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Description

FIELD OF THE DISCLOSURE

[0001] The present disclosure pertains to interventional medical systems, and, more particularly, to relatively compact implantable medical devices and delivery tools thereof.

BACKGROUND

[0002] The traditional implantable cardiac pacemaker includes a pulse generator device to which one or more flexible elongate lead wires are coupled. The device is typically implanted in a subcutaneous pocket, remote from the heart, and each of the one or more lead wires extends therefrom to a corresponding electrode, coupled thereto and positioned at a pacing site, either endocardial or epicardial. Mechanical complications and/or MRI compatibility issues, which are sometimes associated with elongate lead wires and well known to those skilled in the art, have motivated the development of implantable cardiac pacing devices that are wholly contained within a relatively compact package, the entirety of which is configured for implant in close proximity to a pacing site. Such a relatively compact intra-cardiac device configured for dual chamber pacing may be implanted as shown in the schematic diagram of Figure 1. Figure 1 illustrates a dual chamber intra-cardiac pacing device including a first portion 10 implanted in a right ventricle RV of a heart, in proximity to an apex thereof, and a second portion 20 implanted in a right atrium RA of the heart, within an appendage 102 thereof. Figure 1 further illustrates the device including a leadlet 12 that connects first portion 10 to second portion 20. There is a need for improved interventional medical systems facilitating the implant of relatively compact intra-cardiac dual chamber pacing devices like that illustrated in Figure 1. US 2004/147973 A1 describes inter cardiac pacemakers (ICPs) employing different fixation strategies depending on the intended implantation site.

BRIEF SUMMARY

[0003] According to embodiments disclosed herein, an implantable medical device includes a ventricular portion, which has an electrode and a fixation mechanism, both mounted in proximity to a distal end of a hermetically sealed housing of the ventricular portion, an atrial portion, which has a core extending from a first end thereof to a second end thereof, along a longitudinal axis of the atrial portion, and a flexible leadlet that extends from a proximal end of the ventricular portion housing to the first end of the atrial portion core, the leadlet being coupled to an atrial electrode mounted in proximity to the second end of the core; wherein the atrial portion includes an open channel formed along the core thereof, the open channel extending between the first and second ends of the core and being sized to receive the leadlet therein, when the leadlet is folded over on itself.

[0004] According to some embodiments, a plurality of elastically deformable tines form a fixation mechanism of the atrial portion and are fixedly mounted to the core, being spaced apart from one another around a perimeter of the core. Each tine preferably includes: a proximal, spring portion being fixedly attached to the atrial portion core and having a spring-biased pre-formed curvature, the pre-formed curvature, in proximity to the core, extending in a first direction, generally parallel to the axis of the atrial portion, and then sweeping laterally, outward from the axis; and a distal portion including a proximal section, a hook section, and tip section terminated by a rounded free distal end, the proximal section extending from the proximal, spring portion and being pre-formed to extend in a second direction and along a relatively straight line to the hook section, the proximal section being oriented, by the spring-biased pre-formed curvature of the proximal, spring portion, so that the second direction is generally opposite the first direction, and the relatively straight line intersects the axis at an acute angle of between about 30 degrees and about 50 degrees, the hook section having a deformable pre-formed curvature that extends from the proximal section back toward the axis of the atrial portion, the tip section being pre-formed to extend along a relatively straight line from the hook section to the rounded free distal end, and the tip section being oriented, by the pre-formed curvature of the hook section, when un-deformed, to extend toward the axis of the atrial portion, such that the tip section and the proximal section enclose an angle in a range from about 90 degrees to about 120 degrees; and wherein, when the atrial portion of the device is loaded within a tubular sidewall of a delivery tool, so that the rounded free distal end of each tine engages an inner surface of the sidewall, to hold the proximal, spring portion of each tine in a spring-loaded condition, each tip section of the distal portion extends away from the axis of the atrial portion at an acute angle in a range from about 45 degrees to about 75 degrees for deployment of the corresponding rounded free distal end out from the tool tubular sidewall; and upon deployment of the rounded free distal end of each tine, the tip section of each distal portion rotates away from the axis to approach an angle of 90 degrees, relative to the axis, in response to an initial release of the spring-loaded condition of the corresponding proximal, spring portion.

[0005] The device may be included in an interventional medical system along with a delivery tool that includes a tubular sidewall and a tether extending therein, the tubular sidewall defining a lumen and having a slot formed therein, wherein the slot extends proximally from an open end thereof, which is coincident with a distal opening of the lumen. The device is loaded in the delivery tool such that the second end of the atrial portion core faces the proximal end of the ventricular portion housing, such that the atrial portion thereof is contained within the lumen

with a segment of the leadlet extending alongside the atrial portion, and with another segment of the flexible leadlet being folded over on itself proximal to the atrial portion, and such that the tether is engaged with the other segment of the leadlet at a fold therein. The slot of the tool is configured to allow passage of the flexible leadlet therethrough when the atrial portion is positioned in proximity to the distal opening of the lumen for deployment from the tool.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] The following drawings are illustrative of particular embodiments of the present invention and therefore do not limit the scope of the invention. The drawings are not to scale (unless so stated) and are intended for use in conjunction with the explanations in the following detailed description. Embodiments will hereinafter be described in conjunction with the appended drawings wherein like numerals denote like elements, and:

Figure 1 is a schematic diagram showing an exemplary dual chamber intra-cardiac pacing device implanted in a right side of a heart;
Figure 2A is a plan view of a relatively compact dual chamber intra-cardiac pacing device, according to some embodiments;
Figure 2B is a schematic section showing an atrial portion of the device of Figure 2A implanted, according to some embodiments and methods;
Figure 3A is an elevation view of an exemplary fixation component which may be employed by the atrial portion of the device, according to some embodiments;
Figure 3B is a perspective view of the component of Figure 3A, according to some embodiments;
Figure 3C is a plan view of a portion of the component of Figures 3A-B, prior to forming, according to some embodiments;
Figure 3D is a plan view of a portion of the component of Figures 3A-B, prior to forming, according to some alternate embodiments;
Figure 4A is a plan view, with a partial cut-away section, of an interventional medical system, according to some embodiments;
Figure 4B is a cross-section view through section line B-B of Figure 4A, according to some embodiments;
Figure 5A is a schematic diagram of the system of Figure 4A advanced into a right ventricle for deployment of a ventricular portion of the device of Figure 2A;
Figure 5B is a schematic diagram of a delivery tool of the system positioned in a right atrium for deployment of the atrial portion of the device;
Figure 5C is a cross-section view through a distal end of a delivery tool of the system, according to some embodiments;
Figure 6A is a schematic showing a spring loaded condition of the fixation component of the atrial portion of the device, according to some embodiments;
Figure 6B is a schematic showing an initial release of the fixation component from the spring loading shown in Figure 6A;
Figure 6C is a schematic showing rotation for initial penetration of the fixation component after the initial release of Figure 6B;
Figure 6D is a schematic showing fixation component movement, subsequent to initial penetration;
Figure 6E is a schematic showing fixation component movement, subsequent to penetration;
Figure 6F is a schematic showing fixation component movement, subsequent to penetration;
Figure 7A is a plan view of a distal portion of an alternate embodiment of a portion of the system shown in Figure 4A
Figure 7B is an end view of the distal portion of Figure 7A;
Figure 8A is a plan view, with a partial cut-away section, of a portion of an interventional medical system, according to some alternate embodiments;
Figure 8B is an end view of an inner assembly of a delivery tool of the system of
Figure 8A, according to some embodiments;
Figure 8C is an exemplary cross-section view through the inner assembly, according to some embodiments;
Figure 8D is a plan view of the system of Figure 8A, according to some embodiments;
Figures 8E-F are longitudinal cross-section views through portions of the system, the general locations of which are indicated in Figure 8D, according to some embodiments;
Figure 9A is a schematic diagram of the system of Figures 8A-E advanced into a right ventricle for deployment of a ventricular portion of the device of Figure 2A, according to some methods;
Figure 9B is a schematic diagram of a delivery tool of the system positioned in a right atrium for deployment of the atrial portion of the device, according to some methods;
Figure 9C is a plan view, with a partial cut-away section, of a portion of the interventional medical system of Figures 8A-E, according to some embodiments;
Figure 10A is a schematic diagram related to some retrieval methods with a delivery tool described in conjunction with Figures 4A-B;
Figure 10B is a schematic diagram related to some retrieval methods with the delivery tool described in conjunction with Figures 8A-F; and
Figure 11 is a schematic diagram related to an alternate deployment method.

DETAILED DESCRIPTION

[0007] The following detailed description is exemplary

in nature and is not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the following description provides practical examples, and those skilled in the art will recognize that some of the examples may have suitable alternatives.

[0008] Figure 2A is a plan view of a relatively compact dual chamber intra-cardiac pacing device 1200, according to some embodiments. Figure 2A illustrates device 1200 including a ventricular portion 100, an atrial portion 200, and a flexible leadlet 120 that connects ventricular portion 100 to atrial portion 200 Ventricular portion 100 is shown including a hermetically sealed housing 105, preferably formed from a biocompatible and biostable metal such as titanium, which contains a pulse generator (e.g., a power source and an electronic controller - not shown), a plurality of fixation tines 103, and an electrode 106, for example, being coupled to the pulse generator by a conductor of an hermetic feedthrough assembly (not shown) that is constructed according to methods known to those skilled in the art of implantable medical devices. Housing 105 may be overlaid with an insulative layer, for example, medical grade polyurethane, parylene, or silicone, and another electrode 107 may be formed by removing a portion of the insulative layer to expose the metallic surface of housing 105. According to the illustrated embodiment, electrode 106 may function for bipolar pacing and sensing, in conjunction with electrode 107, when elastically deformable fixation tines 103 hold electrode 106 in intimate tissue contact at a target implant site, for example, within right ventricle RV as illustrated schematically in Figure 1. Exemplary embodiments of fixation tines 103 are described in commonly assigned United States Patent 9,155,882.

[0009] With further reference to Figure 2A, atrial portion 200 includes a core 250 that extends from a first end 201 thereof to a second end 202 thereof, along a longitudinal axis 2 of atrial portion 200, and to which another electrode 206 is mounted, in proximity to second end 202. Leadlet 120 is shown extending from a proximal end 101 of device ventricular portion 100 to first end 201 of core 250. According to the illustrated embodiment, a conductor 122 (Figure 4B) of leadlet 120, which extends through another hermetic feedthrough assembly (not shown) of ventricular portion 100, and within an insulative tubular member 121 of leadlet 120, electrically couples the aforementioned pulse generator (contained within housing 105) to electrode 206. Conductor 122 may be formed by one or more wires, for example, MP35N alloy known to those skilled in the art, in a coiled or cabled configuration; and insulative tubular member 121 may be any suitable medical grade polymer, for example, polyurethane, silicone rubber, or a blend thereof. Core 250 may be formed from any suitable medical grade polymer, such as, polyurethane, silicone, polyethylene, or polyether ether ketone (PEEK), for example, being insert molded around a shank (not shown) of electrode 206, to which conductor 122 is coupled. According to an exemplary embodiment, a length of flexible leadlet 120, from proximal end 101 of ventricular portion housing 105 to first end 201 of atrial portion core 250 is in a range from about 15 cm to about 20 cm. It should be noted that, according to some alternate embodiments, atrial portion 200 includes another electrode mounted to core 250 and spaced apart from electrode 206, toward first end 201, to provide bipolar pacing and sensing in right atrium RA. In this case, leadlet 120 includes a pair of conductors isolated from one another, to electrically couple each atrial electrode to the pulse generator.

[0010] Figure 2A further illustrates atrial portion 200 including a plurality of elastically deformable fixation tines 303 spaced apart around a perimeter of core 250 and being fixedly mounted thereto, for example, via a base 301 to which each tine 303 is joined, as described below in conjunction with Figures 3A-B. According to the illustrated embodiment, elastically deformable fixation tines 303 hold electrode 206 of atrial portion 200 in intimate tissue contact at a target implant site within right atrium RA, for example, as illustrated schematically in Figure 2B. In Figure 2A, one of tines 303 is shown divided into first, second, and third segments S1, S2, S3, each of which is pre-formed into, and elastically deformable from, the illustrated shape thereof. According to the illustrated embodiment, each first segment S1 is fixedly attached to core 250, and extends around a pre-formed curvature to the corresponding second segment S2, which extends proximally along a relatively straight line to the corresponding third segment S3. Figure 2A illustrates third segment S3 extending around a pre-formed curvature to a free distal end 352 of tine 303.

[0011] Figure 2B is a schematic section showing atrial portion 200 of device 1200 implanted in right atrium RA, according to some embodiments and methods. With reference to Figure 2B, a portion the right atrial wall, for example, in appendage 102 (Figure 1), is shown having a laminate structure that includes an inner layer of pectinate muscle PM and an outer layer of visceral pericardium VP, which forms the epicardial surface. Figure 2B illustrates atrial portion 200 secured at the implant site by fixation tines 303 penetrating through the layer of pectinate muscle PM without perforating through visceral pericardium VP, which could result in pericardial effusion. Tines 303, according to embodiments disclosed herein, are configured for spring-loaded release when atrial portion 200 of device 1200 is deployed out through a distal opening of a delivery tool, for example, a distal opening 403 of a lumen 435 of a delivery tool 400 in an interventional medical system 1240 (Figures 4A-B), or a distal opening 802 of a lumen 825 of a delivery tool 800 of a system 8280 (Figures 8A-E). In either case, upon release of the spring loading, tine free distal end 352 penetrates pectinate muscle PM without perforating visceral pericardium VP. It should be noted that alternate suitable implant sites for embodiments of fixation member tines described herein can be along any endocardial surface defined by pectinate muscle PM. The spring-loaded release and exemplary methods for deploying device 1200 are de-

scribed below in conjunction with Figures 4A-B, 5A-B, 6A-F, 7A-B, 8A-E, and 9A-C. However, implantable medical devices having alternative tine configurations, for example, those more suitable for fixation to endocardial surfaces where pectinate muscle PM is not present, can be employed by the systems and methods described below, and such systems and methods are not outside the scope of the present invention.

[0012] Figures 3A-B are elevation and perspective views of a fixation component 300 that forms the fixation mechanism for atrial portion 200 of device 1200, according to some embodiments. Figures 3A-B illustrate the aforementioned base 301 from which a plurality of tines 303 extend, being spaced apart from one another around a perimeter of base 301. Tines 303 are shown in a relaxed, or pre-formed spring-biased condition. In Figure 3A, a longitudinal axis 3 of component 300 is shown being defined by base 301 such that, when base 301 is mounted around atrial portion core 250, and a perimeter of component 300 extends around electrode 206, axis 3 is generally aligned along longitudinal axis 2 of atrial portion 200 (Figure 2A). With reference to Figure 3B, base 301 is shown including an inward bending segment 310 directed toward axis 3 between each adjacent pair of tines 303. With reference back to Figure 2A, when component 300 is mounted on core 250 of device atrial portion 200, each of inward bending segments 310 may provide clearance for a groove, or open channel 253 of atrial portion 200, which can be a molded feature of core 250. Core 250 may be inserted molded around component 300, or component 300 may be snap fit, staked or bonded to a separately-molded core 250, according to methods known in the art. (However, in some alternate embodiments, tines 303 may be individually mounted to core 250 without being integrated together by any base.) Figure 2A illustrates channel 253 extending between first and second ends 201, 202 of core 250. According to the illustrated embodiment, channel 253 is sized to receive leadlet 120 therein, for example, to provide clearance for leadlet 120 to extend alongside core 250 within delivery tool 400, as will be described below in conjunction with Figures 4A-B. Although only one channel 253 is shown in Figure 2A, some embodiments of core 250 include a plurality of channels 253, for example, one between each adjacent pairs of tines 303, as shown in Figure 4B.

[0013] Tines 303 are preferably formed from a super-elastic material, for example, a Nickel-Titanium alloy (Nitinol). Fixation component 300 may be cut from a medical grade Nitinol tubing that conforms to the chemical, physical, mechanical, and metallurgical requirements of the ASTM F2063 standard, and has a wall thickness of about 0.005 inch (1 inch = 2,54 cm). In this case, tines 303 are integrally formed with base 301 and each tine 303 may have a constant thickness t of 0.005 inch $\pm$ 0.001 inch. After cutting the tubing, tines 303 and base 301 are formed into the configuration shown in Figures 3A-B by holding each in the illustrated shape, while heat treating according to methods known to those skilled in the art.

[0014] Figure 3A illustrates each tine 303 including a proximal, spring portion 33, which corresponds to first segment S1 of Figure 2A, and a distal portion 35, which corresponds to second and third segments S2, S3 of Figure 2A, and which is terminated by free distal end 352. Free distal end 352 is preferably rounded, as shown in Figure 3A. Figure 3A further illustrates distal portion 35 including a proximal section 35-P, a hook section 35-H, and a tip section 35-T. The shaped configuration and width of each tine 303, along with the super-elastic stiffness properties of Nitinol, provide a sufficient spring force and structural stiffness for tines 303 to engage tissue for the fixation of device atrial portion 200 at an implant site when deployed by delivery tool 400 or delivery tool 800, as described in greater detail below. With reference to Figure 3A, each tine 303 has a width w which is preferably no less than about 0.02 inch, for example, being in a range from about 0.025 inch to about 0.032 inch (1 inch = 2,54 cm). Such a width provides the aforementioned structural stiffness, as well as a radiopaque density that facilitates fluoroscopic visualization during and after the implant procedure.

[0015] With further reference to Figure 3A, according to the illustrated embodiment, each proximal, spring portion 33 is fixedly attached to base 301 and has a spring-biased pre-formed curvature, which, in proximity to the base, extends in a first direction d1, generally parallel to axis 3, and then sweeps laterally, outward from axis 3 to distal portion proximal section 35-P. Distal portion proximal section 35-P, according to the illustrated embodiment, is pre-formed to extend in a second direction d2 and along a relatively straight line (dashed line), being oriented, by the spring-biased pre-formed curvature of proximal, spring portion 33, so that second direction d2 is generally opposite first direction d1, and the relatively straight line intersects axis 3 at an acute angle θ According to some embodiments, angle θ is between about 30 degrees and about 50 degrees. In an exemplary embodiment of component 300, to be employed by an exemplary embodiment of device 1200 in which atrial portion core 250 has an outer diameter of about 0.26 inch (20 French), the spring-biased pre-formed curvature of each proximal, spring portion 33 is defined by a single radius of 0.067 inch $\pm$ .010 inch; a distance A between base 301 and each intersection of proximal, spring portion 33 and distal portion proximal segment 35-P is 0.092 inch $\pm$ 0.005 inch; a length of each distal portion proximal segment 35-P is 0.100 inch $\pm$ 0.005 inch; and angle θ is about 45 degrees.

[0016] With further reference to Figure 3A, each distal portion hook section 35-H has a deformable pre-formed curvature that extends from proximal, spring portion 33 back toward axis 3. Figure 3A further illustrates tip section 35-T of distal portion 35 extending from hook section 35-H along a relatively straight line to rounded free distal end 352. Tip section 35-T is shown oriented by the pre-formed curvature of hook section 35-H, when un-de-

formed, to extend toward axis 3, such that tip section 35-T and proximal section 35-P are shown enclosing an angle φ, which, according to the illustrated embodiment, is no less than about 90 degrees, but can be up to about 120 degrees. In the aforementioned exemplary embodiment of component 300, the deformable pre-formed curvature of each hook section 35-H, when un-deformed, is defined by a single radius of about 0.05 inch; and a length of each tip section 35-T is 0.064 inch ± 0.005 inch (1 inch = 2,54 cm).

[0017] Figures 3C-D are plan views of alternate tine embodiments prior to being formed into the configuration of Figure 3A, wherein tine 303-105° of Figure 3C is suitable for an exemplary component 300 in which angle φ is about 105 degrees, and wherein tine 303-90° of Figure 3D is suitable for an exemplary component 300 in which angle φ is about 90 degrees. With further reference to Figures 3C-D, an exemplary width w of each tine 303 is 0.028 inch ± 0.001 inch, and, in the tine embodiment of Figure 3C, rounded free distal end 352 of tine 303-105° has an enlarged width defined by a diameter of 0.030 inch ± 0.001 inch.

[0018] Figure 4A is a plan view, with a partial cut-away section, of interventional medical system 1240, according to some embodiments, which includes device 1200 (Figure 2A) and delivery tool, wherein device 1200 is shown loaded in delivery tool 400 for deployment; and Figure 4B is a cross-section view through section line B-B of Figure 4A, according to some embodiments. Figure 4A illustrates tool 400 including a handle 410, an elongate outer member 430, and an elongate inner member 420, which extends within lumen 435 of outer member 430, and around which outer member 430 is slideably engaged, for example, via a control member 412 of handle 410, as described below. Figure 4A further illustrates inner member 420 including a distal end 422, which is configured to engage device atrial portion 200 by abutting first end 201 of core 250. An entirety of device 1200 is shown loaded within a tubular sidewall 432 of outer member 430 that defines a distal portion of outer member lumen 435. With reference back to Figure 2A, prior to loading device 1200 into delivery tool 400, atrial portion 200 is reoriented relative to ventricular portion 100 by bending leadlet 120, per arrow B, so that a first segment 12-1 of leadlet 120 extends within open channel 253 of core 250, so that a second segment 12-2, folded over on itself, extends within distal end 422 of inner member 420, and so that tines 303 are adjacent ventricular portion proximal end 101. To load device 1200 into tool 400, the operator may employ a tether 480 of tool 400 (seen in Figure 4A) by engaging tether 480 around leadlet 120 at a zone 124 (Figure 2A) that coincides with the aforementioned fold per arrow B. According to the illustrated embodiment, opposing lengths of tether 480 extend within lumens 425 of inner member 420 so that tether 480 loops around leadlet 120 for engagement therewith, and proximal ends 481 of the tether lengths protrude from a proximal port opening 415 of delivery tool 400, where an operator may grasp them. The operator may pull ends 481 of tether 480, to draw folded segment 12-2 of leadlet 120 in through a distal opening 403 of lumen 435, followed by atrial portion 200, with core first end 201 leading, and then followed by ventricular portion 100. Figure 4A illustrates tether 480 looped around zone 124 such that folded second segment 12-2 of leadlet 120 extends within distal end 422 of inner member 420, when device 1200 is loaded in delivery tool 400, and, with reference to Figure 4B, first segment 12-1 of leadlet 120 can be seen extending in one of a plurality of channels 253 of core 250, according to some embodiments. It should be noted that a snare-type tool, such as is known to those skilled in the art, may be employed in lieu of tether 480, such that the term "tether" may broadly refer to such a snare. According to the illustrated embodiment, an inner surface 42 of tubular sidewall 432 first engages fixation tines 303 of atrial portion 200, and then ventricular portion tines 103, as device 1200 is pulled into lumen 435, to deform each set of tines 103, 303, per arrows D1 and D2 (Figure 2A), respectively, and to hold tines 103, 303 of the loaded device 1200 in a spring-loaded condition, for example, as shown in Figure 4A. According to the above-described exemplary embodiments of fixation tines 303, when atrial portion core 250 and ventricular portion housing 105 are each sized to an outer diameter of about 0.26 inch (20 French), a diameter of lumen 435, defined by inner surface 42, is about 0.28 inch (21 French). In alternate embodiments, described below, starting with Figure 8A, an implantable device includes an atrial portion that is downsized relative to the ventricular portion.

[0019] With further reference to Figure 4A, a proximal end of outer member 430 is coupled to control member 412 of handle 410 such that an entirety of outer member 430 is movable with respect to inner member 420, via control member 412; thus, an operator may retract outer member 430, per arrow W, relative to device 1200 and inner member 420, to deploy device 1200 out through distal opening 403. According to the illustrated embodiment, and with reference back to Figure 1, the operator first deploys ventricular portion 100 of device 1200 at an implant site in right ventricle RV of the patient, and then deploys atrial portion 200 at an implant site in right atrium RA of the patient.

[0020] Figure 5A is a schematic diagram of system 1240 within right ventricle RV, after the operator has deployed ventricular portion 100. According to some methods, the operator deploys ventricular portion 100 by advancing system 1240 through a venous system of the patient, for example, from a femoral venous access site and up through an inferior vena cava IVC of the patient into right atrium RV and across the tricuspid valve into right ventricle RV, until a distal end 43 of delivery tool 400 abuts the target implant site. With distal end 43 abutting the implant site, the operator applies a push force through tool 400 while retracting outer member 430, as described above, to release fixation tines 103 of ventricular portion 100 out through distal opening 403 for engage-

ment with tissue at the implant site. With reference back to Figure 4A, the abutment of inner member 420 against first end 201 of core 250 of device atrial portion 200, and the abutment of tine tip sections 35-T of atrial portion 200 against proximal end 101 of device ventricular portion 100 together apply pressure to stabilize ventricular portion 100 as the operator withdraws outer member 430. With reference to Figure 5A, once fixation tines 103 of ventricular portion 100 are completely released from the spring-loaded condition, for full engagement with tissue at the implant site, the operator withdraws, per arrow E, delivery catheter 400, with atrial portion 200 still contained therein, back into right atrium RA, while first segment 12-1 and second segment 12-2 of leadlet 120 slide through channel 253 of atrial portion core 250 and out through distal opening 403 of outer member 430.

[0021] Figure 5B is a schematic diagram of delivery tool 400 positioned in right atrium RA for deployment of device atrial portion 200. Figure 5B illustrates distal opening 403 of outer member 430 directed into atrial appendage 102 where the operator will abut distal end 43 against pectinate muscle PM (Figure 2B) and apply a push force through delivery tool 400 prior to retracting outer member 430, relative to inner member 420 and atrial portion 200, to release the spring loading of fixation tines 303 for engagement with pectinate muscle PM at the implant site, as shown in Figure 2B. Figure 5C is a cross-section view through distal end 43 of delivery tool 400 showing atrial portion 200 positioned for deployment. With reference to Figure 5C, it may be appreciated that tether 480 was free to move distally, as the operator retracted delivery tool 400 from right ventricle RV into right atrium RA, and leadlet first and second segments 12-1, 12-2 slid out through distal opening 403. Figure 5C illustrates a third segment 12-3 of leadlet extending within channel 253 of core 250, and distal portion tip section 35-T of spring-loaded tines 303 located in close proximity to distal opening 403. (Leadlet third segment 12-3 is also shown in Figure 2A, for reference.) The spring loaded condition of tines 303 is described in greater detail below, in conjunction with Figure 6A.

[0022] Delivery tool 400 may include articulating features to facilitate the above-described navigation. For example, inner member 420 of delivery tool 400 may include a pull wire assembly (not shown) integrated therein. With reference back to Figure 4A, the pull wire assembly may be coupled to another control member 411 of handle 410 that, when moved per arrow A, causes inner member 420 and outer member 430 to bend along distal portions thereof. A length of outer member 430, between handle 410 and distal opening 403, when outer member 430 is in the position shown in Figure 4A, may be about 110 cm, for example, to reach into the right ventricle RV from the femoral access site. Suitable construction detail for a delivery tool like tool 400 is described in co-pending and commonly assigned U.S. Patent Application 2015/0094668, Serial No. 14/039,937 (Atty. Docket No. C00005393.USU1; filed on September 27, 2013). However, it should be noted that, according to some alternative embodiments and methods, delivery tool 400 may be configured so that an operator can move inner member 420 relative to outer member 430 to deploy one or both of ventricular and atrial portions 100, 200 of device 1200 out through distal opening 403, and, in these embodiments, inner member 420 and/or outer member 430 may include a pull wire assembly to facilitate navigation.

[0023] Figures 6A-F are schematics outlining a sequence of events corresponding to the release of the spring loading for above-described embodiments of fixation tines 303 for device atrial portion 200. (Although the schematics show tines 303 integrally formed with base 301, as in above-described embodiments of component 300, it should be understood that the sequence of events in Figures 6A-F may also apply to alternate embodiments in which tines 303 are not integrally formed with base 301.) Figure 6A illustrates a maximum deformation of tines 303 when held in the spring-loaded condition by the engagement of rounded free distal end 352 with inner surface 42 of outer member tubular sidewall 432, wherein proximal, spring portion 33 becomes relatively straightened, and a location of the maximum principle strain along each tine 303 is in relatively close proximity to base 301 (designated by dashed-line circle). With reference back to Figure 3A, the aforementioned exemplary length of distal portion tip section 35-T and the aforementioned associated angle φ (no less than 90 degrees) help to keep the deformed tines 303 from touching one another within lumen 435 and to prevent free distal ends 352 from being pulled proximally, per arrow P, when outer member 430 is retracted to release the spring loading of tines 303. Figure 6A further illustrates tip section 35-T extending away from axis 3 at an acute angle δ, which is preferably in a range from about 45 degrees to about 75 degrees for an initial release of the spring loading of each tine 303, upon retraction of outer member 430, as depicted in Figure 6B. With reference to Figure 6C, once free distal end 352 is released from engagement with inner surface 42 for deployment into tissue at the implant site, the spring force of proximal, spring portion 33 and the pre-formed curvature of distal portion hook section 35-T cause distal portion tip section 35-T to immediately rotate away from axis 3 to an angle π, which approaches 90 degrees, so that tip section 35-T is oriented approximately normal to axis 3 for initial penetration of pectinate muscle PM. Thus each tine free distal end 352 is deployed in a direction toward pectinate muscle PM that ultimately prevents tines 303 from perforating the underlying visceral pericardium VP (reference Figure 2B). Figures 6D-F illustrates the subsequent movement of tines 303, being driven by the release of proximal, spring portion 33 from the spring loading. According to the illustrated embodiment, this release of proximal, spring portion 33 causes free distal end 352, after penetrating through pectinate muscle PM in a first direction, at a first location P1, to penetrate back through in an opposite direction, at a second location P2, so that

device 20 may be securely fixed at the implant site, as illustrated in Figure 2B.

[0024] The configuration of tine distal portion 35, for example, embodied by the aforementioned exemplary lengths of proximal section 35-P and tip section 35-T, and the pre-formed curvature of hook section 35-H, provide a structural stiffness and reach to each tine 303 that is sufficient for deformation and subsequent penetration of free distal end 352 through pectinate muscle PM, as shown in Figure 2B, but is not sufficient for penetration through visceral pericardium VP. Even if the operator ends up advancing the system into appendage 102 so that distal opening 403 of tool 400 abuts visceral pericardium VP, between folds of pectinate muscle PM, free distal end 352, according to this configuration of tines 303, is not backed-up by sufficient stiffness to penetrate through visceral pericardium VP, so tip section 35-T of tine distal portion 35 is redirected, laterally, toward pectinate muscle PM.

[0025] It should be noted that an operator may employ fixation component 300 to secure atrial portion 200 in atrial appendage 102 in an alternative fashion, wherein tines 303 are fully released from the spring-loaded condition without engaging any tissue (Figure 6F), and then atrial portion 200 is advanced to the implant site so that tines 303 wedge between opposing surfaces of pectinate muscle PM within atrial appendage 102.

[0026] With reference back to Figures 2A-B, according to some embodiments, for example, in order to assure intimate contact of electrode 206 with tissue, when fixation component 300 secures atrial portion 200 at a target implant site, electrode 206 is spaced distally apart from second end 202 of atrial portion core 250 by a distance along longitudinal axis 2. Electrode 206 may be approximately flush with an intersection between proximal, spring portion 33 and distal portion 35, or spaced distally apart from the intersection by a distance X that may be up to about 2 mm, as depicted in Figure 2A.

[0027] With reference back to Figure 5C, the position of leadlet 120, in proximity to distal opening 403 of delivery tool 400, may interfere with tines 303, when tip segments 35-T thereof are positioned for release out through distal opening 403. Figures 7A-B are a plan view and an end view of a distal portion of tool 400 including an alternate embodiment outer member 730 (in lieu of outer member 430), in which a slot 73-S is formed in a sidewall 732 of outer member 730. Sidewall 732, similar to sidewall 432 of outer member 430, defines a lumen 735 of outer member 730, in which inner member 420 is slideably engaged, and which has a distal portion sized to contain device 1200 in a similar fashion to that described above for lumen 435 of outer member 430 (Figure 4A). Figure 7A illustrates slot 73-S extending proximally from an open end thereof, which coincides with a distal opening 703 of lumen 735. Figures 7A-B illustrate leadlet 120 passing laterally out through slot 73-S, when tip segments 35-T of tines 303 are positioned in proximity to distal opening 703, for example, after ventricular portion 100 has been deployed. According to the illustrated embodiment, slot 73-S allows leadlet 120 to move laterally away from tines 303 of atrial portion 200 prior to the deployment of atrial portion 200 out through distal opening 703, for example, to prevent leadlet 120 from becoming trapped against tissue at the implant site when tines 303 are released from spring loading for engagement with the tissue.

[0028] Device 1200 may be loaded into outer member 730 in a similar fashion to that described above for loading device 1200 into outer member 430. But, with further reference to Figure 7B, it may be appreciated that care must be taken when drawing atrial portion 200 into lumen 735 through distal opening 703, to load device 1200 into outer member 730, so that none of tines 303 catch in slot 73-S, and so free distal end 352 of each tine tip segment 35-T rests against a location on an inner surface 72 of sidewall 732 that is circumferentially offset from slot 73-S.

[0029] According to some alternate embodiments, atrial portion 200 of device 1200 may be downsized relative to ventricular portion 100 of device 1200, and included with delivery tool 800 in a system 8280, portions of which are shown in Figures 8A-F. Figure 8A illustrates such a device 1200 prior to loading into delivery tool 800; and Figures 8D-F illustrate system 8280 with device 1200 loaded in delivery tool 800. Delivery tool 800 includes an elongate outer member 830 and an inner assembly 850. Inner assembly 850, which is slideably engaged within a lumen 835 of outer member 830 (Figures 8D-F), is shown protruding distally from a distal opening 803 of lumen 835 in Figure 8A. Figure 8A further illustrates inner assembly 850 including an elongate inner member 820, an elongate sheath 810, which is slideably engaged within lumen 825 of inner member 820, and a tether 880, which is engaged with leadlet 120 of device 1200, being looped thereabout. According to the illustrated embodiment, sheath 810 includes side-by-side longitudinally extending lumens 815 that have openings located at a distal-facing surface 81 of sheath 810, and opposing lengths of tether 880 extend within lumens 815 of sheath 810 to form the loop that engages leadlet 120 in proximity to distal-facing surface 81; and proximal ends 881 of these tether lengths, which may be seen in Figure 8D, protrude from a proximal port opening of delivery tool 800 where an operator may grasp them. With further reference to Figure 8A, in conjunction with Figure 2A, leadlet 120 is folded over on itself along third segment 12-3 for engagement with the loop of tether 880, for example, such that the bend thereof that is engaged by the tether loop is spaced about one inch apart from first end 201 of atrial portion core 250. According to the illustrated embodiment, tether 880 together with sheath 810 may be employed to pull atrial portion 200 of device 1200, per arrow Q, into lumen 825 of inner member 820 so that atrial portion 200 is contained in lumen 825 and tines 303 of atrial portion 200 are spring-loaded, as shown in Figure 8F, with free distal ends 352 of tip segments 35-T resting against an inner surface 823 of a sidewall 822 of inner

member 820 that defines lumen 825. Subsequently, after sheath 810 has been pulled proximally within lumen 825 of inner member 820, until leadlet 120 is contained therein and a distal end 82 of inner member 820 abuts proximal end 101 of ventricular portion housing 105, outer member 830 may be advanced relative to inner assembly 850 so that a distal end 83 of outer member 830 contains ventricular portion 100 of device 1200, as shown in Figure 8E. It should be noted that tether 880 and sheath 810 may be in the form of any suitable snare-type tool, known to those skilled in the art. Figure 8A further illustrates sidewall 822 of inner member 820 having a slot 82-S formed therein along distal end 82 thereof, wherein slot 82-S extends proximally from an open end thereof, which coincides with a distal opening 802 of lumen 825. Slot 82-S, similar to slot 73-S described above for outer member 730, allows leadlet 120 to move laterally away from tines 303 of atrial portion 200 prior to the deployment of atrial portion 200 out through distal opening 802, for example, to prevent leadlet 120 from becoming trapped against tissue at the implant site when tines 303 are released from spring loading for engagement with the tissue. The deployment of atrial portion 200, according to some methods, is described below in conjunction with Figure 9B.

[0030] It may be appreciated that care must be taken, when drawing atrial portion 200 into lumen 825 through distal opening 803, so that none of tines 303 catch in slot 73-S. Thus, with reference to Figure 8B, which is an end view of inner assembly 850, an orientation guide for atrial portion 200 may be included in inner assembly 850. Figure 8B illustrates the loop of tether 880 spanning lumens 815 and extending over a groove 811, which is formed in distal-facing surface 81 of sheath 810 as the orientation guide. According to the illustrated embodiment, groove 811 is sized to receive third segment 12-3 of leadlet 120, so that by positioning folded third segment 12-3 in groove 811, the operator can orient atrial portion 200 with tines 303 circumferentially offset from slot 82-S, when pulling atrial portion 200 into distal end 82 of inner member 820. (The resulting position of tines is shown with dashed lines in Figure 8B.) In some embodiments, an outer surface of sheath 810 may interlock with inner surface 823 of inner member 820, for example, via an optional interlocking spline configuration shown in the exemplary cross-section of Figure 8C, to keep sheath 810 and member 820 in a predetermined circumferential orientation with respect to one another, for example, the orientation shown in Figure 8B.

[0031] With further reference to Figure 8D, general relative locations of ventricular portion 100 and atrial portion 200 are indicated when device 1200 is loaded into delivery tool 800 for deployment, for example, being spaced about 15 cm to 20 cm apart from one another, which corresponds to the aforementioned exemplary length of flexible leadlet 120. Figures 9A-C outline some exemplary methods for deploying device 1200 from delivery tool 800. Like tool 400, described above, tool 800 may have a length of approximately 110 cm to reach into right ventricle RV. Furthermore, delivery tool 800 may include articulating features to facilitate the navigation thereof as described below. For example, outer member 830 may include a pull-wire assembly integrated therein, according to construction features known to those skilled in the art.

[0032] Figure 9A is a schematic diagram of delivery tool 800 positioned within right ventricle RV, after the operator has deployed ventricular portion 100. According to some methods, the operator deploys ventricular portion 100 by advancing tool 800 through a venous system of the patient, for example, from a femoral venous access site and up through an inferior vena cava IVC of the patient into right atrium RA and across the tricuspid valve into right ventricle RV, until distal opening 803 of delivery tool 800 abuts the target implant site. With distal opening 803 abutting the implant site, the operator applies a push force through tool 800 while retracting outer member 830 relative to inner assembly 850 and device 1200 (arrow W of Figure 8E), to release fixation tines 103 of ventricular portion 100 out through distal opening 803 for engagement with tissue at the implant site, as shown in Figure 9A. With reference back to Figure 8E, the abutment of inner member distal end 82 against ventricular portion proximal end 101 applies pressure to stabilize ventricular portion 100 as the operator retracts outer member 830. Once ventricular portion 100 is deployed, the operator may withdraw outer member 830 and inner member 820, relative to sheath 810 and tethered device 1200, back up into right atrium RA (arrow E of Figure 9A) in order to deploy atrial portion 200.

[0033] Figure 9B is a schematic diagram of delivery tool 800 positioned in right atrium RA for deployment of device atrial portion 200. Figure 9B illustrates distal end 82 of inner member 820 still protruding distally from distal opening 803 of outer member 830 and directed into atrial appendage 102, where the operator will abut distal end 82 against pectinate muscle PM (Figure 2B) for deployment of atrial portion 200 at a target implant site. Figure 9B further illustrates a length of leadlet 120 that has passed out from inner member 820 as the operator withdrew outer member 830 and inner member 820 into right atrium RA. With reference to the cross-section view in Figure 9C, atrial portion 200 and distal-facing surface 81 of sheath 810 also became located in closer proximity to distal opening 802 of inner member 820, as the operator withdrew outer member 830 and inner member 820 into right atrium RA. With distal opening 802 of inner member 820 abutting pectinate muscle PM, the operator may apply a push force to atrial portion 200, through sheath 810, per arrow F, to release the spring loading of fixation tines 303 for engagement with pectinate muscle PM at the implant site, as shown in Figure 2B. (Note that Figures 6A-F, and the corresponding description thereof, may also pertain to the release of tines 303 from inner member 820.) Figure 9C further illustrates leadlet 120 extending laterally away from atrial portion 200, as allowed by slot

82-S (Figure 8A), when atrial portion 200 is positioned for deployment; thus, leadlet 120 will not become trapped against tissue at the implant site, when tines 303 are released from spring loading for engagement with the tissue.

[0034] Once ventricular portion 100 and atrial portion 200 of device 1200 are both deployed at respective implant sites, by any of the above-described delivery tools 400, 800, tether 480, 880 may be released from leadlet 120 of device 1200, for example, by pulling one of tether ends 481, 881 proximally from the corresponding lumen 425, 815, to unloop tether 480, 880. However, before unlooping tether 480, 880, if the operator determines that device 120 needs to be retrieved, for example, for repositioning, tether 480, 880 may be employed to disengage, and reload into tool 400, 800, atrial portion 200 followed by ventricular portion 100 of device 1200. Figures 10A-B are schematic diagrams related to some retrieval methods. Figure 10A shows delivery tool 400 positioned relative to flexible leadlet 120 and the loop of tether 480 advanced distally out from inner member 420 to cinch around leadlet 120, preferably at the aforementioned zone 124 (Figure 2A) so that, in retrieving device, leadlet 120 can be folded at the same location at which it was initially folded for loading, as described above in conjunction with Figures 2A and 4A. According to some preferred embodiments, a radiopaque marker may be coupled to leadlet 120 at zone 124 so the operator can locate zone 124 under fluoroscopy. Figure 10B shows delivery tool 800 positioned relative to flexible leadlet 120, and the loop of tether 880 advanced out from sheath 810 to cinch around leadlet 120 along third segment 12-3, for example, at the preferred location described above for loading atrial portion 200 into delivery tool 800, about one inch away from atrial portion core 250.

[0035] Finally, in some alternative methods, an operator may choose to initially load device 1200 into a delivery tool, for example, tool 800 described above, so that the orientation of the loaded ventricular and atrial portions 100, 200 are as shown in Figure 2A, without flexible leadlet 120 being folded over on itself, and without tines 303 of atrial portion 200 being spring-loaded in the delivery tool. If so, after deploying ventricular portion 100 to the implant site in right ventricle RV, as shown in Figure 9A, the operator can retract an entirety of delivery tool 800, per arrow E, until atrial portion 200 exits distal opening 802 of inner member 820. Then, the operator may advance sheath 810 with respect to inner member 820 until tether 880 extends out from distal opening 802, as shown in Figure 11, and maneuver tether 880 to loop around leadlet 120 in proximity to atrial portion 200. Once tether 880 is secured around leadlet 120, the operator may pull, per arrow Q (Figure 8A), atrial portion 200 into lumen 825 of inner member 820 so that tines 303 are spring-loaded, as shown in Figure 9C, and then position tool 800 in right atrium RA to deploy atrial portion 200 at the target implant site, for example, in the same manner as was described above in conjunction with Figure 9B.

With further reference to Figure 11, an enlarged perspective view of inner member distal end 82 is shown, wherein, according to some embodiments, distal end 82 is terminated by a beveled edge 82-B, for example, to facilitate the passage of leadlet 120 into slot 82-S when the operator pulls atrial portion 200 into lumen 825.

[0036] In the foregoing detailed description, specific exemplary embodiments have been described. However, it may be appreciated that various modifications and changes can be made without departing from the scope of the invention as set forth below.

Claims

1. An interventional medical system comprising:

an implantable medical device comprising:

a ventricular portion (100) including an hermetically sealed housing (105) extending from a proximal end (101) thereof to a distal end thereof, a ventricular electrode (106) mounted in proximity the housing distal end, and a fixation mechanism (103) mounted in proximity to the housing distal end;
an atrial portion (200) including a core (250) extending from a first end (201) thereof to a second end (202) thereof, along a longitudinal axis (3) of the atrial portion, an atrial electrode (206) mounted in proximity to the second end of the core, and a fixation mechanism mounted in proximity to the second end of the core; and
a leadlet (120) extending from the proximal end of the ventricular portion housing to the first end of the atrial portion core, the leadlet including a conductor (122) and an insulative tubular member (121) in which the conductor extends, the conductor being coupled to the atrial electrode of the atrial portion; and

a delivery tool (400) comprising:

a tubular sidewall (432) that defines a lumen (425) and has a slot formed therein, the slot extending proximally from an open end thereof, the open end of the slot being coincident with a distal opening of the lumen; and
a tether (480) extending within the tubular sidewall;

wherein the device is loaded in the delivery tool such that the second end of the atrial portion core faces the proximal end of the ventricular portion housing, such that the atrial portion is

contained within the lumen with a segment (12-1) of the flexible leadlet extending alongside the atrial portion, and with another segment (12-2) of the leadlet being folded over on itself proximal to the atrial portion, and such that the tether is engaged with the other segment of the leadlet at a fold therein; and
the slot is configured to allow passage of the flexible leadlet therethrough when the atrial portion is positioned in proximity to the distal opening of the lumen for deployment from the tool.

2. The system of claim 1, wherein the device atrial portion includes an open channel (253) formed along the core thereof, the open channel extending between the first and second ends of the core and being sized to receive the leadlet of the device therein.

3. The system of any of claims 1-2, wherein the device leadlet further includes a radiopaque maker designating a zone (124) along a length of the leadlet for creating the fold in the leadlet.

4. The system of any of claims 1-3, wherein the fixation mechanism of the device atrial portion comprises a plurality of elastically deformable tines (103) fixedly mounted to the core and spaced apart from one another around a perimeter of the core; and wherein each tine comprises:

a proximal, spring portion (33) being fixedly attached to the atrial portion core and having a spring-biased pre-formed curvature, the pre-formed curvature, in proximity to the core, extending in a first direction (d1), generally parallel to the axis (2) of the atrial portion, and then sweeping laterally, outward from the axis; and
a distal portion (35) including a proximal section (35-P), a hook section (35-H), and tip (35-T) section terminated by a rounded free distal end (352), the proximal section extending from the proximal, spring portion and being pre-formed to extend in a second direction (d2) and along a relatively straight line to the hook section, the proximal section being oriented, by the spring-biased pre-formed curvature of the proximal, spring portion, so that the second direction is generally opposite the first direction, and the relatively straight line intersects the axis at an acute angle of between about 30 degrees and about 50 degrees, the hook section having a deformable pre-formed curvature that extends from the proximal section back toward the axis of the atrial portion, the tip section being pre-formed to extend along a relatively straight line from the hook section to the rounded free distal end, and the tip section being oriented, by the pre-formed curvature of the hook section, when un-deformed, to extend toward the axis of the atrial portion, such that the tip section and the proximal section enclose an angle (φ) in a range from about 90 degrees to about 120 degrees; and
wherein the rounded free distal end of each tine of the loaded device engages an inner surface (42) of the delivery tool sidewall, to hold the proximal, spring portion of each tine in a spring-loaded condition, and so that each tip section of the distal portion extends away from the axis of the atrial portion at an acute angle (δ) in a range from about 45 degrees to about 75 degrees for deployment of the corresponding rounded free distal end out from the sidewall; and
upon deployment of the rounded free distal end of each tine, the tip section of each distal portion rotates away from the axis to approach an angle (π) of 90 degrees, relative to the axis, in response to an initial release of the spring-loaded condition of the corresponding proximal, spring portion.

5. The system of any of claims 1-4, wherein an intersection between the proximal spring portion and the distal portion of each device tine is spaced distally from the second end of the device atrial portion core, and the device atrial electrode is flush with, or spaced distally apart from the intersection between the proximal, spring portion and the distal portion of each tine by a distance in a range from about 0 mm to about 2 mm.

6. The system of any of claims 1-5, wherein:

the tubular sidewall of the delivery tool comprises an elongate outer member (430), and the ventricular portion of the loaded device is contained within the lumen defined by tubular sidewall; and
the delivery tool further comprises an inner (850) assembly that extends within the lumen of the outer member, the outer member being slideably engaged around the inner assembly, and the inner assembly comprising:

an elongate inner member (420) including a distal end that receives the folded over leadlet of the loaded device therein, and that engages the first end of the atrial portion of the loaded device; and
the tether extending within the inner member, proximally from where the tether is engaged with the loaded device leadlet.

7. The system of any of claims 1-6, wherein the tubular sidewall of the delivery tool comprises an elongate inner member; and wherein the delivery tool further comprises:

an elongate outer member including a longitudinally extending lumen, the lumen of the outer member having the inner member slideably engaged therein, and having a distal portion that contains the ventricular portion of the loaded device; and
a sheath slideably engaged within the lumen defined by the tubular sidewall of the inner member, the sheath including side-by-side longitudinally extending lumens in which the tether extends, proximally from where the tether is engaged with the loaded device leadlet.

8. The system of claim 7, wherein the sheath further includes a groove formed in a distal-facing surface thereof, between the side-by-side lumens, the groove being sized to receive the loaded device leadlet therein.

9. The system of any of claims 7-8, wherein an outer surface of the sheath interlocks with an inner surface of the tubular sidewall of the inner member.

10. The system of claims 1-9 comprising:

an elongate tubular sidewall sized to fit in sliding engagement within an elongate outer member of the delivery tool, the tubular sidewall defining a longitudinally extending lumen sized to contain a portion of the medical device therein, and the tubular sidewall having a slot formed therein, the slot extending proximally from an open end thereof, and the open end of the slot being coincident with a distal opening of the lumen;
an elongate sheath slideably engaged within the lumen defined by the tubular sidewall, the sheath including side-by-side longitudinally extending lumens, each lumen of the sheath having an opening located at a distal-facing surface of the sheath; and
a tether having opposing lengths extending within the side-by-side lumens of the sheath to form a loop that engages with the medical device in proximity to the distal-facing surface of the sheath.

11. The system of any of claims 7-10, wherein the sheath further includes a groove formed in the distal-facing surface thereof, between the openings of the side-by-side lumens.

12. The system of any of claims 7-11, wherein an outer surface of the sheath interlocks with an inner surface of the tubular sidewall.

13. A system comprising an implantable medical device, according to any of Claims 1-12, and a delivery tool, according to either of Claims 1 through 12.

Patentansprüche

1. Interventionelles medizinisches System, Folgendes umfassend:

eine implantierbare medizinische Vorrichtung, Folgendes umfassend:

einen ventrikulären Abschnitt (100), der ein hermetisch abgedichtetes Gehäuse (105), das sich von einem proximalen Ende (101) davon zu einem distalen Ende davon erstreckt, eine ventrikuläre Elektrode (106), die in der Nähe des distalen Endes des Gehäuses angebracht ist, und einen Befestigungsmechanismus (103) beinhaltet, der in der Nähe des distalen Endes des Gehäuses angebracht ist;
einen Vorhofabschnitt (200), der einen Kern (250), der sich von einem ersten Ende (201) davon zu einem zweiten Ende (202) davon entlang einer Längsachse (3) des Vorhofabschnitts erstreckt, eine Vorhofelektrode (206), die in der Nähe des zweiten Endes des Kerns angebracht ist, und einen Befestigungsmechanismus beinhaltet, der in der Nähe des zweiten Endes des Kerns angebracht ist; und
ein Leadlet (120), das sich von dem proximalen Ende des Gehäuses des ventrikulären Abschnitts zu dem ersten Ende des Kerns des Vorhofabschnitts erstreckt, wobei das Leadlet einen Leiter (122) und ein isolierendes röhrenförmiges Element (121) beinhaltet, in dem sich der Leiter erstreckt, wobei der Leiter mit der Vorhofelektrode des Vorhofabschnitts gekoppelt ist; und

ein Abgabewerkzeug (400), Folgendes umfassend:

eine röhrenförmige Seitenwand (432), die ein Lumen (425) definiert und einen darin ausgebildeten Schlitz aufweist, wobei sich der Schlitz proximal von einem offenen Ende davon erstreckt, wobei das offene Ende des Schlitzes mit einer distalen Öffnung des Lumens übereinstimmt; und
eine Leine (480), die sich innerhalb der röhrenförmigen Seitenwand erstreckt;

wobei die Vorrichtung derart in das Abgabewerkzeug geladen ist, dass das zweite Ende des Vorhofabschnittkerns dem proximalen Ende des Gehäuses des ventrikulären Abschnitts derart zugewandt ist, dass der Vorhofabschnitt innerhalb des Lumens mit einem Segment (12-1) des flexiblen Leadlets, das sich entlang des Vor-

hofabschnitts erstreckt, und einem anderen Segment (12-2) des Leadlets enthalten ist, das über sich selbst proximal zu dem Vorhofabschnitt gefaltet ist, und derart, dass die Leine mit dem anderen Segment des Leadlets and einer Falte darin in Eingriff steht; und
der Schlitz derart konfiguriert ist, dass er den Durchtritt des flexiblen Leadlets dahindurch ermöglicht, wenn der Vorhofabschnitt in der Nähe der distalen Öffnung des Lumens zum Entfalten aus dem Werkzeug positioniert ist.

2. System nach Anspruch 1, wobei der Vorhofabschnitt der Vorrichtung einen offenen Kanal (253), der entlang des Kerns davon ausgebildet ist, beinhaltet, wobei sich der offene Kanal zwischen dem ersten und dem zweiten Ende des Kerns erstreckt und derart bemessen ist, dass er das Leadlet der Vorrichtung darin aufnimmt.

3. System nach einem der Ansprüche 1-2, wobei das Leadlet der Vorrichtung ferner eine röntgendichte Markierung beinhaltet, die eine Zone (124) entlang einer Länge des Leadlets zum Erstellen der Falte in dem Leadlet kennzeichnet.

4. System nach einem der Ansprüche 1-3, wobei der Befestigungsmechanismus des Vorhofabschnitts der Vorrichtung mehrere elastisch verformbare Zinken (103) beinhaltet, die fest an dem Kern angebracht sind und voneinander um einen Umfang des Kerns herum beabstandet sind; und wobei jede Zinke Folgendes umfasst:

einen proximalen Federabschnitt (33), der fest mit dem Kern des Vorhofabschnitts verbunden ist und eine federvorgespannte vorgeformte Krümmung aufweist, wobei sich die vorgeformte Krümmung in der Nähe des Kerns in einer ersten Richtung (d1) im Allgemeinen parallel zu der Achse (2) des Vorhofabschnitts erstreckt und dann seitlich von der Achse nach außen streicht; und
einen distalen Abschnitt (35), der einen proximalen Bereich (35-P), einen Hakenbereich (35-H) und einen Spitzen(35-T)bereich beinhaltet, der durch ein gerundetes freies distales Ende (352) abgeschlossen wird, wobei sich der proximale Bereich von dem proximalen Federabschnitt erstreckt und vorgeformt ist, um sich in einer zweiten Richtung (d2) und entlang einer relativ geraden Linie zu dem Hakenbereich zu erstrecken, wobei der proximale Bereich derart durch die federvorgespannte vorgeformte Krümmung des proximalen Federabschnitts ausgerichtet ist, dass die zweite Richtung im Allgemeinen der ersten Richtung entgegengesetzt ist und die relativ gerade Linie die Achse in einem spitzen Winkel zwischen etwa 30 Grad und etwa 50 Grad schneidet, wobei der Hakenbereich eine verformbare vorgeformte Krümmung aufweist, die sich von dem proximalen Bereich zurück zu der Achse des Vorhofabschnitts erstreckt, wobei der Spitzenbereich vorgeformt ist, um sich entlang einer relativ geraden Linie von dem Hakenbereich zu dem gerundeten freien distalen Ende zu erstrecken, und wobei der Spitzenbereich durch die vorgeformte Krümmung des Hakenbereichs, wenn nicht verformt, ausgerichtet ist, um sich zu der Achse des Vorhofabschnitts derart zu erstrecken, dass der Spitzenbereich und der proximale Bereich einen Winkel (<p) in einem Bereich von etwa 90 Grad bis etwa 120 Grad einschließen; und
wobei das gerundete freie distale Ende jeder Zinke der geladenen Vorrichtung mit einer inneren Oberfläche (42) der Abgabewerkzeugseitenwand in Eingriff steht, um den proximalen Federabschnitt jeder Zinke in einer federgeladenen Bedingung zu halten und derart, dass sich jeder Spitzenbereich des distalen Abschnitts von der Achse des Vorhofabschnitts in einem spitzen Winkel (δ) in einem Bereich von etwa 45 Grad bis etwa 75 Grad zum Entfalten des entsprechenden gerundeten freien distalen Endes von der Seitenwand weg erstreckt; und
und sich der Spitzenbereich jedes distalen Abschnitts beim Entfalten des gerundeten freien distalen Endes jeder Zinke von der Achse weg dreht, um sich einem Winkel (π) von 90 Grad relativ zu der Achse als Reaktion auf ein anfängliches Lösen der federgeladenen Bedingung des entsprechenden proximalen Federabschnitts zu nähern.

5. System nach einem der Ansprüche 1-4, wobei ein Schnittpunkt zwischen dem proximalen Federabschnitt und dem distalen Abschnitt jeder Vorrichtungszinke distal von dem zweiten Ende des Vorhofabschnittskerns der Vorrichtung beabstandet ist und die Vorhofelektrode der Vorrichtung bündig mit dem Schnittpunkt zwischen dem proximalen Federabschnitt und dem distalen Abschnitt jeder Zinke ist oder von diesem um einen Abstand in einem Bereich von etwa 0 mm bis etwa 2 mm beabstandet ist.

6. System nach einem der Ansprüche 1-5, wobei:

die röhrenförmige Seitenwand des Abgabewerkzeugs ein längliches äußeres Element (430) umfasst und der ventrikuläre Abschnitt der geladenen Vorrichtung innerhalb des durch die röhrenförmige Seitenwand definierten Lumens enthalten ist; und
das Abgabewerkzeug ferner eine innere (850) Anordnung umfasst, die sich innerhalb des Lu-

mens des äußeren Elements erstreckt, wobei das äußere Element gleitend um die innere Anordnung herum in Eingriff steht und die innere Anordnung Folgendes umfasst:
ein längliches inneres Element (420), das ein distales Ende, das das umgefaltete Leadlet der geladenen Vorrichtung darin aufnimmt und das mit dem ersten Ende des Vorhofabschnitts der geladenen Vorrichtung in Eingriff steht; und
wobei sich die Leine innerhalb des inneren Elements proximal von dort erstreckt, wo die Leine mit dem Leadlet der geladenen Vorrichtung in Eingriff steht.

7. System nach einem der Ansprüche 1-6, wobei die röhrenförmige Seitenwand des Abgabewerkzeugs ein längliches inneres Element umfasst; und wobei das Abgabewerkzeug ferner Folgendes umfasst:

ein längliches äußeres Element, das ein sich in Längsrichtung erstreckendes Lumen beinhaltet, wobei das Lumen des äußeren Elements das innere Element gleitend darin in Eingriff nimmt und einen distalen Abschnitt aufweist, der den ventrikulären Abschnitt der geladenen Vorrichtung enthält; und
eine Hülle, die gleitend innerhalb des Lumens, das durch die röhrenförmige Seitenwand des inneren Elements definiert wird, in Eingriff genommen wird, wobei die Hülle sich nebeneinander in Längsrichtung erstreckende Lumina beinhaltet, in denen sich die Leine proximal von dort, wo die Leine mit dem Leadlet der geladenen Vorrichtung in Eingriff steht, erstreckt.

8. System nach Anspruch 7, wobei die Hülle ferner eine Rille, die in einer distal ausgerichteten Oberfläche davon ausgebildet ist, zwischen den nebeneinanderliegenden Lumina beinhaltet, wobei die Rille bemessen ist, um das Leadlet der geladenen Vorrichtung darin aufzunehmen.

9. System nach einem der Ansprüche 7-8, wobei eine äußere Oberfläche der Hülle sich mit einer inneren Oberfläche der röhrenförmigen Seitenwand des inneren Elements verriegelt.

10. System nach den Ansprüchen 1-9, Folgendes umfassend:

eine längliche röhrenförmige Seitenwand, die bemessen ist, um innerhalb eines länglichen äußeren Elements des Abgabewerkzeugs in einem gleitenden Eingriff zu passen, wobei die röhrenförmige Seitenwand ein sich in Längsrichtung erstreckendes Lumen definiert, um einen Abschnitt der medizinischen Vorrichtung darin zu enthalten, und wobei die röhrenförmige Seitenwand einen darin ausgebildeten Schlitz aufweist, wobei sich der Schlitz proximal von einem offenen Ende davon erstreckt und wobei das offene Ende des Schlitzes mit einer distalen Öffnung des Lumens übereinstimmt;
eine längliche Hülle, die innerhalb des Lumens, das durch die röhrenförmige Seitenwand definiert ist, gleitend in Eingriff steht, wobei die Hülle sich nebeneinander in Längsrichtung erstreckende Lumina beinhaltet, wobei jedes Lumen der Hülle eine Öffnung aufweist, die sich an einer distal ausgerichteten Oberfläche der Hülle befindet; und
eine Leine mit entgegengesetzten Längen, die sich innerhalb der nebeneinanderliegenden Lumina der Hülle erstrecken, um eine Schleife auszubilden, die mit der medizinischen Vorrichtung in der Nähe der distal ausgerichteten Oberfläche der Hülle in Eingriff steht.

11. System nach einem der Ansprüche 7-10, wobei die Hülle ferner eine Rille beinhaltet, die in der distal ausgerichteten Oberfläche davon zwischen den Öffnungen der nebeneinanderliegenden Lumina ausgebildet ist.

12. System nach einem der Ansprüche 7-11, wobei eine äußere Oberfläche der Hülle sich mit einer inneren Oberfläche der röhrenförmigen Seitenwand verriegelt.

13. System, umfassend eine implantierbare medizinische Vorrichtung nach einem der Ansprüche 1-12 und ein Abgabewerkzeug nach einem der Ansprüche 1 bis einschließlich 12.

Revendications

1. Système médical d'intervention comprenant :

un dispositif médical implantable comprenant :

une partie ventriculaire (100) comportant un boîtier hermétiquement scellé (105) s'étendant d'une extrémité proximale (101) de celui-ci à une extrémité distale de celui-ci, une électrode ventriculaire (106) montée à proximité de l'extrémité distale du boîtier et un mécanisme de fixation (103) monté à proximité de l'extrémité distale du boîtier ;
une partie auriculaire (200) comportant un centre (250) s'étendant d'une première extrémité (201) de celle-ci à une seconde extrémité (202) de celle-ci, le long d'un axe longitudinal (3) de la partie auriculaire, une électrode auriculaire (206) montée à proximité de la seconde extrémité du centre et

un mécanisme de fixation monté à proximité de la seconde extrémité du centre ; et
une canule (120) s'étendant de l'extrémité proximale du boîtier de la partie ventriculaire à la première extrémité du centre de la partie auriculaire, la canule comportant un conducteur (122) et un élément tubulaire isolant (121) dans lequel s'étend le conducteur, le conducteur étant couplé à l'électrode auriculaire de la partie auriculaire ; et

un outil d'administration (400) comprenant :

une paroi latérale tubulaire (432) qui définit une lumière (425) et a une fente formée dans celle-ci, la fente s'étendant de manière proximale à partir d'une extrémité ouverte de celle-ci, l'extrémité ouverte de la fente coïncidant avec une ouverture distale de la lumière ; et
une attache (480) s'étendant à l'intérieur de la paroi latérale tubulaire ;

dans lequel le dispositif est chargé dans l'outil d'administration de telle sorte que la seconde extrémité du centre de la partie auriculaire fasse face à l'extrémité proximale du boîtier de la partie ventriculaire, de telle sorte que la partie auriculaire est contenue dans la lumière avec un segment (12-1) de la canule flexible s'étendant le long de la partie auriculaire, et avec un autre segment (12-2) de la canule étant plié sur lui-même à proximité de la partie auriculaire, et de telle sorte que la canule y est mise en prise avec l'autre segment de la canule au niveau d'un pli dans celle-ci ; et
la fente est conçue pour y permettre le passage de la canule flexible lorsque la partie auriculaire est positionnée à proximité de l'ouverture distale de la lumière pour un déploiement à partir de l'outil.

2. Système selon la revendication 1, dans lequel la partie auriculaire du dispositif comporte un canal ouvert (253) formé le long du centre de celle-ci, le canal ouvert s'étendant entre les première et seconde extrémités du centre et étant dimensionné pour y recevoir la canule du dispositif.

3. Système selon l'une quelconque des revendications 1 à 2, dans lequel la canule du dispositif comporte en outre un marqueur radio-opaque désignant une zone (124) le long d'une longueur de la canule pour créer le pli dans la canule.

4. Système selon l'une quelconque des revendications 1 à 3, dans lequel le mécanisme de fixation de la partie auriculaire du dispositif comprend une pluralité de dents (103) élastiquement déformables montées fixement sur le centre et espacées les unes des autres autour d'un périmètre du centre ; et dans lequel chaque dent comprend :

une partie de ressort proximale (33) étant attachée de manière fixe au centre de la partie auriculaire et ayant une courbure préformée et sollicitée par ressort, la courbure préformée, à proximité du centre, s'étendant dans une première direction (d1), généralement parallèle à l'axe (2) de la partie auriculaire, puis balayant latéralement vers l'extérieur de l'axe ; et
une partie distale (35) comportant une section proximale (35-P), une section de crochet (35-H) et une section de pointe (35-T) terminée par une extrémité distale libre arrondie (352), la section proximale s'étendant à partir d'une partie de ressort proximale et étant préformée pour s'étendre dans une seconde direction (d2) et le long d'une ligne relativement droite jusqu'à la section de crochet, la section proximale étant orientée par la courbure préformée et sollicitée par ressort de la partie de ressort proximale, de sorte que la seconde direction soit généralement opposée à la première direction et que la ligne relativement droite forme une intersection avec l'axe selon un angle aigu compris entre environ 30 degrés et environ 50 degrés, la section de crochet ayant une courbure préformée déformable qui s'étend depuis la section proximale vers l'arrière en direction de l'axe de la partie auriculaire, la section de pointe étant préformée pour s'étendre le long d'une ligne relativement droite allant de la section de crochet jusqu'à l'extrémité distale libre arrondie, et la section de pointe étant orientée par la courbure préformée de la section de crochet, quand elle n'est pas déformée, pour s'étendre vers l'axe de la partie auriculaire, de telle sorte que la section de pointe et la section proximale encadrent un angle (φ) compris dans une plage allant d'environ 90 degrés à environ 120 degrés ; et
dans lequel l'extrémité distale libre arrondie de chaque dent du dispositif chargé est mise en prise avec une surface interne (42) de la paroi latérale de l'outil d'administration, afin de maintenir la partie de ressort proximale de chaque dent dans un état à ressort, et de sorte que chaque section de pointe de la partie distale s'étend en s'éloignant de l'axe de la partie auriculaire selon un angle aigu (δ) dans une plage allant d'environ 45 degrés à environ 75 degrés pour le déploiement de l'extrémité distale libre arrondie correspondante à l'extérieur de la paroi latérale ; et
lors du déploiement de l'extrémité distale libre arrondie de chaque dent, la section de pointe

de chaque partie distale est en rotation en s'éloignant de l'axe pour se rapprocher d'un angle (π) de 90 degrés, relatif à l'axe, en réponse à une libération initiale de l'état à ressort de la partie de ressort proximale correspondante.

5. Système selon l'une quelconque des revendications 1 à 4, dans lequel une intersection entre la partie de ressort proximale et la partie distale de chaque dent du dispositif est espacée distalement de la seconde extrémité du centre de la partie auriculaire du dispositif, et l'électrode auriculaire du dispositif est alignée avec ou espacée distalement de l'intersection entre la partie de ressort proximale et la partie distale de chaque dent par une distance comprise dans une plage allant d'environ 0 mm à environ 2 mm.

6. Système selon l'une quelconque des revendications 1 à 5, dans lequel :

la paroi latérale tubulaire de l'outil d'administration comprend un élément externe allongé (430), et la partie ventriculaire du dispositif chargé est contenue à l'intérieur de la lumière définie par la paroi latérale tubulaire ; et
l'outil d'administration comprend en outre un ensemble interne (850) qui s'étend à l'intérieur de la lumière de l'élément externe, l'élément externe étant mis en prise de manière coulissante autour de l'ensemble interne, et l'ensemble interne comprenant :
un élément interne allongé (420) comportant une extrémité distale qui y reçoit la canule repliée du dispositif chargé et qui est mise en prise avec la première extrémité de la partie auriculaire du dispositif chargé ; et
l'attache s'étendant à l'intérieur de l'élément interne, de manière proximale à partir de l'endroit où l'attache est mise en prise avec la canule du dispositif chargé.

7. Système selon l'une quelconque des revendications 1 à 6, dans lequel la paroi latérale tubulaire de l'outil d'administration comprend un élément interne allongé ; et l'outil de distribution comprenant en outre :

un élément externe allongé comportant une lumière s'étendant longitudinalement, la lumière de l'élément externe y ayant l'élément interne mis en prise de manière coulissante, et ayant une partie distale qui contient la partie ventriculaire du dispositif à ressort ; et
une gaine mise en prise de manière coulissante dans la lumière définie par la paroi latérale tubulaire de l'élément interne, la gaine comportant des lumières s'étendant longitudinalement côte à côte dans lesquelles l'attache s'étend, de manière proximale à partir de l'endroit où l'attache est mise en prise avec la canule du dispositif chargé.

8. Système selon la revendication 7, dans lequel la gaine comporte en outre une rainure formée dans une surface orientée distalement de celle-ci, entre les lumières côte à côte, la rainure étant dimensionnée pour y recevoir la canule du dispositif chargé.

9. Système selon l'une quelconque des revendications 7 à 8, dans lequel une surface externe de la gaine se verrouille avec une surface interne de la paroi latérale tubulaire de l'élément interne.

10. Système selon les revendications 1 à 9, comprenant :

une paroi latérale tubulaire allongée dimensionnée pour entrer en prise de manière coulissante dans un élément externe allongé de l'outil d'administration, la paroi latérale tubulaire définissant une lumière s'étendant longitudinalement et dimensionnée pour y contenir une partie du dispositif médical, et la paroi latérale tubulaire y ayant une fente formée, la fente s'étendant de manière proximale à partir d'une extrémité ouverte de celle-ci, et l'extrémité ouverte de la fente coïncidant avec une ouverture distale de la lumière ;
une gaine allongée mise en prise de manière coulissante dans la lumière définie par la paroi latérale tubulaire, la gaine comportant des lumières s'étendant longitudinalement côte à côte, chaque lumière de la gaine ayant une ouverture située au niveau d'une surface à orientation distale de la gaine ; et
une attache ayant des longueurs opposées s'étendant au sein des lumières côte à côte de la gaine pour former une boucle qui se met en prise avec le dispositif médical à proximité de la surface à orientation distale de la gaine.

11. Système selon l'une quelconque des revendications 7 à 10, dans lequel la gaine comprend en outre une rainure formée dans la surface à orientation distale de celle-ci, entre les ouvertures des lumières côte à côte.

12. Système selon l'une quelconque des revendications 7 à 11, dans lequel une surface externe de la gaine se verrouille avec une surface interne de la paroi latérale tubulaire.

13. Système comprenant un dispositif médical implantable selon l'une quelconque des revendications 1 à 12, et un outil d'administration, selon l'une quelconque des revendications 1 à 12.

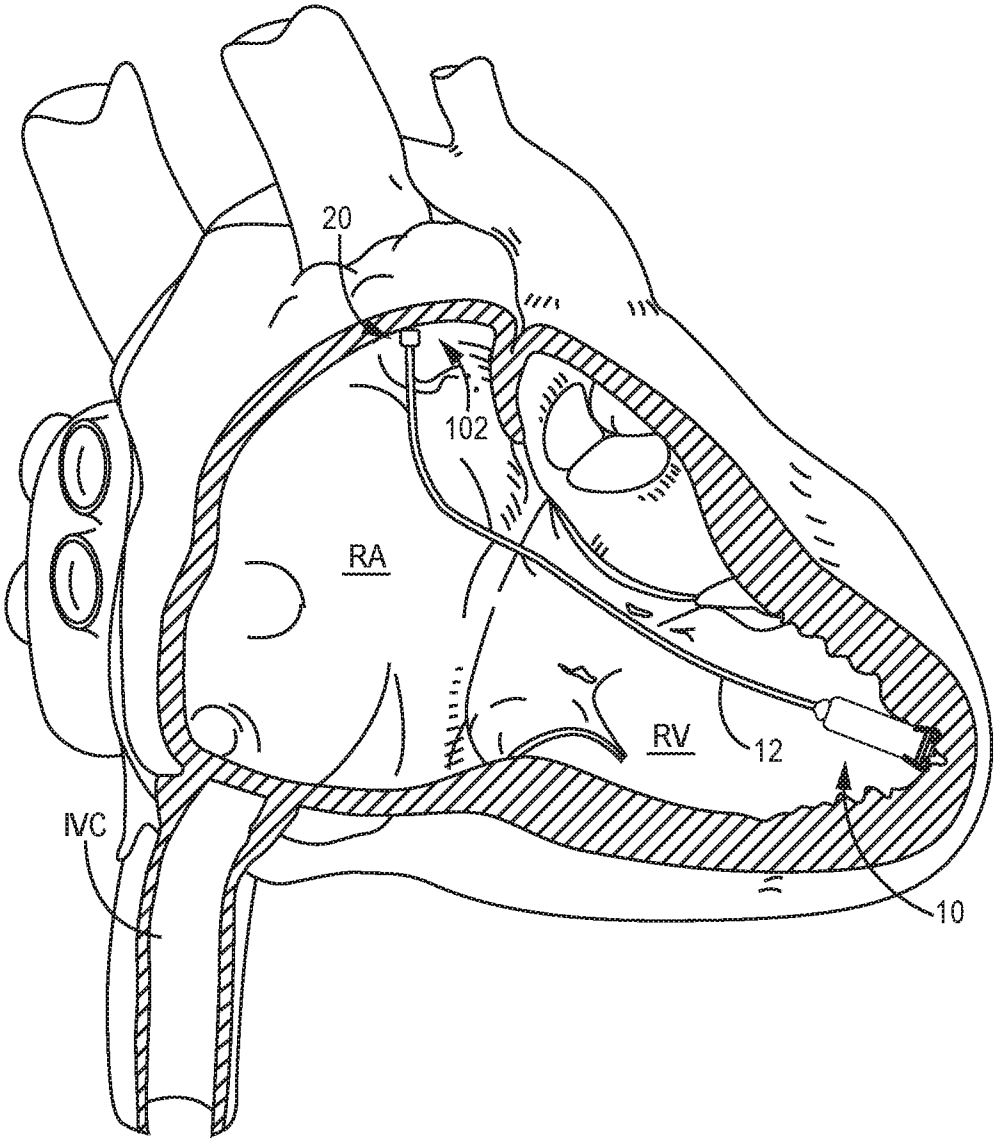
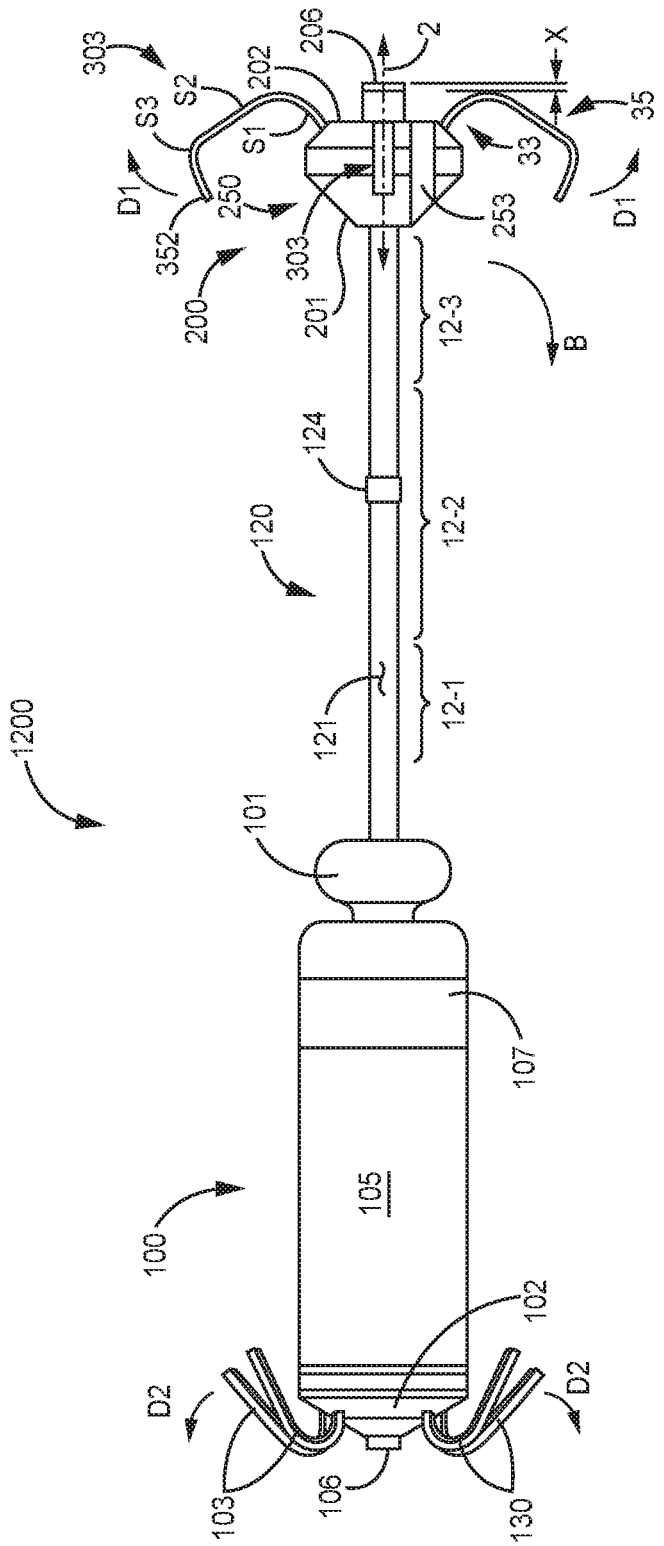


FIG. 1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S2
S3
S1
202
206
2
X
35
33
D1
D1
352
250
303
253
200
201
12-3
B
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12-2
121
12-1
101
107
105
100
102
D2
D2
103
106
130

FIG. 2A

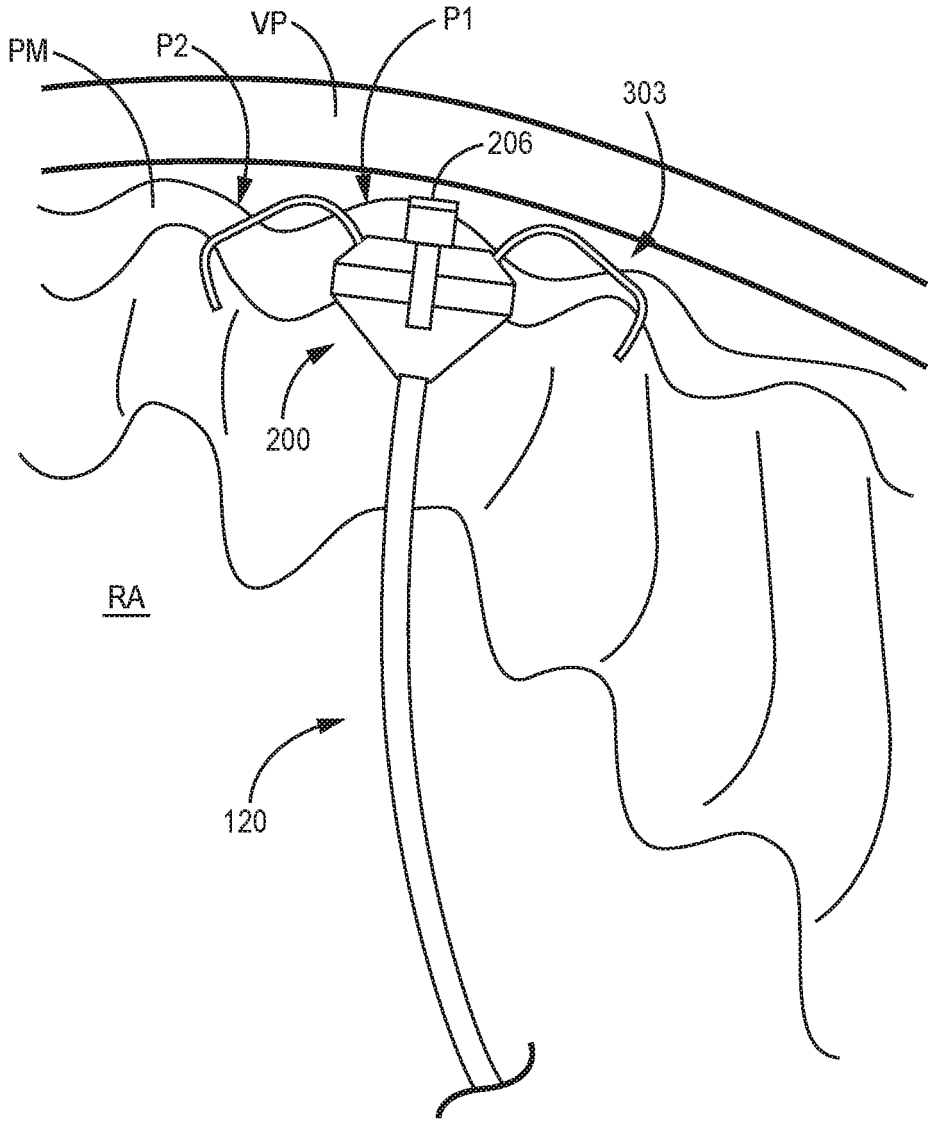
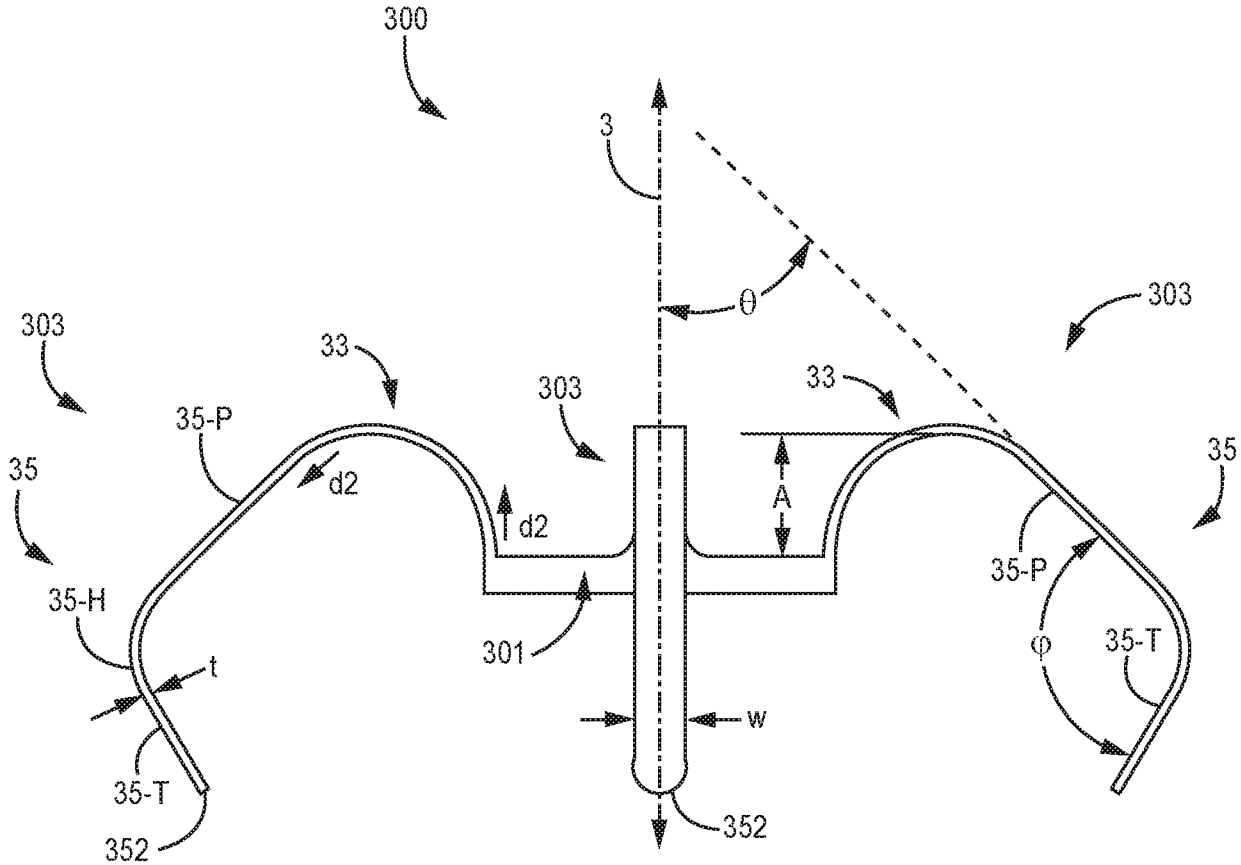


FIG. 2B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θ
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d2
d2
A
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35-H
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φ
35-T
w
35-T
352
352

FIG. 3A

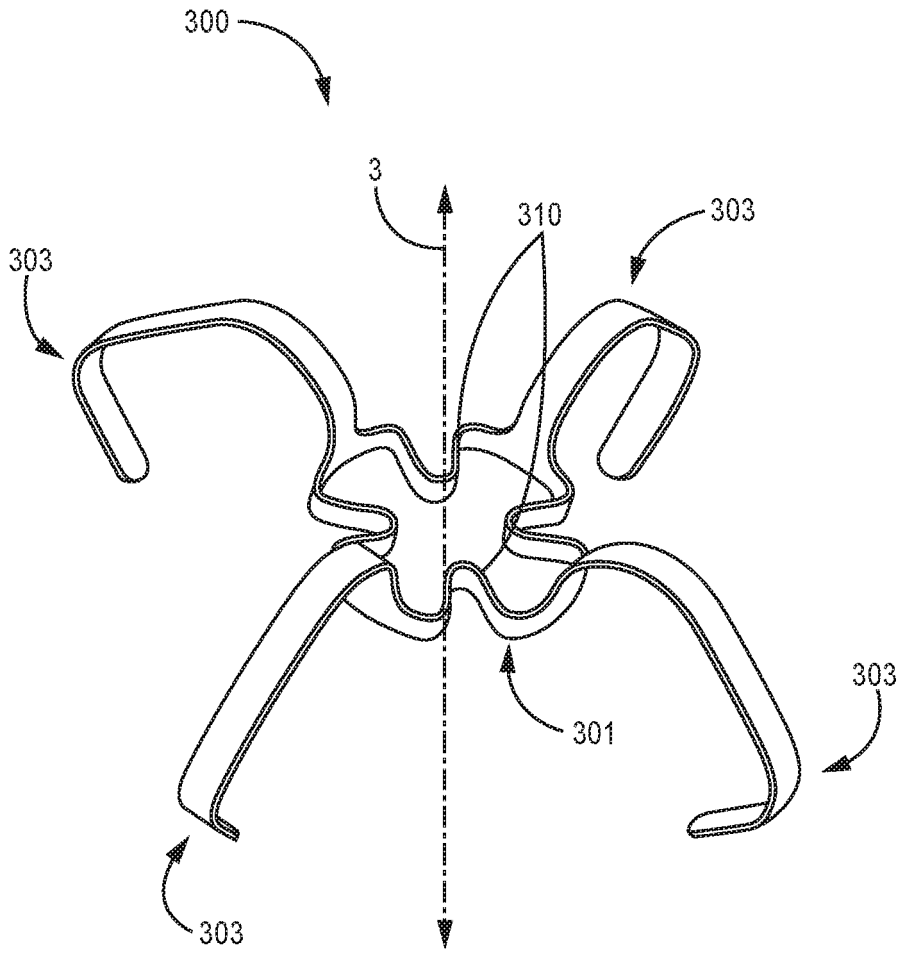


FIG. 3B

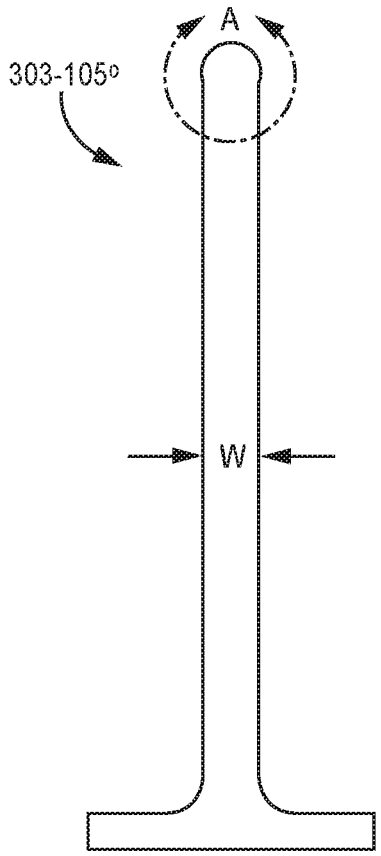
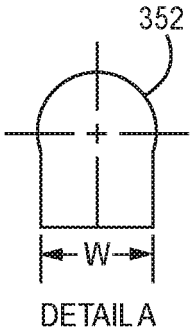


FIG. 3C



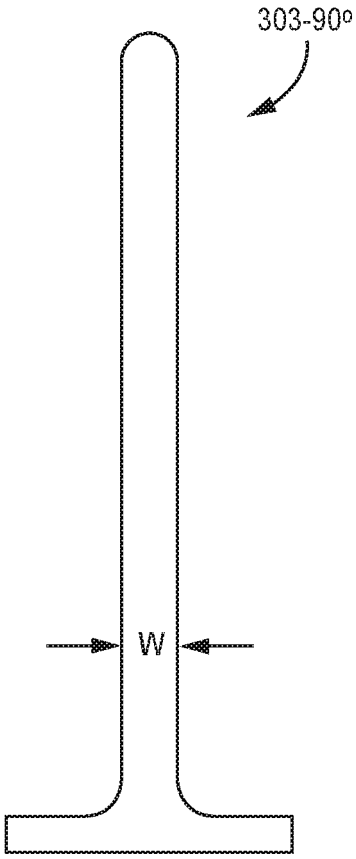
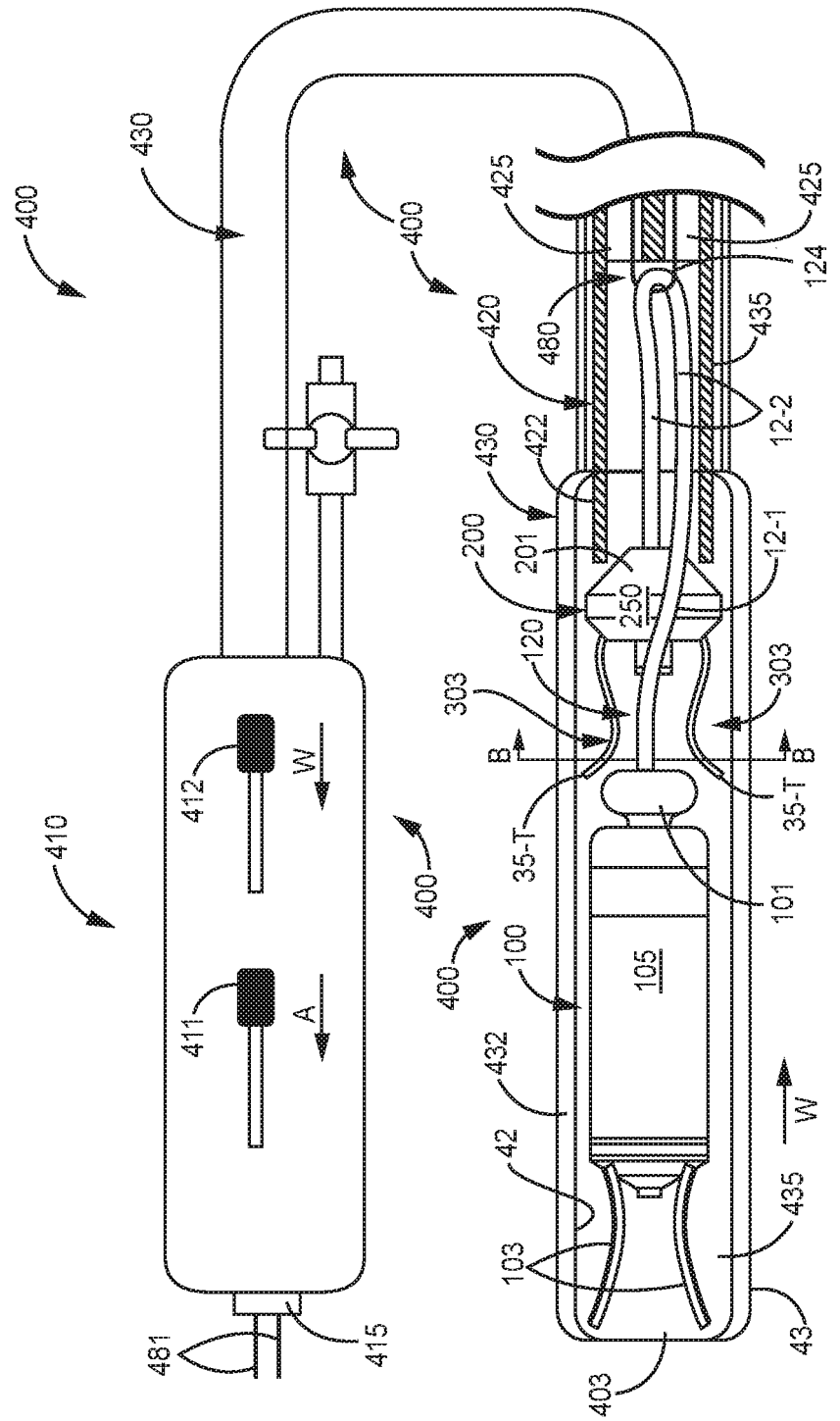


FIG. 3D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B
35-T
35-T
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A
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1240

FIG. 4A

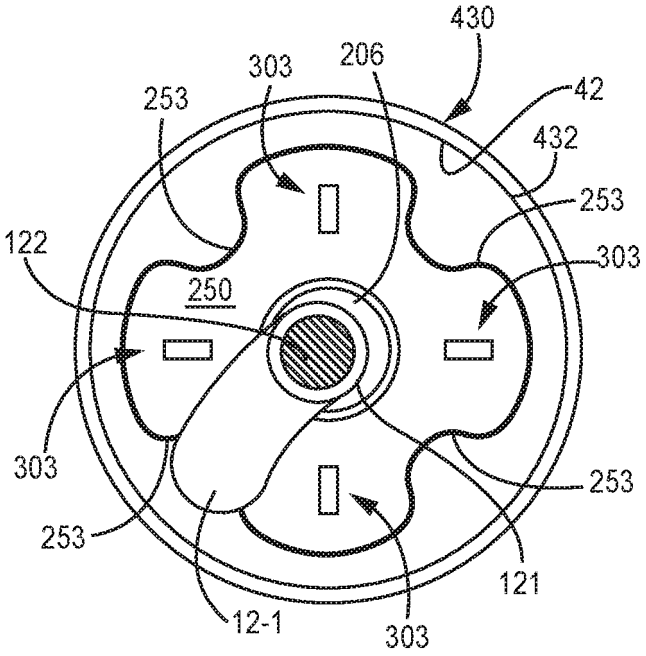

FIG. 4B

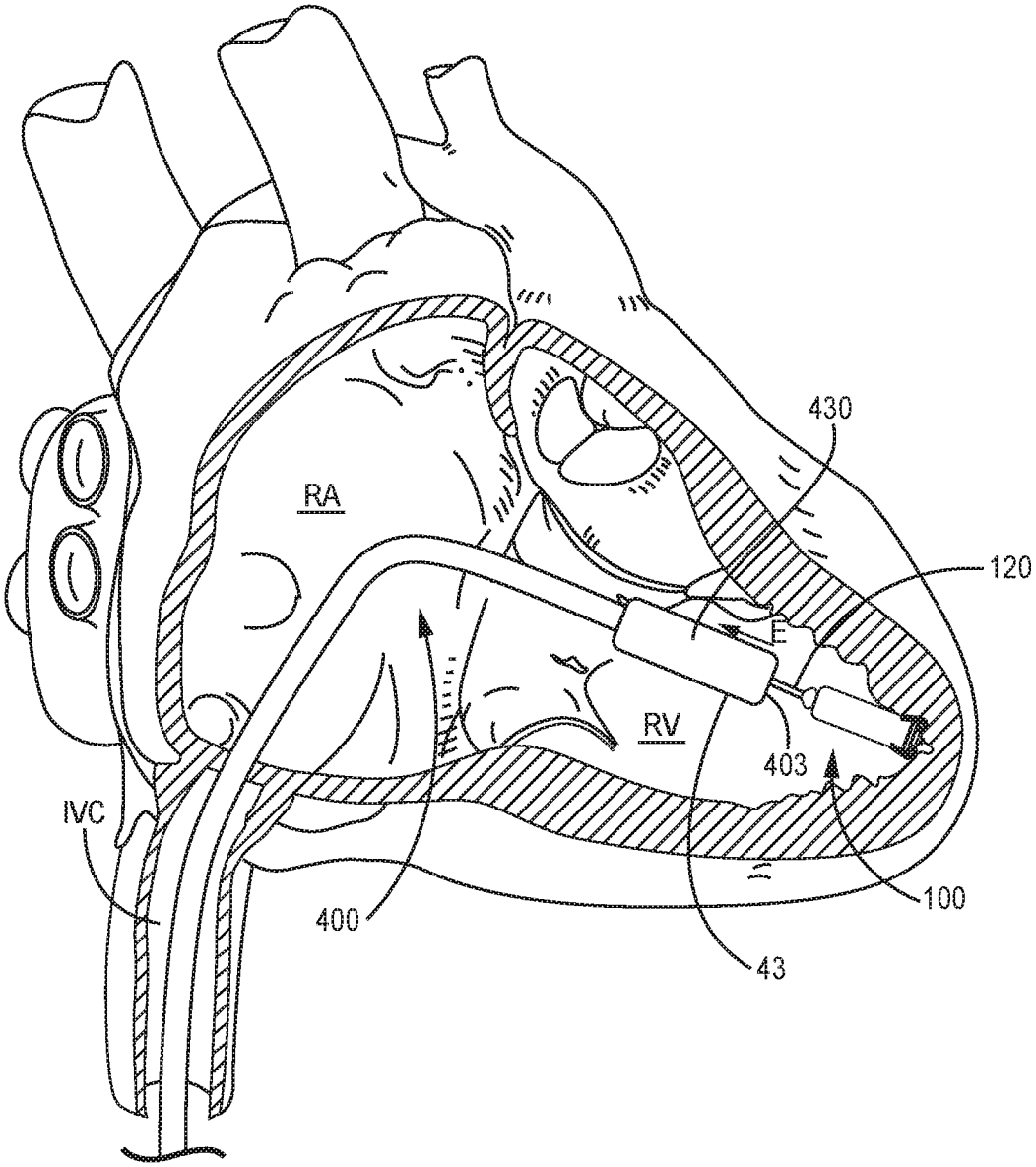

FIG. 5A

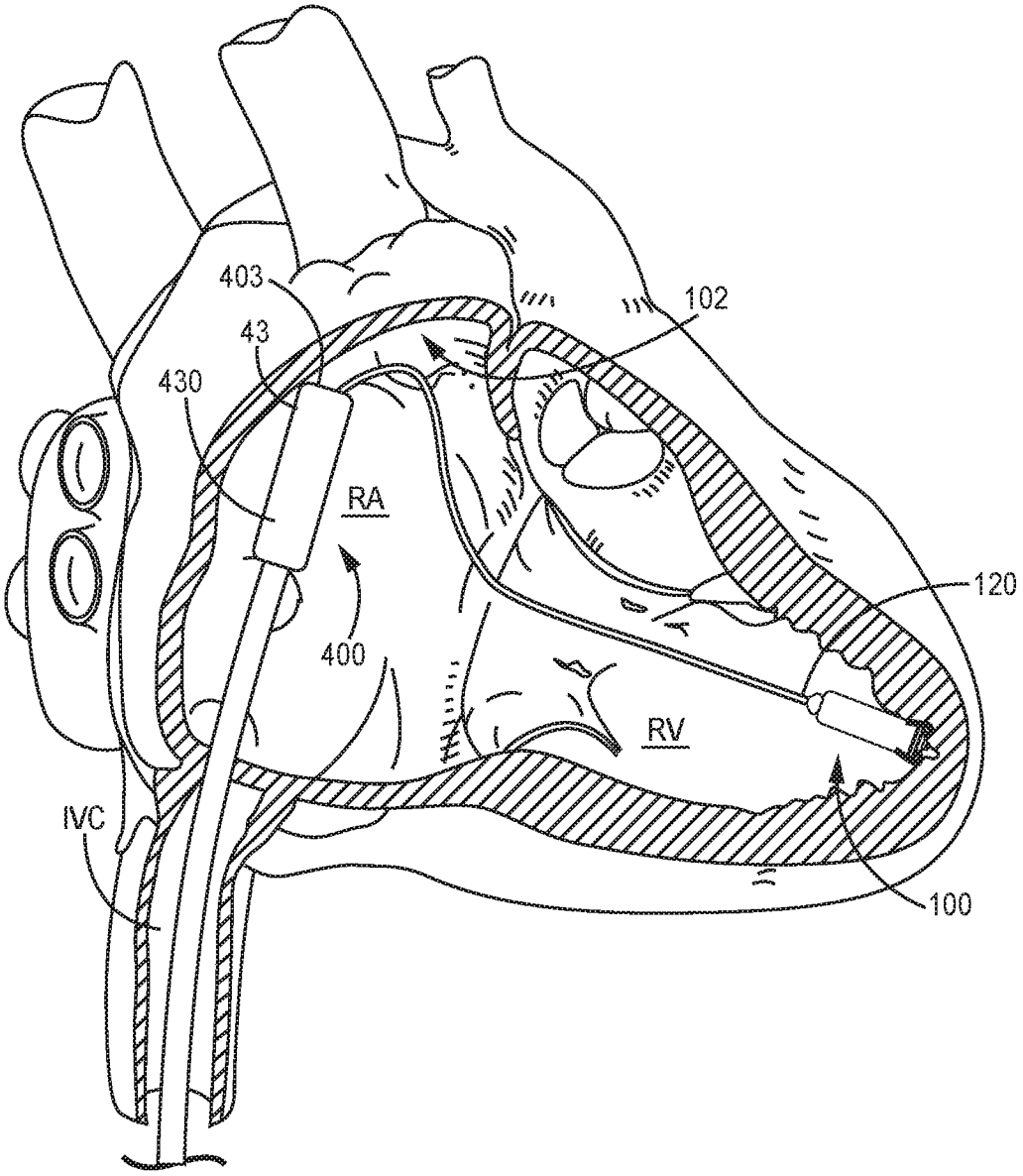

FIG. 5B

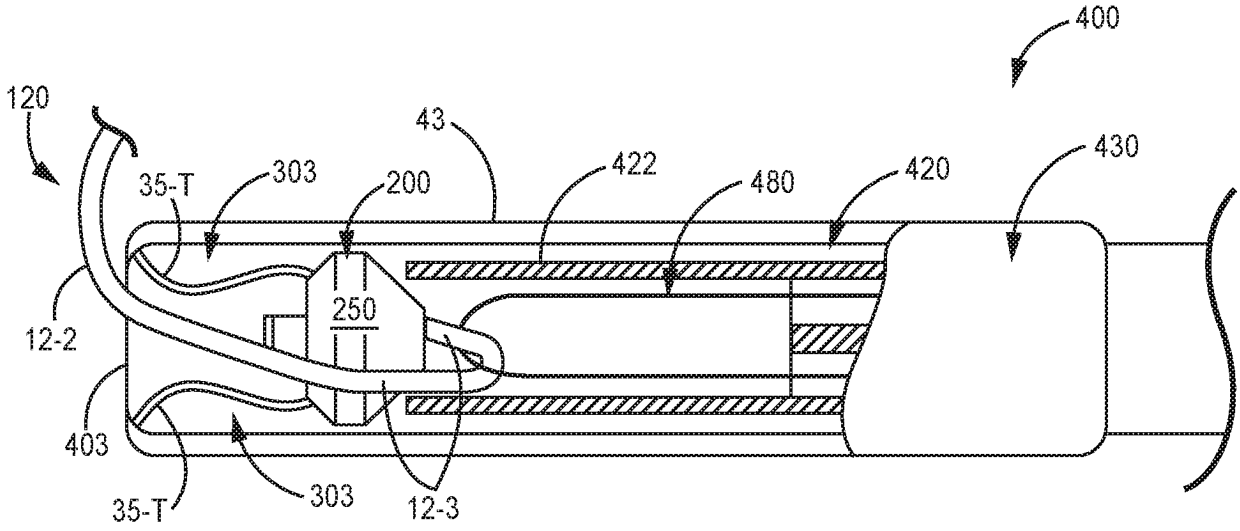

FIG. 5C

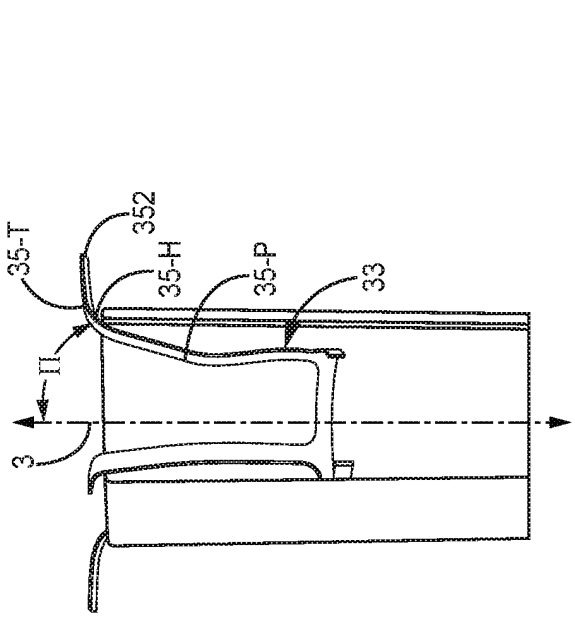

FIG. 6C

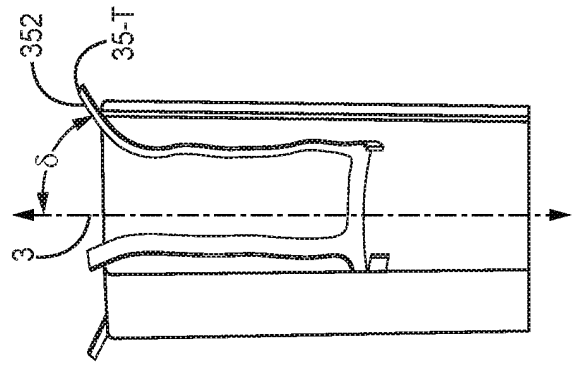

FIG. 6B

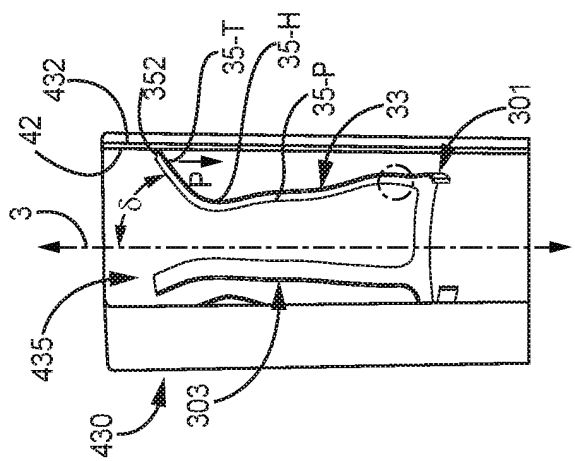

FIG. 6A

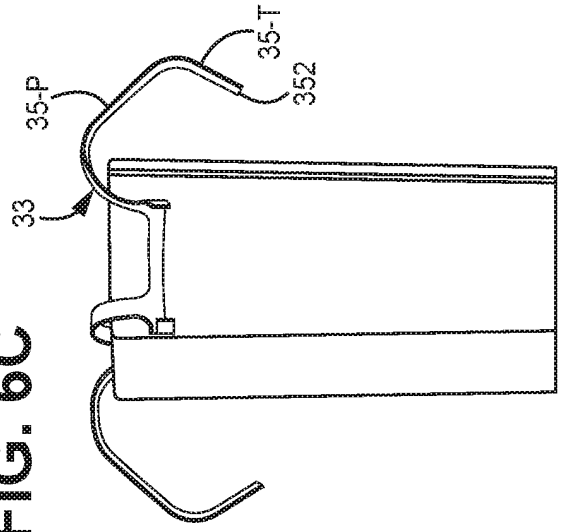

FIG. 6F

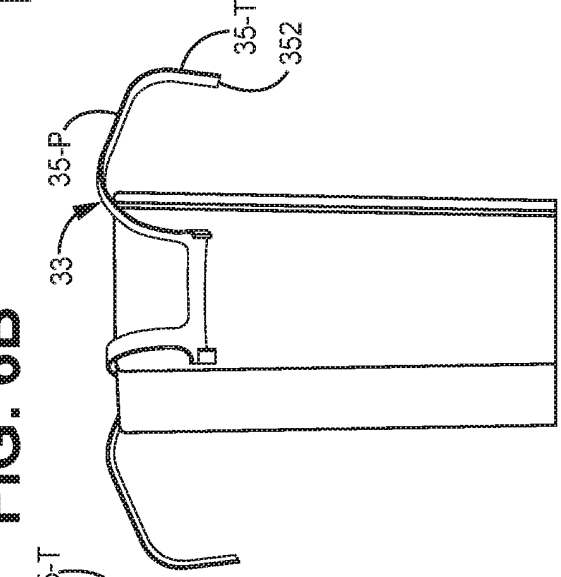

FIG. 6E

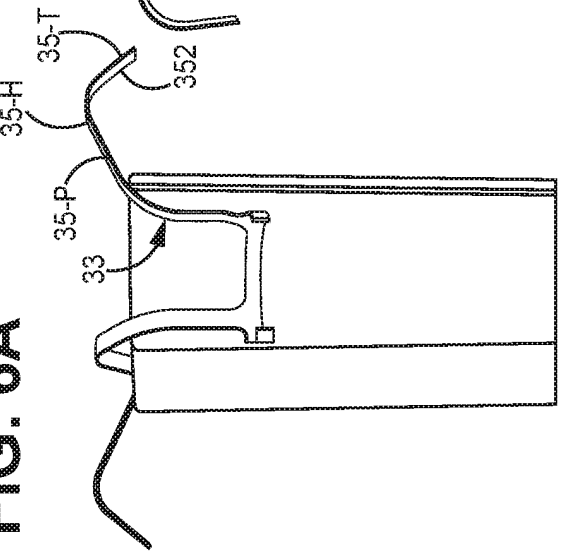

FIG. 6D

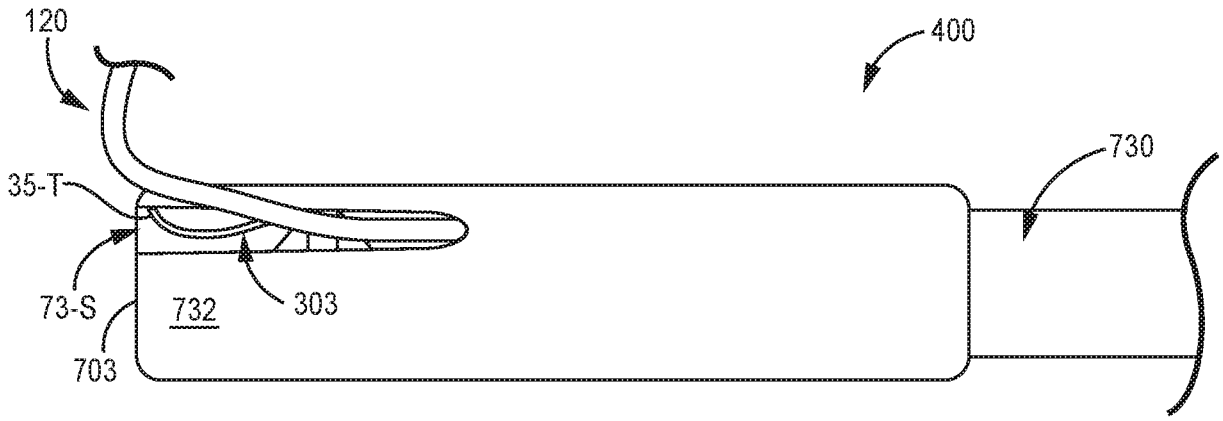
120
400
730
35-T
73-S
732
303
703

FIG. 7A

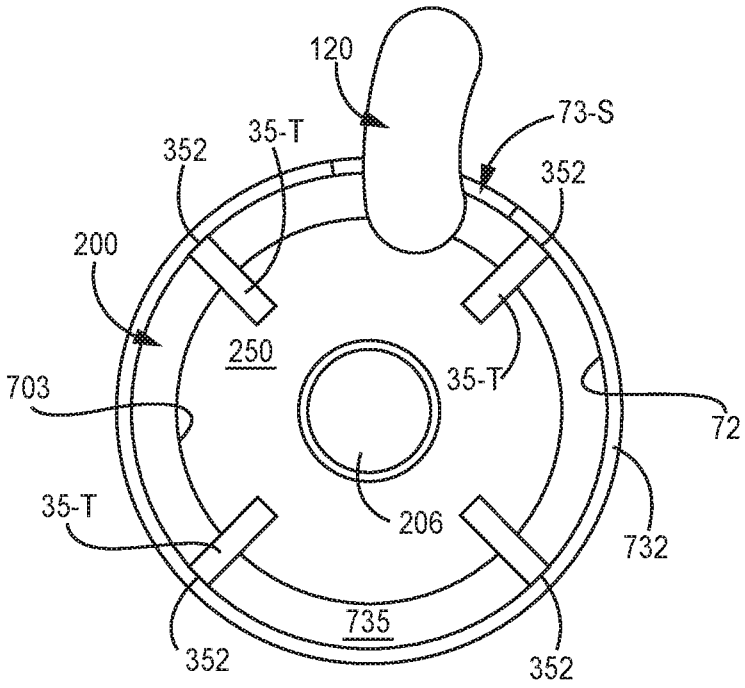
120
73-S
35-T
352
352
200
250
35-T
703
72
35-T
206
732
735
352
352

FIG. 7B

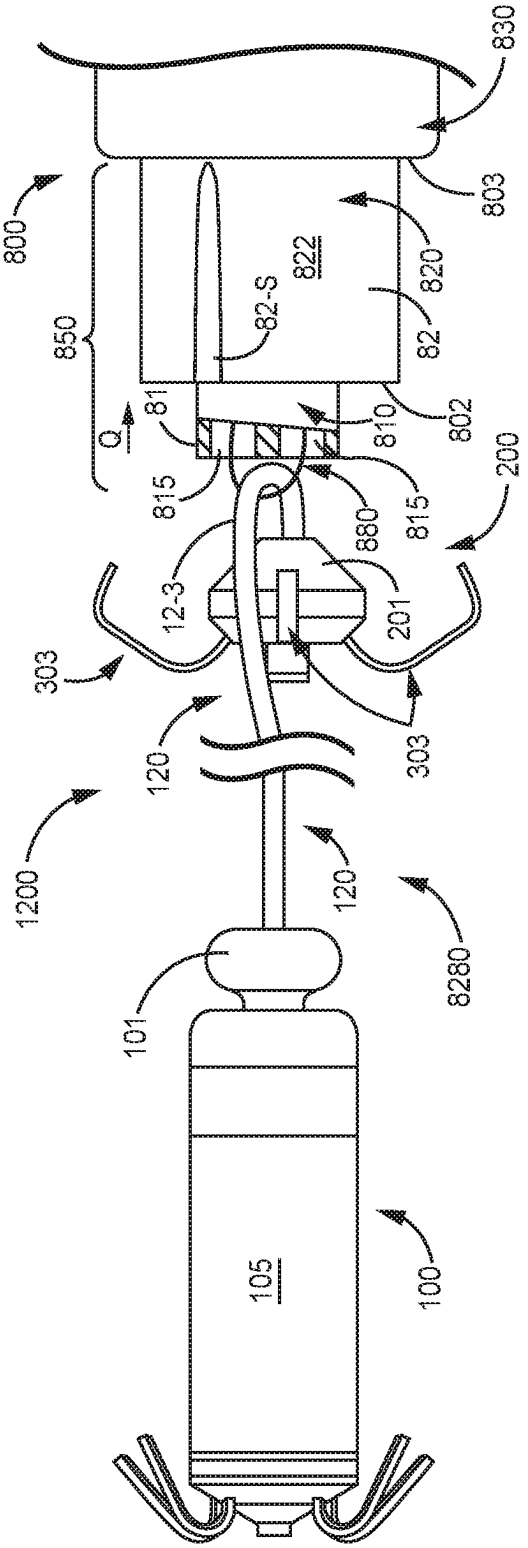

FIG. 8A

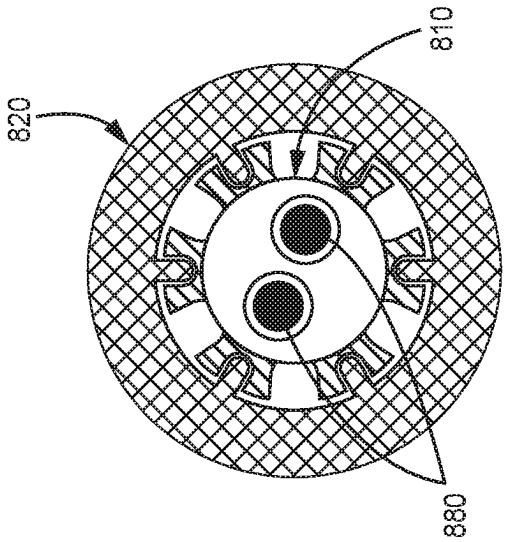

FIG. 8C

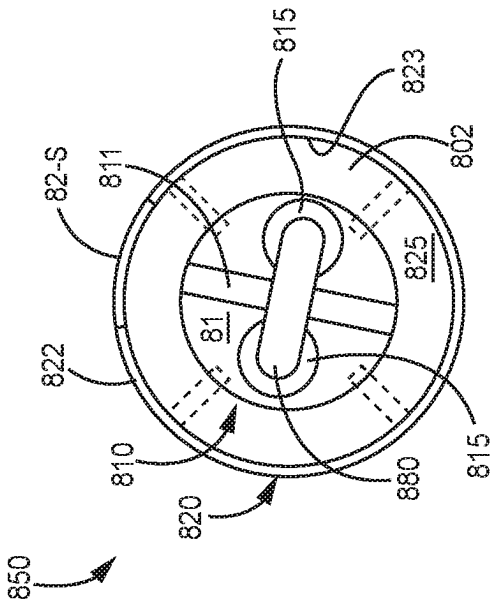

FIG. 8B

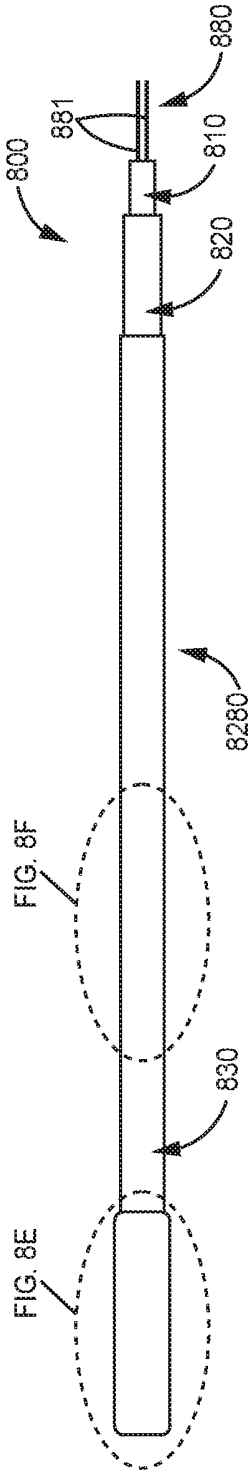

FIG. 8D

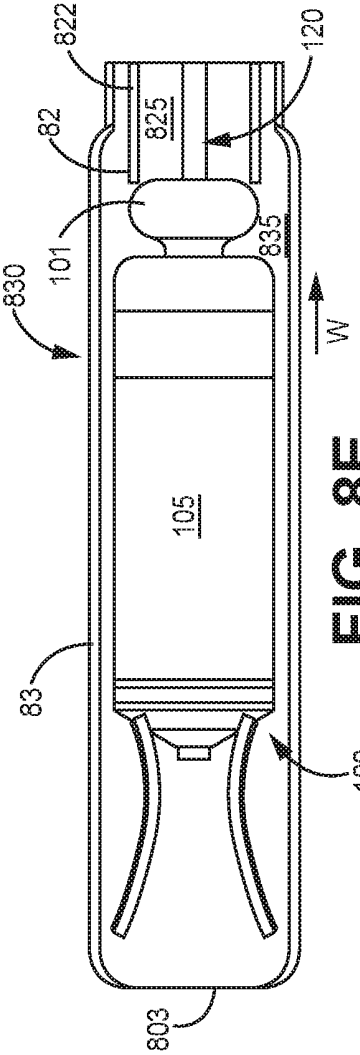

FIG. 8E

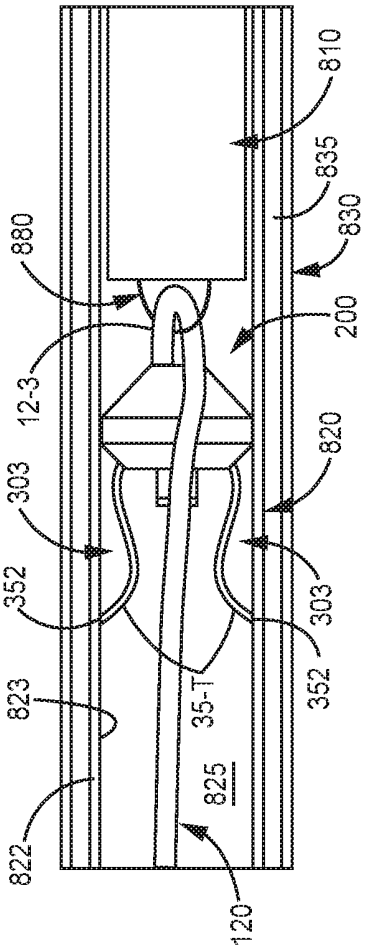

FIG. 8F

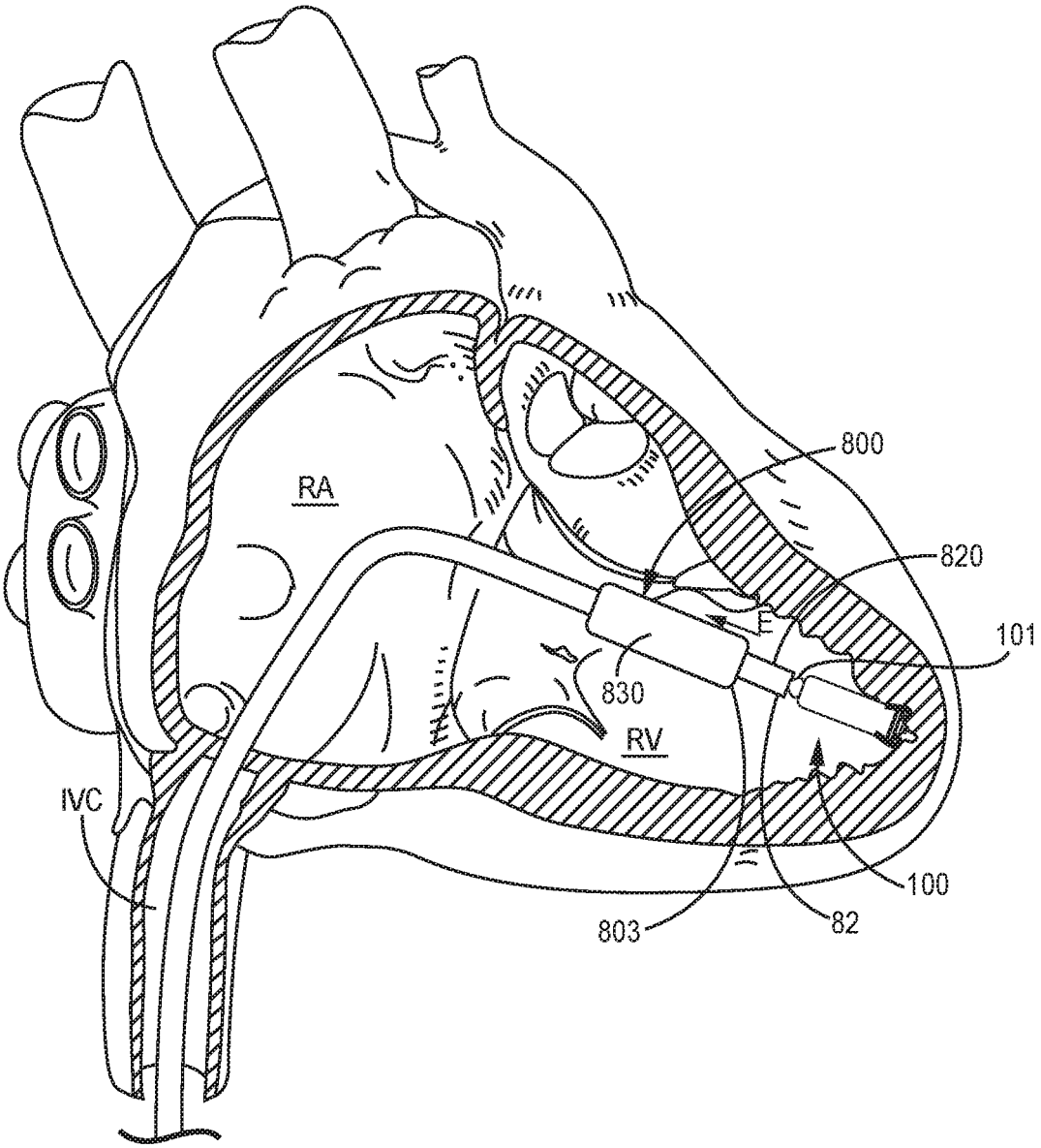

FIG. 9A

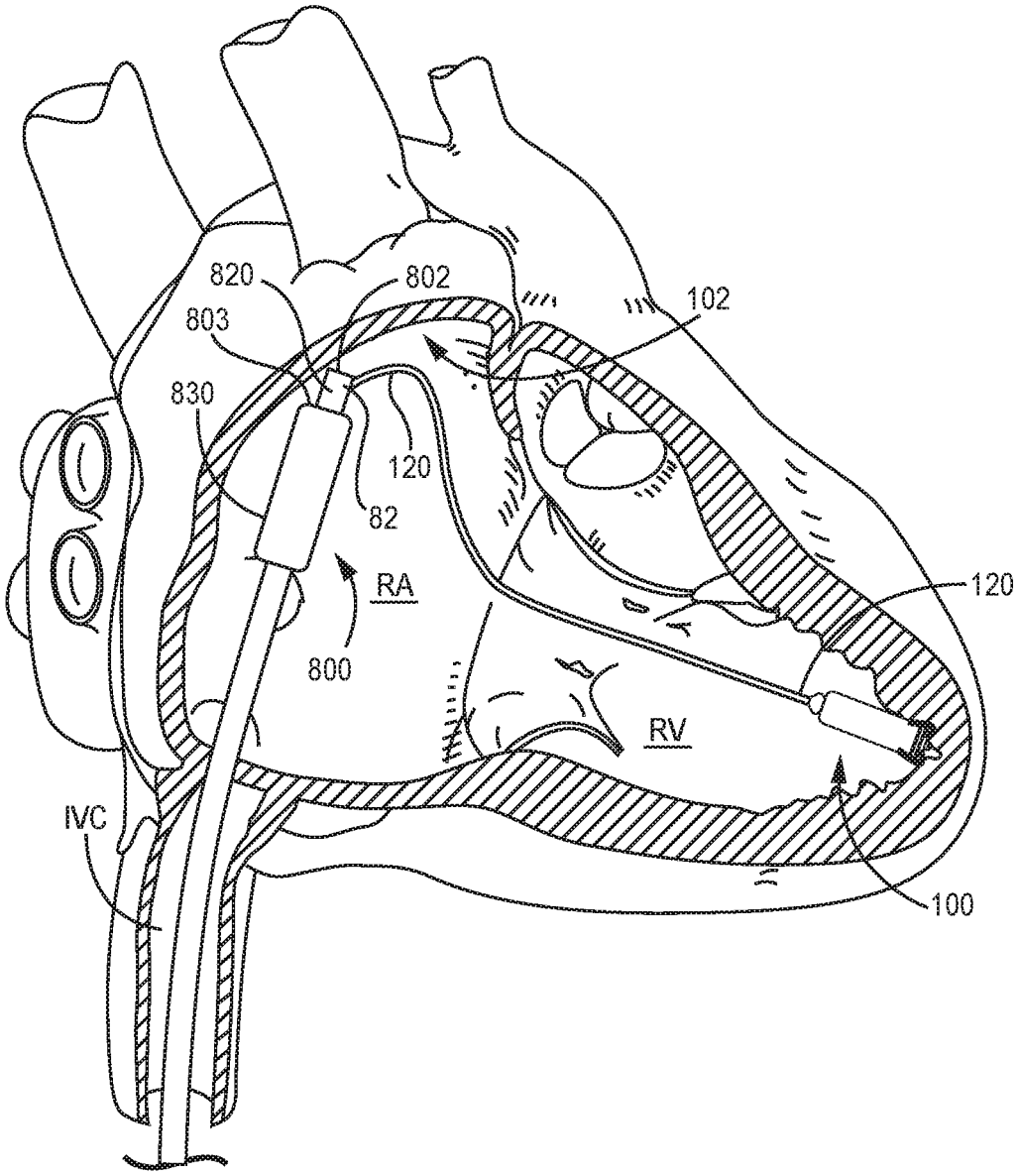

FIG. 9B

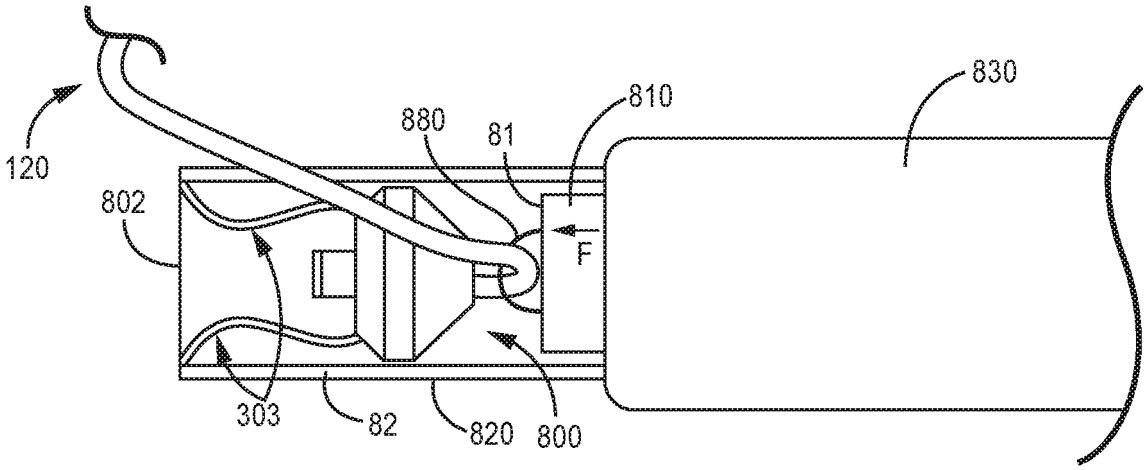

FIG. 9C

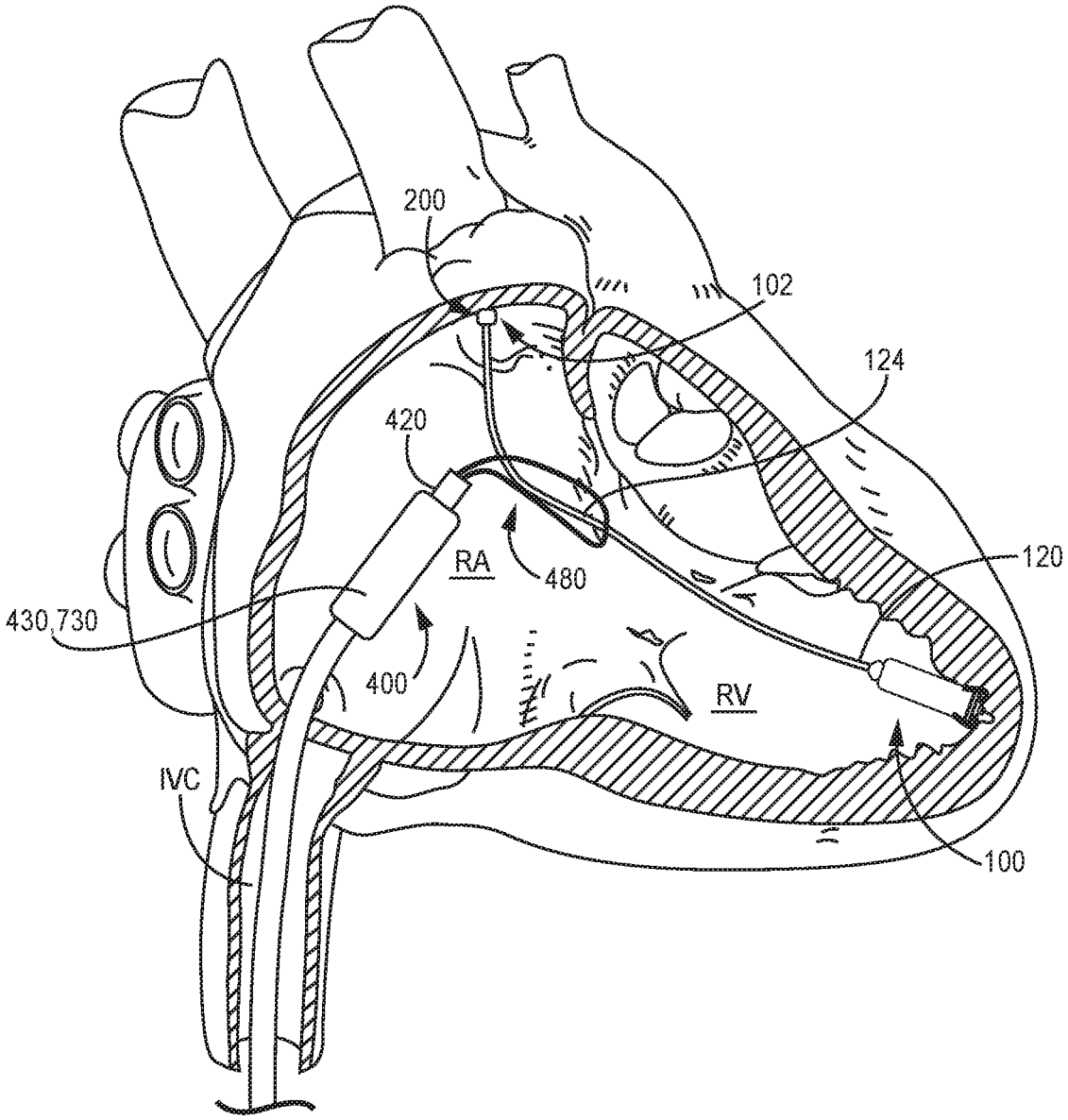

FIG. 10A

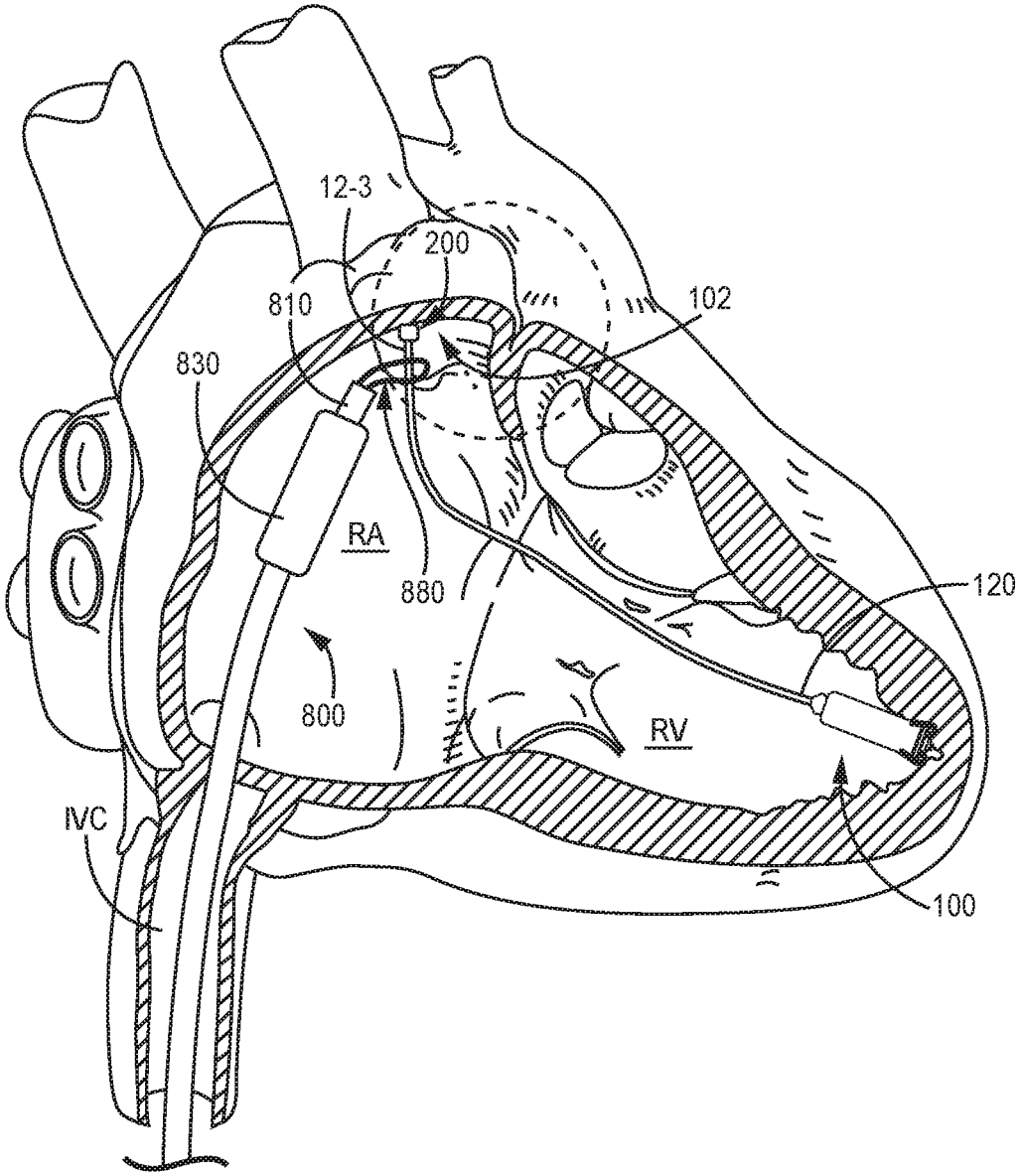

FIG. 10B

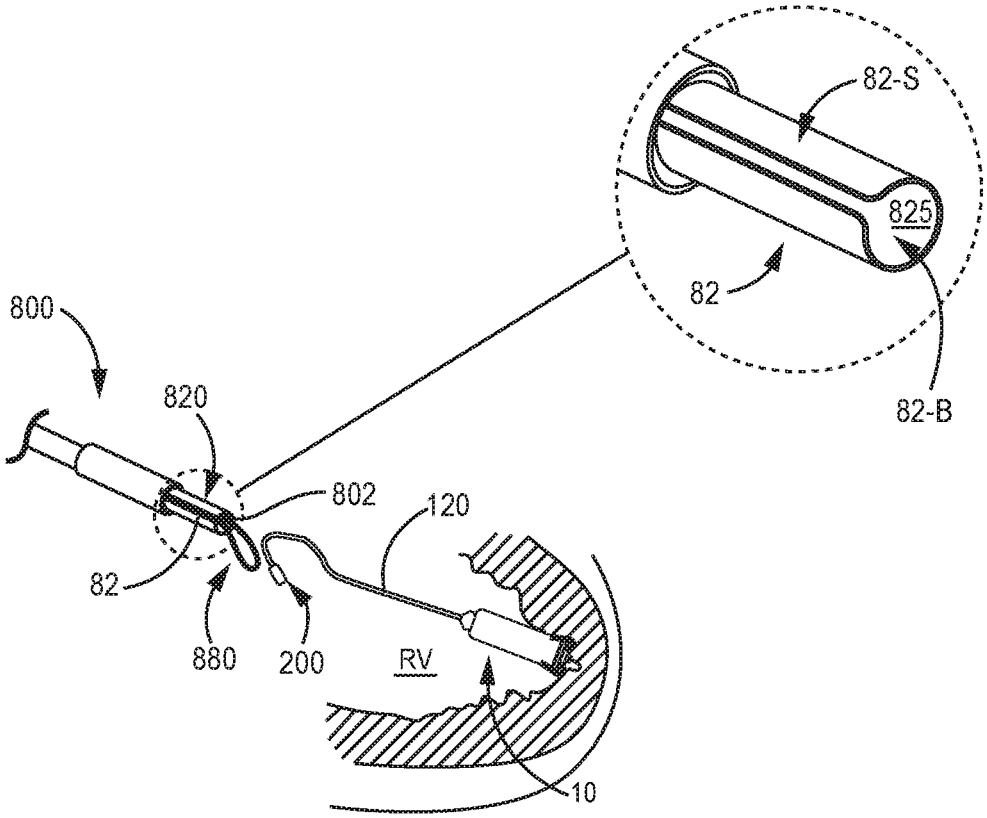

FIG. 11

REFERENCES CITED IN THE DESCRIPTION

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- US 9155882 B **[0008]**
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申请(专利权)人(译)	美敦力公司，INC.		
当前申请(专利权)人(译)	美敦力公司，INC.		
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IPC分类号	A61N1/375 A61N1/05 A61N1/362 A61N1/368 A61N1/372 A61B5/00		
CPC分类号	A61N1/057 A61N1/0573 A61N1/3622 A61N1/3684 A61N1/3688 A61N1/37205 A61N1/3756 A61B5/6882 A61N2001/058		
优先权	62/281312 2016-01-21 US 15/410085 2017-01-19 US		
其他公开文献	EP3405258A1		
外部链接	Espacenet		

摘要(译)

植入式医疗装置包括心室和心房部分，以及在两者之间延伸的柔性引线。沿着心房部分的芯部形成的心房部分的开放通道的尺寸设置成在将心房引线自身折叠时将心房引线容纳在其中。一种介入医疗系统，包括所述装置和递送工具。工具的管状侧壁限定内腔并具有在其中延伸的系绳。形成在侧壁中的狭槽从其开口端向近侧延伸，与内腔的远侧开口重合。当心房部分包含在管腔内时，导线的一部分与心房部分并排延伸。引线的另一部分在自身上折叠，靠近心房部分，使绳索与之接合。当心房部分定位成通过远端开口展开时，狭缝可允许引线穿过其中。

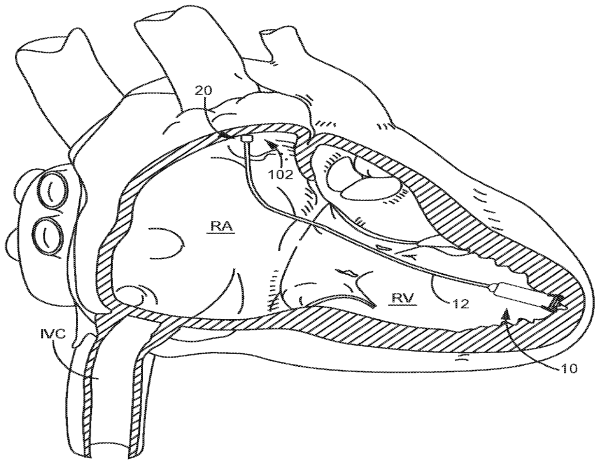

FIG. 1