Feb. 23, 1971 L. R. SAUVAGE ET AL 3,564,617

PROSTHETIC HEART VALVE BURIED SEWING RING

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Fig. 1.

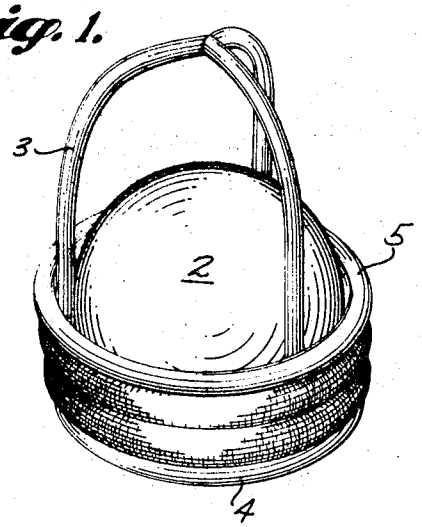


Fig. 3.

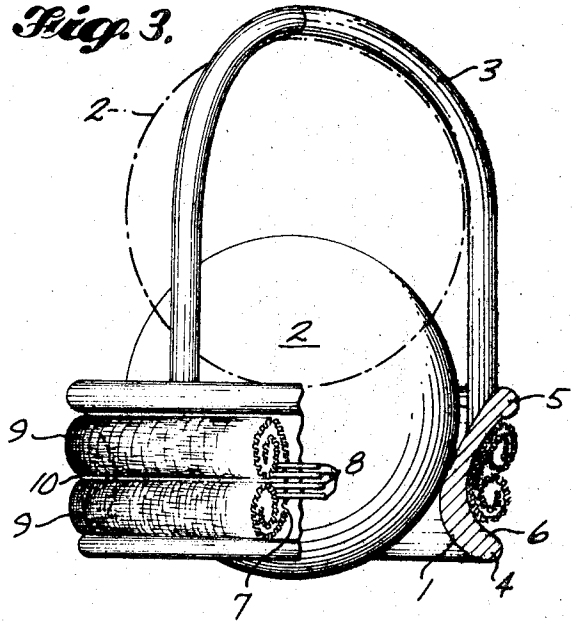
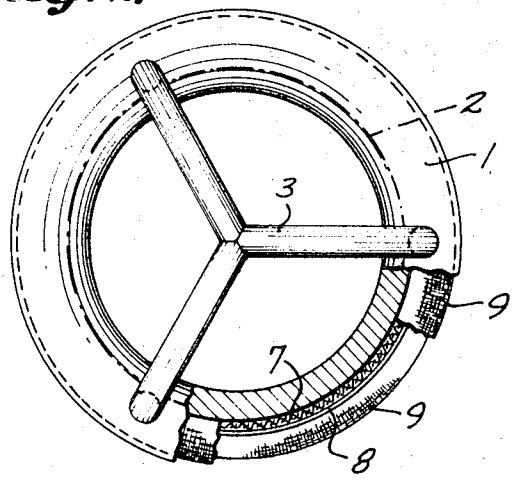


Fig. 2.



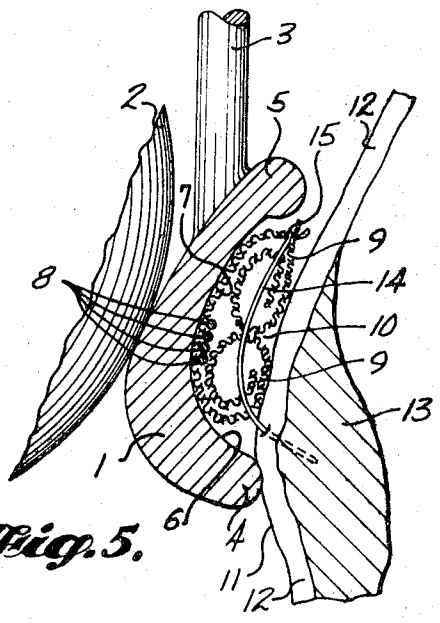
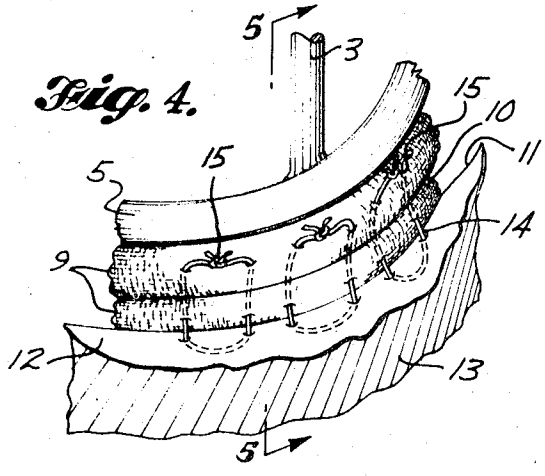


Fig. 5.

Fig. 4.



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PROSTHETIC HEART VALVE BURIED SEWING RING

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ABSTRACT OF THE DISCLOSURE

A sewing ring of limp knit synthetic plastic material is received in the external anticlastic groove of a rigid prosthetic heart valve venturi ring so that very little if any of the sewing ring protrudes out of the groove. Such sewing ring includes a central band portion and opposite axial free edge portions curled to form loose rolls having a crevice between them. The central band of the sewing ring is anchored in the bottom of the groove by several wraps of ligature inserted through the crevice and binding the band of the sewing ring to the groove bottom. The edge rolls of the sewing ring are connected only by the band central portion and are not sewed together prior to implantation but both of such edge rolls are secured in a heart blood passage by sutures spaced circumferentially about the sewing ring during implantation.

The sewing ring of the present invention is particularly applicable to prosthetic heart valves of the ball type. In the past, considerable difficulty has been experienced in implanting such a prosthetic heart valve in a heart which would enable it to be held securely in place over a long period of time despite the natural body pulsations of the tissue adjacent to it and which implantation would not induce excessive growth of scar tissue tending to obstruct the blood passage in which the valve is placed. Sewing rings for such heart valves are shown in the Edwards U.S. Pats. 3,099,016, 3,130,419 and 3,263,239 for example.

As shown by comparison of FIGS. 1 and 2 in Pat. 3,099,016, the sewing ring **12** projects a substantial distance radially from the port ring **14**. The sewing ring **12** must, of course, be sufficiently small to be received in orifice in which the valve is implanted and the radius of the passage through the port ring **14** will be less than the radius of the circumference of the sewing ring **12** by the radial extent of such sewing ring and the port ring. Consequently, the area of the passage through the port ring is quite small.

In addition, the combination of the upstream face of the port ring **14** and the upstream face of the exposed portion of the sewing ring **12** co-operate to form an annular shoulder of substantial width disposed transversely of the direction of blood flow which will impede such flow and tend to produce turbulence.

It appears that the patentee discovered that blood clots tended to form in front of the abrupt wall of the port ring **14** and sewing ring **12**, in Pat. 3,099,016 and consequently in Pat. 3,130,419 the same patentee proposed to provide a shield **25** on the upstream side of the valve to cover the sewing ring. In order to mount such a shield as shown in FIG. 3 of this patent, it was necessary to restrict farther the passage through the base ring **10**. The purpose of this shield is stated to be to completely enclose a space around all the cut and sewed tissue adjacent to the opening in which the valve is installed.

In the later patent, 3,263,239, another type of sewing ring is shown including a skirt flared downstream from the base ring **11**.

It is therefore evident that the provision of a satisfactory sewing ring for a prosthetic heart valve has posed a problem and the purported solutions to this problem offered by Pats. 3,130,419 and 3,263,239 has been to increase the complexity of the sewing ring and related parts, and to enlarge the ring assembly of the valve by adding components or structure to the valve ring assembly.

The objects of the present invention are:

(1) To provide a sewing ring for a prosthetic heart valve which will reduce the incidence of thrombus formation by shielding it from the blood stream flowing through the valve assembly without reducing the area of the passage for flow of blood through the assembly.

(2) To provide a sewing ring of small cross section and shaped so as to be buried in an annular groove in the valve seat ring and insure ingrowth of fibrous tissue from the host into the valve seat ring groove and around the sewing ring.

(3) To provide a sewing ring for a prosthetic heart valve which will be compact so as to enable the valve seat ring to be designed to minimize restriction of the body orifice in which it is placed.

(4) To provide a sewing ring which can be anchored securely both to a prosthetic heart valve and to the tissue of the heart valve site.

(5) To provide a sewing ring for prosthetic heart valve which will enable such valve to be implanted quickly and easily and which can then be secured in place most expeditiously.

FIG. 1 is a top perspective of a prosthetic heart valve to which the sewing ring of the present invention has been applied. FIG. 2 is an end view of such a heart valve with parts broken away. FIG. 3 is a side view of such valve having parts broken away. FIG. 4 is an enlarged detail top perspective of a fragmentary portion of the heart valve implanted in an appropriate body site, and FIG. 5 is an axial section taken on line **5—5** of FIG. 4.

A principal deficiency of prosthetic valves has been found to be a drop in blood pressure between the upstream side and the downstream side of a prosthetic valve implantation which is much greater than the drop in blood pressure between the upstream side and the downstream side of a corresponding natural heart valve. It is, therefore, very important both that the area of the passage for flow of blood through a prosthetic heart valve be as large as possible and that the blood flow be as smooth as possible to minimize such pressure drop. Turbulence can be reduced by streamlining of the passage through the valve seat ring such as by making it of venturi shape. In order for such shape to be most effective, however, it is desirable for the opening into the venturi passage of the valve seat ring to lie as close as possible to the wall of the body passage at the upstream side of the valve. The sewing ring of the present invention enables the valve seat ring to be thus disposed and also enables the passage through it to be as large as possible with respect to the orifice of the body in which the valve assembly is implanted.

The prosthetic heart valve shown in the drawings to which the sewing ring of the present invention is applied includes a rigid venturi valve seat ring **1** of metal or other rigid material in which a valve ball **2** seats. The movement of this valve ball is limited by being received within a cage **3**, such as formed of three or more rods projecting axially outwardly from the outflow side of the valve seat ring. The inflow axial lip **4** of this ring is flared and rounded and the outflow lip **5** is flared and of bulb cross section. The outer side of the ring **1** between the lips **4** and **5** is of anticlastic shape providing an out-

wardly opening groove **6** of an axial width several times as great as its depth.

The sewing ring of the present invention is lodged in the outwardly opening external groove **6** of the venturi valve seat ring **1** and is received substantially entirely within such groove. Such sewing ring includes an inner central band portion **7** of anticlastic shape closely overlying the bottom of the valve seat ring groove and anchored in such groove by several wraps **8** of ligature. The opposite axial free edge portions of the sewing ring central band are curled oppositely toward each other to form inturned rolls **9** on them, as shown best in FIGS. 3 and 5, each of which rolls preferably includes more than a single convolution. Such two rolls are preferably of substantially equal diameter which approaches one-half of the axial extent of the sewing ring. Such rolls may be somewhat flattened radially as indicated in FIGS. 3 and 5, but in any event, are loosely rolled so that they can be easily compressed or extended radially.

By making the diameters of the edge rolls **9** slightly less than one-half the axial extent of the sewing ring, a crevice **10** is formed between the two rolls **9** so that the ligature wraps **8** can be easily passed through such crevice to engage the outer side of the sewing ring central band **7** for securing it to the valve seat ring of the heart valve.

The sewing ring **7, 9** preferably is made of knit, woven or felted, nonmetallic, synthetic fiber limp sheet material such as a fluorocarbon resin, for example polytetrafluorethylene (Teflon), or polyester fiber (Dacron). Such material has been found to be most durable and most compatible with body tissue. The material from which the sewing ring is made can be furnished in the form of a tube from which sections can be cut to make the sewing ring.

Before the sewing ring is installed in the groove **6** of the valve seat ring its opposite edges will tend to curl inward and can easily be formed into rolls exceeding a single convolution in extent, as shown in FIGS. 3 and 5. When thus formed, the sewing ring can be stretched over the lip **4** of the valve seat ring **1** and seated in the groove **6** for reception of the ligature wraps **8** through the crevice **10**, as indicated in FIGS. 3 and 5.

When the valve is to be placed in the heart **12** as a substitute for the natural aortic valve, mitral valve or other valve, the valve seat ring **1** will be placed in the most restricted portion of the blood passage **11**. The valve is held in its proper location by sutures **14** passed through both rolls **9** of the sewing ring and through the tissue **13** around the passage **11**. Each suture forms a complete loop as shown in FIG. 4 and is secured by a knot **15**. Such sutures are spaced circumferentially around the sewing ring.

The rolls **9** are sufficiently resilient and flexible so that local portions of them can be drawn into close engagement with the body orifice for the valve, which is of noncircular and/or irregular contour. After implantation of the heart valve the crevice **10** will still be somewhat open because the rolls are connected together only by the central band portion **7**, that is, they are unconnected by stitching other than the body-attaching sutures **14**. Consequently, body tissue can grow into the crevice between the sewing ring edge rolls and around opposite axial edges of the sewing ring so as further to anchor the sewing ring to the body and tend to close any gap between the wall **11** and the valve seat ring **1**.

As is evident particularly from FIGS. 3 and 5, the sewing ring has a greater extent axially than radially both before and after implantation and, in fact, has an axial

width approximately twice as great as its radial width. At least the major portion of the cross section of the sewing ring, and preferably substantially its entire radial thickness, is received within the groove **6** of the sewing ring. Because of such disposition and proportions of the sewing ring, the valve seat ring **1** and the passage through it can be made of maximum size for the particular passage in which it is to be received without appreciably stretching such passage. Moreover, as shown best in FIG. 5, the inflow edge lip **4** of the valve seat ring can be disposed close alongside and even contact the wall of the passage **11** both to fair the passage for flow of blood into the valve seat ring **1** and to shield the sewing ring from being contacted by such blood. A space left at the bulb lip **5** on the trailing edge of the valve seat ring **1** is much less detrimental than having a space between the leading edge lip **4** and the passage wall. The space between the lip **5** and the host wall will enable sutures **14** to be inserted between such valve lip and the wall. After implantation of the heart valve, tissue will grow into the valve seat ring groove **6** at opposite sides of the sewing ring and into the crevice **10** between the rolls **9** as well as filling the space between the heart orifice wall **11** and the trailing edge lip **5** of the valve seat ring.

We claim:

1. In a prosthetic heart valve having a valve seat ring with an outwardly opening groove for reception in a heart blood passage, the improvement comprising a buried sewing ring of limp nonmetallic porous sheet material including an inner central band portion seated on the bottom of such outwardly opening valve seat ring groove, and free outer curled edge portions on opposite edges of said central band portion connected only by said central band portion, said curled edge portions, prior to attachment to a heart blood passage, being curled outwardly and toward each other to define a freely spreadable crevice therebetween extending into such valve seat ring groove for receiving tissue ingrowth.

2. The improvement defined in claim **1**, in which the sewing ring free outer curled edges are readily flexible rolls, each roll having an external convolution curled from the central band portion of the sewing ring outwardly and toward the opposite roll and said rolls being loosely curled and thereby easily compressible and extensible radially to fit irregularities of a heart blood passage opening.

3. The improvement defined in claim **2**, in which each roll is received substantially entirely within the groove of the valve seat ring.

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