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Gabbay

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[54] **NATURAL TISSUE HEART VALVE PROSTHESIS**

[75] Inventor: **Shlomo Gabbay**, Short Hills, N.J.

[73] Assignee: **Shelhigh, Inc.**, Millburn, N.J.

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[51] **Int. Cl.**[6] **A61F 2/24**

[52] **U.S. Cl.** **623/2**

[58] **Field of Search** 623/2, 900

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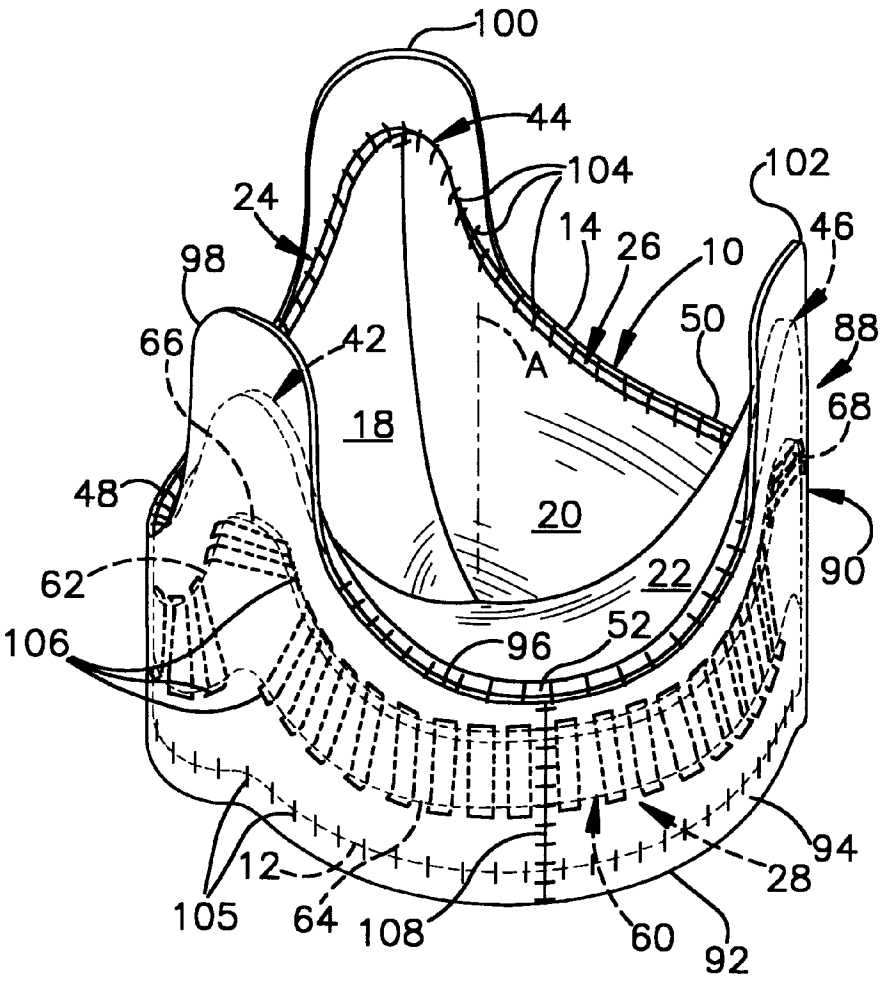
Primary Examiner—David H. Willse

Attorney, Agent, or Firm—Tarolli, Sundheim, Covell Tummino & Szabo

[57] **ABSTRACT**

A heart valve prosthesis (**88**; **128**) having a plurality of leaflets (**18**, **20** and **22**; **138**, **140** and **142**). The valve (**10**; **130**) is covered with a sheath (**90**; **172**) of natural tissue. The sheath (**90**; **172**) extends from an inflow end (**12**; **132**) of the valve (**10**; **130**) beyond an outflow end (**14**; **134**) of the valve (**12**; **132**) to define a plurality of lobes (**98**, **100** and **102**; **182**, **184** and **186**). A substantially flexible annular ring (**60**; **162**) may be positioned between the sheath (**90**; **172**) and the heart valve (**10**; **132**) to provide additional stability.

27 Claims, 3 Drawing Sheets



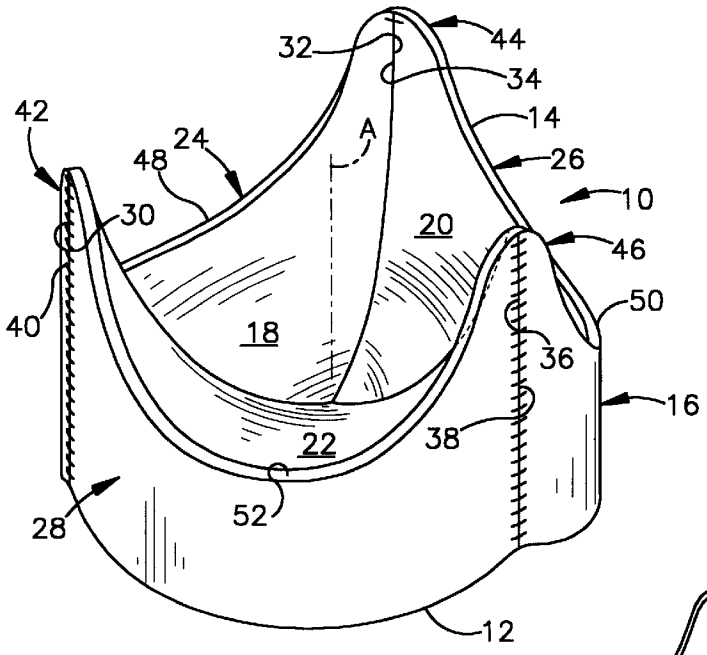


Fig.1

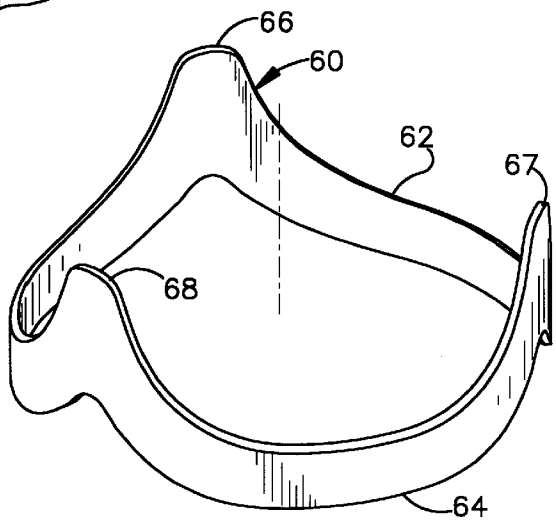


Fig.2

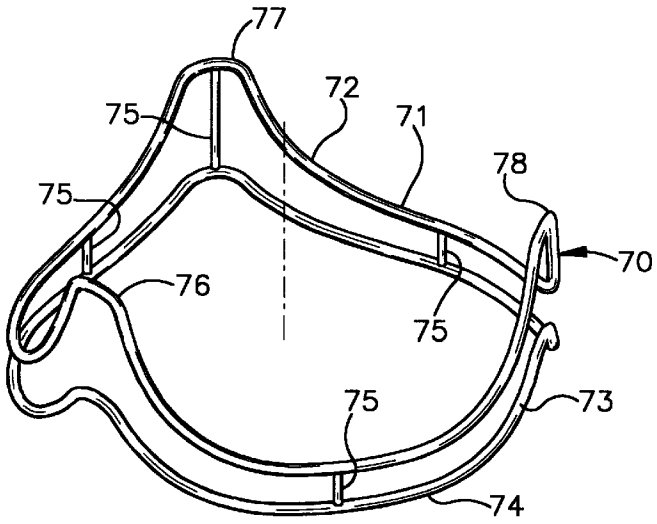


Fig.3

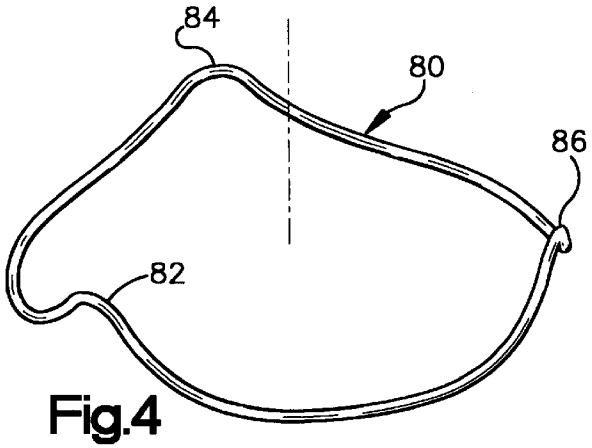


Fig.4

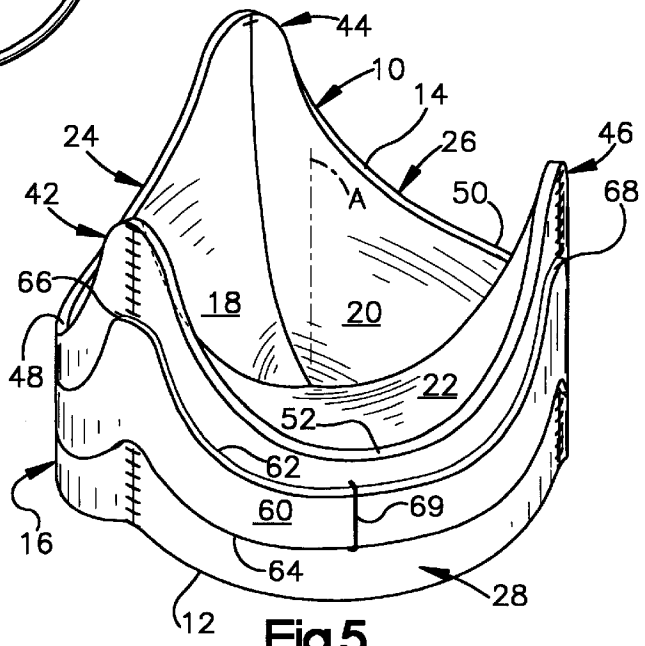


Fig.5

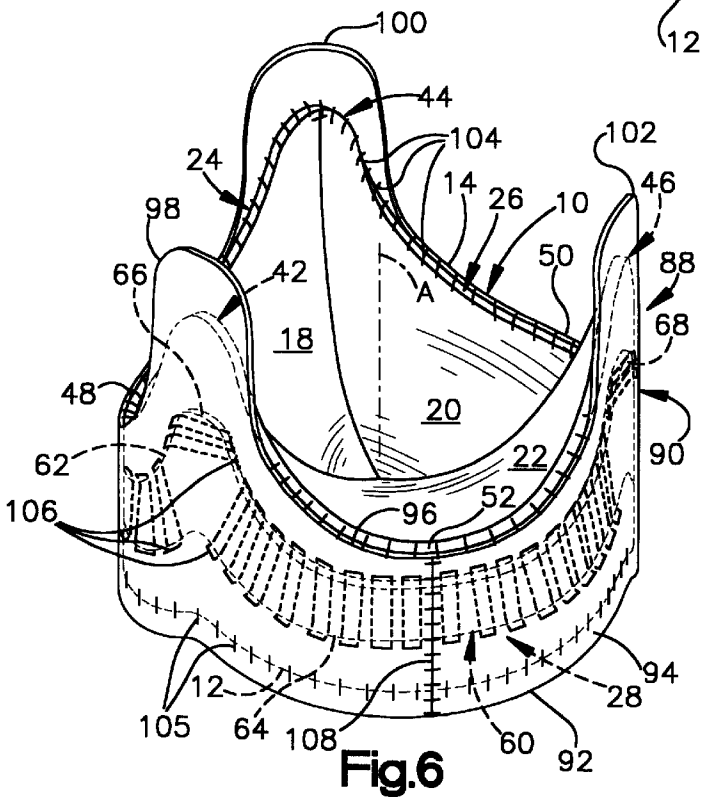


Fig.6

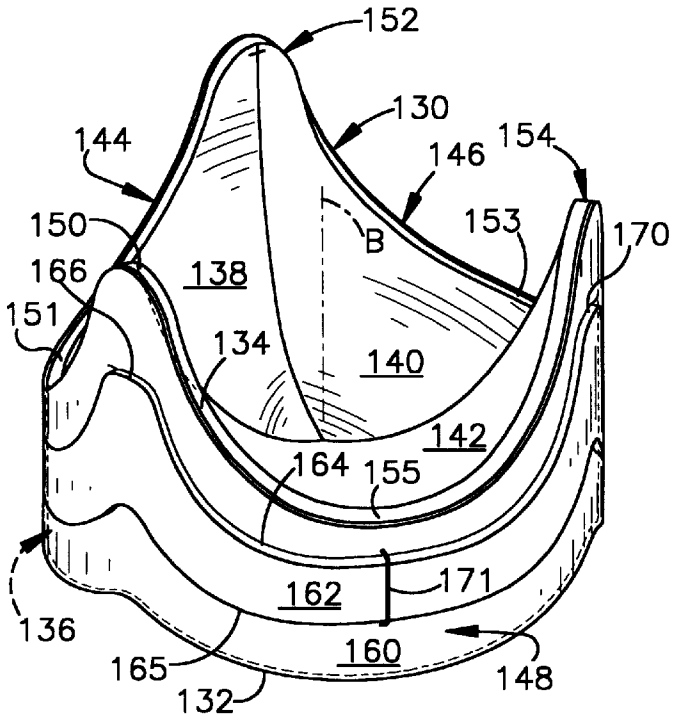


Fig.7

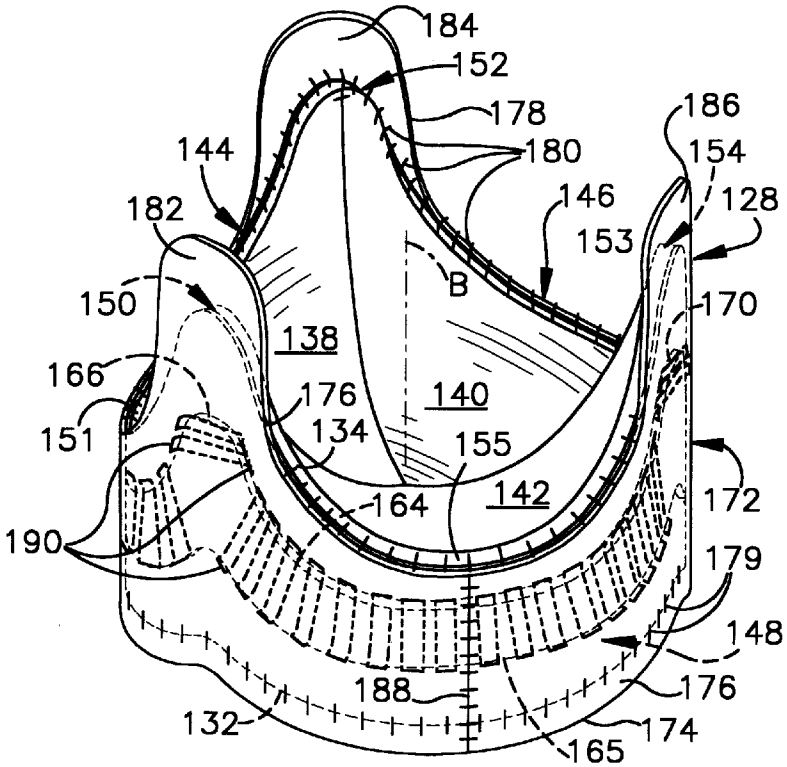


Fig.8

NATURAL TISSUE HEART VALVE PROSTHESIS

TECHNICAL FIELD

The present invention relates to a BIOS-prosthesis, and more particularly to a natural tissue heart valve prosthesis and a method for making the prosthesis.

BACKGROUND OF THE INVENTION

Numerous types of heart valve prostheses have been developed for replacing defective heart valves in human patients. One common type of heart valve prosthesis includes a natural tissue heart valve mounted within a sent. The sent generally provides strength and rigidity to the heart valve. Typically, the sent is covered with a textile material, such as Dacron™, which provides a substrate to which the heart valve may be secured. While the sent provides desired rigidity and strength, which inhibits the inward deflection of the sent posts, it also decreases the hemodynamics of the valve. This is because the stent substantially increases the side wall thickness of the prosthesis, which reduces the size of the flow orifice for a prosthesis having a given outer diameter. The textile covering also tends to abrade cusps of the valve.

In order to overcome the disadvantages associated with the stented heart valve prosthesis, there has been an increasing tendency to form natural tissue heart valve prostheses with no stent. These are called stentless valves. Stentless valves exhibit improved hemodynamics and are less resistant to blood flow. In addition, stentless valves, as compared to stented valves, are more resistant to structural failure because the rigidity of a stent can cause damage to the moving cusps. The improved hemodynamic characteristics of stentless valves also can cause beneficial remodeling of the heart muscle. Specifically, it has been determined that several months after implantation of a stentless valve in the aortic position, there is a noticeable improvement in the size of a left ventricle.

Even though a stentless prosthesis offers improved results over its stented counterpart, in practice, conventional stentless prostheses have not been completely satisfactory. It requires a greater degree of surgical proficiency to implant a stentless prosthesis. It usually also requires additional time to perform the procedure. Accordingly, a very small number of surgeons are willing to implant a stentless valve.

There also are technical problems associated with the implantation of a typical natural tissue heart valve prosthesis having no stent. In general, a stentless prosthesis is deformable. Thus, if the aortic annulus is calcified, the implanted valve can be deformed and become dysfunctional. Such deformation of the valve might cause the cusps to be unleveled, resulting in inadequate coaptation of the cusps and backflow. It also has been determined that the sizing of stentless valves is not well defined for surgeons. Therefore, a sizing mismatch may occur, which can cause the valve to be stenotic or insufficient.

SUMMARY OF THE INVENTION

The present invention is directed to a heart valve prosthesis that includes a natural tissue heart valve having a generally cylindrical side wall portion extending between an inflow end and an outflow end of the heart valve. The side wall portion has an outer surface. The heart valve also includes a plurality of leaflets disposed within the side wall portion of the valve. Each of the leaflets has an associated side wall portion and side edges. Adjacent side edges of adjacent leaflets and adjacent portions of their respective associated side wall portions define commissures. The heart valve prosthesis also includes an outer sheath of natural tissue covering the outer surface of the heart valve. The outer sheath has an outflow end that extends beyond the outflow end of the heart valve adjacent the commissures to define a plurality of lobes.

Another feature of the present invention is directed to a method of making a heart valve prosthesis. The method includes the step of providing a heart valve having an inflow end, an outflow end, and a generally cylindrical side wall portion extending between the inflow end and the outflow end. The heart valve also includes a plurality of leaflets disposed within the side wall portion. Each of the leaflets has an associated side wall portion and a pair of side edges, with adjacent side edges of adjacent leaflets and adjacent portions of their respective associated side wall portions defining commissures. The method also includes attaching an annular ring of a substantially flexible material about the side wall portion of the valve positioned intermediate the inflow and outflow ends of the valve. A sheath of pericardial tissue covers the annular ring and the outer surface of the heart valve. The sheath has an inflow end portion and an outflow end portion. The outflow end portion of the sheath is extended beyond the outflow end of the heart valve to define a plurality of lobes adjacent the commissures.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the present invention are illustrated in the accompanying drawings, in which:

FIG. **1** is a perspective view of a heart valve used in an embodiment of the present invention;

FIG. **2** is a perspective view of a ring used in an embodiment of the present invention;

FIG. **3** is another embodiment of a ring which may be used as a substitute for the ring of FIG. **2**;

FIG. **4** is yet another embodiment of a ring;

FIG. **5** is a perspective view illustrating the ring of FIG. **3** attached to the heart valve of FIG. **1**;

FIG. **6** is a perspective view of an embodiment of a heart valve prosthesis in accordance with the present invention;

FIG. **7** is a perspective view illustrating the ring of FIG. **3** attached to a valve structure, which may be used in another embodiment of the present invention; and

FIG. **8** is a perspective view of another embodiment of a heart valve prosthesis in accordance with the present invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

FIG. **1** illustrates a preferred embodiment of a natural tissue heart valve, generally indicated at **10**. The heart valve **10** includes an inflow end **12**, an outflow end **14** and a central axis, indicated at A, extending through the inflow and outflow ends **12** and **14**, respectively. The valve **10** also has a generally cylindrical side wall portion **16** formed of a valve wall extending between the inflow end **12** and the outflow end **14**. The heart valve **10** also includes a plurality of leaflets or cusps **18**, **20** and **22** mounted within the side wall portion **16**. Each of the leaflets **18**, **20** and **22** has a respective associated side wall portion **24**, **26** and **28** and respective pairs of opposed side edges **30** and **32**, **34** and **36** and **38** and **40**. Adjacent pairs of side edges **30** and **40**, **32** and **34**, **36** and **38** together with adjacent portions of their respective asso-

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