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(54) **VALVE SIZER AND METHOD OF USE**

division of application No. 08/646,850, filed on May 8, 1996, now Pat. No. 5,885,228.

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(57) **ABSTRACT**

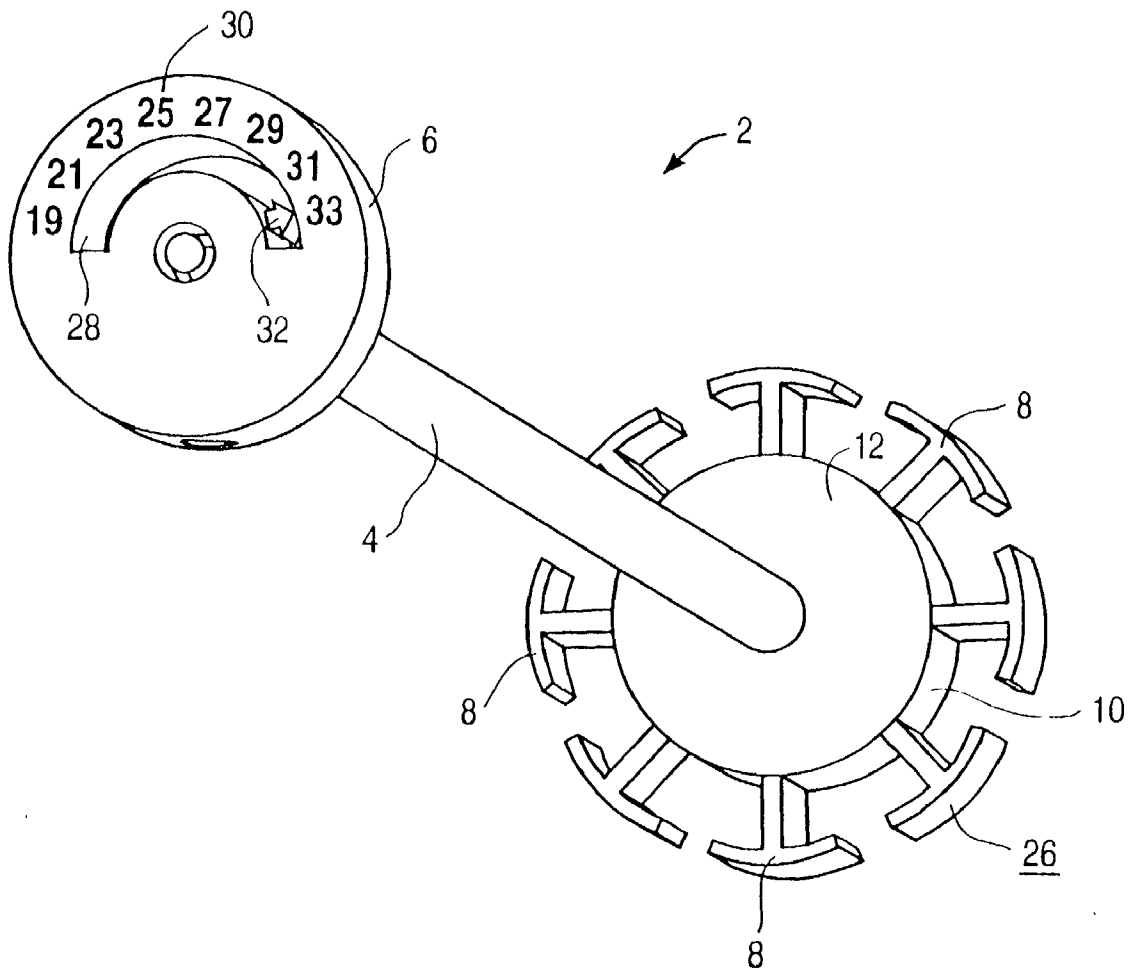
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Related U.S. Application Data

(60) Continuation of application No. 09/514,453, filed on Feb. 25, 2000, now Pat. No. 6,322,526, which is a

A valve sizer having a movable element mounted to the distal end of a shaft. A valve sizing portion includes the movable element so that the valve sizing portion may be adjusted to correspond to a number of different available replacement valve sizes. An indicator mounted to the proximal end of the shaft indicates the valve size corresponding to the outer dimension of the valve sizing portion.



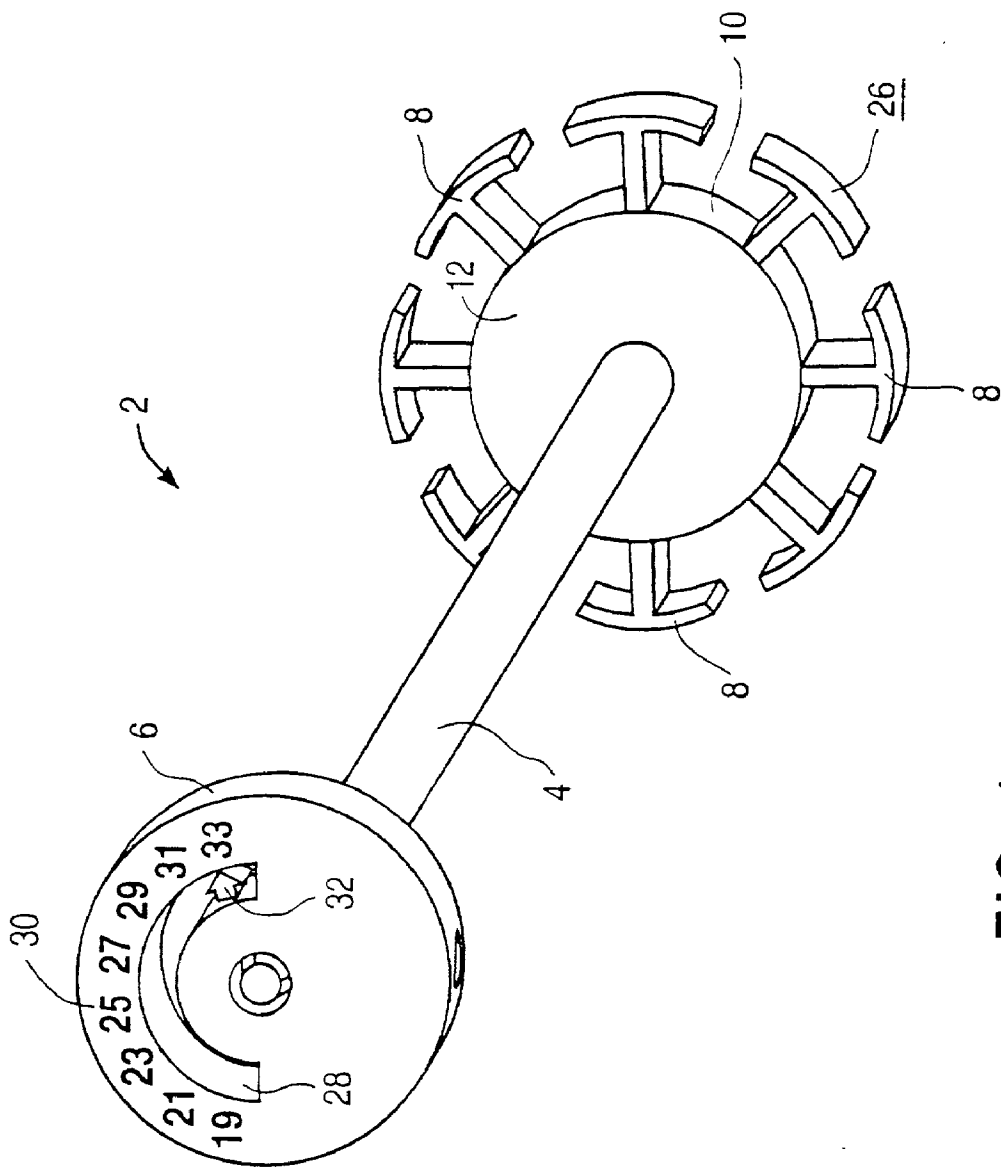


FIG. 1

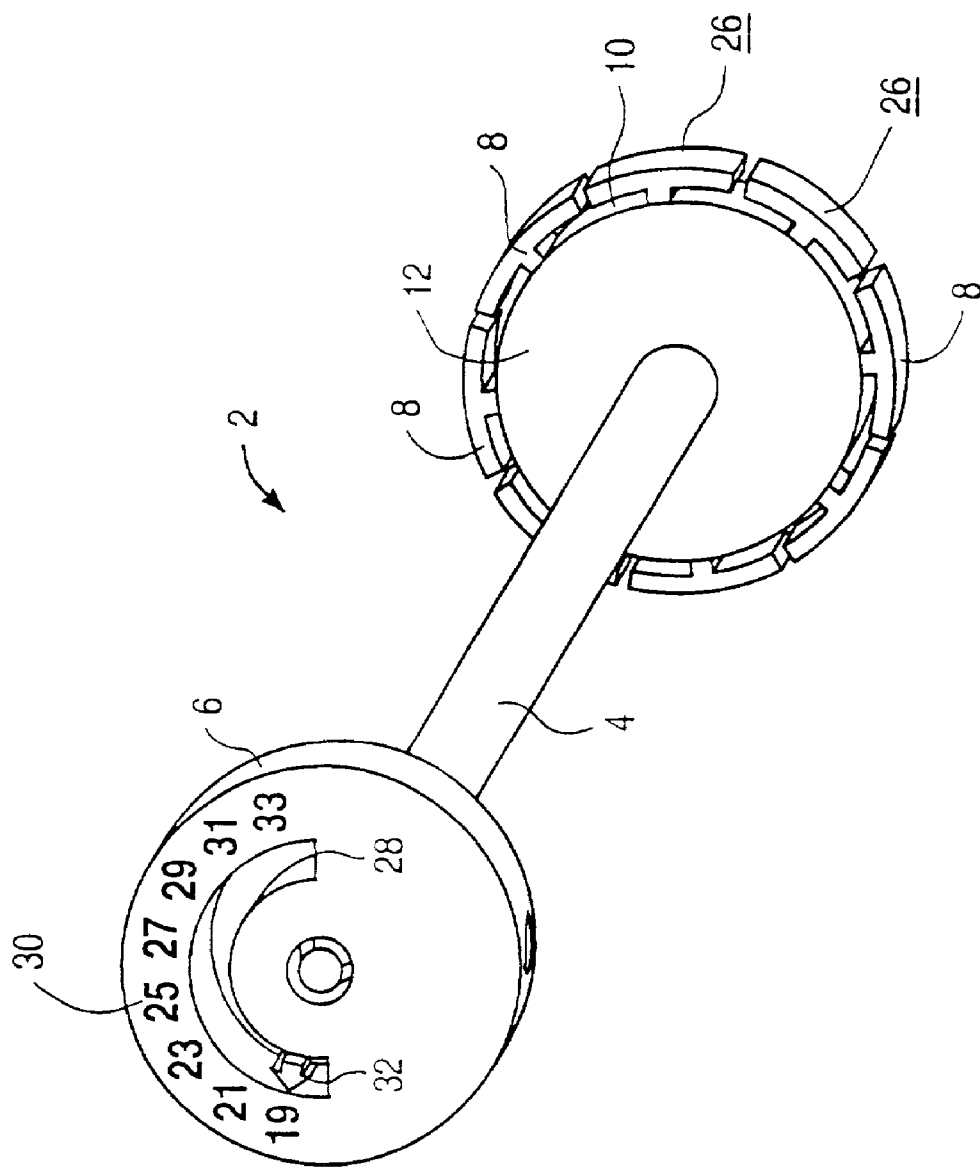


FIG. 2

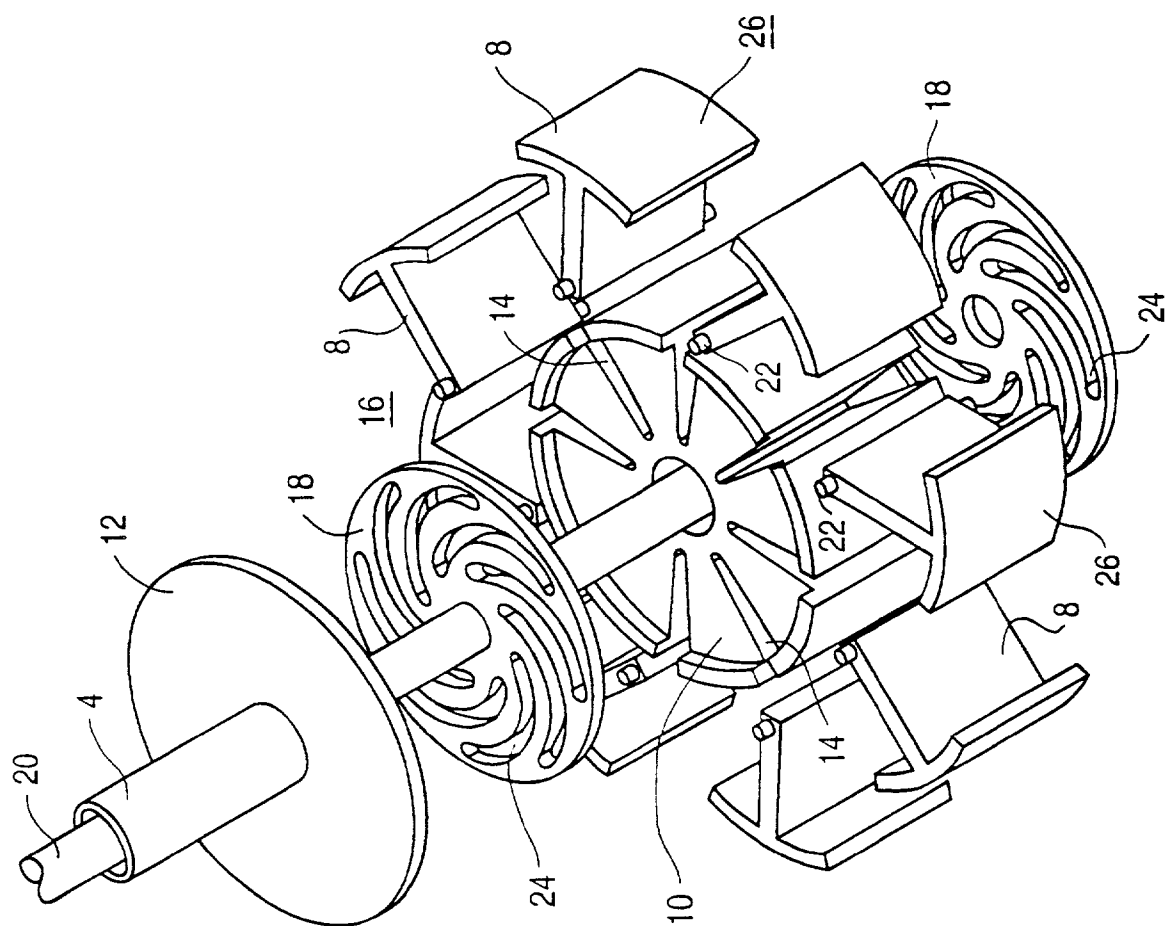


FIG. 3

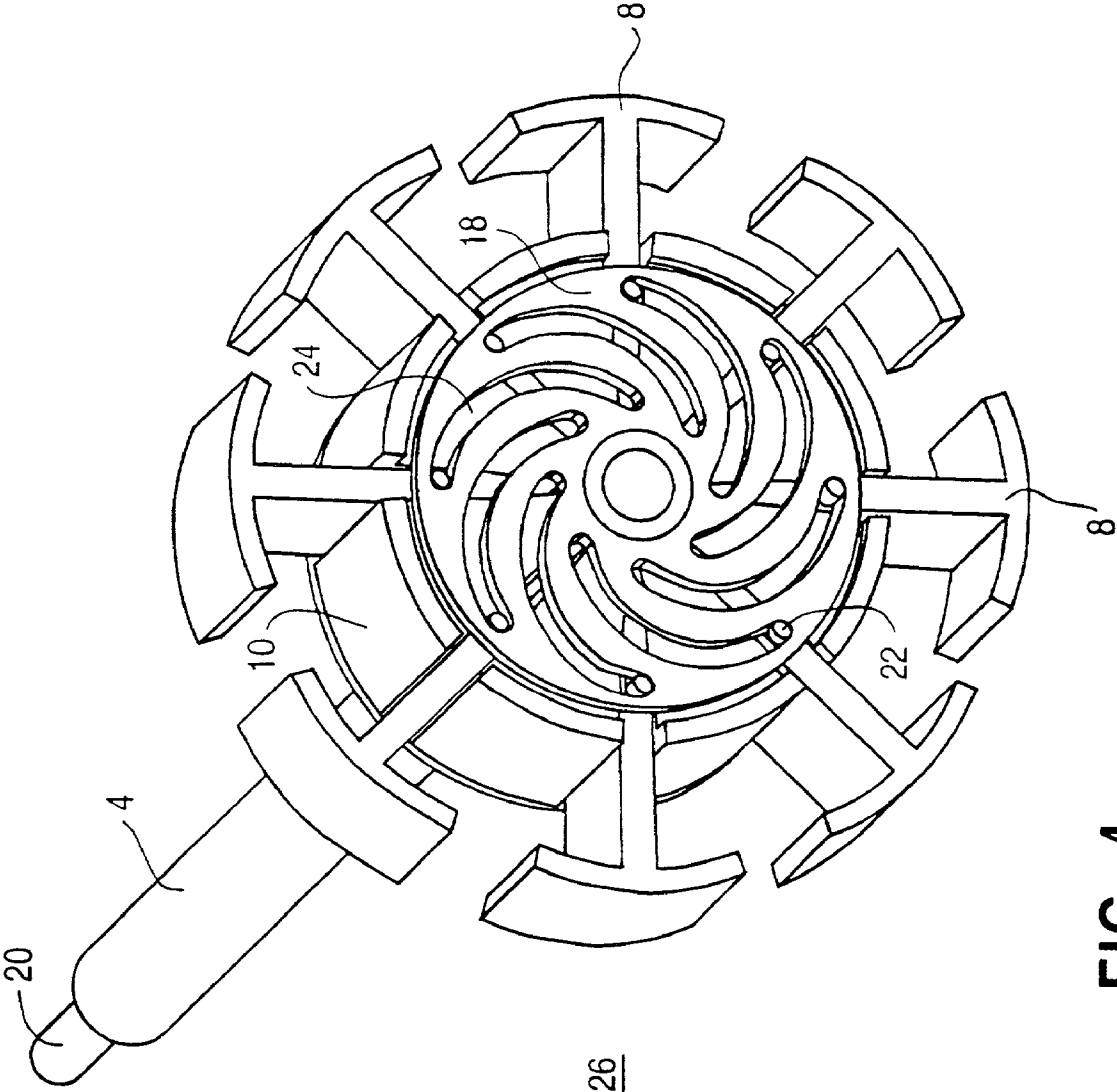


FIG. 4

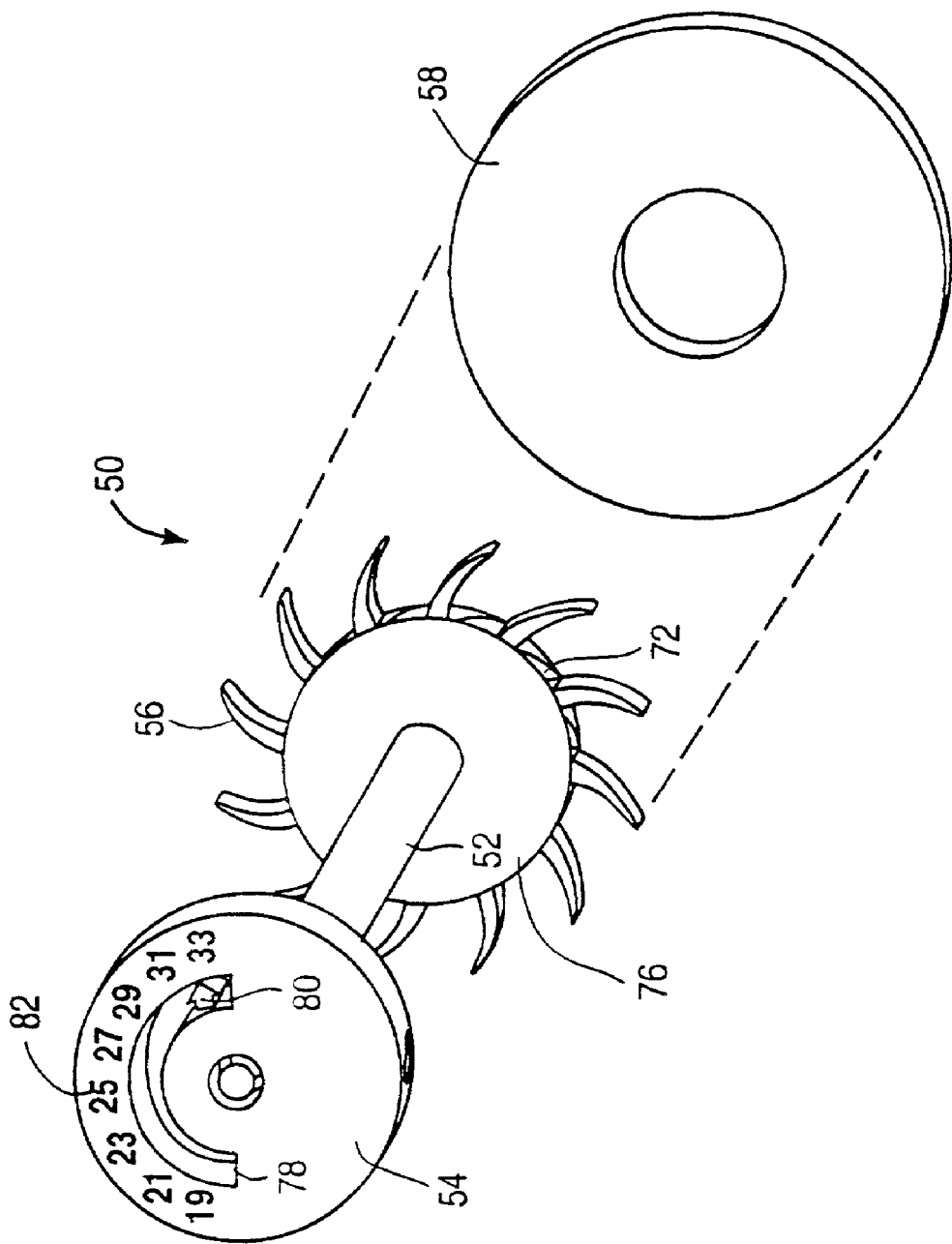


FIG. 5

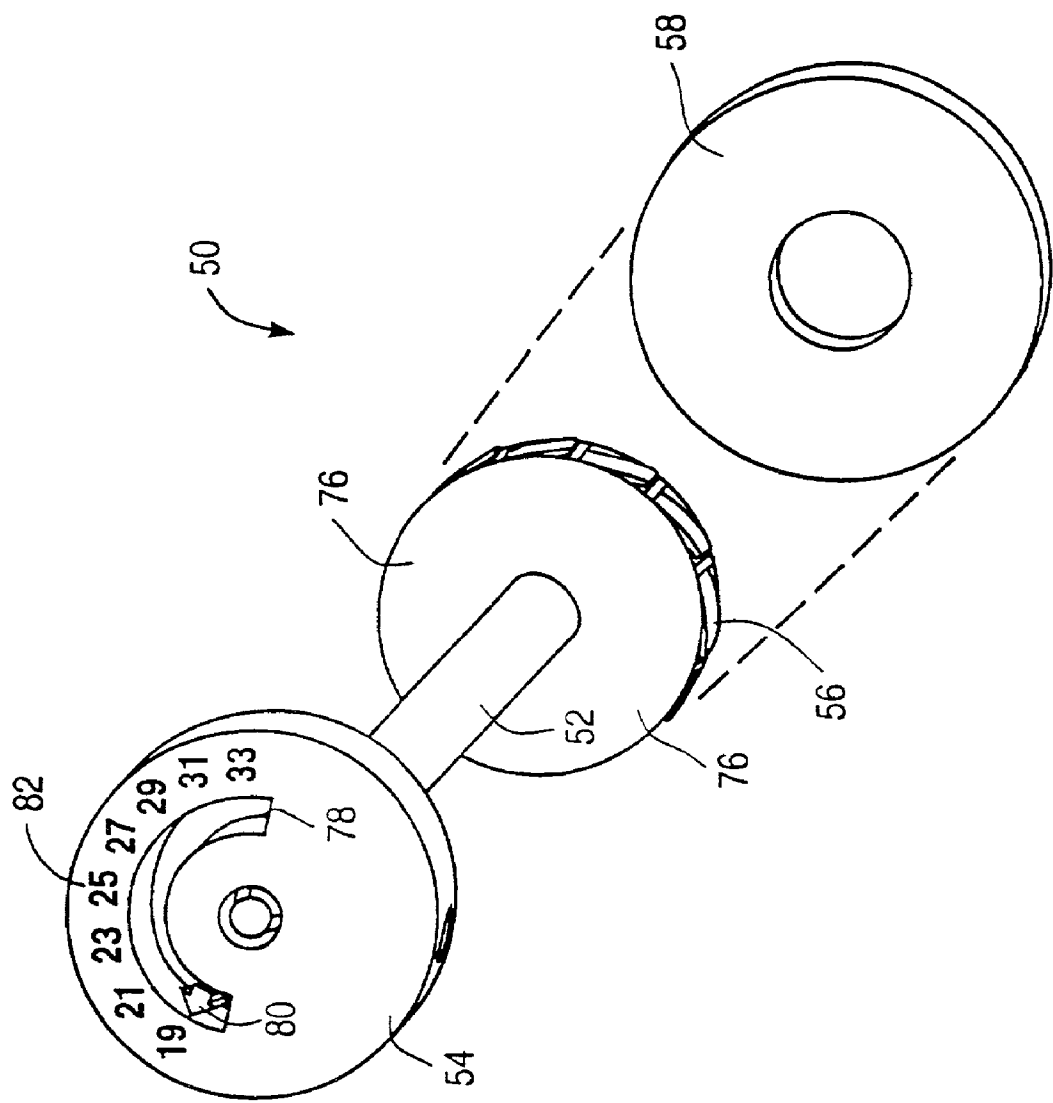


FIG. 6

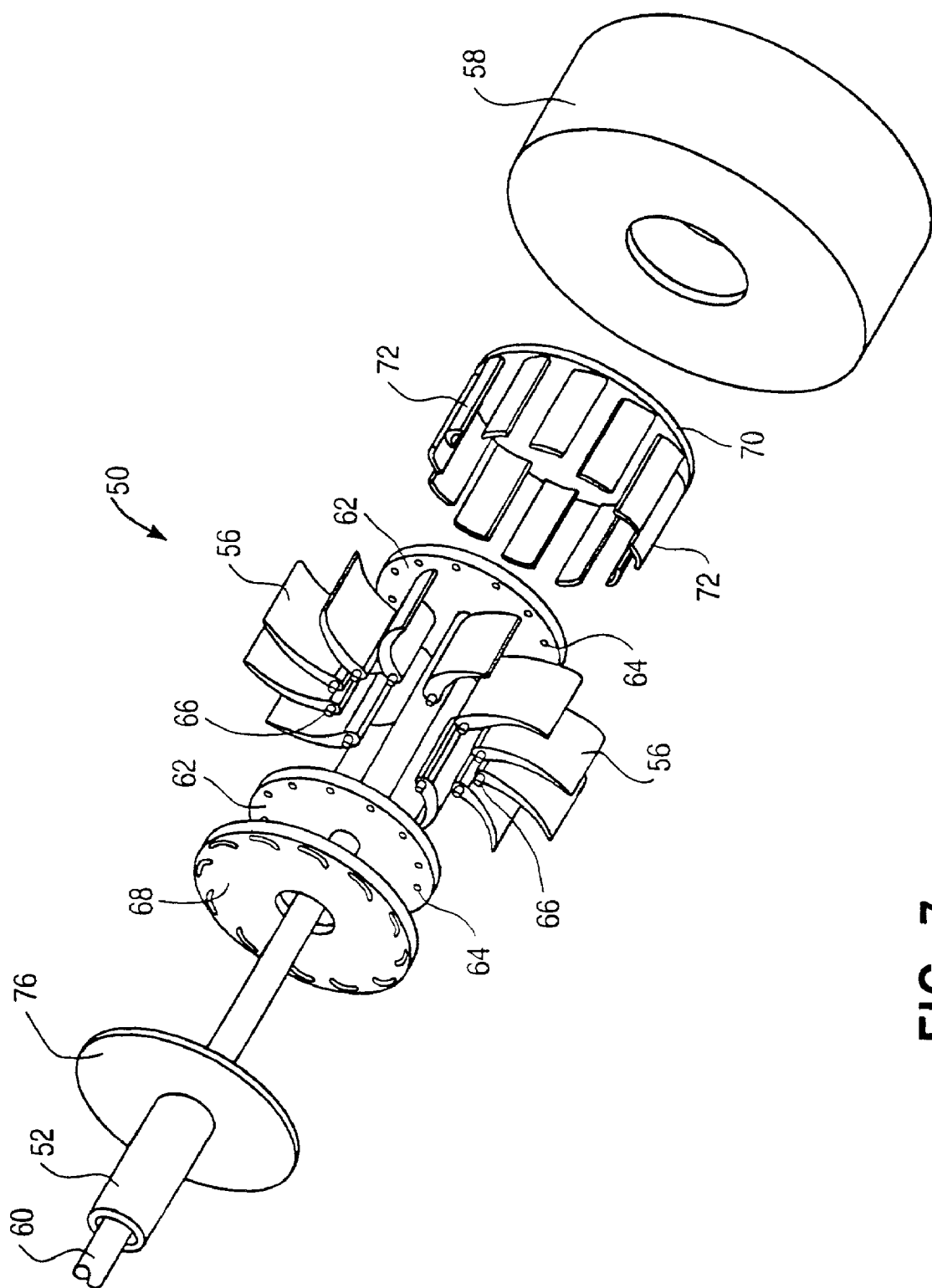


FIG. 7

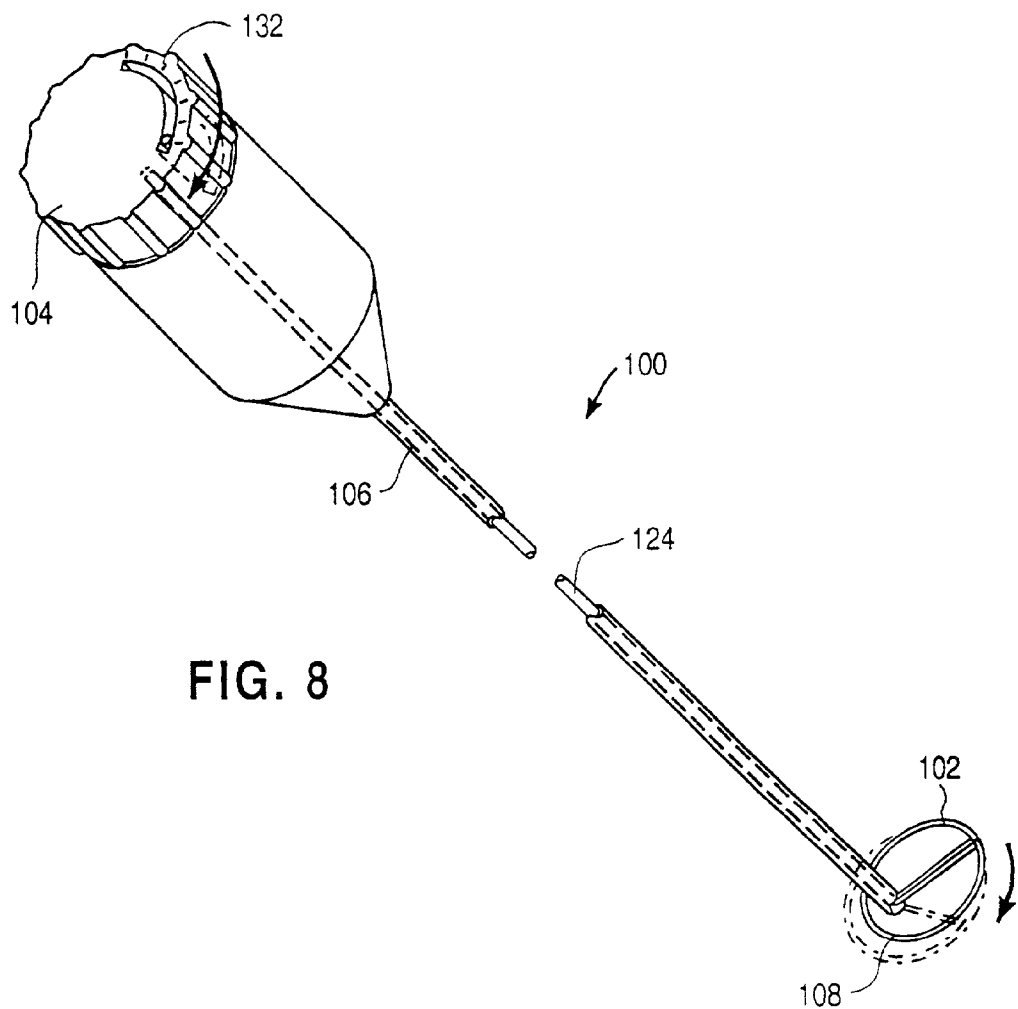


FIG. 8

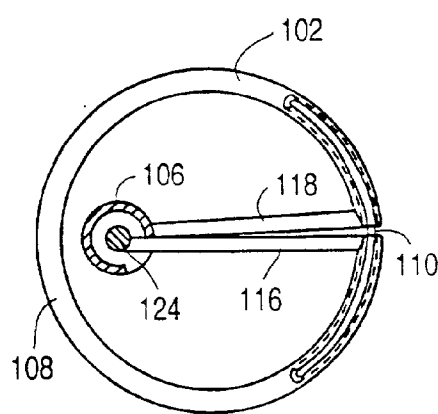


FIG. 9

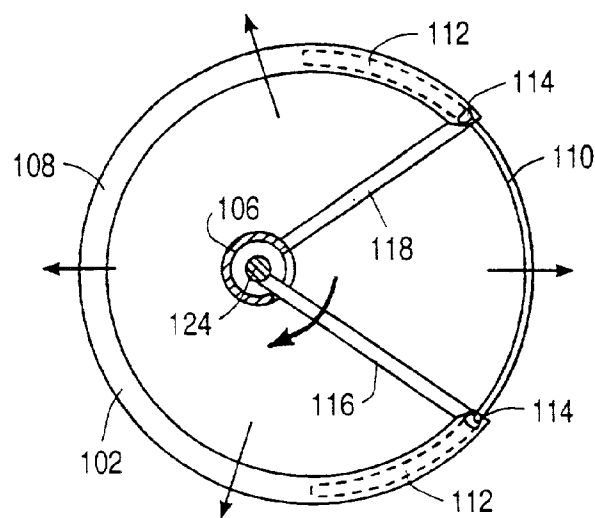


FIG. 10

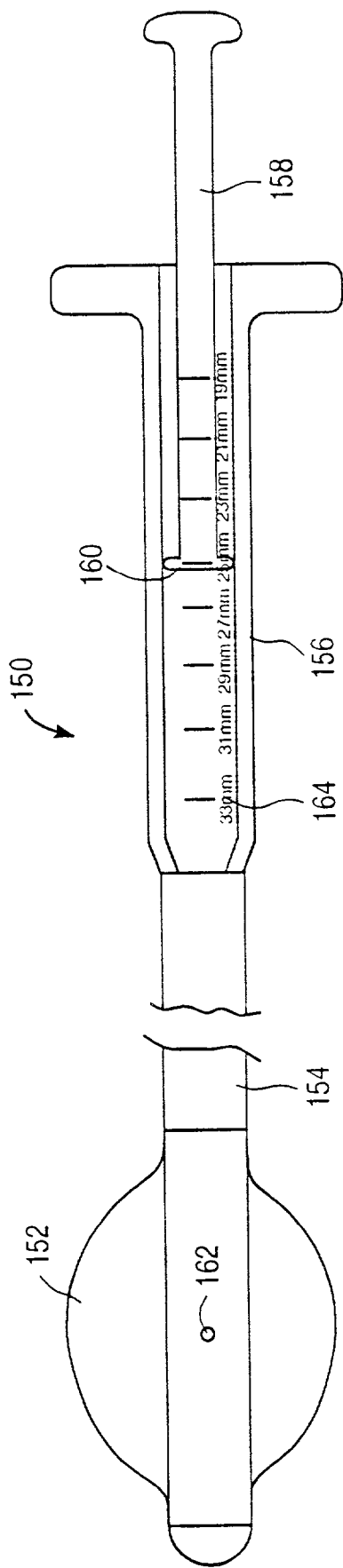
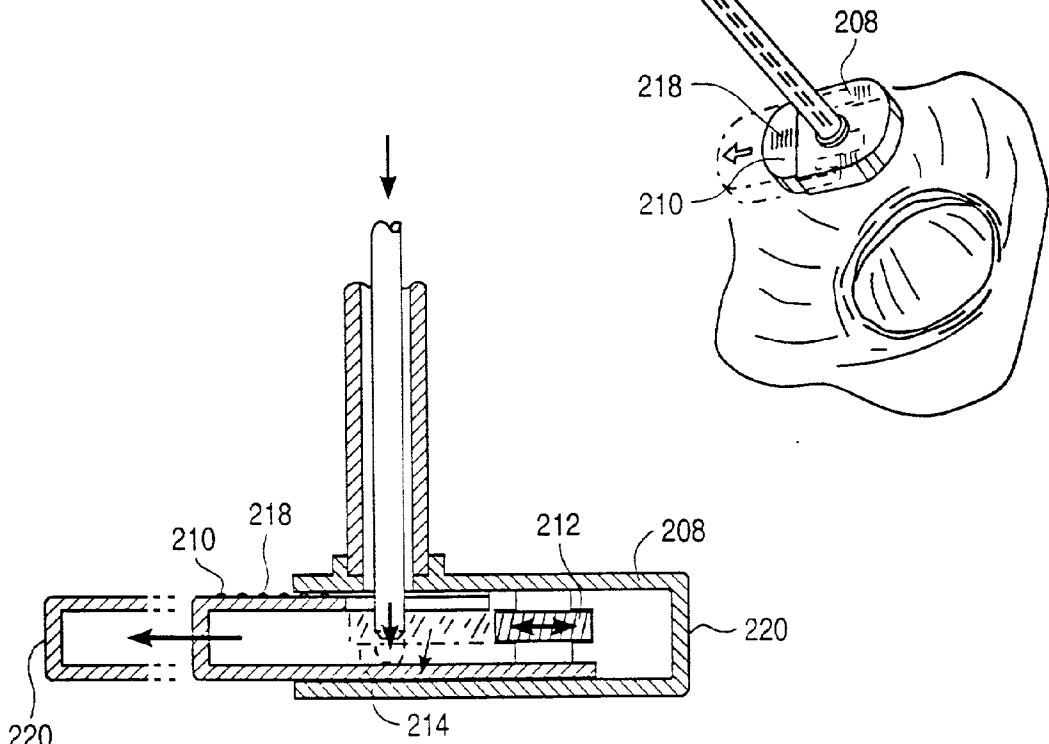
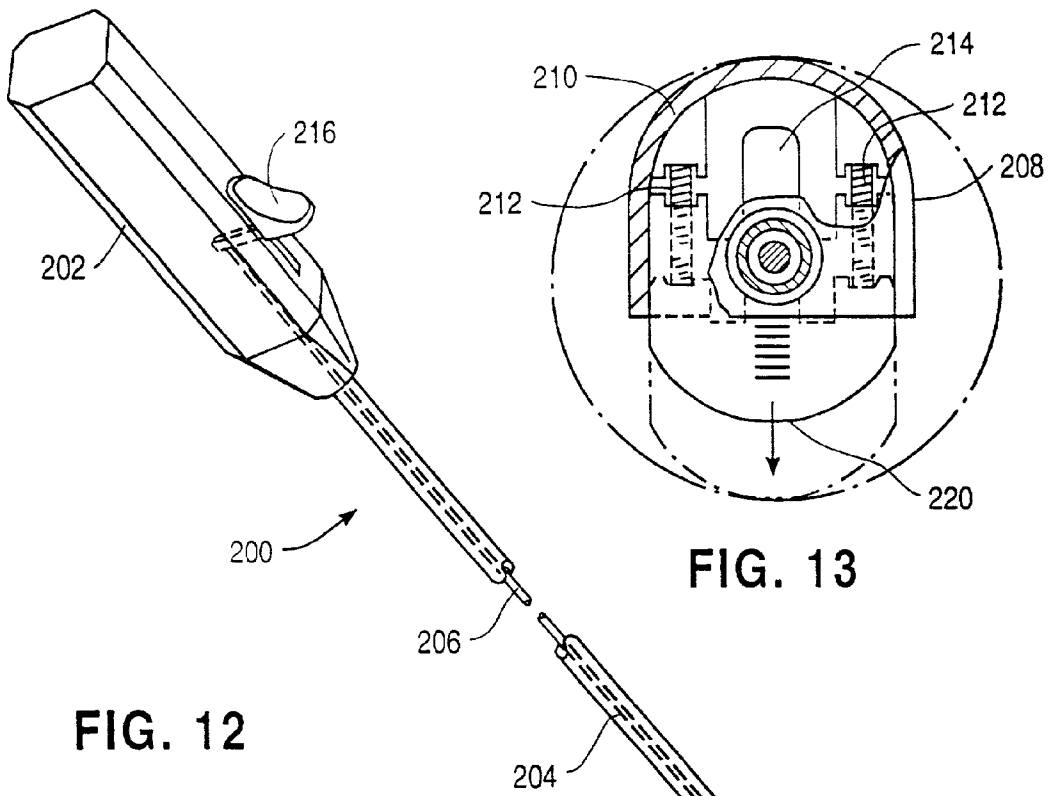


FIG. 11



VALVE SIZER AND METHOD OF USE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a divisional of copending U.S. patent application Ser. No 08/646,850, filed May 8, 1996.

FIELD OF THE INVENTION

[0002] The present invention is directed to methods and apparatus for determining the appropriate replacement valve size when replacing a patient's cardiac valve.

BACKGROUND OF THE INVENTION

[0003] Replacement of a diseased or malfunctioning cardiac valve requires accurate sizing of the valve annulus. After the diseased or malfunctioning cardiac valve has been removed, the surgeon measures the patient's valve annulus to determine the appropriate replacement valve size.

[0004] A conventional system for measuring a patient's valve annulus includes a number of varying size discs which can be attached to a rod. Each of the discs has a size which corresponds to an available valve size. The surgeon attaches one of the discs to the rod, inserts the disc into the patient's valve annulus and checks the fit of the disc within the valve annulus. If the surgeon is not satisfied with the fit, the surgeon removes the disc from the rod, attaches another disc to the rod and inserts the new disc into the valve annulus. This procedure is repeated until the surgeon is satisfied that the appropriate valve size has been identified.

[0005] A problem with the known method and apparatus for sizing a patient's valve annulus is the time required to try a number of discs. For each valve size the surgeon tries, the surgeon must remove one of the discs and attach another one. This procedure increases the overall surgery time which increases the risk to the patient and also increases the cost of the procedure.

[0006] Thus, it is a specific object of the present invention to reduce the amount of time required to size a patient's valve annulus by providing a device which can identify a number of different appropriate valve sizes without requiring withdrawal of the device from the patient.

SUMMARY OF THE INVENTION

[0007] The present invention solves the problems with the prior art by providing a valve sizer which is only introduced into the patient once and can identify a number of appropriate replacement valve sizes. The valve sizer includes an elongate shaft having a proximal end and a distal end with a movable element coupled to the distal end of the shaft. A valve sizing portion has an outer dimension which is at least partially defined by the movable element. A valve size indicator is provided at the proximal end of the shaft. An actuator is also provided at the proximal end for moving the movable element so that the valve sizing portion corresponds to the various valve sizes.

[0008] In a preferred embodiment, the movable element includes a plurality of arms having outer surfaces generally forming a circular shape. A rod extends through the shaft and is operatively coupled to the actuator. The rod is rotatable relative to the shaft so that rotation of the rod moves the movable element. A disc is attached to the rod. The disc has

a plurality of slots which receive pins attached to the plurality of arms. Camming surfaces are coupled to the shaft and configured to engage and cam the plurality of arms when the actuator is actuated to move the movable element.

[0009] In another preferred embodiment, the valve sizer includes a ring mounted to and elongate shaft. An actuator is mounted to the proximal end of the shaft and is operatively coupled to the ring for expanding and retracting the ring. The ring preferably includes a first part and a second part slidably coupled to the first part. The second part is slidably received in a recess in the first part. Two levers are connected to the ends of the first part. One of the levers is attached to the shaft and another lever is attached to a rod extending through the shaft so that rotation of the rod relative to the shaft expands and retracts the ring.

[0010] In yet another preferred embodiment, the valve sizer has a balloon mounted to **[text missing or illegible when filed]** balloon may be inflated with a fluid passing through the lumen. The tube preferably includes a valve size indicator which indicates an outer dimension of the balloon when the balloon is inflated.

[0011] These and other features will become apparent with the following description of the preferred embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIG. 1 is a perspective view of a first valve sizer having arms in an expanded position.

[0013] FIG. 2 shows the first valve sizer of FIG. 1 with the arms in a retracted position.

[0014] FIG. 3 is an exploded perspective view of the distal end of the first valve sizer.

[0015] FIG. 4 is a bottom perspective view of the first valve sizer with the arms in the expanded position.

[0016] FIG. 5 is a perspective view of a second valve sizer having arms in an expanded position with a sheath exploded from the assembly for clarity.

[0017] FIG. 6 shows the second valve sizer of FIG. 5 with the arms in a retracted position and the sheath exploded from the assembly for clarity.

[0018] FIG. 7 is an exploded perspective view of the distal end of the second valve sizer.

[0019] FIG. 8 is a perspective view of a third valve sizer having an expandable ring.

[0020] FIG. 9 shows the ring of the third valve sizer in a retracted position.

[0021] FIG. 10 shows the ring of the third valve sizer in an expanded position.

[0022] FIG. 11 shows a fourth valve sizer having an inflatable balloon.

[0023] FIG. 12 is a perspective view of a fifth valve sizer.

[0024] FIG. 13 is a partial cut-away of the distal end of the fifth valve sizer.

[0025] FIG. 14 is a cross-sectional view of the distal end of the fifth valve sizer.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0026] Referring to FIGS. 1 and 2, a first valve sizer 2 is shown. The valve sizer 2 has a tube 4 and an actuator 6 at the proximal end of the tube 4. A number of arms 8 [text missing or illegible when filed] below. FIG. 1 illustrates the arms 8 in an extended position and FIG. 2 illustrates the arms 8 in a retracted position. Rotation of the actuator 6 moves the arms 8 from the retracted position to the expanded position as will be described below.

[0027] Referring to FIG. 3, the distal end of the valve sizer 2 is shown. The spacer 10 is attached to the bottom of a disc 12 which is attached to the tube 4. The spacer 10 includes slots 14 which guide movement of the arms 8 between the retracted and extended positions. The spacer 10 includes two recesses 16, only one of which is shown, which receive slotted discs 18. The slotted discs 18 are mounted to a rod 20 which extends through the tube 4. As will be discussed below, the rod 20 and tube 4 are coupled to the actuator 6 so that rotation of the actuator 6 rotates the rod 20 and slotted discs 18 with respect to the tube 4. Thus, the rod 20 and slotted discs 18 form a unitary structure while the tube 4, disc 12 and spacer 10 form another unitary structure.

[0028] The arms 8 include pins 22 which are positioned in slots 24 of the slotted discs 18. Rotation of the rod 20 causes the pins 22 to slide in the slots 24 of the slotted discs 18 thereby moving the arms 8 in the slots 14 of the spacer 10 between the expanded and retracted positions. Referring to FIG. 4, a bottom view is shown with the arms 8 in the expanded position.

[0029] The arms 8 are preferably T-shaped with a curved outer surface 26 but may take any other shape. The outer surfaces 26 of the arms 8 generally form a circular peripheral shape when in the retracted and expanded positions. The outer surfaces 26 of the arms 8 define a valve sizing portion which engages the patient's valve annulus when sizing the replacement valve. The maximum outer dimension of the valve sizer 2 is preferably no more than 17 mm, more preferably no more than 18 mm, and most preferably no more than 19 mm, when in the retracted position. The outer surfaces 26 of opposing arms 8 preferably have a maximum outer dimension of at least 30 mm and more preferably at least 33 mm when in the expanded position. The preferred dimensions of the valve sizer 2 in the retracted position permits insertion of the valve sizer 2 between adjacent ribs in a patient when performing a minimally invasive valve procedure such as described in U.S. patent application Ser. No. 08/163,241 to Sterman et al., filed Dec. 6, 1993, which is incorporated herein by reference. Alternatively, the valve sizer 2 may be provided in two size ranges, preferably 17-27 mm and 23-33 mm.

[0030] Referring again to FIGS. 1 and 2, the actuator 6 includes a slot 28 with markings 30 indicating various valve sizes. A pointer 32 is coupled to the tube 4 and points to the marking 30 indicating the valve size corresponding to the outer dimension of the arms 8. The actuator 6 is coupled to the rod 20 so that rotation of the actuator 6 causes the pointer 32 to move along the slot 28. The markings 30 preferably indicate an outer diameter of 19 to 33 mm. Although it is preferred to use the rotating actuator 6 to move the arms 8, any other actuation mechanism may be used including a trigger, sliding lever, or scissors-type actuator 6.

[0031] A method of selecting an appropriate valve size is now described with reference to FIGS. 1-3. A method of replacing a patient's cardiac valve is described in U.S. patent application Ser. No. 08/163,241. The valve sizer 2 is preferably introduced into the patient between adjacent ribs in the patient without cutting or significantly deflecting the ribs. The valve sizer 2 is sized and configured so that it has a profile of no more than 20 mm, and more preferably no more than 19 mm, so that the valve sizer 2 may be introduced between adjacent ribs in the patient. The surgeon then positions the arms 8 in the valve annulus and rotates the actuator 6 until the arms 8 contact the valve annulus. The surgeon then reads the appropriate valve size with the pointer 32 and markings 30. The actuator 6 is then rotated again so that the arms 8 and in the retracted position of FIG. 2 for removing the valve sizer 2 from the patient.

[0032] Referring to FIGS. 5 and 6, a second preferred valve sizer 50 is shown. The valve sizer 50 includes a tube 52 having an actuator 54 at the proximal end. A number of arms 56 are movable from the retracted position shown of FIG. 1 to the expanded position shown in FIG. 2. A flexible sheath 58 is positioned around the arms 56 but is shown separated from the device for clarity. The sheath 58 is preferably made of silicone, however, any other suitable material may be used.

[0033] An exploded view of the distal end of the second preferred valve sizer 50 is shown in FIG. 7. A shaft 60 extends through the tube 52 and is connected to the actuator 54 as will be described below. Two discs 62 having holes 64 therein are mounted to the shaft 60. The arms 56 have pins 66 which engage the holes 64 in the discs 62 so that the arms 56 are free to rotate relative to the discs 62. The arms 56 are preferably curved but may take any other shape. The outer dimensions of the valve sizer 50 in the expanded and retracted positions are preferably the same as the first the patient's valve annulus when the actuator 54 is positioned outside the patient's chest.

[0034] Top and bottom plates 68, 70 are attached a sealing plate 76 which is attached to the tube 52. The bottom plate 70 has a number of camming elements 72 which engage the arms 56 for moving the arms 56 from the retracted to expanded position as described below. The top plate 68 has openings 74 which receive the camming elements 72. Thus, the top and bottom plates 68, 70, sealing plate 76 and tube 52 form a unitary structure. Although it is preferred to provide the top plate 68, the top plate 68 may be omitted and the camming elements 72 may be attached directly to the sealing plate 76.

[0035] The camming elements 72 are positioned and configured to engage and deflect the arms 56 outward when the shaft 60 is rotated. The camming elements 72 are curved members but may take any other shape which cooperates with the arms 56 to cam the arms 56 outward when the shaft 60 is rotated with respect to the tube 52. The valve sizer 50 may include a locking mechanism (not shown), such as a ratchet and pawl, for locking the valve sizer 50. Alternatively, the actuator 54 may be designed with frictional resistance to turning which effectively locks the arms 56.

[0036] Referring again to FIGS. 5 and 6, the actuator 54 has a slot 78 which receives a pointer 80. The pointer 80 is coupled to the tube 52 so that the pointer 80 moves along the slot 78 when the actuator 54 is rotated. The actuator 54

includes markings **82** which indicate the valve size corresponding to the size defined by the outer dimension of the arms **56** and sheath **58**. The markings **82** preferably indicate an outer diameter of between 19 and 33 mm. Although it is preferred to use the rotating actuator **54**, any other actuation mechanism may be used. The method of using the second valve sizer **50** is the same as the first valve sizer **2** and a description of the method of use is omitted here.

[0037] Referring to FIGS. 8-10, a third valve sizer **100** is shown. The third valve sizer **100** has a ring **102** which is movable between the retracted position of FIG. 9 to the expanded position of FIG. 10. An actuator **104** is mounted to the proximal end of a tube **106** and is used to move the ring **102** between the retracted and expanded positions as will be described in greater detail below.

[0038] The ring **102** includes a first part **108** and a second part **110** slidably coupled [text missing or illegible when filed] can assume the expanded and retracted positions of FIGS. 9 and 10. The first part **108** has recesses **112** which are sized to slidably receive the second part **110**. The second part **110** includes stops **114** which prevent the first and second parts **108**, **110** from becoming detached. First and second levers **116**, **118** are attached to first and second ends **120**, **122** of the first part **108**, respectively. The first lever **116** is attached to a shaft **124** and the second lever **118** is attached to the tube **106** so that rotation of the shaft **124** relative to the tube **106** moves the first and second levers **116**, **118** with respect to one another.

[0039] The actuator **104** has an arcuate slot **128** therein which receives a pin **130** attached to the tube **106**. The actuator **104** is attached to the shaft **124** so that rotation of the actuator **104** moves the first lever **116** with respect to the second lever **118**. The actuator **104** also preferably includes size indicators **132** which indicate the valve size corresponding to the size of the ring **102**. The ring **102** preferably has the same dimensions as the arms **56** of the first valve sizer when in the expanded and retracted positions.

[0040] Use of the third valve sizer **100** is now described. The valve sizer **100** is introduced into the patient with the ring **102** in the retracted position of FIG. 9. The surgeon positions the ring **102** within the valve annulus and rotates the actuator **104** until the ring **102** engages the valve annulus. The surgeon then reads the indicators **132** to determine the appropriate valve size. The actuator **104** is rotated so that the ring **102** assumes the retracted position and the valve sizer **100** is removed from the patient. Although it is preferred to provide the first and second levers **116**, **118** for the expandable ring **102**, any other mechanism may be used including a ring **102** having teeth which engage a rotatable gear. Alternatively, the ring **102** may be a flexible ring which simply extends from the distal end of the shaft with the ring being expanded and retracted by simply lengthening or shortening the flexible ring. Furthermore, although the ring **102** is preferably relatively flat, the ring **102** may be somewhat thick to form a cylinder without departing from the scope of the invention.

[0041] Referring to FIG. 11, a fourth preferred valve sizer **150** is shown. The valve sizer **150** includes a balloon **152** mounted to the distal end of a rigid tube **154**. A cylinder **156** is attached to the proximal end of the tube **154** and a plunger **158** having a piston **160** is slidable within the cylinder **156**. The tube **154** has a hole **162** through [text missing or illegible when filed] made of any conventional elastomeric material and is preferably made of polyurethane or a thermoplastic elastomer.

[0042] The cylinder **156** is calibrated so that a given volume of fluid or gas injected into the balloon **152** expands the balloon **152** to a known size. The cylinder **156** preferably includes indicators **164** which indicate the valve size corresponding to the diameter of the balloon **152**. The balloon **152** is inflated and deflated by manipulating the plunger **158**. The balloon **152** preferably has a maximum outer dimension of no more than 17 mm, and more preferably no more than 19 mm, and expands to a maximum outer dimension of at least 30 mm and more preferably at least 33 mm. Although the balloon **152** is shown as being somewhat elongate the balloon **152** may also take any other shape such as a torus, sphere or any other suitable shape. Furthermore, although it is preferred that the balloon **152** expand around the entire periphery of the tube the balloon **152** may be configured to expand from a side of the tube **154** rather than all around the tube **154**. Although tube **154** is preferably rigid, the tube **154** may be malleable to allow the tube **154** to conform to a desired shape.

[0043] A method of using the fourth valve sizer **150** is now described. The balloon **152** is inserted into the patient's valve annulus in the deflated condition and the surgeon depresses the plunger **158** until the balloon **152** engages the valve annulus. The surgeon then reads the indicators **164** to determine the appropriate valve size. The balloon **152** is then deflated and the valve sizer **150** is removed from the patient.

[0044] Referring to FIGS. 12-14, a fifth valve sizer **200** is shown. The fifth valve sizer **200** has a handle **202** from which extends a tube **204** and a shaft **206**. A first element **208** is attached to the tube **204**. A second element **210** is linearly slidable with respect to the first element **208** from the retracted solid-line position of FIG. 13 to the expanded, dotted-line position of FIG. 13. A pair of springs **212** bias the first and second elements **208**, **210** toward the expanded position.

[0045] Referring to FIGS. 13 and 14 the tube **204** is attached to the first element **208** at a flange. The shaft **206** extends through the first element **208** toward a deflectable tongue **214** attached to the second element **210**. The first and second elements **208**, **210** are locked to one another by moving the shaft **206** downward into contact with first element **208** by actuating thumb switch **216** (FIG. 12) which is coupled to the shaft **206**. The tongue **214** is deflected downwardly by the shaft **206** into frictional [text missing or illegible when filed] together. The second element **210** preferably includes valve size indications **218** which indicate the valve size corresponding to the size between outer edges **220** of the first and second elements **208**, **210**. The fifth valve sizer **200** preferably has the same dimensions as the first valve sizer **2** when in the expanded and retracted positions. Although it is preferred to use the springs **212** and the deflectable tongue **214** to move and lock the first and second elements **208**, **210** together, it is within the scope of the invention to provide any other moving and locking mechanism. For example, the fifth valve sizer **200** may include a rotatable shaft having a gear which engages a rack in the second element **210** for moving the second element **210** with respect to the first element **208**. A proximal size indicator could be used with the gear and rack configuration.

[0046] Use of the fifth valve sizer **200** is now described. The valve sizer **200** is introduced into the patient's valve annulus with the first and second elements **208**, **210** in the retracted position. The surgeon then manipulates the thumb switch **216** so that the shaft **206** moves proximally and releases the tongue **214**. The first and second elements **208**, **210** are then biased outwardly by the springs **212** until they

contact the valve annulus. The surgeon then manipulates the thumb switch **216** again to lock the first and second elements **208, 210** together. The surgeon then removes the valve sizer **200** and reads the valve sizer indications **218** to determine the appropriate valve size.

[0047] The above description merely describes the preferred embodiments and it is understood that variations of the preferred embodiment are within the scope of the invention which is defined by the claims. For example, although the preferred valve sizers are attached to shafts which do not articulate it is within the scope of the invention to provide articulating or malleable shafts so that the distal ends may be pivoted. Furthermore, although it is preferred to use the valve sizers when performing a minimally invasive valve replacement procedure, the valve sizer may also be used in a conventional open-chest procedure.

What is claimed is:

1. A valve sizer for determining an appropriate replacement valve size when performing a valve replacement procedure, comprising:

- a shaft having a proximal end and a distal end;
- a movable element coupled to the distal end of the shaft, the movable element being movable between a first position and a second position;
- a valve sizing portion having an outer dimension, the valve sizing portion being at least partially defined by the movable element;
- an indicator at the proximal end of the shaft, the indicator indicating a replacement valve size corresponding to the outer dimension of the valve sizing portion; and
- an actuator at the proximal end of the elongate shaft, the actuator being operatively coupled to the movable element for moving the movable element between the first and second positions.

2. The valve sizer of claim 1, wherein:

the movable element includes a plurality of arms, the plurality of arms having outer surfaces generally forming a generally circular shape in a plane perpendicular to a longitudinal axis defined by the shaft, the plurality of arms being movable between the first and second positions.

3. The valve sizer of claim 1, wherein:

the plurality of arms move in a plane substantially perpendicular to a longitudinal axis defined by the shaft.

4. The valve sizer of claim 1, further comprising:

a rod extending through at least a portion of the shaft, the rod being operatively coupled to the actuator.

5. The valve sizer of claim 4, wherein:

the rod is rotatable relative to the shaft, the rod being coupled to the actuator so that rotation of the rod relative to the shaft moves the movable element between the first and second positions.

6. The valve sizer of claim 4, further comprising:

a disc attached to the rod;

the movable element including a plurality of arms;

the disc having a plurality of slots which receive pins attached to the plurality of arms.

7. The valve sizer of claim 1, further comprising:

a plurality of camming surfaces coupled to the shaft, the plurality of camming surfaces being configured to engage and cam the plurality of arms when the actuator is actuated to move the movable element from the first position to the second position.

8. The valve sizer of claim 1, wherein:

the outer dimension is no more than 21 mm when the movable element is in the first position.

9. The valve sizer of claim 8, wherein:

the outer dimension is no more than 19 mm when the movable element is in the first position.

10. The valve sizer of claim 8, wherein:

the outer dimension is at least 31 mm when the movable element is in the second position.

11. The valve sizer of claim 8, wherein:

the outer dimension is at least 33 mm when the movable element is in the second position.

12. A valve sizer for measuring a patient's valve annulus, comprising:

a shaft having a distal end and a proximal end;

a ring mounted to the distal end of the shaft, the ring being movable from a first position to a second position, the first position having a smaller diameter than the second position; and

an actuator mounted to the proximal end of the shaft, the actuator being operatively coupled to the ring for moving the ring from the first position to the second position.

13. The valve sizer of claim 12, wherein:

the ring includes a first part and a second part slidably coupled to the first part.

14. The valve sizer of claim 12, wherein:

the second part is slidably received in a recess in the first part, the first part having first and second ends.

15. The valve sizer of claim 14, further comprising:

a first lever coupled to the first end of the first part;

a second lever coupled to the second end of the first part, the second lever being rotatable relative to the first lever;

the actuator being operatively coupled to at least one of the first and second levers for rotating the first lever with respect to the second lever.

16. A valve sizer for measuring a patient's valve annulus, comprising:

a shaft having a proximal end, a distal end, and an inflation lumen;

a balloon mounted to the distal end of the shaft, the balloon being fluidly coupled to the lumen; and

an indicator which indicates an outer dimension of the balloon when the balloon is inflated.

17. The valve sizer of claim 16, further comprising:

a cylinder mounted to the proximal end of the shaft, the cylinder having a [text missing or illegible when filed] a piston slidably disposed within the cylinder;

the indicator comprising markings on the cylinder.