(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 3 405 252 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent:
26.02.2020 Bulletin 2020/09

(21) Application number: **17702282.9**

(22) Date of filing: **20.01.2017**

(51) Int Cl.:
A61N 1/05 *(2006.01)* ***A61N 1/362*** *(2006.01)*
A61N 1/375 *(2006.01)* ***A61N 1/368*** *(2006.01)*
A61N 1/372 *(2006.01)* ***A61B 5/00*** *(2006.01)*

(86) International application number:
PCT/US2017/014352

(87) International publication number:
WO 2017/127689 (27.07.2017 Gazette 2017/30)

(54) INTERVENTIONAL MEDICAL SYSTEMS

INTERVENTIONELLE MEDIZINISCHE SYSTEME

SYSTÈMES MÉDICAUX D'INTERVENTION

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(30) Priority: **21.01.2016 US 201662281312 P**
19.01.2017 US 201715410085

(43) Date of publication of application:
28.11.2018 Bulletin 2018/48

(73) Proprietor: **Medtronic, Inc.**
Minneapolis, Minnesota 55432 (US)

(72) Inventors:
- **DRAKE, Ronald, A.**
  Minneapolis, MN 55432 (US)
- **CHEN, Xin**
  Minneapolis, MN 55432 (US)
- **EGGEN, Michael, D.**
  Minneapolis, MN 55432 (US)
- **BONNER, Matthew, D.**
  Minneapolis, MN 55432 (US)
- **GRUBAC, Vladimir**
  Minneapolis, MN 55432 (US)
- **COLIN, Brian, P.**
  Minneapolis, MN 55432 (US)
- **GARDESKI, Kenneth, C.**
  Minneapolis, MN 55432 (US)
- **SEIFERT, Kevin, R.**
  Minneapolis, MN 55432 (US)

(74) Representative: **Zimmermann & Partner Patentanwälte mbB**
Postfach 330 920
80069 München (DE)

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Printed by Jouve, 75001 PARIS (FR)

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. US 2013/110127 A1 relates to a multi-piece dual-chamber leadless intra-cardiac medical device. US 2015/039069 A1 relates to a fixation for implantable medical devices. 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.

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 described 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. 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-deformed, 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 (1 inch = 2,54 cm).

[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 engagement 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.

[0030] 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.

[0031] 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.

[0032] 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.

[0033] 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.

[0034] 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.

[0035] 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.

[0036] 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.

Claims

1. An implantable medical device comprising:

   a ventricular portion (100) comprising 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) comprising a core (250) extending from a first end (201) thereof to a second end (202) thereof, along a longitudinal axis (2) of the atrial portion, an atrial electrode (206) mounted in proximity to the second end of the core, a fixation mechanism (300) mounted in proximity to the second end of the core, and an open channel (253) formed along the core, the channel extending between the first and second ends of the core; and
   a flexible leadlet (120) extending from the proximal end of the ventricular portion housing to the first end of the atrial portion core, the leadlet comprising 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 the open channel of the atrial portion being sized to receive the leadlet therein when the leadlet is folded over on itself.

2. The device of claim 1, wherein the flexible leadlet further comprises a radiopaque marker designating a zone (124) along a length of the leadlet for creating a fold in the leadlet to fold the leadlet over on itself.

3. The device of any of claims 1 or 2, wherein the fixation mechanism of the atrial portion comprises a plurality of elastically deformable tines (303) 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 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 section (35-T) 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 (θ) 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, when the atrial portion of the device is loaded within a tubular sidewall (432) of a delivery tool (400), 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 (δ) 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 (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.

4. The device of any of claims 1-3, wherein an intersection between the proximal spring portion and the distal portion of each tine is spaced distally from the second end of the atrial portion core, and the 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 (X) in a range from about 0 mm to about 2 mm.

Patentansprüche

1. 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) umfasst, der in der Nähe des distalen Endes des Gehäuses angebracht ist;

einen Herzvorhofabschnitt (200), der einen Kern (250), der sich von einem ersten Ende (201) davon zu einem zweiten Ende (202) davon entlang einer Längsachse (2) des Herzvorhofabschnitts erstreckt, eine Herzvorhofelektrode (206), die in der Nähe des zweiten Endes des Kerns angebracht ist, einen Befestigungsmechanismus (300), der in der Nähe des zweiten Endes des Kerns angebracht ist, und einen offenen Kanal (253) umfasst, der entlang des Kerns ausgebildet ist, wobei sich der Kanal zwischen dem ersten und zweiten Ende des Kerns erstreckt; und

ein flexibles Leadlet (120), das sich von dem proximalen Ende des Gehäuses des ventrikulären Abschnitts

zu dem ersten Ende des Herzvorhofabschnittkerns erstreckt, wobei das Leadlet einen Leiter (122) und ein isolierendes rohrförmiges Element (121) umfasst, in dem sich der Leiter erstreckt, wobei der Leiter mit der Herzvorhofelektrode des Herzvorhofabschnittes gekoppelt ist, und der offene Kanal des Herzvorhofabschnitts bemessen ist, um das Leadlet darin aufzunehmen, wenn das Leadlet auf sich selbst gefaltet wird.

2. Vorrichtung nach Anspruch 1, wobei das flexible Leadlet ferner einen strahlungsundurchlässigen Markierer umfasst, der eine Zone (124) entlang einer Länge des Leadlets kennzeichnet, um eine Falte in dem Leadlet zu erzeugen, um das Leadlet auf sich selbst zu falten.

3. Vorrichtung nach einem der Ansprüche 1 oder 2, wobei der Befestigungsmechanismus des Herzvorhofabschnitts mehrere elastisch verformbare Zinken (303) umfasst, 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 Herzvorhofabschnitts verbunden ist und eine federvorgespannte vorausgebildete Wölbung aufweist, wobei sich die vorausgebildete Wölbung in der Nähe des Kerns in einer ersten Richtung (d1) erstreckt, die im Allgemeinen parallel zu der Achse des Herzvorhofabschnitts ist, und dann seitlich von der Achse nach außen schwenkt; und einen distalen Abschnitt (35) einschließlich eines proximalen Teilstücks (35-P), eines Hakenteilstücks (35-H), und

eines Spitzenteilstück (35-T), das durch ein abgerundetes freies distales Ende (352) beendet wird, wobei sich das proximale Teilstück von dem proximalen Federabschnitt erstreckt und vorausgebildet ist, um sich in einer zweiten Richtung (d2) und entlang einer relativ geraden Linie zu dem Hakenteilstück zu erstrecken, wobei das proximale Teilstück durch die federvorgespannte vorausgebildete Wölbung des proximalen Federabschnitts derart ausgerichtet ist, dass die zweite Richtung im Allgemeinen entgegen der ersten Richtung ist und die relativ gerade Linie die Achse in einem spitzen Winkel (θ) zwischen etwa 30 Grad und etwa 50 Grad schneidet, wobei das Hakenteilstück eine verformbare vorausgebildete Wölbung aufweist, die sich von dem proximalen Teilstück zurück in Richtung der Achse des Herzvorhofabschnitts erstreckt, wobei das Spitzenteilstück vorausgebildet ist, um sich entlang einer relativ geraden Linie von dem Hakenteilstück bis zu dem abgerundeten freien distalen Ende zu erstrecken, und wobei das Spitzenteilstück durch die vorausgebildete Wölbung des Hakenteilstücks, wenn es nicht verformt ist, ausgerichtet ist, um sich in Richtung der Achse des Herzvorhofabschnitts derart zu erstrecken, dass das Spitzenteilstück und das proximale Teilstück einen Winkel (φ) in einem Bereich von etwa 90 Grad bis etwa 120 Grad umschließen; und

wobei, wenn der Herzvorhofabschnitt der Vorrichtung innerhalb einer rohrförmigen Seitenwand (432) eines Abgabewerkzeugs (400) derart belastet wird, dass das abgerundete freie distale Ende jedes Zinken eine innere Oberfläche der Seitenwand in Eingriff nimmt, um den proximalen Federabschnitt jedes Zinken in einem federbelasteten Zustand zu halten, wobei sich jedes Spitzenteilstück des distalen Abschnitts von der Achse des Herzvorhofabschnitts in einem spitzen Winkel (δ) in einem Bereich von etwa 45 Grad bis etwa 75 Grad weg erstreckt, um das entsprechende abgerundete freie distale Ende aus der rohrförmigen Seitenwand des Werkzeugs herauszufahren; und

wobei bei dem Ausfahren des abgerundeten freien distalen Endes jedes Zinken, sich das Spitzenteilstück jedes distalen Abschnitts von der Achse weg dreht, um einen Winkel (π) von 90 Grad, bezogen auf die Achse, als Reaktion auf eine anfängliche Freigabe des federbelasteten Zustands des entsprechenden proximalen Federabschnitts anzunähern.

4. Vorrichtung nach einem der Ansprüche 1-3, wobei ein Schnittpunkt zwischen dem proximalen Federabschnitt und dem distalen Abschnitt jedes Zinken distal von dem zweiten Ende des Herzvorhofabschnittskerns beabstandet ist, und die Herzvorhofelektrode mit dem Schnittpunkt zwischen dem proximalen Federabschnitt und dem distalen Abschnitt jedes Zinken um einen Abstand (X) in einem Bereich von etwa 0 mm bis etwa 2 mm bündig oder distal von diesem beabstandet ist.

Revendications

1. Dispositif médical implantable comprenant :

une partie ventriculaire (100) comprenant un logement scellé hermétiquement (105) s'étendant d'une extrémité proximale (101) de celle-ci à une extrémité distale de celle-ci, une électrode ventriculaire (106) montée à proximité de l'extrémité distale du logement, et un mécanisme de fixation (103) monté à proximité de l'extrémité distale du logement ;

une partie atriale (200) comprenant un compartiment central (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 (2) de la partie atriale, une électrode atriale (206) montée à proximité de la seconde extrémité du compartiment central, un mécanisme de fixation (300) monté à proximité de la seconde extrémité du compartiment central, et un canal ouvert (253) formé le long du compartiment central, le canal s'étendant entre les première et seconde extrémités du compartiment central ; et

une canule flexible (120) s'étendant à partir de l'extrémité proximale de la partie ventriculaire du logement jusqu'à la première extrémité du compartiment central de la partie atriale, la canule comprenant un conducteur (122) et un élément tubulaire isolant (121) dans lequel s'étend le conducteur, le conducteur étant couplé à l'électrode atriale de la partie atriale, et le canal ouvert de la partie atriale étant dimensionné de façon à recevoir la canule en son sein lorsque la canule est repliée sur elle-même.

2. Dispositif selon la revendication 1, dans lequel la canule flexible comprend en outre un marqueur radioopaque désignant une zone (124) le long d'une longueur de la canule permettant de créer un pli dans la canule pour replier la canule sur elle-même.

3. Dispositif selon l'une quelconque des revendications 1 et 2, dans lequel le mécanisme de fixation de la partie atriale du dispositif comprend une pluralité de dents élastiquement déformables (303) montées fixement au compartiment central et espacées les unes des autres autour d'un périmètre du compartiment central ; et dans lequel chaque dent comprend :

une partie proximale en ressort (33) étant attachée fixement au compartiment central de la partie atriale et présentant une courbure préformée contrainte par ressort, la courbure préformée, à proximité du compartiment central, s'étendant dans une première direction (d1), généralement parallèle à l'axe de la partie atriale, et s'écartant ensuite vers l'extérieur, en balayage latéral, par rapport à l'axe ; et une partie distale (35) comportant une section proximale (35-P), une section crochet (35-H), et
une section pointe (35-T) terminée par une extrémité distale libre arrondie (352), la section proximale s'étendant à partir de la partie proximale en ressort et étant préformée de façon à s'étendre dans une seconde direction (d2) et le long d'une ligne relativement droite jusqu'à la section crochet, la section proximale étant orientée, par la courbure préformée contrainte par ressort de la partie proximale en ressort, de telle sorte que la seconde direction est généralement opposée à la première direction, et que la ligne relativement droite forme une intersection avec l'axe à un angle aigu (θ) compris entre environ 30 degrés et environ 50 degrés, la section crochet présentant une courbure préformée déformable qui s'étend à partir de la section proximale de façon à revenir vers l'axe de la partie atriale, la section pointe étant préformée de façon à s'étendre le long d'une ligne relativement droite allant de la section crochet jusqu'à l'extrémité distale libre arrondie, et la section pointe étant orientée, par la courbure préformée de la section de crochet, dans son état non déformé, de façon à s'étendre vers l'axe de la partie atriale, de telle sorte que la section 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, lorsque la partie atriale du dispositif est chargée à l'intérieur d'une paroi latérale tubulaire (432) d'un outil d'administration (400), de telle sorte que l'extrémité distale libre arrondie de chaque dent vient en prise avec une surface intérieure de la paroi latérale, afin de maintenir la partie proximale en ressort de chaque dent dans un état enclenché du ressort, que chaque section pointe de la partie distale s'étend de façon à s'éloigner de l'axe de la partie atriale selon un angle aigu (δ) compris dans une plage allant d'environ 45 degrés à environ 75 degrés pour le déploiement de l'extrémité distale libre arrondie correspondante vers l'extérieur à partir de la paroi latérale tubulaire de l'outil ; et
lors du déploiement de l'extrémité distale libre arrondie de chaque dent, la section pointe de chaque partie distale pivote de façon à s'éloigner de l'axe pour se rapprocher d'un angle (π) de 90 degrés, relativement à l'axe, en réponse à un relâchement initial de l'état enclenché du ressort de la partie proximale en ressort correspondante.

4. Dispositif selon l'une quelconque de revendications 1 à 3, dans lequel une intersection entre la partie proximale en ressort et la partie distale de chaque dent est espacée distalement de la seconde extrémité du compartiment central de la partie atriale du dispositif, et l'électrode atriale du dispositif affleure l'intersection entre la partie proximale en ressort et la partie distale de chaque dent, ou en est espacée distalement à hauteur d'une distance (X) comprise dans une plage allant d'environ 0 mm à environ 2 mm.

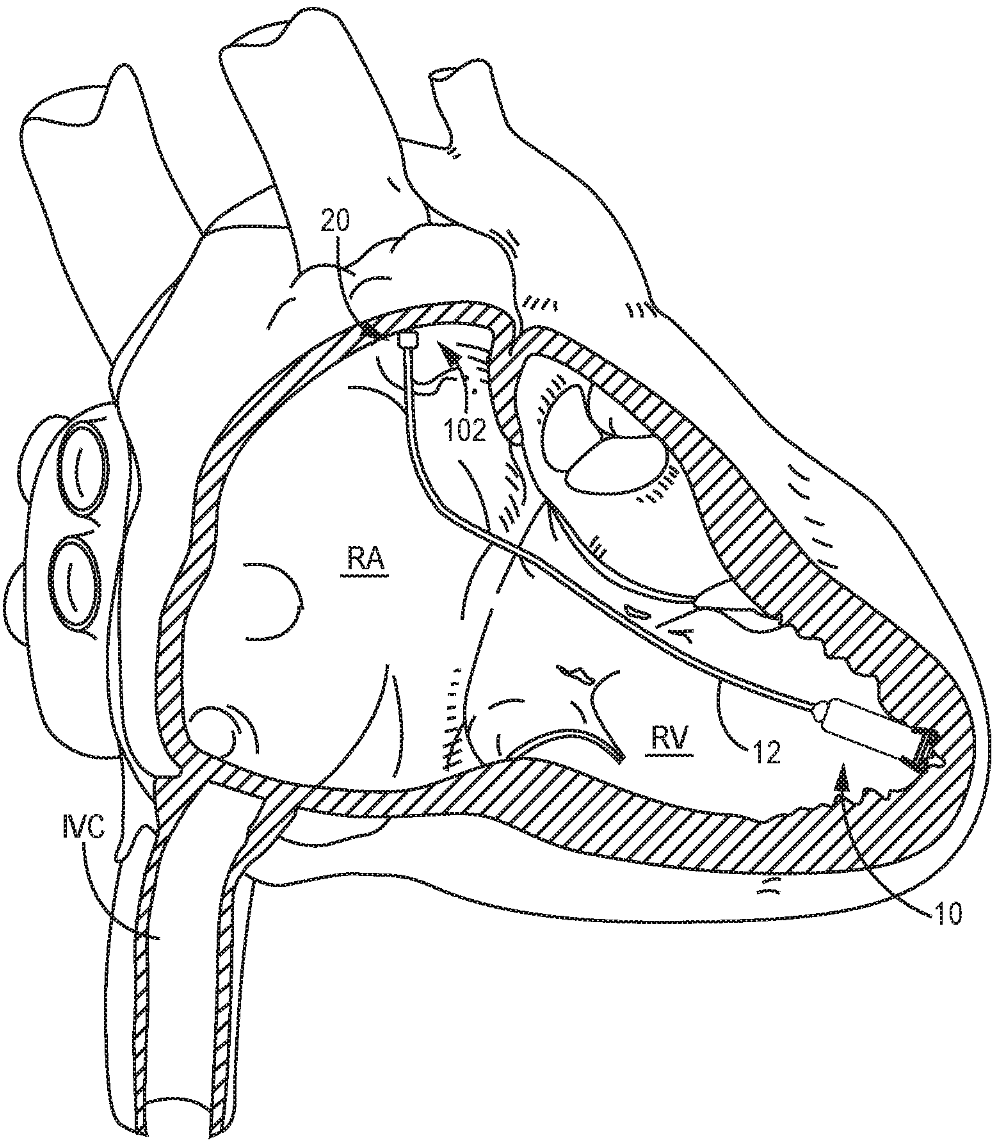
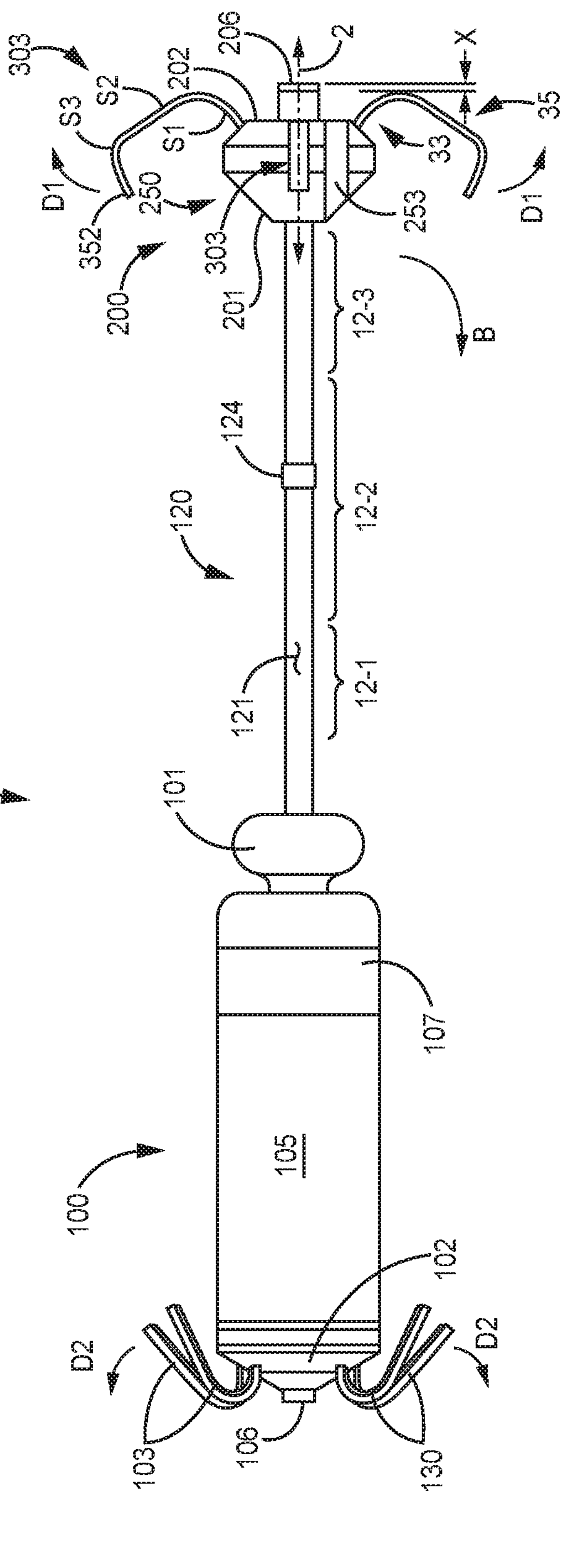


FIG. 1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100
105
107
101
120
121
124
12-1
12-2
12-3
200
201
202
206
2
X
35
33
303
S1
S2
S3
D1
352
250
253
B
D2
102
103
106
130

FIG. 2A

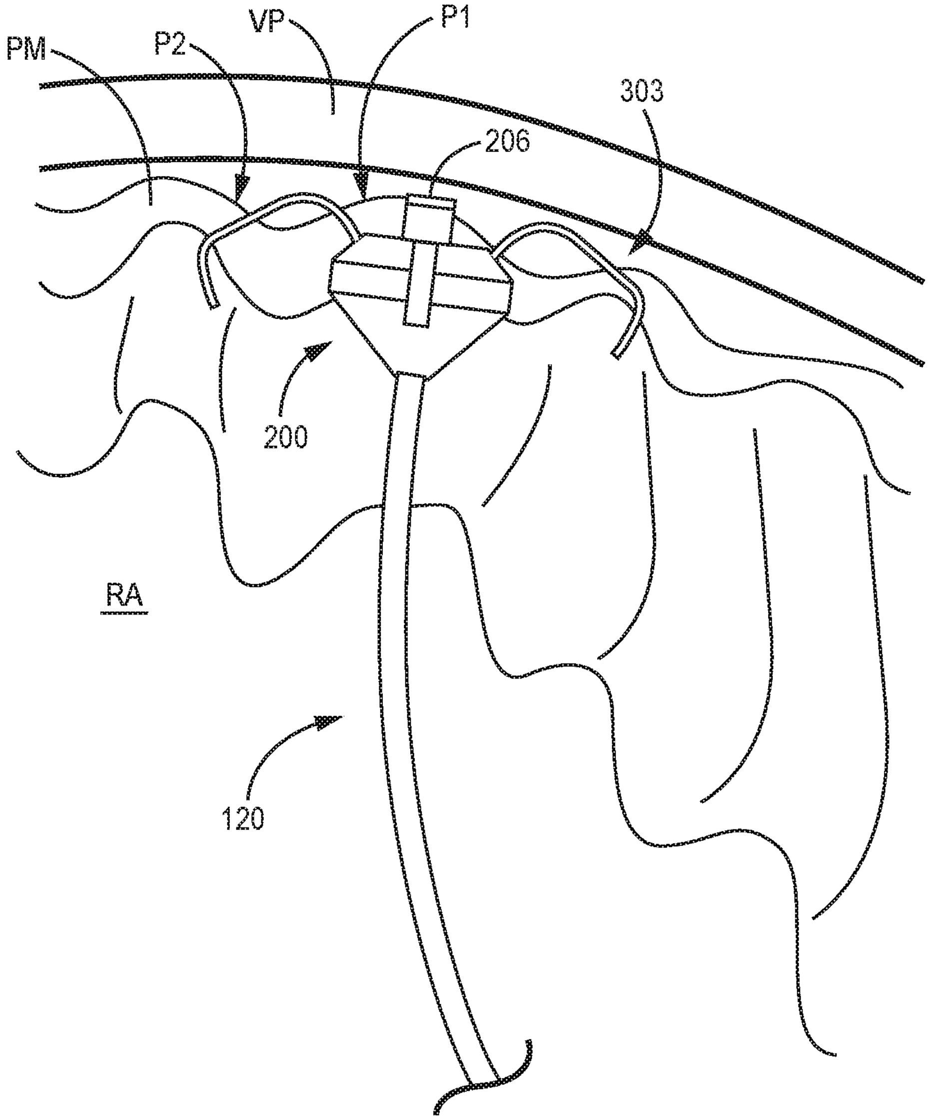


FIG. 2B

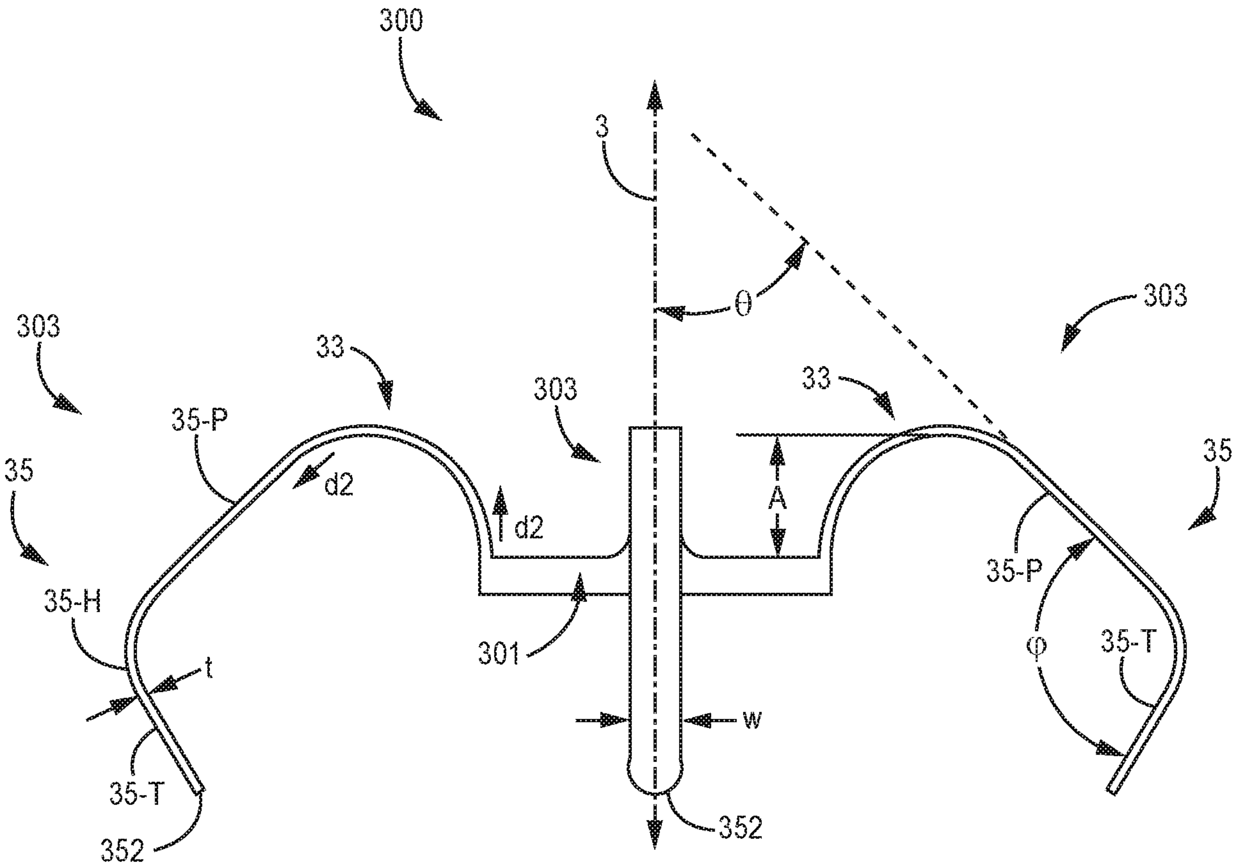

300
3
θ
303
303
33
33
303
35-P
35
35
d2
d2
A
35-P
35-H
301
φ
35-T
t
w
35-T
352
352

FIG. 3A

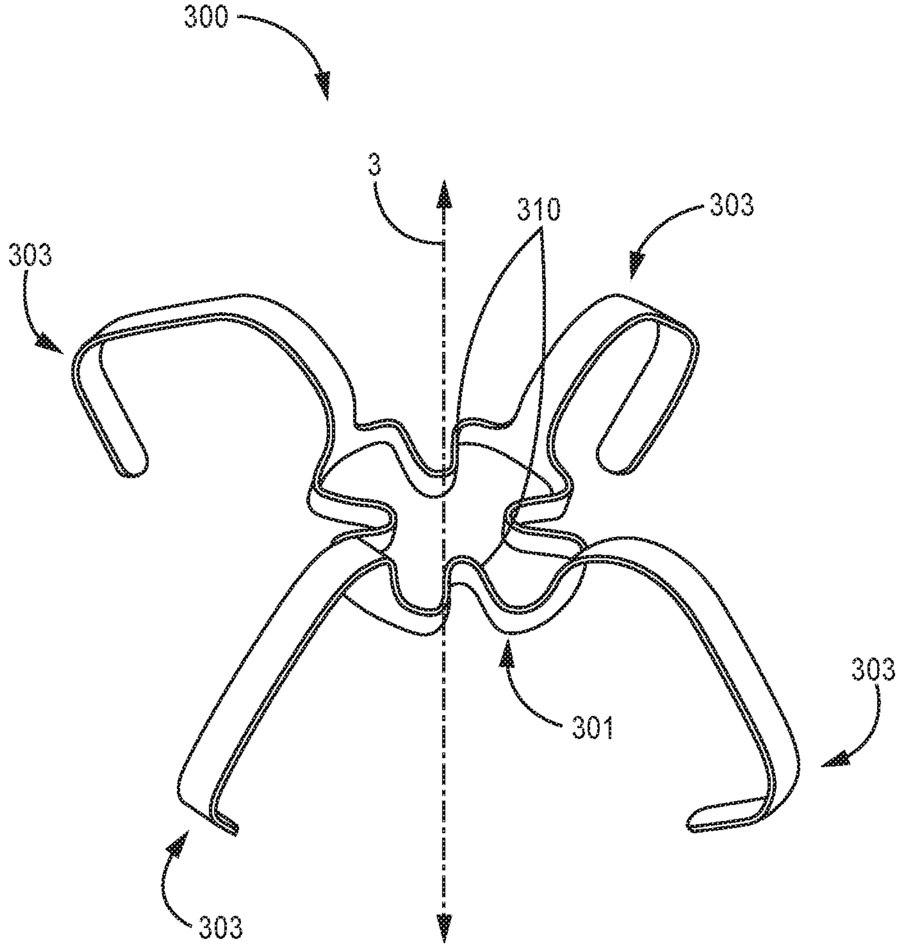
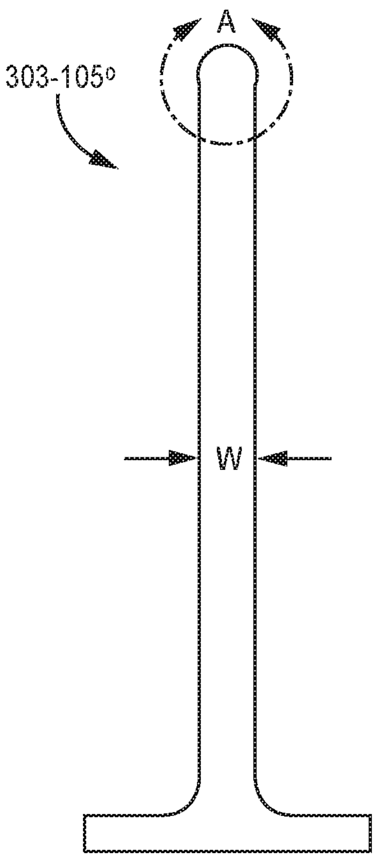
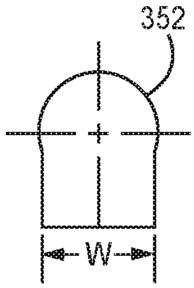


FIG. 3B





DETAIL A

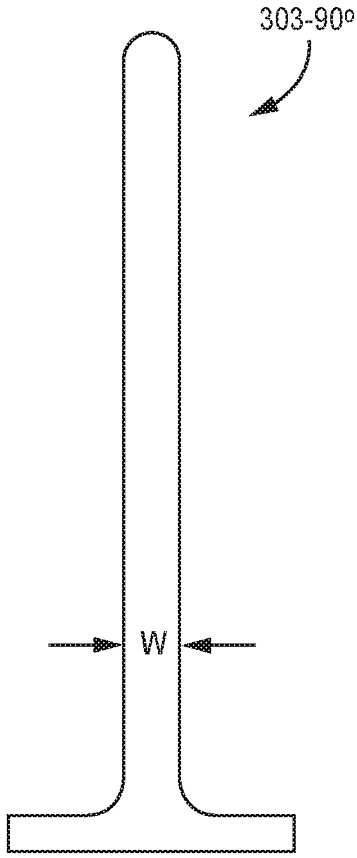


FIG. 3C

FIG. 3D

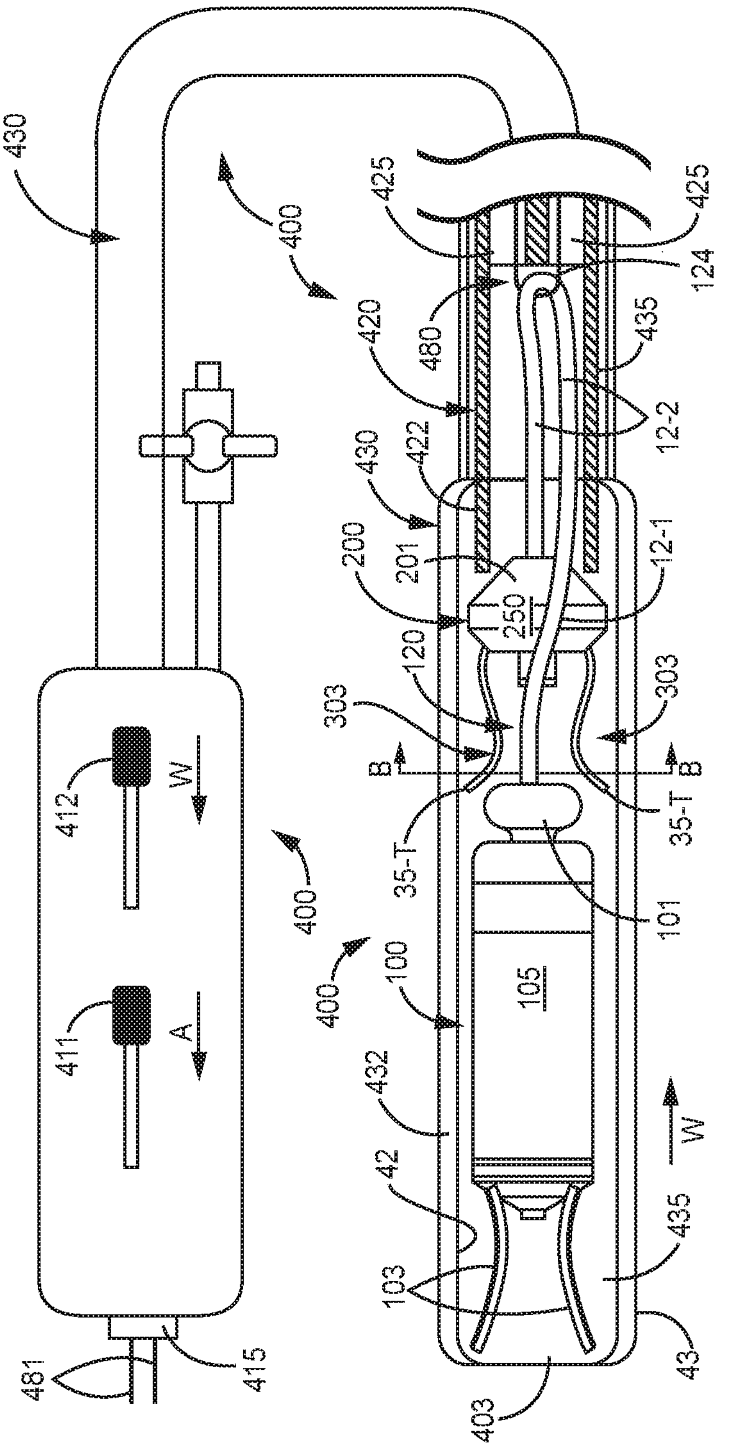

400
430
410
412
W
411
A
481
415
425
124
435
480
420
12-2
422
200
201
250
12-1
120
303
B
35-T
101
100
105
432
42
103
43
403
1240

FIG. 4A

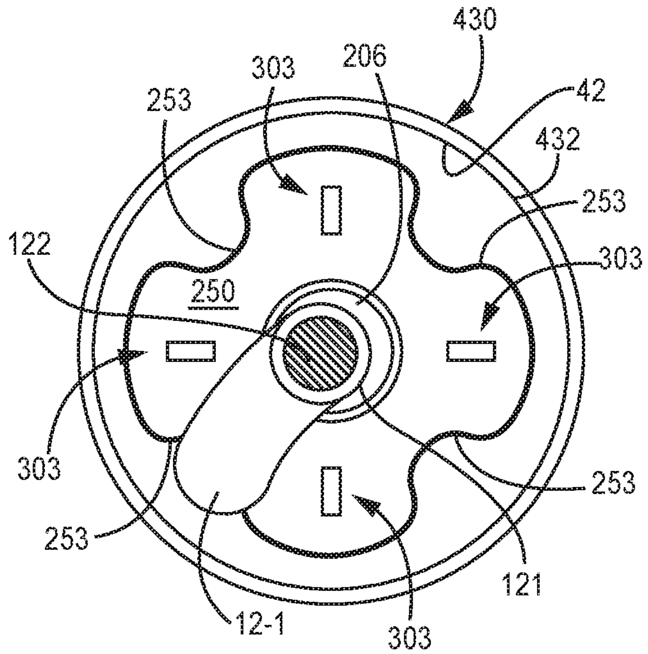


FIG. 4B

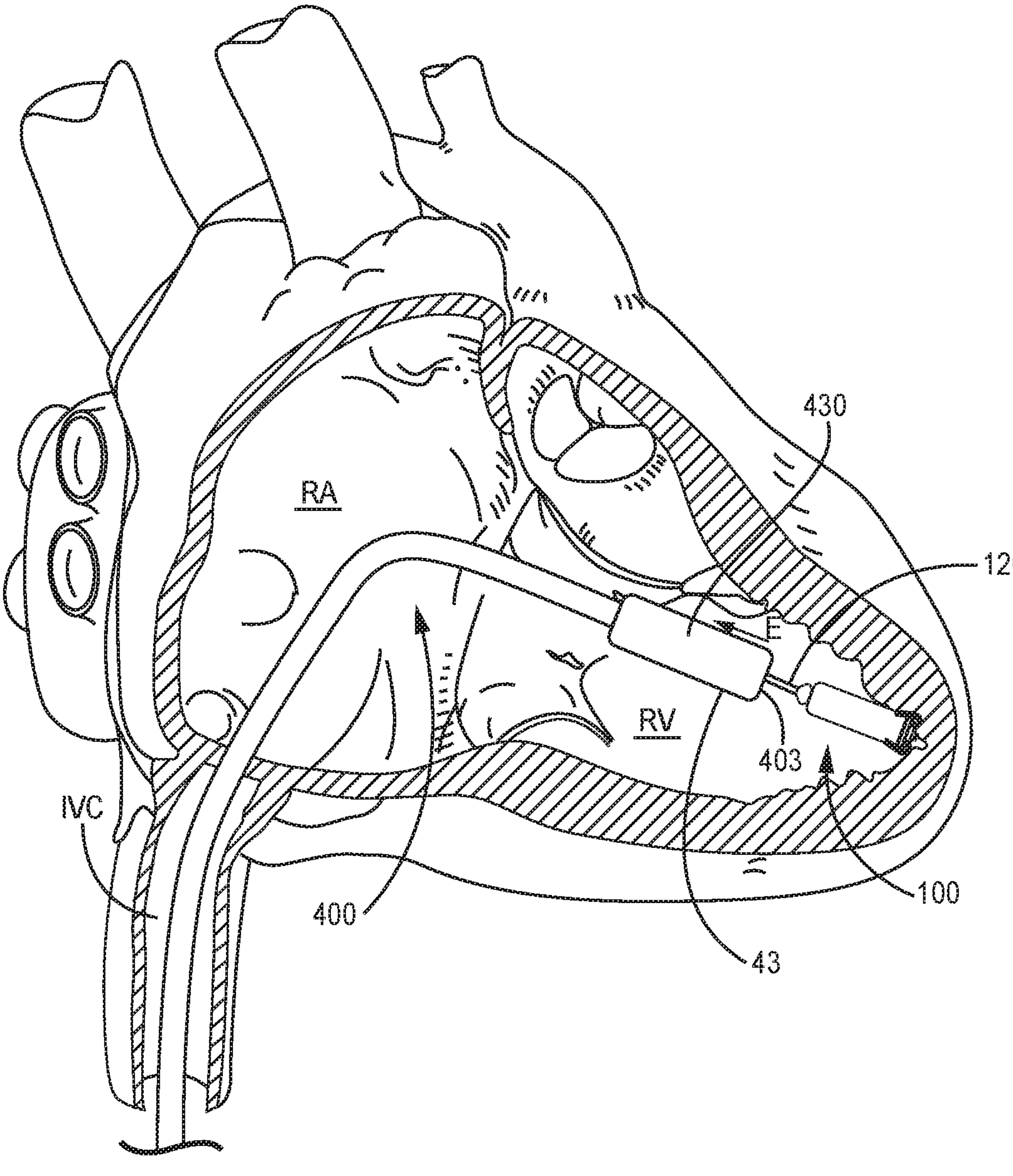


FIG. 5A

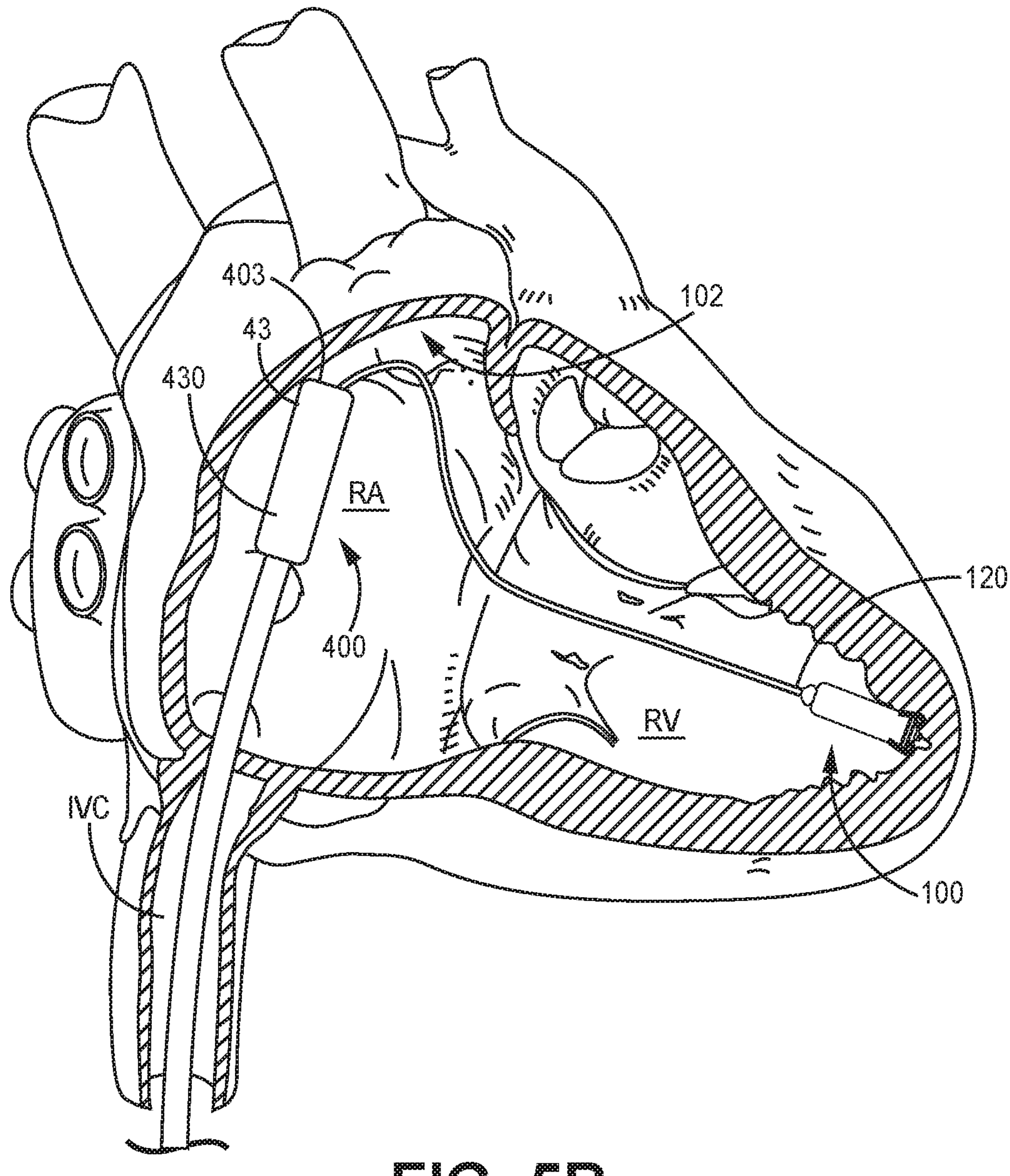


FIG. 5B

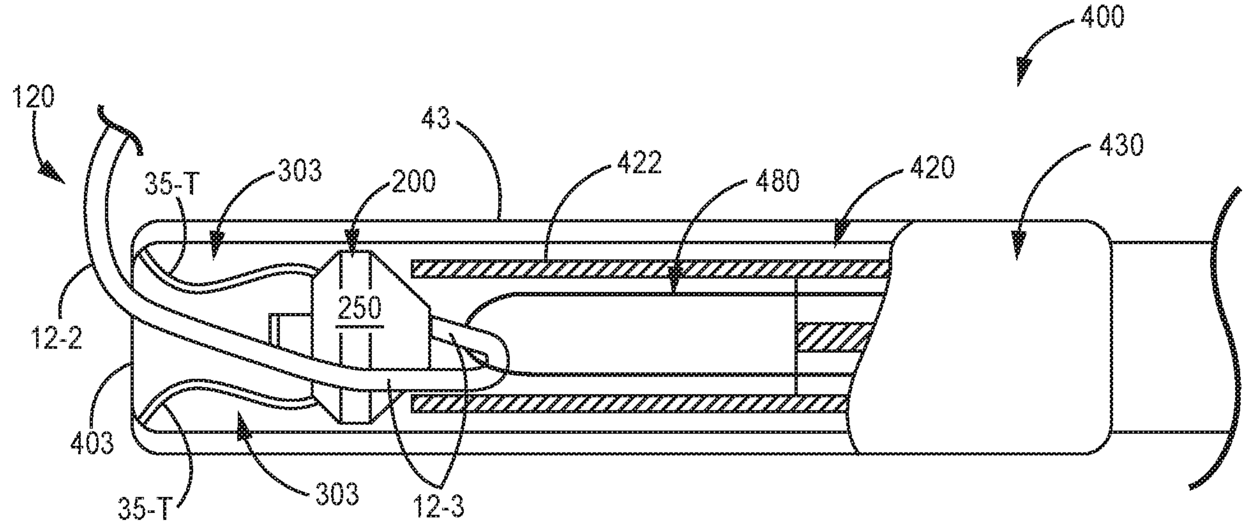


FIG. 5C

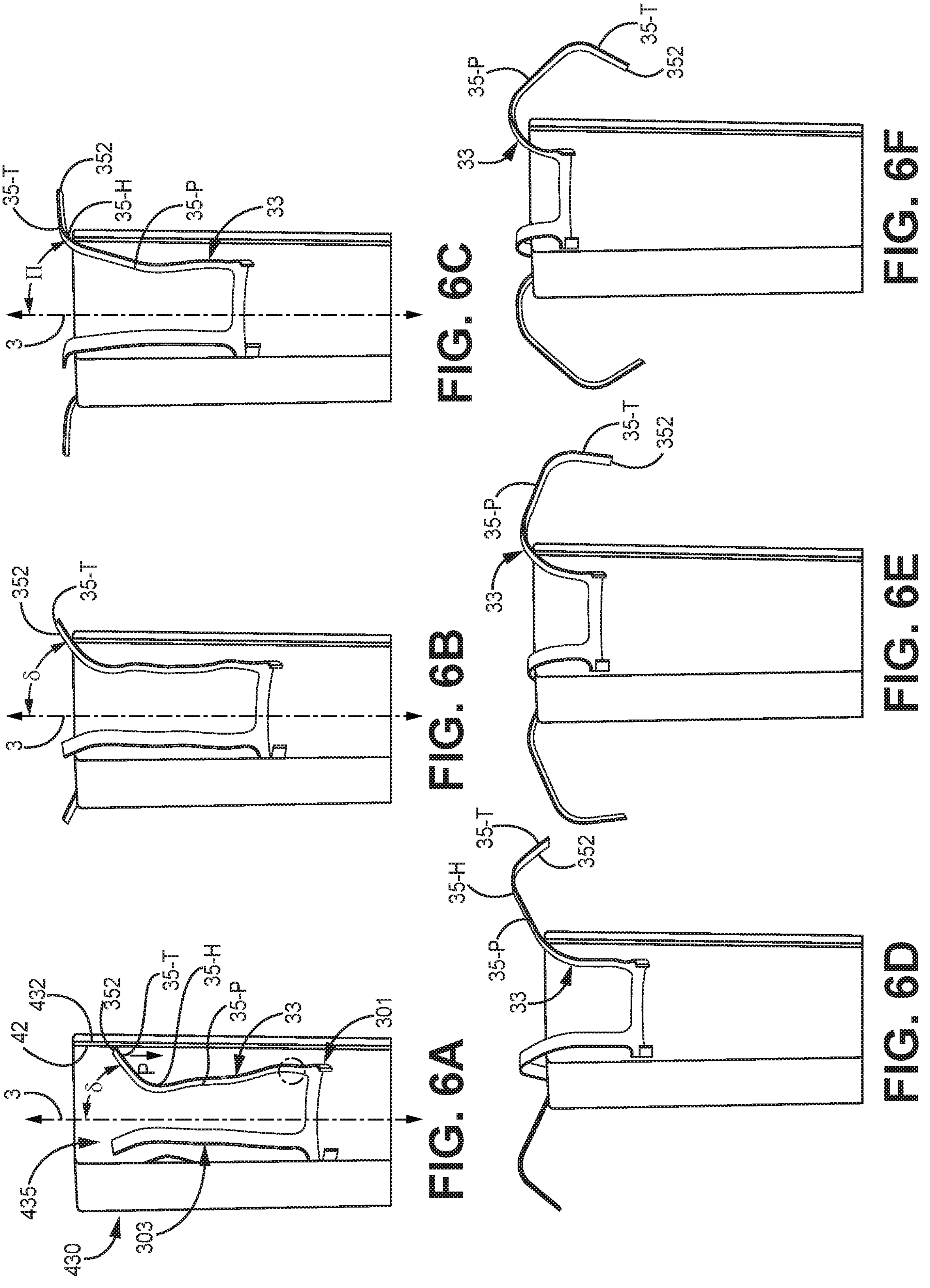


FIG. 6A

FIG. 6B

FIG. 6C

FIG. 6D

FIG. 6E

FIG. 6F

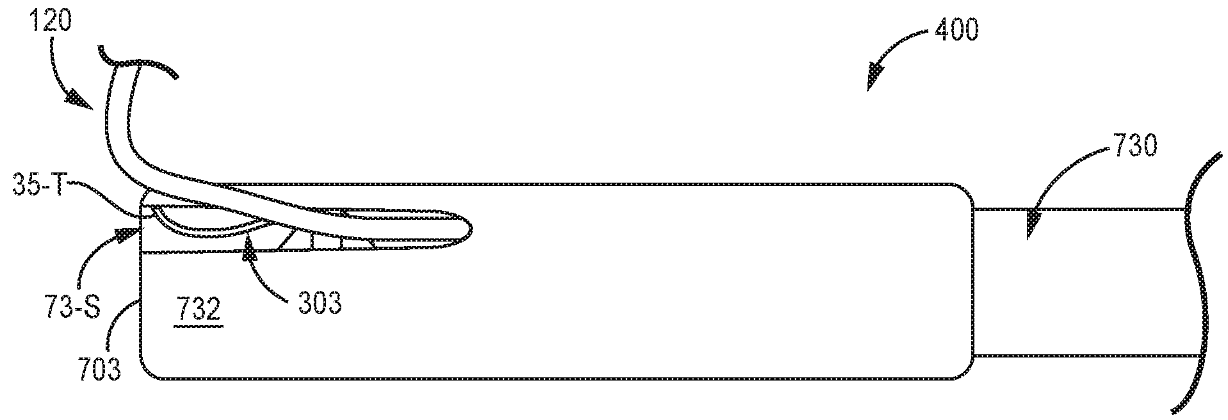

120
400
730
35-T
73-S
732
303
703

FIG. 7A

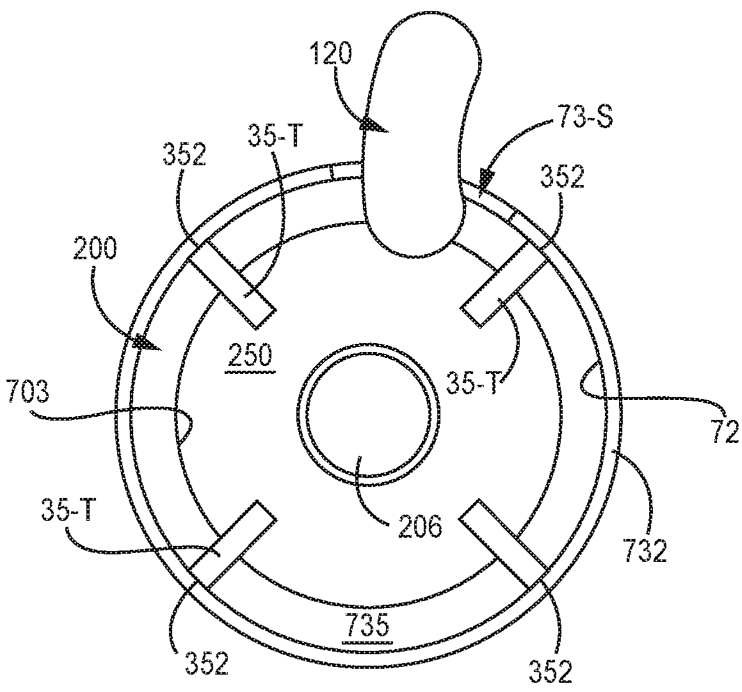

120
73-S
352
35-T
352
200
250
35-T
703
72
35-T
206
732
735
352
352

FIG. 7B

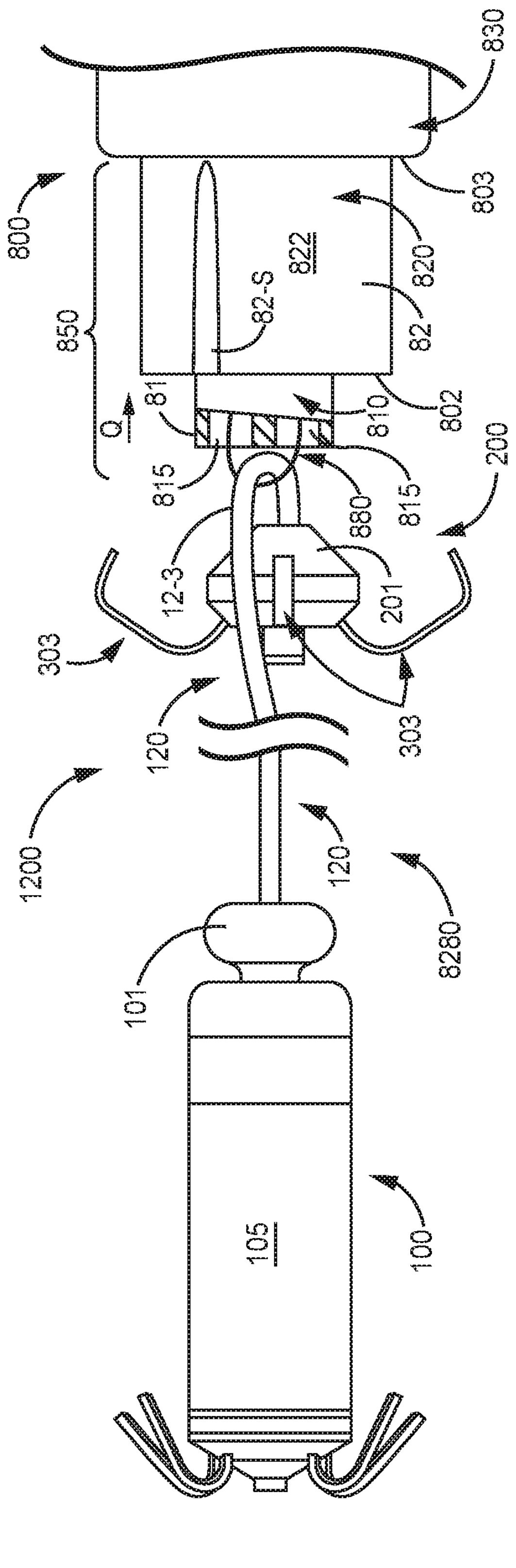


FIG. 8A

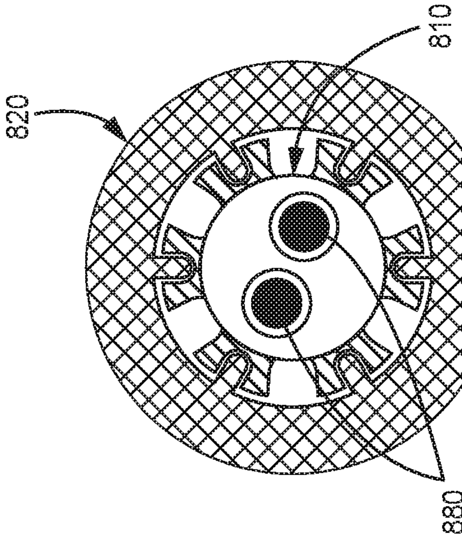


FIG. 8C

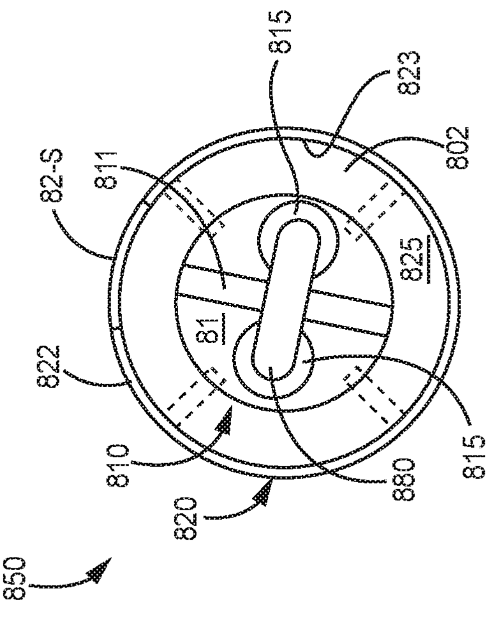


FIG. 8B

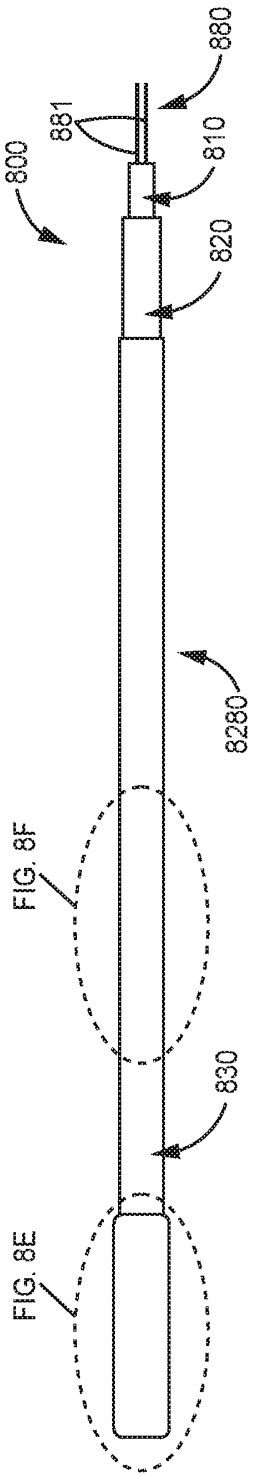


FIG. 8D

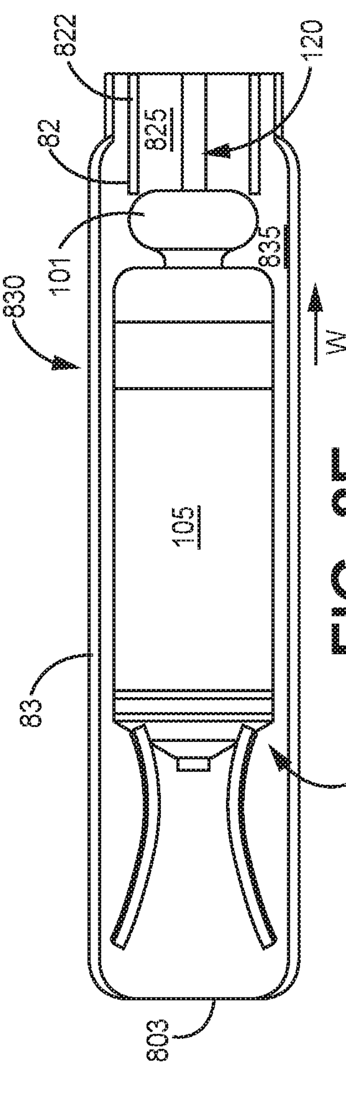


FIG. 8E

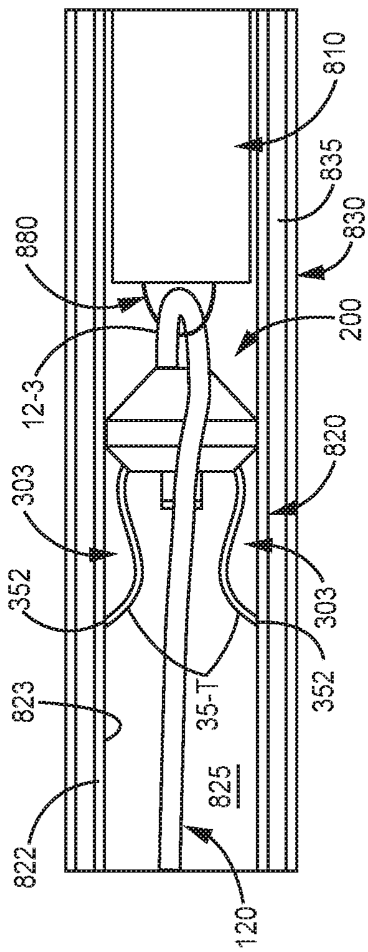


FIG. 8F

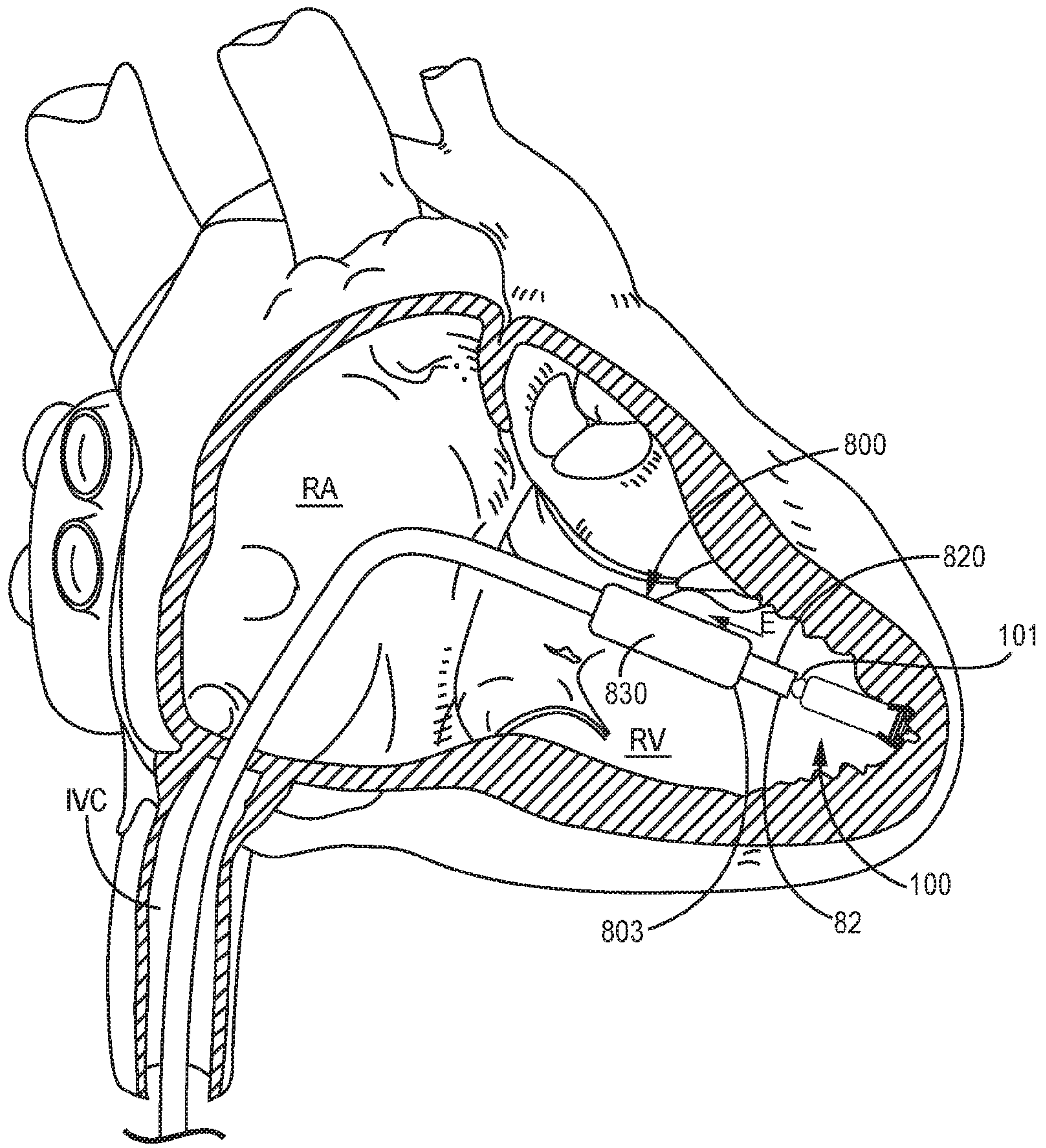


FIG. 9A

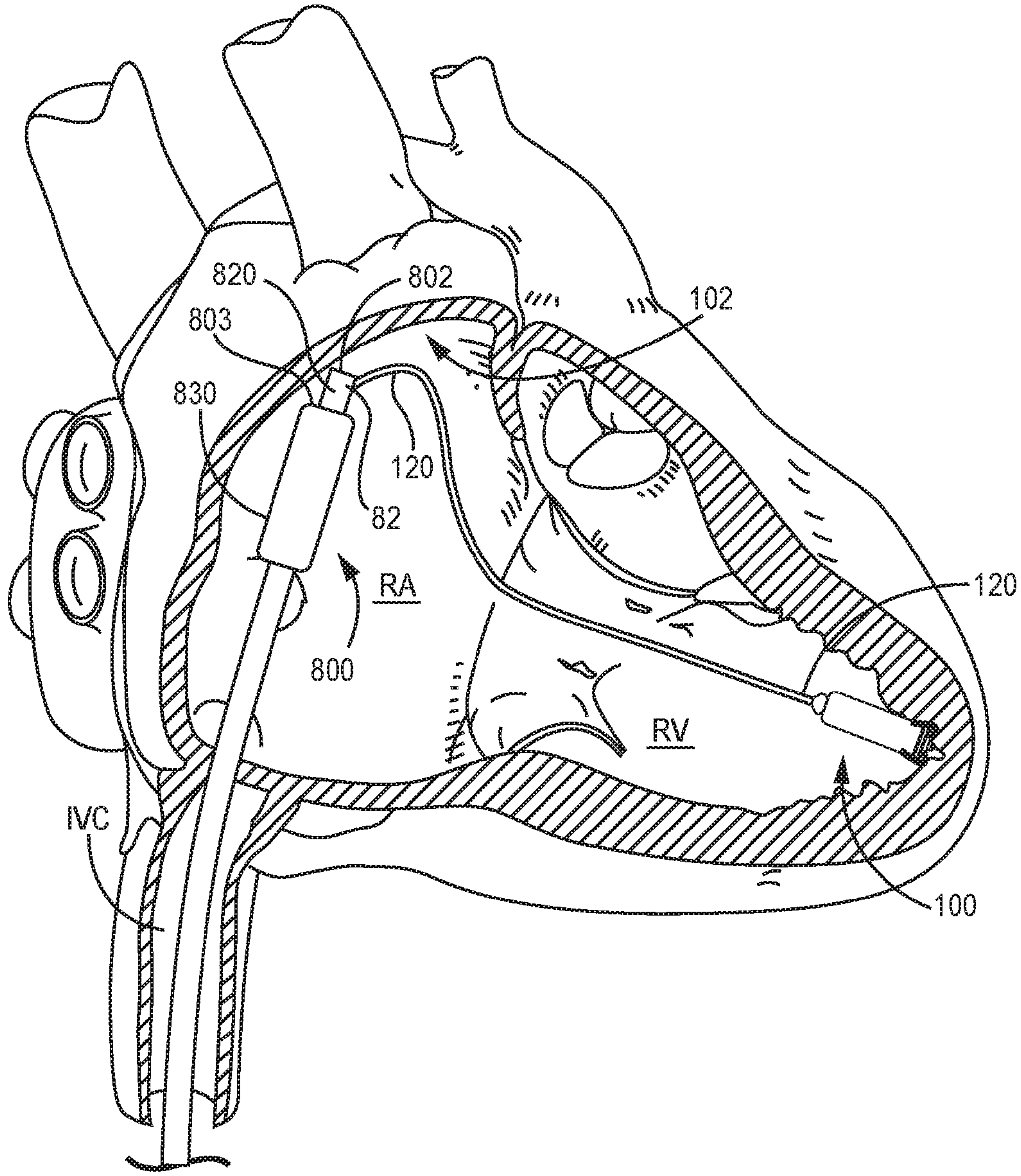


FIG. 9B

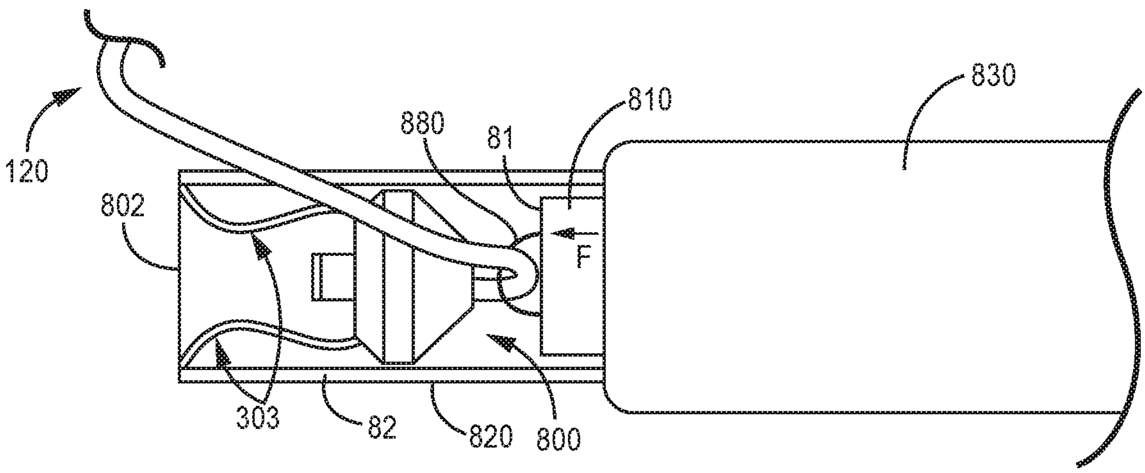


FIG. 9C

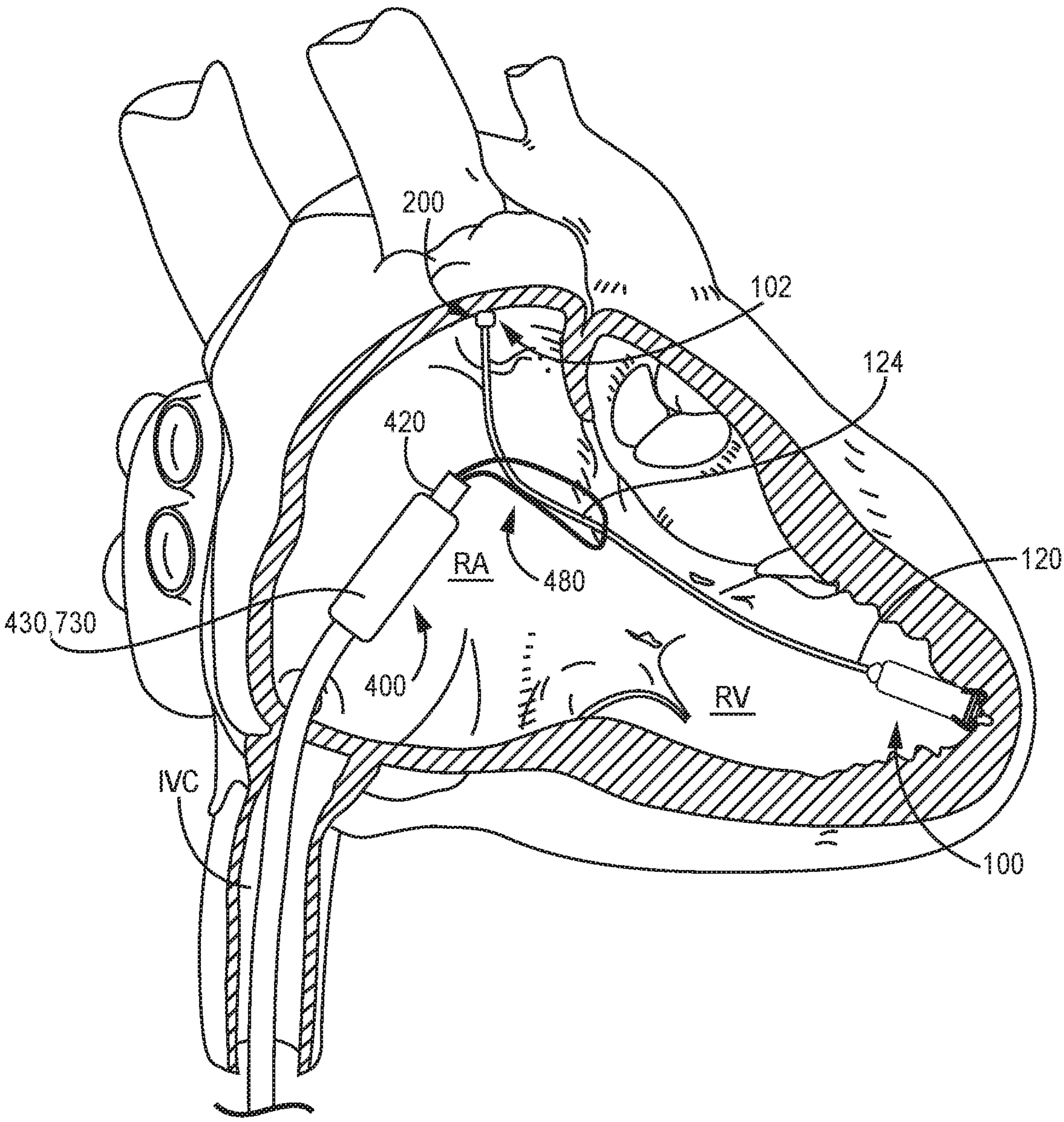


FIG. 10A

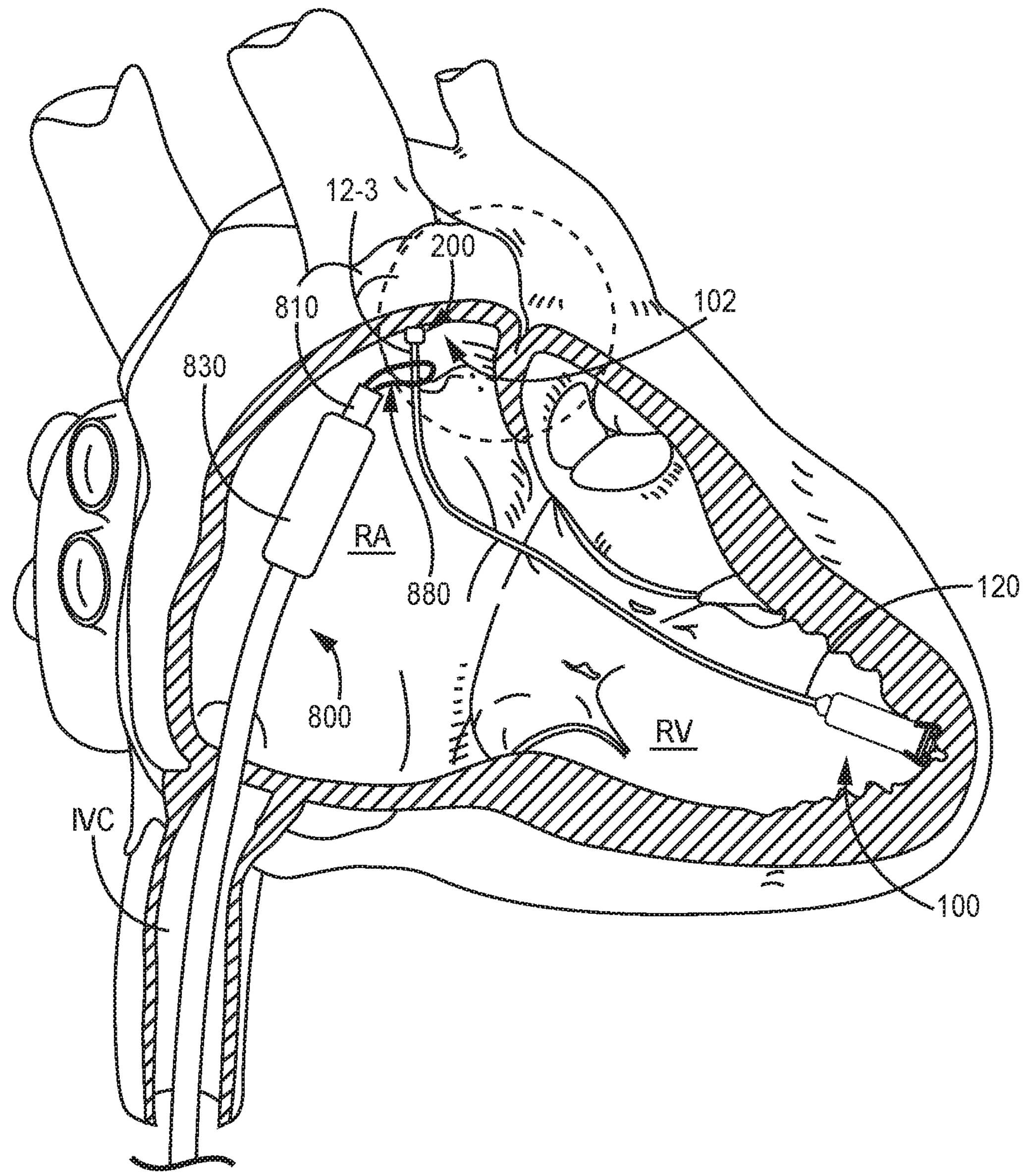


FIG. 10B

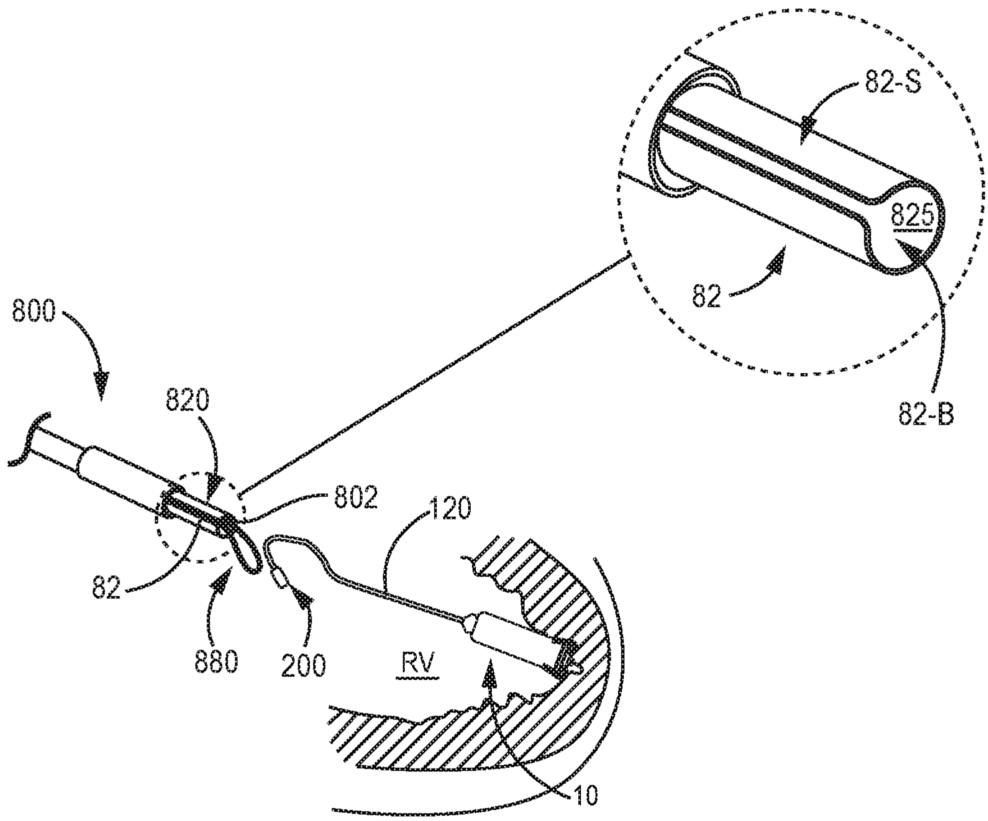


FIG. 11

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	介入医疗系统		
公开(公告)号	[EP3405252B1](EP3405252B1)	公开(公告)日	2020-02-26
申请号	EP2017702282	申请日	2017-01-20
[标]申请(专利权)人(译)	美敦力公司		
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.		
[标]发明人	DRAKE RONALD A CHEN XIN EGGEN MICHAEL D BONNER MATTHEW D GRUBAC VLADIMIR COLIN BRIAN P GARDESKI KENNETH C SEIFERT KEVIN R		
发明人	DRAKE, RONALD, A. CHEN, XIN EGGEN, MICHAEL, D. BONNER, MATTHEW, D. GRUBAC, VLADIMIR COLIN, BRIAN, P. GARDESKI, KENNETH, C. SEIFERT, KEVIN, R.		
IPC分类号	A61N1/05 A61N1/362 A61N1/375 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	EP3405252A1		
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。

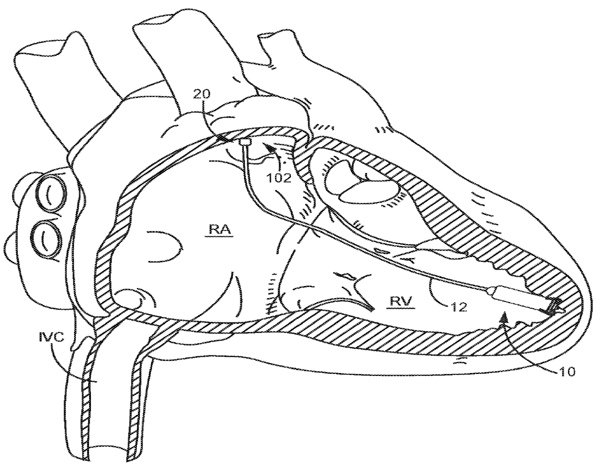

FIG. 1