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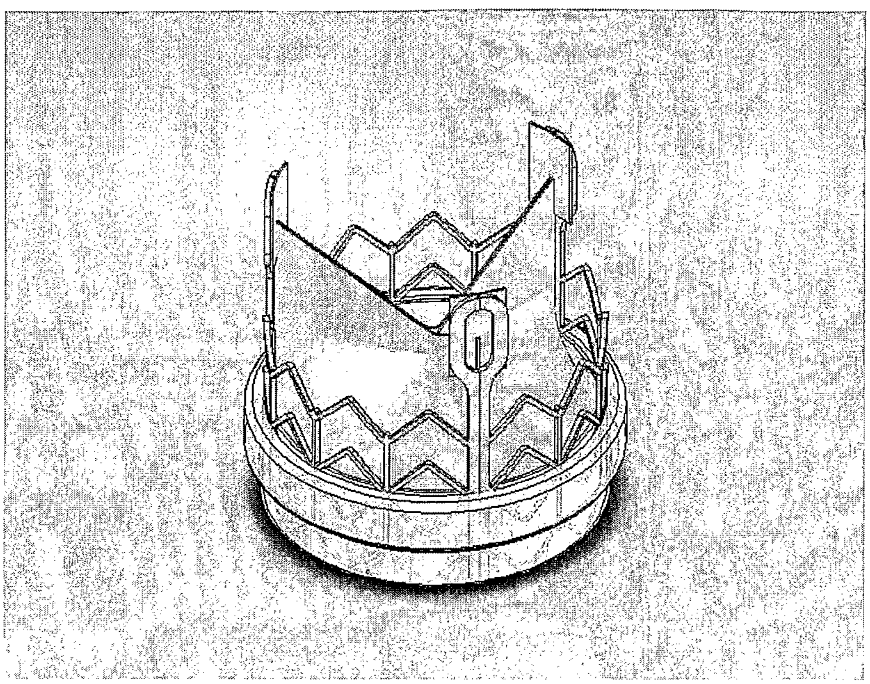
(54) Title: IMPLANTABLE PROSTHETIC VALVE



(57) Abstract: The present invention provides valve prostheses adapted to be initially crimped in a narrow configuration suitable for catheterization through body ducts to a target location and adapted to be deployed by state in the target location.

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DESCRIPTION

Implantable Prosthetic Valve

This application claims the benefit of U.S. Provisional Application No. 60/565,118, filed April 23, 2004.

Field of the Invention

The present invention relates to implantable devices. More specifically, the present invention relates to heart valve prosthetic devices for cardiac implantation. The present invention may also be utilized in other body cavities, vessels, or ducts.

Background of the Invention

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.

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.

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.

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.

Because of the potential severity of the clinical consequences of valve disease, valve replacement surgery is becoming a widely used medical procedure, described and illustrated in numerous books and articles. When replacement of a valve is necessary, the diseased or abnormal valve is typically cut out and replaced with either a mechanical or tissue valve. A conventional heart valve replacement surgery involves accessing the heart in a patient's thoracic cavity through a longitudinal incision in the chest. For example, a median sternotomy requires cutting through the sternum and forcing the two opposite halves of the rib cage to be spread apart, allowing access to the thoracic cavity and the heart within. The patient is then placed on cardiopulmonary bypass, which involves stopping the heart to permit access to the internal chambers. Such open heart surgery is particularly invasive and involves a lengthy and difficult recovery period. Reducing or eliminating the time a patient spends in surgery is thus a goal of foremost clinical priority.

One strategy for reducing the time spent in surgery is to eliminate or reduce the need for suturing a replacement valve into position. Toward this end, valve assemblies that allow implantation with minimal or no sutures would be greatly advantageous. Attaching a valve such as a tissue valve to a support structure such as a stent may enable a valve assembly that allows implantation with minimal or no sutures. It is important that such valve constructs are configured such that the tissue leaflets or the support valve don't come into contact with the support structure, either during the collapsed or expanded state, or both in order to prevent abrasion. Such contact is capable of contributing undesired stress on the valve leaflet. Moreover, it is advantageous that such support structures are configured to properly support a tissue valve having a scalloped inflow annulus such as that disclosed in the U.S. patent application serial number 09/772,526 which is incorporated by reference herein in its entirety.

Accordingly, there is a need for a valve replacement system comprising a collapsible and expandable valve assembly that is capable of being secured into position with minimal or no suturing; facilitating an anatomically optimal position of the valve; maintaining an open pathway for other vessel openings of vessels that may be located in the valvular sinuses; and minimizing or reducing stress to the tissue valve leaflets. The valves of the present invention may comprise a plurality of joined leaflets with a corresponding number of commissural tabs. Generally, however, the desired valve will contain two to four leaflets and commissural tabs. Examples of other suitable valves are disclosed in U.S. Patent Applications 09/772,526, 09/853,463, 09/924,970, 10/121,208, 10/122,035, 10/153,286, 10/153,290, the disclosures of all of which are incorporated by reference in their entirety herein. Likewise, the systems and methods disclosed in U.S. Patent Application 10/831,770, filed April 23, 2004, are fully incorporated by reference herein.

As mentioned above, an open-heart valve replacement is a long tedious procedure. For implantation of a bioprosthetic valve in the aortic position, a surgeon typically opens the aorta and excises the native valve. The surgeon then inserts the prosthetic valve through the opening in the aortic wall and secures the prosthesis at the junction of the aorta and the left ventricle. The inflow annulus of the valve faces the left ventricle and, relative to the surgeon's perspective, may be

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