Jan. 30, 1968 M. L. EDWARDS ET AL 3,365,728

UPHOLSTERED HEART VALVE HAVING A SEALING RING ADAPTED FOR DISPENSING MEDICAMENTS

Filed Dec. 18, 1964

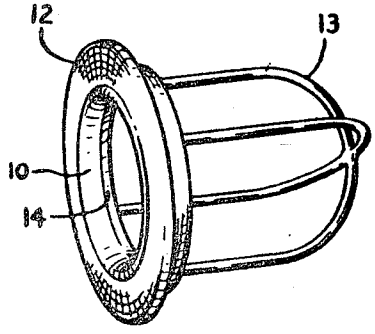


Fig 2

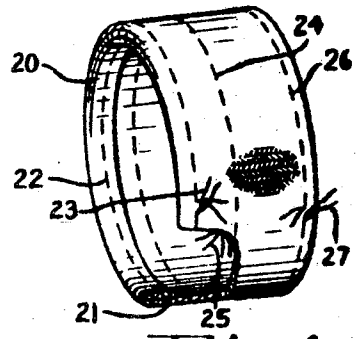


Fig 4

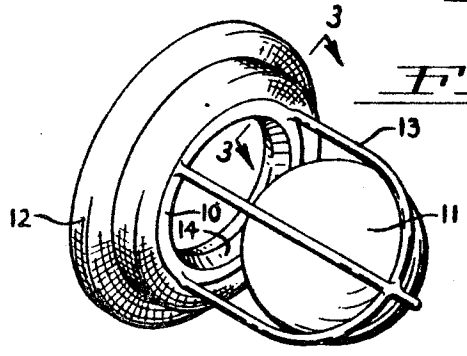


Fig 1

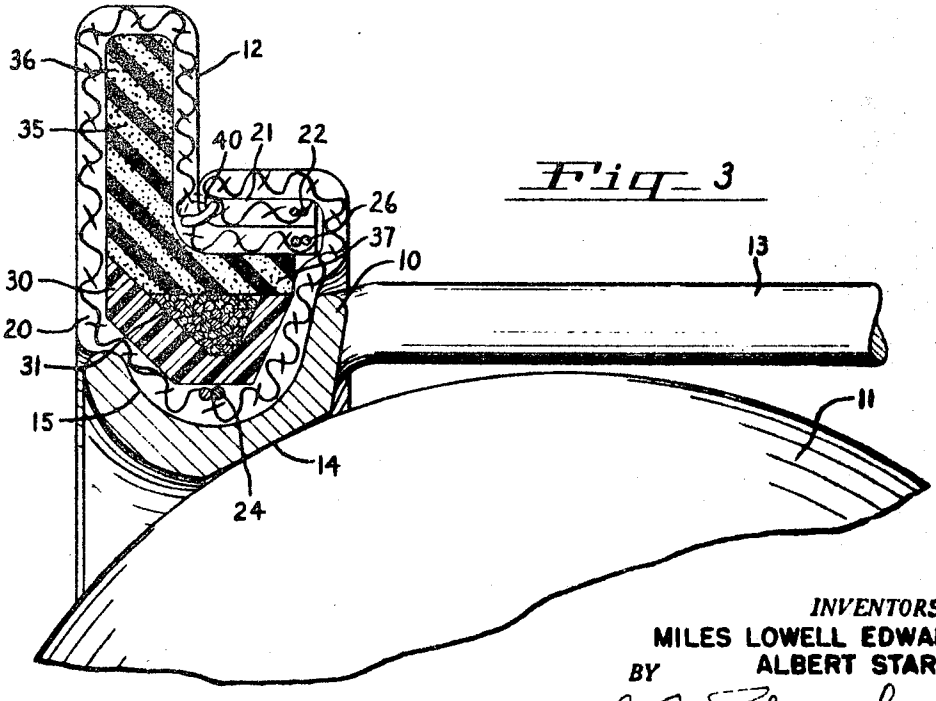


Fig 3

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Edwards v. Aortic Innovations
U.S. Patent 11,497,634
Edwards Ex. 1013

United States Patent Office

3,365,728
Patented Jan. 30, 1968

3,365,728

UPHOLSTERED HEART VALVE HAVING A SEALING RING ADAPTED FOR DISPENSING MEDICAMENTS

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Filed Dec. 18, 1964, Ser. No. 419,526
11 Claims. (Cl. 3—1)

ABSTRACT OF THE DISCLOSURE

A prosthesis such as a heart valve having an upholstered cushion ring to accommodate and seal against irregularities in the bed of tissue in which the prosthesis is implanted. The cushion ring is suturable and is secured to the prosthesis by being enfolded in a cloth sleeve connected with the prosthesis. The cushion ring may be made of silicone foam rubber capable of absorbing and gradually exuding a medicament such as an anticoagulant or antibiotic.

This invention relates to improvements in a heart valve prosthesis.

Objects of the invention are to provide features that promote healing after implantation, to provide an improved sewing or suture ring for attaching the valve to living tissue, to provide a better seal between the valve and the natural orifice in which it is implanted, to provide an upholstered cushion element in the sewing ring which will readily adjust itself to an irregular contour of the natural orifice, to provide a valve having an effective vehicle for medicament such as anticoagulant drugs or antibiotics and to provide the foregoing features for prostheses other than heart valves.

The present valve comprises a valve ring or body having a movable valve member. Connected to the periphery of the valve ring is a suturable sewing ring by which the valve may be connected by sutures with living tissue around the natural orifice in which the valve is implanted. The sewing ring is upholstered with a ring of compressible cushion material which will conform to irregularities in the bed in which the valve is placed whereby a good seal is established and leakage between the valve and the tissue is prevented. This upholstery ring may be made of a material which may be utilized as a vehicle for medicament such as anticoagulant drugs or antibiotics. An atrioventricular valve is illustrated by way of example, for use in either the mitral or tricuspid positions, but important features of the invention are also applicable to valves for other positions in the heart, such as the aortic valve. The general features of the upholstery ring are also useful in prostheses other than heart valves.

The invention will be better understood and the foregoing and other objects and advantages will become apparent from the following description of the preferred embodiment illustrated on the drawing. Various changes may be made, however, in details of construction and arrangement of parts and certain features may be used without others. All such modifications within the scope of the appended claims are included in the invention.

In the drawing:

FIGURE 1 is a perspective view of an atrioventricular valve prosthesis embodying the features of the invention;

FIGURE 2 is a perspective view from a different angle with the ball removed;

FIGURE 3 is an enlarged view on the line 3—3 of FIGURE 1; and

FIGURE 4 is an enlarged perspective view of the cloth sleeve used for the sewing ring.

The valve comprises, essentially, three parts, these being a valve ring **10**, a movable valve member **11** and a suturable sewing ring **12**. The valve ring **10** is preferably made of a strong and inert metal such as Stellite which is non-corrodable and has a minimum foreign body reaction with the blood. This ring is preferably cast and includes as an integral part thereof a cage **13**. The movable valve member **11** preferably comprises a silicone rubber ball which is confined in the cage **13** and adapted to seat against an annular seating surface **14** in the ring **10**. The ring **10** is shaped to provide an outwardly facing channel **15** extending around the ring.

The sewing ring **12** is formed in part of the cloth sleeve **20** shown in FIGURE 4. The material of the sleeve is preferably knitted from a synthetic fiber such as Teflon so as to be freely stretchable. One edge is inturned to form a hem **21**. This hemmed edge portion includes a double draw string **22** having free ends **23** available on the outside of the sleeve for tightening the draw string. An intermediate portion of the sleeve is equipped with a double draw string **24** having free ends **25** available on the inside of the sleeve for tightening this draw string. In the opposite edge of the sleeve there is a double draw string **26** having free ends **27** available on the outside of the sleeve.

In constructing the sewing ring the sleeve **20** is first applied over the channel **15** with the hemmed edge **21** overlying the cage **13** and the opposite edge extending beyond the left side of ring **10** in FIGURE 3. The sleeve is positioned so that draw string **24** overlies the channel **15**. Then the draw string **24** is tightened and its ends are tied. This holds the sleeve in position for the next operation.

A channel-shaped spreader ring **30** is then applied over the cloth in the channel **15**. This ring is preferably made of a suitable inert plastic such as Teflon and contains a diagonal split so that the ring may be applied to the channel and constricted on the cloth **20**. The spreader ring is clamped tightly against the cloth by one or more windings of Teflon thread **31**.

The valve is then ready for placement of the flanged cushion ring **35**. This ring is preferably molded from silicone foam rubber with an L-shaped cross section having an outstanding radial flange or leg **36** and a shorter axially directed flange or leg **37**. Axial flange **37** is seated on the winding **31** and on the opposite edge portions of spreader ring **30** as shown.

The left end of sleeve **20** is folded over the flange **36** and also over the flange **37**, as shown. This end of the sleeve is secured by tightening draw string **26** and tying the ends. Then the hemmed edge **21** is folded over the flange **37** on top of the first layer of cloth and the draw

string 22 is tightened and tied. After the hemmed edge 21 is folded over, the knot in draw string 22 will be on the under side of this hem so that the knot may be tucked under and covered by the hem. Finally, the extreme edge of the hem is secured to the underlying layer of cloth by stitching 40 in the corner between flanges 36 and 37 and the cloth is pressed to make it lie smoothly on the cushion ring 35. The draw strings and stitching 40 are preferably made of Teflon thread.

In the implantation of the valve in mitral position, the radial flange 36 is sutured to the annulus of the natural orifice and to the atrium side. The rubber cushion ring 35 conforms to any irregularities of tissue contour which may exist because of disease or other causes and forms an effective seal against the tissue. The layer of cloth 20 overlying the flange 36 provides an effective medium for the ingrowth of tissue over the whole surface of the sewing ring so that, upon healing, the sewing ring becomes permanently connected with the tissue in addition to, and independently of, the applied sutures. Both the cloth 20 and cushion ring 35 are capable of expansion and contraction, and distortion in any direction, with natural movements of the supporting tissue during pulsations of the heart so that there is no tendency for the sewing ring to pull loose from the supporting tissue.

The silicone rubber of the cushion ring 35 provides a vehicle for a medicament. The major problems in valve implantation are blood clotting and infection. Silicone rubber has the capacity to absorb an anticoagulant drug, such as heparin, or a suitable antibiotic, and exude the drug slowly over a relatively long period of time while healing is in progress. Thus, the cushion ring supplies the medicament directly at the point where it is needed. All of the well-known anticoagulants and antibiotics which are commonly used in heart operations are absorbable in and exudable from silicone rubber. The two types of drugs may be used together in ring 35, if desired.

This characteristic of silicone rubber is inherent in the nature of the material and does not depend upon a sponge-like porosity to hold the medicament in openings of visible size. The medicament is retained in the body of the rubber and not in the openings resulting from its foamy texture. Preferably, such openings are closed and sealed on the surfaces of the ring by a surface film of the rubber. In this way the rubber cushion element may function effectively as a seal against the leakage of blood and still hold the desired medicament by absorption. However, the rubber may have a somewhat open pore sponge-like texture, if desired, and still function effectively as a seal. This type of texture will accommodate ingrowth of tissue throughout the body of the ring. The described sealed surface of the present ring is punctured in many places by sutures in implantation, which affords adequate opportunity for ingrowth.

The cloth itself is not capable of holding such a medicament for slow release over a long period of time. If the medicament were to be absorbed into the cloth, it would be quickly washed away into the blood stream and become entirely ineffective long before the need for the medicament ceases to exist. For this reason the cloth is not impregnated with medicament.

The silicone rubber ball 11 may also be employed as a dispenser for absorbed medicament, if desired.

By making suitable changes in the structural details, the principal features of the present construction may be embodied in valves for other positions such as the aortic and in prostheses other than heart valves.

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. An upholstered heart valve comprising a valve ring having a movable valve member, said valve ring having an outwardly facing channel therearound, a cloth sleeve, means securing an intermediate portion of said sleeve in said channel, a pre-shaped ring of coherent, suturable cushion material of L-shaped cross section having one leg of the L seated on said securing means and the other leg in outstanding position, the end portions of said sleeve being folded over said cushion ring and over each other in overlapping relation on said seated leg, circumferential draw strings in said overlapped portions of said sleeve, and stitching securing said overlapped portions to each other.

2. An upholstered heart valve comprising a valve ring having a movable valve member, an outwardly facing channel around said ring, a cloth sleeve having a plurality of draw strings, one of said draw strings being tightened in said channel, means clamping a portion of said sleeve in said channel, a pre-shaped suturing and sealing ring of coherent, suturable cushion material enclosed in another portion of said sleeve, and a draw string in said other portion holding said cushion ring to said valve ring.

3. A flanged atrioventricular valve comprising a valve ring having a movable valve member, an outwardly facing channel around said ring, a cloth sleeve having draw strings in its end and intermediate portions, said intermediate draw string being tightened in said channel, means clamping said intermediate portion of said sleeve in said channel, a pre-shaped ring of coherent, suturable cushion material surrounding said clamping means, said cushion ring having a radial flange and an axial flange, one end of said sleeve being folded over said cushion ring and secured on said axial flange by one of said end draw strings, the other end of said sleeve being folded over said axial flange and secured by the other end draw string, and stitches securing said two sleeve ends together in the corner between said two flanges.

4. An upholstered heart valve comprising a valve ring having a movable valve member, said valve ring having an outwardly facing channel therearound, a cloth sleeve having a portion secured in said channel, a pre-shaped ring of coherent, suturable cushion material extending outside of said channel, an annular fold of said sleeve enclosing said cushion ring and securing said cushion ring to said valve ring, and circumferential draw strings in the portion of said sleeve secured in said channel and in said folded portions of said sleeve.

5. An upholstered heart valve comprising a valve ring having a movable valve member, a cloth having a portion secured around the periphery of said ring and having an outstanding annular fold extending around said periphery, and a pre-shaped filler ring of coherent, suturable cushion material seated substantially against said valve ring and filling said fold of cloth, said cushion ring imparting shape and body to said fold of cloth but being resilient and compressible to accommodate and seal against irregularities of the bed of tissue in which the valve is placed.

6. A heart valve as defined in claim 5, said cushion ring being made of a molded material.

7. A heart valve as defined in claim 6, said molded material being foam rubber.

8. A heart valve as defined in claim 5, said valve ring having a peripheral channel therearound, and means securing said portion of said cloth in said channel.

9. A heart valve as defined in claim 8, said securing means comprising a winding of filamentary material.

10. A heart valve as defined in claim 5, said cloth comprising a sleeve.

11. A heart valve as defined in claim 10, said sleeve containing circumferential draw strings.

References Cited

UNITED STATES PATENTS

3,093,831	6/1963	Jordan	3—1
3,099,016	7/1963	Edwards	3—1

(Other references on following page)

5

UNITED STATES PATENTS

3,279,996	10/1966	Long et al.	167—82
3,263,239	8/1966	Edwards et al.	3—1

OTHER REFERENCES

"Prosthetic Replacement of the Mitral Valve," Lancet, Nov. 24, 1962, p. 1087.

"Evolution of Aortic Valvular Prothesis" by Earle B. Kay et al., Journal of Thoracic and Cardiovascular Surgery, March 1963, pp. 372–381, vol. 45, No. 3.

"Evolution of Two Prostheses for Total Replacement of the Mitral Valve," Frederick S. Cross et al., Journal of Thoracic and Cardiovascular Surgery, December 1963, pp. 719–725, vol. 46, No. 3.

6

"Sutureless Aortic and Mitral Prosthetic Valves," George J. Magovern et al., Journal of Thoracic and Cardiovascular Surgery, vol. 48, No. 3, September 1964, pp. 346–361.

"A Hinged-Leaflet Valve for Total Replacement of the Human Aortic Valve" by Vincent Goff et al., Journal of Thoracic and Cardiovascular Surgery, vol. 48, No. 5, November 1964, pp. 713–725.

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