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[Continued on next page]

(54) Title: EMBOLIC DEVICE AND METHODS OF USE

(57) Abstract: An embolic device and methods of use are disclosed. The embolic device can be a soft braided structure. The embolic device can be deployed with a deployment tool that can maintain the longitudinal structural integrity of the embolic device while the embolic device is being translated along a catheter to the target site.

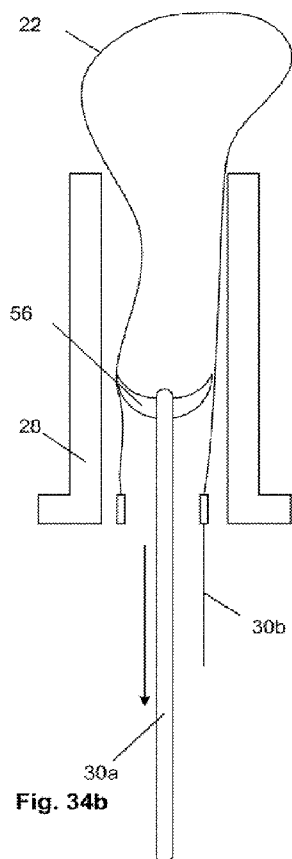


Fig. 34b





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1
2 TITLE OF THE INVENTION

3 EMBOLIC DEVICE AND METHODS OF USE

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6

7 CROSS-REFERENCE TO RELATED APPLICATIONS

8 **[0001]** The present application claims priority to U.S. Provisional Application Nos. 61/597,029,
9 filed 9 February 2012; and 61/721,367, filed 1 November 2012, both of which are incorporated
10 by reference in their entireties.
11

12 BACKGROUND

13 1. Technical field:

14 **[0002]** Embolic devices and method of deploying the same are disclosed. More specifically,
15 stents and neurological uses of the same are disclosed.
16

17 2. Background of the Art:

18 **[0003]** Coils are used to fill or embolize neurological aneurysms. These neuro coils are typically
19 made from platinum. They tend to be small coils or springs which can be shaped into a
20 secondary shape of a more complex curve in order to help fill the aneurysm sacks. One alternate
21 type of neuro vascular embolization stent coil device 10 has a braid-stent coil structure 12
22 suspended about a core structure 14 and may be used for aneurysm treatment, somewhat as
23 shown in Figure 1. The coils 12 can be inserted into an aneurysm 16 of a blood vessel 18 as
24 shown in Figure 2a with the intent of embolizing the aneurysm 16. Figure 2b shows that
25 separate stents 20 can be placed across the neck of the aneurysm 16. Stent coils 12, due to their
26 ability to expand once deployed outside of the delivery system or deployment tool, have the
27 advantage of filling an aneurysm 16 with less length than a non-expanding coil device. Also, the
28 porous structure formed by the stent portion of the stent coil can be more effective than a solid
29 structure like a coil in achieving inter-aneurysmal hemostasis due to its inherent interstices.

30 **[0004]** The stent coil devices 10 must be sufficiently soft so as not to damage the aneurysm or
31 surrounding vascular wall. However, deployment of the stent coil devices 10 can be difficult if

the stent coil devices 10 are not sufficiently rigid to sustain pushing or the stent coil 10 is too long, such as in excess of 10 cm. The stent coil devices 10 are loaded into catheters and delivered to the aneurysm 16 by pushing on the proximal end of the stent coil device 10 with another stent-coil or a pusher element. However, without improvements to the device design if the stent coil is not rigid enough or is too long, it will buckle or lock in the catheter, causing a jam and preventing further controlled deployment through the catheter.

[0005] Additionally, aneurysms 16 with larger mouths are very difficult to treat with coils. The coils may slip back out of the aneurysm sack. A typical 7mm in diameter neurological aneurysm would often be filled with five to seven individual spring shaped coils, which creates a longer and more complicated procedure than if the number of devices was reduced.

[0006] Accordingly, a deployment tool for delivering a soft, long stent-coil or other embolic device is desired. A deployment tool that can prevent longitudinal structural failure, buckling, and locking of the embolic device in the deployment catheter is also desired. A deployment tool that can retract and reposition the embolic device in the catheter is also desired. In addition to solutions for delivering a soft, long stent-coil which includes an inner core member such as a coil, a deployment tools is also desired to easily deploy, retrieved and detach a long, soft stent which has no core member.

SUMMARY OF THE INVENTION

[0007] Devices and methods for deploying a soft, long, elongated embolism device, are disclosed. The device can be used to treat aneurysms, such as aneurysms in neurovascular target sites.

[0008] An apparatus for deployment of an embolic device to a vascular target site is disclosed. The apparatus can have a force-transfer element. The force-transfer element can have a leader and a radial force transferor. The leader can have a coil. The radial force transferor can have a radial bump. The bump can have a rubber. The bump can have a braided configuration.

[0009] A method for deploying an embolic device to a vascular target site is disclosed. The method can include translating the embolic device along the hollow channel of a catheter. Translating can include maintaining longitudinal tension in the embolic device

[0010] The method can include attaching the embolic device to an inner force-transfer element. The inner force-transfer element can be at least partially radially inside of the embolic device.

1 [0011] Attaching can include frictionally abutting the inner force-transfer element against the
2 embolic device. The inner force-transfer element can include a prong. The method can include
3 inserting the prong through the embolic device.

4 [0012] Inserting the prong can include extending the prong radially outward from the inner
5 force-transfer element. The embolic device can have an open cell, and inserting the prong can
6 include inserting the prong through the open cell. Maintaining longitudinal tension in the
7 embolic device can include attaching the deformable layer to prongs and/or bumps attached to
8 the coil configured to aid pushing the embolic device, where the embolic device can include a
9 stent-coil.

10 [0013] An apparatus for embolizing a vascular target site is disclosed. The apparatus can have
11 an embolic device. The apparatus can have an inner force-transferring element configured to
12 transfer force to the embolic device during the deployment of the embolic device. The apparatus
13 can have a catheter.

14 [0014] The inner force-transferring element can have a leader and a radial force transferor. The
15 radial force transferor can have a flare. The radial force transferor can have a bump. The bump
16 can have an elastomeric material. The elastomeric material can have a rubber. The bump can
17 have a braided configuration. The radial force transferor can have a proximal attachment. The
18 radial force transferor can have a proximal attachment and a distal attachment.

19
20
21 BRIEF DESCRIPTION OF THE DRAWINGS

22 [0015] Figure 1 illustrates a variation of a stent coil.

23 [0016] Figures 2a and 2b illustrate variations of using stent coils in aneurysms.

24 [0017] Figure 3 illustrates a variation of a braided embolic device.

25 [0018] Figures 4a, 4b, 4c and 4d illustrate a method of deploying the embolic device with a
26 variation of the deployment tool.

27 [0019] Figures 4b' and 4b" are variations of cross-sections E-E and F-F, respectively, of Figure
28 4b.

29 [0020] Figures 5a through 5d illustrate a method of deploying the embolic device with a
30 variation of the deployment tool.

31 [0021] Figures 6a and 6b are close-up views of a variation of the braided embolic device.

32 [0022] Figures 7a and 7b are close-up views of a variation of the braided embolic device.

1 [0023] Figures 8a and 8b illustrate a method of deploying the embolic device with a variation of
2 the deployment tool.

3 [0024] Figures 9a and 9b are a side view and a close-up side view, respectively, of a variation of
4 the embolic device.

5 [0025] Figures 10a through 10c illustrate a method of radial expansion of the distal end of a
6 variation of the flare.

7 [0026] Figures 11a and 11b are front (i.e., longitudinally axial) and side views, respectively, of a
8 variation of the flare.

9 [0027] Figures 12a and 12c are front and side views, respectively of a variation of the flare and
10 the deforming layer, and a side view of the flare on a mandrel or core.

11 [0028] Figures 13a and 13b are front and side views, respectively of a variation of the flare and
12 the deforming layer.

13 [0029] Figures 14a through 14c illustrate a variation of the flare.

14 [0030] Figure 15 illustrates a variation of the embolic device with the flare and core.

15 [0031] Figure 16 illustrates a variation of making the flare.

16 [0032] Figure 17 illustrates a variation of the embolic device and the deployment tool.

17 [0033] Figure 18 illustrates a cut-away schematic view of a length of the embolic device and the
18 deployment tool.

19 [0034] Figures 19a through 19d illustrate a variation of a method for making the flares.

20 [0035] Figures 20a through 20d illustrate a method of using the flare.

21 [0036] Figures 21a and 21d illustrate variations of the flare.

22 [0037] Figure 22a is a side cut-away view of a variation of the embolic device.

23 [0038] Figure 22b is a variation of cross-section A-A of Figure 22a.

24 [0039] Figure 23a illustrates a variation of the core.

25 [0040] Figure 23b is a close-up view of a length of Figure 23a.

26 [0041] Figure 23c illustrates a variation of the embolic device.

27 [0042] Figures 24a and 24b illustrate a method of deploying the embolic device with a variation
28 of the deployment tool.

29 [0043] Figures 25a through 25c illustrate a method of deploying the embolic device with a
30 variation of the deployment tool.

- 1 [0044] Figures 26a and 26b illustrate a method of deploying the embolic device with a variation
2 of the deployment tool.
- 3 [0045] Figure 27a illustrates a variation of the embolic device loaded on a deployment tool.
- 4 [0046] Figures 27b and 27c are variations of cross-sections E'-E' and F'-F', respectively, of
5 Figure 27a.
- 6 [0047] Figures 28a through 28c illustrate a variation of the deployment tool and embolic device.
- 7 [0048] Figures 29 and 30 illustrate variations of the deployment tool and embolic device.
- 8 [0049] Figures 31a and 31b illustrate a variation of the deployment tool and embolic device.
- 9 [0050] Figures 32a and 32b illustrate a method of deploying the embolic device with a variation
10 of the deployment tool.
- 11 [0051] Figure 33 illustrates a variation of the deployment tool and the embolic device.
- 12 [0052] Figures 34a through 34d illustrate a method of using a variation of the deployment tool.
- 13 [0053] Figures 35a through 39b illustrate various devices and methods of use.
- 14 [0054] Figures 44a through 44c are cross-sectional views of a method of deploying the embolic
15 device with a variation of the deployment tool.
- 16 [0055] Figures 45a through 45c are cross-sectional views of a method of deploying the embolic
17 device with a variation of the deployment tool.
- 18 [0056] Figures 46a and 46b are cross-sectional views of a method of deploying the embolic
19 device with a variation of the deployment tool.
- 20 [0057] Figure 46a' is a cross-sectional view of a variation of section B-B of Figure 46a.
- 21 [0058] Figures 47 is a cross-sectional view of a method of deploying the embolic device with a
22 variation of the deployment tool.
- 23 [0059] Figure 48a is a cross-sectional view of a variation of the deployment tool and embolic
24 device.
- 25 [0060] Figure 48b is a cross-sectional view of a variation of the deployment tool and embolic
26 device.
- 27 [0061] Figures 49a and 49b are cross-sectional views of a method of deploying the embolic
28 device with a variation of the deployment tool.
- 29 [0062] Figures 50a through 50c are cross-sectional views of a method of deploying the embolic
30 device with a variation of the deployment tool.

[0063] Figure 51a is a cross-sectional view of a variation of the embolic device and a portion of the deployment tool and a method for making the same.

[0064] Figures 51b and 51c are cross-sectional views of a method of deploying the embolic device with a variation of the deployment tool.

[0065] Figures 52a and 52b are cross-sectional views of a method of deploying the embolic device with a variation of the deployment tool.

DETAILED DESCRIPTION

[0066] Figure 3 illustrates a variation of an embolic device 22 in a relaxed configuration, such as after being released from or before insertion into a catheter. The embolic device 22 can be a stent, coil, or stent-coil. The embolic device 22 can have or be made from fabric. The embolic device 22 can be made from a braided, woven or knitted material, such as a fabric. The embolic device 22 can be self-expandable.

[0067] The embolic device 22 can be formed into one or more configurations along the length of the embolic device 22. For example, the embolic device 22 can have a straight length 24a, cylindrical length (not shown), a figure-eight length 24b, a coil length 24c, a sine curve length 24d (with the sine curve out of plane with the direction of the device 22), or combinations thereof.

[0068] The embolic device 22 can have a compact or delivery diameter, for example when the device is compacted into a catheter during delivery to a target site. The delivery diameter can be from about 0.1 mm to about 1.0 mm, more narrowly from about 0.2 mm to about 0.8 mm, more narrowly from about 0.25 mm to about 0.69 mm, for example about 0.5 mm.

[0069] The embolic device 22 can be configured to expand radially by factors from about 1.5 to about 20 times, for example about 5 times the delivery diameter when not constrained inside of the catheter compared to when constrained by the catheter.

[0070] The embolic device 22 can be made by weaving, knitting or braiding filaments into tubes and shaping them. For example, the filaments can have diameters less than about 0.001 in. The tubes can be annealed into more complex 3-D shapes, such as shown in Figure 3. The embolic device 22, such as the braided fabric coils, can be highly flexible, such as being able to conform to a tight 2mm radius without damaging or plastically deforming the device shape and porous structures with pore sizes ranging from about 0.01mm^2 to about 0.25mm^2 .

1 [0071] The distal end of the embolic device 22, for example the first end of the embolic device
2 22 deployed into the aneurysm sack, can have a fabric anchor. The fabric anchor can be
3 configured to seat or keep the device in the sack and not escaping after the device is positioned
4 into the target aneurysm sack. The fabric anchor can lodge in the mouth of the sack, obstructing
5 the mouth and preventing the remainder of the device from escaping the aneurysm.

6 [0072] A typical 7mm in diameter aneurysm can be filled with about one to about four, for
7 example about three of the embolic devices 22. The embolic device 22 can interlock with other
8 embolic devices and may tend to stay within the aneurysm sack. The embolic devices 22 can be
9 used to fill larger neck aneurysms. The embolic devices 22 can interlock with each other. The
10 embolic device 22, such as stent-coils, for example due to their self-expanding nature, can resist
11 coil compaction inside of the aneurysm. Coil compaction in the aneurysm space, which is a
12 common problem with typical coils and can occur weeks, months or years after the embolization,
13 resulting in the need for additional embolizations of the aneurysm to reduce its risk of future
14 rupture. The embolic device 22 can be used with a frame the inside of the aneurysm like a vessel
15 liner, for example to block subsequently deployed embolic devices movement out the neck of the
16 aneurysm. The stent-coil can be placed near the neck of the aneurysm. The porous outside layer
17 of the stent-coil structure can enhance the ability to heal the aneurysm by providing a scaffold for
18 new cell growth and attachment. The stent-coil structure can be placed inside the aneurysm neck
19 or inside the parent vessel to aid in vessel occlusion in arterial venous malformations, fistulas or
20 to any target where it is desirable to slow or arrest blood flow. When treating aneurysms the
21 stent-coil deployed inside the aneurysm can reduce the risk of a subsequent stroke and the need
22 for putting the patient on long term blood thinner or anti-coagulants as compared to placing a
23 flow diverting stents in the parent artery at the mouth of the aneurysm.

24 [0073] The embolic device 22 can be filled with a filler before or after deployment in the
25 aneurysm.

26 [0074] The embolic devices 22 can have radiopaque and/or echogenic visualization markers.
27 The fibers of the embolic device 22 can be made from interbraided wire, for example made from
28 platinum, platinum alloys (e.g., platinum-iridium alloy), and gold. The deployment tools, such
29 as the catheters, pushers and mandrels, can have one or more markers. The embolic devices 22
30 can be inserted into multiple vascular target sites to embolize aneurysm sacks. A first embolic

1 device can be inserted into a first aneurysm and a second embolic device can be inserted into a
2 second aneurysm.

3 **[0075]** Any or all elements of the embolic device 22 and/or other devices or apparatuses
4 described herein can be made from, for example, platinum, platinum alloys for example with
5 gold filaments, a single or multiple stainless steel alloys, nickel titanium alloys (e.g., Nitinol),
6 cobalt-chrome alloys (e.g., ELGILOY® from Elgin Specialty Metals, Elgin, IL;
7 CONICHROME® from Carpenter Metals Corp., Wyomissing, PA), nickel-cobalt alloys (e.g.,
8 MP35N® from Magellan Industrial Trading Company, Inc., Westport, CT), molybdenum alloys
9 (e.g., molybdenum TZM alloy, for example as disclosed in International Pub. No. WO
10 03/082363 A2, published 9 October 2003, which is herein incorporated by reference in its
11 entirety), tungsten-rhenium alloys, for example, as disclosed in International Pub. No. WO
12 03/082363, polymers such as polyethylene terephthalate (PET), polyester (e.g., DACRON®
13 from E. I. Du Pont de Nemours and Company, Wilmington, DE), poly ester amide (PEA),
14 polypropylene, aromatic polyesters, such as liquid crystal polymers (e.g., Vectran, from Kuraray
15 Co., Ltd., Tokyo, Japan), ultra high molecular weight polyethylene (i.e., extended chain, high-
16 modulus or high-performance polyethylene) fiber and/or yarn (e.g., SPECTRA® Fiber and
17 SPECTRA® Guard, from Honeywell International, Inc., Morris Township, NJ, or DYNEEMA®
18 from Royal DSM N.V., Heerlen, the Netherlands), polytetrafluoroethylene (PTFE), expanded
19 PTFE (ePTFE), polyether ketone (PEK), polyether ether ketone (PEEK), poly ether ketone
20 ketone (PEKK) (also poly aryl ether ketone ketone), nylon, polyether-block co-polyamide
21 polymers (e.g., PEBAX® from ATOFINA, Paris, France), aliphatic polyether polyurethanes
22 (e.g., TECOFLEX® from Thermedics Polymer Products, Wilmington, MA), polyvinyl chloride
23 (PVC), polyurethane, thermoplastic, fluorinated ethylene propylene (FEP), absorbable or
24 resorbable polymers such as polyglycolic acid (PGA), poly-L-glycolic acid (PLGA), polylactic
25 acid (PLA), poly-L-lactic acid (PLLA), polycaprolactone (PCL), polyethyl acrylate (PEA),
26 polydioxanone (PDS), and pseudo-polyamino tyrosine-based acids, extruded collagen, silicone,
27 zinc, echogenic, radioactive, radiopaque materials, a biomaterial (e.g., cadaver tissue, collagen,
28 allograft, autograft, xenograft, bone cement, morselized bone, osteogenic powder, beads of bone)
29 any of the other materials listed herein or combinations thereof. Examples of radiopaque
30 materials are barium sulfate, zinc oxide, titanium, stainless steel, nickel-titanium alloys, tantalum
31 and gold.

1 [0076] The embolic device 22 can be made from substantially 100% PEEK, substantially 100%
2 titanium or titanium alloy, or combinations thereof.

3 [0077] The embolic device 22 can be made partially or completely from biodegradable and/or
4 bioabsorbable materials.

5 [0078] Any or all elements of the embolic device 22 and/or other devices or apparatuses
6 described herein, can be, have, and/or be completely or partially coated with agents for adhesion,
7 cell ingrowth, cell toxicity (e.g., cytostatic and/or cytotoxic) or combinations thereof.

8 [0079] The embolic device 22 and/or elements of the device and/or other devices or apparatuses
9 described herein can be filled, coated, layered and/or otherwise made with and/or from fillers
10 and/or glues known to one having ordinary skill in the art and/or a therapeutic and/or diagnostic
11 agent. Any of these fillers and/or glues can include growth factors.

12 [0080] The agents within these matrices can include any agent disclosed herein or combinations
13 thereof, including radioactive materials; radiopaque materials; cytogenic agents; cytotoxic
14 agents; cytostatic agents; thrombogenic agents, for example polyurethane, cellulose acetate
15 polymer mixed with bismuth trioxide, and ethylene vinyl alcohol; lubricious, hydrophilic
16 materials; phosphor cholene; anti-inflammatory agents, for example non-steroidal anti-
17 inflammatories (NSAIDs) such as cyclooxygenase-1 (COX-1) inhibitors (e.g., acetylsalicylic
18 acid, for example ASPIRIN® from Bayer AG, Leverkusen, Germany; ibuprofen, for example
19 ADVIL® from Wyeth, Collegeville, PA; indomethacin; mefenamic acid), COX-2 inhibitors
20 (e.g., VIOXX® from Merck & Co., Inc., Whitehouse Station, NJ; CELEBREX® from
21 Pharmacia Corp., Peapack, NJ; COX-1 inhibitors); immunosuppressive agents, for example
22 Sirolimus (RAPAMUNE®, from Wyeth, Collegeville, PA), or matrix metalloproteinase (MMP)
23 inhibitors (e.g., tetracycline and tetracycline derivatives) that act early within the pathways of an
24 inflammatory response. Examples of other agents are provided in Walton et al, Inhibition of
25 Prostaglandin E₂ Synthesis in Abdominal Aortic Aneurysms, Circulation, July 6, 1999, 48-54;
26 Tambiah et al, Provocation of Experimental Aortic Inflammation Mediators and Chlamydia
27 Pneumoniae, Brit. J. Surgery 88 (7), 935-940; Franklin et al, Uptake of Tetracycline by Aortic
28 Aneurysm Wall and Its Effect on Inflammation and Proteolysis, Brit. J. Surgery 86 (6), 771-775;
29 Xu et al, Sp1 Increases Expression of Cyclooxygenase-2 in Hypoxic Vascular Endothelium, J.
30 Biological Chemistry 275 (32) 24583-24589; and Pyo et al, Targeted Gene Disruption of Matrix
31 Metalloproteinase-9 (Gelatinase B) Suppresses Development of Experimental Abdominal Aortic

Aneurysms, J. Clinical Investigation 105 (11), 1641-1649 which are all incorporated by reference in their entirety.

[0081] METHODS OF USE

[0082] Figure 4a illustrates that the embolic device 22 can be loaded into a deployment device or deployment tool 26 for inserting and deployment into a target site. The target site can be a vascular aneurysm. The deployment tool 26 can have a catheter 28, a coil or other pusher 30, a support mandrel 32, and combinations thereof. The embolic device 22 can be a braided configuration.

[0083] The support mandrel 32 can have an outer diameter about equal to the inner diameter of the embolic device 22. The embolic device 22 can float over the mandrel 32, e.g., the gap distance between the mandrel 32 and braid or other embolic device 22 can be from about 0.001 in. to about 0.010 in. The embolic device 22 can be fitted onto and frictionally attached (e.g., from the tight fit) to the support mandrel 32 before deployment. The embolic device 22 can translatably slide with respect to the support mandrel 32 if the friction resistance between the mandrel 32 and the embolic device 22 is overcome. The support mandrel 32 can have a support mandrel hub 34 or handle extending radially from the remainder of the mandrel 32. The support mandrel hub 34 can be proximal of the embolic device 22. The support mandrel 32, for example via the support mandrel hub 34, can be longitudinally translatably fixed to the pusher 30.

[0084] The pusher 30 can be slidably placed over the proximal end of the support mandrel 32. The distal end of the pusher 30 can abut, and/or be rigidly attached to the proximal end of the embolic device 22 at the abutment point 36. The pusher 30 can have an inner diameter approximately equal to the inner diameter of the embolic device 22. The pusher 30 can have an outer diameter equal to or greater than the outer diameter of the embolic device 22. The embolic device 22 can be releasably attached to the pusher 30.

[0085] The catheter 28 can have a catheter hub 38 at the proximal end of the catheter.

[0086] The pusher 30 and mandrel 32 can be translated longitudinally concurrently, as shown by arrow.

[0087] Figure 4b illustrates that the pusher 30 can be translatably pushed longitudinally with respect to the catheter 28, as shown by arrow. Driven by the pusher 30, the mandrel 32 and embolic device 22 can translate with respect to the catheter 28, for example, until the support

mandrel hub 34 abuts the catheter hub 38. The tight fit of the support mandrel 32 inside the embolic device 22 can prevent the embolic device 22 from buckling inward or outward (since outward buckling requires inward buckling).

[0088] Figures 4b' and 4b'' illustrate that the pusher can fit between the support mandrel 32 and the catheter 28. The support mandrel 32 can be almost complete encircled or completely encircled along a part of the length of the support mandrel 32 by the pusher 30. The pusher 30 can also have a pusher slot 40. The support mandrel hub 34 can slide through the pusher slot 40, for example to limit the travel distance of the mandrel 32 (e.g., the pusher slot 40 can extend along part, but not all of the length of the pusher 30, for example, to prevent the mandrel 32 from sliding out of the proximal and/or distal ends of the pusher 30). The mandrel 32 can be positioned in, and/or distal to, and/or proximal to the catheter 28. The mandrel 32 can be retained by the catheter 28, for example, so as not to be implanted with the embolic device 22.

[0089] Figure 4c illustrates that the pusher 30 can continue to push, as shown by arrow, the embolic device 22 after the support mandrel hub 34 has abutted the catheter hub 38. The pusher 30 can longitudinally translate with respect to the mandrel 32, pushing the embolic device 22 out of the distal end of the catheter 28 and off of the distal end of the support mandrel 32. The distal end of the support mandrel 32 can remain in the catheter 28. The embolic device 22 can be retracted into the catheter 22 by the pusher 30, for example to reposition the embolic device 22 at the target site.

[0090] Figure 4d illustrates that the pusher 30 can continue to push, as shown by advancing arrow, the embolic device 22. The embolic device 22 can be fully delivered out of the catheter 28. The embolic device 22 can be detached from the pusher 30. The embolic device 22 can self-expand (e.g., radially while contracting longitudinally) when released from the constraints of the support mandrel 32 and the catheter 28. The pusher 30 and the remainder of the deployment tool 26 can be withdrawn from the catheter 28, target site and/or patient, as shown by retracting arrow.

[0091] Figures 5a through 5d illustrate that the embolic device 22 can be deployed by a deployment tool 26 similar to the deployment tool 26 shown in Figures 4a through 4d, except the body of the mandrel 32 co-extensive with the pusher 30 can be outside of the pusher 30. For example, the pusher 30 can be laterally adjacent to the mandrel 32. The support mandrel 32 can also have a support mandrel beam 42 extending between the support mandrel body 44 within the

1 embolic device 22 and the support mandrel hub 34. The pusher 30 can releasably attach to the
2 entire terminal circumference of the proximal end of the embolic device 22, or to only a
3 fractional angular portion of the circumference. The pusher 30 and mandrel 32 can be translated
4 longitudinally concurrently, as shown by arrow in Figure 5a. The pusher 30 can be pushed or
5 pulled (e.g., to withdraw the pusher and/or retract the embolic device 22), as shown by arrows in
6 Figures 5c and 5d.

7 **[0092]** Figures 6a and 6b illustrate that the embolic device 22 can have a braid angle 46. The
8 braid angle 46 can be the angle between two crossing filaments or fibers viewed along the
9 direction of the longitudinal axis. The braid angle 46 when the device 22 is in a radially
10 contracted configuration (e.g., when loaded in a catheter) can be from about 20° to about 30°.
11 The braid angle 46 when the device is in a radially expanded configuration (e.g., when deployed
12 out of a catheter) can be from about 40° to about 60°, for example about 50°. The fibers or
13 filaments can be 0.0008 in. metal (e.g., Nitinol) wires heat set on a manufacturing mandrel
14 having a diameter of about 1 mm.

15 **[0093]** Figures 7a and 7b illustrate that the embolic device 22 can have a braid angle 46 in a
16 radially expanded configuration from about 100° to about 110°. When the device 22 is in a
17 radially contracted configuration, the braid angle 46 can be from about 50° to about 70°.

18 **[0094]** The deployment tools can deploy, retrieve and reposition the embolic device 22 (e.g., a
19 stent-coil) fabricated with small or large braid angles 46. The deployment tools can push the
20 stent-coil braid structure inside a catheter and into an aneurysm.

21 **[0095]** For example, the proximal end of a 12cm long, braided embolic device 22 having a
22 collapsed braid angle 46 of about 20° (e.g., as shown in Figure 6a, 6b) can be pushed inside a
23 0.021" ID catheter 28.

24 **[0096]** Figure 8a illustrates that the embolic device 22 can have a deforming layer 48 (referred to
25 in the figures as a braid, although the deforming layer can be braided, knitted, woven, or
26 combinations thereof) and, optionally, a force-transfer element, such as a core 50. The force-
27 transfer element or core 50 can be configured to transfer a distally translational force from the
28 user (e.g., manually or automatically, such as from a motor), to the embolic device 22, and/or the
29 deforming layer 48 (i.e., if the force-transfer element 50 is retained by the deployment device 26
30 during use and not deployed in the aneurysm). The force transfer or translation element 50 can
31 have a leader 52 and a radial force transferor, such as a flare 54 or a bump, that can transfer the

translational force from the leader 52 to the deformable layer 48. The force transfer element can be partially or completely radially interior to the deforming layer 48. The core 50 can be implanted with the deforming layer 48. The core 50 can also be a component of the deployment tool 26 instead and not implanted.

[0097] The core 50 can have a flexible, central extend member or leader 52, such as a flexible coil, rod, polymeric extrusion, other flexible elongated element, or combinations thereof, and one or more radial pressure members, such as flares 54, bumps or combinations thereof. For example, two, three or more flares 54 can be attached to the leader 52 at evenly spaced longitudinal lengths (e.g., every about 3 cm) along the core 50. The flares 54 can be radially expandable. The flares 54 can be configured to radially expand when the core is longitudinally translated distally within the catheter 28 and/or with respect to the deforming layer 48. The flares 54 can be configured to radially contract when the core 50 is longitudinally translated proximally with respect to the catheter 28 and/or the deforming layer 48.

[0098] The flares 54 can be attached to the core 50 at the proximal ends of the flares 54. The distal ends of the flares 54 can radially contract and expand. The distal ends of the flares 54 can releasably attach to the deforming layer 48. For example, the flare 54 can attach to the deforming layer 48 when the distal end of the flare 54 radially expands and the distal end of the flare 54 can radially engage with and attach to the deforming layer 48, while the proximal end of the flare 54 remains attached to the core 50.

[0099] The core 50 can be made from platinum, tantalum-doped polymer such as Nylon, polyester, or combinations thereof, or any other materials disclosed herein or combinations thereof. The core 50 can have a solid cross-section or be a hollow tube (e.g., to minimize structural rigidity). As the core 50 is longitudinally translated distally, the flares 54 can radially expand against the catheter 28 wall and drag or push the embolic device 22 (by transmitting force through the deforming layer 48) at the locations of the flare 54, for example to prevent or minimize buckling or longitudinal collapse of the embolic device 22 or deforming layer 48.

[0100] The pusher 30 can be longitudinally advanced, pushing the embolic device 22 distally. The pusher 30 can detached from direct connection with the embolic device 22 and retract (i.e., move proximally), in which case the flares 54 can radially retract and the embolic device 22 can remain longitudinally unmoved. In this manner, the embolic device 22 can be progressively

translated distally in discrete increments as the pusher 30 can be repeatedly advanced a fraction of the length of catheter 28 and retracted in a ratcheting motion.

[0101] As described herein, the coil pusher 30 can be used to push and pull the embolic device 22.

[0102] Figure 8b illustrates that as the embolic device 22 exits the distal end of the catheter 28, the embolic device 22 (or deforming layer 48 in the situation where the core 50 is a portion of the embolic device 22) can radially expand and detach from the flares 54. The distal and/or proximal terminal ends of the embolic device 22 or deforming layer 48, can be releasably or non-releasably attached to the core 50.

[0103] Figures 9a and 9b illustrate a variation of the embolic device 22 having the deforming layer 48, for example made from a braided material, and the core 50. The core 50 can be made from a coil (e.g., a platinum coil with or without a stretch-resistant element) or a solid or tubular rod (e.g., a polymer extrusion). The core 50 can be a guidewire (e.g., a Transcend EX from Boston Scientific of Natick, MA). The core 50 can have a core outer diameter from about 0.012 in to about 0.013 in, for example about 0.0125 in.

[0104] The flares 54 can be attached to the core 50. The flares 54 can have prongs 56 that can extend radially from the body of the flare 54. The prongs 56 can be configured to radially extend and retract. The prongs 56 can extend through the cells 58 of the braided deforming layer 48 when the prongs 56 are in a radially expanded configuration and the deforming layer 48 is in a radially contracted configuration.

[0105] The deforming layer 48 can be made from a braid of wires 60, for example from about 16 to about 48, for example about 24 wires. The deforming layer 48 can have an outside diameter from about 0.0160 in to about 0.0170 in. in a contracted configuration, for example about 0.0165 in. The deforming layer 48 can have an outside diameter when heat set and undeformed from about 0.75 mm to about 1.2 mm. The wires 60 can be any material disclosed herein such as monofilament or multifilament polymer (e.g., PET, Nylon) or metal (e.g., platinum, Nitinol), a hybrid of materials in a single braid, or combinations thereof. The wires 60 can have a 0.001 in. diameter. The wires 60 can have a length of about 1.1 mm from intersecting one wire to the next wire. The embolic device 22 can be loaded into a catheter 28. The catheter 28 can have an inner diameter, such as from about 0.015 to about 0.025 in., for example about 0.019 in.

[0106] Figures 10a through 10c illustrate that the proximal end of the flare 54 can be attached to the core 50. The distal end of the flare 54 can be radially expandable. The distal end of the flare 54 can have prongs 56 that can extend distally and radially. The flare 54 can be made from tubing (e.g., polyimide or any other material disclosed herein) and can be cut or frayed at the distal end of the flare 54 to form the prongs 56.

[0107] Figures 11a and 11b illustrate that the prongs 56 can be arranged into angularly aligned or misaligned rows extending proximally from the distal end of the flare 54. For example, the flare 54 can have four longitudinally-spaced rows of prongs 56. The prongs 56 can be angularly spaced evenly around the flare 54. For example, the center of the prong 56 can each extend away from the flare 54 at about 45° away from the center of the angularly-adjacent prong 56.

[0108] Figures 12a through 12c illustrate that the flare 54 can be configured to push the deforming layer 48 or embolic device 22 with the prongs 56. The prongs 56 can be formed from the terminal ends of a flare braid 64. For example, the proximal end of the flare 54 can have a cohesion layer 62. The cohesion layer 62 can be polymer bonded to the proximal end of the flare braid 64. The distal end of the flare braid 64 can be out of the cohesion layer 62 with no polymer and can radially expand beyond the cohesion layer 62. The flare braid 64 can be inverted and form two flare braid layers (e.g., a radially inner layer and a radially outer layer) within the cohesion layer 62, as seen in Figures 12a and 12b.

[0109] Figures 13a and 13b illustrate a variation of the flare 54 similar to the flare in Figures 12a through 12c except the flare braid 64 forms only one flare braid layer in the cohesion layer 62.

[0110] The deforming layer 48 can be a braid having from about 8 to about 32 ends. The deforming layer 48 can be made from wires 60 or filaments that can have a diameter from about 0.0015 in to about 0.002 in, for example about 0.001 in.

[0111] Figures 14a through 14c illustrate that the flare 54 can be made from a braid. For example, the flare 54 can be made from braided wire. The wires of the flare 54 can be made from any material disclosed herein or combinations thereof, for example Nitinol. The flare 54 can have about 24 wires. The wires of the flare 54 can be from about 0.0005 in. to about 0.0011 in. for example about 0.0008 in. in diameter. The flare prongs 56, formed by the ends of the wires forming the flare, can interdigitate with the cells 58 of the deformable layer 48. As shown in Figure 14b, the proximal end of each flare 54 can be fixedly attached, as shown by arrow, to the leader 52 of the core 50.

[0112] Figure 15 illustrates that the flares 54 can be spaced along the core 50. For example, along a 30 cm core, the flares 54 can be longitudinally spaced apart with the first prongs of each flare at 12cm, 15 cm, 18cm, 21 cm, 24 cm, and 27 cm from the proximal end of the core 50. The flares 54 can also be placed, for example, with the the first prongs of each flare at 3 cm, 6 cm, and 9 cm from the proximal end of the core 50.

[0113] Figure 16 illustrates that the flare 54 can be a flare braid 64. The flare braid 64 can be braided over a first manufacturing mandrel (not shown). The flare braid 64 can then be inverted (i.e., turned inside out) over a second manufacturing mandrel 66. A cohesion layer 62 can then be formed by applying melted polymer onto the proximal end of the flare 54. The prongs 56 or fingers can be uncoated with the polymer.

[0114] The flare 54 can be made from about 24 wires (i.e., and 24 ends). For example, the wires can be about 0.0008 in. in diameter. The first manufacturing mandrel can be about 2 mm in diameter. The second manufacturing mandrel 66 can have a second manufacturing mandrel diameter 68 of about 0.015 in..

[0115] Figure 17 illustrates that the prongs 56 can extend through the cells 58 of the deformable layer 48 of the embolic device 22. The prongs 56 can radially restrain the braided wires 60 of the deformable layer 48, for example, preventing the deformable layer 48 from completely expanding when outside of the catheter 28. The core 50 can be retracted to withdraw the prongs 56 from the embolic device 22, allowing the embolic device 22 to radially expand completely.

[0116] Figure 18 illustrates that the prongs 56 can pass through the cells 58 of the embolic device 22 and contact the inner wall of the catheter 28 when the flare 54 is in the catheter 28. When the flare 54 is deployed from the catheter 28, the prongs 56 can release and detach from the embolic device 22. The prongs 56 can extend orthogonally (i.e., perpendicular) to the longitudinal axis of the core 50 as short as possible while still engaging the embolic device 22. For example, the leader 54 (e.g., a coil) of the core 50 can have an outer diameter of about 0.015 in. The catheter 28 can have an inner diameter of about 0.021 in. The prongs 56 can extend orthogonally about 0.003 in. The core 50 can have a single prong 56 per unit length (e.g., a single prong 56 extending from each flare 54) or multiple prongs 56 per unit length, as shown in Figure 17. The prong 56 can extend at a prong angle 70 from about 70° to about 110° from the longitudinal axis 72 of the leader 52.

[0117] Figure 19a illustrates that a flare braid 64 can be made on a first manufacturing mandrel 74. A portion of the length of the braid 64 can be coated, for example with a polymer, to form a cohesion layer 62.

[0118] Figures 19b and 19c illustrate that the flare braid 64 can be cut laterally or radially through the cohesion layer 62, resulting in two flares 54. The terminal ends of the flare braids 64 not in the adhesion layer or cohesion layer 62 can be flared radially outward, forming prongs 56. Figure 19d illustrates that the first manufacturing mandrel 74 can be removed from the flare 54.

[0119] Figure 20a illustrate that the catheter 28 can be retracted, as shown by arrow, from the embolic device 22.

[0120] Figure 20b illustrates that the embolic device 22 can radially expand and that the core 50 and flares 54 can be longitudinally advanced, as shown by arrow, with respect to the embolic device 22. The prongs 56 from the flare 54 can extend through the cells 58 in the braid of the deforming layer 48. The prongs 56 can engage the embolic device 22 and/or deforming layer 48 and attach the embolic device 22 and/or the deforming layer 48 to the core 50 via the flares 54.

[0121] Figure 20c illustrates that the core 50 can be retracted, as shown by arrow, with respect to the embolic device 22. The prongs 56 can withdrawn from the cells 58 of the embolic device 22 and detach the embolic device 22 and/or the deforming layer 48 from the flares 54.

[0122] Figure 20d illustrates that the core 50 and flares 54 can be advanced again, as shown by arrow. The prongs 56 can radially expand and pass through cells 58 on the embolic device 22. The prongs 56 can attach to the embolic device 22 and/or the deforming layer 48 and connect the embolic device 22 and/or the deforming layer 48 to the core 50. The core 50 can push the embolic device 22.

[0123] Figures 21a and 21b illustrate that the prongs 56 can extend perpendicular to the longitudinal axis of the device when the prongs are engaged in the deforming layer 48. The the deforming layer 48 can have a 1.00 mm braid, and that the prongs 56 can be made from a Nitinol braid.

[0124] Figures 22a and 22b illustrate that the prongs 56 can be elastic. For example, the prongs 56 can be made from a heat memory alloy, such as Nitinol. The prongs 56 can be straight when in an unbiased configuration. The prongs 56 can extend from the outside of a first lateral side of the flexible leader 52 (e.g., a coil) of the core 50, through the center of the coil and extend out the opposite, second lateral side of the leader 52. The prongs 56 can extend from the outside of a

1 first lateral side of the coil or leader 52 of the core 50, along the perimeter of the coil or leader 52
2 and extend out the opposite, second lateral side of the coil or leader 52, or at any angle along the
3 perimeter, such as at about 90°. The prong 56 can be fixed to the coil or leader 52 and extend
4 radially outward from the coil or leader 52, but not extend along the perimeter or traverse the
5 inner area of the coil or leader 52. The prong 56 can be longer or shorter than the internal
6 diameter of the catheter 28. The prong 56 can be fused, melted, welded, adhered, or otherwise
7 attached to the turns of the coil or leader 52. When on a length of the core 50 that is positioned
8 in the catheter 28, the ends of the prong 56 radially outside of the coil or leader 52 can press and
9 bend against the catheter 28. When on a length of the core 50 that is positioned in the catheter
10 28, the prongs 56 can pass through the cells 58 of the deformable layer 48, for example a braided
11 deformable layer, and can transfer the translational force from the leader 52 of the core 50 to the
12 deformable layer 48, as shown in Figure 22a.

13 **[0125]** When the deformable layer 48 exits the distal end of the catheter 28, for example at the
14 target aneurismal site, the deformable layer 48 can radially self-expand. The deformable layer
15 48 can release from the prongs 56. When the prongs 56 exit the catheter 28, the prongs 56 can
16 revert to an unbiased configuration, for example having a straight configuration.

17 **[0126]** The proximal terminal end of the deformable layer 48 can be attached to the coil or leader
18 52. The deformable layer 48 can be not directly attached to the coil or leader 52. For example
19 the deformable layer 48 can be radially spaced from the leader 52 and mechanically
20 communicating with the leader 52 via the prongs 56.

21 **[0127]** Figures 23a and 23b illustrate that the prongs 56 can extend radially outwardly from the
22 coil or leader 52 of the core 50. The prong 56 can be between the winds of the coil or leader 52
23 (as shown in Figure 23b) and/or can extend directly from the longitudinal center of a wind of the
24 coil or leader 52. The prongs 56 can extend radially from the coil or leader 52. The prongs 56
25 can extend at a prong angle 70 of from about 45° to about 135°, more narrowly from about 85°
26 to about 95° to the longitudinal axis of the leader 72.

27 **[0128]** The prongs 56 can be, for example, about 0.001 in. in diameter by about 0.003 to 0.010 in
28 in length.

29 **[0129]** Figure 23c illustrates that the prongs 56 can extend through the cells 58 formed by the
30 struts or wires 60 of the deformable layer 48. The prongs 56 can press against the struts 60 of

1 the deformable layer 48, for example to transfer a longitudinal translation force from the core 50
2 to the deformable layer 48.

3 **[0130]** Figures 24a and 24b illustrate that the embolic device 22 can be deployed using the
4 methods described herein. The embolic device 22 can have narrow sections 76 along the length
5 of the embolic device 22. For example, the embolic device 22 can be heat set during
6 manufacturing to form narrow sections 76 when the embolic device is in an unbiased
7 configuration (e.g., not subject to constraining forces of the catheter 28). The core 50 can be
8 fixed to the deforming layer 48, for example at the narrow sections 76. The narrow sections 76
9 can occur at the flares 54. The distal terminal end of the deforming layer 48 can have a diameter
10 (e.g., from being heat set) about equal to or less than the core diameter, for example to attach the
11 distal end of the deforming layer 48 to the core 50.

12 **[0131]** Figure 25a illustrates that the deployment tool 26 can have a support mandrel 32. The
13 support or pushing mandrel 32 can have a flare 54 at the distal end of the mandrel 32. The flare
14 54 can be unidirectionally attached to the embolic device 22 and/or deforming layer 48, allowing
15 relative translation only when the embolic device 22 and/or deforming layer 48 is moving
16 distally with respect to the flare 54. The push mandrel 32 can have a push mandrel handle or hub
17 34. The push mandrel handle 34 can be controllably engaged between the puller 30 (i.e. the
18 “pusher” in other variations can primarily pull the coil in tension in the present variation) and/or
19 the push mandrel 32. The deformable layer 48 can be rigidly and detachably connected to the
20 puller 30 at the abutment point 36. The abutment point 36 can be an abutment (i.e., denoting no
21 overlap between the deformable layer 48 and the puller 30) or an overlap.

22 **[0132]** The deployment tool 26 can have the coil puller 30 that can be releasably attached to the
23 proximal end of the embolic device 22. The push mandrel 32 can be longitudinally distally
24 translated (i.e., advanced) through the catheter 28 with the puller 30 and the embolic device 22.
25 The puller 30 can hold the embolic device 22 so that the embolic device 22 remains in tension
26 between the flare 54 and the proximal end of the embolic device 22, for example to minimize
27 kinking of the embolic device 22 in the catheter 28.

28 **[0133]** The puller 30 can be a passively dragged with the mandrel 32 when the mandrel 32 is
29 initially advanced through the catheter 28.

[0134] Figure 25b illustrates that the push mandrel 32 can be longitudinally translated, as shown by arrow 78, along the catheter 28 while tension, as shown by arrow 80, remains on the puller 30.

[0135] Figure 25c illustrates that when the embolic device 22 begins to exit the distal end of the catheter 28, the puller 30 and push mandrel 32 can be repeatedly placed in compression and tension, as shown by arrows, with each other to ratchet the embolic device 22 off the distal end of the push mandrel 32.

[0136] Figure 26a illustrates that the embolic device 22 can be retrieved after deployment out of the catheter 28. For example, if the puller 30 is attached to the proximal end of the embolic device 22, the flare 54 can engage the embolic device 22 and deliver tension on the embolic device 22 between the flare 54 and the puller 30. The push mandrel handle 34 can be configured to manipulatively longitudinally fix the push mandrel 32 to the puller 30, for example by squeezing the mandrel handle 34. The puller 30 can then be retracted while longitudinally fixed with respect to the mandrel 32, as shown by arrow. The embolic device 22 in tension will radially contract. The radially contracted embolic device 22 can fit within the catheter 28. The puller 30 can then retract a contracted length of the embolic device 22 into the catheter 28.

[0137] Figure 26b illustrates that the flare 54 can be compliant during retraction of the puller 30 so the embolic device 22 can slide over the flare 54. The push mandrel handle 34 can be manipulated to control between locking the push mandrel 32 to the puller 30 and controlling either the puller 30 or the push mandrel 32 alone.

[0138] Figures 27a and 27b illustrate that the push mandrel 32 can have a longitudinal push mandrel slot 82. The push mandrel slot 82 can extend along part or all of the push mandrel length. The puller 30 can have a puller slot 40. The puller slot 40 can be aligned with the push mandrel slot 82.

[0139] Figure 27c illustrates that the push mandrel handle 34 can be slidably received by the puller slot 40 and the push mandrel slot 82. The push mandrel handle 34 can have a handle engagement element 84, such as a spring-loaded key, rod or ratchet pawl. The push mandrel handle 34 can controllably attach to and detach from the push mandrel 32, the puller 30 or both, for example to longitudinally fix and unfix the push mandrel 32 to the puller 30.

[0140] Figure 28a through 28c illustrate that the core 50 can have one or more bumps 86. The bumps 86 can be radially larger than the core 50. For example, the outer diameter of the bump

86 can match the inner diameter of the embolic device 22 and/or deforming layer 48 when in a radially contracted configuration (e.g., loaded in the catheter 28). The bump outer diameter can be about 0.0215 in. and the catheter inner diameter can be about 0.0220 in. The core 50 can have an outer diameter from about 0.002 in. to about 0.010 in. smaller than the outer diameter of the bump 86. The bump length can be from about 1 mm to about 10 mm. Bumps 86 can be spaced apart, for example, by a bump spacing 88 of about 3 cm longitudinally from each other on the core 50. Bumps 86 can be soft, tacky, expandable foam or rubber. Bumps 86 can have knurls. Bumps 86 can be heat sensitive. Bumps 86 can expand into the cells 58 in the embolic device 22 and/or deforming layer 48.

[0141] Figure 29 illustrates that the bumps 86 can have a diameter from about 0.0200 in. to about 0.0210 in., for example about 0.0205 in. The first bump 86 can be about 10 cm from the proximal terminal end of the core 50. The additional bumps 86 can be spaced evenly at a bump spacing 88 of about 3cm apart in the distal direction along the core 50. The bumps 86 can be made from acrylonitrile butadiene styrene (ABS) or any other material disclosed herein or combinations thereof.

[0142] Figure 30 illustrates that the bump 86 can have a braided, woven or knitted configuration. The bump 86 can have a wireframe. When the bump 86 is attached to the core 50 or coil or leader 52, the proximal and/or distal end of the braided bump 86 may be fixed to the leader 52. When just the proximal end of the bump 86 is fixed, the braid of the bump 86 can radially expand further when the distal end is forced to slide proximally, for example, causing the bump 86 to exert more radial force onto the inside of the deformable layer 48, for example a stent structure (not shown).

[0143] Figure 31a illustrates that the bump 86 can have a distal bump collar 90a and/or a proximal bump collar 90b. The bump collars 90 can be fixed or integral with the remainder of the bump 86. For example, the bump 86 can have a braid of wires or fibers, and the collars 90 can be coated lengths of the braid at the longitudinally terminal ends of the braid.

[0144] The proximal and/or distal bump collars 90 can be longitudinally and/or rotatably fixed, anchored or locked, and/or longitudinally slidably attached to the leader 52 (e.g., coil) of the core 50. For example, the proximal bump collar 90b can be fixed to the coil or leader 52. The distal bump collar 90a can be slidably attached to the coil or leader 52.

[0145] When the bump 86 is in the catheter 28, as the coil or leader 52 is translated distally, the bump 86 can press into the deformable layer 48, pressing the deformable layer 48 into the radially inner surface of the catheter wall. The drag from the catheter wall can be transferred through the deformable layer 48 (which can be in compression between the bump 86 and the catheter 28) and to the most radially-expanded length of the bump 86. The bump 86 at that most radially-expanded length can be pushed proximally by the drag force. If the proximal bump collar 90b is fixed to the coil or leader 52 and the distal bump collar 90a is slidably attached to the coil or leader 52, the bump 86 can longitudinally shorten and radially expand, for example, exerting more radial force against the deformable layer 48 (e.g., compressing the deformable layer 48 harder against the catheter 28), and transferring more of the longitudinally translating force from the coil or leader 52 to the deformable layer 48.

[0146] Figure 31b illustrates that the deformable layer 48 or embolic device 22 can be on and pressed against the bump 86 as the bump 86 exits the catheter 28. The deformable layer 48 or embolic device 22 can radially expand. As the bump 86 translates distally away the distal port of the catheter 28, the deformable layer 48 or embolic device 22 can radially separate from the bump 86.

[0147] Figures 32a illustrates that the bumps 86 can be sized to frictionally interface the inside wall of the catheter 28 with the embolic device 22 and/or deformable layer 48. Where the embolic device 22 and/or deformable layer 48 is pressed between the bump 86 and the catheter 28, the core 50 can distally translate and pull (e.g., drag) the embolic device 22 distally.

[0148] Figure 32b illustrates that when the embolic device 22 exits the distal terminal end of the catheter 28, the embolic device 22 can radially expand away from the bumps 86. The bumps 86 can be in contact or not in contact with the deforming layer 48 or embolic device 22 after deployment.

[0149] Figure 33 illustrates that the embolic device 22 can have two prongs 56 extending bilaterally from the pusher 30a. The prongs 56 can be as shown or any other prongs or pushing mechanism shown herein, such as the prongs 56 shown and described in Figure 17. The prongs 56 can be flexible and radially extendable and retractable. The prongs 56 can have a convex, arced, or crescent configuration. The prongs 56 can be configured to unidirectionally interface the embolic device 22 and/or deformable layer 48. For example, the prongs 56 can engage the embolic device 22 and transfer force from the pusher 30a to the embolic device 22 when the

1 pusher 30a is translated distally and the prongs 56 can disengage the embolic device 22 when the
2 pusher 30a is translated proximally.

3 **[0150]** The pusher 30a can be rigid, for example a rigid rod or beam. The puller 30b can be rigid
4 or flexible, for example a linkage, cord, fabric or polymer ribbon, or combinations thereof.

5 **[0151]** The embolic device 22 can have one or more flexible or rigid device collars 92, for
6 example at the distal terminal end and/or the proximal terminal end of the embolic device 22 or
7 deformable layer 48. The proximal device collar 92b can be attached to a puller wire or lead
8 extending proximally from the proximal device collar 92b.

9 **[0152]** The deployment tool 26 can have a translational controller 94. The translational
10 controller 94 can be slidably attached with the pusher 30a and the puller 30b. The translational
11 controller 94 can have a pusher advancement control. The pusher advancement control 96a can
12 be a knob or button that can pressure fit against the pusher 30a to lock the pusher 30a and/or
13 translate the pusher 30a. The translational controller 94 can have a puller retraction control 96b.
14 The puller retraction control 96b can be a knob or button that can pressure fit against the puller
15 30b to lock the puller 30b and/or translate the puller 30b.

16 **[0153]** Figure 34a illustrates a variation of the deployment tool 26 and embolic device 22 similar
17 to those shown in Figure 33 (the translational controller 94 is not shown for illustrative
18 purposes). The pusher 30b can be translated, as shown by arrow 98, in a distal direction. The
19 prongs 56 can transfer distal force from the pusher 30a to the embolic device 22. The embolic
20 device 22 can be translated, as shown by arrow 100, distally, out of the distal end of the catheter
21 28. The prongs 56 can be positioned near the distal end of the catheter 28. The puller 30b can
22 have a proximally-directed force applied to maintain tension in the length of the embolic device
23 22 proximal to the prongs 56.

24 **[0154]** Figure 34b illustrates that the pusher 30a can be retracted (i.e., translated proximally), as
25 shown by arrow, with respect to the catheter 28 and the embolic device 22, for example to reset
26 the position of the pusher 30a to prepare to push more length of the embolic device 22 out of the
27 catheter 28. The ratchet length or stroke length between the prongs 56 (or any fixed point on the
28 rigid pusher 30a) at a distal-most position and at a proximal-most position during use can be
29 from about 3 cm to about 15 cm, for example about 5 cm.

30 **[0155]** If the prongs 56 are retracted too far, the embolic device 22 distal to the prongs 56 can
31 longitudinally collapse, jam or crumple (e.g., because of insufficient column strength). The

embolic device 22 can block the catheter 28 or otherwise impair distal translation of the embolic device 22.

[0156] Figure 34c illustrates that a contraction sheath 102 can be distally translated between the puller 30b and the embolic device 22. The contraction sheath 102 can be a rigid or semi-rigid and semi-flexible cylindrical configuration. The contraction sheath 102 can be distally translated at least until the contraction sheath 102 longitudinally overlaps the prongs 56. The contraction sheath 102 can press the prongs distally and inwardly, radially contracting the prongs 56. The radially contracted prongs 56 can be disengaged and unattached from the embolic device 22.

[0157] Figure 34d illustrates that the pusher 30a can be distally translated with the contraction sheath 102, as shown by arrows, translating the contracted prongs 56 distally. When the pusher 30a and the prongs 56 are at a desired longitudinal position, the contraction sheath 102 can be retracted, releasing the prongs 56. The prongs 56 can radially expand and unidirectionally engage with and attach to the embolic device 22, as shown in Figure 34a.

[0158] While the pusher 30a and prongs 56 are retracting, as shown in Figure 34b, and/or while the prongs 56 are in the contraction sheath 102, the puller 30b can be proximally pulled to retract the embolic device 22 into the catheter 28.

[0159]

[0160] Figures 35a and 35b illustrate a device and method for deploying the deformable layer 48. The mandrel 32 can have radially extending pushing spines 146 (e.g., fingers). The spines can extend distally and proximally. The pushing spines can engage the deformable layer 48 and act as pushing or pulling elements for ratcheting the layer 48 distally or proximally. A hypotube 148 inside of the catheter 28 can prevent premature extension of the spines.

[0161] Figure 36a through 36e illustrate that the deformable layer 48 can be pushed out of the catheter 28 with a support mandrel 32. A sheath 142 can have radially inwardly extending fingers 144, some of which can extend proximally. The sheath 142 can be used to retract the layer 48 and to maintain tension in the sheath during distal deployment. The mandrel 32 can be used to translate the layer 48 distally.

[0162] Figures 37a and 37b illustrate that the deformable layer 48, for example a braid, can be held in tension by a pull wire attached to the proximal end of the braid. The braid can be rigidly attached to the distal end of the coil at a distal attachment point. The braid can radially expand when it is unconstrained from the catheter upon deployment.

1 [0163] Figures 38a and 38b illustrate a method for retrieving the braid or deformable layer 48 of
2 Figures 37a and 37b.

3 [0164] Figures 39a and 39b illustrate pushing or pulling the deformable layer 48 or braid through
4 the catheter 28 with interwoven stiffening pushing elements 160 in the braid, such as
5 longitudinally stiffening elements 160.

6 [0165] Figure 44a illustrates that embolic device 22 can have a core 50 fixedly attached to the
7 braid or deformable layer 48. The braid or deformable layer 48 can extend distally from the core
8 50. For example, the braid or deformable layer 48 can be rigidly attached to the core 50 at a
9 distal layer anchor 104a. The braid or deformable layer 48, for example at a braid overhand or
10 deformable layer overhang 106, can extend distal to the distal braid anchor 104a when the distal
11 end of the deformable layer 48 is in the catheter 28.

12 [0166] The deformable layer overhang 106 can fold over itself. In the deformable layer
13 overhang 106, the deformable layer 48 can extend in two layers (e.g., a first sub-layer 105a
14 extending distally and then folding over at a fold 107 at the distally terminal end of the
15 deformable layer 48 into a second sub-layer 105b) between the core 50 and the catheter 28. The
16 overhang 106 can slide between the core 50 and catheter 28 with minimal friction or can press on
17 the core 50 and the catheter 28, for example pressing the deformable layer 48 into the core 50
18 distal to the distal braid anchor 104a, inducing traction to hold the overhang 106 longitudinally
19 fixed relative to the core 50 during distal translation of the core 50 with respect to the catheter
20 28.

21 [0167] The core 50 can have a distal flare 54a distal to the distal braid anchor 104a. The distal
22 flare 54a can releasably attach to the overhang 106.

23 [0168] The deformable layer 48 can be rigidly and fixedly attached to the core 50 at a proximal
24 braid anchor 104b. The core 50 can be detachably attached to the pusher and/or puller 30
25 immediately proximal to the proximal braid anchor 104b.

26 [0169] A flare spacing 108 can be the length between the nearest terminal ends of adjacent flares
27 54. The flare spacing 108 can be from about 1 cm to about 5 cm, for example about 3 cm. The
28 flares 54 can attach to the deformable layer 48 when the core 50 is moved distally with respect to
29 the catheter 28. The flares 54 can detach from the deformable layer 48 when the core 50 is
30 pulled proximally with respect to the catheter 28.

1 [0170] Figure 44b illustrates that the core 50 can be translated distally, as shown by arrow 110,
2 out of the distal port of the catheter 28. As the distal end of the deformable layer 48 exits the
3 distal end of the catheter 28, the deformable layer overhang 106 can radially expand and
4 longitudinally foreshorten, as shown by arrows 112.

5 [0171] Figure 44c illustrates that the embolic device 22 can be pushed, as shown by arrow 110,
6 entirely out of the distal end of the catheter 28. The deformable layer 48 can radially expand and
7 foreshorten further, as shown by arrows 112, with the catheter 28 no longer radially constraining
8 any of deformable layer 48.

9 [0172] The embolic device 22 can be angularly and translatably oriented with the coil pusher and
10 puller 30 when positioned in the aneurysm. The embolic device 22 can detach from the pusher
11 30, for example by detaching the core 50 from the coil pusher 30. The coil pusher 30 can
12 reattach to the core 50 and pull the embolic device 22 into the catheter 28, as shown by the
13 reverse of Figures 44a through 44c and temporally reversing the description above.

14 [0173] Figure 45a illustrates that the embolic device 22 can have a first deformable layer 48a,
15 second deformable layer 48b, and third deformable layer 48c. The first deformable layer 48a can
16 be attached to the core 50 at a distal first deformable layer anchor 104a', and a proximal first
17 deformable layer anchor 104b'. The second deformable layer 48b can be attached to the core 50
18 at a distal second deformable layer anchor 104a'' and a proximal second deformable layer
19 anchor 104b''. The third deformable layer 48c can be attached to the core 50 at a distal third
20 deformable layer anchor 104a''' and a proximal third deformable layer anchor 104b'''. The
21 longitudinal distance from the proximal first deformable layer anchor to the second deformable
22 layer anchor can be a deformable layer spacing 114. The deformable layer spacing can be from
23 0.5 cm to about 5 cm, for example about 1 cm.

24 [0174] The first, second and third deformable layer 48a, 48b, and 48c can each have a respective
25 overhang 106a, 106b and 106c. The first, second and third deformable layer 48a, 48b, and 48c
26 can have first, second and third folds 107a, 107b, and 107c, respectively. The folds 107 can be
27 distal to the respective distal deformable layer anchors. The first second and third deformable
28 layers 48a, 48b, and 48c can each have first and second deformable layer sub-layers 105a' and
29 105b', 105a'' and 105b'', and 105a''' and 105b''', respectively.

1 [0175] The folded configuration of the deformable layers 48 having two sub-layers 105 of the
2 deformable layer 48 between the core 50 and the catheter 28 can produce the same friction and
3 traction as explained herein, for example for Figure 44a, for each braid in Figure 45a.

4 [0176] Figure 45b illustrates that the embolic device 22 can be translated, for example by the
5 coil pusher 30 pushing and translating the core 50, as shown by arrow 110, out of the distal port
6 of the catheter 28. When the first deformable layer 48a exits the catheter 28, the first deformable
7 layer 48a can radially expand and foreshorten as shown by arrows 112a. The second and third
8 deformable layers 48b and 48c can be radially constricted and contracted in the lumen of the
9 catheter 28.

10 [0177] Figure 45c illustrates that the core 50 can be translated so the second and third
11 deformable layers 48b and 48c can exit the distal port of the catheter 28. The second and third
12 deformable layers 48b and 48c can radially expand and foreshorten as shown by arrows 112b.

13 [0178] Figures 46a and 46b illustrate a method of deploying the embolic device 22 with a
14 variation of the deployment tool 26. The deployment tool 26 can have a ratchet sleeve 142. The
15 ratchet sleeve 142 can slide between the deformable layer 48 and the core 50. The ratchet sleeve
16 can have ratchet fingers 144 extending distally or orthogonally and radially outward from the
17 distal end of the ratchet sleeve 142. The ratchet fingers 144 can interdigitate with the cells 58 in
18 the deformable layer 48 when the ratchet sleeve 142 is translated distally and transmit force to the
19 embolic device 22 to push the embolic device 22 distally. When the ratchet sleeve 142 is pulled
20 proximally, the ratchet fingers 144 can release from the deformable layer 48. The ratchet sleeve
21 48 can be repeatedly translated distally and proximally, as shown by arrows, to push the embolic
22 device 22 out of the catheter 28. The pusher or puller 30 can abut and stop the embolic device
23 22 from moving proximally when the ratchet sleeve 142 is translated proximally.

24 [0179] Figure 46a' is a cross-sectional view of a variation of section B-B of Figure 46a.

25 [0180] Figure 46b illustrates that after the embolic device is fully deployed from the catheter 28,
26 the abutment point can be passively (e.g., if never fixedly attached) or actively severed (e.g.,
27 electrolyzed, unscrewed, corroded) between the embolic device 22 and the deployment tool 26.

28 [0181] Figure 47 illustrates a method of deploying the embolic device with a variation of the
29 deployment tool. Figure 47 illustrates a deployment tool similar to the tool in Figures 46a and
30 46b, but with no pusher or puller 30. The deformable layer 48 can be heat set to a shape larger
31 than the catheter diameter. When the deformable layer 48 exits the catheter 28, the deformable

layer springs to a larger diameter and the larger diameter resists pulling back into the distal port of the catheter 28. The deformable layer 28 will expand when unconstrained by the catheter 28 and the fingers 144. The ratchet sleeve 142 can be attached to a pull wire (not shown) to pull on the ratchet sleeve 142. When the device of Figure 47 is deployed, it is similar to the device shown in Figure 46b.

[0182] Figure 48a illustrates that the leader 52 can have a coil that can have a winding with a coil primary section 116 and peaks 118, such as first, second and third peaks 118a, 118b, and 118c, as shown.

[0183] The primary section 116 can have lengths on either or both ends of the most proximal and distal peaks 118 and between adjacent peaks 118. The primary section 116 can have a primary diameter 120. Lengths of the primary section 116 separated by a peak 118 can have equal or different primary diameters 120. The primary diameter 120 can be constant along the length of a contiguous (i.e., not separated by a peak) primary section 116. The primary diameter 120 can be constant along the length of all primary sections 116 for the core 50 or can vary between the primary sections 116 (e.g., the primary diameter 120 can be larger or smaller for one primary section 116 compared to the adjacent primary section 116).

[0184] Each peak 118 can be the radially outermost winding for a wave formed in the coil. The peaks 118 can press the deformable layer 48 into the wall of the catheter 28. The peak 118 can frictionally drag the deformable layer 48 longitudinally along the catheter lumen when the pusher 30 is pushed or pulled, resulting in the leader 52 being longitudinally translated with respect to the catheter 28. The deformable layer 48 can be taught (i.e., in tension) between adjacent peaks 118.

[0185] The primary diameter 120 can be from about 0.005 inches to about 0.050 inches, for example about 0.015 inches. The peak diameter 122 can be from about 0.010 inches to about 0.055 inches, for example about 0.020 inches. For example, the peak diameter 122 can be from about 5% to about 50%, or for example about 10% larger than the primary diameter 120.

[0186] The peaks 118 can be separated by wave gaps 124. The wave gaps 124 can be from about 0.001 to about 0.010 inches, for example about 0.002 inches. The wave gaps 124 can be equal to the dimensions disclosed for bump spacing 88 and vice versa.

[0187] The coil of the leader 52 can be open pitch or closed pitch. The coil can be a single winding along the length of the coil (e.g., wound and shaped, such as with heat, on a mandrel

1 with the desired shape of the primary sections and waves). The coil can be made from bonding
2 or welding a winding of the coil primary section 116 to a coil formed as a wave, and attaching
3 additional primary sections 116 and waves as needed for the desired shape.

4 **[0188]** The distal terminal end of the deformable layer 48 can be attached to the leader 52 or coil
5 (not shown for illustrative purposes) or unattached to the leader 52 or coil (as shown).

6 **[0189]** Figure 48b illustrates that the core 52 can have bumps or peaks 118 radially extending
7 from the leader 52. The deformable layer 48 can be attached (e.g., by heat setting or cinching) at
8 constant or variable periodic longitudinal lengths to slide rings 126. The slide rings can be rigid
9 or flexible. The slide rings 126 can radially constrain the deformable layer 48 at the points
10 where the slide rings 126 attach to the deformable layer 48. The slide rings 126 can have a
11 diameter smaller than the diameter of the inner diameter of the catheter 128 and smaller than the
12 diameter of the deformable layer 48 in a radially unconstrained configuration. The slide rings
13 126 can be longitudinally fixed to the leader 52 or longitudinally slidable on the leader 52. The
14 inner diameter of the slide rings 126 can be smaller than the outer diameter of the bumps or
15 peaks 118. The slide rings 126 can slide along the primary sections 116 and interference fit, abut
16 with or stop at the bumps or peaks 118.

17 **[0190]** When pushing the leader 52, the constrained portions of the deformable layer 48 at and
18 adjacent to the rings 126 can overlap and engage with the bumps or peaks 118, to allow short
19 sections of deformable layer 48 to be individually pushed through the catheter 28.

20 **[0191]** The coil of the elader 52 can be open pitch or closed pitch. The peaks 118 can be formed
21 by bonding and/or welding different diameter sections of the leader 52, such as different
22 diameters of coils, together.

23 **[0192]** Figure 49a illustrates that the core 50 can have a first, second and third leader 52a, 52b,
24 and 52c. The leaders 52 can be longitudinally separate and disconnected from each other. For
25 example, a first break 128a can be between the first leader 52a and the second leader 52b. A
26 second break 128b can be between the second leader 52b and the third leader 52c.

27 **[0193]** The deformable layer 48 can be heat set to a larger unbiased expanded diameter (e.g.,
28 from about 1 mm to about 3 mm) than the forcibly contracted diameter of the deformable layer
29 48 when the deformable layer 48 is in the catheter 28. For example, the deformable layer 48 can
30 be heat set and then can be stretched and cinched down and attached onto the straight core 50 or
31 terminal ends of the leader 52 or combined leaders 52a, 52b, and 52c. The deformable layer 48

1 can be taught against the core 50 in the catheter 28. The deformable layer 48 can be rigidly
2 attached to the core 50 at the distal and/or proximal ends of the core 50 and deformable layer 48.

3 **[0194]** The embolic device 22 can have a flexible inner elongated element, such as an inner
4 suture 130, that can be fixedly attached to the distal end (e.g., at a distal suture anchor 132) and
5 proximal end of the core 50. The inner suture 130 can extend through a hollow channel along
6 the length of the core 50. For example, the inner suture 130 can be threaded through the inner
7 diameters of the leaders 52a, 52b, and 52c, such as in the lumen of coils. The inner suture 130
8 can be made from any material disclosed herein, for example NiTi wire or a loose NiTi helical-
9 shaped element. The inner suture 130 can have slack (i.e., be longer than the core 50) when the
10 embolic device 22 is in the catheter 28.

11 **[0195]** The leaders 52a, 52b, and 52c can be longitudinally aligned in the catheter 28 (i.e., the
12 longitudinal axis of each leader 52 can be collinear).

13 **[0196]** Figure 49b illustrates that the leaders 52 can “train wreck” (i.e., the longitudinal axis of
14 at least two leaders 52, for example all the leaders 52, can be longitudinally non-aligned or non-
15 collinear). The train wrecked core 50 can press the deformable layer 48 (e.g., at the ends of each
16 train wrecked leader 52) against the inner wall of catheter 28. For example, the core 50 can
17 frictionally drag the deformable layer 48 at the pressure points. The deformable layer 48 can be
18 taught between the train wreck pressure points. The deformable layer 48 on the train-wrecked
19 core 50 can be non-cinched.

20 **[0197]** Figure 49b illustrates that the pusher 30 can be distally translated, as shown by arrow 98.
21 As the embolic device 22 exits the distal end of the catheter 28, the deformable layer 48 can
22 return to an unbiased configuration, radially expanding and foreshortening, as shown by arrows
23 112. Any or all of the leaders 52a, 52b, and 52c can rotate about their respective transverse or
24 lateral axes, as shown by arrows 134a, 134b, and 134c, respectively, after the respective leader
25 52a, 52b and 52c has exited the distal port of the catheter 28. The rotating leaders 52a, 52b, and
26 52c move away from each other at the respective breaks 128. The rotating leaders 52 can
27 foreshorten the core 50 and the deformable layer 48, no longer in tension, can radially expand
28 and foreshorten. The inner suture 130 can remain inside of or otherwise attached to the leaders
29 52 after deployment.

30 **[0198]** A detachment zone 136 or point (such as the abutment point 36, which can share any or
31 all characteristics with the detachment zone 136 and vice versa) can be at the juncture or joint of

the pusher 30 and the embolic device 22. The detachment zone 136 can be a non-insulated junction, a resistive, low melting point material, screw thread, or combinations thereof. For example, the embolic device 22 can be detached from the pusher 30 by unscrewing, electrolysis corrosion, melting, or combinations thereof.

[0199] If the deployed embolic device 22 is retracted into the catheter for reorientation or removal, the inner suture 130 can longitudinally align (i.e., straighten out) the leaders 52a, 52b, and 52c as the leaders 52 are translationally withdrawn into the catheter 28.

[0200] The leader 52 can be continuous (e.g., have no breaks along the length of the core 50) and buckle easily when deployed into an aneurysm, along the length of the leader 52 or at the locations of the breaks 128 as shown in Figure 49a. The expansion force of the deformable layer 48 can be greater than the bending or buckling resistance of the leader 52 once the embolic device 22 exits the distal port of the catheter 28. The core 50 can then buckle at one or more locations along the length of the core 50.

[0201] The leader 52 can be heat shaped into a tight (such as a closed pitch coil, e.g., diameter from about 2 mm to about 10 mm) secondary shape. The secondary shape can be the unbiased heat set shape that the leader 52 can return to when not constrained in catheter 28. After the embolic device 22 exits the distal port of the catheter 28, the leader 52 can collapse into a shorter secondary helical shape and the deformable layer 48 can foreshorten and radially expand.

[0202] Figure 50a illustrates that the distal end of the deformable layer 48 can be unattached to the core 50. The proximal end of the deformable layer 48 can be attached to the core 50, for example to the first leader 52a, at the proximal deformable layer anchor 104b.

[0203] Figure 50b illustrates that the leaders 52 can train wreck in the catheter 28, for example, when the pusher 30 is translated distally, as shown by arrow, as described herein. The first leader 52a can have a first leader rotation 134a. The second leader 52b can have a second leader rotation 134b in the same or opposite direction as the first leader rotation 134a. The third leader 52c can have a third leader rotation (the third leader 52c is shown in Figure 50b as unrotated). The leader rotations 134 can be about lateral or transverse axes extending through each respective leader 52a, 52b, or 52c. The leaders 52 can rotate to press the deformable layer 48 into the catheter 28 at pressure points 137. For example, the core 50 can frictionally drag the deformable layer 48 at the pressure points 137. The deformable layer 48 can be taught between the train wreck pressure points 137.

1 [0204] Figure 50c illustrates that the distal end of the deformable layer 48 can radially expand
2 and open when the embolic device 22 exits the distal port of the catheter 28. The deformable
3 layer 48 can be attached to the core 50 at the proximal terminal end, for example at the proximal
4 deformable layer anchor 104b. The deformable layer 48 can be radially spaced away from the
5 core 50 along the entire length of the core 50 except at the proximal terminal end of the core 50.

6 [0205] The embolic device 22 can be retrieved and retracted into the catheter 28. The catheter
7 28 can radially contract the deformable layer 48 when the embolic device 22 is pulled into the
8 catheter 28.

9 [0206] Figure 51a is a cross-sectional view of a variation of a method for making a variation of
10 the embolic device 22 and a portion of the deployment tool 26, such as the pusher 30. The core
11 50 can have flexible connectors 138a and 138b between the separated leaders 52a, 52b and 52c.
12 The flexible connectors 138 can be rigidly and/or fixedly attached at each the respective leader
13 52 at each end of the flexible connector 138. The flexible connectors 138 can be made of a
14 polymeric material, metal (i.e., Platinum or NiTi), other materials described herein, or
15 combinations thereof. The flexible connectors 138 can be relatively straight, helical, wavy (ie.
16 like an open or closed pitch coil), dumbbell-shaped, or combinations thereof. The flexible
17 connectors 138 can be configured to allow collapsing of the space between adjacent leaders 52 at
18 low longitudinally compressive loads, or at longitudinally compressive loads less than the
19 longitudinally compressive force exerted on the leaders 52 by the deformable layer 48 when the
20 embolic device 22 is deployed outside the catheter 28.

21 [0207] Figures 51b and 51c are cross-sectional views of a method of deploying the embolic
22 device of Figure 51a with a variation of the deployment tool having a catheter and a pusher.

23 [0208] Figure 51b illustrates that as the pusher is distally translated, as shown by arrow 98, the
24 breaks 128 can shorten, as shown by arrows 140.

25 [0209] Figure 51c illustrates that when the embolic device 22 exits from the distal port of the
26 catheter 28, the leaders 52 can rotate individually as described here and shown by arrows 134.
27 The deformable layer 48 can radially expand and foreshorten, as shown by arrows 112, and
28 described herein.

29 [0210] Figures 52a and 52b illustrate a method of deploying the embolic device 22 with a
30 variation of the deployment tool 26. The deployment tool 26 can have a ratchet sleeve 142. The
31 ratchet sleeve 142 can slide between the catheter 28 and the deformable layer 48. The rather

sleeve 142 can have ratchet fingers 144 extending radially inwardly and orthogonal and/or distally from the distal end of the ratchet sleeve 142. The ratchet sleeve 142 can be longitudinally oscillated (i.e., translated distally and proximally), as shown by arrows, to ratchet the embolic device 22 distally. The ratchet fingers 144 can extend radially inward and interdigitate with the cells 58 in the deformable layer 48 when the ratchet sleeve 142 is translated distally, transmitting force to the embolic device 22 and translating the embolic device distally. When the ratchet sleeve 142 is translated proximally, the ratchet fingers 144 can pull out of the cells 58, radially retract against the inner wall of the ratchet sleeve 142, and slide against or not touch the deformable layer 48 as the ratchet sleeve 142 translates proximally with respect to the embolic device 22. The pusher 30 can hold the embolic device 22 as the ratchet sleeve is translated proximally.

[0211] Figure 52b illustrates that the deformable layer 48 can radially expand and foreshorten, as shown by arrows 112 and described herein, when the embolic device is deployed from the distal port of the catheter.

[0212] Figures 49a through 52b can have cores 50 that can have single leaders 52 extending over the length of the core 50 instead of multiple, separate leaders 52a, 52b, and 52c. The single leaders 52 can have weakened or more flexible sections, such as coil windings, at the breaks 128, or the single leaders 52 can have a constant strength and flexibility along the length of the single leader 52.

[0213] The embolic devices 22 can be from about 2 cm to about 30 cm in length, more narrowly from about 3 cm to about 12 cm in length, for example about 2 cm, about 3cm, about 10 cm, about 12 cm or about 30 cm in length. The deformable layer 48 can be from about 2 cm to about 30 cm in length, more narrowly from about 3 cm to about 12 cm in length, for example about 2 cm, about 3cm, about 10 cm, about 12 cm or about 30 cm in length. Multiple shorter deformable layers 48 can be used on a single longer core 50. For example, ten 3 cm long deformable layers 48 can be on one 30 cm long core 50.

[0214] Using a single element, the deployment tool 26 can deploy and/or retrieve the embolic device 22 to or from a target site when the embolic device 22 comprises no core 50 (e.g., having just the deformable layer 48). Using a single element, the deployment tool 26 can deploy and/or retrieve the embolic device 22 to or from a target site when the embolic device 22 comprises the core 50 and the deformable layer 48. The deployment tool 26 can utilize separate deployment

1 and retrieval elements to deploy and/or retrieve the embolic device 22 to or from a target site
2 when the embolic device 22 comprises no core 50 (e.g., having just the deformable layer 48).
3 The deployment tool 26 can utilize separate deployment and retrieval elements when the embolic
4 device 22 comprises the core 50 and the deformable layer 48.

5 **[0215]** U.S. Patent Application No. 11/079,753, filed 14 March 2005 (i.e., Publication No. US
6 2005/0222605), which is incorporated by reference herein in its entirety, discloses variations of
7 pushers, prongs and other components and elements that can be used in combination with any of
8 the elements disclosed herein.

9 **[0216]** Any elements described herein as singular can be pluralized (i.e., anything described as
10 “one” can be more than one). Any species element of a genus element can have the
11 characteristics or elements of any other species element of that genus. The above-described
12 configurations, elements or complete assemblies and methods and their elements for carrying out
13 the invention, and variations of aspects of the invention can be combined and modified with each
14 other in any combination.

CLAIMS

We claim:

1. A system for deployment of an embolic device to a vascular target site comprising:
the embolic device comprising a leader and a first radially expandable element attached to the leader; and
a catheter;
wherein the embolic device is slidably positioned in the catheter, and wherein the first radially expandable element is in a folded configuration such that a first layer and a second layer of the first radially expandable element are positioned between the catheter and the leader.
2. The system of Claim 1, wherein the leader comprises a coil core.
3. The system of Claim 1, wherein the first radially expandable element comprises a first braid.
4. The system of Claim 1, wherein the first radially expandable element comprises a first fold, and wherein the first radially expandable element is attached to the leader at a first attachment point, and wherein the first attachment point is proximal to first fold.
5. The system of Claim 1, wherein the embolic device comprises a second radially expandable element attached to the leader proximal to the first radially expandable element.
6. The system of Claim 5, wherein the second radially expandable is in a folded configuration such that a first layer and a second layer of the second radially expandable element are positioned between the catheter and the leader.
7. The system of Claim 6, wherein the second radially expandable element comprises a second fold, and wherein the second radially expandable element is attached to the leader at a second attachment point, and wherein the second attachment point is proximal to second fold.
8. The system of Claim 1, wherein the leader further comprises a flare.

1 9. The system of Claim 8, wherein the flare is configured to unidirectionally attach to the
2 radially expandable element.

4 10. The system of Claim 1, wherein a length of the first radially expanding element is in
5 longitudinal tension.

7 11. The system of Claim 1, wherein the first radially expanding element is frictionally abutted
8 against the leader.

10 12. An embolic device for deployment in a vascular target site comprising:

11 a leader comprising a coil, wherein the coil comprises a winding with a first length, a
12 second length distal to the first length, and a third length distal to the second length, and wherein
13 the first length has a first diameter and wherein the second length has a second diameter larger
14 than the first diameter, and wherein the third length has a third diameter smaller than the second
15 diameter; and

16 a radially expandable element attached to the leader.

18 13. The device of Claim 11, wherein the first radially expandable element comprises a first
19 braid.

21 14. The device of Claim 11, wherein the third diameter is equal to the first diameter.

23 15. A system for deploying the embolic device of Claim 10 comprising:

24 the embolic device of Claim 10; and

25 a catheter, wherein the embolic device is in the catheter, and wherein the braid is between
26 the coil and the catheter, and wherein the second length of the coil presses the braid against the
27 catheter.

29 16. The system of Claim 15, wherein the radially expanding element is frictionally abutted
30 against the leader.

- 1 17. An embolic device for deployment in a vascular target site comprising:
2 a leader having a first coil and a second coil, wherein the first coil is separate from the
3 second coil, and wherein the first coil is proximal to the second coil;
4 a flexible element attached to the proximal end of the leader and the distal end of the
5 leader; and
6 a braid attached to the leader;
7
- 8 18. The device of Claim 17, wherein the flexible element is longer than the leader when the
9 leader is in a straight configuration.
10
- 11 19. A system for deploying the embolic device of Claim 17 comprising:
12 the embolic device of Claim 17; and
13 a catheter, wherein the embolic device is in the catheter, and wherein the braid is between
14 the first coil and the catheter, and wherein the first coil presses the braid against the catheter.
15
- 16 20. The system of Claim 19, wherein the radially expanding element is frictionally abutted
17 against the leader.
18
- 19 21. The system of Claim 19, wherein a length of the first radially expanding element is in
20 longitudinal tension.
21
- 22 22. An apparatus for deployment of an embolic device to a vascular target site comprising:
23 a force-transfer element comprising a leader and a radial force transferor;
24 wherein the leader comprises a coil;
25 and wherein the radial force transferor comprises a radial bump.
26
- 27 23. The apparatus of Claim 22, wherein the bump comprises a rubber.
28
- 29 24. The apparatus of Claim 22, wherein the bump comprises a braided configuration.
30
- 31 25. A method for deploying an embolic device to a vascular target site comprising:

1 translating the embolic device along the hollow channel of a catheter;

2 wherein translating comprising maintaining longitudinal tension in the embolic device.

3
4 26. The method of Claim 25, further comprising attaching the embolic device to an inner force-
5 transfer element, and wherein the inner force-transfer element is at least partially radially inside
6 of the embolic device.

7
8 27. The method of Claim 26, wherein attaching comprises frictionally abutting the inner force-
9 transfer element against the embolic device.

10
11 28. The method of Claim 26, wherein the inner force-transfer element comprises a prong and
12 wherein the method further comprises inserting the prong through the embolic device.

13
14 29. The method of Claim 28, wherein inserting the prong comprises extending the prong radially
15 outward from the inner force-transfer element.

16
17 30. The method of Claim 29, wherein the embolic device has an open cell, and wherein inserting
18 the prong comprises inserting the prong through the open cell.

19
20 31. The method of Claim 26, wherein maintaining longitudinal tension in the embolic device
21 comprises configuring prongs and/or bumps on the coil to aid pushing the embolic device.

22
23 32. An apparatus for embolizing a vascular target site comprising:

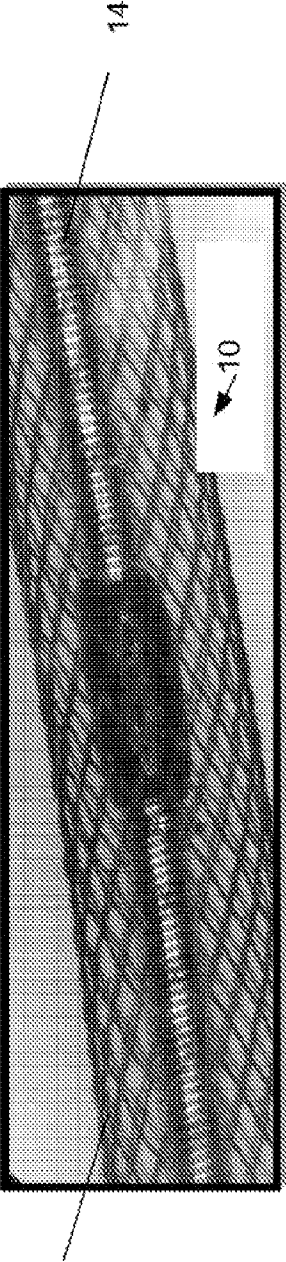
24 an embolic device; and

25 an inner force-transferring element configured to transfer force to the embolic device
26 during the deployment of the embolic device.

27
28 33. The apparatus of Claim 32, further comprising a catheter.

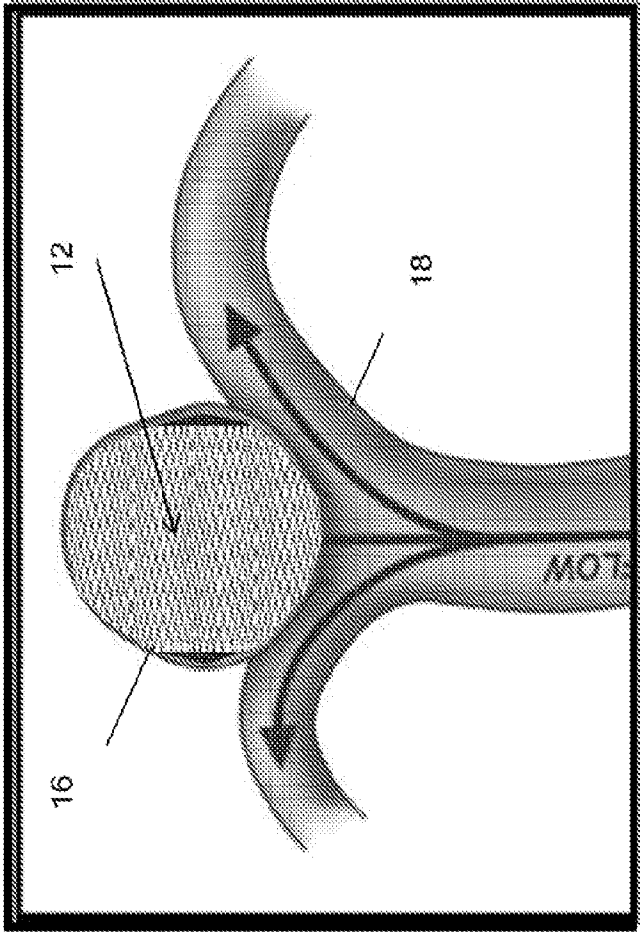
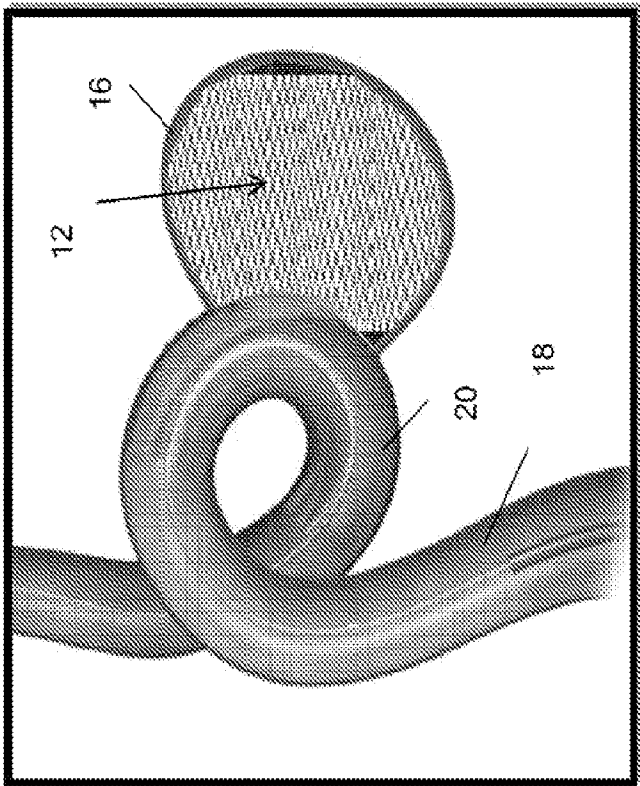
29
30 34. The apparatus of Claim 32, wherein the inner force-transferring element comprises a leader
31 and a radial force transferor.

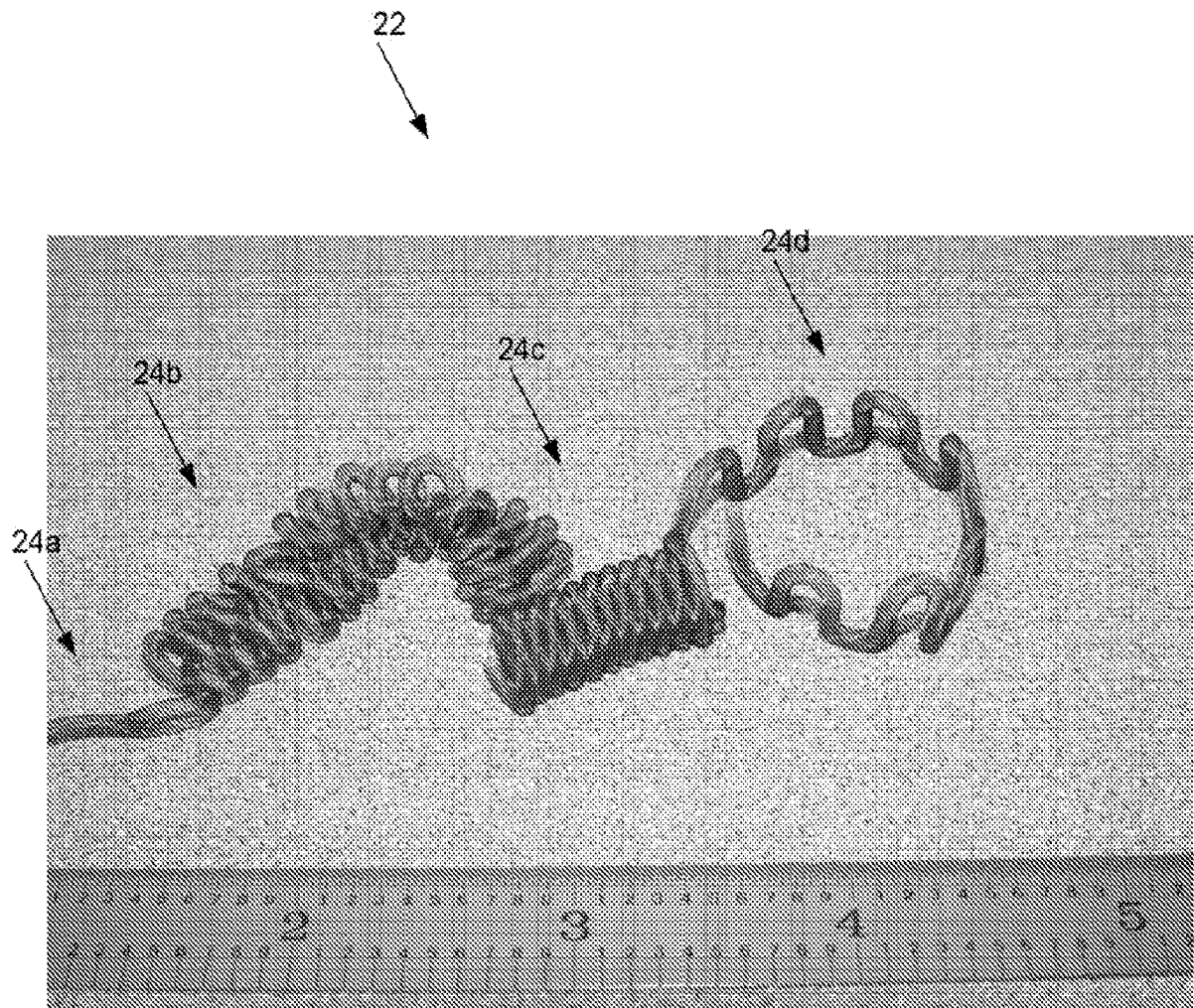
- 1
- 2 35. The apparatus of Claim 34, wherein the radial force transferor comprises a flare.
- 3
- 4 36. The apparatus of Claim 34, wherein the radial force transferor comprises a bump.
- 5
- 6 37. The apparatus of Claim 36, wherein the bump comprises an elastomeric material.
- 7
- 8 38. The apparatus of Claim 37, wherein the elastomeric material comprises a rubber.
- 9
- 10 39. The apparatus of Claim 36, wherein the bump comprises a braided configuration.
- 11
- 12 40. The apparatus of Claim 34, wherein the radial force transferor comprises a proximal
- 13 attachment.
- 14
- 15 41. The apparatus of Claim 34, wherein the radial force transferor comprises a proximal
- 16 attachment and a distal attachment.
- 17
- 18

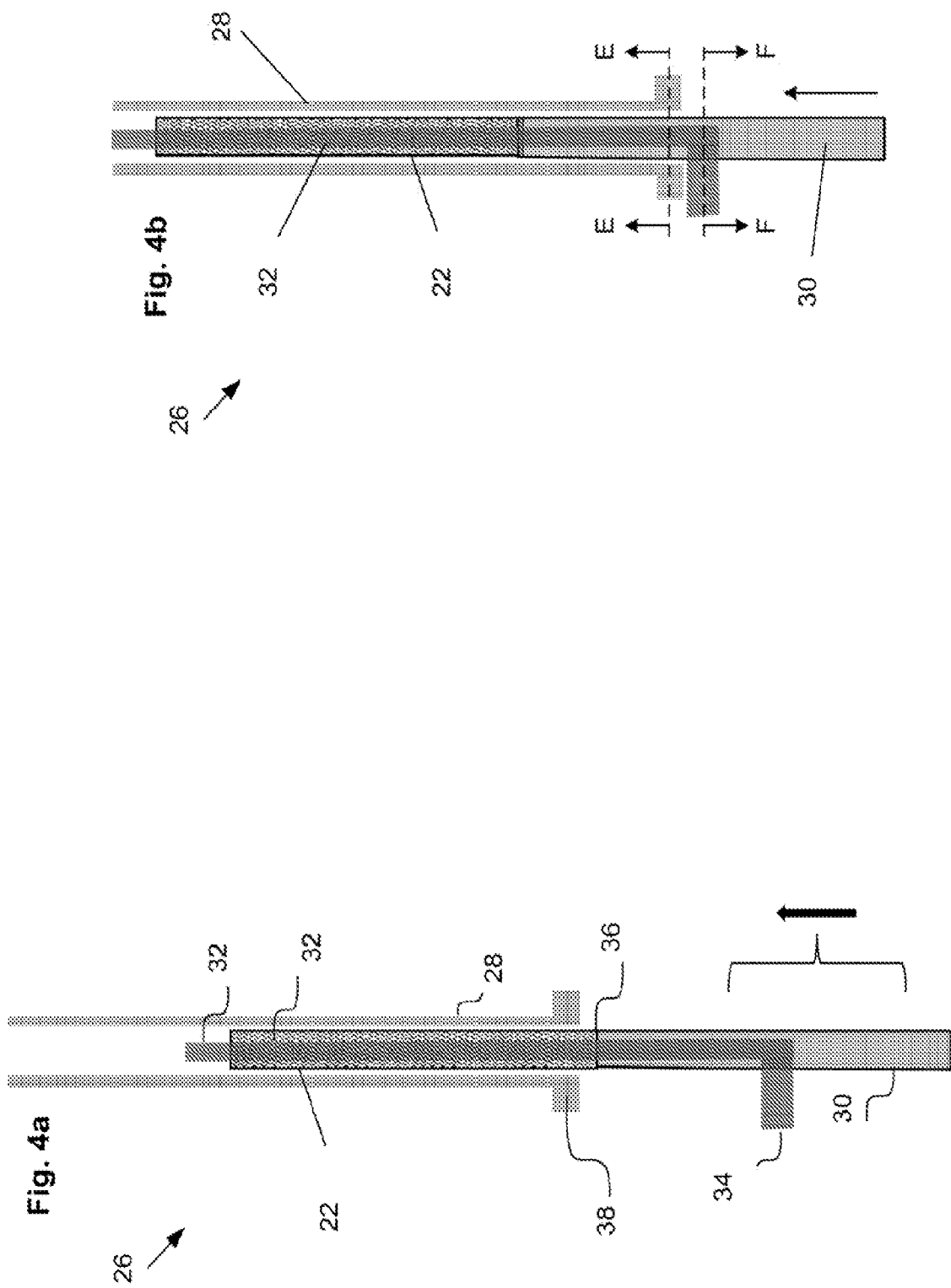


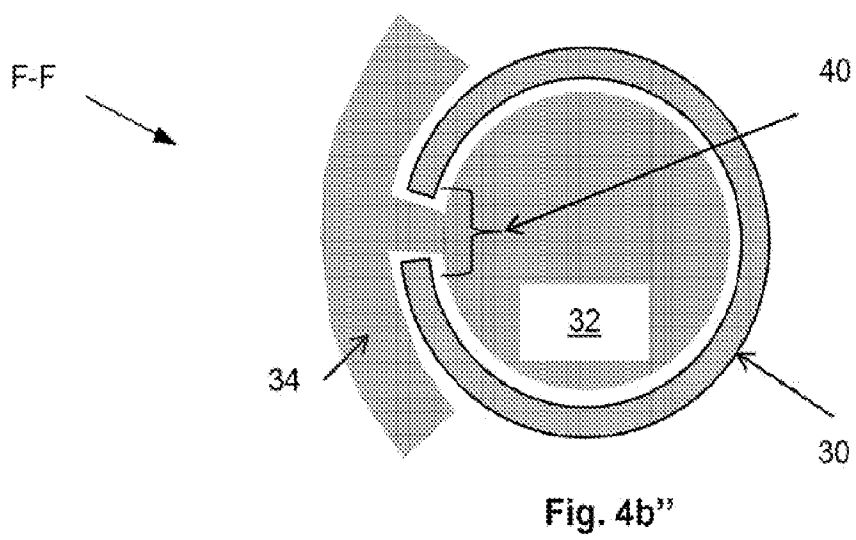
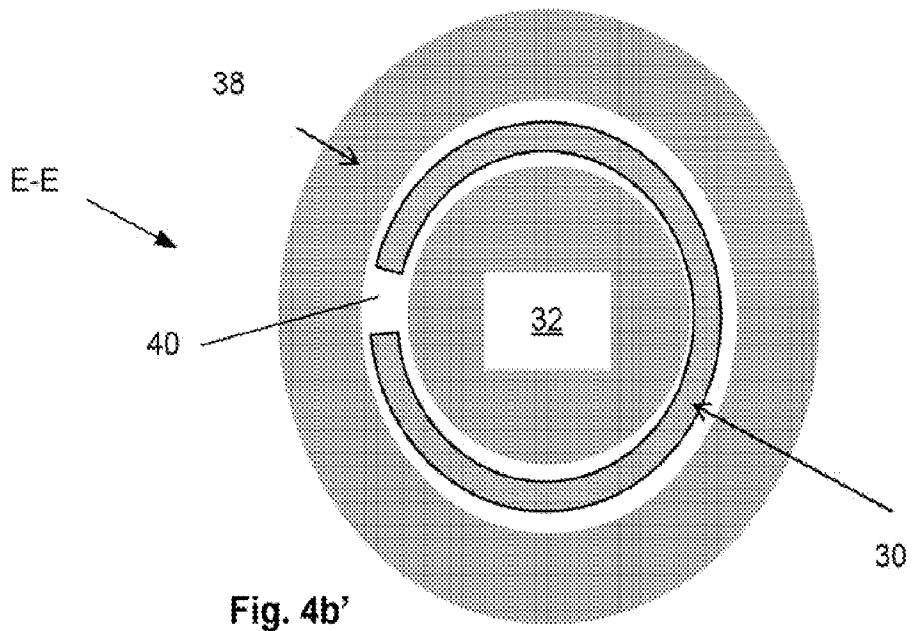
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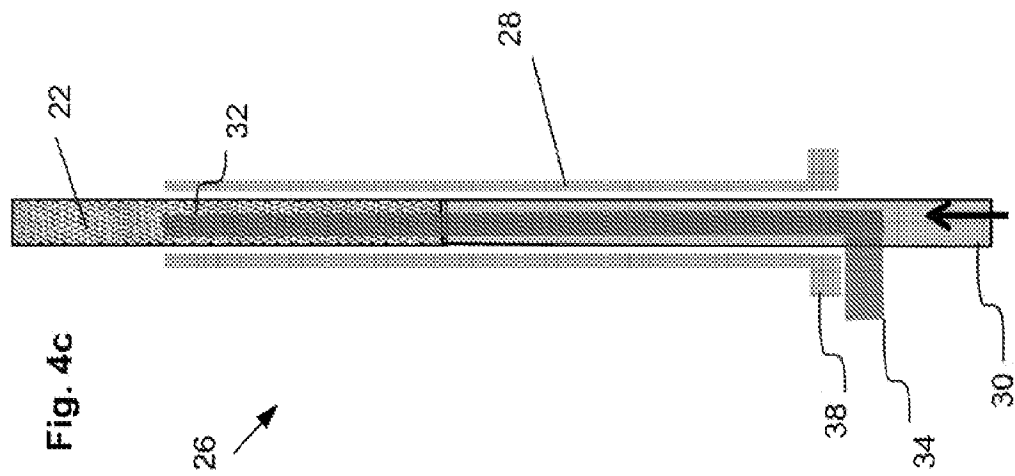
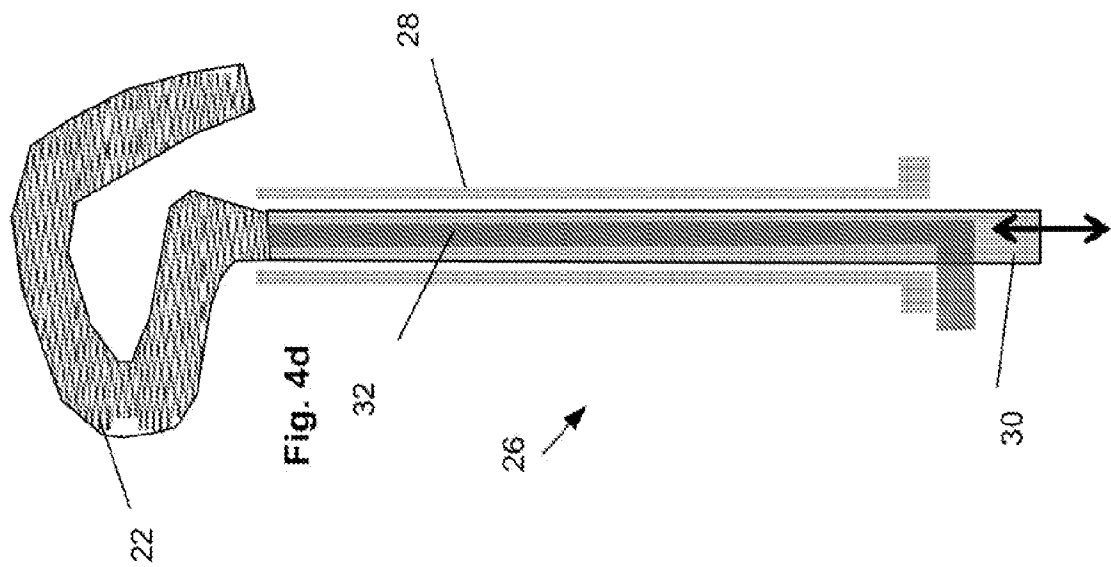
Fig. 1

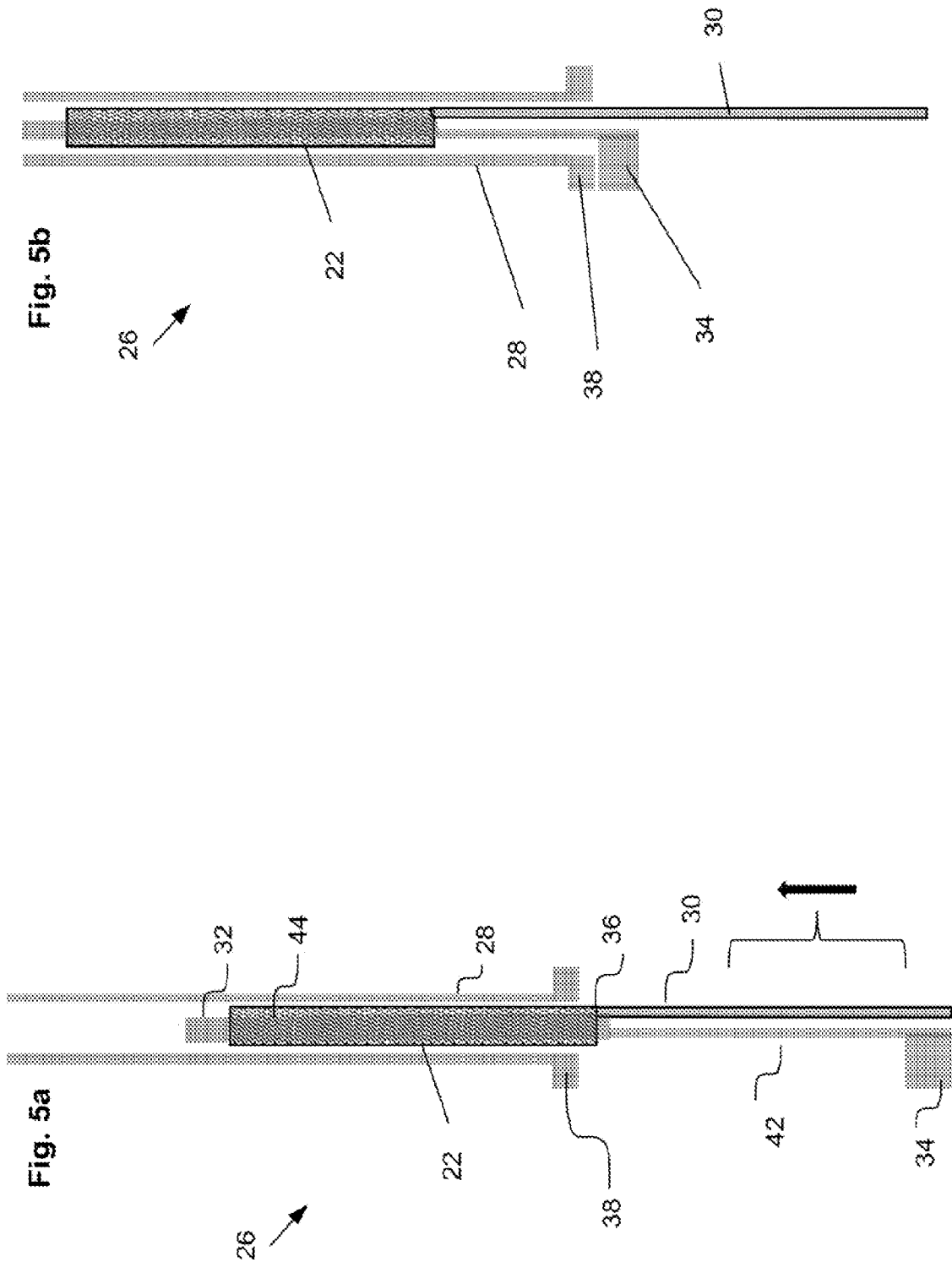


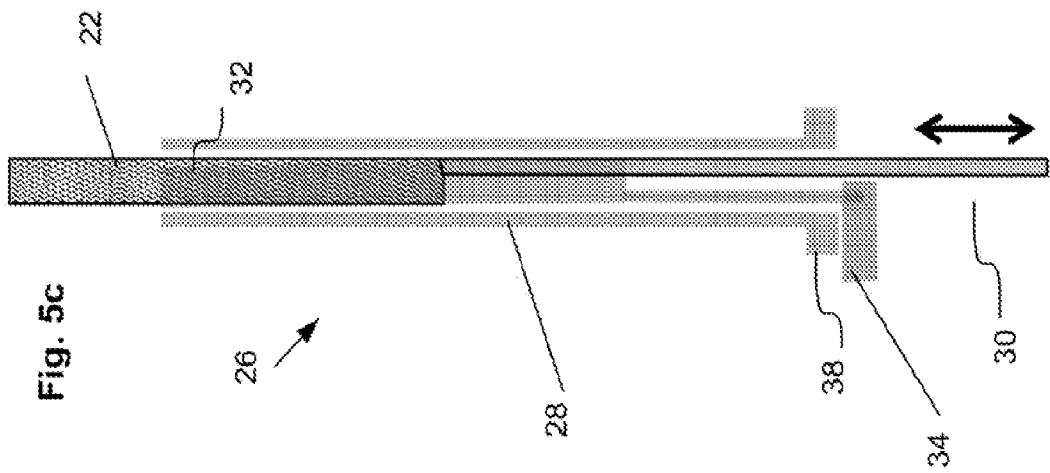
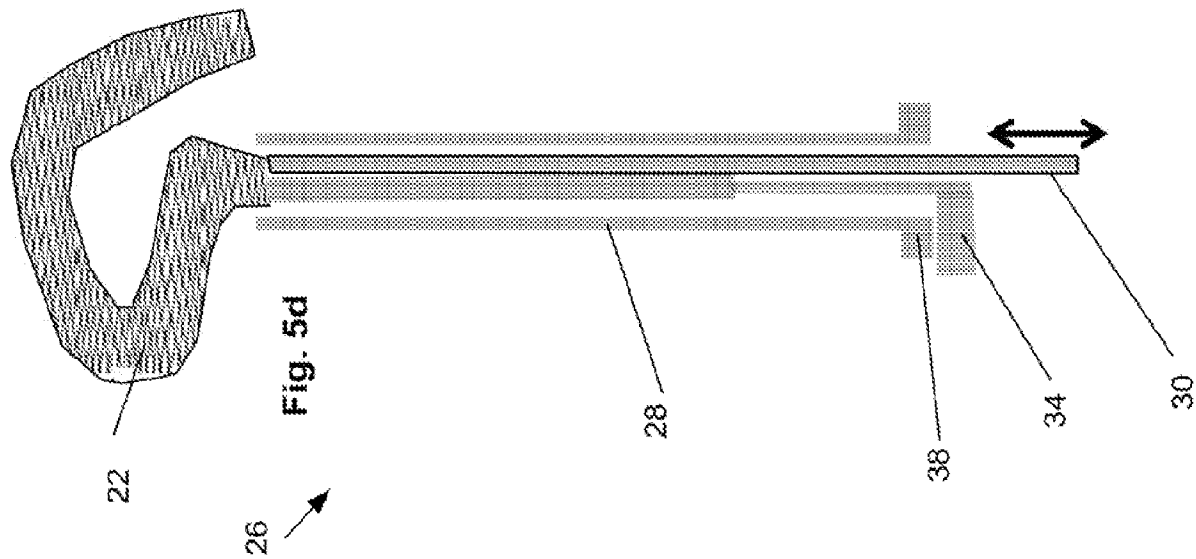
**Fig. 3**

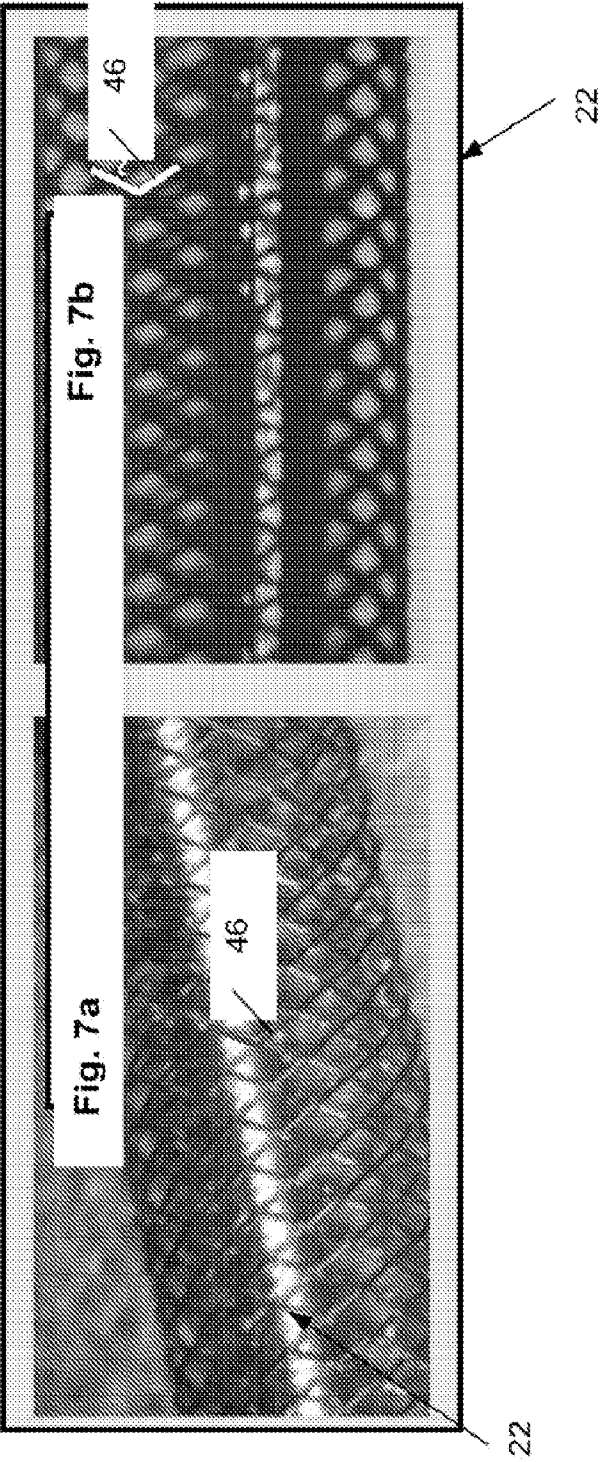
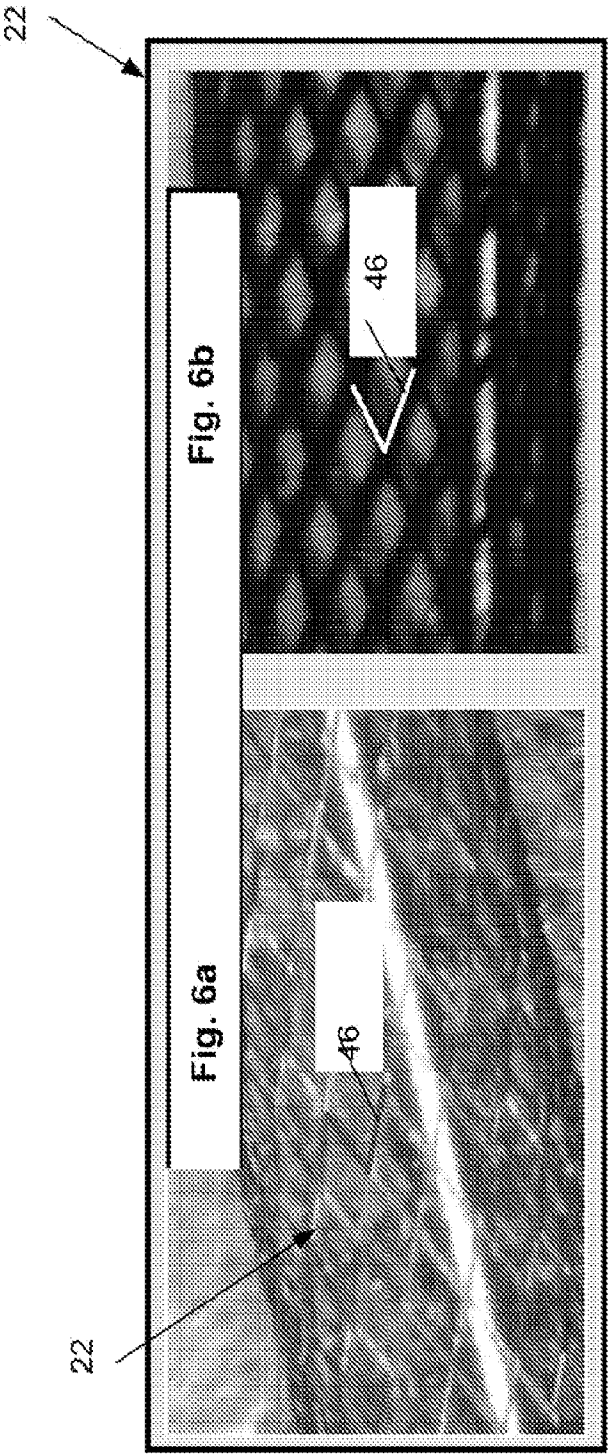


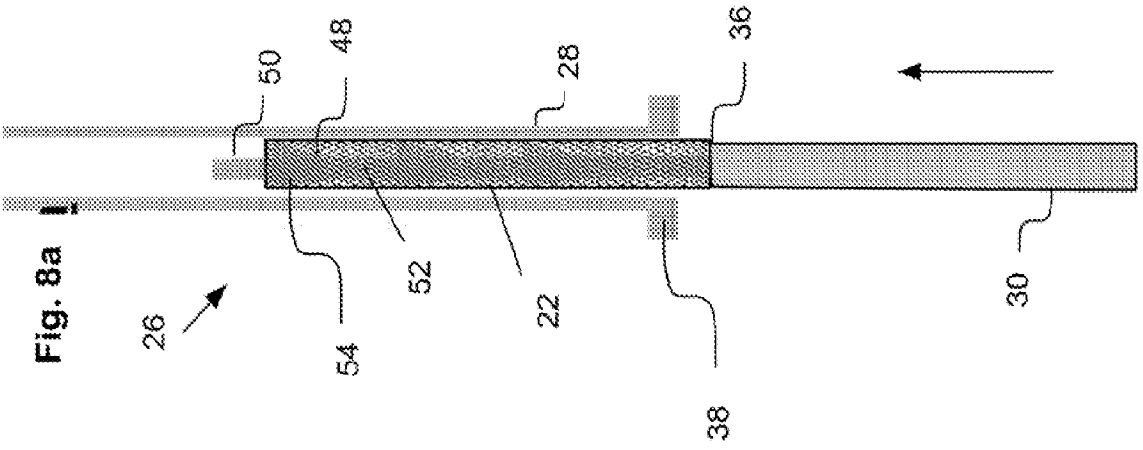
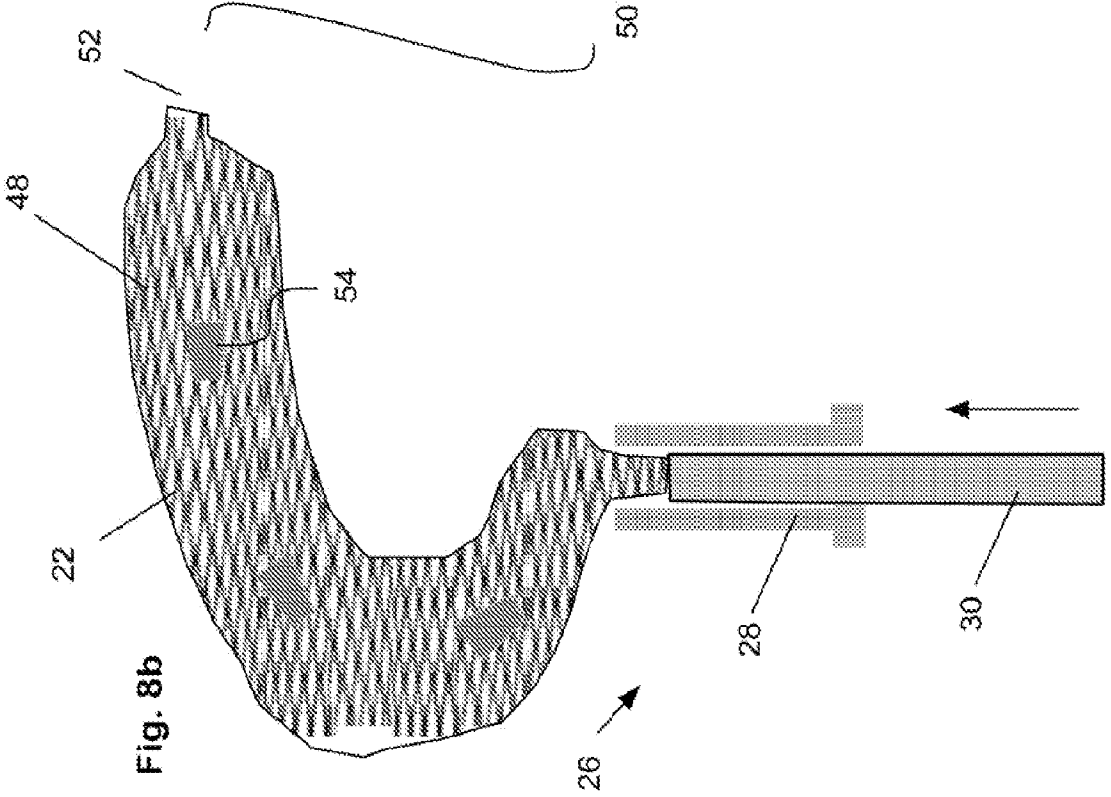


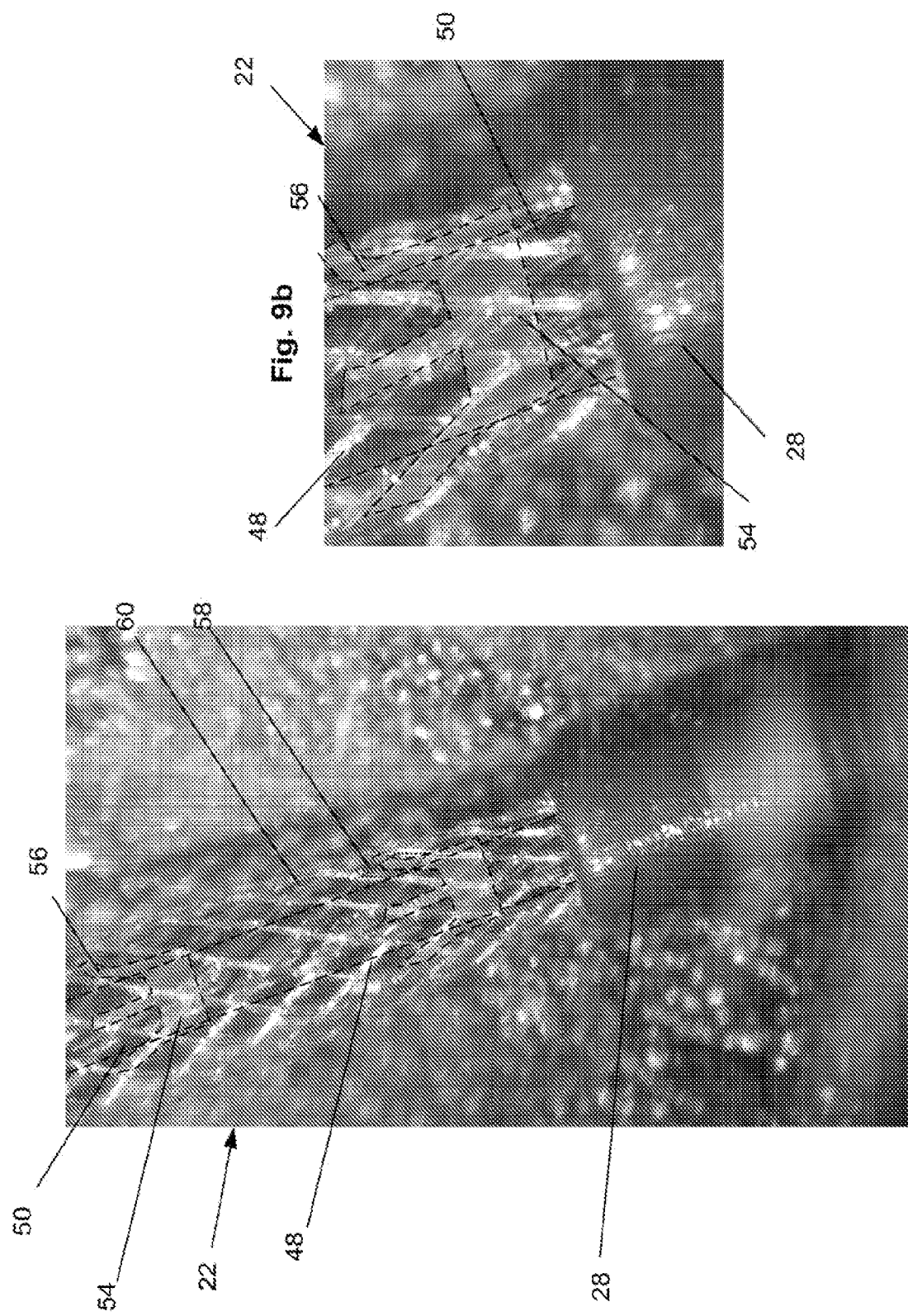












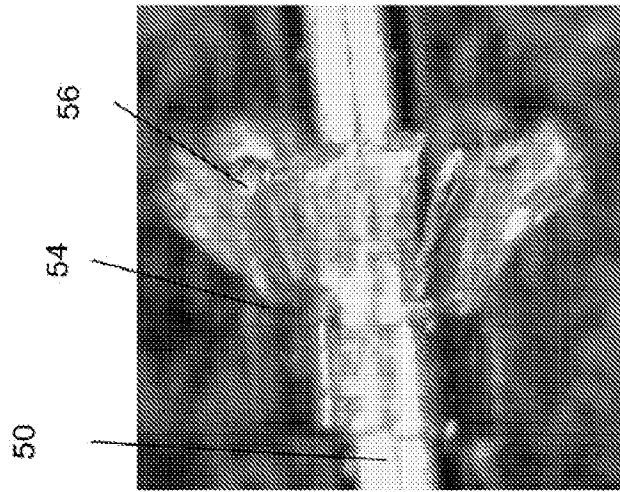


Fig. 10a

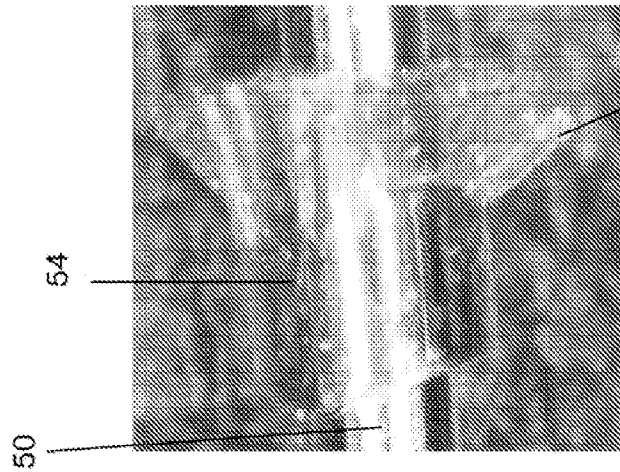


Fig. 10b

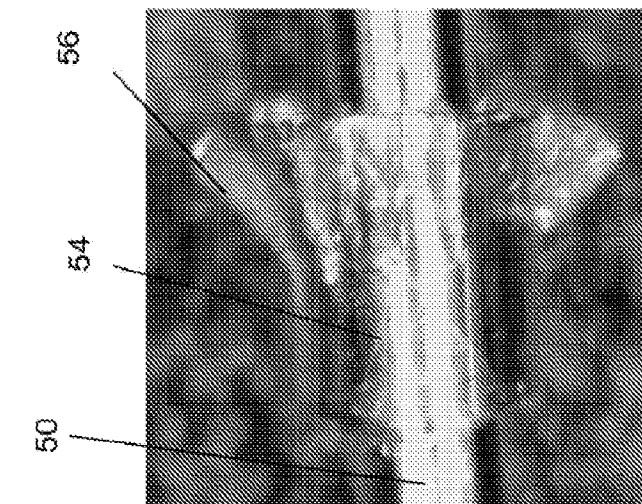


Fig. 10c

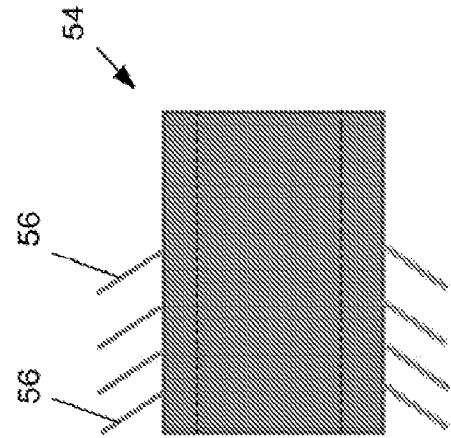


Fig. 11a

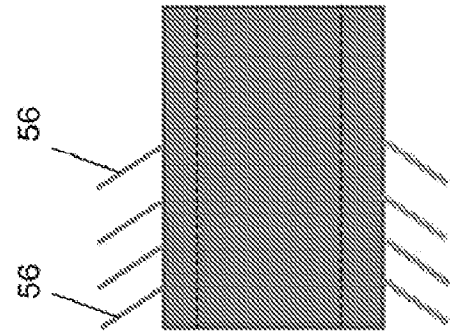


Fig. 11b

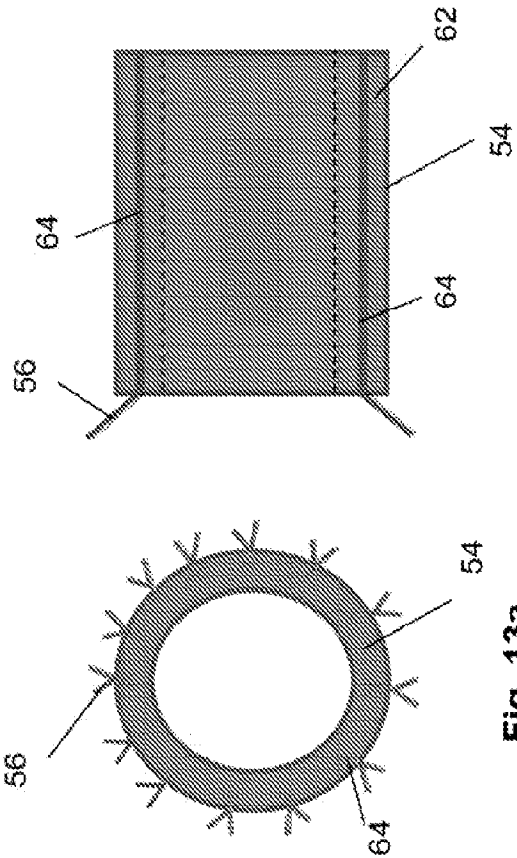


Fig. 13a

Fig. 13b

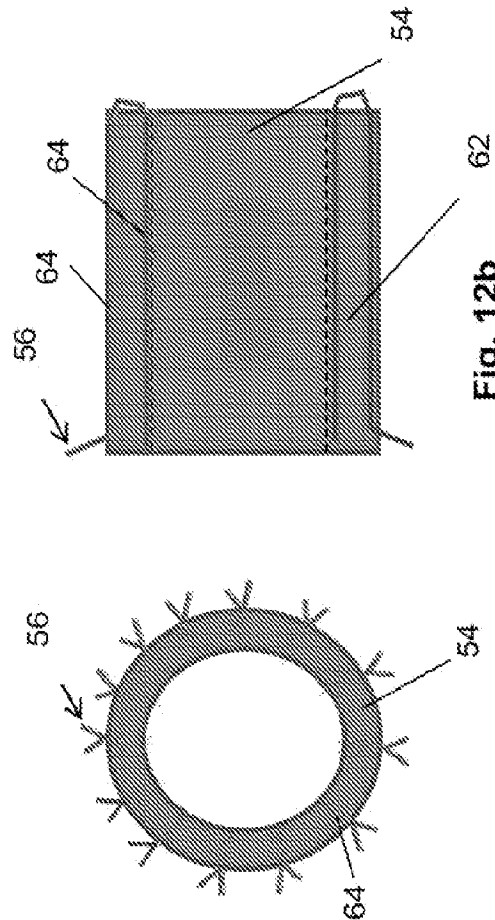


Fig. 12a

Fig. 12b

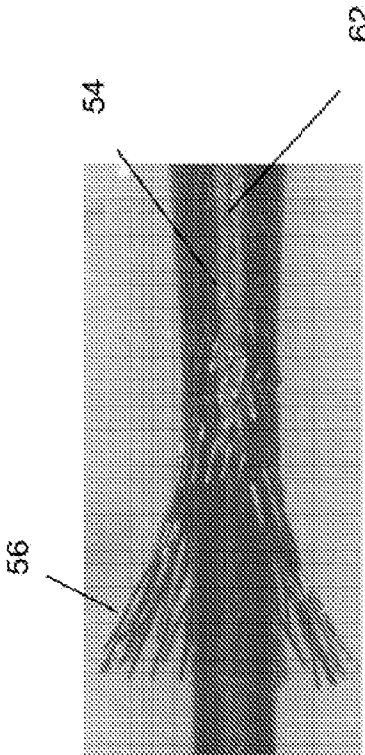


Fig. 12c

Fig. 14b

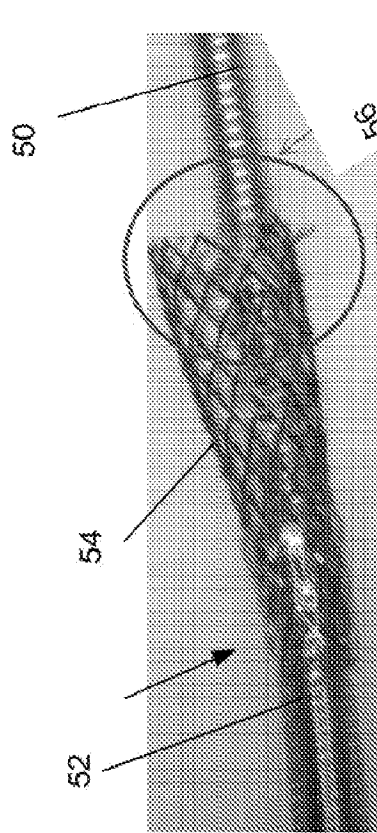


Fig. 14c

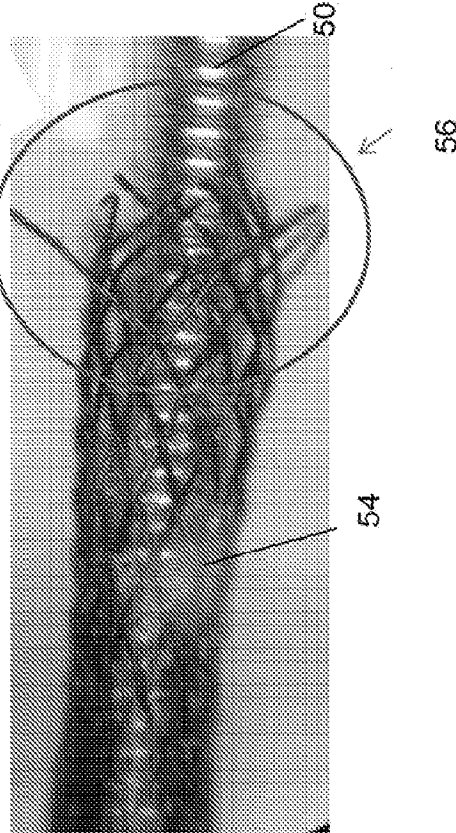
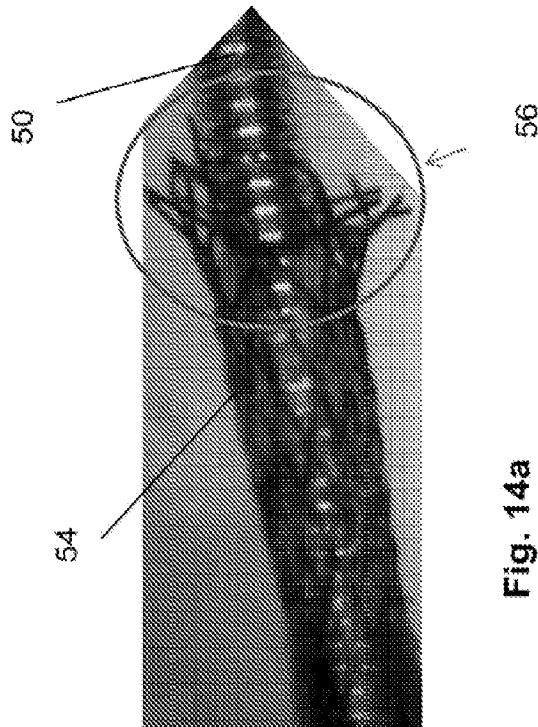


Fig. 14a



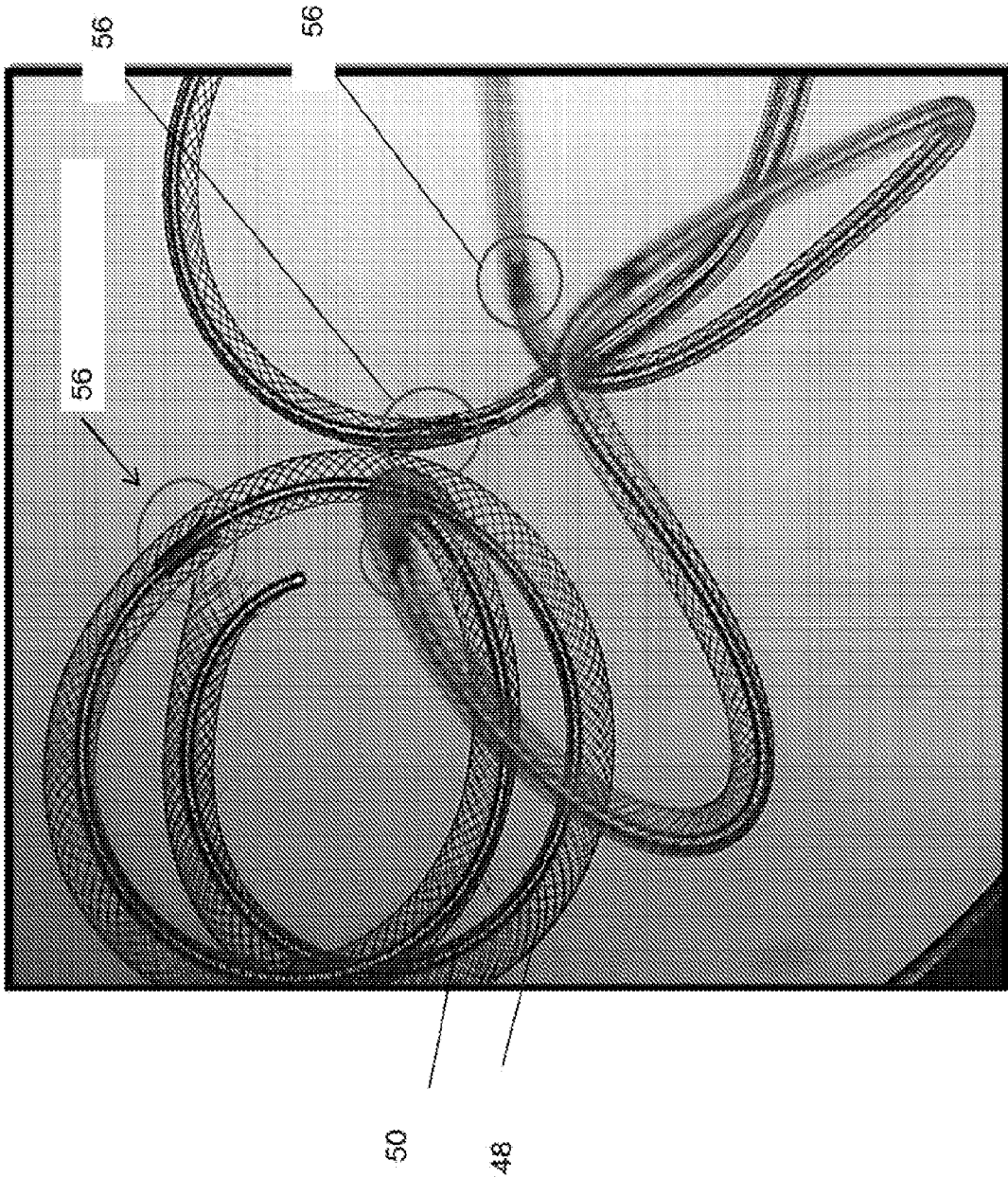


Fig. 15

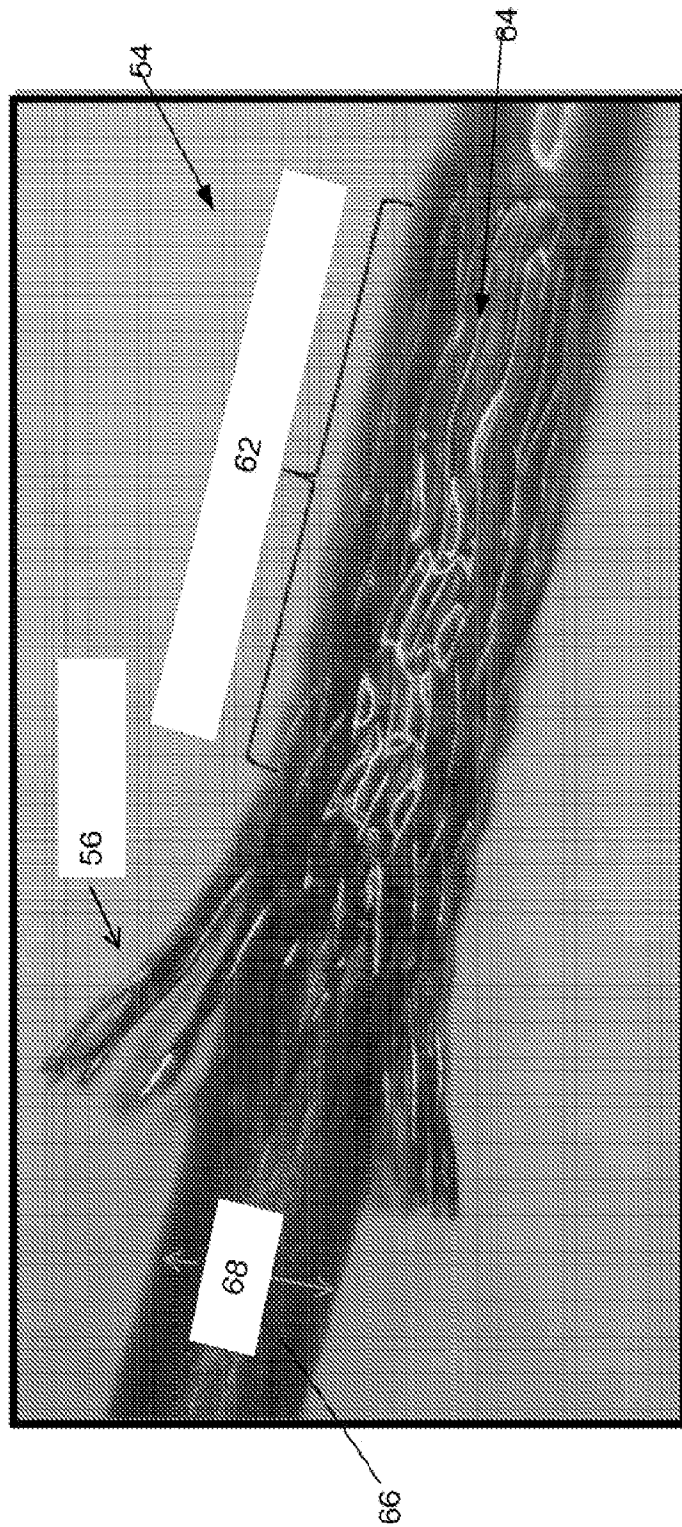


Fig. 16

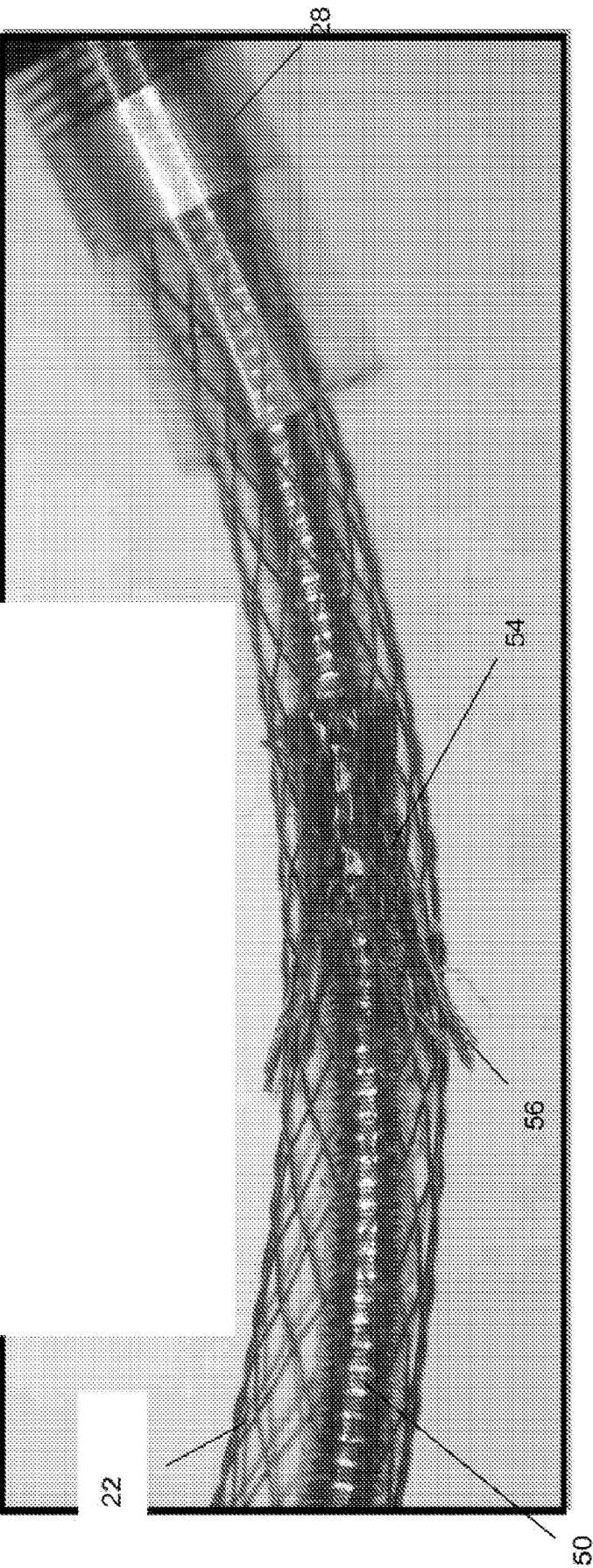


Fig. 17

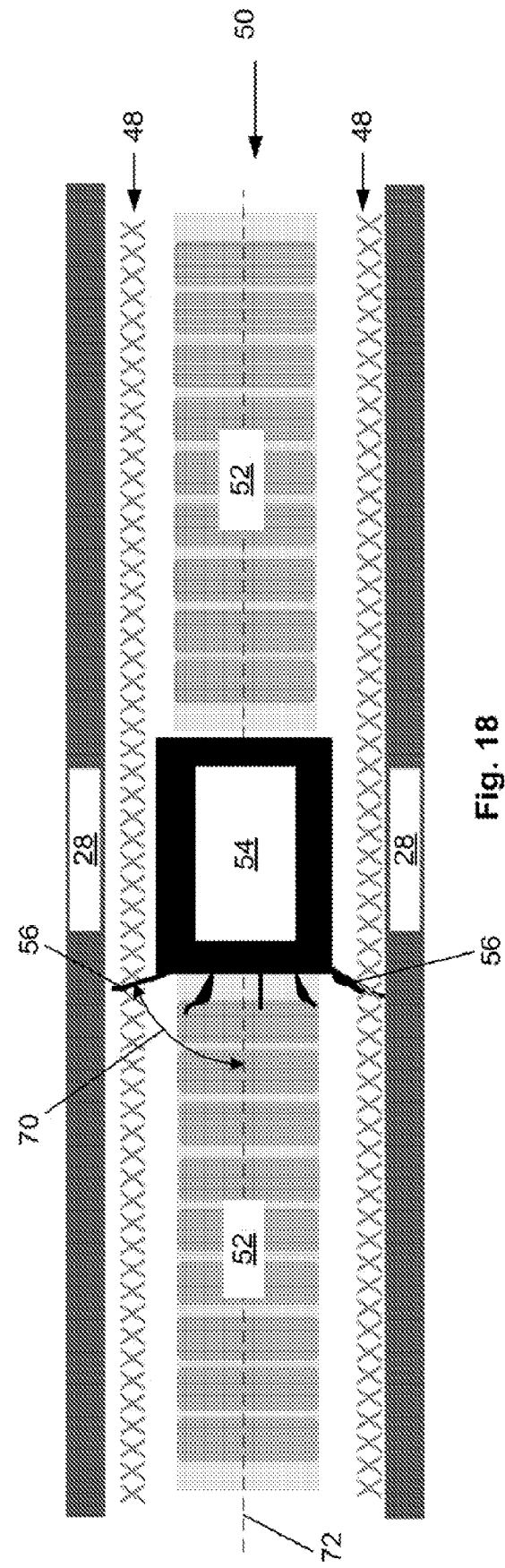
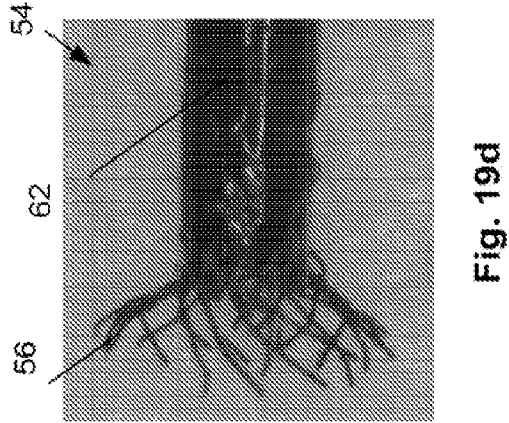
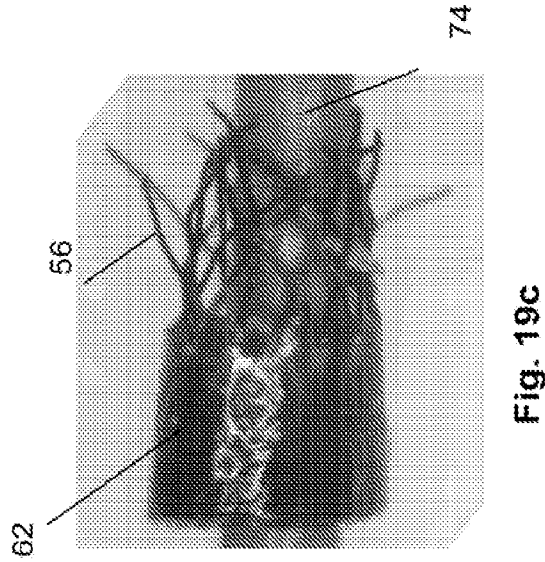
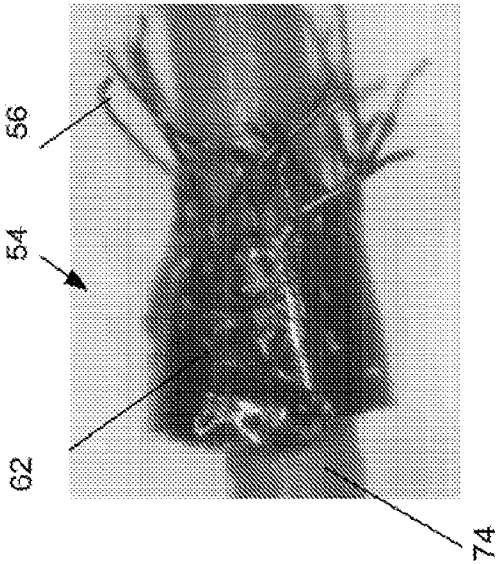
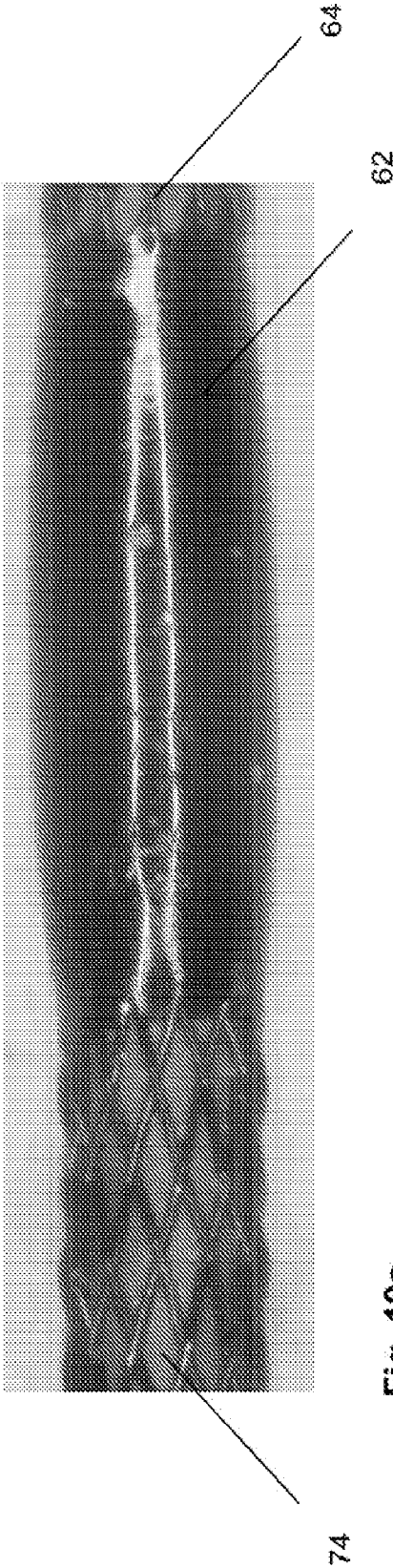


Fig. 18



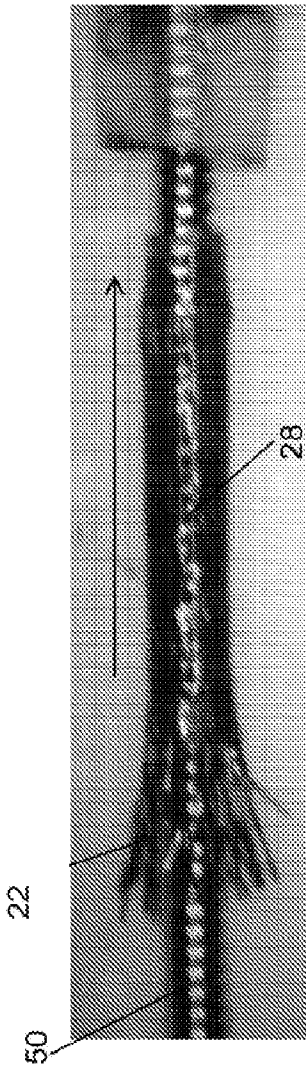


Fig. 20a

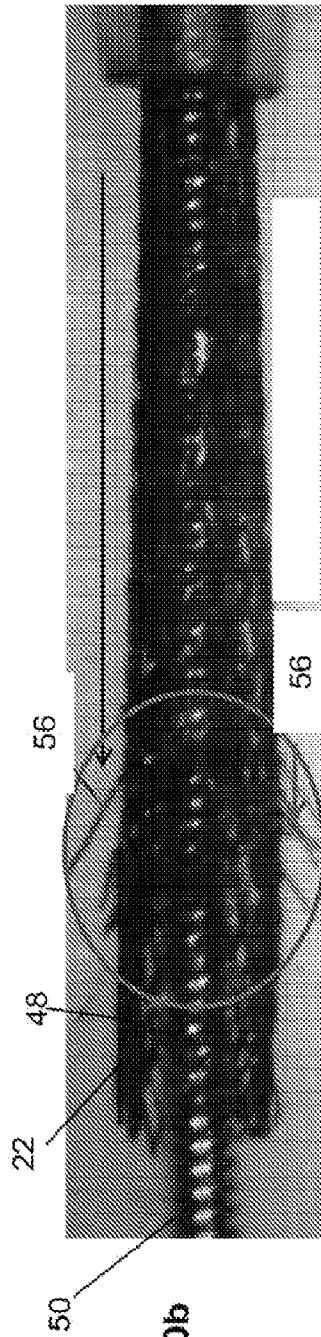


Fig. 20b

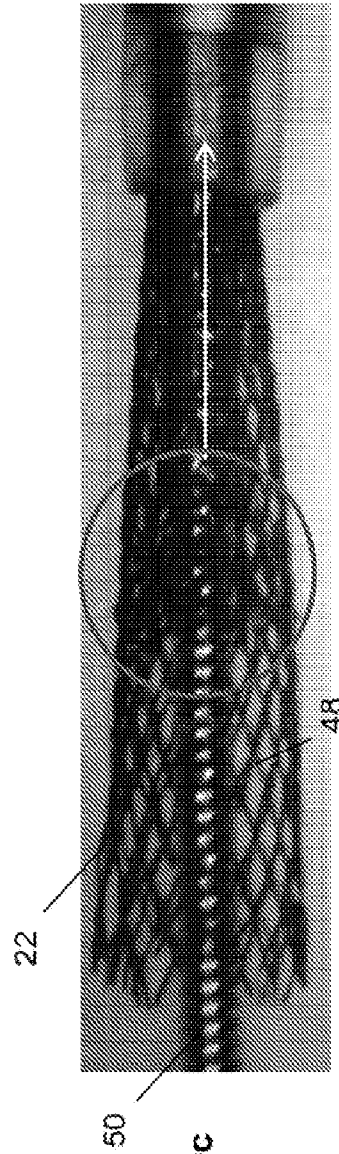


Fig. 20c

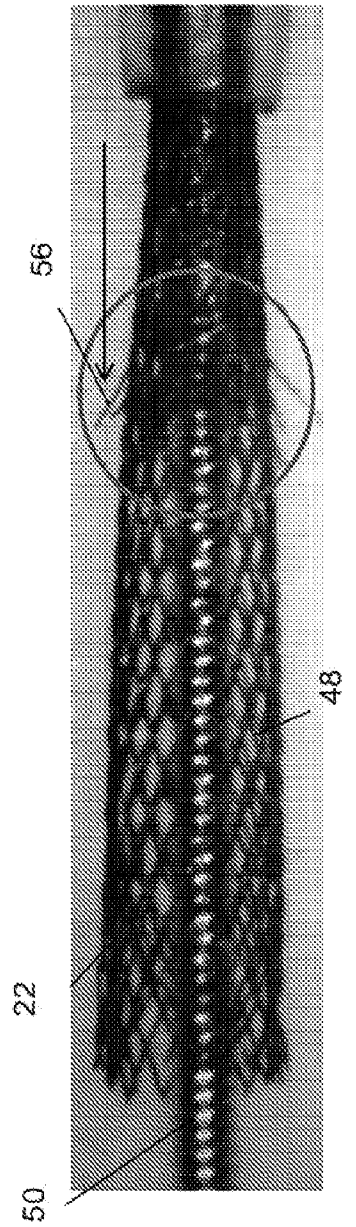


Fig. 20d

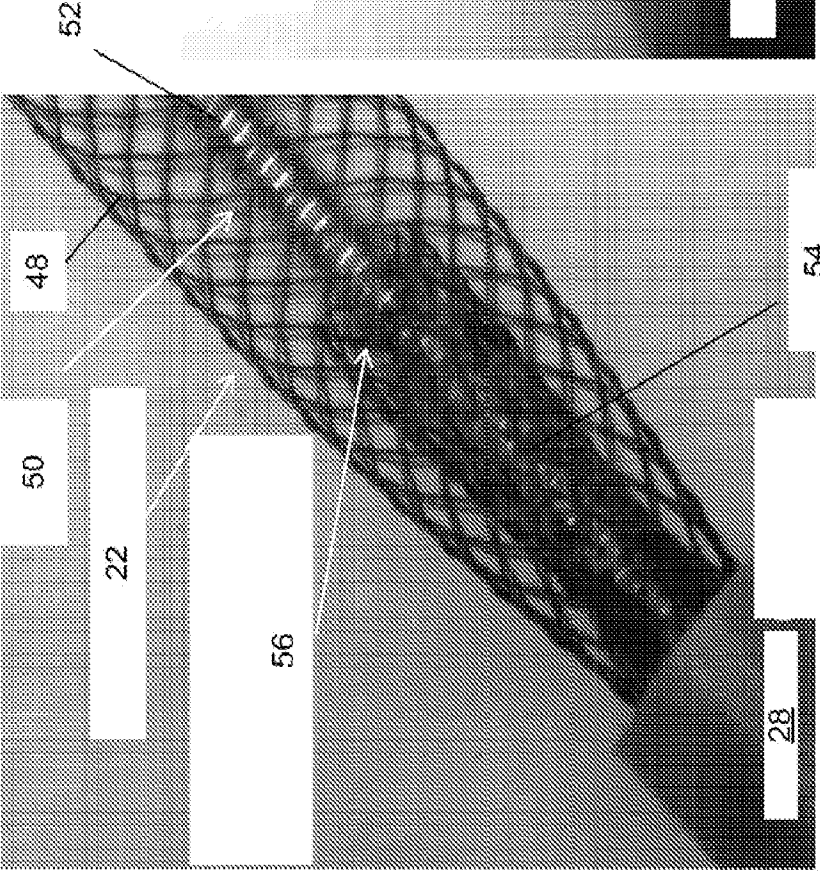


Fig. 21a

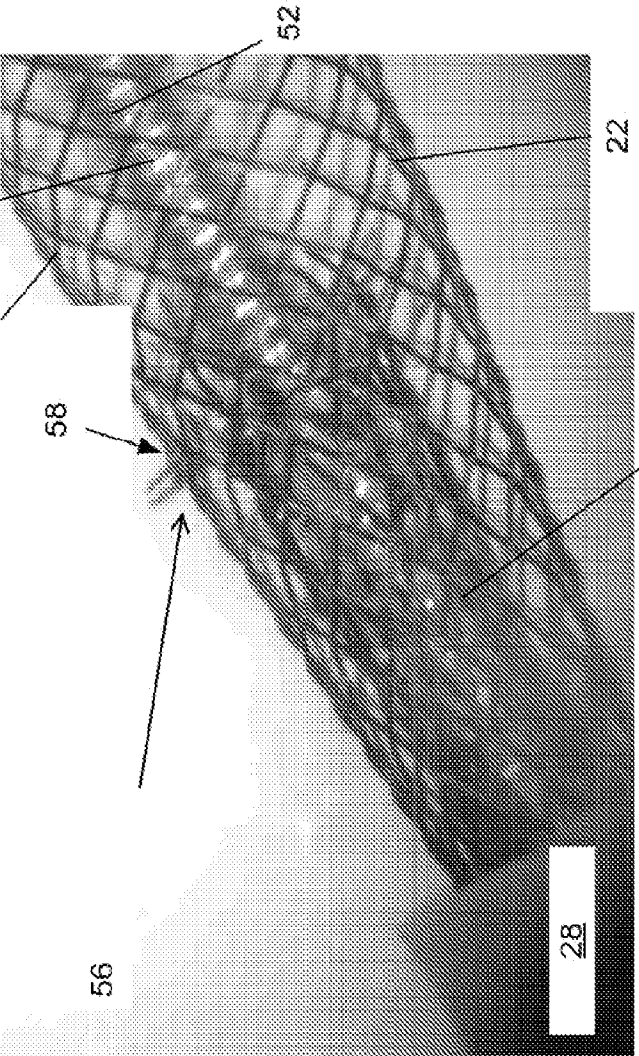


Fig. 21b

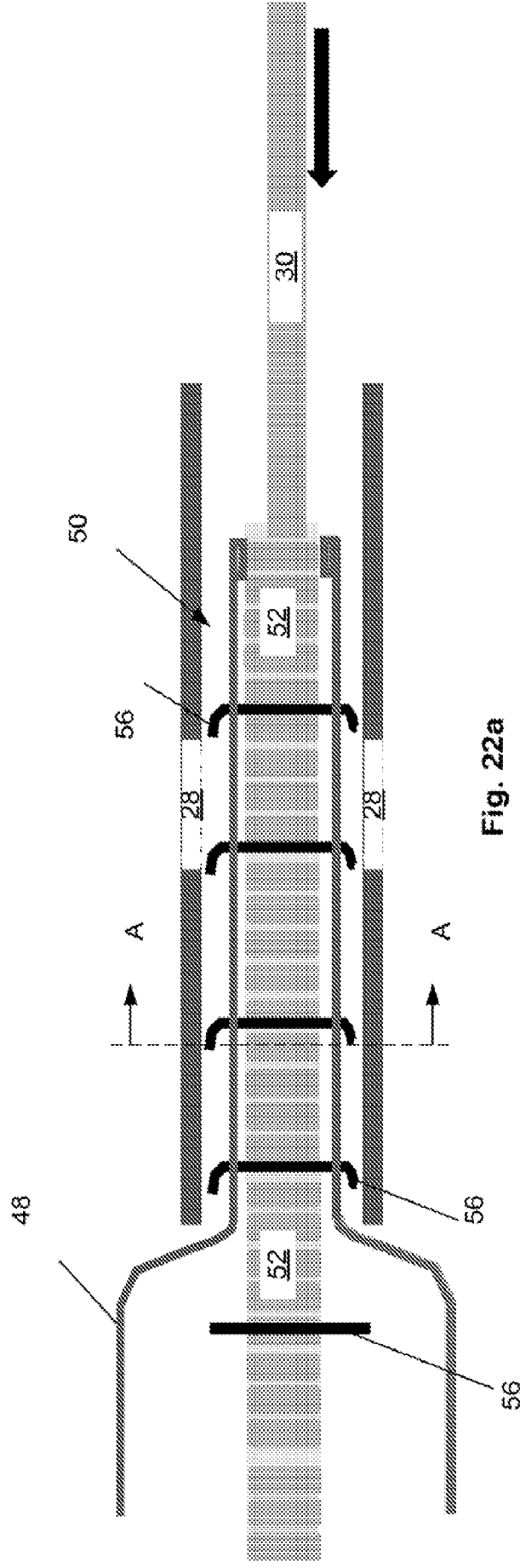


Fig. 22a

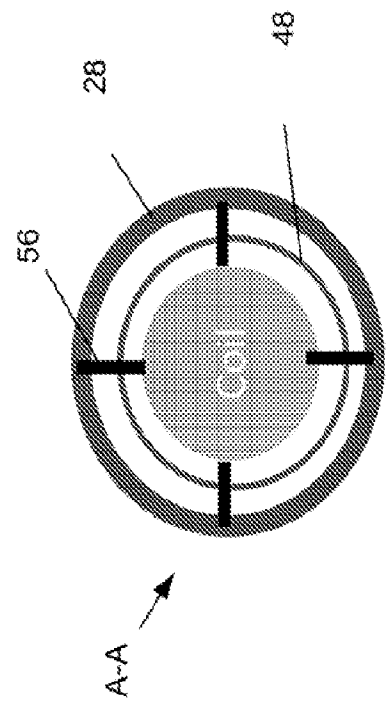


Fig. 22b

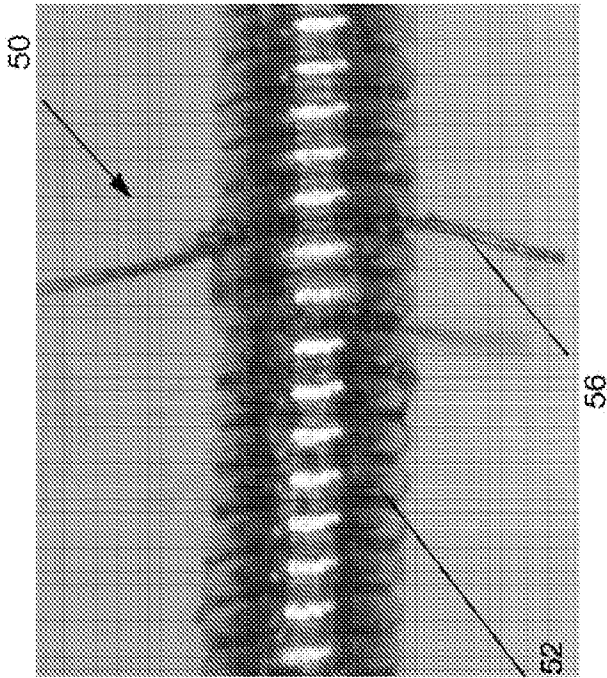
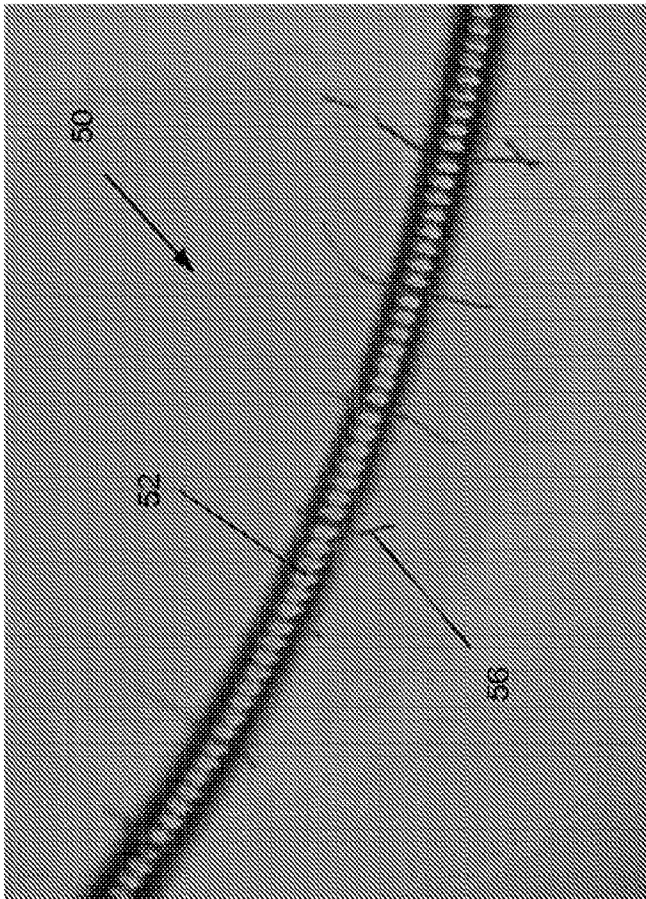


Fig. 23b

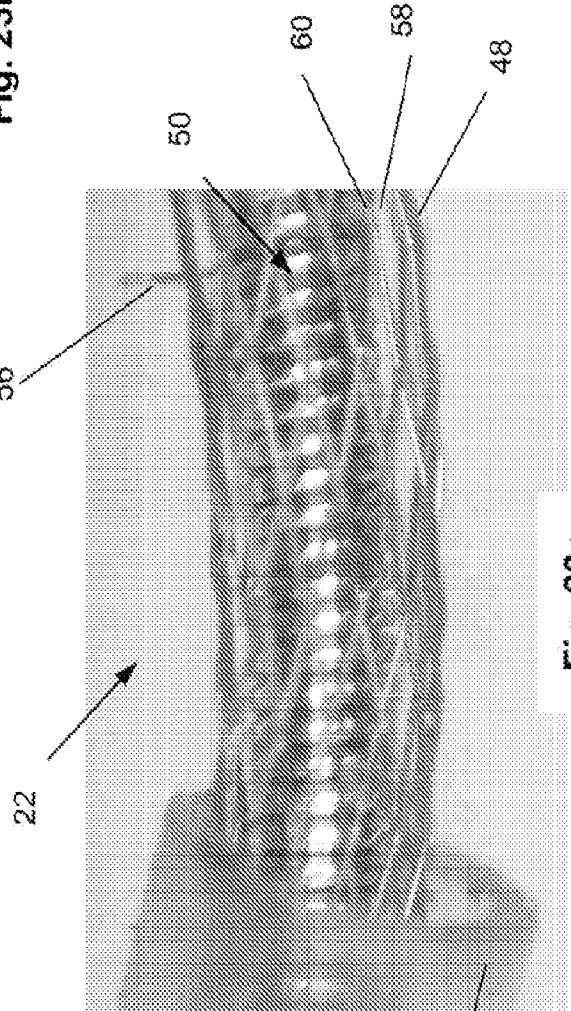


Fig. 23c

Fig. 23a

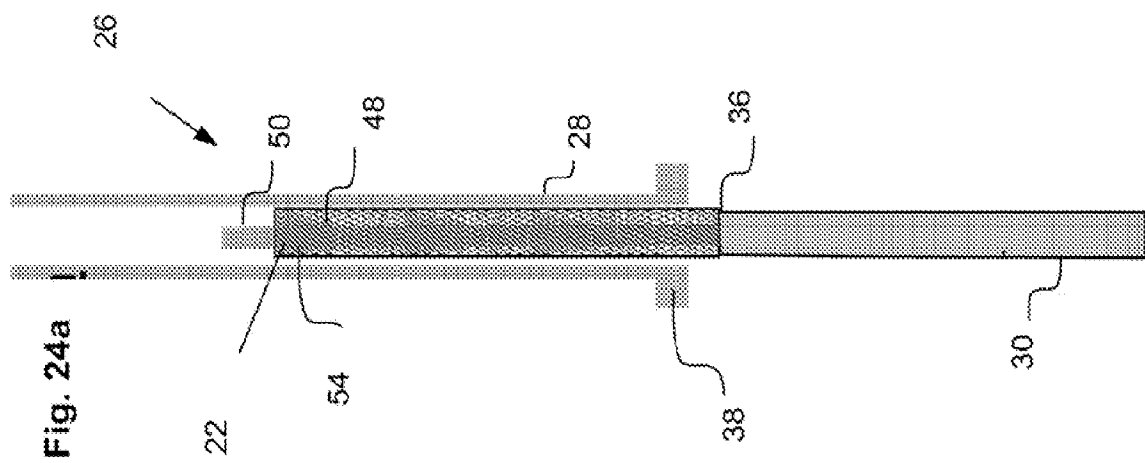
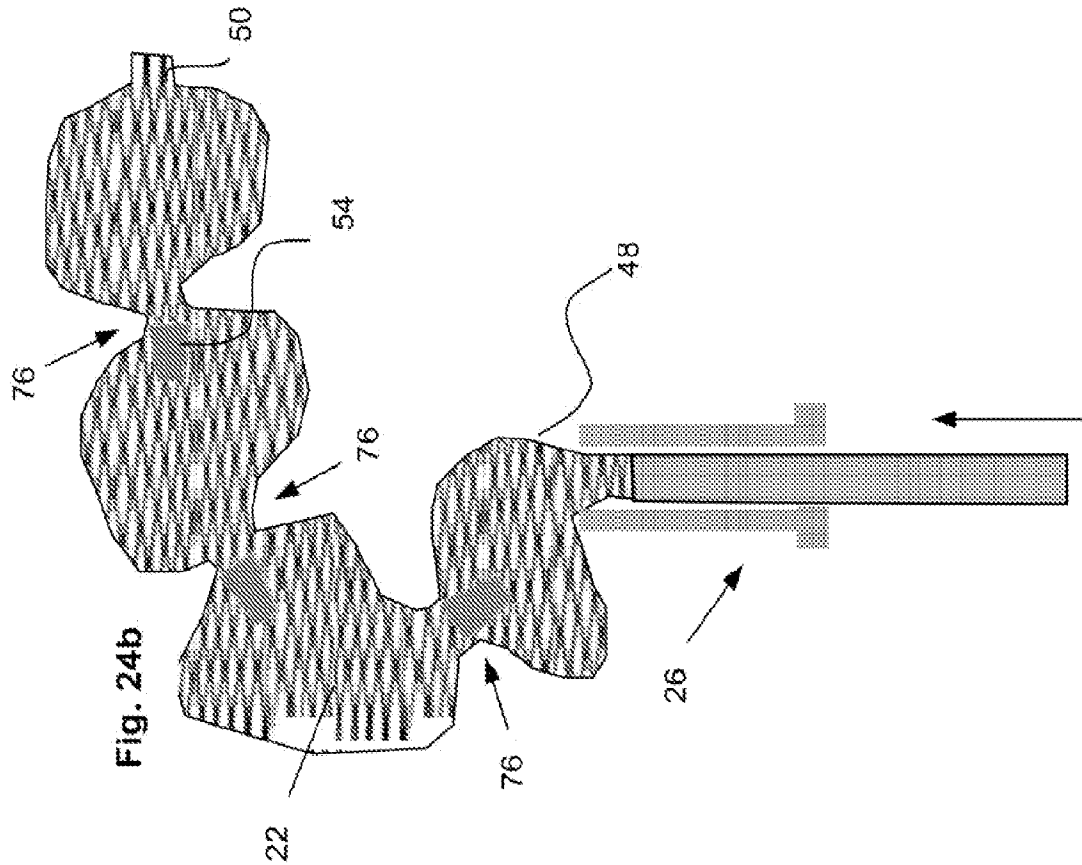


Fig. 25c

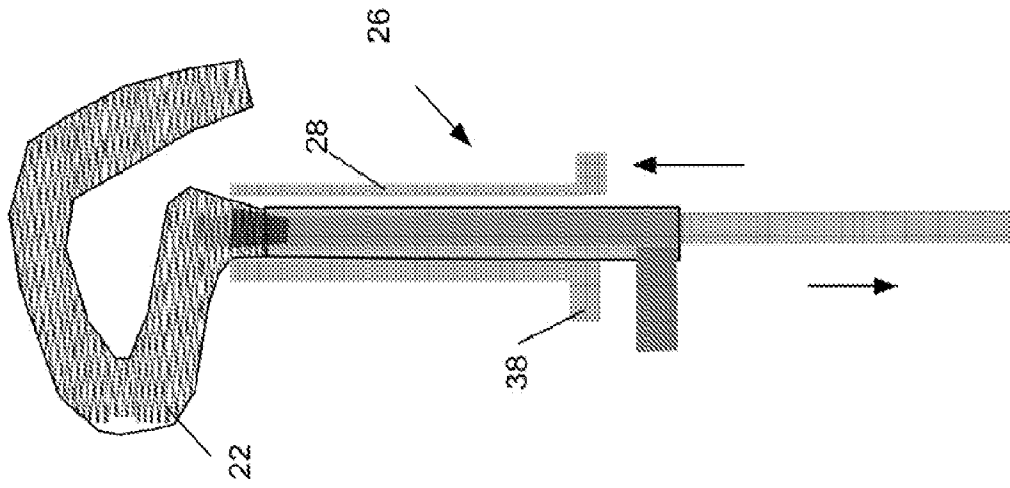


Fig. 25b

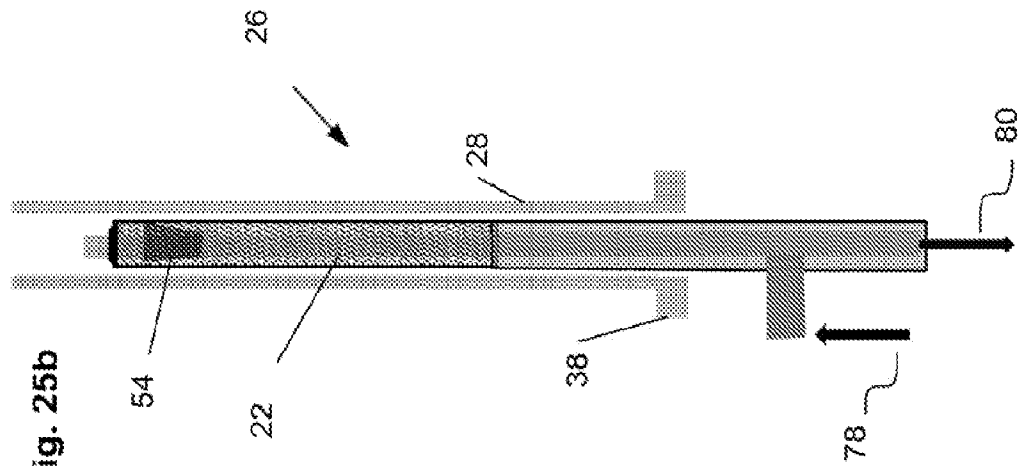
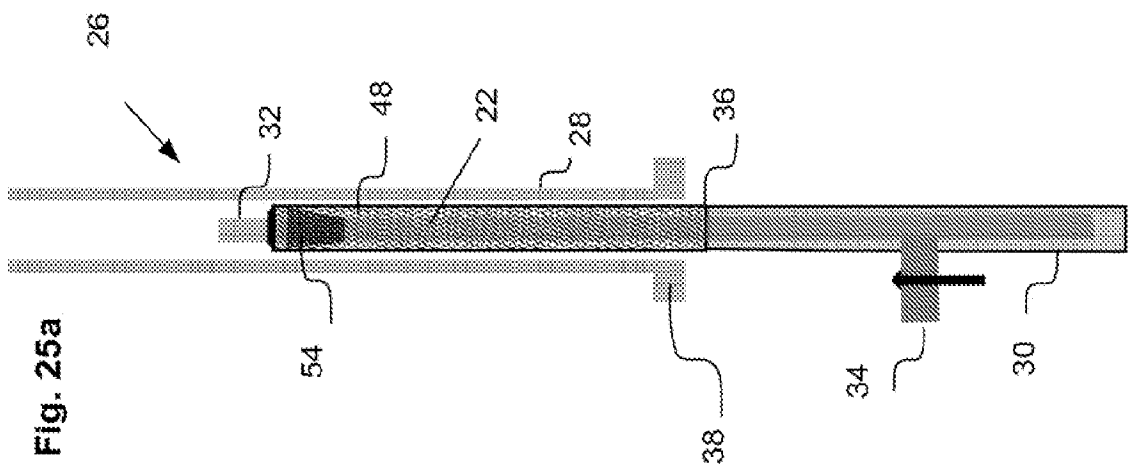
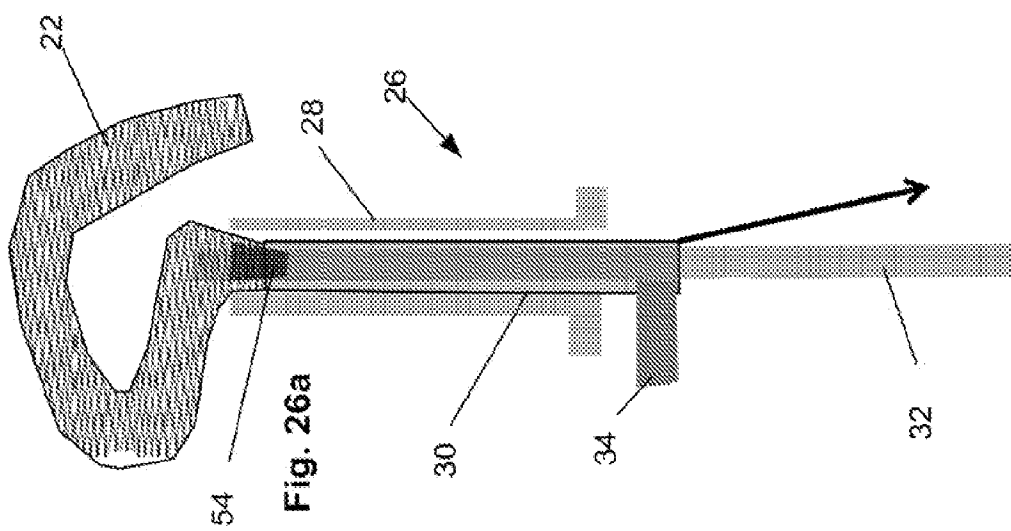
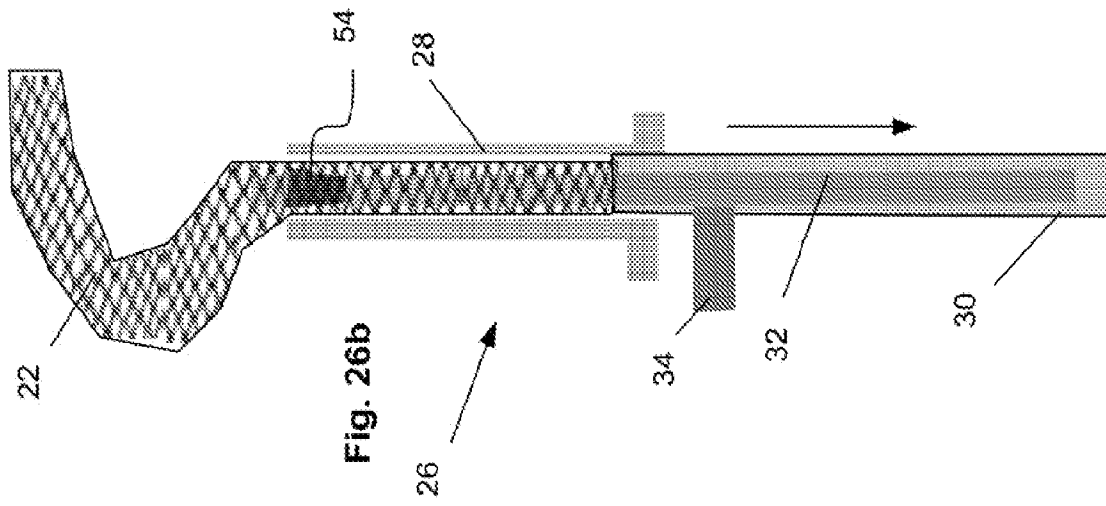


Fig. 25a





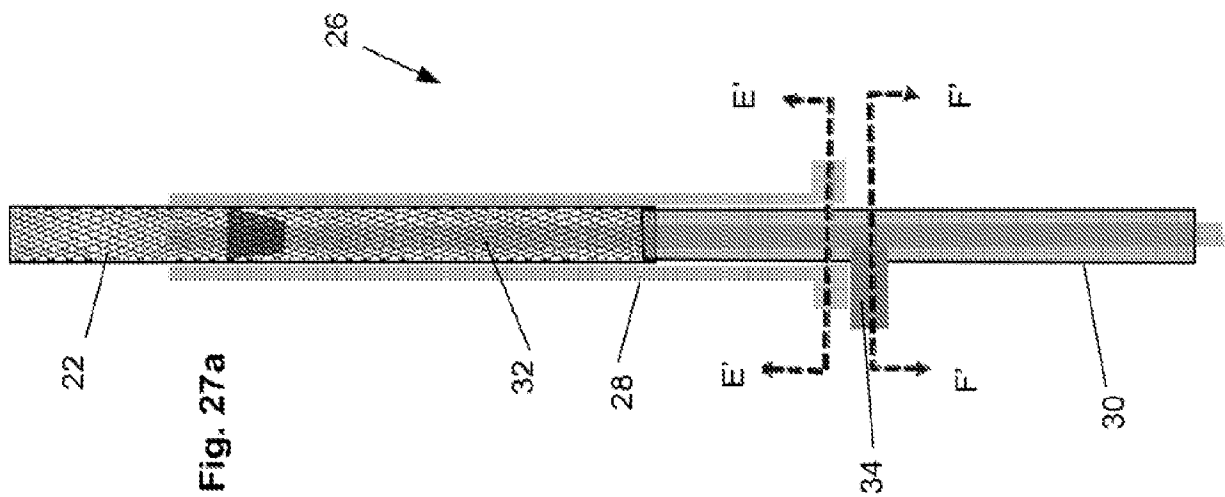


Fig. 27a

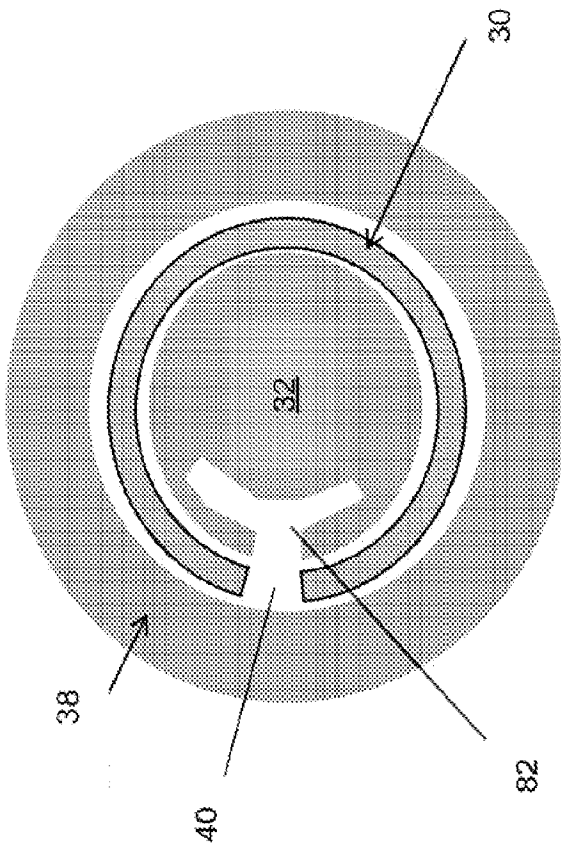


Fig. 27b

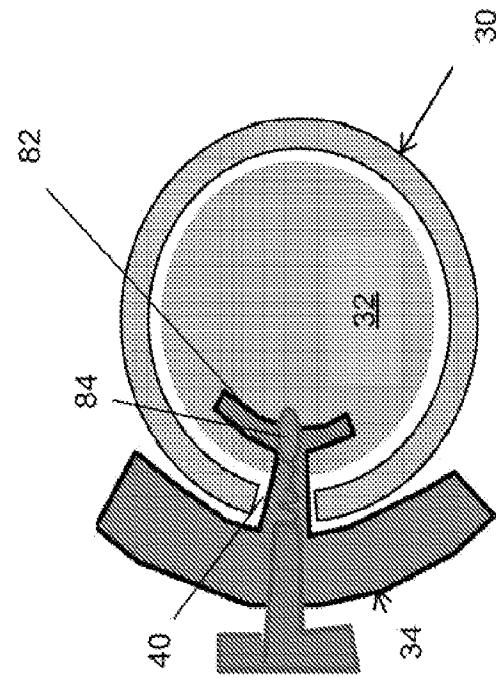
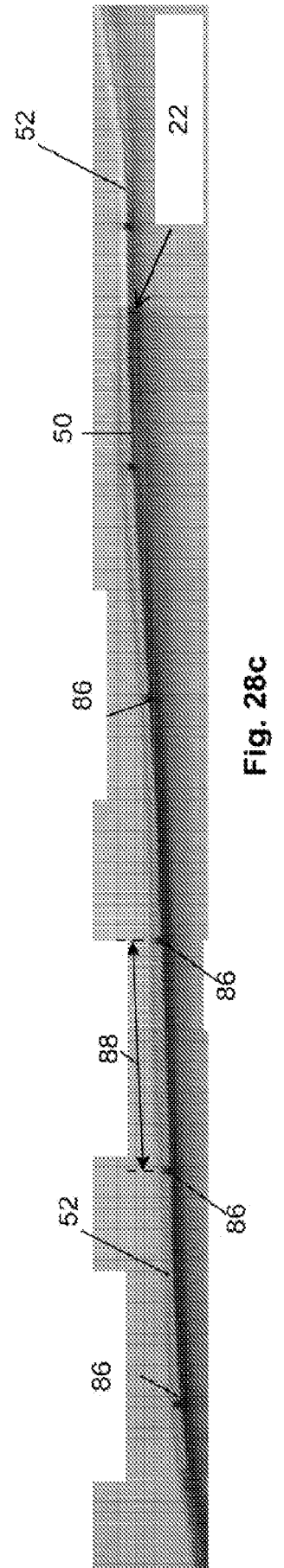
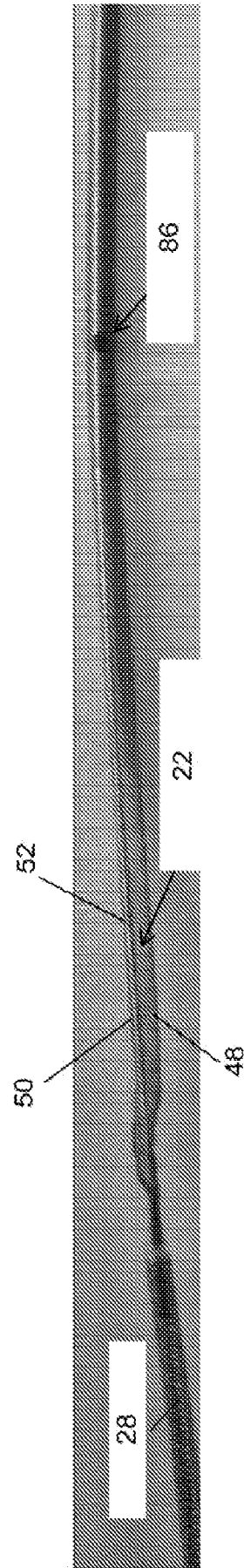
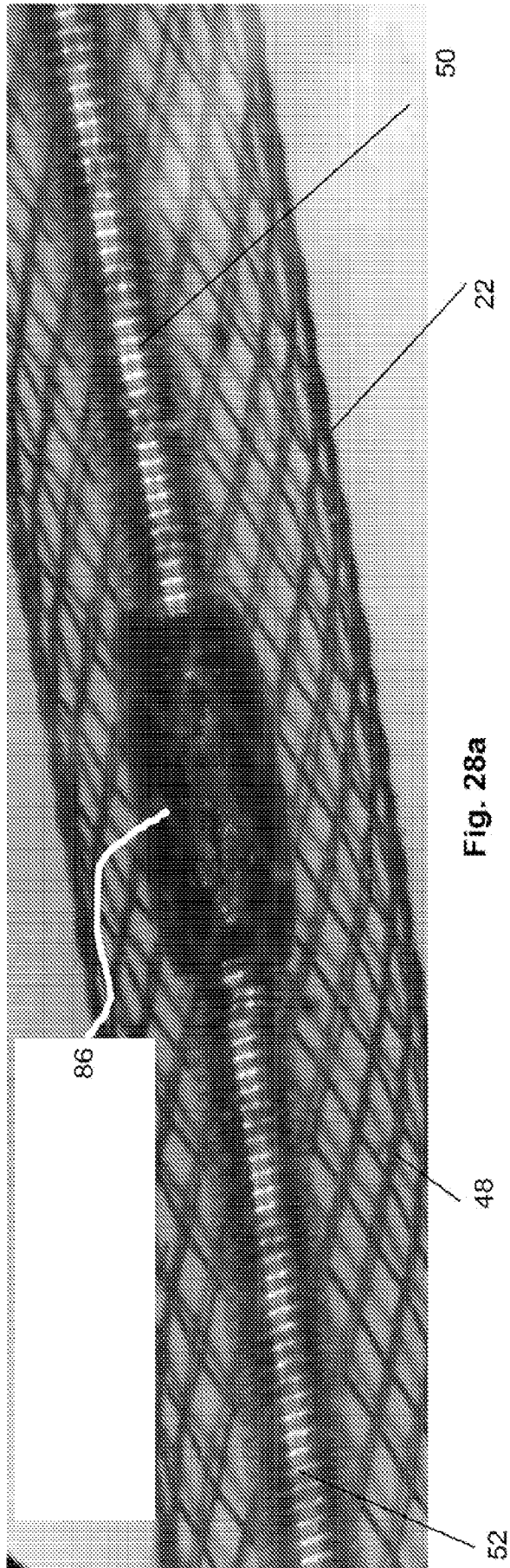


Fig. 27c



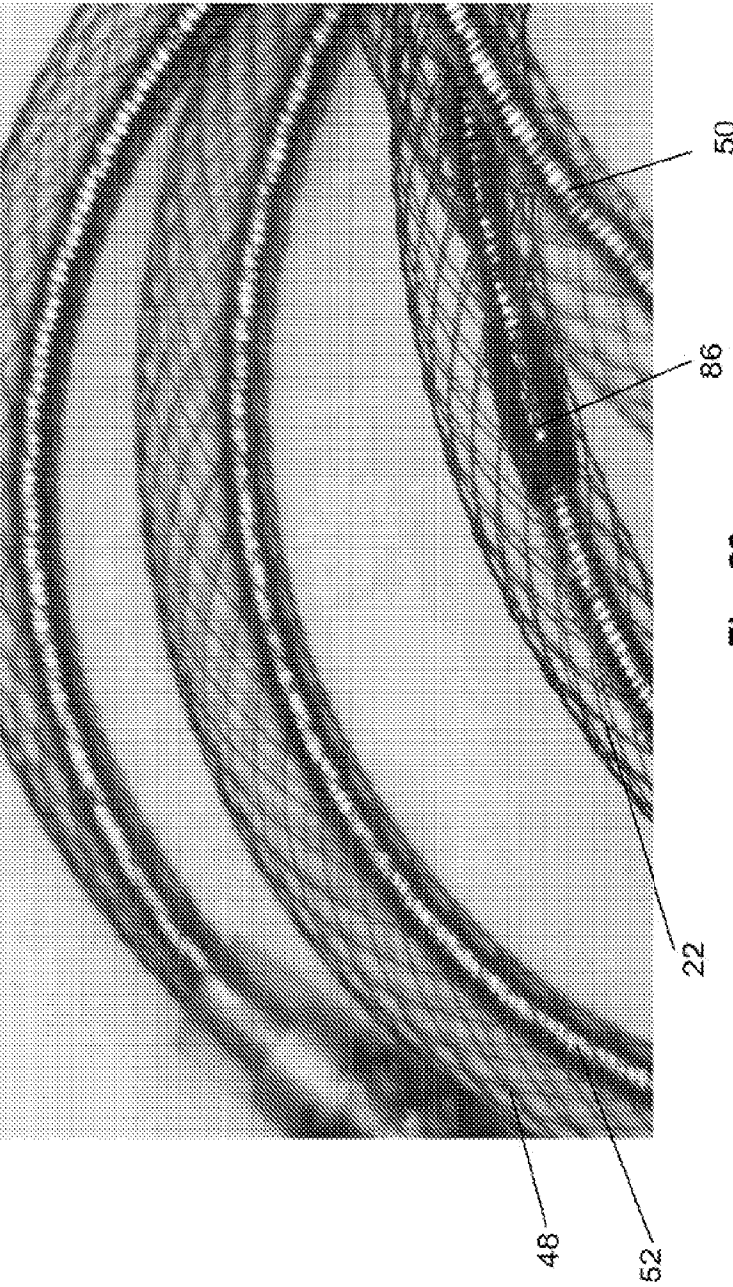


Fig. 29

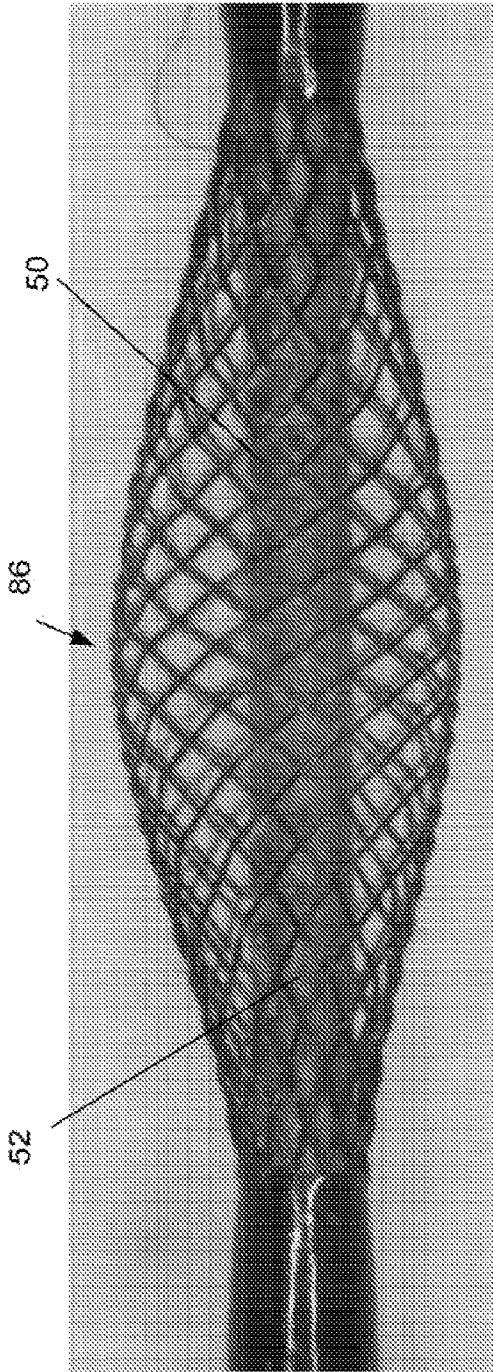


Fig. 30

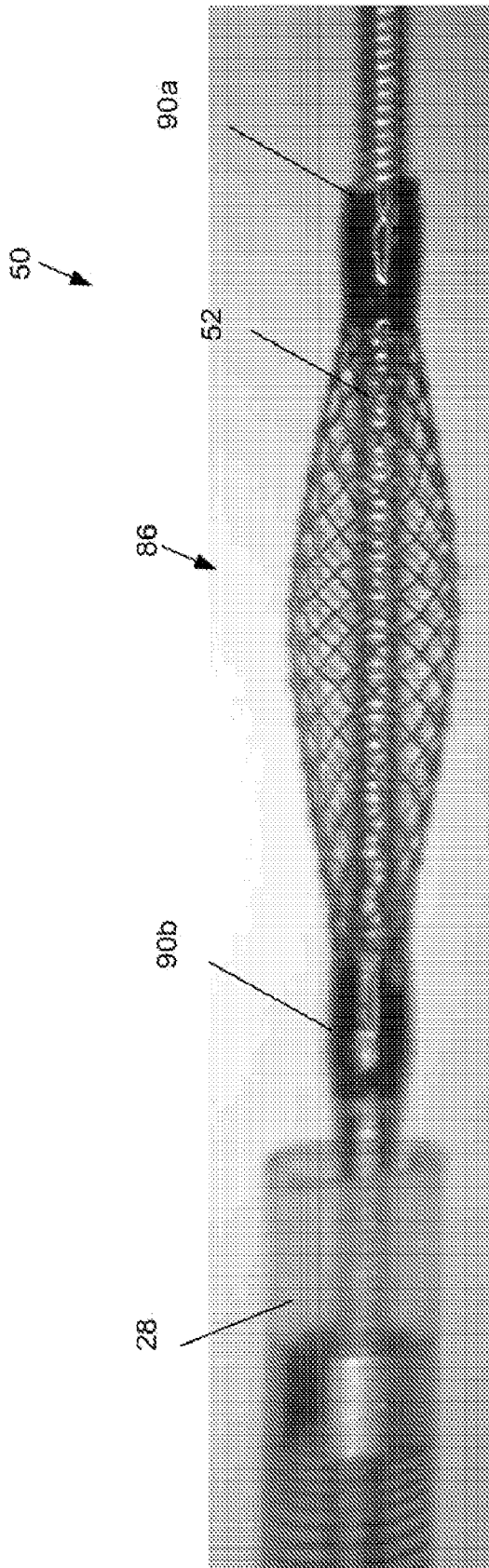


Fig. 31a

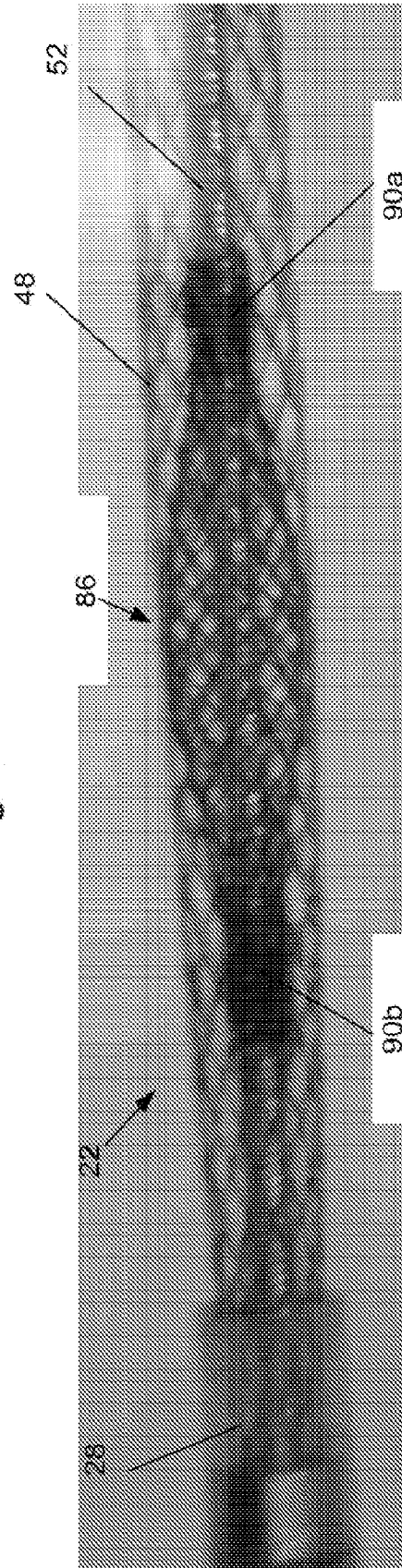
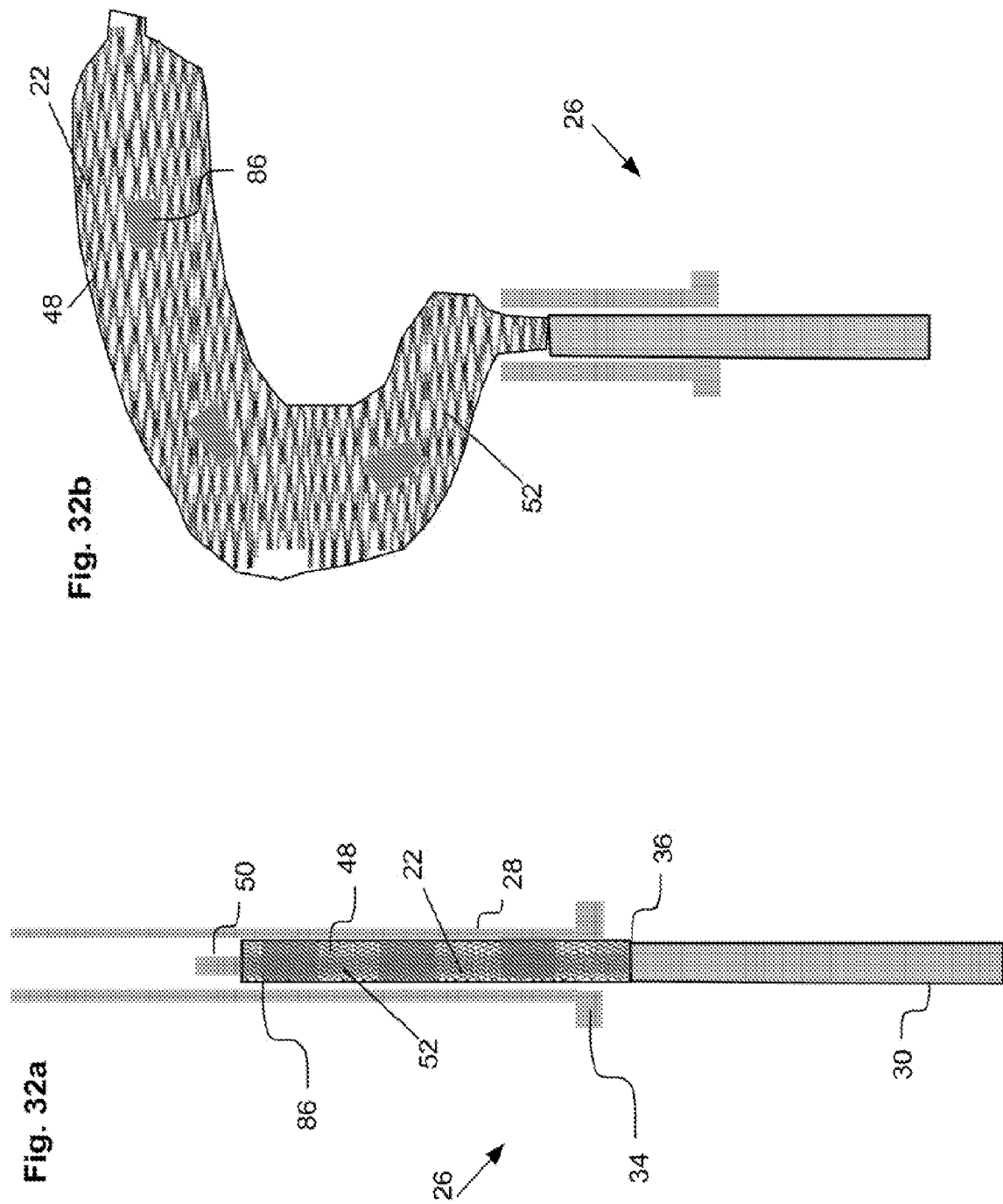
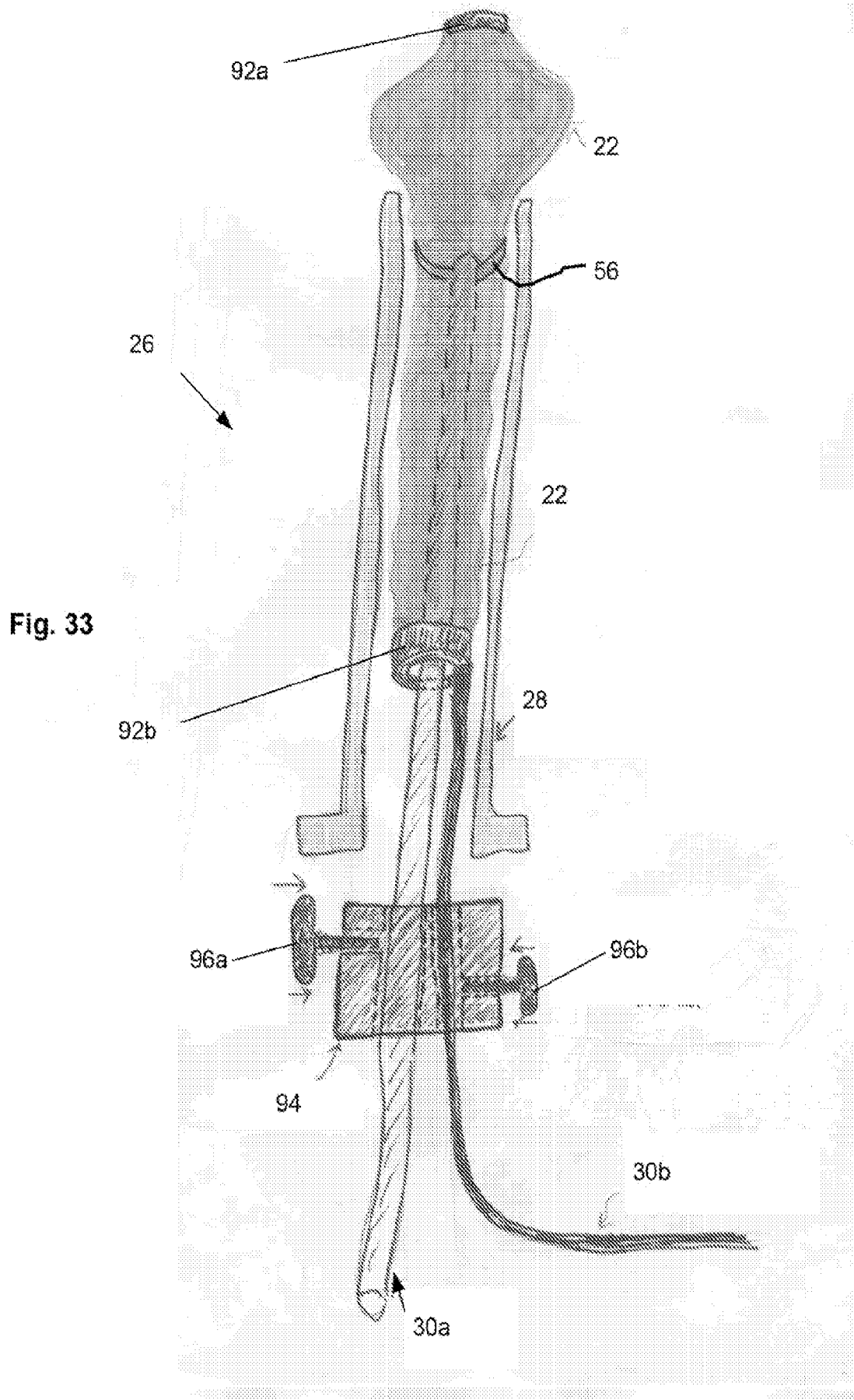
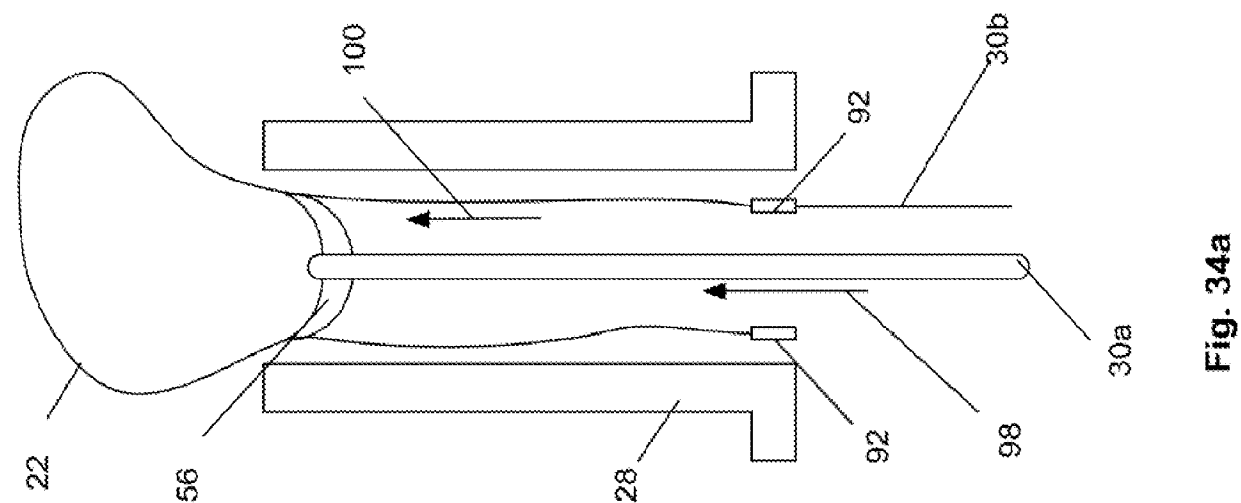
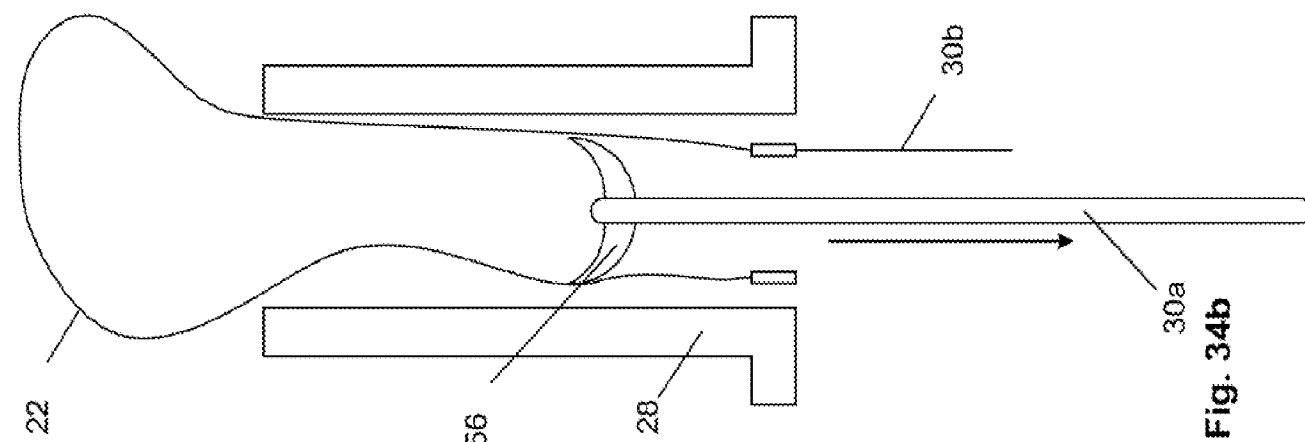
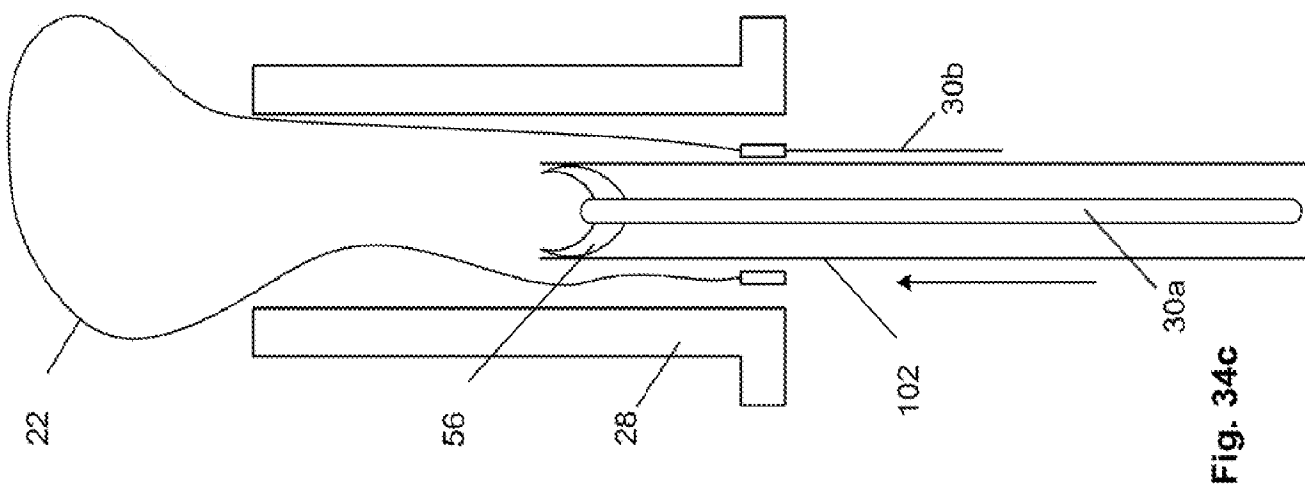
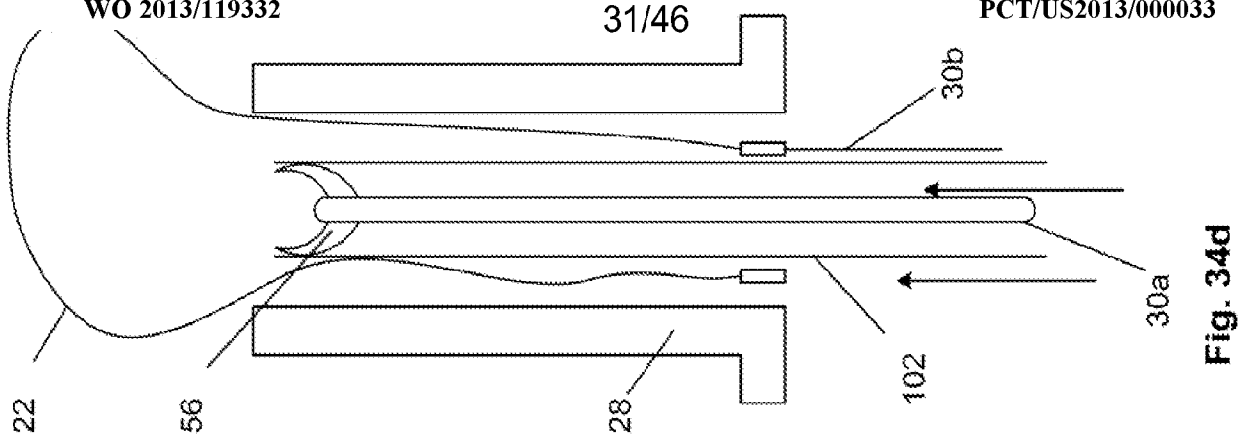
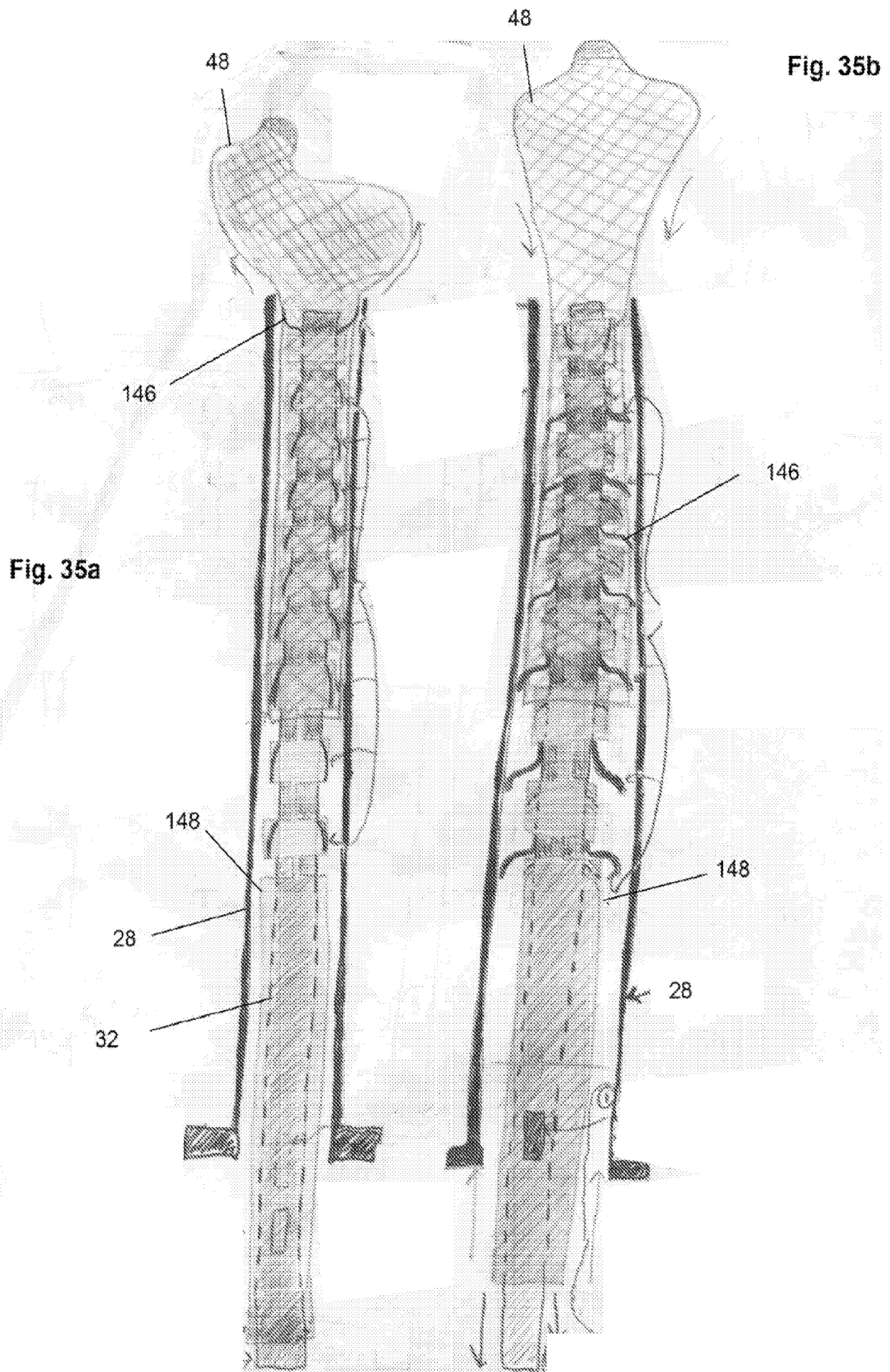


Fig. 31b









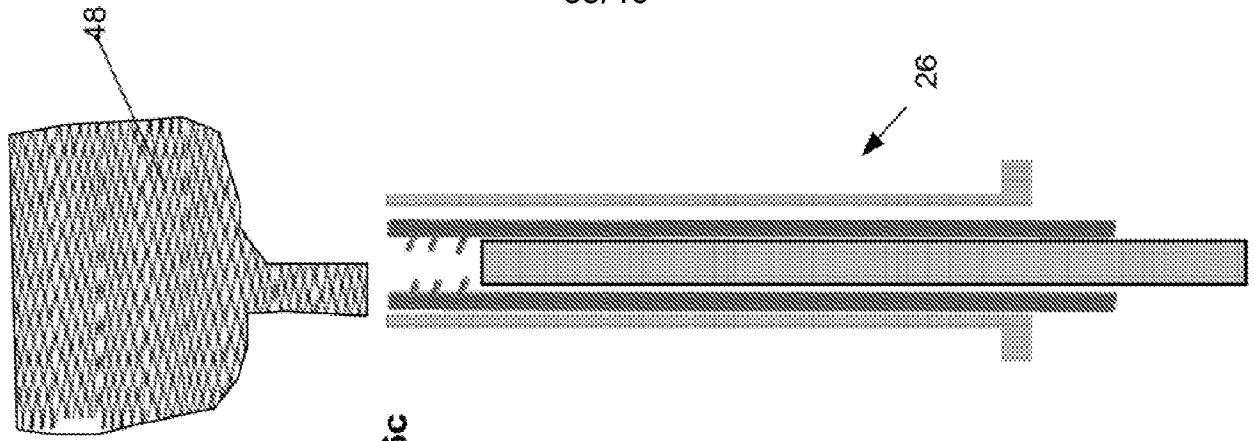


Fig. 36c

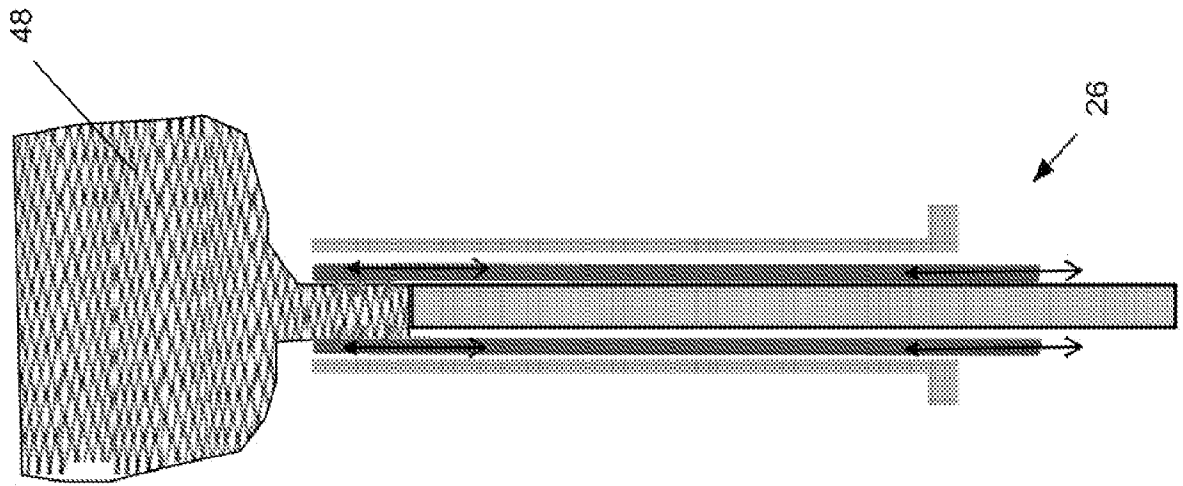


Fig. 36b

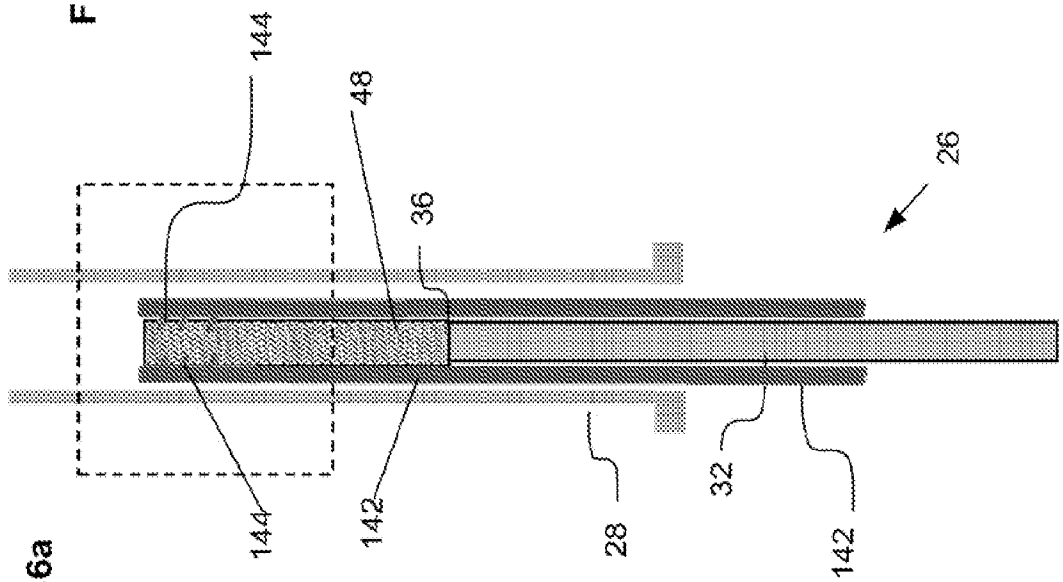
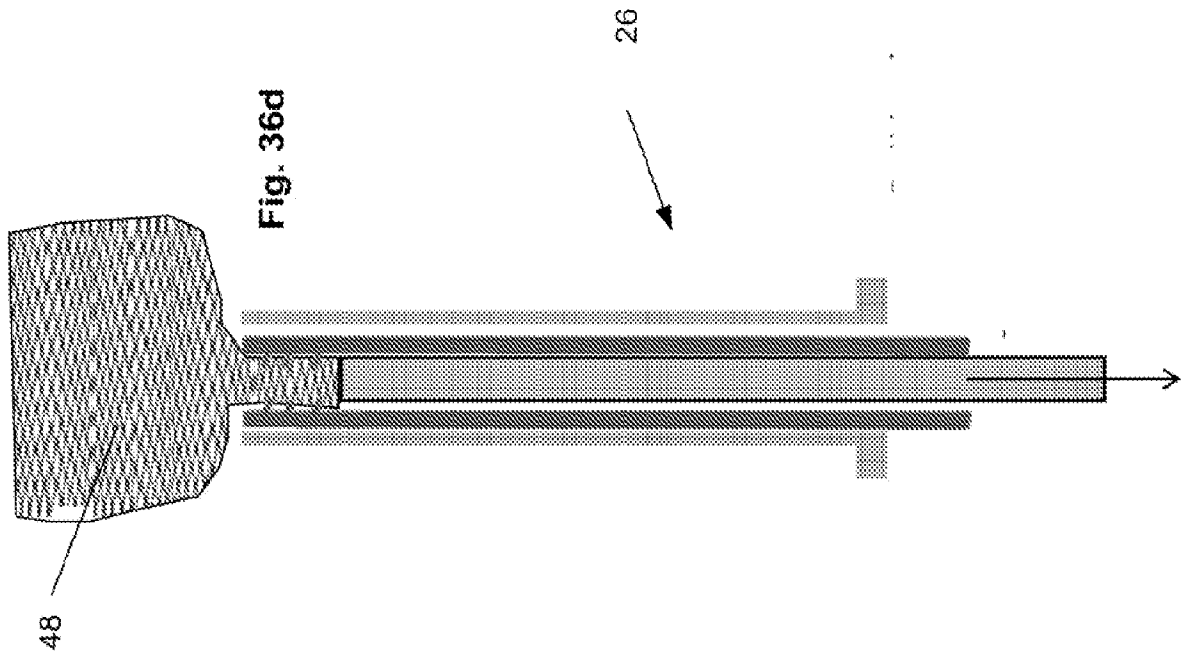
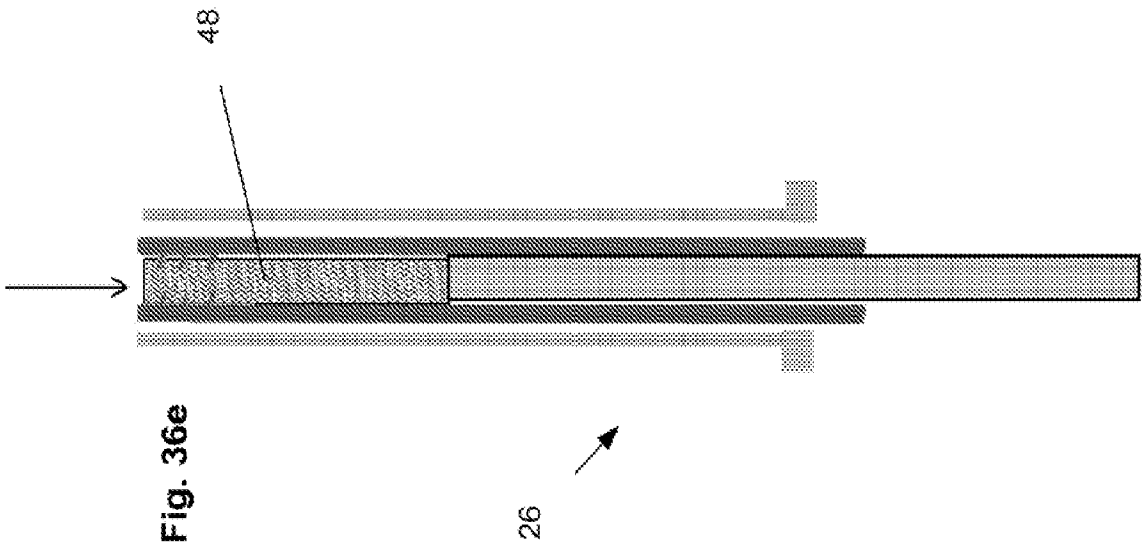
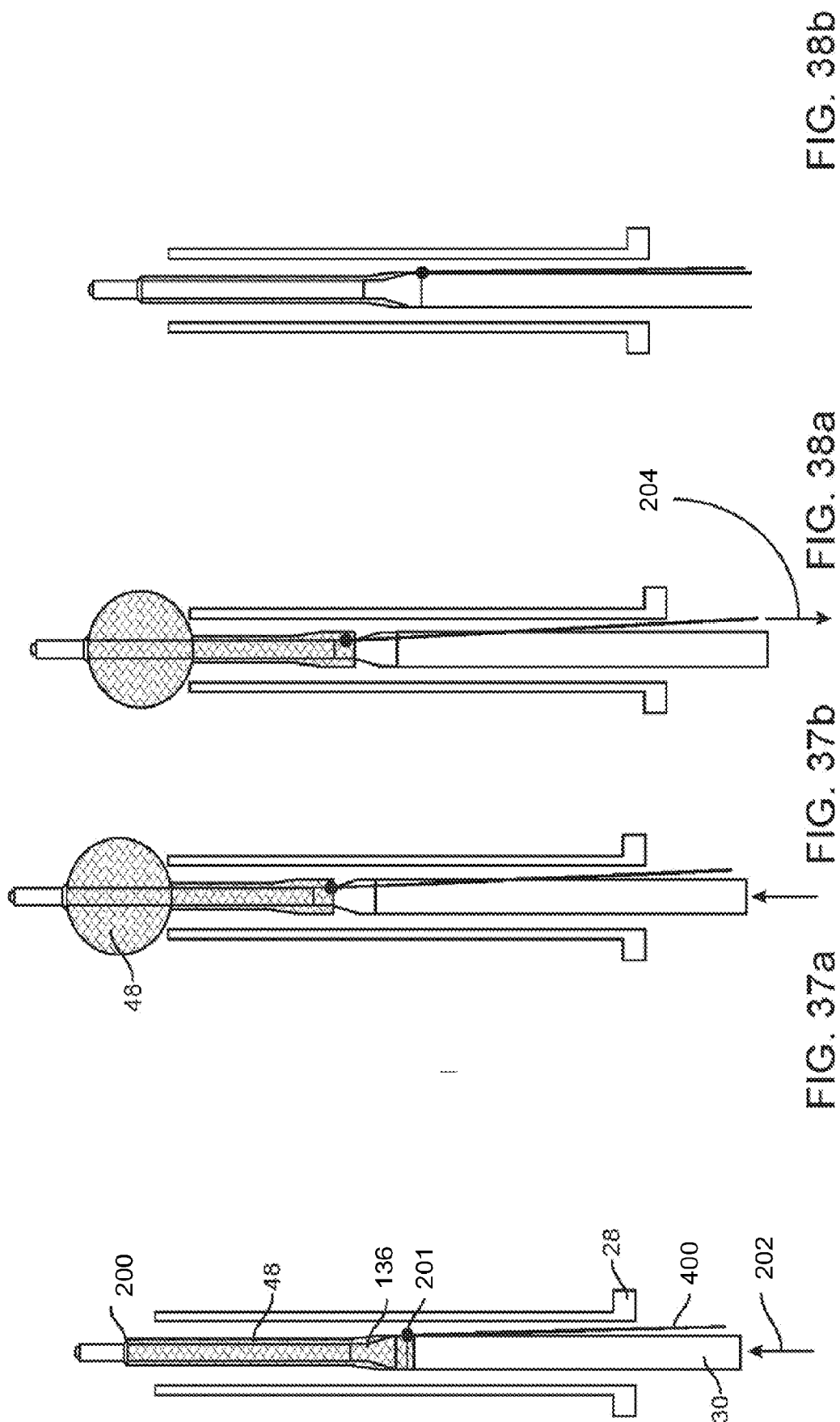


Fig. 36a





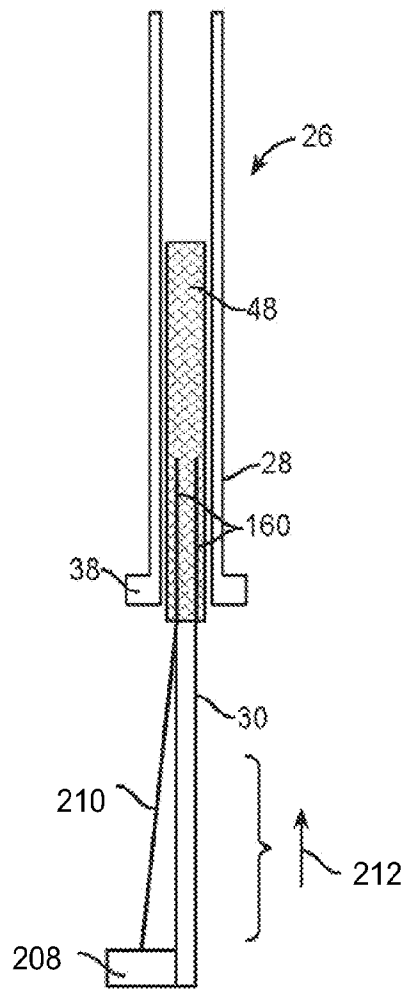


FIG. 39a

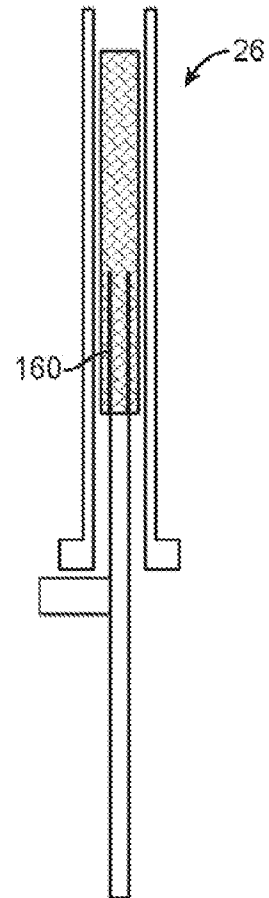


FIG. 39b

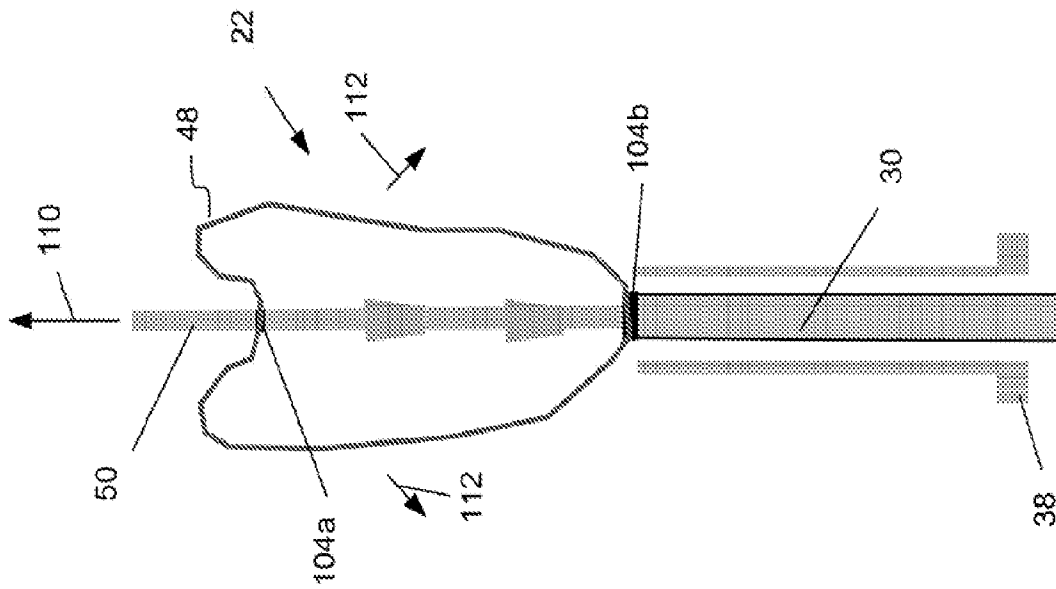


Fig. 44c

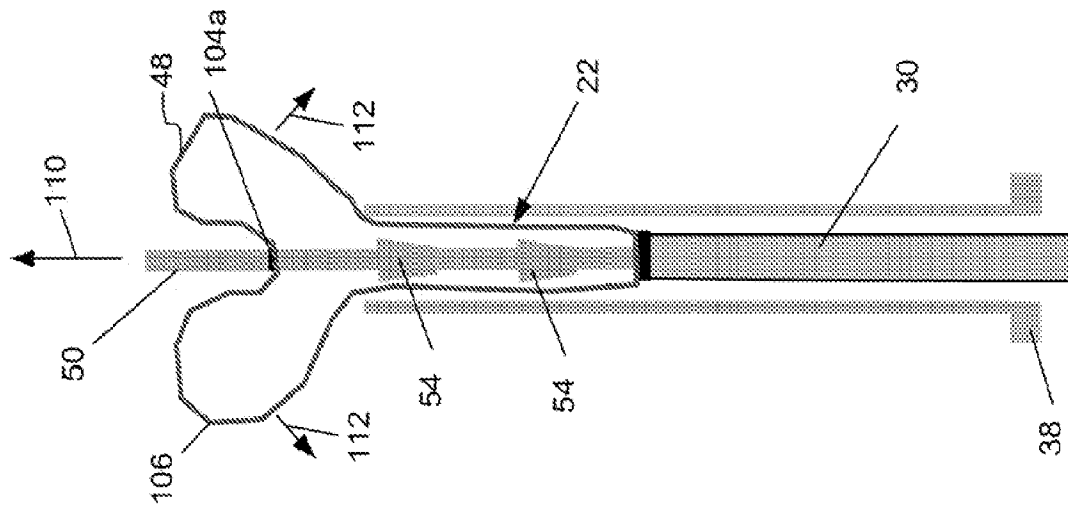


Fig. 44b

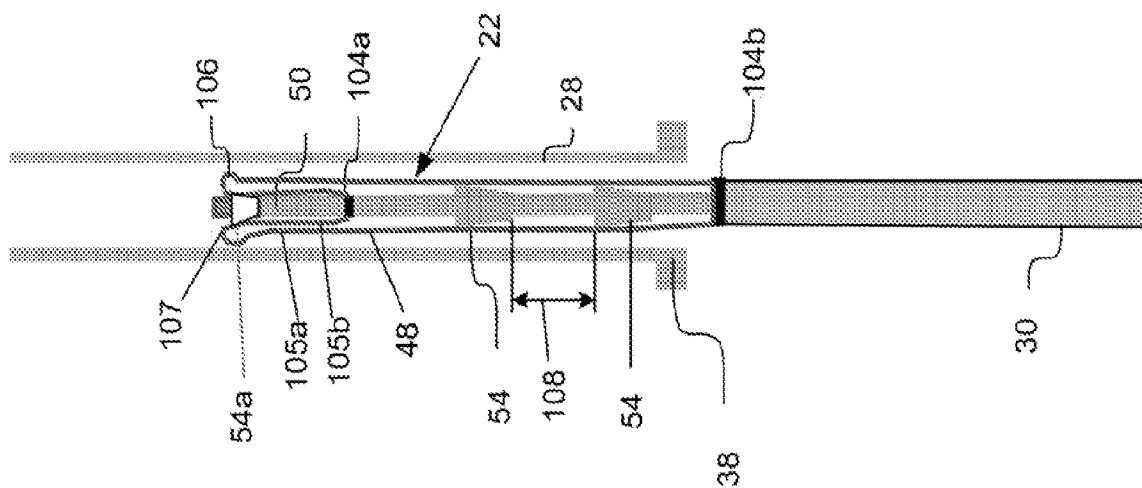


Fig. 44a

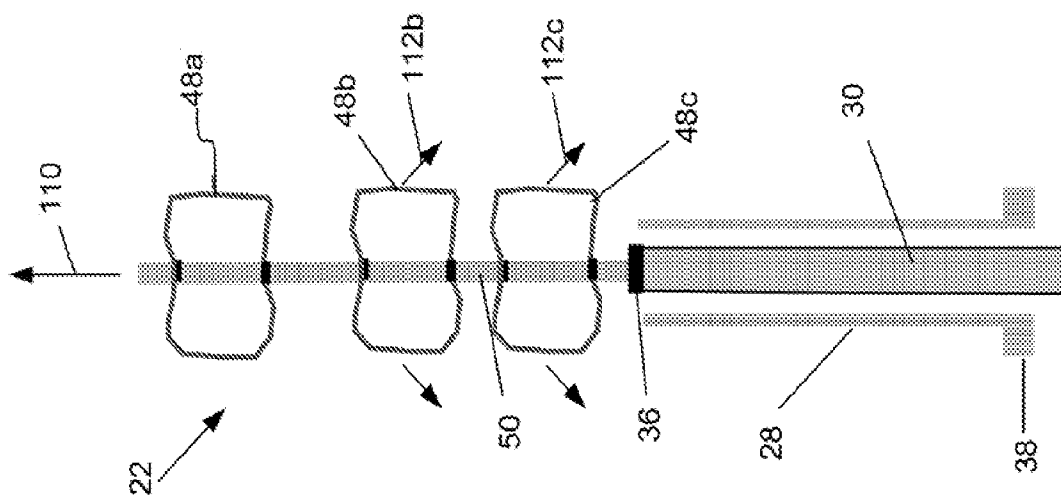


Fig. 45c

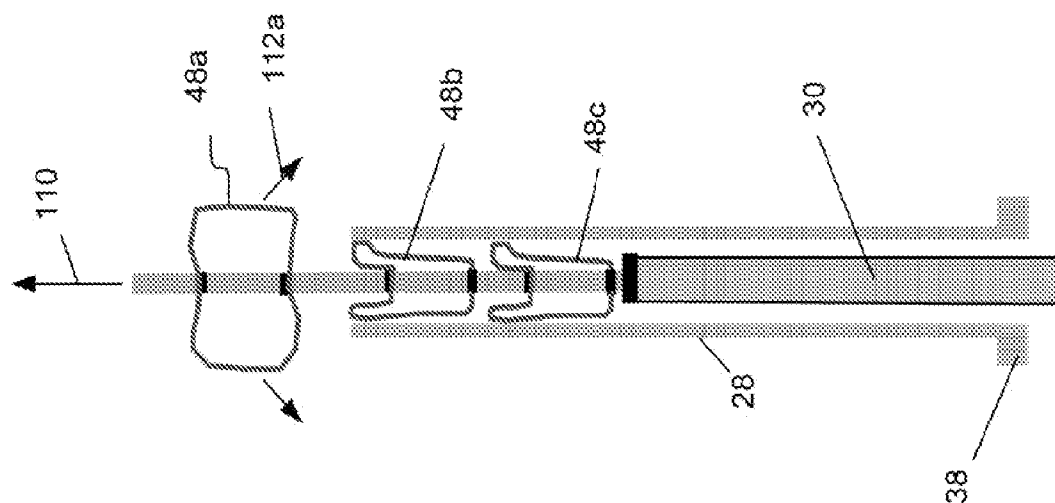


Fig. 45b

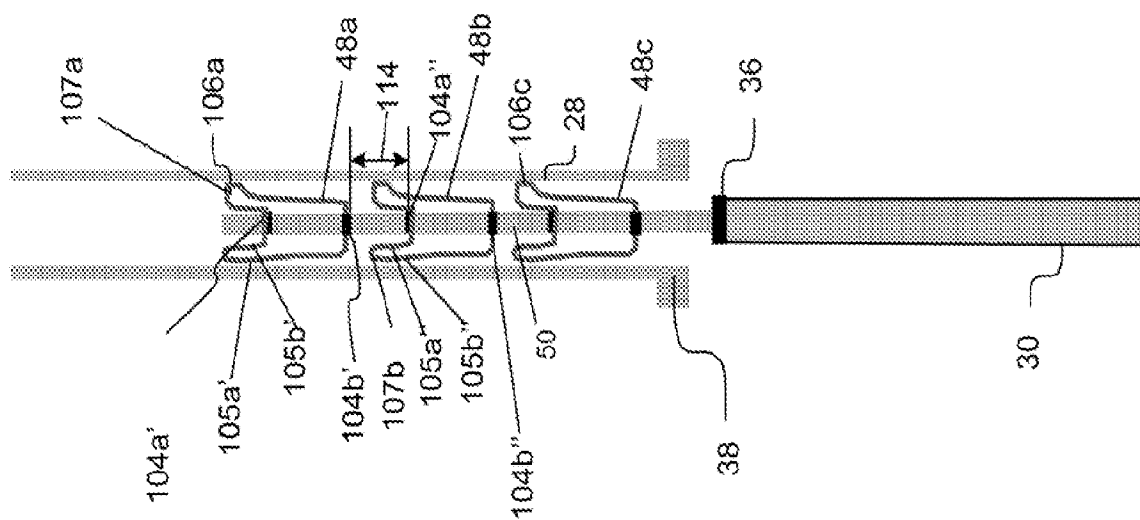
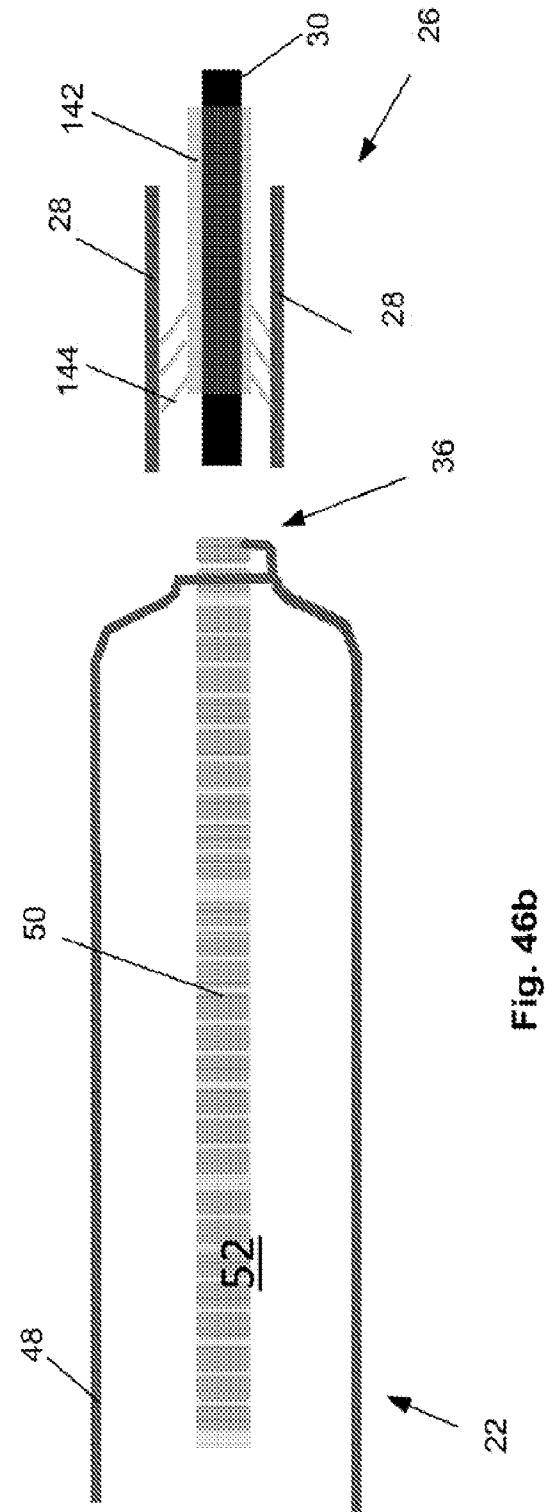
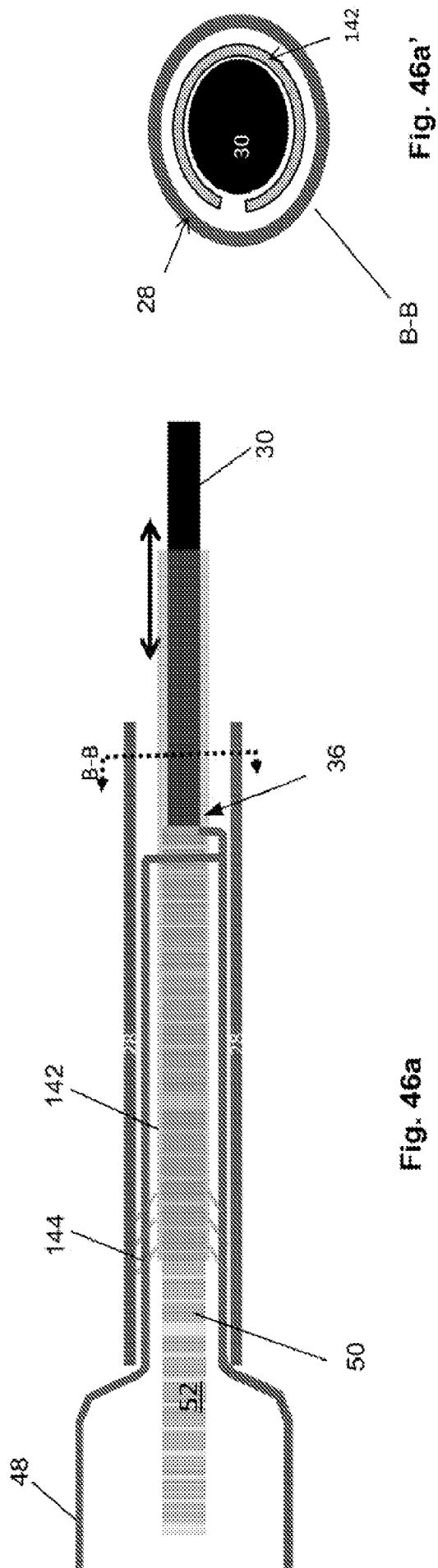


Fig. 45a



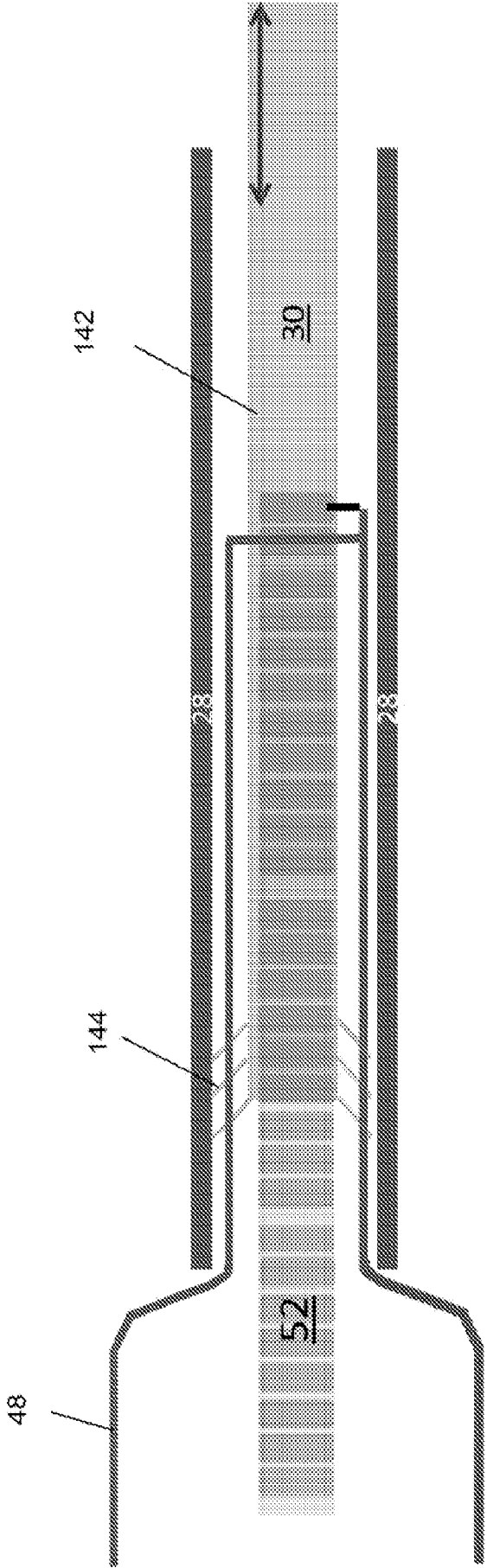


Fig. 47a

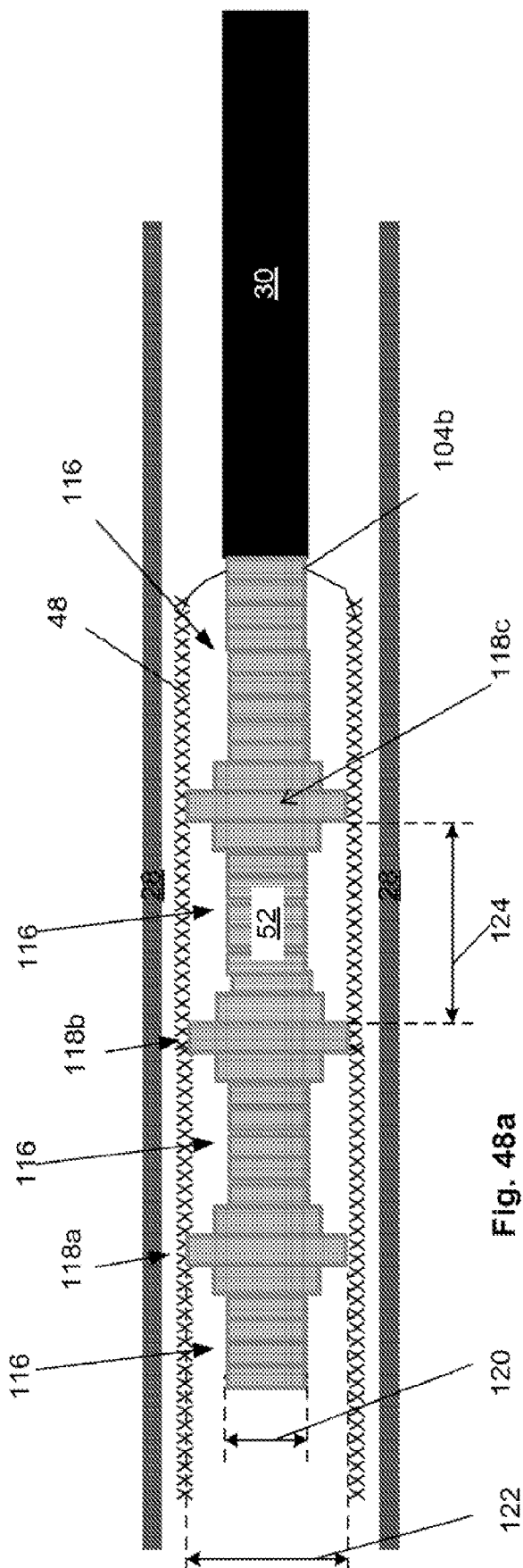


Fig. 48a

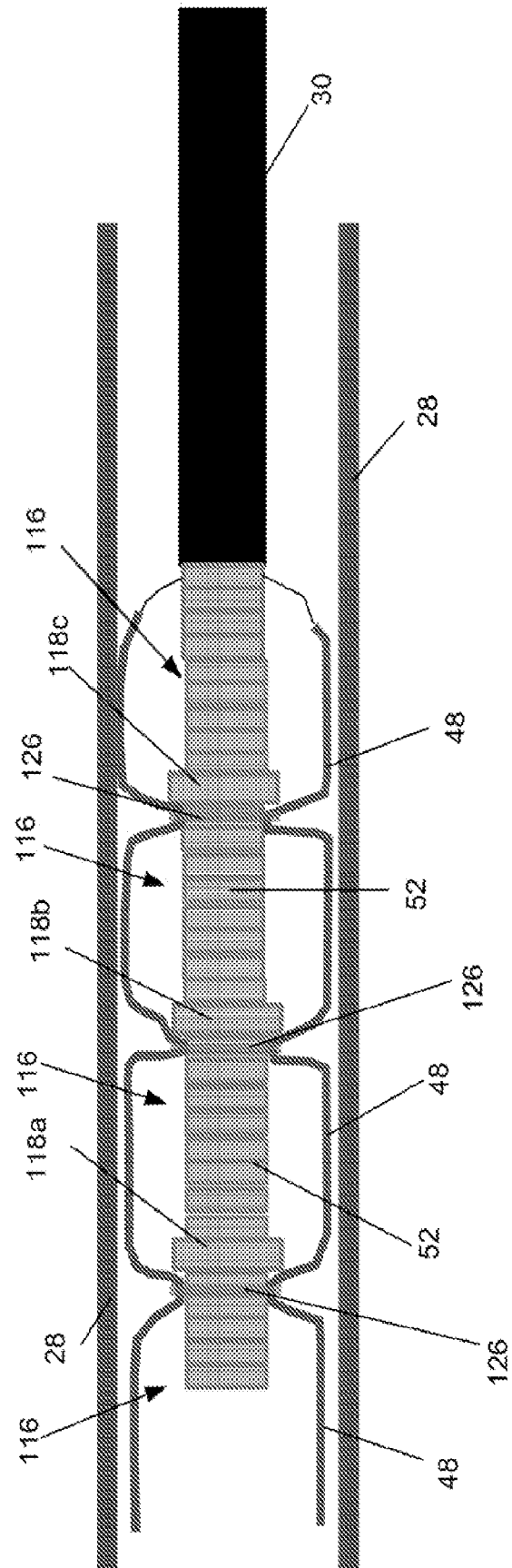


Fig. 48b

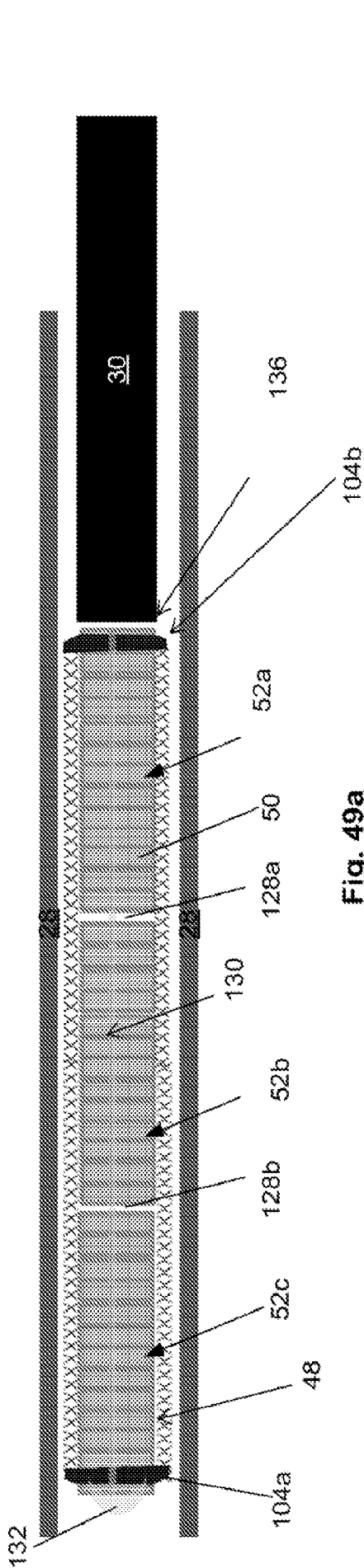


Fig. 49a

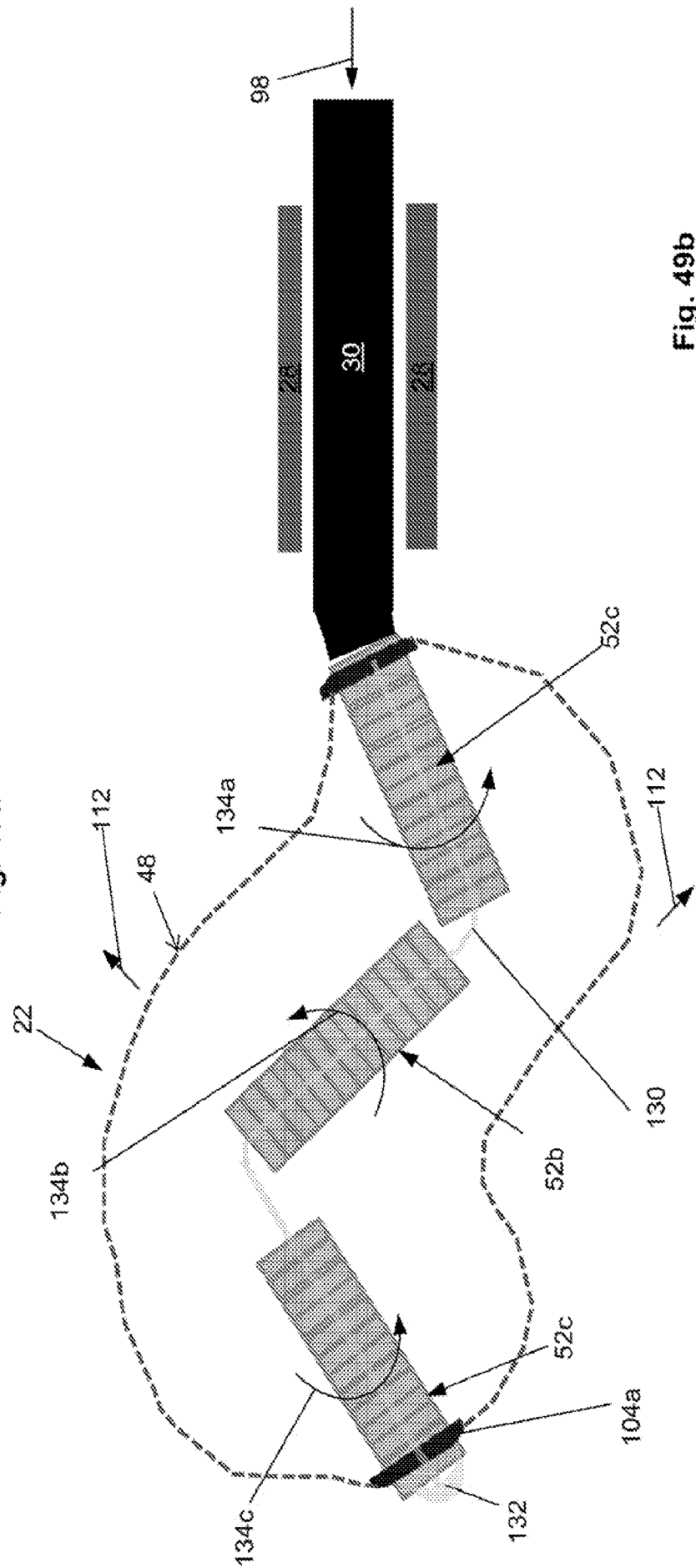


Fig. 49b

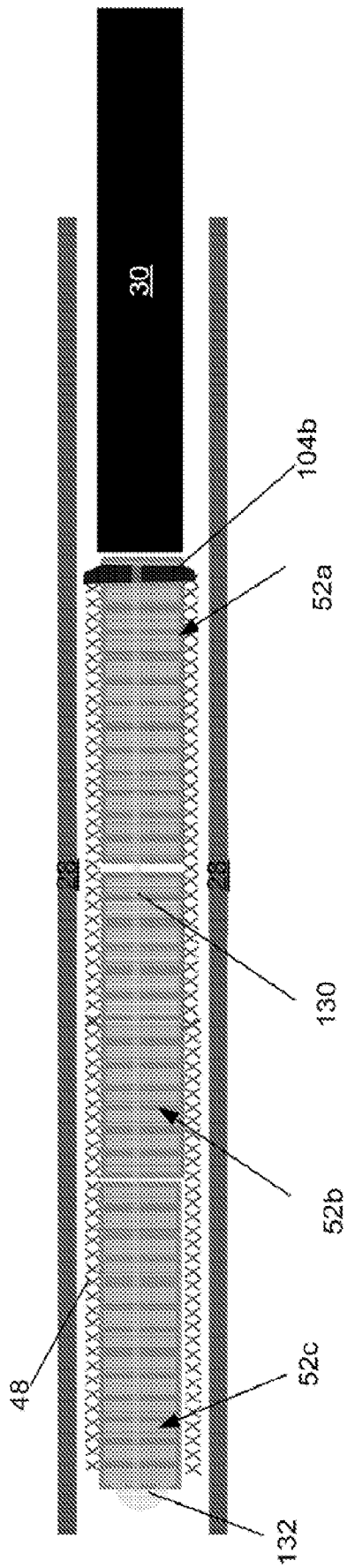


Fig. 50a

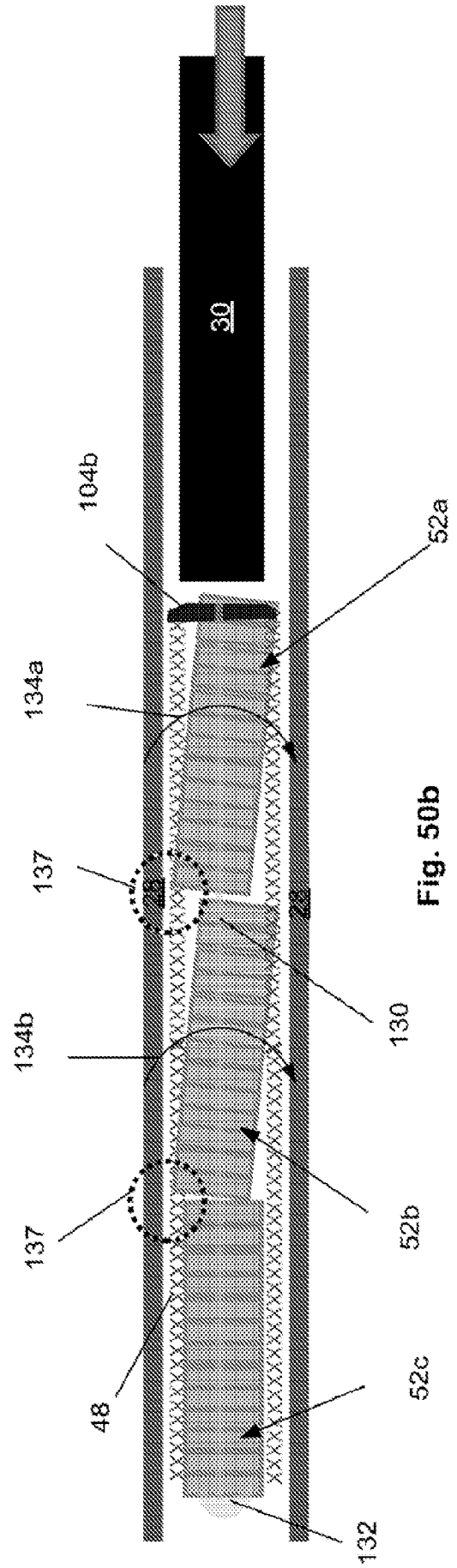


Fig. 50b

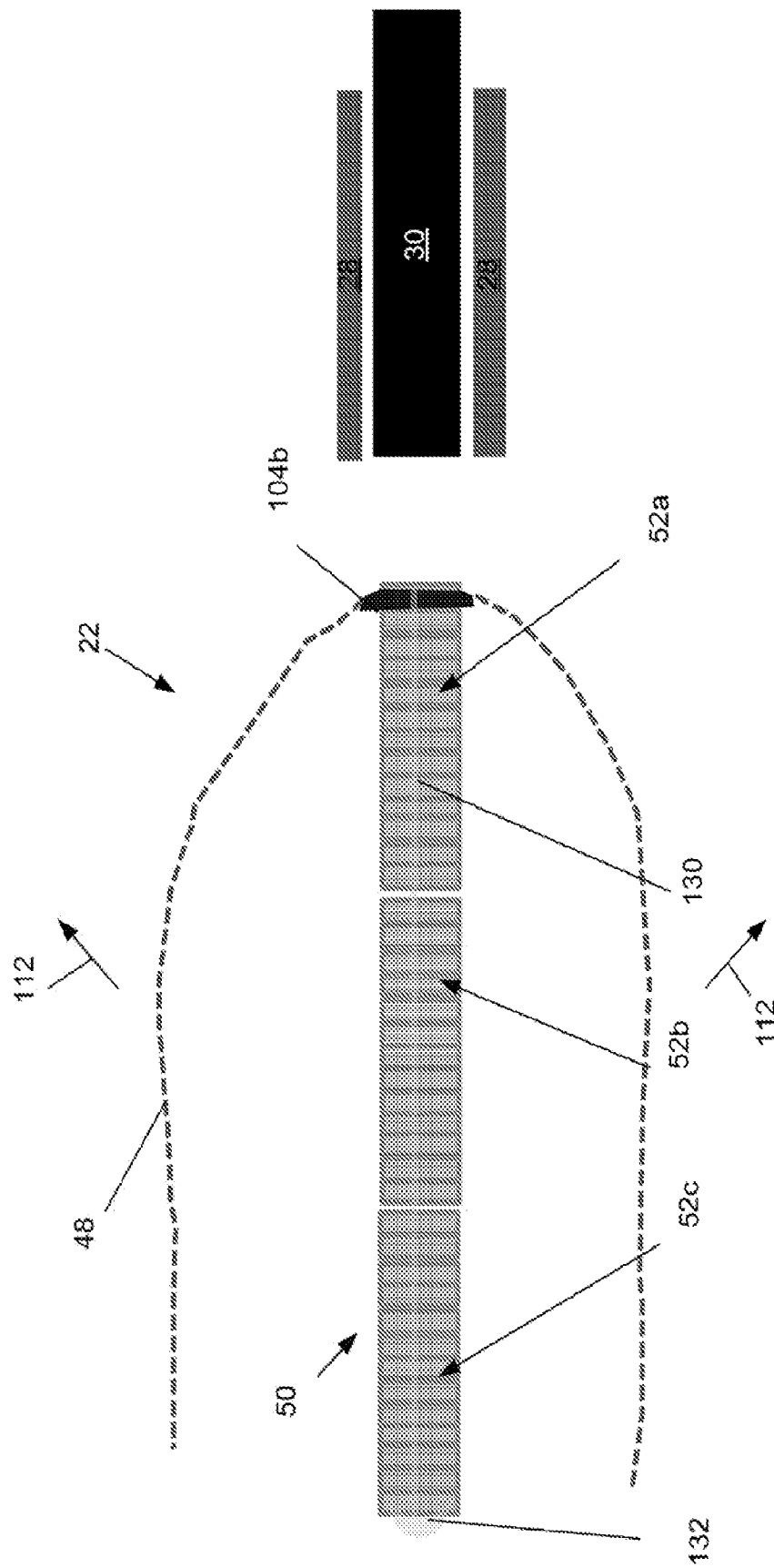


Fig. 50c

