

- [54] COLLET FOR HOLDING HEART VALVE

- [76] Inventors: **Lawrence Anderson; Bruce D. Bentzen**, both c/o Medical Incorporated, 5200 W. 78th St., Minneapolis, Minn.

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- [21] Appl. No.: 394,482

Related U.S. Application Data

- [63] Continuation-in-part of Ser. No. 287,420, Sept. 8, 1972, Pat. No. 3,828,787.

- [52] U.S. Cl. 128/303 R, 3/DIG. 3

- [51] Int. Cl..... A61b 17/00

- [58] **Field of Search** 128/303, 92; 3/1, DIG. 3;
81/3

- [56]
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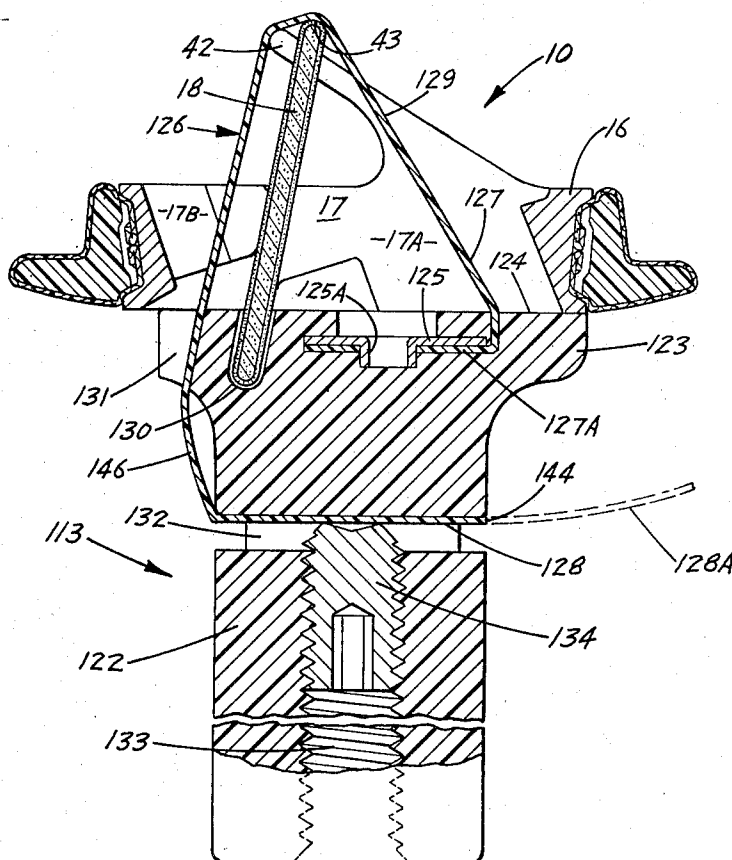
Primary Examiner—Richard A. Gaudet

Assistant Examiner—J. Yasko

- [57] ABSTRACT

A holder for a pivoting disc heart valve used to implant the valve in a heart. The holder has an elongated handle carrying a disposable collet. The collet has a body adapted to be releasably connected to the end of the handle. One end of the body has an enlarged head having a groove for accommodating a portion of the valve disc to hold the disc in the open position. Secured to the head is an elongated flexible band adapted to be positioned over the side arms and disc of the valve to cover the side arms and disc. A portion of the band is attached to the body to hold the band in engagement with the side arms and disc.

20 Claims, 16 Drawing Figures



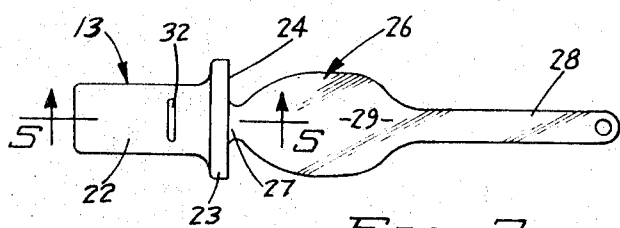


FIG. 2

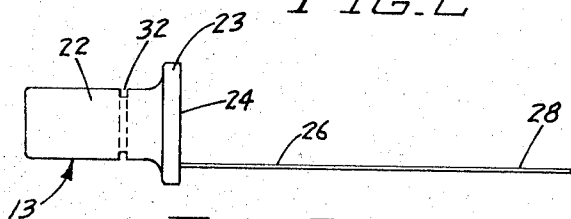


FIG. 3

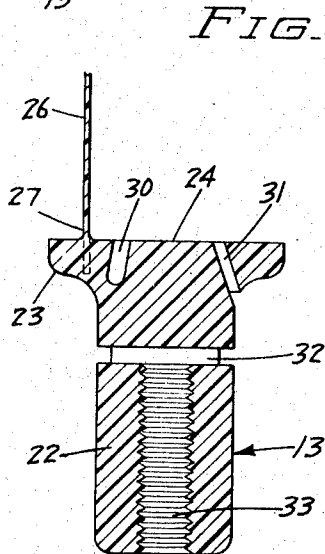


FIG. 5

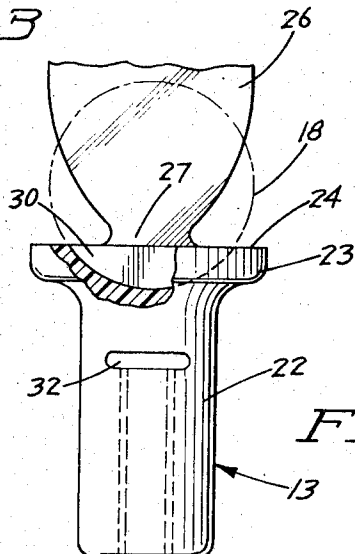


FIG. 6

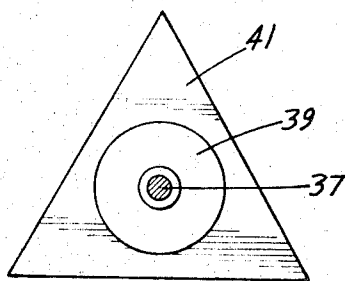


FIG. 7

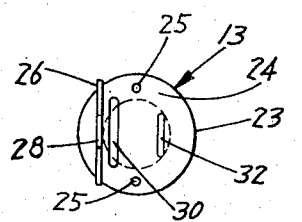


FIG. 4

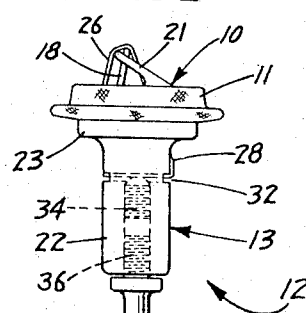


FIG. 1

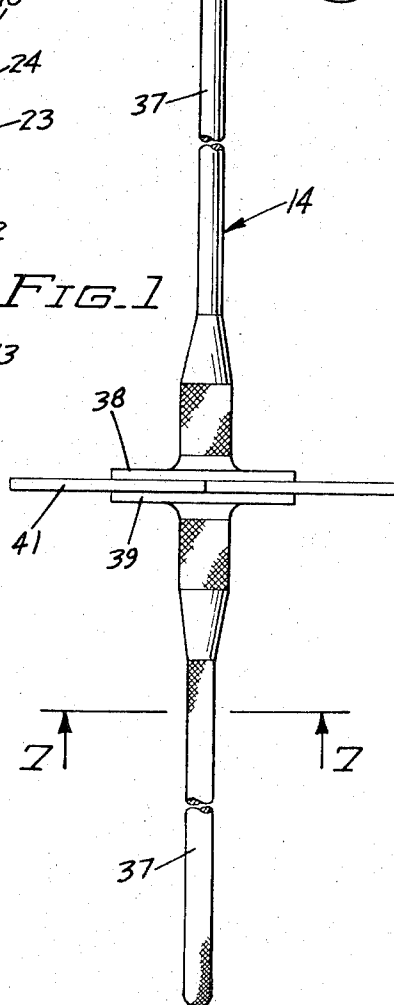


FIG. 8

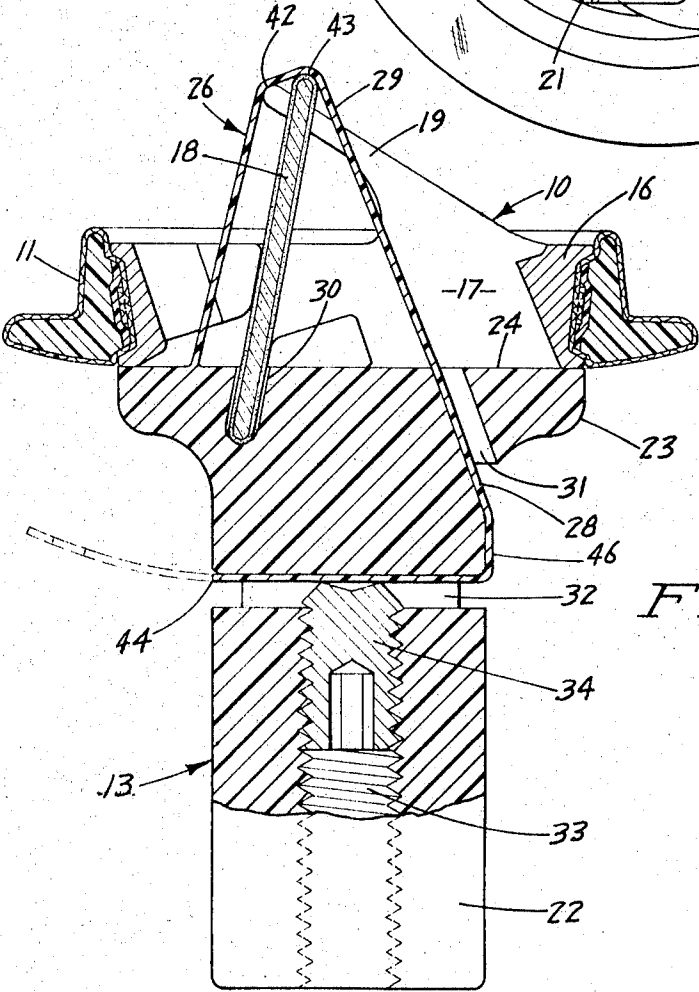
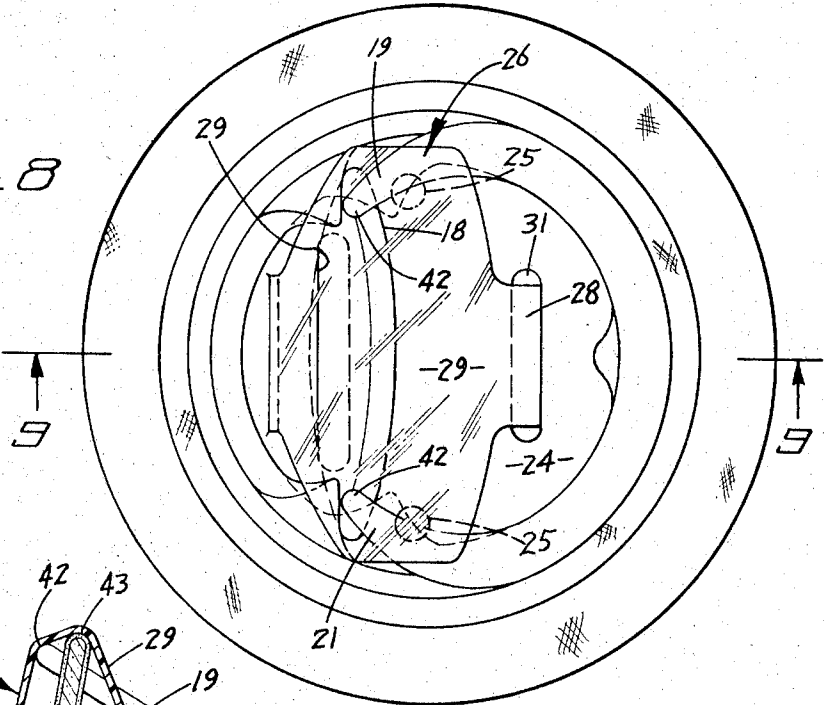


FIG. 9

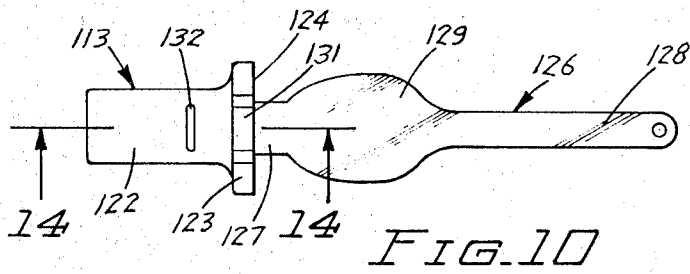


FIG. 10

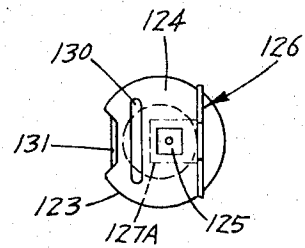


FIG. 12

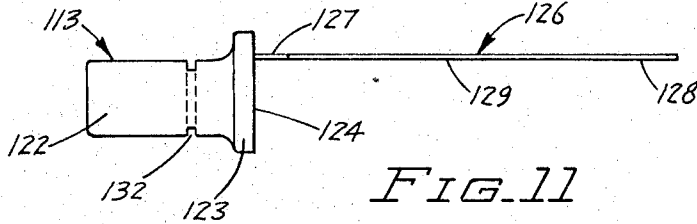


FIG. 11

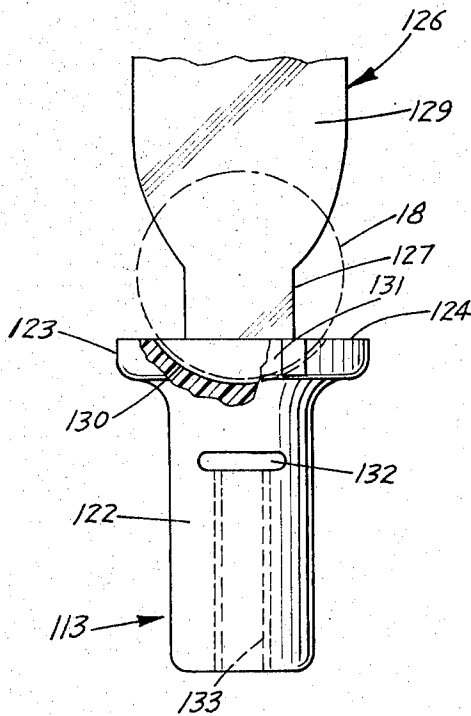


FIG. 13

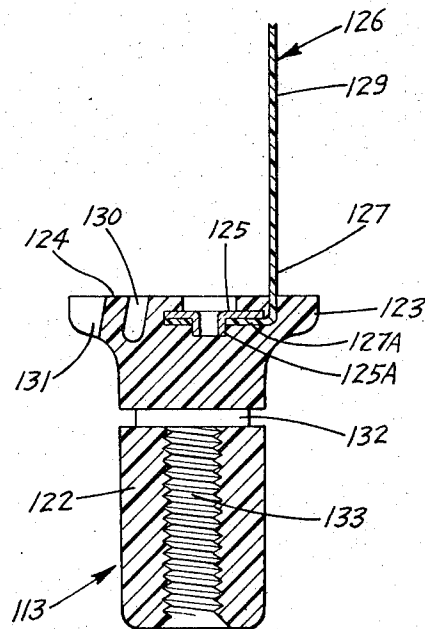
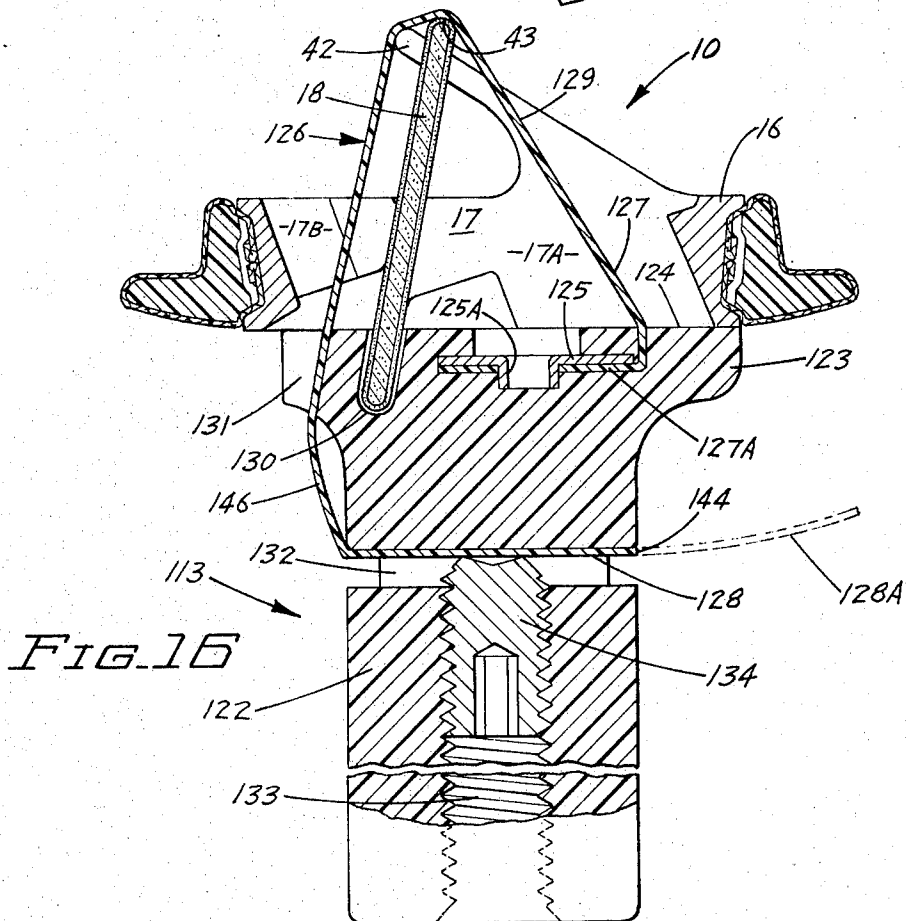
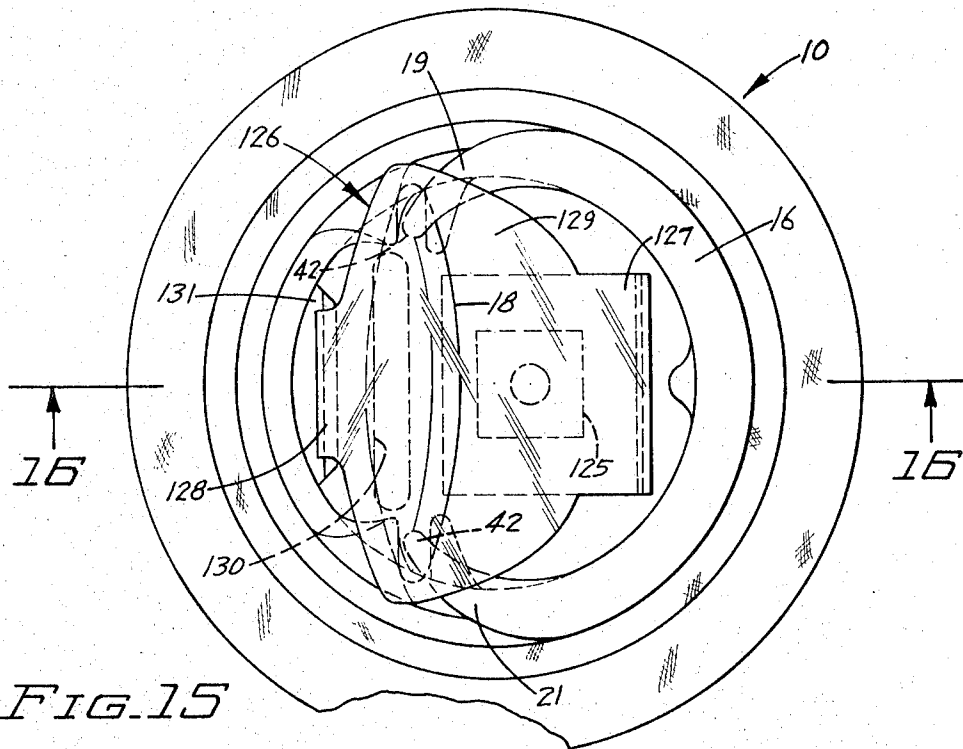


FIG. 14



COLLET FOR HOLDING HEART VALVE

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of U.S. Ser. No. 287,420, now U.S. Pat. No. 3,828,787.

BACKGROUND OF THE INVENTION

Holding structures are used with prosthetic heart valves during surgical procedures to facilitate the implantation of valves in the heart. These holders have elongated handles connected to collets. The valve base is releasably retained on the collets until the suturing member or skirt is attached to the heart tissue with sutures. The collet is then released, permitting the valve to function. The collet does not eliminate the possibility of snagging a stitch over a portion of the valve or forcing portions of the valve into the heart tissue. Also, when the collet is removed from the valve, there is a possibility that one or more parts of the holding structure of the collet will be lost in the heart.

SUMMARY OF THE INVENTION

The invention is related to a holder for a heart valve which facilitates the implantability of the valve. The holder has a collet adapted to releasably accommodate a pivoting disc valve, as shown in U.S. Pat. No. 3,476,143 and U.S. Pat. No. 3,737,919. The pivoting disc valve has an annular base carrying a suturing member. The base has a passage accommodating a pivoting disc which selectively moves to open and closed positions to allow flow of blood through the passage and restrict the flow of blood through the passage. Arm means secured to the base cooperate with pivot structures and the disc to retain the disc in assembled free-floating relation with the base. The collet has a body carrying a head. The head has an annular portion engageable with one side of the valve base and a groove for accommodating a portion of the disc to hold the disc in the open position. An elongated flexible band is secured to the head. The band is positionable over the arm means and the open disc to cover and protect the outer ends of the arms and the disc. The band also holds the valve in assembled relation with the collet. In use, the band prevents the possibility of snagging a stitch over an arm and forcing the arm into heart tissue, i.e., myocardium. The band has an end portion attached to the body to hold the valve base on the head and the band in protective engagement with the arms and disc. A section of the end portion of the band is exposed so that it can be cut after the valve has been implanted. The band can only be cut in one place, thereby eliminating the possibility of having band or collet structural pieces being lost in the wound.

IN THE DRAWINGS

FIG. 1 is a side elevational view of a heart valve mounted on a valve holder equipped with the collet of the invention;

FIG. 2 is a plan view of the collet of the valve holder;

FIG. 3 is a side elevational view of FIG. 2;

FIG. 4 is an elevational view of the right end of FIG. 2;

FIG. 5 is an enlarged sectional view taken along the line 5—5 of FIG. 2;

FIG. 6 is a fragmentary side view, partly sectioned, of the collet;

FIG. 7 is a sectional view taken along line 7—7 of FIG. 1;

FIG. 8 is a top plan view of a heart valve mounted on the collet;

FIG. 9 is a sectional view taken along line 9—9 of FIG. 8;

FIG. 10 is a plan view of a modified collet of the valve holder of the invention;

FIG. 11 is a side elevational view of FIG. 10;

FIG. 12 is an elevational view of the right end of FIG. 10;

FIG. 13 is a fragmentary side view, partly sectioned, of the collet;

FIG. 14 is an enlarged sectional view taken along the line 14—14 of FIG. 10;

FIG. 15 is a top plan view of a heart valve mounted on the collet; and

FIG. 16 is a sectional view taken along line 16—16 of FIG. 15.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the drawings, there is shown in FIG. 1 a pivoting disc heart valve indicated generally at 10 carrying an annular suturing member or collar 11. Valve 10 is mounted on a holder indicated generally at 12. Holder 12 has a collet 13 connected to an elongated handle 14. Holder 12 is used to position the valve in the heart and hold the valve in position during heart surgery.

Heart valve 10 is a pivoting disc valve as shown in U.S. Pat. No. 3,486,143 and U.S. Pat. No. 3,737,919. Referring to FIG. 9, valve 10 has an annular base 16 having a passage 17 permitting the flow of blood through the base. Operatively located within passage 17 is an occluder or disc 18. The disc 18 is operable to pivot between open and closed positions. As shown in FIG. 9, the disc 18 is in its open position. A pair of side arms or struts 19 and 21 project upwardly from base 16 in the direction of the opening pivot movement of the disc and cooperate with separate portions of the outer peripheral edge of the disc 18 and pivot members to retain the disc in free floating pivotal relation with the base.

Returning to FIGS. 1 to 6, the collet 13 has a cylindrical body 22 of plastic material, as Teflon or Delrin. The upper end of the body 22 has an enlarged circular head 23. The top of the head has a flat surface or face 24. Face 24 has a diameter equal to the diameter of the proximal side of the base 16, as shown in FIG. 9. Face 24 has an annular surface that engages the proximal side of the base 16. Head 23 has a pair of holes 25 providing passages through the head to minimize blood pressure buildup across the valve during the implant procedure. An elongated flexible sheet member or band 26 is joined to the head 23 with connecting section 27. As shown in FIG. 5, connecting section 27 is integral with the head 23. The band 26 is a flexible plastic strap, as Teflon, made separately from the body 22. During the molding of the plastic body 22, connection section 27 is molded into the head. Band 26 has a longitudinal ribbon or tail 28 extended longitudinally from an enlarged cover section 29. Section 29 has an elongated elliptical shape and has a width to cover the ends of the arms 19 and 21 and the upper outer peripheral edge of disc 18, as shown in FIG. 8.

As shown in FIGS. 5 and 6, the head 23 has a groove or semi-circular recess 30 inwardly of and adjacent the connecting section 27. The groove has an arcuate configuration slightly larger than the curvature of the outer peripheral edge of the disc 18 and a slight inward incline. Groove 30 accommodates a peripheral portion of the disc, as shown in broken lines in FIG. 6, to hold the disc in an inclined open position when the valve is mounted on the collet 13. When the disc 18 is in the open position, it does not rest on the bottom of groove 30 so that the disc 18 does not hold the base 16 off the surface 24 of head 23. Located opposite groove 30 is an opening or passage 31. Passage 31 extends from surface 24 downwardly through the head 23. The upper portion of body 22 has a transverse passage 32. One end of passage 32 is aligned or in registration with the exit opening of passage 31. Body 22 has a longitudinal threaded passage 33 open to the transverse passage 32. As shown in FIGS. 1 and 9, a set screw 34 is threaded into the passage 33 and engages the ribbon 28.

The handle 14 has a threaded end 36 of a size to be threaded into the open end of passage 33, as shown in FIG. 1. The threaded end 36 is mounted on an elongated shaft or rod 37. The midsection of rod 37 has a pair of outwardly directed circular flanges 38 and 39. Interposed between the flanges 38 and 39 is a triangular shaped flexible sheet member 41. Member 41 is a flexible sheet of plastic, rubber or like material used as a suture holder during the implant procedure. Member 41 can have other shapes, as square, round and the like.

In use, as shown in FIGS. 8 and 9, the valve base 16 is positioned on the face 24. The disc 18 is in an open position with a portion of the disc located in the recess 30. The flexible sheet member 26 extends upwardly through the passage 17 and over the ends 42 of arms 19 and 21 and over the upper outer peripheral edge 43 of the disc 18. The enlarged cover section 29 of the flexible sheet member 26 has a width and length sufficient to cover the opposite sides of disc 18 as well as the outer ends 42 of the arms 19 and 21. The ribbon 28 extends downwardly through the large opening 17 and through the passage 31. The end of ribbon 28 extends transversely through transverse passage 32. The flexible sheet member 26 is pulled tight to firmly engage the sheet member with the arms 19 and 21 and disc 18. The set screw 34 is turned into transverse groove 33 to hold the ribbon in a taut condition. The extreme outer end of the ribbon 28 is cut at 44, as indicated by broken lines in FIG. 9. Each mitral valve is shipped in assembled relation with a disposable collet 13. The valve is encased in the collet 13 so that it can be implanted after sterilization.

There are a variety of successful methods of implanting heart valves. Any of the standard methods are applicable to implantation of pivoting disc valves. The following discussion is one technique that can be used to implant the pivoting disc heart valve.

After the body cavity is opened, the heart is electrically fibrillated and opened to expose the diseased heart tissue. The diseased heart tissue is excised, leaving a 2-3 mm remnant of the patient's own valve tissue. After the diseased valve tissue has been removed, the proper size prosthesis is selected by visual inspection aided by valve obturator sizers. The collet 13 on the selected valve is then turned into the handle end 36.

The valve placement is facilitated by initially placing four stay sutures equidistance about the annulus. A su-

ture is placed at each commissure and one at the mid-points therebetween. Mattress sutures are placed in the heart tissue through the suturing collar and up through the suture holder 41. The handle 14 is then used to slide the heart valve into place within the annulus in the heart. The sutures are then tied with the valve holder in place. The head 23 and the band 26 over the ends of the arms 19 and 21 and the disc 18 prevent the sutures from being snagged or looped over arms 19 and 21 or around the base 17. In addition, the band 26 functions as a shield preventing the forcing of an arm into the heart tissue, i.e., myocardium.

The holder 12 is removed from the valve by cutting the ribbon 28 at the location 46 shown in FIG. 9. The collet 13 can be longitudinally moved from the valve base. One section of the ribbon is retained on the collet by set screw 34. The other section of the band 26 attached to head 23 will move around the arms 19 and 21 and disc 18, thereby eliminating the possibility of any foreign object being lost in the heart chamber.

If there are any subannular abnormalities that appear to interfere with free disc movement, the valve base can be rotated relative to the suturing member to orient the disc away from calcifications. The orientation of the disc is done after all of the stitches have been tied. Preferably, the valve disc is oriented so that the downward moving portion of the disc is toward the septum. The atriotomy is then closed and the heart is allowed to restart by removing the fibrillatory electrodes and defibrillating as necessary.

Referring to FIG. 10, there is shown a modified collet 113 useable with the handle 14 of FIG. 1 to position a heart valve in the heart and hold the valve in position during surgery.

Referring to FIG. 16, valve 10 has an annular base 16 having a passage 17 permitting the flow of blood through the base. Operatively located within passage 17 is an occluder or disc 18. The disc 18 is operable to pivot between open and closed positions. As shown in FIG. 16, the disc 18 is in its open position with a small opening 17A on one side of the disc and a large opening 17B on the opposite side of the disc. A pair of side arms 19 and 21 project upwardly from base 16 in the direction of the opening pivot movement of the disc 18 and cooperate with separate portions of the outer peripheral edge of the disc 18 and pivot members to retain the disc in free floating pivotal relation with the base 16.

Returning to FIGS. 10 to 14, the collet 113 has a cylindrical body 122 of plastic material, as Teflon or Delrin. The upper end of body 122 has an enlarged circular head 123. The top of the head has a flat surface or face 124. Face 124 has a diameter equal to the outside diameter of the proximal side of the base 16, as shown in FIG. 16. Face 124 has an annular flat surface that engages the proximal side of the base 16.

An elongated flexible sheet member or band 126 is joined to the head 123 with connecting section 127. As shown in FIGS. 14 and 16, connection section 127 is secured to head 123. The band 126 is a flexible plastic strap, as Teflon, made separately from the body 122. During the molding of the plastic body 122, connecting section 127 is molded into the head. Section 127 has a portion 127A mounted on a metal member 125. Member 125 has a downwardly directed hub or post 125A extended through a hole in portion 127A. Metal member 125 is molded into head 123 to firmly secure the

band 126 to the body 122. Band 126 has a longitudinal ribbon or tail 128 extended longitudinally from an enlarged cover section 129. Section 129 has an elongated elliptical shape and has a width to cover the ends of the arms 19 and 21 and the upper outer peripheral edge of disc 18, as shown in FIG. 15.

As shown in FIGS. 14 and 16, the head 123 has a groove or semi-circular recess 130 in the side opposite the connecting section 127. Groove 130 extends generally parallel to the transverse extent of section 127 and has an arcuate configuration slightly larger than the curvature of the outer peripheral edge of the disc 18 and a slight inward incline. Groove 130 accommodates a peripheral portion of the disc 18, as shown in broken lines in FIG. 13, to hold the disc in an inclined open position when the valve is mounted on the collet 113. When the disc 18 is in the open position, it does not rest on the bottom of groove 130 so that the disc does not hold the base 16 off the surface 124 of head 123. Located adjacent the groove 130 is an opening or groove 131. Groove 131 has a side wall extended from surface 124 downwardly at a slight outward angle through head 123. The upper portion of body 122 has a transverse passage 132. One end of passage 132 is aligned or in registration with the groove 131. Body 122 has a longitudinal threaded passage 133 open to the transverse passage 132. As shown in FIG. 16, a set screw 134 is threaded into the passage 133 and engages ribbon 128. The handle 14 has a threaded end 36 of a size to be threaded into the open end of passage 133, as shown in FIG. 1.

In use, as shown in FIGS. 15 and 16, the valve base 16 is positioned on the face 124. The disc 18 is in an open position with a portion of the disc located in the recess 130. The flexible sheet member 126 extends upwardly through the large opening 17A of the passage 17 over the upper outer peripheral edge 43 of the disc 18 and over the ends 42 of the arms 19 and 21. The enlarged cover section 29 of the flexible sheet member 126 has a width and length sufficient to cover the opposite sides of the disc 18 as well as the outer ends 42 of the arms 19 and 21. The ribbon 128 extends downwardly through the small opening 17B of passage 17 and through groove 131. Groove 131 provides a passage through the head 123 to minimize blood pressure buildup across the valve during the implant procedure. The end of ribbon 128 extends transversely through transverse passage 132. The flexible sheet member 126 is pulled tight to firmly engage the sheet member with the arms 19 and 21 and the disc 18 and the side wall of groove 131. The set screw 134 is turned into transverse groove 133 to hold the ribbon in a taut condition. The extreme outer end 128A of the ribbon 128 is cut at 144, as indicated by broken lines in FIG. 16. Each mitral valve is shipped in assembled relation with a disposable collet 113. The valve is encased in the collet 113 so that it can be implanted after sterilization. The valve can be implanted in a heart with collet 113 by the procedure described with reference to the valve shown in FIG. 1. The head 123 and the band 126 over the ends of the arms 19 and 21 and the disc 18 prevent the sutures placed in the sewing ring from being snagged or looped over arms 19 and 21 or around the base 17. In addition, the band 126 functions as a shield preventing the forcing of an arm into the heart tissue.

The collet 113 is removed from the valve by cutting the ribbon 128 at the location 146 shown in FIG. 16.

The collet 113 can be longitudinally moved from the valve base. One section of the ribbon 128 is retained in the collet 113 by set screw 134. The other section of the band 126 attached to head 123 will move through the small opening 17A, around arms 19 and 21 and discs 18 and through the large opening 17B, thereby eliminating the possibility of any foreign object being lost in the heart chamber.

While there have been shown and described preferred embodiments of the valve holding collets, it is understood that modifications, changes in size and material can be made by those skilled in the art without departing from the spirit of the invention.

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

1. A collet for holding a heart valve having a base, a passage through the base, a disc positionable in the passage for movement to open and closed positions, and arm means secured to the base cooperating with the disc to retain the disc in assembled relation with the base comprising: a body having a head, said head having a portion engageable with one side of the base, a groove for accommodating a portion of the disc to hold the disc in the open position, an elongated means having a first portion secured to said head, means located in said head to secure the first portion to said head, said elongated means extended through the passage and positionable over the arm means and disc, and means to secure a second portion of the elongated means to the body to hold the elongated means in position over the arm means and disc.

2. The collet of claim 1 wherein: the head has an outwardly directed annular section at one end of the body, said section having an annular portion engageable with one side of the base when the valve is mounted on the collet, said groove being located in one side of the portion of the head and said first portion attached to and extended from the side opposite said one side.

3. The collet of claim 1 wherein: the head has an opening for accommodating a first portion of the elongated means, said opening in the head being located adjacent said groove, said body having a passage aligned with the opening in the head for receiving a second portion of the elongated means, said means to secure the elongated means in the body extended into the passage in the body and engageable with the second portion of the elongated means to hold the elongated means in position over the arm means and the disc.

4. The collet of claim 1 wherein: the elongated means is an elongated flexible sheet member having an enlarged section positionable over the arm means and disc and a ribbon section, said means securing the sheet member to the body comprising means engageable with the ribbon section.

5. The collet of claim 1 wherein: the means located in the head is a member embedded in said head and the elongated means is a sheet member having a portion cooperating with said member to secure the sheet member to the head.

6. The collet of claim 1 wherein: the body, the head and elongated means are made of plastic material and the means located in the head is a metal member.

7. A collet for holding a heart valve having a base, a passage through the base, valving means movable for movement to open and closed positions, and means secured to the base cooperating with the valving means

to retain the valving means in assembled relation with the base comprising: a body having a portion engageable with one side of the base, said portion having a means for accommodating a portion of the valving means to hold the valving means in the open position, an elongated means having a first portion secured to said body and extended adjacent the portion of the body engageable with one side of the base, means located in said body to secure said first portion to said body, said elongated means extended through the passage in the base and adapted to cooperate with the heart valve to hold the base on the body, said elongated means having an end section, and means engageable with the end section to secure the end section to the body.

8. The collet of claim 7 wherein: the body has a head with an outwardly directed annular section, said section having an annular portion engageable with one side of the base of the valve when the valve is mounted on the collet, said means for accommodating a portion of the valving means comprising a groove located in one side of the portion of the head and said elongated means attached to and extended from the side opposite said one side of the head.

9. The collet of claim 8 wherein: said head has an opening for accommodating a first portion of the elongated means, said opening in the head being located adjacent the means for accommodating a portion of the valving means, said body having a passage aligned with the opening in the head for receiving a second portion of the elongated means, said means to secure the elongated means to the body extended into the passage in the body and engageable with the second portion of the elongated means to hold the elongated means in a fixed position.

10. The collet of claim 7 wherein: the means for accommodating a portion of the valving means includes a groove in the body for receiving said portion of the valving means.

11. The collet of claim 7 wherein: the elongated flexible means is an elongated flexible sheet member having an enlarged section, said end section being an elongated ribbon section attached to the enlarged section.

12. The collet of claim 7 wherein: said body is a cylindrical member having a longitudinal threaded passage open to a transverse passage, said transverse passage adapted to receive a portion of said end section of the elongated means, said means engageable with the end section being located in the longitudinal passage.

13. A collet comprising a body having a head, said head having an annular portion and a face, a first groove through said head open to said face, a second groove in said head open to said face adjacent to said first groove, elongated means secured to the head, said elongated means having an end section extended through said first groove, and means engageable with the end section extended through said first groove to secure the end section to the body.

14. The collet of claim 13 wherein: said body is an elongated cylindrical member having means to attach the body to an elongated handle.

15. The collet of claim 14 wherein: the head has an outwardly directed annular section at one end of the body.

16. The collet of claim 13 wherein: said body has a passage aligned with the first groove in the head for receiving the end section of the elongated means, said means engageable with the end section extended into the passage and engageable with the end section.

17. The collet of claim 16 wherein: said body is a cylindrical member having a longitudinal passage open to said passage in the body, said means engageable with the end section being located in the longitudinal passage.

18. The collet of claim 13 wherein: the elongated means is an elongated flexible sheet member having an enlarged section, said end section being an elongated ribbon section attached to the enlarged section.

19. The collet of claim 13 wherein: a member is embedded in said body, the elongated means is a flexible sheet member having a portion cooperating with said member to secure the sheet member to the body.

20. The collet of claim 19 wherein: the body, head and flexible means are made of plastic material, and said member is metal.

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