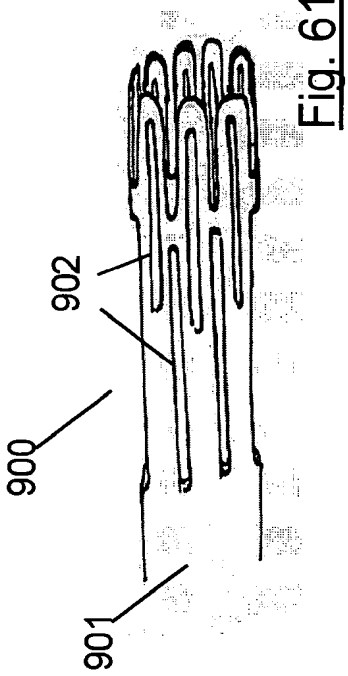


Fig. 61a

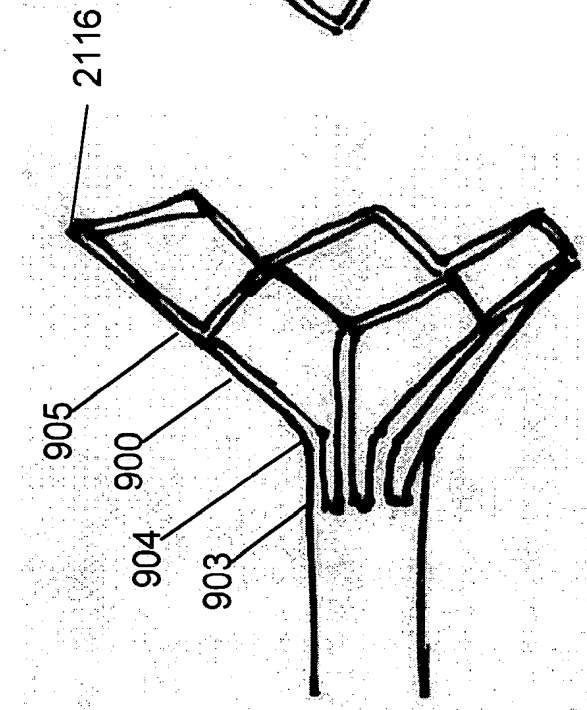


Fig. 61b

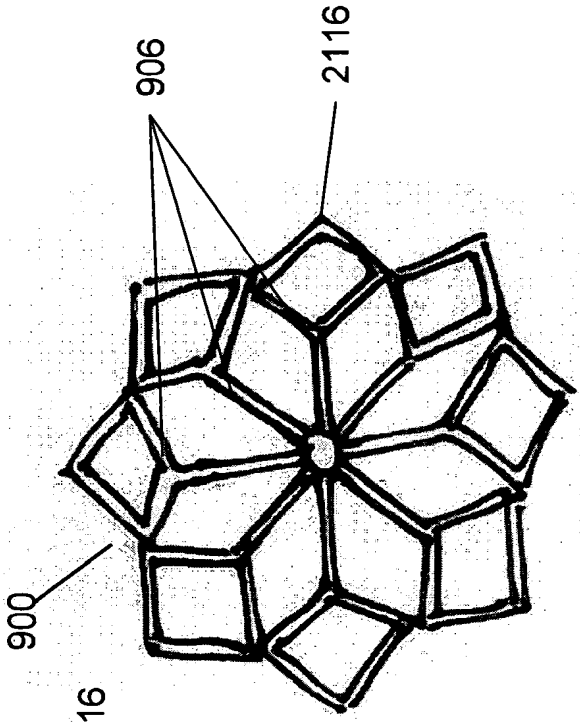


Fig. 61c

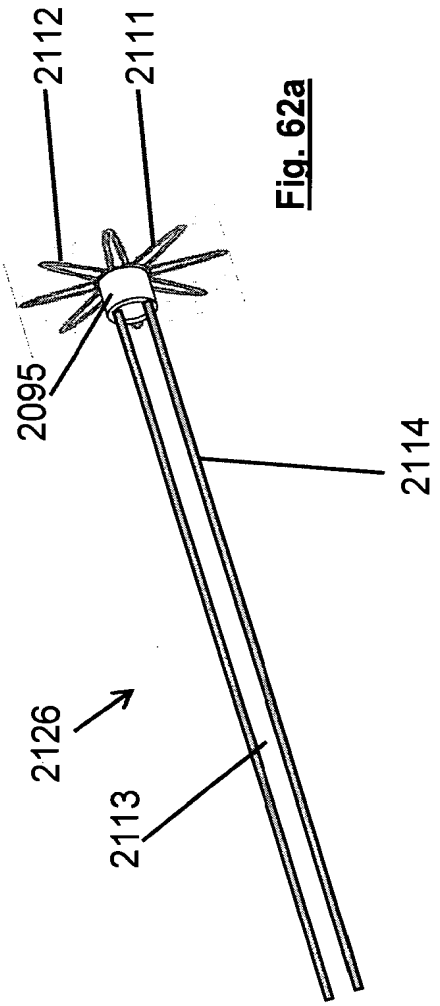


Fig. 62a

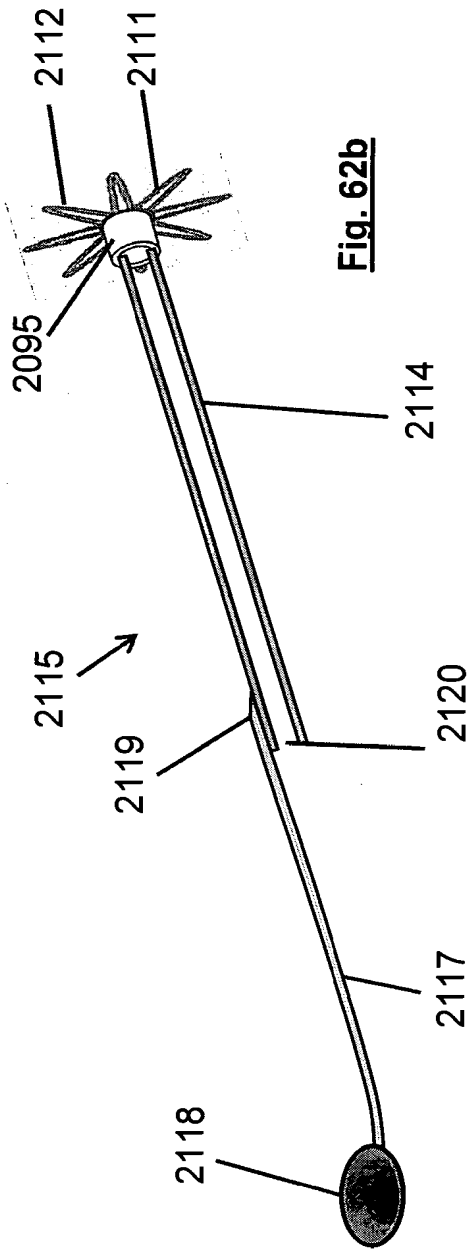


Fig. 62b

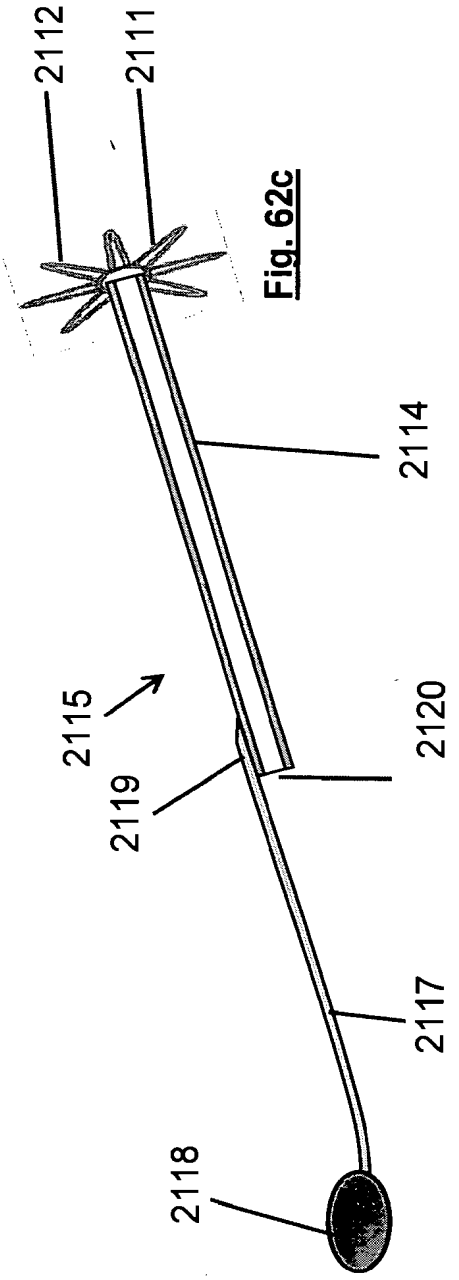


Fig. 62c

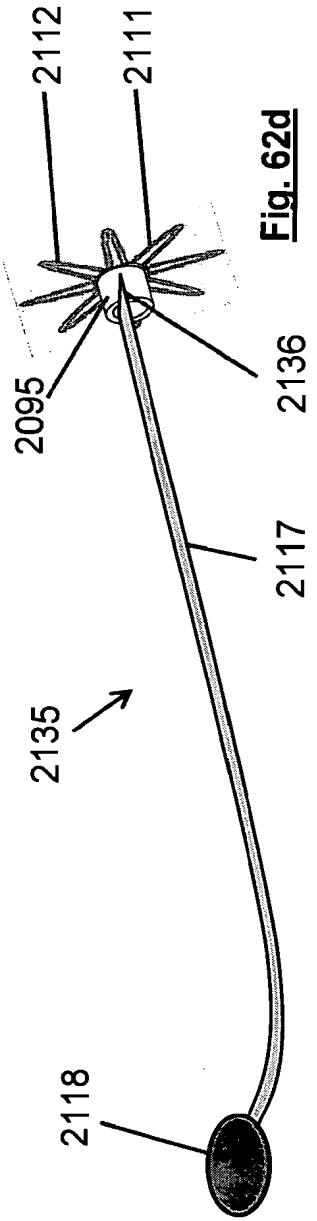


Fig. 62d

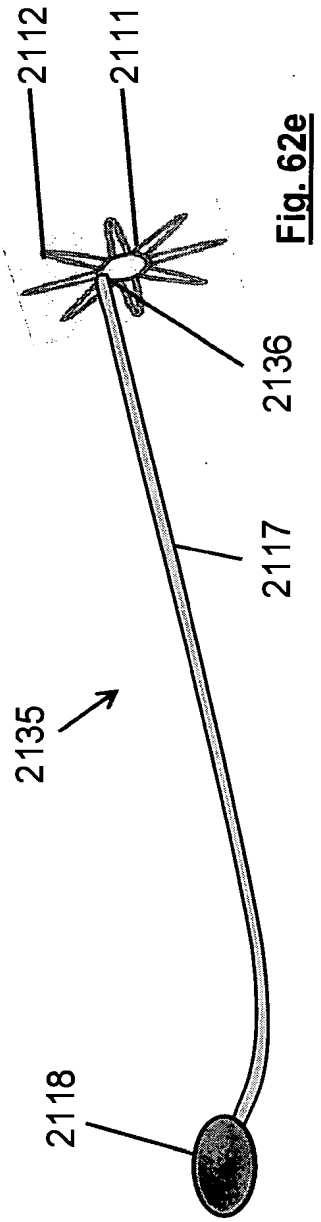


Fig. 62e

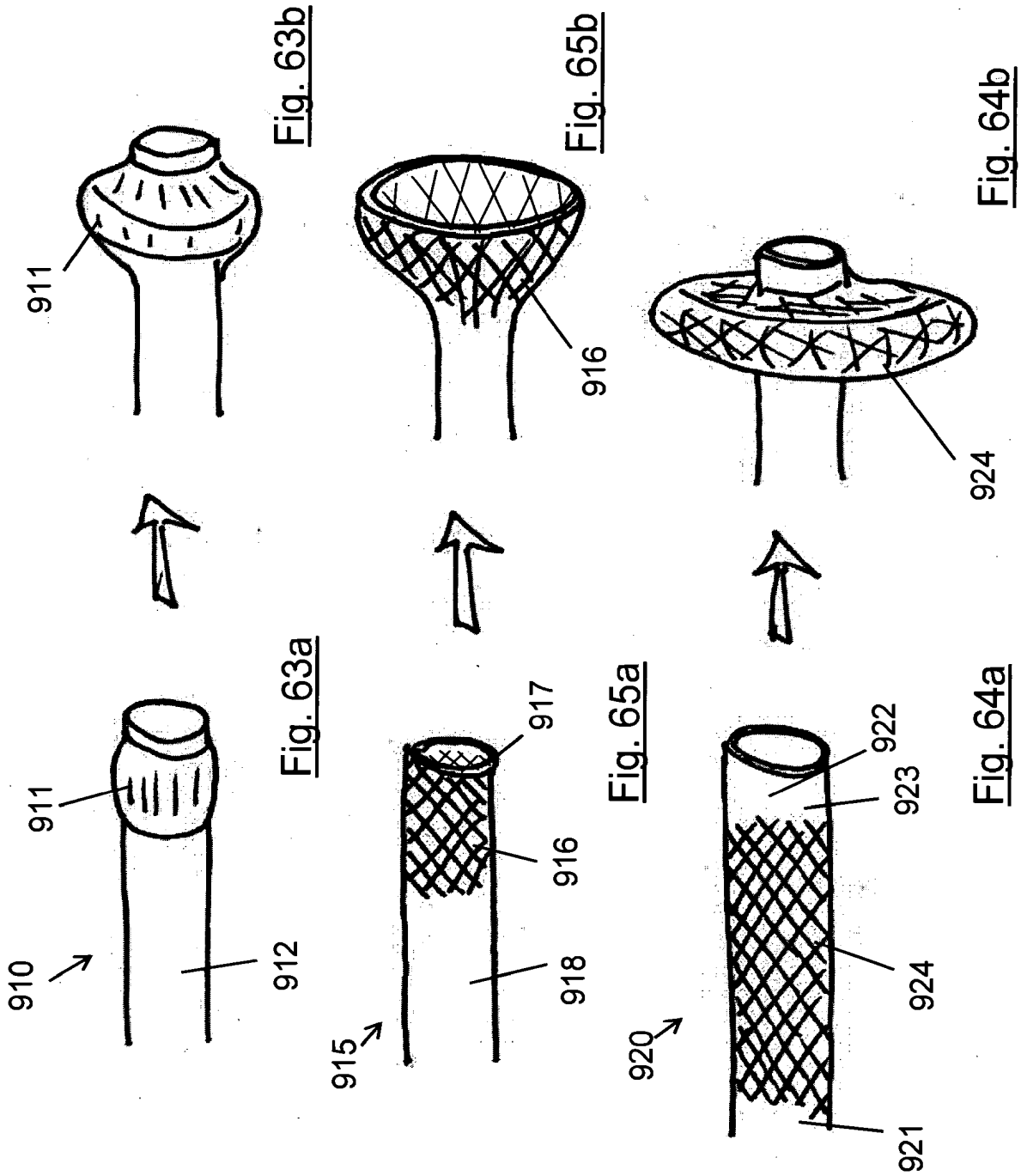


Fig. 63b Fig. 63a Fig. 65b Fig. 65a Fig. 64b Fig. 64a

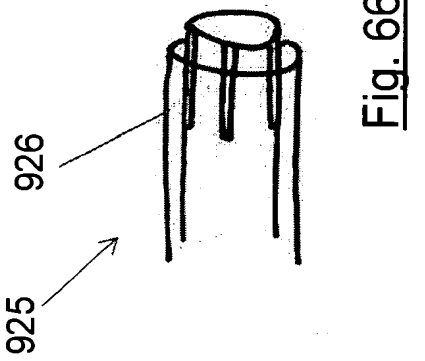


Fig. 66a

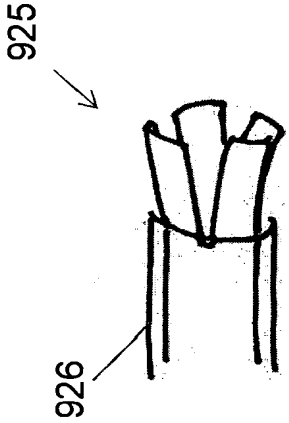


Fig. 66b

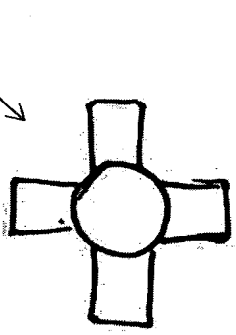


Fig. 66c

Fig. 67a

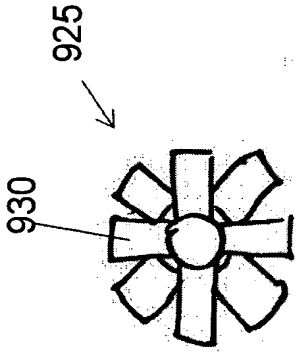


Fig. 67b

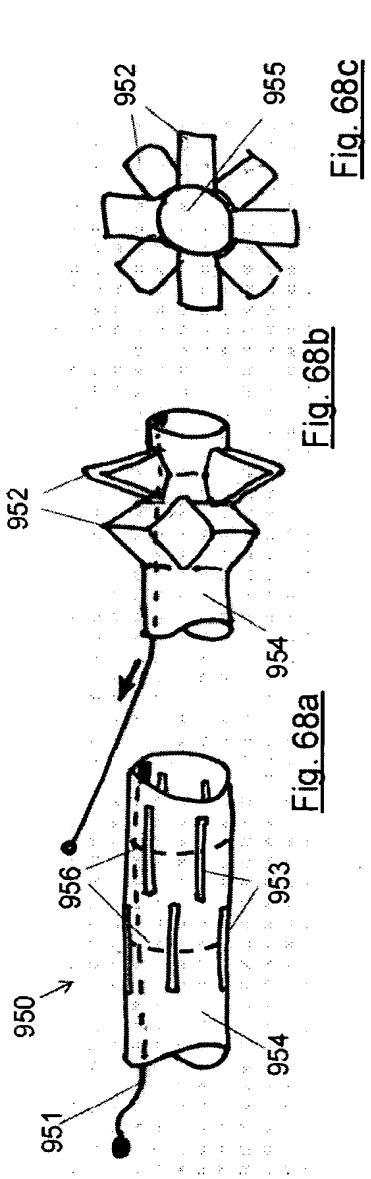


Fig. 68c

Fig. 68b

Fig. 68a

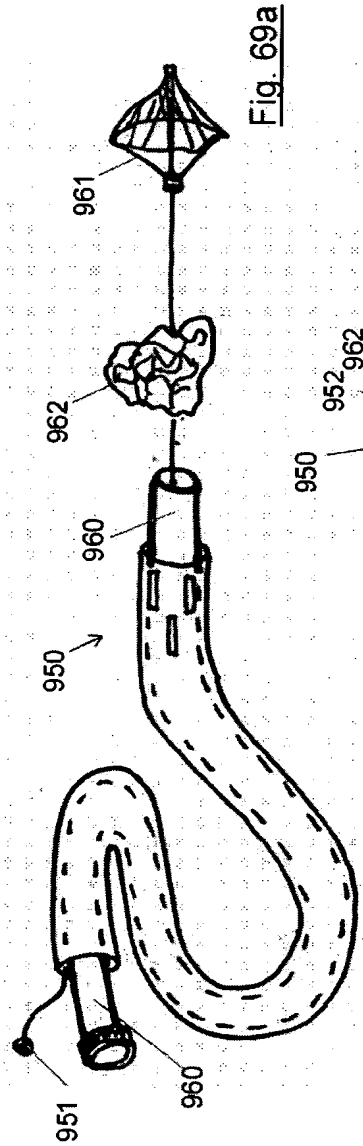


Fig. 69a

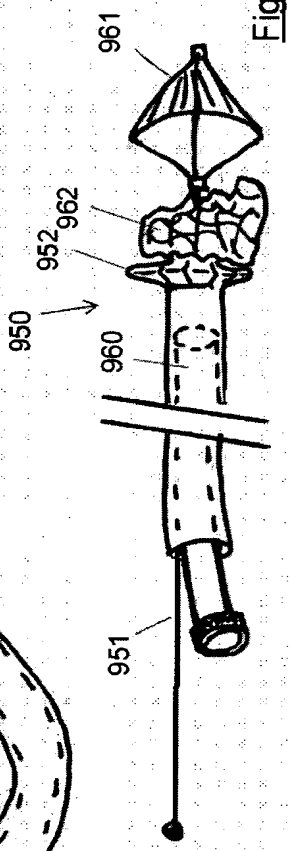


Fig. 69b

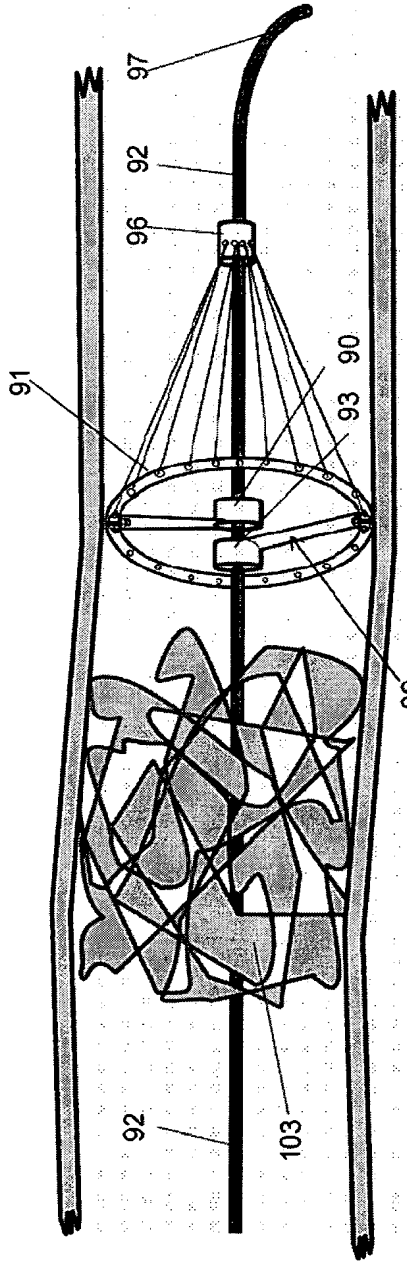


Fig. 70

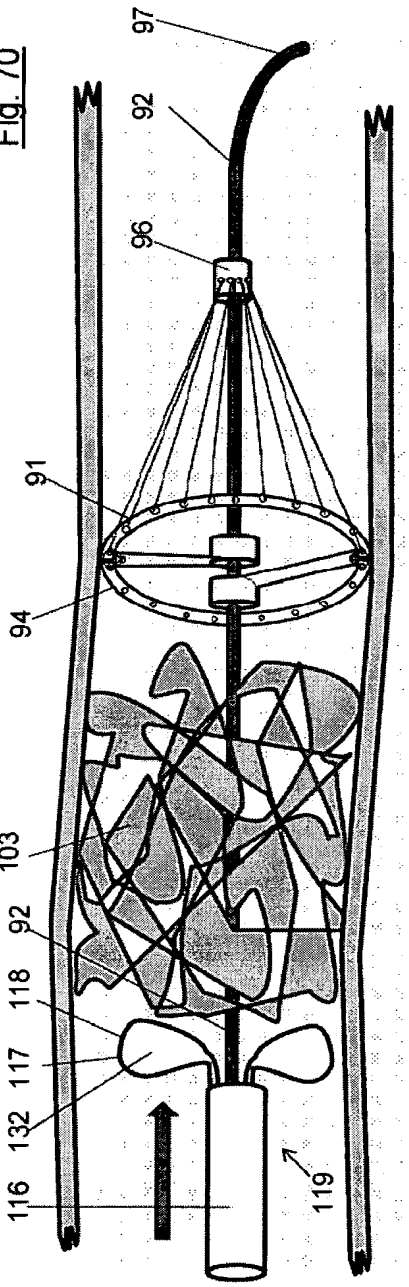


Fig. 71

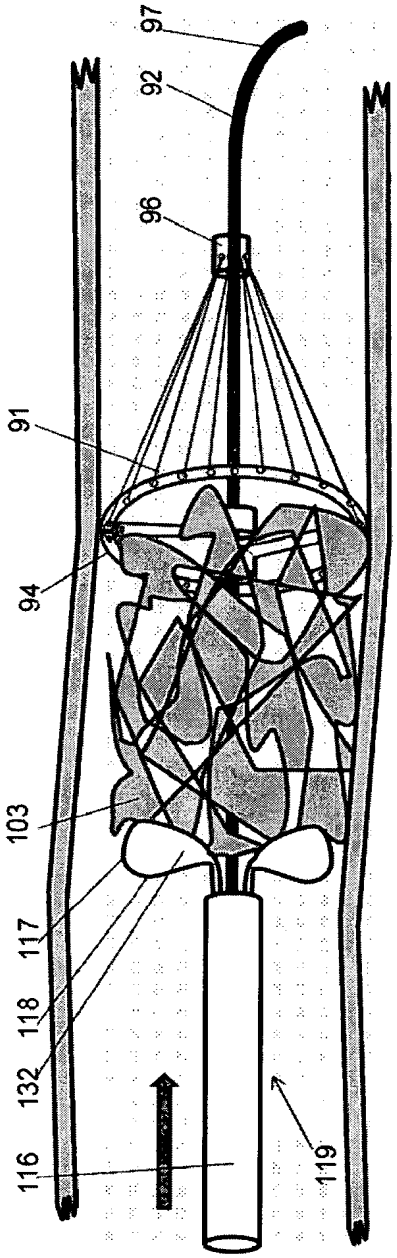

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Fig. 72

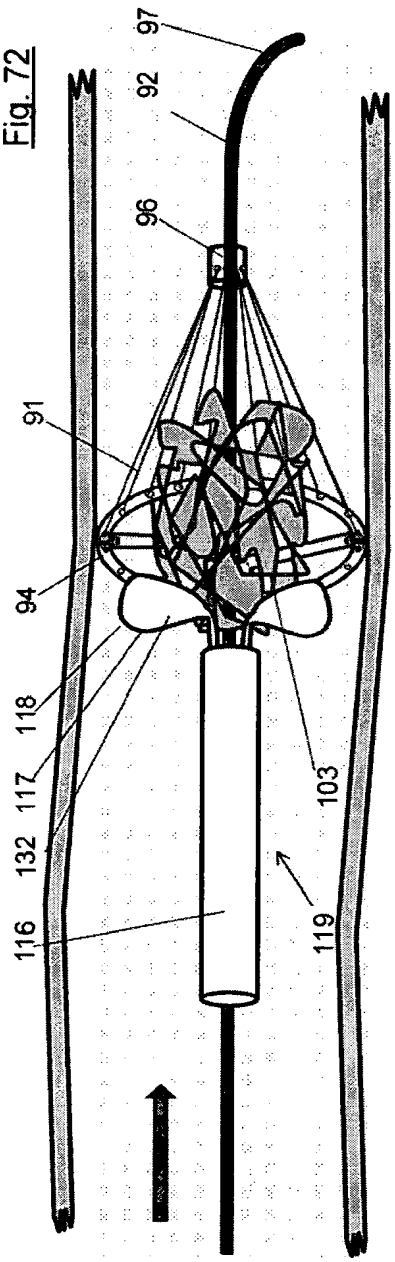

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Fig. 73

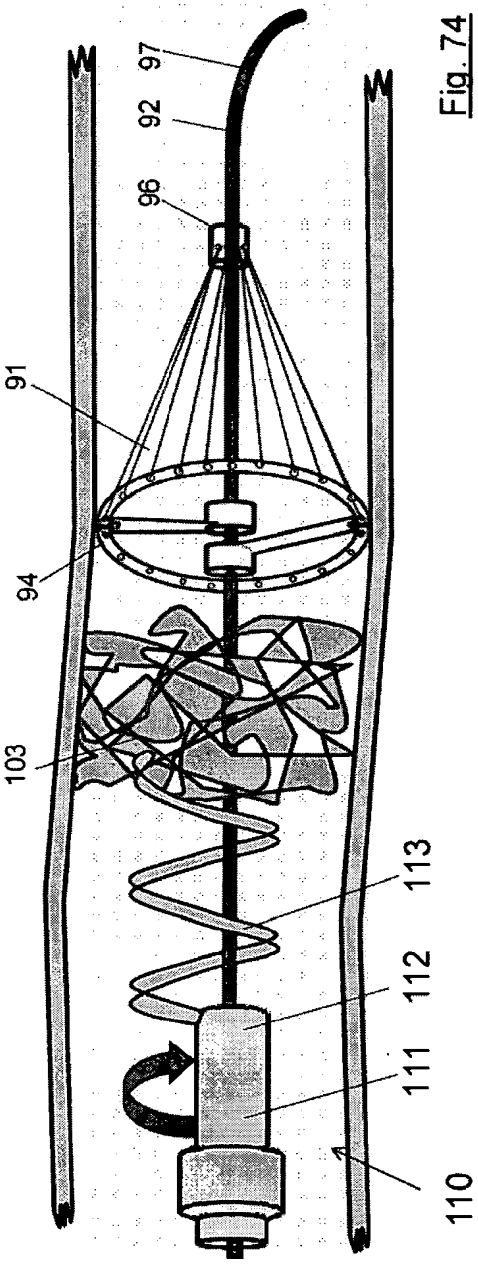


Fig. 74

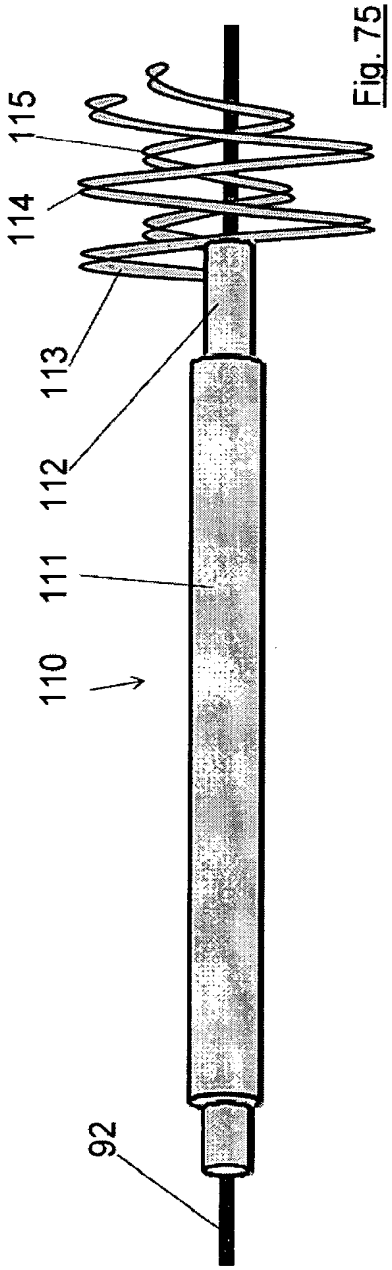


Fig. 75

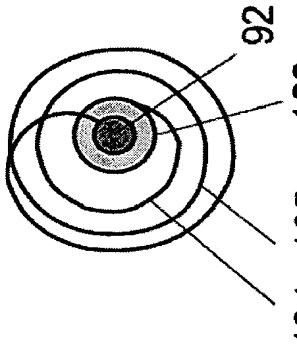


Fig. 76b

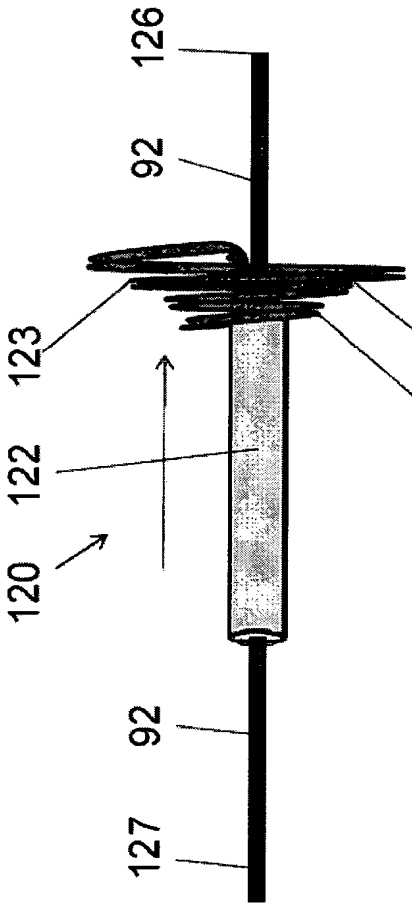
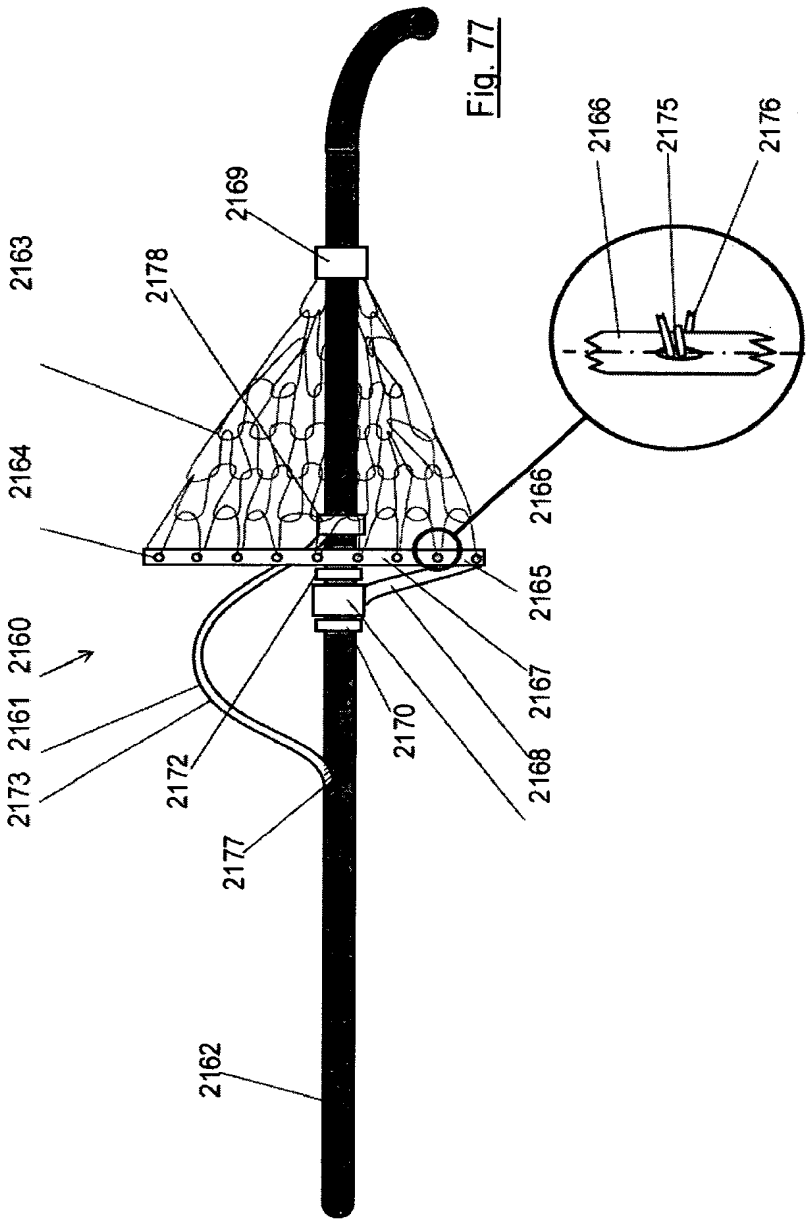


Fig. 76a

Fig. 77


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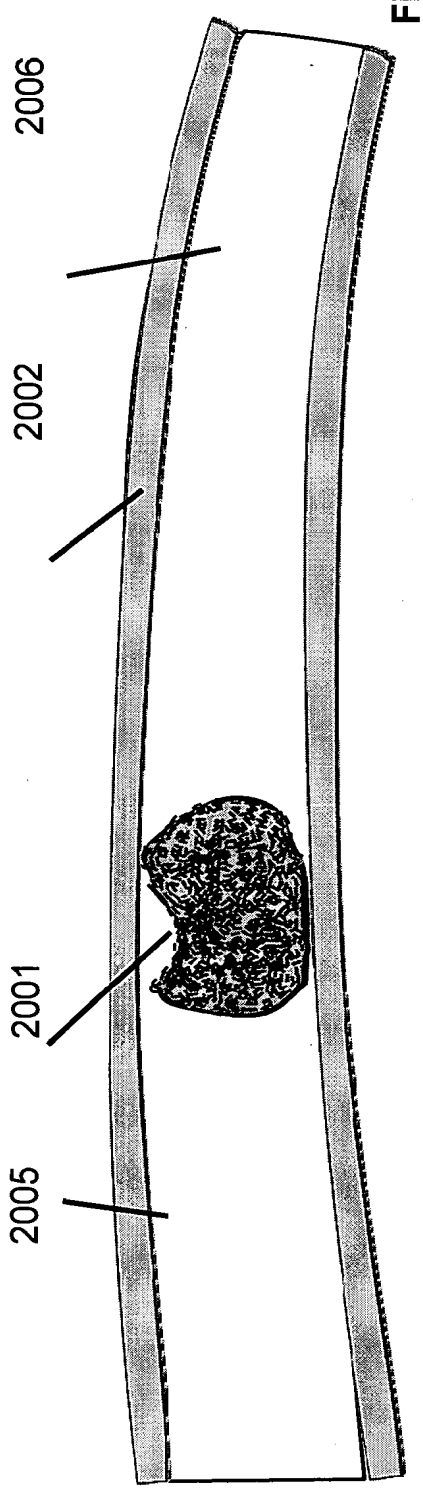


Fig. 78a

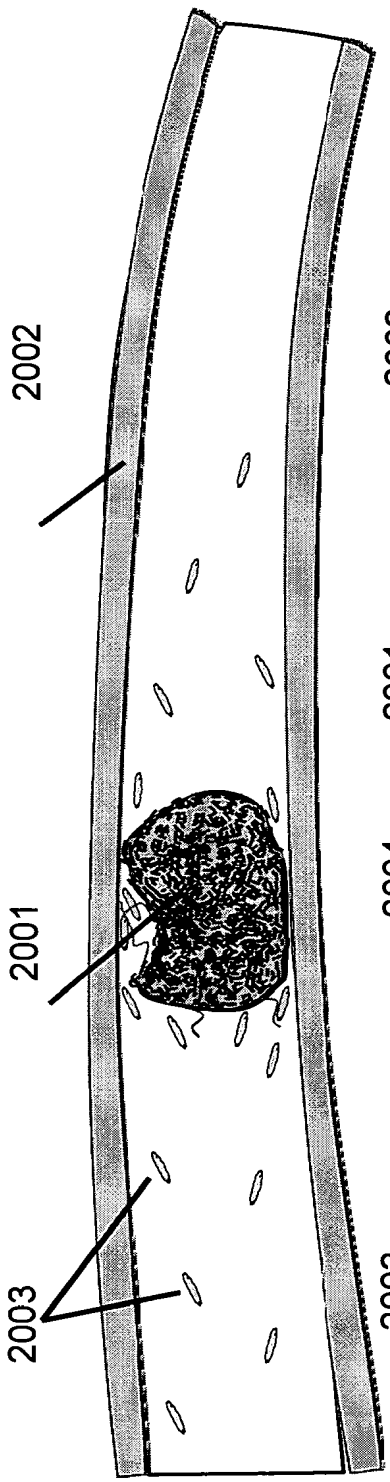


Fig. 78b

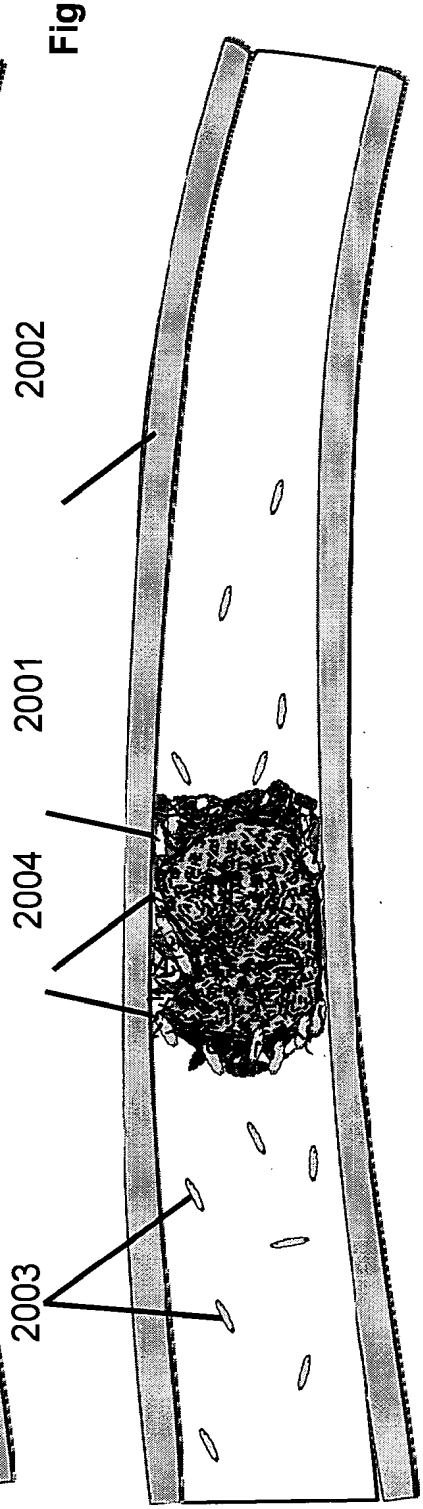


Fig. 78c

Fig. 79a

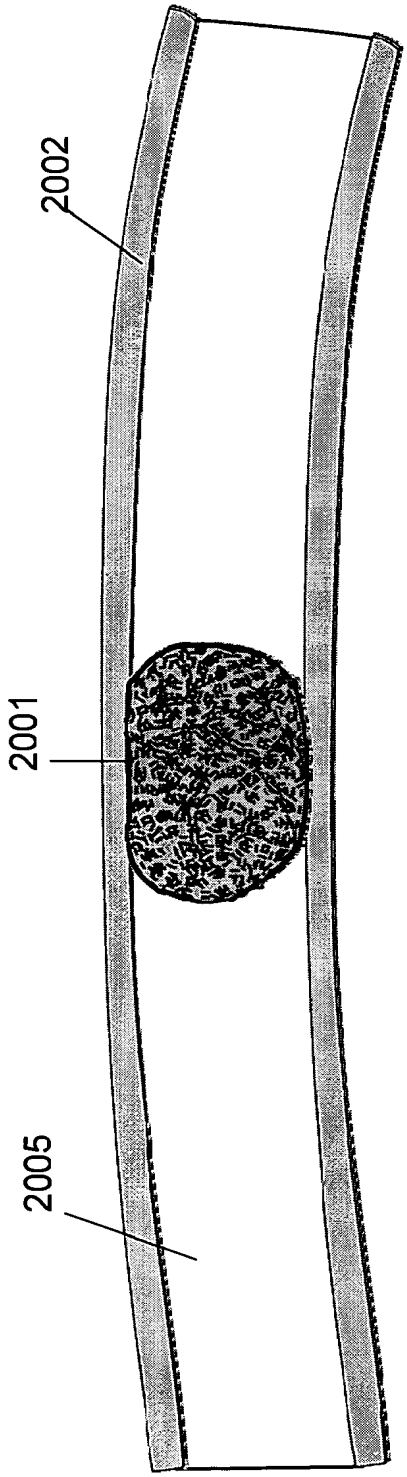


Fig. 79b

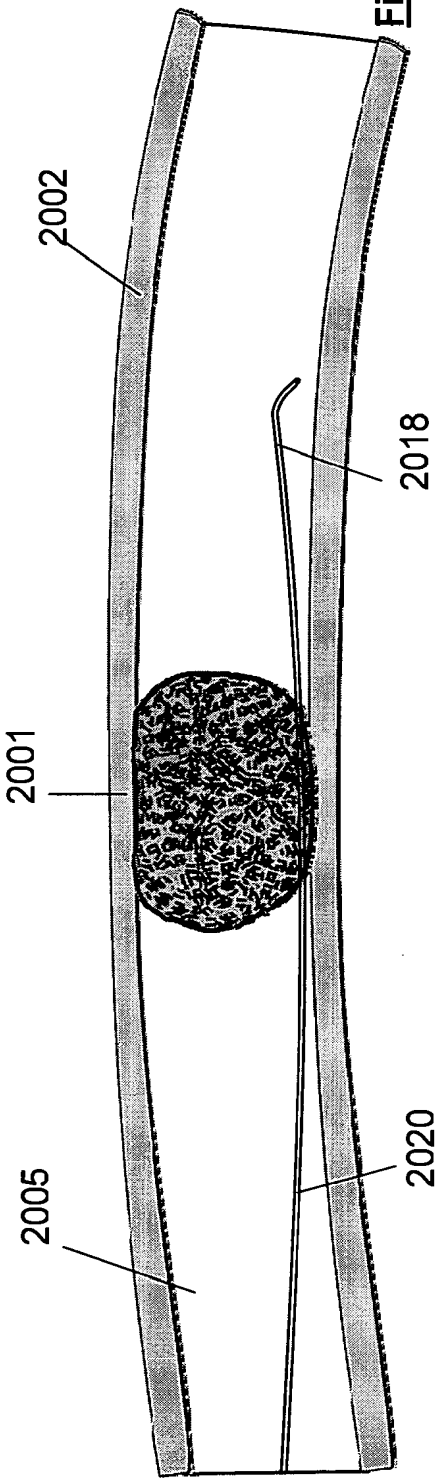


Fig. 79c

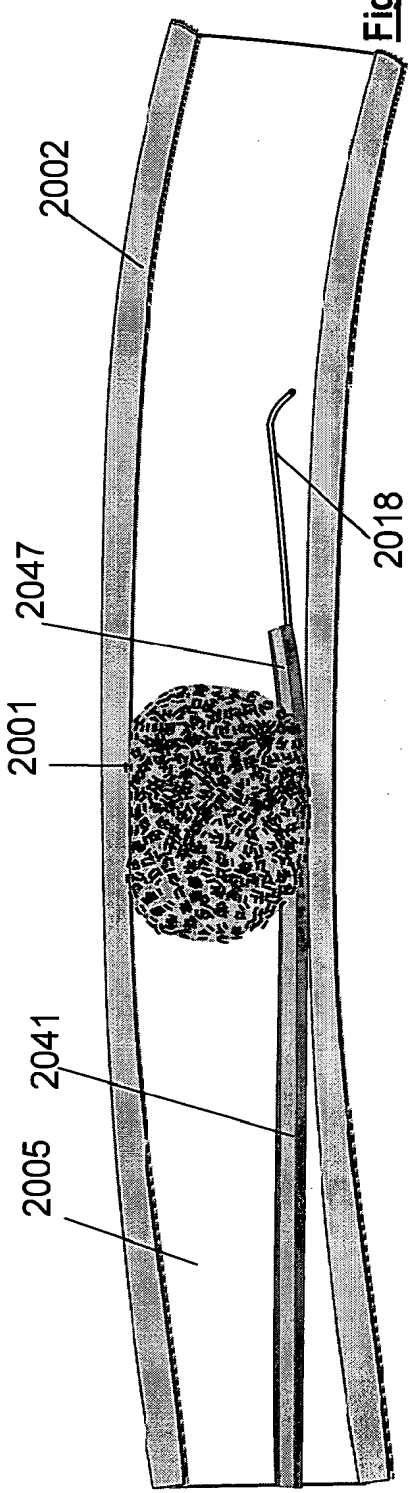


Fig. 79d

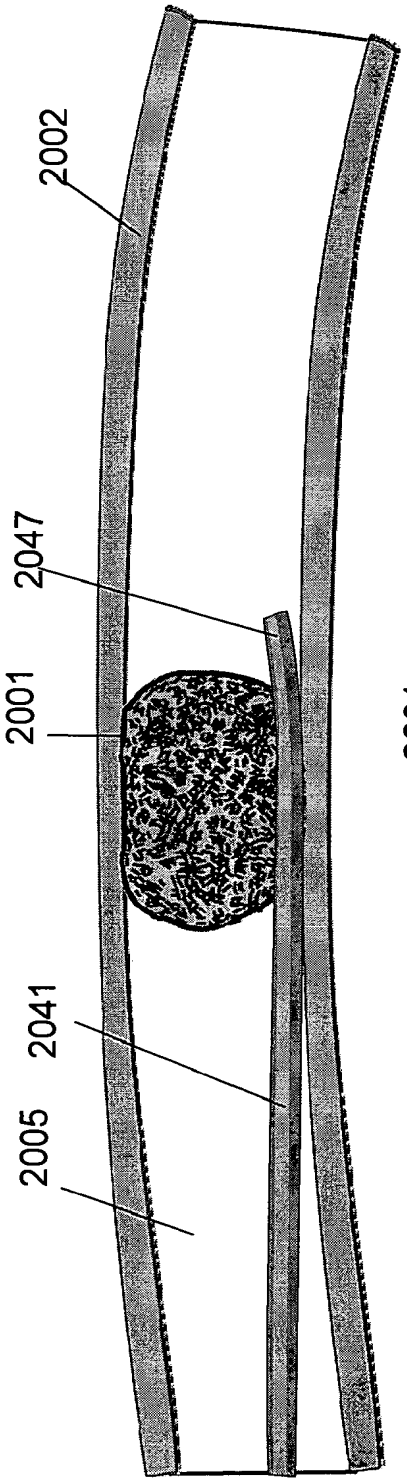


Fig. 79e

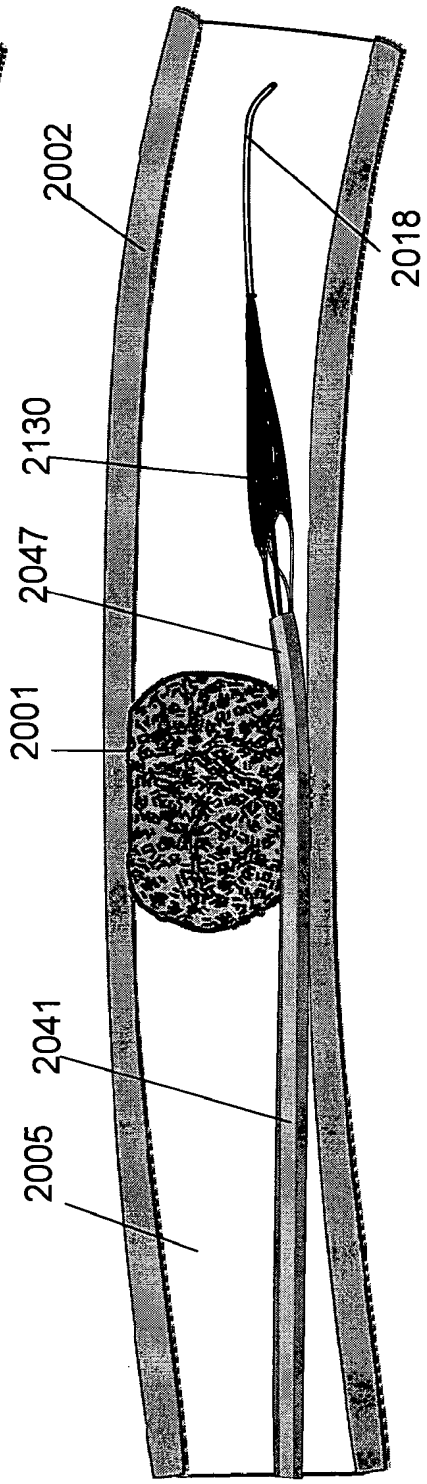
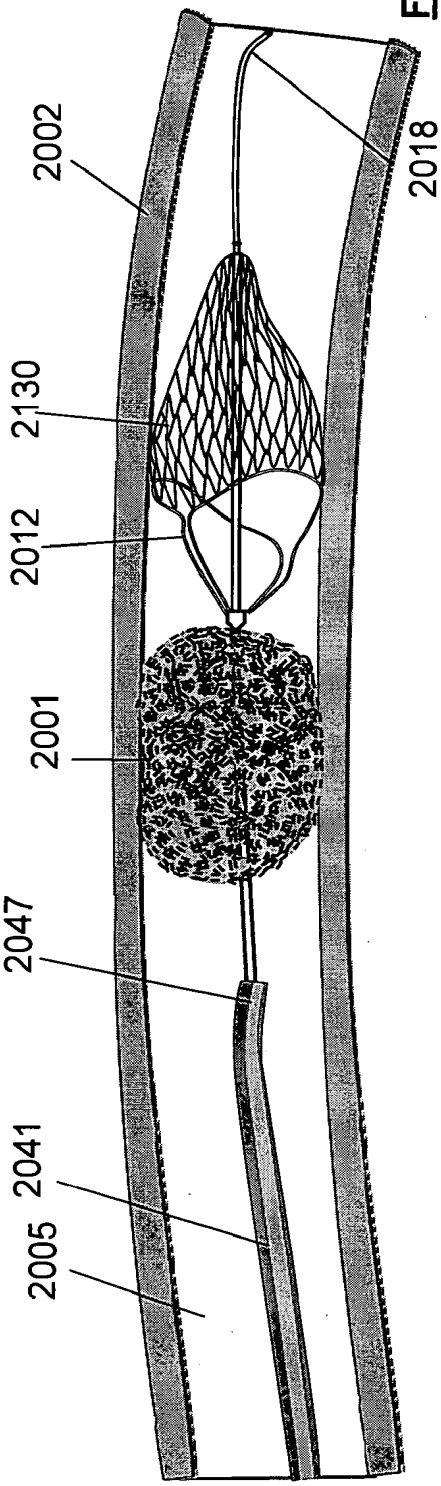


Fig. 79f



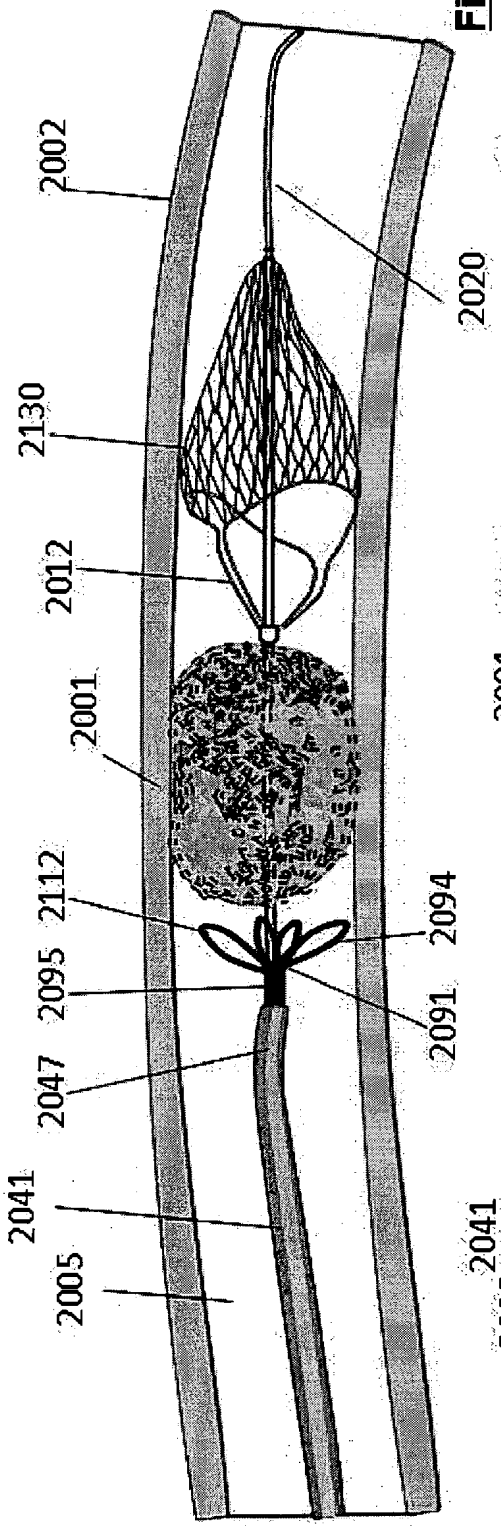


Fig. 79g

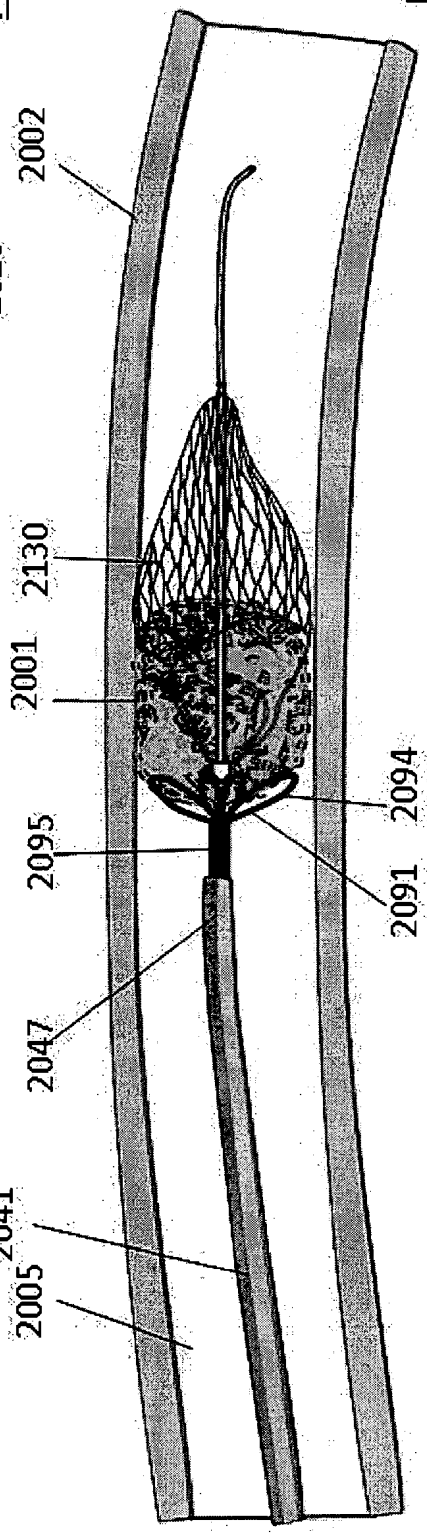


Fig. 79h

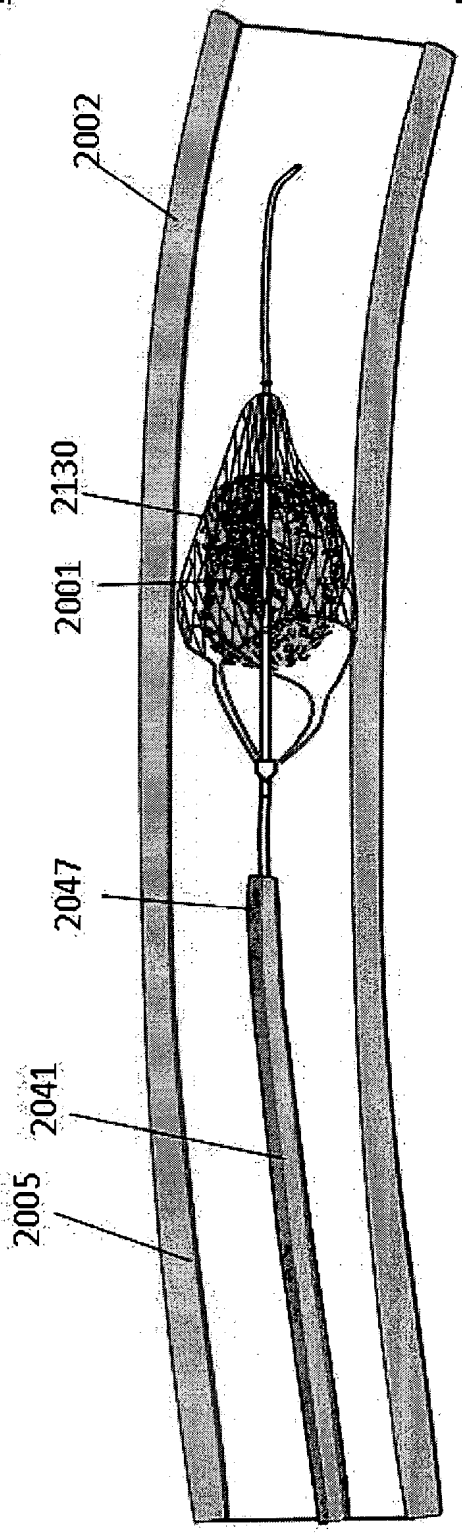


Fig. 79i

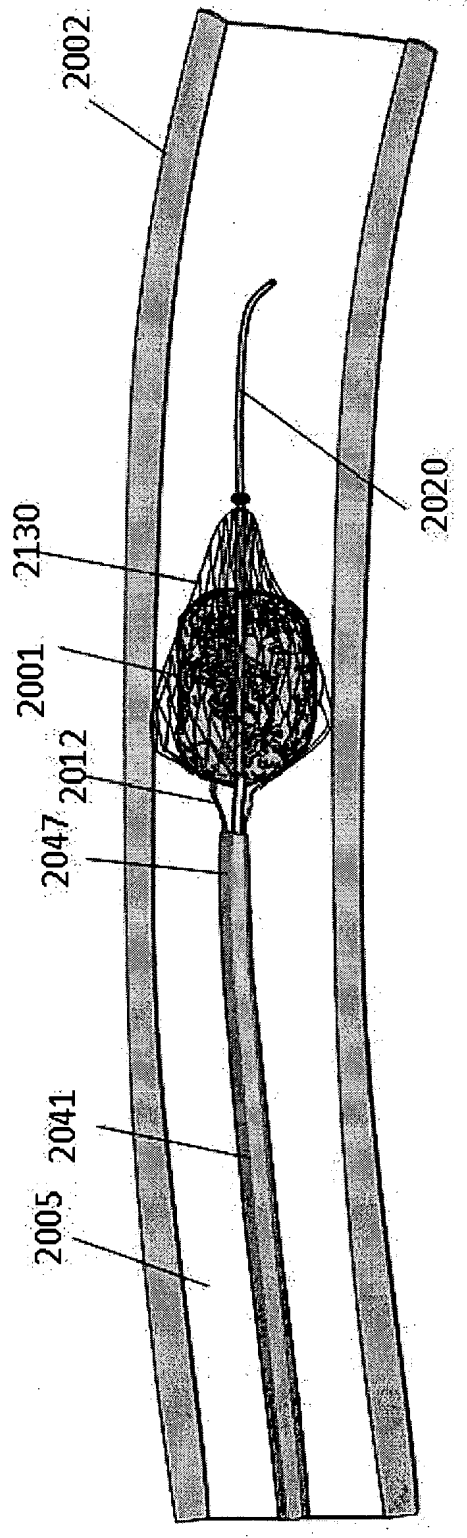


Fig.79j

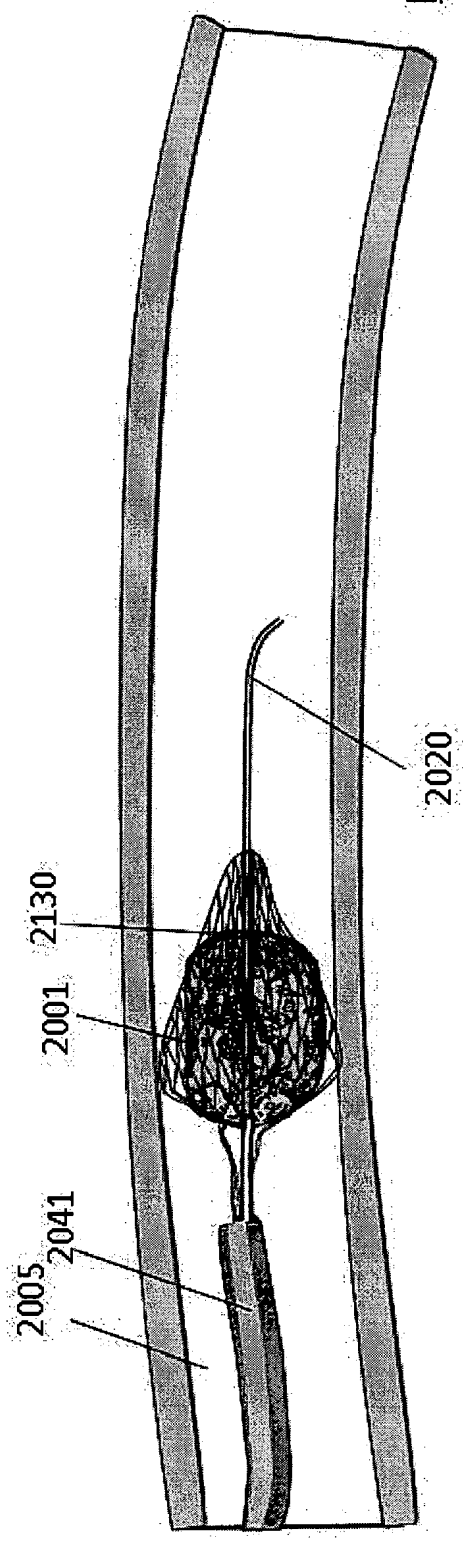


Fig.79k

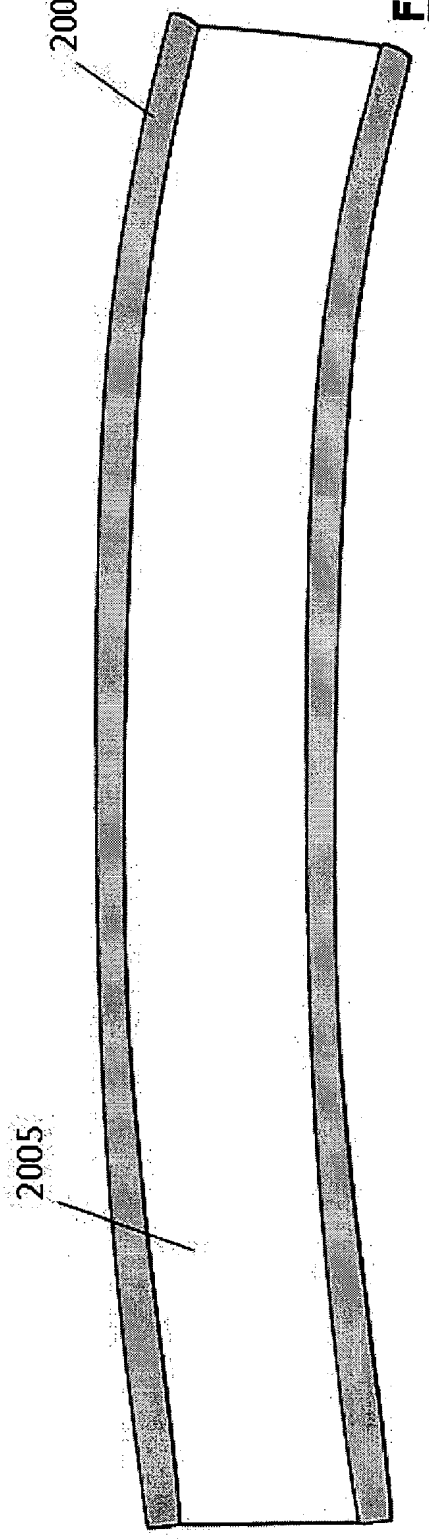


Fig.79l

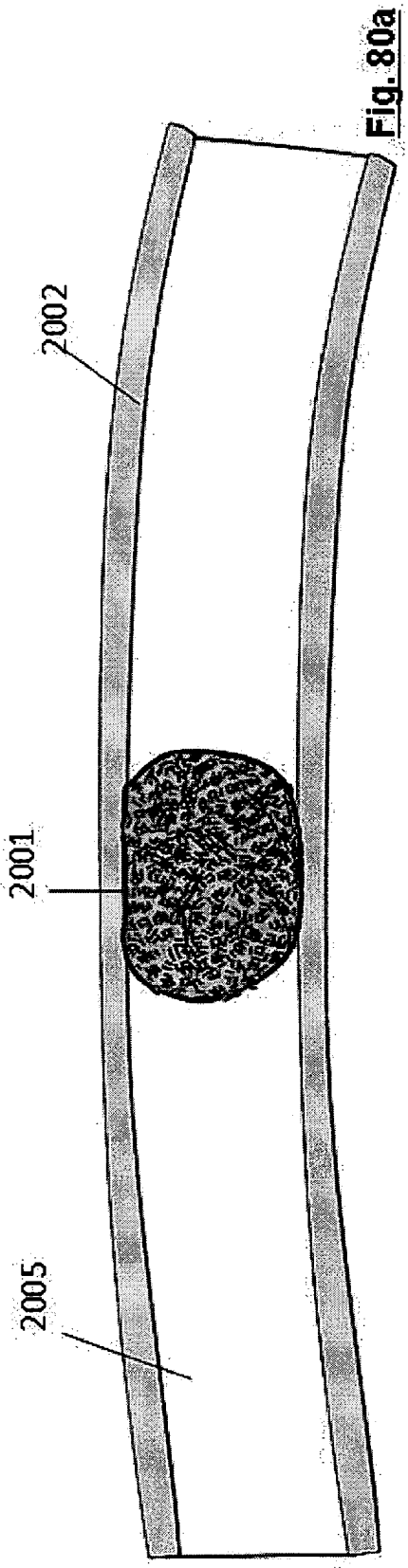


Fig. 80a

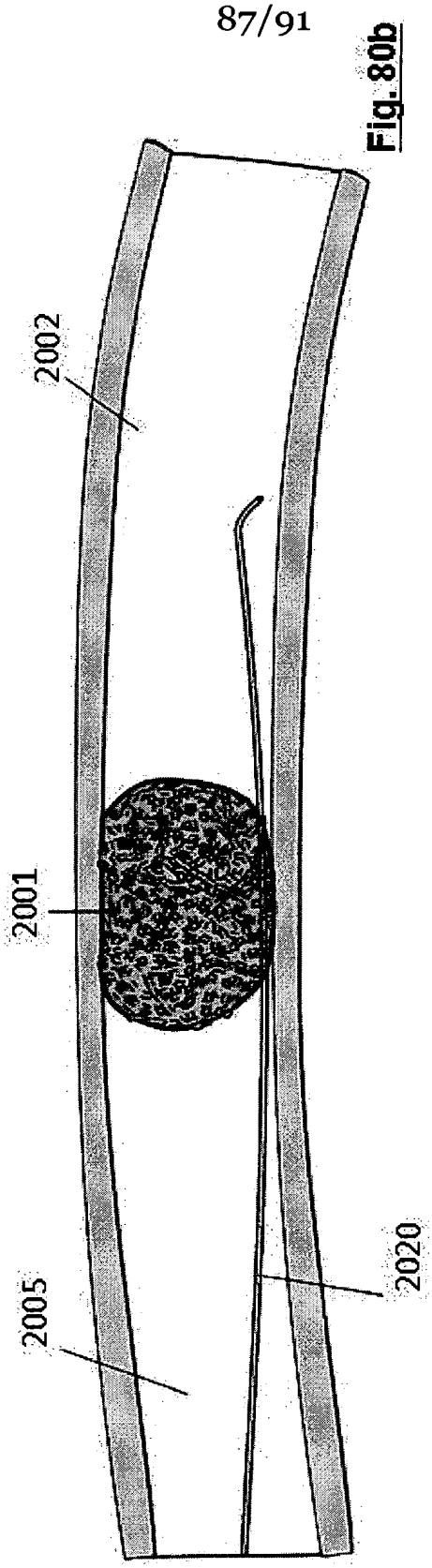


Fig. 80b

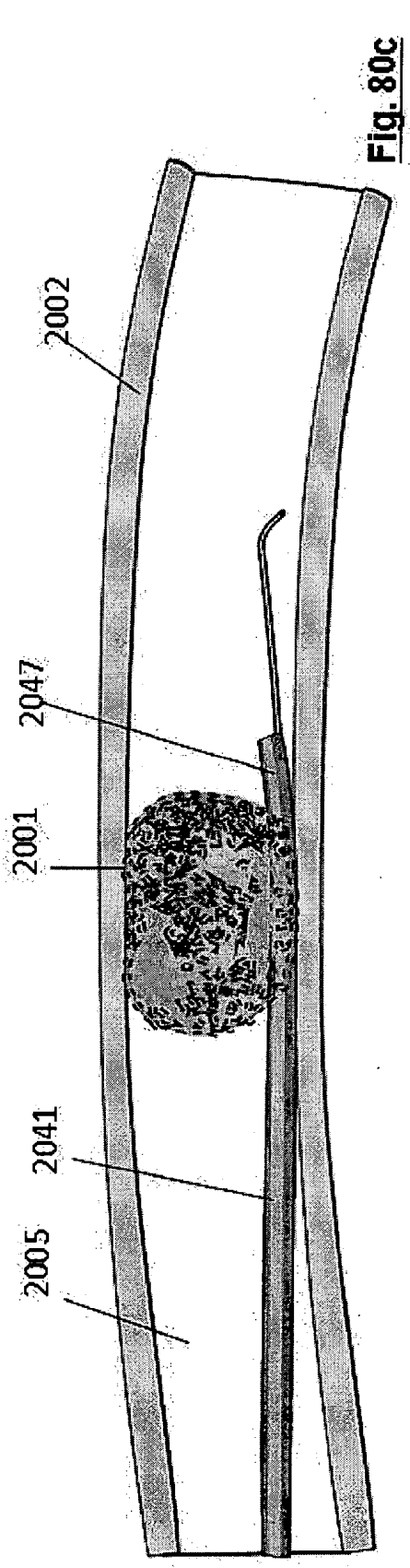


Fig. 80c

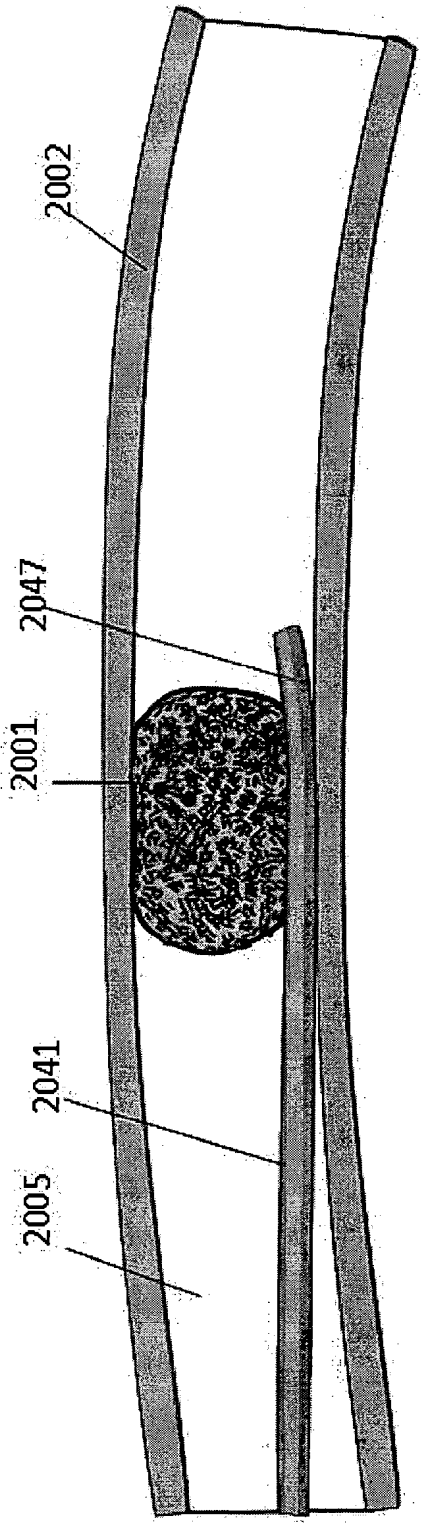


Fig. 80d

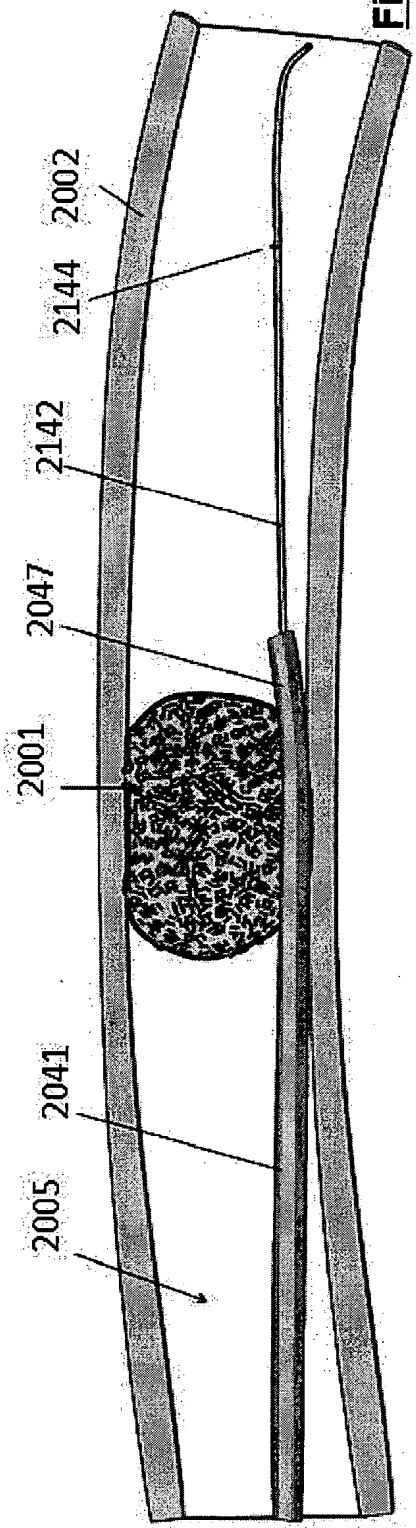


Fig. 80e

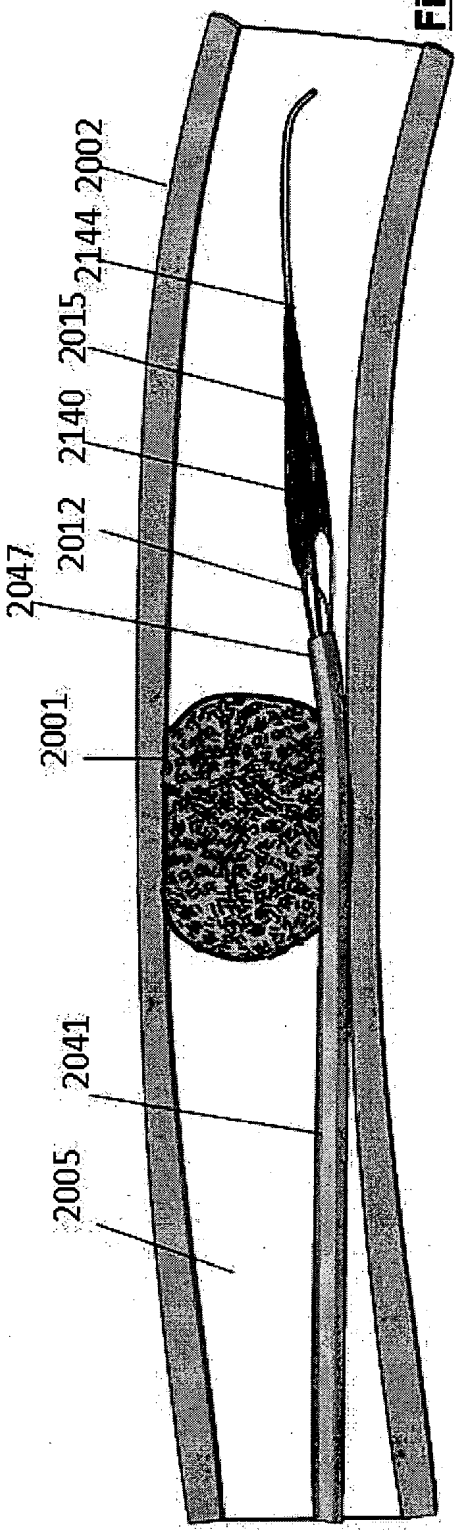


Fig. 80f

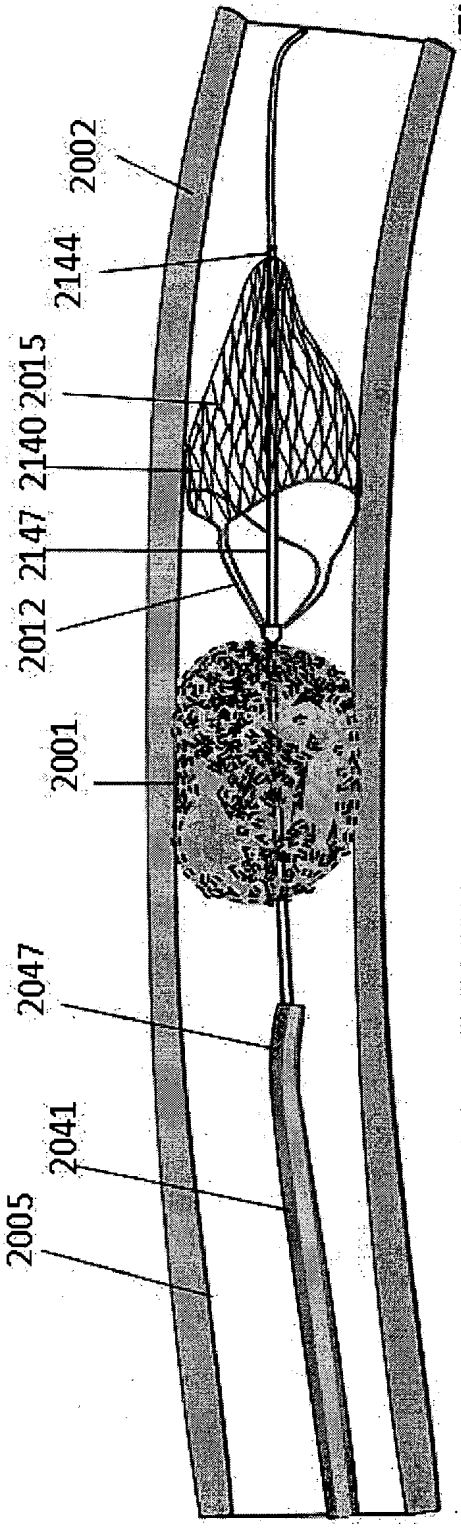


Fig. 80g

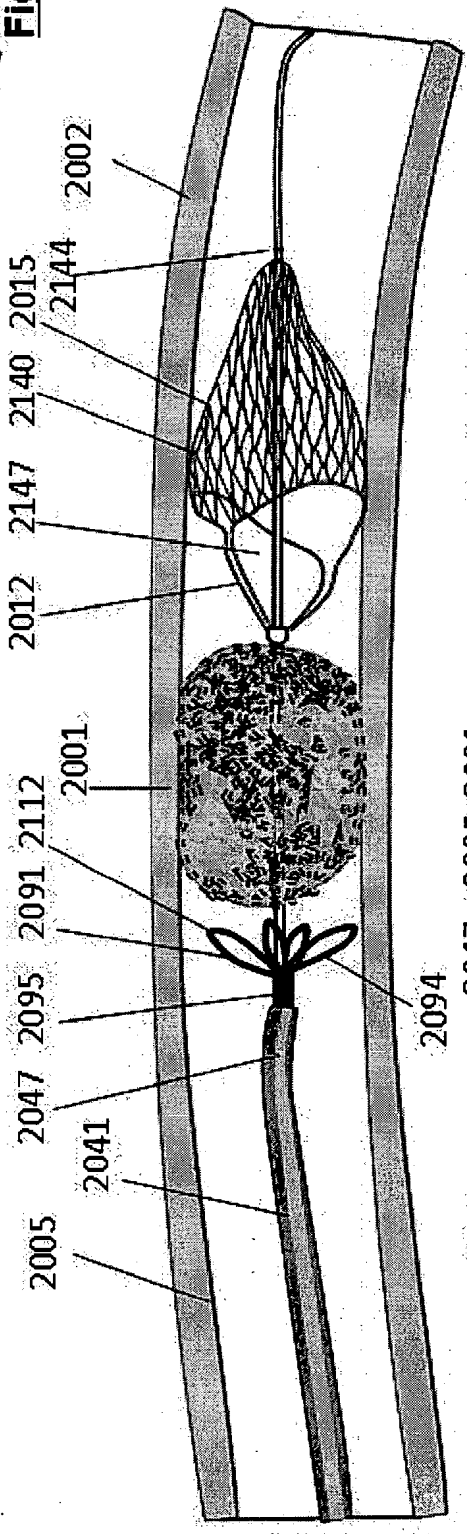


Fig. 80h

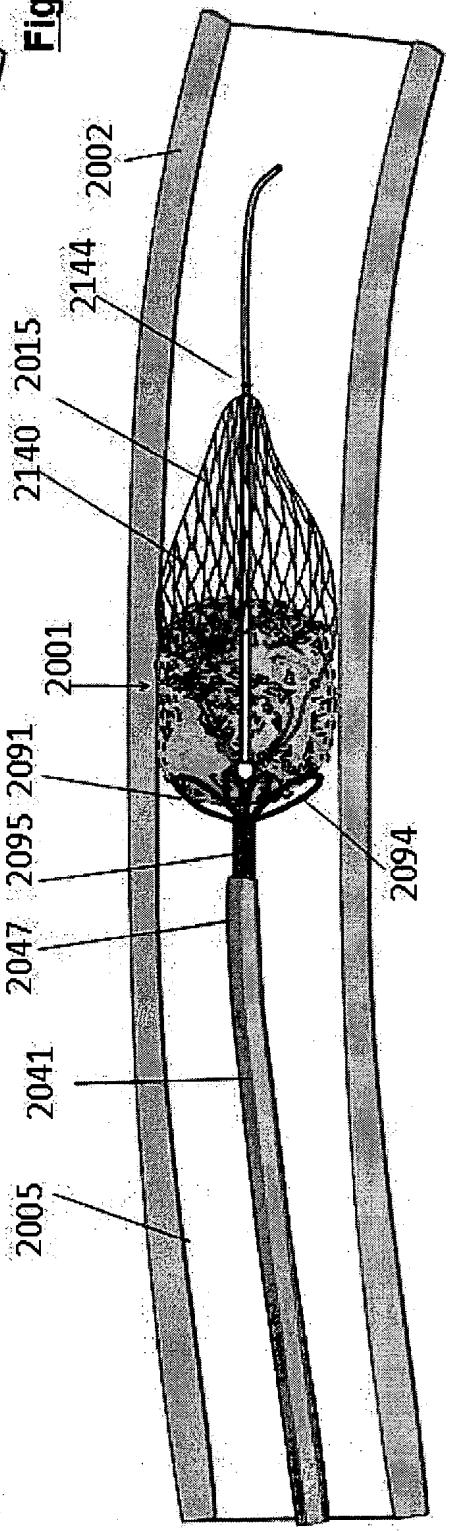


Fig. 80i

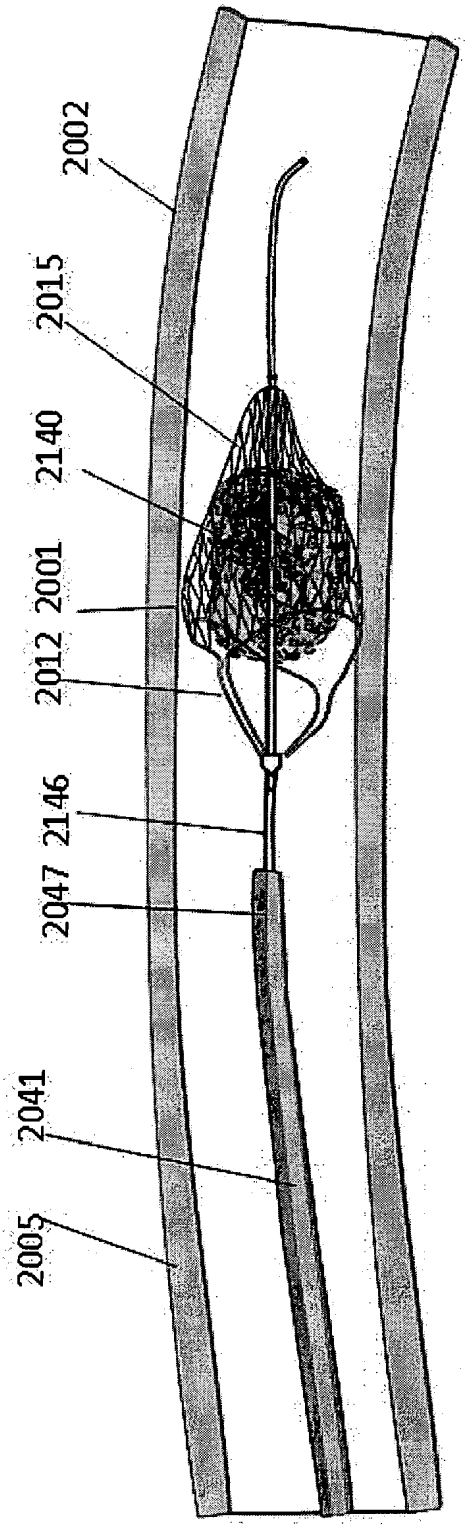


Fig. 80j

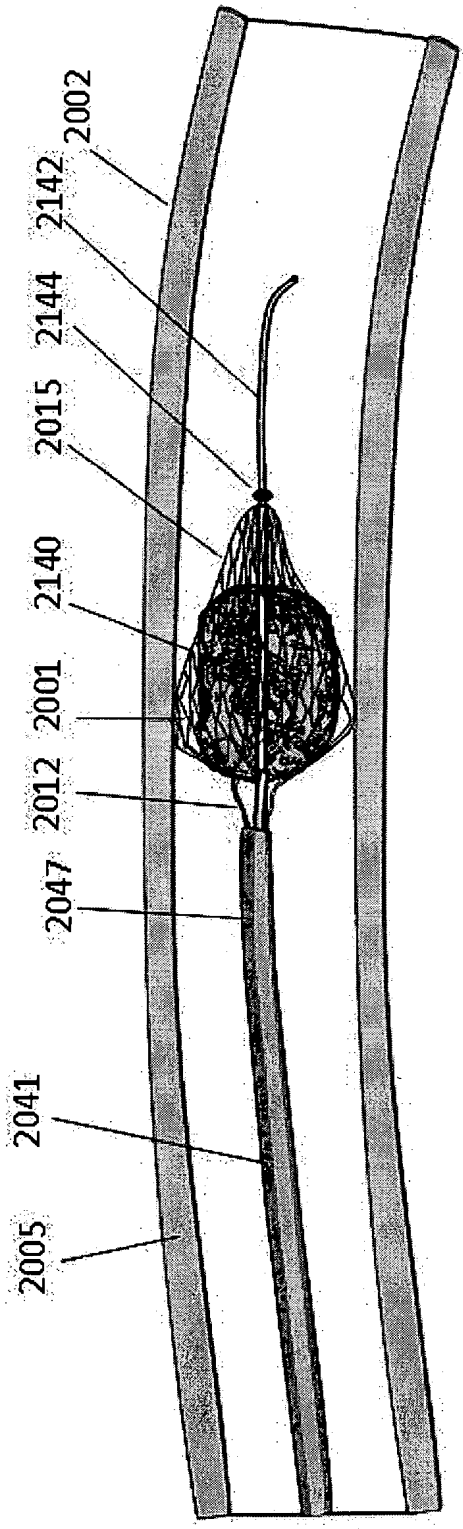


Fig. 80k

Fig. 80l

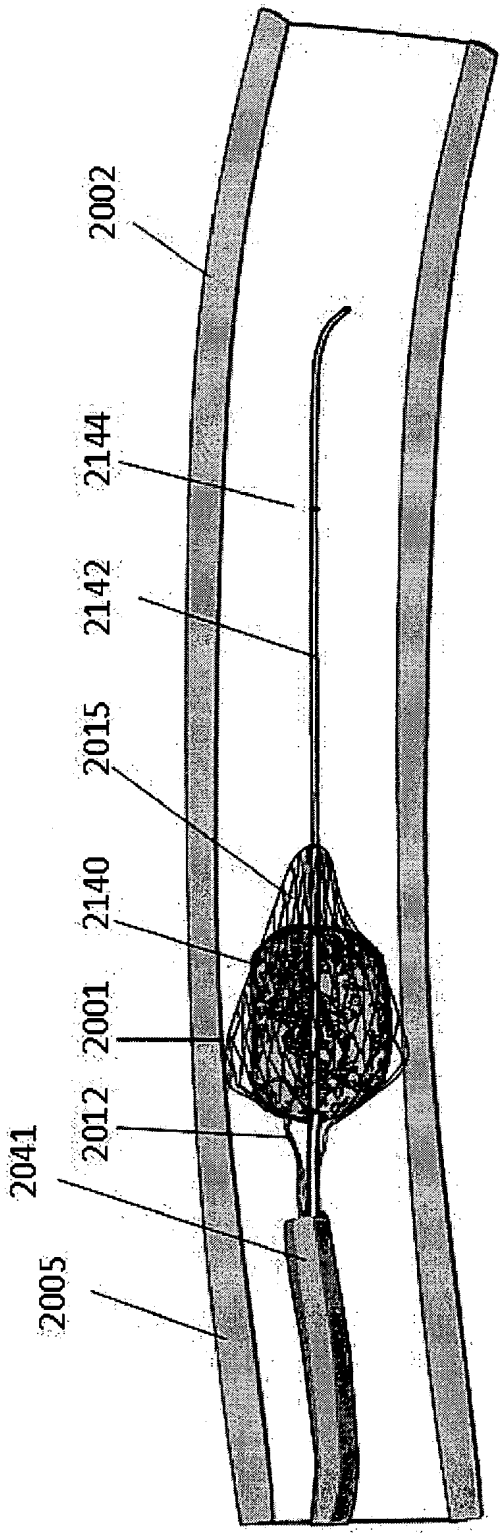
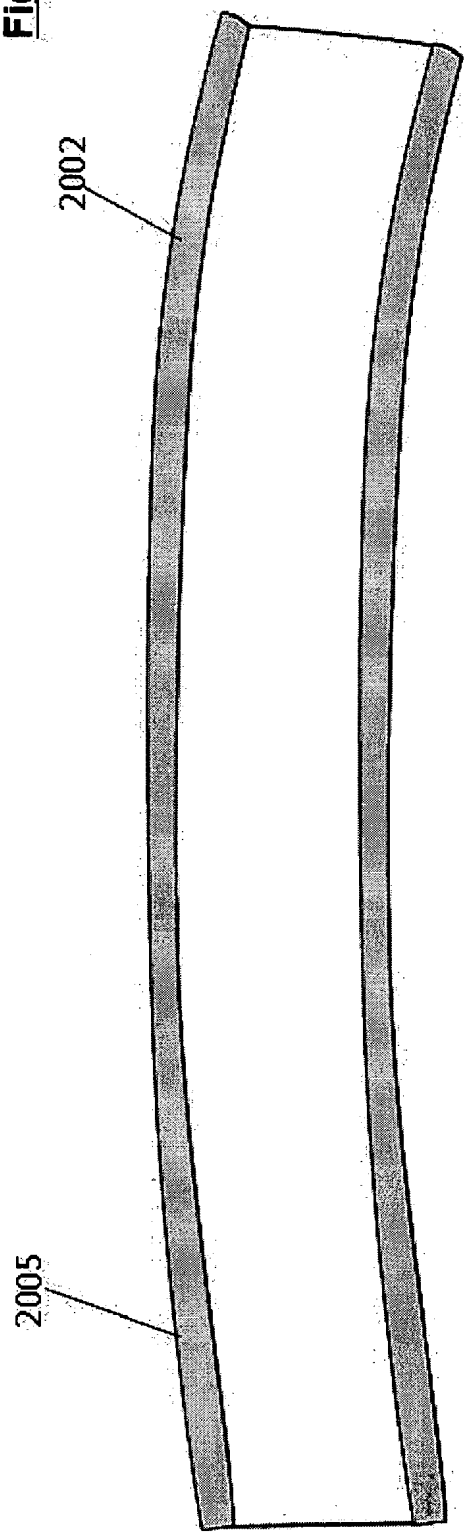


Fig. 80m



INTERNATIONAL SEARCH REPORT

International application No
PCT/IE2009/000051

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/221

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2008/034615 A (PHENOX GMBH [DE]; HANNES RALF [DE]; SCHNEIDER MANUEL [DE]; PRACHT HOLG) 27 March 2008 (2008-03-27)	1-3,5-8, 10,11, 13-19, 23,24
Y	figures 1-6,8,16	4,25-34
X	US 2007/225749 A1 (MARTIN BRIAN B [US] ET AL) 27 September 2007 (2007-09-27)	35-44
Y	figures 3D-3I paragraphs [0057], [0063]	25-34
Y	WO 2007/054307 A (PHENOX GMBH [DE]; MILOSLAVSKI ELINA [DE]; HANNES RALF [DE]; PRACHT HOL) 18 May 2007 (2007-05-18) figures 15a,b	4

-/--

[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 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
10 November 2009	20/11/2009

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

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/IE2009/000051

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2004/153118 A1 (CLUBB THOMAS L [US] ET AL) 5 August 2004 (2004-08-05) figures 1A-1C	1,34
P,X	WO 2009/086482 A (LAZARUS EFFECT INC [US]; MARTIN BRIAN B [US]; FOLLMER BRETT [US]; AGUI) 9 July 2009 (2009-07-09) figures 3G,5A-F,8A-F,12A-D	1-3,5, 7-11, 13-27, 35-37

2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IE2009/000051

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

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

1. [X] Claims Nos.: 45
because they relate to subject matter not required to be searched by this Authority, namely:

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

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

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

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

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

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

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

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

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

Remark on Protest

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

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

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IE2009/000051

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2008034615 A	27-03-2008	DE 102006044831 A1	03-04-2008
		EP 2094170 A2	02-09-2009
US 2007225749 A1	27-09-2007	US 2007185501 A1	09-08-2007
		US 2007197103 A1	23-08-2007
		US 2007198029 A1	23-08-2007
		US 2007198030 A1	23-08-2007
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		EP 1948042 A2	30-07-2008
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		US 2007198051 A1	23-08-2007
		WO 2004066826 A2	12-08-2004
WO 2009086482 A	09-07-2009	NONE	

Espacenet

Bibliographic data: JP2004097807 (A) — 2004-04-02

THROMBUS CAPTURING CATHETER

Inventor(s): ISSHIKI TAKAAKI; KATAISHI YUICHI; MIYAGAWA KATSUYA; KATAOKA HIDEAKI ± (ISSHIKI TAKAAKI, ; KATAISHI YUICHI, ; MIYAGAWA KATSUYA, ; KATAOKA HIDEAKI)

Applicant(s): NIPRO CORP ± (NIPRO CORP)

Classification: **- international:*A61B17/00; A61M1/34; B01D39/16;*** (IPC1-7): A61B17/00; A61M1/34; B01D39/16

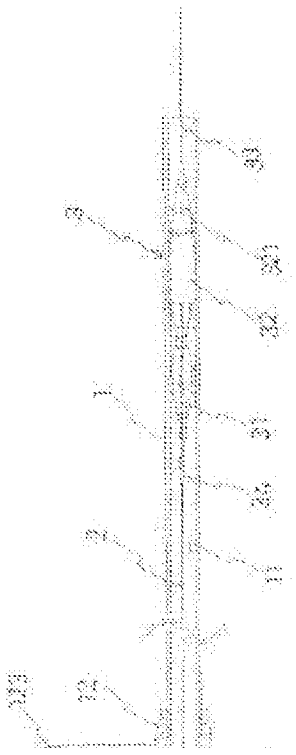
- cooperative:

Application number: JP20030294616 20030818

Priority number (s): JP20030294616 20030818 ; JP20020239678 20020820

Abstract of JP2004097807 (A)

PROBLEM TO BE SOLVED: To provide a thrombus capturing catheter which captures the thrombus, or the like, certainly so that a percutaneous angioplasty can be performed easily without interrupting the blood flow to a lesional periphery. ; SOLUTION: This thrombus capturing catheter includes a sheath 1 in which the proximal end of a lumen 11 is closed by a closing member 12, a flexible shaft 2 inserted in the lumen 11 in the sheath 1, and a thrombus capturing member 3 provided at the distal end portion of the shaft 2 and inserted in the distal end portion of the sheath 1. The thrombus capturing member 3 includes a crossing wire member 31, which is made with two or more wires 311 crossing spirally, converged at the distal end and the proximal end, and swollen at the





middle portion, and a filter 32 provided at the distal end side of this crossing wire member 31. The thrombus capturing member 3 is inserted in the sheath 1 as the contracted state while the distal end is slidably attached to the shaft 2 and the proximal end is fixed to the shaft 2. By this structure, when the sheath 1 is pulled to the proximal end side, the thrombus capturing member 3 comes out from the sheath 1 and expands. ; COPYRIGHT: (C)2004,JPO

(19)日本国特許庁(JP)　(12)公開特許公報(A)　(11)特許出願公開番号
特開2004-97807
(P2004-97807A)
(43)公開日　平成16年4月2日(2004.4.2)

(51)Int.Cl.[7]	F I		テーマコード（参考）
A61B 17/00	A61B 17/00	320	4C060
A61M 1/34	A61M 1/34	500	4C077
B01D 39/16	B01D 39/16	A	4D019

審査請求 未請求　請求項の数 6　OL　（全 12 頁）

(21)出願番号　特願2003-294616(P2003-294616)
(22)出願日　平成15年8月18日(2003.8.18)
(31)優先権主張番号　特願2002-239678(P2002-239678)
(32)優先日　平成14年8月20日(2002.8.20)
(33)優先権主張国　日本国(JP)

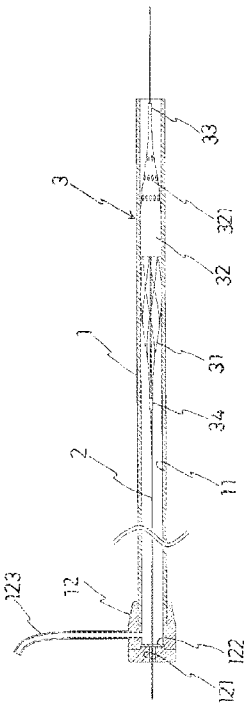
(71)出願人　000135036
ニプロ株式会社
大阪府大阪市北区本庄西３丁目９番３号
(72)発明者　一色　高明
東京都　世田谷区成城２－１６－１９
(72)発明者　片石　有一
横浜市金沢区六浦町９８３番地１９３
(72)発明者　宮川　克也
大阪市北区本庄西３丁目９番３号　ニプロ株式会社内
(72)発明者　片岡　秀彰
大阪市北区本庄西３丁目９番３号　ニプロ株式会社内

Ｆターム(参考)　4C060 EE21　MM25

最終頁に続く

(54)【発明の名称】血栓捕捉カテーテル

(57)【要約】
【課題】　血栓等を確実に捕捉することができ、病変部末梢側への血流を遮断することなく、経皮的血管形成術を容易に行うことのできる血栓捕捉カテーテルを提供する。
【解決手段】　血栓捕捉カテーテルは、ルーメン１１の基端が閉鎖部材１２で閉鎖されたシース１と、このシース１のルーメン１１に挿着された柔軟なシャフト２と、このシャフト２の先端部分に設けられ、シース１の先端部分に挿着された血栓捕捉部材３、とを含んでなる。血栓捕捉部材３は、複数のワイヤ３１１が螺旋状に交叉されてなる先端と基端が収束し中間が膨らんだ交叉ワイヤ部材３１と、この交叉ワイヤ部材３１の先端側に設けられたフィルター３２を含んでなり、その先端がシャフト２にスライド可能に取り付けられるとともに、基端がシャフト２に固定され、シース１に収縮状態で挿着されている。この構成により、シース１を基端側に引いたときに、血栓捕捉部材３がシース１の外に出て拡張する。
【選択図】　図１



【特許請求の範囲】
【請求項１】
基端から先端に貫通するルーメンを有し、該ルーメンの基端が閉鎖部材で閉鎖されたシースと、該シースのルーメンに進退自在に挿着された、先端と基端を有する柔軟なシャフトと、該シャフトの先端部分に設けられ、前記シースの先端部分に該先端から出し入れ可能に挿着された血栓捕捉部材、とを含んでなり、該血栓捕捉部材は、複数のワイヤが螺旋状に交叉されてなる、先端と基端が収束し中間の膨らんだ形状を有する交叉ワイヤ部材とを含んでなり、前記血栓捕捉部材は、先端が前記シャフトにスライド可能に取り付けられるとともに、基端が該シャフトに固定され、前記シースに収縮状態で挿着されており、該シースを基端側に引いたときに、前記血栓捕捉部材がシースの外に出て拡張するようにされてなる血栓捕捉カテーテル。
【請求項２】
交叉ワイヤ部材の膨らんだ中間部分を含む先端側に、孔を有するフィルターが設けられてなる請求項１記載の血栓捕捉カテーテル。
【請求項３】
フィルターの孔径が５０μｍ～１０００μｍ、好ましくは５０μｍ～５００μｍ、最も好ましくは１００μｍ～２００μｍである請求項２記載の血栓捕捉カテーテル。
【請求項４】
閉鎖部材の軸上にシャフトを挿通可能な孔が設けられるとともに、該孔に隣接して先端側に止血弁が設けられており、シャフトの基端側が該孔と止血弁を通してシースの外に突出されている請求項１～３の何れかに記載の血栓捕捉カテーテル。
【請求項５】
シースの先端側側壁にシャフトを挿通可能な側孔が設けられるとともに、シースの先端側に該側孔に連通しかつ血栓捕捉部材を挿入可能な第２のルーメンが形成され、血栓捕捉部材より基端側のシャフト部分が該側孔を通してシースの外に突出されている請求項１～３の何れかに記載の血栓捕捉カテーテル。
【請求項６】
閉鎖部材に側注チューブが設けられてなる請求項１～５のいずれかに記載の血栓捕捉カテーテル。
【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、冠動脈や頚動脈、静脈グラフトなどの血管狭窄部で経皮的血管形成術を行う際、遊離した血栓等を捕捉する血栓捕捉カテーテルに関する。
【背景技術】
【０００２】
従来より、冠動脈や頚動脈、静脈グラフトなどの血管狭窄部において、ステント、ＰＯＢＡ（Plain Old Balloon Atherectomy）等の経皮的血管形成術が行われている。この手術は、血管狭窄部でステント留置やバルーン拡張を行い、血流を確保する血行再建術の一つであり、所期の成果を挙げている。
【０００３】
しかしながら、上記の方法では、狭窄部を拡張したものの術中遊離したプラークや血栓などが病変部末梢側へ流れ、梗塞、No Reflow現象などをきたし、再　流が得られないことがある。そして、このような血栓等によって引き起こされる合併症は重篤なものが多い。
【０００４】
例えば、冠動脈において血栓が関与している不安定狭心症や急性心筋梗塞などでは、ステント留置やバルーン拡張により血栓が押し出され、病変部末梢側の血管が閉塞されることがある。その結果、心筋に十分な酸素や栄養が供給されなくなり、心筋壊死等の心筋障害を引き起こす。また、同様に、脳に血液を供給している血管が詰まると、所謂脳梗塞を

引き起こし脳組織が死んだ状態になる。特に頚動脈は動脈硬化により狭窄が起こりやすく、脳への血流が不足したり、狭窄部に生じた血栓により脳梗塞を引き起こしやすい。このような脳梗塞の症状としては、麻　、しびれ、失語症、意識障害などがあり、一度失ってしまった機能は、リハビリテーションをしても１００％の回復は見込めず、その後の患者の生活に大きな影響を与える。また、古く変成した静脈グラフト狭窄部には、多量の血栓が付着しているため注意が必要とされている。

【０００５】

このように、血栓による梗塞は重篤な合併症を引き起こすものであるため、経皮的血管形成術において病変部末梢側の保護が求められつつあり、既にGuard Wire(登録商標；特許文献１参照)やFilter Wire EX（登録商標；特許文献２参照）などのカテーテルデバイスが開発されている。

【０００６】

【特許文献１】特表２００１－５１４５４４号公報

【特許文献２】特表２００２－５０５１５１号公報

【０００７】

Guard Wireは、ガイドワイヤー先端部にバルーンを備えたものであり、その先端が病変部通過後、付属の装置でバルーンを拡張させて、ステント留置やＰＯＢＡを施行し、その後、付属の吸引装置を用いて血栓を吸引する。その際、病変部末梢側の血流は遮断されており、遊離した血栓の流出を防ぐことが出来る。しかしながら、術中、末梢側への血流を確保できず、虚血時間が長くなれば患者に与える影響が大きく、問題がある。また、バルーンの拡張、収縮のための専用装置が必要であり、操作が複雑になる、術者が特別なトレーニングを必要とするという問題もある。

【０００８】

また、Filter Wire EXは、ガイドワイヤー先端部にフィルターを設けたものであり、病変部末梢側の血流を確保しながら血栓を捕捉することができる。しかしながら、このものはガイドワイヤーがフィルターの中央に位置していないため、血管壁に均等に密着できず、血栓が末梢側へ流出する可能性が十分にある。

【０００９】

このようなわけで、ステント留置やＰＯＢＡの施行に際し、術中病変部末梢側への血流確保と、血栓等を確実に捕捉するための血管壁への高い密着性や、操作性の改良が渇望されている。

【発明の開示】

【発明が解決しようとする課題】

【００１０】

本発明は、如上の事情に鑑みてなされたもので、血栓等を確実に捕捉することができ、病変部末梢側への血流を遮断することなく、経皮的血管形成術を容易に行うことのできる血栓捕捉カテーテルを提供することを目的とする。

【課題を解決するための手段】

【００１１】

本発明者等は上記課題を解決するために、鋭意検討の結果、複数の螺旋状ワイヤが交叉されてなる部材であって、先端と基端が収束し中間の膨らんだ形状を有し、好ましくはこの膨らんだ中間部分を含む先端側にフィルターを設けたものを、血栓捕捉部材として採用すれば、術中病変部末梢側への血流確保と、血管壁への高い密着性をともに満足できることに想到し、本発明を完成した。すなわち、本発明は、

基端から先端に貫通するルーメンを有し、このルーメンの基端が閉鎖部材で閉鎖されたシースと、このシースのルーメンに進退自在に挿着された、先端と基端を有する柔軟なシャフトと、このシャフトの先端部分に設けられ、前記シースの先端部分にその先端から出し入れ可能に挿着された血栓捕捉部材、とを含んでなり、この血栓捕捉部材は、複数のワイヤが螺旋状に交叉されてなる、先端と基端が収束し中間の膨らんだ形状を有する交叉ワイヤ部材を含んでなり、前記血栓捕捉部材は、先端が前記シャフトにスライド可能に取り

付けられるとともに、基端がこのシャフトに固定され、前記シースに収縮状態で挿着されている。そして、このような構成により、本発明の血栓捕捉カテーテルでは、シースを基端側に引いたときに、血栓捕捉部材がシースの外に出て拡張する。

また、交叉ワイヤ部材の膨らんだ中間部分を含む先端側に孔を有するフィルターを設けることが好ましい。これにより小さな血栓の捕捉も可能である。フィルターの孔径は、５０ｕｍ～１０００ｕｍ、好ましくは５０ｕｍ～５００ｕｍ、最も好ましくは１００ｕｍ～２００ｕｍである。

また、シャフトの進退操作のためにシャフトをシースの外に出しておく必要がある。そのためには、閉鎖部材の軸上にシャフトを挿通可能な孔を設けるとともに、この孔に隣接して先端側に止血弁を設け、シャフトの基端側がこの孔と止血弁を通してシースの外に突出するようにしてもよく、また、シースの先端側側壁にシャフトを挿通可能な側孔が設けるとともに、シースの先端側に該側孔に連通しかつ血栓捕捉部材を挿入可能な第２のルーメンを形成し、血栓捕捉部材より基端側のシャフト部分がこの孔を通してシースの外に突出するようにしてもよい。

また、閉鎖部材に側注チューブを設け、血液の凝固を防ぐためのヘパリンなどを注入できるようにしてもよい。

【発明の効果】

【００１２】

本発明を採用することにより、血栓等を確実に捕捉することができ、病変部末梢側への血流を遮断することなく、経皮的血管形成術を容易に行うことができる。

さらに、血栓捕捉性能は、ワイヤが直線状であると血液と触れる部分はワイヤのテーパー状の外側一部分（ワイヤ径とワイヤの本数に依存）だけとなるが、ワイヤが螺旋状であるため血液と触れる部分はワイヤのテーパー状の外側一部分だけでなくテーパー状内側も含まれ、より接触面積が大きくなり多くの血栓を捕捉することが可能となる。

加えて、血管密着性は、ワイヤが螺旋状であるため血管壁に（屈曲部では特に）より柔軟に（組織に優しく）密着することが可能となる。その密着により、血流等による位置ズレも起こり難くすることができる。

【発明を実施するための最良の形態】

【００１３】

次に、本発明の実施例について、図面を用いて説明する。

図１は本発明の一実施例を示す説明図であり、図２は本発明の他の実施例を示す説明図、図３は本発明における血栓捕捉部材の一実施例を示す平面図、図４は図２、図３における血栓捕捉部材を含む先端部分の拡大図、図５は図３のＡ－Ａ線拡大断面図、図６は血栓捕捉部材を含む先端部分の他の実施例を示す図である。また、図７～１２は本発明の血栓捕捉カテーテルを用いた経皮的血管形成術の説明図、図１３は本発明の更に他の実施例を示す先端部分の拡大図である。

本発明の血栓捕捉カテーテルは、図１～図４に示す様に、ルーメン１１の基端が閉鎖部材１２で閉鎖されたシース１と、このシース１のルーメン１１に挿着された柔軟なシャフト２と、このシャフト２の先端部分に設けられ、シース１の先端部分に挿着された血栓捕捉部材３、とを含んでなる。血栓捕捉部材３は、複数のワイヤ３１１が螺旋状に交叉されてなる先端と基端が収束し中間が膨らんだ交叉ワイヤ部材３１と、この交叉ワイヤ部材３１の先端側に設けられたフィルター３２を含んでなり、その先端がシャフト２にスライド可能に取り付けられるとともに、基端がシャフト２に固定され、シース１に収縮状態で挿着されている。この構成により、シース１を基端側に引いたときに、血栓捕捉部材３がシース１の外に出て拡張するようになっている。

【００１４】

シース１は、ポリウレタンやポリエステル、ポリエチレン、フッ素樹脂等のプラスチックで形成された管状部材であって、基端から先端に貫通するルーメン１１を有しており、このルーメン１１の基端はシース１の基端に設けられた閉鎖部材１２で閉鎖されている。

閉鎖部材１２は、ポリプロピレンやＡＢＳ樹脂、ポリ塩化ビニル、ポリエチレン、ポリ

エチレンテレフタレート等のプラスチックや、ステンレス鋼や真　などの金属で形成された管状部材であり、その先端開口部にシース１が挿着されている。閉鎖部材１２の基端は閉鎖されているが、シャフト２の進退操作のためシャフト２をシース１の外に出しておく必要がある。シャフト２をシース１の外に出すためには、図１に示すように、閉鎖部材１２の基端の軸上にシャフト２を挿通可能な孔１２１を設けるとともに、この孔１２１に隣接して先端側に止血弁１２２を設け、シャフト２の基端側がこの孔１２１と止血弁１２２を通してシース１の外に突出するようにしてもよい。また、図２に示すように、シース１の先端側側壁にシャフト２を挿通可能な側孔１８を設けるとともに、シース１の先端側にこの側孔１８に連通しかつ血栓捕捉部材３を挿入可能な第２のルーメン１４を形成し、血栓捕捉部材３より基端側のシャフト２部分がこの側孔１８を通してシース１の外に突出するようにしてもよい。

また、閉鎖部材１２には、側注チューブ１２３を設け、血液の凝固を防ぐためのヘパリンなどを注入できるようにしてもよい。

但し、側注チューブ１２３を閉鎖部材１２に設けていない場合には、第２のルーメン１４を設ける必要はない。

【００１５】

シース１にはシャフト２およびこのシャフト２の先端部分に設けられた血栓捕捉部材３が挿着されている。

シャフト２は、ステンレス鋼やニッケルーチタン合金などの可　性を有する金属で形成された線状部材であり、図２に示すように変形してシース１の側孔１８を通過する程度の柔軟性を有している。シャフト２としては、経皮的血管形成術に使用するガイドワイヤーを採用しても良い。シャフト２の先端部分にはシャフト２を囲　して血栓捕捉部材３が設けられており、血栓捕捉部材３は、基端がシャフト２に固定され、先端がシャフト２にスライド可能に取り付けられている。

シャフト２の先端部には、シース１とシャフト２の間の段差を無くすために、血栓捕捉部材３に近接して先端側に、図６に示すような円錐状部材２１を設けてもよい。この円錐状部材２１は、基端側がシース１と同等の外径を有し、先端側に縮径する部材であって、これにより、病変部に対して血栓捕捉カテーテルをスムーズに通過させることが可能になる。円錐状部材２１の形成材料としては、生体適合材料が好ましく、後述のフィルター３２と同様の材料が採用可能である。

【００１６】

血栓捕捉部材３は、シース１の先端部分にその先端から出し入れ可能に挿着されており、複数のワイヤ３１１が螺旋状に交叉されてなる先端と基端が収束し中間の膨らんだ形状を有する交叉ワイヤ部材３１と、この交叉ワイヤ部材３１の膨らんだ中間部分を含む先端側に設けられたフィルター３２を含んでなる。ここで、フィルターの孔径は、５０μｍ～１０００μｍ、好ましくは５０μｍ～５００μｍ、最も好ましくは１００μｍ～２００μｍである。フィルターの孔径が５０μｍ未満だと血液の流れが妨げられ、１０００μｍを超えるとフィルターを設ける意義がなくなる。なお血栓捕捉部材３は、図１３に示すように、フィルターを設けず複数のワイヤー３１１のみからなっていてもよい。血栓が大きい場合、この複数のワイヤ３１１の編み目で血栓を捕捉することが可能である。なお、この場合の複数のワイヤの本数は、８～１６本好ましくは８～１４本、最も好ましくは８～１２本である。

【００１７】

血栓捕捉部材３は、先端にスライドリング３３を備え基端に固定リング３４を備えており、このスライドリング３３と固定リング３４により、その先端がシャフト２にスライド可能に取り付けられるとともに、基端がシャフト２に固定されている。血栓捕捉部材３（シース１に挿着される前は図３に示すような拡張状態になっている）は、図４に示すようにその全体がシース１に収縮状態で挿着されており、シース１を基端側に引いたときに、血栓捕捉部材３がシース１の外に出て拡張するようになっている。

ワイヤ３１１の形成材料としては、形状記憶合金が採用可能であり、一般にＮｉ－Ｔｉ

系合金、Ｃｕ－Ｚｎ－Ａｌ系合金、Ｃｕ－Ａｌ－Ｎｉ系合金等が採用される。ワイヤ３１１の形成材料として形状記憶合金を採用した場合、血栓捕捉部材３（正確には複数のワイヤ３１１が螺旋状に交叉されてなる部材）は、通常、図３に示すような形状（復元形状）に記憶されている。血栓等が多い病変部に適用するために、血栓をより多く捕捉可能な様に、血栓捕捉部材３をより長く形成してもよい。

尚、血栓捕捉部材３の外径は、特に限定するものではないが、３．０、３．５、４．０、４．５、５．０、５．５、６．０、６．５、７．０、７．５、８．０ｍｍの外径を有するものが採用され、病変部の血管径に応じて使い分けるようにするのが好ましい。

【００１８】

フィルター３２は、好ましくは生体適合性材料の、例えばポリウレタンや、ポリエチレン、ポリエステル、ポリプロピレン、ポリアミド、ポリテトラフルオロエチレン、ポリフッ化ビニリデン等の合成樹脂からなる不織布または織編物から形成された、図３に示すような漏斗状（限定するものではない）の部材であり、基端側の膨部３２１と先端側の収束部３２２からなり、膨部３２１の収束部３２２への移行部分には、血栓等を捕捉するが体液は透過することのできる大きさの複数の孔３２３が設けられている。フィルター３２は、複数のワイヤ３１１が螺旋状に交叉されてなる部材の膨らんだ中間部分を含む先端側に被覆されており、少なくともその膨部３２１は交叉ワイヤ部材３１に糸などで結束されており、収束部３２２の先端は後述のスライドリング３３に隣接している。フィルター３２を複数のワイヤ３１１が螺旋状に交叉されてなる交叉ワイヤ部材３１の復元形状にディッピング成形し、その後、血栓等を捕捉するが体液は透過することのできる大きさの孔を複数穿ち、複数のワイヤ３１１が螺旋状に交叉されてなる部材に被覆してもよい。

【００１９】

図５は図３のＡ－Ａ線拡大断面図であり、スライドリング３３とシャフト２の関係を示している。スライドリング３３は、内側リング３３１と外側リング３３２からなり、ワイヤ３１はこの２つのリング３３１、３３２の間に挟まれる様に構成されており、シャフト２は内側リング３３１にスライド可能に挿着されている。リング３３１、３３２は、ステンレス鋼等の金属から形成されており、リング３３１、３３２と複数のワイヤ３１１の接着にはCO_2レーザー、ＹＡＧレーザー等のレーザー溶接機を用いたスポット溶接や圧着などが採用可能である。

特に図示はしないが、固定リング３４もスライドリング３３と同様の構成をしており、シャフト２は内側リング３３１に固定されている。シャフト２と固定リング３４を固定するには、スライドリング３３と同様の方法で接着すればよい。ここで、固定リング３４はシャフト２に対して回動可能に設けてもよい。この場合、固定リング３４をシャフト２と接着せず、例えば固定リング３４の両端に極近接してシャフト２に環状リブ（図示していない）を設けるなどの方法が採用可能である。

【００２０】

次に、本発明の血栓捕捉カテーテルを用いた経皮的血管形成術について図面（図７～１２）を用いて説明する。

先ず、図１に示すような血栓捕捉カテーテルＣを用意し、これを目的とする血管付近に予め留置したガイディングカテーテル（図示していない）に挿入する。次に、シャフト２の先端部を血管狭窄部ＴＥまで導入し（図７参照）、次いで血栓捕捉部材３が収縮状態で収納されているシース１の先端部も血管狭窄部ＴＥの末梢側まで挿入する（図８参照）。シャフト２を固定した状態でシース１を基端側（手前）に引くと、血栓捕捉部材３がシース１のルーメン１１から出て復元形状に拡張し、血管壁ＶＷに密着する（図９参照）。次に、シース１をガイディングカテーテルから抜去し、別途用意したバルーンカテーテル４をシャフト２に沿って血管狭窄部ＴＥまで挿入する（図１０参照）。バルーン４１を拡張し、その際遊離した血栓を血栓捕捉部材で捕捉する（図１１参照）。バルーン４１による血管拡張後、バルーンカテーテル４をガイディングカテーテルから抜去し、シャフト２を固定した状態でシース１を先端側に押し出すと、血栓捕捉部材３は再びシース１内に収納される（図１２参照）。最後に血栓捕捉カテーテルＣをガイディングカテーテルと一緒に

抜去すれば、経皮的血管形成術が完了する。

【図面の簡単な説明】

【００２１】

【図１】本発明の一実施例を示す説明図である。

【図２】本発明の他の実施例を示す説明図である。

【図３】本発明における血栓捕捉部材の一実施例を示す平面図である。

【図４】図２、図３における血栓捕捉部材を含む先端部分の拡大図である。

【図５】図３のＡ－Ａ線拡大断面図である。

【図６】血栓捕捉部材を含む先端部分の他の実施例を示す図である。

【図７】本発明の血栓捕捉カテーテルを用いた経皮的血管形成術の説明図である。

【図８】本発明の血栓捕捉カテーテルを用いた経皮的血管形成術の説明図である。

【図９】本発明の血栓捕捉カテーテルを用いた経皮的血管形成術の説明図である。

【図１０】本発明の血栓捕捉カテーテルを用いた経皮的血管形成術の説明図である。

【図１１】本発明の血栓捕捉カテーテルを用いた経皮的血管形成術の説明図である。

【図１２】本発明の血栓捕捉カテーテルを用いた経皮的血管形成術の説明図である。

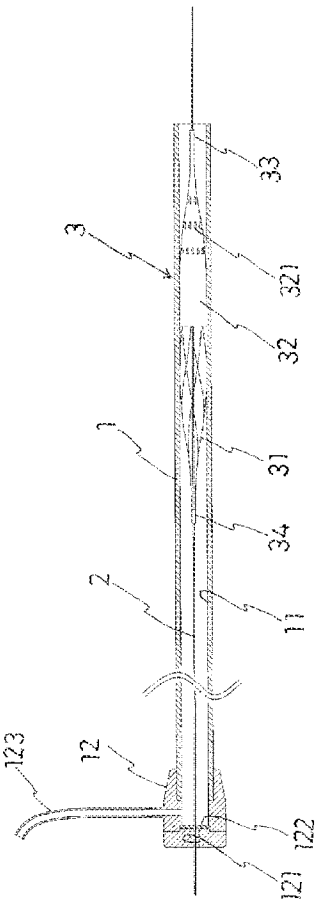
【図１３】本発明の更に他の実施例を示す部分拡大図である。

【符号の説明】

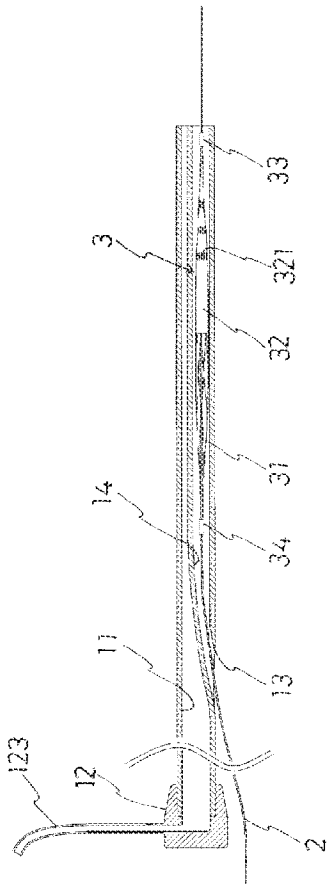
【００２２】

１　シース
１１　ルーメン
１２　閉鎖部材
１２１　孔
１２２　止血弁
１２３　側注チューブ
１３　側孔
１４　第２のルーメン
２　シャフト
２１　円錐状部材
３　血栓捕捉部材
３１　交叉ワイヤ部材
３１１　ワイヤ
３２　フィルター
３２１　膨部
３２２　収束部
３２３　孔
３３　スライドリング
３３１　内側リング
３３２　外側リング
３４　固定リング
４　バルーンカテーテル
４１　バルーン
Ｃ　血栓捕捉カテーテル
ＶＷ　血管壁
ＴＥ　血管狭窄部

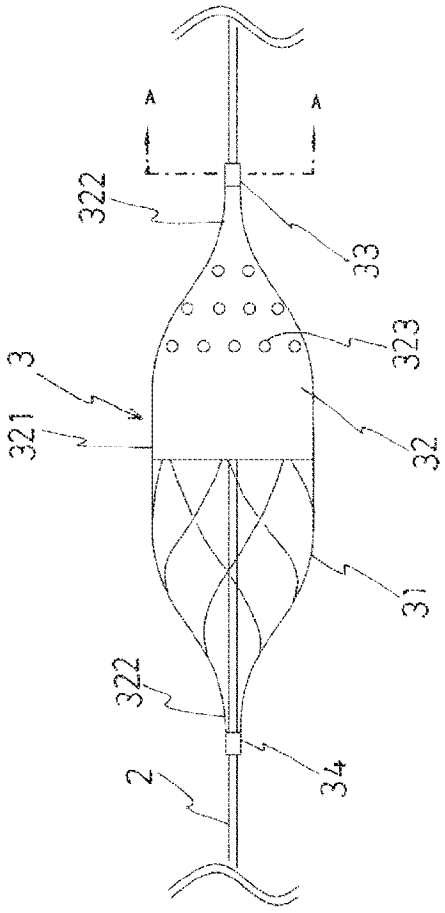
【図１】


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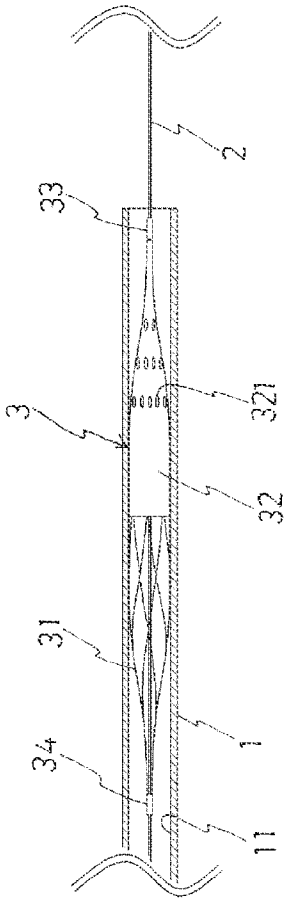
【図２】


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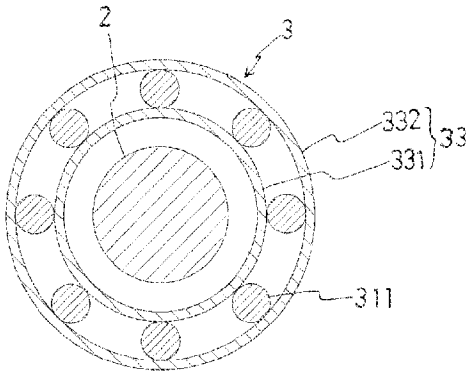
【図３】


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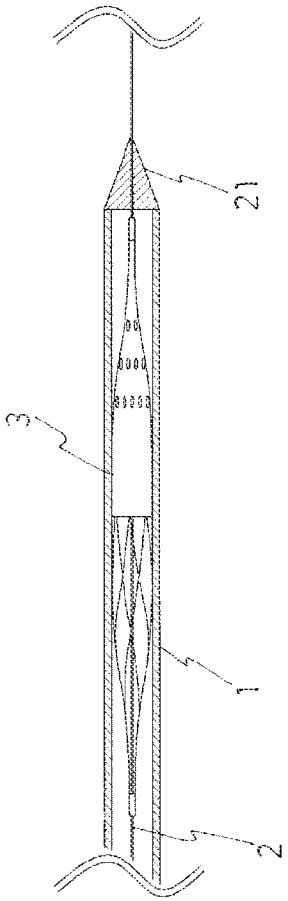
【図４】


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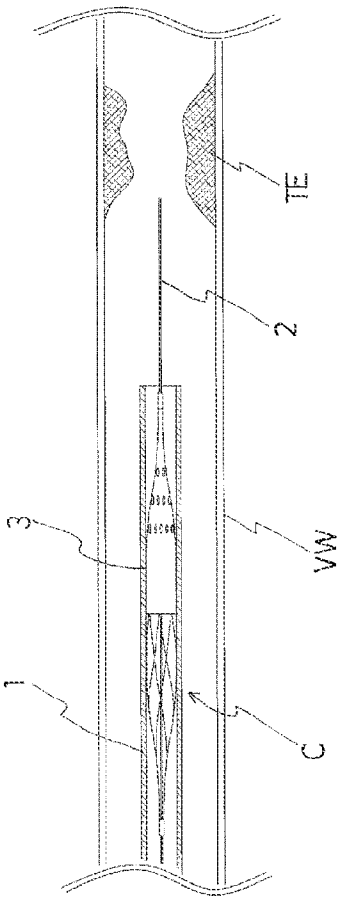
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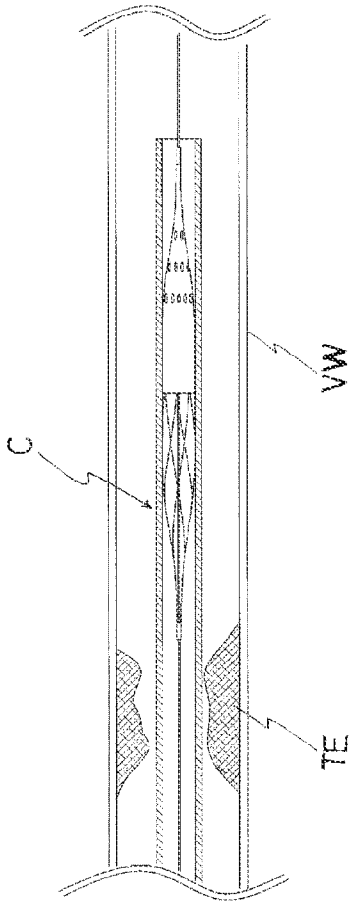
【図６】



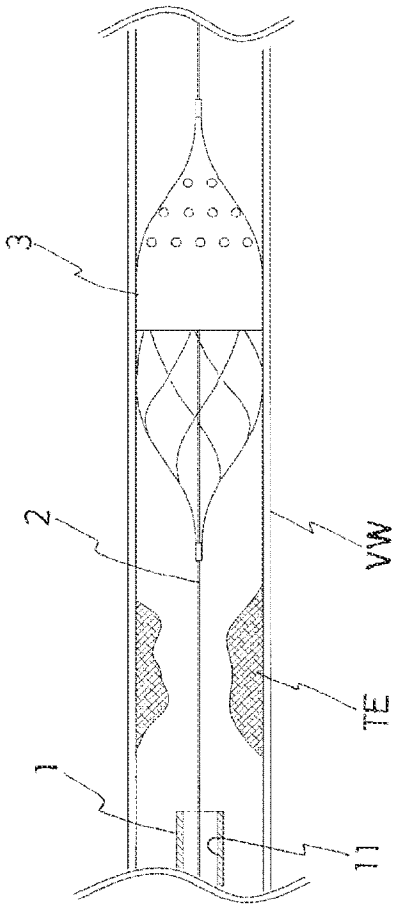
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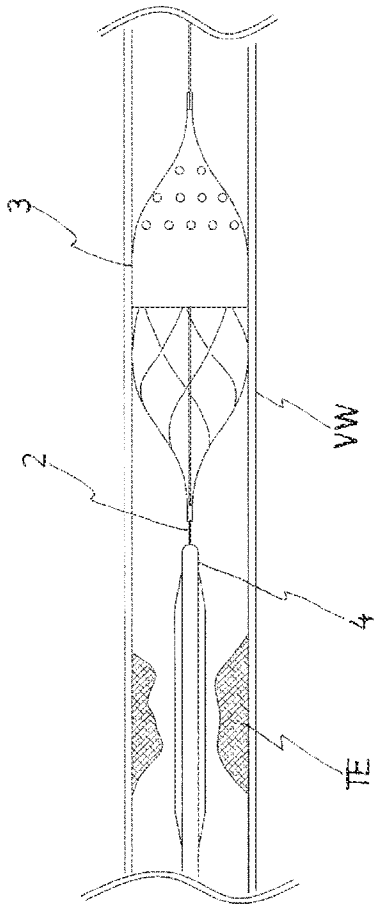
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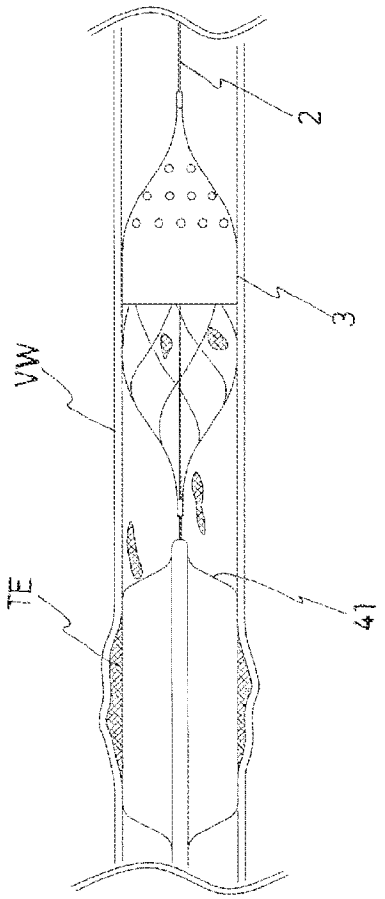
【図９】



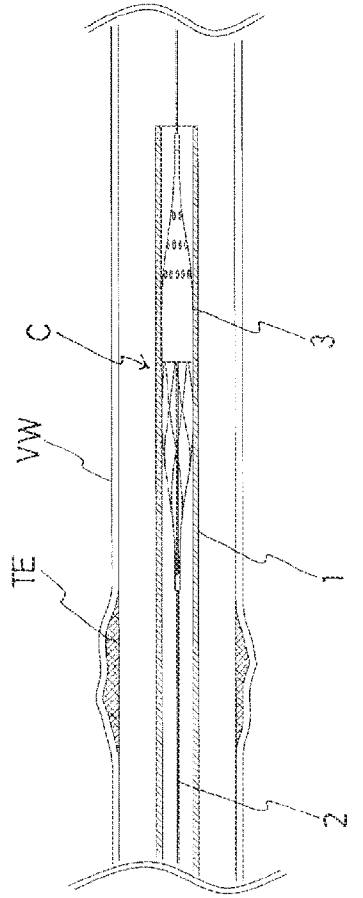
【図１０】



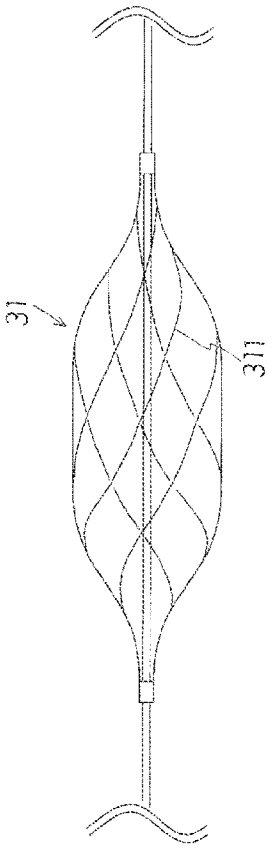
【図１１】



【図１２】



【図１３】



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(71) Applicant *(for all designated States except US)*: MICROVENA CORPORATION [US/US]; 1861 Buerkle Road, White Bear Lake, MN 55110-5246 (US).

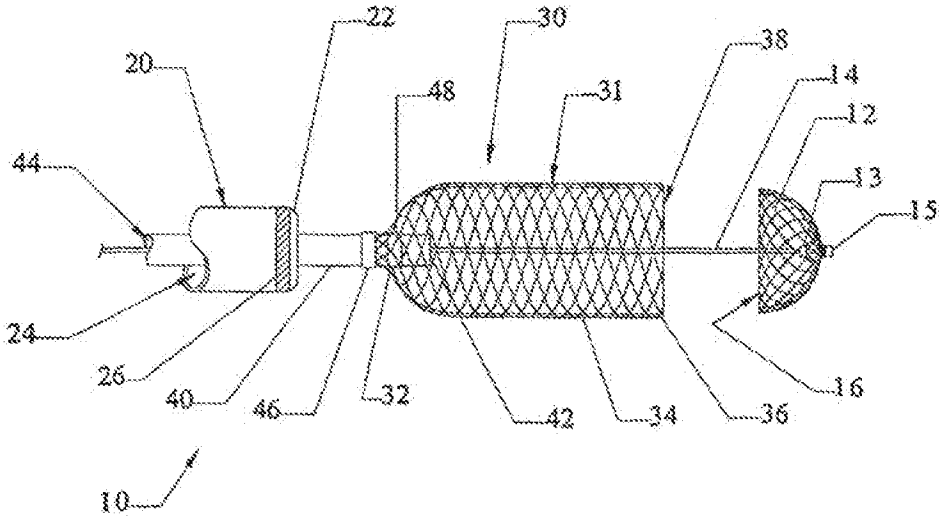
(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: KUSLEIKA, Richard, S. [US/US]; 18188 Ullmann Circle, Eden Prairie, MN 55346 (US). NGUYEN, Duy [US/US]; 1861 Buerkle Road, White Bear Lake, MN 55110-5246 (US). ANDERSON, Kent [US/US]; 1861 Buerkle Road, White Bear Lake, MN 55110-5246 (US).

(74) Agents: HOTCHKISS, Edward, S. et al.; Fredrikson & Byron, P.A., 1100 International Centre, 900 2nd Avenue South, Minneapolis, MN 55402-3397 (US).

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(57) Abstract

The present invention provides a medical device retrieval system comprising a working element carried by a flexible, elongate shaft, the working element having a proximal profile and the shaft extending proximally from the working element and a retrieval cover slidably carried along the shaft of the medical device, the cover having a deployed configuration and being capable of being compressed into a compressed configuration for deployment, yet resiliently substantially return to the deployed configuration; the cover in its deployed configuration having a radially reduced proximal portion, a distally open distal end defining a distal opening having a maximum dimension at least as great as the maximum dimension of the proximal profile of the working element of the medical device, and an elongate internal recess defined between the proximal portion and the distal end.

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MINIMALLY INVASIVE MEDICAL DEVICE DEPLOYMENT AND RETRIEVAL SYSTEM

FIELD OF THE INVENTION

The present invention generally relates to minimally invasive surgical procedures, e.g., angioplasty and atherectomy procedures, and has particular utility in connection with retrieving a medical device which has already been deployed. In one embodiment, the invention provides a vascular filter which can be retrieved with minimal risk of dumping the entrained contents back into the patient's bloodstream.

BACKGROUND OF THE INVENTION

In some medical procedures, a minimally invasive medical device is used to capture or dislodge material from within a patient's vascular system or other body vessel. For example, in certain procedures, balloon catheters are positioned such that the deflated balloon is placed distally of a vascular occlusion. Typically these vascular occlusions are relatively soft, uncalcified deposited along the walls of an artery. The balloon then may be inflated and drawn proximally. This will tend to dislodge any atheromatous material and withdraw it proximally with the balloon. In current procedures, an aspiration catheter will be moved distally into position adjacent the balloon and will be used to aspirate the dislodged material from the vessel.

A number of other minimally invasive surgical procedures are being used to treat vascular occlusions. These procedures include rotational atherectomy and balloon angioplasty. With the increasing use of vascular stents, it has been discovered that tissue or other material may build up inside a stent, reducing the patency of the vessel through the stent. In the course of improving the patency of the blood vessel utilizing these techniques, there is a risk that the material which was formally causing the obstruction within the vessel can simply float downstream with the flow of blood to the vessel. Accordingly, there is an

increasing recognition of the value of taking steps to capture the dislodged material.

A number of researchers have proposed various traps or filters for capturing the particulate matter or other embolic particles let loose in such procedures. Some filters are permanently implanted within the vessel. Emboli trapped within the filter are either aspirated out of the interior of the filter or are dissolved using drugs. Other filters are intended to be temporary in nature, typically being removed after the angioplasty, atherectomy or other procedure is complete. Generally, the goal is to retract the filter with the thrombi trapped therein. Unfortunately, many designs of such temporary filters may get relatively difficult or complex to retract the trap back in to the catheter through which it was delivered without simply dumping the trapped thrombi back in to the bloodstream.

One particularly advantageous vascular filter is shown in co-pending U.S. Patent Application No. 08/272,425, and International Patent Application No. PCT/US95/08613, which was published as International Publication No. WO 96/01591, the teachings of which are specifically incorporated herein by reference.

Figures 11-16 of WO 96/01591 are attached hereto as Figures 1-6 of the present application. Figure 1 is a vascular trap which is suitable for use in temporarily filtering embolic particles and the like from blood passing through a patient's vascular system. This device would most frequently be used to filter emboli from a patient's blood when another medical procedure is being performed, such as by using the trap in conjunction with a rotating cutting blade during an atherectomy, with a balloon catheter during angioplasty, or with a device used to clear the lumen of a stent during a stent cleaning procedure. It is to be understood, though, that the trap could also be used in other similar applications, such as in channels in patient's bodies other than their vascular systems.

The vascular trap 250 of Figures 1A and 1B comprises a generally umbrella-shaped basket 270 carried adjacent a distal end of a guidewire 260. The guidewire in this embodiment includes a tapered distal section 262 with a spirally wound coil 264 extending a distal length of the wire. Guidewires having such a distal end are conventional in the art. The basket 270 is positioned generally distally of the coil 264, and is desirably attached to the guidewire approximately with the proximal end of the tapered section as shown in these drawings.

The basket 270 of the device shown in WO 96/01591 (shown in its collapsed configuration in Figure 1A) includes a distal band 272 and a proximal band 274. The distal band may be made of a radiopaque material, such as gold, platinum or tungsten, and is affixed directly to the shaft of the guidewire 260. This attachment may be made by any suitable means, such as by welding, brazing or soldering. Alternatively, the distal band 272 may comprise a bead of a biocompatible cementitious material, such as a curable organic resin. WO 96/01591 teaches that a radiopaque metal or the like can be imbedded in the cementitious material to increase the visibility of the band for fluoroscopic observation. The proximal band 274 may be formed of a hypotube sized to permit the tube to slide along the guidewire during deployment. The inventors of that prior application suggest that the hypotube be made of a metallic material; a thin-walled tube of a NiTi alloy should suffice. If so desired, the proximal band may be formed of a more radiopaque metal, or a NiTi alloy band can have a radiopaque coating applied to its surface.

As taught in some detail in WO 96/01591, the basket 270 taught therein is formed of a metal fabric. The metal fabric of this embodiment is optimally initially formed as a tubular braid and the ends of the wires forming the braid can be attached together by means of the bands 272, 274 before the fabric is cut to length. These bands 272, 274 will help prevent the metal fabric from unraveling during the forming process. (The method of forming the basket 270 is described in great detail in WO 96/01591 and this process is still believed to provide a

suitable means for creating such a basket. The process is also discussed briefly below in connection with Figure 6.)

When the device is in its collapsed state for deployment in a patient's vessel (as illustrated in Figure 1A), the basket 270 of this device is said to be collapsed toward the axis of the guidewire 260. The distal 272 and proximal 274 bands are spaced away from one another along the length of the guidewire, with the fabric of the device extending therebetween. This publication teaches it is preferred that the basket is in its collapsed engages the outer surface of the guidewire to permit the device to be deployed through a relatively small lumen of a catheter or another medical device.

When the device is deployed in a patient's vascular system, the basket will take on an expanded configuration wherein it extends outwardly of the outer surface of the guidewire. As best seen in Figure 1B, the shape of the basket 270 when deployed may generally resemble a conventional umbrella or parachute, having a dome-like structure curving radially outwardly from the guidewire moving proximally from the distal band 272. It is to be understood that other suitable shapes could easily perform the desired filtering function, such as a conical shape wherein the slope of the device changes more linearly than the smooth, rounded version shown in Figure 1B. A relatively flat, disc shape may also suffice, but it is preferred that the device have a cavity or recess (discussed below) to better retain emboli or other material captured thereby. In this expanded configuration, the two bands 272, 274 are closer together, with the distal band 272 optimally being spaced only a short distance from the proximal band 274, as illustrated.

In moving from its collapsed state (Figure 1A) to its expanded state (Figure 1B), the metal fabric of this device turns in on itself, with a proximal portion 282 of the collapsed basket being received within the interior of a distal portion 284 of the collapsed basket. This produces a two-layered structure having a proximal lip 286 spaced radially outwardly of the guidewire, defining a proximally-facing cup-shaped cavity 288 of the basket. When blood (or any other fluid) flows through the basket in a distal direction, any particulate matter in

the blood, e.g. emboli released into the bloodstream during atherectomy or angioplasty procedures, will tend to be trapped in the cavity 288 of the basket.

WO 96/01591 teaches that the precise dimensions of the metal fabric can be varied as desired for various applications. If the device 250 is to be used as a vascular filter to trap emboli released into the blood, for example, this reference teaches that the pores (i.e. the openings between the crossing metal strands) of the fabric are desirably on the order of about 1.0 mm. These inventors deemed this to be the minimum size of any particles which are likely to cause any adverse side effects if they are allowed to float freely within a blood vessel. They teach that the pores should not be too small, though, because the blood (or other fluid) should be free to pass through the wall of the basket 270. If so desired, the basket may be coated with a suitable anti-thrombogenic coating to prevent the basket from occluding a blood vessel in which it is deployed.

When a fabric having 1.0 mm pores is used to form this basket 270, the forming process reorients the wires relative to one another and in some areas (e.g. adjacent the proximal lip 286) the pores tend to be larger than 1.0 mm. However, because the basket's walls are formed of essentially two thicknesses 282, 284 of the fabric, the effective pore size of the device may be significantly reduced even at these locations.

The device 250 of Figures 11 is also provided with tethers 290 for collapsing the basket 270 during retraction. The basket may include four independent tether wires, each of which extends proximally from the proximal lip 286 of the deployed basket. The authors suggested, though, that the four tether wires illustrated in the drawings be formed of two longer wires, with each wire extending peripherally about a portion of the proximal lip of the basket. These tether wires may be intertwined with the wires of the metal fabric to keep the tethers in place during use. When such tethers are retracted or drawn down toward the guidewire, the wires extending along the proximal lip of the basket will tend to act as drawstrings, drawing the proximal end of the basket radially inwardly toward the guidewire. This tends to close the basket and entrap any

material caught in the cavity 288 of the basket during use so that the basket can be retracted without the use of a cover.

The tether wires 290 may extend along much of the length of the guidewire so that they will extend outside the patient's body during use of the device 250. When it is desired to collapse the basket for retrieval, the operator can simply hold the guidewire 260 steady and retract the tethers with respect to the guidewire. This can tend to be relatively cumbersome, though, and may be too difficult to effectively accomplish without breaking the tethers if the device is deployed at a selective site reached by a tortuous path, such as in the brain.

To address this issue, the authors suggest, as shown in Figures 1A and 1B, that the tethers 290 be attached to the guidewire 260 at a position spaced proximally of the basket. The tethers may, for example, be attached to a metal strap 292 or the like and this strap 292 may be affixed to the shaft of the guidewire. When it is desired to close the proximal end of the basket for retraction, they suggest urging an external catheter (not shown) distally toward the basket 270. When the catheter encounters the radially extending tethers, the distal end of the catheter will tend to draw the tethers toward the guidewire as the catheter is advanced, which will, in turn, tend to draw the proximal end of the basket closed.

Figures 2A and 2B illustrate an alternative embodiment of the device shown in Figures 1A and 1B, also in accordance with the teachings of WO 96/01591. Figure 2A shows the device collapsed in a catheter C for deployment while Figure 2B shows the device in its deployed configuration. In Figures 2A and 2B, the basket 270 is much the same as that outlined above in connection with Figures 1A and 1B. In the embodiment of Figures 12, though, the distal band 272 is affixed to the guidewire 260' at the distal tip of the guidewire. The guidewire 260' is of the type referred to in the art as a "movable core" guidewire. In such guidewires, a core wire 265 is received within the lumen of a helically wound wire coil 266 and the core wire 265 extends distally beyond the distal end of the coil 266. A thin, elongate safety wire 268 may extend along the entire lumen of the coil 266 and the distal end of the safety wire may be attached to

the distal end of the coil to prevent loss of a segment of the coil if the coil should break.

In the embodiment of Figures 1 A and 1B, the proximal ends of the tethers 290 are attached to a metal strap 292 which is itself attached the shaft of the guidewire 260. In Figures 2A and 2B, the tethers are not attached to the core wire 265 itself. Instead, the tethers are attached to the coil 266 of the guidewire. The tethers may be attached to the coil by any suitable means, such as by means of laser spot welding, soldering or brazing. The tethers 290 may be attached to the coil 266 at virtually an spot along the length of the coil. As illustrated in these drawings, for example, the tethers may be attached to the coil adjacent the coil's distal end. However, if so desired the tethers may be attached to the coil at a location space more proximally from the basket 270.

An external catheter such as that referred to in the discussion of Figures 1A, but not shown in that figure, is illustrated in Figures 2A and 2B. Once the basket 270 is deployed in a patient's vessel to substantially reach the expanded configuration shown in Figure 2B and the basket has performed its intended filtration function, the external catheter C can be urged distally toward the basket 270. As this catheter is urged forward, the tethers will tend to be drawn into the distal end of the catheter, which is substantially narrower than the proximal lip 286 of the basket. This will tend to draw the tethers down toward the guidewire and help close the basket, as explained above.

Figures 3-5 illustrate yet another alternative embodiment of a vascular trap in accordance with WO 96/01591. This vascular trap 300 includes a basket 320 received over a guidewire 310. In most respects, the basket 320 is directly analogous to the basket 270 illustrated in Figures 1-2. The basket 320 includes a proximal band 322 and a distal band 324. As in the device of Figures 2A and 2B, the distal band may be attached to the guidewire adjacent its distal end. If so desired, though, a structure such as is shown in Figures 1A and 1B, wherein the guidewire extends distally beyond the basket, could instead be used.

As best seen in its collapsed state (shown in Figure 3), the basket includes a distal segment 325 and a proximal segment 326, with the distal end

of the distal segment being attached to the distal band 324 and the proximal end of the proximal segment being attached to the proximal band 322. When the basket 320 is in it expanded configuration (shown in Figure 4), the proximal segment 326 is received within the distal segment 325, defining a proximal lip 328 at the proximal edge of the device. The wall of the basket thus formed also includes a cavity 329 for trapping solids entrained in a fluid, such as emboli in a patient's blood stream.

The basket 320 of Figures 3-5 is also shaped a little bit differently than the basket 270 of the previous drawings. The primary difference between these two baskets is that the basket 320 is a little bit shorter along its axis that is the basket 270. This different basket shape is simply intended to illustrate that the basket of a vascular trap in accordance with the invention can have any of a wide variety of shapes and no particular significance should be attached to the slightly different shapes shown in the various drawings.

In the vascular traps 250 and 250' of Figures 1 and 2, respectively, tethers were used to draw down the proximal end of the basket 270 to close the basket for retraction. In the embodiment shown in Figures 3-5, though, the trap 300 includes a basket cover 340 positioned proximally of the basket 320. The basket cover may also be formed of a metallic tubular braid and is also adapted to be collapsed to lay generally along the outer surface of the guidewire 310. The cover 340 is not directly affixed to the guidewire at any point, though, but is instead intended to be slidable along the guidewire. As best seen in Figures 3 and 4 wherein the cover is in its collapsed state, the cover 340 includes a distal hypotube 342 and a proximal control hypotube 344, with the distal hypotube being attached to the distal end of the cover 340 and the proximal control hypotube 344 being attached to the proximal end of the cover.

The cover 340 is shown in its deployed, expanded configuration in Figure 5. As shown in that figure, the cover has a similar structure to that of the basket 320, but is oriented to be open distally rather that proximally, as is the basket. As best seen in Figures 3 and 4 wherein the cover is in its collapsed state, the cover has a distal segment 352 and a proximal segment 354. When the cover is

deployed by urging it distally out of the distal end of the deployment catheter C, the cover 340 will tend to resiliently return to its expanded configuration and the distal hypotube 342 will slide axially proximally along the guidewire toward the proximal control hypotube 344. This will invert the collapsed cover so that the distal section 352 is generally received within the proximal section 354, defining a distal lip 358 of the cover.

WO 96/01591 teaches that the proximal control hypotube 344 of this cover may extend along a substantial portion of the length of the catheter 310 so that it extends out of the patient's body when the device 300 is in place. By grasping the control hypotube and moving it relative to the guidewire 310, an operator can control the position of the cover 340 with respect to the basket 320, which is affixed to the guidewires. As explained in more detail below in connection with the use of the device 300, once the basket has been deployed and has been used to filter objects entrained in the fluid (e.g. emboli in blood), the cover 340 may be deployed and the trap may be drawn proximally toward the cover by moving the guidewire proximally with respect to the control hypotube 344.

The inner diameter of the distal lip 358 of the cover is desirably slightly larger than the outer diameter of the proximal lip 328 of the basket. Hence, when the basket is drawn proximally toward the cover it will be substantially enclosed therein. The cover will therefore tend to trap any emboli (not shown) or other particulate matter retained within the cavity 330 of the basket. A retrieval sheath S may then be urged distally to engage the outer surface of the cover 340. This will tend to cause the cover to collapse about the basket, tightly engaging the outer surface of the basket. This somewhat collapsed structure can then be withdrawn from the patient's channel and removed from the patient's body. By enclosing the basket within the cover, the likelihood of any filtered debris within the basket being lost as the basket is retrieved will be substantially eliminated.

Figure 6 illustrates the molding element 370 suggested in WO 96/01591 for use in making a basket 270. Although the basket 320 and cover 340 of the

trap 300 are shaped somewhat differently, an analogous molding element can be used for these portions of the trap 300 as well by simply modifying some of the dimensions of the molding element 370, but retaining the basic shape and structure of the molding element. It also should be understood that the molding element 370 is merely one possible molding element for forming a shape such as that of the basket 270 and WO 96/01591 teaches a variety of different molding elements and notes that other designs will be apparent to those skilled in the art.

The molding element 370 of Figure 6 has an outer molding section 372 defining a curved inner surface 374 and an inner molding section 376 having an outer surface 378 substantially the same shape as the curved inner surface 374 of the outer molding section. The inner molding section 376 should be sized to be received within the outer molding section, with a piece of the metal fabric (not shown) being disposed between the inner and outer molding sections. In a preferred embodiment, the inner surface 374 of the outer molding element and the outer surface 378 of the inner molding section each include a recess (375 and 379, respectively) for receiving an end of the braid. The molding surface of this molding element 370, to which the fabric will generally conform, can be considered to include both the inner surface 374 of the outer molding section and the outer surface 378 of the inner molding section.

WO 96/01591 teaches that the two molding sections 372, 376 are spaced apart from one another and a length of a tubular braid of metal fabric (not shown in Figure 6) is disposed between these molding sections. Optimally, one end of the fabric is placed in the recess 375 of the outer molding section and the other end of the fabric is placed in the recess 379 in the inner molding section. As noted above, the ends of the tubular fabric can be clamped prior to this molding process to limit the likelihood that the fabric will unravel. The inner and outer molding sections can then be urged generally toward one another. As the ends of the wire approach one another, the tubular braid will tend to invert upon itself and a surface of the tubular braid will generally conform to either the inner surface 374 of the outer molding section or the outer surface 378 of the inner

molding section, arriving at a shape analogous to that of the basket 270 of the traps 250, 250'. The two molding sections can them be locked in place with respect to one another and the metal fabric may be heat treated to set the wires in this deformed configuration.

This published international application also teaches how one may use the traps 250, 250' and 300 taught therein. It suggests that these traps be deployed for use in conjunction with another medical device and that they will most frequently be retracted from the patient's body after use. WO 96/01591 uses a balloon angioplasty procedure and an atherectomy procedures as contexts for illustrating a method of using such traps. In balloon angioplasty, balloon catheters having inflatable balloons at their ends are positioned within a blood vessel so that the balloon is positioned within a stenosis. These balloons are positioned by tracking the balloon catheter along a guidewire or the like; the balloons typically have a central bore therethrough. Once the balloon is properly positioned, it is inflated and urges radially outwardly against the stenosis. This will tend to squeeze the stenosis against the walls of the vessel, improving patency of the vessel.

When the stenosis is treated in this fashion, though, there is a risk that some debris will break free and enter the blood flowing through the vessel. If left unchecked, this embolus can drift downstream and embolize a distal portion of the vessel. Depending on where the embolus comes to rest, the embolization can result in significant tissue or organ damage. In order to prevent, or at least substantially limit, such embolization, WO 96/01591 suggests the use of a vascular trap 250, 250' or 300 of with the balloon catheter. The device should be sized to permit it to be passed through the lumen of the particular balloon catheter to be used in the angioplasty.

In one method taught in WO 96/01591, the trap is deployed first. The basket (270 or 320) of the trap is guided to a position located downstream of the desired treatment site through an introduction catheter (e.g. the catheter C in Figures 12-15). The basket is then urged distally beyond the end of the catheter, which permits the basket to resiliently substantially return to its

expanded configuration from its collapsed configuration within the catheter. Once the trap is in place, the balloon catheter can be exchanged for the introduction catheter, and the balloon catheter can track the guidewire (260 or 310) of the vascular trap. The balloon can then be positioned within the stenosis and expanded, as outlined above. Once the angioplasty has been completed, the balloon can be deflated again and withdrawn proximally out of the patient.

WO 96/01591 also explains that the balloon catheter can be used to perform the same function as performed by the introduction catheter in the preceding embodiment. In this embodiment, the balloon catheter is positioned in the patient's vessel so that the distal end of the balloon catheter is located downstream of the stenosis. The vascular trap (250, 250' or 300) of the invention is then passed through the lumen of the balloon catheter and the basket is urged out of the distal end of the catheter. The basket will resiliently substantially return to its preferred expanded configuration, whereupon the balloon catheter can be retracted along the shaft of the device's guidewire until the balloon is properly positioned within the stenosis.

If so desired, the balloon catheter can instead be provided with a length of standard catheter extending distally beyond the distal end of the balloon. The balloon can then be positioned within the stenosis and the basket can be urged out of the distal end of the distal extension of the catheter. In such an embodiment, the length of the distal extension of the catheter should be sufficient to properly position the basket with respect to the balloon when the basket exits the distal end of the catheter. This will eliminate the need to perform the separate step of retracting the balloon into position within the stenosis after the basket is deployed. The balloon can then be expanded, deflated and withdrawn as described above.

WO 96/01591 teaches that much the same procedure can be used to deploy a vascular trap for use in an atherectomy procedure. In such procedures, a cutting head is positioned at the distal end of an elongate, hollow shaft and the cutting head has a bore extending therethrough. The trap can be deployed in either of the methods outlined above, but it is anticipated that in

most instances the first procedure will be used, i.e. the basket will be deployed with an introduction catheter, which will be removed so that the cutting device can be guided over the guidewire of the vascular trap. This publication also stresses that the device 250, 250' and 300 could be used in other medical procedures in other bodily channels besides a patient's vascular system.

Since the trap is positioned downstream of the stenosis, any debris released during one of these procedures will tend to drift distally toward the basket and be caught therein. In order to prevent any emboli from simply floating past the trap, it is preferred that the proximal lip (288 or 328) of the basket be at least as large as the lumen of the vessel. WO 96/01591 suggests that the natural dimension of the proximal lip (i.e. where the basket has fully returned to its expanded configuration) be made somewhat greater than the vessel's inner diameter so the basket will firmly engage the wall of the vessel.

The method of retracting the basket will depend on which embodiment of the vascular trap is used, namely whether or not the device includes a cover 340. The device 250 or 250' of Figures 1 or 2, respectively, do not include such a cover. However, they do include tethers 290 which extend proximally from the proximal lip 288 of the basket to an attachment to the guidewire. In either of these embodiments, a retrieval catheter can be introduced over the guidewire and urged distally toward the basket. As explained above in connection with Figures 1 and 2, this will tend to draw the tethers down toward the guidewire, effectively closing the proximal end of the basket 270. Once the basket is sufficiently closed, such as when the proximal lip of the basket engages the distal tip of the retrieval catheter, the catheter and the vascular trap can be retracted together from the patient's body. By substantially closing the proximal end of the basket in such a fashion, any emboli which are captured in the basket when it is deployed can be retained within the basket until it is removed from the patient's body.

If so desired, a balloon catheter or like device can instead be used, with the balloon catheter being used to draw down the tethers 290 and collapse the basket. The vascular trap can then be withdrawn with the balloon catheter

rather than having to separately introduce a removal catheter to remove the trap.

In withdrawing the embodiment illustrated in Figures 3-5, the cover 340 is positioned over the proximal lip of the basket before the vascular trap 300 is retracted. Once the medical procedure is completed and any debris has been captured in the basket, the cover 340 is allowed to resiliently substantially return to its expanded configuration. Once it is deployed proximally of the basket, the basket 320 can be drawn proximally toward the cover 340 until it engages or is received within the cover, as noted above in connection with Figure 5.

In actuality, the cover 340 of Figures 3-5 may be unable to return to its full expanded configuration due to the confines of the vessel in which it is deployed. As explained previously, the cover 340 is desirably larger than the basket 320 so that the basket can be received within the cover. However, the basket is optimally sized to engage the walls of the vessel to prevent the unwanted passage of emboli or other debris around the edges of the basket. Accordingly, the distal lip 358 of the cover will engage the wall of the channel before it expands to its full size. The walls of most bodily channels, such as blood vessels, tend to be somewhat elastic, though. The cover 340 will therefore tend to urge harder against the wall of the vessel than the smaller basket and may stretch the vessel a little bit more than will the basket. In this fashion, the cover may still be able to expand to a dimension large enough to permit the basket to be received in the cavity 356 of the cover. If not, the distal lip 358 of the cover can simply be brought into close engagement with the proximal lip 328 of the basket to generally seal the basket.

Once the cover 340 is brought into engagement with the basket 320, whether by receiving the basket within the cover or, less preferably, by engaging the lips 358, 328 of the cover and the basket, the device can be withdrawn proximally from the patient's vascular system. The cover will tend to prevent any emboli caught in the basket during deployment from being inadvertently lost during withdrawal.

The vascular traps 250, 250' and 300 shown in Figures 1-6 represent a significant advancement over previously available devices. The embodiment of Figures 3-5 shows particular promise in that the cover permits the user to withdraw the basket with the emboli entrained therein without having to take any additional precautions to minimize the chances that these emboli will be accidentally dumped back into the bloodstream.

SUMMARY OF THE INVENTION

The present invention provides a medical device retrieval system and a method of retrieving a medical device. In accordance with one embodiment of the invention, a medical device retrieval system includes a medical device and a retrieval cover. The medical device comprises a working element carried by a flexible, elongate shaft. The working element has a proximal profile and the shaft extends proximally from the working element. The retrieval cover is slidably carried along the shaft of the medical device. The cover has a deployed configuration and is capable of being compressed in a compressed configuration for deployment, yet resiliently substantially returned to the deployed configuration. The cover in its deployed configuration has a radially reduced proximal portion. A distally open distal end defining a distal opening having a maximum dimension at least as great as the maximum dimension on the proximal profile of the working element of the medical device, and an elongate internal recess defined between the proximal portion on the distal end. The cover in its compressed configuration is radially compressed inwardly toward the shaft and is distally open, with the distal end defining the distal-most portion of the cover. Optimally, the retrieval cover is designed to maintain this general orientation wherein the distal end of the device is always the distal-most portion of the cover, regardless of the configuration of the device.

This medical device retrieval system may further include a retrieval sheath which is slidable along the shaft of the medical device. Such a sheath, if included, is desirably positioned distally on the cover when the cover is in its deployed configuration. This retrieval sheath may have an inner diameter

smaller than the outer diameter of the cover in its deployed configuration. This sheath is adapted to slide distally along the cover to compress the cover about the medical device.

In accordance with a further embodiment, the present invention provides a medical device retrieval system which comprises a medical device, a retrieval sheath, a deployment stylet and a retrieval cover. The medical device comprises a working element carried by a flexible, elongate shaft having an outer diameter. The working element has a proximal profile and the shaft extends proximally from the working element. The retrieval sheath is slidable along the shaft of the medical device and optimally has a beveled distal end with a distal lumen. The deployment stylet is slidable along the shaft of the medical device and has a distal tip. This distal tip tapers distally from a first diameter approximating the diameter of the distal lumen of the sheath to a second diameter more closely approximating the outer diameter of the medical device shaft. This provides a transition between the shaft of the medical device and the distal end of the retrieval sheath when the deployment stylet is positioned such that a distal tip extends distally beyond the distal end of the retrieval sheath. The retrieval cover is slidable along the shaft of the medical device and is exchangeable for the stylet along that shaft. The cover has a deployed configuration and is capable of being compressed into a compressed configuration for sliding within the lumen of the retrieval sheath yet resiliently substantially return to the deployed configuration. In its deployed configuration, the cover has a radially reduced proximal portion, a distally open distal end, and an elongate internal recess defined between the proximal portion and the distal end. The distal end defines a distal opening having a maximum dimension at least as great as the maximum dimension of the proximal profile of the working element of the medical device. In its compressed configuration, the cover is radially compressed inwardly toward the shaft and is distally open, with the distal end defining the distal-most portion of the cover.

Another embodiment of the invention provides a retractable medical device system including a medical device, a retrieval cover and a retrieval

sheath. The medical device comprises a working element carried by a flexible, elongate shaft. The retrieval cover is slidable along the shaft of the medical device. The cover has a radially reduced proximal portion, a distally open distal end an elongate tubular wall extending therebetween and defining a recess. The working element of the medical device is completely retained within the recess of the cover such that the tubular wall extends distally beyond the medical device. The retrieval sheath has a lumen and is slidable with respect to both the medical device and the cover. At least a proximal length of the working element of the medical device and the cover are retained within the lumen of the retrieval sheath, with the retrieval sheath regularly compressing the proximal length of the cover such that an intermediate portion of the wall tightly engages the surface of the medical device. This will tend to effectively trap any emboli or other materials retained by the medical device.

As noted above, the present invention contemplates a method. One such method involves receiving particulate or other form material within a channel of a patient's body. As a first step in performing this method, one provides a medical device having a working element and a flexible, elongate shaft adapted to follow a path within the channel; a distally open cover slidable with respect to the shaft; and a retrieval sheath movable with respect to the cover on the shaft. The medical device is positioned within the vessel to engage a wall of the channel and trap the material within the channel. Either during such positioning or after the medical device has been positioned and while it is trapping material within the channel, the cover and the retrieval sheath may be positioned so they are spaced proximally of the working element along the shaft of the medical device. The cover is radially compressed within the lumen of the retrieval sheath such that it has a distally open distal end and a wall defining a recess, the wall engaging an inner surface of the retrieval sheath. The cover is moved distally with respect to the retrieval sheath, thereby permitting the cover to radially expand into a deployed configuration wherein the distal end remains distally open and the enclosure is radially expanded. The cover expands radially outwardly into the deployed configuration without having to invert on itself. The

cover is then moved distally into engagement with a surface of the medical device to form therebetween an enclosure. The retrieval sheath may then be moved distally with respect to the cover to urge to cover to collapse about the medical device and tightly engage the surface of the medical device.

BRIEF DESCRIPTION OF THE DRAWINGS

Figures 1A is a schematic side view in accordance with WO 96/01591, showing a vascular trap in a collapsed state for deployment in a patient's vascular system;

Figure 1B is a schematic side view of the medical device of Figure 1A in an expanded state for deployment in a patient's vascular system;

Figure 2A is a schematic side view in accordance with WO 96/01591, showing an alternative vascular trap in a collapsed state within a catheter for deployment;

Figure 2B is a schematic side view of the device of Figure 2A, showing the device deployed distally of the catheter;

Figure 3 is a schematic perspective view in accordance with WO 96/01591 showing a vascular trap and a cover, both of which are collapsed within a catheter for deployment in a channel in a patient's body;

Figure 4 is a schematic side view of the device of Figure 3 in a partially deployed state, wherein the vascular trap has been deployed, but the cover is still collapsed within the catheter;

Figure 5 is a schematic side view of the device of Figure 3 in a fully deployed state;

Figure 6 illustrates one embodiment of a molding element which may be used in making a portion of the vascular traps shown in Figures 1-5;

Figure 7 is a schematic illustration of a retrieval sheath catching on a vascular obstruction proximally of the desired distal deployment site;

Figure 8 is a schematic side view of a device in accordance with the present invention with both the trap and the cover fully deployed;

Figure 9 is a schematic cross sectional view showing the device of Figure 8 wherein the trap has been deployed but the cover has retained within the retrieval sheath;

Figure 10 is a schematic illustration showing the invention deployed within a patient's vessel and having emboli retained therein;

Figure 11 is view similar to Figure 10, but showing the trap being retracted into the confines of the cover;

Figure 12 is a schematic, partially cut away view of the device of Figures 10 and 11 showing the cover being retracted within the retrieval sheath;

Figure 13 is a schematic partial cross sectional view of a distal portion of a medical device retrieval system of the invention utilizing a deployment stylet; and

Figure 14 is a schematic side view of a distal length of an alternative retrieval sheath for use with the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figures 8-12 schematically illustrate the operation of one embodiment of the present invention. Figure 8 illustrates certain operative portions of the medical device retrieval system 10 of the invention in a fully deployed state. As noted above, the retrieval system of the invention is intended to be used in connection with a medical device having a working element carried by flexible, elongate shaft. In these drawings, the medical device is typified as a vascular trap similar to the vascular trap 250 of Figure 11, but omitting the tethers 290. The working element of this medical device is a basket 12, which may be substantially as outlined above in connection with the description of the basket 270. The shaft in this design may simply comprise a guidewire 14. While the construction and operation of the basket 12 may be substantially the same as

that outline for the baskets shown in Figures 1-5, it is generally preferred that the proximal band 13 of this basket be attached to the guidewire while the distal band 15 be permitted to slide along the guidewire. Hence, when the basket 12 is released from a delivery catheter and the basket is allowed to achieve a radially expanded configuration, the distal end of the collapsed device (272 in Figure 1A) will slide approximately toward the proximal end (274) of the collapsed device.

It should be recognized that the medical device can be varied as desired. For example, the medical device used in connection with the present retrieval system could instead by a balloon catheter, wherein the working element would be the balloon portion of the catheter and the shaft would comprise the body of the catheter extending proximally of the balloon.

The other elements of the retrieval system 10 generally comprise a retrieval sheath 20 and a cover 30. It is to be understood that these drawings are intended merely for illustrative purposes and are not drawn to scale. In actual operation, the retrieval sheath 20 and the shaft 40 of the cover would likely be much smaller. These elements are simply drawn larger to make the various components easier to see in the attached illustrations.

The cover 30 includes a radially expandable body 31 carried by a shaft 40. The body has a proximal portion 32 which is radially compressed into close proximity with the shaft 40 and is desirably attached directly thereto. A tubular wall 34 extends distally from the proximal portion and terminates in a distally open end 36. The body 31 defines a recess 38 within which the working element of the medical device may be retracted, as explained more fully below. The majority of the length of this recess is defined by the generally tubular wall 34.

This radially expandable body 31 can be formed of any suitable material. As explained more fully below, it is preferred that this body be capable of being collapsed within the retrieval sheath 20 for deployment, radially expand into a deployed configuration, yet be readily collapsed by the retrieval sheath to tightly

engage the working element of the medical device. Any material which achieves this function may be used.

In one embodiment (not shown), the body 31 is formed of a flexible plastic material, which may be reinforced with one or more flexible metal hoops or the like to bias the tubular plastic member into a funnel-like configuration.

The illustrated embodiment is shown as comprising a series of flexible metal wires. As explained in some detail in International Publication No. WO 96/01591, such a radially expandable device may be made rather conveniently utilizing a metal fabric having strands formed of a material which is both resilient and which can be heat treated to substantially set a desired shape. Materials such as elgiloy, hastelloy, incoloy, certain grades of stainless steel and shape memory alloys. Of these materials, shape memory alloy such as nitinol are particularly preferred.

In one useful embodiment, the radially expandable body 31 is formed using the techniques outlined in WO 96/01591, starting with a metal fabric comprising both nitinol and platinum. For example, the fabric may be a generally tubular fabric formed of 48 wires having a diameter on the order of about 0.0015 inches and a pic rate of about 80-100 pics per inch. Of the 48 wires used to form this metal fabric, a relatively small percentage of the wires (e.g. 4-6 wires) may be formed of platinum or some other relatively radiopaque material to enhance visibility of the device on a fluoroscope without unduly affecting the resiliency of the fabric. If so desired, the wires can be coated with a therapeutic agent or with an antithrombogenic material. For example, the wires may be coated with heparin or with a known platelet-deactivating drug, e.g., a 2B-3A antagonist.

This radially expandable body 31 is carried by a axially slidable shaft 40. This shaft may take the form of a metallic hypotube, such as that discussed in connection with the embodiment of Figures 3-5. More preferably, though, the shaft 40 comprises a flexible plastic material of the type that is commonly used in forming medical catheters. If friction of this shaft 40 with the retrieval sheath

20 and/or the shaft 14 of the medical device is anticipated to present a problem, this shaft 40 of the cover may be formed of polytetrafluoroethylene or another suitable low-friction material.

The radially expandable body 31 may be attached to the shaft 40 in any suitable manner. Presumably, the ends of the wires defining the body 31 could be simply cast into the plastic defining the flexible shaft 40. However, the embodiment shown in the drawings is somewhat easier to make, utilizing a pair of marker bands 46 and 48 to attach the body to the shaft by clamping the proximal end about the exterior of the sheath. Forming these clamps of a radiopaque material will make it easier to track the position of the cover 30 as it is deployed. In the illustrated embodiment, the cover comprises an exterior layer and an interior layer of the metal fabric, much like the basket 270 described above in connection with Figures 1-5. In this configuration, the proximal marker band 46 may be used to clamp the exterior layer of the metal fabric to the exterior of the shaft 40 while the distal marker band 48 is used to clamp the interior layer of the fabric to the shaft.

In the illustrated embodiment, the shaft 40 includes a lumen 44 through which the shaft 14 of the medical device is received, thereby permitting the cover 30 to track that shaft for deployment. The shaft 40 shown in Figures 8 and 9 extends distally beyond the distal marker band 48 such that the distal tip 42 of the shaft is received within the recess 38 of the cover. Not only will this make manufacturing easier, but it will reduce the likelihood that any guidewire or other device passing through the lumen 44 of the shaft 40 will get caught up in the metal fabric defining the radially expandable body 31.

The retrieval sheath 20 may simply take the form of a standard medical catheter, with a tip as described below. This sheath has a generally tubular wall defining a lumen 24 within which the shaft 14 of the medical device and the shaft 40 of the cover may be slidably received. The differences in the diameters of these three elements 20, 40 and 14 are exaggerated in Figures 8 and 9 to

illustrate operation of the device. In reality, these diameters would likely be substantially closer than those shown.

The distal tip 22 of the retrieval sheath 20 may be beveled to produce a smoother tip. (The advantage of this tip construction will be highlighted below in connection with the discussion of Figures 7, 13 and 14.) If so desired, a marker band 26 may be incorporated into the wall of the retrieval sheath 20 adjacent the distal tip 22. This will help an operator visualize the relative position of the retrieval sheath 20, the cover 30 and the basket 12 during operation.

Figure 9 is a schematic cross sectional view of the device illustrated in Figure 8 prior to deployment of the cover. In operation, the medical device will typically be put in place first. As outlined above in connection with Figures 1 and 2, the basket 12 may be positioned distally of a particular treatment site and the treatment device (e.g. a balloon catheter or an atherectomy device) can be guided over the shaft 14 of the trap to perform the intended procedure. In the use of the retrieval system of the invention with such a trap, one would typically deploy the retrieval sheath 20 and the cover 30 after the basket 12 has been in place for some time rather than deploying all three elements at substantially the same time. It should be understood, though, that simultaneous deployment may be appropriate in other circumstances, such as when a cover 30 and retrieval sheath 20 are used in connection with a Foley catheter or the like.

Whereas Figure 8 illustrates the cover in its deployed configuration, Figure 9 illustrates the cover in a compressed configuration which is suitable for deployment. Even in its compressed configuration, it can be seen that the body 31 of the catheter generally includes a radially reduced proximal portion 32, an elongate tubular wall 34 and a distally open distal end 36 which defines the distal-most portion of the cover. This is indirect contrast to the structure shown in Figures 3 and 4, which show the cover 340 of that device in its collapsed state. In this collapsed state, the cover 340 has a distal segment 352 and a proximal segment 354, both of which are generally tubular in shape and lie proximate the exterior surface of the guide wire 310. Once this cover is

deployed as shown in Figure 5, though, the cover must invert on itself to position the distal section 352 generally within the proximal section 354 to define a distal lip 358 of the cover. This distal lip 358 is merely an intermediate point along the longer, axially expanded configuration of the device when it is collapsed, as shown in Figures 3 and 4.

There are a number of advantages of the structure of the present cover 30 over the mechanically more complex design of Figures 3-5. In the cover 340 of Figures 3-5, the cover must invert on itself before it can be used to enclose the basket 320. The resilient nature of the metal fabric used to form the cover 340 will tend to resiliently draw the distal hypotube 342 proximally toward the proximal control hypotube 344 once the constraint of the deployment catheter C has been removed.

The walls of the vessel can hinder complete inversion of the cover 340, though. In particular, if the inner diameter of the vessel within which the cover is to be deployed is significantly smaller than the outer diameter of the fully deployed cover, the cover may take on a sausage-like configuration, with the distal and proximal segments 352, 354 of the cover expanding into engagement with the wall of the vessel, but being unable to expand sufficiently to allow the distal hypotube to invert the distal segment 352 so that it may be received within the proximal section 354. In such a circumstance, the cover will not define a suitable recess for receiving the basket 320 therein.

The design shown in Figures 8-12 does not require that the radially expandable body 31 invert on itself to reach its fully deployed configuration. Instead, the recess 38 will always remain in place. Deployment of the body 31 distally beyond the distal tip 22 of the retrieval sheath will simply allow this recess to expand to a size wherein it may readily receive the working element of the medical device with which the cover is used.

While Figures 8 and 9 schematically illustrate the structure of the device and its various elements, Figures 10-12 are intended to schematically illustrate the manner in which the cover 30 may be used to retrieve a basket 12 which is

full of emboli or other particular material. In Figure 10, the deployment catheter C (discussed above in connection with Figures 1-5) is shown extending into the lumen of the vessel and terminating proximally of the position of the basket 12. The cavity of the basket 12 is filled with emboli E. If one were to simply pull the guidewire 12 proximally, this will tend to evert the generally umbrella-shaped basket 12, raising the possibility that the emboli E could be dumped into the bloodstream of the vessel.

In Figure 10, the retrieval sheath 20 is positioned proximally of the basket 12, leaving a space between the distal tip 22 of the sheath 20 and the basket 12. In this Figure, the cover 30 is still within the lumen 24 of the retrieval sheath 20, much as in the configuration shown in cross section in Figure 9.

Once the retrieval sheath, with the cover retained therein, is properly positioned, the shaft 40 of the cover 30 may be advanced distally with respect to the sheath 20. This may be accomplished either by holding the sheath 20 stationary and advancing the shaft 40 of the cover distally or by holding the shaft 40 of the cover relatively stationary and withdrawing the retrieval sheath 20 proximally to expose the readily expandable body 31 beyond the distal tip 22 of the sheath 20.

When the body 31 of the cover exits the distal end of the retrieval sheath 20, it will tend to resiliently substantially return to the configuration schematically illustrated in Figure 8. Unlike the cover 340 of Figures 3-5, the body 31 of the present invention will begin to radially expand into its final shape as soon as the distal end 36 clears the distal tip 22 of the sheath 20. Accordingly, there is no need to deploy the cover 30 so that even the proximal marker band 46 is positioned distally of the distal tip 22 of the retrieval sheath as shown in Figure 8. Instead, the proximal portion 32 of the body 31 may remain within the lumen of the retrieval sheath 20, as suggested in Figure 11, without compromising operation of the cover 30.

Figure 11 illustrates the device wherein the cover has been sufficiently deployed to define a recess large enough to receive the body of the basket 12

therein. To achieve the configuration shown in Figure 11, the shaft 14 of the vascular trap is withdrawn proximally, drawing the basket 12 within the enclosure 38.

As noted above in connection with Figure 8, the presently preferred embodiment of such vascular trap employs a proximal band 13 which attaches a proximal end of the metal fabric defining the basket directly to the shaft of the guidewire 14 while the distal connector 15 is allowed to slide along the length of the shaft 14. Accordingly, when the operator pulls proximally on the guidewire 14, this will tend to elongate the trap and cause it to evert. In the absence of aspiration or a cover 30, this could present some difficulties.

Prior to withdrawing the shaft 14 proximally, the distal end 36 of the cover is desirally brought immediately adjacent the basket 12. In a preferred embodiment, the distal end 36 of the body 31 of the cover defines a distal opening having a maximum dimension which is at least as great as the maximum dimension of the proximal profile of the basket 12, i.e., the maximum dimension of the proximal projection of the deployed basket. If the vessel is large enough, this would permit the cover to simply slide around the basket 12 without significantly stressing the basket and causing it to collapse in any way. More likely than not, though, there will be insufficient clearance between the basket 12 and the wall of the vessel to permit the cover to readily slide between the vessel and the basket. Accordingly, the distal end of the cover will typically be brought into engagement with a surface of the basket 12. This will form between the cover and the basket and enclosure that includes both the cavity of the basket and the recess 38 of the cover. This movement of the cover distally into engagement with the medical device may be achieved either by actually physically moving the cover distally in an absolute sense, or simply withdrawing the basket 12 toward the cover which will effectively move the cover distally with respect to the medical device.

Figure 11 illustrates the relative positions of the elements of the invention if the operator continues to withdraw the guidewire 14 proximally after the cover

initially engages the surface of the basket 12. The basket has started to evert into a more oblong shape rather than the umbrella-shape shown in Figure 10. Nonetheless, the emboli still are retained within the enclosure defined by the cover and the basket.

In one preferred embodiment, the body 31 of the cover is at least as long as the working element of the medical device which is to be retrieved therewith. This permits the working element to be entirely enclosed by the cover during the retrieval process, enhancing the likelihood of a successful retrieval without inadvertent dumping of the matter captured by the medical device back into the patient's body. While the cover can be little longer than the working element of the medical device, it is anticipated that the cover may be significantly longer than that working element. This will permit an operator greater flexibility in using the device without adding unduly to the cost.

Figure 12 schematically illustrates the next stage of the method of removing the medical device from the patient's vascular system. In this view, the retrieval sheath has been moved distally with respect to the cover. As suggested above, this may be achieve either by moving the retrieval sheath distally along the cover or by withdrawing the cover (and, optimally, the medical device) proximally while holding the retrieval sheath 20 stationary. Urging the retrieval sheath distally with respect to the cover urges the cover to collapse about the medical device received therein. This causes the cover to tightly engage the surface of the medical device, helping better encase any particular matter received within the enclosure and limit the likelihood that it may spill back into the patient's vascular system. It also presents the device with a radially reduced profile, making it easier to withdraw the device from the patient's body without undue trauma.

Looking at the device in Figure 12, the system has a particular configuration which is unique to the present invention. In this configuration, the working element of the medical device is completely retained within the recess 38 of the body 31 of the cover such that the distal end 36 of the cover 30 is

positioned distally beyond the distal end of the working element 12. In Figure 12, at least a proximal length of the basket 12 and the body 31 of the cover are retained within the lumen of the retrieval sheath 20. This retrieval sheath radially compresses the proximal length of the cover such that an intermediate portion of the generally tubular wall 34 of the body 31 tightly engages a surface of the basket 12.

If so desired, the cover 30 and basket 12 may be further retracted so that they are both completely enclosed within the lumen of the retrieval sheath 20 prior to withdrawing the device from the patient's vessel. This is not necessary for effective operation of the current device, though, and may be left up to the physician's choice during the procedure. It should also be noted that the configuration shown in Figure 12 may be further collapsed by withdrawing the basket 12, cover 30 and retrieval sheath 20 proximally into the deployment catheter C, thereby further encasing the emboli and making it easier to withdraw the device from the vascular system.

Figure 7 illustrates one problem which could be encountered in deploying a medical device retrieval system 10 of the invention across a vascular obstruction. The vascular obstruction in Figure 7 is typified as a stent 4 having a stenotic lesion 6 partially occluding the lumen thereof, but this is selected merely for illustration. Much the same problem could also be encountered with a variety of other vascular obstructions.

The illustrated deployment sheath 20 has a blunt distal tip 22'. Due to the curvature of the vessel where the stent is located, the retrieval sheath tends to drift upwardly toward the outside of the curve rather than easily tracking the shaft 14 of the medical device through the center of the vessel. This problem becomes even more pronounced if the retrieval sheath is made stiffer, such as by incorporating metallic braid into the wall of the sheath, to improve pushability. In some instances, it can take undue time and effort to manipulate the distal tip of the retrieval sheath to clear the obstruction. In addition, use of excess force or movement of the sheath to clear the obstruction risks displacing the working

element (not shown) of the medical device from the treatment site where it has been deployed.

Figures 13 and 14 illustrate two proposed solutions to ameliorate these deployment difficulties. A first solution is illustrated in Figure 13 while Figure 14 illustrates another improvement which may be used alone or in conjunction with the device of Figure 13.

Turning first to Figure 13, the retrieval sheath 20 shown therein includes a deployment stylet 70 slidably received in the lumen 24 thereof. This stylet has a lumen 75 within which the shaft 14 of the medical device is received, permitting the stylet to slide along that shaft 15 with the retrieval sheath 20. The stylet 70 is provided with an elongate tubular body 72 and a tapering distal tip 74. In use, the body 72 of the stylet desirably extends along the entire length of the retrieval sheath so that the proximal end of the sheath (not shown) extends proximally beyond the proximal end of the retrieval sheath so an operator may selectively control the stylet independently of the guide wire and of the retrieval sheath.

The distal tip 74 of the stylet tapers from its proximal end 76 to its distal end 78. At its proximal end, the distal tip has an outer diameter which approximates the diameter of the lumen 24 of the retrieval sheath at the distal end 22 thereof. As illustrated, it is not intended that the stylet 70 completely fill the lumen 24 of the sheath as that would lead to undue friction in moving the stylet relative to the sheath. The outer diameter of the sheath at the proximal end 76 of the tip 74 need only be close enough to the diameter of the distal lumen of the sheath 20 to avoid a sharp, traumatic change in diameter which would be likely to catch on vascular obstructions and hinder deployment of the sheath 20 in the vessel. The transition from the distal tip 74 of the stylet to the outer diameter of the sheath 20 can be further eased by proving the distal tip 22 of the sheath 20 with a beveled distal end.

The distal end 78 of the stylet's distal tip 74 has an outer diameter which more closely approximates the outer diameter of the medical device shaft 14. It is not expected that this distal end 78 be infinitely thin and track directly against the surface of the shaft 14. Again, it is sufficient that the distal end 78 of the

stylet be close enough to the diameter of the shaft 14 of the medical device to avoid a sharp, traumatic change in diameter which would be likely to catch on vascular obstructions and hinder deployment of the sheath 20 in the vessel.

When the stylet is deployed such that its distal tip 74 extends distally beyond the distal tip 22 of the retrieval sheath, the stylet provides a transition between the shaft 14 of the medical device and the distal end of the retrieval sheath 20. This makes it easier to track the shaft 14 and guide the device into position across a vascular obstruction. Figure 13 illustrates the stylet positioned such that the proximal end 76 of the distal tip 74 is positioned immediately adjacent the distal tip 22 of the retrieval sheath, but this is not necessary. If the body 72 of the stylet has a substantially constant diameter over the relevant length, the stylet can be moved distally relative to the sheath 20 such that the body extends beyond the distal end of the sheath. This will not case any undue problem as the outer diameter of the body is desirably substantially the same as the outer diameter of the proximal end 76 of the distal tip.

Use of the retrieval sheath 20 with the stylet 70 can be varied. If so desired, one can use the stylet in each and every deployment of the retrieval system of the invention. However, as outlined below, use of the stylet adds an additional step to the retrieval process and its use may be reserved for those circumstances where the operator either expects to encounter a vascular obstruction or has already encountered such an obstruction.

In use, the stylet 70 and the cover 30 are exchangeable for one another, i.e., either the stylet or the cover may track along the shaft 14 within the lumen 24 of the retrieval sheath, but both cannot be used at the same time. Instead, one must be removed and replaced with the other. If the operator anticipates a vascular obstruction (or he or she wants to avoid exchanging devices twice if an obstruction is encountered), he or she can initially deploy the sheath 20 with the stylet. This may be accomplished by positioning the stylet 70 with respect to the sheath 20 such that the distal tip 74 of the stylet extends distally beyond the distal tip 22 of the sheath. Optimally, both the stylet and the sheath are advanced together along the shaft 14 until the distal tip 22 of the sheath is in a

desired position with respect to the working element of the medical device. (In most circumstances, this will be at a location wherein the distal tip of the sheath is near the working element, but spaced proximally therefrom, as discused above in connection with Figure 11.)

Once the sheath is in position, the stylet 70 may be exchanged for the cover 30. This may be done in much the same fashion that catheters are exchanged in a typical balloon angioplasty procedure or the like. In most circumstances, an exchange wire will be attached to the proximal end of the shaft 14 of the medical device and the stylet 70 can be retracted proximally onto the exchange wire. Thereafter, the exchange wire can be disconnected and the cover may be advanced along the shaft 14 through the lumen 24 of the retrieval sheath. Using the marker band 26 of the retrieval sheath and the marker band 13 of the basket 12 (for example), any final adjustments to the position of the sheath with respect to the working element of the medical device can be made prior to deployment of the cover.

The cover may then be moved distally with respect to the sheath 20, either by distally advancing the cover or proximally retracting the sheath. As noted above, this permits the body 31 of the cover to radially expand into a deployed configuration wherein the distal end remains distally open and the enclosure is radially expanded. The cover may then be moved distally with respect to the working element of the medical device and into engagement with a surface of the medical device to form therebetween an enclosure. Optimally (but not necessarily, depending on the configuration of the medical device and the shape of the cover), the cover is advanced further with respect to the working element until the entire working element is effectively received in the recess 38 of the cover. Thereafter, the retrieval sheath is moved distally with respect to the cover to urge the cover to collapse about the working element and tightly engage the surface of the working element to retain any debris in the enclosure.

Figure 14 illustrates another improvement of the sheath 20 of the invention. In this embodiment, a distal length 21 of the sheath 20 is bent at an

angle with respect to the body of the sheath. If a vascular obstruction is encountered, this distal bend will permit the operator to clear the obstruction by reorienting the sheath so that the distal tip 22 thereof is spaced toward the center of the vessel and away from the obstruction, whereupon the sheath can be further advanced. An angle of between about 5 and about 30° is believed to be sufficient for most purposes without unduly interfering with the proper deployment and retrieval of the cover 30. The length of the distal length 21 can be varied as needed. In most circumstances, it is envisioned that the distal length 21 will be 5 cm or less, with a length of 1 cm to 3 cm being most likely. As noted previously, the sheath 20 of Figure 14 with its bent distal length 21 may be used instead of or in conjunction with the stylet 70 shown in Figure 13.

While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptations and modifications may be made therein without departing from the spirit of the invention and the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A medical device retrieval system, comprising:

a) a medical device comprising a working element carried by a flexible, elongate shaft, the working element having a proximal profile and the shaft extending proximally from the working element; and

b) a retrieval cover slidably carried along the shaft of the medical device, the cover having a deployed configuration and being capable of being compressed into a compressed configuration for deployment, yet resiliently substantially return to the deployed configuration; the cover in its deployed configuration having a radially reduced proximal portion, a distally open distal end defining a distal opening having a maximum dimension at least as great as the maximum dimension of the proximal profile of the working element of the medical device, and an elongate internal recess defined between the proximal portion and the distal end; the cover in its compressed configuration being radially compressed inwardly toward the shaft and being distally open with the distal end defining the distal-most portion of the cover.

2. The system of claim 1 further comprising a retrieval sheath, the retrieval sheath being slidable along the shaft of the medical device and being positioned distally of the cover when the cover is in its deployed configuration.

3. The system of claim 2 where in the retrieval sheath has an inner diameter smaller than an outer diameter of the cover in its deployed configuration, the sheath being adapted to slide distally along the cover to compress the cover about the medical device.

4. The system of claim 2 wherein the retrieval sheath has a body and a distal tip comprising a distal length of the retrieval sheath, the distal tip being bent at an angle of between about 5 and about 30° with respect to the body.

5. The system of claim 4 wherein the distal tip is between about 1 cm and about 5 cm in length.

6. The system of claim 4 wherein the distal tip further comprises a radiopaque marker band.

7. A medical device retrieval system, comprising:

a) a medical device comprising a working element carried by a flexible, elongate shaft having an outer diameter, the working element having a proximal profile and the shaft extending proximally from the working element;

b) a retrieval sheath being slidable along the shaft of the medical device, the retrieval sheath having a beveled distal end with a distal lumen;

c) a deployment stylet slidable along the shaft of the medical device, the deployment stylet having a distal tip tapering distally from a first diameter approximating a diameter of the distal lumen of the sheath to a second diameter more closely approximating the outer diameter of the medical device shaft, providing a transition between the shaft of the medical device and the distal end of the retrieval sheath when the deployment stylet is positioned such that the distal tip extends distally beyond the distal end of the retrieval sheath; and

d) a retrieval cover slidable along the shaft of the medical device and being exchangeable for the stylet therealong, the cover having a deployed configuration and being capable of being compressed into a compressed configuration for siding within the lumen of the retrieval sheath yet resiliently substantially return to the deployed configuration; the cover in its deployed configuration having a radially reduced proximal portion, a distally open distal end defining a distal opening having a maximum dimension at least as great as the maximum dimension of the proximal profile of the working element of the medical device, and an elongate internal

recess defined between the proximal portion and the distal end; the cover in its compressed configuration being radially compressed inwardly toward the shaft and being distally open with the distal end defining the distal-most portion of the cover.

8. A retractable medical device system, comprising:

a) a medical device comprising a working element carried by a flexible, elongate shaft;

b) a retrieval cover slidable along the shaft of the medical device, the cover having a radially reduced proximal portion, a distally open distal end and an elongate tubular wall extending therebetween and defining a recess; the working element of the medical device being completely retained within the recess of the cover such that the tubular wall extends distally beyond the medical device; and

c) a retrieval sheath, the retrieval sheath having a lumen and being slidable with respect to both the medical device and the cover, at least a proximal length of the working element of the medical device and the cover being retained within the lumen of the retrieval sheath, the retrieval sheath radially compressing the proximal length of the cover such that an intermediate portion of the wall tightly engages a surface of the medical device.

9. A method of retrieving particulate or other foreign material within a channel of a patient's body, comprising:

a) providing a medical device having a working element and a flexible, elongate shaft adapted to follow a path within the channel; a distally open cover slidable with respect to the shaft; and a retrieval sheath moveable with respect to the cover and the shaft;

b) positioning the medical device within the vessel to engage a wall of the channel and trap the material within the channel, the cover and the retrieval sheath being spaced proximally of the working element along the shaft of the medical device, the cover being radially compressed within the lumen of the retrieval sheath such

that it has a distally open distal end and a wall defining a recess, the wall engaging an inner surface of the retrieval sheath;

c) moving the cover distally with respect to the retrieval sheath, thereby permitting the cover to radially expand into a deployed configuration wherein the distal end remains distally open and the enclosure is radially expanded, the cover expanding radially outwardly into the deployed configuration without having to invert on itself;

d) moving the cover distally with respect to the medical device and into engagement with a surface of the medical device to form therebetween an enclosure;

e) moving the retrieval sheath distally with respect to the cover to urge the cover to collapse about the medical device and tightly engage the surface of the medical device.

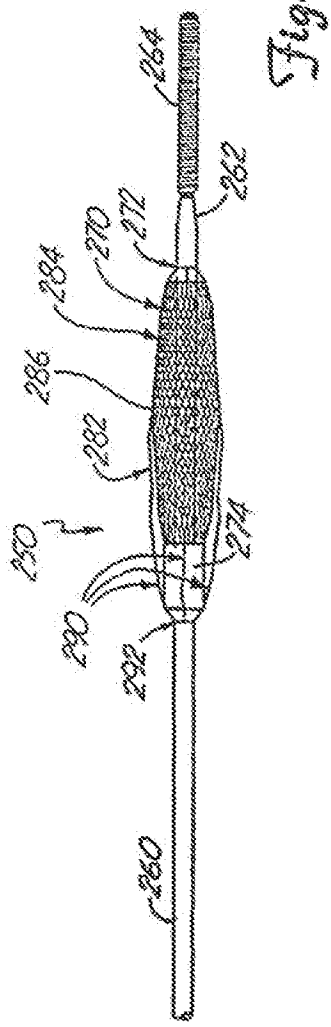

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Fig. 1A

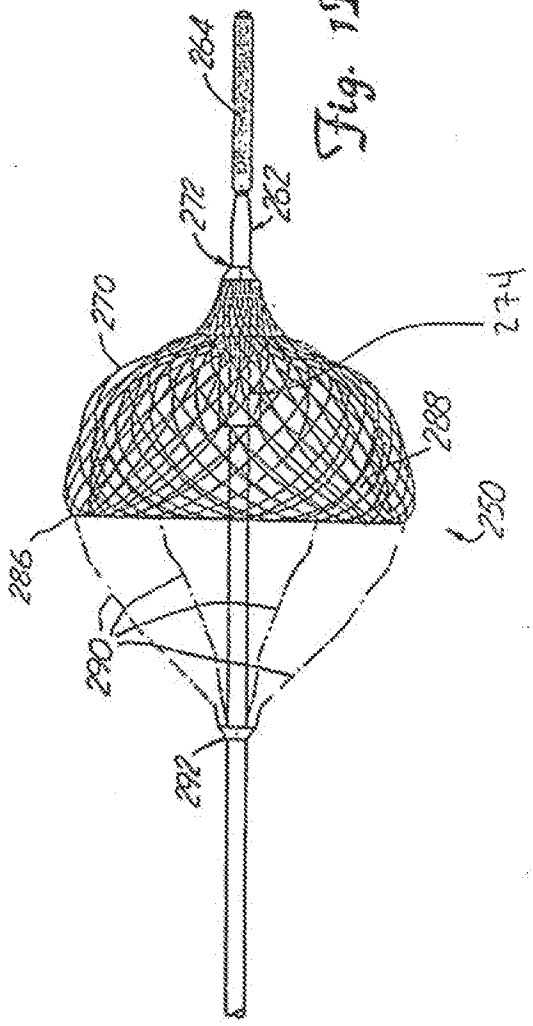

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Fig. 1B

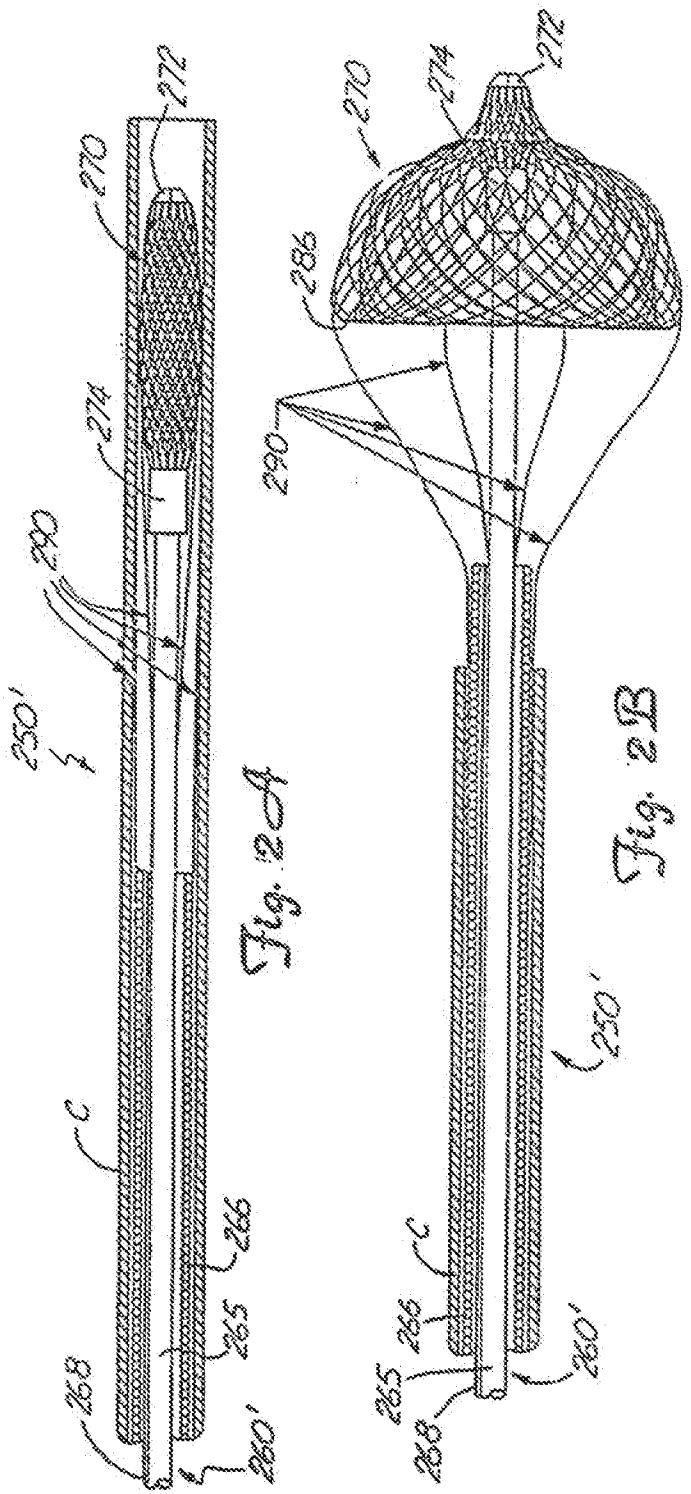

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Fig. 2A

Fig. 2B

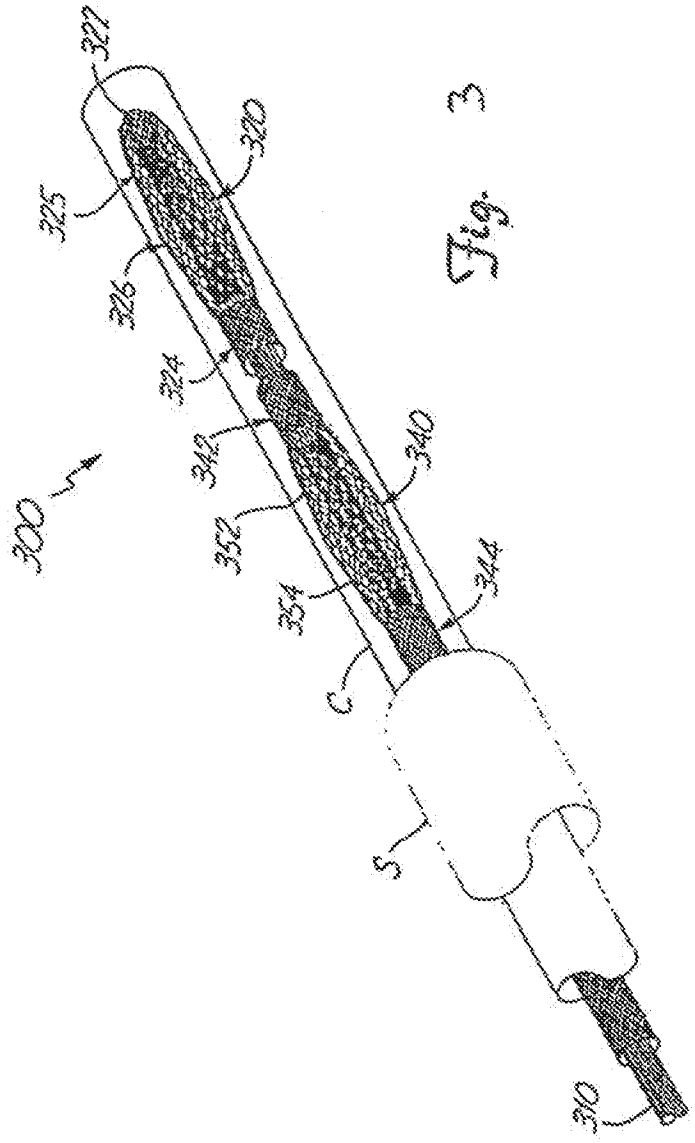


Fig. 3

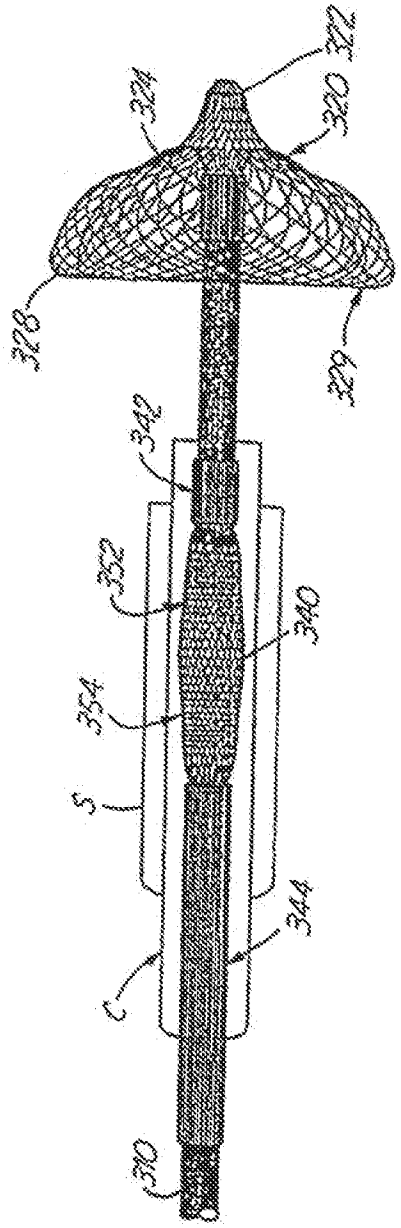


Fig. 4

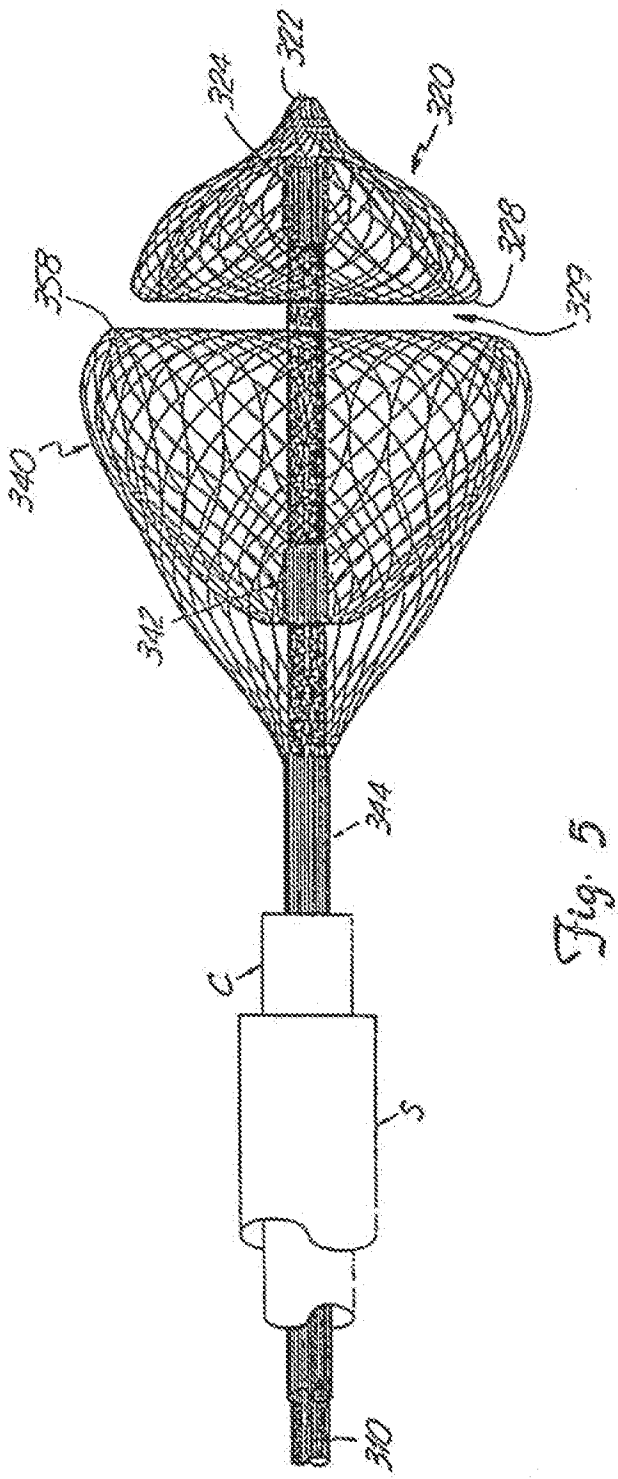


Fig. 5

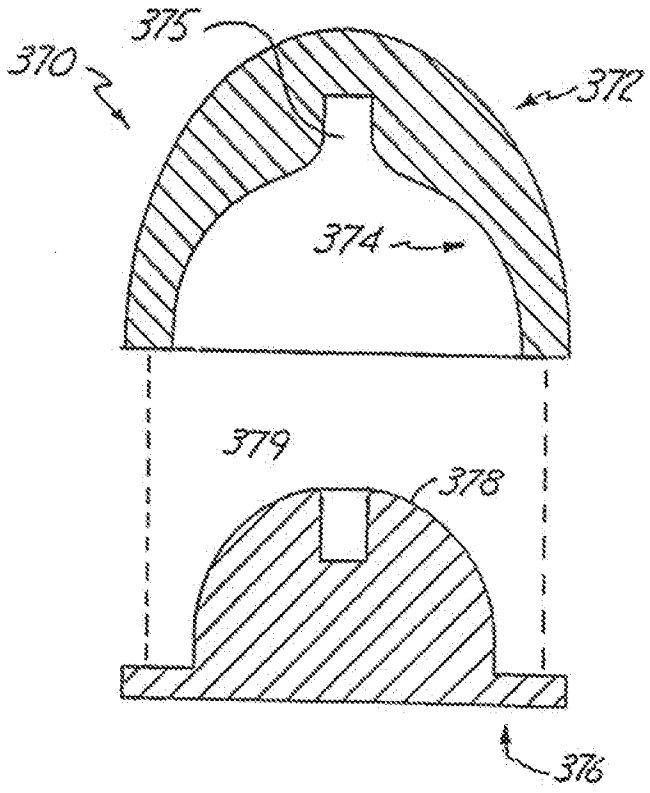


Fig. 6

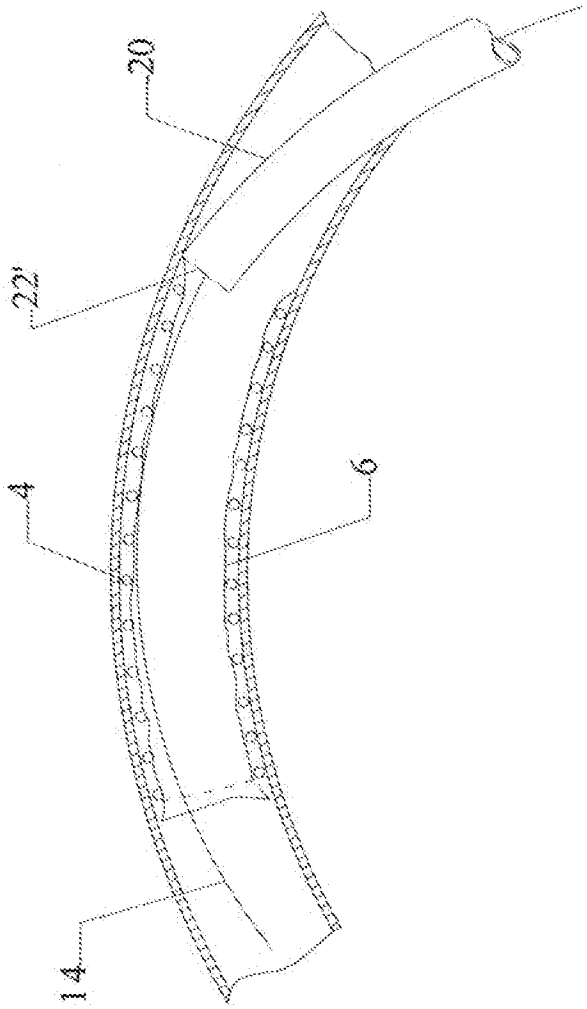


FIG. 7

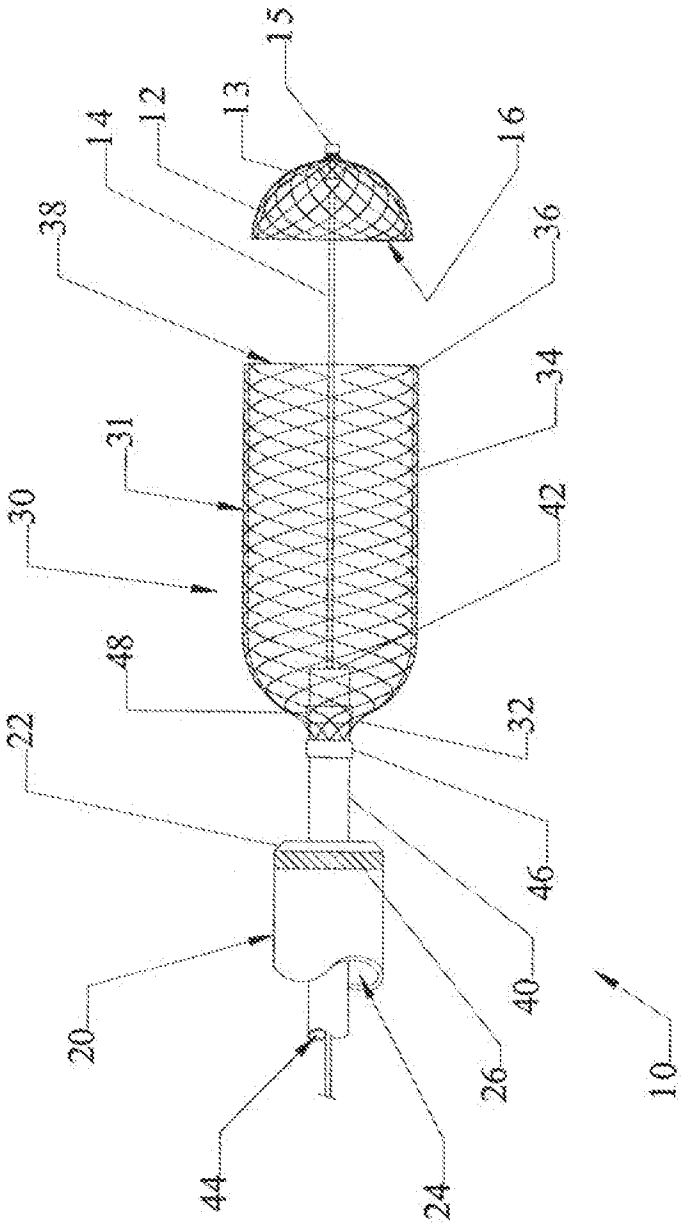


FIG. 8

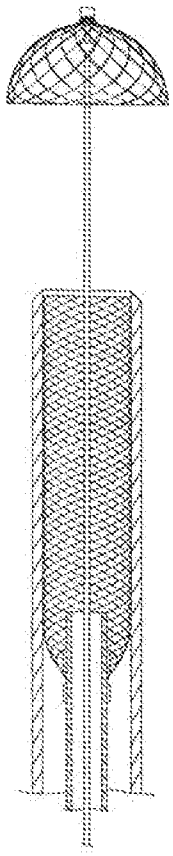


FIG. 9

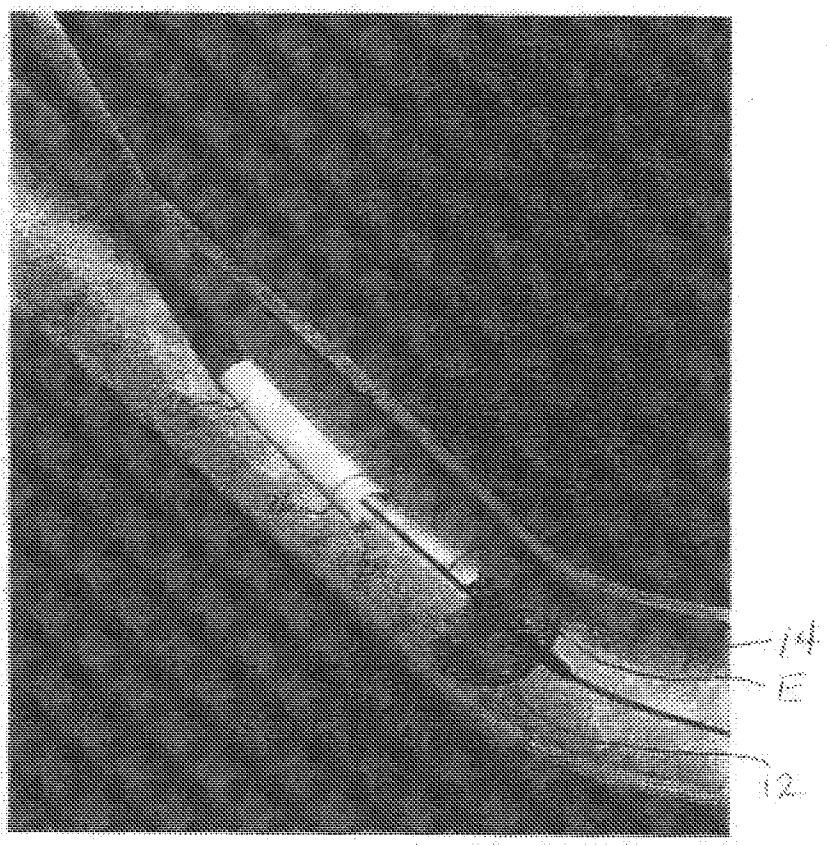


FIG. 10

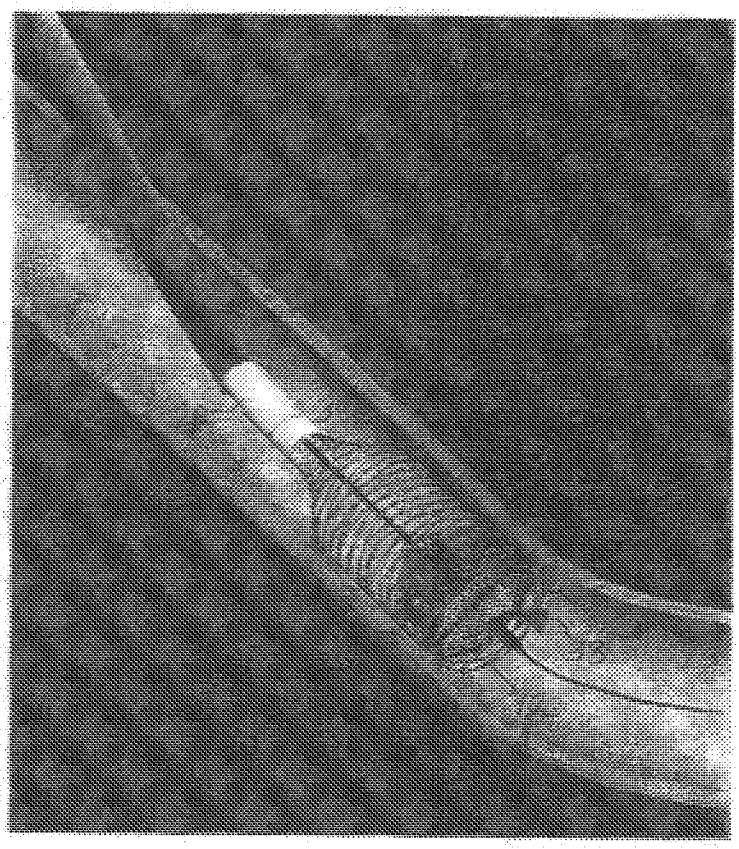


Fig. 11



FIG. 12

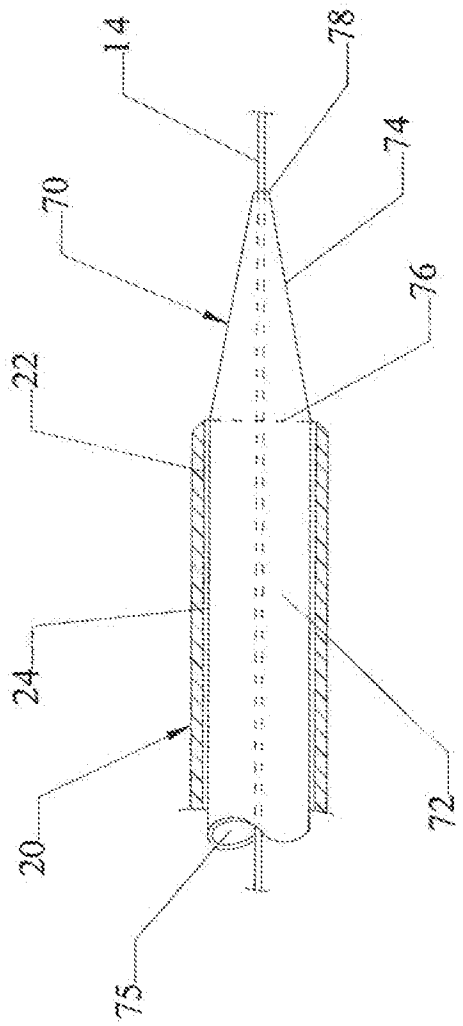


FIG. 13

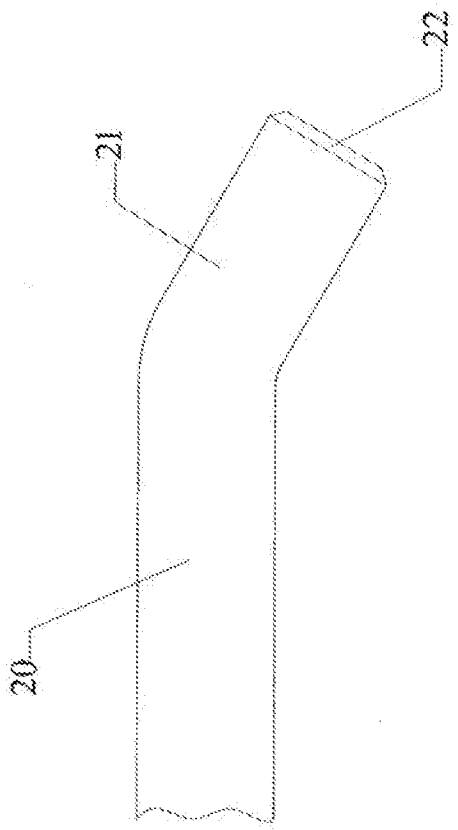


FIG. 14

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/06212

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/01 A61B17/22

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 102 415 A (VORWERK DIERK ET AL) 7 April 1992 (1992-04-07)	1-3
Y	the whole document	7,8
Y	WO 91 11209 A (BOSTON SCIENT CORP) 8 August 1991 (1991-08-08)	7,8
A	page 8, line 32 -page 9, line 15; figure 1	1
X	US 5 662 671 A (PASTRONE GIOVANNI ET AL) 2 September 1997 (1997-09-02)	1-4
A	abstract; figure 1	7,8
A	WO 96 01591 A (MICROVENA CORP) 25 January 1996 (1996-01-25) cited in the application abstract; figure 15	1-8

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

☒ Patent family members are listed in annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 July 2000	12/07/2000

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

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

INTERNATIONAL SEARCH REPORT

information on patent family members

Inter nal Application No
PCT/US 00/06212

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5102415 A	07-04-1992	DE 8910603 U	07-12-1989
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(71) Applicant *(for all designated States except US)*: **POSSIS MEDICAL, INC.** [US/US]; 9055 Evergreen Boulevard N.W., Minneapolis, MN 55433-8003 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **ANSEL, Gary, M., M.D.** [US/US]; 2115 Waltham Road, Colombus, OH 43221 (US). **BONNETTE, Michael, J.** [US/US]; 2733 2nd Avenue South, Minneapolis, MN 55408 (US). **JANSE, Dan, T.** [US/US]; 6592 Albert Court, Lino Lakes, MN 55038 (US). **LE, Hieu, V.** [US/US]; 3400 94th Avenue North, Brooklyn Park, MN 55443 (US).

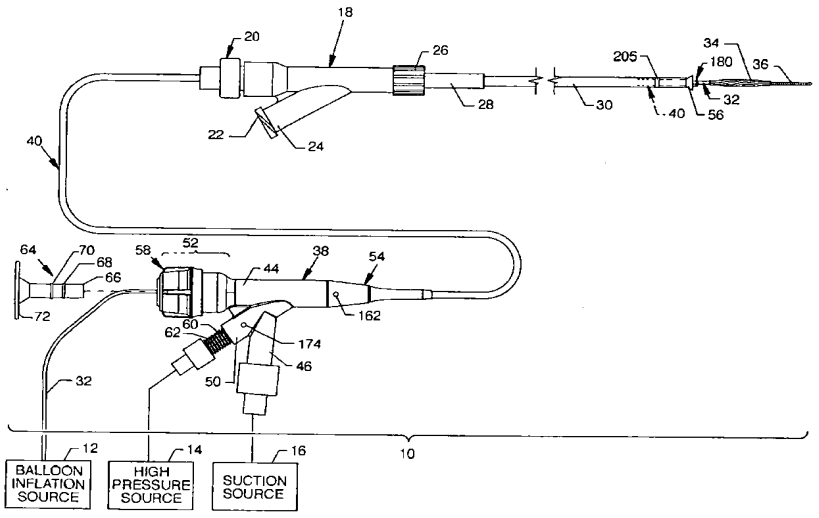
(74) Agent: **JAEGER, Hugh, D.**; Hugh D. Jaeger, P.A., 1000 Superior Boulevard, Suite 302, Wayzata, MN 55391-1873 (US).

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[Continued on next page]

(54) Title: THROMBECTOMY CATHETER SYSTEM WITH OCCLUDER AND METHOD OF USING SAME



(57) Abstract: A thrombectomy catheter system with occluder and method of using same for removal of tissue, such as thrombus and the like, form a vessel in the body. Multiple catheters and an occluder-bearing guidewire tube at a thrombus site provide for expandable deployment of a compliant occluder against the vasculature walls distal to the thrombus. The expanded occluder is maneuvered proximally to urge thrombus into close proximity with a retractable capture cone located distally on a capture catheter where the thrombus is dislodged, entrained, and broken into pieces by the action of a fluid jet emanator and then evacuated through the capture catheter.

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THROMBECTOMY CATHETER SYSTEM WITH OCCLUDER AND METHOD OF USING SAME

CROSS REFERENCES TO RELATED APPLICATIONS

[0001] None.

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

[0002] The present invention is for a thrombectomy catheter system with occluder and method of using same.

DESCRIPTION OF THE PRIOR ART

[0003] Prior art devices for addressing and influencing thrombotic deposits often included angioplasty devices where thrombotic deposits were merely reshaped outwardly and the vessel surrounding the thrombotic material was correspondingly urged to expand to allow greater blood throughflow. Such devices were often equipped with a filter or a balloon-style occluder distal to the thrombotic occlusion to filter out or constrain any thrombotic material which may be dislodged during such reshaping angioplasty processes to prevent recirculation of such thrombotic material in the vasculature. Often an occluder-like balloon would be utilized distal to the thrombotic deposit from which a cleansing fluid would be discharged in a less than aggressive fashion in order to carry any dislodged thrombotic material proximally to a collection device. While performing angioplasty involving the reshaping of the thrombotic material, little was done to actively and aggressively cause thrombotic materials to be urged into maceration devices for breaking up and carrying away the thrombotic materials. Such a function is provided by the present invention.

SUMMARY OF THE INVENTION

[0004] The general purpose of the present invention is to provide a thrombectomy catheter system with occluder and method of using same.

[0005] According to the present invention, there is provided a thrombectomy catheter system with occluder and method of using same for removal of tissue, such as thrombus and the like, from a vein or other vessel in the body. Several structures are provided for placement in a vein, artery or other vessel of the body to provide for removal of thrombus or like material. One such structure is a guide catheter attached to a manifold where the guide catheter is advanced into the vasculature to position the distal end of the guide catheter just proximal of a thrombus site. Another structure is an occluder guidewire tube having a distally located inflatable, expandable or distendable compliant occluder, which can be a balloon occluder or a mesh occluder, and a guidewire coil which is advanced distally through and beyond the distal end of the guide catheter to and through the thrombus at the thrombus site to a location whereat the occluder can be inflated, expanded or distended. Another structure includes a capture catheter suitably attached to a manifold that includes or supports at least the following components: a retractable capture cone being part of the capture catheter structure and being distally located on the capture catheter, a high pressure or hypo tube having a distally located fluid jet emanator, and a hemostasis nut. The retractable capture cone and the fluid jet emanator fixedly co-locate distally at the distal end of the capture catheter. The distal end of the capture catheter with the co-located retractable capture cone and fluid jet emanator are advanced distally over and about the occluder

guidewire tube and within the guide catheter to be positioned distally just beyond the distal end of the guide catheter and just proximal to the thrombus site where the retractable capture catheter cone is expandingly deployed in a cone shape against the artery, vein or other vessel wall. Expanded deployment of the retractable capture cone provides a structure to receive displaced thrombus for breakup and maceration by the fluid jet emanator, which provides proximally directed fluid jet streams. The occluder, which could distend, expand or inflate, compliantly conforms to the shape of the vein wall or other vessel wall and is maneuvered proximally by maneuvering the occluder guidewire tube proximally, thereby urging and displacing the thrombus proximally into or near the deployed retractable capture cone where the thrombus comes into contact with and is impinged by the proximally directed fluid jet streams of the fluid jet emanator for breakup and maceration and subsequent evacuation through the capture catheter.

[0006] The method of use of the present invention incorporates the following steps:

[0007] 1. Advancing the distal end of the guide catheter into a blood vessel or other vessel to a position just proximal of a thrombus buildup.

[0008] 2. Loading and advancing the distal end of the occluder guidewire tube through the hemostasis nut and into and through a manifold and thence through a lumen of the guide catheter.

[0009] 3. Advancing the distal end of the occluder guidewire tube including the guidewire coil and the occluder beyond the distal end of the guide catheter and through and beyond the thrombus.

[0010] 4. Loading the distal end of the capture catheter, including the retractable capture cone and the fluid jet emanator, over the proximal end of the occluder guidewire tube.

[0011] 5. Inflating, expanding or distending the occluder to occlude the blood vessel or other vessel.

[0012] 6. Positioning the capture catheter to a position to expandingly deploy the retractable capture cone just beyond the distal end of the guide catheter.

[0013] 7. Providing and activating high pressure medium to the fluid jet emanator to form rearwardly directed fluid jets.

[0014] 8. Positioning the expanded, inflated or distended occluder proximally to impinge, impact, dislodge, reshape and redistribute thrombus and to urge and deliver such thrombus into the retractable capture cone.

[0015] 9. Macerating, dislodging, reducing and breaking up repositioned thrombus delivered to the retractable capture cone by interaction of the rearwardly directed fluid jets with the thrombus.

[0016] 10. Evacuating the macerated, dislodged, reduced and broken-up thrombus.

[0017] Discussion of the above steps is provided with reference to **FIGS. 1 and 13-17.**

[0018] According to embodiments of the present invention, there are provided thrombectomy catheter systems with occluders.

[0019] One significant aspect and feature of the present invention is a thrombectomy catheter system with occluder incorporating a guide catheter.

[0020] Another significant aspect and feature of the present invention is a thrombectomy catheter system with occluder incorporating a capture catheter having a retractable capture cone.

[0021] Still another significant aspect and feature of the present invention is a thrombectomy catheter system with occluder incorporating expansion struts to expand a retractable capture cone.

[0022] Another significant aspect and feature of the present invention is a thrombectomy catheter system with occluder having a retractable capture cone of expandable mesh.

[0023] Yet another significant aspect and feature of the present invention is a thrombectomy catheter system with occluder having a retractable capture cone which is deployable and which is retractable.

[0024] A further significant aspect and feature of the present invention is a thrombectomy catheter system with occluder having a retractable capture cone which receives and collects thrombus for breakup and maceration.

[0025] A further significant aspect and feature of the present invention is a thrombectomy catheter system with occluder having a fluid jet emanator co-located with a retractable capture cone which receives thrombus for breakup and maceration.

[0026] A still further significant aspect and feature of the present invention is a thrombectomy catheter system with occluder having an occluder guidewire tube having a distally located occluder which can be

inflatable, deflatable, expandable, distendable, and compliant.

[0027] A still further significant aspect and feature of the present invention is a thrombectomy catheter system with occluder having a distally located occluder which can be inflated, expanded or distended, and which can be positioned by proximal movement of the occluder guidewire tube to urge thrombus into the retractable capture cone to come under the influence of a fluid jet emanator.

[0028] In alternative embodiments, another significant aspect and feature of the present invention is a controllable-shape mesh occluder for use with the thrombectomy catheter system with occluder.

[0029] In alternative embodiments, another significant aspect and feature of the present invention is a flexible shaped mesh occluder for use with the thrombectomy catheter system with occluder.

[0030] Having thus enumerated certain significant aspects and features of the present invention, it is the principal object of the present invention to provide a thrombectomy catheter system with occluder and method of using same.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] Other objects of the present invention and many of the attendant advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, in which like reference numerals designate like parts throughout the figures thereof and wherein:

[0032] **FIG. 1** is a plan view of the thrombectomy catheter system with occluder, the present invention, shown in use with supporting operational sources;

[0033] **FIG. 2** is an exploded isometric view of the thrombectomy catheter system with occluder;

[0034] **FIG. 3** is an exploded cross sectional side view of a manifold and associated components;

[0035] **FIG. 4** is an assembled cross sectional side view of the manifold and associated components shown in **FIG. 3**;

[0036] **FIG. 5** is an exploded view in partial cross section of a manifold and associated components;

[0037] **FIG. 6** is an assembled view in partial cross section of the components of the manifold and associated components shown in **FIG. 5**;

[0038] **FIG. 7** is an isometric view showing the retractable capture cone in a deployed state at the distal end of a capture catheter;

[0039] **FIG. 8** is a cross section view along line 8-8 of **FIG. 7** showing the retractable capture cone in a deployed state at the distal end of a capture catheter;

[0040] **FIG. 9** is an isometric view of the fluid jet emanator located distally at one end of the high pressure tube;

[0041] **FIG. 10** is a transparent isometric view in partial cross section illustrating the alignment and attachment of the high pressure tube within the lumen of the capture catheter, which also favorably influences and provides for the alignment and fixed positioning of the fluid jet emanator with the retractable capture cone;

[0042] **FIG. 11** is a longitudinal cross sectional view of the distal region of the capture catheter including the collapsed retractable capture cone, and the fluid jet emanator aligned over the occluder guidewire tube in the distal region of the guide catheter;

[0043] **FIG. 12** is a longitudinal cross sectional view of the distal region of the occluder guidewire tube;

[0044] **FIG. 13** is a longitudinal cross sectional view showing the distal end of the guide catheter advanced into a blood vessel to a position just proximal of a buildup of thrombus or other undesirable embolic materials;

[0045] **FIG. 14** is a longitudinal cross sectional view showing the distal end of the occluder guidewire tube, including the guidewire coil and an occluder in the form a balloon, advanced through and beyond a thrombus site in a blood vessel and showing the distal end of the guide catheter just proximal of the thrombus site;

[0046] **FIG. 15** is a longitudinal cross sectional view showing elements of the thrombectomy catheter system with occluder within a blood vessel and showing saline or other suitable medium as provided by a balloon inflation source to pressurize the lumen of the occluder guidewire tube and to deliver pressurized saline through the plurality of inflation orifices to inflate and expand the balloon occluder to occlude the blood vessel;

[0047] **FIG. 16** is a view like **FIG. 15** but showing the inflated balloon occluder impinging and urging thrombotic deposits for fluid jet impingement at the retractable capture cone;

[0048] **FIG. 17** is a view like **FIG. 16** but showing the inflated balloon occluder near impingement with the retractable capture cone where the majority of the thrombus has been macerated at the retractable capture cone and evacuated through the lumen of the capture catheter;

[0049] **FIG. 18**, an alternative embodiment, illustrates a retractable capture cone of flexible plastic mesh formed by weaving, braiding, or other such interlacing of strands, filaments or the like having position memory in a deployed state at the distal end of a capture catheter;

[0050] **FIG. 19** is a cross section view of the capture catheter and retractable capture cone along line 19-19 of **FIG. 18**;

[0051] **FIG. 20**, an alternate embodiment, is an exploded isometric view depicting an alternative fluid jet emanator and the relationship of the capture catheter support band to a high pressure tube;

[0052] **FIG. 21** is an assembled isometric view of the elements of **FIG. 20**;

[0053] **FIG. 22** is a transparent isometric view of the elements of **FIGS. 20 and 21** in partial cross section illustrating the alignment and attachment of the high pressure tube within a lumen of a capture catheter;

[0054] **FIG. 23** is a cross section view of an alternative embodiment incorporating a controllable-shape mesh occluder;

[0055] **FIG. 24** is a view illustrating the use of the elements of **FIG. 23**;

[0056] **FIG. 25** is an isometric view of an alternative embodiment incorporating a flexible shaped mesh occluder;

[0057] **FIG. 26** is a cross section view of the embodiment of **FIG. 25** showing the flexible shaped mesh occluder of **FIG. 25** in a compressed state; and,

[0058] **FIG. 27** is a view llustrating the use of the elements of **FIG. 26**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0059] **FIG. 1** is a plan view of the thrombectomy catheter system with occluder 10, the present invention, shown in use with supporting operational sources including, but not limited to, a balloon inflation source 12, a high pressure source 14, and a suction source 16. **FIG. 2** is an exploded isometric view of the thrombectomy catheter system with occluder 10. With reference to **FIGS. 1 and 2**, structure of the present invention is now described. Externally visible components, or portions of components, of the thrombectomy catheter system with occluder 10, as illustrated in **FIGS. 1 and 2**, include a first structure including a manifold 18, also known as a Y-adapter, a hemostasis nut 20 which secures in the proximal end of the manifold 18, a Luer connection 22 located at the proximal end of an angled manifold branch 24 extending from the manifold 18, a Luer fitting 26 secured to the distal end of the manifold 18, a strain relief 28, which can be flexible, secured to the distal end of the manifold 18 by the Luer fitting 26, and a guide catheter 30 suitably attached to the distal end of the manifold 18 via the strain relief 28. Another structure is an occluder guidewire tube 32 having an occluder, in this embodiment in the form of a balloon occluder 34, which can be an elastomer similar to polyurethane, silicone, latex or the like, which is inflatable and deflatable and which is compliant. Alternatively, balloon occluder 34 can be an inflatable and deflatable balloon of stiffer polymeric materials such as polyester or PET or composite material, and which may unfold as it is inflated; for example, balloon occluder 34 can also function like an angioplasty balloon. Other embodiments show occluders which are

non-inflatable, yet compliant. The balloon occluder 34 is located at the distal portion of the occluder guidewire tube 32. A guidewire coil 36, which is flexible, is located distal to the balloon occluder 34 and distal to the occluder guidewire tube 32. Another structure includes a one-piece manifold 38 having multiple components extending therefrom or attached thereto including a capture catheter 40, a high pressure tube 42, and other components as described herein. The visible portion of the one-piece manifold 38 includes a central tubular body 44, an exhaust branch 46 having branch passage 47 (**FIG. 5**) and a Luer connection 48 and a flangeless high pressure connection branch 50 extending angularly from the central tubular body 44, and a cavity body 52 extending proximally from the central tubular body 44. The proximal end of the capture catheter 40 secures to the manifold 38 by an interceding streamlined flexible strain relief 54. The proximal end of the capture catheter 40 extends through the streamlined flexible strain relief 54 to communicate with the manifold 38. The capture catheter 40 extends distally to include a distally located retractable capture cone 56, the retractable capture cone 56 being shown in the deployed and expanded position. Also shown is a hemostasis nut 58 aligned to and snappingly engaged with the proximal region of the cavity body 52, and a high pressure connection port 60 having threads 62 which is secured such as by, but not limited to, adhesive, to the high pressure connection branch 50. Also provided is an introducer 64 having a hollow shaft 66, annular rings 68 and 70 about the hollow shaft 66, and an actuating handle 72. A self-sealing hemostasis valve 76 aligns in

cavity 78 located proximally in the cavity body 52 to seal about the occluder guidewire tube 32.

[0060] As used herein, the term guide catheter referring to item 30 can be a standard guide catheter as is known in percutaneous interventions, but the meaning is intended to be more general, and to include any generally tubular element through which capture catheter 40, or variations or alternative embodiments thereof, can pass and which restrains the retractable capture cone 56, or variations or alternative embodiments thereof, when the retractable capture cone 56 is retracted within the tubular element. Guide catheter 30 can have other characteristics typical of other tubular elements such as guiding catheters, introducer sheaths, guiding sheaths, angiographic catheters, infusion catheters, and so forth, but must additionally provide for passage of the capture catheter 40, or variations or alternative embodiments thereof, and provide for restraining the retractable capture cone 56, or variations or alternative embodiments thereof, in an unexpanded configuration when retractable capture cone 56 is retracted therein. Variations or alternative embodiments of capture catheters, retractable capture cones, fluid jet emanators, occluders in the form of balloon occluders or mesh occluders and the like, are described later in detail which can be operated in the structures of the invention to perform similar functions within the teachings of the invention.

[0061] **FIG. 3** is an exploded cross sectional side view of the manifold 18 and associated components. The manifold 18 includes a centrally located tapered passage 80 aligned along the longitudinal axis of the manifold 18 and a branch passage 82 which extends along the axis of the manifold branch 24 and which intersects with and is connected to the central tapered passage 80. The proximal end of the manifold 18 houses a multi-radius cavity 84 including a round outer cavity portion 86 and a connected round inner and smaller cavity portion 88 having a threaded surface 90 on the proximal portion thereof. The hemostasis nut 20 includes a body 92 having a grasping surface 94 extending thereabout, a threaded surface 96 extending from the body 92, an annular surface 98 at the end of the threaded surface 96, and a passageway 100 aligned centrally to the longitudinal axis of the hemostasis nut 20. The passageway 100 has a wide radius at the proximal end which decreases toward the distal end. The initial wide radius is helpful for insertion of the capture catheter 40, other guidewires, and the like. A seal 102 aligns to a distally located annular surface 104 of the round inner cavity portion 88 and bears around, about and against the annular surface 98 of the hemostasis nut 20 to seal the tapered passage 80 of the manifold 18 to the passageway 100 in the hemostasis nut 20, as required. The multi-radius cavity 84 and its internal geometry accommodate corresponding geometry of the hemostasis nut 20 and the seal 102.

[0062] Luer fitting 26 is utilized to secure the strain relief 28 and the guide catheter 30 to the distal end of the manifold 18. The strain relief 28 is comprised of a tube 106, a central bore 108 internal to the tube 106 which accommodates the guide catheter 30, an annular

flange 110 about the tube 106, and a tapered proximal tube mouth end 112. It is to be noted that the outer diameter of the tube 106 is constant from the annular flange 110 to the distal end of the tube 106, and that the outer diameter steadily decreases from the annular flange 110 to the tapered proximal tube mouth end 112 to provide a tapered tube surface 114 which conforms, for purpose of a proper fit, to the taper of the tapered central passage surface 118 of the tapered passage 80. The tapered proximal tube mouth end 112 allows for easily accomplished alignment of the capture catheter 40, other guidewires or other assemblies within a lumen 119 located in the guide catheter 30. The Luer fitting 26 includes threads 120 which threadingly engage corresponding threads 122 at the distal end of the manifold 18. The Luer fitting 26 bears against the annular flange 110 of the strain relief 28 to force the tapered tube surface 114 of the strain relief 28 against the tapered central passage surface 118 of the tapered passage 80 to effect a suitable and stable seal.

[0063] **FIG. 4** is an assembled cross sectional side view of the manifold 18 and associated components shown in **FIG. 3.**

[0064] **FIG. 5** is an exploded view in partial cross section of the manifold 38 and associated components, and **FIG. 6** is an assembled view in partial cross section of the components of the manifold 38 and associated components shown in **FIG. 5**. A portion of the occluder guidewire tube 32 is also shown in engagement with the manifold 38 and other associated components.

[0065] The manifold 38 and associated components include a self-sealing hemostasis valve 76 and also a hemostasis nut 58 which aligns over and about threads 123 at the proximal region of the manifold 38. Portions of the hemostasis nut 58 and all of the self-sealing hemostasis valve 76 are accommodated internally by the cavity 78 located in the cavity body 52 of the manifold 38. The cavity 78 is for the most part tubular in shape including a tubular cavity wall 126 and a planar surface 128 which is annular and circular and which intersects the tubular cavity wall 126. A cavity extension 130, being for the most part tubular, extends distally from the cavity 78 beginning at the planar surface 128 to intersect and connect with an orifice 132. The orifice 132 is common to the cavity extension 130, the cavity 78, and a tapered central passageway 134 located central to the central tubular body 44. The cavity 78 accommodates the self-sealing hemostasis valve 76, which aligns to planar surface 128.

[0066] The hemostasis nut 58, which can provide a slidable seal about the occluder guidewire tube 32, includes a centrally located cylindrical boss 136, a beveled passageway 138 extending through and in part forming the cylindrical boss 136, and internal threads 140 distanced from the cylindrical boss 136 by a distally located space 142 extending along the internal threads 140

and along the distal portion of the cylindrical boss 136. A proximally located space 144 is located adjacent to the distally located space 142. An annular stop surface 146 is located at the proximal region of the proximally located space 144. The distally located space 142 accommodates the proximal end 148 of the manifold 38 including threads 123 located along and about the outer proximal portion of the cavity body 52 of the manifold 38. Also included in the hemostasis nut 58 is an annular lip 150 which can be utilized for snap engagement of the introducer 64 or other particular styles or types of introducers as required. The hemostasis nut 58 threadingly engages the manifold 38 where the internal threads 140 of the hemostasis nut 58 engage and are advanced along the threads 123 of the manifold 38 until advancement of the hemostasis nut 58 is predeterminately stopped by impingement of the annular stop surface 146 against the proximal end 148 of the manifold 38, whereby and whereupon the cylindrical boss 136 is brought to bear directly against the self-sealing hemostasis valve 76 resultingly bringing pressure to bear as required against the self-sealing hemostasis valve 76 to effect sealing with the cavity wall 126 of the cavity 78, to seal the self-sealing hemostasis valve 76 to the occluder guidewire tube 32 and to seal the self-sealing hemostasis valve 76 to the planar surface 128. In the alternative, a suitable adhesive can be applied to the internal threads 140 of the hemostasis nut 58 and/or to the threads 123 of the manifold 38 to ensure permanent fixation of the hemostasis nut 58 to the manifold 38. Such adhesive application ensures fixed and non-adjustable sealing of the self-sealing hemostasis valve 76 to the occluder guidewire tube 32. The self-sealing hemostasis valve 76 is captured

in the cavity 78 by engagement of the hemostasis nut 58 to the cavity body 52 of the manifold 38, as shown in **FIG. 6**. Due to the similar geometrical configurations of the opposing faces and associated structure therebetween of the self-sealing hemostasis valve 76, the self-sealing hemostasis valve 76 can be inserted into the cavity 78 without regard to the orientation of the opposing sides.

[0067] The streamlined flexible strain relief 54 is fitted and adhesively or otherwise suitably affixed to the distal interior portion of the manifold 38. The streamlined flexible strain relief 54 can be fashioned of flexible plastic, rubber, or the like and includes a constant radius region 152 adjoined by a short tapered region 154, each region fitting to and being accommodated respectively by the distal portion of the tapered central passageway 134 and an included short tapered region 156 of the tapered central passageway 134 of the manifold 38, as shown in **FIG. 6**. Adjoining the short tapered region 154 of the streamlined flexible strain relief 54 is a tapered region 158 located distally thereto. A passageway 160 extends along the length of the streamlined flexible strain relief 54 for accommodation and passage of the occluder guidewire tube 32 and the high pressure tube 42. An adhesive injection port 162 (see also **FIG. 1**) can be located at a suitable location extending through an exterior tapered region 164 of the manifold 38, which is flangeless, to introduce adhesive 166 to the distal interior region of the manifold 38 including the distal end of the tapered central passageway 134 and the included short tapered region 156 of the tapered central passageway 134. Such adhesive injection can be accomplished when the streamlined flexible strain relief 54 is mated to the distal end of the manifold 38 as

shown in **FIG. 6**, or adhesive may be applied to the mated surfaces separately, or electronic welding or bonding can be incorporated, or adhesive may be otherwise suitably applied as applicable to the art.

[0068] The threaded high pressure connection port 60 is fitted and adhesively or otherwise suitably affixed to the interior of a high pressure connection branch passageway 124 of the high pressure connection branch 50. The threaded high pressure connection port 60 has a passageway 168 and is fitted to and adhesively or otherwise suitably affixed to the interior of the flangeless high pressure connection branch 50 of the manifold 18. Opposing flats 170 are located at the distal portion of the threaded high pressure connection port 60 to adequately receive adhesive 172 in close communication to ensure proper physical fixation and adhering of the threaded high pressure connection port 60 within the high pressure connection branch passageway 124 of the high pressure connection branch 50. An adhesive injection port 174 (**FIG. 1**) is located at a suitable location to extend through the high pressure connection branch 50 of the manifold 38 to introduce adhesive 172 to the interior region of the high pressure connection branch 50. The adhesive 172, in addition to adhering the flats 170 of the threaded high pressure connection port 60 to the high pressure connection branch passageway 124, also bonds the appropriate portions of the threads 62 of the threaded high pressure connection port 60 to the high pressure connection branch passageway 124. Adhesive injection can be accomplished when the threaded high pressure connection port 60 is mated to the high pressure connection branch 50 of the manifold 38, as shown in **FIG. 6**. Adhesive could also be applied to the mated surfaces separately, or

electronic welding or bonding can be incorporated, or adhesive may be otherwise suitably applied as applicable to the art. Also shown is a ferrule 178 which aligns and suitably secures within the passageway 168 of the threaded high pressure connection port 60, the combination of which aligns partially within the high pressure connection branch passageway 124 of the high pressure connection branch 50.

[0069] One end of the high pressure tube 42 is utilized for delivery of high pressure ablation liquids and suitably secures in a center passage of the ferrule 178 to communicate with the passageway 168 of the threaded high pressure connection port 60. The high pressure tube 42 also extends through the high pressure connection branch passageway 124, through part of the tapered central passageway 134, through the streamlined flexible strain relief 54, through the capture catheter 40, and to the distal end of the capture catheter 40 to align within the retractable capture cone 56 where termination is provided in the form of a fluid jet emanator 180 (see **FIGS. 1, 2 and 9**).

[0070] FIG. 7 is an isometric view showing the retractable capture cone 56 in a deployed state at the distal end of the capture catheter 40. The retractable capture cone 56 and a portion of the capture catheter 40 can be a composition of materials including a plurality of expansion struts 182a-182n where, for illustration purposes, expansion strut 182a is shown distant from the structure of the deployed retractable capture cone 56. The expansion struts 182a-182n are preferably metallic or are of other such suitable material which can be formed to provide spring-like qualities having position memory in order to expandingly form the cone-like shape of the retractable capture cone 56. The expansion struts 182a-182n are encapsulated in polymers forming the capture catheter 40 and retractable capture cone 56 such as, but not limited to, PTFE, PEBAX, polyethylene, PET, polyamide, polyurethane or silicone. The expansion struts 182a-182n are preferably of metallic material such as, but not limited to, stainless steel, nitinol, nickel, platinum, iridium or tungsten. The expansion struts 182a-18n are preformed having a bend or curve 184 located between a straight strut portion 186 which resides generally in the non-cone-shaped distal region of the capture catheter 40 and a straight strut portion 188 directed at an angle from the first straight strut portion 186 and residing in the retractable capture cone 56. The interior conical surface 190 of the retractable capture cone 56 connects to and is in common with a lumen 192 extending the length of the capture catheter 40.

[0071] **FIG. 8** is a cross section view of the retractable capture cone 56 along line 8-8 of **FIG. 7** showing more clearly the expansion struts 182a-182n located within the retractable capture cone 56.

[0072] **FIG. 9** is an isometric view of the fluid jet emanator 180 located distally at one end the high pressure tube 42. The fluid jet emanator 180 is a loop formed of the high pressure tube 42. A lumen 194 delivers high pressure saline or other such suitable fluid to the fluid jet emanator 180. A plurality of rearwardly and proximally directed jet orifices 196a-196n are located along the proximally facing portion of the fluid jet emanator 180. High pressure saline delivered by the lumen 194 is forced into the fluid jet emanator 180 to cause saline fluid jets 198a-198n to emanate from the rearwardly and proximally directed jet orifices 196a-196n. Such fluid jets 198a-198n are directed into the retractable capture cone 56 and are utilized to macerate, entrain and carry away thrombus, as later described in detail. The loop center 200 of the fluid jet emanator 180 accommodates passage of the occluder guidewire tube 32. A capture catheter support band 201 such as shown in this and alternate embodiments suitably attaches such as by a weld 203 to the high pressure tube 42 to maintain the position and orientation of the fluid jet emanator 180 with respect to the center of the support band 201 and also to the centerline of the capture catheter 42, as shown in **FIG. 10.** Although the fluid jet emanator 180 is shown as a loop formed of the high pressure tube 42, other suitably fashioned or shaped emanator designs can be utilized as an emanator and the use of the fluid jet emanator 180 having a loop shall not be considered to be limiting to the scope of the invention. For example, J-shaped, L-shaped, U-shaped, arcuate-shaped, semi-torodial-shaped, or other-shaped emanator(s) can be utilized. The emanator can have a single jet orifice from which a single fluid jet emanates, or a plurality of jet

orifices from which a plurality of fluid jets emanate. The preferred configuration includes a plurality of proximally directed jet orifices.

[0073] **FIG. 10** is a transparent isometric view in partial cross section illustrating the alignment and attachment of the high pressure tube 42 within the lumen 192 of the capture catheter 40, which also favorably influences and provides for the alignment and fixed positioning of the fluid jet emanator 180 with the retractable capture cone 56. Such fixed positioning and alignment is provided by the capture catheter support band 201 being fixedly aligned within the lumen 192 of the capture catheter 40. The capture catheter support band 201 is positionally fixed within the lumen 192 by frictional engagement of a cylindrically shaped radiopaque marker band 205, such as shown in this and alternate embodiments, engaged over and about the capture catheter 40.

[0074] **FIG. 11** is a longitudinal cross section view of the distal region of the capture catheter 40 including the collapsed retractable capture cone 56, and the fluid jet emanator 180 aligned in the distal region of the capture catheter 40 prior to deployment of the retractable capture cone 56. Also shown is the occluder guidewire tube 32 aligned within the lumen 192 of the capture catheter 40. Also shown is the guide catheter 30 in which the capture catheter 40 aligns.

[0075] **FIG. 12** is a longitudinal cross sectional view of the distal region of the occluder guidewire tube 32. Shown in particular is a weld 202 which joins together the extreme distal portion of the occluder guidewire tube 32, the proximal end of the guidewire coil 36, and the proximal end of a tapered flexible core 204. A weld 206 is also included at the distal end of the guidewire coil 36 to secure the distal end of the tapered flexible core 204 to the distal end of the guidewire coil 36 and to provide for smooth entry into a vessel or body cavity device orifice. The balloon occluder 34 aligns around and about the distal portion of the occluder guidewire tube 32 and the distal and proximal ends of the balloon occluder 34 secure by adhesive 208 or other suitable attachment means to the periphery of the occluder guidewire tube 32. Such securing seals the balloon occluder 34 to the periphery of the occluder guidewire tube 32 to allow sustained inflation of the balloon occluder 34 by pressurizing the lumen 193 with a medium such as liquid or gas whereby such pressurizing medium is delivered through a plurality of inflation orifices 210a-210n located around and about the distal portion of the occluder guidewire tube 32. Alternatively, a single inflation orifice can be used, although this is not the preferred configuration.

MODE OF OPERATION

[0076] **FIGS. 1 and 13-17** illustrate the mode of operation of the thrombectomy catheter system with occluder 10 and the method of using the same. **FIG. 1** shows the thrombectomy catheter system with occluder 10 in use with supporting operational sources including, but not limited to, a balloon inflation source 12, a high pressure source 14, and a suction source 16. Fluoroscopy is incorporated to monitor the position of the invasive components of the system in the region of thrombus residing in the vasculature.

[0077] As shown in **FIG. 13**, the distal end of the guide catheter 30 is advanced into a blood vessel 214 or other vessel to a position just proximal of a buildup of thrombus 212 or other undesirable embolic materials. Such advancement involves the manipulation of the manifold 18 to which the guide catheter 30 is attached.

[0078] The distal end of the occluder guidewire tube 32 is then loaded through the hemostasis nut 20 and into and through the manifold 18 and thence through the lumen 119 of the guide catheter 30 and advanced beyond the distal end of the guide catheter 30. The distal end of the occluder guidewire tube 32, including the guidewire coil 36 and the balloon occluder 34, is advanced through and beyond the thrombus 212, as shown in **FIG. 14**, whereby the proximal end of the balloon occluder 34 is positioned just distal of the thrombus 212. The proximal end of the occluder guidewire tube 32 of suitable length is left extending a suitable distance beyond the proximal end of the hemostasis nut 20 for accommodation of the capture catheter 40 and various associated components of the manifold 38 attached thereto.

[0079] The distal end of the capture catheter 40, including the retractable capture cone 56 and the fluid jet emanator 180, is then loaded over the proximal end of the occluder guidewire tube 32 where the lumen 192 of the capture catheter 40 and the loop center 200 of the fluid jet emanator 180 accommodate the occluder guidewire tube 32. Saline or other suitable medium as provided by the balloon inflation source 12 pressurizes the lumen 193 of the occluder guidewire tube 32 to deliver pressurized saline 195 through the plurality of inflation orifices 210a-210n to inflate and expand the balloon occluder 34 to occlude the blood vessel 214, as shown in

FIG. 15. The manifold 38 is then maneuvered to ensure full and proper positioning of the capture catheter 40 and especially the retractable capture cone 56 with respect to the distal end of the guide catheter 30 and the thrombus 212, as shown in **FIG. 15.** The retractable capture cone 56, when positioned suitably beyond the distal end of the guide catheter 30, expands with the aid of the expansion struts 182a-182n to a cone shape to contact the inner periphery of the blood vessel 214. When the balloon occluder 34 is inflated and when the retractable capture cone 56 is fully deployed, each against the wall of the blood vessel 214, maceration and removal of thrombus 212 is then commenced, as shown in and as described with reference to **FIGS. 16 and 17.**

[0080] As shown in **FIG. 16**, high pressure medium such as high pressure saline such as provided by the high pressure source 14 is delivered by the lumen 194 of the high pressure tube 42 and forced into the fluid jet emanator 180 to cause rearwardly directed saline fluid jets 198a-198n (also seen in **FIG. 9**) to emanate from the rearwardly directed jet orifices 196a-196n. Such fluid jets 198a-198n are directed into the retractable capture cone 56 and are utilized to macerate, entrain and carry away thrombus 212, the delivery of which is caused by the proximal urging of the inflated balloon occluder 34. Proximally directed urging of the thrombus 212 by the inflated balloon occluder 34 is facilitated by manipulation of the manifold 38 which, being connected to and in direct communication with the occluder guidewire tube 32 and attached inflated balloon occluder 34, impinges, dislodges, reshapes and redistributes the thrombus 212 in a proximal direction for subsequent interaction with the rearwardly directed saline fluid jets 198a-198n. Proximally urged thrombus 212 is forced by the proximally directed balloon occluder 34 into the deployed retractable capture cone 56 proximally towards, about and around the fluid jet emanator 180 where the proximally directed fluid jets 198a-198n impinge, dislodge, macerate, reduce and otherwise influence the shape and structure of the thrombus 212 for evacuation. Suction appropriately applied to the lumen 192 of the capture catheter 40, such as by the suction source 16, creates a low pressure which, along with the rearwardly directed fluid jets 198a-198n, carries the macerated thrombus 212 proximally for collection at the suction source 16.

[0081] **FIG. 17** shows the inflated balloon occluder 34 near impingement with the retractable capture cone 56 where the majority of the thrombus 212 has been macerated at the retractable capture cone 56 and evacuated through the lumen 192 of the capture catheter 40. Subsequent to removal of thrombus 212, the balloon occluder 34 can be deflated and collapsed to the same size or smaller size than the capture catheter 40 such as by relieving or even applying negative pressure at the balloon inflation source 12. Such reduction in size of the balloon occluder 34 allows manipulation of the occluder guidewire tube 32 proximally to retract the collapsed balloon occluder 34 into the capture catheter 40. Once the collapsed balloon occluder 34 is contained inside the confines of the capture catheter 40, the capture catheter 40 can be retracted proximally to retractably collapse the retractable capture cone 56 to conform to the inner regions of the guide catheter 30 whereupon the capture catheter 40 and the occluder guidewire tube 32 can be withdrawn simultaneously, if desired. Alternatively, the guide catheter 30, the capture catheter 40 and the occluder guidewire tube 32 could be advanced distally as required to facilitate the removal of other thrombus as required.

[0082] Many of the following alternative embodiments and illustrations include originally shown and described elements of the invention. Alternative versions of first embodiment elements may include reference numerals having suffixes where the numeral relates to a previously described invention element of an element and the addition of a suffix, except for element pluralities, indicates that an alternate version of an element is shown and utilized.

[0083] **FIG. 18** is an alternative embodiment where the retractable capture cone 56 and expansion struts 182a-182n previously described are replaced by a retractable capture cone 216 preferably of flexible plastic mesh 217 formed by weaving, braiding, or other such interlacing of strands, filaments or the like, preferably of Nitinol, or other materials such as nylon or polyurethane, or metallic or other non-metallic flexible materials all having position memory. The retractable capture cone 216 functions much the same as the retractable capture cone 56 whereby the retractable capture cone 216 can conformingly assume a cylindrical shape when residing adjacent to, in alignment with, and in communication with a lumen 192a of a capture catheter 40a where such capture catheter 40a replaces and is like capture catheter 40 but includes a distal annular recess 220 for accommodation and suitable attachment, such as by, but not limited to, adhesive 219 (**FIG. 19**), depending on the material used, of the proximal end of the retractable capture cone 216. The retractable capture cone 216 because of positional memory can expand outwardly to form a conical or other suitable useful shape which can contact the inner periphery of the blood vessel 214. The retractable capture cone 216 is of close-knit material, such as described above, which does not allow fluids to pass therethrough and which functions in a somewhat identical manner to the retractable capture cone 56 where a conical surface 218 on the inside of the retractable capture cone 216 functions to channel thrombus 212 and receive fluid jets 198a-198n for thrombus maceration and subsequent thrombus evacuation through the lumen 192a of the capture catheter 40a according to the teachings of the invention.

[0084] **FIG. 19** is a cross section view of the capture catheter 40a and retractable capture cone 216 along line 19-19 of **FIG. 18.** Shown in particular is the annular recess 220 which accommodates the proximal end of the retractable catheter cone 216 and which accommodates a suitable attachment medium such as an adhesive 219, or, alternatively, weldments or other attachment means. The annular recess 220 provides for attachment of the retractable capture cone 216 having no protrusions or irregular surfaces which can interfere with smooth unencumbered passage of the union of the capture catheter 40a and the retractable capture cone 216 at the distal tip of the guide catheter 30.

[0085] **FIGS. 20, 21 and 22** illustrate an alternative embodiment fluid jet emanator 222 which can be utilized in lieu of the previously described fluid jet emanator 180. **FIG. 20** is an exploded isometric view depicting the alternative fluid jet emanator 222 and the relationship of the capture catheter support band 201 to a high pressure tube 42a. **FIG. 21** is an assembled isometric view of the elements of **FIG. 20**; and **FIG. 22** is a transparent isometric view of the elements of **FIGS. 20 and 21** in partial cross section illustrating the alignment and attachment of the high pressure tube 42a within the lumen 192 of the capture catheter 40 which also favorably influences and provides for the alignment and fixed positioning of the fluid jet emanator 222 with the retractable capture cone 56. Such fixed positioning and alignment is provided by the capture catheter support band 201 being fixedly aligned within the lumen 192 of the capture catheter 40. The capture catheter support band 201 secures such as by a weld 224 or other suitable attachment means to the lower surface of the high pressure tube 42a. The capture catheter support band 201 is fixed at a suitable position along the interior (lumen 192) of the capture catheter 40 by the compressional frictional engagement of a radiopaque marker band 205 over and about the capture catheter 40, as shown in **FIG. 22**.

[0086] The high pressure tube 42a is reduced in diameter at the high pressure tube 42a distal end 226 for suitable engagement with the fluid jet emanator 222. The fluid jet emanator 222 is built as a structure outwardly resembling the general shape of a disk. The fluid jet emanator 222 includes a cylindrical main body 228, an annular manifold groove 230 in the form of a circular groove at the proximal end of the cylindrical main

body 228, a centrally located tubular extension 232 extending proximally from the proximal end of the main body 228 and being coaxial with the annular manifold groove 230, a manifold plate 234 aligned to the annular manifold groove 230 and the adjacent planar annular surfaces having a plurality of jet orifices 236a-236n, a centrally located hole 238, and an offset hole 240. The centrally located hole 238 is aligned to and accommodated by the tubular extension 232. The manifold plate 234 is also aligned substantially to the proximal end of the main body 228 during the mating of the centrally located hole 238 and the tubular extension 232. A passageway 242 aligns to the longitudinal axis of the main body 228, the center of the tubular extension 232 and to the center of the centrally located hole 238 of the manifold plate 234. An annular manifold is formed when the manifold plate 234 is mated over and about the annular manifold groove 230 of the main body 228, at which time the plurality of jet orifices 236a-236n and the offset hole 240 are brought into close communicational sealed alignment with the annular manifold groove 230 in the main body 228.

[0087] High pressure fluid such as saline or other suitable solution is delivered through the lumen 194a of the high pressure tube 42a to the fluid jet emanator 222 and distributed through the formed manifold to the plurality of jet orifices 236a-236n, whereby high velocity jet flow emanates proximally for maceration of thrombus delivered to the retractable capture cone 56 by the balloon occluder 34 or other suitably fashioned structure described herein for subsequent evacuation through the capture catheter 40.

[0088] The radiopaque marker band 205 positions near and over and about the distal end of the capture catheter 40 for engagement of the capture catheter 40 by compressional frictional engagement and causes the capture catheter 40 to frictionally engage the capture catheter support band 201, as shown in **FIG. 22.** In the alternative, the capture catheter 40a and the mesh style retractable capture cone 216 previously described could be incorporated in lieu of the capture catheter 40 and the retractable capture cone 56 shown in **FIG. 22.**

[0089] **FIG. 23** is a cross section view of an alternative embodiment incorporating a controllable-shape mesh occluder 244 having structure providing a shape when expanded and distended substantially similar to and performing the same thrombotic influencing function as the previously described inflated balloon occluder 34. The controllable-shape mesh occluder 244 is not inflatable but has a shape which is controllable and which is distendingly expandable. The controllable-shape mesh occluder 244 is fabricated of flexible mesh 246, which can be a braid, a weave, or other interlacing strands or the like of metallic or non-metallic flexible materials, which optionally can include positional memory. The flexible mesh 246 is of close-knit material, such as described above, which does not allow fluids to pass therethrough. The controllable-shape mesh occluder 244 and the occluder guidewire tube 32a can be utilized in lieu of the balloon occluder 34 and the occluder guidewire tube 32 previously described according to the teachings of the invention where the controllable-shape mesh occluder 244 is positioned and expandingly deployed to assume a shape generally resembling the balloon occluder 34.

[0090] The occluder guidewire tube 32a, having a lumen 193a, replaces and is like the occluder guidewire tube 32, but includes a distal annular recess 248 for accommodation and suitable attachment thereto, such as by, but not limited to, adhesive 247, depending on the material used, of the proximal end of the flexible mesh 246 which forms the controllable-shape mesh occluder 244. A control rod 250 extends in the lumen 193a the length of the occluder guidewire tube 32a to exit the occluder guidewire tube 32a at the proximal end of the occluder guidewire tube 32a and to extend beyond so that

the physician operator may adjustably control the control rod 250. The distal portion of the control rod 250 which extends beyond the distal end of the controllable-shape mesh occluder 244 has the shape and characteristics of the tip of any ordinary coronary guidewire of the previously shown tapered flexible core 204 to form a tapered flexible core 250a. A weld 202a attaches the proximal end of a guidewire coil 36a to the proximal end of the tapered flexible core 250a, and a weld 206a attaches the distal end of the guidewire coil 36a to the distal end of the tapered flexible core 250a. In the alternative, the control rod 250 and the tapered flexible core 250a could be separate elements mutually joined with the guidewire coil 36a at weld 202a. The distal end of the controllable-shape mesh occluder 244 suitably attaches, such as by use of adhesive 247 or other suitable means to the distal end of the control rod 250 adjacent to the weld 202a.

[0091] **FIG. 24** is a view in cross section illustrating the use of the elements of **FIG. 23** where the controllable-shape mesh occluder 244 and the occluder guidewire tube 32a and associated components are loaded through the guide catheter 30 (not shown) and utilized in lieu of the balloon occluder 34 and the occluder guidewire tube 32. As no inflation of a balloon is required, the balloon inflation source 12 of **FIG. 1** is not utilized. Several loading and positioning techniques can be utilized. In a first technique, if the controllable-shape mesh occluder 244 includes mesh 246 which does not exhibit positional memory, the control rod 250 is simply advanced a suitable distance distally, thereby pulling the attached controllable-shape mesh occluder 244, which maintains a low profile because of tension along the controllable-shape mesh occluder 244, and the attached occluder guidewire tube 32a through the guide catheter 30.

[0092] In a second technique, whether the mesh 246 exhibits or does not exhibit positional memory, loading is accomplished in the following manner. Prior to and/or during loading, the physician operator controls the relationship of and positions the control rod 250 in a distal direction with respect to the occluder guidewire tube 32a to cause the controllable-shape mesh occluder 244 to assume and maintain a collapsed low profile, as shown in **FIG. 23**, followed by unitary advancement of the guidewire coil 36a, the low profile controllable-shape mesh occluder 244, and the distal end of the occluder guidewire tube 32a distally beyond the thrombus 212 to a position such as shown in **FIG. 14**. Then after either loading technique is utilized, the occluder guidewire tube 32a is held steady and the control rod is retracted proximally a sufficient distance to cause expansion and

distention of the controllable-shape mesh occluder 244 to be compliant with and to occlude the blood vessel 214 or other blood carrying structure where the occluding relationship of the occluder guidewire tube 32a and the controllable-shape mesh occluder 244 is maintained and is then unitarily retracted proximally to urge thrombus 212 in a proximal direction juxtaposing the subsequently loaded retractable capture cone 56 and capture catheter 40 and other components for maceration according to the teachings of the invention. Upon completion of the procedure the control rod 250 can be repositioned distally with respect to the occluder guidewire tube 32a to collapse the controllable-shape mesh occluder 244 and to withdraw the guidewire coil 36a, the low profile controllable-shape mesh occluder 244, and the distal end of the occluder guidewire tube 32a unitarily.

[0093] **FIG. 25** is an isometric view of an alternative embodiment incorporating an occluder having structure substantially similar to and performing the same thrombotic influencing function as the previously described inflated balloon occluder 34. Shown in particular is a flexible shaped mesh occluder 252 which is not inflatable but has a predetermined shape which is flexible, compressible, and utilizes positional memory to maintain a balloon-like shape suitable for occluding a blood vessel and for urging thrombotic material proximally for maceration. The flexible shaped mesh occluder 252 is fabricated of mesh 254, which can be a braid, a weave, or other interlacing strands or the like of metallic or non-metallic flexible materials which include position memory. The mesh 254 is of close-knit material, such as described above, which does not allow fluids to pass therethrough. The flexible shaped mesh occluder 252 can be utilized in lieu of the balloon occluder 34 previously described according to the teachings of the invention where the flexible shaped mesh occluder 252 is positioned and expandingly deployed to assume a shape generally resembling the balloon occluder 34.

[0094] **FIG. 26** is a cross section view of the embodiment of **FIG. 25** showing the flexible shaped mesh occluder 252 in a compressed state forced to a low profile from positional memory such as for transferring through a lumen.

[0095] The flexible shaped mesh occluder 252 aligns over and about a control rod 256. The control rod 256 extends in the lumen 119 the length of the guide catheter 40 to exit the manifold 38 at the hemostasis nut 58 so that the physician operator may adjustably control the control rod 256. The distal portion of the control rod 256 which extends beyond the distal end of the flexible shaped mesh occluder 252 has the shape and characteristics of the tip of any coronary guidewire of the previously shown tapered flexible core 204 to form a tapered flexible core 256a. A weld 202b attaches the proximal end of a guidewire coil 36b to the proximal end of the tapered flexible core 256a, and a weld 206b attaches the distal end of the guidewire coil 36b to the distal end of the tapered flexible core 256a. In the alternative, the control rod 256 and the tapered flexible core 256a could be separate elements mutually joined with the guidewire coil 36b at weld 202b. The distal end of the flexible shaped mesh occluder 252 suitably attaches, such as by use of adhesive 247 or other suitable means, to the distal end of the control rod 256 adjacent the weld 202b. The proximal end of the flexible shaped mesh occluder 252 slidingly aligns to the control rod 256 and is free to position thereupon, thereby allowing the geometry of the flexible shaped mesh occluder 252 to be varied.

[0096] **FIG. 27** is a view illustrating the use of the elements of **FIG. 26** where the flexible shaped mesh occluder 252, the control rod 256, and associated components are utilized in lieu of the balloon occluder 34 and the occluder guidewire tube 32. As no inflation of a balloon is required, the balloon inflation source 12 of **FIG. 1** is not utilized. The flexible shaped mesh occluder 252, the control rod 256, and associated components are introduced into the blood vessel 214 through the guide catheter 30 (not shown) where the distal end of the guide catheter 30 is first positioned through and distal to the thrombus 212.

[0097] Initially during use of the flexible shaped mesh occluder 252, the flexible shaped mesh occluder 252 is compressed to assume a low profile, as shown in **FIG. 26**, for insertion into the manifold 38, the capture catheter 40, the manifold 18 and the guide catheter 30. During loading the physician operator controls the relationship of and positions the control rod 256 in a distal direction with respect to the guide catheter 30 where the flexible shaped mesh occluder 252 continues to assume and maintain a collapsed low profile as shown in **FIG. 26** followed by unitary advancement of the guidewire coil 36b, the low profile coompressed flexible shaped mesh occluder 252, and the distal end of the control rod 256 distally to a position just short of the distal end of the guide catheter 30 but beyond the thrombus 212. Thus, a short distal portion of the guide catheter 30 distal to the thrombus 212 contains the guidewire coil 36b, the low profile flexible shaped mesh occluder 252 and the distal end of the control rod 256. Then after such loading, the control rod 256 is held steady and the guide catheter 30 is positioned proximally a sufficient distance to

disengage from surrounding and encompassing contact with the flexible shaped mesh occluder 252 allowing expansion and distention of the flexible shaped mesh occluder 252 to be compliant with and to occlude the blood vessel 214 or other blood carrying structure where the occluding relationship of the control rod 256 and the flexible shaped mesh occluder 252 is maintained with the blood vessel 214 and is then unitarily retracted proximally to urge thrombus 212 in a proximal direction juxtaposing the subsequently loaded retractable capture cone 56 and capture catheter 40 and other components for maceration according to the teachings of the invention. Upon completion of the procedure, the guide catheter 30 can be advanced distally and the control rod 256 can be repositioned proximally with respect to guide catheter 30 to engage and collapse and compress the flexible shaped mesh occluder 252 and withdraw the guidewire coil 36b, the low profile compressed flexible shaped mesh occluder 252, and the distal end of the control rod 256 unitarily.

PARTS LIST

10	thrombectomy catheter system with occluder	64	introducer
		66	hollow shaft
		68	annular ring
12	balloon inflation source	70	annular ring
		72	actuating handle
14	high pressure source	76	self-sealing hemostasis valve
16	suction source	78	cavity
18	manifold or Y-adaptor	80	tapered passage
		82	branch passage
20	hemostasis nut	84	multi-radius cavity
22	Luer connection		
24	manifold branch	86	round outer cavity portion
26	Luer fitting		
28	strain relief	88	round inner cavity portion
30	guide catheter		
32	occluder guidewire tube	90	threaded surface
		92	body
32a	occluder guidewire tube	94	grasping surface
		96	threaded surface
34	balloon occluder	98	annular surface
36	guidewire coil	100	passageway
36a-b	guidewire coils	102	seal
38	manifold	104	distal annular surface
40	capture catheter		
40a	capture catheter	106	tube
42	high pressure tube	108	central bore
		110	annular flange
42a	high pressure tube	112	tapered proximal tube mouth end
44	central tubular body	114	tapered tube surface
46	exhaust branch	118	tapered central passage surface
47	branch passage		
48	Luer connection	119	lumen
50	high pressure connection branch	120	threads
		122	threads
52	cavity body	123	threads
54	streamlined flexible strain relief	124	branch passageway
		126	cavity wall
		128	planar surface
56	retractable capture cone	130	cavity extension
		132	orifice
58	hemostasis nut	134	tapered central passageway
60	high pressure connection port		
		136	cylindrical boss
62	threads		

138	beveled passageway	200	loop center
140	internal threads	201	capture catheter support band
142	distally located space	202	weld
144	proximally located space	202a-b	welds
146	annular stop surface	203	weld
148	proximal end	204	tapered flexible core
150	annular lip	205	radiopaque marker band
152	constant radius region	206	weld
154	short tapered region	206a-b	welds
156	short tapered region	208	adhesive
158	tapered region	210a-n	inflation orifices
160	passageway	212	thrombus
162	adhesive injection port	214	blood vessel
164	exterior tapered region	216	retractable capture cone
166	adhesive	217	mesh
168	passageway	218	conical surface
170	flat	219	adhesive
172	adhesive	220	annular recess
174	adhesive injection port	222	fluid jet emanator
178	ferrule	224	weld
180	fluid jet emanator	226	distal end
182a-n	expansion struts	228	main body
184	bend or curve	230	annular manifold groove
186	straight strut portion	232	tubular extension
188	straight strut portion	234	manifold plate
190	conical surface	236a-n	jet orifices
192	lumen	238	centrally located hole
192a	lumen	240	offset hole
193	lumen	242	passageway
193a	lumen	244	controllable-shape mesh occluder
194	lumen	246	mesh
194a	lumen	247	adhesive
195	pressurized saline	248	annular recess
196a-n	jet orifices	250	control rod
198a-n	fluid jets	250a	tapered flexible core
		252	flexible shaped mesh occluder
		254	mesh

256	control rod
256a	tapered flexible core

[0098] Various modifications can be made to the present invention without departing from the apparent scope thereof.

IT IS CLAIMED:

1. A method for thrombectomy comprising the steps of:

a. providing a guide catheter, the guide catheter having a distal end and a proximally situated manifold with a hemostasis nut and a lumen, and providing an occluder guidewire tube having a proximal end and a distal end, with a guidewire coil and an occluder at the distal end, and providing a capture catheter, the capture catheter having a distal end with a retractable capture cone and a fluid jet emanator, the fluid jet emanator including at least one jet orifice, and a proximally located manifold;

b. advancing the distal end of the guide catheter into a vessel to a position adjacent to and proximal to a thrombus buildup;

c. loading and advancing the distal end of the occluder guidewire tube through the hemostasis nut and into and through the manifold of the guide catheter and thence through the lumen of the guide catheter;

d. advancing the distal end of the occluder guidewire tube, including the guidewire coil and the occluder, beyond the distal end of the guide catheter and through and beyond the thrombus buildup;

e. loading the distal end of the capture catheter, including the retractable capture cone and the fluid jet emanator over the proximal end of the occluder guidewire tube;

f. expanding the occluder to occlude the vessel;

g. positioning the capture catheter to an appropriate position and expandingly deploying the retractable capture cone adjacent to and just beyond the distal end of the guide catheter, thereby isolating the thrombus in the vessel between the deployed retractable capture cone and the expanded occluder;

h. providing and activating a high pressure medium to the fluid jet emanator so as to form rearwardly directed fluid jets;

i. macerating, dislodging, reducing, and breaking up the thrombus with the fluid jets; and,

j. evacuating the macerated, dislodged, reduced and broken-up thrombus.

2. The thrombectomy method of claim 1, further comprising the step of repositioning the expanded occluder proximally to impinge, impact, dislodge, reshape and redistribute thrombus and to urge and deliver such thrombus into the retractable capture cone.

3. The thrombectomy method of claim 2, wherein the step of repositioning includes manipulation of the manifold of the capture catheter.

4. The thrombectomy method of claim 2, wherein the step of repositioning is continued to near impingement of the occluder with the retractable capture cone.

5. The thrombectomy method of claim 1, wherein the vessel is a blood vessel.

6. The thrombectomy method of claim 5, wherein the blood vessel is a vein or an artery.

7. The thrombectomy method of claim 1, further comprising the step of monitoring the position of the guide catheter distal end with fluoroscopy.

8. The thrombectomy method of claim 1, further comprising the step of manipulating the manifold of the guide catheter while advancing the guide catheter.

9. The thrombectomy method of claim 1, wherein the at least one jet orifice is one of a plurality of jet orifices.

10. The thrombectomy method of claim 1, wherein the at least one jet orifice is rearwardly directed.

11. The thrombectomy method of claim 1, further comprising the step of collapsing the occluder subsequent to removing the thrombus.

12. The thrombectomy method of claim 11, further comprising the step of withdrawing the collapsed occluder through the retractable capture cone.

13. The thrombectomy method of claim 12, further comprising the step of retracting the retractable capture cone proximally to retractably collapse the retractable capture cone to conform to the guide catheter.

14. The thrombectomy method of claim 13, further comprising the step of withdrawing the guide catheter, the capture catheter, and the occluder guidewire tube simultaneously.

15. The thrombectomy method of claim 13, further comprising the step of repositioning the guide catheter, the capture catheter, and the occluder guidewire tube simultaneously and distally to adjacent to and proximal to another thrombus site, to prepare for additional thrombus removal.

16. A system for thrombectomy comprising:

a. a guide catheter, the guide catheter having a distal end and a proximally situated manifold with a hemostasis nut and a lumen;

b. an occluder guidewire tube having a proximal end and a distal end, with a guidewire coil and an occluder at the distal end; and,

c. a capture catheter, the capture catheter having a distal end with a retractable capture cone and a fluid jet emanator, the fluid jet emanator including at least one jet orifice, and a proximally located manifold; wherewith thrombus may be isolated in the vasculature between the retractable capture cone, when deployed, and the occluder, when expanded, then disrupted and macerated by action of fluid jets, for removal from the body by suction applied at the retractable capture cone, thereby avoiding undesired release of thrombus portions within the vasculature.

17. The system as defined in claim 16, wherein the occluder is an inflatable balloon.

18. The system as defined in claim 16, wherein the occluder is a controllable-shape mesh.

19. The system as defined in claim 16, wherein the occluder is a flexible shaped mesh.

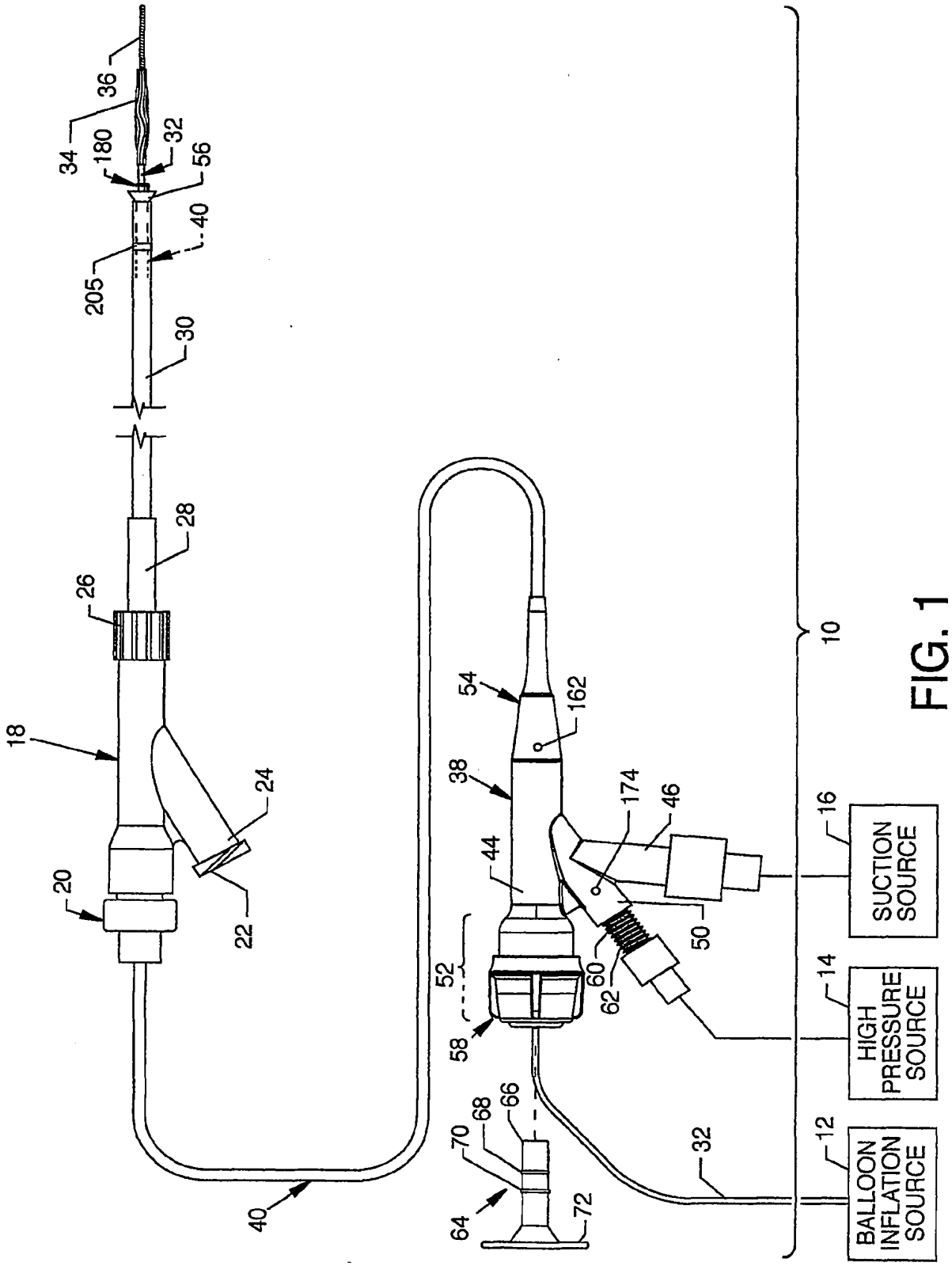

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SUCTION SOURCE
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HIGH PRESSURE SOURCE
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BALLOON INFLATION SOURCE

FIG. 1

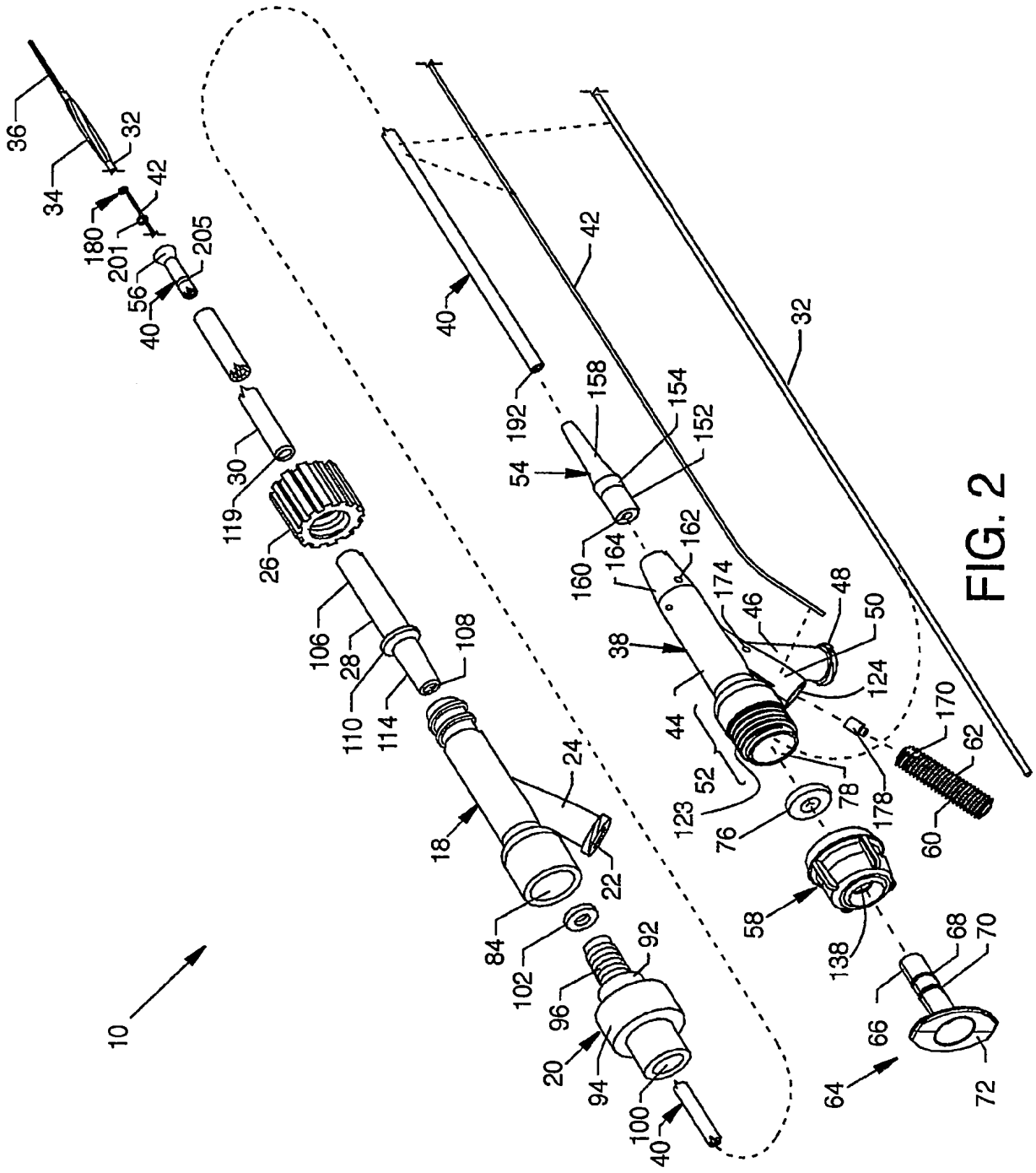

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FIG. 2

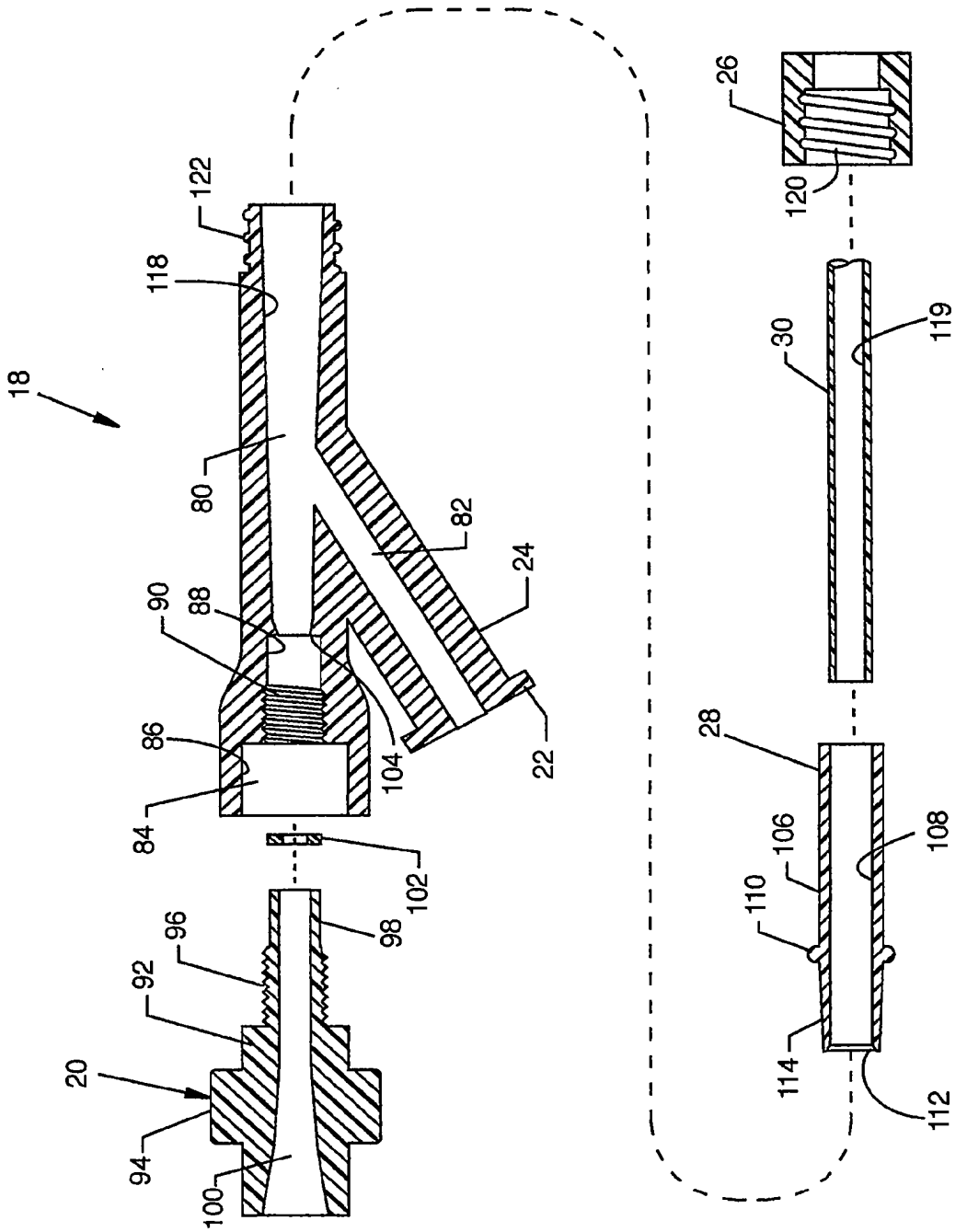

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FIG. 3

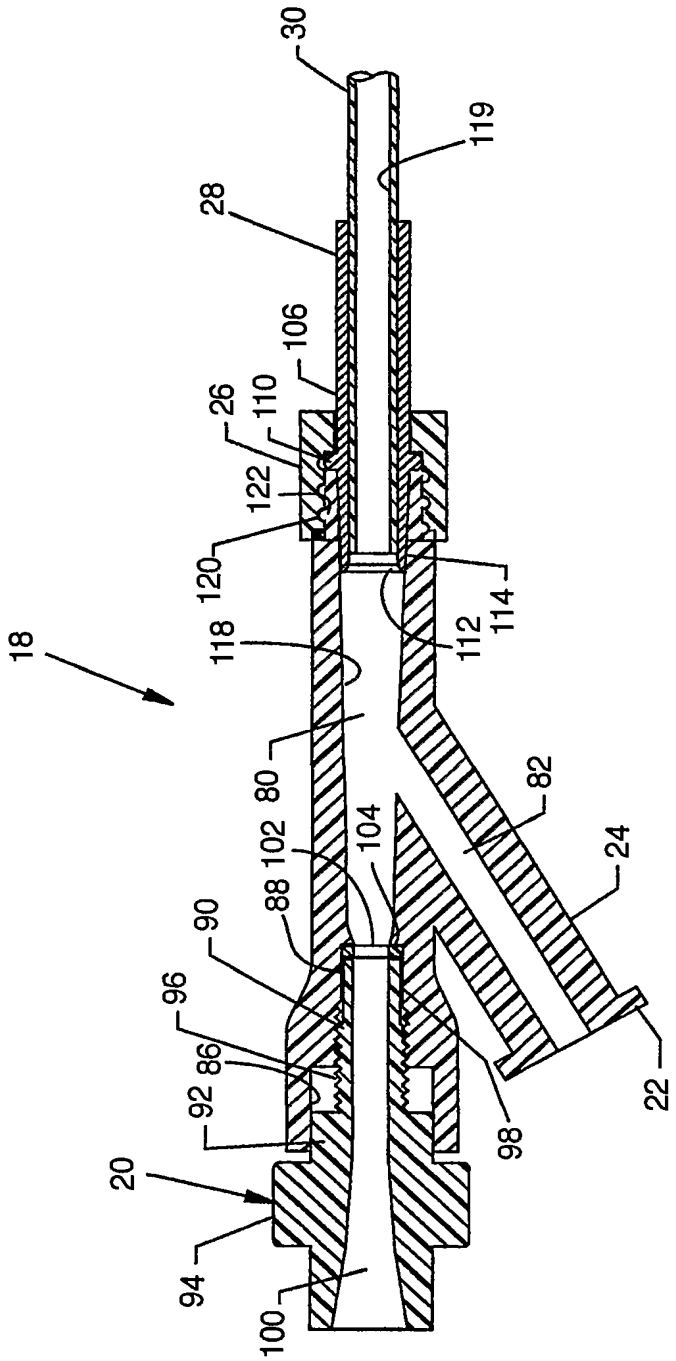

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FIG. 4

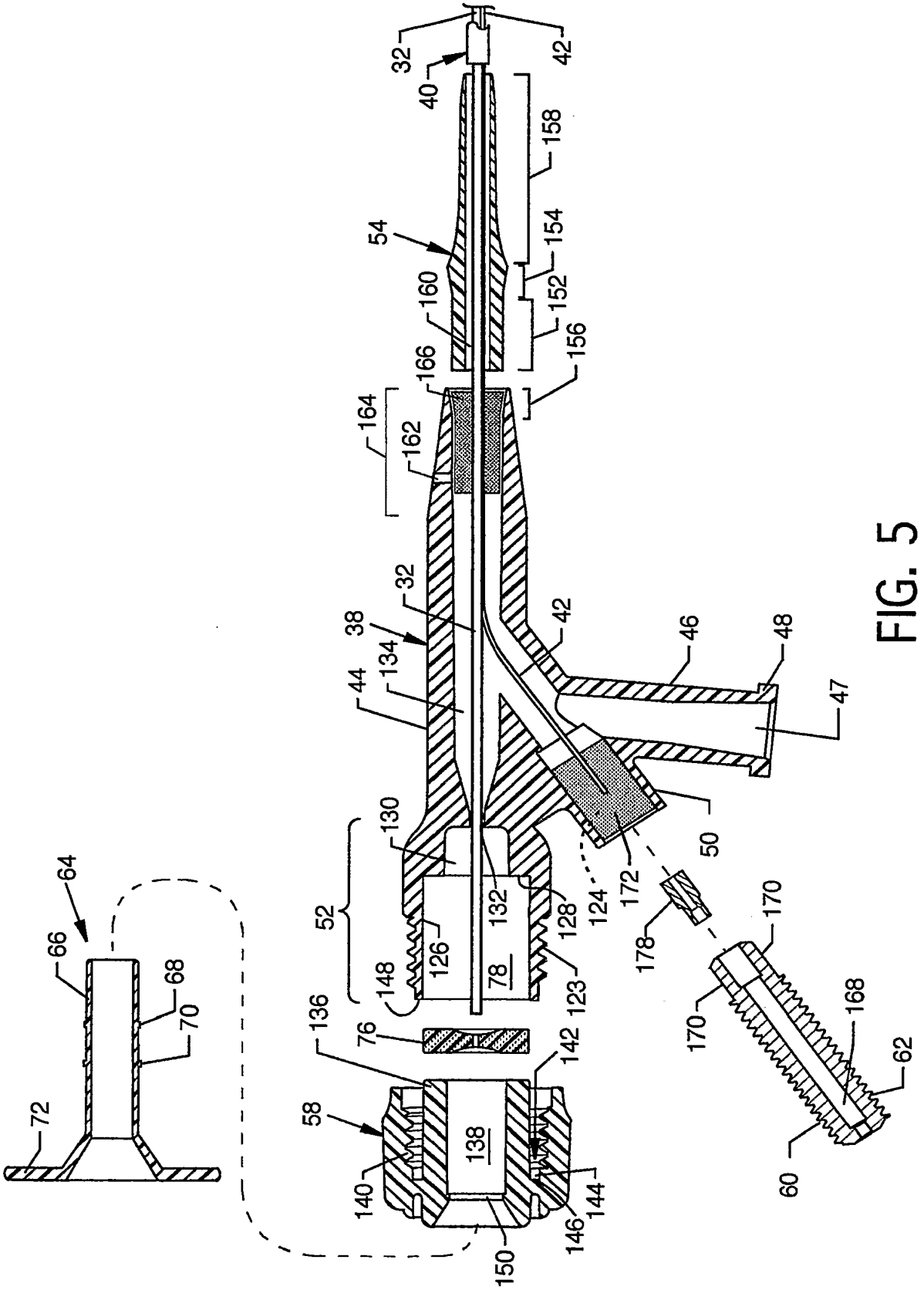

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FIG. 5

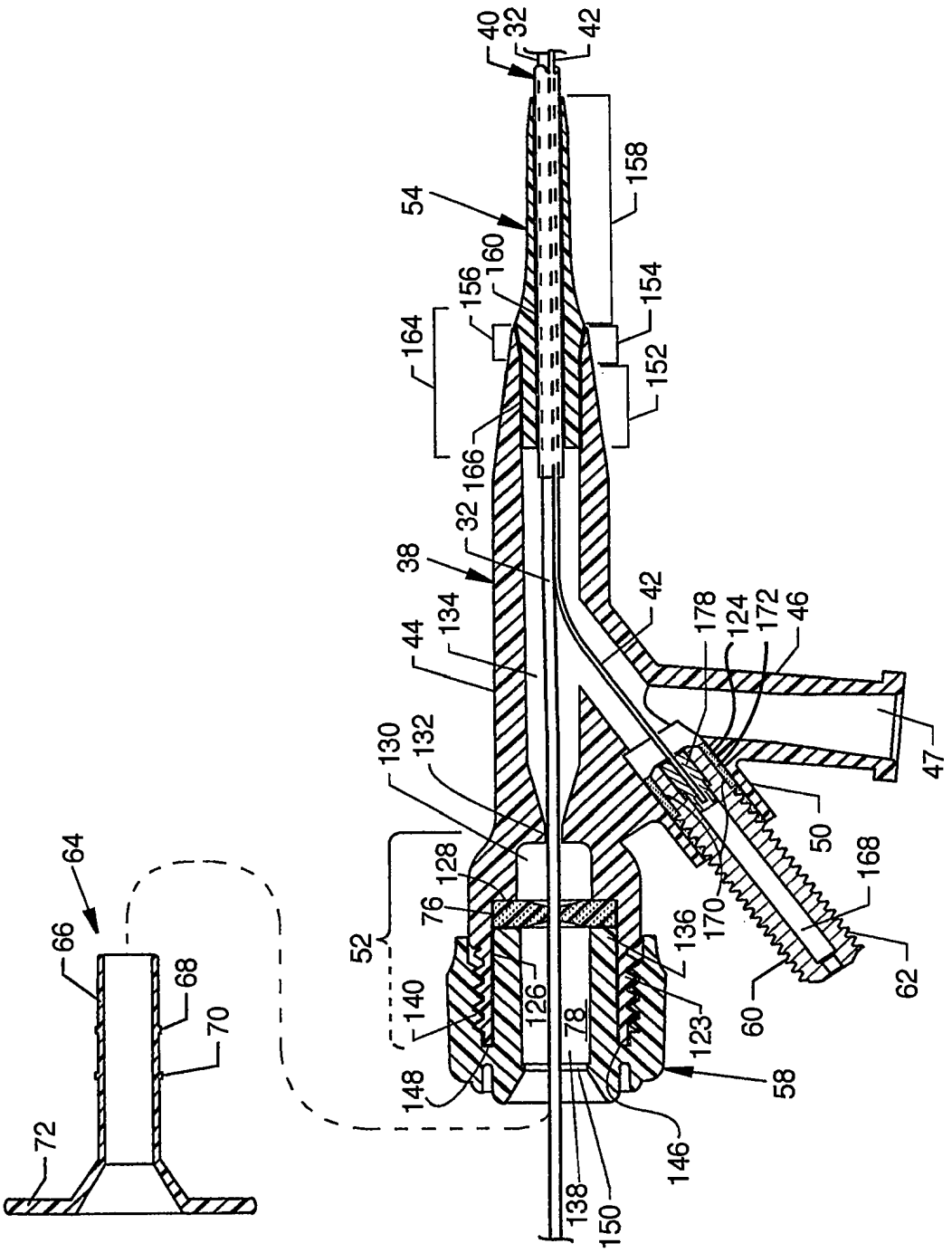

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FIG. 6

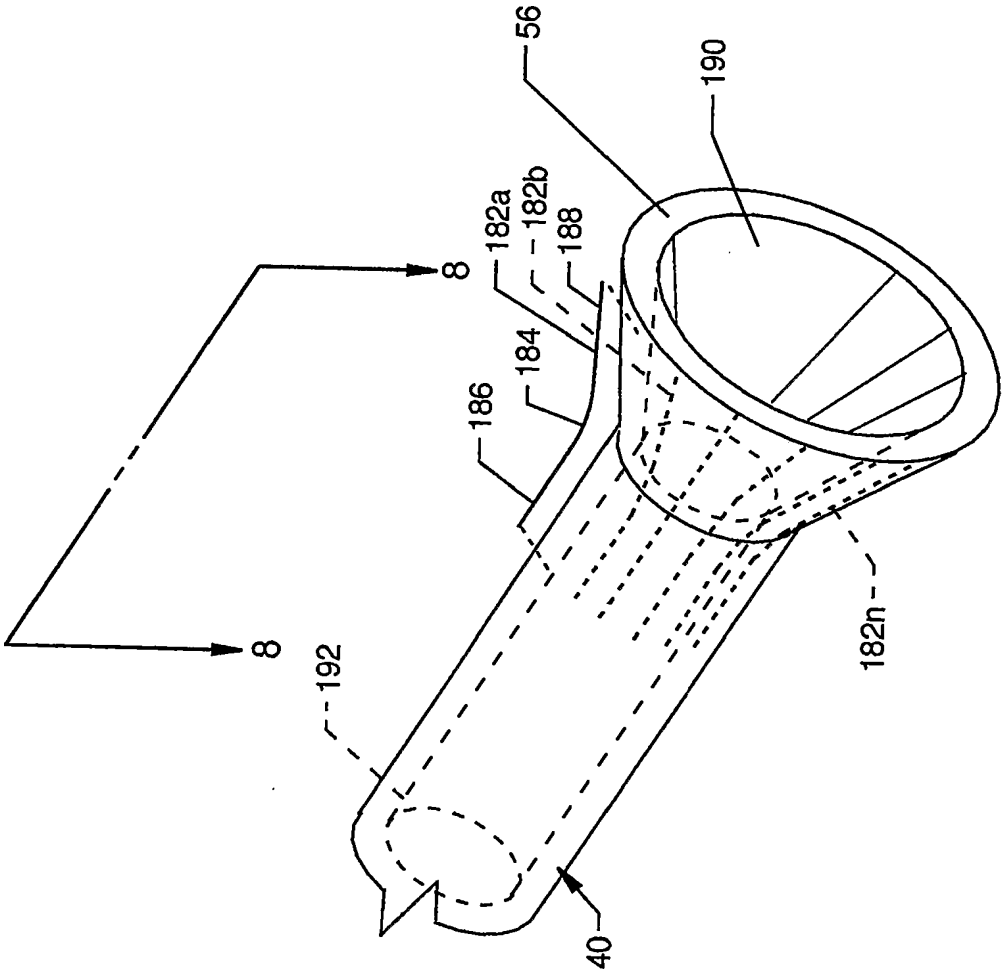


FIG. 7

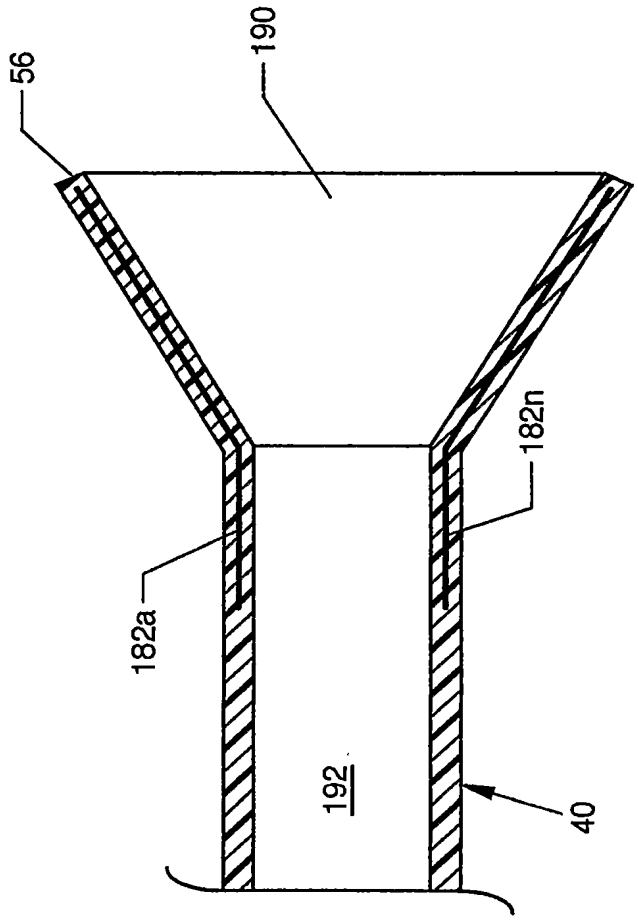


FIG. 8

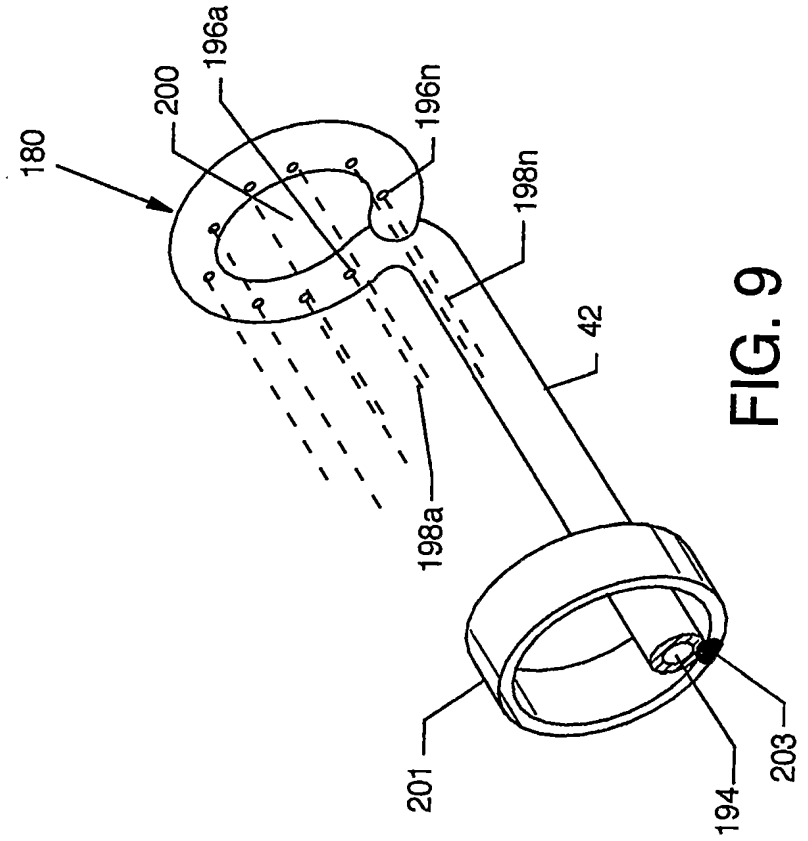


FIG. 9

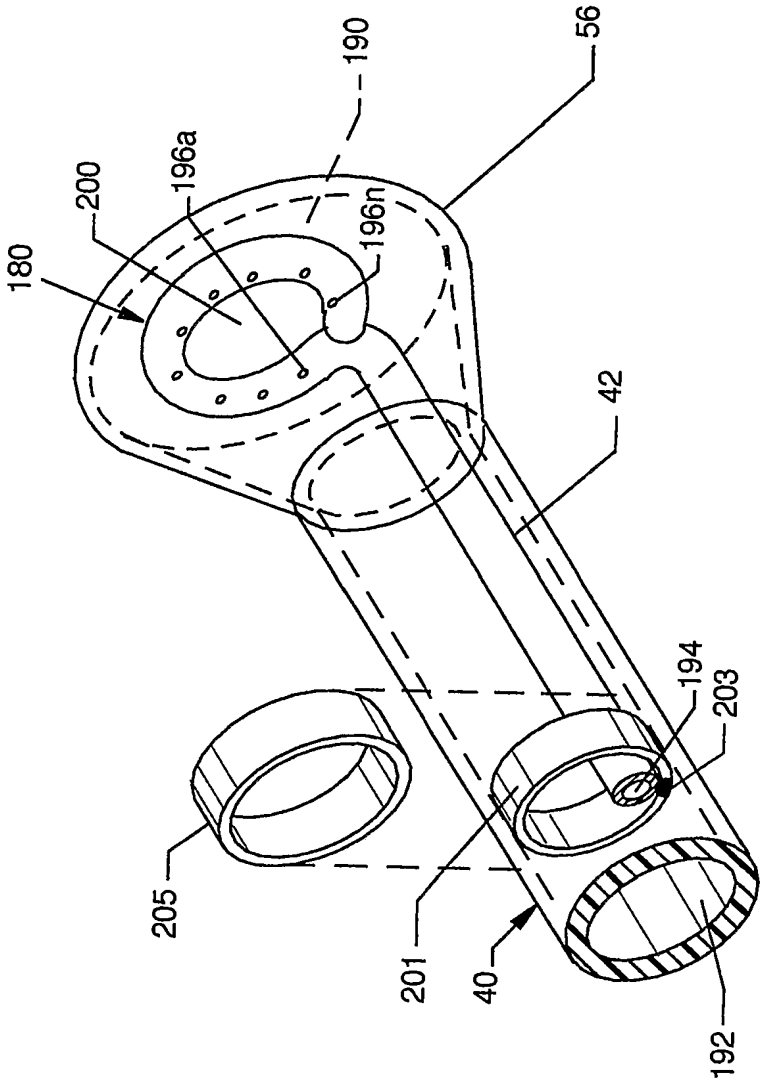


FIG. 10

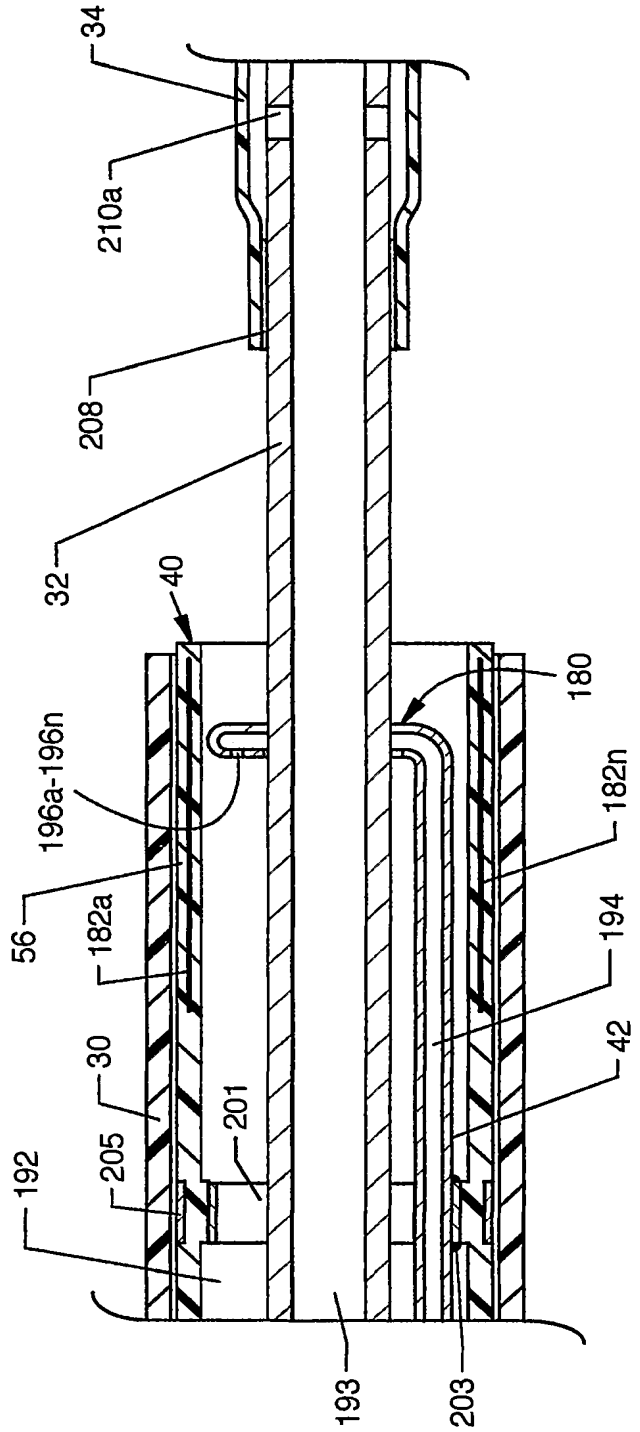

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FIG. 11

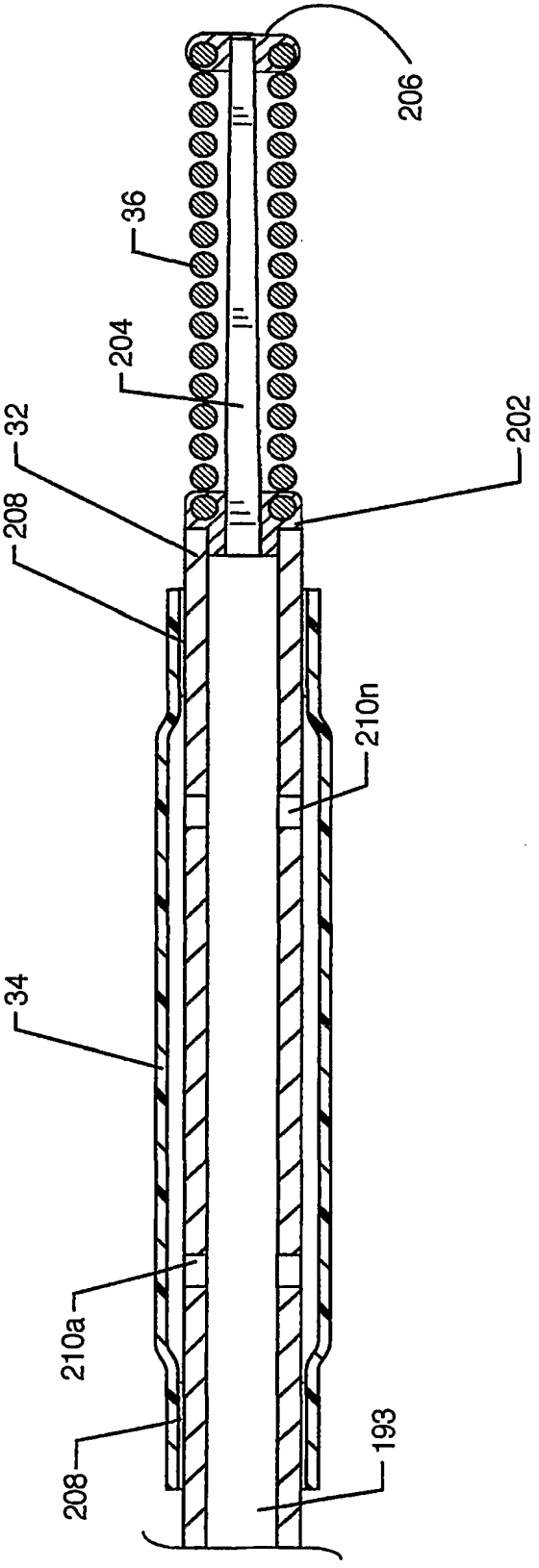


FIG. 12

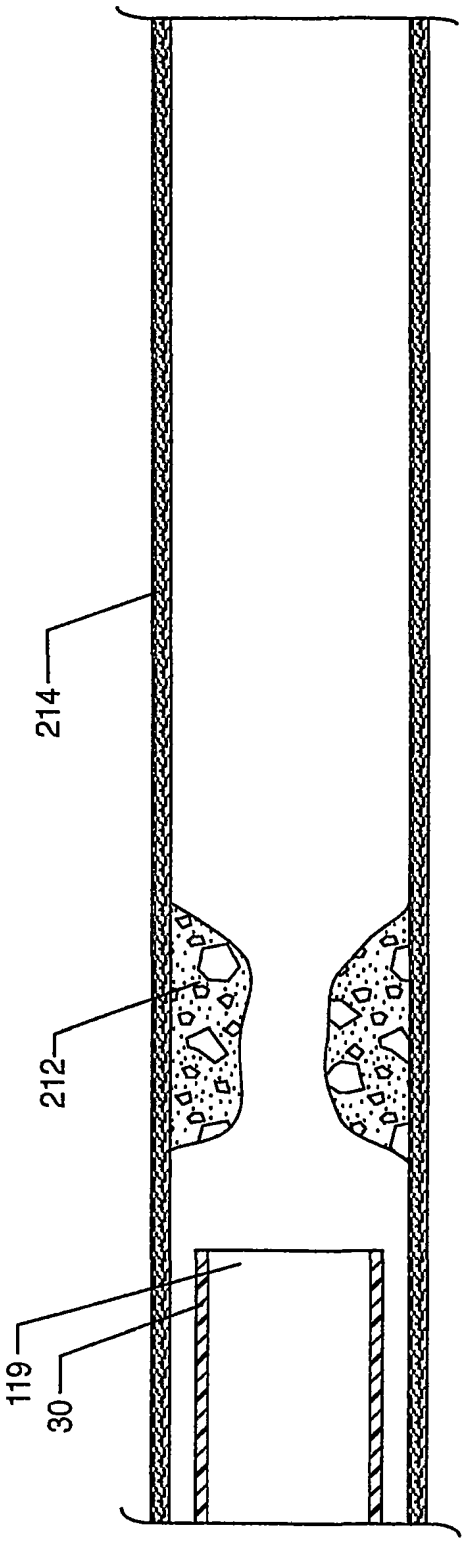


FIG. 13

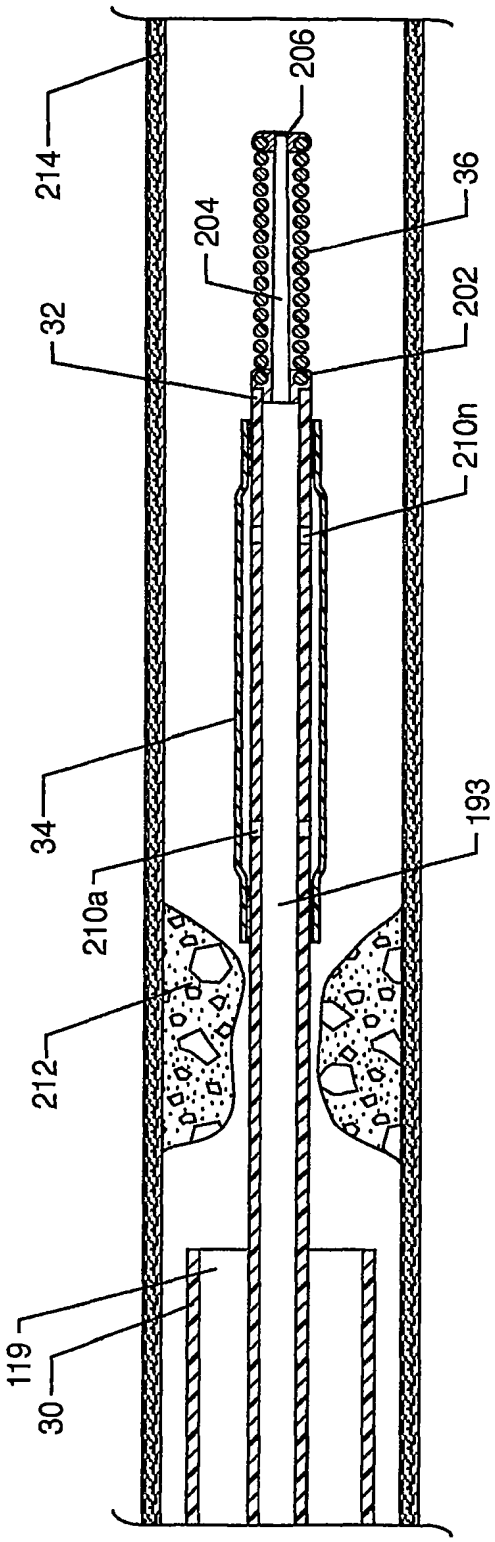


FIG. 14

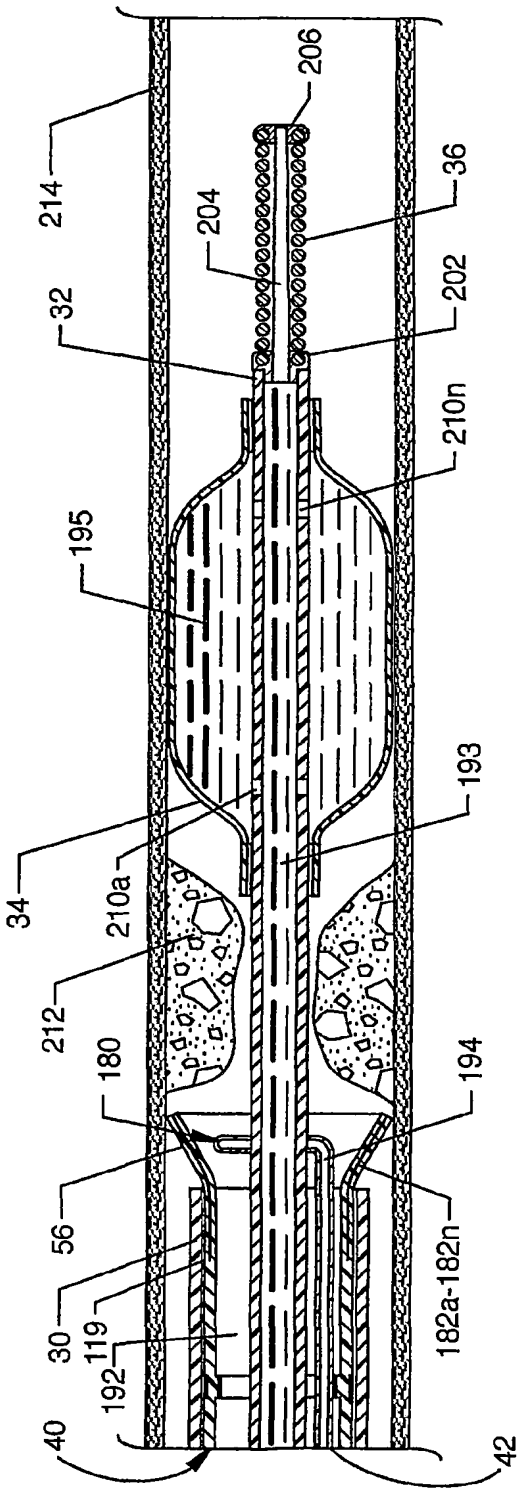

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FIG. 15

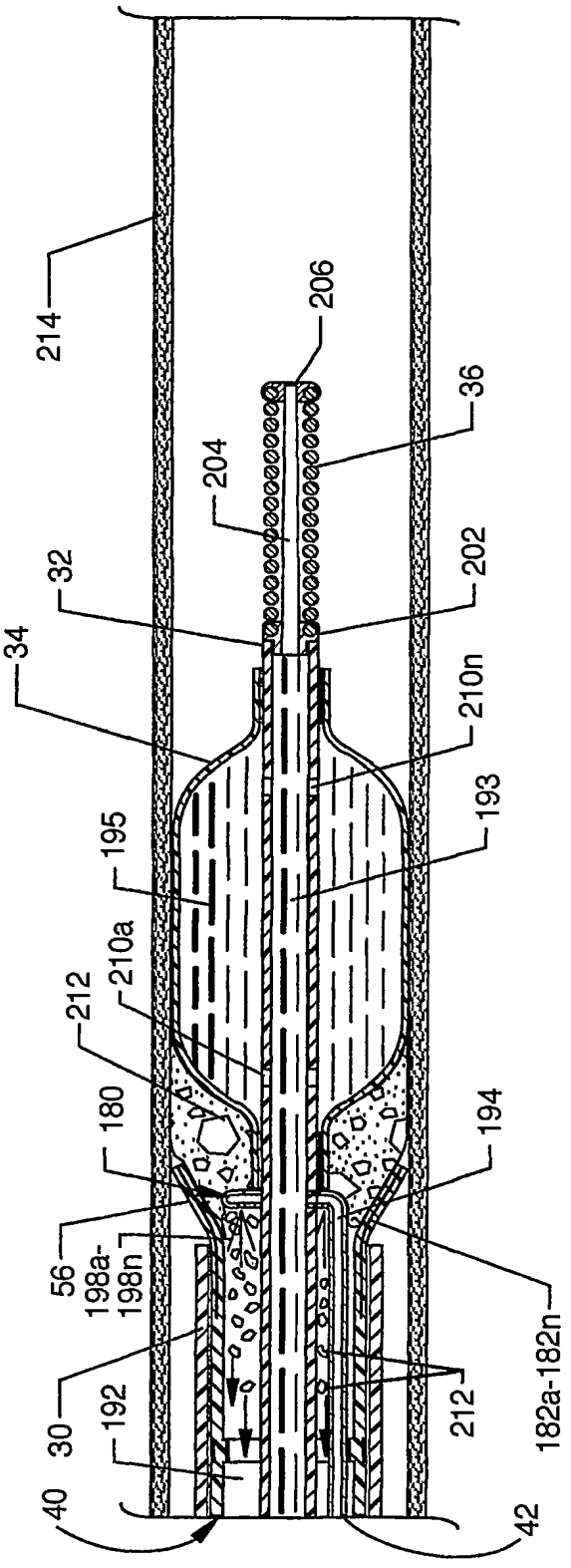

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FIG. 16

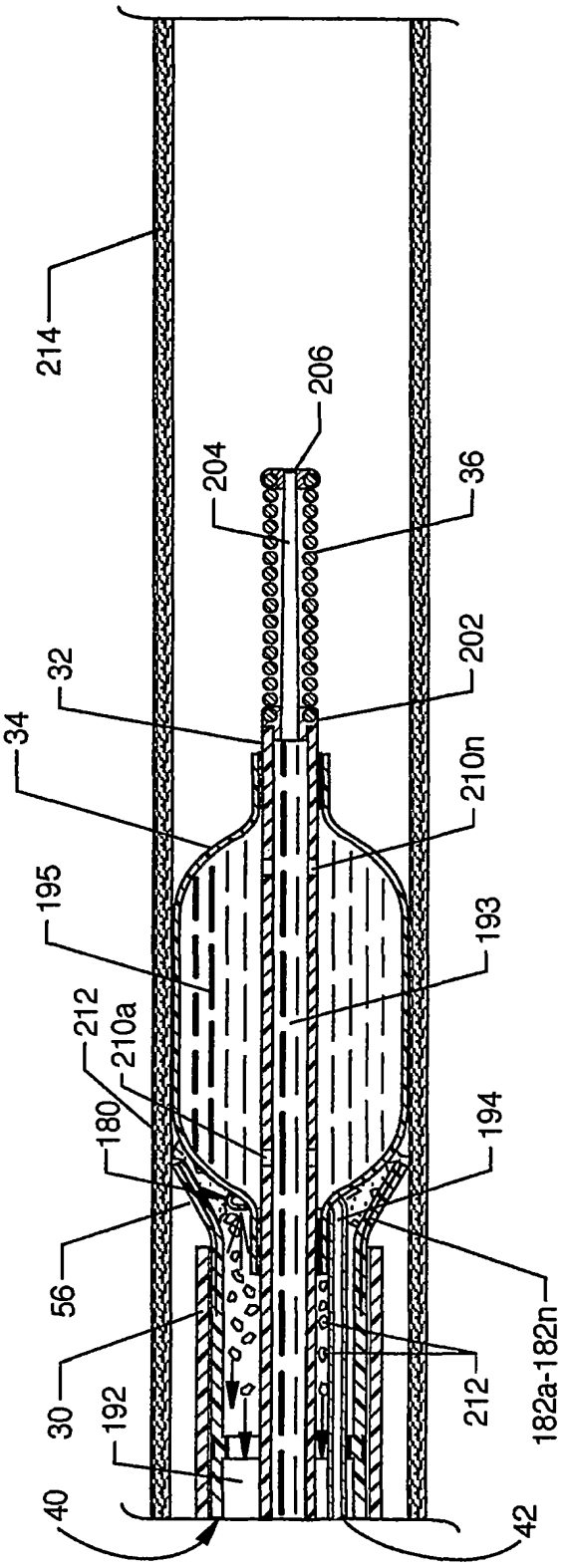

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FIG. 17

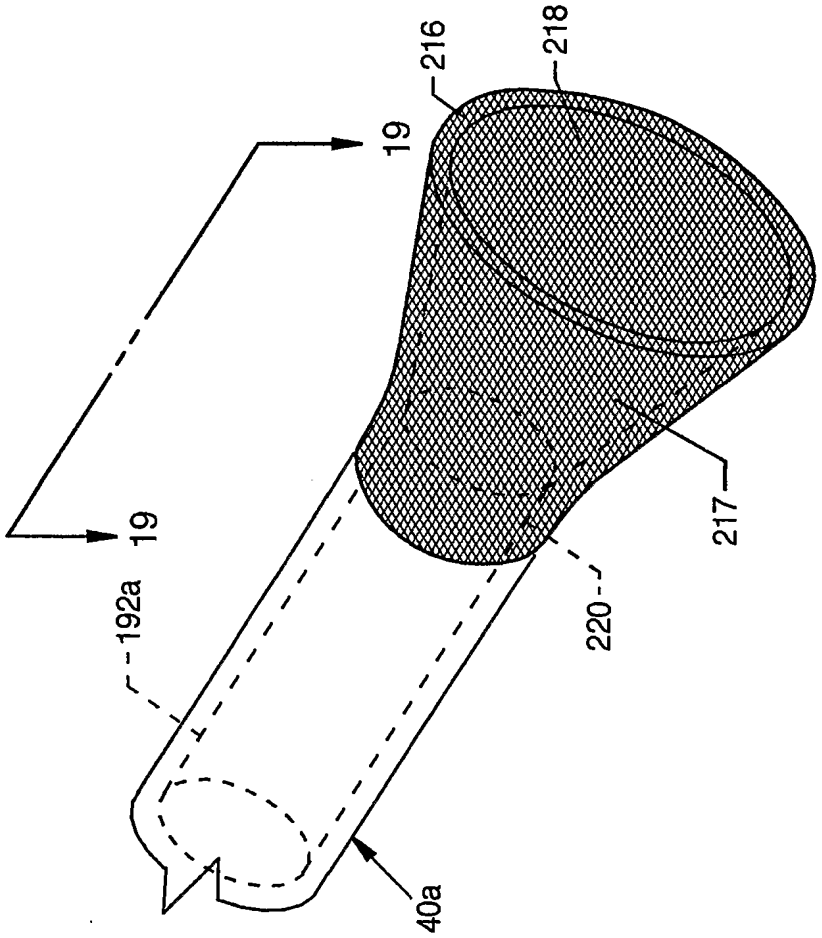


FIG. 18

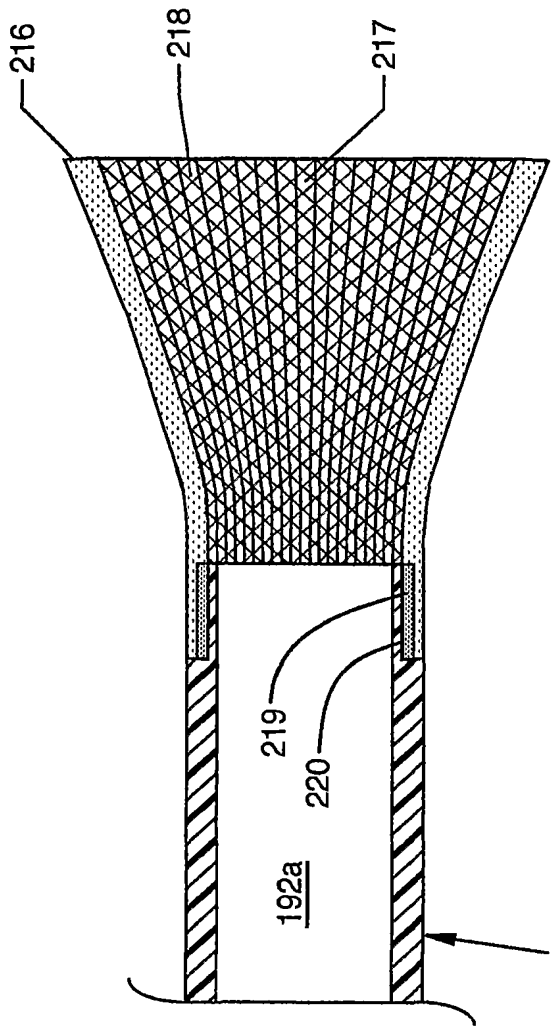


FIG. 19

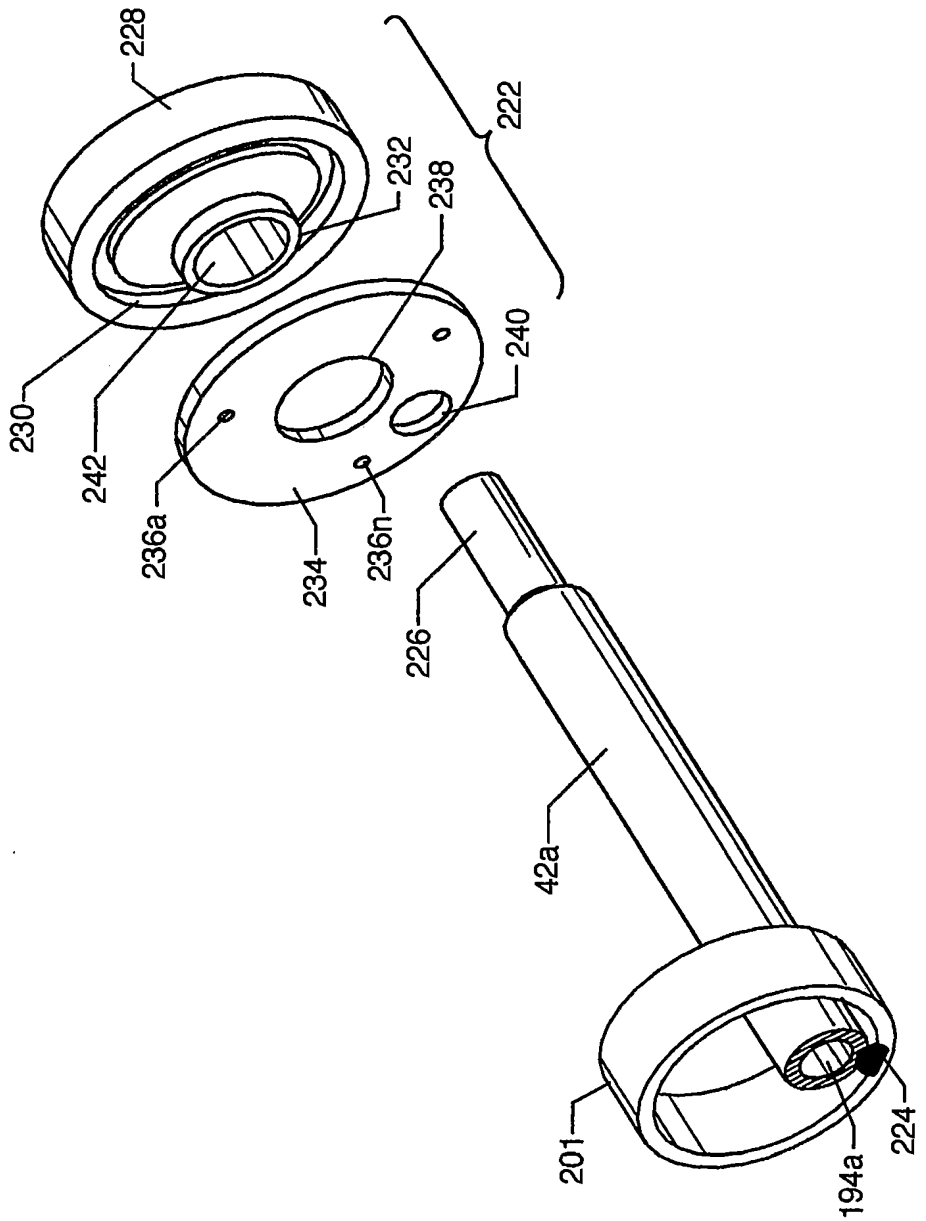


FIG. 20

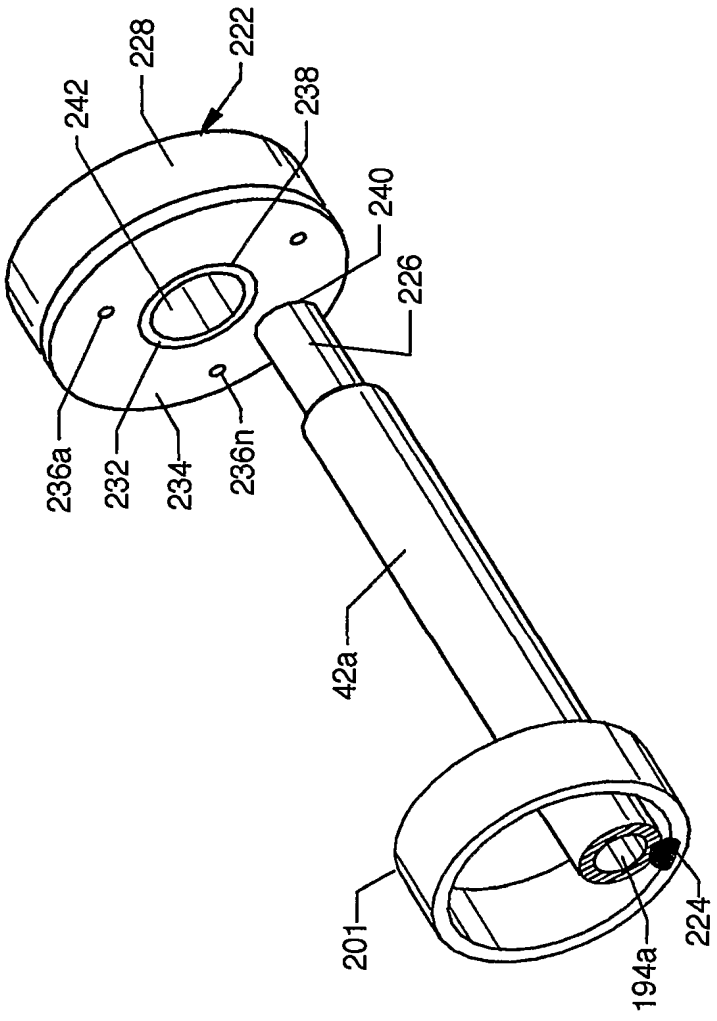


FIG. 21

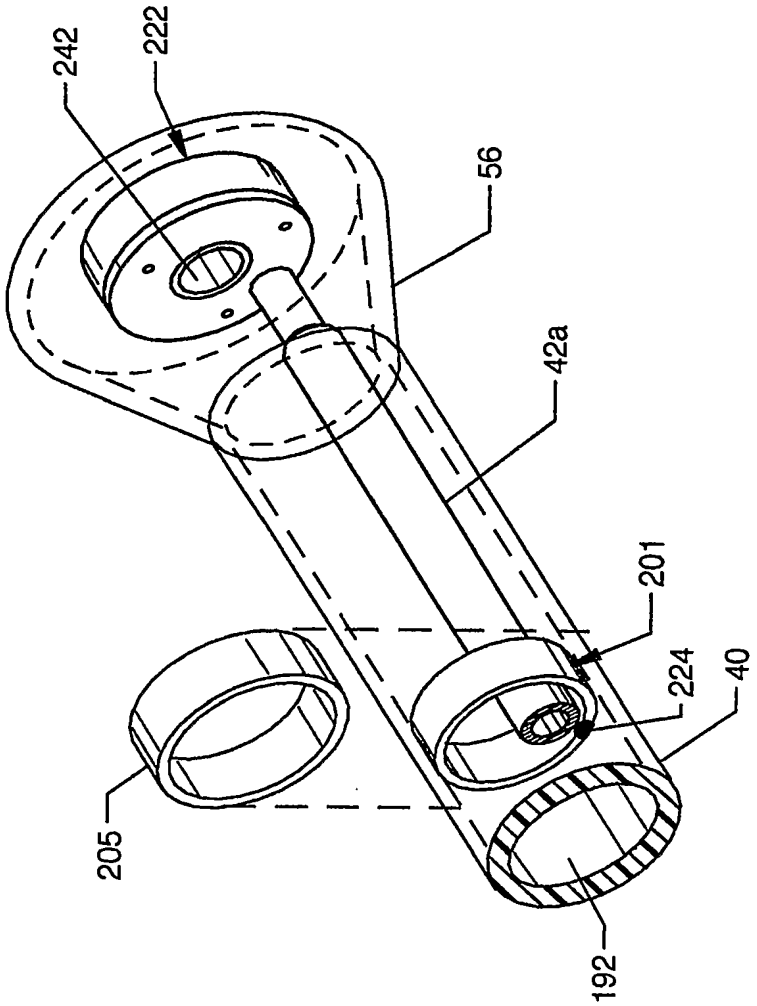


FIG. 22

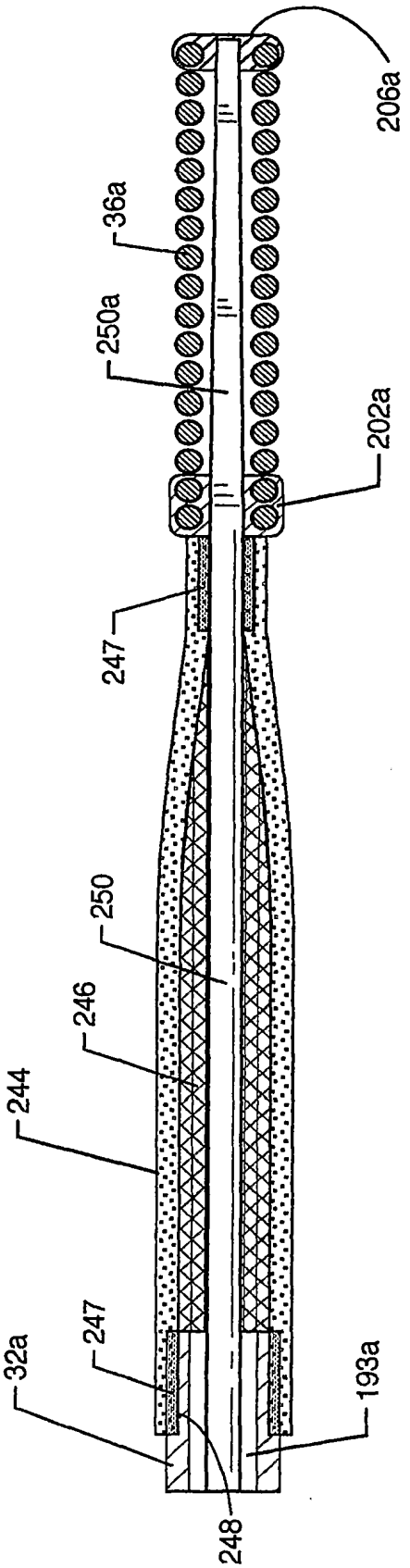


FIG. 23

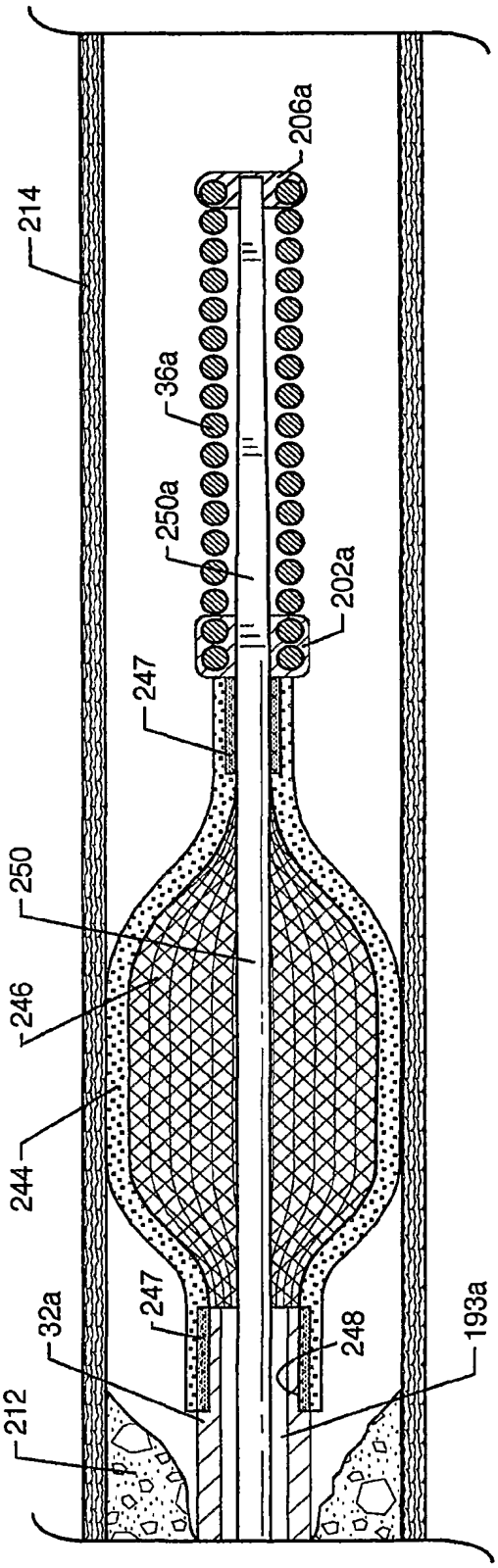


FIG. 24

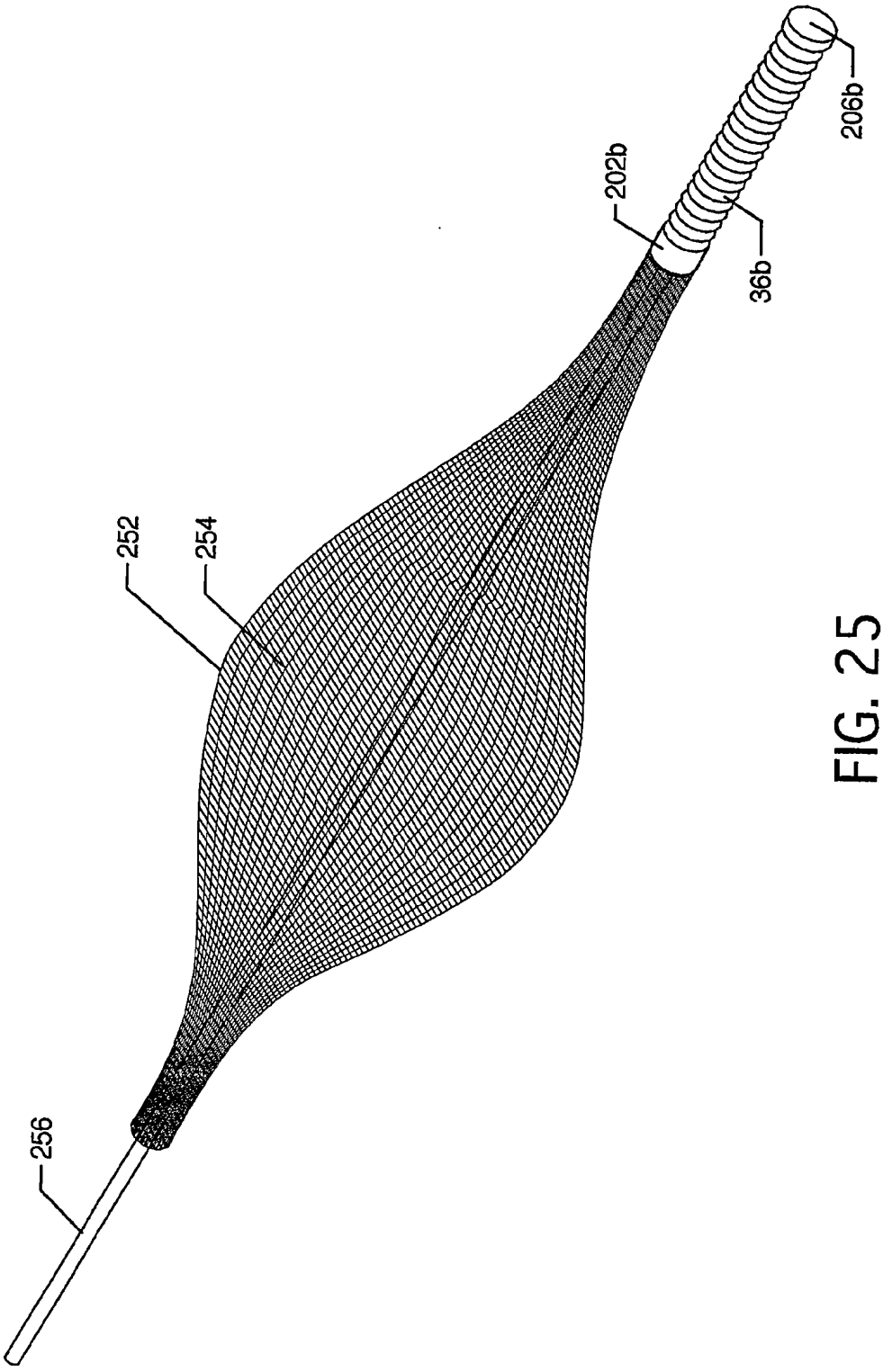


FIG. 25

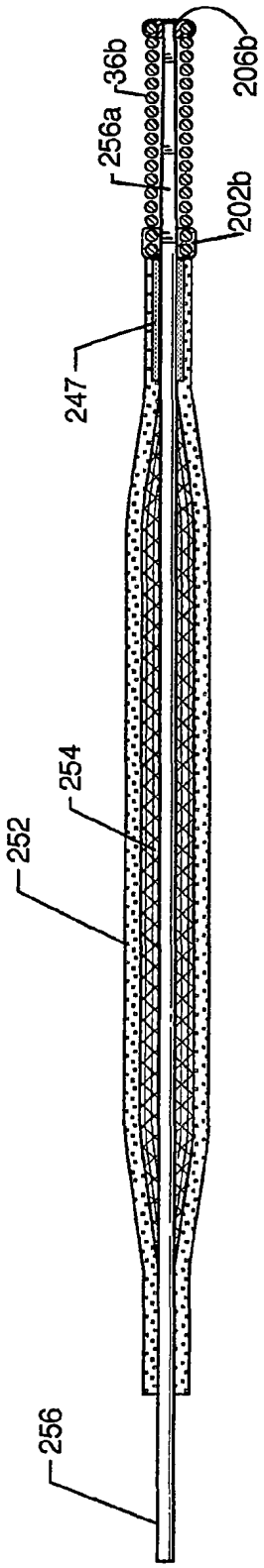


FIG. 26

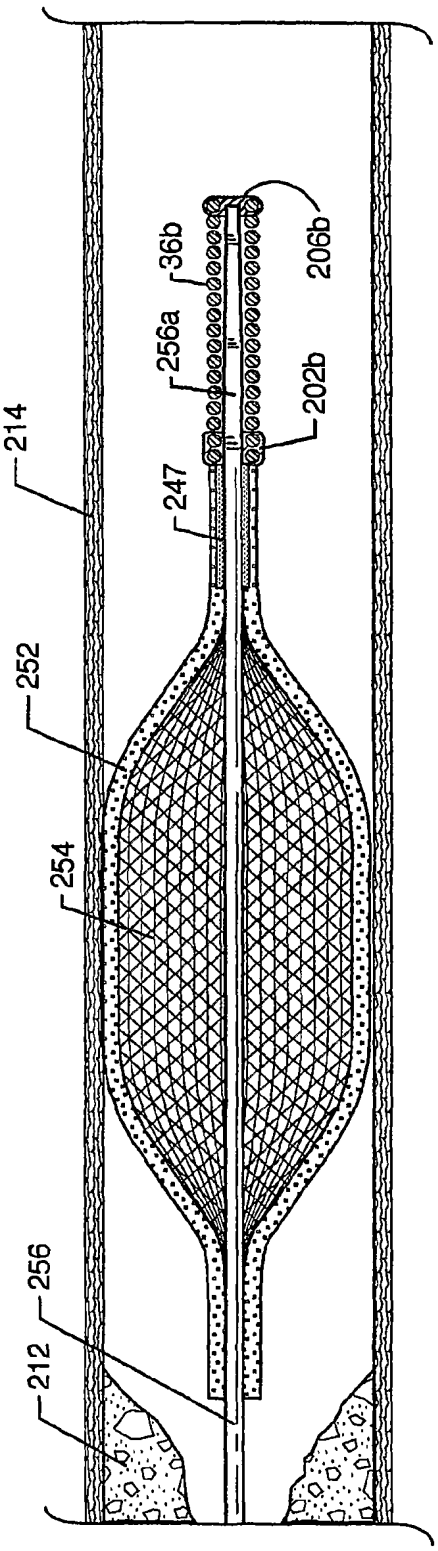


FIG. 27

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(71) Applicant *(for all designated States except US)*: **COHEREX MEDICAL, INC.** [US/US]; 3598 West 1820 South, Salt Lake City, UT 84104 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **LINDER, Richard, J.** [US/US]; 7810 Chatsworth Court, Sandy, UT 84093 (US). **EDMISTON, Daryl, R.** [US/US]; 754 West Marsh Cove, Draper, UT 84020 (US).

(74) Agent: **JENSEN, Bradley, B.**; Holland & Hart, 60 E. South Temple, Suite 2000, Salt Lake City, UT 84111 (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))*

(54) **Title**: CLOT RETRIEVAL METHOD AND DEVICE

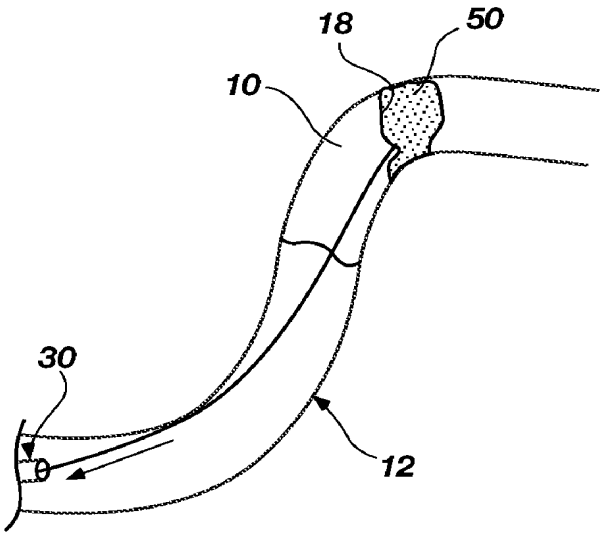


FIG. 2E

(57) **Abstract**: Devices, systems and methods for retrieving clot material from a vasculature lumen are provided. In one embodiment, a medical device includes a handle, a catheter, a tether member and a clot retrieval element. The catheter extends from the handle and the clot retrieval element is configured to be positioned within a distal portion of the catheter with the tether member extending between the handle and the clot retrieval element. The clot retrieval element is configured to be deployed from within the catheter so that the catheter moves proximally relative to and separate from the clot retrieval element while maintaining attachment to the clot retrieval element via the tether member. Further, the clot retrieval element is configured to be pulled by the tether member to abut against a distal side of a clot with proximal movement of the tether member to pull the clot from the vasculature lumen.

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CLOT RETRIEVAL METHOD AND DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of United States Provisional Patent Application No. 61/074,116, entitled CLOT RETRIEVAL METHOD AND DEVICE, filed on June 19, 2008, the disclosure of which is incorporated by reference herein in its entirety.

TECHNICAL FIELD

[0002] The present invention relates generally to a catheter system and, more specifically, a catheter system for retrieving clots from the vasculature.

BACKGROUND

[0003] Clot formation within the vasculature can result in various thromboembolic disorders, such as stroke, pulmonary embolism, peripheral thrombosis, artherosclerosis, and the like. Unfortunately, due to unhealthy lifestyles and poor eating habits, clot formation within the vasculature is becoming more common. Further, even if one minds their eating habits and lives a healthy lifestyle, many are still susceptible to these disorders due to their genetic makeup. Thus, it is desirable to eliminate or remove clot formations from within the vasculature to prevent the possibility of such disorders as noted above.

[0004] The medical industry has provided various devices and systems, sometimes referred to as embolectomy devices, to remove foreign matter from the vasculature. Many of these devices and systems are catheter based. For example, one catheter based system is described as a device having adhesive disposed thereon. The device is directed to the clot or

occlusion and it contacts the clot with an adhesive covered surface of the device. The device is asserted to "stick" to the clot and withdraw the clot along with the catheter and device.

[0005] Another device includes a "basket" that is positioned such that the clot or foreign matter is within the interior of the basket. An opening or mouth of the basket is configured to be closed or cinched so as to capture the clot inside of the basket and the basket is then withdrawn from the blood vessel. Other devices may include a macerator that breaks up the clot into smaller particles. The smaller particles may then be captured by use of a filter or by vacuum means.

[0006] However, such systems have been found to have various limitations. Often, such structures are either highly complex in their use and implementation. Additionally, many of such structures and rather complex and difficult to manufacture. Moreover, some of these devices and systems lack the ability to sufficiently or effectively remove foreign matter entirely from the vasculature as desired. Further, many systems have been found to be harsh on the inner vessel walls and cause damage to the walls. Some of the known systems introduce additional medical risks to a patient. Therefore, it would be desirable to provide an embolectomy catheter system that is, for example, safe, less complex to use and to manufacture while also being effective in retrieving clot matter from the vasculature system.

DISCLOSURE OF THE INVENTION

[0007] The present invention is directed to medical devices, systems and methods for retrieving clot material from a vasculature lumen. In accordance with one embodiment, a medical device configured to retrieve clot material from a vasculature lumen is provided and includes a handle having a catheter extending therefrom. At least one clot retrieval element is configured to be positioned within a distal portion of a lumen defined through the catheter, the at

least one clot retrieval element being operably attached to the handle by way of a tether member extending through the lumen of the catheter. The at least one clot retrieval element is configured to be deployed from within the catheter from a contracted state to an expanded state. When the at least one clot retrieval member is in the expanded state, it conforms to the geometry of the vasculature lumen and applies pressure to the vasculature lumen.

[0008] In accordance with another embodiment of the present invention, a method is provided for retrieving a clot from a vasculature lumen. The method includes extending a catheter within a vasculature lumen through a clot and positioning a distal portion of the catheter distally of the clot. At least one clot retrieval element is deployed from the distal portion of the catheter while maintaining attachment to the at least one clot retrieval element via a tethering member extending through the catheter. The at least one clot retrieval element is conformed to a geometry of the vasculature lumen and pressure is applied to a wall of the vasculature lumen by the at least one clot retrieval element. The distal portion of the catheter is displaced proximally with respect to the clot and the at least one clot retrieval element abuts against a distal side of the clot. The clot is pulled proximally through the vasculature lumen with the clot retrieval element abutted against a distal side of the clot.

BEST MODE(S) FOR CARRYING OUT THE INVENTION

[0009] The foregoing and other advantages of the invention will become apparent upon reading the following detailed description and upon reference to the drawings in which:

[0010] FIG. 1 is a side view of a medical device system, according to an embodiment of the present invention;

[0011] FIG. 1A is a cross-sectional view of a distal portion of the medical device system depicting a clot retrieval element constrained in the distal portion of the medical device system according to one embodiment;

[0012] FIG. 1B is a cross-sectional view of the distal portion of the medical device system depicting the clot retrieval element being deployed from the distal portion of the medical device system according to one embodiment;

[0013] FIGS. 2A through 2F depict a method for retrieving a clot from a vessel in the vasculature according to an embodiment of the present invention;

[0014] FIG. 3 is a front view of a clot retrieval element according to one embodiment of the present invention;

[0015] FIG. 3A is a cross-sectional view, taken along section A-A, of the clot retrieval element depicted in FIG. 3;

[0016] FIG. 4 is a front view of another embodiment of a clot retrieval element according to an embodiment of the present invention;

[0017] FIG. 4A is a cross-sectional view, taken along section A-A of the clot retrieval element of FIG. 4;

[0018] FIG. 5 is a perspective view of a clot retrieval element according to another embodiment of the present invention;

[0019] FIG. 6 is a perspective view of a clot retrieval element according to an embodiment of the present invention;

[0020] FIG. 7 is a cross-sectional view of a clot retrieval element according to another embodiment of the present invention;

[0021] FIG. 8 is a perspective view of a clot retrieval element having a cylindrical configuration according to one embodiment of the present invention;

[0022] FIG. 9 is a perspective view of a clot retrieval element having a spherical configuration according to another embodiment of the present invention;

[0023] FIG. 10 is a perspective view of a clot retrieval element having multiple protrusions extending from the element, according to an embodiment of the present invention; and

[0024] FIG. 11 is a side view of a clot retrieval element including multiple clot retrieval portions interconnected to each other with a tethering system according to another embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0025] Referring to FIG. 1, a medical device system 20 is shown according to an embodiment of the present invention. Such a medical device system 20 may be employed as an embolectomy catheter. The medical device system 20 includes a handle 22 and a catheter 30 extending distal of the handle. The handle 22 may include a port 24 for passing fluid through the catheter as will be appreciated by those of ordinary skill in the art. The handle 22 may also include an actuator 26 configured to control and manipulate a clot retrieval element 50 disposed in a distal portion 32 of the catheter 30. As such, the actuator 26 is operably interconnected with the clot retrieval element 50 such as through a tethering system or tethering member 40 (shown in dashed lines) extending through catheter 30 between the handle 22 and the clot retrieval element 50. The catheter 30 may be formed from flexible polymeric materials, such as known to those of ordinary skill in the art, that are suitable and configured for delivery within various vessels within the vasculature including, for example, intracranial vessels. In one embodiment, the catheter may be configured to include structure for over-the-wire delivery with a guide wire. In another embodiment, the catheter can include suitable structure to be delivered via a guide

wire employing, what is commonly termed as, rapid exchange. In still another embodiment, the catheter may be sized and configured as a micro-catheter for suitable delivery within an intracranial vessel. Such micro-catheter may be guided through the vasculature by a suitable sized guide wire as known in the art.

[0026] FIGS. 1A and 1B disclose enlarged cross-sectional views of the distal portion 32 of the catheter 30, depicting the clot retrieval element 50 positioned within the catheter (FIG. 1A) and being deployed from the catheter (FIG. 1B). In particular, the clot retrieval element 50 is sized and configured to be positioned within the distal portion 32 of the catheter 30 in a compact and constrained configuration (see FIG. 1A). With such an arrangement, the catheter 30 may include an inner lumen 34 extending at least partially through a length of the catheter so that a lumen end 36 of the inner lumen 34 is positioned proximally adjacent the clot retrieval element 50. Such lumen end 36 is sized and configured to act with the actuator 26 (FIG. 1) to provide a back-stop for the clot retrieval element 50. Further, the tethering member 40, interconnected to the handle 22 (FIG. 1), may extend through the inner lumen 34. Such tethering member 40 can be operably interconnected with, or otherwise attached to the clot retrieval element 50. The clot retrieval element 50 can be moved from the catheter 30 with the actuator 26 by moving the catheter 30 in a proximal direction, as indicated by arrows 38, while the inner lumen 34 maintains a substantially fixed position (relative to the catheter 30) to act as a back-stop to the clot retrieval element 50. In another embodiment, the inner lumen 34 can be moved in a distal direction while the catheter 30 is moved proximally or remains in a fixed position. Thus, the clot retrieval element 50 may be deployed from the distal portion 32 of the catheter 30 by relative movement of the catheter 30 and the inner lumen 34.

[0027] As the clot retrieval element 50 is deployed and becomes exposed from the catheter 30, the clot retrieval element 50 self expands to an enlarged or expanded configuration.

Such a clot retrieval element 50 expands to a size and configuration that enables it to conform to the dimension of the vasculature lumen its being deployed within. Thus, the clot retrieval element 50 may expand to effect contact with the entire circumference of a vasculature lumen at a given location. In the expanded configuration, the clot retrieval element 50 can remain interconnected to the medical device system 20 via the tethering member 40.

[0028] Further, the clot retrieval element 50 is configured to provide an expansion force or a radial outward force against the vessel wall while in the expanded configuration. This force may be applied radially to the entire circumference of the vasculature lumen at a given cross-section thereof. The engagement of the clot retrieval element 50 may be effected for a desired distance along the length of the vessel wall. For example, in one embodiment, it may be desirable to engage the vessel wall about its circumference and for a length of at least 1 millimeter (mm) or at least 2 mm. In another embodiment, it may be desirable to engage the vessel wall for a length of between approximately 3 mm and approximately 7 mm. In another embodiment, it may be desirable to engage the wall for a length that is approximately equal to a diameter of the vessel in which the clot retrieval element is to be disposed.

[0029] The clot retrieval element 50 may be formed from a polymeric material or any other suitable self expanding material that is generally soft and supple and that will not cause damage to the vessel walls. Further, in one embodiment, the clot retrieval element 50 may include a porous material, such as foam, mesh, fabric, felt and/or any other suitable material having a porous structure that will facilitate the clot retrieval element to be placed in compact configuration and self expand to an enlarged or expanded configuration that substantially conforms to the dimension of, for example, the vessel the clot retrieval element is disposed within. Some example materials that the clot retrieval element may be formed from include, without limitation, polyurethane, polytetrafluoroethylene (PTFE – sometimes marketed under

the trademark Teflon®), expanded PTFE (ePTFE), polyester, silicon, polyethylene terephthalate (PET – sometimes marketed under the trademark Dacron®, composites or combinations thereof, or any other suitable material known to one of ordinary skill in the art. It is also contemplated that the clot retrieval element 50 can include a marker by, for example, impregnating or coating the clot retrieval element to facilitate viewing the placement and position of the clot retrieval element within the vasculature as well as within the medical device system utilizing conventional imaging techniques. The marker can also be provided with the tethering member. Such marker can be formed from a radio-opaque material, such as tantalum, gold, platinum or alloys thereof, or any other suitable radio-opaque material, such as barium sulfate, as known in the art.

[0030] Referring now to FIGS. 2A through 2F a method is described for retrieving a clot 10 from a vessel 12. FIG. 2A shows an example of a vasculature lumen or vessel 12 with a clot 10 formed therein. Such a vasculature lumen may be an intracranial vessel, a peripheral vessel, or any other vasculature lumen having a clot formed therein. FIG. 2B depicts the catheter 30 of the medical device system 20 of the present invention positioned within the vessel 12 and the distal portion 32 of the catheter 30 extending distally beyond the clot 10. Positioning the catheter 30 distally of the clot 10 may be accomplished, for example, utilizing a micro-catheter for intracranial applications, or utilizing over-the-wire or rapid-exchange techniques for the same or for other applications. Of course, as known to one of ordinary skill in the art, the catheter 30 may include various structures associated with the employment of over-the-wire or rapid exchange techniques, or it may employ structures and features associated with micro-catheters.

[0031] Once in the distal position (e.g., as shown in FIG. 2B), the user can then deploy the clot retrieval element 50 from the catheter 30 as depicted in FIG. 2C (See also FIG. 1B).

Once deployed, the clot retrieval element 50 expands from the constrained compact configuration (as contained within the catheter 30) to an expanded configuration such that the clot retrieval element 50 contacts the wall 14 of the vessel 12. Moreover, as noted above, the clot retrieval element 50 expands so as to conform with the size and shape of the vessel 12 and may press against the wall 14 with a desired magnitude of radial force or pressure. As depicted in FIG. 2D, the catheter 30 may be displaced proximally, as depicted by arrow 16, with respect to the clot 10 while maintaining attachment to the clot retrieval element 50 with the tethering member 40. As the catheter 30 continues to be withdrawn, moving proximally, the clot retrieval element 50 also moves proximally to abut against a distal side 18 of the clot 10 as depicted in FIG. 2E.

[0032] As depicted in FIG. 2F, the catheter 30 (not shown) and clot retrieval element 50 continue to move proximally to ultimately withdrawn the clot from the vessel 12. During removal of the clot 10, the clot retrieval element 50 is maintained on a distal side 18 of the clot 10 as the catheter 30 is withdrawn from the vessel 12 due to the clot retrieval element conforming to the blood vessel and effectively filling the cross-sectional area of the vessel on the distal side of the clot 10 by application of a continual outward force against the wall 14 of the vessel 12. In this manner, the clot 10 is withdrawn from the vessel 12 as the catheter 30 and clot retrieval element 50 are also withdrawn from the vessel 12. It is also contemplated that as the clot 10 is withdrawn from a vessel 12, the clot 10 may be pulled toward the catheter it may be suctioned into and through the catheter. It is noted that, in the embodiment shown and described with respect to FIGS. 2A – 2F, normal blood flow within the vessel 12 is along the catheter 30 towards the deployed clot retrieval element 50 (i.e., opposite to the direction indicated by 16).

[0033] FIGS. 3 and 3A disclose an embodiment of a clot retrieval element 50 with a tethering member 40 attached thereto. Such a clot retrieval element 50 may be substantially

cylindrical in shape (in its expanded form) with a proximal side 52, a distal side 54 and an outer radial surface 56. The proximal side 52 may include a rim portion 58 located peripherally between the radial surface 56 and a cavity surface 60 at the proximal side 52. The cavity surface 60 can extend from the rim portion 58 in a concave configuration within the proximal side 52 to define a cavity 62. Further, the proximal side 52 of the clot retrieval element 50 can include the tethering member 40 centrally extending into the cavity surface 60. The cavity 62 of the clot retrieval element 50 may be sized and configured to assist in capturing and holding a clot as the clot retrieval element 50 is pulled proximally through the vasculature. As previously set forth, the clot retrieval element 50 can be formed from a polymeric material, such as foam. As such, in one embodiment, the polymeric material or foam can be formed with a higher density at the proximal side to assist in supporting the rim portion 58 of the clot retrieval element 50. One method for forming the clot retrieval element 50 may include a molding process as known by those of ordinary skill in the art. In another embodiment, the proximal side 52 of the clot retrieval element 50 may include one or more layers 64 (shown in dashed lines) of a strengthening material to increase the structural support of the rim portion 58 and cavity surface 60 and substantially prevent potential collapsing of the rim portion 58 when pulling the clot retrieval element 50. In one embodiment, the added layer 64 may include a polymer film laminated to the proximal side 52. Such a material may include, for example, ePTFE or polyurethane (PU). In another embodiment the proximal side 52 may be stiffened by, for example, the selective addition of an adhesive to the matrix material (e.g., foam) forming the body of the clot retrieval element 50. Such an adhesive may include, for example, an acrylic or silicone based adhesive material.

[0034] As previously discussed, the clot retrieval element 50 includes a tethering member 40 centrally extending into the proximal side 52 of the clot retrieval element 50 and

within the cavity surface 60. In one embodiment, the tethering member 40 may include a line portion 42 and multiple end portions 44 extending from the line portion 42. The line portion 42 includes a proximal end (not shown) and a distal end 46, the proximal end being operably interconnected to the handle (see FIG. 1) and the distal end extending within the clot retrieval element 50. In one embodiment, the line portion 42 may include multiple lines or filaments wound together or braided to comprise the line portion. The multiple lines, at the distal end 46, may be separated to comprise the multiple end portions 44 each extending in different directions within the body of the clot retrieval element 50. Such multiple end portions 44 can be configured to be positioned throughout the clot retrieval element 50 in random positions or in predetermined positions with many, if not all, extending at an angle relative to the line portion 42. With this arrangement, the multiple end portions 44 extending throughout the clot retrieval element 50 are configured to support and maintain attachment to the clot retrieval element in the expanded configuration while applying a force to the clot retrieval element to pull it through the vessel both before and after engaging the clot.

[0035] FIGS. 4 and 4A disclose another embodiment of a clot retrieval element 70. The clot retrieval element is generally similar to that which is described in the previous embodiment. However, in the presently considered embodiment, the clot retrieval element 70 may be configured to define multiple cavities 82 in a proximal side 72 of the clot retrieval element 70. In particular, the proximal side 72 of the clot retrieval element 70 may include a rim portion 74 located peripherally between a radial surface 76 and a cavity surface 78. The cavity surface 78 may include one or more cross members 80 to help define the multiple cavity portions 82 within the proximal side 72 of the clot retrieval element 70. A tethering member 84 may extend through the cross member 80 which may provide added strength and support with regard to the interconnection of the tethering member 84 and the clot retrieval element 70. With

this arrangement, the clot retrieval element 70 can abut against a distal side of a clot and, as the clot retrieval element 70 is pulled against the clot, at least a portion of the clot can be captured within the multiple cavity portions 82 defined in the clot retrieval element 70. As in the previous embodiment, the proximal side 72 of the clot retrieval element 70 can be formed of a higher density of foam than that of the distal side of the clot retrieval element and/or the proximal side may include one or more layers to assist in supporting the rim portion and cross member (or members) of the clot retrieval element 70 when being employed to capture a clot.

[0036] Referring now to FIG. 5, another embodiment of a clot retrieval element 90 coupled with a tethering member 92 is shown. In this embodiment, the tethering member 92 includes a line portion 94 with multiple end portions 96 extending from the line portion. The line portion 94 may include, for example, multiple lines wound together and, at a distal end of the line portion 94, the multiple end portions 96 may be configured to extend distally to attach to the proximal side 91 of the clot retrieval element 90 at discrete attachment points 98. The attachment points 98 may be reinforced to withstand desired forces when the tethering member is pulled, thus applying forces to each of the attachment points 98 through the end portions 96.

[0037] FIG. 6 discloses another embodiment of the tethering member 102 operatively interconnected to a clot retrieval element 100. In particular, the tethering member 102 may include a line portion 104 and a holding portion 106 comprising multiple loop portions. The line portion 104 can include, for example, multiple lines wound together while the holding portion 106 may include the multiple lines in a non-wound configuration such that the multiple lines extend externally around a distal portion 101 of the clot retrieval element 100 to hold or encompass the clot retrieval element within the wrapped multiple lines extending therearound. In one embodiment, attachment points may be disposed at one or more positions about the clot retrieval element 100 to help maintain spacing of the individual lines of the holding portion.

[0038] Referring to FIG. 7, a cross-sectional view of a tethering member 112 attached to a clot retrieval element 110 according to another embodiment is shown. The clot retrieval element includes a hollow portion 112 or an evacuated volume defined therein. In this embodiment, the tethering member 114 may include a line portion 116 and a holding portion 118. Similar to the previous embodiments, the line portion 116 may include multiple lines wound together to form the line portion 116. The holding portion 118 extends from the line portion 116 and also can include the multiple lines therewith. The individual lines of the holding portion 118 may extend internally through the clot retrieval element 110 in loop configurations such that they return back to the line portion 116. Such loops can also include undulations 120 to support and stabilize the clot retrieval element 110. As depicted, the holding portion 118 can extend through the clot retrieval element 110 by extending around the hollow portion 112 defined in the clot retrieval element 110. In one embodiment, the line or lines of the holding portion 118 are coupled at one end or at both ends to the line portion 116 such as by knots or other fastening mechanisms or techniques. In another embodiment, the line or lines of the holding portion 118 may be unitary extensions of the line portion 116 at one end or both ends of the line portions.

[0039] The tethering system or tethering member used in various embodiments of the present invention may be formed from any suitable metallic or polymeric material. In one embodiment, the tethering member may be formed from one or more wires of a metallic material, such as Nitinol, or any other suitable metallic material. Such wire or wires can also be employed to provide a modulation to the radial force of the clot retrieval element when expanded. This may be accomplished, for example, by varying the diameter of the wire along its length. This may also be accomplished by utilizing a shape memory alloy, such as Nitinol, which is heat set so that the unconstrained profile provides a desired expansive force in

contacting a vessel wall. Yet another example of accomplishing modulation of the radial force might include using "wires" that are constructed of tube material and are strategically cut to exhibit variable strut widths. Other means of providing a modulation of the radial force may also be used, and such examples are not intended to be limiting.

[0040] In another embodiment, the tethering member can be formed from a high tensile fiber of, for example, a single line, or fiber bundle, braid or multiple bundles braided, and formed from a any suitable polymeric material, such as PET, providing sufficient tensile strength suitable to act as a tether and interconnection between the clot retrieval element and the handle to maintain attachment to the clot retrieval element while pulling the clot retrieval element through the vasculature to withdraw the clot therefrom. In any case, the tethering member can extend between the clot retrieval element and the handle and can include additional components as known to one of ordinary skill in the art to control and enable maneuverability, for example, via the handle. Further, the tethering member can be attached to the clot retrieval element by other suitable techniques such as by molding the tethering member into the clot retrieval element.

[0041] FIG. 8 discloses one embodiment of a clot retrieval element 130, depicted in a non-constrained, expanded configuration. In particular, the clot retrieval element 130 can be substantially cylindrical in shape with a proximal surface 132 and a distal surface 134 generally being flat. As previously set forth, the clot retrieval element 130 can be made from a polymeric and/or metallic material, such as foam, to provide the characteristics that employ both the compact and expanded configurations while providing sufficient strength to engage and pull a clot through the vasculature and while not causing damage to the vasculature during the process. Further, as shown in dashed lines, the clot retrieval element 130 can include a hollow portion

136 to minimize the size or volume of the compact configuration while maximizing the size or volume of the expanded configuration of the clot retrieval element 130.

[0042] FIG. 9 is similar to the embodiment depicted in FIG. 8, except in this embodiment the clot retrieval element 140 is substantially spherical in shape when in a non-constrained fully expanded configuration. It should be noted that when expanded in a vessel, the clot retrieval element 140 will preferably be in a substantially cylindrical shape (or at least having a portion that is substantially cylindrical, with potentially domed end portions) due to the constraints of the vessel dimension and resistance to any radial pressure applied by the clot retrieval element 140. In this embodiment, the clot retrieval element 140 can also include a hollow portion (not shown) to maximize the ratio of expansion volume to contraction volume.

[0043] FIG. 10 discloses another embodiment of the clot retrieval element 150, also depicted in a non-constrained, expanded configuration, that includes multiple protrusions 152 extending therefrom to provide a textured surface to the clot retrieval element. In this embodiment, the multiple protrusions 152 can extend from the radial surface 156 of the clot retrieval element 150, wherein the proximal side 154 may not include the protrusions. Such multiple protrusions 152 can be employed to scrub and catch any residual clot matter located along the vessel wall as the clot retrieval element 150 is being pulled against the clot and through the vasculature. Such protrusions can be configured to be supple so as to not damage the vessel wall. As such, the multiple protrusions 152 scrub the vessel wall of any clot residue left on the vessel wall as the majority of the clot is being withdrawn from the vessel. In one embodiment, the protrusions 152 may be formed of the same material as the body of the clot retrieval element 150, and may be formed, for example, by molding the clot retrieval element to exhibit such protrusions 152.

[0044] Referring now to FIG. 11, there is disclosed another embodiment of a clot retrieval element 160 that includes multiple clot retrieval portions or discrete bodies. For example, the clot retrieval element 160 of this embodiment can include a proximal clot retrieval portion 162 (or discrete body), an intermediate clot retrieval portion 164 (or discrete body) and a distal clot retrieval portion 166 (or discrete body). Such clot retrieval portions can be separated from each other while remaining coupled to each other by a tethering member 168 extending between each clot retrieval portion. In other words, spaces or gaps may be defined between adjacent clot retrieval portions.

[0045] The clot retrieval portions 162, 164, and 166 may be lined in a sequence with multiple clot retrieval portions (two or more). The clot retrieval portions can be sized and configured similar to the various embodiments previously described. The more distal clot retrieval portions may act to catch and retrieve any clot matter that was not captured by the more proximal clot retrieval portions. Thus, the additional clot retrieval portions provide redundancy and help to ensure the most complete removal of clot matter from the vasculature. This may occur when the system is being withdrawn so that the additional clot retrieval portions catch potential clot matter that may have become loose and migrated after the proximal-most clot retrieval portion bypasses the original position of the clot. In one embodiment, the various clot retrieval portions can be substantially similar in size, shape and material. In another embodiment, the clot retrieval portions can include variations in size, shape and material to effect slightly different functions. For example, in one embodiment the proximal-most clot retrieval portion 162 and the distal-most clot retrieval portion 166 can be configured similar to the clot retrieval element disclosed in FIGS. 3 and 3A, while a mid clot retrieval portion 164 may be configured similar to the clot retrieval element with protrusions depicted in FIG. 10. In

this manner, the clot retrieval element 160 depicted in FIG. 11 can maximize the effectiveness in removing or retrieving a clot from the vasculature.

[0046] It is also noted that various features described with reference to one specific embodiment may be employed in other embodiments. While the invention may be susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and have been described in detail herein. However, it should be understood that the invention is not intended to be limited to the particular forms disclosed. Rather, the present invention includes all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the following appended claims.

CLAIMS

What is claimed is:

1. A medical device configured to retrieve clot material from a vasculature lumen, comprising:

a handle having a catheter extending therefrom;

at least one clot retrieval element configured to be positioned within a distal portion of a lumen defined through the catheter, the at least one clot retrieval element operably attached to the handle with a tether member extending through the lumen of the catheter;

wherein the at least one clot retrieval element is configured to be deployed from within the catheter from a contracted state to an expanded state such that, when in the expanded state, the at least one clot retrieval element conforms to the geometry of the vasculature lumen and applies pressure to the vasculature lumen.

2. The medical device of claim 1, wherein the at least one clot retrieval element comprises a foam material.

3. The medical device of claim 1, wherein the at least one clot retrieval element includes at least a portion that is substantially cylindrical when in the expanded state.

4. The medical device of claim 3, wherein the at least one clot retrieval element includes a proximal end, a radial wall and a distal end, and wherein at least a portion of the proximal end exhibits a concave surface.

5. The medical device of claim 4, wherein a volume of material at the proximal end is exhibits a higher density than a volume of material at the distal end.

6. The medical device of claim 4, wherein at least one clot retrieval method further comprises at least one cross member extending across a portion of the proximal end.

7. The medical device of claim 4, wherein at least one clot retrieval element further comprises a reinforcing layer disposed on the proximal end.

8. The medical device of claim 1, wherein the tether member includes a plurality of lines, wherein ends of the plurality of lines are disposed within an interior portion of the at least one clot retrieval element.

9. The medical device of claim 8, wherein the ends of the plurality of lines are each positioned at different locations within the interior portion of the at least one clot retrieval element.

10. The medical device of claim 1, wherein the at least one clot retrieval element includes a body having a substantially hollow area defined therein.

11. The medical device of claim 1, wherein at least one clot retrieval element includes a plurality of discrete clot retrieval elements coupled with the tether member and spaced apart from one another.

12. The medical device of claim 11, wherein at least one of the plurality of clot retrieval elements includes a plurality of protrusions on a radial surface thereof.

13. The medical device of claim 11, wherein each of the plurality of clot retrieval elements are configured substantially identical to one another.

14. The medical device of claim 1, wherein the catheter is configured as a micro-catheter.

15. A method of retrieving a clot from a vasculature lumen, the method comprising:

extending a catheter within a vasculature lumen through a clot;

positioning a distal portion of the catheter distally of the clot;

deploying at least one clot retrieval element from the distal portion of the catheter while maintaining attachment to the at least one clot retrieval element via a tethering member extending through the catheter;

conforming the at least one clot retrieval element to a geometry of the vasculature lumen and applying pressure to a wall of the vasculature lumen with the at least one clot retrieval element;

displacing the distal portion of the catheter proximally with respect to the clot;

abutting the at least one clot retrieval element against a distal side of the clot; and

pulling the clot proximally through the vasculature lumen with the clot retrieval element abutted against a distal side of the clot.

16. The method according to claim 15, further comprising maintaining pressure on the vasculature lumen while moving the distal portion of the catheter proximally with respect to the clot.

17. The method according to claim 15, further comprising maintaining pressure on the vasculature lumen while pulling the clot proximally through the vasculature lumen.

18. The method according to claim 15, wherein deploying at least one clot retrieval element from the distal portion of the catheter further comprising deploying a body comprising a foam material from the distal portion of the catheter.

19. The method according to claim 15, wherein deploying at least one clot retrieval element from the distal portion of the catheter includes deploying a plurality of discrete, spaced apart clot retrieval elements coupled together by the tethering member.

20. The method according to claim 19, wherein deploying a plurality of discrete, spaced apart clot retrieval elements includes deploying a plurality of substantially identical clot retrieval elements.

21. The method according to claim 19, wherein deploying a plurality of discrete, spaced apart clot retrieval elements includes deploying at least one clot retrieval element having a plurality of protrusions on a radial surface thereof.

22. The method according to claim 15, wherein deploying at least one clot retrieval element from the distal portion of the catheter includes deploying a clot retrieval element having a substantially convex surface in at least a portion of a proximal end of the clot retrieval element.

23. The method according to claim 15, wherein deploying at least one clot retrieval element from the distal portion of the catheter includes deploying a clot retrieval element having a volume of material at a proximal end thereof exhibiting a first density and a volume of material at a distal end thereof exhibiting a second density, the first density being greater than the second density.

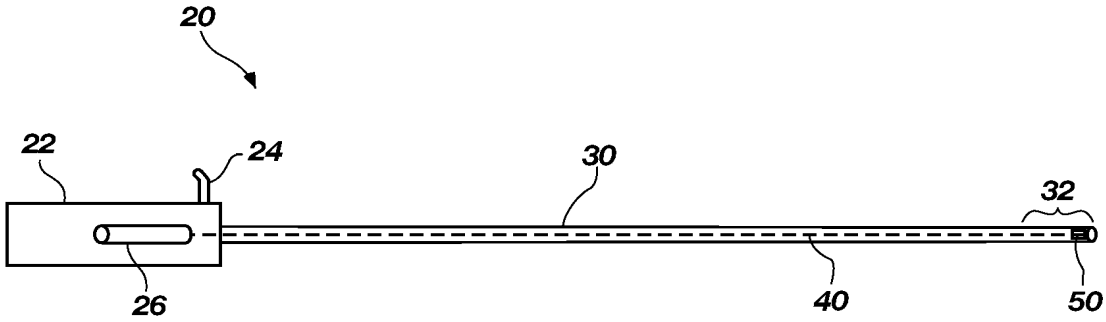


FIG. 1

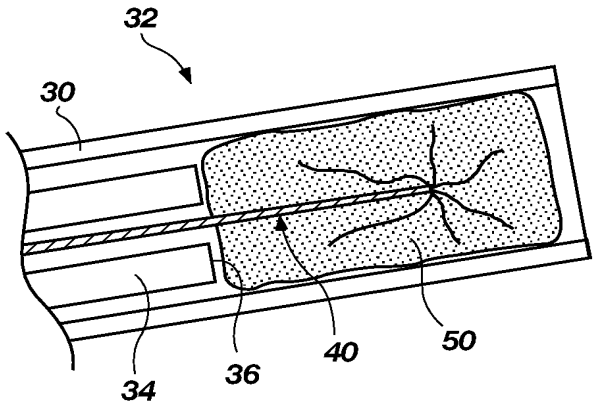


FIG. 1A

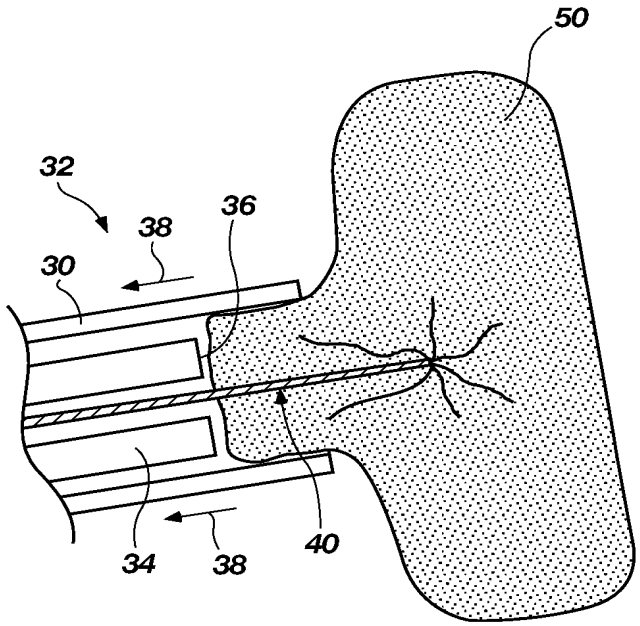


FIG. 1B

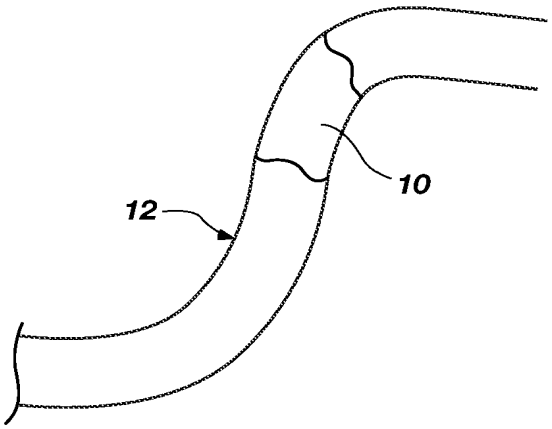


FIG. 2A

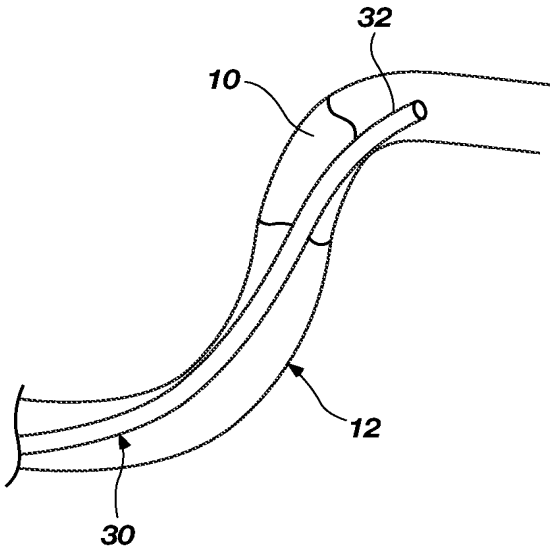


FIG. 2B

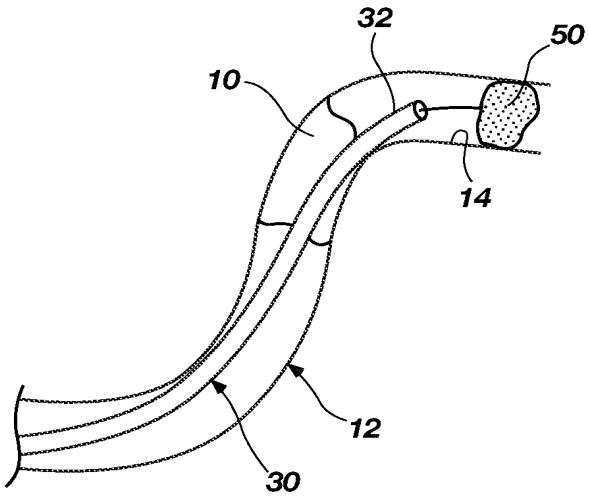


FIG. 2C

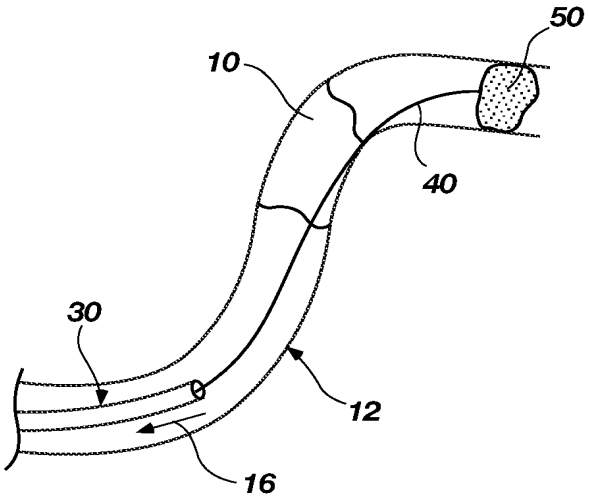


FIG. 2D

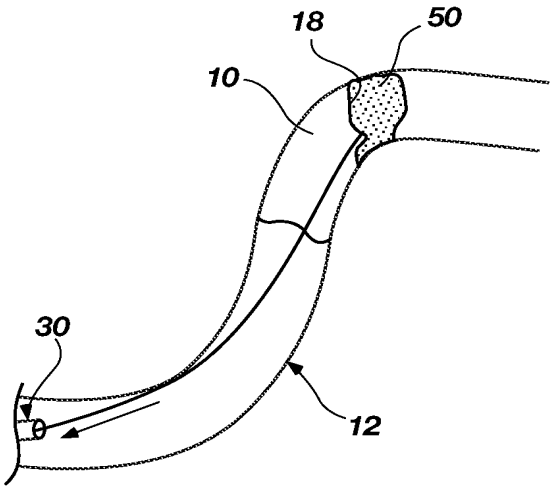


FIG. 2E

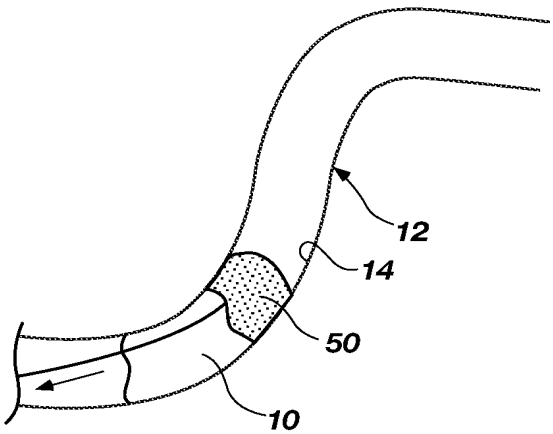


FIG. 2F

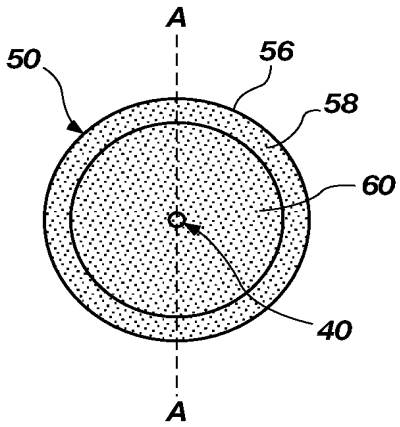


FIG. 3

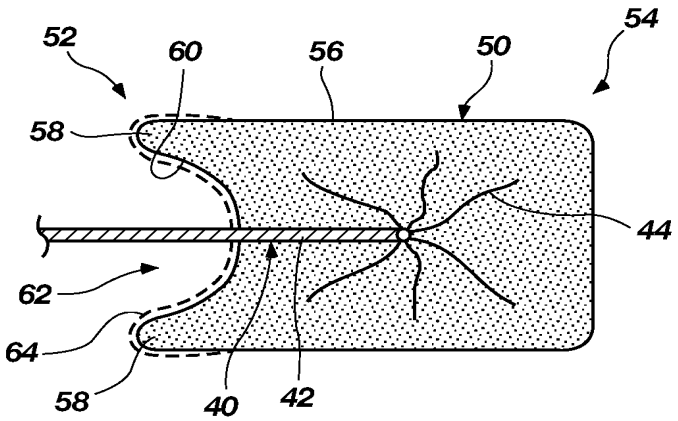


FIG. 3A

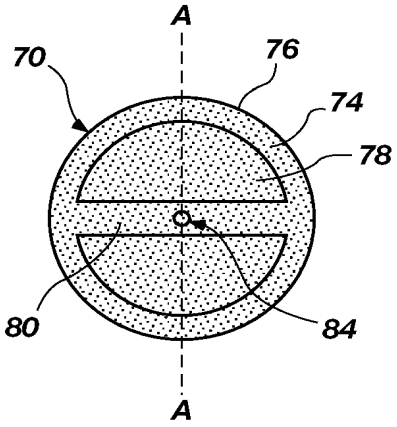


FIG. 4

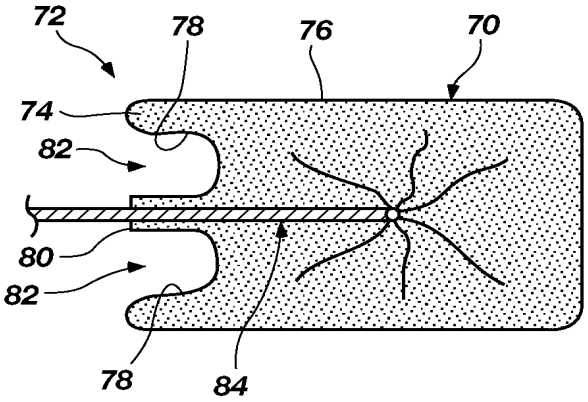


FIG. 4A

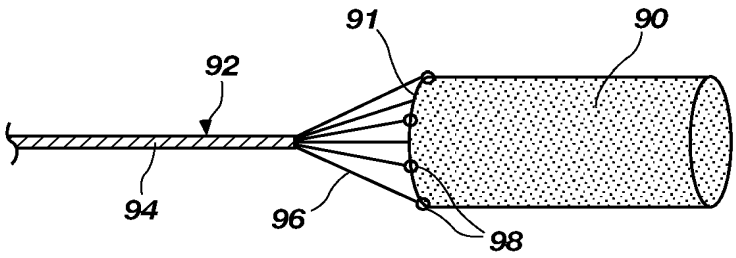


FIG. 5

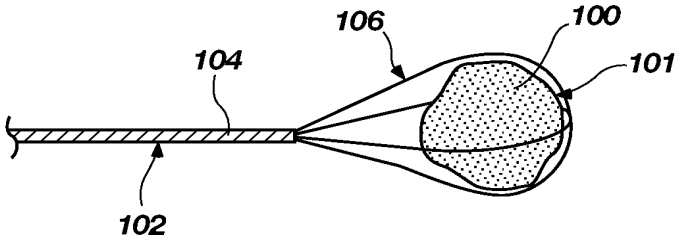


FIG. 6

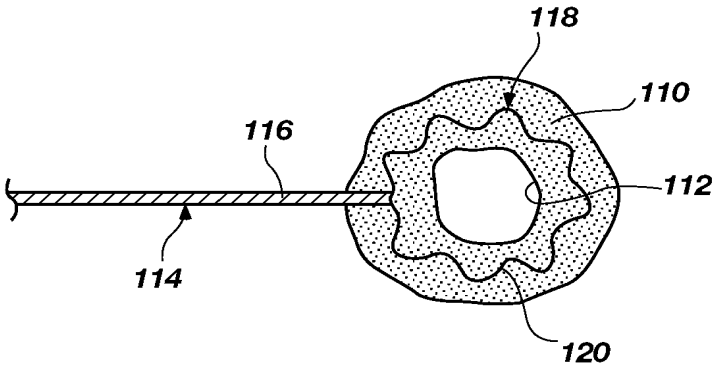


FIG. 7

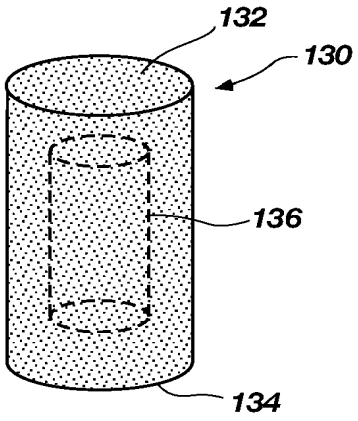


FIG. 8

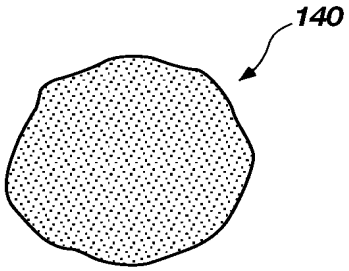


FIG. 9

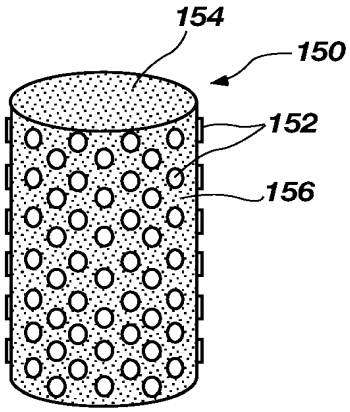


FIG. 10

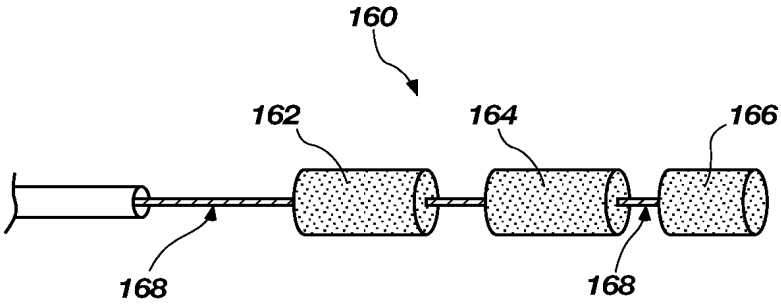


FIG. 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/048049

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

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 A61F

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2007/059349 A (COOK INC [US]; MAGNUSON MARK A [US]; PARKER FRED T [US]) 24 May 2007 (2007-05-24)	1-4,6, 10,14
A	abstract; figures 1,3a-3B,4-7	5,7-9,11
X	US 6 336 934 B1 (GILSON PAUL [IE] ET AL) 8 January 2002 (2002-01-08)	1-4,6, 10,14
A	abstract; figures 1,2,8-10,20-22 column 9, lines 13-34	5,7-9,11
X	US 2008/045881 A1 (TEITELBAUM GEORGE P [US] ET AL) 21 February 2008 (2008-02-21) abstract; figures 3B,3D,3E,3I paragraphs [0047], [0060] - [0062]	1-4,6, 8-11,13, 14

-/--

[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 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
10 September 2009	21/09/2009

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	Macaire, Stéphane

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	US 2007/179513 A1 (DEUTSCH HARVEY L [US]) 2 August 2007 (2007-08-02) abstract; figures 3,4,6,7,15 paragraphs [0002] - [0004], [0051]	1-4,6, 11-14
X	US 2003/055452 A1 (JOERGENSEN IB ERLING [DE] ET AL) 20 March 2003 (2003-03-20) abstract; figures 1a,5a-5e	1-4,6, 10,14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/048049

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

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

1. [X] Claims Nos.: 15-23
because they relate to subject matter not required to be searched by this Authority, namely:

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

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

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

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

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

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable 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 reportcovers 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/US2009/048049

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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PCT/IL2009/000834

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30 August 2009 (30.08.2009)

(25) Filing Language: English

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(30) Priority Data:
61/093,173 29 August 2008 (29.08.2008) US
61/119,369 2 December 2008 (02.12.2008) US

(71) Applicant *(for all designated States except US)*: **RAPID MEDICAL LTD.** [IL/IL]; 42 HaYuvalim St., 17906 Shimshit (IL).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **ECKHOUSE, Ronen** [IL/IL]; 42 HaYuvalim St., 17906 Shimshit (IL). **SUDIN, Yuri** [IL/IL]; 13 Migdal Hamenora, 71700 Modiin (IL). **ECKHOUSE, Shimon** [IL/IL]; 52 Hag St., 34980 Haifa (IL).

(74) Agent: **DR. EYAL BRESSLER LTD.**; 11 Tuval St., Lazrom House, 52522 Ramat Gan (IL).

(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, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

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

Published:

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

(54) **Title**: EMBOLECTOMY DEVICE

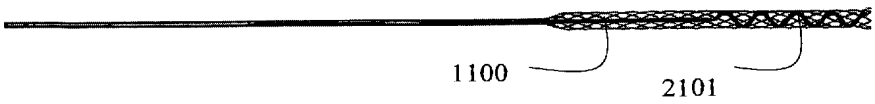


Fig. 1A

(57) **Abstract**: It is one object of the present invention to provide a device for extracting a clot from a blood vessel in a non fragmented manner, comprising: 1. an endless wire coupled to a spring-like helical member having a plurality of loops; said loops are positioned at an angle A relatively to the main longitudinal axis of said blood vessel; and, are adapted to radially encircle at least a portion of the outer circumference of said clot; and, 2. a tubular mesh-like net for both enveloping said helical member and enclosing said clot therein; wherein at least a portion of said clot is contemporaneously confined within said loops and said mesh-like net, such that radial compression forces and longitudinal shearing forces are exerted on said clot and the tendency of said clot to fragment is mitigated.

WO 2010/023671 A2

EMBOLECTOMY DEVICE

FIELD OF THE INVENTION

[1] The present invention relates to a minimally invasive or surgical device deliverable through an intravascular catheter to the site of an occlusion (e.g., emboli and thrombi). It is designed to remove emboli, even when found in the distal, tortuous neurovasculature. The device includes several sections.

BACKGROUND OF THE INVENTION

[2] The present invention provides a thrombectomy device which is designed to extract occlusion (e.g., emboli and thrombi) found in the human vasculature, particularly in the distal, tortuous neurovasculature, with a low or minimized pulling or extractive force.

[3] Emboli occasionally form around the valves of the heart and then are dislodged and follow the blood flow into the distal regions of the body. They are particularly dangerous if the clot passes into the neurovascular where it results in an ischemic stroke. As discussed below, many such occlusions occur in the middle cerebral artery (MCA), although it is not the only site where emboli lodge. Obviously, when blood flow is inhibited or cut off completely from a portion of the brain, the brain's oxygen supply is limited causing severe disability or death.

[4] In procedures for removing emboli using the Fogarty catheter or other similar catheters, it is typical, first, to locate the clot using a contrast agent under fluoroscopy. The embolectomy catheter is then inserted and directed to the clot. For example, a distal tip of a balloon catheter may be carefully inserted through the center of the clot. Once the balloon has passed through to the distal side of the clot, the balloon is inflated. The balloon catheter is then gradually and gently withdrawn. The balloon, in this way, acts to pull the clot proximal to the balloon. The majority of procedures using a Fogarty catheter repeat these steps until the pertinent vessel is cleared of clot material.

[5] Such vaso-occlusions occur in a wide variety of sites within the body. The lodging of clots in various sites is complicated by the presence of atherosclerosis. This disease causes the vessels to become tortuous and narrowed. These anomalies are often considered to be the result of the

growth of atherosclerotic plaque. Clots occurring in these diseased vessels are difficult to remove using balloon or Fogarty catheters.

[6] Removal of emboli using balloon catheters is rife with potential problems. One such problem occurs during removal of a clot. The resistance to such removal often causes the balloon portion of the catheter to evert over the tip of the catheter. Should the user need to partially deflate the balloon during such a deflation, the distal tip of the balloon may become distended and angulated. Another difficulty with balloon catheters is the possibility of damage to the intima of arteries. Inflation pressures can create forces significant enough to shear such a vessel lining or to dislodge plaque lodged on such a wall. In the worst case, the balloon may rupture leaving balloon detritus in the bloodstream.

[7] Movement of a balloon in the MCA can displace the clot through more proximal branches into other large vessels such as the internal carotid artery (ICA) and then into other vessels

[8] There are a variety of different devices intended for use in replacing balloon catheters and in using a device other than a balloon catheter in so removing the emboli

[9] One such device is shown in U.S. Pat. No. 4,030,503 to Clark III. This patent describes a spiral helix affixed to the distal end of a catheter. In particular, the spiral helix is designed to be rotated and pushed forward through the clot. It is said that the helix screws into the clot, and when it is firmly embedded or is past the clot, the catheter is pulled out of the vessel without rotation. The catheter is said to operate like a corkscrew.

[10] A similar catheter is described in U.S. Pat. No. 4,706,671 to Weinrib. This catheter also has a coil section at its distal end. The coil section is said to be stretched initially into a generally linear insertion position for removing inwardly in a vessel. The coil member is then expanded into the form of a hollow conical scoop to then scoop clot material from the blood vessel. The coil member is stiffened by an internal wire which is then removed. The hollow passageway is then filled with a liquid to stiffen the coils. The coils are said to be of an elastomeric material.

[11] U.S. Pat. No. 4,762,130 to Fogarty et al., describes a helical balloon attached to the distal end of a catheter. The helical or bellowed balloon is maintained in a generally linear condition and passed into a clot. Once the catheter balloon within the clot is inflated, the balloon and adjoining clot are removed together.

[12] Another similar device used more to grip and shear atherosclerotic deposits rather than to remove thrombi is described in U.S. Pat. No. 4,890,611 to Monfort et al. This device

incorporates a pair of helical wires placed on the distal end of a wire. The flexible wire is pulled against a flexible catheter, the helical loops cut through and is said to retain sections of plaque for removal.

[13] A thrombus extraction system is shown in U.S. Pat. No. 5,011,488, to Ginsberg. In this device, a deflated (but inflatable) balloon having a proximal conic shape is passed through a targeted thrombus. The balloon is then expanded and retracted so that the proximal end pulls the thrombus into contact with an aspirator. The aspirator then removes the thrombotic material from the vessel.

[14] The Ginsburg patent describes an alternative wire-based configuration of the expandable member. In this variation, a wire coil is attached to an extension wire which may be moved between an extended position and a retracted position. The retracted or expanded configuration is illustrated to have a conical shape. The cone's proximal end is shown to be smaller than the distal end.

[15] U.S. Pat. No. 5,112,347, to Taheri, shows an inflatable balloon-type embolectomy catheter. The balloon has a number of "fingers" arranged in a leaf spring arrangement inside the balloon. The balloon is hydraulically inflated and forms a cone after inflation. The deflated device is shown in FIGS. 11 through 14 to be passed distally past a clot before inflation. After inflation, the large end of the balloon collects the embolism as it is pulled past the appropriate site in the vessel.

[16] U.S. Pat. No. 5,192,286, to Phan et al., shows a retrieval catheter for removing materials from various body lumens. The retrieval catheter is shown to have a slack net which may be collapsed for passage into lumen past the material to be collected. The net is unfolded after such passage and materials such as uretral stones are removed.

[17] U.S. Pat. No. 5,411,509, to Hilal, shows an embolectomy catheter having a distal elastomeric foam tip. The foam tip has an actuator means suitable for forming the foam section both longitudinally and radially in response to activation of the actuation. In practice, the catheter tip is pressed past an embolism, inflated, and retracted proximally along with the clot.

[18] U.S. Pat. No. 5,490,859, to Mische et al., shows an intravascular occlusion material removal device having an expandable material removal element made up of a number of wires passing between the two ends of such element, a catheter shaft, a drive shaft for spinning the element within the blood vessel, and a collection portion placed on the material removal element for collecting any occlusion material removed by the expandable material removal element. The

drive shaft may be operated by a motor connected to the drive shaft proximate to the proximal end of the drive shaft.

[19] Another patent literature relates to the use of a net which encircle the clot. Such teaching can be found in US application no. US2005/0101986, US application no. US20060287670, US application no. US20070038241, US application no. US20030009189 and PCT application on. WO9923976. The major drawback of such nets are the fact that the clot or clot might fragment within the blood vessel and hence not be extracted as a whole from said blood vessel.

[20] None of above mentioned patents and patent applications discloses a device which is especially adapted to apply radial compression forces and longitudinal shearing forces on the clot so as to mitigate the tendency of the clot to fragment.

SUMMARY OF THE INVENTION

The present invention provides a minimally invasive medical device deliverable through an intravascular catheter to the site of a occlusion. It is designed to remove clot from the vasculature, and is particularly useful in removing clot from distal, tortuous vasculature.

The device of the present invention is designed to remove clot, even when found in the distal, tortuous neurovasculature.

The present invention provides an embolectomy device for removal of clot from vasculature comprises a rotatable spring-like helical member having a plurality of loops and a tubular mesh-like net.

The rotating member may be configured to expand to approximate the diameter of the vessel and to at least partially envelope the clot and also to aid in the separation of the clot from the vessel wall.

The rotating member approximates the clot and envelopes it by its rotation. The rotating member may also be used with various intravascular catheters or especially design ones, as will be described hereinafter.

The rotating member may serve several purposes. First, the loops of the rotating element are configured so that it will separate the clot from the arterial wall, at least partially envelope the clot, manipulate the clot reciprocally and/or rotationally with respect to the main longitudinal axis of the clot and extracts it.

The mesh-like net encapsulates the clot (confined within the coil) therein.

It is one object of the present invention to provide a device for extracting a clot from a blood vessel in a non fragmented manner, comprising:

an endless wire coupled to a spring-like helical member having a plurality of loops; said loops are positioned at an angle *A* relatively to the main longitudinal axis of said blood vessel; and, are adapted to radially encircle at least a portion of the outer circumference of said clot; and,

a tubular mesh-like net for both enveloping said helical member and enclosing said clot therein;

wherein at least a portion of said clot is contemporaneously confined within said loops and said mesh-like net, such that radial compression forces and longitudinal shearing forces are exerted on said clot and the tendency of said clot to fragment is mitigated.

It is another object of the present invention to provide the embolectomy device as defined above, wherein said spring-like helical member and/or said mesh-like net comprising means for applying vibration on said clot.

It is another object of the present invention to provide the embolectomy device as defined above, wherein said mesh-like net is made of material selected from a group consisting of woven fabrics, non-woven fabrics, gauze-like fabrics, materials having multiple openings, and fluid-permeable membranes or any combination thereof.

It is another object of the present invention to provide the embolectomy device as defined above, wherein said mesh-like net additionally comprising materials selected from a group consisting of woven fabrics, non-woven fabrics, gauze-like fabrics, materials having multiple openings, and fluid-permeable membranes or any combination thereof.

It is another object of the present invention to provide the embolectomy device as defined above, wherein said spring-like helical member is coupled to said mesh-like net.

It is another object of the present invention to provide the embolectomy device as defined above, wherein said distal portion of said mesh-like net is adapted to switch from an expended-configuration to a restricted-configuration; said expended-configuration is operative to allow insertion of at least a portion of a target clot in to said mesh-like net's distal portion; and said restricted configuration is operative to retain said clot within said mesh-like net.

It is another object of the present invention to provide the embolectomy device as defined above, wherein said distal portion of said mesh-like net is operative to self-expand from its expended-configuration to its restricted-configuration.

It is another object of the present invention to provide the embolectomy device as defined above, wherein said mesh-like net is an elongated sleeve comprising a restricting sphincter located at the distal end of said sleeve, adapted to retain at least a portion of the target clot within said mesh-like net.

It is another object of the present invention to provide the embolectomy device as defined above, wherein said helical member is characterized by a cross-sectional area selected from a group consisting of circular, oval, round, square, rectangular, triangular, regular or irregular shapes, or any combination thereof.

It is another object of the present invention to provide the embolectomy device as defined above, additionally comprising a motor adapted to rotate said helical member.

It is another object of the present invention to provide the embolectomy device as defined above, wherein said helical member additionally comprising protrusions for assisting in the separation of said clot from said vasculature.

It is another object of the present invention to provide the embolectomy device as defined above, additionally comprising vibration means applied on said clot.

It is another object of the present invention to provide the embolectomy device as defined above, additionally comprising a corkscrew-like effecter, having a coil-like distal end, adapted to penetrate and cross said clot.

It is another object of the present invention to provide the embolectomy device as defined above, wherein the diameter of said helical member is variable so as to better adjust to the diameter of said clot or said blood vessel.

It is another object of the present invention to provide the embolectomy device as defined above, wherein said device additionally comprising:

a proximal effecter characterized by a folded configuration and an open configuration;

a distal effecter characterized by a folded configuration and an open configuration;

said proximal effecter, in said open configuration is adapted for grasping a proximal portion of said clot; said proximal effecter, in said open configuration is adapted for grasping a distal portion of said clot;

wherein both said effecters, when open, are oppositely positioned and are adapted to operate in concert, for trapping said clot such that said clot is (i) manipulatable along

and/or around the main longitudinal axis of said blood vessel; and, (ii) extracted out of said blood vessel.

It is another object of the present invention to provide the embolectomy device as defined above, wherein said distal effecter is operative to cross said clot in said FOLDED configuration and then to be expanded to an OPEN configuration.

It is another object of the present invention to provide the embolectomy device as defined above, wherein said distal effecter is operative to self-expand from its FOLDED configuration to its OPEN configuration.

It is another object of the present invention to provide the embolectomy device as defined above, wherein said distal effecter is incorporated or otherwise connected with said proximal effecter to form a single effecter.

It is another object of the present invention to provide the embolectomy device as defined above, wherein said angle A ranges from about 0 degrees to about 180 degrees.

It is another object of the present invention to provide the embolectomy device as defined above, additionally comprising aspiration means.

It is another object of the present invention to provide the embolectomy device as defined above, wherein at least one of said loops and/or said mesh-like net is coated with lubricious polymeric material selected from hydrophilic polymer material.

It is another object of the present invention to provide the embolectomy device as defined above, wherein said spring-like helical member is characterized by single, double, or triple pitch.

It is another object of the present invention to provide the embolectomy device as defined above, wherein the cross section of at least one of said loops and/or said mesh-like net varies.

It is another object of the present invention to provide a method for removing a clot from blood vessel. The method comprising steps selected inter alia from:

i. obtaining an embolectomy device comprising:
    a. an endless wire coupled to a spring-like helical member having a plurality of loops; said loops are positioned at an angle *A* relatively to the main longitudinal axis of said blood vessel;
    b. a tubular mesh-like net;
ii. integrating said spring-like helical member with said tubular mesh-like net;

iii. approximating said clot;

iv. rotating said helical member;

v. radially encircling at least a portion of the outer circumference of said clot by said plurality of loops;

vi. entrapping said clot confined within said loops;

vii. inserting said confined clot into said tubular mesh-like net;

viii. extracting said clot confined within said loops and said mesh-like net from said blood vessel;

wherein said step of entrapping said clot confined within said loops by said tubular mesh-like net exerts radial compression forces and longitudinal shearing forces on said clot such that the tendency of said clot to fragment is mitigated.

It is another object of the present invention to provide the method as defined above, additionally comprising step of selecting the material of said mesh-like net from a group consisting of woven fabrics, non-woven fabrics, gauze-like fabrics, materials having multiple openings, and fluid-permeable membranes or any combination thereof.

It is another object of the present invention to provide the method as defined above, additionally comprising step of integrating said spring-like helical member to said tubular mesh-like net.

It is another object of the present invention to provide the method as defined above, additionally comprising step of configuring the distal portion of said mesh-like net to switch from an expended-configuration to a restricted-configuration; said expended-configuration is operative to allow insertion of at least a portion of a target clot into said mesh-like net's distal portion; and said restricted configuration is operative to retain said clot within said mesh-like net.

It is another object of the present invention to provide the method as defined above, additionally comprising step of configuring said mesh-like net to self-expand from said expended-configuration to said restricted-configuration.

It is another object of the present invention to provide the method as defined above, additionally comprising step of retaining at least a portion of the target clot within said mesh-like net.

It is another object of the present invention to provide the method as defined above, additionally comprising step of applying vibration on said clot.

It is another object of the present invention to provide the method as defined above, additionally comprising step of grasping (i) the proximal portion of said clot via a proximal effecter characterized by a FOLDED configuration and an OPEN configuration; and, (ii) the distal portion of said clot via a distal effecter characterized by a FOLDED configuration and an OPEN configuration; such that said clot is, when grasped by said effecters in said open configuration, is manipulatable along and/or around the main longitudinal axis of said blood vessel.

It is another object of the present invention to provide the method as defined above, additionally comprising steps of crossing said clot via said distal effecter in said FOLDED configuration; and, expanding to said OPEN configuration.

It is another object of the present invention to provide the method as defined above, additionally comprising step of configuring said distal effecter to self-expand from its FOLDED configuration to its OPEN configuration.

It is another object of the present invention to provide the method as defined above, additionally comprising step of incorporating said distal effecter with said proximal effecter to form a single effecter.

It is another object of the present invention to provide the method as defined above, additionally comprising step of selected the cross sectional area of said helical member from a group consisting of circular, oval, round, square, rectangular, triangular, regular or irregular shapes, or any combination thereof.

It is another object of the present invention to provide the method as defined above, additionally comprising step of adjusting the diameter of said loops to the diameter of said clot.

It is another object of the present invention to provide the method as defined above, additionally comprising step of penetrating and crossing said clot via a corkscrew-like effecter.

It is another object of the present invention to provide the method as defined above, additionally comprising step of selecting said angle A to be higher than about 0 degrees and lower than about 180 degrees.

It is another object of the present invention to provide the method as defined above, additionally comprising step of applying vibration on said clot.

It is another object of the present invention to provide the method as defined above, additionally comprising step of coating said loops and/or said mesh-like net with lubricious polymeric material selected from hydrophilic polymer material.

It is another object of the present invention to provide the method as defined above, additionally comprising step of coupling said spring-like helical member to said mesh-like net.

It is another object of the present invention to provide a method for removing a clot from blood vessel. The method comprising steps selected inter alia from:

i. obtaining an embolectomy device comprising:

   a. an endless wire coupled to a spring-like helical member having a plurality of loops; said loops are positioned at an angle *A* relatively to the main longitudinal axis of said blood vessel;

   b. a tubular mesh-like net;

ii. integrating said spring-like helical member with said tubular mesh-like net;

iii. rotating said helical member to approximate said clot whilst simultaneously approximating said mesh-like net to said clot;

iv. radially encircling at least a portion of the outer circumference of said clot by said plurality of loops whilst simultaneously entrapping said clot, confined within said loops, within said mesh-like net; and,

v. extracting said mesh-like net from said blood vessel;

wherein said step of entrapping said clot confined within said loops by said tubular mesh-like net exerts radial compression forces and longitudinal shearing forces on said clot such that the tendency of said clot to fragment is mitigated.

It is another object of the present invention to provide the method as defined above, additionally comprising step of selecting the material of said mesh-like net from a group consisting of woven fabrics, non-woven fabrics, gauze-like fabrics, materials having multiple openings, and fluid-permeable membranes or any combination thereof.

It is another object of the present invention to provide the method as defined above, additionally comprising step of integrating said spring-like helical member to said tubular mesh-like net.

It is another object of the present invention to provide the method as defined above, additionally comprising step of configuring the distal portion of said mesh-like net to switch from an expended-configuration to a restricted-configuration; said expended-configuration is

operative to allow insertion of at least a portion of a target clot into said mesh-like net's distal portion; and said restricted configuration is operative to retain said clot within said mesh-like net.

It is another object of the present invention to provide the method as defined above, additionally comprising step of configuring said mesh-like net to self-expand from said expended-configuration to said restricted-configuration.

It is another object of the present invention to provide the method as defined above, additionally comprising step of retaining at least a portion of the target clot within said mesh-like net.

It is another object of the present invention to provide the method as defined above, additionally comprising step of applying vibration on said clot.

It is another object of the present invention to provide the method as defined above, additionally comprising step of grasping (i) the proximal portion of said clot via a proximal effecter characterized by a FOLDED configuration and an OPEN configuration; and, (ii) the distal portion of said clot via a distal effecter characterized by a FOLDED configuration and an OPEN configuration; such that said clot is, when grasped by said effecters in said open configuration, is manipulatable along and/or around the main longitudinal axis of said blood vessel.

It is another object of the present invention to provide the method as defined above, additionally comprising steps of crossing said clot via said distal effecter in said FOLDED configuration; and, expanding to said OPEN configuration.

It is another object of the present invention to provide the method as defined above, additionally comprising step of configuring said distal effecter to self-expand from its FOLDED configuration to its OPEN configuration.

It is another object of the present invention to provide the method as defined above, additionally comprising step of incorporating said distal effecter with said proximal effecter to form a single effecter.

It is another object of the present invention to provide the method as defined above, additionally comprising step of selected the cross sectional area of said helical member from a group consisting of circular, oval, round, square, rectangular, triangular, regular or irregular shapes, or any combination thereof.

It is another object of the present invention to provide the method as defined above, additionally comprising step of adjusting the diameter of said loops to the diameter of said clot.

It is another object of the present invention to provide the method as defined above, additionally comprising step of penetrating and crossing said clot via a corkscrew-like effecter.
It is another object of the present invention to provide the method as defined above, additionally comprising step of selecting said angle A to be higher than about 0 degrees and lower than about 180 degrees.
It is another object of the present invention to provide the method as defined above, additionally comprising step of applying vibration on said clot.
It is another object of the present invention to provide the method as defined above, additionally comprising step of coating said loops and/or said mesh-like net with lubricious polymeric material selected from hydrophilic polymer material.
It is another object of the present invention to provide the method as defined above, additionally comprising step of coupling said spring-like helical member to said mesh-like net.

It is another object of the present invention to provide a method for removing a clot from blood vessel. The method comprising steps selected inter alia from:

i. obtaining an embolectomy device comprising:
    a. an endless wire coupled to a spring-like helical member having a plurality of loops; said loops are positioned at an angle *A* relatively to the main longitudinal axis of said blood vessel;
    b. a tubular mesh-like net;
ii. integrating said spring-like helical member with said tubular mesh-like net;
iii. approximating said clot;
iv. entrapping said clot via said mesh-like net;
v. rotating said helical member thereby radially encircling at least a portion of the outer circumference of said clot by said plurality of loops;
vi. extracting said mesh-like net from said blood vessel;

wherein said step of radially encircling at least a portion of the outer circumference of said clot by said plurality of loops exerts radial compression forces and longitudinal shearing forces on said clot such that the tendency of said clot to fragment is mitigated.

It is another object of the present invention to provide the method as defined above, additionally comprising step of selecting the material of said mesh-like net from a group consisting of woven fabrics, non-woven fabrics, gauze-like fabrics, materials having multiple openings, and fluid-permeable membranes or any combination thereof.

It is another object of the present invention to provide the method as defined above, additionally comprising step of configuring the distal portion of said mesh-like net to switch from an expended-configuration to a restricted-configuration; said expended-configuration is operative to allow insertion of at least a portion of a target clot into said mesh-like net's distal portion; and said restricted configuration is operative to retain said clot within said mesh-like net.

It is another object of the present invention to provide the method as defined above, additionally comprising step of integrating said spring-like helical member to said tubular mesh-like net.

It is another object of the present invention to provide the method as defined above, additionally comprising step of configuring said mesh-like net to self-expand from said expended-configuration to said restricted-configuration.

It is another object of the present invention to provide the method as defined above, additionally comprising step of retaining at least a portion of the target clot within said mesh-like net.

It is another object of the present invention to provide the method as defined above, additionally comprising step of applying vibration on said clot.

It is another object of the present invention to provide the method as defined above, additionally comprising step of grasping (i) the proximal portion of said clot via a proximal effecter characterized by a FOLDED configuration and an OPEN configuration; and, (ii) the distal portion of said clot via a distal effecter characterized by a FOLDED configuration and an OPEN configuration; such that said clot is, when grasped by said effecters in said open configuration, is manipulatable along and/or around the main longitudinal axis of said blood vessel.

It is another object of the present invention to provide the method as defined above, additionally comprising steps of crossing said clot via said distal effecter in said FOLDED configuration; and, expanding to said OPEN configuration.

It is another object of the present invention to provide the method as defined above, additionally comprising step of configuring said distal effecter to self-expand from its FOLDED configuration to its OPEN configuration.

It is another object of the present invention to provide the method as defined above, additionally comprising step of incorporating said distal effecter with said proximal effecter to form a single effecter.

It is another object of the present invention to provide the method as defined above, additionally comprising step of selected the cross sectional area of said helical member from a group consisting of circular, oval, round, square, rectangular, triangular, regular or irregular shapes, or any combination thereof.

It is another object of the present invention to provide the method as defined above, additionally comprising step of adjusting the diameter of said loops to the diameter of said clot.

It is another object of the present invention to provide the method as defined above, additionally comprising step of penetrating and crossing said clot via a corkscrew-like effecter.

It is another object of the present invention to provide the method as defined above, additionally comprising step of selecting said angle A to be higher than about 0 degrees and lower than about 180 degrees.

It is another object of the present invention to provide the method as defined above, additionally comprising step of applying vibration on said clot.

It is still an object of the present invention to provide the method as defined above, additionally comprising step of coating said loops and/or said mesh-like net with lubricious polymeric material selected from hydrophilic polymer material.

It is lastly an object of the present invention to provide the method as defined above, additionally comprising step of coupling said spring-like helical member to said mesh-like net.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1a illustrates an out-of-scale manner a schematic view (cross section) of the device according to a preferred embodiment of the present invention.

Figures 1b-1g illustrating an out-of-scale manner a schematic view (cross section) partially illustrating the minimally invasive embolectomy device according to one embodiment of the invention (namely the coil).

Figures 2a to 2e illustrate the entire device (i.e., the coil and the tubular mesh-like net) as described by the present invention.

Figure 3a illustrates a second embodiment of the device as described by the present invention in which an inner corkscrew-like effecter is utilized.

Figures 4a-4c illustrating the rotatable spring-like helical effecter integrated with the tubular mesh-like net.

Figures 5a-5k illustrate an embodiment in which the device additionally comprising a distal and proximal clasps.

Figure 6 is a view of an intravascular catheter according to the present invention and an associated guide wire.

Figures 7A, 7B, 7C, illustrate another embodiment of the catheter provided by the present invention.

Figures 8A and 8B illustrate another embodiment of the catheter provided by the present invention.

Figures 9A and 9B illustrate another embodiment of the catheter provided by the present invention.

Figure 10A illustrates the rotatable spring-like helical effecter of the embolectomy device protruding out of the catheter.

Figures 11A, 11B, and 11C illustrate another embodiment of the catheter provided by the present invention.

Figure 12 illustrates another embodiment of the catheter provided by the present invention.

Figure 13 illustrates another embodiment of the present invention.

Figures 14A and 14B illustrate the operation of a heat activated variation of the catheter.

Figure 15 illustrates a schematic depiction of a method of using the catheter according to one embodiment of the present invention.

Figures 16A and 16B illustrate the embolectomy device utilizing the rotatable spring-like helical effecter.

Figure 16C illustrates a variation of a rotating helical assembly.

Figures 17A and 17B illustrate another embodiment of the embolectomy device utilizing the rotatable spring-like helical effecter.

Figure 17C illustrates another variation of the rotatable spring-like helical effecter.

Figures 18A-18C illustrate the distal tip of the catheter with a rotating element configured to remove a clot as a whole from an artery.

Figure 19 shows a procedure for removing a clot using the variation shown in Figures 18A-18C.

Figures 20A, 20B(1), and 20B(2) show further variations of the device in which the catheter has an expandable distal-most portion.

Figure 21 shows a partial cutaway side view of one variation of the expanded catheter tip.

Figure 22 shows a perspective view of the device shown on Figure 20B(2).

Figures 23A and 23B show a partial cutaway side view of the expanded catheter tip.

Figures 24 and 25show perspective views of other variations of the expanded catheter tip.

Figure 26 shows a method for using the device depicted in Figures 16A and following.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[21] The following description is provided, alongside all chapters of the present invention, to enable any person skilled in the art to make use of said invention and sets forth the best modes contemplated by the inventor of carrying out this invention. Various modifications, however, will remain apparent to those skilled in the art, since the generic principles of the present invention have been defined specifically to provide a minimally invasive implement that is designed to restore flow in human vasculature by extraction of clots from the same, even in distal, narrow neurovasculature.

[22] The term **"crossing"** refers hereinafter to act of intersecting clot and penetrating its interior.

[23] The term **"about"** refers hereinafter to a range of 25% below or above the referred value.

[24] The term **"non-fragmented manner"** refers hereinafter to extraction of clots intact. i.e., the clot is removed as a whole without the danger of fragmenting within the vasculature.

The device of the present invention is intended to be used as a flow restoration device. Even in those instances where the clot is not or cannot be completely removed, the device of the present invention is believed to be useful in removing the clot in a non-fragmented manner (i.e., as a whole) and thereby permitting restoration of partial blood flow.

Furthermore, the device of the present invention is sufficiently flexible to be placed in distal tortuous anatomy and hence is useful in treating blocking clot found there.

[25] As described, the present invention provides an embolectomy device for extracting a clot in an intact manner from a blood vessel without fragmenting it. The device comprises an endless wire having a distal end. The distal end comprising a spring-like helical member having a plurality of loops. The loops are positioned at an angle *A* relatively to the main longitudinal axis of said blood vessel, and radially encircle [without crossing] at least a portion of the outer circumference of the clot. It is acknowledge that angle A ranges from about 0 degrees to about 180 degrees, namely 90 to 180 degrees.

[26] The device also comprises a tubular mesh-like net for both enveloping the helical member and enclosing the clot therein.

[27] By configuring the embolectomy device to contain both the mesh-like net and the spring-like helical member - coil, the entire clot mass is confined within the mesh-like net during reciprocal movement (i.e., extraction) of the clot, so as to provide *(i)* extraction of the entire mass of the clot from the blood vessel (in a non-fragmented manner); and, *(ii)* prevention of re-entry of clot mass or fragments thereof into the blood vessel.

[28] Further more, by contemporaneous confining the clot within the loops and the mesh-like net, radial compression forces and longitudinal shearing forces are exerted on said clot such that the tendency of said clot to fragment is mitigated.

[29] Treatments for embolic occlusions include catheterization of the patient and introduction of tissue plasminogen activator (t-PA), urokinase, or streptokinase to the site of the occlusion. Additionally the embolic occlusion may be penetrated--often with a microcatheter--and the t-PA or urokinase or streptokinase introduced distally of the occlusion.

[30] Reference is mow made to figure 1a illustrating an out-of-scale manner a schematic view of the device as provided by the present invention. As can be seen from the figure, the device comprises a rotatable spring-like helical member 2101 and a tubular mesh-like net 1100.

[31] Figures 1b-1d presenting in an out-of-scale manner a schematic view (cross section) of the rotatable spring-like helical member 2101 used in the minimally invasive embolectomy device according to one embodiment of the invention (the tubular mesh-like net will be described in figures 2).

[32] The device, according to one embodiment, comprises a rotatable spring-like helical member, adapted to grasp and separate the clot from the artery wall and extracts it from outside of the artery. The helical member comprises a plurality of loops which are positioned at an angle *A* relatively to the main longitudinal axis of said blood vessel. It is acknowledged that angle *A* ranges from about 0 degrees to about 180 degrees, namely 90 to 180 degrees.

[33] Said grasping and separating is performed by spiral-like encircling (i.e., enveloping, without crossing) of at least a portion of the outer circumference of the clot by the plurality of loops. The encircling is performed without intersecting or crossing the clot; and by manipulating the clot reciprocally and/or rotationally with respect to the main longitudinal axis.

[34] Such a feature of extracting a clot without crossing it is highly desired for enabling an extraction in an intact manner of the clot (i.e., extraction of the clot's entire mass; in a non fragmented manner).

[35] Crumbling of the clot may occur when the clot is crossed (i.e., intersected), and fragments can be left within the blood vessel.

[36] The device additionally comprises a tubular mesh-like net (as illustrated in the following figures, namely figure 2) for both enveloping the helical member and enclosing the clot therein. The mesh-like net enables extraction of the entire clot mass during the extraction in a non fragmented manner, such that reentry of clot mass or fragments thereof into said blood vessel is prevented.

[37] The mesh-like net (as will be described hereinafter) may have several features, e.g., mechanical, chemical, thermal, etc., allowing it to engage a clot or embolism. The mesh-like net may also be in communication with a vacuum source allowing enhanced grasp of the clot or embolism for removal or other treatment. The mesh-like net may be used with a guidewire to direct the catheter to the site of the clot or clot.

[38] In light of that, the shaft of the mesh-like net is hollow so as to enable introduction of wires.

[39] According to some embodiments, the spring-like helical member may include one or more distally located, protrusions for assisting in the separation of the clot or embolism from the wall of the artery.

[40] According to other embodiment, the spring-like helical member and/or the mesh-like net may comprise means for applying vibration on the clot so as to facilitate its extraction.

[41] As a matter of practical experience, a large proportion of emboli sloughed into the brain are seldom longer than about 1.5 centimeters and, for a variety of reasons both physiological and hemodynamic, often settle in the middle cerebral artery (MCA). The path from the site of origin of a traveling clot --often the heart-- to the MCA is via the common carotid artery past the branch point forming the external and internal carotid arteries into the internal carotid artery (ICA). The MCA is generally considered to be the continuation and termination of the ICA past the siphon and pat the branching of a variety of other arteries, e.g., the ophthalmic artery, the anterior communicating artery, , and others.

[42] The etiology of such an occlusion is varied, varying, and complicated. Treatments for such embolic occlusions include catheterization of the patient and introduction of tissue plasminogen activator (t-PA), urokinase, or streptokinase to the site of the occlusion. Additionally the embolic occlusion may be penetrated or crossed.

[43] As described above, the device of the present invention is intended to be used in removing clots or at least recanalizing (at least partially) occluded vascular lumen.

[44] Reference is made again to figure 1b presenting in an out-of-scale manner a schematic view (cross section) of a minimally invasive embolectomy device according to one embodiment of the invention.

[45] We will first illustrate the grasping of the clot by means of the wire having a plurality of loops and then the extraction of the grasped clot by the mesh-like net.

[46] As described above, the device is designed to extract clot (1010) found in the human vasculature (1020), particularly in the distal, tortuous neurovasculature with a low or minimized pulling or extractive force outside the body of the patient.

[47] The device comprises an endless wire (116) having a distal end (2102). The distal end comprising a spring-like helical member (2101) for capturing the clot (1010). The helical

member comprising a plurality of loops (2201) positioned at an angle *A* relatively to the main longitudinal axis (as illustrated in the figure as B) of the blood vessel (1020).

[48] The loops radially encircling at least a portion of the outer circumference of the clot (1010). It is acknowledged that angle *A* ranges from about 0 degrees to about 180 degrees, namely 90 to 180 degrees.

[49] It should be emphasized that the plurality of loops (2201) effectively separates the clot from its outer surface *without* crossing the clot.

[50] Hence, the loops are configured to (i) spirally encircle (e.g., envelope) the clot without intersecting and crossing the clot; and, (ii) manipulate said clot reciprocally and/or rotationally with respect to the main longitudinal axis of the clot; such that its separation from the internal wall of the vessel is facilitated.

[51] The loops warp the outer circumference of the clot, and apply a preset and well directed force, to grasp the clot in a vector which is approximately parallel to its main longitudinal axis, namely a force applied from and towards the clot's distal and/or proximal poles.

[52] Reference is thus made to figure 1c which illustrates the manipulation that can be exerted on the clot by the loops. The endless wire, as described above, is characterized by a distal spool (spring-like) portion. By applying rotational maneuvers and/or linear reciprocating movement (1031 and 1041, respectively), clot 1010 reciprocated and/or circularly actuateed (1040 and 1030, respectively), until it is separated from vascular wall 1020.

[53] Consequently, as illustrated in figure 1d, working wire is pulling the clot into a standard catheter, which in return extracts it from outside of the body.

[54] As mentioned above, the loops are positioned at an angle *A* relatively to the main longitudinal axis of the blood vessel (1020) and angle A ranges from about 0 degrees to about 180 degrees, namely 90 to 180 degrees.

[55] Figures 1e-1h illustrate a clot encircled by said plurality of loops at different angles.

[56] According to one embodiment, the coil tips that can be utilized is selected from a group consisting of a loop at the end, a bulge or any combination thereof.

[57] As described above, the device also comprises a tubular mesh-like net which is an essential member of the device. The mesh-like net will be described hereinafter.

[58] Reference is now made to figure 2a which illustrates the tubular mesh-like net 1100.

[59] According to one embodiment of the present invention, once the clot (1010) has been separated from the vascular wall and encircled by the loops, it is inserted within the tubular mesh-like net (1100) via its distal inlet (1101), as see figure 2a. therefore, the clot is first confined by the loops and only then encircled by the mesh-like tubular net.

[60] According to another embodiment, the clot is simultaneously encircled by the loops and entrapped by the mesh-like net, according to yet another embodiment, the clot is first entrapped by the mesh-like net and only then it is encircled by the loops.

[61] In each of the above described embodiments the device is adapted to ***(i)*** reversibly envelope and grasp clot (1010) (via the loops and the mesh-like net) and, in doing so, separates the clot from the vascular wall; and then, ***(ii)*** when clot (1010) is secured within mesh-like net (1100) and the loops, extracting the enveloped clot form within the body outside the body.

[62] Hence, the device is useful to (i) free the clot from its surrounding vascular wall by applying reciprocal/rotational maneuvers; (ii) enforce the clot towards the mesh-like net's distal inlet in a safe manner, i.e., in a way the clot does not break to small pieces and does not escape, i.e., as a whole; and (iii), position the clot, as is, within the mesh-like net in a safe manner, i.e., in a way in which the clot does not disengage to small pieces and does not escape, as a whole, downstream away from the mesh-like net.

[63] It is emphasized that when the clot is contemporaneously confined within the loops and the mesh-like net, radial compression forces and longitudinal shearing forces are exerted on the clot, such that the tendency of said clot to fragment mitigates.

[64] Reference is now made to figure 2b illustrating different embodiments of the mesh-like net. According to one embodiment of the invention, the distal inlet of the mesh-like net (1101) is a constricting sphincter-like orifice. The diameter of orifice is regulated, e.g., by means of operating wires 1011 and 1012, by electrical charge (in case of Nitinol made sphincters) by electro-active polymers, by temperature (e.g., heat in case of Nitinol made sphincters) etc.

[65] By pulling wires 1011 and 1012, or by activating the distal portion of the mesh-like net 1010, the diameter of the orifice is reduced, e.g., from open configuration 1013 to semi close configuration 1014 (see figure 2c), or to a totally close configuration (not shown here).

[66] According to another embodiment of the invention, all operating wires are pulled (1050) and clasped clot 1500, now free from its native vascular wall 1020 is pulled via predetermined track 1021 outside of the patent body (see figure 2d).

[67] Reference is now made to figure 2e illustrating the key innovation of the present invention. According to the present invention, two combined forces are applied on said clot once said clot is contemporaneous confined within the loops and the mesh-like net:

[68] (a) radial compression forces applied by the mesh-like net 3001; and,

[69] (b) longitudinal shearing forces applied by the loops 3002. As described above, the loops warp the outer circumference of the clot, and apply a preset and well directed force, to grasp the clot in a vector which is approximately parallel to its main longitudinal axis, namely a force applied from and towards the clot's distal and/or proximal poles.

[70] The combination of said two forces exerted on the clot mitigates tendency of the clot to fragment, such that it can be extracted from the blood vessel wholly (i.e., its entire mass is extracted).

[71] It should be emphasized that the force is applied locally, i.e., no stress is applied on adjunctive vessels.

[72] When one pulls or compress an object, a plurality of tearing points will be created within said object. The main feature of the present invention lies in the fact that the combination of the two forces mitigates any tearing that might occur as a result of massive compression or pulling forces.

[73] It is according to yet another embodiment of the invention wherein an inner-coil assembly is utilized.

[74] Reference is now made to figure 3a, in which the device additionally comprising a corkscrew-like effecter 118, having a coil-like 2002 distal end, adapted to effectively anchor the clot from its inner portion, and an endless wire 2001 which terminates in a operating portion 2003 of the effecter, locate in the very proximal end, namely outside the body of the patient.

[75] It is in the scope of the invention wherein the corkscrew-like effecter is utilized either with or without the rotatable spring-like helical effecter.

[76] It is acknowledge that sequence of grabbing and extracting the clot via the mesh-like net, the loops (of the spring-like helical member), and the corkscrew-like effecter can be varied.

[77] According to another embodiment of the present invention each of the above described loops can additionally comprise vibration means can be utilized to assist in removing the clot from the vascular wall.

[78] According to another embodiment, aspiration can be applied to assist in the separation and extraction of the clot from the vessel.

[79] According to another embodiment, the endless wire and/or the spring-like helical member and/or the mesh-like net are coated with lubricious polymeric material such as a hydrophilic polymer material, e.g., one containing polyvinylpyrrolidone.

[80] According to another embodiment, the endless wire and/or the spring-like helical member and/or the mesh-like net may have multiple polymeric layers and include woven braids, flat ribbon coils, or wire coils between those layers to provide stiffness, kink resistance, etc.

[81] According to another embodiment, the endless wire and/or the spring-like helical member and/or the mesh-like net are characterized by a varied diameter so as to better fit the clot.

[82] According to another embodiment, the endless wire and/or the spring-like helical member and/or the mesh-like net are characterized by several different diameters along its length so as to better fit the clot

[83] Reference is now made to figures 4a-4c illustrating the wire and loops integrated with the tubular mesh-like net (see figure 4a); solely the wire and loops (see figure 4b); and, solely the tubular mesh-like net (see figure 4c).

[84] It is acknowledge that there are numerous operating modes of the device:

[85] **<u>First mode</u>**

[86] (a) the clot is approximated by the integrated spring-like helical member and mesh-like net;

[87] (b) the spring-like helical member protrudes out of the distal end of the device;

[88] (c) the spring-like helical member is rotated such that at least a portion of the outer circumference of the clot is encircled by the plurality of loops and confined within the same;

[89] (d)the spring-like helical member confining at least a portion of the clot is pulled and inserted into the tubular mesh-like net; and,

[90] (e) the mesh-like net is extracted from the blood vessel in a non fragmented manner (i.e., the entire mass of the clot is extracted);

[91] (f) the device together with the clot are removed from the body.

[92] **<u>Second mode</u>**

[93] (a) the clot is approximated by the integrated spring-like helical member and tubular mesh-like net;

[94] (b) the spring-like helical member is rotated to approximate the clot whilst simultaneously the tubular mesh-like net approximates the same;

[95] (c) as a result of such rotation, at least a portion of the outer circumference of the clot is encircled by the plurality of loops and confined within the loops and the mesh-like net; and,

[96] (d) the mesh-like net confining the loops (which encircles the clot) is extracted from the blood vessel in a non fragmented manner (i.e., the entire mass of the clot is extracted).

[97] Third mode

[98] (a) the clot is approximated by the integrated spring-like helical member and mesh-like net;

[99] (b) the tubular mesh-like net protrudes out of the distal end of the device and enclose the clot;

[100] (c) the spring-like helical member protrudes out of the distal end of the device;

[101] (d) the spring-like helical member is rotated such that at least a portion of the outer circumference of the clot is encircled by the plurality of loops and confined within the same; and,

[102] (e) the mesh-like net is extracted from the blood vessel in a non fragmented manner (i.e., the entire mass of the clot is extracted).

[103] Additionally, as described above, the clot can be crossed via the corkscrew-like effecter 118.

[104] Reference is now made to another embodiment of the present invention, according to which the device additionally comprising between two opposing, multi-element collection assemblies, i.e., distal clasp and proximal clasp. The two clasps combined with the spring-like helical member will extract the clot with a low or minimized pulling or extractive force in an intact manner (i.e., the entire clot is extracted from the body).

[105] Reference is now made to figures 5a-5k illustrating said embodiment combining a distal and proximal clasp together with the spring-like helical member.

[106] Figure 5a illustrates the spring-like helical member (2101) and the plurality of loops (2201), which are positioned at an angle *A* relatively to the main longitudinal axis of the blood vessel 1020. It is acknowledged that angle *A* ranges from about 0 degrees to about 180 degrees.

[107] The combined device is adapted to ***(i)*** reversibly grasp a clot (1010) between two opposing, multi-element collection assemblies, i.e., distal clasp (1300) and proximal clasp (1400) and, confined within the plurality of loops. In doing so, the clot is separated from the vascular wall. The device is also adapted to ***(ii)*** insert the clot (1010) within of mesh-like net (1100, see figure 5b) via it's the distal inlet (1101); and then,***(iii),*** when clot (1010) is secured within mesh-like net (1100), extracting enveloped clot form within the body.

[108] The following disclosure discloses the operation of the clasps. It should be emphasized that the claps can be activated prior to, during or after the clot has been grasped by the spring-like helical member (2101).

[109] The following figures demonstrate the activation of the claps after the clot has been encapsulated via the loops (2201) of the spring-like helical member (2101). However, as mentioned above the clot can be grasped by the claps prior to or simultaneously being encapsulated by the loops.

[110] Figure 5b illustrates a clot (1010) in an occluded vascular lumen (1020). A mesh-like net-like graft (1100) is inserted within lumen (1020), e.g., in a percutaneous manner, such that its distal end is located adjacent the clot. Guidewire 1200, operated from its proximal portion (1201), is inserted through the mesh-like net (1100) and manipulated to cross the clot, e.g., by means of an effecter 1210 located in its very distal end. The effecter is selected, in a non-limiting manner, from a group consisting of a coil-like, screw-like or drill-like head, reciprocally and/or rotatably operated in one or by a sequence of maneuvers.

[111] According to one possible embodiment of the invention, a small-diameter bore (1013) is provided within clot (1010). According to yet another embodiment, guidewire (1200) crosses the clot without forming a noticeable bore.

[112] Figure 5c illustrates yet another embodiment of the invention, wherein distal clasp (1300) is reversibly folded to a thin arrow-like member, crossing the clot by means of a guidewire. According to this embodiment, distal clasp (1300) has a FOLDED-configuration, e.g., an arrow-like spiral wound or otherwise collapsed member of a respectively thin cross section and narrow circumference; and an OPEN-configuration, e.g., a canopy, cymbal or mesh-like net-like member of a wider cross section and longer circumference. The endless guidewire 1013 is operated in its proximal portion (1320) outside the body of patient, and exceeds to the clot's distal end (1310).

[113] Figure 5d illustrates the distal clasp (1300) in its OPEN configuration. The diameter of the clasp, in this illustration, is adapted to fit in size and shape the inner diameter of the blood vessel 1020. Figure 5e illustrates both distal clasp (1300) and proximal clasp (1400) in their OPEN configuration. Distal clasp and proximal clasp are manipulated by means of at least one operating wires 1310 and 1410, respectively.

[114] Figure 5f illustrates a possible mode of action of the device especially adapted to ***(i)*** reversibly grasp clot (1010) between the two opposing distal clasp (1300) and proximal clasp (1400) and confined within the loops of the spring-like helical member.

[115] One or both of the clasps are manipulated, e.g., either linearly (1041) or rotatably (1031) by means of operating wires in, e.g., ***(i)*** a single reciprocal stroke along the long longitudinal axis of the blood vessel, wherein clot is maneuvered in a reciprocate facilitated motion (1040); ***(ii)*** a set of reciprocal motions, for example in-and-out opposite motions, a vibrating set of reciprocal motions, etc.; ***(iii)*** a single rotating stroke around the long longitudinal axis of the blood vessel, wherein clot is maneuvered in a circle facilitated motion (1030); ***(iv)*** a set of rotational motions, for example circular opposite motions, a vibrating set of circular motions, etc.; and ***(v)***any combination of the same. By those maneuvers, the clot is separated from the vascular wall 1020.

[116] Figure 5g illustrates the step wherein clot (1010) which was separated from the vascular wall is inserted within mesh-like net (1100) via its distal inlet (1101), by pulling distal clasp (1300) inside the mesh-like net.

[117] Figures 5h and 5i illustrate each a secured physical conjugate of an enveloping mesh-like net 1100, containing distal and proximal clasps (1300 and 1400, respectively) and the loops of the spring-like helical member that immobilize clot 1010 within the structure.

[118] According to annother embodiment of the invention, distal inlet of the mesh-like net (1101) is a constricting sphincter-like orifice. The diameter of orifice is regulated, e.g., by means of operating wires 1011 and 1012, by electrical charge (in case of Nitinol made sphincters) by electro-active polymers etc. By pulling wires 1011 and 1012, or by activating the distal portion of the mesh-like net 1010, the diameter of the orifice is reduced, e.g., from open configuration 1013 to semi close configuration 1014, or to a totally close configuration (not shown here).

[119] Figure 5j illustrates the last step, in which the enveloped clot (see conjugate 1500) is safely extracted form within the body outside the body. According to another embodiment of the

invention, all operating wires are pulled (1050) and clasped clot 1500, now free from its native vascular wall 1020 is pulled via predetermined track 1021 outside of the patient's body.

[120] It is according to yet another embodiment of the invention wherein an inner-coil assembly is utilized. Reference is now made to figure 5k, presenting a corkscrew-like effecter (as described above), having a coil-like distal end (5002), adapted to effectively anchor the clot from its inner portion, and an endless wire (5001) which is terminated in a operating portion of the effecter, locate in the very proximal end (5003), namely outside the body of the patient.

[121] It is acknowledged in this respect that distal and proximal clasps as defined in any of the above are provided useful to effectively clasp a clot from its both distal and proximal surfaces in an opposite cymbal-stroking coordinated manner and thus to *(i)* free the clot from its surrounding vascular wall by applying reciprocal/rotational maneuvers; *(ii)* enforce the clot towards the mesh-like net's distal inlet in a safe manner, i.e., in a way the clot does not disengage to small pieces and does not escape, as a whole, downstream away from the mesh-like net; and *(iii)*, positioned the clot, as is, within the mesh-like net and providing a proximal-distal structural clot-grasping element in a safe manner, i.e., in a way the clot does not disengage to small pieces and does not escape, as a whole, downstream away from the mesh-like net.

[122] The claps combined with the plurality of loops of the spring-like helical member further provide a better grasping of the clot so as to provide a full extraction.

[123] It is acknowledged that each and both the corkscrew-like effecter implanted within the clot, and the spring-like helical member warping the outer circumference of the same, are adapted to apply a preset and well directed force, and to grasp the clot in a vector which is approximately parallel to its main longitudinal axis, namely a force applied from and towards the clot's distal and/or proximal poles. Hence, both internal and external coils are provided useful to (i) free the clot from its surrounding vascular wall by applying reciprocal/rotational maneuvers; (ii) enforce the clot towards the mesh-like net's distal inlet in a safe manner, i.e., in a way the clot does not disengage to small pieces and does not escape, as a whole, downstream away from the mesh-like net; and (iii), positioned the clot, as is, within the mesh-like net and providing a proximal-distal structural clot-grasping element in a safe manner, i.e., in a way the clot does not disengage to small pieces and does not escape, as a whole, downstream away from the mesh-like net.

[124] It should be emphasized that the combined device (i.e., containing both the spring-like helical member having a plurality of loops and the distal and proximal claps) may operate by different modes of operations (i) first encircling the clot by the loops and mesh-like net; then grasping the same by the claps; (ii) first grasping the clot by the claps and then encircling the same via the loops and mesh-like net; or, (iii) simultaneously grasping the clot by the claps and encircling the same via the loops and mesh-like net.

[125] It should be pointed out that both the spring-like helical member (and hence the loops) and the tubular mesh-like net are characterized by elastic mechanical properties which enables them to contract and hence to apply pressure on the clot.

[126] According to another embodiment of the present invention, an especially dedicated catheter is provided. Said dedicated catheter which will be discussed hereinafter. This catheter system comprises several important sections that may be used cooperatively together with the above mentioned tubular mesh-like net and/or the above mentioned spring-like helical member. Alternatively it may be provided as a stand alone device.

[127] Reference is now made to figure 6 illustrating an intravascular catheter (102) that may have the distal clot-engaging features.

[128] Also shown in the figure a guidewire (114) that may be used to direct the intravascular catheter (102) to the target site. Typically, such an intravascular catheter (102), when used in the neurovasculature, is a microcatheter that may be made up of a number of sections (104, 106, 108, 110) of different flexibilities.

[129] The more-distal sections are typically more flexible and often have decreasing diameters. The most distal section (110) of a suitable microcatheter may be, for instance, 2.0-5.0F, 2.5-3.5F. The distal end of the catheter (102) often includes a radio-opaque marker (112).

[130] The catheters may be produced from a variety of materials. Catheters produced by integrating layers of different compositions to achieve specific results are also well known. For instance, providing a thin inner layer of a lubricious polymer (including fluoropolymers such as polytetrafluoroethylene (PTFE or TFE), ethylene-chlorofluoroethylene (ECTFE), fluorinated ethylene propylene (FEP), polychlorotrifluoroethylene (PCTFE), polyvinylfluoride (PVF), or polyvinylidenefluoride (PVDF)) to allow easy movement of guidewires is appropriate. Other appropriate inner liner materials include polyethylene, polypropylene, polyvinyl chloride (PVC), ethyl vinyl acetate (EVA), polyurethanes, polyamides, polyethylene terephthalate (PET), and their mixtures and copolymers. Outer coverings of polyethylene or of EVA or

their mixtures, copolymers, etc. or thermoplastic elastomers, including those containing polyesters as components, such as HYTREL are useful.

[131] A variety of other polymers may be used, depending upon the use to which the catheter section is placed. For instance, if the section is a proximal section, stiffer polymers such as polyimides, polyamides (such as the Nylons), high density polyethylene (HDPE), polypropylene, polyvinylchloride, various fluorocarbon polymers (for instance: PTFE, FEP, vinylidene fluoride, their mixtures, alloys, copolymers, block copolymers, etc.), polysulfones, or the like, are appropriate. Blends, alloys, mixtures, copolymers and block copolymers of these materials are also suitable if desired.

[132] If a more flexible section is required, those sections may comprise a more flexible material such as polyurethanes, low density polyethylene (LDPE), polyvinylchloride, THV, etc. and other polymers of suitable softness or a modulus of elasticity.

[133] Each of the polymers noted herein may be used in conjunction with radio-opaque filler materials such as barium sulfate, bismuth trioxide, bismuth carbonate, powdered tungsten, powdered tantalum, or the like so that the location of various portions of the catheter sections may be radiographically visualized within the human body.

[134] The catheters may have multiple polymeric layers and include woven braids, flat ribbon coils, or wire coils between those layers to provide stiffness, kink resistance, etc.

[135] The catheter may be covered or coated with a lubricious polymeric material such as a hydrophilic polymer material, e.g., one containing polyvinylpyrrolidone.

[136] An endless wire (116) is coupled to a spring-like helical member having a plurality of loops is used.

[137] A suitable guidewire (114) may be used to deliver the distal end of the catheter (102) to a site proximate to the clot. If the endless wire (116) is not used, the guidewire (114) is then removed from the catheter (102) and the vacuum source (118) attached to aspirate the clot.

[138] The endless wire (116) may be used with intravascular catheter (102) having distal features for engaging a clot or a catheter not having those features.

[139] In any case, the spring-like helical member, namely the loops, of the endless wire (116) may be inserted in the catheter and rotated to draw the clot inside the catheter.

[140] Figure 7A shows a close-up, side-view of the distal end (130) of one variation of the catheter (102). A radio-opaque marker band (132) is also shown.

[141] Reference is now made to figure 7B illustrating another embodiment, according to which, a set of hooks (134) are extended from the distal end of the catheter when its in a position adjacent a clot. Said hooks are provided in order to engage with the clot, e.g., by penetrating the clot and hence alleviate its release from the vessel.

[142] It should be mentioned that a vacuum may be applied through the catheter lumen.

[143] Figure 7C shows a perspective view of the distal end (130) showing the hooks (134). In this view, all the hooks (134) rotate in the same direction as they extend from that distal end. The direction of the extended hooks (134) may be varied to enhance the strength of the clot's grasping.

[144] Figure 8A shows a close-up, side-view of the distal end (140) of another variation of the catheter component (102). A radio-opaque marker band (132) is also shown. When this variation is introduced to a position adjacent to the clot, a set of pins (142) is extended from that distal end (see Figure 8B) to engage the clot, e.g., by penetrating the clot.

[145] It should be mentioned that a vacuum may be applied through the catheter lumen for facilitating the extraction of the clot.

[146] Reference is now made to figures 9A and 9B illustrating the distal end of a catheter having a collapsible structure that collapses upon imposition of a vacuum and extends hooks (134 in Figure 8B) or pins (142 in Figure 8B) into a clot.

[147] Figure 9A shows a close-up, cross-sectional, side-view of the distal end of the catheter component (150). The catheter body (152) extends proximally (as shown in Figure 6). A movable distal ring (154) is separated from the catheter body (152) by a collapsible bellows (156). The bellows (156) are shown in the "at rest" (fig. 9B) or extended position (fig. 9A). After the catheter contacts the clot, the catheter lumen is essentially sealed. Subsequent imposition of a vacuum upon that catheter lumen causes (i) the bellows (152) to collapse; (ii) the distal ring (154) to slide proximally, and the pins (158) to extend distally into the clot.

[148] Figure 9B shows the bellows (152) in a collapse condition and the pins (158) extending through the distal ring (154) into the clot.

[149] As a matter of general design criteria, the bellows (156) should be sufficiently stiff so that during passage of the catheter tip to the clot site (and the inevitable contact of that tip with the catheter walls), the bellows (156) will not collapse allowing extension of the pins (158) during that transit. Conversely, the bellows (156) should be just stiff enough that when the distal end

of the catheter contacts the clot and a vacuum applied to the catheter lumen (159), the bellows (156) will collapse.

[150] According to an embodiment of the present invention, the combination of the catheter, as any of the described above, utilizing the endless wire having a spring-like helical member which comprises a plurality of loops (see figure 10A, which illustrated the loops extending from the catheter body) is provided.

[151] Reference is now made to figure 11A illustrating another embodiment of the catheter as provided by the present invention. In said embodiment, the active clot's engaging feature is a reactive or adhesive region (172) that adheres to a targeted clot upon contact with that clot.

[152] Figures 11B and 11C show the combination of the catheter shown in Figure 11A with an exterior slideable sleeve (174) that, in Figure 11B, is extended to protect the reactive or adhesive region (172) as the catheter passes to the target clot. Figure 11C shows the sleeve (174) after retraction to expose the reactive or adhesive region (172).

[153] The catheter (180) shown in Figure 12 includes a nosepiece (182) containing a heating element that either directly heats the clot upon contact with the clot or activates a grasping end on the catheter upon heating.

[154] Figure 13 illustrates a partial, cross-sectional, side-view of the distal tip (182) of the catheter component (180) shown in Figure 12. The heating element (184) in this variation is placed distally to provide maximum heat transfer to the clot. Electrical current is supplied through wire (186).

[155] Figures 14A and 14B illustrate a variation of the catheter component (180) found in Figure 12 having a heat-actuated region that shrinks upon that heating to grasp the clot.

[156] Figure 14A provides a partial cross-sectional view of the distal tip of the variation shown in Figure 12. The catheter body (186) comprises a distal tip (188) having a heat-shrinkable polymer, e.g., pre-oriented polyolefin, polyvinylchloride (PVC), fluoropolymers such as FEP, PTFE, polyvinylidene fluoride (e.g., KYNAR), neoprene, silicone elastomers, and fluorocarbon elastomers (e.g., VITON, FLUOREL). The distal tip (188) contains one or more heating elements (190) which, when heated, cause that distal tip (188) to shrink and grasp the clot and perhaps shrink the clot itself. In Figure 14B, the distal tip (188) has shrunk to provide a smaller opening.

[157] Figure 15 schematically shows a typical procedure for using one of the different variations of the catheter as described above (i.e., the extending pins) in order to remove a clot (200) from an artery (202).

[158] In step (a), the distal end of a microcatheter (204) has been placed in the vicinity of the target clot (200) using a guidewire (206).

[159] In step (b), the microcatheter (204) has approached the clot (200). The guidewire (206) that was used to direct that microcatheter (204) has been withdrawn.

[160] In step (c), the microcatheter (204) has contacted the clot (200). A clot engaging component -- in this example: extending pins (210) -- has been extended into the clot and the catheter (204) connected to a vacuum source to secure the catheter (204) to the clot (200).

[161] In step (d), the catheter (204) is being withdrawn along with the clot (200).

[162] Figures 16A to 17C illustrate the use the embolectomy device, namely the endless wire with the spring-like helical member and the plurality of loops, in removing a clot.

[163] As described above, endless wire 116 may be used with one of the specially dedicated catheter described above or any other standard catheter.

[164] In figures 16A-17C the endless wire is illustrated with a more standard intravascular catheters. As described above, the wire is designed to draw clot into the distal end of such catheters. The user may select the catheter's diameter suitable for the target clot and the surrounding artery.

[165] Figure 16A1 provides a partial, cutaway, side-view of the loops of the spring-like helical member (300) (of the endless wire) having a rotating helix (302) within a catheter body (304). The depicted helix (302) is shown as a ribbon; it may be constructed by cutting an appropriately sized hypotube into a helix or by winding a ribbon into the noted helix (302).

[166] The width of the ribbon or thread may be constant or varying over the length of the helix. The helix (302) may have a constant pitch or a varying one. The helix (302) may be a single, double, or triple pitch.

[167] The helix extends from the distal end proximally for at least a portion of the distance to a drive assembly that rotates the helix (302).

[168] The helix (302) may have an extension (306) that, as the helix (302) is rotated, separates a target clot from an arterial wall and transports the clot into the mesh-like net as described above (not shown)and eventually through the catheter lumen (or).

[169] An optional guide wire or core wire (308) (also denoted above as the corkscrew-like effecter 2002), that may be used to provide rotational or axial stability (see figure 16A2). The core wire (308) may be extended distally from the catheter body (304) into the body of a target embolism (or along the clot's periphery along the arterial wall) and, in many instances, provides a predictable center of rotation for the rotating helix.

[170] The core wire can be used as a screw penetrating internally into the clot (unlike the loops of the endless wire described above which merely encircles the clot).

[171] As described above, the clot can be initially encircled by the loops of the spring-like helical member, then by the net and only then be crossed by the core wire (308). Alternatively, the clot can be initially encircled by the net, then by the loops of the spring-like helical member, and only then be crossed by the core wire (308). Alternatively, the clot can be initially encircled simultaneously by both the net and by the loops of the spring-like helical member, and only then be crossed by the core wire (308).

[172] Finally, Figures 16A1 and 16A2 illustrate an optional outer sheath (310) fitting loosely about catheter body (304) that allows the user to inject medicines or contrast agents at the clot site.

[173] It should be emphasized that the rotatable spring-like helical effecter may be operated with or without the core wire (308).

[174] A variation of this component involves affixing the rotatable spring-like helical effecter (302) to the core wire (308) at one or more sites and rotating the two together.

[175] Typically, the catheter body (304) lumen will be attached to a vacuum source, although this is not required.

[176] Figure 16B illustrates a side view of the extension (306) located on the spring-like helical member (of the endless wire)within a catheter body (304).

[177] Figure 16C illustrates another embodiment (305) of the endless wire and namely, the spring-like helical member.

[178] According to this embodiment, the depicted rotating helix assembly (305) comprises a distal ribbon-form helix (307) and a hollow more-proximal drive shaft (309). The drive shaft (309) is shown to have a number of flexibility slots (311) allowing the shaft (309) to smoothly flex

during rotation of the rotating helix assembly (305) and to flex with greater bend angles. The ribbon-form helix (307) is attached to the drive shaft (309) by an appropriate joining method, e.g., welding, soldering, gluing, etc. The helix (307) and the drive shaft (309) may comprise the same materials of construction, e.g., metallic materials such as stainless steels or superelastic alloys such as nitinol and polymeric materials such as PEEK or a Nylon, or may be different.

[179] The length of the ribbon-form helix (307) may be reasonably short, e.g., less than about 2-3 inches. Longer helix components may bind during rotation.

[180] Figures 17A and 17B illustrate another embodiment (310) of the endless wire substantially similar to the variation shown in Figures 16A and 16B, with the exception of the shape of the rotating helix (312) which is a wire and that the wire-form rotating helix (312) is wrapped around a central core wire (314).

[181] The wire-form rotating helix (312) and the central core wire (314) in this variation may rotate together, although this is not a requirement.

[182] The wire-form rotating helix (312) may have a diameter such as seen with the ribbon-form rotating helix (302) shown in Figure 16A. Additionally the wire-form rotating helix (312) may be utilized without the central core wire (314).

[183] The wire comprising the wire-form rotating helix (312) may have a circular cross-section or other cross sections suitable to the designer, e.g., oval or fin-like projections, to enhance carriage of the embolic fragments through the catheter body (306). The cross-section of that wire may be constant or vary as desired by the designer.

[184] Figure 17C is a side view of another embodiment (315) of the endless wire. According to this embodiment, the endless wire (315) comprises a distal wire-form helix (317) and a hollow more-proximal drive shaft (319). The drive shaft (319) is also shown to have a number of flexibility slots (321). The wire-form helix (317) is attached to the drive shaft (319) by an appropriate joining method.

[185] Figures 18A-18C show a variation of the rotating element in a catheter tip designed to extract a clot into the catheter in a substantially complete and whole form rather than macerating it.

[186] Figure 18A provides an end view of the catheter (420) enclosing a rotating helical element (422) having an extended portion (424). Because the extended portion (424) has substantially

no radial component, it may be used to separate a target clot from the artery wall, particularly when used with vacuum in the catheter lumen and with a guidewire.

[187] Figure 18B shows a side-view of the catheter (420) and the tip or extension (424) of the rotating helical element. The distal most end of the extended portion (424) is blunt for the reasons of preventing damage to the intima of the artery and preventing penetration of the clot. The Figure also shows a radio-opaque band (426) allowing radiographic visualization of the position of that tip.

[188] Figure 19 illustrates a method for using the endless wire, as described above for extracting a clot.

[189] It is widely known that if a catheter is strongly attached to the clot and the clot is disengaged from the arterial wall, the clot may be safely and easily pulled from that vessel with minimum stress deflection to the wall. The pulling action helps reduce the friction between the clot and the vessel wall and can also help in removing the clot in one piece.

[190] In step (a) a clot (452) in an artery (450) is shown. A guidewire (454) has been introduced past the clot (452). A catheter (456) containing the endless wire and the plurality of loop (458) approaches the clot (452).

[191] The catheter (456) diameter has been chosen to approach the inner diameter of the artery (450).

[192] In step (b), the distal end of the catheter (456) has contacted the clot (452). A vacuum may be applied to the catheter's (456) lumen to firmly attach the catheter (456) to the clot (452). Rotation of the helix (458) via the hollow drive shaft (460) begins. Such rotation encircles the clot from the out surface. It should be emphasized that the loops of the endless wire does not cross the clot. Such an action may lead to crumbling of the clot.

[193] In step (c), the rotating helix (458) has disengaged the clot (452) from the arterial wall (450). Now the clot is being confined via the tubular mesh-like net (not shown in the figure). Finally clot (452) is being pulled into the catheter (456).

[194] In step (d), the catheter (456) with the included clot (452) is being pulled and extracted from the artery (450).

[195] It should be emphasized (as described above) that the clot can be encircled first by the net and then by the loops of the helical member (i.e., the helix); the clot can be first encircled by the

the loops of the helical member (i.e., the helix) and then by the net; or simultaneously by the net and the loops.

[196] Figure 20A illustrates yet another embodiment of device (460) having both an expandable, rotatable, helical member (462) and a micro-catheter (464) having a distal section that is expandable upon reaching a target clot. This embodiment also includes a central core member, a guidewire (468), and an outer covering or sheath (470) allowing control of the expansion of the catheter (464) tip. The guidewire (468) may be withdrawn before beginning the grasping of the clot.

[197] As noted above, the tip of the catheter (464) and the rotatable member (462) are expanded to a size approximating the inner diameter of the vessel in the region of the target clot to aid in the separation of the clot from the vessel wall. Such separation reduces the force needed to extract the clot from the vessel and also enhances the potential that the clot may be extracted from the vessel as a single, undivided mass.

[198] Figures 20B(1) and 20B(2) show two variations of the device (460) after expansion of the catheter (464) and the rotatable member (462).

[199] The more-proximal driving member (472) used to turn the rotatable member (462) is also visible in the Figures.

[200] Figure 20B(1) shows the variation in which the loops(462) of the spring-like helical member of the endless wire extend distally from the micro-catheter (464) when extracting the target clot. In operation, the rotating member (462) is turned using the driving member (472) and at least partially envelopes the target clot and subsequently or simultaneously enclosed by the mesh-like net and eventually drawn into the catheter (464) for extraction from the blood vessel.

[201] On the other hand, Figure 20B(2) shows a variation in which the loops(462) of the spring-like helical member is maintained substantially within the catheter (464) tip. In this variation, the clot is drawn into the catheter (464) tip rather than being pulled in later. As the rotating member (462) is turned, it encircles the clot and then the clot is being enclosed by the net (as mention above this operation mode is optionally).

[202] It should be emphasized that both the loops of the spring-like helix member and the mesh-like net can be characterized by a varied dimensions. Furthermore, the spring-like helix member may have a constant and/or a varying pitch.

[203] Figure 21 illustrates another embodiment of an expandable catheter tip (480) having pre-shaped, longitudinal ribs (482) that, upon withdrawal of the control sheath (470 in Figures 16A, 16B(1), and 16B(2)) form an expanded region in the catheter tip (480). Although the supporting ribs (482) may be springy, e.g., comprising an elastic material such as nitinol or the like, they may also be malleable and formed in-situ perhaps by the expandable rotatable member.

[204] Figure 22 provides a perspective, partial cutaway view of another variation of the device (490) shown in Figures 20A and 20B(2). The variation (490) includes the expanded micro-catheter (492), expanded rotatable member (494), guidewire (496), and control sheath (498). The driving member (500) for rotating the rotatable member (494) is also visible.

[205] In this variation and in the other variations of the rotating member shown here, the cross-section of the wire itself may have a variety of cross-sections, e.g., round, oval, square, rectangular, triangular, hollow, etc. and other irregular shapes.

[206] If hollow, the rotating member may be used to advance contrast material to its distal tip. The wire or ribbon making up the rotating member may be at least partially wound with a smaller wire to accomplish either or both of the goals of providing radio-opacity to at least a part of the rotating member -- by applying a radio-opaque wire comprising, e.g., platinum or gold -- or to enhance the resistance of the member to kinking.

[207] It should be emphasized that said embodiment (490) additionally comprises a tubular net (not shown in the figure) into which the clot is inserted. As described above, the net and/or the helix may have varying dimensions.

[208] Figures 23A and 23B illustrate, respectively, a collapsed catheter tip (510) having individual undulating rings (512 in Figure 23A) that expand, upon release, to form circular rings (514 in Figure 23B). Again, the rings (512, 514) may be formed of a springy material having a pre-formed shape or of a malleable material that is formed into rings in situ.

[209] Figure 24 illustrates another variation of a catheter tip (520) in which the structure used to expand and maintain the shape of the expanded catheter tip (520) comprises a stent-like structure (522). In this variation, the stent-like structure (522) is included within (or attached to) the catheter wall (524). The strength of the structure (522) need not, of course, be of that needed in stent service, since the strength needed to hold the catheter open is much less than that needed to maintain the patency of an artery. Said another way: the structure (522) is fully retractable.

[210] Figure 25 shows still another variation of a catheter tip assembly (530) in which the structure used to expand and maintain the shape of the expanded catheter tip (532) comprises a stent-like structure (534). In this variation, the stent-like structure (534) is bare but attached to the body of the catheter tip (530). Again, the structure (534) may be self-expanding or expanded using a balloon or the like. The structure may be coated with a lubricious coating, e.g., such as a polymer, to increase the ease with which the structure (534) moves between the embolism and the vessel wall during introduction.

[211] The stent-like structures (522, 534) may be of any convenient form such as shown in the Figures or may be of another similar shape having the functions described above. Braided wires or ribbons or laser cut tubes are also appropriate.

[212] Figure 26 illustrates a method for utilizing the embolectomy device.

[213] In step (a) of Figure 26 a clot (540) lodged in artery (542) is illustrated. The microcatheter (544) having an expandable distal end, an endless wire (not shown) coupled to a spring-like helical member having a plurality of loops (546), and a guidewire (548). A retractable sheath (550) for controlling and initiating expansion of, and for controlling the retraction of, the microcatheter (544) and the rotatable helical member (546), is also shown.

[214] Step (b) illustrates the extension of the microcatheter (544) from the sheath (550) and the self-expansion of the distal end of the microcatheter (544) and the rotating helix member (546). The expanded distal end of the microcatheter (544) has contacted the clot (540) and the rotation of the helical member (546) has provided progression of that helical member (546) partially around the exterior of the clot (540).

[215] As a practical matter, there are several ways that the helical member (546) may cooperate with the microcatheter (544) in enveloping the clot. First, the rotatable member (546) may move axially along the clot (540) and followed by a subsequent axial movement of the catheter (544). Second, the rotatable member (546) may be rotated, enveloping the clot (540), while the catheter (544) is held stationary, or at least not rotated. Third, the rotatable member (546) is rotated, enveloping the clot (540), and the catheter (544) is simultaneously rotated.

[216] Step (c) shows the retraction of the clot (540) into the catheter's (544) distal region or tip. In the effectuation of steps (a) and (b), the clot (540) has been separated from the wall of the artery (542) lessening the force needed to remove the clot (540). The catheter (544) is then withdrawn extracting the clot from the artery (542) and restoring blood flow to the artery (542).

[217] Alternatively, the clot is first encircle by said rotatable member (546) and then inserted into a tubular mesh-like net (not shown) which is then extracted from the artery (542). Yet alternatively, the clot is simultaneously encircle by said rotatable member (546) and the tubular mesh-like net; only then extracted from the body.

[218] In the foregoing description, embodiments of the invention, including preferred embodiments, have been presented for the purpose of illustration and description. They are not intended to be exhaustive or to limit the invention to the precise form disclosed. Obvious modifications or variations are possible in light of the above teachings. The embodiments were chosen and described to provide the best illustration of the principals of the invention and its practical application, and to enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the invention as determined by the appended claims when interpreted in accordance with the breadth they are fairly, legally, and equitably entitled.

CLAIMS

1. A device for extracting a clot from a blood vessel in a non fragmented manner, comprising:

   an endless wire coupled to a spring-like helical member having a plurality of loops; said loops are positioned at an angle *A* relatively to the main longitudinal axis of said blood vessel; and, are adapted to radially encircle at least a portion of the outer circumference of said clot; and,

   a tubular mesh-like net for both enveloping said helical member and enclosing said clot therein;

   wherein at least a portion of said clot is contemporaneously confined within said loops and said mesh-like net, such that radial compression forces and longitudinal shearing forces are exerted on said clot and the tendency of said clot to fragment is mitigated.

2. The embolectomy device of claim 1, wherein said spring-like helical member and/or said mesh-like net comprising means for applying vibration on said clot.

3. The embolectomy device of claim 1, wherein said mesh-like net is made of material selected from a group consisting of woven fabrics, non-woven fabrics, gauze-like fabrics, materials having multiple openings, and fluid-permeable membranes or any combination thereof.

4. The embolectomy device of claim 1, wherein said mesh-like net additionally comprising materials selected from a group consisting of woven fabrics, non-woven fabrics, gauze-like fabrics, materials having multiple openings, and fluid-permeable membranes or any combination thereof.

5. The embolectomy device of claim 1, wherein said spring-like helical member is coupled to said mesh-like net.

6. The embolectomy device of claim 1, wherein said distal portion of said mesh-like net is adapted to switch from an expended-configuration to a restricted-configuration; said expended-configuration is operative to allow insertion of at least a portion of a target clot in to said mesh-like net's distal portion; and said restricted configuration is operative to retain said clot within said mesh-like net.

7. The embolectomy device of claim 6, wherein said distal portion of said mesh-like net is operative to self-expand from its expended-configuration to its restricted-configuration.
8. The embolectomy device of claim 1, wherein said mesh-like net is an elongated sleeve comprising a restricting sphincter located at the distal end of said sleeve, adapted to retain at least a portion of the target clot within said mesh-like net.
9. The embolectomy device of claim 1, wherein said helical member is characterized by a cross-sectional area selected from a group consisting of circular, oval, round, square, rectangular, triangular, regular or irregular shapes, or any combination thereof.
10. The embolectomy device of claim 1, additionally comprising a motor adapted to rotate said helical member.
11. The embolectomy device of claim 1, wherein said helical member additionally comprising protrusions for assisting in the separation of said clot from said vasculature.
12. The embolectomy device of claim 1, additionally comprising vibration means applied on said clot.
13. The embolectomy device of claim 1, additionally comprising a corkscrew-like effecter, having a coil-like distal end, adapted to penetrate and cross said clot.
14. The embolectomy device of claim 1, wherein the diameter of said helical member is variable so as to better adjust to the diameter of said clot or said blood vessel.
15. The embolectomy device of claim 1, wherein said device additionally comprising:

    a proximal effecter characterized by a folded configuration and an open configuration;

    a distal effecter characterized by a folded configuration and an open configuration;

    said proximal effecter, in said open configuration is adapted for grasping a proximal portion of said clot; said proximal effecter, in said open configuration is adapted for grasping a distal portion of said clot;

    wherein both said effecters, when open, are oppositely positioned and are adapted to operate in concert, for trapping said clot such that said clot is (i) manipulatable along and/or around the main longitudinal axis of said blood vessel; and, (ii) extracted out of said blood vessel.
16. The embolectomy device of claim 15, wherein said distal effecter is operative to cross said clot in said FOLDED configuration and then to be expanded to an OPEN configuration.

17. The embolectomy device of claim 15, wherein said distal effecter is operative to self-expand from its FOLDED configuration to its OPEN configuration.
18. The embolectomy device of claim 15, wherein said distal effecter is incorporated or otherwise connected with said proximal effecter to form a single effecter.
19. The embolectomy device of claim 1, wherein said angle A ranges from about 0 degrees to about 180 degrees.
20. The embolectomy device of claim 1, additionally comprising aspiration means.
21. The embolectomy device of claim 1, wherein at least one of said loops and/or said mesh-like net is coated with lubricious polymeric material selected from hydrophilic polymer material.
22. The embolectomy device of claim 1, wherein said spring-like helical member is characterized by single, double, or triple pitch.
23. The embolectomy device of claim 1, wherein the cross section of at least one of said loops and/or said mesh-like net varies.
24. A method for removing a clot from blood vessel, comprising steps of:
    i. obtaining an embolectomy device comprising:
        a. an endless wire coupled to a spring-like helical member having a plurality of loops; said loops are positioned at an angle *A* relatively to the main longitudinal axis of said blood vessel;
        b. a tubular mesh-like net;
    ii. integrating said spring-like helical member with said tubular mesh-like net;
    iii. approximating said clot;
    iv. rotating said helical member;
    v. radially encircling at least a portion of the outer circumference of said clot by said plurality of loops;
    vi. entrapping said clot confined within said loops;
    vii. inserting said confined clot into said tubular mesh-like net;
    viii. extracting said clot confined within said loops and said mesh-like net from said blood vessel;

wherein said step of entrapping said clot confined within said loops by said tubular mesh-like net exerts radial compression forces and longitudinal shearing forces on said clot such that the tendency of said clot to fragment is mitigated.

25. The method according to claim 24, additionally comprising step of selecting the material of said mesh-like net from a group consisting of woven fabrics, non-woven fabrics, gauze-like fabrics, materials having multiple openings, and fluid-permeable membranes or any combination thereof.
26. The method according to claim 24, additionally comprising step of configuring the distal portion of said mesh-like net to switch from an expended-configuration to a restricted-configuration; said expended-configuration is operative to allow insertion of at least a portion of a target clot into said mesh-like net's distal portion; and said restricted configuration is operative to retain said clot within said mesh-like net.
27. The method according to claim 26, additionally comprising step of configuring said mesh-like net to self-expand from said expended-configuration to said restricted-configuration.
28. The method according to claim 26, additionally comprising step of retaining at least a portion of the target clot within said mesh-like net.
29. The method according to claim 24, additionally comprising step of applying vibration on said clot.
30. The method according to claim 24, additionally comprising step of grasping (i) the proximal portion of said clot via a proximal effecter characterized by a FOLDED configuration and an OPEN configuration; and, (ii) the distal portion of said clot via a distal effecter characterized by a FOLDED configuration and an OPEN configuration; such that said clot is, when grasped by said effecters in said open configuration, is manipulatable along and/or around the main longitudinal axis of said blood vessel.
31. The method of claim 30, additionally comprising steps of crossing said clot via said distal effecter in said FOLDED configuration; and, expanding to said OPEN configuration.
32. The method of claim 30, additionally comprising step of configuring said distal effecter to self-expand from its FOLDED configuration to its OPEN configuration.
33. The method of claim 30, additionally comprising step of incorporating said distal effecter with said proximal effecter to form a single effecter.

34. The method according to claim 24, additionally comprising step of selected the cross sectional area of said helical member from a group consisting of circular, oval, round, square, rectangular, triangular, regular or irregular shapes, or any combination thereof.
35. The method according to claim 24, additionally comprising step of adjusting the diameter of said loops to the diameter of said clot.
36. The method according to claim 24, additionally comprising step of penetrating and crossing said clot via a corkscrew-like effecter.
37. The method according to claim 24, additionally comprising step of selecting said angle A to be higher than about 0 degrees and lower than about 180 degrees.
38. The method according to claim 24, additionally comprising step of applying vibration on said clot.
39. The method according to claim 24, additionally comprising step of coating said loops and/or said mesh-like net with lubricious polymeric material selected from hydrophilic polymer material.
40. The method according to claim 24, additionally comprising step of coupling said spring-like helical member to said mesh-like net.
41. A method for removing a clot from blood vessel, comprising steps of:
    i. obtaining an embolectomy device comprising:
        a. an endless wire coupled to a spring-like helical member having a plurality of loops; said loops are positioned at an angle *A* relatively to the main longitudinal axis of said blood vessel;
        b. a tubular mesh-like net;
    ii. integrating said spring-like helical member with said tubular mesh-like net;
    iii. rotating said helical member to approximate said clot whilst simultaneously approximating said mesh-like net to said clot;
    iv. radially encircling at least a portion of the outer circumference of said clot by said plurality of loops whilst simultaneously entrapping said clot, confined within said loops, within said mesh-like net; and,
    v. extracting said mesh-like net from said blood vessel;

wherein said step of entrapping said clot confined within said loops by said tubular mesh-like net exerts radial compression forces and longitudinal shearing forces on said clot such that the tendency of said clot to fragment is mitigated.

42. The method according to claim 41, additionally comprising step of selecting the material of said mesh-like net from a group consisting of woven fabrics, non-woven fabrics, gauze-like fabrics, materials having multiple openings, and fluid-permeable membranes or any combination thereof.
43. The method according to claim 41, additionally comprising step of configuring the distal portion of said mesh-like net to switch from an expended-configuration to a restricted-configuration; said expended-configuration is operative to allow insertion of at least a portion of a target clot into said mesh-like net's distal portion; and said restricted configuration is operative to retain said clot within said mesh-like net.
44. The method according to claim 41, additionally comprising step of configuring said mesh-like net to self-expand from said expended-configuration to said restricted-configuration.
45. The method according to claim 41, additionally comprising step of retaining at least a portion of the target clot within said mesh-like net.
46. The method according to claim 41, additionally comprising step of applying vibration on said clot.
47. The method according to claim 41, additionally comprising step of grasping (i) the proximal portion of said clot via a proximal effecter characterized by a FOLDED configuration and an OPEN configuration; and, (ii) the distal portion of said clot via a distal effecter characterized by a FOLDED configuration and an OPEN configuration; such that said clot is, when grasped by said effecters in said open configuration, is manipulatable along and/or around the main longitudinal axis of said blood vessel.
48. The method of claim 47, additionally comprising steps of crossing said clot via said distal effecter in said FOLDED configuration; and, expanding to said OPEN configuration.
49. The method of claim 47, additionally comprising step of configuring said distal effecter to self-expand from its FOLDED configuration to its OPEN configuration.
50. The method of claim 47, additionally comprising step of incorporating said distal effecter with said proximal effecter to form a single effecter.

51. The method according to claim 41, additionally comprising step of selected the cross sectional area of said helical member from a group consisting of circular, oval, round, square, rectangular, triangular, regular or irregular shapes, or any combination thereof.
52. The method according to claim 41, additionally comprising step of adjusting the diameter of said loops to the diameter of said clot.
53. The method according to claim 41, additionally comprising step of penetrating and crossing said clot via a corkscrew-like effecter.
54. The method according to claim 41, additionally comprising step of selecting said angle A to be higher than about 0 degrees and lower than about 180 degrees.
55. The method according to claim 41, additionally comprising step of applying vibration on said clot.
56. The method according to claim 41, additionally comprising step of coating said loops and/or said mesh-like net with lubricious polymeric material selected from hydrophilic polymer material.
57. The method according to claim 41, additionally comprising step of coupling said spring-like helical member to said mesh-like net.
58. A method for removing a clot from blood vessel, comprising steps of:
    i. obtaining an embolectomy device comprising:
        a. an endless wire coupled to a spring-like helical member having a plurality of loops; said loops are positioned at an angle *A* relatively to the main longitudinal axis of said blood vessel;
        b. a tubular mesh-like net;
    ii. integrating said spring-like helical member with said tubular mesh-like net;
    iii. approximating said clot;
    iv. entrapping said clot via said mesh-like net;
    v. rotating said helical member thereby radially encircling at least a portion of the outer circumference of said clot by said plurality of loops;
    vi. extracting said mesh-like net from said blood vessel;

wherein said step of radially encircling at least a portion of the outer circumference of said clot by said plurality of loops exerts radial compression forces and longitudinal shearing forces on said clot such that the tendency of said clot to fragment is mitigated.

59. The method according to claim 58, additionally comprising step of selecting the material of said mesh-like net from a group consisting of woven fabrics, non-woven fabrics, gauze-like fabrics, materials having multiple openings, and fluid-permeable membranes or any combination thereof.

60. The method according to claim 58, additionally comprising step of configuring the distal portion of said mesh-like net to switch from an expended-configuration to a restricted-configuration; said expended-configuration is operative to allow insertion of at least a portion of a target clot into said mesh-like net's distal portion; and said restricted configuration is operative to retain said clot within said mesh-like net.

61. The method according to claim 58, additionally comprising step of configuring said mesh-like net to self-expand from said expended-configuration to said restricted-configuration.

62. The method according to claim 58, additionally comprising step of retaining at least a portion of the target clot within said mesh-like net.

63. The method according to claim 58, additionally comprising step of applying vibration on said clot.

64. The method according to claim 58, additionally comprising step of grasping (i) the proximal portion of said clot via a proximal effecter characterized by a FOLDED configuration and an OPEN configuration; and, (ii) the distal portion of said clot via a distal effecter characterized by a FOLDED configuration and an OPEN configuration; such that said clot is, when grasped by said effecters in said open configuration, is manipulatable along and/or around the main longitudinal axis of said blood vessel.

65. The method according to claim 64, additionally comprising steps of crossing said clot via said distal effecter in said FOLDED configuration; and, expanding to said OPEN configuration.

66. The method of claim 64, additionally comprising step of configuring said distal effecter to self-expand from its FOLDED configuration to its OPEN configuration.

67. The method of claim 64, additionally comprising step of incorporating said distal effecter with said proximal effecter to form a single effecter.

68. The method according to claim 58, additionally comprising step of selected the cross sectional area of said helical member from a group consisting of circular, oval, round, square, rectangular, triangular, regular or irregular shapes, or any combination thereof.
69. The method according to claim 58, additionally comprising step of adjusting the diameter of said loops to the diameter of said clot.
70. The method according to claim 58, additionally comprising step of penetrating and crossing said clot via a corkscrew-like effecter.
71. The method according to claim 58, additionally comprising step of selecting said angle A to be higher than about 0 degrees and lower than about 180 degrees.
72. The method according to claim 58, additionally comprising step of applying vibration on said clot.
73. The method according to claim 58, additionally comprising step of coating said loops and/or said mesh-like net with lubricious polymeric material selected from hydrophilic polymer material.
74. The method according to claim 58, additionally comprising step of coupling said spring-like helical member to said mesh-like net.

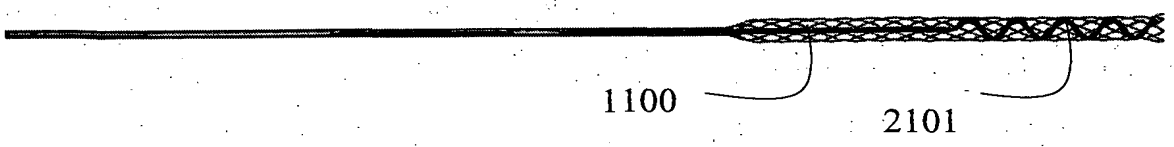


Fig. 1A

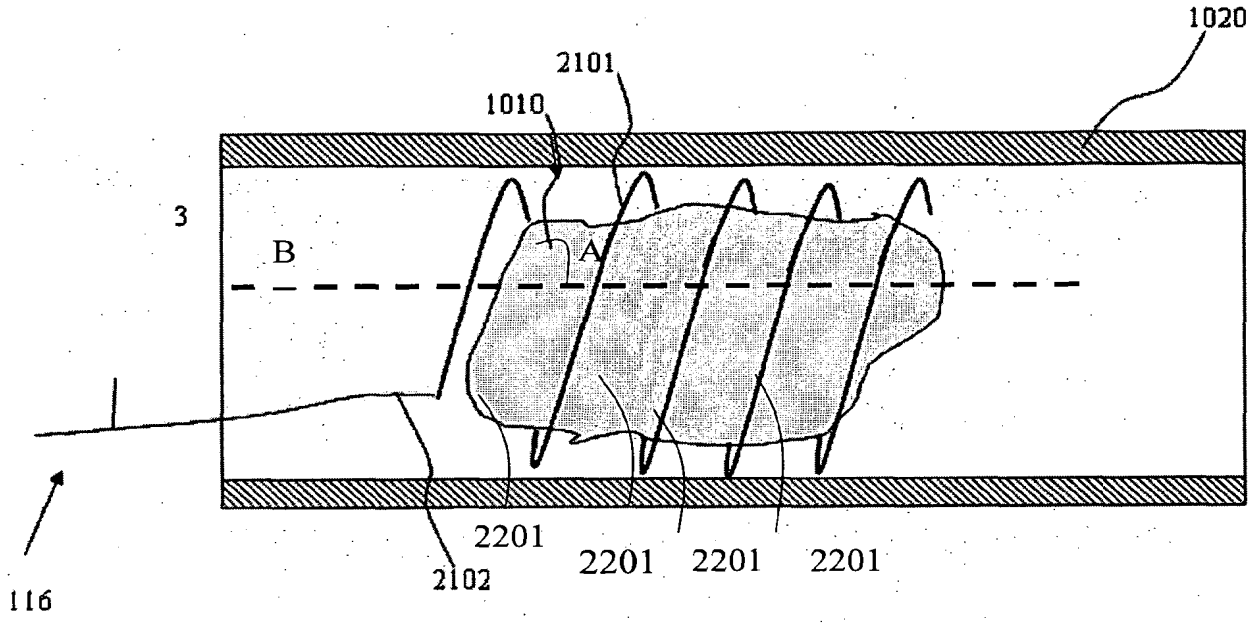

1020
2101
1010
3
B
A
2201
2201
2201
2201
2102
116

Fig. 1B

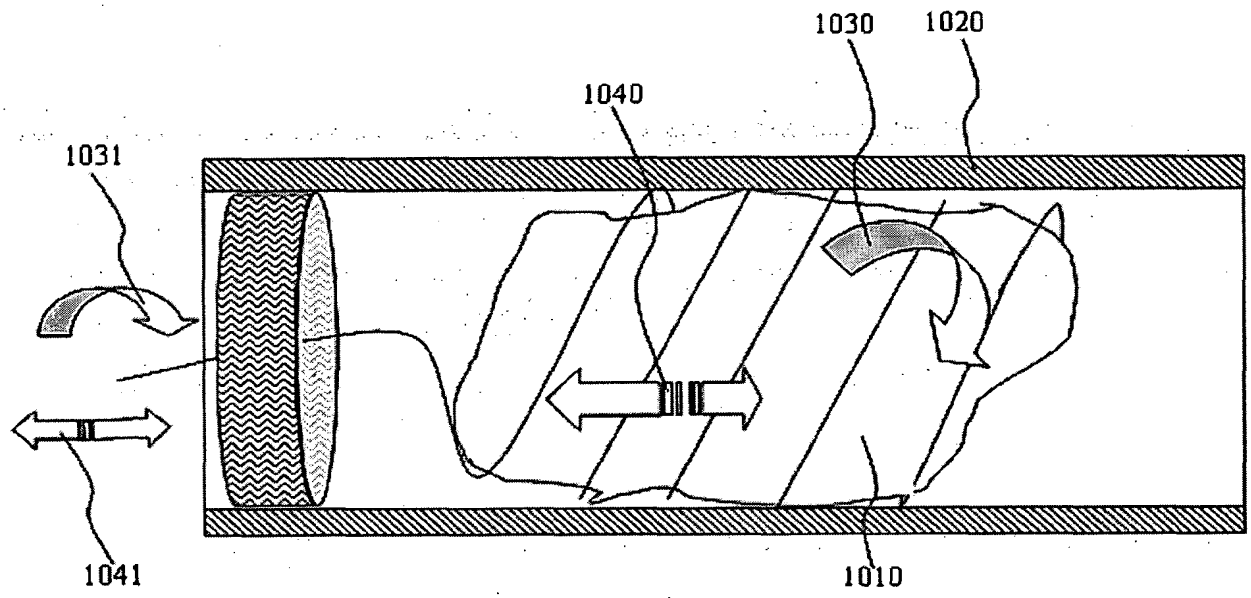

1030
1020
1040
1031
1041
1010

Fig. 1C

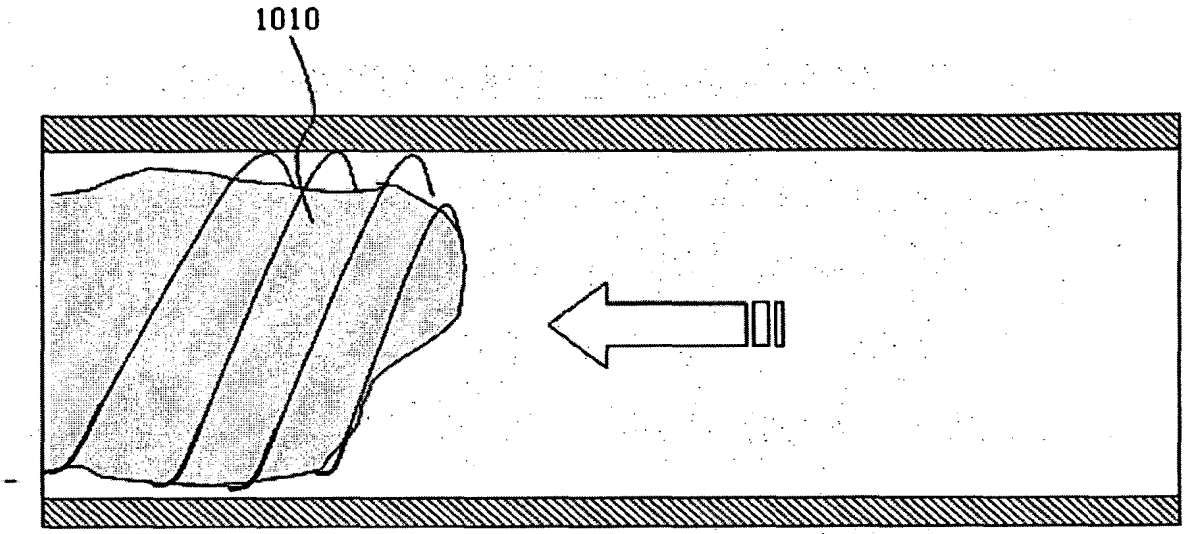


Fig. 1D

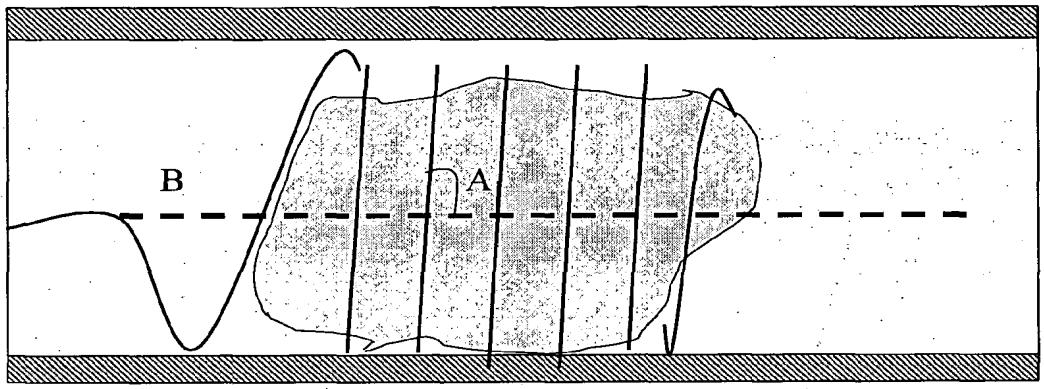


Fig 1E

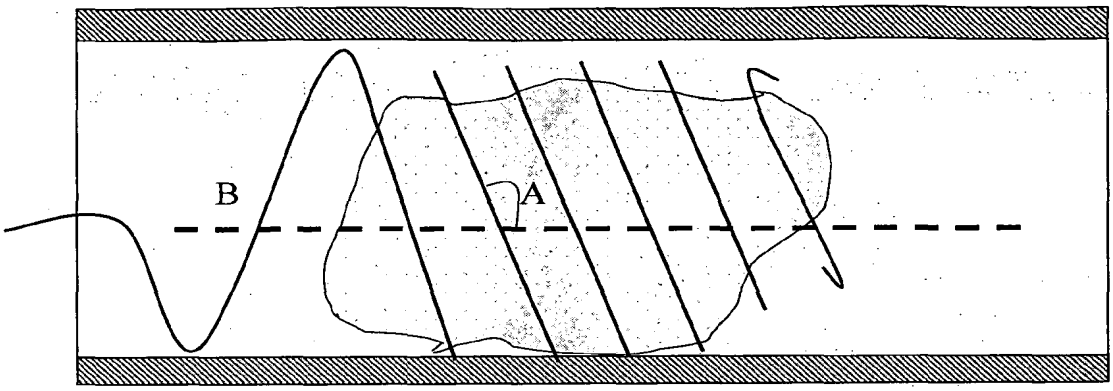


Fig. 17

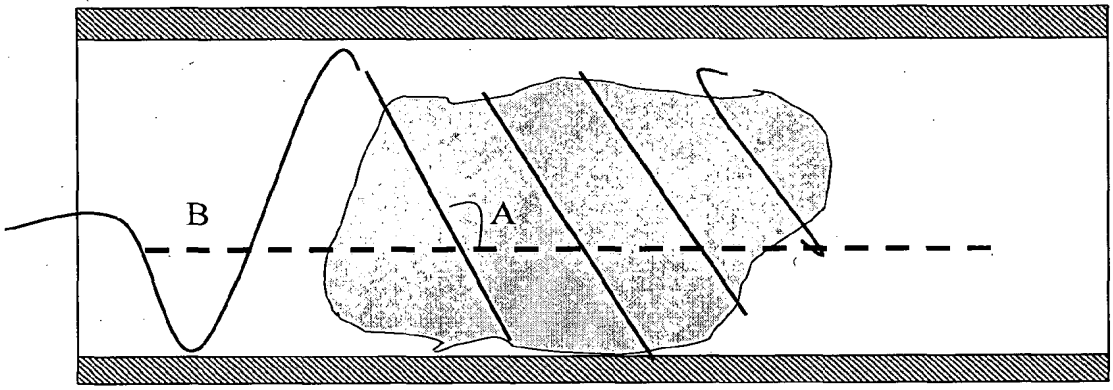


Fig. 19

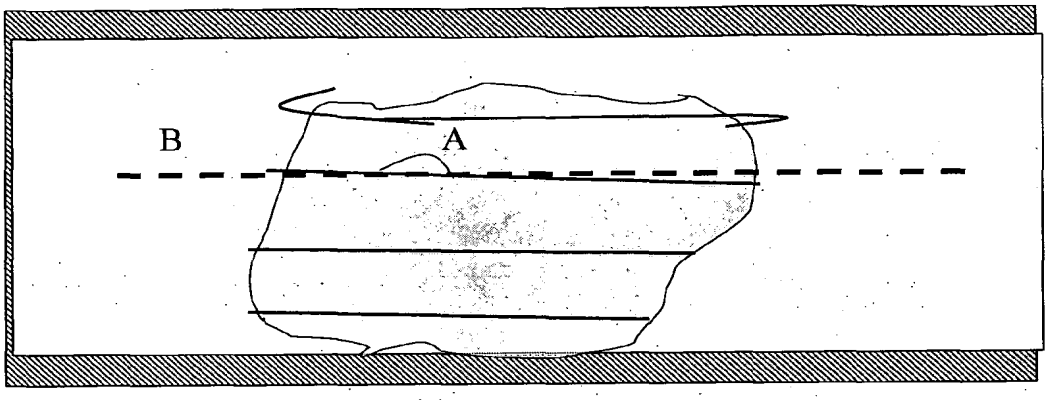


Fig. 17A

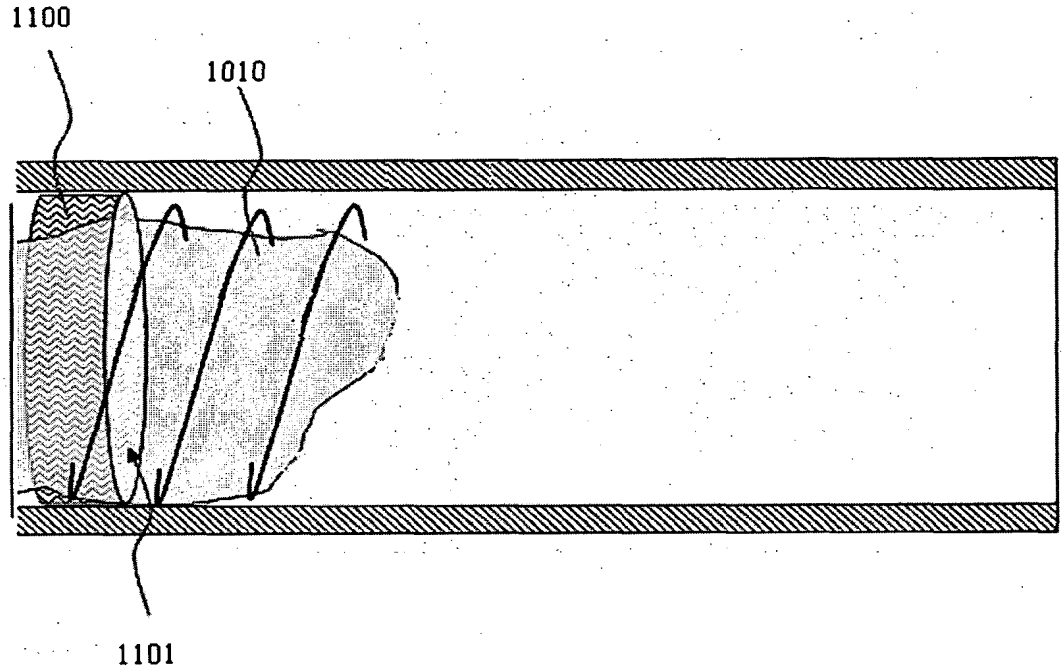


Fig. 2A

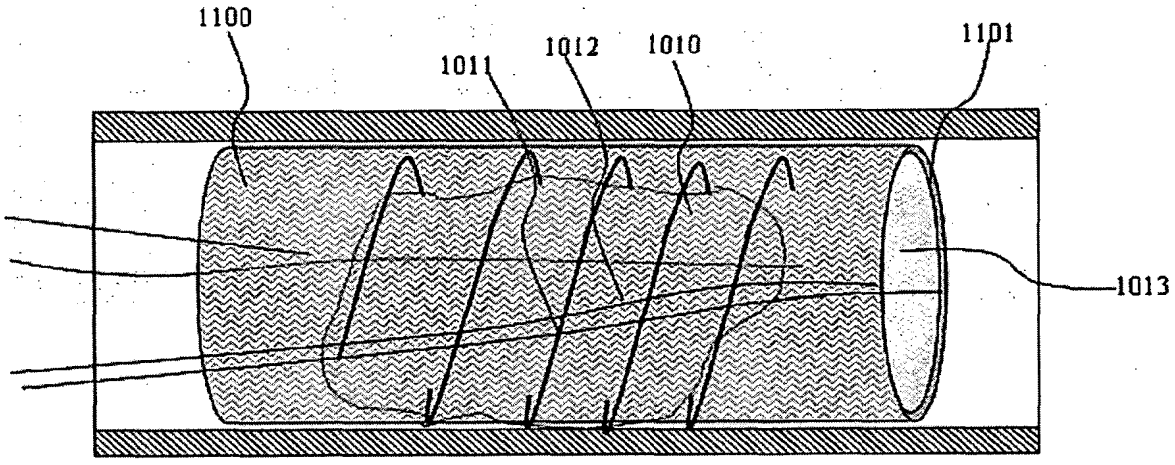


Fig. 2B

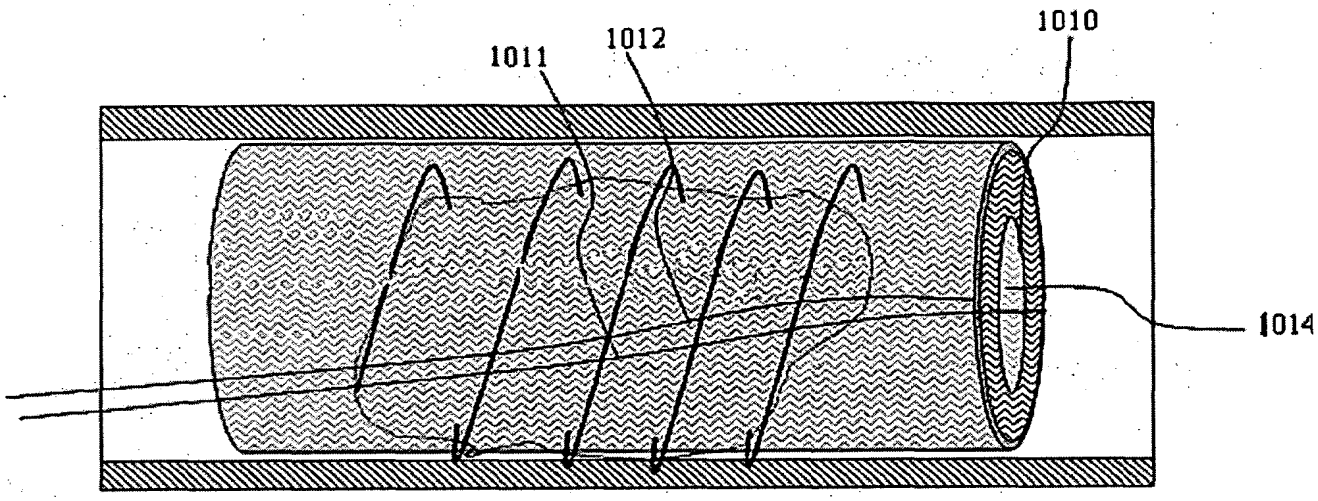


Fig. 2C

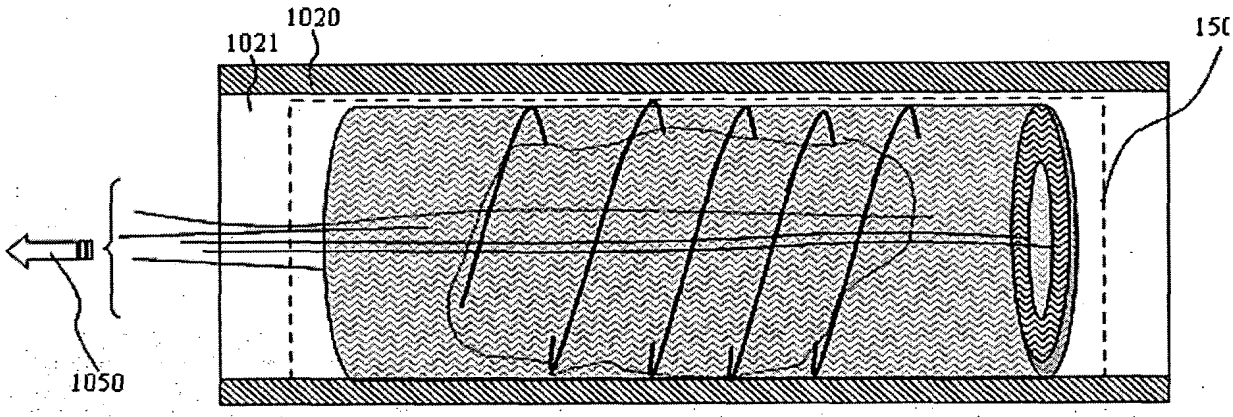


Fig. 2D

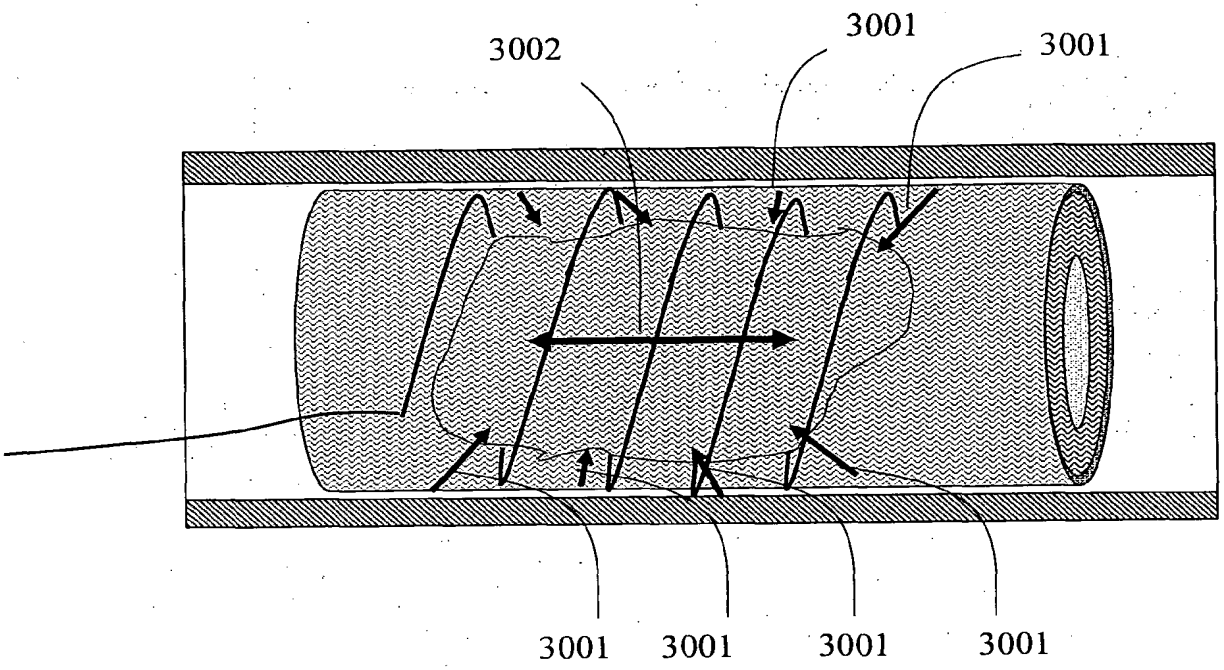


Fig. 2E

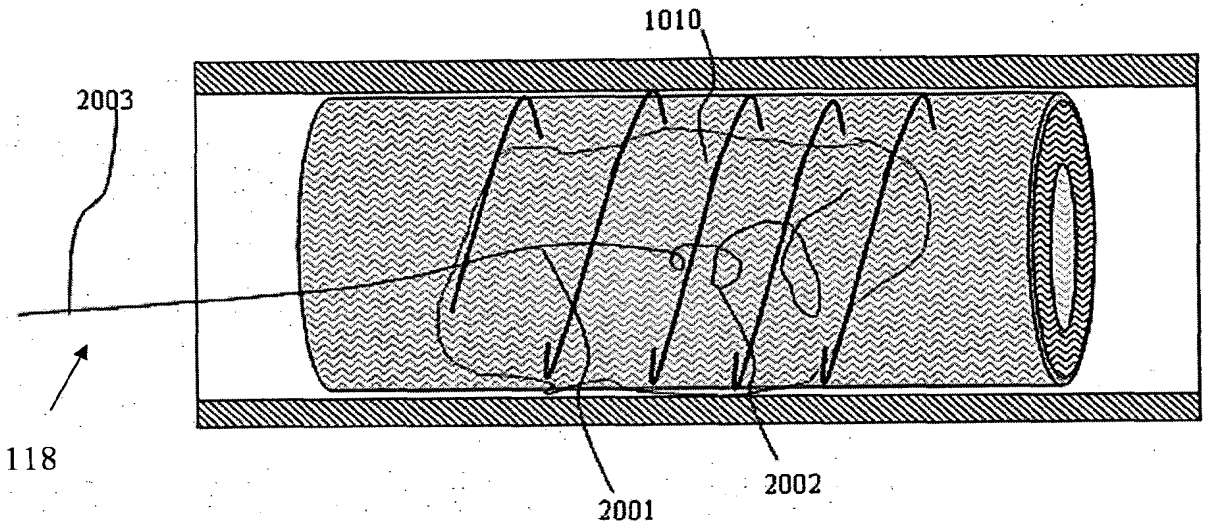


Fig. 3A



Fig. 4A



Fig. 4B



Fig. 4C

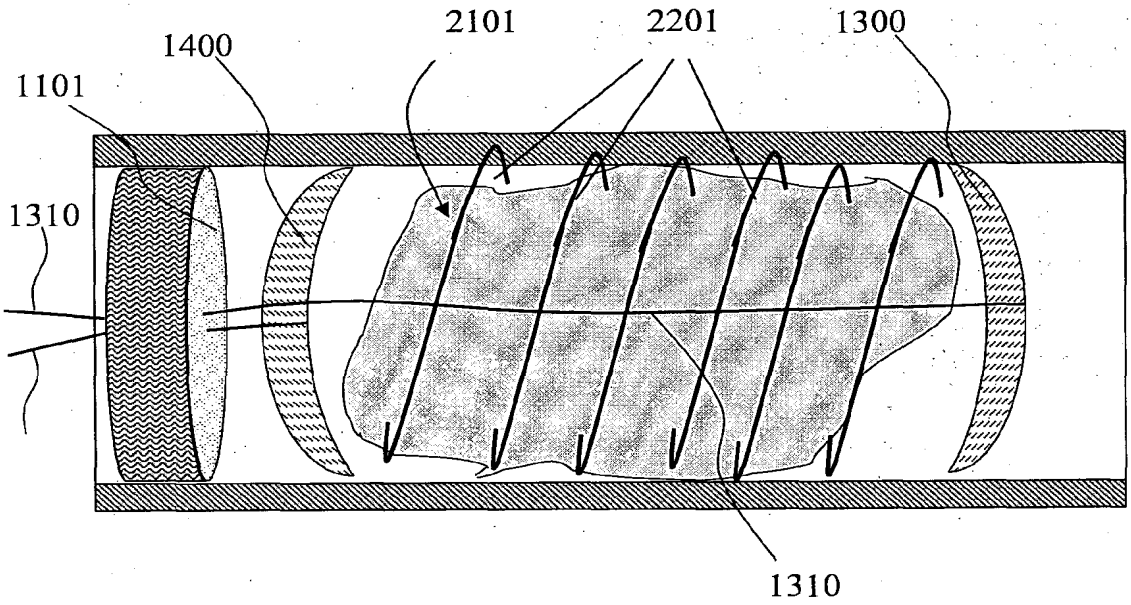


Fig 5A

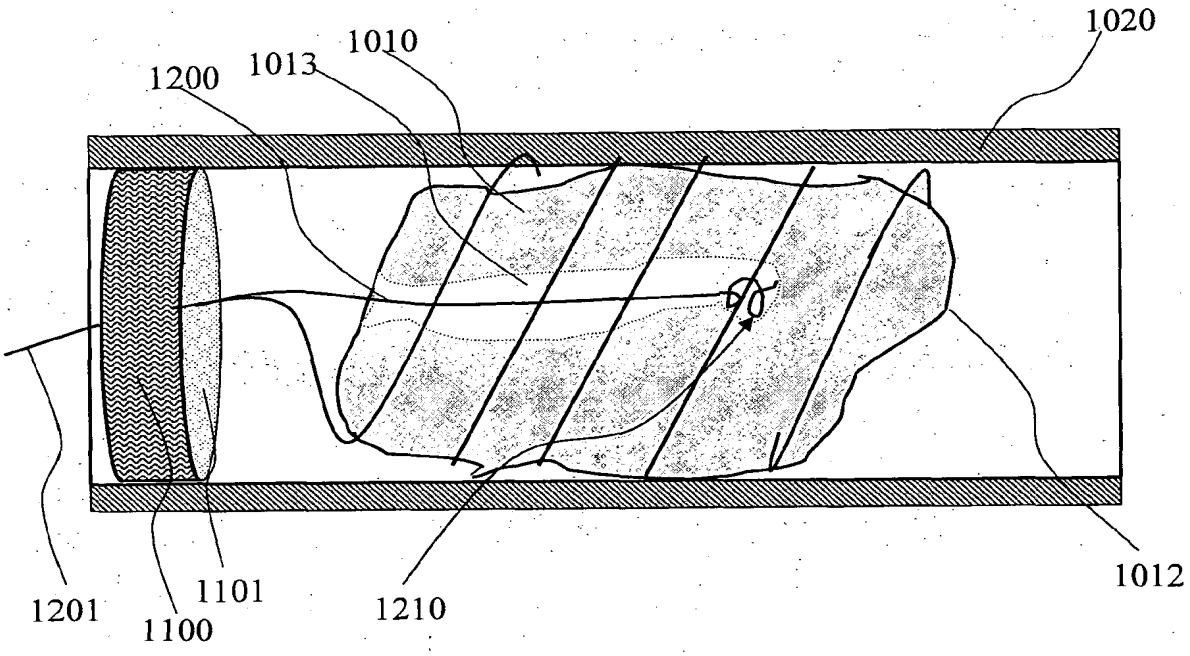

1020
1010
1013
1200
1012
1201
1101
1100
1210

Fig. 5B

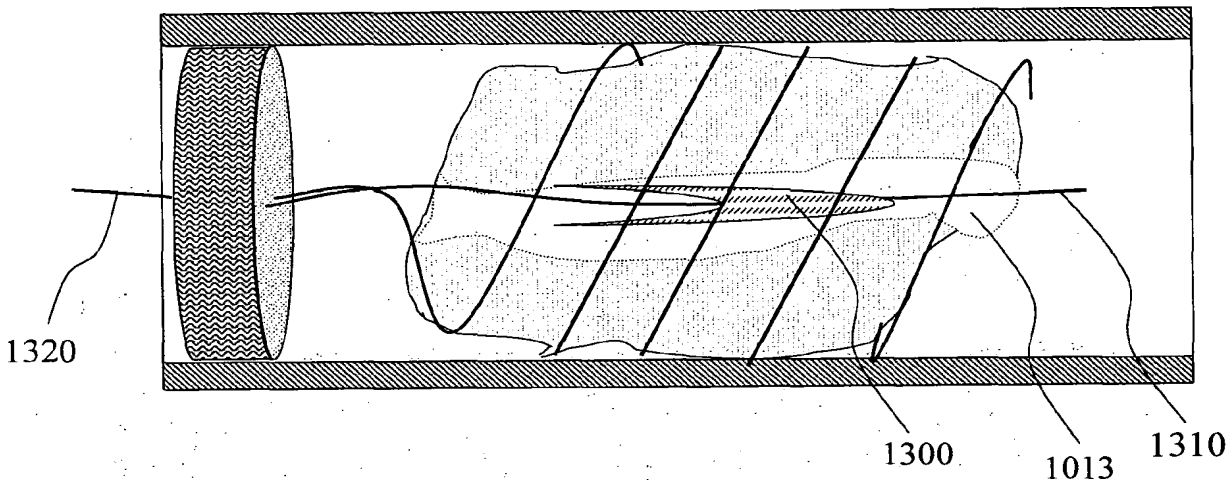

1320
1300
1013
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Fig. 5C

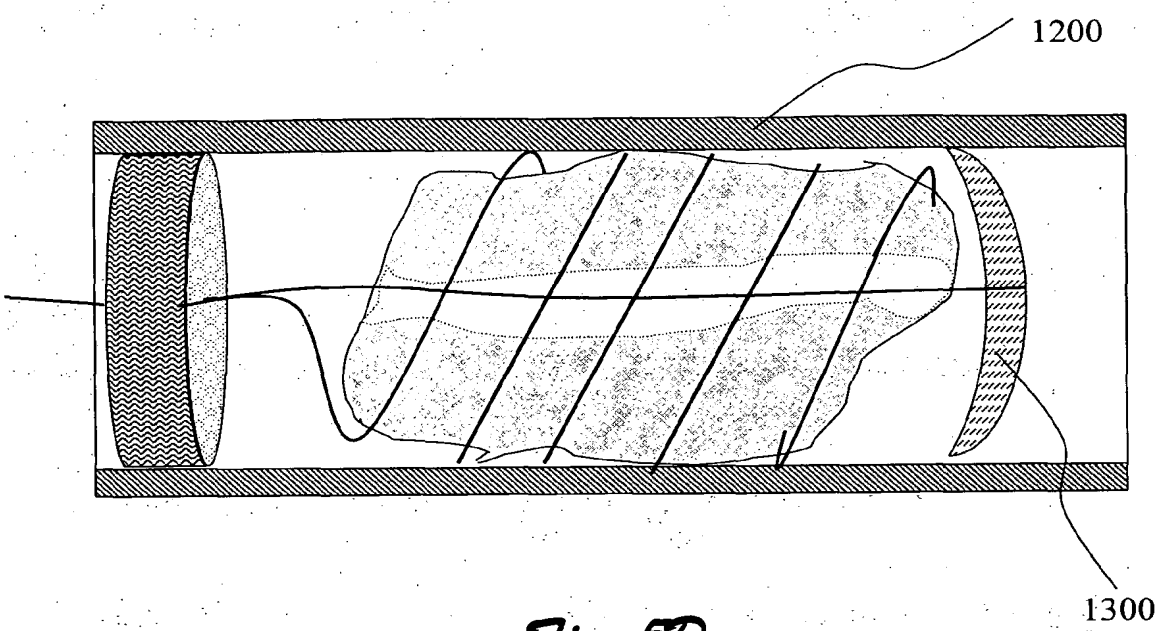


Fig. 5D

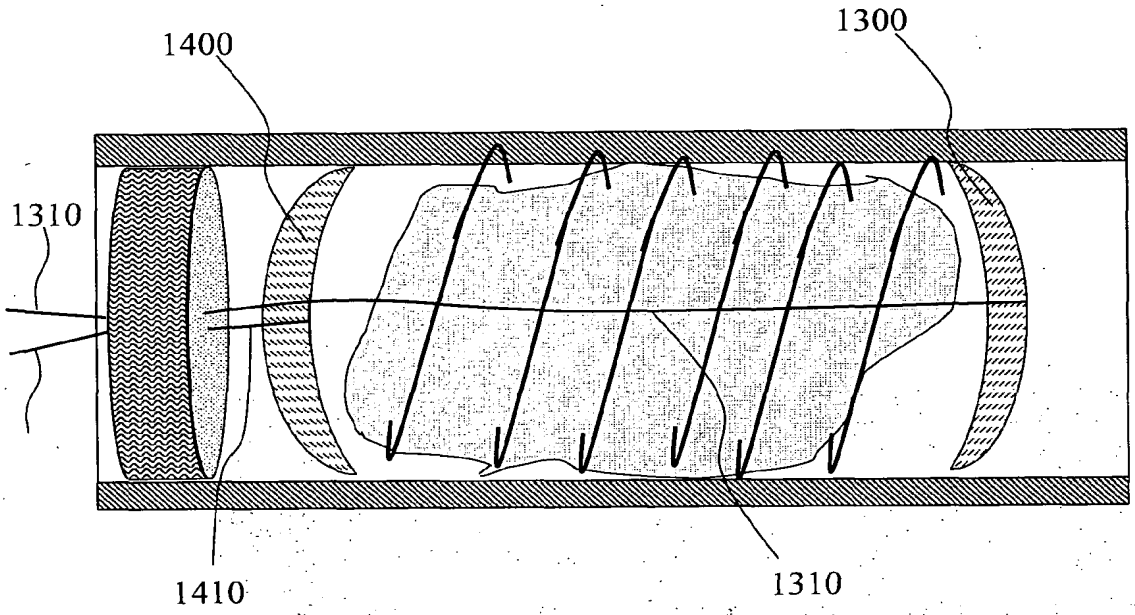


Fig. 5E

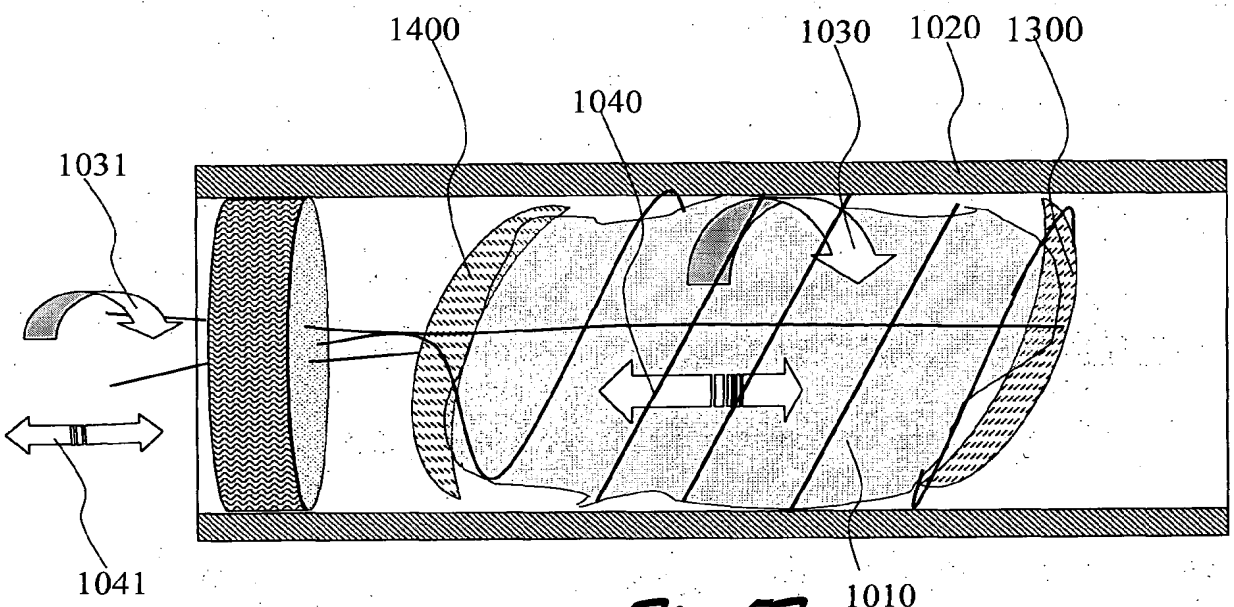


Fig. 5F

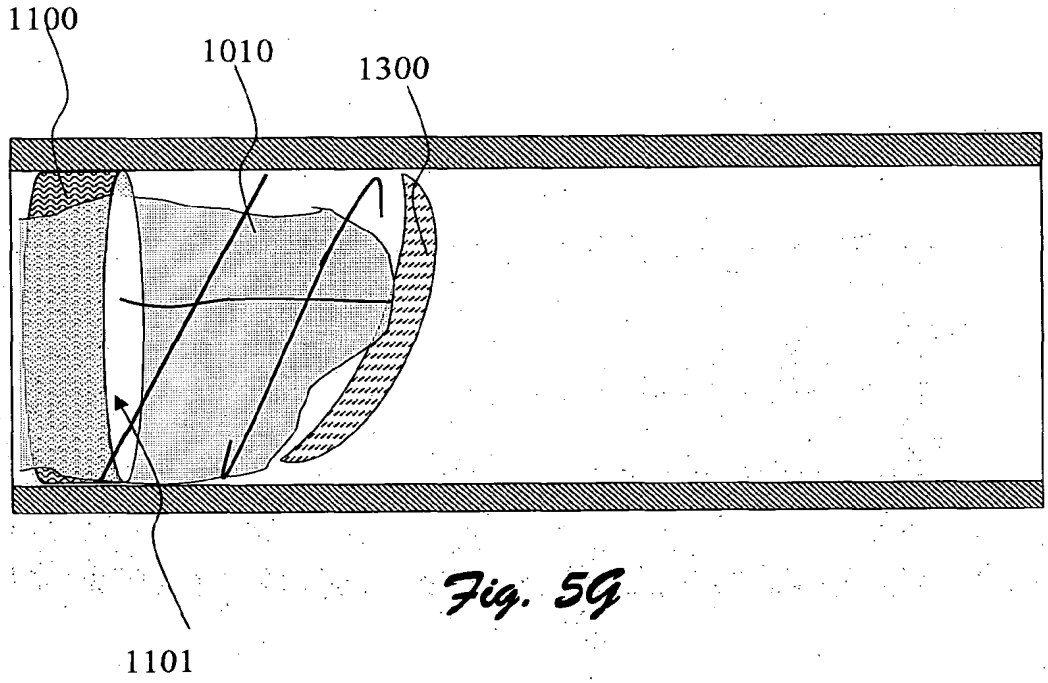


Fig. 5G

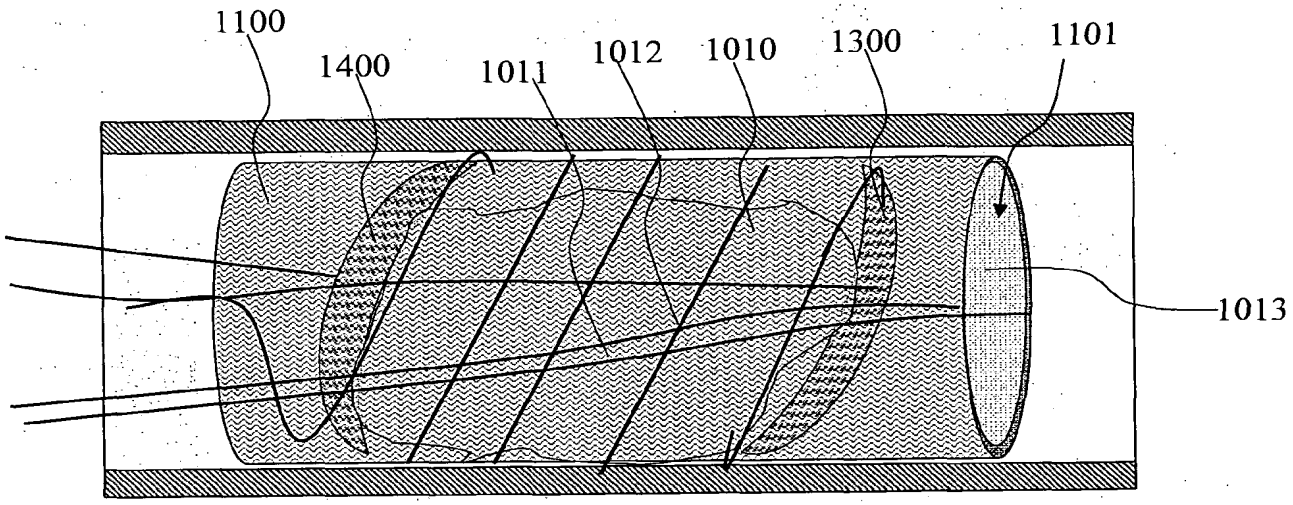


Fig. 5H

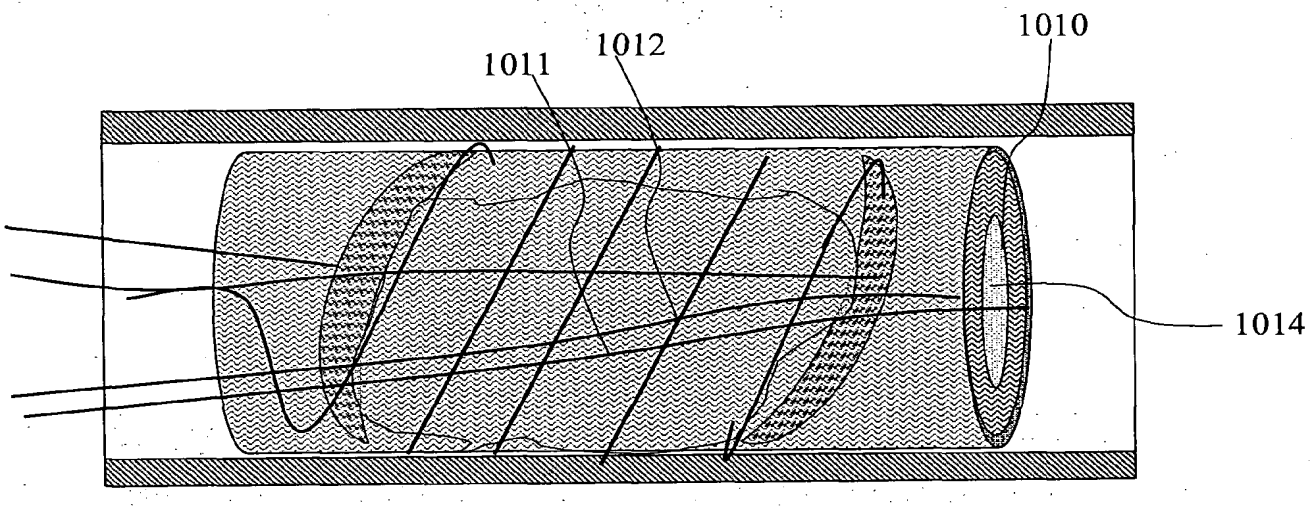


Fig. 5I

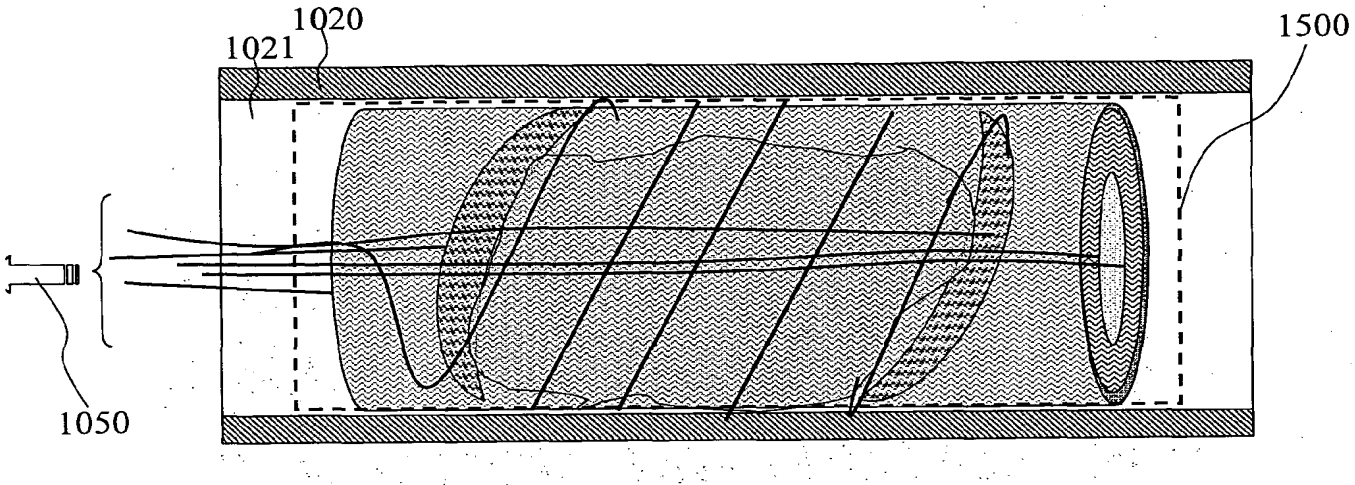


Fig. 5J

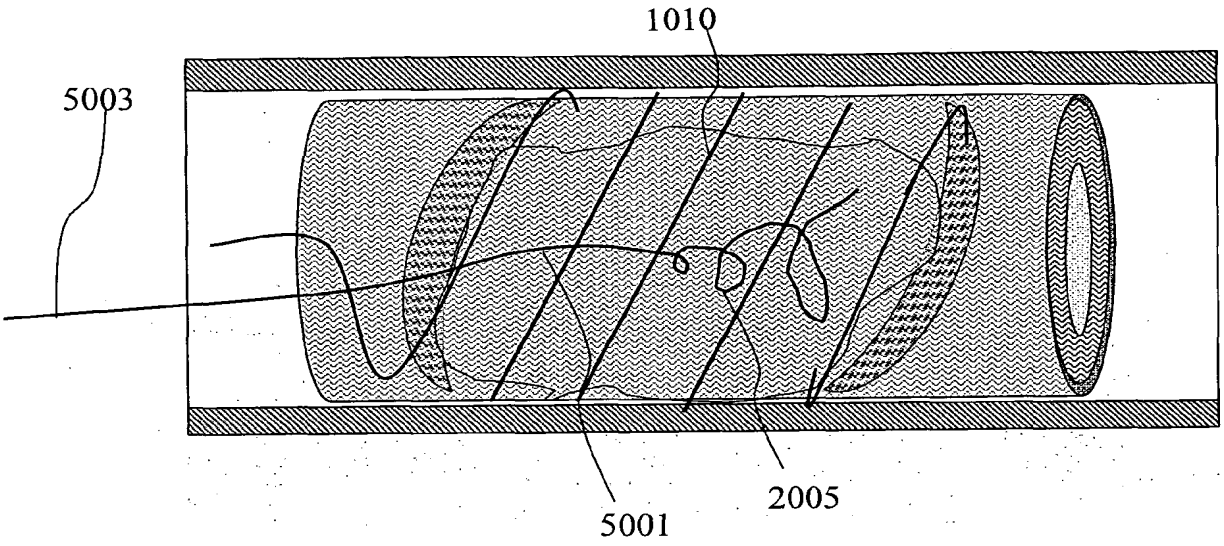


Fig. 5K

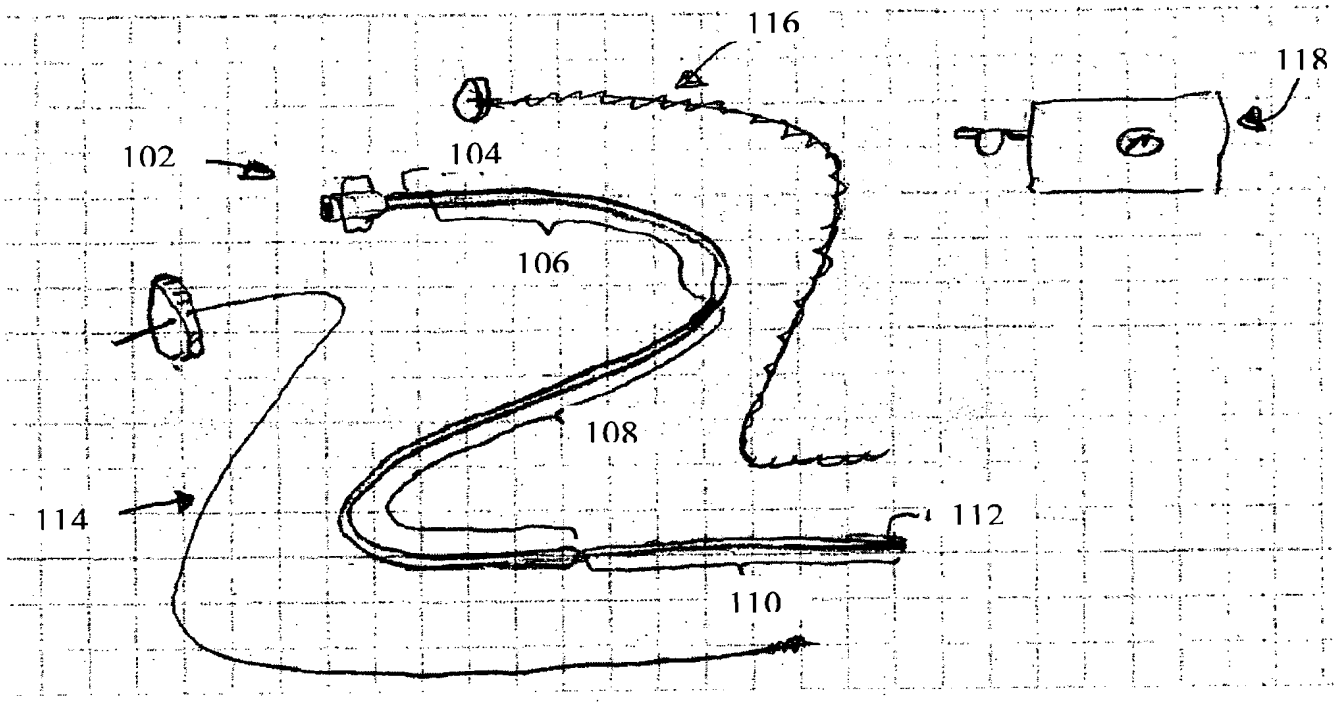


Fig. 6

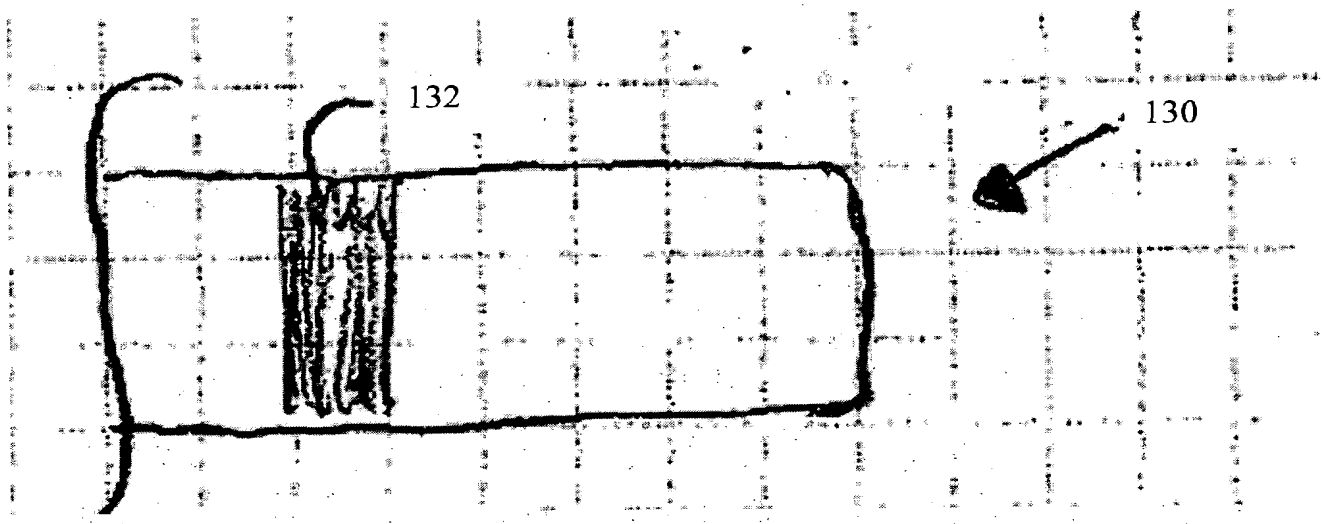


Fig. 7A

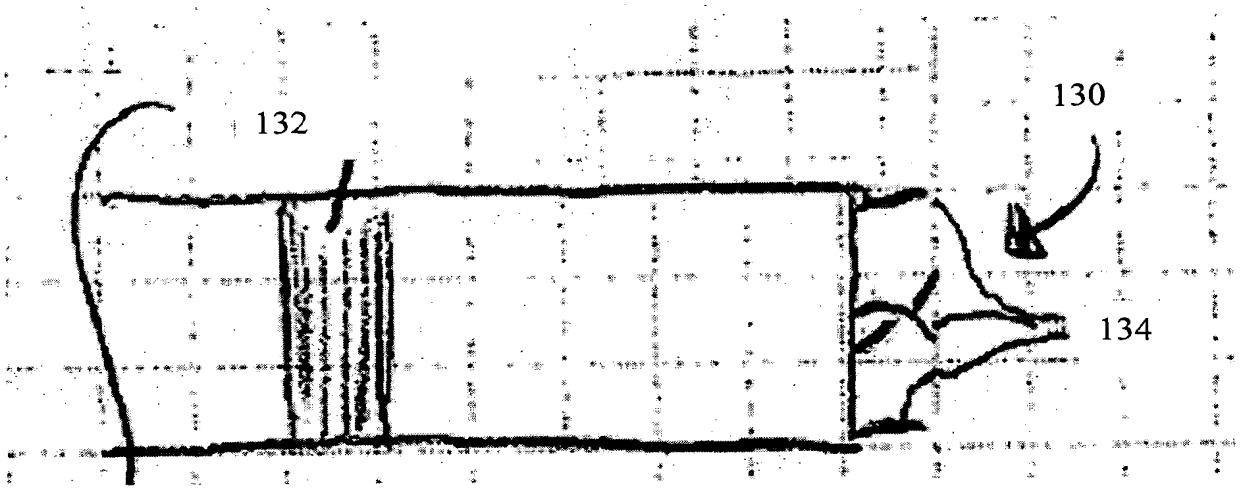


Fig. 7B

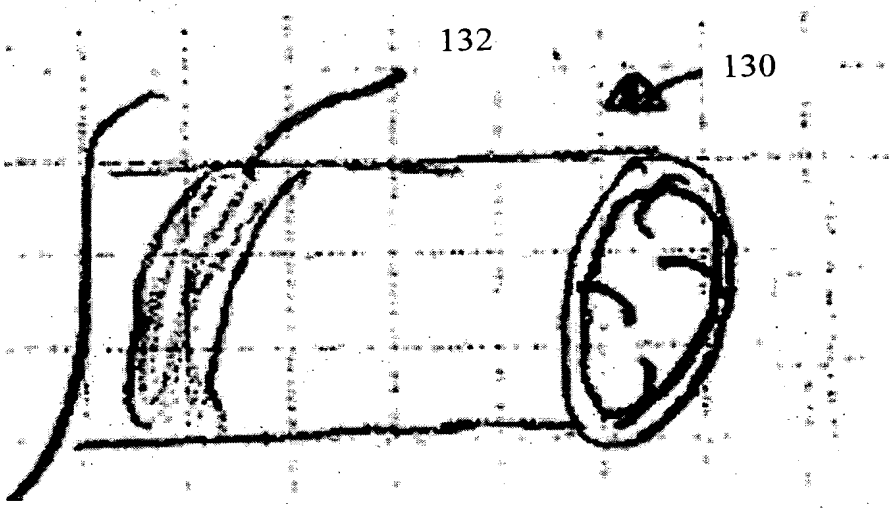


Fig. 7C

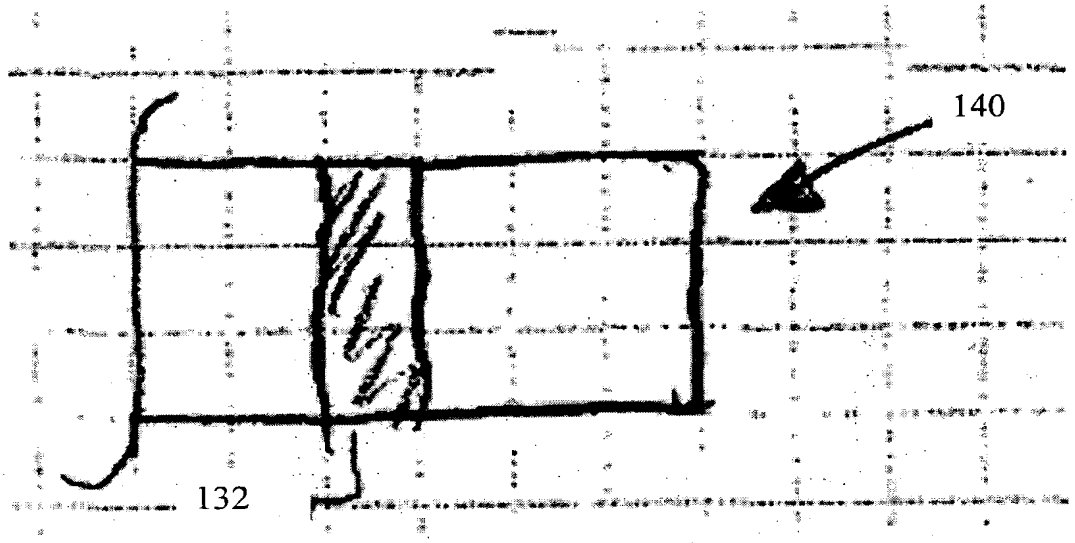


Fig. 8A

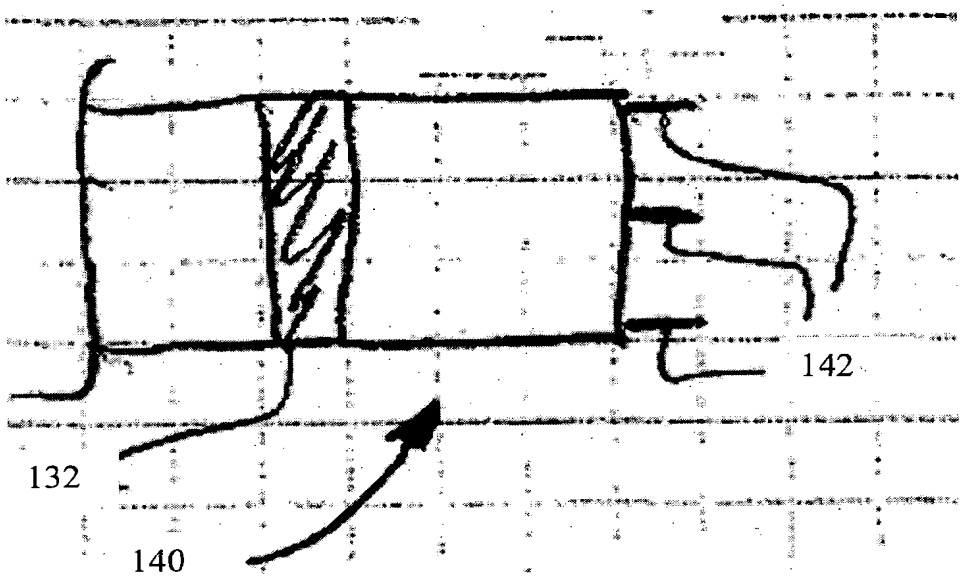


Fig. 8B

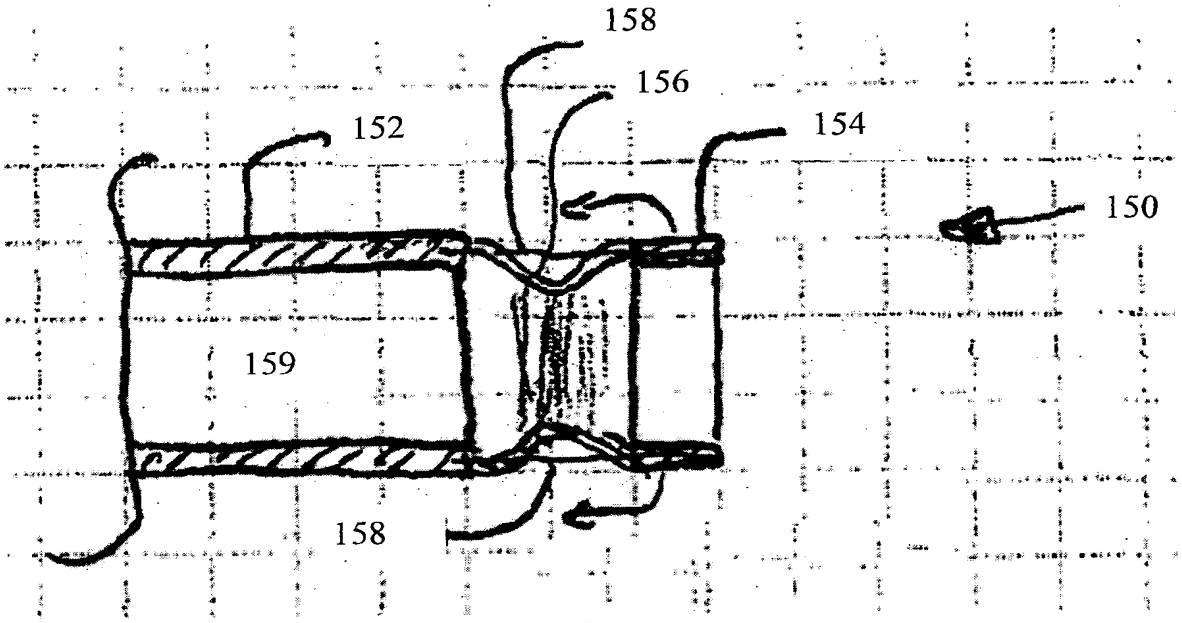


Fig. 9A

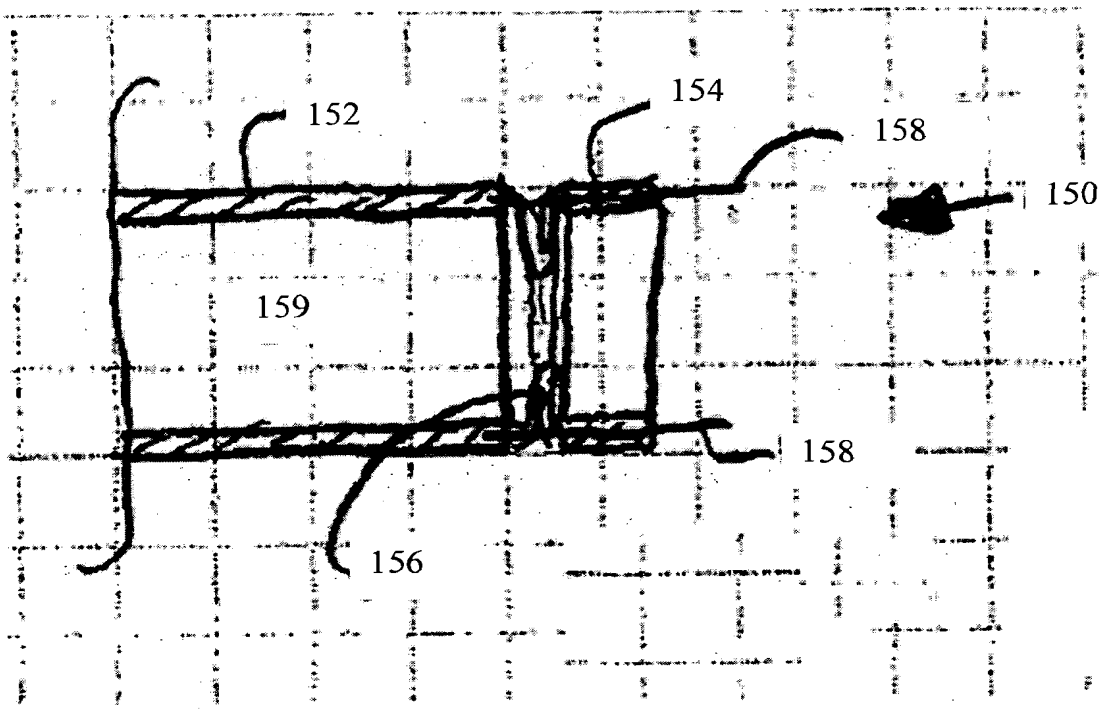


Fig. 9B

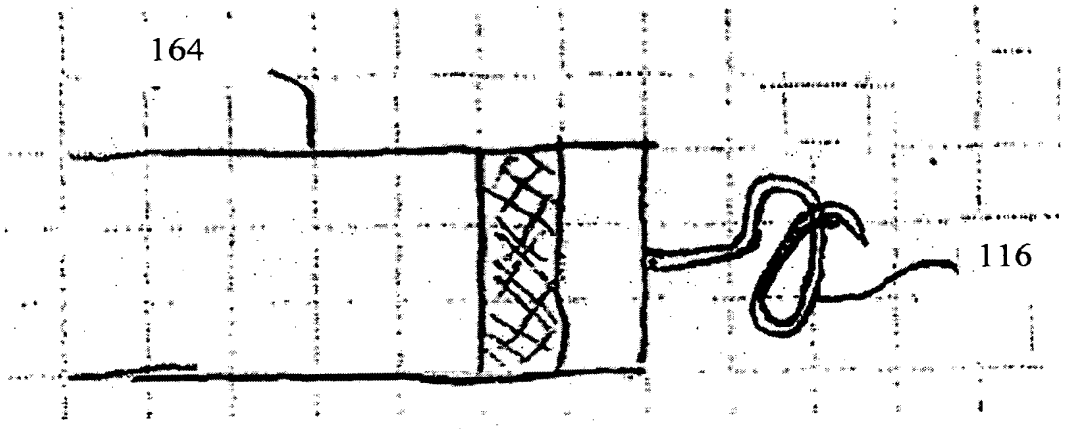


Fig. 10A

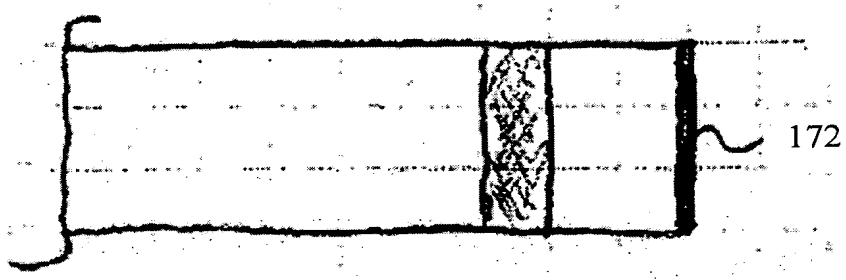


Fig. 11A

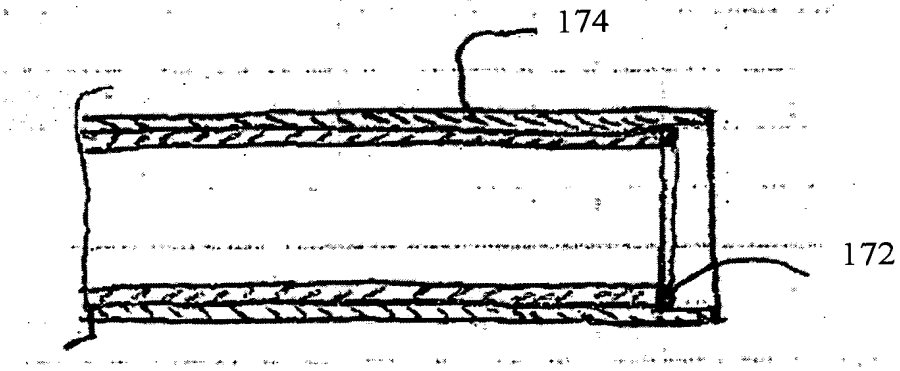


Fig. 11B

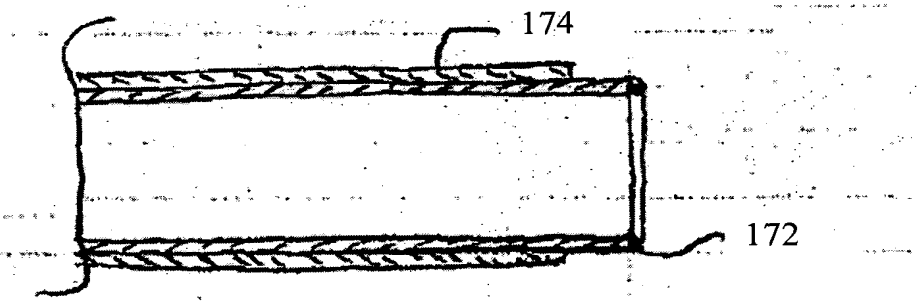


Fig. 11C

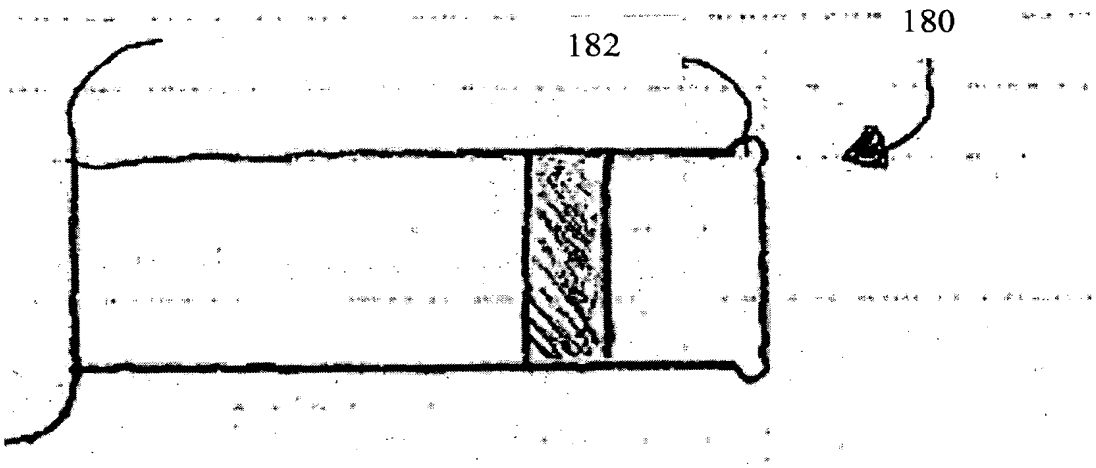


Fig 12

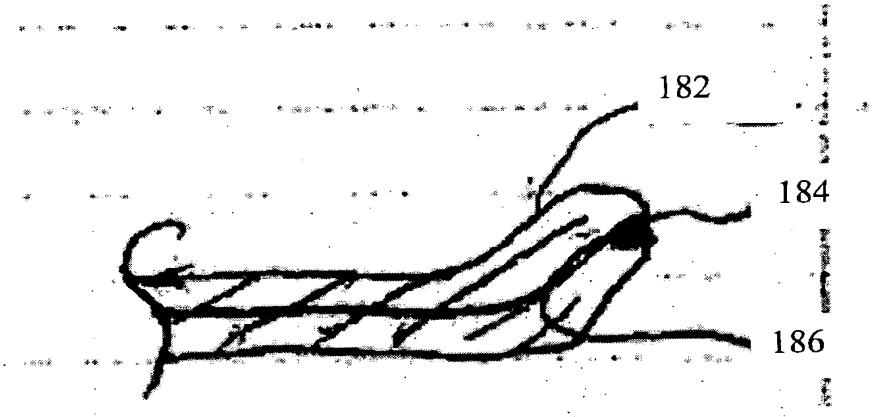


Fig. 13

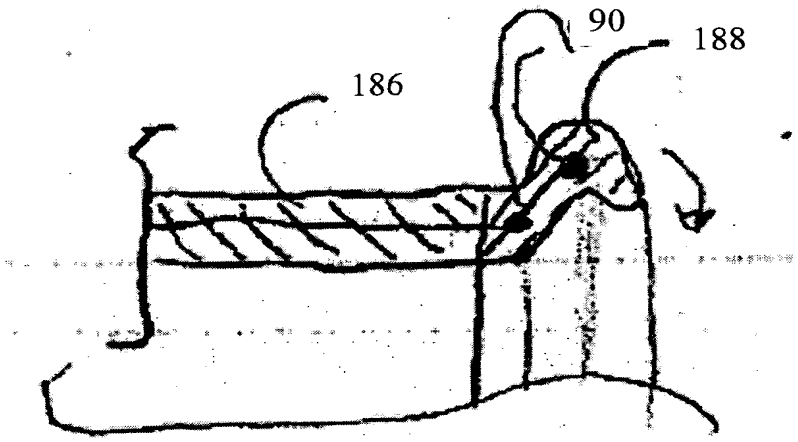


Fig. 14A

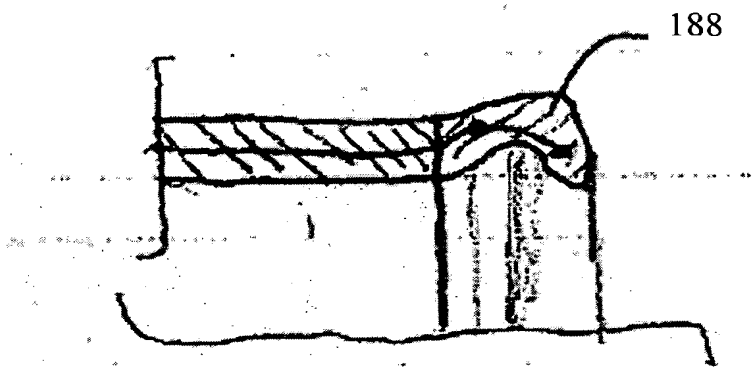


Fig. 14B

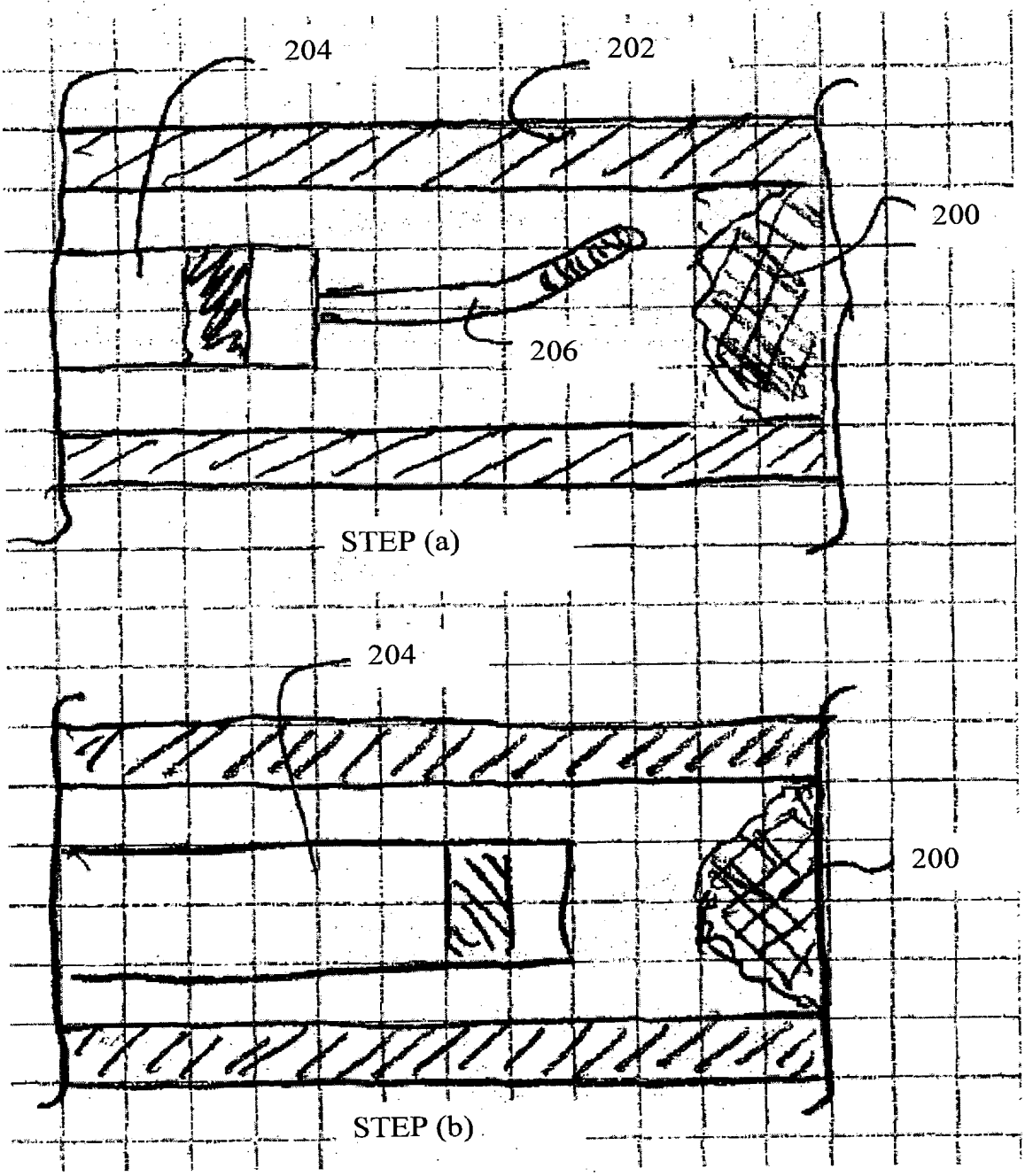


Fig. 15A

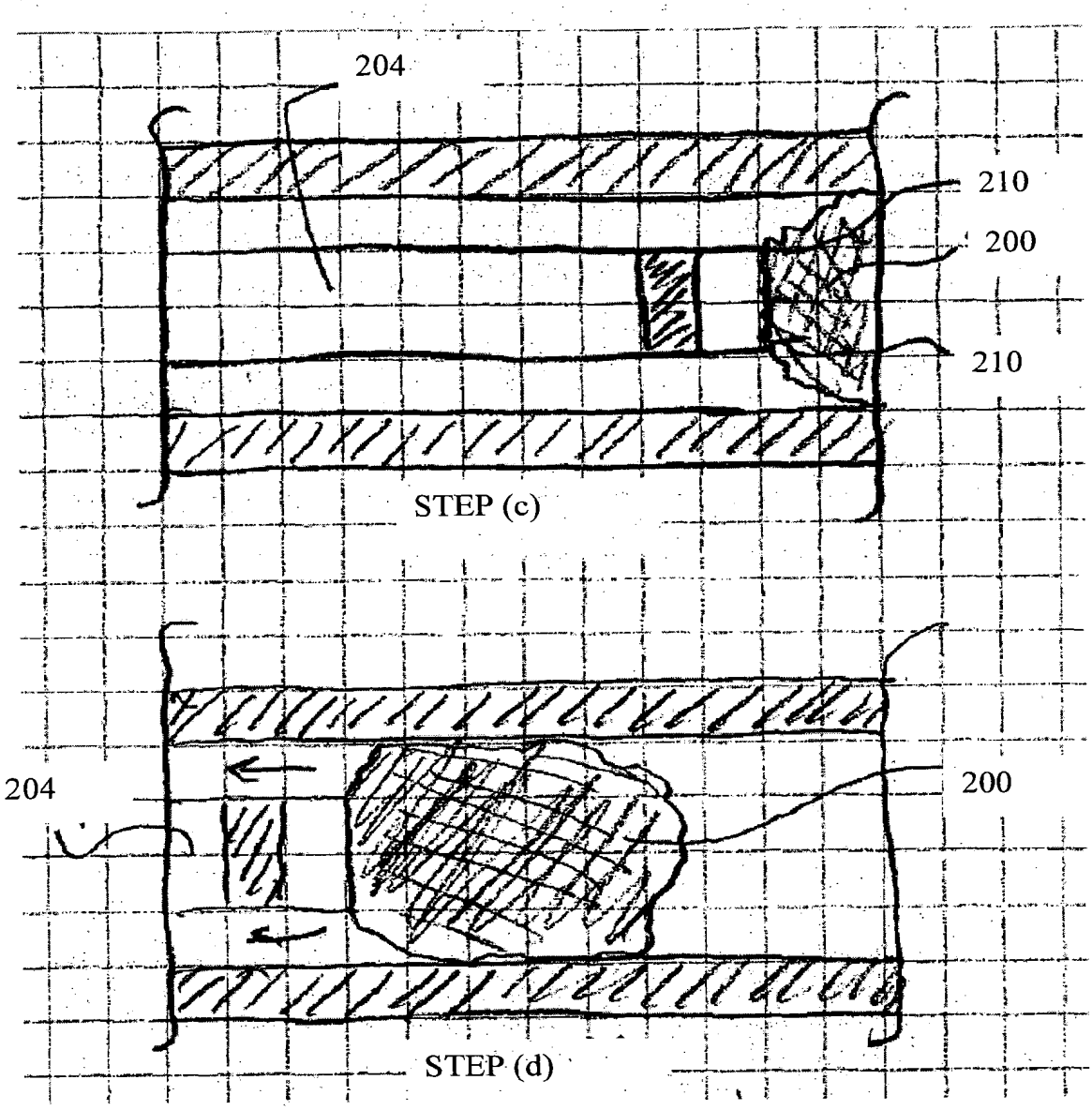


Fig. 15B

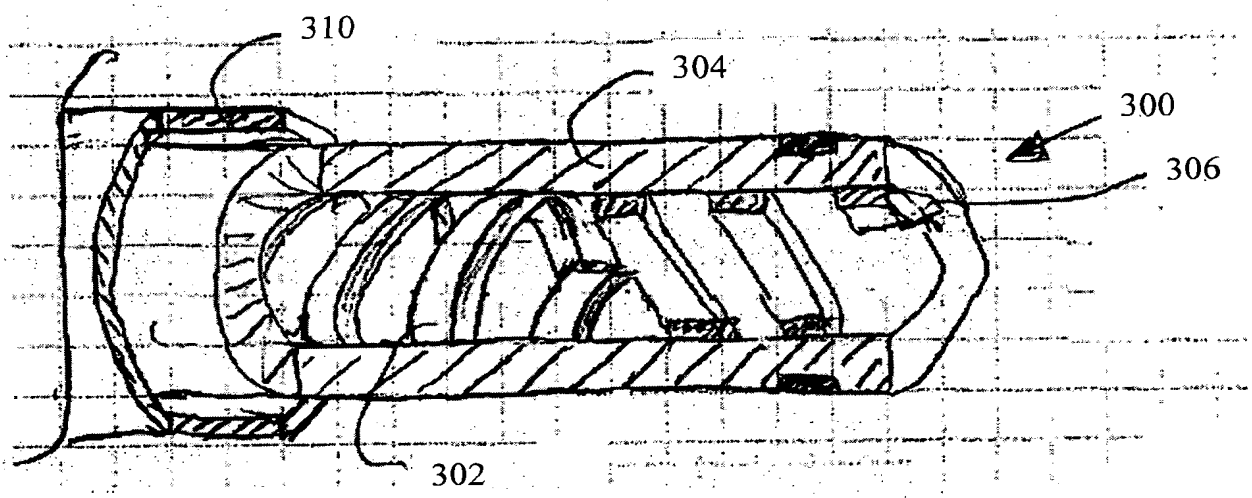


Fig. 16A1

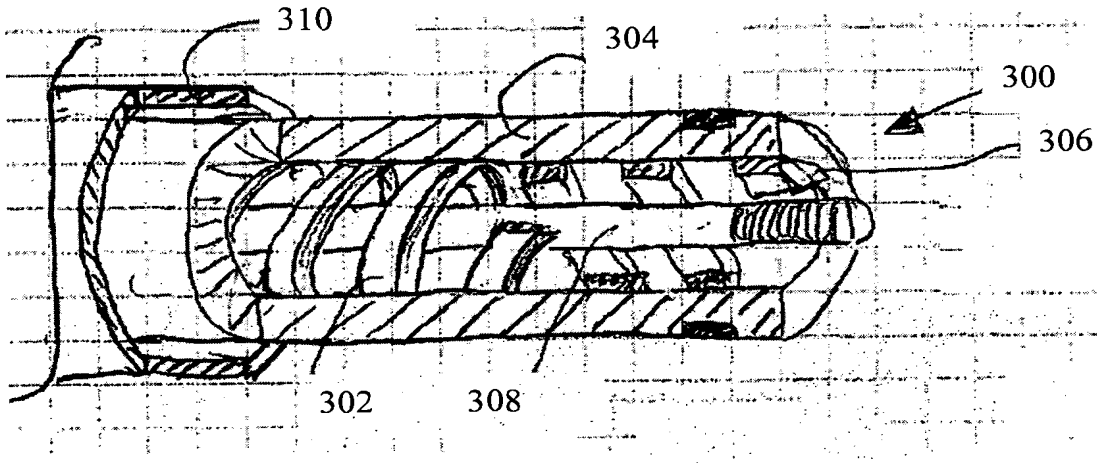


Fig. 16A2

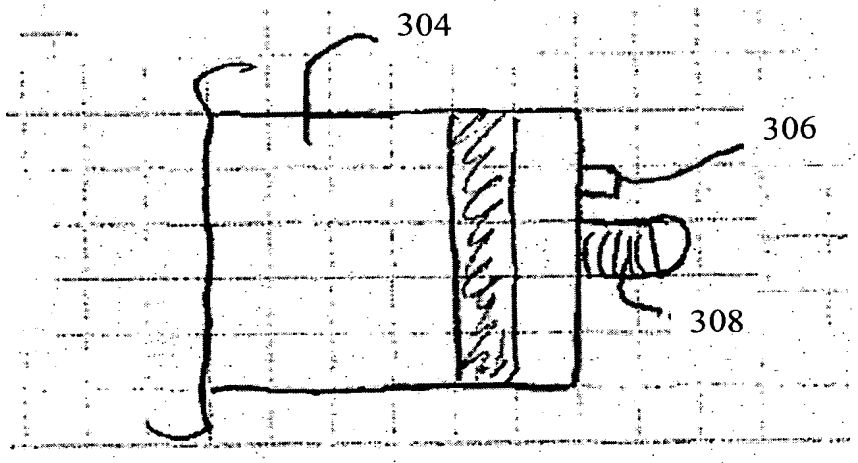


Fig. 16B

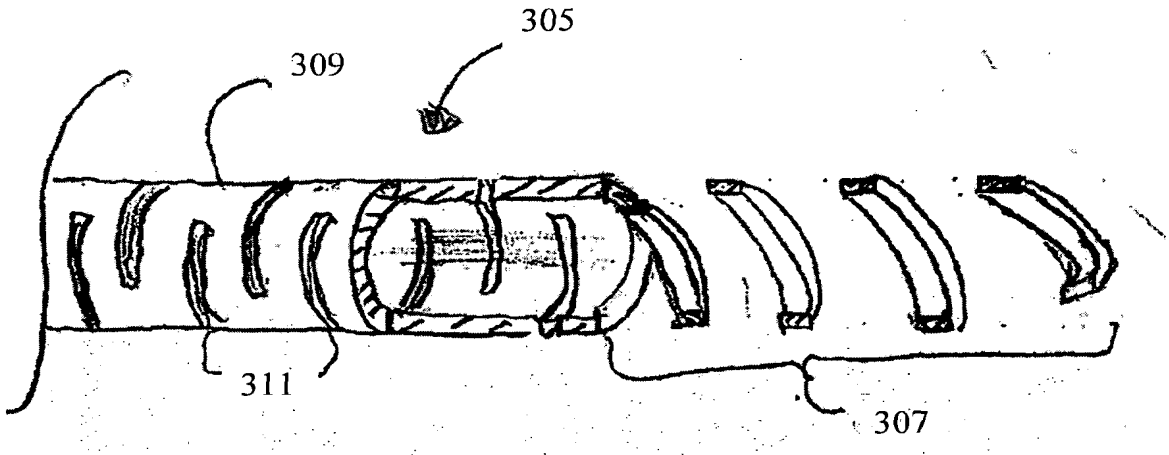


Fig. 16C

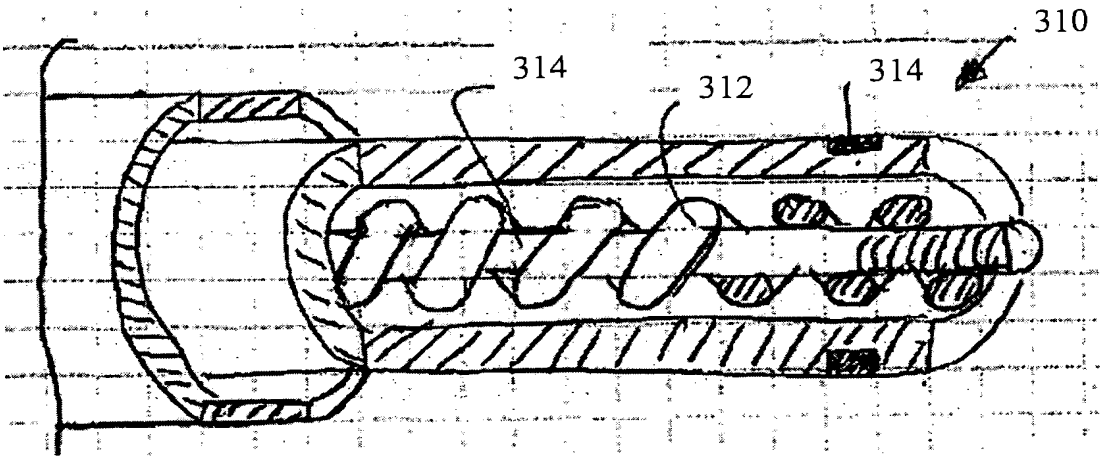


Fig. 17A

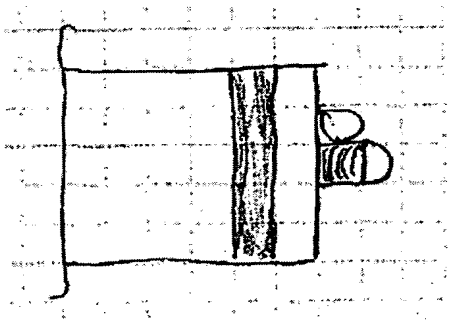


Fig. 17B

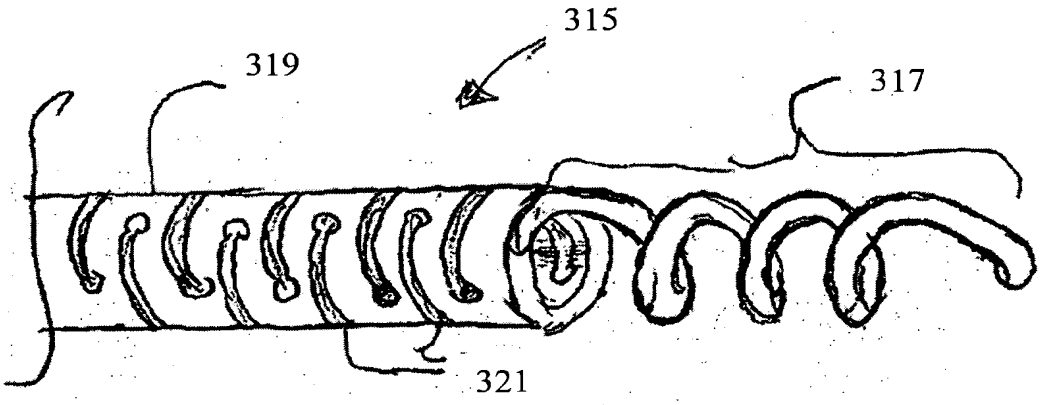


Fig. 17C

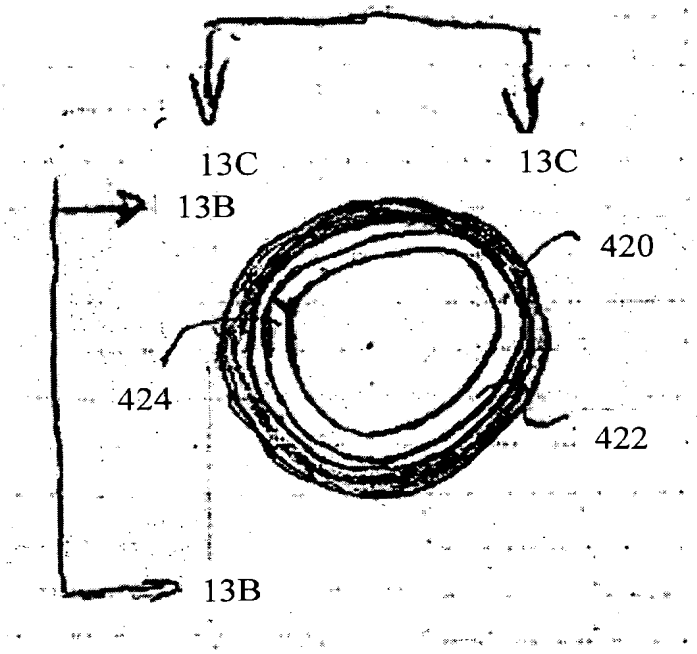


Fig. 18A

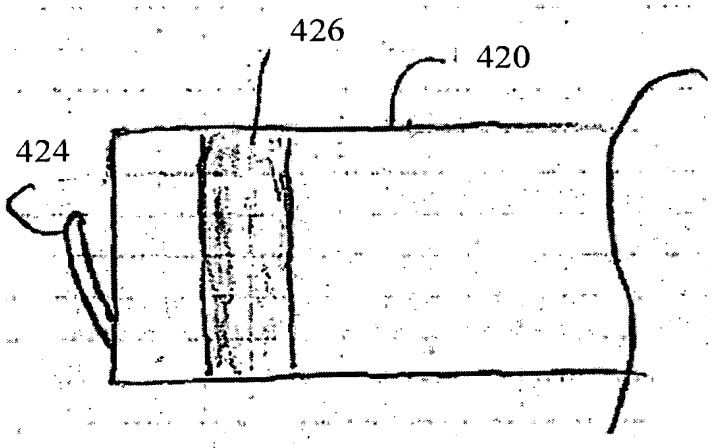


Fig. 18B

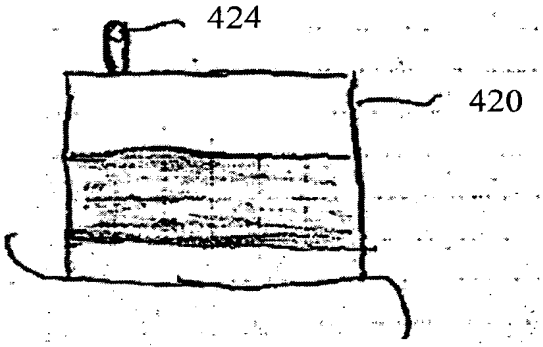


Fig. 18C

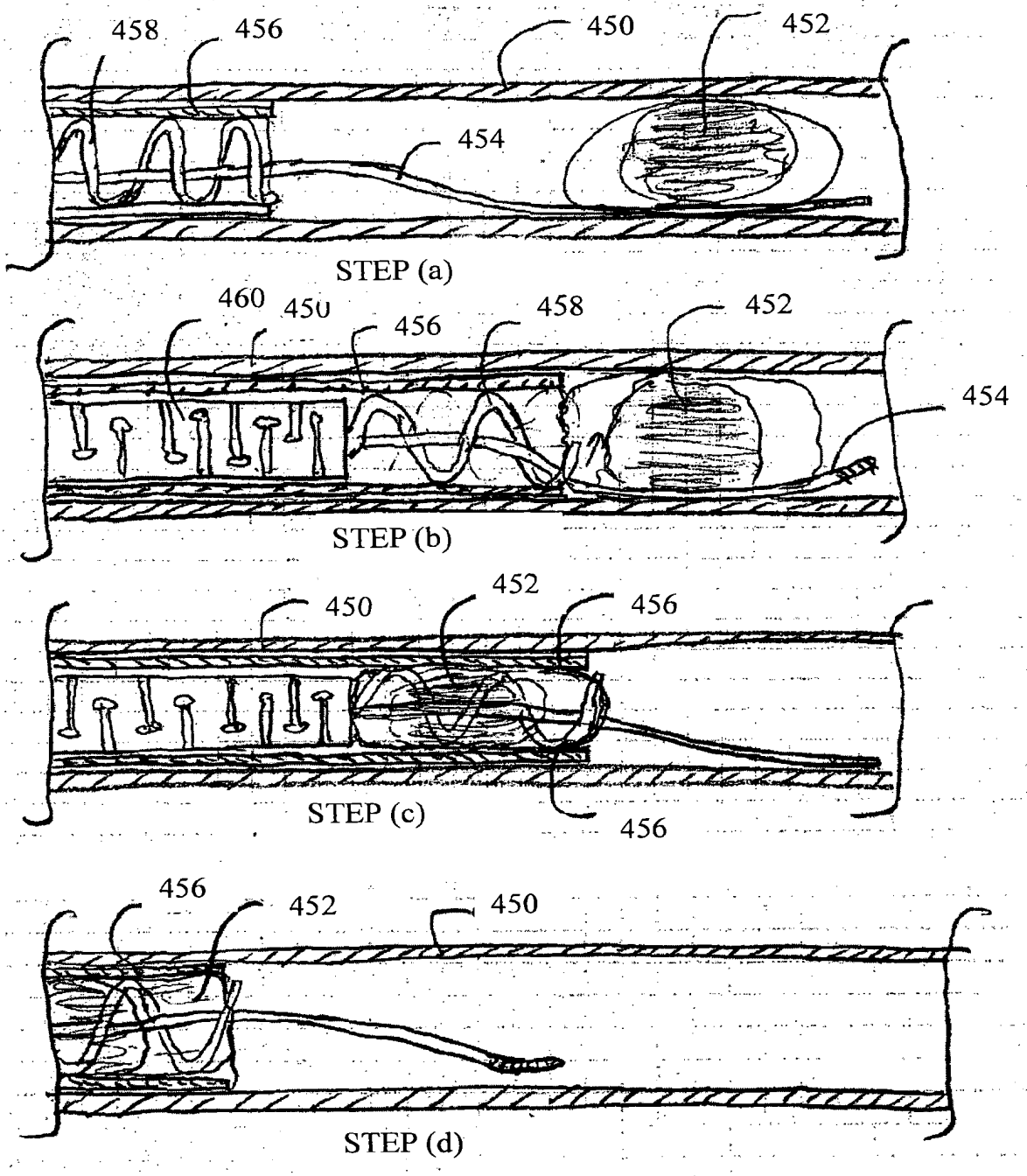

458
456
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452
454
STEP (a)
460
450
456
458
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454
STEP (b)
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STEP (c)
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STEP (d)

Fig. 19

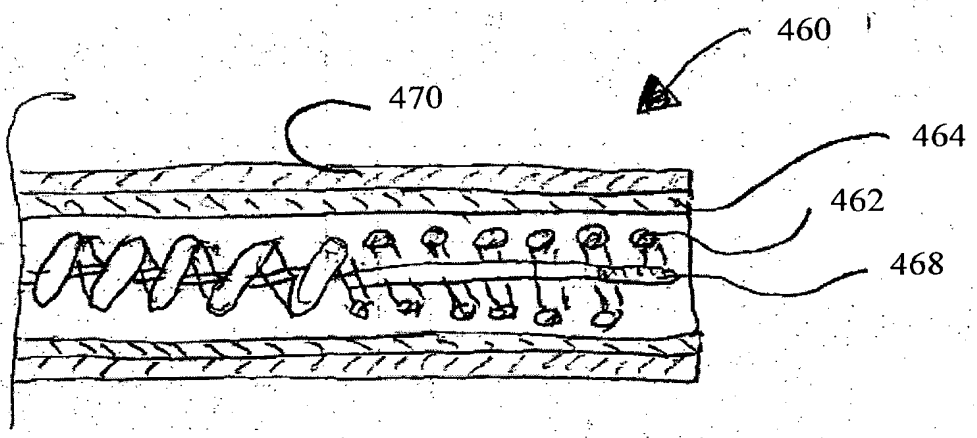


Fig. 20A

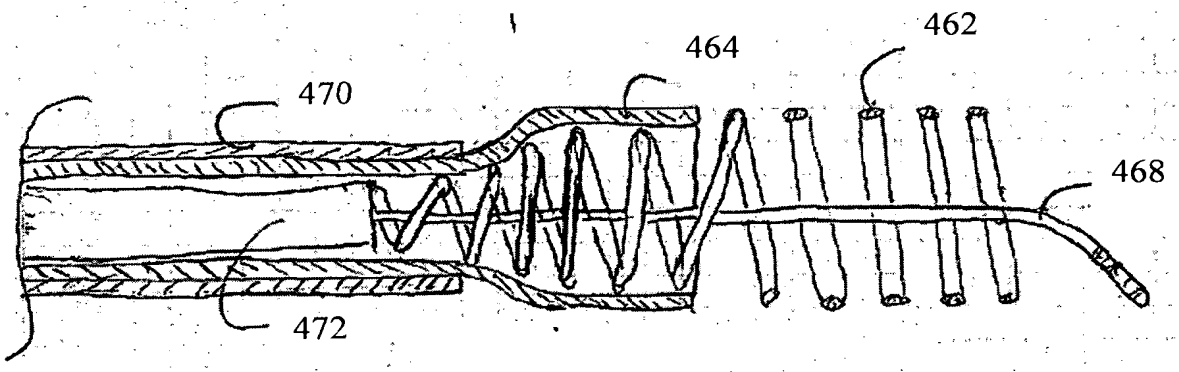


Fig. 20B(1)

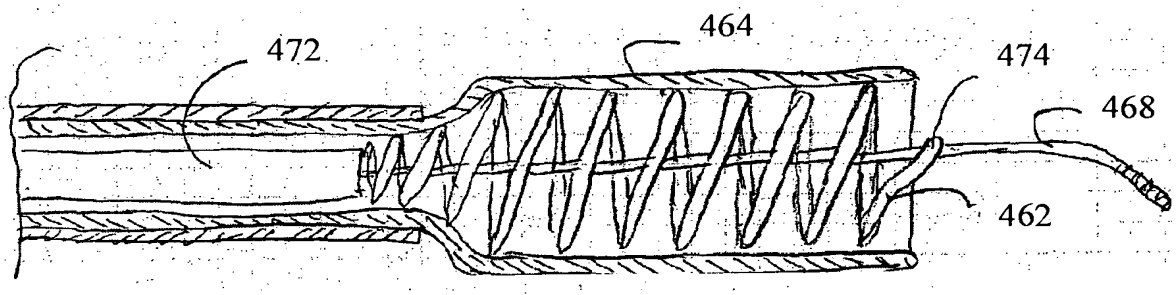


Fig. 20B(2)

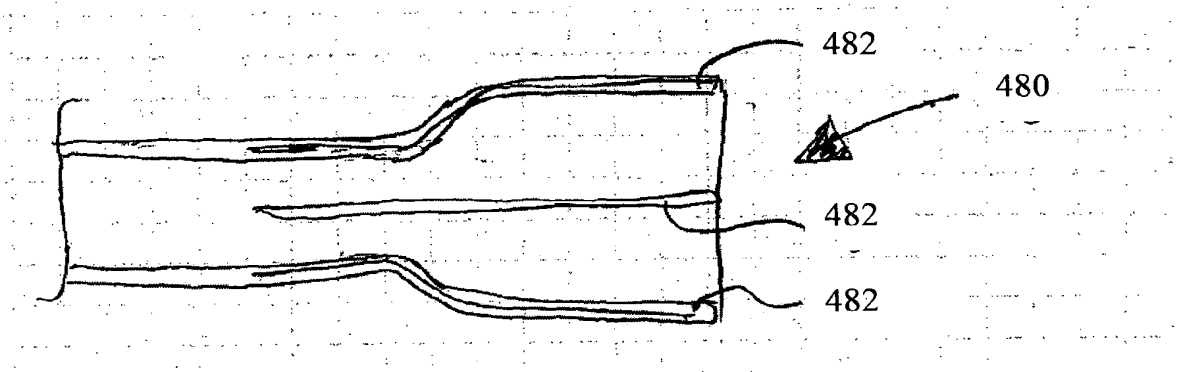


Fig. 21

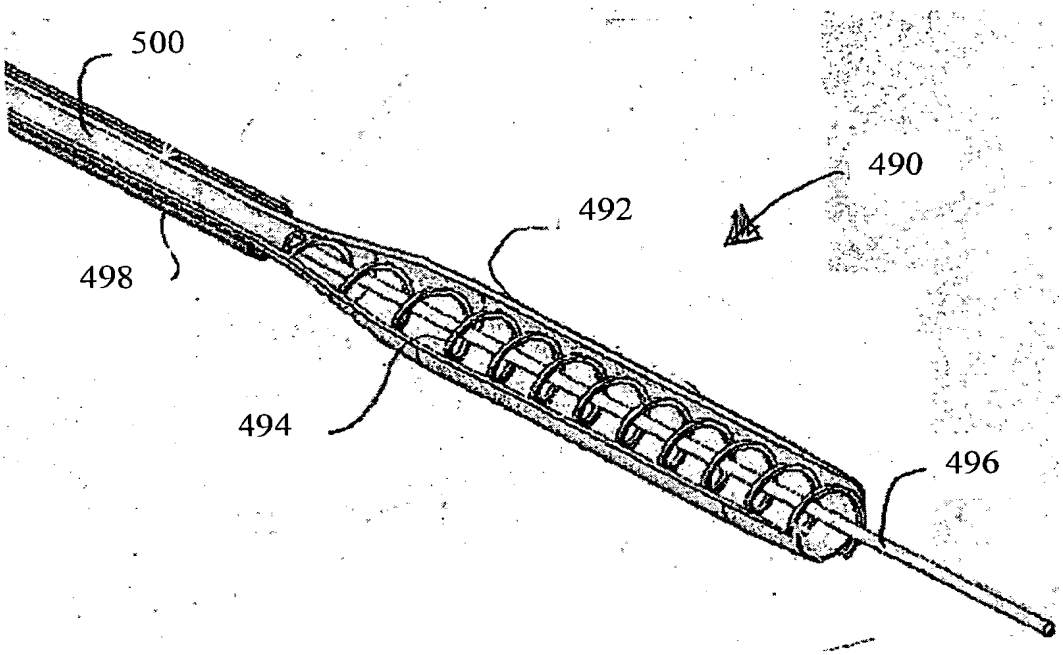


Fig. 22

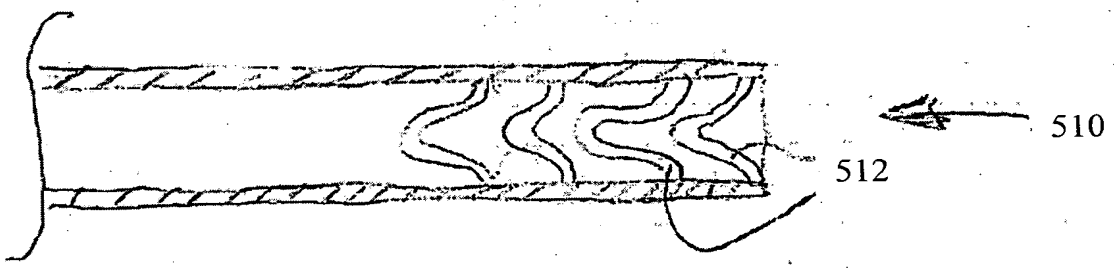


Fig. 23A

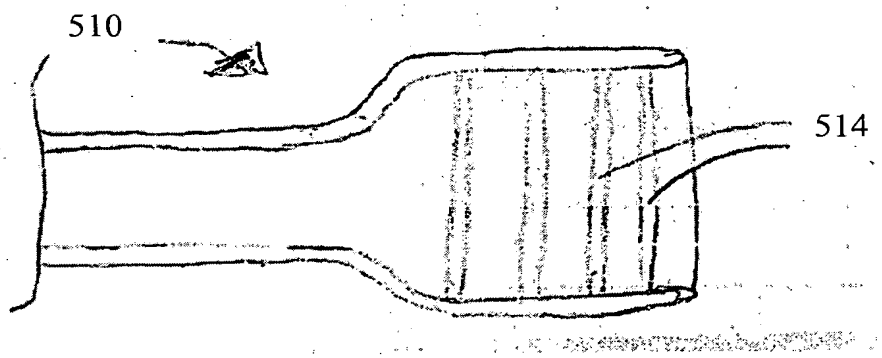


Fig. 23B

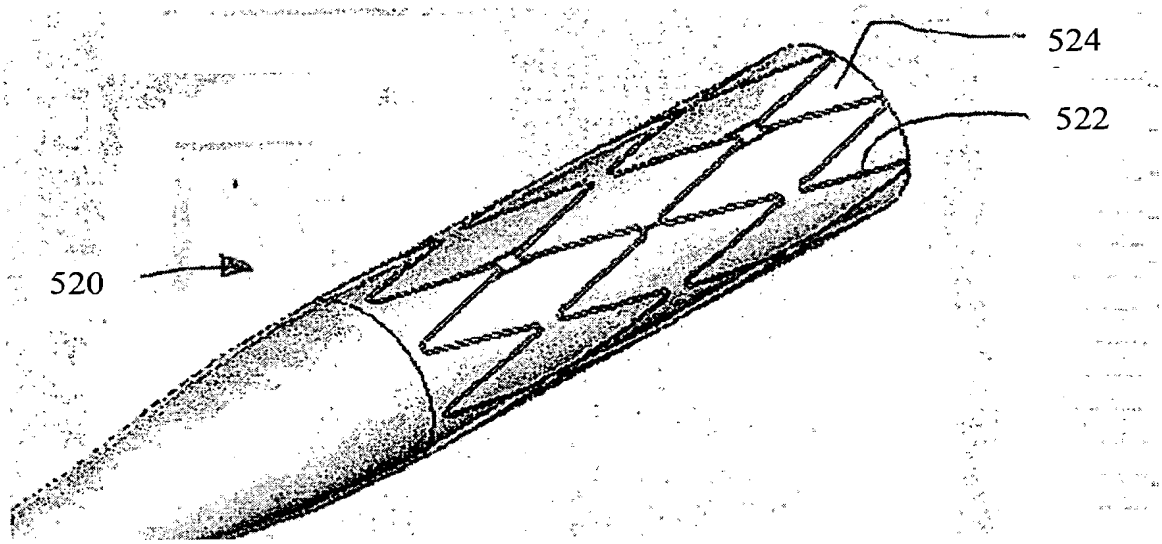


Fig. 24

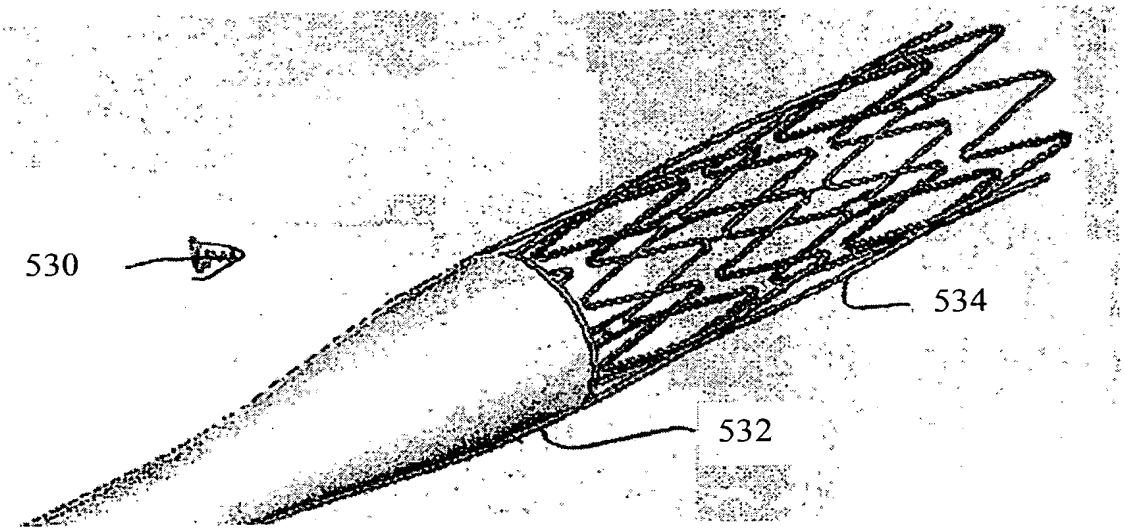


Fig. 25

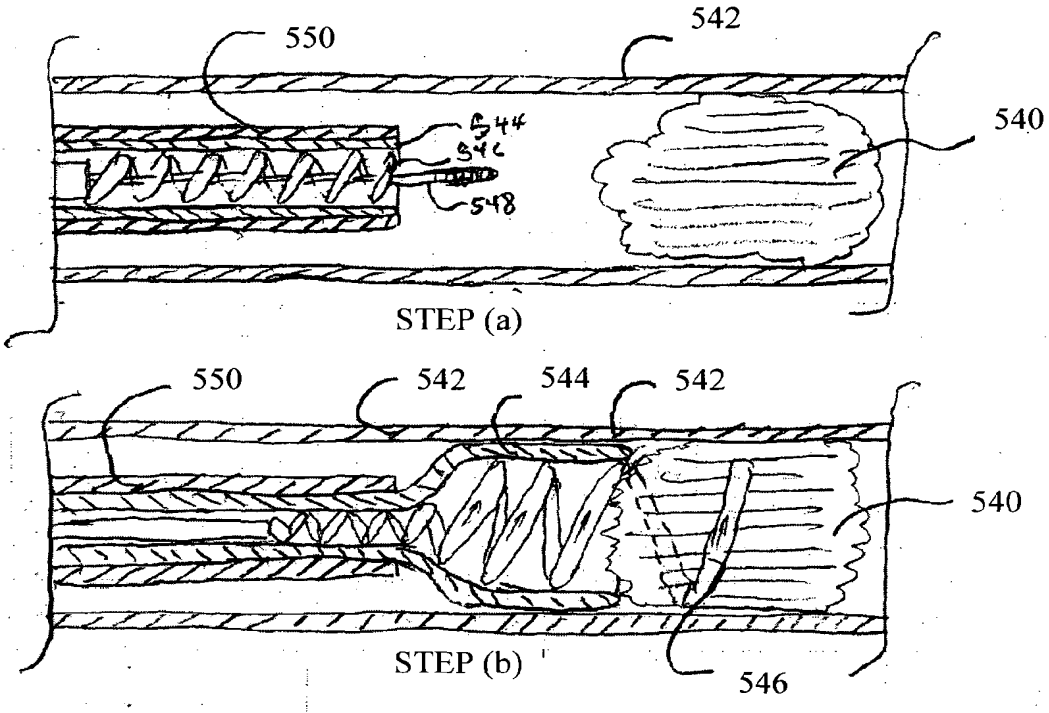


Fig. 26A

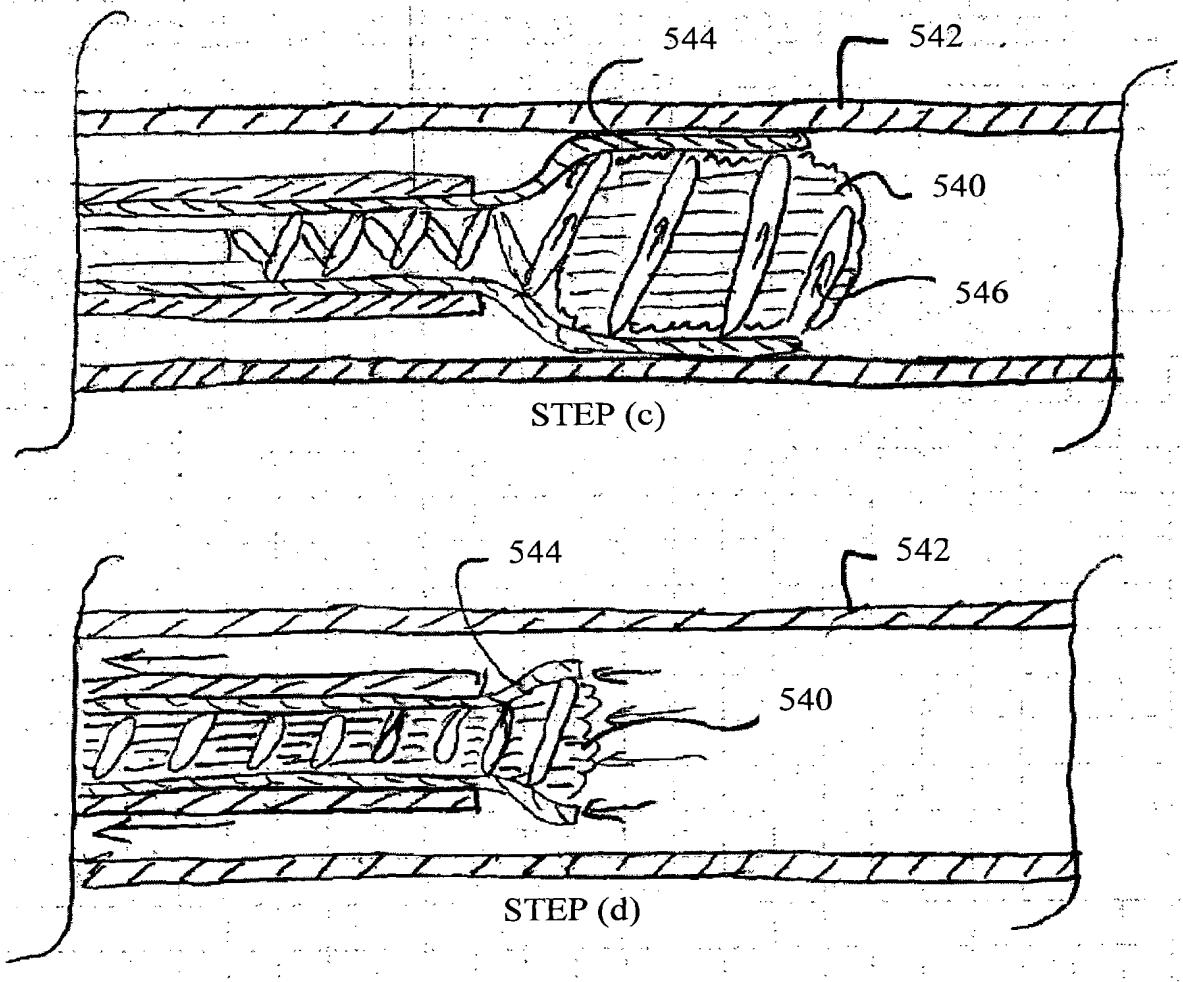


Fig. 26B

(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

(19) Weltorganisation für geistiges Eigentum
Internationales Büro

(43) Internationales Veröffentlichungsdatum
12. Mai 2011 (12.05.2011)

PCT

(10) Internationale Veröffentlichungsnummer
WO 2011/054531 A2

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5. November 2010 (05.11.2010)

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(26) Veröffentlichungssprache: Deutsch

(30) Angaben zur Priorität:
10 2009 052 002.3
5. November 2009 (05.11.2009) DE

(71) Anmelder: **ACANDIS GMBH & CO. KG** [DE/DE]; Kolpingstrasse 5, 76327 Pfinztal (DE).

(72) Erfinder; und

(75) Erfinder/Anmelder *(nur für US)*: **CATTANEO, Giorgio** [DE/DE]; Enzstraße 8, 76199 Karlsruhe (DE).

(74) Anwalt: **KILCHERT, Jochen**; Meissner, Bolte & Partner GbR, Postfach 86 06 24, 81633 München (DE).

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Veröffentlicht:

— *ohne internationalen Recherchenbericht und erneut zu veröffentlichen nach Erhalt des Berichts (Regel 48 Absatz 2 Buchstabe g)*

(54) **Title**: MEDICAL DEVICE FOR THE RECANALISATION OF BODY CAVITIES, SET COMPRISING SUCH A DEVICE, AND METHOD FOR PRODUCING A MEDICAL DEVICE

(54) **Bezeichnung** : MEDIZINISCHE VORRICHTUNG ZUM REKANALISIEREN VON KÖRPERHOHLRÄUMEN, SET UMFASSEND EINE DERARTIGE VORRICHTUNG UND VERFAHREN ZUR HERSTELLUNG EINER MEDIZINISCHEN VORRICHTUNG

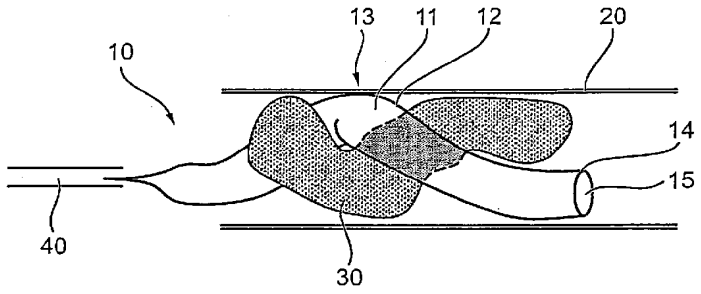


FIG. 1

(57) **Abstract**: The invention relates to a medical device for the recanalisation of body cavities (20). Said device comprises a recanalisation element (10) that can be inserted into the body cavity (20), can be converted from a compressed state into an expanded state and has, in said expanded state, a tubular hollow body (11) such that the body cavity (20) can be recanalised, the outer contour of said recanalisation element (10) forming at least one helical winding (13). In addition, the invention relates to a set comprising such a device and a supply system (40).

(57) **Zusammenfassung**:

[Fortsetzung auf der nächsten Seite]

WO 2011/054531 A2

Die Erfindung betrifft eine medizinische Vorrichtung zum Rekanalisieren von Körperhohlräumen (20) mit einem in den Körperhohlraum (20) einführbaren Rekanalisationselement (10), das von einem komprimierten Zustand in einen expandierten Zustand überführbar ist, und im expandierten Zustand einen rohrförmigen Hohlkörper (11) aufweist derart, dass der Körperhohlraum (20) rekanalisierbar ist, wobei die Außenkontur des Rekanalisationselements (10) wenigstens eine spiralförmige Windung (13) bildet. Ferner betrifft die Erfindung ein Set mit einer derartigen Vorrichtung und einem Zufuhrsystem (40).

Medizinische Vorrichtung zum Rekanalisieren von Körperhohlräumen, Set umfassend eine derartige Vorrichtung und Verfahren zur Herstellung einer medizinischen Vorrichtung

Beschreibung

Die Erfindung betrifft eine medizinische Vorrichtung zum Rekanalisieren von Körperhohlräumen sowie ein Set umfassend eine derartige medizinische Vorrichtung.

Die Bildung von Konkrementen in Körperhohlräumen, insbesondere von Thromben in Blutgefäßen, kann zu einem Verschluss des Körperhohlraums führen. Bei einem Verschluss von Blutgefäßen kommt es zu einer Unterversorgung des nachfolgenden Gewebes mit Nährstoffen und Sauerstoff und in der Folge zu gesundheitlichen Beeinträchtigungen für den Patienten. Um dem entgegenzuwirken, besteht das medizinische Ziel, die Blockierung des Körperhohlraums insbesondere des Blutgefäßes, zu lösen, also das Gefäß zu rekanalisieren.

Eine technische Möglichkeit zur Lösung dieses medizinischen Problems besteht darin, das Blutgefäß im Bereich des Thrombus aufzuweiten, um dadurch eine Strömungspassage am Thrombus vorbei zu eröffnen. Geeignete Vorrichtungen umfassen meist ein stentartiges Gebilde, das durch einen Katheter an den Behandlungsort geführt wird. Der Stent wird im Bereich des Thrombus freigesetzt, wobei eine Radialkraft, die der Stent auf den Thrombus und das Blutgefäß ausübt, bewirkt, dass der Thrombus an die Gefäßwand gedrückt wird. Durch die Öffnungen in der Stentwandung kann das Blut hindurchströmen, so dass eine Rekanalisation erfolgt. Gleichzeitig zur mechanischen Aufweitung des Blutgefäßes wird eine medikamentöse Behandlung durchgeführt, wobei antithrombogene Wirkstoffe in die Blutbahn injiziert werden, die im Bereich des Thrombus ihre Wirkung entfalten. Dieser Vorgang wird als medikamentöse Lyse bezeichnet. Bei der medikamentösen Lyse besteht jedoch die Gefahr, dass der Thrombus nur teilweise aufgelöst wird. In der Folge können unvollständig gelöste Thrombuspartikel durch die Blutströmung mitgerissen werden und weitere Gefäßverschlüsse verursachen.

Für die weitere Behandlung bleiben in diesem Fall zwei Möglichkeiten. Einerseits kann der Stent bzw. das stentartige Gebilde vollständig im Gefäß freigesetzt werden, um sicherzustellen, dass die verbleibenden Thrombusbestandteile nicht durch die Blutströmung weitergeschwemmt werden. In der Folge ist eine langfristige medikamentöse Behandlung des Patienten mit gerinnungshemmenden Mitteln erforderlich, um die Bildung weiterer Blutgerinnsel im Bereich des Stents zu vermeiden. Durch die Verabreichung von gerinnungshemmenden Mitteln erhöht sich allerdings das Blutungsrisiko. Überdies sind mit einem dauerimplantierten Stent weitere Risiken verbunden, beispielsweise die Gefahr der In-Stent-Thrombose sowie entzündliche Reaktionen der Gefäßwand. Andererseits besteht bei verbleibenden Thrombenbestandteilen nach der medikamentösen Behandlung die Möglichkeit, den Thrombus mit Hilfe des stentartigen Gebildes zu entfernen, wobei das stentartige Gebilde aus dem Blutgefäß herausgezogen wird, sobald es sich im Bereich des Stents aufgespannt hat. Dabei wird riskiert, dass sich Thrombusbestandteile beim Transport ablösen, insbesondere beim Übergang in Gefäße mit größerem Querschnittsdurchmesser. Die abgelösten Thrombusbestandteile können in stromabwärts gelegene, kleinere Gefäße geschwemmt werden und zu weiteren Gefäßverschlüssen führen.

Eine weitere medizinische Möglichkeit zur Wiederherstellung der Gewebedurchblutung stromabwärts eines Gefäßverschlusses besteht in der vollständigen Entfernung des Thrombus. Eine dazu geeignete Vorrichtung ist beispielsweise aus der Druckschrift WO 2008/088920 A2 bekannt. Die bekannte Vorrichtung umfasst einen Katheter, in dem ein Führungsdraht längsverschieblich angeordnet ist. Der Führungsdraht umfasst eine expandierbare Spitze, die im expandierten Zustand eine spiralförmige Struktur aufweist. Zur Entfernung eines Thrombus wird der Katheter durch den Thrombus hindurchgeschoben, wobei beim Zurückziehen des Katheters die Spitze des Führungsdrahtes freigesetzt wird. Die Spitze nimmt die spiralförmige, korkenzieherartige Struktur an und verhakt sich mit dem Thrombus, so dass dieser durch Zurückziehen des Führungsdrahtes aus dem Blutgefäß entfernt werden kann. Um zu verhindern, dass sich Bestandteile des Thrombus ablösen und zu weiteren Gefäßverschlüssen führen, ist es notwendig, den Führungsdraht langsam und vorsichtig aus dem Blutgefäß zu ziehen. Diese Notwendigkeit verhindert jedoch eine schnelle Entfernung des Thrombus und somit eine schnelle Rekanalisation des Blutgefäßes. Das medizinische Ziel, eine möglichst schnelle Wiederherstellung des Blutflusses zu erreichen, wird dadurch nicht erreicht.

Die Aufgabe der Erfindung besteht darin, eine Vorrichtung anzugeben, die einerseits eine schnelle und zuverlässige Rekanalisierung eines Körperhohlraums und andererseits eine sichere Entfernung eines Konkrements aus einem Körperhohlraum ermöglicht. Ferner besteht die Aufgabe der Erfindung darin, ein Set umfassend eine derartige Vorrichtung anzugeben bzw. ein Verfahren zur Herstellung einer derartigen Vorrichtung anzugeben.

Erfindungsgemäß wird diese Aufgabe im Hinblick auf die medizinische Vorrichtung durch den Gegenstand des Patentanspruchs 1 im Hinblick auf das Set durch den Gegenstand des Patentanspruchs 21 gelöst und im Hinblick auf das Verfahren durch den Gegenstand des Anspruchs 24 gelöst. Überdies ist im nebengeordneten Anspruch 22 eine weitere medizinische Vorrichtung angegeben.

Die Erfindung beruht auf dem Gedanken, eine medizinische Vorrichtung zum Rekanalisieren von Körperhohlräumen mit einem in den Körperhohlraum einführbaren Rekanalisationselement anzugeben. Das Rekanalisationselement ist von einem komprimierten Zustand in einen expandierten Zustand überführbar. Das Rekanalisationselement weist im expandierten Zustand einen rohrförmigen Hohlkörper auf derart, dass der Körperhohlraum rekanalisierbar ist. Die Außenkontur des Rekanalisationselements bildet, insbesondere im expandierten Zustand, wenigstens eine spiralförmige Windung.

Die erfindungsgemäße Lösung kombiniert also die Vorteile der aus dem Stand der Technik bekannten Systeme in neuartiger Weise, indem einerseits eine schnelle und zuverlässige Rekanalisation und andererseits eine sichere Entfernung des Konkrements erreicht wird. Dazu weist die erfindungsgemäße Vorrichtung einen äußerst einfachen und sicher handhabbaren Aufbau auf, nämlich den spiralförmig gewundenen, rohrförmigen Hohlkörper. Mit anderen Worten umfasst das Rekanalisationselement einen rohrförmigen Hohlkörper, der im Wesentlichen rotationssymmetrisch ausgebildet ist, wobei die Rotationsachse bzw. die Mittellängsachse des Hohlkörpers im expandierten Zustand spiralförmig gewunden ist. Das Rekanalisationselement kann also eine im Wesentlichen korkenzieherartige Außenstruktur aufweisen, wobei die Korkenzieherwindungen durch den rohrförmigen Hohlkörper gebildet sind. Die rotationssymmetrische Konfiguration des Hohlkörpers oder der durch den Hohlkörper gebildeten spiralförmigen Windung schließt nicht aus, dass der Außendurchmesser des Hohlkörpers oder der spiralförmigen Windung variabel ist.

Bei einer bevorzugten Ausführungsform der erfindungsgemäßen Vorrichtung ist der Hohlkörper durch eine rohrförmige Wandung begrenzt, die zumindest in einem proximalen Abschnitt eine Öffnung aufweist. Durch die Öffnung in einem proximalen Abschnitt der Hohlkörperwandung ist sichergestellt, dass der Hohlkörper, der aufgrund seiner rohrförmigen Struktur zumindest an einem distalen Ende des Rekanalisationselements eine axiale Öffnung aufweisen kann, vollständig durchströmbar ist. Bei Verwendung des Rekanalisationselements in einem Blutgefäß wird also durch die Öffnung im proximalen Abschnitt der Wandung sichergestellt, dass die Blutströmung in den Hohlkörper eintreten kann, so dass die Rekanalisationswirkung des Hohlkörpers erreicht ist. Alternativ oder zusätzlich kann in einem distalen Abschnitt des Hohlkörpers eine Öffnung vorgesehen sein.

Generell bildet die Wandung eine in Umfangsrichtung gekrümmte Begrenzungsfläche oder Begrenzungshülle, insbesondere eine im Umfangsrichtung gekrümmte, kontinuierliche bzw. gewebeartige Begrenzungsfläche, die die Außenkontur des Hohlkörpers bestimmt. Die Wandung bildet also eine im Wesentlichen flächige Außenkontur des Hohlkörpers.

Die Wandung kann zumindest abschnittsweise eine perforierte Struktur aufweisen. Die perforierte Struktur gewährleistet eine sichere Rekanalisation, wobei im Gebrauch weitere Strömungskanäle, die einen Kanal um den Thrombus bilden, eröffnet werden. Beispielsweise kann – in Abhängigkeit der gewählten Steigung der spiralförmigen Windung – durch den Hohlkörper mit der perforierten Wandungsstruktur eine Strömungspassage bereitgestellt werden, die vorwiegend entlang der Gefäßwand verläuft. Das bedeutet, dass ein größerer Anteil der Rekanalisationsströmung in axialer Richtung bezüglich des Hohlkörpers durch die perforierte Struktur hindurchtritt. Ein kleinerer Anteil umströmt das Konkrement in Umfangsrichtung durch den spiralförmigen Hohlkanal, den der Hohlkörper bildet. Dazu ist ein besonders flacher Steigungswinkel zweckmäßig. Bei einem steileren Steigungswinkel kann der Hohlkörper hingegen eine Strömungspassage bilden, die sich in Bezug auf das Körperhohlgefäß nicht vorwiegend in axialer Richtung erstreckt, sondern primär oder nahezu ausschließlich eine Umfangskomponente aufweist. Es ist auch möglich, dass sich die axiale Strömungspassage entlang der Gefäßwand und die sich über den Umfang erstreckende Strömungspassage überlagern. Die perforierte Struktur bietet den weiteren Vorteil, dass eine zusätzliche medikamentöse Behandlung, beispielsweise eine Thrombolyse, effizienter durchführbar ist, da über die perforierte

Struktur ein im Wesentlichen großflächiger Zugang, also eine relativ große Angriffsfläche, zum Konkrement bereitgestellt wird.

In diesem Zusammenhang wird darauf hingewiesen, dass sich die Anzahl der fadenförmigen Elemente auf eine Querschnittsebene des Hohlkörpers bezieht. Dabei ist nicht ausgeschlossen, dass das Rekanalisationselement beispielsweise insgesamt aus der Hälfte der angegebenen fadenförmigen Elemente hergestellt ist, die jeweils an einem Ende des Hohlkörpers umgelenkt und zurückgeführt sind.

Bei einer bevorzugten Ausführungsform umfasst die geflochtene Gitterstruktur fadenförmige Elemente, die an einem distalen Ende der Gitterstruktur geschlossene Schlaufen bilden. Durch die Schlaufen wird ein atraumatisches Ende der Gitterstruktur bereitgestellt, wodurch Verletzungen der Gefäßwand vermieden werden.

Vorzugsweise umfasst die Wandung, insbesondere die perforierte Struktur, ein lasergeschnittenes oder in Dünnschichttechnik hergestelltes, insbesondere gesputtertes, Strukturelement. Besonders bevorzugt ist es, wenn die Wandung, insbesondere die perforierte Struktur, eine geflochtene Gitterstruktur aufweist. Dabei kann die geflochtene Gitterstruktur wenigstens 8, insbesondere wenigstens 12, insbesondere wenigstens 16, insbesondere wenigstens 18, insbesondere wenigstens 20, insbesondere wenigstens 24, insbesondere wenigstens 32, insbesondere wenigstens 36, insbesondere wenigstens 38, fadenförmige Elemente umfassen. Die vorgenannten Ausführungsbeispiele haben den gemeinsamen Vorteil einer einfachen Herstellung, wobei die Verwendung einer geflochtenen Gitterstruktur zusätzlich eine besonders geeignete Feinmaschigkeit ermöglicht. Dadurch wird eine besonders effektive Rekanalisationswirkung erreicht, wobei gleichzeitig durch die feinen Maschen sichergestellt ist, dass sich möglicherweise ablösende Thrombusbestandteile nicht in den Strömungskanal bzw. die Strömungspassage begeben. Ein weiterer Vorteil der geflochtenen Gitterstruktur besteht darin, dass damit eine relativ hohe Flexibilität des Hohlkörpers erreicht wird. Dadurch ist es besonders effizient möglich, das Rekanalisationselement in einen komprimierten, insbesondere gestreckten, und einen expandierten, insbesondere spiralförmigen, Zustand zu überführen.

Erfindungsgemäß ist vorgesehen, dass das Rekanalisationselement, insbesondere der Hohlkörper, von einem komprimierten Zustand in einen expandierten Zustand überführbar ist. Vorteilhafterweise weist der Hohlkörper im komprimierten Zustand innerhalb eines Zufuhrsystems ein geradliniges bzw. zylinderförmiges Profil auf. Bei der

Expansion nimmt der Hohlkörper bzw. das Rekanalisationselement die spiralförmige Windung an. Dabei kann die spiralförmige Windung unterschiedliche Steigungen aufweisen. Eine größere Steigung hat den Vorteil, dass die Länge des Hohlkörpers, also die Längserstreckung des Hohlkörpers im komprimierten Zustand, vergleichsweise klein ist. Das bedeutet, dass auch das Verhältnis zwischen Länge des Rekanalisationselements, also Länge über alle Windungen, zur Länge des Hohlkörpers verhältnismäßig klein ist, wobei der Hohlkörper grundsätzlich eine größere Länge aufweist als das gesamte Rekanalisationselement.

Der Vorteil eines relativ kleinen Längenverhältnisses bzw. eines relativ kurzen Hohlkörpers besteht darin, dass die Reibung zwischen der Wandung des Hohlkörpers im komprimierten Zustand und einem Zufuhrsystem reduziert ist, da die Berührungsfläche zwischen Zufuhrsystem und Hohlkörper relativ klein ist. Die Schiebekraft bzw. Zugkraft, die erforderlich ist, um das Rekanalisationselement bzw. den Hohlkörper im Zufuhrsystem zu bewegen, ist daher relativ gering, wodurch die Handhabbarkeit verbessert wird. Um dies zu erreichen, hat es sich als besonders vorteilhaft erwiesen, wenn die spiralförmige Windung eine Steigung von wenigstens 10 mm, insbesondere wenigstens 15mm, insbesondere wenigstens 20 mm, insbesondere wenigstens 25 mm, insbesondere wenigstens 30 mm, aufweist. Eine Steigung von wenigstens 30 mm ist besonders vorteilhaft bei einem Einsatz der medizinischen Vorrichtung in Körpergefäßen mit einem Gefäßdurchmesser von höchstens 3 mm. Bei Gefäßdurchmessern von höchstens 5 mm, insbesondere im Bereich zwischen 3 mm und 5 mm, hat sich eine Steigung der spiralförmigen Windung von wenigstens 30 mm, insbesondere wenigstens 40 mm, insbesondere wenigstens 50 mm als vorteilhaft erwiesen. Bei Gefäßen bzw. Hohlräumen, die einen Querschnittsdurchmesser aufweisen, der größer als 5 mm beträgt, wird vorzugsweise eine medizinische Vorrichtung eingesetzt, bei der die spiralförmige Windung des Hohlkörpers eine Steigung von wenigstens 30 mm, insbesondere wenigstens 40 mm, insbesondere wenigstens 50 mm, insbesondere wenigstens 60 mm, insbesondere wenigstens 70 mm, insbesondere wenigstens 80 mm, insbesondere wenigstens 90 mm, insbesondere wenigstens 100 mm aufweist.

Alternativ kann es vorteilhaft sein, wenn das Rekanalisationselement eine höhere Anhaftaffinität zum Thrombus bzw. allgemein zu dem Konkrement aufweist. Dies kann beispielsweise durch eine höhere Anzahl von spiralförmigen Windungen erreicht werden. Dabei weisen die einzelnen Windungen eine vergleichsweise kleine Steigung auf. Besonders bevorzugt ist eine Steigung der spiralförmigen Windung von höchstens 30

mm, insbesondere höchstens 20 mm, insbesondere höchstens 10 mm, insbesondere höchstens 8 mm, insbesondere höchstens 7 mm, insbesondere höchstens 6 mm, insbesondere höchstens 5 mm, insbesondere höchstens 3 mm, insbesondere höchstens 2 mm. Dabei beziehen sich Angaben hinsichtlich der Steigung der spiralförmigen Windung im Rahmen dieser Anmeldung generell auf eine volle Windung, also eine Windung, die einen Umlaufwinkel von 360° aufweist. Die Angabe der Steigung bezieht sich also generell auf eine volle Umdrehung des Hohlkörpers um eine zentrale Windungsachse.

Um die vorgenannten Vorteile und Wirkungen zu erreichen, ist es ferner bevorzugt, wenn das Verhältnis zwischen der Steigung der spiralförmigen Windung und einem Querschnittsdurchmesser des Hohlkörpers höchstens 1000 %, insbesondere höchstens 200 %, insbesondere höchstens 180 %; insbesondere höchstens 160 %, insbesondere höchstens 150 %, insbesondere höchstens 140 %, insbesondere höchstens 130 %, insbesondere höchstens 120 %, beträgt. Die spiralförmige Windung kann außerdem einen Steigungswinkel aufweisen, der wenigstens 45°, insbesondere wenigstens 60°, insbesondere wenigstens 70°, insbesondere wenigstens 80°, beträgt. Alternativ kann der Steigungswinkel höchstens 45°, insbesondere höchstens 40°, insbesondere höchstens 35°, insbesondere höchstens 30°, insbesondere höchstens 25°, insbesondere höchstens 20°, betragen.

Bei einer bevorzugten Ausführungsform der erfindungsgemäßen Vorrichtung weist der Hohlkörper im expandierten Zustand zumindest abschnittsweise unterschiedliche Querschnittsdurchmesser auf. Das ermöglicht einen besonders flexiblen Einsatz des Rekanalisationselements.

Vorzugsweise weist der Hohlkörper im expandierten Zustand an einem distalen Ende einen größeren Querschnittsdurchmesser als in einem proximalen Abschnitt auf. Eine derartige Konfiguration ermöglicht eine besonders stabile Anhaftung des Hohlkörpers bzw. allgemein des Rekanalisationselements an einem Konkrement. Überdies ermöglicht der größere Querschnittsdurchmesser an einem distalen Ende eine verbesserte Abdichtung des Rekanalisationselements mit einer Gefäßwand, insbesondere beim Zurückziehen des Rekanalisationselements, wobei das Konkrement durch größer werdende Körperhohlräume gezogen wird. Gleichzeitig wird die Reibung des Rekanalisationselements an der Gefäßwand reduziert. Eine Verletzung von Gefäßen, insbesondere ein Reizung der Gefäßwände, wird somit vermieden.

Eine besonders bevorzugte Ausgestaltung der erfindungsgemäßen Vorrichtung sieht vor, dass der Hohlkörper im expandierten Zustand an einem distalen Ende des Rekanalisationselements einen Filterabschnitt bildet. Der Filterabschnitt kann beispielsweise durch einen vergrößerten Querschnittsdurchmesser am distalen Ende gebildet sein. Der Hohlkörper bzw. die Wandung des Hohlkörpers kann also an einem distalen Ende eine Filterfunktion übernehmen, so dass sich ablösende Konkrementpartikel aufgefangen werden. Die Bildung von Emboli bzw. weiteren Gefäßverschlüssen, insbesondere stromabwärts des Behandlungsortes, wird dadurch vermieden.

Vorzugsweise ist das Rekanalisationselement proximal mit einem Zufuhrelement, insbesondere einem Führungsdraht, verbunden. Das Zufuhrelement ermöglicht auf einfache Weise die sichere Handhabung des Rekanalisationselements. Überdies ermöglicht das Zufuhrelement, insbesondere der Führungsdraht, eine haptische Rückmeldung an den Anwender des Rekanalisationselements, so dass eine feinfühlige und genaue Rekanalisation ermöglicht ist.

Das Rekanalisationselement kann ferner eine einen Wirkstoff freisetzende, insbesondere antithrombogene, Beschichtung aufweisen. Dadurch wird auf besonders vorteilhafte Weise die mechanische Rekanalisation und Entfernung eines Konkrements mit einer medikamentösen Behandlung unterstützt. Bei der Entfernung von Thromben aus Blutgefäßen kann insbesondere eine antithrombogene Beschichtung vorteilhaft sein, die eine Blutgerinnung im Bereich der porösen Struktur der Wandung des Hohlkörpers bzw. in den Maschen der Gitterstruktur verhindert und die Aufrechterhaltung der rekanalisierten Strömungspassage sicherstellt.

Bei einer weiteren bevorzugten Ausführungsform ist vorgesehen, dass das Rekanalisationselement zumindest abschnittsweise eine fluiddichte Abdeckung aufweist. Die Abdeckung kann beispielsweise einen Kunststoff, vorzugsweise Polyurethan oder Elasteon, umfassen. Die Abdeckung kann sich sowohl abschnittsweise als auch vollständig über das Rekanalisationselement, insbesondere den Hohlkörper bzw. die Wandung des Hohlkörpers, erstrecken. Durch die fluiddichte Abdeckung wird das Risiko von weiteren Gefäßverschlüssen durch Ablösen von Konkrementpartikeln vermindert.

Die fluiddichte Abdeckung kann ein oder mehrere Saugöffnungen umfassen, die im Gebrauch einem Konkrement zugewandt sind. Die Saugöffnungen sind also vorteilhafterweise auf einem Innenumfang bzw. einer Innenkontur des Rekanalisations-

elements angeordnet. Beispielsweise kann die Wandung des Hohlkörpers eine fluiddichte Beschichtung umfassen, wobei in einer den Innenumfang des gesamten Rekanalisationselements definierten Wandungsebene die Saugöffnungen angeordnet sind. Die Saugöffnungen können beispielsweise durch Wandungsbereiche gebildet sein, die keine Abdeckung aufweisen bzw. in denen die Abdeckung geöffnet ist, so dass die Wandungsstruktur, beispielsweise eine geflochtene Gitterstruktur, die als Trägerstruktur für die Abdeckung dient, freigelegt ist. Generell ist vorgesehen, dass die Saugöffnungen eine Fluidverbindung zwischen dem Hohlraum, der durch den Hohlkörper gebildet ist, und dem Innenraum des Rekanalisationselements, also dem durch die spiralförmig gewundene Struktur begrenzten Raumvolumen, in dem das Konkrement im Gebrauch angeordnet ist, bildet. Durch die Saugöffnungen wird erreicht, dass das Konkrement an das Rekanalisationselement angesaugt bzw. umgekehrt das Rekanalisationselement, insbesondere der Hohlkörper, an das Konkrement angesaugt wird. Damit wird sichergestellt, dass sich das Konkrement nicht vom dem Rekanalisationselement löst, insbesondere beim Abtransport des Konkrements durch größere Körperhohlräume.

Bei einer weiteren bevorzugten Ausführungsform ist das Rekanalisationselement an einem distalen Ende mit einem Betätigungselement verbunden. Das Betätigungselement erstreckt sich im Wesentlichen längsaxial entlang des Rekanalisationselements. Vorteilhafterweise verläuft das Betätigungselement zumindest teilweise entlang einer Außenkontur und/oder entlang einer Innenkontur des Rekanalisationselements. Mit Hilfe des Betätigungselements wird ermöglicht, dass das Rekanalisationselement in längsaxialer Richtung im Sinne einer Längenänderung betätigbar ist. Durch das Betätigungselement kann das Rekanalisationselement also in Längsrichtung komprimiert werden bzw. allgemein die Steigung der spiralförmigen Windung beeinflusst werden. Beispielsweise kann das Rekanalisationselement durch das Betätigungselement derart betätigbar sein, dass das Rekanalisationselement im Gebrauch streckbar ist. Auf diese Weise ändert sich der Innendurchmesser, also die Dimension der Innenkontur, des Rekanalisationselements, wodurch eine verbesserte Anhaftung bzw. Fixierung des Konkrements erreichbar ist. Dabei kann das Betätigungselement längsaxial durch das Rekanalisationselement, also entlang einer Innenkontur, oder außerhalb des Rekanalisationselements, insbesondere entlang einer Außenkontur, verlaufen.

Gemäß einem nebengeordneten Aspekt beruht die Erfindung auf dem Gedanken, ein Set anzugeben, das die zuvor beschriebene medizinische Vorrichtung und ein

Zufuhrsystem für eine derartige Vorrichtung umfasst. Aus Sterilitätsgründen ist ein derartiges Set vorteilhaft.

Die Erfindung wird im Folgenden anhand von Ausführungsbeispielen unter Bezugnahme auf die beigefügten, schematischen Zeichnungen näher erläutert. Darin zeigen:

Fig. 1:	eine Seitenansicht einer erfindungsgemäßen medizinischen Vorrichtung gemäß einem bevorzugten Ausführungsbeispiel im Gebrauch;
Fig. 2:	eine Seitenansicht einer erfindungsgemäßen medizinischen Vorrichtung gemäß einem weiteren Ausführungsbeispiel im Gebrauch;
Fig. 3a und 3b:	jeweils eine Seitenansicht der medizinischen Vorrichtung gemäß Fig. 2 mit unterschiedlichen Steigungen der spiralförmigen Windung; und
Fig. 4 bis 7:	jeweils eine Seitenansicht einer erfindungsgemäßen medizinischen Vorrichtung gemäß einem weiteren Ausführungsbeispiel im Gebrauch;
Fig. 8	eine Tabelle mit bevorzugten Größenverhältnissen der medizinischen Vorrichtung und
Fig. 9	eine Seitenansicht einer medizinischen Vorrichtung nach einem weiteren erfindungsgemäßen Ausführungsbeispiel mit verschlossenem distalen Ende.

In Fig. 1 ist ein Ausführungsbeispiel der medizinischen Vorrichtung gezeigt, wobei die medizinische Vorrichtung ein Rekanalisationselement 10 aufweist, das im Gebrauch, wie in Fig. 1 dargestellt, einen expandierten Zustand aufweist. Dabei bildet das Rekanalisationselement 10 im expandierten Zustand einen Hohlkörper 11, der im Wesentlichen rohrförmig ausgebildet ist. Das Rekanalisationselement 10 bildet mit anderen Worten einen Hohlkanal, der durch eine rohrförmige Wandung 12 begrenzt ist. Der Hohlkörper 11 bzw. allgemein das Rekanalisationselement 10 ist ferner spiralförmig

gewunden, wobei das Rekanalisationselement 10 bzw. der Hohlkörper 11 bei dem Ausführungsbeispiel gemäß Fig. 1 eine einzige spiralförmige Windung 13 aufweist. Der Hohlkörper 11 bzw. allgemein das Rekanalisationselement 10 bildet eine Spirale.

Die medizinische Vorrichtung ist in Fig. 1 im Gebrauch dargestellt, also im Zusammenwirken mit einem Konkrement 30 in einem Körperhohlraum 20. Der Körperhohlraum 20 kann beispielsweise ein Blutgefäß umfassen. In diesem Fall bildet das Konkrement 30 vorzugsweise ein Blutgerinnsel bzw. einen Thrombus. Durch die spiralförmige Windung 13 wird das Rekanalisationselement 10 mit dem Konkrement 30 verschränkt bzw. allgemein formschlüssig mit dem Konkrement 30 verbunden. Vorzugsweise umhüllt das Rekanalisationselement 10 bzw. der Hohlkörper 11 das Konkrement 30.

Um eine effiziente Rekanalisation zu bewirken, weist das Rekanalisationselement 10 bzw. der Hohlkörper 11 an einem distalen Ende 14 eine axiale Öffnung 15 auf. Ferner kann das Rekanalisationselement 10 an einem proximalen Ende bzw. in einem proximalen Abschnitt 18 eine Öffnung aufweisen, so dass Fluide vollständig durch den Hohlkörper 11 strömen können. Die proximale Öffnung kann im Wesentlichen radial bezüglich des Hohlkörpers 11 ausgerichtet sein. Vorzugsweise ist die proximale Öffnung in der Wandung 12 angeordnet. Es ist auch möglich, dass die Wandung 12 des Hohlkörpers 11 eine perforierte Struktur aufweist. Das bedeutet, dass die Wandung 12 zumindest abschnittsweise ein oder mehrere Öffnungen umfasst, durch die Körperfluide, insbesondere Blut in den Hohlkörper 11 einströmen bzw. allgemein durch die Wandung 12 hindurchströmen können. Zumindest im proximalen Abschnitt 18 des Rekanalisationselements kann eine derartige perforierte Struktur vorgesehen sein.

Generell kann der Hohlkörper 11 wenigstens eine Eintrittsöffnung und wenigstens eine Austrittsöffnung umfassen, um die Durchströmbarkeit des Hohlkörpers 11 sicherzustellen. Die Eintritts- und/oder Austrittsöffnungen können sowohl axiale Öffnungen, als auch radiale Öffnungen, die in der Wandung 12 ausgebildet sind, umfassen. Die Durchströmbarkeit des Hohlkörpers 11 kann auf verschiedene Arten erfolgen. Wenn der Hohlkörper in der Form eines Gittergeflechts ohne Abdeckung ausgebildet ist, wird durch die Spiralform des Hohlkörpers ein Ringkanal gebildet, der sich um das mittig vom Hohlkörper 11 gehaltene Konkrement erstreckt. Die Eintritts- und Austrittsöffnung des Höhlkörpers 11 erfolgt somit durch die Zellöffnungen bzw. Maschen der Gitterstruktur, die die Wandung des Hohlkörpers 11 bildet. Der

Hohlkörper 11 ist somit seitlich durchströmbar. Wie beispielsweise in den Figuren 1 bis 6 gezeigt, weist das proximale Ende 21 des Hohlkörpers 11 einen Übergangsbereich 21a auf, der die von der Katheterspitze in distaler Richtung gesehene erste Windung 13 des spiralförmigen Hohlkörpers 11 mit dem Führungsdraht 41 verbindet. Der Übergangsbereich 21a verjüngt sich in proximaler Richtung derart, dass die Drähte bzw. allgemein die die Gitterstruktur bildenden Gitterelemente zusammenlaufen und in den Führungsdraht übergehen oder mit diesem verbunden sind. In distaler Richtung weitet sich der Übergangsbereich 21a bis der Durchmesser des Übergangsbereichs 21a dem Durchmesser der ersten Windung 13 der Spirale des Hohlkörpers 11 entspricht. Im Übergangsbereich 21a ist die Wandung zipfelartig ausgebildet.

Der Übergangsbereich 21a kann sich axial erstrecken. Dies bedeutet, dass der Übergangsbereich 21a eine im wesentlichen geradlinig verlaufende und daher nicht spiralförmig gekrümmte Mittelachse aufweist. Diese Form ist nicht zwingend. Der Übergangsbereich 21a kann eine Spirale bilden, die die Spiralform des Hohlkörpers 11 im Bereich der Windungen 13 fortsetzt. Im Übergangsbereich 21a nimmt der Außendurchmesser der Spirale in proximaler Richtung ab. Dabei kann die Spiralform des Übergangsbereichs 21a am distalen Ende des Führungsdrahtes 41 beginnen.

Aufgrund der sich verjüngenden Form des Übergangsbereichs 21a wird im implantierten Zustand die Wandung seitlich angeströmt. Die Blutströmung gelangt durch die Zellöffnungen der Gitterstruktur ins Lumen des Hohlkörpers 11. In diesem Sinne ist der Hohlkörper 11 durchströmbar. Die Eintrittsöffnungen bilden dabei keine geometrisch definierte einheitliche Gesamtöffnung. Die Gesamtöffnung für den Eintritt der Blutströmung setzt sich aus den seitlich angeströmten bzw. seitlich anströmbaren Zellöffnungen der Gitterstruktur im Übergangsbereich 21a zusammen und ist in diesem Sinne geometrisch undefiniert.

Durch den Übergangsbereich 21a wird überdies erreicht, dass zwischen dem Zufuhrsystem 40 bzw. dem Führungsdraht 41 einerseits und der ersten Windung 13 andererseits ein Abstand gebildet ist. Dieser Abstand bewirkt, dass im implantierten Zustand ein freier, d.h. vom Konkrement nicht überdeckter Abschnitt des Hohlkörpers 11 vorhanden ist, der als Eintrittsöffnung bzw. als eine Vielzahl von Eintrittsöffnungen (Zellöffnungen) fungiert.

Im Übergangsbereich 21a können im Fall eines Geflechts die Drähte paarweise oder mehrfach zusammengeführt sein, um die Zellöffnungen zu vergrößern. Die zusammengeführten Drähte können verdrillt sein.

Zusätzlich oder alternativ kann das proximale Ende des Hohlkörpers eine geometrisch definierte Eintrittsöffnung aufweisen, die einen quer zur Blutströmung bzw. zur Mittelachse des Hohlkörpers verlaufenden Durchströmungsquerschnitt bildet. Die Eintrittsöffnung kann sich geneigt zur Mittelachse des Hohlkörpers 11 erstrecken und einen wiedereinziehbare Abschlusskante bilden. Ein Beispiel hierfür ist in den Figuren 2 bis 13 und den zugehörigen Beschreibungstextstellen, insbesondere auf S. 15 bis 31 der DE 10 2009 056 450 offenbart, die auf die Anmelderin zurückgeht und die durch Verweis in diese Anmeldung mit eingeschlossen ist.

Das distale Ende 22 kann in entsprechender Weise wie das proximale Ende 21 ausgeführt sein, s. Fig. 6, wobei sich die Verjüngung in distaler Richtung erstreckt. Die vorgenannten Merkmale des Übergangsbereichs 21a werden auch im Zusammenhang mit dem distalen Ende 22 offenbart, wobei die Spitze des distalen Bereichs 22 frei ist.

Anstelle der Verjüngung gemäß Fig. 6 kann das distale Ende 22 eine Aufweitung aufweisen, deren Durchmesser größer ist als der Durchmesser des Hohlkörpers 11 im mittleren Bereich des Rekanalisationselements 10. Es ist auch möglich, dass der Durchmesser des Hohlkörpers 11 entlang der Spirale konstant bleibt. Diese Formen des distalen Endes 22 werden im Zusammenhang mit einer Gitterstruktur ohne Abdeckung offenbart, deren Wandung seitlich durchströmbar ist sowie im Zusammenhang mit einer Gitterstruktur mit Abdeckung..

Die Eintrittsöffnung bzw. die Austrittsöffnung kann am proximalen bzw. distalen Ende des Hohlkörpers 11 im Sinne einer Rohröffnung vorgesehen sein. Die Öffnung ist geometrisch definiert und weist beispielsweise ein kreisförmiges Querschnittsprofil auf. Dabei kann vorgesehen sein, dass die Eintrittsöffnung und/oder die Austrittsöffnung verschließbar sind. Die Verschließbarkeit beispielsweise der Austrittsöffnung hat den Vorteil, dass Medikamente in den Hohlkörper eingebracht werden können, die dort während einer bestimmten Zeitdauer verbleiben und dort auf den Thrombus bzw. das eingefangene Konkrement einwirken. Danach kann die Austrittsöffnung geöffnet werden, so dass das Gefäß rekanalisiert wird. Die vorstehende Beschreibung der Eintritts- bzw. Austrittsöffnung wird im Zusammenhang

mit allen Ausführungsbeispielen bzw. generell im Zusammenhang mit der Erfindung offenbart.

Das Körperfluid kann durch die perforierte Struktur im proximalen Abschnitt 18 in den Hohlkörper einströmen und das Konkrement 30 durch den Hohlkanal, der durch den Hohlkörper 11 gebildet ist, passieren. An der axialen Öffnung 15 kann das Körperfluid in einem Bereich austreten, der stromabwärts des Konkrements 30 angeordnet ist. Auf diese Weise ist das Körpergefäß bzw. der Körperhohlraum 20 rekanalisiert. Die perforierte Struktur kann sich auch über weitere Abschnitte des Hohlkörpers 11, beispielsweise über die gesamte Wandung 12, erstrecken. Insbesondere ist es vorteilhaft, wenn die Wandung 12 vollständig eine geflochtene Gitterstruktur aufweist. Eine geflochtene Gitterstruktur ermöglicht eine besonders kleine Komprimierung des Rekanalisationselements 10 und erleichtert dessen Zufuhr in einen kleinen Körperhohlraum. Ferner kann durch die geflochtene Gitterstruktur eine besonders hohe Feinmaschigkeit erreicht werden, so dass ein Eindringen von Konkrementpartikeln in den Hohlkörper 11 und somit in den rekanalisierten Strömungskanal vermieden wird.

Hinsichtlich der Feinmaschigkeit ist es vorteilhaft, wenn die Maschengröße bzw. Porengröße höchstens 1 mm, insbesondere höchstens 0,8 mm, insbesondere höchstens 0,6 mm, insbesondere höchstens 0,5 mm, insbesondere höchstens 0,4 mm, insbesondere höchstens 0,3 mm, insbesondere höchstens 0,2 mm, beträgt. Dabei entspricht die Porengröße dem Durchmesser eines virtuellen, größtmöglichen Kreises, der in der Umfangsebene bzw. Wandungsebene des Hohlkörpers 11 in eine Masche bzw. Zelle hineinbeschrieben werden kann. Die Porengröße bzw. Maschengröße kann dabei im distalen Bereich des Hohlkörpers 11, insbesondere in Filterabschnitt 16 größer oder kleiner sein als in einem mittleren Abschnitt bzw. funktionalen Bereich des Rekanalisationselements 10. Die hohe Feinmaschigkeit, also die vorgenannten, kleinen Porengrößen, ermöglichen eine Verbesserung der Filterfunktion. Überdies wird mit einer derartigen kleinen Porengröße bzw. Maschengröße die Durchlässigkeit der Wandung 12 für Körperfluide, insbesondere Blut, reduziert, so dass die Rekanalisationsströmung vorzugsweise entlang der Wandung 12, insbesondere innerhalb des durch den Hohlkörper 11 gebildeten Hohlkanals, geleitet wird.

Es ist auch möglich, dass die Porengröße bzw. Maschengröße wenigstens 0,2 mm, insbesondere wenigstens 0,4 mm, insbesondere wenigstens 0,6 mm, insbesondere wenigstens 0,8 mm, insbesondere wenigstens 1,0 mm, insbesondere wenigstens

1,2 mm, insbesondere wenigstens 1,5 mm, insbesondere wenigstens 2,0 mm, beträgt. Dadurch wird ein höherer Durchfluss durch die Wandung 12 bzw. die Maschen der Gitterstruktur, die die Wandung 12 bilden, ermöglicht. Auf diese Weise kann eine zusätzliche Strömungspassage für die Rekanalisationsströmung bereitgestellt werden, die sich beispielsweise zwischen dem Konkrement 30 und der Gefäßwand des Körperhohlraums 20 erstreckt (Fig. 3b).

In diesem Zusammenhang wird darauf hingewiesen, dass das Rekanalisationselement 10 im komprimierten Zustand bzw. im gecrimpten Zustand vorzugsweise eine im Wesentlichen geradlinige Struktur aufweist. Die spiralförmige Windung 13 bildet sich erst bei der Expansion des Rekanalisationselements 10. Es ist aber auch möglich, dass das Rekanalisationselement 10 im komprimierten Zustand eine Spiralform aufweist, die beispielsweise gegenüber der Spiralform im dem expandierten Zustand weniger ausgeprägt ist.

Im komprimierten bzw. gecrimpten Zustand des Rekanalisationselements 10 bildet der Hohlkörper 11 vorteilhafterweise eine drahtbündelähnliche Querschnittsstruktur. Das bedeutet, dass der Hohlkörper 11 im Wesentlichen keinen durchströmbaren Hohlkanal bildet. Der Hohlkanal entsteht vielmehr durch die Aufweitung des Hohlkörpers 11, insbesondere der Gitterstruktur des Hohlkörpers 11, während der Expansion des Rekanalisationselements 10. Der Hohlkörper 11 verhält sich also stentähnlich.

Insgesamt kann das Rekanalisationselement 10 eine Rückstellkraft bzw. Radialkraft aufweisen, die die Expansion bewirkt oder zumindest unterstützt. Die Rückstellkraft wirkt sowohl auf den Hohlkörper 11, als auch auf die spiralförmige Windung 13. Dabei wird Rückstellkraft bzw. Radialkraft bei der Expansion wirksam und ermöglicht bzw. unterstützt die Bildung des Hohlkanals im Hohlkörper 11 und die Bildung der spiralförmigen Windung 13 des Rekanalisationselements 10. Mit anderen Worten wird durch die Expansion der Rekanalisationsvorrichtung sowohl der Gesamtdurchmesser der Vorrichtung, d.h. der Außendurchmesser des spiralförmig gewundenen Hohlkörpers 11 als auch der Querschnittsdurchmessers des Hohlkörpers 11 selbst vergrößert.

Im Allgemeinen kann das Rekanalisationselement 10 unterschiedliche Konfigurationen umfassen. Beispielsweise kann das Rekanalisationselement 10 in einem – in Bezug auf die Axialrichtung – mittleren Abschnitt eine geflochtene Gitterstruktur umfassen. Alternativ oder zusätzlich kann die geflochtene Gitterstruktur auch in einem distalen

Abschnitt 17 des Rekanalisationselement 10 vorgesehen sein. Im proximalen Abschnitt 18 kann die perforierte Struktur größere Öffnungen, insbesondere eine größere Maschenweite als im mittleren Abschnitt des Rekanalisationselements 10 aufweisen. Die Öffnungen im mittleren Abschnitt sind vorteilhafterweise derart angepasst, dass einerseits ein Medikament direkt an das Konkrement 30 gelangen kann und andererseits eine Filterfunktion erreicht wird, so dass Konkrementpartikel einer bestimmten Größe und – insbesondere beim Einsatz der medizinischen Vorrichtung in Blutgefäßen – Blutpartikel einer bestimmten Größe effizient zurückgehalten werden. Hingegen können die Öffnungen der perforierten Struktur im proximalen Abschnitt 18 vergleichsweise größer ausgebildet sein, um einen möglichst widerstandsarmen Durchfluss zu gewährleisten.

Um die Größe der Öffnungen bzw. die Maschengröße in den unterschiedlichen Abschnitten des Rekanalisationselements 10 zu erreichen, ist es vorteilhaft, wenn die im mittleren Abschnitt die geflochtene Gitterstruktur bildenden fadenförmigen Elemente im proximalen Abschnitt 18 eine andere Flechtart aufweisen oder ungeflochten sind. Beispielsweise kann die geflochtene Gitterstruktur im mittleren Abschnitt eine Flechtart aufweisen, die als 1-über-1 oder 1-über-2 oder 1-über-3 bezeichnet wird. Bei einer festgelegten Anzahl von fadenförmigen Elementen bzw. Drähten wird dadurch eine relativ kleine Rautengröße der Gittergeflechtmaschen erreicht. Im proximalen Abschnitt 18 kann hingegen eine Flechtart gewählt sein, die im Wesentlichen einer 2-über-2 oder 3-über-3 oder 4-über-4 oder 5-über-5-Flechtung entspricht. Dabei können sich die Drähte bzw. allgemein fadenförmigen Elemente paarweise oder in Dreier- bzw. Vierergruppen nebeneinander anordnen, wodurch die Maschengröße bzw. Rautengröße erhöht wird. Die erhöhte Maschengröße kann einen verbesserten Durchfluss, insbesondere Blutdurchfluss, bewirken.

Hinsichtlich der Flechtarten ist es besonders bevorzugt, wenn zwei oder mehr fadenförmige Elemente, insbesondere Drähte, die die Wandung 12 bilden, im proximalen Abschnitt 18 zusammengeführt sind. Die zusammengeführten Drähte können im proximalen Abschnitt 18 verdrillt, miteinander verflochten oder andersartig miteinander verbunden sein. Dabei ist es unerheblich, ob die zusammengeführten Drähte im mittleren Abschnitt des Hohlkörpers 11 gegenläufig oder gleichläufig angeordnet sind. Im proximalen Abschnitt 18 verlaufen die zusammengeführten Drähte bzw. fadenförmigen Elemente in Form einer Drahtgruppe vorzugsweise in axialer Richtung bzw. parallel zur Mittelachse des Hohlkörpers 11. Die Mittelachse des Hohlkörpers 11 ist im expandierten Zustand spiralförmig gewunden bzw. folgt der

spiralförmigen Windung 13. Es ist auch möglich, dass die Drahtgruppe in einem Winkel zur Mittelachse des Hohlkörpers 11 verläuft. Das bedeutet, dass die Drahtgruppe in der Wandungsebene eine Spiralform beschreibt. Vorzugsweise sind im proximalen Abschnitt 18 mehrere Drahtgruppen vorgesehen, die in die gleiche Richtung verlaufen. Es ist nicht ausgeschlossen, dass die Drahtgruppen in der Wandung 12 in unterschiedlichen Richtungen angeordnet sind. Die Drahtgruppen können sich auch überkreuzen. Vorzugsweise verlaufen die Drahtgruppen im proximalen Abschnitt 18 allerdings derart, dass eine Überkreuzung vermieden ist. Dazu ist eine parallele bzw. annähernd parallele Anordnung der Drahtgruppen zweckmäßig.

Der proximale Abschnitt 18 kann trichterförmig ausgebildet sein. Die Drahtgruppen bzw. die Gruppen der fadenförmigen Elemente können im proximalen Abschnitt 18 bzw. zu einem proximalen Ende des Hohlkörpers 11 hin in Richtung der Mittelachse des Hohlkörpers 11 zusammenlaufen. Im Bereich der Mittelachse können die die Wandung 12 bildenden fadenförmigen Elemente bzw. die den proximalen Abschnitt 18 bildenden Drahtgruppen zu einem gemeinsamen Strang verbunden sein. Der so gebildete gemeinsame Strang kann ferner mit einem Zufuhrelement, insbesondere einem Führungsdraht 41, fest verbunden oder verbindbar sein. Es ist auch möglich, dass der proximale Strang mit dem Zufuhrelement bzw. dem Führungsdraht 41 einteilig ausgebildet ist.

In einer besonders bevorzugten Konfiguration sind im proximalen Abschnitt 18 jeweils zwei Drähte, die im mittleren Abschnitt in unterschiedlichen Windungsrichtungen angeordnet sind, zu einer Drahtgruppe verdrillt. Im Bereich der proximalen Trichterspitze, d.h. am proximalen Ende des Hohlkörpers 11, kann die Verdrillung der zwei Drähte aufgelöst sein. Die beiden Drähte verlaufen dann beide in den proximal gebildeten Strang, allerdings nicht in der ursprünglichen verdrillten Anordnung. Vielmehr kann einer der beiden im proximalen Abschnitt 18 verdrillten Drähte im proximalen Strang in einer ersten Richtung verlaufen. Der zweite Draht ist im proximalen Strang in einer anderen, insbesondere gegenläufigen, Richtung angeordnet. Beispielsweise können alle Drähte bzw. fadenförmigen Elemente, die im Bereich des proximalen Endes des Hohlkörpers 11 auf der Mittelachse zusammengeführt sind und ursprünglich in derselben Richtung verlaufen, zu einem inneren proximalen Strang verdrillt sein. Die anderen Drahtelemente bzw. fadenförmigen Elemente, die eine gegenläufige Anordnung aufweisen, können um den inneren Strang herumgewickelt bzw. verdrillt sein und einen, den inneren Strang

umhüllenden, äußeren Strang bilden, wobei die Wickelrichtung bzw. Verdrillrichtung im äußeren Strang vorzugsweise gegenüber dem inneren Strang umgekehrt ist. Der proximale Strang ist also im Querschnitt zweischichtig aufgebaut, wobei sich die beiden Schichten durch die unterschiedliche Verdrillrichtung unterscheiden. Auf diese Weise ergibt sich eine besonders stabile Konfiguration des proximalen Strangs, wodurch eine gute Verbindung des verformbaren bzw. expandierbaren Hohlkörpers mit dem Zufuhrelement, insbesondere dem Führungsdraht 41, erreicht wird.

Die Positionierung des Rekanalisationselements 10 in einem Körperhohlraum 20 erfolgt vorzugsweise durch Zufuhr des Rekanalisationselements 10 über ein Zufuhrsystem 40, wie in Fig. 1 dargestellt. Das Zufuhrsystem 40 kann einen medizinischen Katheter umfassen. Während der Behandlung kann das Rekanalisationselement 10 mit dem Zufuhrsystem 40, insbesondere dem Führungsdraht 41, verbunden sein bzw. verbunden bleiben, so dass durch Zurückziehen des Zufuhrsystems 40 das mit dem Rekanalisationselement 10 gekoppelte Konkrement 30 aus dem Körperhohlraum 20 entfernbar ist. Es ist ferner möglich, das Rekanalisationselement 10 durch entsprechende Bewegung des Zufuhrsystems 40 bzw. des Führungsdrahts 41 in das Zufuhrsystem 40 zurückzuziehen und somit zu repositionieren. Durch gleichzeitiges Ziehen des Führungsdrahts 41 und des Zufuhrsystems 40 kann das Konkrement 30, insbesondere ein Thrombus, entfernt werden, ohne das Konkrement 30 in das Zufuhrsystem 40, insbesondere einen Katheter, hineinzuziehen. Es ist in diesem Zusammenhang denkbar, dass ein weiterer, größerer Katheter vorgesehen ist, der im Gebrauch weiter proximal angeordnet ist. Der Führungsdraht 41, das Rekanalisationselement 10, das Konkrement 30 und das Zufuhrsystem 40 können in den größeren Katheter hineingeführt bzw. gezogen werden, um dann mit dem größeren Katheter vollständig aus dem Körper entfernt zu werden.

In Fig. 2 ist ein weiteres Ausführungsbeispiel der medizinischen Vorrichtung gezeigt, wobei das Rekanalisationselement 10 einen Hohlkörper 11 umfasst, der mehrere Windungen 13 bildet. Konkret weist das Rekanalisationselment 10 bzw. der Hohlköper 11 gemäß Fig. 2 fünf Windungen auf. Generell weist das Rekanalisationselement 10 im Wesentlichen eine spiralförmige Form bzw. Kontur auf. Eine andere Anzahl von Windungen ist möglich. Beispielsweise kann der Hohlkörper 11 höchstens 12, insbesondere höchstens 11, insbesondere höchstens 10, insbesondere höchstens 9, insbesondere höchstens 8, insbesondere höchstens 7, insbesondere höchstens 6, insbesondere höchstens 5, insbesondere höchstens 4, insbesondere höchstens 3,5, insbesondere höchstens 3, insbesondere höchstens 2,5, insbesondere höchstens 2,

insbesondere höchstens 1,5, insbesondere höchstens 1 Windungen bilden. Eine höhere Anzahl an Windungen 13 ist möglich. Wie aus Fig. 2 ferner ersichtlich ist, weisen die Windungen 13 jeweils den gleichen Steigungswinkel bzw. die gleiche Steigung auf. Das schließt nicht aus, dass die Windungen 13 unterschiedliche Steigungen bzw. Steigungswinkel umfassen.

Der Steigungswinkel bzw. die Steigung der einzelnen Windungen, sind durch die physiologischen Gegebenheiten am Behandlungsort beeinflussbar. Beispielsweise kann eine Gefäßkrümmung oder die Form des Konkrements 30 dazu führen, dass die Steigungswinkel der einzelnen Windungen 13 variieren. Dasselbe gilt für den Windungsdurchmesser, also den Außendurchmesser des Rekanalisationselements 10. Das Rekanalisationselement 10 ist insgesamt flexibel und passt sich zweckmäßigerweise der Form des Konkrements 30 bzw. der Kontur des Körperhohlraums 20 an.

In Fig. 2 ist der Vorgang gezeigt, bei dem das Konkrement 30 aus dem Körperhohlraum 20 entfernt wird, wobei das Konkrement 30 beim Zurückziehen des Zufuhrsystems 40 durch größere Gefäßabschnitte geführt wird. Die Darstellung gemäß Fig. 2 mach deutlich, dass mit dem erfindungsgemäßen Rekanalisationselement 10 eine sichere Fixierung des Konkrements 30 erreicht wird, so dass das Konkrement 30 vollständig, insbesondere unter Vermeidung von Partikelablösung, aus dem Körperhohlraum 20, insbesondere einem Blutgefäß, entfernbar ist. Gleichzeitig erfolgt bereits während der Behandlung eine Rekanalisation des Körperhohlraums 20 durch den Hohlkörper 11. In Fig. 2 ist ferner gezeigt, dass der Hohlkörper 11 bzw. das Rekanalisationselement 20 proximal mit einem Führungsdraht 41 des Zufuhrsystems 40 verbunden ist. Der Führungsdraht 41 ermöglicht eine besonders einfach kontrollierbare Betätigung des Rekanalisationselements 10. Insbesondere ermöglicht der Führungsdraht 41 die Fixierung des Rekanalisationselements 10 im Bereich des Behandlungsortes, wobei durch Zurückziehen des Zufuhrsystems 40, insbesondere einer Katheterhülle, die Freisetzung des Rekanalisationselements 10 erfolgt. Dabei nimmt das Rekanalisationselement 10 den expandierten Zustand mit der spiralförmigen Struktur an.

Im Vergleich zu bekannten, sich geradlinig erstreckenden Systemen ermöglicht die medizinische Vorrichtung mit dem spiralförmig gewundenen Rekanalisationselement 10 eine Abdeckung bzw. Fixierung bzw. Sicherung des Konkrements 30 zu allen Seiten. Dadurch wird vermieden, dass sich das Konkrement 30 bzw. Konkrement-

bestandteile ablösen, wenn das Konkrement 30 beim Entfernen in größere Körperhohlgefäße gezogen wird. Insbesondere beim Passieren von Gefäßverzweigungen während der Entfernung des Konkrements 30 hält das spiralförmige Rekanalisationselement 10 das Konkrement 30 in einer festen Umklammerung, so dass ein unkontrolliertes Ablösen des Konkrements 30 bzw. von Konkrementpartikeln vermieden wird. Das spiralförmig gewundene Rekanalisationselement 10 bewirkt nicht nur einen Partikelablöseschutz in Umfangsrichtung bzw. zu allen Seiten des Konkrements 30, sondern ermöglicht auch, das Konkrement 30 radial zu komprimieren. Dazu erstreckt sich das Rekanalisationselement 10, insbesondere der Hohlkörper 11, radial außen um das Konkrement 30. Der Hohlkörper 11 umschlingt also durch die spiralförmige Windung 13 das Konkrement 30. Durch die Komprimierung werden das Ablösen und der Abtransport des Konkrements 30 erleichtert.

Fig. 3a zeigt durch entsprechende Strömungspfeile deutlich, wie die sofortige Rekanalisation eines Körperhohlraums 20 vorteilhaft erreicht wird. Durch den Hohlkörper 11 wird nach Freisetzen des Rekanalisationselements 10 eine Strömungspassage geschaffen, die im Wesentlichen spiralförmig um das Konkrement 30 führt. Bei der Thrombusbehandlung wird auf diese Weise schnell und sicher eine Blutströmung wiederhergestellt, so dass stromabwärts gelegene Gewebeareale schnell wieder mit Nährstoffen, insbesondere Sauerstoff, versorgt werden.

Bei dem Ausführungsbeispiel gemäß Fig. 3a bildet der Hohlkörper 11 mehrere, insbesondere fünf, Windungen 13, die einen relativ großen Steigungswinkel bzw. eine relativ große Steigung aufweisen. Im Unterschied zu einem Rekanalisationselement 10 mit einer kleineren Steigung der Windungen 13 (Fig. 3b) weist der Hohlkörper 11 bei dem Ausführungsbeispiel gemäß Fig. 3a im komprimierten Zustand eine relativ kleine Längserstreckung auf. Der Hohlkörper 11 des Rekanalisationselement 10 gemäß Fig. 3a ist also im komprimierten Zustand kürzer als der Hohlkörper 11 des Rekanalisationselements 10 gemäß Fig. 3b. Der im komprimierten Zustand kürzere Hohlkörper 11 erleichtert die Zuführung des Rekanalisationselements 10 durch das Zufuhrsystem 40, da die Schiebe- bzw. Zugkraft innerhalb des Zufuhrsystems 40 aufgrund einer geringeren Reibung reduziert ist. Auch im expandierten Zustand weist der Hohlkörper 11 gemäß Fig. 3a eine kleinere Kontaktfläche zum Körperhohlraum 20, insbesondere zu einer Gefäßwand, auf so dass eine Repositionierung des Rekanalisationselements 10 erleichtert ist. Überdies bildet der Hohlkörper 11 gemäß Fig. 3a eine relativ kurze Strömungspassage, so dass der Strömungswiderstand

reduziert ist. Der Durchfluss durch das rekanalisierte Körpergefäß bzw. den rekanalisierten Körperhohlraum 20 wird somit erhöht.

Bei dem Ausführungsbeispiel gemäß Fig. 3b weist das Rekanalisationselement 10 eine vergleichsweise höhere Anzahl von Windungen 13 auf, wobei die Windungen 13 eine kleinere Steigung umfassen. Auf diese Weise wird der Kontakt zwischen dem Rekanalisationselement 10 und dem Konkrement 30 intensiviert, was eine verbesserte Fixierung des Konkrements 30 zur Folge hat. Überdies ermöglicht die Konfiguration gemäß Fig. 3b die Bereitstellung einer weiteren Strömungspassage, die nicht nur spiralförmig um das Konkrement 30 verläuft, sondern sich direkt zwischen der Gefäßwand des Körperhohlraums 20 und dem Konkrement 30 erstreckt. Durch die perforierte Struktur, insbesondere die geflochtene Gitterstruktur, des Hohlkörpers 11 bzw. der Wandung 12 wird ermöglicht, dass das Körperfluid im Wesentlichen geradlinig an dem Konkrement 30 vorbeiströmen kann. Der Hohlkörper 11 bildet also im Wesentlichen einen Abstandshalter zwischen der Gefäßwand des Körperhohlraums 20 und dem Konkrement 30. Der Strömungsquerschnitt im rekanalisierten Körperhohlraum 20 wird somit erweitert. Der Durchflusswiderstand wird dabei vermindert und somit der Rekanalisationsgrad bzw. der Durchfluss durch das rekanalisierte Gefäß bzw. den rekanalisierten Körperhohlraum 20 erhöht. Dies wird besonders vorteilhaft erreicht, wenn der Hohlkörper 11 eine Wandung 12 aufweist, die eine geflochtene Gitterstruktur umfasst. Das bedeutet, dass der Hohlkörper 11 bzw. allgemein das Rekanalisationselement 10 eine im Wesentlichen stentartige Struktur aufweist. Die Strömung des Körperfluids, insbesondere des Blutes, erfolgt dabei durch die Maschen der stentartigen Struktur.

Im Allgemeinen kann der Außendurchmesser des Rekanalisationselements 10, also der Außendurchmesser der Windungen 13, variieren. Beispielsweise kann das Rekanalisationselement 10 in einem distalen Abschnitt 17 eine distale Windung 13' aufweisen, die einen kleineren Außendurchmesser aufweist als die Windung 13 in einem proximalen Abschnitt 18. Das Rekanalisationselement 10 kann sich also – bezogen auf die spiralförmigen Windungen 13, 13' – verjüngen, wobei bevorzugt vorgesehen ist, dass sich das Rekanalisationselement 10 in distale Richtung, also zum distalen Abschnitt 17 hin, verjüngt. Dabei kann das Rekanalisationselement 10 insgesamt ein konusförmiges Profil bilden. Es ist auch möglich, dass das Rekanalisationselement 10 eine Spitze aufweist, die sich konusförmig verjüngt, wobei der Außendurchmesser der einzelnen Windungen 13' im distalen Abschnitt kleiner wird. Die Außenkontur des Rekanalisationselements 10 im proximalen Abschnitt 18 kann eine andere Form

aufweisen. Beispielsweise kann die Außenkontur im proximalen Abschnitt 18 zylinderförmig gestaltet sein. Durch den verjüngten distalen Abschnitt 17 wird vermieden, dass Konkrementpartikel, die sich möglicherweise vom Konkrement 30 ablösen, frei in den Körperhohlraum 20 gelangen und durch das Körperfluid, insbesondere Blut, in stromabwärts gelegene Areale geschwemmt werden. Das konusförmig gestaltete Ende des Rekanalisationselements 10 bildet also im Wesentlichen eine Filterfunktion.

Eine zusätzliche oder alternative Möglichkeit zur Bereitstellung einer Filterfunktion am distalen Ende 14 des Rekanalisationselements 10, ist in Fig. 5 dargestellt. Fig. 5 zeigt ein Ausführungsbeispiel der medizinischen Vorrichtung, die im Wesentlichen einen ähnlichen Aufbau wie das Ausführungsbeispiel gemäß Fig. 1 aufweist. Der Unterschied besteht darin, dass bei dem Rekanalisationselement gemäß Fig. 5 der Hohlkörper 11 am distalen Ende 14 einen Filterabschnitt 16 bildet. Dazu weist der Hohlkörper 11 am distalen Ende 14 einen vergrößerten Querschnittsdurchmesser auf. Der Querschnittsdurchmesser des Hohlkörpers 11 ist am distalen Ende 14 größer als in einem proximalen Abschnitt 18 des Rekanalisationselements 10. Der Hohlkörper 11 gemäß Fig. 5 bildet also am distalen Ende 14 eine Aufweitung. Auf diese Weise überdeckt der Hohlkörper 11 am distalen Ende 14 die gesamte Querschnittsfläche des Körperhohlraums 20 und fungiert als Filter. Durch die perforierte Struktur der Wandung 12 des Hohlkörpers 11, insbesondere durch die geflochtene Gitterstruktur, wird weiterhin gewährleistet, dass eine effiziente Rekanalisation des Körperhohlraums 20 erfolgt.

Bei einem weiteren Ausführungsbeispiel, das in Fig. 6 dargestellt ist, verjüngt sich das distale Ende 14 des Hohlkörpers 11. Der Hohlkörper 11 bildet also eine distale Spitze, die im Wesentlichen konusförmig geformt sein kann. Das Rekanalisationselement 10 weist somit insgesamt im Wesentlichen eine korkenzierartige Kontur auf. Durch die distale Spitze bzw. das sich verjüngende distale Ende 14 des Hohlkörpers 11 passt sich das Rekanalisationselement 10 bei Vorschieben in kleinere Gefäße besser der Gefäßkontur an. Das distale Ende 14 des Hohlkörpers 11 ist ferner mit einem Betätigungselement 19 gekoppelt, das parallel zum Führungsdraht 41 durch das Zufuhrsystem 40 verläuft. Das Betätigungselement 19 ermöglicht die im Wesentlichen axiale Betätigung des Rekanalisationselements 10. Das bedeutet, dass beispielsweise durch Ziehen des Betätigungselements 19 in proximale Richtung das Rekanalisationselement 10 axial komprimiert wird. Die Steigung der spiralförmigen Windungen 13 wird somit reduziert. Alternativ kann durch eine Bewegung des Betätigungselements 19 in distale Richtung das Rekanalisationselement 10 gestreckt

werden. Durch die Streckung wird der Außendurchmesser des Rekanalisationselements 10 bzw. der spiralförmigen Windung 13 reduziert, so dass das Konkrement 30 weiter fixiert wird. Zusätzlich wird der Abstand zwischen dem Außenumfang des Rekanalisationselements 10 und der Gefäßwand erhöht, so dass die Reibung des Rekanalisationselements 10 an der Gefäßwand beim Zurückziehen reduziert oder aufgehoben wird. Die Gefäßwand bzw. der Körperhohlraum 20 wird somit geschont.

Der Hohlkörper 11 bzw. die Wandung 12 können eine vollständige, insbesondere geschlossene, Abdeckung 12a aufweisen. Das bedeutet, dass bei dem Ausführungsbeispiel gemäß Fig. 6 die Wandung 12 beispielsweise vollständig mit einer fluiddichten Abdeckung 12a überzogen ist. Die Wandung 12 kann auch selbst fluiddicht ausgebildet sein. Die für die Rekanalisation erforderliche Strömungspassage bzw. Rekanalisationspassage wird in diesem Fall dadurch erreicht, dass die spiralförmigen Windungen 13 bzw. allgemein der Hohlkörper 11 das Konkrement 30 vollständig spiralförmig umschlingt und komprimiert. Dadurch wird eine Strömungspassage eröffnet, die sich zwischen dem Außenumfang des Konkrements bzw. dem Außenumfang, insbesondere der Außenkontur, des Rekanalisationselements 10 und der Gefäßwand des Körperhohlraums 20 erstreckt. Zwischen dem Konkrement 30 bzw. der Außenkontur des Rekanalisationselements 10 und der Gefäßwand des Körperhohlraums 20 wird also ein Strömungsspalt, insbesondere ein Ringspalt, gebildet, der eine Fluidströmung an dem Konkrement 30 vorbei ermöglicht.

Das Betätigungselement 19 kann generell durch das Rekanalisationselement 10, insbesondere durch die spiralförmigen Windungen 13 verlaufen. Alternativ kann das Betätigungselement 19 entlang einer Außenkontur des Rekanalisationselements 10 bzw. der spiralförmigen Windungen 13 verlaufen.

Bei einer weiteren Variante gemäß Fig. 7 ist vorgesehen, dass der Hohlkörper 11 bzw. die Wandung 12 zumindest teilweise mit einer Abdeckung 12a versehen ist bzw. mit einer Abdeckung 12a bespannt ist. Vorzugsweise ist der Hohlkörper 11 vollständig mit der Abdeckung 12a versehen. Die Abdeckung 12a kann Saugöffnungen 12b umfassen, die vorzugsweise in Richtung der zentralen Achse des spiralförmig gewundenen Rekanalisationselements 10 gerichtet bzw. im Gebrauch dem Konkrement 30 zugewandt sind. Die medizinische Vorrichtung ist in diesem Falle vorzugsweise mit einer Aspirationseinheit (nicht dargestellt) gekoppelt, so dass in dem Hohlkörper 11 ein Unterdruck erzeugbar ist. Durch die Saugöffnungen wird dabei erreicht, dass das

Konkrement 30 durch das Rekanalisationselement 10 angesaugt wird. Die feste Verbindung zwischen dem Rekanalisationselement 10 und dem Konkrement 30 wird somit gestärkt. Vorzugsweise ist die Wandung 12, insbesondere bei Verwendung einer Aspirationseinheit im Bereich des distalen Abschnitts 17 bzw. des proximalen Abschnitts 18 vollständig mit der Abdeckung 12a bespannt. Auf diese Weise wird verhindert, dass durch den erzeugten Unterdruck Körperfluid, insbesondere Blut, angesaugt wird. Der Unterdruck kann daher die maximale Leistung erreichen.

Um den Unterdruck, der vorzugsweise außerhalb des Körpers erzeugt wird, über das Zufuhrsystem 40 in den Hohlkörper 11 einzuleiten, kann im proximalen Abschnitt 18 des Rekanalisationselements 10 eine Öffnung vorgesehen sein, die im Gebrauch innerhalb des Zufuhrsystems 40 angeordnet ist und eine Fluidverbindung zwischen dem Zufuhrsystem 40 und dem Hohlkörper 11 bereitstellt.

Es ist denkbar, dass der proximale Abschnitt 18 und/oder distale Abschnitt 17 partiell mit der Abdeckung 12a versehen sind. Auf diese Weise wird ermöglicht, dass höhere absolute Unterdruckwerte erreichbar sind. Durch die Öffnungen, insbesondere Saugöffnungen 12b, in der Abdeckung 12a können auch Medikamente an den Behandlungsort geleitet werden.

Für die geflochtene Gitterstruktur sind die folgenden Konstruktionsmerkmale vorteilhaft:

Zur Verwendung der medizinischen Vorrichtung in Körperhohlräumen, insbesondere Blutgefäßen, mit einem Gefäßdurchmesser von 2 mm bis 3 mm weist das Rekanalisationselement 10, insbesondere die spiralförmige Windung 13, vorzugsweise einen Außendurchmesser im Bereich von 2 mm bis 8 mm, insbesondere 3 mm bis 6mm, insbesondere 3 mm bis 5 mm. Dabei umfasst der Hohlkörper 11 vorzugsweise einen Querschnittsdurchmesser im Bereich von 1 mm bis 2,5 mm, insbesondere 1,5 mm bis 2,5 mm, insbesondere 1,8 mm bis 2,2 mm.

Für einen Gefäßdurchmesser bzw. Durchmesser des Körperhohlraums 20 von 3 mm bis 4 mm hat sich ein Außendurchmesser des Rekanalisationselements 10 bzw. der spiralförmigen Windung 13 im Bereich von 3 mm bis 10 mm, insbesondere 4 mm bis 8 mm, insbesondere 4 mm bis 6 mm, als vorteilhaft erwiesen. Der Hohlkörper 11 kann in diesem Fall einen Querschnittsdurchmesser im Bereich von 1 mm bis 3 mm, insbesondere 1,5 mm bis 2,5 mm, insbesondere 2,0 mm bis 2,5 mm aufweisen.

Wenn die medizinische Vorrichtung in Körperhohlräume 20 mit einem Querschnittsdurchmesser von 4 mm bis 5 mm eingesetzt wird, ist es vorteilhaft, wenn das Rekanalisationselement 10 bzw. die Windung 13 einen Außendurchmesser aufweist, der sich von 4 mm bis 12 mm, insbesondere von 5 mm bis 10 mm, insbesondere von 5 mm bis 7 mm, erstreckt. Der Hohlkörper 11 weist dabei vorzugsweise einen Querschnittsdurchmesser im Bereich von 1,5 mm bis 4 mm, insbesondere 2 mm bis 3 mm, insbesondere 2,5 mm bis 3 mm auf.

Weitere bevorzugte Werte für den Durchmesser des Hohlkörpers 11 bzw. den Außendurchmesser des Rekanalisationselements 10 in Relation zum Durchmesser des Körperhohlraums 20 sind in der Tabelle gemäß Fig. 8 dargestellt. Für weitere Gefäßdurchmesser lassen sich die entsprechenden Dimensionen der medizinischen Vorrichtung berechnen.

Grundsätzlich kann der Außendurchmesser des Rekanalisationselements 10 bzw. der spiralförmigen Windung 13 im expandierten Zustand etwas größer sein als der Querschnittsdurchmesser des Zielgefäßes bzw. Körperhohlraums 20. Damit wird bewirkt, dass sich das Rekanalisationselement 10 fest an die Gefäßwand anlegt. Es ist auch möglich, dass der Außendurchmesser des Rekanalisationselements 10 kleiner als das Lumen bzw. der Durchmesser des Zielgefäßes ist. In diesem Falle wird erreicht, dass das Rekanalisationselement 10 die Gefäßwand im Wesentlichen nicht berührt. Dadurch wird eine weitere Strömungspassage geschaffen, die zwischen der Gefäßwand und dem Außenumfang des Rekanalisationselements 10 ausgebildet ist. Vorteilhaft ist dabei, dass einerseits der Widerstand für den Durchfluss des Körperfluids, insbesondere der Strömungswiderstand für fließendes Blut, weiter reduziert, der Thrombus bzw. allgemein das Konkrement 30 fester fixiert und andererseits die Gefäßwand des Körperhohlraums 20 geschont wird, wenn das Rekanalisationselement 10 in proximaler Richtung aus dem Gefäß gezogen wird.

Bei den vorgenannten Konfigurationen entspricht der Querschnittsdurchmesser des Hohlkörpers 11 im Wesentlichen dem Querschnittsdurchmesser des Gittergeflechts bzw. der geflochtenen Gitterstruktur, die die Wandung 12 des Hohlkörpers 11 bildet. Besonders bevorzugt ist es, wenn die geflochtene Gitterstruktur acht fadenförmige Elemente umfasst, wobei die fadenförmige Elemente, insbesondere Drähte, vorzugsweise einen Querschnittsdurchmesser im Bereich von 40 µm bis 76 µm, insbesondere 50 µm bis 68 µm, umfasst. Es können auch 6 bis 12 fadenförmige Elemente

vorgesehen sein, die einen Querschnittsdurchmesser im Bereich von 50 µm bis 68 µm aufweisen. Ferner ist es möglich, dass 6 bis 18 fadenförmige Elemente vorgesehen sind, die einen Querschnittsdurchmesser im Bereich von 35 µm bis 76 µm aufweisen.

Im Allgemeinen können unterschiedliche fadenförmige Elemente, insbesondere Drähte, zur Bildung der geflochtenen Gitterstruktur kombiniert werden. Beispielsweise können insgesamt 16 Drähte vorgesehen sein, wobei 8 Drähte einen Querschnittsdurchmesser von 76 µm und weitere 8 Drähte einen Querschnittsdurchmesser von 40 µm aufweisen. Alternativ kann eine erste Hälfte der fadenförmigen Elemente einen Querschnittsdurchmesser von 68 µm und eine zweite Hälfte der fadenförmigen Elemente einen Querschnittsdurchmesser von 50 µm aufweisen. Es ist auch möglich, dass die geflochtene Gitterstruktur aus 6 fadenförmigen Elementen, die einen Querschnittsdurchmesser von 68 µm aufweisen, und weiteren 12 fadenförmigen Elementen bzw. Drähten mit einem Querschnittsdurchmesser von 50 µm gebildet ist. Eine weitere Alternative sieht vor, die geflochtene Gitterstruktur aus 6 Drähten mit einem Querschnittsdurchmesser von 76 µm und weiteren 18 Drähten mit einem Querschnittsdurchmesser von 35 µm auszubilden.

Prinzipiell sind alle Kombinationen aus unterschiedlichen Drähten möglich. In einer bevorzugten Konfiguration umfasst das Rekanalisationselement 10 eine geflochtene Gitterstruktur, die aus gleichen Drähten gebildet ist, wobei die Drahtanzahl 16, 20 oder 24 Drähte betragen kann, die jeweils einen Durchmesser von 50 µm, 63 µm, 69 µm oder 76 µm aufweisen können. Alle weiteren Kombinationen aus Drahtanzahl und Drahtstärke sind möglich, wobei innerhalb des Rekanalisationselements 10 auch unterschiedlichen Drahtstärken vorgesehen sein können.

Die Anzahl der fadenförmigen Elemente bzw. Drähte wird dabei durch einen senkrechten Querschnitt durch den Hohlkörper 11 ermittelt. Die Drahtanzahl bezieht sich also auf die Anzahl der Drähte, die durch eine zum rohrförmigen Geflecht, insbesondere zum Hohlkörper 11 bzw. zur spiralförmig gewundenen Mittelachse des Hohlkörpers 11, senkrechten Ebene verlaufen.

Es ist besonders vorteilhaft, wenn die fadenförmigen Elemente, insbesondere Drähte, an einem Ende der geflochtenen Gitterstruktur, insbesondere am distalen Ende 14 des Rekanalisationselements 10 geschlossene Schlaufen bilden. Die Drähte werden also am distalen Ende 14 umgelenkt und durch die Gitterstruktur des Hohlkörpers 11 zu-

rückgeführt. Auf diese Weise wird erreicht, dass die Verletzungsgefahr für die Gefäßwand eines Körperhohlraums 20 reduziert wird. Es wird also ein atraumatisches Geflechtende gebildet. Es ist auch möglich, dass die fadenförmigen Elemente am distalen Ende 14 zur Bildung der Schlaufen miteinander verbunden sind, beispielsweise durch eine Hülse. Dabei sind die Verbindungen der drahtförmigen Elemente vorzugsweise in der Umfangsebene der geflochtenen Gitterstruktur des Hohlkörpers 11 angeordnet.

Vorzugsweise umfasst der Hohlkörper 11, insbesondere die geflochtene Gitterstruktur, ein selbstexpandierendes Material, beispielsweise eine Nickel-Titan-Legierung. Das Rekanalisationselement 10 kann auch einen selbstexpandierenden Kunststoff aufweisen. Generell können die selbstexpandierenden Eigenschaften durch einen Formgedächtniswerkstoff, insbesondere ein Formgedächtnismetall oder einen Formgedächtniskunststoff, erreicht werden.

Der Hohlkörper 11 bzw. allgemein das Rekanalisationselement 10 kann durch Laserschneiden aus einem Rohrmaterial oder Flachmaterial hergestellt sein. Bei der Verwendung eines Flachmaterials wird dieses anschließend in eine Rohrform gebogen und an den sich berührenden Längskanten verbunden, beispielsweise verschweißt oder verlötet. Alternativ kann der Hohlkörper 11 bzw. das Rekanalisationselement 10 durch eine Dünnschichttechnik, insbesondere ein Sputterverfahren, hergestellt werden. Besonders bevorzugt ist es, wenn der Hohlkörper 11 bzw. das Rekanalisationselement 10 durch Flechten von Drähten hergestellt wird, wobei die Drähte sowohl Metalldrähte, als auch Kunststoffdrähte oder eine Kombination davon umfassen können. Die Herstellung des Rekanalisationselements 10 erfolgt vorzugsweise in einer teilweise expandierten Form. Vorzugsweise wird der Hohlkörper 11 in einer geraden, zylindrischen Form geflochten – bedarfsweise mit sich aufweitenden oder verjüngenden Endabschnitten (proximale Trichterform bzw. distaler Filterabschnitt) – und auf einem spiralförmigen Dorn einer Wärmebehandlung unterzogen, so dass sich die spiralförmige Windung 13 einstellt. Das endgefertigte Rekanalisationselement 10 wird anschließend komprimiert bzw. gecrimpt und in ein Zufuhrsystem 40 geladen. Das Zufuhrsystem 40 umfasst vorzugsweise einen medizinischen Katheter und kann zusätzlich ein Zufuhrelement, beispielsweise den Führungsdraht 41, aufweisen. Es ist auch möglich, dass die Zufuhr des Rekanalisationselements 10 durch den Katheter pneumatisch oder hydraulisch erfolgt. Über den Katheter können ferner medizinische Wirkstoffe, insbesondere antithrombogene Medikamente, an den Behandlungsort geführt werden.

Die erfindungsgemäße medizinische Vorrichtung eignet sich besonders zur Rekanalisation von Blutgefäßen, die durch einen Thrombus verschlossen sind. Dabei kann sowohl ein partieller, als auch vollständiger Verschluss vorliegen. Bevorzugt ist der Einsatz der medizinischen Vorrichtung zur Rekanalisation von Herzkranzgefäßen, zerebralen Gefäßen, Pulmonalarterien oder Karotisarterien. Weitere Anwendungsmöglichkeiten sind beispielsweise die Rekanalisation von Strömungskanälen der Harnwege, beispielsweise des Harnleiters.

Die Erfindung ist nicht auf eine medizinische Vorrichtung zum Rekanalisieren von Körperhohlräumen beschränkt. Vielmehr wird allgemein eine medizinische Vorrichtung mit einem in einen Körperhohlraum einführbaren Hohlkörper 11 offenbart, der von einem komprimierten Zustand mit einem ersten Querschnittsdurchmesser in einen expandierten Zustand mit einem zweiten Querschnittsdurchmesser überführbar ist, der größer als der erste Querschnittsdurchmesser ist. Im expandierten Zustand ist der Hohlkörper 11 spiralförmig gewunden bzw. bildet einen spiralförmigen Hohlkanal. Insofern entspricht der Hohlkörper dem vorstehend beschriebenen Hohlkörper. Andere Anwendungsmöglichkeiten als die Rekanalisierung von Körperhohlräumen sind mit dem spiralförmig gewundenen Hohlkörper, der selbst wiederum expandierbar ist, möglich. Mit anderen Worten wird ein stentähnlicher Hohlkörper mit spiralförmig gewundener Außenkontur bzw. ein spiralförmig gewundener Stent offenbart und beansprucht.

Der Vorteil des zu einem Hohlkanal expandierbaren Hohlkörpers 11 mit spiralfömiger Außenkontur besteht darin, dass durch Streckung der Spiralform eine Verlängerung des Implantats herbeigeführt werden kann, ohne dass dabei das Lumen bzw. der Querschnittsdurchmesser des Hohlkörpers 11 verringert wird im Gegensatz zu einem nicht-spiralförmigen, zylindrischen Stent. Dies ermöglicht die Fixierung des Hohlkörpers an den Enden in an sich bekannter Weise durch Expansion im Gefäß. Der mittlere Bereich des Hohlkörpers kann frei beweglich sein und folgt aufgrund der Verlängerung durch Streckung der Spiralform der Gefäßdehnung, die durch die Pulsation auftritt. Dabei tritt keine Verringerung des Lumens des Hohlkörpers 11 auf. Damit eignet sich das Implantat zur Behandlung von Aneurysmen (Fusiformenaneurysmen).

Bei einer bevorzugten Ausgestaltung der Erfindung kann ein distales Ende 22 des Hohlkörpers 11 fluidicht verschlossen sein, insbesondere derart, dass ein in den

Hohlkörper 11 eingebrachtes Medikament im implantierten Zustand im Bereich des Hohlkörpers 11 zurückgehalten wird. Ein Beispiel hierzu wird anhand von Fig. 9 erläutert.

Darin ist ein spiralförmiger expandierbarer Hohlkörper 11 ähnlich wie der Hohlkörper 11 gemäß Fig . 5 gezeigt. Der Hohlkörper 11 weist eine Wandung 12 aus einer Gitterstruktur, insbesondere aus einem Gittergeflecht auf. Das distale Ende 22 ist fluiddicht, insbesondere fluidicht und fest, verschlossen. Hierfür kann sich beispielsweise das das distale Ende 22 in proximaler Richtung verjüngen, so dass ein distaler Verschluss gebildet ist. Konkret können die Gitterelemente, insbesondere die Drahtelemente nach innen geführt und an der Spitze des distalen Endes 22 verbunden sein. Hierfür kann eine Hülse 23 vorgesehen sein, in der die freien Enden der Drahtelemente gehalten sind. Die Drahtelemente können auch anderweitig fixiert sein, bspw. durch Verdrillen.

Das distale Ende 22 ist mit einer fluidichten Abdeckung 24 fest verbunden. Zweck der Abichtung ist es, Medikamente, bspw. Thromben lösende Mittel im Bereich proximal vor der Abdeckung zurückzuhalten, damit diese auf einen Thrombus einwirken können, der von dem spiralförmigen Hohlkörper 11 umschlungen ist, wie in Fig. 9 gezeigt. Für den dafür erforderlichen Verschluss des Gefäßes ist das distale Ende 22 aufgeweitet, insbesondere trompetenförmig aufgeweitet. Der Durchmesser des distalen Endes 22 ist größer als der Durchmesser des Lumens des Hohlkörpers 11 im Bereich der Windung 13. Der Durchmesser des distalen Endes 22 ist mindestens so groß wie der Außendurchmesser der Spirale. Damit wird erreicht, dass sich das distale Ende 22 an die Gefäßwand im Bereich der Abdeckung anlegt und diese abdichtet. Für den Fall, dass ein sich stark verjüngendes Gefäß abgedichtet werden soll, kann der Durchmesser des distalen Endes 22 auch kleiner als der Außendurchmesser der Spirale sein.

Die Einwirkung des Medikaments auf den gefangenen Thrombus wird durch die unbedeckte Gitterstruktur des Hohlkörpers 11 im Bereich der Windung 13 erreicht. Die Abdeckung 24 endet etwas vor der Windung 13 und wirkt wie eine Kappe.

Der Hohlkörper 11 kann fest oder lösbar mit dem Führungsdraht verbunden sein.

Die vorstehend genannten Merkmale des distal verschlossenen Hohlkörpers werden sowohl in Kombination als auch einzeln im Zusammenhang mit den anderen Beispielen

bzw. allgemein im Zusammenhang mit der Erfindung offenbart. Beispielsweise können mehr als eine Windung 13 vorgesehen sein.

Das Verfahren zur Herstellung eines derartigen Hohlkörpers bzw. einer derartigen medizinischen Vorrichtung umfasst den Schritt, wonach der Hohlkörper auf einen spiralförmigen Dorn aufgeschoben und wärmebehandelt wird, sodass dem Hohlkörper eine Spiralform aufgeprägt wird, die sich bei entsprechender Umgebungstemperatur im Gebrauch einstellt. Der Hohlkörper ist dementsprechend aus einem Formgedächtswerkstoff hergestellt und selbst-expandierbar. Die Gitterstruktur des Hohlkörpers kann in an sich bekannter Weise hergestellt sein, beispielsweise durch Flechten oder Schneiden oder durch ein Abscheideverfahren.

Bezugszeichenliste

10	Rekanalisationselement
11	Hohlkörper
12	Wandung
12a	Abdeckung
12b	Saugöffnung
13	Windung
13'	distale Windung
14	distales Ende
15	axiale Öffnung
16	Filterabschnitt
17	distaler Abschnitt
18	proximaler Abschnitt
19	Betätigungselement
20	Körperhohlraum
21	proximales Ende
21a	Übergangsbereich
22	distales Ende
23	Hülse
24	Abdeckung
30	Konkrement
40	Zufuhrsystem
41	Führungsdraht

Ansprüche

1. Medizinische Vorrichtung zum Rekanalisieren von Körperhohlräumen (20) mit einem in den Körperhohlraum (20) einführbaren Rekanalisationselement (10), das von einem komprimierten Zustand in einen expandierten Zustand überführbar ist und im expandierten Zustand einen rohrförmigen Hohlkörper (11) aufweist derart, dass der Körperhohlraum (20) rekanalisierbar ist, wobei die Außenkontur des Rekanalisationselements (10) wenigstens eine spiralförmige Windung (13) bildet.

2. Medizinische Vorrichtung nach Anspruch 1,
d a d u r c h g e k e n n z e i c h n e t, dass
der Hohlkörper (11) durch eine rohrförmige Wandung (12) begrenzt ist, die zumindest in einem proximalen Abschnitt (18) und/oder in einem distalen Abschnitt (17) mindestens eine Öffnung aufweist.

3. Medizinische Vorrichtung nach Anspruch 2,
d a d u r c h g e k e n n z e i c h n e t, dass
die Wandung (12) zumindest abschnittsweise eine perforierte Struktur aufweist.

4. Medizinische Vorrichtung nach Anspruch 2 oder 3,
d a d u r c h g e k e n n z e i c h n e t, dass
die Wandung (12), insbesondere die perforierte Struktur, ein lasergeschnittenes oder durch Dünnschichttechnik hergestelltes, insbesondere gesputtertes, Strukturelement umfasst.

5. Medizinische Vorrichtung nach Anspruch 1,
d a d u r c h g e k e n n z e i c h n e t, dass
die Wandung (12), insbesondere die perforierte Struktur, eine geflochtene Gitterstruktur aufweist.

6. Medizinische Vorrichtung nach Anspruch 5,
d a d u r c h g e k e n n z e i c h n e t, dass
die geflochtene Gitterstruktur fadenförmige Elemente umfasst, die an einem distalen Ende der Gitterstruktur geschlossene Schlaufen bilden.

7. Medizinische Vorrichtung nach Anspruch 5 oder 6,
d a d u r c h g e k e n n z e i c h n e t, dass
die geflochtene Gitterstruktur wenigstens 8, insbesondere wenigstens 12, insbesondere wenigstens 16, insbesondere wenigstens 20, insbesondere wenigstens 24, insbesondere wenigstens 32, insbesondere wenigstens 36, insbesondere wenigstens 48, fadenförmige Elemente umfasst.

8. Medizinische Vorrichtung nach wenigstens einem der Ansprüche 1 bis 7,
d a d u r c h g e k e n n z e i c h n e t, dass
die spiralförmige Windung (13) eine Steigung von wenigstens 10 mm, insbesondere wenigstens 15 mm, insbesondere wenigstens 20 mm, insbesondere wenigstens 25 mm, insbesondere wenigstens 30 mm,
oder
höchstens 30 mm, insbesondere höchstens 20 mm, insbesondere höchstens 10 mm, insbesondere höchstens 8 mm, insbesondere höchstens 7 mm, insbesondere höchstens 6 mm, insbesondere höchstens 5 mm, insbesondere höchstens 3 mm, insbesondere höchstens 2 mm, aufweist, bezogen auf einen Umlaufwinkel des Hohlkörpers (11) von 360°.

9. Medizinische Vorrichtung nach wenigstens einem der Ansprüche 1 bis 8,
d a d u r c h g e k e n n z e i c h n e t, dass
das Verhältnis zwischen der Steigung der spiralförmigen Windung (13) und einem Querschnittsdurchmesser des Hohlkörpers (11) höchstens 1000%, insbesondere höchstens 600%, insbesondere höchstens 200%, insbesondere höchstens 180%, insbesondere höchstens 160%, insbesondere höchstens 150%, insbesondere höchstens 140%, insbesondere höchstens 130%, insbesondere höchstens 120%, beträgt.

10. Medizinische Vorrichtung nach wenigstens einem der Ansprüche 1 bis 9,
d a d u r c h g e k e n n z e i c h n e t, dass
die spiralförmige Windung (13) einen Steigungswinkel aufweist, der wenigstens 45°, insbesondere wenigstens 60°, insbesondere wenigstens 70°, insbesondere wenigstens 80°,
oder
höchstens 45°, insbesondere höchstens 40°, insbesondere höchstens 35°, insbesondere höchstens 30°, insbesondere höchstens 25°, insbesondere

höchstens 20°, beträgt.

11. Medizinische Vorrichtung nach wenigstens einem der Ansprüche 1 bis 10, dadurch gekennzeichnet, dass der Hohlkörper (11) im expandierten Zustand zumindest abschnittsweise unterschiedliche Querschnittsdurchmesser aufweist.

12. Medizinische Vorrichtung nach Anspruch 11, dadurch gekennzeichnet, dass der Hohlkörper (11) im expandierten Zustand an einem distalen Ende (14) einen größeren Querschnittsdurchmesser als in einem proximalen Abschnitt (18) aufweist.

13. Medizinische Vorrichtung nach wenigstens einem der Ansprüche 1 bis 12, dadurch gekennzeichnet, dass der Hohlkörper (11) im expandierten Zustand an einem distalen Ende (14) des Rekanalisationselements (10) einen Filterabschnitt (16) bildet.

14. Medizinische Vorrichtung nach wenigstens einem der Ansprüche 1 bis 13, dadurch gekennzeichnet, dass die spiralförmige Windung (13) in einem distalen Abschnitt (17) des Rekanalisationselements einen kleineren Windungsdurchmesser als in einem proximalen Abschnitt (18) des Rekanalisationselements (10) aufweist.

15. Medizinische Vorrichtung nach wenigstens einem der Ansprüche 1 bis 14, dadurch gekennzeichnet, dass das Rekanalisationselement (10) proximal mit einem Zufuhrelement, insbesondere einem Führungsdraht (41), verbunden oder verbindbar ist.

16. Medizinische Vorrichtung nach wenigstens einem der Ansprüche 1 bis 15, dadurch gekennzeichnet, dass das Rekanalisationselement (10) eine einen Wirkstoff freisetzende, insbesondere antithrombogene, Beschichtung aufweist.

17. Medizinische Vorrichtung nach wenigstens einem der Ansprüche 1 bis 16, dadurch gekennzeichnet, dass das Rekanalisationselement (10), insbesondere der Hohlkörper (11),

wenigstens abschnittsweise eine fluiddichte Abdeckung (12a) aufweist.

18. Medizinische Vorrichtung nach Anspruch 17,
d a d u r c h g e k e n n z e i c h n e t, dass
die fluiddichte Abdeckung (12a) ein oder mehrere Saugöffnungen (12b) umfasst, die im Gebrauch einem Konkrement (30) zugewandt sind.

19. Medizinische Vorrichtung nach wenigstens einem der Ansprüche 1 bis 16,
d a d u r c h g e k e n n z e i c h n e t, dass
das Rekanalisationselement (10) an einem distalen Ende (14) mit einem Betätigungselement (19) verbunden ist, das sich im Wesentlichen längsaxial entlang des Rekanalisationselements (10) erstreckt.

20. Medizinische Vorrichtung nach Anspruch 18,
d a d u r c h g e k e n n z e i c h n e t, dass
das Betätigungselement (19) zumindest teilweise entlang einer Außenkontur und/oder einer Innenkontur des Rekanalisationselements (10) verläuft.

21. Set umfassend eine medizinische Vorrichtung nach Anspruch 1 und ein Zufuhrsystem (40) für eine derartige Vorrichtung.

22. Medizinische Vorrichtung mit einem in einen Körperhohlraum einführbaren Hohlkörper (11) , der von einem komprimierten Zustand mit einem ersten Querschnittsdurchmesser in einen expandierten Zustand mit einem zweiten Querschnittsdurchmesser überführbar ist, der größer als der erste Querschnittsdurchmesser ist, wobei der Hohlkörper (11) im expandierten Zustand spiralförmig gewunden ist.

23. Vorrichtung nach Anspruch 22
d a d u r c h g e k e n n z e i c h n e t, dass
das ein distales Ende (22) des Hohlkörpers (11) fluidicht verschlossen ist.

24. Verfahren zur Herstellung einer medizinischen Vorrichtung, bei dem ein expandierbarer und komprimierbarer Hohlkörper (11) aus einem Formgedächtsniswerkstoff auf einem spiralförmigen Dorn aufgeschoben und wärmebehandelt wird, so dass dem Hohlkörper (11) eine Spiralform aufgeprägt wird.

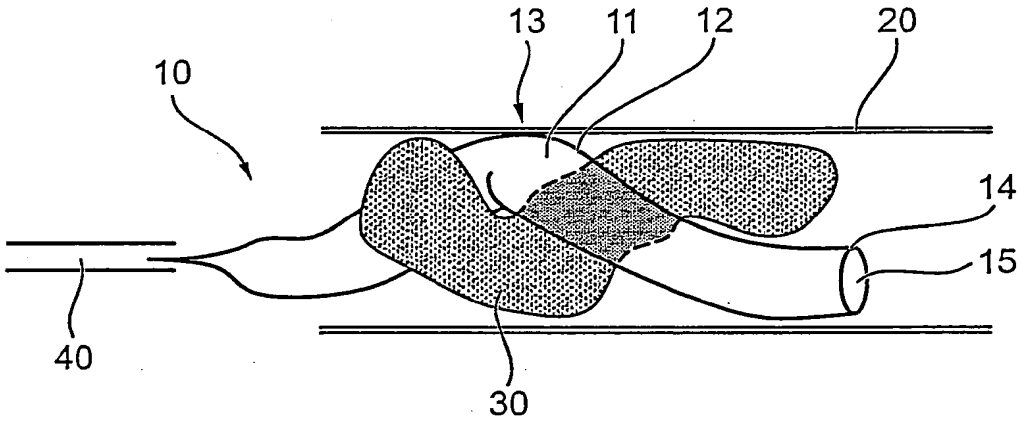


FIG. 1

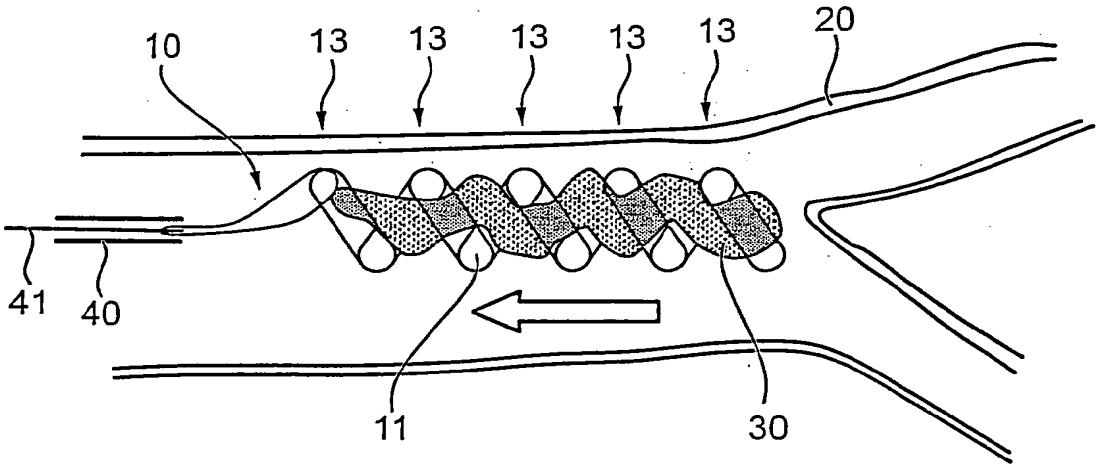


FIG. 2

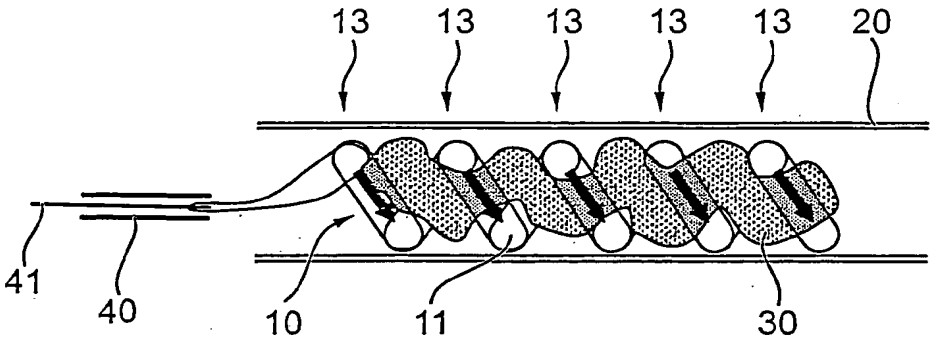


FIG. 3a

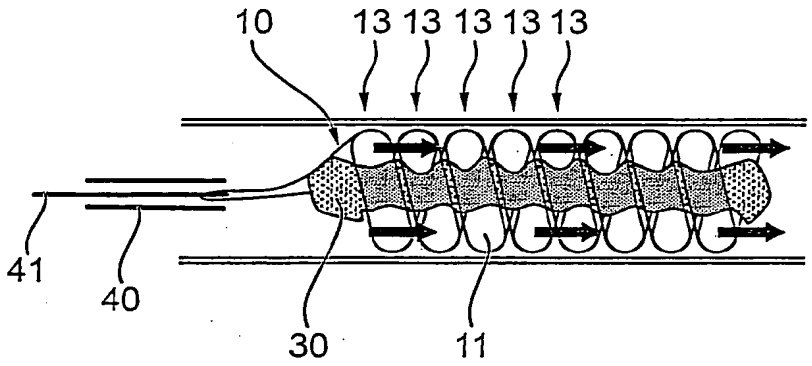


FIG. 3b

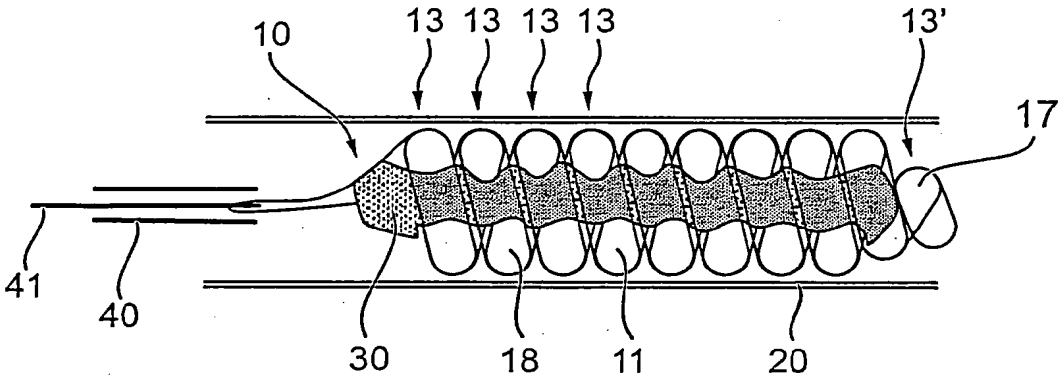


FIG. 4

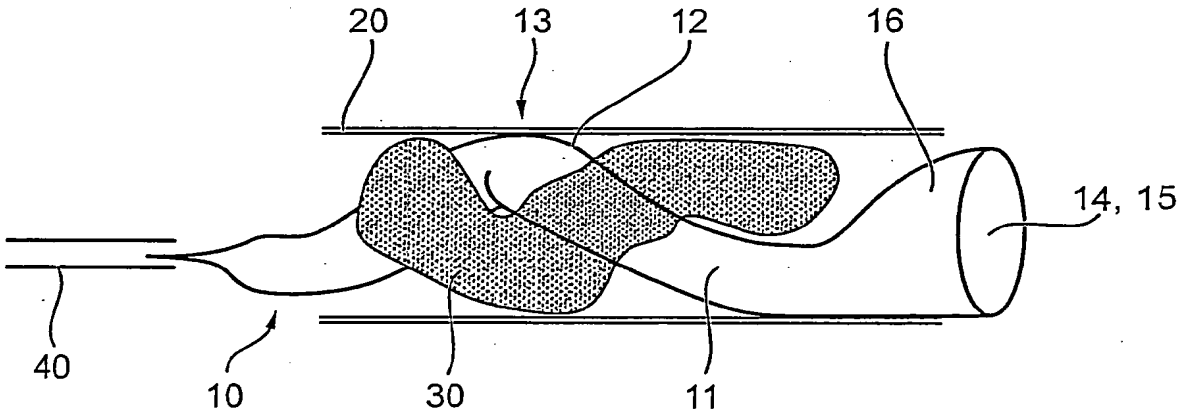


FIG. 5

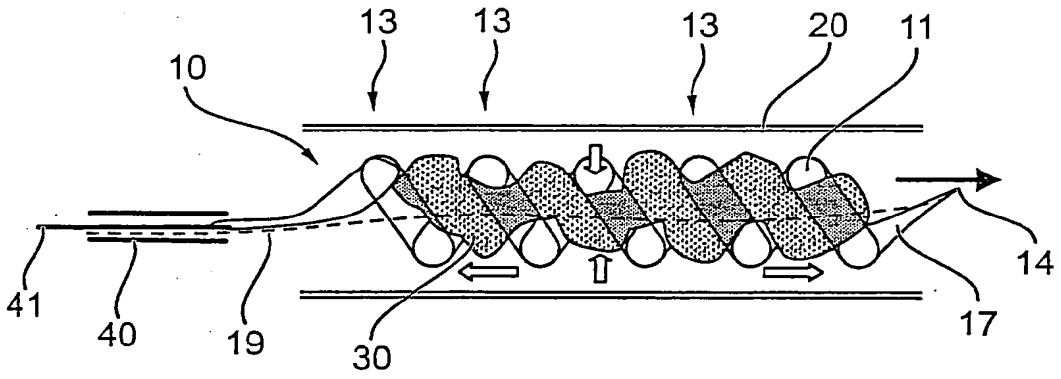

13
13
13
20
11
10
14
41
40
19
30
17

FIG. 6

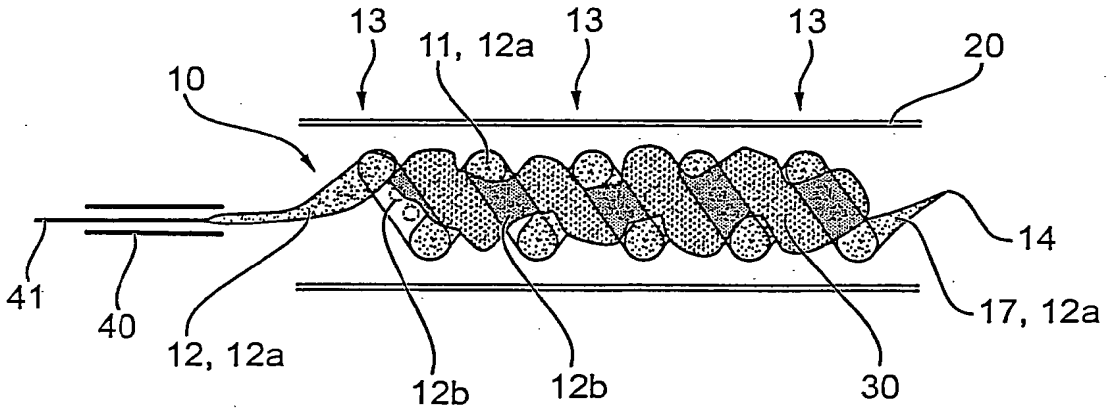

13
11, 12a
13
13
20
10
14
41
40
12, 12a
12b
12b
30
17, 12a

FIG. 7

Durchmesser des Hohlkörpers (mm)	Außendurchmesser des Rekanalisationselements bzw. der spiralförmigen Windungen (mm)	Gefäßdurchmesser (mm)
Von 1 bis 2,5	Von 2 bis 8	Von 2 bis 3
Von 1,5 bis 2,5	Von 3 bis 6	
Von 1,8 bis 2,2	Von 3 bis 5	
Von 1 bis 3	Von 3 bis 10	Von 3 bis 4
Von 1,5 bis 2,5	Von 4 bis 8	
Von 2,0 bis 2,5	Von 4 bis 6	
Von 1,5 bis 4	Von 4 bis 12	Von 4 bis 5
Von 2 bis 3	Von 5 bis 10	
Von 2,5 bis 3	Von 5 bis 7	

FIG. 8

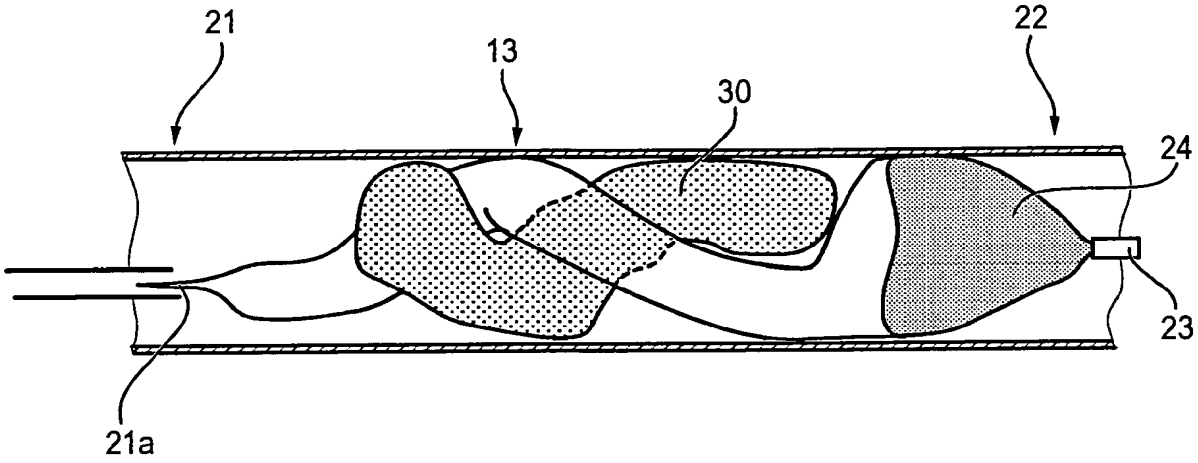


FIG. 9