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(54) Bioprosthetic heart valve

(57) A bovine bioprosthetic heart valve comprising a stent 1 made of a biocompetent and fatigue resistance material, said stent comprising a waist 1a and three spaced apart prongs 16 projecting therefrom, said waist having three curvatures vertically consecutively and said prongs being at the mounts formed at the junctions of said curvatures, said stent being covered with a biocompetent and durable polymer cloth (1d) stitched thereto, and three leaflets 3 of bovine pericardium mechanically cleaned and shaped and treated with anticalcific solution and preserved in a preservative solution, said leaflets each being disposed on the outer surface of said stent between adjacent prongs and stitched (1e) to the waist and prongs, and a sewing ring (4) of a biocompetent and durable polymer cloth located over said waist and stitched thereto.

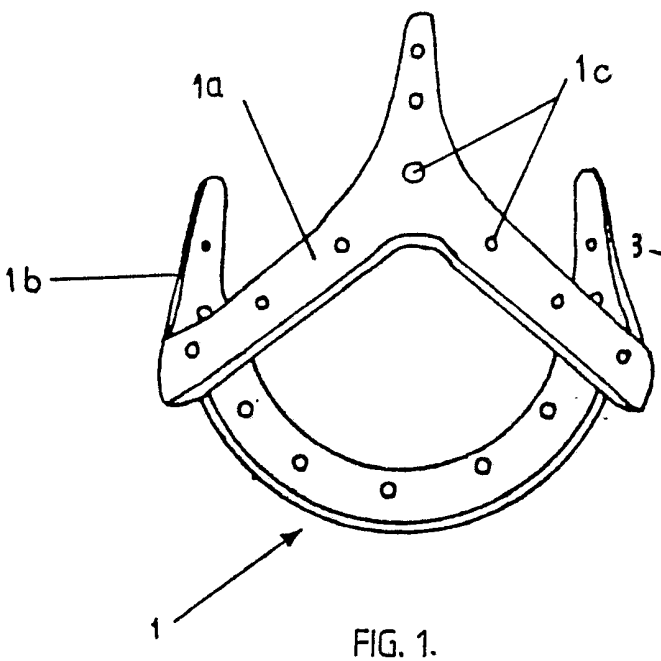

FIG. 1.

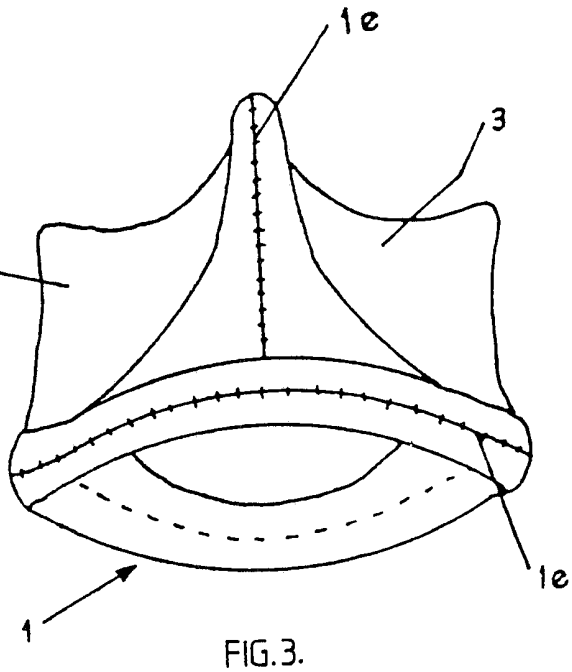

FIG. 3.

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The drawing(s) originally filed was (were) informal and the print here reproduced is taken from a later filed formal copy.

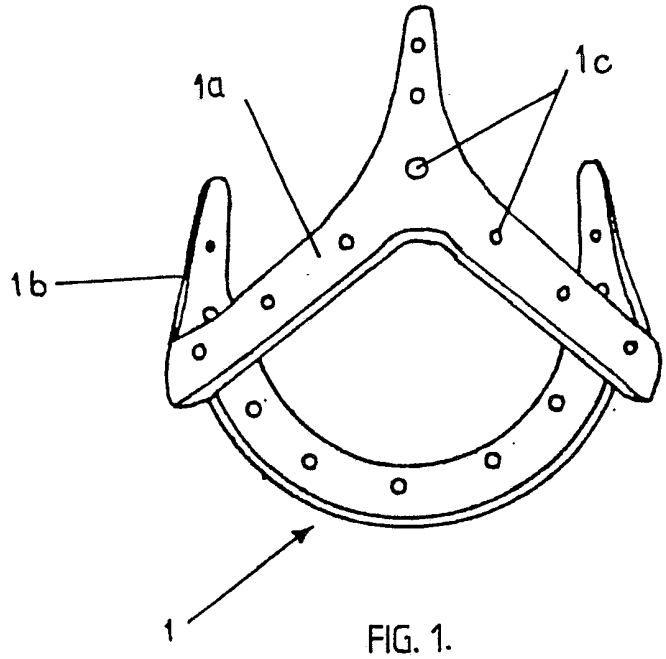

FIG. 1.

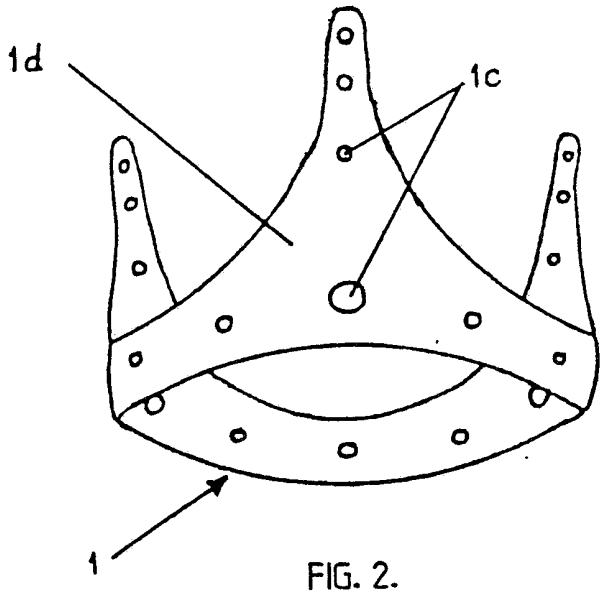

FIG. 2.

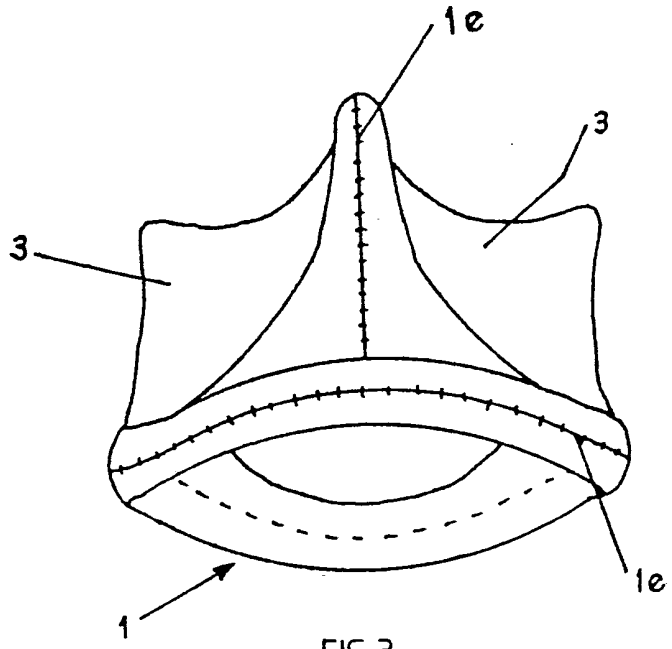

FIG.3.

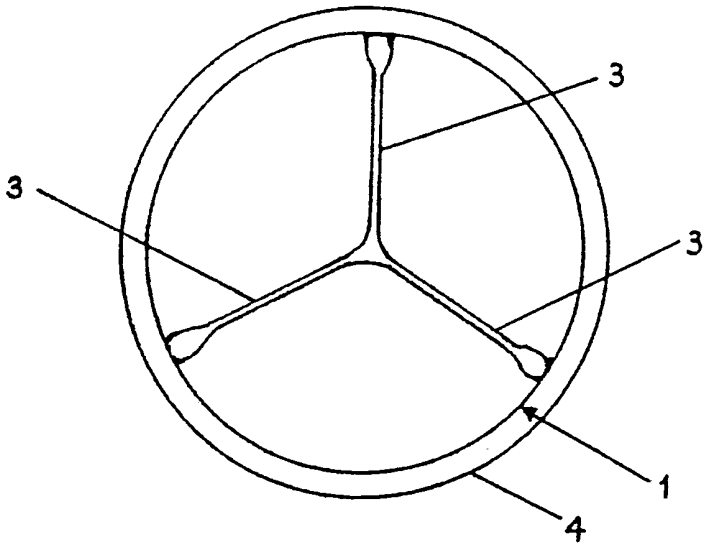

FIG. 4.

BIOPROSTHETIC HEART VALVE

This invention relates to a bioprosthetic heart valve.

Bovine bioprosthetic heart valves are used as replacements for diseased natural aortic, mitral, tricuspid and pulmonary heart valves. A typical conventional bovine bioprosthetic heart valve comprises a stent consisting of a straight waist provided with three spaced apart prongs projecting therefrom and three leaflets of bovine pericardium mechanically cleaned and shaped and treated with anticalcific solution and preserved in a preservative solution. The leaflets are disposed on the inner surface of the stent between the prongs and stitched on to the waist and prongs. The stent is usually made of biocompetent flexible plastic material such as polypropylene. The adjoining free ends of the leaflets are provided with commissural stitches. Such a valve also includes a sewing ring of biocompetent and durable polymer cloth such as dacron cloth provided over the waist and stitched thereto. A disadvantage of such a valve is that the stent being flexible leakage of blood may occur between the outer surface of the waist and the implantation site (paravalvular leakage). Another disadvantage of such valve is that with time the plastic stent may become brittle and break. In fact there are known instances where the valve has become disfunctional due to fracture of the stent. Another disadvantage of such valve is that since the leaflets are disposed on the inner surface of the stent and the adjoining free ends of the leaflets are provided with

commissural stitches, the primary opening provided by the waist is larger than the secondary opening provided by the free ends of the leaflets. This will cause pressure drop when blood flows through the valve. Another disadvantage of such a valve is that it has been found to calcify particularly in younger patients. Another disadvantage of such a valve is that the waist being straight the prongs are long and there are chances of the prongs rupturing small left ventricle of the heart and the ascending aorta when implanted at the aortic position.

The object of the present invention is to obviate the above disadvantages and provide an improved bovine bioprosthetic heart valve.

According to the present invention there is thus provided a bovine bioprosthetic heart valve comprising a stent made of a biocompetent and fatigue resistant material, such as zirconium, said stent comprising a waist and three spaced apart prongs projecting therefrom, said waist having three curvatures vertically consecutively and said prongs being at the mounts formed at the junctions of said curvatures, said stent being covered with a biocompetent and durable polymer cloth, such as dacron cloth, stitched thereto, and three leaflets of bovine pericardium mechanically cleaned and shaped and treated with anticalcific solution and preserved in a preservative solution said leaflets each being disposed on the outer surface of said stent between adjacent prongs and stitched to the waist and prongs and a sewing ring of a biocompetent and durable polymer cloth, such as dacron cloth,

located over said waist and stitched thereto.

An embodiment of the invention is described hereinbelow with reference to the accompanying drawings, in which :

Fig. 1 is isometric view of the stent;

Fig. 2 is isometric view of the stent after covering it with a biocompetent and durable polymer cloth such as dacron cloth;

Fig. 3 is elevation of the bovine bioprosthetic heart valve without the sewing ring; and

Fig. 4 is plan of the valve of Fig. 3 including the sewing ring.

Referring to the drawings, 1 is a zirconium stent comprising a waist 1a and three spaced apart prongs 1b projecting therefrom (See Fig.1). Stitching holes provided in stent 1 are marked 1c. The waist 1a is provided with three curvatures vertically consecutively (not marked but can be seen in Fig. 1) and the prongs 1b are at the mounts (not marked but can be seen in Fig. 1) formed at the junctions of the curvatures. The stent 1 is covered with a biocompetent and durable polymer cloth such as dacron cloth 1d (See Fig.2). Three leaflets marked 2 of bovine pericardium merchanically cleaned and shaped and treated with anticalcific solution/and such as polyoxy sorbitan monooleate ('Tween 80') preserved in a preservative solution such as glutaraldehyde are disposed on the outer surface of the stent between the prongs and stitched on to the waist and prongs (See Figs. 3 and 4). The stitches are marked 1e. 4 is a sewing ring of biocompetent and durable polymer cloth such as dacron cloth located on the waist and stitched thereto. At the time of

implantation, the valve is stitched on to the site of implantation through the sewing ring.

The above embodiment is by way of example and should not be considered to be limitative of the scope of the present invention.

An advantage of the improved valve is that zirconium being biocompatable and very fatigue resistant and rigid there are no chances of paravalvular leakage at implantation site and failure of the valve due to brittleness of the stent. The improved valve is, therefore, safe and reliable and has longer life.

Another advantage of the improved valve is that since the leaflets are mounted on the outer surface of the stent and since there are no commissural stitches at the adjoining free ends of the leaflets the secondary opening provided by the free ends of the leaflets is larger than the primary opening provided by the waist. Consequently there will not be any pressure drop when blood flows through the valve and comparatively more blood will flow through the valve and the ventricle will not be subjected to undesirable excess pressure.

Another advantage of the improved valve is that since the waist is provided with curvatures with mounts at the junctions thereof and since the prongs are provided at the mounts, the prongs can be shorter. Therefore, there are no chances of the prongs rupturing the small left ventricle of the heart and the ascending aorta when it is implanted at the aortic position.

Another advantage of the improved valve is that by treating the leaflets with an effective selected anticalcific solution chances of decalcification can be eliminated thereby increasing the life of the valve.

CLAIMS:

1. A bovine bioprosthetic heart valve comprising a stent made of a biocompetent and fatigue resistance material, said stent comprising a waist and three spaced apart prongs projecting therefrom, said waist having three curvatures vertically consecutively and said prongs being at the mounts formed at the junctions of said curvatures, said stent being covered with a biocompetent and durable polymer cloth stitched thereto, and three leaflets of bovine pericardium mechanically cleaned and shaped and treated with anticalcific solution and preserved in a preservative solution said leaflets each being disposed on the outer surface of said stent between adjacent prongs and stitched to the waist and prongs and a sewing ring of a biocompetent and durable polymer cloth located over said waist and stitched thereto.

2. A bovine bioprosthetic heart valve according to Claim 1, wherein the stent is made of zirconium.

3. A bovine bioprosthetic heart valve according to Claim 1 or Claim 2, wherein the polymer cloth with which the stent is covered is dacron cloth.

3. A bovine bioprosthetic heart valve according to any one of claims 1 to 3, wherein the sewing ring is made of dacron cloth.

4. A bovine bioprosthetic heart valve substantially as hereinbefore described with reference to the accompanying drawings.

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