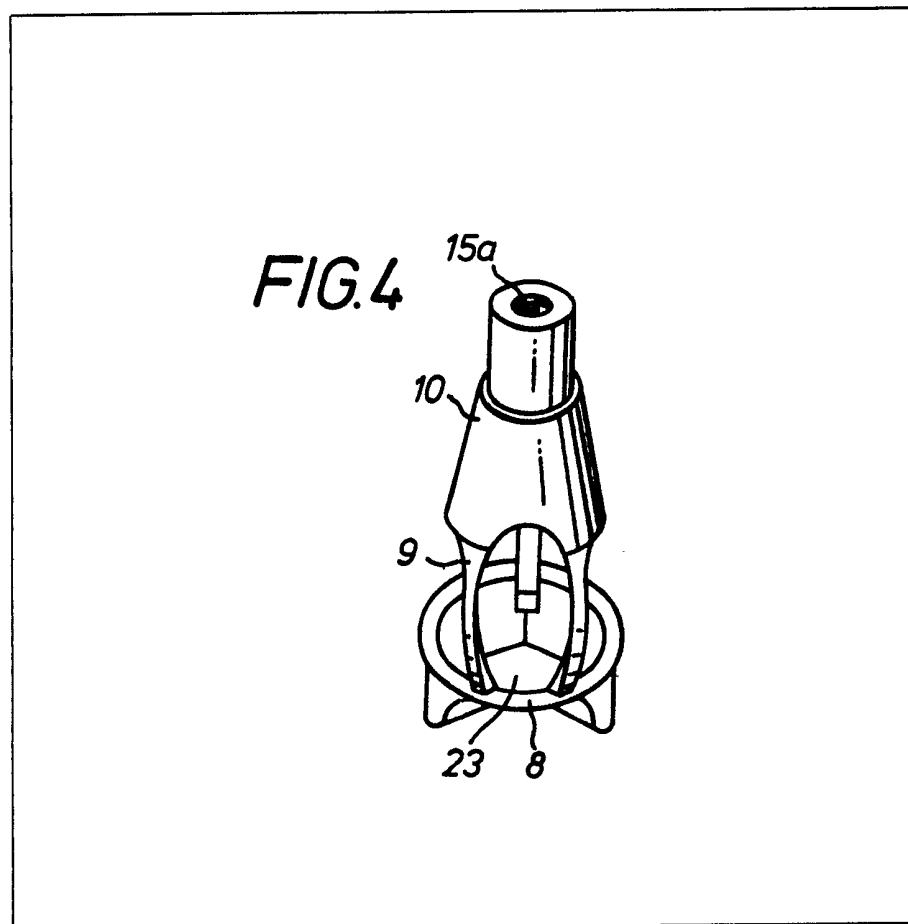


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(54) Disposable heart valve unit

(57) A disposable heart valve unit; comprising: a valve holder 10 having a central threaded core 15a at one end and a plurality of separate projecting legs 9 at the other end; an artificial heart valve 8 comprising an annular ring and inwardly positioned flaps attached to the ring; and sutures attaching the ends of the legs to the ring.



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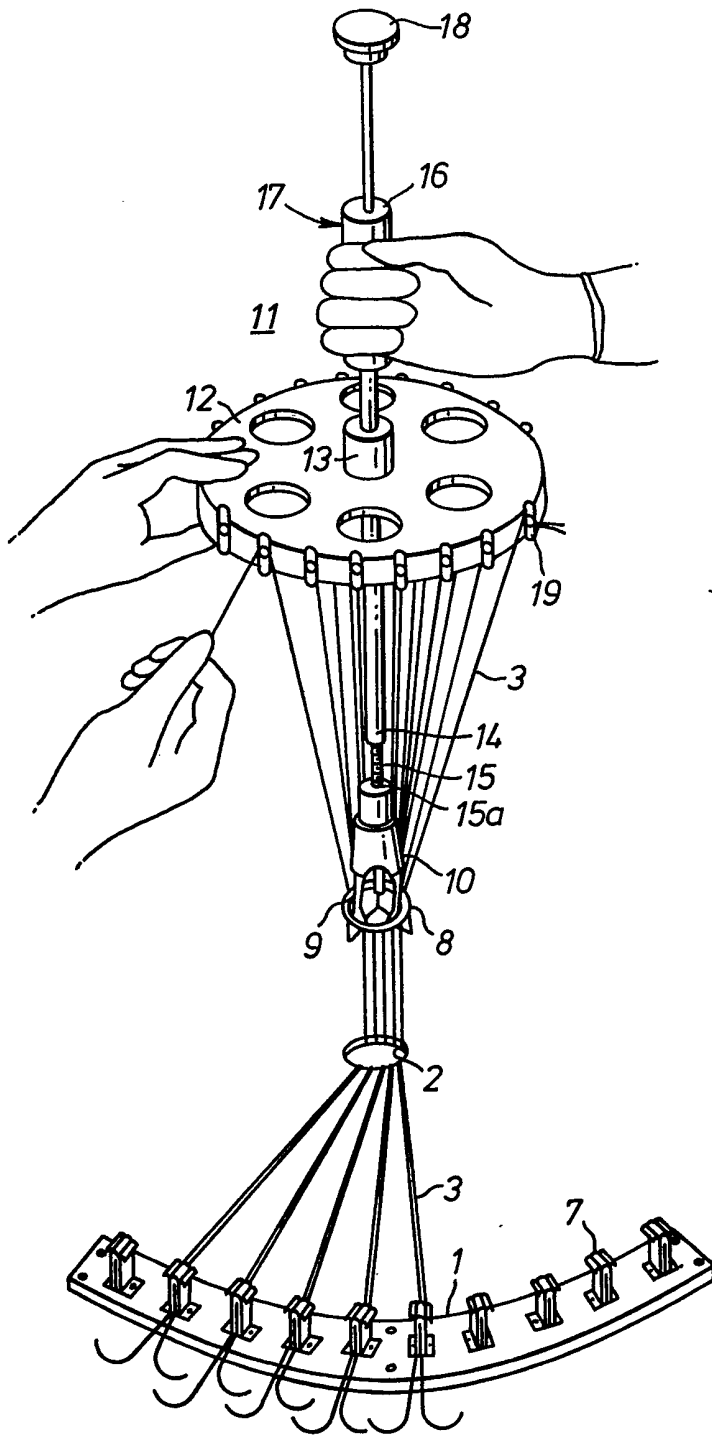


FIG. 1

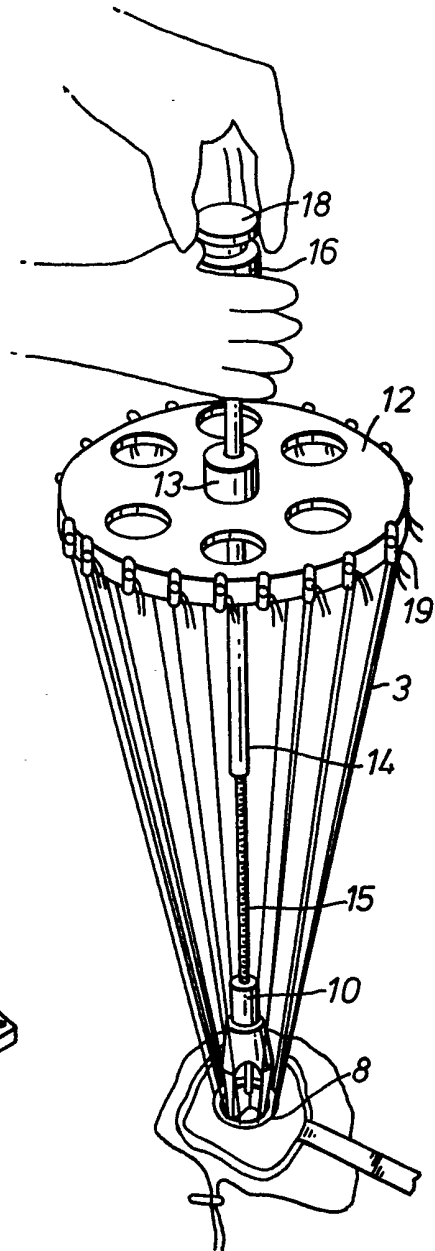


FIG. 2

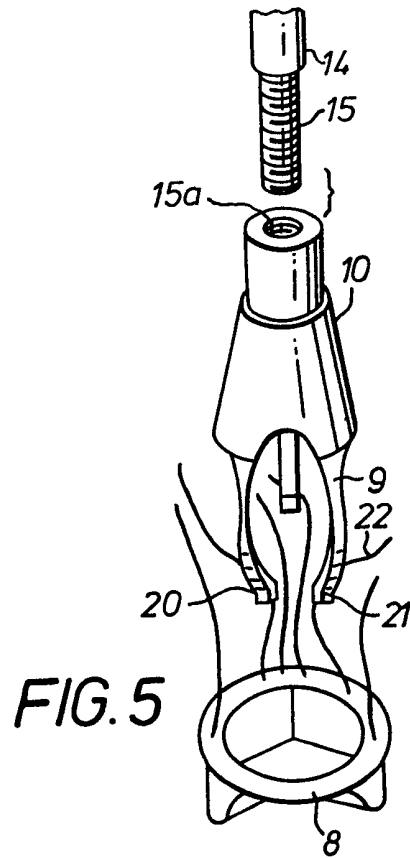
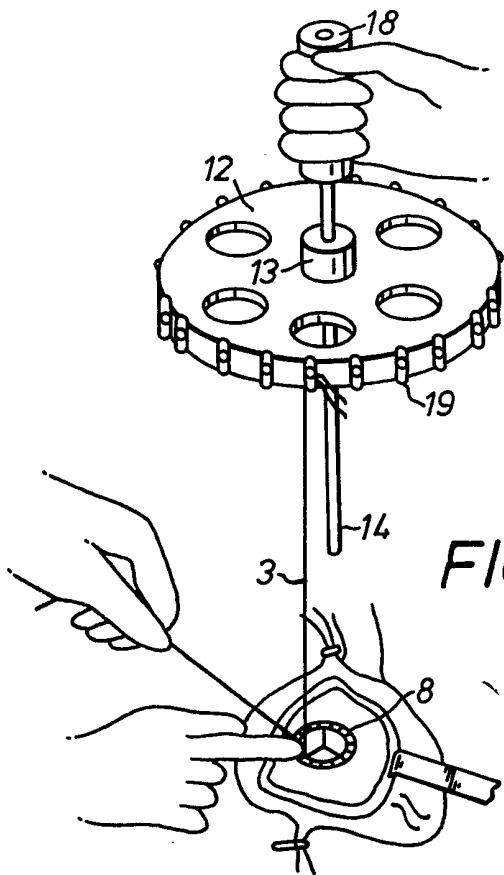
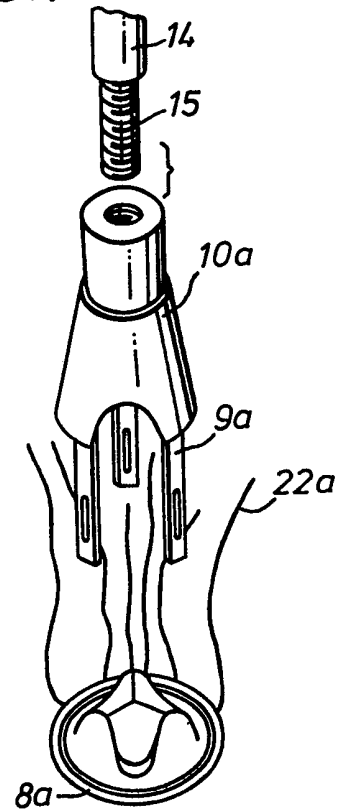
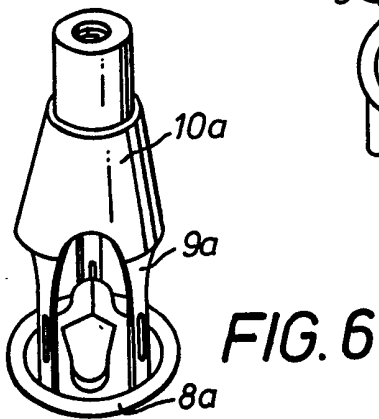
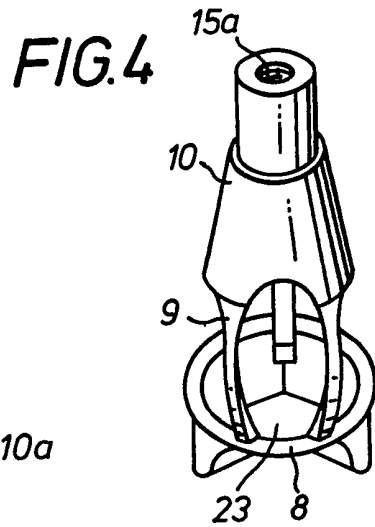


FIG. 7



## SPECIFICATION

**Disposable heart valve unit**

5 This invention relates to surgical devices and more particularly to a disposable heart valve unit.

In accordance with this invention we provide a disposable heart valve unit; comprising:  
 10 a valve holder having a central threaded core at one end and a plurality of separate projecting legs at the other end; an artificial heart valve comprising an annular ring and inwardly positioned flaps attached to said rings; and  
 15 sutures attaching the ends of said legs to said annular ring.

In the drawings:

20 *Figure 1* illustrates apparatus for positioning a valve of a heart valve unit in accordance with this invention;

*Figures 2 and 3* illustrate sequential steps taking place during the implantation and suturing of an artificial valve following the initial step illustrated in *Fig. 1*;

25 *Figure 4* illustrates a heart valve unit comprising a mitral valve and valve holder in accordance with this invention;

*Figure 5* illustrates the disconnection between the valve holder and the artificial mitral valve of the unit shown in *Fig. 4*; and

30 *Figures 6 and 7* are similar to *Figs. 4 and 5*, showing an artificial aortic valve.

Fig. 1 illustrates a prosthetic device positioning apparatus 11 as described and claimed in our co-pending Application No. 35 divided out of Application No. 49628/78 for use in the attachment to the annulus 2 of a diseased heart valve of an artificial valve 8 releasably held in a valve holder 10, the valve 8 and holder 10 together forming a  
 40 disposable heart valve unit in accordance with this invention. It is assumed that the diseased natural valve has already been removed; the patient at this point being maintained by  
 45 artificial means such as an external heart-lung machine. Basic sutures 3 are now in place and are being held by individual suture holders 7 mounted on frame 1, which together form a suture organizer which is described  
 50 and claimed in Application No. 49628/78 from which this application has been divided out. The mitral valve 8, to be attached to the annulus 2, is temporarily attached by sutures  
 55 3 to the arms 9 extending from a disposable plastic valve holder 10. Holder 10 may be made from Plexiglass (R.T.M.) or other suitable material which with the valve 8 comprises a preconnected disposable heart valve unit individually packaged and supplied to the  
 60 surgeon.

The application and attachment of artificial valve 8, to the annulus 2 of the diseased valve is effected through the positioning apparatus 11 which comprises a plastic disc 12  
 65 provided with an integral hub 13 through

which may be slidably moved, a rod 14 preferably of stainless steel and provided with an externally threaded projection 15 engaging an internally threaded opening 15a in the top  
 70 of disposable valve holder 10. Spaced above and integral with hub 13 is a hand grip 16 having a threaded opening into which a set of screw 17 is threaded. The upper end of rod 14 is provided with a knob 18.

75 A plurality of spring clips 19 are attached about the outer periphery of the disc 12 for holding sutures 3 in a manner hereinafter described.

Disposable valve holder 10 and its attached  
 80 mitral valve 8 comprising the heart valve unit in accordance with this invention are illustrated in more detail in *Figs. 4 and 5*, from which it will be seen that legs 9 extending from valve holder 10 have cut-out portions  
 85 20 engaging the inner periphery of valve 8, legs 9 additionally being formed with openings 21 by means of which the valve 8 and valve holder 10 are joined together by sutures 22. Thus the initial unitary structure comprises valve holder 10 and valve 8 to be later  
 90 disconnected as more clearly illustrated in *Fig. 5*. Valve 8 is provided with the usual valve cusps 23 which may be made of suitable material and in the present form may actually  
 95 be the valve cusps removed from an animal such, for example, as a pig.

*Figs. 6 and 7* are similar to *Figs. 4 and 5* but illustrate a heart valve unit comprising a disposable valve holder 10a with an aortic  
 100 valve 8a. In this form of the invention, legs 9a of valve holder 10a may be straight and form a unit with valve 8a by attachment with sutures 22a.

The manner in which the apparatus described above is utilized in an actual operation will now be described in more detail with  
 105 particular reference to *Figs. 1, 2 and 3*.

As shown in *Fig. 1*, disc 12 supporting the heart valve unit comprising valve 8 and holder  
 110 10 is being held directly above mitral annulus 2, some of the sutures 3 remaining in holder 10 while others have already been threaded through valve 8 and are supported on disc 12 by the spring clips 19. In *Fig. 2*, the valve is shown in place, having been pushed downwardly by rod 14 and sutures 3 attach valve  
 115 8 to annulus 2 and are all retained on clips 19 of the disc 12. By loosening set screw 17 and rotating knob 18, threaded extension 15 of rod 14 is removed from the top of valve 8 and disposable valve holder 10 is discarded,  
 120 leaving valve 8 in place. As shown in *Fig. 3*, the operation is substantially over, all sutures 3 but one having been tied and valve 8 is firmly in place, having been attached to the heart and more specifically to annulus 2.

Obviously the same procedure is used in replacing the aortic valve except that in this case valve 8a and disposable holder 10a are  
 130 utilized. The number of legs projecting from

the body of the holder may be varied and differently positioned depending upon the shape of the prosthetic device, i.e., as for a semilunar valve.

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#### CLAIMS

1. A disposable heart valve unit; comprising: a valve holder having a central threaded core at one end and a plurality of separate projecting legs at the other end; an artificial heart valve comprising an annular ring and inwardly positioned flaps attached to said rings; and sutures attaching the ends of said legs to said annular ring.
2. A disposable heart valve unit as claimed in Claim 1, wherein the ends of each said legs are provided with an opening there-through, the ends of said legs being annularly spaced at a diameter equal to the inside diameter of said annular ring, and said sutures extend through the surface of said ring and said holes, whereby the valve holder and heart valve comprise a separable unitary structure.
3. A disposable heart valve unit as claimed in Claim 2, wherein said heart valve is a mitral valve and in which the ends of each of said legs are provided with an inward notch abutting the inner surface of said annular ring.
4. A disposable heart valve unit substantially as described herein with reference to the accompanying drawings.

#### 35 CLAIMS (Filed 30 Nov 1981)

1. A disposable heart valve unit; comprising: a valve holder having a central threaded core at one end and a plurality of separate projecting legs at the other end; an artificial heart valve comprising an annular ring and inwardly positioned flaps attached to said ring; and sutures attaching the ends of said legs to said annular ring.
2. A disposable heart valve unit as claimed in Claim 1, wherein the ends of each of said legs are provided with a hole or opening therethrough, the ends of said legs being annularly spaced at a diameter equal to the inside diameter of said annular ring, and said sutures extend through the surface of said ring and said holes, whereby the valve holder and heart valve comprise a separable unitary structure.