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(54) DEPLOYMENT CATHETER FOR ENDOLUMINAL DEVICES

FREISETZUNGSKATHETER FÜR ENDOLUMINALE VORRICHTUNGEN

DÉPLOIEMENT DE DISPOSITIFS ENDOLUMINAUX

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Description

BACKGROUND

Cross Reference to Related Applications

[0001] This application is a non-provisional of, and claims priority to, U.S. Provisional Patent Application No. 61/412,647, entitled "Deployment of Endoluminal Devices," filed November 11, 2010.

Field

[0002] The present disclosure relates to the transcatheter delivery and remote deployment of implantable medical devices and, more particularly, implantable intraluminal devices of either the self-expanding type or the balloon expandable type.

Discussion of the Related Art

[0003] Endoluminal therapies typically involve the insertion of a delivery catheter that transports an implantable prosthetic device into the vasculature through a small, often percutaneous, access site in a remote vessel. Once access to the vasculature is achieved, the delivery catheter is used to mediate intraluminal delivery and subsequent deployment of the prosthesis via one of several techniques. In this fashion, the prosthesis can be remotely implanted to achieve a therapeutic outcome. In contrast to conventional surgical therapies, endoluminal treatments are distinguished by their "minimally invasive" nature.

[0004] Expandable endoprostheses are generally comprised of a stent component with or without a graft covering over the stent interstices. They are designed to spontaneously dilate (i.e., elastically recover) or to be balloon-expanded from their delivery diameter, through a range of intermediary diameters, up to a maximal, predetermined functional diameter. The endoluminal delivery and deployment of expandable endoprostheses pose several unique problems. First, the endoprosthesis itself must be radially compacted to a suitable introductory size (or delivery diameter) to allow insertion into the vasculature, then it must be constrained in that compacted state and mounted onto a delivery device such as a catheter shaft. Subsequently, the constraint must be removed in order to allow the endoprosthesis to expand to its functional diameter and achieve the desired therapeutic outcome. A variety of ways of constraining and releasing an expandable device are known in the art.

[0005] US 2006/0015171 A1 discloses a constraining sheath for use around an endoprosthesis. The endoprosthesis is coaxially enclosed within and substantially covered by the constraining sheath, which is an outer, removable tubular sheath, preferably made of ePTFE. The sheath is preferably corrugated circumferentially along at least a portion of the length of the endoprosthesis. The

constraining sheath and endoprosthesis are preferably mounted together as an assembly at the distal end of a delivery means such as a catheter shaft, for delivery of the endoprosthesis to a desired location within a body conduit such as an artery. The constraining sheath is removed by the application of tension to a tensile member such as a tether to cause sequential pulling out of the corrugations followed by release and deployment of the endoprosthesis. The use of a corrugated constraining sheath in comparison to a non-corrugated sheath results in a more smoothly applied tensile force to effect the endoprosthesis release as well as requiring less maximum force. Another stent delivery catheter is disclosed in US5873906.

[0006] It remains desirable to provide improved systems for endoluminal delivery of stents or stent grafts to vascular treatment sites.

[0007] This need is overcome by a catheter assembly according to claim 1 and a method of manufacture of the catheter assembly according to claim 9.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] In the following drawings:

Fig. 1 is a side view of a catheter assembly having a compacted and constrained medical device near a distal end of the catheter.

Figs. 2a through 2c are partial side perspective views of an expandable medical device shown in various stages of deployment.

Figs. 3a through 3c, 3c' and 3c" are side views and perspective views depicting a method of making a flexible constraining sleeve with two releasable seams.

Figs 4a through 4c are side views and a perspective view of a lock wire for releasably coupling the medical device to the catheter.

DETAILED DESCRIPTION

[0009] Persons skilled in the art will readily appreciate that various aspects of the present disclosure can be realized by any number of methods and apparatuses configured to perform the intended functions. Stated differently, other methods and apparatuses can be incorporated herein to perform the intended functions. It should also be noted that the accompanying drawing figures referred to herein are not all drawn to scale, but can be exaggerated to illustrate various aspects of the present disclosure, and in that regard, the drawing figures should not be construed as limiting. Finally, although the present disclosure can be described in connection with various principles and beliefs, the present disclosure should not be bound by theory.

[0010] Throughout this specification and in the claims, the term "distal" can refer to a location that is, or a portion of an intraluminal device (such as a stent-graft) that when

implanted is, further downstream with respect to blood flow than another portion of the device. Similarly, the term "distally" can refer to the direction of blood flow or further downstream in the direction of blood flow.

[0011] The term "proximal" can refer to a location that is, or a portion of an intraluminal device that when implanted is, further upstream with respect to blood flow. Similarly, the term "proximally" can refer to the direction opposite to the direction of blood flow or upstream from the direction of blood flow.

[0012] With further regard to the terms proximal and distal, and because the present disclosure is not limited to peripheral and/or central approaches, this disclosure should not be narrowly construed with respect to these terms. Rather, the devices and methods described herein can be altered and/or adjusted relative to the anatomy of a patient.

[0013] In various embodiments, a catheter assembly is disclosed which utilizes a single flexible sleeve that releasably maintains an expandable device, such as an expandable endoluminal graft, to a dimension suitable for endoluminal delivery of the device to a treatment site, such as a vascular member in a patient's body; and further limits expansion of the device to an outer peripheral dimension that is smaller than an unconstrained or fully deployed outer peripheral dimension thereby facilitating selective axial and/or rotational positioning of the device at the treatment site prior to full deployment and expansion of the device toward engagement with inner walls of the vasculature at the treatment site.

[0014] In various embodiments, for example as shown in Figure 1, the catheter assembly, which is generally indicated at 100, includes a catheter 102, an expandable device 104 and a restraining member or flexible sleeve 106. The catheter 102 extends longitudinally and has opposite proximal 110 and distal 108 ends. The catheter 102 also includes a lumen 112 extending between the proximal 110 and distal 108 ends.

[0015] The expandable device 104 is disposed at or near the proximal end 110 of the catheter 102. The device 104 is expandable to engage surrounding tissue at the treatment site, such as inner surfaces of a vascular member. The device 104 can include a self-expanding nitinol frame that expands the device 104 upon deployment at the treatment site. The device 104 can also be balloon expandable.

[0016] In various embodiments, the flexible sleeve 106 extends around the device 104 and has a first outer peripheral dimension 208, at which the flexible sleeve 106 constrains and releasably maintains the device 104 in a collapsed state or small diameter delivery profile suitable for endoluminal delivery and advancement through typical vasculature to a treatment site. Fully opening the sleeve 106 allows the device 104 to fully expand toward an unconstrained or fully deployed outer peripheral dimension of the device 104, wherein the device 104 is fully expanded and not constrained by the flexible sleeve and/or vasculature. It should be appreciated that the de-

vice can be oversized relative to the intended vasculature to be treated to promote engagement between the device and the inner walls of the vasculature at the treatment site.

[0017] The flexible sleeve can have various configurations for constraining the sleeve. In various embodiments, the sleeve 106 includes generally opposite portions or edges each with a plurality of openings. The openings are arranged to form stitch lines that extend along the opposite portions of the sleeve 106. The sleeve 106 can extend around the device 104 and the opposite portions brought together to form a releasable seam 206, as shown in Figure 2a. The releasable seam 206 can be held together by an elongated coupling member extending through or woven through the openings. Examples of coupling members include control tethers, wires, lines, and the like. The control member can extend through a catheter shaft 102 and be accessed through proximal connectors as indicated, for example, at 112, 114 or 116. Tensioning, actuation and displacement of the coupling member from the openings allows the sleeve 106 to open along the seam 206 and the device 104 to expand toward a larger diameter. Examples of restraining members and coupling members for releasably maintaining expandable devices in a collapsed state for endoluminal delivery can be found in U.S. 6,352,561 to Leopold et al.

[0018] According to the invention the flexible sleeve 106 is configured to maintain the device 104 in an intermediate state, as illustrated in Figure 2b, in which the sleeve 106 is maintained at a second outer peripheral dimension that is larger than the first outer peripheral dimension of the sleeve 106, yet smaller than the fully deployed outer peripheral dimension of the device 104. Thus, when the device 104 is positioned generally at or near the treatment site, the flexible sleeve 106 can be actuated to allow the sleeve 106 to expand or be pushed outwardly toward the intermediate state by a generally radially outward force applied by expansion of the device 104 by, for example, a balloon and/or by a stent or wire frame portion of the device. Maintaining the device in the intermediate state allows the clinician to adjust the axial and/or rotational position of the device with respect to the vasculature prior to full release and expansion of the device toward the fully deployed outer peripheral dimension and engagement with surrounding vasculature tissue.

[0019] According to the invention the sleeve is maintained in this intermediate state or second outer peripheral dimension 204 by a second releasable seam 202 held together by a portion of the same coupling member used to secure the first releasable seam or, alternatively, by a separate coupling member separate from the first releasable seam, which, however, is not covered by the invention. Thus, in various embodiments, a single flexible sleeve is formed having a multi-stage deployment. In a dual stage configuration, for example, the sleeve can have a first outer peripheral dimension, indicated at 208 in Figure 2a, releasably maintained by a first releasable

seam 206 and a second outer peripheral dimension, indicated at 204 in Figure 2b, releasably maintained by a second releasable seam 202. In various other embodiments, the sleeve can be formed with more than two states or stages and associated multiple outer peripheral dimensions can be utilized leading toward the final fully deployed outer peripheral dimension by incorporating additional releasable seam arrangements.

[0020] A method of forming a restraining member in accordance with the present disclosure is generally illustrated by the sequence of Figures 3a through 3c, in which a restraining member have a multi-stage deployment is formed by interconnecting portions of a flexible sheet together to form a releasable seam to define a lumen with a first outer peripheral dimension and interconnecting other portions of the flexible sheet together to form another releasable seam to reduce the size of the lumen to a second outer peripheral dimension. Shown in Figure 3a is an edge view of a flexible sheet material 200 that will be subsequently formed into a restraining member. In various embodiments, the sheet can be formed by flattening a tube of flexible material, such as ePTFE, so that the resulting lumen is double-walled.

[0021] The sheet 200 is folded over onto itself to form a lumen, as shown in Figure 3b. Portions or edges of the folded sheet 200 are then stitched with a coupling member to form a releasable seam 202. The resulting lumen limits expansion of the device to the intermediate state, as discussed above.

[0022] Other portions of the flexible sheet are then folded and interconnected to form an additional releasable seam 206 to further reduce the size of the lumen to an outer peripheral dimension suitable for endoluminal delivery of the device. The cross sectional area 210 roughly illustrates the area in which the device will be constrained.

[0023] The seams 202, 206, as shown in the illustrated embodiment in Figure 3C, are generally radially aligned or positioned substantially along the same side of the area 210. In various other embodiments, however, the seams can be offset rotationally about the area 210. The seams, for example, can be disposed on opposite sides of the area 210 relative to each other.

[0024] To reiterate the delivery sequence, the device (Figure 1, 104) is initially constrained to a small diameter delivery state as shown in Figure 2a. The flexible sleeve 106, while in this small diameter state, has a small or first outer peripheral dimension 208 suitable for endoluminal delivery of the device to a treatment site. When the releasable first seam 206 is actuated, the sleeve 106 will expand to a larger diameter state or second outer peripheral dimension 204, as shown in Figure 2b, due to a generally radially outward force applied by the expansion of the device 104, either by balloon and/or by a stent or wire frame portion of the device. To complete delivery or full deployment of the device at the treatment site, the releasable second seam 202 is actuated which "splits open" the sleeve 106 to allow the device to expand toward the fully deployed outer peripheral dimension and en-

gage surrounding tissue at the treatment site.

[0025] In various embodiments, a flexible sleeve used for a constraint can comprise materials similar to those used to form a graft. In various other embodiments, the precursor flexible sheet (Figure 2a, 200) can be formed from a flattened, thin wall tube. A thin wall tube (as well as a sheet) can incorporate "rip-stops" in the form of longitudinal high strength fibers attached or embedded into the sheet or tube wall.

[0026] To allow manipulation and repositioning of the partially expanded device via a catheter, the device, in various embodiments, is releasably coupled to the catheter. In various embodiments, a partially or fully expanded stent or stent graft may be releasably coupled to a catheter by, for example, removable tie-lines, clips and the like.

[0027] In other embodiments, as shown in Figures 4a and 4c, a catheter shaft 400 having generally opposite distal 404 and proximal ends 406 is positioned adjacent a stent graft wall 412, either internally or externally with respect to the stent graft. To releasably couple the catheter shaft 400 to the stent graft wall 412, an elongated member 402, such as a wire, can extend through a distal end 404 of the catheter shaft 400. The elongated member 402 can further extend through the catheter lumen and extend outwardly through a distal side wall opening 408. The elongated member can form a loop, penetrating the graft wall 412 through at least one aperture 413 in the graft wall 412 and returning into the catheter lumen through a proximal side wall opening 410. The elongated member 402 is, by this arrangement, releasably coupled to the graft wall, allowing manipulation and repositioning of the graft as required. Alternatively, the elongated member can extend through an apice of a wire frame or at least extend around a portion of the wire frame to releasably couple the catheter shaft to the stent graft wall.

[0028] When the graft is positioned at a desired location along the treatment site, the catheter 400 can be disengaged from the graft wall 412 to allow removal of the catheter from the treatment site and allow the stent graft to remain in place at the treatment site. More specifically, as shown in Figure 4b, the catheter can be released from the graft wall by retracting the elongated member 402 in a distal direction as depicted by direction arrow 414. The elongated member can exit both catheter side wall holes 408, 410 and be fully withdrawn from the catheter lumen.

[0029] An elongated member 402, as shown in Figure 4b, can be threaded through a graft wall, through a stent frame or through a graft/stent coupling element such as a hook. In various embodiments, elongated members can also be attached to a graft through a "cork-screw" configuration. Such a cork-screw can be twisted to engage and penetrate a graft wall (or lock to a stent frame) and be un-twisted to release the elongated member from the graft/stent.

[0030] Elongated members or lock wires, in various embodiments, can be formed from metallic, polymeric or

natural materials and can comprise conventional medical grade materials such as nylon, polyacrylamide, polycarbonate, polyethylene, polyformaldehyde, polymethylmethacrylate, polypropylene, polytetrafluoroethylene, polytrifluorochlorethylene, polyvinylchloride, polyurethane, elastomeric organosilicon polymers; metals such as stainless steels, cobalt-chromium alloys and nitinol. In other various embodiments, elongated members or lock wires can also be formed from high strength polymer fibers such as ultra high molecular weight polyethylene fibers (e.g., Spectra®, Dyneema Purity®, etc.) or aramid fibers (e.g., Technora®, etc.).

[0031] When the graft is positioned at a desired location along the treatment site, the flexible sleeve 106 can be further actuated to allow the sleeve 106 to "split open" and fully release the device 104, as illustrated in Figure 2c. The device 104 can then expand toward the fully deployed outer peripheral dimension and engage the vascular wall. Referring back to Figure 4b, the catheter can be released from the graft wall of the now-deployed device 104 by retracting the elongated member 402 in a distal direction as depicted by direction arrow 414. The elongated member can exit both catheter side wall holes 408, 410 and be fully withdrawn from the catheter lumen.

[0032] Stents can have various configurations as known in the art and can be fabricated, for example, from cut tubes, wound wires (or ribbons) or flat patterned sheets rolled into a tubular form. Stents can be formed from metallic, polymeric or natural materials and can comprise conventional medical grade materials such as nylon, polyacrylamide, polycarbonate, polyethylene, polyformaldehyde, polymethylmethacrylate, polypropylene, polytetrafluoroethylene, polytrifluorochlorethylene, polyvinylchloride, polyurethane, elastomeric organosilicon polymers; metals such as stainless steels, cobalt-chromium alloys and nitinol and biologically derived materials such as bovine arteries/veins, pericardium and collagen. Stents can also comprise bioresorbable materials such as poly(amino acids), poly(anhydrides), poly(caprolactones), poly(lactic/glycolic acid) polymers, poly(hydroxybutyrates) and poly(orthoesters).

[0033] Potential materials for a graft member include, for example, expanded polytetrafluoroethylene (ePTFE), polyester, polyurethane, fluoropolymers, such as perfluorelastomers and the like, polytetrafluoroethylene, silicones, urethanes, ultra high molecular weight polyethylene, aramid fibers, and combinations thereof. One preferred embodiment for a graft material is ePTFE. Other embodiments for a graft member material can include high strength polymer fibers such as ultra high molecular weight polyethylene fibers (e.g., Spectra®, Dyneema Purity®, etc.) or aramid fibers (e.g., Technora®, etc.). The graft member can include a bioactive agent. In one embodiment, an ePTFE graft includes a carbon component along a blood contacting surface thereof.

[0034] Typical materials used to construct catheters can comprise commonly known materials such as Amorphous Commodity Thermoplastics that include Polyme-

thyl Methacrylate (PMMA or Acrylic), Polystyrene (PS), Acrylonitrile Butadiene Styrene (ABS), Polyvinyl Chloride (PVC), Modified Polyethylene Terephthalate Glycol (PETG), Cellulose Acetate Butyrate (CAB); Semi-Crystalline Commodity Plastics that include Polyethylene (PE), High Density Polyethylene (HDPE), Low Density Polyethylene (LDPE or LLDPE), Polypropylene (PP), Polymethylpentene (PMP); Amorphous Engineering Thermoplastics that include Polycarbonate (PC), Polyphenylene Oxide (PPO), Modified Polyphenylene Oxide (Mod PPO), Polyphenylene Ether (PPE), Modified Polyphenylene Ether (Mod PPE), Thermoplastic Polyurethane (TPU); Semi-Crystalline Engineering Thermoplastics that include Polyamide (PA or Nylon), Polyoxyethylene (POM or Acetal), Polyethylene Terephthalate (PET, Thermoplastic Polyester), Polybutylene Terephthalate (PBT, Thermoplastic Polyester), Ultra High Molecular Weight Polyethylene (UHMW-PE); High Performance Thermoplastics that include Polyimide (PI, Imidized Plastic), Polyamide Imide (PAI, Imidized Plastic), Polybenzimidazole (PBI, Imidized Plastic); Amorphous High Performance Thermoplastics that include Polysulfone (PSU), Polyetherimide (PEI), Polyether Sulfone (PES), Polyaryl Sulfone (PAS); Semi-Crystalline High Performance Thermoplastics that include Polyphenylene Sulfide (PPS), Polyetheretherketone (PEEK); and Fluoropolymers that include Fluorinated Ethylene Propylene (FEP), Ethylene Chlorotrifluoroethylene (ECTFE), Ethylene, Ethylene Tetrafluoroethylene (ETFE), Polychlorotrifluoroethylene (PCTFE), Polytetrafluoroethylene (PTFE), Polyvinylidene Fluoride (PVDF), Perfluoroalkoxy (PFA). Other commonly known medical grade materials include elastomeric organosilicon polymers, polyether block amide or thermoplastic copolyether (PEBAX) and metals such as stainless steel and nickel/titanium alloys.

[0035] It will be apparent to those skilled in the art that various modifications and variations can be made in the present invention within the scope of the appended claims and their equivalents.

Claims

1. A catheter assembly comprising:

a catheter (102) having opposite proximal and distal ends, the catheter having a lumen extending between the proximal and distal ends of the catheter;

an expandable device (104) disposed at the distal end of the catheter and expandable toward a fully deployed outer peripheral dimension; and a flexible sleeve (106) extending around the device, **characterised in that** the flexible sleeve has a releasable first seam (206) that maintains the sleeve at a first dimension suitable for en-

- doluminal delivery (208) of the device to a treatment site, and a releasable second seam (202) that maintains the sleeve at a second dimension (204) larger than the first dimension (208) and smaller than the fully deployed outer peripheral dimension of the device (104), wherein the first and second seams (206, 202) are releasably held together by a common coupling member.
2. The catheter assembly as set forth in claim 1, wherein the coupling member comprises a control tether, a wire, or a line.
 3. The catheter assembly as set forth in claim 1, wherein a substantial portion of an inner surface of the flexible sleeve (106) remains in contact with the device (104) before and after actuation of the second coupling member.
 4. The catheter assembly as set forth in claim 1, wherein the device (104) remains constrained by the flexible sleeve (106) both before and after actuation of the first coupling member.
 5. The catheter assembly as set forth in claim 1, wherein the first seam (206) and second seam (202) are generally radially aligned with respect to a longitudinal axis of the catheter, optionally wherein the second seam (202) is disposed between the longitudinal axis of the catheter (102) and the first seam (206); and optionally wherein the flexible sleeve (106) is formed from a flattened tube to form a double-walled lumen extending about the device (104), and optionally wherein the flattened tube is formed of ePTFE.
 6. A catheter assembly as set forth in claim 1, wherein the releasable first seam (206) maintains the sleeve at a first outer peripheral dimension (208) suitable for endoluminal delivery and deployment of the device to a treatment site, and the releasable second seam (202) limits expansion of the sleeve (106) to a second outer peripheral dimension (204) larger than the first outer peripheral dimension (208) and smaller than the fully deployed outer peripheral dimension of the device (104) after release of the releasable first seam (206).
 7. The catheter assembly as set forth in claim 6 including at least a portion of an elongated member (402) extending through the catheter lumen and being movable relative to the catheter (400).
 8. The catheter assembly as set forth in claim 7, wherein a portion of the elongated member (402) exits the catheter lumen through a distal side wall opening (408) so as to extend along an outside surface of the catheter, and enters the catheter lumen through a proximal side wall opening (410); optionally wherein the portion of the elongated member (402) engages the device between the distal and proximal side openings (408, 410) thereby releasably coupling the device and the catheter; and optionally wherein the device (104) includes a stent frame and the portion of the elongated member (402) engages the stent frame thereby releasably coupling the device (104) and the catheter (400); and optionally wherein the portion of the elongated member (402) extends between an apice of the stent frame and a graft wall (412) thereby releasably coupling the device (104) and the catheter (400).
 9. A method of forming a catheter assembly, said method comprising:
 - releasably coupling an expandable device (104) and a catheter (102);
 - forming a restraining member (106) by releasably interconnecting opposing portions of a flexible sheet (200) together to form a releasable seam (206) with a coupling member to maintain the restraining member and device at a first outer peripheral dimension (208) suitable for endoluminal delivery of the device to a treatment site, and by releasably interconnecting other opposing portions of the flexible sheet together to form another releasable seam (202) with the coupling member to maintain the restraining member and device at a second outer peripheral dimension (204) larger than the first outer peripheral dimension (208) and smaller than a fully deployed outer peripheral dimension of the device (104).
 10. The method as set forth in claim 9 including maintaining each of the releasable seams (202, 206) with an elongated member woven along a plurality of openings formed along opposing portions of the flexible sheet.
 11. The method as set forth in claim 9 including loading the device (104) in a compacted state in the restraining member and retaining the device in the first outer peripheral dimension (208).
 12. The method as set forth in claim 9 including releasably coupling the device (104) and the catheter (400) by extending an elongated member (402) through the catheter (400) and through a portion of the device (104).
 13. The method as set forth in claim 12 including weaving the elongated member (402) between portions of a graft wall (412) and a stent frame of the device, optionally loading the device in a compacted state in the restraining member while the device (104) and catheter (400) are releasably coupled by the elon-

gated member (402) and retaining the device (104) in the first outer peripheral dimension (208).

herum erstreckt, und optional wobei der abgeflachte Schlauch aus ePTFE gebildet ist.

Patentansprüche

1. Katheteranordnung, umfassend:

einen Katheter (102) aufweisend entgegengesetzte proximale und distale Enden, wobei der Katheter ein Lumen aufweist, das sich zwischen dem proximalen und distalen Ende des Katheters erstreckt;
eine expandierbare Vorrichtung (104), die am distalen Ende des Katheters angeordnet ist und und zu einer vollständig entfalteten äußeren peripheren Dimension expandierbar ist; und
eine flexible Hülse (106), die sich um die Vorrichtung herum erstreckt, **dadurch gekennzeichnet, dass** die flexible Hülse eine lösbare erste Naht (206), die die Hülse an einer ersten Dimension hält, die zur endoluminalen Übergabe (208) der Vorrichtung an eine Behandlungsstelle geeignet ist, und eine lösbare zweite Naht (202), die die Hülse an einer zweiten Dimension (204) hält, die größer als die erste Dimension (208) und kleiner als die vollständig entfaltete äußere periphere Dimension der Vorrichtung (104) ist, aufweist, wobei die erste und zweite Naht (206, 202) durch ein gemeinsames Verbindungselement lösbar zusammengehalten werden.

2. Katheteranordnung nach Anspruch 1, wobei das Verbindungselement eine Steuerleine, einen Draht oder eine Leine umfasst.

3. Katheteranordnung nach Anspruch 1, wobei ein wesentlicher Teil einer Innenfläche der flexiblen Hülse (106) in Berührung mit der Vorrichtung (104) vor und nach Betätigung des zweiten Verbindungselements bleibt.

4. Katheteranordnung nach Anspruch 1, wobei die Vorrichtung (104) durch die Hülse (106) sowohl vor als auch nach Betätigung des ersten Verbindungselements eingezwängt bleibt.

5. Katheteranordnung nach Anspruch 1, wobei die erste Naht (206) und zweite Naht (202) im Allgemeinen in Bezug auf eine Längsachse des Katheters radial ausgerichtet sind, optional
wobei die zweite Naht (202) zwischen der Längsachse des Katheters (102) und der ersten Naht (206) angeordnet ist; und optional
wobei die flexible Hülse (106) aus einem abgeflachten Schlauch gebildet ist, um ein doppelwandiges Lumen zu bilden, das sich um die Vorrichtung (104)

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6. Katheteranordnung nach Anspruch 1, wobei die lösbare erste Naht (206) die Hülse an einer ersten äußeren peripheren Dimension (208) hält, die zur endoluminalen Übergabe und Entfaltung der Vorrichtung an eine Behandlungsstelle geeignet ist, und die lösbare zweite Naht (202) die Expansion der Hülse (106) zu einer zweiten äußeren peripheren Dimension (204) begrenzt, die größer als die erste äußere periphere Dimension (208) und kleiner als die vollständig entfaltete äußere periphere Dimension der Vorrichtung (104) nach Lösen der lösbaren ersten Naht (206) ist.

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7. Katheteranordnung nach Anspruch 6, umfassend zumindest einen Teil eines länglichen Elements (402), das sich durch den Katheterlumen erstreckt und relativ zum Katheter (400) bewegbar ist.

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8. Katheteranordnung nach Anspruch 7, wobei ein Teil des länglichen Elements (402) aus dem Katheterlumen durch eine distale Seitenwandöffnung (408) austritt, um sich entlang einer Außenfläche des Katheters zu erstrecken, und in den Katheterlumen durch eine proximale Seitenwandöffnung (410) eintritt; optional
wobei der Teil des länglichen Elements (402) mit der Vorrichtung zwischen der distalen und proximalen Seitenöffnung (408, 410) in Eingriff steht, wodurch er die Vorrichtung und den Katheter lösbar verbindet; und optional
wobei die Vorrichtung (104) einen Stentrahmen umfasst und der Teil des länglichen Elements (402) mit dem Stentrahmen in Eingriff steht, wodurch er die Vorrichtung (104) und den Katheter (400) lösbar verbindet; und optional
wobei der Teil des länglichen Elements (402) sich zwischen einem Scheitelpunkt des Stentrahmens und einer Graftwand (412) erstreckt, wodurch er die Vorrichtung (104) und den Katheter (400) lösbar verbindet.

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9. Verfahren zum Bilden einer Katheteranordnung, wobei das Verfahren Folgendes umfasst:

lösbares Verbinden einer expandierbaren Vorrichtung (104) und eines Katheters (102);
Bilden eines Begrenzungselements (106) durch lösbares miteinander Verbinden von gegenüberliegenden Teilen einer flexiblen Folie (200), um eine lösbare Naht (206) mit einem Verbindungselement zu bilden, um das Begrenzungselement und die Vorrichtung an einer ersten äußeren peripheren Dimension (208) zu halten, die zur endoluminalen Übergabe der Vorrichtung an eine Behandlungsstelle geeignet ist,

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und durch lösbarem miteinander Verbinden von anderen gegenüberliegenden Teilen der flexiblen Folie, um eine weitere lösbare Naht (202) mit dem Verbindungselement zu bilden, um das Begrenzungselement und die Vorrichtung an einer zweiten äußeren periphären Dimension (204) zu halten, die größer als die erste äußere periphäre Dimension (208) und kleiner als eine vollständig entfaltete äußere periphäre Dimension der Vorrichtung (104) ist.

10. Verfahren nach Anspruch 9, umfassend das Halten von jeder der lösbaren Nähte (202, 206) mit einem länglichen Element, das entlang einer Vielzahl von Öffnungen gewebt ist, die entlang gegenüberliegenden Teilen der flexiblen Folie gebildet sind.

11. Verfahren nach Anspruch 9, umfassend das Laden der Vorrichtung (104) in einem kompaktierten Zustand in dem Begrenzungselement und Halten der Vorrichtung in der ersten äußeren periphären Dimension (208).

12. Verfahren nach Anspruch 9, umfassend das lösbar Verbinden der Vorrichtung (104) und des Katheters (400) durch Ziehen eines länglichen Elements (402) durch den Katheter (400) und durch einen Teil der Vorrichtung (104).

13. Verfahren nach Anspruch 12, umfassend das Weben des länglichen Elements (402) zwischen Teilen einer Graftwand (412) und einem Stentrahmen der Vorrichtung, optional das Laden der Vorrichtung in einem kompaktierten Zustand in dem Begrenzungselement, während die Vorrichtung (104) und der Katheter (400) durch das längliche Element (402) lösbar verbunden sind, und das Halten der Vorrichtung (104) in der ersten äußeren periphären Dimension (208).

Revendications

1. Ensemble cathéter comprenant :

un cathéter (102) ayant des extrémités proximale et distale opposées, le cathéter ayant une lumière s'étendant entre les extrémités proximale et distale du cathéter ;

un dispositif extensible (104) disposé à l'extrémité distale du cathéter et extensible vers une dimension périphérique extérieure complètement déployée ; et

un manchon flexible (106) s'étendant autour du dispositif, **caractérisé en ce que** le manchon flexible possède une première couture détachable (206) qui maintient le manchon à une première dimension convenant à l'administration

intraluminale (208) du dispositif à un site de traitement, et une deuxième couture détachable (202) qui maintient le manchon à une deuxième dimension (204) plus grande que la première dimension (208) et plus petite que la dimension périphérique extérieure complètement déployée du dispositif (104), dans lequel les première et deuxième coutures (206, 202) sont maintenues ensemble, de façon amovible, par un élément d'accouplement commun.

2. Ensemble cathéter selon la revendication 1, dans lequel l'élément d'accouplement comprend une attache de contrôle, un fil métallique, ou un cordon.

3. Ensemble cathéter selon la revendication 1, dans lequel une partie substantielle de la surface intérieure du manchon flexible (106) reste en contact avec le dispositif (104) avant et après l'actionnement du deuxième élément d'accouplement.

4. Ensemble cathéter selon la revendication 1, dans lequel le dispositif (104) reste maintenu par le manchon flexible (106) avant et après l'actionnement du premier élément d'accouplement.

5. Ensemble cathéter selon la revendication 1, dans lequel la première couture (206) et la deuxième couture (202) sont alignées dans le sens général radial par rapport à un axe longitudinal du cathéter, optionnellement dans lequel la deuxième couture (202) est disposée entre l'axe longitudinal du cathéter (102) et la première couture (206) ; et optionnellement dans lequel le manchon flexible (106) est formé d'un tube aplati pour former une lumière à double paroi s'étendant autour du dispositif (104), et optionnellement dans lequel le tube aplati est formé d'ePTFE.

6. Ensemble cathéter selon la revendication 1, dans lequel la première couture détachable (206) maintient le manchon à une première dimension périphérique extérieure (208) convenant à l'administration intraluminale et au déploiement du dispositif à un site de traitement, et la deuxième couture détachable (202) limite l'expansion du manchon (106) à une deuxième dimension périphérique extérieure (204) plus grande que la première dimension périphérique extérieure (208) et plus petite que la dimension périphérique extérieure complètement déployée du dispositif (104) après détachement de la première couture détachable (206).

7. Ensemble cathéter selon la revendication 6, comportant au moins une partie d'un élément allongé

(402) s'étendant à travers la lumière du cathéter et mobile par rapport au cathéter (400).

8. Ensemble cathéter selon la revendication 7, dans lequel une partie de l'élément allongé (402) sort de la lumière du cathéter par une ouverture distale de la paroi latérale (408) de manière à s'étendre le long d'une surface extérieure du cathéter, et entre dans la lumière du cathéter par une ouverture proximale de la paroi latérale (410) ; optionnellement dans lequel la partie de l'élément allongé (402) s'engage avec le dispositif entre les ouvertures latérales distale et proximale (408, 410) en couplant ainsi de manière détachable le dispositif et le cathéter ; et optionnellement dans lequel le dispositif (104) comporte une armature d'endoprothèse et la partie de l'élément allongé (402) s'engage avec l'armature d'endoprothèse, pour coupler ainsi de manière détachable le dispositif (104) et le cathéter (400) ; et optionnellement dans lequel la partie de l'élément allongé (402) s'étend entre un apex de l'armature d'endoprothèse et une paroi de greffe (412) pour coupler ainsi de manière détachable le dispositif (104) et le cathéter (400).

9. Procédé de formation d'un ensemble cathéter, ledit procédé comprenant :

le couplage de manière détachable d'un dispositif extensible (104) et d'un cathéter (102) ;
la formation d'un élément de retenue (106) en interconnectant ensemble de manière détachable des parties opposées d'une feuille flexible (200) pour former une couture détachable (206) avec un élément de couplage pour maintenir l'élément de retenue et le dispositif à une première dimension périphérique extérieure (208) convenant à l'administration intraluminale du dispositif à un site de traitement, et en interconnectant ensemble de manière détachable d'autres parties opposées de la feuille flexible pour former une autre couture détachable (202) avec l'élément d'accouplement afin de maintenir l'élément de retenue et le dispositif à une deuxième dimension périphérique extérieure (204) plus grande que la première dimension périphérique extérieure (208) et plus petite qu'une dimension périphérique extérieure complètement déployée du dispositif (104).

10. Procédé selon la revendication 9 incluant le maintien de chacune des coutures détachables (202, 206) avec un élément allongé tissé le long d'une pluralité d'ouvertures formées le long de parties opposées de la feuille flexible.

11. Procédé selon la revendication 9, incluant le char-

gement du dispositif (104) dans un état compacté dans l'élément de retenue et la retenue du dispositif dans la première dimension périphérique extérieure (208).

12. Procédé selon la revendication 9, incluant le couplage de manière détachable du dispositif (104) et du cathéter (400) en étendant un élément allongé (402) à travers le cathéter (400) et à travers une partie du dispositif (104).

13. Procédé selon la revendication 12, incluant le tissage de l'élément allongé (402) entre des parties d'une paroi de greffe (412) et d'une armature d'endoprothèse du dispositif, en chargeant optionnellement le dispositif dans un état compacté dans l'élément de retenue tandis que le dispositif (104) et le cathéter (400) sont couplés de manière détachable par l'élément allongé (402) et en maintenant le dispositif (104) dans la première dimension périphérique extérieure (208).

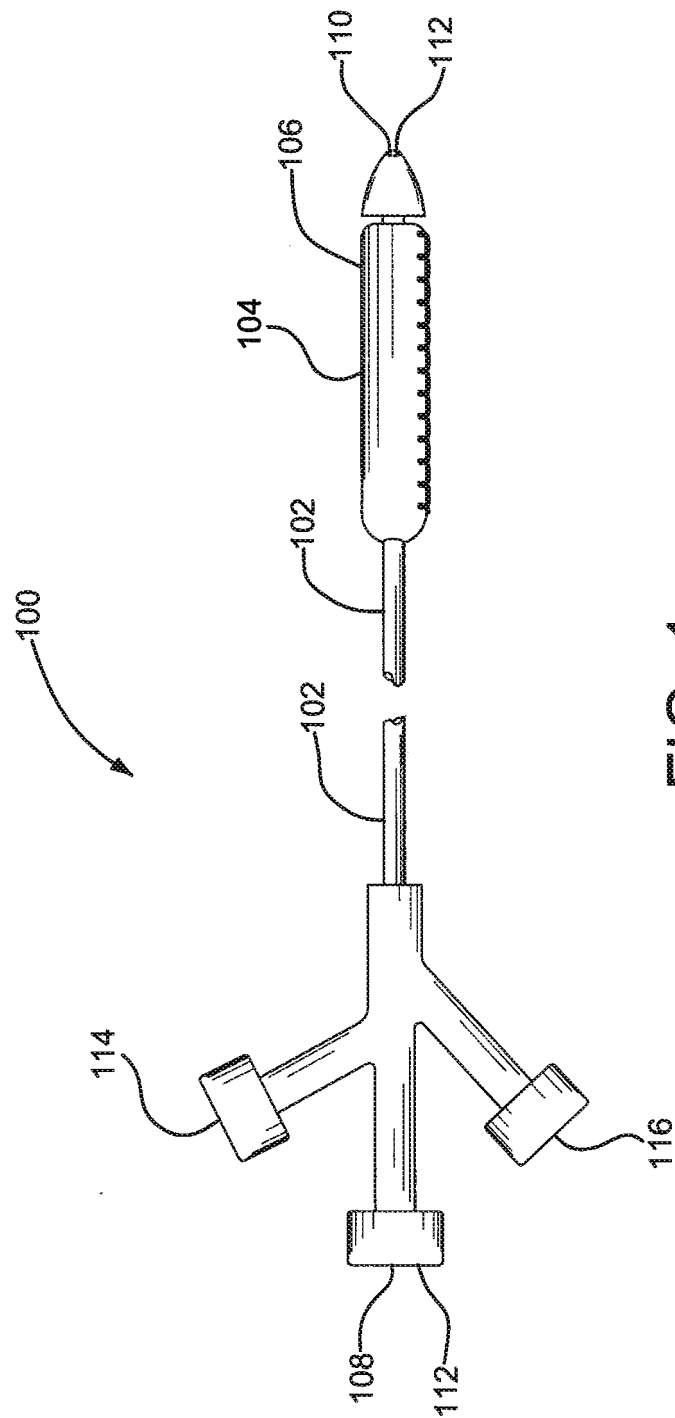


FIG. 1

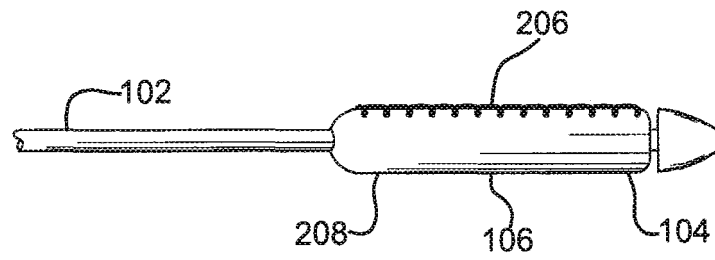


FIG. 2a

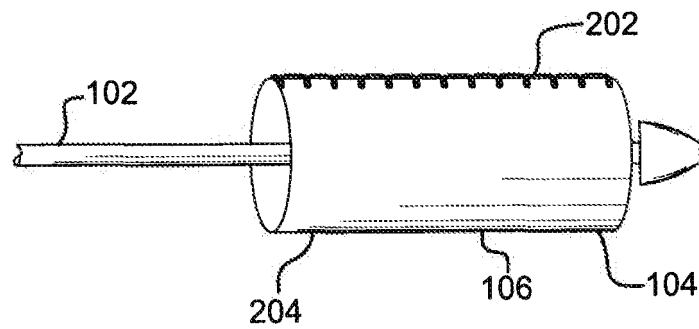


FIG. 2b

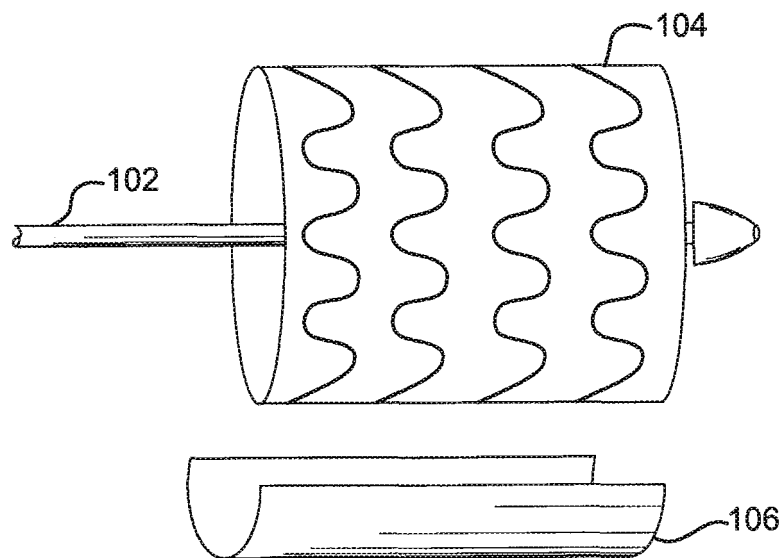


FIG. 2c



FIG. 3a

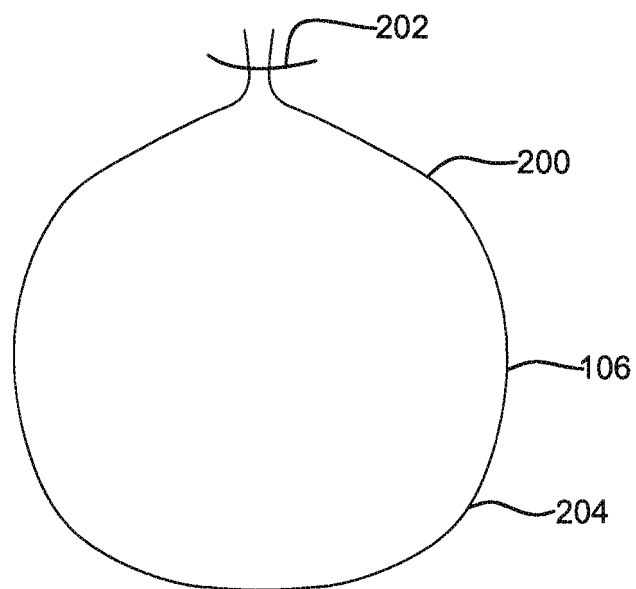


FIG. 3b

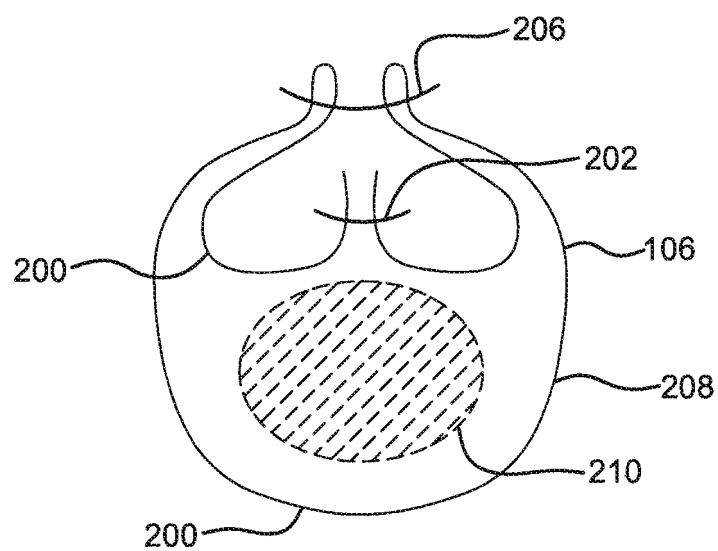


FIG. 3c

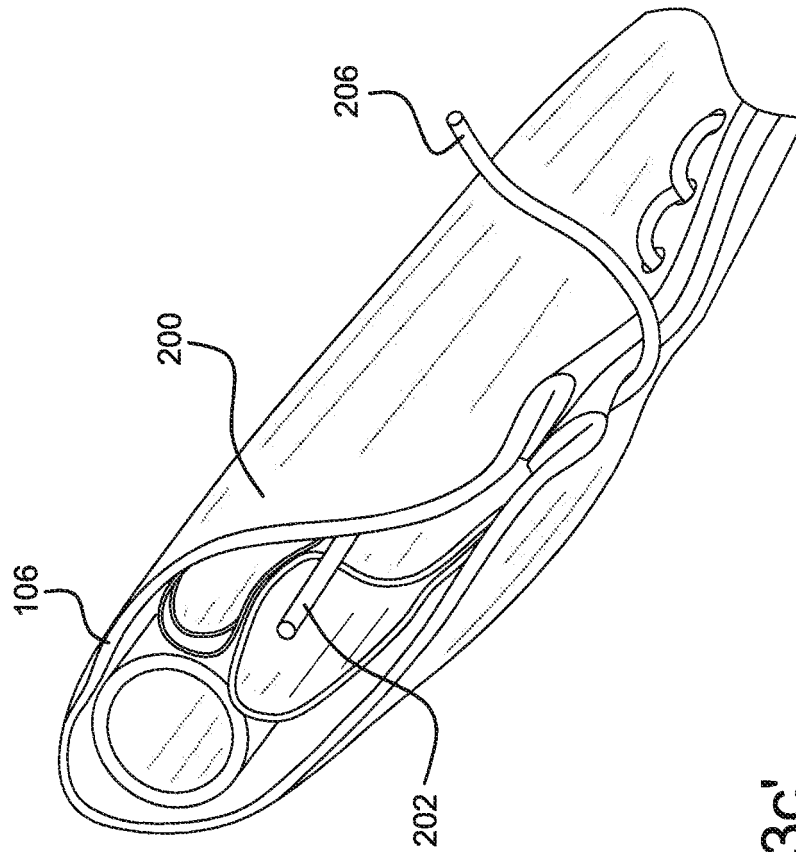


FIG. 3c'

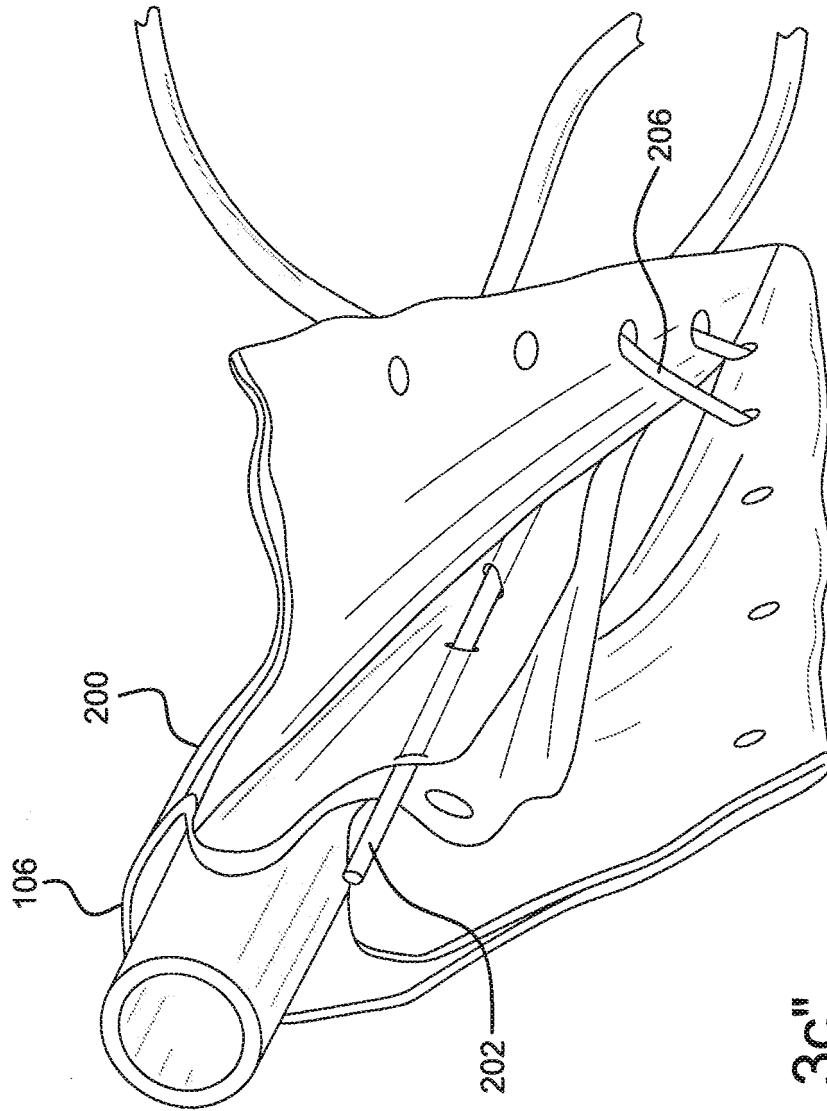


FIG. 3c"

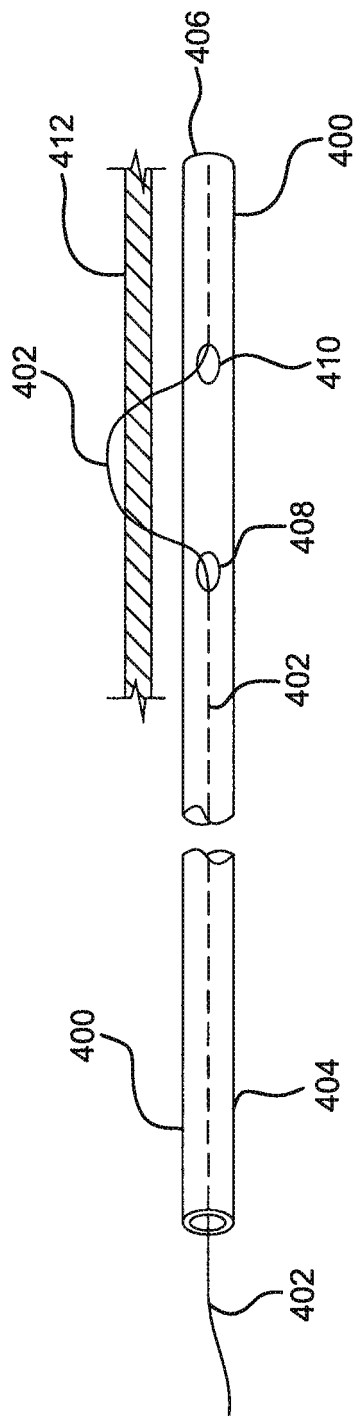


FIG. 4a

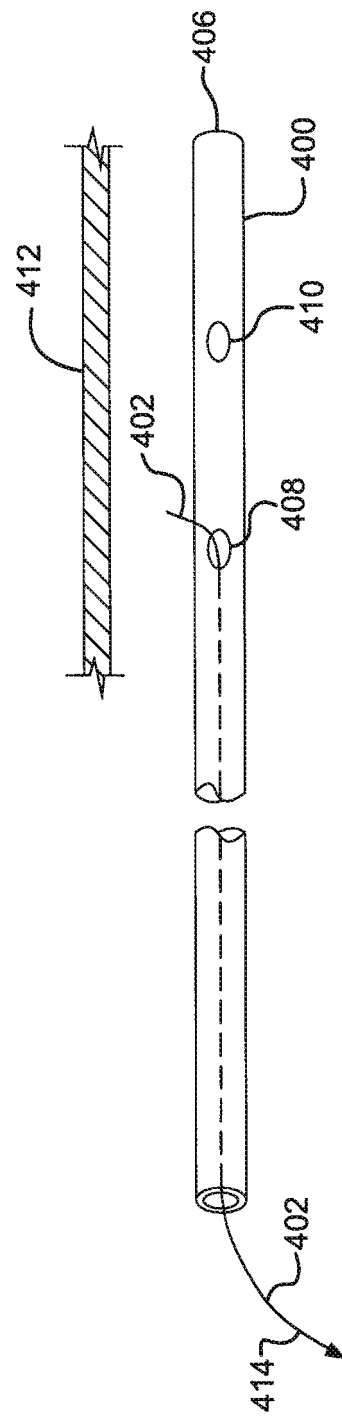


FIG. 4b

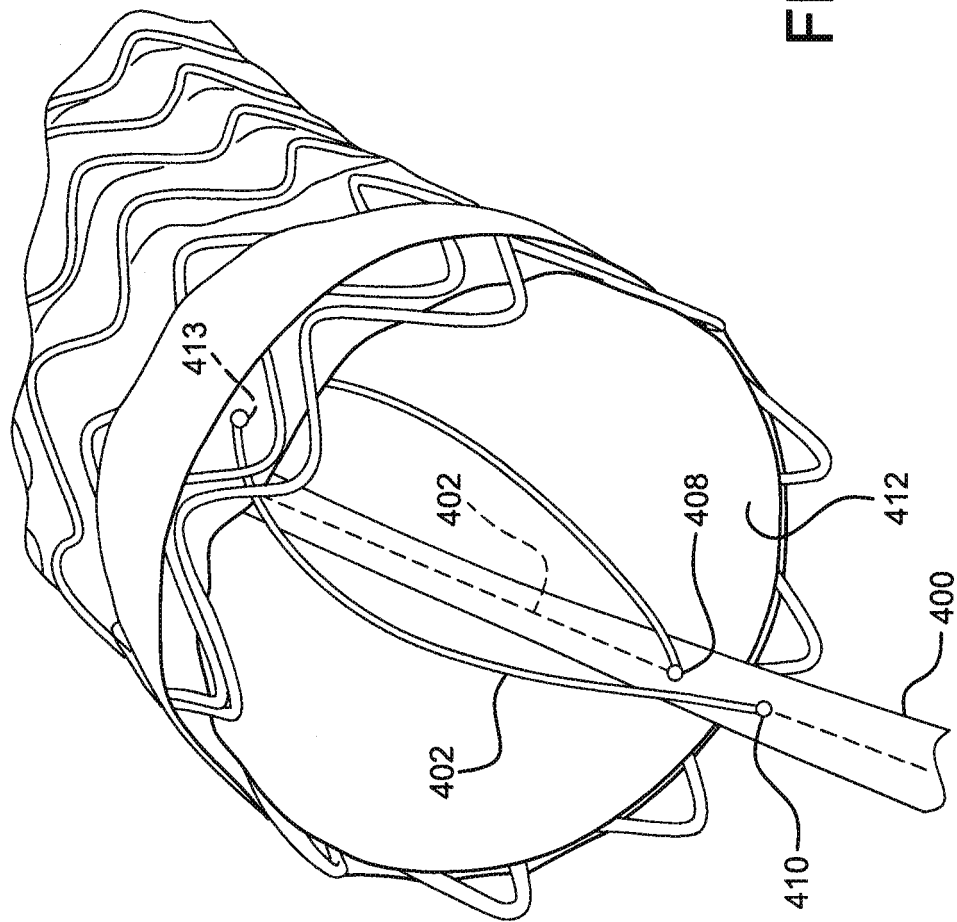


FIG. 4c

REFERENCES CITED IN THE DESCRIPTION

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