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(54) **CATHETER TREATMENT SEGMENT**

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A61B 18/24	(2006.01)
A61M 29/02	(2006.01)
A61N 5/06	(2006.01)

(52) **U.S. Cl.**

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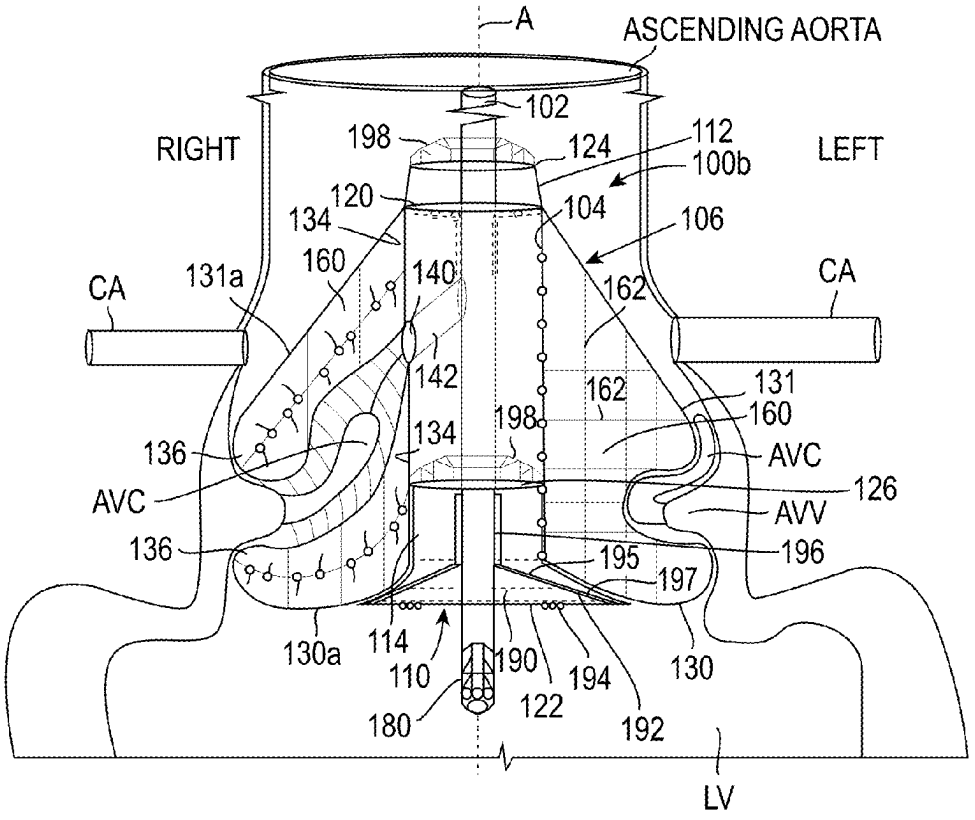
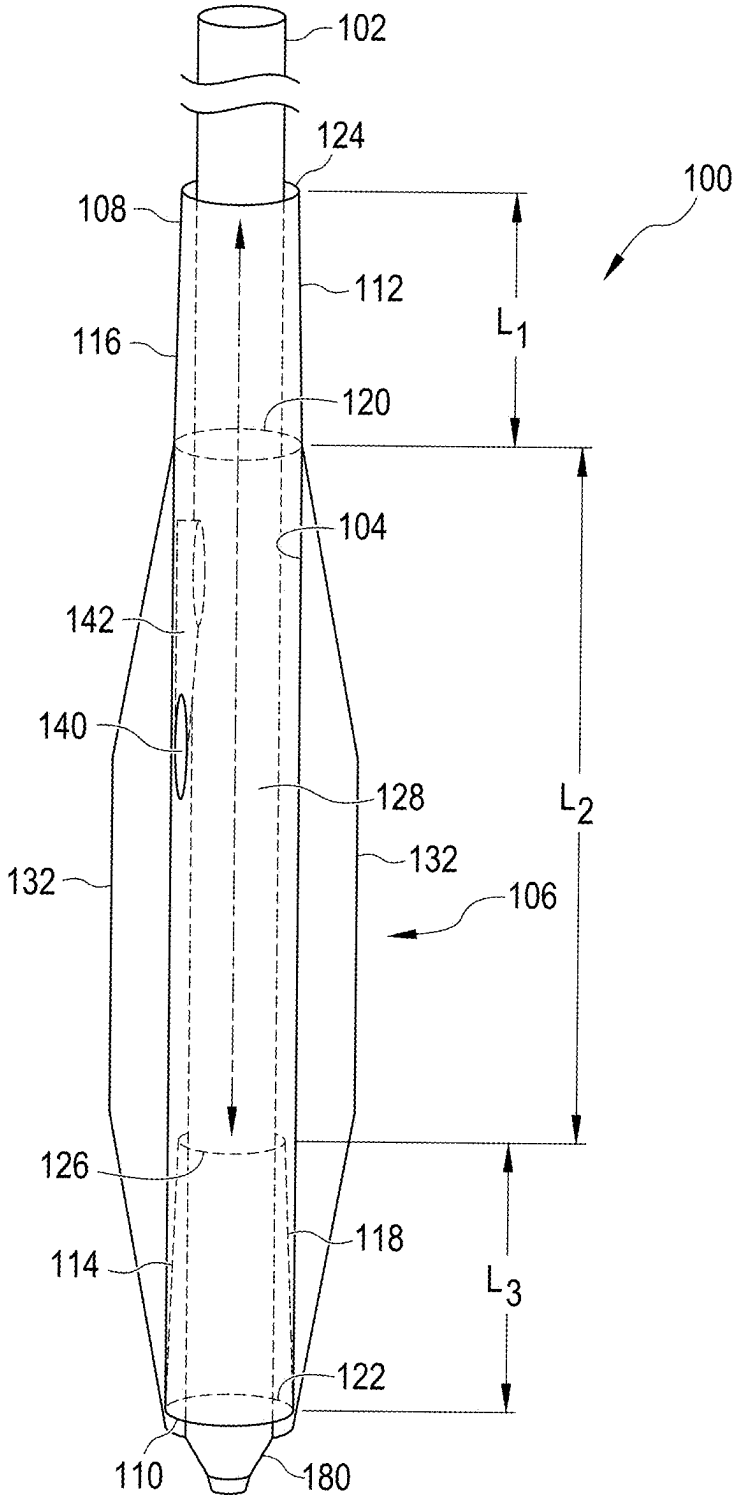
(57) **ABSTRACT**

Treatment segments of a catheter for heart valve treatment have a distal catheter body having a collapsible and expandable through conduit operatively connected to a collapsible and expandable valve cusp enclosure. The through conduit has a first end sealed by a first annular valve and a second end sealed by a second annular valve, which each have an elastic body, a distal end connected to the valve cusp enclosure, and a proximal end sealingly engaged to the distal catheter body in a deployed, closed position. The through conduit and the distal ends of each of the first and second annular valves are configured to expand with the valve cusp enclosure at a rate proportionate to a patient's blood pressure and a volume of blood displaced during expansion, and the elastic body and proximal ends thereof are configured to open and close in response to systolic and diastolic blood flow.

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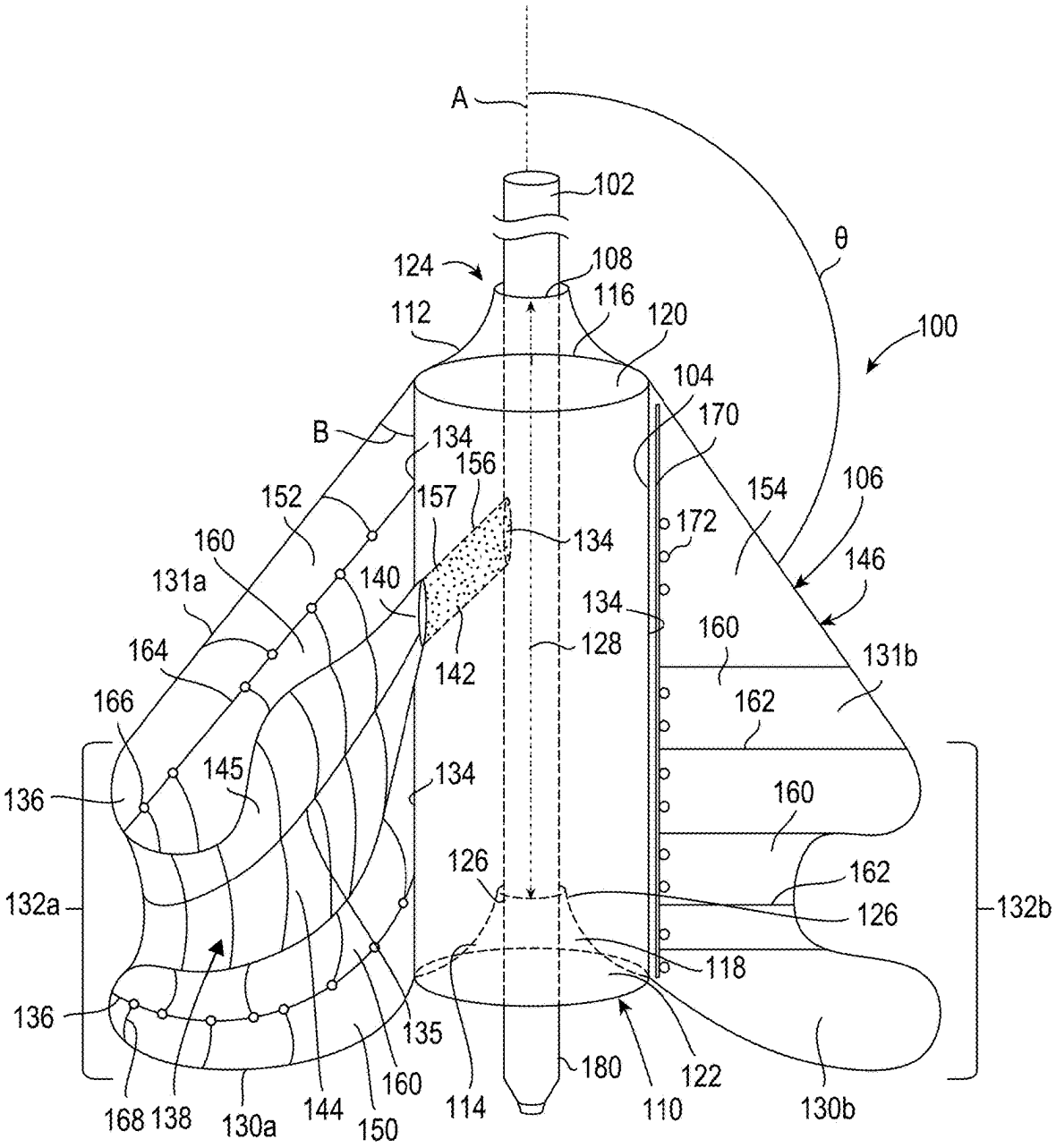
124
100
108
112
L_1
116
120
104
142
140
128
L_2
132
132
106
126
118
114
L_3
122
110
180

FIG. 1


A
102
θ
124
108
116
112
120
100
104
170
B
134
156
152
157
154
106
172
160
134
146
131a
140
134
160
164
128
131b
142
166
162
145
134
136
160
126
162
132a
126
132b
118
136
135
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122
160
168
138
130a
144
150
114
110
130b

FIG. 2

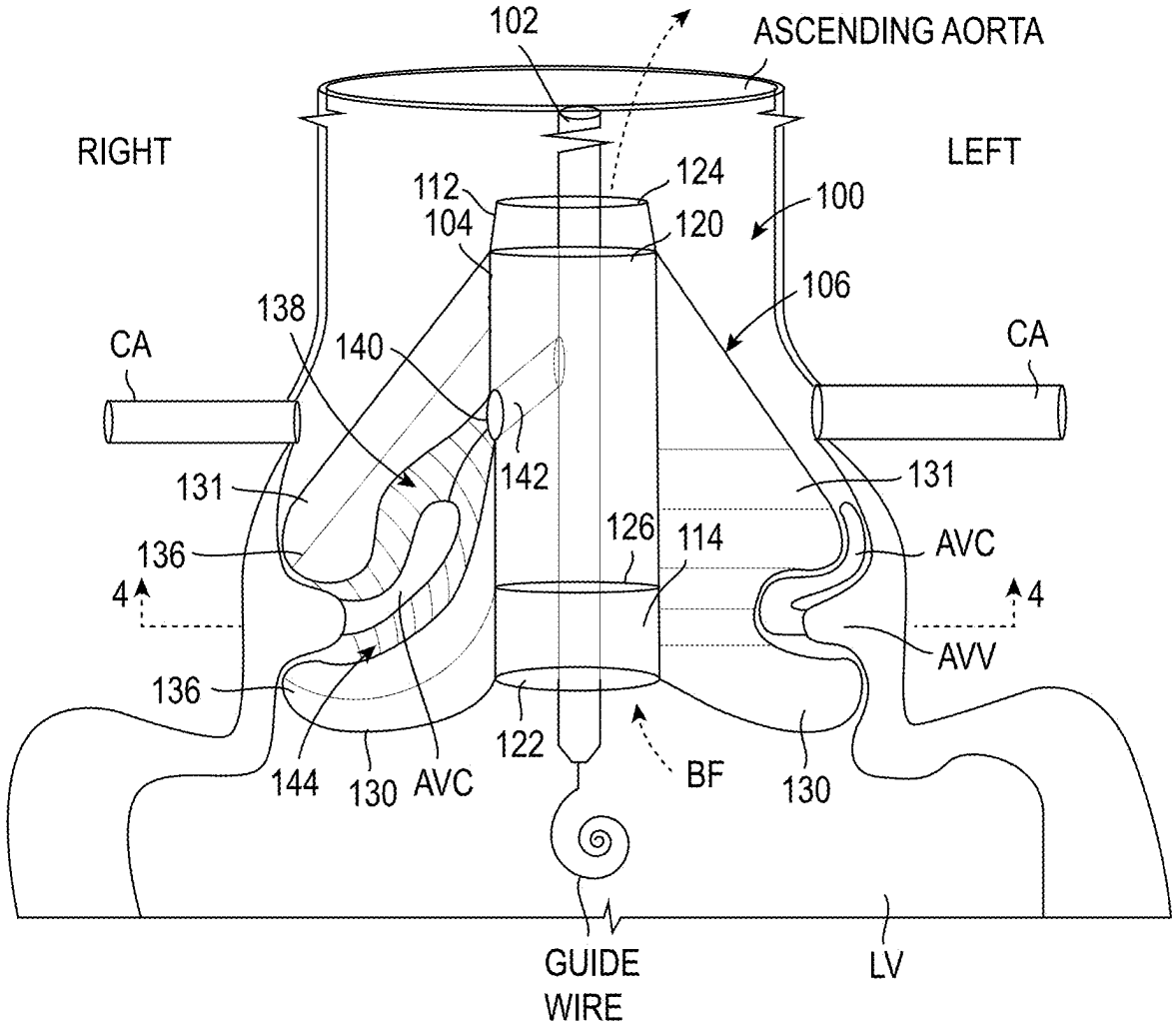

102
ASCENDING AORTA
RIGHT
LEFT
112
104
124
120
100
106
138
140
CA
CA
131
142
131
126
114
136
AVC
4
4
AVV
136
144
130
AVC
122
BF
130
GUIDE
WIRE
LV

FIG. 3

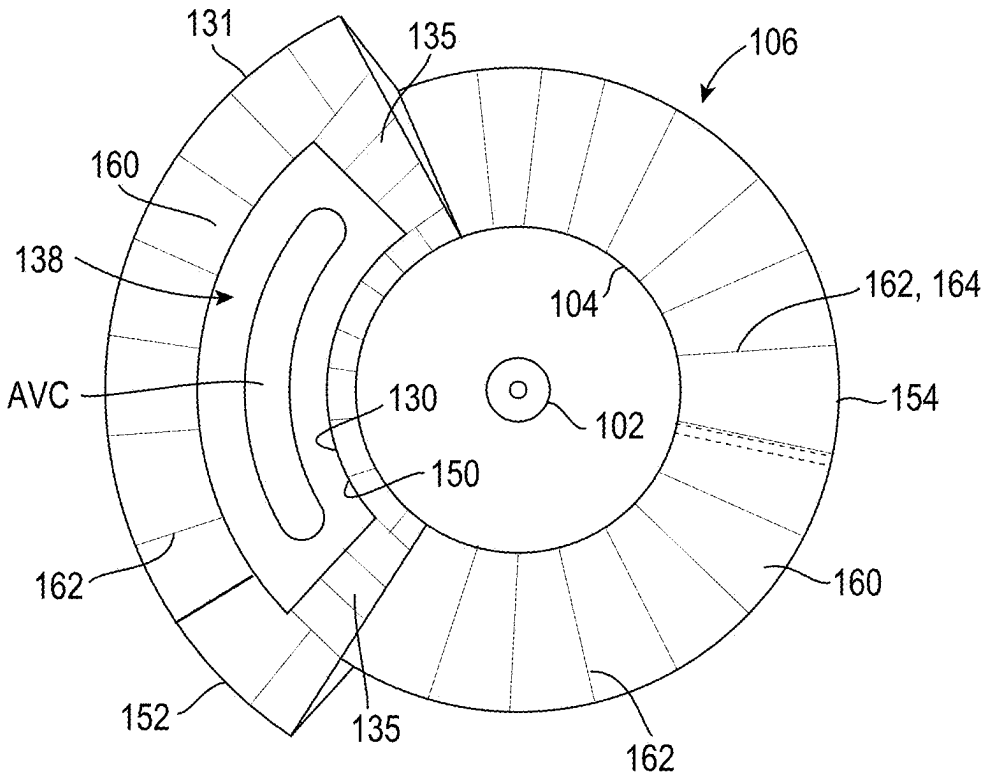
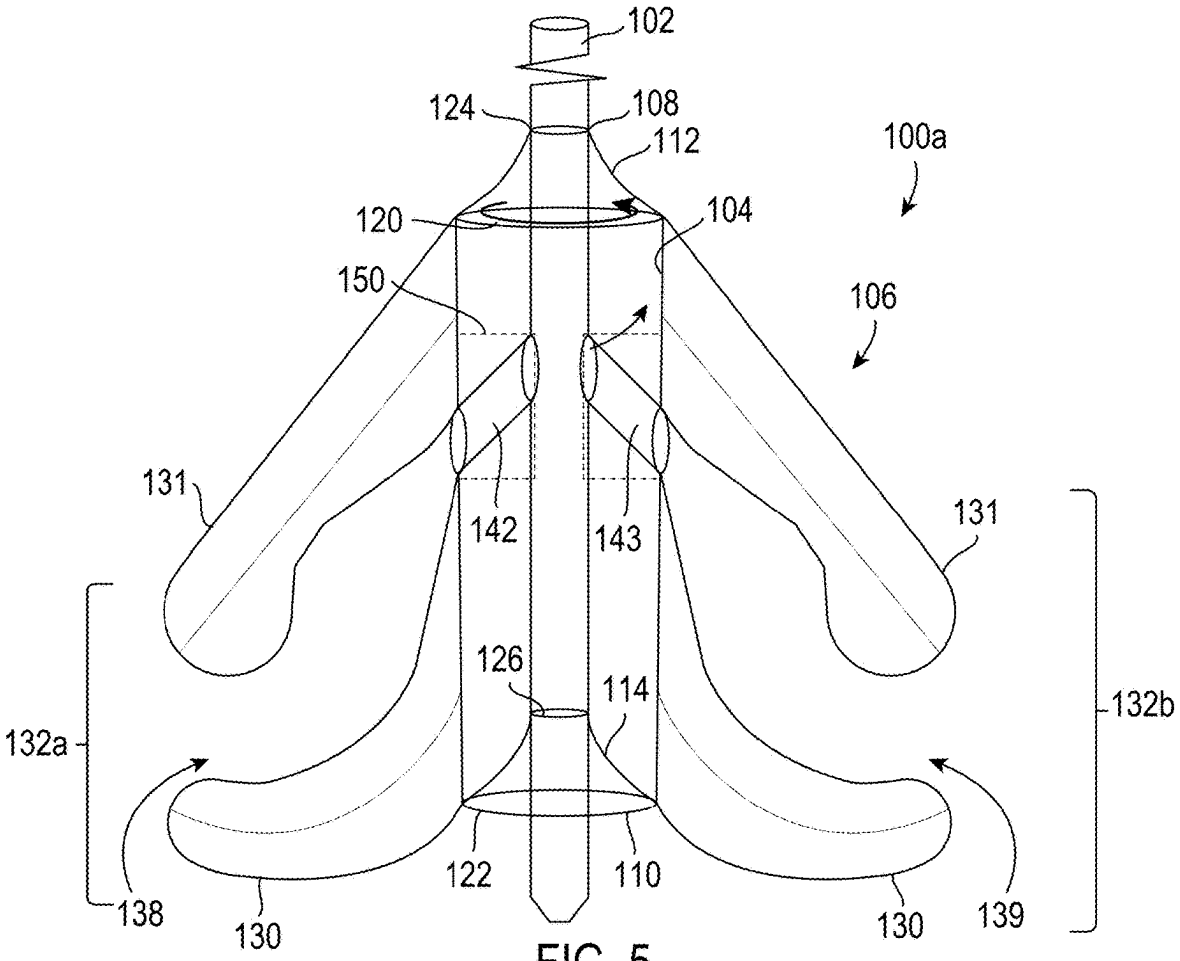

131
135
106
160
138
104
162, 164
AVC
130
102
154
150
162
160
152
135
162

FIG. 4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124
108
112
100a
120
104
150
106
131
142
143
131
126
114
132a
132b
122
110
138
130
130
139

FIG. 5

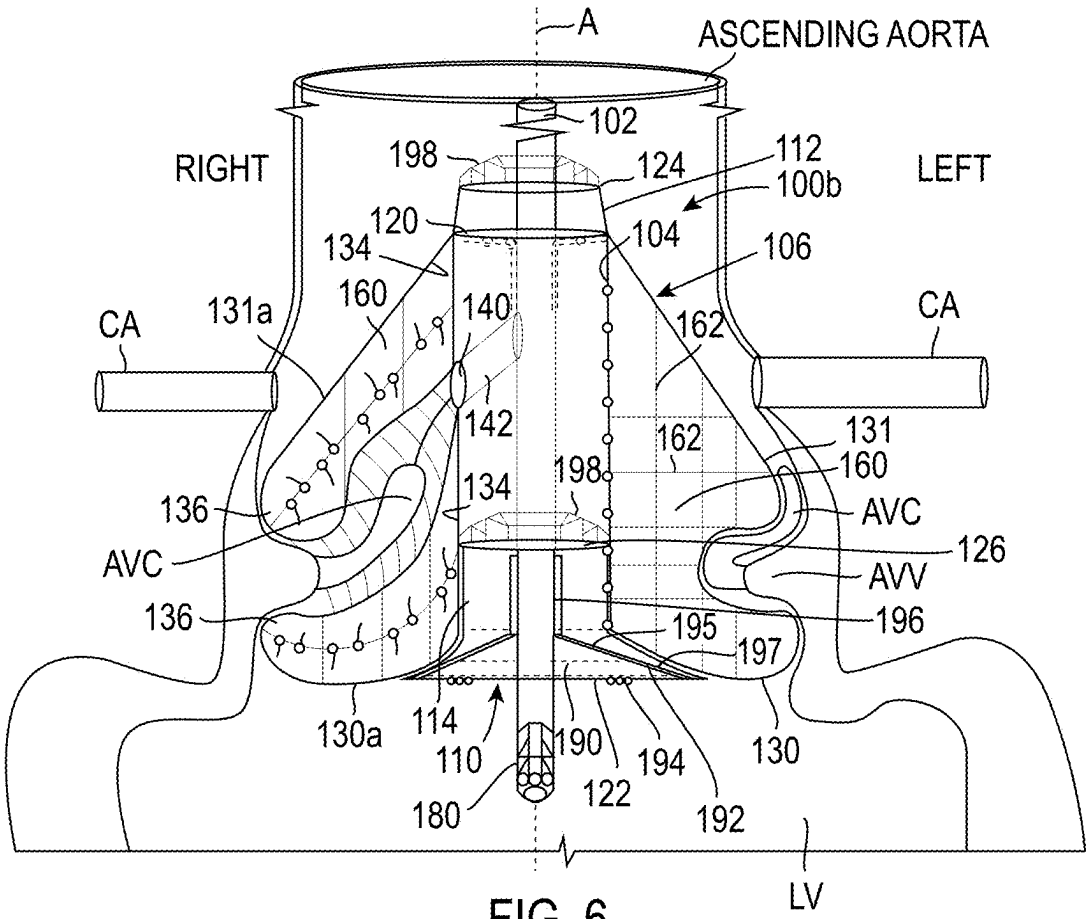

A
ASCENDING AORTA
102
RIGHT
198
124
112
100b
LEFT
120
104
106
134
160
131a
140
162
CA
CA
142
162
131
198
160
134
136
AVC
126
AVC
AVV
136
195
196
197
130a
114
110
190
194
130
180
122
192
LV

FIG. 6

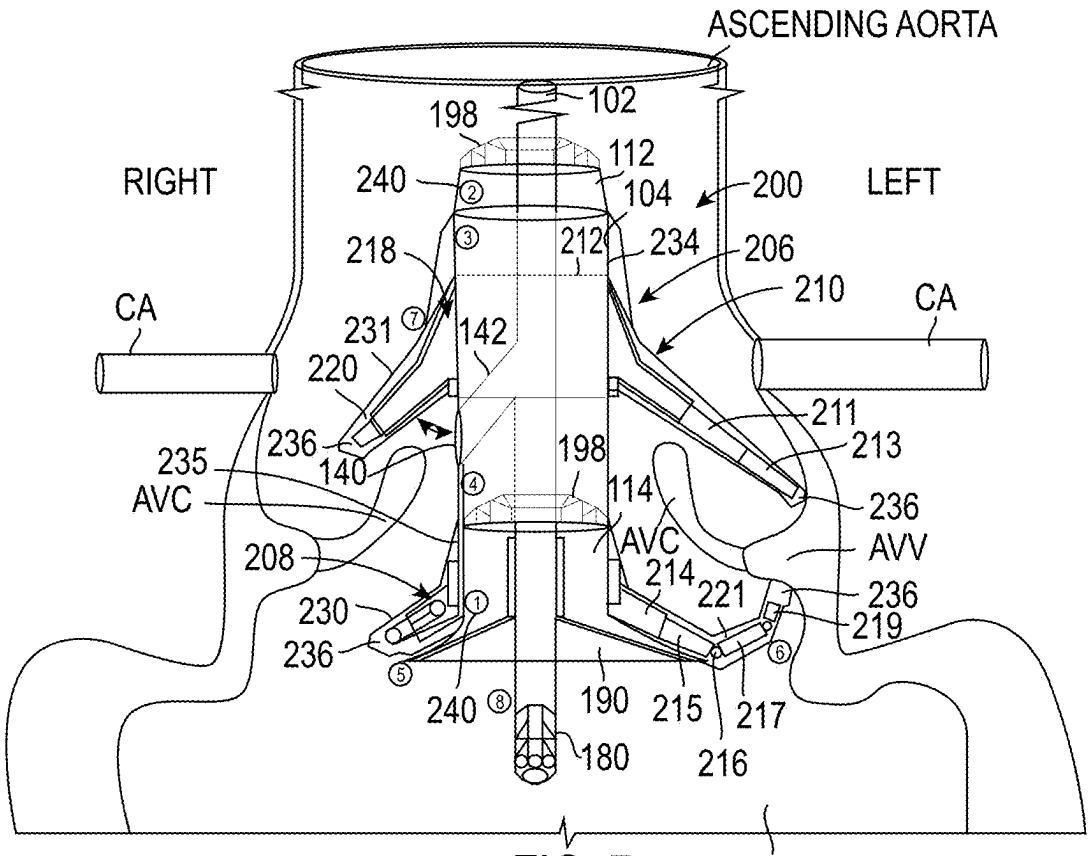

ASCENDING AORTA
198
102
112
RIGHT
240
104
200
LEFT
218
212
234
206
210
CA
CA
231
142
220
211
213
236
235
140
198
AVC
114
236
AVC
AVV
208
214
221
236
230
219
236
240
190
215
217
180
216
LV

FIG. 7

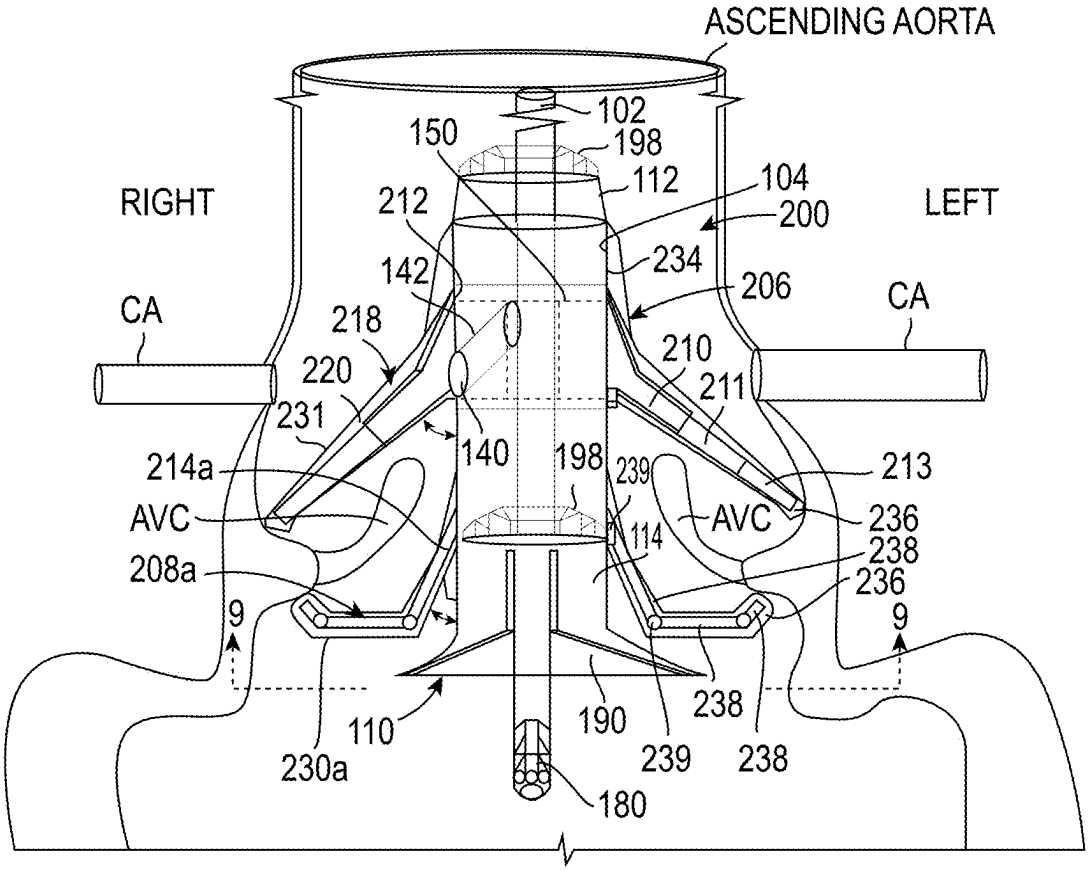
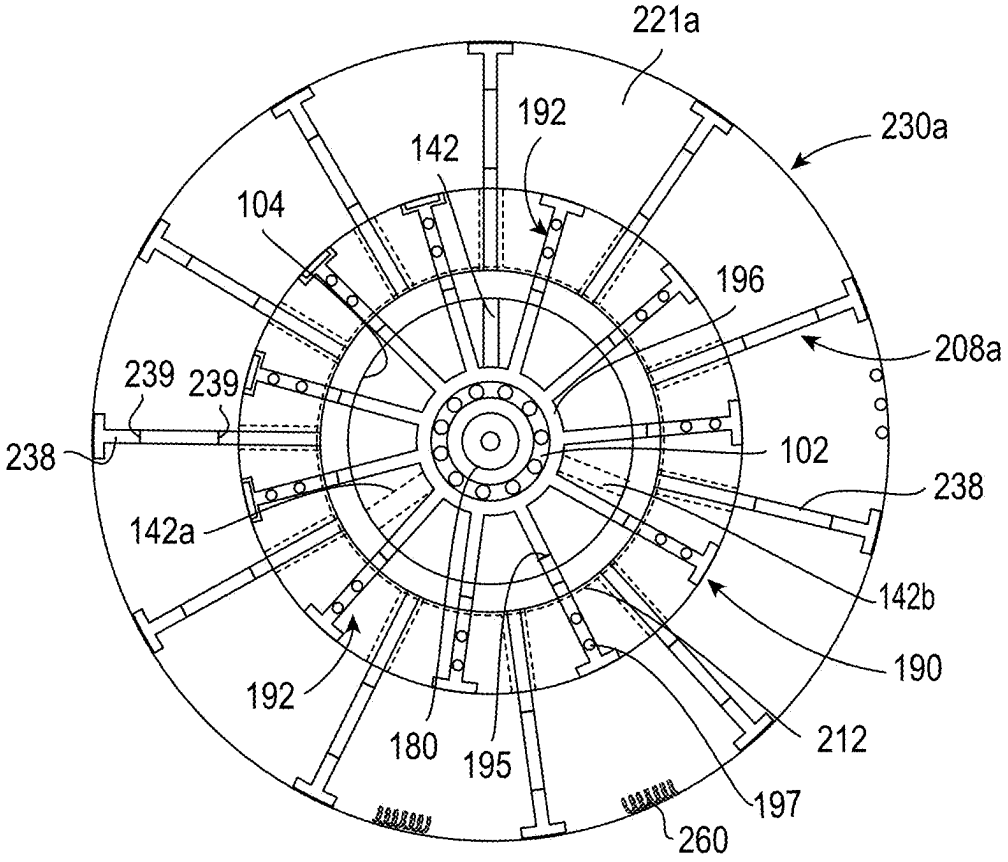

ASCENDING AORTA
102
150
198
112
104
200
RIGHT
212
LEFT
234
142
206
CA
218
CA
210
220
211
231
140
198
239
213
214a
AVC
AVC
236
114
238
208a
236
9
9
110
190
238
239
238
230a
180

FIG. 8


221a
192
230a
142
104
196
208a
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239
238
102
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142a
142b
190
192
212
180
195
197
260

FIG. 9

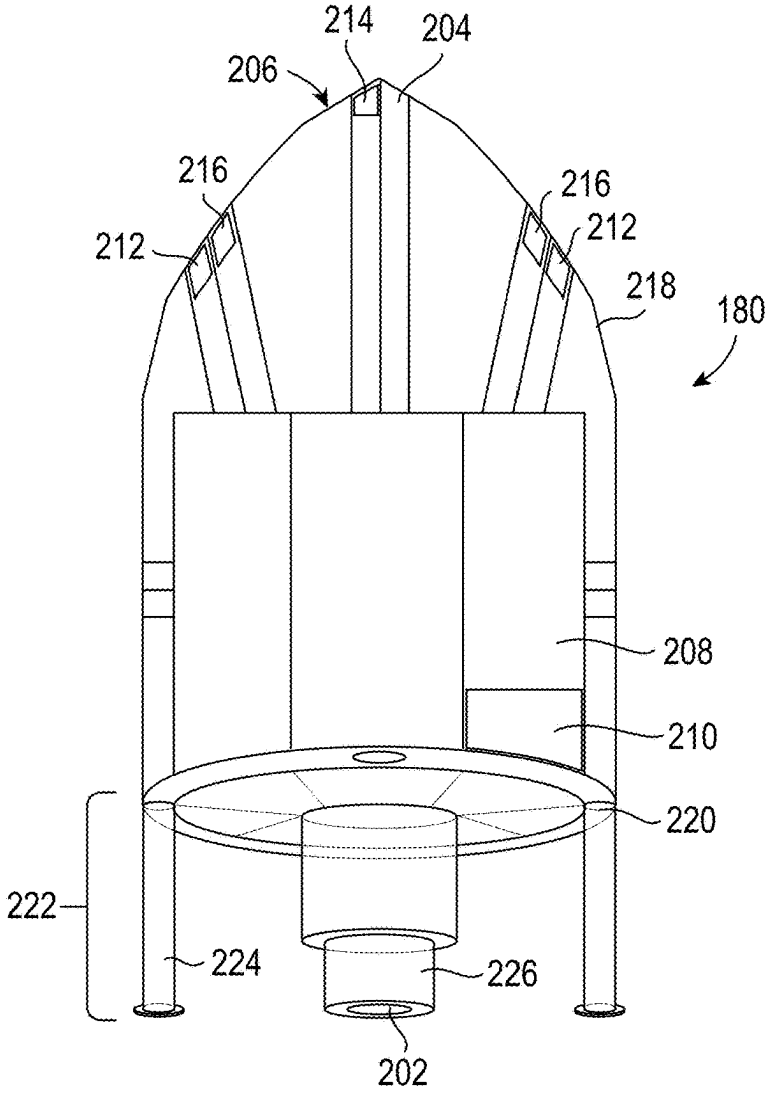

214
204
206
216
216
212
212
218
180
208
210
220
222
224
226
202

FIG. 10

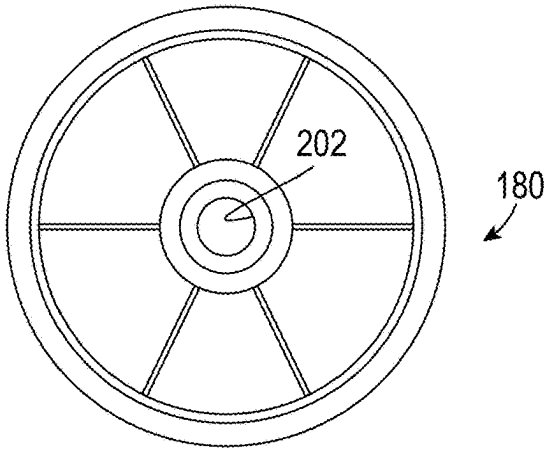

202
180

FIG. 11

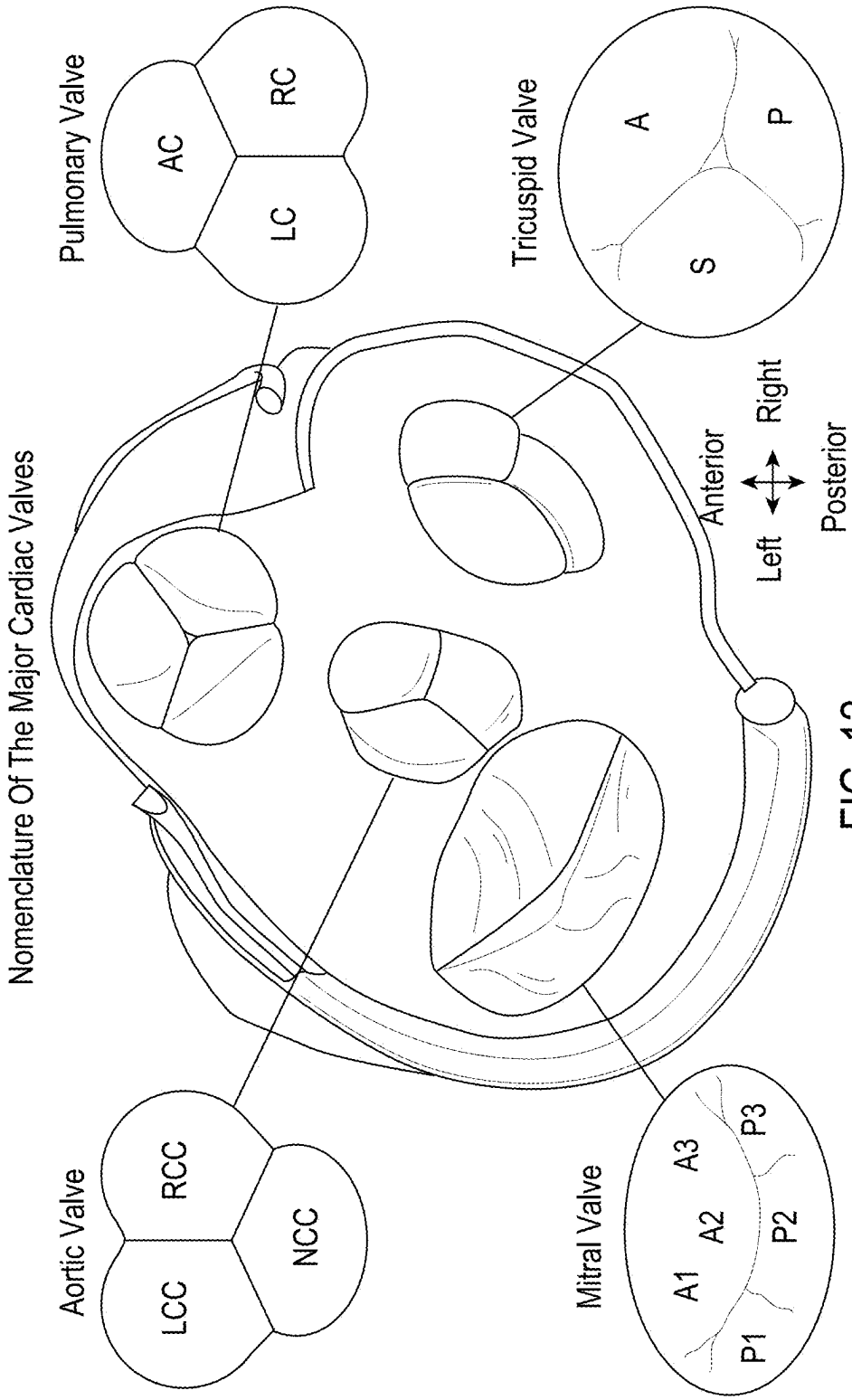

Nomenclature Of The Major Cardiac Valves
Pulmonary Valve
AC
RC
LC
Tricuspid Valve
A
P
S
Anterior
Right
Left
Posterior
Aortic Valve
RCC
LCC
NCC
Mitral Valve
A3
P3
A1
A2
P2
P1

FIG. 12

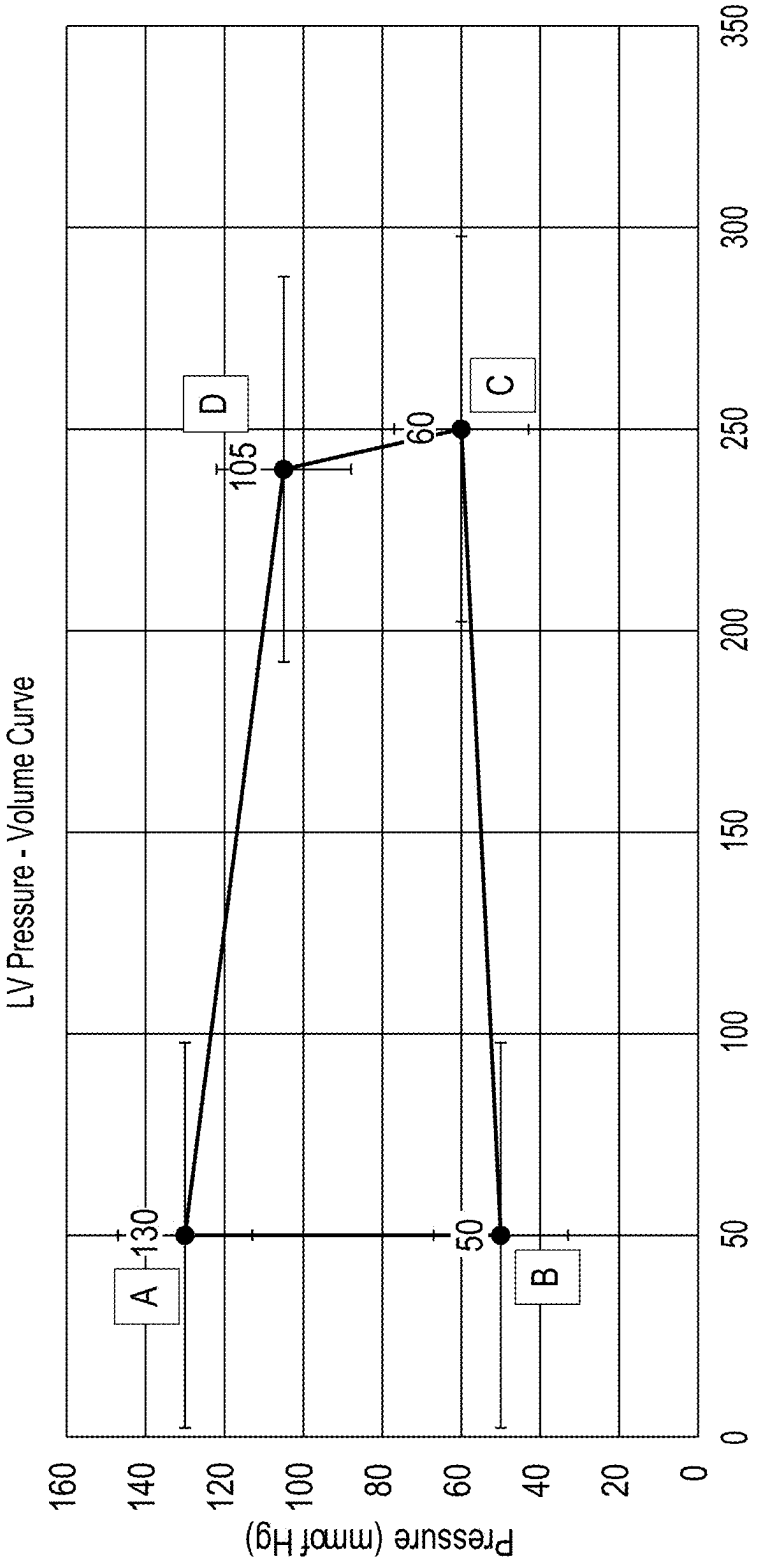

LV Pressure - Volume Curve
Pressure (mmHg)
Volume (ml)
160
140
120
100
80
60
40
20
0
0
50
100
150
200
250
300
350
A
B
C
D
130
50
60
105

FIG. 13

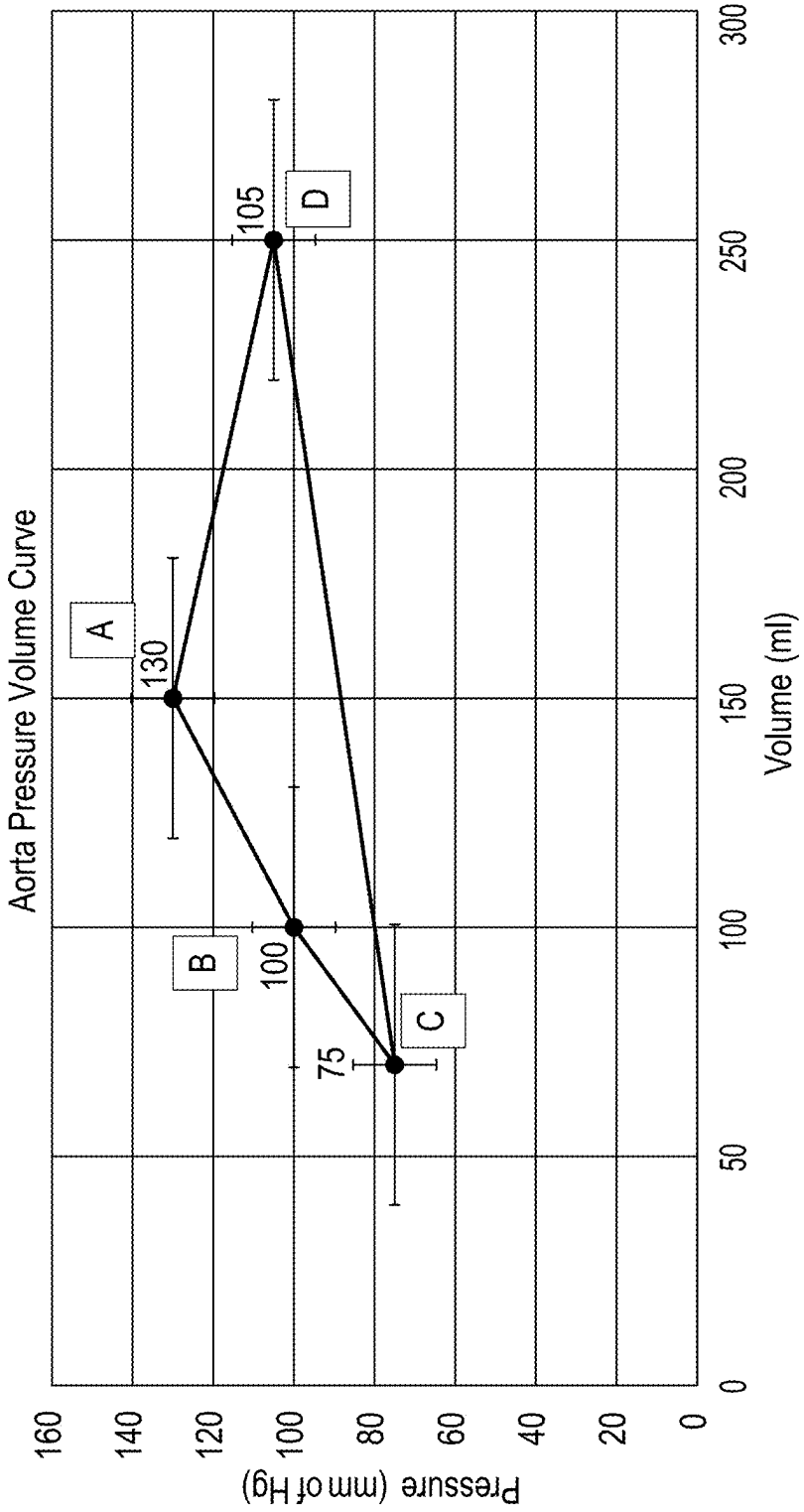

Aorta Pressure Volume Curve
Pressure (mm of Hg)
Volume (ml)
0
20
40
60
80
100
120
140
160
0
50
100
150
200
250
300
A
B
C
D
130
100
75
105

FIG. 14

Aortic Valve Cusp Dimension

Mean Cusp Thickness	Base Region (mm)	Rest of Cusp (mm)	Deformation (mm)	Remodel (mm)	Coefficient of Elasticity
LCC	0.692	0.362	3	0.181	38610164.14
NCC	0.812	0.475	3	0.237	50662508.20
RCC	0.86	0.482	3	0.241	51409113.58

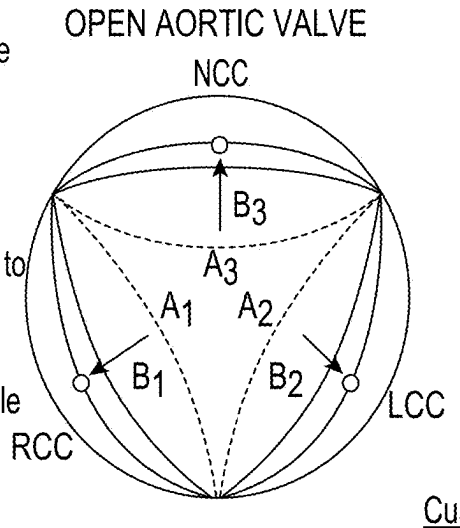
Cusp height	millimeters	mean
LCC	12-25	20 +/- 2.1
NCC	14-28	20.7 +/1 2.2
RCC	12-25	20 +/- 2.1

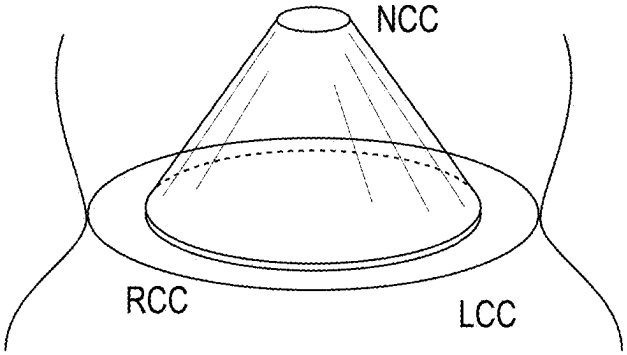
FIG. 15

A = Position of leaflet cusp (valve closed) at end of systole (A_1, A_2, A_3). No Tangential Stress (S_T)

B = Position of leaflet cusps (valve open) in peak diastole (B_1, B_2, B_3). Cusp flexion due to Tangential Stress (ST).

In a normal valve, positions of valve cusps during peak systole are equal or $B_1 = B_2 = B_3$.





Cusp Coefficient of Elasticity

$S_T = [(d/dt_{systole}) * (Mb * vb)]$

where

M_b = mass (volume) of blood

v_b = velocity of blood flow,

t_{sys} = Systolic time interval

$M_b = 0.6 * VED = (VED - VES)$

where

V_{ED} = End-Diastolic Volume

V_{ES} = End-Systolic Volume

V_b = LAOT / tSYSm/s

m = meters

s = seconds

thus, Stroke Volume (SV) = Mb

LL= distance from tip of leaflet (Node of Arantius) to the apex of the arc traversed by the leaflet from its insertion into the Annulus of the aortic valve.

rC= radius of Cusp of leaflet of valve

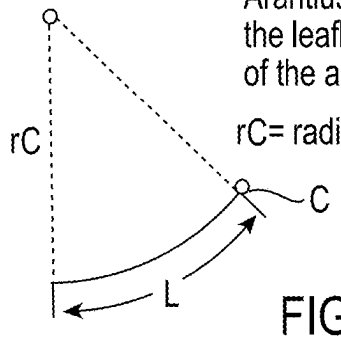


FIG. 16

BP mm of Hg	Aortic Shear Pressure N/m^2	Aortic Shear Pressure T n/cm^2	T on cusp N/cm^2	Cusp size cm^2	Area AV cm^2
	1	10000		1.3333	4
1	133.32239				
120	15998.69	159986868	213315824		
80	10665.79	106657912	142210549.3		

FIG. 17

ECHO PARAMETER	NORMAL AV	MILD AS	MOD AS	SERVE AS
PEAK VELOCITY M/SEC	<2.5	2.5-3	3.0-4.0	>4
MEAN GRADIENT MM HG	10	20	30	40
AORTIC VALVE AREA CM^2	2	1.5	1-1.5	<1

FIG. 18

FORECASTING LUMEN DIMENSIONS DIAMETER IN MM	PRESTENOTIC REGION MM	PRESTENOTIC REGION MM	FORECASTE RADIUS OF STENOTIC SEGMENT
CORONARY ARTERY LAD	3.92	2.1	3.01
CAROTID ARTERY	6.1	4.66	5.38
FEMORAL ARTERY	6.6	4.8	5.7

FIG. 19

REMODELING EFFECT ON LCC	FACTORING VALUES	CUSP THICKNESS MM	CUSP HEIGHT MM
LCC TIP	CUSP APEX	0.2800	9.5000
LOCATION BELOW TIP	0.25	0.2914	8.7500
THICKNESS LESS THAN AT BASE	0.011444444	0.3029	8.0000
THICKNESS AT APEX OF CUSP	0.28	0.3143	7.2500
		0.3258	6.5000
		0.3372	6.0000
		0.3487	5.5000
		0.3601	5.0000
		0.3716	4.5000
		0.3830	4.2500
		0.3944	4.0000
		0.4059	3.7500
		0.4173	3.5625
		0.4288	3.3750
		0.4402	3.1875
		0.4517	3.0000
		0.4631	2.8125
		0.4746	2.6250
		0.4860	2.4375
		0.4974	2.2500
		0.5089	2.0625
		0.5203	1.9375
		0.5318	1.8125
		0.5432	1.6875
		0.5547	1.5625
		0.5661	1.4375
		0.5776	1.3125
		0.5890	1.1875
		0.6004	1.1250
		0.6119	1.0625
		0.6233	1.0000
		0.6348	0.9375
		0.6462	0.8750
		0.6577	0.8125
		0.6691	0.7500
		0.6806	0.6875
	CUSP BASE	0.6920	0.6250

FIG. 20

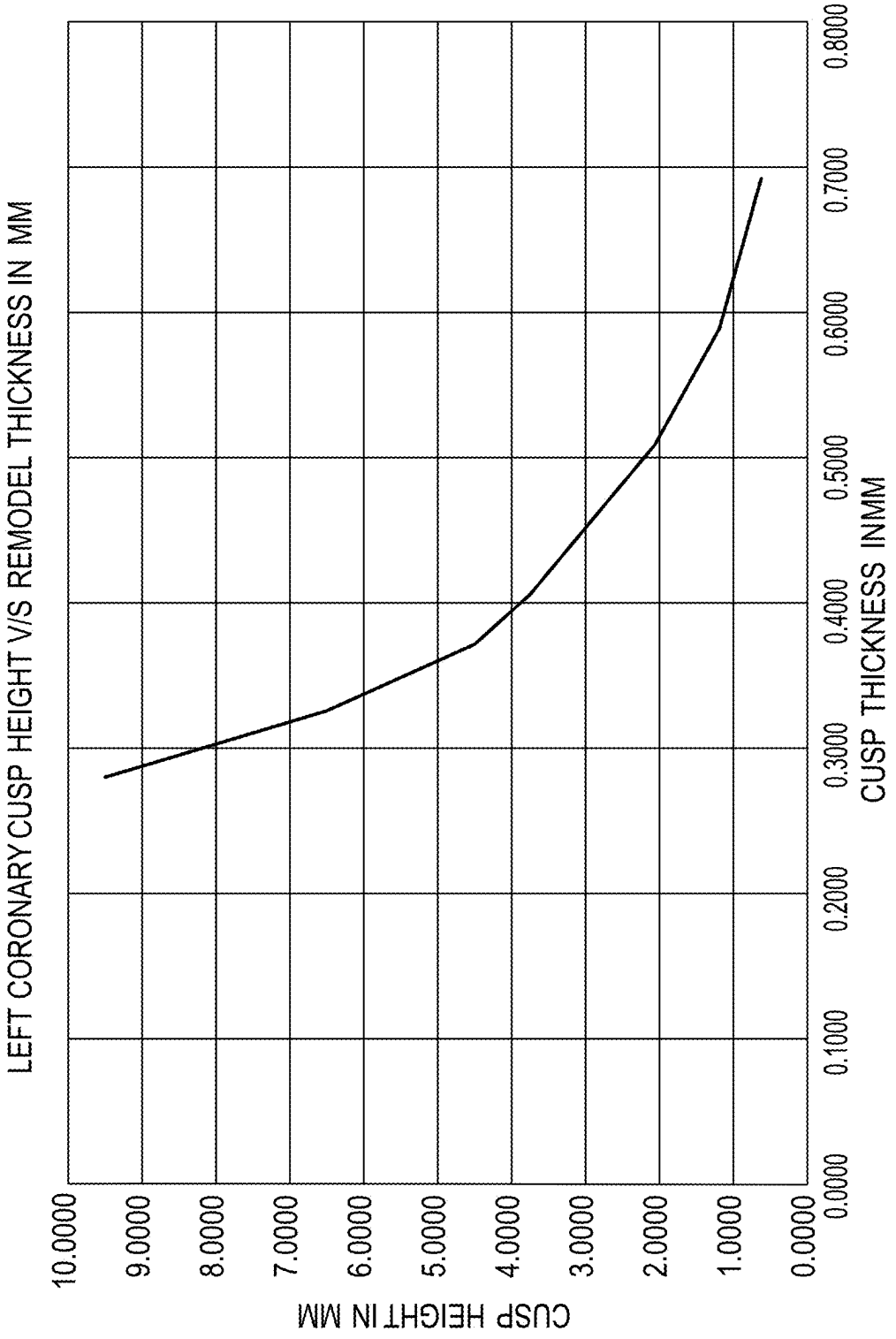
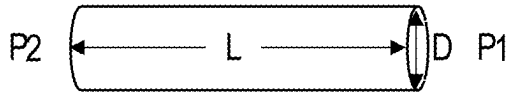

LEFT CORONARY CUSP HEIGHT V/S REMODEL THICKNESS IN MM
CUSP HEIGHT IN MM
10.0000
9.0000
8.0000
7.0000
6.0000
5.0000
4.0000
3.0000
2.0000
1.0000
0.0000
0.0000
0.1000
0.2000
0.3000
0.4000
0.5000
0.6000
0.7000
0.8000
CUSP THICKNESS INMM

FIG. 21

Poiseuille's Law: Volume flow rate in a tube = $Q_V = v * A$ (m^3/s)

where v = Velocity of blood flow (any liquid),

A = Cross-sectional area of the tube (Aorta)



$$Q_V = K*[(P1 = P1) *(D^4) /(L *\eta]$$

where η = viscosity of blood,

K = Constant,

D = diameter of tube (Aorta)

Thus, 10% reduction in D gives 34% reduction in flow; and

50% reduction in D reduces flow by 94%.

In a tube (Aorta), volume moved across a narrow segment increases velocity across the segment, $V_1 * A_1 = V_2 * A_2$

where, $V_2 * A_2 = Q_{V2}$ in the narrow segment with smaller diameter D_2,

$V_1 * A_1 = Q_{V1}$ in the part of the tube with larger diameter D_1.

Expressing tangential stress or shear stress as a tangent of linear force F = d/dt * (M * V)

where M = mass of liquid (blood)

V = Velocity of liquid (blood).

When lateral stress shape is nearly triangular (such as in the aortic Pressure/volume curve), the tangential stress is substantially equivalent to linear force for low angles of slippage.

FIG. 22A

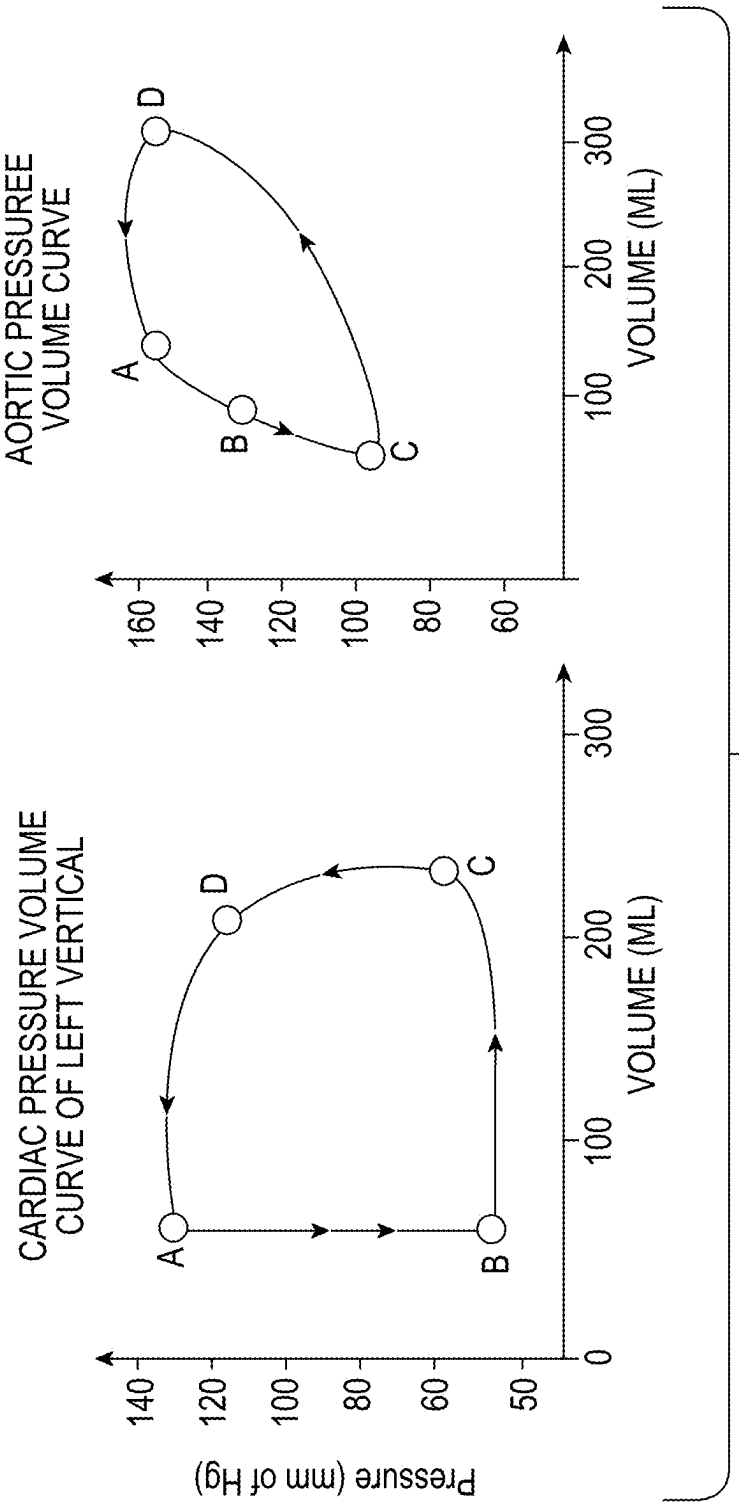

CARDIAC PRESSURE VOLUME
CURVE OF LEFT VERTICAL
Pressure (mm of Hg)
140
120
100
80
60
50
A
B
C
D
0
100
200
300
VOLUME (ML)
AORTIC PRESSUREE
VOLUME CURVE
160
140
120
100
80
60
A
B
C
D
100
200
300
VOLUME (ML)

FIG. 22B

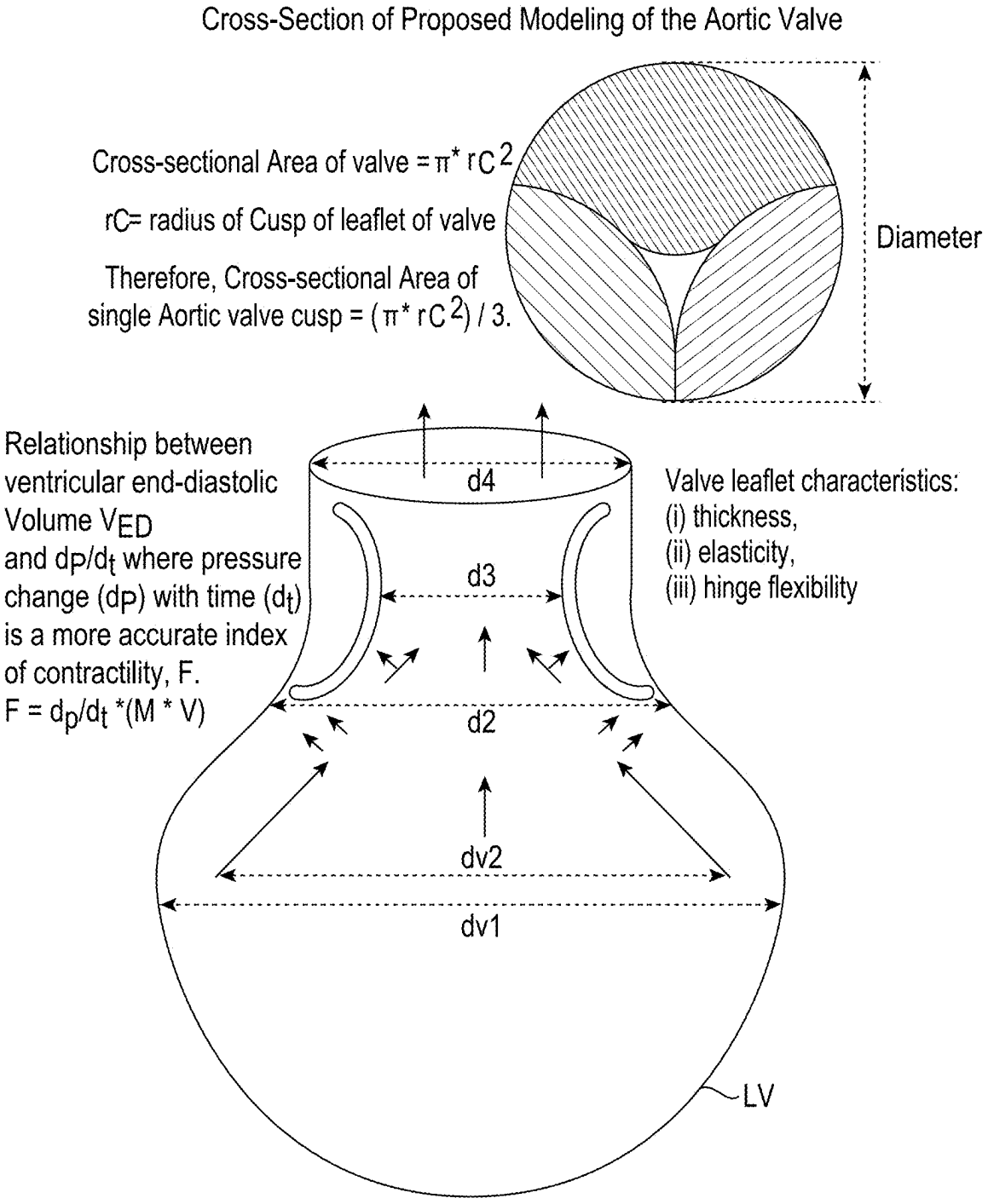

Cross-Section of Proposed Modeling of the Aortic Valve
Cross-sectional Area of valve = π* rC 2
rC= radius of Cusp of leaflet of valve
Therefore, Cross-sectional Area of single Aortic valve cusp = (π* rC 2) / 3.
Diameter
Relationship between ventricular end-diastolic Volume VED and dP/dt where pressure change (dP) with time (dt) is a more accurate index of contractility, F.
F = dP/dt *(M * V)
d4
d3
d2
dv2
dv1
LV
Valve leaflet characteristics:
(i) thickness,
(ii) elasticity,
(iii) hinge flexibility

FIG. 23

CATHETER TREATMENT SEGMENT

TECHNICAL FIELD

[0001] This application relates to catheters, more particularly, to catheters having a treatment segment for the aortic valve that has a valve cusp enclosure to create a bloodless field around at least one aortic valve cusp while providing a dual valved through conduit for blood flow from the ventricle to the aorta.

BACKGROUND

[0002] Catheters are used in various procedures for delivering therapeutic means to a treated site (e.g., body organ or passageway such as blood vessels). In many cases, a small inflatable balloon is guided to the treatment site. Once the balloon is in place, it is inflated by the operator to affix it in place, to expand a blocked vessel, to place treatment means (e.g., a stent) and/or to deliver surgical tools (e.g., knives, drills, etc.) to a desired site. One such procedure is transcatheter aortic valve replacement (TAVR), which is a minimally invasive method. This is typically used to treat aortic stenosis instead of open-heart surgery. Here, the aortic valve cusps are hyperextended radially outward and an artificial valve is positioned therebetween. The risks of the procedure include post-placement anticoagulation, blood vessel complications, valve slippage or leaking, stroke, heart arrhythmias, myocardial infarction, infection, and sometimes death.

[0003] U.S. Pat. No. 7,744,620 discloses a valvuloplasty catheter that uses one or more balloons to hyperextend a cusp of the aortic valve, thereby dislodging calcium deposits therefrom. In the embodiment of FIG. 8 thereof, a perfusion channel is present inside the balloon catheter and a single one-way valve that passively opens to allow blood flow. The perfusion channel closes when returning blood flow occurs. The blood is ventricular blood flowing into aorta. This is a universal need of all catheters that operate on the aortic valve and require blood flow from ventricle to exit into the aorta. The problem with this perfusion channel is that there is no method or design to address preferential flow, regulated volume or pressure of blood flow and thus greater risk of brain injury and organ damage due to lack of adequate perfusion pressure or blood flow. Moreover, the single one-way valve allows some antegrade flow of blood to reduce the resistance and prevent distal migration of the catheter. But a single valve is too weak to prevent retrograde flow of blood at high pressure. The pressure distal to the valve in the ventricle drops considerably and leaves the catheter in a position where it will collapse if it is flexible enough to be advanced through the arterial system of the subject. If the catheter is too rigid to withstand the variations of blood pressure below this valve, then it will not advance through the arterial tree of the subject.

[0004] There is a need for improved procedures and catheters that reduce the risks noted above, especially a catheter that is collapsible and flexible such that it can travel through the arterial system, and that has a means for continued blood flow of the patient without the need for a cardiopulmonary bypass pump. Moreover, there is a need to remodel and/or restore the aortic valve rather than require aortic valvuloplasty or aortic valve replacement after severe aortic stenosis with advanced calcification and fibrosis.

SUMMARY

[0005] In one aspect, treatment segments of a catheter for heart valve treatment have a distal catheter body having a collapsible and expandable through conduit operatively connected to a collapsible and expandable valve cusp enclosure. The through conduit has a first end sealed by a first annular valve and a second end sealed by a second annular valve, which each have an elastic body, a distal end connected to the valve cusp enclosure, and a proximal end sealingly engaged to the distal catheter body in a deployed, closed position. The through conduit and the distal ends of each of the first and second annular valves are configured to expand with the valve cusp enclosure at a rate proportionate to a patient's blood pressure and a volume of blood displaced during expansion, and the elastic body and proximal ends thereof are configured to open and close in response to systolic and diastolic blood flow.

[0006] In all aspects, the elongate body of the through conduit is configured to retain blood between systolic opening and diastolic closing of the first and second annular valves. The first annular valve and the second annular valve can be each frustoconically-shaped in a deployed, closed position.

[0007] In one aspect, the valve cusp enclosure has one or more ventricular cusp and aortic cusp pairs, wherein each pair has attached ends at the through conduit, the attached ends being spaced apart and having a catheter working port exit therebetween, each pair defines a pocket therebetween, and each pair has free ends configured to engage a patient's inferior surface of the aortic valve and superior surface of the aortic valve, respectively. The catheter working port exit is a terminal end of a port that extends radially from the distal catheter body through the through conduit. The port is expandable and collapsible between a deployed state and a transport state, respectively. In one embodiment, the pocket is configured to receive a single one of a patient's valve cusp therein. In another embodiment, the pocket is configured to receive two or more of a patient's valve cusps therein.

[0008] The one or more ventricular cusp and aortic cusp pairs each comprise an inflatable balloon having a plurality of individually controlled inflation chambers. The aortic cusp of the one or more ventricular cusp and aortic cusp pairs is controllably inflatable to maintain blood flow to the right and left coronary arteries. The through conduit has a length configured to position the first annular valve superior relative to the right and left coronary arteries. The aortic cusp is controllably inflatable to increase blood flow to the left and right coronary arteries.

[0009] The one or more ventricular cusp and aortic cusp pairs each comprise a plurality of telescoping, operatively expandable links housed inside a biomaterial. Each of the plurality of telescoping, operatively expandable links terminate with a foot configured to engage the respective inferior or superior surface of the annulus of the aortic valve. Each of the plurality of telescoping, operatively expandable links comprise one or more elbow joints defining an axis of rotation about which the more distal link is rotatable.

[0010] In another aspect, a treatment segment can include an electrocardiogram sensor, and the through conduit and the distal ends of each of the first and second annular valves are configured to expand controllably based on data from the electrocardiogram sensor.

[0011] In another aspect, methods of remodeling a cusp of a heart valve of a patient in need thereof are disclosed herein.

The method includes introducing a catheter having a heart valve treatment segment as described herein to a target heart valve, deploying the collapsible and expandable valve cusp enclosure into an expanded state in which a cusp of a heart valve in need of remodeling is enclosed in an isolated pocket and simultaneously expanding the through conduit into a corresponding expanded state, removing blood from the isolated pocket via the catheter to form a bloodless field surrounding the cusp of the heart valve, remodeling the cusp of the heart valve, collapsing the valve cusp enclosure, and removing the catheter from the patient. Introducing the catheter can include feeding the catheter through a patient's artery based on robotics in a terminal cap guided by fiberoptic imaging or infrared or IVUS videography or EKG sensors that seek cardiac sinus node electric homing, or a combination thereof. Deploying the valve cusp enclosure can include inflating a plurality of balloon segments with a fluid. Determining a lipid burden or calcium burden or fibrous scar tissue can include application of near-infrared spectroscopy plus intravascular ultrasound or a capacitive micromachines ultrasound transducer and fiberoptic cameras.

[0012] In one embodiment, the method includes advancing a tool through the catheter into the bloodless field and remodeling by one or more of:

[0013] i) removing fibrotic, calcific, and/or lipid laden material from a surface of the cusp using the tool;

[0014] ii) smoothing a surface of the cusp using the tool;

[0015] iii) preparing a surface of the cusp to accept a resurfacing material using the tool; and

[0016] iv) applying a resurfacing material to a surface of the cusp.

[0017] The "removing," item (i) above, can include a laser treatment of the surface of the cusp. The resurfacing material can be an elastin and/or stem cells. In another embodiment, the resurfacing material can be a drug treatment, such as collagen and/or carbon dots. When the resurfacing material is collagen, the method includes activating the collagen by application of an activating wavelength of energy.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] FIG. **1** is a side perspective view of one embodiment of a catheter in its collapsed form for travel through an artery of a patient and showing some of the interior structures thereof.

[0019] FIG. **2** is a longitudinal cross-section of the first embodiment in a deployed state showing some of the interior structures thereof.

[0020] FIG. **3** is a longitudinal cross-section of the first embodiment in a deployed state in the aortic root with one cusp of an aortic valve in a bloodless field defined by lobes of the catheter.

[0021] FIG. **4** is a transverse cross-sectional view taken along line **4-4** in FIG. **3**, but only showing the catheter and the aortic valve cusp present in the pocket.

[0022] FIG. **5** is a longitudinal cross-section of a second embodiment of a catheter in a deployed state.

[0023] FIG. **6** is a longitudinal cross-section of a third embodiment of a catheter in a deployed state.

[0024] FIG. **7** is a longitudinal cross-section of a fourth embodiment of a catheter in a partially deployed state.

[0025] FIG. **8** is a longitudinal cross-section of a fifth embodiment of a catheter in a fully deployed state.

[0026] FIG. **9** is a view of the distal end of the catheter of FIG. **8** from the ventricle of the heart as represented by the line **9-9**.

[0027] FIG. **10** is a side perspective view of a terminal cap for any of the embodiments of catheters disclosed herein and showing some of the interior structures of the terminal cap.

[0028] FIG. **11** is a plan view of the proximal end of the terminal cap of FIG. **10**.

[0029] FIG. **12** is an illustration of the cusps of the aortic valve.

[0030] FIG. **13** is a left ventricle pressure volume curve.

[0031] FIG. **14** is an aorta pressure volume curve.

[0032] FIG. **15** is a chart of aortic valve cusp dimensions.

[0033] FIG. **16** is a series of mathematical equations corresponding to the anatomy of the aortic valve.

[0034] FIG. **17** is a chart of values having the tangential shear calculated therein.

[0035] FIG. **18** is a chart of the velocity of blood and the smallest concentric area of the aortic valve relative to the degree of stenosis present in the aortic valve.

[0036] FIG. **19** is a chart of computer derived dimensions for remodeling the aortic valve.

[0037] FIG. **20** is a chart of computer-generated calculations and resulting incremental increase in thickness of the left coronary cusp of the aortic valve after remodeling.

[0038] FIG. **21** is a graph of the left coronary cusp height against remodel thickness in millimeters from the data in FIG. **20**.

[0039] FIG. **22**A is a series of mathematical equations related to blood flow and tangential sheer.

[0040] FIG. **22**B presents graphs, (i) a cardiac pressure volume curve of the left ventricle and (ii) an aortic pressure volume curve thereof.

[0041] FIG. **23** is an anatomy illustration of the ventricle and aortic valve and corresponding mathematical equations.

DETAILED DESCRIPTION

[0042] The following detailed description will illustrate the general principles of the invention, examples of which are additionally illustrated in the accompanying drawings. In the drawings, like reference numbers indicate identical or functionally similar elements.

[0043] The catheters disclosed herein enable treatment of aortic stenosis and/or ankylosis in its early stages, such as when mild or moderate, but is also suitable if it is severe. If treated early, it may be possible to prevent left ventricular longitudinal or concentric remodeling or hypertrophy and left ventricular fibrosis. Moreover, it may be possible to prevent right ventricular hypertension, left atrial enlargement, and decreased left ventricular systolic function. The catheters will enable a medical professional to remodel the aortic valve cusps to return flexibility and mobility thereto by any one or more of the following: (i) remove calcification, (ii) synthesize fibrosa epithelium on the aortic side of the cusp, (iii) synthesize ventricularis epithelium on the ventricular side of the cusp, (iv) synthesize spongiosa inside the body of the cusp, (v) remove lipid material from the sub-epithelium of the cusp, and (vi) remodel the cusps morphology to its more native valve shape.

[0044] The examples discussed herein are focused on the aortic valve. The heart has three other valves as well, the mitral valve, pulmonary valve, and tricuspid valve. The catheter and systems disclosed herein can be used to remodel cusps of the other valves too.

[0045] Turning to FIGS. **1-3**, a first embodiment of a treatment segment of a catheter, generally referred to by the reference number **100**, for heart valve treatments is shown in a transport state in FIG. **1** and in a deployed state in FIGS. **2** and **3**. The treatment segment **100** has a distal catheter body **102** having a collapsible and expandable through conduit **104** in surrounding relationship to the distal catheter body **102** and operatively connected to a collapsible and expandable valve cusp enclosure **106**. In the transport state, the components of the treatment segment are collapsed against the catheter body and have a profile small enough to be transported through a patient's arteries and aorto-ventricular system and flexible enough to navigate through the aorta, pulmonary artery, etc.

[0046] The diameter of the treatment segment **100** may range from 6 to 40 French, more preferably 12 French (12F) to 18 French (18F). The diameter can be customized to an individual's circulatory system size. The length of the treatment segment **100** has an overall length that can be customized to fit the height of the aortic root, location of the ostia of the right coronary artery and the left coronary artery origins, the height of the sinus of Valsalva and the structure of the left ventricle outflow tract of the intended patient. The width of the treatment segment **100** is customized to fit the ascending aortic diameter, aortic root diameter, aortic valve annular diameter, valvular opening (restricted by aortic stenosis) and the diameter of the ventricular outflow tract of the intended patient.

[0047] The through conduit **104** has a first end **108** sealed by a first annular valve **112** and a second end **110** sealed by a second annular valve **114**, and each of the first and second annular valves **112**, **114** have an elastic body **116**, **118**, a distal end **120**, **122** connected to the valve cusp enclosure and a proximal end **124**, **126**, respectively, sealingly engaged to the distal catheter body in a deployed, valves closed position as shown in FIG. **2**. The through conduit **104** and the distal ends **120**, **122** of each of the first and second annular valves **112**, **114** are configured to expand with the valve cusp enclosure **106** at a rate proportionate to a patient's blood pressure and a volume of blood displaced during expansion, and the elastic body **116**, **118** and proximal ends **124**, **126** of each of the first and second annular valves **112**, **114** are configured to open and close in response to systolic and diastolic blood flow, respectively, thereby moving the proximal end **124**, **126** of each in and out of sealing engagement with the distal catheter body **104**.

[0048] In other words, each of the first and second annular valves **112**, **114** are configured to allow blood to flow from the ventricle into the aorta. The second annular valve **114** has a proximal end **126** that is expansible (elastic) and inflates with each heartbeat from the pressure generated by the blood pressure as the ventricle generates a systolic force and then deflates due to its elastic nature during diastole and hugs the distal catheter body **104** such that there is no reverse flow. This allows blood to flow to the proximal end **124** of the first annular valve **112** during systole and not during diastole. The systolic blood pressure transmitted proximally due to opening of the proximal end **126** of the second annular valve **114** now allows the blood to flow through the first annular valve **112**, distal to proximal, and the pressure expands the proximal end **124** of the first annular valve **112** with each stroke volume of blood delivered to it. The proximal end **124** is elastic and deflates during diastole; thus, hugging the distal catheter body **104** and preventing reversal of blood flow (BF), labeled in FIG. **3**. In other words, blood can continue to flow through the heart when a procedure is being performed, thereby enabling a longer period of time for treatment procedures.

[0049] The through conduit **104** has an elongate body **128** configured to retain blood between systolic opening and diastolic closing of the first and second annular valves **112**, **114**. The first annular valve **112** and the second annular valve **114** are each frustoconically-shaped in a deployed, valves closed position as shown in FIG. **2** with the proximal ends **124**, **126** closed onto the distal catheter body **102**. The through conduit **104** has a length L configured to position the first annular valve **112** superior relative to the right and left coronary arteries. As seen in FIG. **1**, the length L has been labeled as length portions L**1** for the first annular valve **112**, L**2** for the portion of the through conduit between the proximal end of the second annular valve **114** and the distal end of the first annular valve **112**, and L**3** for the length of the second annular valve **114**. L**1** can range from 1 cm to 5 cm. L**2** can range from 4 cm to 20 cm. L**3** can range from 2 to 6 cm.

[0050] With reference to FIG. **3**, in a deployed state at the left ventricle (LV) aortic valve annulus (AVV), the second end **110** of the treatment segment **100** including a distal-most lobe **130** of the valve cusp enclosure **106** and the second annular valve **114**, which can be referred to as a distal ventricular valve. The treatment segment **100** is positioned with its second end **110** in the ventricular outflow tract below the aortic valve cusps (AVC) and in the deployed state the distal-most lobe **130** engages the inferior surface of the AVV. The first end **108** of the treatment segment **100** includes the first annular valve **112**, which can be referred to as a proximal aortic valve. The treatment segment is positioned with its first end **108** in the aortic root cranially positioned relative to or superior to both the right coronary artery (right CA) and the left coronary artery (left CA).

[0051] Each of the first and second annular valves **112**, **114** can be made of a solid flexible elastic polymer such as polytetrafluoroethylene or Dacron® by DuPont. The solid flexible elastic polymer may be thicker at the distal end and gradually becomes thinner proximally, such that the proximal end has a specific retractive property. In one embodiment, the proximal end has a stiffness of the elastic property that enables the valve to open at pressures of 150 mm of Hg to 200 mm of Hg. In another embodiment, the proximal end has a stiffness of the elastic property that enables the valve to open at pressures of 120 mm of Hg to 150 mm of Hg. In yet another embodiment, the proximal end has a stiffness of the elastic property that enables the valve to open at pressures of 90 mmm of Hg to 120 mm of Hg. The selected pressure range will vary from patient to patient based on historical blood pressure demonstrated prior to the procedure.

[0052] As noted above, each of the first and second annular valves **112**, **114** have their respective distal ends **120**, **122** configured to expand with the valve cusp enclosure **106** at a rate proportionate to a patient's blood pressure and a volume of blood displaced during expansion. This expansion can be accomplished by robotics (see FIGS. **6-9**), a multi-segmented balloon (see FIGS. **1-3**), or electrical signals (wired or wireless), e.g., activation of a shape memory alloy. The diameter achieved by any one of these expansion means is adjustable and can be configured to the individual

size of the anatomy and hemodynamics of circulation and blood pressure or cardiac output of the intended patient.

[0053] Continuing to refer to FIGS. **1-3**, in all embodiments, the valve cusp enclosure **106** has a first ventricular cusp and aortic cusp pair **132***a* that are attached to and extend from the through conduit **104**. The attachment portion is referred to herein as respective attached ends **134** of each of the ventricular cusp and the aortic cusp of said pair **132***a*. The ventricular cusp **130** and the aortic cusp **131** are spaced apart proximate a working port exit **140** that is positioned therebetween and, when inflated/deployed, define a pocket **138** shaped to receive an aortic valve cusp (AVC) cusp therebetween. The pair **132***a* are permanently joined to one another by opposing vertical segments **135** to define the pocket **138**. The vertical segments **135** extend radially from the attached ends **134** to the free end **136** of the cusps. In the embodiment of FIGS. **2-4** that treats one valve, the vertical segments **135** deploy simultaneously with the deployment of the two (aortic and ventricular) cusps. Each of the ventricular cusp **130** and the aortic cusp's **131** free end **136** is configured to engage a patient's inferior surface of the aortic valve and superior surface of the aortic valve, respectively, as shown in FIG. **3**, which forms a fluid-tight seal to the AVV so that a bloodless field can be created around the AVC.

[0054] In one embodiment, the port **142** and its exit **140** are merely a part of an inflatable balloon system (aortic and ventricular cusps **130**, **131** and vertical segments **135**) such that the port is simply a conduit defined by the balloon itself. Thus, when the balloon inflates, the central hollow area of the port **142** extends out to the tip of the valve leaflet and opens up for operative communication with the pocket **138**.

[0055] The working port exit **140** is a terminal end of port **142** that extends radially from the distal catheter body **102** through the through conduit **104**. The port **142** may be oriented at an angle relative to the central longitudinal axis A of the catheter body **102**, with the working port exit **142** oriented toward the second annular valve **114**. The angle is dependent on the degree of inflation of the valve cusp enclosure **106**. The greater the inflation of the valve cusp enclosure **106**, the more horizontal (closer to 90 degrees) the port **142** will be relative to the catheter body **102**. The port **142** is made of a material similar to the valve cusp enclosure **106**, so as to be able to convert from a transport state to a deployed state, i.e., it is elastic and will be stretched via attachment to the valve cusp enclosure **106**. The port can be about 12F to 18F dimensionally and have a length in a range of 0.5 cm to 2.5 cm.

[0056] The walls of the port **142** can include inflatable chambers to receive a fluid to aid in deployment of the port. In another embodiment, the port **142** is constructed of concentric telescoping tubes **156** that can extend passively with expansion of the valve cusp enclosure **106**, i.e., an attachment thereto. In any of the embodiment, the wall of the port **142** can include lumen or conduits in operative communication with the valve cusp enclosure **106**, sensors position at the working port exit **140** or in the wall defining the pocket **138** of the valve cusp enclosure **106**. The wall of the port **142** can include a plurality of layers, in any number suitable to provide an adequate number of lumen and/or conduits. In some embodiment, the wall of the port **142** include two to 10 layers of material.

[0057] In another embodiment, the port **142** includes high tensile, light weight titanium and/or plastic multi-linked multi-rotational prongs **157** attached along the exterior surface thereof or integrated into a wall of the port. The prongs can lengthen or shorten the port **142** in increments of microns and move the port directionally in X—Y—Z axes in increments of 1/10 of a degree up to increments of 1 degree.

[0058] As best shown in the comparison of FIGS. **1** and **2**, the port **142** is expandable and collapsible between a deployed state (FIG. **2**) and a transport state (FIG. **1**), respectively. As shown in FIG. **3**, the first ventricular cusp and aortic cusp pair **132***a* is configured to receive a single AVC, and via the fluid-tight engagement of the pair **132***a* with the AVV, the port **142** is used to remove blood from the pocket to facilitate repair of the AVC in a bloodless field. Tools can then be advanced through the catheter body **102**, through the port **142**, into the pocket **138** to treat the AVC. Since this treatment segment treats a single AVC, after treatment of a first AVC, the valve cusp enclosure **106** can be returned to a transport state, rotated, and re-deployed to the deployed state with a different AVC positioned in the pocket **138**.

[0059] Still referring to FIGS. **2-3**, the valve cusp enclosure **106** includes a secondary ventricular cusp and aortic cusp pair **132***b*, having a secondary ventricular cusp **130** and a secondary aortic cusp **132**, which can define a pocket **138** to isolate a second and/or third valve cusp or are collectively shaped and/or inflated to lift one or more of the AVCs away from the ventricle toward the aortic wall during the treatment procedure. When there is a second pocket **139**, the second pocket **139** will counterbalance the treatment cusp assembly and prevent dislodging thereof in the opposite direction. The pocket **139** may be made deep by inflating the aortic and ventricular cusps more **130**, **131** relative to the vertical segments **135**, thus leaving the two untreated leaflets (or one cusp if this is a bicuspid aortic valve) undeformed. This is especially important when the untreated valve cusps are heavily calcified and ankylosed and will need treatment also.

[0060] Generally, the ventricle cusps **130**, in the expanded, deployed state, protrude radially outward from the through conduit **104** and are angled toward the ventricle. The pocket surface **144** defined by the ventricle cusps **130** are concave. The concavity can generally match the shape of the inferior surface of the AVC. The aortic cusps **131**, in the expanded, deployed state, protrude radially outward from the though conduit and are angled toward the ventricle. The angle of the aortic cusps **131** relative to a central longitudinal axis A of the catheter and the radial outmost surface **146** of the aortic cusp is an obtuse angle Θ, which keeps the valve cusp enclosure **106** from blocking the coronary arteries and is at an angle β relative to the exterior surface of the through conduit **104**. The angle β can be in a range of 10 to 60 degrees for the superior surface of each cusp, sometimes 30 to 60 degrees. The pocket surface **145** defined by the first aortic cusp **131** is contoured to have a convex portion and a concave portion. The contour of the pocket surface **145** is generally opposite of the shape of the superior surface of the AVC. The free end **136** of each cusp of the valve cusp enclosure **106** is expandable circumferentially, i.e., the cusp fans out to engage and cover the base of the AVC at the AVV.

[0061] The treatment segment **100** may be removably, replaceably secured to the catheter body **102**. The connection can have an interlocking mechanism for retention of the treatment segment **100**. This feature facilitates changing the treatment segment for one of a different size, specifications, or sending capabilities.

[0062] In an embodiment where the coronary artery ostia are more proximal to the aortic valve in the sinus of Valsalva, the degree of inflation of the first and second superior or cranial or proximal segments of the balloon of the valve cusp enclosure **106** will determine the angle and balloon surface's proximity to the coronary ostium. The exterior surface of the valve cusp enclosure **106** can flexibly bulge inward in a convex manner with the weight of blood in the proximal aorta during diastole by preferentially creating reduction in internal pressure in the balloon segment during systole to allow blood to pool in this area and returning the pressure back up during diastole so as to push the blood in the direction of the coronary artery cusp. This creates a current of blood flow from the aorta directed into the ostium of the coronary artery thus improving coronary perfusion during diastole while increasing the volume of blood available for the coronary artery filling pressure during systole.

[0063] Referring now to FIG. **5**, in another embodiment, the treatment segment **100***a* can have a first and a second ventricular cusp and aortic cusp pair **132***a*, **132***b*, which each have a port **142**, **143**, respectively, as described above and define a pocket **138**, **139**, respectively, as described above. Here, there would be four balloons, one each for each cusp. All other features being the same or similar and having like reference numbers, the description of which does not require duplication. Alternately, the illustration of FIG. **5** can represent a single enlarged pair **132***a*, which is sized to receive all AVCs at the same time, each positioned proximate one of the ports **142**, **143**. The AVCS can be treated simultaneously or sequentially. Alternately, in FIG. **5**, port **142** can represent a first position of the port and port **143** a second position of the port, the port section **150** represented by the dashed lines being rotatable about the catheter body **102** to align with second AVC for treatment thereof.

[0064] FIGS. **1-5** present a valve cusp enclosure **106** that has is inflatable balloon system. The one or more ventricular cusp and aortic cusp pairs **132***a*, **132***b* can each comprise a plurality of individually controlled inflation chambers, which are in fluid communication with a fluid source via the catheter body. The fluid source may be a liquid, such as saline, or other suitable, biocompatible liquid. The aortic cusp **131** of the one or more ventricular cusp and aortic cusp pairs is controllably inflatable to maintain blood flow to the right and left coronary arteries, i.e., when inflated it does not block the right and left coronary arteries as shown in FIG. **3** and discussed above. This allows fresh blood to flow into the coronary arteries in an unimpeded manner after it has been ejected out of the proximal tip of the proximal valve with each heartbeat into the aortic root and the sinus of Valsalva while also still maintaining runoff into the coronary arteries during diastole (as is physiologically present in normal coronary circulation) thus allowing full perfusion of the coronary arterial system. The plurality of individually controlled inflation chambers can run longitudinally (see FIG. **4**, radially outward (see FIG. **2**), and a combination thereof, and inflation of each can be controlled by an operator. The inflation can be accomplished simultaneously or sequentially relative to any number of the plurality of individually controlled inflation chambers.

[0065] Referring to FIG. **2** and FIG. **4**, the ballon system can be described as having a first balloon **150** defining the first ventricle cusp **130***a*, a second ballon **152** defining the first aortic cusp **131***a*, and a third ballon **154** defining both the secondary ventricle cusp **130***b* and secondary aortic cusp **131***b*. Each balloon **150**, **152**, **154** has a plurality of internal chambers **160** separated from one another by internal walls **162**. The plurality of internal chambers **160** are inflatable to differing pressures, thereby, when inflated partially or fully, the balloon has a three-dimensional shape to form a pocket **138** or to deflect an AVC as shown in FIG. **3**. Each balloon can have any number of chambers. Each ballon **150**, **152**, **154** can include a manifold **164**, which may be shaped as a rib, running longitudinally from the attached end **134** to the fee end **136**. This can be generally centrally positioned in each ballon. Each manifold **164** includes a plurality of valves **166** and optionally conduits **168**, one each in fluid communication an individual chamber **160** of the respective ballon. The valves **166** of the most proximal chamber(s) of each ballon **150**, **152**, **154** are set to a first opening and closing pressure. The valves **166** moving from the proximal chambers to the distal chambers closest to the free end **136** have respectively, second, third, fourth, nth opening and closing pressure, which are each different such that the first opening and closing pressure is lower, than the second, which is lower than the third, etc. for each balloon to inflate in a concentric, proximal to distal manner.

[0066] The third balloon **154**, which is the largest of the three balloons has a plurality of horizontal chambers **160** in stacked relationship, like floors of a high-rise building, and has a plurality of vertical walls **163** (FIG. **4**) within that are concentrically arranged therein, like apartments in the high-rise building. It can also have walls that are perpendicular to the concentric walls and thus form many cubical cells at each vertical level of all the segments of the balloon. Still referring to FIG. **2**, this balloon **154** can have a multi-level manifold **170** having valves **172** in fluid communication with conduits, one each in communication with a single chamber. The pressures can be preset as described above to open the ballon proximal to distal. In another embodiment, the pressures for opening and closing the valves can be the same for simultaneously inflating and deflating the plurality of chambers.

[0067] In all embodiment, each chamber **160** of each balloon can have a pressure sensor, stretch receptor (embedded in a wall of each chamber), and/or a pressure transducer in electrical communication with an operating system for individualized control of the inflation thereof to a desired volume monitored and adjusted in real time by the operator or via an AI system and/or robotic system. This provides the advantage of control of the inflation of the distal most chambers to provide the desired pressure for the fluid tight seal against the endothelium or aortic annulus. It also allows for variable inflation of various chambers/segments to account for anatomic variation in a patient's vascular structure.

[0068] In one embodiment, the balloon chambers can be arranged as radially arranged inflatable layers that fill with fluid from the innermost to the outermost.

[0069] The inflation of the ballon system can begin from the distal end and progress to the proximal end, or vice versa, as well as from inner most to outermost in the radial direction. In the deployed state at the aortic valve the ballons are configured to acquire a size that is about half to two-thirds of the cross-sectional area of the natural aortic valve (and aortic root) and equal to or smaller than the aortic valve orifice it is sitting in.

[0070] The balloons can made of conventional balloon catheter materials or herein after developed materials. In another embodiment, layered cross-linked polytetrafluoroethylene (PTFE) membrane is used to make the balloons and internal segments of the balloons. Layered cross-linked polytetrafluoroethylene (LCL-PTFE) membrane is a thermoplastic polymer, elastic and highly flexible, solid at body temperature, self-lubricating with high strength and toughness, which is hydrophobic and radiation-resistant (it provides ultra-violet protection). Other possible materials include a light weight tightly woven nylon, synthetic silk, polypropylene, or extruded ultra-thin carbon fabric. LCL-PTFE membrane, when used to build the balloon will have varied thicknesses. The varied thicknesses depend on the elasticity property demanded from each aspect of the balloon.

[0071] Turning now to FIGS. **6**, an embodiment of the treatment segment is shown with some additional features and is represented herein as treatment segment **100***b*. The first additional feature is a funnel-shaped entrance **190** at the distal end **110** of the through conduit **104** formed upon deployment and expansion of the through conduit **104** and/or the valve cusp enclosure **106**. The distal end **110** includes expansion means **192** integrated into an elastic polymer material to form the funnel-shaped entrance **190**. The expansion means **192** can be a plurality as circumferential elastic rings spaced apart a distance relative to the longitudinal axis A within an elastic polymer material, wherein the elasticity of the rings increases as the rings progress toward most-distal. The expansion means **192** can have frustoconical layers that slide against each other to elongate and form the funnel-shaped entrance. The expansion means **192** can be a material than can elongate or change shape in response to a signal, such as a thermal, optical, or electric signal. One examples is shape memory material, which can be a metal or a polymer. The shape memory material can be in the shape of circumferential rings as noted above or positioned similarly to a framework of an umbrella. In another embodiment, a spring-loaded terminal ring **194** defines the mouth of the funnel-shaped entrance **190**, which can be expanded at deployment of the treatment segment **100***b* and retracted post-treatment. The spring-loaded terminal ring **194** can be made of metal, such as titanium or a titanium-magnesium alloy.

[0072] The expansion means **192** can also be a plurality of hinged titanium or a titanium-magnesium alloy rods each having at least two segments connected by a hinge. In this embodiment, a proximal rod **195** is hinged to an inner ring **196** that is secured to the exterior of the catheter body **102** and a distal rod **197** is hinged at its first end to the proximal rod opposite the inner ring and at its second end to an outer ring **194** (which can be elastic or are spring loaded). The distal and proximal rods **195**, **197** fold proximally and are stored inside the balloon material in the transport state. Any and all of these funnel-shaped entrances, in particular, the expansion means **192** can also, because of its position, support the ventricular cusp(s) **130**.

[0073] Still referring to FIG. **6**, any of these expansion means **192** can also be present at the distal end **120** of the first annular valve **112** to assist the through conduit **104** in expanding during deployment of the treatment segment **100***b*, as represented by the dashed rods and hinges. The expansion of the first and second annual valves **112**, **114** are linked to the expansion of the ballon system of the valve cusp enclosure **106** in an incrementally proportionate manner. In one embodiment, when the balloons system expands with introduction of a fluid media, the first and second annular valves **112**, **144** can include mechanical means that expand based on robotic assistance (computer-controlled movements by introduction of electrical, thermal, or other forms of energy to the mechanical means.

[0074] A second additional feature shown in FIG. **6** is a mesh or sieve-like material **198** extending from the proximal end **124**, **126** of one or both of the first annular valve **112** and the second annular valve **114**. The mesh or sieve-like material **198** may have an axial length of about 2 cm to about 5 cm and can have elastic properties enabling the material to close against the catheter body and then open away therefrom during blood flow through the through conduit **104**. The mesh or sieve-like material **198** is present to filter the blood to prevent blood clots from flowing into the aorta.

[0075] Turning now to FIGS. **7-9**, a different embodiment for the valve cusp enclosure, represented here by reference **206**, of an alternate style treatment segment **200** is disclosed. The treatment segment shown in FIG. **7** is a partially deployed state and comprises the additional features described in FIG. **6**. The features that are the same or similar to FIG. **6** have the same reference numbers and are as described above. The treatment segment **200** shown in FIG. **8** is in a fully deployed state.

[0076] Referring to the aortic cusp **231** of the valve cusp enclosure **206** of both of FIGS. **7** and **8**, each include a mechanical skeletal structure **218** that has a plurality of radially outward and ventricularly angled expandable arm segments **210** extending from a central hub **212** seated on and expandable and contractable with the through conduit **104**. In one embodiment, the central hub **212** is made of a thermally activatable material enabling expansion and contraction thereof in response to thermal energy (increase and decrease, respectively). The expansion and contraction of the central hub **212** and the expansion and contraction of the arm segments **210**, **220** are robotically controlled by operative communication between each and the printed circuit board in the terminal cap and/or an external operating system. The robotic control enables simultaneous and/or independent expansion and control of the central hub and any and all arm segments.

[0077] The mechanical skeletal structure **218** is located inside an annular sheath **220** that is fixedly attached to the treatment segment with a fluid tight connection, i.e., the attached end **234**. The annular sheath **220** is formed of a material that has elastic and/or plasticity properties and an appropriate texture to engage the annulus of the aortic valved for a fluid tight seal. The material can include a magnesium alloy rubber or plastic. The elasticity and/or plasticity property is necessary for the expandable arm segments to be deployed radially outward. In one embodiment, the sheath is formed of LCL-PTFE membrane. The LCL-PTFE membrane can be pulled over or extruded over the skeletal structure **208**, **218** of each cusp (single, double, or triple cusps) depending on whether the cusps are designed for single valve coverage, bicuspid valve coverage or coverage over all three valves and fixedly attached to the catheter body. In another embodiment, the LCL-PTFE membrane (superior and inferior) is continuous between the arms of the skeletal structure to create a webbed effect (like the

feet of a duck). Sensors, wiring, and other electronics can be built into the LCL-PTFE membrane using a multi-material 3D additive printing process.

[0078] Other components of the treatment segment can be made of or coated/surfaced with LCL-PTFE. LCL-PTFE provides a smooth glassy surface that reduces friction between the surface of the catheter or component thereof and red blood cells, which reduces the likelihood of mechanical destruction of the red blood cells and traumatic hemolysis.

[0079] During deployment, a first arm segment **211** is advance from the expandable arm segment **210**, and a second arm segment **213** is advanced from the first arm segment **211**. These are slidingly telescoping segments nested one inside the other. The terminal end of the annual sheath **220** can be spring loaded between each of the expandable arm segments, so that deployment thereof, in particular, the second arm segment **213**, spreads the sheath into its fully circumferential configuration, such as that shown for the ventricle cusp **230** in FIG. **9**. The spring-loaded feature of the aortic cusp **231** or the ventricle cusp **230** can be a result of the elasticity of the sheath material **220** itself or springs **260** can be present as represented in FIG. **9**. The expansion and retraction of the expandable arm segments **210** can be by wired mechanical connections or a result of shape memory material forming the arm segments **211**, **213**. The expansion of the expandable arm segments **210** can extend the aortic cusp **231** to two cm to six cm.

[0080] Still referring to FIG. **7**, the ventricle cusp **230** of the valve cusp enclosure **206** of include a mechanical skeletal structure **208** that has a plurality of radially outward and ventricularly angled expandable arm segments **214** extending from a central hub seated on and expandable and contractable with the through conduit **104**. In one embodiment, the central hub is the same as hub **212** or is independent therefrom and is made of a thermally activatable material enabling expansion and contraction thereof in response to thermal energy (increase and decrease, respectively). The expansion and contraction of the central hub and the expansion and contraction of the arm segments **214** are robotically controlled by operative communication between each and the printed circuit board in the terminal cap and/or an external operating system. The robotic control enables simultaneous and/or independent expansion and control of the central hub and any and all arm segments. The robotic control enables expansion or contraction of any of the cusps in increments of 1 μm to 10 μm.

[0081] The mechanical skeletal structure **208** is located inside an annular sheath **221** that is fixedly attached to the treatment segment with a fluid tight connection, i.e., the attached end **235**. The annular sheath **221** is formed of the same material described above for the aortic sheath. The expandable arm segment **214** includes a first arm segment **215** that is advanced therefrom. The first arm segment **215** has a plurality of hinges **215** operatively coupling secondary segments **217** and **219**, respectively, thereto to for a single elongate arm. The terminal secondary segment **219** rotates about its one of the plurality of hinges **215** to hold the terminal end **236** of the annular sheath **221** in engagement with the ventricle side of the annuls of the aortic valve. The first arm segment **215** can be slidingly telescoping relative to the expandable arm segment **214**, i.e., it can be nested inside the expandable arm segment **214**. The terminal end of the annual sheath **220** can be spring loaded between each of the expandable arm segments, so that deployment of the secondary arm segments **217** and **219** spreads the sheath into its fully circumferential configuration, as shown for the ventricle cusp **230** in FIG. **9**. The spring-loaded feature is as describe above. The expansion and retraction of the expandable arm segments **214** can be by wired mechanical connections or a result of shape memory material forming the first arm segment **215**. As illustrated in FIG. **9**, the expandable arm segments **214** of the skeletal structure **208** can be placed at various intervals circumferentially to regulate the radius and cross-sectional area of the valve cusp enclosure **206**.

[0082] Referring again to FIG. **7**, a plurality of sensors **240**, especially blood pressure sensors, are positioned on the exterior of the ventricular cusp **230** in the ventricle, on the exterior of the aortic cusp **231** generally proximate the coronary artery(ies), inside the through port **104**, in the first annular valve **112**, in the second annular valve **114**, at the cap **180**, and at the entrance to the second annular valve. Seven pressure sensors are illustrated in FIG. **7** as Circles that either have a number therein or a "P" for pressure. While seven sensors are shown, there can any number of sensors at myriad positions. These sensors may relay measure and transmit any information required for diagnostics and therapeutics. The sensors may function individually or collectively to create data points related to arterial lumen, ventricle, electrical data, lipid content of endothelium, blood pH, chemistry, oxygen levels, ultrasonic data (a few non-limiting examples). The pressure sensors measure systolic and diastolic blood pressure and send the data to the PCB in the cap **180** and to the external operating system. The data is used to regulate the amount of opening of the first and second annular valves **112**, **114**; thus, ensuring that the systemic BP is maintained to pre-procedure levels and that the blood pressure inside the through conduit **104**, between the two annular valves, is maintained to a steady level.

[0083] Still referring to FIG. **7**, the secondary segments **215**, can be spring loaded, to help maintain engagement with the annulus of the aorta valve and to facilitates pulsatile fore and aft movement of the annular ventricle cusp **230**, thereby adjusting for systolic and diastolic variations in the diameter of the ventricular side and aortic side of the outflow tract. Likewise, the arm segments **211** and **213** of the annular aortic cusp **231** can be spring loaded also. During ventricular systole, the expandable arm segments **214** proximate to accommodate the shortening and narrowing of the left ventricle outflow tract and vice-versa during diastole.

[0084] Turning now to FIG. **8**, the valve cusp enclosure **206** has an annular aortic cusp **231** that is the same as that shown in FIG. **7**. The port **140** can be on a rotatable hub **150** as described above with respect to FIG. **5**. The annular ventricle cusp **230***a* is different than the one in FIG. **7**, in that no telescoping segments are present. Instead, the skeletal structure **208***a* has a plurality of circumferentially spaced apart expandable arms **214***a* that each have a plurality of hingedly-connected segments **238** (hinges **239**) that define an elongate arm. The plurality of segments **238** can be spring loaded for engagement with the annulus of the aortic valve as described above. FIG. **9** shows the annular ventricle cusp **230***a* and the funnel-shaped entrance **190** at the distal end **110** of the through conduit **104** in a deployed state. The sheath **221***a* can have the same features and is made of the same materials discussed above.

[0085] In both embodiments disclosed in FIGS. **7-9**, the skeletal structure **213** and the terminal ends **236** of the aortic cusps **231**, collectively may be referred to as "feet." The deployment angle of each foot is individually adjustable based upon location of individual coronary artery ostia. The feet **213** and terminal end **236** can be directed to the wall of the Sinus of Valsalva either closer to the annulus or even in proximity to the coronary artery ostium. Coronary ostial perfusion can be increased by the feet of the aortic cusp immediately distal to the coronary ostium so as to create directional blood flow to the coronary artery.

[0086] The sheath covering the skeletal structure in FIGS. **7-9** can include or define a plurality of chambers that are inflatable. The fluid used to fill the chambers can be the same as described above for the balloon system. In one embodiment, the skeletal structure is robotically deployed first and then fluid is introduced to the chambers. In another embodiment, fluid is introduced to the chambers first and the robotics is used for finer adjustments and positioning of the feet. When chambers are present in the sheath, the chambers can be segmented with valve-controlled fluid communication therebetween. The manifold and valve system described for the ballon system above can be present here also. In one embodiment, compartments organized in a linear fashion from proximal the catheter body to distal from the catheter body include valves therebetween then open sequentially under preselected pressure so that the chambers fill first proximally and last distally.

[0087] Turning now to FIGS. **10** and **11**, enlarged views of a cap **180** are provided to better exemplify features thereof. The cap **180** has a working channel **202** having an open end **204** at the terminal end **206** of the cap **180** to allow egress and ingress of a tool (not shown). Prior to deployment of a tool, the cap **180** is closed, thereby blood or other fluids do not ingress or egress through the cap **180**. Rather blood or other fluids flow around the cap **180** to the second annular valve **114**. The tool can be inserted into the ventricle and advanced to the left atrium and even through the mitral valve, if desired. In one embodiment, the tool includes sensors to measure blood pressure, blood flow (ultrasound), EKG electrical activity and can transmit electrical stimulus to the atrium or the ventricle to generate pacemaker functionality. In another embodiment, the tool can perform therapeutics such as thermal (ablation), cold ablation, closing a hole(s) in the heart (ASD or VSD), apply grafting materials, build electrical networks in the heart muscle of ventricle or atrium, pass balloon to pulsate blood in the atrium, snare atrial clots or implant umbrella catheters to prevent clots or strokes.

[0088] The diameter of the cap **180** is preferably in a range of 12F to 18F and has a length of about 0.5 cm to 3 cm. The cap **180** terminates with a conical tip **218** that has a smooth curved dome-shaped. The cap **180** has a base **220** that defines a plug **220** receivable in the terminal end of the catheter body. The plug **220** include electrical terminals **224** and working channel connectors **226** for communication between the catheter, an external operating system, and the equipment and/or printed circuit board **208** and power source **210**. The cap **180** may be built from biocompatible materials. Some example materials include polymers, titanium, aluminum, magnesium, silver, and alloys containing any one or more of these metals or a composite containing any one or more of these materials. Additional details about the operating system and connection to the catheter body is disclosed in co-pending U.S. application Ser. No. 17/815,282.

[0089] The cap **180** encloses a printed circuit board **208** operatively connected to an enclosed power source **210**. The printed circuit board **208** can have any and all features described in co-pending U.S. Application No. 63/494,799 and 63/494,800. The power source **210** can be a battery, which can be a pre-charged, rechargeable, or continuously charged by an external power source through wires built into the wall of the catheter body **102**. The power source **210** can power any equipment carried or built into the cap **180**. The equipment can include (i) sensors **212**, such as intravascular ultrasound (IVUS), capacitive micromachined ultrasonic transducers (CMUT), infra-red sensors, oxygen sensors, blood pressure sensors, etc., (ii) imaging **214**, such as fiberoptics, cameras, etc. as individual items or as arrays, and (iii) emitters **216**, such as LEDs, infra-red, or other light sources. Dual illumination modalities or multi-modal illumination offers optimal illumination of vasculature, lumens, or cardia imaging, i.e., LEDs and infra-red emitters are both present, which can assist in performing intra-cardiac surgical repair of the ventricle, atrium, and valves in-situ (thus, obliterating the need for trans-thoracic surgery). Endo-myocardial reinforcement with Teflon/Dacron or other materials or electrical wiring can be embedded in the myocardium to strengthen the heart muscle and provide electrical stimulation.

[0090] The equipment is electrically and operatively in communication with the printed circuit board **208** to provide a feedback loop for an operator or computer guided positioning of the catheter and treatment segment **100**, imaging the aortic valve, sensing pressures in the ventricle and aorta, providing continuous EKG recordings and pressure dynamics with ventricular outflow and aortic blood flow and coronary artery flow. The communication can be wired or wireless, and when wireless can include Bluetooth two-way communication and can include WIFI capabilities. Geo-positioning can be included for transportation of the treatment segment **100** to the aortic valve and for proper positioning for deployment thereof. Geo-positioning can also be used to locate electrical abnormalities in the atrium or the ventricle and map problem areas for transcatheter ablation and for rebuilding innate electrical circuits or implant electrical circuits. This could take the place of an implantable pacemaker.

[0091] All data transmitted and received via the cap **180** can be recorded in Blockchain using NFT to build non-destructible data sequence of events for the purpose of recording and machine learning. AI or Machine Learning programs assists robotics through IOT (Internet of Things) referenced anatomical accuracy in the vascular tree of a given subject. IOT referenced GPS is accurate to the level of a nanometer when assisted by fiberoptic camera illuminated with IR/cold LED and ultrasonically guided by IVUS/CMUT present in the cap **180**.

[0092] In one embodiment, the cap **180** includes a fiberoptic camera system, which may include one fiberoptic camera filament or multiple radial systems of fiberoptic filaments to capture a 360-180-degree view of the vasculature. The fiberoptic camera system captures images and/or video in real time and is ultimately connected to a display such as a computer screen through a wired or wireless connection.

[0093] The sensor in the cap **180** transmit data to the printed circuit board **208**, to the catheter, to the catheter's operating system, which is typically external to the patient, and to any robotic system included in the catheter and/or treatment segment **100**. The data can be used for myriad functions, including robotics navigation, robotic deployment of the treatment segment, and AI systems involved in navigation, placement, and/or treatment of the aortic valve cusps. Systolic and diastolic BP, blood temperature, and oxygen saturation assists in optimizing the centralized location of the catheter tip inside vasculature. This method prevents dissections, plaque rupture and perforation. EKG recording is important to regulate and time the opening and closing of the proximal end of the first annular valve **112** and the proximal end of the second annular valve **114**. When QRS complex of the EKG is arrived at, robotics can assist dilation of the proximal ends of the first and second annular valve **112**, **114** in the embodiments of FIGS. **7-9** while the onset of T wave brings about gradual closure of the proximal ends. The EKG-synchronized opening and closing of the first and second annular valves **112**, **114** maintains stable blood pressure inside the treatment segment **100**, thus maintaining a stable diameter of the entire catheter. The stability of the catheter cross-sectional dimension maintains stable positioning of the valve cusp enclosure **106**, thus stabilizing positions of all other processes that occur related to valve cusp remodeling. The prevention of oscillation of the entire assembly that naturally occurs during systole and diastole of the heart creates a stable platform for all robotically assisted remodeling processes.

[0094] Still referring to FIGS. **10-11**, continuous BP recording provides additional information regarding left ventricle outflow tract pressures. This helps the synchronization of inflation of the valve cusp enclosure **106**. As the valve cusp enclosure **106** gradually inflates or robotically expands, the blood flow through the through conduit **104** incrementally increases as the blood flow around the catheter and balloons gradually decrease. One goal is to maintain constant net blood flow and stroke volume into the aorta and stable blood pressures in the aortic root during the procedure, thus maintaining physiology similar to that the subject is accustomed. A second goal is to remodel the aortic valve to improve perfusion (to levels pre-aortic stenosis or aortic valve disease). The collective goals minimize or prevent damage to the brain and other organs seen with traditional systems that usually cause drop in blood pressure during procedures involving the aortic valve.

[0095] The catheter body **102** can be any commercially available catheter. The catheter body **102** is typically about 4 to about 6 feet in length and is made of traditional catheter materials, which can include polytetrafluoroethylene or cross-linked polyethylene, but can be any length necessary to reach a treatment site. The catheter body includes at the distal end, a treatment segment **100**, **200**, described herein, a main body or shaft that is inside the vasculature of the patient, and a proximal end connected to an operating system that is located outside the patient's body. The catheter body **102** has, running the internal length thereof, lumens of various dimensions and functions, at least one lumen is a delivery sheath through which any number of tools can be deployed to and through the port **142** for treatment of an aortic valve cusp. Additionally, electronics, fluid conduits, etc. can be built into the wall of the catheter body **102** rather than being inside a lumen. One lumen can be a fluid delivery tube in fluid communication with the balloons **150**, **152**, **154** and the manifolds **164** therein for delivering fluid to inflate the balloon or removal of fluid to deflate the balloon. The wall of the main body can have built in conduits, electrical wires, shape memory materials, and can define a plurality of lumen for communication with any aspect of the treatment segment, including the valve cusp enclosure, the terminal cap, any and all sensors, and other tools/equipment.

[0096] In one embodiment, the distil end of the catheter body most-proximate the cap **180** comprises a shape memory material, such as a thermally activated shape memory polymer in operative communication with electrical wires in the wall of the catheter body that can transmit heat to the thermally activated shape memory polymer. Thermal activation of this polymer adjusts the flexibility of the cap and/or distil end of the catheter body to impart a bend thereto for navigation of the catheter through curves in the vasculature.

[0097] The catheter can include a computer-communicative guidance system. The catheter wall(s) or lumen therein include a plurality of metal or metal alloy wires that have tensile strength and flexibility spaced apart about the circumference of the catheter. In one embodiment, the number of wires ranges from four to 36. These wires run at least the length of the treatment segment and terminate at the base of the cap **180**. These wires enable the computer to track and perform navigation thereof by guiding a latitude of about 180 degrees in all directions. In one embodiment, data from the IVUS in the cap is communicated to the computer-system to create a visual display on a computer screen and function as a component of the guidance system. In another embodiment, the proximal end and the distal end of each of the first and second annular valves and other components of the treatment segment, including the terminal cap, can have an imprinted marker system that is configured to be in operative communication with a computer system as part of a computer-communicative guidance system. The imprinted marker system may communicate with the computer using Bluetooth emitting Wi-Fi configured blockchain enable NFT.

[0098] In another aspect, the catheter body **102**, lumens therein, the exterior of the cap **180**, or any other feature of the catheter that has a diameter can be constructed to has electromagnetically coupled bands or thermally activated bands (such as shape memory materials) spaced at intervals that are arranged in a manner to enable enlargement or contraction of the diameter thereof. In one embodiment, the intervals can be 0.1 μm to 5 μm, or larger such as 4 mm to 10 mm. Introduction of current or heat can activate the band to change the diameter of the respective feature. The catheter, its lumen and the side port may benefit from this feature in order to transport a large tool or instrument to the treatment site. This feature is meant for diameter change without any elongate of the respect feature. In other embodiment, however, the change in diameter occur along with elongation.

[0099] The treatment segment **100**, **200** can include sensors and other electronic equipment in positions other than the cap **180**, such as inside the through conduit **104** and either or both of the first and second annular valves **112**, **114**, on the exterior of the catheter body **102**, on the exterior of the valve cusp enclosure **106**, **206**, in the wall(s) of the valve cusp enclosure that define the pocket **138**, and even in the

terminal ends **136**, **236** of any lobe of the valve cusp enclosure **106**, **206**. The sensors can include a blood pressure sensor, infra-red sensors, EKG, etc. The electronic equipment can include imaging technologies, such as fiber optics, IVUS and/or CMUT, illuminated fiberoptic electron microscopy and guided biopsy. The electronic equipment can include illumination technologies, such as LEDs and infrared emitters.

[0100] In one embodiment, blood flow sensors are placed on the exterior of the proximate the coronary arteries and proximate the left ventricle to measure the volume and pressure of blood flowing from left ventricle to the aorta. As the valve cusp enclosure is deployed, these sensors record changes in blood pressure and provide the data the onboard PCB of the cap and/or the external operating system so that the through conduit **104** and first and second valves **112**, **114** are opened proportionally thereto. Sensors placed on exterior of the catheter, exterior of the valve cusp enclosure, and inside the through conduit and valves can measure flow rates/velocities, blood systolic/diastolic pressures, cross-sectional area during expansion and contraction of the valve cusp enclosure and the through conduit, oxygen concentration and temperature. The sensors help compare the results of ventricular stroke volume and pressures with aortic stroke volume and pressures and provide feedback to modulate the opening and closing of the first and second annular valves. This provides the patient/subject with adequate perfusion of all organs.

[0101] In any of the embodiment, each terminal end **136**, **236** of a cusp of the valve cusp enclosure can include touch and/or pressure sensors therein. The data from such sensors can aid in ensuring adequate pressure for a fluid tight seal to the annulus of the aorta. The terminal ends **136**, **236** can also include imaging and illuminating equipment to aid an operator in guiding the same into contact with the annulus of the aorta.

[0102] In any of the embodiment, the EKG technology and the data it provides can be used by the computer system(s) to open or close the first and second annular valves **112**, **114** as needed to control the blood flow and blood pressure of the patient. Under some conditions, the two valves **112**, **114** open simultaneously. Under other conditions as determined based on the EKG data, the second annular valve **114** is opened first and the first annular valve **112** is opened about 2 msec to 20 msec later. Under yet other conditions as determined based on the EKG data, the first annular valve **112** is opened first and the second annular valve is opened about 2 msec to 20 msec later.

[0103] In all embodiments, the imaging device can be any commercially available imaging device or hereinafter developed technology. In one embodiment, the imaging device is selected from near-infrared spectroscopy plus intravascular ultrasound, fiberoptics, or capacitive micromachine ultrasound transducer. Imaging will be in real time, thereby enabling the operator or computer to make decisions about balloon inflation, balloon size, and balloon positioning relative to a treatment site.

Deployment of the Catheter

[0104] In one embodiment, a catheter with the treatment segment **100**, which includes the terminal cap **180**, is transported to the aortic valve over a guide wire, where once the distal and proximal valves **112**, **114** are located at their appropriate positions, as described above, the expandable valve cusp enclosure **106** is expanded, and the guide wire can be withdrawn. In the deployed state, all sensors, imaging, and other electronics are activated, and two-way communication therewith is functional and confirmed. Data is recorded either internal or external to the treatment segment **100**. All such communications can be wired or wireless. In one embodiment, such communication use WIFI, Blockchain and NFT's via an Internet of Things (IoT) and/or servers. As used herein, "Internet of Things" has its common ordinary meaning-devices with sensors, processing ability, software and other technologies that connect and exchange data with other devices and systems over the Internet or other communications networks.

[0105] In one embodiment, the distal end of the treatment segment is opened (possibly funnel-shaped) proportionally to inflation/deployment of the valve cusp enclosure. As the peri-catheter space begins to occlude due to inflation/deployment of the valve cusp enclosure, the through conduit dilates to take up the function of transferring blood flow into the aorta. The cap of the treatment segment measures systolic and diastolic blood pressure in the left ventricle outflow tract and the data is relayed to the computer system. Based on this data, the robotics open the proximal end of the second annular valve during systole timed to beginning of the QRS complex on EKG data.

[0106] Machine learning (AI) and the robotics use the data from above mentioned inputs to generate strategy for the entire procedure. Data is used to measure the topology of the native aortic valve, measure calcification, amount of narrowing and annular calcification and strength, thickness of cusps and other relevant data, to continuously modulate the amount of opening of the valve cusp enclosure **206**, and to calibrate the amount of opening to match the patient's needs such as BP, volume of blood flow, and to match the size of pre-procedure aortic valve opening. The system has the capability to incrementally increase the internal size of the first and second annular valves **112**, **114** and inter-valvular segment of valve cusp enclosure **206** to match the intra-procedure and post-procedure increasing size of the aortic valve as the modeling process makes the valve cusps more pliable and the stenotic aortic valve opens wider.

[0107] The ventricle cusp deploys first, which coincides with deployment of the first and second annular valves. The ventricle cusp deployment begins with robotic extension of a proximal segment first, then the middle segment and then the terminal segment of each arm of the skeleton structure of all arms simultaneously, which spreads the valve from center to periphery.

[0108] In the deployed state, examples being shown in FIGS. **3**, **6-9**, blood flow from the ventricle is fully conducted through the through conduit **104** and no blood is moving in peri-catheter region as it is sealed off by the valve cusp enclosure **106**. Aortic blood pressure and cardiac output are now stable. Next, the bloodless field is created around the one or more aortic valve cusps being treated. Via the port **142**, the pocket **138** formed by the valve cusp enclosure **106** is flushed and aspirated using an aspiration catheter. Saline or similar material is used to flush the space within the pocket **138**. Imaging, such as fiberoptics, is used to confirm the successful creation of the bloodless field.

[0109] Once the bloodless field is created, the aortic valve can be treated and remodeled one cusp at a time. Each cusp can be treated and remodeled first on the aortic side and then on the ventricular side, or vice versa. The bloodless field

gives the operator the freedom to treat and remodel a valve cusp and make simultaneous comparisons to the other cusps to ensure that the cusps will seat securely after remodeling is complete.

[0110] The tools used to treat the aortic valve cusps can be fed through the catheter body **102** individually or collectively to and through the port **142** into the pocket **138**. The catheter body **102** may include therein one or more aspirators, imaging device, cutting tool, and other tools needed during the medical procedure. After completion of the treatment and administration of a drug treatment, if needed, the tools and balloon catheter are removed from the patient. Following the medical procedure, the medical professional may instruct the patient regarding a post-care regimen of drug treatments, activities, and the like.

[0111] An example tool is an aspiration and infusion system configured to infuse saline into the field of operation and aspirate the saline and flushed materials out of the field such as to eliminate blood, calcium, fibrinous material, and other tissue components broken down during treatment of the heart valve.

[0112] The method can include introduction of a tool configured to determine the lipid burden of the surfaces of the valve. The tool can assist in determining whether the lipid burden includes a high lipid burden, a low lipid burden, or a high to low lipid burden ratio. The tool can be a near-infrared spectroscopy plus intravascular ultrasound or a capacitive micromachine ultrasound transducer. These tools can also be used for imaging the valve and its surfaces. The capacitive micromachine ultrasound transducer is much smaller than other imaging devices.

[0113] Another example tool is a laser. The laser may be an ultraviolet laser, such as an excimer or exciplex laser. One commercially available laser is the ELCA™ laser from Phillips (FDA approved) adapted to fit the lumen utilized for delivery to the treatment site. When activated, the laser breaks calcium crystals, burns fibrous tissue on ventricular and aortic surfaces of cusps, and/or melts lipid material of each valve cusp. Each of these tasks may require a different wavelength for the laser; thus, the laser can have an adjustable wavelength. Alternately, different lasers can be transported to the treatment site through the lumen of the catheter. When cutting with the laser, gentle saline flush can be applied.

[0114] Another tool may be configured to deliver medications or products directly into the left ventricle or into the operable area of the active valve cusp. In another embodiment, the catheter itself or a tool carried thereby infuses medications or chemicals used for radiographic or other data acquisition, diagnostics, or therapeutics of the heart, coronary arteries, or other organs of the patient.

[0115] The illuminated fiberoptic electron microscopy and guided biopsy can be used to assist in-situ diagnosis of medical pathology like cancer, amyloidosis, fungus or bacterial vegetations on valve leaflets or endocardium. It can also be used to map extent of graft-vs-host rejection, endomyocardial biopsies etc., and other organ evaluations in a similar manner.

[0116] The balloon catheters disclosed herein and the various methods of use of such balloon catheters can be implemented to treat the aortic valve cusps in myriad ways, such as: changing the cross-sectional area of the aortic valve, treating aortic ankylosis, i.e., bring back flexibility and mobility to the cusps, remove calcifications from the cusps, replace and/or synthesize fibrosa epithelium on the aortic side of a cusp, replace and/or synthesis ventricularis epithelium on the ventricular side of the cusp, replace and/or synthesize spongiosa inside the body of the cusp, remove lipid material from the sub-epithelium of the cusp, and recreate the aortic valve anatomically, morphologically, and functionally.

[0117] In all embodiments disclosed herein, a coating of heparin, clopidogrel, sirolimus, or tacrolimus can be present to prevent blood from clotting along any and all surfaces of the treatment segment and/or catheter body **102**, including the mesh or sieve-like material **198**.

[0118] While the catheter herein is described for treating the aortic valve, it can be configured for treatment of other valves in the heart, other organ systems, and it can be made in a miniaturized version for functionality in other lumens, such as the coronary artery, other blood vessels, an in other organs, such as systems like the GI tract (small intestine, colon, stomach, pancreas), hepato-biliary system, urinary tract system, spinal cord, musculoskeletal and orthopedics, respiratory and pulmonary endoscopy and provide insight into diagnostics and provide therapeutics to include nano-therapeutics and theranostics in those systems. Oncology drug delivery may be possible through this system. The bloodless field created by this invention can be used in other systems and applications such as tumor management as well. The systems and methods disclosed herein can include AI computer-generated calculations for the cross-sectional area of a lumen of the aorta or of the ventricle. This is also applicable to any other lumen of the body. As described above, having capacity to recreate flow dynamics will assist in forecasting the cross-sectional area of the tube or lumen that will create laminar flow of fluids.

[0119] Referring now to FIG. **12**, an illustration of the cusps of the aortic valve is provided including the abbreviation labels for the left coronary cusp (LCC), right coronary cusp (RCC), and non-coronary cusp (NCC). Dimensions for standard aortic valve cusps are provided in FIG. **15**. The dimensions reflect that the thickness of the base of the cusp is typically twice that of the rest of the cusp.

[0120] A left ventricular (LV) pressure-volume curve is provided as FIG. **13**. The values presented therein are for descriptive, exemplary purposes only. The LV Pressure-Volume curve is a loop that starts at the end of systole with the closure of the Aortic Valve (A). The ventricle relaxes (diastole) and pressure drops while the mitral valve has not yet opened. The mitral valve opens (B) and blood fills the left ventricle. The pressure begins to increase and finally the ventricle fills up and begins the onset of systole (C). Mitral valve closes rapid contraction of LV increases its pressure till the Aortic Valve opens (D) and blood flows rapidly into the aorta and the ventricle empties out with the final contraction and then the Aortic Valve closes (A) and the cycle begins again. In the treatment methods disclosed herein, an LV Pressure-Volume curve is mapped into a computer by generating data of myriad cycles for a patient to create a mean and at least six standard deviations. This data will be used in modeling morphology and elastic properties for the patient's aortic valve cusps and therefrom implementing a treatment.

[0121] An aortic Pressure-Volume Curve is provided as FIG. **14**. The values presented therein are for descriptive, exemplary purposes only. A-D correspond to the same systolic and diastolic events described above with respect to

FIG. **13**. Hereto, for the treatment methods, an aortic Pressure-Volume Curve is mapped into a computer by generating data of myriad cycles for a patient to create a mean and at least six standard deviations. A maxima and minima for the volume and pressures flowing across the aortic valve an into the aorta are determined. In a diseased state, such as aortic stenosis, there will be significant deviation from normal values. The purpose of mapping a patient's Pressure Volume Curves is to see the pathological pressure changes. This data will be used in modeling morphology and elastic properties for the patient's aortic valve cusps and therefrom implementing a treatment. The goal is to restore normal pressure-volume loops, which will help increase the longetivity of the modelled aortic valve and reduce long term risk of stroke, blindness and congestive heart failure.

[0122] The method involves implementing algorithms to convert tangential shear (T), also known as Wall Shear Stress (WSS), into blood pressure in mm of Mercury (and vice versa) at a level of a narrowest cross-sectional area of the aortic valve in systole, based on values derived from the ventricular side of the valve and aortic side of the valve. T is then used to determine the pressure exerted by a column of blood (blood follows Newtonian principle of fluid) on the body of each aortic valve cusp surface and on the frame of the aortic valve cusp. Since all three cusps will be exposed to the same amount of T due to being at the same level in the path of blood coming from LV to Aorta, the assumption is that all three cusps will have same degree of blood pressure exerted on their surface areas. Referring to FIG. **16**, the body of each cusp (RCC, LCC and NCC) will need to undergo equal amounts of deformation (A→B where B**1**=B**2**=B**3**) during ventricular systole to maximize the aortic valve cross-sectional area at its narrowest level or "smallest cross-sectional area" during systole). This must occur in response to rising and falling blood pressure from the LV outflow tract during systole such that the remodeled aortic valve provides the most efficient transfer of blood from the left ventricle to the aorta. This deformation is proportionate to the tangential shear stress created by the blood flow (following Newtonian Fluid principles and second law of motion). Values for T are calculated and presented in FIG. **17**.

[0123] To create this deformation of the aortic valve cusp(s) remodelling will incrementally thicken the body of each diseased valve transversely with the thinnest portion in the center and the thickest portion adjacent to the cusp frame where the body of the cusp will end and the frame will begin. The amount of deformation will be the greatest in the center and almost absent at the periphery where the body is inserted into the annulus and the frame. The cusp require elasticity to move effectively, which is expressed herein as a cusp coefficient of elasticity. Still referring to FIG. **17**, the cusp coefficient of elasticity (St) is given by the formula: St=d/dt(M*V). St is also the equal to the tangential stress T (or WSS) applied by a Newtonian fluid to a fluid-solid interface at a given velocity and viscosity of the fluid, dt is systolic time interval during which there is forward flow of blood from ventricle through the aortic valve to the aorta, M is the mass of blood moved and V is the velocity (1 m/s for a normal aortic valve) at which blood is moved. Assuming the rheological properties of blood remain constant (blood density=1060 Kg/m where pure water density=1000 kg/m), the mass of blood moved can be calculated based on volume (stroke volume per ventricular contraction) being an average of 95 ml (+/−14 ml). Mass=volume*density.

[0124] Normal cusp thickness is not the same throughout the cusp surface as discussed above with respect to FIG. **15**. When remodeling is being performed, a LASER is used to thin down the aortic (spongiosa) and the ventricular (Ventricularis) calcified and fibrous lining down to the fibrosa layer. Then, the lining of the cusp is built back up, for example by 3D printing spongiosa, ventricularis, interstitium, or a combination thereof onto the cusp. These are printed to a minimum numbers of millimeters so as to restore the original minima and maxima of the cusp thickness and to maintain the coefficient of elasticity. About 3 mm of deformation is necessary at the center of each cusp and is about 3 times higher resistance to deformation (at least twice the thickness in the base region) at the periphery of the cusp where less or no deformation is required. The bases of the cusps also have adherence to the Aorto-ventricular junction or annulus.

[0125] The treatment method includes AI aided reconstruction of the Node or nodules of Arantius of one or more of the aortic valve cusps. The node a structure present on the tip of each cusp, which is flush with the ventricular surface and spearhead shaped on the aortic surface. The three nodules (one at the tip of each cusp) approximate to produce a cone effect when the valve is closed. This helps blood to slide down into the aortic side of the cusps and cause the cusps to sag like a tent. See FIG. **16**. This sag allows better approximation of the cusp frames along commissural lines and creates a snug fit of the valve to prevent regurgitation of blood into the ventricle. The node is destroyed or undergoes hypertrophy due to aortic stenosis or post repair aortic incompetence. This will be remodeled using AI to precisely create the exact dimensions. The reconstructed node will be 1.2 mm-2.5 mm tall, 0.8 mm-1.2 mm thick at the base and span the two frames from the apex approximately 1.2 mm-1.4 mm wide. When all three cusp tips have a node, together they will form a dome like cap on the aortic side of the closed aortic valve in diastole. The node is known to prevent aortic insufficiency.

[0126] AI calculates the value of thickness of the cusp body at each incremental distance from the center of the cusp body based how much deformation (B) is needed to create the largest vale for the smallest cross-sectional area (SMCA). A LASER is used to thin down the calcified fibrotic valve thickness until all calcified and fibrotic material is removed. Then AI aided remodeling and 3D printing of tissue increases the thickness back to the normal thickness or slightly thicker valve cusps to withstand the shear pressure T. The tissue material for 3D printing can withstand/produce 1,752,000,000 cycles of cardiac contractions so as to reflect 100 beats per minute for 40 years. In one embodiment, the tissue material is a nanotechnology material, which can include elastin and/or stem cells. In another embodiment, the tissue material is a drug treatment that comprises collagen and/or carbon dots comprising stem cells, as disclosed in co-pending U.S. Application No. 63/494,794. When this drug treatment is use, the method further includes activate the collagen by application of an activating wavelength of energy.

[0127] Referring now to FIG. **18**, in aortic stenosis the velocity of blood is 2.5-2.9 m/s in mild stenosis, 3.0-4.0 m/s in moderate stenosis and >4.0 m/s in severe aortic stenosis. The normal aortic valve diameter is 21 mm to 23 mm and thus normal SMCA of arotic valve is 3-4 cm^2 with <1 cm^2 being severe aortic stenosis.

[0128] The method will also include mapping a patient's anatomy of their aortic root, aortic valve and left ventricle using the features of the treatment segments **100** disclosed herein, especially features for imaging, mapping, and sensing present in the terminal cap **180**. Such measurements will provide actual dimensions, pressures, flow dynamics and pressure gradients at the aortic valve of the patient. AI is then used to calculate ideal values for the patient post-remodeling of the aortic valve. AI forecasts ideal stroke volume, blood flow velocity, ideal SMCA, cusp dimensions and thickness, elasticity and tensile strength of the cusp body and frame. This information is used while perform remodeling of the aortic valves cusps for recreation of all normal valve dimensions during remodeling.

[0129] Mapping vessel or lumen dimensions and flow dynamics of tubes along with respect to liquids or solids that flow through the lumen or tube or valve: In the above example, blood viscosity and blood flow dynamics are being calculated. Upstream and downstream luminal dimensions and flow dynamics will be recorded during remodeling procedure. With reference to FIG. **22**, in a lumen or tube such as a coronary artery a particular level of stenosis should be remodeled to achieve ideal luminal cross-section that is congruent with that what is upstream and downstream to the stenosis. It would be pointless to enlarge the stenotic region to a size larger than upstream to the stenotic region because it will only result in creating an upstream bottleneck. It could also result in creating the Bernoulli effect which would in turn alter tangential shear stress on endothelial wall and cause disproportionate endothelial growth response and accelerate restenosis. Mapping of flow dynamics in a stenotic vessel can distort the picture of what would be ideal flow dynamics after remodeling has restored the stenosis to normal lumen dimensions. We know that V**1***A**1**=V**2***A**2**, where V**1** is velocity of Newtonian fluid in a tube with cross-sectional area A**1** and V**2** and A**2** are for the narrower distal segment of the same tube (diagram on volume flow rate below). Pre-stenotic coronary lumen will have reduced velocities due to stenotic distal lesion (bottleneck) effect. Data acquired from aortic root fluid dynamics will be used by AI to aid in determining ideal velocities and transfer of blood volume (density, mass calculations) to forecast oxygen transfer to coronary artery after atherolysis aided opening of stenosis and how much atherolysis is needed to this ideal luminal cross-section. See FIG. **19**,

[0130] The cap **180** of the catheter include myriad sensors, including IVUS, which are used to measure proximal and distal dimensions in a patient to reach conclusions about dimensions. Then, a computer, such as an AI driven computer system, performs calculations to assign the forecasted dimensions of the stenotic segment, and robotics guide a LASER to perform precise degree of remodeling of the aortic valve. The computer can map ranges of pressures exerted by flow dynamics on lumen or valve cusps, map maxima and minima for excursion of lumen or valve cusps during normal and extreme levels of flow. In a patient experiencing aortic stenosis it is not possible to directly visualize the normal excursion of the aortic valve cusps, therefore AI driven computer-generated forecasts of valve cusp dimensions are performed. Computer assisted graphics and AI will precisely create excursion of the valve cusps. Once one or more of the aortic cusps are remodeled, a tool can be used to perform excursions of the valve cusp to confirm adequate opening and adequate elasticity have been achieved to open and shut the cusp. This tool will measure thickness, elasticity, compute shear stress, excursion of valve under stress and under rest conditions, flexibility, and ability to close properly and seal the aortic inlet.

[0131] With reference to FIGS. **16**, **22**, and **23**, the computer-generated forecasts can be based on various calculations, such as tensile force, elastic quotient, vector mapping of pressures, shear force, turbulence coefficient and viscosity of fluid & Bernoulli coefficient. Mapping of the ventricular structure and dimensions along with ventricular contractility data is useful to determine the end systolic volume (ESV) and end diastolic volume (EDV) of the left ventricle. Other data related to the rate of narrowing in the ventricular outflow tract will be used to forecast outflow tract velocities using algorithms to forecast velocities that will result from remodeling of the Aortic Valve. These will be tested by the equipment, sensors, etc. present in the cap **180** of the catheter. The computer-generated forecasts can include normalizing a stress rate and a strain rate at fluid-solid boundaries and tangential stress, calculating maxima, minima, and range of valve cusp thickness, calculating maxima, minima, and range of valve elasticity, distortion resistance, calculating maxima, minima, and range of valve range of motion, and calculating precise valve dimensions, shape, and size.

[0132] Referring to FIGS. **12** and **16**, each cusp of the aortic valve has a generally triangular shape forming $\frac{1}{3}^{rd}$ the circumference of the aortic annulus in which the three valve cusps are seated forming an inverted Mercedes Benz sign at the center. Each cusp also has a curvilinear sweep from the periphery to the center in a way that the tip of each cusp curves caudal to cranial into the aortic root away from the ventricle. In cross-section, this forms a cardioid shape. Cardioid is a shape when a circle is drawn around a central circle using the same radius. It is observed that about half the length of each cusp towards the center of the aortic valve is curved as a cardioid while the remaining peripheral half is linear. The cardioid shape of the aortic valve cusp is an inverse curve of a parabola with the radius of the aortic valve annulus and about 25 degrees to 30 degrees of arc angle. AI and computer graphics will be used to build the frame of each cusp using this geometric principle.

[0133] As mentioned above, each cusp dimension will be constructed using computer graphic interface (CGI) and inputs from the cap **180** technology. An animation of all cusps, which includes pre-treatment animations of valve morphology and excursion and AI driven generation of proposed and predicted effects of LASER remodeling including mapping the thickness of all layers of the valve cusps and excursion of valves in response to various heart rates and blood flow velocity and pressure, will be created. CGI and repeat cycling decay simulation methods used in biomedical engineering to test longevity of product in accelerated short timeframes will be performed albeit in virtual space. Complex mathematical equations and programs will be used to carry out the necessary durability assessment of the valve cusps.

[0134] The method can also include computer-generated based calculations of ventricularis and aortic endothelial structure (thickness and/or smoothness) and morphology ideal for elasticity, solid-liquid surface friction/inertia, and prevention of fluidic restriction, stagnation, eddy currents, and degree of cusp sag that will create a tight seal during diastole to prevent valvular regurgitation. These are the final calculations performed as all the above inputs and function-

alities are completed. Simulation of cusp sag when valves are closed in diastole. Impact of shear stress from column of blood in aorta will be confirmed to match the 3 mm sag that is expected from the proper thickness of the remodeled valve cusps using materials of appropriate types, appropriate amounts, density, and elastic properties. Calculations and resulting incremental increase in thickness of a cusp of the aortic valve, after remodeling, are demonstrated as shown in FIGS. **20** and **21**. The thickness at the base of the cusp, where it is attached to the annulus, averages at 0.692 mm at a height of 0.625 mm from the lowest point on the annulus. Remodeling gradually decreases the thickness of the cusp from base to the apex of the cusp where the Node of Arantius is inserted and where the free tips of the three cusps come together during valve closure. The purpose of incremental thickening of the cusp from apex to base favors the impact of T (WSS) forces on valve cusp opening. The thicker base flexes almost none while the much thinner apex flexes the most in response to the ventricular outflow jet. The goal is to reach effective height and function of the cusps.

[0135] Referring now to FIG. **23**, a top view and a cross-sectional view of the left ventricle is illustrated with dimensions noted for use in the mathematical equations set forth therein. Cross-sectional Area of single Aortic valve cusp=(π*rC2)/3, and the relationship between ventricular end-diastolic Volume V_{ED} and dP/dt where pressure change (dP) with time (dt) is a more accurate index of contractility, F.

$$F = dp/dt * (M * V)$$

Factors affecting movement of cusps of leaflets during systole and diastole include:

[0136] 1. Cusp edge rigidity

[0137] 2. Cusp leaflet flexibility and ability to sag, close and open.

[0138] 3. Blood velocity

[0139] 4. Cross-sectional area of the aortic valve

[0140] 5. Ventricular contractility

wherein

[0141] P_s=systolic Pressure in left ventricle

[0142] P_d=Diastolic Pressure in left ventricle

[0143] T_{sys}=Systolic time Interval

[0144] M_b=Mass of blood (volume)

[0145] V_b=Blood flow velocity

[0146] d_4=Aortic diameter above the sinus of Valsalva

[0147] d_3=Diameter of aortic valve opening (systolic valve opening)

[0148] d_2=diameter at aortic valve annulus

[0149] d_{v1}=Left Ventricular diameter in diastole

[0150] d_{v2}=Left Ventricular diameter in systole

[0151] η=viscosity of blood.

[0152] An advantage of the system disclosed herein is the ability to create a complete separation of the ventricle from the aorta, secure the position of the first annular valve and second annular valves in the treatment segment of the catheter as described herein to provides unidirectional (ventricle to aorta) unimpeded flow of blood with each heartbeat while preventing backward blood flow from aorta into the ventricle (aortic regurgitation) during treatment of the cusp of the aortic valve. Another advantage is the ability to apply machine learning algorithms, artificial intelligence, and robotics integrated with data acquired from direct intraluminal imaging, video, remodeling, and pre- and post-procedure direct visualization of aortic valve. This and other areas of the vascular system may be studied during insertion and withdrawal of the catheter without the use of contrast dye, which can cause damage to kidneys.

[0153] Although the invention is shown and described with respect to certain embodiments, modifications will occur to those skilled in the art upon reading and understanding the specification, and the present invention includes all such modifications.

What is claimed is:

1. A treatment segment of a catheter for heart valve treatment comprising:

a distal catheter body having a collapsible and expandable through conduit in surrounding relationship thereto and operatively connected to a collapsible and expandable valve cusp enclosure,

wherein the through conduit has a first end sealed by a first annular valve and a second end sealed by a second annular valve, and each of the first and second annular valves have an elastic body, a distal end connected to the valve cusp enclosure and a proximal end sealingly engaged to the distal catheter body in a deployed, closed position;

wherein the through conduit and the distal ends of each of the first and second annular valves are configured to expand with the valve cusp enclosure at a rate proportionate to a patient's blood pressure and a volume of blood displaced during expansion, and the elastic body and proximal ends of each of the first and second annular valves are configured to open and close in response to systolic and diastolic blood flow, respectively, thereby moving the proximal end of each in and out of sealing engagement with the distal catheter body.

2. The treatment segment of claim **1**, wherein the elongate body of the through conduit is configured to retain blood between systolic opening and diastolic closing of the first and second annular valves.

3. The treatment segment of claim **1**, wherein the first annular valve and the second annular valve are each frustoconically-shaped in a deployed, closed position.

4. The treatment segment of claim **1**, wherein the valve cusp enclosure comprises:

one or more ventricular cusp and aortic cusp pairs, wherein each pair has attached ends at the through conduit, the attached ends being spaced apart and having a catheter working port exit therebetween, each pair defines a pocket therebetween, and each pair has free ends configured to engage a patient's inferior surface of the aortic valve and superior surface of the aortic valve, respectively.

5. The treatment segment of claim **4**, wherein the catheter working port exit is a terminal end of a port that extends radially from the distal catheter body through the through conduit, wherein the port is expandable and collapsible between a deployed state and a transport state, respectively.

6. The treatment segment of claim **4**, wherein the pocket is configured to receive a single one of a patient's valve cusp therein.

7. The treatment segment of claim **4**, wherein the pocket is configured to receive two or more of a patient's valve cusps therein.

8. The treatment segment of claim **4**, wherein the one or more ventricular cusp and aortic cusp pairs each comprise an inflatable balloon having a plurality of individually controlled inflation chambers.

9. The treatment segment of claim **8**, wherein the aortic cusp of the one or more ventricular cusp and aortic cusp pairs is controllably inflatable to maintain blood flow to the right and left coronary arteries.

10. The treatment segment of claim **9**, wherein the through conduit has a length configured to position the first annular valve superior relative to the right and left coronary arteries.

11. The treatment segment of claim **9**, wherein the aortic cusp is controllably inflatable to increase blood flow to the left and right coronary arteries.

12. The treatment segment of claim **4**, wherein the one or more ventricular cusp and aortic cusp pairs each comprise a plurality of telescoping, operatively expandable links housed inside a biomaterial.

13. The treatment segment of claim **12**, wherein each of the plurality of telescoping, operatively expandable links terminate with a foot configured to engage the respective inferior or superior surface of the annulus of the aortic valve.

14. The treatment segment of claim **10**, wherein each of the plurality of telescoping, operatively expandable links comprise one or more elbow joints defining an axis of rotation about which the more distal link is rotatable.

15. The treatment segment of claim **1**, further comprising an electrocardiogram sensor; wherein the through conduit and the distal ends of each of the first and second annular valves are configured to expand controllably based on data from the electrocardiogram sensor.

16. A method of remodeling a cusp of a heart valve of a patient in need thereof, the method comprising:

introducing a catheter having a heart valve treatment segment according to claim **1** to a target heart valve;

deploying the collapsible and expandable valve cusp enclosure into an expanded state in which a cusp of a heart valve in need of remodeling is enclosed in an isolated pocket and simultaneously expanding the through conduit into a corresponding expanded state;

removing blood from the isolated pocket via the catheter to form a bloodless field surrounding the cusp of the heart valve;

remodeling the cusp of the heart valve;

collapsing the valve cusp enclosure; and

removing the catheter from the patient.

17. The method of claim **16**, wherein introducing the catheter comprises feeding the catheter through a patient's artery based on robotics in a terminal cap guided by fiberoptic imaging or infrared or IVUS videography or EKG sensors that seek cardiac sinus node electric homing, or a combination thereof.

18. The method of claim **16**, wherein deploying the valve cusp enclosure comprises inflating a plurality of balloon segments with a fluid.

19. The method of claim **18**, wherein determining a lipid burden or calcium burden or fibrous scar tissue includes application of near-infrared spectroscopy plus intravascular ultrasound or a capacitive micromachines ultrasound transducer and fiberoptic cameras.

20. The method of claim **16**, wherein the method further comprises advancing a tool through the catheter into the bloodless field and remodeling comprises one or more of:

i) removing fibrotic, calcific, and/or lipid laden material from a surface of the cusp using the tool;

ii) smoothing a surface of the cusp using the tool;

iii) preparing a surface of the cusp to accept a resurfacing material using the tool; and

iv) applying a resurfacing material to a surface of the cusp.

21. The method of claim **20**, wherein removing comprises a laser treatment of the surface of the cusp.

22. The method of claim **20**, wherein the resurfacing material comprises elastin and/or stem cells.

23. The method of claim **20**, wherein the resurfacing material comprises a drug treatment.

24. The method of claim **23**, wherein the drug treatment comprises collagen and/or carbon dots comprising stem cells, and the method further comprises activating the collagen by application of an activating wavelength of energy.

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