ABSTRACT: A valve insertion unit for holding a heart valve or like prosthetic device to be inserted within the body, for engaging and spreading an expandable valve-receiving ring previously implanted in the body, for moving the valve into position within the ring, releasing the ring over the valve and releasing the valve from the holder. The valve holder is normally biased opened, fingers are used to spread the ring and are biased to a normally closely spaced-apart position, and movement of the holder along the fingers while portions of the holder engage the fingers expands the ring. When the holder, in an extreme axial position of travel, leaves the ends of the fingers, the ring automatically snaps into position to hold the valve in place within the body and the valve holder releases it grip on the valve so the entire instrument may be removed from the body.
SURGICAL INSTRUMENT FOR IMPLANTING A PROSTHETIC HEART VALVE OR THE LIKE

BACKGROUND OF THE INVENTION

The present invention is directed generally to surgical instruments, and more particularly to a surgical instrument or tool adapted to facilitate insertion of a prosthetic device such as a replacement heart valve or the like into position within a person or animal in a simple, rapid and accurate manner. More particularly, in one embodiment, the invention is directed as a tool for use during surgery to insert an atrio-ventricular into the annulus fibrosis of a heart of a person.

Recently, as extensive and complex surgery becomes more common, many attempts have been made to insure that a person or animal being surgically operated upon undergoes the least exposure to damage which is consistent with performing the steps necessary to an operation. For example, as open heart surgery has become more common, there has been a need not only for improved surgical techniques and prosthetic devices to bring about the results desired, such as methods of implanting improved synthetic heart valves and the like, but also a need for means of assuring that the surgical patient is exposed to potentially dangerous and damaging conditions for the least possible time.

Thus, it is now somewhat common to replace a damaged heart valve, such as the atrio-ventricular heart valve, this surgery requires that the heart be open and the blood of the patient be circulated by artificial means. Artificial blood circulation pumps, although satisfactory in general sense, are known by those skilled in medicine to cause some measurable damage to the blood of the patient, and therefore increase the likelihood that the patient will suffer either immediate or eventual adverse affects from such exposure.

Therefore, there has been a need for minimizing the time during which the heart of a patient must remain open during surgery, and attempts to satisfy this need have included the provision of heart valves having improved means for implantation thereof. For example, copending application Ser. No. 721,360 filed Apr. 15, 1968, discloses a heart valve which is held in place by resilient snapping down into the annulus fibrosis of a patient before the valve is inserted, and which then supports the valve in position within the heart. This construction has significantly simplified the suturing techniques heretofore, used, and as a result, has decreased the time during which the heart must remain open during surgery. This construction eliminates the time consuming formerly used method of sewing the valve in position, and includes a generally ring-shaped frame unit 16, and a plurality of means in the form of rods or fingers 18 for engaging and spreading apart an expansible snapring 20, such as a silicone rubber or stainless steel snapring. The remote ends 22 of the fingers 18 engage the ring 20 while the proximate ends 24 of the fingers 18 are fixedly attached to the frame 16. A valve 26 is removably held between an upper semicircular collar 28 and a lower circular collar 30, which combine to form valve receiving means in the form of a holder 32. Preferably, the collars 28, 30 are biased apart by a pair of valve holder rods 34 which terminate at the proximate ends 36 thereof in an annular ring 38 which serves as a frame for the valve holder 32.

An alignment ring 40 having a plurality of openings 42 therein, may be disposed between the frame 16 and the holder 32 for receiving the fingers 18, in a manner and for purposes which will be described in further detail herein.

Referring now in particular to FIG. 1, the surgical tool 10 is shown to comprise means for engaging and spreading an expansible ring in the form of a ring spreader assembly 12 and means for receiving a synthetic heart valve in the form of a valve holder assembly 14 including a generally ring-shaped frame unit 16, and a plurality of means in the form of rods or fingers 18 for engaging and spreading apart an expansible snapring 20, such as a silicone rubber or stainless steel snapring. The remote ends 22 of the fingers 18 engage the ring 20 while the proximate ends 24 of the fingers 18 are fixedly attached to the frame 16. A valve 26 is removably held between an upper semicircular collar 28 and a lower circular collar 30, which combine to form valve receiving means in the form of a holder 32. Preferably, the collars 28, 30 are biased apart by a pair of valve holder rods 34 which terminate at the proximate ends 36 thereof in an annular ring 38 which serves as a frame for the valve holder 32.

An alignment ring 40 having a plurality of openings 42 therein, may be disposed between the frame 16 and the holder 32 for receiving the fingers 18, in a manner and for purposes which will be described in further detail herein.

Referring now to FIGS. 2 and 3, it can be seen that the ends 22 of the fingers 18 are normally biased to a closely spaced-apart position by the inherent resiliency of the fingers 18, but that the ends 22 are free to move during surgery to space-apart position such as that shown in FIG. 2 by moving the upper and lower semicircular collars 28, 30 which comprise the holder 32 axially of the fingers 18. This is accomplished because the openings 42 in the collars 28, 30 receive the fingers 18 and act as means for spreading them apart upon axial holder move-
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ment which occurs when the frame 38 of the valve holder assembly 14 is moved axially of the instrument 10 toward the ends 22, 30 of the frame 18.

In FIG. 3, it is shown that, when the entire holder assembly 14 is moved to a sufficient axial extent, such as to the extreme right hand position shown in FIG. 3, the collars 28, 30 move free of the rod ends 22, thereby enabling the resilient, outwardly biased rods 34 to move the collars 28, 30 radially apart, and the ends 22 of the fingers 18 to return to a closely spaced-apart position.

Referring now to FIGS. 4 and 5, a silicone rubber ring 20 is shown as being sewn in place within the annulus fibrosis 44 of the atrio-ventricular heart wall 46 by a plurality of sutures 48. The interior of the ring 20 is engaged by the remote ends 22 of the fingers 18, and this serves to spread the expansible ring 20 apart a preset distance as the collars 28, 30 are moved toward the axially remote ends 22 of the fingers 18. As shown in FIG. 4, the valve 26 includes a nose portion 50, partially defined by a plurality of supporting members 52 which also serve to cage a ball 54, which is the operational portion of the valve 26. Around the exterior of the valve seat 56 is a ring-containing groove 58, partially defined by a shoulder portion 60 which is added to engage the ring 20 to ensure proper registry of the ring 20 in the groove 58. A land 62 in the holder 32 releasably engages a second shoulder 64 on the valve 26. Thus, the land 62 on the collars 28, 30 engages the valve 26 and holds it in position as long as the collars 28, 30 are held closed by engagement between the openings 42 therein and the fingers 18.

FIG. 5 shows that, in operation of the device, as the extreme axial movement limit of the collars 28, 30 is reached, the shoulder portion 60 of the valve has engaged the ring 20 so that it is in a position of registry with the groove 58 and the ring 20 cannot move past the desired position. As the ends 22 of the fingers 18 undergo radial movement with respect to the holder 32, and are withdrawn into the openings 42, the ends 22 no longer engage the ring which snaps into the groove 58 to support the valve 26 in a desired position within the heart. Slight further movement of the collars 28, 30 with respect to the rod ends 22 allows the collars 28, 30 to release the valve, and the entire unit is then withdrawn.

When it is desired to repeat the operating cycle for another operation, a valve is placed between the collars 28, 30, the collars are then closed, and the alignment ring 40 is moved towards the remote ends 22 of the fingers 18, thereby spacing the ends 22 apart a distance equal to their spacing when engaged with the openings 42. This allows the collars 28, 30 to be placed over the fingers 18 in a simple operation and enables the entire valve holder assembly, including a valve 26 held therein, to be moved to the left as shown in the drawings. This permits the ends 22 of the rods or fingers 18 to return to their closely spaced-apart position for entry into the center of the ring. This action is illustrated in FIG. 7, which shows a valve 26 held in the collars 28, 30, the frame 38 moved to an extreme left-hand position, and the ends 22 of the fingers 18 closely spaced apart.

In use, when the heart wall or membrane is open, the flexible rubber or expansible steel snapping 20 is rapidly sewn directly into place within the annulus fibrosis in the place from which the natural atrio-ventricular valve has been removed. Since the ring 20 and the valve 26 to be inserted therein are separate pieces, the valve does not interfere with the sewing operation. Immediately after the ring is located and sewn in the desired position, the ends 22 of the rods or fingers 18 are placed within the snapping 20 and the ring 38 is manipulated so as to move the valve into position within the split ring 32 and subsequently released therefrom in one operation, while the ring 20 is in registry with the groove 58. The entire device, in a surgical implantation position thus makes it possible to simplify heart surgery and greatly reduce the time required for implantation of a valve within the heart, thereby reducing the time during which the heart must remain open and during which the blood of the patient is being circulated by artificial means.

In a preferred embodiment, the unit is made of a stainless steel construction for corrosion resistance, and ease of sterilization even though the construction is such that other materials may be used, particularly if a lower cost disposable unit is desired to be made.

We claim:

1. A surgical instrument for use in inserting a prosthetic device in a desired position of use at least partially within an expansible retaining ring, said instrument comprising in combination, means for engaging said ring on the interior thereof and for spreading said ring upon radially outward movement of said engaging means, means for receiving a valve for insertion within said ring, said receiving means being normally biased to an open position for release of a valve held therein and being adapted to hold a valve therein in a closed position thereof, means associated with said receiving means for expanding said ring-spreading means by engagement therewith while said valve is held within said receiving means, said receiving means and said spreading means being arranged so that said valve may be moved by said receiving means into a position of engagement with said ring, and further movement of said receiving means removes said ring from said engaging means and releases said spreading means from said engaging means, whereby said valve may be released from said receiving means upon engagement of said valve with said ring.

2. An instrument as defined in claim 1 in which said receiving means comprises a split ring having an annular groove therein for receiving a portion of said valve.

3. An instrument as defined in claim 1 in which said receiving means comprises a ring having a groove therein for receiving said valve and said spreading means comprises a plurality of openings in said receiving means engaging with said engaging means, whereby said engaging means are positioned so as to be in diametrical registry with said spreading means as said receiving means is moved along said engaging means.

4. An instrument as defined in claim 1 in which said engaging means comprises a plurality of stiff but resilient fingers attached to a frame element, said fingers being biased toward a closely spaced-apart position at the ends thereof opposite the ends thereof which are received by said frame.

5. An instrument as defined in claim 1 in which said engaging means comprises a plurality of fingers mounted in a frame and extending axially therefrom, said receiving means comprises a split collar having an annular groove therein for receiving a valve, and in which said receiving means includes a plurality of openings therein for engaging said fingers, and in which said receiving means includes a pair of stiff but resilient fingers biasing said split collar to an open position thereof, whereby said first-mentioned fingers are urged apart by axial movement of said receiving means and whereby engagement of said first-mentioned fingers with said receiving means retains said receiving means in a closed position thereof as long as said openings are engaged with said fingers.

6. A surgical tool for use in inserting a prosthetic device in a desired position of use at least partially within an expansible retaining ring comprising, in combination, a ring spreader assembly including a ring spreader frame unit, a plurality of spaced apart, elongated flexible ring-spreaders attached to the proximate ends thereof to said frame unit and being biased toward and closely spaced apart from one another at the remote ends thereof for entry into the center of said expansible ring, a valve holder assembly including a frame unit, a plurality of spaced apart, elongated means for supporting a valve holder unit, said means being joined at the proximate ends thereof to said valve holder frame unit and being inherently biased apart from each other at the remote ends thereof, a valve holder unit adapted to receive and hold a valve therein when in a closed position, and to release said valve when in an open position thereof, said supporting means being attached at their remote ends to portions of said valve holder unit, said valve holder assembly and said ring-spread assembly being freely axially movably in relation to each other, and means on said valve holder unit for spreadingly en-
gaging said fingers in one axial position of said holder and for releasing said valve holder in another axial position of said holder, whereby, during axial movement of said valve holder along said fingers, engagement between said holder unit and said fingers spreads said fingers apart to expand said expandable ring engaged by said remote ends of said fingers to allow insertion of said valve unit through said ring in an expanded condition of said ring, and upon further axial movement, said ring is engaged by said valve, and removed axially from the ends of said fingers, whereupon said valve holder is released from said fingers and allowed to open for release of said valve therefrom.