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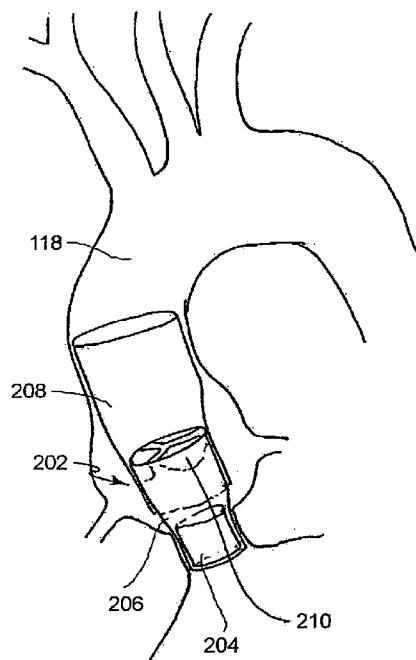
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(54) Title: AORTIC VALVE STENT GRAFT

FIGURE 5



(57) Abstract: An implantable endoluminal prosthesis for replacing a damaged aortic valve is provided. In one embodiment, the prosthesis includes a balloon-expandable stent (204), a tubular conduit (206) that extends into the ascending aorta, and a self-expanding stent (208). The tubular conduit extends across the balloon-expandable stent (204). The tubular conduit includes an artificial valve (210). The self-expanding stent (208) extends across the tubular conduit into the ascending aorta. The balloon-expandable stent (204), the tubular conduit (206), and the self-expanding stent (208) are coupled to provide unidirectional flow of fluid into the aorta and further into the coronary arteries. Also described is a method of implanting the endoluminal prosthesis.



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AORTIC VALVE STENT GRAFT

DescriptionTechnical Field

The present invention relates to an endoluminal prosthesis such as an aortic valve stent graft.

The described embodiments relate to implantable medical devices and methods, and more particularly to an implantable medical device for the repair of a damaged endoluminal valve, such as an aortic valve, and a method for implanting the same.

Background of the Invention

The aortic valve functions as a one-way valve between the heart and the rest of the body. Blood is pumped from the left ventricle of the heart, through the aortic valve, and into the aorta, which in turn supplies blood to the body. Between heart contractions the aortic valve closes, preventing blood from flowing backwards into the heart.

Damage to the aortic valve can occur from a congenital defect, the natural aging process, and from infection or scarring. Over time, calcium may build up around the aortic valve causing the valve not to open and close properly. Certain types of damage may cause the valve to "leak," resulting in "aortic insufficiency" or "aortic regurgitation." Aortic regurgitation causes extra workload for the heart and can ultimately result in weakening of the heart muscle and eventual heart failure.

After the aortic valve becomes sufficiently damaged, the valve may need to be replaced to prevent heart failure and death. One current approach involves the use of a balloon-expandable stent to place an artificial valve at the site of the defective aortic valve. Another current approach involves the positioning of an artificial valve at the site of the aortic valve using a self-expanding stent. However, these techniques are imperfect. The normal aortic valve functions well because it is suspended from above through its attachment to the walls of the coronary sinus in between the coronary orifices, and it has leaflets of the perfect size and shape to fill the space in the annulus. These features are difficult to replicate in a percutaneously implanted prosthetic valve. The size of the implantation site depends on the unpredictable effects of the balloon dilation of a heavily calcified

native valve and its annulus. Balloon dilation can lead to poor valve function with a persistent gradient or regurgitation through the valve. The diameter of the aortic valve is small and thus the diameter of the dilation is not always predictable, especially with a self-expanding stent. In addition, the shape of the aortic valve is not circular, which can also lead to regurgitation outside the valve.

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Summary of the Invention

The present invention seeks to provide an improved endoluminal prosthesis, an improved aortic heart valve and an improved method of replacing an aortic valve in a patient.

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

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

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According to an aspect of the present invention, there is provided a prosthesis for replacing an aortic valve as specified in claim 9.

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The described embodiments provide an endoluminal prosthesis for replacing an aortic valve in a subject. In one embodiment, the prosthesis comprises a first stent, a tubular conduit, and a second stent. The tubular conduit may comprise a valve, wherein at least a portion of the tubular conduit overlaps at least a portion of the first stent. The second stent overlaps at least a portion of the tubular conduit. In use, ones of the first stent, the tubular conduit, and the second stent are coaxially arranged for unidirectionally passing fluid through the prosthesis.

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In one embodiment, the first stent comprises a balloon-expandable stent and the second stent comprises a self-expanding stent. The self-expanding stent may at least partially surround the tubular conduit, and the tubular conduit may at least partially surround the balloon-expandable stent. Alternatively, both the balloon-expandable stent and the self-expanding stent may at least partially surround the tubular conduit. The valve may comprise an artificial valve, which may be located at the distal end of the tubular conduit.

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In one exemplary method of operation, an endoluminal prosthesis may be introduced into the vascular system. The endoluminal prosthesis comprises a first

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5 stent, a tubular conduit comprising a valve, and a second stent, wherein at least a portion of the tubular conduit overlaps at least a portion of the first stent, and at least a portion of the tubular conduit overlaps at least a portion of the second stent. The prosthesis is advanced within the vascular system towards an aortic annulus. Then, at least a portion of the prosthesis is expanded into engagement with the aortic annulus.

10 The first stent, the tubular conduit and the second stent may be advanced into the vascular system in a sequential manner or simultaneously. In operation, the first stent, the tubular conduit and the second stent may be configured for unidirectionally passing fluid through the prosthesis and substantially or 15 completely inhibiting retrograde flow through the prosthesis.

15 Other systems, methods, features and advantages of the teachings herein will be, or will become, apparent to one with skill in the art upon examination of the following figures and detailed description. It is intended that all such additional systems, methods, features and advantages be within the scope of the claims.

Brief Description of the Drawings

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

20 Figure 1 is a partial cutaway view of a heart and an aorta;

Figure 2 is a cutaway side view of an endoluminal prosthesis;

Figure 3 is a top plan view of the prosthesis of Figure 2;

Figure 4 is a bottom plan view of the prosthesis of Figure 2;

Figure 5 is a partial cutaway view of an aorta with an implanted 25 prosthesis;

Figure 6 is another partial cutaway view of an aorta with an implanted prosthesis;

Figure 7 is an illustration of a braided stent;

Figure 8 is a top plan view of one embodiment of a barb attached to a stent;

30 Figure 9 is a perspective view of the barb attached to a stent of Figure 8;

Figure 10 is a side view of one embodiment of a barb;

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Figure 11 is a side view of a portion of a stent with a ring of barbs pointing out from each apex;

Figures 12A-12B illustrate one embodiment of an artificial valve during diastole and systole, respectively;

5 Figures 13A-13B are a side view and top view, respectively, of one embodiment of a supportive frame for an artificial valve;

Figure 14 is an illustration of one example of an artificial valve with a supportive frame;

10 Figure 15 is an illustration of another example of an artificial valve with a supportive frame; and

Figure 16 is a perspective view of selected segments of a deployment device with an aortic stent graft partially deployed.

Detailed Description

15 In the present application, the term "proximal" refers to a direction that is generally closest to the heart during a medical procedure, while the term "distal" refers to a direction that is furthest from the heart during a medical procedure.

20 Figure 1 shows a partial cut-away view of a heart 102 and an aorta 104. The heart 102 may comprise an aortic valve 106 that does not seal properly. This defect of the aortic valve 106 allows blood to flow from the aorta 104 back into the left ventricle 108, leading to a disorder known as aortic regurgitation. A bicuspid mitral valve 110 generally prevents blood from flowing further backwards into the left atrium. Also shown in Figure 1 are a brachiocephalic trunk 112, a left common carotid artery 114, a left subclavian artery 116, and a right ventricle 120. A portion of the aorta 104 referred to herein as an ascending aorta 118 is shown located between the aortic valve 106 and the brachiocephalic trunk 112.

25 Figure 2 illustrates a first embodiment of a prosthetic device in the form of an aortic stent graft 202. In this embodiment, the aortic stent graft 202 comprises three generally tubular members arranged in coaxial configuration, comprising from inside to outside: a balloon-expandable stent 204, a conduit 206, and a self-expanding stent 208. The conduit 206 includes an artificial valve 210. The artificial valve 210 is shown in an open configuration, allowing unidirectional blood flow through the prosthesis, in the direction indicated by an arrow 240. In this

embodiment, the conduit 206 is shown as a thin walled conduit. Also in this embodiment, the artificial valve 210 is shown near a distal end of the conduit 206.

The shape, size, and dimensions of each of the members of the prosthetic device 202 may vary. Consequently, the overall size and shape of the aortic stent 5 graft prosthesis may vary. The size of a preferred prosthetic device is determined primarily by the diameter of the vessel lumen (preferably for a healthy valve/lumen combination) at the intended implant site, as well as the desired length of the overall stent and valve device. Thus, an initial assessment of the location of the natural aortic valve in the patient is determinative of several aspects of the 10 prosthetic design. For example, the location of the natural aortic valve in the patient will determine the dimensions of the stents and the tubular conduit, the type of valve material selected, and the size of deployment vehicle. The length of the self-expanding stent 208 is sufficient enough to overlap with the conduit 206 and extend to engagement with the ascending aorta 118.

15 In the embodiment shown in Figure 2, the conduit 206 is shown as completely covering the length of the balloon-expandable stent 204. However, in some embodiments the conduit 206 may only partially cover the length of the balloon-expandable stent 204. What is essential is that the length of the conduit 206 is sufficient to overlap at least a part of the balloon-expandable stent 204, to 20 thereby provide coupling that provides flow of fluid through the prosthesis. Similarly, the length of the self-expanding stent 208 can vary. What is essential is that the length of the self-expanding stent 208 is sufficient to overlap the conduit 206, to thereby provide coupling that provides flow of fluid through the prosthesis.

25 In this embodiment, the tubular members are preferably axially uniform. Furthermore, the tubular members shown in Figure 2 are presented as roughly cylindrical. In some embodiments, one or more of these tubular members may be contoured. For example, one or more of the members may be gradually tapering, that is they may be tubular gradually narrowing distally or tubular gradually widening distally. The tubular members may further be elliptical, conical, or have 30 combinations of regular shapes or irregular shapes that conform to the shape of the recipient's anatomy.

Figure 3 is a top plan view of the prosthesis of Figure 2, showing the artificial valve 210 in a closed position. In this view, the artificial valve 210 can be seen as attached to the conduit 206. The artificial valve 210 shown in this example includes three leaflets. Also shown in Figure 3 is the self-expanding stent 208. As can be seen in Figure 3, the tubular members are presented as coaxial and as roughly cylindrical. As described above, and in some embodiments, one or more of these tubular members may be contoured, tapered, conical, or have irregular shapes that conform to the shape of the lumen.

Figure 4 is a bottom plan view of the prosthesis of Figure 2, showing the artificial valve 210 in a closed position. In addition to the conduit 206 and the self-expanding stent 208, this view shows the balloon-expandable stent 204, which is the innermost member.

The prosthesis of these embodiments may be introduced and deployed in a subject's vascular system so that it reaches the aortic annulus, as shown in Figures 5 and 6. Preferably, the prosthesis has a compressed state for delivery and an expanded state upon deployment within the artery. Once the prosthesis is deployed and implanted at the site of the aortic annulus, the artificial valve of the prosthesis functionally replaces the aortic valve of the subject. Note the different embodiments of an implanted prosthesis shown in Figures 5 and 6. In Figure 5, the self-expanding stent 208 at least partially surrounds the tubular conduit 206, and the tubular conduit 206 at least partially surrounds the balloon-expandable stent 204. In Figure 6, both the balloon-expandable stent 204 and the self-expanding stent 208 at least partially surround the tubular conduit 206. In both embodiments, the prosthesis allows unidirectional flow of fluid from the heart into the aorta.

Introduction and deployment of the members that comprise the prosthesis can be simultaneous. In this situation, each of the components may be mounted on a balloon catheter. The balloon is aligned with the aortic annulus, then expanded to dilate substantially simultaneously the aortic annulus and deploy the balloon expandable stent 204 and remainder of the prosthesis. By substantially simultaneously deploying each component of the prosthesis at the same time the annulus is dilated, potentially fatal regurgitation problems may be avoided.

In another embodiment, introduction and deployment of the individual members can be sequential. If sequential deployment of the components is provided, a physician may need to stop blood flow due to potentially fatal aortic regurgitation problems associated with dilation of the aortic annulus and subsequent individual insertion of the prosthetic components.

In another embodiment, the deployment can be a combination of simultaneous and sequential, that is some members of the prosthesis can be deployed simultaneously, whereas other or others can be deployed sequentially.

The self-expanding stent 208 included in the prosthesis may be a modified Gianturco "Z stent" or any other form of self-expanding stent. The Z-stent design is preferred for straight sections of the aorta, as it provides both significant radial force as well as longitudinal support.

In certain preferred embodiments, the self-expanding stent 208 can be a braided stent, as illustrated in Figures 6 and 7. A long, open mesh stent as depicted in Figures 6 and 7 provides the necessary downstream support without the struts that would be required were the valve to be supported via annular attachment alone. The design of this stent requires flexibility, resistance to compressive loading, and an atraumatic interface with the aorta. The self-expanding stent may have two zones, a lower (proximal) zone of narrow diameter and fixed length (resistance to compression), and an upper (distal) zone of wider diameter and variable length (flexibility). A braided stent, such as a Wallstent, may comprise two such zones by varying the braid angle. If the stent were made of Nitinol, its exact braid shape could be determined by heat setting after the wires had all been bent and joined into the basic shape. The proximal end of the stent can be made more atraumatic by joining the ends of the wires as loops.

Typically, the prosthesis has a circular cross-section when fully expanded, so as to conform to the generally circular cross-section of a blood vessel lumen. In one example, the balloon expandable stent 204 and the self-expanding stent 208 may include struts and acute bends or apices that are arranged in a zigzag configuration in which the struts are set at angles to each other and are connected by the acute bends. The stents may include a curved or hooped portion. The present embodiments can be used with a wide variety of stents, including, but not

limited to, shape memory alloy stents, expandable stents, and stents formed in situ. Any stent shape suitable for expansion to fit the pertinent anatomical space may be used.

Preferably, the self-expanding stent 208 is formed from Nitinol, stainless steel, or elgiloy. Examples of other materials that may be used to form stents include: carbon or carbon fiber, tantalum, titanium, gold, platinum, inconel, iridium, silver, tungsten, cobalt, chromium, cellulose acetate, cellulose nitrate, silicone, polyethylene terephthalate, polyurethane, polyamide, polyester, polyorthoester, polyanhydride, polyether sulfone, polycarbonate, polypropylene, high molecular weight polyethylene, polytetrafluoroethylene, or another biocompatible polymeric material, or mixtures or copolymers of these; polylactic acid, polyglycolic acid or copolymers thereof; a polyanhydride, polycaprolactone, or polyhydroxybutyrate valerate. Still other biocompatible metals, alloys, or other biodegradable polymers or mixtures or copolymers may be used.

The aortic stent graft 202 may include a biocompatible graft material attached to at least a portion of any stent. The graft material may be connected to the artificial valve. In one embodiment, the graft material forms a lumen, which lumen is adapted to seal against the wall of the aorta at a site proximal to the aortic annulus. In this embodiment, the blood flows through the lumen of the stent graft and the artificial valve regulates the unidirectional flow of blood through the prosthesis.

The biocompatible graft material is preferably non-porous so that it does not leak under physiologic forces. The graft material is preferably made of woven Dacron® polyester (VASCUTEK® Ltd., Renfrewshire, Scotland, UK).

Preferably, the graft material is formed without seams. The tubular graft can be made of any other at least substantially biocompatible material including such fabrics as other polyester fabrics, polytetrafluoroethylene (PTFE), expanded PTFE, and other synthetic materials. Naturally occurring biomaterials, such as collagen, are also highly desirable, particularly a derived collagen material known as extracellular matrix (ECM), such as small intestinal submucosa (SIS). An element of elasticity may be incorporated as a property of the fabric or by subsequent treatments such as crimping. The dimensions of the graft may vary

according to the dimensions of the artery that is treated. For each patient, a graft can be selected that has diameters that exceed those of the recipient artery. The stent is relied upon to exert sufficient radial outward force to effect a seal between the graft material and the inner wall of the aorta.

5 To anchor the aortic stent graft to the wall of the arterial lumen, attachment systems are preferably included on the balloon-expandable stent 204 and/or the self-expanding stent 208. The preferred attachment system includes arterial wall engaging members, for example protrusions or barbs 230, as shown in Figures 2-4, 8-11, and 16.

10 Preferably, sharp metal barbs 230 project outward from the surface of the prosthesis 202. Barbs 230 can be attached to one or more members of the prosthesis 202. In one embodiment, barbs 230 are attached to the self-expanding stent 208. In another embodiment, barbs 230 are attached to a balloon-expandable stent 204. Yet in another embodiment, barbs 230 are attached to both the self-expanding stent 208 and the balloon-expandable stent 204. The barbs 230 point caudally, cranially, or in both directions. The barbs 230 are soldered, brazed, glued to a stent or integrally formed at any point, for example, by etching. The number of barbs is variable. In one embodiment, barbs 230 may extend from the self-expanding stent 208 to engage the ascending aorta arterial 15 wall when deployed, and additional barbs may extend from the balloon-expandable stent 204 to engage the coronary sinus. Aortic stent grafts can be used with and without barbs. In the event barbs are omitted, the stents may be configured so that the radial forces exerted upon the coronary sinus and the ascending aorta are enough to hold the balloon-expandable stent 204 and self-expanding stent 208 in place, respectively.

20 Referring to Figures 8 and 9, the arrow indicates outward deflection of an exemplary barb 230. Point A indicates the apex of the barb 230; points B and C indicate points of attachment of the barb 230 to the stent. As the stent expands upon deployment, ΔAC (delta AC) would have to exceed ΔAB (delta AB), if the barb 230 were to remain in the plane of the stent. However, the stent material can 25 neither stretch nor conform much. The disparity is resolved by the apex A of the

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barb 230 moving outwards and downwards, as indicated by the arrows in Figures 9 and 10.

In the absence of the balloon, the barb 230 might move into the lumen of the stent. To be sure it moves as planned, the barb 230 can be made so that it starts with a slight outward deflection, as shown in Figures 8-11. A sharp apex could be made to function as a barb, especially for a very short stent. In this embodiment, the initial bend is even more important, otherwise the sharp point can puncture the balloon. In a preferred embodiment, as illustrated in Figure 11, a stent has barbs 230 pointing out from each apex in an expanded state.

As noted above, the aortic stent graft 202 preferably includes an artificial valve 210. The purpose of this artificial valve 210 is to replace the function of the recipient's native damaged or poorly performing aortic valve. The artificial valve 210 is preferably located at the distal end of the conduit 206, further from the heart. In one example, the artificial valve 210 can be coupled to the conduit 206 with a suture.

The artificial valve 210 preferably includes one or more leaflets. Indeed a tubular conduit, sutured longitudinally to opposite sides of the neck of the self-expanding stent 208 would function as a bicuspid valve. In another embodiment, three suture lines would create a tricuspid valve with less redundancy. Preferably, and as shown in Figures 2-4, the artificial valve 210 includes three leaflets. The leaflets are arranged in the prosthesis such that the leaflets mimic a naturally occurring aortic valve. The artificial valve 210 "opens" to allow blood flow when the pressure on the proximal side of the artificial valve 210 is greater than pressure on the distal side of the artificial valve. Thus, the artificial valve 210 regulates the unidirectional flow of fluid from the heart into the aorta.

The leaflets of the artificial valve 210 can be fabricated from any at least substantially biocompatible material including such materials as polyester fabrics, polytetrafluoroethylene (PTFE), expanded PTFE, and other synthetic materials known to those of skill in the art. Preferably, the leaflets are fabricated from naturally occurring biomaterials. The leaflets can include a derived collagen material, such as an extracellular matrix. The extracellular matrix can be small

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intestinal submucosa, stomach submucosa, pericardium, liver basement membrane, urinary bladder submucosa, tissue mucosa, dura mater, or the like.

The normal, native aortic valve is suspended from above through its attachment to the walls of the coronary sinus in between the coronary orifices, and it has leaflets of the perfect size and shape to fill the space in the annulus. While suspended valves resist the forces created by diastolic pressure on closed leaflets through attachment to downstream support, it is also possible to support the membrane "leaflets" of an artificial valve from below, just as the struts of a modern stent support the fabric. This approach is described below and has particular advantages in sites where the base of the valve is wide and suitable sites for downstream anchoring are few.

Various artificial valve designs may be used. These designs preferably have at least two membranes with overlapping holes/slits/flaps so that there is no direct path from one side to the other. In the phase of flow (systole for the aortic valve, diastole for the mitral) the membranes lift from the underlying supports, separate and allow blood to escape through their holes. This works best if the outer membrane(s) is slightly baggier than the inner membrane(s). A wide variety of slots and flaps is possible.

In the example shown in Figure 12, the inner membrane has a central hole 250 and the outer membrane has a series of peripheral slits 260 that allow for passage of fluid. In some embodiments, the slits 260 can be almost the whole area of the outer part so that the intervening fabric is just a series of radial tethers. Figure 12 illustrates the operation of such an artificial valve, during A) diastole, and B) systole. The arrows in Figure 12B indicate the direction of blood flow through the slits and thus through the valve during systole.

The artificial valve flap need not be a floppy membrane; it could have some rigidity to better support itself in the presence of a rudimentary peripheral attachment mechanism. A single disc could be formed in situ from a spiral ribbon, like a flattened out watch spring. If the whole valve were conical it would transmit the longitudinal forces generated by the pressure gradient of diastole to its edges, where a robust stent would secure the mechanism to the annulus. Separation of the coils layers would allow flow in systole.

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In some embodiments, the anchoring/support framework for the artificial valve 210 can take a number of shapes, such as cylinder, flattened ball, doughnut, double disc and so on, as illustrated in part in Figures 13 to 15. Of all these, the doughnut may provide more support through tensioning the valve membrane than by direct contact with the membrane's underside. Shown in Figure 13 is an example of a mesh ball or doughnut, illustrating the positioning of an outer membrane 270, an inner membrane 272, and radial slots 274.

The double disc version, shown in Figure 14, could be made with a substantially completely impervious covering (no slits or holes), to serve not as a valve but as a baffle or barrier. Indeed, one side of the valve could be thinner than the other to close off some intravascular space. The thin side would sit outside the space and present a smooth, flush surface. The thick side would sit within the space and fill it up, while also providing stability.

Illustrated in Figure 14 are the valve membranes 280, and the position of the native aortic valve 282. The direction of blood flow is indicated with an arrow 284. The mesh ball valve designs, such as the design shown in Figure 14, might benefit from having the wires of the weave start and end at the margins of the disc. They would tend to spike the surrounding tissue (or in the case of the double disc, the intervening tissue) and secure the mesh in place.

In general, the supportive frame need not only be a mesh ball or a disc. In some embodiments, the membrane could be conical (tent shaped), e.g. similar to an over-the-wire Greenfield® filter, as shown in Figure 15. Illustrated in Figure 15 are the valve membranes 292, the umbrella frame 294, and one or more attachment hooks 296.

The aortic stent graft is introduced into a recipient's vascular system, delivered, and deployed using a deployment device, or introducer. The deployment device delivers and deploys the aortic stent graft within the aorta at a location to replace the aortic valve, as shown in Figures 5 and 6. The deployment device may be configured and sized for endoluminal delivery and deployment through a femoral cut-down. Typically, the deployment device includes a cannula or a catheter, capable of having a variety of shapes. The aortic stent graft may be radially collapsed and inserted into the catheter or cannula using conventional

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methods. In addition to the cannula or catheter, various other components may need to be provided in order to obtain a delivery and deployment system that is optimally suited for its intended purpose. These include and are not limited to various outer sheaths, pushers, stoppers, guide wires, sensors, etc.

5 Examples of delivery systems for endoluminal devices are known in the art. U.S. Patent Application Publication No. US 2003/0149467 A1 "Methods, Systems and Devices for Delivering Stents" provides examples of available stent delivery systems. Another example of a system and method of delivering endovascular devices was previously described in U.S. Patent No. 6,695,875
10 "Endovascular Stent Graft." PCT Patent Publication No. WO98/53761 "A Prosthesis and a Method of Deploying a Prosthesis" discloses an introducer for a prosthesis that retains the prosthesis so that each end can be moved independently. As well, the Zenith® TAA Endovascular Graft uses a delivery system that is commercially available from Cook Inc., Bloomington, Indiana.

15 In an embodiment, a trigger wire release mechanism is provided for releasing a retained end of a stent graft and includes a stent graft retaining device, a trigger wire coupling the stent graft to the stent graft retaining device, and a control member for decoupling the trigger wire from the stent graft retaining device. Preferably, the trigger wire arrangement includes at least one trigger wire
20 extending from a release mechanism through the deployment device, and the trigger wire is engaged with the proximal end of the aortic stent graft. In a preferred embodiment, where the aortic stent graft is modular and includes multiple portions, there can be multiple trigger wires extending from the release mechanism through the deployment device, each of the trigger wires engaging
25 with at least one portion of the aortic stent graft. Preferably, the aortic stent graft includes three members (balloon-expandable stent, conduit, and self-expanding stent). Thus, in a preferred embodiment, three trigger wires individually engage each of these three members of the prosthesis. Individual control of the deployment of each of the members of the prosthesis enables better control of the
30 deployment of the prosthesis as a whole.

Figure 16 shows an exemplary introducer that may be used to deploy the aortic stent graft described above. The introducer is used for deploying an aortic

stent graft 202 in an arterial lumen of a patient during a medical procedure. The introducer includes an external manipulation section 301, and a proximal positioning mechanism or attachment region 302. The introducer can also have a distal positioning mechanism or attachment region 303. During a medical procedure to deploy the aortic stent graft, the proximal and distal attachment regions 302 and 303 will travel through the arterial lumen to a desired deployment site. The external manipulation section 301, which is acted upon by a user to manipulate the introducer, remains outside of the patient throughout the procedure.

As illustrated in Figure 16, the aortic stent graft 202 is retained in a compressed condition by a sheath 330. The sheath 330 can radially compress the aortic stent graft 202 over a distal portion of a thin walled tube 315. The thin walled tube 315 is generally flexible and may include metal. A tube 341, which can be made of plastic, is coaxial with and radially outside the thin walled tube 315. The distal end of the tube 341 is adjacent to the proximal end of the aortic stent graft 202. The tube 341 acts as a pusher to release the stent graft 202 from the introducer during delivery.

The tube 341 is "thick walled", which is to say the thickness of the wall of tube 341 is several times that of the thin walled tube 315. Preferably, the tube 341 is five or more times thicker than the thin walled tube 315. The sheath 330 is coaxial with and is positioned radially outside the thick walled tube 341. The thick walled tube 341 and the sheath 330 extend proximally to the external manipulation region 301, as shown in Figure 16. The thin walled tube 315 extends to the proximal end of the introducer. The introducer further includes haemostatic sealing means 331 radially disposed about the sheath and the thick walled tube 341. The haemostatic sealing means 331 control the loss of blood through the introducer during a procedure.

The introducer may include an aortic stent graft control member 381 as illustrated in Figure 16. The stent graft control member 381 is disposed on the dilator portion 334 of the external manipulation section 301. During deployment of the aortic stent graft 202, the sheath 330 is withdrawn proximally over the thick walled tube 341. The haemostatic sealing means 331 generally fits tightly about

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the sheath 330, resulting in a great amount of friction between the sheath 330 and the thick walled tube 341. As a result, withdrawal of the sheath 330 over the thick walled tube 341 can be difficult. In order to overcome the friction, the operator must have a very tight grip on the thick walled tube 341. Axial positioning of the 5 aortic stent graft 202 may be compromised by the difficulty in gripping the thick walled tube 341. The control member 381 solves this problem by providing the operator with a better grip on the dilator and by decreasing the force that the operator must exert to control and stabilize the thick walled tube 341 during sheath 330 withdrawal. The control member 381 is generally tubular and includes an 10 inner dilator facing surface 382 and an outer grip surface 383. The control member 381 is slidably disposed on the thick walled tube 341 between the haemostatic sealing means 331 and the release wire actuation section to allow the operator to use the control member 381 at any position along the dilator.

15 The outer grip surface 383 is designed so that the control member 381 fits the operator's hand comfortably and securely. As such, the outer grip surface 383 may have a diameter that greatly exceeds the diameter of the thick walled tube 341. The outer grip surface 383 may be generally axially uniform. In another embodiment, the outer grip surface 383 may be generally axially non-uniform, resulting in a contoured gripping surface. Figure 16 illustrates a control member 20 381 having a generally non-uniform outer grip surface 383, wherein the control member is generally shaped like an hour glass. The outer grip surface 383 may include a smooth surface finish, or alternately, the outer grip surface may include a rough or textured surface finish. Rough or textured surface finishes are beneficial because they provide increased surface area contact between the operator and 25 the control member 381, thereby increasing the operator's leverage. Multiple surface finishes may be selected to provide various utilitarian and tactile benefits.

30 The control member 381 is generally deformable so that when the operator grips the control member 381, the control member 381 compresses against the thick walled tube 341. The control member 381 transfers the force exerted by the operator to the thick walled tube 341. The dilator facing surface 382 may include a generally smooth surface. Alternately, the dilator facing surface 382 may have a rough or textured surface. A rough or textured surface

may create a more "sticky" or "tacky" contact between the control member 381 and the thick walled tube 341, thereby increasing the force that is transferred by the operator to the dilator.

The dilator facing surface 382 may include a generally uniform surface.

5 Alternately, the dilator facing surface 382 may include a generally non-uniform surface. For example, the dilator gripping surface 382 may include a plurality of engageable projections that extend radially inward towards the thick walled tube 341. When the operator grips the control member 381 against the thick walled tube 341, engageable projections engage the surface of the thick walled tube.

10 Engageable projections increase the surface contact area between the control member 381 and the thick walled tube, thereby increasing the force that the control member transfers from the operator to the thick walled tube 341. Engageable projections may include any geometric or non-geometric shape. For example, engageable projections may include "O" shapes, lines, dashes, "V" shapes, or the like.

15

The distal attachment region 303 includes a retention device 310. The retention device 310 holds the distal end of the aortic stent graft in a compressed state. The retention device 310 has at its distal end a long tapered flexible extension 311. The flexible extension 311 includes an internal longitudinal aperture which facilitates advancement of the tapered flexible extension 311 along a previously inserted guide wire. The longitudinal aperture also provides a channel for the introduction of medical reagents. For example, it may be desirable to supply a contrast agent to allow angiography to be performed during placement and deployment phases of the medical procedure.

25 The distal end of the thin walled tube 315 is coupled to the flexible extension 311. The thin walled tube 315 is flexible so that the introducer can be easily advanced. The thin walled tube extends proximally through the introducer to the manipulation section 301, terminating at a connection means 316. The thin walled tube 315 is in mechanical communication with the flexible extension, allowing the operator to axially and rotationally manipulate the distal attachment region 303 with respect to the aortic stent graft 202. The connection means 316 is adapted to accept a syringe to facilitate the introduction of reagents into the thin

30

walled tube 315. The thin walled tube 315 is in fluid communication with the flexible extension 311, which provides for introduction of reagents through the aperture into the arterial lumen.

5 The trigger wire release actuation section of the external manipulation section 301 includes an elongate body 336. Distal and proximal trigger wire release mechanisms 324, 325 are disposed on the elongate body 336. End caps 338 are disposed on proximal and distal ends of the elongate body 336. End caps 338 include longitudinally-facing laterally opposed surfaces defining distal and proximal stops 388, 389. Distal and proximal trigger wire release mechanisms 10 324, 325 are slidably disposed on the elongate body 336 between distal and proximal stops 388, 389. Distal and proximal stops 388, 389 retain the distal and proximal trigger wire release mechanisms 324, 325 on the elongate body 336. The actuation section includes a locking mechanism for limiting the axial displacement of trigger wire release mechanisms 324, 325 on the elongate body 15 336.

Referring to the external manipulation section 301, a pin vise 339 is mounted onto the proximal end of the elongate body 336. The pin vise 339 has a screw cap 346. When screwed in, the vise jaws clamp against (engage) the thin walled metal tube 315. When the vise jaws are engaged, the thin walled tube 315 20 can only move with the body 336, and hence the thin walled tube 315 can only move with the thick walled tube 341. With the screw cap 346 tightened, the entire assembly can be moved as one with respect to the sheath 330.

25 The self-expanding stent 208 causes the aortic stent graft 202 to expand during its release from the introducer 301, shown in Figure 16. The stent graft shown in this example also includes barbs 230 that extend from the distal end of the self-expanding stent 208. When the self-expanding stent 208 is deployed (released), the barbs 230 anchor the distal end of the aortic stent graft 202 to the surrounding lumen (not shown). Upon endoluminal deployment, the balloon-expandable stent 204 is inflated and expanded. Expansion of the balloon-expandable stent can be caused by inflation of the catheter between the sleeves 30 so that the ends of the stent are withdrawn from the respective sleeves and the stent released and expanded into position. The tubular conduit 206 is also

expanded upon release from the introducer. When the tubular conduit 206 is positioned between the balloon-expandable stent 204 and the self-expanding stent 208 and is in contact with those two stents, expansion of those two stents 204 and 208 results in expansion of the tubular conduit 206 as well. Preferably, the tubular conduit 206 is thin walled, which aids in its expansion when released.

While various embodiments of the invention have been described, the invention is not to be restricted except in light of the attached claims and their equivalents. Moreover, the advantages described herein are not necessarily the only advantages of the invention and it is not necessarily expected that every embodiment of the invention will achieve all of the advantages described.

It is to be understood that the features of the different embodiments described herein may be combined with one another in any appropriate way and that a feature described in connection with one embodiment is thus not restricted to use with that embodiment alone.

It is also to be understood that the artificial valve 210 may not normally replace physically the heart valve, which would remain surgically untouched, but could be in addition to this and perform the function of the heart valve. It is not excluded, however, that the artificial valve 210 could replace physically the heart valve.

It is not to be excluded that more than one valve might be provided in the prosthesis.

This patent application claims the benefit of priority of U.S. Provisional Application Serial No. 60/986,908, entitled "Aortic Valve Stent Graft," filed November 9, 2007, the disclosure of which is hereby incorporated by reference in its entirety.

CLAIMS

1. An endoluminal prosthesis including:
 - a first stent;
 - a tubular conduit provided with an aortic valve replacement, wherein at least a portion of the tubular conduit overlaps at least a portion of the first stent;5 and
 - a second stent operable to overlap at least a portion of the tubular conduit, wherein ones of the first stent, the tubular conduit, and the second stent are coaxially arranged for unidirectionally passing fluid through the prosthesis.
- 10 2. An endoluminal prosthesis according to claim 1, wherein the first stent comprises a balloon-expandable stent and the second stent comprises a self-expanding stent.
- 15 3. An endoluminal prosthesis according to claim 2, wherein the self-expanding stent at least partially surrounds the tubular conduit, and the tubular conduit at least partially surrounds the balloon-expandable stent.
4. An endoluminal prosthesis according to claim 2 or 3, wherein both the balloon-expandable stent and the self-expanding stent at least partially surround the tubular conduit.
5. An endoluminal prosthesis according to any preceding claim, wherein the 20 aortic valve replacement includes an artificial valve.
6. An endoluminal prosthesis according to any preceding claim, wherein the aortic valve replacement is located at a distal end of the tubular conduit.
7. An endoluminal prosthesis according to any preceding claim, including one or more barbs.
- 25 8. An endoluminal prosthesis according to any preceding claim, wherein at least one of the first and second stents includes a braided bottle stent.
9. A prosthesis for replacing an aortic valve including:
 - at least first, second and third tubular members,
 - wherein one of the first, second or third tubular members is provided with a 30 valve, and
 - wherein ones of the first tubular member, the second tubular member, and

the third tubular member are coaxially arranged for unidirectionally passing fluid through the prosthesis.

10. A prosthesis according to claim 9, wherein at least one of the first, second and third tubular members includes a balloon-expandable stent.

5 11. A prosthesis according to claim 9 or 10, wherein at least one of the first, second and third tubular members includes a braided bottle stent.

12. A prosthesis according to claim 9, 10 or 11, wherein at least one of the first, second and third tubular members includes a self-expanding stent.

10 13. A prosthesis according to any one of claims 9 to 12, wherein the second tubular member includes a tubular conduit, wherein the valve is located at a distal end of the tubular conduit.

14. A prosthesis according to any one of claims 9 to 13, including one or more barbs.

15 15. A method of replacing an aortic valve in a subject, including the steps of: introducing into a vascular system an endoluminal prosthesis including a first stent, a tubular conduit provided with a valve, and a second stent, wherein at least a portion of the tubular conduit overlaps at least a portion of the first stent, and at least a portion of the tubular conduit overlaps at least a portion of the second stent;

20 advancing the endoluminal prosthesis within the vascular system towards an aortic annulus; and

expanding at least a portion of the prosthesis into engagement with the aortic annulus.

25 16. A method according to claim 15, wherein the first stent includes a balloon expandable stent and the second stent comprises a self-expanding stent, the method including the step of introducing the balloon expandable stent, the tubular conduit, and the self-expanding stent into the vascular system in a sequential manner.

30 17. A method according to claim 15 or 16, wherein the first stent includes a balloon expandable stent and the second stent includes a self-expanding stent, the method including the step of introducing the balloon expandable stent, the

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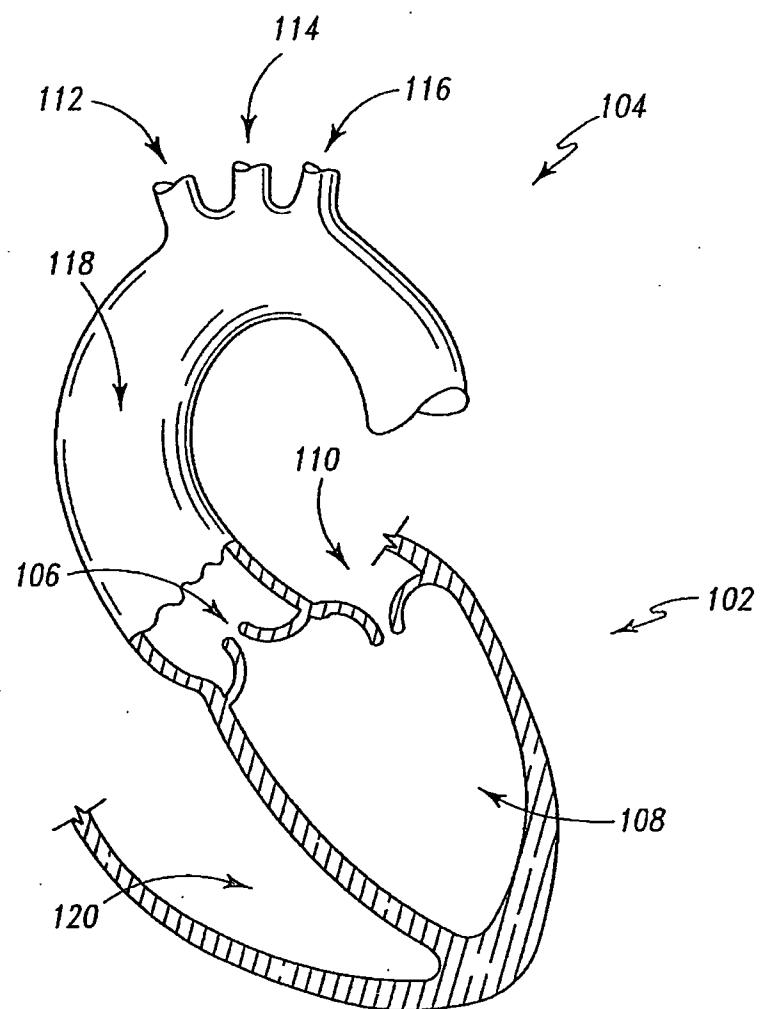
tubular conduit, and the self-expanding stent into the vascular system substantially simultaneously.

18. A method according to claim 15, 16 or 17, wherein the first stent, the tubular conduit and the second stent are provided for unidirectionally passing fluid through the prosthesis and at least inhibiting retrograde flow through the prosthesis.

5 19. A method according to any one of claims 15 to 18, including the step of expanding the first stent into engagement with the aortic annulus.

20. A method according to any one of claims claim 15 to 19, including the step 10 of positioning the second stent in the subject's ascending aorta.

FIGURE 1



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FIGURE 2

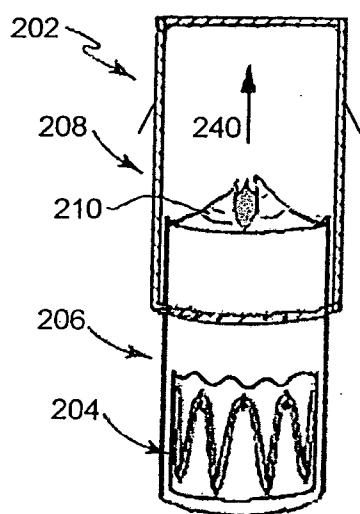


FIGURE 3

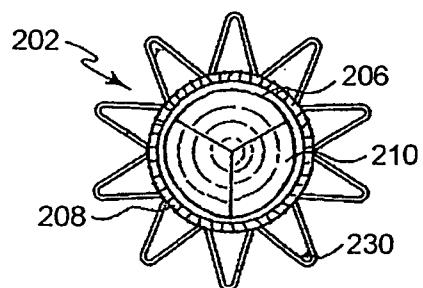
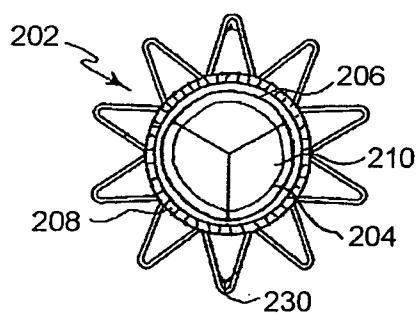
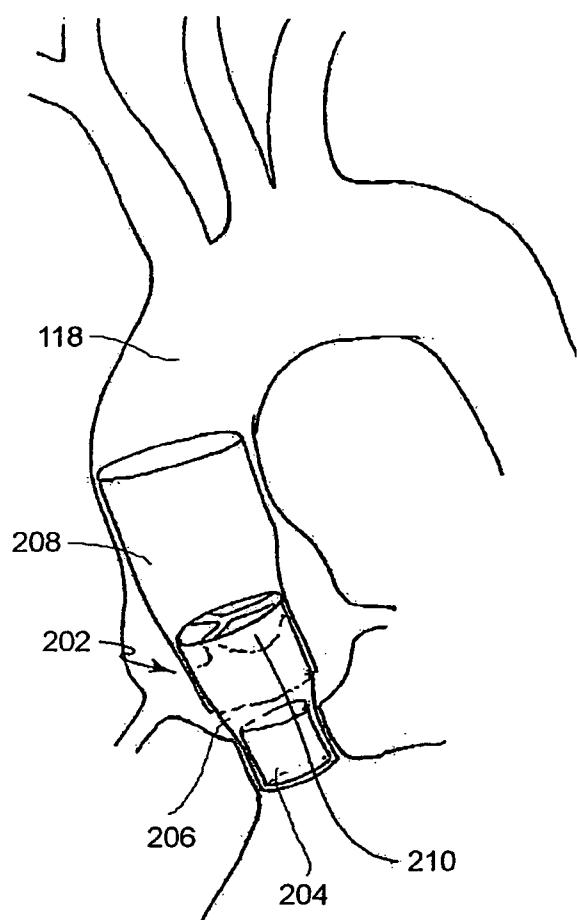


FIGURE 4



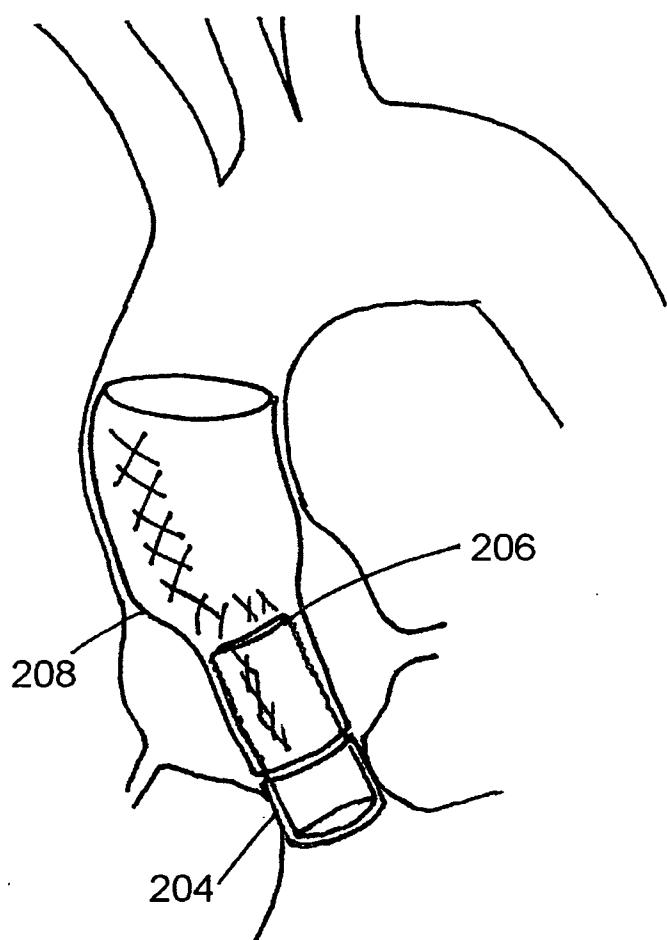
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FIGURE 5



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FIGURE 6



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FIGURE 7

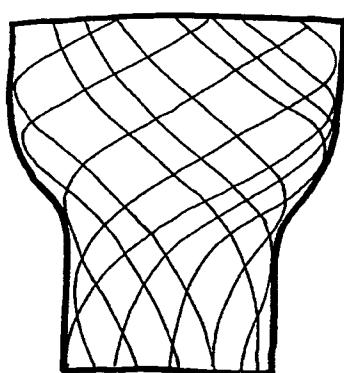


FIGURE 8

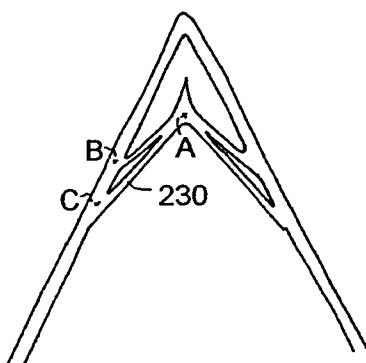


FIGURE 9

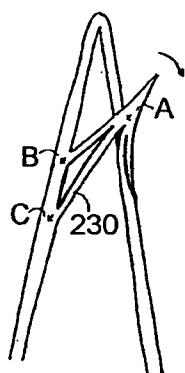
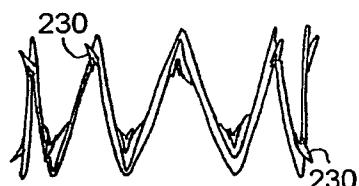


FIGURE 10



FIGURE 11



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FIGURE 12

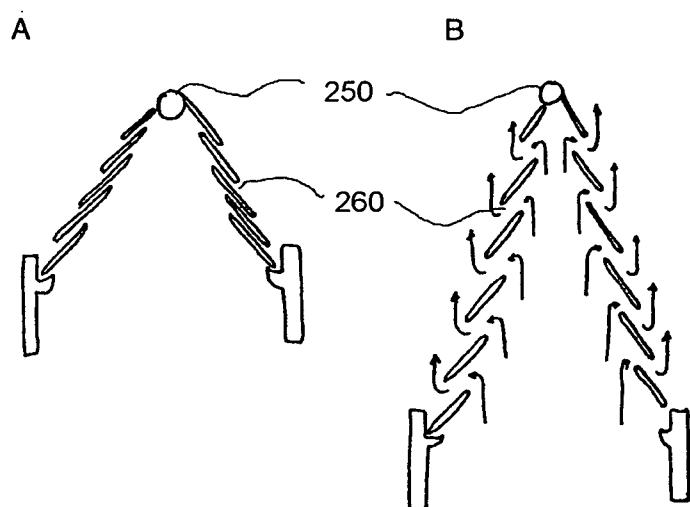
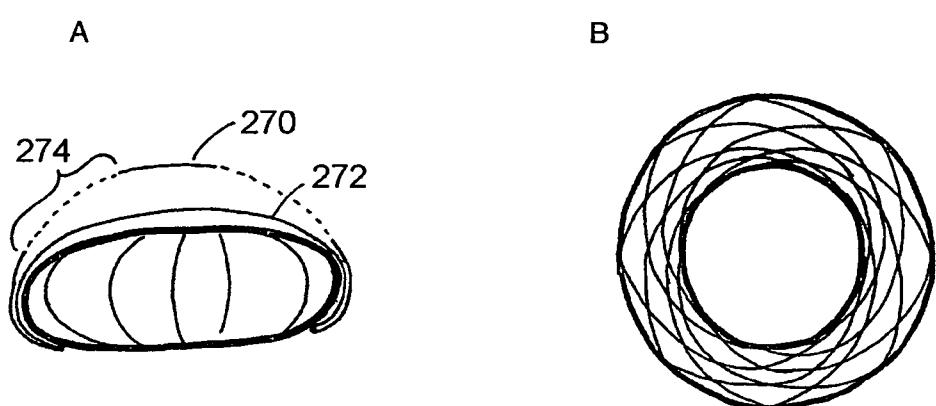


FIGURE 13



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FIGURE 14

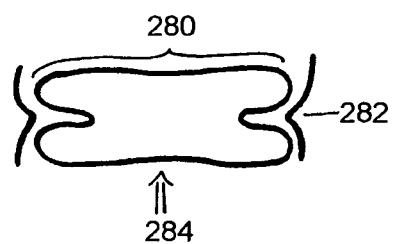


FIGURE 15

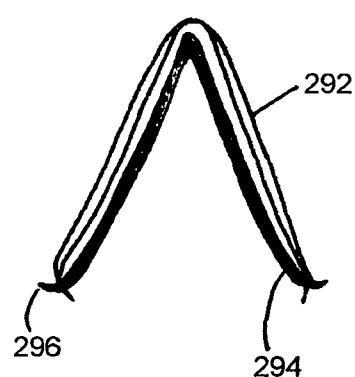
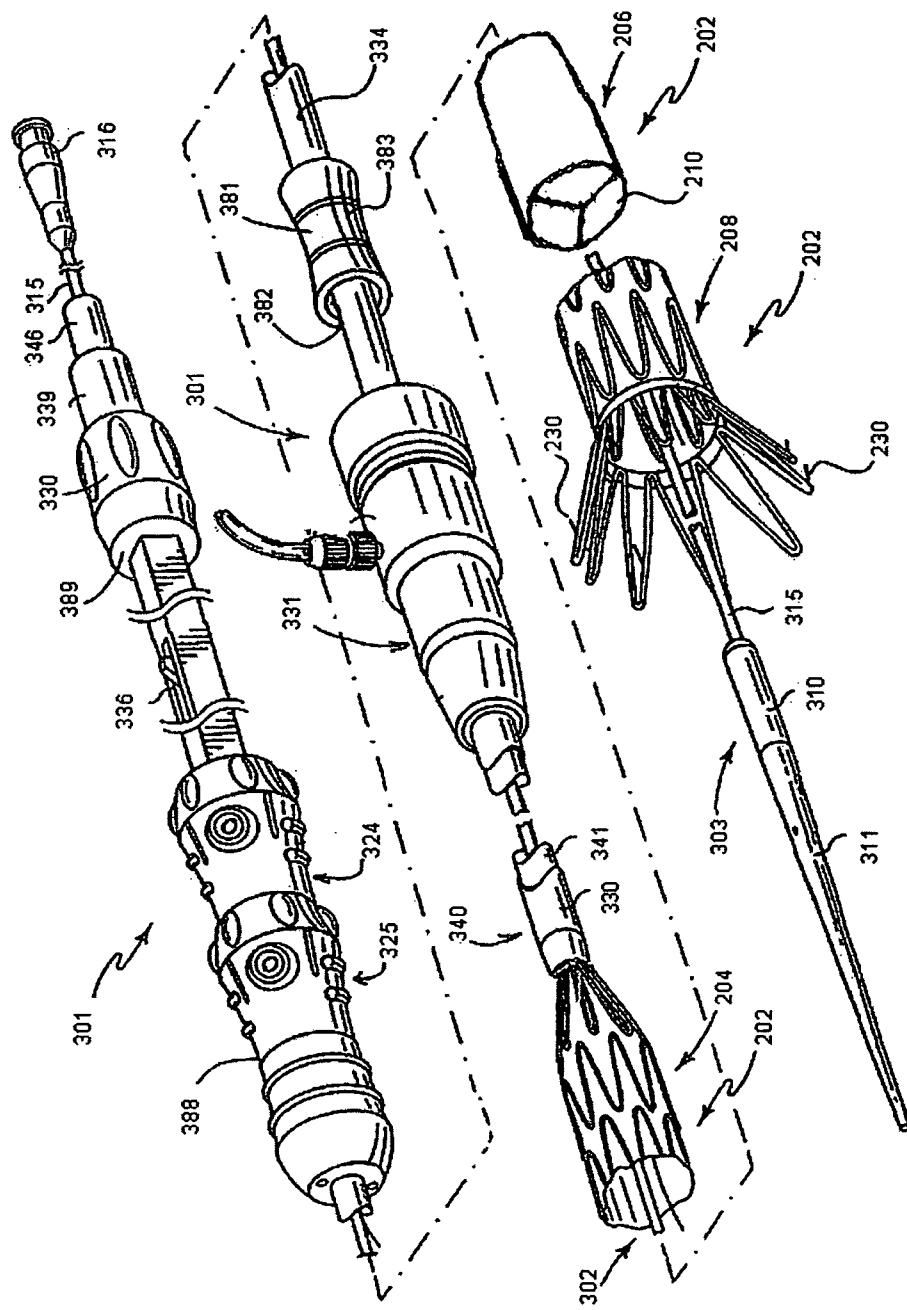


FIGURE 16



INTERNATIONAL SEARCH REPORT

| |
|------------------------------|
| International application No |
| PCT/US2008/012500 |

| |
|-------------------------------------|
| A. CLASSIFICATION OF SUBJECT MATTER |
| INV. A61F2/24 |

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| X | WO 2005/011535 A (COOK INC [US]; CASE BRIAN C [US]; OSBORNE THOMAS A [US]; FLAGLE JACOB) 10 February 2005 (2005-02-10) the whole document ----- | 1-14 |
| X | US 2007/244546 A1 (FRANCIS RICHARD W A [US]) 18 October 2007 (2007-10-18) paragraphs [0015] - [0050]; figures 3,4 ----- | 9,10,12, 14 |
| P, X | DE 10 2007 045188 A1 (PEROUSE LAB [FR]) 5 June 2008 (2008-06-05) paragraphs [0001] - [0016], [0087] - [0095]; figures 7-9 ----- | 9,10,12 |

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

29 January 2009

Date of mailing of the international search report

06/02/2009

Name and mailing address of the ISA/

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Authorized officer

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/012500

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 15-20 because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT – Method for treatment of the human or animal body by surgery
2. Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/012500

| Patent document cited in search report | Publication date | Patent family member(s) | | Publication date |
|--|------------------|-------------------------|---|--|
| WO 2005011535 A | 10-02-2005 | US | 2005085900 A1 | 21-04-2005 |
| US 2007244546 A1 | 18-10-2007 | NONE | | |
| DE 102007045188 A1 | 05-06-2008 | BR CN FR US | PI0704886 A 101172055 A 2906454 A1 2008082166 A1 | 13-05-2008 07-05-2008 04-04-2008 03-04-2008 |