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Declarations under Rule 4.17:
— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

(54) **Title:** ANNULOPLASTY RING SIZER

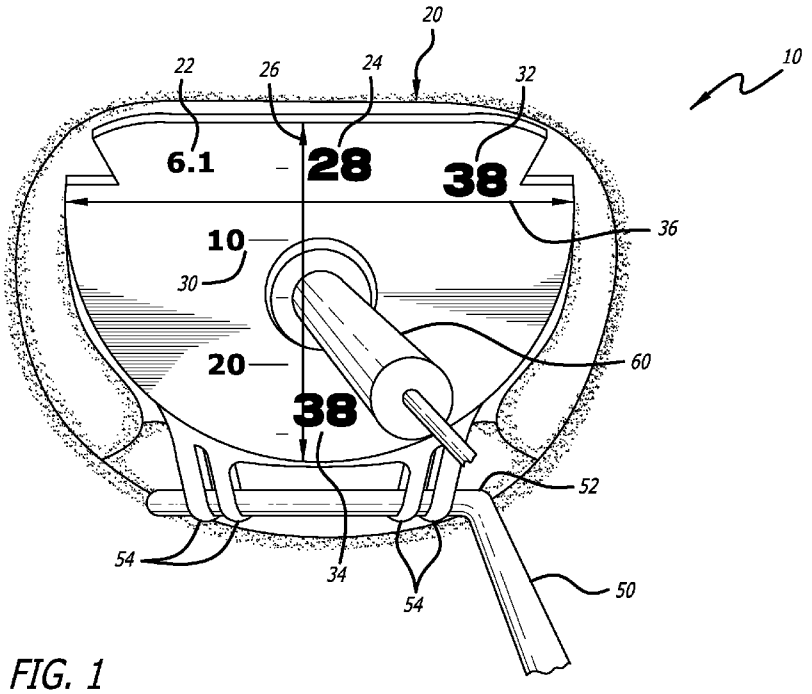


FIG. 1

(57) **Abstract:** A ring sizer including a face plate that has markings usable to provide measurements of a valve. The sizer may include a clear face plate on which the markings are provided such that the valve is visible through the face plate facilitating accurate measurements of various valve dimensions and optimal ring sizing.

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[Continued on next page]

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ANNULOPLASTY RING SIZER

RELATED APPLICATIONS

[0001] This application claims priority to and benefit of U.S. Provisional Application Serial No. 62/683,397 filed June 11, 2018 entitled *Annuloplasty Ring Sizer*, which is hereby incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

[0002] Annuloplasty procedures involve remodeling a heart valve by installing a ring around the valve annulus. The ring is sized to reduce the size of the enlarged valve back to an optimal size to reestablish coaptation of the valve leaflets. These rings come in a variety of shapes and sizes. As such, a key component of a successful annuloplasty procedure is an accurate measurement of the target valve so an optimally-sized annuloplasty ring can be selected. Measurement of the native valve is accomplished with a valve sizer.

[0003] Valve sizers are typically valve-shaped rings or similar structures attached to an elongated instrument handle. The sizers are provided in sets that include numerous sizers, identified by a single number indicating the diameter across the annulus in millimeters. However, valves, such as mitral valves, are not circular, and thus generalizing them using a single measurement can result in inaccuracies, due to the variety of valve shapes. Compounding this problem is the fact that the limited information provided by existing sizers is easily misinterpreted by physicians, as valve repair is not a common procedure.

[0004] If a ring is improperly selected, implantation of the ring will lead to a “failed” repair. For example, if the ring is too large, incomplete coaptation will occur, resulting in residual valve leakage. A ring that is too small can also result in residual leakage, as well as a condition known as “systolic anterior motion,” which is an obstruction of flow within the heart.

[0005] It would thus be advantageous to provide a valve sizer that provides more information to a physician, such that an optimal ring may be selected.

OBJECTS AND SUMMARY OF THE INVENTION

[0006] In one aspect of the invention, a valve sizer is provided that allows a physician to take various measurements of a valve.

[0007] Another aspect of the invention involves a valve sizer that allows a physician to measure a valve without requiring the physician to insert numerous sizers on a trial-and-error basis.

[0008] Another aspect of the invention provides a sizer made of a clear material, such as plastic, that includes a scale, allowing the physician to see through the sizer such that he or she may measure the valve.

[0009] Another aspect of the invention is a sizer that is attached to a handle made of a material, such as any of a variety of metals or plastics, that may have various lengths or have an elongatable or telescoping configuration.

[0010] Yet another aspect of the invention is a sizer having a handle that is flexible, allowing easier access to the heart.

[0011] Still another aspect of the invention is a sizer that may be used as an aid in repair or replacement of any heart valve undergoing repair or replacement.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] These and other aspects, features and advantages of which embodiments of the invention are capable of will be apparent and elucidated from the following description of embodiments of the present invention, reference being made to the accompanying drawings, in which

[0013] Fig. 1 is a is an elevation of an embodiment of a sizer of the invention.

DESCRIPTION OF EMBODIMENTS

[0014] Specific embodiments of the invention will now be described with reference to the accompanying drawings. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth

herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. The terminology used in the detailed description of the embodiments illustrated in the accompanying drawings is not intended to be limiting of the invention. In the drawings, like numbers refer to like elements.

[0015] Referring now to Figure 1 there is shown a sizer 10 of the invention. Sizer 10 generally includes a face plate 20 connected to a handle 50.

[0016] The face plate 20 may be formed of a variety of materials, such as metals or plastics. Advantageously, the face plate 20 could be formed of clear plastic, such that the extents of the native valve annulus may be visible through the face plate 20.

[0017] The face plate 20 includes a plurality of markings. Beginning in the upper left-hand corner of the face plate, as depicted in Figure 1, is a first marking 22 denoting the surface area of the sizer. First marking 22 in Figure 1 is 6.1 indicating that the surface area of the sizer is 6.1 cm^2.

[0018] Moving clockwise around the face plate 20, the second marking 24 denotes the anterior posterior (AP) distance. In Figure 1, AP distance is 28mm, as an example. As denoted by the vertical arrows 26 next to the marking 24, the AP distance is the distance from the top of the sizer to the bottom of the sizer in millimeters. To provide further clarification, the arrow 26 may be color-coordinated with the second marking 24.

[0019] Typically, AP distance is only available from charts, and is an estimation. The present invention provides actual AP measurement. In one embodiment, a calibrated scale 30 is provided next to the arrows 26 such that a physician can use the face plate 20 to obtain a measurement of the AP distance, if the sizer height does not match the valve height.

[0020] Continuing clock-wise, a third numeral marking 32 is provided, shown as the number 38 in the example of Figure 1. This number denotes the maximum distance across the sizer 10, in millimeters. This is the sole number typically provided by sizers and is used to identify the sizer itself. For example, the sizer of Figure 1

would typically be referred to as a "38 sizer." Keeping with this convention, a fourth marking 34 is provided (as a 38 in Figure 1), in a larger font at the bottom of the face plate 20.

[0021] To avoid confusion, an arrow 36 may be provided under the marking 32, and optionally color-coordinated with marking 32, that shows the third marking 32 corresponds to the maximum distance across the sizer 10.

[0022] The face plate 10 is connected to a handle 50. The handle 50 may be made of various metals, plastics, or similar materials, and may be flexible or rigid, depending on the surgical approach to the valve. Additionally, the handle 50 may be telescoping or otherwise capable of being elongated.

[0023] In Figure 1, the handle 50 is shown as having a 90 degree bend 52 that is hingedly-connected to the face plate 20 with connectors 54 for easy translation through a vessel. The angular relationship between the face plate 20 and the handle 50 may be controlled with a push rod 60. The push rod 60 may be connected to the center of the face plate 20 via a thread or other connection mechanism. The push rod 60 is offset from the handle 50 to provide leverage and is preferably located in a location where it will not interfere with the visualization of the markings.

[0024] Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the claimed invention. Accordingly, it is to be understood that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

What is claimed is:

1. An annuloplasty ring sizing tool comprising a face plate attached to a handle, the faceplate including a plurality of markings wherein the plurality of markings at least includes a number representing the surface area of the face plate as well as a calibrated scale usable to measure a dimension of a native valve.

2. The annuloplasty ring of claim 1 wherein the plurality of markings further includes a linear vertical dimension of the face plate.

3. The annuloplasty ring of claim 1 wherein the plurality of markings further includes a linear horizontal dimension.

4. The annuloplasty ring of claim 1 wherein the face plate is hingedly attached to the handle.

5. The annuloplasty ring of claim 4 further comprising a push rod for controlling an angular relationship between the face plate and the handle.

6. The annuloplasty ring of claim 1 wherein said face plate comprises clear plastic such that native features are visible through the face plate.

7. The annuloplasty ring of claim 2 wherein the plurality of markings further includes a vertical line adjacent the linear vertical dimension marking.

8. The annuloplasty ring of claim 3 wherein the plurality of markings further includes a horizontal line adjacent the linear horizontal dimension marking.

9. The annuloplasty ring of claim 7 wherein the vertical line marking and the vertical line dimension are of a same color.

10. The annuloplasty ring of claim 8 wherein the horizontal line marking and the horizontal line dimension are of a same color.

11. A method of measuring a native valve for use in selecting an annuloplasty ring comprising:

providing a clear face plate having a scale marking thereon against the native valve;

viewing extents of the native valve through the clear face plate;

using said scale to measure said extents of the native valve.

12. The method of claim 11 wherein using said scale to measure said extents of the native valve comprises using said scale to measure an anterior posterior dimension of the native valve.

13. The method of claim 11 further comprising aligning said face plate with said native valve by manipulating a handle to which the face plate is hingedly attached.

14. The method of claim 13 further comprising controlling an angle between said handle and said face plate by manipulating a push rod to which the face plate is attached.

15. A device for measuring at least one dimension of a native valve comprising a clear face plate attached to a handle, said clear face plate including at least on marking thereon usable to measuring said dimension.

16. The device of claim 15 wherein the at least one marking comprises a scale.

17. The device of claim 15 wherein the at least one marking comprises an anterior posterior length.

18. The device of claim 15 wherein the at least one marking comprises a surface area of the face plate.

19. The device of claim 15 wherein the at least one marking comprises a maximum distance across the face plate.

20. The device of claim 15 wherein the at least one marking includes an anterior posterior length and a vertical line of a first color; and a maximum distance across the face plate and a horizontal line of a second color.

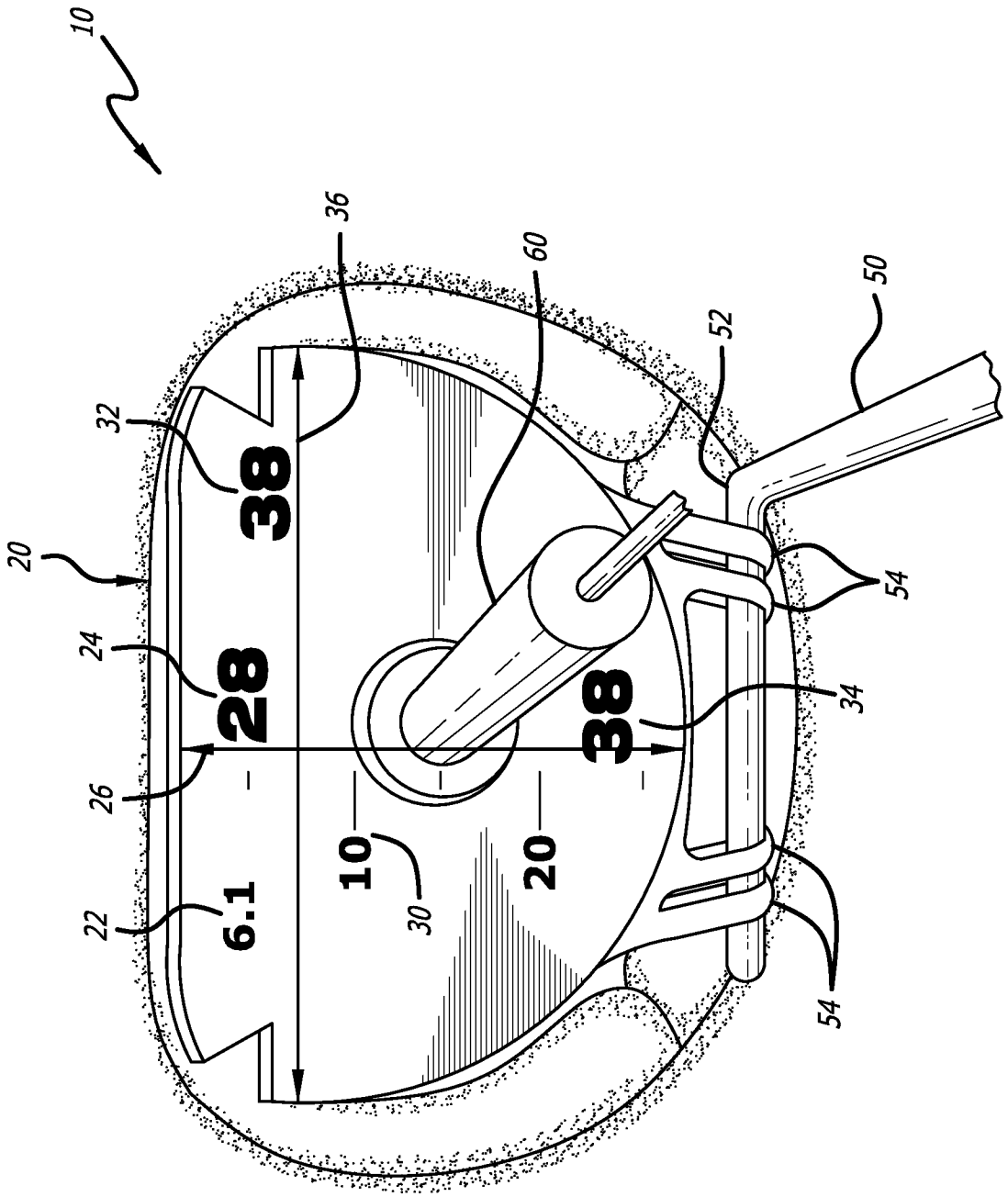


FIG. 1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2019/036623

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/24; A61F 2/82; A61F 2/95 (2019.01)
CPC - A61F 2/2496; A61F 2/2442; A61F 2/2445 (2019.05)

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)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 600/587; 606/148; 623/2 (keyword delimited)

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	DE 299 11 694 U1 (JOSTRA MEDIZINTECHNIK AG) 26 August 1999 (26.08.1999) see machine translation and original	1-3, 6-10 ---------- 4
X --- Y	US 6,019,739 A (RHEE et al) 01 February 2000 (01.02.2000) entire document	11, 12, 15-20 ---------- 13
Y	US 2014/0277421 A1 (EDWARDS LIFESCIENCES CORPORATION) 18 September 2014 (18.09.2014) entire document	4, 13
A	US 6,004,329 A (MYERS et al) 21 December 1999 (21.12.1999) entire document	1-20
A	US 2009/0192600 A1 (RYAN) 30 July 2009 (30.07.2009) entire document	1-20
A	US 2012/0253457 A1 (WINSTON et al) 04 October 2012 (04.10.2012) entire document	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
04 August 2019	26 AUG 2019
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774