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HEART VALVE WITH SHIELDED SEWING RING

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Fig. 1

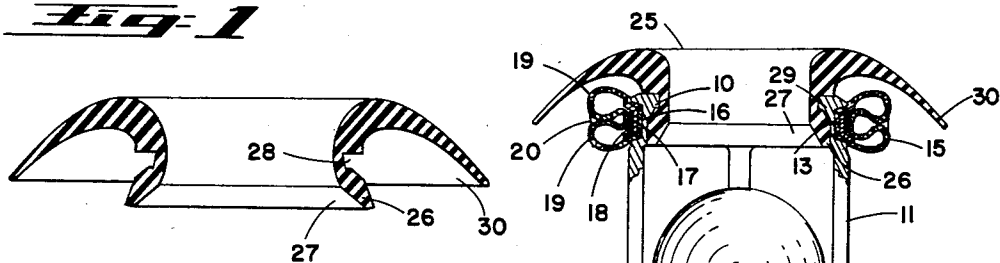


Fig. 3

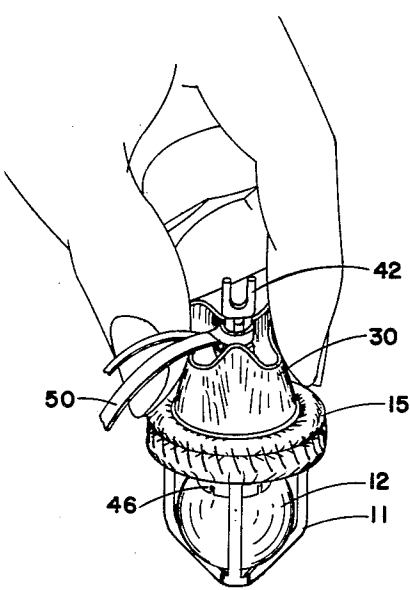


Fig. 4

Fig. 2

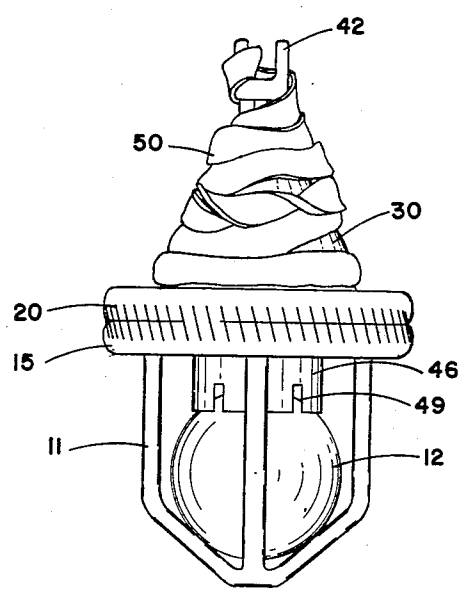
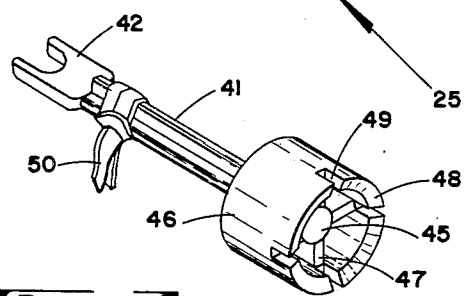


Fig. 5

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HEART VALVE WITH SHIELDED SEWING RING
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This invention relates to improvements in an artificial valve to take the place of a natural heart valve which does not function properly as a result of malformation at birth or damage from disease.

In installing such a valve, the surgeon removes a certain amount of tissue which formed the natural valve and then secures the artificial valve by sewing it to living tissue. Bleeding occurs, and there exists the problem of preventing the formation or release of blood clots into the circulatory system with the attendant danger to the patient. Experience has shown the clotting problem to be prevalent on the inlet side of the valve and not serious on the outlet side. Large clots occlude the large passages producing a condition of thrombosis while smaller clots produce a similar effect when they reach the smaller arteries. While blood clotting may often be controlled by the administration of anticoagulants, it is, nevertheless, desirable to be able to install the valve without anticoagulants.

The general objects of the present invention are, therefore, to provide a heart valve which may be used without anticoagulants, and to provide an improvement in heart valves that will prevent the release of blood clots from the cut tissue of the natural valve into the blood stream. More particular objects are to provide means for confining any blood clots that may form on the cut tissue of the natural valve and to provide a shield on an artificial valve which will cover and enclose the area of the cut tissue on the intake side of the valve which is most subject to the formation of blood clots resulting from the valve surgery. Another object is to provide means for collapsing the shield in order to provide access to the sewing ring on the valve during installation of the valve.

The present valve has an annular sewing ring which is sewed to living tissue around the periphery of the opening from which the natural valve parts have been removed. The valve body carries a flexible annular rubber shield having a peripheral lip in the form of a flap which projects outwardly beyond the sewing ring. This form of construction is of particular advantage in the mitral position where the surgeon works from the intake side of the valve. The shield confines any clots that may be formed and prevents them from entering the blood stream. A special retractor is provided for holding the valve open and collapsing the shield during installation so that the surgeon will have access to the sewing ring.

Additional objects and advantages will become apparent and the invention will be better understood from the following description of the preferred embodiment illustrated on the accompanying drawing. Various changes may be made, however, in the construction and arrangement of parts, and all such modifications within the scope of the appended claims are included in the invention.

In the drawing:

FIGURE 1 is a sectional view of the shield of the invention;

FIGURE 2 is a perspective view of a retractor used in the installation of the valve;

FIGURE 3 is a sectional view of the complete valve;

FIGURE 4 is a perspective view illustrating the use of the retractor; and

FIGURE 5 is an elevation view showing the valve with its shield collapsed and retracted in condition for installation in a patient.

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Referring first to FIGURE 3, the valve body comprises a circular base ring 10 having an integral four-legged closed cage 11 to retain a ball 12 of suitable inert resilient material such as silicone rubber. The body and cage member may be made of a suitable plastic or metal alloy which is non-corrodible and inert to blood and living tissue. Base ring 10 is formed with an outward facing peripheral channel 13 in which is clamped the loosely folded fabric of a sewing ring 15. This sewing ring is made of a suitable inert synthetic fiber, such as a finely knitted Teflon.

A mid-portion of the fabric is clamped in the bottom of the channel 13 by a spreader ring 16 which comprises three 120° arcuate segments of a stainless metal or a plastic such as Teflon. These segments are channel-shaped in cross section, having side flange portions with an outward flare slightly greater than the flare angle of the side walls of the channel 13. When the segments of spreader ring 16 are bound tightly against the fabric in the bottom of channel 13 by two layers of stainless steel wire 17, the flanges of the spreader ring pinch the fabric tightly against the side walls of the channel, whereby the clamped portion of the fabric is made secure in the base ring 10. Instead of a stainless metal, a suitable inert synthetic fiber may be used for the binding, such as Teflon.

In forming the sewing ring, the outer edges 18 of the fabric are doubled back against the binding wire 17, and then the outwardly projecting loose folds 19 are sewed together at 20. This form of construction provides a flexible annular pad which may be sewed to the living tissue about the heart opening in which the valve is installed. The sewing ring will accommodate itself to heart openings of different size and yet hold the valve body in position without excessive freedom of movement from the hydraulic pressure variations developed in the heart.

The shield 25, of a suitable inert resilient material such as silicone rubber, is molded to the channel shape shown in cross section in FIGURE 1. This shield has an inner annular lip 26 with a bevelled conical or spherical ball seat surface 27 on its inner side. Groove 28 in the outer side of lip 26 provides a secure interlock with an internal flange 29 on the base ring 10. From this point the shield curves outwardly in umbrella shape with diminishing thickness to provide a thin and very flexible outer annular lip 30.

Inner lip 26 is molded with a slight outward flare to a diameter slightly exceeding the inside diameter of the corresponding part of the base ring 10 whereby the lip 26 must be compressed when it is inserted in the base ring 10. This results in a tight fit between the lip and base ring. The joint is cemented to secure the shield permanently to the base ring. It will be observed in FIGURE 3 that the outer flexible lip 30 not only overhangs the sewing ring 15 to a considerable extent in an outward radial direction but also droops in surrounding relation to the sewing ring so that the edge of the lip is disposed in the mid-plane of the sewing ring.

Shield 25 has an open center for the free passage of blood through the ring 10 when the valve is open as shown in FIGURE 3. When the valve is closed, the ball 12 seats against the tapered surface 27 in a liquid tight joint. The movement of the ball against its seat produces a rubber-to-rubber contact which is substantially silent in operation and does not involve hard surfaces against which the blood corpuscles might be crushed.

The rubber seat portion 27 may be used without the shield lip 30 in cases where a shield is not necessary and also these two parts may be made as separate inserts, if desired. When the base ring 10 is made of metal, it is particularly desirable to employ a cushion insert to form the ball seat.

In order to install the valve, the lip 30 of the shield 25

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must be collapsed and retracted to provide access to the sewing ring 15, since the surgeon must work from the top end of the valve as viewed in FIGURE 3. The retractor 40 in FIGURE 2 is provided for this purpose. The retractor comprises a longitudinally ribbed shank 41 of X-shaped cross section having a flat notched end 42 slightly wider than the shank proper. The other end of the shank forms a circular hub 45 which is connected with a cylindrical rim 46 by a plurality of spokes 47. The end of ring 46 is bevelled at 48 to fit the curvature of ball 12 and is notched at 49.

In preparing the valve for installation, one end of a rubber band 50 is secured to the shank 41 of the retractor. Then the valve is held in upright position and the retractor is inserted to rest on the ball. The fingers of one hand are manipulated to gather the shield lip 30 around the shank of the retractor, as shown in FIGURE 4, while the other hand is used to wind the rubber band around the retracted shield lip. In doing this the rubber band is tensioned slightly and then its free end is hooked over the forked end 42 of the retractor as shown in FIGURE 5. This leaves the sewing ring 15 freely accessible from the top for the work of the surgeon in sewing it to the living tissue. The rubber band presses the retractor downward holding the ball against its cage, the rim 46 stabilizing the retractor on the ball.

The purpose of holding the valve open is to prevent trapping air in the chamber or passage beyond the valve. Any air behind the valve may escape freely, not only around the rim 46 but also through notches 49, the spaces between spokes 47, and the spaces between the ribs of shank 41, regardless of how tightly the shield may be bound by the rubber band. As seen in FIGURE 2, two of the shank ribs stand out from the opposite side faces of the end portion 42 so that these air escape passages cannot be closed by the shield.

When the sewing ring 15 has been completely sewed or sutured to the living tissue, the rubber band is unhooked from the forked end 42 of the retractor and unwound from around shield lip 30. Then the retractor is withdrawn by the rubber band, allowing the shield lip 30 to spring back to its original shape as shown in FIGURE 3. The lip will thus bear lightly against the body tissue, conforming to the shape of the latter and completely enclosing a space around all the cut and sewed tissue adjacent to the opening in which the valve is installed. Any blood clots forming in this area are confined behind the shield and cannot pass into the blood stream.

It will be noted that the shield is disposed on the inlet side of the valve. The blood velocity is generally lower on this side than on the outlet side and clot formation is found to be prevalent on the inlet side. It has been found that clot formation does not present a problem on the outlet side and so no shield is provided on that side.

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:

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1. A heart valve comprising a base ring having an outwardly directed channel, an annular padded sewing ring secured in said channel, a ball cage integral with one side of said base ring, a ball in said cage, and a flexible shield mounted in said base ring, said shield having an outer lip overlying said sewing ring and an inner lip forming a seat for said ball.

2. A heart valve comprising: a valve body; a movable valve member contained in said body; a suturing ring for connecting said valve body with the heart tissues by sutures, said suturing ring surrounding and being connected with said valve body and having a circular periphery radially outstanding from the valve body and having a substantial axial extent; said suturing ring comprising a layer of fabric folded upon itself to provide said substantial axial extent of said suturing ring, and a shield mounted on said valve body, said shield having a flexible outstanding annular lip around said body at one side of said suturing ring.

3. 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, other portions of said cloth extending outward from said body and folded upon themselves to form an annular suturing ring around said body, and a shield mounted on said body, said shield having a flexible outstanding annular lip around said body at one side of said suturing ring.

4. A heart valve as defined in claim 3, said lip being of umbrella shape and overhanging and surrounding a portion of said suturing ring.

5. A heart valve comprising a circular valve body defining a valve port with an outwardly facing channel therearound, a movable valve member cooperating with said port, a cloth having a portion intermediate its ends clamped in the bottom of said channel, portions of said cloth projecting from opposite sides of said channel being stitched together to form a suturing ring, and a shield mounted on said body, said shield having a flexible outstanding annular lip around said body at one side of said suturing ring.

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