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(54) **Title**: LOW PROFILE COMPOSITE ENDOLUMINAL PROSTHESES

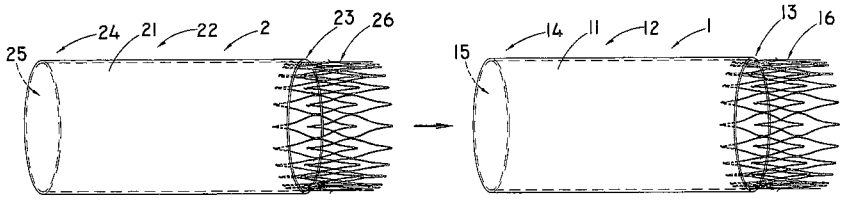

FIG. IA

(57) **Abstract**: A composite endoluminal prosthesis (3) has an expanded configuration and a compressed configuration and comprises a first prosthesis module (1) and a second prosthesis module (2). The first prosthesis module (1) and second prosthesis module (2) each comprise an unstented graft (12, 22) having a lumen (15, 25) and an anchor (16, 26) extending proximally from the graft. In the expanded configuration the first prosthesis anchor (16) engages an interior surface of a body vessel and the second prosthesis anchor (26) engages an interior surface of the first prosthesis lumen.

LOW PROFILE COMPOSITE ENDOLUMINAL PROSTHESES

Technical Field

The present disclosure relates to endoluminal prostheses for endovascular treatments and procedures, in particular composite endoluminal prostheses and to methods of deploying such prostheses in a body vessel.

Background Art

Aneurysms occur in blood vessels in locations where, due to age, disease or genetic predisposition, insufficient blood vessel strength or resiliency may cause the blood vessel wall to weaken and/or lose its shape as blood flows through it, resulting in a ballooning or stretching of the blood vessel at the limited strength/resiliency location, thus forming an aneurysmal sac. Left untreated, the blood vessel wall may continue to expand to the point where the remaining strength of the blood vessel wall is insufficient and the blood vessel will fail at the aneurysm location, often with fatal result.

To prevent rupture, various implantable prostheses may be introduced into the blood vessel. Minimally invasive methods for implantation of these prostheses have been developed to deliver these prostheses within the lumen of a body vessel. These prostheses are advantageously inserted intravascularly, such as from an implantation catheter. For example, to prevent rupture of an aneurysm, a tubular stent graft may be introduced into the blood vessel and deployed and secured in a location within the blood vessel such that the stent graft spans the aneurysmal sac. The outer surface of the stent graft, at its opposed ends, abuts and seals against the interior wall of the blood vessel at a location where the blood vessel wall has not suffered a loss of strength or resiliency. The stent graft channels the blood flow through the hollow interior of the stent graft, thereby reducing, if not eliminating, any stress on the blood vessel wall at the aneurysmal sac location.

U.S. Patent No. 6,695,875 discloses a main stent graft body and an attachment tube at its proximal end that together span an aneurysm. U.S. Patent No. 7,105,017, WO 2007/053592 and U.S. Patent Application No. 2005/0113905

disclose modular prosthetic assemblies, for example an endoluminal prosthesis having modules for interconnection including a first prosthetic module and a second prosthetic module.

One particular example of endoluminal prostheses for treating abdominal aortic aneurysms is a bifurcated stent graft. Bifurcated stent grafts may be implanted for the repair of an aneurysm at or in the vicinity of the aortic bifurcation. The proximal end of the bifurcated stent graft defines a single lumen for placement within the aorta, while the distal end of the bifurcated stent graft defines a bifurcated region that encompasses two lumens for placement in the iliac arteries.

In a conventional stent graft, the graft material must be extremely strong, wear resistant and substantially impermeable to liquids, such that it provides a barrier to blood flow. This combination of attributes generally necessitates a thick or bulky graft material. For example, one commonly utilized graft material possessing these attributes is tightly woven polyester, which has a thickness of about 0.2 to 0.3 mm. Adding to the bulk of a typical stent graft device are a plurality of sutures, which are typically employed to attach the graft material to the stent(s) of the stent graft device.

In order to achieve the aspects of stent graft function described above, the combination of the stent(s), the graft material and the sutures results in a prosthesis with a bulk that can limit the compressibility of the prosthesis. Consequently, delivery of conventional stent grafts may require a larger than preferred diameter delivery sheath, making delivery of the stent graft via percutaneous entry into the femoral artery, for example, infeasible. In addition, the larger the diameter of the delivery sheath and the bulk of the enclosed stent graft may limit the flexibility during endoluminal placement.

Disclosure of the Invention

The present invention seeks to provide an improved stent graft assembly, and improved stent graft kit and an improved method of fitting a stent graft assembly to a patient.

According to an aspect of the present invention, there is provided a composite endoluminal prosthesis as specified in claim 1 or 16.

According to another aspect of the present invention, there is provided a bifurcated composite endoluminal prosthesis as specified in claim 12.

The prosthesis may be provided as an assembly and in some embodiments and implementations as a kit of modular units arrangeable into a unitary structure.

In a first embodiment, a composite endoluminal prosthesis is provided. The composite endoluminal prosthesis has an expanded configuration and a compressed configuration and comprises a first prosthesis and a second prosthesis. The first prosthesis comprises an unstented graft having a lumen and an anchor extending proximally from the graft. The second prosthesis comprises an unstented graft having a lumen and an anchor extending proximally from the graft. In the expanded configuration, the first prosthesis anchor engages an interior surface of a body vessel and the second prosthesis anchor engages an interior surface of the first prosthesis lumen.

In another embodiment, a bifurcated composite endoluminal prosthesis is provided. The composite endoluminal prosthesis has an expanded configuration and a compressed configuration and comprises a first prosthesis, a second prosthesis, and a third prosthesis. The first prosthesis comprises an unstented graft having a lumen and an anchor extending proximally from the graft. The second prosthesis comprises an unstented graft having a lumen and an anchor extending proximally from the graft. The third prosthesis comprises an unstented graft having a lumen and an anchor extending proximally from the graft. In the expanded configuration, the first prosthesis anchor engages an interior surface of a body vessel and the second prosthesis anchor engages the third prosthesis anchor within the first prosthesis lumen.

In another embodiment, a composite endoluminal prosthesis is provided. The composite endoluminal prosthesis has an expanded configuration and a compressed configuration and comprises a first prosthesis and a second prosthesis. The first prosthesis and second prosthesis each comprise a tubular graft having a proximal end, a distal end, and an unstented body extending therebetween, the body defining a lumen, and an anchor attached to the graft

proximal end such that the anchor does not substantially overlap the graft. In the expanded configuration, the first prosthesis anchor engages an interior surface of a body vessel and the second prosthesis anchor engages an interior surface of the first prosthesis lumen.

Other systems, methods, features and advantages will be, or will become, apparent to one with skill in the art from the following drawings and detailed description. It is intended that all such additional systems, methods, features and advantages within this description be within the scope of the claims.

Brief Description of the Drawings

Embodiments of the present invention are described below, by way of example only, with reference to the accompanying drawings, in which:

FIGS. 1A – 1B depict an embodiment of prosthesis including a first prosthesis and a second prosthesis which can be assembled into a composite endoluminal prosthesis;

FIGS. 2A – 2D depict different embodiments of anchor-graft attachment at the graft proximal end;

FIGS. 3A and 3B show the fitting and coupling of the first prosthesis and the second in a body vessel having an aneurysm to provide the composite endoluminal prosthesis;

FIG. 4 depicts an assembled multi-part composite endoluminal prosthesis deployed within a body vessel and spanning an aneurysm;

FIG. 5 depicts a composite bifurcated endoluminal prosthesis deployed within a body vessel at a point of bifurcation and spanning an aneurysm;

FIGS. 6A and 6B depict a second prosthesis and a third prosthesis expanded within a first prosthesis lumen;

FIG. 7 depicts a composite bifurcated endoluminal prosthesis comprising distal branches deployed within a body vessel at a point of bifurcation and spanning an aneurysm; and

FIG. 8 depicts a composite bifurcated endoluminal prosthesis comprising a tapered anchor deployed within a body vessel at a point of bifurcation and spanning an aneurysm.

Description of the Preferred Embodiments

The present disclosure provides for composite endoluminal prostheses and methods for bridging a defect in a body vessel. Exemplary aspects are described below in reference to the composite endoluminal prostheses' application in connection with endovascular treatment of aneurysms and dissections, particularly abdominal aortic aneurysms. However, it is likewise applicable to any suitable endovascular treatment or procedure including, without limitation, endovascular treatment of thoracic aortic aneurysms and dissections.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure pertains. In case of conflict, the present document, including definitions, will control. Preferred methods and materials are described below, although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present disclosure. All publications, patent applications, patents and other references mentioned herein are incorporated by reference in their entirety. The materials, methods, and examples disclosed herein are illustrative only and not intended to be limiting.

Definitions

"Prosthesis" means any replacement for a body part or for a function of that body part, or any device that enhances or adds functionality to a physiological system.

"Implantable" refers to an ability of a prosthetic implant to be positioned, for any duration of time, at a location within a body, such as within a body vessel. Furthermore, the terms "implantation" and "implanted" refer to the positioning, for any duration of time, of a prosthetic implant at a location within a body, such as within a body vessel.

"Body vessel" means any tube-shaped body passage lumen that conducts fluid, including but not limited to blood vessels such as those of the human vasculature system, esophageal, intestinal, billiary, urethral and ureteral passages.

"Endoluminal" describes objects that are found or can be placed inside a body vessel or other space in the human or animal body. This includes lumens such as blood vessels, parts of the gastrointestinal tract, ducts such as bile ducts,

parts of the respiratory system, etc. "Endoluminal prosthesis" thus describes a prosthesis that can be placed inside of these body vessels.

"Branch vessel" refers to a vessel that branches off from a main vessel. For example, the "branch vessels" of the thoracic and abdominal aorta include the iliac, celiac, inferior phrenic, superior mesenteric, lumbar, inferior mesenteric, middle sacral, middle suprarenal, renal, internal spermatic, ovarian (in the female), innominate, left carotid, and left subclavian arteries. As another example, the hypogastric artery is a branch vessel to the common iliac, which is a main vessel in this context. Thus, it should be seen that "branch vessel" and "main vessel" are relative terms.

"Graft" means a generally cannular or tubular member which acts as an artificial vessel. A graft by itself or with the addition of other elements can be an endoluminal prosthesis.

"Stent" means any device or structure that adds rigidity, expansion force, or support to a prosthesis.

"Stent graft" refers to a prosthesis comprising a stent and a graft material associated therewith that forms a lumen through at least a portion of its length.

The terms "about" or "substantially" used with reference to a quantity includes variations in the recited quantity that are equivalent to the quantity recited, such as an amount that is insubstantially different from a recited quantity for an intended purpose or function.

"Proximal" means that position or portion of a component which is closest to the patient's heart.

"Distal" means that position of portion of a component which is furthest from the patient's heart.

"Biocompatible" refers to a material that is substantially non-toxic in the in vivo environment of its intended use, and that is not substantially rejected by the patient's physiological system (i.e., is non-antigenic). This can be gauged by the ability of a material to pass the biocompatibility tests set forth in International Standards Organization (ISO) Standard No. 10993 and/or the U.S. Pharmacopeia (USP) 23 and/or the U.S. Food and Drug Administration (FDA) blue book memorandum No. G95-1, entitled "Use of International Standard ISO-

10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing." Typically, these tests measure a material's toxicity, infectivity, pyrogenicity, irritation potential, reactivity, hemolytic activity, carcinogenicity and/or immunogenicity. A biocompatible structure or material, when introduced into a majority of patients, will not cause a significantly adverse, long-lived or escalating biological reaction or response, and is distinguished from a mild, transient inflammation which typically accompanies surgery or implantation of foreign objects into a living organism.

"Extracellular matrix" (ECM) is a collagen-rich substance that is found in between cells in animal tissue and serves as a structural element in tissues. It is generally a complex mixture of polysaccharides and proteins secreted by cells. The extracellular matrix can be isolated and treated in a variety of ways. Following isolation and treatment, it is referred to as an "extracellular matrix material," or ECMM. ECMMs may be isolated from submucosa (including small intestine submucosa), stomach submucosa, urinary bladder submucosa, tissue mucosa, dura mater, liver basement membrane, pericardium or other tissues.

"Submucosa" refers to a layer of collagen-containing connective tissue occurring under the mucosa in most parts of the alimentary, respiratory, urinary, and genital tracts of animals. A specific example of an ECMM is small intestinal submucosa (SIS), such as is described in U.S. Patent No. 6,206,931, which is incorporated herein by reference.

Composite Endoluminal Prostheses

FIGS. 1A and 1B depict an exemplary composite or modular endoluminal prosthesis. In this example, the composite prosthesis 3 is formed of a first prosthesis module 1 and a second prosthesis module 2. The first prosthesis module 1 includes a tubular graft 11 and an anchor, such as a stent 16. Suitable anchors also include any means for attaching a medical device to a body vessel wall, for example suturing, stapling, searing, bonding, gluing, bioadhesives, and the like. The graft 11 comprises an unstented body 12 with an internal lumen 15 extending between a proximal end 13 and a distal end 14. The stent 16 is attached to and extends proximally from the graft 11 near the graft proximal end 13.

The second prosthesis module 2 includes a graft 21 and an anchor, such as stent 26. Though the second prosthesis graft 21 is illustrated as a tubular graft, the graft 21 may be of any suitable graft structure, such as a bifurcated graft. The graft 21 comprises an unstented body 22 with an internal lumen 25 extending between a proximal end 23 and a distal end 24. The stent 26 is attached to and extends proximally from the graft 21 near the graft proximal end 23. The second prosthesis module may be of any suitable graft structure, such as a bifurcated graft or a tubular graft.

The anchors may be attached or adhered to the grafts 11, 21 in any suitable manner, including but not limited to welding, stitching, sutures, bonding, and adhesives. In one example, depicted in FIG. 2A, sutures 52 may space the anchor 50 from the graft proximal end 53 such that the anchor 50 does not overlap the graft 51, thereby permitting a reduced prosthesis delivery profile and enhanced flexibility during endoluminal delivery. In another example, depicted in FIG. 2B, the anchor 55 is sutured 57 to the graft proximal end 58 such that the stent has a minimal overlap 60 with the graft 56. Alternatively, the anchor 55 may be integrated directly into a woven graft fabric. Minimizing the stent-graft overlap 60 also permits for enhanced delivery flexibility and a reduced prosthesis delivery profile.

In a further example, depicted in FIG. 2C, a solution of polymeric film 61 may be cast directly around the anchor 62 and the proximal graft end 63, thereby attaching the anchor to the graft with no or minimal overlap. In one example, the anchor 62 comprises multiple eyelets 64. The multiple eyelets 64 provide increased surface area for the polymeric film 61 to interface with the anchor 62 and further attach the anchor to the graft. Additionally, the multiple eyelets 64 allow thread or sutures 65 to be looped to further attach the anchor to the graft proximal end 63. Multiple eyelets 64 also allow for thread or suture loops in multiple planes, for example longitudinal threads 65 and circumferential threads 65' and 65". Looped thread or sutures may further reduce the prosthesis delivery profile because they have less bulk compared to knotted thread or sutures. In yet another example, depicted in FIG. 2D, a polymeric film 66 may be cast directly around the anchor 67 and a fabric graft end 68 such that the fabric 68 and anchor

67 do not overlap. A suture 69 may be woven through the anchor eyelets and the fabric graft 68 to further attach the anchor 67 and fabric graft 68. For example, the suture 69 may be a continuous suture comprising only one knot to minimize bulk related to multiple suture knots.

FIGS. 3A and 3B show a composite or modular endoluminal prosthesis 70 deployed in a body vessel 80 having a lesion, such as aneurysm 81, such that the composite endoluminal prosthesis 70 spans the aneurysm 81. The composite endoluminal prosthesis 70 results from the initial deployment of a first prosthesis module 71 within the body vessel 80, followed by a subsequent deployment of the second prosthesis module 75 at least partially within the first prosthesis lumen 72. The first and second prosthesis modules 71, 75 permit for a reduced delivery profile and reduced diameter delivery sheath, allowing delivery via percutaneous entry. In addition, the reduced diameter of the delivery sheath and reduced bulk of the enclosed first and second prosthesis modules 71, 75 allow for greater flexibility during endoluminal placement.

The first prosthesis anchor 74 serves to seal the first prosthesis module 71 against and to the vessel 80, thereby channelling fluid flow through the first prosthesis lumen 72. In one example, a supplementary stent (not shown) may be deployed inside the first prosthesis lumen 72 to provide additional sealing force to seal the first prosthesis module 71 against the vessel 80. The supplementary stent may be particularly useful in applications where the first prosthesis is deployed in tortuous anatomy, such as the abdominal aorta. In the preferred embodiment, such a supplementary stent would be deployed after deployment of the first prosthesis module 71.

Deployment of the second prosthesis module 75 within the first prosthesis lumen 72 further channels fluid flow through the second prosthesis lumen 79. Though the second prosthesis graft 75 is illustrated as a tubular graft, the graft 75 may comprise any suitable graft form, such as a bifurcated graft. The composite endoluminal prosthesis 70 thereby reduces, if not eliminates, any stress on the vessel 80 at the site of the aneurysm 81. In one example, the second prosthesis anchor 76 is deployed completely within the first prosthesis lumen 72, such that the second prosthesis proximal end 77 is proximal to the first prosthesis distal end

73. The second prosthesis distal end 78 is thereby distal to the first prosthesis distal end 73.

The second prosthesis module 75 may be sealed against and to the first prosthesis lumen 72 such that it cannot move within or along the length of the first prosthesis module 71. This may be achieved, for example, via an anchor 76 with high radial force. Alternatively or additionally, the first prosthesis lumen 72 may contain an element against which the second prosthesis module 75 is located. There may be a number of such elements along the length of the first prosthesis module 71 such that the combined length of the first and second prosthesis modules may be chosen by a surgeon to tailor the device to a specific patient.

For example, the first prosthesis lumen 72 may include a mechanism within the lumen 72 to aid in positioning the second prosthesis module 75. In one example, the mechanism includes graduated markers 82 within the first prosthesis lumen 72 defining patient-specific composite prosthesis lengths. In operation, the second prosthesis module would be deployed in the first prosthesis lumen 72 on one of the markers 82, thereby selecting a given length for the composite endoluminal prosthesis 70.

In another example, the second prosthesis module 75 may be free to move or slide within the first prosthesis lumen 72, under hydrodynamic or other forces, until being stabilized by the patient anatomy (e.g. the iliac bifurcation) thereby tailoring the device to a specific patient. The maximum distance that the second prosthesis module 75 is permitted to slide within the first prosthesis module 71 may be limited by markers present on the first prosthesis module 71, such that the second prosthesis module remains within the first.

In a further example, the first prosthesis module 71 may comprise a tubular graft having a taper. For example, a tapered tubular graft may comprise a graft proximal end diameter that is greater than the graft distal end diameter. A tapered graft may better approximate the anatomy at the point of treatment. In one particular example, the first prosthesis module may comprise a tapered tubular graft having a proximal end diameter of about 48 mm and a distal end diameter of about 36 mm to about 38 mm. A tapered graft having these dimensions may be particularly suited for deployment in the abdominal aorta. A tapered graft may also

assist with the second prosthesis module sealing against the first prosthesis lumen. The tapered graft distal end diameter may be less than the second prosthesis proximal end diameter, such that when the second prosthesis module is deployed in the first prosthesis lumen the second prosthesis module movement is limited due to friction and the second prosthesis module having a greater proximal end diameter compared to the first prosthesis distal end diameter.

The first prosthesis and the second prosthesis modules can have a compressed and an expanded configuration. The first prosthesis and the second prosthesis modules may radially expand from a compressed, or unexpanded, delivery configuration to one or more radially expanded deployment configurations. The expanded configuration can have any suitable cross-sectional configuration, including circular or elliptical. In one example, the first prosthesis and second prosthesis modules can be oriented along the longitudinal axis of a body vessel in the expanded or compressed configurations. In some examples, the expanded configurations can be resiliently further extended in one or more radial directions.

In one example, the first prosthesis and the second prosthesis modules can be self-expanding or balloon expandable. For example, the anchors may comprise self-expanding stents. Self-expanding stents can be compressed into a low-profile delivery conformation and then constrained within a delivery system for delivery to a point of treatment in the lumen of a body vessel. At the point of treatment, the self-expanding stents can be released and allowed to subsequently expand toward their pre-compression geometry.

The dimensions of the first prosthesis module, the second prosthesis module, and the composite endoluminal prosthesis are determined by the intended use of the prosthesis. Ideally, the prosthesis modules are constructed so as to provide the optimum fit within the vasculature to be treated. For example, the first prosthesis module may comprise a tapered tubular graft, and/or the second prosthesis module may comprise a tubular or bifurcated graft. The dimensions of the vasculature may be determined by a variety of methods, including intraoperative intravascular ultrasound (IVUS) and radiologic studies such as computerized tomography (CT), magnetic resonance imaging (MRI), angiography.

Although the composite endoluminal prosthesis of FIGS. 1 and 3 is shown comprising two prosthesis modules, the composite endoluminal prosthesis may include more than two prosthesis modules. The specific number chosen will depend on several factors, including the type and configuration of the composite endoluminal prosthesis. For example, the composite endoluminal prosthesis may comprise 1, 2, 3, 4, 5, 6, 7, 8, or more prosthesis modules. The composite endoluminal prosthesis only need to provide the functionality described herein.

In one example, the number of prosthesis modules that are employed will depend on the length of the lesion to be treated, where additional prosthesis modules are employed until the lesion is bridged. For example, it may be desirable to employ a larger number of prosthesis modules in conjunction with a longer lesion. In one example, depicted in FIG. 4, a composite prosthesis 90 may comprise three prosthesis modules. The first prosthesis module 71, the second prosthesis module 75, and a third prosthesis module 91 are combined to provide the composite endoluminal prosthesis 90. The third prosthesis module 91 includes a tubular graft 92 and an anchor, such as stent 97. The graft 92 comprises an unstented body 93 defining a lumen 94 extending between a proximal end 95 and a distal end 96. The stent 97 is attached to and extends proximally from graft proximal end 95. As with the first prosthesis module 71 and the second prosthesis module 75, the third prosthesis module 91 can be converted from a compressed configuration to an expanded configuration, and may be self-expanding or balloon expandable.

The composite endoluminal prosthesis 90 may be assembled by first deploying the first prosthesis module 71 within a body vessel 98. Once the first prosthesis module 71 has been secured within the body vessel 98, the second prosthesis module 75 may be deployed at least partially within the first prosthesis lumen and attached to the first prosthesis module 71. Subsequently, the third prosthesis module 91 may be deployed at least partially within the second prosthesis lumen 25 and secured to the second prosthesis module 75 via the stent 97. The composite endoluminal prosthesis 90 spans the lesion, such as aneurysm 99, thereby reducing, if not eliminating, any stress on the vessel 98 at the site of the aneurysm 99.

In another embodiment, the composite or modular endoluminal prosthesis may also comprise a composite bifurcated endoluminal prosthesis. For example, FIG. 5 shows a composite bifurcated endoluminal prosthesis 100 comprising a first prosthesis module 110, a second prosthesis module 120, and a third prosthesis module 130. The composite bifurcated endoluminal prosthesis 100 may be deployed within a main vessel 101 having a lesion, such as aneurysm 102, adjacent a point of bifurcation 103. In this example, the composite bifurcated endoluminal prosthesis 100 extends into both branch vessels 104, 105. The first prosthesis module 110 serves to seal the composite endoluminal prosthesis 100 against the main vessel 101. The second prosthesis module 120 and the third prosthesis module 130 are subsequently deployed at least partially within the first prosthesis lumen 113.

The first prosthesis module 110 includes a tubular graft 111 and an anchor, such as stent 116. The graft 111 comprises an unstented body 112 with an internal lumen 113 extending between a proximal end 114 and a distal end 115. The stent 116 is attached to and extends proximally from the graft proximal end 114.

In one example, a supplementary anchor, such as stent 117, may provide mechanical support to the first prosthesis module 110 in the expanded configuration and/or assist in sealing the first prosthesis module 110 to the body vessel 101. The supplementary anchor 117 is deployed separately from the first prosthesis module 110, and may be attached or adhered to the first prosthesis module 110 by any means, including but not limited to radial force, anchoring devices such as barbs (*e.g.,* barbs 54, 59), markers (*e.g.*, markers 82) and adhesives. The supplementary anchor may be deployed in the first prosthesis lumen 113. The supplementary anchor may or may not overlap with the first prosthesis anchor 116. In examples where the supplementary anchor 117 is deployed overlapping the first prosthesis anchor 116, the supplementary anchor provides additional sealing force to the first prosthesis module 110. In this example, the first prosthesis anchor 116 may comprise a radial force sufficient to expand the first prosthesis module 110, and supplementary anchor 117 may seal

the first prosthesis module 110 to the vessel 101. An anchor having a lower radial force permits for a reduced delivery profile.

The second prosthesis module 120 includes a tubular graft 121 and an anchor, such as stent 126. The graft 121 comprises a body 122 with an internal lumen 123 extending between a proximal end 124 and a distal end 125. The stent 126 is attached to and extends proximally from the graft proximal end 124. The stent 126 may or may not overlap the graft 121. The second prosthesis module has a diameter 127 that is less than the diameter 118 of the first prosthesis module 110.

The third prosthesis module 130 includes a tubular graft 131 and an anchor, such as stent 136. The graft 131 comprises a body 132 with an internal lumen 133 extending between a proximal end 134 and a distal end 135. The stent 136 is attached to and extends proximally from the graft proximal end 134. The stent 136 may or may not overlap the graft 131. The third prosthesis module has a diameter 137 that is less than the diameter 118 of the first prosthesis 110.

The second and third prosthesis modules 120, 130 may be identical or different. For example, the prosthesis modules 120, 130 may have the same or different lengths, the same or differing widths, may be symmetrical or asymmetrical, or may comprise the same or differing materials. In one example, the second and third prostheses graft bodies 122, 132 are unstented. In another example, the second and third prosthesis modules 120, 130 may include stents about the graft body 122, 132 and/or distal end 125, 135. Stents about the graft body and distal end may assist the composite bifurcated endoluminal prosthesis 100 in sealing the body vessel lesion.

The composite bifurcated endoluminal prosthesis 100 is formed by first deploying the first prosthesis module 110, such that the first prosthesis module 110 is positioned in the main vessel 101 and the distal end 115 is situated proximal to the bifurcation 103 and the branch vessels 104, 105. The first prosthesis proximal end 114 is secured in place by attaching the anchor 116 to the main vessel 101. Optionally, the supplementary anchor 117 is subsequently deployed within the first prosthesis lumen 113, distal to the first prosthesis proximal end 114. In a further step, the second and third prosthesis modules 120,

130 are deployed at least partially within the first prosthesis lumen 113 and attached to the first prosthesis module 110 via the anchors 126, 136. The second prosthesis distal end 125 and the third prosthesis distal end 135 are located within the branch vessels 104, 105, respectively.

The composite bifurcated endoluminal prosthesis 100 will preferably achieve a seal at the first prosthesis proximal end 114, thereby excluding the aneurysm 102. The second and third prostheses' distal ends 125, 135 contact the vessel walls of the branch vessels 104, 105. This should assist to exclude the entire aneurysm 102 and, as a result, the hemodynamic pressures within the aneurysm 102 may be reduced.

The second and third prosthesis modules 120, 130 may interfere with one another to provide sealing forces about the about the first prosthesis lumen 113. For example, in FIGS. 6A and 6B, the second prosthesis proximal end 124 interferes with the third prosthesis proximal end 134 within the first prosthesis lumen 113. FIG. 6A depicts the second prosthesis proximal end 124 and with the third prosthesis proximal end 134 having a D-shaped radial contour within the first prosthesis lumen 113. Alternatively, the second prosthesis proximal end 124 and with the third prosthesis proximal end 134 may expand asymmetrically in the first prosthesis lumen 113, as depicted in FIG. 6B. Any voids 119 within with first prosthesis lumen 113 may fill with fluid and, in one example, the fluid may clot and prevent any possible fluid leakage.

The first prosthesis module may be tailored to minimize any voids 119 in the expanded configuration. For example, the first prosthesis module may include distal branches. For example, FIG. 7 depicts a first prosthesis module 140 comprising two branches 142, 143 extending distally from the graft body 141. The branches 142, 143 may be identical or different. For example, the branches may have the same or different lengths, the same or different widths, may be symmetrical or asymmetrical, or may comprise the same or different materials. In this example, the composite bifurcated prosthesis 150 is formed by first deploying the first prosthesis module 140 in the main vessel 151. The first prosthesis proximal end 144 is secured in place by attaching the anchor 145 to the main

vessel 151. The branches 142, 143 may be situated proximal to the branch vessels 152, 153 or, alternatively, extend into the branch vessels 152, 153.

In a subsequent step, the second and third prosthesis modules 120, 130 are deployed at least partially within the first prosthesis lumen 146 and attached to the first prosthesis module 140 via the anchors 126, 136. The body sections of the second and third prosthesis modules 122, 132 are located within a corresponding branch of the first prosthesis module 142, 143, respectively. The second prosthesis distal end 125 and the third prosthesis distal end 135 are located within the branch vessels 152, 153.

In another example, the composite bifurcated endoluminal prosthesis may comprise alternative anchors. For example, FIG. 8 shows a composite bifurcated endoluminal prosthesis 160 comprising a first prosthesis module 170, a second prosthesis module 180, and a third prosthesis module 190. The composite bifurcated endoluminal prosthesis 160 may be deployed within body vessel 161 with a lesion, such as an aneurysm 162. In this example, the second prosthesis module 180 comprises a tapered anchor 181. At least a portion 182 of the anchor 181 has a diameter 183 equal to or greater than the diameter 171 of the first prosthesis lumen 172. Anchor 181 tapers from portion 182 to a diameter 184 equal to the second prosthesis graft proximal end 185. In one example, anchor 181 is configured such that fluid flow is permitted to flow substantially unimpeded through the anchor 181 to the third prosthesis module 190.

Stents

In general, stents for use in connection with the devices taught herein, such as stents 16, 26, or otherwise, typically comprise a plurality of apertures or open spaces between metallic filaments (including fibres and wires), segments or regions. Typical structures include: an open-mesh network comprising one or more knitted, woven or braided metallic filaments; an interconnected network of articulable segments; a coiled or helical structure comprising one or more metallic filaments; and, a patterned tubular metallic sheet (*e.g.*, a laser cut tube).

The stents may be self-expanding or balloon-expandable, and may be deployed according to conventional methodology, such as by an inflatable balloon catheter, by a self-deployment mechanism (after release from a catheter), or by

other appropriate means. The stents may be bifurcated, configured for any body vessel including coronary arteries and peripheral arteries (*e.g.*, renal, superficial femoral, carotid, and the like), a urethral stent, a biliary stent, a tracheal stent, a gastrointestinal stent, or an esophageal stent, for example. The stents may be any suitable vascular stent such as the commercially available Gianturco-Roubin FLEX-STENT®, GRII™, SUPRA-G, ZILVER, or V FLEX coronary stents from Cook Incorporated (Bloomington, IN). For example, the stent 80 depicted in FIG. 3A and 3B comprises a modified chuter stent having eyelets.

The stents may be made of one or more suitable biocompatible materials such as stainless steel, Nitinol, MP35N, gold, tantalum, platinum or platinum iridium, niobium, tungsten, iconel, ceramic, nickel, titanium, stainless steel/titanium composite, cobalt, chromium, cobalt/chromium alloys, magnesium, aluminium, or other biocompatible metals and/or composites or alloys such as carbon or carbon fibre, cellulose acetate, cellulose nitrate, silicone, cross-linked polyvinyl alcohol (PVA) hydrogel, cross-linked PVA hydrogel foam, polyurethane, polyamide, styrene isobutylene-styrene block copolymer (Kraton), polyethylene teraphthalate, polyester, polyorthoester, polyanhydride, polyether sulfone, polycarbonate, polypropylene, high molecular weight polyethylene, polytetrafluoroethylene, or other biocompatible polymeric material, or mixture of copolymers thereof; polyesters such as, polylactic acid, polyglycolic acid or copolymers thereof, a polyanhydride, polycaprolactone, polyhydroxybutyrate valerate or other biodegradable polymer, or mixtures or copolymers thereof; extracellular matrix components, proteins, collagen, fibrin or other therapeutic agent, or mixtures thereof. Desirably, the stents comprise stainless steel or Nitinol.

In the expanded configuration, the stents may have a radial force sufficient to maintain the prosthesis at a desired treatment location within a body vessel. For example, FIG. 3 depicts the composite endoluminal prosthesis 70 in the expanded configuration at the site of an aneurysm 81. The first prosthesis stent 74 may have a radial force sufficient to maintain the first prosthesis module 71 at a location proximal to the aneurysm 81. The radial force exerted by the second prosthesis stent 76 may be sufficient to maintain the second prosthesis module 75

within the first prosthesis lumen 71. In one example, the second prosthesis stent 76 exerts less radial force than the first prosthesis stent 74.

In one example, additional radial force may be supplied by supplementary anchors, such as supplementary anchor 117 depicted in FIG. 5. Radial force of the attached stents may be thus reduced. For example, the radial force of the stents 74, 76 may be sufficient to expand the prosthesis modules 71, 75 and temporarily maintain the expanded prosthesis modules 71, 75 at a desired location in the body vessel. Subsequently, supplementary anchors may be expanded and provide radial force necessary to maintain the first 71 and second 75 prosthesis modules within the body vessel at the desired treatment location.

Alternatively or in addition to radial force, the stents or grafts may optionally include supplemental attachment means such as anchoring devices to maintain the prosthesis at a desired location within a body vessel. The art provides a wide variety of structural features that are acceptable for use in prostheses as anchoring devices, and any suitable structural feature can be used. In one example, individual barbs may be used to maintain prostheses in a body vessel, permitting a reduction in stent radial force. The barbs may be secured to the anchors or grafts by any suitable means, including but not limited to welding, integral barbs, bonding, and adhesives. For example, FIGS. 2A and 2B illustrate a plurality of barbs 54, 59 attached to and extending from a prosthesis anchor 50, 55, respectively. Referring again to FIG. 3, the first prosthesis anchor 74 may includes barb to provide for anchoring of the first prosthesis module 71 to the vessel 80 at a desired treatment location. Thus, once the anchor 74 is deployed within the desired body vessel 80, the anchor 74 is expanded such that the barbs engage the tissue of the body vessel 80, securing the first prosthesis module 71 within the body vessel 80. The second prosthesis anchor 76 may also includes barbs. When the second prosthesis module 75 is deployed at least partially within the first prosthesis module 71, the barbs should engage the first prosthesis module 71, thus securing the second prosthesis module 75 to the first prosthesis module 71.

Graft Material

The grafts may include any biocompatible material which is suitable for facilitating repair to the injured or diseased body vessel. The graft material may be synthetic, naturally-derived material, and/or manufactured.

For example, graft material may include a film, a coating, a sheet of biocompatible fabrics, non-woven materials or porous materials. Examples of biocompatible polymers from which a graft can be formed include polyesters, such as poly(ethylene terephthalate), polylactide, polyglycolide and copolymers thereof; fluorinated polymers, such as polytetrafluoroethylene (PTFE), expanded PTFE and poly(vinylidene fluoride); polysiloxanes, including polydimethyl siloxane; and polyurethanes, including polyetherurethanes, polyurethane ureas, polyetherurethane ureas, polyurethanes containing carbonate linkages and polyurethanes containing siloxane segments. In addition, materials that are not inherently biocompatible may be subjected to surface modifications in order to render the materials biocompatible. Examples of surface modifications include polymerization of biocompatible polymers from the material surface, coating of the surface with a cross-linked biocompatible polymer, and chemical modification with biocompatible functional groups. Thus, any polymer that may be formed into a porous sheet can be used to make a flexible covering, provided the final porous material is biocompatible. Polymers that can be formed into a porous sheet include polyolefins, polyacrylonitrile, nylons, polyaramids and polysulfones, in addition to polyesters, fluorinated polymers, polysiloxanes and polyurethanes as listed above.

In one embodiment, the graft material may comprise a biocompatible polyurethane, for example THORALON (THORATEC, Pleasanton, CA). As described in U.S. Patent Application Publication No. 2002/0065552 A1 , incorporated herein by reference, THORALON is a polyetherurethane urea blended with a siloxane-containing surface modifying additive. THORALON has been used in certain vascular applications and is characterized by thromboresistance, high tensile strength, low water absorption, low critical surface tension and good flex life. A variety of other biocompatible polyurethanes/polycarbamates and urea linkages (hereinafter "-C(O)N or CON

type polymers") may also be employed. Biocompatible CON type polymers modified with cationic, anionic and aliphatic side chains may also be used. See, for example, U.S. Pat. No. 5,017,664, which is incorporated herein by reference in its entirety. Other biocompatible CON type polymers include: segmented polyurethanes, such as BIOSPAN; polycarbonate urethanes, such as BIONATE; polyetherurethanes, such as ELASTHANE; (all available from POLYMER TECHNOLOGY GROUP, Berkeley, CA); siloxane-polyurethanes, such as ELAST-EON 2 and ELAST-EON 3 (AORTECH BIOMATERIALS, Victoria, Australia); polytetramethyleneoxide (PTMO) and polydimethylsiloxane (PDMS) polyether-based aromatic siloxane-polyurethanes, such as PURSIL-10, -20, and -40 TSPU; PTMO and PDMS polyether-based aliphatic siloxane-polyurethanes, such as PURSIL AL-5 and AL-10 TSPU; aliphatic, hydroxy-terminated polycarbonate and PDMS polycarbonate-based siloxane-polyurethanes, such as CARBOSIL-10, -20, and -40 TSPU (all available from POLYMER TECHNOLOGY GROUP). Examples of siloxane-polyurethanes are disclosed in U.S. Pat. Application Publication No. 2002/0187288 A1, which is incorporated herein by reference in its entirety.

In addition, any of these biocompatible CON type polymers may be end-capped with surface active end groups, such as, for example, polydimethylsiloxane, fluoropolymers, polyolefin, polyethylene oxide, or other suitable groups. See, for example the surface active end groups disclosed in U.S. Pat. No. 5,589,563, which is incorporated herein by reference in its entirety.

Examples of biocompatible polyesters include DACRON® (DUPONT, Wilmington, DE) and TWILLWEAVE® MICREL (VASCUTEK, Renfrewshire, Scotland).

Another potential biocompatible graft material is ECMM, such as a purified collagen-based matrix derived from submucosa tissue. Upon implantation into a host, ECMM may undergo remodelling and induce the growth of endogenous tissues. When implanted, ECMM may be able to serve as a matrix for, promote and/or induce the growth of endogenous tissue and undergo a process of bio-remodelling. Common events related to this bio-remodelling process may include: widespread and rapid neovascularisation, proliferation of granulation

mesenchymal cells, biodegradation/resorption of implanted purified intestinal submucosa material, and lack of immune rejection.

Studies have shown that warm-blooded vertebrate submucosa may be capable of inducing host tissue proliferation, bio-remodelling and regeneration of tissue structures following implantation in a number of in vivo microenvironments including lower urinary tract, body wall, tendon, ligament, bone, cardiovascular tissues and the central nervous system. Upon implantation, cellular infiltration and a rapid neovascularisation may be observed and the submucosa material may be bio-remodelled into host replacement tissue with site-specific structural and functional properties. This may occur as a result of one or more of the components of submucosa including, for example, glycosaminoglycans, glycoproteins, proteoglycans, and/or growth factors, including Transforming Growth Factor-[alpha], Transforming Growth Factor-[beta], and/or Fibroblast Growth Factor 2 (basic).

ECMM is preferably obtained from human or other mammalian sources, including animals raised for meat production, e.g., pigs, cattle and sheep or other warm-blooded vertebrates. More specifically, ECMM is preferably made from a submucosa isolated from the alimentary, respiratory, urinary or genital tracts, renal capsule or other appropriate sources. In general, purified submucosa is prepared from these tissue sources by determining the purified submucosa from both the smooth muscle layers and the mucosal layers. The preparation of intestinal submucosa is described in U.S. Patent No. 4,902,508, and the preparation of tela submucosa is described in U.S. Patent Application Serial No. 08/916,490, both of which are incorporated herein by reference. The preparation of submucosa is also described in U.S. Patent No. 5,733,337 and in 17 Nature Biotechnology 1083 (Nov. 1999); and WIPO Publication WO 98/221 58, dated 28 May 1998, which is the published application of PCT/US97/14855.

Purified tela submucosa, a preferred type of ECMM, has been previously described in U.S. Patent Nos. 6,206,931, 6,358,284 and 6,666,892 as a bio-compatible, non-thrombogenic material that enhances the repair of damaged or diseased host tissues. U.S. Patent Nos. 6,206,931, 6,358,284 and 6,666,892 are incorporated herein by reference. Purified submucosa extracted from the

small intestine ("small intestine submucosa" or "SIS") is a more preferred type of ECMM for use in this disclosure. Another type of ECMM, isolated from liver basement membrane, is described in U.S. Patent No. 6,379,710, which is incorporated herein by reference. ECMM may also be isolated from pericardium, as described in U.S. Patent No. 4,502,159, which is also incorporated herein by reference.

In a further example, the grafts may comprise a porous biocompatible polymer in which a collagenous biomaterial has been dispersed, as is disclosed in U.S. Provisional Application Serial No. 60/558,794 filed March 31, 2004 and U.S. Provisional Application Serial No. 60/558,667 filed March 31, 2004, which are hereby incorporated herein by reference.

The grafts may be made of a single material, or may be a blend, weave, laminate or composite of two or more materials. The graft material may also include other additives, such as plasticizers, compatibilizers, surface modifiers, biological materials such as peptides and enzymes, and therapeutic agents such as drugs or other medicaments.

In addition to xenogenic biomaterials, such as SIS, autologous tissue can be harvested as well. Additionally Elastin or Elastin Like Polypetides (ELPs) and the like offer potential as a material to fabricate the flexible covering or discrete shaping members to form a device with exceptional biocompatibility. Another alternative is use of allographs such as harvested native valve tissue. Such tissue is commercially available in a cryopreserved state.

In one example, to achieve enhanced collapsibility for the first prosthesis 1 and second prosthesis 2, the material from which the grafts 11, 21 are produced may be selected based on the material's ability to achieve an enhanced collapsibility. Furthermore, the biocompatible graft materials selected for the grafts 11, 21 may be the same or different. For example, when the graft materials are different, the graft 11 may comprise a woven, fine denier polyester, while the graft 21 may comprise PTFE.

Bioadhesives

Alternatively or in addition to anchoring members, bioadhesives may be used for attachment. Bioadhesive may be included in any suitable part of the

prosthesis. Preferably, the bioadhesive is attached to an abluminal surface of the graft. Selection of the type of bioadhesive, the portions of the prosthesis comprising the bioadhesive, and the manner of attaching the bioadhesive to the prosthesis can be chosen to perform a desired function upon implantation. For example, the bioadhesive can be selected to promote increased affinity of the desired portion of prosthesis to the section of the body vessel against which it is urged.

Bioadhesives for use in conjunction with the composite prosthesis include any suitable bioadhesives. For example, appropriate bioadhesives include, but are not limited to, the following: (1) cyanoacrylates such as ethyl cyanoacrylate, butyl cyanoacrylate, octyl cyanoacrylate, and hexyl cyanoacrylate; (2) fibrinogen, with or without thrombin, fibrin, fibropectin, elastin, and laminin; (3) mussel adhesive protein, chitosan, prolamine gel and transforming growth factor beta(TGF-B); (4) polysaccharides such as acacia, carboxymethyl-cellulose, dextran, hyaluronic acid, hydroxypropyl-cellulose, hydroxypropyl-methylcellulose, karaya gum, pectin, starch, alginates, and tragacanth; (5) polyacrylic acid, polycarbophil, modified hypromellose, gelatin, polyvinyl-pylindone, polyvinylalcohol, polyethylene glycol, polyethylene oxide, aldehyde relative multifunctional chemicals, maleic anhydride co-polymers, and polypeptides; and (6) any bioabsorbable and biostable polymers derivitized with sticky molecules such as arginine, glycine, and aspartic acid, and copolymers.

Furthermore, commercially available bioadhesives that may be used include, but are not limited to: FOCALSEAL® (biodegradable eosin-PEG-lactide hydrogel requiring photopolymerization with Xenon light wand) produced by Focal; BERIPLAST® produced by Adventis-Bering; VIVOSTAT® produced by ConvaTec (Bristol-Meyers-Squibb); SEALAGEN™ produced by Baxter; FIBRX® (containing virally inactivated human fibrinogen and inhibited-human thrombin) produced by CryoLife; TISSEEL® (fibrin glue composed of plasma derivatives from the last stages in the natural coagulation pathway where soluble fibrinogen is converted into a solid fibrin) and TISSUCOL® produced by Baxter; QUIXIL® (Biological Active

Component and Thrombin) produced by Omrix Biopharm; a PEG-collagen conjugate produced by Cohesion (Collagen); HYSTOACRYL® BLUE (ENBUCRILATE) (cyanoacrylate) produced by Davis & Geck; NEXACRYL™ (N-butyl cyanoacrylate), NEXABOND™, NEXABOND™ S/C, and TRAUMASEAL™ (product based on cyanoacrylate) produced by Closure Medical (TriPoint Medical); DERMABOND® which consists of 2-octyl cyanoacrylate produced as DERMABOND® by (Ethicon); TISSUEGLU® produced by Medi-West Pharma; and VETBOND® which consists of n-butyl cyanoacrylate produced by 3M.

Method of Delivery

The composite prosthesis may be configured for delivery to a body vessel. For example, a composite prosthesis may be compressed to a delivery configuration within a retaining sheath that is part of a delivery system, such as a catheter-based system. Upon delivery, the composite prosthesis can be expanded, for example, by inflating a balloon from inside the anchors. The delivery configuration can be maintained prior to deployment of the medical device by any suitable means, including a sheath, a suture, a tube or other restraining material around all or part of the compressed prosthesis, or other methods.

Composite prostheses can be deployed in a body vessel by means appropriate to their design. Composite prostheses of the present disclosure can deployed using conventional methods known in the art and employing percutaneous transluminal catheter devices. The composite prostheses are designed for deployment by any of a variety of in situ expansion means.

For example, a first prosthesis module and second prosthesis module may be mounted onto individual catheters that hold these prostheses as they are delivered through the body vessel and then releases the first prosthesis module and second prosthesis module to form the composite endoluminal prosthesis, permitting the composite endoluminal prosthesis to expand and contact the body vessel. This deployment is effected after the first and second prosthesis modules have been introduced percutaneously, transported transluminally and positioned at a desired location by means of the catheter. For example, the prostheses may be

positioned at the distal end of a catheter with a removable sheath or sleeve placed over the prostheses to hold the prostheses in a compressed delivery configuration with a relatively small diameter. The prostheses may then be implanted at the point of treatment by advancing the catheter over a guide wire to the location of the lesion, aligning the prostheses with any branch vessels, and then withdrawing the sheath from over the prosthesis. The first prosthesis module may expand and seal against the wall of the body vessel at the site of treatment. The second prosthesis module may expand and seal against the lumen of the first prosthesis module. The catheter, sleeve, and guide wire may then be removed from the patient.

The second prosthesis module may be sealed against the lumen of the first prosthesis module such that it cannot move within or along the length of the first prosthesis module. This may be achieved, for example, via an anchor with high radial force, or the first prosthesis lumen may contain an element against which the second prosthesis module is located. There may be a number of these elements along the length of the first prosthesis module such that the combined length of the first and second prosthesis modules may be chosen by a surgeon to tailor the device to a specific patient. Alternatively, the second prosthesis module may be free to move or slide within the first prosthesis module, under hydrodynamic or other forces, until being stabilized by the patient anatomy (e.g. the iliac bifurcation) thereby tailoring the device to a specific patient. The maximum distance that the second prosthesis module is permitted to slide within the first prosthesis module may be limited by elements present on the first prosthesis module, such that the second prosthesis module remains within the first.

In one example, shown in FIG. 3, the first prosthesis module 71 may be delivered endovascularly to a lesion site in a compressed, or unexpanded, delivery configuration. For example, for treatment of an abdominal aortic aneurysm, a compressed main graft may be delivered via a 12 to about 14 Fr sheath to a location immediately distal the renal arteries. Following placement of the compressed first prosthesis module 71 at the desired location of treatment, the sheath may be withdrawn, deploying the first prosthesis module 71. The first

prosthesis module 71 may be held in place at the treatment location by anchor 74 at the delivery location. The first prosthesis module 71 may expand due to blood flow through the first prosthesis module 71, similar to a wind sock effect.

Following deployment of the first prosthesis module 71 at the desired treatment location, the second prosthesis module 75 and, optionally, further prosthesis modules may be delivered endovascularly to the treatment location. For example, the second prosthesis module 75 may be compressed to a delivery configuration in a sheath and delivered to a location near the first prosthesis lumen 72. Upon locating the second prosthesis module 75, the sheath may be withdrawn allowing the second prosthesis module 75 to expand. In one example, shown in FIG. 7, where the composite endoluminal prosthesis 150 includes a first prosthesis module having legs 22, the first branch 26 may be cannulated prior to delivery of the second prosthesis module 50.

Optionally, the third prosthesis module 130 may be compressed to a delivery configuration in a sheath and delivered to a location within the first prosthesis lumen 21. Upon locating the third prosthesis module 60, the sheath may be withdrawn allowing the third prosthesis module 60 to expand. In one example, where the composite prosthesis 150 includes a first prosthesis module 140 having legs 142, 143, the second branch 143 may be cannulated via an up-and-over guide catheter prior to delivery of the third prosthesis module 130.

After placement, the second prosthesis module may expand in the first prosthesis lumen. For example, the second prosthesis anchor 76 may expand and seal the second prosthesis module 75 in the first prosthesis lumen 72.

While various aspects and examples have been described, it will be apparent to those of ordinary skill in the art that many more examples and implementations are possible within the scope of the disclosure. Accordingly, the disclosure is not to be restricted except in light of the attached claims and their equivalents.

The disclosures in United States patent application no. 61/057,083, from which this application claims priority, and in the abstract accompanying this application are incorporated herein by reference.

CLAIMS

1. A composite endoluminal prosthesis having an expanded configuration and a compressed configuration, the composite endoluminal prosthesis including:

a first prosthesis module comprising an unstented graft provided with a lumen and an anchor extending proximally from the graft;

a second prosthesis module comprising an unstented graft provided with a lumen and an anchor extending proximally from the graft;

wherein in the expanded configuration the second prosthesis anchor engages an interior surface of the first prosthesis lumen.

2. A composite endoluminal prosthesis according to claim 1, wherein the first prosthesis anchor does not overlap the first graft and the second prosthesis anchor does not overlap the second graft.

3. A composite endoluminal prosthesis according to claim 1 or 2, wherein the first prosthesis anchor is operable to exert a radial force sufficient to engage a body vessel interior surface and the second prosthesis anchor is operable to exert a radial force sufficient to engage the interior surface of the first prosthesis lumen.

4. A composite endoluminal prosthesis according to claim 1, 2 or 3, wherein the first prosthesis module includes at least one graduated marker within the first prosthesis lumen, the at least one marker demarcating composite endoluminal prosthesis lengths against which the second prosthesis module is located in the expanded configuration.

5. A composite endoluminal prosthesis according to any preceding claim, wherein the first prosthesis module includes a tapered graft provided with a proximal end and a distal end, the graft proximal end having a diameter that is greater than the graft distal end diameter.

6. A composite endoluminal prosthesis according to any preceding claims, wherein in the expanded configuration the second prosthesis module is operable to slides within the first prosthesis lumen until stabilized by a patient's anatomy.

7. A composite endoluminal prosthesis according to any preceding claim, where at least one of the first prosthesis module and second prosthesis module includes a plurality of barbs attached to and extending from the anchor.

8. A composite endoluminal prosthesis according to any preceding claim, wherein in the expanded configuration the composite prosthesis has a length that is greater than the length of the first prosthesis module or second prosthesis module but less than the combined length of the first prosthesis and second prosthesis modules.

9. A composite endoluminal prosthesis according to any preceding claim, wherein the first prosthesis anchor is attached to the first prosthesis graft and the second prosthesis anchor is attached to the second graft by an attachment mechanism including sutures and/or polyurethane.

10. A composite endoluminal prosthesis according to any preceding claim, including a third prosthesis module including an unstented graft provided with a lumen and an anchor extending proximally from the graft.

11. A composite endoluminal prosthesis according to claim 10, wherein the composite endoluminal prosthesis is a bifurcated composite endoluminal prosthesis.

12. A bifurcated composite endoluminal prosthesis having an expanded configuration and a compressed configuration, the bifurcated composite endoluminal prosthesis including :

a first prosthesis module comprising an unstented graft provided with a lumen and an anchor extending proximally from the graft;

a second prosthesis module comprising an unstented graft provided with a lumen and an anchor extending proximally from the graft;

a third prosthesis module comprising an unstented graft provided with a lumen and an anchor extending proximally from the graft;

wherein in the expanded configuration the first prosthesis anchor engages an interior surface of a body vessel;

wherein in the expanded configuration the second prosthesis anchor engages the third prosthesis anchor and an interior surface of the first prosthesis lumen; and

wherein in the expanded configuration the third prosthesis anchor engages the second prosthesis anchor and the interior surface of the first prosthesis module.

13. A composite endoluminal prosthesis according to claim 12, wherein the first prosthesis anchor does not overlap the first graft, the second prosthesis anchor does not overlap the second graft, and the third prosthesis anchor does not overlap the third graft.

14. A bifurcated composite endoluminal prosthesis according to claim 12 or 13, wherein the second and third prosthesis modules include an expanded radial contour selected from the group consisting of a generally elliptical expanded radial contour, a D-shaped expanded radial contour, and a generally cylindrical expanded radial contour.

15. A bifurcated composite endoluminal prosthesis according to claim 12, 13 or 14, wherein the first prosthesis module includes a first branch extending distally from the graft, and a second branch extending distally from the graft; wherein in the expanded configuration the second prosthesis graft reinforces the first branch and the third prosthesis graft reinforces the second branch.

16. A composite endoluminal prosthesis having an expanded configuration and a compressed configuration, the composite endoluminal prosthesis including:

a first prosthesis module and a second prosthesis module, the first and second prosthesis modules each comprising a tubular graft provided with a proximal end, a distal end, and an unstented body extending therebetween, the body including an internal lumen, and an anchor attached to the graft proximal end such that the anchor does not substantially overlap the graft;

wherein in the expanded configuration the first prosthesis anchor engages an interior surface of a body vessel and the second prosthesis anchor engages an interior surface of the first prosthesis lumen.

17. A composite endoluminal prosthesis according to claim 16, wherein in the expanded configuration the second prosthesis anchor is proximal to the first prosthesis distal end.

18. A composite endoluminal prosthesis according to claim 16 or 17, wherein the first prosthesis anchor does not overlap the first graft and the second prosthesis anchor does not overlap the second graft.

19. A composite prosthesis according to claim 16, 17 or 18, wherein the first prosthesis anchor is operable to exert a radial force sufficient to engage the body vessel interior surface and the second prosthesis anchor is operable to exert a radial force sufficient to engage the interior surface of the first prosthesis lumen.

20. A composite prosthesis according to claim 16, 17, 18 or 19, wherein at least one of the first prosthesis anchor and second prosthesis anchor includes a plurality of barbs attached to and extending from the anchor.

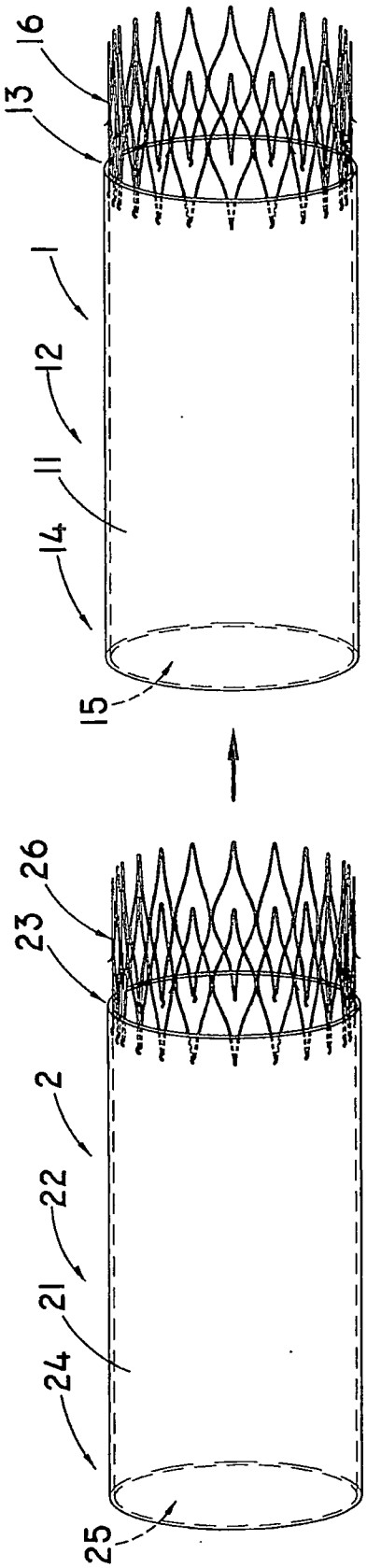

FIG. IA

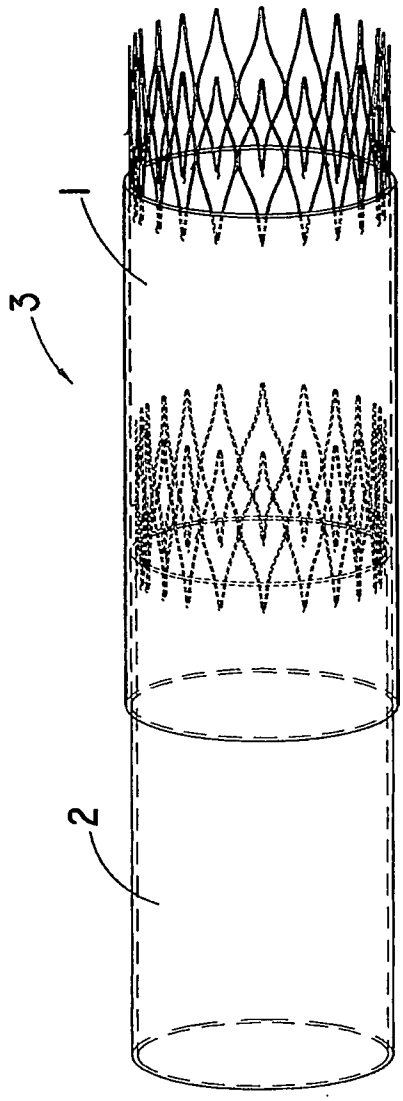

FIG. IB

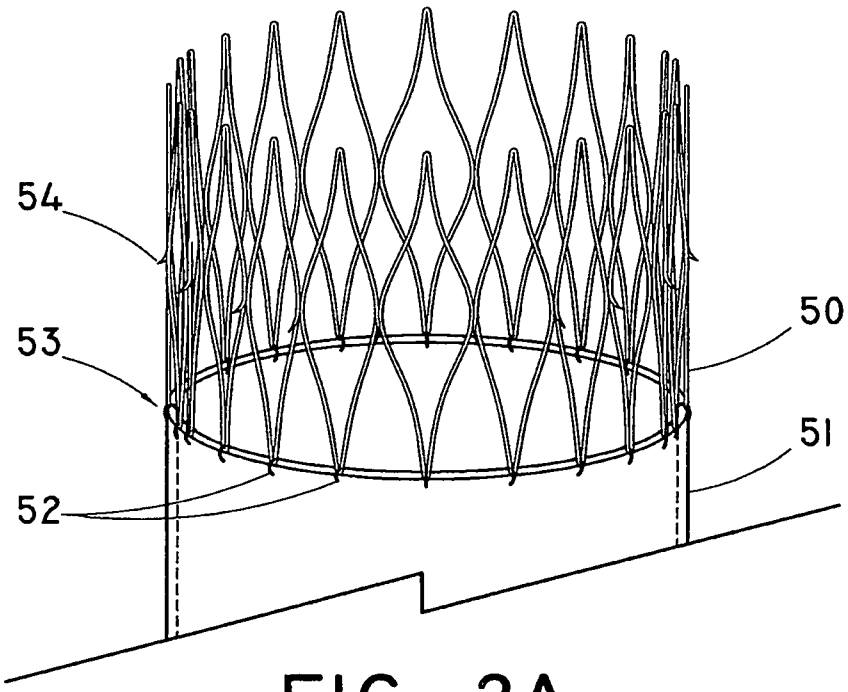

FIG. 2A

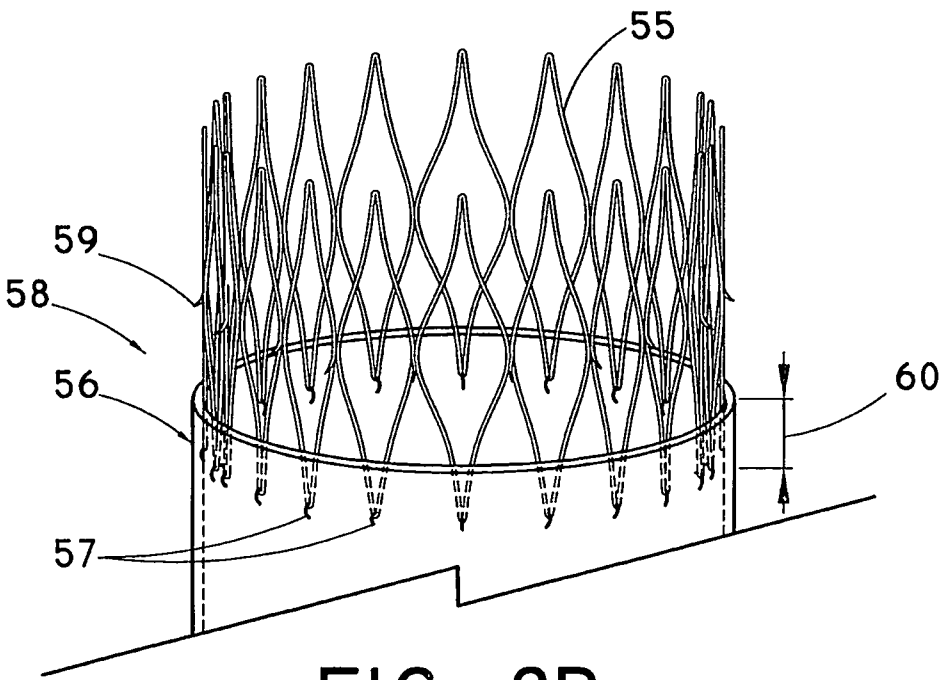

FIG. 2B

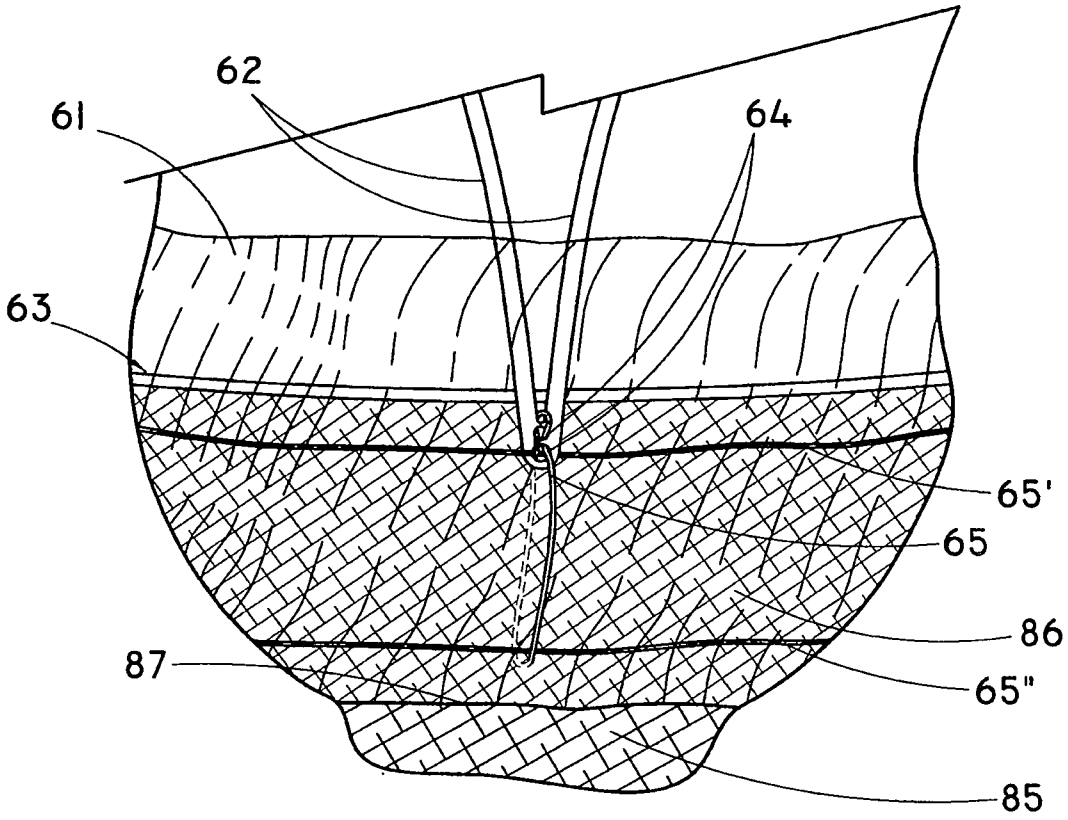

FIG. 2C

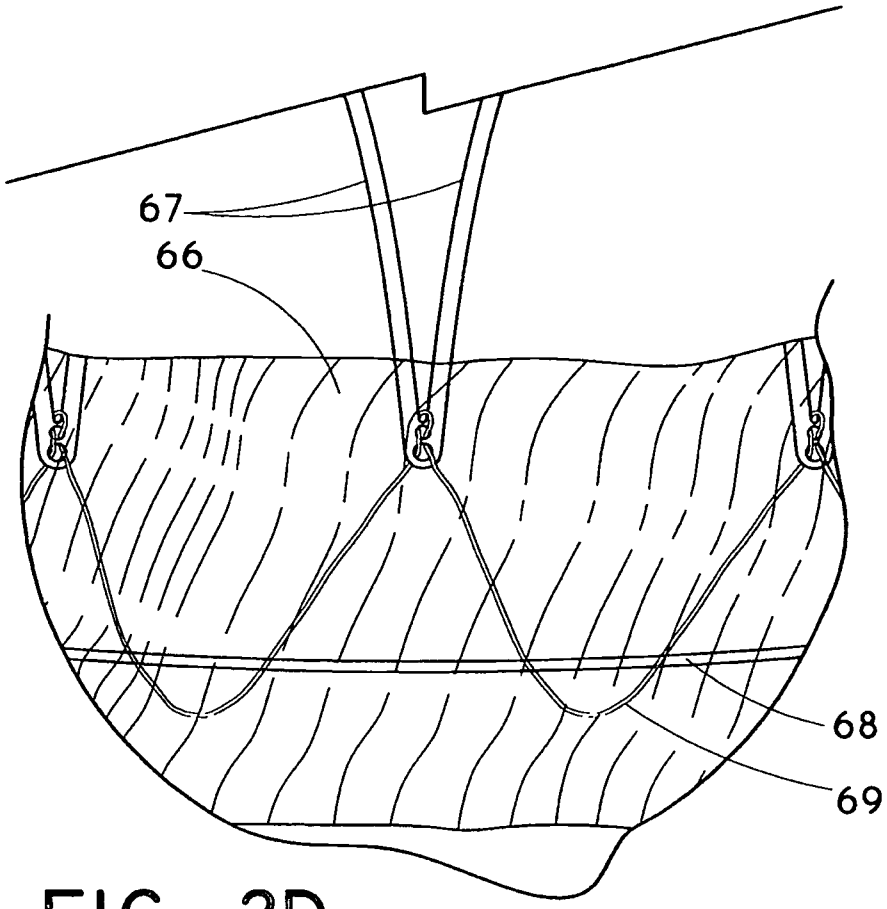

FIG. 2D

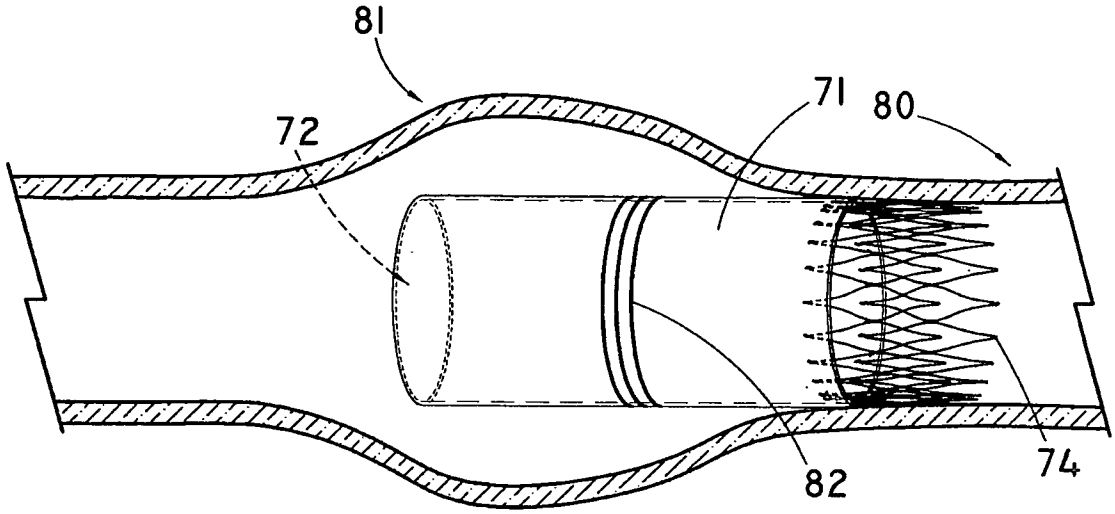

FIG. 3A

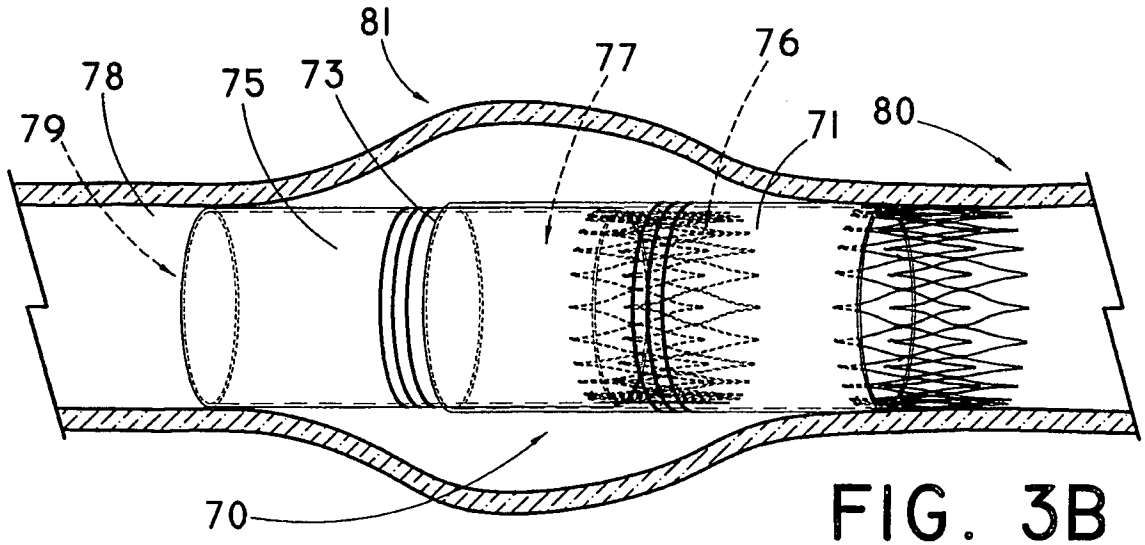

FIG. 3B

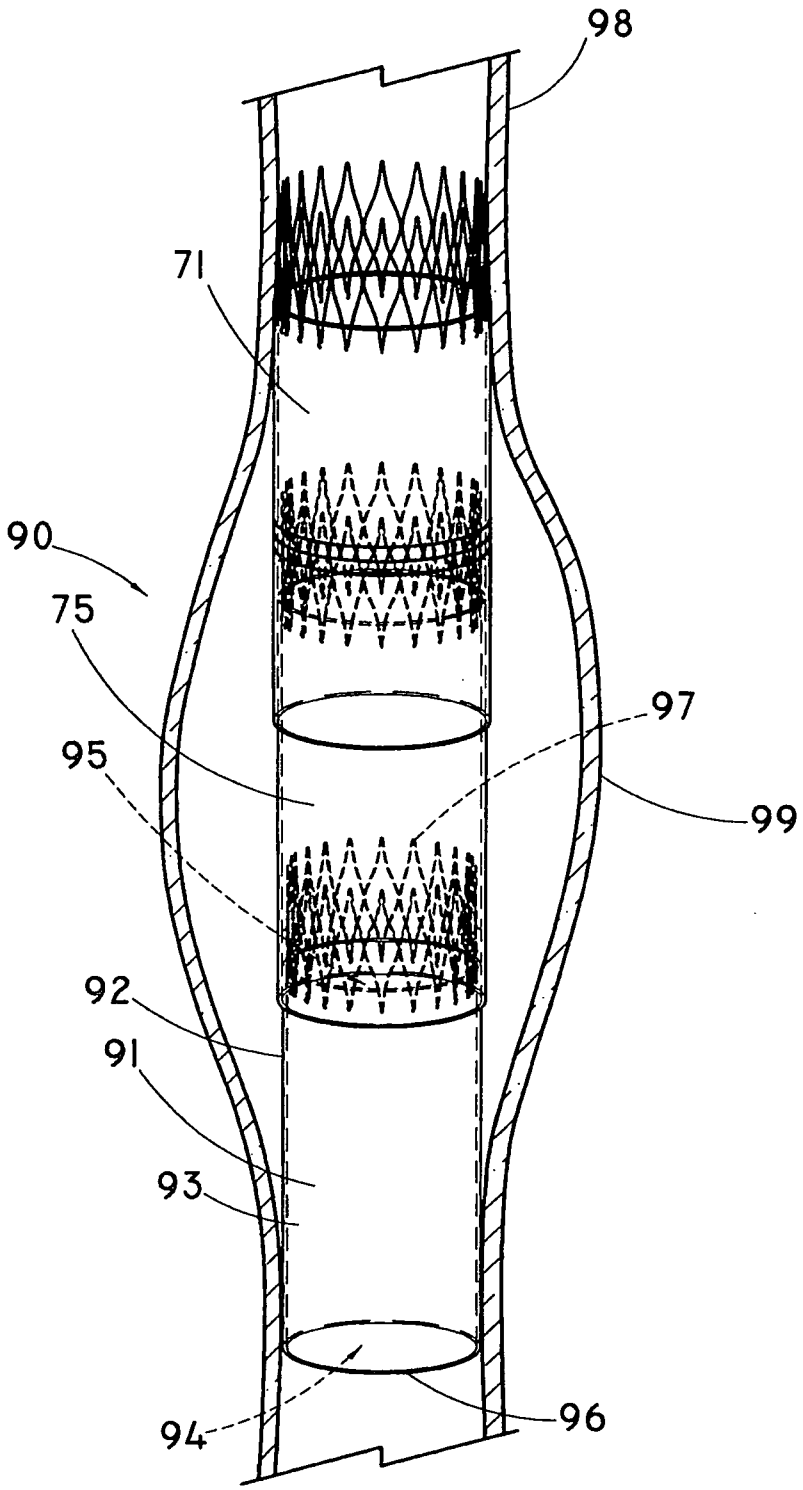

FIG. 4

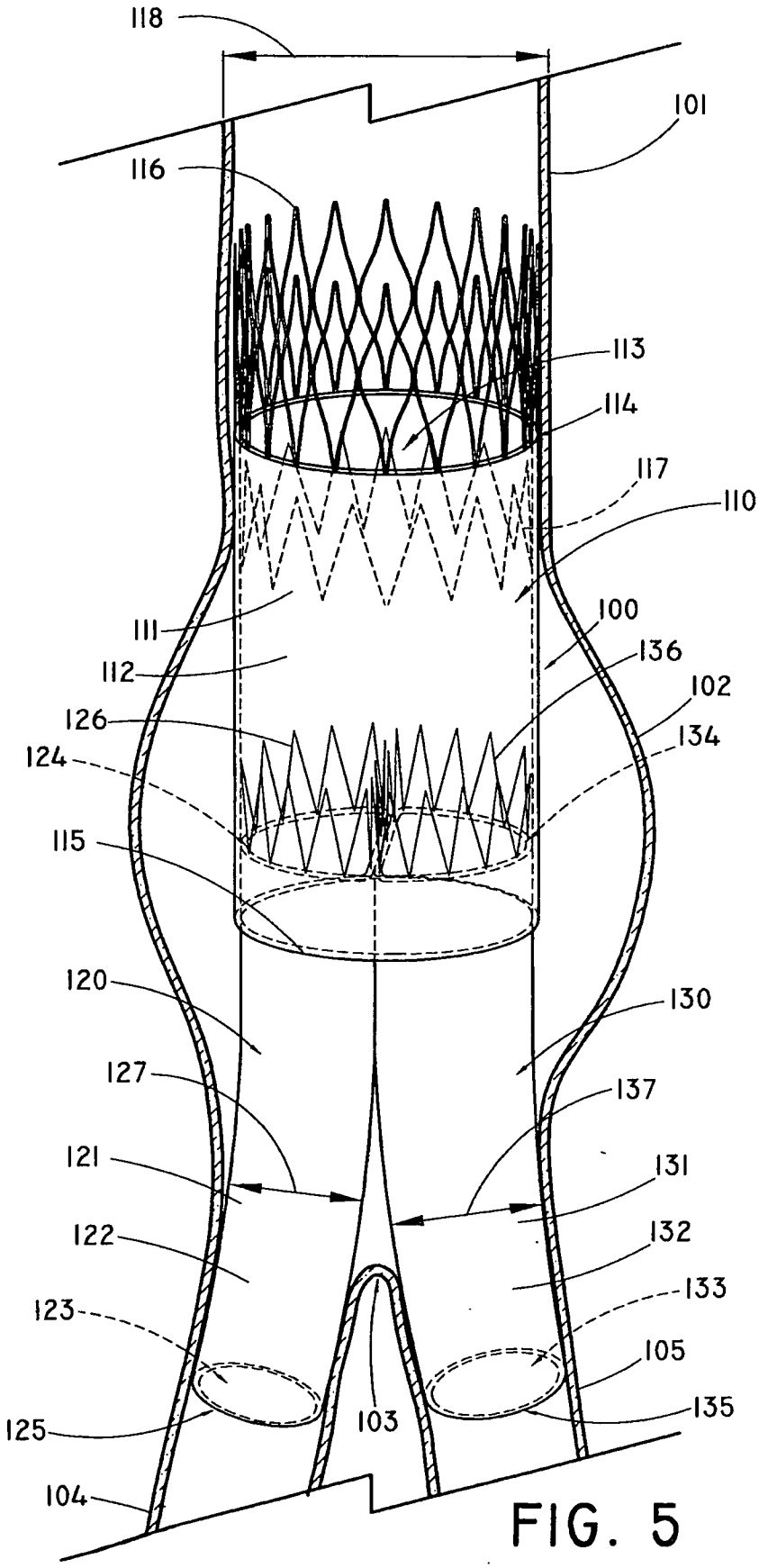
118
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FIG. 5

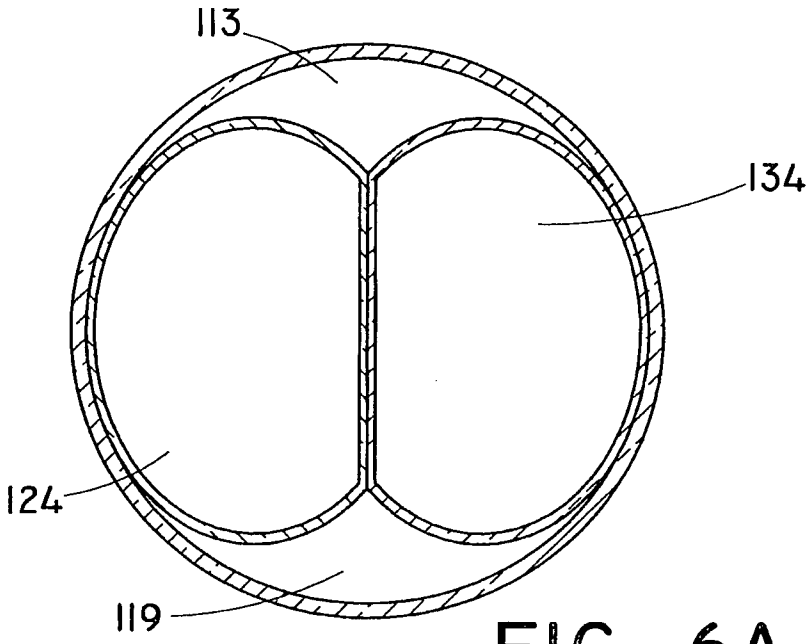

FIG. 6A

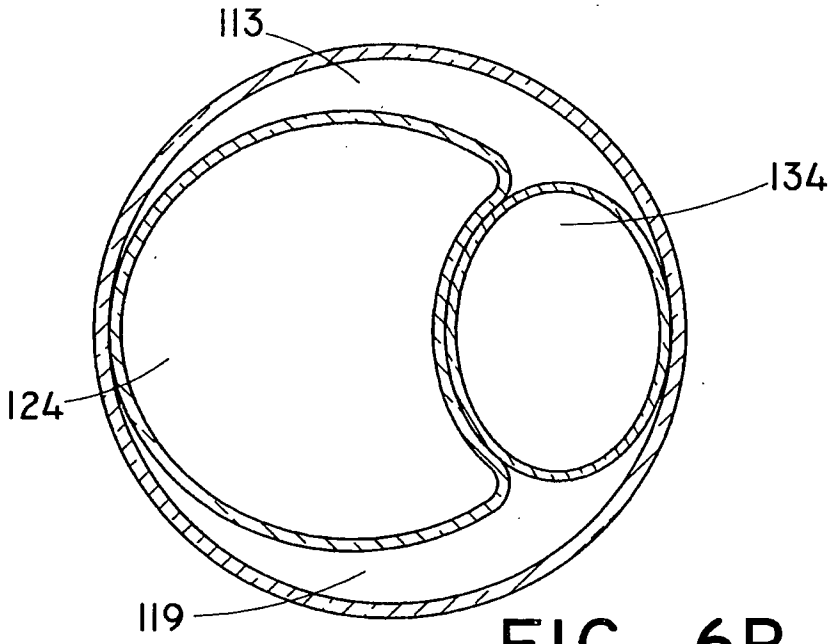

FIG. 6B

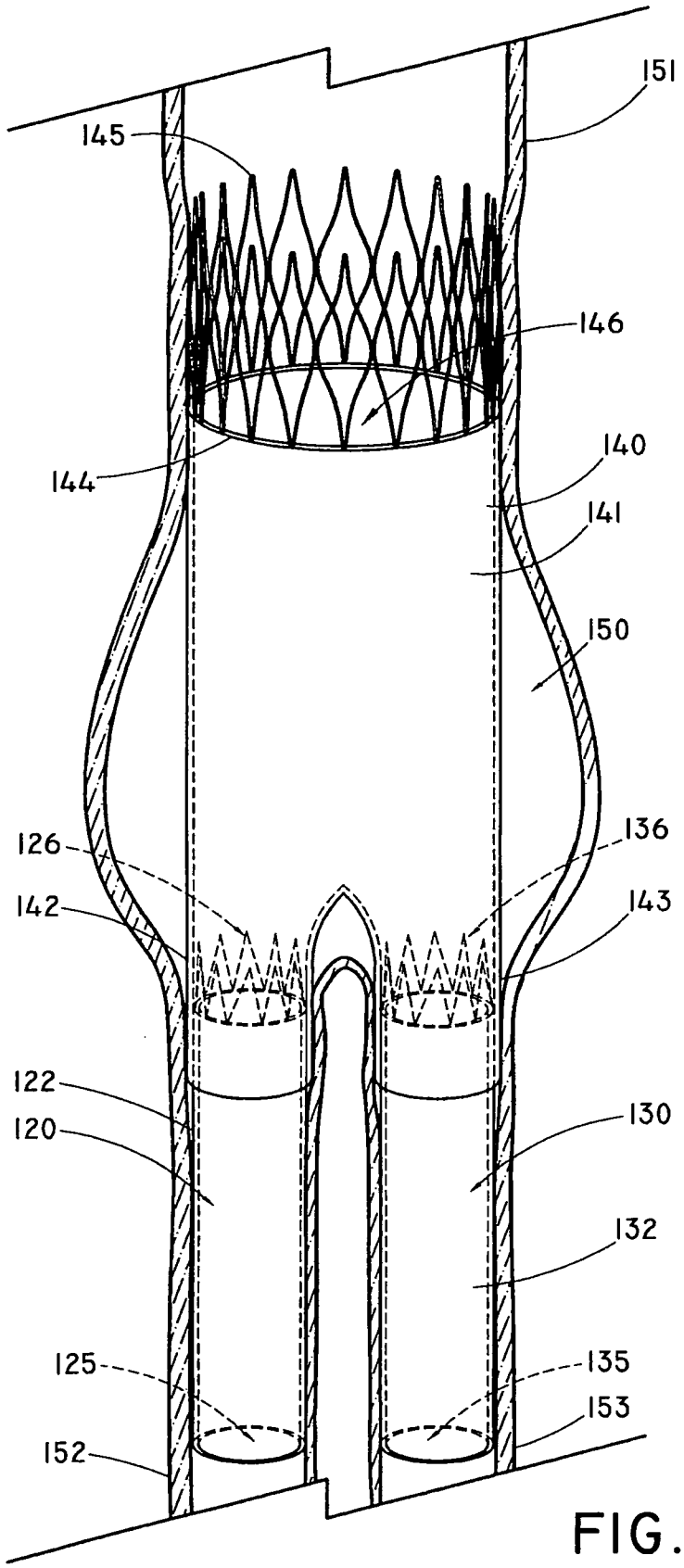
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FIG. 7

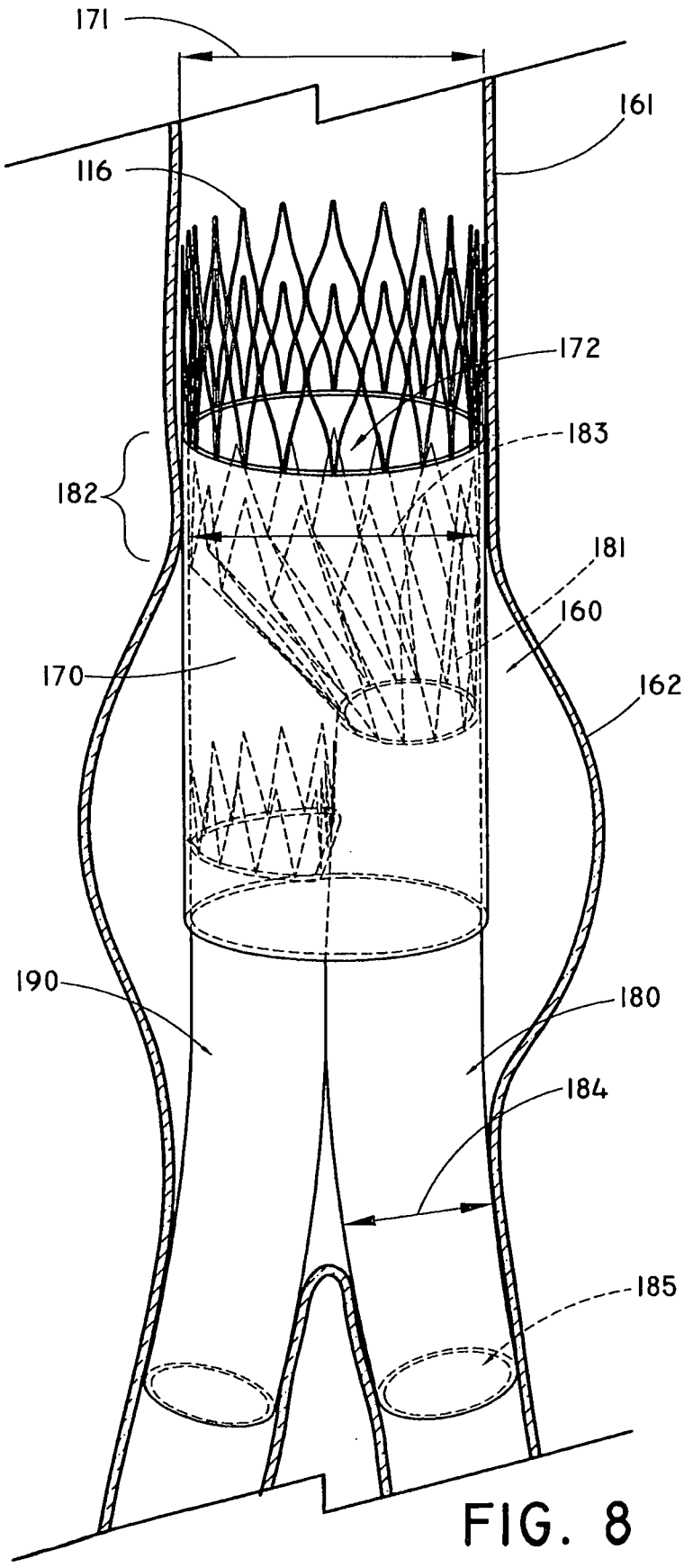

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/003263

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/06
ADD. A61F2/00 A61F2/82

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 practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 7 220 274 B1 (QUINN STEPHEN F [US]) 22 May 2007 (2007-05-22) column 15, line 26 - column 16, line 42 figures 3A,3B,4A,4B,13A-14B column 8, line 43 - column 9, line 44	1-20
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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
6 August 2009	17/08/2009

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	Portoni, Luisa

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/003263

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International application No
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