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(54) Title: DELIVERY DEVICE WITH FILLER TUBES

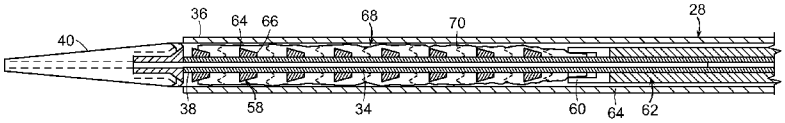

FIG. 2

(57) Abstract: A delivery system for implanting a prosthesis includes a handle; an inner control tube extending from the handle, the inner control tube having a proximal end at the handle and a distal end remote from the handle; a tip at the distal end of the inner control tube; and a plurality of filler tubes along the inner control tube, the plurality of filler tubes fixed to the inner control tube, each filler tube having a proximal end and a distal end, the distal end having an outer diameter greater than that of the proximal end. The delivery system can be employed to implant a stent graft in a patient.

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DELIVERY DEVICE WITH FILLER TUBES

RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Application No. 62/318,459, filed on April 5, 2016. The entire teachings of the above application is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] Aortic disease, including aneurysms and dissections, can be life-threatening conditions. Implantation of stent grafts that span the site of the aneurysm can be used to treat aortic disease. Prostheses that include a stent at the most proximal end of graft material having proximal apices that extend beyond the proximal end of the graft material ("bare stent") can be delivered to disease sites in the aorta by use of devices that capture the proximal apices. Depending upon the anatomy of the location of the aortic disease, a prosthesis without a bare stent may be delivered to the site of the diseased aorta.

[0003] Stent grafts that do not have a bare metal stent for clasping (anchoring) generally are pushed out the sheath instead of being pulled out of the sheath when the sheath is retracted. Since self-expanding grafts typically have varying stent diameters, the largest section of the stent graft will increase the drag on the sheath, causing stents that are less compressed to bunch together. This bunching causes a foreshortening over the entire length of the stent.

[0004] Current technology for deploying a prosthesis without a bare stent is generally limited to the following options – first, the prosthesis can simply be pushed out of the delivery system by placing a component on the inner member that is fixed relative to the prosthesis and the outer member. The fixed component having a diameter that is substantially the same as the inner diameter of the outer sheath, thus providing a stop for the prosthesis and effectively pushing out the prosthesis from the distal end of the prosthesis only when the outer sheath is retracted relative to the inner member. This type of deployment may result in deployments that are less accurate relative to the ability to deploy the proximal end of the prosthesis and predict the position of the distal end of the prosthesis due to potential compression of the prosthesis. The second type of deployment mechanism would be a

clasping mechanism that engages with the proximal end of the prosthesis on the inner surface of the prosthesis inside the graft material. The issue with this type of mechanism is that the combination of the stent, graft and proximal clasping mechanism all in the same location creates a high profile condition. A variant of this second design is the use of release wire that engages with the proximal end of the prosthesis, but does not create a high profile condition. Some issues with this variant include a more complicated delivery system and known clinical conditions caused by release wires that break, kink or get stuck in the prosthesis.

[0005] Therefore, a need exists for new and improved delivery devices to treat aortic disease that improve the efficiency and accuracy of endovascular repair.

SUMMARY OF THE INVENTION

[0006] The present invention relates to a delivery device assembly and a method of implanting a stent graft to treat vascular damage, such as an aortic aneurysm.

[0007] In an embodiment, the invention is a delivery device assembly, including a handle, an inner control tube extending from the handle, the inner control tube having a proximal end at the handle and a distal end remote from the handle; a tip at the distal end of the inner control tube; and a plurality of filler tubes along the inner control tube, the plurality of filler tubes fixed to the inner control tube, each filler tube having a proximal end and a distal end, the distal end having an outer diameter greater than that of the proximal end.

[0008] In another embodiment, the invention is a method of implanting a stent graft, comprising the steps of directing a stent graft to an implantation site, the stent graft being captured between an inner control tube that extends distally from a handle and is within the stent graft, and an introducer catheter that extends distally from the handle and about the stent graft, the stent graft including a plurality of stents along a graft component of the stent graft, wherein at least a portion of the stents are partitioned from each other by at least one filler tube of a plurality of filler tubes fixed to the inner control tube; and actuating the handle to retract the introducer catheter proximally from about the stent graft, the at least one filler tube preventing longitudinal movement of a stent distal to the filler tube, thereby preventing longitudinal movement of the stent graft during retraction of the introducer catheter, the retraction of the introducer catheter causing implantation of the stent graft.

[0009] The filler tubes are tapered, each having a distal end and a proximal end, wherein the distal end has a diameter greater than the proximal end. Each distal end acts as a ledge

that mechanically interferes with distal migration of stents of the stent graft; as the sheath is pulled back, the distal ends will prevent the stents of the stent graft from moving with the sheath. The distal ends have a mono-directional function that keep the graft from compressing (shortening) as the sheath is retracted. Also, an inner control tube can be retracted into the introducer sheath following release of the stent graft while minimizing any vessel trauma. The filler tubes are gaped to lay approximately in between neighboring stents.

[0010] Control of a prosthesis via filler tubes distributed along its length facilitates accurate placement of the prosthesis, as well as ensuring that the prosthesis does not become compressed or otherwise distorted. Such deployment has two benefits: the prosthesis can be deployed with optimal accuracy at the proximal end; and, since the prosthesis is deployed substantially without distortion, the length of the prosthesis can be maintained, thereby ensuring that both the lumen and the prosthesis are not compromised by axially infolded material and allowing the physician to predict where the distal end of the prosthesis will land in the patient's anatomy.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The foregoing will be apparent from the following more particular description of example embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating embodiments of the present invention.

[0012] FIG. 1 is a perspective view of one embodiment of a delivery assembly of the invention.

[0013] FIG. 1A is a detail of the distal end of an introducer sheath, intermediate tube, and inner control tube of the delivery device of FIG. 1.

[0014] FIG. 2 is a partial cross-sectional view of one embodiment of the delivery assembly of FIG. 1 prior to deployment of a stent graft prosthesis from within a distal sheath of the delivery assembly.

[0015] FIG. 3 is a cross-sectional view, in perspective, of a hemostasis valve suitable for use with the invention.

[0016] FIG. 3A is a detail of FIG. 3 showing the relationship between the hemostasis valve, an intermediate tube and an inner control tube of one embodiment of the invention.

[0017] FIG. 4 is a perspective view of the delivery assembly of FIG. 1, showing two options for retraction of the introducer sheath from the stent graft.

[0018] FIG. 5 is a cross-section of the delivery assembly following partial retraction of the introducer sheath.

[0019] FIG. 6 is a perspective view of the delivery assembly of FIG. 1, wherein the introducer sheath has been fully retracted from the stent graft.

[0020] FIGs. 7A and 7B are perspective views of the embodiment shown in FIGs. 1 and 6, wherein the release pin is removed from the handle and hemostasis valve to permit retraction of the handle, the intermediate tube, and the inner control tube from the surgical site of the patient.

[0021] FIG. 8 is a cross-sectional view of the delivery assembly of FIG. 5 after partial retraction of a control tube and the tip within the stent graft.

[0022] FIGs. 9A and 9B are perspective views of the delivery assembly of the invention, wherein the tip has been completely retracted from the handle.

DETAILED DESCRIPTION OF THE INVENTION

[0023] The features and other details of the invention, either as steps of the invention or as combinations of parts of the invention, will now be more particularly described and pointed out in the claims. It will be understood that the particular embodiments of the invention are shown by way of illustration and not as limitations of the invention. The principal features of this invention can be employed in various embodiments without departing from the scope of the invention.

[0024] When reference is made herein to a prosthesis to be delivered, or implanted in a patient, such as vascular repair device, the word "proximal" means that portion of the prosthesis or component of the prosthesis that is towards the heart of the patient and "distal" means that portion of the prosthesis or component of the prosthesis that is away from the heart of the patient.

[0025] When, however, reference is made to a delivery system or a component of a delivery system employed to deliver, or implant a vascular repair device, such as a nose cone or handle of a delivery device, the word, "proximal," as employed herein, means closer to the clinician using delivery system. Likewise, "distal" means, when reference is made to a

delivery system or a component of a delivery system, such as a nose cone or handle of a delivery device, means further away from the clinician using the delivery system.

[0026] For clarity, the word "proximate" means close to as opposed to the meanings ascribed to "proximal" or "distal" as described above with respect to either the vascular repair device or delivery system.

[0027] Vascular repair devices of the invention can be implanted, for example, by transfemoral access. Additional vascular repair devices that are directed into the vascular repair devices of the invention can be implanted, for example, by supraaortic vessel access (e.g., through the brachial artery), or by transfemoral or transapical access, or by access from some other branches of major blood vessels, including peripheral blood vessels.

[0028] In one embodiment, represented in FIGs. 1-8, delivery assembly 10 of the invention, includes handle 12. Handle 12 has proximal end 14 and distal end 16, and defines a conduit. Handle 12 is formed of a suitable material, such as a suitable metal, such as aluminum, or a plastic, as would be known to those of skill in the art. Examples of suitable plastics include a polystyrene, a polypropylene, a polyvinyl chloride, a nylon carbonate, a polyester, a polyurethane, or any other suitable engineering plastic, as is known in the art. Hemostasis valve 18 includes proximal end 20 and distal end 22. Proximal end 20 of hemostasis valve 18 is releasably fixed to internal lead screw assembly 24 that is longitudinally moveable within the conduit of handle 12. Hemostasis valve 18 can be released from internal lead screw assembly 20 within the conduit of handle 12 by removal of release pin 26, as will be explained below. One example of a suitable hemostasis valve is described in U.S. Patent No.: 9,439,751, issued September 13, 2016, the relevant teachings of which are incorporated herein by reference in their entirety.

[0029] Introducer sheath 28 extends from hemostasis valve 18, to which it is fixed. Introducer sheath 20 includes proximal end 30 at hemostasis valve 18 and distal end 32. Introducer sheath 28 is fabricated of a suitable material, such as polyethylene terephthalate (e.g. Dacron®), fluorinated ethylene propylene (FEP), polytetrafluoro ethylene (i.e. Teflon®) or some other suitable flexible material, as is known to those of skill in the art. In one particular embodiment, introducer sheath is fabricated as a tube includes coiled Nitinol, a high density polyether (HDPE)/polyether block amide (e.g. PEBAX®), a stainless steel (SS) coil, and aramid fibers. Introducer sheath 28 defines a conduit. The conduits of handle 12, hemostasis valve 18, and introducer sheath 28, are essentially coaxial.

[0030] Inner control tube 34 extends through the conduits of handle 12, hemostasis valve 18, and introducer sheath 28. Inner control tube 34 has proximal end 36 that is proximal to proximal end 14 of handle 12 (FIG. 1) and distal end 38 at distal end 32 of introducer sheath 28 (FIG. 2). Inner control tube 34 defines a luminal conduit through which a guidewire (not shown) can be directed.

[0031] Tip 40 is fixed to distal end 38 of inner control tube 34 and also defines a conduit through which a guidewire can be directed. Tip 40 is formed of a suitable material, such as TECOTHANE® aromatic polyether based thermoplastic polyurethane (TPU), as is known to those skilled in the art.

[0032] Inner control tube 34 is fixed to handle 12 at proximal end 14. In one embodiment, inner control tube 34 is releasably fixed to handle 12 at proximal end 14, such as by use of pin 42 and can be retracted independently through introducer sheath 28 and handle 12, either manually or by a suitable mechanism, such as is described in U.S. Patent No.: 8,998,970, the relevant teachings of which are incorporated herein by reference in their entirety.

[0033] Typically, tip 40 has a smaller outside diameter than the conduit of introducer sheath 28 and the conduit of handle 12, so that inner control tube 34 and tip 40 can be retracted through introducer sheath 28 and the conduit of handle 12, and thereby be removed from within introducer sheath 28 and handle 12.

[0034] Handle includes distal grip 44 and handle body 46 extending proximally from proximal end 48 of distal grip 44, handle body 46 defines a conduit and track 50 along a portion of the length of distal grip 44 and handle body 46. Internal lead screw assembly 24 extends within the conduit of handle 12, and is moveable along major axis 52 of the conduit. Internal lead screw assembly 24 also includes threaded portion 54 that extends through track 50. Lead screw nut 56 extends about handle body 46 and is threadably engaged with threaded portion 54 of internal lead screw assembly 24, whereby rotation of lead screw nut 56 while abutting distal grip 44 causes movement of internal lead screw assembly 24 relative to handle 12 and wherein lead screw nut 56 simultaneously is slidable along handle body 46 while engaged with internal lead screw assembly 24, thereby providing at least two mechanisms for causing movement of internal lead screw assembly 24 relative to handle 12. Internal lead screw assembly 24 of delivery assembly 10 of the invention defines a central

opening essentially coaxial with handle 12, wherein inner control tube 34 extends through internal lead screw assembly 24, but, as described above, is fixed to handle 12.

[0035] As can be seen in FIG. 2, inner control tube 34 includes filler tubes 58 distributed and fixed to inner control tube 34 along its length from tip 40 to buttress 60 at intermediate tube 62. Intermediate tube 62 is fixed to inner control tube 34. Optionally, intermediate tube 62 and inner control tube 34 can be a unitary object. Filler tubes 58 are fixed to inner control tube 34 and have an outer diameter at distal end 64 that is greater than an outer diameter at proximal end 66 of at least a portion of filler tubes 58. Filler tubes are formed of a suitable material, such as is known in the art. Examples of such suitable material include polyether ether ketone (PEEK), acrylonitrile butadiene styrene (ABS), or any suitable engineering plastic, as described above with respect to handle 12.

[0036] Stent graft 68 extends about inner control tube 34 and filler tubes 58. Filler tubes 58 are distributed between stents 70 of stent graft 68, whereby distal movement of stents 70 along stent 68 graft during retraction of introducer sheath 28 is inhibited by interface with distal ends 64 of filler tubes 58, thereby preventing longitudinal compression of stent graft 68 during deployment and implantation of stent graft 68 at the aneurysm.

[0037] As shown in at least one of FIGs. 3 and 3A, hemostasis valve 18 of delivery assembly 10 includes hemostasis valve body 72 defining a central orifice through which inner control tube 34 extends, and flush valve orifice 74 extending substantially normal to the central orifice. Sheath valve knob 78 is threadably coupled to hemostasis valve body 72. Introducer sheath 28 extends distally from cap 76 and defines a lumen that is substantially aligned with the central opening of hemostasis valve 18. Inner control tube 34 extends through introducer sheath 28. Wiper valve 80 is at opening of hemostasis valve body 72 proximal to flush valve orifice 74. Wiper valve 80 forms a seal about inner control tube 34. X-valve 82 is at the central opening of the hemostasis valve body 72 proximal to wiper valve 80. X-valve 82 forms a seal about a guidewire (not shown) upon withdrawal of inner control tube 34 from hemostasis valve body 72. Sheath valve 84 is at the central opening of hemostasis valve body 72 and proximal to x-valve 82, sheath valve 84 being operable by activation of sheath valve knob 78 to thereby seal the central opening. In an embodiment, x-valve 82 includes a nitinol gasket.

[0038] In another embodiment, the invention is a method for delivering a stent graft to an aneurysm site. The method includes, in one embodiment, the steps of directing a distal end

of delivery assembly to an abdominal aortic aneurysm (AAA), a thoraco-abdominal aortic aneurysm (TAAA) or a thoracic aortic aneurysm (TAA), such as delivery assembly 10 of FIGs. 1-10. Thereafter introducer sheath 28 is retracted from stent graft 68 by at least one of rotation of lead screw nut 56, as shown by arrow 86 and Option I shown in FIG. 4, thereby exposing a proximal end of stent graft 68 to the aneurysm as shown in FIG. 5. Returning to FIG. 4, introducer sheath 28 can also be retracted simply by pulling lead screw nut 56 in a proximal direction along handle 46 without rotation of lead screw nut 56, as shown in Option II.

[0039] Following complete release of stent graft 68 from within introducer sheath 28, as shown in FIG. 6, release pin can be removed from internal lead screw assembly 24, as shown in FIGs. 7A and 7B. Once hemostasis valve 18 is released from internal lead screw assembly 24, inner control tube 34 and tip 40 can be retracted through implanted prosthesis stent graft, as shown in FIG. 8, and through hemostasis valve 18, as shown in FIG. 9A.

[0040] Hemostasis valve 18 is then closed by rotating sheath valve knob 78, as shown in FIG. 9B to prevent blood loss until other surgical steps, such as implantation of further stent graft components through hemostasis valve are completed. Hemostasis valve 18 and introducer sheath 28 can then be removed from the subject to complete the surgical procedure.

[0041] The relevant teachings of all patents, published applications and references cited herein are incorporated by reference in their entirety. The relevant teachings of U.S. Patent Nos. 8,292,943; 7,763,063; 8,308,790; 8,070,790; 8,740,963; 8,007,605; 9,320,631; 8,062,349; 9,198,786; 8,062,345; 9,561,124; 9,173,755; 8,449,595; 8,636,788; 9,333,104; 9,408,734; 9,408,735; 8,500,792; 9,220,617; 9,364,314; 9,101,506; 8,998,970; 9,554,929; 9,439,751 and U.S. Patent Application Nos. 14/226,005; 14/675,102; 15/099,974; 15/040,460; 14/575,673; 14/924,102; 15/166,818; 15/167,055; 14/736,978; 13/454,447; 15/384,663; 13/788,724; 15/417,467; 15/230,601; 14/272,818 and 14/861,479 are incorporated by reference in their entirety.

[0042] While this invention has been particularly shown and described with references to example embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the scope of the invention encompassed by the appended claims.

CLAIMS

What is claimed is:

1. A delivery device assembly, comprising:
   a) a handle;
   b) an inner control tube having a distal end, the inner control tube extending from the handle, the inner control tube having a proximal end at the handle and a distal end remote from the handle;
   c) a tip at the distal end of the inner control tube; and
   d) a plurality of filler tubes along the inner control tube, the plurality of filler tubes fixed to the inner control tube, each filler tube having a proximal end and a distal end, the distal end having an outer diameter greater than that of the proximal end.

2. The delivery device assembly of Claim 1, wherein at least one of the plurality of filler tubes has an outer diameter that is tapered between the proximal end and the distal end.

3. The delivery device of Claim 2, wherein the distal end of the plurality of filter tubes is wider than the proximal end.

4. The delivery device assembly of Claim 2, further including an introducer catheter extending distally from the handle to the tip at the distal end of the inner control tube, and extending about the inner control tube and the plurality of filler tubes, wherein the introducer catheter is retractable from at least a portion of the inner control tube and the plurality of filler tubes.

5. The delivery device assembly of Claim 4, further including a stent graft extending between the inner control tube and the introducer catheter, and including self-expanding stents, at least a portion of which are partitioned from each other by at least one of the plurality of filler tubes, whereby retraction of the introducer catheter will cause the distal end of at least one of the plurality of filler tubes to interfere with longitudinal movement of a self-expanding stent immediately distal to that filler tube,

thereby preventing longitudinal movement of the stent graft during retraction of the introducer catheter.

6. The delivery device assembly of Claim 5, wherein at least a portion of the stents of the stent graft include angled stents that define distal and proximal apices.

7. The delivery device assembly of Claim 6, wherein the stents of the stent graft are formed of a metal alloy.

8. The delivery device of Claim 7, wherein the metal alloy is a shape memory alloy.

9. The delivery device of Claim 8, wherein the shape memory alloy is nitinol.

10. A method of implanting a stent graft, comprising the steps of:

a) a directing a stent graft to an aneurysm site, the stent graft being captured between an inner control tube that extends distally from a handle and is within the stent graft, and an introducer catheter that extends distally from the handle and about the stent graft, the stent graft including a plurality of stents along a graft component of the stent graft, wherein at least a portion of the stents are partitioned from each other by at least one filler tube of a plurality of filler tubes fixed to the inner control tube; and

b) actuating the handle to retract the introducer catheter proximally from about the stent graft, the at least one filler tube preventing longitudinal movement of a stent distal to the filler tube, thereby preventing longitudinal movement of the stent graft during retraction of the introducer catheter, the retraction of the introducer catheter causing implantation of the stent graft.

11. The method of Claim 10, wherein at least one of the filler tubes has an outer diameter that is tapered between the proximal end and the distal end.

12. The method of Claim 11, wherein the distal end of the plurality of filter tubes is wider than the proximal end.

13. The method of Claim 12, wherein at least a portion of the stents of the stent graft include angled stents that define distal and proximal apices.

14. The method of Claim 11, wherein the stents of the stent graft are formed of a metal alloy.

15. The method of Claim 14, wherein the metal alloy is a shape memory alloy.

16. The method of Claim 15, wherein the shape memory alloy is nitinol.

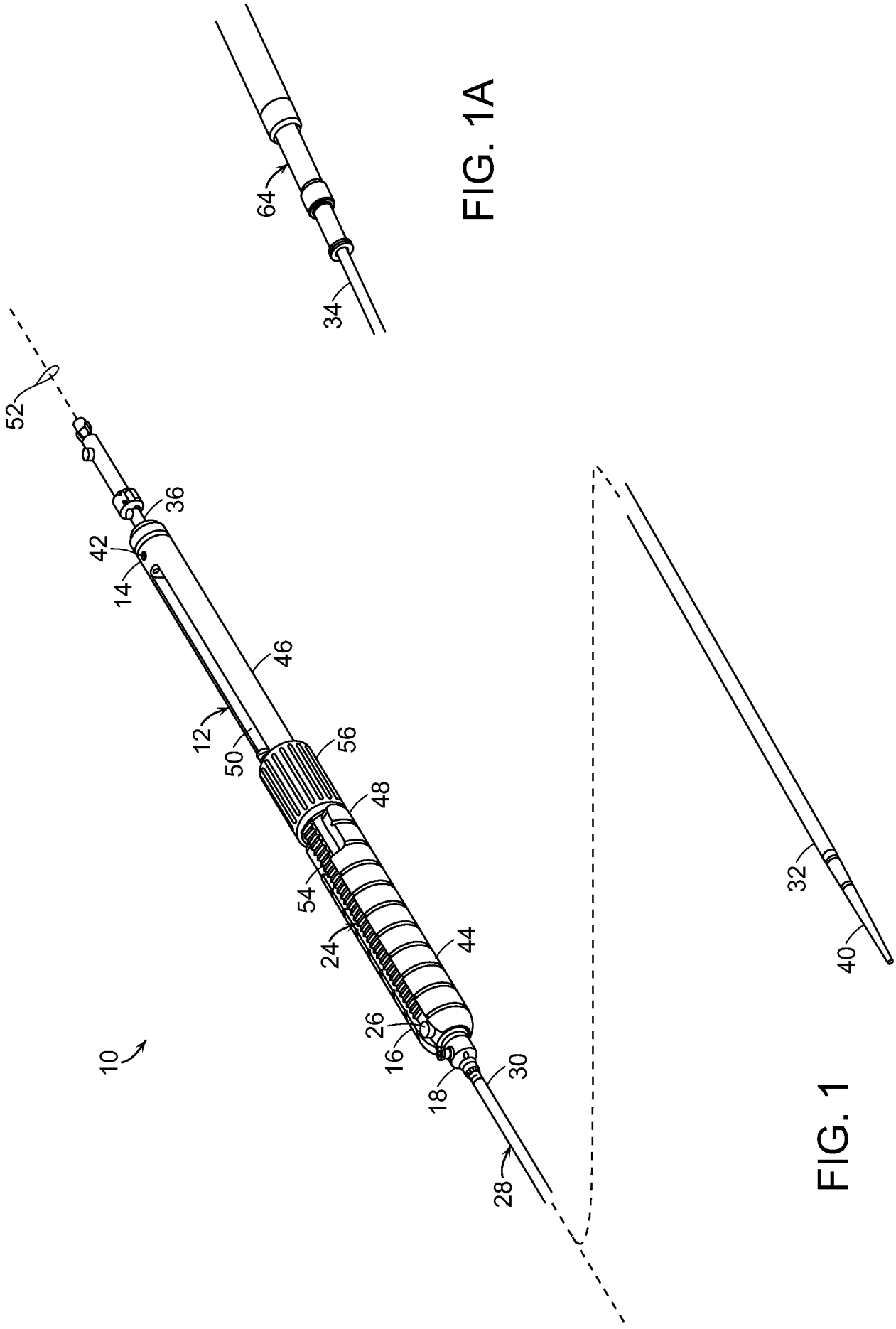

FIG. 1A

FIG. 1

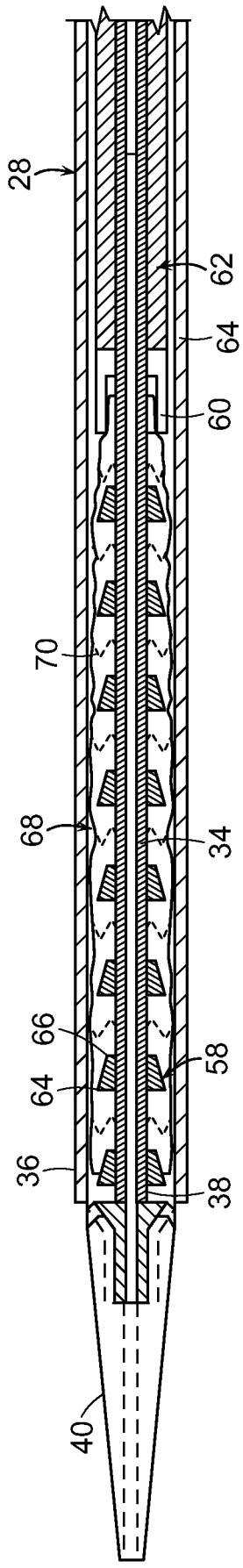

FIG. 2

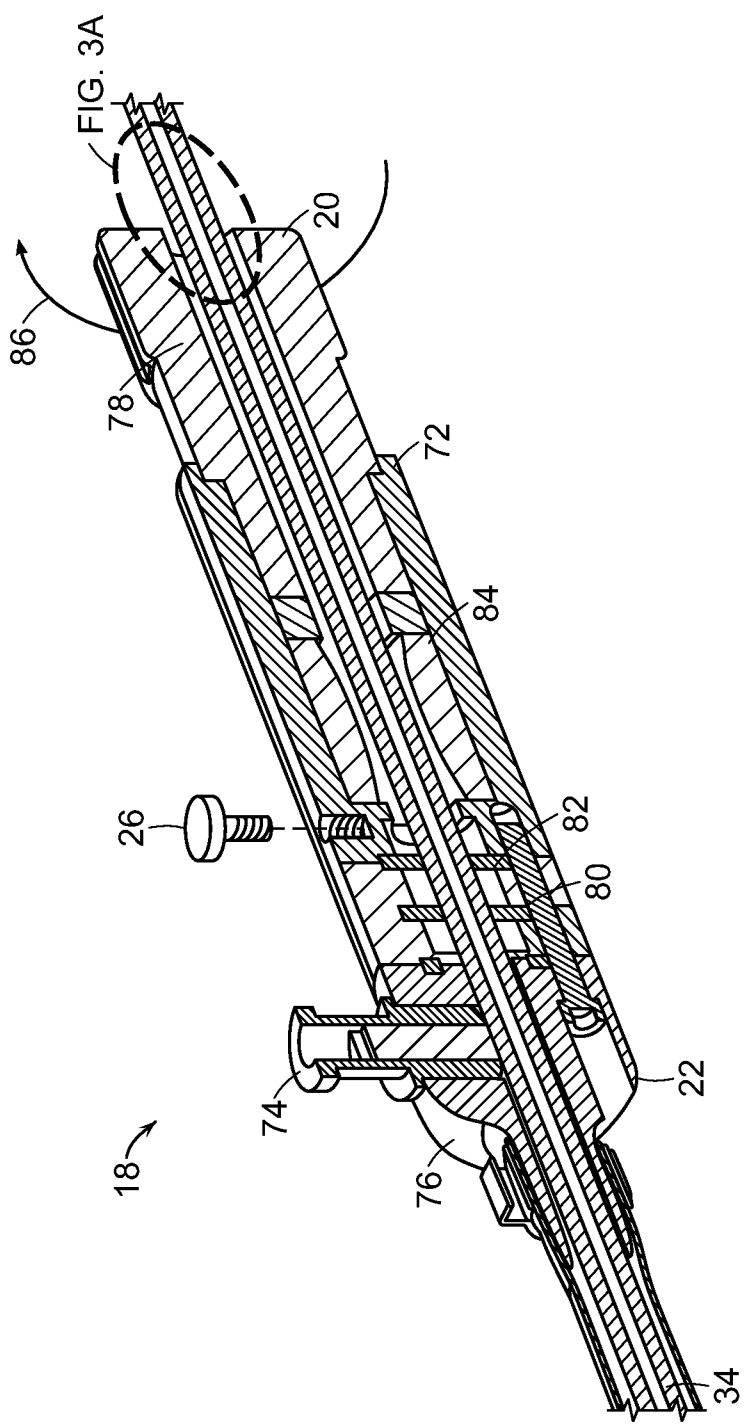

FIG. 3

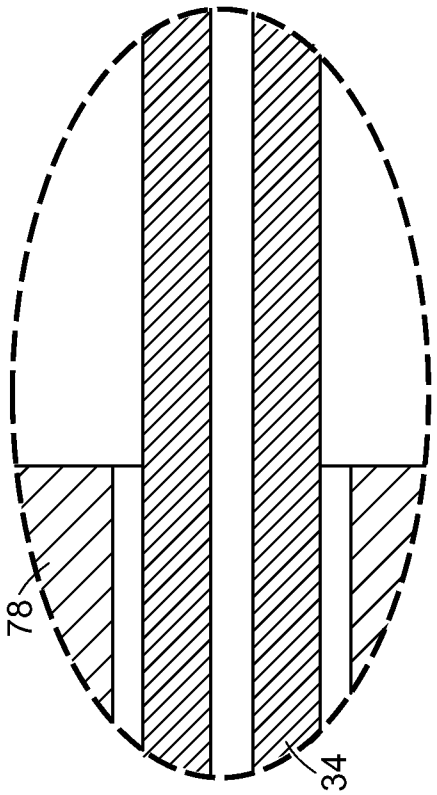

FIG. 3A

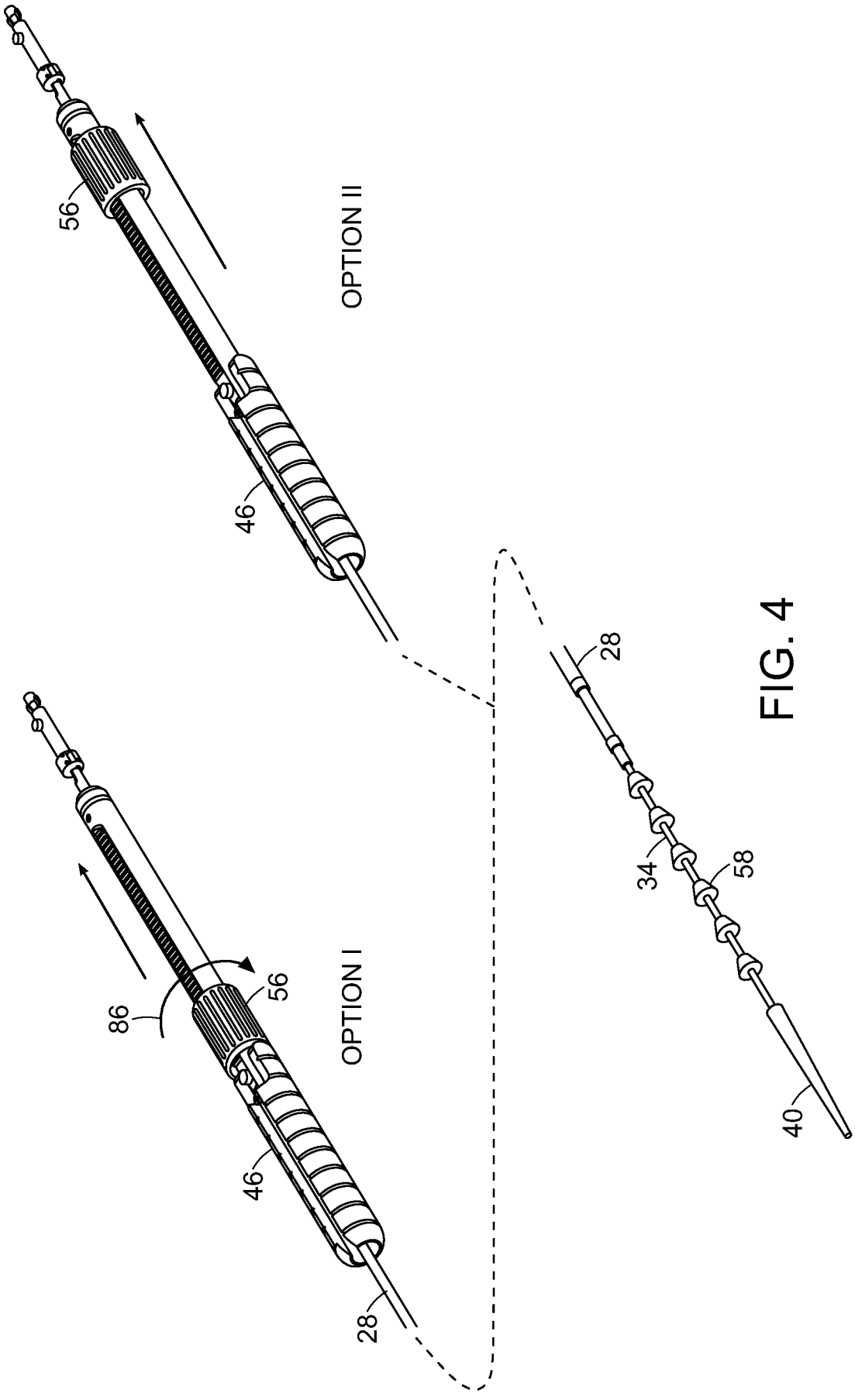

FIG. 4

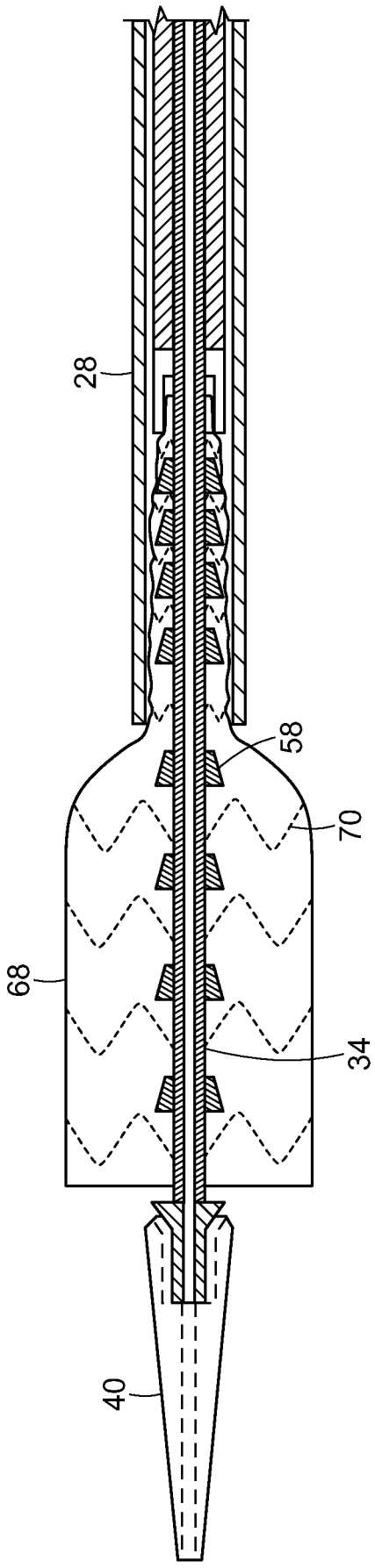

FIG. 5

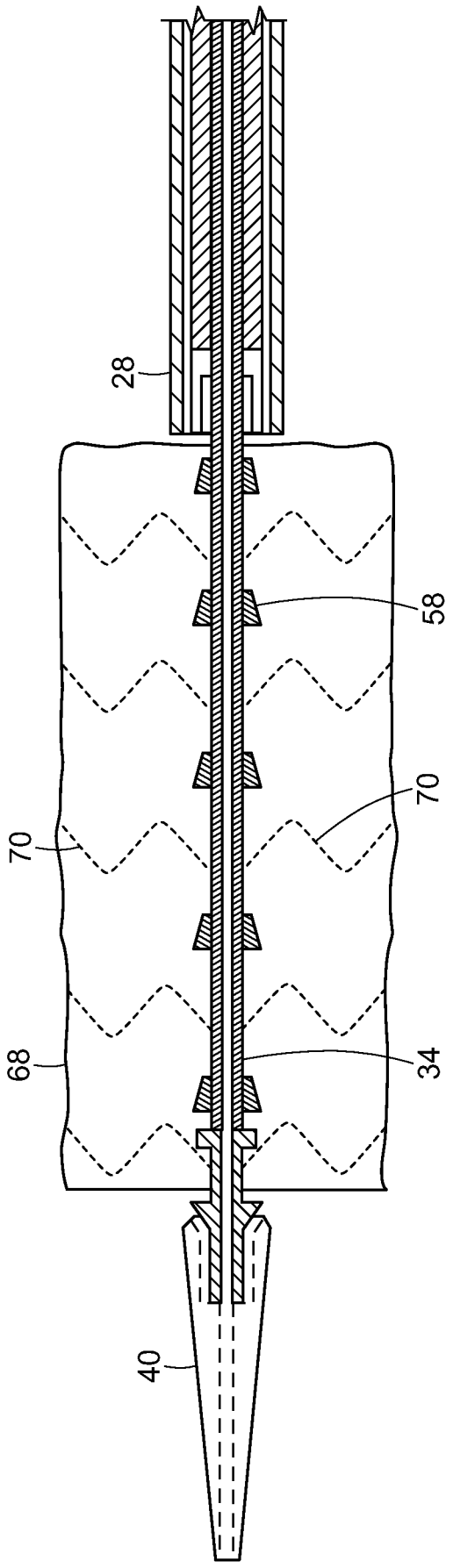

FIG. 6

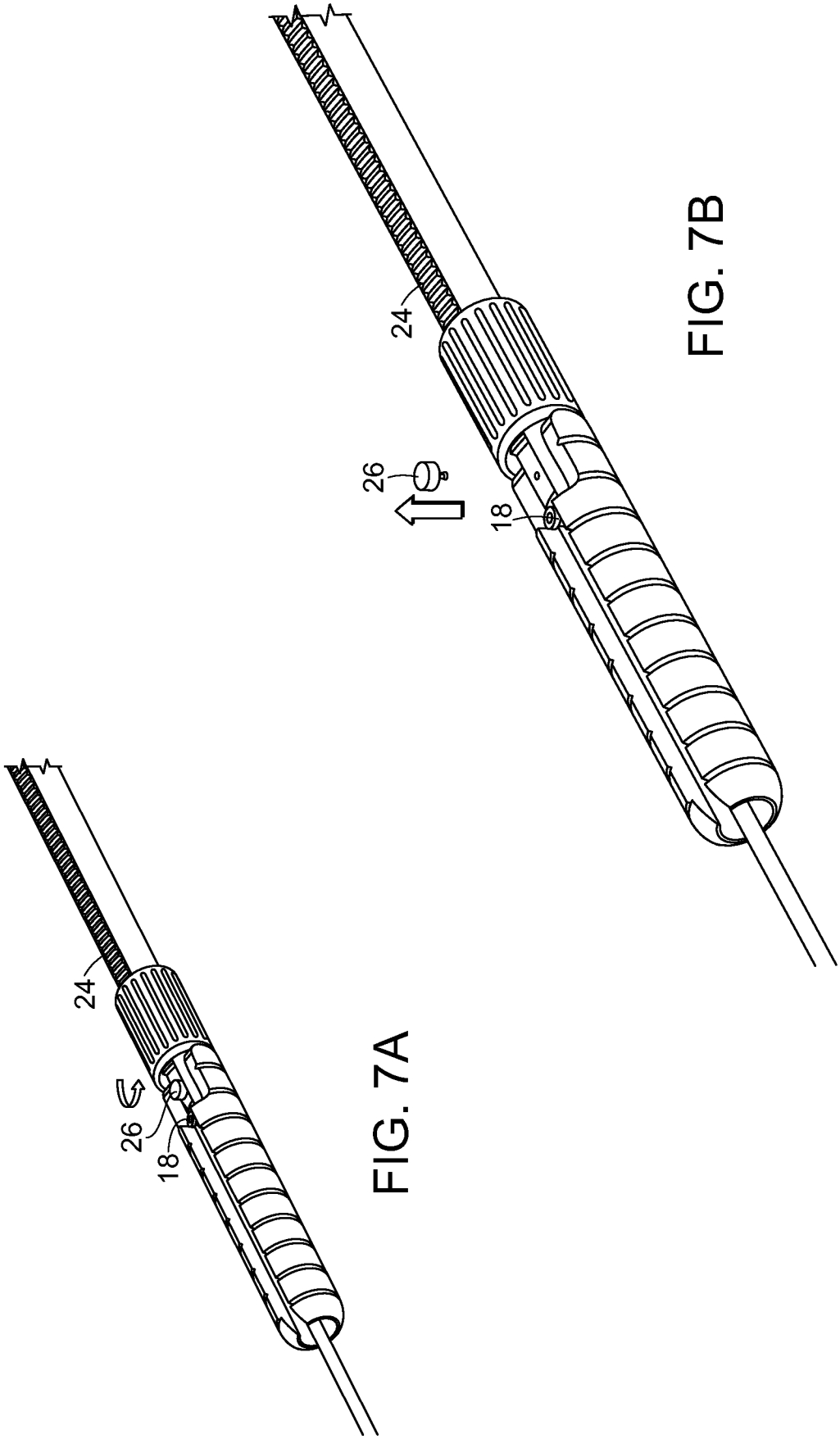

FIG. 7B

FIG. 7A

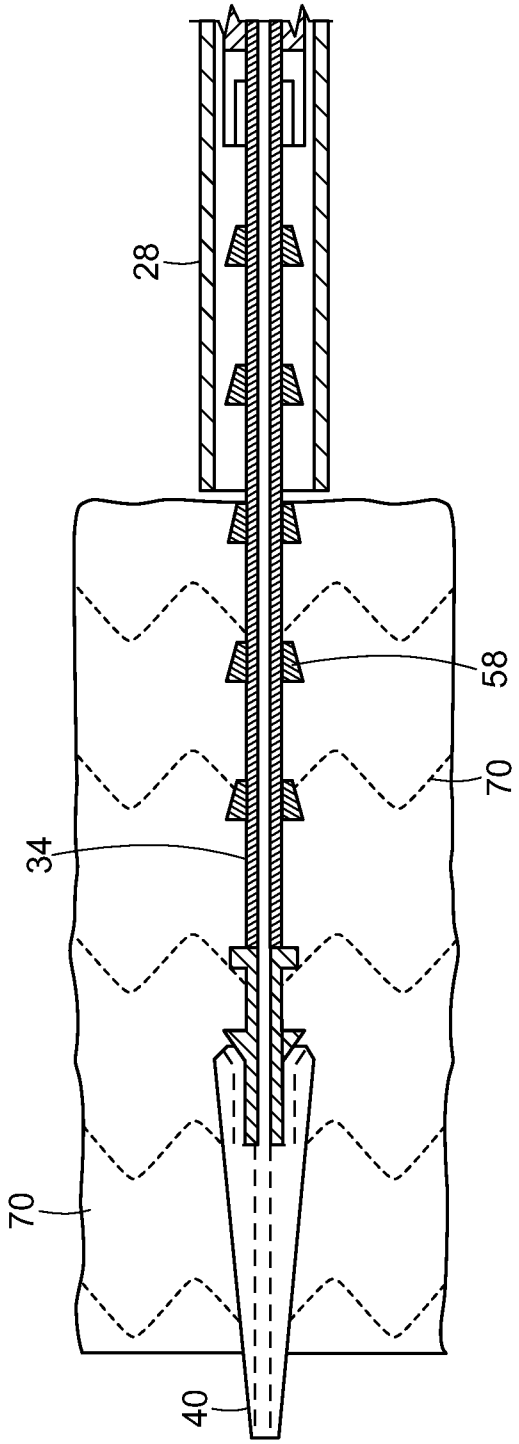

FIG. 8

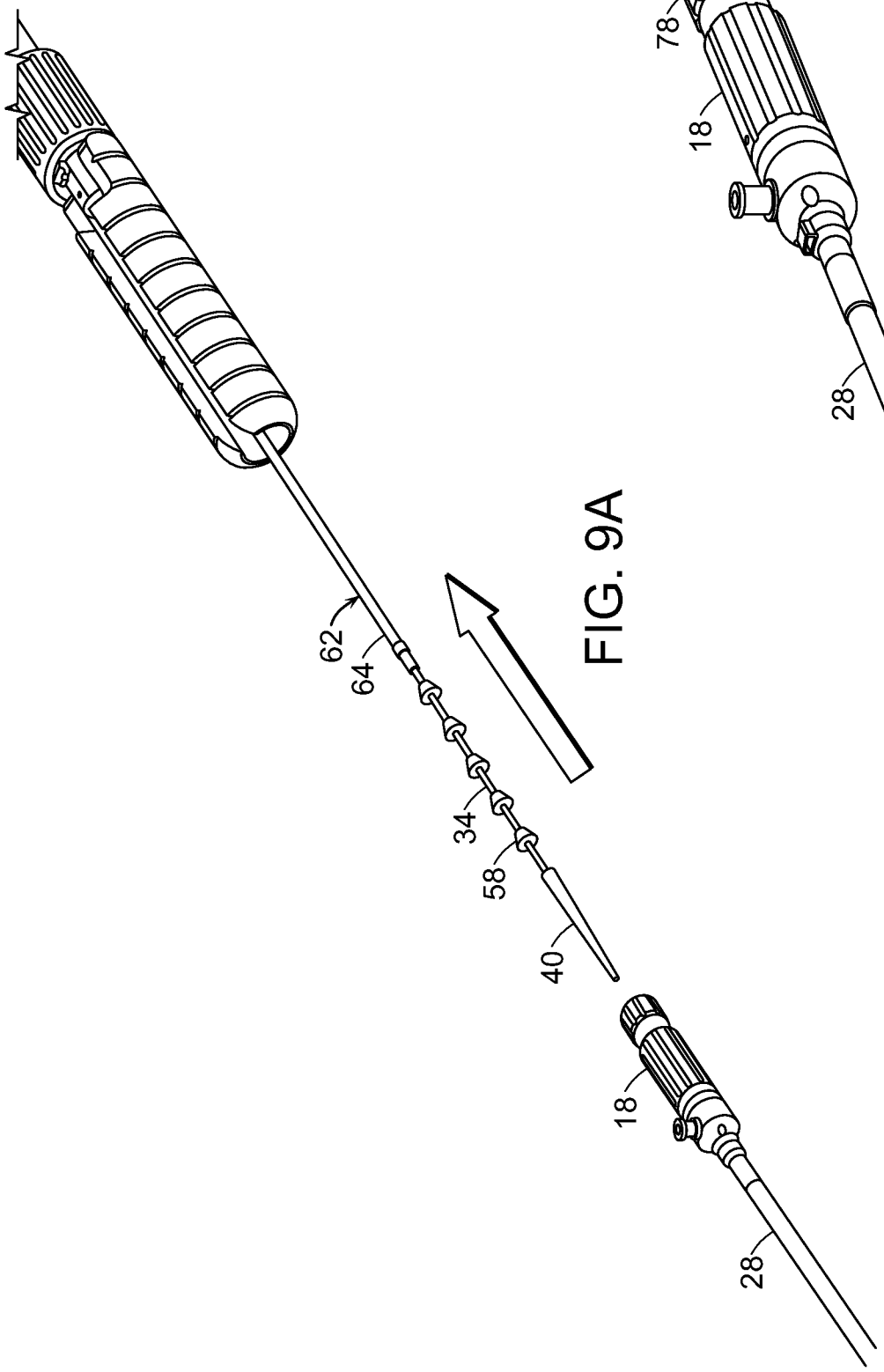

FIG. 9A

FIG. 9B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/025849

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/966
ADD. A61F2/07

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP 1 803 423 A2 (CORDIS CORP [US]) 4 July 2007 (2007-07-04) paragraphs [0013] - [0021]; figures 1-7	1-6 7-9
X	US 2010/274226 A1 (HANSEN PALLE M [DK]) 28 October 2010 (2010-10-28) paragraphs [0058] - [0064], [0077]; figure 7	1-6
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Y A	US 2012/271408 A1 (COLGAN DARRAGH [IE] ET AL) 25 October 2012 (2012-10-25) paragraphs [0077], [0147] - [0152]; figures 4d, 17-18	7-9 1-6

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

☒ See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 May 2017	07/06/2017

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/025849

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

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

1. [X] Claims Nos.: 10-16
because they relate to subject matter not required to be searched by this Authority, namely:

Claim 10-16 are considered a method for treatment of the human or animal body by surgery (Rule 39.1(iv) PCT) as it involves the insertion and delivery of an implant in the body

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

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

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

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

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

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

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

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

Remark on Protest

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

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

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2017/025849

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