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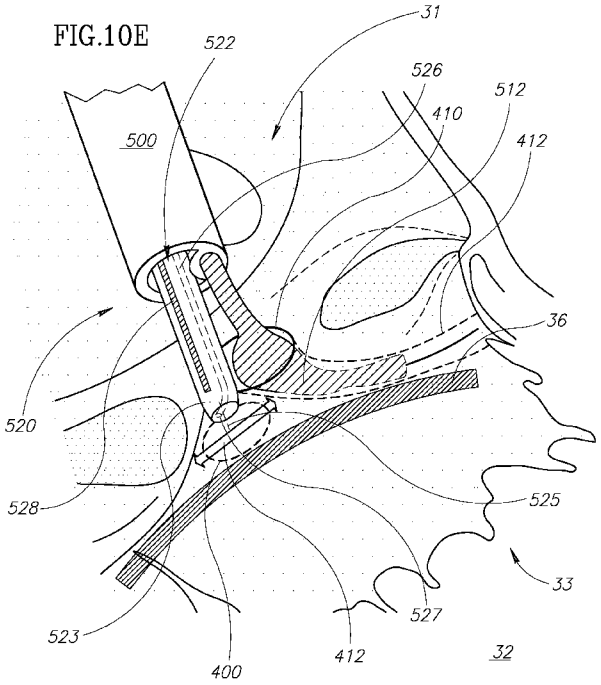



(57) Abstract: Apparatus for preforming a procedure in a heart, the apparatus comprising: an anchor configured to be inserted into a chamber of the heart and controlled to anchor to a feature of the chamber; and an implementer configured to be inserted into the heart chamber to perform a procedure in a target region of the heart and to be constrained by a location of the feature to which the anchor is attached.

WO 2018/008019 A2

# APPARATUS FOR DELIVERING ELECTRICAL SIGNALS TO THE HEART

## RELATED APPLICATIONS

[0001] This application claims benefit under 35 U.S.C. 119(e) of U.S. Provisional Applications 62/358,027, filed July 3, 2016 and 62/358,037, filed July 3, 2016, the disclosures of which are incorporated herein by reference.

## FIELD

[0002] Embodiments of the disclosure relate to providing electrical stimulation to cardiac muscle.

## BACKGROUND

[0003] The human heart comprises two blood pumps that operate in synchrony to oxygenate and deliver oxygenated blood to the body. A first pump receives deoxygenated blood from the various parts the body, and pumps the blood through the lungs to be oxygenated. The second pump receives the oxygenated blood from the lungs and pumps it to flow through the blood vessels of the circulatory system and deliver oxygen and nutrients to the body parts. The two pumps are located adjacent each other in the heart and each pump comprises two chambers, an atrium that receives blood and a ventricle that pumps blood.

[0004] The first pump is located on the right side of the heart and comprises the right atrium and right ventricle. The second pump is located on the left side of the heart and comprises the left atrium and left ventricle of the heart. Deoxygenated blood enters the right atrium, and during a diastolic part of the heart cycle the right ventricle is relaxed and the blood flows from the right atrium into the right ventricle via a tricuspid valve located between the right atrium and right ventricle. The right ventricle contracts during the systolic part of the heart cycle to pump the deoxygenated blood that it receives from the right atrium out of the ventricle and into the pulmonary artery via a pulmonary valve for oxygenation in the lungs. The tricuspid and pulmonary valves control direction of blood flow in the right side of the heart. The tricuspid valve, for example, opens to let deoxygenated blood flow from the right atrium into the right ventricle and closes to prevent deoxygenated blood from regurgitating into the right atrium when the right ventricle contracts. The left atrium receives oxygenated blood from the lungs via pulmonary veins. Oxygenated blood flows from the left atrium into the left ventricle during diastole via a bicuspid valve referred to as the mitral valve. During systole the

left ventricle contracts to pump the oxygenated blood that it receives from the left atrium out of the heart through the aortic valve and into the aorta for delivery to the body. The mitral and aortic valves operate to control direction of blood flow in the left side of the heart. For example, the mitral valve opens during diastole to enable blood to flow from the left atrium to the left ventricle and closes to prevent regurgitation of oxygenated blood from the left ventricle to the left atrium during systole when the left ventricle contracts to pump oxygenated blood into the aorta.

[0005] Each cardiac valve comprises a set of matching "flaps", also referred to as "leaflets" or "cusps", which are mounted to and extend from a supporting ring structure of fibrous tissue, referred to as the annulus of the valve. The leaflets are configured to align and overlap each other, or coapt, along free edges of the leaflets to close the valve when a blood pressure gradient across the valve operates to generate blood flow through the valve in an undesired direction. The valve opens and their free edges part when the leaflets are pushed away from each other by a positive gradient in blood pressure in a desired direction of blood flow.

[0006] Efficient cardiac function can be complex and cardiac valve and/or muscle may become compromised by disease or injury to an extent that warrants surgical intervention to effect repair or replacement and provide a person suffering from cardiac malfunction with an acceptable state of health and quality of life. For example, to restore proper blood flow in the heart, a patient may require surgical replacement of a native heart valve with an artificial heart valve, or emplacement of a pacemaker to deliver electrical signals to heart muscle and control temporal function of the heart.

## SUMMARY

[0007] An aspect of an embodiment of the disclosure relates to providing apparatus, hereinafter also referred to as a myocardial electrical coupling facilitator (MECF) that is configured to be implanted in a heart to facilitate electrical contact to heart muscle for delivery of an electrical signal to the heart.

[0008] In an embodiment, the MECF optionally includes a first electrode, a second electrode and a conductive bridge that mechanically and electrically connects the first and second electrodes. The first electrode is configured to be coupled electrically to an electrical lead of an electrical signal generator, hereinafter also referred to as a cardiac signal generator, and receive electrical signals that the generator produces for stimulating heart muscle. The second electrode may be configured to be implanted in a region of the heart muscle on an antegrade side of a cardiac valve and make electrical

contact to the heart muscle. The first electrode may be referred to as a "lead mating electrode", or "mating electrode", and the second electrode may be referred to as a "myo-contact electrode" or "myo-contact". The bridge may be electrically insulated to prevent electrical contact of the bridge with heart tissue that the bridge may physically touch after the MECF is implanted in the heart. Optionally, the bridge is configured to be mounted to the annulus of the valve.

[0009] In an embodiment of the disclosure, the MECF comprises a terminating lead electrode of a signal generator lead that is configured to match and be connected to the mating electrode to provide electrical contact between the signal generator lead and the mating electrode. A signal generator terminating lead electrode may hereinafter also be referred to as a "lead electrode" or a "terminating electrode". In an embodiment the mating electrode may be magnetized so that the lead electrode is directed and drawn to the MECF mating electrode by a magnetic field between them when the lead electrode is brought sufficiently close to the MECF mating electrode. The magnetic attraction facilitates connecting the signal generator lead electrode to the MECF mating electrode. Optionally, the mating electrode and lead electrode have matching screw threads to establish and maintain robust and reliable connection between the electrodes. Alternatively or additionally, the mating electrode may have a snap connection element for connecting the mating electrode with a matching snap connection element in the lead electrode. Optionally, the snap connection element in the mating electrode includes a recess or protuberance formed in the mating electrode that is configured to receive a male element or female element respectively comprised in the lead electrode.

[0010] In an embodiment, a MECF may comprise a cardiac muscle socket that is configured to be anchored into cardiac tissue and receive a signal generator terminating lead electrode to electrically and mechanically connect the signal generator terminating electrode with cardiac tissue. Optionally the socket, hereinafter ales referred to as a "septal socket" is configured to be anchored into septal tissue of a heart.

[0011] In an embodiment of the disclosure a MECF may comprise a culvert, also referred to as a "septal culvert" that is configured to be inserted into a region of the septum of a heart to provide a lumen through which a terminating lead electrode of a cardiac signal generator may be passed to make electrical contact with cardiac muscle. In an embodiment, the culvert is configured to provide a lumen, which may also be referred to as a "passageway", that extends from an atrium of the heart to a ventricle of the heart.

[0012] An aspect of an embodiment of the disclosure relates to providing a cardiac navigation and delivery apparatus (CANDEL). In an embodiment CANDEL is configured to locate an advantageous region of the heart for placing a cardiac signal generator lead for electrically stimulating heart muscle of a ventricle so that the lead detours around a cardiac valve between the ventricle and its associated atrium. In an embodiment CANDEL comprises an anchor and an implementer that are configured to be delivered and introduced into an atrium of the heart by a catheter. The "CANDEL" catheter optionally comprises an anchor lumen for the anchor and an implementer lumen for the implementer. With a distal end of the CANDEL catheter advantageously positioned in the right atrium the anchor is configured to be pushed through the anchor lumen to exit the lumen via an anchor lumen exit port at the distal end to enter the atrium. The anchor is configured to be operated in the atrium to anchor the catheter distal end to a feature of the atrium and thereby to at least partially constrain motion of the catheter distal end. The implementer is configured to be pushed through the implementer lumen and exit the catheter via an implementer lumen port at the CANDEL catheter distal end. Motion of the implementer in the atrium outside of the catheter is limited by the constraints on motion of the catheter distal end generated by anchoring of the catheter to the feature of the atrium. The CANDEL anchor, implementer and catheter are configured so that the limitations on motion of the implementer operate to position the implementer in a vicinity of a target region of the heart to which the implementer may be moved so that it may be operated to implement a desired medical procedure.

[0013] In an embodiment of the disclosure, the anchor is designed to be introduced into right atrium to anchor the CANDEL catheter to the coronary sinus, and position the distal end of the catheter in the vicinity of the coronary crux cordis. In an embodiment, the implementer may be formed having at last one passage through which at least a penetration needle may be introduced to penetrate the intraventricular septum and form at least one through channel extending from the atrium to at least one of the ventricles. The channel to a ventricle may be configured so that a signal generator lead may be threaded through the channel to make electrical contact with and deliver electrical signals to stimulate ventricular muscle. In an embodiment the at least one channel may be configured to receive a cardiac septal culvert. Optionally a channel of the at least one channel is a blind channel configured to receive a myo-contact electrode and/or a cardiac muscle socket of a MECF.

[0014] This summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used to limit the scope of the claimed subject matter

## BRIEF DESCRIPTION OF FIGURES

[0015] Non-limiting examples of embodiments of the invention are described below with reference to figures attached hereto that are listed following this paragraph. Identical features that appear in more than one figure are generally labeled with a same label in all the figures in which they appear. A label labeling an icon representing a given feature of an embodiment of the disclosure in a figure may be used to reference the given feature. Dimensions of features shown in the figures are chosen for convenience and clarity of presentation and are not necessarily shown to scale.

[0016] FIG. 1 schematically shows a cross section of a human heart and a conventional pacemaker for regulating the heart pace;

[0017] FIG. 2A schematically shows a cross section of the human heart with a myocardial electrical coupler (MECF) installed in the right atrium of the heart alongside a prosthetic tricuspid valve, in accordance with an embodiment of the disclosure;

[0018] FIG. 2B schematically shows a catheter being used to introduce a cardiac signal generator lead having a lead electrode into the right atrium of the heart to connect with the mating electrode of the MECF shown in Fig. 2A, in accordance with an embodiment of the disclosure;

[0019] FIG. 2C shows the generator lead electrode shown in Fig. 2B mated to the MECF and the catheter being withdrawn from the heart, in accordance with an embodiment of the disclosure;

[0020] FIG. 3A shows a perspective view of a MECF mounted to a prosthetic tricuspid valve, in accordance with an embodiment of the disclosure;

[0021] FIG. 3B schematically shows a cross section of the MECF shown in Fig. 3A, in accordance with an embodiment of the disclosure;

[0022] FIG. 3C schematically shows a perspective view of the MECF shown in Figs. 3A and 3B encapsulated in a protective cap to insulate a mating electrode of the MECF from body fluid, in accordance with an embodiment of the disclosure;

[0023] FIG. 4A schematically shows a catheter being used to implant a helical myo-contact electrode of a MECF into a septum of a heart, in accordance with an embodiment of the disclosure;

[0024] FIG. 4B schematically shows the MECF shown in Fig. 4A after implantation and a catheter introducing a cardiac signal generator lead having a terminating electrode into the right atrium to connect the terminating electrode with the mating electrode of the implanted MECF, in accordance with an embodiment of the disclosure;

[0025] FIG.5A schematically shows an enlarged perspective view of the MECF shown in Figs. 4A-4B, in accordance with an embodiment of the disclosure;

[0026] FIG. 5B schematically shows a cardiac signal generator lead housed in a catheter, the lead having a terminating electrode configured to mate with a MECF mating electrode, in accordance with an embodiment of the disclosure;

[0027] FIG. 5C schematically shows an enlarged perspective view of the cardiac signal generator lead terminating electrode shown in Fig. 5B mated with the MECF mating electrode, in accordance with an embodiment of the disclosure;

[0028] Fig. 6A-6B schematically show a MECF comprising a septal socket implanted into a septum of a heart and a lead terminating electrode configured to terminate a cardiac signal generator lead and to seat in the septal socket, in accordance with an embodiment of the disclosure;

[0029] Figs. 7A and 7B schematically show cutaway and cross section views respectively of a heart in which a septal culvert of a MECF is implanted in a septum of the heart for guiding a cardiac signal generator lead terminating electrode from, the heart's right atrium to right ventricle, in accordance with an embodiment of the disclosure;

[0030] Fig. 7C schematically shows a cutaway perspective view of a right atrium of a heart indicating where a septal culvert may be implanted to provide a passageway for guiding a cardiac signal generator lead from the heart's right atrium to the right or left ventricle, in accordance with an embodiment of the disclosure;

[0031] Figs. 8A - 8H schematically illustrate a procedure in which the cardiac culvert shown in Figs. 7A and 7B may be implanted in a heart and apparatus for performing the procedure, in accordance with an embodiment of the disclosure;

[0032] Fig. 9A and 9B schematically show a variation of the implanting apparatus shown in Figs. 8A-8H, in accordance with an embodiment of the disclosure;

[0033] Figs 10A -10E schematically show a procedure for introducing and positioning a CANDEL catheter, anchor, and implementer in the right ventricle of a heart in accordance with an embodiment of the disclosure; and

[0034] Figs 11A -11C schematically shows using the CANDEL implementer to puncture the interventricular septum to provide a passageway for, optionally, threading a pacemaker lead into the right ventricle that detours the tricuspid valve, in accordance with an embodiment of the disclosure.

## DETAILED DESCRIPTION

[0035] FIG. 1 shows a schematic cutaway cross section of a human heart 20 having a right atrium 31 and a right ventricle 32 that communicate via a tricuspid valve 33 and a left atrium 41 and left ventricle 42 that communicate via a mitral valve 43. The tricuspid valve 33 has a fibrous ring-like tissue region 36, hereinafter annulus 36, and three leaflets 34, only two of which are shown in Fig. 1, connected to the annulus. Right ventricle 32 communicates with the pulmonary artery via the pulmonary valve (not shown). The left ventricle 42 communicates with the aorta 50 via the aortic valve 51.

[0036] Deoxygenated blood returning from parts of the body enters right atrium 31 via the superior vena cava 30 and inferior vena cava (IVC, see FIG. 7A), and passes through tricuspid valve 33 to enter right ventricle 32 during diastole when the right ventricle is relaxed and leaflets 34 of the tricuspid valve 33 are separated to open tricuspid valve 33 as schematically shown in Fig. 1. Flow of deoxygenated blood into the right atrium via the superior vena cava 30 and inferior vena cava generates blood pressure for separating leaflets 34, enabling flow through tricuspid valve 33 into the right ventricle 32. During systole, right ventricle 32 contracts to pump the deoxygenated blood through pulmonary valve and into the pulmonary artery (not shown) for delivery to the lungs for oxygenation. During systole, the pumping pressure of right ventricle 32 causes leaflets 34 of tricuspid valve 33 to coapt and close the tricuspid valve to prevent deoxygenated blood pumped by right ventricle 32 from regurgitating into right atrium 31. Chordae tendineae 131 connected to papillary muscles 132 in right ventricle 32 constrain range of motion of leaflets 34 so that pumping pressure of the right ventricle during systole do not evert the leaflets into right atrium 31 and allow regurgitation.

[0037] Oxygenated blood from the lungs enters left atrium 41 and passes through mitral valve 43 to enter left ventricle 42 during diastole when leaflets 44 and 45 are separated (as shown in Fig. 1) to open the mitral valve and the left ventricle is relaxed. Flow of

oxygenated blood into the left atrium and through mitral valve 33 into the left ventricle is schematically indicated by dashed block arrows 71. During systole left ventricle 32 contracts to pump the oxygenated blood through the aortic valve 51 and into the aorta 50 for delivery to the body. During systole leaflets 44 and 45 coapt to close mitral valve 43 and prevent oxygenated blood pumped by the left ventricle from regurgitating into the left atrium

[0038] The heart tricuspid, mitral, and aortic valves, 33, 39, 43, and 51, and the pulmonary valve (not shown) operate to direct flow of blood in the heart and out from the heart and their proper and efficient function can be complex and dependent on coordinated temporal cooperation of their leaflets, annuli, chordae, and papillary and cardiac muscles. Various different disease processes may compromise heart function and result, for example, in cardiac arrhythmias and/or damage to a heart valve that compromises valve functioning and cardiac performance. Resultant cardiac dysfunction may become so severe as to require alleviating surgical intervention. For example, functioning of a cardiac valve may be compromised by various degrees of stenosis, calcification, distortion of the valve annulus, and faulty ventricle functioning. Valve dysfunction and possible resultant regurgitation may become so severe as to warrant surgical intervention to replace a natural cardiac valve with a prosthetic valve. Disturbance in cardiac rhythms may become so pronounced as to require implantation of a pacemaker into a person's body to restore normal cardiac temporal rhythms.

[0039] However, surgical intervention to alleviate a cardiac dysfunction may itself generate deterioration in cardiac performance. A valve replacement may, after time, for example generate arrhythmic disabilities. And conventional pacemaker implantation, which may involve threading pacemaker lead wires between leaflets of a cardiac valve, may cause physical damage to the valve and valve function.

[0040] By way of example, Fig. 1 shows a pacemaker 55 conventionally implanted in a person's body in the chest just under the skin. Leads 57 and 58 from pacemaker 55 are threaded through the superior vena cava 30 from the pacemaker to right atrium 31 and right ventricle 32, respectively. Lead 57 has a terminating electrode represented by a dashed line 59 implanted into a region of the muscle of right atrium 31 and pacemaker lead 58 has a terminating electrode represented by a dashed line 60 implanted into a region of the muscle of right ventricle 32. To reach right ventricle 32, pacemaker lead 58 is passed through tricuspid valve 33 between leaflets 34 of the valve. Pacemaker 55 generates electrical signals that are propagated from the pacemaker via leads 57 and 58

to the regions of cardiac muscle in which terminating electrodes 59 and 60 of the leads are lodged to control cardiac rhythm.

[0041] Whereas pacemaker 55 may operate to provide heart 20 with substantially normal heart rhythm, pacemaker lead 58 may, over an extended period of time, damage structure and/or operation of tricuspid valve 33. Damage caused by pacemaker lead 58 to tricuspid valve 33 may for example include leaflet perforation, and/or damage to leaflet motion as a result of entanglement of leaflet 34 and/or chordae 131 with lead 58. The damage may generate tricuspid valve regurgitation (TR).

[0042] Figs 2A-3C schematically show a myocardial electrical coupler, a MECF 69, operable to connect a cardiac signal generator, such as pacemaker 55 (Fig. 1), to a person's heart, that may reduce risk associated with conventional pacemaker connections to the heart. MECF 69 provides medical professionals with a modular conductive coupling to heart tissue that may be installed into a patient's heart during a valve replacement operation for later use, as may be needed, for connecting a pacemaker to the patient. MECF 69 may repeatedly be used to connect, disconnect and reconnect a pacemaker to the patient's heart.

[0043] Fig. 2A schematically shows a perspective, cutaway cross section view of a heart 20 in which a natural tricuspid valve 33 (Fig. 1) has been replaced by a prosthetic valve 65 to which MECF 69 has been mounted and implanted into heart tissue in accordance with an embodiment of the disclosure. Prosthetic valve 65 may include an annulus 66 and three leaflets 67, of which only two leaflets are schematically shown in the figure.

[0044] MECF 69 comprises a mating electrode 70, a myo-contact electrode 75, and a bridge 77 that mechanically and electrically connects the mating electrode to the myo-contact electrode. Bridge 77 is optionally covered with an insulating layer represented by hatching 90 on the bridge to prevent electrical contact between the bridge and tissue that physically touches the bridge. MECF 69 is mounted to annulus 66 of the prosthetic valve, and myo-contact electrode 75 is anchored into cardiac muscle in a region of an intra-ventricular septum 35 of heart 20 on an antegrade side of prosthetic valve 65 to provide electrical contact with the heart muscle. Mating electrode 70 is optionally formed having a groove or recess 72 for locking onto a matching male connecting element of a lead electrode. The mating electrode is optionally magnetized to generate a magnetic field that may attract the lead electrode to facilitate connecting the mating

electrode to the lead electrode. A magnetic field generated by the magnetized mating electrode is schematically represented in Fig. 2A and figures that follow by arrows 71.

[0045] Figs 2B and 2C schematically illustrate a procedure for connecting a lead terminating electrode 81 of optionally a pacemaker lead 80 to mating electrode 70 of MECF 69, in accordance with an embodiment of the disclosure. Lead terminating electrode 81 is connected to an internal conductor 82 of pacemaker lead 80 over which signals generated by a pacemaker connected to pacemaker lead 80 propagate from the pacemaker to the lead terminating electrode.

[0046] Fig. 2B schematically shows a perspective, cutaway cross section view of heart 20 in which pacemaker lead 80 and lead terminating electrode 81 are being introduced into right atrium 31, in a direction indicated by a block arrow adjacent the terminating electrode, via a catheter 180 threaded through superior vena cava 30 and into right atrium 31. Lead terminating electrode 81 may be U shaped having two resilient arms each mounted with or having formed thereon an optionally hemispherical protrusion 83 matched to seat in groove 72 of mating electrode 70. Lead terminating electrode 81 is optionally magnetized so that polarity of a magnetic field, represented by an arrow 84, that is generated by lead terminating electrode 81 is opposite that of MECF 69 mating electrode 70. As catheter 180 is pushed further into right atrium 31, or lead terminating electrode 81 is pushed out from the catheter and further into the right atrium, magnetic fields 71 and 84 cause lead terminating electrode 81 to be drawn to mating electrode 70. When sufficiently close to mating electrode 70, the magnetic fields cooperate, with the possible aid of manual maneuvering of pacemaker lead 80 in catheter 180, to snap the lead terminating electrode to the mating electrode so that hemispheres 83 seat in groove 72 and lead terminating electrode 81 is mechanically and electrically robustly connected to mating electrode 70. Fig. 2C schematically shows lead terminating electrode 81 connected to mating electrode 70 of MECF 69 and catheter 180 being withdrawn, in a direction indicated by a block arrow adjacent the terminating electrode, from right atrium, 31.

[0047] Figs. 3A-3C schematically show enlarged and detailed views of MECF 69, in accordance with an embodiment of the disclosure. As shown in the figures, bridge 77 may be formed as a U shaped collar, curved to receive annulus 66 of prosthetic valve 65. Optionally, bridge 77 is formed having holes 85 (Fig. 3A) for receiving a suture 86 for fastening the bridge to annulus 66 and may be coated by electrical insulation 90 (Fig. 3B), for preventing electrical contact between the bridge and bodily tissue

touching the bridge. Mating electrode 70 may be provided with a protective coating or cap 87 (Fig. 3C) that seals it from contact with, and possible damage by, bodily fluids during a period in which it is located in a patient's body before being used to connect to a pacemaker lead. Prior to mating with lead terminating electrode 81, protective coating 87 may be breached or removed to enable electrical contact of the mating electrode 70 with lead terminating electrode 81.

[0048] It is noted that whereas in Figs. 2A-3C and the description of the figures, electrode 70 is schematically shown as a male electrode configured to be connected with a female lead terminating electrode 81. In an embodiment, mating electrode 70 may be formed as a female electrode and lead terminating electrode 81 as a male electrode. For example, mating electrode 70 may comprise a tube having a lumen configured to receive a lead terminating electrode 81 shaped as a post configured to be inserted into the lumen. An opening of the lumen may be sealed by a thin membrane of a resilient material such as silicone to protect the internal surfaces of the tube delimiting the lumen. The membrane is punctured by the lead terminating electrode when the lead terminating electrode is pushed into the lumen of the mating electrode to electrically and physically connect the lead terminating electrode to the mating electrode.

[0049] Figs. 4A-5C schematically show a MECF 105 in accordance with another embodiment of the disclosure. As shown in Fig. 4A and figures that follow, MECF 105, which is shown greatly enlarged in an inset 141 in Fig. 4A-5A, comprises a myo-contact electrode 109 shaped to be screwed into a region of tissue and a lead mating electrode 107 having a shape that facilitates applying torque to the lead electrode to screw MECF 105 into a region of tissue. Optionally, myo-contact electrode 109 has a threaded screw shape, or as schematically shown in the figures, a helical, corkscrew, shape. In an embodiment, mating electrode 107 is shaped as a panel that may be inserted into a matching "socket" of a tool so that rotating the tool and thereby the socket rotates MECF 105. Optionally, as described above for the case of MECF 69 mating electrode 107 may be magnetized to facilitate connecting MECF 105 to a pacemaker lead terminating electrode. MECF 105 may be implanted into a region of the heart in an open heart procedure or in a transcatheter procedure. By way of example, Fig. 4A schematically shows a MECF 105 being implanted in the intra-ventricular septum of heart 20 along an edge of annulus 36 of natural tricuspid valve 33, in accordance with an embodiment of the disclosure.

[0050] Fig. 4B schematically shows MECF 105 after implantation and at a time at which a pacemaker lead 80, a portion of which is shown greatly enlarged in Fig. 5B, is being introduced into atrium 31 to connect the pacemaker lead to MECF 105. In an embodiment, pacemaker lead 80 comprises an optionally ribbon shaped conductor 101 connected to a lead terminating electrode 81 described above with respect to Fig. 2B. The ribbon shaped conductor may be advantageous in manipulating pacemaker lead 80 to orient the lead terminating electrode when connecting lead terminating electrode 81 and thereby pacemaker lead 80 to mating electrode 107. Fig. 5C schematically shows lead terminating electrode 81 connected to mating electrode 107.

[0051] Figs. 6A and 6B schematically show another MECF 200 for providing electrical coupling to cardiac muscle of a heart 20, in accordance with an embodiment of the disclosure. MECF 200 optionally includes a septal socket 220 and a matching lead terminating electrode 235 configured for seating in septal socket 220. Septal socket 220 may be configured to be, and is shown by way of example in Fig. 6A, implanted into intra-ventricular septum 35 of heart 20. Lead terminating electrode 235 is configured to terminate an electrical lead and is shown in Fig. 6A by way of example terminating a pacemaker lead 58 being introduced into atrium 31 and prior to the lead terminating electrode being inserted into septal socket 220. In Fig. 6A septal socket 220 and lead terminating electrode 235 are shown enlarged for convenience of presentation in insets 250 and 251 respectively. Fig. 6B schematically shows an enlarged image of MECF 200 in which lead terminating electrode 235 is inserted into septal socket 220.

[0052] Septal socket 220 is optionally formed having an internal lumen 221 configured to receive lead terminating electrode 235 through an entrance aperture 222 and a conical external surface 223 having formed thereon features configured to enable convenient insertion and anchoring of the socket into septal tissue 35. For example external surface 223 may be formed having a helical ridge (not shown) that enables the socket to be inserted into septal tissue with a screw motion, or as shown in Figs. 6A and 6B having spurs 224 that protrude from the external surface 223 to anchor septal socket 220 to septal tissue 35. To facilitate inserting socket 220 into the septal tissue, spurs 224 are optionally tilted so that they lie along portions of a helical line and the septal socket may be screwed into the septal tissue.

[0053] In an embodiment, lead terminating electrode 235 and septal socket 220 are formed so that once inserted into septal socket 220, lead terminating electrode 235 may be held securely in the septal socket. Optionally, as schematically shown in insets 250

and 251 lead terminating electrode 235 is formed having threads 229 that match threads (not shown) in lumen 221 of septal socket 220 so that lead terminating electrode 235 may be screwed into socket 220. Optionally, slots 226 are formed in septal socket 220 so that as lead terminating electrode 235 is screwed into lumen 221, portions 227 of socket 220 between slots 226 splay outward to securely grip septal tissue that contacts the socket.

[0054] In an embodiment, lead terminating electrode 235 comprises a contact tip 236 for making electrical contact with septal tissue after the lead electrode is inserted into septal socket 220. Septal socket 220 may be formed from an insulating material, for example a suitable polymer such as silicone, silicone rubber, polyurethane, or PTFE (polyethene-co-tetrafluoroethene). Optionally, septal socket 220 has an open exit aperture 237 through which contact tip 236 of lead terminating electrode 235 protrudes as shown in Fig. 6B to contact septal tissue 35 after the lead electrode is inserted into the septal socket.

[0055] Figs. 7A and 7B schematically show another MECF 300 in accordance with an embodiment of the disclosure. MECF 300 comprises a cardiac culvert 302, shown greatly enlarged in an inset 252, having a lumen 304, also referred to as a passageway 304, through which, by way of example, electrical lead 58 of pacemaker 55 may be threaded to make contact with heart tissue.

[0056] Fig. 7A schematically shows a cutaway perspective view of heart 20 in which cardiac culvert 302 is inserted into a region 400, which may be referred to as a deployment or target region, of the heart tissue. Optionally, deployment region 400 is a region in the vicinity of the coronary sinus ostium 410 (Fig. 7C) along a posteroseptal wall 402 (Fig. 7B) of the heart, in which cardiac culvert 302 is deployed to penetrate from right atrium 31 into right ventricle 32 of heart 20. Fig. 7B shows a schematic cross section of heart 20 through a plane AA indicated in Fig. 7A. The cross section shows right atrium 31 and right ventricle 32, and the location of culvert 302 in deployment tissue region 400 outside of annulus 36 of tricuspid valve 33 towards the posteroseptal wall 402 of the heart. Fig 7C schematically shows a cutaway perspective view of right atrium 31, tricuspid valve 33 and deployment tissue region 400 in which cardiac culvert 302 is implanted in accordance with an embodiment of the disclosure.

[0057] In an embodiment, as shown in inset 253 in Fig. 7A cardiac culvert 302 comprises a tube-like body 303 that defines lumen 304 and is optionally formed having anchoring spurs 306 and proximal and distal retainer annuli 307 and 308 respectively.

After deployment of cardiac culvert 302 in a region of cardiac tissue, such as a deployment tissue region 400, anchoring spurs 306 and proximal and distal retainer annuli 307 and 308 operate to anchor the cardiac culvert to the tissue. Tube like body 303 may be straight, or as schematically shown in Fig. 7B, curved to conform to a contour of the heart and facilitate in guiding electrical lead 58 from right atrium 31 to enter right ventricle 32 in an advantageous direction for placement in cardiac tissue bounding the right ventricle for example to provide septal or apical pacing.

[0058] Optionally, tube-like body 303 is self-expanding or forcibly expanding, and cardiac culvert 302 may be introduced into a region of cardiac tissue in which it is to be deployed in a collapsed state. After introduction, cardiac culvert 302 self-expands, or is forcibly expanded, for example by a suitable balloon apparatus, from the collapsed state to a deployed, expanded state, in which culvert lumen 304 securely lodges in the cardiac tissue and may function as an advantageous passageway for an electrical lead of, optionally, a pacemaker, such as pacemaker 55 (Fig. 7A). To provide integration of cardiac culvert 302 with tissue into which it is implanted, outside surfaces of tube-like body 303 may be coated with a biocompatible material that fosters bonding of the cardiac culvert to the surrounding tissue. Optionally the biocompatible material comprises PET (polyethylene terephthalate) or PTFE (polytetrafluoroethylene). In an embodiment, a diameter of a cross section of lumen 304 is determined to provide a snug fit between the electrical lead and the wall of the lumen to obviate regurgitation of blood from right ventricle 32 to right atrium 31 when the ventricle contracts. To mitigate possible damage to the electrical lead and/or cardiac culvert 302, the internal surface of tube body 303 that bounds lumen 304 may be covered by a relatively soft, smooth material such as for example silicone. In an embodiment, a diameter of the lumen is greater than a diameter of the electrical lead at least by about 0.2 mm (millimeters). Optionally, the lumen diameter is greater than or equal to the electrical lead diameter plus about 0.4 mm. In an embodiment the lumen diameter is greater than or equal to the electrical lead diameter plus about 1 mm. In an embodiment the electrical lead diameter is equal to or greater than about 1 mm. Optionally, the electrical lead diameter is greater than or equal to about 2 mm.

[0059] Functioning of features of cardiac culvert 302 and a procedure for introducing cardiac culvert 302 to a region of cardiac tissue in accordance with an embodiment, are described with reference to Figs. 8A-8H. By way of example in the figures it is assumed

that cardiac culvert 302 is self-expanding and formed from a suitable shape memory alloy, such as nitinol, and/or a suitable shape memory polymer, such as a polyurethane.

[0060] Figs. 8A and 8B schematically show a cutaway cross section of heart 20 and of right atrium 31 and right ventricle 32 at the beginning of a procedure to deploy culvert 302 in deployment tissue region 400 shown in Figs. 7A-7C in a vicinity of the coronary sinus ostium 410 (Fig. 7C) along posteroseptal wall 402.

[0061] As shown in Figs. 8A and 8B, at onset of the deployment procedure, a cardiac culvert deployment guide catheter 370 and a culvert deployment orientation guide wire 361 are introduced into right atrium 31 optionally via superior vena cava 30. Culvert deployment orientation guidewire 361 is passed through tricuspid valve 33 into right ventricle 32, optionally so that an end 362 of the guidewire 361 is located at a region of the right ventricle near the apex 21 of heart 20. In an embodiment, guidewire 361 is formed having a fiducial marker represented by a solid circle 363 near or at end 362 so that the end of guidewire 361 may readily be identified in images of heart 20 acquired by a suitable imaging modality used to monitor progress of the deployment procedure during its performance. Fiducial marker 363 may for example be a radio-opaque or ultrasound opaque marker to facilitate imaging by radiant energy or ultrasound respectively. In an embodiment, guidewire 361 comprises a fiducial 364, hereinafter also referred to as a "target fiducial", that indicates a region of the guidewire located in a central location of right ventricle 32 when end 362 of the guidewire is located near apex 21 of the heart.

[0062] Culvert deployment guide catheter 370 is positioned in right atrium 31 so that an end 371 of the culvert deployment guide catheter is located at deployment tissue region 400 of cardiac tissue bounding the right atrium into which cardiac culvert 302 is intended to be introduced. Optionally, culvert deployment guide catheter 370 comprises a culvert perforating guidewire 380, which may be introduced and positioned in right atrium 31 together with the culvert perforating guidewire. Alternatively, perforating guidewire 380 may be threaded through culvert guide catheter 370 after the guide catheter is introduced and positioned in right atrium 31.

[0063] Perforating guidewire 380 may have a sharpened tip 381 and is sufficiently stiff and pushable so that the perforating guidewire may be used to perforate deployment tissue region 400 and provide a through-hole between right atrium 31 and right ventricle 32 in which cardiac culvert 302 is to be implanted. Optionally, perforating guidewire 380 comprises a pressure sensor (not shown) such as an optical or piezoelectric sensor

to measure pressure of the tissue environment in which tip 381 is located and provide an indication when the tip has penetrated through deployment tissue region 400. According to an embodiment of the disclosure, perforating guidewire 380 is pushed to penetrate deployment tissue region 400 and provide the through-hole in a direction that lies along an optionally curved trajectory indicated by a dashed line 404 shown in Fig. 8B that extends between end 371 of culvert deployment guide catheter 370 and target fiducial 364.

[0064] Fig. 8C schematically shows an enlarged image of a small portion of deployment tissue region 400, culvert deployment guide catheter 370, and perforating guidewire 380 after the perforating guidewire has been pushed to penetrate the deployment tissue region.

[0065] Following penetration of deployment tissue region 400 a culvert deployment apparatus 390 schematically shown in Fig. 8D is threaded along perforating guidewire 380 in culvert guide catheter 370 to a location at which perforating guidewire 380 entered deployment tissue region 400. Culvert deployment apparatus 390 optionally comprises a pull-back sheath 391 that holds and restrains cardiac culvert 302 in a compressed state, and a pusher rod 392.

[0066] As schematically shown in Fig. 8E, after introducing and positioning culvert deployment apparatus 390 in culvert deployment guide catheter 370, pull-back sheath 391 and pusher rod 392 are pushed in a distal direction along perforating guidewire 380 into deployment tissue region 400 to position cardiac culvert 302 at a desired location at the hole punctured in the deployment tissue region by perforating guidewire 380. Fig. 8F shows a cross section view of deployment tissue region 400 and culvert deployment apparatus 390 shown in Fig. 8E.

[0067] Following positioning of cardiac culvert 302 in deployment tissue region 400, pull-back sheath 391 is retracted proximally relative to cardiac culvert 302 and push rod 392. The push rod operates to maintain culvert 302 properly located in deployment tissue region 400 and prevent cardiac culvert 302 from being dragged along and retracted from deployment tissue region 400 with retraction of pull-back sheath 391. Fig. 8G schematically shows pull-back sheath 391 just as it is first being retracted from deployment tissue region 400. In the figure a distal end 311 of cardiac culvert 302 is freed from restraining forces exercised by the pull-back sheath and the end is self-expanding to form retainer annuli 308 (Fig. 7B, Fig. 8H). Fig. 8H schematically shows culvert deployment apparatus 390 after pull-back sheath 391 has been sufficiently

retracted to completely free the cardiac culvert to expand to its fully expanded, deployed state with anchoring spurs 306 and retainer annuli 307 and 308 extended to anchor cardiac culvert 302 in place. Once freed from pull-back sheath 391 and positioned in deployment tissue region 400, cardiac culvert 302 is available to receive pacemaker electrical lead 58.

[0068] It is noted that in the above description, perforating guidewire 380 is operated to puncture deployment tissue region 400 independent of culvert deployment apparatus 390. Culvert deployment apparatus 390 is operated to position cardiac culvert 302 in deployment tissue region 400 after perforating guidewire 380 is used to form a puncture hole in the deployment tissue region. In an embodiment, perforating guidewire 380 and culvert deployment apparatus 390 may be operated together to simultaneously puncture and position cardiac culvert 302 in deployment tissue region 400. When operated together simultaneously to puncture and position cardiac culvert 302 in deployment tissue region 400, the perforating guidewire and culvert deployment apparatus are locked together with sharpened tip 381 of the penetrating guidewire operating as a nose cone for the culvert deployment apparatus.

[0069] In an embodiment, perforating guidewire 380 may be formed with a nose cone 382 for operation with culvert deployment apparatus 390. Nose cone 382 may be displaced from sharpened tip 381 of the perforating guidewire. Fig. 9A schematically shows perforating guidewire 380 and culvert deployment apparatus 390 having a nose cone 382 proximally displaced from sharpened tip 381 for operation with culvert deployment apparatus 390. In the figure, perforating guidewire 380 and culvert deployment apparatus 390 are shown after the perforating guidewire has been used to penetrate deployment tissue region 400 and prior to positioning of cardiac culvert 302 in the deployment tissue region. To deploy cardiac culvert 302 into deployment tissue region 400 culvert deployment apparatus 390 may be advanced distally along perforating guidewire 380 towards nose cone 382 until the culvert butts up on the nose cone. Thereafter pull-back sheath 391, pusher rod 392, and cardiac culvert 302 are pushed into the hole punctured in deployment tissue region 400 by the perforating guidewire until the cardiac culvert is properly positioned in the deployment tissue region. Fig. 9B schematically shows perforating guidewire 380 and culvert deployment apparatus 390 just after positioning culvert 302 in deployment tissue region 400. After positioning cardiac culvert 302 in deployment tissue region 400, pull-back sheath 391 may be retracted to deploy the cardiac culvert. Thereafter, pusher rod 392, pull-back

sheath 391, culvert deployment guide catheter 370, and perforating guidewire 380 may be removed from the heart. Nose cone 382 is dimensioned small enough so that after expansion of cardiac culvert 302 in deployment tissue region 400 the nose cone does not prevent perforating guidewire 380 from being readily retracted through the culvert and removed from heart 20.

[0070] It is noted that whereas Figs. 7A-9A schematically show a cardiac culvert 302 being implanted and used to connect a cardiac signal generator lead to a deployment tissue region of a right ventricle 32, practice of embodiments of the disclosure are not limited to facilitating electrical connection to the right ventricle. For example, a cardiac culvert may be implanted in a region of the heart septum to provide passage of a lead from optionally the right septum to a region of the left ventricle. Optionally, a cardiac culvert may be formed having two exit apertures configured to enable first and second cardiac generator leads to be connected respectively to heart tissue in the right and left ventricles to provide simultaneous pacing of both the right and left ventricles.

[0071] Figs 10A -10E schematically illustrate introducing and positioning a CANDEL catheter 500, anchor 510, and implementer 520 in right atrium 31 of heart 20 shown in a cutaway view in Fig. 1A, to position the implementer for performing a procedure at a deployment tissue region 400 of the heart, in accordance with an embodiment of the disclosure. In an embodiment, the deployment tissue region is by way of example, a region of the crux cordis of the heart and may be referred to as crux cordis 400. And, as described below and schematically shown in Figs. 10B-11C, CANDEL anchor 510 may comprise a balloon anchor, and implementer 520 may comprise a needle positioner operable to direct a needle for puncturing cardiac tissue in the region of the crux cordis.

[0072] Fig. 10A schematically shows CANDEL catheter 500 optionally formed to have an anchor lumen 501 and an implementer lumen 502 and having a distal end 504 located optionally in right atrium 31 of the heart in proximity to the heart's crux cordis 400. In accordance with an embodiment, CANDLE catheter 500 is introduced into atrium 31 over a guidewire 506 passed through anchor lumen 501. The guidewire is threaded through the heart superior vena cava (SVC) 30 into right atrium 31, through ostium 410 of coronary sinus (CS) 412 and into the coronary sinus. For spatial orientation, Fig. 10 schematically shows landmark features of atrium 31 in the vicinity of crux cordis 400, including annulus 36 and leaflets 34 of tricuspid valve 33, location of right ventricle 32, and the ostium, labeled by the acronym "IVC", of the inferior vena cava (IVC).

Crux cordis 400 lies over the interventricular septum, which extends under the crux cordis in a direction indicated by a block arrow 401.

[0073] In an embodiment, CANDEL anchor 510 may comprise an inflatable balloon 512, schematically shown in Fig. 10B, which is configured to be threaded in a deflated state through anchor lumen 501 over guidewire 506 and into CS 412. Fig. 10B shows balloon 512 after introduction of CANDEL catheter 500 into right atrium 31 and balloon 512 threaded over guidewire 506 and into CS 412. After positioning in CS 412, balloon 512 is inflated to secure the position of the balloon in the CS and tether thereby distal end 504 of CANDEL catheter 500 to the CS. Fig. 10C schematically shows balloon 512 inflated to fill a portion of CS 412 and anchor the balloon securely in the CS.

[0074] Once distal end 504 is tethered, implementer 520, optionally comprising a needle director 522 in accordance with an embodiment of the disclosure, may be pushed through implementer lumen 502 of CANDEL catheter 500 so that needle director 522 exits distal end 504 of the catheter in a vicinity of crux cordis 400. Fig. 10D schematically shows needle director 522 pushed out from distal end 504 of catheter 500 and having a distal end 523 in a vicinity of crux cordis 400. For convenience of viewing details, Fig. 10E schematically shows an enlarged image of the needle director in a neighborhood of crux cordis 400.

[0075] Needle director 522 may comprise a body having a longitudinal axis 525 and is optionally formed having at least one needle channel 526 through which a needle for puncturing cardiac tissue may be pushed to exit the needle director via a needle aperture 527 at distal end 523 of the needle director. By way of example, needle director 522 comprises a single needle channel 526, which may be curved as shown in Figs. 10D and 10E so that a needle pushed out through channel 526 exits the needle director at a desired angle relative to axis 525. Optionally, needle director 522 is rotatable about longitudinal axis 525 by operation of a pusher rod (not shown) comprised in implementer 520 that extends from the needle director along implementer lumen 502 to an implementer, optionally manual, controller at a proximal end (not shown) of CANDEL catheter 500. Optionally, needle director 522 comprises at least one, optionally radiopaque, fiducial 528 to facilitate determining position and orientation of needle director 522 from images of the needle director acquired during a procedure employing CANDEL implementer 520 while the needle director is located in atrium 31.

[0076] Figs. 11A-11C schematically show greatly enlarged images of needle director 522 after being introduced into atrium 31 and positioned and oriented at crux cordis 400 to puncture interventricular septum 600 at a location below the crux cordis, in accordance with an embodiment of the disclosure. Interventricular septum 600 separates the right ventricle 32 from the left ventricle 42 whose locations in Figs. 11A-11C relative to septum 600 are indicated by the locations of labels 32 and 42 in the figures. By way of example in Figs. 11A-11C needle director 522 is being used to puncture interventricular septum 600 to form a though-hole in the septum through which a lead of a cardiac signal generator, such as lead 58 of pacemaker 55 (Fig. 1) may be introduced into the right ventricle to stimulate heart muscle.

[0077] Fig. 11A schematically shows CANDEL catheter 500 and needle director 522 positioned to orient axis 525 of the needle director substantially perpendicular to a plane along which annulus 36 (Figs. 10A-10E) of tricuspid valve 33 lies, and parallel to a plane along which interventricular septum 600 separates the right and left ventricle 32 and 42. The plane along which septum 600 separates the right from the left ventricle is schematically represented in Fig. 11A and figures that follow by a dashed rectangle 601, and may be referred to as plane 601.

[0078] In an embodiment at least one fiducial 528 may be used to rotate needle director 522 about axis 525 to an azimuth angle for which a needle for puncturing septum 600 pushed out through needle aperture 527 exits channel 526 and punctures the septum along a desired direction. Optionally, as shown in Fig. 11A at least one fiducial 528 comprises at least two, optionally substantially rectangular radiopaque fiducials 528 that are parallel to and intersect a same plane, which may be referred to as a fiducial plane, indicated by a dashed rectangle 531. In an embodiment, fiducial plane 531 is substantially perpendicular to a plane indicated by a dashed rectangle 532 that intersects and is substantially parallel to needle channel 526.

[0079] In an embodiment, during the procedure to puncture intraventricular septum 600 needle director 522 may be rotated based on images acquired of fiducials 528 so that plane 531 is substantially parallel to plane 601, and plane 532 along which needle channel 526 lies is substantially perpendicular to plane 601. Fig. 11B schematically shows needle director 522 after rotation, with needle channel plane 532 substantially perpendicular to plane 601. Following the rotation, a needle pushed though needle channel 526 to exit needle director 522 will puncture interventricular septum 600 and enter right ventricle 32 to form a channel suitable for introducing a lead of a pacemaker

into the right ventricle without having to pass through the tricuspid valve. Fig. 11C schematically shows a needle 700 pushed through and out from needle channel 526 through needle aperture 527 to puncture septum 600,enter right ventricle 32 and form a puncture through-hole 702 in the septum, in accordance with an embodiment of the disclosure.

[0080] It is noted that subsequent to puncturing septum 600, needle 700 may be removed to enable a lead of a pacemaker (not shown) to be threaded through needle channel 526 of needle director 522 and the puncture hole made by needle 700 and into right ventricle 32. To facilitate the pacemaker lead meeting the puncture hole it is advantageous that after needle 700 is removed from needle director 522 that needle channel 526 of the needle director remain aligned with the puncture hole.

[0081] Optionally, to provide for such alignment, end 523 of needle director 522 may comprise a set of at least two spurs that extend away from the needle director in a direction substantially parallel to axis 525. Following rotation of needle director 522 to align needle channel plane 532 substantially perpendicular to plane 601, and prior to pushing needle 700 out from the needle director via needle aperture 527, needle director 522 may be pressed into crux cordis 400 so that the spurs penetrate and lodge into tissue in the region of the crux cordis. The lodged spurs operate to maintain registration of needle aperture 527 with through-hole 702 after needle 700 is removed from needle director 522.

[0082] In the above description, needle director 522 of CANDEL implementer 520 is configured having a single needle channel and used to provide a puncture through-hole into right ventricle 32, practice of embodiments of the disclosure is not limited to forming through-holes into the right ventricle nor to needle directors having only a single needle channel. Rotation of needle director 522 about axis 525 by $180^{o}$ relative to the orientation of needle director 522 shown in Fig. 11C provides for using the needle director to form a puncture through-hole into the left ventricle. And at least one needle channel 526 may comprise two or more needle channels. For example, a needle director in accordance with an embodiment similar to needle director 522 may have two needle channels 526. The two needle channel may have opposite curvature and have needle apertures 527 on opposite sides of fiducial plane 531. Such a needle director may be used to create puncture through-holes to both right and left ventricles 32 and 42 without

having to rotate the needle director about axis 525 between forming the puncture through-holes.

[0083] It is further noted that practice of embodiments of the disclosure is not limited to CANDEL implementers having needle directors. A CANDEL implementer in accordance with an embodiment may for example have a CANDEL implementer in accordance with an embodiment configured to implant a septal culvert and comprise a culvert deployment apparatus similar to culvert deployment apparatus 390 shown in Fig. 8D.

[0084] In the description and claims of the present application, each of the verbs, "comprise" "include" and "have", and conjugates thereof, are used to indicate that the object or objects of the verb are not necessarily a complete listing of components, elements or parts of the subject or subjects of the verb.

[0085] Descriptions of embodiments of the invention in the present application are provided by way of example and are not intended to limit the scope of the invention. The described embodiments comprise different features, not all of which are required in all embodiments of the invention. Some embodiments utilize only some of the features or possible combinations of the features. Variations of embodiments of the invention that are described, and embodiments of the invention comprising different combinations of features noted in the described embodiments, will occur to persons of the art. The scope of the invention is limited only by the claims as follows.

# CLAIMS

1. Apparatus for delivering an electrical signal to the heart, the apparatus comprising:

a first electrode configured to electrically couple to a cardiac signal generator and receive electrical signals that the generator produces for stimulating heart muscle;

a second electrode configured to be implanted in a region of the heart muscle on an antegrade side of a cardiac valve the cardiac valve comprising an annulus and leaflets for controlling blood flow between an atrium and a ventricle of the heart; and

a bridging member configured to be mounted to the annulus and electrically connect the first and second electrodes.

2. The apparatus of claim 1 wherein the bridging member comprises electrical insulation configured to prevent electrical contact of the bridging member with cardiac tissue with which the bridging member makes physical contact.

3. The apparatus of claim 1 or claim 2 wherein the first electrode is shaped to match a lead electrode of a lead configured to connect a signal generator to the first electrode.

4. The apparatus according to claim 3 wherein the first electrode is magnetized to attract the lead electrode.

5. The apparatus of claim 3 or claim 4 wherein the first electrode is configured with at least one screw thread to connect with the lead electrode.

6. The apparatus of any of claims 3-5 wherein the first electrode has at least one snap connection element configured to connect with a matching snap connection element in the lead electrode.

7. The apparatus of claim 6 wherein the at least one snap connection element comprises at least one recess formed in the first electrode and configured to receive a male element comprised in the lead electrode.

8. The apparatus according to any of the preceding claims wherein the first electrode comprises a flat panel having two relatively large planar parallel surfaces joined by relatively narrow edge surfaces.

9. The apparatus according to any of the preceding claims wherein the first electrode comprises a cylindrically symmetric region.

10. The apparatus according to any of the preceding claims wherein the bridging member comprises a collar shaped to mate with the annulus.

11. The apparatus of claim 9 wherein the collar is formed having at least one hole for receiving a suture for fastening the collar to the annulus.

12. The apparatus according to any of the preceding claims and comprising a protective coating that seals the first electrode from contact with bodily fluids.

13. The apparatus of claim 12 wherein the protective coating is removable to enable electrical contact of the first electrode with the lead electrode.

14. The apparatus of claim 12 wherein the protective coating is breachable to enable electrical contact of the first electrode with the lead electrode.

15. The apparatus according to any of the preceding claims wherein the second electrode is configured to be screwed into a region of tissue.

16. The apparatus according to claim 15 wherein the second electrode comprises a portion having a helix

17. A myocardial helical connector for delivering an electrical signal to the heart, the connector comprising:

a magnetized socket plug contact configured to electrically couple to an electrical signal generator and to receive a signal therefrom;

a helical contact electrically connected to said socket plug contact and configured to be screwed into cardiac tissue; and

a bridging member that electrically connects the socket plug contact to the helical contact.

18. The connector of claim 17 and comprising electrical insulation configured to prevent electrical contact of the bridging member with cardiac tissue with which the bridging member makes physical contact.

19. A cardiac culvert configured to be implanted in cardiac tissue, the culvert comprising:

a tube having first and second ends and a wall having internal and external surfaces wherein the internal surface defines a lumen having an opening at each of the first and second ends; and

at least one feature on the external surface configured to anchor the tube in cardiac tissue in which the culvert is implanted.

20. The cardiac culvert according to claim 19 wherein the at least one feature comprises a helical ridge.

21. The cardiac culvert according to claim 19 or claim 20 wherein the at least one feature comprises at least one spur that extends out from the external surface.

22. The cardiac culvert according to claim 21 wherein the spurs lie along a helical line

23. The cardiac culvert according to any of claims 19-22 wherein the tube comprises a retaining annulus that extends out from at least one of the first and second ends of the tube.

24. The cardiac culvert according to claim 23 wherein the tube comprises a retaining annulus that extends out from each of the first and second ends of the tube.

25. The cardiac culvert according to any of claims 19-24 wherein when implanted the culvert is curved to follow a desired contour of the cardiac tissue in which the culvert is implanted.

26. The cardiac culvert according to claim 25 wherein the curvature has a radius of curvature greater than or equal to about 5 mm.

27. The cardiac culvert according to any of claims 19-26 wherein the cardiac culvert is configured to be implanted in cardiac tissue that bounds on a first side of an atrium of the heart and on a second side of a ventricle of the heart.

28. The cardiac culvert according to claim 27 wherein the ventricle is the right ventricle

29. The cardiac culvert according to claim 27 wherein the ventricle is the left ventricle

30. The cardiac culvert according to any of claims 27-29 wherein the cardiac culvert has a length greater than or equal to about 15 mm.

31. The cardiac culvert according to claim 27-30 wherein the atrium is the right atrium.

32. The cardiac culvert according to claim 31 wherein the cardiac tissue is tissue bounding the coronary sinus.

33. The cardiac culvert according to claim 31 wherein the cardiac tissue is tissue bounding the coronary sinus ostium.

34. The cardiac culvert according to any of claims 19-33 wherein the tube has a collapsed state and an expanded state and a maximum external cross section substantially perpendicular to a line between the first and second ends of the tube is smaller in the collapsed state than in the expanded state.

35. The cardiac culvert according to claim 34 wherein the tube is configured to be self-expanding.

36. The cardiac culvert according to claim 34 wherein the tube is configured to be forcibly expanded.

37. A method of providing a passageway through a region of cardiac tissue having first and second sides, the method comprising:

puncturing the tissue with a guidewire having an end configured to facilitate the puncturing to form a hole that extends through the tissue from the first to the second sides of the tissue; and

inserting into the hole a cardiac culvert having first and second apertures and a lumen that extends between the apertures so that the first and second apertures are located on the first and second sides of the cardiac tissue respectively.

38. Apparatus for preforming a procedure in a heart, the apparatus comprising:

an anchor configured to be inserted into a chamber of the heart and controlled to anchor to a feature of the chamber; and

an implementer configured to be inserted into the heart chamber to perform a procedure in a target region of the heart and to be constrained by a location of the feature to which the anchor is attached.

39. The apparatus according to claim 38 wherein the feature is a region of the coronary sinus of the heart.

40. The apparatus according to claim 39 wherein the anchor is configured to be inserted into the coronary sinus via the coronary sinus ostium.

41. The apparatus according to claim 40 wherein the anchor comprises an inflatable balloon comprising at least a first portion that is operable to be inflated in the coronary sinus to secure a position of the balloon in the coronary sinus.

42. The apparatus according to claim 41 wherein the balloon is configured to be guided into the coronary sinus over a guidewire inserted into the heart and the coronary sinus.

43. The apparatus according to claim 42 wherein the balloon is configured to be guided to the coronary sinus ostium through a lumen of a catheter guided over the guidewire so that a distal end of the catheter is located in the heart chamber.

44. The apparatus according to claim 43 wherein the balloon is configured so that when inflated the first portion limits motion of the distal end of the catheter relative to the ostium of the coronary sinus.

45. The apparatus according to claim 44 wherein the balloon comprises a second portion configured to remain in the lumen and be inflated to secure the catheter to the balloon when the first portion is located in the coronary sinus.

46. The apparatus according to any of claims 43-45 wherein the implementer is configured to be pushable through the same catheter through which the guidewire is threaded to exit the distal end of the catheter and be introduced into the heart chamber.

47. The apparatus according to claim 46 wherein the implementer comprises a needle director having a distal end and formed to have at least one needle channel ending in a needle aperture at the distal end of the needle director through which a needle may be passed to exit the needle to puncture a region of tissue.

48. The apparatus according to claim 47 wherein the needle director comprises a longitudinal axis and the at least one needle channel comprises a needle channel formed having a curved region that ends at the needle aperture and directs exit of the needle in a desired direction relative to the longitudinal axis.

49. The apparatus according to claim 48 and comprising at least one fiducial marking configured to facilitate determining position and orientation of the needle director when located in the heart.

50. The apparatus according to claim 49 wherein the at least one fiducial marking comprises at least two fiducial markings that define a plane.

51. The apparatus according to claim 50 wherein the curved needle channel is a planar channel that intersects and lies along a plane.

52. The apparatus according to claim 51 wherein the plane defined by the at least two fiducials is substantially perpendicular to the plane along which the curved needle channel lies.

53. Apparatus for preforming a procedure in a heart, the apparatus comprising:

a catheter having at least one lumen and a distal end configured to be introduced into a chamber of the heart with the distal end located in the chamber;

an anchor configured to be pushed through a lumen of the at least one lumen to exit the distal end of the catheter and be controlled to anchor to a feature of the chamber to limit motion of the distal end of the catheter to a neighborhood of the feature; and

an implementer configured to be pushed through a lumen of the at least one lumen to exit the distal end of the catheter and perform a procedure at a target region accessible by the implementer while motion of the distal end of the catheter is limited to the neighborhood.

54. The apparatus according to claim 53 wherein the feature is the coronary sinus and the anchor comprises an inflatable balloon having at least a first portion that is operable to be inflated in the coronary sinus to secure a position of the balloon in the coronary sinus.

55. The apparatus according to claim 53 or claim 54 wherein the implementer comprises a needle director having a distal end and formed to have at least one needle channel ending in a needle aperture at the distal end of the needle director through which a needle may be passed to exit the needle to puncture a region of tissue.

56. The apparatus according to claim 55 wherein the needle director comprises a longitudinal axis and the at least one needle channel comprises a needle channel formed having a curved region that ends at the needle aperture and directs exit of the needle in a desired direction relative to the longitudinal axis.

57. The apparatus according to claim 56 and comprising at least one fiducial marking configured to facilitate determining position and orientation of the needle director when located in the heart.

58. A method of introducing a lead of cardiac signal generator for delivering an electrical signal to a heart, the method comprising:

introducing a catheter into the heart so that a distal end of the catheter is located in the right atrium;

pushing an inflatable balloon in a deflated state through the lumen and into the coronary sinus of the heart via the ostium of the coronary sinus;

inflating the balloon to anchor the balloon to the coronary sinus and limit motion of the distal end of the catheter;

pushing a needle director having a distal end and at least one needle channel ending in a needle aperture at the distal end of the needle director through the catheter and into the right atrium;

orienting the needle director relative to a plane through the crux cordis along which the interventricular septum separates the left and right ventricles so that a needle may be pushed out through a needle channel of the at least one needle channel to penetrate the septum and enter the right ventricle;

pushing the needle director so that the distal end of the needle director presses on the crux cordis;

pushing a needle out through the needle channel to penetrate a region of the crux cordis and form a though-hole through the septum that extends into the right ventricle;

using the through hole to introduce the lead into the right ventricle.

59. The method according to claim 58 wherein using the through hole comprises passing the lead through the through hole.

60. The method according to claim 59 wherein passing the lead through the through-hole comprises inserting a cardiac culvert into the through-hole and passing the lead through the through hole.

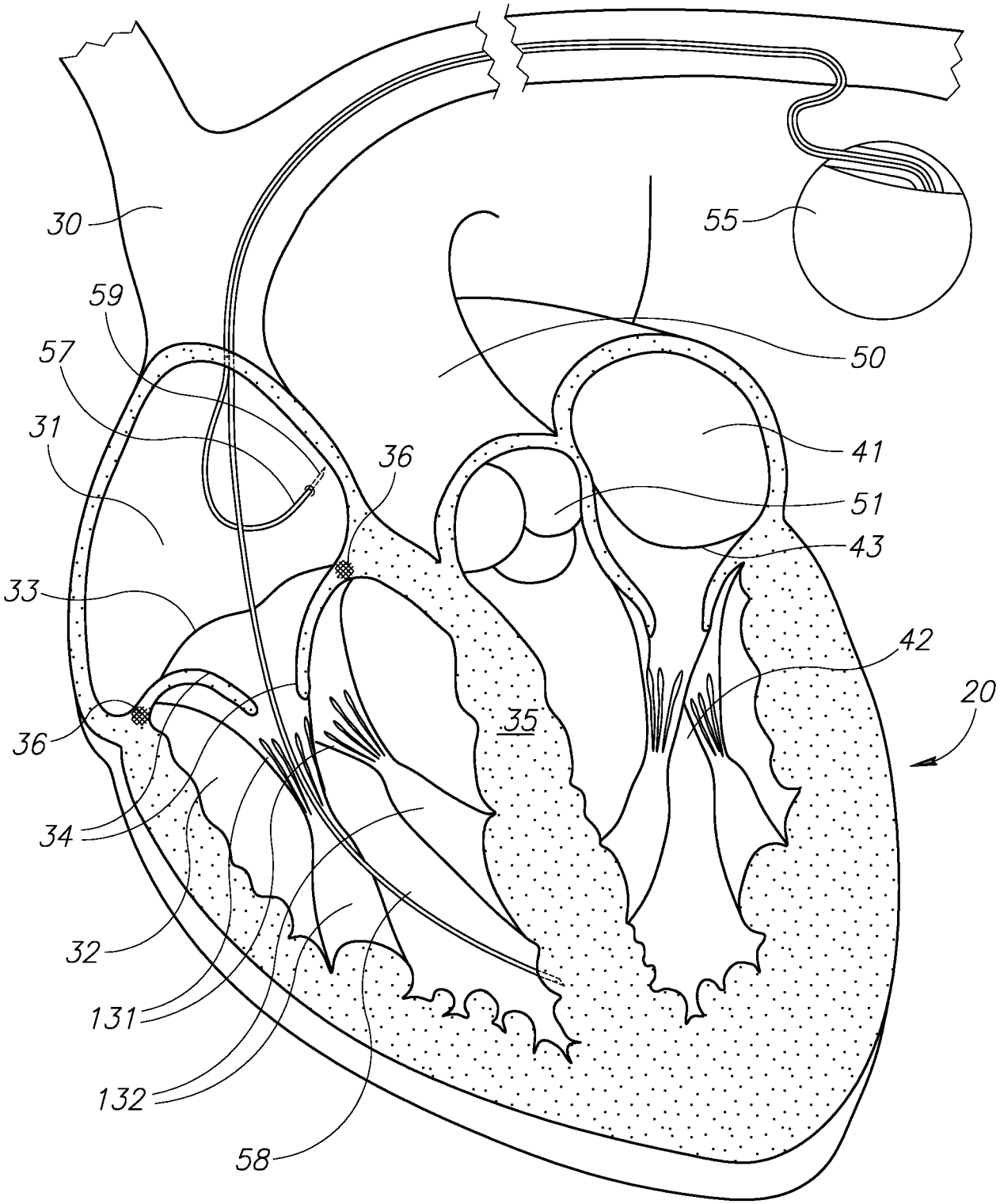



FIG.1
PRIOR ART

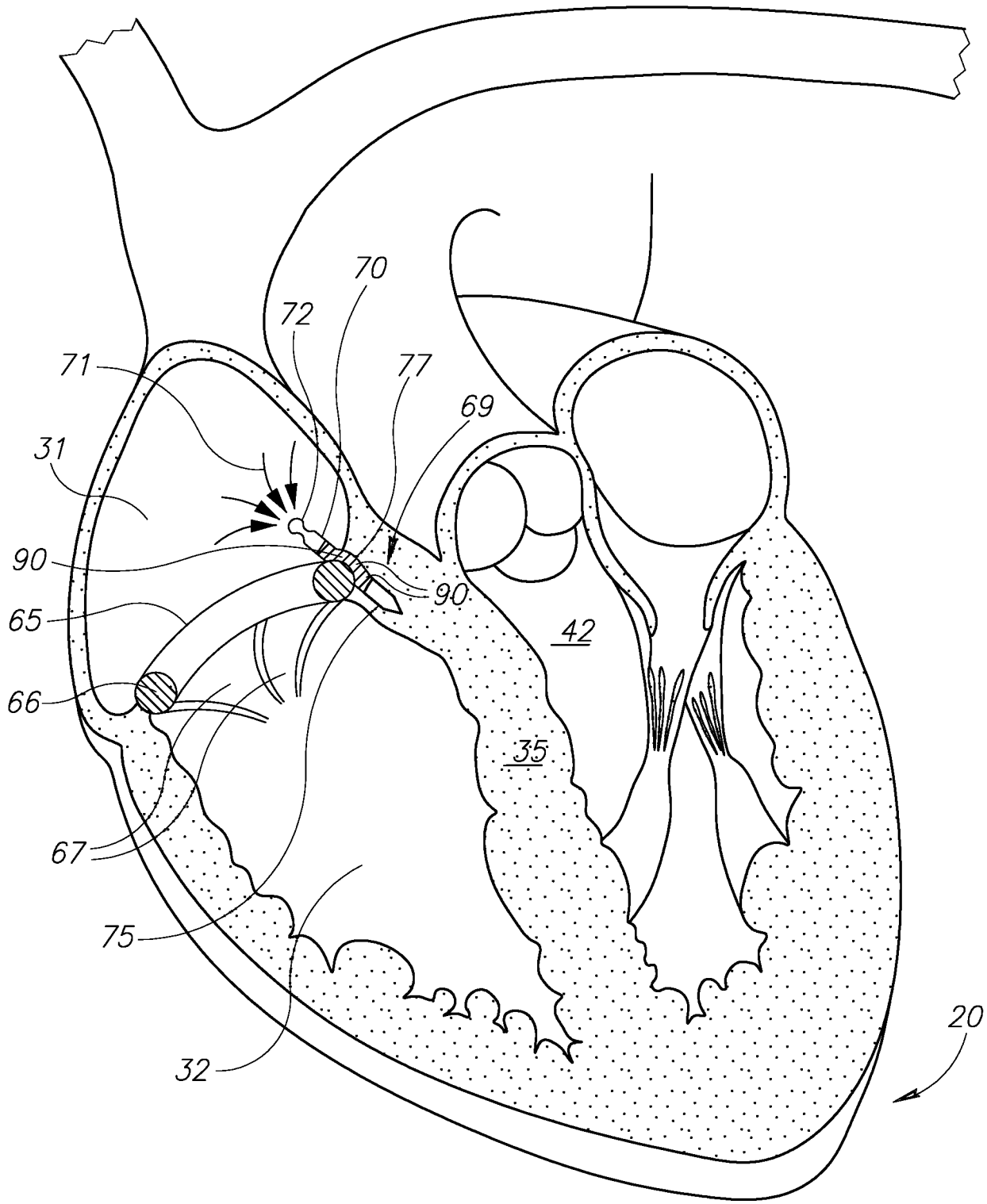
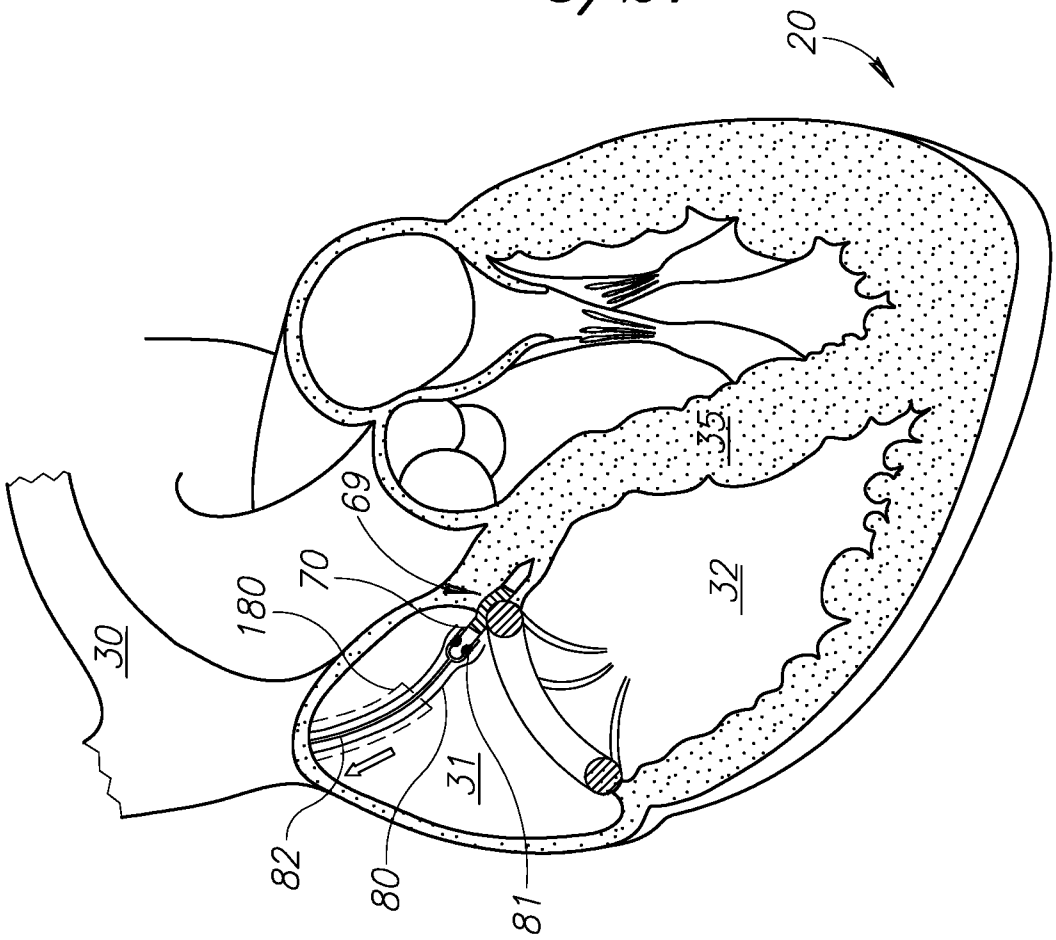



FIG.2A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180
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31
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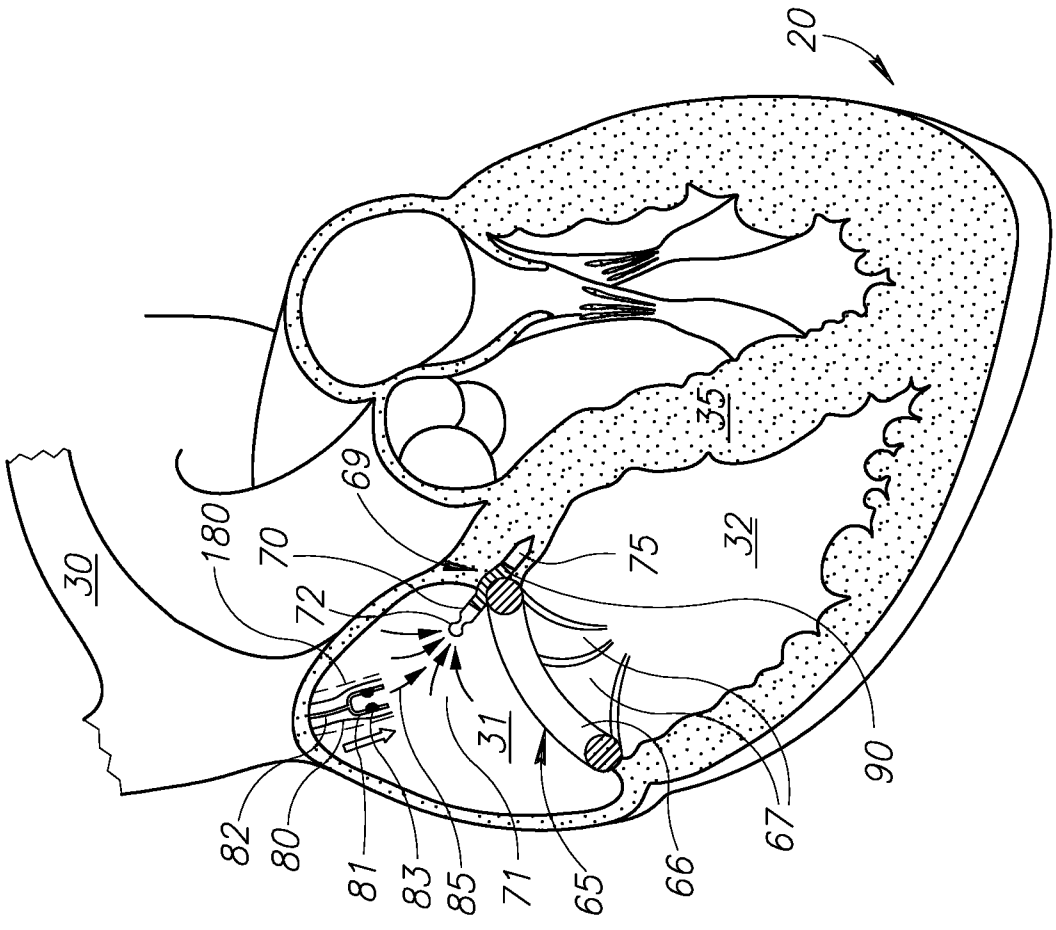
80
81

FIG.2C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66
67

FIG.2B

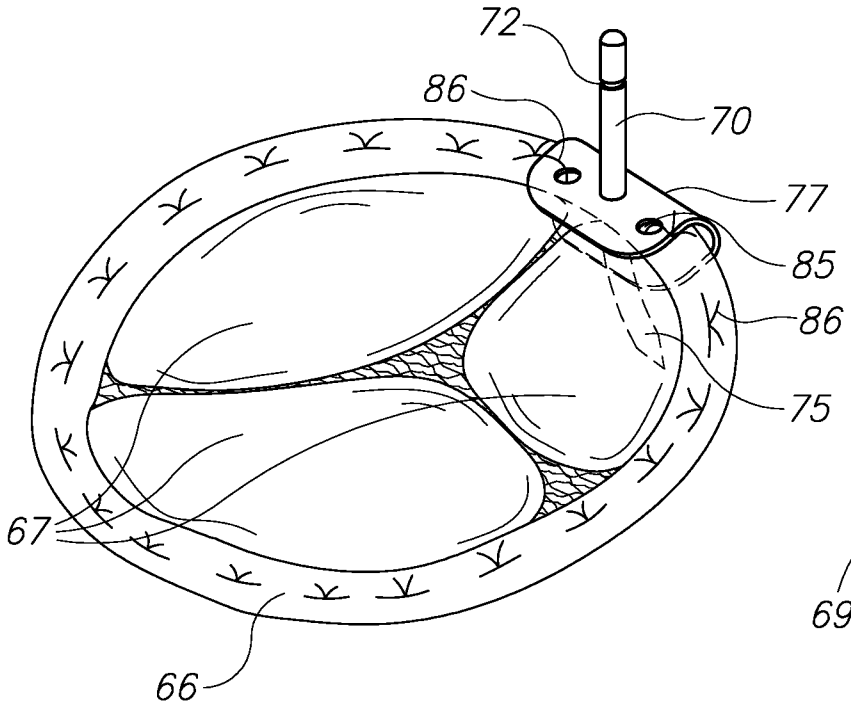



FIG.3A

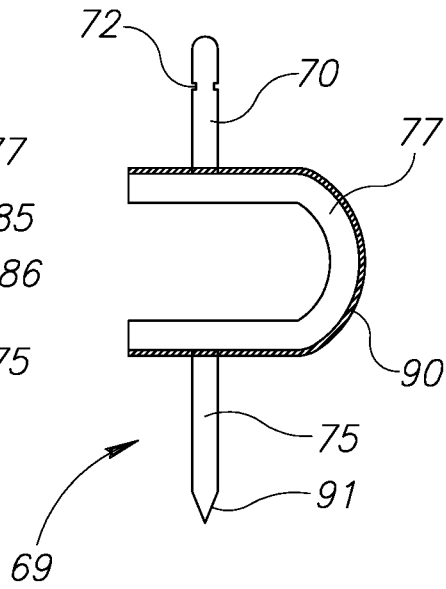



FIG.3B

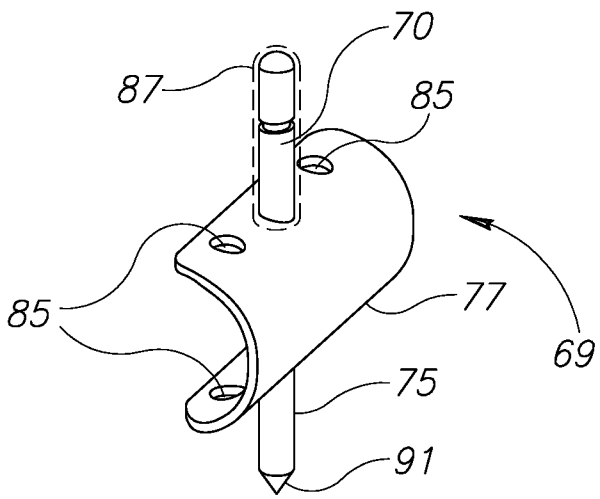



FIG.3C

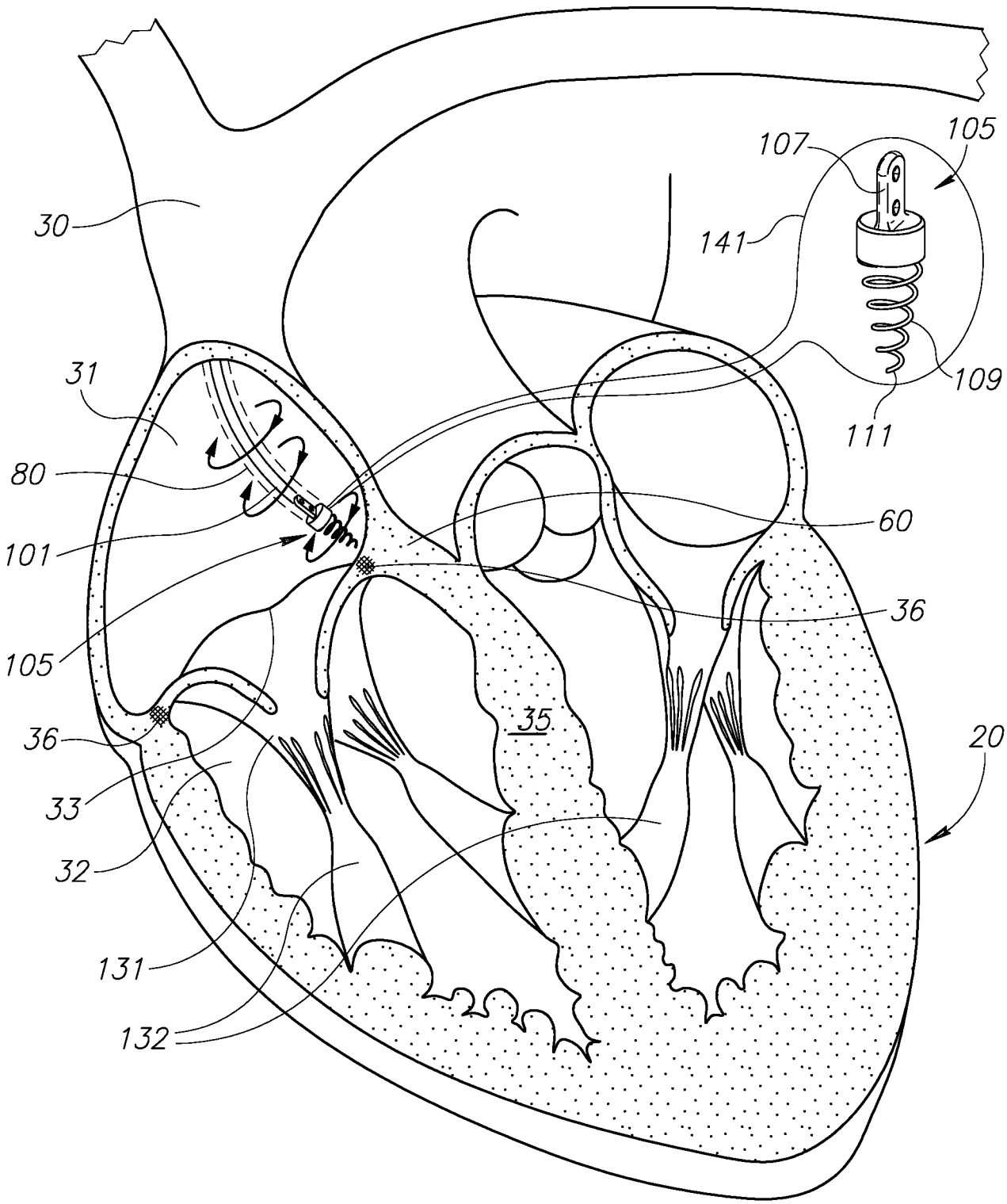



FIG.4A

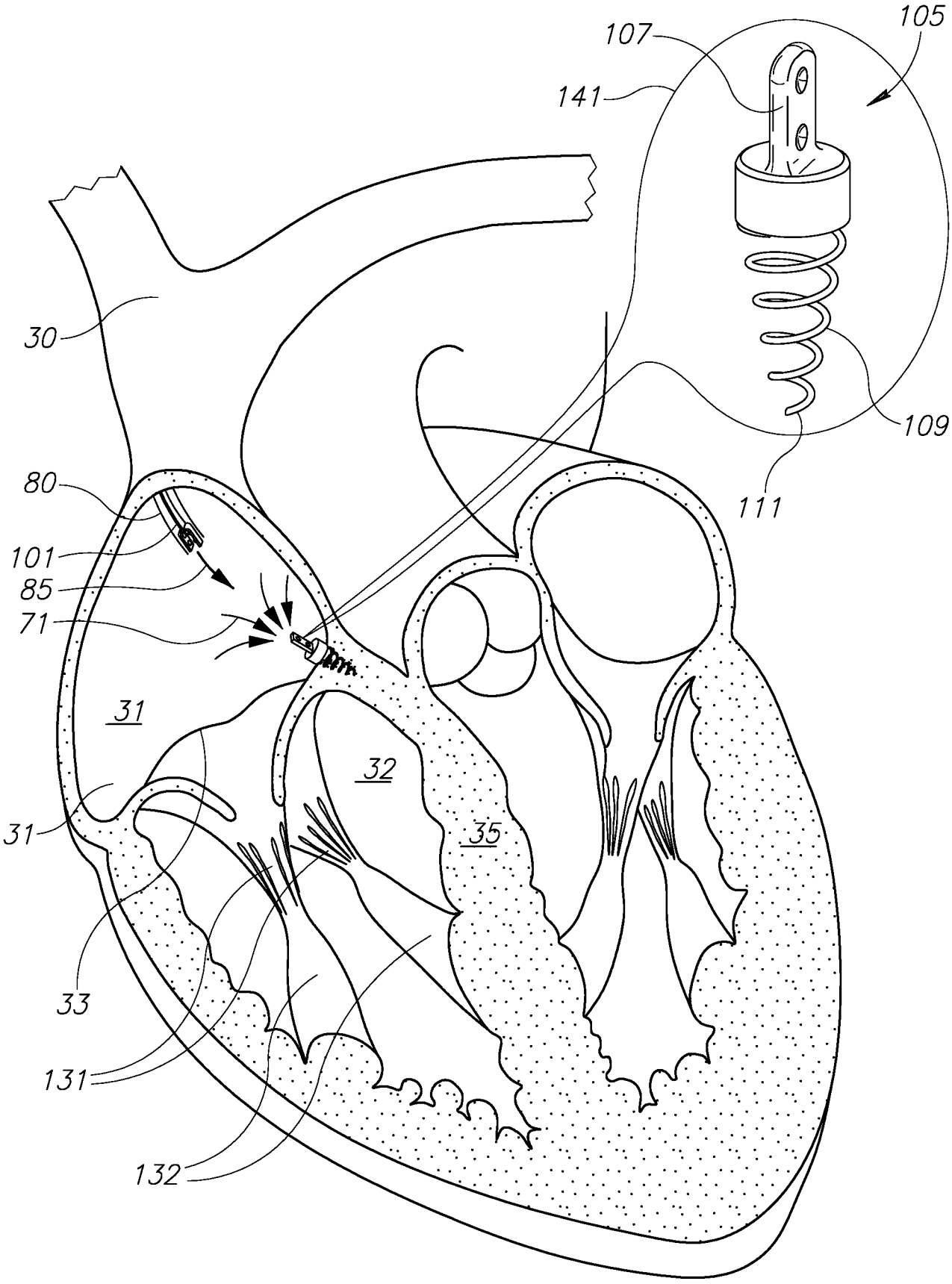



FIG.4B

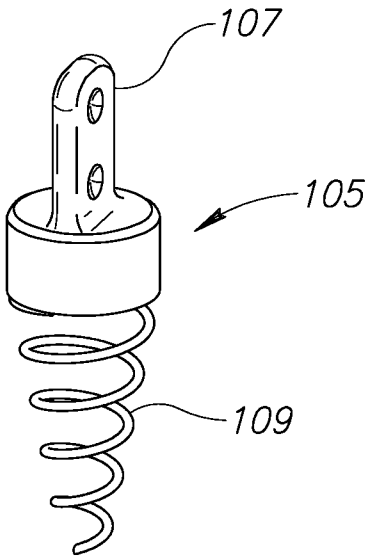



FIG.5A

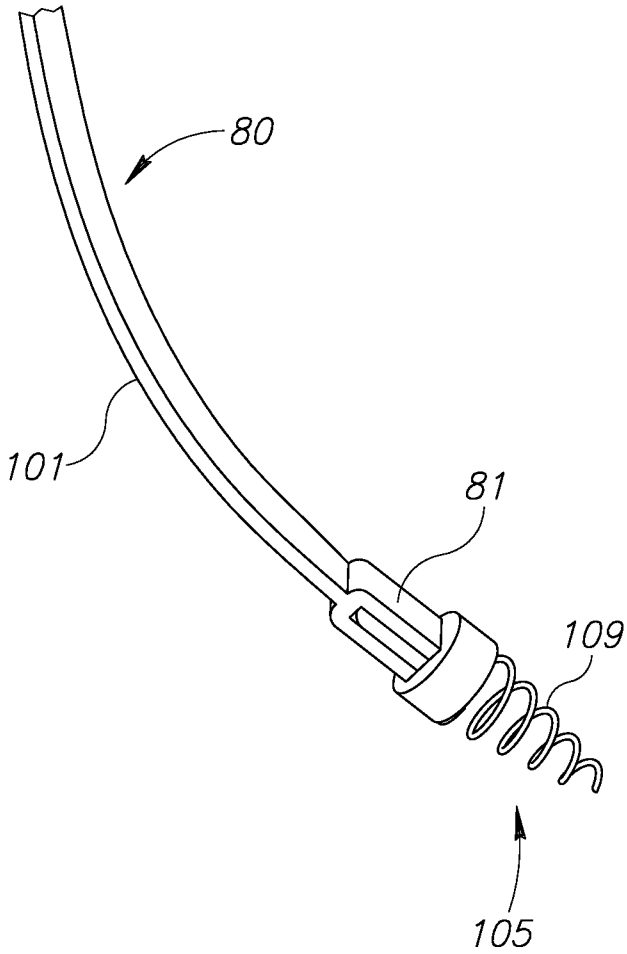



FIG.5C

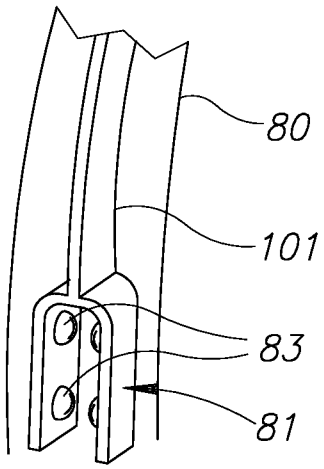
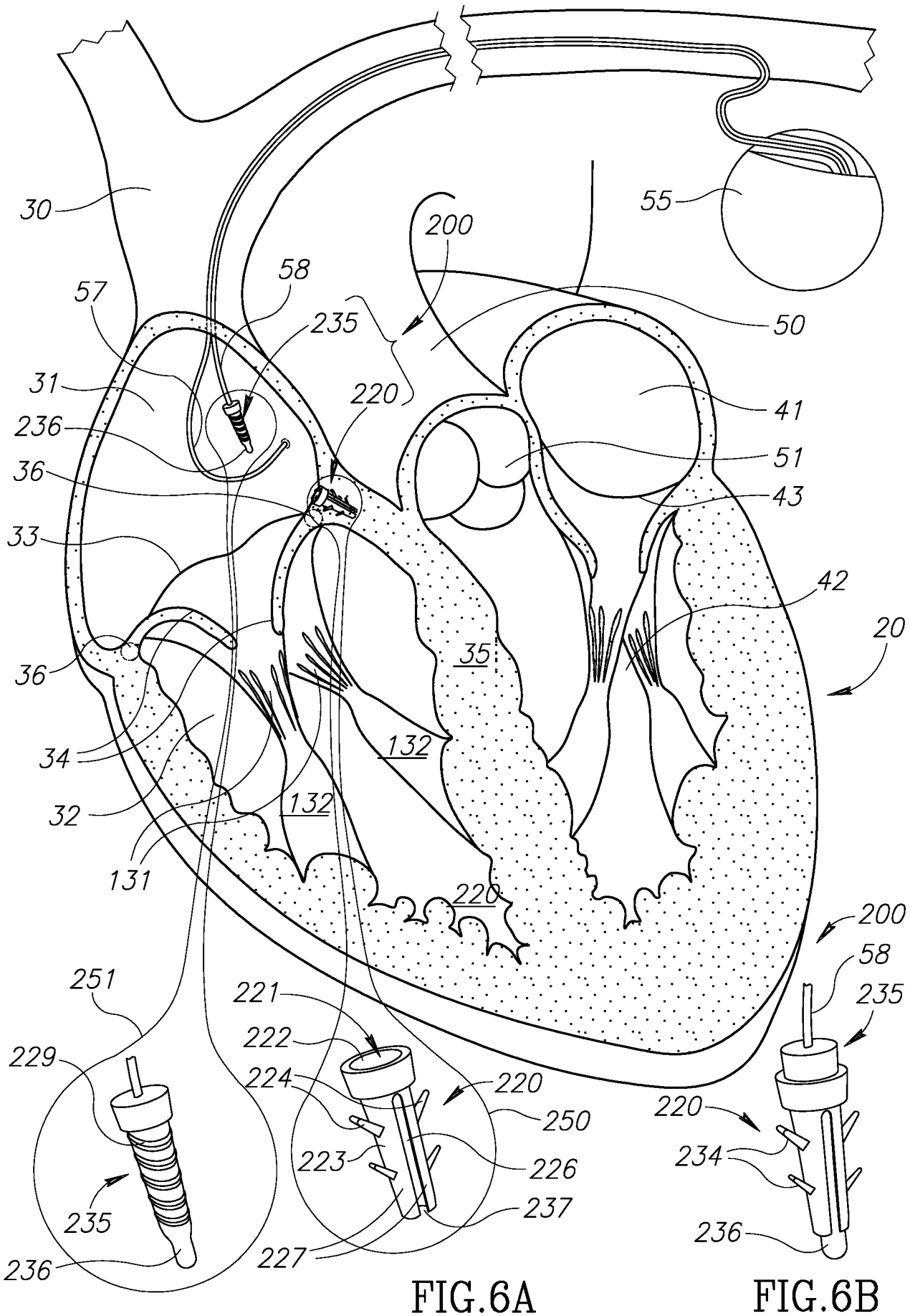



FIG.5B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131
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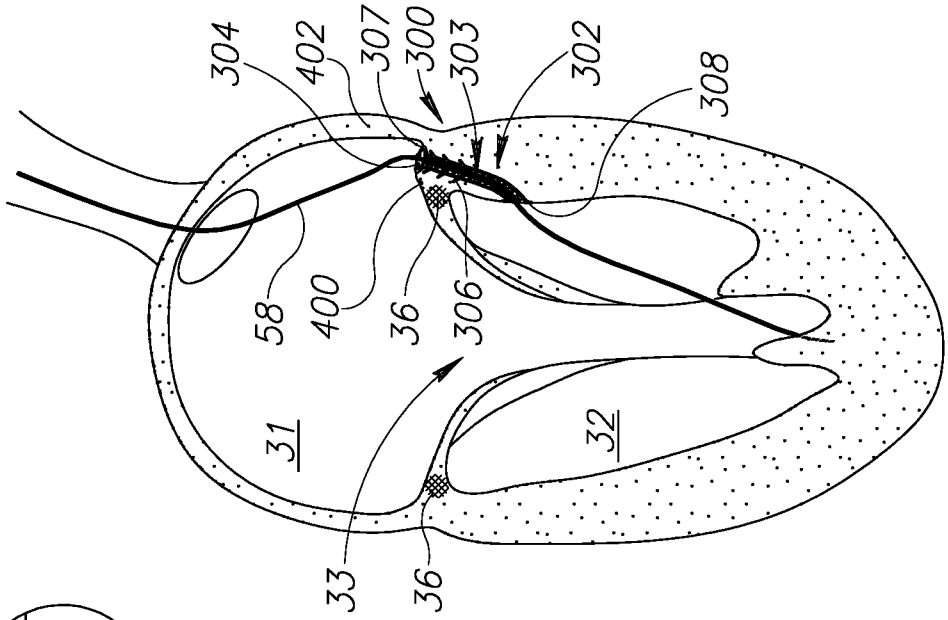
227
236

FIG.6A FIG.6B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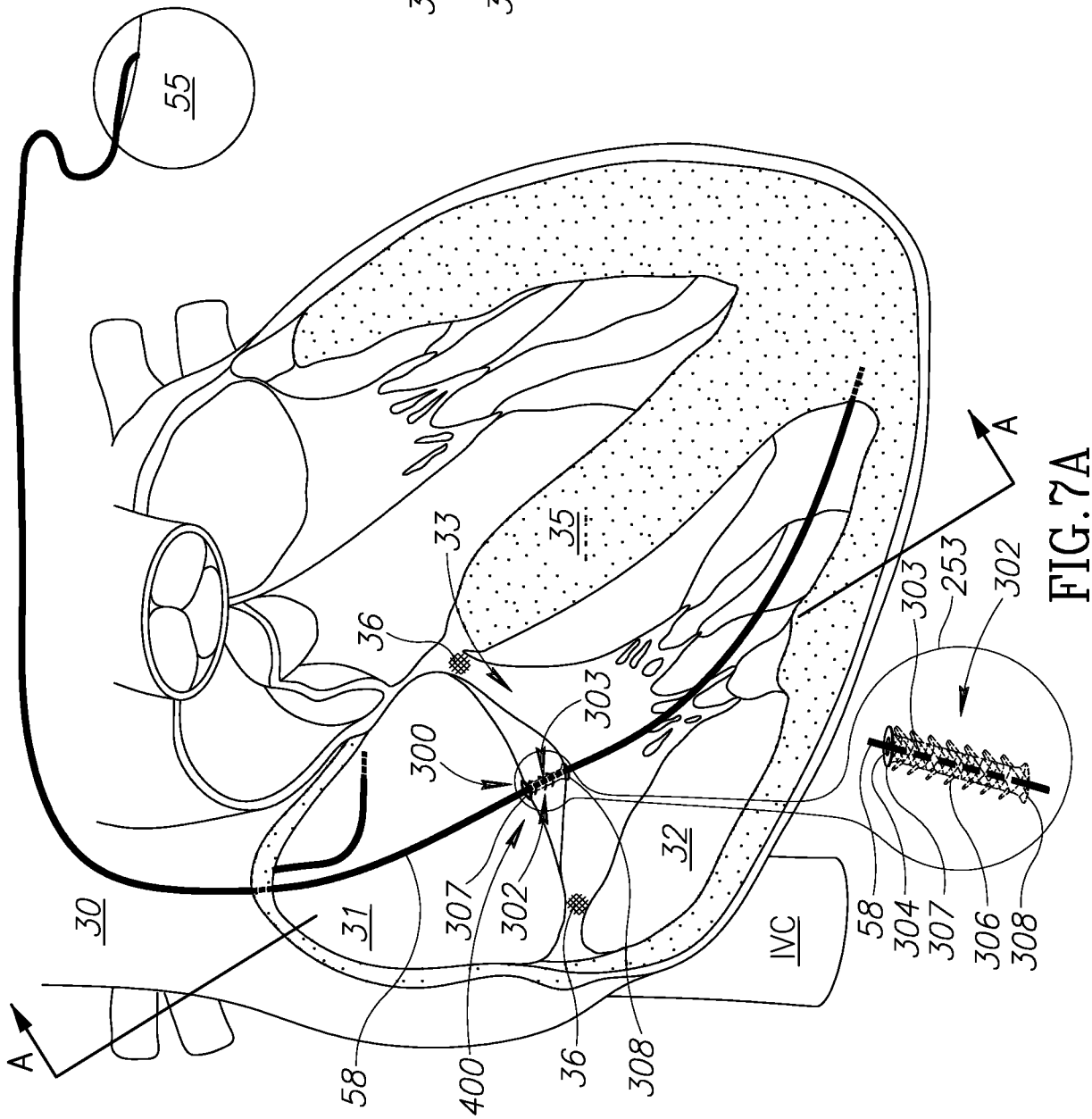
36

FIG.7B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IVC
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253
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58
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308

FIG.7A

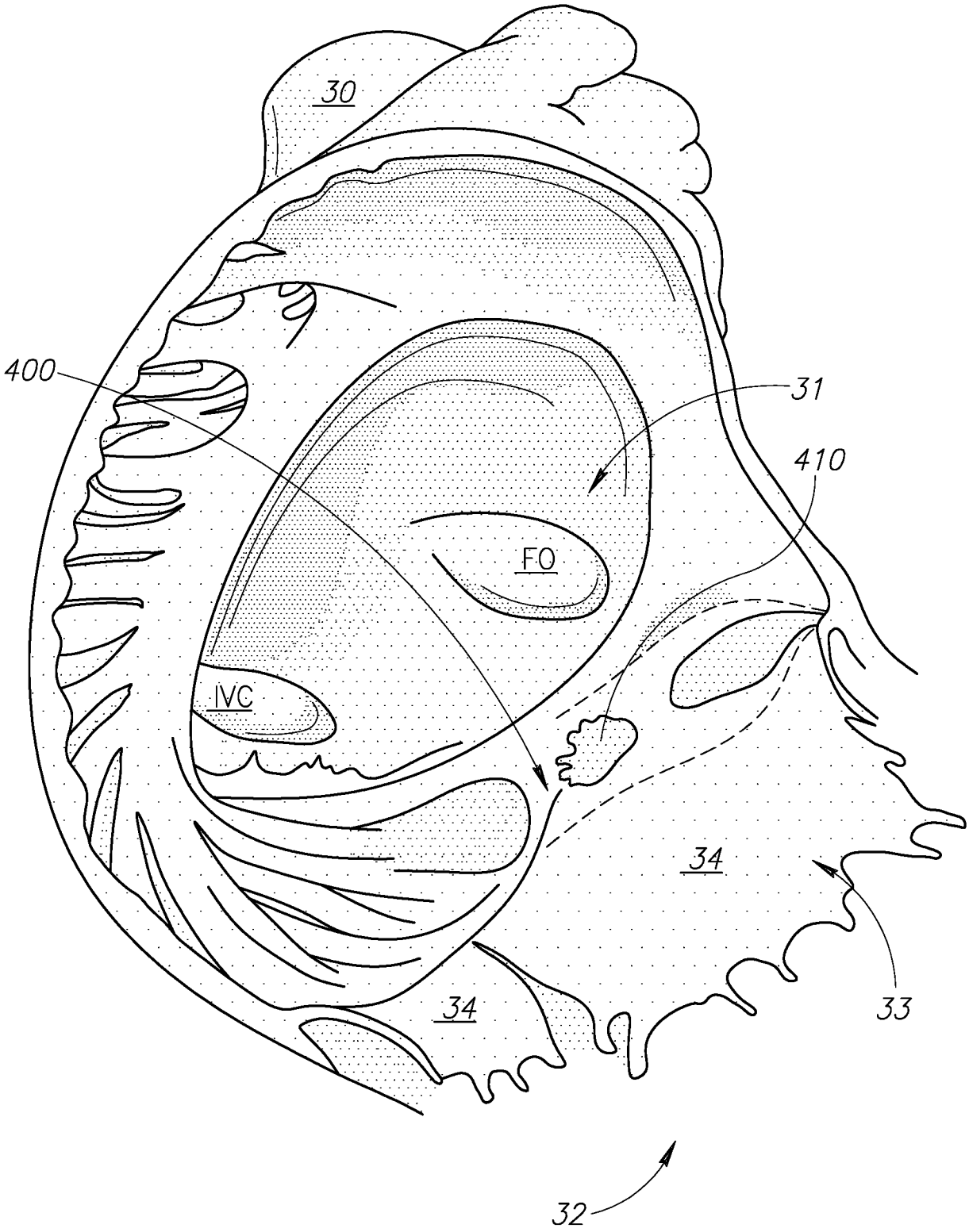



FIG.7C

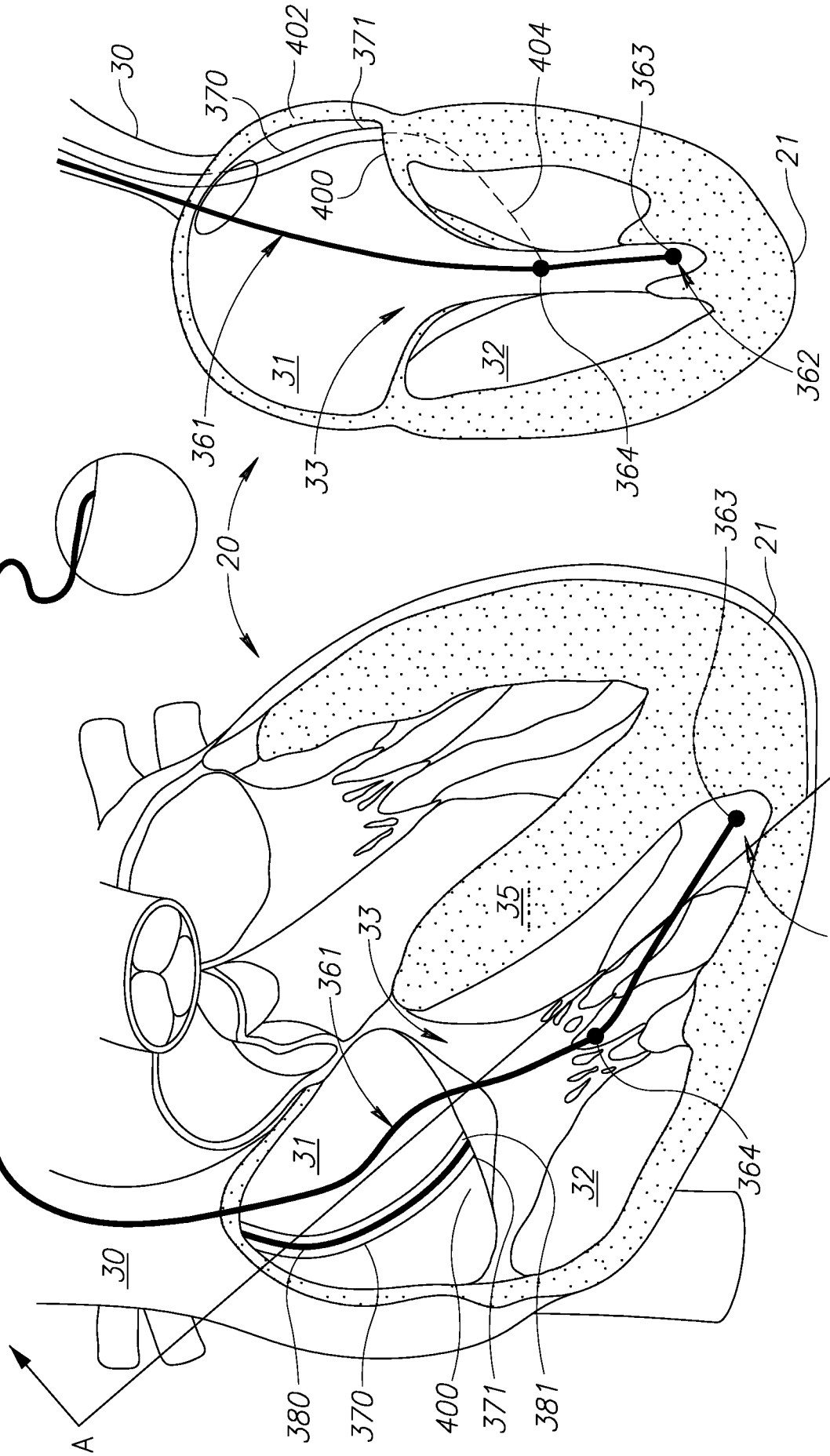



FIG.8A

FIG.8B

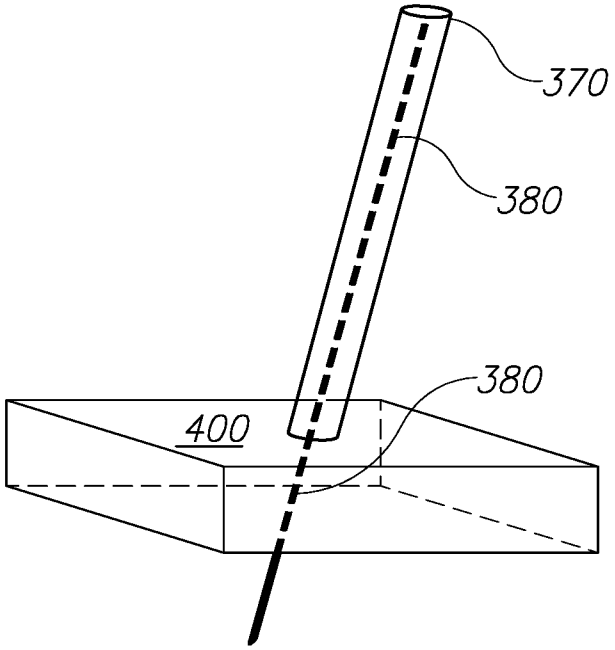



FIG.8C

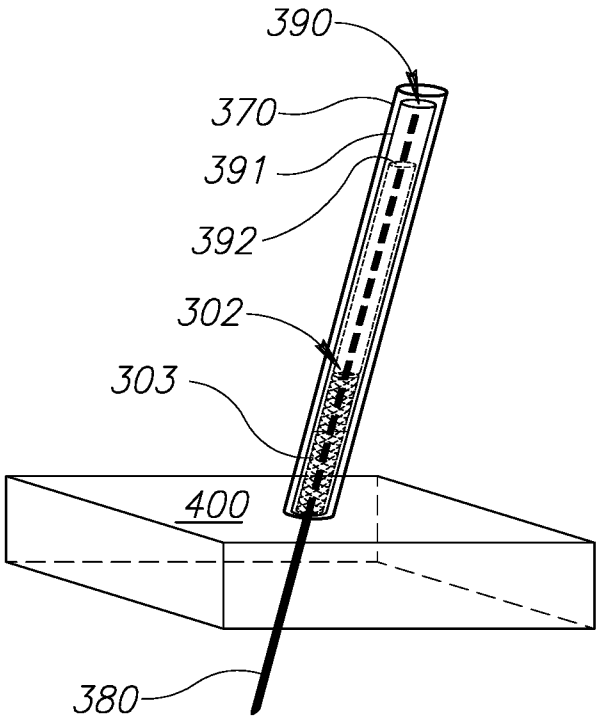



FIG.8D

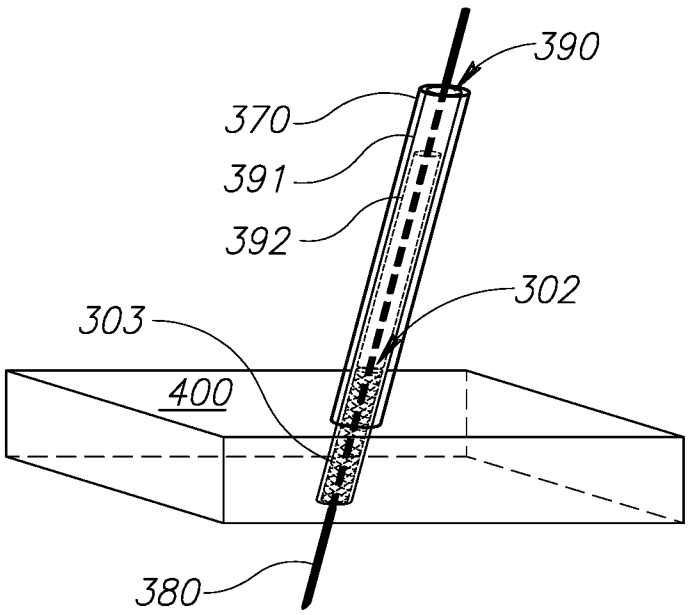



FIG.8E

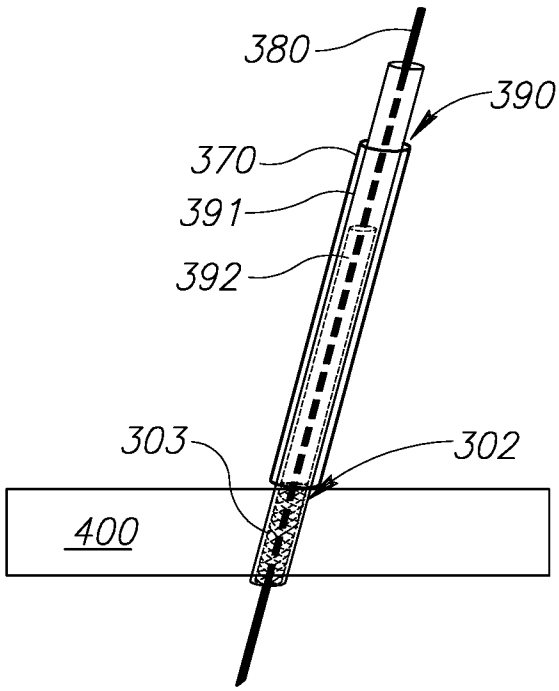



FIG.8F

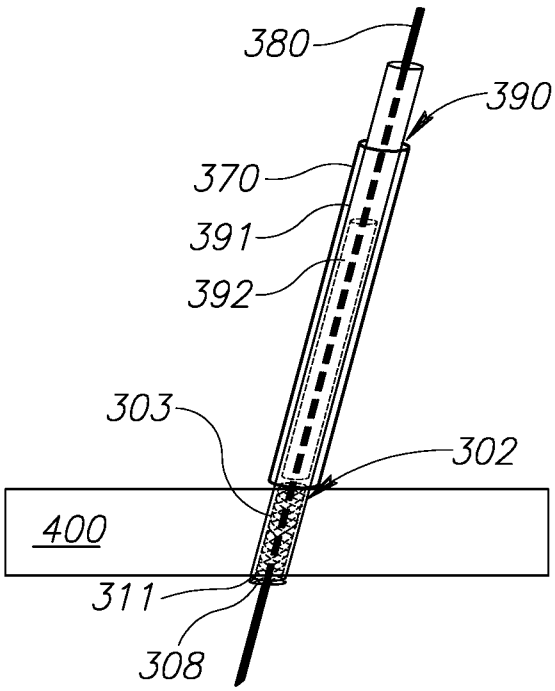



FIG.8G

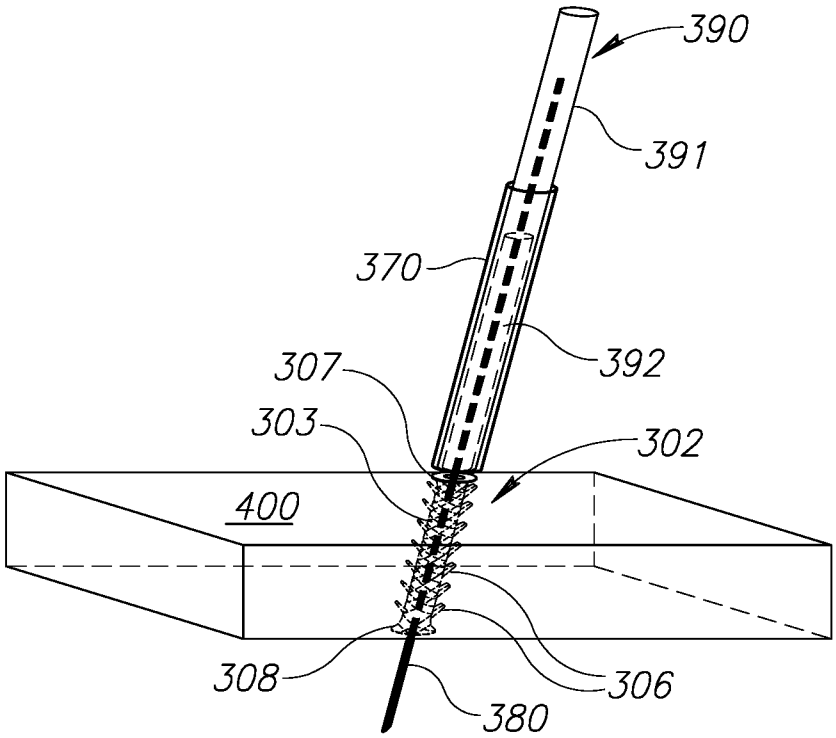
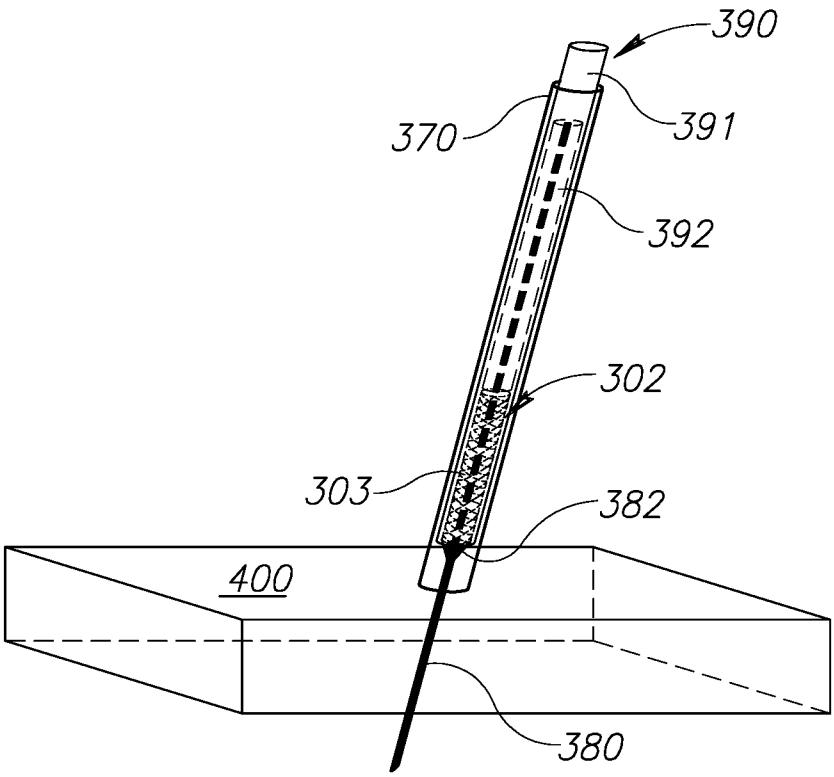



FIG.8H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370
391
392
302
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382
400
380

FIG.9A

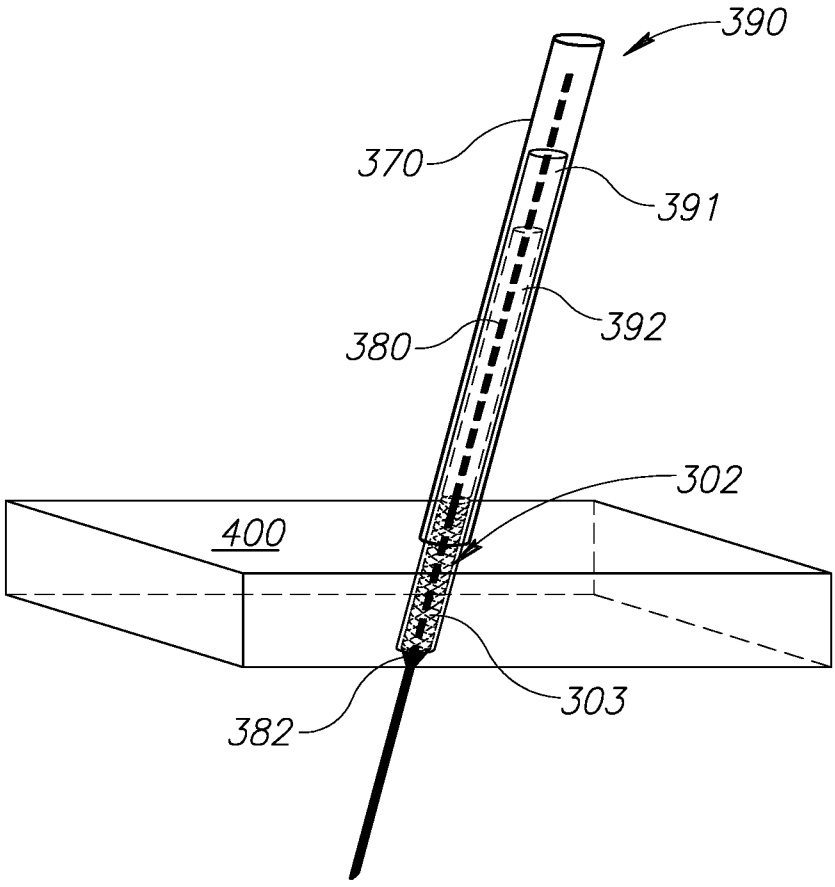
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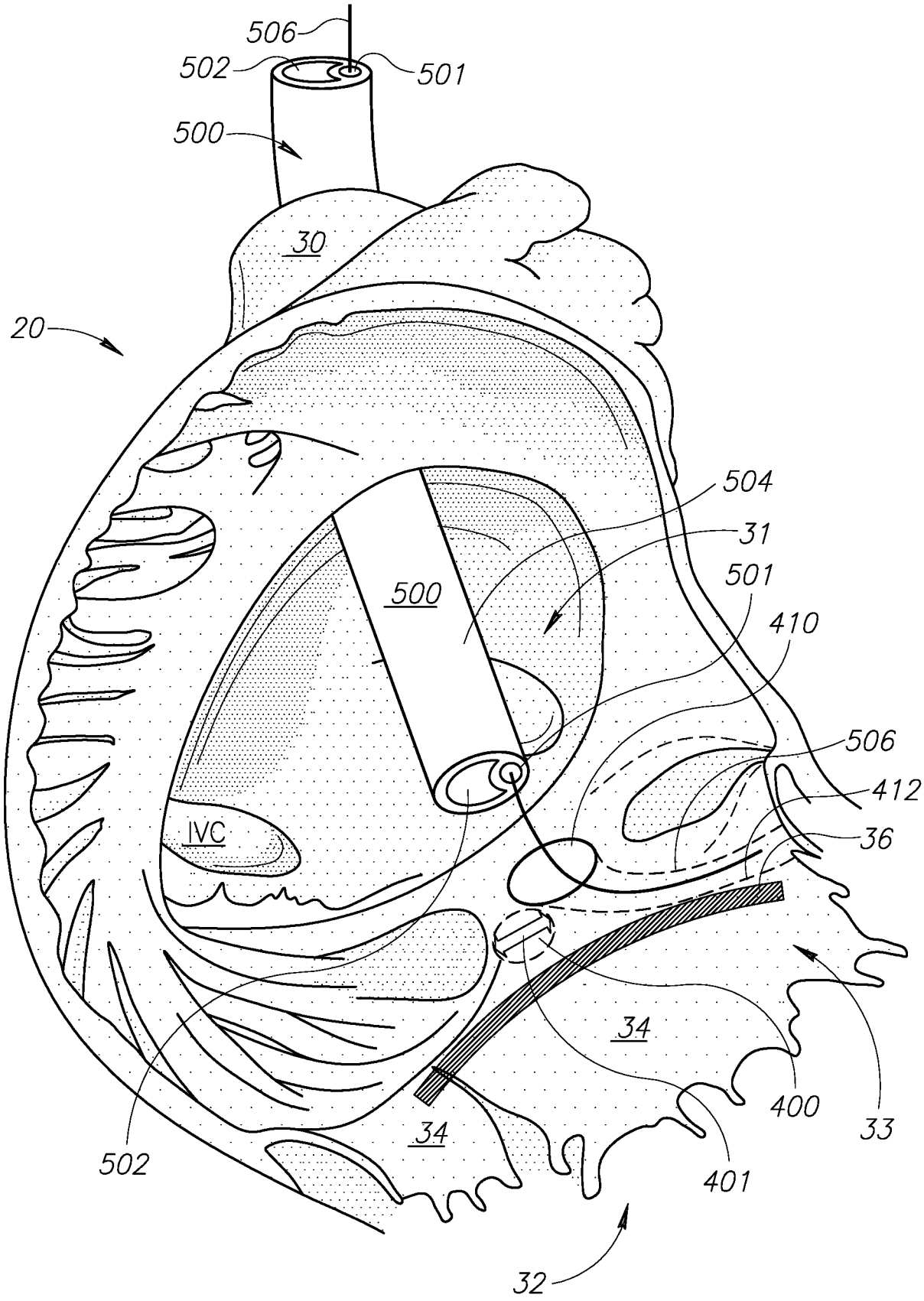
FIG.9B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501
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501
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410
506
412
IVC
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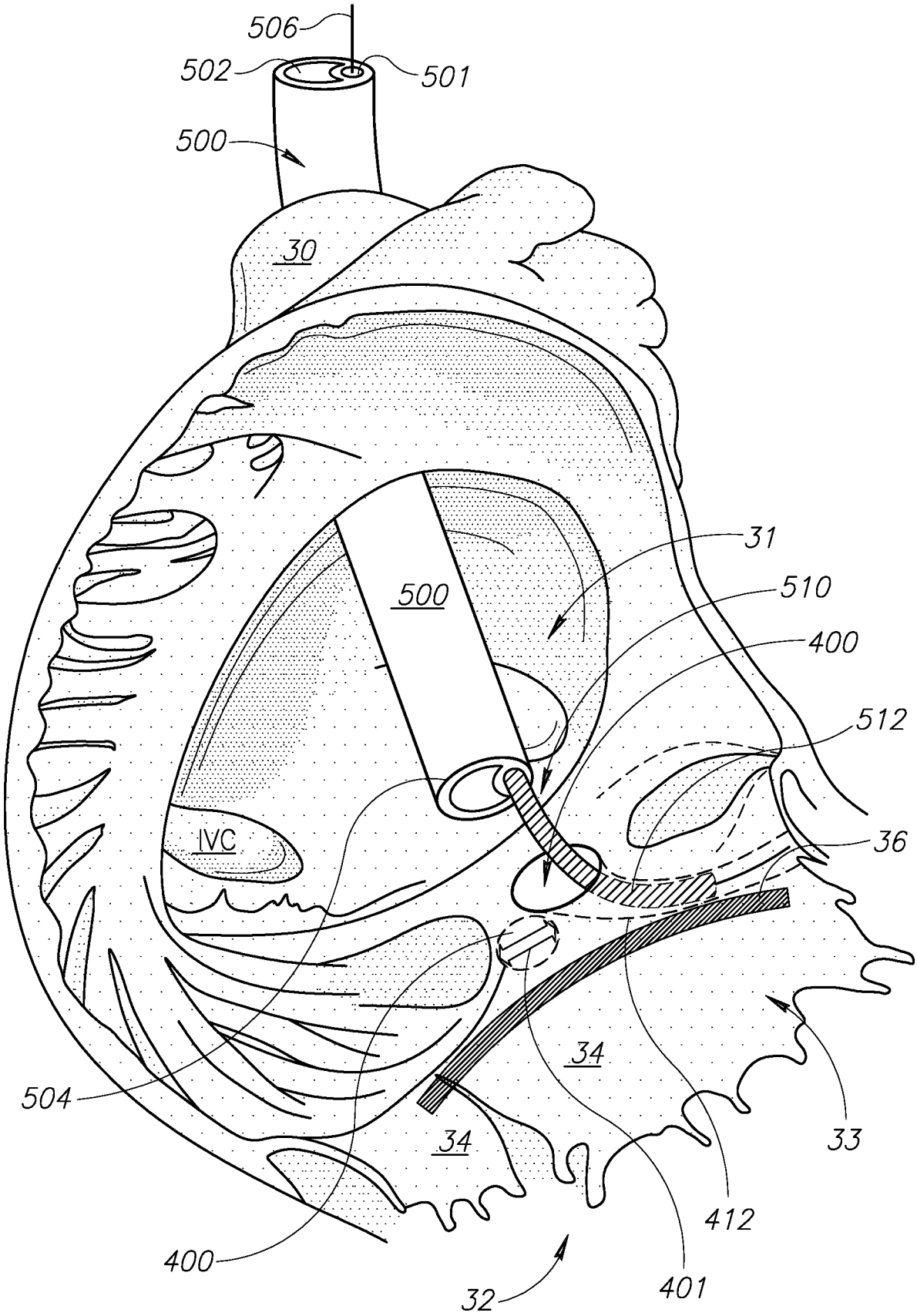
400
33
502
34
401
32

FIG.10A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510
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512
IVC
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504
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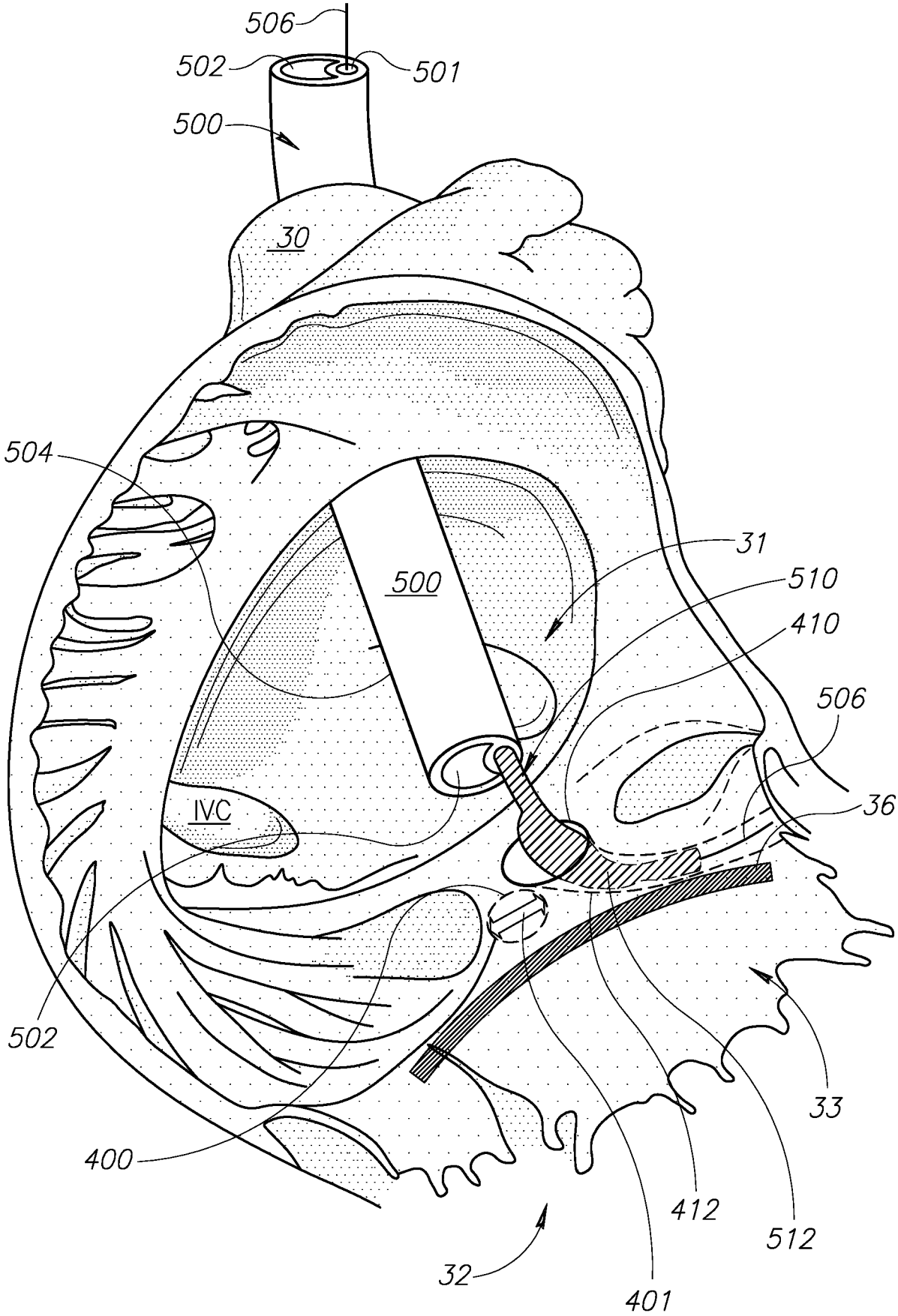
33
412
400
401
32

FIG.10B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504
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410
506
IVC
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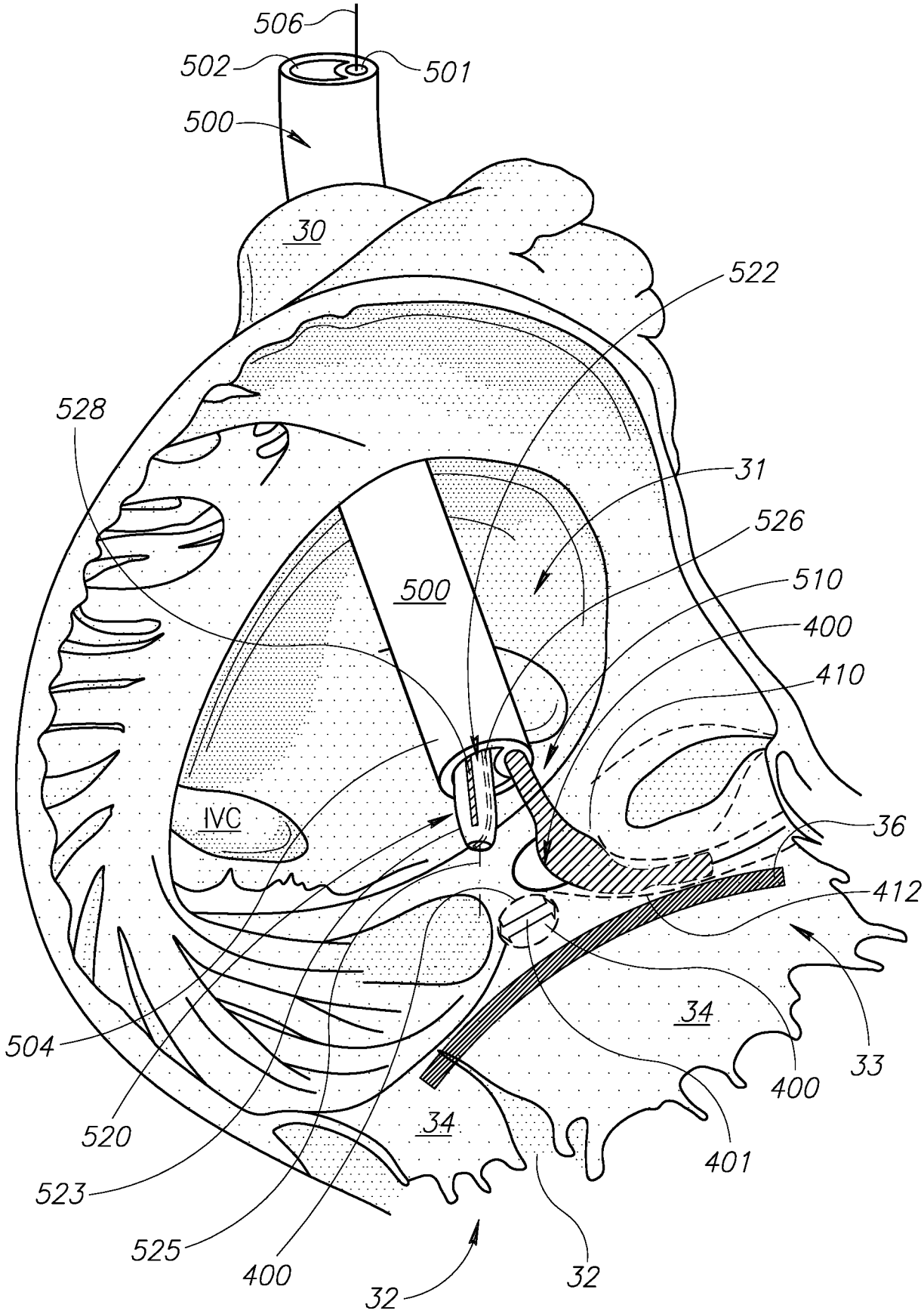
33
412
512
32
401

FIG.10C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528
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IVC
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401
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FIG.10D

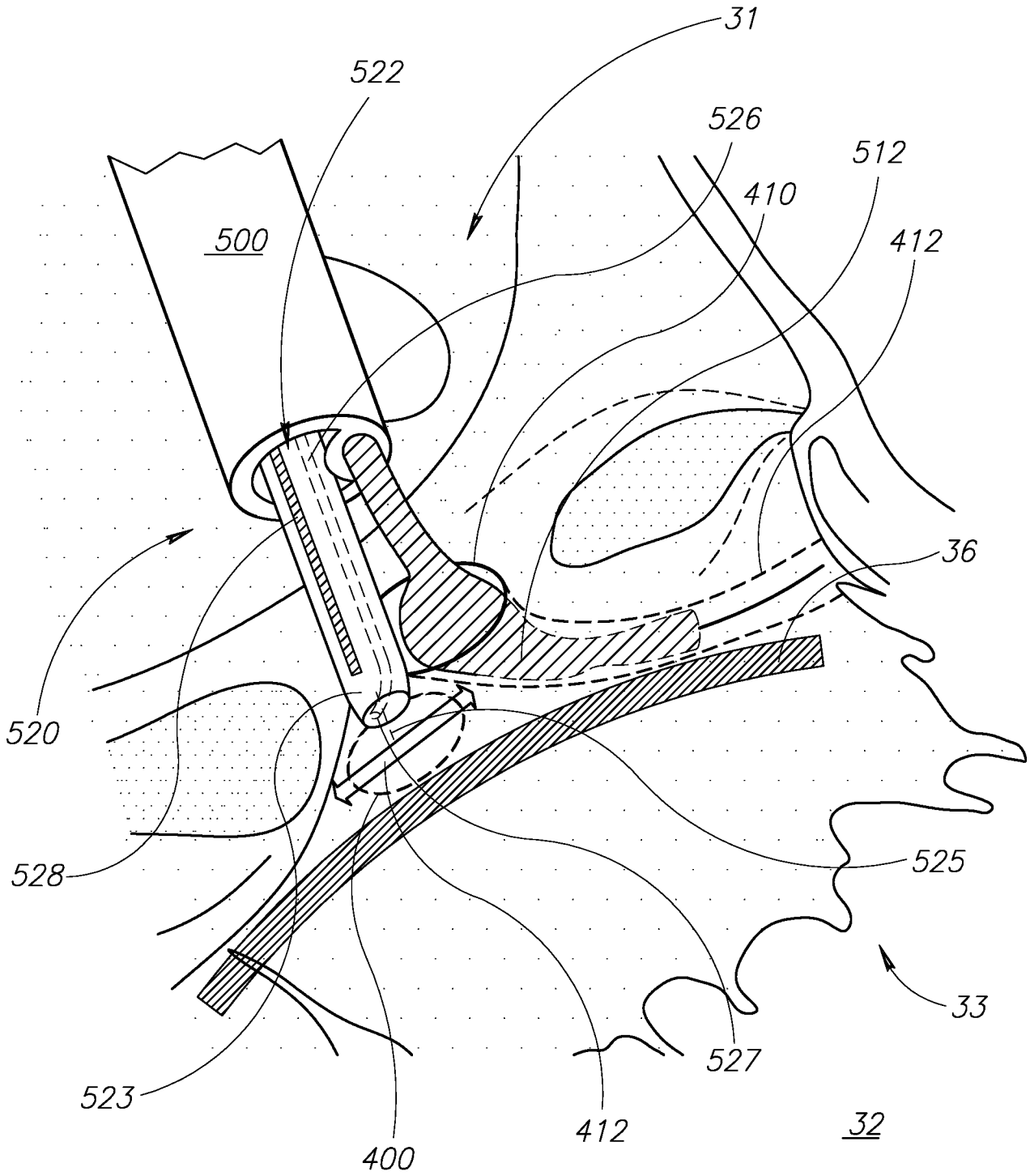



FIG.10E

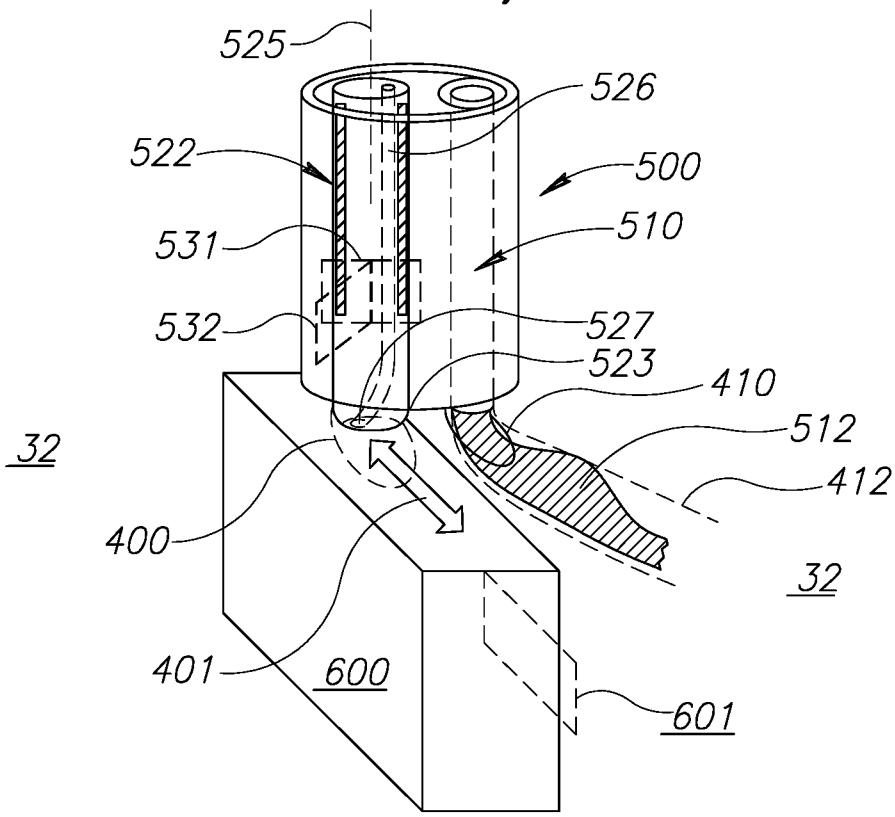



FIG.11A

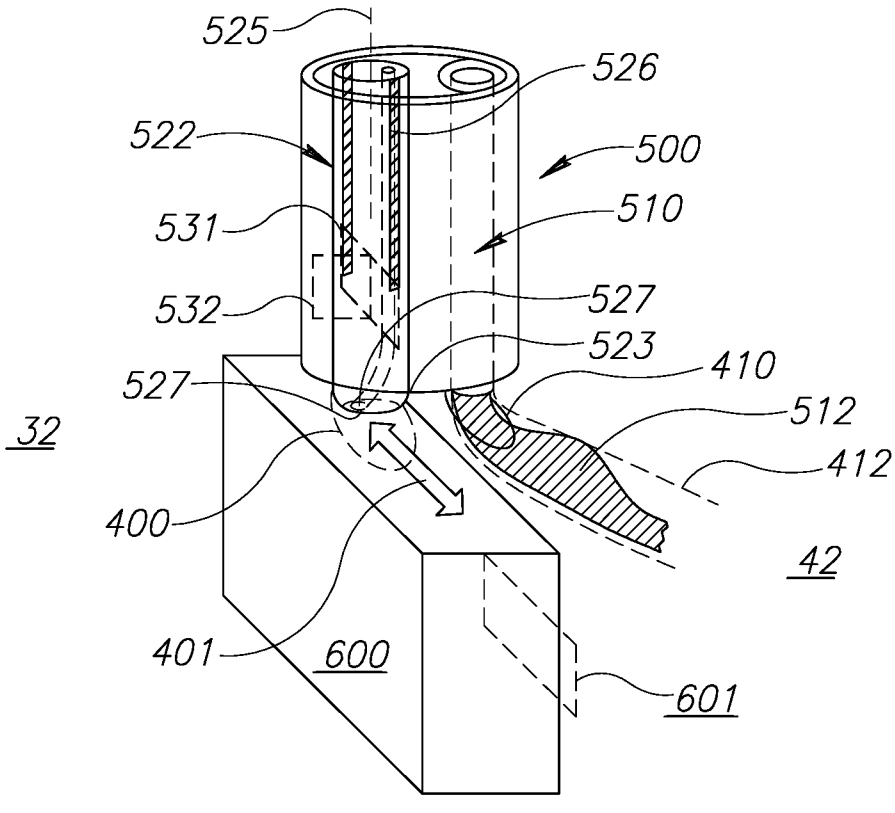
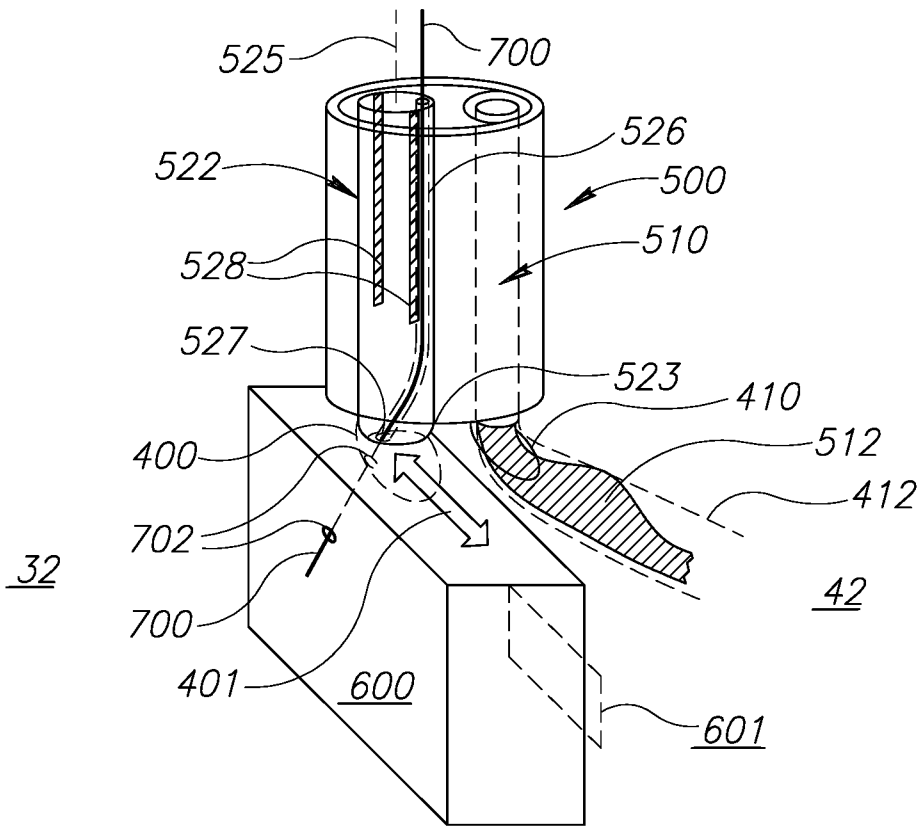



FIG.11B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412
702
32
42
700
401
600
601

FIG.11C