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(71) Applicant: **TRIVASCULAR, INC.** [US/US]; 3910 Brickway Boulevard, Santa Rosa, CA 95403 (US).

(72) Inventors: **ARISTIZABAL, Diego**; 3910 Brickway Boulevard, Santa Rosa, CA 95403 (US). **CHOBOTOV, Michael, V.**; 3910 Brickway Boulevard, Santa Rosa, CA 95403 (US).

(74) Agents: **SCOLA, Daniel, A., Jr.** et al.; Hoffmann & Baron, LLP, 6900 Jericho Turnpike, Syosset, NY 11791-4407 (US).

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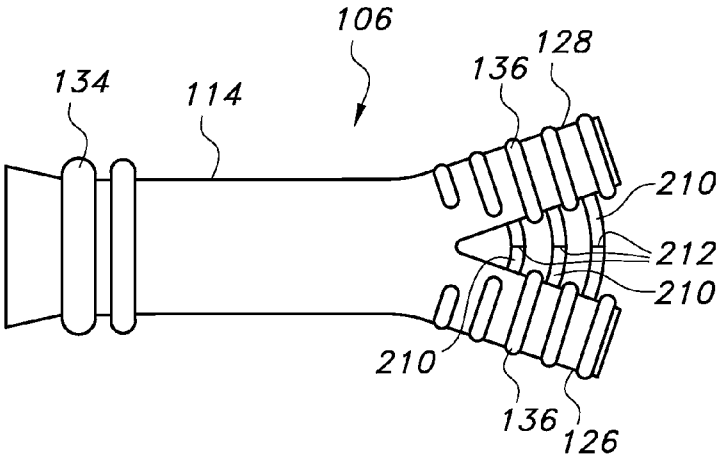

FIG. 21

(57) Abstract: An endovascular delivery system includes a bifurcated and inflatable prosthesis including a main tubular body having an open end and opposed ipsilateral and contralateral legs defining a graft wall therein between. A tether is disposed securably disposed to the contralateral leg, and the contralateral leg is releasably restrained towards the ipsilateral leg tether to prevent undesirable movement of the contralateral leg. A release wire within the endovascular delivery system releasably retains the tether near the ipsilateral leg. The contralateral leg (128) may also be restricted from significant longitudinal movement so as to prevent bunching up of the contralateral leg during delivery of the endovascular prosthesis by a web (210) of biocompatible material disposed between the contralateral leg (128) and the ipsilateral leg (126) and secured to the contralateral leg and the ipsilateral leg.

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BIFURCATED ENDOVASCULAR PROSTHESIS HAVING TETHERED CONTRALATERAL LEG

CROSS-REFERENCE TO RELATED APPLICATIONS:

This application claims the benefit of U.S. Provisional Application No. 61/660,105, filed June 15, 2012, the contents of which are incorporated by reference herein.

FIELD OF THE INVENTION:

The present invention is related to an endovascular delivery system for an endovascular prosthesis. More particularly, the present invention is related to an endovascular delivery system having a bifurcated and inflatable prosthesis having a tether from a contralateral leg to restrain movement of the contralateral leg with respect to an ipsilateral leg of the prosthesis.

BACKGROUND OF THE INVENTION:

An aneurysm is a medical condition indicated generally by an expansion and weakening of the wall of an artery of a patient. Aneurysms can develop at various sites within a patient's body. Thoracic aortic aneurysms (TAAs) or abdominal aortic aneurysms (AAAs) are manifested by an expansion and weakening of the aorta which is a serious and life threatening condition for which intervention is generally indicated. Existing methods of treating aneurysms include invasive surgical procedures with graft replacement of the affected vessel or body lumen or reinforcement of the vessel with a graft.

Surgical procedures to treat aortic aneurysms can have relatively high morbidity and mortality rates due to the risk factors inherent to surgical repair of this disease as well as long hospital stays and painful recoveries. This is especially true for surgical repair of TAAs, which is generally regarded as involving higher risk and more difficulty when compared to surgical repair of AAAs. An example of a surgical procedure involving repair of a AAA is described in a book titled Surgical Treatment of Aortic Aneurysms by Denton A. Cooley, M.D., published in 1986 by W.B. Saunders Company.

Due to the inherent risks and complexities of surgical repair of aortic aneurysms, endovascular repair has become a widely-used alternative therapy, most notably in treating AAAs. Early work in this field is exemplified by Lawrence, Jr. et al. in "Percutaneous Endovascular Graft Experimental Evaluation", Radiology (May 1987) and by Mirich et al. in "Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study," Radiology (March 1989). Commercially available endoprostheses for the endovascular treatment of AAAs include the Endurant™ and Talent™ Abdominal Stent Grafts sold by Medtronic, Inc. of Minneapolis, MN; the Zenith Flex® AAA Endovascular Graft and the Zenith TX2® TAA Endovascular Graft, both sold by Cook Medical, Inc. of Bloomington, IN; the AFX™ Endovascular AAA system sold by Endologix, Inc. of Irvine, CA; and the Gore® Excluder® AAA Endoprosthesis sold by W.L. Gore & Associates, Inc. of Flagstaff, AZ. A commercially available stent graft for the treatment of TAAs is the Gore® TAG® Thoracic Endoprosthesis sold by W.L. Gore & Associates, Inc. of Flagstaff, AZ.

When deploying devices by catheter or other suitable instrument, it is advantageous to have a flexible and low profile stent graft and delivery system for passage through the various guiding catheters as well as the patient's sometimes tortuous anatomy. Many of the existing endovascular devices and methods for treatment of aneurysms, while representing significant advancement over previous devices and methods, use systems having relatively large transverse profiles, often up to 24 French. Also, such existing systems have greater than desired lateral stiffness, which can complicate the delivery process. In addition, the sizing of stent grafts may be important to achieve a favorable clinical result. In order to properly size a stent graft, the treating facility typically must maintain a large and expensive inventory of stent grafts in order to accommodate the varied sizes of patient vessels due to varied patient sizes and vessel morphologies. Alternatively, intervention may be delayed while awaiting custom size stent grafts to be manufactured and sent to the treating facility. As such, minimally invasive endovascular treatment of aneurysms is not available for many patients that would benefit from such a procedure and can be more difficult to carry out for those patients for whom the procedure is indicated. What have been needed are stent graft systems, delivery systems and methods that are adaptable to a wide range of patient anatomies and that can be safely and reliably deployed using a flexible low profile system.

SUMMARY OF THE INVENTION:

In one aspect of the present invention an endovascular delivery system includes a bifurcated and inflatable prosthesis including a main tubular body having an open end and opposed ipsilateral and contralateral legs defining a graft wall therein between, the ipsilateral and contralateral legs having open ends, and the main tubular body and the ipsilateral and contralateral legs having inflatable channels; the ipsilateral leg including an ipsilateral tab extending from the open end of the ipsilateral leg, the tab including at least two holes; an elongate guidewire having at least two outwardly projecting members, the outwardly projecting members being sized to at least partially fit within the at least one of the at least two holes of the ipsilateral tab; a release wire slidable disposed within the at least two outwardly projecting members of the elongate guidewire and within one of the at least two holes of the ipsilateral tab; and a tether having opposed contralateral and ipsilateral ends, the contralateral end of the tether being securably disposed at the open end of the contralateral leg, the ipsilateral end of the tether having a hole, the release wire being slidably disposed through the hole of the tether to so engage the tether; wherein withdrawal of the release wire releases the ipsilateral tab and the tether from the elongate guidewire. The elongate guidewire may be extendable through the ipsilateral leg and through the main tubular body.

When the release wire engages the tether, the open end of the contralateral leg is proximally disposed and restrained towards the open end of the ipsilateral leg. In such a restrained position, the contralateral leg is restricted from significant longitudinal movement so as to prevent bunching up of the contralateral leg and is also is restricted from significant rotational movement so as to prevent misalignment within a bodily lumen.

The endovascular delivery system may further include an elongate outer tubular sheath having an open lumen and opposed proximal and distal ends with a medial portion therein between, the proximal end of the outer tubular sheath securably disposed to a first handle; an elongate inner tubular member having a tubular wall with an open lumen and opposed proximal and distal ends with a medial portion therein between, the inner tubular member having a longitudinal length greater than a longitudinal length of the outer tubular sheath, the inner tubular member being slidably disposed within the open lumen of the outer tubular sheath, the proximal end of the inner tubular member securably disposed to a second handle; the elongate guidewire slidably disposed within the inner tubular member; the distal end of the outer tubular sheath being slidably disposed past and beyond the distal end of the

inner tubular member to define a prosthesis delivery state and slidably retractable to the medial portion of the inner tubular member to define a prosthesis unsheathed state.

The prosthesis may include non-textile polymeric material; for example, polytetrafluoroethylene. In some embodiments, the polytetrafluoroethylene may be non-porous polytetrafluoroethylene. The prosthesis may further include a metallic expandable member securably disposed at or near the open end of the main tubular body of the prosthesis.

In another aspect of the present invention, a method for delivering a bifurcated prosthesis, includes providing a bifurcated and inflatable prosthesis including: a main tubular body having an open end and opposed ipsilateral and contralateral legs defining a graft wall therein between, the ipsilateral and contralateral legs having open ends, and the main tubular body and the ipsilateral and contralateral legs having inflatable channels; the ipsilateral leg including an ipsilateral tab extending from the open end of the ipsilateral leg, the tab including at least two holes; providing an elongate guidewire having at least two outwardly projecting members, the outwardly projecting members being sized to at least partially fit within at least one of the at least two holes of the ipsilateral tab; providing a release wire slidable disposed within the at least two outwardly projecting members of the elongate guidewire and within the at least two holes of the ipsilateral tab; providing a tether having opposed contralateral and ipsilateral ends, the contralateral end of the tether being securably disposed at the open end of the contralateral leg, the ipsilateral end of the tether having a hole, the release wire being slidably disposed through the hole of the tether to so engage the tether; and withdrawing the release wire to release the ipsilateral tab and the tether from the elongate guidewire.

When the release wire engages the tether, the open end of the contralateral leg is proximally disposed and restrained towards the open end of the ipsilateral leg and the contralateral leg is restricted from significant longitudinal movement so as to prevent bunching up of the contralateral leg. The contralateral leg is also restricted from significant rotational movement so as to prevent misalignment within a bodily lumen.

In some aspects of the present invention, the endovascular prosthesis may be a modular endovascular graft assembly including a bifurcated main graft member formed from

a supple graft material having a main fluid flow lumen therein. The main graft member may also include an ipsilateral leg with an ipsilateral fluid flow lumen in communication with the main fluid flow lumen, a contralateral leg with a contralateral fluid flow lumen in communication with the main fluid flow lumen and a network of inflatable channels disposed on the main graft member. The network of inflatable channels may be disposed anywhere on the main graft member including the ipsilateral and contralateral legs. The network of inflatable channels may be configured to accept a hardenable fill or inflation material to provide structural rigidity to the main graft member when the network of inflatable channels is in an inflated state. The network of inflatable channels may also include at least one inflatable cuff disposed on a proximal portion of the main graft member which is configured to seal against an inside surface of a patient's vessel. The fill material can also have transient or chronic radiopacity to facilitate the placement of the modular limbs into the main graft member. A proximal anchor member may be disposed at a proximal end of the main graft member and be secured to the main graft member. The proximal anchor member may have a self-expanding proximal stent portion secured to a self-expanding distal stent portion with struts having a cross sectional area that is substantially the same as or greater than a cross sectional area of proximal stent portions or distal stent portions adjacent the strut. At least one ipsilateral graft extension having a fluid flow lumen disposed therein may be deployed with the fluid flow lumen of the graft extension sealed to and in fluid communication with the fluid flow lumen of the ipsilateral leg of the main graft member. At least one contralateral graft extension having a fluid flow lumen disposed therein may be deployed with the fluid flow lumen of the graft extension sealed to and in fluid communication with the fluid flow lumen of the contralateral leg of the main graft member. For some embodiments, an outside surface of the graft extension may be sealed to an inside surface of the contralateral leg of the main graft when the graft extension is in a deployed state. For some embodiments, the axial length of the ipsilateral and contralateral legs may be sufficient to provide adequate surface area contact with outer surfaces of graft extensions to provide sufficient friction to hold the graft extensions in place. For some embodiments, the ipsilateral and contralateral legs may have an axial length of at least about 2 cm. For some embodiments, the ipsilateral and contralateral legs may have an axial length of about 2 cm to about 6 cm; more specifically, about 3 cm to about 5 cm.

In another aspect of the present invention, an endovascular prosthesis may include a bifurcated and inflatable prosthesis having a main tubular body having an open end and

opposed ipsilateral and contralateral legs defining a graft wall therein between, where the ipsilateral and contralateral legs have open ends, and further where the main tubular body and the ipsilateral and contralateral legs have inflatable channels; and a web of biocompatible material disposed between the contralateral leg and the ipsilateral leg and secured to the contralateral leg and the ipsilateral leg. The inclusion of the web with the endovascular prosthesis may prevent, restrict or inhibit the contralateral leg from significant longitudinal movement so as to prevent bunching up of the contralateral leg during delivery of the endovascular prosthesis. The inclusion of the web with the endovascular prosthesis may also prevent, restrict or inhibit significant rotational movement of the contralateral leg during delivery so as to prevent misalignment within a bodily lumen. The web may be releasably secured to the contralateral leg and the ipsilateral leg.

These and other features and advantages of the present invention will become apparent from the following detailed description of illustrative embodiments thereof, which is to be read in connection with the accompanying drawings. Corresponding reference element numbers or characters indicate corresponding parts throughout the several views of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS:

FIG. 1 depicts an initial deployment state of the endovascular delivery system of the present invention within a patient's vasculature.

FIG. 2 depicts a deployment state of the endovascular delivery system of the present invention within a patient's vasculature after withdrawal of an outer sheath.

FIG. 3 depicts a deployment state of the endovascular delivery system of the present invention within a patient's vasculature after an initial and partial stent deployment.

FIG. 4 depicts a deployment state of the endovascular delivery system of the present invention within a patient's vasculature after a stent deployment.

FIG. 5 depicts a deployed bifurcated endovascular prosthesis with graft leg extensions.

FIG. 6 is a side elevational view of the endovascular delivery system of the present invention.

FIG. 7 is a side elevational and partial cutaway view of the proximal portion of the endovascular delivery system of the present invention.

FIG. 8 is a partial perspective and partial cutaway view of the proximal portion of the endovascular delivery system of the present invention.

FIG. 9 is an elevational view of the prosthesis of the present invention having a flap at the ipsilateral leg.

FIG. 10 is a partial elevational view of a distal stop on a delivery guidewire for restraining the ipsilateral leg of the prosthesis during certain delivery stages of the prosthesis.

FIG. 11 is an exploded and partial cut-away view of the distal stop initially engaging the ipsilateral leg flap.

FIG. 12 is an exploded and partial cut-away view of the distal stop engaging the ipsilateral leg flap.

FIG. 13 is a schematic depiction of the ends of the contralateral and ipsilateral graft legs having a contralateral tether.

FIG. 14 is a schematic depiction of a release wire releasably engaging a portion of the tether of FIG. 13.

FIGS. 15 through 18 depict alternate embodiments of the present invention for restraining the contralateral leg.

FIGS. 19 through 21 depict further alternate embodiments of the present invention for restraining the contralateral leg

DETAILED DESCRIPTION OF THE INVENTION:

Embodiments of the invention are directed generally to methods and devices for treatment of fluid flow vessels with the body of a patient. Treatment of blood vessels is specifically indicated for some embodiments, and, more specifically, treatment of aneurysms, such as abdominal aortic aneurysms. With regard to graft embodiments discussed herein and components thereof, the term "proximal" refers to a location towards a patient's heart and the term "distal" refers to a location away from the patient's heart. With regard to delivery system catheters and components thereof discussed herein, the term "distal" refers to a location that is disposed away from an operator who is using the catheter and the term "proximal" refers to a location towards the operator.

FIG. 1 illustrates an embodiment of a deployment sequence of an embodiment of an endovascular prosthesis (not shown), such as a modular stent graft assembly. For endovascular methods, access to a patient's vasculature may be achieved by performing an arteriotomy or cut down to the patient's femoral artery or by other common techniques, such as the percutaneous Seldinger technique. For such techniques, a delivery sheath (not shown) may be placed in communication with the interior of the patient's vessel such as the femoral artery with the use of a dilator and guidewire assembly. Once the delivery sheath is positioned, access to the patient's vasculature may be achieved through the delivery sheath which may optionally be sealed by a hemostasis valve or other suitable mechanism. For some procedures, it may be necessary to obtain access via a delivery sheath or other suitable means to both femoral arteries of a patient with the delivery sheaths directed upstream towards the patient's aorta. In some applications a delivery sheath may not be needed and the delivery catheter of the present invention may be directly inserted into the patient's access vessel by either arteriotomy or percutaneous puncture. Once the delivery sheath or sheaths have been properly positioned, an endovascular delivery catheter or system, typically containing an endovascular prosthesis such as but not limited to an inflatable stent-graft, may then be advanced over a guidewire through the delivery sheath and into the patient's vasculature.

FIG. 1 depicts the initial placement of the endovascular delivery system 100 of the present invention within a patient's vasculature. The endovascular delivery system 100 may be advanced along a guidewire 102 proximally upstream of blood flow into the vasculature of the patient including iliac arteries 14, 16 and aorta 10 shown in FIG. 1. While the iliac arties

14, 16 may be medically described as the right and left common iliac arteries, respectively, as used herein iliac artery 14 is described as an ipsilateral iliac artery and iliac artery 16 is described as a contralateral iliac artery. The flow of the patient's blood (not shown) is in a general downward direction in FIG. 1. Other vessels of the patient's vasculature shown in FIG. 1 include the renal arteries 12 and hypogastric arteries 18.

The endovascular delivery system 100 may be advanced into the aorta 10 of the patient until the endovascular prosthesis (not shown) is disposed substantially adjacent an aortic aneurysm 20 or other vascular defect to be treated. The portion of the endovascular delivery system 100 that is advance through bodily lumens is in some embodiments a low profile delivery system; for example, having an overall outer diameter of less than 14 French. Other diameters are also useful, such as but not limited to less than 12 French, less than 10 French, or any sizes from 10 to 14 French or greater. Once the endovascular delivery system 100 is so positioned, an outer sheath 104 of the endovascular delivery system 100 may be retracted distally so as to expose the prosthesis (not shown) which has been compressed and compacted to fit within the inner lumen of the outer sheath 104 of the endovascular delivery system 100.

As depicted in FIG. 2, once the endovascular delivery system 100 is so positioned, the outer sheath 104 of the endovascular delivery system 100 may be retracted distally so as to expose the endovascular prosthesis 106 which has been compressed and compacted to fit within the inner lumen of the outer sheath 104 of the endovascular delivery system 100. The outer sheath 104 may be formed of a body compatible material. In some embodiments, the biocompatible material may be a biocompatible polymer. Examples of suitable biocompatible polymers may include, but are not limited to, polyolefins such as polyethylene (PE), high density polyethylene (HDPE) and polypropylene (PP), polyolefin copolymers and terpolymers, polytetrafluoroethylene (PTFE), polyethylene terephthalate (PET), polyesters, polyamides, polyurethanes, polyurethaneureas, polypropylene and, polycarbonates, polyvinyl acetate, thermoplastic elastomers including polyether-polyester block copolymers and polyamide/polyether/polyesters elastomers, polyvinyl chloride, polystyrene, polyacrylate, polymethacrylate, polyacrylonitrile, polyacrylamide, silicone resins, combinations and copolymers thereof, and the like. In some embodiments, the biocompatible polymers include polypropylene (PP), polytetrafluoroethylene (PTFE), polyethylene terephthalate (PET), high density polyethylene (HDPE), combinations and copolymers thereof, and the like. Useful

coating materials may include any suitable biocompatible coating. Non-limiting examples of suitable coatings include polytetrafluoroethylene, silicone, hydrophilic materials, hydrogels, and the like. Useful hydrophilic coating materials may include, but are not limited to, alkylene glycols, alkoxy polyalkylene glycols such as methoxypolyethylene oxide, polyoxyalkylene glycols such as polyethylene oxide, polyethylene oxide/polypropylene oxide copolymers, polyalkylene oxide-modified polydimethylsiloxanes, polyphosphazenes, poly(2-ethyl-2-oxazoline), homopolymers and copolymers of (meth) acrylic acid, poly(acrylic acid), copolymers of maleic anhydride including copolymers of methylvinyl ether and maleic acid, pyrrolidones including poly(vinylpyrrolidone) homopolymers and copolymers of vinyl pyrrolidone, poly(vinylsulfonic acid), acryl amides including poly(N-alkylacrylarnide), poly(vinyl alcohol), poly(ethyleneimine), polyamides, poly(carboxylic acids), methyl cellulose, carboxymethylcellulose, hydroxypropyl cellulose, polyvinylsulfonic acid, water soluble nylons, heparin, dextran, modified dextran, hydroxylated chitin, chondroitin sulphate, lecithin, hyaluranon, combinations and copolymers thereof, and the like. Non-limiting examples of suitable hydrogel coatings include polyethylene oxide and its copolymers, polyvinylpyrrolidone and its derivatives; hydroxyethylacrylates or hydroxyethyl(meth)acrylates; polyacrylic acids; polyacrylamides; polyethylene maleic anhydride, combinations and copolymers thereof, and the like. In some embodiments, the outer sheath 104 may be made of polymeric materials, e.g., polyimides, polyester elastomers (Hytrel®), or polyether block amides (Pebax®), polytetrafluoroethylene, and other thermoplastics and polymers. The outside diameter of the outer sheath 104 may range from about 0.1 inch to about 0.4 inch. The wall thickness of the outer sheath 104 may range from about 0.002 inch to about 0.015 inch. The outer sheath 104 may also include an outer hydrophilic coating. Further, the outer sheath 104 may include an internal braided or otherwise reinforced portion of either metallic or polymeric filaments. In addition to being radially compressed when disposed within an inner lumen of the outer sheath 104 of the endovascular delivery system 100, a proximal stent 108 may be radially restrained by high strength flexible belts 110 in order to maintain a small profile and avoid engagement of the proximal stent 108 with a body lumen wall until deployment of the proximal stent 108 is initiated. The belts 110 can be made from any high strength, resilient material that can accommodate the tensile requirements of the belt members and remain flexible after being set in a constraining configuration. Typically, belts 110 are made from solid ribbon or wire of a shape memory alloy such as nickel titanium or the like, although other metallic or polymeric materials are possible. Belts 110 may also be made of braided metal filaments or braided or

solid filaments of high strength synthetic fibers such as Dacron®, Spectra or the like. An outside transverse cross section of the belts 110 may range from about 0.002 to about 0.012 inch, specifically, about 0.004 to about 0.007 inch. The cross sections of belts 110 may generally take on any shape, including rectangular (in the case of a ribbon), circular, elliptical, square, etc. The ends of the belts 110 may be secured by one or more stent release wires or elongate rods 112 which extend through looped ends (not shown) of the belts 110. The stent release wires or elongate rods 112 may be disposed generally within the prosthesis 106 during delivery of the system 100 to the desired bodily location. For example, the stent release wires or elongate rods 112 may enter and exit the guidewire lumen 122 or other delivery system lumen as desired to affect controlled release of the stent 108, including if desired controlled and staged release of the stent 108. Once the outer sheath 104 of the endovascular delivery system 100 has been retracted, the endovascular delivery system 100 and the endovascular prosthesis 106 may be carefully positioned in an axial direction such that the proximal stent 108 is disposed substantially even with the renal arteries.

In some embodiments, the endovascular prosthesis 106 includes an inflatable graft 114. The inflatable graft may be a bifurcated graft having a main graft body 124, an ipsilateral graft leg 126 and a contralateral graft leg 128. The inflatable graft 114 may further include a fill port 116 in fluid communication with an inflation tube 118 of the endovascular delivery system 100 for providing an inflation medium (not shown). The distal portion of the endovascular delivery system 100 may include a nosecone 120 which provides an atraumatic distal portion of the endovascular delivery system 100. The guidewire 102 is slidably disposed within a guidewire lumen 122 of the endovascular delivery system 100.

As depicted in FIG. 3, deployment of the proximal stent 108 may begin with deployment of the distal portion 130 of stent 108 by retracting the stent release wire or rod 112 that couples ends of belt 110 restraining the distal portion 130 of the stent 108. The distal portion 130 of stent 108 may be disposed to the main graft body 124 via a connector ring 142. The stent 108 and/or the connector ring 142 may be made from or include any biocompatible material, including metallic materials, such as but not limited to, nitinol (nickel titanium), cobalt-based alloy such as Elgiloy, platinum, gold, stainless steel, titanium, tantalum, niobium, and combinations thereof. The present invention, however, is not limited to the use of such a connector ring 142 and other shaped connectors for securing the distal portion 130 of the stent 108 at or near the end of the main graft body 124 may suitably be

used. Additional axial positioning typically may be carried out even after deploying the distal portion 130 of the stent 108 as the distal portion 130 may provide only partial outward radial contact or frictional force on the inner lumen of the patient's vessel or aorta 10 until the proximal portion 132 of the stent 108 is deployed. Once the belt 110 constraining the proximal portion 132 of the stent 108 has been released, the proximal portion 132 of the stent 108 self-expands in an outward radial direction until an outside surface of the proximal portion 132 of the stent 108 makes contact with and engages an inner surface of the patient's vessel 10.

As depicted in FIG. 4, after the distal portion 130 of the stent 108 has been deployed, the proximal portion 132 of the stent 108 may then be deployed by retracting the wire 112 that couples the ends of the belt 110 restraining the proximal portion 132 of the stent 108. As the proximal portion 132 of the stent 108 self-expands in an outward radial direction, an outside surface of the proximal portion 132 of the stent 108 eventually makes contact with the inside surface of the patient's aorta 10. For embodiments that include tissue engaging barbs (not shown) on the proximal portion 132 of the stent 108, the barbs may also be oriented and pushed in a general outward direction so as to make contact and engage the inner surface tissue of the patient's vessel 10, which further secures the proximal stent 108 to the patient's vessel 10.

Once the proximal stent 108 has been partially or fully deployed, the proximal inflatable cuff 134 may then be filled through the inflation port 116 with inflation material injected through an inflation tube 118 of the endovascular delivery system 100 which may serve to seal an outside surface of the inflatable cuff 134 to the inside surface of the vessel 10. The remaining network of inflatable channels 136 may also be filled with pressurized inflation material at the same time which provides a more rigid frame like structure to the inflatable graft 114. For some embodiments, the inflation material may be a biocompatible, curable or hardenable material that may cured or hardened once the network of inflatable channels 136 are filled to a desired level of material or pressure within the network or after passage of a predetermined period of time. Some embodiments may also employ radiopaque inflation material to facilitate monitoring of the fill process and subsequent engagement of graft extensions (not shown). The material may be cured by any of the suitable methods discussed herein including time lapse, heat application, application of electromagnetic energy, ultrasonic energy application, chemical adding or mixing or the like. Some

embodiments for the inflation material that may be used to provide outward pressure or a rigid structure from within the inflatable cuff 134 or network of inflatable channels 136 may include inflation materials formed from glycidyl ether and amine materials. Some inflation material embodiments may include an in situ formed hydrogel polymer having a first amount of diamine and a second amount of polyglycidyl ether wherein each of the amounts are present in a mammal or in a medical device, such as an inflatable graft, located in a mammal in an amount to produce an in situ formed hydrogel polymer that is biocompatible and has a cure time after mixing of about 10 seconds to about 30 minutes and wherein the volume of said hydrogel polymer swells less than 30 percent after curing and hydration. Some embodiments of the inflation material may include radiopaque material such as sodium iodide, potassium iodide, barium sulfate, Visipaque 320, Hypaque, Omnipaque 350, Hexabrix and the like. For some inflation material embodiments, the polyglycidyl ether may be selected from trimethylolpropane triglycidyl ether, sorbitol polyglycidyl ether, polyglycerol polyglycidyl ether, pentaerythritol polyglycidyl ether, diglycerol polyglycidyl ether, glycerol polyglycidyl ether, trimethylolpropane polyglycidyl ether, polyethylene glycol diglycidyl ether, resorcinol diglycidyl ether, glycidyl ester ether of p-hydroxy benzoic acid, neopentyl glycol diglycidyl ether, 1,6-hexanediol diglycidyl ether, bisphenol A $(PO)_2$ diglycidyl ether, hydroquinone diglycidyl ether, bisphenol S diglycidyl ether, terephthalic acid diglycidyl ester, and mixtures thereof. For some inflation material embodiments, the diamine may be selected from (poly)alkylene glycol having amino or alkylamino termini selected from the group consisting of polyethylene glycol (400) diamine, di-(3-aminopropyl) diethylene glycol r, polyoxypropylenediamine, polyetherdiamine, polyoxyethylenediamine, triethyleneglycol diamine and mixtures thereof. For some embodiments, the diamine may be hydrophilic and the polyglycidyl ether may be hydrophilic prior to curing. For some embodiments, the diamine may be hydrophilic and the polyglycidyl ether is hydrophobic prior to curing. For some embodiments, the diamine may be hydrophobic and the polyglycidyl ether may be hydrophilic prior to curing.

The network of inflatable channels 136 may be partially or fully inflated by injection of a suitable inflation material into the main fill port 116 to provide rigidity to the network of inflatable channels 136 and the graft 114. In addition, a seal is produced between the inflatable cuff 134 and the inside surface of the abdominal aorta 10. Although it is desirable to partially or fully inflate the network of inflatable channels 136 of the graft 114 at this stage

of the deployment process, such inflation step optionally may be accomplished at a later stage if necessary.

Once the graft 114 is deployed and the inflatable channels 136 thereof have been filled and expanded, another delivery catheter (not shown) may be used to deploy a contralateral graft extension 138, as depicted in FIG. 5. The contralateral graft extension 138 is in an axial position which overlaps the contralateral leg 128 of the graft 114. The amount of desired overlap of the graft extension 138 with the contralateral leg 128 may vary depending on a variety of factors including vessel morphology, degree of vascular disease, patient status and the like. However, for some embodiments, the amount of axial overlap between the contralateral graft extension 138 and the contralateral leg 128 may be about 1 cm to about 5 cm; more specifically, about 2 cm to about 4 cm. Once the contralateral graft extension 138 has been deployed, an ipsilateral graft extension 140 may be similarly deployed in the ipsilateral graft leg 126.

For some deployment embodiments, the patient's hypogastric arteries may be used to serve as a positioning reference point to ensure that the hypogastric arteries are not blocked by the deployment. Upon such a deployment, the distal end of a graft extension 138 or 140 may be deployed anywhere within a length of the ipsilateral leg 126 or contralateral leg 128 of the graft 114. Also, although only one graft extension 140, 138 is shown deployed on the ipsilateral side and contralateral side of the graft assembly 114, additional graft extensions 140, 138 may be deployed within the already deployed graft extensions 140, 138 in order to achieve a desired length extension of the ipsilateral leg 126 or contralateral leg 128. For some embodiments, about 1 to about 5 graft extensions 138, 140 may be deployed on either the ipsilateral or contralateral sides of the graft assembly 114. Successive graft extensions 138, 140 may be deployed within each other so as to longitudinally overlap fluid flow lumens of successive graft extensions.

Graft extensions 138, 140, which may be interchangeable for some embodiments, or any other suitable extension devices or portions of the main graft section 124 may include a variety of suitable configurations. For some embodiments, graft extensions 138, 140 may include a polytetrafluoroethylene (PTFE) graft 142 with helical nitinol stent 144.

Further details of the endovascular prosthesis 106 and/or graft extensions 138, 140 may be found in commonly owned U.S. Patent Nos. 6,395,019; 7,081,129; 7,147,660; 7,147,661; 7,150,758; 7,615,071; 7,766,954 and 8,167,927 and commonly owned U.S. Published Application No. 2009/0099649, the contents of all of which are incorporated herein by reference in their entirety. Details for the manufacture of the endovascular prosthesis 106 may be found in commonly owned U.S. Patent Nos. 6,776,604; 7,090,693; 7,125,464; 7,147,455; 7,678,217 and 7,682,475, the contents of all of which are incorporated herein by reference in their entirety. Useful inflation materials for the inflatable graft 114 may be found in may be found in commonly owned U.S. Published Application No. 2005/0158272 and 2006/0222596, the contents of all of which are incorporated herein by reference in their entirety. Additional details of an endovascular delivery system having an improved radiopaque marker system for accurate prosthesis delivery may be found in commonly owned U.S. Provisional Application No. 61/660,413, entitled "Endovascular Delivery System With An Improved Radiopaque Marker Scheme", filed June 15, 2012, and having Attorney Docket No. 1880-42P, the contents of which are incorporated the herein by reference in their entirety.

Useful graft materials for the endovascular prosthesis 106 include, but are not limited, polyethylene; polypropylene; polyvinyl chloride; polytetrafluoroethylene (PTFE); fluorinated ethylene propylene; fluorinated ethylene propylene; polyvinyl acetate; polystyrene; poly(ethylene terephthalate); naphthalene dicarboxylate derivatives, such as polyethylene naphthalate, polybutylene naphthalate, polytrimethylene naphthalate and trimethylenediol naphthalate; polyurethane, polyurea; silicone rubbers; polyamides; polyimides; polycarbonates; polyaldehydes; polyether ether ketone; natural rubbers; polyester copolymers; silicone; styrene-butadiene copolymers; polyethers; such as fully or partially halogenated polyethers; and copolymers and combinations thereof. In some embodiments, the graft materials are non-textile graft materials, e.g., materials that are not woven, knitted, filament-spun, etc. that may be used with textile grafts. Such useful graft material may be extruded materials. Particularly useful materials include porous polytetrafluoroethylene without discernable node and fibril microstructure and (wet) stretched PTFE layer having low or substantially no fluid permeability that includes a closed cell microstructure having high density regions whose grain boundaries are directly interconnected to grain boundaries of adjacent high density regions and having substantially no node and fibril microstructure , and porous PTFE having no or substantially no fluid permeability. Such PTFE layers may lack distinct, parallel fibrils that interconnect adjacent nodes of ePTFE, typically have no

discernable node and fibril microstructure when viewed at a magnification of up to 20,000. A porous PTFE layer having no or substantially no fluid permeability may have a Gurley Number of greater than about 12 hours, or up to a Gurley Number that is essentially infinite, or too high to measure, indicating no measurable fluid permeability. Some PTFE layers having substantially no fluid permeability may have a Gurley Number at 100 cc of air of greater than about 10^6 seconds. The Gurley Number is determined by measuring the time necessary for a given volume of air, typically, 25 cc, 100 cc or 300 cc, to flow through a standard 1 square inch of material or film under a standard pressure, such as 12.4 cm column of water. Such testing maybe carried out with a Gurley Densometer, made by Gurley Precision Instruments, Troy, NY. Details of such useful PTFE materials and methods for manufacture of the same may be found in commonly owned U.S. Patent Application Publication No. 2006/0233991, the contents of which are incorporated herein by reference in their entirety.

FIG. 6 is a side elevational view of the endovascular delivery system 100 of the present invention. The endovascular delivery system 100 may include, among other things, the nosecone 120; the outer sheath 104; a retraction knob or handle 152 for the outer sheath 104; a flush port 154 for the outer sheath 104; an outer sheath radiopaque marker band 156; an inner tubular member or hypotube 150; an inflation material or polymer fill connector port 158; an inflation material or polymer fill cap 160; a guidewire flush port 162; a guidewire flush port cap 164; a guidewire port 166; and nested stent release knobs 168; interrelated as shown. The inner tubular member 150 may be formed from any of the above-described materials for the outer sheath 104. In addition, a portion of the inner tubular member 150 or even the entire inner tubular member 150 may be in the form of a metallic hypotube. Details of useful metallic hypotubes and endovascular delivery systems containing the same may be found in commonly owned U.S. Provisional Application No. 61/660,103, entitled "Endovascular Delivery System With Flexible And Torqueable Hypotube", Attorney Docket 1880-43P, filed June 15, 2012, the contents of which are incorporated herein by reference in their entirety.

The flush port 154 for the outer sheath 104 may be used to flush the outer sheath 104 during delivery stages. The outer sheath 104 may have a radiopaque marker band to aid the practitioner in properly navigating the delivery system 100 to the desired bodily site. The outer sheath 104 is retractable by movement of the retraction knob or handle 152 for the outer

sheath 104 by a practitioner towards the proximal handle assembly 170 of the delivery system 100. The inner tubular member or hypotube 150 is disposed from the inner tubular member or hypotube 150 toward a proximal portion of the delivery system 100. The inflation material or polymer fill connector port 158 and the inflation material or polymer fill cap 160 are useful for providing inflation material (e.g., polymeric fill material) to inflate proximal inflatable cuffs 134 and the network of inflatable channels 136 of the inflatable graft 114. The guidewire flush port 162 and the guidewire flush port cap 164 are useful for flushing the guidewire port 166 during delivery stages of the delivery system 100. The nested stent release knobs 168 contains a series of nested knobs (not shown) that that are used to engage release mechanisms for delivery of the endovascular prosthesis 106. Further details, including but not limited to methods, catheters and systems, for deployment of endovascular prostheses are disclosed in commonly owned U.S. Patent Nos. 6,761,733 and 6,733,521 and commonly owned U.S. Patent Application Publication Nos. 2006/0009833 and 2009/0099649, all of which are incorporated by reference herein in their entirety.

FIG. 7 is a side elevational and partial cutaway view of the proximal portion 172 of the endovascular delivery system 100 of the present invention, and FIG. 8 is a partial perspective and partial cutaway view of the proximal portion 172 of the endovascular delivery system 100 of the present invention. The proximal portion 172 of the endovascular delivery system 100 includes prosthesis/stent holders 174 disposed upon a prosthesis/stent holder guidewire 176. The holders 174 are useful releasably securing the endovascular prosthesis 106 (not shown) within the delivery system 100. The holders 174 inhibit or substantially inhibit undesirable longitudinal and/or circumferential movement of the endovascular prostheses 106 during delivery stages of the delivery system 100. Belts 110 serve to restrain the endovascular prosthesis 106 in a radially constrained stage until desired release of the endovascular prosthesis 106.

FIG. 9 is an elevational view of the prosthesis 106 of the present invention having a flap 180 at the ipsilateral leg 126. The flap 180 may be made from any of the above-described graft materials. In some embodiments, the flap 180 is made from polytetrafluoroethylene. The flap 180 may include two holes 182. The width of the flap may be from about 10% to about 90% of the circumference of the ipsilateral leg 126. In some embodiments, the width is from about 30% to about 60%; in other embodiments, from about 45% to about 55%. The flap 182 may contain two holes 182 as shown in FIG. 9, one hole, or

more than two holes. A hole diameter of about 0.06 inches is useful, although hole diameters may be higher or lower. In the case of more than one hole, the hole diameters may vary between or among holes.

FIG. 10 is a partial elevational view of one embodiment including a distal stop 186 on a delivery guidewire 184 for restraining the ipsilateral leg 126 of the prosthesis 106 during certain delivery stages of the prosthesis 106. The distal stop 186 includes two raised projections 188 securably attached to a guidewire 184. A release wire 190 is slidably disposed within the projections 188. As depicted in FIGS. 11 and 12, the distal stop 186 is useful for releasably securing the ipsilateral leg 126, in particular the flap 180, to the distal stop 186 and the guidewire 184. The raised projections 188 may be secured or disposed within one or both of the flap holes 182. The release wire 190 is thus releasably inter-looped or inter-laced within or to the flap 180.

FIG. 13 is a schematic depiction of the ends of the contralateral and ipsilateral graft legs 128, 126 of the prosthesis 106 having a contralateral tether 192. The contralateral tether 192 has a contralateral end 196 and an opposed ipsilateral end 198. The contralateral end 196 is securably disposed to the end of the contralateral leg 128. The contralateral tether 192 may also be made from any of the above-described graft materials. In some embodiments, the contralateral tether 192 is made from polytetrafluoroethylene. As depicted in FIGS. 13 and 14, the release wire 190 releasably engages a portion of the tether 192. In some embodiments, the release wire 190 is slidably disposed through a hole 194 near the ipsilateral end 198 of the tether 192 as depicted in FIG. 13. When the release wire 190 is engaged with the tether 192, undesirably longitudinal movement, such as bunching, of the contralateral leg 128 is mitigated or even prevented as the contralateral leg 128 is ultimately and relatively restrained by the release wire and the ipsilateral leg 126 is relatively restrained by the distal stop 186 and the release wire 190. The contralateral tether 192 may also mitigate or prevent undesirable rotation of the contralateral leg 128 with respect to the ipsilateral leg 126 when the tether 192 is so engaged with the release wire 190.

In some embodiments, the tether 192 can withstand aggressive cannulation without disconnecting from the contralateral leg 128. For example, the tether 192 may have a tensile strength greater than 0.5 pounds-force per square inch (psi), which is an approximate maximum force which may be applied clinically. The tether 192 may have a tensile strength

of about 2.0 psi. Such a tensile strength is non-limiting. Use of the contralateral tether 192 also allows filling of the inflatable graft 114 without impingement of the fill tube 116 or the network of channels 136. In the case of narrow distal aortic necks or in acute aortoiliac angles, a "ballerina" type crossover configuration (also referred to as a "barber pole: configuration) of the ipsilateral and contralateral graft legs may be used by a practitioner. In such a "ballerina" type crossover configuration the two iliac graft limbs may cross each other one or more times distal to the aortic body but before entering the iliac arteries of a patient treated with a bifurcated graft. Such a "ballerina" type crossover configuration may be achieved even with the use of the tether 192 with the inflatable graft 114 of the present invention. Moreover, use of the tether 192 prevents undesirably leg 126, 128 flipping during positioning of the inflatable graft 114.

The tether 192 width may be from about 2 to 5 mm, and its length may be from about 5 to 20 mm. These dimensions are non-limiting dimensions, and other suitable dimensions may be used. For example, in some embodiments (not shown), the contralateral tether 192 may have an ipsilateral end 198 that is not configured for engagement with a release wire 190 but rather is configured to run through the inner tubular member 150 and terminate at the proximal handle assembly 170 of the delivery system and releasably secured to a component thereof, such as an additional knob on handle assembly 170. A longer contralateral tether 192 of such a configuration may be manipulated by the physician-user in the same manner to mitigate or prevent undesirable movement or rotation of one or both legs 126, 128 during positioning of the inflatable graft 114 as described herein. This may provide beneficial positioning control or manipulation of the legs 126, 128, as opposed to must mitigating or preventing undesirable movement. Such a longer tether 192 would not necessary have to come all the way out of the handle 170, but alternatively could be engaged by a control wire or other control mechanism terminating at or near the handle 170.

The present invention, however, is not limited to the use of the tether 192 to restrain the contralateral leg 128 during deployment, and other suitably arrangements may be used. For example, as depicted in FIGS. 15 and 16, the release wire 190 may be looped through a hole 200 in the contralateral leg 128. As depicted in FIG 17, a loop 202 of polymeric material, such a polytetrafluoroethylene, may be disposed between the contralateral leg 128 and the ipsilateral leg 126. The loop 202 may be withdrawn via a release wire (not shown) which may have only one end (not shown) the loop secured thereto. Moreover, as depicted in

FIG. 18, a relatively stiffer polymeric member 204, such as a polyamide tube of thread, may be used to restrain movement of the contralateral leg 128 relative to the ipsilateral leg 126. Such a polymeric member 204 may be secured to the release wire 190 or to another release wire within the delivery system 100. These examples of non-tethering restrains are not limiting and other restraining arrangements may be suitably be used.

The present invention, however, is not limited to the use of the above-described tether 192, the above-described release wire 190 and/or the above-described a loop 202 to restrain the contralateral leg 128 during deployment, and other suitably arrangements may be used. For example, as depicted in FIGS. 19 through 21, a web 210 may be disposed between the contralateral leg 128 and the ipsilateral leg 126. The web 210 may be fabricated from any useful biocompatible materials, including biocompatible materials used to form endovascular prosthesis 106 or sections of the endovascular prosthesis 106, such as the contralateral leg 128 and/or the ipsilateral leg 126.

As depicted in FIG. 19, the web 210 may be substantially disposed between the contralateral leg 128 and the ipsilateral leg 126 to so constrain relative movement of the legs 128, 126 during initial stages of deployment of the endovascular prosthesis 106. The web 210 may be cut or otherwise separated into portions during delivery by the practitioner so as to facilitate proper placement of the contralateral leg 128 and the ipsilateral leg 126. During delivery of the endovascular prosthesis 106. Such portions may be removed by the practitioner or may remain within the aortic aneurysm 20. Furthermore, the web 210 may contain a weakened portion or tear-line 212. The tear-line 212 may be configured to allow separation of one portion of the web 210 from another portion of the web 210 upon application of a displacement force (not shown) by the practitioner to separate of properly position the contralateral leg 128 and the ipsilateral leg 126 within the aortic aneurysm 20 or proximal to the aortic aneurysm 20, for example near or within the iliac arteries 14, 16. As such, the web 210 may be secured to the contralateral leg 128 and the ipsilateral leg 126, including releasably secured to the contralateral leg 128 and the ipsilateral leg 126.

FIG. 20 is a cross-section view of the contralateral leg 128, the ipsilateral leg 126 and the web 210 taken along the 20-20 axis of FIG. 19. As depicted in FIG. 20, the web 210 is a sheet of material inter-connecting or inter-engaging the contralateral leg 128 and the ipsilateral leg 126. While the web 210 is as a planar sheet in FIGS. 19 and 20, the present

invention is not so limited. The web 210 may be non-planar in shape (not shown), for example having slag or folded over sections to permit a degree of movement between the contralateral leg 128 and the ipsilateral leg 126. Furthermore, the web 210 is not limited to being a sheet of material. For example, the web 210 may itself be perforated, such as but not limited to a screen configuration, where the web 210 may have interstitial openings (not shown) or openable interstitial apertures (not shown) to permit greater flexibility over a planar sheet of material. Moreover, as depicted in FIG. 21, a plurality of webs 210 may suitable be used to inter-connecting or inter-engaging the contralateral leg 128 and the ipsilateral leg 126.

The web 210 may be shaped, configured or constructed to allow more leg independent mobility at the distal portions of the legs 126, 128 as compared to proximal leg portions near the bifurcation portion of the graft or prosthesis 106. For example, the web 210 may have a curved and/or indented distal edge(s) or portion(s) near the distal portions of the legs 126, 128, where such curved and/or indented distal web edge(s) or portion(s) allows or permits the legs 126, 128 more relative independent movement as compared to a regular-shaped or triangular-shaped web 210 as depicted in FIG. 19. Such increased leg independent mobility at the distal portions of the legs 126, 128 may also be achieved by any suitable means. On additional, non-limiting example includes varying the thickness of the web 210 to achieve such increased leg independent mobility at the distal portions of the legs 126, 128. For example, portions of the web 210 near the distal portions of the legs 126, 128 could have reduced thickness, i.e., thinner, as compared to portions of the web 201 near the bifurcation of the graft or prosthesis 106. Further, the materials of construction of the web 210 may vary such that web portions near the distal portions of the legs 126, 128 include materials having greater modulus of flexibility and/or elasticity as compared materials portions of the web 201 near the bifurcation of the graft or prosthesis 106.

The following embodiments or aspects of the invention may be combined in any fashion and combination and be within the scope of the present invention, as follows:

Embodiment 1. An endovascular delivery system, comprising:

a bifurcated and inflatable prosthesis comprising:

a main tubular body having an open end and opposed ipsilateral and contralateral legs defining a graft wall therein between, said ipsilateral

and contralateral legs having open ends, and said main tubular body and said ipsilateral and contralateral legs having inflatable channels;

said ipsilateral leg comprising an ipsilateral tab extending from the open end of said ipsilateral leg, said tab comprising at least two holes;

an elongate guidewire having at least two outwardly projecting members, said outwardly projecting members being sized to at least partially fit within the at least one of said at least two holes of said ipsilateral tab;

a release wire slidable disposed within the at least two outwardly projecting members of the elongate guidewire and within one of the at least two holes of said ipsilateral tab; and

a tether having opposed contralateral and ipsilateral ends, said contralateral end of the tether being securably disposed at said open end of said contralateral leg, said ipsilateral end of the tether having a hole, said release wire being slidably disposed through the hole of the tether to so engage the tether;

wherein withdrawal of the release wire releases the ipsilateral tab and the tether from the elongate guidewire.

Embodiment 2. The endovascular delivery system of embodiment 1, wherein, when said release wire engages said tether, the open end of the contralateral leg is proximally disposed and restrained towards the open end of the ipsilateral leg.

Embodiment 3. The endovascular delivery system of embodiment 2, wherein the contralateral leg is restricted from significant longitudinal movement so as to prevent bunching up of the contralateral leg.

Embodiment 4. The endovascular delivery system of embodiment 2, wherein the contralateral leg is restricted from significant rotational movement so as to prevent misalignment within a bodily lumen.

Embodiment 5. The endovascular delivery system of embodiment 1, wherein said elongate guidewire is extendable through the ipsilateral leg and through the main tubular body.

Embodiment 6. The endovascular delivery system of embodiment 1, further comprising:

an elongate outer tubular sheath having an open lumen and opposed proximal and distal ends with a medial portion therein between, the proximal end of the outer tubular sheath securably disposed to a first handle;

an elongate inner tubular member having a tubular wall with an open lumen and opposed proximal and distal ends with a medial portion therein between, the inner tubular member having a longitudinal length greater than a longitudinal

length of the outer tubular sheath, the inner tubular member being slidably disposed within the open lumen of the outer tubular sheath, the proximal end of the inner tubular member securably disposed to a second handle;

said elongate guidewire slidably disposed within the inner tubular member;

the distal end of the outer tubular sheath being slidably disposed past and beyond the distal end of the inner tubular member to define a prosthesis delivery state and slidably retractable to the medial portion of the inner tubular member to define a prosthesis unsheathed state.

Embodiment 7. The endovascular delivery system of embodiment 1, wherein the prosthesis comprises non-textile polymeric material.

Embodiment 8. The endovascular delivery system of embodiment 1, wherein the non-textile polymeric material of the prosthesis comprises extruded polytetrafluoroethylene.

Embodiment 9. The endovascular delivery system of embodiment 8, wherein said extruded polytetrafluoroethylene is non-porous polytetrafluoroethylene.

Embodiment 10. The endovascular delivery system of embodiment 1, wherein the prosthesis further comprises a metallic expandable member securably disposed at or near the open end of the main tubular body of said prosthesis.

Embodiment 11. A method for delivering a bifurcated prosthesis, comprising:

providing a bifurcated and inflatable prosthesis comprising:

a main tubular body having an open end and opposed ipsilateral and contralateral legs defining a graft wall therein between, said ipsilateral and contralateral legs having open ends, and said main tubular body and said ipsilateral and contralateral legs having inflatable channels;

said ipsilateral leg comprising an ipsilateral tab extending from the open end of said ipsilateral leg, said tab comprising at least two holes;

providing an elongate guidewire having at least two outwardly projecting members, said outwardly projecting members being sized to at least partially fit within at least one of said at least two holes of said ipsilateral tab;

providing a release wire slidable disposed within the at least two outwardly projecting members of the elongate guidewire and within the at least two holes of said ipsilateral tab;

providing a tether having opposed contralateral and ipsilateral ends, said contralateral end of the tether being securably disposed at said open end of said contralateral leg, said ipsilateral end of the tether having a hole, said release

wire being slidably disposed through the hole of the tether to so engage the tether; and

withdrawing the release wire to release the ipsilateral tab and the tether from the elongate guidewire.

Embodiment 12. The method of embodiment 11, wherein, when said release wire engages said tether, the open end of the contralateral leg is proximally disposed and restrained towards the open end of the ipsilateral leg.

Embodiment 13. The method of embodiment 12, wherein the contralateral leg is restricted from significant longitudinal movement so as to prevent bunching up of the contralateral leg.

Embodiment 14. The method of embodiment 12, wherein the contralateral leg is restricted from significant rotational movement so as to prevent misalignment within a bodily lumen.

Embodiment 15. An endovascular prosthesis, comprising:

a bifurcated and inflatable prosthesis comprising:

a main tubular body having an open end and opposed ipsilateral and contralateral legs defining a graft wall therein between, said ipsilateral and contralateral legs having open ends, and said main tubular body and said ipsilateral and contralateral legs having inflatable channels; and

a web of biocompatible material disposed between the contralateral leg and the ipsilateral leg and secured to the contralateral leg and the ipsilateral leg;

wherein the contralateral leg is restricted from significant longitudinal movement so as to prevent bunching up of the contralateral leg during delivery of the endovascular prosthesis.

Embodiment 16. The endovascular prosthesis of embodiment 15, wherein the contralateral leg is restricted from significant rotational movement so as to prevent misalignment within a bodily lumen.

Embodiment 17. The endovascular prosthesis of embodiment 15, wherein the web is releasably secured to the contralateral leg and the ipsilateral leg.

While various embodiments of the present invention are specifically illustrated and/or described herein, it will be appreciated that modifications and variations of the present

invention may be effected by those skilled in the art without departing from the spirit and intended scope of the invention. Further, any of the embodiments or aspects of the invention as described in the claims or in the specification may be used with one and another without limitation.

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WHAT IS CLAIMED IS:

1. An endovascular delivery system, comprising:

a bifurcated and inflatable prosthesis comprising:

a main tubular body having an open end and opposed ipsilateral and contralateral legs defining a graft wall therein between, said ipsilateral and contralateral legs having open ends, and said main tubular body and said ipsilateral and contralateral legs having inflatable channels;

said ipsilateral leg comprising an ipsilateral tab extending from the open end of said ipsilateral leg, said tab comprising at least two holes;

an elongate guidewire having at least two outwardly projecting members, said outwardly projecting members being sized to at least partially fit within the at least one of said at least two holes of said ipsilateral tab;

a release wire slidable disposed within the at least two outwardly projecting members of the elongate guidewire and within one of the at least two holes of said ipsilateral tab; and

a tether having opposed contralateral and ipsilateral ends, said contralateral end of the tether being securably disposed at said open end of said contralateral leg, said ipsilateral end of the tether having a hole, said release wire being slidably disposed through the hole of the tether to so engage the tether;

wherein withdrawal of the release wire releases the ipsilateral tab and the tether from the elongate guidewire.

2. The endovascular delivery system of claim 1, wherein, when said release wire engages said tether, the open end of the contralateral leg is proximally disposed and restrained towards the open end of the ipsilateral leg.

3. The endovascular delivery system of claim 2, wherein the contralateral leg is restricted from significant longitudinal movement so as to prevent bunching up of the contralateral leg.

4. The endovascular delivery system of claim 2, wherein the contralateral leg is restricted from significant rotational movement so as to prevent misalignment within a bodily lumen.

5. The endovascular delivery system of claim 1, wherein said elongate guidewire is extendable through the ipsilateral leg and through the main tubular body.

6. The endovascular delivery system of claim 1, further comprising:

an elongate outer tubular sheath having an open lumen and opposed proximal and distal ends with a medial portion therein between, the proximal end of the outer tubular sheath securably disposed to a first handle;

an elongate inner tubular member having a tubular wall with an open lumen and opposed proximal and distal ends with a medial portion therein between, the inner tubular member having a longitudinal length greater than a longitudinal length of the outer tubular sheath, the inner tubular member being slidably disposed within the open lumen of the outer tubular sheath, the proximal end of the inner tubular member securably disposed to a second handle;

said elongate guidewire slidably disposed within the inner tubular member;

the distal end of the outer tubular sheath being slidably disposed past and beyond the distal end of the inner tubular member to define a prosthesis delivery state and slidably retractable to the medial portion of the inner tubular member to define a prosthesis unsheathed state.

7. The endovascular delivery system of claim 1, wherein the prosthesis comprises non-textile polymeric material.

8. The endovascular delivery system of claim 1, wherein the non-textile polymeric material of the prosthesis comprises extruded polytetrafluoroethylene.

9. The endovascular delivery system of claim 8, wherein said extruded polytetrafluoroethylene is non-porous polytetrafluoroethylene.

10. The endovascular delivery system of claim 1, wherein the prosthesis further comprises a metallic expandable member securably disposed at or near the open end of the main tubular body of said prosthesis.

11. A method for delivering a bifurcated prosthesis, comprising:

providing a bifurcated and inflatable prosthesis comprising:

a main tubular body having an open end and opposed ipsilateral and contralateral legs defining a graft wall therein between, said ipsilateral and contralateral legs having open ends, and said main tubular body and said ipsilateral and contralateral legs having inflatable channels;

said ipsilateral leg comprising an ipsilateral tab extending from the open end of said ipsilateral leg, said tab comprising at least two holes;

providing an elongate guidewire having at least two outwardly projecting members, said outwardly projecting members being sized to at least partially fit within at least one of said at least two holes of said ipsilateral tab;

providing a release wire slidable disposed within the at least two outwardly projecting members of the elongate guidewire and within the at least two holes of said ipsilateral tab;

providing a tether having opposed contralateral and ipsilateral ends, said contralateral end of the tether being securably disposed at said open end of said contralateral leg, said ipsilateral end of the tether having a hole, said release wire being slidably disposed through the hole of the tether to so engage the tether; and

withdrawing the release wire to release the ipsilateral tab and the tether from the elongate guidewire.

12. The method of claim 11, wherein, when said release wire engages said tether, the open end of the contralateral leg is proximally disposed and restrained towards the open end of the ipsilateral leg.

13. The method of claim 12, wherein the contralateral leg is restricted from significant longitudinal movement so as to prevent bunching up of the contralateral leg.

14. The method of claim 12, wherein the contralateral leg is restricted from significant rotational movement so as to prevent misalignment within a bodily lumen.

15. An endovascular prosthesis, comprising:

a bifurcated and inflatable prosthesis comprising:

a main tubular body having an open end and opposed ipsilateral and contralateral legs defining a graft wall therein between, said ipsilateral and contralateral legs having open ends, and said main tubular body

and said ipsilateral and contralateral legs having inflatable channels; and

a web of biocompatible material disposed between the contralateral leg and the ipsilateral leg and secured to the contralateral leg and the ipsilateral leg;

wherein the contralateral leg is restricted from significant longitudinal movement so as to prevent bunching up of the contralateral leg during delivery of the endovascular prosthesis.

16. The endovascular prosthesis of claim 15, wherein the contralateral leg is restricted from significant rotational movement so as to prevent misalignment within a bodily lumen.

17. The endovascular prosthesis of claim 15, wherein the web is releasably secured to the contralateral leg and the ipsilateral leg.

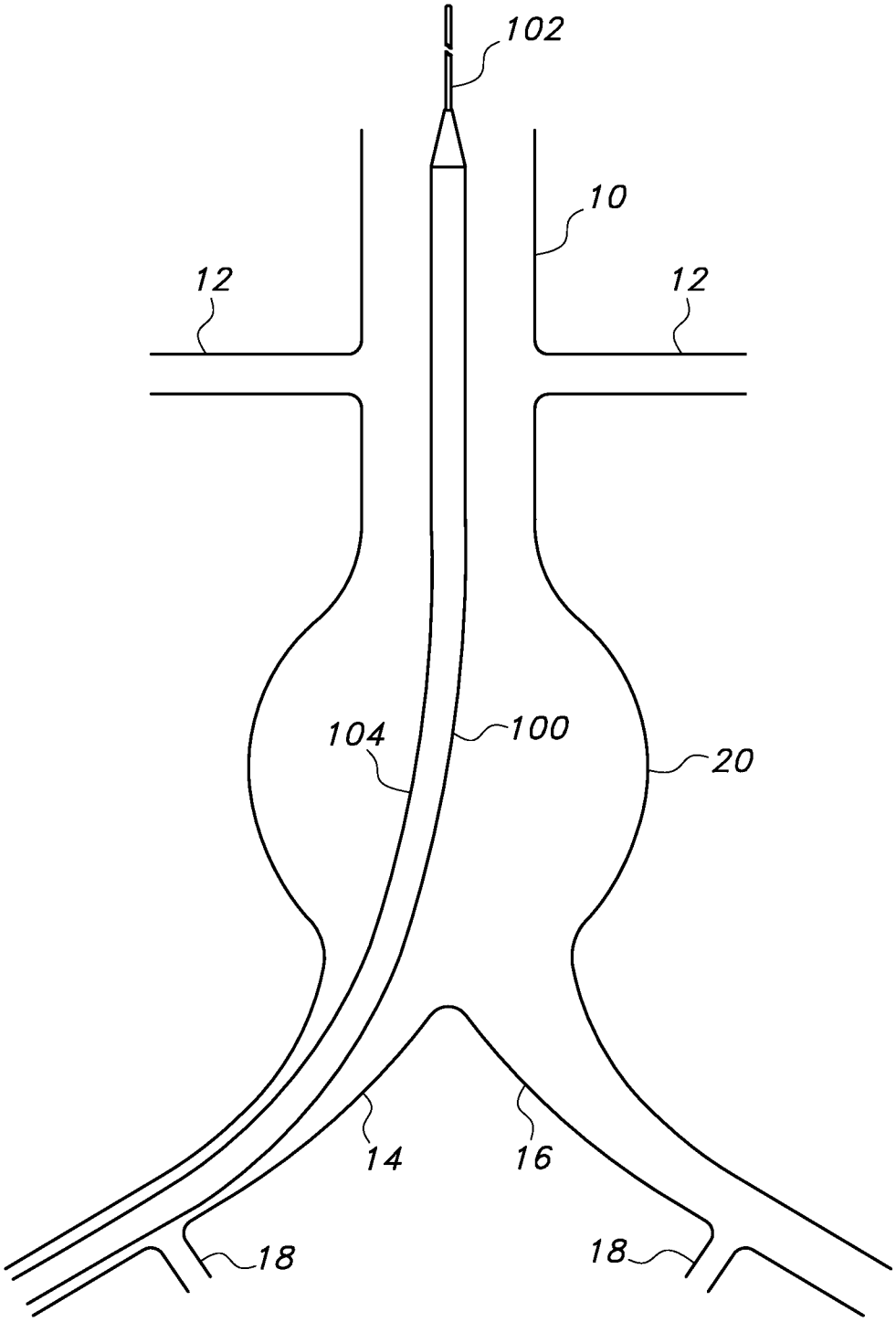

FIG. 1

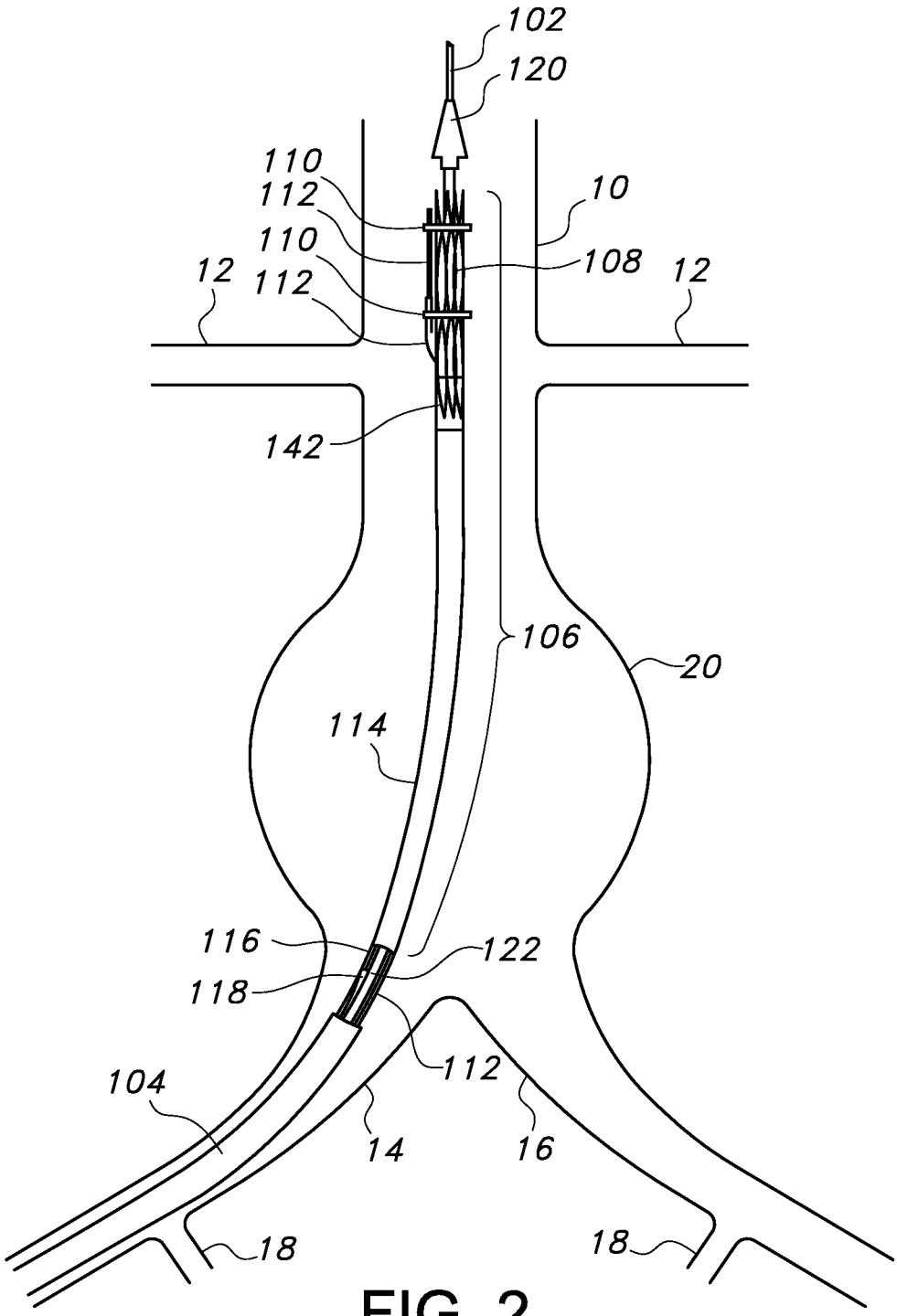
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FIG. 2

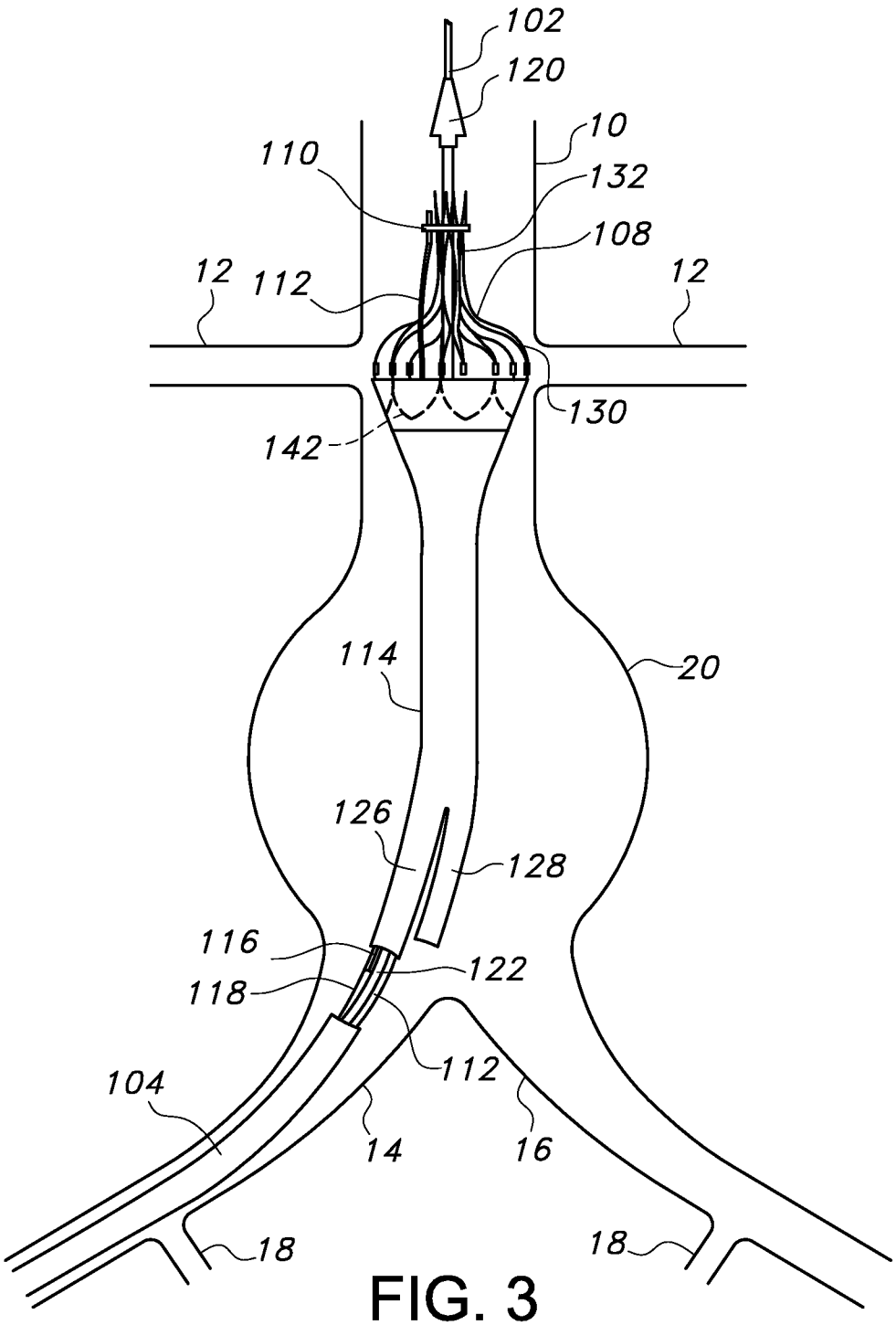
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FIG. 3

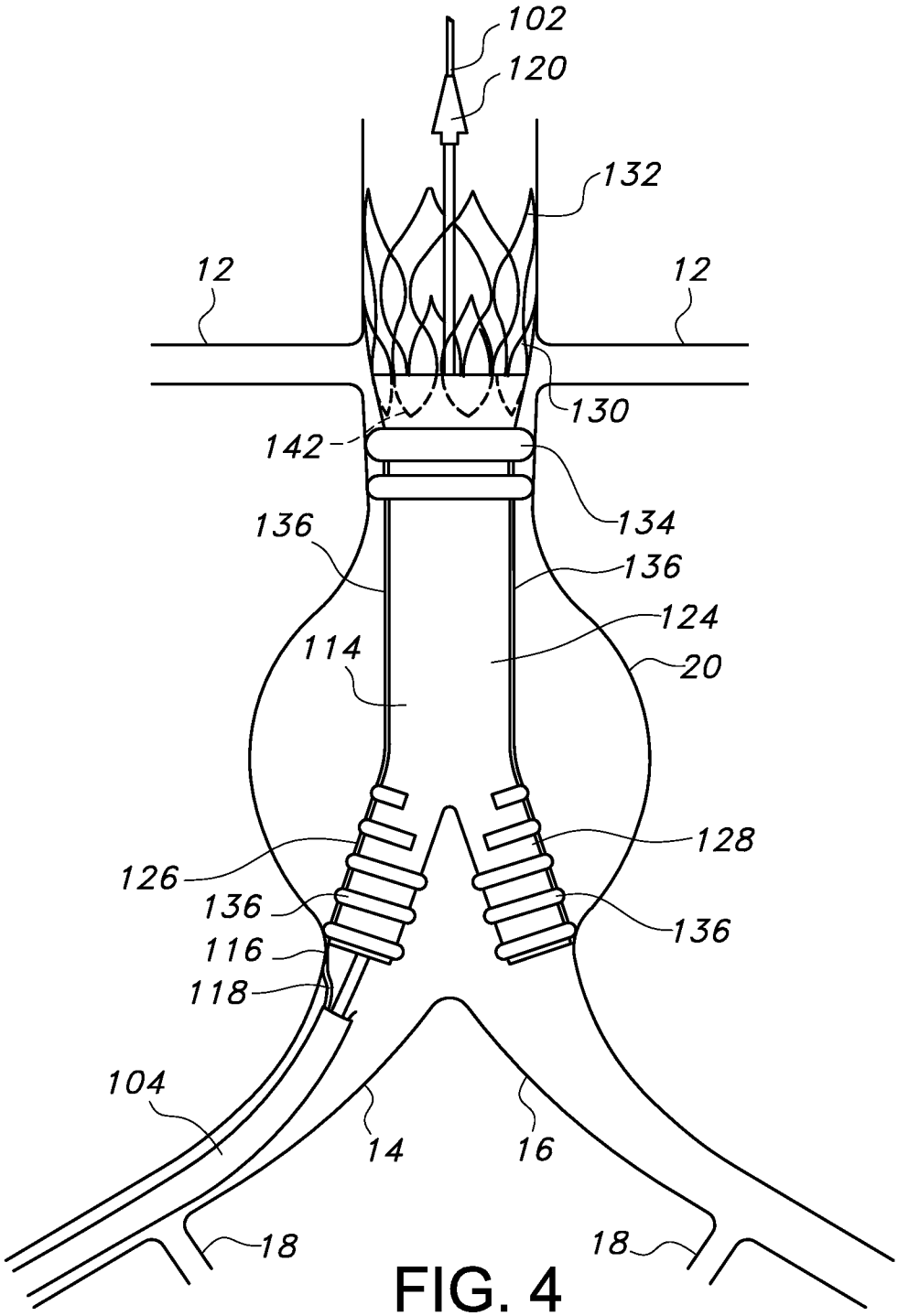
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FIG. 4

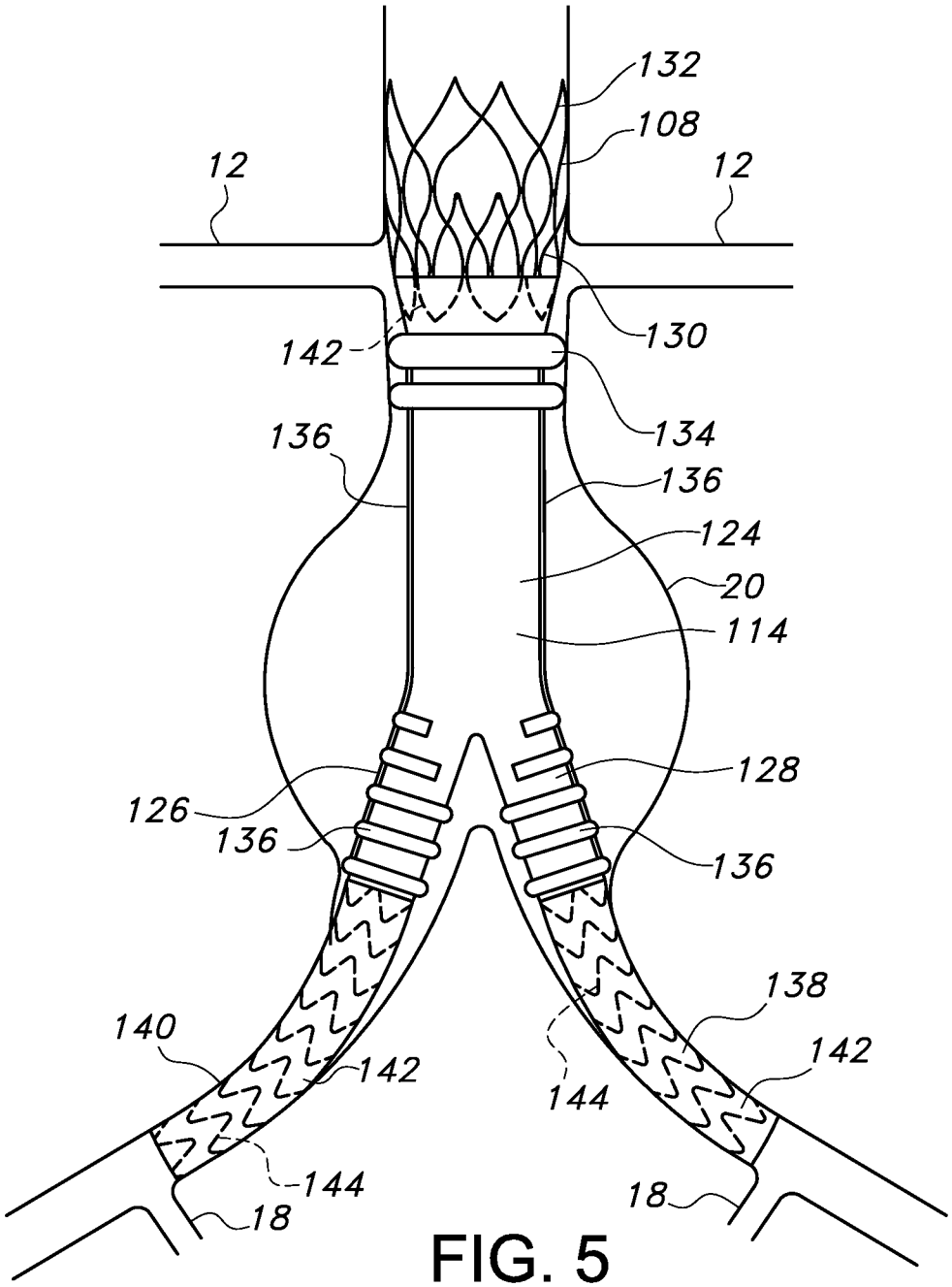
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FIG. 5

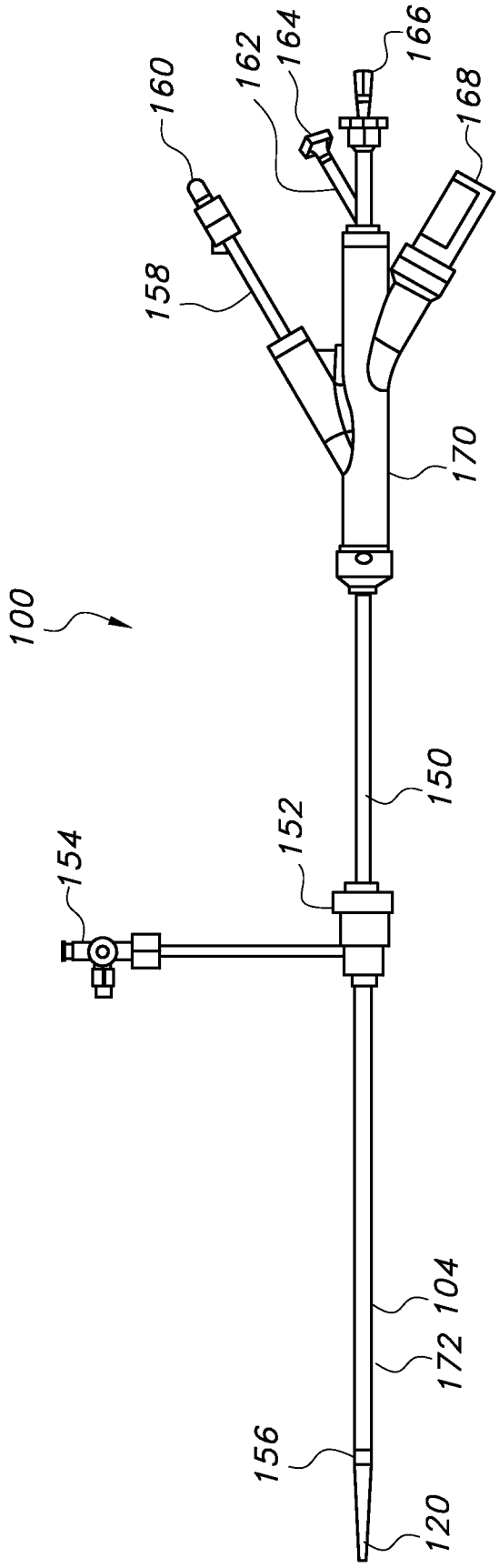

FIG. 6

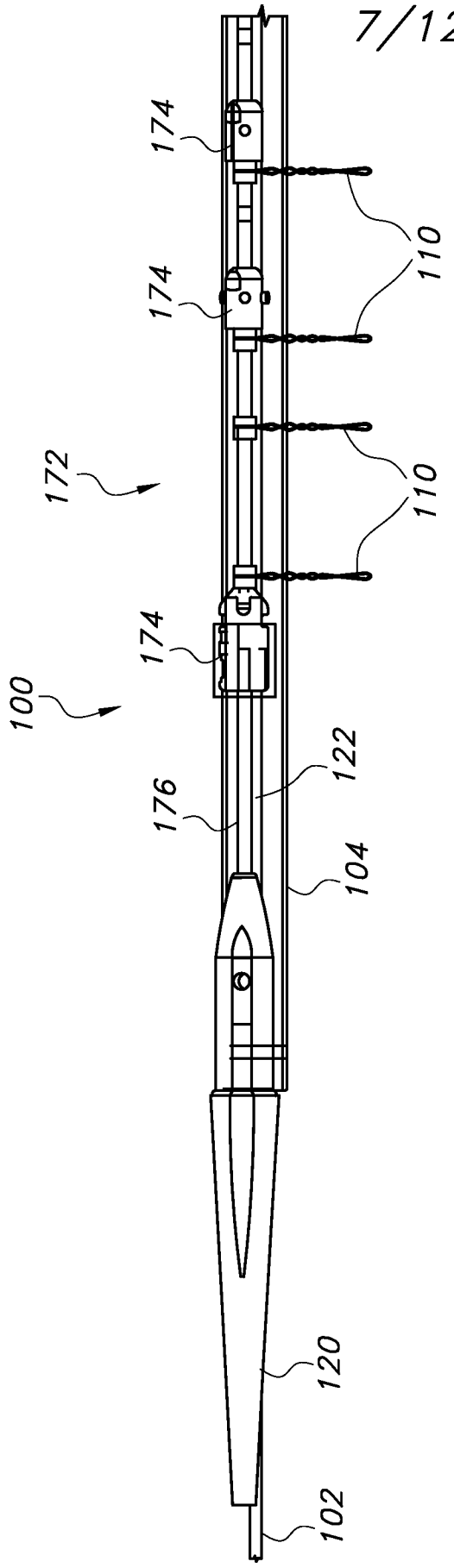

FIG. 7

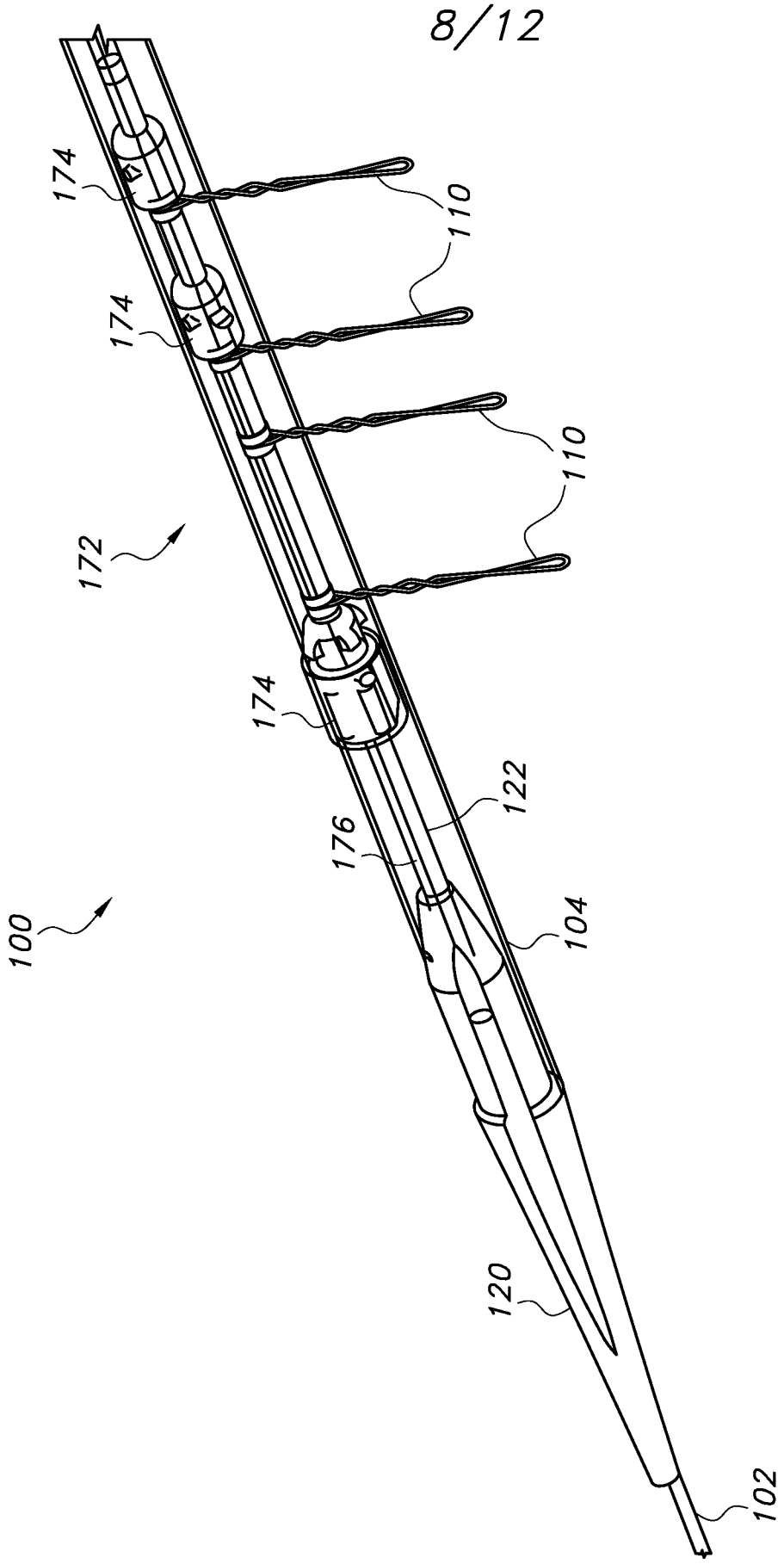

FIG. 8

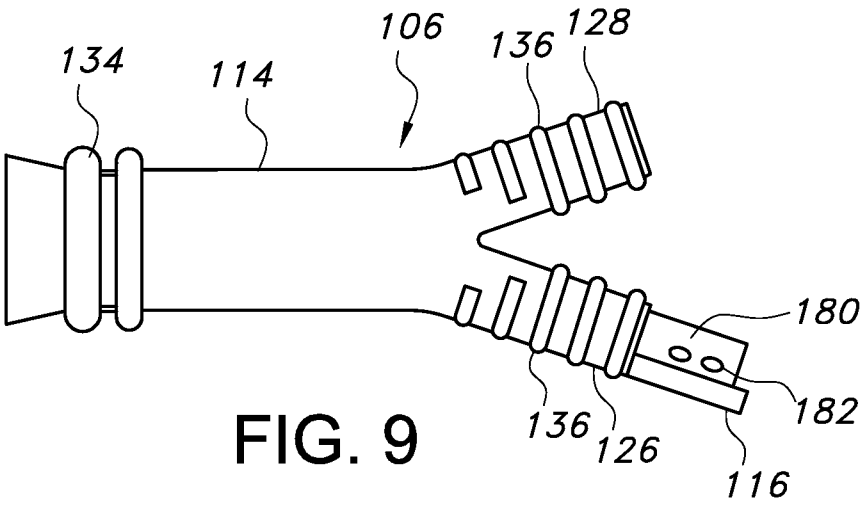

FIG. 9

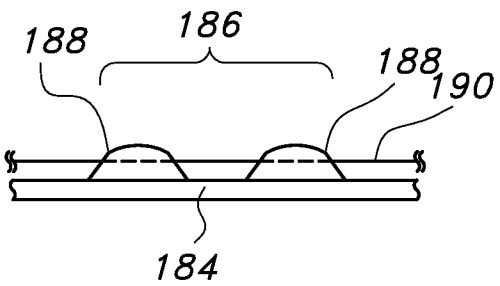

FIG. 10

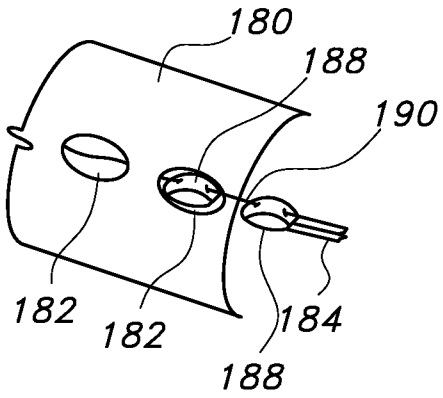

FIG. 11

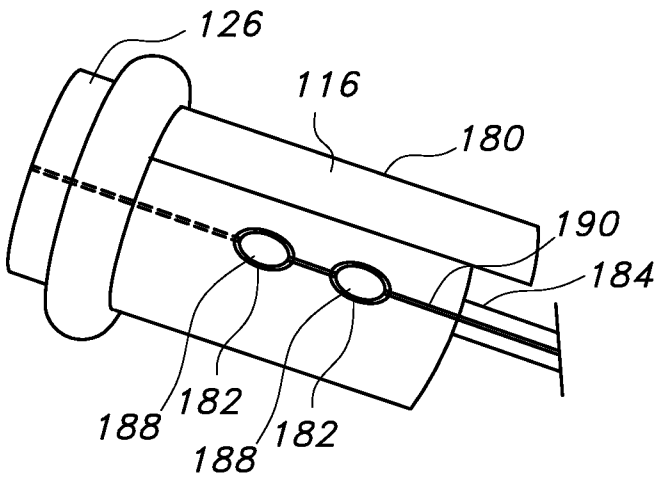

FIG. 12

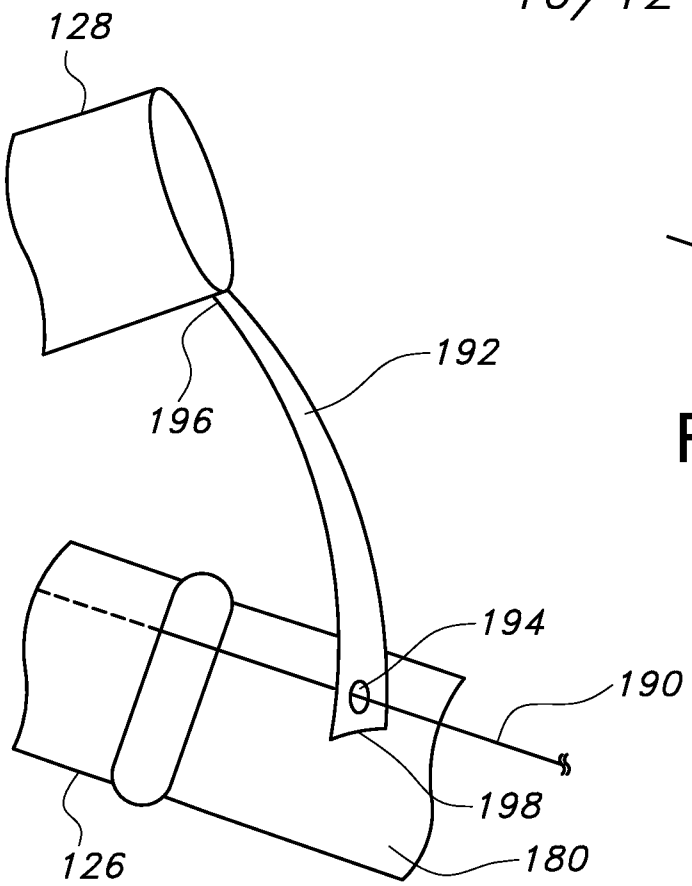

FIG. 13

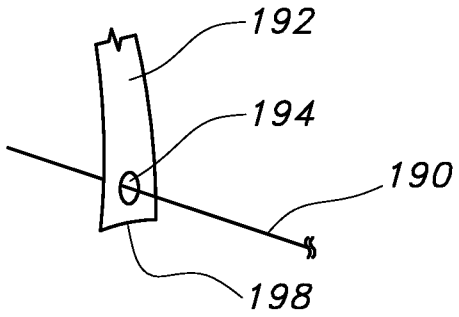

FIG. 14

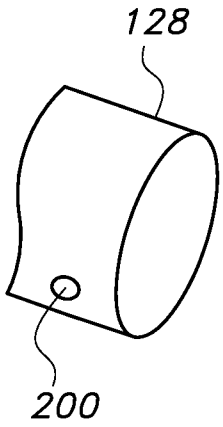

FIG. 16

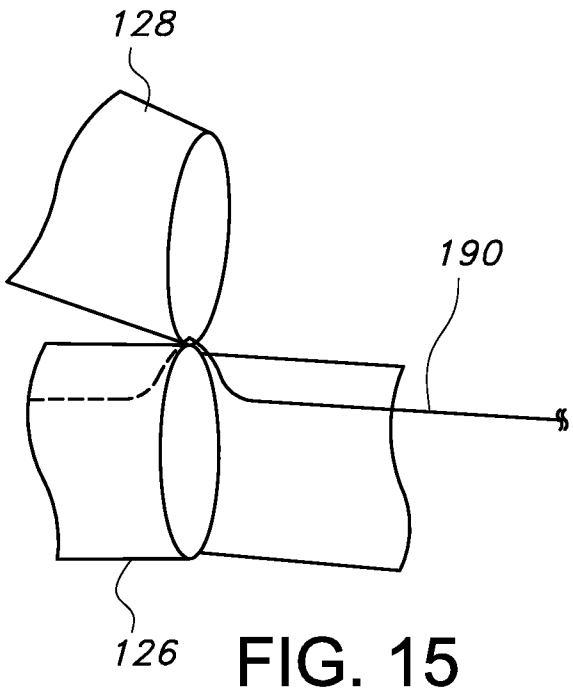

FIG. 15

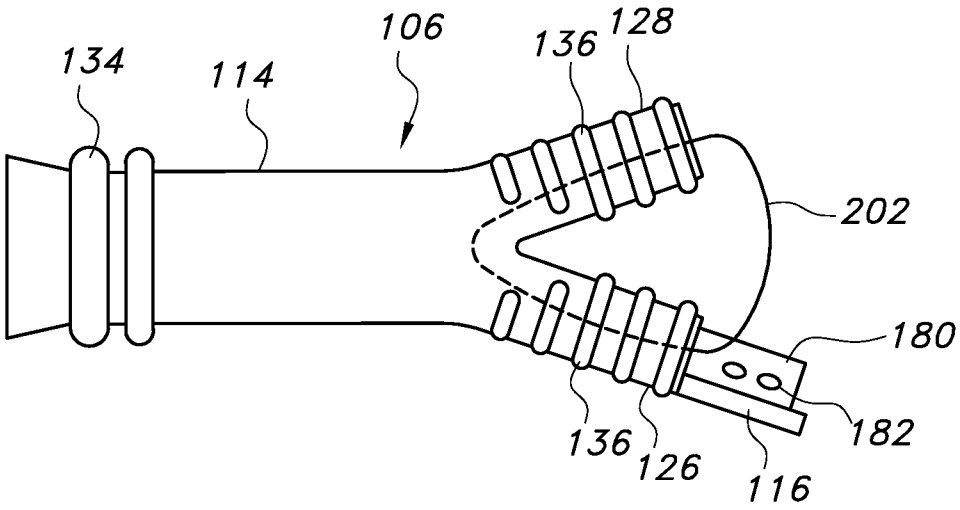
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FIG. 17

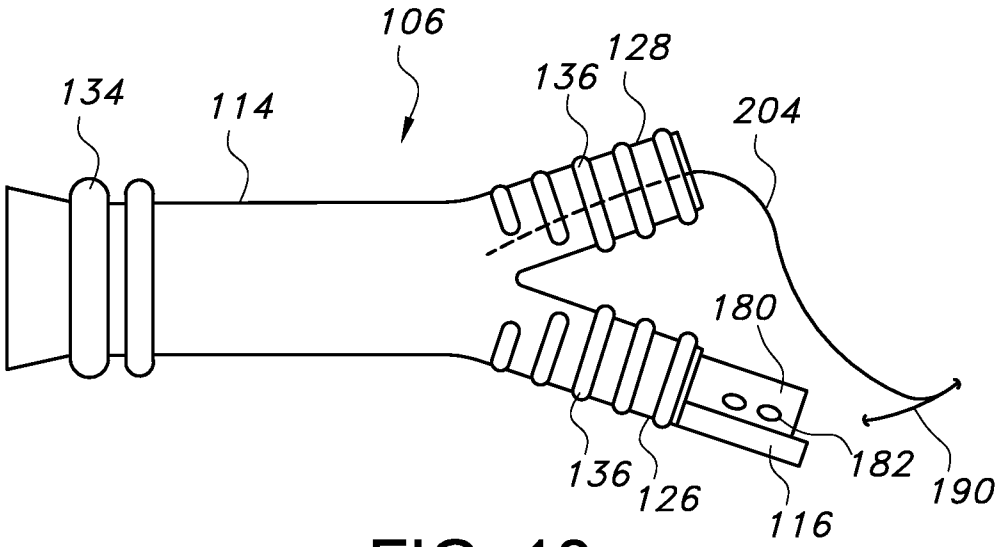
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FIG. 18

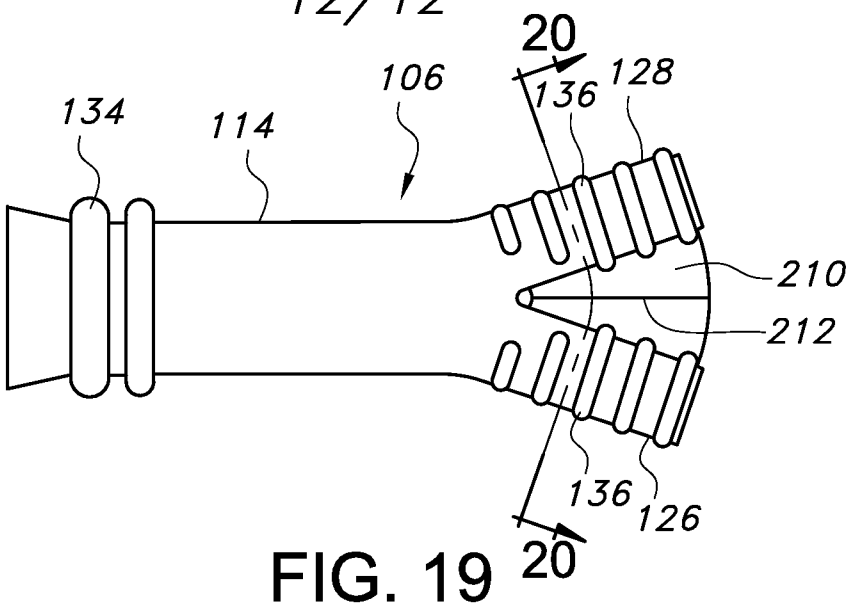

FIG. 19

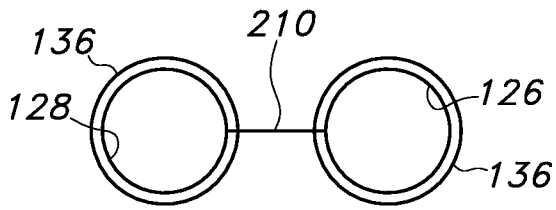

FIG. 20

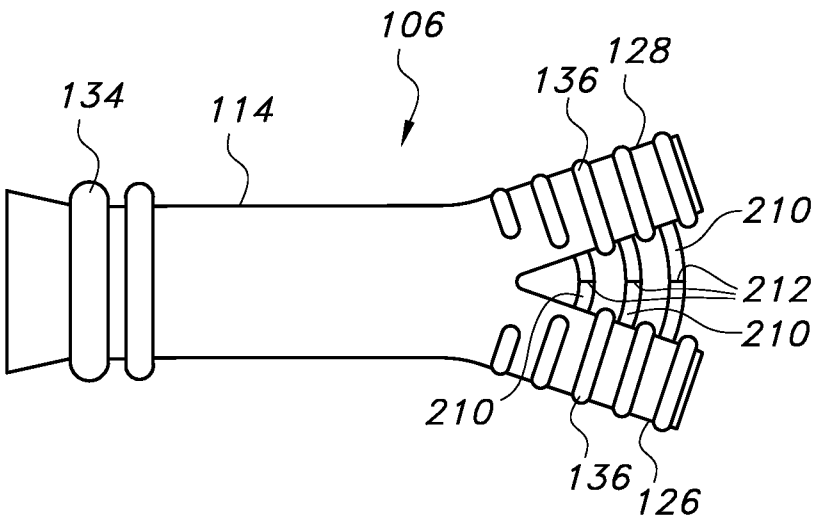

FIG. 21

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/043630

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/07 A61F2/954
ADD.

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2009/099649 A1 (CHOBOTOV MICHAEL V [US] ET AL) 16 April 2009 (2009-04-16)	15-17
A	paragraphs [0072] - [0073]; figures 8-14	1-10
Y	US 2007/050015 A1 (O'BRIEN MARK E [US] ET AL) 1 March 2007 (2007-03-01) paragraphs [0024] - [0026]; figures 4A-4C	15-17
Y	EP 2 111 828 A2 (CORDIS CORP [US]) 28 October 2009 (2009-10-28)	15-17
A	paragraphs [0079] - [0080]; figures 1, 21	1-10
Y	WO 00/69367 A1 (BOSTON SCIENT CORP [US]; STRECKER ERNST PETER [DE]) 23 November 2000 (2000-11-23) page 16, line 23 - page 17, line 6; figure 4	15-17

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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

"E" earlier 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 October 2013	06/11/2013

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	Prechtel, A

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/043630

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2008/103587 A1 (HENDERSON JAMIE [US] ET AL) 1 May 2008 (2008-05-01) paragraphs [0068] - [0069]; figures 3B, 3C, 3D	15-17
E	WO 2013/151924 A1 (TRIVASCULAR INC [US]) 10 October 2013 (2013-10-10) the whole document	1-10

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/043630

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.: 11-14
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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

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

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

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

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers 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/US2013/043630

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2009099649 A1	16-04-2009	AU 2008308474 A1	09-04-2009
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		WO 2013151924 A1	10-10-2013