United States Patent [19]

Bédard

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[45] **Date of Patent: Mar. 26, 1985**

[54] **CARDIAC VALVE PROSTHESIS HOLDER**

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[73] Assignee: **Molrose Management, Ltd.**, Ontario, Canada

[21] Appl. No.: **457,514**

[22] Filed: **Jan. 13, 1983**

[51] **Int. Cl.**[3] **A61F 1/22**

[52] **U.S. Cl.** ..... **3/1.5**; 128/334 R

[58] **Field of Search** ..... 3/1.5, 1; 128/334 R, 128/334 C

[56] **References Cited**

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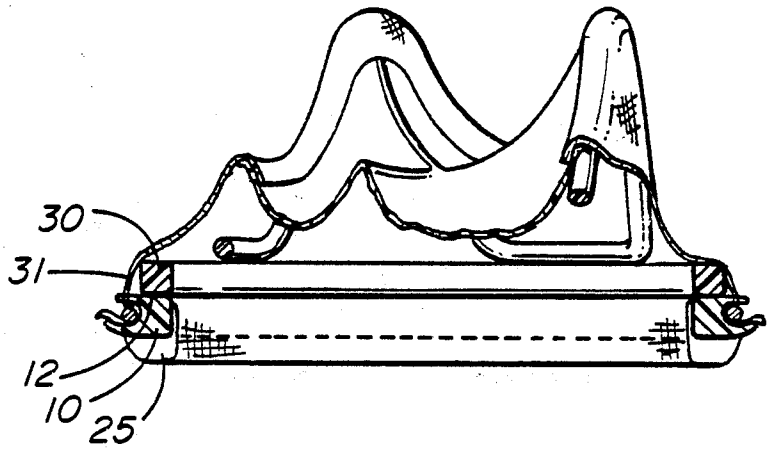
Primary Examiner—Ronald L. Frinks

[57] **ABSTRACT**

An implantable device which is suited for implantation into a human or animal heart for receiving and removably holding a valve prosthesis is described. The device comprises a ring structure which is adapted to be fixed to the tissue around the orifice of a heart valve after excision of the diseased or damaged natural valve has been effected. In use, the ring structure is fixed in place and then the appropriate valve prosthesis is attached to the ring. When the valve prosthesis fails and has to be replaced with a new prosthesis, the damaged prosthesis can be detached from the ring allowing a replacement prosthesis to be fixed to the ring without affecting the connection between ring structure and tissue.

6 Claims, 16 Drawing Figures



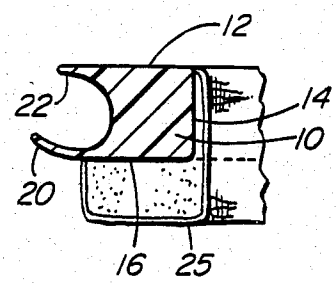


FIG. 1

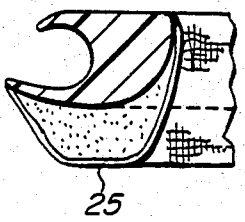


FIG. 4

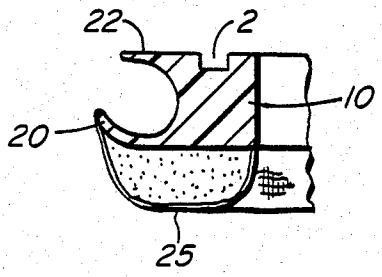


FIG. 2

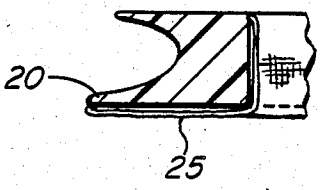
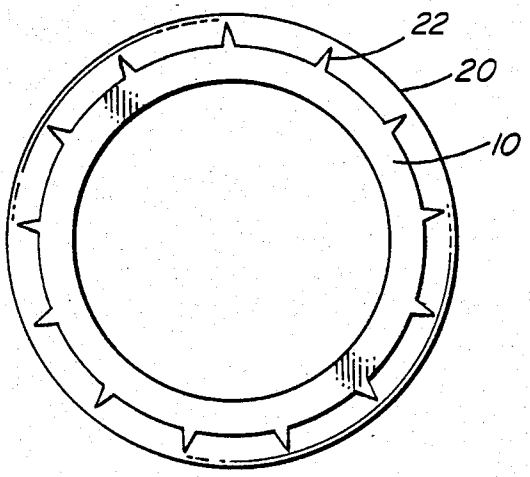


FIG. 5



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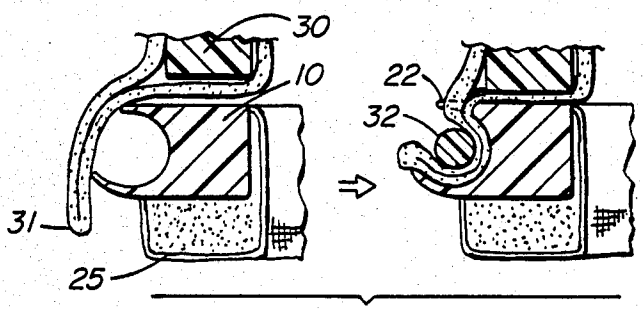

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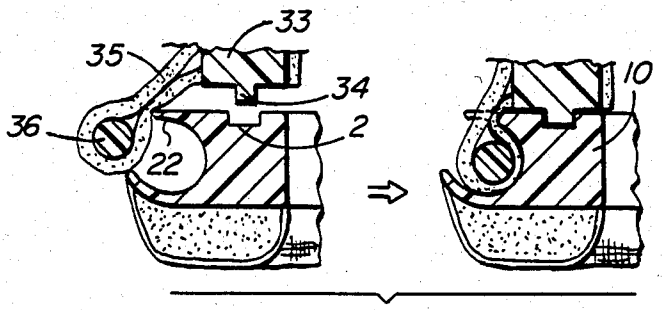


FIG. 7

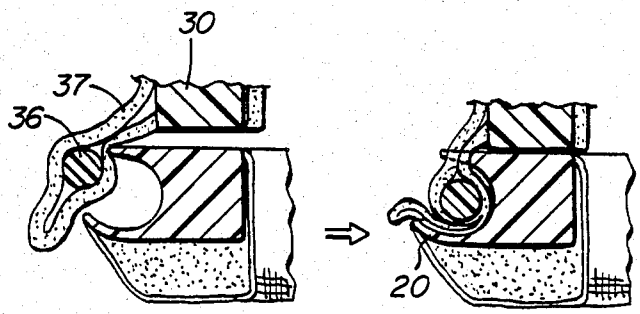
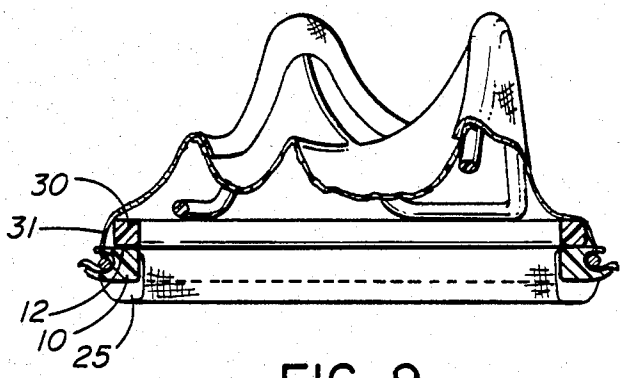


FIG. 8



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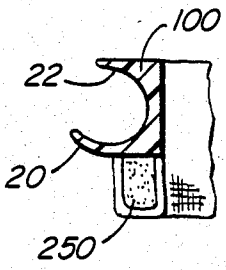

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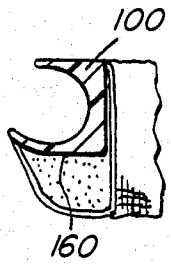

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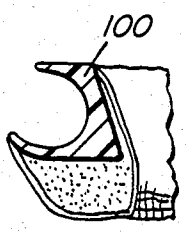

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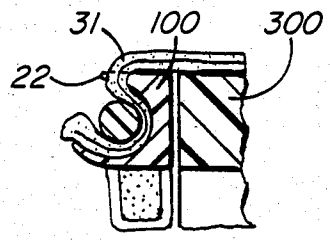

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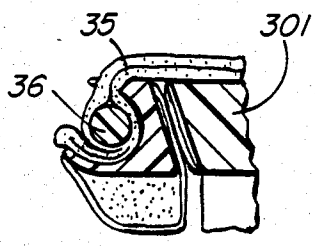

FIG. 14

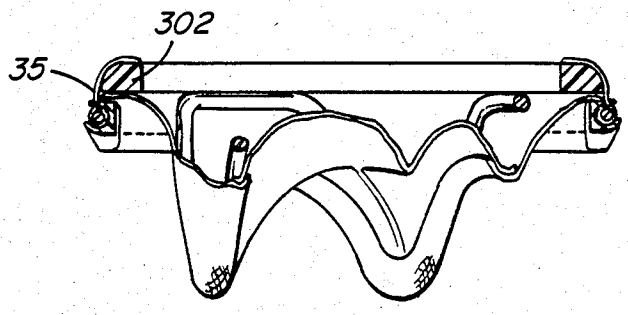

FIG. 15

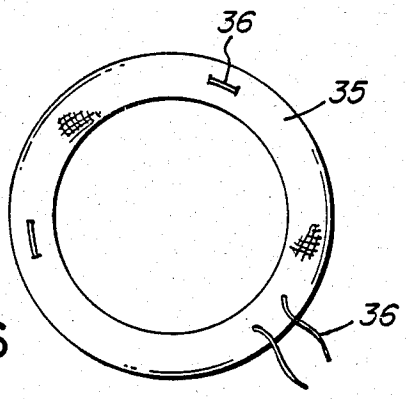

FIG. 16

CARDIAC VALVE PROSTHESIS HOLDER

This invention relates to a device adapted to be implanted into a human or animal heart for receiving and removably holding in place a valve prosthesis. More particularly, the invention relates to a ring arrangement adapted to be attached to tissue surrounding a diseased or damaged cardiac valve to facilitate insertion and replacement of a valve prosthesis.

An implantable device of this kind should be durable and last for many years while exposed to body fluids and wear caused by movement of the valve prosthesis relative to the ring in response to the constantly changing pressure exerted on the valve. Furthermore, such a ring arrangement requires provisions permitting the ring to be securely fixed to the tissue surrounding the valve orifice. In use, the ring should allow free flow through the valve and any obstruction of the valve orifice should be kept to a minimum such as by using a ring arrangement with an orifice substantially identical to that of the valve and the valve prosthesis. A ring of this kind further requires provisions for securing a valve prosthesis to the ring in such a way that the prosthesis can easily be replaced as required, but does not become disconnected unless removed by a surgeon. Moreover, the ring arrangement should be made of or covered with materials which are inert and also substantially non-thrombogenic.

Valve prostheses have been used to replace various diseased or damaged natural valves. Among the four heart valves, the aortic valve, the mitral valve, the pulmonic valve and the tricuspid valve, the aortic and mitral valves are most frequently replaced.

The mitral valve controls the flow of blood between the left atrium and the left ventricle and the aortic valve controls the blood flow from the left ventricle into the aorta.

Generally the known cardiac valve prostheses are either bioprostheses and mechanical prostheses. The bioprostheses are generally made of a suitable animal tissue on a metal or plastic frame while the mechanical prostheses are made entirely of metal and/or plastic material.

The valve prostheses are adapted to be stitched to the tissue surrounding the diseased valve that is being replaced. To this effect the valve prosthesis frame includes a generally circular structure, the valve seat, which is mostly made of metal or plastic and which is usually provided with a woven or knitted fabric to facilitate suturing. The fabric surrounding the circular structure and often also other parts of the valve frame is mostly called a sewing ring or skirt.

Heart valve prostheses are subject to severe wear and often have to be replaced after a relatively short time. Other factors which necessitate replacement of an implanted valve prosthesis are the patient's adverse reaction to the implant, physical or chemical changes in the components of the valve, particularly those components which are of biological origin, or other material failure.

Every time replacement of an implanted prosthesis is effected, the sutures holding the prosthesis in place have to be removed and the new valve prosthesis has to be stitched to the same tissue area as the previous one. In this way the tissue surrounding the valve orifice becomes perforated and scarred and with each replacement operation it becomes progressively more difficult to secure the implant to the tissue.

In an effort to test and compare the performance of various valve prostheses in vivo Wexler et al (J. Cardiovasc. Surg. (Torino) 11,236–38, 1970) proposes the temporary implantation of an elastic sewing ring into the heart of a laboratory animal in which the various prostheses are to be tested. Wexler's elastic sewing ring is made of rubber bands covered with fabric and provided with four wires which are looped around the rubber bands and extend through the fabric to facilitate gripping of the sewing ring. The sewing ring is placed around a valve prosthesis and inserted into the valve opening. The sewing ring is stitched to the tissue and in this way holds in place the prosthesis to be tested. When the testing of the thus implanted valve prosthesis is completed, generally after about 1 hour, the sewing ring is expanded to release the first valve prosthesis and allow insertion of the second. In this way the rubber sewing ring allows rapid replacement of the valve prosthesis. Of course, Wexler's rubber sewing ring is designed only for very short term use in animal tests. The ring could not safely be implanted for any long term use, since the material is subject to fairly rapid deterioration and since, even prior to any noticeable deterioration, the rubber ring could easily be accidentally disconnected from the valve prosthesis as a result of the pressure differentials encountered in the heart. Moreover the protruding wires are likely to cause damage to the surrounding tissue.

Accordingly, the present invention provides an implantable device such as a ring arrangement which is suited for implantation into a human or animal heart for receiving a valve prosthesis. The ring is adapted to be fixed to the tissue around the orifice of the heart valve after excision of the diseased or damaged natural valve has been effected. Once the ring is fixed in place the appropriate valve prosthesis can be attached to the ring. When the valve prosthesis fails and has to be replaced with a new prosthesis, the damaged prosthesis is detached from the ring and the new replacement prosthesis is fixed to the ring. Since the connection between the ring and the tissue is not affected by this replacement of valve prostheses no additional perforation of the tissue takes place. This has the advantage that the operation is less traumatic for the patient and that the new valve prosthesis is as securely attached to the tissue as the old one was, even if over the years the valve prosthesis has to be replaced several times.

As the life expectancy of most bioprostheses is presently not yet known, surgeons often hesitate to use a bioprosthesis due to the uncertainty as to how often it will have to be replaced. Mechanical prostheses are often used instead, even though bioprostheses have some intrinsic advantages over the mechanical prostheses. For example, bioprostheses are generally less thrombogenic than mechanical prostheses which means that, while patients with mechanical valve prostheses have to be maintained on anticoagulants, patients with a bioprosthesis do not generally require long term anticoagulant therapy. As implantation of a ring according to the invention considerably facilitates replacement of valve prostheses, whether mechanical or bioprostheses, the ring allows surgeons to use bioprostheses more freely.

Use of the ring arrangement according to the invention also reduces the risk of perivalvular leaks developing, i.e. of blood passing between the tissue and the

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