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Gabbay

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(54) **APPARATUS AND METHOD FOR SUPPORTING A HEART VALVE**

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(58) **Field of Search** 623/2.38, 2.39, 623/2.4, 2.12–2.19, 900, 904; 600/37

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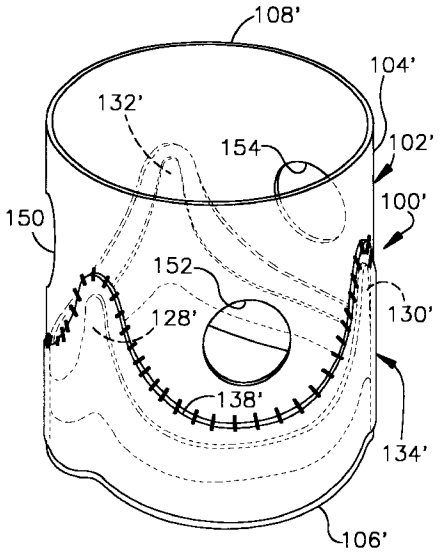
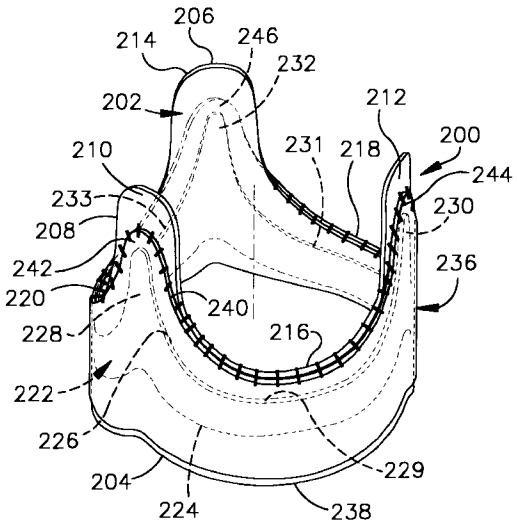
(57) **ABSTRACT**

An apparatus and method are disclosed for supporting a heart valve with a flexible girdle. The girdle has an elongated cylindrical sidewall having an axial length at least commensurate with the heart valve. The girdle is disposed around a tubular valve wall of the heart valve being implanted so that the inflow end of the girdle is adjacent the inflow end of the tubular valve wall. The inflow ends of the girdle and heart valve may then be sutured together to implant the valve. The girdle provides support to stabilize the heart valve and inhibit deformation thereof.

44 Claims, 3 Drawing Sheets





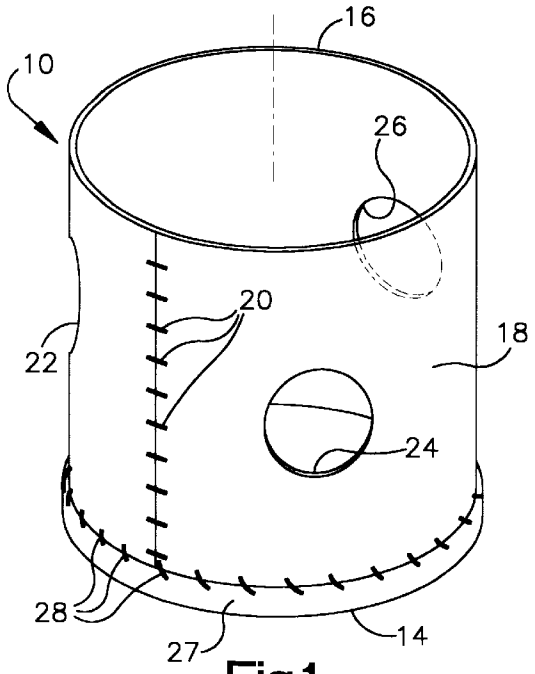


Fig.1

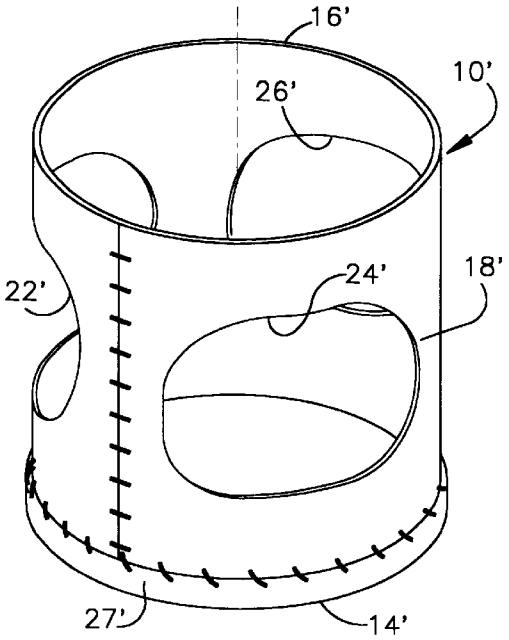


Fig.2

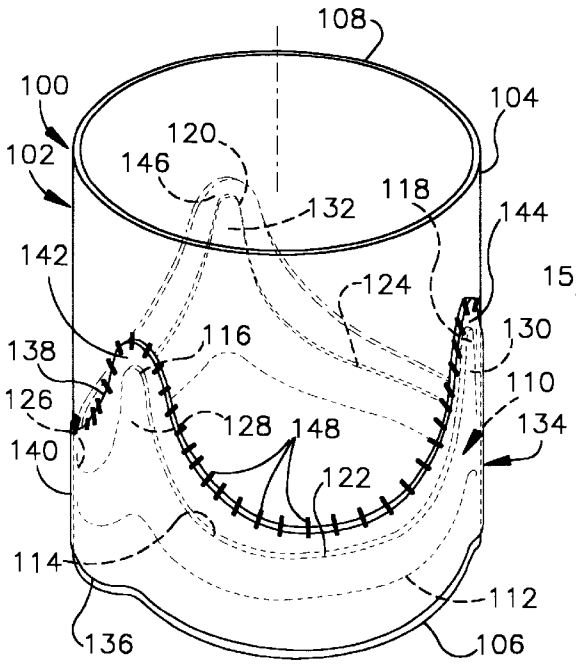


Fig.3

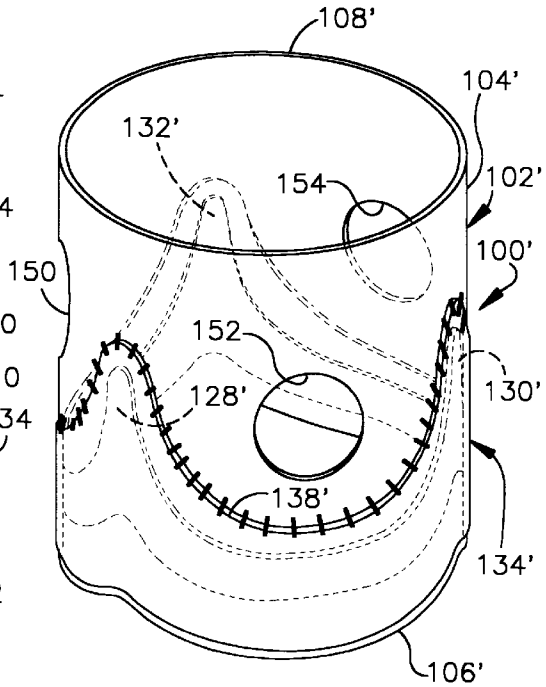


Fig.4

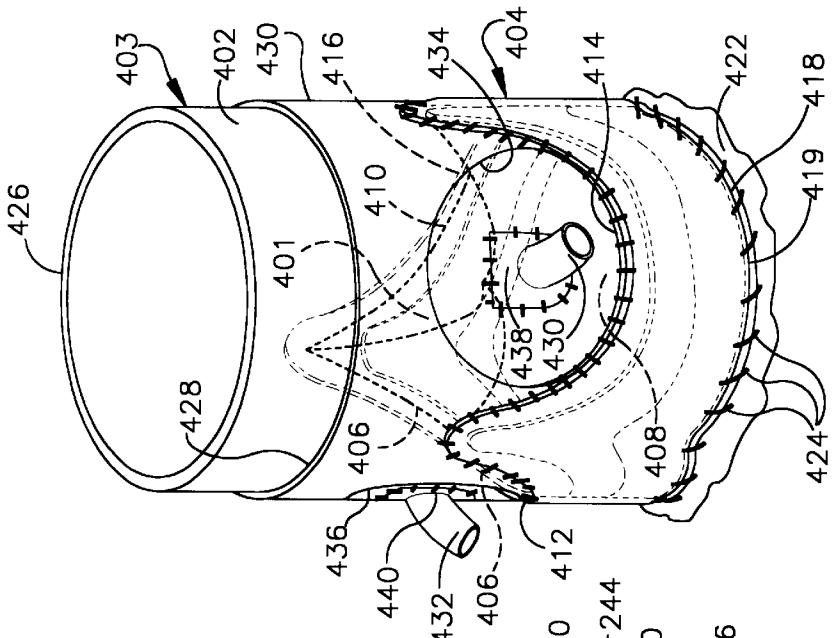


Fig.9

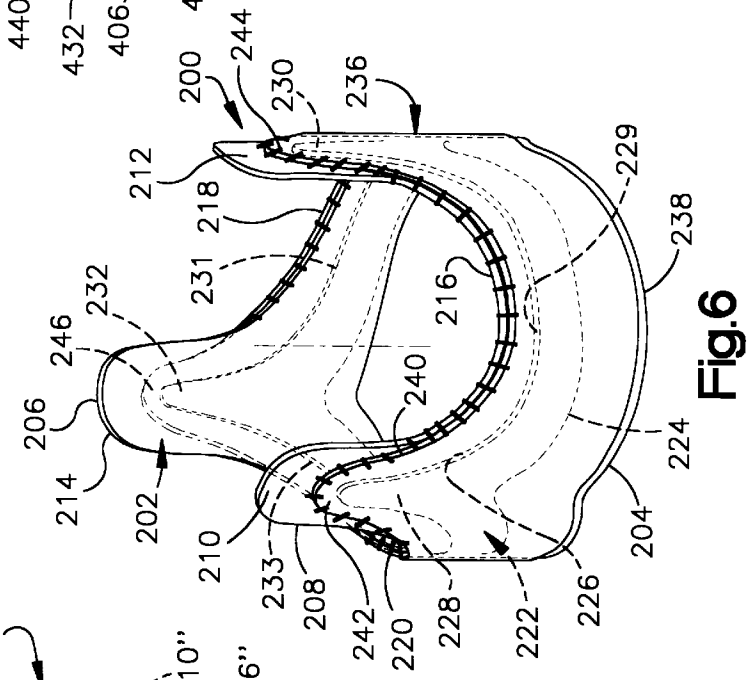


Fig.6

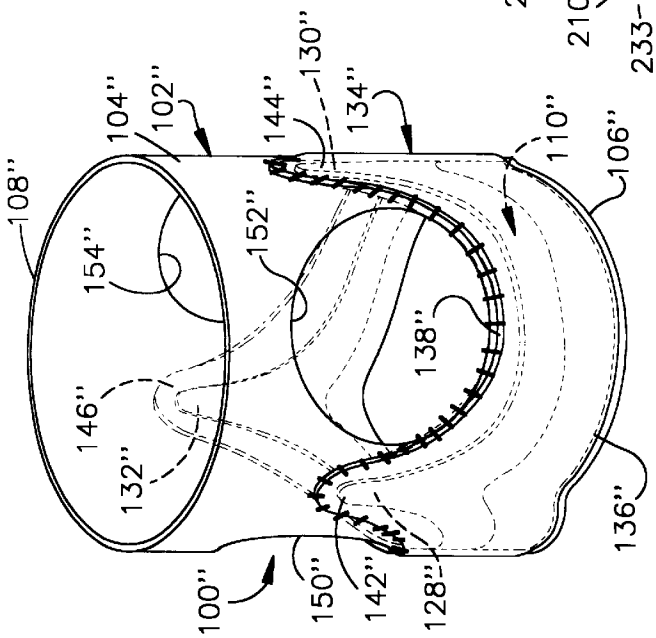


Fig.5

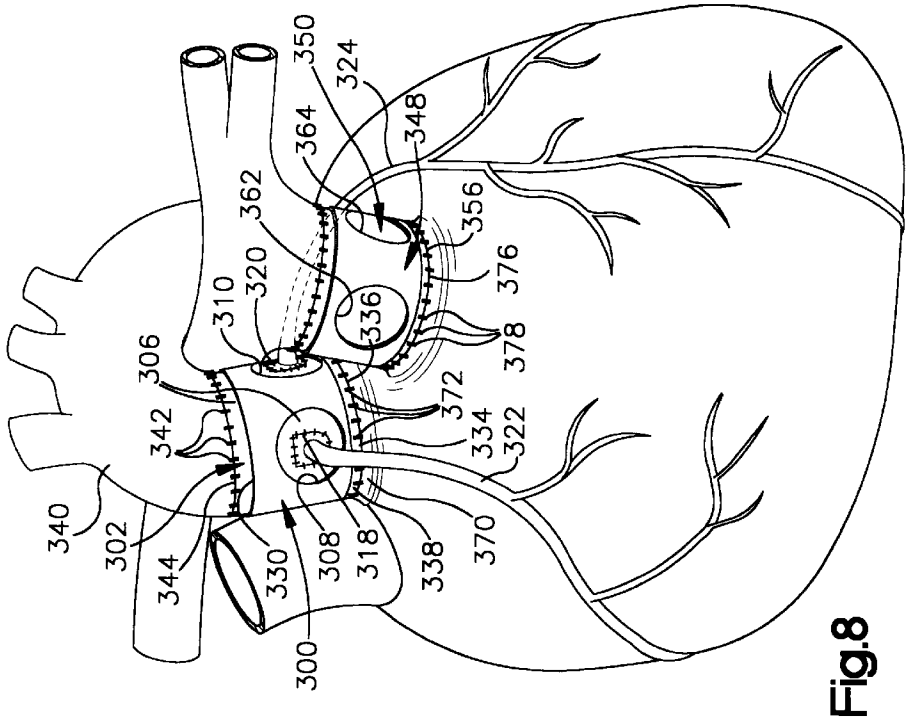


Fig.8

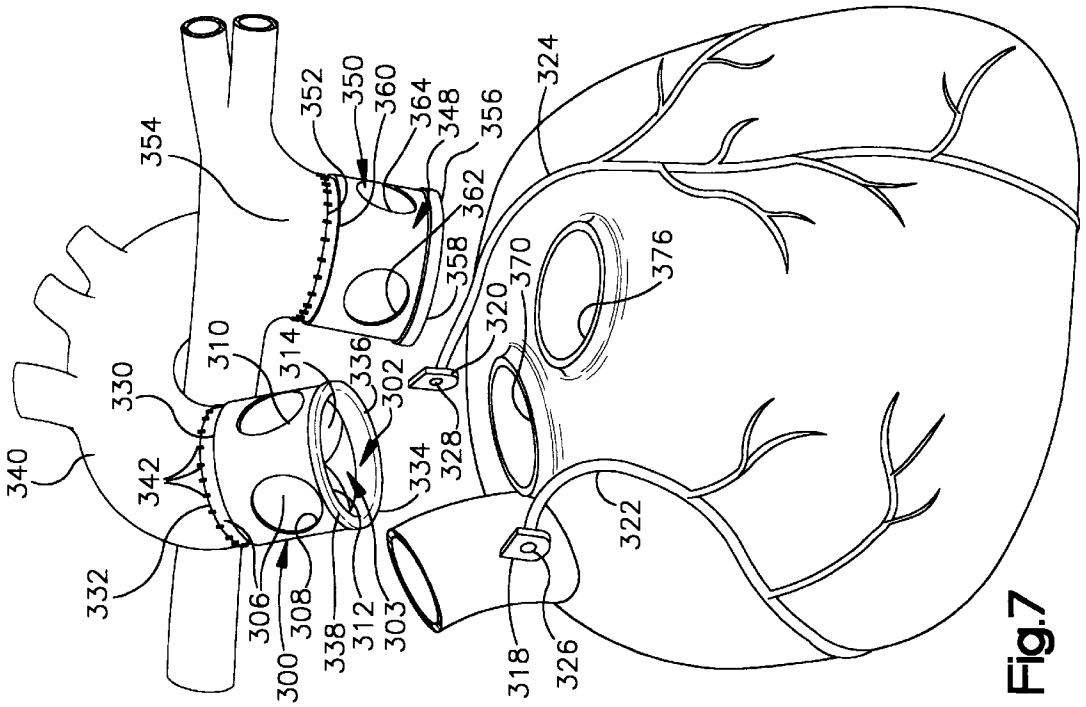


Fig.7

APPARATUS AND METHOD FOR SUPPORTING A HEART VALVE

CROSS REFERENCE TO RELATED APPLICATION

This application is related to U.S. patent application Ser. No. 09/1052,707, now U.S. Pat. No. 5,935,163, which was filed Mar. 31, 1998 and entitled Natural Tissue Heart Valve Prosthesis.

TECHNICAL FIELD

The present invention relates to an apparatus and method for supporting a heart valve. More particularly, the present invention relates to an apparatus and method for supporting a heart valve by disposing a girdle externally about the valve.

BACKGROUND OF THE INVENTION

The use of a patient's healthy pulmonic valve as an autograft to replace a diseased aortic valve has been gaining worldwide acceptance as a viable alternative for replacing the patient's diseased aortic valve. This procedure is known as the Ross procedure after the surgeon who introduced the procedure in 1967.

The Ross procedure is performed by transplanting a patient's healthy pulmonic valve along with a portion of the pulmonary artery to replace the aortic valve and a few centimeters of the aorta. The left and right coronary arteries are attached to the valve wall of the pulmonary autograft after making small slits through the valve wall into coronary sinuses of the autograft.

The pulmonic valve is typically replaced by a homograft, such as a pulmonic or aortic heart valve from a cadaver. The Ross procedure is preferred over other heart valve replacement procedures, especially for individuals who are unable to take anticoagulation drugs. The Ross procedure has received substantial discussion in various publications.

For example, Oury et al., An Appraisal of the Ross Procedure: Goals and Technical Guidelines, Operative Techniques in Cardiac and Thoracic Surgery, Vol. 2, No. 4 (November), 1997: pp. 289–301, describes the Ross procedure as well as some alternative techniques for performing the procedure.

Black et al., Modified Pulnronary Autograft Aortic Root Replacement: The Sinus Obliteration Technique, Ann Thoracic Surgery, 1995; 60:1434–1436, describes a rather complicated technique to remedy a frequent problem of dilation of the pulmonary autograft following the Ross procedure. This approach utilizes large coronary buttons to replace the pulmonary sinus completely and leaves the non-coronary aortic sinus to support the non-coronary sinus of the pulmonary autograft.

SUMMARY OF THE INVENTION

The present invention is directed to an external support apparatus for a heart valve that is disposed within an elongated tubular valve wall. The apparatus includes a girdle having an elongated cylindrical sidewall with inflow and outflow ends that are spaced apart an axial length that is at least substantially commensurate with the axial length of the heart valve disposed within the tubular valve wall.

Preferably, at least two apertures are formed through the sidewall of the girdle and spaced axially from the inflow end thereof. The apertures are spaced circumferentially apart for generally radial alignment with corresponding sinuses of the heart valve which is to be supported by the girdle. The inflow end of the girdle preferably is folded toward the outflow end to provide additional support at its inflow end.

In another embodiment, the girdle, as described above, is further supported by a stent disposed externally about the sidewall of the girdle.

Yet another embodiment of the present invention is directed to a method for improving implantation of a heart valve having inflow and outflow ends and located within a tubular valve wall. An elongated cylindrical girdle is disposed about the tubular valve wall and the heart valve located therein so as to inhibit deformation of the heart valve. The girdle has a cylindrical sidewall portion with inflow and outflow ends spaced apart an axial length at least substantially commensurate with the axial length of the heart valve located within the zubular valve wall. The inflow end of the girdle is positioned adjacent the inflow end of the tubular valve wall. During implantation of the heart valve, the inflow ends of the valve and girdle preferably are secured together to an outflow annulus of the heart.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other features and advantages of the present invention will become apparent to those skilled in the art to which the present invention relates upon reading the following description with reference to the accompanying drawings, wherein:

FIG. **1** is a first embodiment of an apparatus in accordance with the present invention;

FIG. **2** is a second embodiment of an apparatus in accordance with the present invention;

FIG. **3** is a third embodiment of an apparatus in accordance with the present invention;

FIG. **4** is a fourth embodiment of an apparatus in accordance with the present invention;

FIG. **5** is a fifth embodiment of an apparatus in accordance with the present invention;

FIG. **6** is a sixth embodiment of an apparatus in accordance with the present invention;

FIG. **7** is an is ometric view of the apparatus of FIG. **1** mounted to a heart valve being implanted to a patient's heart;

FIG. **8** is an isometric view, similar to FIG. **7**, illustrating a completed heart valve transplant procedure using the apparatus of FIG. **1**; and

FIG. **9** is an isometric view of the apparatus of FIG. **5** disposed about a heart valve in accordance with the present invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

FIG. **1** illustrates a first embodiment of a heart valve girdle **10** in accordance with the present invention. The girdle **10** has an inflow end **14** and an outflow end **16** spaced apart by a length of a cylindrical sidewall **18**. The terms "inflow" and "outflow" are used herein to refer to ends of the girdle which are to be positioned at corresponding ends of a heart valve.

Because the girdle **10** is to be mounted externally about a heart valve, such as an autogenous or homogenous heart valve disposed within a length of a tubular valve wall, the axial length of the sidewall **18** is at least substantially commensurate with the axial length of the heart valve which

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