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(54) SEALABLE ATTACHMENT OF ENDOVASCULAR STENT TO GRAFT

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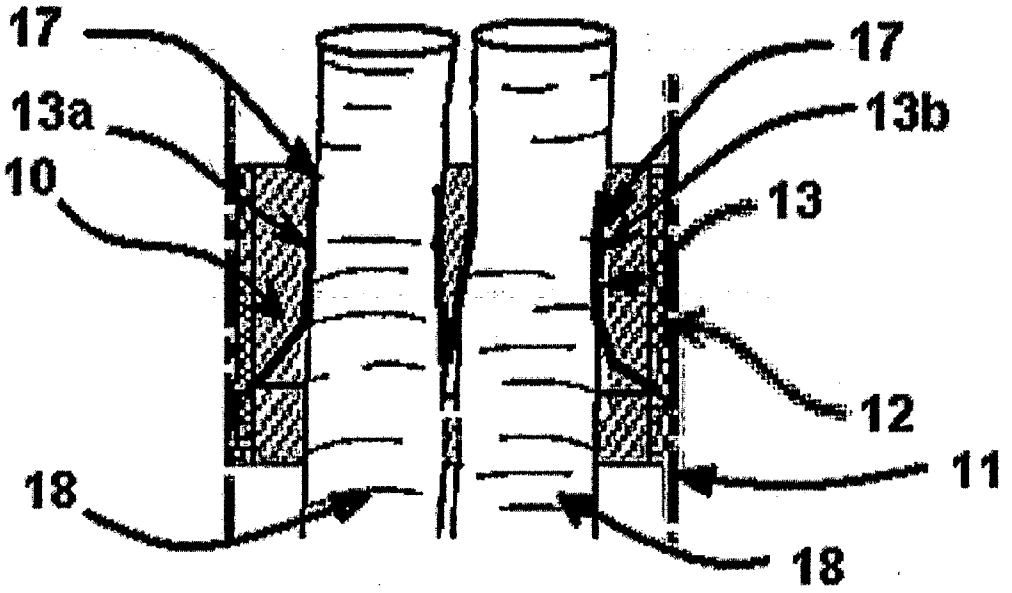
(52) **U.S. Cl.** ..... **623/1.13**

(57) **ABSTRACT**

An endovascular prosthesis of the present invention includes an expandable stent and a means for sealably attaching a tubular graft to the stent within the stent's lumen. The means of sealably attaching a graft includes membranes, foams, polymeric materials and combinations thereof. Additionally, the present invention includes methods of forming an endovascular prosthesis and methods of implanting an endovascular prosthesis within a vessel to provide sealable securement of a tubular graft within the stent's lumen.



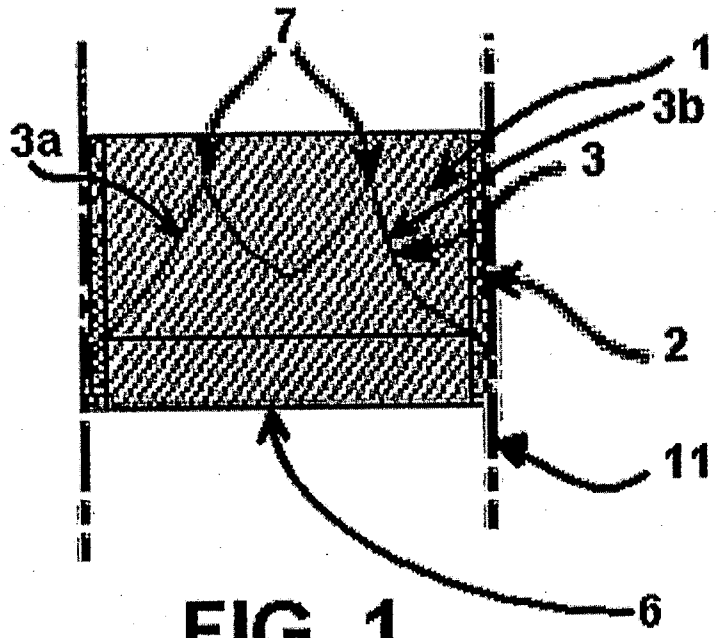



FIG. 1

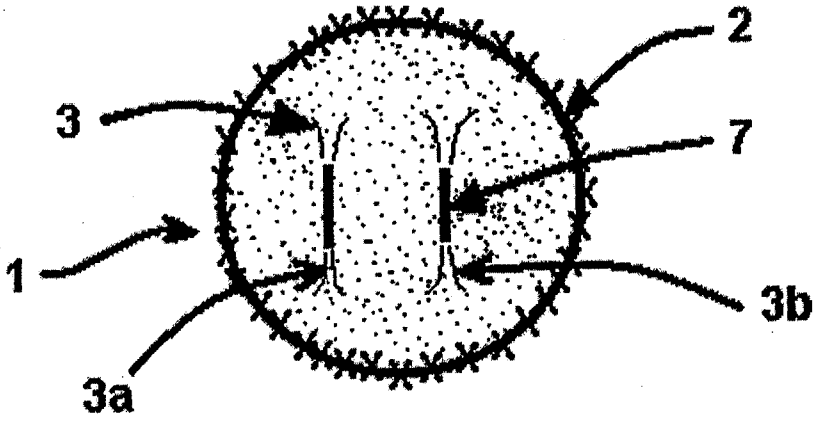
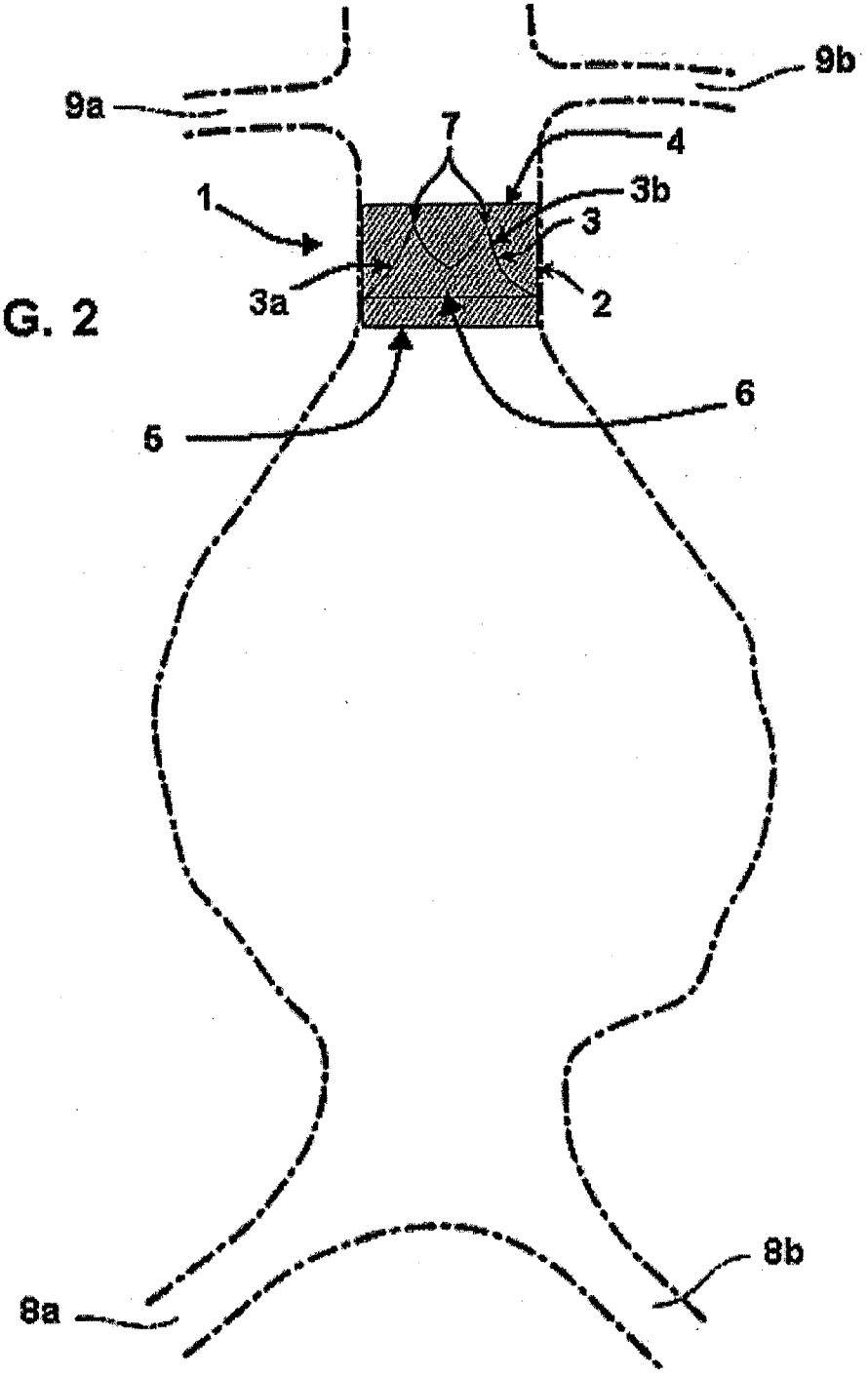



FIG. 3

FIG. 2



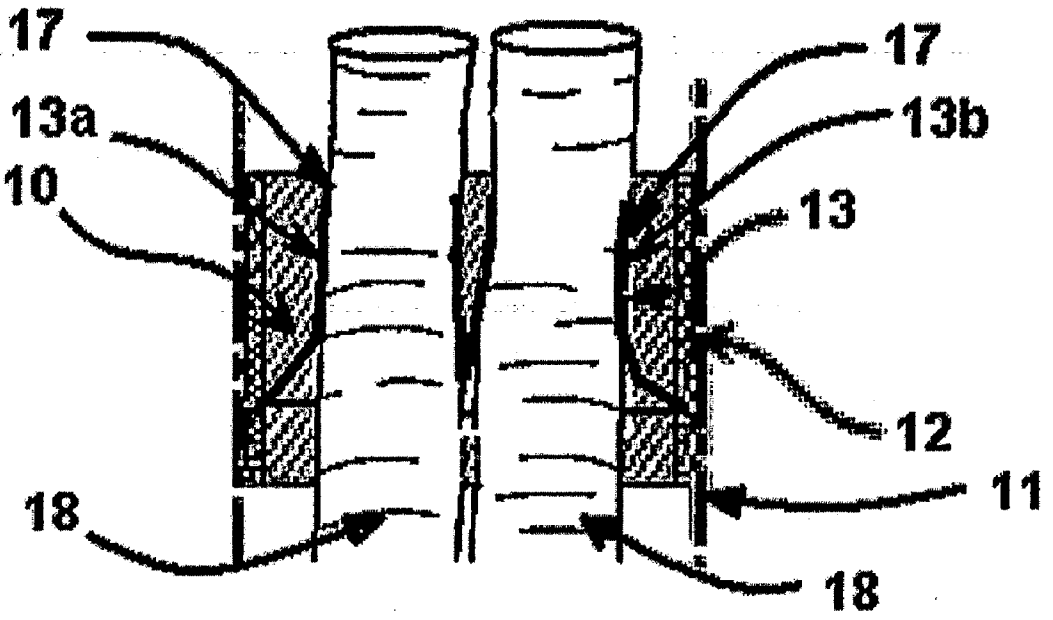



FIG. 4

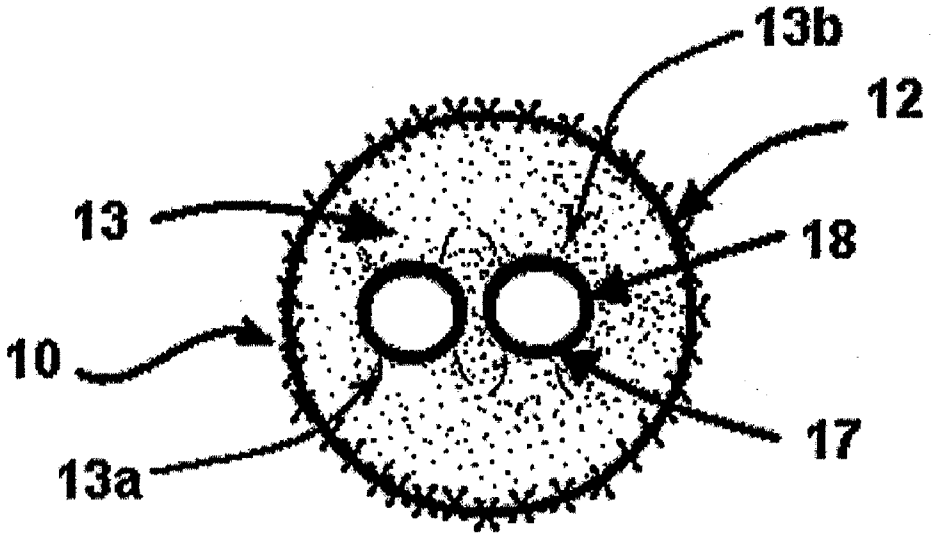
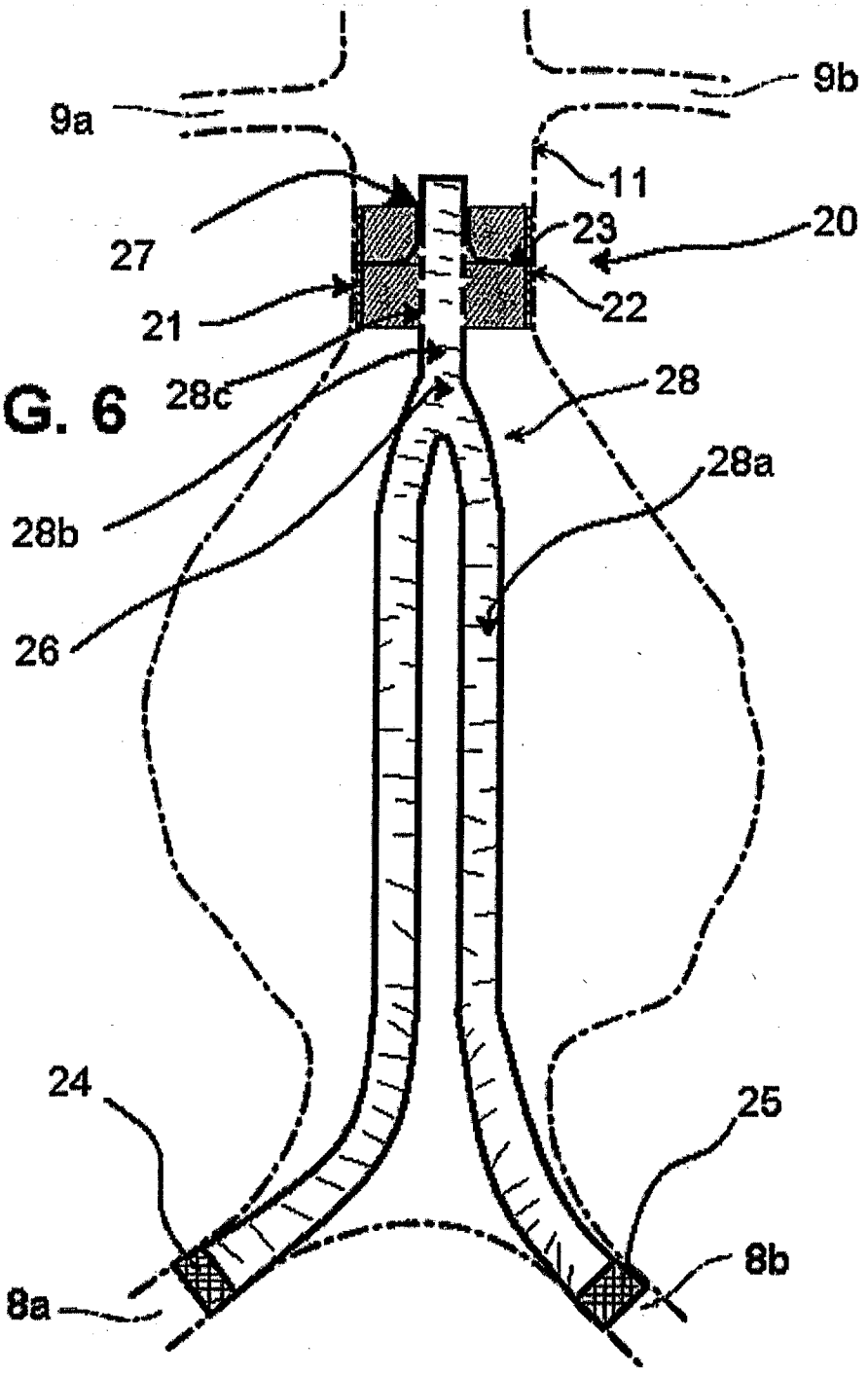



FIG. 5

FIG. 6



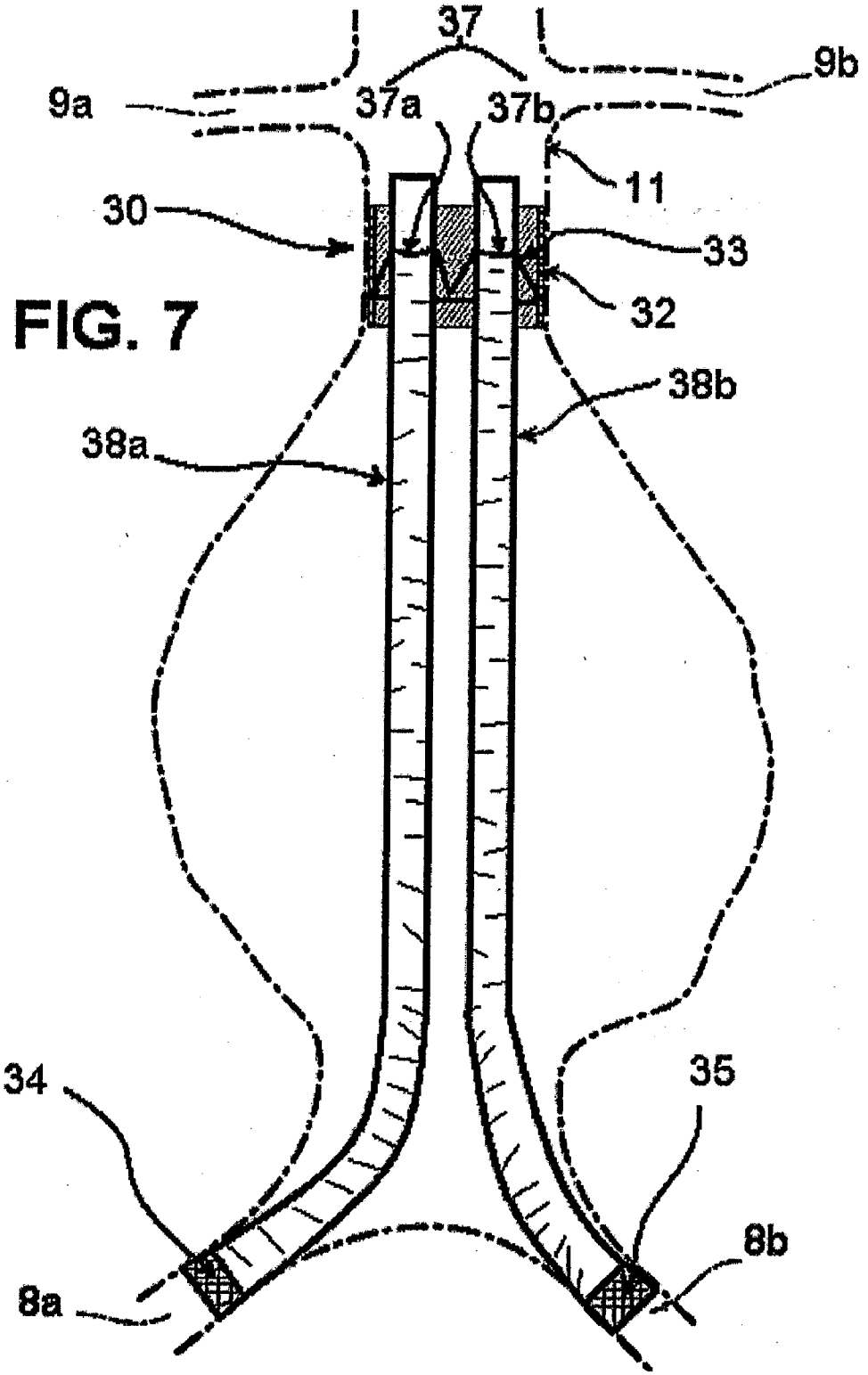
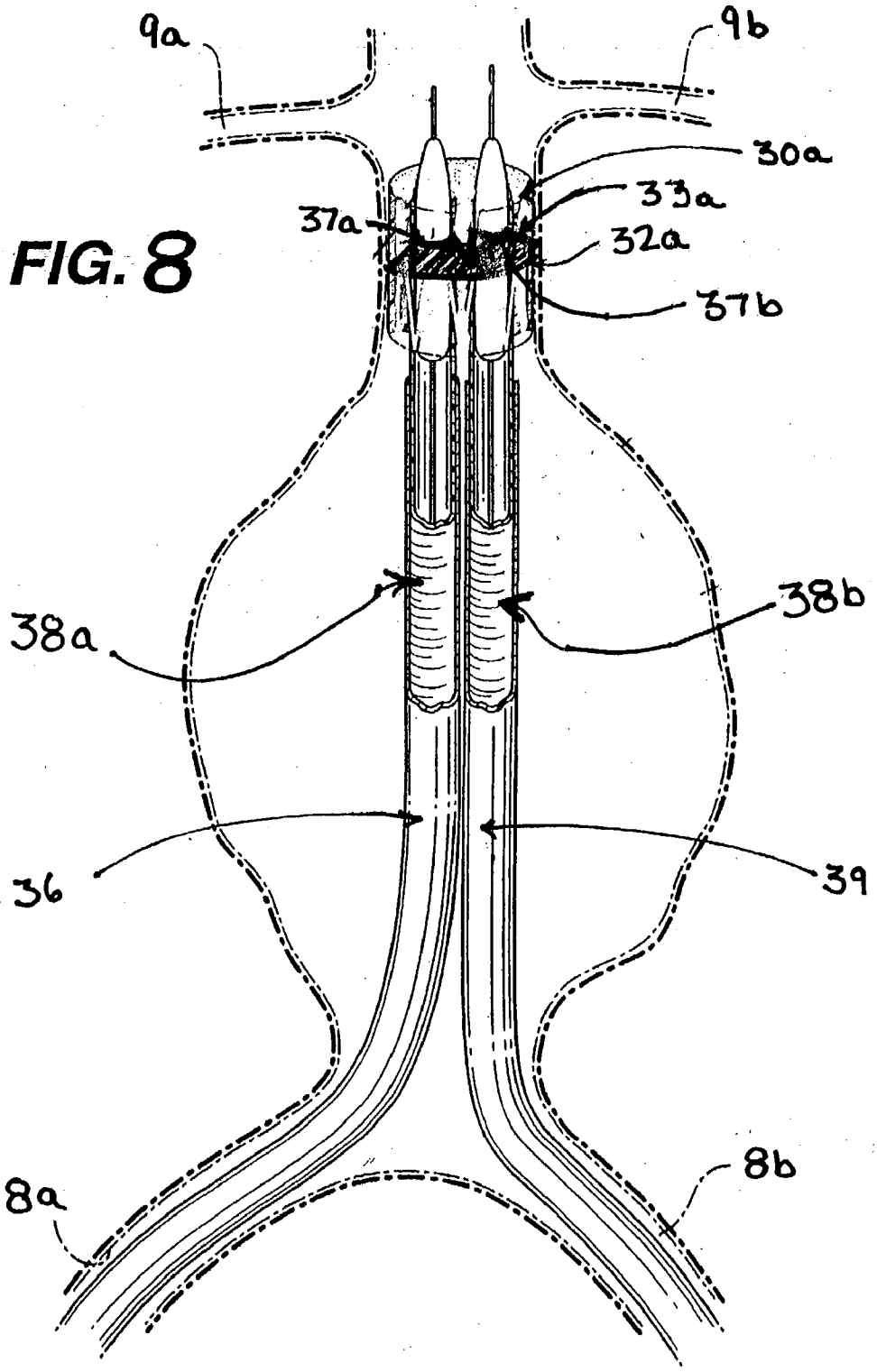



FIG. 7

FIG. 8



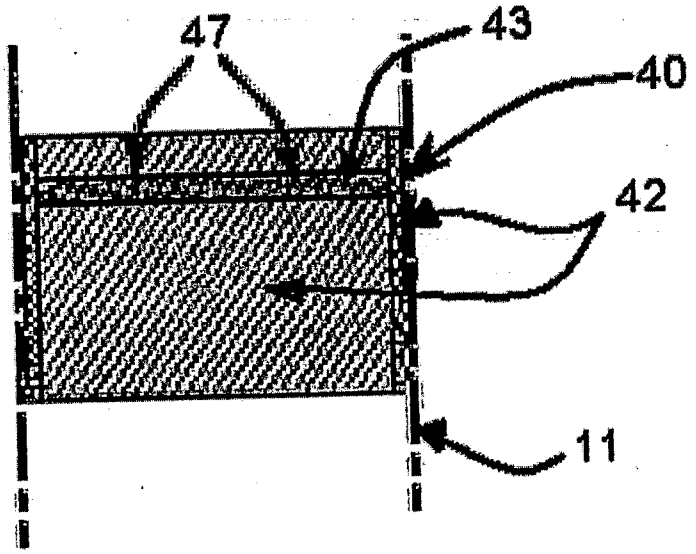



FIG. 9

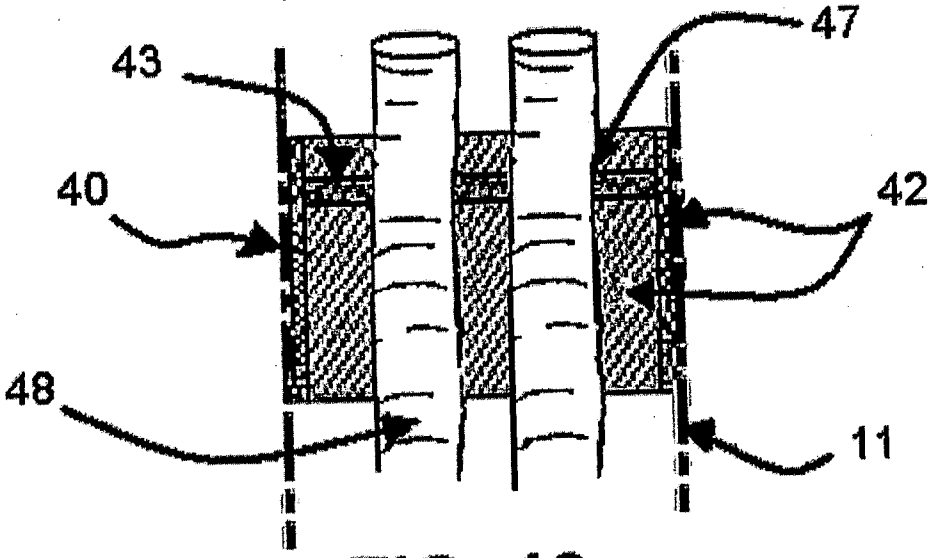



FIG. 10

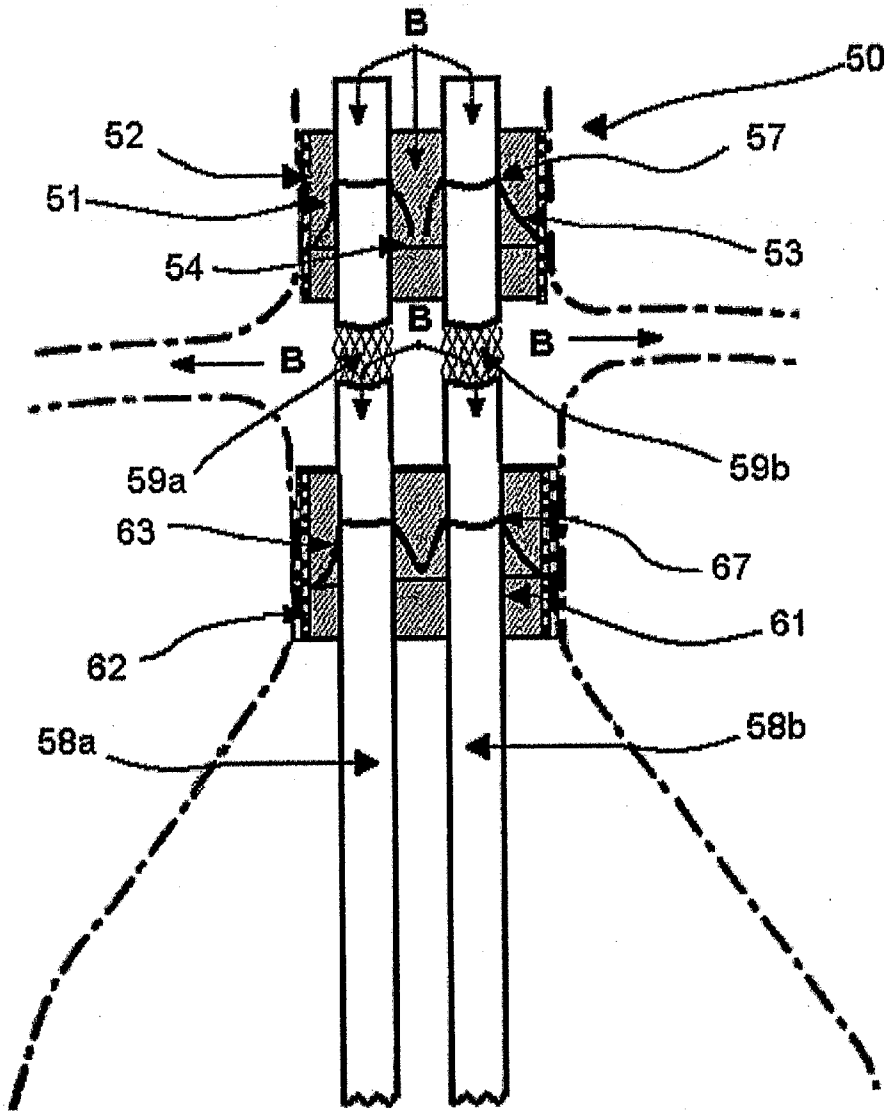



FIG. 11

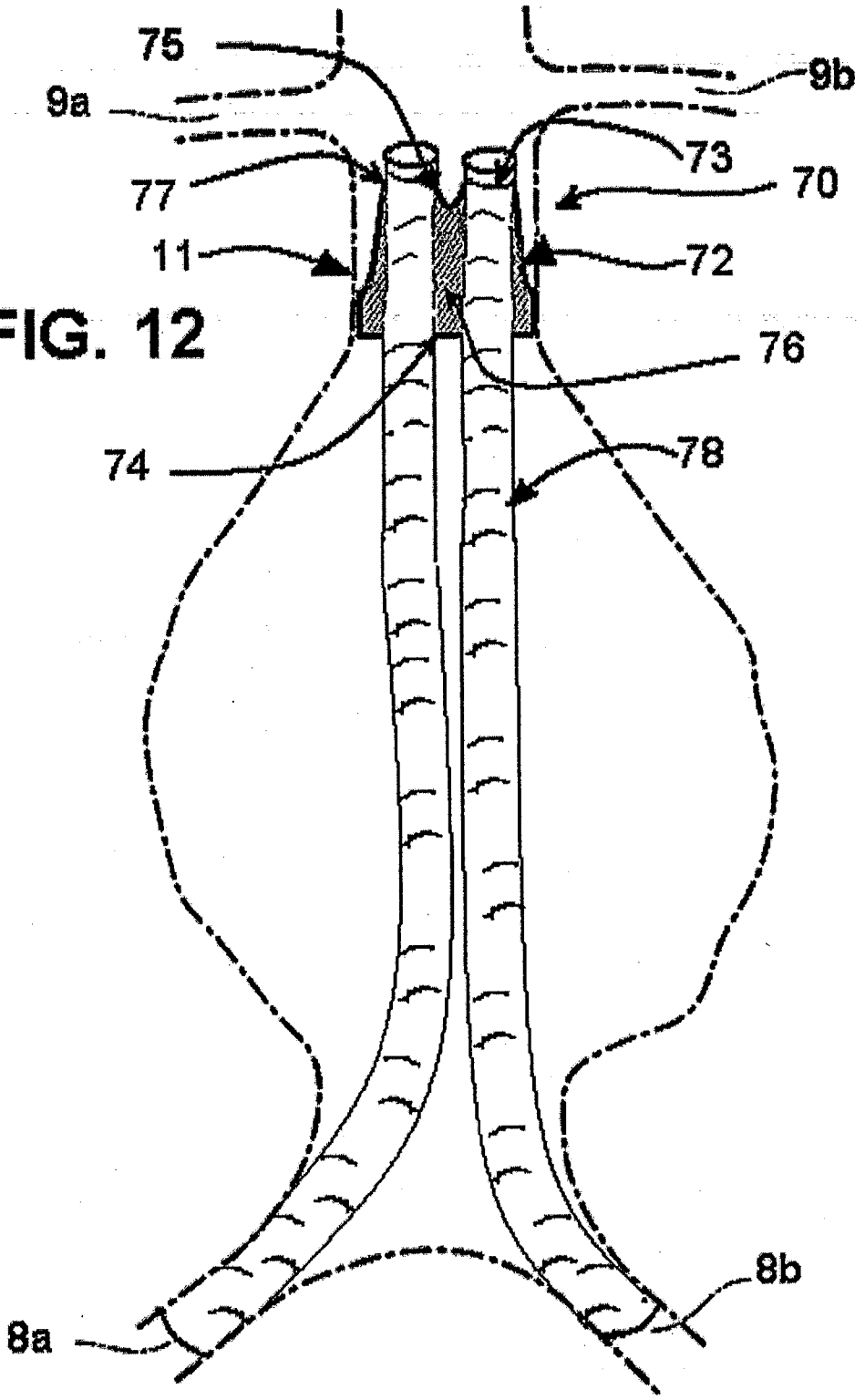



FIG. 12

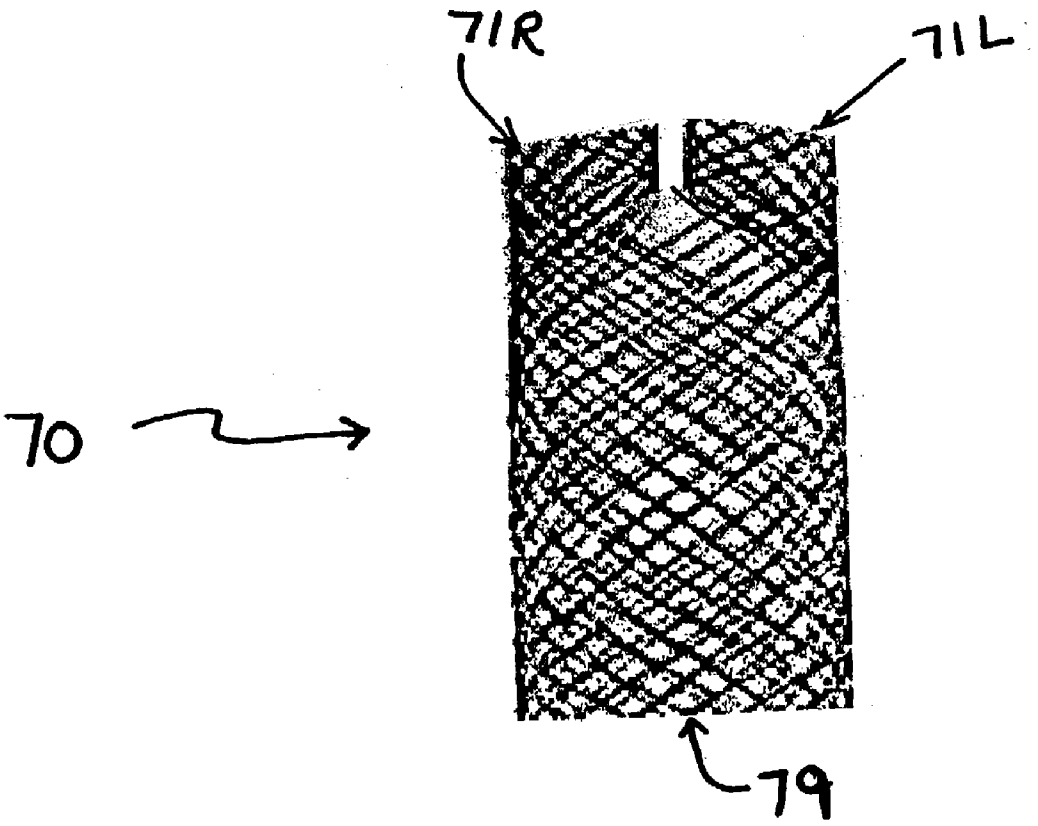



FIG. 13

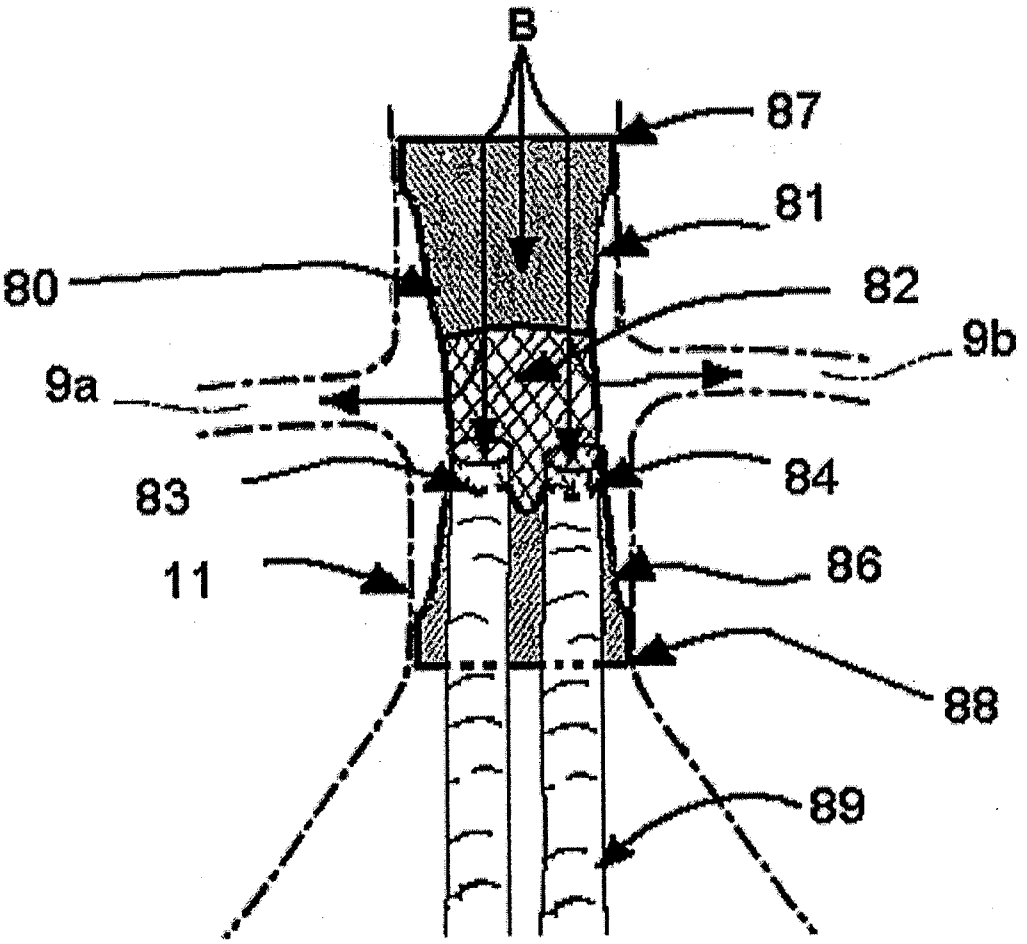



FIG. 14

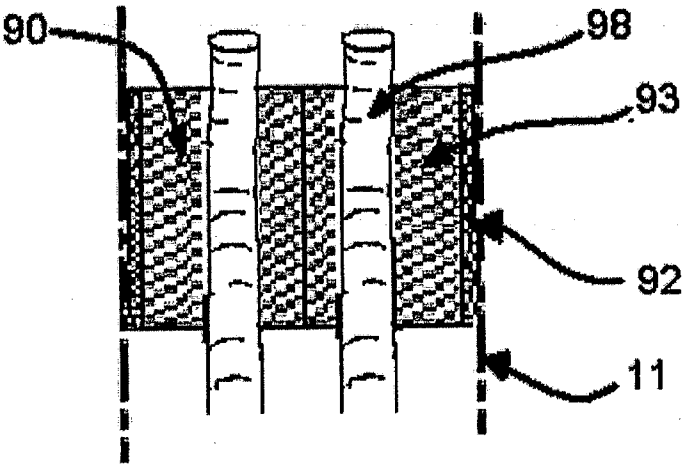



FIG. 15

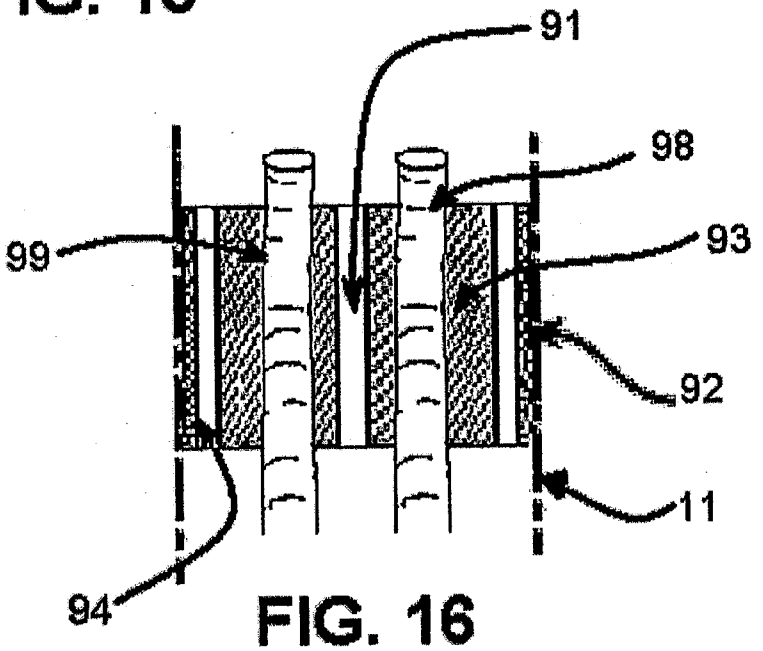



FIG. 16

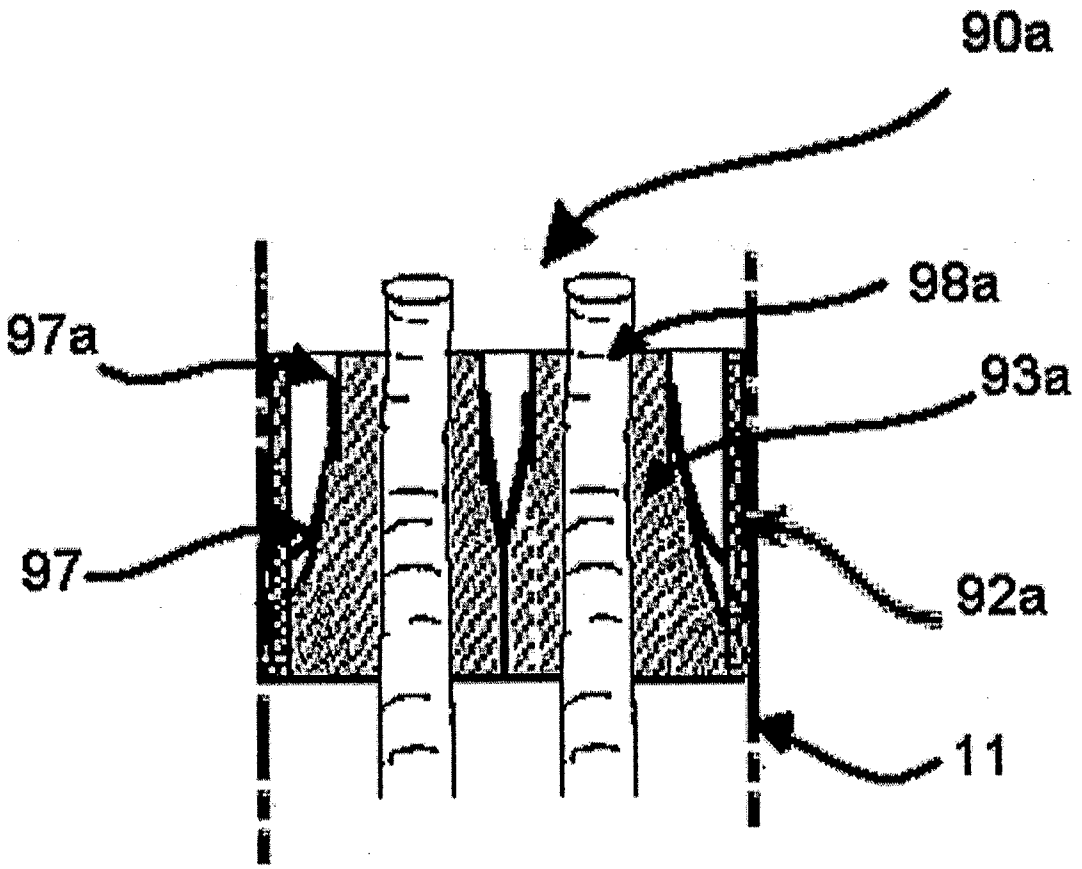



FIG. 17

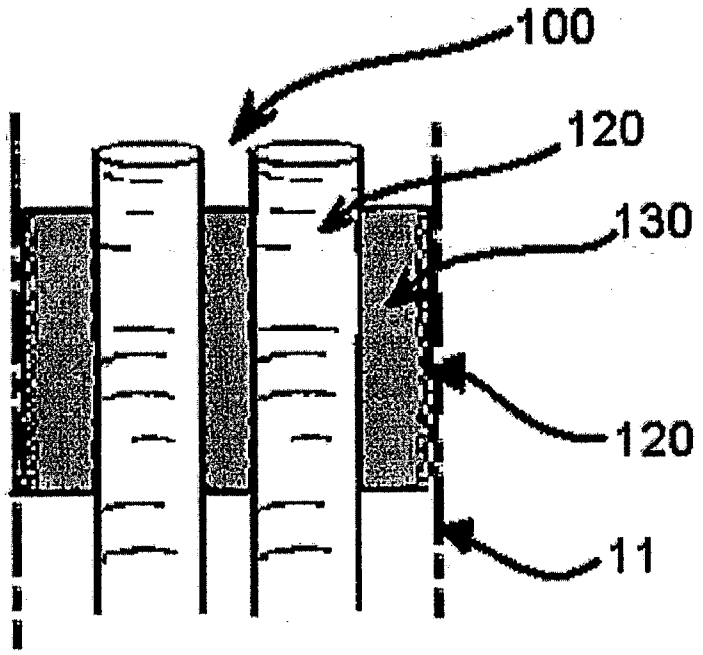



FIG. 18

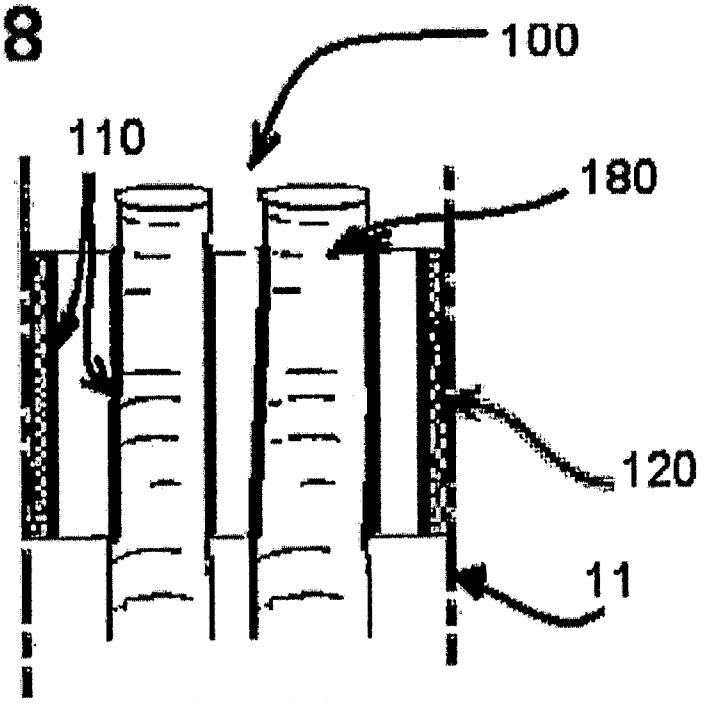



FIG. 19

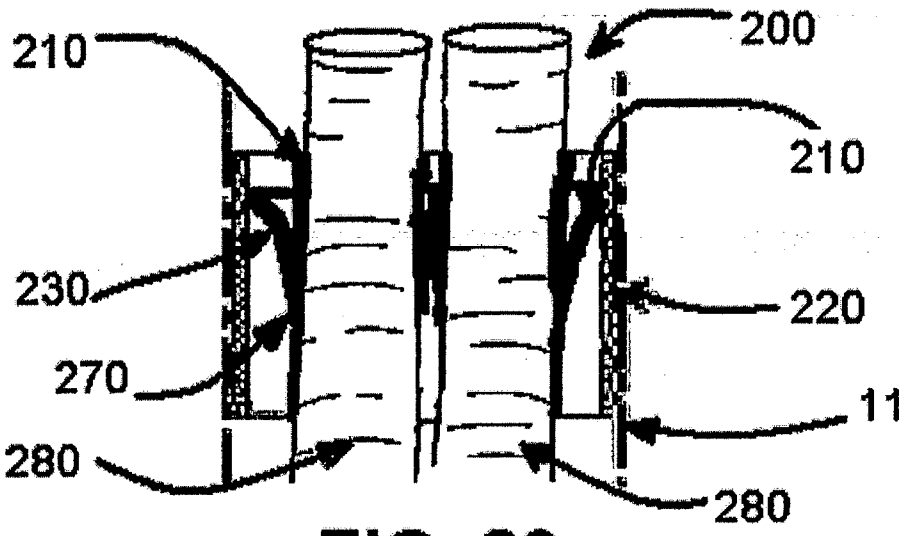



FIG. 20

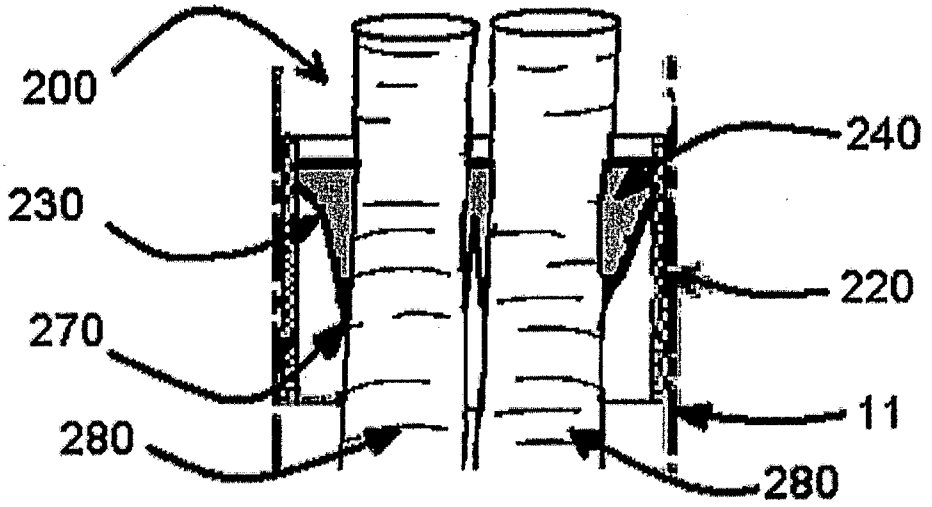



FIG. 21

# SEALABLE ATTACHMENT OF ENDOVASCULAR STENT TO GRAFT

## FIELD OF THE INVENTION

[0001] The present invention relates to an endovascular prosthesis for intraluminal delivery, and a method of implanting the endovascular prosthesis for repairing an aorta. More particularly, the present invention relates to endovascular prosthesis including a stent and a means for sealably attaching a graft thereto for use in a blood vessel or a bifurcated system, such as an abdominal aortic artery where it bifurcates to the common iliac arteries.

## BACKGROUND OF THE INVENTION

[0002] An abdominal aortic aneurysm ("AAA") is an abnormal dilation of the arterial wall of the aorta in the region of the aorta that passes through the abdominal cavity. The condition most commonly results from atherosclerotic disease. Abdominal aortic aneurysms are typically dissecting aneurysms, which are aneurysms that are formed when there is a tear or fissure in the arterial lining or wall through which blood is forced and eventually clots, forming a thrombosis which swells and weakens the vessel. Abdominal aortic aneurysms typically do not cause pain and are easily detected by physical examination. The aneurysm may rupture if it is not detected and treated, causing massive hemorrhaging which is likely to be fatal to the patient.

[0003] Treatment of AAAs typically comprises some form of arterial reconstructive surgery, commonly referred to as a "triple-A" procedure. One such method is bypass surgery, in which an incision is made into the abdominal cavity, the aorta is closed off above and below the site of the aneurysm, the aneurysm is resected, and a synthetic graft or tube sized to approximate the diameter of the normal aorta is sutured to the vessel to replace the aneurysm and to allow blood flow through the aorta to be reestablished.

[0004] Many patients experiencing such AAAs, however, are over 65 years of age and often have other chronic illnesses which increase the risk of pre-operative or post-operative complications. Thus, such patients are not ideal candidates for triple-A procedures. Further, this procedure is generally not performed successfully once an aneurysm has ruptured due to the extensiveness of the surgery and the time required to prepare a patient for surgery. The mortality rate for patient experiencing such ruptured aneurysms is over 65%.

[0005] As a result of the aforementioned disadvantages to conventional surgical methods, minimally invasive techniques have been developed for the repair of AAAs. Such methods involve placement of a stent-graft at the site of the aneurysm by a catheter, known as an introducer, which serves as a deployment device. The stent-graft and its deployment system are typically introduced into the blood stream percutaneously and negotiated by means of a guidewire to the site of the aneurysm where the stent is caused to be radially expanded. Such procedures are desirable as they can be performed using local anesthesia and do not expose the patient to many of the same risks associated with triple-A procedures. But the bifurcated structure and environment of the abdominal aortic and the technology of the prior art stent-grafts continue to be plagued with issues associated with long term stability.

[0006] In such minimally invasive repair procedures, the bifurcated structure of the abdominal aortic arch necessitates the use of a uniquely-structured bifurcated stent-graft. Typically, aneurysms, occlusions or stenoses will occur at the location where the aortic arch bifurcates into the iliac arteries and may also occur at the iliac arteries. The in situ positioning of stent-grafts in this area is more difficult than the positioning of such devices in the lumen of non-bifurcated vessels. As both limbs of a bifurcated stent-graft are inserted and advanced through a single branch of the femoral arterial system, one of the limbs of the stent-graft must ultimately be pulled or drawn into the contralateral branch so that the stent-graft is suitably positioned across both the aortic aneurysm and the associated common iliac aneurysms to supply circulation to each of the lower limbs.

[0007] Bifurcated stent-grafts are frequently too bulky to advance through a single iliac artery, particularly in view of the fact that the limb for the contralateral branch of the stent-graft must be inserted together with the limb of the ipsilateral branch. Additionally, care must be taken to not twist or kink the stent-graft as it is placed in the contralateral artery. The caudal portion of the graft must not stretch across the mouth of the internal iliac artery which would result in inadvertent occlusion of that artery. The procedure of drawing one limb of the stent-graft from one femoral artery to the contralateral femoral artery requires placement of a cross-femoral catheter using a closable wire basket prior to insertion of the stent-graft.

[0008] This procedure requires significant and skillful wire catheter manipulation, frequently within the aneurysmal cavity. As such, care must be taken to avoid disturbing or dislodging thrombic or embolic material from within the aneurysmal sac. Additional factors such as the severe tortuosity of the iliac arteries and the marked angulation of the aortoiliac junction resulting from the tendency of the abdominal aortic artery to extend caudally during aneurysm formation combine to make deployment of endoluminal bifurcated grafts time consuming and at increased risk of procedural complications and failure.

[0009] To overcome the aforementioned risks associated with the use of one-piece stent-grafts in the repair of aneurysms occurring in bifurcated vessels, two component bifurcated designs have been developed which may be assembled in situ. The first component consists of the upper trunk, which is positioned just below the renals, a stump, and an iliac limb. The second component is then deployed into the stump, connecting the device to the contralateral iliac limb. These devices have had a number of issues, which include fabric wear, kinking, and endoleaks at the upper neck and at the stump junction; in addition, some have proven to be difficult to manufacture, not secure to vessel wall, or difficult to assemble in situ.

[0010] The main reason for lack of success with endoluminal repair focuses around the fact that the vascular system in general, and more apparent in an aneurysm sac is the morphology continues to change. The morphological environment leads to unexpected and unanticipated stress which is placed on the stent-grafts used to treat the disease. Such wearing and endoleaking necessitates the repair of these devices, requiring additional surgical procedures which may include replacement of the device. Consequently, there is a

continuing need for the development of stents with attached grafts and techniques useful for the repair of aneurysms in general, and AAAs.

## SUMMARY OF THE INVENTION

[0011] In view of the foregoing, it is an object of the present invention to provide an endovascular prosthesis and method of implanting the prosthesis into a vessel that provides a means for sealably attaching a tubular graft within the endovascular prosthesis. Additionally, the present invention provides for a prosthesis that is flexible and durable to adjust to the morphological environment and is able to assemble in situ.

[0012] The present invention includes an endovascular prosthesis including an expandable stent having an inner lumen, and a means for sealably attaching a tubular graft within the lumen of the stent. The means of sealably attaching a graft includes membranes, foams, polymeric materials and combinations thereof.

[0013] Another embodiment of the present invention, there is provided an endovascular prosthesis including an expandable stent and a membrane supported by the stent and extending across the lumen. The membrane further including a graft receiving member for sealably receiving at least one tubular graft therethrough.

[0014] The present invention further provides an endovascular prosthesis as above-described and the membrane further including an electrostatically spun material having a graft receiving opening for sealably receiving at least one tubular graft therethrough.

[0015] An embodiment of the present invention, there is provided a bifurcated endovascular prosthesis including a first prosthetic component and a second component. The first component is similar to those described-above including a stent, a membrane extending transversely across the inner lumen of the stent and attached thereto. The membrane additionally having an opening. The second prosthetic component being extended through the opening in a substantially fluid tight seal. The second component further including one or more grafts.

[0016] A further embodiment of the present invention, there is provided a multi-component endovascular prosthetic system including two prosthesis and a tubular graft. Each prosthesis including an expandable stent and a membrane extending transversely across the inner lumen and attached to the stent. Each membrane further having a graft receiving opening. The tubular graft being extended sealably through a graft receiving opening of each prosthesis for directing fluid through the tubular graft.

[0017] Another embodiment of the present invention, there is provided an endovascular prosthesis including a stent having an inner lumen, a distal end and a proximal end, the distal end having an opening, and the proximal end having two openings opposing the distal opening; and a puncturable membrane extending across each of the proximal end openings.

[0018] Another aspect of the present invention, there is provided an endovascular prosthesis including an expandable stent, a first graft and a second graft. The expandable stent has a distal end and a proximal end, and an opening extending therethrough. The first graft being attached to the distal end of the stent within the opening, and having an inner lumen extending therethrough. The second graft being attached to the proximal end of the stent within the opening and spaced from the first graft. The second graft having at least two inner lumens extending therethrough and a membrane extending transversely across each of the inner lumens of the second graft.

[0019] Another embodiment of the present invention, there is provided an endovascular prosthetic assembly including an expandable stent and a tubular graft inserted within the inner lumen of the stent. The graft having an expanded foam attached to the exterior surface of the graft. The expandable foam sealably securing the tubular graft to the stent.

[0020] One aspect of the present invention, there is provided a kit of parts for assembly into an endovascular prosthetic system. The kit including an expandable stent for insertion into a body endovascularly; a tubular graft adapted to be inserted within the stent, the tubular graft having an interior surface for body fluid flow and an exterior surface; and an expandable foam on the exterior surface of the tubular graft. The expandable foam being adapted to expand within the stent to sealably secure the tubular graft to the stent.

[0021] A further embodiment of the present invention, there is provided an endovascular prosthetic assembly including a stent, a tubular graft extending into the stent and a polymeric material sealably supporting the tubular graft to the stent.

[0022] Another aspect of the present invention there is provided, a kit of parts for assembly into an endovascular prosthetic system. The kit including a stent having a primary reactive material being disposed on the inner surface of the stent; a tubular graft adapted to extend within the inner lumen, the graft having the primary material being disposed on the exterior surface; and a secondary material reactive with the primary material. The second material being adapted to be applied to the primary material upon insertion of the graft within the inner lumen, the secondary material being reactive with the primary material to form a seal between the graft and the stent.

[0023] A further aspect of the present invention there is provided methods of forming and methods of implanting the various endovascular prosthesis of the present invention within a vessel.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0024] **FIG. 1** is an enlarged plan view of the endovascular prosthesis of the present invention including a stent and attached membrane having graft receiving members.

[0025] **FIG. 2** is a plan view of an endovascular prosthesis of **FIG. 1** implanted in abdominal aorta.

[0026] **FIG. 3** is a top view of the endovascular prosthesis of **FIG. 1** showing the graft receiving members.

[0027] **FIG. 4** shows the endovascular prosthesis of **FIG. 1** further including grafts.

[0028] **FIG. 5** is a top view of the endovascular prosthesis of **FIG. 3** including grafts therethrough.

[0029] **FIG. 6** shows the bifurcated endovascular prosthesis of **FIG. 2** including a branched graft.

[0030] **FIG. 7** shows the endovascular prosthesis of **FIG. 2** including tubular prosthesis for a bifurcated system.

[0031] **FIG. 8** shows the endovascular prosthesis of **FIG. 7** showing a deployment of tubular prosthesis for a bifurcated system.

[0032] **FIG. 9** is a plan view of an endovascular prosthesis of the present invention showing a stent and a membrane.

[0033] **FIG. 10** shows the endovascular prosthesis of **FIG. 9** further including tubular graft.

[0034] **FIG. 11** shows a multi-component endovascular prosthetic system of the present invention.

[0035] **FIG. 12** shows an endovascular prosthesis of the present invention combined with tubular grafts.

[0036] **FIG. 13** is an enlarged plan view of an endovascular prosthesis of **FIG. 12** including a stent and attached membrane.

[0037] **FIG. 14** is a plan view of an endovascular prosthesis of the present invention showing a stent, grafts and membranes in combination with tubular grafts.

[0038] **FIG. 15** is a plan view of the endovascular prosthesis system of the present invention showing the expandable foam in the expanded state.

[0039] **FIG. 16** shows the endovascular prosthetic assembly of **FIG. 15** showing the expandable foam.

[0040] **FIG. 17** is a plan view of an endovascular prosthesis of the present invention showing a stent having an attached membrane in combination with an expandable foam.

[0041] **FIG. 18** is a plan view of an endovascular prosthetic system of the present invention showing a polymeric material sealably supporting a tubular graft to a stent.

[0042] **FIG. 19** shows the endovascular prosthetic system of **FIG. 18** showing a primary reactive material on a graft and stent.

[0043] **FIG. 20** is a plan view of an endovascular prosthesis of the present invention showing primary material on the membrane and grafts.

[0044] **FIG. 21** shows the endovascular prosthesis of **FIG. 20** showing the polymeric material sealably securing the tubular graft to a membrane.

## DETAILED DESCRIPTION OF THE INVENTION

[0045] The present invention relates to an endovascular prosthesis for intraluminal delivery, as shown in **FIGS. 1-21**. The prosthesis is particularly suited for use as a vascular prosthesis. The prosthesis of the present invention overcomes the aforementioned problems of the prior art including leaking and wearing between a tubular prosthesis and a stent. Additionally, the prosthesis of the present invention provides flexibility to adapt to the morphology of the vascular environment. The prosthesis of the present invention includes minimal components to provide for a simple assembly in situ.

[0046] One embodiment of the present invention is a prosthesis **1** as shown in **FIG. 1-3**. The prosthesis **1** is a generally tubular structure which includes a stent **2** and a membrane **3**.

[0047] The stent **2** of the present invention is similar to those known in the art. The stent **2** can be open-celled or porous which is in direct contact with the aortic wall. This permits ingrowth of cells for the stabilization of implanted endoprosthesis, and device fixation. The stent may further be coated with various materials as known in the art to encourage cell growth therethrough. In addition, the stent **2** may incorporate a covering, or a graft composite (not shown) to prevent blood flow therethrough. The stent **2** may be covered or coated on the stent's exterior, interior or both depending on the application.

[0048] As is known in the art, a stent has two diameters, the compressed diameter and the expanded diameter wherein the compressed diameter is substantially smaller than the expanded diameter. The compressed diameter of a stent varies depending on the materials of construction and structure of a stent. In general, the compressed diameter must be small enough to allow for implantation through the vasculature via a minimally invasive deployment system (not shown). The expanded diameter needs to be substantially the same diameter-as the vasculature in which it is to replace or repair. The expanded diameter needs to be large enough to allow a stent to sufficiently secure to the aortic wall without acting as a driving force to expand or dilate the vessel.

[0049] Various stent types and stent constructions may be employed in the invention. Stents may be capable of radially contracting, as well, and in this sense can best be described as radially distensible, deformable or conformable. Stents may be balloon expandable or self-expandable. Balloon expanding stents include those that are radially expanded by an applied force. Self-expanding stents include those that have a spring-like action which causes the stent to radially expand, or stents which expand due to the pre-set memory properties of the stent material for a particular configuration at a certain temperature range. Nitinol is one material which has the ability to perform well while both in spring-like elastic mode, as well as in a memory mode based on temperature. Other materials are of course contemplated, such as stainless steel, tantalum, platinum, gold, titanium and other bicompatible metals, as well as shape memory polymers or polymeric based stents, or indeed composites of the aforementioned.

[0050] The configuration of a stent may also be chosen from a host of geometries. For example, wire stents can be fastened into a continuous helical pattern, with or without a wave-like or zig-zag in the wire, to form a radially deformable stent. Individual rings or circular members can be linked together such as by struts, sutures, welding, interlacing or locking of the rings to form a tubular stent structure. Tubular stents useful in the present invention also include those formed by etching or cutting a pattern from a tube. Such stents are often referred to as slotted stents. Furthermore, stents may be formed by etching a pattern into a material or mold and depositing stent material in the pattern, such as by chemical vapor deposition or the like.

[0051] As shown in **FIGS. 1 and 2**, stent **2** has a pair of spaced apart ends, a distal end **4**, and a proximal end **5**, and

a tubular wall structure therebetween. The tubular wall structure has an external surface and an internal surface which defines the inner lumen **6** of stent **2**. The membrane **3** is supported by stent **2** and extends across the inner lumen **6** of stent **2**. The membrane **3** has one or more graft receiving members **7** for sealably receiving at least one tubular graft therethrough. The graft receiving member **7** is defined as a weakened section, a slit, a hole, a penetrable material, a punchout, a puncture, a valve and the like.

[**0052**] Generally, membrane **3** is impermeable to blood, but the membrane material can be permeable to blood and coated to be or become impermeable in situ. Membrane **3** may be made from a variety of well known materials, provided they have the requisite strength characteristics and biocompatibility properties. Membrane **3** is made from a flexible and compressible material. In addition, membrane **3** may be synthetic or natural. Examples of such materials are polymers, elastomers, rubbers, waxes, silicone, parylene, polyurethane, vinyl polycaprolactone, (TEFLON) polytetrafluoroethylene, polypropylene, polyethylene, DACRON, allograph, zeno-graph material, latex, as well as composites of the aforementioned. Examples of commercially available materials are Corethane (Corvita); Carbothane (Thermedics); Silastic, Pellethane, and Parylene (Specialty Coating Systems). The material can be extruded, knitted, woven, or electrostatically spun material.

[**0053**] Additionally, membrane **3** can be coated or impregnated with bio-erodible, biodegradable or degradable material such as polymers, albumin, collagen, heparin or similar coating material. The membrane could have a coating of a biologically inert material, such as PTFE, or porous polyurethane. The coating can be added to the membrane by methods known in the art such as dipping, spraying or vapor disposition on the material.

[**0054**] The thickness of membrane **3** can vary depending on the application and the material of construction of membrane **3**. Generally, the thickness of the membrane is less than the distance between distal end **4** and proximal end **5** of the stent **2**. Therefore, some part of stent **2** extends above and/or below membrane **3**. For example, in a vascular application membrane **3** can range from 0.001 mm-0.6 mm, preferably 0.1 mm-0.4 mm.

[**0055**] Membrane **3** may be a planar surface or a variety of shapes depending on the application. Membrane **3** can be shaped to assist in bonding membrane **3** to stent **2** and/or to provide sealable securement of a tubular graft to membrane **3**. For example, **FIG. 1** shows membrane **3** having a peak formation **3***a* and **3***b*, having the graft receiving member located at the top of the peak formation **3***a* and **3***b*. The peak formation **3***a* and **3***b* assist in sealing between a tubular graft and membrane **3** by providing more surface area contact between the two surfaces, shown in **FIG. 5** as peak formation **13***a* and **13***b* and tubular graft **18**. A cup-shape, or sock-shape membrane assists in attaching the membrane within the stent lumen by providing more surface area for the membrane to bond to a stent.

[**0056**] **FIGS. 1 and 3** show membrane **3** attached to and supported by inner lumen **6** of the stent **2**. Membrane **3** can be attached to stent **2** by adhesive bonding, such as silicone or polyurethane; mechanical attachment, such as sutures or staples; thermal bonding, laminate; or chemical bonding. In addition, the inner surface of stent **2** may be coated with an elastomer or polymer and a solvent may be used to bond the coated inner surface to the membrane. Membrane **3** can be positioned across inner lumen **6** of stent **2** at any location along stent **2** such as across the distal end **4**, the proximal end **5** or there between of stent **2**.

[**0057**] As shown in **FIG. 1-3**, the membrane **3** extends transversely across the inner lumen of stent **2** with a peak formation **3***a* and **3***b* located centrally in the membrane **3**. A graft receiving member **7** is located at the top of each peak formation **3***a* and **3***b*. **FIG. 2** shows the peak formation **3***a* and **3***b* directed in the cephalic direction, but it can be appreciated that the peak formation **3***a* and **3***b* can be inverted such that the top of the peak is directed toward the caudal direction, depending on the desired application. In addition to assisting in sealing a tubular graft to the membrane **3**, the peak formation **3***a* and **3***b* acts as a check valve allowing fluid to flow in one direction across membrane **3**, and closes upon no flow of fluid in that direction. Additionally, the peak formation **3***a* and **3***b* prevents back flow of fluid in the opposite direction through membrane **3**.

[**0058**] The prosthesis of the present invention as described above may be used in combination with one or more grafts. As shown in **FIGS. 4 and 5**, prosthesis **10** is similar to prosthesis **1** of **FIG. 1**, further including graft **18** extending sealably through graft receiving member **17**. The membrane **13** material of the peak formation **13***a* and **13***b* conforms around graft **18** and becomes coextensive with a portion of graft **18** securing graft **18** in a sealable manner. The flow of blood through graft **18** applies outward radial pressure to the graft **18** against membrane **13**, more specifically peak formation **13***a* and **13***b*. Membrane **13** provides an opposing force against graft **18** provided by the membrane's **13** securement to stent **12** restricting its movement and, additionally, the restricted access of the graft **18** through the graft receiving member **17** of membrane **13**. These opposing forces create a seal between graft **18** and membrane **13**. It can be appreciated that one or more peaks may be formed in membrane **13** material depending on the application.

[**0059**] Any known graft material, or tubular prosthesis, and structure may be used to form the graft of the present invention. The graft preferably has generally a tubular configuration. The graft may be made from a variety of well known materials, provided they have the requisite strength characteristics and biocompatibility properties. Examples of such materials are polyester, polypropylene, polyethylene, polytetrafluoroethylene, expanded polytetrafluoroethylene and polyurethane, DACRON, TEFLON (polytetrafluoroethylene), and PTFE coated DACRON as well as composites of the aforementioned. The material can be extruded, woven or knitted, warp or weft knitted. The graft can also be coated or impregnated with a bio-erodible, or degradable material, such as albumin, collagen, heparin or similar coating material. Additionally, the graft could have a coating of a biologically inert material, such as porous polyurethane.

[**0060**] In general, the diameter of graft **18** varies depending on the application but generally at least a portion of graft **18** (or grafts, if multiple grafts used) should be substantially the same diameter as the graft receiving member **17**. Generally, the diameter of graft **18** should be large enough to allow for unobstructed blood flow and prevent retrograde pressure build-up in the blood flow while maintaining sufficient traction against membrane **13** for long-term fixation.

While cylindrical tubular configurations are shown, other tubular configurations may be employed.

[0061] Another embodiment of the present invention is a bifurcated prosthesis **20** as shown in **FIG. 6**. **FIG. 6** shows a first prosthetic component **21** similar to the prosthesis **1** of **FIG. 1** including an expandable stent **22** and a membrane **23** extending transversely across the inner lumen of and attached to the stent **22**. Membrane **23** has one or more graft receiving openings **27** or members. The bifurcated prosthesis **20** further includes a second component **26** including a branched graft **28**. In one embodiment branched graft **28** has an inverted "Y" shape having two leg portions, **28***a* and **28***b*, converging into one trunk portion **28***c*. The trunk portion **28***c* extends into graft receiving member **27** of the membrane **17** creating a substantially fluid tight seal between the outer surface of graft **28** and membrane **23**. The two leg portions, **28***a* and **28***b*, extend into each iliac artery **8** (**8***a* and **8***b*). The leg portions (**28***a* and **28***b*) remain in place by the pressure from the blood flowing therethrough and forcing the leg portions (**28***a* and **28***b*) into each iliac artery **8** (**8***a* and **8***b*). Additional anchoring stents **24** and **25** can be used in combination with the leg portions (**28***a* and **28***b*), as shown in **FIG. 6**, to provide additional securement of graft **17** to the iliac artery wall.

[0062] Another bifurcated embodiment of the present invention is shown in **FIG. 7** which is similar to the above described bifurcated prosthesis **20** of **FIG. 6** including a stent **32**, a membrane **33** extending transversely across the inner lumen of stent **32**, graft receiving members **37** and grafts **38**. However, the bifurcated prosthesis **30** of **FIG. 7** includes two separate graft **38** (**38***a* and **38***b*) instead of the branched graft **28** of **FIG. 6**. As shown in **FIG. 7**, grafts **38** extends into separate graft receiving members **37** (**37***a* and **37***b*) and form a substantially fluid tight seal between grafts **38** and membrane **33**. Additional anchoring stents **34** and **35** can be added for securing grafts **38** to the iliac vessel wall (**8***a* and **8***b*).

[0063] Another embodiment of the present invention is shown in **FIGS. 9 and 10** which is similar to the prosthesis **1** of **FIG. 1** including an expandable stent **42** and a membrane **43** attached to stent **42** and extending transversely across the lumen of stent **42**. Membrane **43** of **FIG. 9** includes electrostatically spun material. **FIG. 9** shows electrostatically spun material formed into a planar disk shape instead of the peak formation of **FIG. 1**. The electrostatically spun material has a graft receiving opening **47**, similar to graft receiving member **7** of **FIG. 1**, for sealably receiving at least one tubular graft therethrough. It can be appreciated that a variety membrane **43** of shapes and locations on stent **42** can be used depending on the application, as above-discussed. Generally, electrostatically spun material is similar to material known in the art for vascular grafts. The spun structure of the membrane provides a porous scaffolding structure for blood to clot within and provide a sealable material. The basic process of electrospinning in well known in the art. The process involves the introduction of electrostatic charge to a stream of polymer melt or solution in the presence of a strong electric field. The predominant form of operation entails charge induction in the fluid through contact with a high voltage electrode in a simple metal or glass capillary spinnerette. A charge jet is produced which accelerates and thins in the electric field, ultimately collecting on a grounded device, typically a plate or belt. Under certain conditions of operation, the fluid jet becomes unstable before it reaches the collector. The onset of instability, with low molecular weight fluids, typically results in a spray of small, charged droplets, in a process known as "electrospinning" permitting. Viscoelastic forces stabilize the jet, with polymeric fluids, permitting the formation of small diameter, charged filaments that appear as an "envelope" or a cone dispersed fluid, and that solidify and deposit on the collector in the form of a nonwoven fabric. Under these conditions, it is common to observe mean fiber diameters on the order of 0.1 $\mu$m, three orders of magnitude smaller than the diameter of the jet entering the unstable region (10-100 $\mu$m). The electrostatic spinning process is described in U.S. Pat. No. 4,044,404 and U.S. Pat. No. 4,323,525, and is hereby incorporated herein by reference. Additionally, the material is permeable. The pore size of the material will usually be between 0.001$\mu$ and 500$\mu$. In order for the material to be sufficiently porous to allow penetration of cells into the surface layers, the average surface pore dimension is preferred to be of the order of 5 to 25$\mu$, more preferably between 7 and 15$\mu$, although pore size in the bulk of the material may average about 1$\mu$. In addition, the membrane may be coated with a material to promote clotting, or provide a non-permeable material to prevent fluid flow, such as collagen, or an elastomer, such as Corethane. Additionally, prosthesis **40** can include multiple layers of materials forming the membrane such as an electrospun layer over a silicon layer.

[0064] Prosthesis **40** can be used in combination with various grafts to provide multi-component systems, bifurcated systems, stent-graft prosthesis and the like, as shown in **FIG. 10**. Prosthesis **40** used in combination with at least one tubular prosthesis **48** extending through the graft receiving opening **47** and sealably supporting the tubular prosthesis **48**. Generally, the tubular prosthesis **48** includes a graft which is positioned through graft receiving opening **47** in a compressed state. The graft **48** may vary in size and shape depending on the desired application. For example, a portion of the graft **48** extending on either side of the graft receiving opening **47** may have a larger diameter opening than the portion extending through the graft receiving opening **47** to provide for additional securement of the graft **48** to the membrane **43**. Once in place, the graft **48** is allowed to expand in the graft receiving opening **47**. The pressure from the blood through the graft **48** secures the graft **48** to the electrostatically spun membrane, as similar described above in regards to prosthesis **1** of **FIG. 1**.

[0065] The above described prosthesis as shown in **FIGS. 1-10** can be loaded into a delivery system for deployment within, a body lumen. The delivery system used is similar to those known in the art. Typically, the delivery system has an introductory device or sheath in which the prosthesis is compressed therein. Once the desired vascular site is reached, the sheath is removed, leaving the stent and attached membrane located endoluminally. Additional components may be used in combination with the above deployed prosthesis such as a tubular graft. A tubular graft is deployed after the initial prosthesis is deployed using the same delivery device with an additional sheath or a separate device.

[0066] Generally, in regards to prosthesis **1** of **FIG. 1**, the delivery system includes an elongated outer sheath which supports the prosthesis **1** in a compressed condition. The

outer sheath is an elongated generally tubular structure which longitudinally surrounds the prosthesis **1**. The outer sheath has a diameter which is sufficiently small so as to be readily inserted within a body lumen.

[**0067**] The deployment system may further include guidewires, multiple sheaths, dilation devices, i.e. balloons, nose caps and pushers, as known in the art.

[**0068**] When the delivery system is positioned at the desired site in the body lumen the outer sheath is retracted with respect to the prosthesis **1**. The retraction of the outer sheath progressively releases stent **2** along its longitudinal (axial) extent and allows the stent **2** to radially expand. As stent **2** further expands membrane **3**, which is positioned within the stent **2**, is deployed. Membrane **3** radially deploys by the radially expanding force of attached stent **2**.

[**0069**] Prosthesis **40** as shown in **FIG. 9** may be deployed using the same method as described above, and known in the art.

[**0070**] Deploying the above-described prosthesis in combination with a graft is a multi-step deployment process. The initial step is deploying the first prosthesis including the stent and attached membrane as above-described.

[**0071**] Generally, after the first prosthesis is positioned and deployed then the tubular prosthesis is positioned and deployed using various systems as known in the art. For example, additional sheaths may be added to the first delivery device, above-described, to deploy the tubular graft after deploying the first prosthesis. An example of a multi-stage delivery device which is useful for delivering the first prosthesis and tubular prosthesis is described in U.S. Pat. No. 6,123,723 to Konya, and is hereby incorporated herein by reference. Alternatively, second separate delivery system can be used to deploy the tubular prosthesis. After the initial prosthesis is deployed as described above, an additional deployment device is used to position the tubular prosthesis within the graft receiving member of the membrane. Once the additional deployment device is in position the sheath is retracted allowing the tubular prosthesis to be placed within the graft receiving member. The tubular prosthesis securably seals to the membrane by the blood flowing through the tubular prosthesis and forcing the tubular prosthesis to radially expand against the membrane. Additionally, stents may be deployed to secure the tubular prosthesis to the arteries.

[**0072**] Similarly, a bifurcated system uses the same multi-step delivery process, as above-described. Additional sheaths and/or deployment devices are used to deploy the tubular prosthesis as above-described. For example, **FIG. 8** shows a bifurcated system where the tubular prosthesis are being implanted after the initial prosthesis **30***a* including stent **32***a* and attached membrane **33***a* is deployed. The tubular prosthesis **38***a* and **38***b* are navigated to the abdomen. This would be accomplished by mounting the tubular prosthesis **38***a* and **38***b* onto catheters **36** and **39** and thereafter percutaneously inserting the catheters into a femoral artery and navigating the tubular prosthesis to the target site. Guidewires can be used to help delivery of the catheter to the target site. Navigating catheters within the human arterial system is well known in the art. An example of a balloon catheter is given in U.S. Pat. No. 5,304,197 issued to Pinchuck et al. on Apr. 19, 1994, which is hereby incorporated herein by reference. The target site is, as previously mentioned, through the graft receiving member **37***a* and **37***b* of the membrane **33***a*. The sheath of the catheter is removed, placing the tubular prosthesis **38***a* and **38***b* within the graft receiving members **37***a* and **37***b*. Removal of the catheter permits the blood to flow through the tubular prosthesis **38***a* and **38***b* further securing such prosthesis **38***a* and **38***b* within the graft receiving members **37***a* and **37***b*, and ultimately sealably securing the tubular prosthesis **38***a* and **38***b* to the stent **32***a*. Distal anchoring stents (not shown) can be used to secure the tubular prosthesis **38***a* and **38***b* to the walls of the iliac arteries. Distal anchoring stents can be mounted on and deployed using the same catheter as used delivering the tubular prosthesis **38***a* and **38***b*. Alternatively, the anchoring stents can be deployed by using a separate deployment device after placement of the tubular prosthesis **38***a* and **38***b* has been completed.

[**0073**] **FIG. 7** shows how the entire system looks after the bifurcated prosthesis **30** including stent **32** and attached membrane **33**, grafts **38** and anchoring stents **34** and **35** have been deployed.

[**0074**] The delivery of prosthesis **20** including a branched graft **28** of **FIG. 6** is similar to the delivery of prosthesis **30** of **FIG. 8**.

[**0075**] Initially the prosthesis **20** including stent **22** and attached membrane **23** are delivered to the desired sight as above-described. A second delivery system is used to implant the branched graft **28** in a compressed state within the graft receiving member **27** of the membrane **23**. Once in place the sheath is removed allowing graft **28** to expand within the graft receiving member **27**, one leg **28***a* of graft **28** is in place and may be anchored with an anchoring stent **24**. A third delivery device is used to properly position the other leg **28***b* of the branched graft **28** and additionally add an anchoring stent **25** to secure the graft within the iliac artery **8***b*. **FIG. 6** shows how the entire system looks after the prosthesis **20** including the branched graft **28** is deployed.

[**0076**] It may be desirable to have additional securement of the prosthesis to the aortic wall. Multiple prosthesis, as described above, can be used in combination to offer securement of the prosthesis cephalically to the renal arteries. For example, **FIG. 11** shows a multi-component endovascular prosthesis **50** of the present invention which includes a first expandable prosthesis **51**, and second expandable prosthesis **61**. The prosthesis, **51** and **61**, are similar to the prosthesis **1** in **FIG. 1** including a stent, and a membrane extending traversely across the inner lumen and attached to the stent, and having one or more graft receiving members. The first expandable prosthesis **51** and second expandable prosthesis **61** include an expandable stent (**52**, **62**), and a membrane (**53**, **63**) having graft receiving openings (**57**, **67**), respectively. **FIG. 11** shows the first expandable prosthesis **51** further including fluid flow opening **54** to provide an outlet for fluid to flow through the membrane **53**. The fluid flow opening **54** includes a slit, a hole, a fluid penetrable material and the like. **FIG. 11** shows a bifurcated system including tubular grafts **58** (which includes **58***a* and **58***b*) which extends sealably through each prosthesis, (**51**, **61**) at the graft receiving opening (**57**, **67**) for directing fluid through the tubular grafts **58**. In addition, **FIG. 11** shows grafts **58** including a porous portion **59** (which includes **59***a* and **59***b*)

disposed on grafts **58** between the first expandable prosthesis **51** and the second expandable prosthesis **61** to allow for fluid exchange through the porous portion **59** of grafts **58**. The porous portion **59** includes a stent, slits, fluid permeable material and the like.

[**0077**] Deployment of prosthesis **50** is similar to those prosthesis as above-described. For an abdominal aortic aneurysm application, the first expandable prosthesis **51** is positioned and deployed cephalic to the renal arteries **9** (includes **9***a* and **9***b*) via a delivery device in the same manner as described above. The same delivery device using additional sheaths or a second delivery device is used to implant second expandable prosthesis **61** between the renal arteries **9** and the abdominal aneurysm. An additional delivery device is used to deliver grafts **58** through the graft receiving opening (**57**, **67**). Graft **58***a* is extended through graft receiving opening (**57**, **67**) of each prosthesis (**51**, **61**), respectively. Second graft **58***b* is extended through graft receiving opening (**57**, **67**). Grafts **58***a* and **58***b* are extended sealable through the graft receiving openings (**57**,**67**) for directing fluid therethrough. The same deployment procedure as above-discussed is used to delivery prosthesis **50**, as known in the art.

[**0078**] A further embodiment of the present invention is an endovascular prosthesis **70** of **FIG. 12**, which is similar to prosthesis **1**, of **FIG. 1** including a stent and a membrane. **FIG. 12** shows the "M" shaped stent **72** having an inner lumen **76**, a distal end **74** and a proximal end **75**. The distal end **74** has an opening and the proximal end **75** has two openings opposed the distal opening. A puncturable membrane **73** extends across each of the proximal end **75** openings for puncturably receiving a graft. The stent **72** of **FIG. 12** is similar to the stents as above-described but is preferably a weave or braid of stent filaments. As shown in **FIG. 13**, a typical braided stent includes a first set of filaments **71**L wound in a first helical direction (to the left as shown in **FIG. 13**) and a second set of filaments **71**R wound in a second, opposite helical direction (to the right as shown in **FIG. 13**), forming a plurality of overlaps **79**. Filaments **71**L and **71**R may be wire, such as nitinol or stainless steel, or may comprise polymer or any type of filaments known in the art. The prosthesis **70** may be a hybrid material having two materials woven or bonded together such as a PTFE and Dacron, where Dacron is bonded on the exterior of the PTFE.

[**0079**] As used herein, a "braided" stent refers to a stent formed of at least two continuous filaments which are interwoven in a pattern, thus forming overlaps **79** as shown in **FIG. 13**. At each overlap, one filament is positioned radially outward relative to the other filament. Following each filament along its helical path through a series of consecutive overlaps, that filament may, for example be in the radial inward position in one overlap and in the radial outward position in a next overlap, or may in the inward position for two overlaps and in the outward position for the next two, and so on. Exemplary braided stents are disclosed in U.S. Pat. No. 4,655,771 to Hans I. Wallsten, and is incorporated herein by referred. The endovascular prosthesis **70** may include a stent-graft composite where the stent is an open structure with a non-permeable graft material attached thereto. A stent-graft composite can further have a stent with one opening at the distal end and a crimped opening at the proximal end supporting a graft which forms the two openings at the proximal end **75**.

[**0080**] The endovascular prosthesis of **FIG. 12** further includes a puncturable membrane **73** which is similar to membrane **3** of **FIG. 1** as described-above having weakened section, opening, slit, or hole for receiving a graft therethrough. Membrane **73** is similarly attached to stent **72** as described above by mechanical, thermal, chemical, and adhesively attached. Membrane **73** and/or graft receiving opening **77** forms a fluid seal between the tubular prosthesis **78** and the stent **72** at the proximal end **75**.

[**0081**] The endovascular prosthesis **70** of **FIG. 12** is shown in combination with tubular prosthesis **78**. Any number of tubular grafts may be used depending on the application. **FIG. 12** shows the tubular prosthesis **78** extending through the distal end **74** opening of the prosthesis **70** and puncturably through membrane **73** thereby forming a fluid seal between the tubular prosthesis **78** and the stent **72** at the proximal end **75**. Blood flow is directed through the tubular prosthesis **78**. The tubular prosthesis **78** are positioned in each iliac artery so that the blood exits the tubular prosthesis **78** into each iliac artery (**8***a*, **8***b*).

[**0082**] The deployment of prosthesis **70** is similar to the manner of deployment described for prosthesis **1** of **FIG. 1**. Generally, the delivery system is positioned in the body lumen, and the outer sheath is retracted with respect to the prosthesis **70**. The retraction of the outer sheath progressively releases the stent **72** along its longitudinal (axial) extent and allows the stent **72** to radially expand. The membrane **73**, which is positioned across the stent lumen **76**, is radially deployed by the radially expanding force of the attached stent **72**.

[**0083**] Additionally, secondary delivery devices are used to deploy tubular prosthesis **78** through the graft receiving membrane **77**, similar to those above-described. The implanted bifurcated system is shown in **FIG. 12**.

[**0084**] A further embodiment of the present invention similar to **FIG. 12** is shown in **FIG. 14** which provides for additional securement of the prosthesis cephalically to the renal arteries **9** (includes **9***a* and **9***b*). **FIG. 14** shows an endovascular prosthesis **80** where a portion of the prosthesis **80** caudal to the renal arteries **9**, similar to the embodiment **70** of **FIG. 12**, has an "M" shaped configuration with an opening at one end and two openings **84** at the opposed end. The endovascular prosthesis **80** of **FIG. 14** is a graft-stent composite including a stent **82**, grafts **86** and membranes **83**. The stent **82** extends the full length of the prosthesis **80** having a distal end **87**, a proximal end **88** and an opening extending therethrough. As shown in **FIG. 14**, a portion of the endovascular prosthesis **80** cephalic to the renal arteries **9** includes a first graft **81** which is attached to the distal end **87** of the stent **82** having an inner lumen therethrough. A portion of the prosthesis **80** caudal to the renal arteries **9** includes a second graft **86** which is attached to the proximal end **88** of the stent **82** and forms the "M" shape, similar to the prosthesis **80** of **FIG. 14**. The second graft **86** forms two smaller lumens **84** within the stent **82** opening. Membrane **83** extends transversely across each of the two lumens **84** of the second graft **86**. Membrane **83** is similar to the construction materials as described for that of prosthesis **1** of **FIG. 1**. Membrane **83** can be attached to graft **86**, in the manner

as above-described, by adhesive bonding, such as silicone or polyurethane; mechanical attachment, such as sutures or staples; thermal bonding, laminate; or chemical bonding. The two grafts **81** and **86** are spaced apart to provide for blood exchange through the stent **82** and renal arteries **9**. The section of the stent **82** between the first graft **81** and second graft **86** may be an open celled structure or a covered stent which is blood-permeable. **FIG. 14** shows the endovascular prosthesis **80** having a wider cross-sectional area at distal end **87** and proximal end **88** where the stent **82** secures the prosthesis **80** to the artery wall, and a narrow cross-sectional area there between. One can appreciate that the endovascular prosthesis **80** may be one cross-sectional area throughout the length of the prosthesis **80** or varying cross-sectional areas as long as the two ends provide for securement to the artery wall and allow for undisturbed blood-flow therethrough.

[**0085**] Prosthesis **80** can be used in combination with a tubular prosthesis **89** as shown in **FIG. 14**. The tubular prosthesis **89** extends through each of the respective membranes **83** and provides a sealable attachment between the graft **86** and the tubular prosthesis **89**. The blood is diverted into each tubular prosthesis **89**. The tubular prosthesis **89** is those known in the art and above-described in reference to the prosthesis **10** in **FIG. 4**.

[**0086**] To deploy the prosthesis **80**, the prosthesis **80** is typically compressed into a radially compressed state into a delivery device, as known in the art and above-described. The prosthesis **80** is then introduced to the lumen into which it is to be deployed, navigated through the lumen to a deployment location, typically a diseased artery such as the aorta. The prosthesis **80** is expanded to a radially expanded state in the deployment location as is known in the art. **FIG. 14** shows the prosthesis **80** deployed across the renal arties **9***a* and **9***b* where the open-cell structure or porous portion of the prosthesis **80** is between the renal arteries **9***a* and **9***b*. The deployment of the tubular prosthesis **89** (**89***a* and **89***b*) of the present invention is thus deployed by a method similar to that described above using a separate delivery device or the same delivery device with additional sheaths or stages, as known in the art. The tubular prosthesis **89** are puncturably delivered through the membrane **83**. The tubular prosthesis are sealably secured to the graft **86** by the outward force from the blood flowing there through and the restricted size of the lumens **84**.

[**0087**] Another embodiment of the present invention which is similar to prosthesis **1** of **FIG. 1** but instead of using a membrane to sealable secure a tubular prosthesis to the stent, a foam **93** is used to securely attaching the tubular prosthesis **98** to the stent **92** as shown in **FIG. 15**. The endoprosthesis **90** of **FIG. 15** includes a stent **92**, and a tubular prosthesis **98** having an expanded foam **93** attached thereto. The stent **92** is similar to those described above being an expandable stent **92** having a distal end, a proximal end and an inner lumen. As shown in **FIG. 16**, stent **92** has an inner surface **94** and an outer surface. The tubular prosthesis **98** is similar to those described above having an interior surface and exterior surface **99**. The expanded foam **93** is attached to the exterior surface **99** of the tubular prosthesis **98**. The tubular prosthesis **98** is placed within the lumen **91** of the stent **92** and the expanded foam **93** sealably secures the tubular prosthesis **98** to the stent **92**.

[**0088**] The expandable foam **93** must be biocompatible and requisite strength characteristics. The foam is similar to those known in the art such as gelatin sponge, collagen sponge, cellulose sponge, hyaluronic acid and foams used for nasal surgery. The expandable foam **93** may be porous or non-porous. The expandable foam **93** is provided in a compressed state prior to placement within the stent **92**. Once in place, the expandable foam **93** is allowed to expand into the matrix of stent **92** to securably attach the tubular prosthesis **98** in the stent lumen **91**. Some expandable foams are non-permeable upon implantation, while others provide a scaffold structure for clot formation. Some scaffold structure foams may dissolve over time leaving a sealable clot formation. Suitable available commercial foams include Spongostern, Surgifoam, (Ferrosan, distributed by Johnson & Johnson); Gelfoam (Pharmacia & UpJohn Company); Avitene Ultrofoam (Bard/Davol); MeroGel Nasal Dressing, Sinus Stent and Otologic Packing, HYAFF (Medtronic Xomed, Jacksonville, Fla.).

[**0089**] The expandable foam **93** is attached to the outer surface **99** of the tubular prosthesis **98** by mechanical, adhesive, thermal, or chemical attachment. As shown in **FIG. 16**, the foam **93** covered graft **98** is placed into the lumen **91** of the stent **92** and the expandable foam **93** is allowed to expand by either a reaction in the vascular environment, such as hydrolysis, or by removing an outside force, such as sheath. The expandable foam **93** expands against and into the structure of the stent **92** securing the tubular prosthesis **98** in place in a sealable manner. As shown in **FIG. 16** one or more tubular prosthesis **98** can be used depending on the application.

[**0090**] Additionally, as shown in **FIG. 17**, the expandable foam **93** covered tubular prosthesis **98** of **FIG. 16** can be used in combination with the prosthesis **1** of **FIG. 1**. Prosthesis **90***a* includes a stent **92***a* and a membrane **97** having a graft receiving member **97***a*, similar to prosthesis **1** of **FIG. 1**. The expandable foam **93***a* covered tubular prosthesis **98***a* is extended through the graft receiving member **97***a*. The expandable foam **93***a* expands within the graft receiving member **97***a* to provide a sealable securement of the tubular prosthesis **98***a* to the membrane **97**, as shown in **FIG. 17**.

[**0091**] Further the embodiment of the present invention is a kit of parts for assembly into an endovascular prosthetic system. The kit includes an expandable stent **92** and a tubular prosthesis **98**. The expandable stent **92** has a distal end, a proximal end and an inner lumen **91** for insertion into a body endovascularly. The tubular prosthesis **98** is adapted to be inserted within the inner lumen **91** of the stent **92**. The tubular prosthesis **98** has an interior surface for body fluid flow and an exterior surface. Additionally, an expandable foam **93** is attached to the exterior surface of the tubular prosthesis **98**. The expandable foam **93** is adapted to expand within the stent **92** to sealably secure the tubular prosthesis **98** to the stent **92**.

[**0092**] Deploying prosthesis **90** is similar to the method of deploying prosthesis **30** of **FIG. 7**. The prosthesis **90** is a multi-step process as above-discussed. The stent **92** is typically compressed into a radially compressed state into a delivery device, as known in the art. The stent **92** is then introduced into the lumen in which it is to be deployed, navigated through the lumen to a deployment location, and then expanded to a radially expanded state in the deployment location, as is known in the art. The expandable foam

**93** covered tubular prosthesis **98** are also compressed into a radially compressed state into a delivery device. Once the tubular prosthesis **98** are positioned within the stent lumen **91** the tubular prosthesis **98** are deployed by removing a restraining element, such as a sheath, of the delivery device. The expandable foam **93** is allowed to expand filling the space within the stent lumen **91**, into the structure of the stent **92**, and sealably securing the tubular prosthesis **98** within the stent **92**. As above-discussed separate delivery devices may be used to deploy each component of the prosthesis **90** or a multi-step delivery device may be used.

[**0093**] In addition, prosthesis **90***a* of **FIG. 17** is deployed using the same delivery system as above-described for prosthesis **90** of **FIG. 16**, except the stent **92** of **FIG. 16** is substituted with the first prosthesis **91***a*. Initially, first prosthesis **91***a* is compressed in a delivery device, delivered to the target site within the lumen and allowed to deploy at the site. The expandable foam **93***a* covered tubular prosthesis **98***a* are delivered via the delivery device in a compressed state into the graft receiving member **97***a*. After placing the delivery device within the graft receiving members **97***a* at the desired location, the delivery device is removed to allow the expandable foam **93***a* to expand within the graft receiving members **97***a*. The expandable foam **93***a* in combination with the graft receiving members **97***a* sealably secure the tubular prosthesis **98***a* to the first prosthesis **91***a*.

[**0094**] A further embodiment of the present invention is an endovascular prosthetic assembly **100** as shown in **FIGS. 18 and 19** which is similar to the prosthesis **90** of **FIG. 15** but instead of using an expandable foam on the grafts to secure the grafts to the stent, a polymeric material **130** is used. **FIG. 19** shows the endovascular prosthetic assembly **100** including a stent **120** and a tubular prosthesis **180** similar to those described above. Endovascular prosthetic assembly **100** further includes a polymeric material **130** sealably supporting the tubular prosthesis **180** to the stent **120**. The polymeric material **130** is a substantially homogenous reaction product of monomer materials which is formed in situ. As shown in **FIG. 18**, the exterior surface of the tubular prosthesis **180** and inner surface of the lumen of the stent **120** are pre-coated with a primary reactive material **110**. The tubular prosthesis **180** is positioned within the inner lumen of the stent **120**. A secondary material (not shown) reactive with the primary material **110** is introduced in the vicinity of tubular prosthesis **180** and the inner lumen of the stent **120**. The primary material **110** and secondary material react forming a polymeric material **130** which sealably supports the tubular prosthesis **180** to the stent **120**.

[**0095**] In general, the polymeric material **130** is biocompatible, slightly thrombotic, and non-toxic. The polymeric material **130** can be a foam or hydrogel. A hydrogel which is useful is one formed from the mixture of a polymer and monomer and an reaction promoter such as a chemical activator or light activator (focal therapeutic). Examples of suitable materials which react to form a hydrogel include polyethylene glycol and iron, or polyethylene glycol and peroxide in addition to light activation or a chemical activator. For additional suitable hydrogel and methods of preparation, refer to U.S. Pat. No. 6,379,373 to Sawhney, which is hereby incorporated herein by reference.

[**0096**] In addition, one or more tubular prosthesis **180** can be used depending on the application. The prosthesis **100** can be offered in a kit form. The kit of parts for assembly into an endovascular prosthetic system **100** includes a stent **120**, a primary reactive material **110**, a tubular prosthesis **180**, and a secondary reactive material. The stent **120** has an inner surface, an outer surface and an inner lumen. The primary reactive material **110** is disposed on said inner surface of the stent **120**. The tubular prosthesis **180** is adapted to extend within the inner lumen of the stent **120**. The tubular prosthesis **180** has an interior surface and an exterior surface, and the primary material **110** is disposed on said exterior surface of the tubular prosthesis **180**. The secondary material is reactive with the primary material **110** and adapted to be applied to the primary material **110** upon insertion of the tubular prosthesis **180** within the inner lumen of the stent **180**. The secondary material is reactive with the primary material **110** to form a seal between the tubular prosthesis **180** and the stent **120**.

[**0097**] Deploying prosthesis **100** is similar to the deployment process of prosthesis **90** of **FIG. 15**. The prosthesis **100** is also a multiple step process as above-discussed. The stent **120** is compressed into a radially compressed state into a delivery device, as known in the art. The stent **120** is then introduced to the lumen into which it is to be deployed, navigated through the lumen to a deployment location, and then expanded to a radially expanded state in the deployment location, as is known in the art. Secondarily, the tubular prosthesis **180** are compressed in a radially compressed state within a delivery device. The tubular prosthesis **180** are positioned within the lumen of the stent **120**. The tubular prosthesis **180** are partially deployed by removing the sheath or delivery device around the portion of the tubular prosthesis **180** which is positioned within the lumen of the stent **120**. A secondary material is injected into the vicinity of the tubular prosthesis **180** and stent **120**. The secondary material is allowed to react with the primary material **110** on the exterior surface of the tubular prosthesis **180** and the interior surface of the stent **120**. The polymeric reaction product **130** from the two materials sealably secures the tubular prosthesis **180** to the stent **120**. As above discussed separate delivery devices may be used to deploy each component of the prosthesis **100** or a multi-step delivery device may be used, as known in the art.

[**0098**] In addition, combining the technology as shown in **FIGS. 18 and 19** with the prosthesis **1** of **FIG. 1**, provides prosthesis **200** as shown in **FIGS. 20 and 21**. In this combination, the membrane **230** and the tubular prosthesis **280** are pretreated with the primary material **210**, as described above. **FIG. 20** shows tubular prosthesis **280** is placed within the stent lumen through the graft receiving member **270** of the membrane **230**. A secondary material is introduced which reacts with the primary material **210** on the tubular prosthesis **280** and the membrane **230**. A polymeric material **240** is formed which sealably secures the tubular prosthesis **280** to the stent **220**, as shown in **FIG. 21**.

[**0099**] Prosthesis **200** is deployed in the same manner as discussed for prosthesis **100** of **FIG. 18**, except stent **120** is replaced with a first prosthesis **219** including a stent **220** and a membrane **230**, attached to the stent **220**, having graft receiving member **270**. The first prosthesis **219** is deployed at the target site using a delivery device as above described. The tubular prosthesis **280** is compressed in a delivery device and then positioned through the graft receiving members **270**. The tubular prosthesis **280** is deployed within

the graft receiving members **270**. A secondary reactive material is introduced in the vicinity of the membrane **230** and the tubular prosthesis **280**. The secondary reactive material is allowed to react with the primary material **210** on the tubular prosthesis **280** and the membrane **230**. The reaction product **240** results in a polymeric material which sealably secures the tubular prosthesis **280** to the membrane **230**. Variations on this method may be used according to the known art.

**[0100]** Having described particular arrangements of the present invention herein, it should be appreciated by those skilled in the art that modifications may be made thereto without departing from the contemplated scope thereof. Accordingly, the arrangements described herein are intended to be illustrative rather than limiting, the true scope of the invention being set forth in the claims appended hereto.

What is claimed is:

**1**. An endovascular prosthesis comprising:

(a) an expandable stent having a distal end, a proximal end and an inner lumen; and

(b) a membrane supported by said stent and extending across said lumen, said membrane including a graft receiving member for sealably receiving at least one tubular graft therethrough.

**2**. An endovascular prosthesis of claim 1, wherein said graft receiving member comprises a slit.

**3**. An endovascular prosthesis of claim 2, wherein said graft receiving member is electrostatically spun material.

**4**. An endovascular prosthesis of claim 1, wherein said graft receiving member comprises a valve.

**5**. An endovascular prosthesis of claim 1, wherein said graft receiving member comprises a weakened section.

**6**. An endovascular prosthesis of claim 1, wherein said graft receiving member comprises a penetrable material.

**7**. An endovascular prosthesis of claim 1, further comprising a second graft receiving member.

**8**. In combination, an endovascular prosthesis of claim 1, and a tubular graft extending sealably through said graft receiving member.

**9**. The combination of claim 8, wherein said tubular graft has an interior surface and exterior surface, and an expandable foam on said exterior surface, said foam being expandable within said graft receiving member, sealably securing said tubular graft to said graft receiving member.

**10**. An endovascular prosthesis of claim 8, further comprising a polymeric material sealably securing said tubular graft to said membrane.

**11**. A method of forming an endovascular prosthesis comprising the steps of:

a. providing an expandable stent defining a lumen therein comprising distal end and a proximal end;

b. providing a membrane including a graft receiving member for sealably receiving at least one tubular graft therethrough; and

c. attaching said membrane to said stent, wherein said membrane extends across said lumen and is supported thereby.

**12**. A method of implanting an endovascular prosthesis within a vessel comprising:

a. providing, in a compressed first diameter, a radially expandable stent having a distal end, a proximal end and an inner lumen; and a membrane supported by said stent and extending across said lumen, said membrane including a graft receiving member for sealably receiving at least one tubular graft therethrough;

b. delivering said stent within a vessel to an area of implantation; and

c. permitting said stent to radially expand to a second diameter; and thereby engage a vessel wall.

**13**. A bifurcated endovascular prosthesis comprising:

(a) a first prosthetic component comprising:

(i) an expandable stent having a distal end, a proximal end and an inner lumen; and

(ii) a membrane extending transversely across said inner lumen and attached to said stent, said membrane having an opening; and

(b) a second prosthetic component extending into said opening in a substantially fluid tight seal, said second component comprising a branched graft.

**14**. A bifurcated endovascular prosthesis of claim 13, wherein said membrane has a first opening and a second opening.

**15**. A bifurcated endovascular prosthesis of claim 14, wherein said branched graft comprises a first graft extending into said first opening, and a second graft extending into said second opening in a substantially fluid-tight seal.

**16**. A bifurcated endovascular prosthesis of claim 15, wherein said membrane comprises polyurethane, polyethylene, polytetrafluoroethylene, and combinations thereof.

**17**. A bifurcated endovascular prosthesis of claim 15, wherein said first opening and second opening each comprises a valve.

**18**. A bifurcated endovascular prosthesis of claim 15, wherein said first prosthetic component is adapted to reside in an aortic artery, and said first graft and second graft are each adapted to respectively reside in separate iliac arteries.

**19**. A method of forming a bifurcated endovascular prosthesis comprising the steps of:

a. providing a first prosthetic component comprising:

(i) an expandable stent having a distal end, a proximal end and an inner lumen; and

(ii) a membrane extending transversely across said inner lumen and attached to said stent, said membrane having an opening;

b. providing a second prosthetic component comprising a branched graft; and

c. extending said second prosthetic component into said opening of said membrane, wherein said membrane forms a substantially fluid tight seal with said second component.

**20**. A method of implanting a bifurcated endovascular prosthesis within a vessel comprising:

a. providing, in a compressed first diameter, a first prosthetic component comprising an expandable stent having a distal end, a proximal end and an inner lumen; and

a membrane extending transversely across said inner lumen and attached to said stent, said membrane having an opening;

b. providing a second prosthetic component comprising a branched graft;

c. delivering said first prosthetic component within a vessel to an area of implantation;

d. permitting said first prosthetic component to radially expand to a second diameter; and thereby engage a vessel wall; and

e. delivering said second prosthetic component within said opening of said stent forming a substantially fluid tight seal between said membrane and said second prosthetic component.

**21**. A method of forming a bifurcated endovascular prosthesis comprising the steps of:

a. providing a prosthetic component comprising:

(i) an expandable stent having a distal end, a proximal end and an inner lumen; and

(ii) a membrane extending transversely across said inner lumen and attached to said stent, said membrane having a first opening and a second opening;

b. providing a first graft having a first inner surface, a first outer surface defining a first interior lumen;

c. providing a second graft having a second inner surface, a second outer surface defining a second interior lumen;

d. extending said first graft into said first opening of said membrane, wherein said membrane forms a substantially fluid tight seal between said prosthetic component and said first graft; and

e. extending said second graft into said second opening of said membrane, wherein said membrane forms a substantially fluid tight seal between said prosthetic component and said second graft.

**22**. A method of implanting a bifurcated endovascular prosthesis within a vessel comprising:

a. providing, in a compressed first diameter, a prosthetic component comprising an expandable stent having a distal end, a proximal end and an inner lumen; and a membrane extending transversely across said inner lumen and attached to said stent, said membrane having an opening;

b. providing a first graft having a first inner surface, a first outer surface defining a first interior lumen;

c. providing a second graft having a second inner surface, a second outer surface defining a second interior lumen;

d. delivering said prosthetic component within a vessel to an area of implantation;

e. permitting said prosthetic component to radially expand to a second diameter; and thereby engage a vessel wall;

f. delivering said first graft within said opening of said stent forming a substantially fluid tight seal between said membrane and said first graft; and

g. delivering said second graft within said opening of said stent forming a substantially fluid tight seal between said membrane and said second graft.

**23**. An endovascular prosthesis comprising:

(a) an expandable stent having an inner lumen, a first end and a second end; and

(b) a membrane attached to said stent extending transversely across said lumen, said membrane comprising electrostatically spun material having a graft receiving opening for sealably receiving at least one tubular graft therethrough.

**24**. In combination, an endovascular prosthesis of claim 23, and at least one tubular prosthesis extending through said graft receiving opening and sealably supporting said at least one tubular prosthesis.

**25**. A method of forming an endovascular prosthesis comprising the steps of:

a. providing an expandable stent having an inner lumen, a first end and a second end;

b. providing a membrane comprising electrostatically spun material having a graft receiving opening for sealably receiving at least one tubular graft therethrough; and

c. attaching said membrane to said stent, wherein said membrane extends transversely across said lumen and is supported thereby.

**26**. A method of implanting an endovascular prosthesis within a vessel comprising:

a. providing, in a compressed first diameter, an expandable stent having a first end, a second end and an inner lumen; and a membrane comprising electrostatically spun material supported by said stent and extending across said lumen, said membrane including a graft receiving opening for sealably receiving at least one tubular graft therethrough;

b. delivering said stent within a vessel to an area of implantation; and

c. permitting said stent to radially expand to a second diameter; and thereby engage a vessel wall.

**27**. A multi-component endovascular prosthetic system comprising:

(a) a first expandable prosthesis comprising:

(i) a first expandable stent having a distal end, a proximal end and an inner lumen; and

(ii) a first membrane extending transversely across said inner lumen and attached to said first stent, said first membrane having a first graft receiving opening;

(b) a second expandable prosthesis spaced from said first prosthesis comprising:

(i) a second expandable stent having a distal end, a proximal end and an inner lumen; and

(ii) a second membrane extending transversely across said inner lumen and attached to said second stent, said second membrane having a second graft receiving opening; and

(c) a tubular graft extending sealably through said first graft receiving opening and said second graft receiving opening for directing fluid through said tubular graft.

**28**. A multi-component endovascular prosthetic system of claim 27, wherein said tubular graft has a porous portion disposed between said first expandable prosthesis and said second expandable prosthesis to allow for fluid flow through said porous portion.

**29**. A multi-component endovascular prosthetic system of claim 28, wherein said porous portion comprises a stent.

**30**. A multi-component endovascular prosthetic system of claim 28, wherein said porous portion comprises slits.

**31**. A multi-component endovascular prosthetic system of claim 28, wherein said porous portion comprises fluid permeable material.

**32**. A multi-component endovascular prosthetic system of claim 27, wherein said first membrane has a pair of first graft receiving openings, said graft receiving openings each receiving a tubular graft therethrough.

**33**. A multi-component endovascular prosthetic system of claim 32, wherein said first membrane has a fluid flow opening.

**34**. A multi-component endovascular prosthetic system of claim 33, wherein said second membrane has a pair of second graft receiving openings, said second graft receiving openings each receiving a tubular graft therethrough.

**35**. A method of forming a multi-component endovascular prosthesis comprising the steps of:

a. providing a first expandable prosthesis comprising:

(i) a first expandable stent having a distal end, a proximal end and an inner lumen; and

(ii) a first membrane extending transversely across said inner lumen and attached to said first stent, said first membrane having a first graft receiving opening;

b. providing a second expandable prosthesis spaced from said first prosthesis comprising:

(i) a second expandable stent having a distal end, a proximal end and an inner lumen; and

(ii) a second membrane extending transversely across said inner lumen and attached to said second stent, said second membrane having a second graft receiving opening; and

c. providing a tubular graft having an outer surface, and an inner surface defining an inner lumen; and

d. extending said tubular graft through said first graft receiving opening and said second graft receiving opening for directing fluid through.

**36**. A method of implanting a multi-component endovascular prosthesis within a vessel comprising:

a. providing, in a compressed first diameter, a first expandable prosthesis comprising a first expandable stent having a distal end, a proximal end and an inner lumen; and a first membrane extending transversely across said inner lumen and attached to said first stent, said first membrane having a first receiving opening;

b. providing, in a compressed second diameter, a second expandable prosthesis comprising a second expandable stent having a distal end, a proximal end and an inner lumen; and a second membrane extending transversely across said inner lumen and attached to said second stent, said second membrane having a second receiving opening;

c. providing a tubular graft having an outer surface, and an inner surface defining a graft inner lumen;

d. delivering said first expandable prosthesis within a vessel to an area of implantation;

e. permitting said first expandable prosthesis to radially expand to a third diameter; and thereby engage a vessel wall;

f. delivering said second expandable prosthesis spaced from said first expandable prosthesis within a vessel to an area of implantation;

g. permitting said second expandable prosthesis to radially expand to a fourth diameter; and thereby engage a vessel wall;

h. delivering said tubular graft within said first receiving opening and said second receiving opening forming a substantially fluid tight seal between said first membrane and said tubular graft, and said second membrane and said tubular graft.

**37**. An endovascular prosthesis comprising:

(a) a stent having an inner lumen, a distal end and a proximal end, said distal end having an opening, and said proximal end having two openings opposing said distal opening; and

(b) a puncturable membrane extending across each of said proximal end openings.

**38**. In combination, an endovascular prosthesis of claim 37, and at least one tubular graft extending through said distal end opening and puncturably through one of said membranes at said proximal end, thereby forming a fluid seal between said tubular graft and said stent at said proximal end.

**39**. The combination of claim 38, further comprising a pair of tubular grafts extending through said distal end, with one tubular graft extending puncturably through each membrane at said proximal end of said stent to thereby form a fluid seal between said tubular graft and said stent at said proximal end.

**40**. A method of forming an endovascular prosthesis comprising the steps of:

a. providing an expandable stent having an inner lumen, a distal end and a proximal end, wherein said distal end having an opening and said proximal end having two openings opposing said distal opening;

b. providing a puncturable membrane; and

c. attaching said membrane to said stent transversely across each of said proximal end openings.

**41**. A method of implanting an endovascular prosthesis within a vessel comprising:

a. providing, in a compressed first diameter, an expandable stent having a distal end, a proximal end and an inner lumen, wherein said distal end having an opening and said proximal end having two openings opposing said distal opening; and a puncturable membrane supported by said stent and extending across said lumen;

b. delivering said stent within a vessel to an area of implantation; and

c. permitting said stent to radially expand to a second diameter; and thereby engage a vessel wall.

**42**. An endovascular prosthesis comprising:

(a) an expandable stent having a distal end, a proximal end, and an opening extending therethrough;

(b) a first graft attached to said distal end of said stent within said opening, and having an inner lumen extending therethrough;

(c) a second graft attached to said proximal end of said stent within said opening and spaced from said first graft, said second graft having at least two inner lumens extending therethrough; and

(d) a membrane extending transversely across each of said inner lumens of said second graft.

**43**. In combination, an endovascular prosthesis of claim 42, and at least two tubular prosthesis, one of such prosthesis extending puncturably through each of said respective membranes.

**44**. A method of forming an endovascular prosthesis comprising the steps of:

a. providing an expandable stent having a distal end and a proximal end, and an opening extending therethrough;

b. providing a first graft having an inner lumen extending therethrough;

c. providing a second graft having at least two inner lumens extending therethrough;

d. providing a membrane;

e. attaching said first graft to said distal end of said stent within said opening;

f. attaching said second graft to said proximal end of said stent within said opening and spaced from said first graft; and

g. attaching said membrane transversely across each of said inner lumens of said second graft.

**45**. A method of implanting an endovascular prosthesis within a vessel comprising:

a. providing, in a compressed first diameter, an expandable stent having a distal end, a proximal end and an opening therethrough, said stent comprising a first graft attached to said distal end of said stent within said opening, and having an inner lumen extending therethrough; a second graft attached to said proximal end of said stent within said opening and spaced from said first graft, said second graft having at least two inner lumens extending therethrough; and a membrane extending transversely across each of said inner lumens of said second graft;

b. delivering said stent within a vessel to an area of implantation; and

c. permitting said stent to radially expand to a second diameter; and thereby engage a vessel wall.

**46**. An endovascular prosthetic assembly comprising:

(a) an expandable stent having a distal end, a proximal end and an inner lumen having an inner surface and an outer surface;

(b) a tubular graft inserted within said inner lumen, said tubular graft having an interior surface and exterior surface; and

(c) an expanded foam attached to said exterior surface of said graft, said expanded foam sealably securing said tubular graft to said stent.

**47**. An endovascular prosthesis of claim 46, wherein said expanded foam is adhesively bonded to said exterior surface of said graft.

**48**. An endovascular prosthesis of claim 46, wherein said expanded foam is mechanically fastened to said exterior surface of said graft.

**49**. An endovascular prosthesis of claim 46, further comprising a second tubular graft inserted within said inner lumen, said second tubular graft having a second interior surface and a second exterior surface, and a second expanded foam bonded to said second exterior surface, said second expanded foam sealably securing said second tubular graft to said stent.

**50**. A kit of parts for assembly into an endovascular prosthetic system, comprising:

(a) an expandable stent having a distal end, a proximal end and an inner lumen for insertion into a body endovascularly;

(b) a tubular graft adapted to be inserted within said inner lumen, said tubular graft having an interior surface for body fluid flow and an exterior surface; and

(c) an expandable foam on said exterior surface of said tubular graft, said expandable foam adapted to expand within said stent to sealably secure said tubular graft to said stent.

**51**. A method of forming an endovascular prosthesis comprising the steps of:

a. providing an expandable stent having a distal end, a proximal end and an inner lumen having an inner surface and an outer surface;

b. providing a tubular graft having an interior surface and exterior surface;

c. providing an expandable foam;

d. attaching said expandable foam to said exterior surface of said graft;

e. inserting said tubular graft within said inner lumen of said stent, wherein said expandable foam is in a compressed state; and

f. allowing said expandable foam to expand within said stent and sealably securing said tubular graft within said stent.

**52**. A method of implanting an endovascular prosthesis within a vessel comprising:

a. providing, in a compressed first diameter, an expandable stent having a distal end, a proximal end, an inner surface, an outer surface and an inner lumen;

b. providing a tubular graft having an interior surface and an exterior surface, said tubular graft having, in a

compressed second diameter, an expandable foam attached to said exterior surface of said graft;

c. delivering said stent within a vessel to an area of implantation;

d. permitting said stent to radially expand to a third diameter; and thereby engage a vessel wall;

e. delivering said graft within said inner lumen of said stent; and

f. permitting said foam of said graft to expand to a fourth diameter, thereby sealably securing said graft to said stent.

**53**. An endovascular prosthetic assembly comprising:

(a) a stent having an inner surface and an outer surface;

(b) a tubular graft extending within said inner lumen, said tubular graft having an interior surface and an exterior surface, and an opening therethrough; and

(c) a polymeric material sealably supporting said tubular graft to said stent.

**54**. An endovascular prosthetic assembly of claim 53 wherein said polymeric material is a hydrogel.

**55**. An endovascular prosthesis of claim 53, further comprising a second tubular graft extending within said inner lumen, said second tubular graft having an interior surface and an exterior surface, and an opening therethrough; and said polymeric material sealably supporting said second tubular graft to said stent.

**56**. A kit of parts for assembly into an endovascular prosthetic system comprising:

(a) a stent having an inner surface, an outer surface and an inner lumen, a primary reactive material being disposed on said inner surface;

(b) a tubular graft adapted to extend within said inner lumen, said graft having an interior surface and an exterior surface, said primary material being disposed on said exterior surface; and

(c) a secondary material reactive with said primary material and adapted to be applied to said primary material upon insertion of said graft within said inner lumen, said secondary material being reactive with said primary material to form a seal between said graft and said stent.

**57**. A method of forming an endovascular prosthesis comprising the steps of:

a. providing a stent having an inner surface, an outer surface and an inner lumen;

b. providing a tubular graft having an interior surface and an exterior surface, and an opening therethrough;

c. providing a primary material;

d. providing a secondary material reactive with said primary material;

b. disposing said primary material on said inner surface of said stent;

e. disposing said primary material on said exterior surface of said tubular graft;

f. inserting said tubular graft within said inner lumen of said stent; and

g. introducing said secondary material into said inner lumen of said stent, wherein said secondary material react with said primary material defining a polymeric material sealably supporting said tubular graft to said stent.

**58**. A method of implanting an endovascular prosthesis within a vessel comprising:

a. providing, in a compressed first diameter, an expandable stent having an inner surface, an outer surface and an inner lumen therethrough, said inner surface of said stent having a primary material disposed about said surface;

b. providing a tubular graft having an interior surface and an exterior surface, said exterior surface of said graft having a primary material disposed about said surface;

c. providing a secondary material reactive with said primary material;

d. delivering said stent within a vessel to an area of implantation;

e. permitting said stent to radially expand to a second diameter; and thereby engage a vessel wall;

f. delivering said graft within said inner lumen of said stent;

g. delivering said second material into said inner lumen of said stent; and

h. permitting said secondary material to react with said primary material defining a polymeric material sealably supporting said tubular graft to said stent.

**59**. An endovascular prosthesis comprising:

(a) an expandable stent having a distal end, a proximal end and an inner lumen; and

(b) means for sealably attaching a tubular graft to said stent within said lumen.

**60**. An endovascular prosthesis of claim 59, wherein said means comprises a membrane supported by said stent and extending across said lumen, said membrane including a graft receiving member for sealably receiving at least one tubular graft therethrough.

**61**. An endovascular prosthesis of claim 59, wherein said means comprises an expandable foam bonded to said tubular graft.

**62**. An endovascular prosthesis of claim 59, wherein said means comprises a polymeric material, said polymeric material comprising the reaction product of a primary material on said inner lumen of said stent and on said tubular graft, and a secondary material thereby forming a sealed attachment between said tubular graft and said stent.

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