June 20, 1967 M. L. EDWARDS 3,325,827

DOUBLE CAGE HEART VALVE

Original Filed April 1, 1963

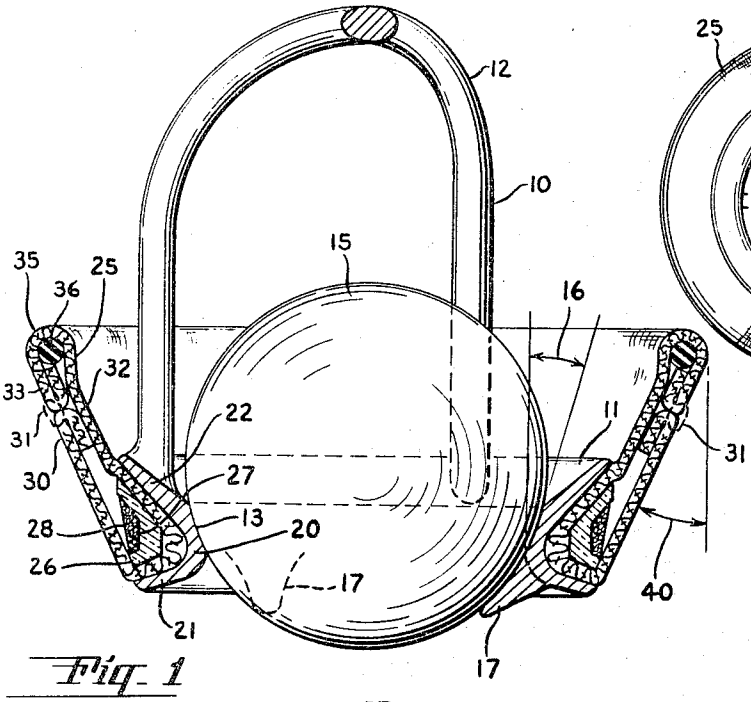


Fig. 1

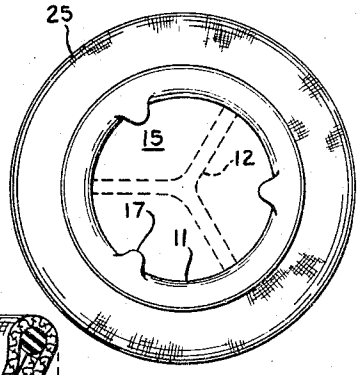


Fig. 3

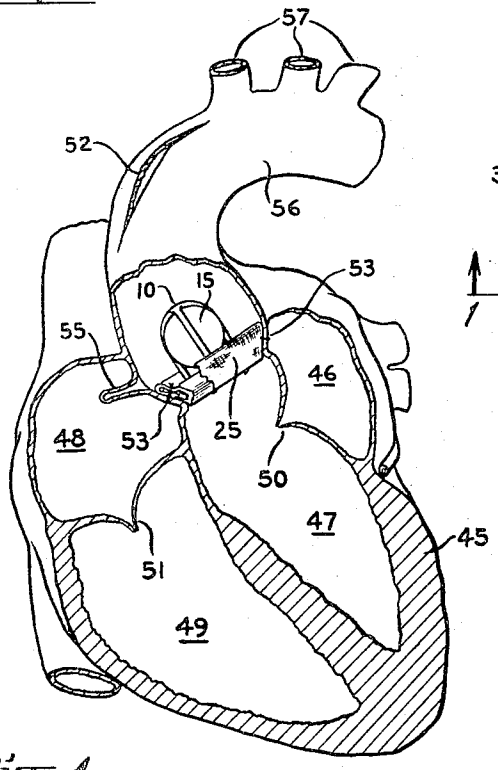


Fig. 4

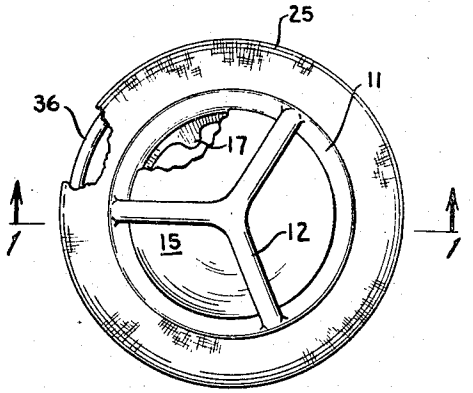


Fig. 2

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DOUBLE CAGE HEART VALVE

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Original application Apr. 1, 1963, Ser. No. 269,299, now Patent No. 3,263,239, dated Aug. 2, 1966. Divided and this application Apr. 11, 1966, Ser. No. 541,841
5 Claims. (Cl. 3—1)

This application is a division of co-pending application Ser. No. 269,299 filed April 1, 1963, now Patent No. 3,263,239 which is in turn a continuation-in-part of Ser. No. 49,044 filed Aug. 11, 1960, now Patent No. 3,099,016.

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

The valve illustrated in said prior Patent 3,099,016 is a mitral valve, although the general features of construction therein disclosed are applicable to both mitral and aorta valves. The claims of said Patent No. 3,263,239 are directed to certain modifications of structure in order to adapt the general principles of Patent No. 3,099,016 for utilization in an aorta valve. The claims in the present application are directed to features which are of advantage in any heart valve where an unusually large port opening is desired in the valve whereby the claimed structure is not limited to aorta valves.

The objects of the invention are, therefore, to provide an improved artificial heart valve and to provide an improved form of construction for heart valves having an unusually large port opening in relation to the size of the movable valve member.

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 Du Pont 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 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 channel **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 smooth 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 is 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 be-

tween 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 provides 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 my invention and in what manner the same may be used, what I 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, a cage for said valve member comprising a plurality of spaced legs projecting upwardly and inwardly from the upper side of said port ring, a plurality of stop fingers for said valve member projecting downwardly and inwardly from the lower side of said port ring, and means for securing the valve to the tissue of a living heart.

2. A heart valve as defined in claim **1**, said securing means comprising a suturing ring secured around the periphery of said port ring.

3. A heart valve as defined in claim **2**, said port ring having an outwardly facing channel therearound and said suturing ring comprising cloth, and a filamentary winding securing said cloth in said channel.

4. A heart valve as defined in claim **1**, said fingers being staggered between said legs.

5. A double cage heart valve prosthesis, said prosthesis having a ball arranged to cooperate with a port in a port ring wherein said port is large enough to make it possible for the ball to pass therethrough, a cage for said ball on the upper side of said port ring comprising a plurality of spaced legs projecting upwardly and inwardly from the upper side of said port ring, a second cage for said ball on the lower side of said port ring comprising a plurality of stop fingers projecting downwardly and inwardly from the lower side of the port ring, and means for securing the prosthesis to the tissue of a living heart.

References Cited

UNITED STATES PATENTS

3,099,016	7/1963	Edwards	3—1
3,143,742	8/1964	Cromie	3—1
3,263,239	8/1966	Edwards et al.	3—1

OTHER REFERENCES

"Development of a Titanium Double-Caged Full-Orifice Ball Valve," by Robert S. Cartwright et al., in Transactions American Society for Artificial Internal Organs, volume X, April 12, 1964, pages 231–236.

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Disclaimer

3,325,827.—*Miles Lowell Edwards*, Santa Ana, Calif. DOUBLE CAGE HEART VALVE. Patent dated June 20, 1967. Disclaimer filed Jan. 2, 1970, by the assignee, *American Hospital Supply Corporation.*

Hereby disclaims the terminal portion of the term of the said patent subsequent to August 2, 1983.

[*Official Gazette April 14, 1970.*]