Aug. 2, 1966 M. L. EDWARDS ETAL 3,263,239

AORTA VALVE WITH EXPANSIBLE SUTURING RING

Filed April 1, 1963

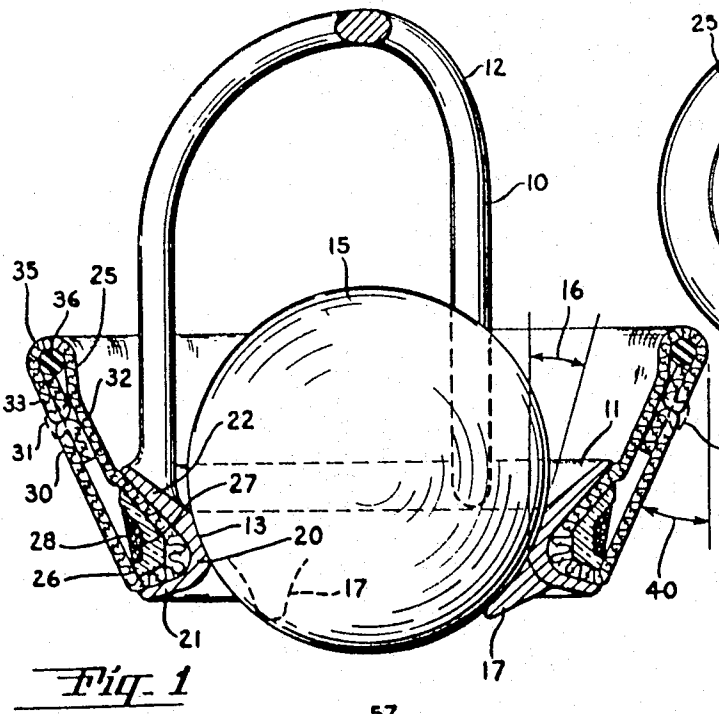

Fig. 1

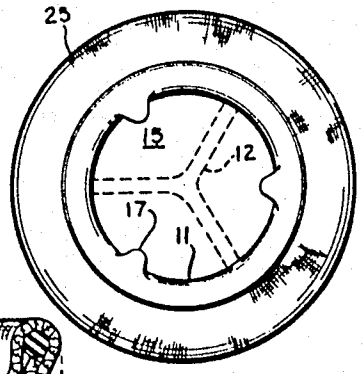

Fig. 3

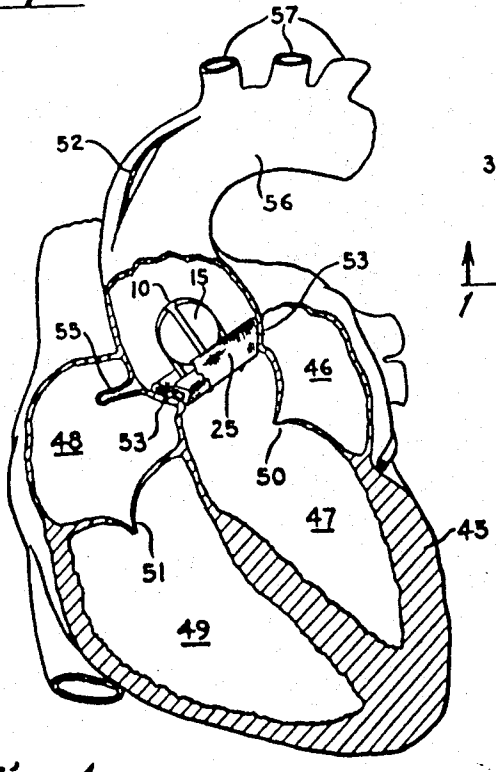

Fig. 4

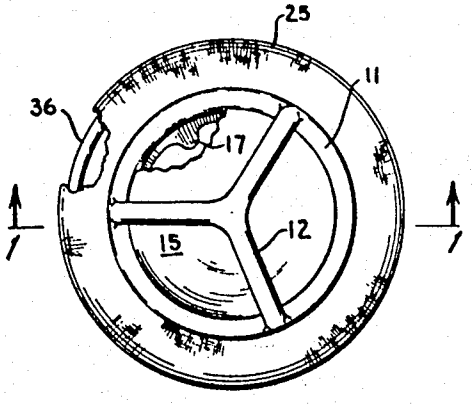

Fig. 2

INVENTORS.
MILES LOWELL EDWARDS
ALBERT STARR

BY
Lee R. Lahrmann
Attorney

United States Patent Office 3,263,239 Patented August 2, 1966

1

3,263,239

AORTA VALVE WITH EXPANSIBLE SUTURING RING

Miles Lowell Edwards, Santa Ana, Calif., and Albert Starr, Portland, Oreg., assignors to Edwards Laboratories, Inc., Santa Ana, Calif., a corporation of California

Filed Apr. 1, 1963, Ser. No. 269,299
13 Claims. (Cl. 3—1)

This application is a continuation-in-part of co-pending application Serial No. 49,044 filed August 11, 1960, now Patent No. 3,099,016.

This invention relates to an artificial valve as a prothesis in a heart to take the place of a defective natural valve.

The valve illustrated in said prior patent is a mitral valve, although the general features of construction therein disclosed are applicable to both mitral and aorta valves. The present application is directed to certain modifications of structure in order to adapt the general principles of the prior invention for utilization in an aorta valve. The present invention is not limited to aorta valves, however.

An aorta valve requires special consideration in its design and construction because the valve body must project into the aorta itself. There is less space for such mechanism in the aorta than in the chamber of the left ventricle which contains the body of the mitral valve. Thus, although the aorta valve must handle the same quantity of blood as the mitral valve, it must be smaller in its outside dimensions whereby special provision must be made to avoid throttling the flow of blood.

The objects of the invention are, therefore, to provide an improved artificial valve, to provide an improved aorta valve, to provide a valve for implantation directly in the entrance to the aorta below the coronary arteries and to provide a sewing ring for an aorta valve of conical skirt shape and made of expansile material which can change in diameter as variations in the blood pressure expand and contract the diameter of the aorta.

The present valve is generally similar to the mitral valve mentioned above but incorporates certain special features to increase the size of the port opening relative to the size of the valve body and to facilitate attachment of the sewing ring to the heart tissue directly at the entrance to the aorta. Other features and advantages will become apparent from the following detailed description of the preferred embodiment illustrated on the accompanying drawing. All variations and modifications within the scope of the appended claims are included in the invention.

In the drawing:

FIGURE 1 is a longitudinal sectional view of a valve embodying the principles of the invention;

FIGURE 2 is a top plan view of the valve in reduced scale with parts broken away;

FIGURE 3 is a bottom plan view of the valve; and

FIGURE 4 is a section of a human heart, showing the present valve installed therein.

The valve comprises an integral body member **10** made of a suitable material which is compatible with the human body. Various types of non-toxic plastic may be used, such as Dupont Lucite acrylic resin, Rohm & Haas Plexiglas acrylic plastic, and the like. Metal is preferable to plastic, however, the preferred material being an alloy known as Stellite which is non-corrodible and inert to blood and living tissue. Stainless steel may also be used.

The entire body **10** comprising a base or port ring portion **11** and a cage portion **12** is preferably made in one piece either as a molding or a casting. The base ring defines a valve port having an internal spherical seat **13** corresponding to the curvature of silicone rubber ball **15**. In order to provide as large a port as possible, the maximum inclination of seat **13** from the vertical is 15° as

2

indicated by the angle at **16**. In order to prevent any possibility of the ball escaping through the port, special retention means may be provided. These comprise three inwardly and downwardly directed stop fingers **17**. Preferably, these stops are disposed between the three legs of cage **12**. The stops may be omitted when the dimensions and angular relationships are such as to prevent the ball from escaping through the port in use. The resilient ball is inserted in the cage by squeezing it between two of the cage legs.

The outside of base ring **11** forms an annular channel **20** having a nearly horizontal bottom wall **21** having a slight downward inclination and an upwardly inclined top wall **22**. In the illustrated embodiment the inclination of wall **22** is approximately 45°. A flexible sewing ring **25** is mounted and secured in channel **20**.

Sewing ring **25** preferably comprises a piece of knitted Teflon cloth having a mid-portion clamped in the channel **20** by a one-piece split spreader ring **26** of suitable material such as Teflon plastic. The spreader ring **26** is itself channel-shaped in cross section with an external shape corresponding generally to the shape of channel **20** and having an outwardly facing channel **27**. The spreader ring is clamped against at least one thickness of the cloth by a winding **28** of Teflon thread which is wound under tension in chanel **27**. When the body member **10** is made of metal, all the other parts should be non-metallic to prevent electrolysis.

The lower end portion **30** of the cloth is folded back on upper portion **32** and stitched with Teflon thread **31** to a folded back upper end portion **33** of the cloth as shown. This produces a bight portion at **35** which encloses a resilient silicone rubber ring **36**. The cloth is formed into a smoth frusto-conical shape by a pressing operation. This results in a sleeve of inverted flaring skirt shape which makes an angle of about 22° with the vertical as indicated by the angle **40**. Rubber ring **36** serves as an extensile element to stiffen the free upper end of the skirt and hold it extended in circular configuration in plan view. The folded end portions at **30** and **33** abut each other to form a pad having a thickness of at least three layers of cloth. This provides secure anchorage for the sutures. Rubber ring **36** is not necessary in small sizes of the valve as then the cloth will hold itself in conical shape without a separate extensile element.

FIGURE 4 shows the manner of installing the valve in a human heart **45**. The heart has a left atrium **46**, a left ventricle **47**, a right atrium **48** and a right ventricle **49**. A mitral valve **50** prevents reverse flow of blood from left ventricle **47** back into left atrium **46** and a mitral valve **51** prevents reverse flow from right ventricle **49** back into right atrium **48**. Blood flows from left ventricle **47** through an aorta valve into aorta **56** from whence it is distributed into main arteries **57** and others leading to different parts of the body. The aorta normally makes a sharp bend between the heart and the arteries **57**, as shown.

The present valve is usually installed by making an incision **52** through the outside of this bend which provides access for surgical treatment of the natural aorta valve. The natural aorta valve parts are removed and the present valve is installed in the same location. The sewing ring **25** is secured to living tissue at the entrance to the aorta by threads or sutures **53** with the cage **12** extending up into the aorta. The suturing is facilitated by the action of extensile rubber ring **36** which holds the upper free end of the skirt portion of the sewing ring expanded into contact with the inside of the aorta wall, as shown. Normally, the aorta increases in size at this point whereby the flare of the skirt of the sewing ring conforms generally with the taper of the aorta.

The combination of upwardly inclined wall 22, the top surface of which conforms to the flow pattern of the blood, and the spacing of stop fingers 17 staggered between cage legs 12 provide maximum flow around the legs 12. This minimizes the tendency toward a shadow in the flow pattern between the legs and the sewing ring where clots could form. Usually about two-thirds of the sutures may be tied against the inner surface of the conical sewing ring adjacent to the legs of the cage. These suture knots are inclined to excite the clot formation. The staggered arrangement of stop fingers and cage legs is to avoid a concentration of impediments in the flow through the valve. This provide maximum washing of blood around the cage legs to the area directly between the leg and the inside of the sewing skirt to minimize the possibility of clot formation at that area.

It is to be noted that the valve is installed below the coronary arteries 55 so that it functions in the circulatory system the same as the natural aorta valve.

A most important feature of the valve is the expansile sewing ring brought about by the nature of the cloth used and the rubber ring placed in the upper extremity of the skirt. It aids the surgeon in selection of a valve. Although measuring devices are used, they are not precise and a certain amount of flexibility here is important.

Another point is that the valve is installed when the aorta is at zero pressure. When in use, the pressure extends the aorta diameter and the sewing ring must expand accordingly.

There is also the important point that the rubber ring being placed at the upper extremity of the skirt causes the pressure difference across the valve, when the valve is in a closed position, to be sealed at the location of the rubber ring forcing the entire area of the skirt outward against the aorta wall, preventing wrinkles. This action is very much like the seal in the leather cup of a bicycle tire pump.

Having now described our invention and in what manner the same may be used, what we claim as new and desire to protect by Letters Patent is:

1. A heart valve comprising a port ring, a movable valve member cooperating with the port in said ring, an outwardly facing annular channel in said port ring, said channel having a bottom side wall inclined slightly downward from the plane of said ring and a top side wall inclined upward at a much greater angle from said plane, an annular sewing ring comprising an upwardly flaring skirt of flexible material capable of being pierced by a needle and suture, and means clamping the lower end of said skirt in said channel.

2. A heart valve comprising a port ring, a movable valve member cooperating with the port in said ring, and an annular sewing ring secured to said port ring, said sewing ring comprising an upwardly flaring skirt of flexible material capable of being pierced by a needle and suture, said skirt comprising multiple layers of cloth formed to frusto-conical shape.

3. A heart valve comprising a port ring, a ball cage on the upper side of said port ring, a ball in said cage cooperating with the port in said ring, a plurality of stop fingers projecting inwardly from said ring to retain said ball in said cage, and an annular sewing ring secured to said port ring, said sewing ring comprising an upwardly flaring skirt of flexible material capable of being pierced by a needle and suture.

4. A heart valve as defined in claim 6, said cage comprising a plurality of spaced legs extending from said port ring and said stop fingers being staggered between said legs.

5. A heart valve comprising a port ring, a ball cage extending upwardly from the upper side of said ring, a ball in said cage, stop fingers projecting inwardly from said ring to retain said ball in said cage, an outwardly facing annular channel in said ring, a piece of cloth having its mid-portion secured in said channel, upper and lower ends of said cloth projecting from said channel being stitched together and formed into a frusto-conical skirt flaring upwardly and outwardly from said channel, and a rubber ring enclosed in a fold in the free upper end of said skirt.

6. A heart valve comprising a port ring, a ball cage extending upwardly from the upper side of said ring, a ball in said cage, a flexible skirt made of material capable of being pierced by a needle and suture, said skirt having its lower end secured about said ring and having a free upper end extending above said ring, and an extensile flexible ring secured in said upper end of said skirt.

7. A heart valve comprising a port ring, a ball cage on one side of said ring, a ball in said cage, and a flexible skirt made of material capable of being pierced by a needle and suture, said skirt having a small lower end secured to said ring and flaring outwardly and upwardly to a free upper end surrounding said cage above said ring.

8. A heart valve comprising a circular valve body having a valve member, a cloth having a portion disposed against said body, means securing said portion of said cloth around said body, and a ring of soft, resilient material enfolded in other portions of said cloth in outstanding position from said body.

9. A heart valve comprising a circular valve body having a valve member, an outwardly facing channel around said body, a cloth having a portion disposed in said channel, means securing said portion of said cloth in said channel, and a soft rubber ring enfolded in other portions of said cloth in outstanding position from said body.

10. A heart valve prosthesis comprising a substantially rigid circular valve body having a valve member and a cloth sleeve having a lower end surrounding and secured to said body, said sleeve extending axially of the valve body and having a substantially circular free upper end surrounding said valve member, spaced radially therefrom and at a substantial distance above said secured end.

11. A heart valve as set forth in claim 10 including circumferentially spaced stop fingers projecting inwardly from the side of said valve body opposite said valve member.

12. A heart valve as defined in claim 10, said valve body having an annular channel therearound, and means securing said lower end of said cloth sleeve in said channel.

13. A heart valve as defined in claim 10 including a soft rubber ring enfolded in said upper end of said sleeve.

References Cited by the Examiner

UNITED STATES PATENTS

1,890,594	12/1932	Turner	273—65.3
2,682,057	6/1954	Lord	3—1
2,688,979	9/1954	Kendrick	137—525.1 X
3,099,016	7/1963	Edwards	3—1
3,143,742	8/1964	Cromie	3—1

RICHARD A. GAUDET, *Primary Examiner.*

R. L. FRINKS, *Assistant Examiner.*

UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,263,239 August 2, 1966

Miles Lowell Edwards et al.

It is hereby certified that error appears in the above numbered patent requiring correction and that the said Letters Patent should read as corrected below.

Column 3, line 13, for "provide" read -- provides --; line 67, for the claim reference numeral "6" read -- 3 --.

Signed and sealed this 1st day of August 1967.

(SEAL)
Attest:

EDWARD M. FLETCHER, JR.
Attesting Officer

EDWARD J. BRENNER
Commissioner of Patents