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(54) Title: HANDHELD DEVICES FOR HEART VALVES FUNCTIONAL ASSESSMENT AND SIZING

(57) Abstract: A hand-held functional valve sizer device (100) having a lon-
gitudinal axis and includes a slider housing portion (105) enclosing multiple
sliders, a handle portion (115) connected to the slider housing portion via a
malleable rod (120). The handle portion includes a handle (125), a guide cas-
ing (130), a ring sizer selecting mechanism, and, a trigger (135) for pushing
down at least one selected ring sizer for functional assessment of the valve,
and, multiple ring sizers (140) protruding from the distal end of the slider
housing portion. Particularly, every ring sizer is operably coupled to each
slider, and an operator selects at least one ring sizer by operating the ring
sizer selecting mechanism for an assessment of the functional aspect of the
valve.
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HANDBHELD DEVICES FOR HEART VALVES FUNCTIONAL ASSESSMENT
AND SIZING

FIELD OF THE INVENTION

Embodiments of the present invention generally relate to the field of medical devices, and, more particularly, to medical devices employed for heart valves functional assessment and sizing.

BACKGROUND OF THE INVENTION

Defects in heart valves and other types of heart diseases are known to reduce the efficiency of the natural heart valve. Valvular heart disease is a well-known condition in which one or more of the valves of the heart fail to function properly inside the body. Particularly, the diameter of the valve is enlarged or annulus deformed such that the cusps of the natural valve do not coapt properly or forms a seal when the valve is in a closed position, which allows regurgitation of blood through the cusps.

Over the years, numerous surgical techniques have been used to replace or repair a diseased or damaged valve. One of the known heart valve condition, valvular regurgitation, may be caused by a dilatation of the tissue surrounding a heart valve, a common cause for e.g., the mitral valve or tricuspid valve disease besides other causes. This condition causes the valve opening to enlarge, which prevents the valve from coapting properly. Specifically, Mitral valve regurgitation (MR) is a condition in which the mitral valve leaflets fail to close properly, allowing significant backflow of blood from the left ventricle into the left atrium during
systole. It is a known fact that occurrence of valve diseases increases dramatically with increase in age, and reaching epidemic levels in the elderly population. If the condition is untreated, valvular regurgitation can cause shortness of breath, decreased cardiac output, intolerance to physical exercise, congestive heart failure and may even result in death.

Generally, such heart valve conditions are commonly treated by repair procedures using a surgical technique known as annuloplasty. In this technique, a prosthetic annuloplasty ring is affixed in the patient proximate the defective natural heart valve or secured to the annulus of the valve to stabilize the shape and size of the annulus. Specifically, cinching or securing the tissue of the annulus to the annular ring can restore the valve opening to its approximate original size and operating efficiency. Moreover, placement and implantation of the annuloplasty ring requires open-heart surgery, which involves putting the patient on a cardiopulmonary bypass machine and stopping the heart.

While performing the operation, the surgeon usually makes an assessment of the valve size by visual measuring of the anterior mitral leaflet or intercommissural distance and comparing with available standard sizer. Generally, the standard sizer of mitral valve is available in various sizes and is semicircular flat plastic body with central handle, which is directly placed over valve leaflet to compare size and to guess how much reduction needs to be done by the surgeon. In practice, the assessment of size is much empirical with significant observer variation and has no relation to valve function. Further, for functional assessment of the valve function the surgeon insufflates water into the ventricular cavity and
checks the amount of backflow of water across the regurgitant valve. In practice, the functional assessment of the valve and sizing are independent steps in valve surgery. Consequently, precise selection of the ring size and contour is a very important decision to be taken by the surgeon to perform heart valve repair surgery.

Therefore, conventionally available valve-sizers are not very precise at actually assessing size and function and provide only an estimate to the surgeon. There is no available sizer device with multiple sizing ability in the prior art with the ability to provide physiologic assessment of the repair procedure in terms of valve function after repair. Moreover, currently in the art no company is manufacturing a sizer with multiple sizing ability, which cannot just act as tool to size the valve, but also helps in functionally assessing the valve function. There remains a need in the art for determining if the repair is not working and thereby saving wastage of the annuloplasty ring. Consequently, it can save thousands of dollars from being spent by the patient for the annuloplasty ring, which is not used eventually. Another important point is that there is a need in the medical domain for a device that is fast and effective to use, preferably single so that precious time is not wasted in sizing in arrested heart.

U.S. Patent Application Publication 20070016287 titled "Methods and apparatus for controlling the internal circumference of an anatomic orifice or lumen" to Cartledge et al. relates to an implantable device for controlling shape and/or size of an anatomical structure or lumen. The implantable device has an adjustable member configured to adjust the dimensions of the implantable device. The
implantable device is housed in a catheter and insertable from a minimally invasive surgical entry. An adjustment tool actuates the adjustable member and provides for adjustment before, during or after the anatomical structure or lumen resumes near normal-to-normal physiologic function.

St. Jude Medical manufactures an annuloplasty ring holder with its biflex adjustable annuloplasty ring. Particularly, the holder employs radially extending projections, which engage the upper and lower surfaces of the ring and serve as suturing templates. However, the holder does not protect the drawstrings during suture placement, nor provide any means for trial adjustments to be made to the drawstrings.

U.S. Pat. No. 7,431,692 titled "Apparatus, system, and method for applying and adjusting a tensioning element to a hollow body organ" granted to Edwards Life Sciences Corporation describes an adjustable support pad for adjustably holding a tensioning line used to apply tension to a body organ. The adjustable support pad can be configured to adjustably hold one or more separate tensioning lines, and to provide for independent adjustment of one or more tensioning lines or groups thereof.

U.S. Pat. No. 8,241,351 titled "Adjustable partial annuloplasty ring and mechanism therefor" granted to Valtech Cardio, Ltd. relates to an apparatus that is configured to be implanted in a body of a subject. The apparatus includes an implant structure having first and second portions thereof, a spool coupled to the implant structure in a vicinity of the first portion thereof, and a flexible member
coupled at a first end thereof to the spool, and not attached at a second end thereof to the spool. The flexible member, in response to rotation of the spool in a first direction thereof, is configured to be wound around the spool, and, responsively, to pull the second end of the flexible member toward the first end of the implant structure, and responsively to draw the first and second portions of the implant structure toward each other. However, the apparatus with the adjustable ring is likely to be costly for manufacturer and for the patients.

U.S. Pat. Application No. 20130110231 titled "heart valve sizing ring and method" relates to a heart valve sizing ring and includes an outer ring; and an inner ring configured and arranged to couple to the outer ring. The outer ring and inner ring having a pair of complementary mating surfaces configured and arranged to grip sutures there between when coupled together. However, in use all the sutures are first placed inside the outer ring and consequently, an inner ring is deployed and coupled together, so for one size this technique provides good assessment but if you have to do the same for three to four sizes then in that case the operator has to remove this sizer and put in next sizer three to four times which is very time consuming, especially while operating on an arrested heart. Secondly, if the surgeon wants to compare different sizes in quick succession it is not possible. For example, if the surgeon is putting 28 size and then 30 size the surgeon can do it individually. However, if the surgeon needs 28 size again then in this case, the surgeon spends three to four minutes on each size and by that time the surgeon might lose the memory of assessment for previous size.
WIPO Patent application number WO/2013/131150 titled "functional sizer for a heart valve implantable device" relates to a functional sizer and method of sizing. The invention provides a sizer that is functional and can be reversibly secured in position, largely using the valve sutures under tension, thereby enabling assessment of fit and performance prior to permanently stitching a heart valve ring prosthesis. However, the present invention relates to a single size technique and permanently secures the ring for annuloplasty using magnetic coupling. Moreover, the invention suffers from the disadvantage that all sizes have to be individually put inside and there is a possibility for the surgeon to lose memory for function if he is performing too much of procedure between different sizing and therefore time consuming.

Consequently, the most important limitation of present techniques in the prior art is that though the surgeon is using ring for reduction annuloplasty but no sizer is available that actually test the function of the valve for multiple sizes. All sizer test anatomical size, which is not a true determinant of function of valve. Further, the surgeon can test the valve only after implanting the ring. Consequently, whether the sizing done is accurate or not is not known to the surgeon. Furthermore, the most important disadvantage of the present available sizer is that if the annuloplasty fails then a costly ring is wasted which the surgeon gets to know only after implanting.

Accordingly, there remains a need in the art to develop and manufacture sizer, which can test annulus for different sizes and subsequently provides improved visual functional result to the surgeon. Consequently, the surgeon can determine
accurate and optimal sizing, and in a condition where annuloplasty is not working than the surgeon can know this without wasting a ring and directly proceed to valve replacement and thus saving time and money.

Therefore, there exists a need in the art for better evaluation of the valve size and thereby an improved sizer device integrating two aspects relating to determining functional assessment of the heart valves and having sizing capability in real time for evaluating the repair done and consequently improve the quality of repair.

**Summary of the invention**

The embodiments of the present disclosure have several features, no single one of which is solely responsible for their desirable attributes. Without limiting the scope of the present embodiments as expressed by the claims that follow, their more prominent features will now be discussed briefly. After considering this discussion, and particularly after reading the section entitled "Detailed Description", one will understand how the features of the present embodiments provide advantages, which include providing a hand-held functional valve sizer device for testing annuloplasty by taking into account the functional status of the valve with respect to regurgitation for different sizes with a single device.

In one embodiment, a hand-held functional valve sizer device for testing annuloplasty by taking into account the functional status of the valve with respect to regurgitation is disclosed. The device is a multiple size testing device. Particularly, the sizer device is having a longitudinal axis and includes a slider housing portion, a handle portion having a proximal end and a distal end, and a
plurality of ring sizers protruding from the distal end of the slider housing portion.

In operation, the particular ring sizer is selected from the plurality of ring sizers by an operator by operating the ring sizer selecting mechanism of the handle portion for an assessment of the functional aspect of the valve.

In accordance with an embodiment of the present invention, the slider housing portion encloses a plurality of sliders. Specifically, the handle portion is connected to the slider housing portion at the proximal end of the slider housing portion via a malleable rod protruding from one end of the handle portion.

In accordance with another embodiment of the present invention, the sizer device includes a slider housing portion, a handle portion, a trigger for sequentially pulling at least one ring sizer for functional assessment of the valve selected by the ring sizer selecting mechanism, and, multiple ring sizers protruding from the distal end of the slider housing portion. Specifically, each ring sizer of the multiple ring sizers is operably coupled to each slider of the multiple sliders. Moreover, each ring sizer of the multiple ring sizers is positioned one inside the other and supported one inside the other. Particularly, the slider housing portion further includes a spring mechanism and the spring mechanism encloses multiple sizer control wire rods. Moreover, the multiple sizer rings all-together preferentially make a funnel shaped sizer device with a lowermost part of funnel making a sizing circumference of the sizer device.

In yet another embodiment of the present invention, the ring sizer selecting mechanism includes a wire guide plate, multiple sizer control wire rods, multiple
followers, a follower control leaf spring member, a cam member, a rack member, a shaft, and a flexible spring member. Specifically, the wire guide plate positions the sizer control wire rods, and each follower positioning each sizer control wire rod of the plurality of sizer control wire rods. Moreover, the follower control leaf spring member positions the followers and the ring sizers to an initial original position and move to a release position when the trigger is pressed by the operator. In operation, the cam member is having a plurality of teeth members selectively operable upon the rack member having a plurality of upstanding teeth. Specifically, the teeth members of the cam member are adapted to engage the corresponding teeth members in the rack member and in operation, the rack member moves in a backward direction and the cam member moves in a forward direction when the trigger is pressed by the operator.

**BRIEF DESCRIPTION OF THE DRAWINGS**

FIG. 1 illustrates a perspective view of a hand-held functional valve sizer device employed for heart valves functional assessment and sizing and an enlarged view of a slider housing portion of the sizer device, according to an embodiment of the invention;

FIG. 2A illustrates a front view of the hand-held functional valve sizer device, according to an embodiment of the invention;

FIG. 2B illustrates an enlarged view of the slider housing portion positioning the multiple ring sizers in place, according to an embodiment of the invention;
FIG. 3A illustrates a perspective view of the ring sizer selecting mechanism of the sizer device, according to another embodiment of the invention;

FIG. 3B illustrates an exploded view of the ring sizer selecting mechanism of the sizer device, according to yet another embodiment of the invention;

FIG. 3C illustrates a cross sectional view of the sizer device illustrating undeployed state of selecting ring sizer by the operator, according to an embodiment of the invention;

FIG. 3D illustrates a front view of the sizer device illustrating deployed state where one of the ring sizer is selected by the operator, according to an embodiment of the invention;

FIG. 4A illustrates an expanded view of the ring sizer operably coupled to the slider of the device, according to an embodiment of the invention;

FIG. 4B illustrates a top view of the multiple ring sizers and the perspective view of the arrangement of the slider mounted on the ring sizer of the device, according to an embodiment of the invention;

FIG. 5A illustrates a perspective view of a hand-held functional valve sizer device for testing annuloplasty by taking into account the functional status of the valve with respect to regurgitation, according to another embodiment of the invention;

FIG. 5B illustrates an expanded view of the ring sizers of the sizer device, according to another embodiment of the invention;
FIG. 6 illustrates a cross-sectional view of the slider housing portion illustrating the spring mechanism and a cross-sectional view of the handle body of the sizer device, according to another embodiment of the invention;

FIG. 7 illustrates a cross-sectional view of the handle body illustrating the functioning of the ring sizer selecting mechanism positioned inside the handle body when the operator releases the trigger, according to preferred embodiment of the present invention;

FIG. 8A illustrates a cross-sectional view of the handle body illustrating the functioning of the ring sizer selecting mechanism positioned inside the handle body when the operator presses and releases the trigger, according to preferred embodiment of the present invention; and

FIG. 8B illustrates a perspective view of the movement of one or more ring sizers when the operator releases and/or presses the trigger, according to another embodiment of the invention;

**Element List**

| Hand-held functional valve sizer device 100 | Slider housing portion 105 |
| Slider 110 | Handle portion 115 |
| Handle 125 | Guide casing 130 |
| Trigger 135 | Malleable Rod 120 |
| Ring sizer 140 | Threading element 145 |
| Knob 150 | Handle body 205 |
| Spring mechanism 210 | Sizer control wire rod 215 |
DETAILED DESCRIPTION OF THE INVENTION

Various embodiments of the present invention are disclosed herein below, which relate to handheld devices for performing valve repairing surgery of the mitral valve. However, the present invention is not limited and may be used on tricuspid valve repair and aortic root/annulus remodeling procedures.

The present invention provides a functional sizer device for sizing a heart valve annulus. Referring to FIG. 1, in an embodiment the hand-held functional valve sizer device 100 has a longitudinal axis and includes a slider housing portion 105 enclosing multiple sliders 110 and a handle portion 115. Specifically, the slider housing portion 105 is having a proximal end 106 and a distal end 107. The slider housing portion 105 acts as a casing to hold the sliders 110 stacked one over the other. The handle portion 115 is connected to the slider housing portion 105 at the proximal end 106 of the slider housing portion 105 via a malleable rod 120. Particularly, the malleable rod 120 of the device 100 can be bent into desired shape and angle to adjust the plane of the sizer 100 with that of the annulus and therefore provides the ease to the operator.
In another embodiment, the malleable rod 120 is used to connect the handle 125 and the slider housing portion 105 by not covering the sizer control wire rods 215 but from outside of the wire rods 215 as illustrated in FIG. 3A and FIG. 3B of the present invention. Particularly, the sizer control wire rods 215 are covered by a flexible spring 121. Consequently, the sizer control wire rods 215 do not spray out and the flexible spring 121 avoids entangling of loose sutures into the wire rods 215.

FIG. 2A illustrates a front view of the hand-held functional valve sizer device 100, and FIG. 2B illustrates an enlarged view of the slider housing portion 105 positioning the multiple ring sizers in place, according to an embodiment of the invention. Particularly, the handle portion 115 includes, a handle 125, a guide casing 130, a ring sizer selecting mechanism, and, a trigger 135 for pushing down one or more selected ring sizers 140 for functional assessment of the valve selected with the help of the ring sizer selecting mechanism by the operator. Particularly, the ring sizer selecting mechanism includes a threading element 145 as illustrated in FIG. 3A and FIG. 3B of the present invention. Particularly, the threading element 145 is used to tighten the handle 125 with respect to the guide casing 130. Moreover, the handle portion 115 is the part of the device 100 which provides the operator to select the desired sizer ring 140 and lock the selected sizer ring 140 in one position for sizing of the valve annulus.

Furthermore, the handle 125 and the trigger 135 form a connection between the ring selector and the actual working functional sizer rings 140. The formed connection provides a method to deploy the selected ring 140 by the operator.
The support mechanism of the device 100 provides support to the sizer rings 140 in a way that they can be bent or shaped according to the need of surgeon. Fig. 3B illustrates assembly of six or seven sizer rings 140 with wire endings to connect with the rest of the sizers. When an individual sizer ring 140 is selected by the operator or surgeon and deployed, the sizer ring 140 travels in a forward direction to about 1.5 cm from the plane of rest of the rings 140 and subsequently the selected sizer ring 140 is used to size the annulus.

The turn knob mechanism of the sizer device 100 is illustrated in FIG. 3C and FIG. 3D of the present invention. FIG. 3C illustrates a cross sectional view of the sizer device 100 illustrating undeployed state of selecting ring sizer 140 by the operator, and FIG. 3D illustrates a front view of the sizer device 100 illustrating deployed state where the operator selects the ring sizer 140 from the device 100, according to an embodiment of the invention. In use, at least one ring sizer 140 is selected from the multiple ring sizers 140 by the operator by operating the ring sizer selecting mechanism of the handle portion 115 for an assessment of the functional aspect of the valve.

In accordance with an exemplary embodiment of the present invention, the operator rotates the threading element 145 in a clockwise direction to hold the handle 125 in any position with respect to the guide casing 130. Generally, the threading element 145 is a threaded screw.

In accordance with another exemplary embodiment of the present invention, the operator rotates the threading element 145 in an anticlockwise direction to hold
the handle 125 in any position.

In both the above mentioned situations, the handle 125 is 360 degree rotatable. In use, the handle 125 can be rotated 360 degree but it does not depend upon threading mechanism or the knob. Additionally, the handle 125 may be rotated to any degree and the selecting knob is independent of the handle 125.

In accordance with an exemplary embodiment of the present invention as illustrated in FIG. 3C, the turn knob mechanism includes a manually actuated knob 150 that is rotatably mounted to the guide casing 130 of the handle portion 115 in a way to be allowed to rotate about the longitudinal axis to thereby select the ring sizer 140 from the multiple ring sizers 140 with respect to the judgement of the operator. Moreover, in undeployed state the operator rotates the knob 150 to select the slider 110. As discussed, every ring sizer 140 is operably coupled to each slider 110 as illustrated in FIG. 4A and FIG. 4B of the present invention and therefore, by selecting the correct slider 110 by rotating the knob 150, the operator is able to determine the correct ring sizer 140 to assess the size and the functional status of the heart valve. Specifically, once the operator determines the needed or desired ring sizer 140, the operator presses the trigger 135 in a deployed state to activate the selected ring sizer 140 as illustrated in FIG. 3B of the present invention.

In accordance with an embodiment of the present invention, the ring sizer selecting mechanism is having a display technique on the knob 150 to illustrate the operator about the size of the ring sizer selected by him. The display
technique can include a number system, a colour coded system or any other available display technique used in the prior art. Persons skilled in the art would appreciate that display techniques other than the display techniques disclosed may also be included in the present device 100.

In accordance with an exemplary embodiment of the present invention, the sizer device 100 further includes multiple ring sizers 140 protruding from the distal end 107 of the slider housing portion 105. In use, each ring sizer 140 of the multiple ring sizers 140 is operably coupled to each slider of the multiple sliders 110. In addition, every ring sizer 140 is positioned one inside the other and supported one inside the other as illustrated in FIG. 4A. Further, the trigger 135 is pressed to move the selected ring sizer 140 from the multiple ring sizers 140 in a downward direction from the multiple sizers 140 towards annulus of the valve. Consequently, the device 100 with multiple ring sizers 140 where one or more ring sizers 140 are being pushed down towards annulus of the valve is more suitable for multiple use. In operation, the selected at least one ring sizer 140 is employed to size the valve according to a parameter. Also, the parameter is function of the valve.

As disclosed hereinabove, various embodiments of the present invention relate to devices with capacity to size the heart valve for various sizes simultaneously with a single sizer. In use, such devices may be passed outside the annular sutures and then subsequently be lowered down into the annulus position to check for final outcome in terms of repair. Such devices possess multiple sizing abilities with sliding mechanism of one ring inside another.
In accordance with an exemplary embodiment of the present invention, the trigger 135 is operably connected to the ring sizer selecting mechanism. In use, the handle 125 is positioned over the guide casing 130 and the threading element 145 is positioned on the handle 125. In operation, the selected ring sizer 140 moves in the downward direction from the multiple sizers 140 towards annulus of the valve in a range of about 1 cm to 1.5 cm. In use, a contour of each ring sizer is selected from a group including a D-shaped with an opening on a longitudinal axis. It will be appreciated that the contour of ring sizer can be D shaped, circular, semicircular, oval, oblong, two dimensional configuration or any three dimensional configuration suitable for sizing purpose.

Those of ordinary skill in the art will appreciate that the multiple sizer rings can be different shaped sets so that a particular set is suitable for one particular sizer design, but with different shaped sizer sets it can suitably be modified for rings of different companies so single device with different sets of sizers can be used for all companies rings. Moreover, the device can be so modified with reduction in parts that some of the joints and parts get reduced and the device is suitable for use as disposable single use device.

In accordance with another embodiment of the present invention, the multiple ring sizers 140 are colour coded. In use, the device 100 can be so assembled for two to three ring sizers or six to seven ring sizers depending on pre-operative assessment so to reduce the operating bulk of the device 100.

In accordance with an embodiment of the present invention, the heart valve sizer
device 100 may further include a slit in middle. In use, various embodiments of
the present invention may possess the capacity to assess not just the size but
functional status of the heart valve.

In accordance with another embodiment of the present invention, the ring sizer
140 further includes a central empty portion. In use, the central empty portion
includes a slit in straight segment. In further use, annular sutures can be passed
inside the cavity of the device 100 and subsequently, the device 100 is pushed
down. Consequently, the operator can change selected sizer ring 140 to all
desirable sizes and valve function can be tested for more than one size. Since
the procedure, does not involve pulling out the device 100 for every size, it saves
a lot of time for the surgeon.

FIG. 5A illustrates a perspective view of a hand-held functional valve sizer device
200 for testing annuloplasty by taking into account the functional status of the
valve with respect to regurgitation and FIG. 5B illustrates expanded view of the
ring sizers 140, according to another embodiment of the invention. Generally, the
sizer device 200 is configured to be used for a single size. In use, the sizer
device 200 has a longitudinal axis and includes, a slider housing portion 105
enclosing multiple sliders 110, a handle body 205, and a malleable rod 120. The
slider housing portion 105 is having a proximal end 106 and a distal end 107.

Particularly, the handle body 205 is connected to the slider housing portion 105
at the proximal end 106 of the slider housing portion 105 via the malleable rod
120 protruding from one end 116 of the handle body 205. In use, the handle body
205 includes, a ring sizer selecting mechanism, and, a trigger 135 for
sequentially pulling the ring sizer 140 for functional assessment of the valve selected by the ring sizer selecting mechanism.

In accordance with an embodiment of the present invention, the sizer device 200 further includes, multiple ring sizers 140 protruding from the distal end 107 of the slider housing portion 105. In use, every ring sizer 140 is operably coupled to every slider of the multiple sliders 110, and every ring sizer 140 is positioned one inside the other and supported one inside the other. In operation, the operator selects the ring sizer 140 with pulling up mechanism by operating the ring sizer selecting mechanism of the handle body 205 for the assessment of the functional aspect of the valve. Specifically in this embodiment, the ring sizers 140 all together preferentially make a funnel shaped sizing device 200 with the lowermost part of funnel making the sizing circumference of the funnel or the sizer device 200. Furthermore, the ring sizers 140 that are pulled up are out of the sizing circumference and the smallest or lowermost part of funnel is sizing circumference of the sizer device 200. Particularly, each ring sizer is positioned slightly below the larger ring sizer as illustrated in FIG. 5B of the present invention. The positioning of the one or more ring sizers increases the thickness of the sizer base and it becomes funnel shaped. Subsequently, the present invention device provides appropriate fits for the sutures positioned at the annulus. Moreover, the present ring sizers of the device don’t interfere or impinge on the atrial wall or the annular wall. Since, the above-mentioned embodiment has a simple handle mechanism the sizer device can also be manufactured for single use.
In accordance with yet another embodiment of the present invention, the walls of the ring sizer are slightly convex on the inner side and slightly concave on the outer side as illustrated in FIG. 5B of the present invention. In operation, when the rings slide over one another the protrusion provided by the convex surface of the inner side of the wall and the slight indentation provided by the concave surface of the outer side may be curved to substantially conform to a portion of the convex surface of the inner side of the wall. Specifically, the convex surface portion of the inner side of the wall of one ring sizer and the concave surface portion of the outer side of the wall of the other ring sizer are coupled together by, for example, a detent or snap fit mechanism so that the rings are not freely mobile in use.

FIG. 6 illustrates a cross-sectional view of the slider housing portion 105 illustrating the spring mechanism 210 and a cross-sectional view of the handle body of the sizer device 200, according to another embodiment of the invention. Particularly, the spring mechanism 210 encloses a plurality of sizer control wire rods 215. Every sizer control wire rod 215 is connected to each slider of the multiple sliders 110. In use, the spring mechanism 210 positions the sizer control wire rods 215 in one position after release of the trigger 135 and selection of the ring sizer 140 by the operator. Therefore, the spring mechanism 210 provides the function of keeping all ring sizers 140 in a defined place after the release of the trigger 135 by the operator. Moreover, the malleable rod 120 surrounds all the sizer control wire rods 215 and is capable of bending to any angle required by the operator.
FIG. 7 illustrates a cross-sectional view of the handle body 205 illustrating the functioning of the ring sizer selecting mechanism positioned inside the handle body when the operator releases the trigger, according to preferred embodiment of the present invention. The ring sizer selecting mechanism includes a wire guide plate 220, multiple followers 225, a follower control leaf spring member 230, a cam member 235, a rack member 245 and a shaft 255. The wire guide plate 220 positions the sizer control wire rods 215 to avoid buckling of wire rods 215. In use, each follower 225 positions every sizer control wire rod 215. The selecting mechanism further includes the follower control leaf spring member 230 to position the followers 225 and the ring sizers 140 to an initial original position and move to a release position when the operator presses the trigger 135 as illustrated in FIG. 8A, of the present invention. Particularly, the cam member 235 is having teeth members 240 which are selectively operable upon the rack member 245 having a plurality of upstanding teeth 250. Moreover, the teeth members 240 of the cam member 235 are adapted to engage the corresponding teeth members 250 in the rack member 245 and in operation, the rack member 245 moves in a backward direction and the cam member 235 moves in a forward direction when the operator presses the trigger 135. Further, the follower control leaf spring member 230 is arranged to be always in contact with the cam member 235, and the shaft 255 extends through the rack member 245. The follower control leaf spring member 230 and the shaft 255 are fastened by a screw member 260 at first end 263 of the shaft 255, and, a flexible spring member 265 enclosing a portion of the shaft 255 and positioning the shaft 255 between the
rack member 245 and the follower control leaf spring member 230.

In use, the flexible spring member 265 is compressed when the operator presses the trigger 135 and in non-operating state the flexible spring member 265 pushes the trigger 135 in place. Generally, the trigger 135 is indirectly connected to the plurality of sizer control wire rods 215 via the cam member 235.

In accordance with an exemplary embodiment of the present invention, the at least one follower 225 rotates back one by one by pressing the leaf spring follower control leaf spring member 230 and an inner ring sizer is selected from the multiple ring sizers 140 and the inner ring sizer moves up when the trigger 135 is pressed by the operator. In use, the inner ring sizer is retracted to about 1 cm and operator pulls the trigger 135 progressively. The trigger 135 is pulled progressively to pull back the multiple ring sizers 140 one by one sequentially as illustrated in FIG. 8B of the present invention. It will be appreciated that the sizer rings in the devices as disclosed hereinabove may possess semicircular, oval, or oblong shape, with a slit in middle, having capacity to assess not just the size but functional status of the heart valve.

In accordance with another embodiment of the present invention, the ring sizer 140 may include one or more holes (not shown) to allow for a hook to pull the ring up or push it down. In use, the ring sizer may further include one or more extensions of the outer rings outside above the plane of valve annulus for facilitation of putting all the sutures inside the ring.

In accordance with yet another embodiment of the present invention, one or more ring sizers may slide over each other sequentially so that the inner most diameter
of the sizer may be increased or decreased, which may be used for sizing the valve annulus.

Those of ordinary skill in the art will appreciate that the above-mentioned embodiments and sizing mechanisms are for exemplary purposes only, and there may exist various other methodologies that may be used to make a functional sizer device. Various embodiments of the present invention relate to heart valve sizer devices having different designs, including, such as, for example, but not limited to, the size, shape, and ergonomics. Additional parameters can further be optimized and various sizes and shapes described herein are for exemplary purposes only, wherein additional modifications may be made consistent with the design considerations as required for a diverse range of applications, which may relate to valve sizes or later developed techniques.

Therefore, as may be seen, various embodiments of the present invention, as herein described above, provide several advantages, such as, for example, but not limited to, multiple benefits to the surgeons, patient and to medical device corporations as the surgeon may have flexibility to better size his valve, thereby improving his quality of repair. Moreover, the present heart valve sizer device determines sizing to be done by visualizing functional status of the valve rather than just analyzing anatomical size.

In circumstances where the surgeon is unable to do a repair than an annular ring is not opened and wasted, thereby saving cost. Various embodiments of the present invention will allow the patients to get better quality of repair without any addition to cost.
The invention should not be considered limited to the specific methods and devices precisely described herein. On the contrary, various modifications will be apparent to those of ordinary skill upon reading the disclosure. Although certain embodiments are described with reference to the mitral valve, use with other valves or anatomical structures is also contemplated. Additionally, the sizing devices according to the invention can be made of disposable materials, for one-time use, or of non-disposable materials, for re-sterilization and subsequent reuse. The foregoing detailed description has been given for clarity of understanding only. No unnecessary limitations are to be understood therefrom.

The entire disclosure of any article, patent or patent application identified herein is hereby incorporated by reference.

While there has been shown and described the preferred embodiment of the instant invention it is to be appreciated that the invention may be embodied otherwise than is herein specifically shown and described and that, within said embodiment, certain changes may be made in the form and arrangement of the parts without departing from the underlying ideas or principles of this invention as set forth in the Claims appended herewith. Therefore, the appended claims are to be construed to cover all equivalents falling within the true scope and spirit of the invention.
Claims

1. A hand-held functional valve sizer device for testing annuloplasty by taking into account the functional status of the valve with respect to regurgitation, said sizer device having a longitudinal axis and comprising:

5 a slider housing portion enclosing a plurality of sliders, said housing portion comprising a proximal end and a distal end;

a handle portion connected to said slider housing portion at said proximal end of said slider housing portion via a malleable rod protruding from one end of said handle portion, said handle portion comprising:

10 a handle;

a guide casing;

a ring sizer selecting mechanism; and,

a trigger for pushing down at least one selected ring sizer for functional assessment of said valve selected by said ring sizer selecting mechanism; and,

15 a plurality of ring sizers protruding from said distal end of said slider housing portion, wherein each ring sizer of said plurality of ring sizers is operably coupled to each slider of said plurality of sliders, and wherein each ring sizer of said plurality of ring sizers is positioned one inside the other and supported one inside the other;

20 wherein at least one ring sizer is selected from said plurality of ring sizers by an operator by operating said ring sizer selecting mechanism of said handle portion for an assessment of the functional aspect of said valve.
2. The sizer device as claimed in Claim 1, wherein said ring sizer selecting mechanism comprises a threading element and a turn knob mechanism.

3. The sizer device as claimed in Claim 2, wherein said threading element is rotated in a clockwise and/or anticlockwise direction to hold said handle in any position required to operate said device by said operator and wherein said handle is 360 degree rotatable.

4. The sizer device as claimed in Claim 2, wherein said turn knob mechanism comprises a manually actuated knob that is rotatably mounted to a guide casing of said handle portion in a way to be allowed to rotate about said longitudinal axis to thereby select said at least one ring sizer from said plurality of ring sizers with respect to said operator, and wherein said ring sizer selecting mechanism comprises a display technique to show which size of said ring sizer is chosen by said knob.

5. The sizer device as claimed in Claim 1, wherein said trigger is pressed to move said selected at least one ring sizer from said plurality of ring sizers in a downward direction from said plurality of sizers towards annulus of said valve and said trigger comprises a locking mechanism to lock said trigger in a contracted position while said device is being operated by said operator.
6. The sizer device as claimed in Claim 1, wherein said selected at least one ring sizer is employed to size said valve according to a parameter and said parameter is function of said valve.

7. The sizer device as claimed in Claim 1, wherein said trigger is operably connected to said ring sizer selecting mechanism.

8. The sizer device as claimed in Claim 1, wherein said handle is positioned over said guide casing and said threading element is positioned on said handle.

9. The sizer device as claimed in Claim 5, wherein said selected at least one ring sizer moves in said downward direction from said plurality of sizers towards annulus of said valve in a range of about 1 cm to 1.5 cm.

10. The sizer device as claimed in Claim 1, wherein a contour of each sizer is selected from a group comprising a D-shaped with an opening on a longitudinal axis, circular, oval, semicircular, tunnel shaped, tubular, wide bodied, two dimensional configuration or any three dimensional configuration suitable for sizing purpose and wherein said plurality of ring sizers are colour coded.

11. The sizer device as claimed in Claim 1, wherein a flexible spring is positioned between said proximal end of said slider housing portion and said handle portion encasing a plurality of sizer control wire rods and wherein each
sizer control wire rod of said plurality of sizer control wire rods is connected to each slider of said plurality of sliders.

12. A hand-held functional valve sizer device for testing annuloplasty by taking into account the functional status of the valve with respect to regurgitation, said sizer device having a longitudinal axis and comprising:

   a slider housing portion enclosing a plurality of sliders, said housing portion comprising a proximal end and a distal end;

   a handle body connected to said slider housing portion at said proximal end of said slider housing portion via a malleable rod protruding from one end of said handle body, said handle body comprising:

   a ring sizer selecting mechanism; and,

   a trigger for sequentially pulling at least one ring sizer for functional assessment of said valve selected by said ring sizer selecting mechanism;

   and,

   a plurality of ring sizers protruding from said distal end of said slider housing portion, wherein each ring sizer of said plurality of ring sizers is operably coupled to each slider of said plurality of sliders, and wherein each ring sizer of said plurality of ring sizers is positioned one inside the other and supported one inside the other;

   wherein at least one ring sizer is selected from said plurality of ring sizers by an operator by operating said ring sizer selecting mechanism for an assessment of the functional aspect of said valve.
13. The sizer device as claimed in Claim 12, wherein said slider housing portion further comprises a spring mechanism and wherein said plurality of rings all together preferentially make a funnel shaped sizer device with a lowermost part of funnel making a sizing circumference of said sizer device.

14. The sizer device as claimed in Claim 13, wherein said spring mechanism encloses a plurality of rods.

15. The sizer device as claimed in Claim 14, wherein each sizer control wire rod of said plurality of sizer control wire rods is connected to each slider of said plurality of sliders.

16. The sizer device as claimed in Claim 14, wherein said spring mechanism positions said plurality of sizer control wire rods in one position after release of said trigger and selection of at least one ring sizer by said operator and said trigger comprises a locking mechanism to lock said trigger in a contracted position while said device is being operated by said operator.

17. The sizer device as claimed in Claim 12, wherein said ring sizer selecting mechanism comprises:

   a wire guide plate to position said plurality of sizer control wire rods;
a plurality of followers, and each follower positioning each sizer control wire rod of said plurality of sizer control wire rods;

da follower control leaf spring member to position said plurality of followers and said plurality of ring sizers to an initial original position and move to a release position when said trigger is pressed by said operator;

a cam member having a plurality of teeth members selectively operable upon a rack member having a plurality of upstanding teeth, wherein said plurality of teeth members of said cam member are adapted to engage the corresponding teeth members in said rack member and in operation, said rack member moves in a backward direction and said cam member moves in a forward direction when said trigger is pressed by said operator;

a shaft extending through said rack member and wherein said follower control leaf spring member and said shaft are fastened by a screw member at one end of said shaft;

a flexible spring member enclosing a portion of said shaft and positioning said shaft between said rack member and said follower control leaf spring member; and

wherein said flexible spring member is compressed when said trigger is pressed by said operator and in non-operating state said flexible spring member pushes said trigger in place.

18. The sizer device as claimed in Claim 17, wherein said follower control leaf spring member is positioned in a way to be always in contact with said cam
member and wherein said trigger is indirectly connected to said plurality of sizer control wire rods via said cam member.

19. The sizer device as claimed in Claim 17, wherein said at least one follower rotates back one by one by pressing said leaf spring follower control leaf spring member and an inner ring sizer is selected from said plurality of ring sizers and said inner ring sizer moves up when said trigger is pressed by said operator.

20. The sizer device as claimed in Claim 19, wherein said inner ring sizer is retracted to about 1 cm and wherein said trigger is pulled progressively to pull back said plurality of ring sizers one by one sequentially.

21. The sizer device as claimed in Claim 12, wherein a contour of each sizer is selected from a group comprising a D-shaped with an opening on a longitudinal axis, circular, oval, semicircular, tunnel shaped, tubular, wide bodied, two dimensional configuration or any three dimensional configuration suitable for sizing purpose.
A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F2/24

ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A6F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>US 2013/110231 AI (DOBRI LOVIC NI KOLA [US]) 2 May 2013 (2013-05-02) cited in the application on paragraph [0035] - paragraph [0037]; figures 7-11</td>
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Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:
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