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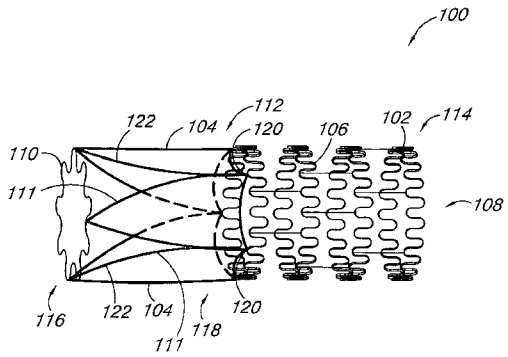

Fig. 1A

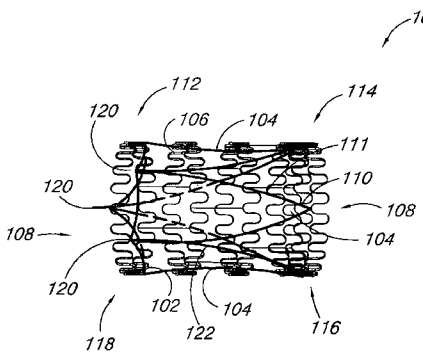

Fig. 1B

(57) Abstract: Apparatus, systems, and methods for percutaneous valve replacement and/or augmentation are provided. The apparatus includes a valve (100) having a valve frame (102), a valve leaflet (104) coupled to the valve frame, and a leaflet transition member (110) coupled to the valve leaflet. The valve leaflet and leaflet transition member can transition from a first position where the valve leaflet and leaflet frame are at least partially outside a lumen of the valve frame to a second position where the valve leaflet and the leaflet transition member are within the lumen of the valve frame.

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Percutaneous Valve, System, and Method

This application claims priority from U.S. Provisional Application Serial No. 60/899,446, filed February 5, 2007, the entire content of which is incorporated herein by reference.

Technical Field

The present disclosure relates generally to apparatus', systems, and methods for use in the vascular system; and more particularly to a percutaneous valve, system, and method for use in the vasculature system.

Background

Valves can become damaged and/or diseased for a variety of reasons. Damaged and/or diseased valves are grouped according to which valve or valves are involved, and the amount of blood flow that is disrupted by the damaged and/or diseased valve. For example, the most common cardiac valve diseases occur in the mitral and aortic valves. Diseases of the tricuspid and pulmonary valves are fairly rare.

The aortic valve regulates the blood flow from the heart's left ventricle into the aorta. The aorta is the main artery that supplies oxygenated blood to the body. As a result, diseases of the aortic valve can have a significant impact on an individual's health. Examples of such diseases include aortic regurgitation and aortic stenosis.

Aortic regurgitation is also called aortic insufficiency or aortic incompetence. It is a condition in which blood flows backward from a widened or weakened aortic valve into the left ventricle of the heart. In its most serious form, aortic regurgitation is caused by an infection that leaves holes in the valve leaflets. Symptoms of aortic regurgitation may not appear for years. When symptoms do appear, it is because the left ventricle must work harder relative to an uncompromised aortic valve to make up for the backflow of blood. The ventricle eventually gets larger and fluid backs up.

Aortic stenosis is a narrowing or blockage of the aortic valve. Aortic stenosis occurs when the valve leaflets of the aorta become coated with deposits. The deposits change the shape of the leaflets and reduce blood flow through the valve. Again, the left ventricle has to work harder relative to an uncompromised aortic valve to make up for the reduced blood flow. Over time, the extra work can weaken the heart muscle.

Brief Description of the Drawings

Figures 1A-1B provide an embodiment of a valve of the present disclosure.

Figures 2A-2B provide an embodiment of a valve of the present disclosure.

Figures 3A-3C illustrate an embodiment of a system according to the present disclosure.

Detailed Description

Embodiments of the present disclosure are directed to an apparatus, a system, and a method for percutaneous valve replacement and/or augmentation. For example, the apparatus can include a valve that can be used to replace an incompetent valve (e.g., an aortic valve, a mitral valve, a tricuspid valve, or a pulmonary valve) or vein in a body lumen. Embodiments of the valve include a valve frame having frame members that define a lumen, and a valve leaflet coupled to the valve frame.

In the various embodiments, the valve leaflets extend away from the lumen of the valve. This configuration allows for more flexibility in the valve frame design as well as the valve leaflet design since the valve is not delivered to a treatment site with the valve leaflets inside the valve frame. In addition to more flexibility in design, this configuration allows for a lower profile of the delivered valve since the valve leaflets are outside the valve frame, allowing the valve frame to be compressed to a greater degree. For example, the valve frame can be at least partially balloon deployed without compressing, or sandwiching, the valve leaflets between the inflatable balloon and the valve frame. Once the valve frame is deployed, the valve leaflets and valve frame can be transitioned to within the lumen of the valve frame and the leaflet transition member can be expanded to secure the leaflet transition member and the valve leaflets into a position to function as a valve. Embodiments of the present disclosure can be used as a prosthetic cardiac valve and/or a prosthetic venous valve, as well as other valves.

The figures herein follow a numbering convention in which the first digit or digits correspond to the drawing figure number and the remaining digits identify an element or component in the drawing. Similar elements or components between different figures may be identified by the use of similar digits. For example, 110 may reference element "10" in Fig. 1, and a similar element may be referenced as 210 in Fig. 2. As will be appreciated, elements shown in the various embodiments herein

can be added, exchanged, and/or eliminated so as to provide any number of additional embodiments of valve and/or system. In addition, as will be appreciated the proportion and the relative scale of the elements provided in the figures are intended to illustrate the embodiments of the present invention, and should not be taken in a limiting sense.

Various embodiments of the present disclosure are illustrated in the figures. Generally, the valve can be implanted within the fluid passageway of a body lumen, for example, for replacement or augmentation of a valve structure within the body lumen (e.g., an aortic valve), to regulate the flow of a bodily fluid through the body lumen in a single direction.

Figures 1A and 1B provide an embodiment of a valve 100 of the present disclosure. Figure 1A illustrates the valve 100 with the valve leaflet 104 in a first position, while Figure 1B illustrates the valve 100 with the valve leaflet 104 in a second position. The valve 100 includes a valve frame 102 and a valve leaflet 104 coupled to the valve frame 102. The valve frame 102 also includes frame members 106 that define a lumen 108. The valve 100 also includes a leaflet transition member 110 coupled to at least a portion of the valve leaflet 104.

As discussed herein, Figure 1A illustrates the valve leaflet 104 and leaflet transition member 110 in a first position, where the valve leaflet 104 and leaflet transition member 110 are at least partially outside the lumen 108 of the valve frame 102 and extend away from the lumen 108. The valve leaflet 104 can also include a leaflet frame 111 that is coupled to a portion of the peripheral edge 122 of the valve leaflet 104. In some embodiments, the leaflet frame 111 can have a U-shape, leaving a portion of a distal end 118 of the valve leaflet 104 free to move between an open and closed position to function as a valve.

In some embodiments, the leaflet frame 111 can be coupled to the leaflet transition member 110. For example, the leaflet frame 111 can be hinged to the leaflet transition member 110 to allow the leaflet transition member 110 to move inside the leaflet frame 111 and invert the leaflet frame 111 from the first position, as shown in Figure 1A, to the second position, as shown in Figure 1B. The valve leaflet 104 can be coupled to the leaflet frame 111 in a variety of ways including sewing, suturing, and/or arc welding, among other methods.

In some embodiments, the valve frame 102 can have an elongate tubular structure with a proximal end 112 and a distal end 114. In some embodiments,

portions of the frame members 106 can define the proximal and distal ends 112, 114 of the valve frame 102. In addition, the valve leaflet 104 can have a proximal end 116 and a distal end 118, where a portion of the distal end 118 of the valve leaflet 104 can be coupled adjacent to the proximal end 112 of the valve frame 102 at junction points 120. As used herein, "junction points" refer to places on the valve frame 102 where the valve leaflet 104 is coupled to the valve frame 102. In some embodiments, the junction points 120 can be located at a number of different positions on the valve frame 102. In some embodiments, the junction points 120 can be located at the same relative position around the valve frame 102. For example, when a valve 100 includes two valve leaflets 104, the junction points 120 can be set opposite each other in a mirror image relationship.

In embodiments where there are more than two leaflets 104, the junction points 120 can be set along the valve frame 102 at positions that are equidistant from each other. This aspect of the disclosure is illustrated in Figure 1, which shows the valve 100 with three valve leaflets 104 having three junction points 120 set on the valve frame 102 at positions that are equidistant from each other. Alternatively, the junction points 120 can be at different relative locations along the valve frame 102. For the various embodiments, the junction points 120 can be located on the valve frame 102 such that the valve leaflet 104 can transition from a first position as shown in Figure 1A to a second position shown in Figure 1B, as will be discussed herein.

As illustrated in Figure 1A, the valve 100 can include the leaflet transition member 110 coupled to at least a portion of the valve leaflet 104 and/or the leaflet frame 111. In some embodiments, the leaflet transition member 110 can be a ring structure that is coupled to the proximal end 116 of the valve leaflet 104. The leaflet transition member 110 can be expandable from a first diameter to a second diameter. As shown in Figure 1A, the leaflet transition member 110 in the first position can have the first diameter. In various embodiments, the leaflet transition member 110 can have a serpentine shape in order to allow the leaflet transition member 110 to expand from the first diameter to the second diameter. The leaflet transition member 110 can also have other shapes, for example, the leaflet transition member 110 can include leaflet transition member 110 portions that can form a coil. The coil portions can allow the leaflet transition member 110 to have a first diameter in the first position and expand to a second diameter. The leaflet transition member 110 can also have other shapes.

In some embodiments, the leaflet transition member 110 can be formed of a shape-memory material. Examples of shape-memory materials include shape memory plastics, polymers, thermoplastic materials, and metal-alloys which are inert in the body. Some shape-memory materials, (e.g., nickel-titanium alloys) can be temperature-sensitive and change shape at a designated temperature or temperature range. Shape memory metal-alloys are generally made from nickel and titanium in specific ratios, commonly known as Nitinol. Other materials are also possible.

Figure 1B provides an embodiment of a valve 100 of the present disclosure when the valve leaflets 104 and leaflet frame 110 are in the second position. As illustrated, the valve leaflet 104 and leaflet transition member 110 can transition from the first position to the second position by pivoting the valve leaflet 104 inside the valve frame 102 at the junction points 120. In the second position, the proximal end 116 of the valve leaflet 104 and at least a portion of the leaflet transition member 110 are within the lumen 108 of the valve frame 102. In some embodiments, the leaflet transition member 110 in the second position can be coupled adjacent to the distal end 114 of the valve frame 102, for example, the leaflet transition member 110 can be coupled to frame members 106 on the distal end 114 of the valve frame 102.

As discussed herein, the leaflet transition member 110 can expand from a first diameter to a second diameter. The leaflet transition member 110 can expand to the second diameter to secure the leaflet frame 110 to the valve frame 102 and/or to secure the leaflet transition member 110 in the second position. As illustrated in Figure 1B, the leaflet transition member 110 can have a serpentine shape to allow the leaflet transition member 110 to expand, however, the serpentine shape can also allow portions of the leaflet transition member 110 to expand through the valve frame 102 and between the frame members 106. By expanding through the valve frame 102 and between the frame members, the leaflet transition member 110 can be held in the second position.

For the various embodiments, the valve frame 102 can be formed of a balloon expandable material, as discussed herein. The valve frame 102 can also be formed of a material with a spring bias. The valve frame 102 can also be a shape memory material, as discussed herein. Other materials are also possible.

For the various embodiments, the frame members 106 and/or the leaflet transition member 110 can have similar and/or different cross-sectional geometries along their length. The similarity and/or the differences in the cross-sectional

geometries can be selected based on one or more desired functions to be elicited from each portion of the valve frame 102. Examples of cross-sectional geometries include rectangular, non-planar configuration (e.g., bent), round (e.g., circular, oval, and/or elliptical), polygonal, arced, and tubular. Other cross-sectional geometries are possible.

The valve 100 can further include one or more radiopaque markers (e.g., tabs, sleeves, welds). For example, one or more portions of the valve frame 102 can be formed from a radiopaque material. Radiopaque markers can be attached to and/or coated onto one or more locations along the valve frame 102. Examples of radiopaque material include, but are not limited to, gold, tantalum, and platinum. The position of the one or more radiopaque markers can be selected so as to provide information on the position, location, and orientation of the valve 100 during its implantation.

The valve 100 further includes the leaflets 104 having surfaces defining a reversibly sealable opening for unidirectional flow of a liquid through the valve 100. Each of the valve leaflets 104 are coupled to the valve frame 102, where the leaflets 104 can repeatedly move between an open state and a closed state for unidirectional flow of a liquid through a lumen of the valve 100. For example, the leaflets 104 can be coupled to the proximal end 112 of the valve frame 102 so as to span and control fluid flow through the lumen of the valve 100. For the present embodiment, the valve 100 includes three of the valve leaflets 104 for a tri-leaflet configuration. As appreciated, mono-leaflet, bi-leaflet and/or other multi-leaflet configurations are also possible.

In some embodiments, the leaflets 104 can be derived from autologous, allogeneic or xenograft material. As will be appreciated, sources for xenograft material (e.g., cardiac valves) include, but are not limited to, mammalian sources such as porcine, equine, and sheep. Additional biologic materials from which to form the valve leaflets 104 include, but are not limited to, explanted veins, pericardium, facia lata, harvested cardiac valves, bladder, vein wall, various collagen types, elastin, intestinal submucosa, and decellularized basement membrane materials, such as small intestine submucosa (SIS), amniotic tissue, or umbilical vein.

Alternatively, the leaflets 104 can be formed from a synthetic material. Possible synthetic materials include, but are not limited to, expanded polytetrafluoroethylene (ePTFE), polytetrafluoroethylene (PTFE), polystyrene-

polyisobutylene-polystyrene (SIBS), polyurethane, segmented poly(carbonate-urethane), polyester, polyethylene (PE), polyethylene terephthalate (PET), silk, urethane, Rayon, Silicone, or the like. In an additional embodiment, the synthetic material can also include metals, such as stainless steel (e.g., 316L) and nitinol. These synthetic materials can be in a woven, a knit, a cast or other known physical fluid-impermeable or permeable configurations. In addition, gold plated metals can be embedded in the leaflet 104 material (e.g., a sandwich configuration) to allow for visualization of the leaflets 104 post placement.

As will be appreciated, the valve 100 can be treated and/or coated with any number of surface or material treatments. Examples of such treatments include, but are not limited to, bioactive agents, including those that modulate thrombosis, those that encourage cellular ingrowth, throughgrowth, and endothelialization, those that resist infection, and those that reduce calcification.

Figures 2A and 2B provide an embodiment of a valve 200 of the present disclosure. As discussed herein, the valve 200 includes a valve frame 202 and a valve leaflet 204 coupled to the valve frame 202. The valve frame 202 also includes frame members 206 that define a lumen 208. As shown in Figures 2A and 2B, the valve leaflets 204 can include a leaflet frame 211, as discussed herein, coupled to at least a portion of the peripheral edge 222 of the valve leaflets 204. In such embodiments, the leaflet frame 211 can act as the leaflet transition member 210.

Figure 2A illustrates the valve leaflet 204 and leaflet transition member 210 (i.e., leaflet frame 211) in a first position, where the valve leaflet 204 and leaflet transition member 210 are at least partially outside the lumen 208 of the valve frame 202 and extend away from the lumen 208. Figure 2B illustrates the valve 200 where the valve leaflet 204 and leaflet transition member 210 are in a second position within the lumen 208 of the valve frame 202, as discussed herein.

As shown in Figures 2A and 2B, in some embodiments, the leaflet frame 211 can be coupled to a portion of a peripheral edge 222 of the valve leaflet 204. In such embodiments, the leaflet frame 211 can form the outside boundary of a portion of the valve leaflet 204 and can hold the valve leaflet 204 in a desired position. As discussed herein, the valve leaflet 204 can have a proximal end 216 and a distal end 218, where a portion of the distal end 218 of the valve leaflet 204 can be coupled adjacent to the proximal end 212 of the valve frame 202 at junction points 220. In some embodiments, the valve leaflet 204 can be coupled to the valve frame 202 such

that the valve leaflet 204 can pivot inside the valve frame 302 at the junction points 220.

In other embodiments, the leaflet transition member 210 (i.e., leaflet frame 211) can be coupled to the peripheral edge 222 of the valve leaflet 204 such that the leaflet transition member 210 is coupled to the proximal end 212 of the valve frame 202. In such embodiments, the leaflet transition member 210 can be hinged to a portion of the valve frame 202 to couple the valve frame 202 and the valve leaflet 204. Also, hinging the leaflet transition member 210 to the valve frame 202 can allow the leaflet transition member 210 and the valve leaflet 204 to transition from the first position to the second position, as shown in Figures 2A and 2B.

In addition, as discussed herein, the leaflet transition member 210 can be coupled to the valve frame 202 to hold the leaflet frame 210 in the second position. In such embodiments, the leaflet transition member 210 can include mechanical members 205 to hold the leaflet transition member 210 to the frame members 206 of the valve frame 202. One embodiment of a mechanical member 205 is shown in Figure 2A as a close-up view. In this embodiment, the mechanical member 205 can be in the form of a clip, where a frame member 206 can slide into the clip 205 to secure the leaflet frame 210 to the valve frame 202. In another embodiment, the mechanical member 205 can be a hook that hooks the leaflet transition member 210 to the frame members in several different locations. Other mechanical member 205 configurations are also possible.

Figures 3A-3C illustrate an embodiment of a system 324 according to the present disclosure. The system 324 includes a valve 300, as described herein, releasably joined to an elongate delivery catheter 326 and an expandable balloon 328 positioned around at least a portion of the elongate delivery catheter 326. The system 324 also includes a retractable sheath 330 positioned around at least a portion of the elongate delivery catheter 326. Also, a portion of the valve 300 is positioned between the elongate delivery catheter 326 and the retractable sheath 330. For example, Figure 3A illustrates an embodiment in which the retractable sheath 330 is positioned around at least a portion of the delivery catheter 326 to releasably hold the leaflet transition member 310 in a delivery state.

In some embodiments, the retractable sheath 330 can be positioned such that the retractable sheath holds the valve frame 302 and the leaflet transition member 310 in a delivery state. In such embodiments, the retractable sheath 330 can be partially

retracted to allow the valve frame 302 to be radially expanded while holding the leaflet transition member 310 in the delivery state. Figure 3B illustrates an embodiment in which valve 300 has expanded to its deployed state, as discussed herein.

In the embodiments illustrated in Figures 3A-3C, the delivery catheter 326 includes an elongate body having a proximal end 332 and a distal end 334. A catheter lumen 336 can extend through the proximal and distal ends 332, 334. In some embodiments, the catheter lumen 336 can receive a guidewire for guiding the placement of the valve 300 in the vasculature.

In some embodiments, the elongate delivery catheter 326 can include a distal tip 338. The distal tip 338 can have a conical configuration, where the tip 338 diameter decreases in size to a point at the distal end 334 of the elongate delivery catheter 338. The distal tip 338 can also include a recessed lip 340 in which a distal portion of the retractable sheath 330 can releasably seat. In embodiments including a retractable sheath 330 extending over the valve frame 302, seating the distal portion of the retractable sheath 330 in the recessed lip 340 can help to hold the valve 300 in its delivery state.

In addition, in such embodiments, the retractable sheath 330 can move longitudinally (e.g., slide) relative the delivery catheter 326 to allow the valve 300 to radially expand from its delivery state to its deployed state. In some embodiments, moving the retractable sheath 330 relative the delivery catheter 326 can be accomplished by pulling a proximal end 342 of the sheath 330 relative a proximal end 332 of the delivery catheter 326.

Figure 3B illustrates an embodiment where the valve 300 has been radially expanded. In some embodiments, the valve 300 can be balloon expandable. In other embodiments, the retractable sheath 330, if positioned over the valve frame 302, can be retracted relative the valve 300 to allow the valve 300 to be radially expanded using the expandable balloon 328. In such embodiments, the elongate delivery catheter 326 can include a lumen fluidly attached to the expandable balloon 328 to allow the balloon 328 to be filled with fluid to radially expand the balloon 328, and thus the valve 300.

In some embodiments, the valve 300 can be formed of a material with a spring bias, where the valve 300 can expand when the sheath 330 has been removed. In such embodiments, the expandable balloon 328 can be used to position the valve 300

and/or secure the valve 300 inside a body lumen. Examples of materials with a spring bias can include, but are not limited to, medical grade stainless steel (e.g., 316L), titanium, tantalum, platinum alloys, niobium alloys, cobalt alloys, alginate, or combinations thereof.

In some embodiments, the expandable balloon 328 can be a perfusion balloon. A perfusion balloon can be used to radially expand the valve frame 302 while allowing fluid, for example, blood, to pass through the delivery catheter 326 and valve 300 while the valve 300 is being positioned in the vasculature.

In the embodiment illustrated in Figures 3A-3C, the valve 300 includes a valve frame 302 having frame members defining a lumen 308, a valve leaflet 304 attached to a portion of the valve frame 302, and a leaflet transition member 310 attached to at least a portion of the valve leaflet 304. Figure 3A illustrates an embodiment where the valve leaflet 304 and leaflet transition member 310 are in a first position extending away from the lumen 308 of the valve 300. Although the embodiments illustrated in Figures 3A-3C show a valve 300 including a leaflet transition member 310 and a leaflet frame 311, the present disclosure includes embodiments where the leaflet frame 310 acts as the leaflet transition member 310, as discussed herein.

To transition the valve leaflets 304 and leaflet transition member 310 from the first position to a second position within the lumen 308 of the valve frame 302, the elongate delivery catheter 326 can include a number of elongate push members 344 releasably coupled to the leaflet transition member 310. The elongate push members 344 can be positioned around the elongate delivery catheter 326, and can be used to push the leaflet transition member 310 inside the lumen 308 of the valve 300.

In some embodiments, the elongate push members 344 can move in a longitudinal direction relative the elongate delivery catheter 326. The elongate push members 344 can be formed of a plastic material, where the elongate push members 344 are moved into the lumen 308 of the valve 300 to push the leaflet transition member 310 and the valve leaflet 304 from the first position to the second position. The elongate push members 344 can also be formed of different materials. For example, the elongate push members 344 can be formed of a wire or thread releasably attached to the leaflet transition member 310. As such, as the elongate push members 344 are moved into the lumen 308 of the valve 300, the elongate push members 344 would pull the leaflet transition member 310 and the valve leaflet 304 from the first

position to the second position. Other methods of transitioning the leaflet transition member 310 and the valve leaflet 304 from the first position to the second position are also possible.

As discussed herein, Figure 3B illustrates an embodiment where the valve frame 302 is radially expanded. Also shown is how the leaflet transition member 310 can remain in a contracted state while the valve frame 302 is expanded. In some embodiments, the leaflet transition member 310 can be formed of a shape-memory material, such as a nickel-titanium alloy, where the leaflet transition member 310 and/or leaflet frame 311 is restrained in a contracted state by the retractable sheath 330.

In some embodiments, the leaflet transition member 310 is formed of a shape memory material, as discussed herein. In such embodiments, the retractable sheath 330 can be used to hold the leaflet transition member 310 in the first position while the valve frame 302 is radially expanded.

Figure 3B also illustrates how a portion of the leaflet frame 311 can expand when the valve frame 302 is radially expanded. In some embodiments, the leaflet frame 311 can be coupled to the proximal end 312 of the valve frame 302 such that when the valve frame 302 is radially expanded, the leaflet frame 311 is coupled to the valve frame 302 at junction points 320 that are equidistant apart, as discussed herein.

In addition, in some embodiments, the leaflet frame 311 can be formed of a shape memory material to allow the leaflet frame 311 to deform when the valve frame 302 is expanded and the leaflet transition member 310 is held in the delivery state. In such embodiments, once the valve frame 302 is expanded and the valve leaflet 304 and leaflet transition member 310 are in the second position, the leaflet frame 311 can transition to a deployed state to hold the valve leaflet 304 in a position to act as a valve.

As discussed herein, the number of elongate push members 344 can be used to push the leaflet transition member 310 inside the lumen 308 of the valve frame 302 to place the valve leaflet 304 and leaflet transition member 310 into the second position. Once the leaflet transition member 310 is inside the lumen 308, the leaflet transition member 310 can be radially expanded inside the valve frame 302 and the number of elongate members 344 can be released from the leaflet transition member 310. In some embodiments, the leaflet transition member 310 can be formed of a material with a spring bias, as discussed herein, and expand when the retractable sheath 330 is

retracted relative the valve 300 to release the leaflet transition member 310 while the elongate push members 344 hold the leaflet transition member 310 in place within the lumen 308 of the valve 300. Once the leaflet transition member 310 is expanded, the elongate push members 344 and the delivery catheter 326 can be retracted through the valve 300.

Alternatively, in embodiments where the leaflet transition member 310 is formed of a shape memory material, the leaflet frame 310 can radially expand when the retractable sheath 330 is retracted relative the valve 300 and the leaflet transition member 310 warms to a certain temperature, for example, at or below normal body temperature (e.g., 37 degrees Celsius).

Figure 3C illustrates an embodiment of the valve frame 302 radially expanded, where the valve leaflet 304 and leaflet transition member 310 are in the second position. As illustrated, once the leaflet transition member 310 and the valve frame 302 are expanded, the expandable balloon 328 and distal tip 338 can be retracted through the lumen 308 of the valve frame 302.

In some embodiments, the leaflet transition member 310 can be secured to the valve frame 302 once the leaflet transition member 310 is in the second position and both the leaflet transition member 310 and the valve frame 302 are radially expanded. For example, as discussed herein, the leaflet transition member 310 can expand from a first diameter to a second diameter where portions of the leaflet transition member 310 extend through the valve frame 302 and between the frame members 306 to secure the leaflet transition member 310 in the second position. In other embodiments, the leaflet transition member 310 and/or leaflet frame 311 can include mechanical members, as discussed herein, to secure the leaflet transition member 310 and/or leaflet frame 311 to the valve frame 302. A combination of mechanical members and expanding the leaflet transition member 310 to extend portions of the leaflet transition member 310 through the valve frame 302 and between the frame members 306 is also possible.

Embodiments of the system 324 can further include an expandable filter that forms a portion of the retractable sheath. Examples of such an embodiment can be found in U.S. Provisional Patent application 60/899,444 and co-pending US Patent Application No. __/___,___ entitled "Percutaneous Valve, System and Method" (docket number 07-00015US), both of which are hereby incorporated by reference in their entirety.

Each of the delivery catheter 326, the retractable sheath 330, and/or the second retractable sheath 346 can be formed of a number of materials. Materials include polymers, such as PVC, PE, POC, PET, polyamide, mixtures, and block co-polymers thereof. In addition, each of the delivery catheter 326, the retractable sheath 330, and/or the second retractable sheath 346 can have a wall thickness and an inner diameter sufficient to allow the structures to slide longitudinally relative each other, as described herein, and to maintain the valve 300 in a delivery state, as discussed herein.

In an additional embodiment, the valve 300 can further include a sealing material 348 positioned on the periphery of the valve frame 302. In one embodiment, once implanted the sealing material 348 can swell due the presence of liquid to occupy volume between the valve frame 302 and the tissue on which the valve 300 has been implanted so as to prevent leakage of the liquid around the outside of the valve 300.

Embodiments can also include a sealing material positioned on a portion of the peripheral edge 322 of the leaflet frame 311 to seal the leaflet frame 311 to the valve frame 302.

A variety of suitable materials for the sealing material 348 are possible. For example, the sealing material 348 can be selected from the general class of materials that include polysaccharides, proteins, and biocompatible gels. Specific examples of these polymeric materials can include, but are not limited to, those derived from poly(ethylene oxide) (PEO), poly(ethylene glycol) (PEG), poly(vinyl alcohol) (PVA), poly(vinylpyrrolidone) (PVP), poly(ethyloxazoline) (PEOX) polyaminoacids, pseudopolyamino acids, and polyethyloxazoline, as well as copolymers of these with each other or other water soluble polymers or water insoluble polymers. Examples of the polysaccharide include those derived from alginate, hyaluronic acid, chondroitin sulfate, dextran, dextran sulfate, heparin, heparin sulfate, heparan sulfate, chitosan, gellan gum, xanthan gum, guar gum, water soluble cellulose derivatives, and carrageenan. Examples of proteins include those derived from gelatin, collagen, elastin, zein, and albumin, whether produced from natural or recombinant sources.

In an additional embodiment, the valve 300 of the present disclosure can include anchoring members attached to the valve frame 302 or frame members 306. Anchoring members can include barbs, hooks, etc.

The embodiments of the valve described herein may be used to replace, supplement, or augment valve structures within one or more lumens of the body. For example, embodiments of the present invention may be used to replace an incompetent cardiac valve of the heart, such as the aortic, pulmonary and/or mitral valves of the heart. In one embodiment, the native cardiac valve can either remain in place or be removed (e.g., via a valvoplasty procedure) prior to implanting the cardiac valve of the present disclosure.

In addition, positioning the system having the valve as discussed herein includes introducing the system into the cardiovascular system of the patient using minimally invasive percutaneous, transluminal techniques. For example, a guidewire can be positioned within the cardiovascular system of a patient that includes the predetermined location. The system of the present disclosure, including the valve as described herein, can be positioned over the guidewire and the system advanced so as to position the valve at or adjacent the predetermined location. In one embodiment, radiopaque markers on the catheter and/or the valve, as described herein, can be used to help locate and position the valve.

The valve can be deployed from the system at the predetermined location in any number of ways, as described herein. In one embodiment, valve of the present disclosure can be deployed and placed in any number of cardiovascular locations. For example, valve can be deployed and placed within a major artery of a patient. In one embodiment, major arteries include, but are not limited to, the aorta. In addition, valves of the present invention can be deployed and placed within other major arteries of the heart and/or within the heart itself, such as in the pulmonary artery for replacement and/or augmentation of the pulmonary valve and between the left atrium and the left ventricle for replacement and/or augmentation of the mitral valve. Other locations are also possible.

Once implanted, the valve can provide sufficient contact with the body lumen wall to prevent retrograde flow between the valve and the body lumen wall, and to securely located the valve and prevent migration of the valve. The valve described herein also displays sufficient flexibility and resilience so as to accommodate changes in the body lumen diameter, while maintaining the proper placement of valve. As described herein, the valve can engage the lumen so as to reduce the volume of retrograde flow through and around valve. It is, however, understood that some

leaking or fluid flow may occur between the valve and the body lumen and/or through valve leaflets.

While the present invention has been shown and described in detail above, it will be clear to the person skilled in the art that changes and modifications may be made without departing from the spirit and scope of the invention. As such, that which is set forth in the foregoing description and accompanying drawings is offered by way of illustration only and not as a limitation. The actual scope of the invention is intended to be defined by the following claims, along with the full range of equivalents to which such claims are entitled. In addition, one of ordinary skill in the art will appreciate upon reading and understanding this disclosure that other variations for the invention described herein can be included within the scope of the present invention.

In the foregoing Detailed Description, various features are grouped together in several embodiments for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted as reflecting an intention that the embodiments of the invention require more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive subject matter lies in less than all features of a single disclosed embodiment. Thus, the following claims are hereby incorporated into the Detailed Description, with each claim standing on its own as a separate embodiment.

Claims

What is claimed:

1. A valve (100), comprising:

a valve frame (102) having a lumen (108);

a valve leaflet (104) attached to a portion of the valve frame (102);

a leaflet transition member (110) attached to at least a portion of the valve leaflet (104), where the valve leaflet (104) and leaflet transition member (110) extend away from the lumen (108) in a first position and transition into a second position in which the valve leaflet (104) and leaflet transition member (110) are inside the lumen (108) of the valve frame (102).

2. The valve (100) of claim 1, where the valve leaflet (104) has a distal end (118) and a proximal end (116), where a portion of the distal end (118) of the valve leaflet (104) is attached adjacent to a proximal end (112) of the valve frame (102).

3. The valve (100) of claim 2, where in the first position the valve leaflet (104) and the leaflet transition member (110) are at least partially outside the lumen (108) of the valve frame (102) with the proximal end (116) of the valve leaflet (104) extending away from both a distal end (114) and a proximal end (112) of the valve frame (102), and where the valve leaflet (104) and leaflet transition member (110) transition from the first position to the second position in which the proximal end (116) of the valve leaflet (104) and at least a portion of the leaflet transition member (110) are within the lumen (108) of the valve frame (102).

4. The valve (100) of claims 1-3, where the leaflet transition member (110) in the second position is coupled to frame members (106).

5. The valve (100) of claims 1-4, where the leaflet transition member (110) expands from a contracted state in the first position to an expanded state in the second position.

6. The valve (100) of claim 5, where the leaflet transition member (110) has a serpentine shape in the contracted state in order to expand from a first diameter to a second diameter in the expanded state.

7. The valve (100) of claims 1-6, where the valve frame (102) includes frame members (106) defining the lumen (108) and the leaflet transition member (110) in the expanded state includes at least a portion of the leaflet transition member (110) that is expanded between the frame members (106) to secure the leaflet transition member (110) in the second position.

8. The valve (100) of claims 1-7, where the leaflet transition member (110) is a ring structure that is coupled to the proximal end (116) of the valve leaflet (104).

9. The valve (100) of claims 1-8, where the valve leaflet (104) includes a leaflet frame (111) coupled to a portion of a peripheral edge (122) of the valve leaflet (104).

10. The valve (100) of claim 9, where the leaflet frame (111) acts as the leaflet transition member (110).

11. A method for deployment of a valve (100), comprising:

radially expanding a valve frame (102) of the valve from a delivery state to a deployed state; and

transitioning a leaflet transition member (110) coupled to a valve leaflet (104) in a first position outside a lumen (108) of the valve frame (102) to a second position inside the lumen (108) of the valve frame (102).

12. The method of claim 11, including coupling at least a portion of the leaflet transition member (110) in the second position to the valve frame (102) in the deployed state.

13. The method of claims 11-12, where transitioning the leaflet transition member (110) in the first position outside the lumen (108) of the valve frame (102) to the second position inside the lumen (108) of the valve frame (102) includes releasing the leaflet transition member (110) from the first position.

14. The method of claims 11-13, including pushing the leaflet transition member (110) in the first position from outside the lumen (108) to the inside of the lumen (108) of the valve frame (102).

15. A system (324), comprising:

an elongate delivery catheter (326);

an expandable balloon (328) positioned around at least a portion of the elongate delivery catheter (326);

a retractable sheath (330) positioned around at least a portion of the elongate delivery catheter (326), where the retractable sheath (330) moves longitudinally relative the elongate delivery catheter (326); and

a valve (100), where a portion of the valve (100) is positioned between the elongate delivery catheter (326) and the retractable sheath (330), and where the valve (100) includes a valve frame (102) having frame members (106) defining a lumen (108), a valve leaflet (104) attached to a portion of the valve frame (102), and a leaflet transition member (110) attached to at least a portion of the valve leaflet (104), where the valve leaflet (104) and leaflet transition member (110) extend away from the lumen (108) of the valve frame (102) in a first position and transition into a second position in which the valve leaflet (104) and leaflet transition member (110) are inside the lumen (108) of the valve frame (102).

16. The system (324) of claim 15, where the portion of the valve (100) positioned between the elongate delivery catheter (326) and the retractable sheath (330) is the leaflet transition member (110) and a portion of the valve leaflet (104).

17. The system (324) of claims 15-16, where the retractable sheath (330) restrains the leaflet transition member (110) in the first position.

18. The system (324) of claims 15-17, further including a number of elongate push members (344) releasably coupled to the leaflet transition member (110) where the elongate push members (344) transition the leaflet transition member (110) and the valve leaflet (104) from the first position to the second position.

19. The system (324) of claims 15-20, where the leaflet transition member (110) is a ring structure coupled to a proximal end (116) of the valve leaflet (104), where the leaflet transition member (110) has a serpentine shape in the first position in order to expand the leaflet transition member (110) from a first diameter to a second diameter.

20. The system (324) of claims 15-21, where the valve leaflet (104) includes a leaflet frame (111) coupled to a portion of a peripheral edge (122) of the valve leaflet (104).

21. The system (324) of claim 20, where the leaflet frame (111) is hinged to a portion of the valve frame (102) to couple the valve frame (102) and valve leaflet (104).

22. A structure for forming a valve (100), comprising:

a valve frame (102) having a distal end (114) and a proximal end (112), and frame members (106) defining a lumen (108);

a valve leaflet (104) having a distal end (118) and a proximal end (116), where a portion of the distal end (118) of the valve leaflet (104) is coupled adjacent to the proximal end (112) of the valve frame (102); and

a leaflet transition member (110) coupled to at least a portion of the valve leaflet (104), where the valve leaflet (104) and the leaflet transition member (110) in a first position are at least partially outside the lumen (108) of the valve frame (102) with the proximal end (116) of the valve leaflet (104) extending away from both the distal end (114) and the proximal end (112) of the valve frame (102).

23. The structure of claim 22, where the valve leaflet (104) and leaflet transition member (110) transition from the first position to a second position in which the proximal end (116) of the valve leaflet (104) and at least a portion of the leaflet transition member (110) are within the lumen (108) of the valve frame (102).

24. The structure of claims 22-23, where the leaflet transition member (110) is a ring structure coupled to the proximal end (116) of the valve leaflet (104).

25. The structure of claims 22-24, where the valve leaflet (104) includes a leaflet frame (111) coupled to a portion of a peripheral edge (122) of the valve leaflet (104), and the leaflet transition member (110) is coupled to the leaflet frame (111).

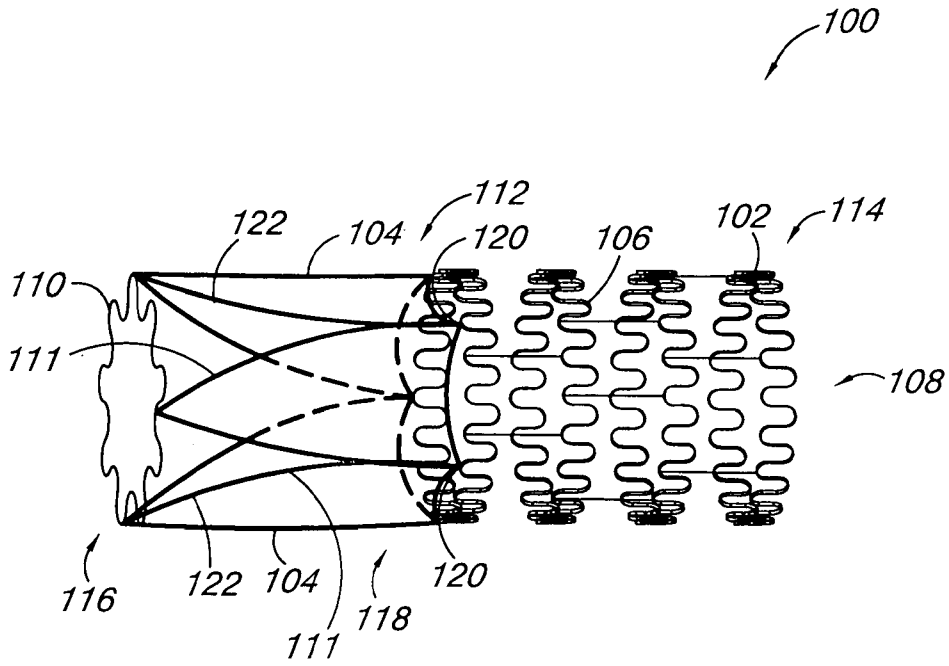
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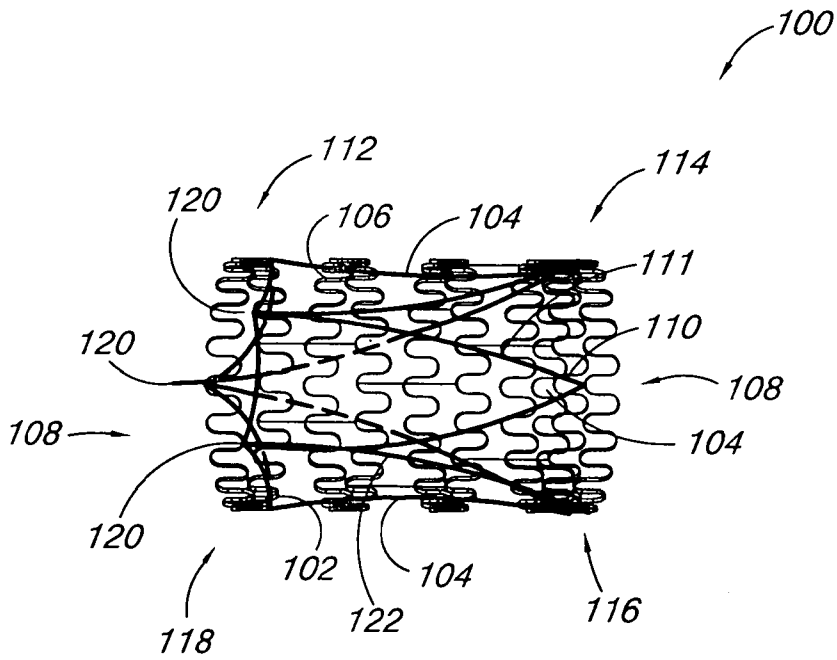
Fig. 1A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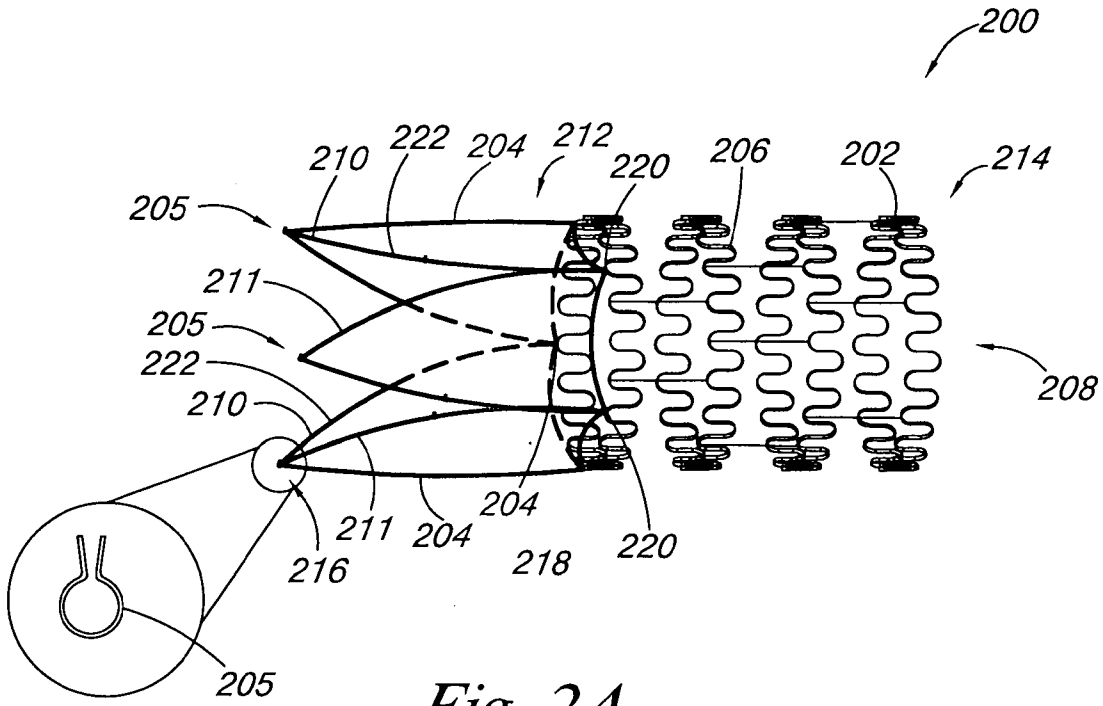
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Fig. 2A

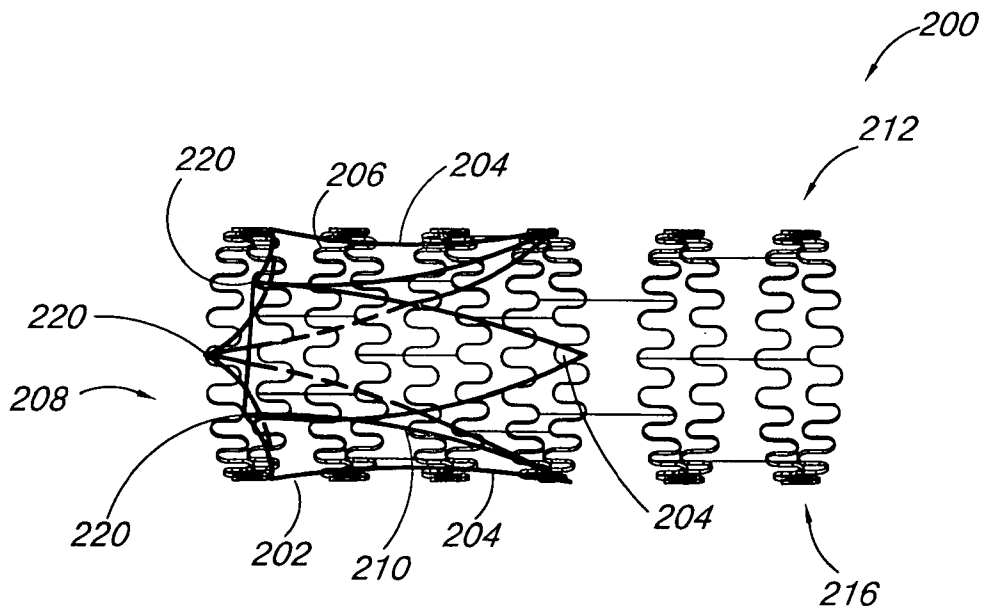
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Fig. 2B

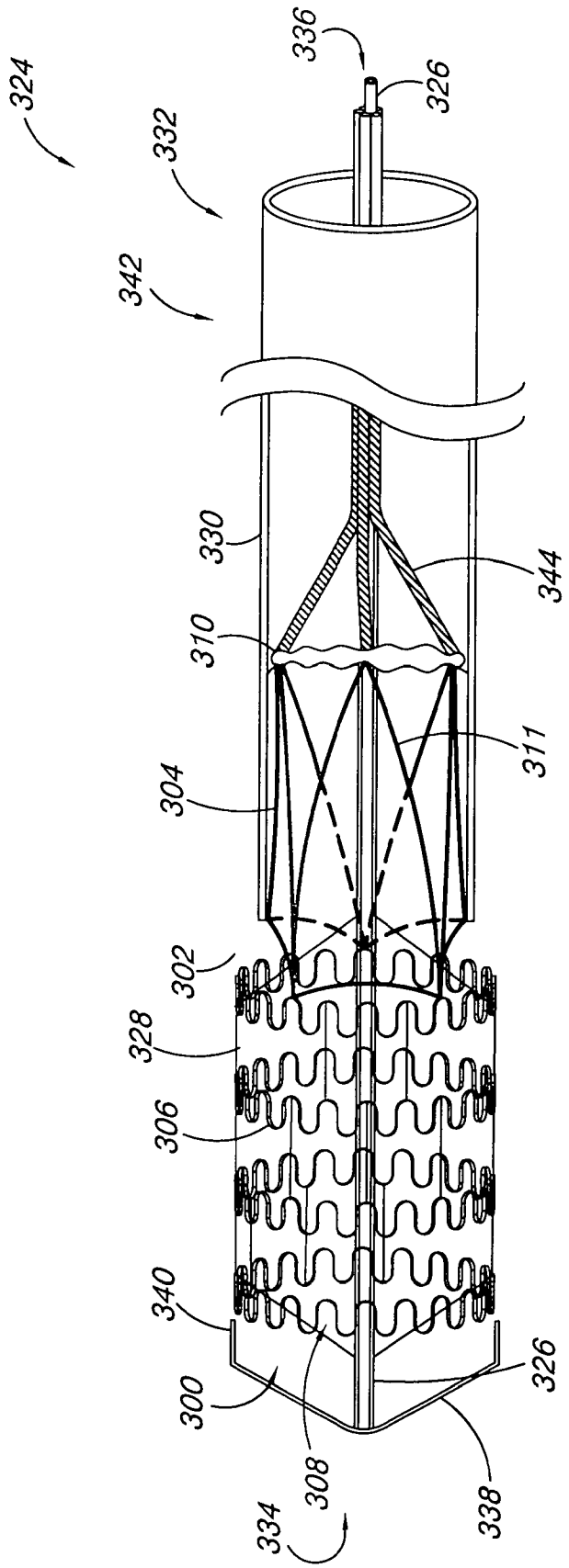
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Fig. 3A

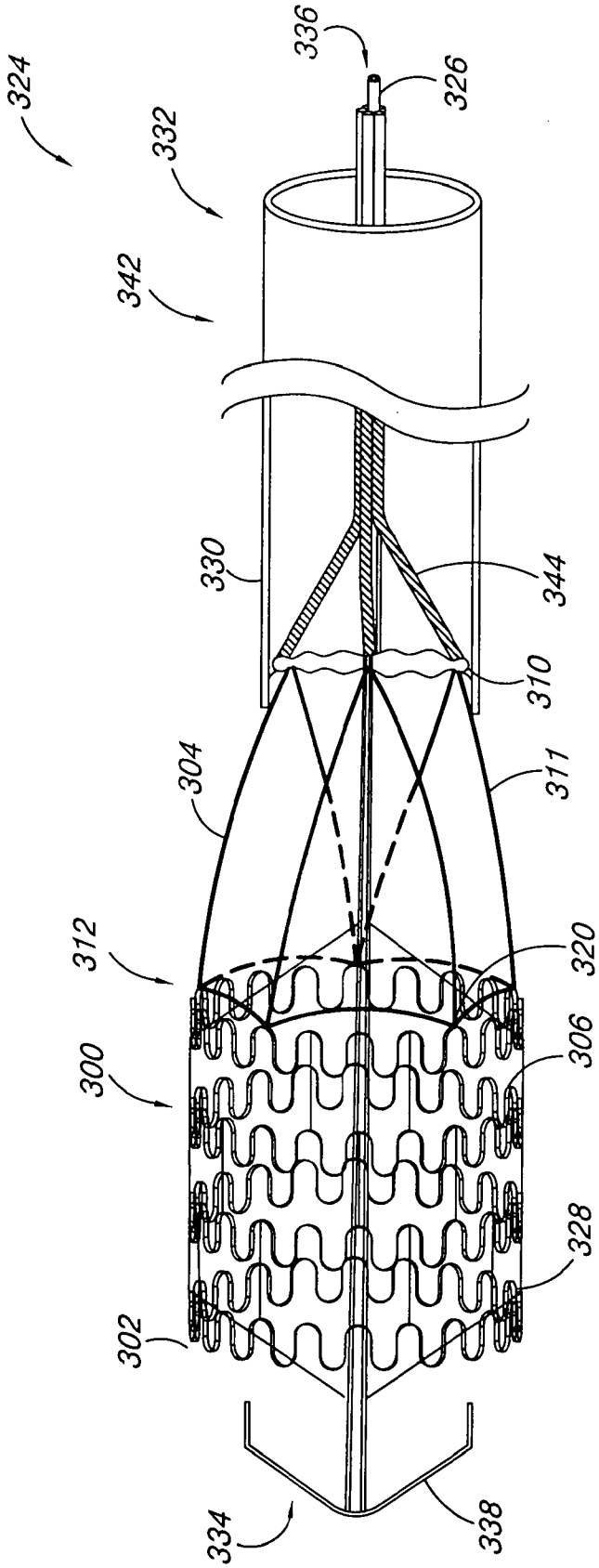
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Fig.3B

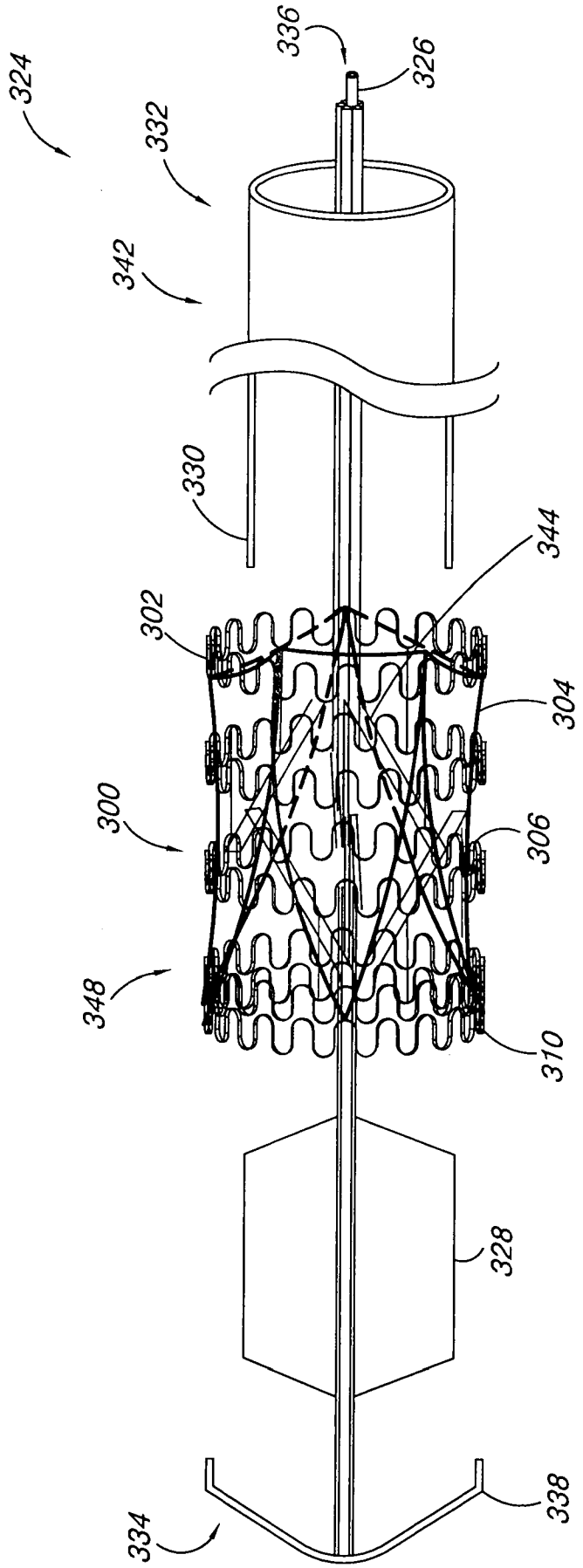

Fig.3C

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/001590

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	US 2005/283231 A1 (HAUG ULRICH R [US] ET AL) 22 December 2005 (2005-12-22) paragraphs [0065], [0152] - [0154]; figures 41-43	1-5,9; 10, 15-17, 20-23,25
X	WO 00/47139 A (HEARTPORT INC [US]) 17 August 2000 (2000-08-17) page 14, line 29 - page 16, line 8; figures 31-38	1-3, 15-17, 22,23

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

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

"E" earlier 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	Date of mailing of the international search report
12 June 2008	02/07/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Prechtel, A

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/001590

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/195180 A1 (KHERADVAR ARASH [US] ET AL) 31 August 2006 (2006-08-31) paragraphs [0049], [0070], [0071], [0077], [0079], [0089]; figures 1-13	1-7,9, 10, 15-17, 20-23,25
A	US 2005/240262 A1 (WHITE JENNIFER K [US]) 27 October 2005 (2005-10-27) paragraphs [0085] - [0093], [0110]; figure 24	1-10, 15-25
A	WO 01/54624 A (3F THERAPEUTICS INC [US]) 2 August 2001 (2001-08-02) the whole document	1-10, 15-25

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/001590

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

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

1. [X] Claims Nos.: 11-14
because they relate to subject matter not required to be searched by this Authority, namely:

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

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

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

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

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

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable 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 reportcovers 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/US2008/001590

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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