



(51) International Patent Classification:
G06G 7/58 (2006.01)

(21) International Application Number:
PCT/US2017/060523

(22) International Filing Date:
08 November 2017 (08.11.2017)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/419,268 08 November 2016 (08.11.2016) US

(71) Applicants: **PRESIDENT AND FELLOWS OF HARVARD COLLEGE** [US/US]; 17 Quincy Street, Cambridge, Massachusetts 02138 (US). **THE GENERAL HOSPITAL CORPORATION** [US/US]; 55 Fruit Street, Boston, Massachusetts 02114 (US). **THE BRIGHAM**

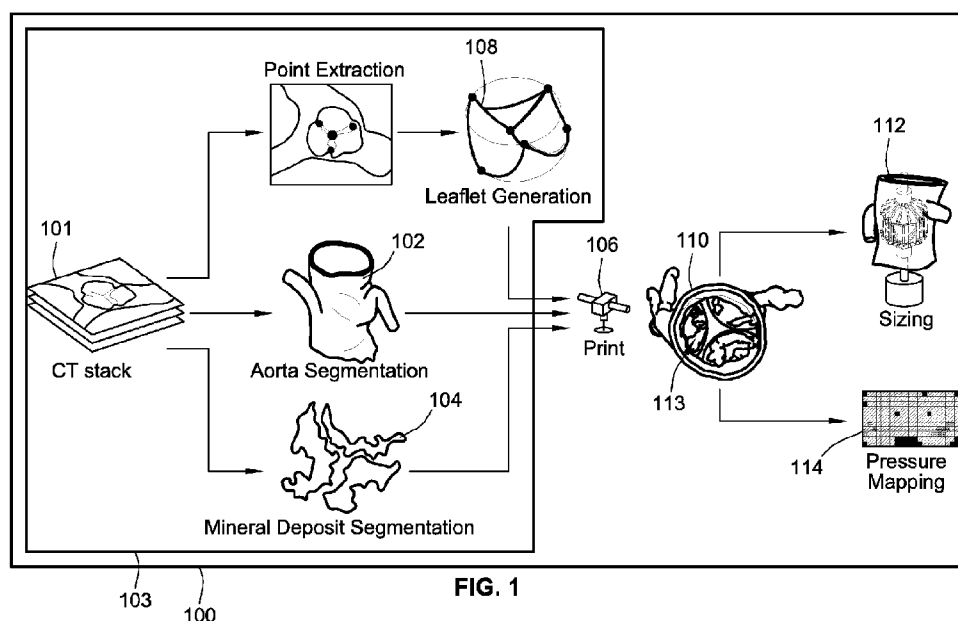
AND WOMEN'S HOSPITAL [US/US]; 75 Francis Street, Boston, Massachusetts 02115 (US).

(72) Inventors: **WEAVER, James, C.**; 60 Oxford St., Cambridge, Massachusetts 02138 (US). **HOSNY, Ahmed**; 114 Line St., Apt. 2, Somerville, Massachusetts 02143 (US). **DILLEY, Joshua, D.**; 160 Commonwealth Avenue, Boston, Massachusetts 02116 (US). **RIPLEY, Beth**; 4245 Roosevelt Way NE, Seattle, Washington 98105 (US). **KELIL, Tatiana**; 125 Pleasant St., Brookline, Massachusetts 02446 (US).

(74) Agent: **RESNICK, David, S.** et al.; Nixon Peabody LLP, 70 W. Madison St., Suite 3500, Chicago, Illinois 60602-4224 (US).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO,

(54) Title: METHODOLOGY AND APPARATUS FOR SIMULATION OF MEDICAL DEVICES



(57) **Abstract:** A system for simulating a medical procedure includes a controller configured to receive medical images of a patient body part and, based on the medical images, to generate a three-dimensional digital model of at least a portion of the patient body part. The system further includes a patient-specific physical phantom formed based on the three-dimensional digital model, the patient-specific physical phantom including an internal cavity. The system also includes a sizer representative of a medical device being inserted within the internal cavity of the patient-specific physical phantom, the sizer being expandable between a plurality of sizes within the internal cavity. Based on sizer measurements, a pressure map identifies areas of excessive contact or lack thereof to show potential leaks.

DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

METHODOLOGY AND APPARATUS FOR SIMULATION OF MEDICAL DEVICES**CROSS-REFERENCE TO RELATED APPLICATION(S)**

[0001] This application claims priority and the benefit of U.S. Provisional Patent Application No. 62/419,268, filed November 8, 2016, which is hereby incorporated by reference herein in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates generally to medical devices, and, more particularly, to sizing and deployment simulation of stent or stent-like medical devices on patient-specific surgical physical phantoms.

BACKGROUND OF THE INVENTION

[0003] In reference to aortic valve disease, an improper function of an aortic valve is primarily based on aortic valve stenosis or aortic regurgitation (AR). Aortic valve stenosis is the most common valvular heart disease in the developed world and in which stiff, fused, thickened, and inflexible valve leaflets lead to narrowing of the aortic valve and, as such, blood flow to the body is limited. The increased pressures required to eject blood cause detrimental myocardial hypertrophy and increased oxygen consumption, leading to ischemia and cell death.

[0004] In aortic regurgitation, valve leaflets do not close completely. Regurgitation causes the blood that is ejected by the heart to immediately flow back onto the heart once the heart stops squeezing and relaxes. The volume overload of the left ventricle leads to eccentric hypertrophy and increased work of the left ventricle.

[0005] Typically, aortic valve surgery requires patients to have a sternotomy incision (i.e., chest is cut open). Open-heart surgery is associated with serious risks in a large number of patients, particularly elderly patients and those with multiple medical comorbidities. An alternative preferred medical procedure to open-heart surgery is transcatheter aortic valve replacement (TAVR) or transcatheter aortic valve implantation (TAVI), which are considered valuable, non-inferior alternatives. For example, the TAVR procedure utilizes a catheter-based delivery system to deliver a prosthetic valve mounted within a stent into a diseased aortic valve. This procedure is minimally invasive and presents less overall risk to the patient.

[0006] However, although TAVR or TAVI procedures are safe alternatives to surgery in appropriately selected patients with aortic stenosis, the procedures suffer from known limitations. For example, there is no direct access to the patient's anatomy to provide precise prosthesis sizing, and the complex three-dimensional anatomy of the aortic root makes it difficult to predict how the prosthetic valve will adapt in the patient. Moreover, because the prosthetic valve is secured at the annular plane in a sutureless fashion, failure to achieve a circumferential seal can result in leaking of blood around the edges of the valve. Leakage results in paravalvular regurgitation or paravalvular leak, which is the most frequent complication after TAVR and which carries increased morbidity and mortality.

[0007] The exact incidence of paravalvular leak is difficult to assess, secondary to heterogeneity, in the current literature in terms of timing and methods of assessment. Reported incidence of paravalvular leak ranges from 41% to 94% in some studies. For example, the Placement of Aortic Transcatheter Valves (PARTNER) trial, which is the only study known that used a core echocardiography laboratory to assess for leak, reported trace or mild paravalvular leaks in 66% of patients and moderate/severe leaks in 12% of patients. A number of other studies have identified moderate or severe leaks to be an independent predictor of short-term and long-term mortality. These patients were also 10 times more likely to not respond to therapy at 6-month follow-up visits.

[0008] The current standard of care for selecting the correct size replacement valve involves making several discrete measurements of the aortic root on two-dimensional (2D) medical images. Measurements made on 2D images can overestimate or underestimate the size of the aortic root, depending on the slice angle of the image, potentially resulting in selection of the wrong size replacement valve. Additionally, the 3D complexity and nature of the anatomy is not fully captured in these 2D images.

[0009] Additionally, multiple discrete measurements often do not translate into a synthesized understanding of the root and how it may interact with a prosthetic valve. Chunky calcifications on the patient's native valve, which may significantly affect the ability of the replacement valve to open fully, often remain unaccounted. Moreover, agreement between multi-model measurements is questionable (i.e., different measurements are obtained using, for instance, CT and MRI). Furthermore, because TAVR is a relatively new technique, it remains unclear and up for debate which 2D measurements should be made and how these measurements translate into the choice of valve size.

SUMMARY OF THE INVENTION

[0010] According to one aspect of the present invention, an expandable sizer is directed to accurately sizing stents or stent-like medical devices, including minimally invasive cardiac valves, on three-dimensional (3D) physical representations of anatomical body parts. The sizer is utilized as a means of pre-surgically and physically simulating the deployment of such devices on patient-specific phantoms.

[0011] According to another aspect of the present invention, a system for simulating a medical procedure includes a controller configured to receive medical images of a patient body part and, based on the medical images, generate a three-dimensional digital model of at least a portion of the patient body part. The system further includes a patient-specific physical phantom formed based on the three-dimensional digital model, the patient-specific physical phantom including an internal cavity. The system also includes a sizer representative of a medical device being inserted within the internal cavity of the patient-specific physical phantom, the sizer being expandable between a plurality of sizes within the internal cavity.

[0012] According to yet another aspect of the present invention, a method for simulating a medical procedure includes receiving medical images of a patient body part, and, based on the medical images, generating, via a controller, a three-dimensional digital model of at least a portion of the patient body part. The method further includes, based on the three-dimensional digital model, forming a patient-specific physical phantom having an internal cavity, and inserting a sizer within the internal cavity of the patient-specific physical phantom, the sizer being representative of a medical device. The method also includes expanding the sizer within the internal cavity between a plurality of sizes.

[0013] According to yet another aspect of the present invention, a method for simulating a medical procedure includes receiving medical images of an aortic sinus, leaflets, and mineral (e.g., calcium) deposits of an aortic root, and, based on the medical images, generating, via a controller, a simulated three-dimensional digital model of the aortic root. Based on the three-dimensional digital model of the aortic root, the method further includes forming a patient-specific physical phantom having an internal cavity, and inserting a sizer within the internal cavity of the patient-specific physical phantom, the sizer being representative of a prosthetic valve. The method also includes expanding the sizer within the internal cavity between at least two different sizes of the sizer, and determining one or more pressure measurements in response to the expanding of the size. The pressure measurements are indicative of pressure contact achieved at a plurality of locations between the sizer and

the patient-specific physical phantom. A prosthetic valve is formed based on the measurements.

[0014] Additional aspects of the invention will be apparent to those of ordinary skill in the art in view of the detailed description of various embodiments, which is made with reference to the drawings, a brief description of which is provided below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] FIG. 1 is a diagrammatic illustration of an overall workflow process and system of sizing simulation and leak prediction.

[0016] FIG. 2 is a screenshot showing a geometric model with a plurality of fiducial points extracted from biomedical images.

[0017] FIG. 3 is a screenshot showing a geometric model representing controls of a first set of primary fiducial points.

[0018] FIG. 4 is a screenshot showing a geometric model representing controls of a second set of primary fiducial points.

[0019] FIG. 5 is a screenshot showing a geometric model representing adjustment of a third set of primary fiducial points.

[0020] FIG. 6 is a screenshot showing a geometric model representing controls of free leaflet edges.

[0021] FIG. 7 is a screenshot showing a geometric model representing a set of secondary controls per leaflet.

[0022] FIG. 8 is a screenshot of a parametric leaflet model and segmented aortic sinus and mineral deposits.

[0023] FIG. 9A is a perspective view of a sizer.

[0024] FIG. 9B is a perspective view of the sizer of FIG. 9A in an expanded form and mounted to a stepper motor.

[0025] FIG. 9C is a perspective view of the sizer of FIG. 9A inserted into a patient phantom.

[0026] FIG. 10A is a perspective view of a sizer in a closed position, without a wrapped flexible sheet, according to another exemplary embodiment.

[0027] FIG. 10B is a perspective view of the sizer of FIG. 10A illustrated in an open position.

[0028] FIG. 11A is a perspective view of a sizer in a closed position, with a wrapped flexible sheet, according to another exemplary embodiment.

[0029] FIG. 11B is a perspective view of the sizer of FIG. 11A illustrated in an open position.

[0030] FIG. 12A is a perspective view illustrating a sizer in a closed position prior to insertion into a patient valve phantom.

[0031] FIG. 12B is a perspective view illustrating the sizer of FIG. 12A first inserted into a patient valve phantom, then set to a specific diameter.

[0032] FIG. 12C is a perspective view illustrating the sizer of FIG. 12B expanded to a different diameter for determining gaps between the sizer and the patient valve phantom.

[0033] FIG. 12D is a perspective view illustrating adjustment of sizer location of the sizer of FIG. 12C within the patient valve phantom.

[0034] FIG. 13 is a flowchart illustrating a sizing workflow process.

[0035] FIG. 14A is a diagrammatic illustrating a patient valve phantom cut open along an axial direction and flattened.

[0036] FIG. 14B is a diagrammatic illustrating pressure mapping of a contact zone between the sizer and the patient valve phantom of FIG. 14A.

[0037] FIG. 15 is a superior view of a leaky patient valve phantom for a patient V.

[0038] FIG. 16 is a superior view of the patient valve phantom of FIG. 15 with an inserted sizer set at a diameter of 20 millimeters (mm).

[0039] FIG. 17 is a superior view of the patient valve phantom of FIG. 15 with the sizer set at a diameter of 23 mm.

[0040] FIG. 18 is a superior view of the patient valve phantom of FIG. 15 with the sizer set at a diameter of 26 mm.

[0041] FIG. 19 is an inferior view of the patient valve phantom of FIG. 15 with the sizer set at a diameter of 26 mm.

[0042] FIG. 20A is an anterior/posterior view of the patient valve phantom of FIG. 15 with the sizer set at a diameter of 26 mm.

[0043] FIG. 20B is side view illustrating an ex-ray image of the sizer in the patient valve phantom of FIG. 15 with a leak on one side.

[0044] FIG. 20C is a contact zone mapping of patient V of FIGs. 15-20B.

[0045] FIG. 21 is a superior view of a non-leaky patient valve phantom for a patient J.

[0046] FIG. 22 is a superior view of the patient valve phantom of FIG. 21 with the sizer set at a diameter of 20 millimeters (mm).

[0047] FIG. 23 is a superior view of the patient valve phantom of FIG. 21 with the sizer set at a diameter of 23 mm.

[0048] FIG. 24 is an inferior view of the patient valve phantom of FIG. 21 with the sizer set at a diameter of 23 mm.

[0049] FIG. 25A is an anterior/posterior view of the patient valve phantom of FIG. 21 with the sizer set at a diameter of 23 mm.

[0050] FIG. 25B is side view illustrating an ex-ray image of the sizer in the patient valve phantom of FIG. 21 with no leaks.

[0051] FIG. 25C is a contact zone mapping of patient J of FIGs. 21-25B.

[0052] FIG. 26A is a flowchart illustrating a prediction grading system.

[0053] FIG. 26B is a plot illustrating sizing and leak prediction data.

[0054] FIG. 26C is a continuation of the plot of FIG. 26B.

[0055] While the invention is susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and will be described in detail herein. It should be understood, however, that the invention is not intended to be limited to the particular forms disclosed. Rather, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION

[0056] While this invention is susceptible of embodiment in many different forms, there is shown in the drawings and will herein be described in detail preferred embodiments of the invention with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the broad aspect of the invention to the embodiments illustrated. For purposes of the present detailed description, the singular includes the plural and vice versa (unless specifically disclaimed); the words “and” and “or” shall be both conjunctive and disjunctive; the word “all” means “any and all”; the word “any” means “any and all”; and the word “including” means “including without limitation.” Where a range of values is disclosed, the respective embodiments includes each value between the upper and lower limits of the range.

[0057] Referring to FIG. 1, an overview is presented to illustrate an overall workflow process of sizing simulation and leak prediction. Generally, the process is directing to selecting a correct prosthetic replacement valve and, hence, reduce risk of paravalvular leak. The process includes (a) creating 3D physical representations of anatomical regions of interest (e.g., the aortic sinus, leaflets, and mineral deposits, such as calcium), and (b) utilizing a physical sizer to simulate the deployment of the actual replacement valve and,

hence physically simulate a transcatheter aortic valve replacement (TAVR) procedure. The process is intended to include any replacement stent, stent-like device, or prosthetic valve for any anatomical body part, including any stent (or stent-like device) for any artery or blood channel. The process is further intended to include any replacement valve physical sizes for all heart valves, including mitral, pulmonary, and tricuspid valves, and any replacement valve physical size for TAVR, including other valve manufacturers on the market. By way of example, the process includes replacement valves of different designs by other manufacturers, such as cylindrical designs, hourglass designs, etc.

[0058] More specifically, a system 100 includes a controller 103 that is configured to receive medical images of a patient body part and, based on the medical images, to generate a three-dimensional digital model of at least a portion of the patient body part. By way of example, the images are provided from a cardiac CT stack 101. Segmentation of the aorta 102 and mineral deposits 104 (e.g., calcium deposits), via the controller 103, is further converted into 3D printable mesh files 106. Then, a reconstruction method allows the 3D modeling of leaflets based on fiduciary points of a leaflet parametric model 108 selected within the CT stack.

[0059] A patient-specific physical phantom 110 is digitally prepared and it is 3D printed on a multi-material printer. In other words, the patient-specific physical phantom 110 is formed based on a three-dimensional digital model and represents a 3D printed version of the aorta, 102, the mineral deposits 104, and the leaflet parametric model 108. Alternatively, the phantom 110 is molded or milled through a subtractive process. The three-dimensional digital model simulates one or more of an aortic root, an aortic sinus, leaflets, and mineral deposits. The aorta/leaflets, and mineral deposits are printed in flexible and rigid materials, respectively. A sizer 112 is, then, inserted into an internal cavity 113 of the phantom 110 to simulate multiple prosthetic sizes while allowing for leak observation. The sizer is representative of a medical device and is expandable between a plurality of sizes within the internal cavity 113 of the phantom 110. The sizer 112 also maps out, via pressure mapping 114, the pressure exerted by the prosthetic sizes on the aortic sinus to identify areas of excessive contact or lack thereof, e.g., to identify leaks.

[0060] Referring to FIG. 2, generally, a patient's medical scan data provides images from which 3D digital models of a region of interest are generated (e.g., models of the aortic sinus and mineral deposits). IN FIG. 2, "L" stands for left, "R" stands for right, and "NC" stands for non-coronary. Because aortic valve leaflets are very thin and cannot be resolved

accurately in medical images, a mathematical relationship between seven fiduciary points is used to parametrically regenerate the leaflets.

[0061] The seven fiduciary points include one point at the coaptation zone of the three leaflets (P0), three points at the fibrous continuities between the interleaflet triangles (leaflet commissures P1, P2, P3), and three points at the basal attachments of each of the three leaflets (hinge points P4, P5, and P6). The viewing plane through the medical images is adjusted to better locate the fiduciary points. Curves are interpolated through these fiduciary points and the geometry of the leaflets is generated. Further minor adjustments allow for fine tuning of the location of the leaflets.

[0062] Then, the digital models are 3D printed into physical patient-specific phantoms. For example, multi-material 3D printers are used with materials of different elastic moduli to match, respectively, the flexibility and rigidity of the aortic sinus and mineral deposits. Alternatively, the phantoms are formed using other modes of fabrication, such as molding, casting, etc.

[0063] Specifically, in this example, the seven fiduciary points are extracted from a biomedical image stack, such as the CT stack 101, by a trained physician. The fiduciary points include a first point (i.e., P0) at the coaptation zone of the three leaflets, three points at the fibrous continuities between the interleaflet triangles (i.e., leaflet commissures P1, P2, and P3), and three points at the basal attachments of each of the three leaflets (i.e., hinge points P4, P5, P6).

[0064] The XYZ coordinates of the fiduciary points P0-P6 are used as input into a parametric model in which curves are interpolated between the inputted fiduciary points to generate the leaflets. Two sets of controls are used to adjust and/or align features of the parametric model. A set of primary controls adjusts the fiduciary points and the free leaflet edges. A set of secondary controls aligns the leaflets with the mineral deposits.

[0065] Referring to FIGs. 3-6, the set of primary controls is adjusted. The primary controls are global and act on the model as illustrated in the exemplary Table 1 provided below.

Table 1

Controls		Leaflet Affected		
Type	Name	Left (L)	Right (R)	Noncoronary (NC)
Primary	P1_X	•	•	
	P2_X	•		•
	P3_Y		•	•
	P4_X	•		
	P4_Z	•		
	P5_X			•
	P5_Z			•
	P6_X		•	
	P6_Z		•	
	FreeEdge_midpoint	•	•	•
Secondary	curve1_midpoint	All secondary controls are per leaflet		
	curve1_endpoint			
	curve2_midpoint			
	curve3_midpoint			
	curve3_endpoint			

[0066] In FIGs. 3-5, geometric models represent respective ones of the six fiduciary point controls, while in FIG. 6 a geometric model represents the free leaflet edges controls. The fiduciary points are moved in 3D space to ensure correct alignment with the aortic sinus anatomy. Adjusting the midpoint location of the free leaflet edge curve ensures it is correctly aligned with mineral deposits. The goal of the primary controls (except freeEdge_midpoint) is to align parametrically generated leaflets with the aortic sinus. The goal of the freeEdge_midpoint and the secondary points is to align parametrically generated leaflets with the mineral deposits.

[0067] Referring to FIG. 7, a set of secondary controls per leaflet (as identified in Table 1 above) are used to align the leaflet with mineral deposits. Opacity of multiple elements is

adjusted to allow unobstructed view during fiduciary point adjustment such that the resultant surface is midway through the mineral deposits. The adjustment of secondary controls ensures that all deposits are well contained within the leaflet and are not “floating.” The leaflet geometry is constructed as a surface spanning the respective two free edges. Three curves between the free edges further define the leaflet geometry. The secondary controls, in turn, allow for adjusting these curves.

[0068] Referring to FIG. 8, an exemplary parametric model of a leaflet 108 is outputted based on inputted fiduciary points 109 to represent a 3D print of a patient-specific phantom 110. The patient-specific phantom 110, thus, includes the parametric model of the leaflet 108, the aorta 102, and the mineral deposits 104. In the parametric leaflet model 108, aortic leaflets are parametrically generated from patient data to fit the aortic sinus.

[0069] According to one example, referring to FIGs. 3-8, a browser-based application generates aortic valve cusps that are typically difficult to resolve and segment from CT data. Initially, coordinates of the seven fiduciary points are uploaded as a .csv file, and the aortic sinus and calcium as .stl files. In reference to the browser-based application, after uploading the .csv and .stl files as described above, the user adjusts the primary and secondary controls using sliders. Eventually, the .stl file of the leaflets is downloaded. This .stl file of the leaflets is combined with a .stl file of the sinus and of the deposits, the combined file being printed all in one as the patient phantom 110.

[0070] Referring to FIGs. 9A-9C, a sizer 130 is used for testing the patient phantom 110. Generally, the size 130 is either manually adjustable for achieving the desired size or is motor-driven for accurate sizing. Specifically, in FIG. 9A the sizer 130 is in a contracted, or closed, form. In this example, the sizer 130 is intended to be hand-driven to expand or contract the mechanism, which is achieved by holding a lower portion 132a of a stud 132 in one hand and using the other hand to rotate an upper portion 132b of the stud 132. Because the sizer is manually driven, scaled marks on the stud 132 provide visual cues to the diameter at which the sizer is set and, hence, allows for adjustment.

[0071] In FIG. 9B, the sizer 130 is mounted onto a stepper motor 140 to allow for accurate rotation of the stud 132 and, hence, accurate expansion and contraction radii. The motor-driven sizer 130 is controlled via a microprocessor that is connected to a graphical user interface (GUI) and by which a desired diameter is set. In FIG. 9C, the sizer 130 is inserted into the patient phantom 110 for testing the fit.

[0072] Referring to FIGs. 10A-11B, a sizer 150 is, generally, a mechanism that converts rotation into radial expansion or contraction and is designed or re-designed to match the

geometry and size options of any stent or stent-like device. The sizer 150 includes a central stud 152 with right-hand and left-hand threads on either side 152a, 152b. An expandable mechanism 154 of interlinked arms 156 is positioned around the stud 152. The mechanism 154, for example, is 3D printed or assembled from machined parts. A flexible sheet 158 is optionally wrapped around the mechanism 154 to provide a closed-cylindrical form (as shown in FIGs. 11A and 11B). By way of example, the flexible sheet 158 is an aluminum sheet, which is used because it springs back into its original stable shape after expansion.

[0073] A pressure-sensitive mat 160 is optionally placed on an outer surface of the flexible sheet 158 to record pressure exerted by the sizer 150 on the aortic sinus and crushed native leaflets. The pressure-sensitive mat 160 is connected to a controller 162 to help generate a surface contact map between the replacement and diseased valves. The surface contact map is generated based on output signals indicative of pressure sensed at various locations between the pressure-sensitive mat 160 and a patient phantom. Areas of low or no contact (i.e., low or no pressure) are more likely to develop into leaks.

[0074] Clockwise and anti-clockwise rotation of the central stud 152 causes the mechanism 154 and the flexible sheet 158 to radially increase and decrease, respectively. The rotation allows for the simulation of a stent or stent-like devices at virtually any size. Various other alternative embodiments include different geometries and/or materials, with a primary feature directed to increasing and decreasing the size of the sizer within a patient phantom.

[0075] Referring to FIGs. 12A-12D, a sizing workflow is illustrated for a phantom 170 and a sizer 180. Generally, the sizer 180 is modeled after an existing replacement valve on the market, such as an Edwards Sapien XT valve, but is sufficiently universal to simulate any stent that maintains its circularity when deployed.

[0076] Specifically, in FIG. 12A the patient valve phantom is prepared, with the sizer 180 being contracted (or closed) to a minimum diameter and inserted into the patient valve phantom 170. The sizer 180 is manually adjusted or adjusted via a remotely controlled motor 182. Optionally, if the sizer 180 is modeled based on a specific existing prosthetic valve, a manufacturer's recommendation is considered for placement of the patient valve phantom 170. For example, the sizer 180 is placed such that it is coaxial with the aortic root and half of the sizer 180 is positioned below the aortic annulus. If different valve sizes are produced by a manufacturer, each valve having a different height, the height of the sizer 180 is modeled after the mean of the height of the different valve sizes. Optionally, the sizer 180 is

redesigned such that the height also changes as it is being opened and/or closed to increase simulation accuracy.

[0077] In FIG. 12B, the collapsed sizer 180 is inserted into the patient valve phantom 170. The sizer diameter is set to a specific value representing the smallest valve size available for use. In FIG. 12C, multiple valve sizes are simulated while checking for leaks and mapping out contact pressure. The diameter of the sizer 180 is adjusted in a D direction to simulate different valve sizes, while gaps between the sizer 180 and the patient valve phantom 170 are examined by eye and noted. Pressure sensor readings map out the pressure distribution between the sizer 180 and the patient valve phantom 170. In FIG. 12D, the sizer 180 is relocated in an H direction to identify the best placement. The position of the sizer 180 within the patient valve phantom 170 is adjusted axially slightly up or down to examine possibilities of better fit at the set diameter. Then, the sizing procedure illustrated and described in reference to FIGs. 12B-12D is repeated for each of the next available sizes.

[0078] Accordingly, based on the above exemplary embodiment, a single sizer allows simulation of all four sizes in which a specific valve is purchased on the market. At each size, the operator visually checks for gaps (which represent possible leaks) between the replacement valve and the aortic wall. The operator also observes how the calcified leaflets react to the expanding replacement valve as it is deployed. Furthermore, the operator moves the sizer up and down along the aortic sinus to explore better fitting locations that minimize possible leaks. Additionally, the operator refers to the digital pressure mat output to correlate with visual observation.

[0079] Referring to FIG. 13, a decision-making flowchart illustrates a sizing workflow process. The testing methodology is a trial-and-error approach in which no specific size is assumed as a testing starting point at step 200. Instead, the smallest available size is tested first. If the first size is loose, the next size is tested at step 202. If a first good fit is achieved at step 204, then leaks/no leaks are noted (visually and/or via a pressure sensor mat) and the next size is tested at step 206. If a second good fit is achieved at step 204, then leaks/no leaks are noted again and a potential excessive stretch of the valve is noted at step 208.

[0080] Referring to FIGs. 14A and 14B, mapping of pressure is illustrated between a sizer and a patient valve phantom. In FIG. 14A, a patient valve phantom is cut open along an axial direction and is flattened out. All three native leaflets 209, i.e., non-coronary (NC), right (R), and left (L), are seen with mineralized deposits 211 on them. For reference to specific locations, general clock face positions (i.e., 1-12) are used.

[0081] In FIG. 14B, pressure mapping of a contact zone is illustrated between the sizer and the patient valve phantom. Areas of no contact that connect the top edge of the sizer with the bottom are potential leak locations (arrow indicators show examples of such locations). Areas of excessively high contact pressure (e.g., higher than a threshold indicated by a physician) are potential aortic root rupture locations. The mapping is done by using either a one-time use passive sensor or an active electrical sensor mat. An example of a one-time use passive sensor is Pressurex®, currently available at www.pressurex.com. An example of an active electrical sensor mat is a Pressure Mapping Sensor 5051 from Tekscan®, described at www.tekscan.com. Because the pressure map output is a gradient of values, the map is thresholded to transform the data into a binary format where it is either in contact or it is not in contact.

[0082] Referring to FIGs. 15-20C, a sequence illustrates testing multiple sizes on a single patient valve phantom 210 for a patient V with a leak. In FIG. 15, the patient valve phantom 210 is without a sizer 212. In FIG. 16, the sizer 212 is inserted within the patient valve phantom 210. The sizer 212 is set at a 20 mm diameter, which results in gaps around the sizer 212. Visual aids in the form of markings in FIG. 16 show the location and severity of such gaps. For example, a marking of “2” shows a mild potential leak, while a marking of “3” shows a more severe potential leak. Optionally, the markings are cross-referenced with a pressure mat output.

[0083] In FIG. 17, the sizer 212 is set at a 23 mm diameter, which also results in gaps around the sizer 212. In FIGs. 18-20A, the sizer 212 is set at a 26 mm diameter, which also results in gaps 214 (i.e., leaks) around the sizer 212 at the 10 o'clock position. In FIG. 20B, an x-ray image of the sizer 212 in the phantom 210 clearly shows a leak L on one side. In FIG. 20C, a contact zone mapping of patient V shows the original map on top, with a thresholded map on the bottom to show differences in pressures indicative of a leak position.

[0084] Referring to FIGs. 21-25C, a sequence illustrates testing multiple sizes on a single patient valve phantom 220 for a patient without a leak. In FIG. 21, the patient valve phantom 220 is without a sizer 222. In FIG. 22, the sizer 222 is inserted within the patient valve phantom 220. The sizer 222 is set at a 20 mm diameter, which results in gaps around the sizer 222. In FIGs. 23-25A, the sizer 222 is set at a 23 mm diameter, which does not result in gaps around the sizer 222. In FIG. 25B, an x-ray image of the sizer 222 in the phantom 220 clearly shows no leaks. In FIG. 25C, a contact zone mapping of patient J shows the original map on top, with a thresholded map on the bottom to show differences in pressures.

[0085] Referring to FIGs. 26A- 26C, a grading system is directed to assessing the accuracy of leak prediction. The flowchart of FIG. 26A is based on grades A-F and shows a 60% matched installed size and a 57% matched leak/no leak prediction at installed size. The data of FIGs. 26B and 26C evidences predictions, if the installed size was guessed correctly or not, as well as the leak or absence thereof.

[0086] Optionally, a prosthetic implant is formed based on pressure measurements made via an expandable sizer and a patient-specific physical phantom (as described above). Thus, after taking the pressure measurements, a patient-specific prosthetic is designed in a way to match the patient anatomy. As such, the patient-specific prosthetic is a “perfect” fit for that patient. According to one example, the patient-specific prosthetic is a heart implant.

[0087] Each of these embodiments and obvious variations thereof is contemplated as falling within the spirit and scope of the claimed invention, which is set forth in the following claims. Moreover, the present concepts expressly include any and all combinations and sub-combinations of the preceding elements and aspects.

CLAIMS

What is claimed is:

1. A system for simulating a medical procedure, the system comprising:
a controller configured to:
 receive medical images of a patient body part,
 based on the medical images, generate a three-dimensional digital model of at
 least a portion of the patient body part;
a patient-specific physical phantom formed based on the three-dimensional digital
model, the patient-specific physical phantom including an internal cavity; and
a sizer representative of a medical device being inserted within the internal cavity of
the patient-specific physical phantom, the sizer being expandable between a plurality of sizes
within the internal cavity.
2. The system of claim 1, wherein the three-dimensional digital model simulates an
aortic root.
3. The system of claim 2, wherein the three-dimensional digital model includes
simulation of aortic sinus, leaflets, and mineral deposits of the aortic root.
4. The system of claim 1, further comprising a medical device formed based on
measurements determined by the plurality of sizes of the sizer within the internal cavity of
the patient-specific physical phantom.
5. The system of claim 4, wherein the medical device is selected from a group consisting
of a stent, a stent-like device, and a prosthetic valve.
6. The system of claim 1, wherein the controller is further configured to parametrically
regenerate patient anatomy of the patient body part from a plurality of fiduciary points
illustrated in the medical images, the three-dimensional digital model being based on the
parametrically regenerated patient anatomy.
7. The system of claim 6, wherein the patient body part includes an aortic sinus, three
leaflets, and mineral deposits, the plurality of fiduciary points including seven fiduciary
points for determining the anatomy of the three leaflets of an aortic valve.

8. The system of claim 7, wherein the seven fiduciary points include a point at a coaptation zone of the three leaflets, three fiduciary points at fibrous continuities between interleaflet triangles, and three hinge fiduciary points at basal attachments of each of the three leaflets.

9. The system of claim 8, wherein the controller is further reconfigured to generate a three-dimensional geometry of the three leaflets in response to interpolating curves through the seven fiduciary points.

10. The system of claim 1, wherein the patient-specific physical phantom is selected from a group consisting of a three-dimensional printed model, a molded model, or a cast model.

11. The system of claim 1, further comprising a pressure-sensitive mat positioned on an outer surface of the sizer and communicatively coupled to the controller, the pressure-sensitive mat providing output signals indicative of pressure sensed at various locations between the sizer and the patient-specific physical phantom.

12. The system of claim 11, wherein the controller is further configured to generate a surface contact map based on the output signals indicative of the pressure sensed at the various locations.

13. A method for simulating a medical procedure, the method comprising:
receiving medical images of a patient body part;
based on the medical images, generating, via a controller, a three-dimensional digital model of at least a portion of the patient body part;
based on the three-dimensional digital model, forming a patient-specific physical phantom having an internal cavity;
inserting a sizer within the internal cavity of the patient-specific physical phantom, the sizer being representative of a medical device; and
expanding the sizer within the internal cavity between a plurality of sizes.

14. The method of claim 13, wherein the medical procedure includes a transcatheter aortic valve replacement (TAVR) procedure.

15. The method of claim 13, further comprising forming a medical device based on measurements determined by the plurality of sizes of the sizer within the internal cavity of the patient-specific physical phantom.

16. The method of claim 13, further comprising parametrically regenerating patient anatomy of the patient body part from a plurality of fiduciary points illustrated in the medical images, the three-dimensional digital model being based on the parametrically regenerated patient anatomy.

17. The method of claim 13, further comprising forming the patient-specific physical phantom via one or more of a three-dimensional printing process, a molding process, and a casting process.

18. A method for simulating a medical procedure, the method comprising:
receiving medical images of an aortic sinus, leaflets, and mineral deposits of an aortic root;
based on the medical images, generating, via a controller, a simulated three-dimensional digital model of the aortic root;
based on the three-dimensional digital model of the aortic root, forming a patient-specific physical phantom having an internal cavity;
inserting a sizer within the internal cavity of the patient-specific physical phantom, the sizer being representative of a prosthetic valve;
expanding the sizer within the internal cavity between at least two different sizes of the sizer;
determining one or more pressure measurements in response to the expanding of the size, the pressure measurements being indicative of pressure contact achieved at a plurality of locations between the sizer and the patient-specific physical phantom; and
forming the prosthetic valve based on the measurements.

19. The method of claim 18, wherein the controller is further configured to parametrically regenerate the aortic leaflets from a plurality of fiduciary points illustrated in the medical images, the plurality of fiduciary points including a point at a coaptation zone of the leaflets,

three fiduciary points at fibrous continuities between interleaflet triangles, and three hinge fiduciary points at basal attachments of each of the leaflets.

20. The method of claim 18, further comprising forming the prosthetic valve via one or more of a three-dimensional printing process, a molding process, and a casting process.

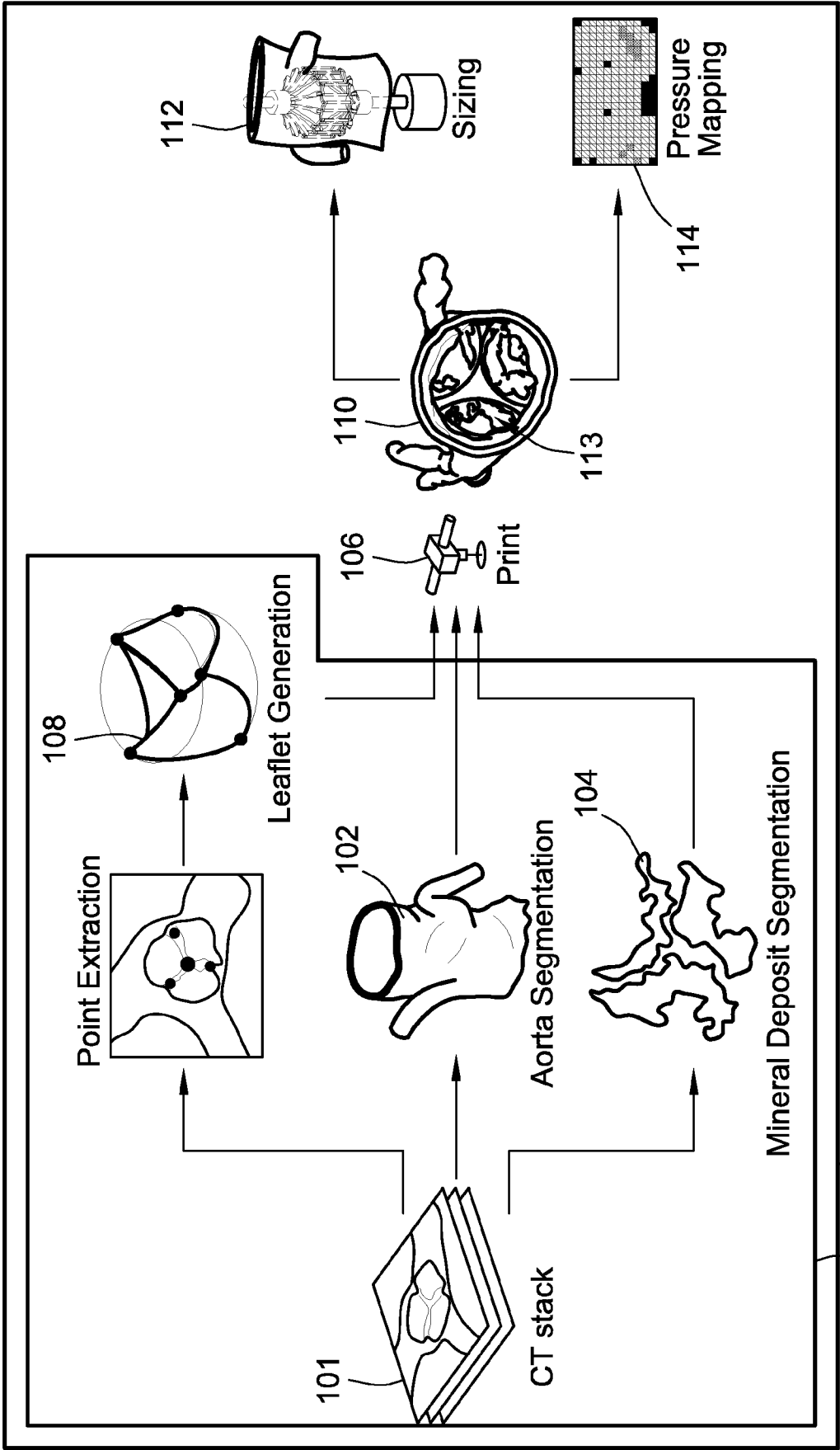


FIG. 1

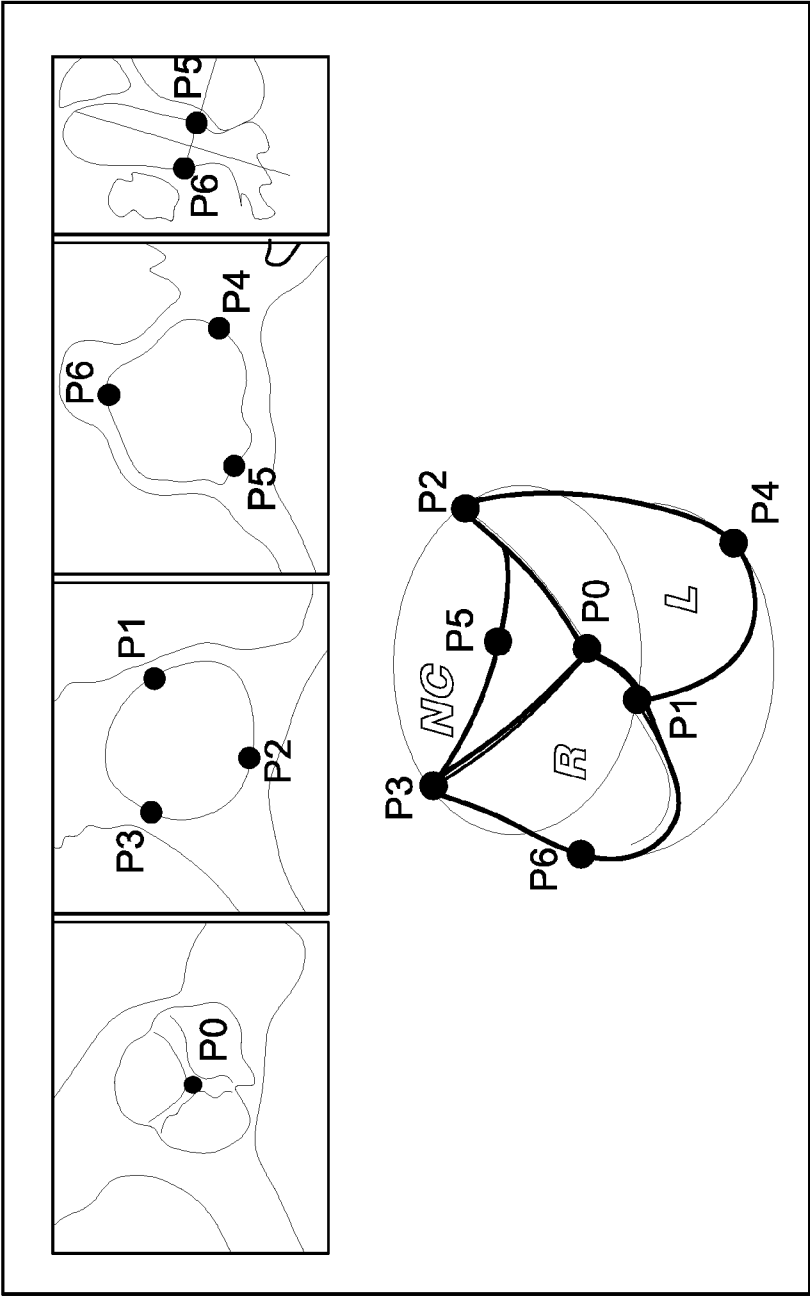


FIG. 2

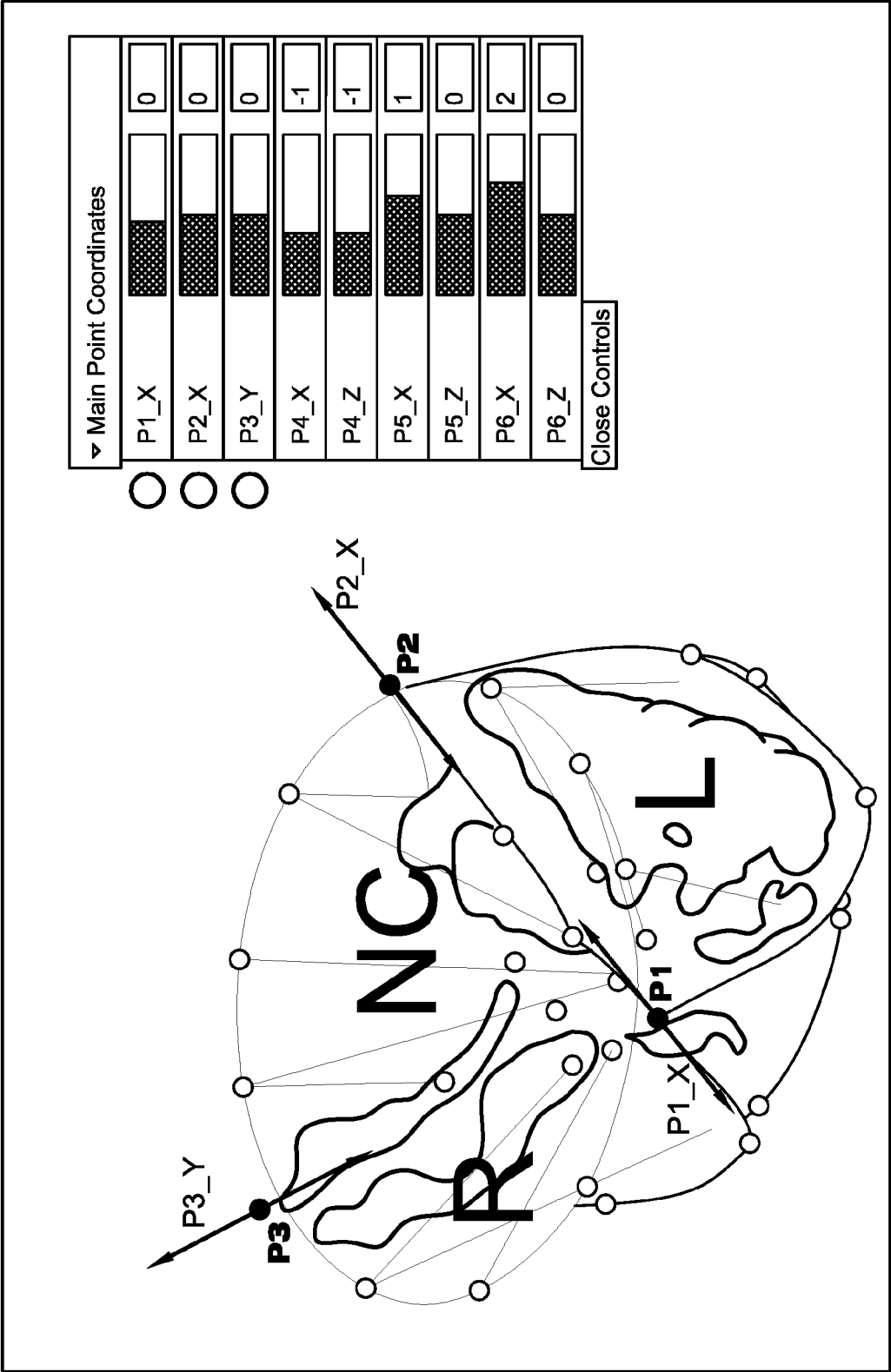


FIG. 3

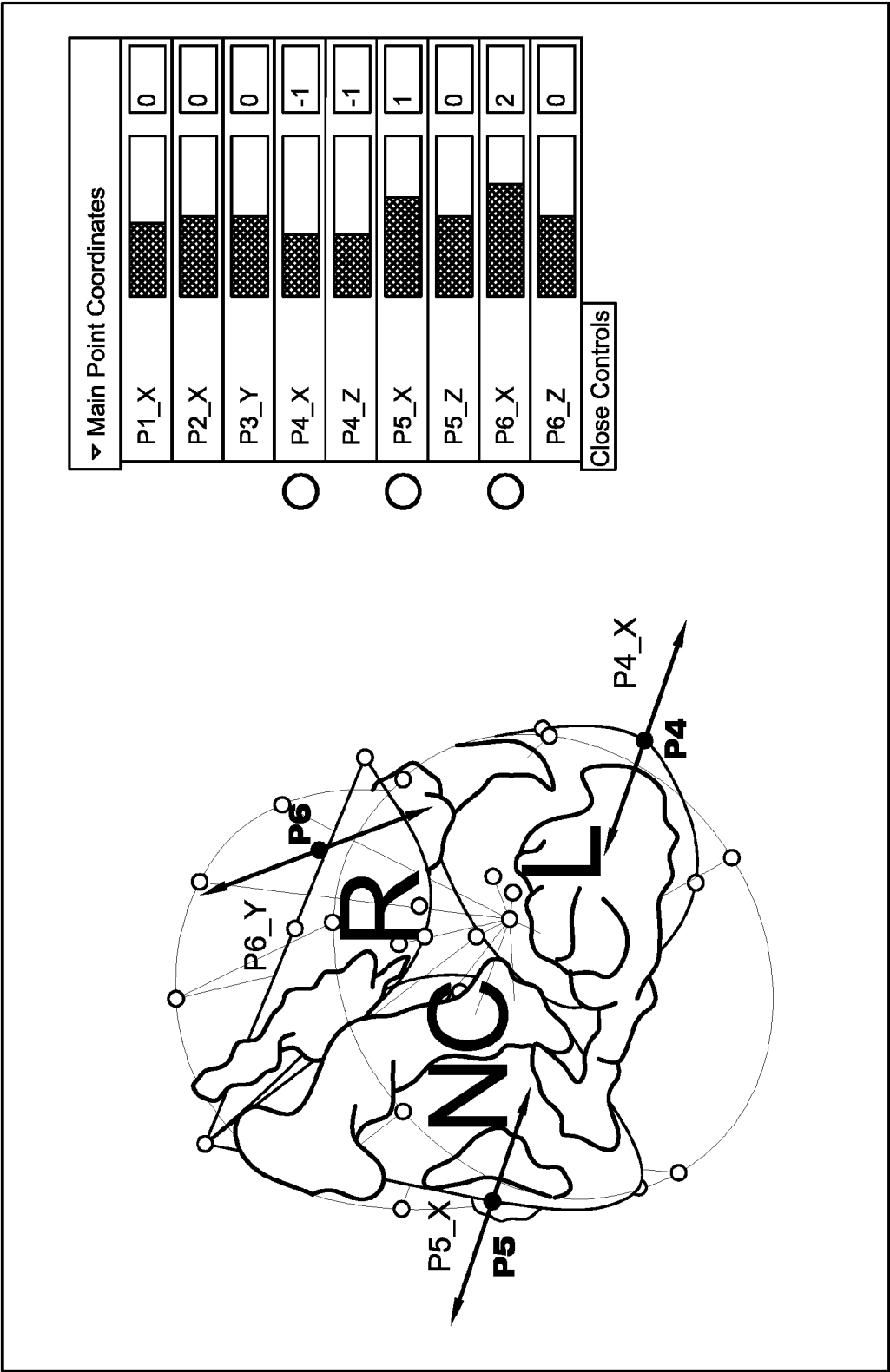


FIG. 4

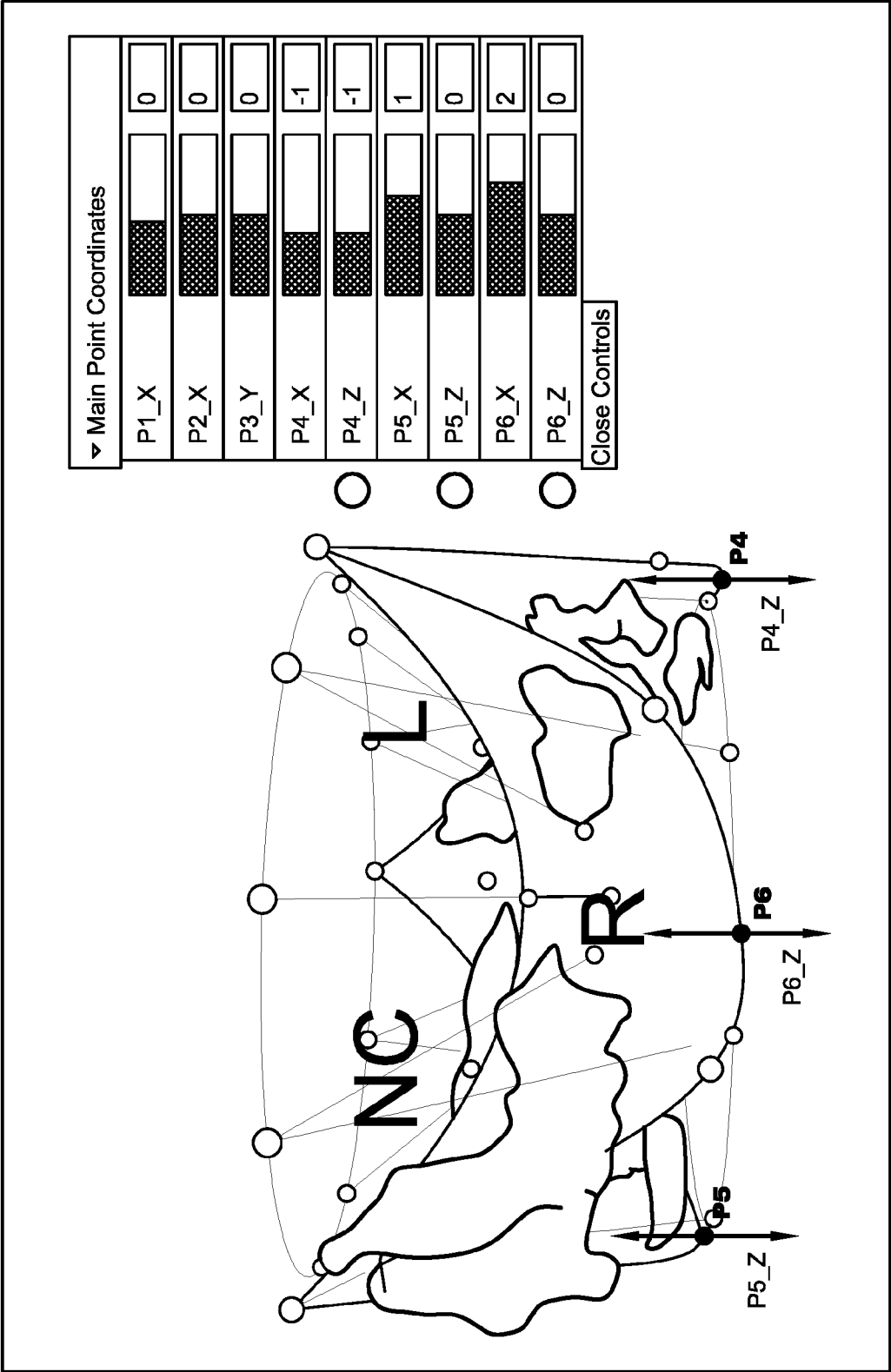


FIG. 5

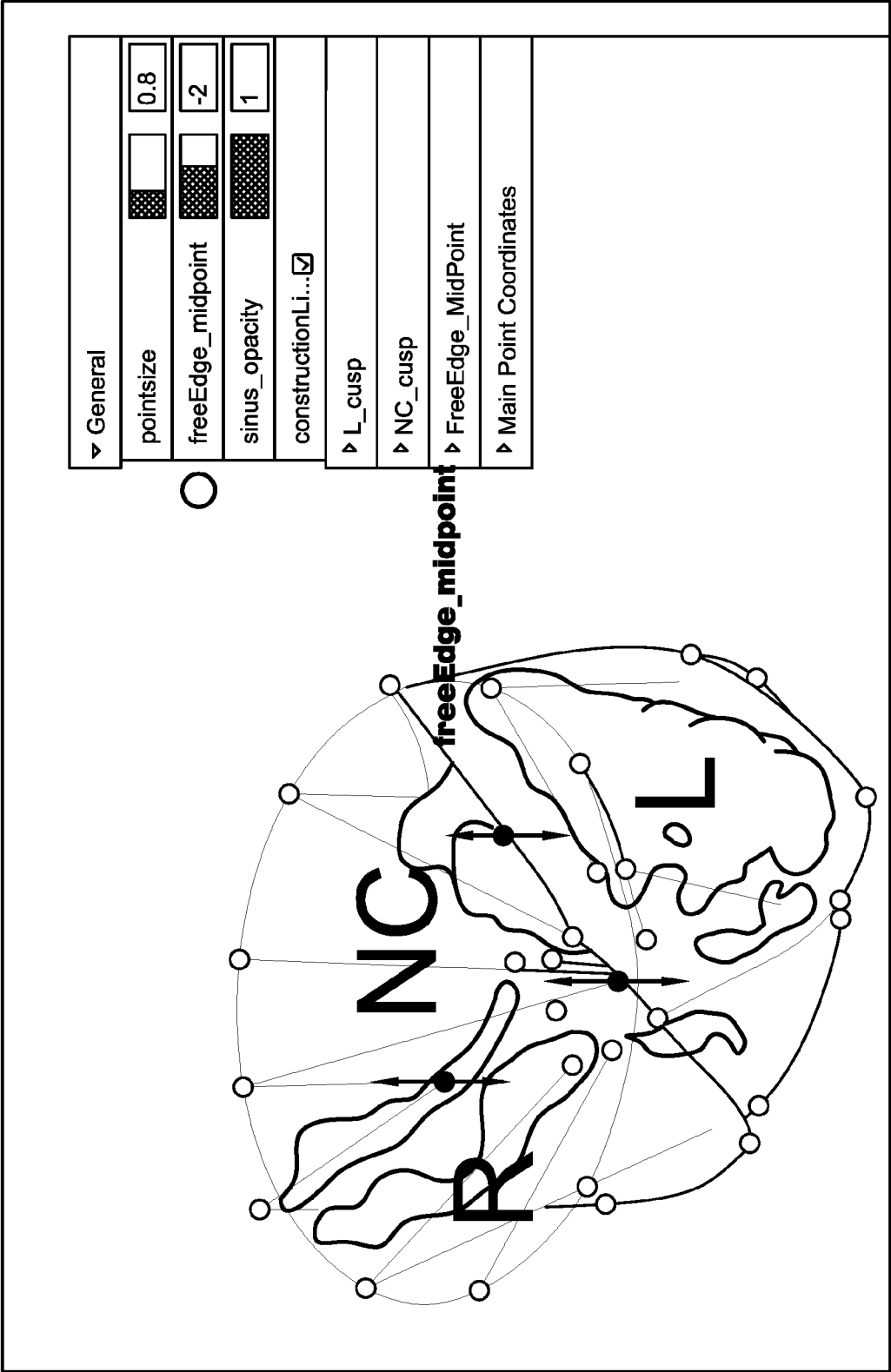


FIG. 6

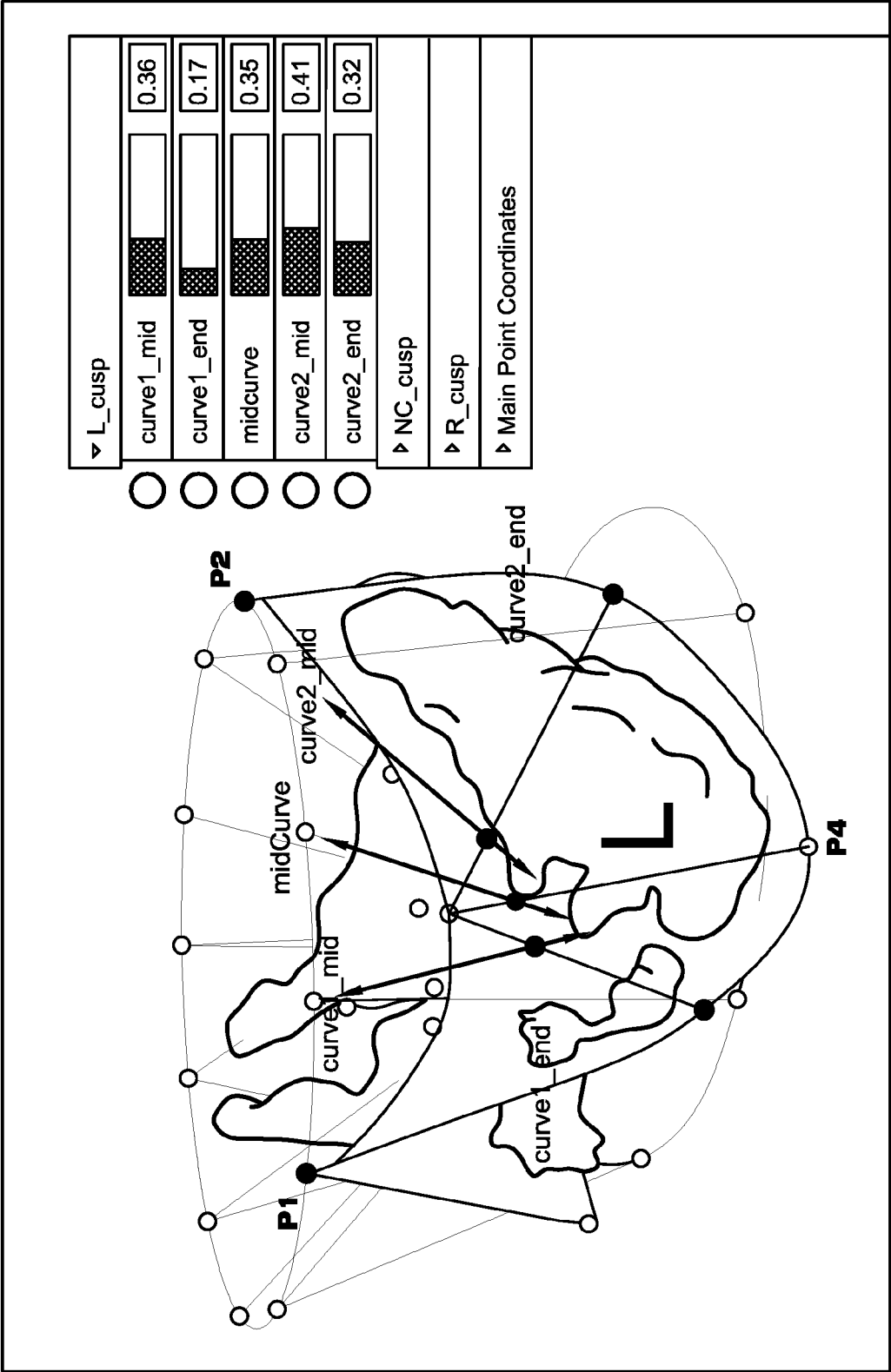


FIG. 7

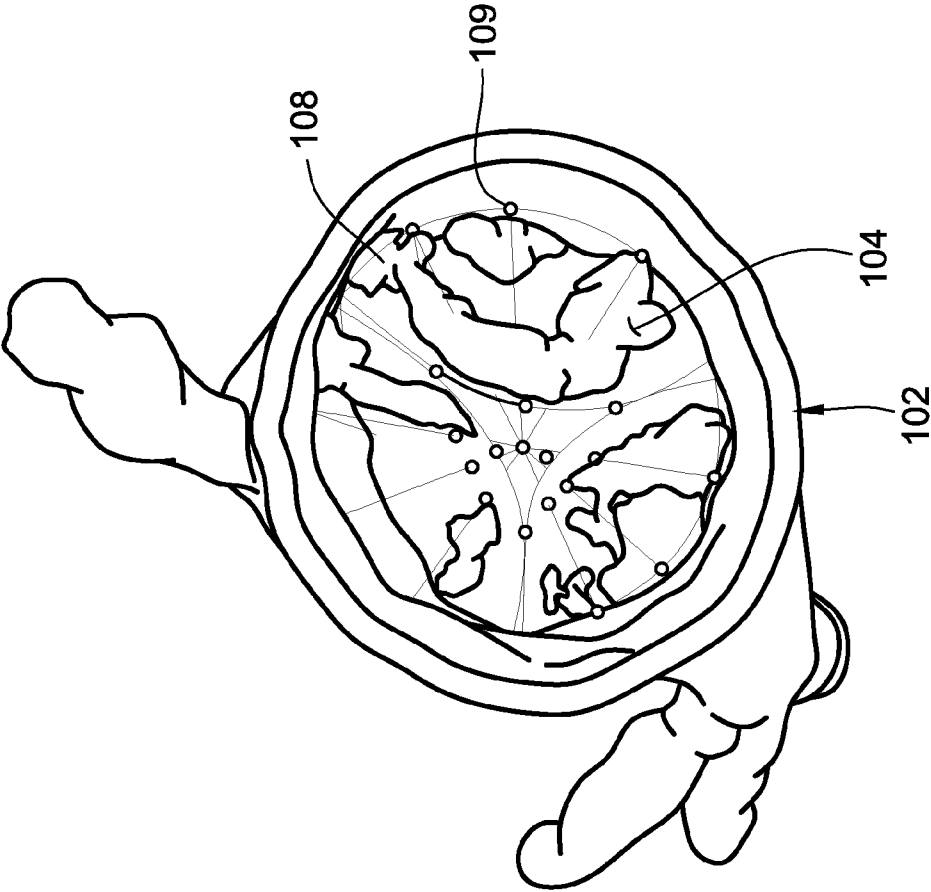


FIG. 8

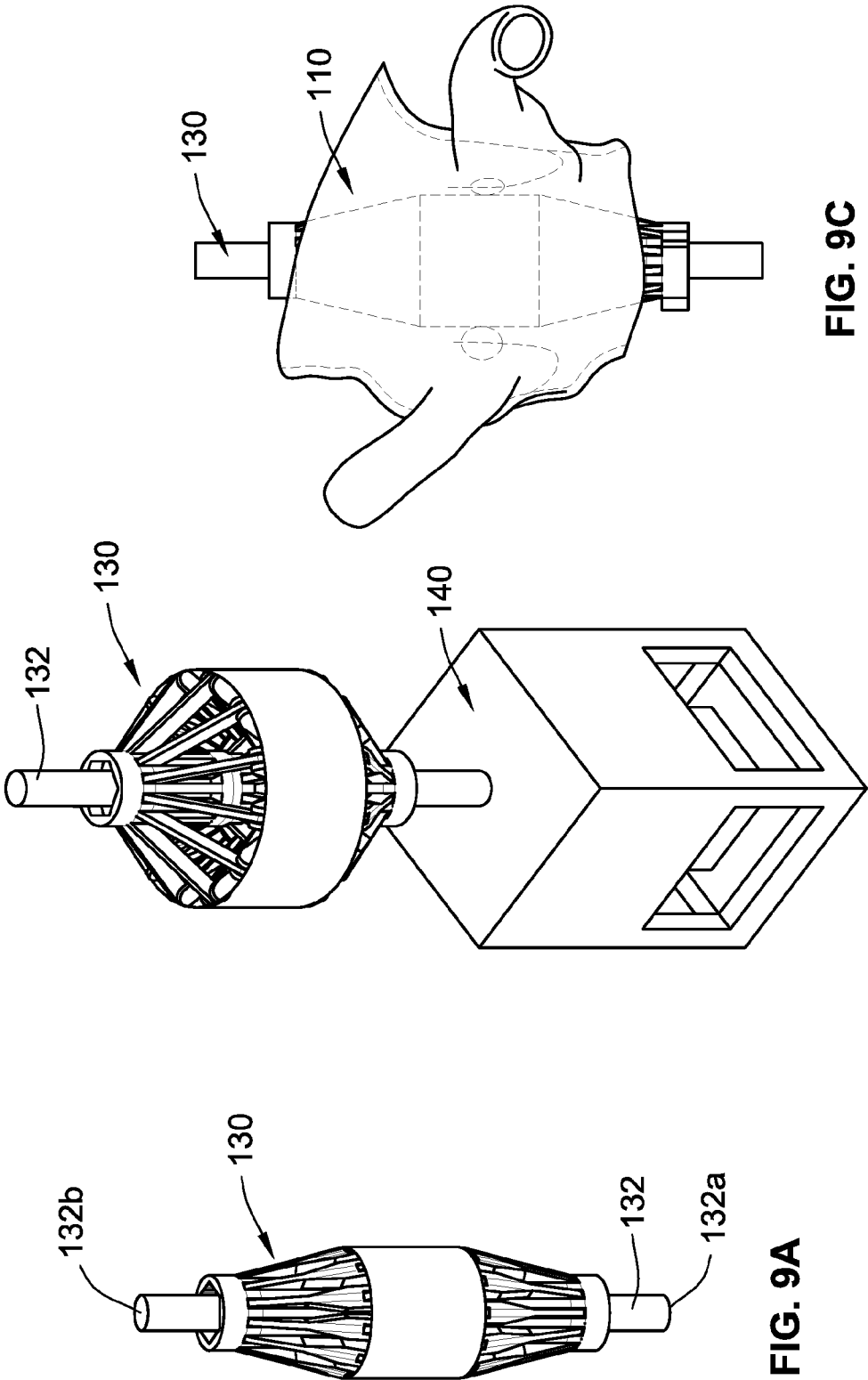
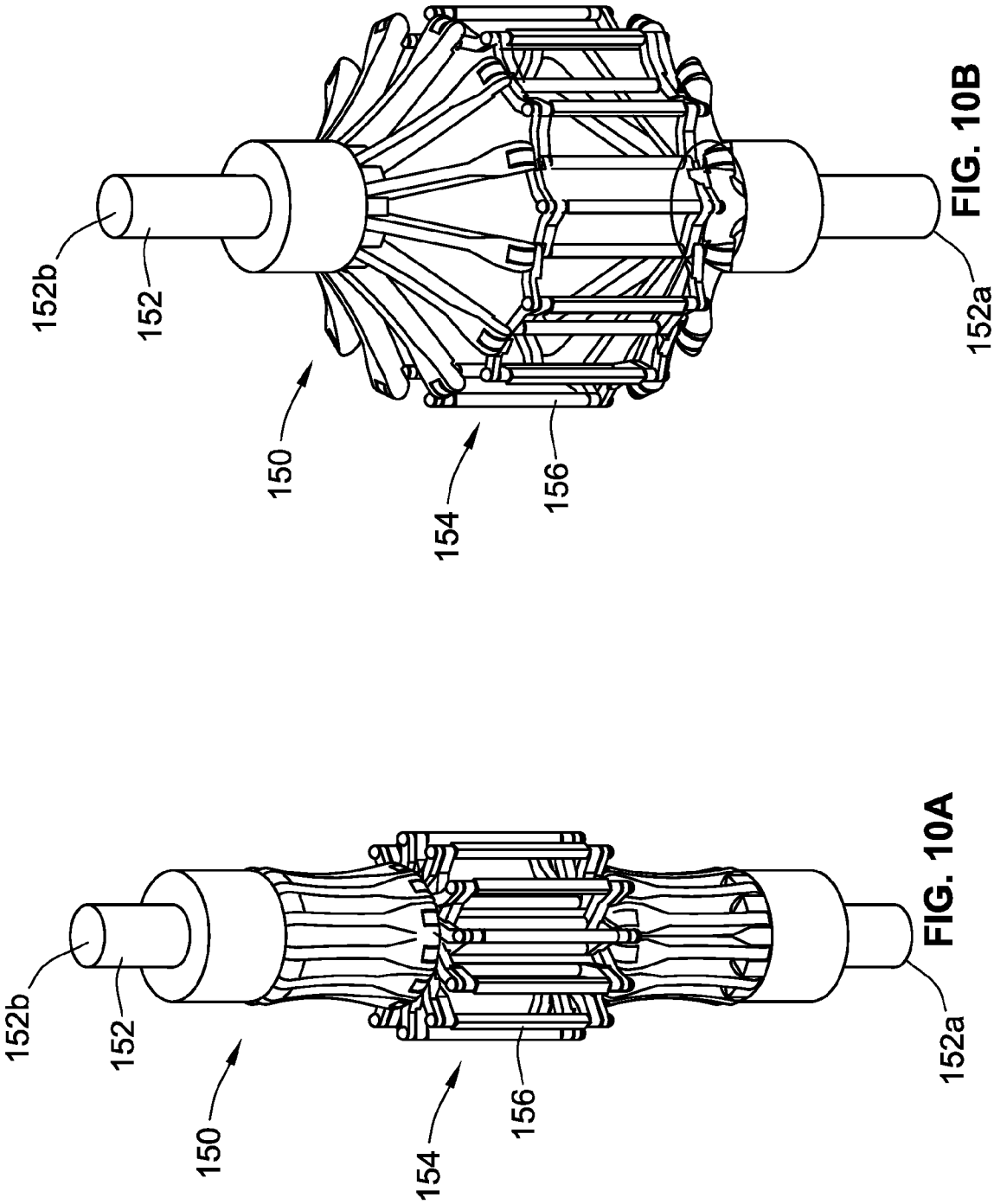
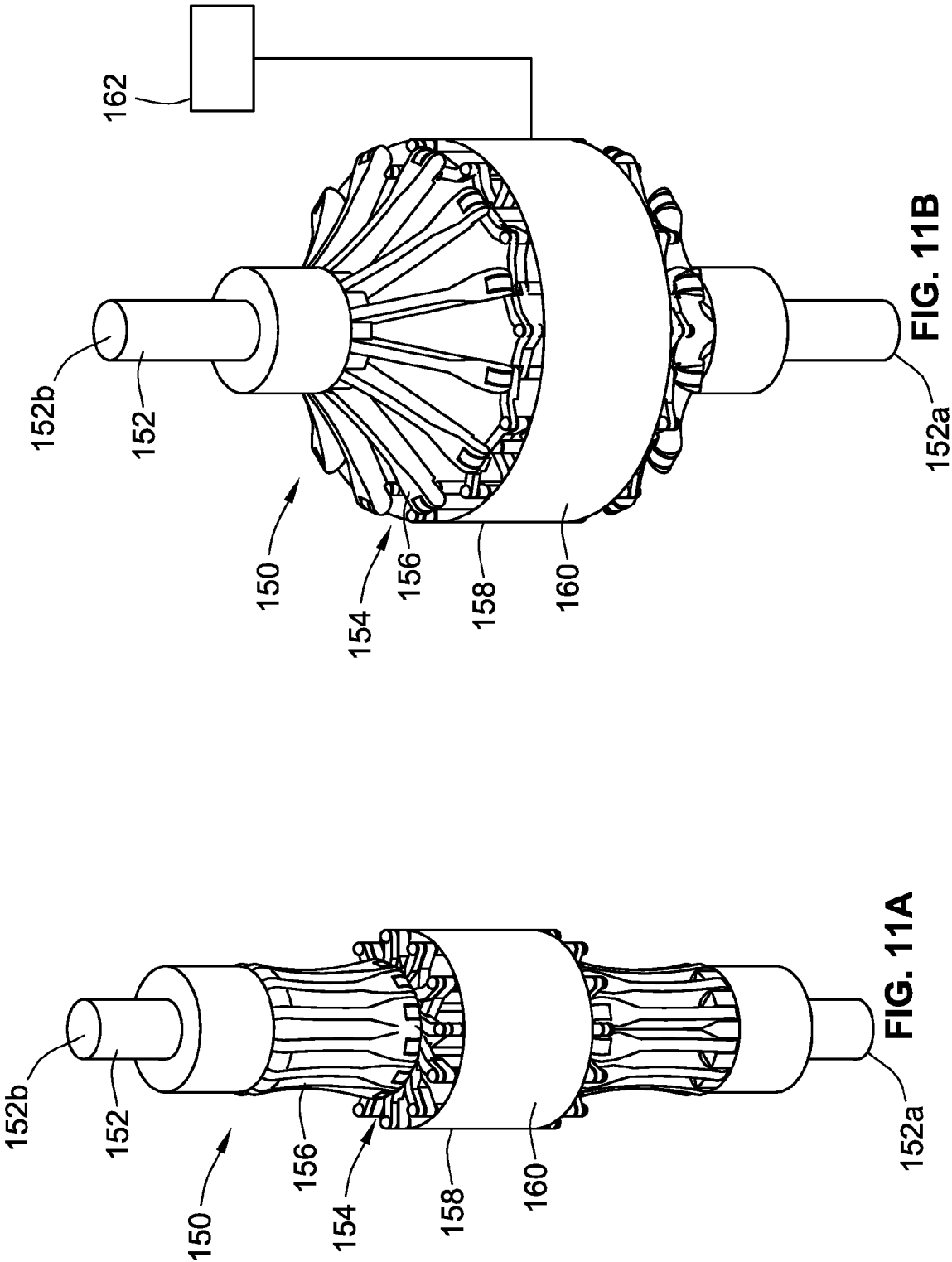


FIG. 9C

FIG. 9B

FIG. 9A





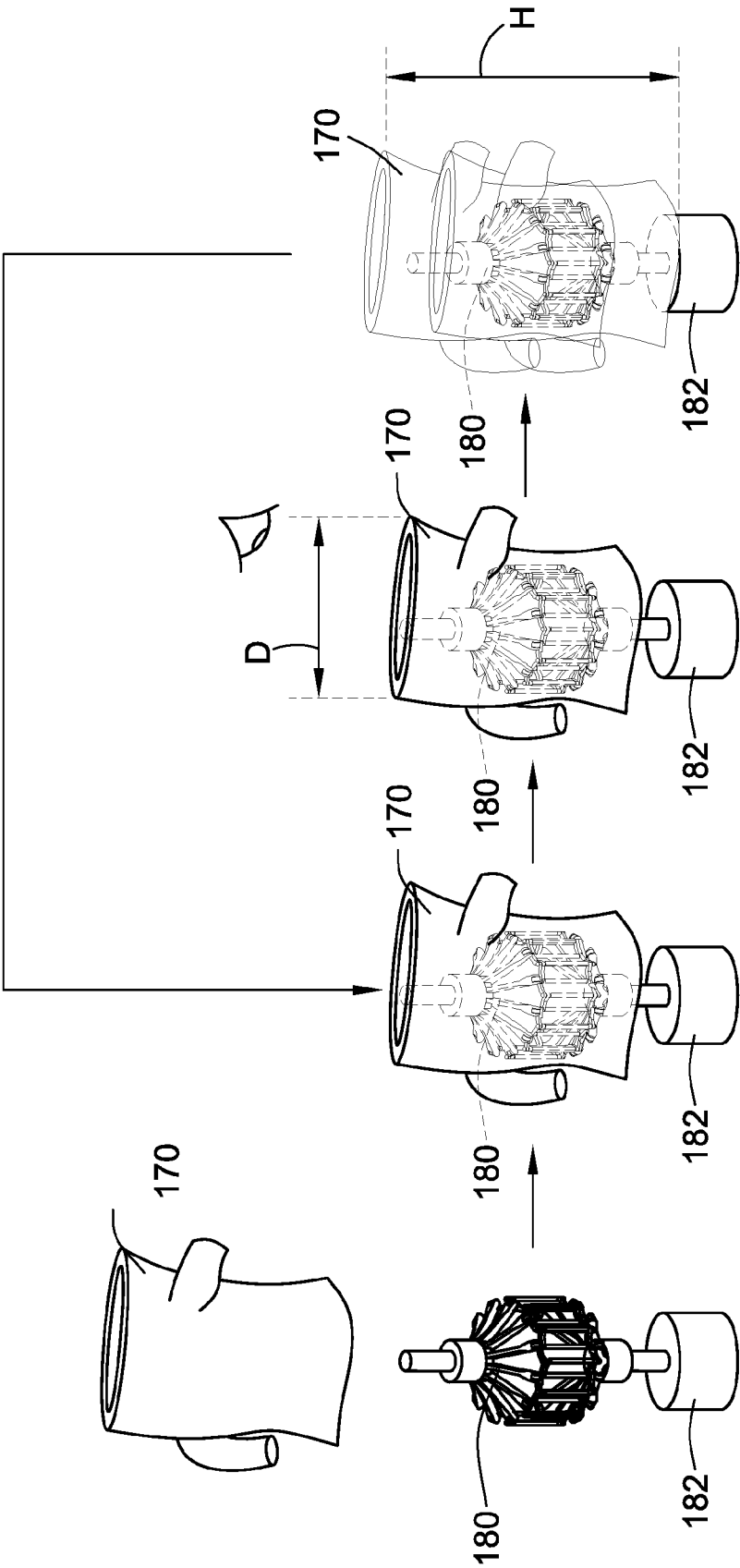


FIG. 12D

FIG. 12C

FIG. 12B

FIG. 12A

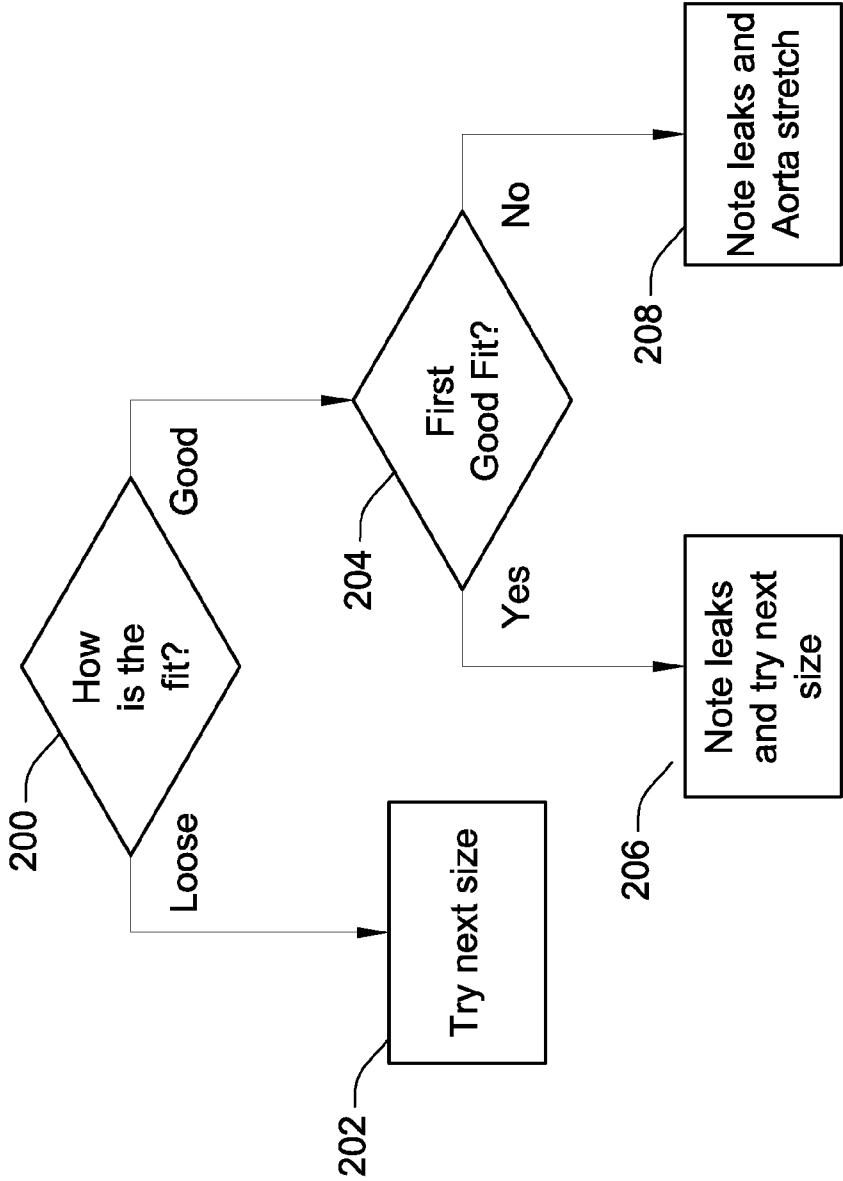


FIG. 13

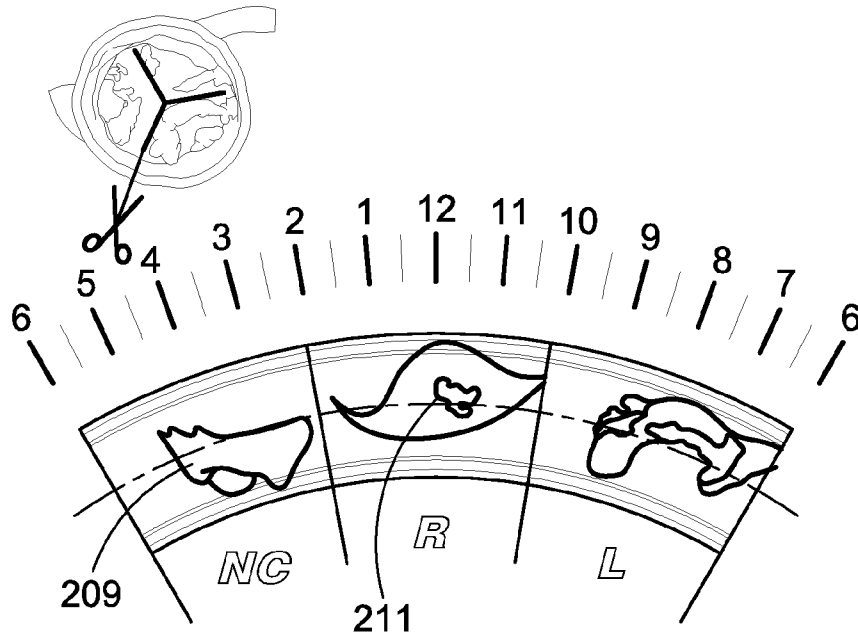


FIG. 14A

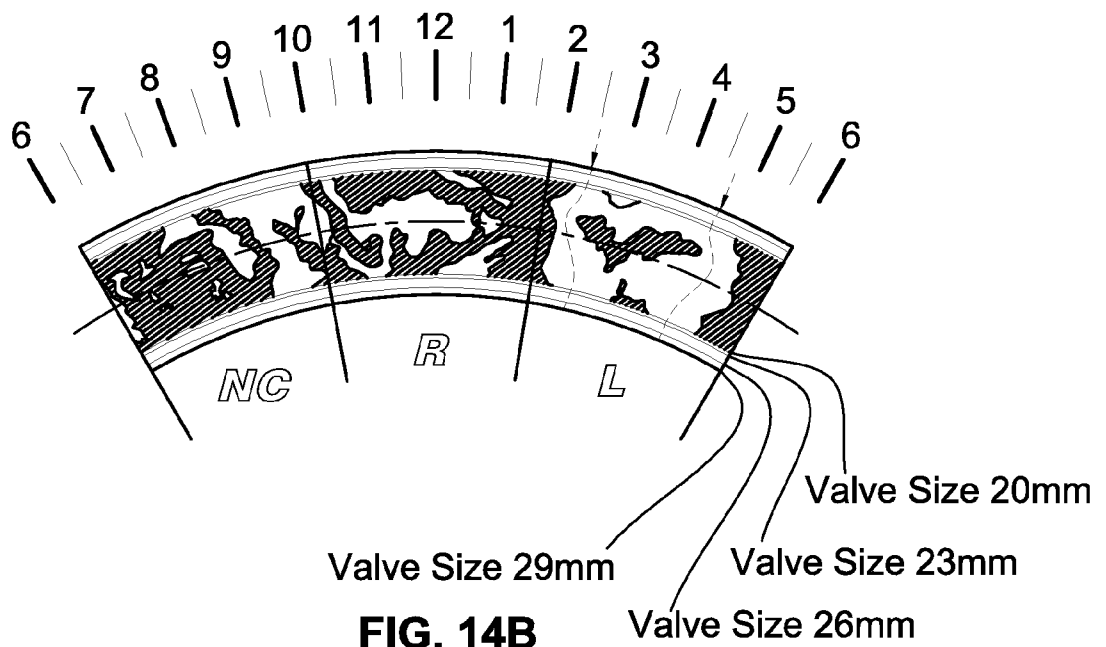


FIG. 14B

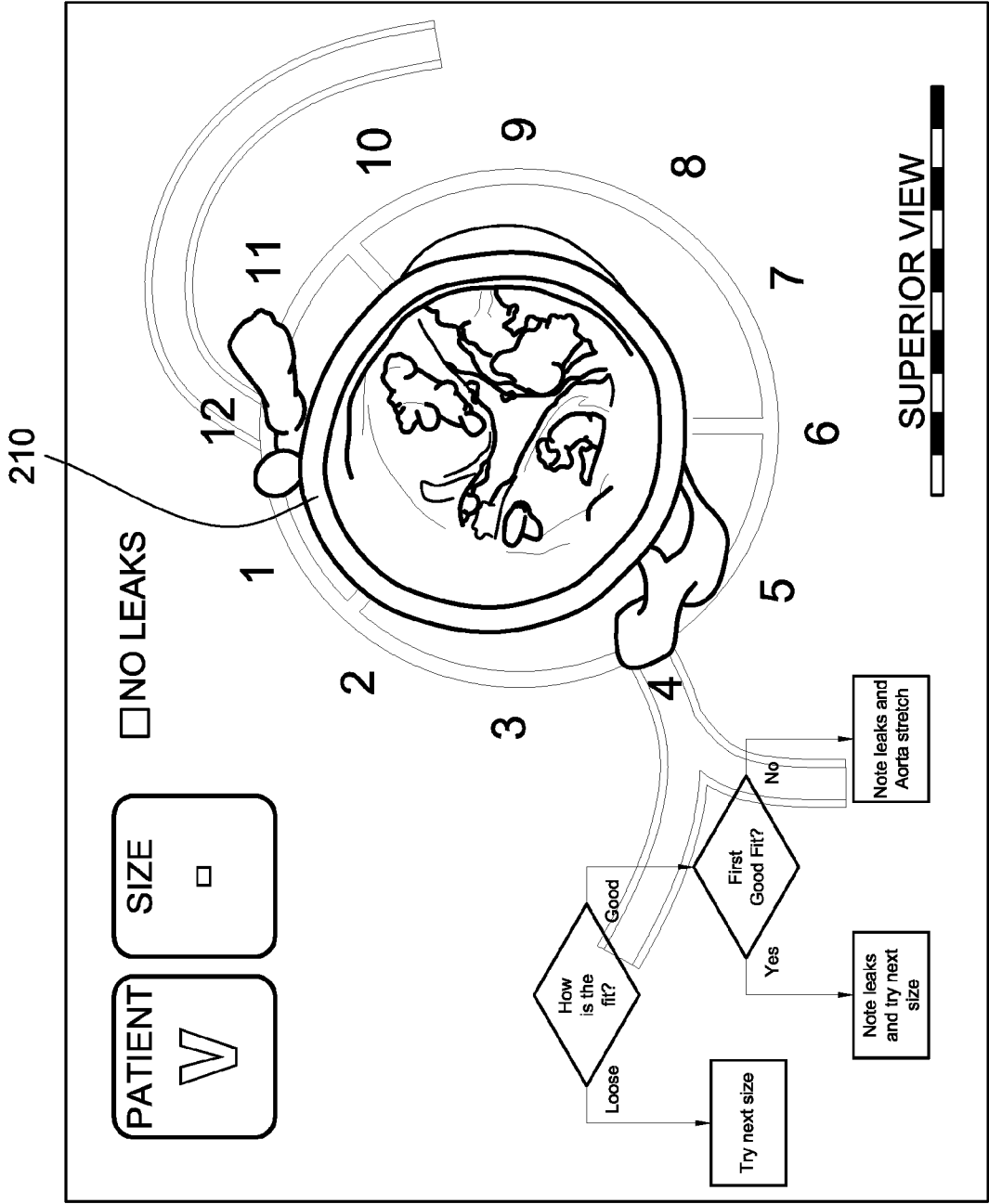


FIG. 15

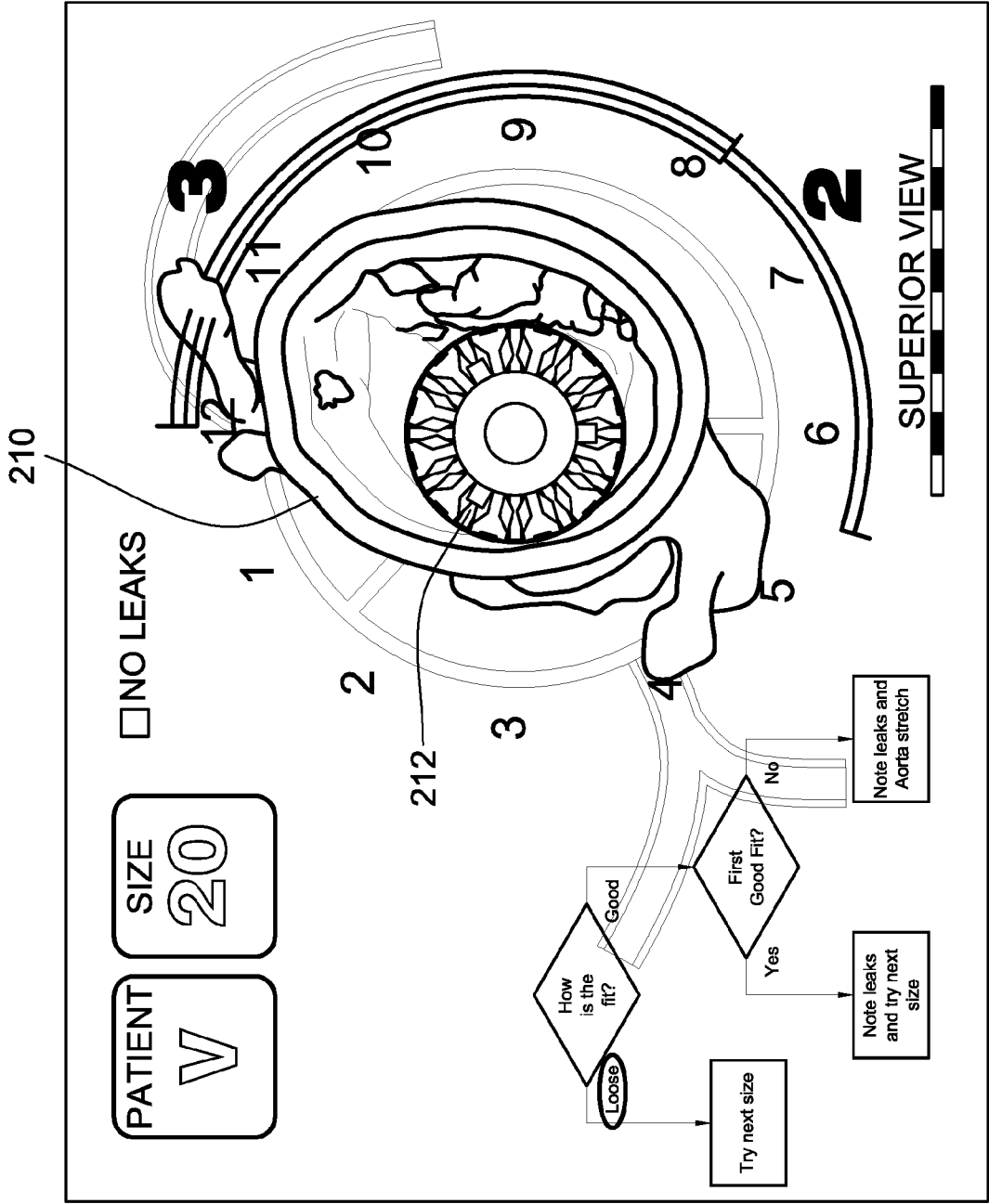


FIG. 16

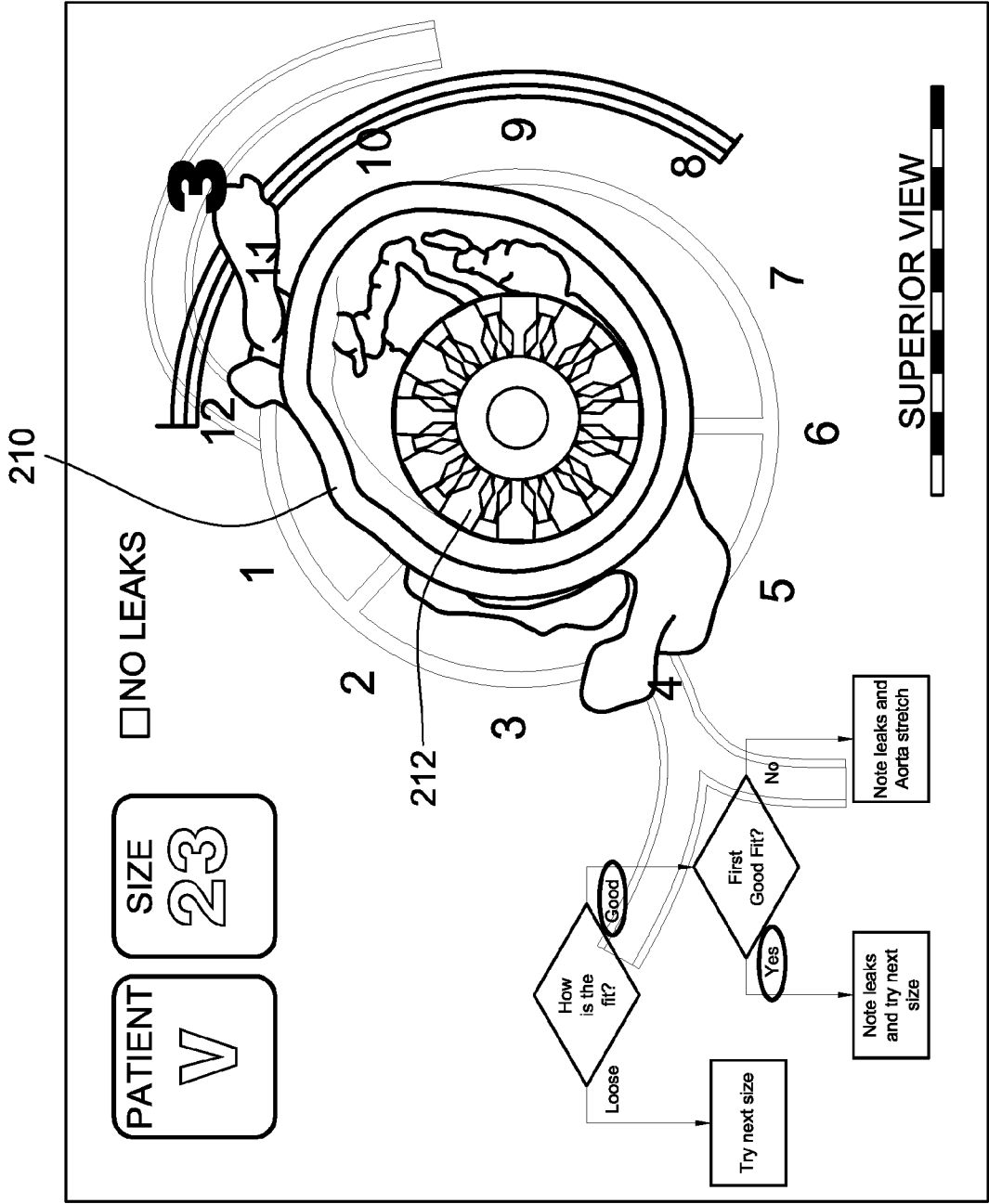


FIG. 17

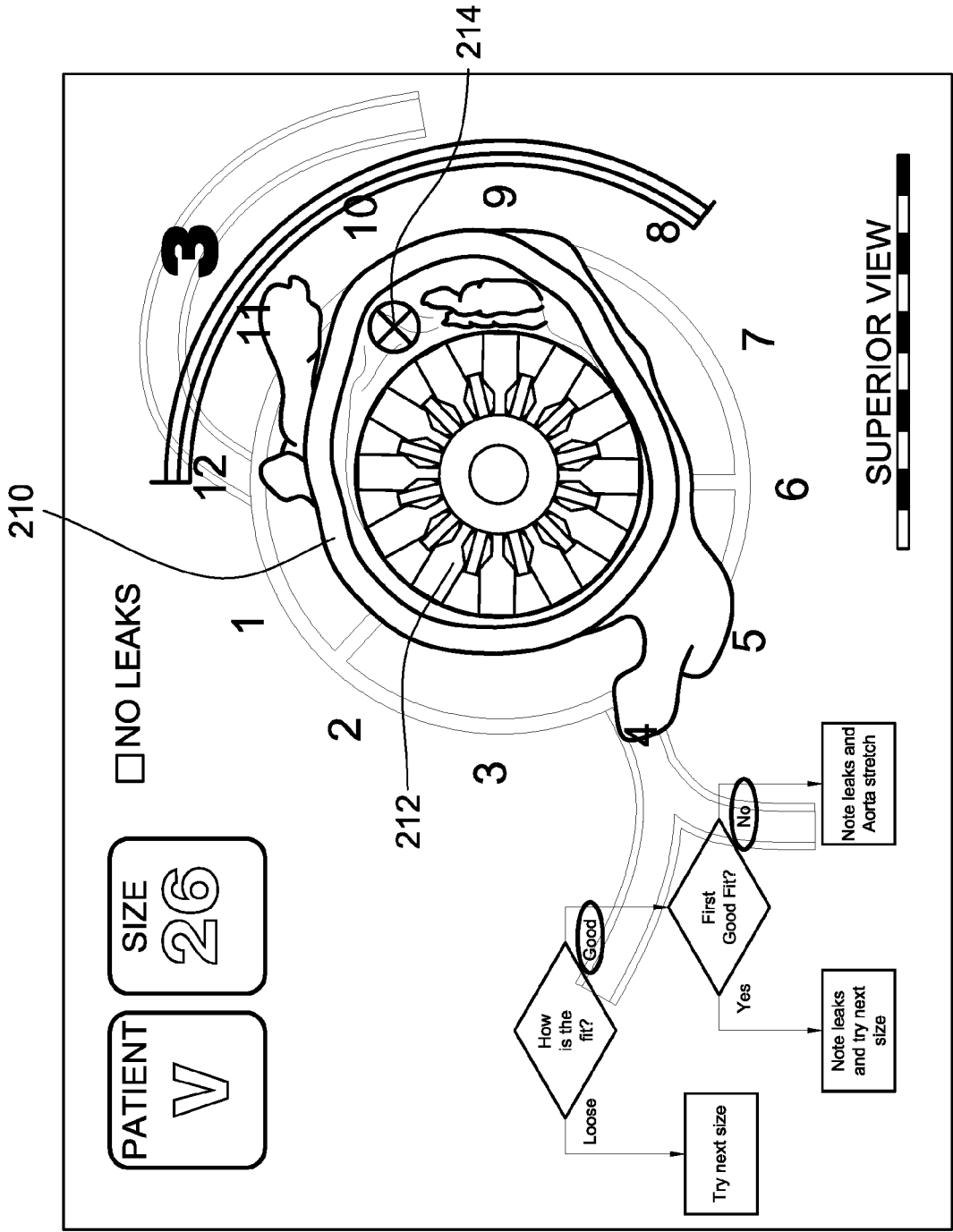


FIG. 18

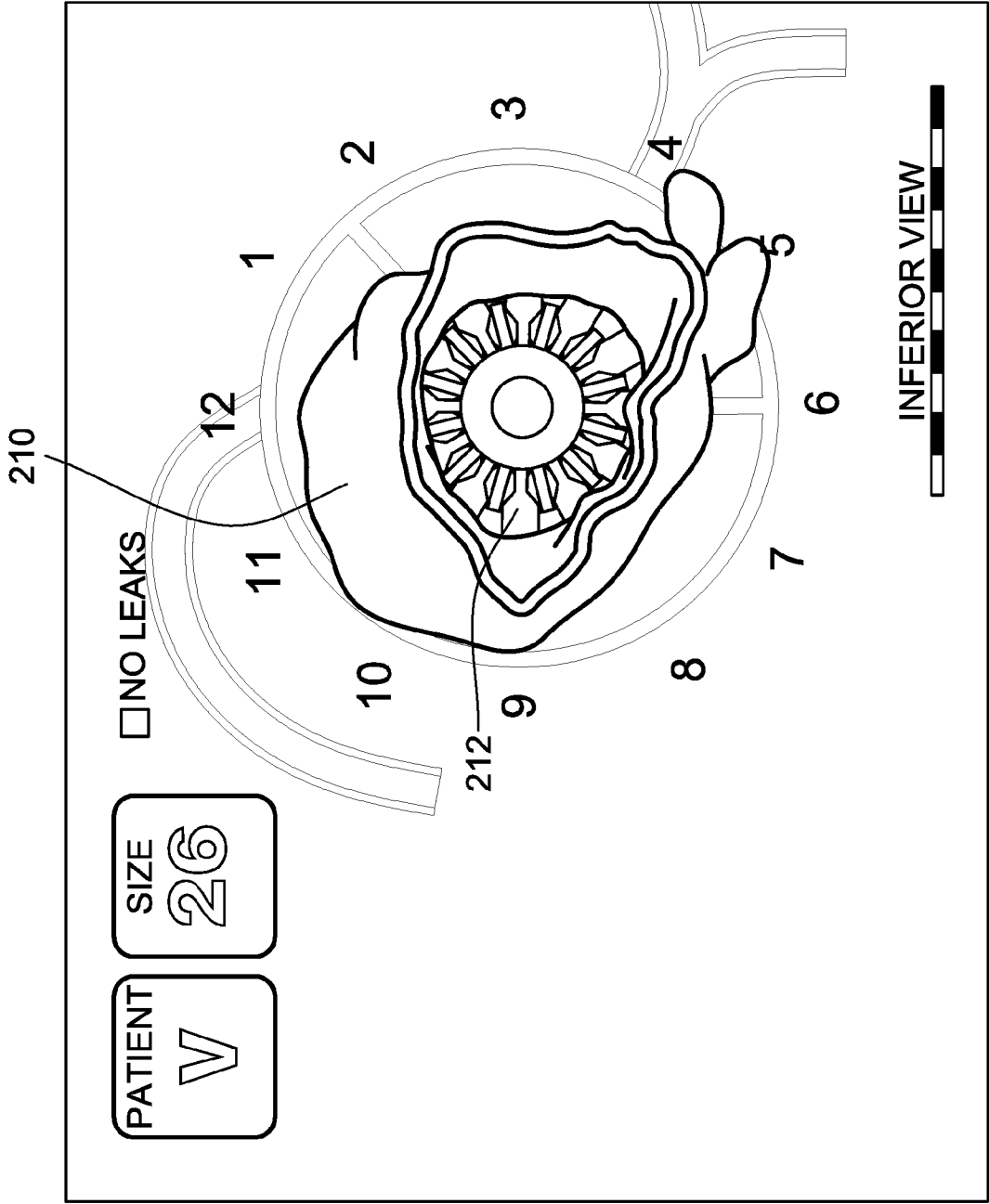


FIG. 19

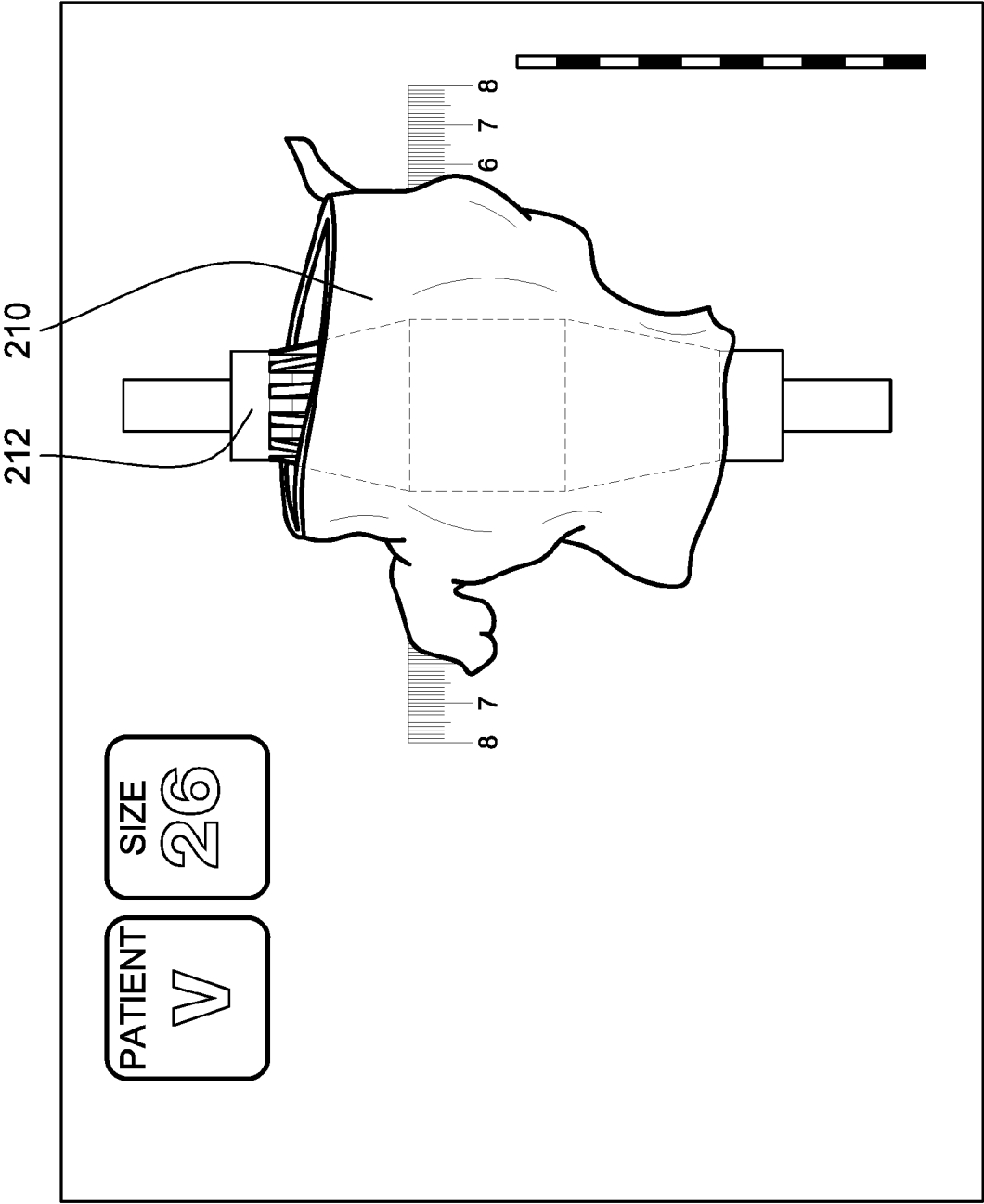


FIG. 20A

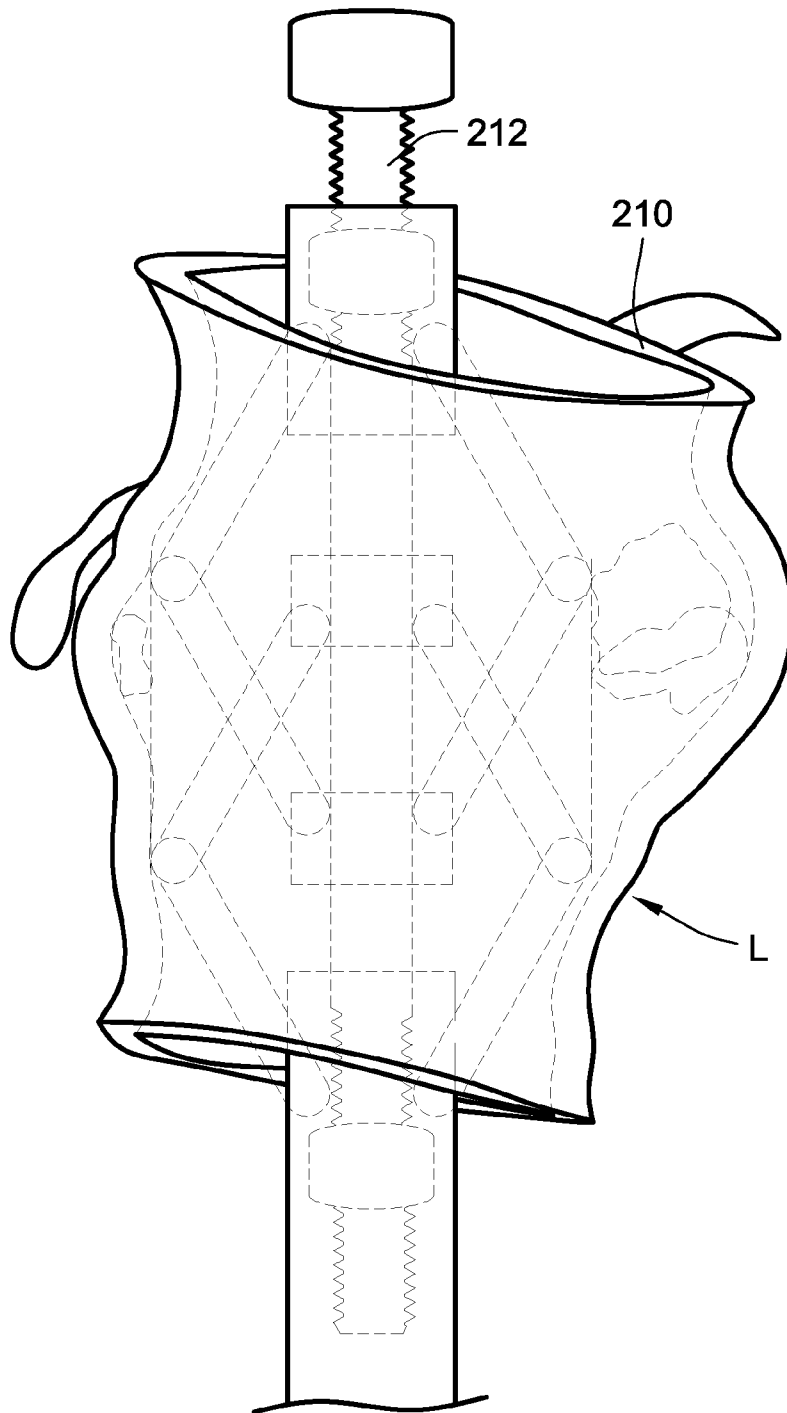


FIG. 20B

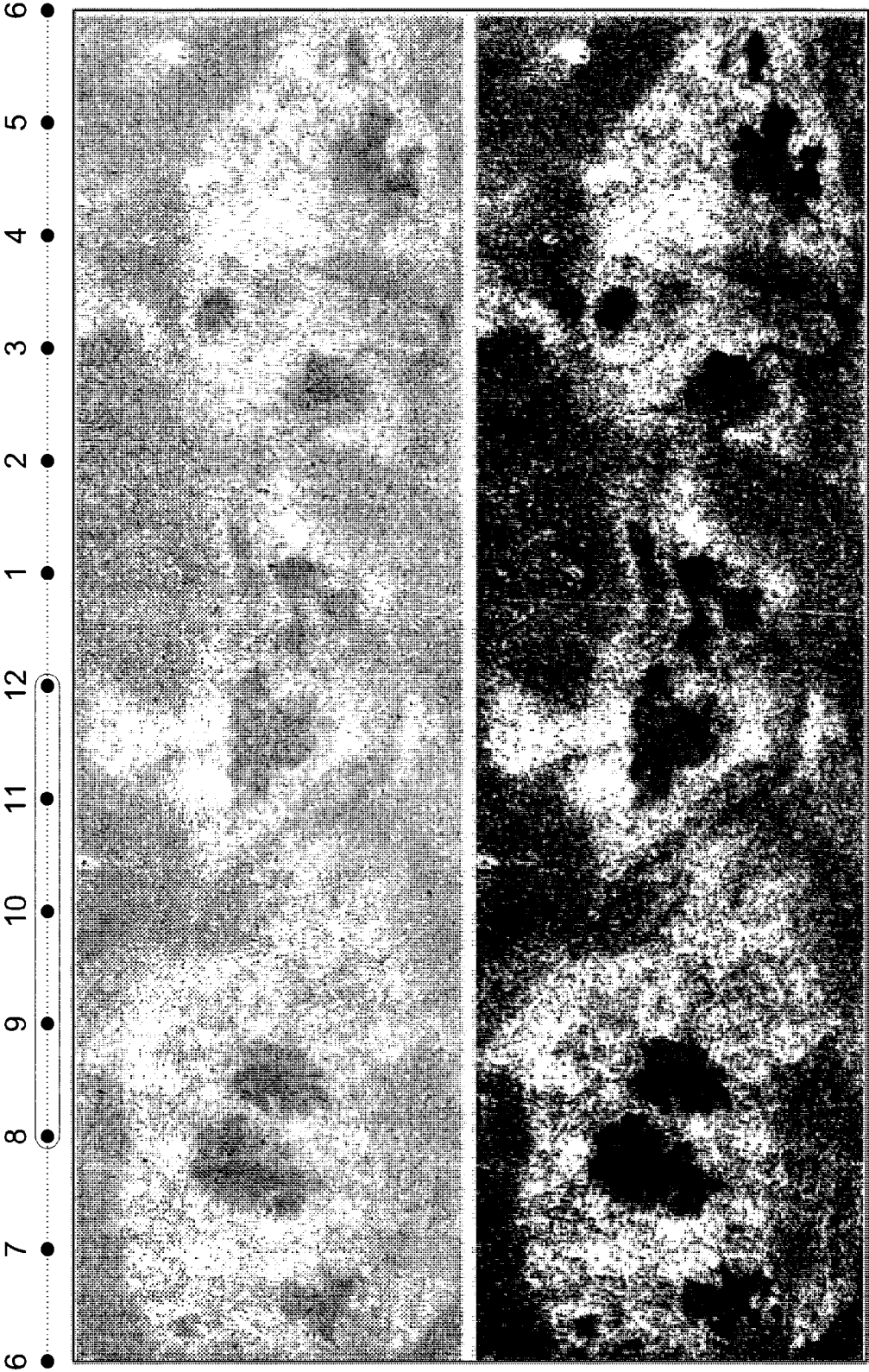
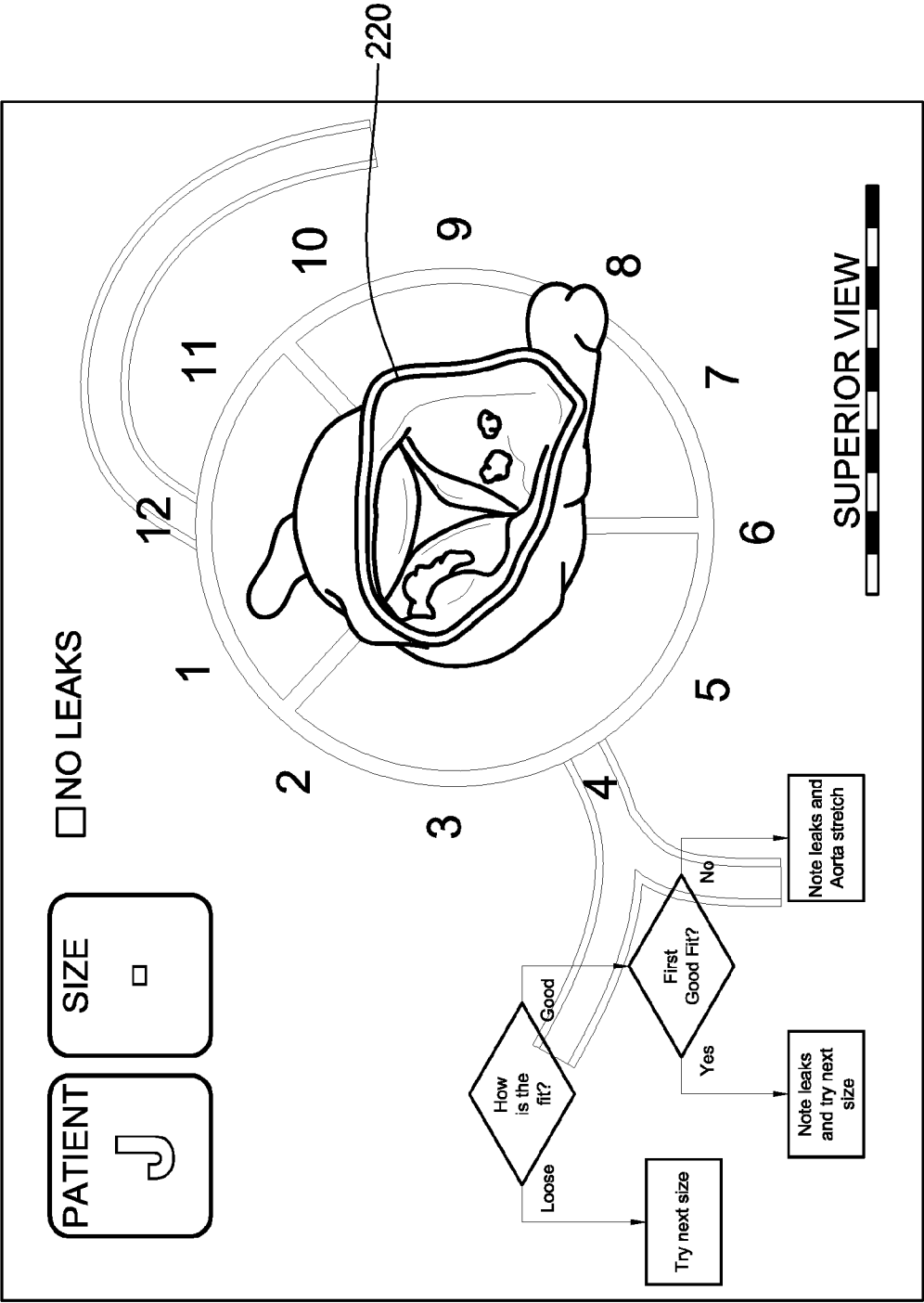


FIG. 20C



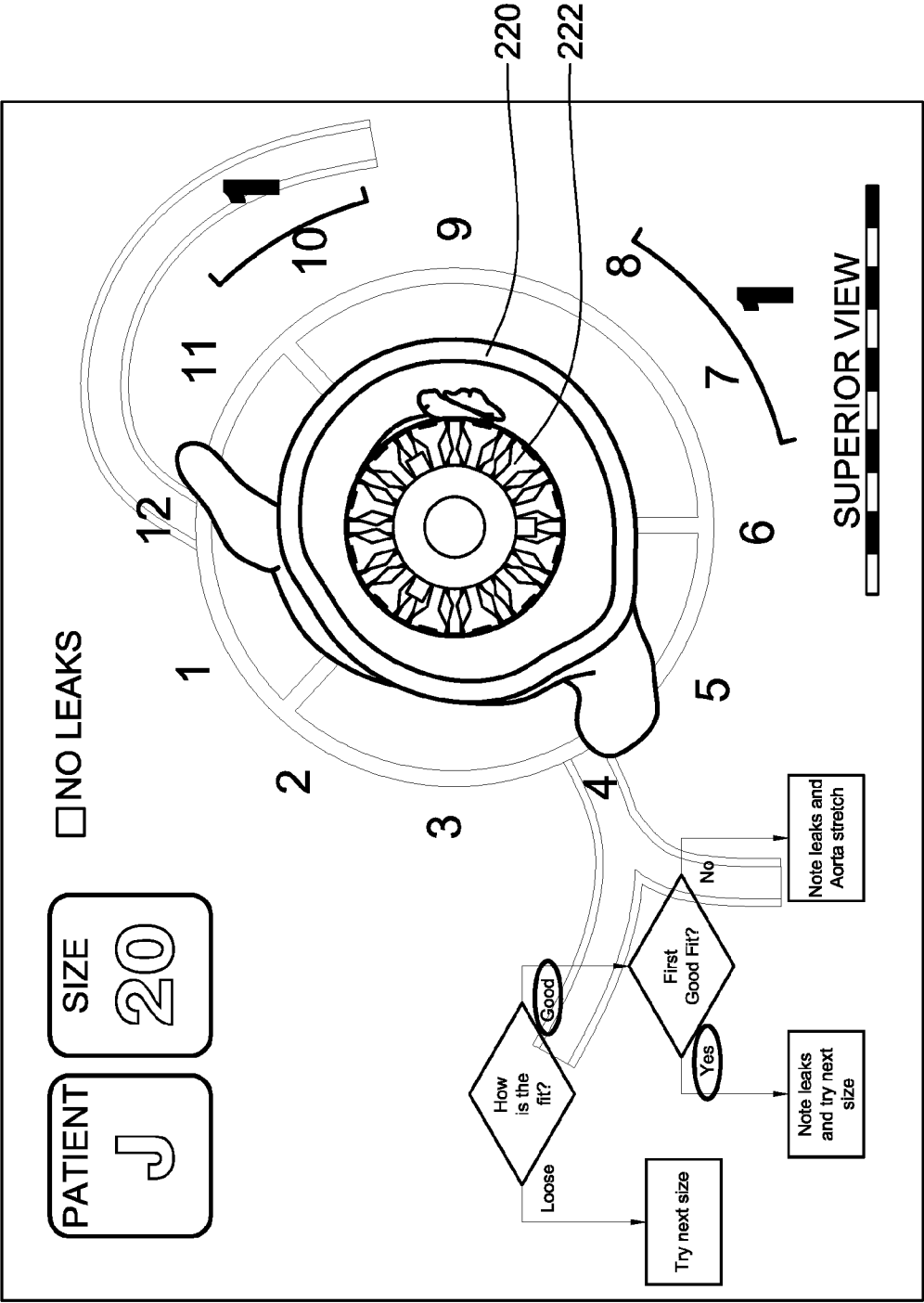


FIG. 22

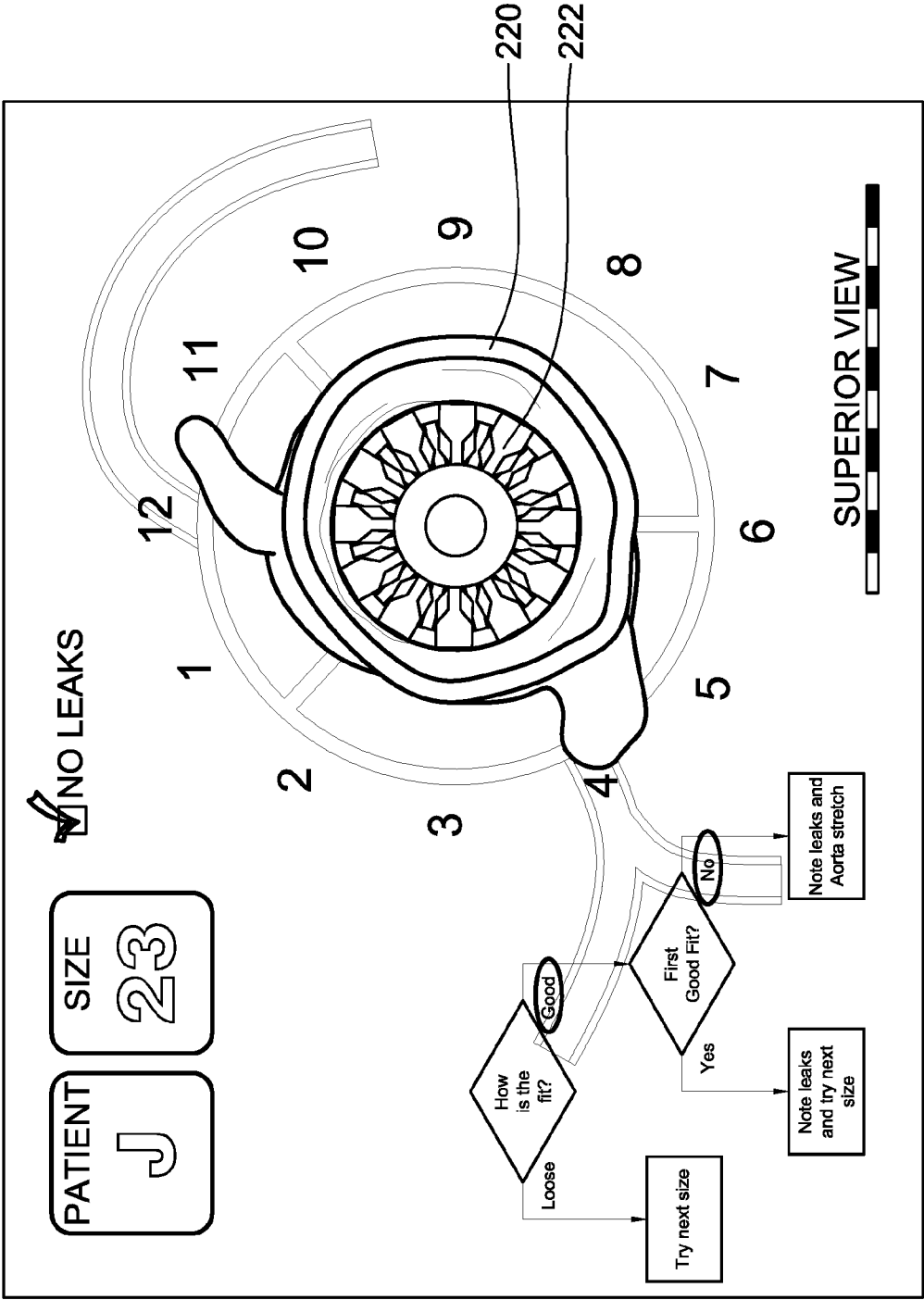


FIG. 23

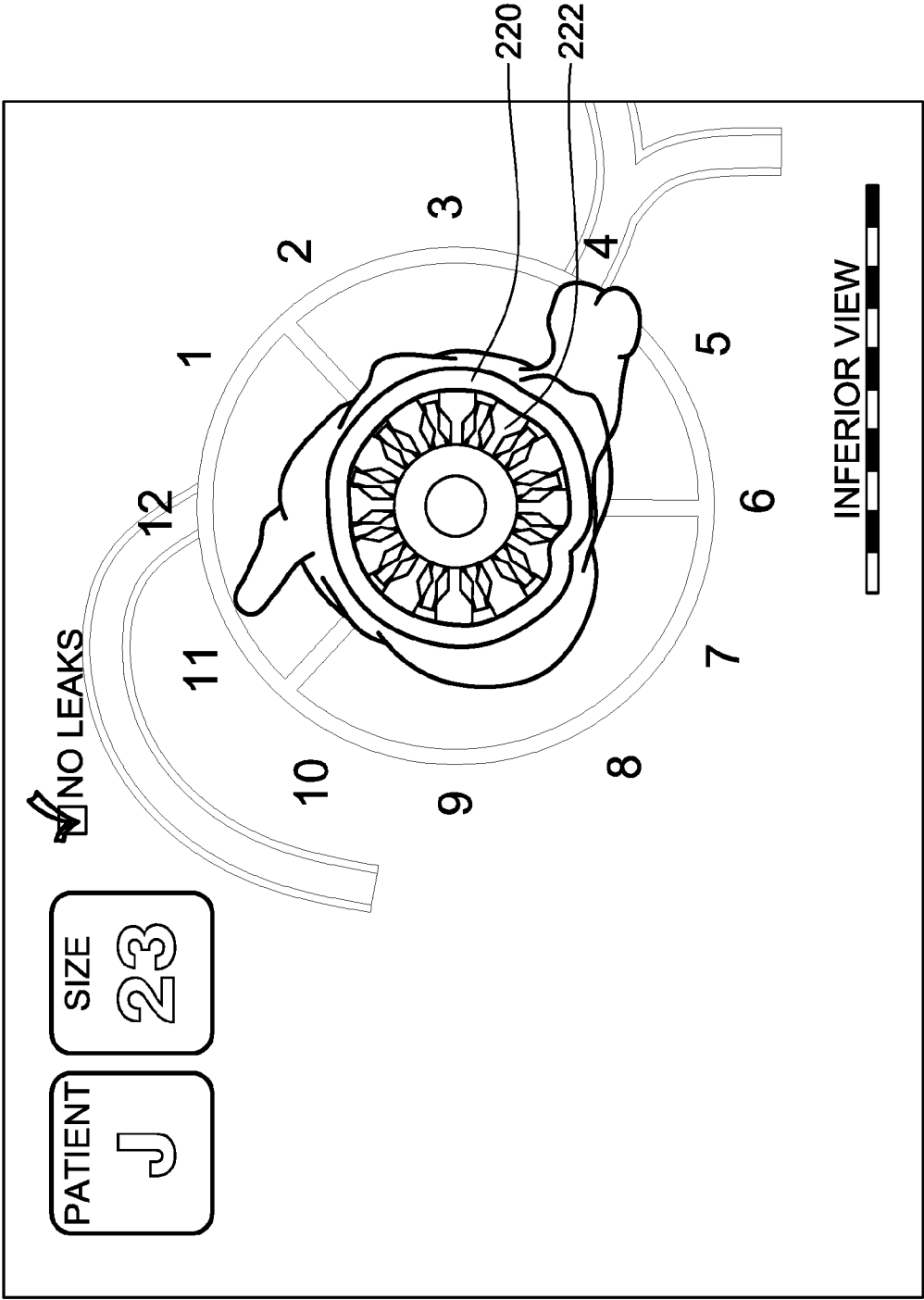
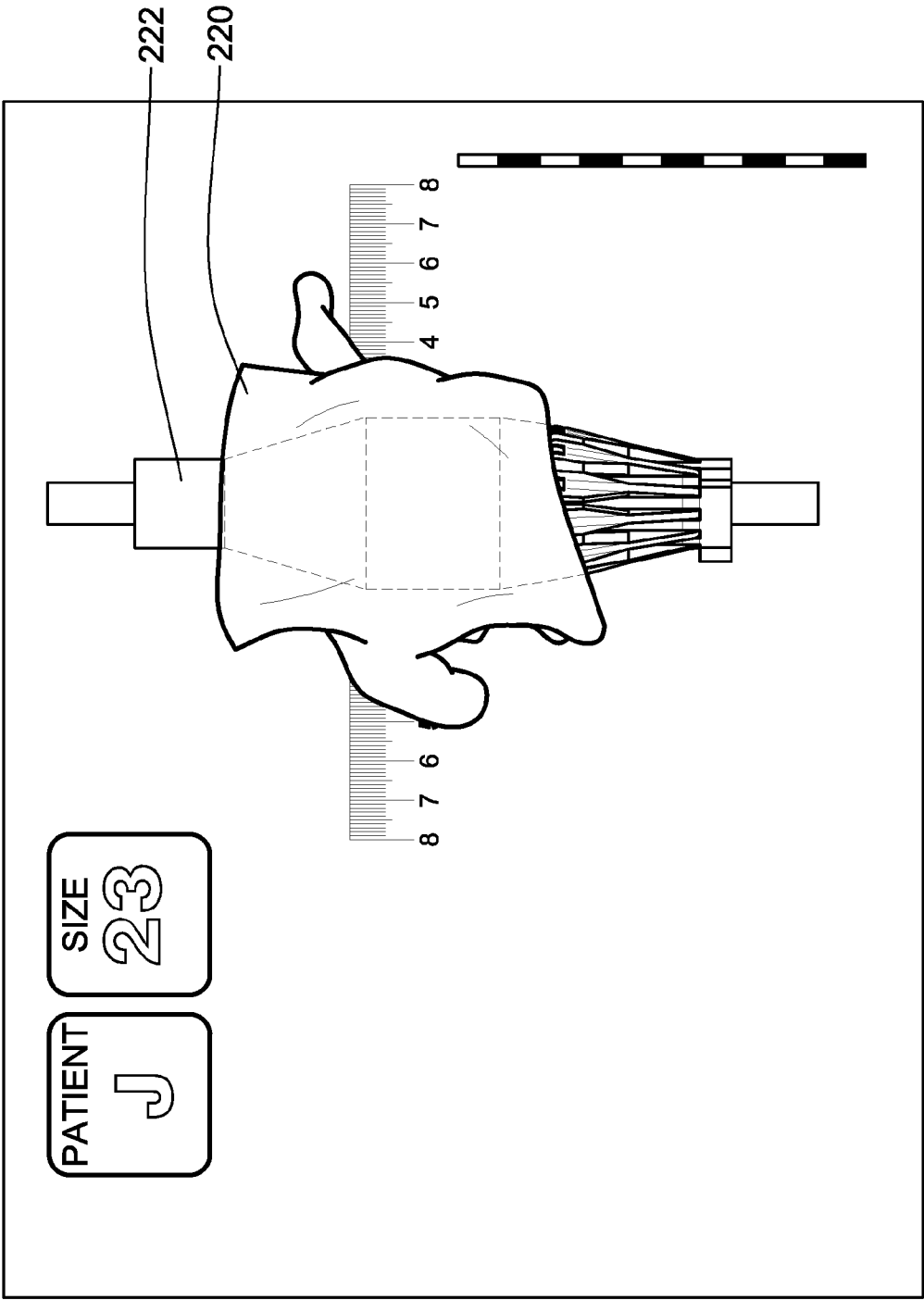


FIG. 24



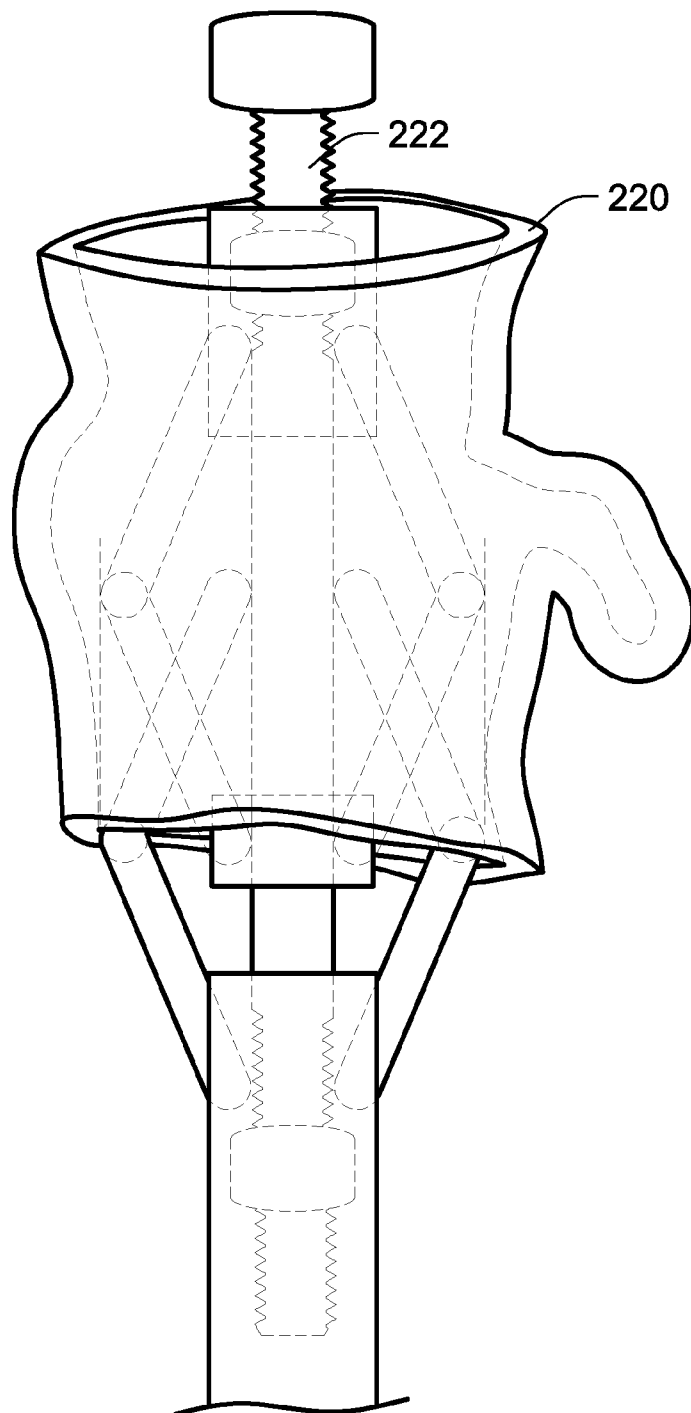


FIG. 25B

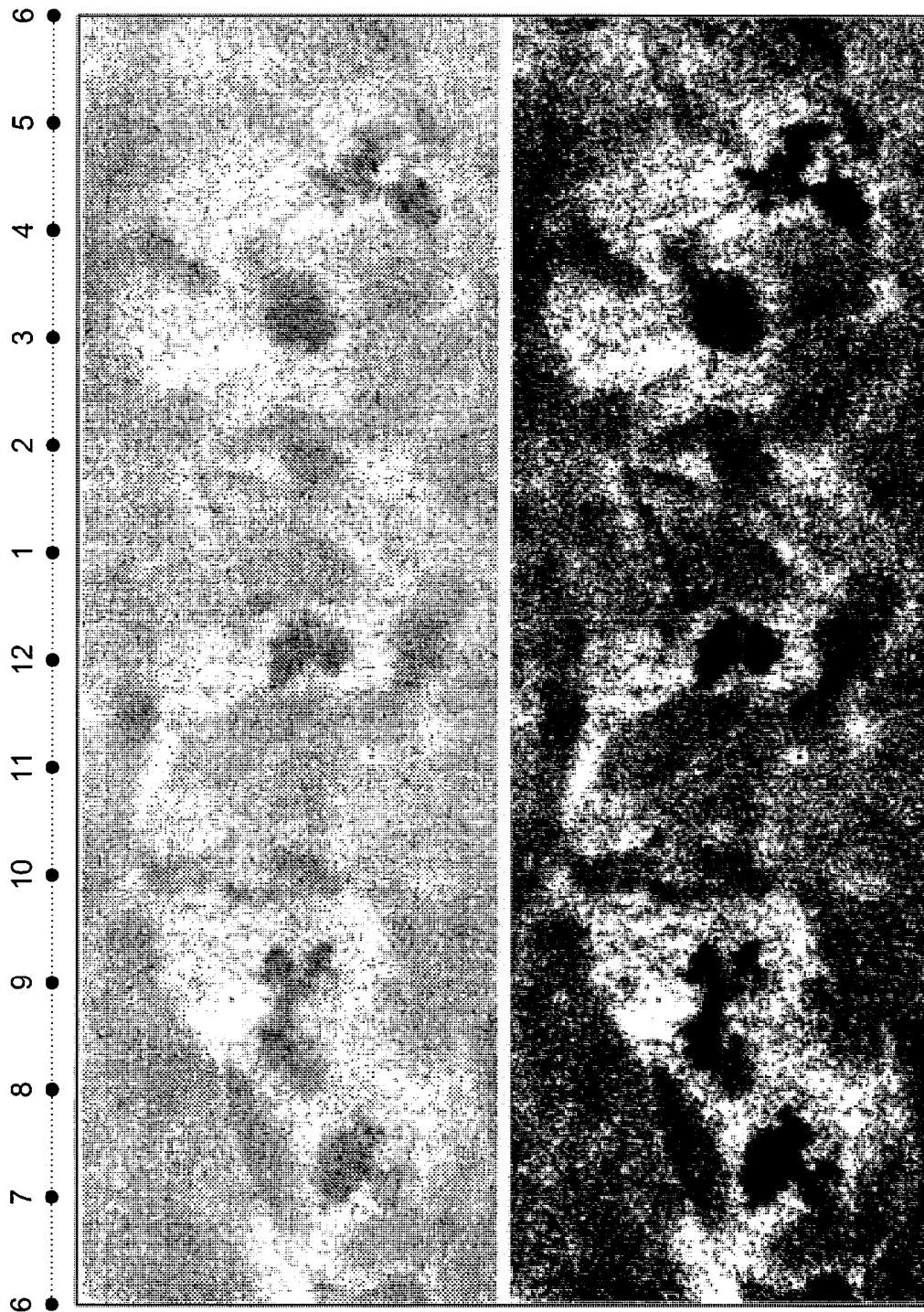


FIG. 25C

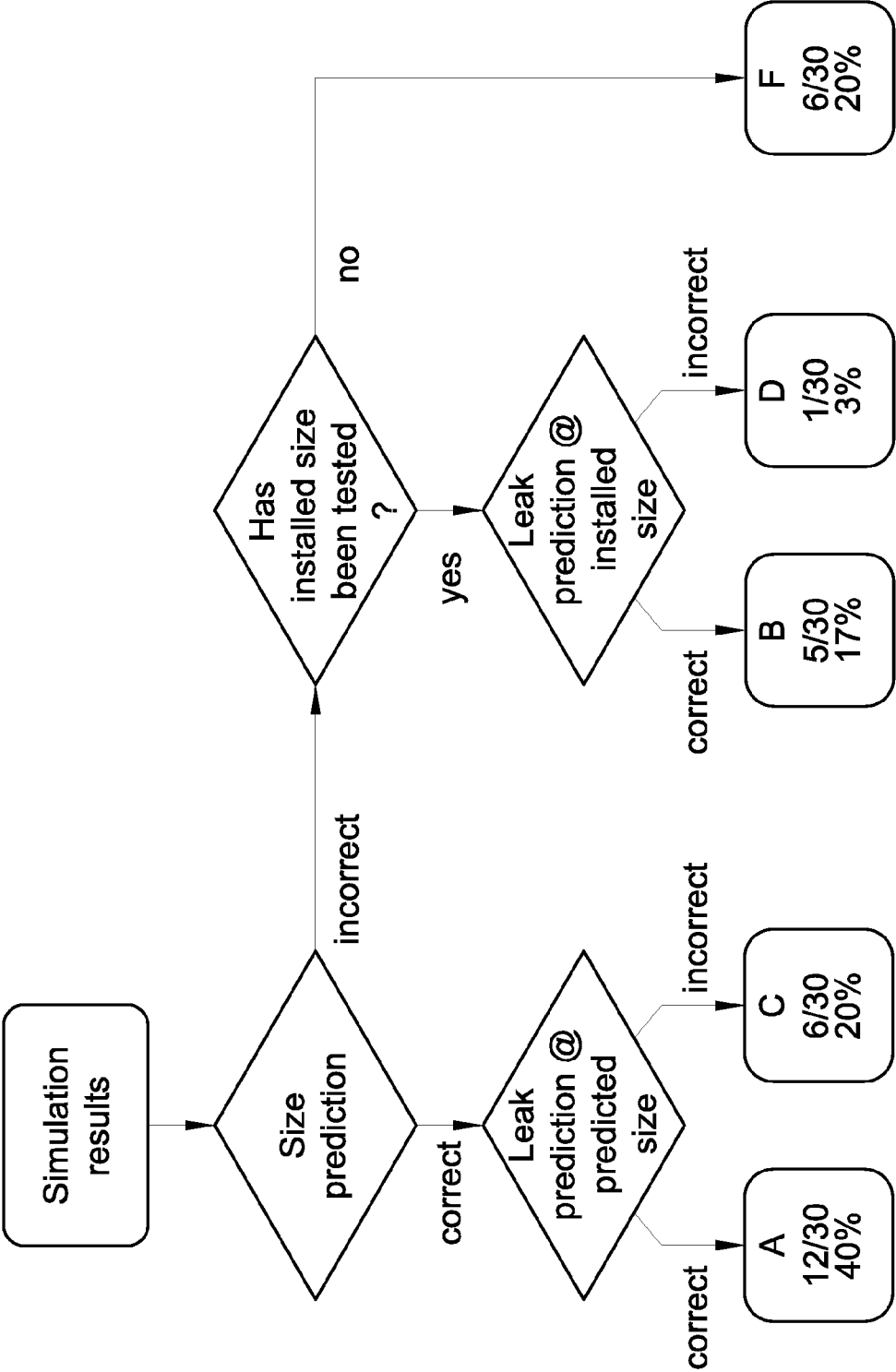


FIG. 26A

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	score	age	gender	TAVR approach	valve type	observed leak position	predicted leak position	match observed predicted L=leak / N=no leak				
								valve size (mm)				
								20	23	26	29	
Patients	A	83	F	Femoral	Sapien	-	-		★ N			
		84	F	Femoral	Evolut Core	-	-			★ N		
		85	M	Femoral	Medtronic Core	12-3	2-5				★ L	
		84	m	subclavian	Core	12-3	12-2,8-9,5-6				★ L	
		90	M	Apical	Sapien	5-7	4-6			★ L		
		84	F	Femoral	Core evolut	-	-		★ N			
		80	F	Femoral	Sapien xt	-	-		★ N			
		80	M	Apical	Sapien xt	6-9	5-7,9-11				★ L	
		90	F	Femoral	Sapien xt	-	-		★ N			
		85	F	Femoral	Core	5-7	5-7				★ L	
		71	M	Femoral	Core	-	-				★ N	
		83	F	Femoral	Sapien	-	-		★ N			
	B	79	F	Femoral	Sapien	5-7	5-7	★ L	←	○ {N}		
		82	M	Apical	Sapien	2-4,5-7	2-4,5-7			★ L	←	○ {L}
		88	F	Femoral	Sapien xt	5-7	4-5,6-7			★ L	←	○ {L}
		80	M	Apical	Sapien	9-12	12-4,7-10			★ L	←	○ {L}
		88	F	Femoral	Sapien	11-1	10-12		★ L	←	○ {L}	

FIG. 26B

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	score	age	gender	TAVR approach	valve type	observed leak position	predicted leak position	match ★ L N observed • [L] [N] predicted ○ {L} {N} L=leak / N=no leak valve size (mm) 20 23 26 29			
Patients	C	80	M	Femoral	Sapien	-	12-2				★ [N] {L}
		88	F	Femoral	Sapien xt	11-1	-		★ [L] {N}		
		85	M	Femoral	Sapien xt	-	3-5			★ [N] {L}	
		86	M	Femoral	Sapien xt	-	6-8				★ [N] {L}
		90	F	Femoral	St. Jude	5-7	-			★ [L] {N}	
		92	F	Femoral	Core	12-3	-			★ [L] {N}	
	D	90	F	Femoral	Sapien	-	-			• [N] {L} ← ○ {N}	
	E	91	F	Femoral	Core evolut	-	4-6			○ {L} → • [N]	
		83	F	Axillary	Core	6-9	-			○ {N} → • [L]	
		90	F	Axillary	Corevalve	-	-			○ {N} → • [N]	
		72	F	Femoral	Core evolut	12-3	-			○ {N} → • [L]	
		81	F	Femoral	Core Evolut	-	-		○ {N} → • [N]		
		89	M	Femoral	Core	-	-		○ {N} → • [N]		

FIG. 26C

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 17/60523

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - G06G 7/58 (2017.01)

CPC - G06F 19/12, G06T 19/00, G06F 19/3437, G06T 2210/41

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

See Search History Document

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	US 2002/0168618 A1 (Anderson et al.) 14 November 2002 (14.11.2002), entire document especially abstract; para [0013], [0018], [0066]-[0087], [0097]-[0101], [0137])	1, 4, 5, 10, 13, 15, 17 ----- 2, 3, 6-9, 11, 12, 14, 16, 18-20
Y	US 2013/0132054 A1 (Sharma et al.) 23 May 2013 (23.05.2013), abstract; para [0022]-[0040]	2, 3, 7-9, 18-20
Y	US 2013/0211510 A1 (Lederman et al.) 15 August 2013 (15.08.2013), abstract; para [0008], [0017], [002], [0024], [0053], [0066], [0069], [0088])	6-9, 14, 16, 19
Y	US 2008/0183274 A1 (LaDuca et al.) 31 July 2008 (31.07.2008), para [0052]	11, 12
Y	US 2015/0250934 A1 (Min et al.) 10 September 2015 (10.09.2015), para [0048]-[0055]	20
Y	US 2016/0228190 A1 (Siemens Aktiengesellschaft) 11 August 2016 (11.08.2016), para [0042], [0045], [0079]	8, 9, 19

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

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"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

21 December 2017 (21.12.2017)

Date of mailing of the international search report

29 JAN 2018

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