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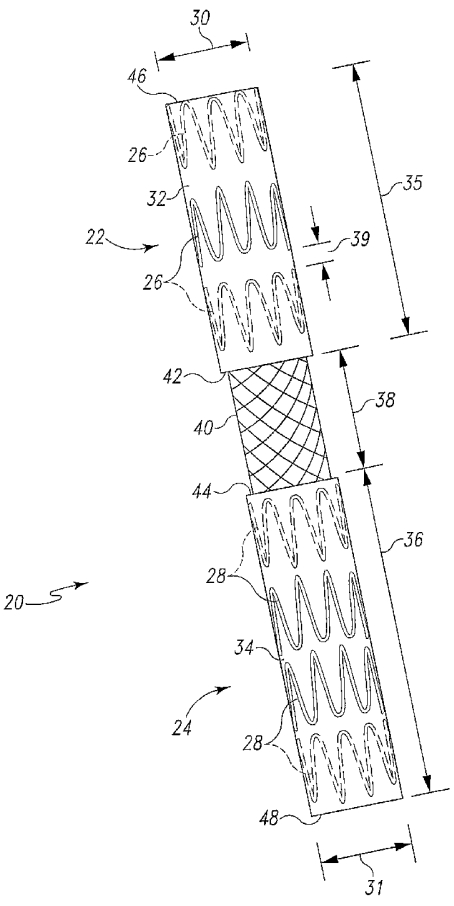
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(54) Title: INTERCONNECTED LEG EXTENSIONS FOR AN ENDOLUMINAL PROSTEHSIS



(57) Abstract: An endoluminal prosthesis includes two stent grafts (22,24) with a flexible bridge (40) extending between and connected to the stent grafts. The prosthesis can be part of a prosthesis assembly for treatment of branched vascular systems and can function as an interconnected leg extension prosthesis in combination with a main bifurcated prosthesis. In treating abdominal aortic aneurysms, the prosthesis can be deployed within both iliac arteries.

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INTERCONNECTED LEG EXTENSIONS FOR AN ENDOLUMINAL PROSTHESIS

RELATED APPLICATIONS

[0001] The present patent document claims the benefit of the filing date under 35 U.S.C. §119(e) of Provisional U.S. Patent Application Serial No. 60/530,388, filed December 17, 2003, which is hereby incorporated by reference.

TECHNICAL FIELD

[0002] This invention relates to prostheses for implantation within the human or animal body for the repair of damaged lumens such as blood vessels.

BACKGROUND

[0003] The functional vessels of human and animal bodies, such as blood vessels and ducts, occasionally weaken or even rupture. For example, in the aortic artery, the vascular wall can weaken or tear, resulting in dangerous conditions such as aneurysm and dissection. Treatment of such conditions can be performed by implanting a prosthesis within the vascular system using minimally invasive surgical procedures. An endoluminal prosthesis typically includes one or more stents affixed to graft material and is delivered to the treatment site by endovascular insertion. Once the endoluminal prosthesis is radially enlarged, it should remain in place indefinitely by self-attachment to the vessel wall, acting as a substitute vessel for the flow of blood or other fluids.

[0004] Treatment of vascular conditions near a branch point with an endoluminal prosthesis can present a number of difficulties. A single, straight section of a tubular prosthesis may not be able to span the aneurysm or dissection and still maintain sufficient contact with healthy vascular tissue to

secure the prosthesis and to prevent endoleaks. For example, most abdominal aortic aneurysms occur at or near the iliac bifurcation, and treatment with an endoluminal prosthesis requires the presence of prosthesis material in the main aorta and in the iliac branch arteries (Dietrich, E.B. *J. Invasive Cardiol.* 13(5):383-390, 2001). Typically, an endoluminal prosthesis for use near a bifurcation will have a main lumen body, for placement within the aorta, and two branch lumens extending from the main lumen body into the branch arteries.

[0005] A simple approach to bifurcated prostheses from a materials perspective is to use a single piece prosthesis. Such unitary structures have a main tubular body and pre-formed leg extensions. The seamless structure provided by this configuration can minimize the probability of leakage within the prosthesis. However, the constrained geometry of branched vasculature makes it extremely difficult to deliver such a large structure to the treatment site. For example, in treating aortic aneurysms, the deployment of a leg extension down the contralateral iliac artery is especially problematic.

[0006] A more common alternative to the single piece approach is the use of a modular system. In these systems, one or both of the leg extensions can be attached to a main tubular body to provide the final prosthesis. Examples of modular systems are described in PCT Patent Application Publication WO98/53761 and in U.S. Patent Application Publication 2002/0198587 A1, which are incorporated herein by reference. Although the delivery of modular systems is less difficult due to the smaller sizes of the individual components, it can still be a complex and time-consuming process to make the precise connections between the body and one or both legs. The difficulty and risk of the treatment procedure can also increase when there are more individual parts to insert, align, and deploy. Possible complications with modular systems include the occurrence of endoleaks, due to imperfect seals between the body and a leg component, and the separation of the legs from the main prosthesis body over time.

BRIEF SUMMARY

[0007] In one aspect of the invention, there is an endoluminal prosthesis, comprising a first stent graft; a second stent graft; and a flexible bridge extending between and connected to the first and second stent grafts.

[0008] In another aspect of the invention, there is an endoluminal prosthesis assembly, comprising a bifurcated prosthesis comprising a main tubular body having a single proximal opening and two distal openings; and an interconnected extension prosthesis comprising a first stent graft, a second stent graft, and a flexible bridge extending between and connected to the first and second stent grafts.

[0009] These aspects may further include an endoluminal prosthesis wherein the first stent graft comprises a plurality of self-expanding stents; wherein the second stent graft comprises a plurality of self-expanding stents; wherein the flexible bridge comprises a wire; wherein the flexible bridge comprises a partial stent; wherein the first and second stent grafts each comprise a stent adjacent the flexible bridge, and the flexible bridge is integral with at least one of the stents; wherein the flexible bridge is integral with both of the stents; and wherein the flexible bridge is integral with one of the stents and is affixed to the other stent. These aspects may further include an endoluminal prosthesis wherein the first and second stent grafts each comprise a stent affixed to the flexible bridge; wherein the first stent graft and the second stent graft each comprise a terminal opening and a central opening, the central openings adjacent to and on opposite ends of the flexible bridge; wherein the flexible bridge is bent at an acute angle when the prosthesis is deployed in a patient; wherein each of the first and second stent grafts comprise an internal stent at the central opening and an internal stent at the terminal opening; wherein the first stent graft further comprises at least one external stent between the central opening and the terminal opening; and wherein the second stent graft further comprises at least one external stent between the central opening and the terminal opening.

[0010] These aspects may further include an endoluminal prosthesis assembly wherein the interconnected extension prosthesis is sized and

configured to engage the two distal openings of a bifurcated stent graft; wherein the bifurcated stent graft comprises a self-expanding stent attached to and extending from the proximal opening; wherein the bifurcated stent graft comprises a shorter stent graft leg between the main tubular body and one of the distal openings and a longer stent graft leg between the main tubular body and the other distal opening; and wherein the first stent graft is longer than the second stent graft, and wherein the first stent graft is sized and configured to engage the distal opening of the shorter stent graft leg and the second stent graft is sized and configured to engage the distal opening of the longer stent graft leg.

[0011] In yet another aspect of the invention, there is a method of treating an aortic aneurysm, comprising inserting into the aortic artery a bifurcated stent graft comprising a main tubular body having a single proximal opening, a first distal opening and a second distal opening; inserting at least a portion of an interconnected extension prosthesis into a first iliac artery, through the first distal opening and into the main tubular body; wherein the interconnected extension prosthesis is in a compressed state and comprises a first stent graft, a second stent graft and a flexible bridge extending between and connected to the first and second stent grafts; inserting at least a portion of the first stent graft through the second distal opening and into a second iliac artery; and allowing the interconnected extension prosthesis to expand to an expanded state such that the first stent graft sealingly engages the second distal opening and the second stent graft sealingly enages the first distal opening.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Figure 1 shows an interconnected leg extension prosthesis.

[0013] Figures 2A – 2E show examples of interconnected leg extension prostheses having varying flexible bridge configurations.

[0014] Figure 3 shows a flexible bridge configured as a partial stent.

[0015] Figures 4A – 4C show examples of irreversible attachments between a flexible bridge and stent graft sections.

[0016] Figures 5A – 5B show examples of interconnected leg extension prostheses having internal stents and a flexible bridge that are an integral portion of a connected zig-zag stent.

[0017] Figure 6 shows a bifurcated prosthesis for treatment of aortic aneurysms.

[0018] Figure 7 shows an interconnected leg extension prosthesis for use with the bifurcated prosthesis of Figure 6.

[0019] Figure 8 shows an example of a prosthesis system with a bifurcated prosthesis and an interconnected leg extension prosthesis.

[0020] Figure 9 shows an introducer for use with an interconnected leg extension prosthesis.

[0021] Figure 10 shows an introducer containing an interconnected leg extension prosthesis during deployment within an aortic aneurysm.

[0022] Figure 11 shows a deployed prosthesis system with a bifurcated prosthesis deployed in the aorta and an interconnected leg extension prosthesis deployed into the iliac arteries.

DETAILED DESCRIPTION

[0023] The present invention relates to an endoluminal prosthesis having leg extensions that are interconnected. The prosthesis includes two stent graft sections separated by a flexible bridge section. The stent graft sections are interconnected by the flexible bridge and can coordinate with a bifurcated prosthesis to form leg portions of an endoluminal prosthesis assembly. In the treatment of an aortic aneurysm, the prosthesis can be delivered through one iliac artery, into a main bifurcated prosthesis, and into the other iliac artery.

[0024] Throughout this specification, when discussing the application of this invention to the aorta, the term distal with respect to a prosthesis is intended to refer to the end of the prosthesis furthest away in the direction of

blood flow from the heart, and the term proximal is intended to mean the end of the prosthesis that, when implanted, would be nearest to the heart.

[0025] The term "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.

[0026] The term "endoluminal" describes objects that are found or can be placed inside a lumen or 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 one of these lumens.

[0027] The term "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.

[0028] The term "stent" means any device or structure that adds rigidity, expansion force or support to a prosthesis. Typically, a stent has a tubular shape when used for endoluminal applications. The term "stent graft" means a stent that has been sewn, sutured, or otherwise connected to graft material. The term "partial stent" means a stent that has does not form a complete tubular shape, and is typically configured as a stent that has been divided along its axis or parallel to its axis.

[0029] Referring to Figure 1, an example of an interconnected leg extension prosthesis **20** contains two tubular stent graft sections **22** and **24** connected by a flexible bridge **40**. Each stent graft section contains at least one stent **26** or **28** attached to a biocompatible graft material **32** or **34**. Each stent graft section has a central opening **42** or **44** near the flexible bridge and a terminal opening **46** or **48** away from the flexible bridge at the ends of the prosthesis. Each end of the flexible bridge is irreversibly attached to one of the stent graft sections at a central opening.

[0030] The graft material covering the stent or stents of each stent graft section is a biocompatible material. Preferably the biocompatible material is in the form of a fabric that is impermeable to liquids, including blood or other physiological fluids. Examples of biocompatible materials include polyesters,

such as poly(ethylene terephthalate), and fluorinated polymers, such as polytetrafluoroethylene (PTFE) and expanded PTFE. Examples of biocompatible polyesters include DACRON (DUPONT, Wilmington, DE) and TWILLWEAVE MICREL (VASCUTEK, Renfrewshire, Scotland). Examples of biocompatible materials also include extracellular matrix (ECM) materials, such as a purified collagen-based matrix derived from submucosa tissue. Examples of ECM materials include pericardium, stomach submucosa, liver basement membrane, urinary bladder submucosa, tissue mucosa, and dura mater. A specific example of an ECM material is small intestinal submucosa (SIS), such as is described in U.S. Patent No. 6,206,931, which is incorporated herein by reference.

[0031] The graft material may be made of a single material, or it 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. The particular graft material on each stent graft section may be the same, or the materials may be different. A single piece of graft material may be used, such that a portion of graft material spans the distance between the central openings.

[0032] The graft material for each stent graft section is secured to one or more stents. For example, standard surgical suturing techniques can be used to secure the graft material to a stent. A stent can be positioned on the interior of the tubular graft material, or it can be positioned on the exterior of the graft material. A stent can also be secured to one of the openings of the tubular graft material such that the stent extends from the material. A stent extending from the graft material can be secured to the interior and/or the exterior of the material. In another example, a stent can be sandwiched between two layers of graft material, and this stent may also be secured by sutures. Examples of suture material include PROLENE® (5-0).

[0033] Stents may have a wide variety of configurations and may be balloon-expandable or self-expanding. Typically, stents have a circular cross-

section when fully expanded, so as to conform to the generally circular cross-section of a body lumen. For example, the stents used in the stent graft sections may be discrete stents having a zig-zag configuration in which straight struts are set at angles to each other and are connected by acute bends. The struts are thus connected into an endless loop, forming a generally tubular structure. Discrete zig-zag stents are also referred to as Gianturco stents or Z-stents. A specific example of a Z-stent is the Z-STENT available from COOK, INC. (Bloomington, IN). In another example, the stents may contain individual stent segments that are connected to provide an elongated, flexible stent. The individual stent segments can have a variety of configurations, including the zig-zag configuration. A specific example of a connected zig-zag stent is the ZILVER™ stent available from COOK, INC..

[0034] Stents may be made of any rigid biocompatible material, such as metal, plastic or ceramic. Preferably the stents are made of a metal, such as stainless steel, nitinol, and other biocompatible alloys. Stents may be equipped with one or more barbs to secure the prosthesis to the vessel wall or to another component of the prosthesis. If the stent is secured to the graft material by suturing, the sutures may be positioned along struts and/or at bends within the stent. For stents having a zig-zag configuration, it may be desirable to employ two sutures at each bend of the stent to further increase the stability of the connection, as described in Australian Provisional Patent Application No. 2002950951, which is incorporated herein by reference.

[0035] The flexible bridge can have a variety of configurations and serves to retain the stent graft sections within a minimum distance of each other. Referring to Figure 2A, the flexible bridge may be a piece of graft material **52** that is sutured to or integral with the graft materials of each of the stent graft sections. Preferably the flexible bridge is made of a material such as metal, plastic or ceramic such that it has some rigidity but can still be bent into an acute angle. For example, referring to Figures 2B and 2C, the flexible bridge may be a portion of metal, plastic or ceramic configured as a wire **54** or a ribbon **56**. Referring to Figures 2B through 2E, a flexible bridge configured as a wire or ribbon may form a relatively linear connection between the stent

graft sections, or may have a more flexible shape, such as a zig-zag (**58**) or sinusoidal (**59**) shape.

[0036] In another example, the flexible bridge includes a portion of one or more stents having a curved cross-section. Referring to Figure 3, in a specific example the flexible bridge **60** is configured as a partial Z-stent, that is a Z-stent that has been cleaved at one point so as not to form an endless loop of stent material. This partial Z-stent bridge is irreversibly attached to stent portions of stent graft sections **61** and **63**. Portions of a wide variety of stent materials and configurations may be used as partial stents for the flexible bridge. Such partial stents preferably have a curved cross-section.

[0037] The flexible bridge is irreversibly attached to the stent graft sections, and can be attached to the graft material and/or to a stent of the stent graft section. The term "irreversible attachment" means that the flexible bridge cannot be separated from the stent graft section under a normal use environment without damaging or destroying either of the two components. A variety of irreversible attachments can be used. For example, the flexible bridge **70** can be irreversibly attached to the stent graft **64** by suturing an end of the bridge to the graft material **66** (Figure 4A). In another example, the flexible bridge **72** can be irreversibly attached to the stent graft **64** by suturing the bridge to a length of graft material **73** that is irreversibly attached to the graft material **66** of the stent graft section (Figure 4B). In yet another example, the flexible bridge **74** can be irreversibly attached to a stent **68** of the stent graft **64** (Figure 4C). Preferably, the flexible bridge is attached to the stent of the stent graft section. The flexible bridge may be integral with one or both stents. That is, the flexible bridge and one or both stents may be formed from a single piece of material. The flexible bridge may be a separate piece of material that has been affixed to one or both stents by any of a variety of methods including welding, brazing, and soldering.

[0038] Preferably, the flexible bridge is a partial stent having a curved cross-section and irreversibly attached to each of the stents located at the central openings. Preferably the flexible bridge is made of a metal, such as stainless steel, nitinol, and other alloys. In a preferred configuration, the

flexible bridge is a partial zig-zag stent and is integral with both of the stents located at the central openings, each of which are also zig-zag stents.

[0039] In another example, the flexible bridge is a partial stent that is a portion of a connected zig-zag stent. In this example, the flexible bridge is integral with each internal stent located at the central opening of each of the stent graft sections. Referring to Figure 5A, internal stents **50** and **51** and the partial stent of the flexible bridge **53** are an integral portion of a single connected zig-zag stent. The internal stents are covered with graft material **55** and **57**. The stent graft sections **65** and **67** may each have additional Z-stents **62** away from the central openings, and these stents may be internal or external. Referring to Figure 5B, internal stents **75** and **76** are covered with graft material **55** and **57**, and extend from the cental opening to the terminal opening of their respective stent graft sections **78** and **79**. These internal stents and the partial stent of the flexible bridge **77** are an integral portion of a single connected zig-zag stent.

[0040] The dimensions of the flexible bridge and each of the stent graft sections are determined by the intended use of the prosthesis. Ideally, each section of the interconnected leg extension prosthesis, and each component of the prosthesis assembly of which the interconnected leg extension prosthesis is a component, is precisely constructed so as to provide the optimum fit of the prosthesis assembly with the vasculature to be treated. 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. Interconnected prostheses may also be constructed so as to have a range of discrete sizes. In this way, the interconnected leg extension prosthesis can be kept in stock for use with other stock components for emergency treatments. This general type of system is described, for example in U.S. Patent Application Publication 2002/0198587 A1.

[0041] One of the possible uses of the interconnected leg extension prothesis is as a component of a prosthesis assembly for treatment of an aortic aneurysm. Such an assembly could include the interconnected leg

extension prosthesis and a bifurcated prosthesis having a main tubular body with a proximal opening and two distal openings. The main tubular body of the bifurcated prosthesis is intended to attach to the healthy tissue above the aneurysm near the proximal opening of the prosthesis. The two openings at the distal end of the main tubular body form the bifurcation that fits over the iliac bifurcation such that each distal opening is at or within one of the iliac branch arteries. An example of such a bifurcated prosthesis is described in WO98/53761.

[0042] In the treatment of aortic aneurysms, the desired dimensions of an interconnected leg extension prosthesis are determined by the dimensions and condition (i.e. healthy or aneurysmal) of the iliac arteries and by the dimensions of the bifurcated prosthesis with which the leg extensions will coordinate. Referring again to Figure 1, in this example the diameter **30** or **31** of a stent graft section will typically range from 8 mm to 24 mm, and the length **35** or **36** will typically range from 15 mm to 125 mm. The distance **38** between the central openings of the stent graft sections in this example will typically range from 30 mm to 60 mm. For a stent graft section containing two or more discrete stents or stent segments, the spacing **39** of the stents along the axis of the stent graft is preferably from 0 mm to 8 mm.

[0043] One specific example of a bifurcated prosthesis for treatment of aortic aneurysms is the ZENITH^{TM} AAA prosthesis system available from COOK, INC., which is generally described in WO98/53761. Referring to Figure 6, this type of bifurcated prosthesis **100** has a main tubular body **102** with a proximal opening **104** and having two distal tubular legs **106** and **108** at the bifurcation **110**. A stent **112** is attached to and extends from the graft material near the proximal opening **104**. This stent contains barbs **114** to provide for anchoring of the prosthesis above the aneurysm. The longer distal leg **106** is typically deployed in the ipsilateral iliac artery, and the shorter distal leg **108** is typically deployed in the contralateral iliac artery. The shorter leg contains one external zig-zag stent **111** between the bifurcation and the distal opening **109**, and the longer leg contains two external zig-zag stents **111** between the bifurcation and the distal opening **107**.

[0044] An example of an interconnected leg extension prosthesis **80** for use specifically with the bifurcated prosthesis of Figure 6 is shown in Figure 7. This example has a longer stent graft section **81** and a shorter stent graft section **82**. These stent graft sections are designed to engage with the shorter and longer legs of the bifurcated prosthesis, respectively. The longer stent graft section contains an internal stent **83** near the central opening **85** and contains three external stents **84** along the length of the section. The shorter stent graft section contains an internal stent **86** near the central opening **88** and contains two external stents **87** along the length of the section. The terminal end **90** or **91** of each stent graft section can contain either an internal stent or an external stent. Internal stents are preferred for the terminal ends of the stent graft sections, as this may provide for enhanced sealing between the vessel wall and the prosthesis.

[0045] Referring still to Figure 7, the flexible bridge **95** is shown in a bent form to illustrate a possible configuration of the prosthesis when deployed at the site of treatment. The flexible bridge is irreversibly attached to each of the internal stents at the central openings. When deployed, these central openings function as the proximal openings for each of the stent graft sections and are intended to coordinate with the distal openings of the bifurcated prosthesis.

[0046] The length of the stent graft sections and the number of stents contained within the sections can vary independently. For example, referring to Figure 8, a bifurcated prosthesis **150** has a longer distal leg **156** and a shorter distal leg **158**. An interconnected leg extension prosthesis **160** for use with this bifurcated prosthesis can have a shorter stent graft section **166** and a longer stent graft section **168**. Preferably the shorter stent graft section contains at least an internal stent at the central opening and another internal stent at the terminal opening. An interconnected leg extension prosthesis **80** as shown in Figure 7 can also be used with bifurcated prosthesis **150**, depending on the treatment requirements.

[0047] An interconnected leg extension prosthesis can be delivered to a treatment site using a variety of endovascular techniques. In treating aortic

aneurysms, a catheter-based introducer can be used to insert a compressed prosthesis into the body through a femoral artery and then into the aorta. The introducer may be similar to those described in WO 03/53761 and in US2002/0198587.

[0048] Referring to Figure 9, an example of an introducer **200** for an interconnected leg extension prosthesis **201** includes a delivery sheath **202**, tapered dilator **204** at proximal end **206**, and a fitting **208** at distal end **210** of the delivery system. Inner cannula **214**, which is connected to handle **216**, extends completely from the tapered dilator **204** to distal end **210**. Joined to the side of fitting **208** is an injection system **212**, for saturating the prosthesis with anticoagulant heparin or other agents prior to deployment, and optionally for the injection of contrast medium or other agents after deployment.

[0049] Referring still to Figure 9, the introducer **200** also includes check-flow valve **226**, pusher **228**, pusher fitting **230** and pin vise **232**, all of which are covered with a protective tube **234**. The protective tube **234** covers the distal end components during handling and is removed prior to use. Tabs **220** are provided at the distal end of short sheath **222**, for peeling away the sheath prior to use. Sheath **222** protects the patency of the introducer lumen at the check-flow valve during shipping and handling, and extends only into fitting **208**. Stylet **224** extends through cannula **214**, through pusher **228** and introducer sheath **202** to a proximal tip **205** that protrudes from the proximal end of the tapered dilator **204**. Stylet **224** is also of protective value during shipping and handling and is likewise removed prior to use in the medical procedure.

[0050] Referring to the cutaway view of Figure 10, delivery system **300** is introduced into the patient in delivery sheath **302** by insertion through ipsilateral iliac artery **350** and into the distal opening **307** of a bifurcated prosthesis **301** that has been deployed in the main aorta. The inner cannula is then bent at an acute angle to direct the dilator **304** down the contralateral artery **351** and past the other distal opening **309** of the bifurcated prosthesis. At this point, the compressed central opening **324** of stent graft section **320** is within the distal portion of leg **308**, the compressed central opening **326** of

stent graft section **322** is within distal portion of leg **306**, and the flexible bridge **332** is bent at an acute angle. The delivery sheath **302** can then be pulled back towards the distal end of the delivery system, sequentially releasing the terminal opening **328** and the central opening **324** of stent graft section **320**, the flexible bridge **332**, and the central opening **326** and the terminal opening **330** of stent graft section **322**.

[0051] Referring to Figure 11, as each stent graft section of the prosthesis is released, that section self-expands and may press against the inner surface of the bifurcated prosthesis or against the vessel wall of the iliac artery. The central opening portions **324** and **326** expand against the distal portions of legs **306** and **308**, establishing a friction fit between the stent graft sections and the bifurcated prosthesis. Thus, the stent graft sections **320** and **322** function as leg extensions for the prosthesis assembly, and central openings **324** and **326** function as the proximal ends of the legs. The terminal openings **328** and **330** engage the vessel wall in the iliac arteries and function as the distal ends of the legs. The attachment of the prosthesis at the implantation site and its sealing engagement to the bifurcated prosthesis and to the vessel walls may be further enhanced by inflating a molding balloon at each site to fully expand the prosthesis to press against the bifurcated prosthesis and/or the vessel wall.

[0052] As is evident from Figure 11, the flexible bridge is bent over the bifurcation within the main prosthesis, and the graft material of each stent graft section overlaps with the graft material of the main prosthesis. Delivery of the complete prosthesis assembly is simplified since both leg extensions are part of a single interconnected component. In addition, this prosthesis system provides a reduced risk of leg extension separation due to the counterbalancing of forces on the two iliac leg stent grafts.

[0053] Throughout this specification various indications have been given as to the scope of the invention but the invention is not limited to any one of these but may reside at two more of these combined together. The examples are given for illustration only and not for limitation.

CLAIMS

1. An endoluminal prosthesis, comprising:

a first stent graft;

a second stent graft; and

a flexible bridge extending between and connected to the first and second stent grafts.

2. The endoluminal prosthesis of claim 1, wherein the first stent graft comprises a plurality of self-expanding stents.

3. The endoluminal prosthesis of claim 2, wherein the second stent graft comprises a plurality of self-expanding stents.

4. The endoluminal prosthesis of claim 1, wherein the flexible bridge comprises a wire.

5. The endoluminal prosthesis of claim 1, wherein the flexible bridge comprises a partial stent.

6. The endoluminal prosthesis of claim 1, wherein the first and second stent grafts each comprise a stent adjacent the flexible bridge, and the flexible bridge is integral with at least one of the stents.

7. The endoluminal prosthesis of claim 1, wherein the first and second stent grafts each comprise a stent affixed to the flexible bridge.

8. The endoluminal prosthesis of claim 1, wherein the first stent graft and the second stent graft each comprise a central opening and a terminal opening, the central openings adjacent to and on opposite ends of the flexible bridge; and the central and terminal openings each comprising an internal stent.

9. The endoluminal prosthesis of claim 8, wherein the first stent graft further comprises at least one external stent between the central opening and the terminal opening.

10. The endoluminal prosthesis of claim 9, wherein the second stent graft further comprises at least one external stent between the central opening and the terminal opening.

11. An endoluminal prosthesis assembly, comprising:

a bifurcated prosthesis comprising a main tubular body having a single proximal opening and two distal openings; and

an extension prosthesis comprising a first stent graft, a second stent graft, and a flexible bridge extending between and connected to the first and second stent grafts.

12. The endoluminal prosthesis assembly of claim 11, wherein the extension prosthesis is sized and configured to engage the two distal openings of the bifurcated prosthesis.

13. The endoluminal prosthesis assembly of claim 11, wherein the bifurcated prosthesis comprises a self-expanding stent attached to and extending from the proximal opening.

14. The endoluminal prosthesis assembly of claim 11, wherein the bifurcated prosthesis comprises a shorter stent graft leg between the main tubular body and one of the distal openings and a longer stent graft leg between the main tubular body and the other distal opening.

15. The endoluminal prosthesis assembly of claim 14, wherein the first stent graft is longer than the second stent graft, and wherein the first stent graft is sized and configured to engage the distal opening of the shorter stent graft leg and the second stent graft is sized and configured to engage the distal opening of the longer stent graft leg.

16. A method of treating an aortic aneurysm, comprising:

inserting into the aortic artery a bifurcated prosthesis comprising a main tubular body having a single proximal opening, a first distal opening and a second distal opening;

inserting at least a portion of an extension prosthesis into a first iliac artery, through the first distal opening and into the main tubular body;

wherein the extension prosthesis is in a compressed state and comprises a first stent graft, a second stent graft and a flexible bridge extending between and connected to the first and second stent grafts;

inserting at least a portion of the first stent graft through the second distal opening and into a second iliac artery; and

allowing the extension prosthesis to expand to an expanded state such that the first stent graft sealingly engages the second distal opening and the second stent graft sealingly enages the first distal opening.

17. The method of claim 16, wherein the bifurcated prosthesis comprises a longer stent graft leg between the main tubular body and the first distal opening and a shorter stent graft leg between the main tubular body and the second distal opening.

18. The method of claim 17, wherein the first stent graft is longer than the second stent graft.

19. The method of claim 16, wherein the flexible bridge is bent at an acute angle when the extension prosthesis is in the expanded state.

20. The method of claim 16, wherein the flexible bridge comprises a wire.

21. The method of claim 16, wherein the flexible bridge comprises a partial stent.

22. The method of claim 16, wherein the first and second stent grafts each comprise a stent adjacent the flexible bridge, and the flexible bridge is integral with at least one of the stents.

23. The method of claim 16, wherein the first and second stent grafts each comprise a stent affixed to the flexible bridge.

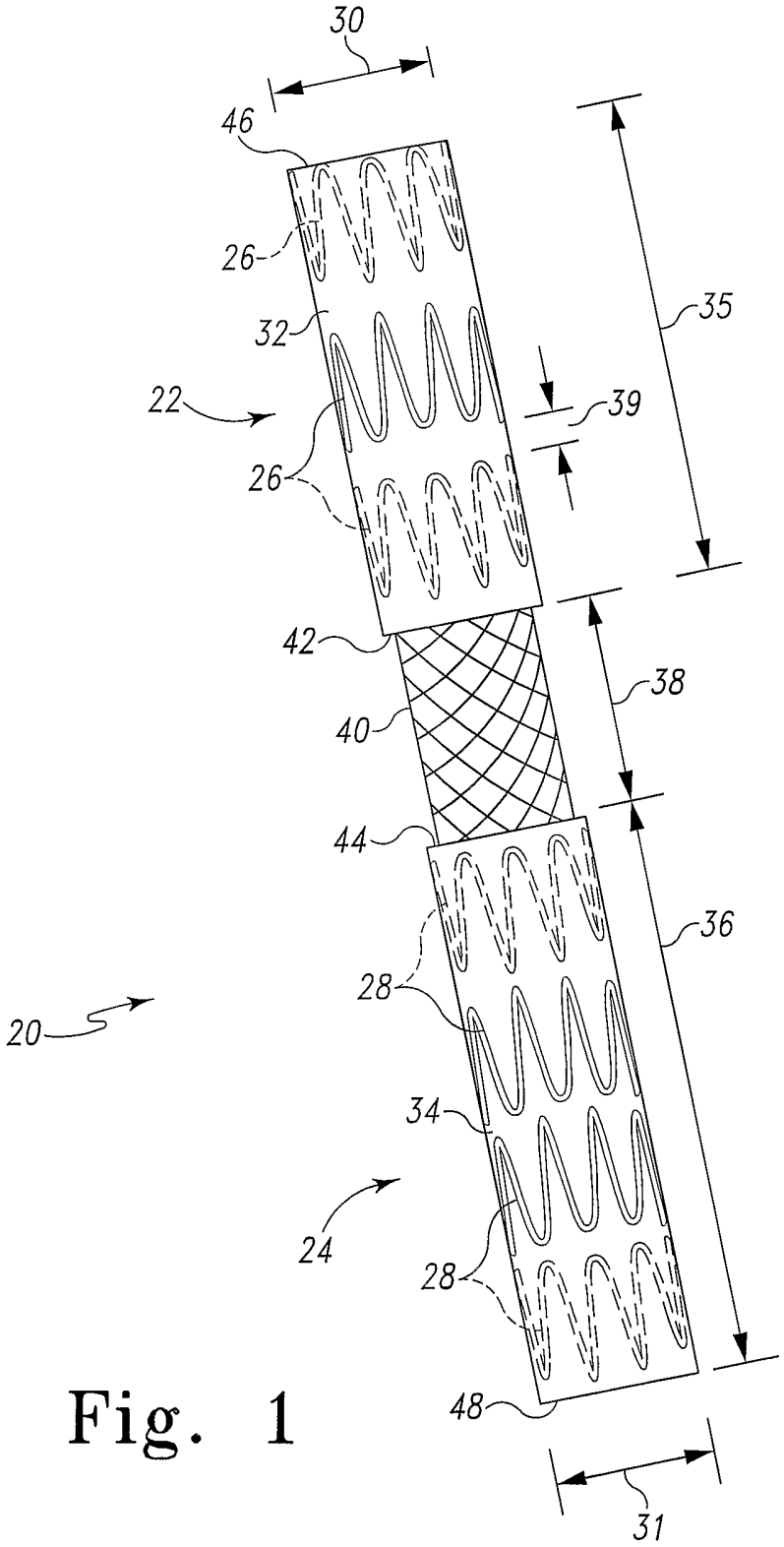


Fig. 1

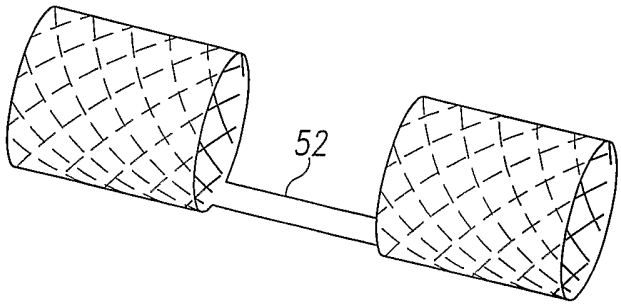


Fig. 2A

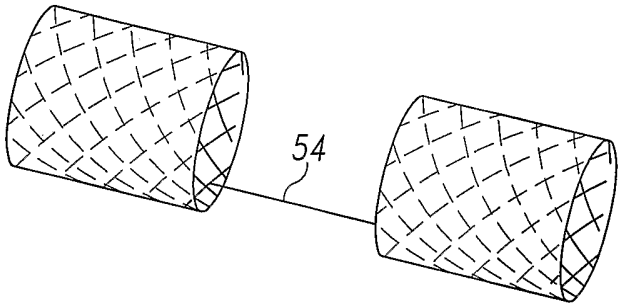


Fig. 2B

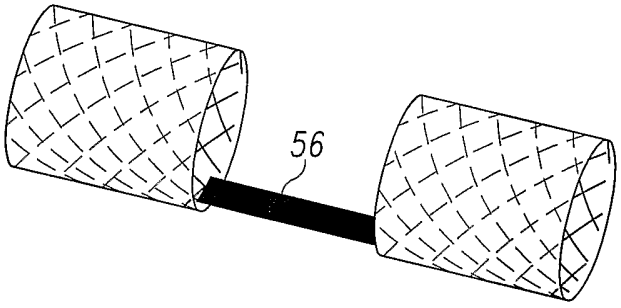


Fig. 2C

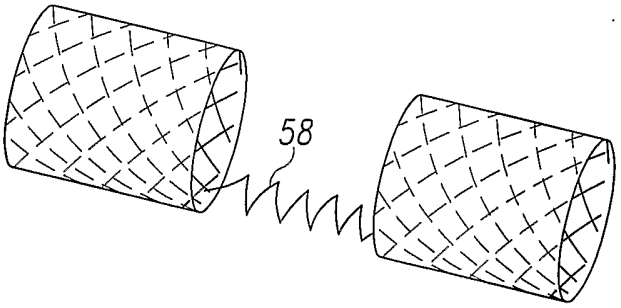


Fig. 2D

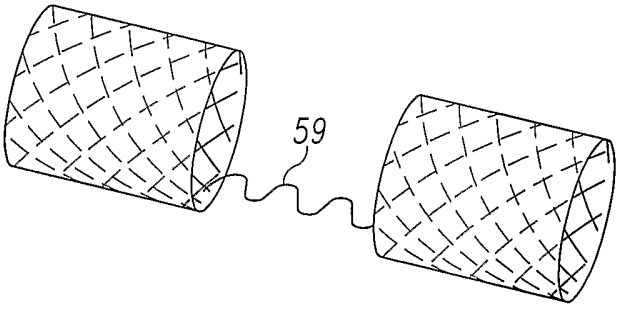


Fig. 2E

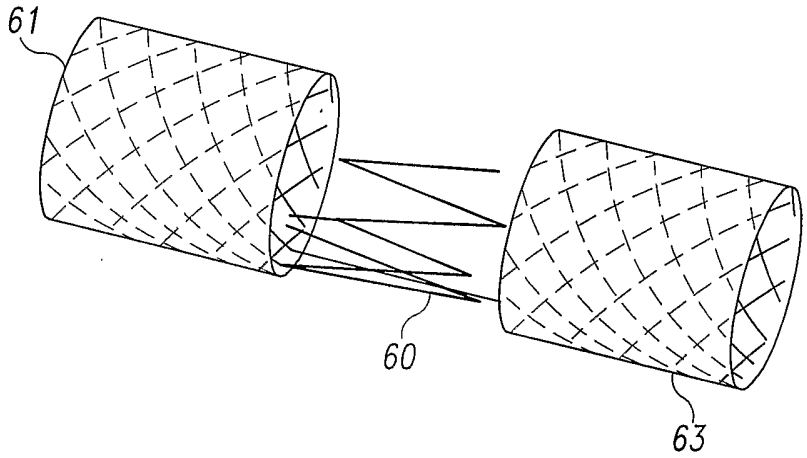


Fig. 3

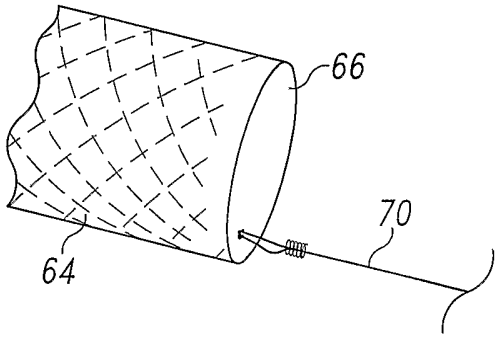


Fig. 4A

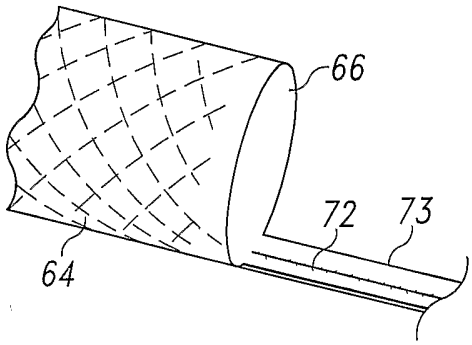


Fig. 4B

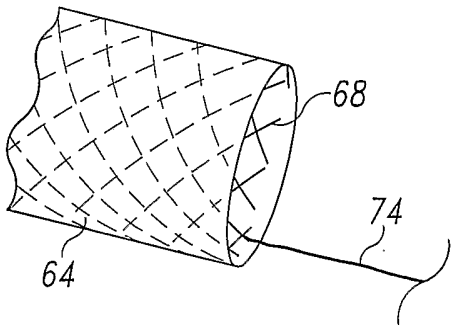


Fig. 4C

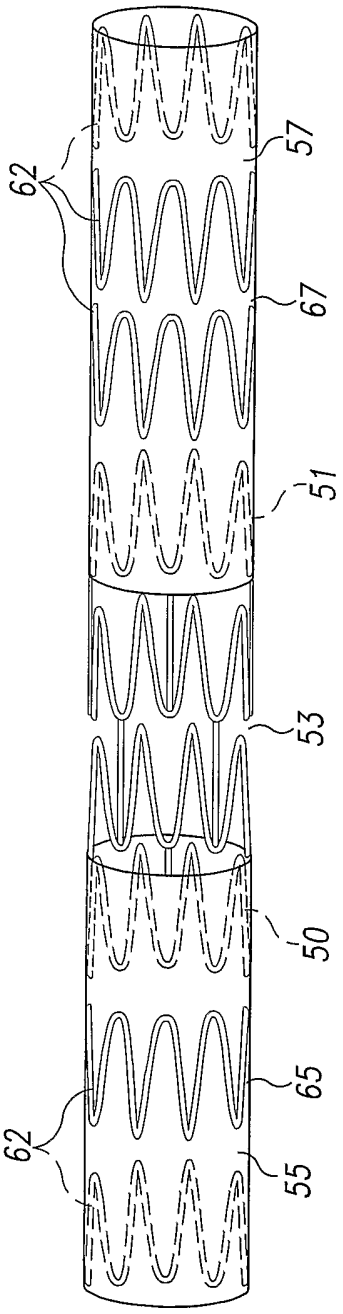


Fig. 5A

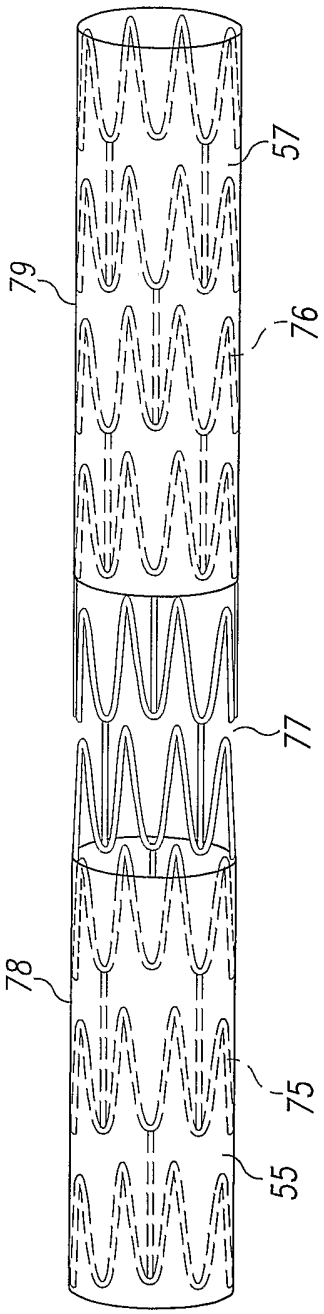


Fig. 5B

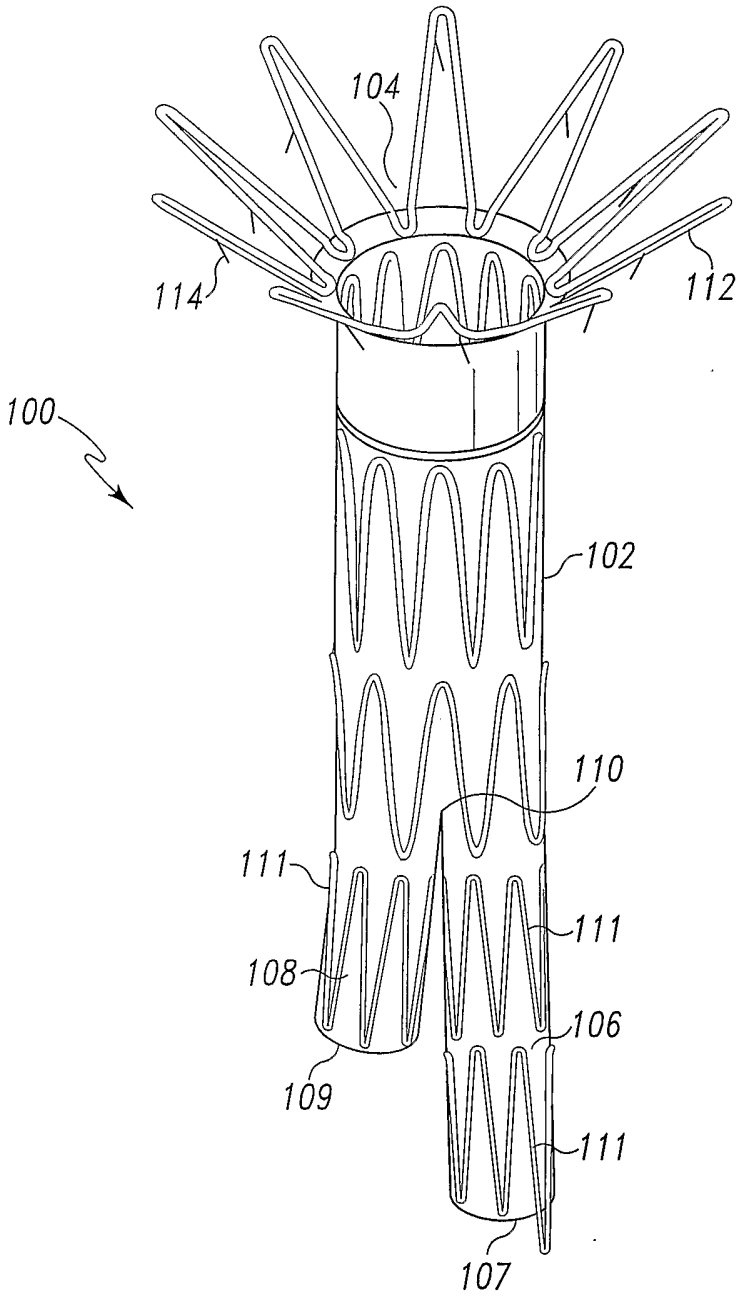


Fig. 6

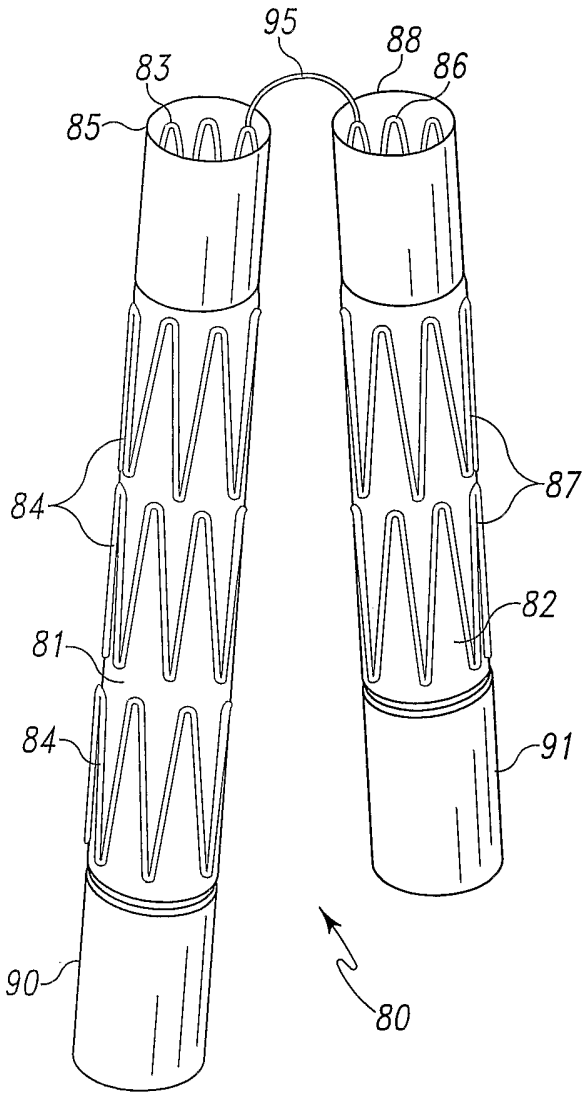


Fig. 7

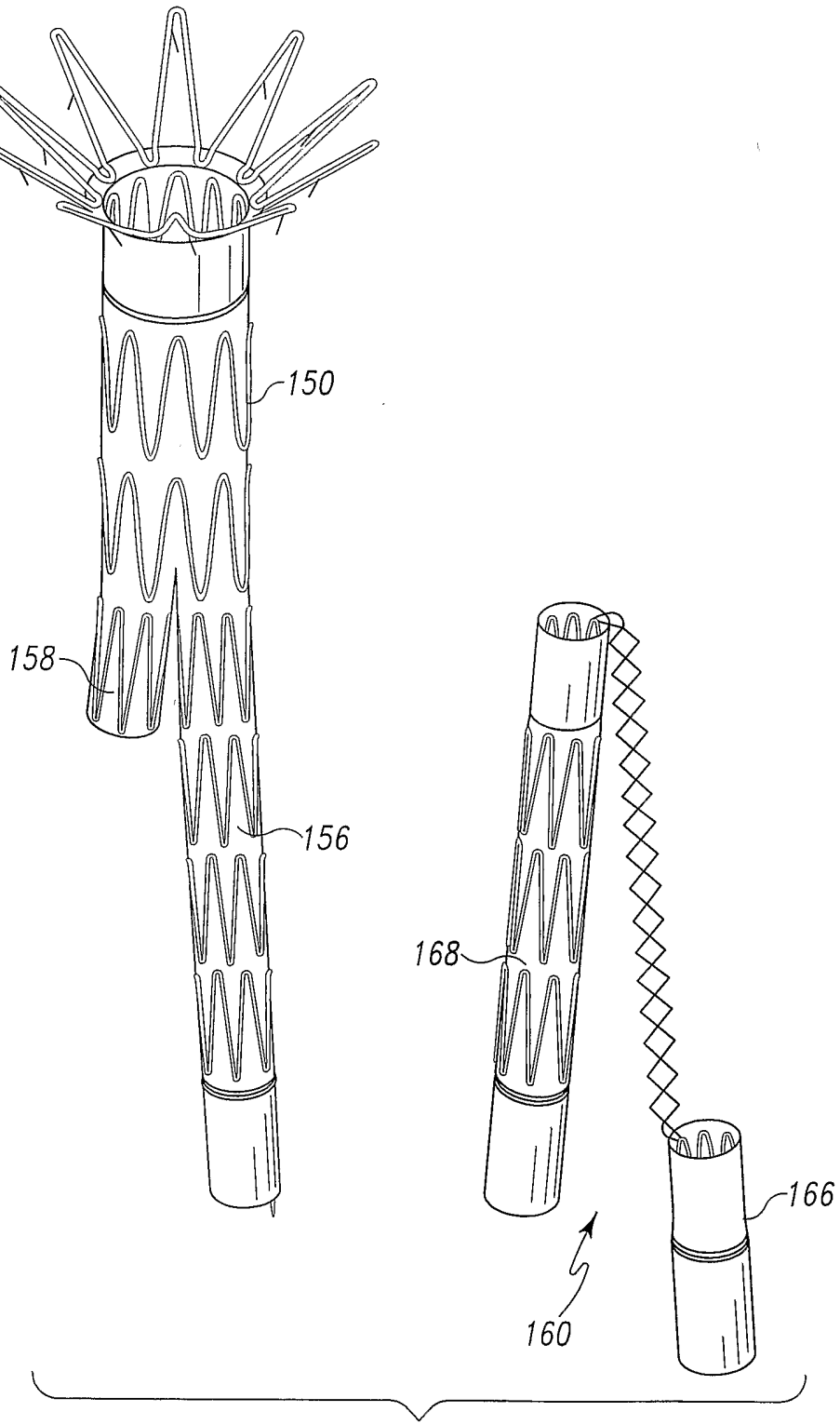


Fig. 8

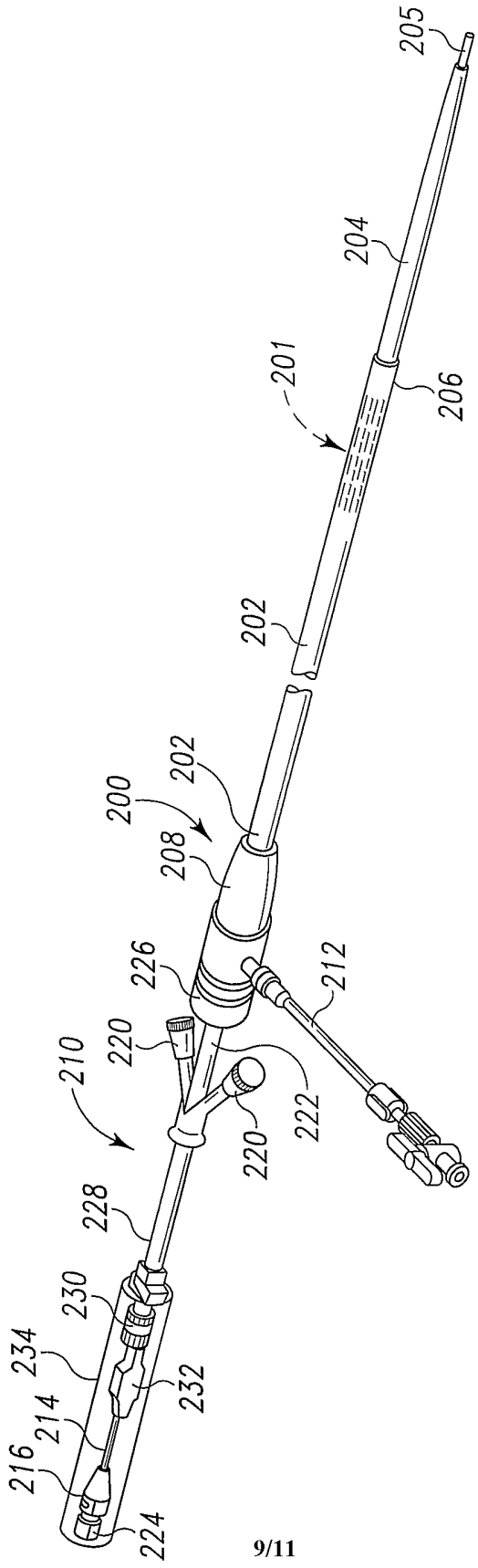

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Fig. 9

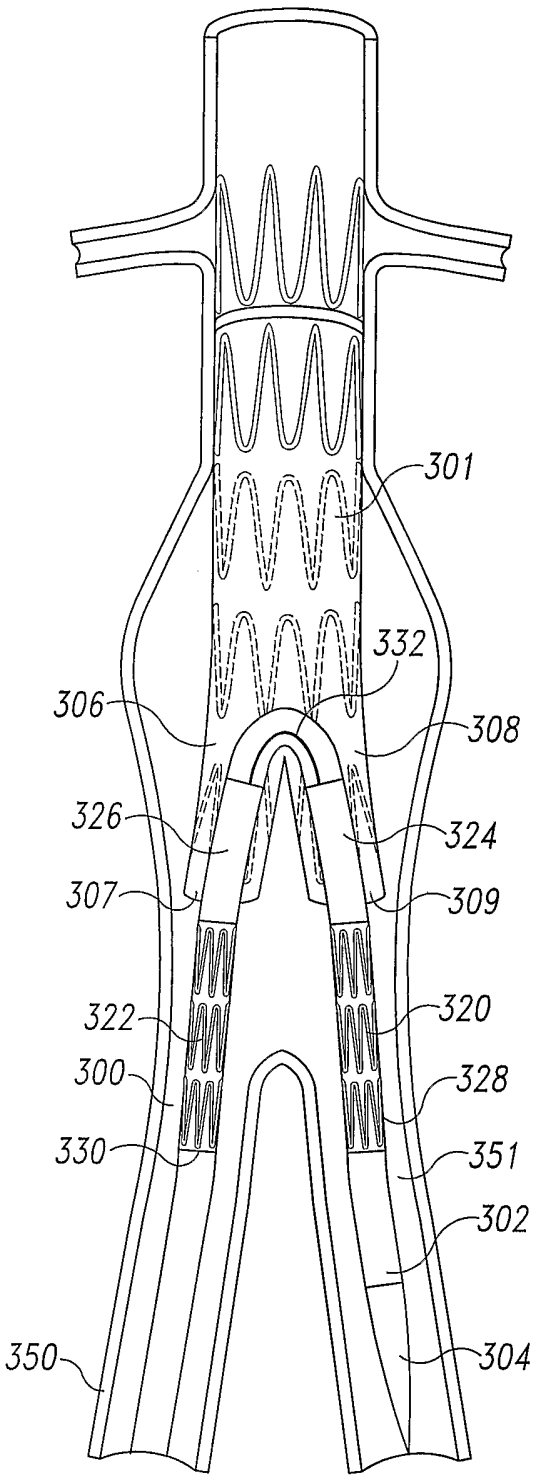

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Fig. 10

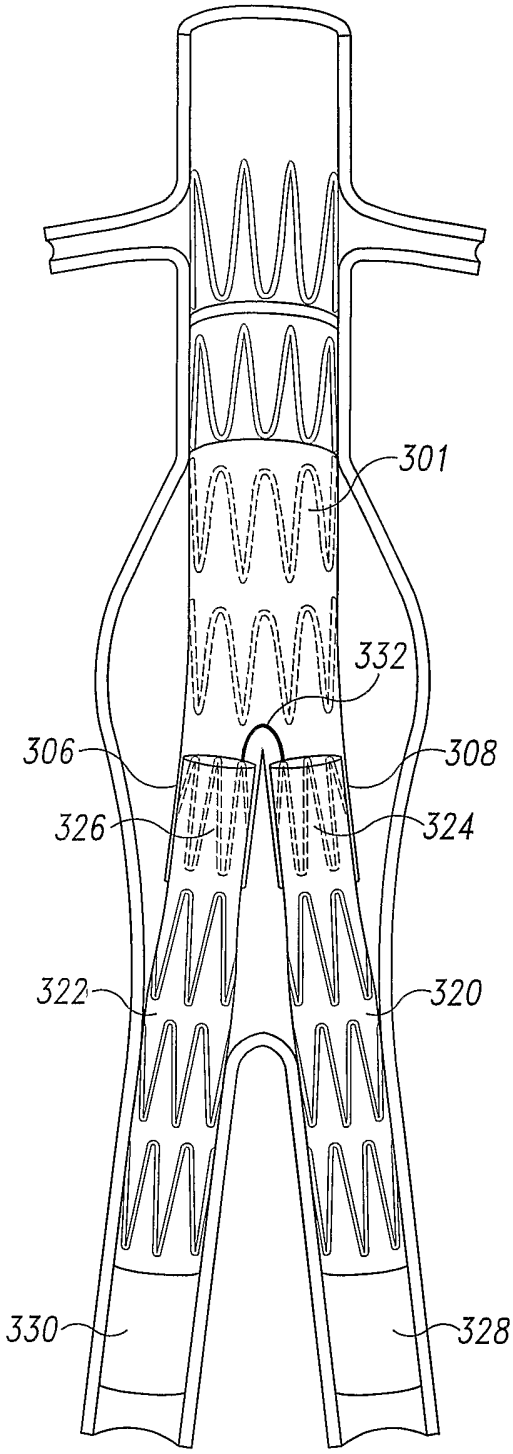


Fig. 11

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US2004/042298

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

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)
IPC 7 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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 2003/149473 A1 (CHOUINARD PAUL F ET AL) 7 August 2003 (2003-08-07) paragraphs '0070! - '0074!; figures 11,12	1-7, 11-15 8-10
X A	EP 0 880 948 A (SCHNEIDER INC) 2 December 1998 (1998-12-02) column 3, line 29 - column 11, line 55; claims; figures	1-7 8-10
P,X	WO 2004/100836 A (COOK INCORPORATED; COOK BIOTECH INCORPORATED; FETTE, CLAY, D; BATES, B) 25 November 2004 (2004-11-25) page 4, line 9 - page 7, line 31	1-3
X	US 2003/158594 A1 (KANG SUNG-GWON ET AL) 21 August 2003 (2003-08-21) paragraphs '0034! - '0050!; claims; figures	1-3

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

[X] Patent family members are listed in 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 document 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

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
3 March 2005	16/03/2005

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, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Serra i Verdaguer, J

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/042298

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	US 2004/210306 A1 (QUIJANO RODOLFO C ET AL) 21 October 2004 (2004-10-21) paragraphs '0049! - '0053!; claims; figure 6	1-4,6
P,X	US 2004/167616 A1 (CAMRUD ALLAN R ET AL) 26 August 2004 (2004-08-26) paragraphs '0087! - '0092!; figures 18-22	1-7
X	US 6 344 056 B1 (DEHDASHTIAN MARK) 5 February 2002 (2002-02-05) column 5, line 57 - column 8, line 31	1-7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/042298

Box 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.: 16-23
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 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 fee, this Authority did not invite payment of any additional fee.

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.

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int bnal Application No
PCT/US2004/042298

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Information on patent family members

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