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(54) **INTRACARDIAC ECHOCARDIOGRAPHY (ICE) CATHETER TIP ASSEMBLY**

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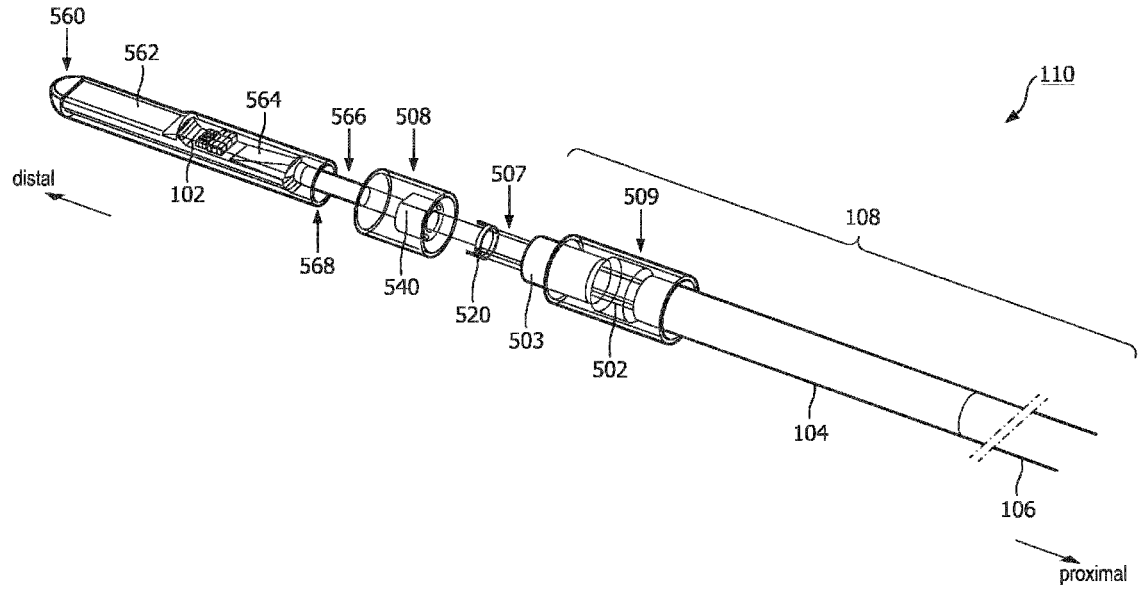
(52) **U.S. Cl.**
CPC ***A61B 8/12*** (2013.01); *A61B 8/0883* (2013.01); ***A61B 8/4461*** (2013.01)

(57) **ABSTRACT**

An imaging catheter assembly is provided. In one embodiment, the imaging catheter assembly includes a flexible elongate member comprising a distal portion and a proximal portion; a tip member coupled to a distal end of the distal portion of the flexible elongate member, wherein the tip member includes a tubular body comprising a closed distal end, an opened proximal end, and a proximal curved top outer wall extending from the proximal opened end and tapering into a distal flat top outer wall towards the closed distal end; and an imaging component mounted within the tip member. In one embodiment, the imaging catheter assembly includes a flexible elongate member; a tip member coupled to a distal end of the flexible elongate member, wherein the tip member includes a cylindrical body and a uniform outer diameter; and an imaging component mounted within the tip member.



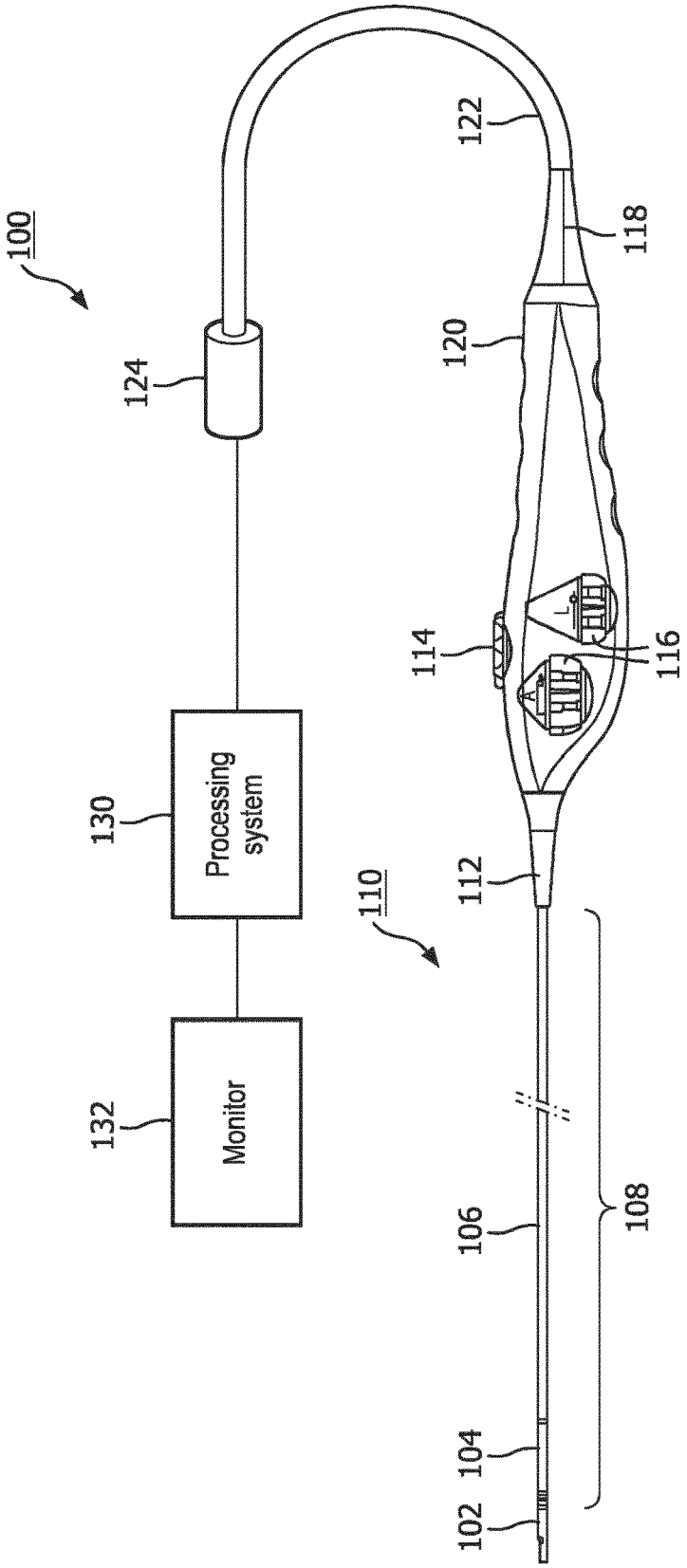

100
124
122
118
120
114
116
L
A
130
Processing system
110
112
132
Monitor
106
108
104
102

FIG. 1

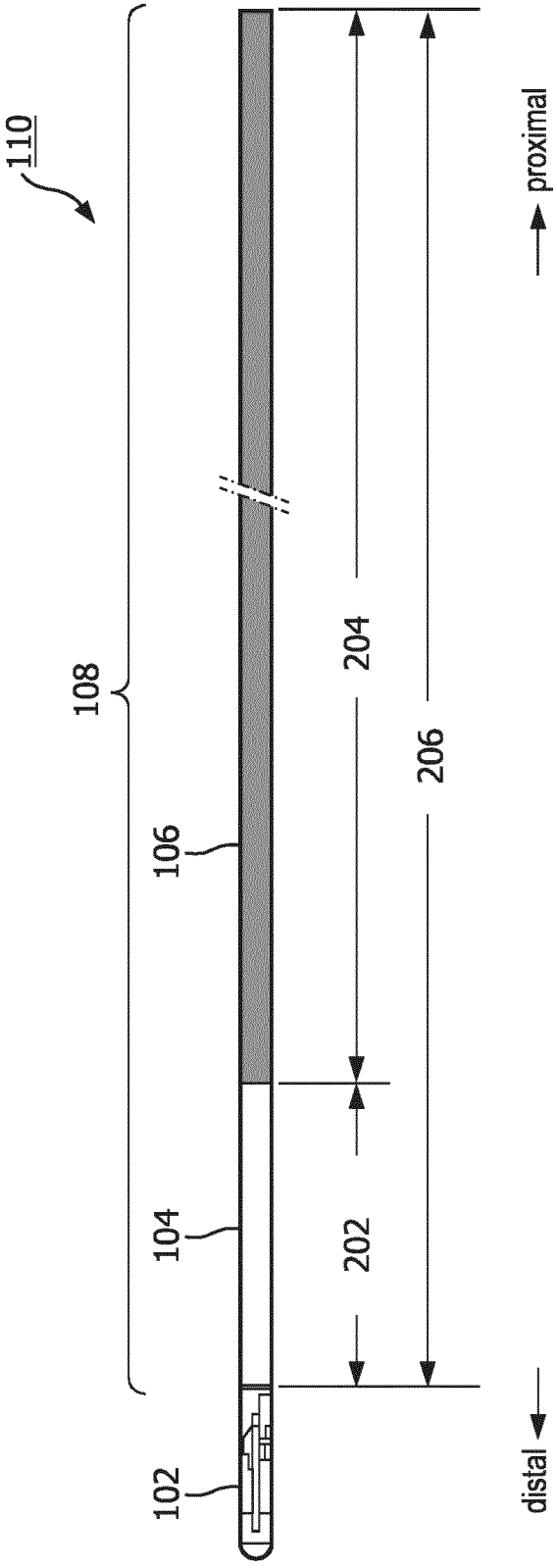
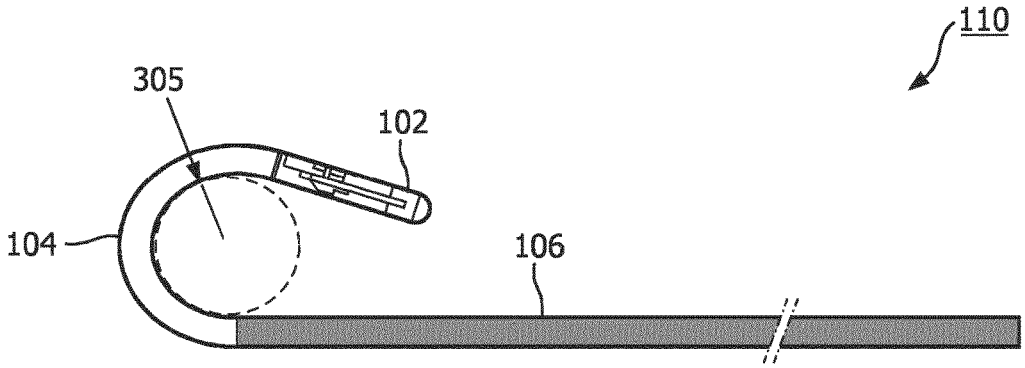


FIG. 2


110
305
102
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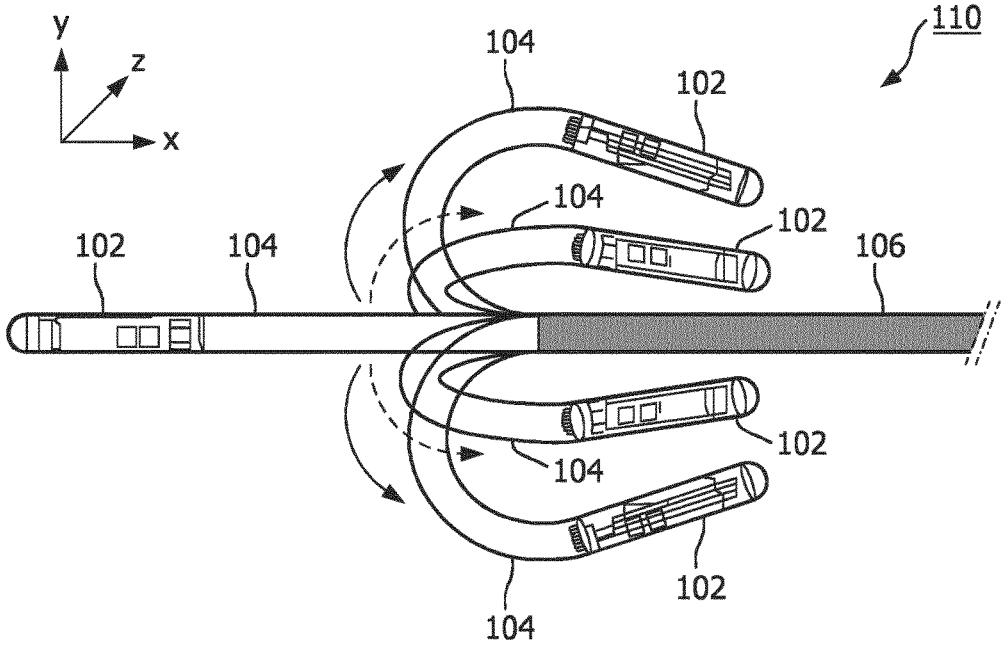
106

FIG. 3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104
102
104

FIG. 4

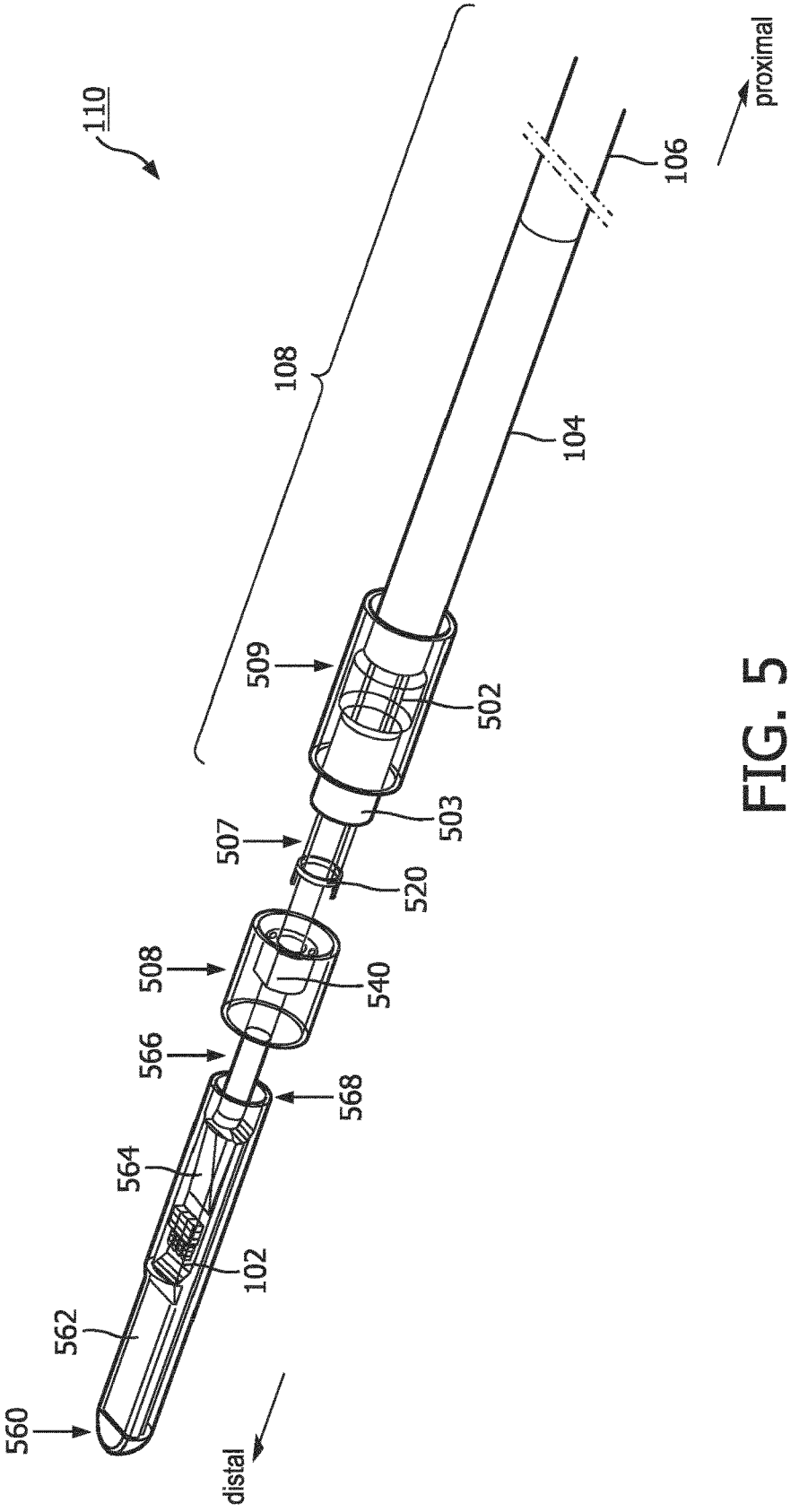

110
108
104
106
proximal
509
502
503
507
520
508
540
566
568
564
102
562
560
distal

FIG. 5

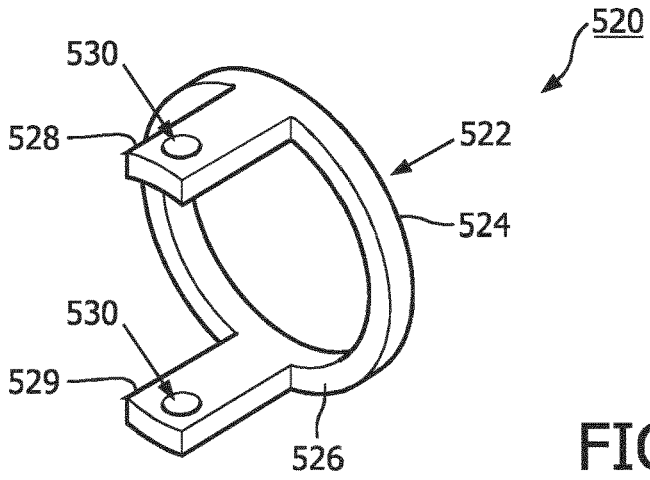


FIG. 6A

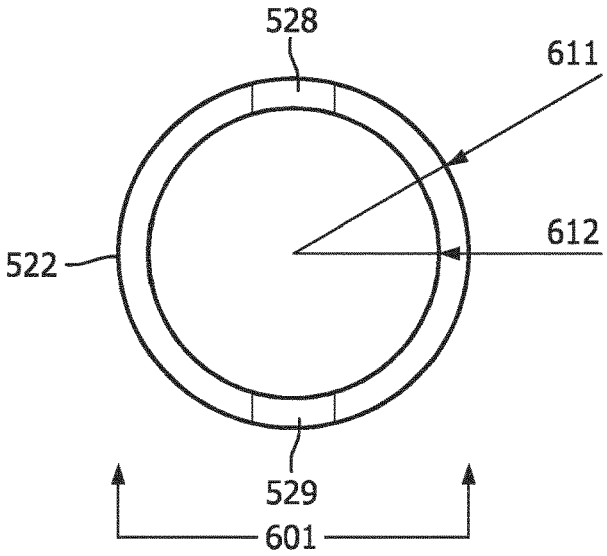


FIG. 6B

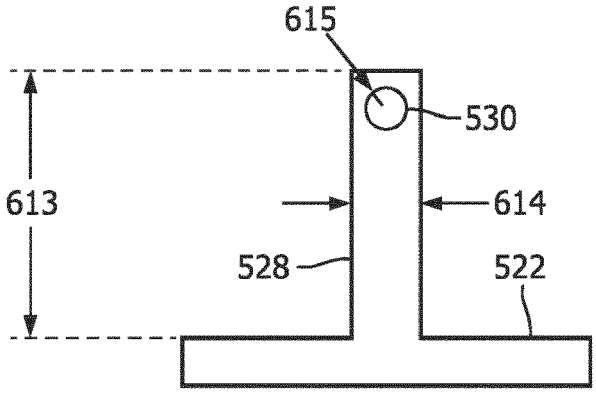


FIG. 6C

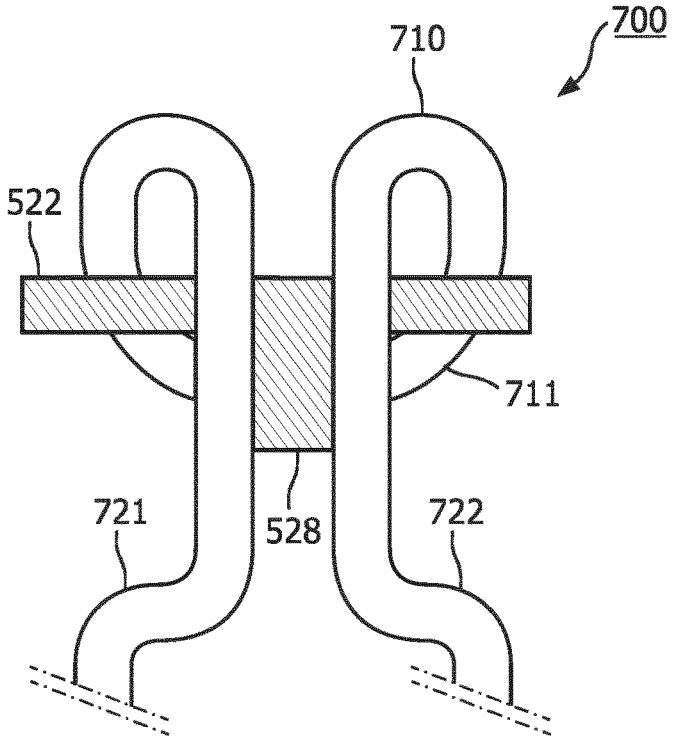


FIG. 7

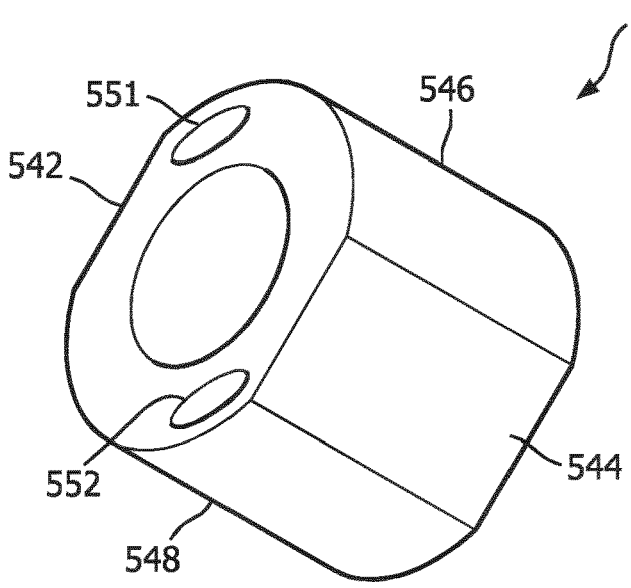


FIG. 8A

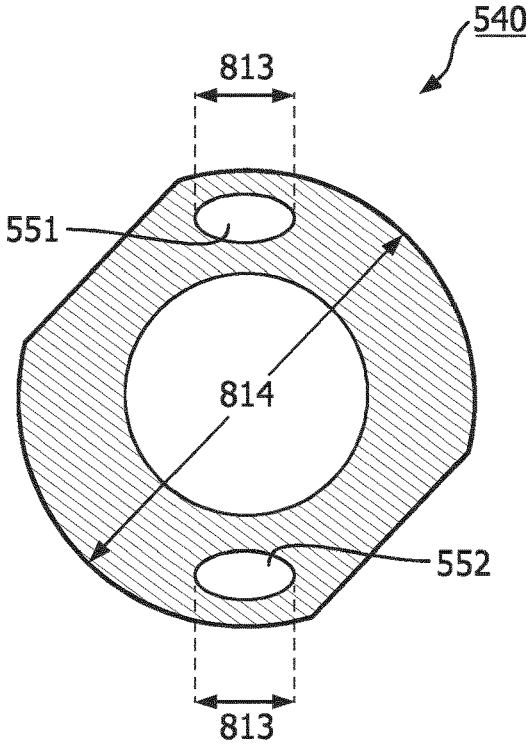


FIG. 8B

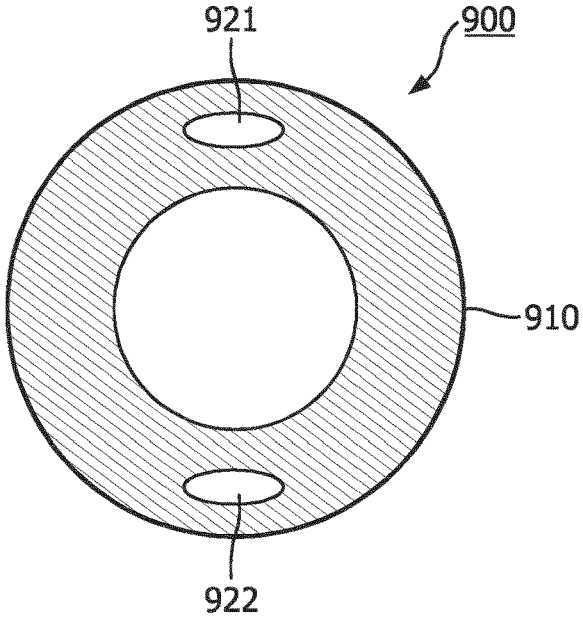


FIG. 9

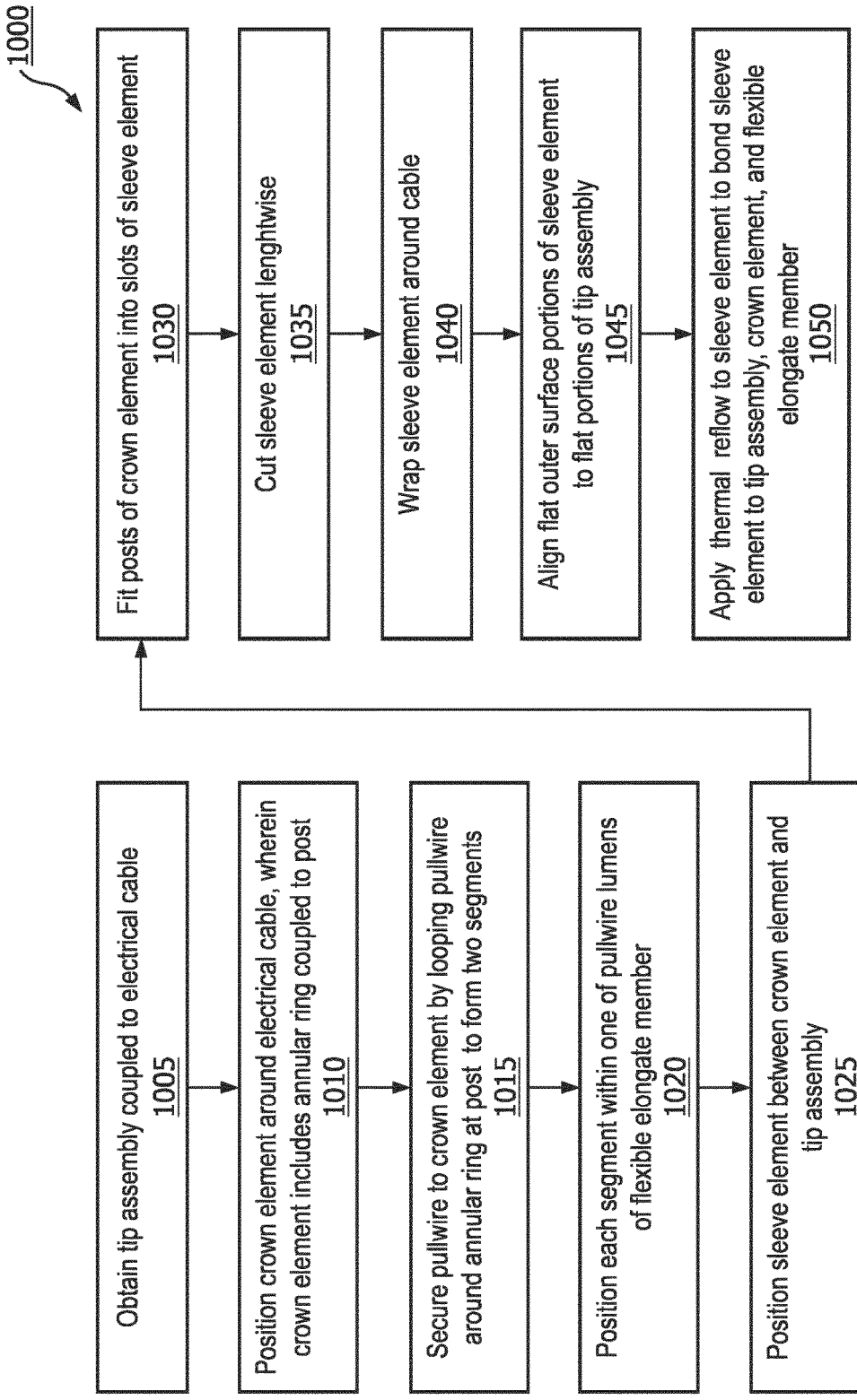

1000
Obtain tip assembly coupled to electrical cable
1005
Position crown element around electrical cable, wherein crown element includes annular ring coupled to post
1010
Secure pullwire to crown element by looping pullwire around annular ring at post to form two segments
1015
Position each segment within one of pullwire lumens of flexible elongate member
1020
Position sleeve element between crown element and tip assembly
1025
Fit posts of crown element into slots of sleeve element
1030
Cut sleeve element lenghtwise
1035
Wrap sleeve element around cable
1040
Align flat outer surface portions of sleeve element to flat portions of tip assembly
1045
Apply thermal reflow to sleeve element to bond sleeve element to tip assembly, crown element, and flexible elongate member
1050

FIG. 10

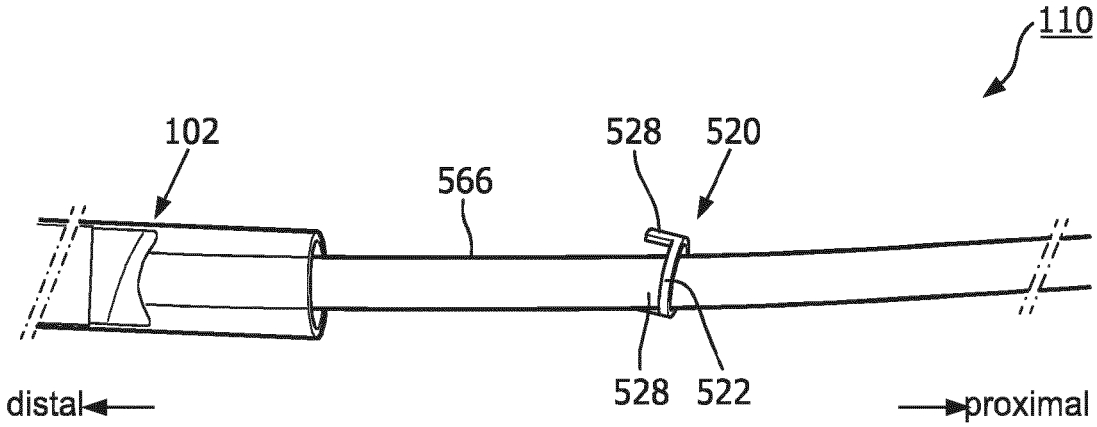

110
102
566
528
520
528
522
distal
proximal

FIG. 11

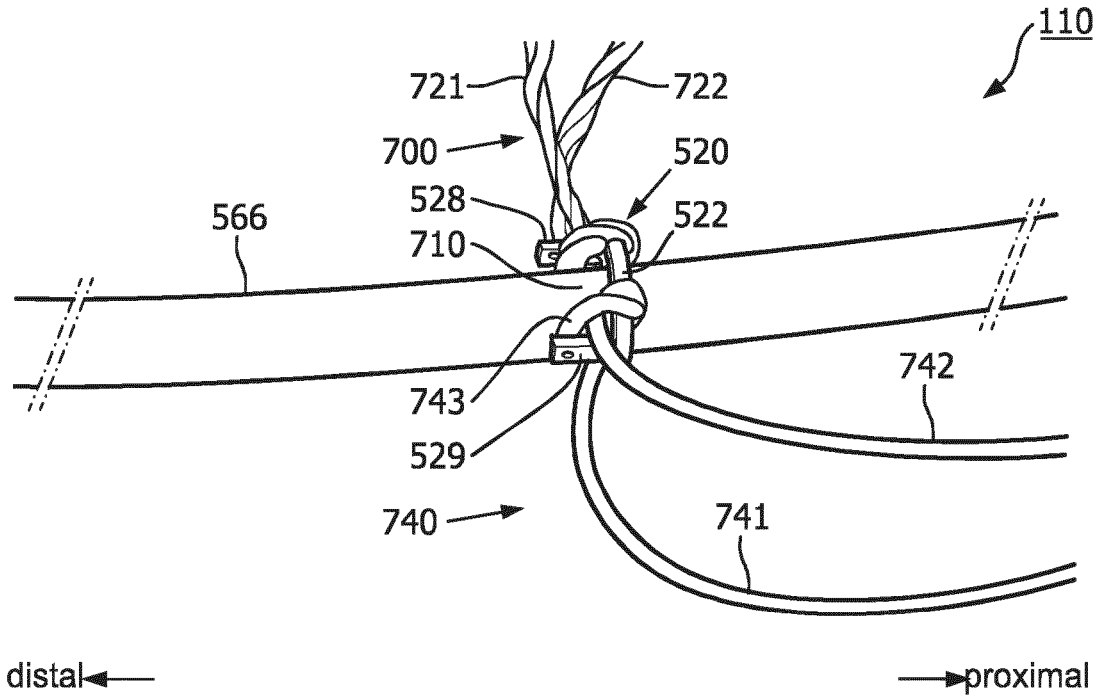

110
721
722
700
520
528
522
566
710
742
743
529
740
741
distal
proximal

FIG. 12

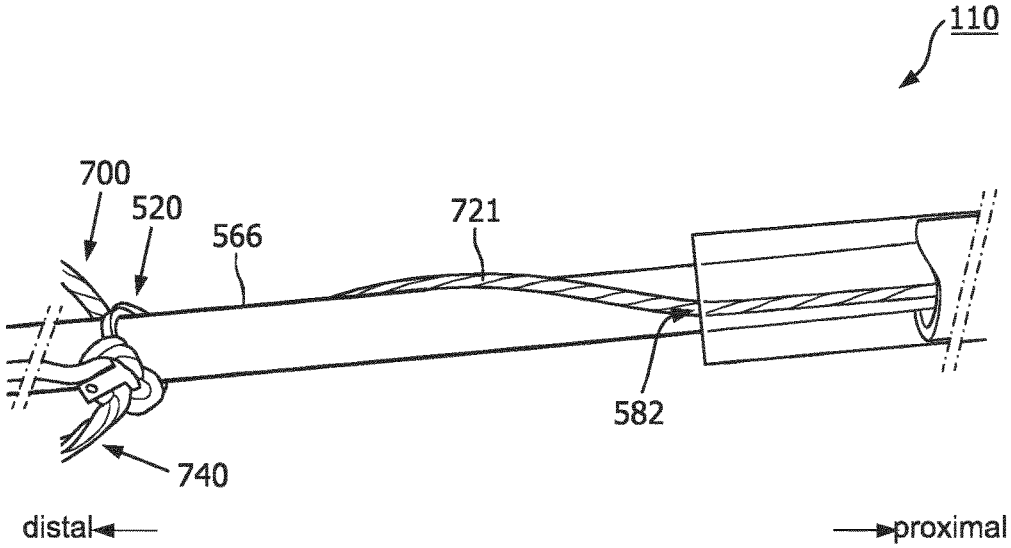

110
700
520
566
721
582
740
distal
proximal

FIG. 13

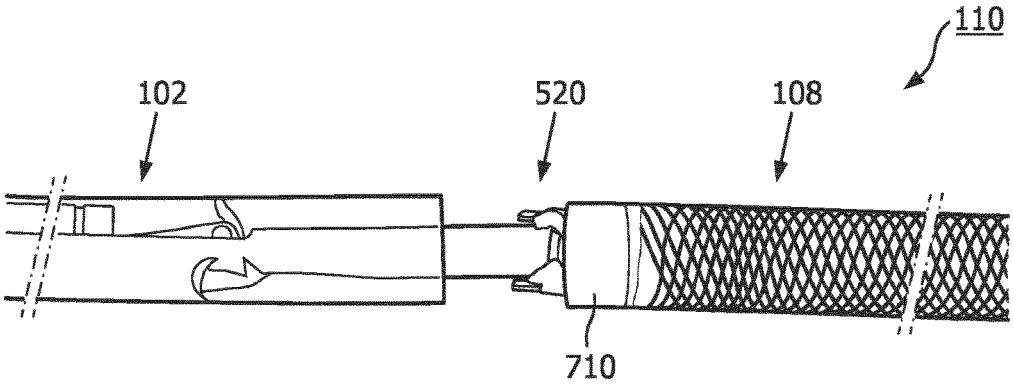

110
102
520
108
710

FIG. 14

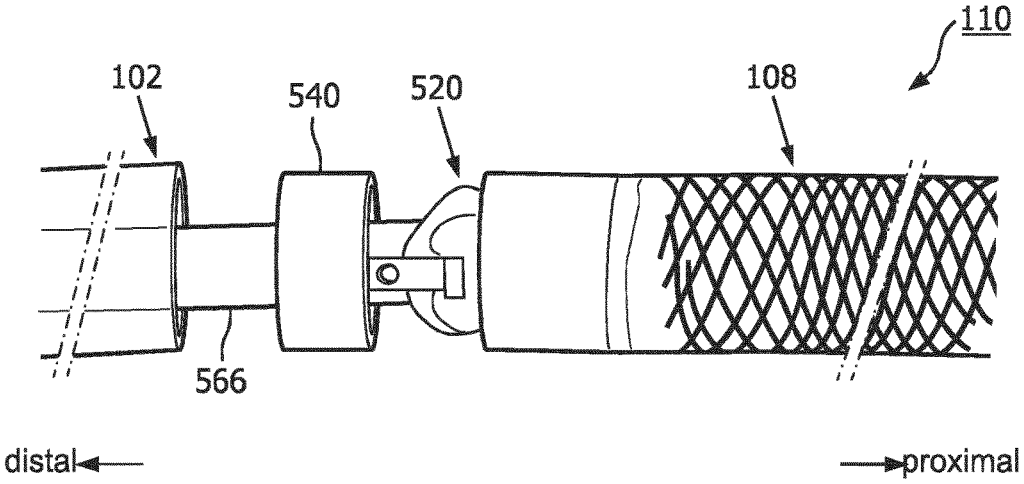

110
102
540
520
108
566
distal
proximal

FIG. 15

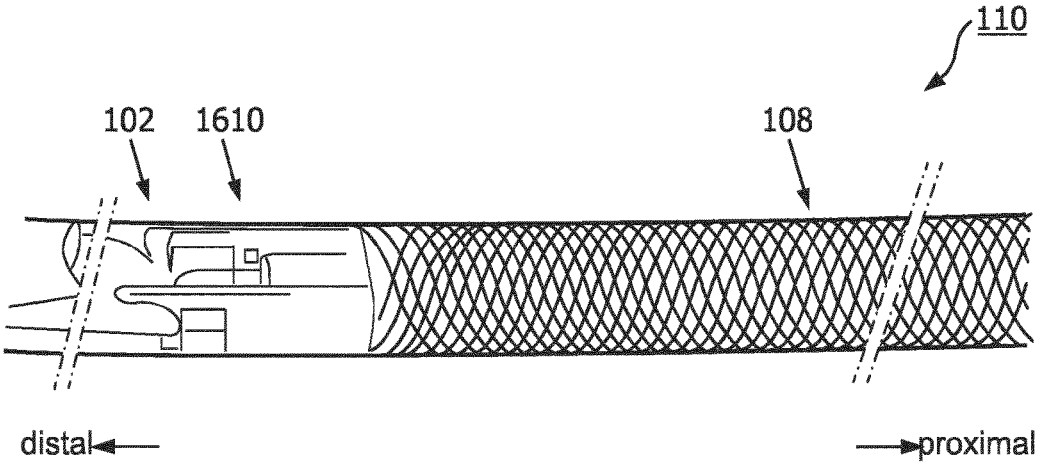
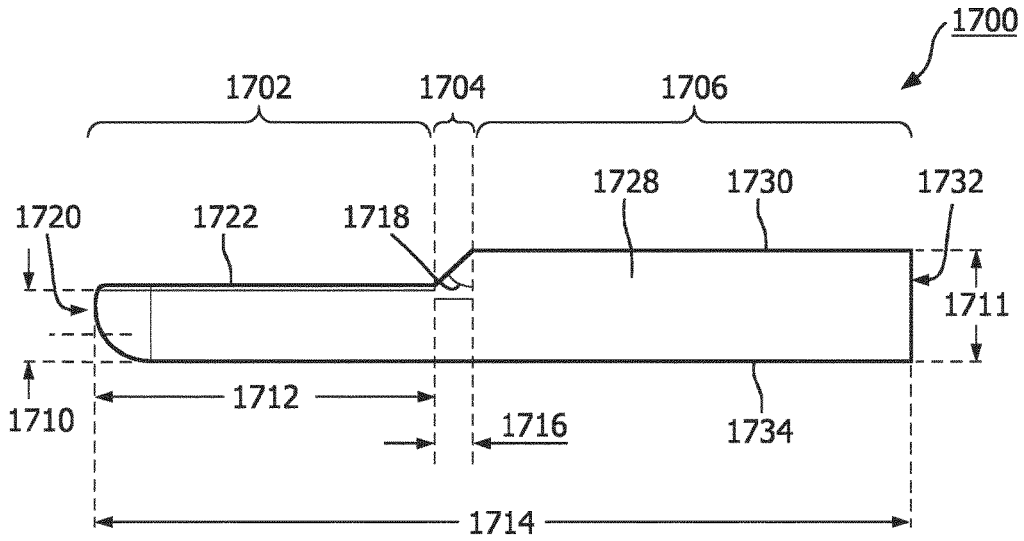

110
102
1610
108
distal
proximal

FIG. 16


1700
1702
1704
1706
1728
1730
1732
1720
1722
1718
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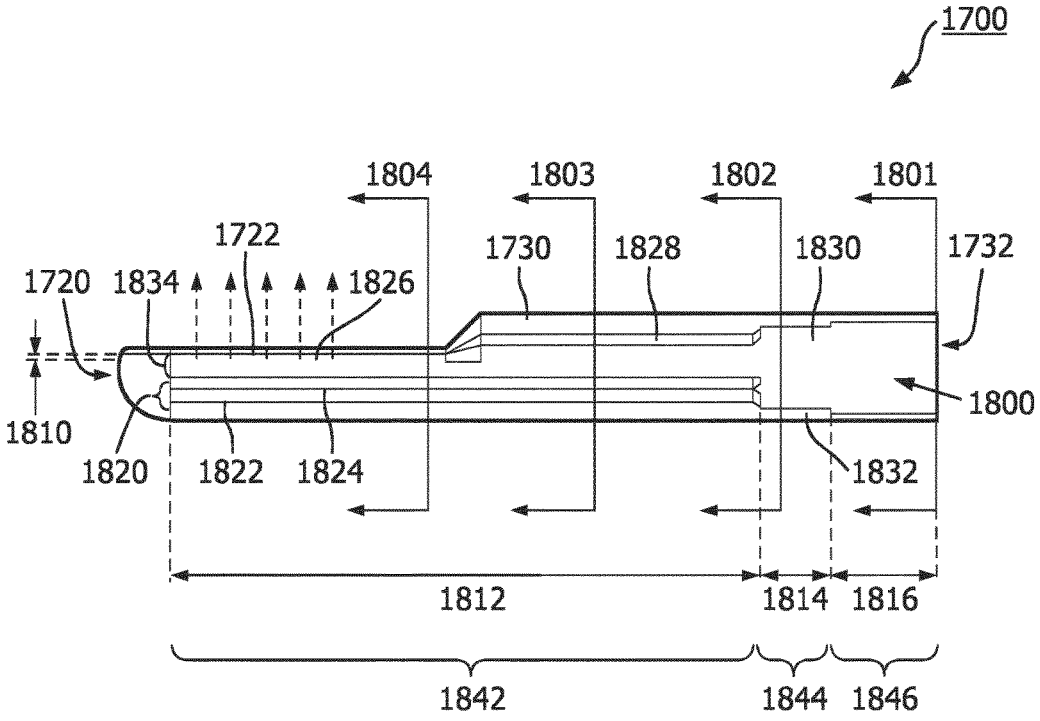
1710
1712
1716
1734
1714

FIG. 17


1700
1804
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1800
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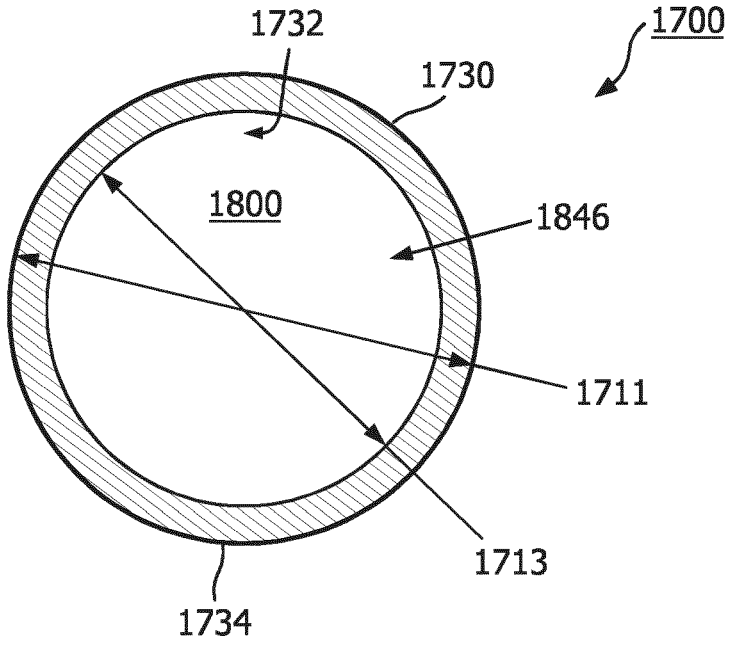
1846

FIG. 18


1732
1700
1730
1800
1846
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1713
1734

FIG. 19

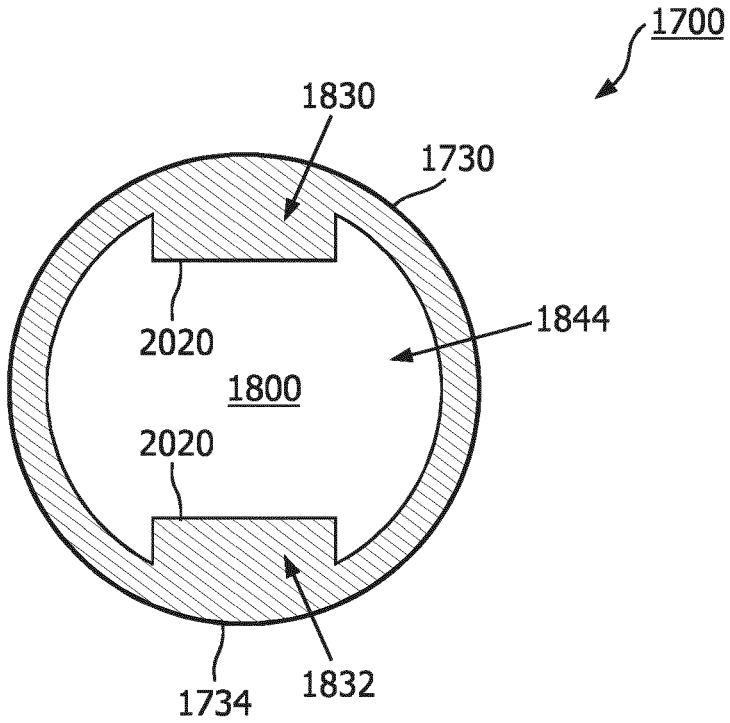

1700
1830
1730
2020
1844
1800
2020
1734
1832

FIG. 20

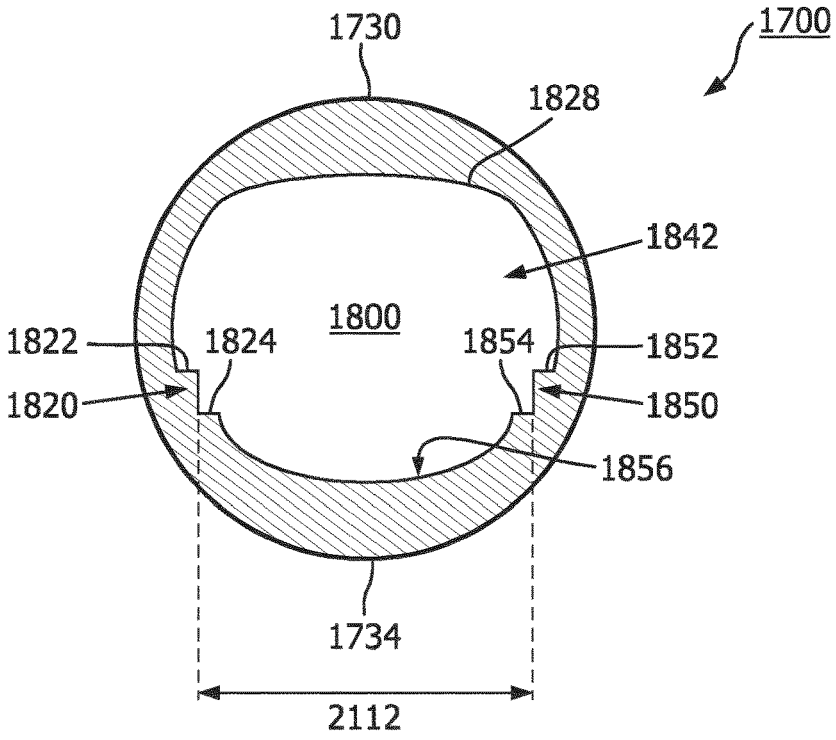

1730
1700
1828
1842
1800
1822
1824
1854
1852
1820
1850
1856
1734
2112

FIG. 21

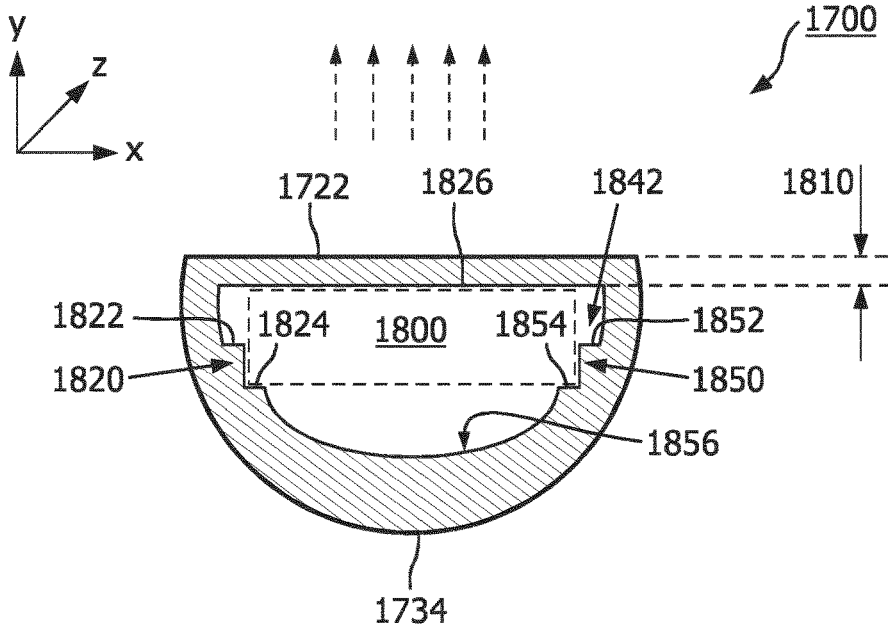

y
z
x
1700
1722
1826
1842
1810
1822
1824
1800
1854
1852
1820
1850
1856
1734

FIG. 22

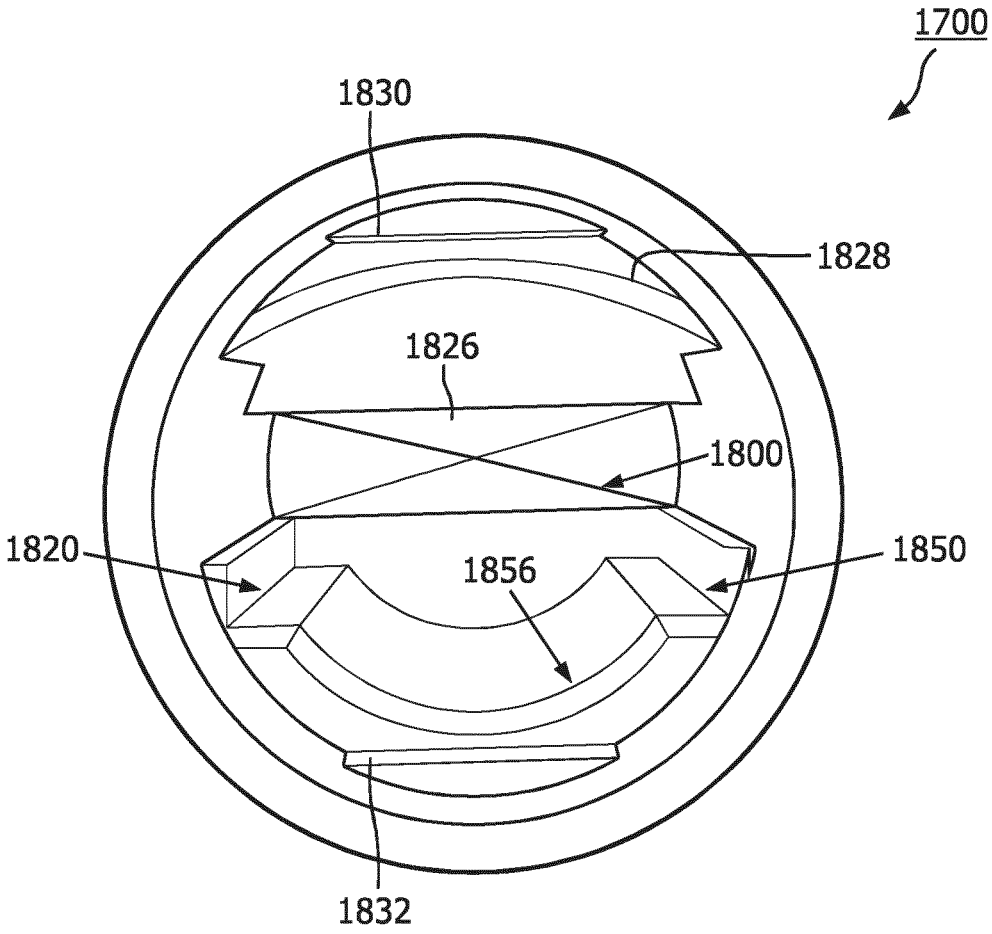
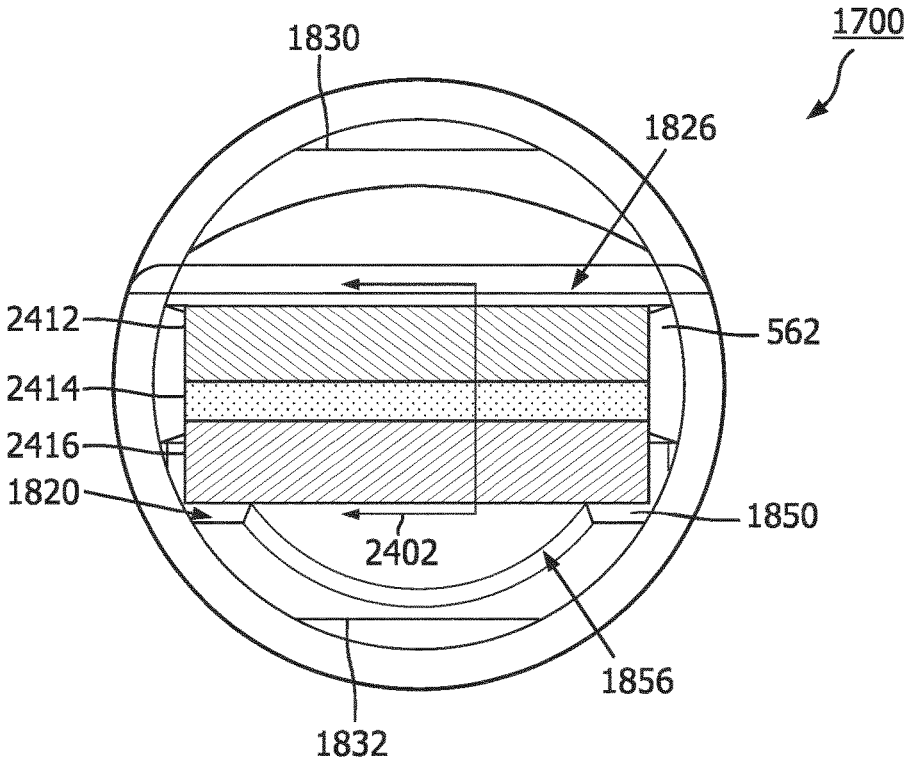


FIG. 23


1700
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1826
2412
562
2414
2416
1820
1850
2402
1856
1832

FIG. 24

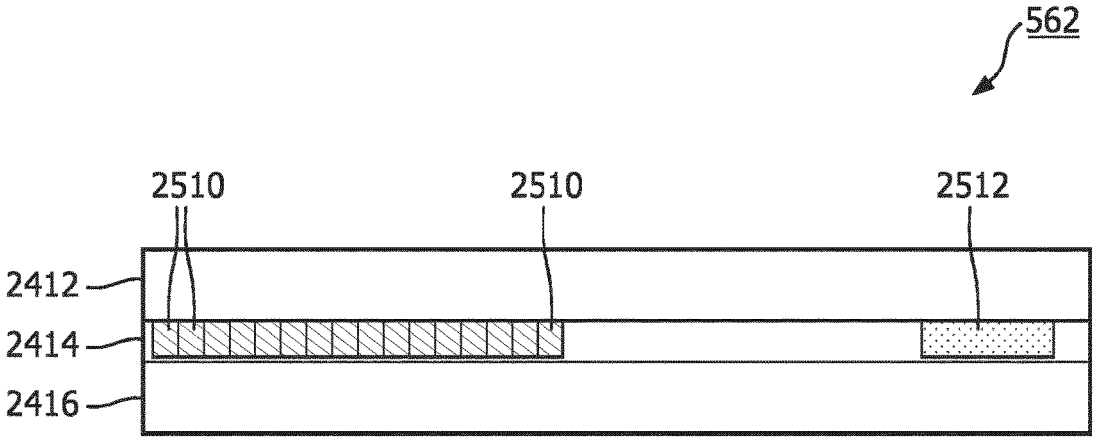

562
2510
2510
2512
2412
2414
2416

FIG. 25

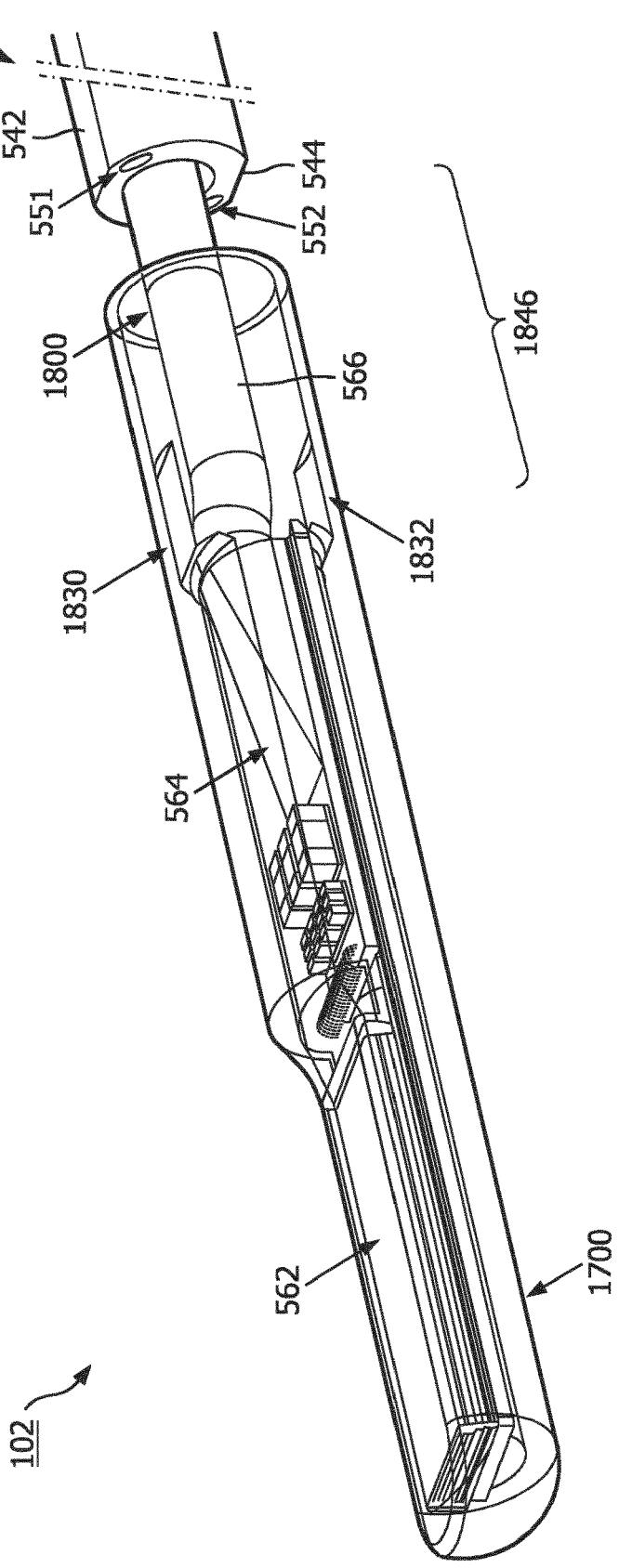
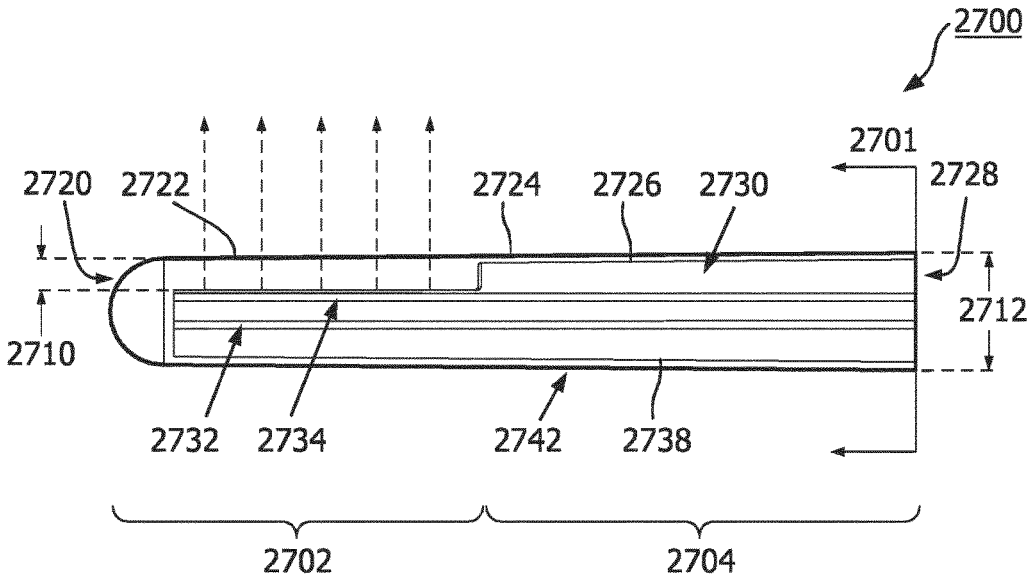


FIG. 26


2700
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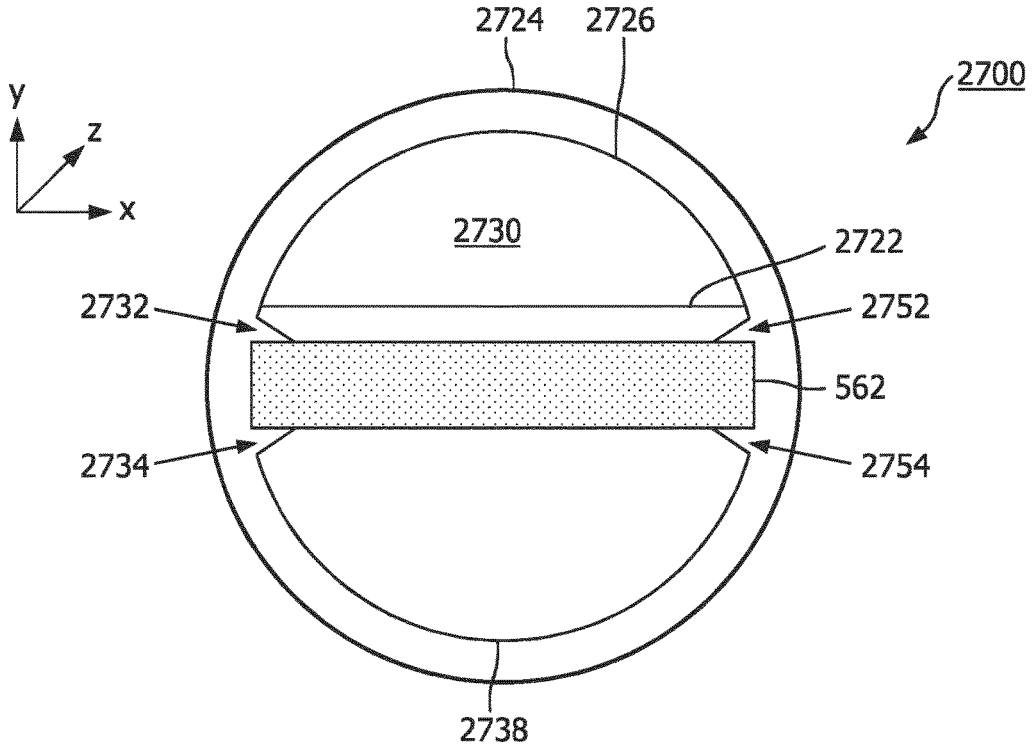
2704

FIG. 27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y
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x
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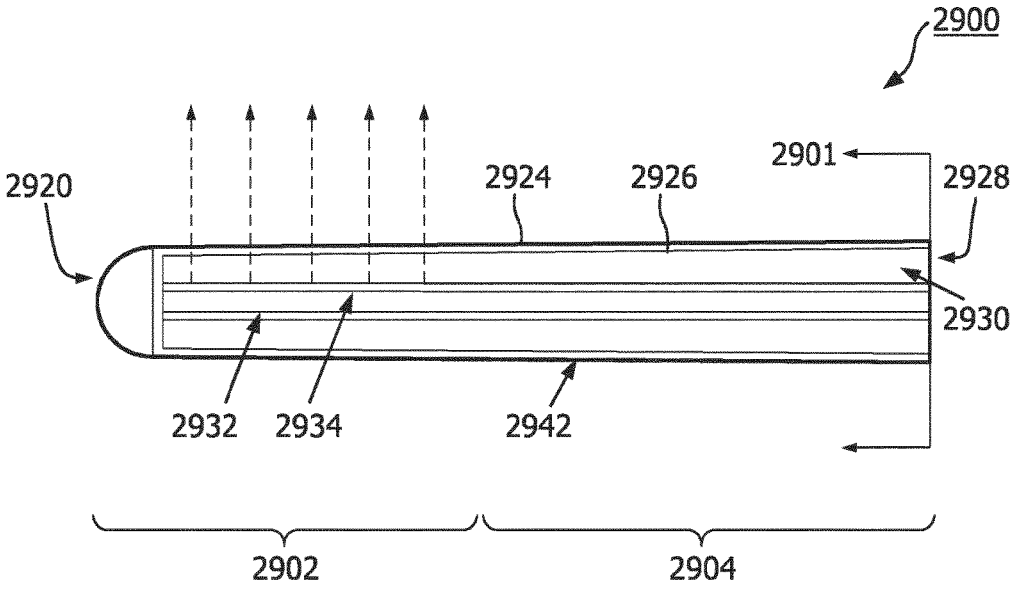
FIG. 28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2934
2942
2902
2904

FIG. 29

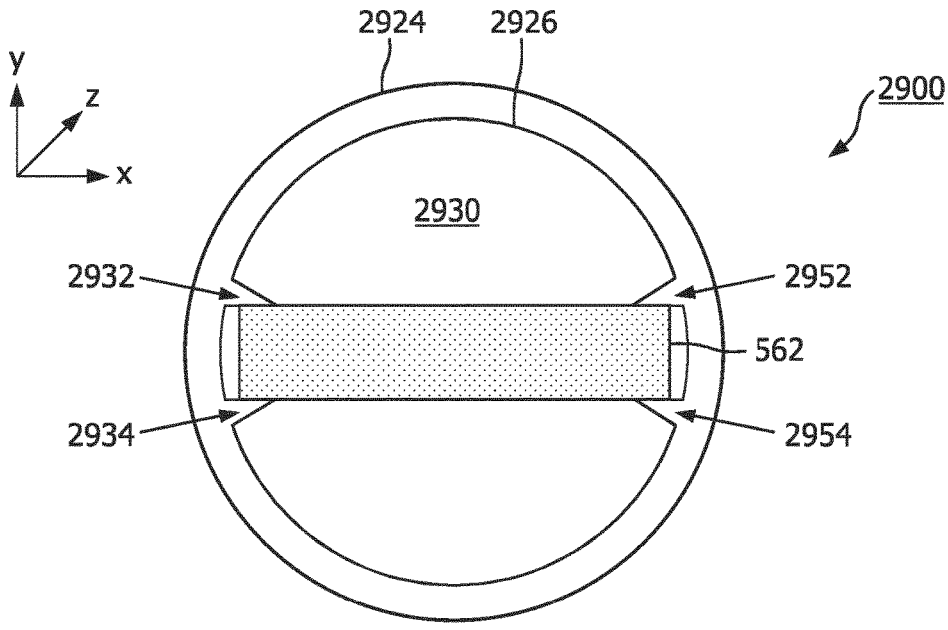
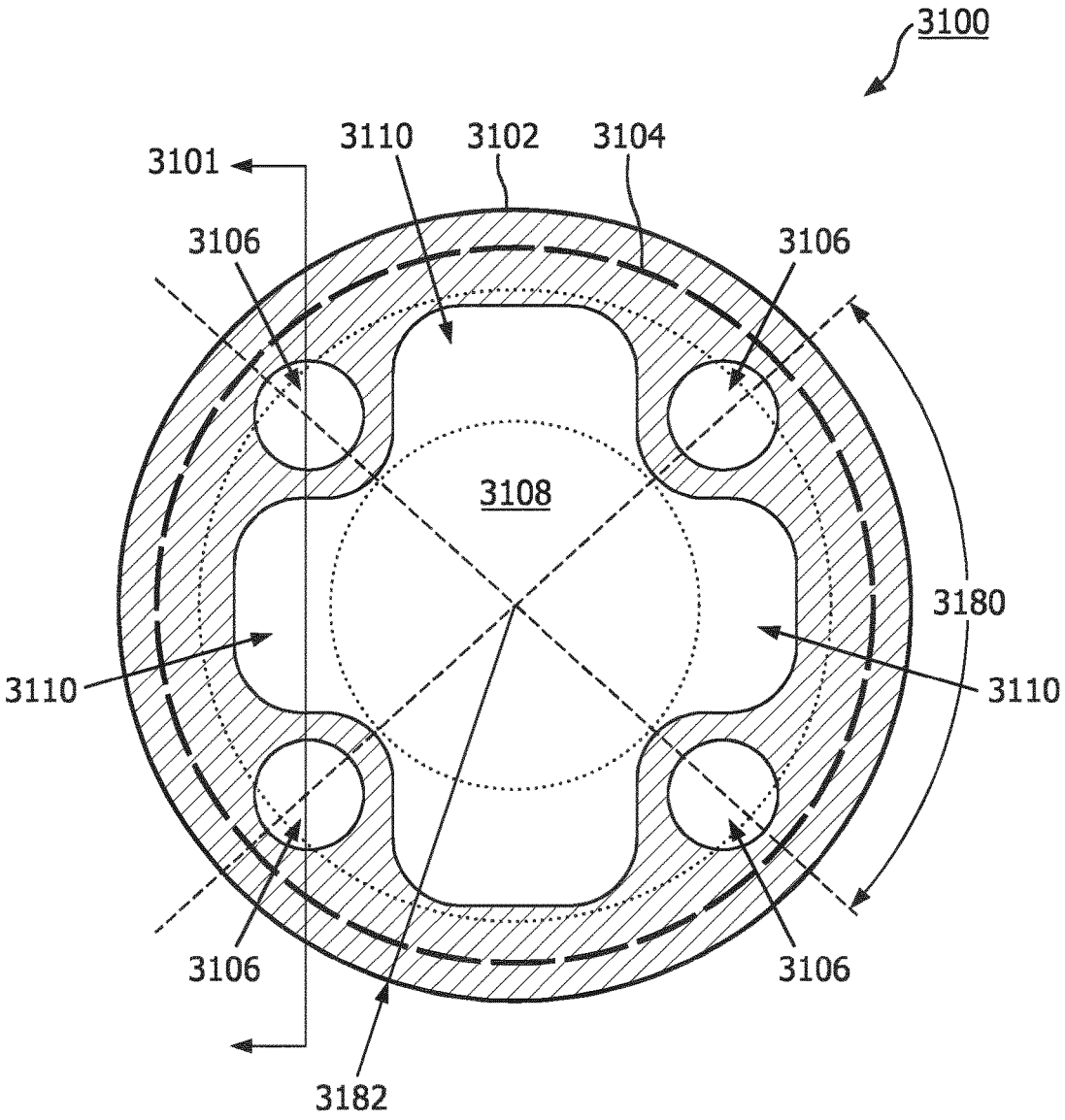

2924
2926
y
z
x
2900
2930
2932
2952
562
2934
2954

FIG. 30


3100
3101
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3104
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3180
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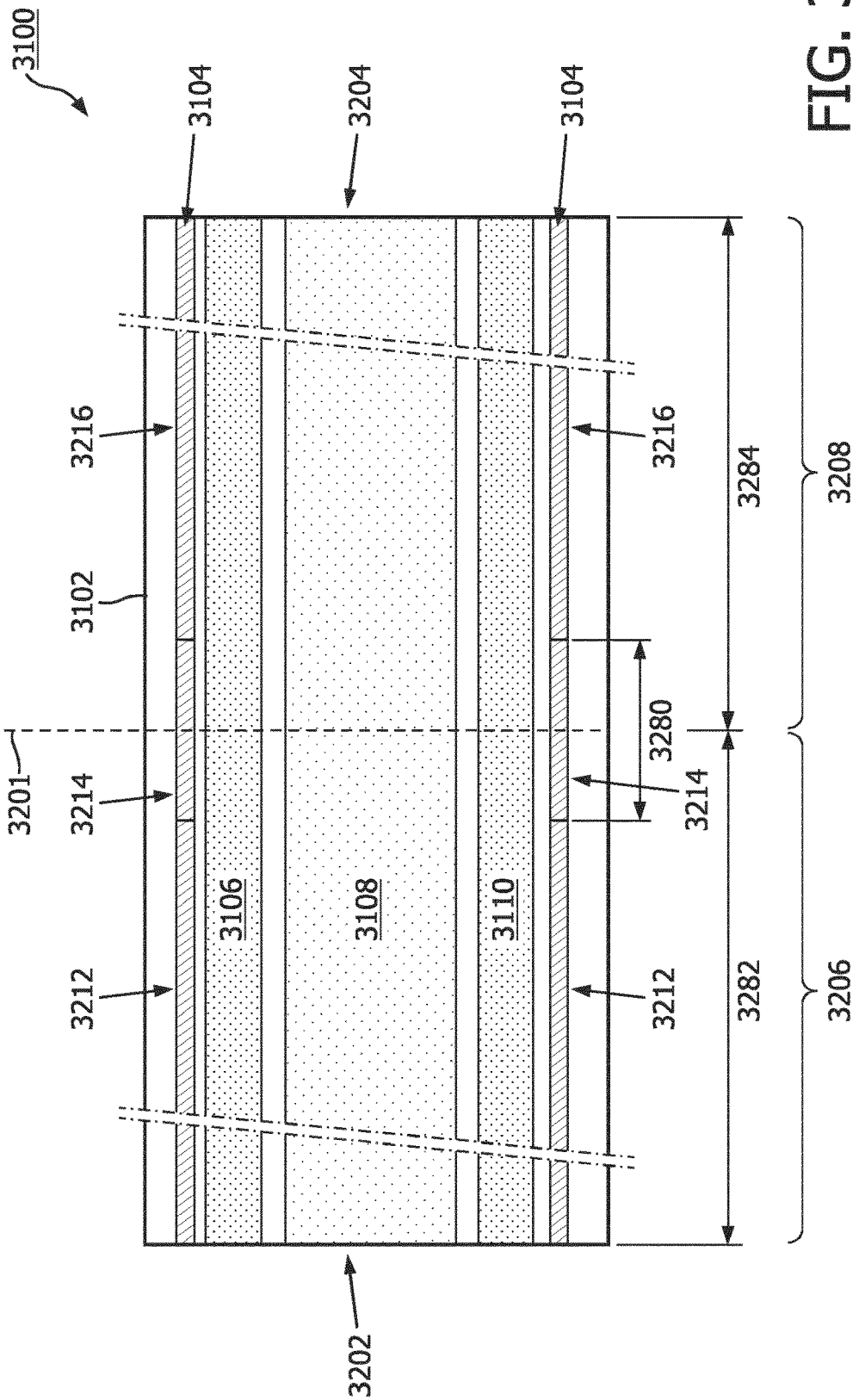
3182

FIG. 31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3202

FIG. 32

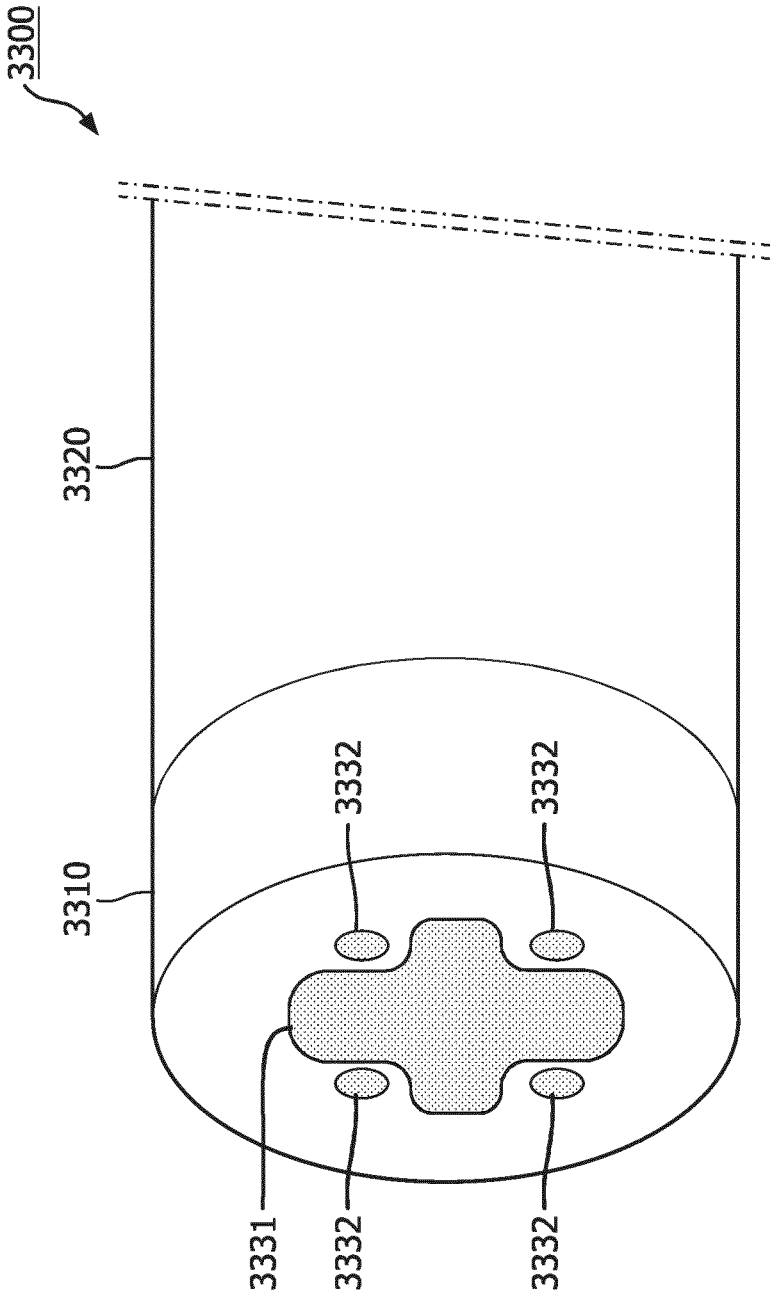
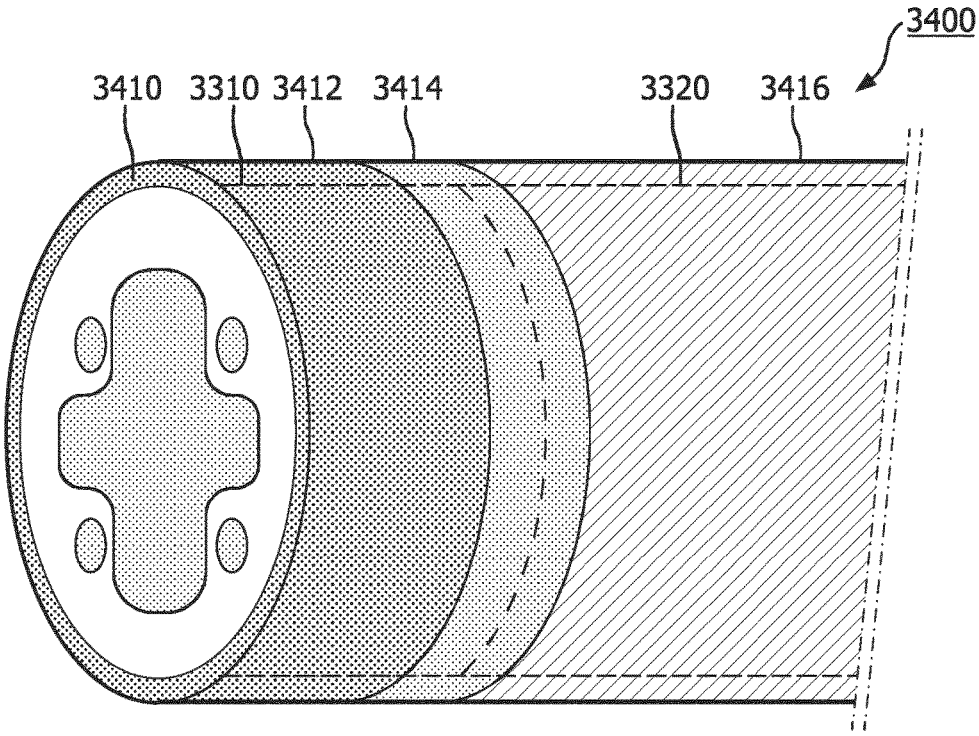


FIG. 33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3412
3414
3320
3416

FIG. 34

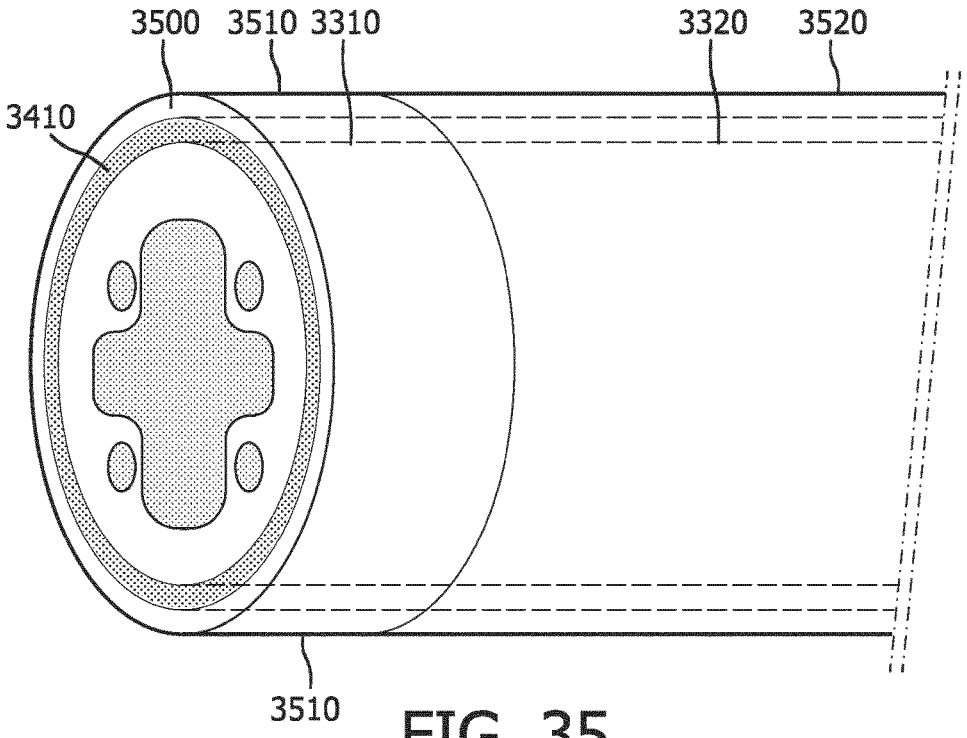
3500
3510
3310
3320
3520
3410
3510

FIG. 35

INTRACARDIAC ECHOCARDIOGRAPHY (ICE) CATHETER TIP ASSEMBLY

TECHNICAL FIELD

[0001] The present disclosure relates generally to ultrasound catheters, in particular, to steerable ultrasound intracardiac echocardiography (ICE) catheters having tip members shaped and sized to optimize ultrasonic imaging performance and to facilitate alignment during manufacturing.

BACKGROUND

[0002] Diagnostic and therapeutic ultrasound catheters have been designed for use inside many areas of the human body. In the cardiovascular system, two common diagnostic ultrasound methods are intravascular ultrasound (IVUS) and intra-cardiac echocardiography (ICE). Typically a single rotating transducer or an array of transducer elements is used to transmit ultrasound at the tips of the catheters. The same transducers (or separate transducers) are used to receive echoes from the tissue. A signal generated from the echoes is transferred to a console which allows for the processing, storing, display, or manipulation of the ultrasound-related data.

[0003] IVUS catheters are typically used in the large and small blood vessels (arteries or veins) of the body, and are almost always delivered over a guidewire having a flexible tip. ICE catheters are usually used to image chambers of the heart and surrounding structures, for example, to guide and facilitate medical procedures, such as transseptal lumen punctures, left atrial appendage closures, atrial fibrillation ablation, and valve repairs. Commercially-available ICE catheters are not designed to be delivered over a guidewire, but instead have distal ends which can be articulated by a steering mechanism located in a handle at the proximal end of the catheter. For example, an ICE catheter may be inserted through the femoral or jugular artery when accessing the anatomy, and steered in the heart to acquire images necessary to the safety of the medical procedures.

[0004] One type of ICE catheter (EP Medsystems ViewFlex™ Intracardiac Ultrasound Deflectable catheter) has a distal articulation in a single plane (both directions), operated by a single wheel that rotates about the lengthwise axis of the handle. The wheel is turned to a specific position for the desired catheter shape, staying in place due to the inherent friction on the wheel mechanism. The catheter is torquable, and can be rotated with the handle to facilitate steering in a second plane. The motions required to simultaneously torque and rotate the catheter often require two-handed operation.

[0005] Another type of ICE catheter (Siemens/ACUSON AcuNav™ Ultrasound Catheter) has an additional steering plane, and each steering plane is utilized by turning one of two corresponding wheels on the handle. These wheels rotate about the lengthwise axis of the handle. A third wheel, which also rotates about the lengthwise axis of the handle, is a locking mechanism for freezing each of the two steering wheels in its respective orientation. The entire catheter need not be torqued. The two steering planes allow a large combination of possible catheter configurations.

[0006] ICE catheters commonly provide steering through pullwires secured to the distal portions of the catheters near the tip assemblies. The pullwires are also referred to as steering lines. The pullwires extend through the bodies of the catheters and are coupled to control wheels at handles of the catheters located at the proximal end of catheters. For example, a pair of pullwires may provide steering in a left-right plane and another pair of pullwires may provide steering in an anterior-posterior plane. Thus, the maneuvering or turning of a control wheel in turn actuates a corresponding pullwire to deflect the distal portion of a catheter in a corresponding direction.

[0007] An ICE catheter typically includes an ultrasound imaging core that generates and receives acoustic energy. The imaging core may include a linear array of transducer elements or transducer elements arranged in any suitable configuration. The imaging core is encased in a tip member located at a furthest distal tip of the catheter. The tip member is covered with acoustic adhesive materials. An electrical cable is soldered to the imaging core and extends through the core of the body of the catheter. The electrical cable may carry control signals and echo signals to facilitate imaging of the heart anatomy.

[0008] The tip member acts as a barrier between the imaging core and the body of a patient. The shape, geometry, and material type of the tip member may have an impact on the ultrasonic imaging performance. For example, the tip member may attenuate, distort, and/or reflect acoustic energy emitted by the transducer elements and echoes from reflections of the acoustic energy by the body.

SUMMARY

[0009] The invention provides devices, systems, and related methods that overcome the limitations associated with existing designs and provide improved ultrasound imaging performance.

[0010] Embodiments of the present disclosure provide a catheter with a tip member configured to improve ultrasonic imaging performance and to facilitate alignment during manufacturing. The outer geometry, the internal cavity, and the wall thickness of the tip member are shaped to minimize attenuations, distortions, and/or reflections of acoustic energy along acoustic pathway of an imaging core encased within the tip member. For example, the tip member is configured to have a circular shaft and a flat window at the distal portion at which the imaging core resides such that the thickness of the wall in the direction of the acoustic waves is minimal The material of the tip member is selected to further minimize the attenuations, distortions, and/or reflections. In addition, the tip member is configured to have a smooth transition from the flat window to the circular shaft to eliminate any ledges or perpendicular surfaces on the outer wall. Further, the internal cavity is configured to function as an alignment agent for aligning the imaging core to pullwires of the catheter body such that actuations of the pullwires can orient the image core to provide a consistent angular view during imaging.

[0011] In one embodiment, an imaging catheter assembly is provided. The imaging catheter assembly includes a tip member comprising a tubular body that includes a closed distal end, an opened proximal end, and a proximal curved top outer wall extending from the proximal opened end and tapering into a distal flat top outer wall towards the closed distal end; a flexible elongate member comprising a distal portion coupled to the open proximal end of the tip member; and an imaging component mounted within the tip member.

[0012] In some embodiments, the closed distal end comprises a rounded profile. In some embodiments, the tip member is constructed from a material including a polyether block amide. In some embodiments, the tubular body includes an inner cavity extending from the proximal opened end towards the distal closed end, and the inner cavity includes a proximal curved top inner wall opposite the proximal curved top outer wall and a distal flat top inner wall opposite the distal flat top outer wall. In some embodiments, the imaging component comprises a planar element that includes an ultrasound transducer array. In some embodiments, the distal flat outer wall at least partially forms an imaging window for the ultrasound transducer array. In some embodiments, the imaging component is positioned within the inner cavity such that the ultrasound transducer array emits ultrasound beams towards and through the distal flat top inner wall and the distal flat top outer wall. In some embodiments, the imaging component is positioned about parallel to the distal flat top inner wall, and a wall thickness between the distal flat top inner wall and the distal flat top outer wall is less than 200 microns. In some embodiments, the imaging component is enclosed within the inner cavity by a material including at least one of a polydimethylsiloxane (PDMS), polyurethane, or ultraviolet (UV) adhesive. In some embodiments, the inner cavity further includes: a first guiding member extending along a first inner sidewall of the inner cavity and a second guiding member extending along a second inner sidewall of the inner cavity, where the first inner sidewall is radially opposite the second inner sidewall and the imaging component is positioned within the tip member guided by the first guide member and the second guide member. In some embodiments, the inner cavity includes a first keyed inner wall surface positioned relative to a propagation direction of the ultrasound beams, wherein the distal portion of the flexible elongate member further comprises a connecting member, and wherein the connecting member includes a second keyed surface inter-engaging with the first keyed inner wall surface. In some embodiments, the imaging catheter assembly further comprises a plurality of steering lines coupled to the connecting member and extending along the flexible elongate member, wherein the plurality of steering lines are oriented relative to the second keyed surface such that translation of each of the plurality of steering lines deflects the tip member in an associated pre-defined direction relative to a longitudinal axis of the flexible elongate member.

[0013] In one embodiment, an imaging catheter assembly is provided. The imaging catheter assembly includes a tip member comprising a cylindrical body that includes a closed distal end and an opened proximal end, the cylindrical body having a substantially uniform diameter between the closed distal end and open proximal end and defining an inner lumen of variable cross-sections, the inner lumen having a distal section with a first cross-section configured to receive an imaging component and proximal section having a second cross-section configured to receive a distal portion of a flexible elongate member, the second cross-section being different than the first cross-section; a flexible elongate member coupled to the open proximal end of the tip member such that at least a distal portion of the flexible elongate member is received within the proximal section of the inner lumen of the tip member; and an imaging component mounted within the distal section of the inner lumen of the tip member.

[0014] In some embodiments, the tip member is constructed from a material including a polyether block amide. In some embodiments, the closed distal end includes a rounded profile. In some embodiments, the proximal section of the inner lumen includes a curved top inner wall and the distal section of the inner lumen includes a flat top inner wall. In some embodiments, the imaging component is a planar element including an ultrasound transducer array, and wherein the imaging component is positioned within the distal section of the inner lumen such that the ultrasound transducer array emits ultrasound beams towards and through the flat top inner wall. In some embodiments, the imaging component is enclosed within the distal section of the inner lumen by a material, the material including at least one of a polydimethylsiloxane (PDMS), polyurethane, or ultraviolet (UV) adhesive. In some embodiments, the distal section of the inner lumen further includes a first guiding member extending along a first inner sidewall and a second guiding member extending along a second inner sidewall opposite the first inner sidewall, wherein the imaging component is positioned between the first guide member and the second guide member. In some embodiments, the distal portion of the flexible elongate member includes a keyed structure to mate with the proximal section of the inner lumen of the tip member in a predefined orientation. In some embodiments, the distal portion of the flexible elongate member includes a connecting member and a plurality of steering lines coupled to the connecting member, the plurality of steering lines extending along the flexible elongate member to a proximal portion of the flexible elongate member. In some embodiments, the plurality of steering lines are oriented relative to the keyed structure such that translation of each of the plurality of steering lines deflects the tip member in an associated pre-defined direction relative to a longitudinal axis of the flexible elongate member.

[0015] Additional aspects, features, and advantages of the present disclosure will become apparent from the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Illustrative embodiments of the present disclosure will be described with reference to the accompanying drawings, of which:

[0017] FIG. **1** is a schematic diagram of an ICE imaging system according to embodiments of the present disclosure.

[0018] FIG. **2** is a schematic diagram of a portion of an ICE device according to embodiments of the present disclosure.

[0019] FIG. **3** is a schematic diagram of a portion of an ICE device under deflection according to embodiments of the present disclosure.

[0020] FIG. **4** is a schematic diagram illustrating deflections planes of an ICE device according to embodiments of the present disclosure.

[0021] FIG. **5** is a schematic diagram illustrating an interconnection within an ICE device between a tip assembly and a flexible elongate member according to embodiments of the present disclosure.

[0022] FIG. **6**A is a perspective view of a crown element according to embodiments of the present disclosure.

[0023] FIG. **6**B is a bottom view of a crown element according to embodiments of the present disclosure.

[0024] FIG. **6**C is a side view of a crown element according to embodiments of the present disclosure.

[0025] FIG. **7** is a side view of a crown element with a pullwire in position according to embodiments of the present disclosure.

[0026] FIG. **8**A is a perspective view of a sleeve element according to embodiments of the present disclosure.

[0027] FIG. **8**B is a top view of a sleeve element according to embodiments of the present disclosure.

[0028] FIG. **9** is a top view of a sleeve element according to embodiments of the present disclosure.

[0029] FIG. **10** is a flow diagram of a method of assembling an ICE device according to aspects of the disclosure.

[0030] FIG. **11** is a schematic diagram illustrating a crown element fitted over an electrical cable, in a stage of assembly, according to embodiments of the disclosure.

[0031] FIG. **12** is a schematic diagram illustrating a pair of pullwires anchored to a crown element, in a stage of assembly, according to embodiments of the disclosure.

[0032] FIG. **13** is a schematic diagram illustrating a pair of pullwires anchored to a crown element and threaded through a flexible elongate member, in a stage of assembly, according to embodiments of the disclosure.

[0033] FIG. **14** is a schematic diagram illustrating a crown element positioned for coupling, in a stage of assembly, according to embodiments of the disclosure.

[0034] FIG. **15** is a schematic diagram illustrating a sleeve element positioned for coupling, in a stage of assembly, according to embodiments of the disclosure.

[0035] FIG. **16** is a schematic diagram illustrating a sleeve element bonded to a tip assembly and a flexible elongate member, in a stage of assembly, according to embodiments of the disclosure.

[0036] FIG. **17** is a side view of a tip member according to embodiments of the present disclosure.

[0037] FIG. **18** is a side perspective view of a tip member according to embodiments of the present disclosure.

[0038] FIG. **19** is a cross-sectional view of a tip member according to embodiments of the present disclosure.

[0039] FIG. **20** is a cross-sectional view of a tip member according to embodiments of the present disclosure.

[0040] FIG. **21** is a cross-sectional view of a tip member according to embodiments of the present disclosure.

[0041] FIG. **22** is a cross-sectional view of a tip member according to embodiments of the present disclosure.

[0042] FIG. **23** is a back perspective view of a tip member according to embodiments of the present disclosure.

[0043] FIG. **24** is a back perspective view of a tip member with an imaging core in position according to embodiments of the present disclosure.

[0044] FIG. **25** is a cross-sectional side view of an imaging core according to embodiments of the present disclosure.

[0045] FIG. **26** is a perspective view of a tip assembly and a sleeve element positioned for coupling according to embodiments of the present disclosure.

[0046] FIG. **27** is a side perspective view of a tip member according to embodiments of the present disclosure.

[0047] FIG. **28** is a back perspective view of a tip member with an imaging core in position according to embodiments of the present disclosure.

[0048] FIG. **29** is a side perspective view of a tip member according to embodiments of the present disclosure.

[0049] FIG. **30** is a back perspective view of a tip member with an imaging core in position according to embodiments of the present disclosure.

[0050] FIG. **31** is a cross-sectional view of a lined variable braided differential durometer multi-lumen catheter shaft according to embodiments of the present disclosure.

[0051] FIG. **32** is a cross-sectional longitudinal view of a lined variable braided differential durometer multi-lumen catheter shaft according to embodiments of the present disclosure.

[0052] FIG. **33** is a perspective view of a multi-lumen inner extrusion in a stage of manufacturing according to embodiments of the present disclosure.

[0053] FIG. **34** is a perspective view of a braid reinforced inner extrusion in a stage of manufacturing according to embodiments of the present disclosure.

[0054] FIG. **35** is a perspective view of a single-lumen outer extrusion inserted over a braided inner extrusion in a stage of manufacturing according to embodiments of the present disclosure.

DETAILED DESCRIPTION

[0055] For the purposes of promoting an understanding of the principles of the present disclosure, reference will now be made to the embodiments illustrated in the drawings, and specific language will be used to describe the same. It is nevertheless understood that no limitation to the scope of the disclosure is intended. Any alterations and further modifications to the described devices, systems, and methods, and any further application of the principles of the present disclosure are fully contemplated and included within the present disclosure as would normally occur to one skilled in the art to which the disclosure relates. For example, while the ICE system is described in terms of cardiovascular imaging, it is understood that it is not intended to be limited to this application. The system is equally well suited to any application requiring imaging within a confined cavity. In particular, it is fully contemplated that the features, components, and/or steps described with respect to one embodiment may be combined with the features, components, and/or steps described with respect to other embodiments of the present disclosure. For the sake of brevity, however, the numerous iterations of these combinations will not be described separately.

[0056] FIG. **1** is a schematic diagram of an ICE imaging system **100** according to embodiments of the present disclosure. The system **100** may include an ICE device **110**, a connector **124**, a control and processing system **130**, such as a console and/or a computer, and a monitor **132**. The ICE device **110** includes a tip assembly **102**, a flexible elongate member **108**, and a handle **120**. The flexible elongate member **108** includes a distal portion **104** and a proximal portion **106**. The distal end of the distal portion **104** is attached to the tip assembly **102**. The proximal end of the proximal portion **106** is attached to the handle **120** for example, by a resilient strain reliever **112**, for manipulation of the ICE device **110** and manual control of the ICE device **110**. The tip assembly **102** can include an imaging core with ultrasound transducer elements and associated circuitry. The handle **120** can include actuators **116**, a clutch **114**, and other steering control components for steering the ICE device **110**, such as deflecting the tip assembly **102** and the distal portion **104**, as described in greater details herein.

[0057] The handle **120** is connected to the connector **124** via another strain reliever **118** and an electrical cable **122**. The connector **124** may be configured in any suitable configurations to interconnect with the processing system

130 and the monitor **132** for processing, storing, analyzing, manipulating, and displaying data obtained from signals generated by the imaging core at the tip assembly **102**. The processing system **130** can include one or more processors, memory, one or more input devices, such as keyboards and any suitable command control interface device. The processing system **130** can be operable to facilitate the features of the ICE imaging system **100** described herein. For example, the processor can execute computer readable instructions stored on the non-transitory tangible computer readable medium. The monitor **132** can be any suitable display device, such as liquid-crystal display (LCD) panel or the like.

[0058] In operation, a physician or a clinician advances the flexible elongate member **108** into a vessel within a heart anatomy. The physician or clinician can steer the flexible elongate member **108** to a position near the area of interest to be imaged by controlling the actuators **116** and the clutch **114** on the handle **120**. For example, one actuator **116** may deflect the tip assembly **102** and the distal portion **104** in a left-right plane and the other actuator **116** may deflect the tip assembly **102** and the distal portion **104** in an anterior-posterior plane, as discussed in greater details herein. The clutch **114** provides a locking mechanism to lock the positions of the actuators **116** and in turn the deflection of the flexible elongate member while imaging the area of interest.

[0059] The imaging process may include activating the ultrasound transducer elements on the tip assembly **102** to produce ultrasonic energy. A portion of the ultrasonic energy is reflected by the area of interest and the surrounding anatomy, and the ultrasound echo signals are received by the ultrasound transducer elements. The connector **124** transfers the received echo signals to the processing system **130** where the ultrasound image is reconstructed and displayed on the monitor **132**. In some embodiments, the processing system **130** can control the activation of the ultrasound transducer elements and the repletion of the echo signals. In some embodiments, the processing system **130** and the monitor **132** may be part of the same system.

[0060] The system **100** may be utilized in a variety of applications such as transseptal lumen punctures, left atrial appendage closures, atrial fibrillation ablation, and valve repairs and can be used to image vessels and structures within a living body. Although the system **100** is described in the context of ICE catheterization procedures, the system **100** is suitable for use with any catheterization procedure. In addition, the tip assembly **102** may include any suitable physiological sensor or component for diagnostic, treatment, and/or therapy.

[0061] FIG. **2** is a schematic diagram of a portion of the ICE device **110** according to embodiments of the present disclosure. The tip assembly **102** and the flexible elongate member **108** are shaped and sized for insertion into vessels of a patient body. The flexible elongate member **108** can be composed of any suitable material, such as polyether block amides. The distal portion **104** and the proximal portion **106** are tubular in shape and may include a primary lumen and one or more pullwire lumens extending longitudinally along the flexible elongate member **108**. The primary lumen is sized and shaped to accommodate an electrical cable interconnecting the tip assembly **102** and the connector **124** for transferring echo signals obtained from the transducer elements. In some embodiments, the primary lumen can be shaped and sized to accommodate other components for diagnostic and/or therapy procedures. The pullwire lumens are sized and shaped to accommodate pullwires, for example, extending from the distal portion **104** to the handle **120**. The pullwires may be coupled to the actuators **116** and the clutch **114** such that the flexible elongate member **108** and the tip assembly **102** are deflectable based on actuations of the actuators **116** and the clutch **114**. In an embodiment, the primary lumen is shaped to facilitate alignment of the pullwire lumens. In addition, the tubular body of the flexible elongate member **108** may include a lined variable braided reinforcement layer configured to provide flexibility and kink resistance. The arrangements and configurations of the pullwires, the primary lumen, the pullwire lumens, the tip assembly **102**, and the lined variable braided reinforcement layer are described in greater details herein. Dimensions of the flexible elongate member **108** can vary in different embodiments. In some embodiments, the flexible elongate member **108** can be a catheter having an outer diameter between about 8 and about 12 French (Fr) and can have a total length **206** between about 80 centimeters (cm) to about 120 cm, where the proximal portion **106** can have a length **204** between about 70 cm to about 118 cm and the distal portion **104** can have a length **202** between about 2 cm to about 10 cm.

[0062] FIG. **3** is a schematic diagram of a portion of the ICE device **110** under deflection according to embodiments of the present disclosure. For example, the flexible elongate member **108** shown in FIG. **2** is referred to as a neutral position. In FIG. **3**, the tip assembly **102** and the distal portion **104** of the flexible elongate member **108** are deflected from the neutral position. In an embodiment, the distal portion **104** may be deflected up to a bend radius **305** of about 27 millimeters (mm) to about 28 mm.

[0063] FIG. **4** is a schematic diagram illustrating deflections planes of the ICE device **110** according to embodiments of the present disclosure. As shown, the tip assembly **102** and the distal portion **104** can be deflected along a first plane as shown by the solid arrows and a second plane as shown by the dotted arrows. In FIG. **3**, the first plane is represented by an x-y plane and the second plane is represented by an x-z plane. For example, the x-y plane may correspond to a left-right plane and the x-z plane may correspond to an anterior-posterior plane for imaging the heart anatomy.

[0064] FIG. **5** is a schematic diagram illustrating an interconnection within the ICE device **110** between the tip assembly **102** and the flexible elongate member **108** according to embodiments of the present disclosure. As shown, the interconnection between the tip assembly **102** and the distal portion **104** of the flexible elongate member **108** includes a crown element **520** and a sleeve element **540**. The crown element **520** is coupled to the distal end of the distal portion **104**. The sleeve element **540** is coupled to the crown element **520** and the proximal end of the tip assembly **102**. The tip assembly **102** includes an imaging core **562** encased in a tip member **560**. For example, the imaging core **562** is a planar element. The tip assembly **102** can include an alignment portion (not shown) shaped to facilitate alignment during manufacturing, as described in greater detail herein. The imaging core **562** is connected to an electrical cable **566** via an electrical interconnection **564**. The electrical cable **566** extends longitudinally along the flexible elongate member **108**. The crown element **520** and the sleeve element **540** are fitted around the electrical cable **566**.

[0065] A more detailed view of the crown element **520** is illustrated in FIG. **6**A and dimensions of the crown element **520** are illustrated in FIGS. **6**B and C. The crown element **520** functions as an anchor for pullwires **507** such that the tip assembly **102** and the distal portion **104** may be deflectable upon actuations of the pullwires **507** in the proximal direction as shown in FIGS. **3** and **4** and described in greater detail herein. The anchoring of the pullwires **507** to the crown element **520** is illustrated in FIG. **7**. The sleeve element **540** functions as an alignment agent to align the crown element **520** and the pullwires **507** such that the deflection may provide predictable or predetermined articulation views as described in greater detail herein. A more detailed view of the sleeve element **540** is illustrated in FIG. **8**A. The alignment between the sleeve element **540** and the tip assembly **102** is illustrated in FIG. **26**.

[0066] In an embodiment, the flexible elongate member **108** may include a lined variable braided enforcement layer to provide flexibility and kink resistance as described in greater detail herein. In such an embodiment, the interconnection further includes a braid containment **502** positioned between an anchoring segment **503** and the distal end of the flexible elongate member **108**. The braid containment **502** may be composed of material such as polyethylene terephthalate (PET) or any suitable material. The anchoring segment **503** can be composed of similar material as the flexible elongate member **108**. The braid containment **502** functions as a termination for the braided reinforcement layer. The braid containment **502** encases the termination of the materials (e.g., stainless steel wires) of the braided reinforcement layer to prevent exposure of the materials outside of the ICE device **110**. The structure of the flexible elongate member **108** and the braided reinforcement layer are described in greater detail herein. The anchoring segment **503** couples the braid containment **502** to the crown element **520** and the sleeve element **540** to allow for thermal reflow when bonding the components at the interconnection.

[0067] The interconnection may further include support members **508** and **509**, which are thin sleeves, to provide protection over connections of different components. The support members **508** and **509** may be composed of any suitable polymeric material. As shown, the support member **508** is positioned over the connections among the sleeve element **540**, the tip assembly **102**, the crown element **520**, and the anchoring segment **503**. The support member **509** is positioned over the connections among the braid containment **502**, the anchoring segment **503**, and the distal portion **104** of the flexible elongate member **108**.

[0068] FIG. **6**A is a perspective view of the crown element **520** according to embodiments of the present disclosure. FIG. **6**B is a bottom view of the crown element **520** according to embodiments of the present disclosure. FIG. **6**C is a side view of the crown element **520** taken along the line **601** of FIG. **6**B according to embodiments of the present disclosure. The crown element **520** includes an annular ring **522** and support legs or posts **528** and **529**. The crown element **520** is composed of a material dissimilar or incompatible with the material of the flexible elongate member **108**. For example, the crown element **520** is composed of a thermoset material such as metal or plastic polymer. The annular ring **522** includes a top surface **524** and a bottom surface **526**. The posts **528** and **529** are positioned about radially opposite of each other on the annular ring **522** and extend about perpendicularly from the bottom surface **526**. Each of the posts **528** and **529** has a hole **530** positioned at an end of each of the posts **528** and **529**, respectively, away from the annular ring **522** and along a central axis of the posts **528** and **529**, respectively. A pair of pullwires such as the pullwires **507** can be secured to the crown element **520**, one at each of the posts **528** and **529**. The edges of the annular ring **522** are curved or rounded, for example, with small radii, to eliminate breakage of the pullwires during multiple actuations.

[0069] Dimensions of the crown element **520** can vary in different embodiments depending on the dimensions of the flexible elongate member **108**. In some embodiments, the annular ring **522** can have an outer radius **611** between about 5 FR and about 11 FR and an inner radius **612** between about 4 FR and about 10 FR. Each of the posts **528** and **529** can have a height **613** between about 1 mm and 3 mm and a width **614** between about 0.25 mm and 1.5 mm. Each hole **530** can have a radius **615** between about 0.05 mm and 0.7 mm. In some embodiments, the outer radius **611** can be less than the outer diameter of the flexible elongate member **108** while the inner radius **612** can be greater than the radius of the primary lumen of the flexible elongate member **108**.

[0070] FIG. **7** is a side view of the crown element **520** taken along the line **601** of FIG. **6**B with a pullwire **700** similar to the pullwires **507** in position according to embodiments of the present disclosure. The pullwire **700** can be composed of metal, hard plastic, or any suitable material. As shown, the pullwire **700** is anchored to the crown element **520** by forming a knot **710** at the post **528** creating segments **721** and **722** separated by the post **528**. The post **528** provides connection security and stability when the segments **721** and **722** are actuated. The separation of the segments **721** and **722** by the post **528** allows actuations of the segments **721** and **722** to be independent of each other, and thus provides consistent bending of the ICE device **110** over multiple actuations of the segments **721** and **722**. For example, an actuation of the segment **721** deflects the ICE device **110** in one direction and actuation of the segment **722** deflects the ICE device **110** in another direction. Another pullwire similar to the pullwires **700** and **507** can be anchored to the crown element **520** at the other post **529** using similar mechanisms to provide deflection of the ICE device **110** along a different plane. Thus, the crown element **520** enables independent and consistent actuations of the pullwire segments. In addition, the head **711** of the knot **710** is placed at the inner wall of the crown element **520** to minimize the amount of dissimilar material outside of the crown element **520** that can weaken the joint between the crown element **520** and the sleeve element **540** after bonding.

[0071] FIG. **8**A is a perspective view of the sleeve element **540** according to embodiments of the present disclosure. FIG. **8**B is a top view of the sleeve element **540** according to embodiments of the present disclosure. The sleeve element **540** has a tubular body and includes flat outer surface portions **542** and **544** and curved outer surface portions **546** and **548**. The sleeve element **540** is composed of a material compatible to the flexible elongate member **108** and the tip assembly **102**. For example, the sleeve element **540** can be composed of a plastic polymer. The flat outer surface portions **542** and **544** have about the same surface area. The curved outer surface portions **546** and **548** have about the same surface area. The flat outer surface portion **542** is adjacent to the curved outer surface portions **546** and **548**.

The flat outer surface portion **544** is adjacent to the curved outer surface portions **546** and **548**. The flat outer surface portions **542** and **544** are about radially opposite of each other. The sleeve element **540** further includes slots **551** and **552** extending longitudinally along the tubular body. The slot **551** is positioned proximal to the flat outer surface portion **542** and curved outer surface portion **546**. The slot **552** is positioned proximal to the flat outer surface portion **544** and curved outer surface portion **548**.

[0072] During assembly or manufacturing, the posts **528** and **529** of the crown element **520** are fitted into the slots **551** and **552**, respectively, and thermally bonded. After the bonding, the holes **530** are filled with the material of the sleeve element **540**. Thus, the holes **530** allow for a stronger bond and improve tensile strength at the joint between the crown element **520** and the sleeve element **540**. Since the pullwires are anchored at the posts **528** and **529** and the posts **528** and **529** are fitted into the slots **551** and **552**, respectively, the positioning of the slots **551** and **552** relative to the flat outer surface portions **542** and **544** can facilitate alignment of the pullwires to the imaging core **562** such that actuations of the pullwires can provide consistent articulation views, as described in greater detail herein.

[0073] Dimensions of the sleeve element **540** can vary in different embodiments depending on the dimensions of the flexible elongate member **108**. For example, the outer diameter **814** may be smaller than the inner diameter of the proximal opening **568** of the tip member **560** such that the sleeve element **540** may be fitted into the proximal opening **568** of the tip member **560**. The widths **813** of the slots **551** and **552** may be greater than the widths **614** of the posts **528** and **529** such that the posts **528** and **529** may be inserted into the slots **551** and **552**, respectively. For example, the material of the sleeve element **540** may be pliable and may conform to the inserted posts **528** and **529**.

[0074] FIG. **9** is a top view of a sleeve element **900** according to embodiments of the present disclosure. The sleeve element **900** can be employed by the ICE device **110** in place of the sleeve element **540**. The sleeve element **900** is similar to the sleeve element **540**, but has a curved outer surface **910** without any flat portion as in the sleeve element **540**. The sleeve element **900** can include slots **921** and **922** similar to the slots **551** and **552**, which can be used for fitting the posts **528** and **529**, respectively, when bonded with the crown element. The sleeve element **900** can be used when the tip assembly **102** does not include an alignment portion for alignment. In some embodiments, a sleeve element can be shaped to have an outer surface portion different from remaining outer surface to allow for alignment, where the outer surface portion can be in any shape suitable for alignment.

[0075] A method **1000** of assembling the ICE device **110** is described with reference made to FIGS. **10-16**. FIG. **10** is a flow diagram of a method **1000** of assembling the ICE device **110** according to aspects of the disclosure. It is understood that additional steps can be provided before, during, and after the steps of method **1000**, and some of the steps described can be replaced or eliminated for other embodiments of the method. The steps of the method **1000** can be carried out by a manufacturer of an ICE device. FIG. **11** is a schematic diagram illustrating the crown element **520** fitted over the electrical cable **566**, in a stage of assembly, according to embodiments of the disclosure. FIG. **12** is a schematic diagram illustrating a pair of pullwires **700** and **740** anchored to the crown element **520**, in a stage of assembly, according to embodiments of the disclosure. FIG. **13** is a schematic diagram illustrating the pair of pullwires **700** and **740** anchored to the crown element **520** and threaded through the flexible elongate member **108**, in a stage of assembly, according to embodiments of the disclosure. FIG. **14** is a schematic diagram illustrating the crown element **520** positioned for coupling, in a stage of assembly, according to embodiments of the disclosure. FIG. **15** is a schematic diagram illustrating the sleeve element **540** positioned for coupling, in a stage of assembly, according to embodiments of the disclosure. FIG. **16** is a schematic diagram illustrating the sleeve element **540** bonded to the tip assembly **102** and the flexible elongate member **108**, in a stage of assembly, according to embodiments of the disclosure.

[0076] Referring to the step **1005** of the method **1000**, in an embodiment, the tip assembly **102** coupled to the electrical cable **566** is obtained. Referring to the step **1010** of the method **1000** and FIG. **11**, in an embodiment, the crown element **520** is positioned around the electrical cable **566**. FIG. **11** illustrates the electrical cable **566** pre-loaded with the crown element **520**. As shown, the crown element **520** is positioned such that the posts **528** and **529** extend towards the tip assembly.

[0077] Referring to the step **1015** of the method **1000** and FIG. **12**, in an embodiment, the pullwire **700** is secured to the crown element **520** by looping the pullwire **700** around the annular ring **522** at the post **528** to form the two segments **721** and **722**. FIG. **12** illustrates a pair of pullwires **700** and **740** anchored to the crown element **520**. The pullwire **700** is anchored to the annular ring **522** at the post **528** using similar knotting mechanisms shown in FIG. **7**. Similarly, the pullwire **740** is anchored to the annular ring **522** at the post **529** by forming a Larks knot **743**, which creates segments **741** and **742**. It should be noted that the heads of the knots **710** and **743** are placed adjacent to the inner wall of the crown element **520**. In an embodiment, the segments **721** and **722** are for steering the distal portion **104** and the tip assembly **102** in a left direction and an anterior direction, respectively. The segments **741** and **742** are for steering the distal portion **104** and the tip assembly **102** in a right direction and a posterior direction, respectively.

[0078] Referring to the step **1020** of the method **1000** and FIG. **13**, in an embodiment, each segment **721** or **722** is positioned within one of a plurality of pullwire lumens **582** of the flexible elongate member **108**. FIG. **13** illustrates the pair of pullwires **700** and **740** anchored to the crown element **520** and threaded through the flexible elongate member **108**. As shown, the segment **721** is threaded through one of the pullwire lumens **582** of the flexible elongate member **108**. Although not shown, each of the segments **722**, **741**, and **742** can be thread through one of the pullwire lumens **582**.

[0079] Referring to the step **1025** of the method **1000** and FIGS. **14** and **15**, in an embodiment, the sleeve element **540** is positioned between the crown element **520** and the tip assembly **102**. FIG. **14** illustrates the crown element **520** positioned for coupling. As shown, the crown element **520** is positioned abutting the distal end of the flexible elongate member **108**. FIG. **15** illustrates the sleeve element **540** positioned for coupling. As shown, the sleeve element **540** is positioned between the crown element **520** and the tip assembly **102**.

[0080] Referring to the step **1030** of the method **1000**, in an embodiment, the posts **528** and **529** are fitted into the slots **551** and **552**, respectively, of the sleeve element **540**.

[0081] Referring to the step **1035** of the method **1000**, in an embodiment, the sleeve element **540** is cut lengthwise.

[0082] Referring to the step **1040** of the method **1000**, in an embodiment, the sleeve element **540** is wrapped around the electrical cable **566**.

[0083] Referring to the step **1045** of the method **1000**, in an embodiment, the flat outer surface portions **542** and **544** are aligned to the flat portions of the tip assembly **102**. The alignment is described in greater detail herein.

[0084] Referring to the step **1050** of the method **1000** and FIG. **16**, in an embodiment, thermal reflow is applied to the sleeve element **540** to bond the sleeve element **540** to the tip assembly **102**, the crown element **520**, and the flexible elongate member **108**. In FIG. **16**, the bonding forms a joint **1610** between the tip assembly **102** and the flexible elongate member **108**. As described above, the sleeve element **540** is composed of a material similar to the materials of the flexible elongate member **108** and the tip assembly **102** while the crown element **520** is composed of a dissimilar material that is thermoset. Thus, the thermal reflow can fuse the sleeve element **540** the flexible elongate member **108** and the tip assembly **102** together while the crown element **520** is embedded within the fused material. As such, the sleeve element **540** can fill the gap and/or space at the joint **1610**. The sleeve element **540** can prevent collapse at the joint **1610** after the reflowing of different parts. In addition, the sleeve element **540** functions as a stopper in adding adhesive to the joint **1610** to maintain adhesive level at the surface of the joint. Further, the sleeve element **540** can increase the tensile strength of the joint **1610**. In some embodiments, the crown element **520** and the sleeve element **540** are concentrically aligned to a primary lumen of the flexible elongate member **108**.

[0085] The crown element **520** and the sleeve element **540** provide several benefits. The crown element **520** provides connection security and stability for individual pullwire segments **721**, **722**, **741**, and **742** when the pullwire segments **721**, **722**, **741**, or **742** is actuated in a proximal direction to deflect the tip assembly **102** and the distal portion **104** in a corresponding direction. In addition, the anchoring of the pullwires **700** and **740** at the posts **528** and **529**, respectively, allow actuations of the pullwire segments **721**, **722**, **741**, and **742** to provide consistent deflection angles. The holes **530** allow for bonding of the sleeve element **540** to the crown element **520** during the thermal reflow, and thus increasing the tensile strength. Further, the crown element **520** is shaped with rounded edges to prevent breakage of the pullwires **700** and **740** over actuations or increase the lifetime of the ICE device **110**. The sleeve element **540** is shaped with the flat outer surface portions **542** and **544** to allow for easy, precise, and consistent alignment of the pullwires **700** and **740** to the imaging core **562**. Thus, the employment of the sleeve element **540** allow for consistent angle of articulations. In addition, the sleeve element **540** can improve tensile strength at the joint between the tip assembly **102** and the flexible elongate member **108**.

[0086] FIG. **17** is a side view of a tip member **1700** according to embodiments of the present disclosure. The tip member **1700** can be employed by the tip assembly **102** in place of the tip member **560**. The tip member **1700** has a tubular body **1728** with a closed round distal tip **1720** and an opened proximal end **1732**. The tip member **1700** includes a distal portion **1702**, a tapered portion **1704**, and a proximal portion **1706** coupled in order from the closed round distal tip **1720** to the opened proximal end **1732**. The tip member **1700** includes a curved bottom outer wall **1734** coupled to a proximal curved top outer wall **1730** at the proximal portion **1706** that smoothly transitions into a distal flat top outer wall **1722** at the distal portion **1702**. The smooth radius transition at the tapered portion **1704** eliminates the need of a perpendicular surface to join the distal flat top outer wall **1722** and the proximal curved top outer wall **1730**. As such, the outer geometry of the tip member **1700** reduces friction and provides smooth surfaces to avoid catching on tissue structures when the tip member **1700** traverses through a patient body and reduces trauma to the patient. In some embodiments, the tip member **1700** can additionally be treated with a hydrophilic material to further reduce friction.

[0087] The tubular body **1728** can be composed of a thermoplastic elastomer material or any suitable biocompatible material that has acoustic impedance matching to blood within a vessel of a patient body when in use. In an embodiment, the tip member **1700** is constructed from a polyether block amide. For example, the polyether block amide can be a thermoplastic elastomer comprising a flexible polyether and rigid polyimide, such as Pebax® 3533 SA 01 MED. Dimensions of the tip member **1700** can vary in different embodiments. Dimensions of the tip member **1700** can vary in different embodiments. In some embodiments, the tip member **1700** can include a length **1714** between about 15 mm to about 30 mm. The distal flat top outer wall **1722** can extend a length **1712** between about 5 mm to about 15 mm. In this regard, the flat top outer wall **1722** can define all or at least a portion of an imaging window for an ultrasound transducer array positioned within the tip member **1700**. The tip member **1700** can include a height **1710** proportional to the outer diameter **1711** of the tip member **1700**. In some embodiment, the height **1710** is at least about 50% of the outer diameter **1711**, with some particular embodiments between about 50% to about 75% of the outer diameter **1711**. The tapered portion **1704** can extend a length **1716** between about 0.5 mm to about 2 mm and tapers at an angle **1718** between about 15 degrees to about 75 degrees relative to a central longitudinal axis of the tip member **1700**.

[0088] FIG. **18** is a side perspective view of the tip member **1700** according to embodiments of the present disclosure. The tip member **1700** includes an inner cavity **1800** having an interface portion **1846**, an alignment portion **1844**, and a receiving portion **1842** coupled in order from the opened proximal end **1732** towards the closed round distal tip **1720**. In addition, the inner cavity **1800** includes a chamber **1834** adjacent and distal to the receiving portion **1842** used for accommodating kerf seal as described in greater detail herein.

[0089] The interface portion **1846** is sized and shaped to couple to the flexible elongate member **108**, for example, via the sleeve element **540**. The alignment portion **1844** is sized and shaped to align to the sleeve element **540** or any suitable connecting member. In an embodiment, the alignment portion **1844** is molded to form alignment members **1830** and **1832** along an inner wall portion of the inner cavity **1800**. In an embodiment, the alignment members **1830** and **1832** are configured to have first keyed surfaces inter-engaging with

second keyed surfaces (e.g., flat outer surface portions **542** and **544**) of the sleeve element **540**. Accordingly, the distal portion of the flexible elongate member can include a keyed structure configured to mate with a proximal section of an inner lumen of the tip member in a predefined orientation.

[0090] The receiving portion **1842** is sized and shaped to receive the imaging core **562**. The geometry of the receiving portion **1842** is configured to facilitate the alignment and positioning of the imaging core **562**. The receiving portion **1842** includes a proximal curved top inner wall **1828** that smoothly transitions into a distal flat top inner wall **1826**. The proximal curved top inner wall **1828** is opposite the proximal curved top outer wall **1730** and the distal flat top inner wall **1826** is opposite the distal flat top outer wall **1722**. In an embodiment, the receiving portion **1842** is molded to form a guide member **1820** having a stepped ledge with a first step **1822** and a second step **1824** extending longitudinally along a sidewall portion of the receiving portion **1842**. The receiving portion **1842** can include another guide member **1850** (shown in FIG. **19**) similar to the guide member **1820** extending longitudinally along a radially opposite sidewall portion of the receiving portion **1842**. The distal flat top inner wall **1826** and the guide members **1820** and **1850** restrict the positioning of the imaging core **562** within the receiving portion **1842**. In an embodiment, the imaging core **562** includes an array of ultrasound transducer elements and is positioned such that ultrasonic waves propagates towards and through the distal flat top inner wall **1826** and the distal flat top outer wall **1722** as shown by the dashed arrows and described in greater details herein. The alignment members **1830** and **1832** are positioned in a pre-defined relation to an orientation of the imaging core **562**.

[0091] Dimensions of the tip member **1700** can vary in different embodiments. In some embodiments, the tip member **1700** includes a uniform thickness **1810** between the distal flat top inner wall **1826** and the distal flat top outer wall **1722** of less than 200 microns such that distortion such as reflection and attenuation of the ultrasonic waves may be minimized. The receiving portion **1842** can extend a length **1812** between about 10 mm to about 28 mm. The alignment portion **1844** can extend a length **1814** between about 1 mm to about 5 mm. The interface portion **1846** can extend a length **1816** between about 1 mm to about 5 mm.

[0092] FIG. **19** is a cross-sectional view of the tip member **1700** taken along the line **1801** of FIG. **18** according to embodiments of the present disclosure. FIG. **19** illustrates the opened proximal end **1732** with interface portion **1846** of the inner cavity **1800**. Dimensions of the opened proximal end **1732** can vary in different embodiments. In some embodiments, the proximal opened end **1732** has a substantially circular shape. The outer diameter **1711** and the inner diameter **1713** may be sized to match the body of a catheter shaft (e.g., the flexible elongate member **108**) such that the tip member **1700** can be coupled to the catheter shaft. For example, a catheter shaft body between about 8 FR and about 12 FR may have a wall thickness between about 100 microns and about 400 microns. To couple to such a catheter shaft, the outer diameter **1711** may be between about 8 FR and about 12 FR and a difference between outer diameter **1711** and the inner diameter **1713** may be between about 100 microns and about 400 microns.

[0093] FIG. **20** is a cross-sectional view of the tip member **1700** taken along the line **1802** of FIG. **18** according to embodiments of the present disclosure. FIG. **20** illustrates the alignment portion **1844** of the inner cavity **1800**. The tip member **1700** is molded to form the alignment members **1830** and **1832** along portions of the inner wall of the alignment portion **1844**. For example, the alignment members **1830** and **1832** are ledges extending transversely across the portions of the inner wall and positioned radially opposite of each other. Each ledge has a flat surface **2020** about perpendicular to the ultrasonic beam propagate direction of the imaging core **562**. Dimensions of the alignment members **1830** and **1832** can vary in different embodiments. For example, the alignment members **1830** and **1832** may be shaped and sized to adapt to the sleeve element **540** (e.g., the flat outer surface portions **542** and **544**) such that the sleeve element **540** and the tip member **1700** may be aligned by inter-engaging the alignment members **1830** and **1832** with the flat outer surface portions **542** and **544**.

[0094] FIG. **21** is a cross-sectional view of the tip member **1700** taken along the line **1803** according to embodiments of the present disclosure. FIG. **21** illustrates the receiving portion **1842** of the inner cavity **1800**, where the tip member **1700** has the proximal curved top outer wall **1730** and the proximal curved top inner wall **1828**. The tip member **1700** is molded to form the guide members **1820** and **1850** along portions of the inner wall of the receiving portion **1842**. The guide members **1820** and **1850** are positioned radially opposite of each other within the receiving portion **1842**. The guide member **1820** includes the step ledge with the first step **1822** and the second step **1824**. Similarly, the guide member **1850** includes a step ledge with a first step **1852** and a second step **1854**. In addition, the tip member **1700** is molded to form a raised U-shaped bottom inner wall **1856** extending longitudinally along the receiving portion **1842** and coupled to the guide members **1820** and **1850**. As described in greater detail herein, the guide members **1820** and **1850** restrict the positioning of the imaging core **562** (not shown). Dimensions of the guide members **1820** and **1850** and the raised U-shaped bottom inner wall **1856** can vary in different embodiments. For example, the dimensions of the guide members **1820** and **1850** and the separation distance **2112** between the guide members **1820** and **1850** are shaped and sized to accommodate the imaging core **562**. The wall thickness of the raised U-shaped bottom inner wall **1856** is configured to minimize acoustic attenuation.

[0095] FIG. **22** is a cross-sectional view of the tip member **1700** taken along the line **1804** according to embodiments of the present disclosure. FIG. **22** illustrates the receiving portion **1842** of the inner cavity **1800**, where the tip member **1700** has the distal flat top outer wall **1722** and the distal flat top inner wall **1826**. The guide members **1820** and **1850** and the distal flat top inner wall **1826** restrict the positioning of the imaging core **562**. For example, the imaging core **562** can be positioned in the tip member **1700** guided by the guide members **1820** and **1850** and the distal flat top inner wall **1826** as shown by the dashed box. The guide members **1820** and **1850** restrict the positioning of the imaging core **562** along a first axis and in a first direction along a second axis about perpendicular to the first axis. In FIG. **22**, the first axis is shown as the x-axis and the second axis is shown as the y-axis. The distal flat top inner wall **1826** restricts the positioning of the imaging core **562** in an opposite direction along the second axis. As described above, the tip member **1700** is sized such that the thickness **1810** between the distal flat top outer wall **1722** and the distal flat top inner wall **1826** is less than **200** micron to minimize distortions such as

reflections and/or deflections of ultrasonic waves (dashed arrows) produced by the imaging core **562** during operation.

[0096] FIG. **23** is a back perspective view of the tip member **1700** according to embodiments of the present disclosure. FIG. **23** illustrates the structure of the inner cavity **1800** viewing from the opened proximal end **1732** as shown by the line **1801**. As shown, the inner cavity **1800** includes the alignment member **1830** and **1832**, the raised U-shaped bottom inner wall **1856**, the guide members **1820** and **1850**, and the distal flat top inner wall **1826**. The raised U-shaped bottom inner wall **1856** is adjacent and distal to the alignment member **1832** and coupled to the guide members **1820** and **1850**.

[0097] FIG. **24** is a back perspective view of the tip member **1700** with the imaging core **562** in position according to embodiments of the present disclosure. FIG. **24** illustrates the positioning of the imaging core **562** in the inner cavity **1800** viewing from the opened proximal end **1732** as shown by the line **1801**. The imaging core **562** is encased within the inner cavity **1800** guided by the guide members **1820** and **1850** and the distal flat top inner wall **1826**. The imaging core **562** can include a transducer circuit layer **2414** embedded between an acoustic stack **2412** and a backing material layer **2416**. The transducer circuit layer **2414** includes ultrasound transducer elements and associated circuitry. The acoustic stack **2412** is composed of materials acoustically matched to the ultrasound transducer elements, the transmission medium, and the target tissue for imaging. The backing material layer **2416** is composed of an acoustically absorptive material so that the backing material layer **2416** can absorb or deaden the ultrasonic waves coming from the back of the transducer circuit layer **2414**. For example, the acoustic stack **2412** can include materials such as PZT, single crystal, CMUT, PMUT, etc. and the backing material layer **2416** can include an epoxy material. The acoustic stack **2412** is positioned almost against the distal flat top inner wall **1826**, creating a thin bond line to further minimize acoustic distortion of the ultrasonic waves. The spaces of the inner cavity **1800** are filled with an encapsulating material to enclose the imaging core **562**. For example, the encapsulating material may include polydimethylsiloxane (PDMS), polyurethane, ultraviolet (UV) adhesives, or any suitable material that have desirable characteristics such as acoustic properties, bonding strength, and ease to work with during manufacturing. In some embodiments, the acoustic stack **2412** includes non-filled air kerfs, for example, along a perimeter of the acoustic stack **2412**. In such embodiments, the perimeter of the acoustic stack **2412** is sealed with a sealing material such as an UV adhesive to seal the non-filled air kerfs prior to filling the inner cavity **1800** with the encapsulating material. The chamber **1834** shown in FIG. **18** can be used to accommodate the sealing material.

[0098] FIG. **25** is a cross-sectional side view of the imaging core **562** taken along the line **2402** of FIG. **24** according to embodiments of the present disclosure. The transducer circuit layer **2414** includes an array of ultrasound transducer elements **2510** coupled to one or more multiplexer chips **2512**, for example, via conductive traces and/or associated circuitry. In some embodiments, the number of ultrasound transducer elements **2510** may be 8, 16, 32, 64, or any suitable number. The ultrasound transducer elements **2510** are composed of piezoelectric material. Exemplary transducers for ICE have a typical thickness of approximately 0.28 mm in the piezoelectric material to enable an 8 megahertz (MHz) ultrasound signal to be generated and transmitted at a typical velocity of 1500 meter per second (m/sec) through blood. The transducer thickness can be of various thicknesses ranging approximately from 0.56 mm to 0.19 mm to generate sufficient penetration depth in tissue imaging. In general, the thickness of the transducers can be adjusted for the frequency of sound in the transmission medium for the desired penetration depth in any tissue imaging. Image intensity can be adjusted by driving voltage on the transducers.

[0099] The multiplexer chips **2512** multiplex control signals, for example, generated by the processing system **130**, and transfer the control signals to corresponding ultrasound transducer elements **2510**. The controls signals can control the emission of ultrasound pulses and/or the reception of echo signals. In the reverse direction, the multiplexer chips **2512** multiplexes echo signals reflected by target tissue and received by the ultrasound transducer elements **2510** multiplexer chips **2512** and transfer the received echo signals, for example, to the processing system **130** for processing and/or display.

[0100] FIG. **26** is a perspective view of the tip assembly **102** and the sleeve element **540** positioned for coupling according to embodiments of the present disclosure. The tip assembly **102** is illustrated with the imaging core **562** in position within the tip member **1700**. The imaging core **562** is coupled to the electrical cable **566** via the electrical interconnection **564**. The electrical cable **566** extends through the alignment portion **1844** and the interface portion **1846** of the inner cavity **1800** and sleeve element **540**. The electrical cable **566** can further extend through the flexible elongate member **108** as shown in FIG. **5**. During manufacturing, the interface portion **1846** can extend over and cover a portion of the sleeve element **540**, the crown element **520**, and the flexible elongate member **108**, thus improving the bonding strength.

[0101] As shown, the tip member **1700** is oriented such that the alignment members **1830** and **1832** are aligned to the flat outer surface portions **542** and **544** of the sleeve element **540**. As described above, the sleeve element **540** includes the flat outer surface portions **542** and **544** and the slots **551** and **552**, which are configured to couple to the crown element **520** in a particular orientation associated with the positioning of the pullwires **700** and **740**. Thus, the sleeve element **540**, the alignment members **1830** and **1832**, and the crown element **520** can be conjunctively designed to allow coupling of the sleeve element **540**, the alignment members **1830** and **1832**, and the crown element **520** in a particular orientation. As such, the sleeve element **540**, the alignment members **1830** and **1832**, and the crown element **520** can be consistently aligned during manufacturing without additional alignment measurement or adjustment. Since the alignment members **1830** and **1832** are oriented in a predefined relation with the ultrasound beam propagation direction of the imaging core **562** and the pullwires **700** and **740** are configured to provide steering of the tip assembly **102**, the actuations of the pullwires **700** and **740** can provide consistent articulation view for imaging. It should be noted that the alignment keying of the sleeve element **540** and the alignment members **1830** and **1832** can be alternatively configured as determined by a person of ordinary skill in the art to achieve similar functionalities.

[0102] The configuration and structure of the tip member **1700** described above provide several benefits such as safe and easy delivery for catheterization, improved tensile strength for steering or navigation, consistent or automatic alignment, and improved image quality. For example, the outer geometry of the tip member **1700** is configured to provide smooth surfaces and smooth edges with small radii. The smooth edges reduce friction when the tip member **1700** traverses a vessel during insertion. The smooth surfaces prevent tears and/or damages to tissue structures during the insertion. The smooth, radius transition from the proximal curved top outer wall **1730** to the distal flat top outer wall **1722** ensure that there are no ledges that can catch on outer features during the insertion. In addition, the smooth edges and smooth surfaces can facilitate crossing of a septum or other anatomical feature during a catheterization procedure. The material type and the wall thickness (e.g., the uniform thickness **1810**) of the tip member **1700** are selected to minimize acoustic distortion, attenuation, and/or reflection. The internal geometry of the tip member **1700** is configured to facilitate alignment during manufacturing. As described, the alignment members **1830** and **1832** provide consistent and predictable alignment between the imaging core **562** and the pullwires **700** and **740**. The tip member **1700** can also include other features, for example, a guidewire lumen, holes, or other geometry to accommodate additional devices or features such as pressure sensors, drug delivery mechanisms, and/or any suitable interventional features.

[0103] FIGS. **27-30** illustrate alternative tip member configurations that can provide substantially similar benefits as the tip member **1700**. FIG. **27** is a side perspective view of a tip member **2700** according to embodiments of the present disclosure. The tip member **2700** can be employed by the tip assembly **102**. The tip member **2700** has a tubular body **2742** with a closed round distal end **2720** and an opened proximal end **2728**. The tip member **2700** includes a distal portion **2702** and a proximal portion **2704**. The tip member **2700** includes a curved outer wall **2724**. For example, the tip member **2700** has at least a substantially uniform external circular or cross-sectional profile. In such manner, the diameter or cross-section of the tip member may be at least substantially uniform between the closed distal end and the open proximal end. In some embodiments, the diameter of the tip member is the same between the closed distal end and open proximal end is the same. In other embodiments, there may be slight change in the diameter (e.g. 1-25% such that it is substantially uniform. For example, the diameter or cross-section may slightly decrease in size as the tip member extends to the distal closed end, providing a tapered shape. Ideally, there is only 1-10% variability in the tip member's diameter or cross-section. In particular embodiments, there is only 1%, 2%, 3%, 4%, or up to 5% variability in the substantially uniform diameter or cross-section. In some embodiments, the curved outer wall **2724** can be designed to provide a lens effect to focus ultrasonic waves. The tubular body **2742** can be constructed from similar materials as the tubular body **1728** of the tip member **1700** member.

[0104] The tip member **2700** includes an inner cavity **2730** extending from the closed proximal end **2728** towards the closed round distal end **2720**. The inner cavity **2730** is configured to receive the imaging core **562**. The inner cavity **2730** includes a proximal curved top inner wall **2726** at the proximal portion **2704** and a distal flat top inner wall **2722** at the distal portion **2702**. The inner cavity **2730** includes a curved bottom inner wall **2738** coupled to the proximal curved top inner wall **2726** and the distal flat top inner wall **2722**. The inner cavity **2730** is molded to form a pair of rails **2732** and **2734** extending along a sidewall portion of the inner cavity **2730** from the proximal opened end **2728** towards the closed round distal end **2720**. The rails **2732** and **2734** are circumferentially spaced apart from each other forming a space for positioning the imaging core **562**. The inner cavity **2730** further includes another pair of rails **2752** and **2754** (shown in FIG. **28**) similar to the rails **2732** and **2734** extending longitudinally along a radially opposite sidewall portion of the inner cavity **2730**. Thus, the rails **2732**, **2734**, **2752**, and **2754** operate as guide members to restrict the positioning of the imaging core **562**. For example, the imaging core **562** is positioned such that the ultrasound transducer elements **2510** emit ultrasonic waves towards and through the distal flat top inner wall **2722** and curved outer wall **2724** at the distal portion **2702** as shown by the dashed arrows. Dimensions of the tip member **2700** can be substantially similar to the tip member **1700**, but the wall thickness **2710** at the distal portion **2702** is greater than 200 microns. For example, the wall thickness **2710** can be between about 25% and about 50% of the outer diameter **2712** of the tip member **2700**.

[0105] FIG. **28** is a back perspective view of the tip member **2700** with the imaging core **562** in position according to embodiments of the present disclosure. FIG. **28** illustrates the positioning of the imaging core **562** in the inner cavity **2730** viewing from the opened proximal end **2728** as shown by the line **2701**. The imaging core **562** is encased within the inner cavity **2730** guided by the rails **2732**, **2734**, **2752**, and **2754** along a first axis and a second axis about perpendicular to the first axis. In FIG. **28**, the first axis is shown as the x-axis and the second axis is shown as the y-axis. The positioning of the imaging core **562** along the z-axis is restricted by the farthest distal end of the inner cavity **2730**. The spaces between the inner cavity **2730** and the imaging core **562** are filled with similar encapsulating material as used for the inner cavity **1800** of the tip member **1700**. The tip member **2700** can further include alignment members similar to the alignment members **1830** and **1832** to facilitate alignment with the sleeve element **540**, the crown element **520**, and the flexible elongate member **108**.

[0106] FIG. **29** is a side perspective view of a tip member **2900** according to embodiments of the present disclosure. The tip member **2900** can be employed by the tip assembly **102**. The tip member **2900** is similar to the tip member **2700**, but has a different internal geometry. The tip member **2900** has a tubular body **2942** with a closed round distal end **2920** and an opened proximal end **2928**. The tip member **2900** includes a distal portion **2902** and a proximal portion **2904**. The tip member **2900** includes a curved outer wall **2924**. The tubular body **2942** can be constructed from similar materials as the tubular body **1728** of the tip member **1700** member and the tubular body **2742** of the tip member **2700** member.

[0107] The tip member **2900** includes an inner cavity **2930** extending from the closed proximal end **2928** towards the closed round distal end **2920**. The inner cavity **2930** is configured to receive the imaging core **562**. The inner cavity **2930** includes a curved inner wall **2926**. The inner cavity **2930** is molded to form a pair of rails **2932** and **2934** extending along a sidewall portion of the inner cavity **2930** from the proximal opened end **2928** towards the closed round distal end **2920**. The rails **2932** and **2934** are circum-

ferentially spaced apart from each other forming a space for positioning the imaging core **562**. The inner cavity **2930** further includes another pair of rails **2952** and **2954** (shown in FIG. **30**) similar to the rails **2932** and **2934** extending longitudinally along a radially opposite sidewall portion of the inner cavity **2930**. Thus, the rails **2932**, **2934**, **2952**, and **2954** operate as guide members to restrict the positioning of the imaging core **562**. For example, the imaging core **562** is positioned such that the ultrasound transducer elements **2510** emit ultrasonic waves towards and through a portion of the curved inner wall **2926** and a portion of curved outer wall **2924** at the distal portion **2902** as shown by the dashed arrows.

[0108] FIG. **30** is a back perspective view of the tip member **2900** with the imaging core **562** in position according to embodiments of the present disclosure. FIG. **30** illustrates the positioning of the imaging core **562** in the inner cavity **2930** viewing from the opened proximal end **2928** as shown by the line **2901**. The imaging core **562** is encased within the inner cavity **2930** guided by the rails **2932**, **2934**, **2952**, and **2954** along a first axis and a second axis about perpendicular to the first axis. In FIG. **28**, the first axis is shown as the x-axis and the second axis is shown as the y-axis. The positioning of the imaging core **562** along the z-axis is restricted by the farthest distal end of the inner cavity **2930**. The spaces between the inner cavity **2930** and the imaging core **562** are filled with similar encapsulating material as used for the inner cavity **1800** of the tip member **1700** and the inner cavity **2730** of the tip member **2700**. The tip member **2900** can further include alignment members similar to the alignment members **1830** and **1832** to provide consistent alignment with the sleeve element **540**, the crown element **520**, and the flexible elongate member **108**.

[0109] FIGS. **31** and **32** illustrate a lined variable braided differential durometer multi-lumen catheter shaft **3100**. The catheter shaft **3100** can be employed by the ICE device **110** in place of the flexible elongate member **108**. FIG. **31** is a cross-sectional view of the lined variable braided differential durometer multi-lumen catheter shaft **3100** taken along a transverse axis of the catheter shaft **3100** according to embodiments of the present disclosure. FIG. **32** is a cross-sectional longitudinal view of the lined variable braided differential durometer multi-lumen catheter shaft **3100** taken along the line **3101** of FIG. **31** according to embodiments of the present disclosure. The catheter shaft **3100** has a distal end **3202** and a proximal end **3204**. The catheter shaft **3100** is tubular in shape with a tubular wall **3102** and a primary lumen **3108**. The primary lumen **3108** extends between the distal end **3202** and the proximal end **3204**, for example, along a central longitudinal axis of the catheter shaft **3100**.

[0110] The tubular wall **3102** is composed of a high durometer polymeric material at a distal segment **3206** and a low durometer polymeric material at a proximal segment **3208**. For example, the high durometer polymeric material may have a durometer between 63 D-80 D and include materials such as a polyether block amide (e.g., Pebax® 72 D) or a suitable nylon. The low durometer polymeric material may have a durometer between 30 D to 55 D and include materials such as a polyether block amide (e.g., Pebax® 35 D or Pebax® 45 D) or a suitable nylon. The highly differing durometer of the tubular wall **3102** between the distal segment **3206** and the proximal segment **3208** creates a sharp transition or a high stiff-to-flex ratio in the catheter shaft **3100**. Thus, the catheter shaft **3100** can be relatively rigid at the proximal segment **3208**, but substantially pliable or flexible at the distal segment **3206**. The steerability of the catheter shaft **3100**, the amount of force to bend the catheter shaft **3100**, and the locality of the bend force and/or actuations may depend on the durometer of the catheter shaft **3100**. The sharp transition may improve the steerability, the amount of force, and/or the locality of the force when the catheter shaft **3100** is in use.

[0111] The catheter shaft **3100** further includes a plurality of secondary lumens **3106** extending longitudinally through a length of the tubular wall **3102**. The primary lumen has a rounded cross-shaped cross-sectional profile. The secondary lumens **3106** are shaped and sized to accommodate pullwires such as the pullwires **507**, **700**, and **740**. Thus, the secondary lumens **3106** are also referred to as pullwire lumens. The secondary lumens **3106** are positioned within the tubular wall **3102** radially spaced apart by an angle **3180** of about 90 degrees. The primary lumen has a cross-shaped cross-sectional profile. The arms **3110** of the cross-shaped cross section form recesses that can anchor the angular positions of the secondary lumens **3106**. For example, the secondary lumens **3106** are positioned between adjacent arms **3110** during manufacturing as described in greater detail herein. The primary lumen **3108** and the secondary lumens **3106** can be lined with a lubricious lining material (not shown) such as a polytetrafluoroethylene (PTFE) material. The lining material creates frictionless surfaces for threading, delivery, and actuations of pullwires or any other suitable diagnostic sensor assembly. In addition, the lining material can function as a support structure to prevent the primary lumen **3108** and the secondary lumens **3106** from collapsing. Further, the lining material can function as a barrier to protect abrasion caused by the frequent shifting or actuations of the pullwires and/or threading of the other diagnostic sensor assembly.

[0112] The catheter shaft **3100** further includes a braided layer **3104** embedded within the tubular wall **3102**. The braided layer **3104** includes a distal portion **3212**, a proximal portion **3216**, and a transition portion **3214** between the distal portion **3212** and the proximal portion **3216**. The braided layer **3104** can be composed of any suitable material and geometry. For example, the braided layer **3104** may include stainless steel flat wires, which may provide optimal usage of radial space and additional strength. The braided layer **3104** has braids with pitches that vary along a length of the tubular wall **3102**. The braids can include any suitable braid pattern. The braid pattern may be selected to improve torque transmission (e.g., a 1:1 ratio from the proximal end **3204** to the distal end **3202**), pushability, and/or kink resistance.

[0113] The braids at the distal portion **3212** are configured to have a higher per inch count (PIC) than the braids at the proximal portion **3216**, for example, by about two times. The higher PIC at the distal portion **3212** provides a great flexibility to the distal segment **3206**. The lower PIC at the proximal portion **3216** creates a stiffer support for the proximal segment **3208**. For example, the distal portion **3212** has a first PIC, the proximal portion **3216** has a second PIC, and the transition portion **3214** has a varying PIC that varies smoothly from the first PIC to the second PIC. As shown, the distal portion **3212** of the braided layer **3104** is aligned to the distal segment **3206** of the catheter shaft **3100**, the proximal portion **3216** of the braided layer **3104** is aligned to the proximal segment **3208** of the catheter shaft

3100, and the transition portion 3214 extends across a coupling point at which the low durometer distal segment 3206 meets the high durometer proximal segment 3208 as shown by the line 3201. The transition portion 3214 can extend a length 3280, for example, between about 5 mm to about 20 mm. The smooth varying braid pitches in the short transition portion 3214 can alleviate the weak kink point resulting from the abrupt transition between the low durometer distal segment 3206 and the high durometer proximal segment 3208.

[0114] Dimensions of the catheter shaft 3100 can vary in different embodiments. In some embodiments, the catheter shaft 3100 may be a 9 Fr catheter. Thus, the catheter shaft 3100 can have an outer diameter 3182 of about 3 mm. The distal segment 3206 can have a length 3282 between about 70 mm to about 81 mm. The length 3282 may vary based on a required bend radius for the catheter shaft 3100. The proximal segment 3208 can have a length 3282 between about 872 mm to 877 mm. The dimensions of the cross-shaped primary lumen 1308 can be sized to allow components (e.g., a printed circuit board (PCB) and/or a coaxial cable) to be thread through the lumen 1308 during assembly instead of using the coaxial cable as an anchor as in some configurations, and thus may improve handling responsiveness during operation. The low durometer material used in in the distal segment 3206 and the braided layer 3104 allows the catheter shaft 3100 to deflect up to a bend radius (e.g., the bend radius 305) of between about 13 mm to about 14 mm instead of about 27 mm to about 28 mm.

[0115] A method of manufacturing the catheter shaft 3100 is described with reference made to FIGS. 33-35. FIG. 33 is a perspective view of a multi-lumen inner extrusion 3300 in a stage of manufacturing according to embodiments of the present disclosure. The inner extrusion 3300 includes a high durometer proximal portion 3320 of a first material (e.g., Pebax® 72 D) and a low durometer distal portion 3310 of a second material (e.g., Pebax® 35 D or Pebax® 45 D). The inner extrusion 3300 includes a primary lumen 3331 (e.g., primary lumen 3108) and a plurality of secondary lumens 3332 (e.g., secondary lumens 3106) extending between the high durometer proximal portion 3320 and the low durometer distal portion 3310.

[0116] FIG. 34 is a perspective view of a braid reinforced inner extrusion 3400 in a stage of manufacturing according to embodiments of the present disclosure. As shown, a braided layer 3410 (e.g., the braided layer 3104) is formed over an outer surface of the inner extrusion 3300. The braided layer 3410 has a first braid portion 3416 (e.g., the proximal portion 3216) with a first braid pitch (e.g., with a first PIC) over the high durometer proximal portion 3320. The braided layer 3410 has a second braid portion 3412 (e.g., the distal portion 3212) with a second braid pitch (e.g., with a second PIC) over the low durometer distal portion 3310. The braided layer 3410 has a third braid portion 3414 (e.g., the transition portion 3214) with variable braid pitches (e.g., varying between the first PIC and the second PIC) across a transition between the high durometer proximal portion 3320 and the low durometer distal portion 3310.

[0117] FIG. 35 is a perspective view of a single-lumen outer extrusion 3500 inserted over the braided inner extrusion 3400 in a stage of manufacturing according to embodiments of the present disclosure. The outer extrusion 3500 includes a high durometer proximal portion 3520 of a first material (e.g., Pebax® 72 D) and a low durometer distal portion 3510 of a second material (e.g., Pebax® 35 D or Pebax® 45 D). The inner extrusion 3300 and the outer extrusion 3500 form the tubular wall 3102 of the catheter shaft 3100. The braided layer 3410 corresponds to the braided layer 3104 embedded within the tubular wall 3102.

[0118] After forming the catheter shaft 3100, pullwires such as the pullwires 700 and 740 may be thread through the secondary lumens 3106 according to predetermined orientations for providing the left, right, anterior, and posterior views. The distal end 3202 of the catheter shaft 3100 may be coupled to a tip assembly such as the tip assembly 102. For example, the coupling may include terminating or enclosing the braided element 3104 in a braid containment such as the braid containment 502. In addition, the coupling can include forming an interconnection as shown in FIG. 5. An electrical cable such as the electrical cable 566 connecting to the tip assembly may be threaded through the primary lumen 3108. The proximal end 3204 of the catheter shaft 3100 may be coupled to a steering control handle such as the handle 120.

[0119] The configuration of the lined variable braided differential durometer multi-lumen catheter shaft 3100 provides several benefits such as kink resistance, flexibility, high torquability, durability, and consistent alignment and articulations. The sharp transition between the low durometer distal segment 3206 and the high durometer proximal segment 3208 and the short transition portion 3214 of the braided element 3104 with varying PIC braids provide the kink resistance. The low durometer distal segment 3206, the high durometer proximal segment 3208, the high PIC braids at the distal portion 3212, and the low PIC braids at the proximal portion 3216 provide flexibility at the distal segment 3206 and rigid support at the proximal segment 3208. The cross-shaped cross-sectional profile of the primary lumen 3108 functions as an alignment agent to align the pullwire lumens or the secondary lumens 3106 such that pullwires such as the pullwires 507, 700, and 740 threaded through the secondary lumens 3106 can provide consistent articulation views under actuations. The primary lumen 3108 and the secondary lumens 3106 are lined with a lining material to provide frictionless surfaces, which may improve durability over multiple usages. Materials of the tubular wall 3102 and the braided element 3104 are selected to improve mechanical characteristics (e.g., the steerability of the catheter shaft 3100).

[0120] Persons skilled in the art will recognize that the apparatus, systems, and methods described above can be modified in various ways. Accordingly, persons of ordinary skill in the art will appreciate that the embodiments encompassed by the present disclosure are not limited to the particular exemplary embodiments described above. In that regard, although illustrative embodiments have been shown and described, a wide range of modification, change, and substitution is contemplated in the foregoing disclosure. It is understood that such variations may be made to the foregoing without departing from the scope of the present disclosure. Accordingly, it is appropriate that the appended claims be construed broadly and in a manner consistent with the present disclosure.

1. An imaging catheter assembly, comprising:

a tip member comprising a tubular body that includes a closed distal end, an opened proximal end, and a proximal curved top outer wall extending from the proximal opened end and tapering into a distal flat top outer wall towards the closed distal end;

a flexible elongate member comprising a distal portion coupled to the open proximal end of the tip member; and

an imaging component mounted within the tip member.

2. The imaging catheter assembly of claim **1**, wherein the closed distal end comprises a rounded profile.

3. The imaging catheter assembly of claim **1**, wherein the tip member is constructed from a material including a polyether block amide.

4. The imaging catheter assembly of claim **1**, wherein the tubular body includes an inner cavity extending from the proximal opened end towards the distal closed end, and wherein the inner cavity includes a proximal curved top inner wall opposite the proximal curved top outer wall and a distal flat top inner wall opposite the distal flat top outer wall.

5. The imaging catheter assembly of claim **4**, wherein the imaging component comprises a planar element that includes an ultrasound transducer array.

6. The imaging catheter assembly of claim **5**, wherein the distal flat top outer wall at least partially forms an imaging window for the ultrasound transducer array.

7. The imaging catheter assembly of claim **5**, wherein the imaging component is positioned within the inner cavity such that the ultrasound transducer array emits ultrasound beams towards and through the distal flat top inner wall and the distal flat top outer wall.

8. The imaging catheter assembly of claim **5**, wherein the imaging component is positioned about parallel to the distal flat top inner wall, and wherein a wall thickness between the distal flat top inner wall and the distal flat top outer wall is less than 200 microns.

9. The imaging catheter assembly of claim **5**, wherein the imaging component is enclosed within the inner cavity by a material including at least one of a polydimethylsiloxane (PDMS), polyurethane, or ultraviolet (UV) adhesive.

10. The imaging catheter assembly of claim **5**, wherein the inner cavity further includes:

a first guiding member extending along a first inner sidewall of the inner cavity; and

a second guiding member extending along a second inner sidewall of the inner cavity,

wherein the first inner sidewall is radially opposite the second inner sidewall, and

wherein the imaging component is positioned within the tip member guided by the first guide member and the second guide member.

11. The imaging catheter assembly of claim **5**, wherein the inner cavity includes a first keyed inner wall surface, wherein the distal portion of the flexible elongate member further comprises a connecting member, and wherein the connecting member includes a second keyed surface inter-engaging with the first keyed inner wall surface.

12. The imaging catheter assembly of claim **11**, further comprising a plurality of steering lines coupled to the connecting member and extending along the flexible elongate member, wherein the plurality of steering lines are oriented relative to the second keyed surface such that translation of each of the plurality of steering lines deflects the tip member in an associated pre-defined direction relative to a longitudinal axis of the flexible elongate member.

13-22. (canceled)

23. The imaging catheter assembly of claim **1**, wherein the tubular body comprises a substantially uniform diameter between the closed distal end and the open proximal end, wherein the inner cavity includes a distal section comprising a first cross-section configured to receive the imaging component, and a proximal section comprising a second cross-section configured to receive the distal portion of the flexible elongate member.

24. The imaging catheter assembly of claim **1**, wherein the first guiding member comprises a first step ledge, and the second guiding member comprises a second step ledge.

25. The imaging catheter assembly of claim **1**, wherein the first guiding member comprises a first pair of rails, and the second guiding member comprises a second pair of rails.

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