US 20240065836A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2024/0065836 A1**

Popp et al. (43) **Pub. Date: Feb. 29, 2024**

(54) **DELIVERY DEVICES FOR HEART VALVE TREATMENT DEVICES**

(71) Applicant: **EDWARDS LIFESCIENCES CORPORATION**, Irvine, CA (US)

(72) Inventors: **Michael J. Popp**, Irvine, CA (US); **Nicolas Schleiger**, Costa Mesa, CA (US); **Kevin Gantz**, Laguna Beach, CA (US); **George Lee Matlock**, Tehachapi, CA (US); **Aric Daniel Stone**, Newport Beach, CA (US); **Eric Robert Dixon**, Villa Park, CA (US); **Charles Henry Bloodworth, IV**, Irvine, CA (US); **Gregory Scott Tyler, II**, Winston-Salem, NC (US); **Asher L. Metchik**, Rolling Hills Estates, CA (US); **Robert Bowes**, Trabuco Canyon, CA (US); **Waina Michelle Chu**, Tustin, CA (US); **Zachary James Zira**, Irvine, CA (US); **Steven Park**, Santa Ana, CA (US)

(21) Appl. No.: **18/496,817**

(22) Filed: **Oct. 27, 2023**

Related U.S. Application Data

(63) Continuation of application No. PCT/US2022/025390, filed on Apr. 19, 2022.

(60) Provisional application No. 63/268,845, filed on Mar. 3, 2022, provisional application No. 63/181,120, filed on Apr. 28, 2021.

Publication Classification

(51) **Int. Cl.**

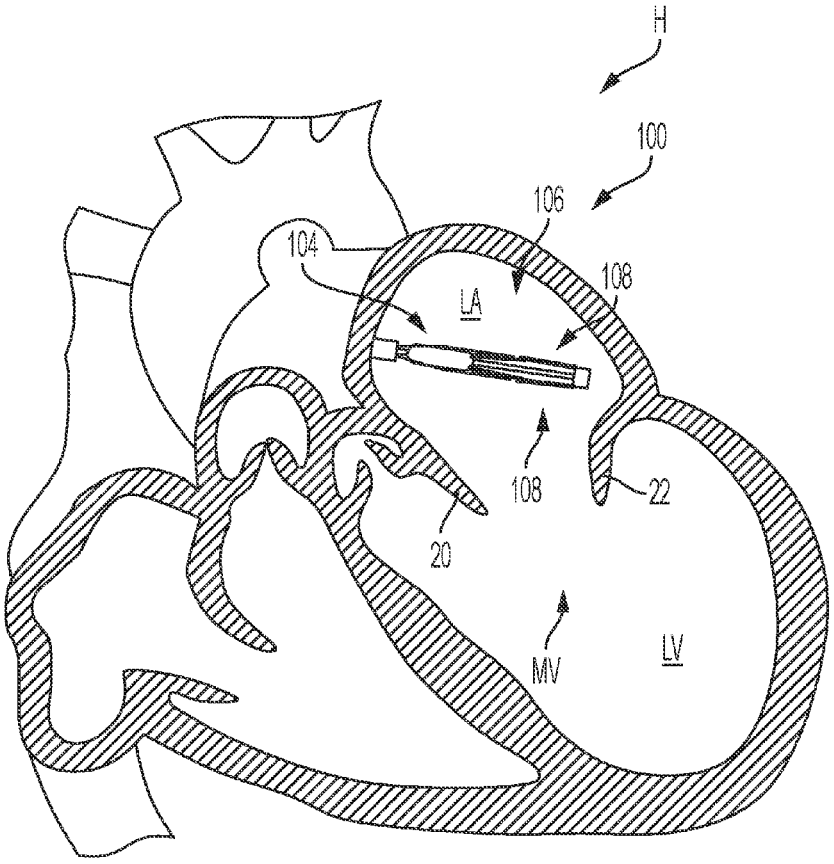
A61F 2/24	(2006.01)
A61M 25/00	(2006.01)
A61M 25/01	(2006.01)

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

CPC ***A61F 2/2436*** (2013.01); ***A61M 25/0023*** (2013.01); ***A61M 25/0053*** (2013.01); ***A61M 25/0136*** (2013.01); *A61M 2025/0004* (2013.01); *A61M 2025/0047* (2013.01); *A61M 2205/0222* (2013.01)

(57) **ABSTRACT**

Components for valve treatment systems are disclosed. Valve treatment systems can include a delivery system for an implantable device. The delivery system can include one or more of clasp control components slidably disposed on a catheter handle, a control element for opening and closing the implantable device, a catheter assembly with features to reduce friction with another catheter assembly, grips for attaching catheter assemblies to clamps, catheter assemblies with features that stiffen or provide variable stiffness, and catheter assemblies with one or more steering control lumens incorporated into a reinforcement layer.



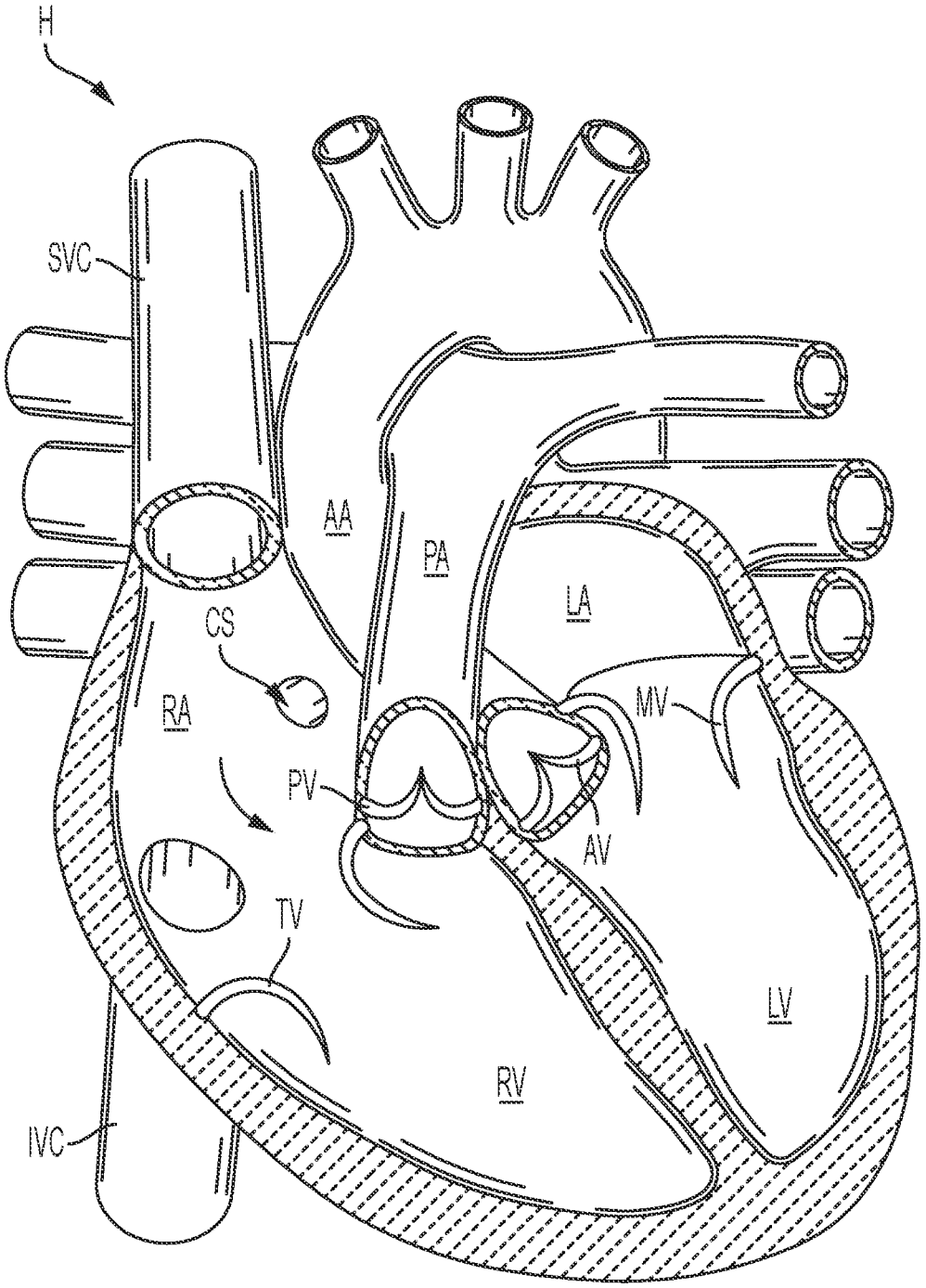


FIG. 1

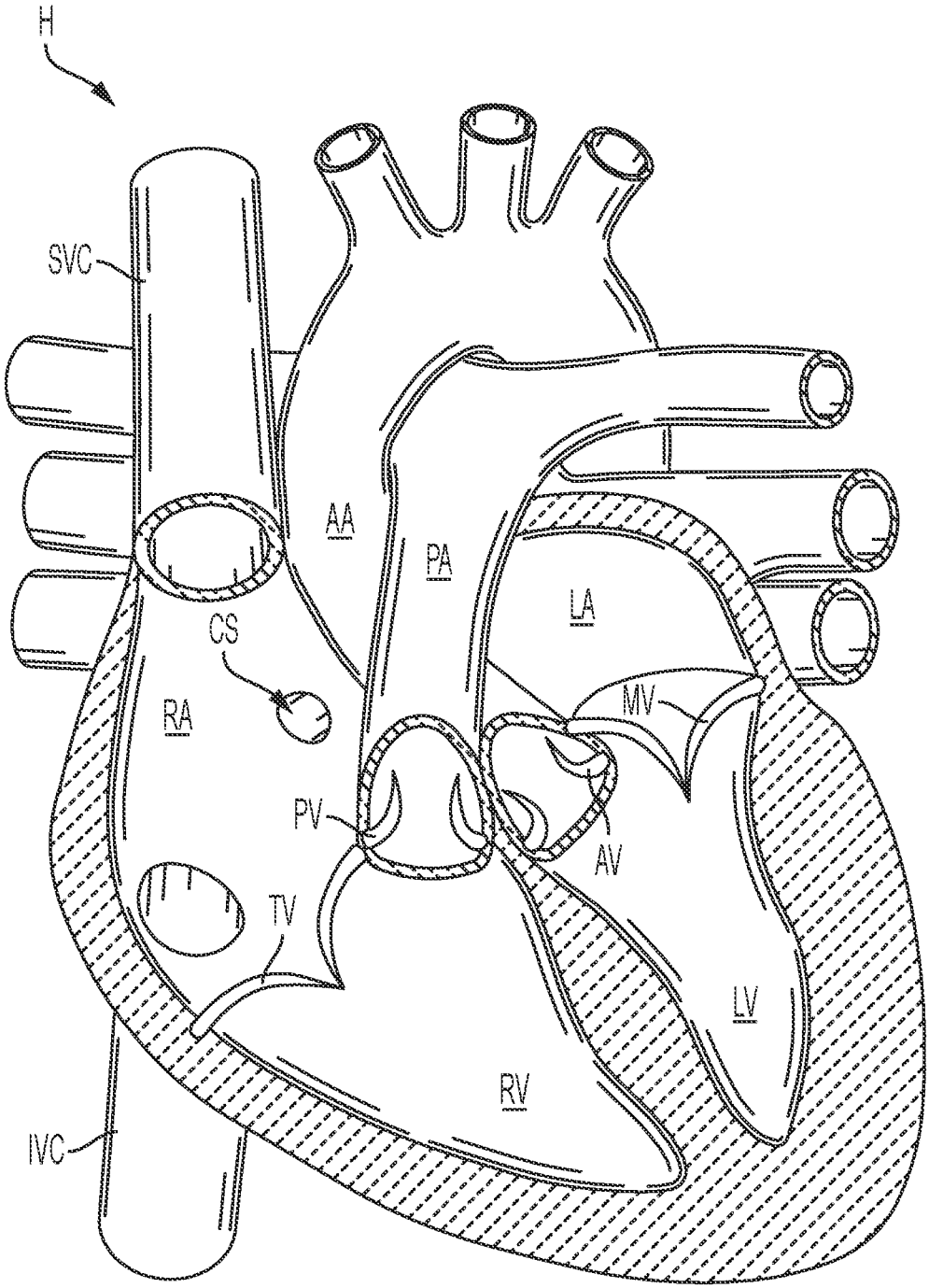


FIG. 2

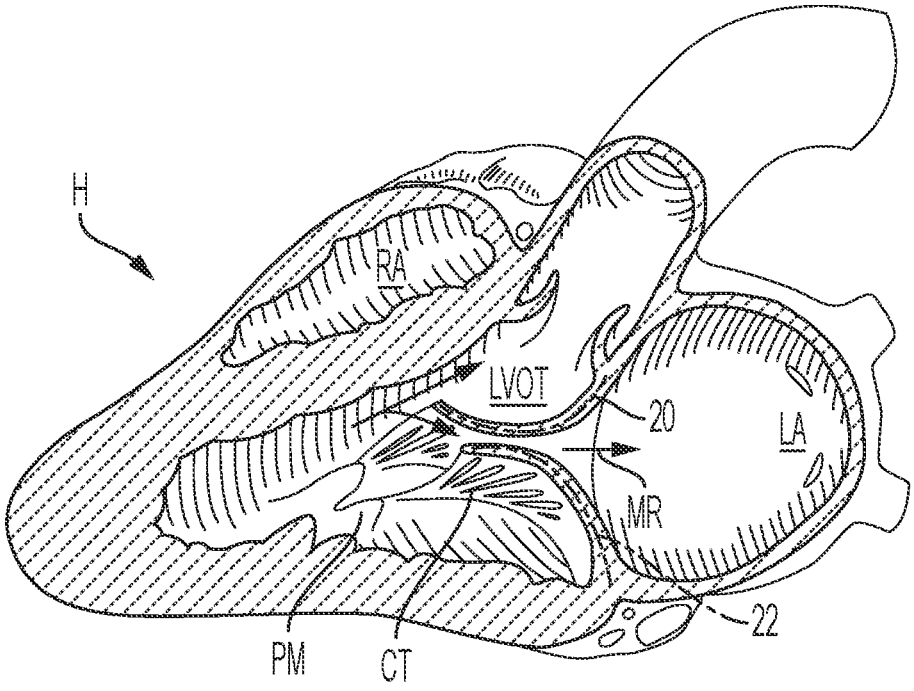


FIG. 3

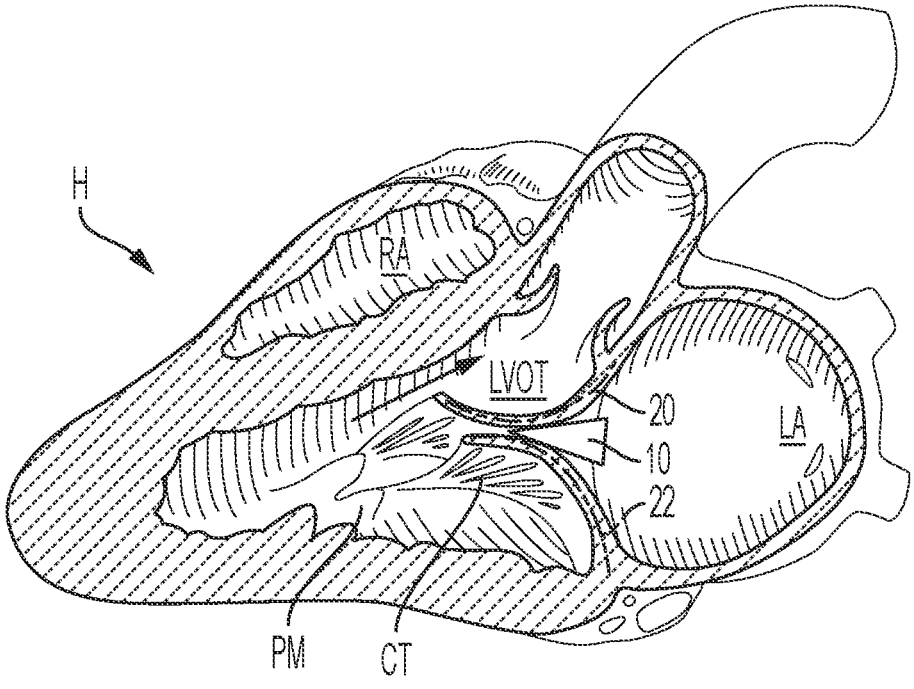


FIG. 4

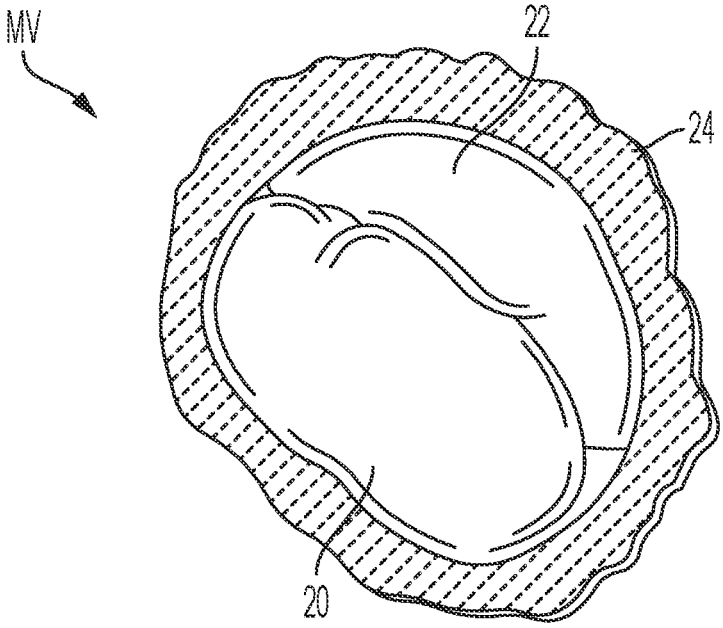


FIG. 5

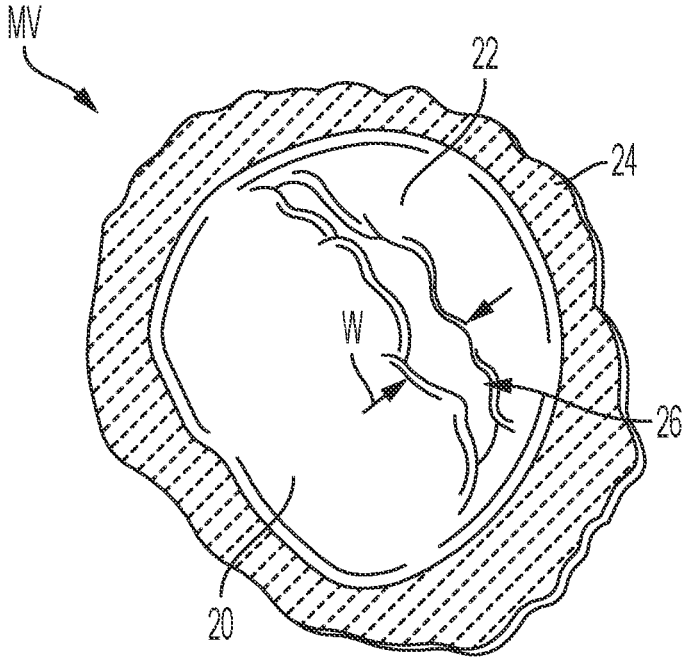


FIG. 6

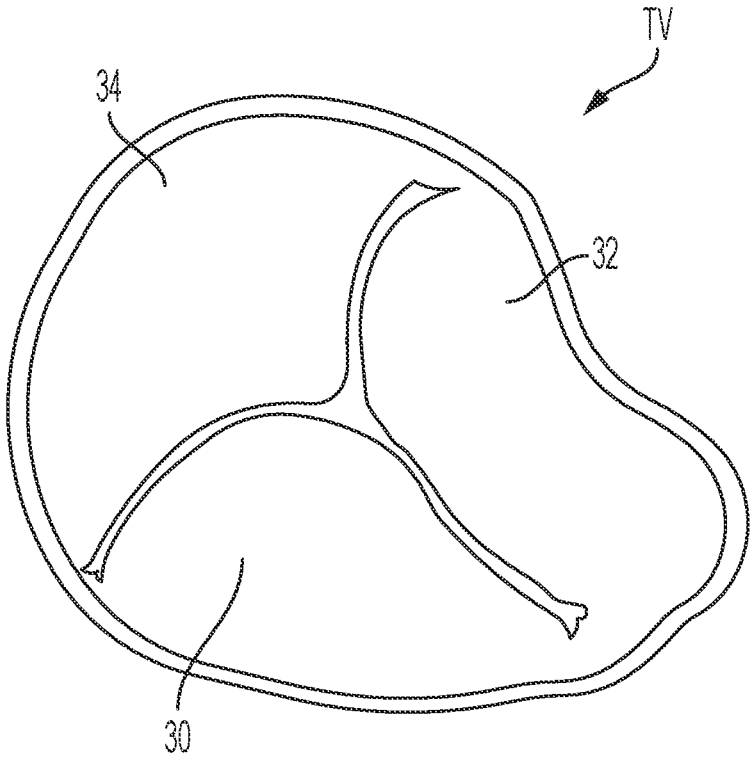


FIG. 7

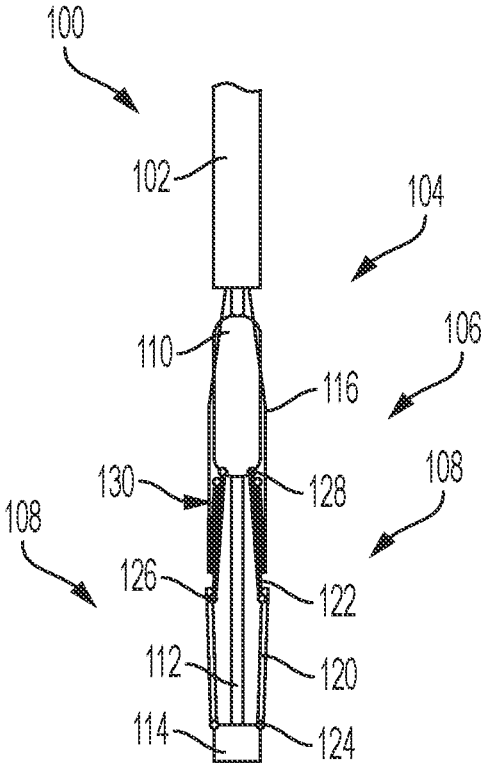


FIG. 8

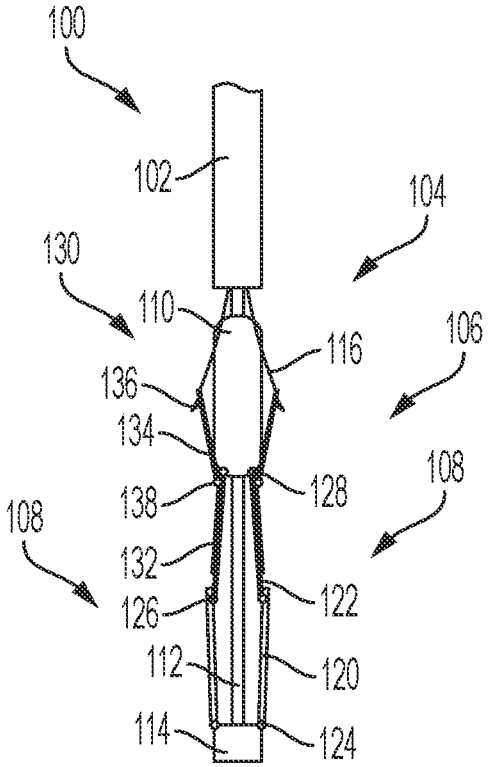


FIG. 9

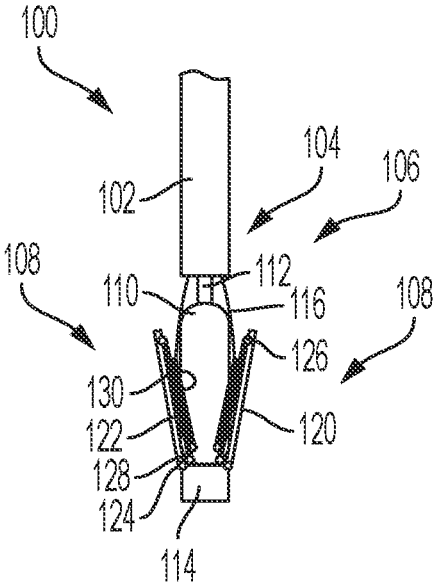


FIG. 10

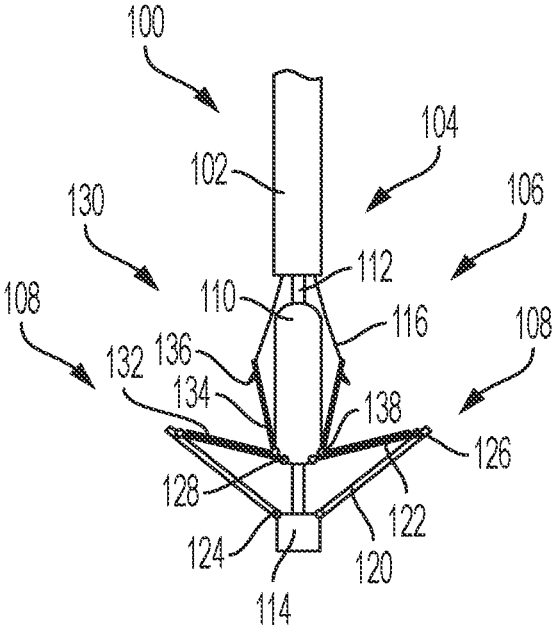


FIG. 11

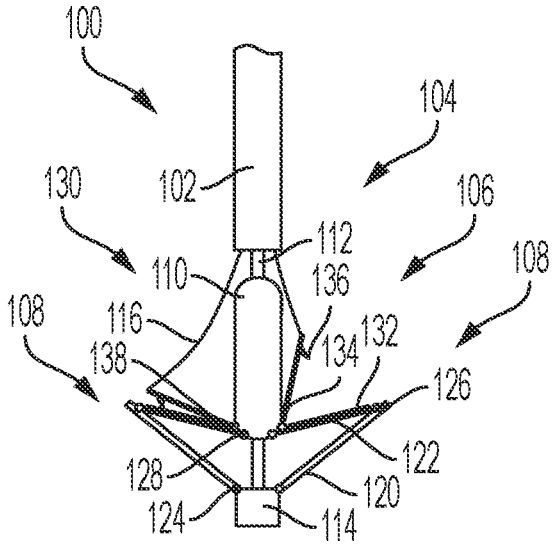


FIG. 12

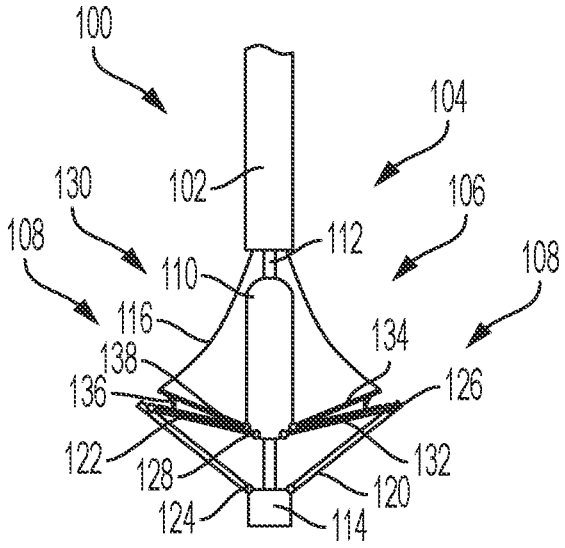


FIG. 13

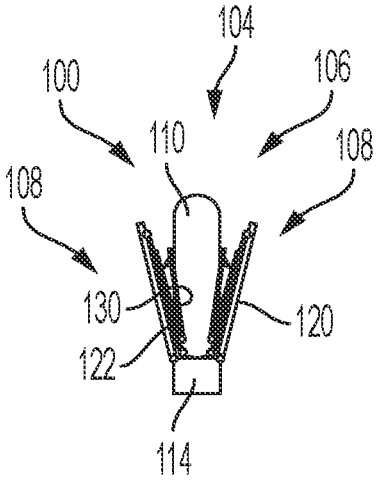


FIG. 14

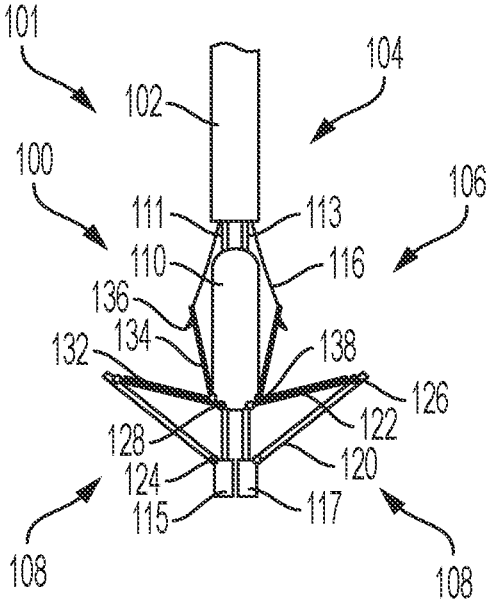


FIG. 15

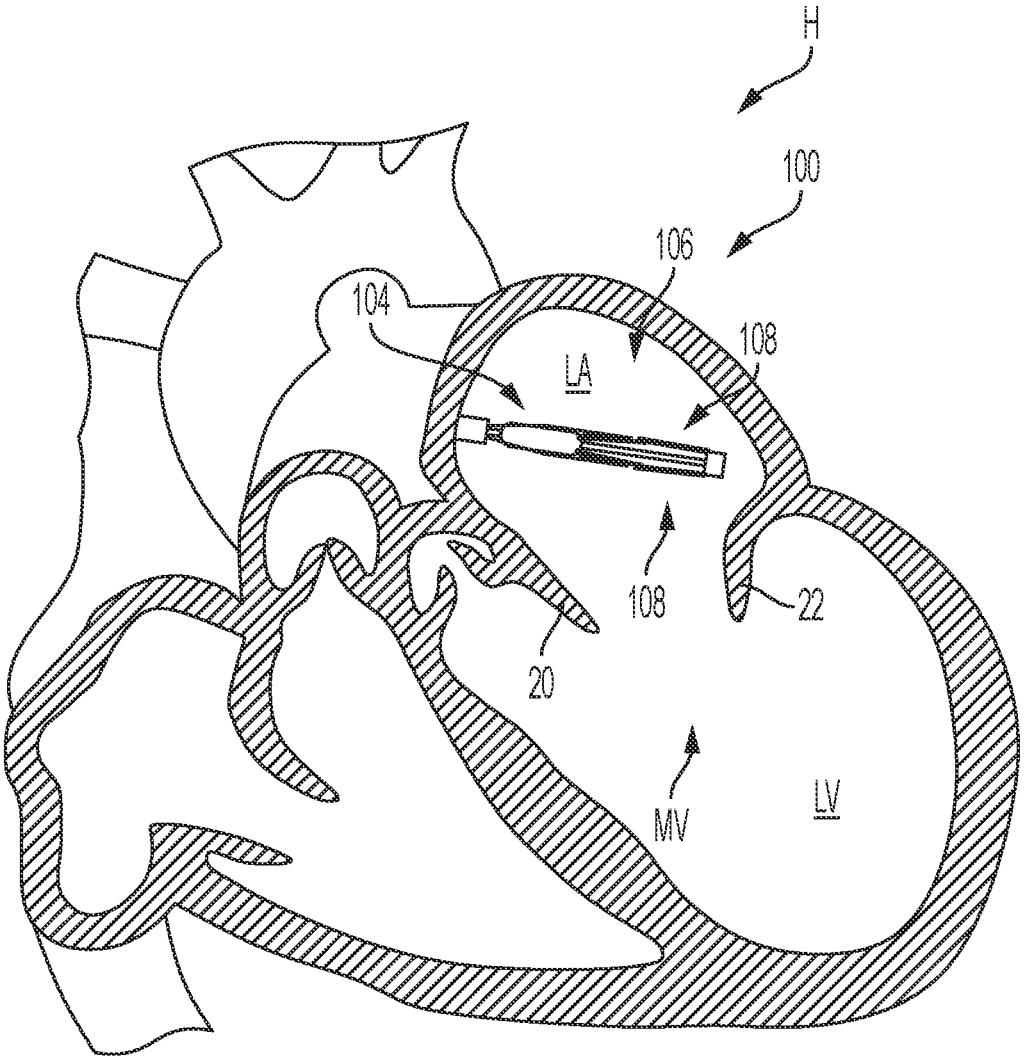


FIG. 16

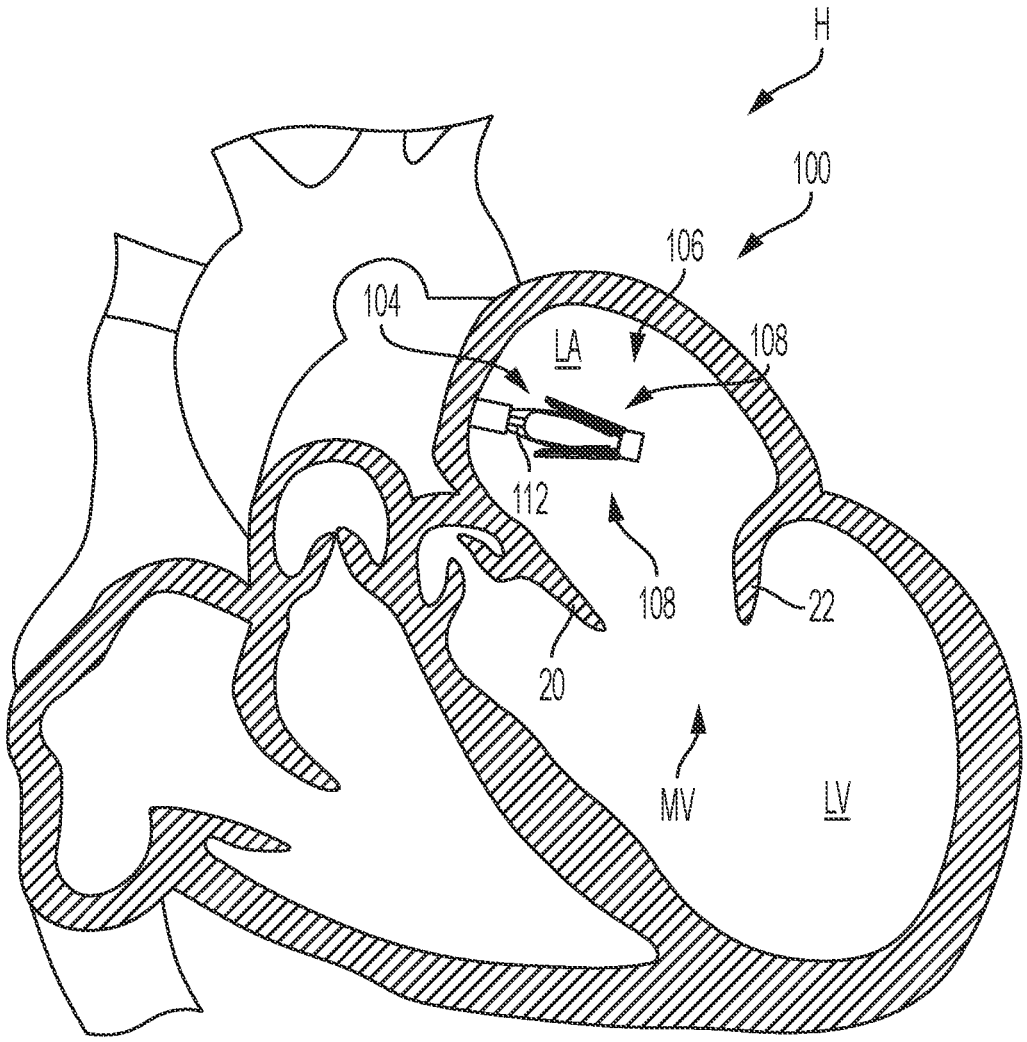


FIG. 17

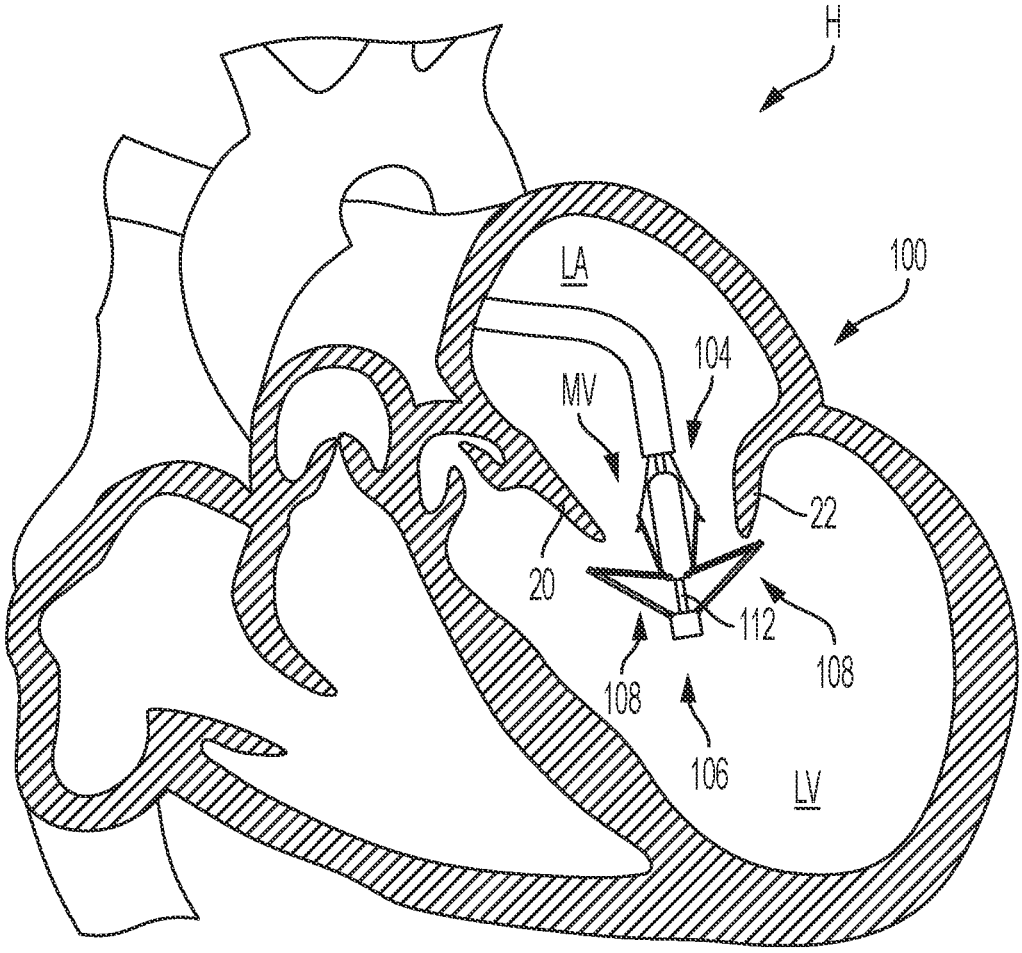


FIG. 18

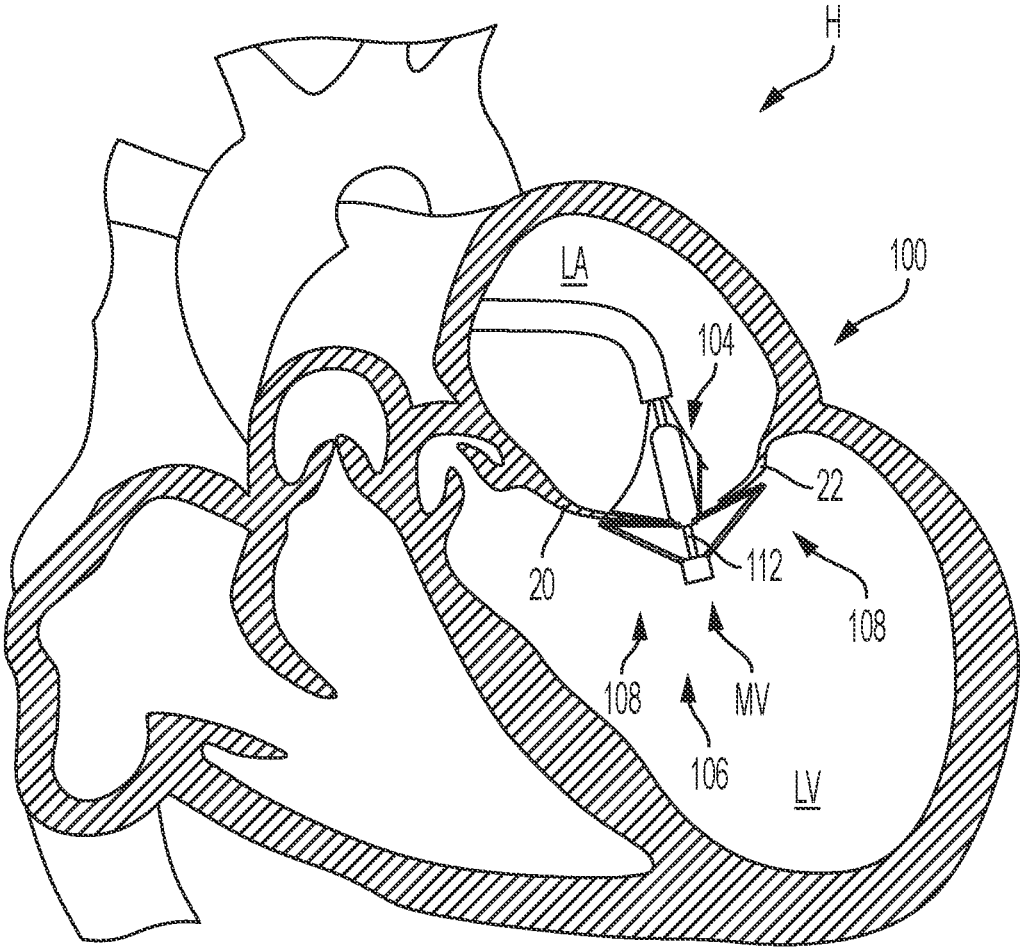


FIG. 19

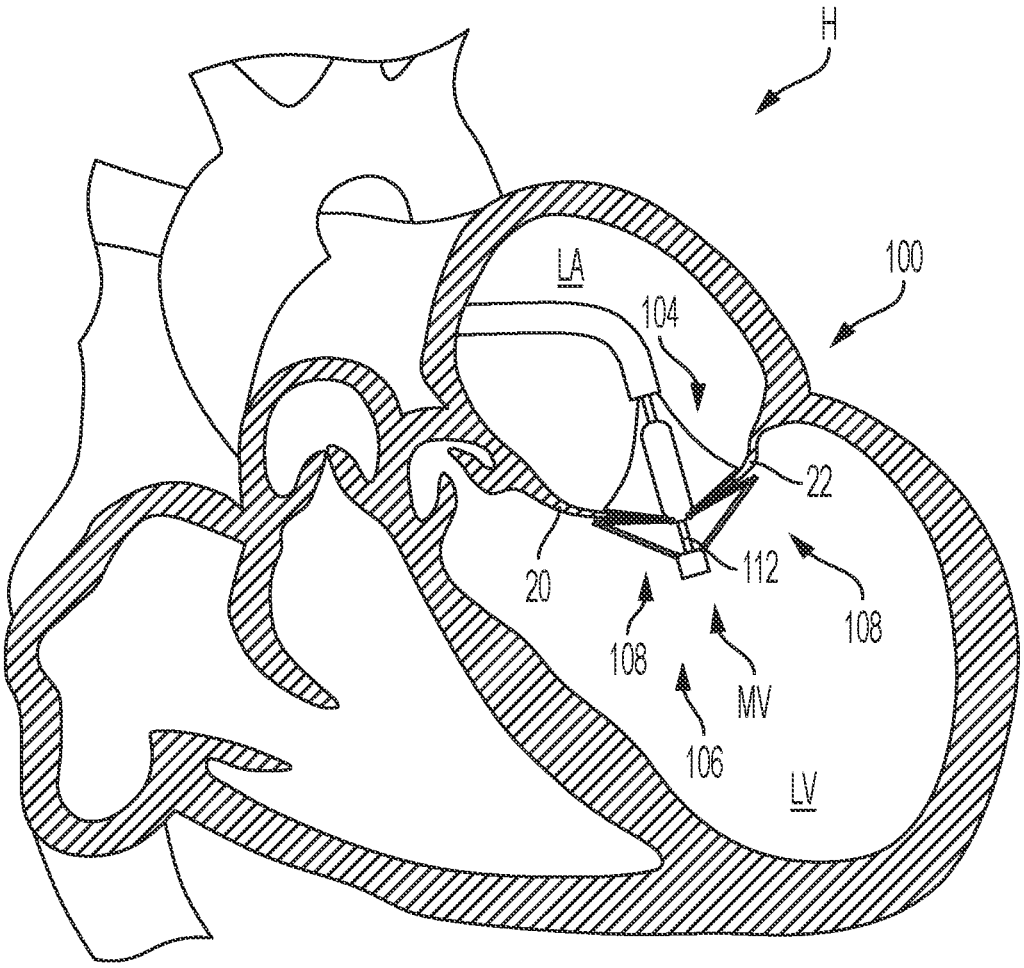


FIG. 20

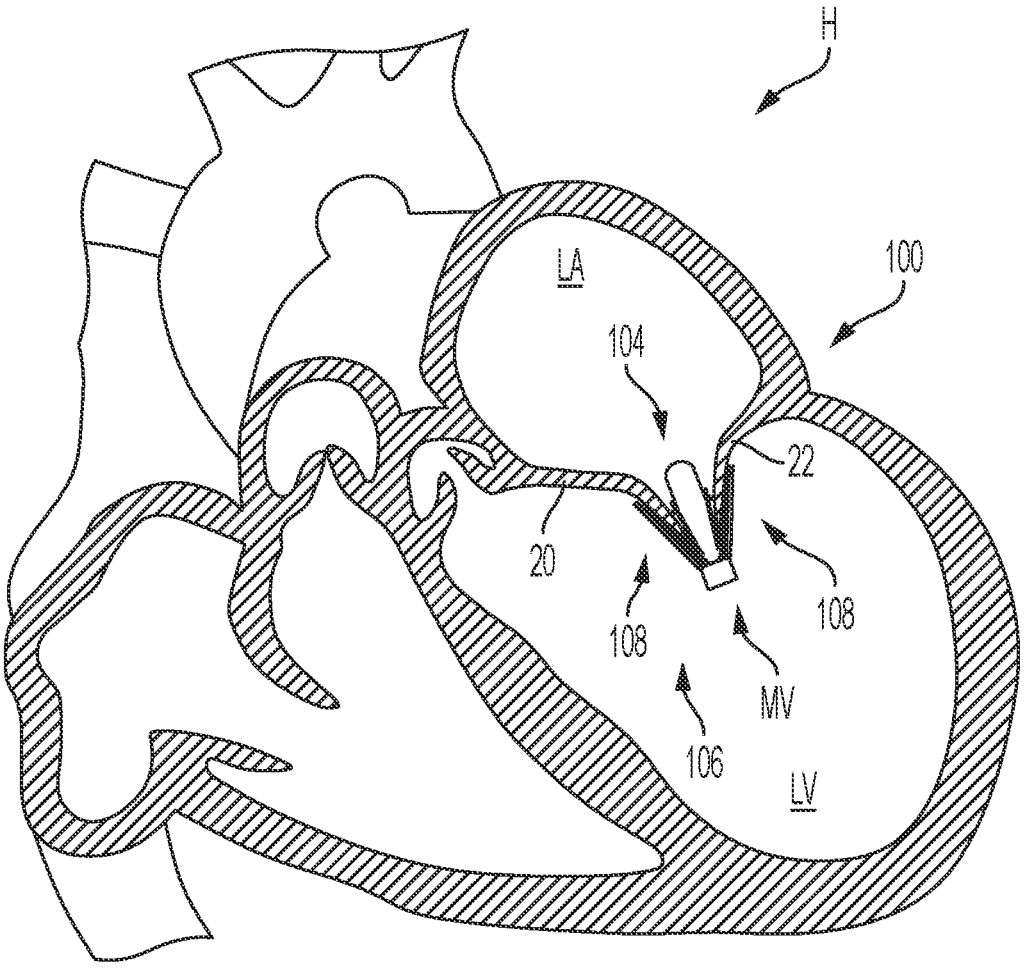


FIG. 21

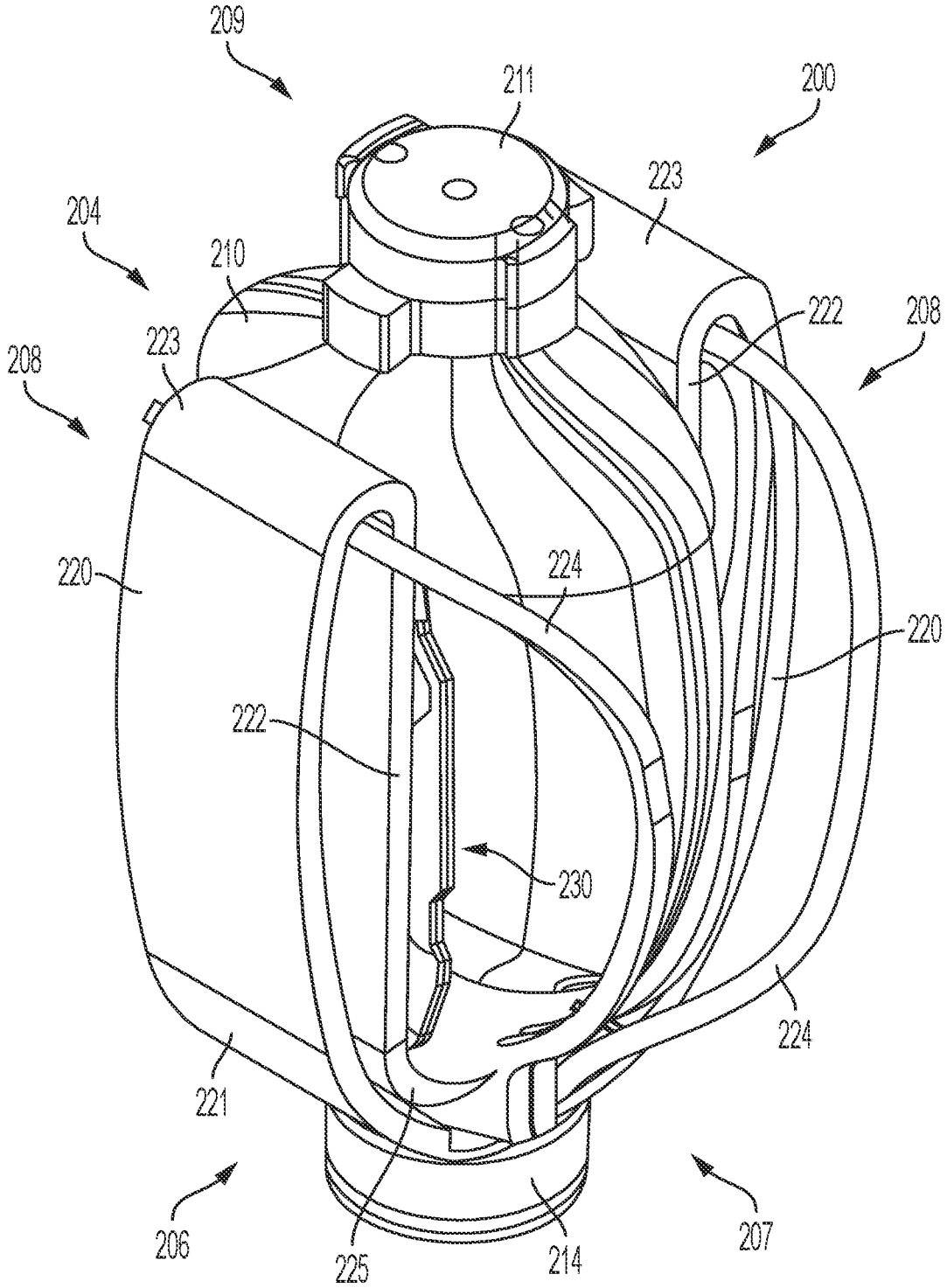

209
211
200
223
204
210
222
208
223
208
220
224
220
222
230
224
221
206
225
214
207

FIG. 22

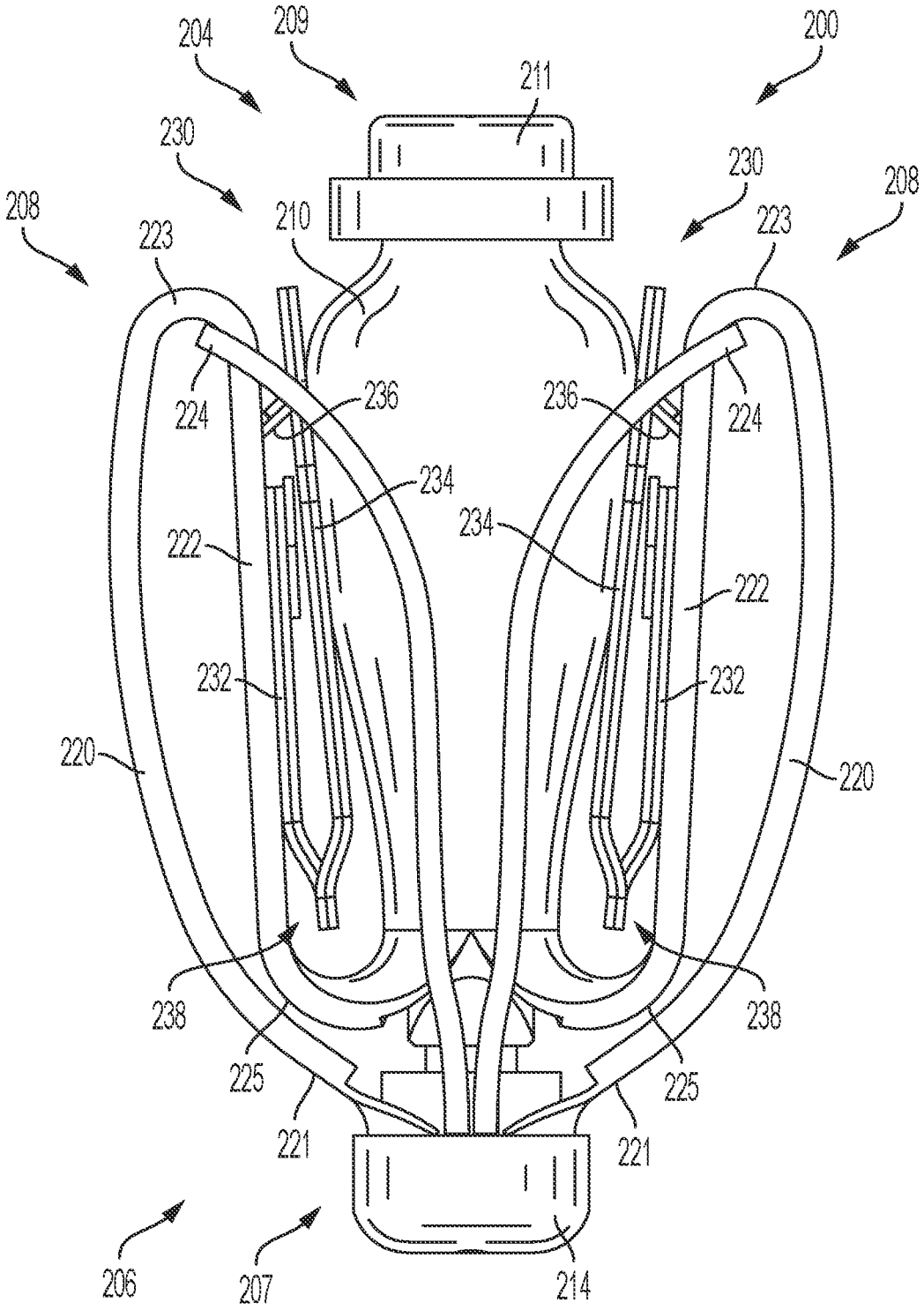

204
209
200
211
230
230
208
208
210
223
223
224
224
236
236
234
234
222
222
232
232
220
220
238
238
225
225
221
221
206
207
214

FIG. 23

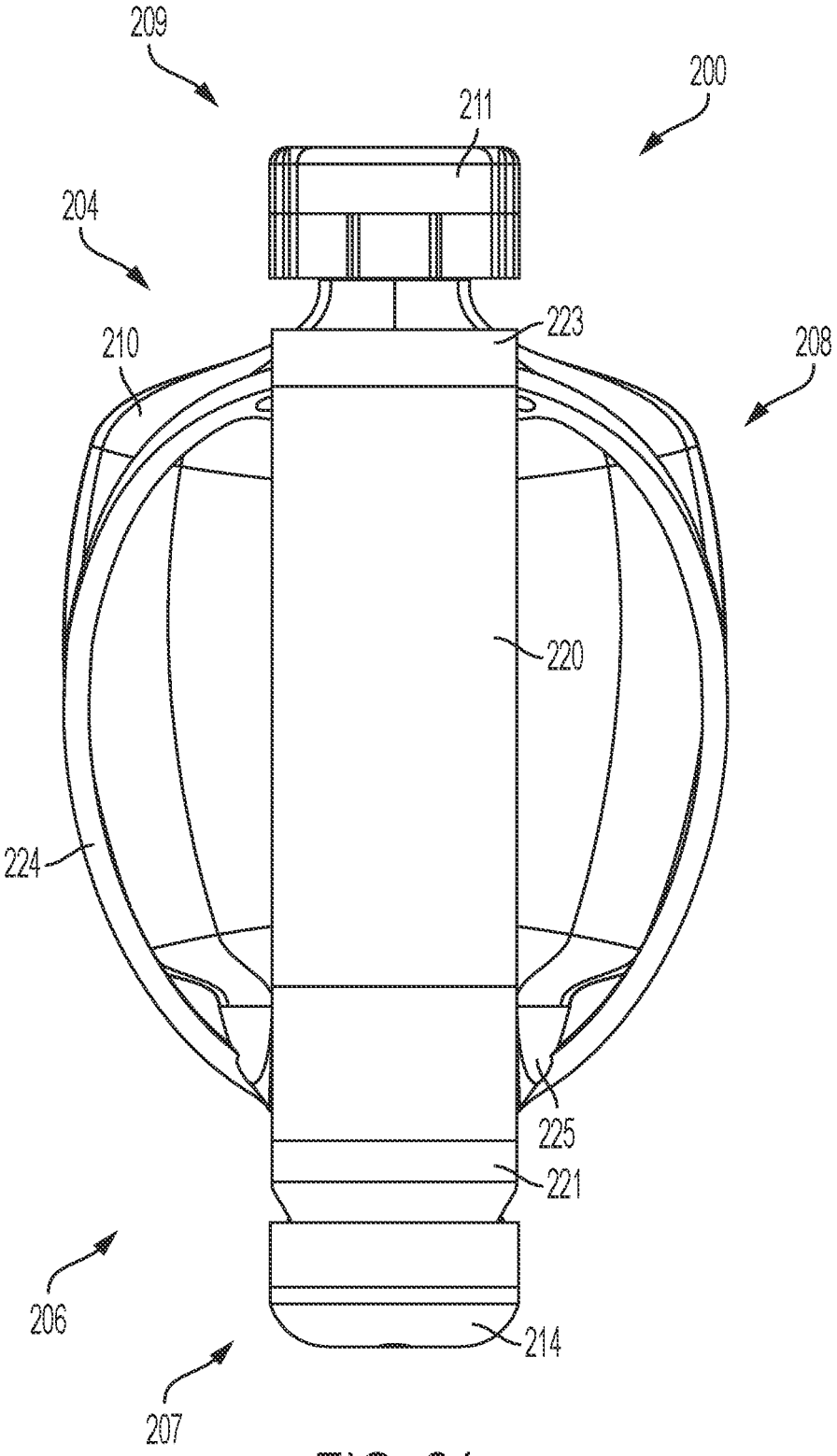


FIG. 24

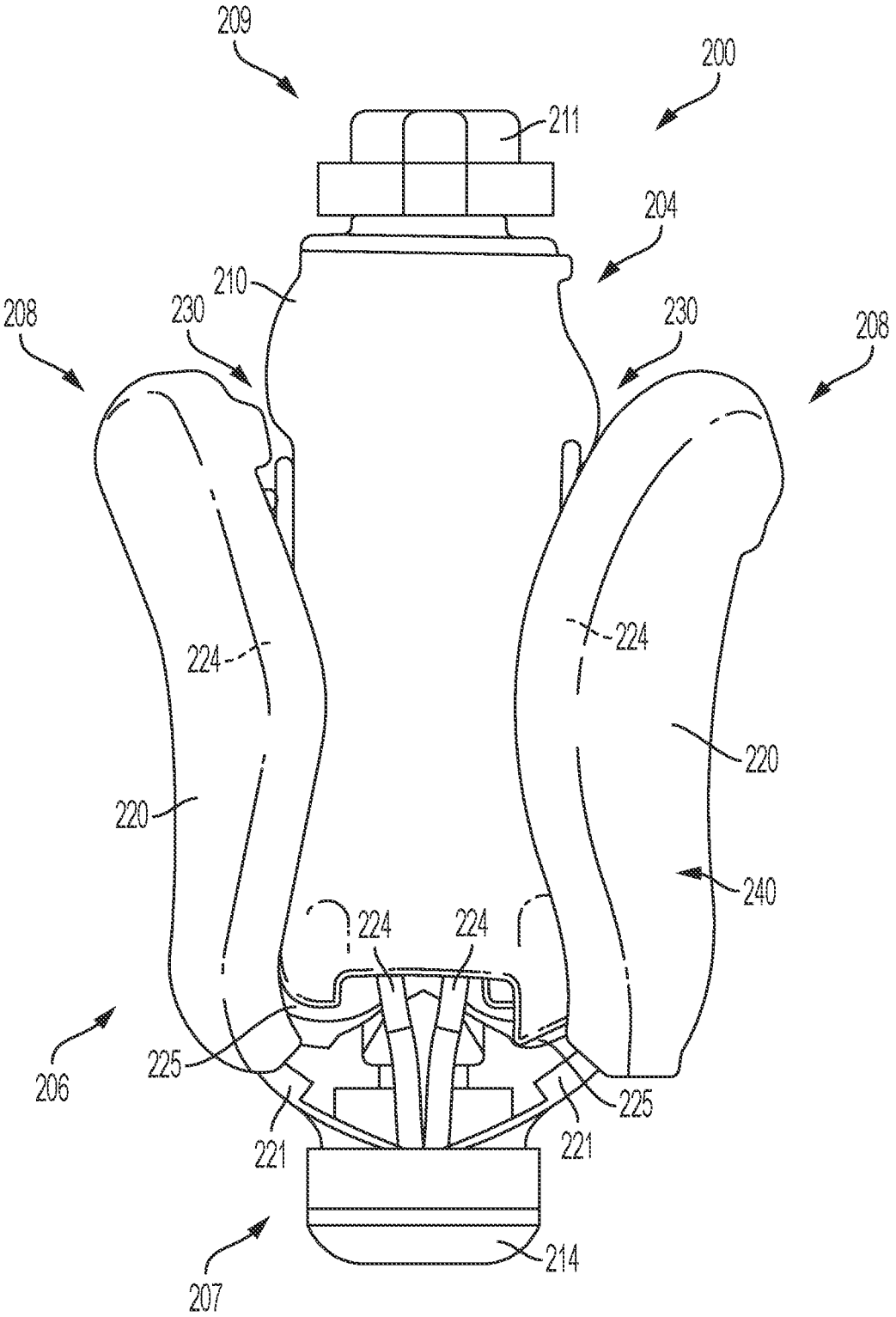

209
200
211
204
210
208
230
230
208
224
224
220
220
240
224
224
206
225
225
221
221
214
207

FIG. 25

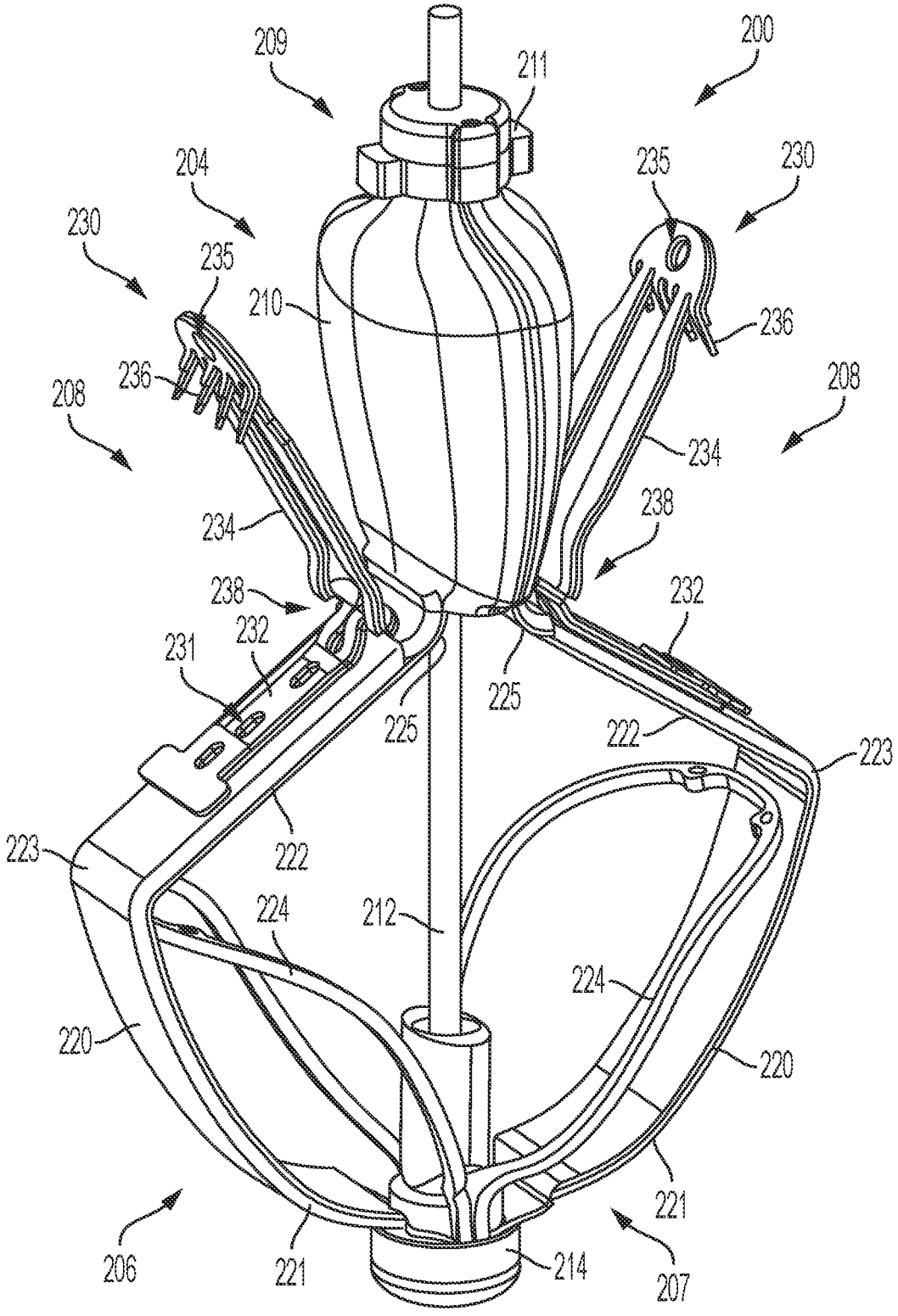

209
211
200
204
235
230
230
235
210
236
236
208
208
234
234
238
238
232
231
232
225
225
222
223
223
222
224
212
224
220
220
221
206
221
214
207

FIG. 26

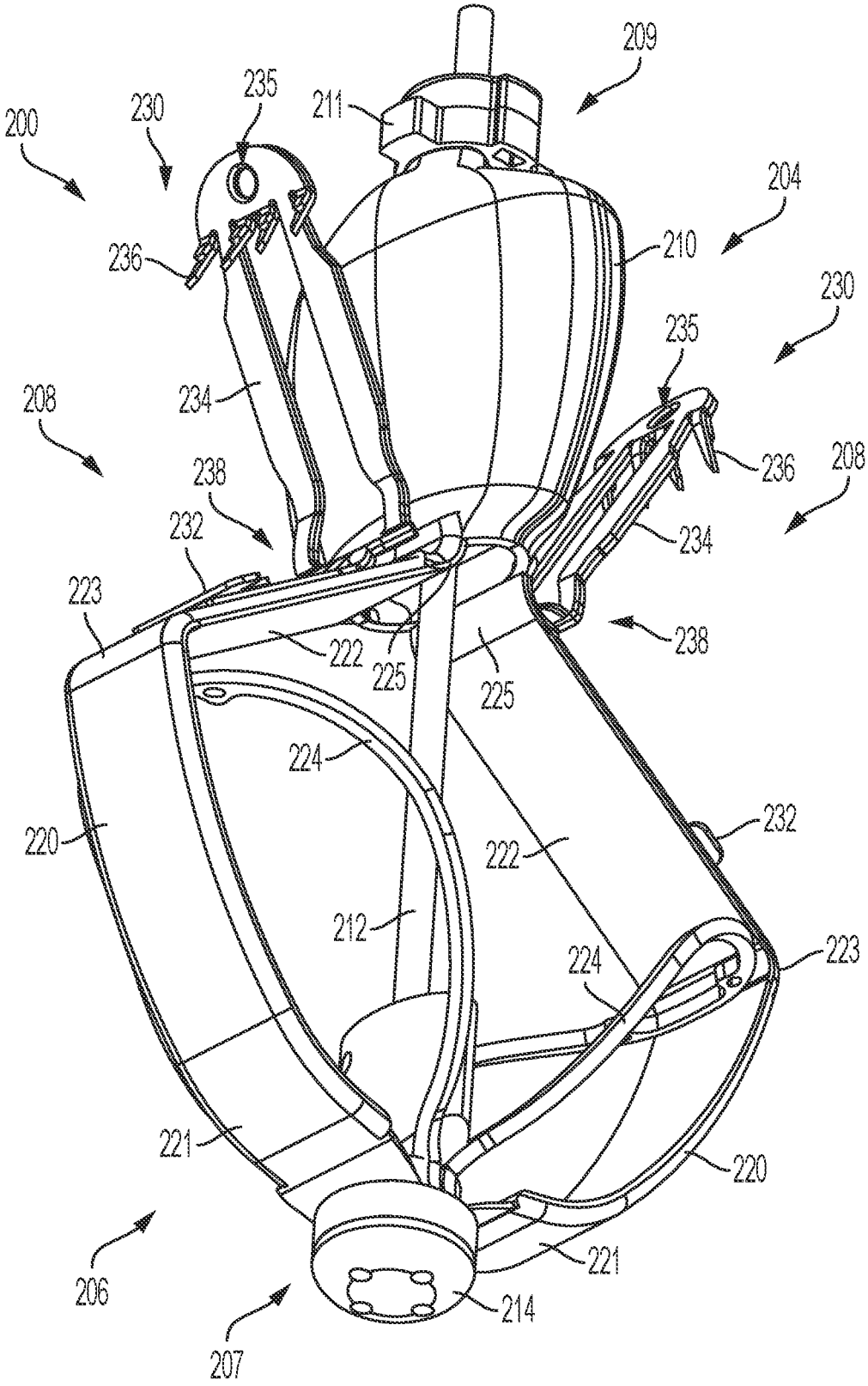

209
235
211
230
200
204
236
210
230
235
208
234
236
208
238
232
234
223
238
222
225
225
224
220
232
222
212
224
223
221
220
206
221
214
207

FIG. 27

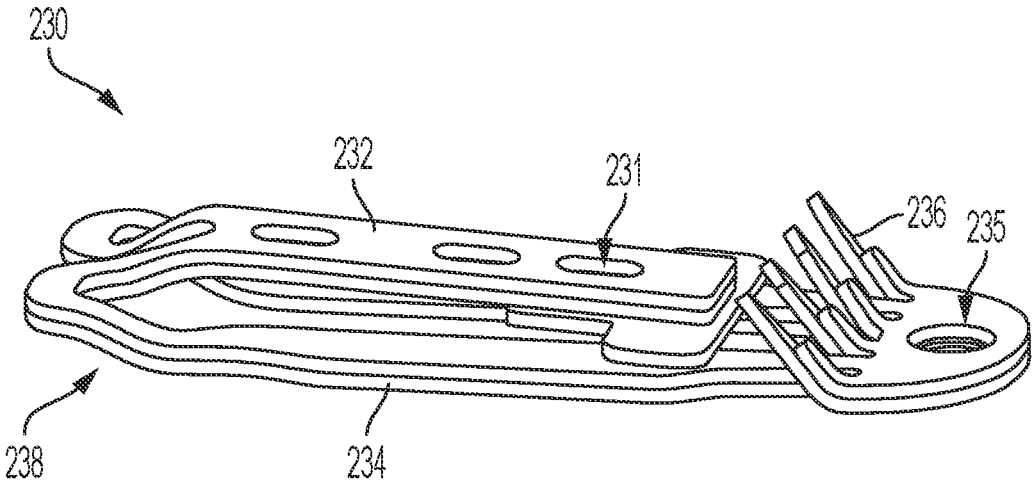


FIG. 28

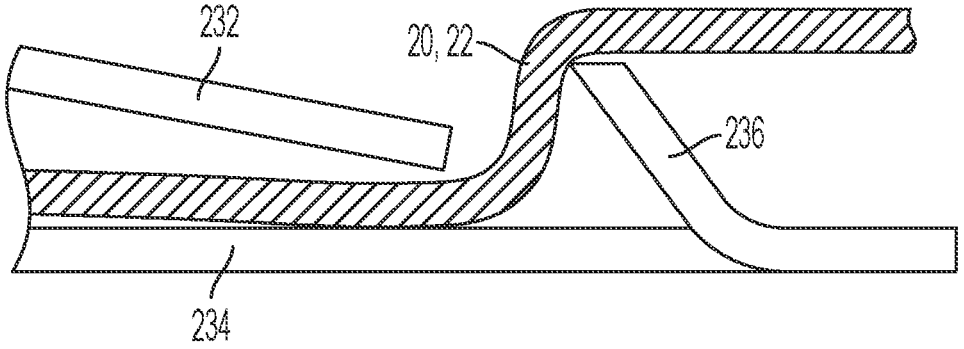


FIG. 29

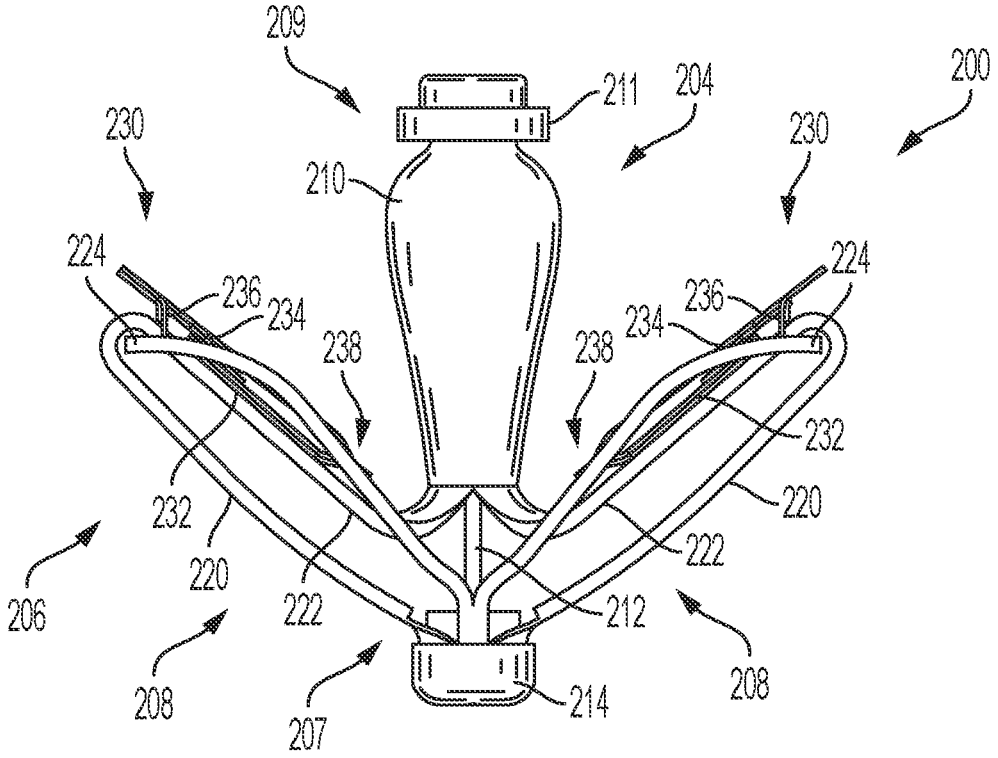

209
211
204
200
230
230
210
224
224
236
234
236
234
238
238
232
232
220
222
220
222
206
212
208
208
214
207

FIG. 30

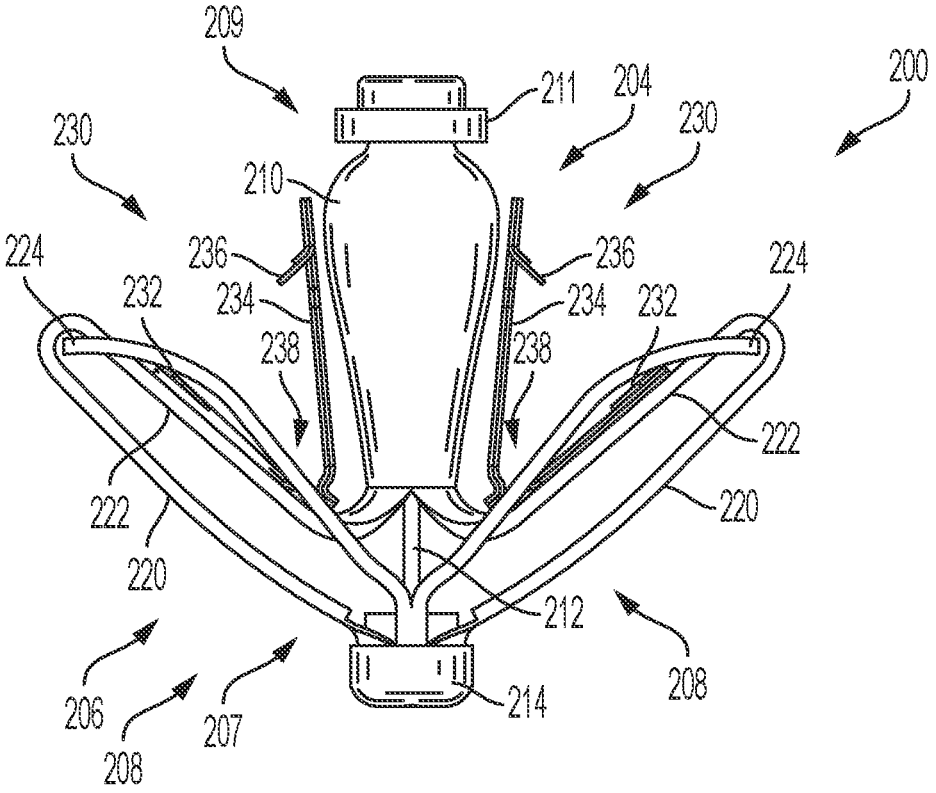

209
211
204
200
230
230
210
224
224
236
236
232
234
234
232
238
238
222
222
220
220
212
206
208
207
214
208

FIG. 31

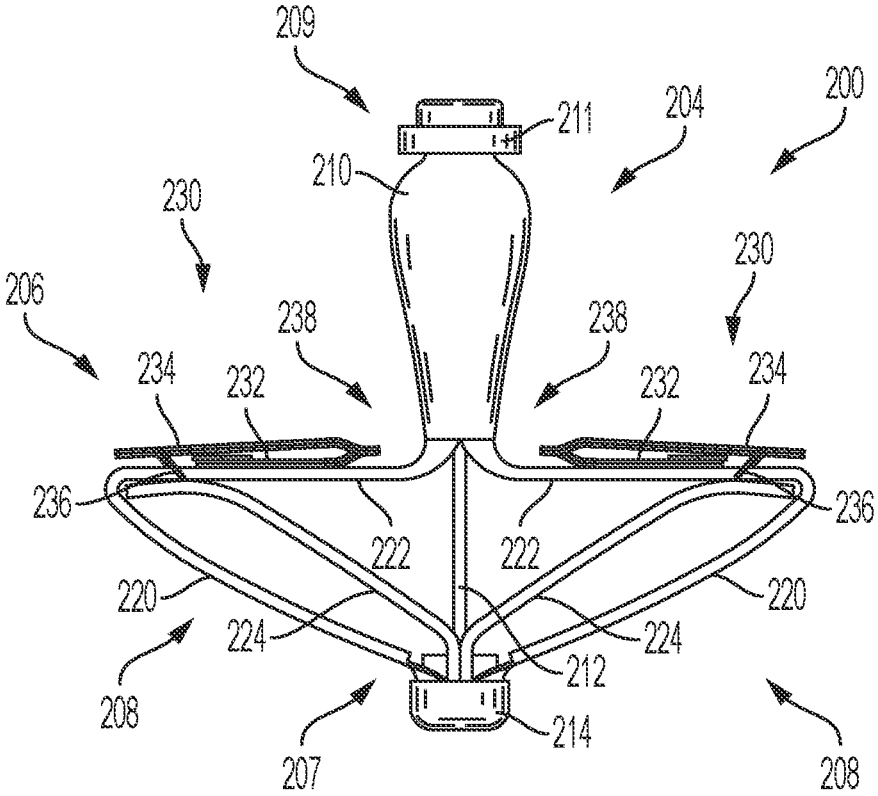

209
211
204
200
210
230
230
206
238
238
234
232
232
234
236
236
222
222
220
220
224
224
212
208
214
207
208

FIG. 32

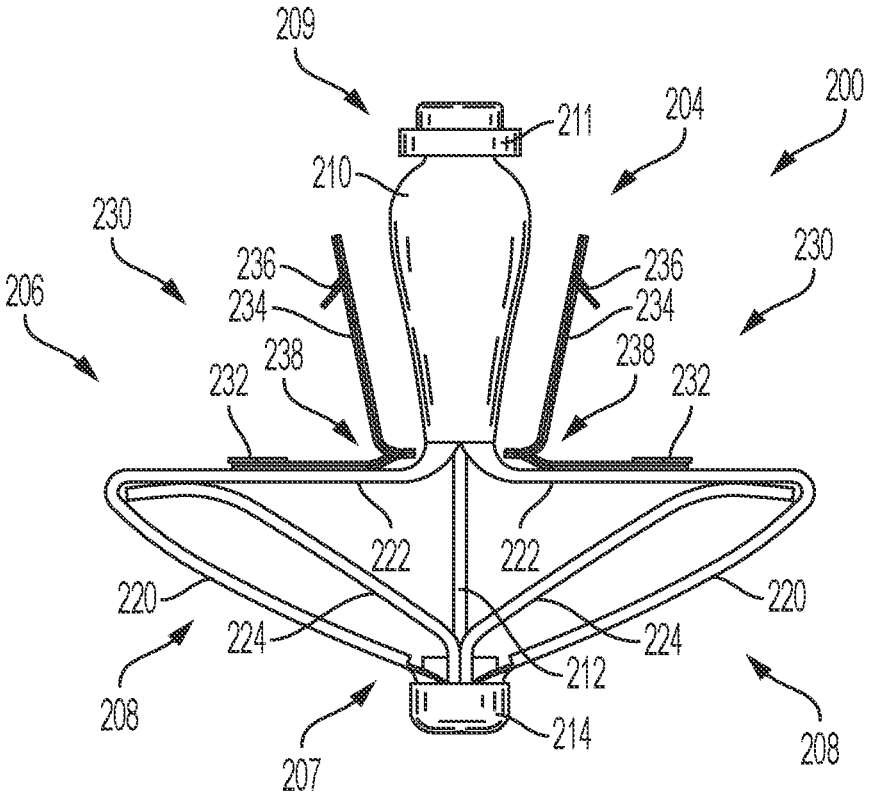

209
211
204
200
210
230
230
206
236
236
234
234
238
238
232
232
222
222
220
220
224
224
212
208
214
207
208

FIG. 33

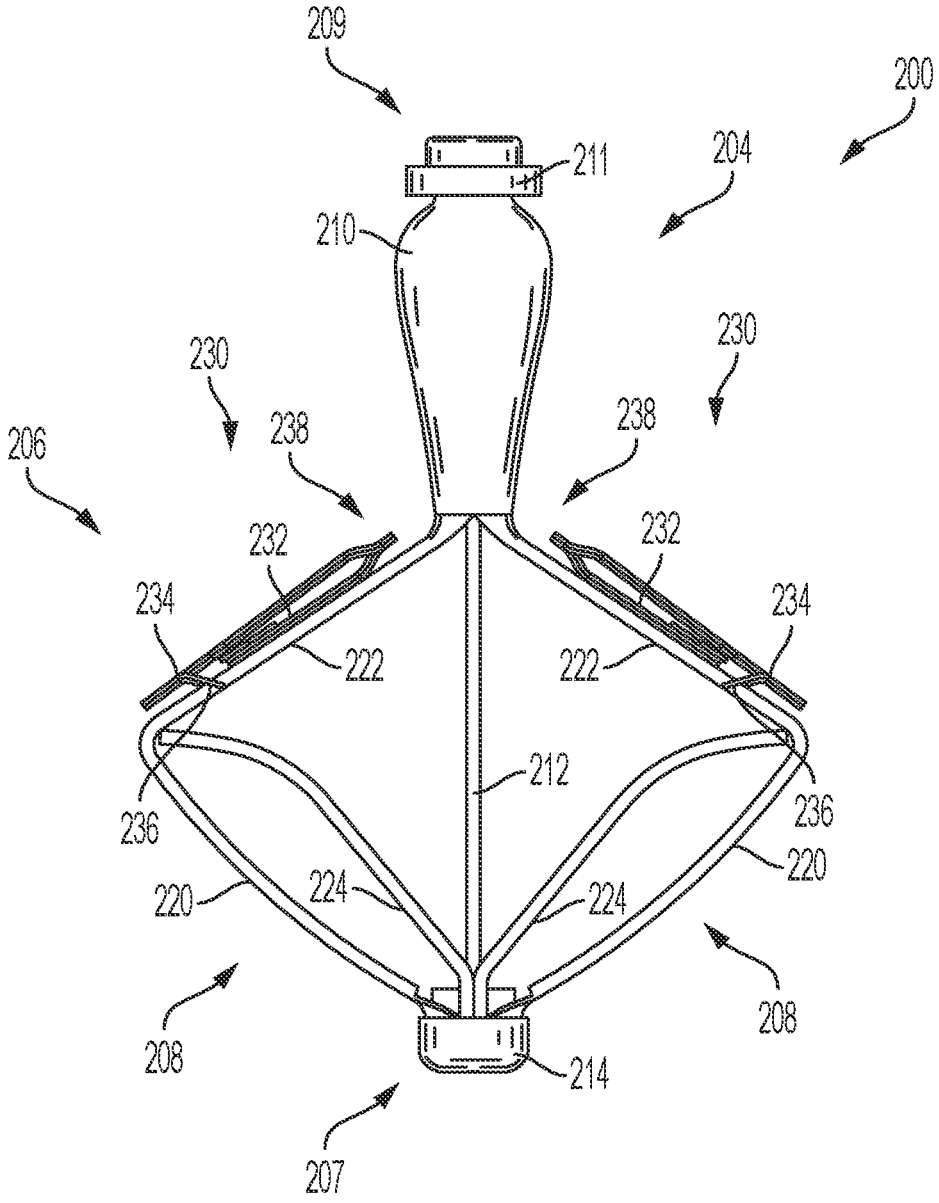

209
200
211
204
210
230
230
238
238
206
232
232
234
234
222
222
212
236
236
220
220
224
224
208
208
214
207

FIG. 34

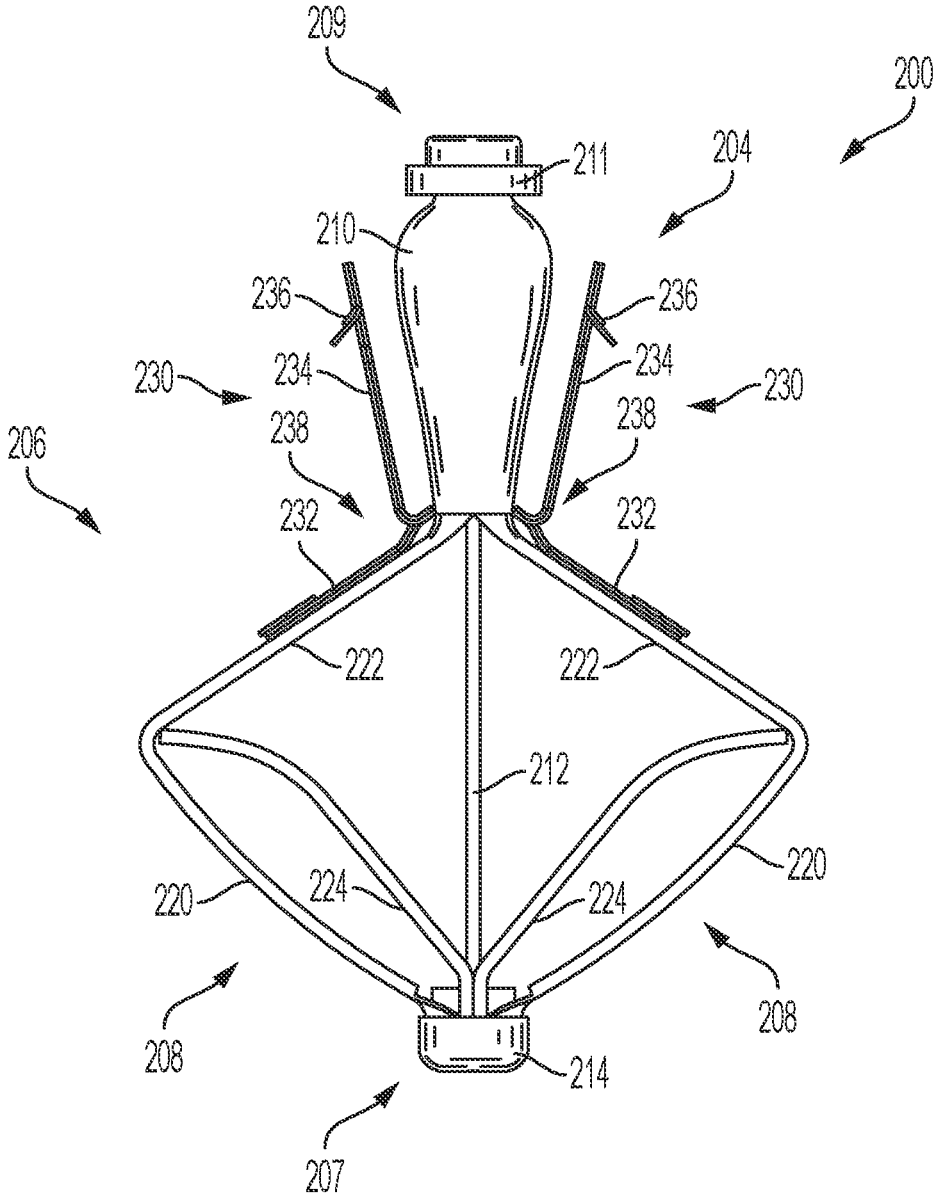

209
200
211
204
210
236
236
230
234
234
230
238
238
206
232
232
222
222
212
220
220
224
224
208
208
214
207

FIG. 35

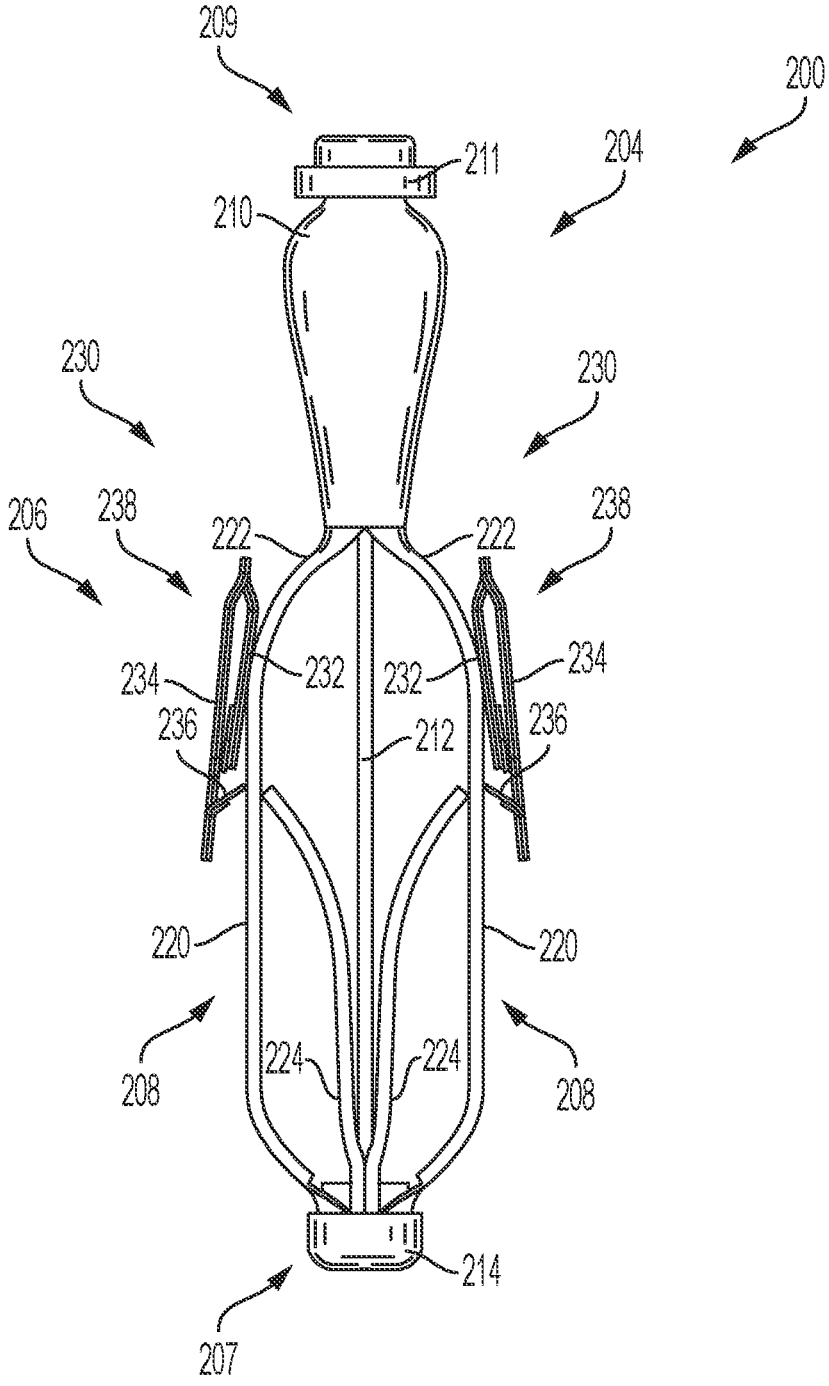

209
200
211
204
210
230
230
206
238
238
222
222
234
232
232
234
236
236
212
220
220
208
224
224
208
214
207

FIG. 36

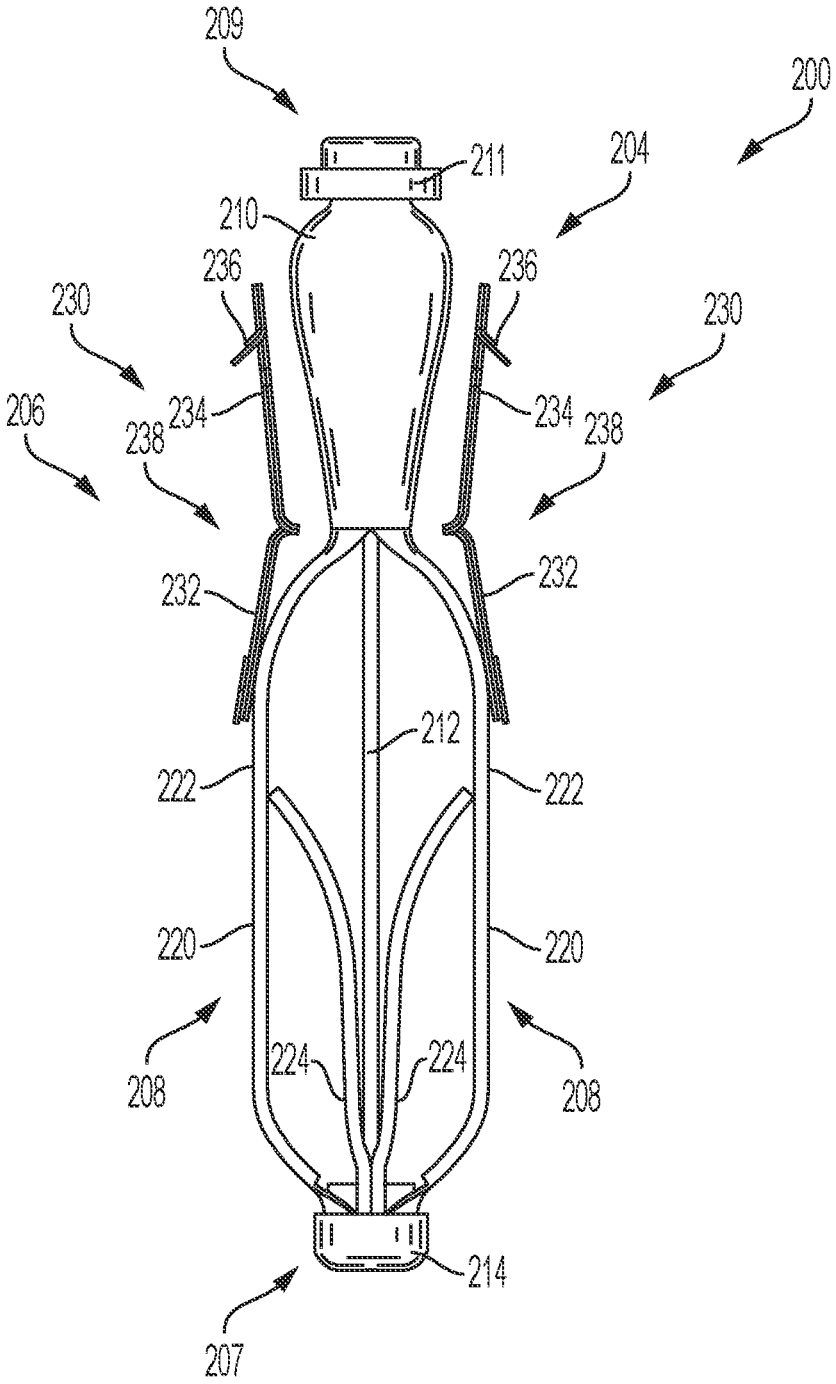

209
200
211
204
210
236
236
230
230
206
234
238
234
238
232
232
212
222
222
220
220
208
224
224
208
214
207

FIG. 37

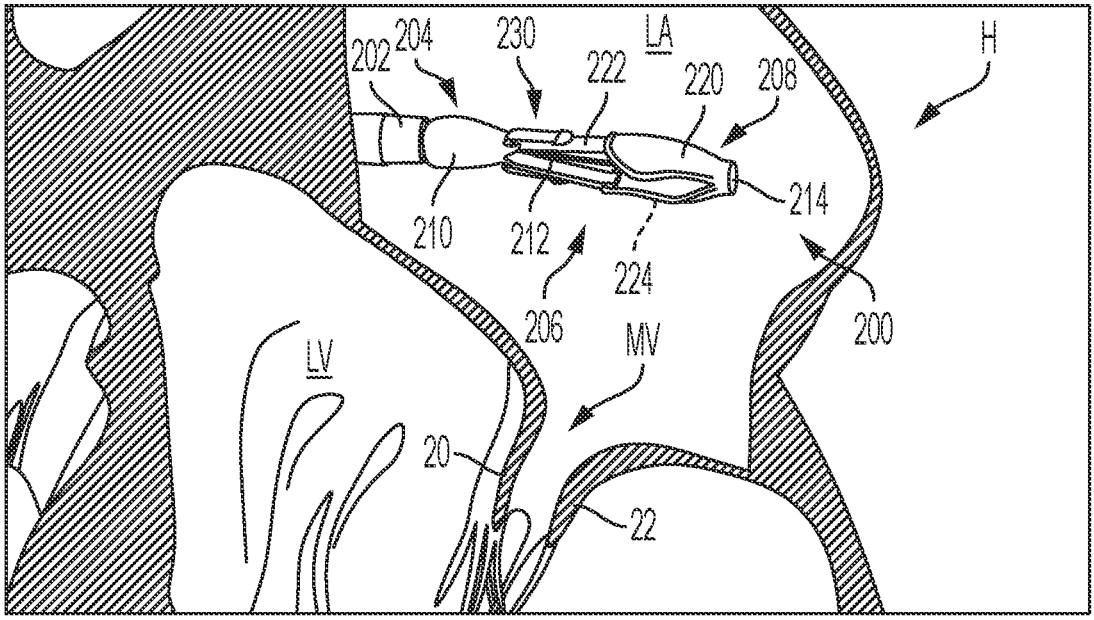

202
204
230
LA
222
220
208
H
214
210
212
224
206
200
MV
LV
20
22

FIG. 38

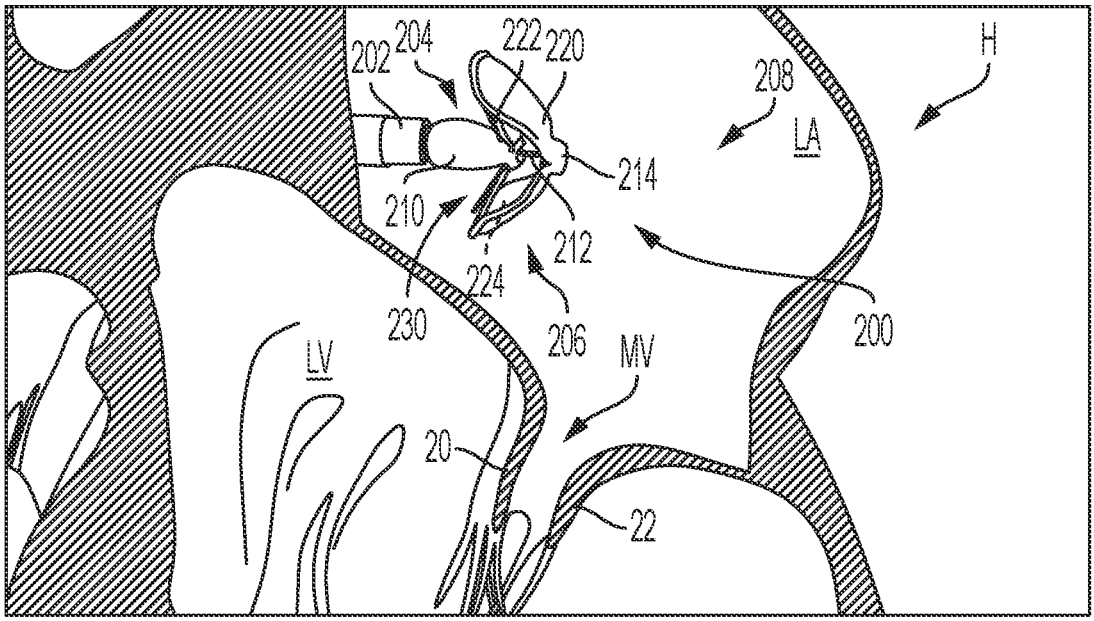

202
204
222
220
H
208
LA
214
210
212
224
230
206
200
MV
LV
20
22

FIG. 39

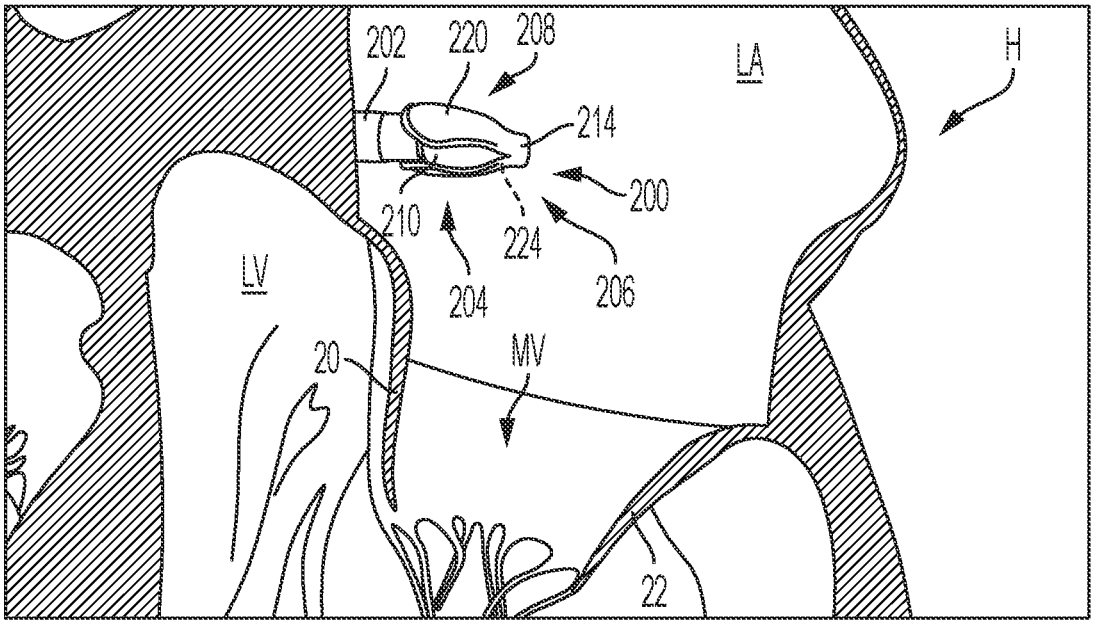

202
220
208
LA
H
214
200
210
224
204
206
LV
20
MV
22

FIG. 40

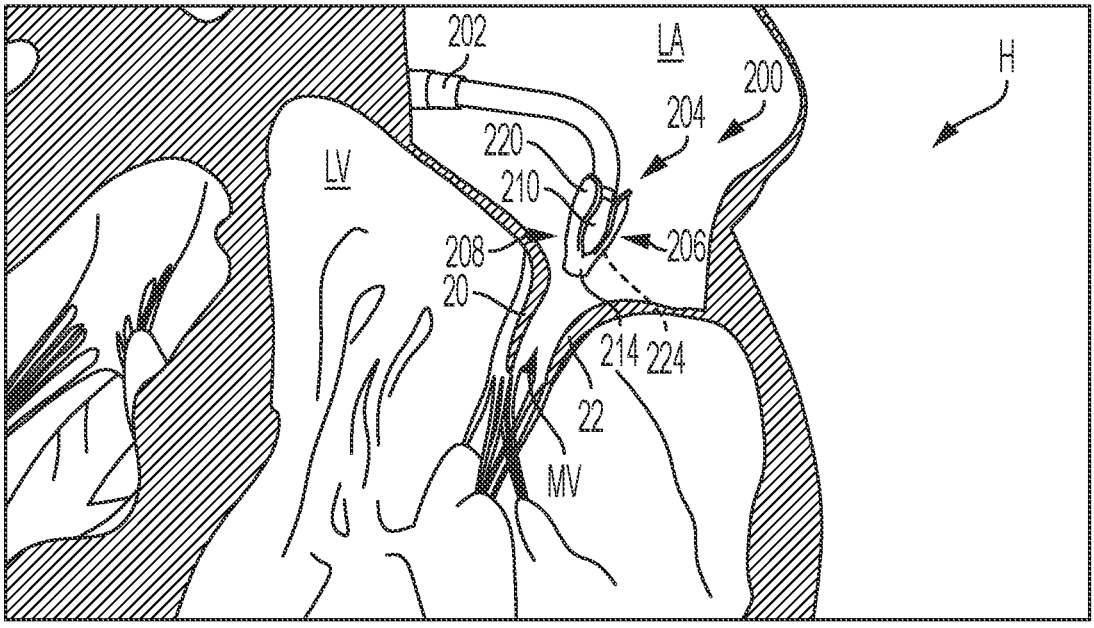

202
LA
200
H
204
220
LV
210
208
206
20
214
224
22
MV

FIG. 41

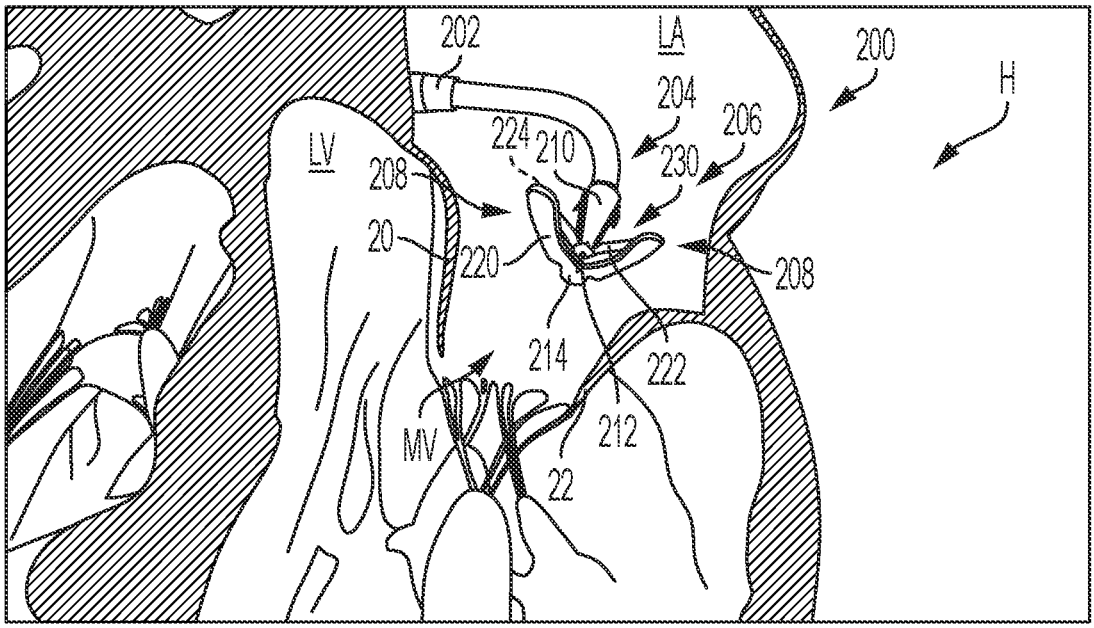

202
LA
200
H
204
206
224
210
LV
208
230
20
220
208
214
222
MV
212
22

FIG. 42

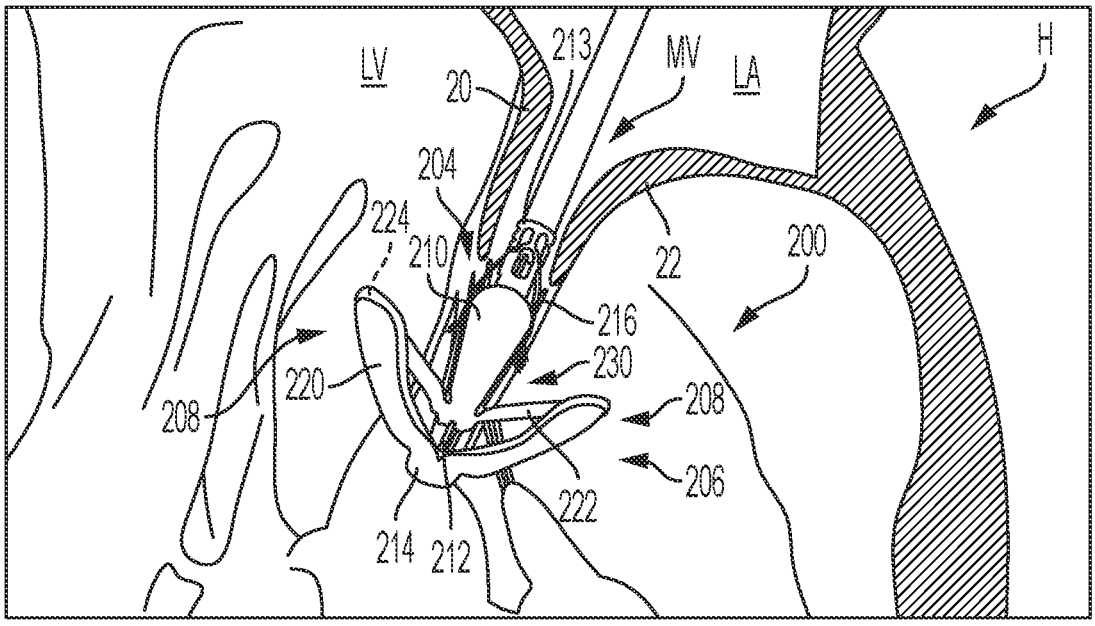

213
LV
MV
LA
H
20
204
224
210
22
200
216
230
220
208
208
206
222
214
212

FIG. 43

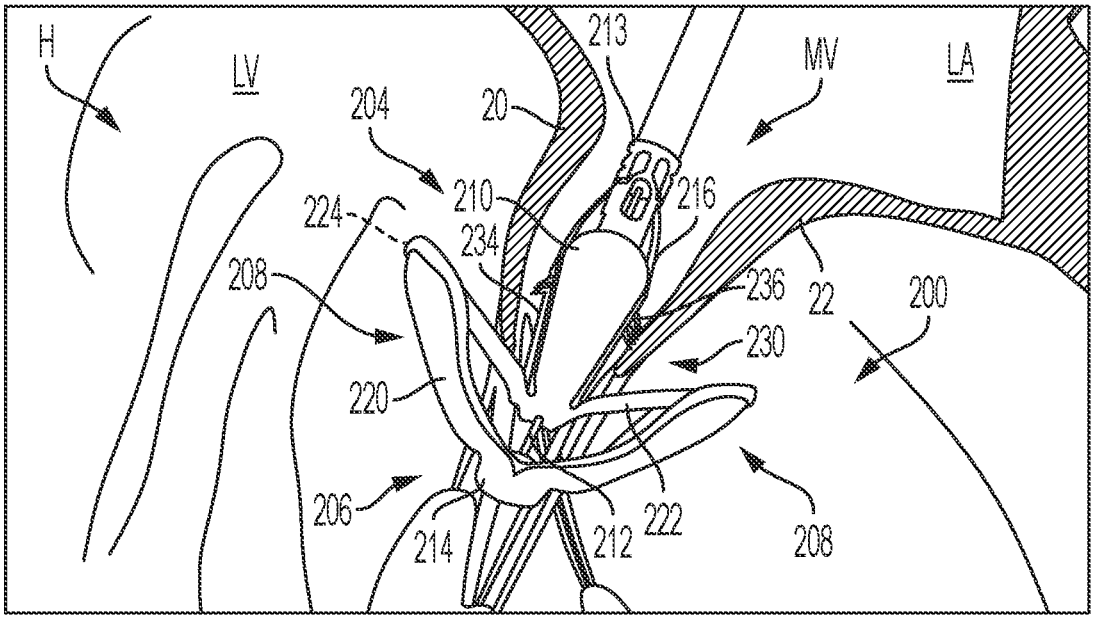

H
LV
213
MV
LA
204
20
210
216
224
234
208
236
22
200
230
220
206
214
212
222
208

FIG. 44

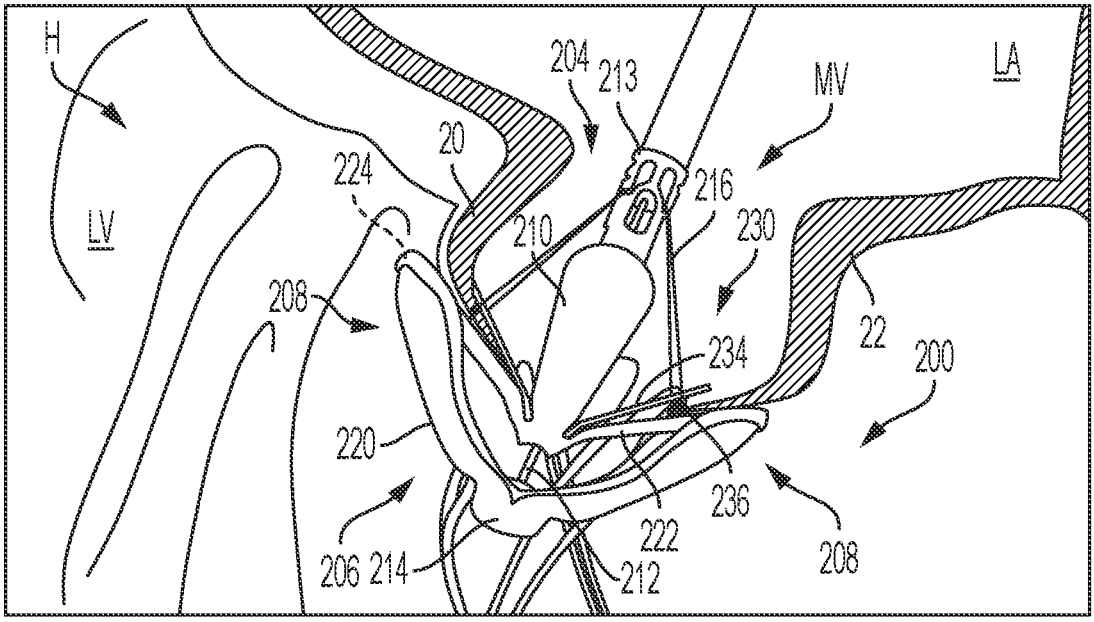

H
204
213
MV
LA
20
224
216
LV
210
230
208
22
234
200
220
236
222
206
214
212
208

FIG. 45

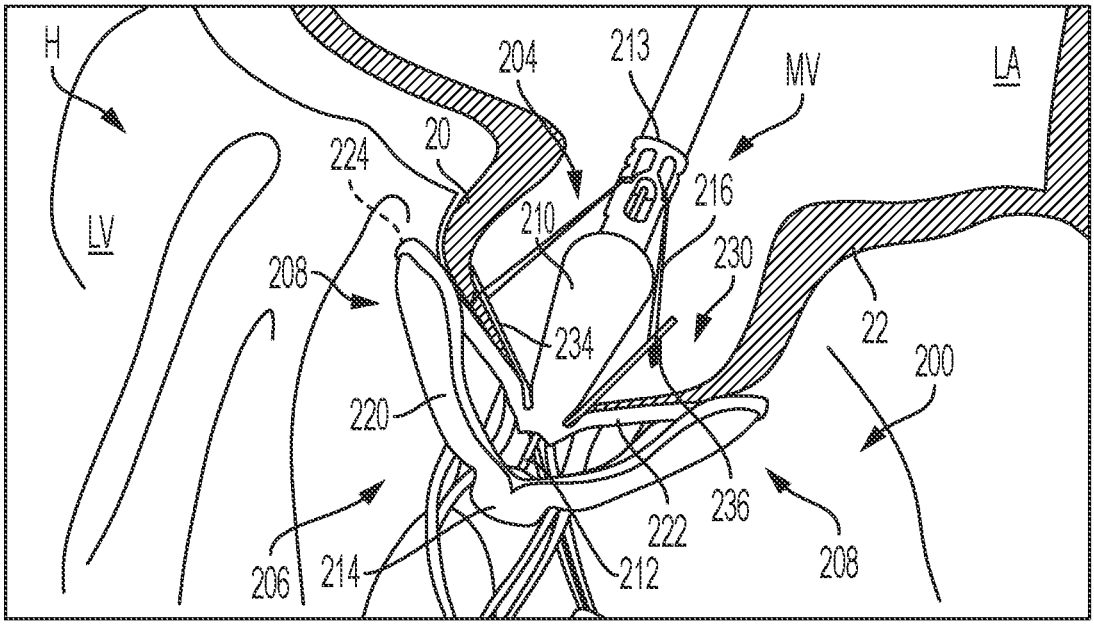

H
204
213
MV
LA
20
224
216
LV
210
230
208
22
234
200
220
236
222
206
214
212
208

FIG. 46

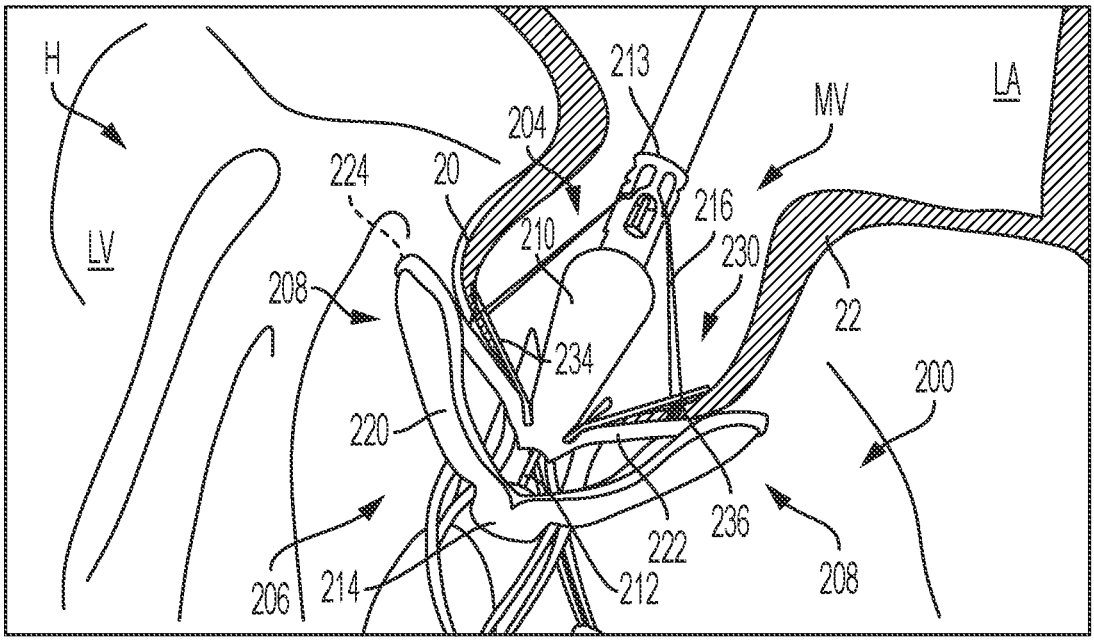

H
213
LA
MV
204
224
20
216
LV
210
230
208
22
234
200
220
236
222
206
214
212
208

FIG. 47

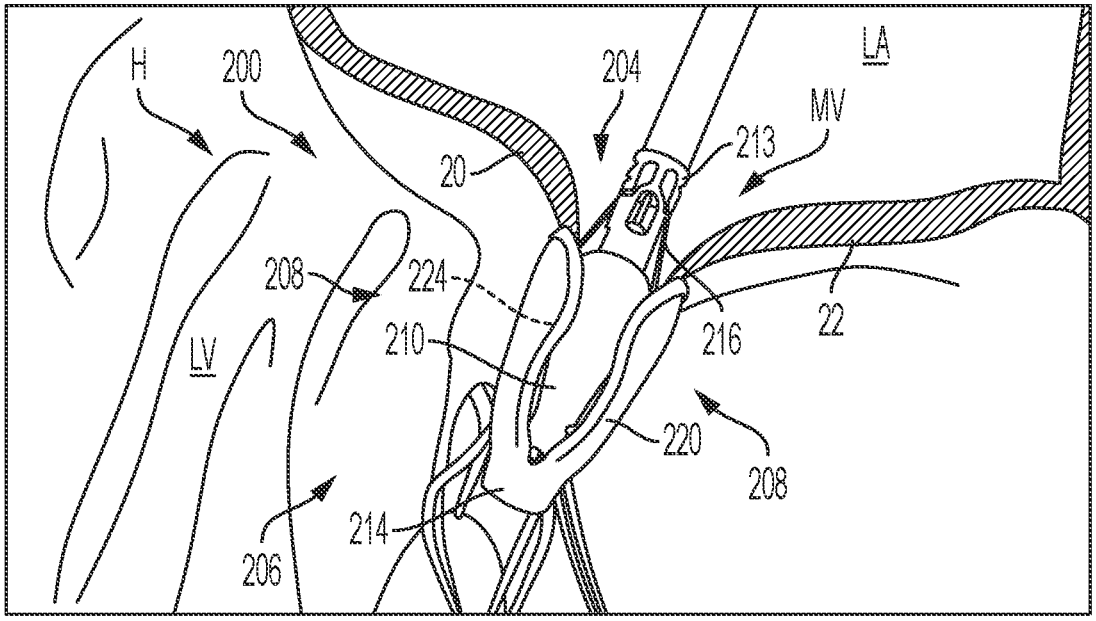

H
200
204
LA
MV
213
20
208
224
210
216
22
LV
220
208
214
206

FIG. 48

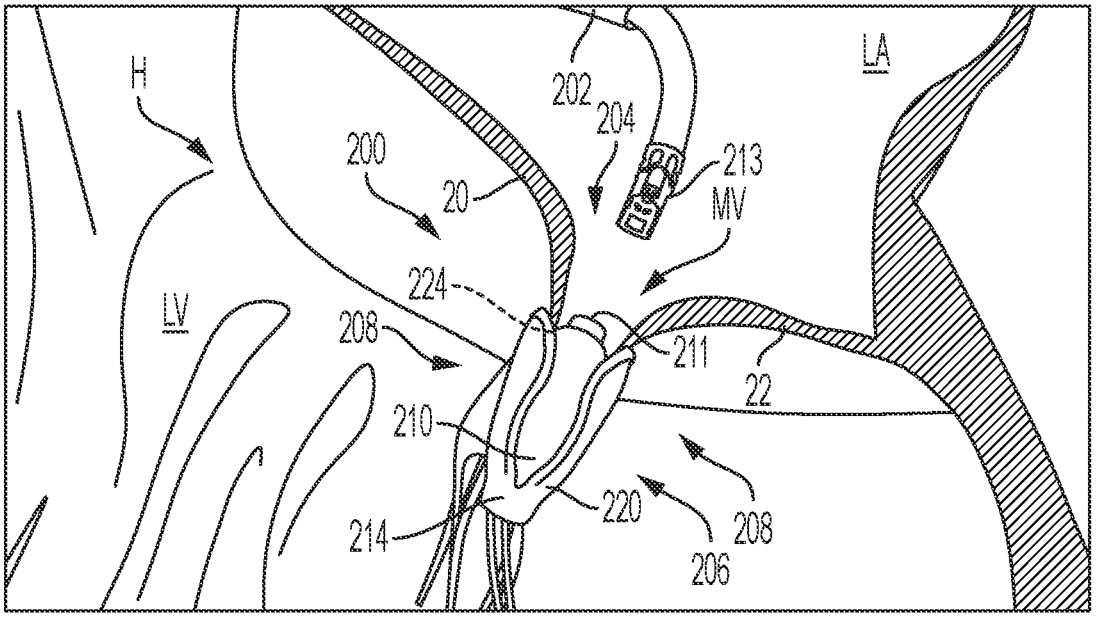

H
202
204
LA
200
213
20
MV
224
LV
208
211
22
210
220
208
214
206

FIG. 49

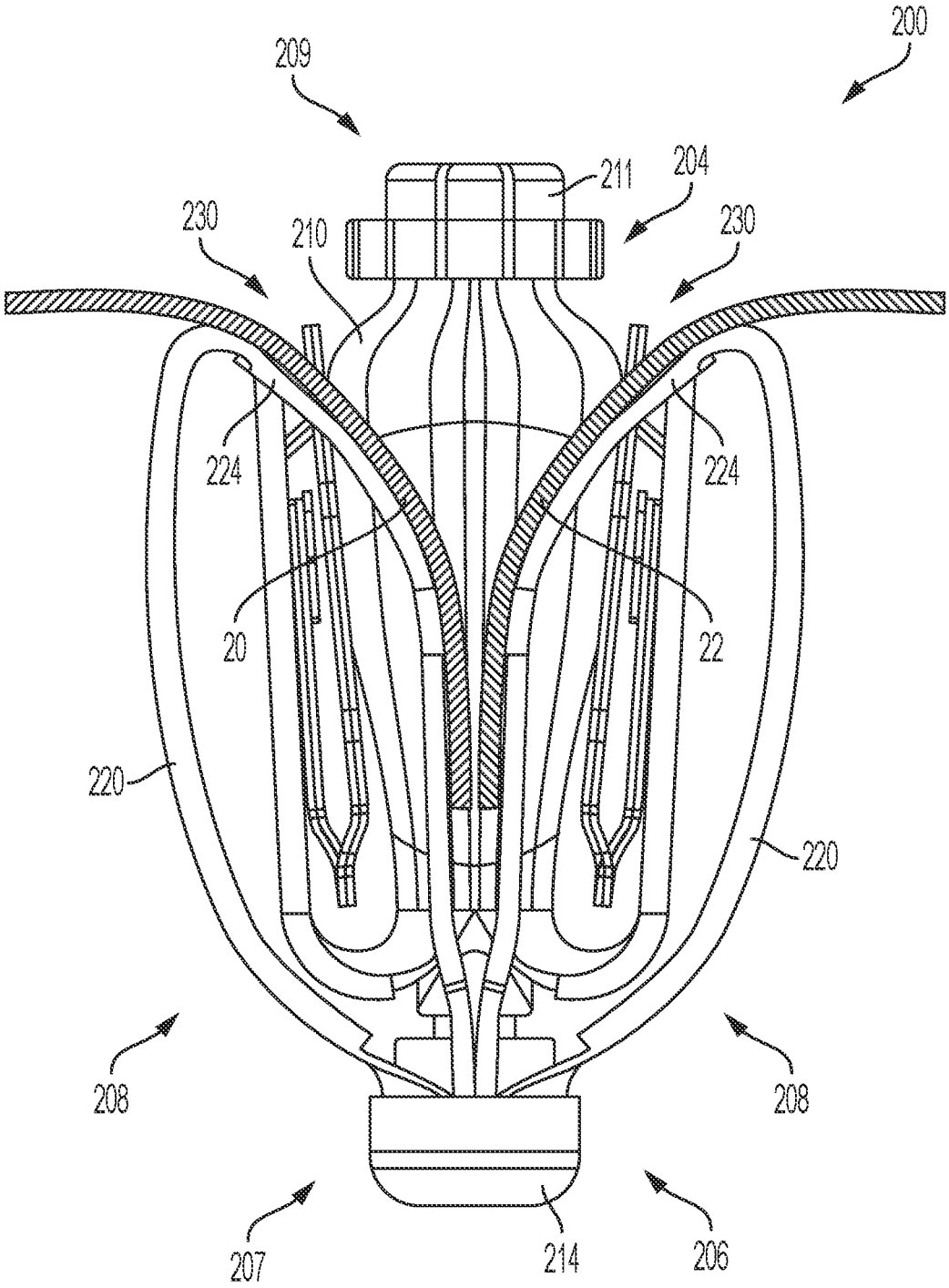

200
209
211
204
230
210
230
224
224
20
22
220
220
208
208
207
214
206

FIG. 50

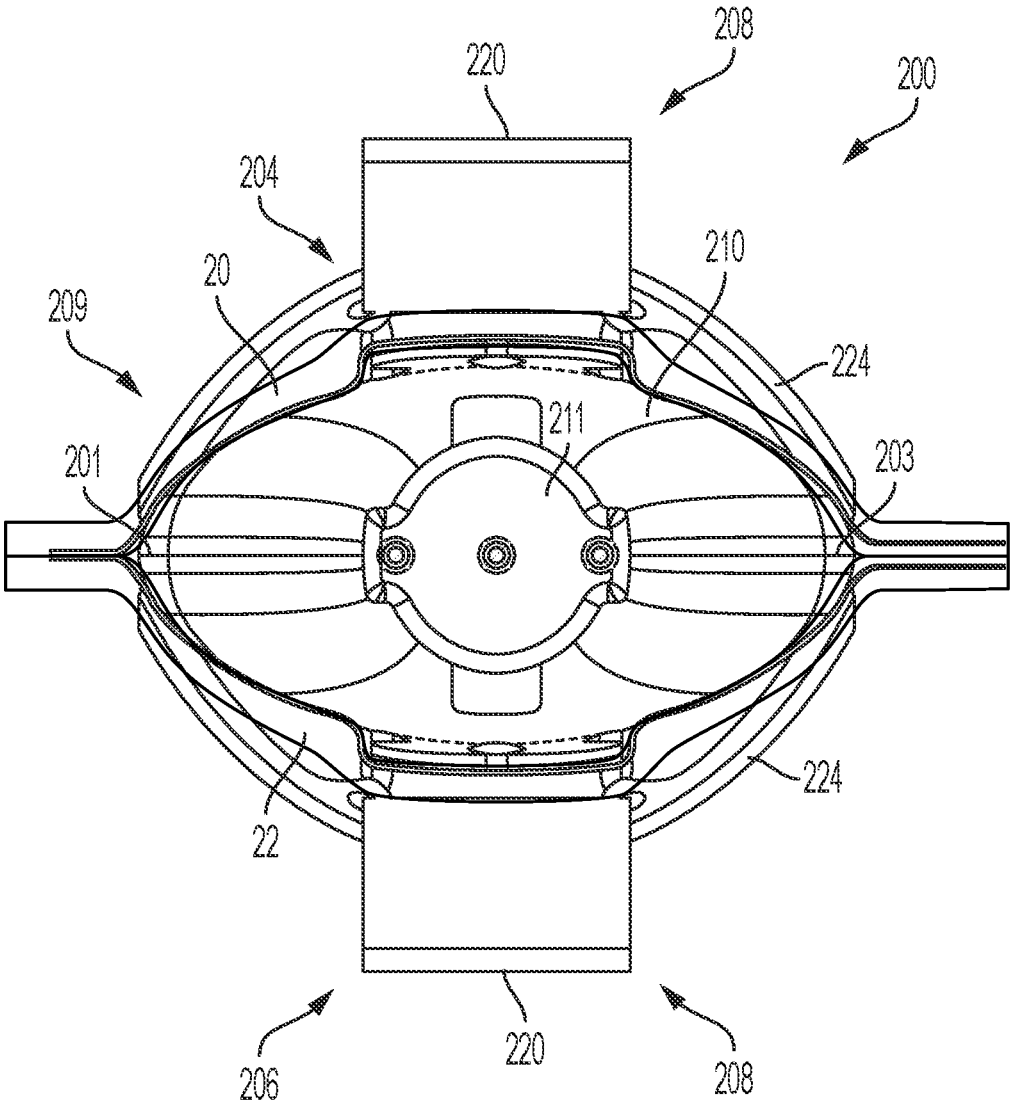


FIG. 51

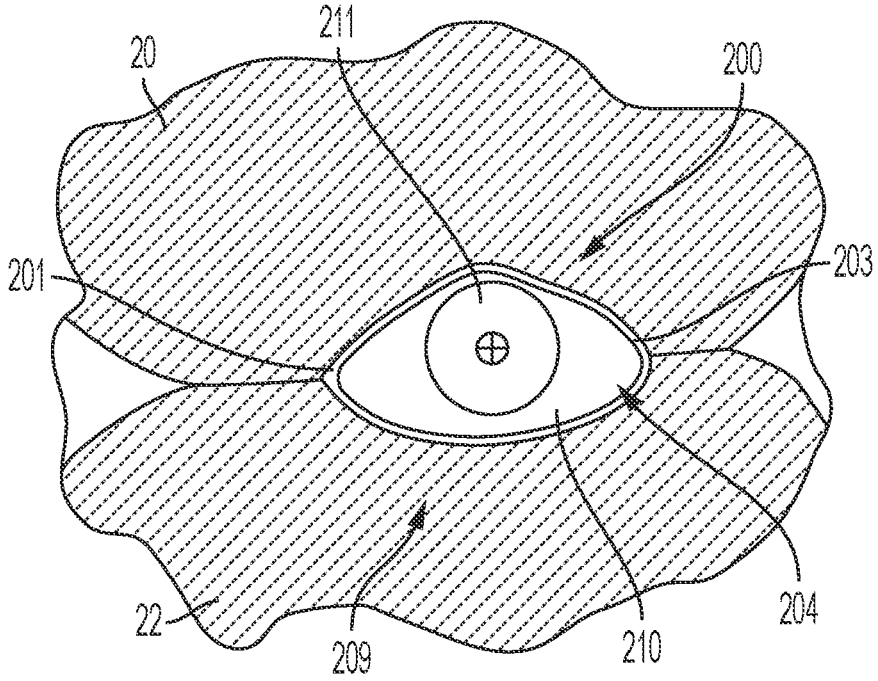

211
20
200
201
203
22
209
210
204

FIG. 52

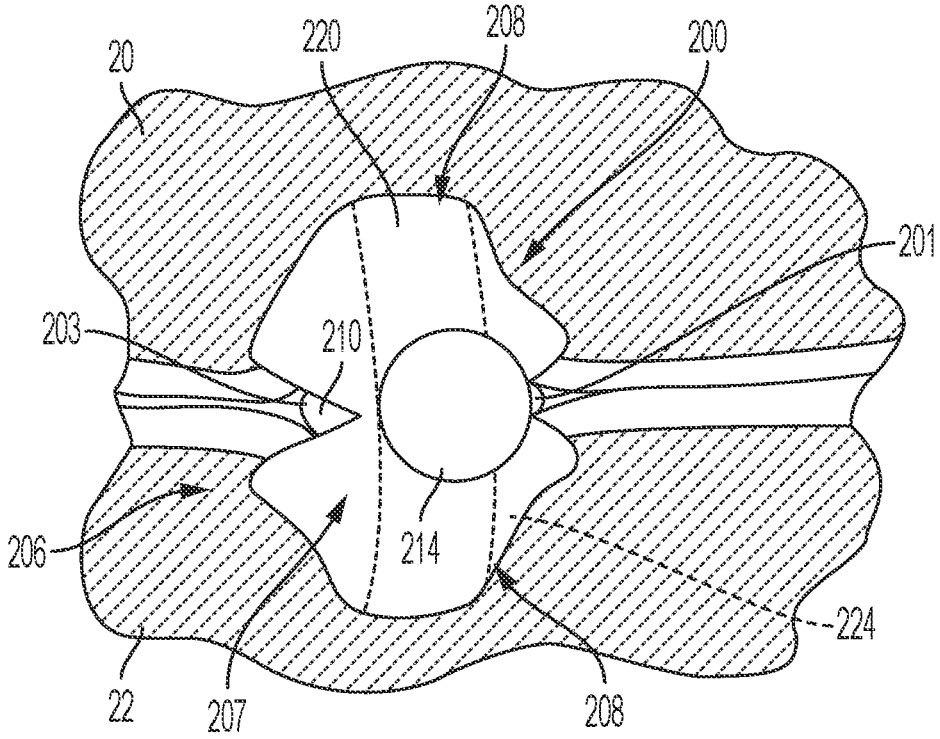

220
208
20
200
201
203
210
214
206
224
22
207
208

FIG. 53

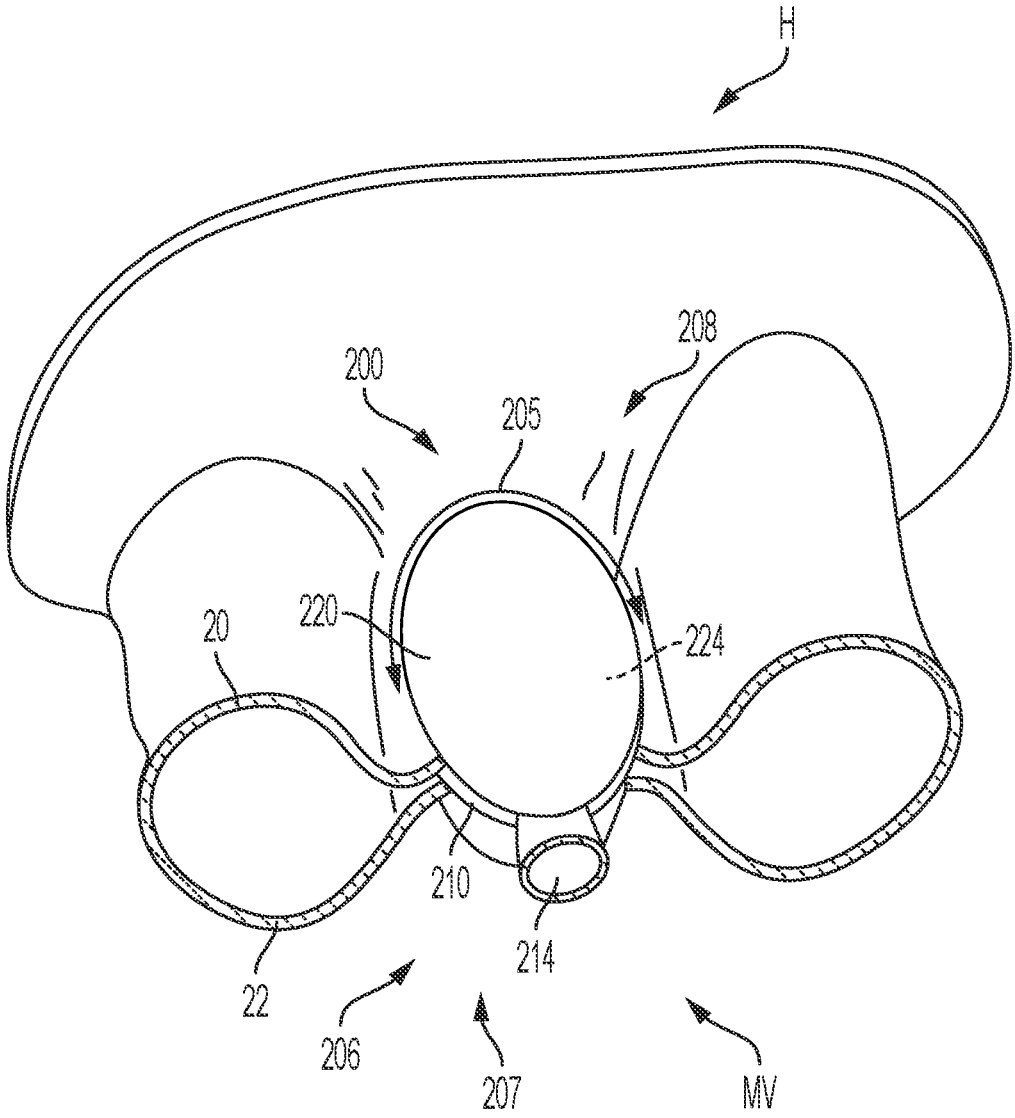


FIG. 54

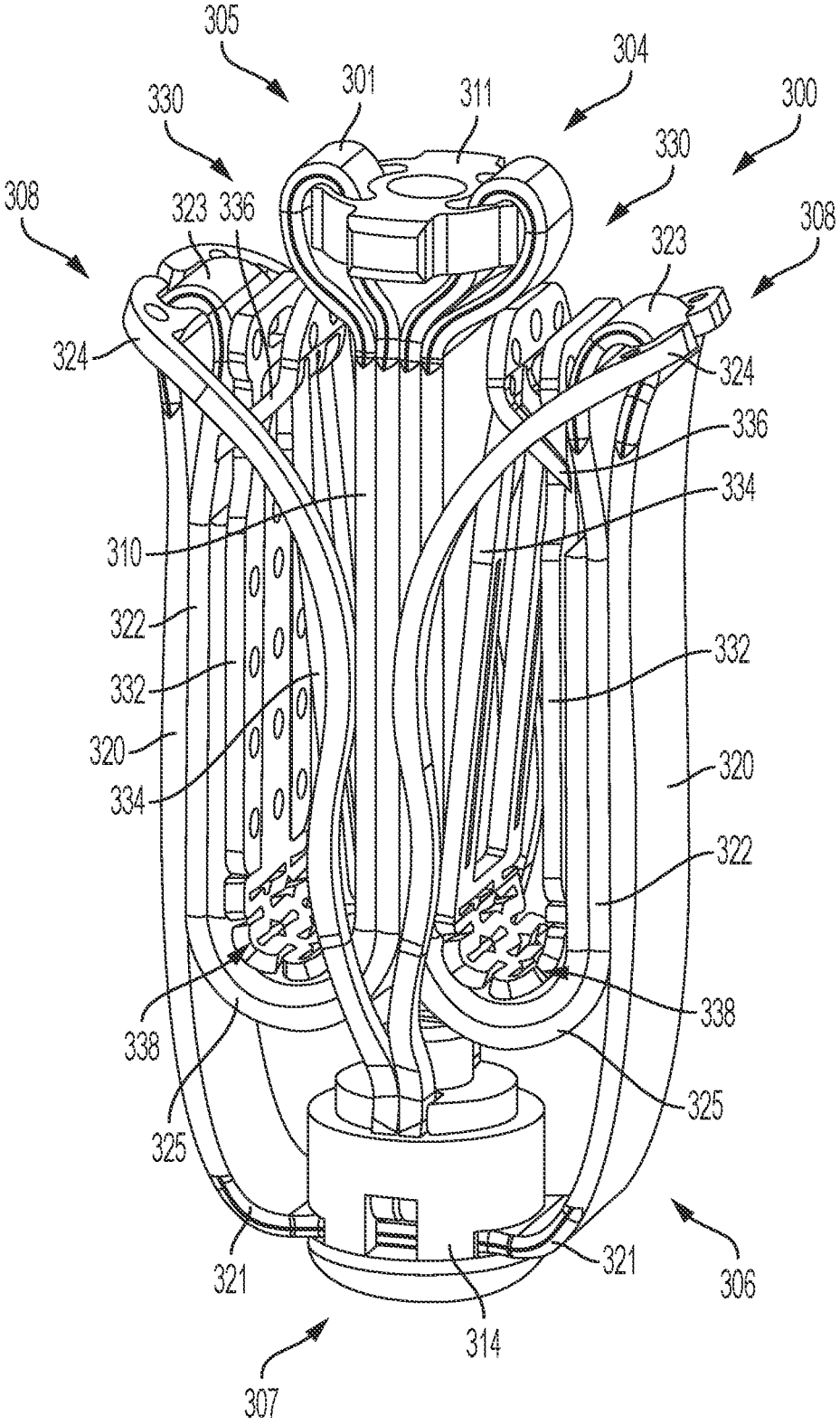

305
301
311
304
330
300
330
308
323
336
323
308
324
324
336
334
310
322
332
332
320
320
334
338
338
325
325
321
321
306
314
307

FIG. 55

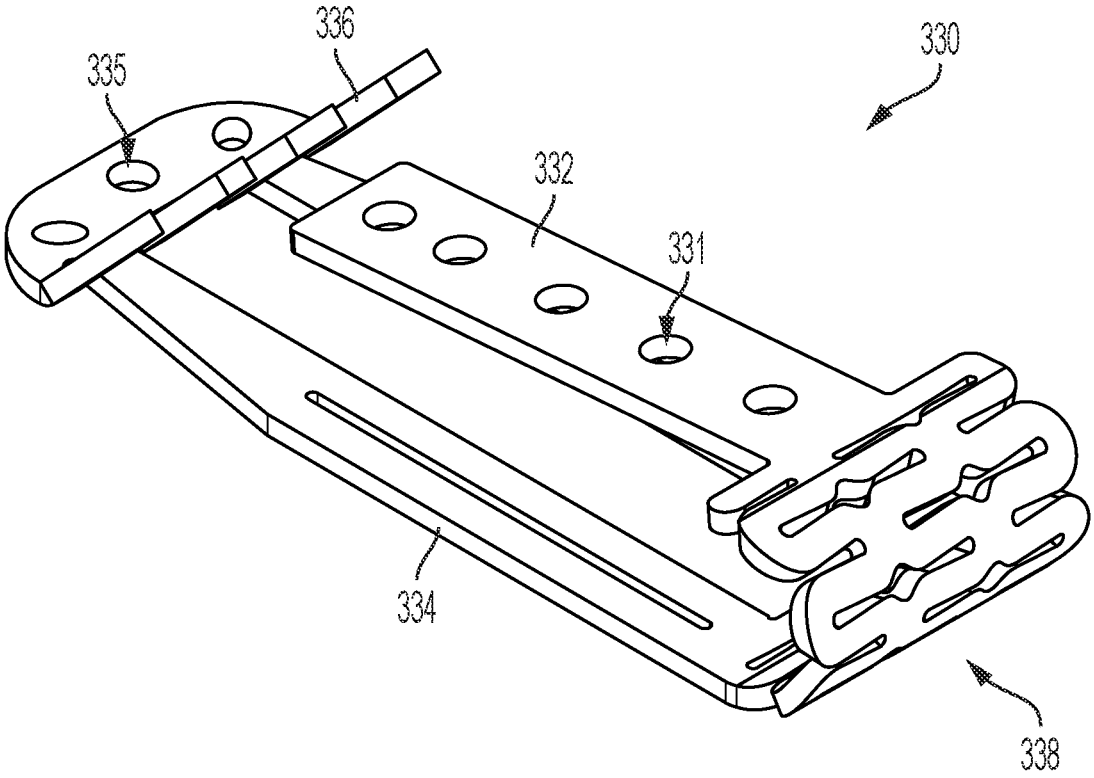


FIG. 56

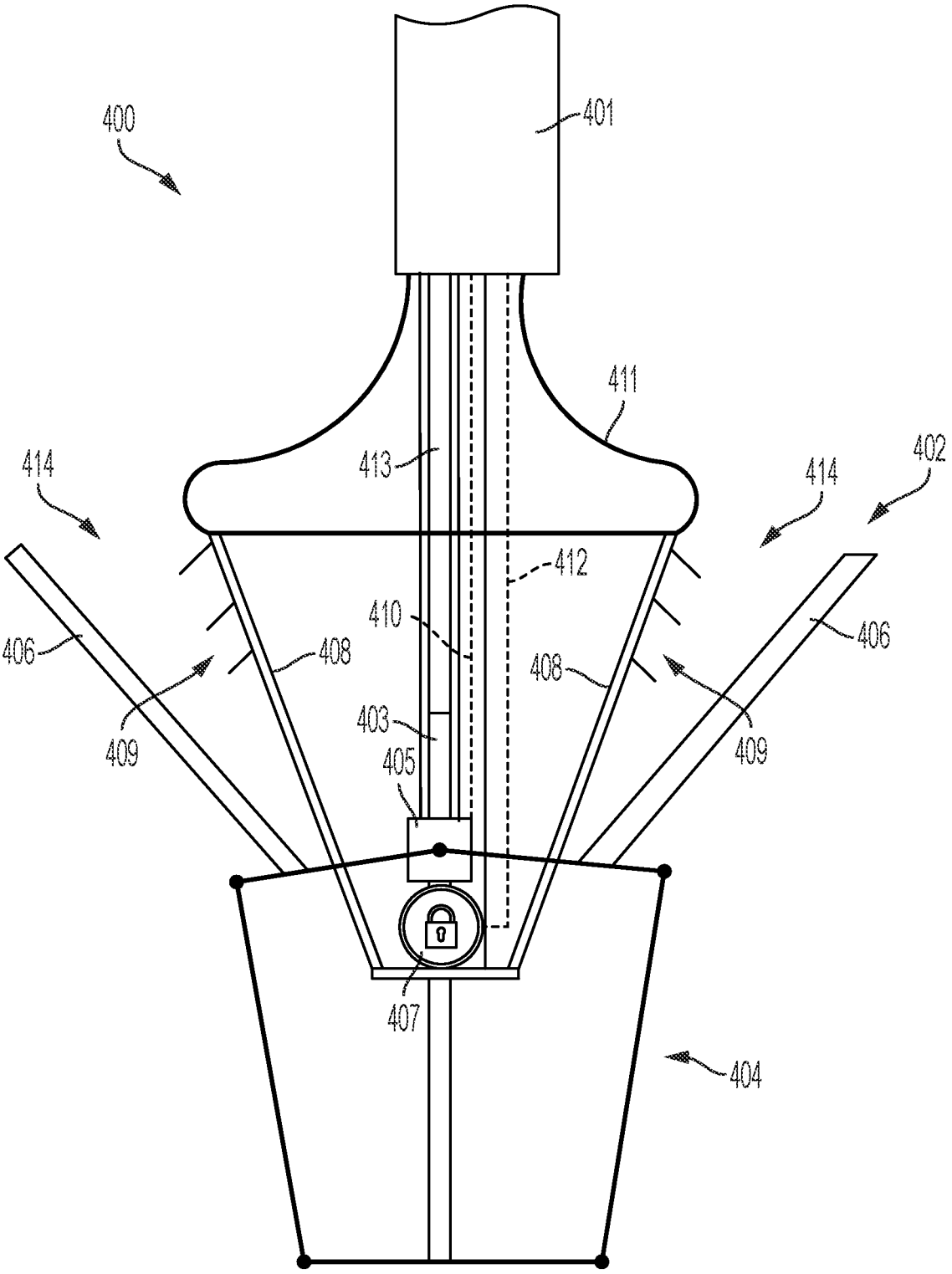

400
401
411
413
414
414
402
412
410
406
408
408
406
403
409
405
409
407
404

FIG. 57

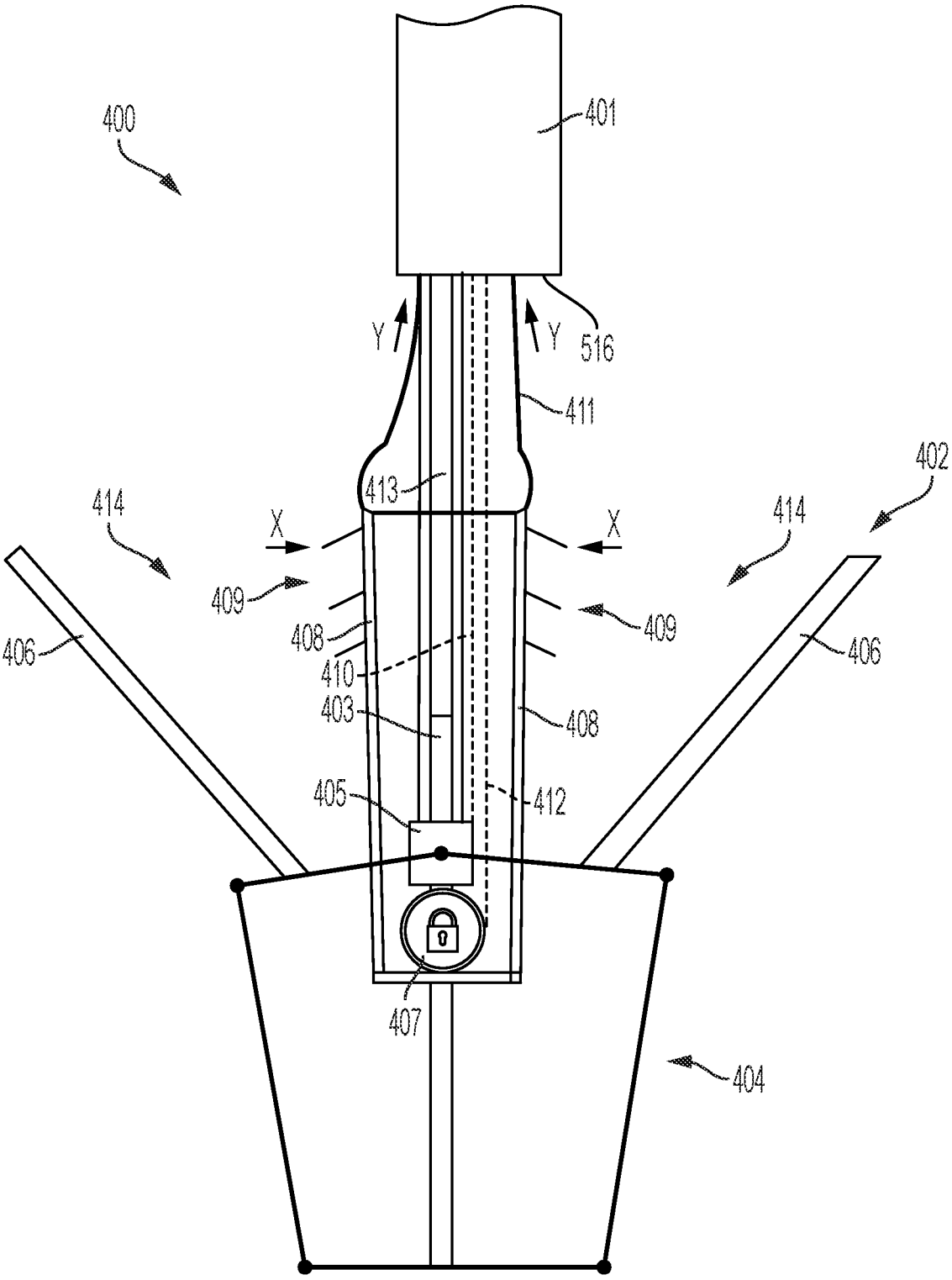

400
401
516
Y
Y
411
413
402
414
414
X
X
409
409
408
406
406
410
403
408
405
412
407
404

FIG. 58

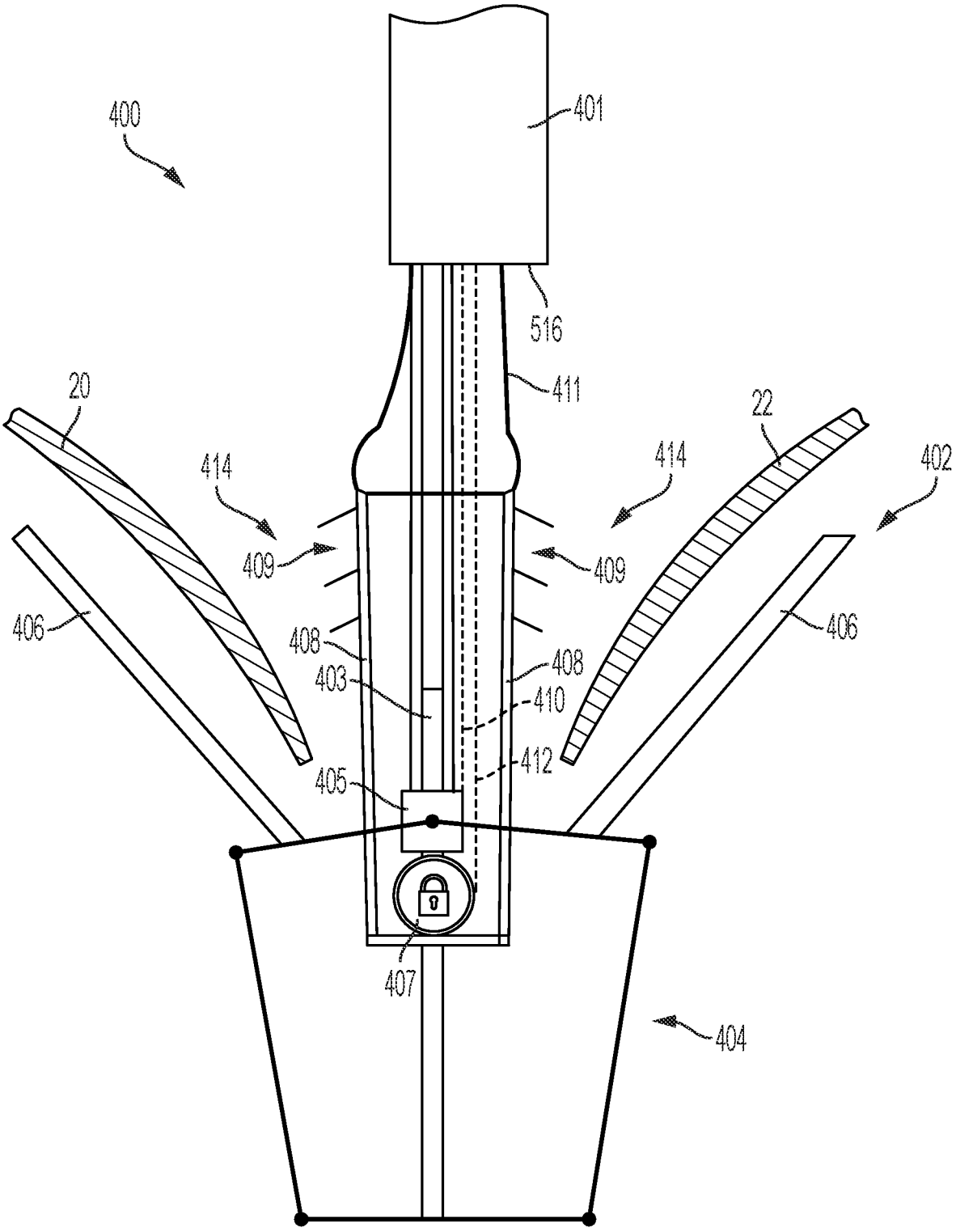

400
401
516
411
20
22
414
414
402
409
409
406
406
408
408
403
410
412
405
407
404

FIG. 59

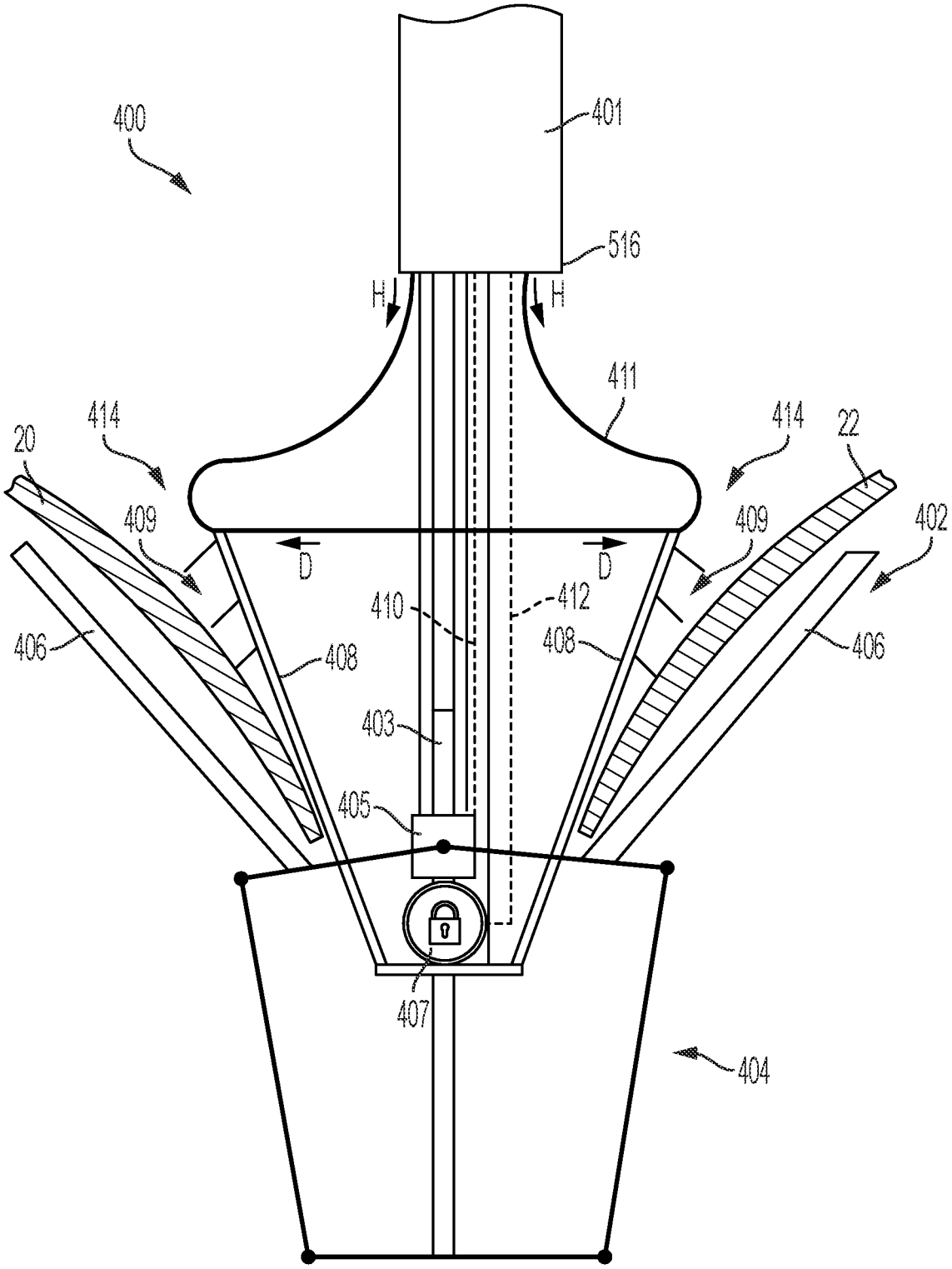

400
401
516
H
H
411
414
414
20
22
409
409
402
D
D
410
412
406
408
408
406
403
405
407
404

FIG. 60

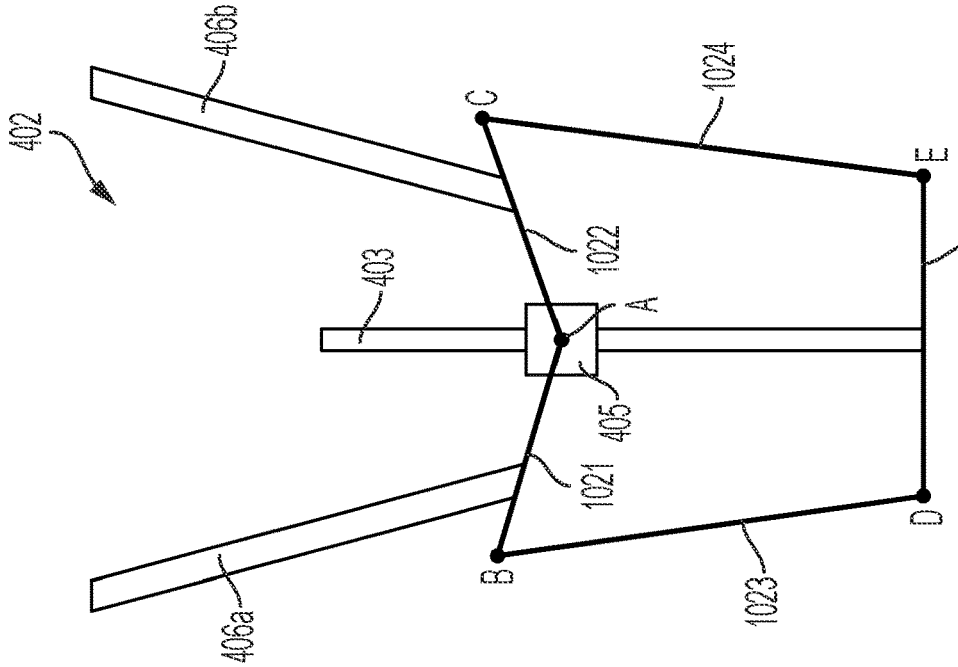


FIG. 61B

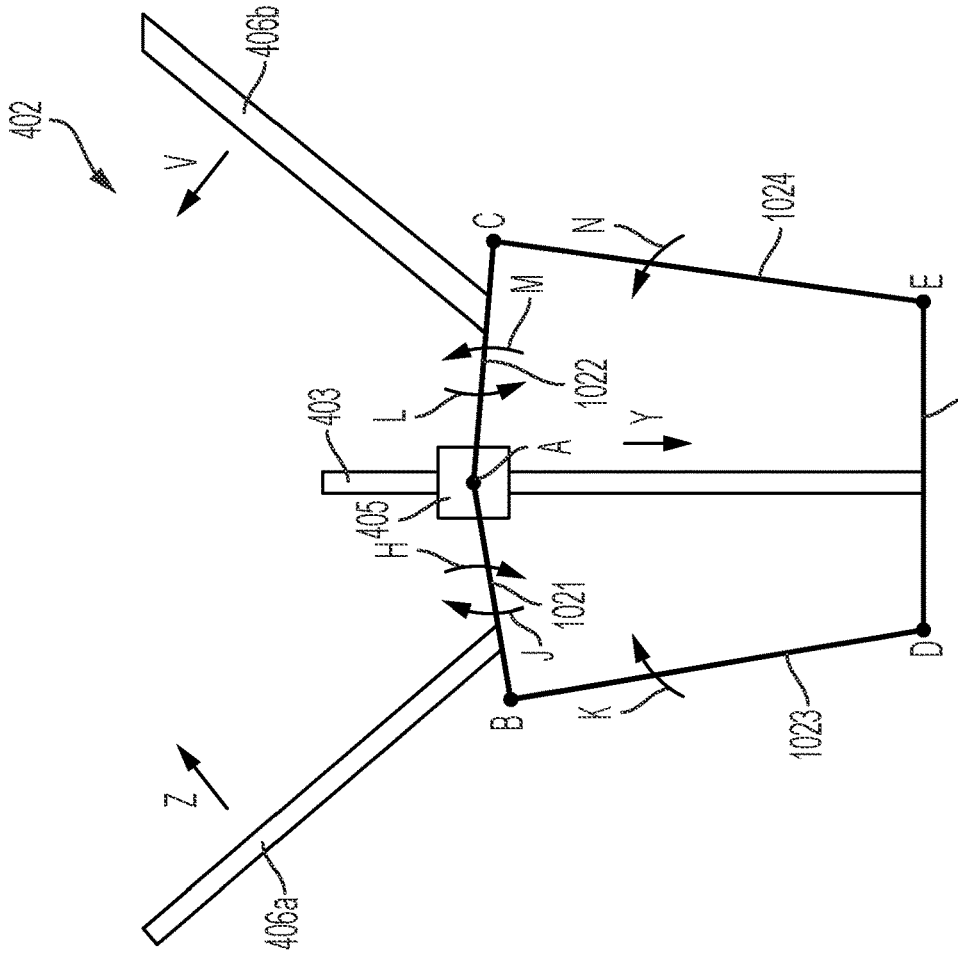


FIG. 61A

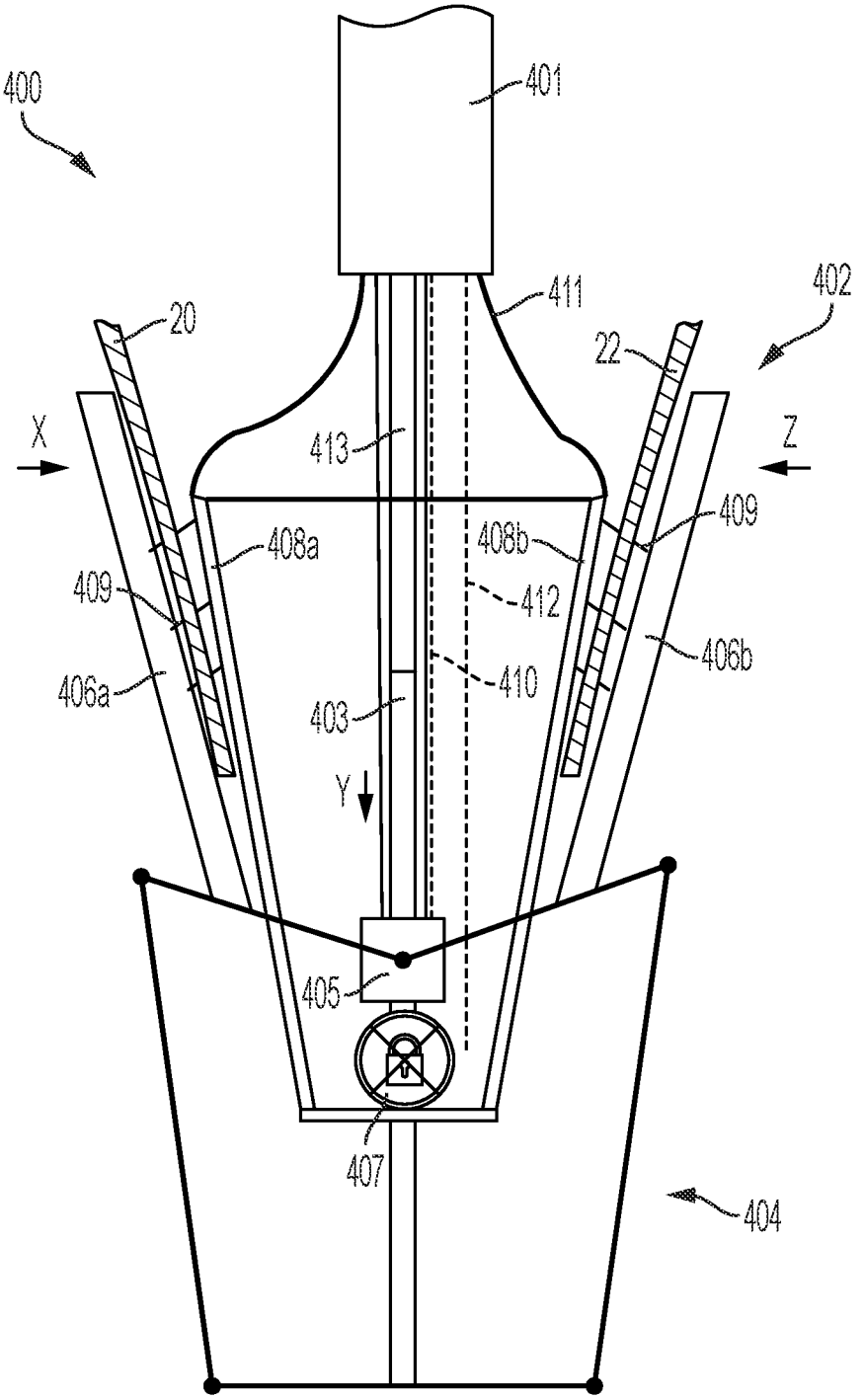

400
401
411
402
20
22
X
Z
413
409
408a
408b
409
412
406b
406a
410
403
Y
405
407
404

FIG. 62

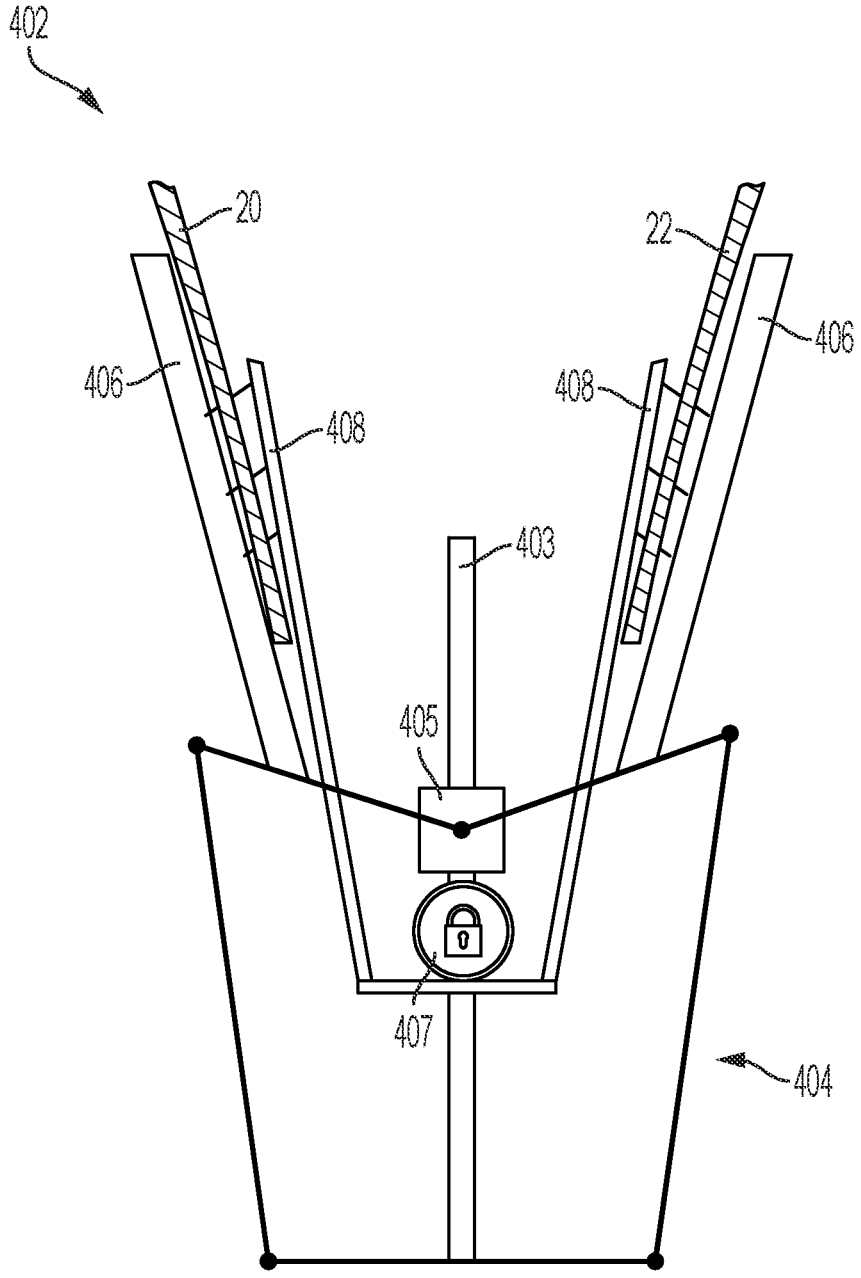


FIG. 63

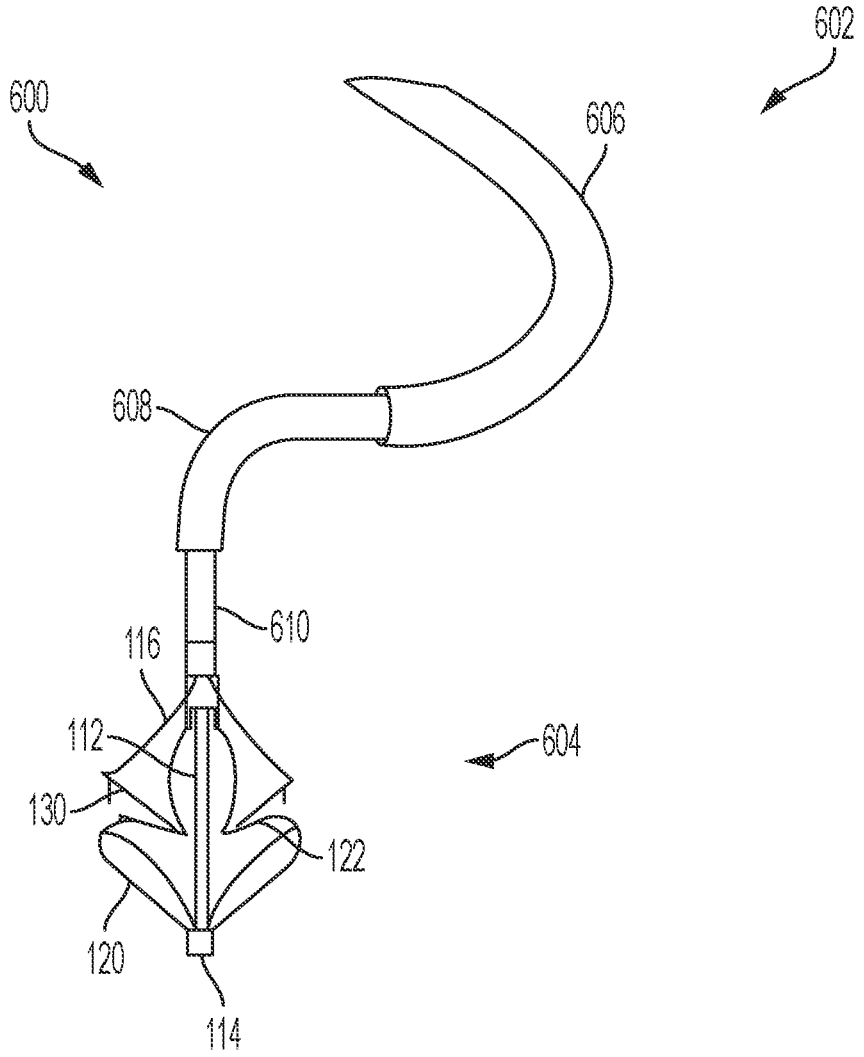


FIG. 64

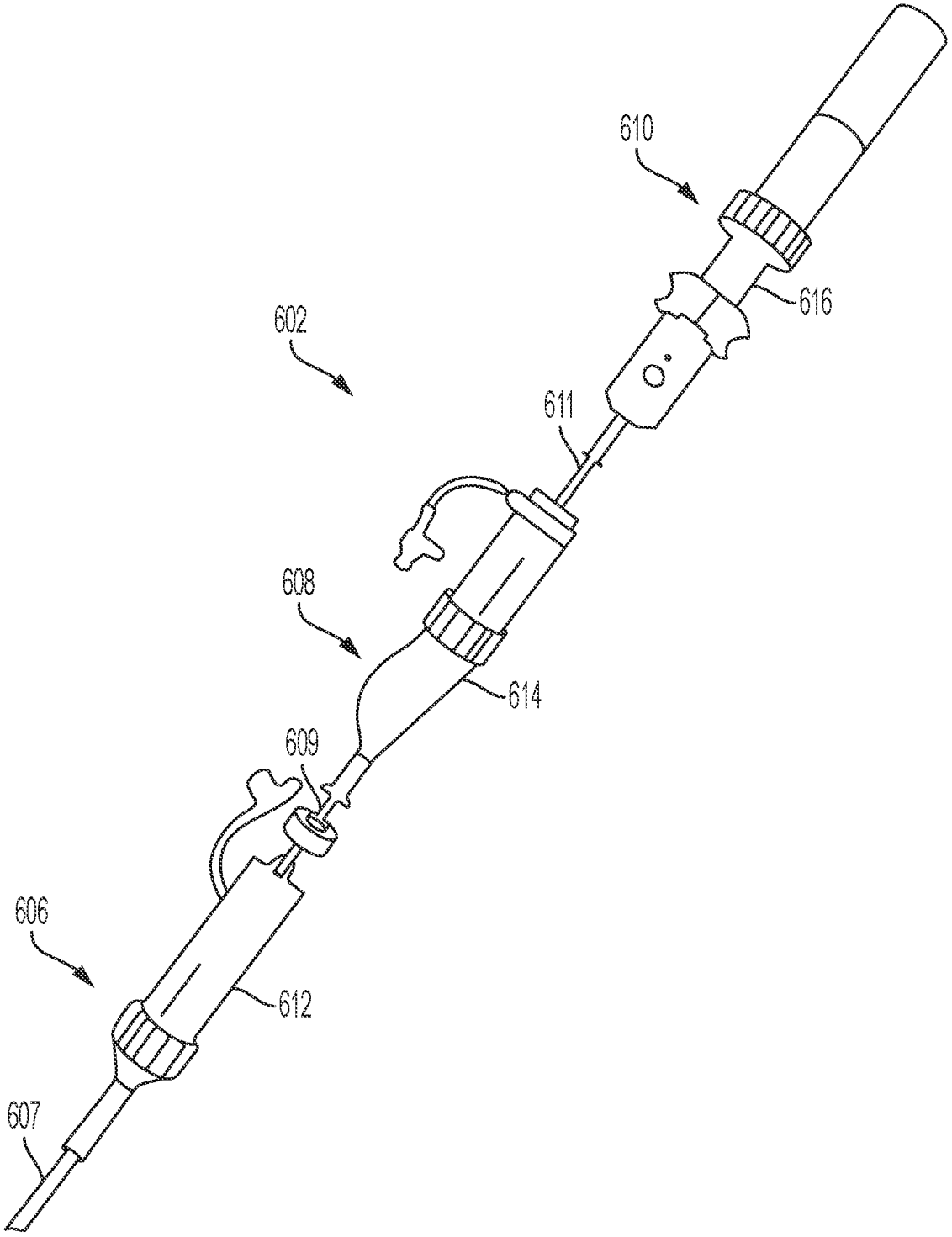


FIG. 65

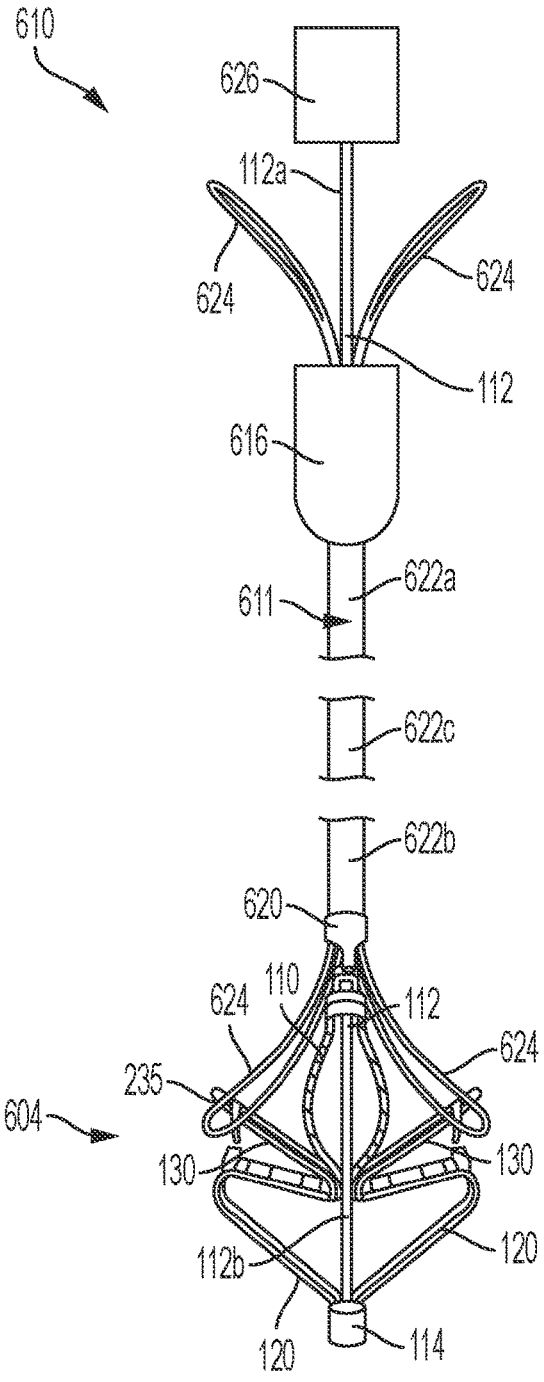

610
626
112a
624
624
112
616
611
622a
622c
622b
620
624
110
112
624
235
604
130
130
112b
120
120
114

FIG. 66

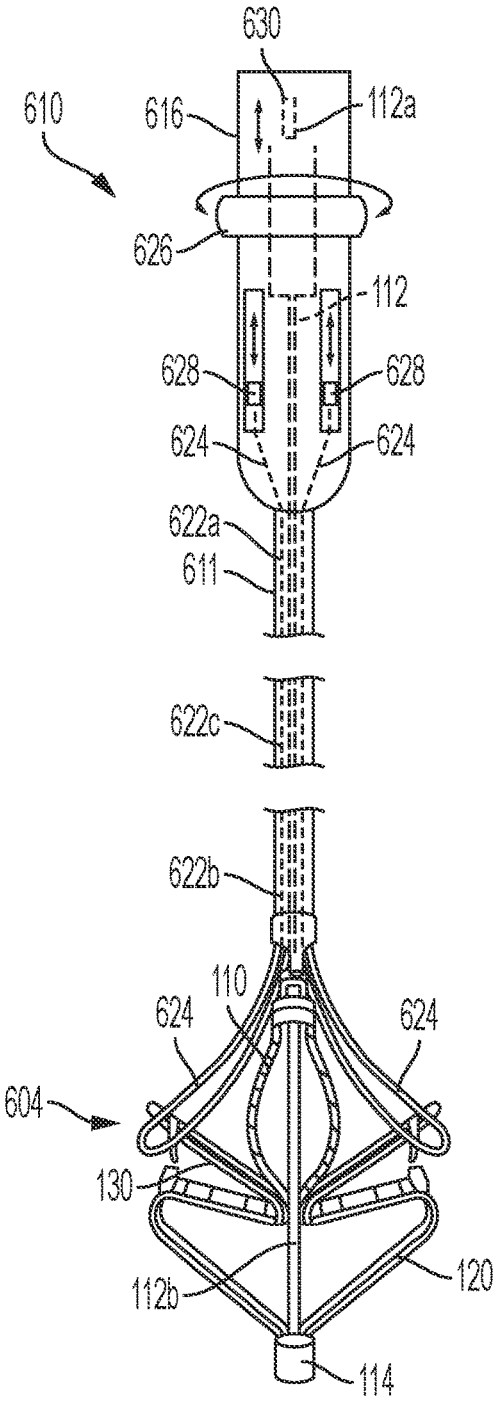

630
610
616
112a
626
112
628
628
624
624
622a
611
622c
622b
110
624
624
604
130
120
112b
114

FIG. 67

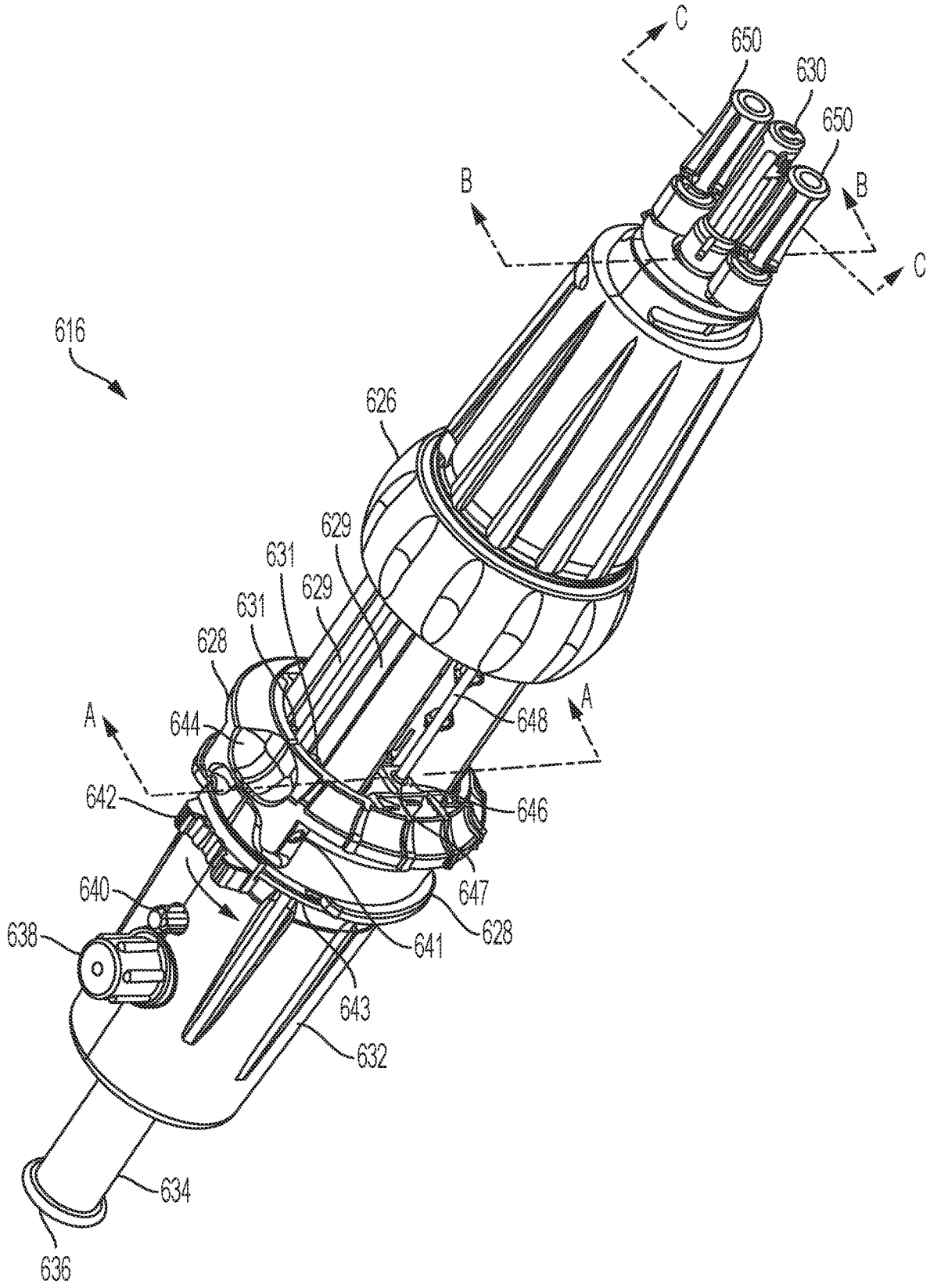

C
650
630
650
B
B
C
616
626
629
631
629
631
628
A
644
A
648
642
646
640
647
638
628
641
643
632
634
636

FIG. 68

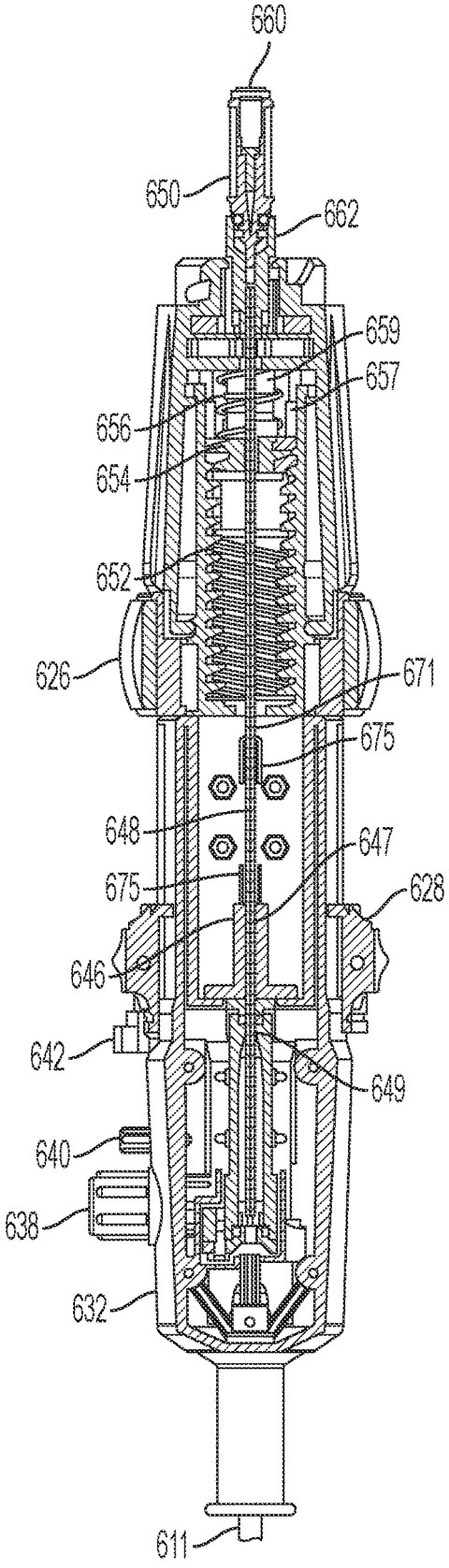

660
650
662
659
657
656
654
652
626
671
675
648
647
675
628
646
642
649
640
638
632
611

FIG. 69

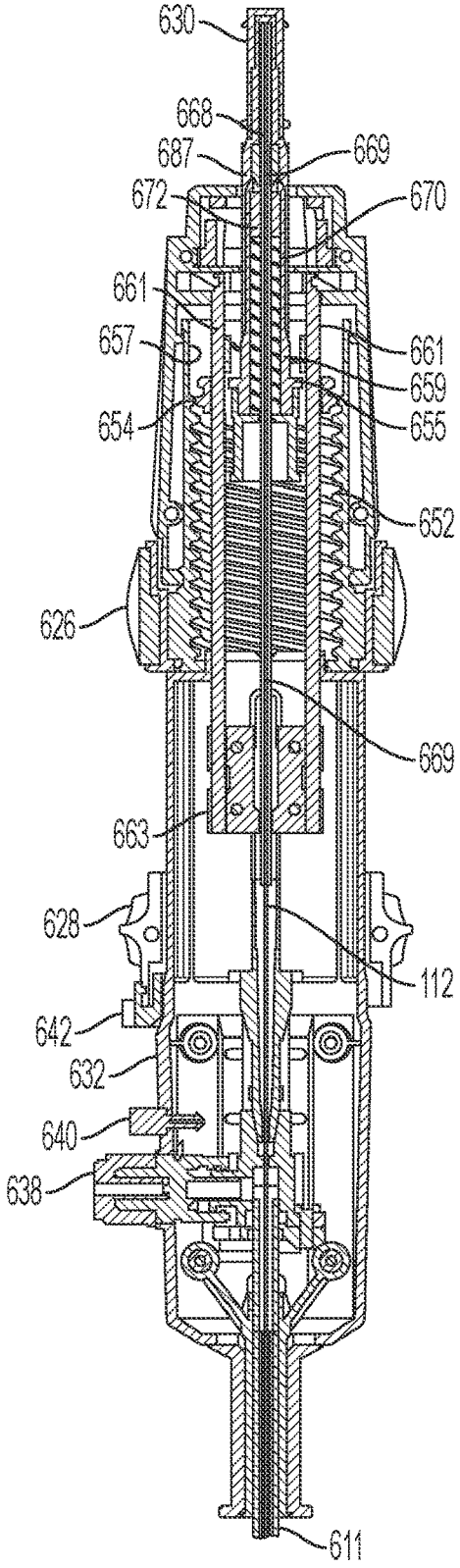

630
668
687
669
672
670
661
657
661
659
654
655
652
626
669
663
628
112
642
632
640
638
611

FIG. 70

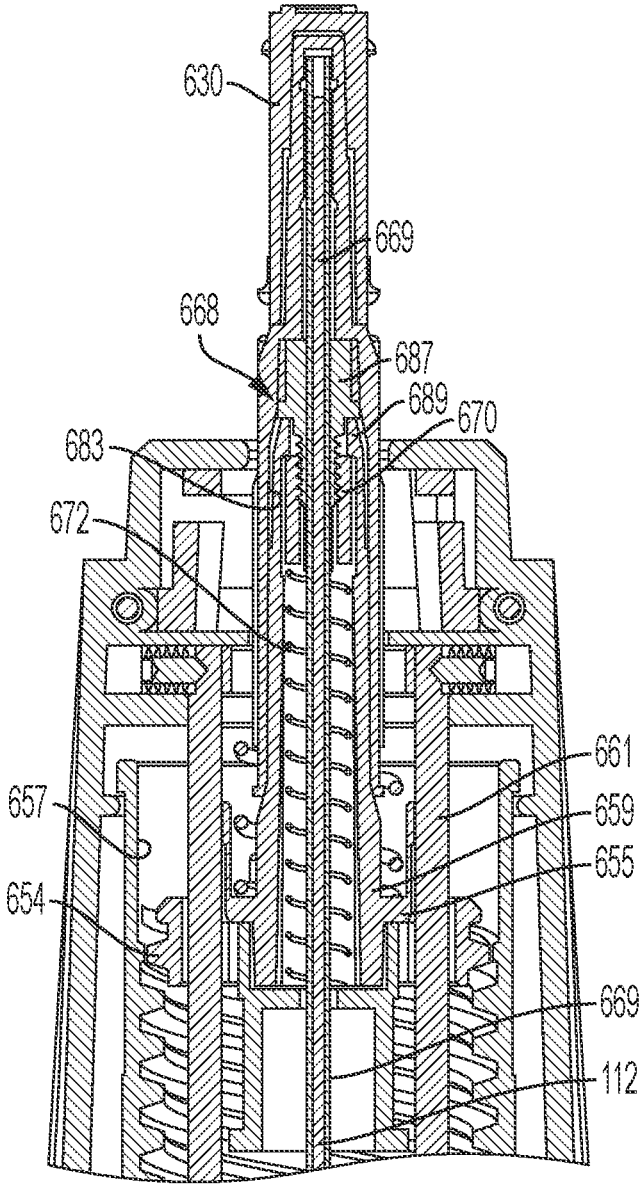


FIG. 70A

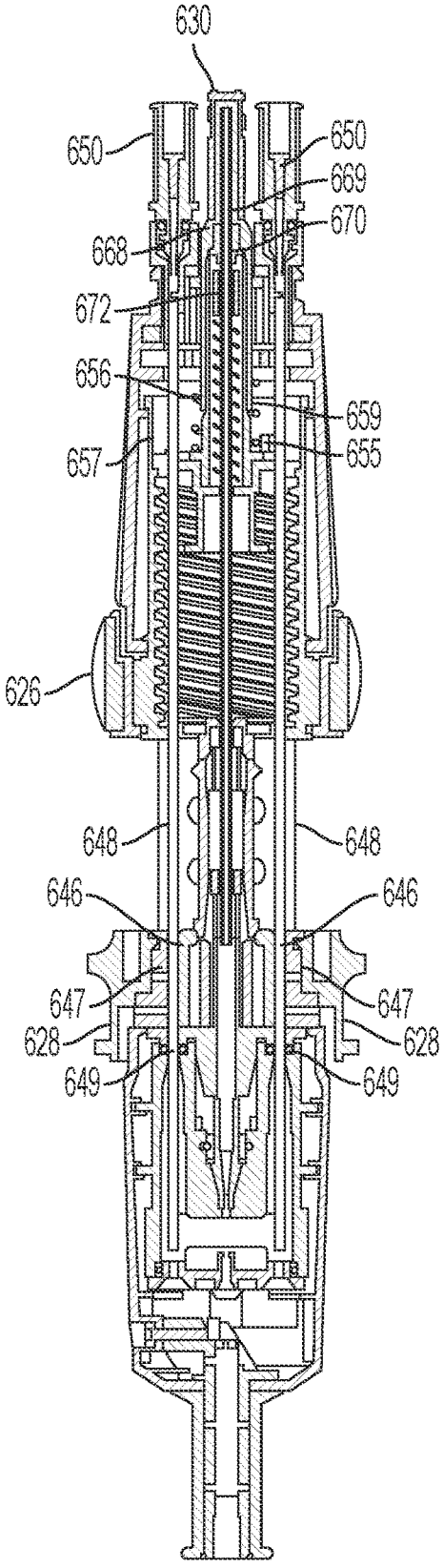

630
650
650
669
670
668
672
656
659
655
657
626
648
648
646
646
647
647
628
628
649
649

FIG. 71

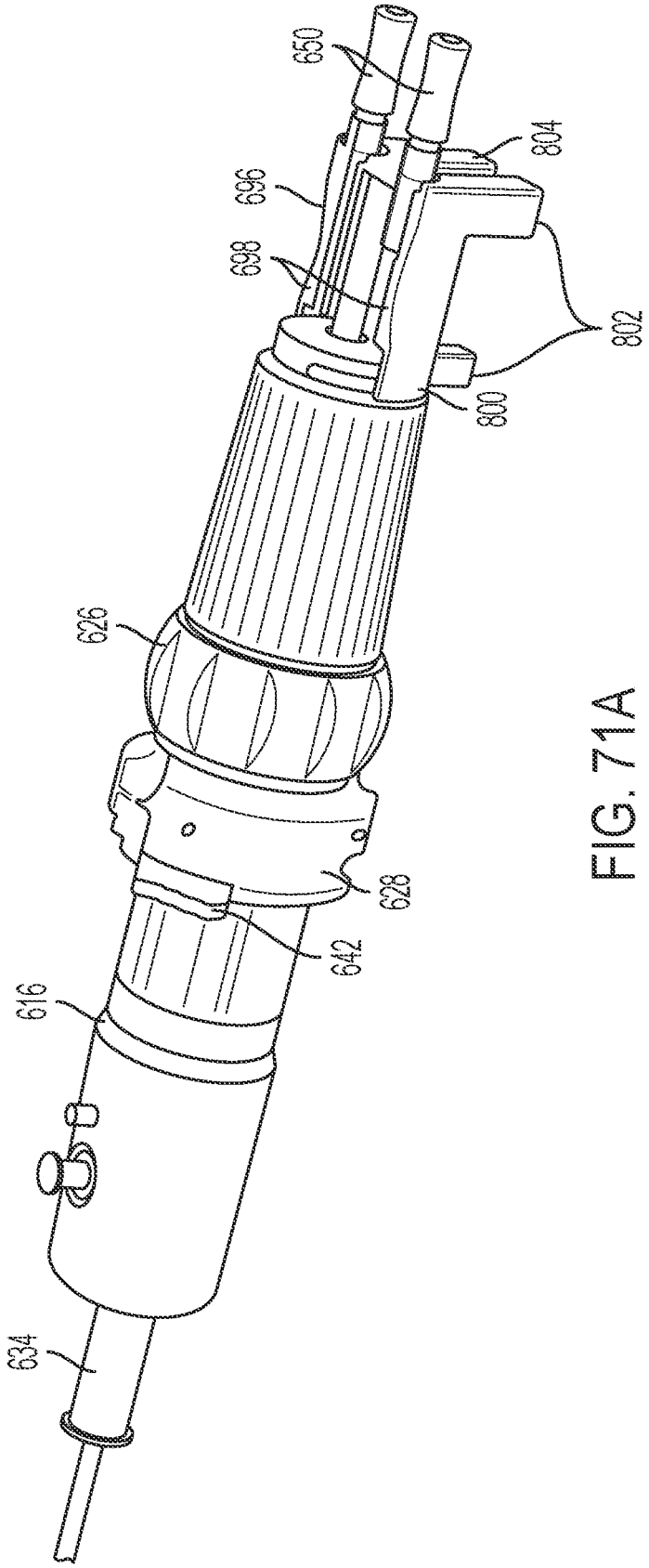


FIG. 71A

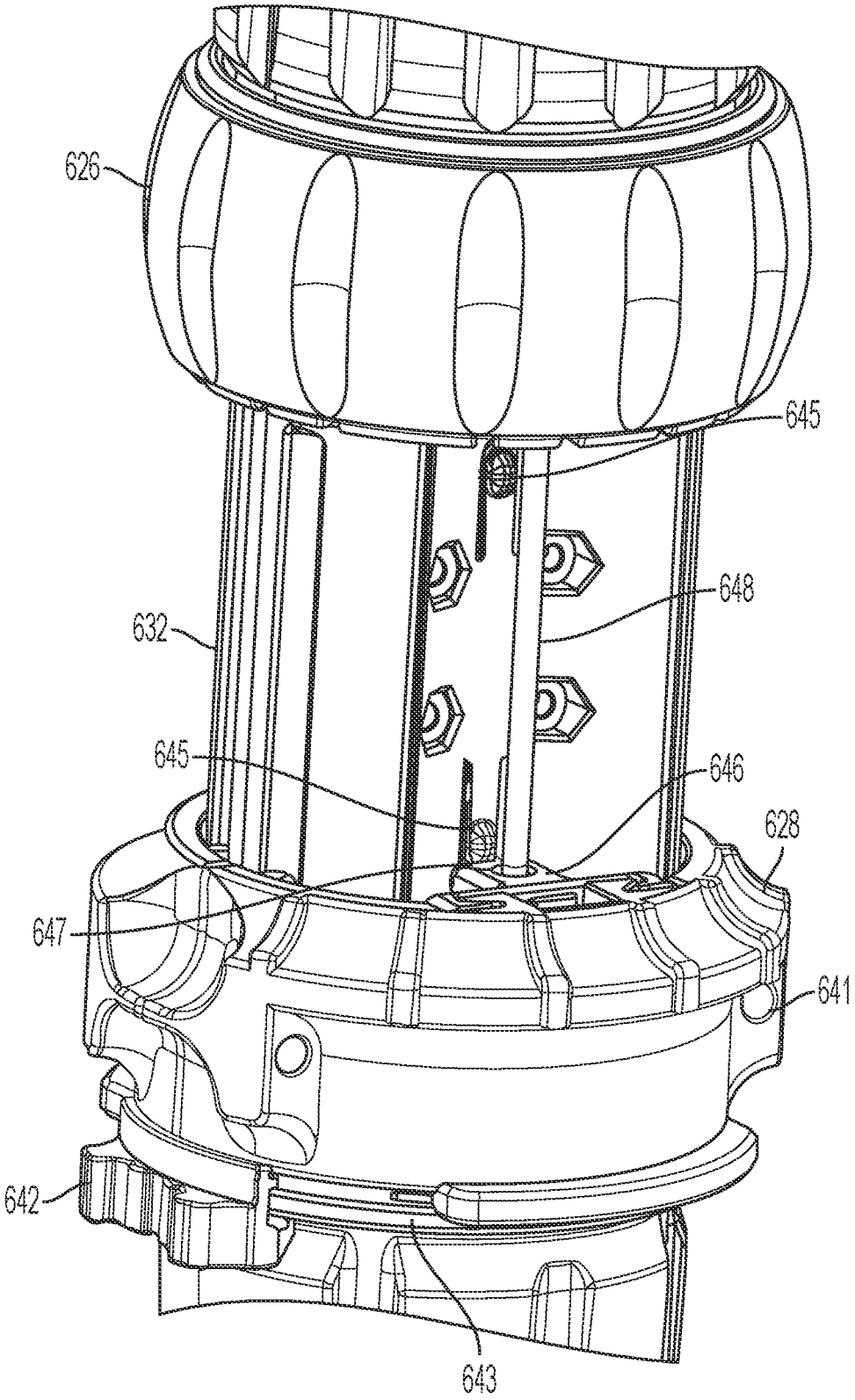


FIG. 72

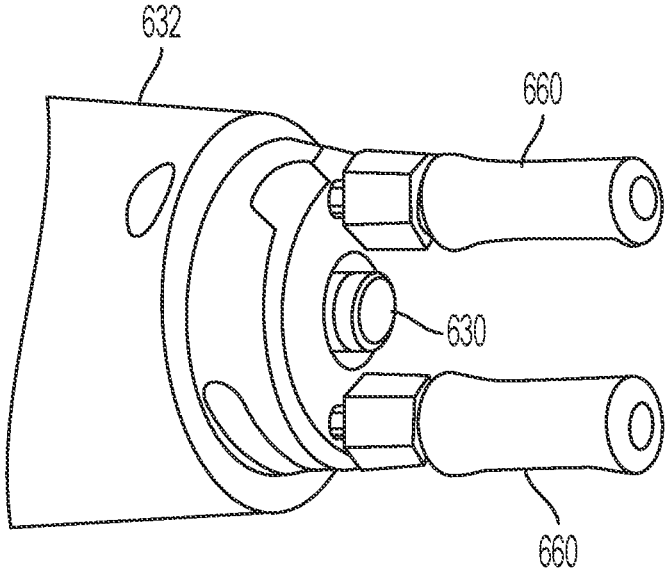


FIG. 73

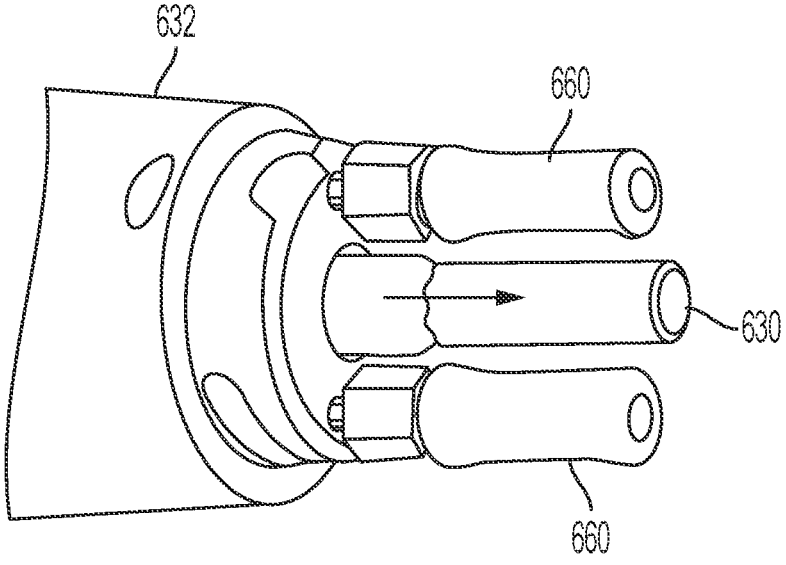


FIG. 74

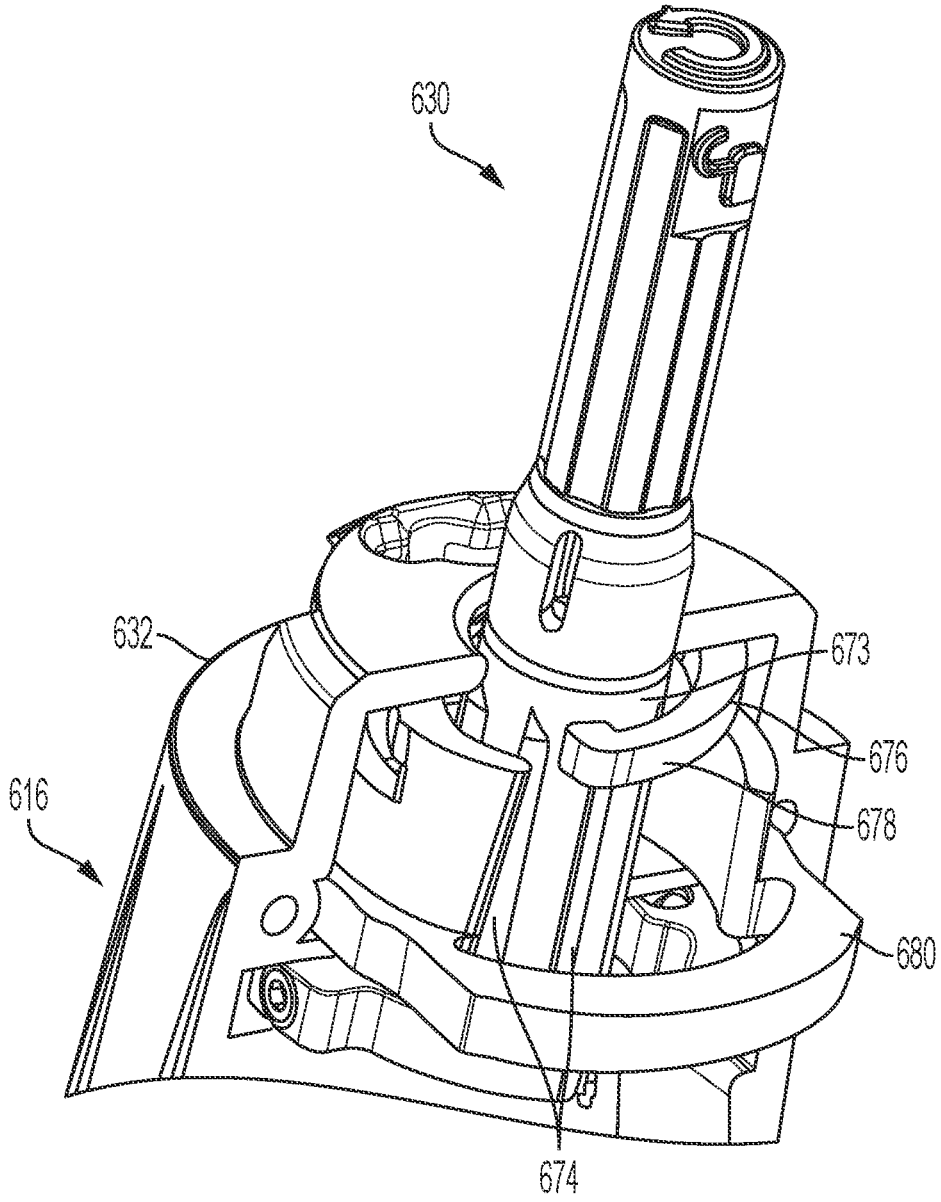


FIG. 75

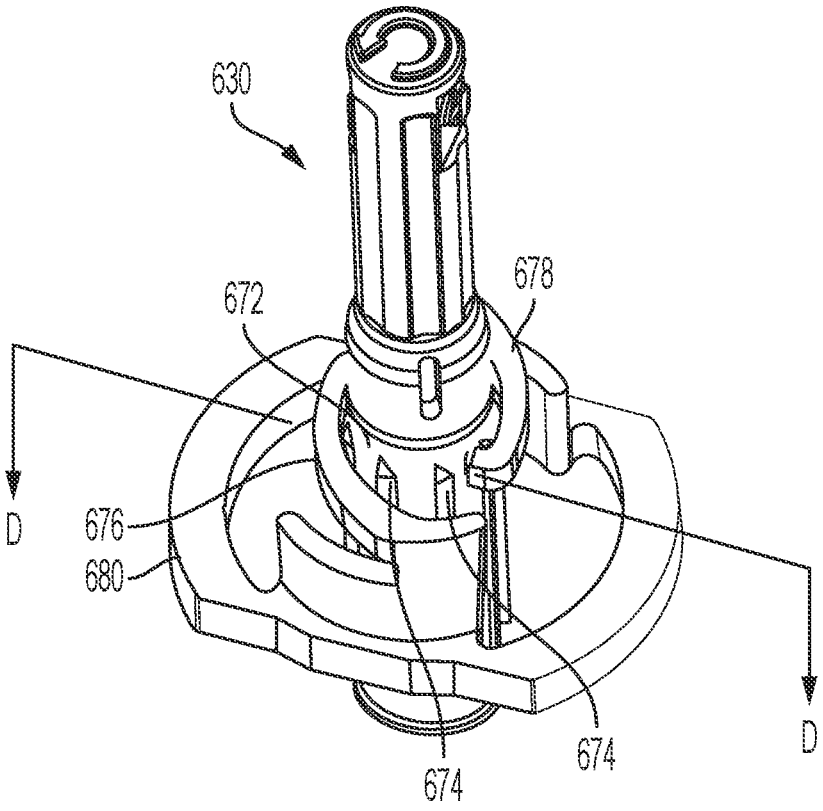


FIG. 76

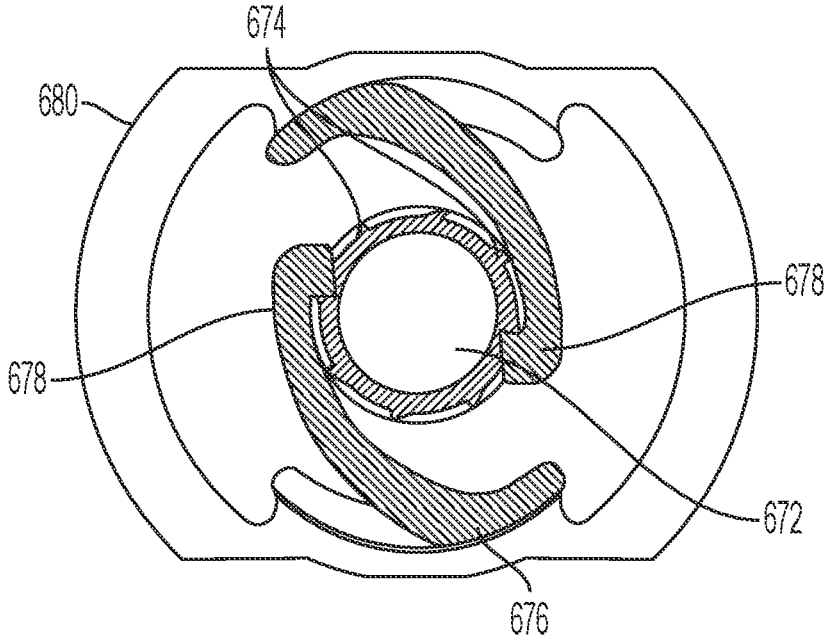


FIG. 77

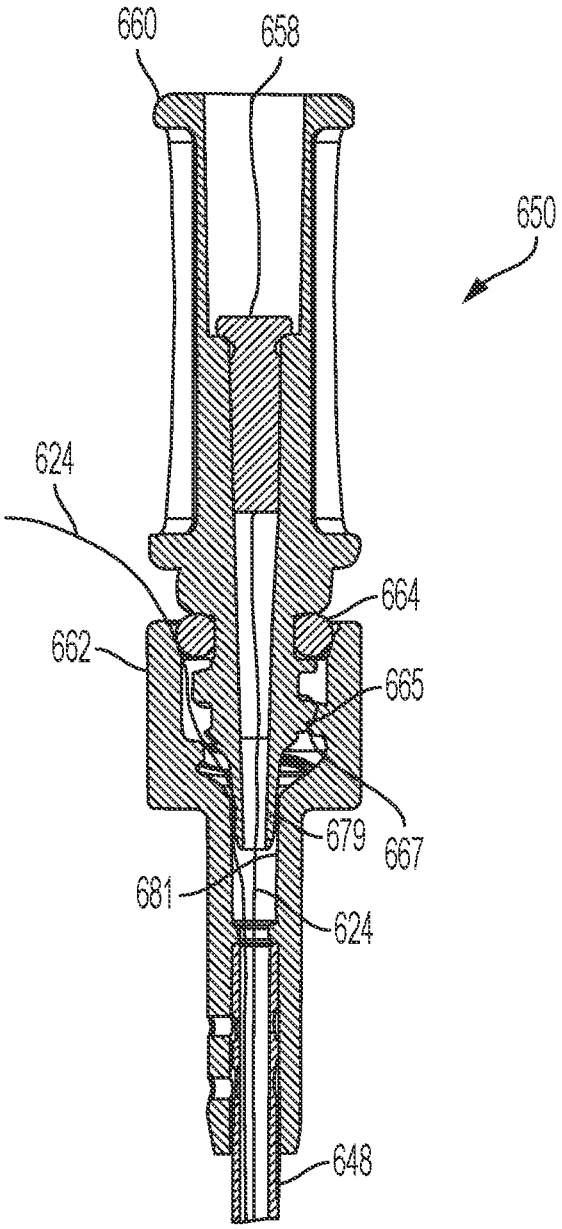


FIG. 78

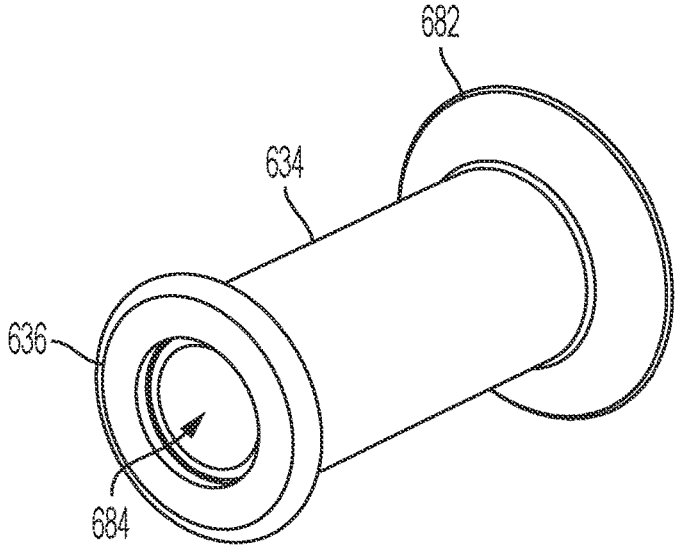


FIG. 79

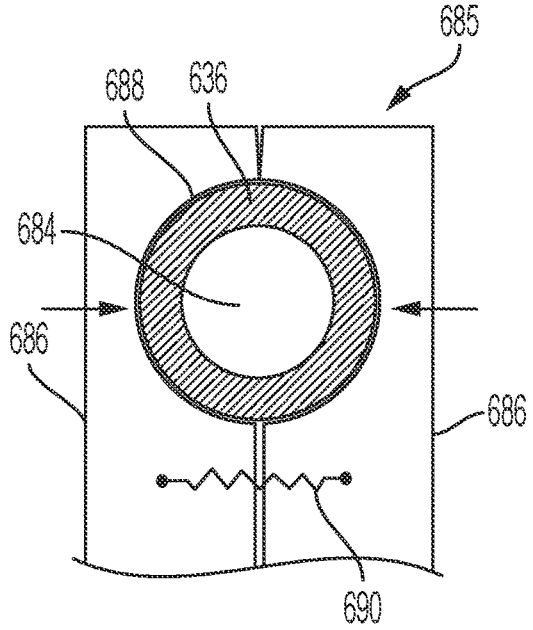


FIG. 80

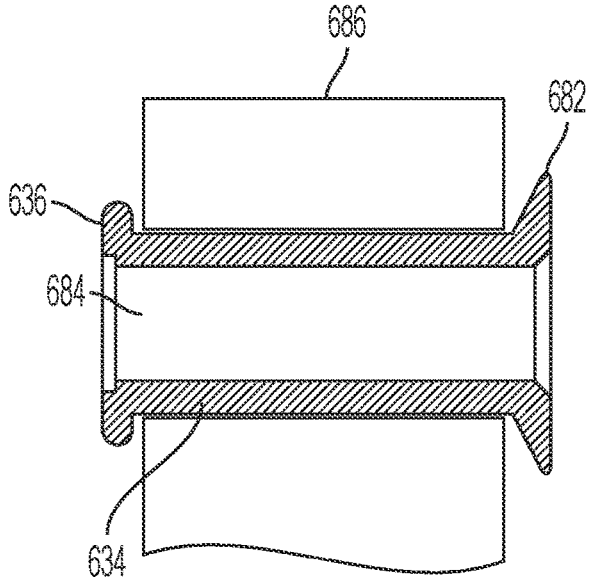


FIG. 81

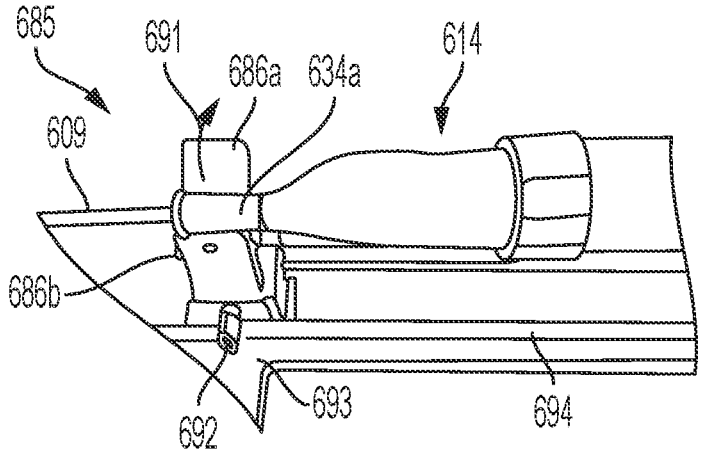


FIG. 82A

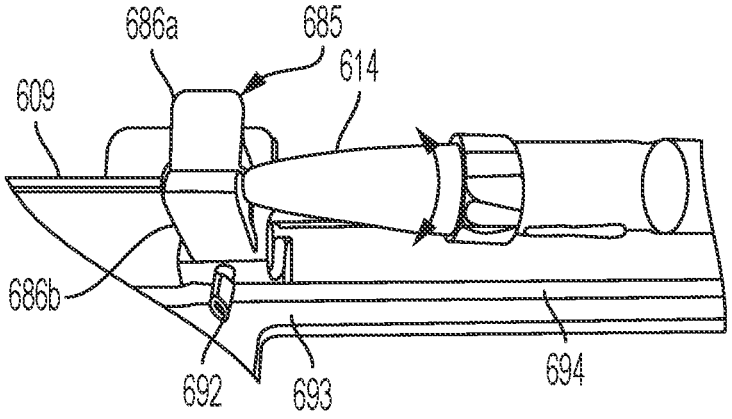


FIG. 82B

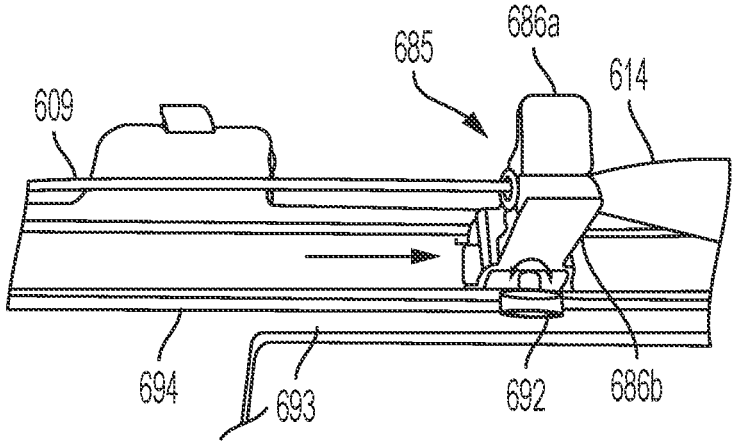


FIG. 82C

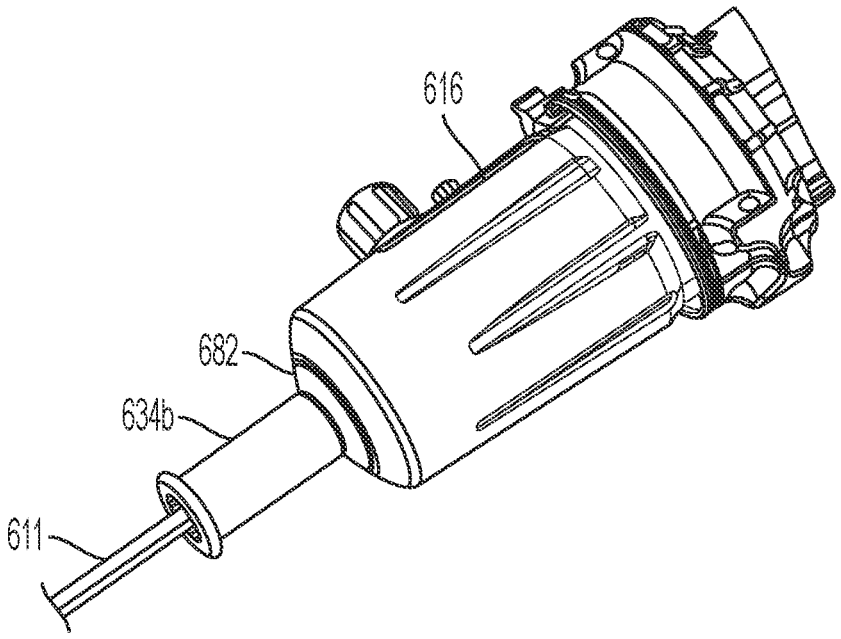


FIG. 83A

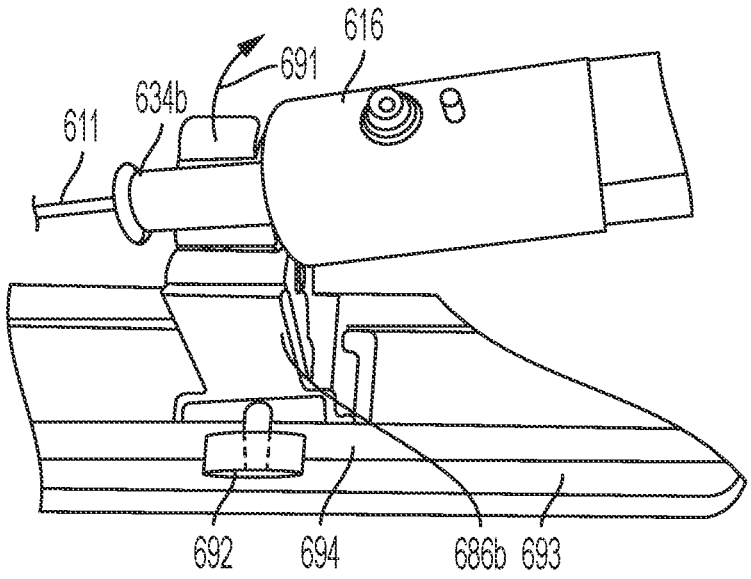


FIG. 83B

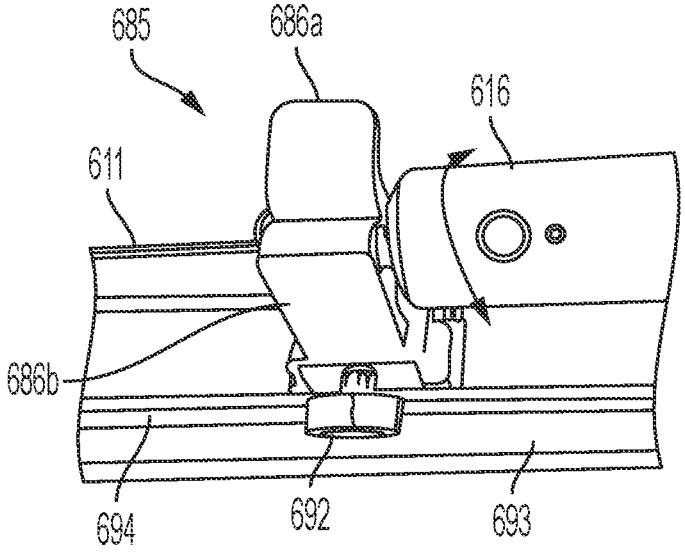


FIG. 83C

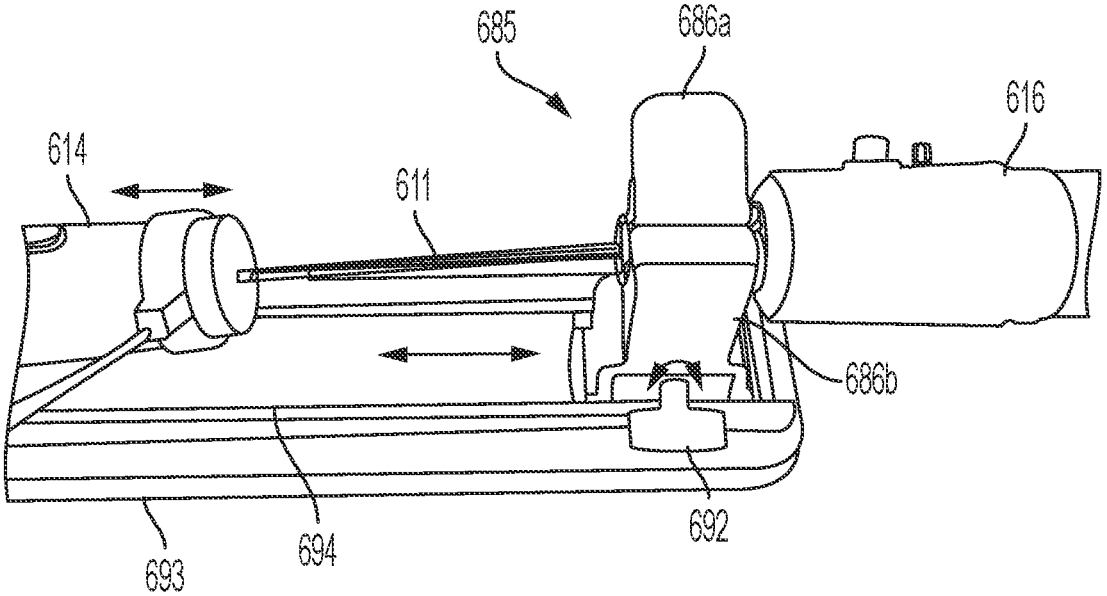


FIG. 84

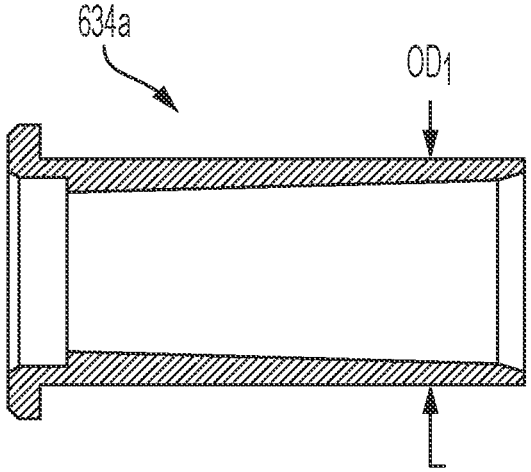


FIG. 85A

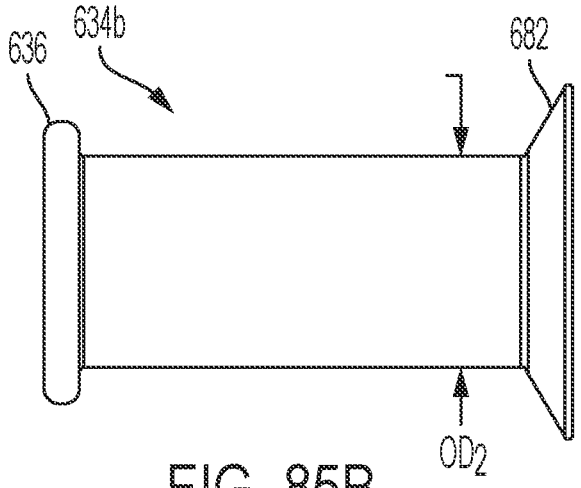


FIG. 85B

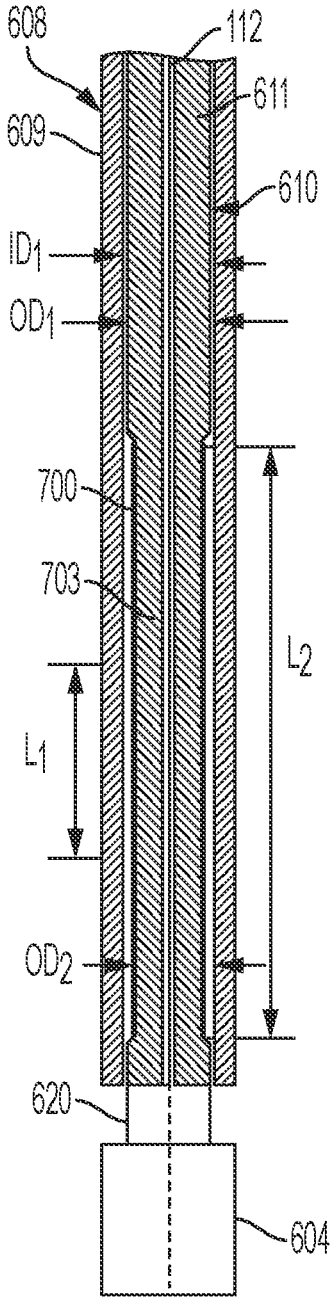

608
112
611
609
610
ID1
OD1
700
703
L2
L1
OD2
620
604

FIG. 86

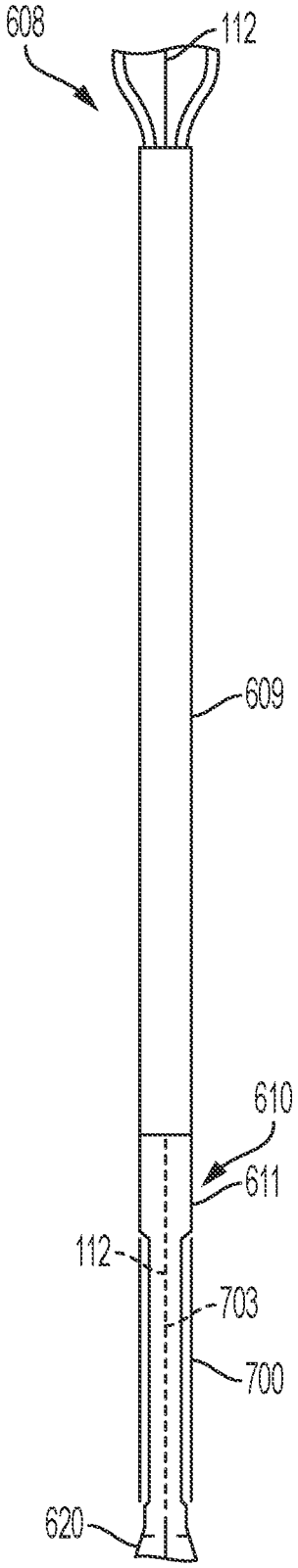

608
112
609
610
611
112
703
700
620

FIG. 87

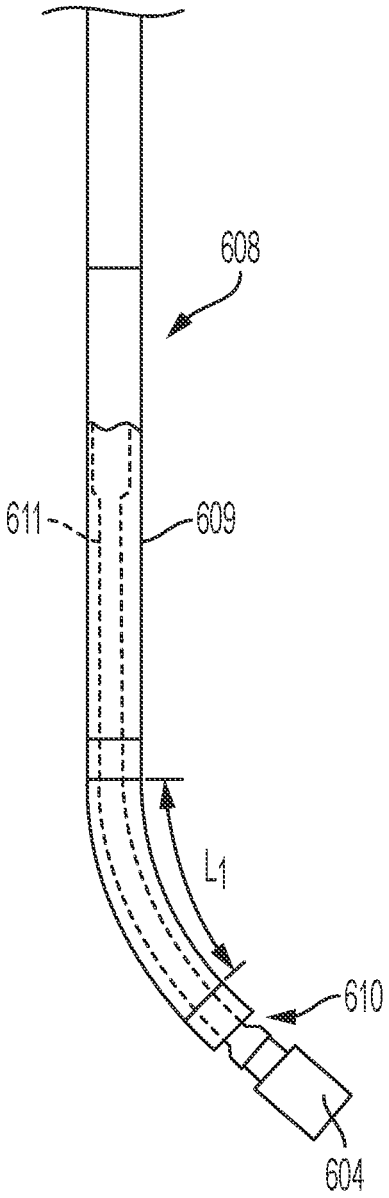


FIG. 88A

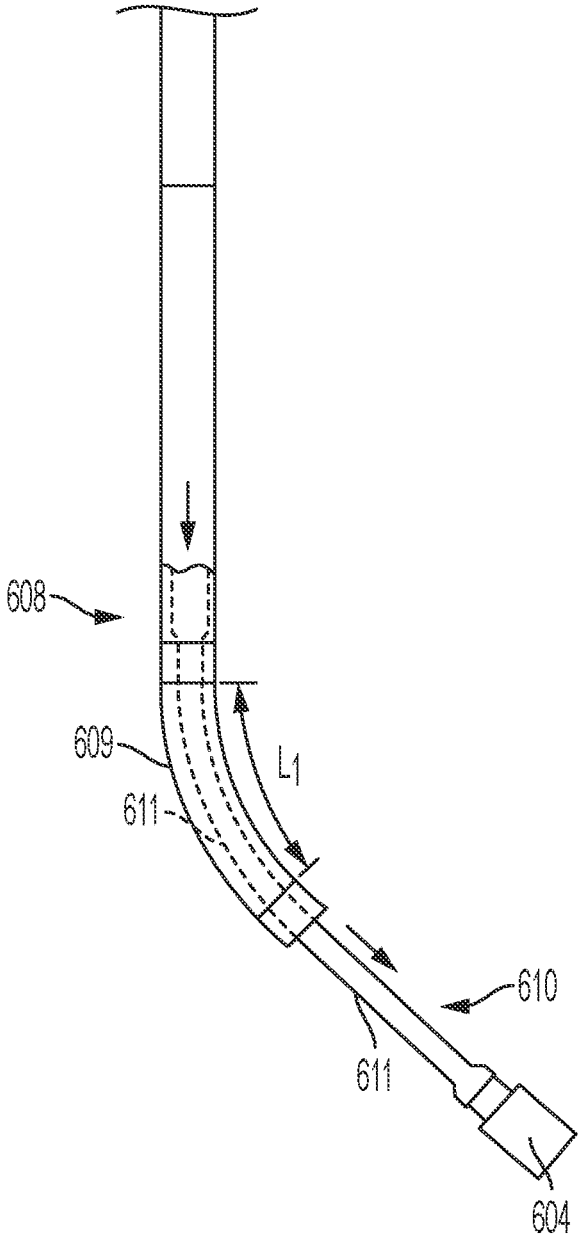


FIG. 88B

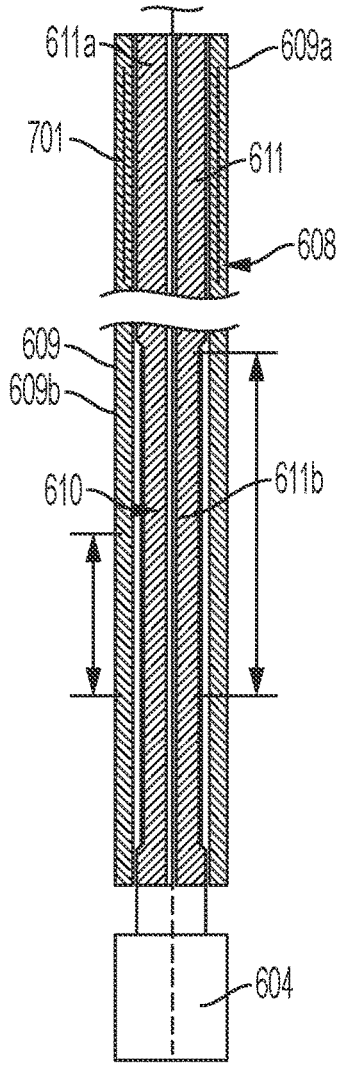


FIG. 89A

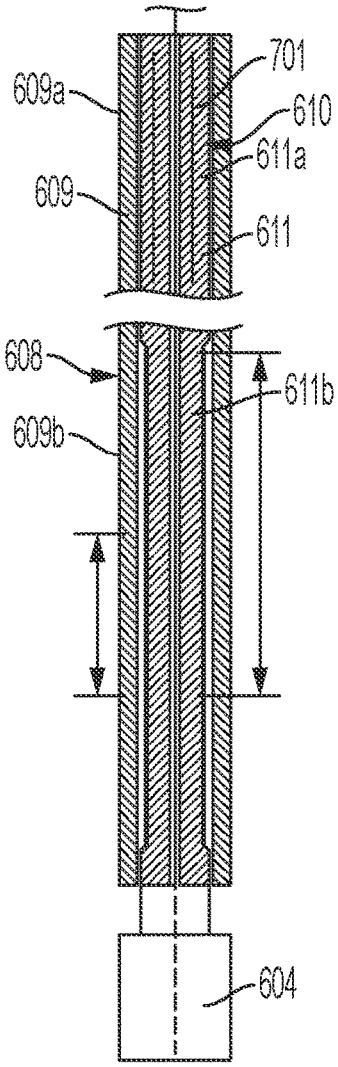


FIG. 89B

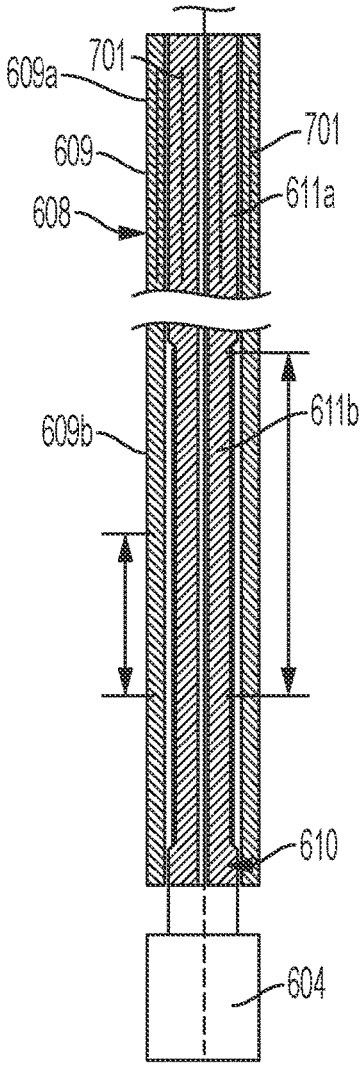


FIG. 89C

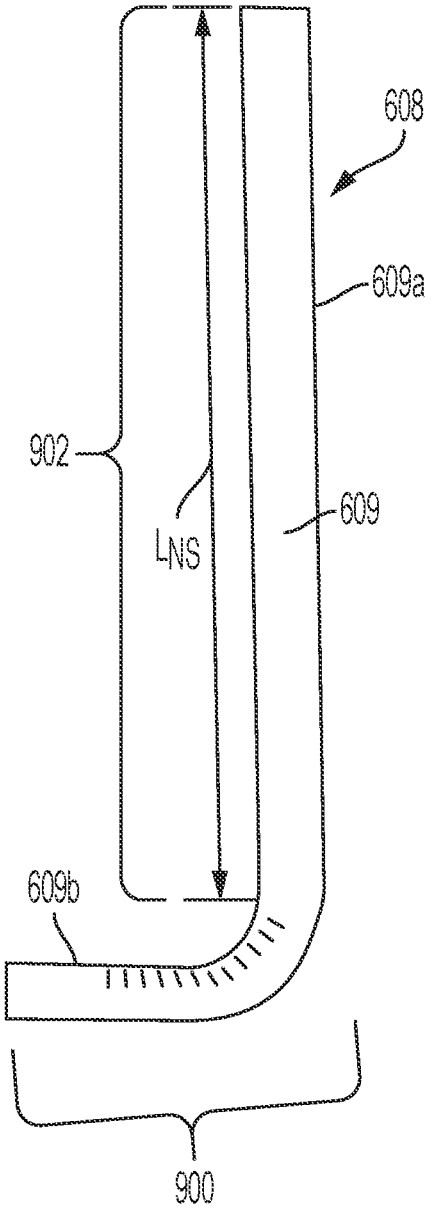


FIG. 90

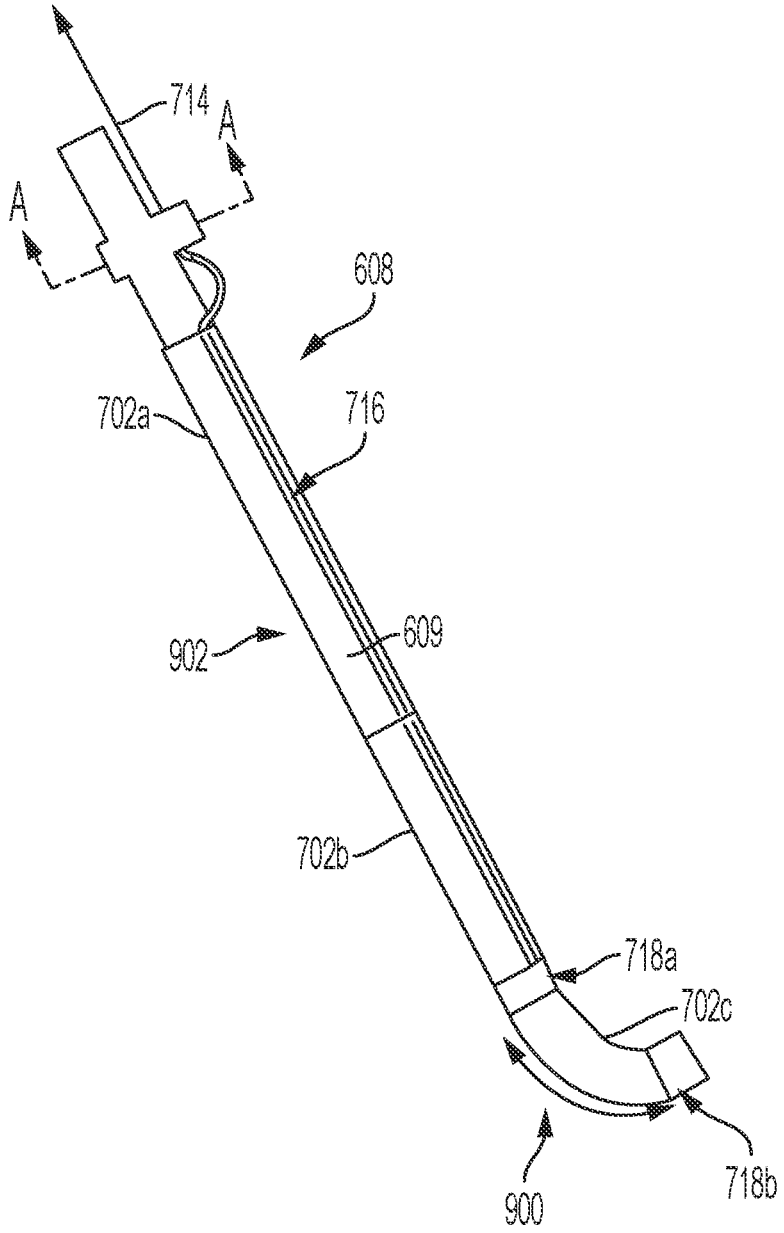


FIG. 91

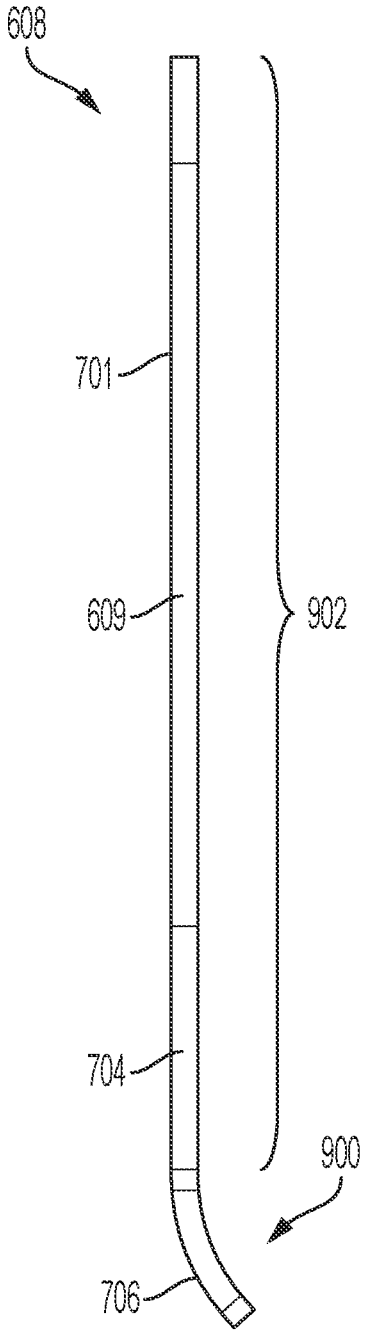


FIG. 92

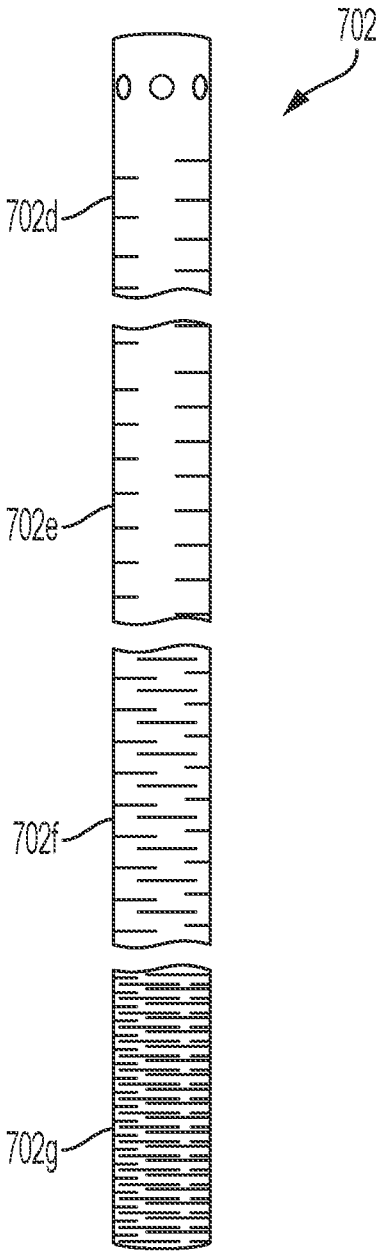


FIG. 93

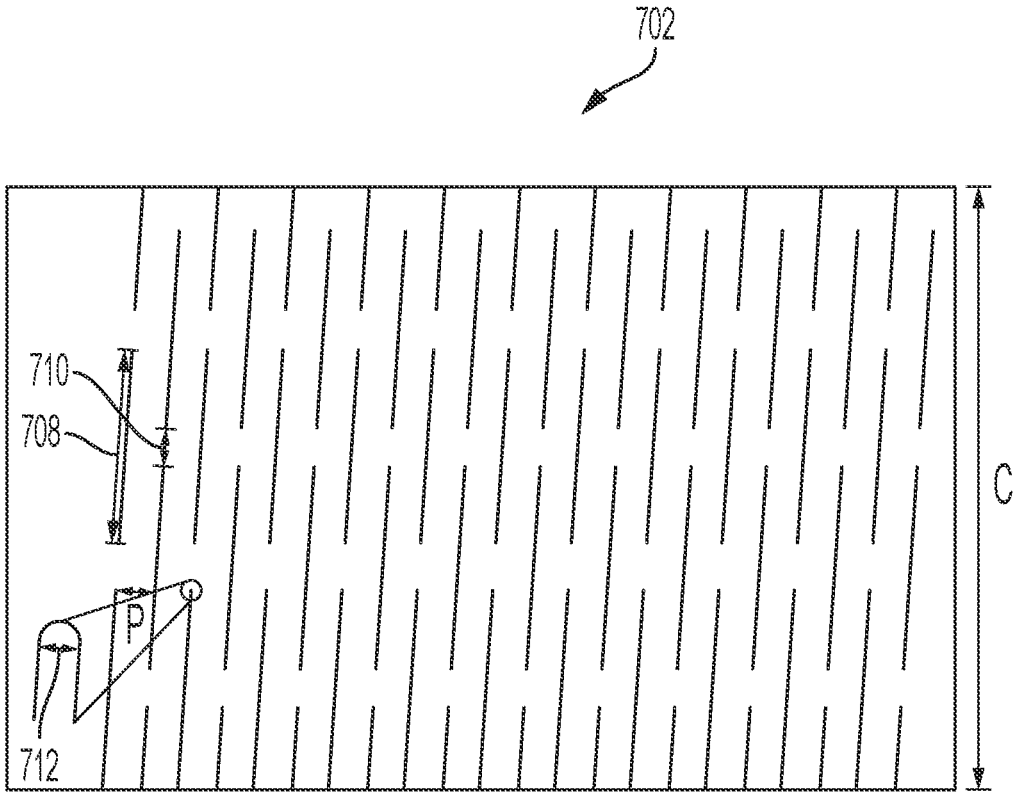


FIG. 94

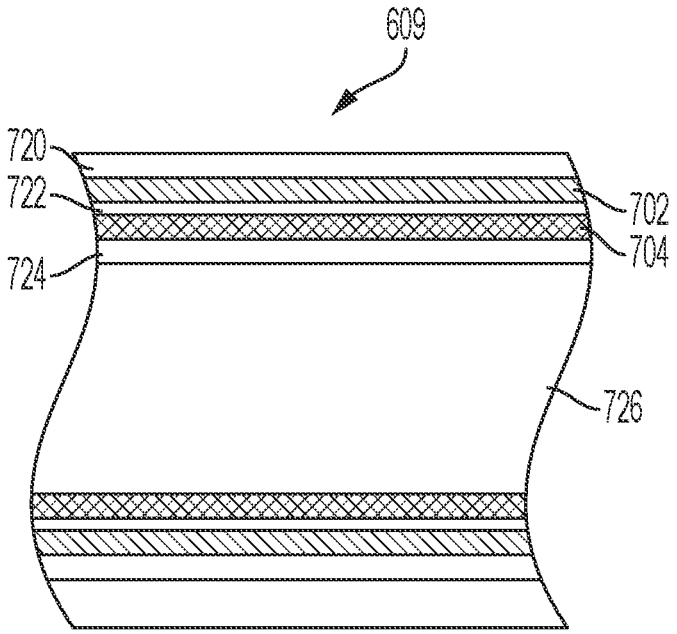


FIG. 95A

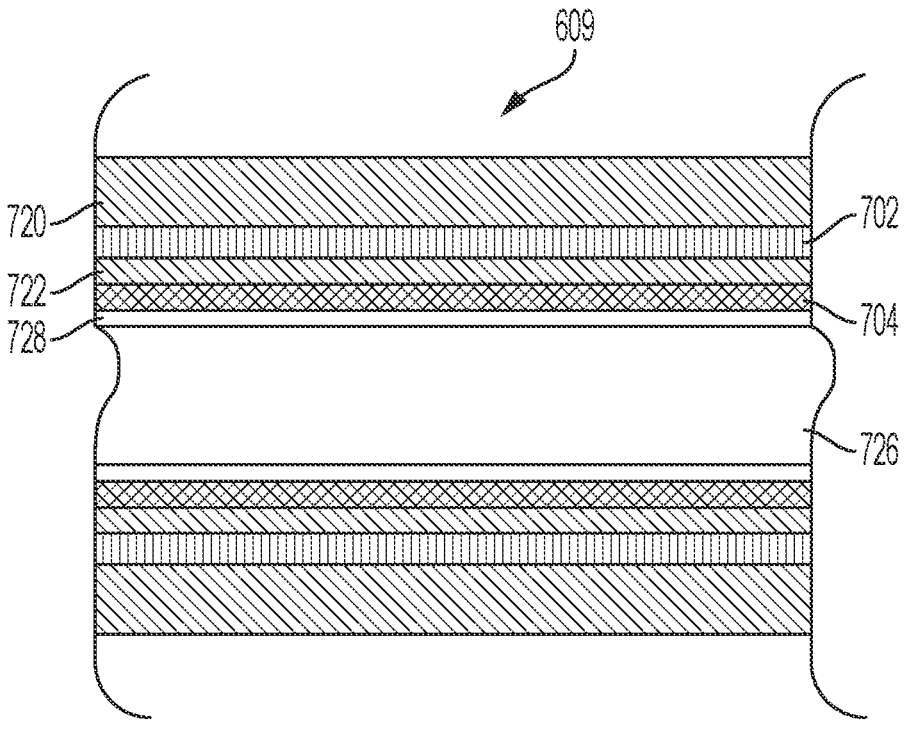


FIG. 95B

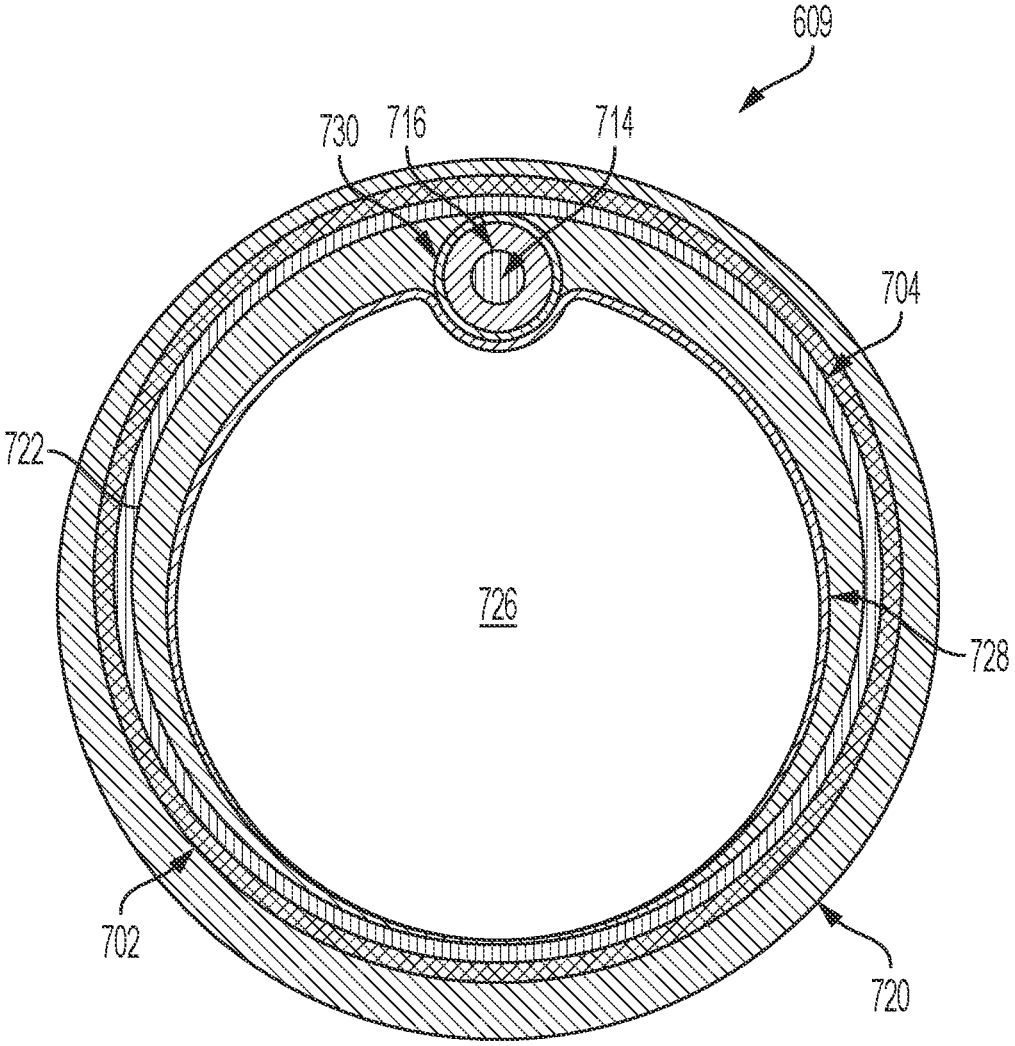


FIG. 96A

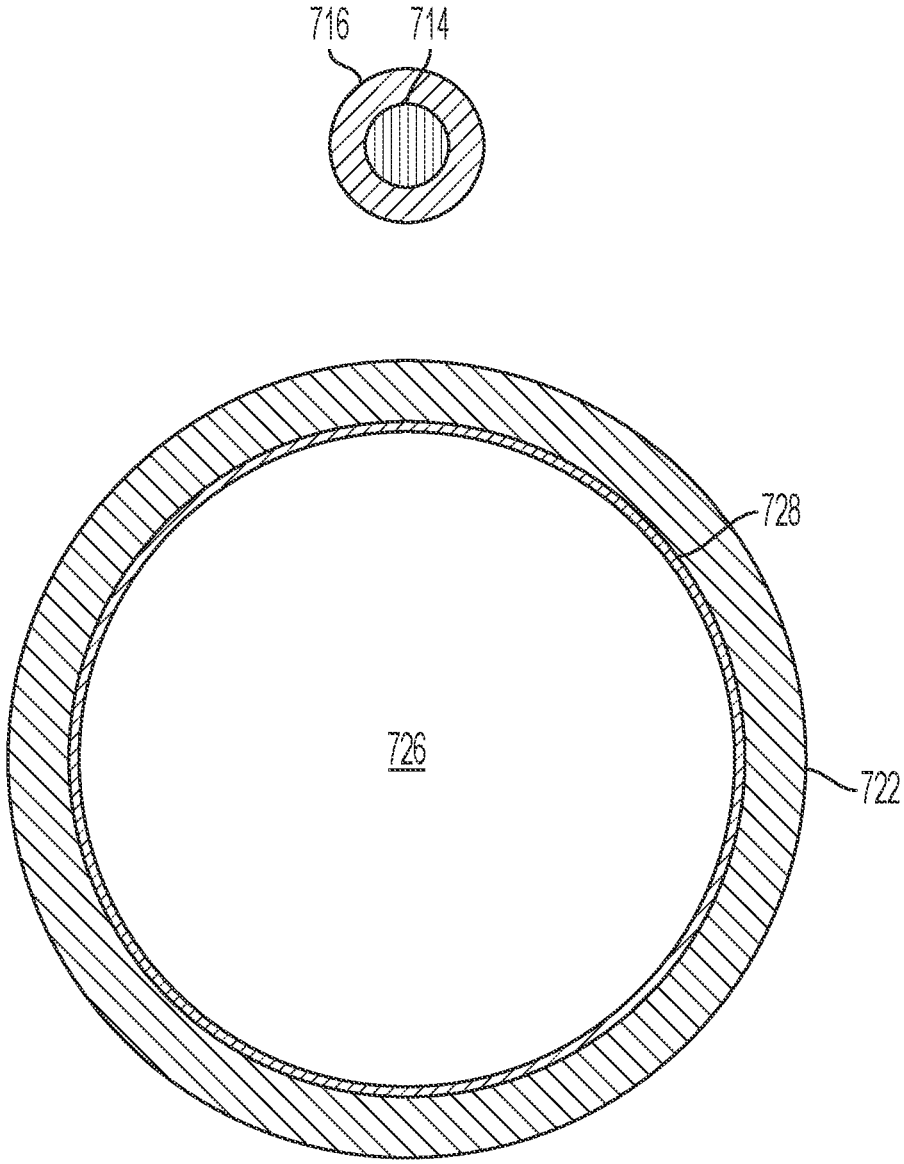


FIG. 96B

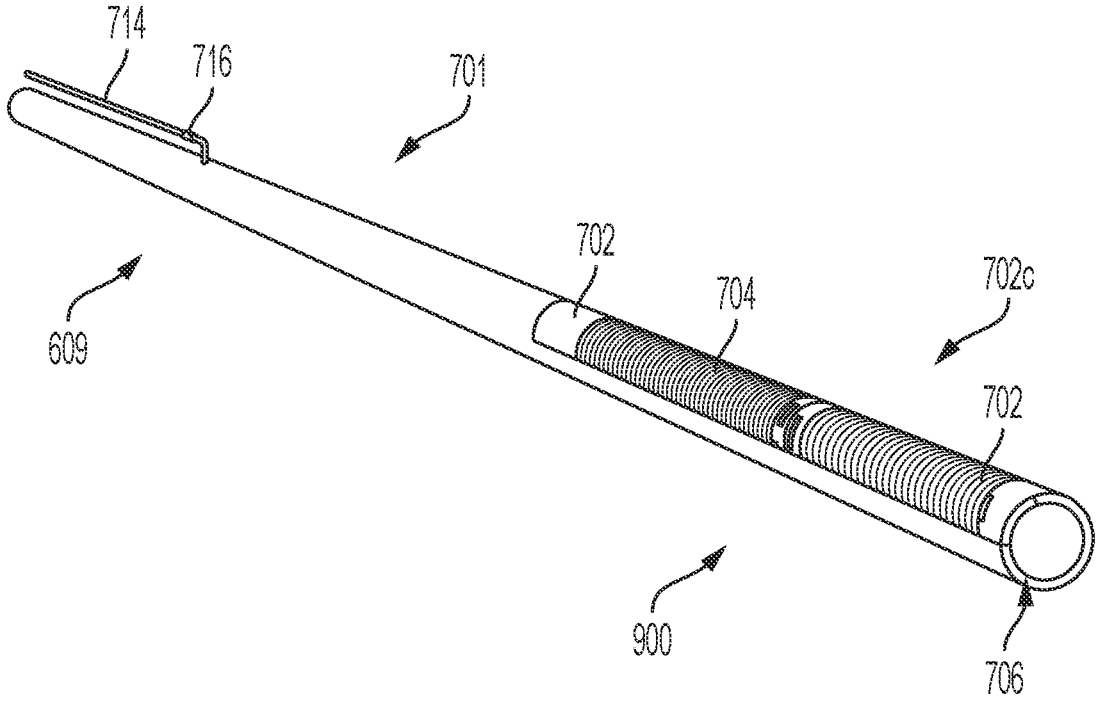


FIG. 97

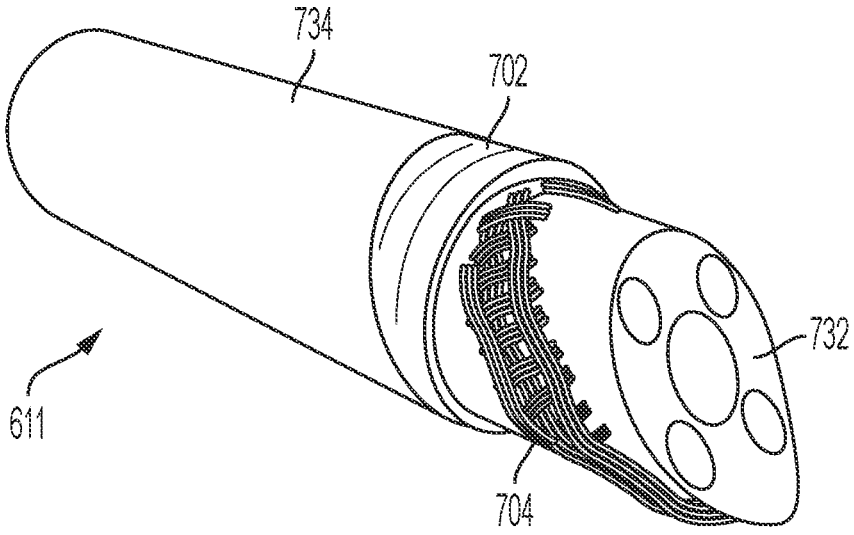


FIG. 98

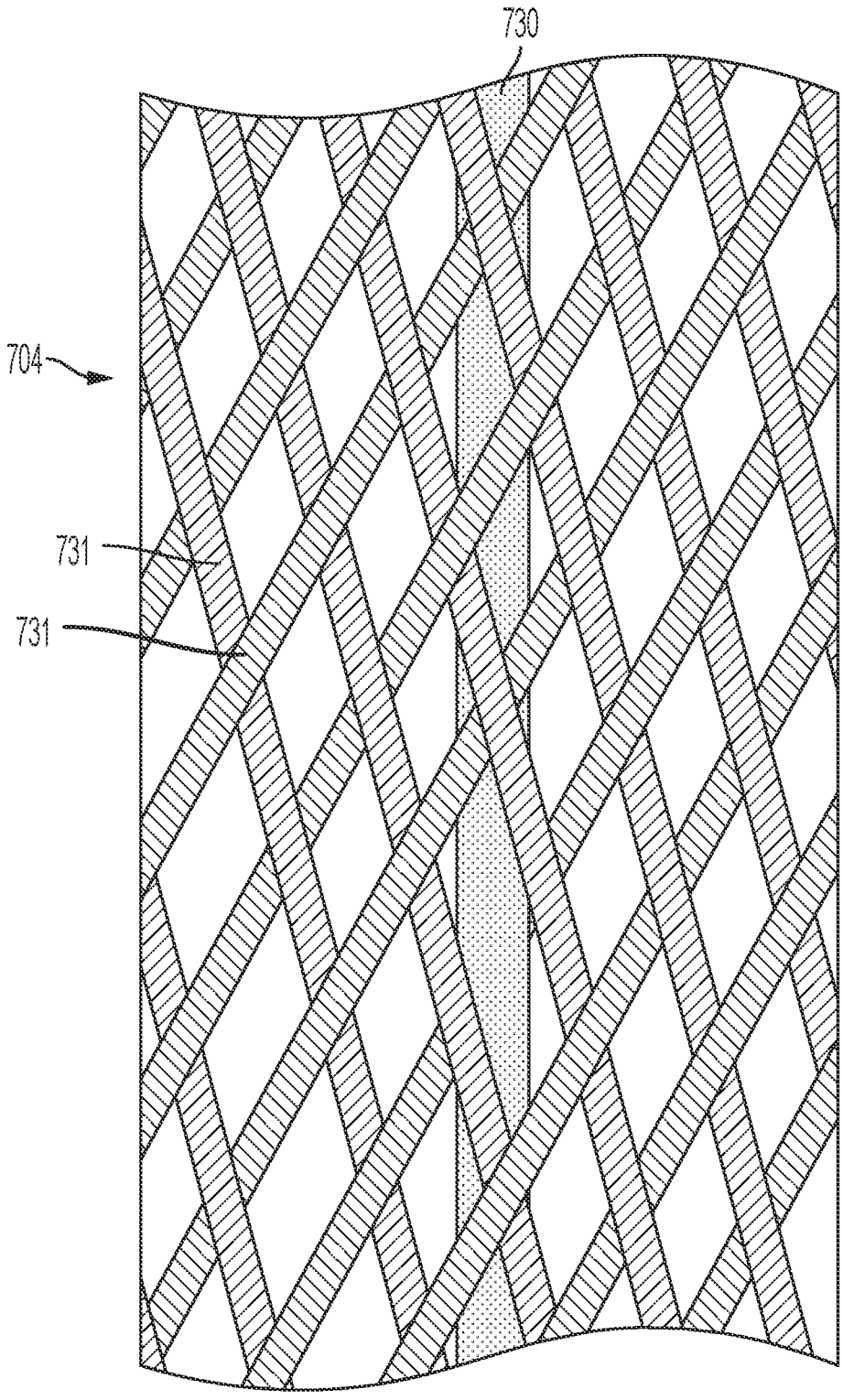


FIG. 99A

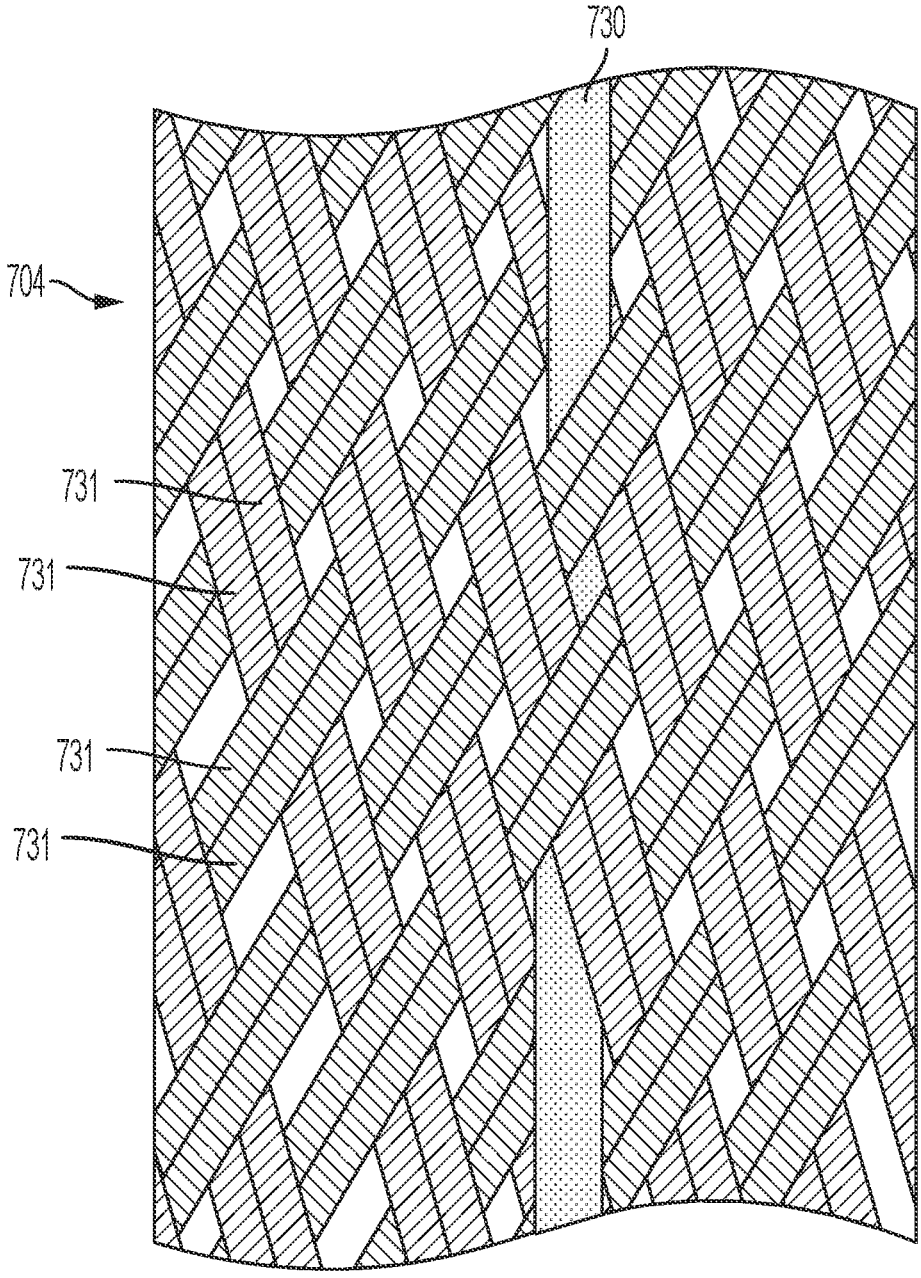


FIG. 99B

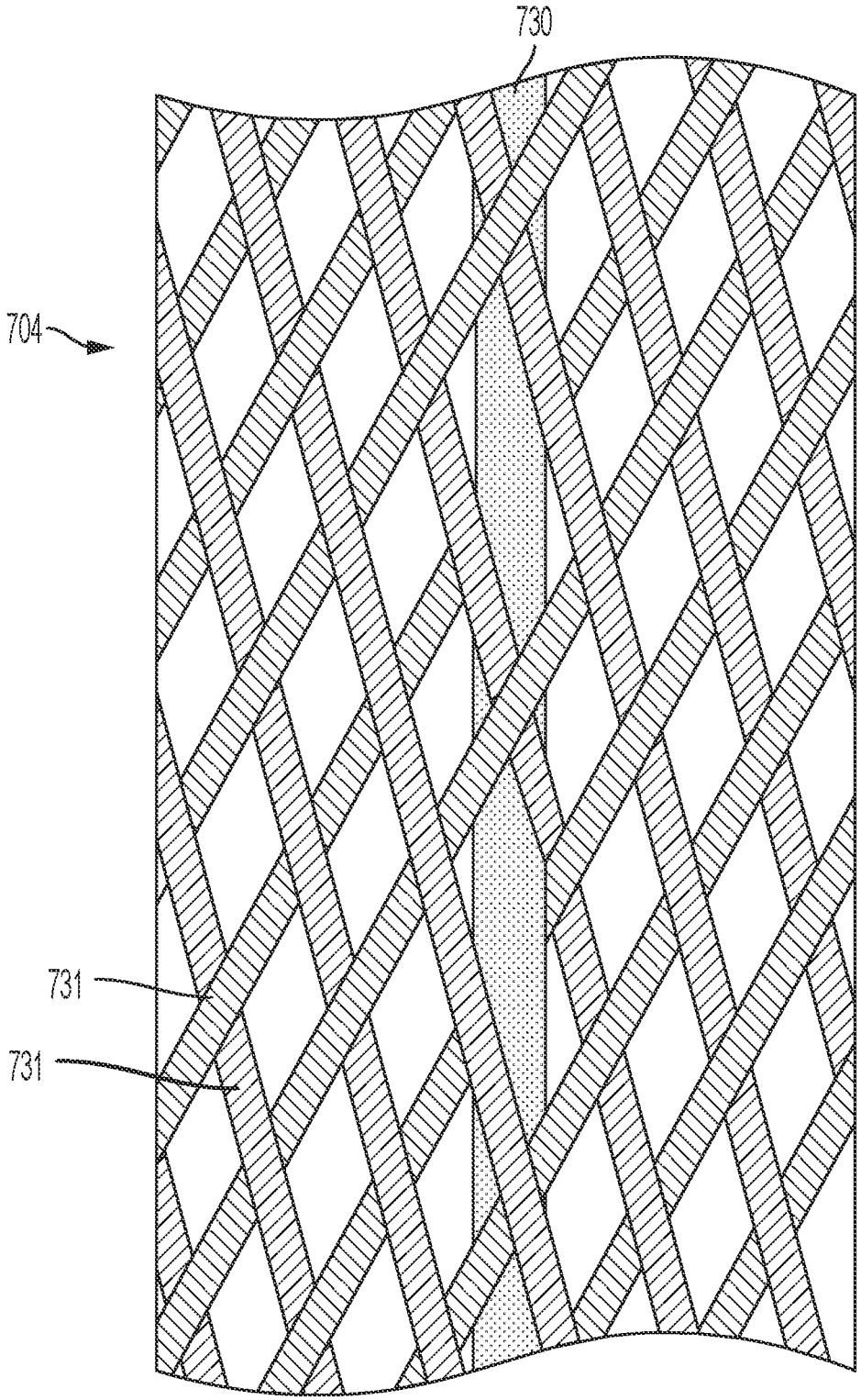


FIG. 99C

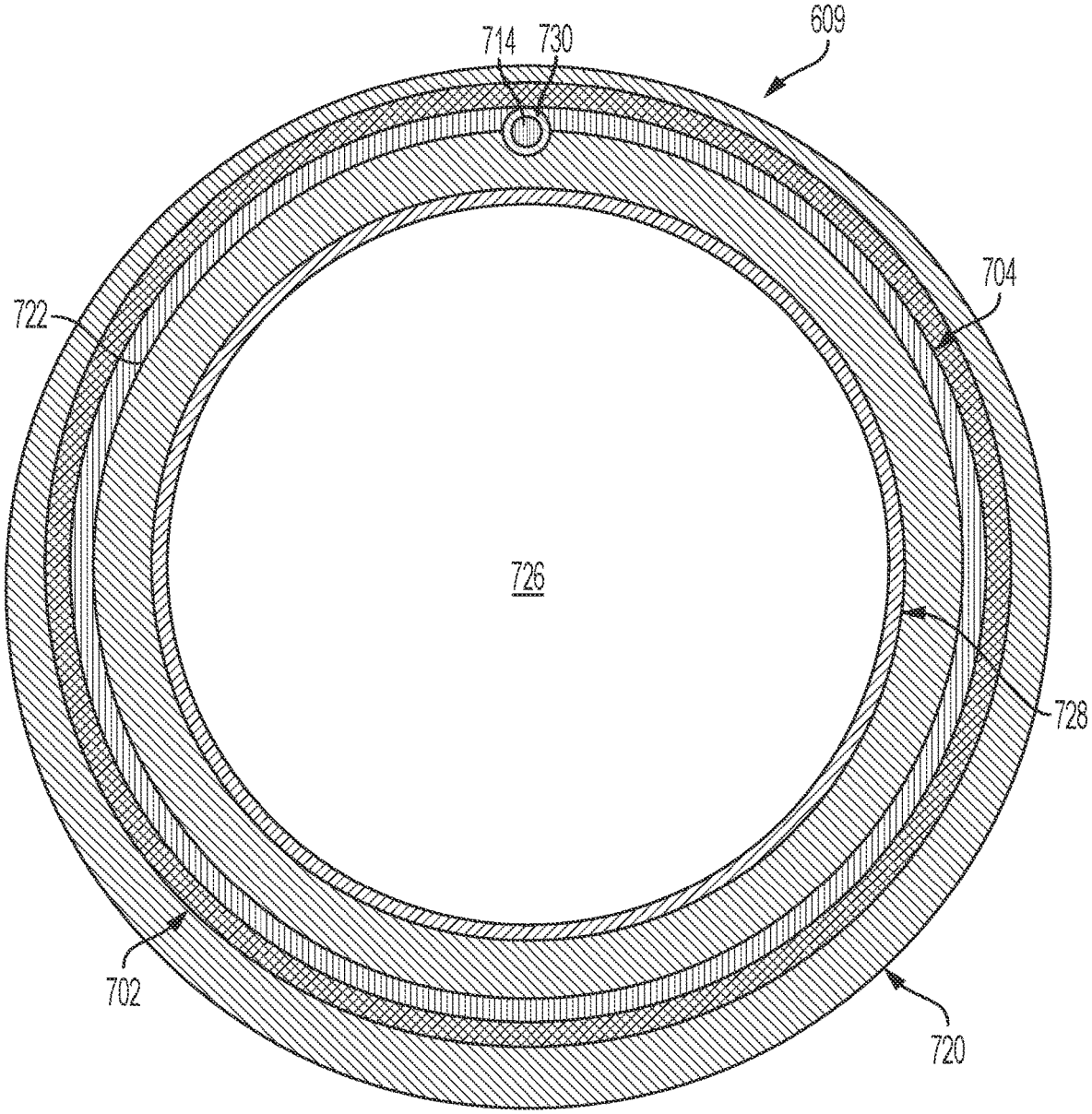


FIG. 99D

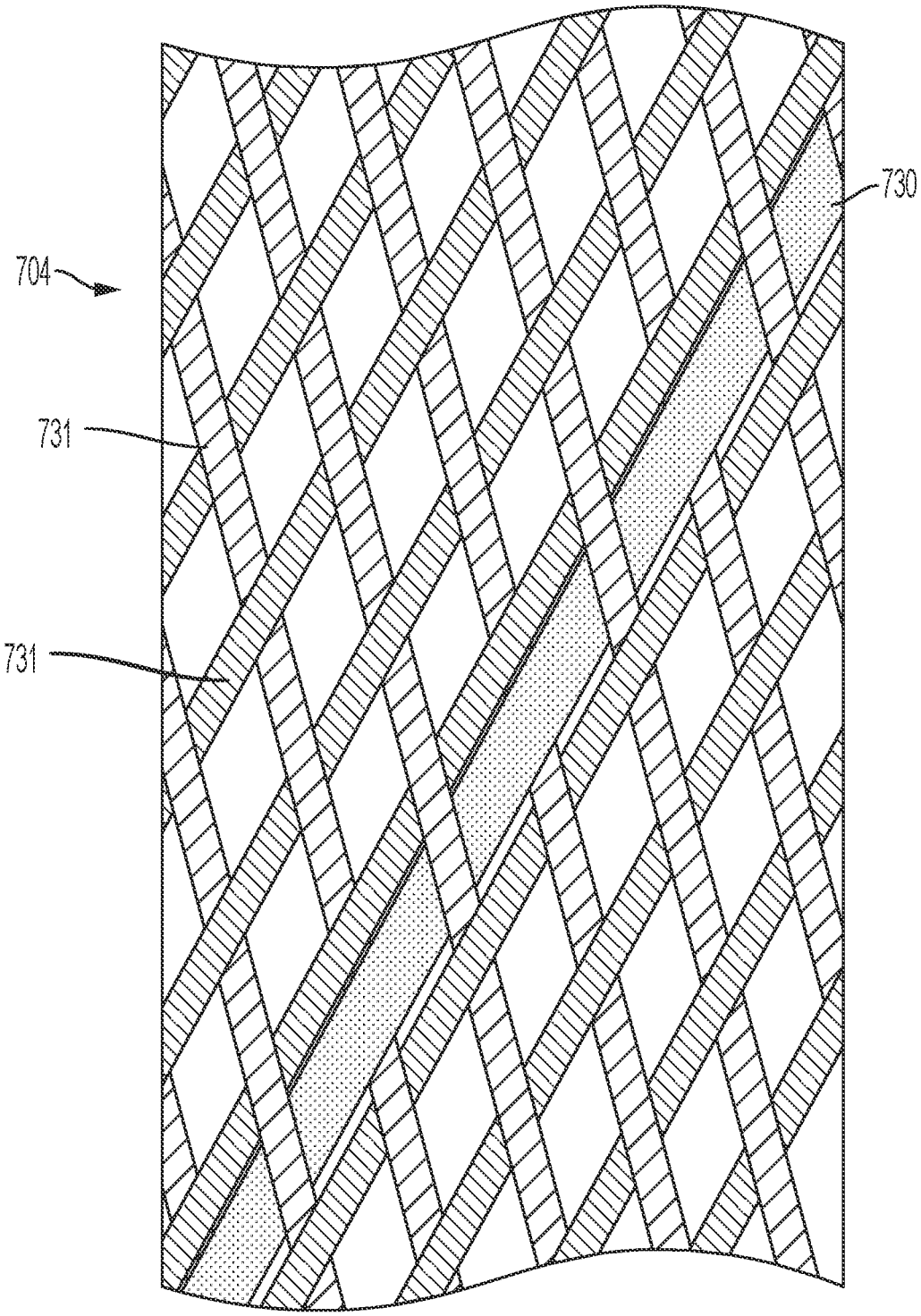


FIG. 99E

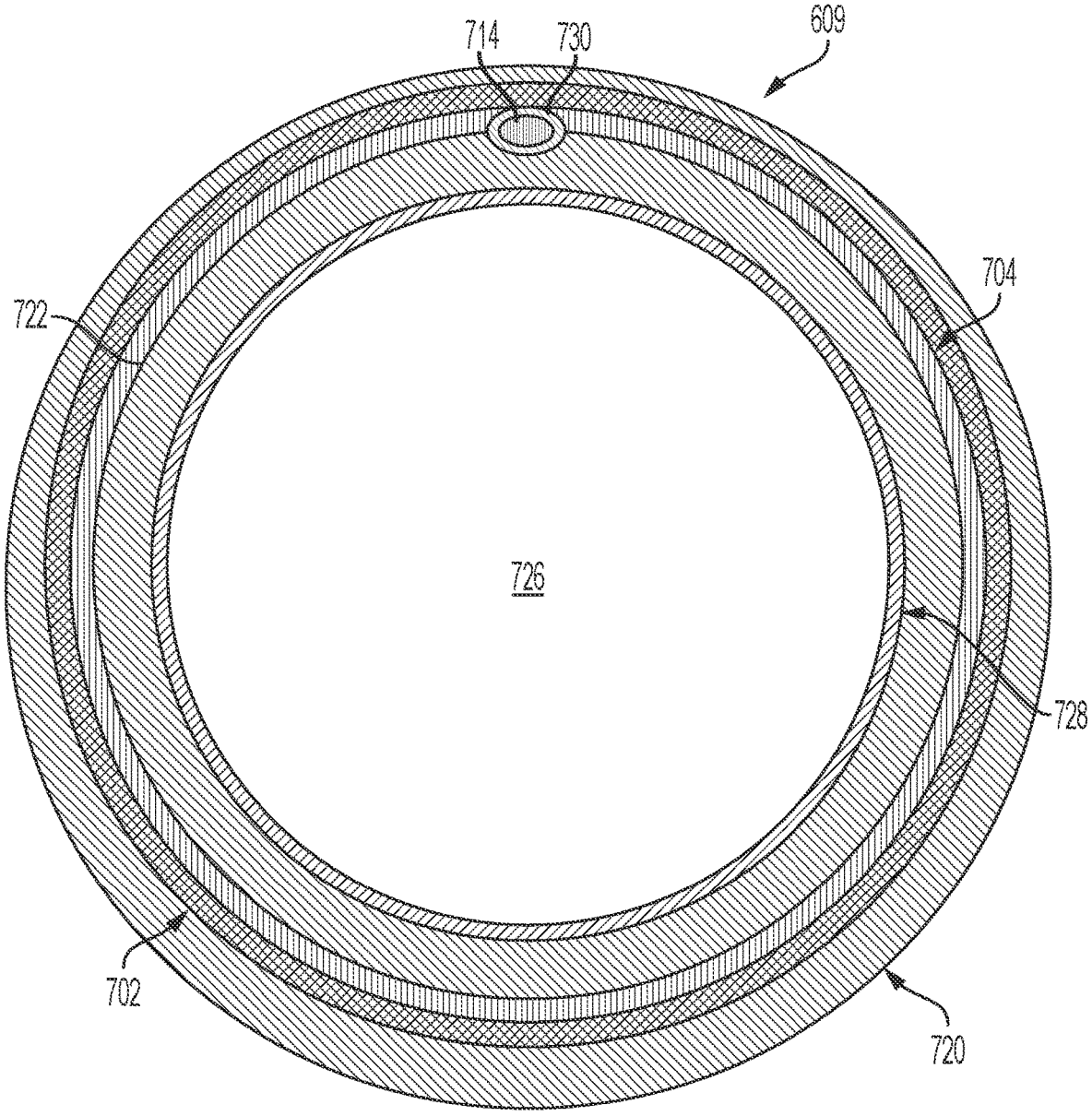


FIG. 99F

DELIVERY DEVICES FOR HEART VALVE TREATMENT DEVICES

RELATED APPLICATIONS

[0001] The present application is a continuation of Patent Cooperation Treaty Application No. PCT/US2022/025390, filed on Apr. 19, 2022, which claims the benefit of U.S. Provisional Patent Application No. 63/181,120, filed on Apr. 28, 2021, titled "Delivery Devices for Heart Valve Treatment Devices," and U.S. Provisional Patent Application No. 63/268,845, filed on Mar. 3, 2022, titled "Delivery Devices for Heart Valve Treatment Devices," all of which are incorporated herein by reference in their entireties for all purposes.

BACKGROUND

[0002] The native heart valves (i.e., the aortic, pulmonary, tricuspid, and mitral valves) serve critical functions in assuring the forward flow of an adequate supply of blood through the cardiovascular system. These heart valves can be damaged, and thus rendered less effective, for example, by congenital malformations, inflammatory processes, infectious conditions, disease, etc. Such damage to the valves may result in serious cardiovascular compromise or death. Damaged valves can be surgically repaired or replaced during open heart surgery. However, open heart surgeries are highly invasive, and complications may occur. Transvascular techniques can be used to introduce and implant devices in a manner that is much less invasive than open heart surgery. As one example, a transvascular technique useable for accessing the native mitral and aortic valves is the trans-septal technique. The trans-septal technique comprises advancing a catheter into the right atrium (e.g., inserting a catheter into the right femoral vein, up the inferior vena cava and into the right atrium). The septum is then punctured, and the catheter passed into the left atrium. A similar transvascular technique can be used to implant a device within the tricuspid valve that begins similarly to the trans-septal technique but stops short of puncturing the septum and instead turns the delivery catheter toward the tricuspid valve in the right atrium.

[0003] A healthy heart has a generally conical shape that tapers to a lower apex. The heart is four-chambered and comprises the left atrium, right atrium, left ventricle, and right ventricle. The left and right sides of the heart are separated by a wall generally referred to as the septum. The native mitral valve of the human heart connects the left atrium to the left ventricle. The mitral valve has a very different anatomy than other native heart valves. The mitral valve includes an annulus portion, which is an annular portion of the native valve tissue surrounding the mitral valve orifice, and a pair of cusps, or leaflets, extending downward from the annulus into the left ventricle. The mitral valve annulus can form a "D"-shaped, oval, or otherwise out-of-round cross-sectional shape having major and minor axes. The anterior leaflet can be larger than the posterior leaflet, forming a generally "C"-shaped boundary between the abutting sides of the leaflets when they are closed together.

[0004] When operating properly, the anterior leaflet and the posterior leaflet function together as a one-way valve to allow blood to flow only from the left atrium to the left ventricle. The left atrium receives oxygenated blood from the pulmonary veins. When the muscles of the left atrium contract and the left ventricle dilates (also referred to as "ventricular diastole" or "diastole"), the oxygenated blood that is collected in the left atrium flows into the left ventricle. When the muscles of the left atrium relax and the muscles of the left ventricle contract (also referred to as "ventricular systole" or "systole"), the increased blood pressure in the left ventricle urges the sides of the two leaflets together, thereby closing the one-way mitral valve so that blood cannot flow back to the left atrium and is instead expelled out of the left ventricle through the aortic valve. To prevent the two leaflets from prolapsing under pressure and folding back through the mitral annulus toward the left atrium, a plurality of fibrous cords called chordae tendineae tether the leaflets to papillary muscles in the left ventricle.

[0005] Valvular regurgitation involves the valve improperly allowing some blood to flow in the wrong direction through the valve. For example, mitral regurgitation occurs when the native mitral valve fails to close properly and blood flows into the left atrium from the left ventricle during the systolic phase of heart contraction. Mitral regurgitation is one of the most common forms of valvular heart disease. Mitral regurgitation can have many different causes, such as leaflet prolapse, dysfunctional papillary muscles, stretching of the mitral valve annulus resulting from dilation of the left ventricle, more than one of these, etc. Mitral regurgitation at a central portion of the leaflets can be referred to as central jet mitral regurgitation and mitral regurgitation nearer to one commissure (i.e., location where the leaflets meet) of the leaflets can be referred to as eccentric jet mitral regurgitation. Central jet regurgitation occurs when the edges of the leaflets do not meet in the middle and thus the valve does not close, and regurgitation is present. Tricuspid regurgitation can be similar, but on the right side of the heart.

SUMMARY

[0006] This summary is meant to provide some examples and is not intended to be limiting of the scope of the invention in any way. For example, any feature included in an example of this summary is not required by the claims, unless the claims explicitly recite the features. Also, the features, components, steps, concepts, etc. described in examples in this summary and elsewhere in this disclosure can be combined in a variety of ways. Various features and steps as described elsewhere in this disclosure can be included in the examples summarized here.

[0007] The present disclosure discloses components for treatment systems (e.g., valve treatment systems). For example, the treatment systems herein can include a delivery system and an implantable device or implant (e.g., a valve repair or replacement device). While not required, these components can make the delivery system easier to use, more ergonomic, more intuitive, and/more accurate than previous delivery systems. One or more of these components can be used with existing delivery systems. Any combination or subcombination of the disclosed components can be used together, but there is no requirement that any of the components disclosed by the present application be used with any other component disclosed by the present application.

[0008] In some implementations, a catheter assembly for controlling a transvascular implantable device includes a handle (which can comprise a handle housing) and a sheath or shaft (e.g., a catheter shaft, tube with a lumen, etc.) that

extends distally from the handle housing. The catheter assembly can also include an actuation element (e.g., actuation wire, actuation shaft, actuation rod, actuation tube, etc.) and a control element (e.g., a control knob, button, switch, slider, motor, combination of these, etc.) to control, actuate, and/or move the actuation element. The control element can be coupled to the actuation element (e.g., actuation wire, actuation shaft, etc.) directly or indirectly. The actuation element can extend through the sheath and be configured to be coupled to the implantable device.

[0009] In some implementations, the control element is a control knob that is rotatable relative to the handle housing. Rotation of the control knob causes axial movement of the actuation element with respect to the handle housing and the sheath.

[0010] In some implementations, the catheter assembly includes one or more clasp control lines and one or more clasp control members (e.g., a pair of clasp control lines and a pair of clasp control members, etc.).

[0011] In some implementations, the one or more actuation lines (e.g., pair of clasp actuation lines) extend through the sheath. Each clasp actuation line is configured to be coupled to the implantable device. Each clasp control member can be axially and/or slidably movable along the handle housing. Movement (e.g., axial movement) of each clasp control member causes a clasp of the implantable device to be moved between an open configuration and a closed configuration.

[0012] In some implementations, a delivery system, such as a delivery system for delivering an implantable device, includes a first catheter assembly (e.g., a steerable catheter assembly, etc.) and a second catheter assembly (e.g., an implant catheter assembly, etc.). The first catheter assembly includes a handle and a sheath or shaft. The sheath or shaft extends from the handle in an axial direction. In some implementations, the sheath or shaft of the first catheter assembly has a distal end portion that is steerable.

[0013] In some implementations, the second catheter assembly includes a handle or handle housing and a sheath or shaft (e.g., a catheter shaft, tube with a lumen, etc.) extending distally from the handle or handle housing. The second catheter assembly can further include an actuation element (e.g., actuation wire, actuation shaft, actuation rod, actuation tube, etc.) and a control element (e.g., a control knob, button, switch, slider, motor, combination of these, etc.). The control element can be coupled to the actuation element directly or indirectly. The actuation element can extend through the sheath and can be configured to be coupled to the implantable device.

[0014] In some implementations, the control element is a control knob that is rotatable relative to the handle housing. Rotation of the control knob causes axial movement of the actuation element with respect to the handle housing and the sheath.

[0015] In some implementations, the second catheter assembly includes one or more clasp control lines (e.g., a pair of clasp control lines, etc.) and one or more clasp control members (e.g., a pair of clasp control members).

[0016] In some implementations, the one or more clasp actuation lines (e.g., pair of clasp actuation lines) extend through the sheath or shaft. Each clasp actuation line is configured to be coupled to the implantable device. In some implementations, each clasp control member is configured to be axially and/or slidably movable along the handle housing. Movement (e.g., axial movement) of each clasp control member causes a clasp of the implantable device to be moved between an open configuration and a closed configuration. The sheath of the second catheter assembly (e.g., implant catheter assembly, etc.) can extend through the first catheter assembly (e.g., steerable catheter assembly). In some implementations, the clasp control members are configured to extend around more than half, more than 90%, all, or substantially all of the handle housing, such that they can be readily actuated by an end user in any rotational orientation of the handle housing.

[0017] In some implementations, an implantable device is coupled to an actuation element and a pair of clasp actuation lines. The actuation element and the pair of clasp actuation lines extend from a distal end of a sheath or shaft of a first catheter assembly (e.g., an implant catheter assembly, etc.). The sheath or shaft is coupled at a proximal end to a handle of the first catheter assembly. In some methods, the sheath or shaft of the first catheter assembly is advanced through a second catheter assembly (e.g., a steerable catheter assembly, etc.) to position the implantable device at a delivery site.

[0018] The method can further comprise actuating a control element (e.g., knob, button, switch, slider, motor, combination of these, etc.) on the handle to cause axial movement of the actuation element to move the implantable device from a fully elongated configuration to an open configuration (e.g., a partially-open configuration as shown in FIGS. **30-31**) or capture-ready configuration. The method can further comprise actuating the control element on the handle to cause axial movement of the actuation element to move the implantable device from the open configuration or capture-ready configuration to a closed configuration.

[0019] In some implementations, the control element is a knob, and actuation of the control element comprises rotating the knob with respect to a housing of the handle of the implant catheter assembly. The rotation of the knob causes axial movement of the actuation element to move the implantable device from a fully elongated configuration to an open configuration or capture ready configuration. The method can further include rotating the knob on the handle with respect to the housing of the handle to cause axial movement of the actuation element to move the implantable device from the open configuration or capture-ready configuration to a closed configuration.

[0020] In some implementations, rotating the knob to move the implantable device from the fully elongated configuration to the open configuration and rotating the knob to move the implantable device from the open configuration to the closed configuration each comprise rotating the knob in a clockwise direction.

[0021] In some implementations, rotating the knob to move the implantable device from the open configuration to the closed configuration comprises rotating the knob until an audible indication is provided by the catheter assembly.

[0022] In some implementations, actuating the control element causes axial movement of a release knob from a retracted position to an extended position with respect to the housing of the handle, wherein the release knob is coupled to the actuation element.

[0023] In some implementations, decoupling the implantable device comprises rotation of the release knob is effective to rotate the actuation element with respect to the implantable device, thereby decoupling the implantable device from the actuation element.

[0024] In some implementations, the method further comprises sliding one or more clasp control members on the handle proximally to cause axial movement of the one or more clasp actuation lines to open one or more clasps (e.g., a pair of clasps) on the implantable device.

[0025] In some implementations, the method further comprises sliding one or more clasp control members on the handle distally to cause axial movement of the pair of clasp actuation lines to close a pair of clasps on the implantable device.

[0026] In some implementations, sliding the pair of clasp control members on the handle comprises sliding each clasp control member of the pair of clasp control members independent of the other clasp control member of the pair of clasp control members.

[0027] The method can further comprise decoupling the implantable device from the actuation element and the pair of clasp actuation lines.

[0028] In some implementations, decoupling the implantable device comprises releasing a first end of each of the pair of clasp actuation lines and pulling a second end of each of the pair of clasp actuation lines to cause the first end of each of the pair of clasp actuation lines to be pulled through the sheath of the catheter assembly, thereby decoupling the implantable device from the pair of clasp actuation lines.

[0029] The above method(s) can be performed on a living animal or on a simulation, such as on a cadaver, cadaver heart, simulator (e.g., with body parts, heart, tissue, etc. being simulated), etc.

[0030] In some implementations, a delivery system, such as a delivery system for delivering an implantable device, includes one or more catheter assemblies. In some implementations the delivery system includes a first catheter assembly (e.g., an implant catheter assembly, etc.) and a second catheter assembly (e.g., a steerable catheter assembly). The first catheter assembly includes a handle, a nose grip, and a sheath. The handle of the first catheter assembly has a plurality of control members positioned thereon.

[0031] In some implementations, a first nose grip having a distal flange is disposed at a distal end of the handle of the first catheter assembly has a passage. The distal flange can be configured to have an outer diameter that is greater than an outer diameter of a central portion of the first nose grip. The sheath of the first catheter assembly extends distally from the handle and through the passage of the first nose grip.

[0032] In some implementations, the second catheter assembly includes a handle, a second nose grip, and a sheath. The second nose grip can be configured to have a distal flange at a distal end of the second nose grip. A proximal end of the second nose grip is connected to a distal end of the handle of the second catheter assembly. The second nose grip includes a passage or lumen. The distal flange of the second nose grip has an outer diameter that is greater than an outer diameter of a central portion of the second nose grip. The sheath of the second catheter assembly can extend distally from the handle and through the passage or lumen of the second nose grip. The sheath of the second catheter assembly has a distal end portion comprising a steerable section.

[0033] In some implementations, an implantable device is coupled to an adapter at a distal end of a sheath of a first catheter assembly (e.g., an implant catheter assembly, etc.). The sheath is coupled at a proximal end to a handle of the first catheter assembly. The sheath extends through a passage or lumen of a first nose grip. The first nose grip extends between a distal flange at a distal end and a proximal end that is connected to a distal end of the handle. In some methods, the first nose grip is coupled to a first clamp that is slidably coupled to a base plate by positioning the first nose grip within an opening of the first clamp. A second nose grip of a second catheter assembly (e.g., a steerable catheter assembly, etc.) is coupled to a second clamp slidably coupled to the base plate by positioning the second nose grip within an opening of the second clamp.

[0034] The method can also include advancing the sheath of the first catheter assembly through the second catheter assembly to position the implantable device at a delivery site. In some implementations, one or more of the first catheter assembly and the second catheter assembly are rotated relative to the base plate to position the implantable device at the delivery site.

[0035] In some implementations, the shaft of the first catheter assembly has a friction fit within at least one of a handle of the second catheter assembly and a shaft of the second catheter assembly.

[0036] In some implementations, the method includes (i) positioning a first locking knob in an unlocked position in which the first clamp is slidable with respect to the base plate, (ii) positioning a second locking knob in an unlocked position in which the second clamp is slidable with respect to the base plate, and (iii) axially moving the handle of the first catheter assembly effective to cause the first clamp and the second clamp to slide with respect to the base plate.

[0037] In some implementations, the method includes positioning the second locking knob in a locked position in which the second clamp is inhibited from sliding with respect to the base plate, and axially moving the handle of the first catheter assembly effective to cause the first clamp to slide with respect to the base plate and to move the shaft of the first catheter assembly axially with respect to the shaft of the second catheter assembly.

[0038] In some implementations, the method includes positioning the first locking knob in a locked position in which the first clamp is inhibited from sliding with respect to the base plate.

[0039] In some implementations, the first nose grip has a first outer diameter, the second nose grip has a second outer diameter, and the opening of the first clamp and the opening of the second clamp are sized identically. In some implementations, the first outer diameter is different than the second outer diameter.

[0040] In some implementations, the second outer diameter is greater than the first outer diameter such that rotating the first catheter assembly relative to the base plate has a different tactile feel as compared to rotating the second catheter assembly relative to the base plate.

[0041] In some implementations, the first nose grip is rotatable relative to the first catheter assembly and the second nose grip is rotatable relative to the second catheter assembly, and rotating at least one of the first catheter assembly and the second catheter assembly relative to the base plate to position the implantable device at the delivery site comprises rotating at least one of the first catheter assembly and the second catheter assembly relative to the base plate while the first nose grip and the second nose grip remain unrotated relative to the base plate.

[0042] In some implementations, the first catheter assembly is an implant catheter assembly, and the second catheter assembly is a steerable catheter assembly.

[0043] The above method(s) can be performed on a living animal or on a simulation, such as on a cadaver, cadaver heart, simulator (e.g., with body parts, heart, tissue, etc. being simulated), etc.

[0044] In some implementations, a catheter assembly for a transvascular delivery system includes a handle housing, and a sheath. The sheath extends longitudinally from the handle. A proximal portion of the sheath is stiffened with respect to the distal portion of the sheath.

[0045] In some implementations, a delivery system, such as a delivery system for delivering an implantable device, includes a first catheter assembly (e.g., a steerable catheter assembly, etc.) and a second catheter assembly (e.g., an implant catheter assembly). The first catheter assembly has a handle and a sheath extending from the handle in an axial direction. The sheath comprises a proximal portion and a distal portion comprising a steerable section. The second catheter assembly has a handle and a sheath comprising a proximal portion and a distal portion. The sheath is extendable or configured to extend coaxially through the sheath of the first catheter assembly. At least one of the proximal portion of the sheath of the first catheter assembly and the proximal portion of the sheath of the second catheter assembly is stiffened relative to the distal portion of the sheath of the first catheter assembly or the distal portion of the sheath of the second catheter assembly, respectively.

[0046] In some implementations, a catheter assembly for a transvascular delivery system includes a handle housing and a sheath. The sheath extends distally from the handle housing between a proximal end and a distal end. The sheath has a first outer diameter along a first length of the sheath and a second outer diameter along a second length of the sheath.

[0047] In some implementations, a catheter assembly for a transvascular delivery system comprises a handle housing and a sheath (e.g., catheter, tube, etc.) extending longitudinally from the handle. The sheath has a proximal portion and a distal portion. The proximal portion of the sheath is configured to have a different stiffness comparted to the distal portion of the sheath.

[0048] In some implementations, the proximal portion of the sheath comprises a material having a higher durometer than materials of the distal portion of the sheath.

[0049] In some implementations, only the proximal portion of the sheath comprises a braid, mesh, or woven material. In some implementations, only the distal portion of the sheath comprises a braid, mesh, or woven material. In some implementations, both the proximal portion and the distal portion of the sheath comprise a braid, mesh, or woven material.

[0050] In some implementations, only the proximal portion of the sheath comprises at least one laser-cut hypotube. In some implementations, only the distal portion of the sheath comprises at least one laser-cut hypotube. In some implementations, both the proximal portion and the distal portion of the sheath comprise at least one laser-cut hypotube.

[0051] In some implementations, the at least one laser-cut hypotube extends through an outer jacket of the sheath.

[0052] In some implementations, the sheath is a multi-layer sheath, and the at least one laser-cut hypotube comprises a layer of the multi-layer sheath.

[0053] In some implementations, the at least one laser-cut hypotube has a stiffness that varies along a length of the at least one laser-cut hypotube.

[0054] In some implementations, the sheath comprises a steerable portion. In some implementations, the steerable portion of the sheath is in the distal portion of the sheath. In some implementations, the steerable portion of the sheath comprises one or more of a pull wire, pull ring, pull wire lumen, etc. In some implementations, pull wire, pull ring, pull wire lumen, etc. are radially inside at least one of the braid (or other mesh or woven material) and the at least one laser-cut hypotube. In some implementations, pull wire, pull ring, pull wire lumen, etc. are radially outside of at least one of the braid (or other mesh or woven material) and the at least one laser-cut hypotube.

[0055] In some implementations, the sheath is a multi-layer sheath, and the proximal portion of the sheath comprises a first layer comprising at least one laser-cut hypotube and a second layer comprising a braid (or other mesh or woven material). In some implementations, the sheath is a multi-layer sheath, and the distal portion of the sheath comprises a first layer comprising at least one laser-cut hypotube and a second layer comprising a braid (or other mesh or woven material).

[0056] In some implementations, the braid, mesh, or woven material is positioned between a lumen extending through the sheath and the at least one laser-cut hypotube.

[0057] In some implementations, the proximal portion of the sheath comprises a first laser-cut hypotube along a first length of the sheath and a second laser-cut hypotube along a second length of the sheath, wherein the first laser-cut hypotube and the second laser-cut hypotube have different stiffnesses.

[0058] In some implementations, the sheath defines a lumen extending longitudinally through the sheath, and wherein the lumen has a cross-section that transitions from having a circular shape to having a non-circular shape.

[0059] The various sheaths described in any of the implementations herein can include any of the features of the sheaths described herein.

[0060] In some implementations, a delivery system for an implantable device includes a first catheter assembly (e.g., an implant catheter assembly, etc.) and a second catheter assembly (e.g., a steerable catheter assembly, etc.). The second catheter assembly has a handle and a sheath extending from the handle in an axial direction. The sheath has a steerable section. The first catheter assembly has a handle and a sheath. The sheath of the first catheter assembly extends coaxially through the sheath of the second catheter assembly. The sheath of the first catheter assembly has a first outer diameter along a first length and a second outer diameter along a second length.

[0061] In some implementations, an implantable device is coupled to an actuation element extending from a distal end of a sheath of a first catheter assembly (e.g., an implant catheter assembly, etc.). The sheath is coupled at a proximal end to a handle of the first catheter assembly. The sheath has a first outer diameter along a first length of the sheath and a second outer diameter along a second length of the sheath. In some methods, the sheath of the first catheter assembly is

advanced through a second catheter assembly (e.g., a steerable catheter assembly, etc.) to position the implantable device at a delivery site.

[0062] In some implementations, a position of the implantable device relative to the delivery site is adjusted by extending the distal end of the sheath of the first catheter assembly relative to a distal end of the sheath of the second catheter assembly. During the adjusting, the second length of the sheath is positioned coaxially within the steerable section of the sheath of the second catheter assembly.

[0063] The above method(s) can be performed on a living animal or on a simulation, such as on a cadaver, cadaver heart, simulator (e.g., with body parts, heart, tissue, etc. being simulated), etc.

[0064] In some implementations, a method of delivering an implantable device comprises obtaining a first catheter assembly coupled to the implantable device and advancing a sheath (e.g., catheter, tubing, lumen, etc.) of the first catheter assembly through a second catheter assembly to position the implantable device at a delivery site. In some implementations, the first catheter assembly comprises an actuation element extendable from a distal end of the sheath, wherein the actuation element is coupled to the implantable device.

[0065] In some implementations, the sheath is coupled at a proximal end to a handle of the first catheter assembly.

[0066] In some implementations, the sheath has a first outer diameter along a first length of the sheath and a second outer diameter along a second length of the sheath. In some implementations, the first length is between the second length of the sheath and the proximal end of the sheath of the first catheter assembly.

[0067] In some implementations, the sheath of the second catheter assembly comprises a steerable section.

[0068] In some implementations, the method includes adjusting a position of the implantable device relative to the delivery site by extending the distal end of the sheath of the first catheter assembly relative to a distal end of the sheath of the second catheter assembly. In some implementations, during the adjusting, the second length of the sheath is positioned coaxially within the steerable section of the sheath of the second catheter assembly.

[0069] In some implementations, the method includes decoupling the implantable device from the actuation element.

[0070] In some implementations, the second outer diameter is smaller than the first outer diameter. In some implementations, a difference between the first outer diameter and the second outer diameter is from about 0.25 to about 0.76 mm. In some implementations, a transition from the first outer diameter to the second outer diameter forms a smooth taper over a distance of from about 25 mm to about 50 mm.

[0071] In some implementations, the sheath includes a lubricated coating on an outer surface of the sheath along the second length of the sheath. In some implementations, the lubricated coating comprises a hydrophilic coating.

[0072] In some implementations, the first catheter assembly is an implant catheter assembly, and the second catheter assembly is a steerable catheter assembly.

[0073] The above method(s) can be performed on a living animal or on a simulation, such as on a cadaver, cadaver heart, simulator (e.g., with body parts, heart, tissue, etc. being simulated), etc.

[0074] In some implementations, a catheter assembly for controlling an implantable device comprises a handle housing, a sheath (e.g., catheter, tube, etc.) extending distally from the handle housing, and an actuation element extending through the sheath, the actuation element configured to be coupled to the implantable device. In some implementations, the catheter assembly further includes a control element coupled to the actuation element, wherein actuation of the control element causes axial movement of the actuation element with respect to the handle housing and the sheath.

[0075] In some implementations, the catheter assembly further comprises a pair of clasp actuation lines (e.g., a first clasp actuation line and a second clasp actuation line) extending through the sheath, each clasp actuation line (e.g., the first clasp actuation line and/or the second clasp actuation line) of the pair of clasp actuation lines is configured to be coupled to the implantable device.

[0076] In some implementations, the catheter assembly further comprises a first clasp control member, wherein actuation of the first clasp control member causes a first clasp of the implantable device to be moved between an open configuration and a closed configuration. In some implementation, the first clasp control member is physically or operatively coupled to the first clasp via one of the pair of clasp actuation lines (e.g., a first clasp actuation line) and such that actuation of the first clasp control member can cause axial movement of the clasp actuation line to move the first clasp between the open configuration and the closed configuration. The first clasp control member can be configured in a variety of ways, e.g., as a knob, slider, latch, switch, button, gear, etc. In some implementations, the first clasp control member is configured to extend around between 45-90% of a circumference of the handle housing, between 60-90% of a circumference of the handle housing, between 75-90% of a circumference of the handle housing, between 85-90% of a circumference of the handle housing, or 90% (or substantially 90%) of a circumference of the handle housing. or substantially 90% of a circumference of the handle housing.

[0077] In some implementations, the first clasp control member is axially movable relative to the handle housing and the sheath, and axial movement of the first clasp control member causes the first clasp of the implantable device to be moved between the open configuration and the closed configuration. In some implementations, the first clasp control member is axially movable relative to the handle housing and the sheath, and axial movement of the first clasp control member causes axial movement of one of the pair of clasp actuation lines (e.g., the first clasp actuation line) such that the first clasp of the implantable device is moved between the open configuration and the closed configuration.

[0078] In some implementations, the catheter assembly further comprises a second clasp control member, wherein actuation of the second clasp control member causes a second clasp of the implantable device to be moved between an open configuration and a closed configuration. In some implementation, the second clasp control member is physically or operatively coupled to the second clasp via one of the pair of clasp actuation lines (e.g., a second clasp actuation line) and such that actuation of the second clasp control member can cause axial movement of the clasp actuation line to move the second clasp between the open configuration and the closed configuration. The second clasp control member can be configured in a variety of ways, e.g., as a

knob, slider, latch, switch, button, gear, etc. In some implementations, the second clasp control member is configured to extend around between 45-90% of a circumference of the handle housing, between 60-90% of a circumference of the handle housing, between 75-90% of a circumference of the handle housing, between 85-90% of a circumference of the handle housing, or 90% (or substantially 90%) of a circumference of the handle housing.

[0079] In some implementations, both of the first clasp control member and the second clasp control member are configured to extend around between 60-90% of a circumference of the handle housing, between 75-90% of a circumference of the handle housing, between 85-90% of a circumference of the handle housing, or 90% (or substantially 90%) of a circumference of the handle housing such that they can be readily actuated by an end user in any rotational orientation of the handle housing. In some implementations, both of the first clasp control member and the second clasp control member are configured to extend 90% (or substantially 90%) of a circumference of the handle housing such that together they encircle the handle housing such that they can be readily actuated by an end user in any rotational orientation of the handle housing.

[0080] In some implementations, the second clasp control member is axially movable relative to the handle housing and the sheath, and wherein axial movement of the second clasp control member causes the second clasp of the implantable device to be moved between the open configuration and the closed configuration. In some implementations, the second clasp control member is axially movable relative to the handle housing and the sheath, and axial movement of the second clasp control member causes axial movement of one of the pair of clasp actuation lines (e.g., the second clasp actuation line) such that the second clasp of the implantable device is moved between the open configuration and the closed configuration.

[0081] In some implementations, the catheter assembly includes a slide lock configured to slide between (i) a first position in which the slide lock is not coupled to at least one of the first clasp control member and the second clasp control member, and (ii) a second position in which the slide lock is coupled to both the first clasp control member and the second clasp control member. In some implementations, when the slide lock is in the first position, the first clasp control member is actuatable independently of the second clasp control member, and when the slide lock is in the second position, the first clasp control member and the second clasp control member are coupled such that actuation of the first clasp member also actuates the second clasp member.

[0082] In some implementations, the first clasp control member and the second clasp control member are actuatable by axial movement thereof, and wherein when the slide lock is in the first position, the first clasp control member is axially moveable independently of the second clasp control member, and when the slide lock is in the second position, the first clasp control member and the second clasp control member are coupled such that the first clasp member and the second clasp member are configured to move axially together when actuated.

[0083] In some implementations, the handle housing comprises a first detent at a first axial position along a path of one of the pair of clasp control members to maintain the one of the pair of clasp control members in a proximal position and a second detent at a second axial position along the path of one of the pair of clasp control members to maintain the one of the pair of clasp control members in a distal position.

[0084] In some implementations, the catheter assembly further comprises an externally threaded retractor coupled to the control element and the actuation element, wherein the externally threaded retractor is rotationally fixed with respect to the handle housing, and wherein actuation of the control element advances the externally threaded retractor in an axial direction, thereby causing linear movement of the actuation element.

[0085] In some implementations, the catheter assembly further comprises a clutch spring positioned about the externally threaded retractor and configured to bias the externally threaded retractor distally towards threads of an internally threaded tube within the handle housing.

[0086] In some implementations, the control element is a control knob and rotation of the control knob causes rotation of the internally threaded tube with respect to the handle housing, which drives the externally threaded retractor to a proximal position in which external threads of the externally threaded retractor and internal threads of the internally threaded tube disengage, and wherein continued rotation of the control knob provides an audible indication.

[0087] In some implementations, a catheter assembly includes a handle housing and a sheath. The sheath extends longitudinally from the handle. The sheath comprises a woven layer. A lumen is interwoven into the woven layer. A flex control element extends through the lumen.

[0088] In some implementations, the flex control element can comprise a wire. The lumen can comprise a metal tube. The lumen can extend in a direction of a length of the sheath and/or the lumen can have a spiral configuration.

[0089] Other features, elements, and components from any of the various implementations and examples herein can also be included in the catheter assembly mutatis mutandis.

[0090] A further understanding of the nature and advantages of the present invention are set forth in the following description and claims, particularly when considered in conjunction with the accompanying drawings in which like parts bear like reference numerals.

BRIEF DESCRIPTION OF THE DRAWINGS

[0091] To further clarify various aspects of implementations of the present disclosure, a more particular description of some examples and implementations will be made by reference to various aspects of the appended drawings. It is appreciated that these drawings depict only example implementations of the present disclosure and are therefore not to be considered limiting of the scope of the disclosure. Moreover, while the figures can be drawn to scale for some examples, the figures are not necessarily drawn to scale for all examples. Examples and other features and advantages of the present disclosure will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0092] FIG. **1** illustrates a cutaway view of the human heart in a diastolic phase;

[0093] FIG. **2** illustrates a cutaway view of the human heart in a systolic phase;

[0094] FIG. **3** illustrates a cutaway view of the human heart in a systolic phase showing mitral regurgitation;

[0095] FIG. **4** is the cutaway view of FIG. **3** annotated to illustrate a natural shape of mitral valve leaflets in the systolic phase;

[0096] FIG. **5** illustrates a healthy mitral valve with the leaflets closed as viewed from an atrial side of the mitral valve;

[0097] FIG. **6** illustrates a dysfunctional mitral valve with a visible gap between the leaflets as viewed from an atrial side of the mitral valve;

[0098] FIG. **7** illustrates a tricuspid valve viewed from an atrial side of the tricuspid valve;

[0099] FIGS. **8-14** show an example of an implantable device or implant, in various stages of deployment;

[0100] FIG. **15** shows an example of an implantable device or implant that is similar to the device illustrated by FIGS. **8-14**, but where the paddles are independently controllable;

[0101] FIGS. **16-21** show the example implantable device or implant of FIGS. **8-14** being delivered and implanted within a native valve;

[0102] FIG. **22** shows a perspective view of an example implantable device or implant in a closed position;

[0103] FIG. **23** shows a front view of the implantable device or implant of FIG. **22**;

[0104] FIG. **24** shows a side view of the implantable device or implant of FIG. **22**;

[0105] FIG. **25** shows a front view of the implantable device or implant of FIG. **22** with a cover covering the paddles and a coaptation element or spacer;

[0106] FIG. **26** shows a top perspective view of the implantable device or implant of FIG. **22** in an open position;

[0107] FIG. **27** shows a bottom perspective view of the implantable device or implant of FIG. **22** in an open position;

[0108] FIG. **28** shows a clasp for use in an implantable device or implant;

[0109] FIG. **29** shows a portion of native valve tissue grasped by a clasp;

[0110] FIG. **30** shows a side view of an example implantable device or implant in a partially-open position with clasps in a closed position;

[0111] FIG. **31** shows a side view of an example implantable device or implant in a partially-open position with clasps in an open position;

[0112] FIG. **32** shows a side view of an example implantable device or implant in a half-open position with clasps in a closed position;

[0113] FIG. **33** shows a side view of an example implantable device or implant in a half-open position with clasps in an open position;

[0114] FIG. **34** shows a side view of an example implantable device or implant in a three-quarters-open position with clasps in a closed position;

[0115] FIG. **35** shows a side view of an example implantable device or implant in a three-quarters-open position with clasps in an open position;

[0116] FIG. **36** shows a side view of an example implantable device in a fully open or fully elongated position with clasps in a closed position;

[0117] FIG. **37** shows a side view of an example implantable device in a fully open or fully elongated position with clasps in an open position;

[0118] FIGS. **38-49** show the example implantable device or implant of FIGS. **30-38**, including a cover, being delivered and implanted within a native valve;

[0119] FIG. **50** is a schematic view illustrating a path of native valve leaflets along each side of a coaptation element or spacer of an example valve repair device or implant;

[0120] FIG. **51** is a top schematic view illustrating a path of native valve leaflets around a coaptation element or spacer of an example valve repair device or implant;

[0121] FIG. **52** illustrates a coaptation element or spacer in a gap of a native valve as viewed from an atrial side of the native valve;

[0122] FIG. **53** illustrates a valve repair device or implant attached to native valve leaflets with the coaptation element or spacer in the gap of the native valve as viewed from a ventricular side of the native valve;

[0123] FIG. **54** is a perspective view of a valve repair device or implant attached to native valve leaflets with the coaptation element or spacer in the gap of the native valve shown from a ventricular side of the native valve;

[0124] FIG. **55** shows a perspective view of an example implantable device or implant in a closed position;

[0125] FIG. **56** shows a perspective view of an example clasp of an example implantable device or implant in a closed position;

[0126] FIG. **57** illustrates a valve repair device with paddles in an open position;

[0127] FIG. **58** illustrates the valve repair device of FIG. **57**, in which the paddles are in the open position and gripping members are moved to create a wider gap between the gripping members and paddles;

[0128] FIG. **59** illustrates the valve repair device of FIG. **57**, in which the valve repair device is in the position shown in FIG. **57** with valve tissue placed between the gripping members and the paddles;

[0129] FIG. **60** illustrates the valve repair device of FIG. **57**, in which the gripping members are moved to lessen the gap between the gripping members and the paddles;

[0130] FIGS. **61**A-**61**B illustrate the movement of the paddles of the valve repair device of FIG. **57** from the open position to a closed position;

[0131] FIG. **62** illustrates the valve repair device of FIG. **57** in a closed position, in which the gripping members are engaging valve tissue;

[0132] FIG. **63** illustrates the valve repair device of FIG. **57** after being disconnected from a delivery device and attached to valve tissue, in which the valve repair device is in a closed and locked condition;

[0133] FIG. **64** illustrates a distal end of an example system or assembly including a delivery system and an implantable device;

[0134] FIG. **65** illustrates a proximal end of the example system or assembly of FIG. **64**;

[0135] FIG. **66** illustrates an example implant catheter assembly for use in a delivery system coupled to an implantable device;

[0136] FIG. **67** illustrates a schematic illustration of an example implant catheter assembly coupled to an implantable device, in which each of the clasp actuation lines is coupled to a clasp control member positioned on the handle and the actuation element is coupled to a control element or knob positioned on the handle;

[0137] FIG. **68** is a perspective view of an example handle of an implant catheter assembly;

[0138] FIG. **69** is a cross-section of the handle of FIG. **68** perpendicular to the plane defined by line A-A, in which one of the clasp control tubes is bisected;

[0139] FIG. **70** is another cross-section of the handle of FIG. **68** perpendicular to the plane defined by line B-B, in which the release knob is bisected;

[0140] FIG. **70**A is an enlarged portion of FIG. **70**;

[0141] FIG. **71** is another cross-section of the handle of FIG. **68** perpendicular to the plane defined by line C-C, in which the release knob and the suture locks are bisected;

[0142] FIG. **71**A is another perspective view of the handle of FIG. **68** in which a clasp setting spacer supports the clasp control tubes;

[0143] FIG. **72** is another perspective view of the handle of FIG. **68** in which the housing includes a pair of detents for fixing the clasp control members into position;

[0144] FIG. **73** is a perspective view of an example proximal end of a handle in which the release knob is in a distal position;

[0145] FIG. **74** is a perspective view of an example proximal end of a handle in which the release knob is in a proximal position;

[0146] FIG. **75** is a perspective view of a partial cut away of a handle including an example release knob having a ratcheting mechanism;

[0147] FIG. **76** is a perspective view of the release knob of FIG. **75** having the ratcheting mechanism;

[0148] FIG. **77** is a cross-sectional view of the release knob of FIGS. **75**-**76** perpendicular to the plane defined by line D-D in which the pawls are sectioned;

[0149] FIG. **78** is a cross-sectional view of an example suture lock in which a clasp actuation line is fixed to a post at one end and extends between a suture lock body and a suture lock body receptacle at a second end after having been coupled to an implantable device;

[0150] FIG. **79** is a perspective view of an example nose grip for coupling a delivery system or component thereof to a stabilization system;

[0151] FIG. **80** is a cross-sectional view of an example clamp of a stabilization system surrounding a nose grip of a delivery system or catheter assembly;

[0152] FIG. **81** is another cross-sectional view of an example clamp of a stabilization system surrounding a nose grip of a delivery system or catheter assembly;

[0153] FIG. **82**A is a perspective view of an example steerable catheter assembly including a nose grip being coupled to a clamp of a stabilization system;

[0154] FIG. **82**B is a perspective view of the example steerable catheter assembly of FIG. **82**A upon closure of the clamp;

[0155] FIG. **82**C illustrates axial movement of the steerable catheter assembly and the clamp of FIGS. **82**A-**82**B with respect to a base plate of the stabilization system;

[0156] FIG. **83**A is a perspective view of an example implant catheter assembly including a nose grip;

[0157] FIG. **83**B is a perspective view of the example implant catheter assembly of FIG. **83**A being coupled to a clamp of a stabilization system;

[0158] FIG. **83**C is a perspective view of the example implant catheter assembly of FIGS. **83**A-**83**B upon closure of the clamp;

[0159] FIG. **84** is a perspective view of a proximal end of a stabilization system coupled to a steerable catheter assembly and an implant catheter assembly and illustrating the axial movement of the steerable catheter assembly and implant catheter assembly with respect to the base plate of the stabilization system;

[0160] FIGS. **85**A and **85**B illustrate the outer diameter of the nose grips of the steerable catheter assembly and the implant catheter assembly;

[0161] FIG. **86** is a cross-section of a shaft of an implant catheter assembly having a reduced outer diameter portion and a low-friction coating positioned within a steerable portion of the shaft of a steerable catheter assembly;

[0162] FIG. **87** is another illustration of a shaft of an implant catheter assembly having a reduced outer diameter portion and a low-friction coating;

[0163] FIG. **88**A illustrates a sheath of an implant catheter assembly having a reduced outer diameter positioned within a sheath of a steerable catheter assembly in a retracted position;

[0164] FIG. **88**B illustrates the sheath of the implant catheter assembly of FIG. **88**A positioned within the sheath of the steerable catheter assembly in an extended position;

[0165] FIG. **89**A illustrates a proximal portion of a sheath of a steerable catheter assembly including a stiffening material;

[0166] FIG. **89**B illustrates a proximal portion of a sheath of an implant catheter assembly including a stiffening material;

[0167] FIG. **89**C illustrates a proximal portion of a sheath of a steerable catheter assembly and a proximal portion of a sheath of an implant catheter assembly including a stiffening material;

[0168] FIG. **90** illustrates a sheath of a steerable catheter assembly having a stiffened length between a proximal end of the steerable catheter sheath and a steerable portion;

[0169] FIG. **91** illustrates a steerable catheter assembly having two hypotubes having different stiffnesses;

[0170] FIG. **92** illustrates a steerable catheter assembly having a laser-cut hypotube positioned over a braid, mesh, or woven material to increase the stiffness of a portion of the steerable catheter assembly;

[0171] FIG. **93** illustrates four segments of a laser-cut hypotube;

[0172] FIG. **94** illustrates a hypotube having an interrupted spiral cut;

[0173] FIGS. **95**A and **95**B are radial cross-sections of example multi-layer sheaths;

[0174] FIG. **96**A is a longitudinal cross-section of another example multi-layer sheath;

[0175] FIG. **96**B is a longitudinal cross-section of a proximal portion of the multi-layer sheath of FIG. **96**A;

[0176] FIG. **97** illustrates an example catheter assembly with portions removed to illustrate internal components;

[0177] FIG. **98** illustrates an example catheter assembly with portions removed to illustrate internal components;

[0178] FIGS. **99**A, **99**B, and **99**C illustrate example braid patterns having a tube for accommodating a flex element woven therein;

[0179] FIG. **99**D is a longitudinal cross-section of an example multi-layer sheath incorporating the braid of any one of FIGS. **99**A-**99**C;

[0180] FIG. **99**E illustrates an example braid pattern having a tube for accommodating a flex element woven therein; and

[0181] FIG. **99**F is a longitudinal cross-section of an example multi-layer sheath incorporating the braid of FIG. **99**E.

DETAILED DESCRIPTION

[0182] The following description refers to the accompanying drawings, which illustrate example implementations of the present disclosure. Other implementations having different structures and operation do not depart from the scope of the present disclosure.

[0183] Example implementations of the present disclosure are directed to systems, devices, methods, etc. for repairing a defective heart valve. For example, various implementations of implantable devices, valve repair devices, implants, and systems (including systems for delivery thereof) are disclosed herein, and any combination of these options can be made unless specifically excluded. In other words, individual components of the disclosed devices and systems can be combined unless mutually exclusive or otherwise physically impossible. Further, the techniques and methods herein can be performed on a living animal or on a simulation, such as on a cadaver, cadaver heart, simulator (e.g., with the body parts, heart, tissue, etc. being simulated), etc.

[0184] As described herein, when one or more components are described as being connected, joined, affixed, coupled, attached, or otherwise interconnected, such interconnection can be direct as between the components or can be indirect such as through the use of one or more intermediary components. Also as described herein, reference to a "member," "component," or "portion" shall not be limited to a single structural member, component, or element but can include an assembly of components, members, or elements. Also as described herein, the terms "substantially" and "about" are defined as at least close to (and includes) a given value or state (preferably within 10% of, more preferably within 1% of, and most preferably within 0.1% of).

[0185] FIGS. **1** and **2** are cutaway views of the human heart H in diastolic and systolic phases, respectively. The right ventricle RV and left ventricle LV are separated from the right atrium RA and left atrium LA, respectively, by the tricuspid valve TV and mitral valve MV; i.e., the atrioventricular valves. Additionally, the aortic valve AV separates the left ventricle LV from the ascending aorta AA, and the pulmonary valve PV separates the right ventricle from the pulmonary artery PA. Each of these valves has flexible leaflets (e.g., leaflets **20**, **22** shown in FIGS. **3**-**6** and leaflets **30**, **32**, **34** shown in FIG. **7**) extending inward across the respective orifices that come together or "coapt" in the flow stream to form the one-way, fluid-occluding surfaces. The native valve repair systems of the present application are frequently described and/or illustrated with respect to the mitral valve MV. Therefore, anatomical structures of the left atrium LA and left ventricle LV will be explained in greater detail. However, the devices described herein can also be used in repairing other native valves, e.g., the devices can be used in repairing the tricuspid valve TV, the aortic valve AV, and the pulmonary valve PV.

[0186] The left atrium LA receives oxygenated blood from the lungs. During the diastolic phase, or diastole, seen in FIG. **1**, the blood that was previously collected in the left atrium LA (during the systolic phase) moves through the mitral valve MV and into the left ventricle LV by expansion of the left ventricle LV. In the systolic phase, or systole, seen in FIG. **2**, the left ventricle LV contracts to force the blood through the aortic valve AV and ascending aorta AA into the body. During systole, the leaflets of the mitral valve MV close to prevent the blood from regurgitating from the left ventricle LV and back into the left atrium LA and blood is collected in the left atrium from the pulmonary vein. In some implementations, the devices described by the present application are used to repair the function of a defective mitral valve MV. That is, the devices are configured to help close the leaflets of the mitral valve to prevent or inhibit blood from regurgitating from the left ventricle LV and back into the left atrium LA. Many of the devices described in the present application are designed to easily grasp and secure the native leaflets around a coaptation element or spacer that beneficially acts as a filler in the regurgitant orifice to prevent or inhibit back flow or regurgitation during systole, though this is not necessary.

[0187] Referring now to FIGS. **1**-**7**, the mitral valve MV includes two leaflets, the anterior leaflet **20** and the posterior leaflet **22**. The mitral valve MV also includes an annulus **24**, which is a variably dense fibrous ring of tissues that encircles the leaflets **20**, **22**. Referring to FIGS. **3** and **4**, the mitral valve MV is anchored to the wall of the left ventricle LV by chordae tendineae CT. The chordae tendineae CT are cord-like tendons that connect the papillary muscles PM (i.e., the muscles located at the base of the chordae tendineae CT and within the walls of the left ventricle LV) to the leaflets **20**, **22** of the mitral valve MV. The papillary muscles PM serve to limit the movements of leaflets **20**, **22** of the mitral valve MV and prevent the mitral valve MV from being reverted. The mitral valve MV opens and closes in response to pressure changes in the left atrium LA and the left ventricle LV. The papillary muscles PM do not open or close the mitral valve MV. Rather, the papillary muscles PM support or brace the leaflets **20**, **22** against the high pressure needed to circulate blood throughout the body. Together the papillary muscles PM and the chordae tendineae CT are known as the subvalvular apparatus, which functions to keep the mitral valve MV from prolapsing into the left atrium LA when the mitral valve closes. As seen from a Left Ventricular Outflow Tract (LVOT) view shown in FIG. **3**, the anatomy of the leaflets **20**, **22** is such that the inner sides of the leaflets coapt at the free end portions and the leaflets **20**, **22** start receding or spreading apart from each other. The leaflets **20**, **22** spread apart in the atrial direction, until each leaflet meets with the mitral annulus.

[0188] Various disease processes can impair proper function of one or more of the native valves of the heart H. These disease processes include degenerative processes (e.g., Barlow's Disease, fibroelastic deficiency, etc.), inflammatory processes (e.g., Rheumatic Heart Disease), and infectious processes (e.g., endocarditis, etc.). In addition, damage to the left ventricle LV or the right ventricle RV from prior heart attacks (i.e., myocardial infarction secondary to coronary artery disease) or other heart diseases (e.g., cardiomyopathy, etc.) can distort a native valve's geometry, which can cause the native valve to dysfunction. However, the majority of patients undergoing valve surgery, such as surgery to the mitral valve MV, suffer from a degenerative disease that causes a malfunction in a leaflet (e.g., leaflets **20**, **22**) of a native valve (e.g., the mitral valve MV), which results in prolapse and regurgitation.

[0189] Generally, a native valve may malfunction in different ways: including (1) valve stenosis; and (2) valve regurgitation. Valve stenosis occurs when a native valve

does not open completely and thereby causes an obstruction of blood flow. Typically, valve stenosis results from buildup of calcified material on the leaflets of a valve, which causes the leaflets to thicken and impairs the ability of the valve to fully open to permit forward blood flow. Valve regurgitation occurs when the leaflets of the valve do not close completely thereby causing blood to leak back into the prior chamber (e.g., causing blood to leak from the left ventricle to the left atrium).

[0190] There are three main mechanisms by which a native valve becomes regurgitant or incompetent-which include Carpentier's type I, type II, and type III malfunctions. A Carpentier type I malfunction involves the dilation of the annulus such that normally functioning leaflets are distracted from each other and fail to form a tight seal (i.e., the leaflets do not coapt properly). Included in a type I mechanism malfunction are perforations of the leaflets, as are present in endocarditis. A Carpentier's type II malfunction involves prolapse of one or more leaflets of a native valve above a plane of coaptation. A Carpentier's type III malfunction involves restriction of the motion of one or more leaflets of a native valve such that the leaflets are abnormally constrained below the plane of the annulus. Leaflet restriction can be caused by rheumatic disease (Ma) or dilation of a ventricle (IIIb).

[0191] Referring to FIG. **5**, when a healthy mitral valve MV is in a closed position, the anterior leaflet **20** and the posterior leaflet **22** coapt, which prevents blood from leaking from the left ventricle LV to the left atrium LA. Referring to FIGS. **3** and **6**, mitral regurgitation MR occurs when the anterior leaflet **20** and/or the posterior leaflet **22** of the mitral valve MV is displaced into the left atrium LA during systole so that the edges of the leaflets **20**, **22** are not in contact with each other. This failure to coapt causes a gap **26** between the anterior leaflet **20** and the posterior leaflet **22**, which allows blood to flow back into the left atrium LA from the left ventricle LV during systole, as illustrated by the mitral regurgitation MR flow path shown in FIG. **3**. Referring to FIG. **6**, the gap **26** can have a width W between about 2.5 mm and about 17.5 mm, between about 5 mm and about 15 mm, between about 7.5 mm and about 12.5 mm, or about 10 mm. In some situations, the gap **26** can have a width W greater than 15 mm. As set forth above, there are several different ways that a leaflet (e.g., leaflets **20**, **22** of mitral valve MV) may malfunction which can thereby lead to valvular regurgitation.

[0192] In any of the above-mentioned situations, a valve repair device or implant is desired that is capable of engaging the anterior leaflet **20** and the posterior leaflet **22** to close the gap **26** and prevent or inhibit regurgitation of blood through the mitral valve MV. As can be seen in FIG. **4**, an abstract representation of an implantable device, valve repair device, or implant **10** is shown implanted between the leaflets **20**, **22** such that regurgitation does not occur during systole (compare FIG. **3** with FIG. **4**). In some implementations, the coaptation element (e.g., spacer, coaption element, gap filler, etc.) of the device **10** has a generally tapered or triangular shape that naturally adapts to the native valve geometry and to its expanding leaflet nature (toward the annulus). In this application, the terms spacer, coaption element, coaptation element, and gap filler are used interchangeably and refer to an element that fills a portion of the space between native valve leaflets and/or that is configured such that the native valve leaflets engage or "coapt" against (e.g., such that the native leaflets coapt against the coaption element, coaptation element, spacer, etc. instead of only against one another)).

[0193] Although stenosis or regurgitation can affect any valve, stenosis is predominantly found to affect either the aortic valve AV or the pulmonary valve PV, and regurgitation is predominantly found to affect either the mitral valve MV or the tricuspid valve TV Both valve stenosis and valve regurgitation increase the workload of the heart H and may lead to very serious conditions if left un-treated; such as endocarditis, congestive heart failure, permanent heart damage, cardiac arrest, and ultimately death. Because the left side of the heart (i.e., the left atrium LA, the left ventricle LV, the mitral valve MV, and the aortic valve AV) are primarily responsible for circulating the flow of blood throughout the body. Accordingly, because of the substantially higher pressures on the left side heart dysfunction of the mitral valve MV or the aortic valve AV is particularly problematic and often life threatening.

[0194] Malfunctioning native heart valves can either be repaired or replaced. Repair typically involves the preservation and correction of the patient's native valve. Replacement typically involves replacing the patient's native valve with a biological or mechanical substitute. Typically, the aortic valve AV and pulmonary valve PV are more prone to stenosis. Because stenotic damage sustained by the leaflets is irreversible, treatments for a stenotic aortic valve or stenotic pulmonary valve can be removal and replacement of the valve with a surgically implanted heart valve, or displacement of the valve with a transcatheter heart valve. The mitral valve MV and the tricuspid valve TV are more prone to deformation of leaflets and/or surrounding tissue, which, as described above, prevents the mitral valve MV or tricuspid valve TV from closing properly and allows for regurgitation or back flow of blood from the ventricle into the atrium (e.g., a deformed mitral valve MV may allow for regurgitation or back flow from the left ventricle LV to the left atrium LA as shown in FIG. **3**). The regurgitation or back flow of blood from the ventricle to the atrium results in valvular insufficiency. Deformations in the structure or shape of the mitral valve MV or the tricuspid valve TV are often repairable. In addition, regurgitation can occur due to the chordae tendineae CT becoming dysfunctional (e.g., the chordae tendineae CT may stretch or rupture), which allows the anterior leaflet **20** and the posterior leaflet **22** to be reverted such that blood is regurgitated into the left atrium LA. The problems occurring due to dysfunctional chordae tendineae CT can be repaired by repairing the chordae tendineae CT or the structure of the mitral valve MV (e.g., by securing the leaflets **20**, **22** at the affected portion of the mitral valve).

[0195] The devices and procedures disclosed herein often make reference to repairing the structure of a mitral valve. However, it should be understood that the devices and concepts provided herein can be used to repair any native valve, as well as any component of a native valve. Such devices can be used between the leaflets **20**, **22** of the mitral valve MV to prevent or inhibit regurgitation of blood from the left ventricle into the left atrium. With respect to the tricuspid valve TV (FIG. **7**), any of the devices and concepts herein can be used between any two of the anterior leaflet **30**, septal leaflet **32**, and posterior leaflet **34** to prevent or inhibit regurgitation of blood from the right ventricle into the right atrium. In addition, any of the devices and concepts pro-

vided herein can be used on all three of the leaflets **30**, **32**, **34** together to prevent or inhibit regurgitation of blood from the right ventricle to the right atrium. That is, the valve repair devices or implants provided herein can be centrally located between the three leaflets **30**, **32**, **34**.

[0196] An example implant or implantable device (e.g., implantable prosthetic device, etc.) can optionally have a coaptation element (e.g., spacer, coaption element, gap filler, etc.) and at least one anchor (e.g., one, two, three, or more). In some implementations, an implantable device or implant can have any combination or sub-combination of the features disclosed herein without a coaptation element. When included, the coaptation element (e.g., coaption element, spacer, etc.) is configured to be positioned within the native heart valve orifice to help fill the space between the leaflets and form a more effective seal, thereby reducing or preventing regurgitation described above. The coaptation element can have a structure that is impervious to blood (or that resists blood flow therethrough) and that allows the native leaflets to close around the coaptation element during ventricular systole to block blood from flowing from the left or right ventricle back into the left or right atrium, respectively. The device or implant can be configured to seal against two or three native valve leaflets; that is, the device can be used in the native mitral (bicuspid) and tricuspid valves. The coaptation element is sometimes referred to herein as a spacer because the coaptation element can fill a space between improperly functioning native leaflets (e.g., mitral valve leaflets **20**, **22** or tricuspid valve leaflets **30**, **32**, **34**) that do not close completely.

[0197] The optional coaptation element (e.g., spacer, coaption element, etc.) can have various shapes. In some implementations, the coaptation element can have an elongated cylindrical shape having a round cross-sectional shape. In some implementations, the coaptation element can have an oval cross-sectional shape, an ovoid cross-sectional shape, a crescent cross-sectional shape, a rectangular cross-sectional shape, or various other non-cylindrical shapes. In some implementations, the coaptation element can have an atrial portion positioned in or adjacent to the atrium, a ventricular or lower portion positioned in or adjacent to the ventricle, and a side surface that extends between the native leaflets. In some implementations configured for use in the tricuspid valve, the atrial or upper portion is positioned in or adjacent to the right atrium, and the ventricular or lower portion is positioned in or adjacent to the right ventricle, and the side surface that extends between the native tricuspid leaflets.

[0198] In some implementations, the anchor can be configured to secure the device to one or both of the native leaflets such that the coaptation element is positioned between the two native leaflets. In some implementations configured for use in the tricuspid valve, the anchor is configured to secure the device to one, two, or three of the tricuspid leaflets such that the coaptation element is positioned between the three native leaflets. In some implementations, the anchor can attach to the coaptation element at a location adjacent the ventricular portion of the coaptation element. In some implementations, the anchor can attach to an actuation element, such as a shaft or actuation wire, to which the coaptation element is also attached. In some implementations, the anchor and the coaptation element can be positioned independently with respect to each other by separately moving each of the anchor and the coaptation element along the longitudinal axis of the actuation element (e.g., actuation shaft, actuation rod, actuation tube, actuation wire, etc.). In some implementations, the anchor and the coaptation element can be positioned simultaneously by moving the anchor and the coaptation element together along the longitudinal axis of the actuation element, e.g., shaft, actuation wire, etc.). The anchor can be configured to be positioned behind a native leaflet when implanted such that the leaflet is grasped by the anchor.

[0199] The device or implant can be configured to be implanted via a delivery system or other means for delivery. The delivery system can comprise one or more of a guide/delivery sheath, a delivery catheter, a steerable catheter, an implant catheter, tube, combinations of these, etc. The coaptation element and the anchor can be compressible to a radially compressed state and can be self-expandable to a radially expanded state when compressive pressure is released. The device can be configured for the anchor to be expanded radially away from the still-compressed coaptation element initially in order to create a gap between the coaptation element and the anchor. A native leaflet can then be positioned in the gap. The coaptation element can be expanded radially, closing the gap between the coaptation element and the anchor and capturing the leaflet between the coaptation element and the anchor. In some implementations, the anchor and coaptation element are optionally configured to self-expand. The implantation methods for various implementations can be different and are more fully discussed below with respect to each implementation. Additional information regarding these and other delivery methods can be found in U.S. Pat. No. 8,449,599 and U.S. Patent Application Publication Nos. 2014/0222136, 2014/0067052, 2016/0331523, and PCT patent application publication Nos. WO2020/076898, each of which is incorporated herein by reference in its entirety for all purposes. These method(s) can be performed on a living animal or on a simulation, such as on a cadaver, cadaver heart, simulator (e.g., with the body parts, heart, tissue, etc. being simulated), etc. mutatis mutandis.

[0200] The disclosed devices or implants can be configured such that the anchor is connected to a leaflet, taking advantage of the tension from native chordae tendineae to resist high systolic pressure urging the device toward the left atrium. During diastole, the devices can rely on the compressive and retention forces exerted on the leaflet that is grasped by the anchor.

[0201] Referring now to FIGS. **8-15**, a schematically illustrated implantable device or implant **100** (e.g., a prosthetic spacer device, valve repair device, etc.) is shown in various stages of deployment. The device or implant **100** and other similar devices/implants are described in more detail in PCT patent application publication Nos. WO2018/195215, WO2020/076898, and WO 2019/139904, which are incorporated herein by reference in their entirety. The device **100** can include any other features for an implantable device or implant discussed in the present application or the applications cited above, and the device **100** can be positioned to engage valve tissue (e.g., leaflets **20**, **22**, **30**, **32**, **34**) as part of any suitable valve repair system (e.g., any valve repair system disclosed in the present application or the applications cited above).

[0202] The device or implant **100** is deployed from a delivery system **102** or other means for delivery. The delivery system **102** can comprise one or more of a catheter, a

sheath, a guide catheter/sheath, a delivery catheter/sheath, a steerable catheter, an implant catheter, a tube, a channel, a pathway, combinations of these, etc. The device or implant **100** includes a coaptation portion **104** and an anchor portion **106**.

[0203] In some implementations, the coaptation portion **104** of the device or implant **100** includes a coaptation element **110** (e.g., spacer, plug, filler, foam, sheet, membrane, coaption element, etc.) that is adapted to be implanted between leaflets of a native valve (e.g., a native mitral valve, native tricuspid valve, etc.) and is slidably attached to an actuation element **112** (e.g., actuation wire, actuation shaft, actuation tube, etc.). The anchor portion **106** includes one or more anchors **108** that are actuatable between open and closed conditions and can take a wide variety of forms, such as, for example, paddles, gripping elements, or the like. Actuation of the means for actuating or actuation element **112** opens and closes the anchor portion **106** of the device **100** to grasp the native valve leaflets during implantation. The means for actuating or actuation element **112** (as well as other means for actuating and actuation elements herein) can take a wide variety of different forms (e.g., as a wire, rod, shaft, tube, screw, suture, line, strip, combination of these, etc.), be made of a variety of different materials, and have a variety of configurations. As one example, the actuation element can be threaded such that rotation of the actuation element moves the anchor portion **106** relative to the coaptation portion **104**. Or, the actuation element can be unthreaded, such that pushing or pulling the actuation element **112** moves the anchor portion **106** relative to the coaptation portion **104**.

[0204] The anchor portion **106** and/or anchors of the device **100** include outer paddles **120** and inner paddles **122** that are, in some implementations, connected between a cap **114** and the means for coapting or coaptation element **110** by portions **124**, **126**, **128**. The portions **124**, **126**, **128** can be jointed and/or flexible to move between all of the positions described below. The interconnection of the outer paddles **120**, the inner paddles **122**, the coaptation element **110**, and the cap **114** by the portions **124**, **126**, and **128** can constrain the device to the positions and movements illustrated herein.

[0205] In some implementations, the delivery system **102** includes a steerable catheter, implant catheter, and means for actuating or actuation element **112** (e.g., actuation wire, actuation shaft, etc.). These can be configured to extend through a guide catheter/sheath (e.g., a transseptal sheath, etc.). In some implementations, the means for actuating or actuation element **112** extends through a delivery catheter and the means for coapting or coaptation element **110** to the distal end (e.g., a cap **114** or other attachment portion at the distal connection of the anchor portion **106**). Extending and retracting the actuation element **112** increases and decreases the spacing between the coaptation element **110** and the distal end of the device (e.g., the cap **114** or other attachment portion), respectively. In some implementations, a collar or other attachment element removably attaches the coaptation element **110** to the delivery system **102**, either directly or indirectly, so that the means for actuating or actuation element **112** slides through the collar or other attachment element and, in some implementations, through a means for coapting or coaptation element **110** during actuation to open and close the paddles **120**, **122** of the anchor portion **106** and/or anchors **108**.

[0206] In some implementation, the anchor portion **106** and/or anchors **108** can include attachment portions or gripping members. The illustrated gripping members can comprise clasps **130** that include a base or fixed arm **132**, a moveable arm **134**, optional barbs, friction-enhancing elements, or other means for securing **136** (e.g., protrusions, ridges, grooves, textured surfaces, adhesive, etc.), and a joint portion **138**. The fixed arms **132** are attached to the inner paddles **122**. In some implementations, the fixed arms **132** are attached to the inner paddles **122** with the joint portion **138** disposed proximate means for coapting or coaptation element **110**. In some implementations, the clasps (e.g., barbed clasps, etc.) have flat surfaces and do not fit in a recess of the inner paddle. Rather, the flat portions of the clasps are disposed against the surface of the inner paddle **122**. The joint portion **138** provides a spring force between the fixed and moveable arms **132**, **134** of the clasp **130**. The joint portion **138** can be any suitable joint, such as a flexible joint, a spring joint, a pivot joint, or the like. In some implementations, the joint portion **138** is a flexible piece of material integrally formed with the fixed and moveable arms **132**, **134**. The fixed arms **132** are attached to the inner paddles **122** and remain stationary or substantially stationary relative to the inner paddles **122** when the moveable arms **134** are opened to open the clasps **130** and expose the optional barbs, friction-enhancing elements, or means for securing **136**.

[0207] In some implementations, the clasps **130** are opened by applying tension to actuation lines **116** attached to the moveable arms **134**, thereby causing the moveable arms **134** to articulate, flex, or pivot on the joint portions **138**. The actuation lines **116** extend through the delivery system **102** (e.g., through a steerable catheter and/or an implant catheter). Other actuation mechanisms are also possible.

[0208] The actuation line **116** can take a wide variety of forms, such as, for example, a line, a suture, a wire, a rod, a catheter, or the like. The clasps **130** can be spring loaded so that in the closed position the clasps **130** continue to provide a pinching force on the grasped native leaflet. This pinching force remains constant regardless of the position of the inner paddles **122**. Optional barbs, friction-enhancing elements, or other means for securing **136** of the clasps **130** can grab, pinch, and/or pierce the native leaflets to further secure the native leaflets.

[0209] During implantation, the paddles **120**, **122** can be opened and closed, for example, to grasp the native leaflets (e.g., native mitral valve leaflets, etc.) between the paddles **120**, **122** and/or between the paddles **120**, **122** and a means for coapting or coaptation element **110**. The clasps **130** can be used to grasp and/or further secure the native leaflets by engaging the leaflets with optional barbs, friction-enhancing elements, or means for securing **136** and pinching the leaflets between the moveable and fixed arms **134**, **132**. The friction-enhancing elements, or other means for securing **136** (e.g., barbs, protrusions, ridges, grooves, textured surfaces, adhesive, etc.) of the clasps **130** increase friction with the leaflets or can partially or completely puncture the leaflets. The actuation lines **116** can be actuated separately so that each clasp **130** can be opened and closed separately. Separate operation allows one leaflet to be grasped at a time, or for the repositioning of a clasp **130** on a leaflet that was insufficiently grasped, without altering a successful grasp on the other leaflet. The clasps **130** can be opened and closed

relative to the position of the inner paddle **122** (as long as the inner paddle is in an open or at least partially open position), thereby allowing leaflets to be grasped in a variety of positions as the particular situation requires.

[0210] Referring now to FIG. **8**, the device **100** is shown in an elongated or fully open condition for deployment from an implant delivery catheter of the delivery system **102**. The device **100** is disposed at the end of the catheter in the fully open position, because the fully open position takes up the least space and allows the smallest catheter to be used (or the largest device **100** to be used for a given catheter size). In the elongated condition the cap **114** is spaced apart from the means for coapting or coaptation element **110** such that the paddles **120**, **122** are fully extended. In some implementations, an angle formed between the interior of the outer and inner paddles **120**, **122** is approximately 180 degrees. The clasps **130** are kept in a closed condition during deployment through the delivery system **102** so that the optional barbs, friction-enhancing elements, or other means for securing **136** (FIG. **9**) do not catch or damage the delivery system **102** or tissue in the patient's heart. The actuation lines **116** can attach to the moveable arms **134**.

[0211] Referring now to FIG. **9**, the device **100** is shown in an elongated detangling condition, similar to FIG. **8**, but with the clasps **130** in a fully open position, ranging from about 140 degrees to about 200 degrees, from about 170 degrees to about 190 degrees, or about 180 degrees between fixed and moveable portions **132**, **134** of the clasps **130**. Fully opening the paddles **120**, **122** and the clasps **130** has been found to improve ease of detanglement or detachment from anatomy of the patient, such as the chordae tendineae CT, during implantation of the device **100**.

[0212] Referring now to FIG. **10**, the device **100** is shown in a shortened or fully closed condition. The compact size of the device **100** in the shortened condition allows for easier maneuvering and placement within the heart. To move the device **100** from the elongated condition to the shortened condition, the means for actuating or actuation element **112** is retracted to pull the cap **114** towards the means for coapting or coaptation element **110**. The connection portion (s) **126** (e.g., joint(s), flexible connection(s), etc.) between the outer paddle **120** and inner paddle **122** are constrained in movement such that compression forces acting on the outer paddle **120** from the cap **114** being retracted towards the means for coapting or coaptation element **110** cause the paddles or gripping elements to move radially outward. During movement from the open to closed position, the outer paddles **120** maintain an acute angle with the means for actuating or actuation element **112**. The outer paddles **120** can optionally be biased toward a closed position. The inner paddles **122** during the same motion move through a considerably larger angle as they are oriented away from the means for coapting or coaptation element **110** in the open condition and collapse along the sides of the means for coapting or coaptation element **110** in the closed condition. In some implementations, the inner paddles **122** are thinner and/or narrower than the outer paddles **120**, and the connection portions **126**, **128** (e.g., joints, flexible connections, etc.) connected to the inner paddles **122** can be thinner and/or more flexible. For example, this increased flexibility can allow more movement than the connection portion **124** connecting the outer paddle **120** to the cap **114**. In some implementations, the outer paddles **120** are narrower than the inner paddles **122**. The connection portions **126**, **128** connected to the inner paddles **122** can be more flexible, for example, to allow more movement than the connection portion **124** connecting the outer paddle **120** to the cap **114**. In some implementations, the inner paddles **122** can be the same or substantially the same width as the outer paddles

[0213] Referring now to FIGS. **11-13**, the device **100** is shown in a partially open, grasp-ready condition. To transition from the fully closed to the partially open condition, the means for actuating or actuation element (e.g., actuation wire, actuation shaft, etc.) is extended to push the cap **114** away from the means for coapting or coaptation element **110**, thereby pulling on the outer paddles **120**, which in turn pull on the inner paddles **122**, causing the anchors or anchor portion **106** to partially unfold. The actuation lines **116** are also retracted to open the clasps **130** so that the leaflets can be grasped. In some implementations, the pair of inner and outer paddles **122**, **120** are moved in unison, rather than independently, by a single means for actuating or single actuation element **112**. Also, the positions of the clasps **130** are dependent on the positions of the paddles **122**, **120**. For example, referring to FIG. **10** closing the paddles **122**, **120** also closes the clasps. In some implementations, the paddles **120**, **122** can be independently controllable. For example, the device **100** can have two actuation elements and two independent caps (or other attachment portions), such that one independent actuation element (e.g., wire, shaft, etc.) and cap (or other attachment portion) are used to control one paddle, and the other independent actuation element and cap (or other attachment portion) are used to control the other paddle.

[0214] Referring now to FIG. **12**, one of the actuation lines **116** is extended to allow one of the clasps **130** to close. Referring now to FIG. **13**, the other actuation line **116** is extended to allow the other clasp **130** to close. Either or both of the actuation lines **116** can be repeatedly actuated to repeatedly open and close the clasps **130**.

[0215] Referring now to FIG. **14**, the device **100** is shown in a fully closed and deployed condition. The delivery system **102** or means for delivery and means for actuating or actuation element **112** are retracted and the paddles **120**, **122** and clasps **130** remain in a fully closed position. Once deployed, the device **100** can be maintained in the fully closed position with a mechanical latch or can be biased to remain closed through the use of spring materials, such as steel, other metals, plastics, composites, etc. or shape-memory alloys such as Nitinol. For example, the connection portions **124**, **126**, **128**, the joint portions **138**, and/or the inner and outer paddles **122**, and/or an additional biasing component (not shown) can be formed of metals such as steel or shape-memory alloy, such as Nitinol-produced in a wire, sheet, tubing, or laser sintered powder—and are biased to hold the outer paddles **120** closed around the means for coapting or coaptation element **110** and the clasps **130** pinched around native leaflets. Similarly, the fixed and moveable arms **132**, **134** of the clasps **130** are biased to pinch the leaflets. In some implementations, the attachment or connection portions **124**, **126**, **128**, joint portions **138**, and/or the inner and outer paddles **122**, and/or an additional biasing component (not shown) can be formed of any other suitably elastic material, such as a metal or polymer material, to maintain the device **100** in the closed condition after implantation.

[0216] FIG. **15** illustrates an example where the paddles **120**, **122** are independently controllable. The device **101**

illustrated by FIG. **15** is similar to the device **100** illustrated by FIG. **11**, except the device **101** of FIG. **15** includes an actuation element that is configured as two independent actuation elements or actuation wires **111**, **113** that are coupled to two independent caps **115**, **117**. To transition a first inner paddle **122** and a first outer paddle **120** from the fully closed to the partially open condition, the means for actuating or actuation element **111** is extended to push the cap **115** away from the means for coapting or coaptation element **110**, thereby pulling on the outer paddle **120**, which in turn pulls on the inner paddle **122**, causing the first anchor **108** to partially unfold. To transition a second inner paddle **122** and a second outer paddle **120** from the fully closed to the partially open condition, the means for actuating or actuation element **113** is extended to push the cap **115** away from the means for coapting or coaptation element **110**, thereby pulling on the outer paddle **120**, which in turn pulls on the inner paddle **122**, causing the second anchor **108** to partially unfold. The independent paddle control illustrated by FIG. **15** can be implemented on any of the devices disclosed by the present application. For comparison, in the example illustrated by FIG. **11**, the pair of inner and outer paddles **122**, **120** are moved in unison, rather than independently, by a single means for actuating or actuation element **112**.

[0217] Referring now to FIGS. **16-21**, the implantable device **100** of FIGS. **8-14** is shown being delivered and implanted within the native mitral valve MV of the heart H. Referring to FIG. **16**, a delivery sheath/catheter is inserted into the left atrium LA through the septum and the implant/device **100** is deployed from the delivery catheter/sheath in the fully open condition as illustrated in FIG. **16**. The means for actuating or actuation element **112** is then retracted to move the implant/device into the fully closed condition shown in FIG. **17**.

[0218] As can be seen in FIG. **18**, the implant/device is moved into position within the mitral valve MV into the ventricle LV and partially opened so that the leaflets **20**, **22** can be grasped. For example, a steerable catheter can be advanced and steered or flexed to position the steerable catheter as illustrated by FIG. **18**. The implant catheter connected to the implant/device can be advanced from inside the steerable catheter to position the implant as illustrated by FIG. **18**.

[0219] Referring now to FIG. **19**, the implant catheter can be retracted into the steerable catheter to position the mitral valve leaflets **20**, **22** in the clasps **130**. An actuation line **116** is extended to close one of the clasps **130**, capturing a leaflet **20**. FIG. **20** shows the other actuation line **116** being then extended to close the other clasp **130**, capturing the remaining leaflet **22**. Lastly, as can be seen in FIG. **21**, the delivery system **102** (e.g., steerable catheter, implant catheter, etc.), means for actuating or actuation element **112** and actuation lines **116** are then retracted and the device or implant **100** is fully closed and deployed in the native mitral valve MV.

[0220] Referring now to FIGS. **22-27**, an example of an implantable device or implant or implant **200** is shown. The implantable device **200** is one of the many different configurations that the device **100** that is schematically illustrated in FIGS. **8-14** can take. The device **200** can include any other features for an implantable device or implant discussed in the present application, and the device **200** can be positioned to engage valve tissue **20**, **22** as part of any suitable valve repair system (e.g., any valve repair system disclosed in the present application). The device/implant **200** can be a prosthetic spacer device, valve repair device, or another type of implant that attaches to leaflets of a native valve.

[0221] In some implementations, the implantable device or implant **200** includes a coaptation portion **204**, a proximal or attachment portion **209**, an anchor portion **206**, and a distal portion **207**. In some implementations, the coaptation portion **204** of the device optionally includes a coaptation element **210** (e.g., a spacer, coaption element, plug, membrane, sheet, etc.) for implantation between leaflets of a native valve. In some implementations, the anchor portion **206** includes a plurality of anchors **208**. The anchors can be configured in a variety of ways. In some implementations, each anchor **208** includes outer paddles **220**, inner paddles **222**, paddle extension members or paddle frames **224**, and clasps **230**. In some implementations, the attachment portion **209** includes a first or proximal collar **211** (or other attachment element) for engaging with a capture mechanism **213** (FIGS. **43-49**) of a delivery system **202** (FIGS. **38-42** and **49**). Delivery system **202** can be the same as or similar to delivery system **102** described elsewhere and can comprise one or more of a catheter, a sheath, a guide catheter/sheath, a delivery catheter/sheath, a steerable catheter, an implant catheter, a tube, a channel, a pathway, combinations of these, etc.

[0222] In some implementations, the coaptation element **210** and paddles **220**, **222** are formed from a flexible material that can be a metal fabric, such as a mesh, woven, braided, or formed in any other suitable way or a laser cut or otherwise cut flexible material. The material can be cloth, shape-memory alloy wire-such as Nitinol—to provide shape-setting capability, or any other flexible material suitable for implantation in the human body.

[0223] An actuation element **212** (e.g., actuation shaft, actuation rod, actuation tube, actuation wire, actuation line, etc.) extends from the delivery system **202** to engage and enable actuation of the implantable device or implant **200**. In some implementations, the actuation element **212** extends through the capture mechanism **213**, proximal collar **211**, and coaptation element **210** to engage a cap **214** of the distal portion **207**. The actuation element **212** can be configured to removably engage the cap **214** with a threaded connection, or the like, so that the actuation element **212** can be disengaged and removed from the device **200** after implantation.

[0224] The coaptation element **210** extends from the proximal collar **211** (or other attachment element) to the inner paddles **222**. In some implementations, the coaptation element **210** has a generally elongated and round shape, though other shapes and configurations are possible. In some implementations, the coaptation element **210** has an elliptical shape or cross-section when viewed from above (e.g., FIG. **51**) and has a tapered shape or cross-section when seen from a front view (e.g., FIG. **23**) and a round shape or cross-section when seen from a side view (e.g., FIG. **24**). A blend of these three geometries can result in the three-dimensional shape of the illustrated coaptation element **210** that achieves the benefits described herein. The round shape of the coaptation element **210** can also be seen, when viewed from above, to substantially follow or be close to the shape of the paddle frames **224**.

[0225] The size and/or shape of the coaptation element **210** can be selected to minimize the number of implants that

a single patient will require (preferably one), while at the same time maintaining low transvalvular gradients. In some implementations, the anterior-posterior distance at the top of the coaptation element is about 5 mm, and the medial-lateral distance of the coaptation element at its widest is about 10 mm. In some implementations, the overall geometry of the device **200** can be based on these two dimensions and the overall shape strategy described above. It should be readily apparent that the use of other anterior-posterior distance anterior-posterior distance and medial-lateral distance as starting points for the device will result in a device having different dimensions. Further, using other dimensions and the shape strategy described above will also result in a device having different dimensions.

[0226] In some implementations, the outer paddles **220** are jointably attached to the cap **214** of the distal portion **207** by connection portions **221** and to the inner paddles **222** by connection portions **223**. The inner paddles **222** are jointably attached to the coaptation element by connection portions **225**. In this manner, the anchors **208** are configured similar to legs in that the inner paddles **222** are like upper portions of the legs, the outer paddles **220** are like lower portions of the legs, and the connection portions **223** are like knee portions of the legs.

[0227] In some implementations, the inner paddles **222** are stiff, relatively stiff, rigid, have rigid portions and/or are stiffened by a stiffening member or a fixed portion **232** of the clasps **230**. The stiffening of the inner paddle allows the device to move to the various different positions shown and described herein. The inner paddle **222**, the outer paddle **220**, the coaptation can all be interconnected as described herein, such that the device **200** is constrained to the movements and positions shown and described herein.

[0228] In some implementations, the paddle frames **224** are attached to the cap **214** at the distal portion **207** and extend to the connection portions **223** between the inner and outer paddles **222**, **220**. In some implementations, the paddle frames **224** are formed of a material that is more rigid and stiff than the material forming the paddles **222**, **220** so that the paddle frames **224** provide support for the paddles **222**, **220**.

[0229] The paddle frames **224** provide additional pinching force between the inner paddles **222** and the coaptation element **210** and assist in wrapping the leaflets around the sides of the coaptation element **210** for a better seal between the coaptation element **210** and the leaflets, as can be seen in FIG. **51**. That is, the paddle frames **224** can be configured with a round three-dimensional shape extending from the cap **214** to the connection portions **223** of the anchors **208**. The connections between the paddle frames **224**, the outer and inner paddles **220**, **222**, the cap **214**, and the coaptation element **210** can constrain each of these parts to the movements and positions described herein. In particular the connection portion **223** is constrained by its connection between the outer and inner paddles **220**, **222** and by its connection to the paddle frame **224**. Similarly, the paddle frame **224** is constrained by its attachment to the connection portion **223** (and thus the inner and outer paddles **222**, **220**) and to the cap **214**.

[0230] Configuring the paddle frames **224** in this manner provides increased surface area compared to the outer paddles **220** alone. This can, for example, make it easier to grasp and secure the native leaflets. The increased surface area can also distribute the clamping force of the paddles **220** and paddle frames **224** against the native leaflets over a relatively larger surface of the native leaflets in order to further protect the native leaflet tissue. Referring again to FIG. **51**, the increased surface area of the paddle frames **224** can also allow the native leaflets to be clamped to the implantable device or implant **200**, such that the native leaflets coapt entirely around the coaptation member or coaptation element **210**. This can, for example, improve sealing of the native leaflets **20**, **22** and thus prevent or further reduce mitral regurgitation.

[0231] In some implementations the clasps comprise a moveable arm coupled to the anchors. In some implementations, the clasps **230** include a base or fixed arm **232**, a moveable arm **234**, optional barbs **236**, and a joint portion **238**. The fixed arms **232** are attached to the inner paddles **222**, with the joint portion **238** disposed proximate the coaptation element **210**. The joint portion **238** is spring-loaded so that the fixed and moveable arms **232**, **234** are biased toward each other when the clasp **230** is in a closed condition. In some implementations, the clasps **230** include friction-enhancing elements or means for securing, such as barbs, protrusions, ridges, grooves, textured surfaces, adhesive, etc.

[0232] In some implementations, the fixed arms **232** are attached to the inner paddles **222** through holes or slots **231** with sutures (not shown). The fixed arms **232** can be attached to the inner paddles **222** with any suitable means, such as screws or other fasteners, crimped sleeves, mechanical latches or snaps, welding, adhesive, clamps, latches, or the like. The fixed arms **232** remain substantially stationary relative to the inner paddles **222** when the moveable arms **234** are opened to open the clasps **230** and expose the optional barbs or other friction-enhancing elements **236**. The clasps **230** are opened by applying tension to actuation lines **216** (e.g., as shown in FIGS. **43-48**) attached to holes **235** in the moveable arms **234**, thereby causing the moveable arms **234** to articulate, pivot, and/or flex on the joint portions **238**.

[0233] Referring now to FIG. **29**, a close-up view of one of the leaflets **20**, **22** grasped by a clasp such as clasp **230** is shown. The leaflet **20**, **22** is grasped between the moveable and fixed arms **232**, **234** of the clasp **230**. The tissue of the leaflet **20**, **22** is not pierced by the barbs or friction-enhancing elements **236**, though in some implementations the barbs **236** can partially or fully pierce through the leaflet **20**, **22**. The angle and height of the barbs or friction-enhancing elements **236** relative to the moveable arm **234** helps to secure the leaflet **20**, **22** within the clasp **230**. In particular, a force pulling the implant off of the native leaflet **20**, **22** will encourage the barbs or friction-enhancing elements **236** to further engage the tissue, thereby ensuring better retention. Retention of the leaflet **20**, **22** in the clasp **230** is further improved by the position of fixed arm **232** near the barbs/friction-enhancing elements **236** when the clasp **230** is closed. In this arrangement, the tissue is formed by the fixed arms **232** and the moveable arms **234** and the barbs/friction-enhancing elements **236** into an S-shaped torturous path. Thus, forces pulling the leaflet **20**, **22** away from the clasp **230** will encourage the tissue to further engage the barbs/friction-enhancing elements **236** before the leaflets **20**, **22** can escape. For example, leaflet tension during diastole can encourage the barbs **236** to pull toward the end portion of the leaflet **20**, **22**. Thus, the S-shaped path can utilize the

leaflet tension during diastole to more tightly engage the leaflets **20**, **22** with the barbs/friction-enhancing elements **236**.

[0234] Referring to FIG. **25**, the device or implant **200** can also include a cover **240**. In some implementations, the cover **240** can be disposed on the coaptation element **210**, the outer and inner paddles **220**, **222**, and/or the paddle frames **224**. The cover **240** can be configured to prevent or reduce blood-flow through the device or implant **200** and/or to promote native tissue ingrowth. In some implementations, the cover **240** can be a cloth or fabric such as PET, velour, or other suitable fabric. In some implementations, in lieu of or in addition to a fabric, the cover **240** can include a coating (e.g., polymeric) that is applied to the implantable device or implant **200**.

[0235] During implantation, the paddles **220**, **222** of the anchors **208** are opened and closed to grasp the native valve leaflets **20**, **22** between the paddles **220**, **222** and the coaptation element **210**. The anchors **208** are moved between a closed position (FIGS. **22-25**) to various open positions (FIGS. **26-37**) by extending and retracting the actuation element **212**. Extending and retracting the actuation element **212** increases and decreases the spacing between the coaptation element **210** and the cap **214**, respectively. The proximal collar **211** (or other attachment element) and the coaptation element **210** slide along the actuation element **212** during actuation so that changing of the spacing between the coaptation element **210** and the cap **214** causes the paddles **220**, **220** to move between different positions to grasp the mitral valve leaflets **20**, **22** during implantation.

[0236] As the device **200** is opened and closed, the pair of inner and outer paddles **222**, **220** are moved in unison, rather than independently, by a single actuation element **212**. Also, the positions of the clasps **230** are dependent on the positions of the paddles **222**, **220**. For example, the clasps **230** are arranged such that closure of the anchors **208** simultaneously closes the clasps **230**. In some implementations, the device **200** can be made to have the paddles **220**, **222** be independently controllable in the same manner (e.g., the device **100** illustrated in FIG. **15**).

[0237] In some implementations, the clasps **230** further secure the native leaflets **20**, **22** by engaging the leaflets **20**, **22** with optional barbs and/or other friction-enhancing elements **236** and pinching the leaflets **20**, **22** between the moveable and fixed arms **234**, **232**. In some implementations, the clasps **230** include barbs that increase friction with and/or can partially or completely puncture the leaflets **20**, **22**. The actuation lines **216** (FIGS. **43-48**) can be actuated separately so that each clasp **230** can be opened and closed separately. Separate operation allows one leaflet **20**, **22** to be grasped at a time, or for the repositioning of a clasp **230** on a leaflet **20**, **22** that was insufficiently grasped, without altering a successful grasp on the other leaflet **20**, **22**. The clasps **230** can be fully opened and closed when the inner paddle **222** is not closed, thereby allowing leaflets **20**, **22** to be grasped in a variety of positions as the particular situation requires.

[0238] Referring now to FIGS. **22-25**, the device **200** is shown in a closed position. When closed, the inner paddles **222** are disposed between the outer paddles **220** and the coaptation element **210**. The clasps **230** are disposed between the inner paddles **222** and the coaptation element **210**. Upon successful capture of native leaflets **20**, **22** the device **200** is moved to and retained in the closed position so that the leaflets **20**, **22** are secured within the device **200** by the clasps **230** and are pressed against the coaptation element **210** by the paddles **220**, **222**. The outer paddles **220** can have a wide curved shape that fits around the curved shape of the coaptation element **210** to grip the leaflets **20**, **22** more securely when the device **200** is closed (e.g., as can be seen in FIG. **51**). The curved shape and rounded edges of the outer paddle **220** also prohibits or inhibits tearing of the leaflet tissue.

[0239] Referring now to FIGS. **30-37**, the implantable device or implant **200** described above is shown in various positions and configurations ranging from partially open to fully open. The paddles **220**, **222** of the device **200** transition between each of the positions shown in FIGS. **30-37** from the closed position shown in FIGS. **22-25** up extension of the actuation element **212** from a fully retracted to fully extended position.

[0240] Referring now to FIGS. **30-31**, the device **200** is shown in a partially open position or capture-ready position. The device **200** is moved into the partially open position by extending the actuation element **212**. Extending the actuation element **212** pulls down on the bottom portions of the outer paddles **220** and paddle frames **224**. The outer paddles **220** and paddle frames **224** pull down on the inner paddles **222**, where the inner paddles **222** are connected to the outer paddles **220** and the paddle frames **224**. Because the proximal collar **211** (or other attachment element) and coaptation element **210** are held in place by the capture mechanism **213**, the inner paddles **222** are caused to articulate, pivot, and/or flex in an opening direction. The inner paddles **222**, the outer paddles **220**, and the paddle frames all flex to the position shown in FIGS. **30-31**. Opening the paddles **222**, **220** and frames **224** forms a gap between the coaptation element **210** and the inner paddle **222** that can receive and grasp the native leaflets **20**, **22**. This movement also exposes the clasps **230** that can be moved between closed (FIG. **30**) and open (FIG. **31**) positions to form a second gap for grasping the native leaflets **20**, **22**. The extent of the gap between the fixed and moveable arms **232**, **234** of the clasp **230** is limited to the extent that the inner paddle **222** has spread away from the coaptation element **210**.

[0241] Referring now to FIGS. **32-33**, the device **200** is shown in a laterally extended or open position. The device **200** is moved into the laterally extended or open position by continuing to extend the actuation element **212** described above, thereby increasing the distance between the coaptation element **210** and the cap **214** of the distal portion **207**. Continuing to extend the actuation element **212** pulls down on the outer paddles **220** and paddle frames **224**, thereby causing the inner paddles **222** to spread apart further from the coaptation element **210**. In the laterally extended or open position, the inner paddles **222** extend horizontally more than in other positions of the device **200** and form an approximately 90-degree angle with the coaptation element **210**. Similarly, the paddle frames **224** are at their maximum spread position when the device **200** is in the laterally extended or open position. The increased gap between the coaptation element **210** and inner paddle **222** formed in the laterally extended or open position allows clasps **230** to open further (FIG. **33**) before engaging the coaptation element **210**, thereby increasing the size of the gap between the fixed and moveable arms **232**, **234**.

[0242] Referring now to FIGS. **34-35**, the example device **200** is shown in a three-quarters extended position. The

device **200** is moved into the three-quarters extended position by continuing to extend the actuation element **212** described above, thereby increasing the distance between the coaptation element **210** and the cap **214** of the distal portion **207**. Continuing to extend the actuation element **212** pulls down on the outer paddles **220** and paddle frames **224**, thereby causing the inner paddles **222** to spread apart further from the coaptation element **210**. In the three-quarters extended position, the inner paddles **222** are open beyond 90 degrees to an approximately 135-degree angle with the coaptation element **210**. The paddle frames **224** are less spread than in the laterally extended or open position and begin to move inward toward the actuation element **212** as the actuation element **212** extends further. The outer paddles **220** also flex back toward the actuation element **212**. As with the laterally extended or open position, the increased gap between the coaptation element **210** and inner paddle **222** formed in the laterally extended or open position allows clasps **230** to open even further (FIG. **35**), thereby increasing the size of the gap between the fixed and moveable arms **232**, **234**.

[0243] Referring now to FIGS. **36-37**, the example device **200** is shown in a fully extended position. The device **200** is moved into the fully extended position by continuing to extend the actuation element **212** described above, thereby increasing the distance between the coaptation element **210** and the cap **214** of the distal portion **207** to a maximum distance allowable by the device **200**. Continuing to extend the actuation element **212** pulls down on the outer paddles **220** and paddle frames **224**, thereby causing the inner paddles **222** to spread apart further from the coaptation element **210**. The outer paddles **220** and paddle frames **224** move to a position where they are close to the actuation element. In the fully extended position, the inner paddles **222** are open to an approximately 180-degree angle with the coaptation element **210**. The inner and outer paddles **222**, **220** are stretched straight in the fully extended position to form an approximately 180-degree angle between the paddles **222**, **220**. The fully extended position of the device **200** provides the maximum size of the gap between the coaptation element **210** and inner paddle **222**, and, in some implementations, allows clasps **230** to also open fully to approximately 180 degrees (FIG. **37**) between the fixed and moveable arms **232**, **234** of the clasp **230**. The position of the device **200** is the longest and the narrowest configuration. Thus, the fully extended position of the device **200** can be a desirable position for bailout of the device **200** from an attempted implantation or can be a desired position for placement of the device in a delivery catheter, or the like.

[0244] Configuring the device or implant **200** such that the anchors **208** can extend to a straight or approximately straight configuration (e.g., approximately 120-180 degrees relative to the coaptation element **210**) can provide several advantages. For example, this configuration can reduce the radial crimp profile of the device or implant **200**. It can also make it easier to grasp the native leaflets **20**, **22** by providing a larger opening between the coaptation element **210** and the inner paddles **222** in which to grasp the native leaflets **20**, **22**. Additionally, the relatively narrow, straight configuration can prevent or reduce the likelihood that the device or implant **200** will become entangled in native anatomy (e.g., chordae tendineae CT shown in FIGS. **3** and **4**) when positioning and/or retrieving the device or implant **200** into the delivery system **202**.

[0245] Referring now to FIGS. **38-49**, an example implantable device **200** is shown being delivered and implanted within the native mitral valve MV of the heart H. As described above, the device **200** shown in FIGS. **38-49** includes the optional covering **240** (e.g., FIG. **25**) over the coaptation element **210**, clasps **230**, inner paddles **222** and/or the outer paddles **220**. The device **200** is deployed from a delivery system **202** (e.g., which can comprise an implant catheter that is extendable from a steerable catheter and/or a guide sheath) and is retained by a capture mechanism **213** (see e.g., FIGS. **43** and **48**) and is actuated by extending or retracting the actuation element **212**. Fingers of the capture mechanism **213** removably attach the collar **211** to the delivery system **202**. In some implementations, the capture mechanism **213** is held closed around the collar **211** by the actuation element **212**, such that removal of the actuation element **212** allows the fingers of the capture mechanism **213** to open and release the collar **211** to decouple the capture mechanism **213** from the device **200** after the device **200** has been successfully implanted.

[0246] Referring now to FIG. **38**, the delivery system **202** (e.g., a delivery catheter/sheath thereof) is inserted into the left atrium LA through the septum and the device/implant **200** is deployed from the delivery system **202** (e.g., an implant catheter retaining the device/implant can be extended to deploy the device/implant out from a steerable catheter) in the fully open condition for the reasons discussed above with respect to the device **100**. The actuation element **212** is then retracted to move the device **200** through the partially closed condition (FIG. **39**) and to the fully closed condition shown in FIGS. **40-41**. Then the delivery system or catheter maneuvers the device/implant **200** towards the mitral valve MV as shown in FIG. **41**. Referring now to FIG. **42**, when the device **200** is aligned with the mitral valve MV, the actuation element **212** is extended to open the paddles **220**, **222** into the partially opened position and the actuation lines **216** (FIGS. **43-48**) are retracted to open the clasps **230** to prepare for leaflet grasp. Next, as shown in FIGS. **43-44**, the partially open device **200** is inserted through the native valve (e.g., by advancing an implant catheter from a steerable catheter) until leaflets **20**, **22** are properly positioned in between the inner paddles **222** and the coaptation element **210** and inside the open clasps **230**.

[0247] FIG. **45** shows the device **200** with both clasps **230** closed, though the optional barbs **236** of one clasp **230** missed one leaflet **22**. As can be seen in FIGS. **45-47**, the out of position clasp **230** is opened and closed again to properly grasp the missed leaflet **22**. When both leaflets **20**, **22** are grasped properly, the actuation element **212** is retracted to move the device **200** into the fully closed position shown in FIG. **48**. With the device **200** fully closed and implanted in the native valve, the actuation element **212** is disengaged from the cap **214** and is withdrawn to release the capture mechanism **213** from the proximal collar **211** (or other attachment element) so that the capture mechanism **213** can be withdrawn into the delivery system **202** (e.g., into a catheter/sheath), as shown in FIG. **49**. Once deployed, the device **200** can be maintained in the fully closed position with a mechanical means such as a latch or can be biased to remain closed through the use of spring material, such as steel, and/or shape-memory alloys such as Nitinol. For example, the paddles **220**, **222** can be formed of steel or Nitinol shape-memory alloy produced in a wire, sheet,

tubing, or laser sintered powder—and are biased to hold the outer paddles **220** closed around the inner paddles **222**, coaptation element **210**, and/or the clasps **230** pinched around native leaflets **20**, **22**.

[0248] Referring to FIGS. **50-54**, once the device **200** is implanted in a native valve, the coaptation element **210** functions as a gap filler in the valve regurgitant orifice, such as the gap **26** in the mitral valve MV illustrated by FIG. **6** or a gap in another native valve. In some implementations, when the device **200** has been deployed between the two opposing valve leaflets **20**, **22**, the leaflets **20**, **22** no longer coapt against each other in the area of the coaptation element **210**, but instead coapt against the coaptation element **210**. This reduces the distance the leaflets **20**, **22** need to be approximated to close the mitral valve MV during systole, thereby facilitating repair of functional valve disease that may be causing mitral regurgitation. A reduction in leaflet approximation distance can result in several other advantages as well. For example, the reduced approximation distance required of the leaflets **20**, **22** reduces or minimizes the stress experienced by the native valve. Shorter approximation distance of the valve leaflets **20**,**22** can also require less approximation forces which can result in less tension experienced by the leaflets **20**, **22** and less diameter reduction of the valve annulus. The smaller reduction of the valve annulus—or none at all—can result in less reduction in valve orifice area as compared to a device without a coaptation element or spacer. In this way, the coaptation element **210** can reduce the transvalvular gradients.

[0249] To adequately fill the gap **26** between the leaflets **20**, **22**, the device **200** and the components thereof can have a wide variety of different shapes and sizes. For example, the outer paddles **220** and paddle frames **224** can be configured to conform to the shape or geometry of the coaptation element **210** as is shown in FIGS. **50-54**. As a result, the outer paddles **220** and paddle frames **224** can mate with both the coaptation element **210** and the native valve leaflets **20**, **22**. In some implementations, when the leaflets **20**, **22** are coapted against the coaptation element **210**, the leaflets **20**, **22** fully surround or "hug" the coaptation element **210** in its entirety, thus small leaks at lateral and medial aspects **201**, **203** of the coaptation element **210** can be prevented or reduced. The interaction of the leaflets **20**, **22** and the device **200** is made clear in FIG. **51**, which shows a schematic atrial or surgeon's view that shows the paddle frame **224** (which would not actually be visible from a true atrial view, e.g., FIG. **52**), conforming to the coaptation element **210** geometry. The opposing leaflets **20**, **22** (the ends of which would also not be visible in the true atrial view, e.g., FIG. **52**) being approximated by the paddle frames **224**, to fully surround or "hug" the coaptation element **210**.

[0250] This coaptation of the leaflets **20**, **22** against the lateral and medial aspects **201**, **203** of the coaptation element **210** (shown from the atrial side in FIG. **52**, and the ventricular side in FIG. **53**) would seem to contradict the statement above that the presence of a coaptation element **210** minimizes the distance the leaflets need to be approximated. However, the distance the leaflets **20**, **22** need to be approximated is still minimized if the coaptation element **210** is placed precisely at a regurgitant gap **26** and the regurgitant gap **26** is less than the width (medial-lateral) of the coaptation element **210**.

[0251] FIG. **50** illustrates the geometry of the coaptation element **210** and the paddle frame **224** from an LVOT perspective. As can be seen in this view, the coaptation element **210** has a tapered shape being smaller in dimension in the area closer to where the inside surfaces of the leaflets **20**, **22** are required to coapt and increase in dimension as the coaptation element **210** extends toward the atrium. Thus, the depicted native valve geometry is accommodated by a tapered coaptation element geometry. Still referring to FIG. **50**, the tapered coaptation element geometry, in conjunction with the illustrated expanding paddle frame **224** shape (toward the valve annulus) can help to achieve coaptation on the lower end of the leaflets, reduce stress, and minimize transvalvular gradients.

[0252] Referring to FIG. **54**, the shape of the coaptation element **210** and the paddle frames **224** can be defined based on an Intra-Commissural view of the native valve and the device **200**. Two factors of these shapes are leaflet coaptation against the coaptation element **210** and reduction of stress on the leaflets due to the coaptation. Referring to FIGS. **54** and **24**, to both coapt the valve leaflets **20**, **22** against the coaptation element **210** and reduce the stress applied to the valve leaflets **20**, **22** by the coaptation element **210** and/or the paddle frames **224**, the coaptation element **210** can have a round or rounded shape and the paddle frames **224** can have a full radius that spans nearly the entirety of the paddle frame **224**. The round shape of the coaptation element **210** and/or the illustrated fully rounded shape of the paddle frames **224** distributes the stresses on the leaflets **20**, **22** across a large, curved engagement area **205**. For example, in FIG. **54**, the force on the leaflets **20**, **22** by the paddle frames is spread along the entire rounded length of the paddle frame **224**, as the leaflets **20** try to open during the diastole cycle.

[0253] Referring now to FIG. **55**, an example of an implantable device or implant **300** is shown. The implantable device **300** is one of the many different configurations that the device **100** that is schematically illustrated in FIGS. **8-14** can take. The device **300** can include any other features for an implantable device or implant discussed in the present application, and the device **300** can be positioned to engage valve tissue **20**, **22** as part of any suitable valve repair system (e.g., any valve repair system disclosed in the present application).

[0254] The implantable device or implant **300** includes a proximal or attachment portion **305**, an anchor portion **306**, and a distal portion **307**. In some implementations, the device/implant **300** includes a coaptation portion **304**, and the coaptation portion **304** can optionally include a coaptation element **310** (e.g., spacer, plug, membrane, sheet, etc.) for implantation between the leaflets **20**, **22** of the native valve. In some implementations, the anchor portion **306** includes a plurality of anchors **308**. In some implementations, each anchor **308** can include one or more paddles, e.g., outer paddles **320**, inner paddles **322**, paddle extension members or paddle frames **324**. The anchors can also include and/or be coupled to clasps **330**. In some implementations, the attachment portion **305** includes a first or proximal collar **311** (or other attachment element) for engaging with a capture mechanism (e.g., a capture mechanism such as the capture mechanism **213** shown in FIGS. **43-49**) of a delivery system (e.g., a delivery system such as the system shown in FIGS. **38-42** and **49**).

[0255] The anchors **308** can be attached to the other portions of the device and/or to each other in a variety of different ways (e.g., directly, indirectly, welding, sutures, adhesive, links, latches, integrally formed, a combination of

some or all of these, etc.). In some implementations, the anchors **308** are attached to a coaptation member or coaptation element **310** by connection portions **325** and to a cap **314** by connection portions **321**.

[0256] The anchors **308** can comprise first portions or outer paddles **320** and second portions or inner paddles **322** separated by connection portions **323**. The connection portions **323** can be attached to paddle frames **324** that are hingeably attached to a cap **314** or other attachment portion. In this manner, the anchors **308** are configured similar to legs in that the inner paddles **322** are like upper portions of the legs, the outer paddles **320** are like lower portions of the legs, and the connection portions **323** are like knee portions of the legs.

[0257] In implementations with a coaptation member or coaptation element **310**, the coaptation member or coaptation element **310** and the anchors **308** can be coupled together in various ways. For example, as shown in the illustrated example, the coaptation element **310** and the anchors **308** can be coupled together by integrally forming the coaptation element **310** and the anchors **308** as a single, unitary component. This can be accomplished, for example, by forming the coaptation element **310** and the anchors **308** from a continuous strip **301** of a braided or woven material, such as braided or woven nitinol wire. In the illustrated example, the coaptation element **310**, the outer paddle portions **320**, the inner paddle portions **322**, and the connection portions **321**, **323**, **325** are formed from the continuous strip of fabric **301**.

[0258] Like the anchors **208** of the implantable device or implant **200** described above, the anchors **308** can be configured to move between various configurations by axially moving the distal end of the device (e.g., cap **314**, etc.) relative to the proximal end of the device (e.g., proximal collar **311** or other attachment element, etc.) and thus the anchors **308** move relative to a midpoint of the device. This movement can be along a longitudinal axis extending between the distal end (e.g., cap **314**, etc.) and the proximal end (e.g., collar **311** or other attachment element, etc.) of the device. For example, the anchors **308** can be positioned in a fully extended, fully elongated, or straight configuration (e.g., similar to the configuration of device **200** shown in FIG. **36**) by moving the distal end (e.g., cap **314**, etc.) away from the proximal end of the device.

[0259] In some implementations, in the straight configuration, the paddle portions **320**, **322** are aligned or straight in the direction of the longitudinal axis of the device. In some implementations, the connection portions **323** of the anchors **308** are adjacent the longitudinal axis of the coaptation element **310** (e.g., similar to the configuration of device **200** shown in FIG. **36**). From the fully elongated or straight configuration, the anchors **308** can be moved to a fully folded or closed configuration (e.g., FIG. **55**), e.g., by moving the proximal end and distal end toward each other and/or toward a midpoint or center of the device. Initially, as the distal end (e.g., cap **314**, etc.) moves toward the proximal end and/or midpoint or center of the device, the anchors **308** bend at connection portions **321**, **323**, **325**, and the connection portions **323** move radially outwardly relative to the longitudinal axis of the device **300** and axially toward the midpoint and/or toward the proximal end of the device (e.g., similar to the configuration of device **200** shown in FIG. **34**). As the cap **314** continues to move toward the midpoint and/or toward the proximal end of the device, the connection portions **323** move radially inwardly relative to the longitudinal axis of the device **300** and axially toward the proximal end of the device (e.g., similar to the configuration of device **200** shown in FIG. **30**).

[0260] In some implementations, the clasps comprise a moveable arm coupled to an anchor. In some implementations, the clasps **330** (as shown in detail in FIG. **56**) include a base or fixed arm **332**, a moveable arm **334**, optional barbs/friction-enhancing elements **336**, and a joint portion **338**. The fixed arms **332** are attached to the inner paddles **322**, with the joint portion **338** disposed proximate the coaptation element **310**. The joint portion **338** is spring-loaded so that the fixed and moveable arms **332**, **334** are biased toward each other when the clasp **330** is in a closed condition.

[0261] The fixed arms **332** are attached to the inner paddles **322** through holes or slots **331** with sutures (not shown). The fixed arms **332** can be attached to the inner paddles **322** with any suitable means, such as screws or other fasteners, crimped sleeves, mechanical latches or snaps, welding, adhesive, or the like. The fixed arms **332** remain substantially stationary relative to the inner paddles **322** when the moveable arms **334** are opened to open the clasps **330** and expose the optional barbs **336**. The clasps **330** are opened by applying tension to actuation lines (e.g., the actuation lines **216** shown in FIGS. **43-48**) attached to holes **335** in the moveable arms **334**, thereby causing the moveable arms **334** to articulate, pivot, and/or flex on the joint portions **338**.

[0262] In short, the implantable device or implant **300** is similar in configuration and operation to the implantable device or implant **200** described above, except that the coaptation element **310**, outer paddles **320**, inner paddles **322**, and connection portions **321**, **323**, **325** are formed from the single strip of material **301**. In some implementations, the strip of material **301** is attached to the proximal collar **311**, cap **314**, and paddle frames **324** by being woven or inserted through openings in the proximal collar **311**, cap **314**, and paddle frames **324** that are configured to receive the continuous strip of material **301**. The continuous strip **301** can be a single layer of material or can include two or more layers. In some implementations, portions of the device **300** have a single layer of the strip of material **301** and other portions are formed from multiple overlapping or overlying layers of the strip of material **301**.

[0263] For example, FIG. **55** shows a coaptation element **310** and inner paddles **322** formed from multiple overlapping layers of the strip of material **301**. The single continuous strip of material **301** can start and end in various locations of the device **300**. The ends of the strip of material **301** can be in the same location or different locations of the device **300**. For example, in the illustrated example of FIG. **55**, the strip of material **301** begins and ends in the location of the inner paddles **322**.

[0264] As with the implantable device or implant **200** described above, the size of the coaptation element **310** can be selected to minimize the number of implants that a single patient will require (preferably one), while at the same time maintaining low transvalvular gradients. In particular, forming many components of the device **300** from the strip of material **301** allows the device **300** to be made smaller than the device **200**. For example, in some implementations, the anterior-posterior distance at the top of the coaptation element **310** is less than 2 mm, and the medial-lateral distance

of the device **300** (i.e., the width of the paddle frames **324** which are wider than the coaptation element **310**) at its widest is about 5 mm.

[0265] The concepts disclosed by the present application can be used with a wide variety of different valve treatment devices. FIGS. **57-63** illustrate one example valve treatment system configured as a valve repair system **400** for repairing a native valve of a patient to which the concepts of the present application can be applied. Though the concepts of the present application can be applied to many more valve treatment systems (e.g., many other valve repair systems and many valve replacement systems).

[0266] The valve repair system **400** includes a delivery system or delivery device **401** and an implant **402** configured as a valve repair device. The implant or valve repair device **402** includes a base assembly **404**, a pair of paddles **406**, and a pair of gripping members **408**. In some implementations, the paddles **406** can be integrally formed with the base assembly. For example, the paddles **406** can be formed as extensions of links of the base assembly. In the illustrated example, the base assembly **404** of the valve repair device **402** has a shaft **403**, a coupler **405** configured to move along the shaft, and a lock **407** configured to lock the coupler in a stationary position on the shaft. The coupler **405** is mechanically connected to the paddles **406**, such that movement of the coupler **405** along the shaft **403** causes the paddles to move between an open position and a closed position. In this way, the coupler **405** serves as a means for mechanically coupling the paddles **406** to the shaft **403** and, when moving along the shaft **403**, for causing the paddles **406** to move between their open and closed positions.

[0267] In some implementations, the gripping members **408** are pivotally connected to the base assembly **404** (e.g., the gripping members **408** can be pivotally connected to the shaft **403**, or any other suitable member of the base assembly), such that the gripping members can be moved to adjust the width of the opening **414** between the paddles **406** and the gripping members **408**. The gripping member **408** can include an optional barbed portion **409** for attaching the gripping members to valve tissue when the implant or valve repair device **402** is attached to the valve tissue. The gripping member **408** forms a means for gripping the valve tissue (in particular tissue of the valve leaflets) with a sticking means or portion such as the barbed portion **409**. When the paddles **406** are in the closed position, the paddles engage the gripping members **408**, such that, when valve tissue is attached to the barbed portion **409** of the gripping members, the paddles act as holding or securing means to hold the valve tissue at the gripping members and to secure the implant **402** to the valve tissue. In some implementations, the gripping members **408** are configured to engage the paddles **406** such that the barbed portion **409** engages the valve tissue member and the paddles **406** to secure the implant **402** to the valve tissue member. For example, in certain situations, it can be advantageous to have the paddles **406** maintain an open position and have the gripping members **408** move outward toward the paddles **406** to engage valve tissue and the paddles **406**.

[0268] While the examples shown in FIGS. **57-63** illustrate a pair of paddles **406** and a pair of gripping members **408**, it should be understood that the implant or valve repair device **402** can include any suitable number of paddles and gripping members.

[0269] In some implementations, the valve repair system **400** includes a placement shaft **413** that is removably attached to the shaft **403** of the base assembly **404** of the valve repair device **402**. After the valve repair device **402** is secured to valve tissue, the placement shaft **413** is removed from the shaft **403** to remove the valve repair device **402** from the remainder of the valve repair system **400**, such that the valve repair device **402** can remain attached to the valve tissue, and the delivery device **401** can be removed from a patient's body.

[0270] The valve repair system **400** can also include a paddle control mechanism **410**, a gripper control mechanism **411**, and a lock control mechanism **412**. The paddle control mechanism **410** is mechanically attached to the coupler **405** to move the coupler along the shaft, which causes the paddles **406** to move between the open and closed positions. The paddle control mechanism **410** can take any suitable form, such as, for example, a shaft or rod. For example, the paddle control mechanism can comprise a hollow shaft, a catheter tube or a sleeve that fits over the placement shaft **413** and the shaft **403** and is connected to the coupler **405**.

[0271] The gripper control mechanism **411** is configured to move the gripping members **408** such that the width of the opening **414** between the gripping members and the paddles **406** can be altered. The gripper control mechanism **411** can take any suitable form, such as, for example, a line, a suture or wire, a rod, a catheter, etc.

[0272] The lock control mechanism **412** is configured to lock and unlock the lock. The lock **407** serves as a locking means for locking the coupler **405** in a stationary position with respect to the shaft **403** and can take a wide variety of different forms and the type of lock control mechanism **412** may be dictated by the type of lock used. In some implementations, the lock **407** takes the form of locks often used in caulk guns. That is, the lock **407** includes a pivotable plate having a hole, in which the shaft **403** of the valve repair device **402** is disposed within the hole of the pivotable plate. In this example, when the pivotable plate is in the tilted position, the pivotable plate engages the shaft **403** to maintain a position on the shaft **403**, but, when the pivotable plate is in a substantially non-tilted position, the pivotable plate can be moved along the shaft (which allows the coupler **405** to move along the shaft **403**). In other words, the coupler **405** is prevented from moving in the direction Y (as shown in FIG. **61**A) along the shaft **403** when the pivotable plate of the lock **407** is in a tilted (or locked) position, and the coupler is allowed to move in the direction Y along the shaft **403** when the pivotable plate is in a substantially non-tilted (or unlocked) position. In some implementations in which the lock **407** includes a pivotable plate, the lock control mechanism **412** is configured to engage the pivotable plate to move the plate between the tilted and substantially non-tilted positions. The lock control mechanism **412** can be, for example, a rod, a suture, a wire, or any other member that is capable of moving a pivotable plate of the lock **407** between a tilted and substantially non-tilted position. In some implementations, the pivotable plate of the lock **407** is biased in the tilted (or locked) position, and the lock control mechanism **412** is used to move the plate from the tilted position to the substantially non-tilted (or unlocked) position. In some implementations, the pivotable plate of the lock **407** is biased in the substantially non-tilted (or unlocked) position, and the lock control mechanism **412** is

used to move the plate from the substantially non-tilted position to the tilted (or locked) position.

[0273] FIGS. **61**A-**61**B illustrate the valve repair device **402** moving from an open position (as shown in FIG. **61**A) to a closed position (as shown in FIG. **61**). The base assembly **404** includes a first link **1021** extending from point A to point B, a second link **1022** extending from point A to point C, a third link **1023** extending from point B to point D, a fourth link **1024** extending from point C to point E, and a fifth link **1025** extending from point D to point E. The coupler **405** is movably attached to the shaft **403**, and the shaft **403** is fixed to the fifth link **1025**. The first link **1021** and the second link **1022** are pivotally attached to the coupler **405** at point A, such that movement of the coupler **405** along the shaft **403** moves the location of point A and, consequently, moves the first link **1021** and the second link **1022**. The first link **1021** and the third link **1023** are pivotally attached to each other at point B, and the second link **1022** and the fourth link **1024** are pivotally attached to each other at point C. One paddle **406***a* is attached to first link **1021** such that movement of first link **1021** causes the paddle **406***a* to move, and the other paddle **406***b* is attached to the second link **1022** such that movement of the second link **1022** causes the paddle **406***b* to move. In some implementations, the paddles **406***a*, **406***b* can be connected to links **1023**, **1024** or be extensions of links **1023**, **1024**.

[0274] In order to move the valve repair device from the open position (as shown in FIG. **61**A) to the closed position (as shown in FIG. **61**), the coupler **405** is moved along the shaft **403** in the direction Y, which moves the pivot point A for the first links **1021** and the second link **1022** to a new position. Movement of the coupler **405** (and pivot point A) in the direction Y causes a portion of the first link **1021** near point A to move in the direction H, and the portion of the first link **1021** near point B to move in the direction J. The paddle **406***a* is attached to the first link **1021** such that movement of the coupler **405** in the direction Y causes the paddle **406***a* to move in the direction Z. In addition, the third link **1023** is pivotally attached to the first link **1021** at point B such that movement of the coupler **405** in the direction Y causes the third link **1023** to move in the direction K. Similarly, movement of the coupler **405** (and pivot point A) in the direction Y causes a portion of the second link **1022** near point A to move in the direction L, and the portion of the second link **1022** near point C to move in the direction M. The paddle **406***b* is attached to the second link **1022** such that movement of the coupler **405** in the direction Y causes the paddle **406***b* to move in the direction V. In addition, the fourth link **1024** is pivotally attached to the second link **1022** at point C such that movement of the coupler **405** in the direction Y causes the fourth link **1024** to move in the direction N. FIG. **61**B illustrates the final position of the valve repair device **402** after the coupler **405** is moved as shown in FIG. **61**A.

[0275] Referring to FIG. **58**, the valve repair device **402** is shown in the open position (similar to the position shown in FIG. **61**A), and the gripper control mechanism **411** is shown moving the gripping members **408** to provide a wider gap at the opening **414** between the gripping members and the paddles **406**. In the illustrated example, the gripper control mechanism **411** includes a line, such as a suture, a wire, etc. that is threaded through an opening in an end of the gripping members **408**. Both ends of the line extend through the delivery opening **516** of the delivery device **401**. When the line is pulled through the delivery opening **516** in the direction Y, the gripping members **408** move inward in the direction X, which causes the opening **414** between the gripping members and the paddles **406** to become wider.

[0276] Referring to FIG. **59**, the valve repair device **402** is shown such that valve tissue **20**, **22** is disposed in the opening **414** between the gripping members **408** and the paddles **406**. Referring to FIG. **60**, after the valve tissue **20**, **22** is disposed between the gripping members **408** and the paddles **406**, the gripper control mechanism **411** is used to lessen the width of the opening **414** between the gripping members and the paddles. That is, in the illustrated example, the line of the gripper control mechanism **411** is released from or pushed out of the opening **516** of the delivery member in the direction H, which allows the gripping members **408** to move in the direction D to lessen the width of the opening **414**. While the gripper control mechanism **411** is shown moving the gripping members **408** to increase the width of the opening **414** between the gripping members and the paddles **406** (FIG. **59**), it should be understood that the gripping members may not need to be moved in order to position valve tissue in the opening **414**. In certain circumstances, however, the opening **414** between the paddles **406** and the gripping members **408** may need to be wider in order to receive the valve tissue.

[0277] Referring to FIG. **62**, the implant or valve repair device **402** is in the closed position and secured to valve tissue **20**, **22**. The valve repair device **402** is secured to the valve tissue **20** by the paddles **406***a*, **406***b* and the gripping members **408***a*, **408***b*. In particular, the valve tissue **20**,**22** is attached to the valve repair device **402** by the barbed portion **409** of the gripping members **408***a*, **408***b*, and the paddles **406***a*, **406***b* engage the gripping members **408** to secure the valve repair device **402** to the valve tissue **20**, **22**.

[0278] In order to move the valve repair device **402** from the open position to the closed position, the lock **407** is moved to an unlocked condition (as shown in FIG. **62**) by the lock control mechanism **412**. Once the lock **407** is in the unlocked condition, the coupler **405** can be moved along the shaft **403** by the paddle control mechanism **410**. In the illustrated example, the paddle control mechanism **410** moves the coupler **405** in a direction Y along the shaft, which causes one paddle **406***a* to move in a direction X and the other paddle **406***b* to move in a direction Z. The movement of the paddles **406***a*, **406***b* in the direction X and the direction Z, causes the paddles to engage the gripping members **408***a*, **408***b* and secure the valve repair device **402** to the valve tissue **20**, **22**.

[0279] Referring to FIG. **63**, after the paddles **406** are moved to the closed position to secure the valve repair device **402** to the valve tissue **20**, **22** (as shown in FIG. **62**), the lock **407** is moved to the locked condition by the lock control mechanism **412** (FIG. **62**) to maintain the valve repair device **402** in the closed position. After the valve repair device **402** is maintained in the locked condition by the lock **407**, the valve repair device **402** is removed from the delivery device **401** by disconnecting the shaft **403** from the placement shaft **413** (FIG. **62**). In addition, the valve repair device **402** is disengaged from the paddle control mechanism **410** (FIG. **62**), the gripper control mechanism **411** (FIG. **62**), and the lock control mechanism **412**. Removal of the valve repair device **402** from the delivery

device **401** allows the valve repair device to remain secured to valve tissue **20**, **22** while the delivery device **401** is removed from a patient.

[0280] During implantation of an implantable device or implant in the native heart valve, movement of the device to the implanted position may be impeded or obstructed by the native heart structures. For example, articulable portions of an implantable device or implant (such as paddle portions of anchors used to secure the device to the native heart valve tissue) may rub against, become temporarily caught, or be temporarily blocked by the chordae tendineae CT (shown in FIGS. **3** and **4**) that extend to the valve leaflets. An example implantable device or implant can be configured to reduce the likelihood of the device or implant getting temporarily caught or blocked by the CT. For example, the implantable device or implant can take a wide variety of different configurations that are configured to be actively or passively narrowed to reduce the width of a paddle frame of an anchor portion of the device and, consequently, reduce the surface area of the device, which will make it easier to move the device/implant past and/or through the CT.

[0281] In some implementations, a delivery system or delivery assembly is configured to make it easier to move the implantable device or implant between its various configurations and/or to implant the implantable device or implant in the native heart valve. For example, controls on a handle used in a delivery system/assembly can be configured to enable improved control of the implantable device or implant, as will be described.

[0282] FIGS. **64-65** show an example of a system or assembly **600** (e.g., a valve treatment system or assembly, valve repair system or assembly, valve replacement system or assembly, etc.) and its components. Referring to FIG. **64**, the system or assembly **600** can comprise the delivery assembly or delivery system **602** and an implantable device or implant **604**. The delivery system **602** can comprise a plurality of catheter assemblies. The delivery system **602** can also comprise one or more optional catheter stabilizers or stabilizing systems/devices (not shown in FIGS. **64** and **65**).

[0283] In some implementations, as shown in the illustrated example in FIG. **65**, the delivery system **602** includes a first catheter assembly **606**, a second catheter assembly **608**, and a third catheter assembly **610**. Though, in some implementation, the delivery system **602** can include fewer or more catheter assemblies than shown. In some implementations, the first catheter assembly **606** is configured as a delivery catheter assembly and will often be referred to as such for illustration herein, though it can also be other types of catheters or catheter assemblies. In some implementations, the second catheter assembly **608** is configured as a steerable catheter assembly and will often be referred to as such for illustration herein, though it can also be other types of catheters or catheter assemblies. In some implementations, the third catheter assembly **610** is configured as an implant catheter assembly and will often be referred to as such for illustration herein, though it can also be other types of catheters or catheter assemblies.

[0284] In some implementations, the second catheter assembly or steerable catheter assembly **608** extends coaxially through the first catheter assembly or delivery catheter assembly **606**, and the third catheter assembly or implant catheter assembly **610** extends coaxially through the second catheter assembly **608** and the first catheter assembly **606**. The implantable device **604** can be releasably coupled to a distal portion of the third catheter assembly or implant catheter assembly **610**, as further described below. It should be appreciated that the implantable device **604** can be any device described herein.

[0285] As shown in FIG. **65**, each of the catheter assemblies (e.g., delivery catheter assembly **606**, the steerable catheter assembly **608**, and the implant catheter assembly **610**) includes a sheath or shaft **607**, **609**, **611** extending from a handle **612**, **614**, **616**, respectively. The handles **612**, **614**, **616** are located at a proximal end of each of the corresponding sheaths or shafts, and include one or more control members to enable a user to manipulate the catheter assembly (e.g., bend or rotate the sheath or shaft of the catheter assembly) or control a component coupled to the corresponding catheter assembly (e.g., a control wire extending through the shaft of the catheter assembly).

[0286] The delivery catheter assembly **606** and the steerable catheter assembly **608** can be used, for example, to access an implantation location (e.g., a native mitral valve region of a heart) and/or to position the implant catheter assembly **610** at the implantation location. Accordingly, in some implementations, the delivery catheter assembly **606** and the steerable catheter assembly **608** are configured to be steerable. The catheter assemblies or features of the catheter assemblies disclosed by U.S. Pat. Nos. 10,653,862 and 10,646,342 can be used as or in the catheter assemblies **606**, **608**, **610**. U.S. Pat. Nos. 10,653,862 and 10,646,342 are hereby incorporated by reference in their entireties.

[0287] FIGS. **66** and **67** illustrate examples of implant catheter assemblies **610**. FIG. **66** illustrates a generalized implant catheter assembly **610** while FIG. **67** is a schematic illustration of an example implant catheter assembly **610**, in which each of the clasp actuation lines **624** is coupled to a clasp control member positioned on the handle **616** and the actuation element **112** is coupled (directly or indirectly) to a control element (e.g., knob **626**, but the control element can also be a button, switch, slider, motor, button that controls a motor, combination of these, etc.) positioned on the handle. In each of the examples illustrated by FIGS. **66** and **67**, the implant catheter assembly **610** can comprise the inner or actuation element **112**, a coupler **620**, an outer shaft **611**, a handle **616** (shown schematically), and clasp actuation lines **624**. A proximal end portion **622***a* of the outer shaft **611** can be coupled to extend distally from the handle **616**, and a distal end portion **622***b* of the outer shaft **611** can be coupled to the coupler **620**. The actuation element **112** can extend distally from the control element or knob **626** (shown schematically in FIG. **66**), through the handle **616**, through the outer shaft **611**, and through the coupler **620**. The actuation element **112** can be movable (e.g., axially and/or rotationally) relative to the outer shaft **611** and the handle **616**. The clasp actuation lines **624** can extend through and be axially movable relative to the handle **616** and the outer shaft **611**. The clasp actuation lines **624** can also be axially movable relative to the actuation element **112**.

[0288] In some implementations, the outer shaft **611** of the implant catheter assembly **610** can be configured to be steerable. For example, although not shown, the implant catheter assembly **610** can comprise an actuation element, such as a pull wire, and a flexible, axially non-compressible pull wire sleeve (e.g., a helical coil).

[0289] As shown in FIG. **66**, the actuation element **112** of the implant catheter assembly **610** can be releasably coupled

to the cap **114** of the device **604**. For example, in some implementations, the distal end portion **112***b* of the actuation element **112** can comprise external threads configured to releasably engage interior threads of the cap **114** of the device **604**. As such, rotating the actuation element **112** in a first direction (e.g., clockwise) relative to the cap **114** of the device **604** releasably secures the actuation element **112** to the cap **114**, while rotating the actuation element **112** in a second direction (e.g., counter-clockwise) relative to the cap **114** of the device **604** releases the actuation element **112** from the cap **114**.

[0290] In the examples of FIGS. **66** and **67**, the outer shaft **611** of the implant catheter assembly **610** is an elongate shaft extending axially between the proximal end portion **622***a*, which is coupled to the handle **616**, and the distal end portion **622***b*, which is coupled to the coupler **620**. The outer shaft **611** can also include an intermediate portion **622***c* disposed between the proximal and distal end portions **622***a*, **622***b*. The outer shaft **611** can be formed from various materials, including metals and polymers. For example, in some implementations, the proximal end portion **622***a* can comprise stainless steel and the distal and intermediate portions **622***b*, **622***c* can comprise polyether block amide (PEBA). The outer shaft **611** can also comprise an outer covering or coating, such as a polymer that is reflowed over the portions **622***a*, **622***b*, and **622***c*.

[0291] As shown in FIGS. **66** and **67**, the clasp actuation lines **624** are coupled to the clasps **130** through holes **235** in the clasps **130** and extend axially through the outer shaft **611** between the clasps **130** and the handle **616**. In some implementations, e.g., as illustrated by FIG. **67**, at the proximal end of the clasp actuation lines **624**, the clasp actuation lines **624** are each operatively and/or physically coupled to a clasp control member **628**. Each clasp control member **628** is configured such that actuation thereof can cause axial movement of the clasp actuation line **624** relative to the handle **616**, outer shaft **611** and/or the actuation element **112**. As will be described in greater detail, in some implementations, each of the clasp control members **628** can be actuated/operated independently of the other clasp control member such that each clasp actuation line **624** is moved independently relative to the handle **616**, outer shaft **611**, the actuation element **112**, and/or the other clasp actuation line **624**. In some implementations, the clasp control members **628** can be operatively or physically fixed (or synchronized) with respect to one another (e.g., locked) such that the clasp actuation lines **624** are axially moved together relative to the outer shaft **611** and the actuation element **112**. In some applications, the clasp control members **628** are configured such that they can be toggled by the end user between independently actuatable and actuatable together (e.g., synchronized).

[0292] The clasp control members **628** can be configured in a variety of ways. In some implementations, one or more of the clasp control members **628** is an axially-moving control or slider coupled to a corresponding clasp actuation line **624** to axially move the clasp actuation line **624** relative to the outer shaft **611** and the actuation element **112**. In some implementations, one or more of the clasp control members **628** comprises a button, switch, latch, gear, etc.

[0293] As described above, in some implementations, the actuation element **112** is coupled at a distal end to the cap **114** of the device **604**. The actuation element **112** extends axially through the outer shaft **611** to the handle **616** and is coupled at a proximal end portion **112***a* to the control element or knob **626**. Although described with respect to various figures herein as being configured as a knob, it should be appreciated that the actuation element **112** can be coupled to any other type of control element, such as another type of rotational control member that is rotatable about the axis of the handle **616**.

[0294] As will be described in greater detail, in some implementations, as the knob **626** is rotated about the axis of the handle **616**, the rotation is translated to axial movement of the actuation element **112**, and is effective to axially advance or retract the actuation element, such a as a rod or wire, to open or close the valve repair device. Optionally, the knob can also drive a paddle release knob **630** (sometimes referred to as an indicator component) between a proximal, or extended, position (as shown in FIG. **74**), and a distal, or retracted, position (as shown in FIG. **73**). In some implementations, the control element can be a button, switch, or the like that causes a motor to rotate a shaft, gear, screw, or other component to cause axial movement of the actuation element **112**.

[0295] Turning now to FIG. **68**, an example of a handle **616** of an implant catheter assembly **610** is shown. In FIG. **68**, the handle **616** includes a housing **632** to which the various controls are coupled.

[0296] In some implementations, an optional nose grip **634** extends axially from a distal end of the housing **632** and facilitates removably coupling the implant catheter assembly to a stabilizer (shown in FIGS. **82**A-C and **83**B-D) during use. In some implementations, the nose grip **634** extends between the housing **632** and a distal flange **636**, and the distal flange **636** limits the axial movement of the handle with respect to the stabilizer. The housing **632** and the nose grip **634** can be formed from various materials, including polymers such as polycarbonate, and can be formed as a unitary body (e.g., through injection molding) or fastened together in any one of a variety of manners, including fasteners, pins, adhesives, or the like.

[0297] In some implementations, as shown for example in FIGS. **69-71**, the housing **632** can comprise open regions or a plurality of lumens, through which the clasp actuation lines **624** and the actuation element **112** extend.

[0298] In some implementations, the handle **616** further comprises a flush port **638**, as shown in FIGS. **68-70**. The flush port **638** is configured for flushing (e.g., with a saline solution) the outer shaft **611** prior to inserting the outer shaft **611** into a patient's vasculature. Additionally, the flush port **638** enables air present in the outer shaft **611** to be removed as fluid is drawn into the proximal end of the outer shaft **611**. Additional information regarding a flush port that can be used in the handle **616** can be found in, for example, International Publication No. WO 2020/112622, the entire contents of which is incorporated by reference herein.

[0299] In some implementations, as shown for example in FIGS. **68-70**, the housing **632** comprises an aperture for receiving a marker/indicator **640** (e.g., a marking pin, tactile marker, visual marker, tag, etc.). The marker/indicator **640** can be a visual and/or tactile indication of which clasp control member is which to help the end user keep track if the handle is rotated.

[0300] In some implementations, the marker/indicator **640** can be a marking pin that is removably coupled with the aperture of the housing **632** for storage of the marking pin **640**. During use, the marking pin **640** can be removed from

the aperture of the housing and inserted into an aperture **641** (shown in FIG. **68**) on one of the clasp control members **628**. For example, the marking pin **640** can be inserted into an aperture **641** on the clasp control member **628** that controls the clasp to be coupled to the posterior leaflet of the mitral valve. Accordingly, in the event that the handle **616** is rotated during use, the user can readily identify the clasp control member **628** for control of the clasp to be coupled to the posterior leaflet (e.g., the marked clasp control member **628**) and the clasp control member **628** for control of the clasp to be coupled to the anterior leaflet (e.g., the unmarked clasp control member **628**). Although the marking pin **640** is described as being coupled to the clasp control member **628** that controls the clasp to be coupled to the posterior leaflet, it is contemplated that the marking pin **640** can be coupled to either of the clasp control members **628** to indicate any particular orientation of the implant catheter assembly.

[0301] In some implementations, a lock **642** is also included and is configured such that it can be actuated or engaged to selectively physically and/or operatively lock the clasp control members **628** together. The lock can be configured in a variety of ways and take different forms. In some implementations, lock **642** is configured as a slide lock that can be actuated or engaged to slide between a first position, in which the slide lock **642** is coupled to one of the clasp control members **628**, to a second position, in which the slide lock **642** is coupled to both of the clasp control members **628**. For example, each of the clasp control members **628** can include a flange **643** to which the slide lock **642** is slidably coupled.

[0302] In some implementations, the slide lock **642** can be moved to the first position (shown in FIG. **71**A and as indicated by the arrow shown in FIG. **68**) in which the slide lock is engaged with the flange **643** of one of the clasp control members **628** (e.g., to enable independent movement of each clasp actuation line relative to the other) and the second position (shown in the FIG. **68**) in which the slide lock **642** is engaged with the flange **643** of both of the clasp control members **628** (e.g., to enable simultaneous movement of the clasp actuation lines) in order to selectively control relative movement between the clasp control members **628**. When the slide lock is in the first position, each of the clasp control members is axially movable independently of the other clasp control member, and when the slide lock is in the second position, the clasp control members are axially movable together. Although not shown in the figures, in some implementations, each flange **643** can include a stop to limit the position of the slide lock **642** along the flange **643**. Moreover, in some implementations, the slide lock **642** can include one or more detents on or near a bottom of the slide lock **642** configured to prevent or inhibit the slide lock **642** from being removed from the flange **643**.

[0303] In some implementations, each of the clasp control members **628** can include one or more tactile or visual indicators to enable the user to differentiate one clasp control member from the other with improved accuracy. For example, one clasp control member **628** can have a different color and/or texture (e.g., ribbed, smooth) than the other clasp control member **628**.

[0304] As shown in the figures, in some implementations, each of the clasp control members **628** is wrapped approximately 180 degrees or otherwise in an actuate manner around the circumference of the housing **632** such that together the clasp control members **628** surround and/or encircle (which can include partially encircling) the housing **632**. Such an arrangement can, for example, enable the clasp control members **628** to be accessible to the user from any angle with a single hand. Moreover, in the example depicted in FIGS. **68** and **71**A, the clasp control members **628** include a depressed region **644** that is generally shaped to receive and cradle the thumb of the user. Although the inclusion of such a depressed region is optional in some examples, it can provide comfort for the user and improve the ease of use of the clasp control members **628** when it is included.

[0305] While various configurations and arrangements of clasp control members **628** are possible, having clasp control members that surround, encircle, or are otherwise readily accessible around a significant portion or majority of the handle (or even a full circumference of the handle) provides significant benefits as compared to a handle with clasp control members on only one side or a small portion of the handle. If clasp control members are on only one side of the handle, they may become very difficult to operate and use at various stages of a procedure, for example, when the catheter handle may be rotated to navigate and/or reposition the device appropriately inside the body of a patient and the clasp control members end up on an underside of the handle. Having clasp control members that encircle or are otherwise readily accessible around a significant portion of the handle (or even a full circumference of the handle) makes it significantly easier to continue to operate/actuate the clasp control members when the handle is rotated into any orientation during a procedure.

[0306] In some implementations, each clasp control member **628** can further comprise one or more keyed projections or tongues that are configured to be received by and slide along a corresponding groove or slot in the housing **632**. As best shown in FIG. **72**, in some implementations, the housing **632** further includes a pair of detents **645**. A first detent **645** is located at a first axial position along a path of one of the clasp control members **628**, and a second detent **645** is located at a second axial position along the path of the clasp control member **628**. For example, in FIG. **72**, one of the detents **645** projects from the housing **632** at a location that places the clasp control member **628** in a fully proximal position (i.e., a fully open position), thereby maintaining the clasp control member **628** in the fully proximal position (i.e., a fully open position) and preventing the clasp control member **628** from moving distally without intention of the user. A second one of the detents **645** projects from the housing **632** at a location that places the clasp control member **628** in a fully distal position (i.e., a fully closed position), thereby maintaining the clasp control member **628** in the fully distal position (i.e., a fully closed position) and preventing the clasp control member **628** from moving proximally without intention of the user. To release the clasp control member **628** for operation of the clasps, the user simply presses the clasp control member **628** with enough force to depresses the detent **645** and slide over the detent **645**. When the clasp control member **628** moved to either the proximal position (open) or distal position (closed), the corresponding detent **645** provides tactile and audible feedback to the user indicative that the clasp control member **628** is in the open or closed position.

[0307] Referring to FIG. **72**, the clasp control member **628** can comprise a coupler **646** configured to attach the clasp control member **628** to a clasp control tube **648**. As described in more detail below, the clasp control tube **648** is

releasably coupled to the clasp actuation lines **624**. Sliding movement of the clasp control member **628** along the housing moves the clasp control tube **648** relative to the housing **632** to open and close the clasps.

[0308] In the example illustrated by FIGS. **68** and **69**, the coupler **646** includes at least one aperture **647**, in which the clasp control tube **648** is connected. The clasp control member **628** is slidably coupled to the housing **632**, such as by the mating channels **629** of the housing **632** and the projections **631** of the clasp control member **628** (see FIG. **68**) and/or by the clasp control tube **648** extending through a guide passage **649** formed in the housing (see FIG. **71**). The clasp control member, the coupler **646**, and the clasp control tube **648** can slide together axially (i.e., distally and proximally) with respect to the housing **632** to open and close the clasp. Only a single coupler **646** and clasp control tube **648** can be seen in FIGS. **68** and **69**. FIG. **71** shows that each clasp control member **628** is fixedly coupled and slides in conjunction with a corresponding clasp control tube **648** in the same manner. The clasp control tube **648** can be fixed at a proximal end to a suture lock **650** that is used to secure the clasp actuation line **624** to the to the clasp control tube **648**.

[0309] In some implementations, each clasp control tube **648** can comprise one or more optional keying features **671** at various positions or all along the axial length of the clasp control tube **648**. In some implementations, no keying features are included. When included, the optional keying features **671** are complementary to corresponding keying features **675** formed in one or more components of the handle **616**, such as in the housing **632** of the handle. These keying features **671**, **675** can prevent or inhibit rotation of the clasp control tube **648** in the housing and thereby limit movement of the clasp control tube to linear movement along the length of the housing **632**. For example, the optional keying feature **671** of the clasp control tube **648** can comprise a wire welded to the external surface of the clasp control tube **648** (see FIG. **69**). In such implementations, one or more portions of the axial path defined by the handle for the clasp control tube **648**, can include a corresponding groove configured to receive the wire and provide a path along which the wire can slide. The optional keying features **671**, **675** can enhance stabilization of the clasp control member **628** by preventing or inhibiting rotation or torquing of the clasp control tube **648** within the handle **616**. For example, the optional keying features **671**, **675** can prevent or inhibit rotation or torquing of the clasp control tube **648** within the handle **616** when the control lines are pulled by the clasp control tube **648** to open the clasps and/or the control lines are pulled through the clasp control tube **648** to release the clasps.

[0310] The suture lock can take a wide variety of different forms. In the example illustrated by FIG. **78**, the suture lock **650** comprises a post **658**, a suture lock body **660**, and a suture lock body receptacle **662**. In the illustrated example, the suture lock body **660** has external threads **665** that mate with internal threads **667** of the suture lock body receptacle **662** to connect the suture lock body and the suture lock body receptacle together. The suture lock body **660** includes a central bore that extends from a first end to a second end of the suture lock body **660**. In some implementations, the central bore of the suture lock body **660** has a diameter that varies from the first end to the second end of the suture lock body **660**. At least a portion of the central bore is sized to receive the post **658**. Accordingly, the diameter of the central bore of the suture lock body **660** can vary to form a flange to limit the position of the post **658** within the bore of the suture lock body **660** while enabling the post **658** to be inserted into a first end of the suture lock body **660**.

[0311] In some implementations, the suture lock body receptacle **662** includes a central bore that extends from a first end to a second end of the suture lock body receptacle **662**. The central bore of the suture lock body receptacle **662** is sized to receive the suture lock body **660** at threaded end of the suture lock body receptacle **662**, and is sized to receive and be attached to the clasp control tube **648** at the second end of the suture lock body receptacle **662**. An optional sealing member or o-ring **664** is positioned around the suture lock body **660** to form a fluid-tight seal between the suture lock body **660** and the suture lock body receptacle **662**.

[0312] In some implementations, the clasp actuation line **624** is fixed at one end of the clasp actuation line **624** to the post **658**, which is inserted into the suture lock body **660**, thereby coupling the clasp actuation line **624** to the suture lock body **660**. In some implementations, the clasp actuation line **624** can be welded, adhered, or otherwise fixedly coupled to the post **658**.

[0313] In some implementations, the clasp actuation line **624** is threaded through the central bore in the suture lock body **660**, through the central bore in the suture lock body receptacle **662**, and through the clasp control tube **648**. The clasp control tube **648** guides and protects the clasp actuation line **624** through the interior of the handle **616**. The clasp actuation line **624** exits the clasp control tube **648** near the distal end of the handle **616** and extends through the outer shaft **611** of the implant catheter assembly **610**. As described herein, the clasp actuation line **624** exits the outer shaft **611** at the distal end of the outer shaft, and is coupled to the device, such as by passing through one or more holes **235** in the clasp **130** (see, e.g., FIGS. **66** and **67**). The clasp actuation line **624** is then threaded back through the outer shaft **611** from the distal end to the proximal end and through the clasp control tube **648** to form a loop in the clasp actuation line **624** that extends from the distal end of the outer shaft **611**. The clasp actuation line **624** then exits the clasp control tube **648** and passes between the suture lock body **660** and the suture lock body receptacle **662** to exit the central bore of the suture lock body receptacle **662**. The threaded connection **665**, **667** between the suture lock body **660** and the suture lock body receptacle **662** can be tightened to pinch the clasp actuation line **624** in position between a tapered nose **679** of the suture lock body **660** and a reduced diameter passage **681** of the suture lock body receptacle **662**. Tightening the threaded connection **665**, **667** also compresses the seal, such as an o-ring, between the suture lock body **660** and the suture lock body receptacle **662** to form a fluid-tight seal between the suture lock body **660** and the suture lock body receptacle **662**.

[0314] In some implementations, an optional spacer or fixture can be used to position the clasp control tubes **648** and/or suture locks **650** while the effective length of the clasp actuation line **624** is set. That is, the optional spacer or fixture sets a correct position of the clasp actuation line **624** corresponding to the clasps in an open position. The clasp actuation lines **624** can then be pulled taught with the clasps in the open position and the suture locks **650** can be tightened to fix the clasp actuation lines **624** to the clasp

control tubes **648**. The optional spacer or fixture can take a variety of different forms. Any device that sets the position of the control tubes **648** and/or suture locks **650** relative to the body of the handle can be used.

[0315] Referring to FIG. **71**A, an example clasp setting spacer **696** is shown supporting the clasp control tube **648** and the suture lock **650** for each clasp in a corresponding groove **698** while the threaded connection between the suture lock body and the suture lock receptacle is tightened. Each groove **698** in the clasp setting spacer **696** is sized to receive the clasp control tube **648** and/or at least a part of the suture lock **650**. The clasp setting spacer **696** can also include a handle supporting end **800** that is configured to couple to and support the handle **616**. In some implementations, the handle supporting end **800** can include a groove that is configured to receive a protrusion on the surface of the handle **616**, thereby enabling the clasp setting spacer **696** to be coupled to the handle **616**.

[0316] As shown in the example in FIG. **71**A, the clasp setting spacer **696** can include one or more pairs of optional feet **802**. The pair of feet **802** interface with a surface on which the handle is placed during clasp setting and provides support to the handle **616**, the clasp control tubes **648**, and the suture locks **650**.

[0317] In some implementations, the clasp setting spacer **696** has a length extending between the handle supporting end **800** and a proximal end **804** of the clasp setting spacer **696**. Although the length of the clasp setting spacer **696** can vary, in some implementations, the length of the clasp setting spacer **696** is selected to provide a pre-determined distance between the suture lock and a proximal end of the handle **616**. Accordingly, in use, the clasp setting spacer **696** receives the clasp control tube **648** and suture lock **650** and secures them in a predetermined position relative to the handle **616** such that when the clasp control line is secured in place between the suture lock body and the suture lock receptacle, the distance of the path of the clasp control line is constant. This ensures that the clap control line has a sufficient length to enable the clasps to move through their full range of motion while not being too long.

[0318] In some implementations, to release the clasp from the clasp actuation line, the suture lock body **660** can be removed (e.g., by unscrewing) from the suture lock body receptacle **662**, freeing the end of the clasp actuation line **624** pinched between the suture lock body **660** and the suture lock body receptacle **662**. Once the clasp actuation line **624** is released, the clasp actuation line can be pulled through the clasp control tube **648**, the outer shaft **611**, the hole **235** of the clasp and back through the outer shaft **611** and clasp control tube **648**. As such, the clasp actuation line **624** is no longer connected to the clasp and is removed from the patient.

[0319] Returning to FIG. **69**, in some implementations, as the clasp control member **628** is moved in a proximal direction, the clasp control tube **648** also moves in the proximal direction, pushing the suture lock **650** in the proximal direction with respect to the handle **616**. As the suture lock **650** moves in the proximal direction, the loop of the clasp actuation line **624** extending from the distal end of the outer shaft **611** moves proximally, pulling the clasp **130**. To release the clasp **130**, such as to grasp the leaflet, the clasp control member **628** is moved in a distal direction, which in turn moves the clasp control tube **648** and suture lock **650** in the distal direction, thereby moving the loop of the clasp actuation line **624** in the distal direction, enabling the clasp **130** to move toward the inner paddles **122**, grasping the leaflet between the clasp **130** and the inner paddle **122**.

[0320] As previously mentioned, in some implementations, the handle **616** can further comprise a control element or knob **626** that can be configured to rotate about an axis of the handle **616** and to control the position of the actuation element **112** relative to the handle **616** and outer shaft **611**. As can be seen in the example of FIGS. **69-71**, the knob **626** is fixedly coupled to an internally threaded tube **652** positioned within the housing **632** of the handle **616**. When the knob **626** is rotated about the axis of the handle **616**, the internally threaded tube **652** rotates with respect to the housing **632**. An externally threaded nut or retractor **654** is positioned within and engaged with the internally threaded tube **652**. The externally threaded nut or retractor **654** and is rotationally fixed with respect to the housing **632**. The externally threaded nut or retractor **654** can be rotationally fixed in a wide variety of different ways. In the example illustrated by FIG. **70**, a pair of guide rods **661** extend axially within the handle **616**, and each of the pair of guide rods **661** is fixed to the housing **632** at both ends of the guide rod **661**. A mounting bracket **663** couples the pair of guide rods **661** to the housing **632** at the distal end of each of the pair of guide rods **661**. Accordingly, as the internally threaded tube **652** is rotated, the externally threaded retractor **654** is advanced linearly in an axial direction (i.e., distally and proximally) along the pair of guide rods **661**.

[0321] In some implementations, the externally threaded retractor **654** is connected to the actuation element **112** such that linear movement of the externally threaded retractor **654** causes linear movement of the actuation element **112**, thereby moving the device between a fully elongated configuration, an open configuration, and a closed configuration, as described herein. The translation of the rotational movement of the knob **626** into linear motion of the actuation element **112** can result in improved control and precision, thereby leading to improved precision during the opening and closing of the device.

[0322] In some implementations, the internally threaded tube **652** includes and unthreaded portion **657**. A clutch spring **656** is positioned around an unthreaded proximal portion **659** of the retractor **654**. The clutch spring presses against a proximal end surface **655** of the threaded portion of the retractor **654**. Proximal movement of the actuation element **112** after closure of the device **604** can result in overclosure or compression of the valve repair device. The position of the unthreaded portion **657** is selected to prevent or inhibit over-retraction of the actuation element **112** and thereby prevent or inhibit over-closing of the valve repair device. That is, the externally threaded retractor **654** is no longer driven proximally when the externally threaded nut or retractor **654** reaches the unthreaded portion **657**. The clutch spring is configured to bias the externally threaded retractor **654** distally (e.g., toward the threads of the internally threaded tube **652**) when the externally threaded retractor **654** has reached the end of the threads of the internally threaded tube **652**. Continued rotation of the knob **626** following disengagement of the external threads of the externally threaded retractor **654** and the internal threads of the internally threaded tube **652** results in an audible indication that the device is in a closed position. The biasing of the externally threaded retractor **654** can also reduce slop in

the threaded connection, thereby improving stability of the paddle angle. The biasing of the externally threaded retractor **654** towards the internal threads of the internally threaded tube **652** ensures that the externally threaded retractor **654** will be re-engaged by the internally threaded tube **652** when the knob **626** is rotated in an opposite direction that corresponds to advancement of the actuation element **112**.

[0323] As shown in FIGS. **70**, **70**A and **71**, in some implementations, the externally threaded retractor **654** can include a central passage **683**. A crimp assembly **668** is coupled in the central passage **683**. The crimp assembly attaches the actuation element **112** that is in an actuation tube **669** to the paddle release knob **630**. The crimp assembly **668** can take a variety of different forms. In the illustrated example, the crimp assembly **668** comprises a collet **687** and a nut **670**. The collet **687** includes external threads and the nut includes internal threads. The collet and nut each have a central bore that is sized to receive the actuation tube **669** which surrounds the actuation element **112**. The actuation element **112** can be fixed to the actuation tube **669** near the proximal end of the actuation tube **669**. The actuation tube **669** is fixed to the crimp assembly **668**, which is fixed to the externally threaded retractor **654**. The external threads on the outer surface of the collet **687** engage with the internal threads of the nut **670**. When tightened, the collet **687** and nut **670** fix the crimp assembly to both the actuation tube **669** and a shoulder **689** at the proximal end of the retractor **654**. The nut is positioned within the central passage **683** of the externally threaded retractor **654**. A spring **672** is also positioned within the central passage **683** of the externally threaded retractor **654** such that the nut **670** is biased against the shoulder **689**. The positioning of the nut **670** against the shoulder **689** allows the collet **687** to be easily attached to the nut **670**.

[0324] In some implementations, in use, the knob **626** is rotated, which rotates the internally threaded tube **652** to rotate with respect to the housing **632**, thereby driving the externally threaded retractor **654** axially. The axial movement of the externally threaded retractor **654** causes axial movement of the actuation element **112**, which moves the device between a fully elongated configuration, an open configuration, and a closed configuration. Axial movement of the externally threaded retractor **654** also causes axial movement of the release knob **630** between a proximal, or extended, position (shown in FIG. **74**) and a distal, or retracted, position (shown in FIG. **73**). Accordingly, in some implementations, the axial position of the release knob **630** with respect to the housing **632** is a visual indicator of the configuration of the device **604**.

[0325] In some implementations, when the device **604** is in a closed configuration (e.g., shown in FIG. **21**), the release knob **630** is in a proximal position, extending from the housing **632**, as shown in FIG. **74**. To release the device from the implant catheter assembly **610**, the release knob **630** is rotated in an unscrewing or loosening direction, which rotates the crimp assembly **668**, the actuation tube **669**, and the actuation element **112**. Rotation of the actuation element **112** extends down the length of the actuation element to the distal end portion **112***b* of the actuation element, thereby unscrewing the actuation element **112** from the cap **114** of the device **604**.

[0326] As shown in FIGS. **75-77**, in some implementations, the release knob **630** comprises an elongated shaft **673** and a plurality of teeth **674** extending from the outer surface of the elongated shaft **673**. Each of the plurality of teeth **674** are uniform, but asymmetrical in shape, with each of the plurality of teeth **674** having a moderate slope on one edge and a much steeper slope on the other edge. A ratchet insert **676** is positioned within the housing **632** of the handle **616**, between the elongated shaft **673** and the housing **632**. The ratchet insert **676** includes one or more pawls **678** flexibly mounted to a ratchet frame **680**. In some implementations, the pawls **678** and the ratchet frame **680** are made from a unitary piece from a material that enables the pawls **678** to flex with respect to the ratchet frame **680**.

[0327] In some implementations, each of the pawls **678** is in contact with the outer surface of the elongated shaft **673**. Accordingly, as the release knob **630** is rotated in the unscrewing or loosening direction, each pawl **678** slides up and over the edge of the tooth **674** with a moderate slope, and springs back into the area between the tooth and an adjacent tooth. In some implementations, the springing back of the pawl into the area between teeth generates an audible indication that a tooth has been cleared. The edge of the tooth **674** with the steeper slope catches the pawl **678** prevents or inhibits the release knob **630** from being rotated in the opposite, tightening direction. Enabling a single direction of rotation of the release knob **630** prevents or inhibits torsion that can build up as a result of the torquing of the actuation element **112** during release of the device **604** from turning the release knob **630** back in the tightening direction.

[0328] Once the actuation element **112** is decoupled from the device **604**, the actuation element **112** can be withdrawn into the implant catheter assembly **610**, and the implant catheter assembly **610** can be withdrawn through the steerable catheter assembly **608** and the delivery catheter assembly **606**.

[0329] Although not shown in the figures, in some implementations a cap is removably couplable to the proximal end of the handle to cover the release knob **630** and the suture locks **650**. Accordingly, the cap can be positioned over the release knob **630** and suture locks **650** to prevent or inhibits the release knob **630** and suture locks **650** from being accidentally contacted or caught on something during manipulation of the implantable device, and removed to access the release knob **630** and suture locks **650**.

[0330] In some implementations, one or more components of the delivery system are couplable to a stabilizer system to further provide improved control of the delivery system during delivery and implantation of the implantable device. As will be described in greater detail, the stabilizer system generally includes one or more clamps slidable with respect to a base plate that can be fixed relative to the patient. One or more components of the delivery system (e.g., one or more catheter assemblies) are received by the one or more clamps to limit movement of the delivery system or one or more components (e.g., catheter assemblies, etc.) thereof in one or more directions. For example, the stabilizer system can prevent or inhibit the delivery system or component(s) thereof from being moved vertically and from side-to-side while enabling the delivery system or one or more components thereof to be moved axially. In some implementations, the clamps receive a nose grip of one or more of the catheter assemblies of the delivery system.

[0331] Turning now to FIGS. **79-81**, an example nose grip **634** is shown in additional detail. In FIG. **79**, the nose grip **634** extends between a distal flange **636** and a proximal

flange **682**. Although the example shown in FIGS. **79** and **81** includes the proximal flange **682**, it is contemplated that some implementations may not include the proximal flange **682**, as shown in FIGS. **82**A and **85**A. Accordingly, the proximal flange **682** is optional. As can be seen in FIGS. **82**A-**84**, the nose grip **634** is coupled at a proximal end of the nose grip **634** to a catheter handle, such as handle **614** of the steerable catheter assembly **608** or handle **616** of the implant catheter assembly **610**. A passage **684** extends through the nose grip **634** from the proximal end to the distal end, enabling the corresponding catheter sheath **609**, **611** to pass through the nose grip **634**.

[0332] In some implementations, the nose grip **634** is formed from or as an outer surface that is coated with a rubber or other material with a relatively high coefficient of friction such that the nose grip **634** does not slip when coupled to a clamp **685**, such as can be incorporated into a stabilizer. However, in some implementations, the material has a coefficient of friction that allows the nose grip **634** to be rotated about an axis when coupled to the clamp **685**, thereby enabling the handle to be rotated during a procedure to rotationally position the implantable device. As shown in FIG. **80**, the clamp **685** generally comprises a pair of jaws **686** forming an opening **688** configured to receive the nose grip **634**. In some implementations, the pair of jaws **686** are coupled to one another through a spring **690**, which biases the pair of jaws **686** toward one another (as shown in FIG. **80**), while enabling the jaws **686** to be opened with an application of an opening force to allow the nose grip **634** to be positioned within or removed from the opening **688**. U.S. Provisional Patent Application Ser. No. 63/073,392, filed on Sep. 1, 2020 discloses examples of clamps that can be used as the clamp **685** and examples of stabilizing systems and devices that can be used with the systems and devices herein. U.S. Provisional Patent Application Ser. No. 63/073,392 is hereby incorporated by reference for all purposes. Any of the devices, methods, etc. can be used in any of the implementations or examples disclosed by the present application.

[0333] As shown in FIGS. **80**-**81**, the nose grip **634** is received in the opening **688** between the jaws **686**, with the distal flange **636** and the proximal flange **682** disposed outside the jaws **686**. The distal flange **636** has an outer diameter that is greater than an outer diameter of a central portion of the nose grip **634** (e.g., the portion of the nose grip between the distal flange and the proximal flange) and greater than a diameter of the opening of the clamp **685**, thereby preventing or inhibiting the nose grip **634** from being pulled out of the clamp **685** unintentionally and from being rotated relative to the clamp **685** unintentionally.

[0334] FIGS. **82**A-**82**C depict an example nose grip **634***a* in conjunction with a handle **614** of a steerable catheter assembly coupled with a clamp **685**. In FIGS. **82**A-**82**C, the clamp **685** comprises a movable jaw **686***a* and a fixed jaw **686***b*. The clamp **685** is opened and closed by pivoting the movable jaw **686***a* relative to the fixed jaw **686***b*. The movable jaw **686***a* is biased with a spring toward the fixed jaw **686***b* so that the clamp **685** remains in a closed condition unless opened by an application of an opening force to the movable jaw **686***a*, as shown by arrow **691** in FIG. **82**A. The nose grip **634***a* is positioned within the opening of the clamp **685** while the clamp is open. Referring to FIG. **62**B, when the opening force **691** is removed from the movable jaw **686***a*, the clamp **685** closes and applies a closing force of the clamp to the nose grip **634***a*. In some implementations, the closing force applied by the clamp **685** is sufficient to stabilize and prohibit unintended rotation of the nose grip **634***a* and, accordingly, the handle **614** and corresponding sheath **609**. However, intentional rotation of the handle **614**, as shown by the rotational arrows in FIG. **82**B, can apply a rotational force to the nose grip **634***a* that is sufficient to overcome the closing force, thereby enabling the handle **614** to be rotated.

[0335] In some implementations, the clamp **685** is coupled to a base plate **693** through one or more mounting rails **694** extending from the base plate **693**. U.S. Provisional Patent Application Ser. No. 63/073,392 discloses examples of base plates and mounting rails that can be used as the base plate **693** and mounting rails **694**, U.S. Provisional Patent Application Ser. No. 63/073,392 and is incorporated by reference herein for all purposes. In some implementations, the one or more mounting rails **694** extend in an axial direction (e.g., proximally and distally) along the base plate **693** and enable the clamp **685** to be moved axially. In some implementations, the clamp **685** is configured to slide with respect to the mounting rails **694** to enable the axial movement of the clamp **685** and, therefore, the steerable catheter assembly when the nose grip **634***a* is positioned within the opening of the clamp **685**. To hold the clamp **685** in a desired location along the mounting rails **694**, a locking knob **692** is rotatable between a first, locked position (shown in FIGS. **82**A and **82**B) and a second, unlocked position (shown in FIG. **82**C).

[0336] In some implementations, the locking knob **692** is connected to a rotating cam portion (not shown) so that rotating the locking knob **692** causes the rotating cam portion to rotate. As the rotating cam portion is rotated, an oblong portion of the rotating camp portion engages a locking foot (not shown), thereby causing the locking foot to move downward to an extended position, which in turn causes the carriage to move upward with respect to the mounting rails **694**. Friction generated between the carriage and the mounting rails **694** retains the clamp **685** in the desired location. To reposition the clamp **685**, the locking knob **692** is rotated to disengage the locking foot so that the clamp **685** can slide along the mounting rail **694**, as shown in FIG. **82**C.

[0337] FIGS. **83**A-**83**C depict an example nose grip **634***b* in conjunction with a handle **616** of implant catheter assembly coupled with a clamp **685**. In FIGS. **83**A-**83**C, the clamp **685** comprises a movable jaw **686***a* and a fixed jaw **686***b*. The clamp **685** is opened and closed by pivoting the movable jaw **686***a* relative to the fixed jaw **686***b*. The movable jaw **686***a* is biased with a spring toward the fixed jaw **686***b* so that the clamp **685** remains in a closed condition unless opened by an application of an opening force to the movable jaw **686***a*, as indicated by arrow **691** in FIG. **83**B. The nose grip **634***a* can positioned within the open clasp. When the opening force is removed from the movable jaw **686***a*, the clamp **685** closes and applies a clamping force to the nose grip **634***a*, as shown in FIG. **83**C. In some implementations, the closing force applied by the clamp **685** is sufficient to stabilize and prohibit unintended rotation of the nose grip **634***a* and, accordingly, the handle **616** and corresponding sheath **611**. However, intentional rotation of the handle **616**, as shown by the rotational arrows in FIG. **83**C, can apply a rotational force to the nose grip **634***a* that is sufficient to overcome the closing force, thereby enabling the handle **616** to be rotated.

[0338] As with the previous example, the clamp **685** can be coupled to a base plate **693** through one or more mounting rails **694** extending from the base plate **693**. In some implementations, the one or more mounting rails **694** extend in an axial direction (e.g., proximally and distally) along the base plate **693** and enable the clamp **685** to be moved axially. The clamp **685** is configured to slide with respect to the mounting rails **694** to enable the axial movement of the clamp **685** and, therefore, the implant catheter assembly when the nose grip **634***a* is positioned within the opening of the clamp **685**. To hold the clamp **685** in a desired location along the mounting rails **694**, a locking knob **692** is rotatable between a first, locked position (not shown) and a second, unlocked position (shown in FIGS. **83**B-C).

[0339] In some implementations, the locking knob **692** is connected to a rotating cam portion (not shown) so that rotating the locking knob **692** causes the rotating cam portion to rotate. As the rotating cam portion is rotated, an oblong portion of the rotating cam portion engages a locking foot (not shown), thereby causing the locking foot to move downward to an extended position, which in turn causes the carriage to move upward with respect to the mounting rails **694**. Friction generated between the carriage and the mounting rails **694** retains the clamp **685** in the desired location. To reposition the clamp **685**, the locking knob **692** is rotated to disengage the locking foot so that the clamp **685** can slide along the mounting rail **694**.

[0340] FIG. **84** depicts a portion of a stabilization system for stabilizing a system or assembly (e.g., a valve treatment system or assembly), such as a system or assembly **600** of FIGS. **64-65**. For example, FIG. **84** depicts the handle **616** and sheath **611** of a catheter assembly (e.g., an implant catheter assembly **610**), with the sheath **611** thereof being received by a proximal end of the handle **614** of another catheter assembly (e.g., a steerable catheter assembly **608**). Although only one catheter assembly (e.g., implant catheter assembly) is shown as being coupled to the stabilization system, it should be appreciated that the handle **614** of the other catheter assembly (e.g., steerable catheter assembly) can also be coupled to a clamp (not shown), e.g., through a nose grip, such as nose grip **634***a*. Moreover, it should be appreciated that the system or assembly can further include one or more additional catheter assemblies (e.g., a delivery catheter assembly **606**) that can also be coupled to a clamp (not shown), e.g., through a nose grip, other attachment point, or the like.

[0341] In some implementations, the sheath **611** enters the handle **614** of the steerable catheter assembly and can extend through the handle and into the sheath **609** of the steerable catheter assembly, as described hereinabove. In some implementations, the sheath **611** has a friction fit within the handle **614**, the sheath **609**, or both. As shown in FIG. **84**, the locking knob **692** of the clamp **685** coupled to the nose grip **634** is positioned in an unlocked position, thereby enabling axial movement of the implant catheter assembly with respect to the base plate **693**. Accordingly, when the locking knob of the clamp coupled to the nose grip **634** of the handle **614** is also in an unlocked position, axial movement of the handle **616** of the implant catheter assembly can cause axial movement of the handle **614** of the steerable catheter assembly and the handle **616** of the implant catheter assembly with respect to the base plate **693**. However, when the locking knob of the clamp coupled to the nose grip **634** of the handle **614** is in a locked position, axial movement of the handle **616** of the implant catheter assembly can cause axial movement of the handle **616** of the implant catheter assembly with respect to the handle **614** of the steerable catheter assembly and the base plate **693**.

[0342] As described herein, the nose grip **634** can be incorporated into the handles **614**, **616** for a steerable catheter assembly and an implant catheter assembly of a delivery system. It is further contemplated that, in some implementations, any one or more of the catheter assemblies included in a delivery system can comprise the nose grip **634** to enable the catheter assembly to be coupled to a stabilization system. Moreover, it is contemplated that in some implementations in which multiple catheter assemblies in a delivery system comprise the nose grip **634**, the nose grip **634** can be the same for each catheter assembly or can differ between catheter assemblies. For example, FIGS. **85**A and **85**B illustrate the nose grip **634***a* and the nose grip **634***b*, as described hereinabove. As shown in FIG. **85**A, the nose grip **634***a*, described herein as being incorporated into the handle **614** of the steerable catheter assembly, does not include a proximal flange, whereas the nose grip **634***b* (FIG. **85**B), described herein as being incorporated into the handle **616** of the implant catheter assembly includes both a distal flange **636** and a proximal flange **682**.

[0343] In some implementations, the nose grip **634***a* has an outer diameter OD_1, and the nose grip **634***b* has an outer diameter OD_2. In some implementations, the outer diameter OD_1 is equal to the outer diameter OD_2. In some implementations, the outer diameter OD_1 is different than the outer diameter OD_2. For example, the outer diameter OD_1 can be greater than the outer diameter OD_2, or the outer diameter OD_1 can be less than the outer diameter OD_2. A difference in the outer diameters OD_1, OD_2 can, for example, enable a different tactile feel upon rotation of the steerable catheter assembly as compared to rotation of the implant catheter assembly. In some implementations, the outer diameter OD_1 of the nose grip **634***a* of the steerable catheter assembly is greater than the outer diameter OD_2 of the nose grip **634***b* of the implant catheter assembly, which can, for example, provide additional friction between the nose grip **634***a* and the opening **688** of the clamp **685** as compared to an amount of friction between the nose grip **634***b* and the opening **688** of the clamp **685**. This can provide a feeling to the user that it is easier to turn the implant catheter assembly and implant than it is to rotate the steerable catheter assembly in the guide sheath or delivery catheter assembly.

[0344] Although the stabilization system can be effective to stabilize the delivery system at proximal locations, in some implementations, one or more of the catheter assemblies comprise features to further improve accuracy of the delivery of the implantable device. For example, movement of the implant catheter assembly through the steerable catheter assembly or while in the steerable catheter assembly (e.g., rotation of the implant catheter shaft to properly orient the implantable device) can alter the trajectory of the steerable catheter sheath, which in turn alters the location of the implantable device coupled to the implant catheter assembly. Accordingly, in some implementations, features can be implemented to reduce friction between the implant catheter shaft and the steerable catheter shaft, to stiffen a proximal portion of the steerable catheter sheath and/or the implant catheter shaft, or both.

[0345] Turning now to FIGS. **86** and **87**, a shaft or sheath **611** of a catheter assembly, e.g., an implant catheter assem-

bly **610**, having a portion of the shaft or sheath **611** with a reduced outer diameter portion **703** is shown. In particular, FIG. **86** shows a cross-section of a shaft or sheath **611** of a catheter assembly, e.g., an implant catheter assembly **610**, extending through a shaft or sheath **609** of another catheter assembly, e.g., a steerable catheter assembly **608**. While described in the context of particular types of catheter assemblies for illustration, similar features and principles can be applied in a variety of catheter assemblies.

[0346] FIG. **87** shows the shaft or sheath **611** of the implant catheter assembly **610** extending from the shaft or sheath **609** of the steerable catheter assembly **608**. As shown in FIG. **86**, the shaft or sheath **609** of the steerable catheter assembly **608** has an inner diameter ID_1 through which the shaft or sheath **611** implant catheter assembly **611** extends. The sheath **609** of the steerable catheter assembly **608** includes a steerable portion having a length L_1, over which the sheath **609** of the steerable catheter assembly **608** can be bent or deformed, as described in greater detail above.

[0347] In some implementations, the outer shaft or sheath **611** of the implant catheter assembly **610** includes a lumen through which an actuation element **112** (which can be the same as or similar to other actuations elements herein) extends, as described in greater detail above. The actuation element **112** extends in an axial direction through a lumen of the sheath or shaft **611** of the implant catheter assembly **610**. In some implementations, the sheath or shaft **611** of the implant catheter assembly has a portion having a first outer diameter OD_1. In some implementations, the portion having the first outer diameter OD_1 extends distally from the handle **616** (FIG. **66**) to the reduced diameter portion **703** having a second outer diameter OD_2, but this portion can extend over a smaller distance in some implementations (e.g., may not extend all the way to the handle). The reduced diameter portion **703** is typically proximate the distal end of the sheath **611** of the implant catheter assembly **610**. The second outer diameter OD_2 is less than the first outer diameter OD_1 of the sheath of the implant catheter assembly.

[0348] In some implementations, the portion of the sheath **611** of the implant catheter assembly **610** having the first outer diameter OD_1 has a length that is greater than the length L_2 of the reduced diameter portion **703** having the second outer diameter OD_2. The length L_2 of the reduced diameter portion **703** is greater than the length L_1 of the steerable portion of the sheath of the steerable catheter assembly **608**. Although the length L_2 of the reduced diameter portion **703** can vary, in some implementations, the length L_2 is greater than or equal to the sum of a stroke distance (i.e., the distance over which the sheath or shaft **611** of the implant catheter assembly **610** is extended from the sheath or shaft **609** of the steerable catheter assembly **608** during delivery of the implantable device) and the length L_1 of the steerable portion of the sheath or shaft **609** of the steerable catheter assembly **608**. Accordingly, the system can be operated such that only the reduced diameter portion **703** of the sheath or shaft **611** is in the steerable portion of the sheath or shaft **609** during use of the implant catheter assembly **610** and the steerable catheter assembly **608** to position and implant the implant or valve repair device **604**. The sheath or shaft **611** of the implant catheter assembly **610** can have a reduced outer diameter over the entire length of the sheath or shaft **611** that will be within the steerable portion of the sheath **609** of the steerable catheter assembly **608**, including when the sheath or shaft **611** implant catheter assembly is retracted and extended with respect to the steerable catheter assembly **608**, as shown in FIGS. **88**A and **88**B.

[0349] The difference between the first outer diameter OD_1 and the second outer diameter OD_2 can vary depending on the particular implementation and can be, for example, from about 0.25 mm to about 0.76 mm, or any range between 0.25 mm and 0.76 mm. In some implementations, the transition from the first outer diameter OD_1 to the second outer diameter OD_2 is gradual, and can form a smooth taper from the first outer diameter OD_1 to the second outer diameter OD_2 over a distance of from about 25 mm to about 50 mm. In some implementations, one or more discrete steps are defined from the first outer diameter OD_1 to the second outer diameter OD_2. Moreover, as shown in FIGS. **86** and **87**, the sheath or shaft **611** of the implant catheter assembly **610** transitions from the first outer diameter OD_1 to the second outer diameter OD_2 and back to the first outer diameter OD_1 along the length of the sheath or shaft **611** of the implant catheter assembly **610**, such that the portion having the second outer diameter OD_1 is between two portions of the implant catheter assembly having the first outer diameter OD_1.

[0350] In some implementations, both of the outer diameters OD_1 and OD_2 are less than the inner diameter ID_1 of the sheath **609** of the steerable catheter assembly **608**, and, as described above, the sheath **611** of the implant catheter assembly **610** has the second outer diameter OD_2 along the length L_1 of the steerable portion of the sheath **609** of the steerable catheter assembly **608**. The reduced outer diameter OD_2 of the sheath **611** of the implant catheter assembly **610** through the steerable portion of the sheath **609** of the steerable catheter assembly **608** reduces friction between the steerable catheter sheath **609** and the implant catheter sheath **611**, which can reduce the amount of cross-talk between the steerable catheter sheath **609** and the implant catheter sheath **611** (e.g. unintended flexing of the steerable catheter sheath **609** and the implant catheter sheath **611** due to friction therebetween), and reduce the need to re-orient the steerable catheter assembly during implant positioning.

[0351] As an alternative to reducing the outer diameter of the sheath of the implant catheter assembly over the steerable length, it is contemplated that, in some implementations, the inner diameter of the sheath of the steerable catheter assembly can be increased over the length L_1 while the outer diameter of the sheath of the implant catheter assembly remains constant. The inner diameter of the portion of the sheath **609** that flexes can be increased by an amount of from about 0.25 mm to about 0.76 mm (or any subrange thereof), and/or the transition from the first inner diameter to the second inner diameter can be over a distance of about 25 mm to about 50 mm. Moreover, in some implementations, both the inner diameter of the sheath of the steerable catheter assembly can be increased and the outer diameter of the sheath of the implant catheter assembly can be decreased to reduce friction between the steerable catheter assembly and the implant catheter assembly through the steerable portion.

[0352] Friction can additionally or alternatively be reduced between the implant catheter shaft and the steerable catheter sheath through the use of a lubricated coating **700**, as shown in FIGS. **86** and **87**. The lubricated coating can take a wide variety of different forms. The coating can be a wet or dry coating or include both wet and dry components.

In FIGS. **86** and **87**, the lubricated coating **700** is applied to an outer surface of the reduced diameter portion **703** of the sheath **611** of the implant catheter assembly **610** having the second outer diameter OD_2. However, it is contemplated that some implementations can include the lubricated coating **700** over a length of a sheath of the implant catheter assembly having a substantially constant outer diameter. Alternatively or additionally, the lubricated coating **700** can be applied to an inner surface of the length L_1 of the steerable portion of the sheath **609** of the steerable catheter assembly **608**. Moreover, although illustrated in FIGS. **86** and **87** as being included along only the length L_2, it is contemplated that the coating can be applied along any additional length of the sheath **611** of the implant catheter assembly **610** or the sheath **609** of the steerable catheter assembly **608**.

[0353] The lubricated coating **700** can be a coating made from a wide variety of different materials. Any material that reduces friction can be used. The lubricated coating **700** can be a coating made, for example, from silicone oil, a hydrophilic material, or another material having a low coefficient of friction, such as perfluoropolyether (PFPE) or expanded polytetrafluoroethylene (ePTFE). Accordingly, the lubricated coating **700** can include hydrophilic coatings, coatings of PFPE lubricants, and ePTFE sleeves, such as coatings made from the materials commercially available under the tradenames CHRISTO-LUBE™ (available from Engineered Custom Lubricants) and SURMODICS SERENE™ (available from Surmodics, Inc.).

[0354] In some implementations, the lubricated coating **700** reduces a coefficient of friction between the outer surface of the sheath **611** of the implant catheter **610** and an inner surface of the sheath **609** of the steerable catheter assembly **608** through the steerable portion of the sheath **609** of the steerable catheter assembly **608**. This reduction in friction can reduce the amount of cross-talk between the steerable catheter sheath **609** and the implant catheter sheath **611** (e.g., unintended flexing of the steerable catheter sheath **609** and the implant catheter sheath **611** due to friction therebetween), and reduce the need to re-orient the steerable catheter sheath during implant orientation.

[0355] Use of a liner (e.g., a lubricious liner) within the lumen of the steerable catheter sheath **609** can alternatively or additionally reduce friction between the steerable catheter sheath **609** and the implant catheter sheath **611**. In some implementations, such a liner is formed from a polyamide doped with a PTFE powder. The PTFE powder can be incorporated into molten polyamide in an amount of from about 5 wt. % to about 30 wt. %, depending on the particular implementation. For example, the PTFE powder can be incorporated into the polyamide in an amount of from about 5 wt. % to about 30 wt. %, from about 5 wt. % to about 25 wt. %, from about 5 wt. % to about 20 wt. %, from about 5 wt. % to about 15 wt. %, from about 7.5 wt. % to about 30 wt. %, from about 7.5 wt. % to about 25 wt. %, from about 7.5 wt. % to about 20 wt. %, from about 7.5 wt. % to about 15 wt. %, or from about 10 wt. % to about 30 wt. %, from about 10 wt. % to about 25 wt. %, from about 10 wt. % to about 20 wt. %, or from about 10 wt. % to about 15 wt. %, including any ranges and sub-ranges therein.

[0356] The polyamide can be a variety of different polyamides. In some implementations, the polyamide is nylon 6,6, nylon 6,12, nylon 4,6, nylon 6, nylon 12, or a combination thereof. In some implementations, the polyamide has a Shore D durometer of **70**D or greater. For example, the polyamide can have a Shore D durometer of **70**D or greater, **75**D or greater, **80**D or greater, or **85**D or greater. According to various implementations, the PTFE-doped polyamide liner may exhibit a coefficient of friction that is less than that of an otherwise identical polyamide liner, while also exhibiting an improved adhesion to a polymer jacket (e.g., a PEBAX or nylon polymer jacket) bound to the outer surface of the polymer liner. The PTFE-doped polyamide liner can define an interior surface of one or more lumens of the guide sheath, the steerable catheter, and/or the implant catheter of the delivery assemblies described herein, or of any other delivery assembly.

[0357] According to some implementations, the inner diameter ID_1 of the sheath **609** of the steerable catheter assembly **608** varies along the length of the sheath **609** and, more particularly, can have a larger inner diameter at or near the ends of the sheath **609** than at an inner diameter at a point located closer to the center of the length of the sheath **609**. For example, in some implementations, the inner diameter ID_1 of the sheath **609** of the steerable catheter assembly **608** is flared at one or both of the proximal end and the distal end of the sheath. The flared inner diameter ID_1 of the sheath **609** can be effective to create a smooth transition between the outer diameter of the sheath **611** of the implant catheter assembly **610** and the outer diameter of the sheath **609** of the steerable catheter assembly **608**, which in turn can reduce an amount of coating (e.g., the lubricated coating **700**) scraped off of the outer surface of the sheath **611** of the implant catheter by the inner surface of the sheath **609** of the steerable catheter assembly **608**.

[0358] As described above, another method of improve accuracy of the delivery of the implantable device includes stiffening a proximal portion of the sheath **609** of the steerable catheter assembly **608** (as shown in FIG. **89**A), the sheath **611** of the implant catheter assembly **610** (as shown in FIG. **89**B), or both (as shown in FIG. **89**C). It is believed that stiffening the proximal portion of the sheaths of the catheter assemblies can reduce torsional deformation, thereby reducing lag between the implant catheter handle rotation and rotation of the implant, reducing the out of plane movement of the sheath of the steerable catheter assembly, or both, depending on the sheath of the catheter assembly that is stiffened.

[0359] In FIGS. **89**A-C, a proximal portion **611***a* of the sheath or shaft **611** of the implant catheter assembly **610** and a distal portion **611***b* of the sheath or shaft **611** of the implant catheter assembly **610** are shown extending through a proximal portion **609***a* of the sheath **609** of the steerable catheter assembly **608** and a distal portion **609***b* of the sheath **609** of the steerable catheter assembly **608**, respectively. The proximal portion **611***a* of the sheath or shaft **611** of the implant catheter assembly **611**, the proximal portion **609***a* of the sheath **609** of the steerable catheter assembly **608**, or both comprise a stiffening material **701**, while the distal portions **609***b*, **611***b* of the sheaths **609**, **611** of the implant catheter assembly **610** and steerable catheter assembly **608** do not include the stiffening material. Accordingly, the proximal portion of the sheath(s) or shafts(s) of the catheter assembly (s) including the stiffening material **701** is/are stiffened as compared to the distal portion(s) of the sheath(s) or shaft(s) of the catheter assembly(s).

[0360] The stiffening material **701** can take a wide variety of different forms. The stiffening material **701** can be, for

example, a laser-cut hypotube, a material having a higher durometer than materials in the distal portion(s) of the sheath(s) or shaft(s) of the catheter assembly(s), one or more braids, one or more meshes, one or more woven materials, or the like. The stiffening material **701** can be incorporated into the catheter sheath(s) or shaft(s) as a layer of a multi-layered sheath, as shown in FIGS. **89**A-C. In the example illustrated by FIG. **89**A, the stiffening material **701** is provided in the proximal portion **609***a* of the steerable catheter shaft or sheath **609**. In the example illustrated by FIG. **89**B, the stiffening material **701** is provided in the proximal portion **611***a* of the implant catheter shaft or sheath **611**. In the example illustrated by FIG. **89**C, the stiffening material **701** is provided in the proximal portion **609***a* of the steerable catheter shaft or sheath **609** and in the proximal portion **611***a* of the implant catheter shaft or sheath **611**.

[0361] FIG. **98** is another illustration of an example implant catheter. As shown in FIG. **98**, the implant catheter **611** includes stiffening material in the form of a braid, mesh, or woven material **704** and a laser-cut hypotube **702** extending over the braid, mesh, or woven material **704**. As described above, the laser-cut hypotube **702** can have a variable or a constant cut pattern along a length of the implant catheter **611**. The braid, mesh, or woven material **704** can extend over a polymer layer **732** (e.g., a PEBA layer) that defines one or more lumens of the implant catheter **611**. Although illustrated in FIG. **98** as including five lumens, it is contemplated that the polymer layer **732** can include one or more lumens depending on the particular implementation. The implant catheter illustrated in FIG. **98** also includes a polymer jacket **734**, which can impart lubricity, stiffness, or other properties to the implant catheter **611**. One or more additional layers can also be included in some implementations, including but not limited to PTFE liners, polymer layers, adhesive layers, or the like.

[0362] FIGS. **90** and **91** illustrate an example of a steerable catheter assembly **608**. The steerable catheter assembly **608** includes a steerable portion **900** and a portion that is not steerable **902**. In some implementations, the stiffness of the sheath of the catheter assembly can vary along the length L_NS of the sheath. Generally, the non-steerable portion is configured to have a greater stiffness at a proximal end than at a distal end. The stiffness of the non-steerable portion **902** can be varied in a variety of different ways. The variable stiffness non-steerable portion **902** can be used with any of the implementations disclosed by the present application or can be used in a delivery system that does not include any of the other features disclosed by the present application. The variable stiffness non-steerable portion can be used in conjunction with a decreased outer diameter of the distal portion of the sheath or shaft **611** of the implant catheter assembly **610** and/or a low-friction coating can be on the decreased outer diameter section of the sheath or shaft **611** of the implant catheter assembly **610**. Further, the sheath **607** of the guide sheath or catheter assembly **606** can include a variable stiffness non-steerable portion in addition to or instead of the variable stiffness non-steerable portion of the sheath or shaft of the steerable catheter assembly **608**.

[0363] As shown in FIG. **90**, in some implementations, when a non-steerable portion **902** of the sheath or shaft **609** of the steerable catheter assembly **608** has a variable stiffness, such as by incorporation of a laser-cut hypotube, the variable stiffness portion can extend any length of the non-steerable portion **902**. Accordingly, in some implementations, a variable stiffness length of the sheath **609** of the steerable catheter assembly **608** is less than or equal to a length L_{NS}. In some implementations, this stiffened length can include one or more stiffnesses.

[0364] A variable stiffness can be achieved in a variety of different ways. In the example illustrated by FIG. **91**, a variable stiffness can be achieved, for example, by using a first laser-cut hypotube **702***a* along a first length of the sheath **609** of the catheter assembly **608** and a second laser-cut hypotube **702***b* along a second length of the sheath **609** of the catheter assembly, where the first laser-cut hypotube **702***a* and the second laser-cut hypotube **702***b* have different stiffnesses. An example catheter that includes one or more laser-cut hypotubes is disclosed by PCT Application No. PCT/US2019/062194, published as WO2020106705A1, filed on Nov. 19, 2019, which is incorporated herein by reference. Any of the features of the devices and systems disclosed by PCT Application No. PCT/US2019/062194 can be used with any of the implementations of the present application.

[0365] In FIG. **91**, an actuation element, such as a pull wire **714** extends along the sheath **609** (typically embedded in the material of the sheath) of the steerable catheter assembly **608** and extends through a compression coil **716** (also typically embedded in the material of the sheath). The compression coil **716** (along with the pull wire **714**) extend along (either inside or outside) the first laser-cut hypotube **702***a* and the second laser-cut hypotube **702***b*. In some implementations, each of the first laser-cut hypotube **702***a* and the second laser-cut hypotube **702***b* are formed as jackets that cover the compression coil **716**. The compression coil **716** is affixed (e.g., welded or adhered) to a first ring **718***a*. At the first ring **718***a*, the pull wire **714** exits the distal end of the compression coil **716** and extends between the first ring **718***a* and a second ring **718***b*, and is affixed (e.g., welded or adhered) to the second ring **718***b*. In some implementations, the first ring **718***a* and the second ring **718***b* are at opposite ends of a third laser-cut hypotube **702***c* having a flex pattern cut into it to enable the sheath **609** of the steerable catheter assembly **608** to flex along the length of the third laser-cut hypotube **702***c*. Accordingly, to steer the sheath of the steerable catheter assembly **608**, the pull wire **714** is pulled in a proximal direction, which causes the second ring **718***b* to move relative to the first ring **718***a*.

[0366] The sheath **609** of the steerable catheter assembly **608** illustrated in FIG. **92** or other catheter assemblies can also have a variable stiffness. A proximal portion **701** of the sheath of the catheter assembly can comprise a laser-cut hypotube positioned over a braid (or other mesh or woven material) which surrounds the tubing or polymer material of the sheath **609** of the catheter assembly **608**. The sheath **609** of the steerable catheter assembly **608** also includes a portion **704** in which no laser-cut hypotube is present, but the braid surrounds the tubing and a portion **706** in which the tubing is not covered by the laser-cut hypotube or the braid. Accordingly, the sheath **609** of the steerable catheter assembly **608** in FIG. **92** has at least three stiffnesses along its length, where each of the hypotube and the braid add to the stiffness of the tubing **706**.

[0367] Referring to FIG. **96**A and FIG. **97**, in some implementations, the sheath **609** includes an elongated middle portion that comprises a braid, mesh, or woven material **704** positioned within a laser-cut hypotube **702**. In some implementations, the braid, mesh, or woven material

704 and the laser-cut hypotube **702** are embedded in fused tubing or polymer material **706** of the sheath **609**. In the example illustrated by FIG. **97**, the sheath **609** also includes a steerable portion **900** that comprises another laser-cut hypotube **702***c*. The braid, mesh, or woven material **704** and the laser-cut hypotube **702** are not included in the steerable portion **900**. The laser-cut hypotube **702***c* has a flex pattern cut into it to enable the sheath **609** to flex along the length of the third laser-cut hypotube **702***c*. Accordingly, to steer the sheath **609**, the pull wire **714** is pulled in a proximal direction. Accordingly, in some implementations, the sheath **609** can include a plurality of layers that are selected to provide various properties (e.g., stiffness, lubricity, etc.) to the sheath **609** (or portions thereof) and which can extend along varying lengths of the sheath **609**.

[0368] Referring to FIG. **93**, in some implementations, a variable stiffness portion can be formed by a single laser-cut hypotube **702** having a variable stiffness along its length. FIG. **93** illustrates four segments (**702***d*, **702***e*, **702***f*, **702***g*) of a laser-cut hypotube, each having a different cut pattern that results in different stiffness in each section. In the illustrated example, the stiffness of the first segment **702***d* is greater than the stiffness of the second segment **702***e*, the stiffness of the second segment **702***e* is greater than the stiffness of the third segment **702***f*, and the stiffness of the third segment **702***f* is greater than the stiffness of the fourth segment **702***g*. In the FIG. **93** example, the uncut area of the first segment **702***d* is greater than the uncut area of the second segment **702***e*, the uncut area of the second segment **702***e* is greater than the uncut area of the third segment **702***f*, and the uncut area of the third segment **702***f* is greater than the uncut area of the fourth segment **702***g*.

[0369] The cut patterns of laser cut hypotubes can take a wide variety of different forms. In the example illustrated by FIG. **91**, the first segment **702***d* has a pitch of about 1.27 mm (0.05 inches), 40° cut, and 51° uncut. The second segment **702***e* has a pitch that transitions from about 1.27 mm (0.05 inches) to about 0.5 mm (0.02 inches), the degrees cut transitions from 400 to 740 cut, and the degrees uncut transitions from 510 to 28.85° uncut. The third segment **702***f* has a pitch of about 0.5 mm (0.02 inches), 74° cut, and 28.85° uncut. The fourth segment **702***g* has a pitch that transitions from about 0.5 mm (0.02 inches) to about 0.1 mm (0.004 inches), the degrees cut transitions from 740 to 940 cut, and the degrees uncut transitions from 28.85° to 8.85° uncut. It should be understood that although four segments are illustrated in FIG. **93**, the laser-cut hypotube can have any suitable number of segments having different stiffnesses. Additionally, it is contemplated that, in some implementations, the stiffness of the hypotube can decrease gradually in a distal direction (as shown in the second segment **702***e* and the fourth segment **702***g*) without defined segments.

[0370] The stiffness of each laser-cut hypotube **702** (or a segment of a hypotube) can be selected, for example, based on a material from which the hypotube is formed, a pitch of cuts, degrees of the circumference of the laser-cut hypotube that are cut, degrees of the circumference of the laser-cut hypotube that are uncut, and a kerf width of each cut. In some implementations, the hypotube is formed from stainless steel or nitinol, although other materials are suitable and contemplated.

[0371] FIG. **94** illustrates a hypotube **702** having an interrupted spiral cut and shown as a rectangular sheet. In FIG. **94**, the circumference of the hypotube is represented by the letter C and the pitch is represented by the letter P. The degrees cut **708** is a length of each cut, and the degrees uncut **710** is a distance between one cut and an adjacent cut in the direction of the circumference C. The kerf width **712** of each cut refers to the width of the space between two adjacent laser cuts at a point at which the sides of the cut are parallel to one another.

[0372] As described above, in some implementations, stiffening materials can be incorporated in the form of a jacket of the sheath **609** of the steerable catheter assembly **608**, or the stiffening materials can be incorporated into the structure of the sheath as layers of a multi-layer sheath. Example multi-layer sheaths are shown in FIGS. **95**A, **95**B, **96**A, and **96**B. The number and type of layers can vary from what is shown. The layers can be extruded, molded, or otherwise formed and combined in a variety of ways.

[0373] FIG. **95**A is a longitudinal cross-section of an example multi-layer sheath that includes (from the outer surface of the multi-layer sheath toward the lumen) a first polymer layer **720**, a laser-cut hypotube **702**, a second polymer layer **722**, a braid, mesh, or woven material **704**, a third polymer layer **724** defining the lumen **726**. Similarly, the multi-layer sheath in FIG. **95**B includes (from the outer surface of the multi-layer sheath toward the lumen) the first polymer layer **720**, the laser-cut hypotube **702**, the second polymer layer **722**, the braid, mesh, or woven material **704**, and the lumen **726**. However, in the example illustrate in FIG. **95**B, a polytetrafluoroethylene (PTFE) liner **728** defines the lumen **726**. As previously described, the use of a PTFE liner **728** can be used to reduce friction along the internal diameter of the lumen **726**. The polymer layers **720**, **722**, **724** can provide torque resistance based on the durometer of the polymer used, and the laser-cut hypotube **702** and the braid, mesh, or woven material **704** can further provide torque resistance to the multi-layer sheath. It is contemplated that a cross-section of the multi-layer sheath can vary along the length of the sheath. For example, as described herein, the laser-cut hypotube **702**, the braid **704**, or both can be present in proximal portions of the sheath, but not in distal portions of the sheath to provide a variable stiffness of the sheath.

[0374] FIG. **96**A illustrates a radial cross-section of an example multi-layer sheath. For example, the cross-section illustrated by FIG. **96**A can correspond to one or more portions of the sheath (e.g., to a middle portion of the sheath, etc.) illustrated by FIG. **97**. The multi-layer sheath example shown in FIG. **96**A includes two lumens. For example, when the multi-layer sheath is used as a sheath **609** of a steerable catheter assembly **608**, the shaft **611** of the implant catheter assembly **610** can pass through the lumen **726**, and the flex element or flex control element **714**, such as the illustrated pull wire, and compression coil **716** can extend through a second lumen, as described above with respect to FIG. **91**. In the example shown in FIG. **96**A, the lumen **726** is defined by a PTFE liner **728**, which is positioned within the second polymer layer **722**.

[0375] In some implementations, a braid, mesh, or woven material **704** is positioned around the second polymer layer **722** and is positioned within the laser-cut hypotube **702**. In some implementations, the first layer of polymer **720** surrounds the laser-cut hypotube **702**. Within the second polymer layer **722** and adjacent to the PTFE liner **728**, a second liner **730** defines the second lumen, through which the flex

control element or flex element **714** (e.g., pull wire, pull suture, tension member, etc.) and compression coil **716** extend. It should be appreciated that other layers and other lumens can be present in some implementations, and the layers can be provided in alternative orders while providing the torque resistance described herein.

[0376] FIG. **96**B illustrates a radial cross-section of an example multi-layer sheath in which the flex element **714** and coil are on the outside of the proximal portion of the sheath. The cross section can correspond to various locations along the length of the sheath. For example, in some implementations, the cross-section illustrated by FIG. **96**B corresponds to a proximal portion of the sheath illustrated by FIG. **97**. In some implementations, the second lumen for accommodating the flex element runs less than the full length of the multi-layer sheath. In some implementations, the lumen of the multi-layer sheath varies along the length of the multi-layer sheath and, for example, can transition from a circular cross-section to a non-circular cross-section along the length of the multi-layer sheath. The cross-section illustrated in FIG. **96**B can correspond to a proximal portion of the multi-layer sheath relative to the radial cross-section illustrated in FIG. **96**A, such as along the line AA in FIG. **91**. As shown in FIGS. **96**B and **97**, the flex element **714** is external to the multi-layer sheath, and the lumen **726** is defined by a PTFE liner **728**, which is positioned within the second polymer layer **722**.

[0377] In some implementations, the braid **704** (or other mesh or woven material), the laser-cut hypotube **702**, and the first layer of polymer **720** that surrounds the laser-cut hypotube **702** do not extend along the proximal length of the multi-layer sheath, enabling the flex element **714** to enter the second lumen of the multi-layer sheath as described above. The lumen **726** has a substantially circular cross-section. In some implementations, a groove in the mandrel used to support the PTFE liner **728** and the second polymer layer **722** is filled at a position corresponding to the proximal end of the multi-layer sheath to enable the lumen **726** illustrated in FIG. **96**B to be formed. In some of these implementations, reflow of the PTFE and/or the polymer used to form the second polymer layer can create a gradual transition between a circular cross-section and the non-circular cross-section illustrated in FIG. **96**A. It should be appreciated that other layers and other lumens can be present in some implementations, and the layers can be arranged in various orders while providing the torque resistance described herein.

[0378] In still further implementations, the braid of the multi-layer sheath can be used to facilitate a passage for the flex control element or flex element (e.g., pull wire, pull suture, tension member, etc.). The incorporation of the passage into the braid can enable the separate lumen (lumen **726**) under the braid, and, in some implementations, the compression coil **716**, to be removed, which can in turn reduce the outer diameter profile of the multi-layer sheath, allow for a more uniform (e.g., circular) profile, allow for a larger inner profile, and/or reduce manufacturing complexity. Various braid patterns incorporating a flex element passage are illustrated in FIGS. **99**A-**99**C and **99**E.

[0379] In FIGS. **99**A-**99**C, a lumen **730** is woven into the braid **704**, with the lumen **730** extending longitudinally or along the direction of the length of the sheath. The lumen can extend along the length of the sheath in a variety of different ways. For example, the lumen can extend longitudinally and wires **731** of the braid are disposed at two opposing angles relative to the lumen. In some implementations, the lumen and the other wires form a triaxial braid. In some implementations, the lumen **730** and the wires **731** of the braid form sixty degree angles or about sixty degree angles relative to one another.

[0380] The lumen **730** can be a tube, such as a thin-walled tube, made from any suitable material. In some implementations, the lumen **730** can be a stainless steel or nitinol hypotube. In some other implementations, the lumen **730** can be a polymeric tube, such as a tube made from polyamide, PEEK, or other polymers known and used in the art. The lumen can be made from any material. In the implementations illustrated in FIGS. **99**A-**99**C, the lumen **730** is incorporated into the braid structure and runs longitudinally along the length of the braid **704**. While providing the passage for the flex element (e.g., pull wire, pull suture, tension member, etc.), the lumen **730** can further reinforce the braid and strength of the multi-layer sheath. In some implementations, the lumen **730** is braided in and out of every other crossing or pick of the braid **704**, although other patterns are contemplated and possible. As illustrated in FIGS. **99**A-**99**C, the lumen **730** can be incorporated into any one of a variety of braid patterns, such as tri-axial braid patterns or any pattern where the lumen extends longitudinally. For example, FIG. **99**A illustrates the longitudinally extending lumen **730** incorporated in a full braid pattern, FIG. **99**B illustrates the longitudinally extending lumen **730** incorporated in a diamond braid pattern, and FIG. **99**C illustrates the lumen **730** incorporated in a half diamond braid pattern.

[0381] FIG. **99**D illustrates a radial cross-section of an example multi-layer sheath in which the flex element **714**, such as the pull wire illustrated in the figure, passes through a longitudinally extending lumen **730** that is woven into the braid **704**. The flex element **714** and the lumen **730** can be used in the same manner as the flex element and the compression coil **716** described above to flex or steer the sheath. For example, application of tension to the flex element **714** in the lumen **730** causes a portion of the sheath to flex. The cross-section can correspond to various locations along the length of the sheath. For example, in some implementations, the cross-section illustrated by FIG. **99**D corresponds to a proximal portion of the sheath illustrated by FIG. **97**. In some implementations, the lumen **730** for accommodating the flex element runs less than the full length of the multi-layer sheath.

[0382] In some implementations, the braid **704** (or other mesh or woven material), the laser-cut hypotube **702**, and the first layer of polymer **720** that surrounds the laser-cut hypotube **702** do not extend along the proximal length of the multi-layer sheath, enabling the flex element **714** to enter the lumen **730** of the multi-layer sheath as described above. The lumen **730** can have a substantially circular cross-section. It should be appreciated that other layers and other lumens can be present in some implementations, and the layers can be provided in alternative orders while providing the torque resistance described herein.

[0383] In FIG. **99**E, the lumen **730** is woven into the braid **704** such that the lumen does not extend only longitudinally or only in the direction of the length of the sheath. For example, the lumen **730** can wrap or twist about the sheath as the lumen extends along the length of the sheath (e.g. in a helical configuration). In some braids, chase wires that

extend along or parallel with another wire of the braid are included. In the implementation illustrated by FIG. **99**E, the lumen **730** replaces a chase wire in the braid.

[0384] As above, the lumen **730** can be a tube, such as a thin-walled tube, made from any suitable material. In some implementations, the lumen **730** can be a stainless steel or nitinol hypotube. In some other implementations, the lumen **730** can be a polymeric tube, such as a tube made from polyamide, PEEK, or other polymers known and used in the art. The lumen **730** can be made from any material. In the implementations illustrated in FIG. **99**E, the lumen **730** is braided into the braid **704** next to another wire of the braid. While providing the passage for the flex element, such as the illustrated pull wire, the lumen **730** can further reinforce the braid and strength of the multi-layer sheath. As a chase wire-type feature, the lumen can reduce bowing of the multi-layer sheath during application of tension to the flex element, as it spirals around the multi-layer sheath. In implementations, the lumen **730** is incorporated as a chase wire feature in a half diamond braid pattern. However, the lumen **730** can have any spiral or helical configuration and can be incorporated into any braid pattern.

[0385] FIG. **99**F illustrates a radial cross-section of an example multi-layer sheath in which the flex element **714** passes through a spiraled, helical, or otherwise winding lumen **730** that is woven into the braid **704**. The cross sections of the lumen **730** and flex element **714** are non-circular (e.g. elliptical or otherwise shaped), since the section extends through the spiraled, helical, or otherwise winding flex element, such as the illustrated pull wire **714**, and lumen **730**. The cross section can correspond to various locations along the length of the sheath. For example, in some implementations, the cross-section illustrated by FIG. **99**F corresponds to a proximal portion of the sheath illustrated by FIG. **97**. In some implementations, the lumen **730** for accommodating the flex element runs less than the full length of the multi-layer sheath.

[0386] In some implementations, the braid **704** (or other mesh or woven material), the laser-cut hypotube **702**, and the first layer of polymer **720** that surrounds the laser-cut hypotube **702** do not extend along the proximal length of the multi-layer sheath, enabling the flex element **714** to enter the lumen **730** of the multi-layer sheath as described above. In contrast to the lumen illustrated in FIG. **99**D, the lumen **730** illustrated in FIG. **99**F has a substantially elliptical cross-section due to its coiled configuration (e.g. not longitudinally extending) within the braid **704**. It should be appreciated that other layers and other lumens can be present in some implementations and can be arranged in various orders while providing the torque resistance described herein.

[0387] While various inventive aspects, concepts and features of the disclosures may be described and illustrated herein as embodied in combination in the example implementations, these various aspects, concepts, and features may be used in many alternative implementations, either individually or in various combinations and sub-combinations thereof. Unless expressly excluded herein all such combinations and sub-combinations are intended to be within the scope covered herein. Still further, while various alternative implementations as to the various aspects, concepts, and features of the disclosures-such as alternative materials, structures, configurations, methods, devices, and components, alternatives as to form, fit, and function, and so on—may be described herein, such descriptions are not intended to be a complete or exhaustive list of available alternative implementations, whether presently known or later developed. One or more of the inventive aspects, concepts, or features can be adapted into additional implementations and uses within the scope of the present application even if such implementations are not expressly disclosed herein.

[0388] Additionally, even though some features, concepts, or aspects of the disclosures may be described herein as being a preferred arrangement or method, such description is not intended to suggest that such feature is required or necessary unless expressly so stated. Still further, example or representative values and ranges may be included to assist in understanding the present application, however, such values and ranges are not to be construed in a limiting sense and are intended to be critical values or ranges only if so expressly stated. Moreover, while various aspects, features and concepts may be expressly identified herein as being inventive or forming part of a disclosure, such identification is not intended to be exclusive, but rather there may be inventive aspects, concepts, and features that are fully described herein without being expressly identified as such or as part of a specific disclosure, the disclosures instead being set forth in the appended claims. Descriptions of example methods or processes are not limited to inclusion of all steps as being required in all cases, nor is the order that the steps are presented to be construed as required or necessary unless expressly so stated. Further, the techniques, methods, operations, steps, etc. described or suggested herein can be performed on a living animal or on a non-living simulation, such as on a cadaver, cadaver heart, simulator (e.g., with the body parts, tissue, etc. being simulated), etc. The words used in the claims have their full ordinary meanings and are not limited in any way by the description of the implementations in the specification.

What is claimed is:

1. A delivery system for an implantable device, the delivery system comprising:

a first catheter assembly having a handle and a sheath extending from the handle in an axial direction, the sheath comprising a steerable section;

a second catheter assembly having a handle and a sheath comprising a proximal end coupled to the handle and a distal end;

the sheath of the second catheter assembly extending coaxially through the sheath of the first catheter assembly;

wherein the sheath of the second catheter assembly has a first outer diameter along a first length and a second outer diameter along a second length;

wherein the second outer diameter is smaller than the first outer diameter;

wherein the sheath of the second catheter assembly is extendable from a distal end of the sheath of the first catheter assembly by a stroke distance; and

wherein the second length is greater than or equal to a sum of the stroke distance and a length of the steerable section of the first catheter assembly, such that the sheath of the second catheter assembly has the second outer diameter through the steerable section of the first catheter assembly.

2. The delivery system for an implantable device according to claim 1, wherein a difference between the first outer diameter and the second outer diameter is from about 0.25 to about 0.76 mm.

3. The delivery system for an implantable device according to claim 1, wherein a transition from the first outer diameter to the second outer diameter forms a smooth taper over a distance of from about 25 mm to about 50 mm.

4. The delivery system for an implantable device according to claim 1, further comprising a lubricated coating on an outer surface of the sheath along the second length of the sheath.

5. The delivery system for an implantable device according to claim 4, wherein the lubricated coating comprises a hydrophilic coating.

6. The delivery system for an implantable device according to claim 1, wherein the first outer diameter and the second outer diameter are each less than an inner diameter of the sheath of the first catheter assembly.

7. The delivery system according to claim 1, wherein the first catheter assembly is a steerable catheter assembly, and the second catheter assembly is an implant catheter assembly.

8. A catheter assembly for controlling an implantable device, the catheter assembly comprising:

a handle housing;

a sheath extending distally from the handle housing;

an actuation element extending through the sheath, the actuation element configured to be coupled to one or more paddles of the implantable device;

a control knob coupled to the actuation element that is rotatable relative to the handle housing, wherein rotation of the control knob causes axial movement of the actuation element with respect to the handle housing and the sheath;

an externally threaded retractor coupled to the control knob and the actuation element, wherein the externally threaded retractor is rotationally fixed with respect to the handle housing, and wherein the rotation of the control knob advances the externally threaded retractor in an axial direction, thereby causing linear movement of the actuation element;

a clutch spring that biases the externally threaded retractor distally towards threads of an internally threaded tube within the handle housing;

a pair of clasp actuation lines extending through the sheath, each clasp actuation line of the pair of clasp actuation lines configured to be coupled to a pair of clasps of the implantable device; and

a pair of clasp control members, wherein each clasp control member of the pair of clasp control members is axially movable relative to the handle housing, wherein the axial movement of each of the pair of clasp control members causes one of the pair of clasps to move between an open configuration and a closed configuration.

9. The catheter assembly according to claim 8, wherein the rotation of the control knob causes rotation of the internally threaded tube with respect to the handle housing, which drives the externally threaded retractor to a proximal position in which external threads of the externally threaded retractor and internal threads of the internally threaded tube disengage, and wherein continued rotation of the control knob provides an audible indication.

10. The catheter assembly according to claim 8, further comprising a release element extending from a proximal end of the handle housing and coupled to the actuation element.

11. The catheter assembly according to claim 10, wherein the release element is a release knob comprising an elongated shaft having a plurality of asymmetrical teeth extending from an outer surface of the elongated shaft, wherein the handle housing comprises a ratchet insert comprising one or more pawls configured to contact the outer surface of the elongated shaft, and wherein the plurality of asymmetrical teeth enables the release knob to be rotated in a first direction to withdraw the actuation element into the catheter assembly and inhibits the release knob from being rotated in a second direction.

12. The catheter assembly according to claim 8 further comprising a nose grip having a distal flange at a distal end of the nose grip and a proximal end connected to a distal end of the handle housing, wherein the nose grip comprises a passage extending from the proximal end to the distal end of the nose grip, wherein the distal flange has an outer diameter that is greater than an outer diameter of a central portion of the nose grip.

13. The catheter assembly according to claim 12, further comprising a proximal flange positioned at the proximal end of the nose grip adjacent to the distal end of the handle housing.

14. The catheter assembly according to claim 8, wherein the handle housing comprises a first detent at a first axial position along a path of one of the pair of clasp control members to maintain the one of the pair of clasp control members in a proximal position and a second detent at a second axial position along the path of one of the pair of clasp control members to maintain the one of the pair of clasp control members in a distal position.

15. The catheter assembly according to claim 8, wherein each of the pair of clasp control members extend approximately 50% of the way around a circumference of the handle housing such that together the pair of clasp control members encircle or otherwise surround the circumference of the handle housing.

16. A catheter assembly for a transvascular delivery system comprising:

a handle housing;

a sheath extending longitudinally from the handle housing;

wherein the sheath has a proximal portion and a distal portion;

wherein the sheath is a multi-layer sheath;

wherein one or more layers of the multi-layer sheath comprise at least one laser-cut hypotube;

wherein the at least one laser-cut hypotube has a stiffness that varies along a length of the at least one laser-cut hypotube; and

wherein the proximal portion of the sheath is stiffer than the distal portion of the sheath.

17. The catheter assembly according to claim 16, wherein the multi-layer sheath has a first lumen extending through the sheath, and the proximal portion of the sheath comprises a layer comprising a braid, mesh, or woven material having a material defining a second lumen woven therethrough.

18. The catheter assembly according to claim 17, wherein the second lumen terminates at a location proximal to a steerable portion of the sheath.

19. The catheter assembly according to claim **17**, wherein the material defining the second lumen comprises a stainless steel hypotube, a nitinol hypotube, or a polymeric tube.

20. The catheter assembly according to claim **16**, wherein the sheath defines a lumen extending longitudinally through the sheath, and wherein the lumen has a cross-section that transitions from having a circular shape to having a non-circular shape.

* * * * *