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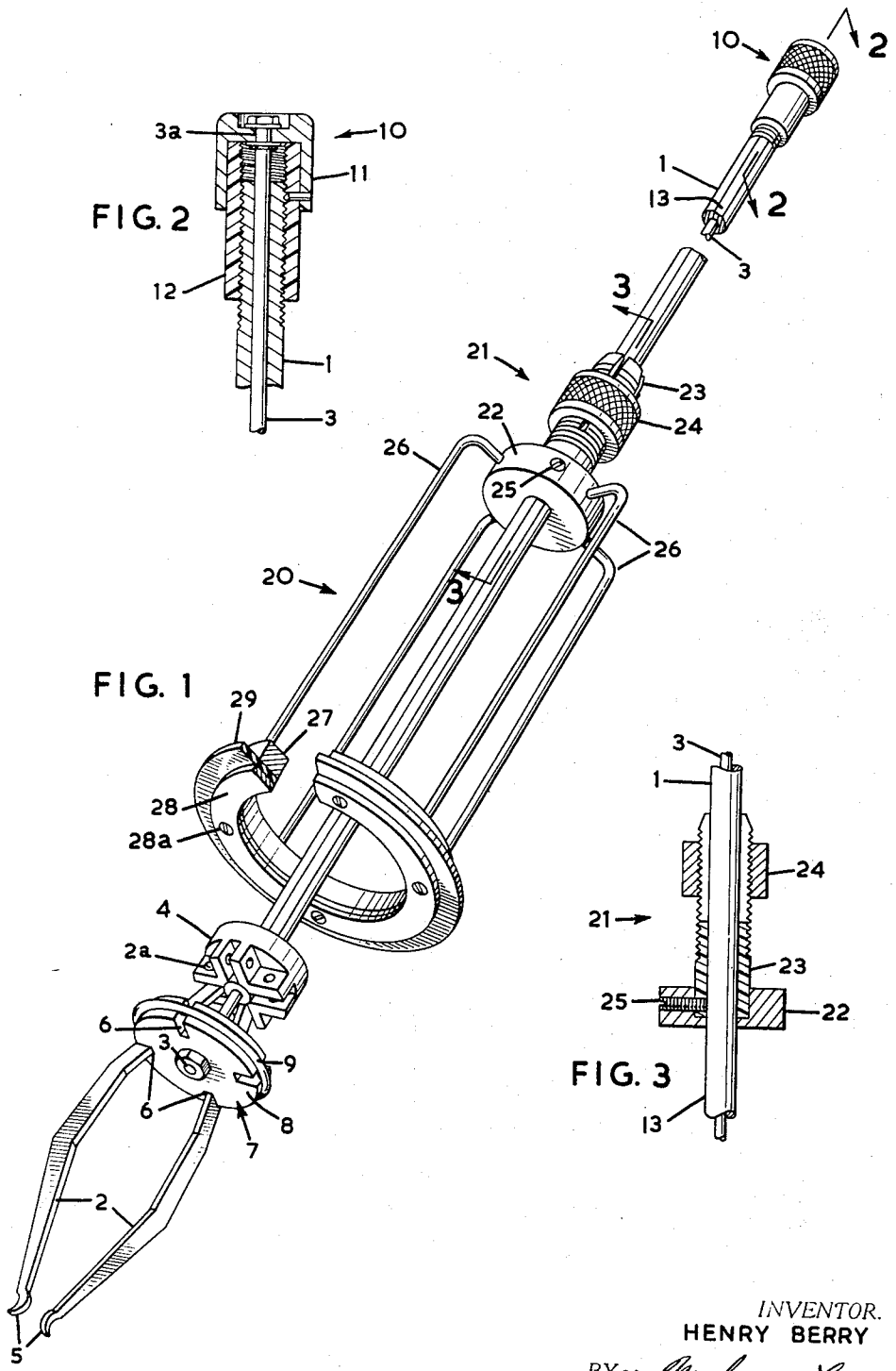
H. BERRY

3,409,013

INSTRUMENT FOR INSERTING ARTIFICIAL HEART VALVES

Filed Oct. 23, 1965

2 Sheets-Sheet 1



INVENTOR.  
HENRY BERRY  
BY *Maybe & Legris*  
ATTORNEYS

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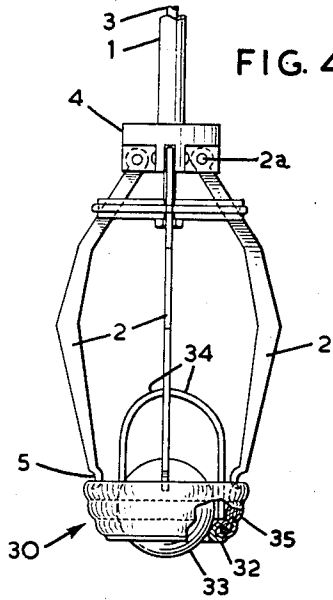


FIG. 4

FIG. 5

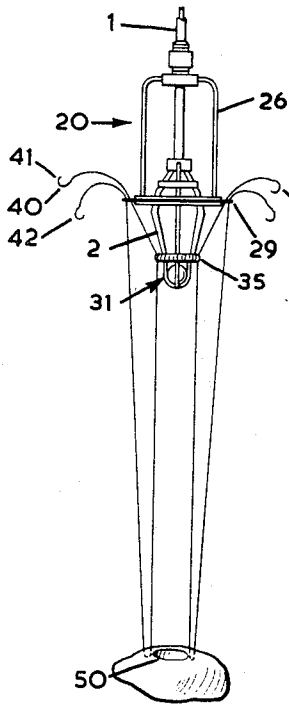
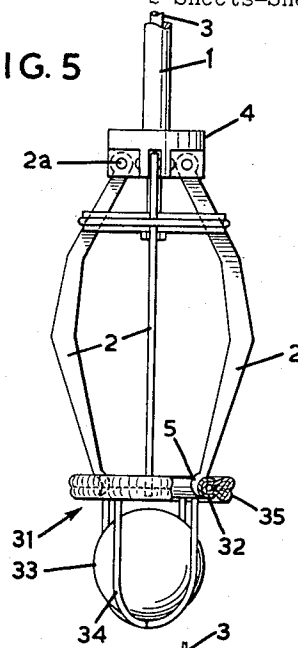


FIG. 6

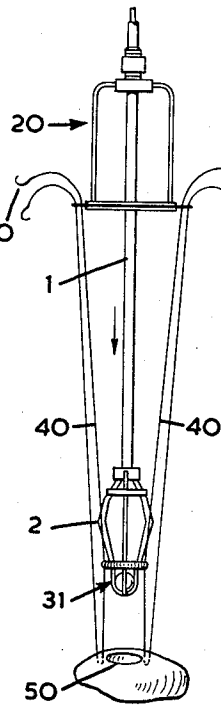


FIG. 7

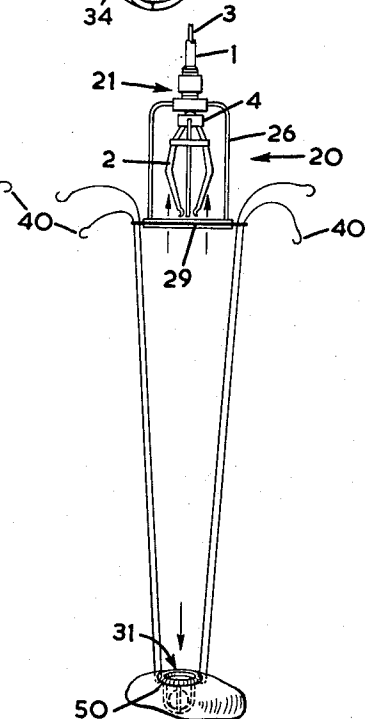


FIG. 8

INVENTOR.  
HENRY BERRY

BY *Maybe & Legris*

ATTORNEYS

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2

3,409,013

## INSTRUMENT FOR INSERTING ARTIFICIAL HEART VALVES

Henry Berry, 170 St. George St.,  
Toronto, Ontario, Canada

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13 Claims. (Cl. 128—303)

### ABSTRACT OF THE DISCLOSURE

A surgical instrument for the suture implantation of a cardiac valve prosthesis comprises a shank, at one end of which are mounted pivotal jaws for gripping the prosthesis, and a suture retaining device mounted on the shank and slidable along the shank to a position where it encompasses the jaws.

This invention relates to an instrument for holding cardiac valve prostheses, and more particularly to an instrument for holding aortic and atrio-ventricular (either mitral or tricuspid) valve prostheses. The invention also relates to a suture retaining device for use with the instrument.

A caged ball valve is frequently the prosthetic replacement of choice in the treatment of cardiac valve disease. Sutureless valves are not entirely satisfactory because variations in the size and structure of the valve annulus of the heart make the use of sutures mandatory in many instances. A suture technique also permits carefully controlled fixation, with each point well tested prior to ligation.

Accurate and stable fixation of these artificial valves requires from twenty to thirty individual sutures. Placement of sutures first in the valve annulus or cusp remnant and then through the prosthetic sewing ring is made difficult by frequent entanglement of the numerous paired ends required for tying after seating the valve. This frustrating and time consuming procedure occurs at the critical period of cardio-pulmonary bypass.

It is an object of the invention to provide an instrument to facilitate the suture implantation of aortic and atrio-ventricular valve prostheses.

The invention consists of a surgical instrument for holding a cardiac valve prosthesis having a ring, the instrument comprising a shank, jaws mounted at one end of the shank and pivotable generally radially relative to each other, each jaw having an outwardly directed hook at the end of the jaw remote from the shank, and means for spreading the jaws radially outwardly to grip the valve prosthesis from within its ring.

The invention further consists of a surgical instrument for the suture implantation of a cardiac valve prosthesis and comprising a shank, at one end of which are mounted jaws for gripping the prosthesis, and a suture retaining device mounted on the shank and slidable along the shank to a position where it encompasses the jaws.

The invention further consists of a suture retaining device for use with an instrument for holding a cardiac valve prosthesis, the device comprising a suture ring of material which can be pierced by suture needles to pass sutures through the suture ring, and means for mounting the suture ring about the instrument and including a rigid ring secured to the suture ring to support the suture ring.

The invention will now be described by way of example with reference to the accompanying drawings which illustrate a preferred embodiment of the invention and in which:

FIG. 1 is a partially broken away perspective view of

a surgical instrument constructed according to the invention;

FIG. 2 is a sectional view along the line 2—2 of FIG. 1;

FIG. 3 is a sectional view along the line 3—3 of FIG. 1;

FIG. 4 is a partially broken away side view of the jaws of the instrument shown in FIG. 1 gripping an aortic valve prosthesis;

FIG. 5 is a partially broken away side view of the jaws of the instrument shown in FIG. 1 gripping an atrio-ventricular valve prosthesis;

FIG. 6 is a schematic view showing an initial step in the suture implantation of an atrio-ventricular valve prosthesis which is held by the instrument shown in FIG. 1, only two sutures being shown for clarity;

FIG. 7 is a schematic view showing how the prosthesis shown in FIG. 6 can be moved down the sutures into the annulus region of the heart, only two sutures again being shown; and

FIG. 8 is a schematic view showing the jaws retracted and the valve seated in the valve annulus of the heart.

The instrument illustrated has a shank 1 and four elongated jaws 2 mounted at one end of the shank. Slidable within the shank 1 is a rod 3. The four jaws 2 are pivotally connected by pins 2a to an anchor element 4 on the shank in such a way that each jaw 2 can pivot radially relative to the shank 1 and to each other. Each jaw 2 has an outwardly directed hook 5 at the end of the jaw 2 remote from the shank 1. The surfaces of the jaws 2 are polished smooth to minimize the risk of scratching the ball 33 of a prosthesis 30 or 31 (FIGURES 4 and 5) because blood clotting may occur at a scratch. To further prevent scratching each jaw 2 bows outwardly between its pivoted end and its hooked end, so that when the jaws 2 grip an aortic valve prosthesis 30 as shown in FIGURE 4 the jaws are clear of the ball 33 of the prosthesis.

Each jaw 2 passes slidably through an aperture 6 in a spacer disc 7 which may, as illustrated in FIGURE 1, consist of notched member 8 and a retaining band 9. The spacer disc 7 is fixed to one end of the rod 3 so that longitudinal motion of the rod 3 in one direction will cause the jaws 2 to pivot away from one another to grip a valve prosthesis as shown in FIGURES 4 and 5, and longitudinal movement of the rod 3 in the opposite direction will cause the jaws 2 to move together to release the valve prosthesis. The end of the rod 3 remote from the jaws is connected to a knob 10 which is threaded onto the shank 1 and journaled on the rod at 3a (FIGURE 2) so that rotation of the knob 10 will cause the rod 3 to move longitudinally relative to the shank 1 and hence cause the jaws 2 to pivot away from one another or together. The knob 10 has an outer part 11 of metal having a knurled outer surface and an inner part 12 which is threaded onto the shank 1 and is made of a self-lubricating material, such as polytetrafluoroethylene supplied by E. I. du Pont de Nemours under the trademark "Teflon TFE."

About the shank 1 and co-axial with it a basket-shaped suture retaining device 20 is slidably mounted by a collar 21. As shown in FIGURE 3 the collar has a metal outer member 22 and an inner member 23 of a self-lubricating material such as polytetrafluoroethylene. The inner member 23 is threaded externally and together with a nut 24 that threads onto it constitutes a collet for temporarily fixing the suture retaining device 20 to the shank, thus preventing sliding of the suture retaining device 20 along the shank. One side of the shank is flattened at 13, and this flattened side, together with a set screw 25 through the collar member 21, prevents rotation of the suture retaining device 20 about the shank. From the outer collar member 22 radiate four arms 26 which are bent to extend towards the jaws 2 parallel to the shaft 1 to form a basket-shaped handle. To the ends of these arms 26 remote from

the collar 21 is attached a rigid ring 27. Secured between this rigid ring 27 and a second rigid ring 28 by screws 28a is a suture ring 29 of material which can be pierced by suture needles to pass sutures through the material. Preferably the suture ring 29 is made of rubber. The suture ring 29 has an outside diameter larger than the outside diameter of the rigid rings 27 and 28. The suture ring 29 and the rigid rings 27 and 28 have an inside diameter sufficiently large to encompass and pass over the jaws 2 at least when the jaws are closed together. As shown in FIGURE 8, the arms 26 of the suture retaining device 20 are sufficiently long that when the device 20 is moved along the shank 1 to a position where the collar 21 is adjacent the anchor element 4, the rings 27, 28 and 29 extend slightly beyond the hooked ends of the jaws 2.

The entire instrument is constructed from non-corrosive and non-toxic materials. It is designed for use with both aortic valve prostheses 30 and atrio-ventricular valve prostheses 31. As shown in FIGURES 4 and 5 these valve prostheses 30 and 31 consist of a ring 32 of inert metal with an inside diameter slightly less than the outside diameter of a ball 33 of silicone rubber, which ball 33 is enclosed within metal hoops 34. The metal ring 32 is U-shaped in radial cross-section with the U opening outwardly. Fixed into the recess defined by the U is a sewing ring 35 of string-like material through which sutures 40 can be passed.

The use of the instrument for the insertion of an atrio-ventricular valve prosthesis 31 will now be described. After the heart of the patient is opened and the diseased atrio-ventricular valve is excised, the diameter of the heart valve annulus 50 is accurately gauged using the instrument's expanding jaws 2. On the basis of this measurement a prosthesis 31 of the correct size is selected. The selected prosthesis 31 is gripped by the outward turning hooks 5 of the jaws 2 which as shown in FIGURE 5, grip the inside of the ring 32 from the side of the prosthesis 31 remote from the hoops 34. A surgical assistant holds the instrument by the basket-shaped handle formed by the arms 26 of the suture retaining device 20 and positions the suture ring 29 in comfortable proximity to the sewing ring 35 of the valve prosthesis 31 as shown in FIGURE 6, the valve prosthesis being positioned in a convenient location relative to the heart. Needles 41 and 42 are preferably provided at both ends of each suture 40. The surgeon passes a suture 40 through the excised valve remnant or annulus 50 of the patient's heart. The sewing ring 35 of the prosthesis 31 is then pierced by the needle 41 on one end of the suture 40 and that end of the suture is passed through the sewing ring 35. Finally the rubber suture ring 29 of the suture retaining device 20 is pierced by the needles 41 and 42 on both ends of the suture 40 and these ends are passed through the suture ring 29. To save time an assisting surgeon may pass the suture 40 through the sewing ring 35 and the suture ring 29 while the surgeon continues with the insertion of further sutures 40 into the valve annulus 50 of the heart. The above description relates to the use of a simple suture technique; a mattress suture technique, in which both ends of the suture 40 are passed through the sewing ring 35 of the prosthesis 31, may also be used. All the sutures 40 are handled in the same way until they have been inserted through the circumference of the annulus 50, through the sewing ring 35 of the prosthesis 31, and through the rubber suture ring 29 of the instrument. The rubber of the ring 29 grips the sutures that have been passed through it but allows the sutures to be tightened. It is helpful to use identifying sutures at the commissures or at each quadrant of the annulus 50 to ensure parallel suture placement in the annulus 50 and in the sewing ring 35 of the prosthesis 31, i.e., to ensure that the sutures 40 extending between the sewing ring 35 and the annulus 50 are substantially parallel and equidistant. The identifying sutures can be of a colour that contrasts with the other sutures. When all the sutures 40 have been inserted they are drawn fairly taut by retracting the instrument. Inadequate sutures 40

can be readily identified and replaced at this stage. The sutures 40 once inserted can be bunched and displaced for exposure, used for retraction purposes, and freely moved about without fear of entanglement, for by retracting the instrument the sutures 40 are quickly straightened out.

As shown in FIGURE 7, the valve prosthesis 31 is moved into the annulus region by sliding the shank 1 of the instrument through the suture retaining device 20 which is held steady towards the valve annulus 50. The prosthesis 31 slides smoothly down the mass of sutures 40 into the annulus region. By turning the knob 10 the jaws 2 are moved inwardly and the valve prosthesis 31 is released. As shown in FIGURE 8, the jaws 2 are then withdrawn relative to the suture retaining device 20 until the anchor element 4 is adjacent the collar 21 of the suture retaining device 20 and the jaws 2 are completely encompassed by the suture retaining device 20 so that the jaws 2 will not interfere with the sutures 40. The valve 31 is seated by hand and secured by tying down the commissural sutures. The remaining sutures 40 are then cut free of the rubber ring 29 in paired ends, drawn taut, and tied securely.

Thirty-inch sutures of polyethylene terephthalate fiber, such as the fiber supplied by E. I. du Pont de Nemours under the trademark "Dacron," are normally used and these give ample length to enable the surgical assistant to hold the instrument and the valve clear of the restricted operating field as shown in FIGURE 6.

The use of the instrument for the insertion of an aortic valve prosthesis 30 is substantially the same as the technique for the insertion of atrio-ventricular valve prosthesis 31. The main difference, as shown in FIGURE 4, is that the sewing ring 35 of the aortic valve prosthesis 30 is gripped instead of the metal ring 32, and it is gripped from the side of the prosthesis 30 on which the hoops 34 are attached rather than from the side of the prosthesis 30 remote from the hoops 34.

Although the instrument has been described and illustrated for use with caged ball valves, it is suitable for all forms of prosthetic heart valves which incorporate a sewing ring; for example, flap valves or discoid valves. It would be possible to sell each valve packaged with a rubber ring 29 and with sutures passed through the rubber ring and the sewing ring of the valve, so that the rubber ring 29 could be clamped between the rigid rings 27 and 28 with sutures already in place connecting the ring 29 and the sewing ring of the valve.

What I claim as my invention is:

1. A surgical instrument for holding a cardiac valve prosthesis having a ring, the instrument comprising a shank, a plurality of jaws, means mounting the jaws at one end of the shank for pivotal movement generally radially relative to each other, each jaw having an outwardly directed hook at the end of the jaw remote from the shank, means for spreading the jaws radially outwardly to grip the valve prosthesis from within its ring, and a suture retaining device mounted on the shank and slidable therealong to a position where it encompasses the jaws with the suture ring extending beyond the hooked ends of the jaws.

2. A surgical instrument as claimed in claim 1, wherein said means for spreading the jaws radially outwardly to grip the valve prosthesis from within its ring include a jaw spacer having apertures through which the jaws pass slidably, and a rod slidable longitudinally through the shank and attached to said spacer whereby longitudinal movement of the rod and spacer in one direction causes the jaws to spread outwardly, and longitudinal movement of the rod and spacer in the opposite direction causes the jaws to close together.

3. A surgical instrument as claimed in claim 2, including a threaded knob at the end of the shank remote from the jaws for moving the rod longitudinally.

4. A surgical instrument as claimed in claim 1 wherein each jaw bows outwardly between its ends.

5. A surgical instrument as claimed in claim 1, where-

5

in the means for spreading the jaws are controllable at the end of the shank remote from the jaws.

6. A surgical instrument as claimed in claim 1, wherein the suture ring is of material which can be pierced by suture needles in order to pass sutures through the suture ring.

7. A surgical instrument as claimed in claim 6, wherein said material of the suture ring is rubber.

8. A surgical instrument as claimed in claim 6, wherein the suture retaining device includes a rigid ring supporting the suture ring.

9. A surgical instrument as claimed in claim 8, wherein the rigid ring is one of two rigid rings located at opposite sides of the suture ring to hold the suture ring.

10. A surgical instrument as claimed in claim 9, wherein the suture ring has an outside diameter larger than that of the rigid rings.

11. A surgical instrument as claimed in claim 8, wherein the suture retaining device includes a collar slidably and non-rotatably mounted on the shank and arms extending from the collar to the rigid ring.

12. A surgical instrument as claimed in claim 11, including a collet for temporarily fixing the collar to the shank.

13. A surgical instrument as claimed in claim 11, wherein the inside diameters of the suture ring and rigid ring are sufficiently large for the rings to encompass and clear the jaws at least when the jaws are closed together,

6

and wherein the arms extend in the longitudinal direction of the shank and are sufficiently long that when the suture retaining device is moved to the end of the shank at which the jaws are located the suture ring extends beyond the hooks at the ends of the jaws.

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RICHARD A. GAUDET, *Primary Examiner*.

RONALD L. FRINKS, *Assistant Examiner*.