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(54) Title: HEART VALVE WITH ANCHORING STRUCTURE HAVING CONCAVE LANDING ZONE

(57) Abstract: A device for reducing paravalvular leakage upon implantation of a replacement heart valve is provided. The valve assembly includes a tissue or bioprosthetic heart valve attached to an anchoring structure. The anchoring structure includes an inlet rim that is substantially C-shaped in cross section to form a concave landing zone. The anchoring structure self-seats when implanted in the sinus of a patient with the proximal and distal ends of the C-shaped inlet rim pushed against the proximal and distal portions of the aortic annulus to effectively prevent paravalvular leakage.

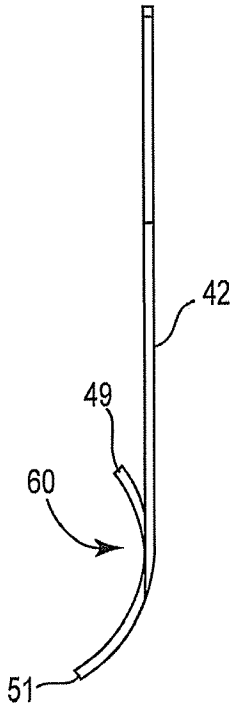

Fig. 5B

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HEART VALVE WITH ANCHORING STRUCTURE HAVING CONCAVE LANDING ZONE

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

[001] The invention relates to an anchoring structure for use in bioprosthetic heart valve replacement systems. More particularly, the invention relates to a pliant bioprosthetic heart valve supported by a tubular anchoring structure with an inflow end that includes a concave landing zone that reduces paravalvular leakage.

DESCRIPTION OF THE RELATED ART

[002] The transport of vital fluids in the human body is largely regulated by valves. Physiological valves are designed to prevent the backflow of bodily fluids, such as blood, lymph, urine, bile, etc., thereby keeping the body's fluid dynamics unidirectional for proper homeostasis. For example, venous valves maintain the upward flow of blood, particularly from the lower extremities, back toward the heart, while lymphatic valves prevent the backflow of lymph within the lymph vessels, particularly those of the limbs.

[003] Because of their common function, valves share certain anatomical features despite variations in relative size. The cardiac valves are among the largest valves in the body with diameters that may exceed 30 mm, while valves of the smaller veins may have diameters no larger than a fraction of a millimeter. Regardless of their size, however, many physiological valves are situated in specialized anatomical structures known as sinuses. Valve sinuses can be described as dilations or bulges in the vessel wall that houses the valve. The geometry of the sinus has a function in the operation and fluid dynamics of the valve. One function is to guide fluid flow so as to create eddy currents that prevent the valve leaflets from adhering to the wall of the vessel at the peak of flow velocity, such as during systole. Another function of the sinus geometry is to generate currents that facilitate the precise closing of the leaflets at the beginning of backflow pressure. The sinus geometry is also important in reducing the stress

exerted by differential fluid flow pressure on the valve leaflets or cusps as they open and close.

[004] Thus, for example, the eddy currents occurring within the sinuses of Valsalva in the natural aortic root have been shown to be important in creating smooth, gradual and gentle closure of the aortic valve at the end of systole. Blood is permitted to travel along the curved contour of the sinus and onto the valve leaflets to effect their closure, thereby reducing the pressure that would otherwise be exerted by direct fluid flow onto the valve leaflets. The sinuses of Valsalva also contain the coronary ostia, which are outflow openings of the arteries that feed the heart muscle. When valve sinuses contain such outflow openings, they serve the additional purpose of providing blood flow to such vessels throughout the cardiac cycle.

[005] When valves exhibit abnormal anatomy and function as a result of valve disease or injury, the unidirectional flow of the physiological fluid they are designed to regulate is disrupted, resulting in increased hydrostatic pressure. For example, venous valvular dysfunction leads to blood flowing back and pooling in the lower legs, resulting in pain, swelling and edema, changes in skin color, and skin ulcerations that can be extremely difficult to treat. Lymphatic valve insufficiency can result in lymphedema with tissue fibrosis and gross distention of the affected body part. Cardiac valvular disease may lead to pulmonary hypertension and edema, atrial fibrillation, and right heart failure in the case of mitral and tricuspid valve stenosis; or pulmonary congestion, left ventricular contractile impairment and congestive heart failure in the case of mitral regurgitation and aortic stenosis. Regardless of their etiology, all valvular diseases result in either stenosis, in which the valve does not open properly, impeding fluid flow across it and causing a rise in fluid pressure, or insufficiency/regurgitation, in which the valve does not close properly and the fluid leaks back across the valve, creating backflow. Some valves are afflicted with both stenosis and insufficiency, in which case the valve neither opens fully nor closes completely.

[006] Because of the potential severity of the clinical consequences of valve disease, numerous surgical techniques may be used to repair a diseased or damaged heart valve. For example, these surgical techniques may include annuloplasty (contracting the valve annulus), quadrangular resection (narrowing the valve leaflets), commissurotomy (cutting the valve commissures to separate the valve leaflets), or decalcification of valve and annulus tissue. Alternatively, the diseased heart valve may be replaced by a prosthetic valve. Where replacement of a heart valve is indicated, the dysfunctional valve is typically removed and replaced with either a mechanical or tissue valve.

[007] In the past, one common procedure has been an open-heart type procedure. However, open-heart valve repair or replacement surgery is a long and tedious procedure and involves a gross thoracotomy, usually in the form of a median sternotomy. In this procedure, a saw or other cutting instrument is used to cut the sternum longitudinally and the two opposing halves of the anterior or ventral portion of the rib cage are spread apart. A large opening into the thoracic cavity is thus created, through which the surgeon may directly visualize and operate upon the heart and other thoracic contents. Replacement heart valves typically include a sewing ring and are sutured into the annulus, resulting in a time intensive surgical procedure. The patient is typically placed on cardiopulmonary bypass for the duration of the surgery.

[008] Minimally invasive valve replacement procedures have emerged as an alternative to open-chest surgery. A minimally invasive medical procedure is one that is carried out by entering the body through the skin or through a body cavity or anatomical opening, but with the smallest damage possible to these structures. Two types of minimally invasive valve procedures that have emerged are percutaneous valve procedures and trans-apical valve procedures. Percutaneous valve procedures pertain to making small incisions in the skin to allow direct access to peripheral vessels or body channels to insert catheters. Trans-apical valve procedures pertain to making a small incision in or near the apex of a heart to allow valve access. The distinction between percutaneous valve procedures and minimally invasive procedures is also highlighted in a recent position statement,

Vassiliades Jr. TA, Block PC, Cohn LH, Adams DH, Borer JS, Feldman T, Holmes DR, Laskey WK, Lytle BW, Mack MF, Williams DO. The clinical development of percutaneous heart valve technology: a position statement of the Society of Thoracic Surgeons (STS), the American Association for Thoracic Surgery (AATS), and the Society for Cardiovascular Angiography and Interventions (SCAI). J Thorac Cardiovasc Surg 2005; 129:970-6).

[009] As valves are implanted less and less invasively, the opportunity for suturing the valves around the annulus is reduced. However, a smaller number of sutures may increase the chance of paravalvular leakage (PVL), i.e. leakage around the valve. A smaller number of sutures may also increase the opportunities for migration and valve stability when placed in-vivo.

[010] Tehrani discloses a superior and inferior o-ring for valve implantation in US Patent Application Publication No. 2006/0271172. Such o-rings cover the entire length of the valve and can therefore not easily be placed within the aortic sinus region. The o-rings presented by Tehrani would also block coronary outflow and adversely affect valve dynamics. The non-circular nature of the o-rings also reduces the radial force needed to adequately conform to irregularities within the implantation site, and is thus not optimal for preventing PVL and migration. The large size of the o-rings disclosed by Tehrani is also not practical as they cannot easily be collapsed down, something that is necessary for minimally invasive valve implantation.

[011] Surgical heart valves include a sewing cuff for direct attachment to the native annulus where the surgeon relies on visual identification to correctly place the inflow ring in the annulus. Minimally invasive heart valves, however, lack any defined feature that interfaces directly with the annulus, instead relying on radial force to hold the valve in position in an attempt to prevent paravalvular leakage. Other conventional designs rely on a "feeler" to locate the native leaflets and when located deploy the valve below the feeler in an attempt to properly seat the valve in the annulus thereby preventing paravalvular leakage. Yet other conventional heart valves rely on a flange construction in which the flange uses double fabric rings to sandwich the device in the native annulus to prevent

paravalvular leakage. However, the double fabric rings require additional surgical time in order for the surgeon to verify that the two rings are placed on opposite sides of the annulus.

[012] In addition, while new less invasive valves produce beneficial results for many patients, these valves may not work as well for other patients who have calcified or irregular annuluses because a tight seal may not be formed between the replacement valve and the implantation site. Therefore, what is needed are methods, systems, and devices for reducing paravalvular leakage around heart valves while preventing valve migration and allowing valve collapsibility.

[013] The invention is directed to solving, or at least reducing, some or all of the aforementioned problems.

BRIEF SUMMARY OF THE INVENTION

[014] The invention provides methods and systems for reducing paravalvular leakage around heart valves. As replacement valve procedures become less and less invasive, the opportunity for suturing the valves around the annulus is reduced. However, minimizing the number of sutures used to secure the replacement valve may increase the chance of paravalvular leakage (PVL), as well as the opportunities for valve migration and valve stability when placed in-vivo.

[015] Leakage associated with a heart valve can be either paravalvular (around the valve) or central (through the valve). Examples of various heart valves include aortic valves, mitral valves, pulmonary valves, and tricuspid valves. Central leakage may be reduced by heart valve design. Paravalvular leakage, on the other hand, may be reduced by creating a seal between the replacement heart valve and the implant site to prevent blood from flowing around the replacement heart valve. It is important that the seal between the replacement heart valve and the implant site does not adversely affect the surrounding tissue. Furthermore, it is important that the seal does not affect the flow dynamics around the replacement heart valve. In the case of the aortic valve, it is also important that the seal does not obstruct coronary flow.

[016] Accordingly, it is one object of the invention to provide methods and devices for preventing paravalvular leakage around a replacement valve, such as a heart valve, while also preventing migration. It should be noted that while reference is made herein to aortic valves, the current invention is not limited to the aortic valve. While replacement valves are typically implanted in native heart valve positions, the replacement valve systems and sealing devices discussed herein may be used to seal any type of in-vivo valve without departing from the intended scope of the invention. Moreover, while the present heart valve with tubular anchoring structure may be used with minimally invasive procedures such as percutaneous, trans-femoral and trans-apical procedures, it is not limited to such procedures and may also be used with surgical, or so called "open-chest," procedures.

[017] In one embodiment of the invention a tubular anchoring structure with a concave landing zone is provided. The anchoring structure includes a body having a proximal or inlet end and a distal or outlet end. The inlet frame has a sinusoidal-shaped single or double rail construction and is commonly referred to as the inlet rim. The outlet frame has a sinusoidal-shaped single or double rail construction. The body of the anchoring structure may be formed of a variety of shapes such as diamond-shaped or hexagonal-shaped patterns. The sinusoidal-shaped single or double rail construction of the inlet rim is C-shaped in cross section and forms the concave landing zone of the invention.

[018] In another embodiment of the invention, a valve assembly that reduces paravalvular leakage is provided. The valve assembly includes a bioprosthetic tissue heart valve attached to an anchoring structure. The anchoring structure includes a body having a proximal or inlet end and a distal or outlet end. The inlet frame has a sinusoidal-shaped single or double rail construction and is commonly referred to as the inlet rim. The outlet frame has a sinusoidal-shaped single, double or triple rail construction and is commonly referred to as the outlet rim. The sinusoidal-shaped construction of the inlet rim is C-shaped in cross section and forms the concave landing zone of the invention. The C-shape in cross

section construction provides a bioprosthetic valve that is self-seating and that requires minimal adjustment.

[019] In another embodiment of the invention, there is provided a valve prosthesis suitable for implantation in body ducts, the device comprising a main conduit body having an inlet and an outlet and pliant leaflets attached at the outlet so that when a flow passes through the conduit from the inlet to the outlet the leaflets are in an open position allowing the flow to exit the outlet, and when the flow is reversed the leaflets collapse so as to block the outlet, wherein the collapsible leaflets may comprise polyurethane or tissue.

[020] In yet another embodiment of the present invention, the leaflets are attached to the main body at the support beams.

[021] In yet another embodiment of the invention the heart valve is movable between a closed position in which the outflow edges of adjacent leaflets engage each other, and an open position in which the outflow edges of adjacent leaflets are separated from each other except along the side edges, the sewn portions of the side edges of the leaflets biasing the leaflets toward a partially closed position.

[022] In another embodiment of the invention, the C-shape in cross section construction forms a landing zone that allows the native annulus to rest in the valley of the inflow region, with the flared rails lying proximally and distally of the annulus.

[023] In yet another embodiment of the invention, the concave landing zone of the bioprosthetic heart valve assembly provides an effective seal between the bioprosthetic replacement heart valve and the implant site to prevent paravalvular leakage.

[024] In yet another embodiment of the invention, the inflow rim forming the concave landing zone comprises a single rail construction.

[025] In yet another embodiment of the invention, the inflow rim forming the concave landing zone comprises a double rail construction.

[026] In a further embodiment of the invention, the inflow rim forming the concave landing zone comprises a triple rail construction.

[027] In a further embodiment of the invention, the construction of the single, double and/or triple rail may include a proximal portion that is longer than the distal portion, for example, to match the flaring of the aortic valve sinuses.

[028] In another embodiment of the invention, the cross-sectional area of the inflow rim includes direct correspondence of the concave portion of the frame to the native annulus. The frame of the inflow rim engages the native annulus, with the flared inflow rails lying above and below the annulus. The radial force exerted by the self-expanding frame holds the valve in position.

[029] In yet another embodiment of the present invention, there is provided a valve prosthesis device suitable for implantation in body ducts, the device comprising a generally cylindrical anchoring structure having deployable construction adapted to be initially crimped in a narrow configuration suitable for surgical, trans-apical, trans-femoral placement, or other catheterization through a body duct, to a target location and adapted to be seated in the target location by the self-expansion of radially compressed forces, the cylindrical anchoring structure provided with a plurality of longitudinally rigid or semi-rigid support beams of fixed length; a valve assembly comprising a flexible conduit having an inlet and an outlet, made of a pliant material having commissural tab portions coupled to the support beams.

[030] The invention provides a method of preventing paravalvular leakage. Using the single, double and/or triple rail flared designs described herein, paravalvular leakage may be reduced by ensuring the inflow rim is substantially pushed against the aorta, hence forming a tight seal. In one method of implantation, a self-expanding replacement valve may be deployed into position with a delivery member, thereby pushing the inflow rim against the aorta to create a seal around the valve. In other words, a self-expandable inflow rim comprising the replacement heart valve provides the radial force necessary to position the bioprosthetic heart valve in the annulus.

[031] It should be noted that for the purposes of this invention, the phrase "generally sinusoidal" is intended to include waves characterized by sine and cosine functions as well as waves which are not rigorously characterized by those functions, but nevertheless resemble such waves. In a more general way, such waves include those which are characterized as having one or more peaks and troughs. As an example, a wave whose peaks and troughs are U-shaped or bulbous is intended to be included. Also intended to be included, without limiting the definition, are waves which are more triangular in shape such as a saw-tooth wave or waves whose peaks and troughs are rectangular.

[032] Although many of the above embodiments are described in reference to the aortic valve in the heart, the claimed invention may also be utilized for procedures related to other valves including, but not limited to, the mitral valve, tricuspid valve, and the pulmonary valve.

[033] The above aspects, features and advantages of the invention will become apparent to those skilled in the art from the following description taken together with the accompanying figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[034] FIG. 1 shows an exemplary valve during normal operation. FIG. 1A shows the valve in the open position during peak flow.

[035] FIG. 1B shows the valve in closed position to prevent backflow of the fluid across the valve.

[036] FIG. 2A is a top view illustrating the anatomy of a typical aortic valve.

[037] FIG. 2B is a cross-sectional view of the aortic valve of FIG. 2A.

[038] FIG. 2C is a perspective view of the aortic valve of FIG. 2A showing the inflow end, outflow end, and commissural posts in phantom lines

[039] FIG. 3 is a schematic representation of the geometry and relative dimensions of the valve sinus region.

[040] FIG. 4 is an exemplary bioprosthetic valve for use with the invention.

[041] FIG. 5A is a perspective view of an exemplary embodiment of a tubular anchoring structure in accordance with the invention cut along line A-A and showing a concave landing zone.

[042] FIG. 5B is a cross-sectional view of the concave landing zone of FIG. 5A.

[043] FIG. 6A is a perspective view of an exemplary embodiment of a anchoring structure in accordance with the invention cut along line A-A and showing a concave landing zone.

[044] FIG. 6B is a cross-sectional view of the concave landing zone of FIG. 6A.

[045] FIG. 7A is an illustration of a heart showing the bundle of His.

[046] FIG. 7B depicts an exemplary embodiment of the tubular anchoring structure of FIG. 5A including the bioprosthetic heart valve of FIG. 4 showing the concave landing zone positioned within an aorta.

[047] FIG. 8 depicts an exemplary embodiment of a tubular anchoring structure including a single rail flared or concave inflow rim dimensioned to lodge inside the sinus cavity.

[048] FIG. 9 depicts an alternative perspective view of the single rail flared or concave inflow rim of FIG. 8.

[049] FIG. 10 depicts an exemplary heart valve prosthesis with pliant leaflets coupled to a tubular anchoring structure including a concave landing zone covered with optional covering.

DETAILED DESCRIPTION OF THE INVENTION

[050] While this invention may be embodied in many different forms, there are described in detail herein various embodiments of the invention. This description is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

[051] For the sake of consistency, the terms "peak" and "trough" are defined with respect to the proximal and distal ends of the anchoring structure in

accordance with the invention. As seen in the Figures, each of the tubular anchoring structures has an inflow end, referred to herein as an inflow rim, and an outflow end, referred to herein as an outflow rim. With respect to the inflow and outflow rims "peaks" are concave relative to the proximal end of the anchoring structure and convex relative to the distal end of the anchoring structure. Troughs, on the other hand, are convex relative to the proximal end of the anchoring structure and concave relative to the distal end of the anchoring structure.

[052] Turning now to the FIGS., the invention relates to methods, systems, and devices for reducing paravalvular leakage in heart valves. FIGS. 1A and 1B generally illustrate one exemplary embodiment of a heart valve 1. As illustrated in FIG. 1, valve 1 includes a distal outflow end 2, a plurality of leaflets 3, and a proximal inflow end 4. A typical valve functions similar to a collapsible tube in that it opens widely during systole or in response to muscular contraction to enable unobstructed forward flow across the valvular orifice, as illustrated in FIG. 1A. In contrast, as forward flow decelerates at the end of systole or contraction, the walls of the tube are forced centrally between the sites of attachment to the vessel wall and the valve closes completely as illustrated in FIG. 1B.

[053] FIGS. 2A, 2B, and 2C illustrate the anatomy of a typical aortic valve. In particular, FIG. 2A shows a top view of a closed valve with three valve sinuses, FIG. 2B shows a perspective sectional view of the closed valve, and FIG. 2C shows a view from outside the vessel wall.

[054] One important consideration in the design of valve replacement systems and devices is the architecture of the valve sinus. Valve sinuses 12 are dilations of the vessel wall that surround the natural valve leaflets. Typically in the aortic valve, each natural valve leaflet has a separate sinus bulge 12 or cavity that allows for maximal opening of the leaflet at peak flow without permitting contact between the leaflet and the vessel wall. As illustrated in FIGS. 2A, 2B, and 2C, the extent of the sinus 12 is generally defined by the commissures 11, vessel wall 13, inflow end 14, and outflow end 15. The proximal intersection between the sinus cavities defines the commissures 11.

[055] FIGS. 2B and 2C also show the narrowing diameter of the sinuses at both inflow end 14 and outflow end 15, thus forming the annulus and sinotubular junction, respectively, of the sinus region. Thus, the valve sinuses form a natural compartment to support the operation of the valve by preventing contact between the leaflets and the vessel wall, which, in turn, may lead to adherence of the leaflets and/or result in detrimental wear and tear of the leaflets. The valve sinuses are also designed to share the stress conditions imposed on the valve leaflets during closure when fluid pressure on the closed leaflets is greatest. The valve sinuses further create favorable fluid dynamics through currents that soften an otherwise abrupt closure of the leaflets under conditions of high backflow pressure. Lastly, the sinuses ensure constant flow to any vessels located within the sinus cavities.

[056] FIG. 3 is a schematic representation of the geometry and relative dimensions of the valve sinus region. As shown in FIG. 3, the valve sinus region is characterized by certain relative dimensions which remain substantially constant regardless of the actual size of the sinuses. Generally, the diameter of the sinus is at its largest at the center of the sinus cavities 16, while there is pronounced narrowing of the sinus region at both the inflow annulus 17 near the inflow end 14 and the outflow sinotubular junction 18 near the outflow end 15. Furthermore, the height of the sinus 19 (i.e. the distance between inflow annulus 17 and outflow annulus 18) remains substantially proportional to its overall dimensions. It is thus apparent that the sinus region forms an anatomical compartment with certain constant features that are uniquely adapted to house a valve. The systems and devices of the invention are designed to utilize these anatomical features of the native sinus region for optimal replacement valve function and positioning.

[057] FIG. 4 is a perspective view of replacement valve 22, which represents one exemplary embodiment of a typical, tri-leaflet replacement valve useable with the valve replacement system in accordance with the invention. One of ordinary skill in the art will appreciate that the replacement valve may also be of two leaflet construction. Replacement valve 22 includes valve body 30 having proximal

inflow end 31 and a distal outflow end 32. Valve body 30 includes a plurality of valve tissue leaflets 33 joined by seams 34 sewn, stitched or otherwise coupled, wherein each seam 34 is formed by a junction of two leaflets 33. A commissural tab 35 co-extensively formed from the valve material extends from each seam 34 at the distal end of valve body 30. Inflow end 31 of valve body 30 includes a peripheral edge that may be scalloped or straight. In addition, inflow end 31 of valve body 30 may optionally comprise reinforcement structure 36 that may be coupled, stitched, adhesively or chemically joined or otherwise attached thereto. The valve replacement system in accordance with the invention may also comprise a reinforcement structure coupled to the bioprosthetic tissue valve and positioned about the inflow end of the tubular anchoring structure as hereinafter will be described. The reinforcement structure may comprise cloth or any porous material that promotes tissue ingrowth. This reinforcement structure may help position and secure the valve prosthesis at the correct position. It may, for example, help hold the valve prosthesis at the inflow annulus when placed in the aortic position.

[058] The valve replacement systems and devices of the invention are not limited, however, to the specific valve illustrated in FIG. 4. For example, although the proximal inflow end 31 of valve body 30 is shown in FIG. 4 with a scalloped peripheral edge, other shapes and configurations are contemplated and within the intended scope of the invention. Valve leaflets 33 may be constructed of any suitable material, including but not limited to expanded polytetrafluoroethylene (ePTFE), equine pericardium, bovine pericardium, or native porcine valve leaflets similar to currently available bioprosthetic aortic valves. Other materials may prove suitable as will be appreciated by one skilled in the art.

[059] FIG. 5A is a perspective view of an exemplary embodiment of a tubular anchoring structure 24 in accordance with the invention cut along line A-A and laid flat and showing a concave landing zone 60. FIG. 5A represents one exemplary embodiment of a typical anchoring or support structure 24 useable with valve replacement system 20 in accordance with the invention. In general, tubular

anchoring structure 24 is designed as a collapsible and expandable anchoring structure adapted to support valve 22 distally along commissural tab region 35 and proximally along the proximal inflow end 31. As shown in FIG. 5A, valve 22 has been detached from tubular anchoring structure 24 so as to focus on the structure and features of the tubular anchoring structure.

[060] Anchoring structure 24 has a generally tubular or cylindrical configuration within which replacement valve 22 may be secured, and includes inflow rim 41, support posts 42 and outflow rim 43. Replacement valve 22 may be secured at the proximal inflow end 31 by attachment to inflow rim 41 of tubular anchoring structure 24 and at the distal outflow end 32 via commissural tabs 35 that are threaded through axially extending slots 44, which are formed in support posts 42 that extend longitudinally from inflow rim 41 to outflow rim 43 of tubular anchoring structure 24. Thus, distal ends 45 of support posts 42 contact outflow rim 43 of tubular anchoring structure 24, whereas proximal ends 46 of support posts 42 contact inflow rim 41 of tubular anchoring structure 24. Support posts 42 may be rigid, substantially rigid or may also include a degree of inward deflection.

[061] As shown in FIG. 5A outflow rim 43 of support structure 24 is depicted as comprising a single wire ring or rail that extends between support posts 42 generally at or above the axially extending slots 44 that reside therein. The outflow rim 43 is configured in an undulating or sinusoidal wave pattern forming peaks 47 and troughs 48. However, the number of rails comprising the outflow rim 43 can comprise numerous other configurations which are contemplated by the invention and may be utilized such as single, double and triple configurations of varying patterns. Inflow rim 41 is depicted as comprising a double wire ring or rail that includes a distal inflow wire ring 49 and a proximal inflow wire ring 51. Distal inflow wire ring 49 and proximal inflow wire ring 51 are configured in an undulating or sinusoidal wave pattern forming peaks 47 and troughs 48. As can be seen, the double wire rail is configured so that a peak 47 of proximal inflow wire ring 51 couples to a trough 48 of distal inflow wire ring 48 thus forming a

diamond pattern although any number of desired shapes may be achieved such as pentagonal, hexagonal, rectangular, etc., all of which are within the scope of the invention.

[062] The inflow rim 41 optionally includes finger-like elements 53 positioned between distal and proximal inflow wire rings 49, 51 extend in an axial direction therefrom. Finger-like elements 53 are designed to lend additional support to fabric that may cover inflow rim 41 to anchor the fabric and permit tissue ingrowth.

[063] In an exemplary embodiment of a tubular anchoring structure 24 illustrated in FIG. 5A, outflow rim 43 is formed with a single ring, while inflow rim 41 is formed with a double ring that extends between support posts 42. However, the number of rings may vary, and numerous other configurations are contemplated. For example, FIG. 6A illustrates a triple ring construction for the inflow rim while FIG. 8 illustrates a single ring construction for the inflow rim.

[064] Both inflow rim 41 and outflow rim 43 of tubular anchoring structure 24 may be formed with an undulating or sinusoidal wave-like configurations. In various embodiments of tubular anchoring structures, inflow rim 41 may have a shorter or longer wavelength (i.e., circumferential dimension from peak to peak) and/or a lesser or greater wave height (i.e., axial dimension from peak to peak) than outflow rim 43. The wavelengths and wave heights of inflow rim 41 and outflow rim 43 may be selected to ensure uniform compression and expansion of tubular anchoring structure 24 without substantial distortion. The wavelength of inflow rim 41 may be further selected to support the geometry of the inflow end of the valve attached thereto, such as the scalloped inflow end 31 of replacement valve 22 shown in FIG. 4. Notably, as shown in FIG. 5A, the undulating or sinusoidal wave pattern that forms inflow rim 41 of tubular anchoring structure 24 may be configured such that proximal ends 46 of vertical support posts 42 are connected to troughs 48 of distal inflow ring 49. This arrangement allows the distal inflow wire ring and proximal inflow wire ring to move together when the valve is in its radially compressed state prior to delivery thus preventing possible damage to the bioprosthetic heart valve. Similarly, the undulating or sinusoidal

wave-like pattern that forms outflow rim 43 of support structure 24 may be configured such that distal ends 45 of support posts 42 are connected at a peak 47 of outflow rim 43.

[065] As shown in FIG. 6A, an alternative embodiment of an inflow rim 41 is shown. Inflow rim 41 comprises a three rail construction including a distal inflow ring 49, a proximal inflow ring 51 and a central inflow ring 62. In this alternative three-rail construction for inflow rim 41, peaks 47 of proximal inflow ring 51 may be joined to the troughs 64 of central inflow ring 62. Peaks 47 of central inflow ring 62 may be joined to the troughs 48 of distal inflow ring 49. This arrangement allows the distal inflow wire ring and proximal inflow wire ring to move together when the valve is in its radially compressed state prior to delivery thus preventing possible damage to the bioprosthetic heart valve.

[066] FIG. 5A and 6A further show that the distal ends 45 of support posts 42 are configured generally in the shape of a paddle with axial slot 44 extending internally within blade 50 of the paddle. Blade 50 of the paddle is oriented toward outflow rim 43 of tubular anchoring structure 24 and connects to outflow rim 43 at a trough of the undulating sinusoidal wave-like pattern of outflow rim 43. An important function of support posts 42 is the stabilization of prosthetic valve 22 in general, and in particular the prevention of any longitudinal extension at points of valve attachment to preclude valve stretching or distortion upon compression of replacement valve system 20. Blades 50 of the paddle-shaped support posts 42 are also designed to accommodate commissural tabs 35 of valve 22.

[067] The number of support posts 42 generally ranges from two to four, depending on the number of commissural posts present in the valve sinus. Thus, in one embodiment of the invention, tubular anchoring structure 24 comprises three support posts for a tri-leaflet replacement valve 22 with a sinus that features three natural commissural posts. Support posts 32 of tubular anchoring structure 24 may be structured to generally coincide with the natural commissural posts of the valve sinus.

[068] Tubular anchoring structure 24 may be formed from any suitable material including, but not limited to, stainless steel or nitinol. The particular

material selected for tubular anchoring structure 24 may be determined based upon whether the support structure is self-expanding or non-self-expanding. For example, preferable materials for self-expanding support structures may include shape memory materials, such as Nitinol.

[069] Turning now to FIGS. 5B and 6B a cross-sectional view of the inflow rim 41 is depicted which illustrates the concave landing zone 60 in accordance with the invention. As can be seen, peaks 47 of the distal inflow ring 49 and troughs 48 of the proximal inflow ring 51 flare outwardly so that inflow rim 41 forms a C-shape in cross section upon deployment. This cross-sectional area 60 of the inflow rim 41, or in other words the concave portion of the frame, directly corresponds to the native annulus. The frame of the inflow rim engages the native annulus, with the flared rails 49, 51 lying above and below the annulus. Upon deployment, the radial force exerted by the self-expanding frame holds the valve in position.

[070] The concave landing zone 60 of the invention substantially prevents paravalvular leakage. Using the double, triple and single rail flared designs as best seen in FIGS. 5A, 5B, 6A, 6B, 8 and 9 paravalvular leakage may be reduced by ensuring the inflow rim 41, 841 is substantially secured proximally and distally of the annulus, hence forming a tight seal. Concave landing zone 60 also allows the surgeon to easily place the bioprosthetic heart valve in the annulus thus minimizing patient time spent in surgery.

[071] FIG. 7A is an illustration of a heart 700 with right and left atriums 710, 712, right and left ventricles 714, 716, aorta 716 and aortic heart valve 718. The bundle of His 720, also known as the AV bundle or atrioventricular bundle comprises a collection of heart muscle cells specialized for electrical conduction that transmits the electrical impulses from the AV node 722 (located between the atria and the ventricles) to the point of the apex of the fascicular branches. The fascicular branches then lead to the Purkinje fibers which innervate the ventricles, causing the cardiac muscle of the ventricles to contract at a paced interval. If the bundle of His is blocked, a serious condition called "third degree heart block," namely the dissociation between the activity of the atria and that of the ventricles,

occurs. A third degree block most likely requires an artificial pacemaker. Consequently, a great number of heart valve replacement surgeries result in secondary operations to implant a pacemaker because the stented portion of the heart valve impinges on the bundle of His.

[072] Thus, those of ordinary skill in the art will appreciate that there are many different configurations that may be employed for the distal and proximal inflow rings 49, 51. For example, each of distal and proximal inflow rims 49, 51 may be substantially of the same vertical height. If each of distal and proximal inflow rings 49, 51 are substantially the same vertical height, the proximal ring may be flared slightly less outwardly to avoid compromising or impinging on the bundle of His while the distal ring 49 may be flared slightly more outwardly to ensure solid engagement with the distal side of the aortic annulus. Alternatively, the proximal inflow ring 51 may be constructed to be shorter than the distal inflow ring or may be flared slightly more outwardly so that upon placement, the proximal inflow ring does not contact and does not impinge on the bundle of His. Alternatively, either of the distal or proximal inflow rings 49, 51 may be constructed to be shorter than the other depending on the anatomy of the particular patient and valve replacement involved. Those of ordinary skill in the art will appreciate, however, that both the distal inflow ring 49 and the proximal inflow ring 51 may be comprised of any number of varying vertical heights and degrees of flare without deviating from the spirit of the invention.

[073] As shown in FIG. 7B, the heart valve replacement system 20 including the exemplary tubular anchoring structure 24 of FIG. 5A and/or 6A has expanded within the sinus cavities of aorta A, thereby forcing inflow rim 41 against inflow annulus 64 of aorta A to form a tight seal between replacement valve 20 and aorta A. More specifically, upon deployment inflow rim 41 assumes a substantially C-shaped in cross section concave landing zone 60 as can be seen in FIGS. 5B, 6B and 7. Distal inflow ring 49 abuts the distal side of the annulus while proximal inflow ring 51 abuts the proximal side of the native annulus.

[074] The concave landing zone 60 prevents and/or minimizes paravalvular leakage and migration of replacement valve 22 from the implantation site. Thus,

with inflow ring 41 in contact with inflow annulus 64, the concave landing zone 60 acts as a gasket to seal the junction between replacement valve system 20 and aorta A. Optionally, inflow ring 41 is covered with fabric to stimulate tissue ingrowth over time and secure the replacement heart valve in position. The fabric may comprise any suitable material including, but not limited to, woven polyester, polyester velour, polyethylene terepthalate, polytetrafluoroethylene (PTFE), or other biocompatible material. The valve assembly may be compressed in ice, loaded into a delivery system, and deployed into the aortic valve position. The self-expanding characteristic of the anchoring structure provides the radial strength required to hold the valve in position after implant.

[075] Turning now to FIGS. 8 and 9, yet another alternative embodiment of an anchoring structure with a concave landing zone in accordance with the principle of the invention is shown. A valve 822 supported by a generally cylindrical or tubular anchoring structure 824 having a concave landing zone 860 is shown. Valve 822 includes optional reinforcement structure 837. In this embodiment, anchoring structure 824 utilizes a diamond and hexagon shaped structure that facilitates collapsibility and dynamic compliance. Those skilled in the art however will appreciate that there are numerous designs for the anchoring structure that can be utilized. As can be seen from FIGS. 8 and 9, inflow rim 841 includes a single wire ring that is structured to flare out from the vertical support posts to anchor it firmly against the aortic inflow valve sinus as hereinbefore disclosed. Outflow ring 866, which is depicted as having a two-rail construction, may optionally also be flared-out to anchor it against the aortic outflow annuli of the valve sinuses. The outflow ring 866 of the anchoring structure 824 is adapted to support the commissural tab regions 821 of the valve 822 while the inflow ring 841, depicted as having a single rail construction, allows the anchoring structure 824 to be securely positioned in a sinus cavity of the vascular passageway. Commissural tabs 35 may be stitched directly to the outflow rim or optionally may be stitched to support posts 850. The single ring of the flared inflow ring 841 of the anchoring structure 824 may comprise an undulating or zigzag pattern to which the valve's optional fabric ring or sewing cuff 837 can be sewn. The inflow ring 841 of the anchoring structure may be connected to the outflow ring 866 by

vertical support posts 850 that are positioned to coincide with the commissural posts of the native sinus region. However, it should be understood that the number of vertical support posts may be adapted to the number of native commissural posts present in the particular sinus region.

[076] Those of ordinary skill in the art will appreciate that there are many different configurations that can be employed for the configuration of inflow rim 841 or outflow rim 866. For example, each of the peaks and troughs may be substantially of the same vertical height. Alternatively, either of the peaks or troughs may be constructed to be shorter than the other depending on the anatomy of the particular patient and valve replacement involved. Those of ordinary skill in the art will appreciate, however, that both the single ring construction may be comprised of any number of vertical heights without deviating from the spirit of the invention.

[077] Referring to FIG. 10 a perspective view of prosthetic heart valve 22 is shown mounted in a tubular anchoring structure with concave landing zone (not shown). Valve 22 is an exemplary embodiment of a typical, tri-leaflet replacement valve useable with the tubular anchoring structure 24 with concave landing zone 60 in accordance with the invention. One of ordinary skill in the art will appreciate that the replacement valve may also be of two leaflet construction. Replacement valve 22 includes valve body 30 having proximal inflow end 31 and a distal outflow end 32. Valve body 30 includes a plurality of valve tissue leaflets 33. A commissural tab 35 co-extensively formed from the valve material extends from each seam 34 at the distal end of valve body 30. As shown in FIG. 10 inflow end 31 of valve body 30 optionally includes reinforcement structure 36 that may be coupled, stitched, adhesively or chemically joined or otherwise attached thereto. The valve replacement system 20 in accordance may also comprise a reinforcement structure coupled to the bioprosthetic tissue valve and positioned about the inflow end of the tubular anchoring structure. The reinforcement structure may comprise cloth or any porous material that promotes tissue in-growth. This reinforcement structure may help position and secure the valve prosthesis at the correct position. It may, for example, help hold the valve

prosthesis at the inflow annulus when placed in the aortic position. Single outflow rail 43 of tubular anchoring structure 24 is operably coupled to paddle-shaped blade 50. In use, the commissural tabs 35 of the valve 22 are aligned with axially extending slots 44 formed in support posts 42. The overall size of the slots 44 correspond in size with tabs 35. In addition, tabs 35 may be optionally covered with a cloth covering 37.

[078] As noted above, valve leaflets 33 may be constructed of any suitable material, including but not limited to expanded polytetrafluoroethylene (ePTFE), equine pericardium, bovine pericardium, or native porcine valve leaflets similar to currently available bioprosthetic aortic valves. Other materials may prove suitable as will be appreciated by one skilled in the art.

[079] It should be noted that the novel anchoring structure device and bioprosthetic valve system in accordance with the invention is designed to be fitted in the annulus without sutures of any kind. However, those of ordinary skill in the art will also appreciate that sutures may or may not be used to secure the bioprosthetic valve system in place in the annulus.

[080] During manufacture, the anchoring structure is cut from a smaller tube and expanded and heat set to the final desired size. Depending on the design, the tips of the single inflow ring and the tips distal inflow ring and the proximal inflow ring in the double and triple constructions may be flared outwardly to form the C-shaped in cross section concave region extending from the cylindrical body of the anchoring structure frame. Additional fingers, such as those shown in FIG. 5A, may be used in any of the constructions and may be flared outwardly to assist in engaging the annulus and support the fabric covering.

[081] Although the invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. A prosthetic heart valve configured to be positioned within an aortic annulus comprising:

a generally cylindrical anchoring structure having an inflow end, an outlet end, and a plurality of support posts therebetween;

an inflow rim formed with said tubular body at the inflow end, said inflow rim including at least one rail having outwardly flared distal and proximal portions that form a substantially C-shaped in cross section concave landing zone;

a pliant prosthetic heart valve including a plurality of leaflets coupled together along at least a portion of their side edges so as to form a substantially tubular valve structure having an inflow end and an outflow end, said outflow end including a plurality of commissure tabs integrally formed with said leaflets, said commissure tabs coupled to said support posts,

wherein the heart valve is movable between a closed position in which the outflow edges of adjacent leaflets engage each other, and an open position in which the outflow edges of adjacent leaflets are separated from each other except along the side edges, the sewn portions of the side edges of the leaflets biasing the leaflets toward a partially closed position.

2. The prosthetic heart valve of claim 1 wherein said inflow rim comprises a single rail.

3. The prosthetic heart valve of claim 1 wherein said inflow rim comprises a double rail including a distal inflow ring and a proximal inflow ring.

4. The prosthetic heart valve of claim 3 wherein said distal inflow ring and said proximal inflow ring are configured in a sinusoidal wave pattern forming a plurality of peaks and a plurality of troughs.

5. The prosthetic heart valve of claim 4 wherein at least one of said plurality of peaks of said proximal inflow ring is operably connected with a trough of at least one of said plurality of troughs of said distal inflow ring.

6. The prosthetic heart valve of claim 1 further comprising a plurality of finger elements extending axially from said inflow rim.

7. The prosthetic heart valve of claim 3 further comprising a plurality of finger elements extending axially from said proximal inflow ring and said distal inflow ring.

8. The prosthetic heart valve of claim 1 further comprising an outflow rim having at least one rail, said outflow rim operably connected with said tubular body.

9. The prosthetic heart valve of claim 8 wherein said outflow rim includes flared distal and proximal portions that form a substantially C-shaped in cross section concave landing zone.

10. The prosthetic heart valve of claim 1 wherein said inflow rim comprises a triple rail including a distal inflow ring operably connected to a central inflow ring and a proximal inflow ring operably connected to said central inflow ring.

11. The prosthetic heart valve of claim 10 wherein said distal inflow ring, said central inflow ring and said proximal inflow ring are configured in a sinusoidal wave pattern forming a plurality of peaks and a plurality of troughs.

12. The prosthetic heart valve of claim 11 wherein said peaks of said distal inflow ring and operably connected to the troughs of said central inflow ring and said peaks of central inflow ring are operably connected to the troughs of said proximal inflow ring.

13. The prosthetic heart valve of claim 1 further comprising a plurality of longitudinal supports posts connecting said inflow and outflow rims.

14. The prosthetic heart valve of claim 13 wherein said support posts include a substantially paddle-shaped blade having an axial slot therethrough and an elongated vertical member.

15. The prosthetic heart valve of claim 14 wherein said elongated vertical member is coupled to said inflow rim and said blade is coupled to said outflow rim.

16. The prosthetic heart valve of claim 15 further comprising a bioprosthetic heat valve including at least two commissural tabs operably coupled with said blade.

17. The prosthetic heart valve of claim 13 wherein said plurality of longitudinal support posts comprise two support posts.

18. The prosthetic heart valve of claim 13 wherein said plurality of longitudinal support posts comprise three support posts.

19. The prosthetic heart valve of claim 1 wherein said distal portion of said C-shaped in cross section concave landing zone is configured to lie proximate the distal side of the aortic annulus and the proximal portion of said C-shaped in cross section concave landing zone is configured to lie proximate the proximal side of the aortic annulus.

20. The prosthetic heart valve of claim 19 wherein the proximal portion of said C-Shaped in cross section concave landing zone is configured to avoid contact with the bundle of His.

21. The prosthetic heart valve of claim 1 wherein said C-shaped in cross section concave landing zone is configured to form a seal between the prosthetic heart valve and the aortic annulus.

22. The prosthetic heart valve of claim 21 wherein said seal substantially reduces or prevents paravalvular leakage.

23. The prosthetic heart valve of claim 21 wherein said seal substantially prevents migration of said heart valve from the implantation site.

24. An anchoring structure adapted to be anchored within a vessel of a body, said anchoring structure comprising a generally cylindrical tubular body having an inflow end and an outflow end; and an inflow rim co-extensively formed with said tubular body at the inflow end, said inflow rim including at least one rail having outwardly flared distal and proximal portions.

25. The prosthetic heart valve of claim 24 wherein said inflow rim comprises a single rail.

26. The prosthetic heart valve of claim 24 wherein said inflow rim comprises a double rail including a distal inflow ring and a proximal inflow ring.

27. The anchoring structure of claim 26 wherein said distal inflow ring and said proximal inflow ring are configured in a sinusoidal wave pattern forming a plurality of peaks and a plurality of troughs.

28. The anchoring structure of claim 27 wherein at least one of said plurality of peaks of said proximal inflow ring is operably connected with a trough of at least one of said plurality of troughs of said distal inflow ring.

29. The anchoring structure of claim 24 further comprising a plurality of finger elements extending axially from said inflow rim.

30. The anchoring structure of claim 26 further comprising a plurality of finger elements extending axially from said proximal inflow ring and said distal inflow ring.

31. The anchoring structure of claim 24 further comprising an outflow rim having at least one rail, said outflow rim operably connected with said tubular body.

32. The anchoring structure of claim 31 wherein said outflow rim includes flared distal and proximal portions that form a substantially C-shaped in cross section concave landing zone.

33. The anchoring structure of claim 24 wherein said inflow rim comprises a triple rail including a distal inflow ring operably connected to a central

inflow ring and a proximal inflow ring operably connected to said central inflow ring.

34. The anchoring structure of claim 33 wherein said distal inflow ring, said central inflow ring and said proximal inflow ring are configured in a sinusoidal wave pattern forming a plurality of peaks and a plurality of troughs.

35. The anchoring structure of claim 34 wherein said peaks of said distal inflow ring and operably connected to the troughs of said central inflow ring and said peaks of central inflow ring are operably connected to the troughs of said proximal inflow ring.

36. The anchoring structure of claim 24 further comprising a plurality of longitudinal supports posts connecting said inflow and outflow rims.

37. The anchoring structure of claim 36 wherein said support posts include a substantially paddle-shaped blade having an axial slot therethrough and an elongated vertical member.

38. The anchoring structure of claim 37 wherein said elongated vertical member is coupled to said inflow rim and said blade is coupled to said outflow rim.

39. The anchoring structure of claim 38 further comprising a bioprosthetic heat valve including at least two commissural tabs operably coupled with said blade.

40. The anchoring structure of claim 36 wherein said plurality of longitudinal support posts comprise two support posts.

41. The anchoring structure of claim 36 wherein said plurality of longitudinal support posts comprise three support posts.

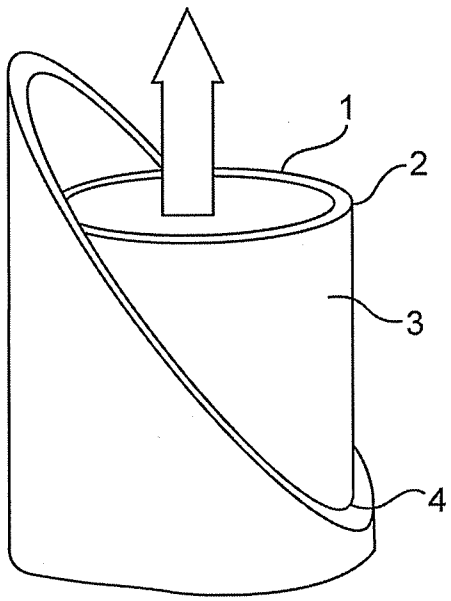

Fig. 1A

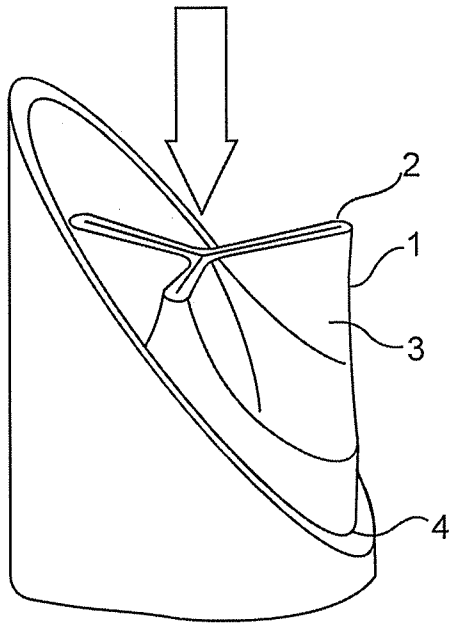

Fig. 1B

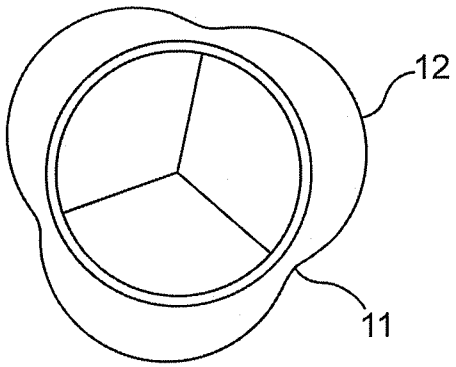

Fig. 2A

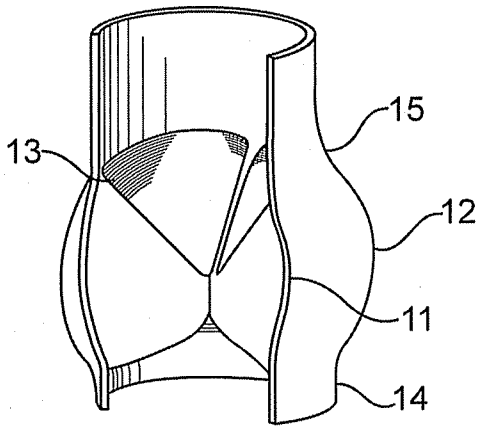

Fig. 2B

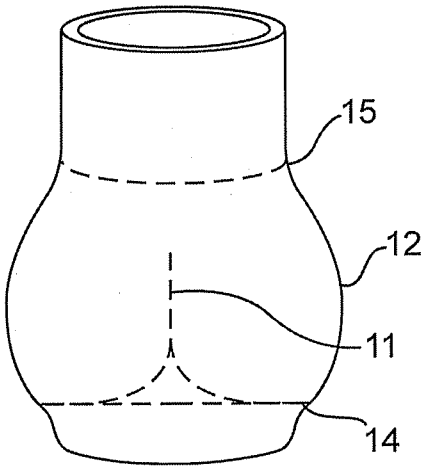

Fig. 2C

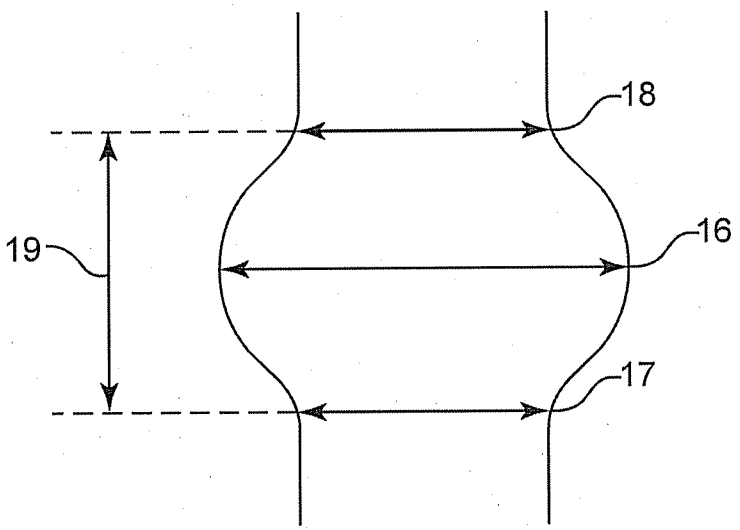

Fig. 3

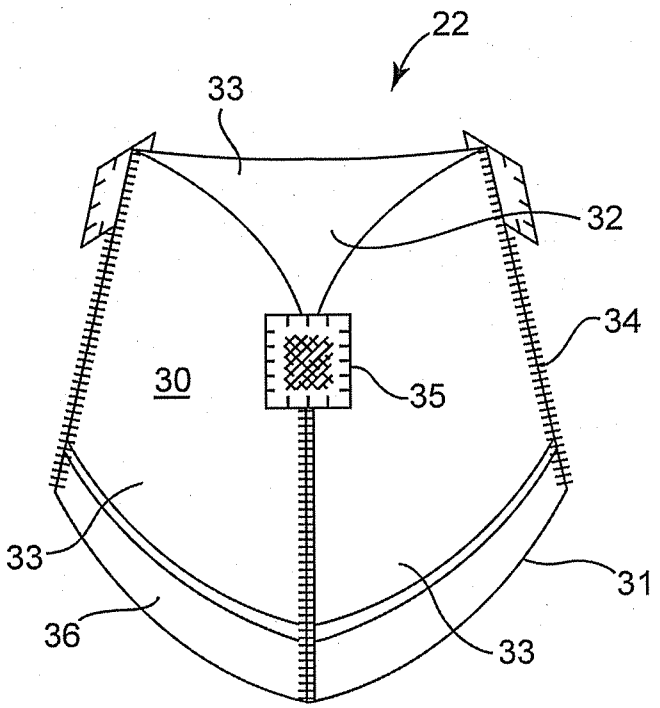

Fig. 4

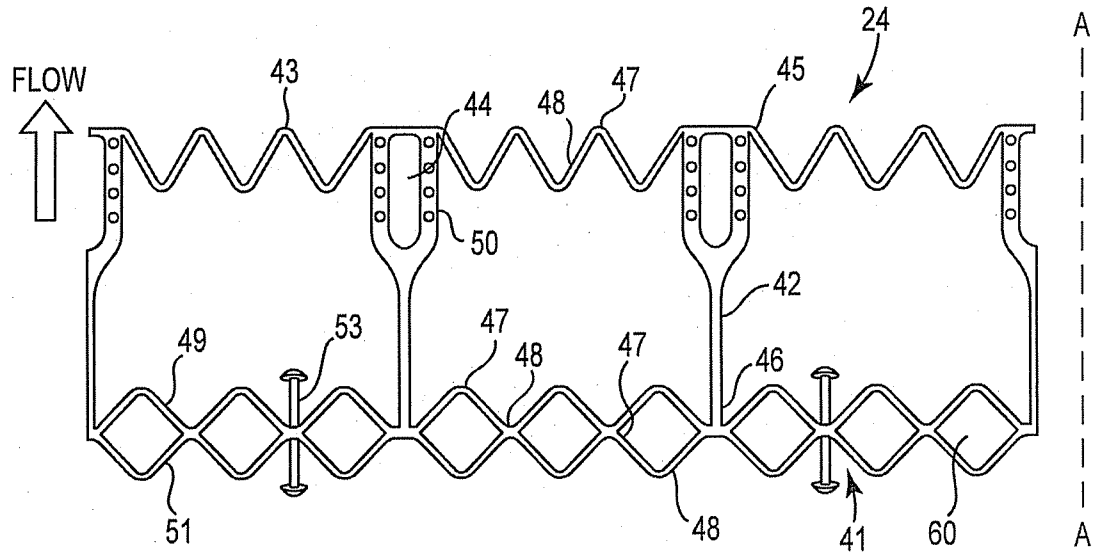
FLOW
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Fig. 5A

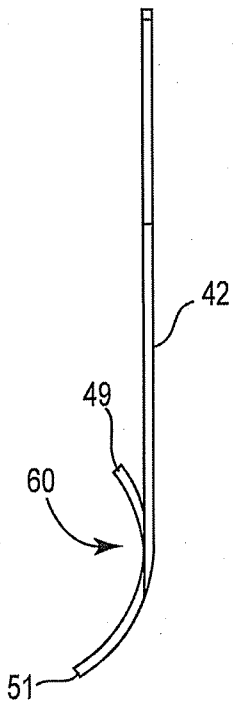
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Fig. 5B

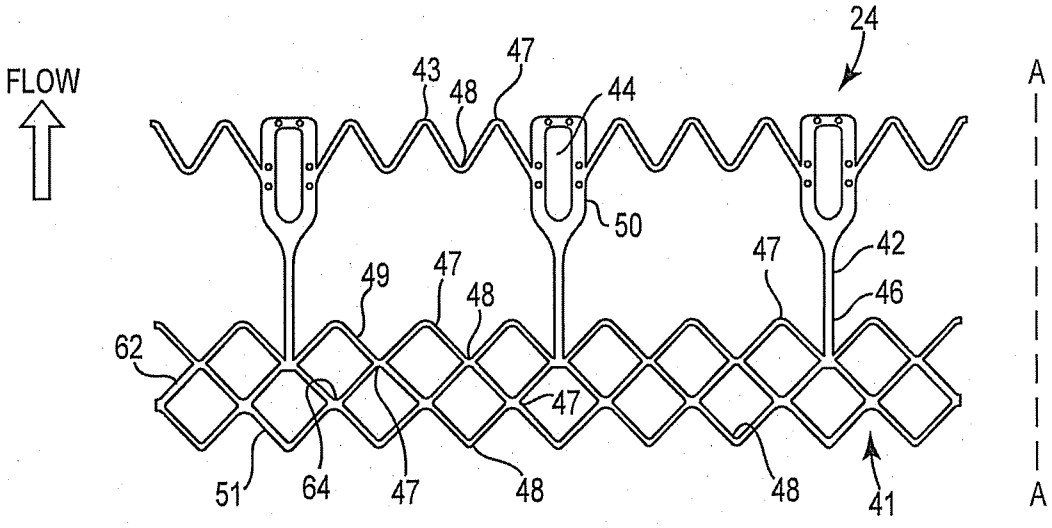
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Fig. 6A

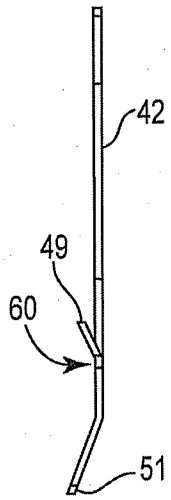
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Fig. 6B

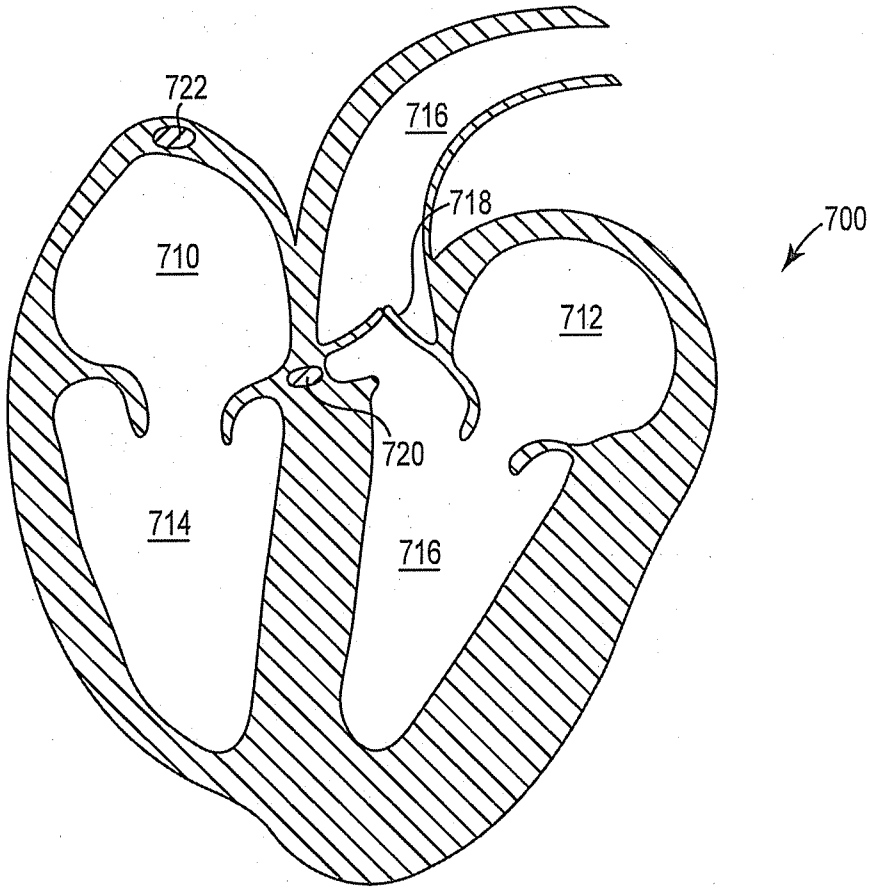

Fig. 7A

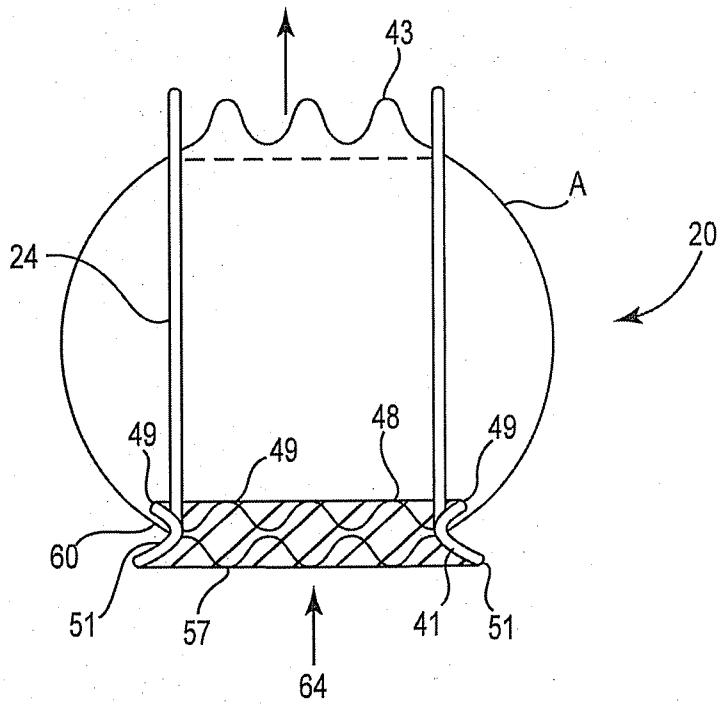

Fig. 7B

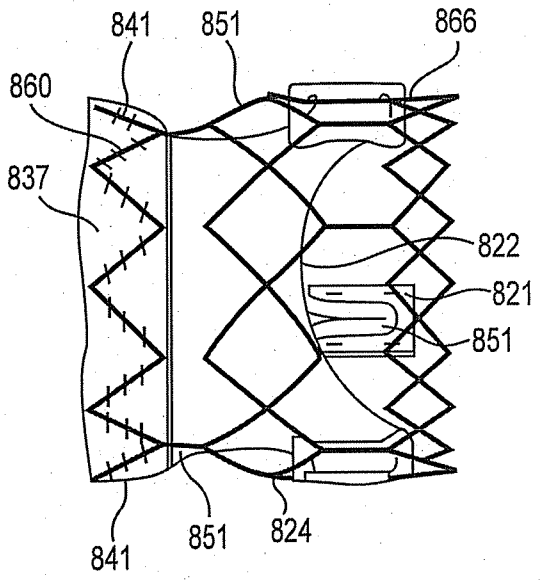
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Fig. 8

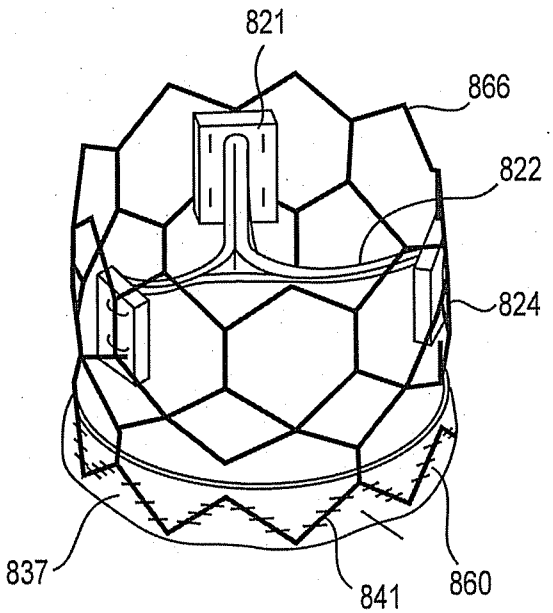
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Fig. 9

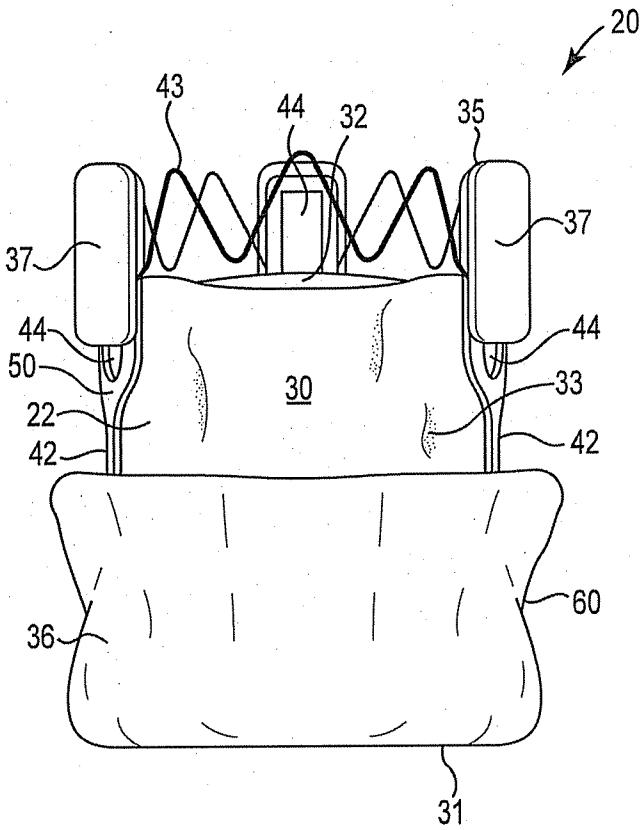

Fig. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 10/01043

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/24 (2010.01)
USPC - 623/2.38
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)
USPC: 623/2.38

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 623/2.1, 2.12, 2.17, 2.18, 2.19, 2. 38, 2.39, 2.4, 2.41 (keyword limited; terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PUBWEST(PGPB, USPT, EPAB, JPAB); Google
Search Terms Used: paravalvular leak$, leak$, seal, bundle of his, stent, concave, valve, heart, implant, prosthe$, prevent$, limit$, migration, mov$

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2009/0005863 A1 (GOETZ et al) 01 January 2009 (01.01.2009) fig 7, para [0059], [0075]	1-2, 6, 8-9, 13, 17-20, 24-25, 29, 31-32, 36, 40-41 --- 3-5, 7, 10-12, 14-16, 21-23, 26-28, 30, 33-35, 37-39
Y	US 2008/0071362 A1 (TUVAL et al) 20 March 2008 (20.03.2008) fig 2B, para [0583]	3-5, 7, 10-12, 14-16, 26-28, 30, 33-35, 37-39
Y	US 2008/0281411 A1 (BERREKLOUW) 13 November 2008 (13.11.2008) fig 10B, para [0046]-[0047], [0063], [0076]	21-23
Y	US 2007/0270944 A1 (BERGHEIM et al) 22 November 2007 (22.11.2007) para [0063]	22-23

☐ Further documents are listed in the continuation of Box C. ☐

* 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 application or patent 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
13 May 2010 (13.05.2010)	28 MAY 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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