United States Patent

[11] 3,574,865

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[54] **PROSTHETIC SUTURELESS HEART VALVE**
8 Claims, 8 Drawing Figs.

[52] **U.S. Cl.** **3/1,** 128/303
[51] **Int. Cl.** **A61f 1/22**
[50] **Field of Search** ..... 128/334, 303; 3/1 (HV); 251/149.1

[56] **References Cited**

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Assistant Examiner—Ronald L. Frinks
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ABSTRACT: This disclosure relates to a prosthetic sutureless heart valve wherein a two-piece snapring is employed in fastening the valve to the heart. The valve has an annular base which contains a check valve and a plurality of pins which pierce the tissue around the valve. The annular snapring fits into the base near the pins to hold the valve and the tissue intact. A smooth, continuous surface is provided for passage of the blood through the valve.

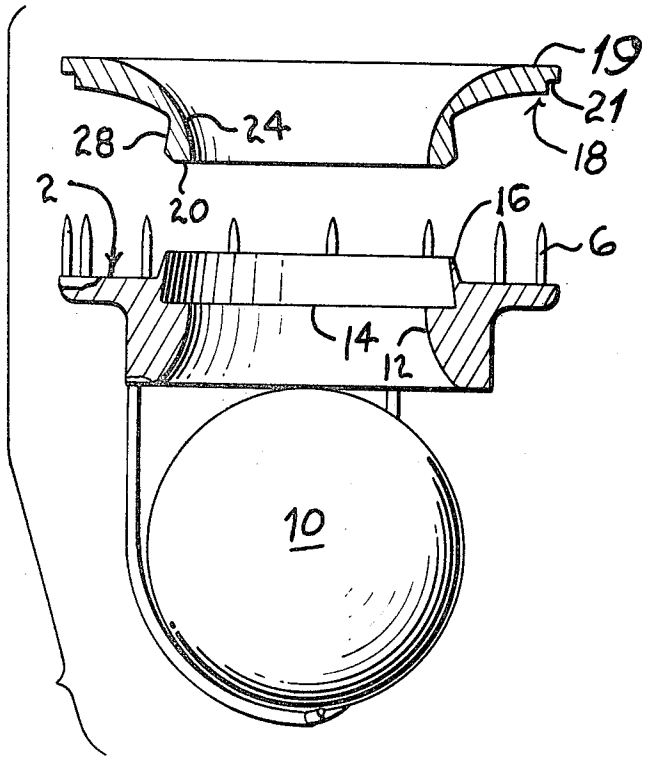

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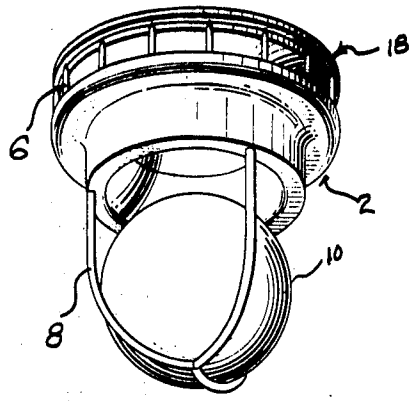
FIG. 1



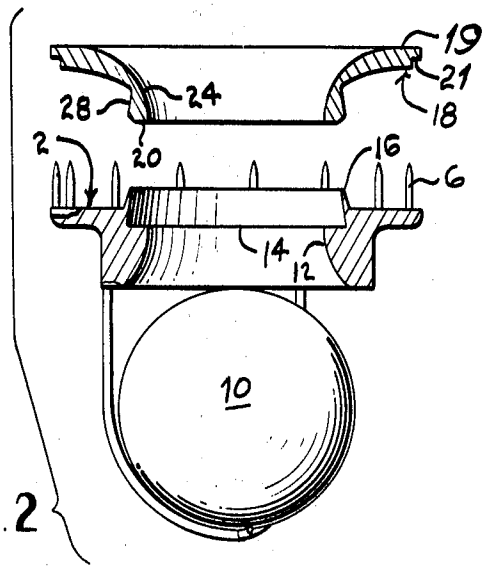


FIG. 2

FIG. 3

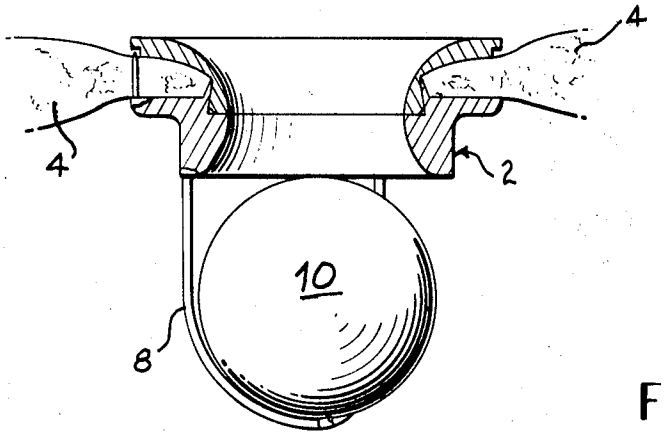


FIG. 4

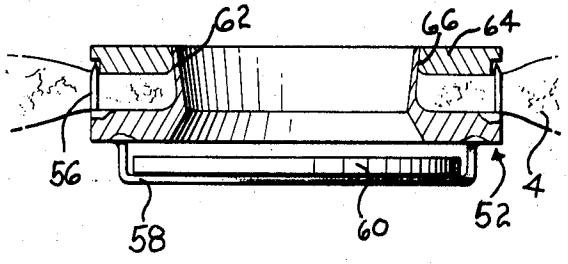


FIG. 5

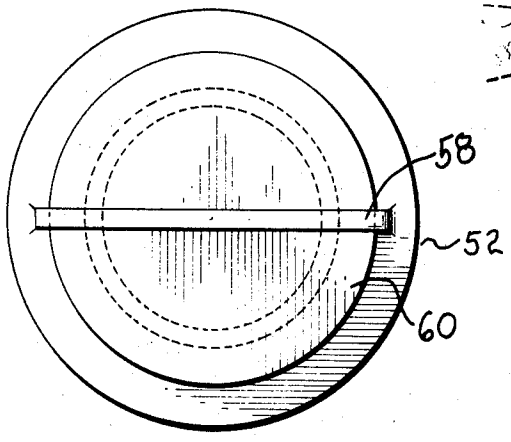


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FIG. 6

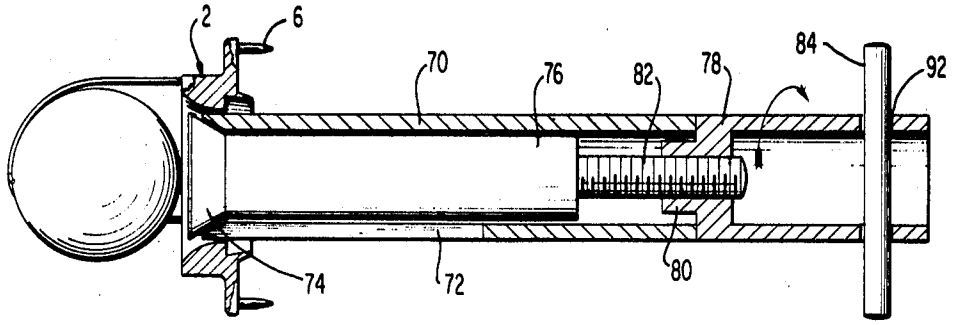


FIG. 7

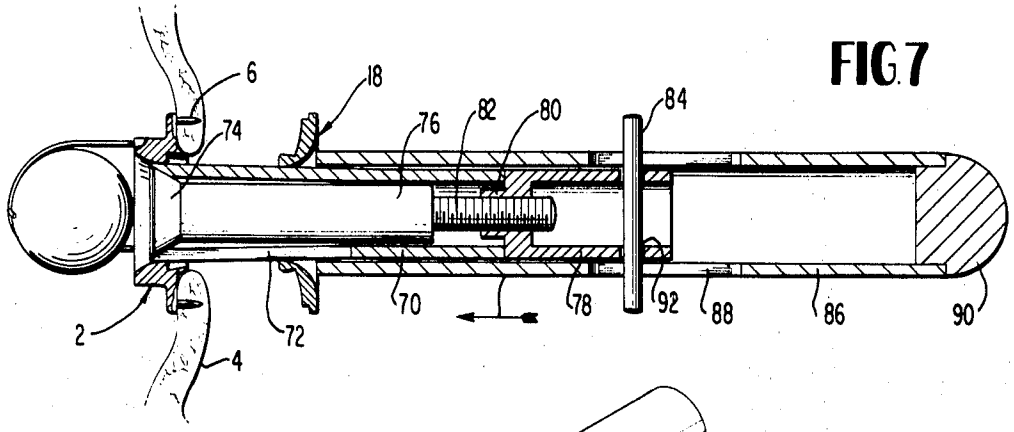
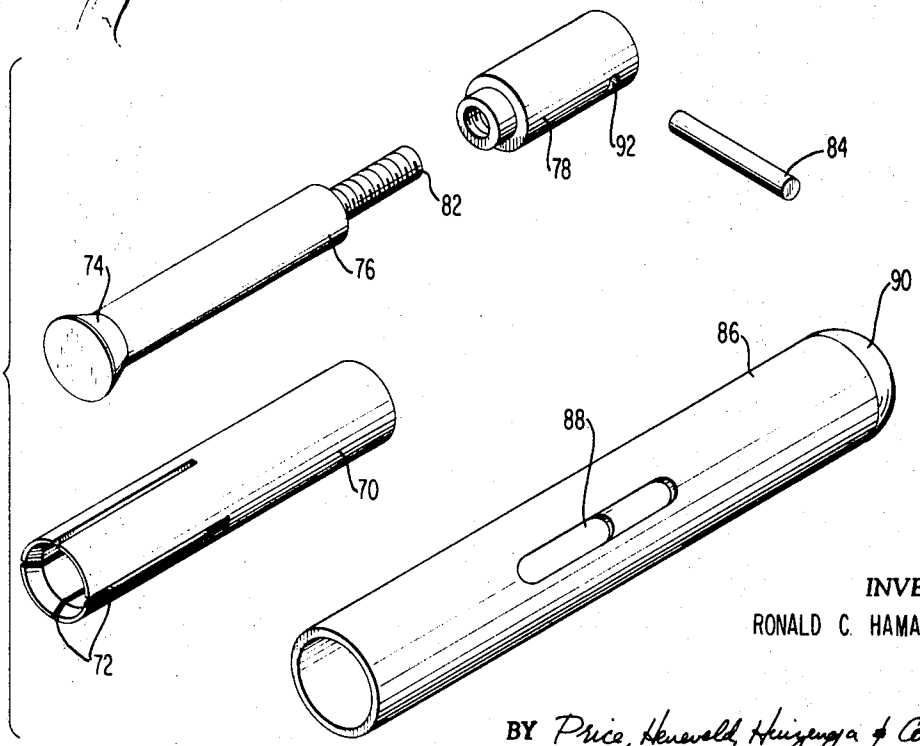


FIG. 8



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PROSTHETIC SUTURELESS HEART VALVE

This invention relates to sutureless heart valves. In one of its aspects it relates to a sutureless heart valve containing an annular shaped base member having a central aperture with a check valve in the aperture, upwardly projecting pins on the base member spaced about the outer portion thereof, an annular snapring having a diameter sufficient to fit over the projecting pins, and means to provide a snap fit between said snapring and said base members, the snapring and the base being so shaped as to form a smooth, continuous surface through the central aperture and through the snapring.

In another of its aspects, the invention relates to a sutureless heart valve as has been hereinbefore described, wherein the check valve is a ball valve, a lenticular valve, or a leaflet valve.

It is not too uncommon to replace a heart valve with a permanent mechanical valve. The original development of these prosthetic valves was directed to sewing the valve into the heart tissue. This method, while being suitable in some instances, is a relatively long process which requires an extended period of cardiopulmonary bypass and protection of the heart by coronary profusion or reduced temperatures. It is highly desirable to have the valve placed in the heart as quickly as possible without suturing.

Cromie, U.S. Pat. No. 3,143,742 discloses a prosthetic sutureless heart valve in which an upper and lower ring contain curved pins which project radially therefrom. A central ring is provided to squeeze the two rings together and cause the pins to rotate about a traverse axis to pierce the tissue surrounding the valve and thereafter lock the tissue in engagement with the valve.

The circulatory system is very delicate and important part of the body. If restrictions or rough surfaces appear within the circulatory system, blood clots can sometimes result. In the arteries and veins and other passageways through which blood flows, it is desirable to provide as smooth as possible a surface in order to avoid turbulent flow which is conducive to formation of blood clots. Thus, in the construction of heart valves, the surface over which the blood flows should be a relatively continuous and smooth surface.

I have now discovered a sutureless heart valve which can be rapidly installed in a heart and which, when assembled, has a smooth, continuous, inner surface through which the blood can flow.

By various aspects of this invention, one or more of the following, or other, objects can be obtained.

It is an object of this invention to provide a sutureless heart valve which can be quickly installed in a heart passage.

It is a further object of this invention to provide a prosthetic heart valve having a smooth, internal surface to minimize the possibility of turbulent flow of blood through the valves.

It is a still further object of this invention to provide a sutureless prosthetic heart valve having a smooth and continuous inner surface to minimize the traumatic effects of prosthetic valves on the circulatory system.

Other aspects, objects, and the several advantages of this invention are apparent to one skilled in the art from a study of this disclosure, the drawings, and the appended claims.

According to the invention there is provided a two-piece prosthetic sutureless heart valve. The valve contains an annular shaped base member having a central aperture with a smooth inner surface and with a check valve positioned therein. The valve also has pins projecting axially of the valve axis on the base and spaced about the outer portion thereof. Tissue is locked into the base structure by an annular shaped snapring which has a diameter sufficient to cooperate with the projecting pins on the base. The annular snapring also has means on the inner portion thereof for snapping into engagement with a cam engaging surface on the base member. The inner surface of the snapring is so shaped as to form a smooth, continuous path over the snapring and through the central aperture.

The invention will now be described with reference to the accompanying drawings in which:

FIG. 1 is a perspective view of an embodiment of the invention;

FIG. 2 is a sectional view through a base member of the valve shown in FIG. 1 as placed into a heart;

FIG. 3 is a sectional view of an assembled valve shown in part in FIG. 2;

FIG. 4 is a sectional view of a modified valve according to the invention;

FIG. 5 is a bottom view of the modified valve shown in FIG. 4;

FIG. 6 is a side view, partly in section, of the valve shown in FIGS. 1 through 3, and a portion of an instrument for holding the valve while it is inserted into the heart;

FIG. 7 is a view similar to FIG. 6 showing the complete instrument for inserting the valve into the heart, and illustrating the method of inserting the valve into the heart; and

FIG. 8 is an exploded view of the holding and positioning instrument shown in FIGS. 6 and 7.

Referring now to the drawings, and FIGS. 1 through 3 in particular, a novel sutureless heart valve has a base 2 and a snap engaging ring 18. The base 2 has a plurality of spaced axially extending ball retaining legs 8 having their outer ends curved inwardly and joined at a central point along the longitudinal axis of the base member. The base also includes a ball valve 10 which is seated against inner annular surface 12 of base member 2. The inner annular surface is smooth and provides a central aperture in the base member. The ball 10 is free to reciprocate within the ball retaining legs 8 to open and close the valve. The base comprises an annular shoulder 14 and an axially and inwardly extending flange member 16. A base further contains a plurality of axially directed prongs 6 spaced about the outer periphery of the base. The snapring 18 comprises an annular ring of sufficient diameter to fit over the projecting pins 6 and has a smooth inner surface 24. Shoulder 20 of ring 18 abuts against shoulder 14 when the ring is snapped in place. The snapring has an inwardly and axially extending shoulder 28 which cooperates with flange 16 of the base member to snap into place. Shoulder 20 is slightly rounded so as to provide a camming surface against flange 16 in the snap engagement of ring 18 with base 2. The smooth inner surface 24 of ring 18 forms a continuous smooth surface with upper flange portion 19. The pins 6 fit into an annular recess 21 when the ring 18 is snapped into place in base 2.

In operation, the normal valve in a heart is removed, thereby leaving an aperture. The base member 2 is pushed through the aperture and pulled back slightly. Tissue 4 is then pulled over the outer annular recess in base 2 and over the projecting pins 6. The tissue does not extend over flange 16. The snapring is then pushed into place with the rounded shoulder 20 camming against flange 16. As can be seen from FIG. 3, the base 2 and the snapring 18 are so shaped as to provide a smooth, continuous surface through the inner aperture of the valve. As can also be seen from FIG. 3, the tissue is held in place between the base 2 and snapring 18 by pins 6.

Referring now to FIGS. 4 and 5, wherein a second embodiment is shown, a base 52 is provided with a bar 58 which retains flexible disc 60, the check valve formed by the flexible disc seating against the inner annular portion of the valve. The base 52 also contains a plurality of axially projecting pins 56 spaced about the outer periphery thereof. The base 52 also contains axially and outwardly extending flange 62 which has a smooth, continuous inner surface. The snapring 64 has a rounded shoulder 66 which cams against the flange 62. The inner annular portion of snapring 64 is shaped at an angle to the axial direction at flange 62 so that a locking engagement is provided between the base 52 and the snapring 64. The external diameter of snapring 64 is sufficient to fit over projecting pins 56 of base 52.

The snapring 64 can be provided with a plurality of axially projecting pins extending toward base 52 in intermediate positions between the outer and inner diameter thereof to further aid in holding tissue 4 in place.

As can be seen from FIGS. 4 and 5, the valve provides a smooth inner surface which mates with the upper snapring to

provide a substantially continuous, smooth surface over which the fluid can flow without increasing dangers of turbulent flow.

Whereas the embodiment of FIG. 1 has been described with reference to a sutureless valve having a ball valve, it is also within the scope of the invention to provide other kinds of check valves in combination with recited structure. Thus, for example, a lenticular valve or the flat, leaflet-type of valve shown in the embodiment of FIGS. 4 and 5 can be provided. Similarly, the ball valve of FIGS. 1 through 3 could be employed in place of the leaflet valve of FIGS. 4 and 5.

EXAMPLE

A valve of the type shown in the FIGS. 1 through 3 was placed into the heart of a dog. During the operation, the normal valve in the dog's heart was cut out and replaced by the valve of the invention. The base of the valve was pushed through the aperture in the heart, and the tissue around the aperture was placed over the pins in the base member. The snapring was then placed on top of the valve and the dog was sewn up. The total time required for insertion of the valve was 7 minutes. An X-ray was taken of the valve, and indicated that the valve was successfully and suitably placed in the heart.

After the dog expired, the heart was removed and dissected. The valve was firmly intact, and operated successfully.

Referring now to FIGS. 6, 7, and 8, a holding tube 70 having a plurality of longitudinal slits 72 is employed in holding base 2 in position within the heart. Positioned within the holding tube 70 is a rod 76 having attached to the end thereof an expander 74. A drawing tube 78 has an end member 80 which threadably engages a threaded portion 82 of rod 76. Drawing tube 78 has a pair of oppositely spaced holes 92 in which is removably positioned a turning pin 84.

When the drawing tube 78 is rotated relative to the holding tube 70, for example in the direction of the arrow shown in FIG. 6, the expander is drawn into holding tube 72 to expand the end of that tube against the inner wall portion of base 2.

A snapring pusher 86 having a longitudinal slot 88 and an end member 90 is provided to push the snapring 18 into fixed engagement with base 2.

In operation, base 2 is positioned on the slotted end of holding tube 70. Drawing tube 78 is rotated with the aid of pin 84 until the expander 74 has forced the end of holding tube 70 against base 2 to firmly hold the same. The base 2 is then positioned in the aperture in the heart and tissue 4 is folded over pins 6. The turning pin 84 is then removed from drawing tube 78 and the snapring 18 is placed over drawing tube 78 and holding tube 70 while the two tubes are held in position. The snapring pusher 86 is then placed over the end of drawing tube 78 while holding the slotted portion of holding tube 70. The longitudinal slots 88 of snapring pusher 86 are positioned opposite holes 92 of drawing tube 78. The turning pin 84 is then inserted through longitudinal slots 88 into holes 92. The snapring pusher 86 is then forced against the snapring by pushing the end 90 of snapring pusher 86, for example with the palm of the hand, while holding the turning pin 84 with two fingers of the same hand. In this manner, the snapring 18 is snapped into place on the base 2.

The tube 70 can be removed by the opposite procedure. The snapring pusher 86 is moved away from the heart while holding pin 84 until the pin reaches the end of slots 88. The holding tube 70 can then be held and the pin 84 is removed. After the snapring pusher 86 has been removed from the end of drawing tube 78, the drawing tube 78 is rotated relative to holding tube 70, with the aid of pin 84, in order to move the expander 74 out of the end of the holding tube 70. After this has been done, the holding tube 70 can be removed from the valve.

Reasonable variation and modification are possible within the scope of the foregoing disclosure, the drawings, and the appended claims to the invention without departing from the spirit thereof.

The embodiment of the invention in which an exclusive property or privilege is claimed are defined as follows:

I claim:

1. A sutureless heart valve comprising:
- an annular-shaped base member having a central aperture therein;
- valve means attached to said base member and operable within said aperture to block flow through said aperture;
- an annular-shaped snapring for joining said base and valve means to the surrounding heart tissue, said snapring being joined to said base member through a snap fit so that the heart tissue is firmly held between said ring and base, the inner surfaces of said ring and base being so shaped to form a smooth continuous surface over said snapring and through said central aperture; and
- a plurality of pins extending in an axial direction between said base member and said snapring so that when said snapring is joined to said base, said pins pierce said heart tissue to anchor said tissue between said base and ring, said pins being spaced radially from said aperture.

2. A sutureless heart valve according to claim 1, wherein said base includes an axially and inwardly extending flange, and said ring includes an axially and outwardly extending surface in juxtaposed relationship with said base flange.

3. A sutureless heart valve according to claim 2, wherein said outwardly and axially extending surface on said ring has a rounded corner for camming against said base flange during assembly of said valve.

4. A sutureless heart valve according to claim 3 wherein said pins are mounted on said base, and said snapring flange is of sufficient diameter to fit over said pins when said snapring is joined to said base, said snapring flange further including an annular recess for receipt of said pins when said snapring is joined to said base to provide positive locking of the tissue between the base and ring.

5. A sutureless heart valve according to claim 1, wherein said valve means is a ball and said base is provided with a plurality of spaced legs extending axially of said base member and having their outer ends curved inwardly and joined at a central point along the longitudinal axis of said base and enclosing said ball which is reciprocatable within said legs and seats against said annular base member to close off said central aperture.

6. A sutureless heart valve according to claim 1, wherein said valve means comprises a movable disc operably adjacent a face of said base member to block flow through said central aperture and means on said base enclosing said disc, said disc being reciprocable in said enclosing means to move away from said base to permit fluid flow through said central aperture.

7. A sutureless heart valve comprising, in combination:
- an annular-shaped base member having a central aperture therein;
- check valve means in said central aperture being attached to said base member;
- an annular shaped snapring;
- means attaching said snapring to said base member through a snap fit, the inner surface of said base member and said snapring being so shaped to form a smooth, continuous surface over said snapring and through said central aperture, said attaching means comprising an axially directed flange with an outwardly extending wall on said snapring and an axially and inwardly extending flange on said base, spaced from said central aperture in juxtaposed relationship with said snapring flange, the inner diameter of said base flange being slightly smaller than the outer diameter of said outwardly extending wall at opposing positions of said wall and said base flange; and
- a plurality of pins extending in an axial direction between said base member and snapring spaced from said aperture.

8. A sutureless heart valve according to claim 7 wherein said outwardly extending wall of said snapring has a rounded edge which is adapted to cam against said inwardly extending flange during assembly of said valve.