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(54) Title: MECHANISM FOR THE DEPLOYMENT OF ENDOVASCULAR IMPLANTS

(57) **Abstract:** A mechanism for the deployment of a filamentous endovascular device includes an elongate, flexible, hollow deployment tube having an open proximal end, and a coupling element attached to the proximal end of the endovascular device. The deployment tube includes a distal section terminating in an open distal end, with a lumen defined between the proximal and distal ends. A retention sleeve is fixed around the distal section and includes a distal extension extending a short distance past the distal end of the deployment tube. The endovascular device is attached to the distal end of the deployment tube during the manufacturing process by fixing the retention sleeve around the coupling element, so that the coupling element is releasably held within the distal extension of the deployment tube. In use, the deployment tube, with the implant attached to its distal end, is passed through a microcatheter to a target vascular site until the endovascular device is deployed within the site. To detach the endovascular device from the deployment tube, a biocompatible liquid is injected through the lumen of the deployment tube so as to apply pressure to the upstream side of the coupling element, which is thus pushed out of the retention sleeve by the fluid pressure, thereby detaching the endovascular device from the deployment tube. The coupling element may be a solid "plug" of polymeric material or metal, or it may be formed of a hydrophilic polymer that softens and becomes somewhat lubricious when contacted by the injected liquid. With the latter type of material, the hydration of the hydrophilic material results in physical changes that reduce the adhesion between the coupling element and the sleeve. Alternatively, the coupling element can be made principally of a non-hydrophilic material, with a hydrophilic coating.



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1 MECHANISM FOR THE DEPLOYMENT
2 OF ENDOVASCULAR IMPLANTS

3
4 CROSS-REFERENCE TO RELATED APPLICATIONS

5 Not Applicable

6
7 FEDERALLY-SPONSORED RESEARCH OR DEVELOPMENT

8 Not Applicable

9
10 BACKGROUND OF THE INVENTION

11 This invention relates to the field of methods and devices for the
12 embolization of vascular aneurysms and similar vascular
13 abnormalities. More specifically, the present invention relates to a
14 mechanism for deploying an endovascular implant, such as a
15 microcoil, into a targeted vascular site, and releasing or detaching the
16 implant in the site.

17 The embolization of blood vessels is desired in a number of
18 clinical situations. For example, vascular embolization has been used
19 to control vascular bleeding, to occlude the blood supply to tumors,
20 and to occlude vascular aneurysms, particularly intracranial
21 aneurysms. In recent years, vascular embolization for the treatment of
22 aneurysms has received much attention. Several different treatment
23 modalities have been employed in the prior art. U.S. Patent No.
24 4,819,637 - Dormandy, Jr. et al., for example, describes a vascular
25 embolization system that employs a detachable balloon delivered to
26 the aneurysm site by an intravascular catheter. The balloon is carried
27 into the aneurysm at the tip of the catheter, and it is inflated inside the
28 aneurysm with a solidifying fluid (typically a polymerizable resin or
29 gel) to occlude the aneurysm. The balloon is then detached from the
30 catheter by gentle traction on the catheter. While the balloon-type

1 embolization device can provide an effective occlusion of many types
2 of aneurysms, it is difficult to retrieve or move after the solidifying
3 fluid sets, and it is difficult to visualize unless it is filled with a contrast
4 material. Furthermore, there are risks of balloon rupture during
5 inflation and of premature detachment of the balloon from the
6 catheter.

7 Another approach is the direct injection of a liquid polymer
8 embolic agent into the vascular site to be occluded. One type of liquid
9 polymer used in the direct injection technique is a rapidly
10 polymerizing liquid, such as a cyanoacrylate resin, particularly
11 isobutyl cyanoacrylate, that is delivered to the target site as a liquid,
12 and then is polymerized *in situ*. Alternatively, a liquid polymer that is
13 precipitated at the target site from a carrier solution has been used. An
14 example of this type of embolic agent is a cellulose acetate polymer
15 mixed with bismuth trioxide and dissolved in dimethyl sulfoxide
16 (DMSO). Another type is ethylene vinyl alcohol dissolved in DMSO.
17 On contact with blood, the DMSO diffuses out, and the polymer
18 precipitates out and rapidly hardens into an embolic mass that
19 conforms to the shape of the aneurysm. Other examples of materials
20 used in this "direct injection" method are disclosed in the following
21 U.S. Patents: 4,551,132 - Pásztor et al.; 4,795,741 - Leshchiner et al.;
22 5,525,334 - Ito et al.; and 5,580,568 - Greff et al.

23 The direct injection of liquid polymer embolic agents has proven
24 difficult in practice. For example, migration of the polymeric material
25 from the aneurysm and into the adjacent blood vessel has presented a
26 problem. In addition, visualization of the embolization material
27 requires that a contrasting agent be mixed with it, and selecting
28 embolization materials and contrasting agents that are mutually

1 compatible may result in performance compromises that are less than
2 optimal. Furthermore, precise control of the deployment of the
3 polymeric embolization material is difficult, leading to the risk of
4 improper placement and/or premature solidification of the material.
5 Moreover, once the embolization material is deployed and solidified, it
6 is difficult to move or retrieve.

7 Another approach that has shown promise is the use of
8 thrombogenic filaments, or filamentous embolic implants. One type of
9 filamentous implant is the so-called "microcoil". Microcoils may be
10 made of a biocompatible metal alloy (typically platinum and tungsten)
11 or a suitable polymer. If made of metal, the coil may be provided with
12 Dacron fibers to increase thrombogenicity. The coil is deployed
13 through a microcatheter to the vascular site. Examples of microcoils
14 are disclosed in the following U.S. patents: 4,994,069 - Ritchart et al.;
15 5,133,731 - Butler et al.; 5,226,911 - Chee et al.; 5,312,415 - Palermo;
16 5,382,259 - Phelps et al.; 5,382,260 - Dormandy, Jr. et al.; 5,476,472 -
17 Dormandy, Jr. et al.; 5,578,074 - Mirigian; 5,582,619 - Ken; 5,624,461
18 - Mariant; 5,645,558 - Horton; 5,658,308 - Snyder; and 5,718,711 -
19 Berenstein et al.

20 The microcoil approach has met with some success in treating
21 small aneurysms with narrow necks, but the coil must be tightly
22 packed into the aneurysm to avoid shifting that can lead to
23 recanalization. Microcoils have been less successful in the treatment of
24 larger aneurysms, especially those with relatively wide necks. A
25 disadvantage of microcoils is that they are not easily retrievable; if a
26 coil migrates out of the aneurysm, a second procedure to retrieve it and
27 move it back into place is necessary. Furthermore, complete packing
28 of an aneurysm using microcoils can be difficult to achieve in practice.

1 A specific type of microcoil that has achieved a measure of
2 success is the Guglielmi Detachable Coil ("GDC"). The GDC
3 employs a platinum wire coil fixed to a stainless steel guidewire by a
4 welded connection. After the coil is placed inside an aneurysm, an
5 electrical current is applied to the guidewire, which oxidizes the weld
6 connection, thereby detaching the coil from the guidewire. The
7 application of the current also creates a positive electrical charge on the
8 coil, which attracts negatively-charged blood cells, platelets, and
9 fibrinogen, thereby increasing the thrombogenicity of the coil. Several
10 coils of different diameters and lengths can be packed into an
11 aneurysm until the aneurysm is completely filled. The coils thus create
12 and hold a thrombus within the aneurysm, inhibiting its displacement
13 and its fragmentation.

14 The advantages of the GDC procedure are the ability to
15 withdraw and relocate the coil if it migrates from its desired location,
16 and the enhanced ability to promote the formation of a stable
17 thrombus within the aneurysm. Nevertheless, as in conventional
18 microcoil techniques, the successful use of the GDC procedure has
19 been substantially limited to small aneurysms with narrow necks.

20 A more recently developed type of filamentous embolic implant
21 is disclosed in U.S. Patent No. 6,015,424 - Rosenbluth et al., assigned
22 to the assignee of the present invention. This type of filamentous
23 embolic implant is controllably transformable from a soft, compliant
24 state to a rigid or semi-rigid state. Specifically, the transformable
25 filamentous implant may include a polymer that is transformable by
26 contact with vascular blood or with injected saline solution, or it may
27 include a metal that is transformable by electrolytic corrosion. One
28 end of the implant is releasably attached to the distal end of an

1 elongate, hollow deployment wire that is insertable through a
2 microcatheter to the target vascular site. The implant and the
3 deployment wire are passed through the microcatheter until the distal
4 end of the deployment wire is located within or adjacent to the target
5 vascular site. At this point, the filamentous implant is detached from
6 the wire. In this device, the distal end of the deployment wire
7 terminates in a cup-like holder that frictionally engages the proximal
8 end of the filamentous implant. To detach the filamentous implant, a
9 fluid (e.g., saline solution) is flowed through the deployment wire and
10 enters the cup-like holder through an opening, thereby pushing the
11 filamentous implant out of the holder by fluid pressure.

12 While filamentous embolic implants have shown great promise,
13 improvement has been sought in the mechanisms for deploying these
14 devices. In particular, improvements have been sought in the
15 coupling mechanisms by which the embolic implant is detachably
16 attached to a deployment instrument for installation in a target
17 vascular site. Examples of recent developments in this area are
18 described in the following patent publications: U.S. 5,814,062 -
19 Sepetka et al.; U.S. 5,891,130 - Palermo et al.; U.S. 6,063,100 - Diaz et
20 al.; U.S. 6,068,644 - Lulu et al.; and EP 0 941 703 A1 - Cordis
21 Corporation.

22 There is still a need for further improvements in field of coupling
23 mechanisms for detachably attaching an embolic implant to a
24 deployment instrument. Specifically, there is still a need for a
25 coupling mechanism that provides for a secure attachment of the
26 embolic implant to a deployment instrument during the deployment
27 process, while also allowing for the easy and reliable detachment of the
28 embolic implant once it is properly situated with respect to the target

1 site. It would also be advantageous for such a mechanism to allow
2 improved control of the implant during deployment, and specifically to
3 allow the implant to be easily repositioned before detachment.
4 Furthermore, the coupling mechanism should be adaptable for use
5 with a wide variety of endovascular implants, and it should not add
6 appreciably to their costs.

7

8

SUMMARY OF THE INVENTION

9 Broadly, the present invention is a mechanism for the
10 deployment of a filamentous endovascular device, such as an embolic
11 implant, comprising an elongate, flexible, hollow deployment tube
12 having an open proximal end, and a coupling element attached to the
13 proximal end of the endovascular device. The deployment tube
14 includes a distal section terminating in an open distal end, with a
15 lumen defined between the proximal and distal ends. A retention
16 sleeve is fixed around the distal section and includes a distal extension
17 extending a short distance past the distal end of the deployment tube.
18 The endovascular device is attached to the distal end of the
19 deployment tube during the manufacturing process by fixing the
20 retention sleeve around the coupling element, so that the coupling
21 element is releasably held within the distal extension proximate the
22 distal end of the deployment tube. In use, the deployment tube, with
23 the implant attached to its distal end, is passed intravascularly through
24 a microcatheter to a target vascular site until the endovascular device is
25 fully deployed within the site. To detach the endovascular device from
26 the deployment tube, a biocompatible liquid (such as saline solution) is
27 injected through the lumen of the deployment tube so as to apply
28 pressure to the upstream (interior) side of the coupling element. The

1 coupling element is thus pushed out of the retention sleeve by the fluid
2 pressure of the liquid, thereby detaching the endovascular device from
3 the deployment tube.

4 The coupling element may be a solid "plug" of polymeric
5 material or metal, or it may be formed of a hydrophilic polymer that
6 softens and becomes somewhat lubricious when contacted by the
7 injected liquid. With the latter type of material, the hydration of the
8 hydrophilic material results in physical changes that reduce the
9 adhesion between the coupling element and the sleeve, thereby
10 facilitating the removal of the coupling element from the sleeve upon
11 the application of liquid pressure. Alternatively, the coupling element
12 can be made principally of a non-hydrophilic material (polymer or
13 metal), coated with a hydrophilic coating.

14 In a specific preferred embodiment, the retention sleeve is made
15 of polyethylene terephthalate (PET), and the coupling element is made
16 of a hydrogel, such as a polyacrylamide/acrylic acid mixture. In
17 another preferred embodiment, both the retention sleeve and the
18 coupling element are made of a polyolefin. In still another preferred
19 embodiment, the retention sleeve is formed of a fluoropolymer, and
20 the coupling element is formed of a metal. Hydrophilic coatings, such
21 as those disclosed in U.S. Patents Nos. 5,001,009 and 5,331,027, may
22 be applied to any of the non-hydrophilic coupling elements.

23 In an alternative embodiment, the retention sleeve is made of a
24 shape memory metal, such as the nickel-titanium alloy known as
25 nitinol. In this alternative embodiment, the coupling element would
26 be made of one of the hydrophilic materials mentioned above, or it
27 may be made of a non-hydrophilic material with a hydrophilic coating.

28 The deployment tube, in the preferred embodiment, comprises a

1 main section having an open proximal end, a distal section terminating
2 in an open distal end, and a transition section connected between the
3 main and distal sections. A continuous fluid passage lumen is defined
4 between the proximal and distal ends. The distal section is shorter and
5 more flexible than the transition section, and the transition section is
6 shorter and more flexible than the main section. This varying
7 flexibility is achieved by making the main section as a continuous
8 length of flexible, hollow tube, the transition section as a length of
9 hollow, flexible laser-cut ribbon coil, and the distal section as a length
10 of flexible, hollow, helical coil. The sections may be joined together by
11 any suitable means, such as soldering.

12 Advantageously, an axial air purge passage may be provided
13 through the coupling element. The purge passage is dimensioned to
14 allow the passage of saline solution through it, but not a relatively high
15 viscosity contrast agent. Before the deployment tube and the attached
16 implant are introduced intravascularly to the target site, a saline
17 solution is injected under low pressure through the lumen of the
18 deployment tube to displace air from the lumen out through the purge
19 passage. After the implant is located within the target site, a high
20 viscosity contrast agent is injected into the deployment tube lumen to
21 purge the remaining saline solution through the purge passage, but,
22 because the contrast agent cannot pass through the purge passage, it
23 builds up pressure on the proximal surface of the coupling element
24 until the pressure is sufficient to push the coupling element out of the
25 retention sleeve.

26 Any of the embodiments may employ an anti-airflow
27 mechanism for preventing the inadvertent introduction of air into the
28 vasculature during deployment of the implant. One such mechanism

1 comprises an airtight, compliant membrane sealingly disposed over the
2 distal end of the deployment tube. The membrane is expanded or
3 distended distally in response to the injection of the liquid, thereby
4 forcing the implant out of the retention sleeve.

5 Another such anti-airflow mechanism comprises an internal
6 stylet disposed axially through the deployment tube. The stylet has a
7 distal outlet opening adjacent the distal end of the deployment tube,
8 and a proximal inlet opening in a fitting attached to the proximal end
9 of the deployment tube. The fitting includes a gas/air venting port in
10 fluid communication with the proximal end of the deployment tube.
11 The gas venting port, in turn, includes a stop-cock valve. In use, the
12 liquid is injected through the stylet with the stop-cock valve open. The
13 injected liquid flows out of the stylet outlet opening and into the
14 deployment tube, hydraulically pushing any entrapped air out of the
15 venting port. When liquid begins flowing out of the venting port,
16 indicating that any entrapped air has been fully purged from the
17 deployment tube, the stop-cock is closed, allowing the continued flow
18 of the liquid to push the implant out of the retention sleeve, as
19 described above.

20 As will be appreciated more fully from the detailed description
21 below, the present invention provides a secure attachment of the
22 embolic implant to a deployment instrument during the deployment
23 process, while also allowing for the easy and reliable detachment of the
24 embolic implant once it is properly situated with respect to the target
25 site. The present invention also provides improved control of the
26 implant during deployment, and specifically it allows the implant to be
27 easily repositioned before detachment. Furthermore, the present
28 invention is readily adaptable for use with a wide variety of

1 endovascular implants, without adding appreciably to their costs.

2

3 BRIEF DESCRIPTION OF THE DRAWINGS

4 Figure 1 is an elevational view of an endovascular device
5 deployment mechanism in accordance with a preferred embodiment of
6 the present invention, showing the mechanism with an endovascular
7 implant device attached to it;

8 Figure 2 is a longitudinal cross-sectional view of the deployment
9 mechanism and the endovascular implant of Figure 1, taken along line
10 2 - 2 of Figure 1;

11 Figure 3 is a cross-sectional view, similar to that of Figure 2,
12 showing the first step in separating the implant from the deployment
13 tube of the deployment mechanism;

14 Figure 4 is a cross-sectional view, similar to that of Figure 3,
15 showing the deployment mechanism and the implant after the act of
16 separation;

17 Figure 5 is a cross-sectional view of the endovascular implant
18 deployment mechanism incorporating a first type of anti-airflow
19 mechanism;

20 Figure 6 is a cross sectional view of the deployment mechanism
21 of Figure 5, showing the mechanism with an endovascular implant
22 device attached to it;

23 Figure 7 is a cross-sectional view, similar to that of Figure 6,
24 showing the implant in the process of deployment;

25 Figure 8 is a cross-sectional view, similar to that of Figure 7,
26 showing deployment device after the implant has been deployed;

27 Figure 9 is an elevational view of the endovascular implant
28 deployment device incorporating a second type of anti-airflow

1 mechanism, showing the device with an implant attached to it;

2 Figure 10 is a cross-sectional view of the distal portion of the
3 deployment device of Figure 9 and the proximal portion of the
4 implant, taken along line 10 - 10 of Figure 9;

5 Figure 11 is a cross-sectional view of the deployment device and
6 the attached implant;

7 Figure 12 is a cross-sectional view, similar to that of Figure 11,
8 showing the implant in the process of deployment;

9 Figure 13 is an elevational view of an endovascular implant
10 deployment device in accordance with a modified form of the preferred
11 embodiment of the invention, showing the device with an implant
12 attached to it;

13 Figure 14 is a cross-sectional view taken along line 14 - 14 of
14 Figure 13;

15 Figures 15-17 are cross-sectional views, similar to that of Figure
16 14, showing the process of deploying the implant;

17 Figure 18 is a cross-sectional view of the endovascular implant
18 deployment device incorporating a modified form of the first type of
19 anti-airflow mechanism, showing the device with an implant attached
20 to it; and

21 Figure 19 is a cross-sectional view, similar to that of Figure 18,
22 showing the implant in the process of deployment.

23

24 DETAILED DESCRIPTION OF THE INVENTION

25 Referring first to Figure 1, a deployment mechanism for an
26 endovascular device, in accordance with the present invention,
27 comprises an elongate, flexible, hollow deployment tube 10 having an
28 open proximal end 11 (see Figure 11) and a distal section terminating

1 in an open distal end 13, with a continuous fluid passage lumen 15
2 defined between the proximal and distal ends. A retention sleeve 12 is
3 fixed around the distal section of the deployment tube 10, and it
4 includes a distal extension 17 extending a short distance past the distal
5 end 13 of the deployment tube. The deployment mechanism further
6 comprises a coupling element 14 fixed to the proximal end of a
7 filamentous endovascular device 16 (only the proximal portion of
8 which is shown), which may, for example, be an embolic implant.

9 The deployment tube 10 is made of stainless steel, and it is
10 preferably formed in three sections, each of which is dimensioned to
11 pass through a typical microcatheter. A proximal or main section 10a
12 is the longest section, about 1.3 to 1.5 meters in length. The main
13 section 10a is formed as a continuous length of flexible, hollow tubing
14 having a solid wall of uniform inside and outside diameters. In a
15 specific preferred embodiment, the inside diameter is about 0.179 mm,
16 and the outside diameter is about 0.333 mm. An intermediate or
17 transition section 10b is soldered to the distal end of the main section
18 10a, and is formed as a length of hollow, flexible laser-cut ribbon coil.
19 In a specific preferred embodiment, the transition section 10b has a
20 length of about 300 mm, an inside diameter of about 0.179 mm, and
21 an outside diameter of about 0.279 mm. A distal section 10c is
22 soldered to the distal end of the transition section 10b, and is formed as
23 a length of flexible, hollow helical coil. In a specific preferred
24 embodiment, the distal section 10c has a length of about 30 mm, an
25 inside diameter of about 0.179 mm, and an outside diameter of about
26 0.253 mm. A radiopaque marker (not shown) may optionally be
27 placed about 30 mm proximal from the distal end of the distal section
28 10c. It will be appreciated that the transition section 10b will be more

1 flexible than the main section 10a, and that the distal section 10c will
2 be more flexible than the transition section 10b.

3 The coupling element 14 is fastened to the proximal end of the
4 endovascular device 16. The endovascular device 16 is advantageously
5 of the type disclosed and claimed in co-pending application Serial No.
6 09/410,970, assigned to the assignee of the present invention, although
7 the invention can readily be adapted to other types of endovascular
8 devices. Specifically, the endovascular device 16 is an embolization
9 device that comprises a plurality of biocompatible, highly-expandible,
10 hydrophilic embolizing elements 20 (only one of which is shown in the
11 drawings), disposed at spaced intervals along a filamentous carrier 22
12 in the form of a suitable length of a very thin, highly flexible filament
13 of nickel/titanium alloy. The embolizing elements 20 are separated
14 from each other on the carrier by radiopaque spacers in the form of
15 highly flexible microcoils 24 (only one of which is shown in the
16 drawings) made of platinum or platinum/tungsten alloy, as in the
17 thrombogenic microcoils of the prior art, as described above. In a
18 preferred embodiment, the embolizing elements 20 are made of a
19 hydrophilic, macroporous, polymeric, hydrogel foam material, in
20 particular a water-swellaable foam matrix formed as a macroporous
21 solid comprising a foam stabilizing agent and a polymer or copolymer
22 of a free radical polymerizable hydrophilic olefin monomer cross-
23 linked with up to about 10% by weight of a multiolefin-functional
24 cross-linking agent. Such a material is described in U.S. Patent No.
25 5,750,585 - Park et al., the disclosure of which is incorporated herein
26 by reference. The material may be modified, or provided with
27 additives, to make the implant visible by conventional imaging
28 techniques.

1 The endovascular device 16 is modified by extending the
2 filamentous carrier 22 proximally so that it provides an attachment site
3 for the coupling element 14 at the proximal end of the carrier 22. A
4 sealing retainer 26 terminates the proximal end of the carrier 22,
5 providing a sealing engagement against the distal end of the coupling
6 element 14.

7 The coupling element 14 is removably attached to the distal end
8 of the deployment tube by the retention sleeve 12, which is secured to
9 the deployment tube 10 by a suitable adhesive or by solder (preferably
10 gold-tin solder). The retention sleeve 12 advantageously covers the
11 transition section 10b and the distal section 10c of the deployment
12 tube, and its proximal end is attached to the distal end of the main
13 section 10a of the deployment tube 10. The retention sleeve 12 has a
14 distal portion that extends distally past the distal end of the
15 deployment tube 10 and surrounds and encloses the coupling element
16 14. The coupling element 14 has an outside diameter that is greater
17 than the normal or relaxed inside diameter of the retention sleeve 12,
18 so that the coupling element 14 is retained within the retention sleeve
19 12 by friction and/or the radially inwardly-directed polymeric forces
20 applied by the retention sleeve 12.

21 The coupling element 14 may be a solid "plug" of polymeric
22 material or metal, or it may be formed of a hydrophilic polymer that
23 softens and becomes somewhat lubricious when contacted by a
24 hydrating liquid, as discussed below. With the latter type of material,
25 the hydration of the hydrophilic material results in physical changes
26 that reduce the adhesion between the coupling element 14 and the
27 sleeve 12, thereby facilitating the removal of the coupling element 14
28 from the sleeve 12 upon the application of liquid pressure to the

1 upstream (proximal) side of the coupling element 14, as will be
2 described below. Alternatively, the coupling element 14 can be made
3 principally of a non-hydrophilic material (polymer or metal), and
4 coated with a hydrophilic coating.

5 In a first preferred embodiment, the retention sleeve 12 is made
6 of polyethylene terephthalate (PET) or polyimide, and the coupling
7 element 14 is made either of a metal (preferably platinum) or of a
8 hydrogel, such as a polyacrylamide/acrylic acid mixture. In another
9 preferred embodiment, both the retention sleeve 12 and the coupling
10 element 14 are made of a polyolefin. In still another preferred
11 embodiment, the retention sleeve 12 is formed of a fluoropolymer, and
12 the coupling element 14 is formed of a metal. Hydrophilic coatings,
13 such as those disclosed in U.S. Patents Nos. 5,001,009 and 5,331,027
14 (the disclosures of which are incorporated herein by reference), may be
15 applied to any of the non-hydrophilic coupling elements 14. In these
16 embodiments, the retention sleeve 12 may be formed as a “shrink
17 tube” that is fitted over the coupling element 14 and then shrunk in
18 place by the application of heat to secure the coupling element in
19 place. The heat shrinking process semi-crystallizes the polymeric
20 chains so that sleeve is somewhat stiffened and made resistant to radial
21 expansion (although still expansible axially). Alternatively, the
22 retention sleeve 12 may be made of an elastic polymer that is stretched
23 to receive the coupling element 14, and then retains the coupling
24 element 14 by the resulting elastomeric forces that are directed radially
25 inwardly.

26 In an alternative embodiment, the retention sleeve 12 is made of
27 a shape memory metal, such as the nickel-titanium alloy known as
28 nitinol. In this alternative embodiment, the coupling element 14

1 would be made of one of the hydrophilic materials mentioned above,
2 or it may be made of a non-hydrophilic material with a hydrophilic
3 coating. In this embodiment, the retention sleeve 12 is radially
4 stretched to receive the coupling element 14, and it retains the coupling
5 element 14 by the forces resulting from the tendency of the shape
6 memory metal to return to its original configuration.

7 Use of the deployment mechanism of the present invention is
8 illustrated in Figures 3 and 4. The endovascular device 16 and the
9 deployment tube 10 are passed intravascularly through the lumen of a
10 microcatheter (not shown) until the endovascular device 16 is situated
11 in a targeted vascular site, such as an aneurysm. A suitable hydrating
12 liquid 30, such as saline solution, is then injected into the interior of
13 the deployment tube, under pressure, as show in Figure 3. The
14 pressure of the liquid against the upstream side of the coupling element
15 pushes the coupling element 14 out of the retention sleeve 12 to
16 separate the endovascular device 16 from the deployment tube, as
17 shown in Figure 4. While the retention sleeve may deform in the axial
18 direction during the separation process, it does not substantially
19 expand in the radial direction. If the coupling element 14 is made of a
20 hydrophilic material, or if it has a hydrophilic coating, the physical
21 changes in the coupling element 14 due to the hydrophilic properties of
22 the coupling element 14 or its coating, as described above, will
23 facilitate the separation process. The deployment tube 10 and the
24 microcatheter are then withdrawn.

25 It will be appreciated that, until the liquid 30 is injected, the
26 deployment tube 10 can be manipulated to shift the position of the
27 endovascular device 16, which will stay attached to the deployment
28 tube 10 during the manipulation. Thus, repositioning of the

1 endovascular device 16 is facilitated, thereby providing better
2 placement of the device 16 within the targeted site.

3 In many instances, it will be desired to take special precautions
4 against the introduction of air into the vasculature. Accordingly, the
5 present invention may be adapted to incorporate an anti-airflow
6 mechanism. A first type of anti-airflow mechanism, illustrated in
7 Figures 5 - 8, comprises a flexible, expansible, compliant membrane
8 40, preferably of silicone rubber, sealingly disposed over the distal end
9 of the deployment tube 10. The distal end of the deployment tube 10 is
10 covered by a thin, flexible, polymeric sheath 42, and the membrane 40
11 is attached to the sheath 42 by a suitable biocompatible adhesive, such
12 as cyanoacrylate. As shown in Figure 6, the endovascular device 16 is
13 attached to the deployment tube 10 by means of the retention sleeve 12
14 and the coupling element 14, as described above, with the membrane
15 40 disposed between the distal end of the deployment tube 10 and the
16 proximal end of the coupling element 14.

17 In use, as shown in Figures 7 and 8, the liquid 30 is injected into
18 the deployment tube, as described above. Instead of directly impacting
19 the coupling element 14, however, it expands the membrane 40 distally
20 from the distal end of the deployment tube 10 (Fig. 7), thereby pushing
21 the coupling element 14 out of the retention sleeve to deploy the
22 endovascular device 16. After the deployment, the membrane
23 resiliently returns to its original position (Fig. 8). Thus, the injected
24 liquid 30 is completely contained in a closed system, and any air that
25 may be entrapped in the deployment tube 10 is prevented from
26 entering the vasculature by the airtight barrier present by the
27 membrane 40.

28 Figures 9 - 12 illustrate a second type of anti-airflow mechanism

1 that may be used with the present invention. This second type of anti-
2 airflow mechanism comprises an internal stylet 50 disposed axially
3 through the deployment tube 10. The stylet 50 has a flexible distal
4 portion 52 terminating in an outlet opening 54 adjacent the distal end
5 of the deployment tube 10, and a proximal inlet opening 56 that
6 communicates with an inlet port 58 in a fitting 60 attached to the
7 proximal end of the deployment tube. The fitting 60 includes a gas
8 venting port 62 in fluid communication with the proximal end of the
9 deployment tube. The gas venting port 62, in turn, includes a stop-
10 cock valve 64.

11 The operation of the second type of anti-airflow mechanism
12 during deployment of the endovascular device 16 is shown in Figures
13 11 and 12. As shown in Figure 11, with the stop-cock valve 64 open,
14 the liquid 30 is injected into the stylet 50 through the inlet port 58 by
15 means such as a syringe 66. The injected liquid 30 flows through the
16 stylet 50 and out of the stylet outlet opening 54 and into the
17 deployment tube 10, hydraulically pushing any entrapped air
18 (indicated by arrows 68 in Figure 11) out of the venting port 62. When
19 the liquid 30 begins flowing out of the venting port 62, indicating that
20 any entrapped air has been fully purged from the deployment tube 10,
21 the stop-cock valve 64 is closed (as shown in Figure 12), allowing the
22 continued flow of the liquid 30 to push the endovascular device 16 out
23 of the retention sleeve 12, as described above.

24 Figures 13-17 illustrate a modification of the preferred
25 embodiment of the invention that facilitates the performance of an air
26 purging step before the deployment tube and the endovascular device
27 are intravascularly passed to the target site. This modification
28 includes a modified coupling element 14' having an axial air purge

1 passage 72. The purge passage 72 is provided through a central
2 coupling element portion 74 contained within an inner microcoil
3 segment 76 located coaxially within the coupling element 14'. The
4 diameter of the purge passage 72 is preferably between about 0.010
5 mm and about 0.025 mm, for the purpose to be described below.

6 A detachment zone indicator sleeve 70, attached to the distal
7 extension 17 of the retention sleeve 12 by a bond joint 71, is disposed
8 coaxially around a proximal portion (approximately one-half) of the
9 distal extension 17 of the retention sleeve 12, leaving approximately
10 the distal half of the distal extension 17 exposed. The detachment
11 zone indicator sleeve 70 thus overlaps the juncture between the
12 coupling element 14' and the distal end of the deployment tube 10, and
13 reinforces the retention sleeve 12 at this juncture against the stresses
14 resulting from the bending of the assembly as it is passed
15 intravascularly to the target vascular site. Furthermore, the
16 detachment zone indicator sleeve 70 restrains the retention sleeve 70
17 from radial expansion. The detachment zone indicator sleeve 70 may
18 be made of polyimide or platinum. If made of polyimide, its color is
19 advantageously one that contrasts with the color of the retention sleeve
20 12, so that the detachment zone (i.e., the juncture between the
21 coupling element 14' and the deployment tube 10) can be easily
22 visualized before the intravascular deployment. If made of platinum,
23 the detachment zone can be visualized within the body by X-ray or
24 other conventional visualization methods.

25 As shown in Figure 15, before the deployment tube 10 and the
26 endovascular device are introduced intravascularly, as described
27 above, saline solution 30 is injected into the lumen 15 to purge air from
28 the mechanism. The purged air exits through the purge passage, as

1 indicated by the arrows 78 in Figure 15, and out the distal end (not
2 shown) of the endovascular device. It may be advantageous to place
3 the distal end of the endovascular device in a receptacle of sterile saline
4 solution, so that the cessation air bubbles may be noted, indicating a
5 complete purging of air. The saline is injected at a sufficiently low
6 pressure (such as by use of a 3 cc syringe), that the coupling element
7 14' is not pushed out of the retention sleeve 12. Some of the saline
8 solution 30 also is purged through the purge passage 72, the diameter
9 of which is sufficiently large to allow the relatively free flow of the
10 saline solution 30 through it.

11 After the endovascular device has been located in the target
12 vascular site, as described above, a contrast agent 73 is injected into the
13 lumen 15, as shown in Figure 16. The contrast agent 73 has a much
14 higher viscosity than the saline solution 30 (3-10 cP vs. approximately
15 1 cP). Therefore, the contrast agent 73 pushes the remaining saline
16 solution 30 out through the purge passage 72. Because of the relatively
17 high viscosity of the contrast agent 73 and the relatively small diameter
18 of the purge passage 72, the contrast agent 73 does not pass easily
19 through the purge passage 72. As the contrast agent 73 continues to
20 flow into the lumen 15, pressure builds up on the proximate side of the
21 coupling element 14', until it is pushed out of the retention sleeve 12,
22 as shown in Figure 17.

23 A modified form of the first type of anti-airflow mechanism is
24 shown in Figures 18 and 19. This modification comprises a flexible,
25 but non-compliant barrier in the form of a non-compliant membrane
26 40', preferably of PET, sealingly disposed over the distal end of the
27 deployment tube 10. The distal end of the deployment tube 10 is
28 covered by a thin, flexible, polymeric sheath 42', and the membrane 40'

1 is attached to the sheath 42' by a suitable biocompatible adhesive, such
2 as cyanoacrylate. As shown in Figure 18, the membrane 40' is shaped
3 so that it normally assumes a first or relaxed position, in which its
4 central portion extends proximally into the lumen 15 of the
5 deployment tube 10. The endovascular device 16 is attached to the
6 deployment tube 10 by means of a frictional fit between the membrane
7 40' and the coupling element 14, the former forming a tight-fitting
8 receptacle for the latter. The retention may be enhanced by a suitable
9 adhesive (e.g., cyanoacrylate). The coupling element 14 is thus
10 contained within lumen 15 near the distal end of the deployment tube
11 10.

12 Figure 19 shows the use of the modified form of the first type of
13 anti-airflow device in the deployment of the endovascular device 16.
14 As described above, the liquid 30 is injected into the deployment tube
15 10, pushing the membrane 40' distally from the distal end toward a
16 second or extended position, in which projects distally from the distal
17 end of the deployment tube 10. As the membrane 40' is pushed toward
18 its extended position, it pushes the coupling element 14 out of the
19 distal end of the deployment tube 10 to deploy the endovascular device
20 16. Thus, the injected liquid 30 is completely contained in a closed
21 system, and any air that may be entrapped in the deployment tube 10
22 is prevented from entering the vasculature by the airtight barrier
23 present by the membrane 40'.

24 It will thus be appreciated that the present invention provides a
25 coupling mechanism that yields a secure attachment of the
26 endovascular device to a deployment instrument during the
27 deployment process, while also allowing for the easy and reliable
28 detachment of the endovascular device once it is properly situated with

1 respect to the target site. The coupling mechanism of the present
2 invention also provides improved control of the endovascular device
3 during deployment, and specifically it allows the endovascular device
4 to be easily repositioned before detachment. In addition, the coupling
5 mechanism of the present invention advantageously includes an
6 effective mechanism for precluding airflow into the vasculature during
7 the deployment process. Furthermore, the coupling mechanism of the
8 present invention is readily adaptable for use with a wide variety of
9 endovascular devices, without adding appreciably to their costs.

10 Although a number of specific embodiments are described
11 above, it should be appreciated that these embodiments are exemplary
12 only, particularly in terms of materials and dimensions. For example,
13 many suitable materials for both the coupling element 14 and the
14 retention sleeve 12 may be found that will yield satisfactory
15 performance in particular applications. Also, the exemplary
16 dimensions given above may be changed to suit different specific
17 clinical needs. These modifications and others that may suggest
18 themselves to those skilled in the pertinent arts are deemed to be
19 within the spirit and scope of the present invention, as defined in the
20 claims that follow.

1 WHAT IS CLAIMED IS:

2

3 1. A deployment mechanism for deploying a filamentous
4 endovascular device having a proximal end, comprising:

5 an elongate, flexible, hollow deployment tube having an
6 open proximal end, a distal section terminating in an open distal
7 end, and a lumen defined between the proximal and distal ends;
8 a retention sleeve fixed around the distal section of the
9 deployment tube and having a distal extension extending a short
10 distance past the distal end of the deployment tube; and

11 a coupling element attached to the proximal end of the
12 endovascular device and releasably held within the distal
13 extension of the retention sleeve proximate the distal end of the
14 deployment tube so as to be displaceable from the retention
15 sleeve in response to fluid pressure applied to the coupling
16 element through the lumen and the distal end of the deployment
17 tube.

18

19 2. The deployment mechanism of Claim 1, wherein the
20 coupling element is formed from a non-hydrophilic material.

21

22 3. The deployment mechanism of Claim 1, wherein the
23 coupling element is formed from a hydrophilic material.

24

25 4. The deployment mechanism of Claim 2, wherein the
26 coupling element is provided with a hydrophilic coating.

27

28 5. The deployment mechanism of Claim 3, wherein the

1 retention sleeve is made of polyethylene terephthalate and the coupling
2 element is made of a hydrophilic polymeric hydrogel.

3

4 6. The deployment mechanism of Claim 1, wherein the
5 retention sleeve and the coupling element are formed from a
6 polyolefin.

7

8 7. The deployment mechanism of Claim 2, wherein the
9 retention sleeve is made of a fluorocarbon and the coupling element is
10 made of metal.

11

12 8. The deployment mechanism of Claim 1, wherein the
13 retention sleeve is made of a shape memory nickel-titanium alloy.

14

15 9. The deployment mechanism of Claim 1, wherein the
16 deployment tube further includes a proximal main section and an
17 intermediate transition section between the main section and the distal
18 section.

19

20 10. The deployment mechanism of Claim 9, wherein the distal
21 section is shorter and more flexible than the transition section, and the
22 transition section is shorter and more flexible than the main section.

23

24 11. The deployment mechanism of Claim 10, wherein the main
25 section is a continuous, tubular section; the transition section is formed
26 as a laser-cut ribbon coil; and the distal section is formed as a helical
27 coil.

28

1 12. The deployment mechanism of Claim 11, wherein the
2 retention sleeve covers the transition section and the distal section of
3 the deployment tube.

4
5 13. The deployment mechanism of Claim 12, wherein the
6 retention sleeve has a proximal end that is attached to the main section
7 of the deployment tube.

8
9 14. The deployment mechanism of Claim 1, wherein the
10 retention sleeve has a relaxed diameter that is less than the diameter of
11 the coupling element.

12
13 15. The deployment mechanism of Claim 1, further comprising:
14 a fluid-tight barrier disposed between the distal end of the
15 deployment tube and the coupling element, the barrier being
16 movable in a distal direction by fluid pressure applied through
17 the lumen to displace the coupling element from the retention
18 sleeve.

19
20 16. The deployment mechanism of Claim 15, wherein the
21 barrier comprises a compliant membrane secured to the deployment
22 tube so as to cover the distal end.

23
24 17. The deployment mechanism of Claim 15, wherein the
25 barrier comprises a flexible membrane secured to the deployment tube
26 so as to cover the distal end and having a central portion, the
27 membrane being movable between a first position, in which its central
28 portion extends proximally into the lumen of the deployment tube, and

1 a second position, in which its central portion is projected distally from
2 the distal end of the deployment tube.

3

4 18. The deployment mechanism of Claim 1, further comprising:

5 a fitting attached to the proximal end of the deployment
6 tube, the fitting having a fluid inlet, a gas venting port in fluid
7 communication with the lumen, and a valve in the gas venting
8 port for controlling gas flow therethrough; and

9 a flexible, hollow stylet disposed axially through the
10 fitting and lumen, the stylet having a distal opening proximate
11 the distal end of the deployment tube and a proximal opening in
12 fluid communication with the fluid inlet of the fitting.

13

14 19. The deployment mechanism of Claim 1, wherein the
15 coupling element includes an axial purge passage therethrough, the
16 purge passage having a diameter that permits the flow of saline
17 solution therethrough, but does not permit the free flow therethrough
18 of a fluid having a viscosity greater than or approximately equal to 3
19 cP.

20

21 20. The deployment mechanism of Claim 1, wherein the
22 retention sleeve is substantially non-expansile in the radial direction.

23

24 21. A method of deploying a filamentous endovascular device
25 into a target vascular site, comprising the steps of:

26 (a) providing a filamentous endovascular device having a
27 proximate end releasably coupled to an elongate, flexible,
28 hollow deployment tube having an open proximal end, a distal

1 section terminating in an open distal end, and a lumen defined
2 between the proximal and distal ends, the endovascular device
3 having a coupling element releasably attached to the
4 deployment tube adjacent the open distal end thereof;

5 (b) introducing the endovascular device intravascularly to
6 the target vascular site while it is attached to the deployment
7 tube; and

8 (c) injecting a liquid under pressure through the lumen to
9 separate the endovascular device from the deployment tube in
10 response to the liquid pressure applied to the coupling element
11 through the open distal end of the deployment tube.

12
13 22. The method of Claim 21, wherein the coupling element is
14 releasably held by a retention sleeve fixed to the distal section of the
15 deployment tube.

16
17 23. The method of Claim 22, wherein the retention sleeve is not
18 substantially expanded in the radial direction during the injection step.

19
20 24. The method of Claim 21, wherein the deployment tube
21 includes a flexible stylet disposed axially through the lumen so as to
22 define a lumen space between the exterior surface of the stylet and the
23 interior the deployment tube, and a closeable gas venting port fluidly
24 coupled to the proximal end of the deployment tube so as to be in fluid
25 communication with the lumen space, the stylet having an inlet near
26 the proximate end of the deployment tube and an outlet near the distal
27 end of the deployment tube, and wherein the injecting step comprises
28 the substeps of:

1 (c)(1) injecting liquid into the stylet inlet, through the
2 stylet outlet, and into the lumen space while the gas venting port
3 is open until the liquid emerges from the gas venting port;
4 (c)(2) closing the gas venting port; and
5 (b)(3) continuing the injection of the liquid until the
6 endovascular device separates from the deployment tube.

7
8 25. The method of Claim 21, wherein the injected liquid in the
9 injecting step applies pressure directly to the coupling element.

10
11 26. The method of Claim 21, wherein the injected liquid in the
12 injecting step applies pressure indirectly to the coupling element
13 through an expansible membrane sealingly attached over the distal end
14 of the deployment tube.

15
16 27. The method of Claim 21, wherein the coupling element
17 includes an axial purge passage having a diameter that permits the flow
18 of saline solution therethrough, but does not permit the free flow
19 therethrough of a fluid having a viscosity greater than or
20 approximately equal to 3 cP, wherein the method further comprises the
21 step of, before the introducing step, purging air from the lumen by
22 injecting saline solution through the lumen with a pressure sufficient to
23 displace air from the lumen through the purge passage but not
24 sufficient to separate the endovascular device from the deployment
25 tube, and wherein the injecting step comprises the step of injecting a
26 contrast agent having a viscosity of at least about 3 cP through the
27 lumen with a pressure sufficient to displace the saline solution from the
28 lumen through the purge passage and to separate the endovascular

1 device from the deployment tube.

2

3 28. A deployment mechanism for intravascularly deploying a
4 filamentous endovascular device having a proximal end into a target
5 vascular site in a patient's vasculature, the deployment mechanism
6 comprising:

7 an elongate, flexible, hollow deployment tube having an
8 open proximal end, a distal section terminating in an open distal
9 end, and a lumen defined between the proximal and distal ends;

10 a retention sleeve fixed around the distal section of the
11 deployment tube and having a distal extension extending a short
12 distance past the distal end of the deployment tube;

13 a coupling element attached to the proximal end of the
14 endovascular device and releasably held within the distal
15 extension of the retention sleeve proximate the distal end of the
16 deployment tube so as to be displaceable from the retention
17 sleeve in response to fluid pressure applied to the coupling
18 element from the fluid passage lumen and the distal end; and

19 anti-air flow means, operatively associated with the
20 deployment tube, for substantially preventing the passage of air
21 from the lumen into the patient's vasculature.

22

23 29. The deployment mechanism of Claim 28, wherein the anti-
24 air flow means comprises:

25 a resiliently expansible, fluid-tight barrier disposed
26 between the distal end of the deployment tube and the coupling
27 element, the barrier being expansible in a distal direction by
28 fluid pressure applied through the lumen, the expansion of the

1 barrier displacing the coupling element from the retention
2 sleeve.

3
4 30. The deployment mechanism of Claim 29, wherein the
5 barrier comprises a resiliently expansible membrane secured to the
6 deployment tube so as to cover the distal end.

7
8 31. The deployment mechanism of Claim 28, wherein the anti-
9 air flow means comprises:

10 a fitting attached to the proximal end of the deployment
11 tube, the fitting having a fluid inlet, a gas venting port in fluid
12 communication with the lumen, and a valve in the gas venting
13 port for controlling gas flow therethrough; and

14 a flexible, hollow stylet disposed axially through the
15 fitting and lumen, the stylet having a distal opening proximate
16 the distal end of the deployment tube and a proximal opening in
17 fluid communication with the fluid inlet of the fitting.

18
19 32. The deployment mechanism of Claim 28, wherein the
20 deployment tube further includes a proximal main section and an
21 intermediate transition section between the main section and the distal
22 section.

23
24 33. The deployment mechanism of Claim 32, wherein the distal
25 section is shorter and more flexible than the transition section, and the
26 transition section is shorter and more flexible than the main section.

27
28 34. The deployment mechanism of Claim 33, wherein the main

1 section is a continuous, tubular section; the transition section is formed
2 as a laser-cut ribbon coil; and the distal section is formed as a helical
3 coil.

4
5 35. The deployment mechanism of Claim 28, wherein the
6 retention sleeve is substantially non-expansile in the radial direction.

7
8 36. A deployment tube for use in a device for intravascularly
9 deploying an endovascular device in a target vascular site in the
10 vasculature of a patient, the deployment tube comprising:
11 a main section having an open proximal end;
12 a distal section terminating in an open distal end; and
13 a transition section in section connected between the
14 main section and the distal section;
15 wherein the distal section is shorter and more flexible
16 than the transition section, and the transition section is shorter
17 and more flexible than the main section; and
18 wherein the main, distal and transition sections define a
19 continuous fluid passage lumen between the proximal and distal
20 ends.

21
22 37. The deployment tube of Claim 36, wherein the main section
23 is a continuous length of hollow, flexible tube; the transition section is
24 a length of hollow, flexible laser-cut ribbon coil; and the distal section
25 is a length of hollow, flexible, helical coil.

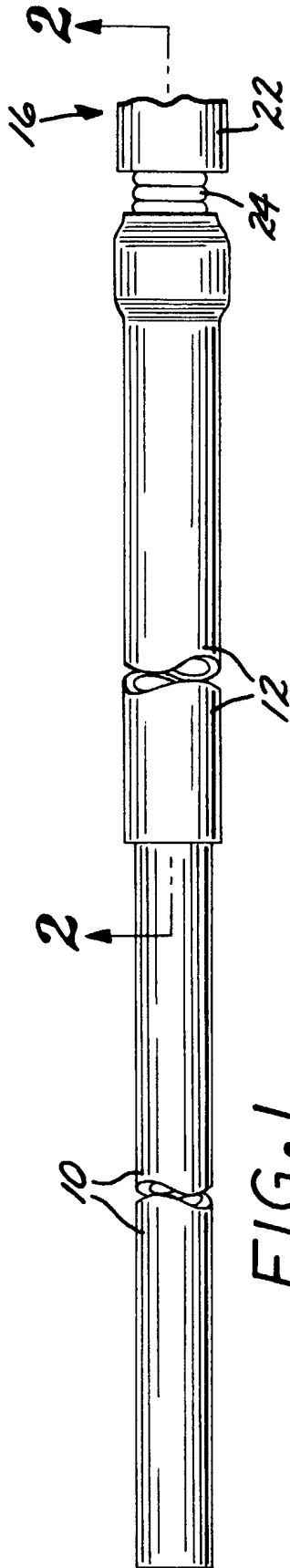


FIG. 1

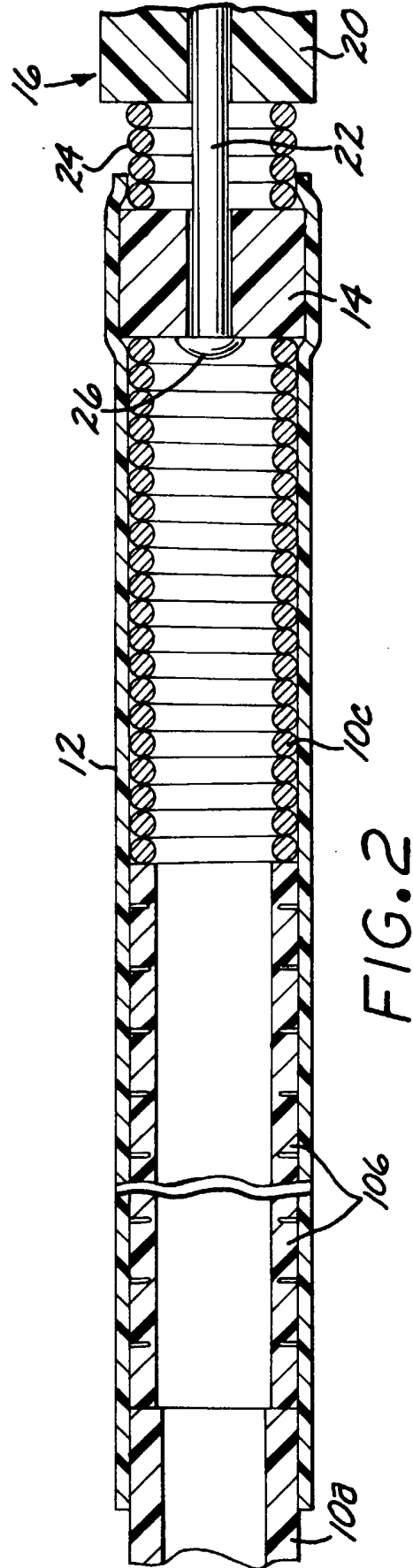
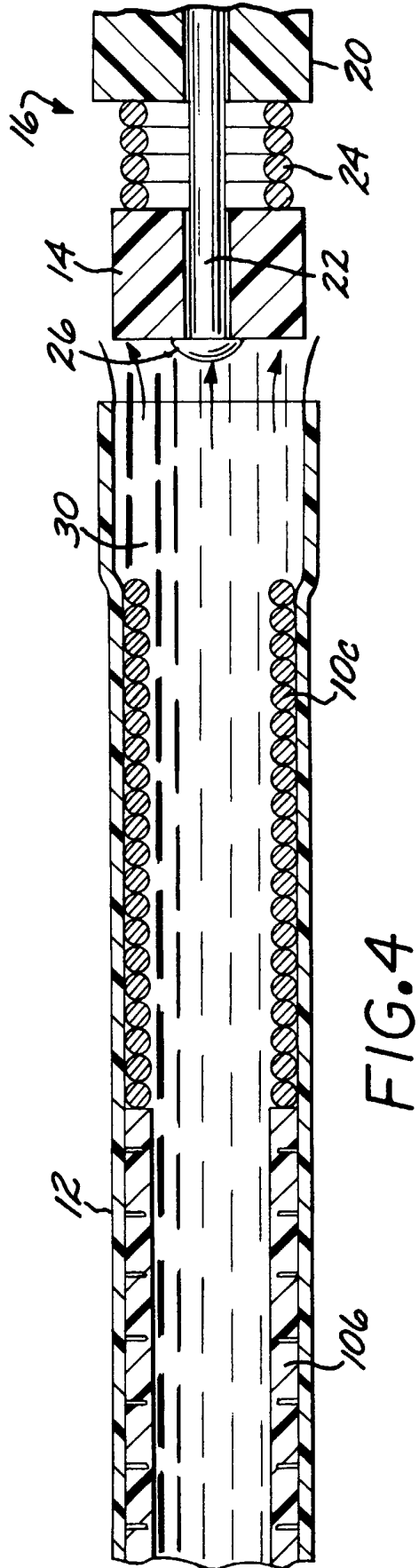
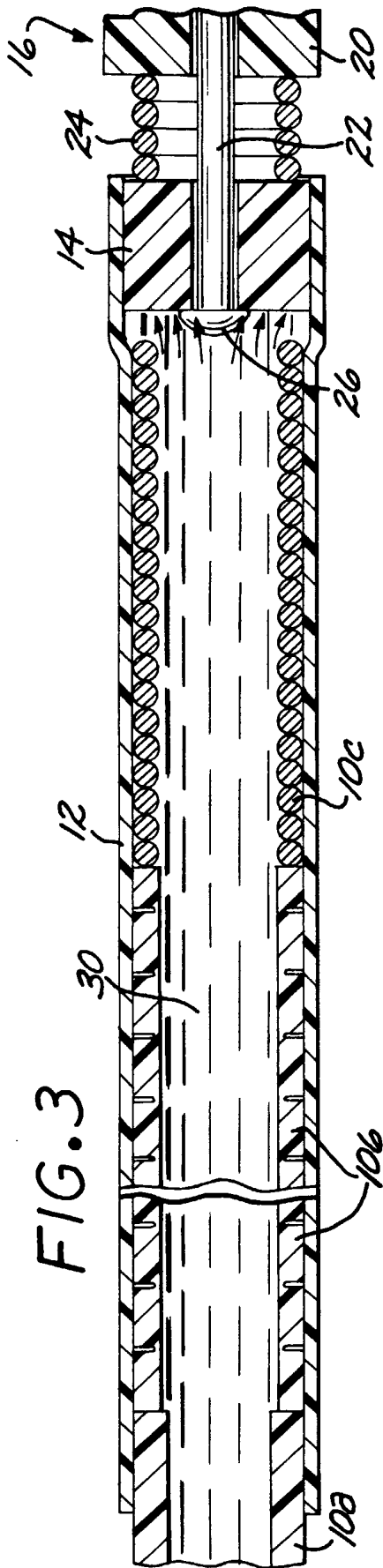


FIG. 2



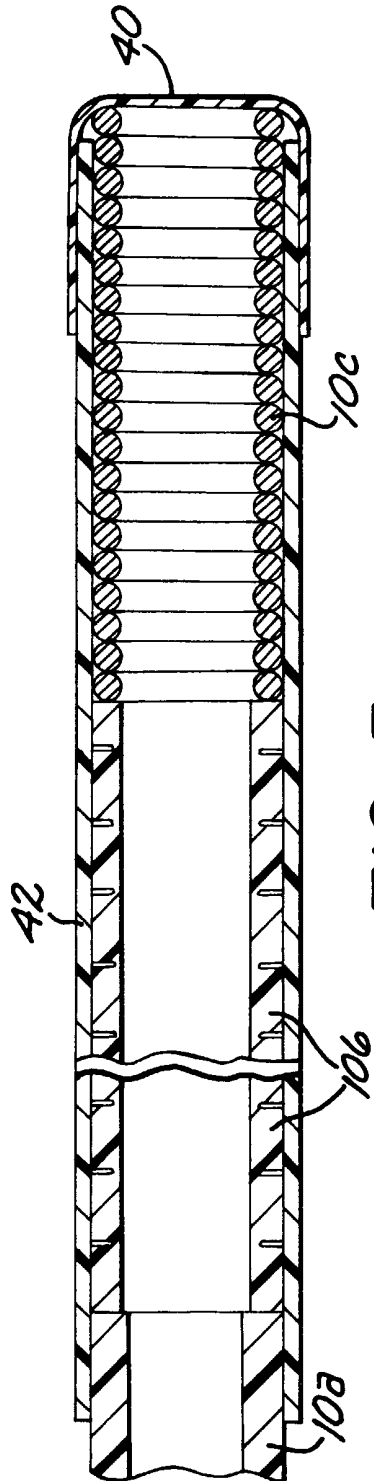


FIG. 5

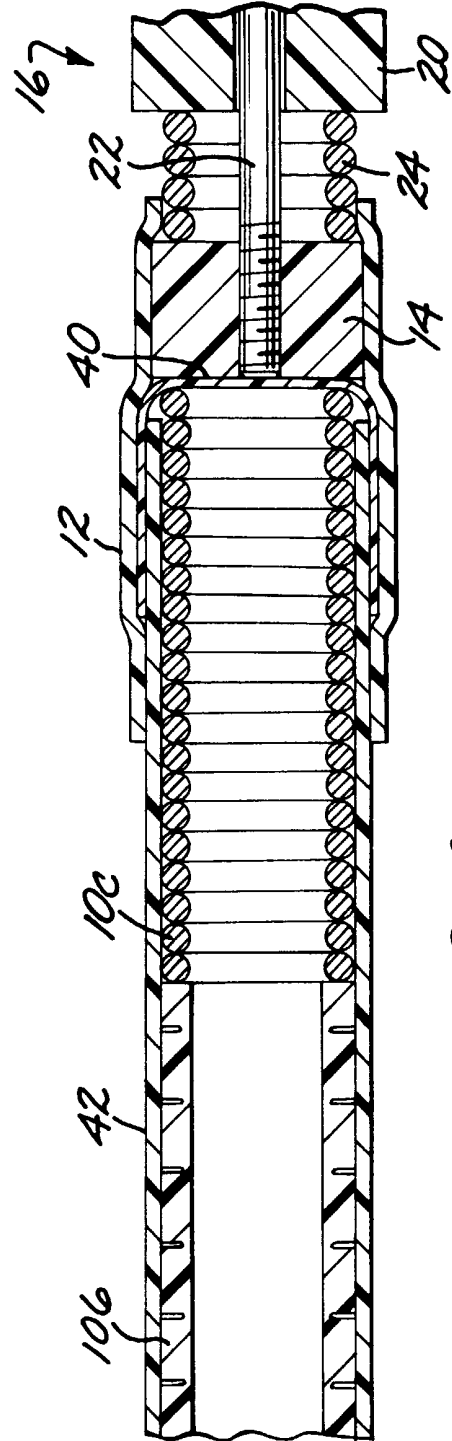


FIG. 6

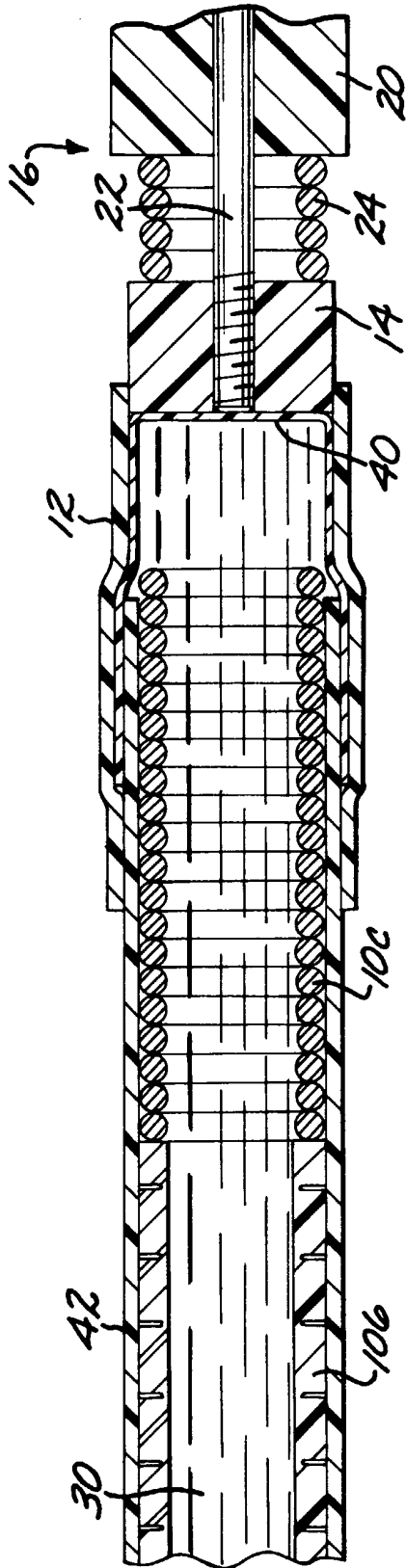


FIG. 7

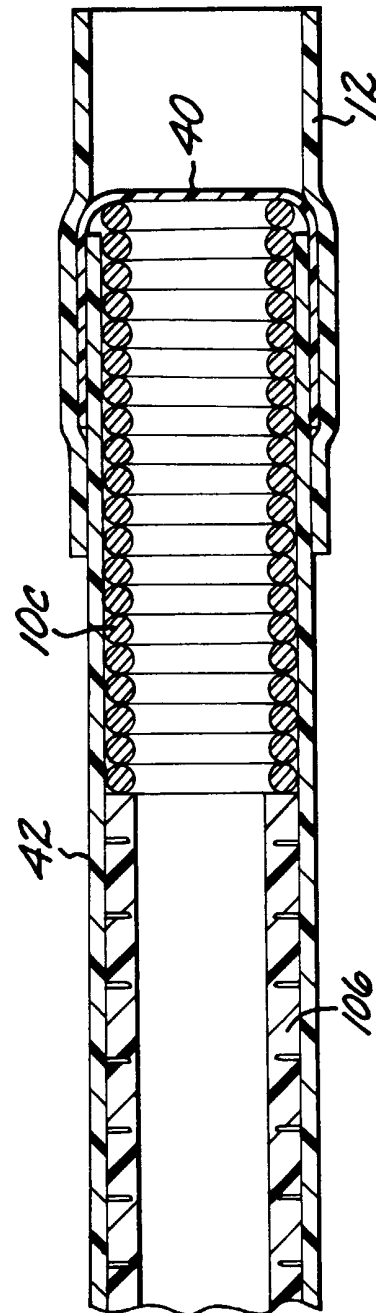
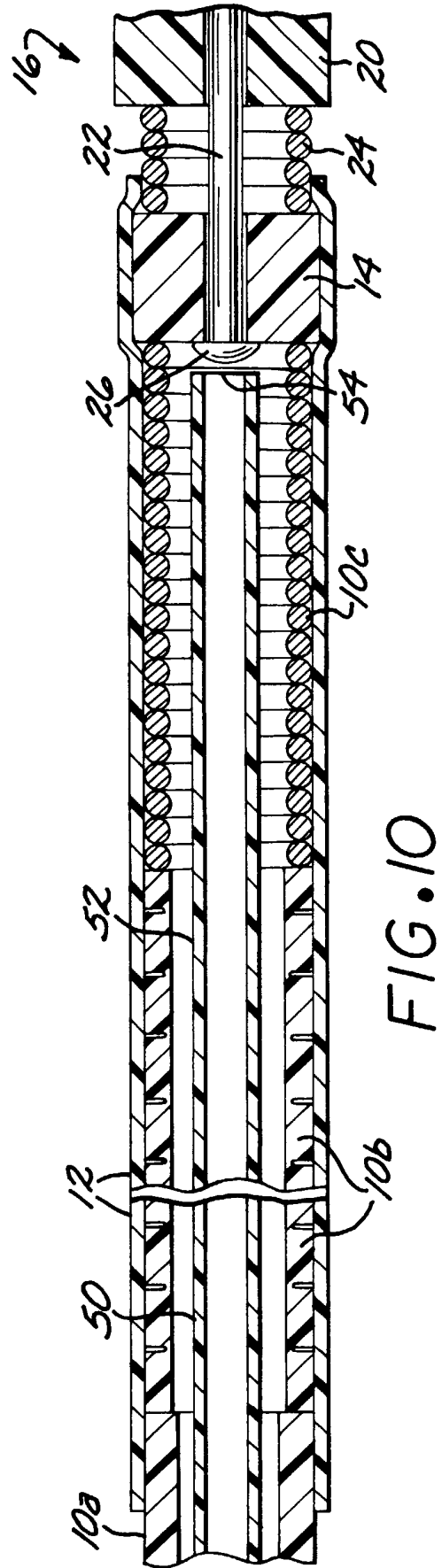
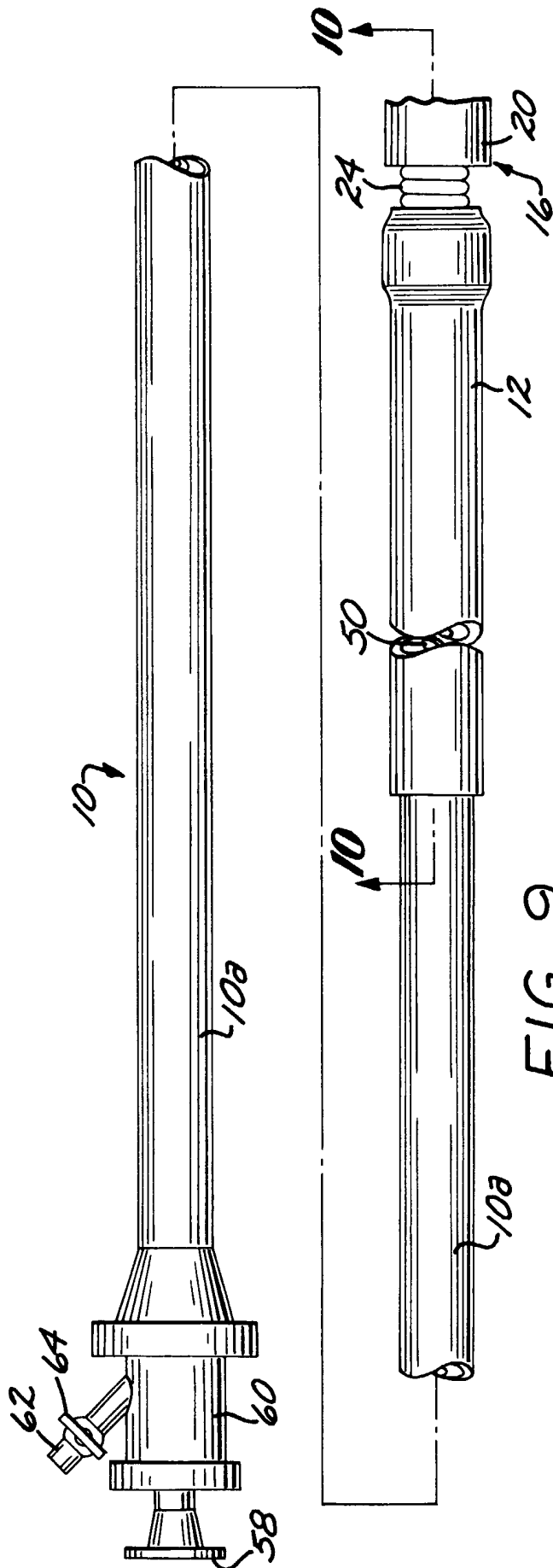
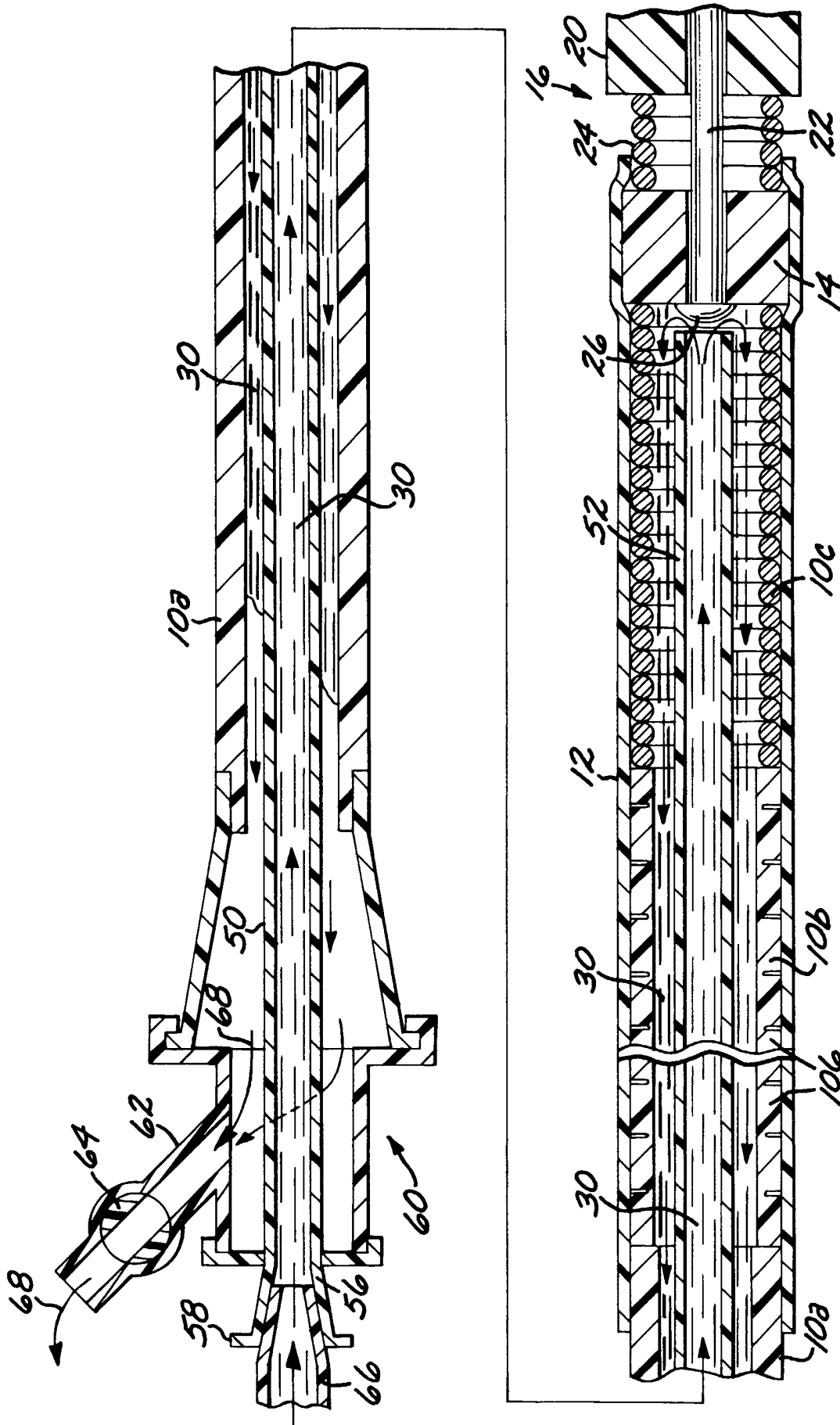


FIG. 8





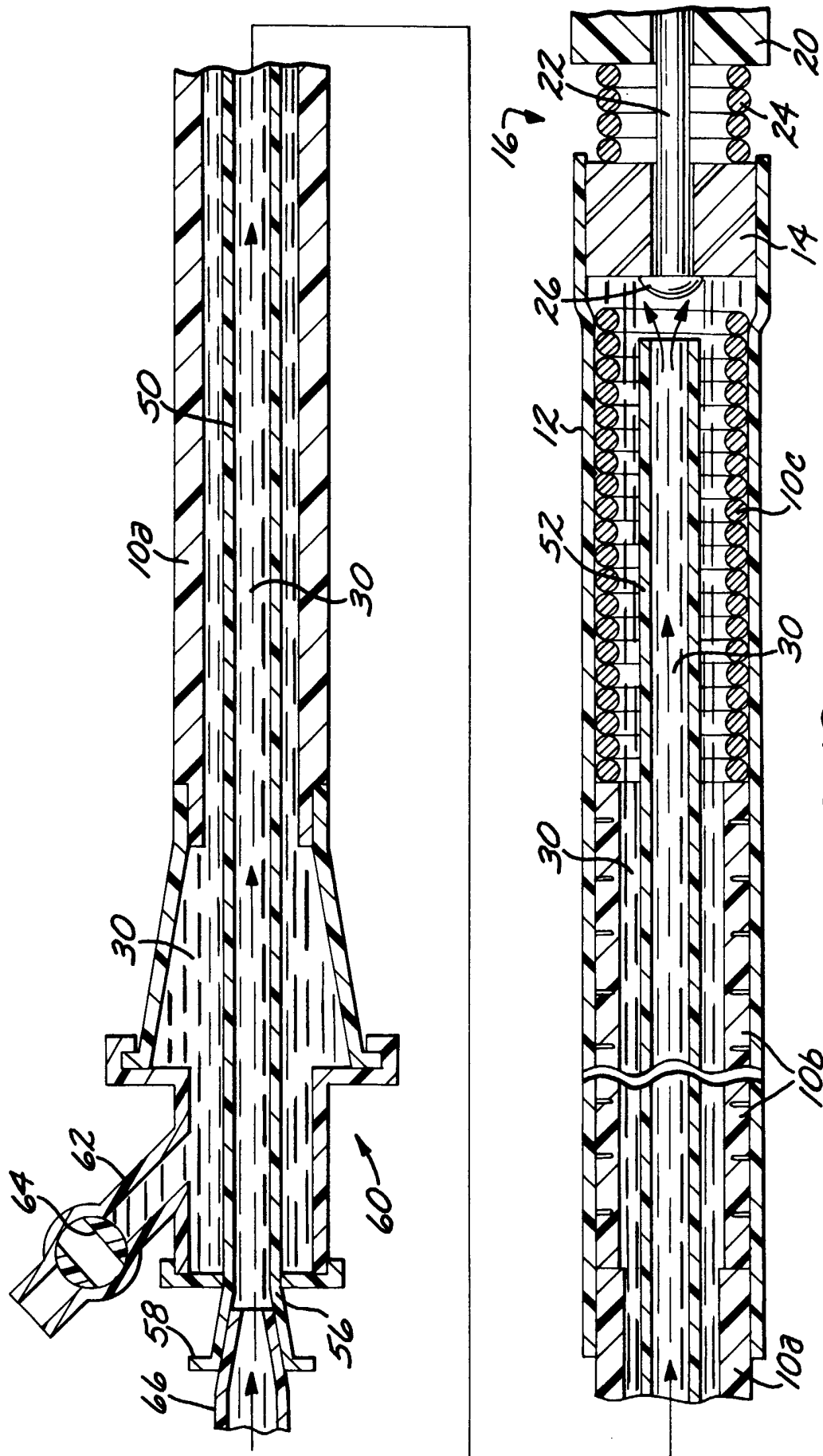
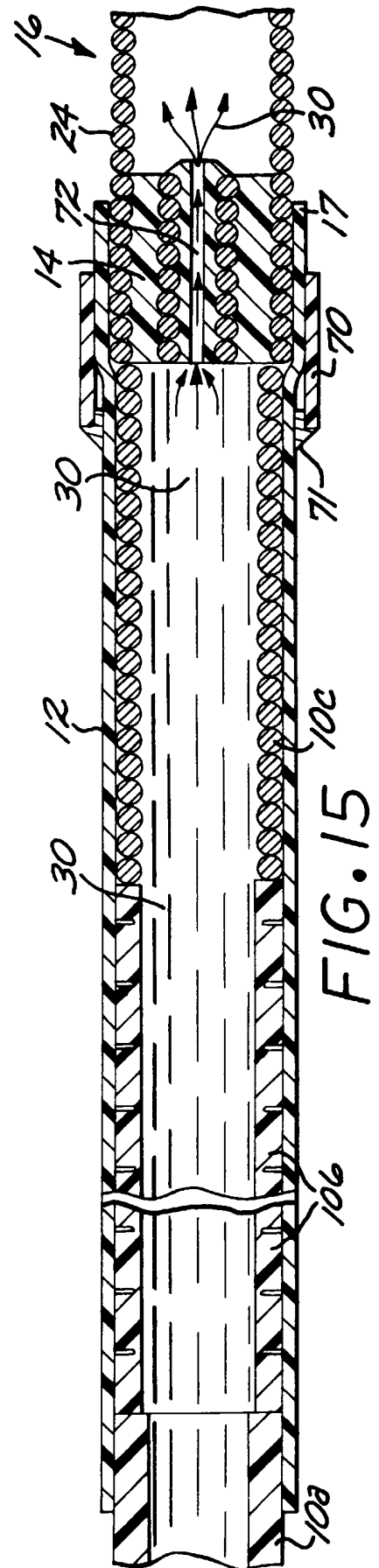
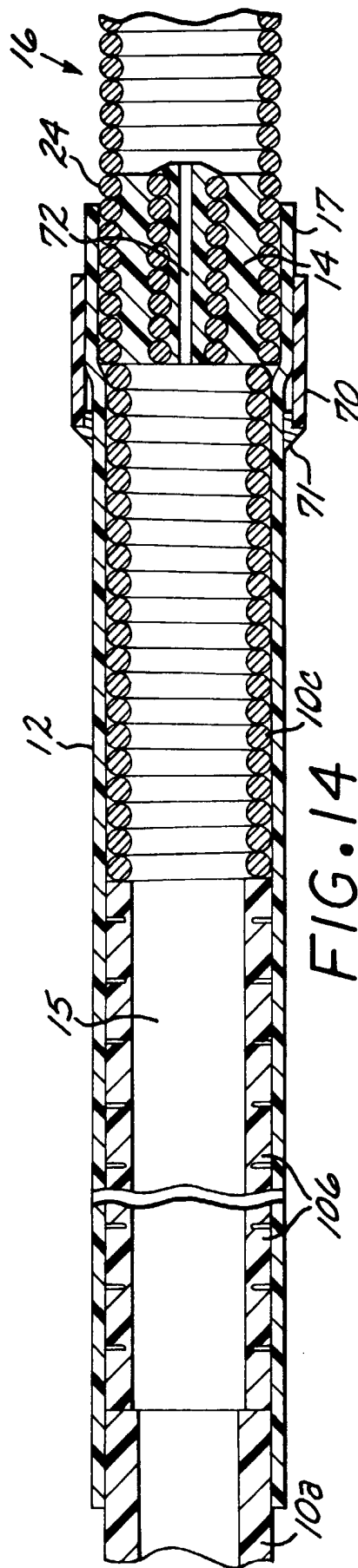
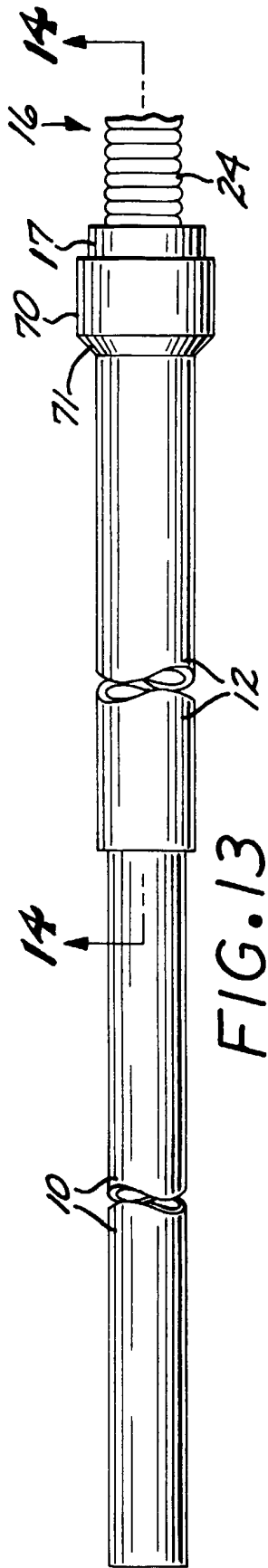


FIG. 12



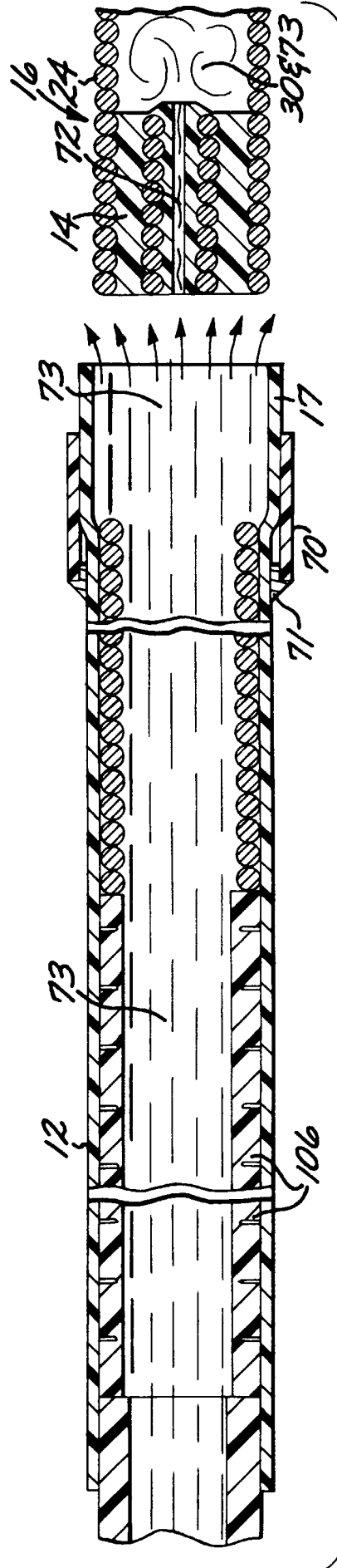
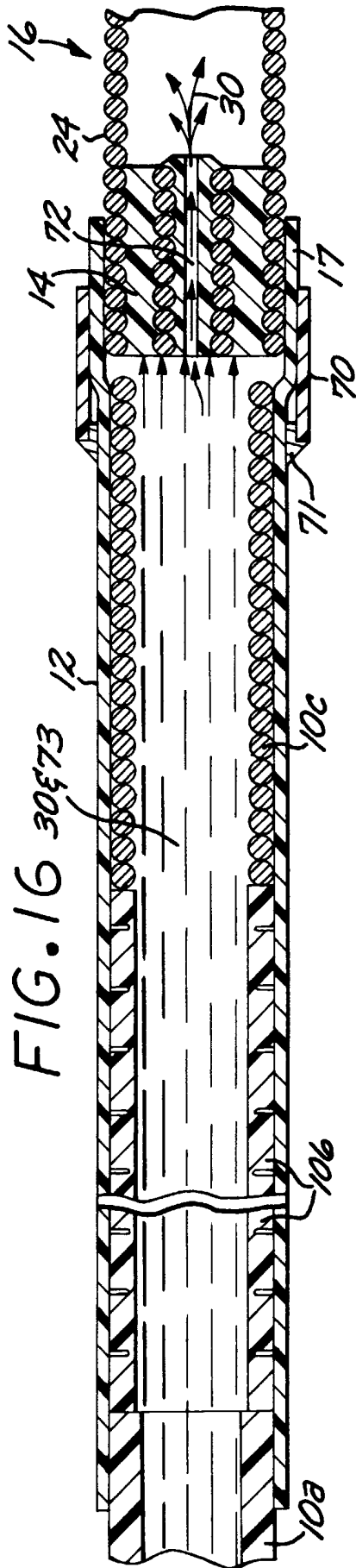


FIG. 17

