

When the annulus, the mitral valve, and the atrial curtain lose the ability to maintain the size of the mitral valve orifice, dilatation can expand this orifice to almost double its size in extreme cases. In such cases, the valve leaflets are far apart at a time in the heart cycle (systole) when they should be in apposition and closing the valve orifice to impede reflux into the chamber (atrium). The annulus is soft and somewhat pliable and exerting pressure radially as is done with the aortic stents lead to more expansion thereby aggravating the condition.

[014] Currently, no prosthetic mitral valve devices have been fully developed and commercialized for placement in a dysfunctional mitral valve or replacement of the native mitral valve function by percutaneous means or catheter-guided means. A very strong need exists for improved designs of valved stents, and devices of delivery that will result in improved embodiments to replace the function of mitral heart valves, and tricuspid valves. These devices must enable the precise delivery, deployment, and deposition of valved stents into the atrioventricular annuli and their engagement with minimal complications and restoration of function as near as possible to that of normal healthy human valves. These devices must also prevent the development of peripheral valvular leaks (PVL), the development of leaks between the implanted valved stent and the native valvular tissue, to which the valve stent must conform very closely. These conditions also require that the valve be operatively paired with a specially designed valve stent and a specially designed delivery system.

SUMMARY OF THE INVENTION

[015] Embodiments of the present invention relates to medical devices and replacement heart valves, preferably those implanted by catheter-guided means. The present application relates particularly to a device with a specific geometry for both the shape-memory metal mounting

frame and the biological membrane cardiac valvular mechanism to be mounted within, that enables the truncated cone geometry of the completed assembly, in one aspect a diffuser, in another an inverted diffuser, to be used as a replacement heart valve without unduly encroaching upon the atrium or upper chamber of the patients' heart, in the first case, or the subvalvular mechanism of the patients atrioventricular valve in the other. This device can be implanted into dysfunctional mitral valves of both, quadruped animals and human hearts by various means, including the threading of catheters containing the diffuser through vessels leading to the heart, that is the operator controls the delivery of the deployment shape of the diffuser at a distance from the target site for final placement of the device where the operator manipulates the apparatus to enable the device to assume the deployed shape. Alternatively, reaching the target site is also possible through direct insertion during open chest, open heart surgery or by direct passage through the apex or tip of the heart into the mitral valve area. Because of the unique design of the valve and the deployment apparatus, a series of specifically selected steps and operations or maneuvers are preformed to accomplish the final deployment and to achieve the final deployed shape and function of the device.

[016] Embodiments of the invention can addresses the need for new geometric designs aimed at minimizing the issues described above for valves implanted at the junction of atria and ventricles, the atrio-ventricular valves, the mitral valve of the left side of the heart, and the tricuspid valve on the right side of the heart, although not limited to these but also allowing their use in treating the remaining heart valves, pulmonic and aortic. With some modifications, the geometry and device may be also used to correct incompetent valves in the venous circulatory systems particularly in the upper and mostly lower limbs.

[016a] A first aspect of the present invention provides a bioprosthetic heart valve assembly having a geometric configuration for implantation in an annulus of the native heart valve comprising, a tubular structure having an entry opening end and an exit opening at opposite ends thereof, wherein the tubular structure is comprised of an expandable stent structure comprised of a plurality of interconnected elements having a compressed configuration and an expanded configuration and wherein a plurality of the elements are comprised of winglets that extend away from the external circumferential surface of the stent in the expanded configuration; a biocompatible material covering a substantial portion of an inner annular region between the entry opening and the exit opening, and a valve comprised of a plurality of leaflets capable of forming a fluid tight seal at the apposing edges thereof wherein the circumference of the plurality of leaflets together form a fluid tight seal about an interior of the valve assembly between the entry opening and the exit opening, wherein the tubular structure has a tapered diameter along a length thereof such that the entry opening and the exit opening have different diameters.

[017] In its simplest embodiment, generally to simplify its fabrication or manufacture, when addressing the device for use in the correction of regurgitation of the mitral valve, the device here described may consist of a circular tubular structure having an entry section or orifice at one end and one exit section or orifice. This tubular structure incorporates a plurality of surfaces of specific shapes and dimensions, made of biological membranes. These surfaces are attached within the tubular structure at one of the margins along a length thereof to create a margin of attachment that joins an arc of its periphery and maintains these surfaces within the inner sector (LUMEN) or volume of the tubular structure, while allowing other margins of

the membrane surfaces, their free margins, to float in the direction in the blood or liquid is flowing. While the free margins of these surfaces allows their excursion toward the inner surface of the circular or cylindrical structure, it is meant to do so under restriction a certain distance from the inner surface of the tubular structure at the end of the excursion to avoid impingement and damage to the floating surface structure. These surfaces however, when the direction of the fluid or blood reverses, will also reverse their excursion to approach adjacent free floating surfaces, at which points the surfaces are shaped and designed to the joiner region as a part of the total surface of apposition so that abutting adjacent surfaces create a closure that impedes the reversal of blood flow. Prosthesis is also comprised of a frame or stent to support the leaflet valvular mechanism.

[018] The mitral apparatus ordinarily appears to be in the form of an inverted diffuser, a device for utilizing part of the kinetic energy of a fluid passing through a machine by gradually increasing the cross-sectional area of the channel or chamber through which it flows so as to decrease its speed and increase its pressure, wherein the diameter of the passage way of the