

[54] **PROSTHETIC CARDIAC VALVE**

[76] Inventors: **Brian John Bellhouse**, The Ridings, Islip near Oxford; **Francis Hewitt Bellhouse**, 34 Hill Rise, Old Woodstock, both of England

[22] Filed: **June 10, 1971**

[21] Appl. No.: **151,740**

[52] U.S. Cl. **3/1, 3/DIG. 3, 137/525.1**

[51] Int. Cl. **A61f 1/22, F16k 15/14**

[58] Field of Search **3/1, DIG. 3; 137/525, 525.1**

[56] **References Cited**

UNITED STATES PATENTS

3,197,788 8/1965 Segger **3/1**

OTHER PUBLICATIONS

"The Direct Approach for the Correction of Aortic Insufficiency" by Charles A. Hufnagel, Journal of the American Medical Association, Vol. 178, No. 3, Oct. 21, 1961, pp. 275-279.

"A Prefabricated Semirigid Tricuspid Aortic Valve Prosthesis" by E. A. Hessel et al, Journal of Thoracic & Cardiovascular Surgery, Vol. 54, No. 2, August, 1967, pp. 227-241 relied upon.

"A Pseudoendocardium For Implantable Blood Pumps" by D. Liotta et al. Trans. Amer. Soc. Artif. Int. Organs, Vol. XII, 1966, pp. 129-134.

"Comparative Study of Cardiac and Vascular Implants in Relation to Thrombosis" by C. A. Hufnagel et al. Surgery, Vol. 61, No. 1, January, 1967 pp. 11-16.

Primary Examiner—Richard A. Gaudet

Assistant Examiner—Ronald L. Frinks

Attorney—Holcombe, Wetherill & Brisebois

[57]

ABSTRACT

A prosthetic aortic or pulmonary valve for permanent cardiac implantation into the natural valve root having a framework which is made from sheet woven of knitted textile fabric material and which consists of an annular ring with three equiangularly spaced projecting legs which extend substantially parallel to one another in the axial direction from the ring. Each leg is folded about its longitudinal center line so that the side edges of the legs form radially outwardly projecting flanges, the adjacent flanges of adjacent legs merging through curves into the portion of the ring lying between those two legs whereby a substantially U-shaped continuous outwardly projecting flange is formed between each pair of the three pairs of adjacent legs. The framework supports three separate cusps made of thin flexible impermeable sheet material, each cusp having a substantially U-shaped edge which overlies one of the substantially U-shaped flanges and is bonded to it, and a free edge which extends between the free ends of the corresponding pair of legs and has a length substantially equivalent to one third of the internal diameter of the framework ring.

6 Claims, 6 Drawing Figures

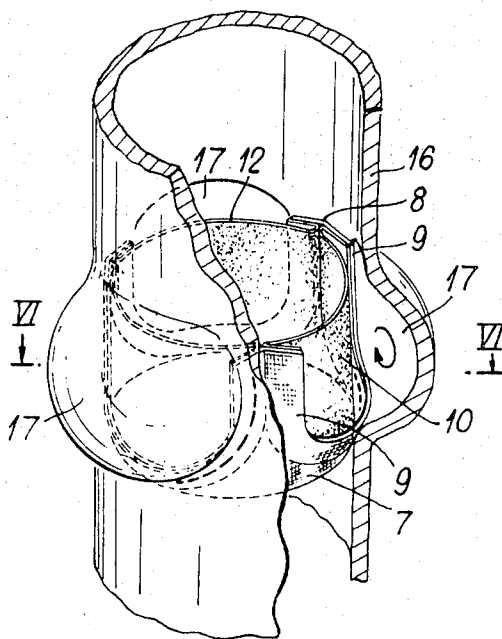


Fig. 1

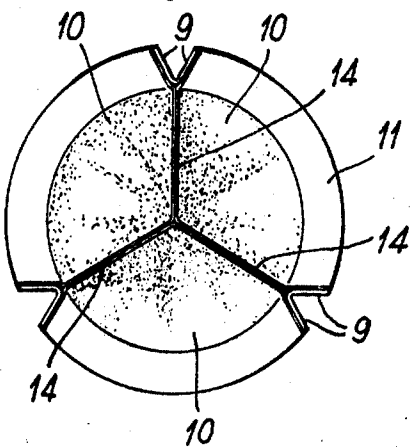


Fig. 3

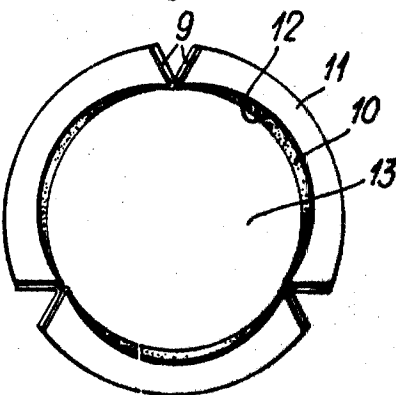


Fig. 2

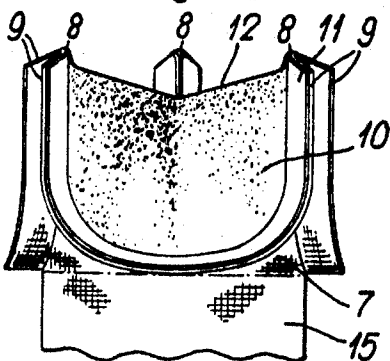
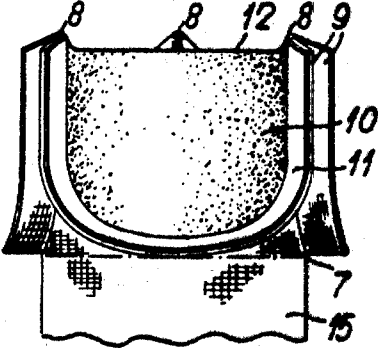
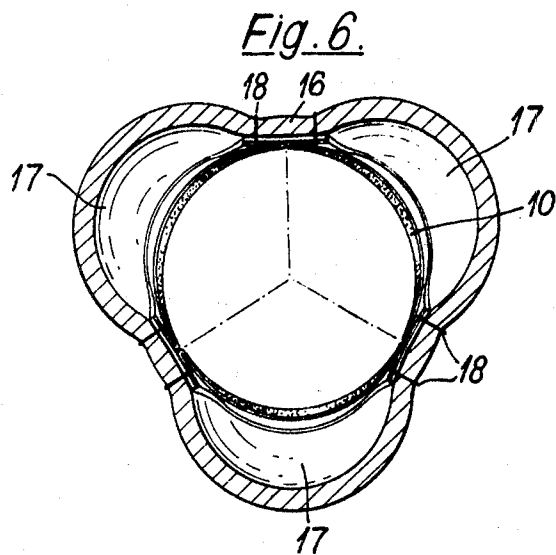
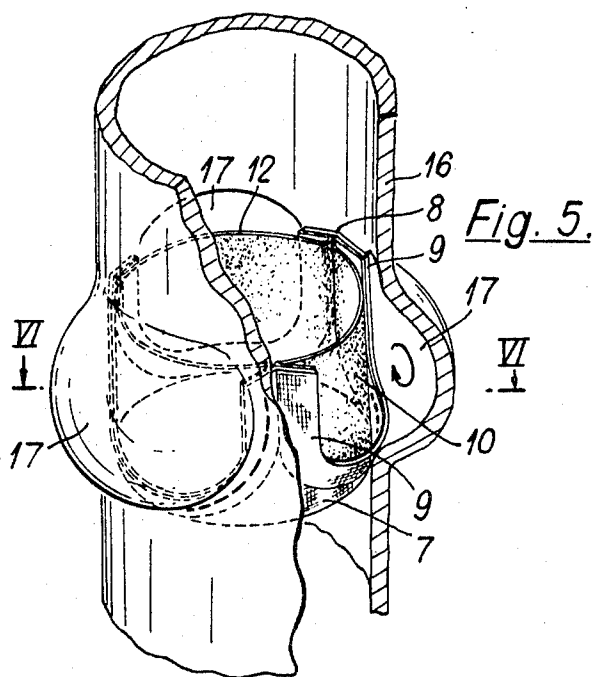


Fig. 4





PROSTHETIC CARDIAC VALVE

As explained in some detail in U.S. Pat. No. 3,608,097, our research has persuaded us that the aortic valve of the human heart is a tricuspid valve which, when the blood is pumped from the left ventricle opens fully to allow the laminar flow of the blood. The three cusps of the valve co-operate with the three sinus bulges in the aortic wall to provide chambers which are open to the flow of blood through openings where the free ends of the cusps terminate short of the distal, that is downstream, ends of the sinuses. At this point the shoulders formed by the ends of the sinuses intercept part of the flow through the valve with the result that vortices, tending to urge the cusps to the closed position, are set up in the chambers. These vortices continue when the blood flow through the valve decelerates at the end of systole with the result that the cusps are moved almost to their closed position before there is any appreciable backflow. We believe that these conditions also exist in the pulmonary valve of the right ventricle and also in the aortic and pulmonary valves of many animals other than humans.

Our present consideration is the provision of a prosthetic aortic or pulmonary valve for permanent implantation in the aortic or pulmonary root where new cusps have to be provided for co-operation with the natural sinus bulges in the root wall.

In the earlier application a prosthetic valve was disclosed in which the cusps were provided by arcuate portions of a unitary cylinder of suitable flexible material, the cylinder being supported by a rigid metallic or plastic skeleton including a ring to which one end of the cylinder is attached and defines the upstream diameter of the valve and three prongs extending axially downstream from the ring at 120° intervals, the wall of the cylinder being secured to the prongs to define the axial edges of the cusps. The downstream end of the cylinder then provides the free edges of the cusps extending between the tips of the three prongs and these edges open into a circular configuration when the valve is open and meet one another along three equiangularly spaced radii when the valve is closed. This construction, although providing the basis for a practical prosthetic valve has two disadvantages. It is difficult to stitch the prongs adequately to the natural valve wall between the sinus bulges and the provision of the rigid skeleton encourages movement between the skeleton and the flexible aortic root, and emphasizes the fact that the prosthetic valve is a foreign body.

In accordance with the present invention a prosthetic aortic or pulmonary valve for permanent cardiac implantation into the natural valve root has a framework which is made from sheet woven or knitted textile fabric material and which consists of an annular ring with three equiangularly spaced projecting legs which extend substantially parallel to one another in the axial direction from the ring, each leg being folded about its longitudinally center line so that the side edges of the legs form radially outwardly projecting flanges, the adjacent flanges of adjacent legs merging through curves into the portion of the ring lying between those two legs whereby a substantially U-shaped continuous outwardly projecting flange is formed between each pair of the three pairs of adjacent legs; the framework supporting three separate cusps made of thin flexible impermeable sheet material, each cusp having a substan-

tially U-shaped edge which overlies one of the substantially U-shaped flanges and is bonded to it, and a free edge which extends between the free ends of the corresponding pair of legs and has a length slightly greater than one third of the internal circumference of the framework ring.

This new arrangement has the advantage that it may be stitched in position in the natural valve root wall by stitches passing through each of the U-shaped flanges and the overlying edges of the cusps. The cusps as well as the framework are then positively stitched in position. The framework, being made of a fabric, provides adequate support for the cusps and is able to conform to the particular shape of a particular natural valve wall, and also to follow the natural dilation and contraction of the valve wall during the blood pumping cycle, both without appreciable irritation.

Preferably the fabric from which the framework is formed is a fine uncut terylene which may be coated with silicone rubber. Velour has the advantage of providing a rough surface into which the natural tissue will grow and knit. The legs and ring of the framework may be cut as an integral piece from the fabric, the legs then being bent out of the plane of the ring before having the cusps attached to them.

At present we prefer to make each of the cusps from a fine woven or knitted terylene fabric coated with silicone rubber. The U-shaped edge of each cusp may be bonded to the complementary flange of the framework by means of a suitable medical quality thermoplastic bonding agent such as silicone rubber.

One example of a prosthetic aortic valve, constructed in accordance with the invention, and its use, are illustrated in the accompanying drawings, in which:

FIG. 1 is a downstream end elevation of the valve shown in the closed position;

FIG. 2 is a side elevation of the valve in the closed position;

FIG. 3 is a view corresponding to FIG. 1 but showing the valve open;

FIG. 4 is a view corresponding to FIG. 2 but showing the valve open;

FIG. 5 is a partially broken away perspective view of the valve in position in a natural aortic root; and,

FIG. 6 is a section taken on the line VI—VI in FIG. 5.

The valve has a framework 7 consisting of a ring with three equiangularly spaced axially extending legs 8, made from terylene velour coated with silicone rubber. The ring and legs are folded to provide outwardly projecting flanges 9 each of which is of U-shaped configuration and is continuous between a corresponding pair of adjacent legs 8. Three similar cusps 10, each of substantially D shape and made of ten denier knitted terylene coated with silicone rubber, overlap and are bonded with a silicone rubber adhesive each by an edge 11 to a corresponding one of the flanges 9. The length of the free straight edge 12 of each cusp 10 is slightly greater than one third of the circumference of the ring 7 so that when the valve is open, as shown in FIG. 3, the cusps define a substantially cylindrical passage 13 for laminar flow through the valve, but when in the closed position shown in FIG. 1, they meet one another along equiangularly spaced radial planes 14 of abutment to close the flow passage.

Prior to implantation the ring 7 is manufactured with an extension 15. However immediately before sliding

the valve into the position in the aortic root the extension 15 is trimmed back, for example to the chain dotted line shown in FIGS. 2 and 4, substantially level with the bases of the U's of the flanges 9.

FIGS. 5 and 6 illustrate the valve sutured into a natural aortic root 16 provided with three natural sinus bulges 17. During implantation the prosthetic valve is secured in the aortic root by means of stitches 18 which pass through the flanges 9 and overlapping edges of the cusps 10, and the aortic wall. It will be appreciated that the U-shape of each flange 9 corresponds substantially to the U-shape of the line of contact with the natural tissue around the bottom and sides of each sinus 17.

In FIG. 5 the flow from the left ventricle of the heart will be upwardly through the valve and because the free edges 12 of the cusps 10 terminate short of the distal ends of the sinuses 17, hemispherical vortices, indicated by the curled arrow in FIG. 5, will be set up as described in our earlier U.S. patent. Consequently during systole, the valve will open and provide an uninterrupted cylindrical passageway for laminar blood flow but as soon as the flow decelerates, the vortices cause the cusps to fold inwards and close substantially immediately.

The flanges 9 provide a most convenient means for suturing the valve to the natural tissue and since the legs 8 and ring 7 are made of extremely pliable fabric, the valve produces the minimum of irritation likely to lead to trauma.

A prosthetic pulmonary valve will be constructed and implanted in a directly analogous manner to that described.

We claim:

1. A prosthetic cardiac arterial valve for permanent cardiac implantation into the natural valve root, said

valve having a framework made from sheet textile fabric material and consisting of an annular ring with three equiangularly spaced projecting legs which extend substantially parallel to one another in the axial direction from said ring, each leg being folded about a longitudinal center line so that side edges of said legs form radially outwardly projecting flanges, the adjacent flanges of adjacent legs merging through curves into the portion of said ring lying therebetween whereby a substantially U-shaped continuous outwardly projecting flange is formed between each pair of the three pairs of said adjacent legs; said framework supporting three separate cusps made of thin flexible impermeable sheet material, each cusp having a substantially U-shaped edge which overlies one of said substantially U-shaped flanges and is bonded thereto, and a free edge which extends between the free ends of the corresponding pair of said legs and has a length substantially equivalent to one third of the internal circumference of said framework ring.

2. A valve according to claim 1, wherein said fabric from which said framework is formed is a fine uncut terylene velour.

3. A valve according to claim 2, wherein said velour is coated with silicone rubber.

4. A valve according to claim 1, wherein said legs and said ring of said framework are cut as an integral piece from said fabric.

5. A valve according to claim 1, wherein each cusp is made from a fine terylene fabric coated with silicone rubber.

6. A valve according to claim 5, in which said terylene fabric is a ten denier warp knitted fabric.

* * * * *

40

45

50

55

60

65