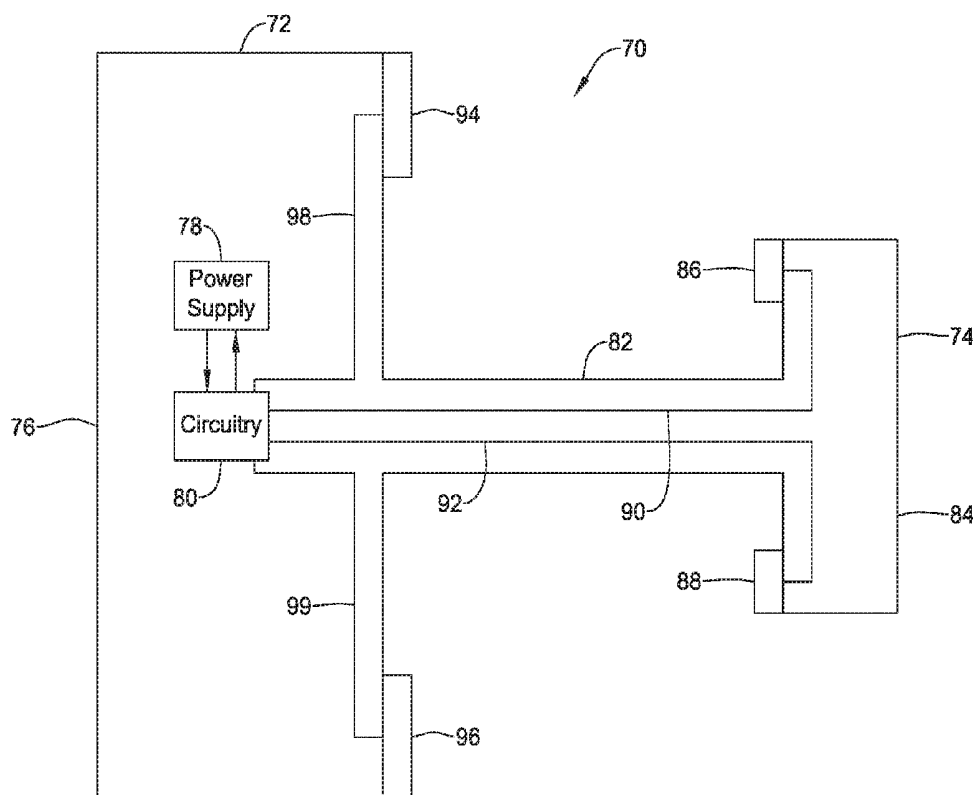




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(19) **United States**(12) **Patent Application Publication**
Liu(10) **Pub. No.: US 2017/0182327 A1**(43) **Pub. Date: Jun. 29, 2017**(54) **IMPLANTABLE MEDICAL DEVICE FOR
DEPLOYMENT ACROSS THE
ATRIOVENTRICULAR SEPTUM**(71) Applicant: **CARDIAC PACEMAKERS, INC., St.**
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Paul, MN (US)(21) Appl. No.: **15/392,668**(22) Filed: **Dec. 28, 2016****Related U.S. Application Data**(60) Provisional application No. 62/271,647, filed on Dec.
28, 2015.**Publication Classification**(51) **Int. Cl.***A61N 1/375* (2006.01)*A61B 5/00* (2006.01)*A61N 1/372* (2006.01)*A61N 1/368* (2006.01)*A61N 1/365* (2006.01)*A61B 5/042* (2006.01)*A61N 1/05* (2006.01)(52) **U.S. Cl.**CPC *A61N 1/3756* (2013.01); *A61B 5/0422*(2013.01); *A61B 5/686* (2013.01); *A61N 1/057*(2013.01); *A61N 1/3684* (2013.01); *A61N**1/36514* (2013.01); *A61N 1/37205* (2013.01)(57) **ABSTRACT**

An implantable medical device (IMD) may be configured for deployment at a patient's atrioventricular septum in order to sense and/or pace a patient's heart. The atrioventricular septum of the patient's heart may have an atrial facing side defining part of the right atrium of the patient's heart and a ventricle facing side defining part of the left ventricle of the patient's heart. The IMD may include a first component configured to be positioned at least in part in the right atrium of the patient's heart proximate the atrioventricular septum, and a second component configured to be positioned at least in part in the left ventricle.



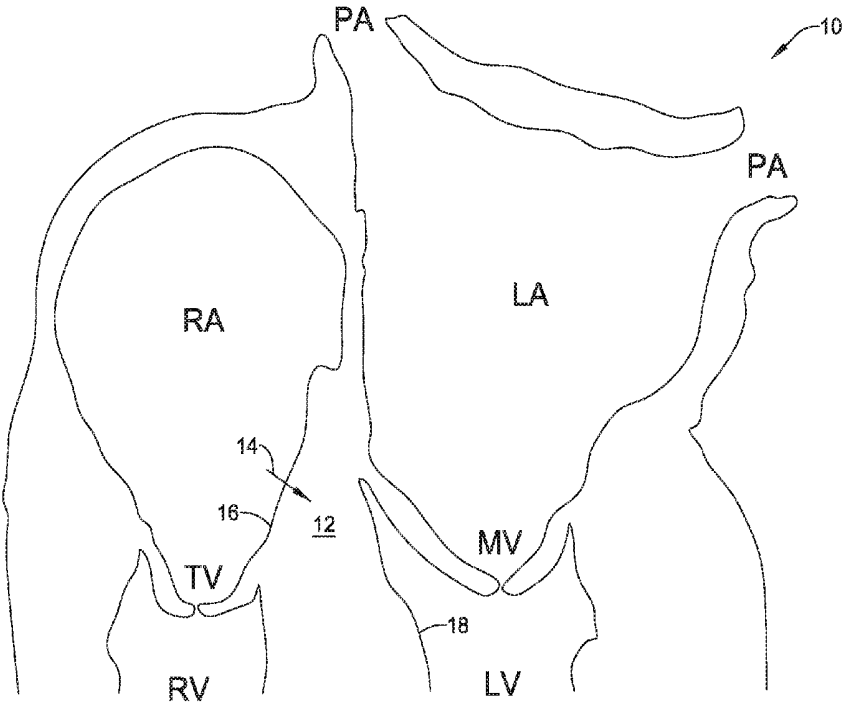


FIG. 1

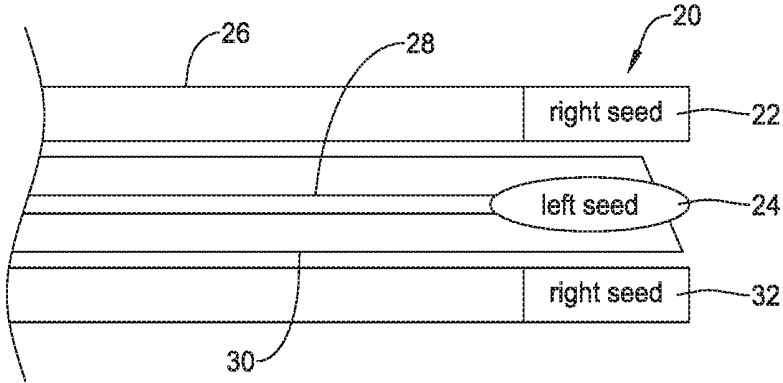


FIG. 2

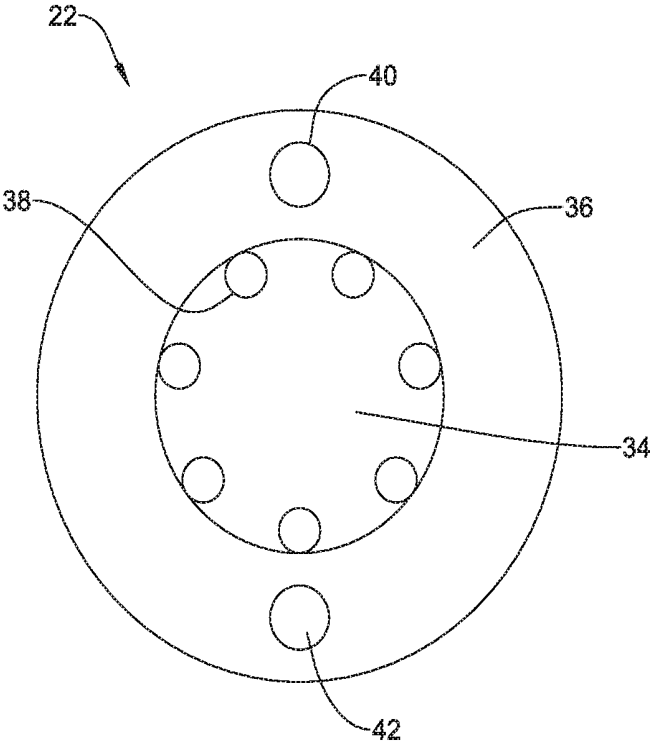
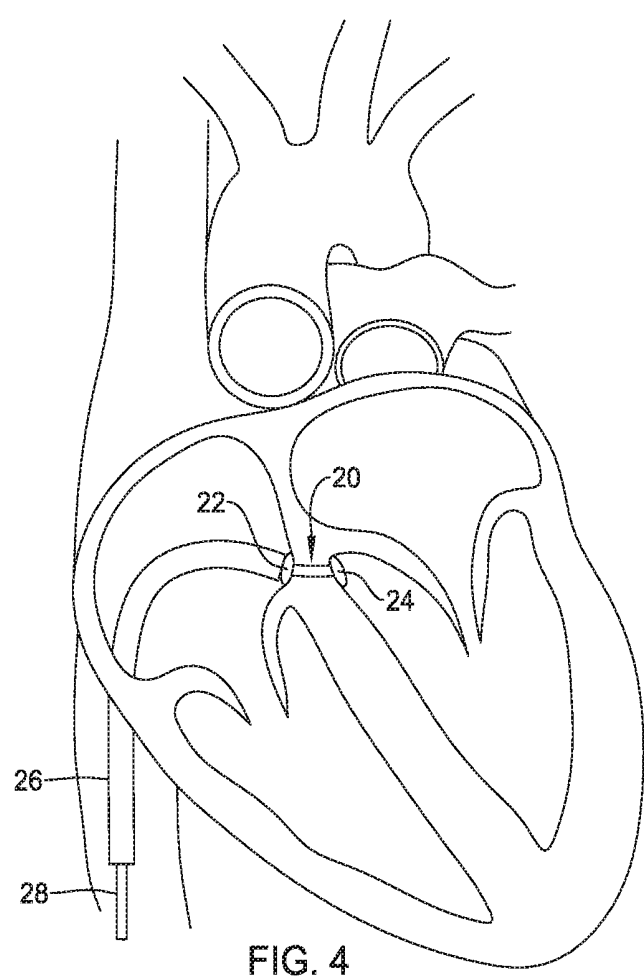


FIG. 3



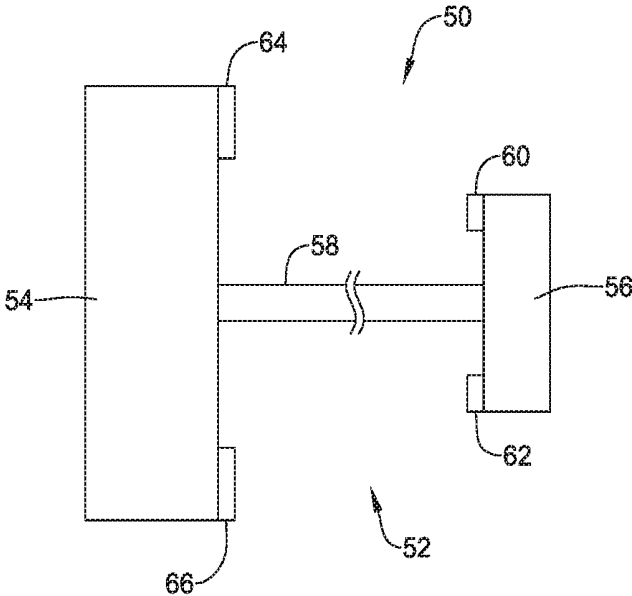


FIG. 5

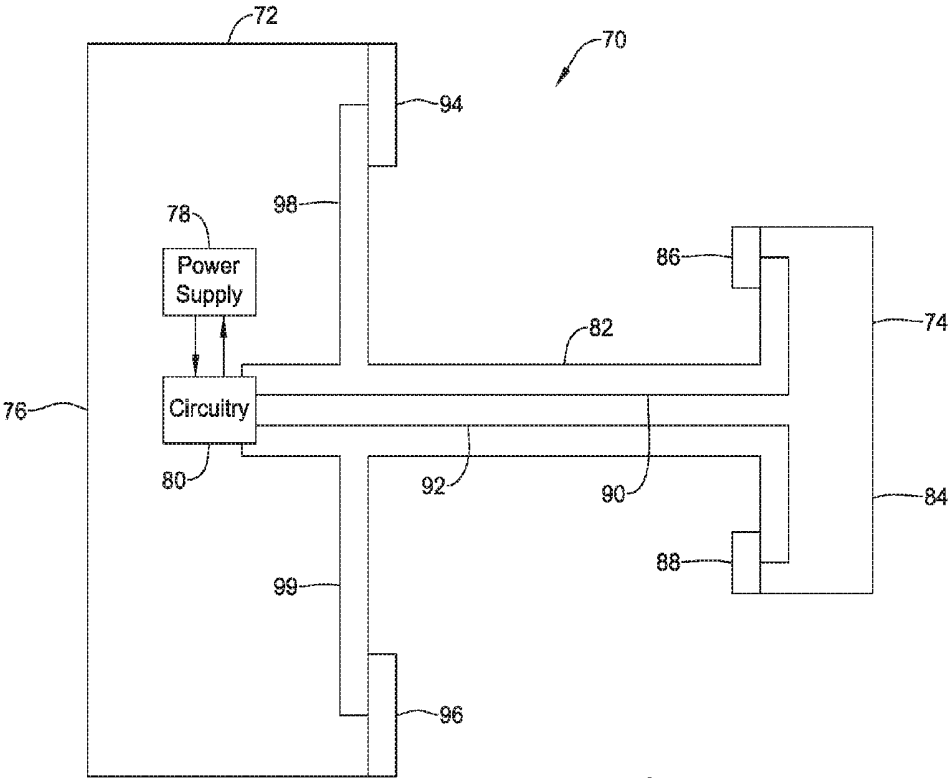


FIG. 6

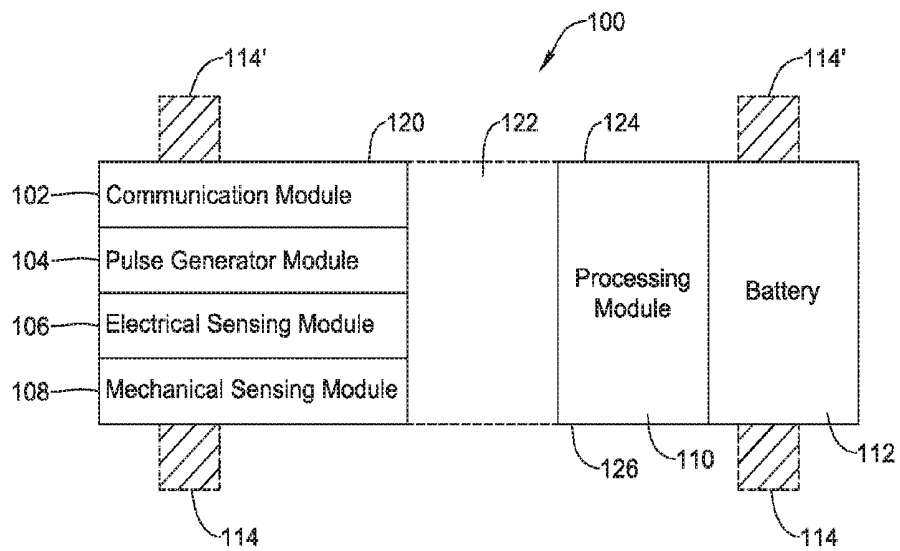


FIG. 7

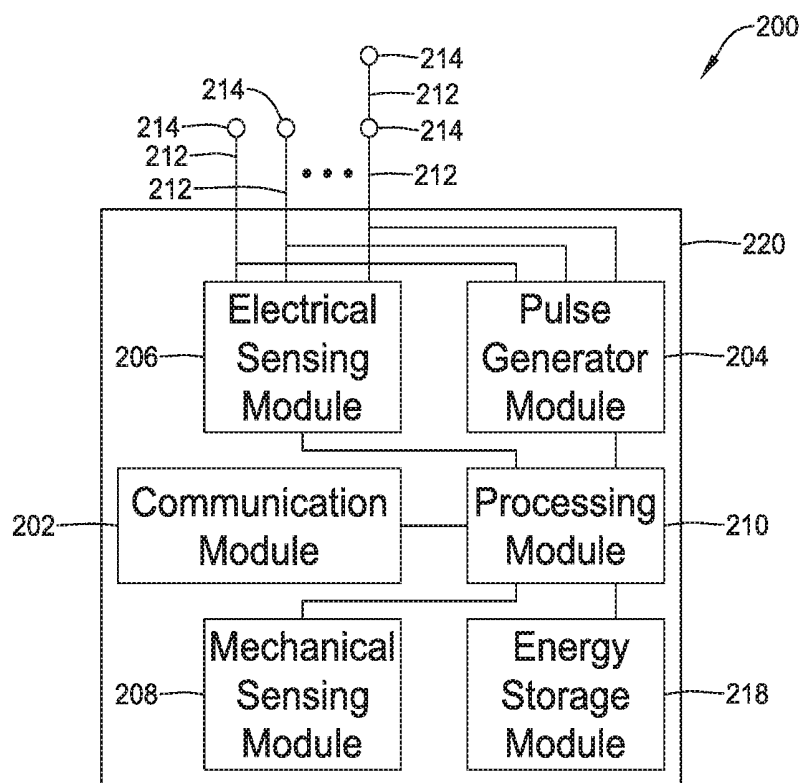


FIG. 8

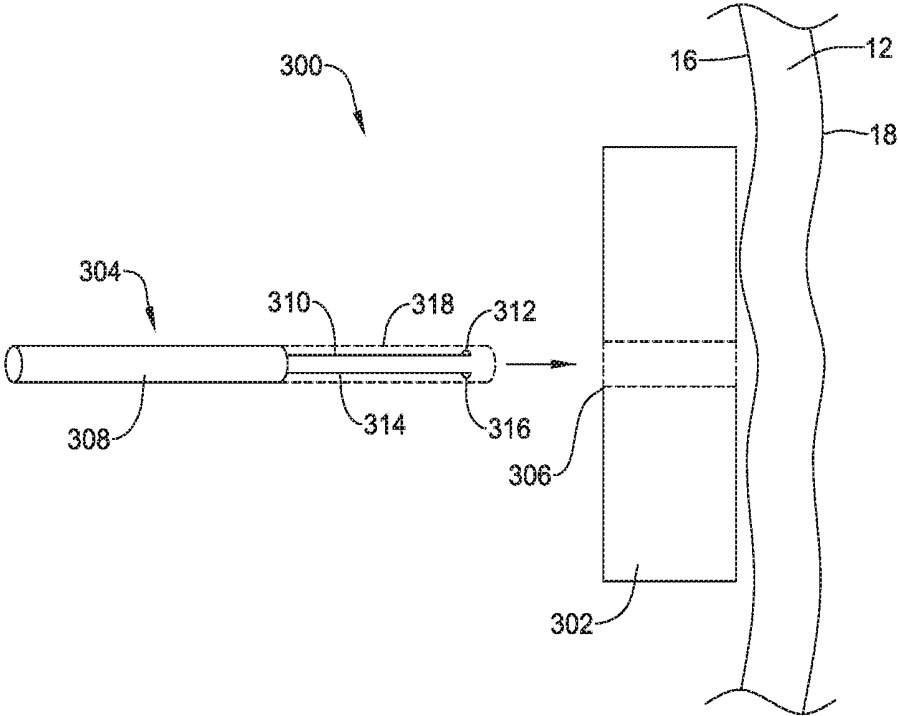


FIG. 9

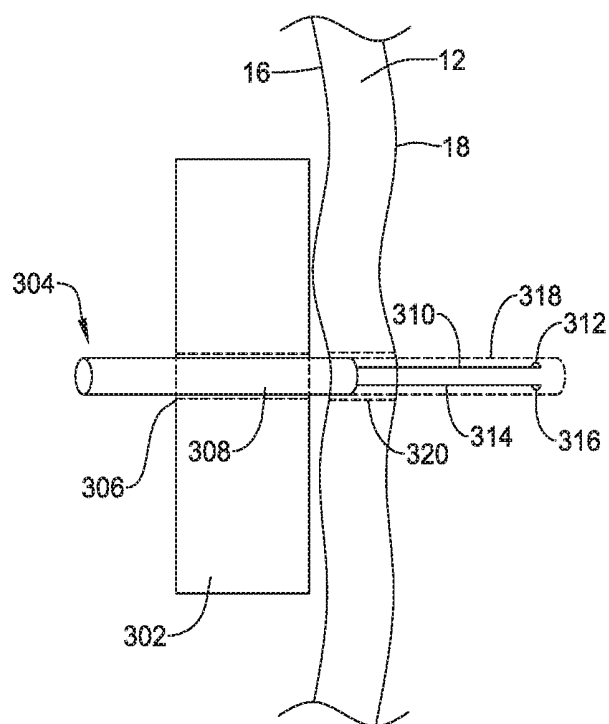


FIG. 10

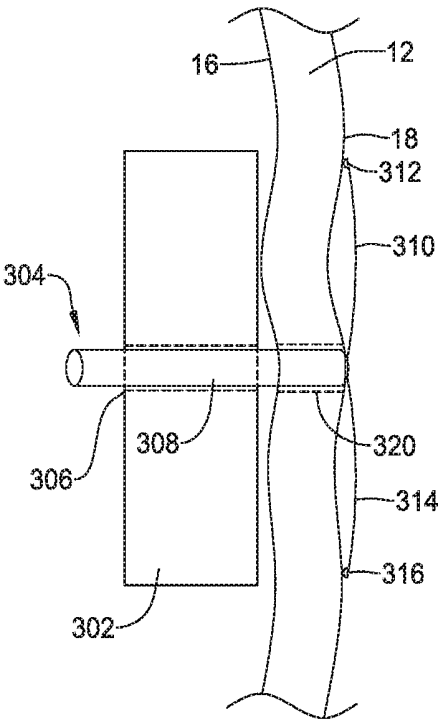


FIG. 11

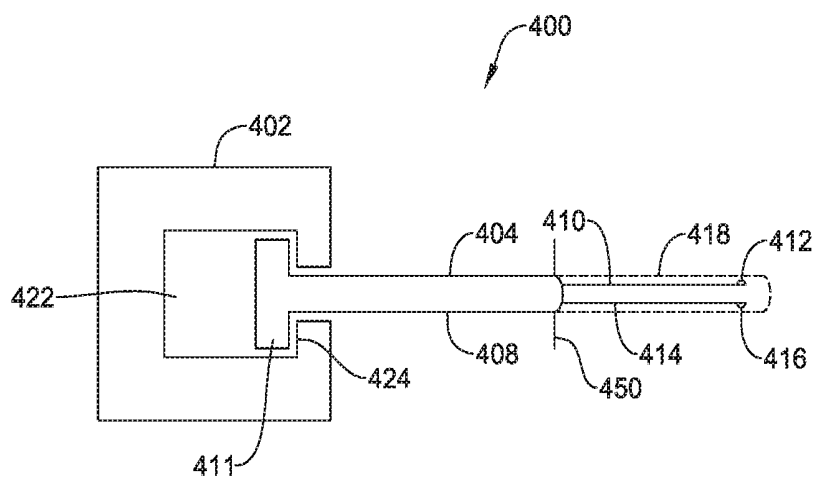


FIG. 12

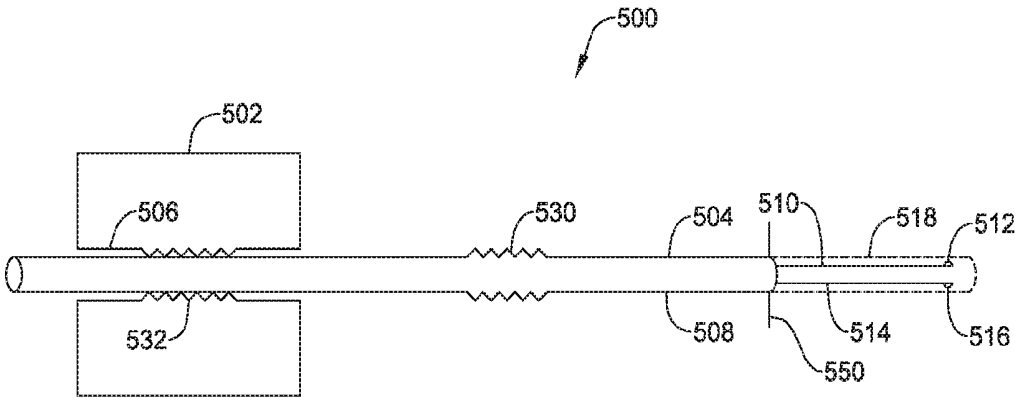


FIG. 13

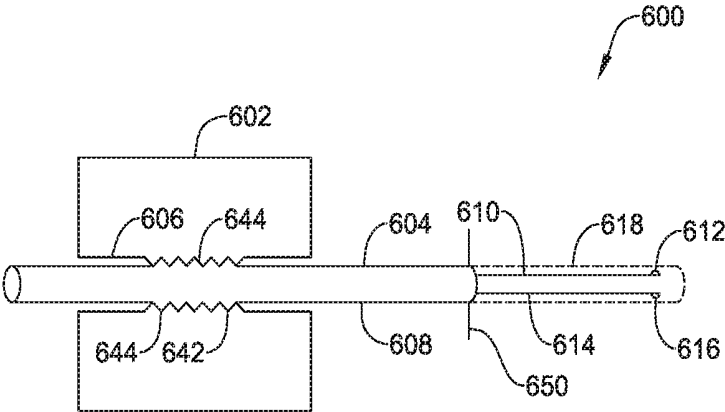


FIG. 14

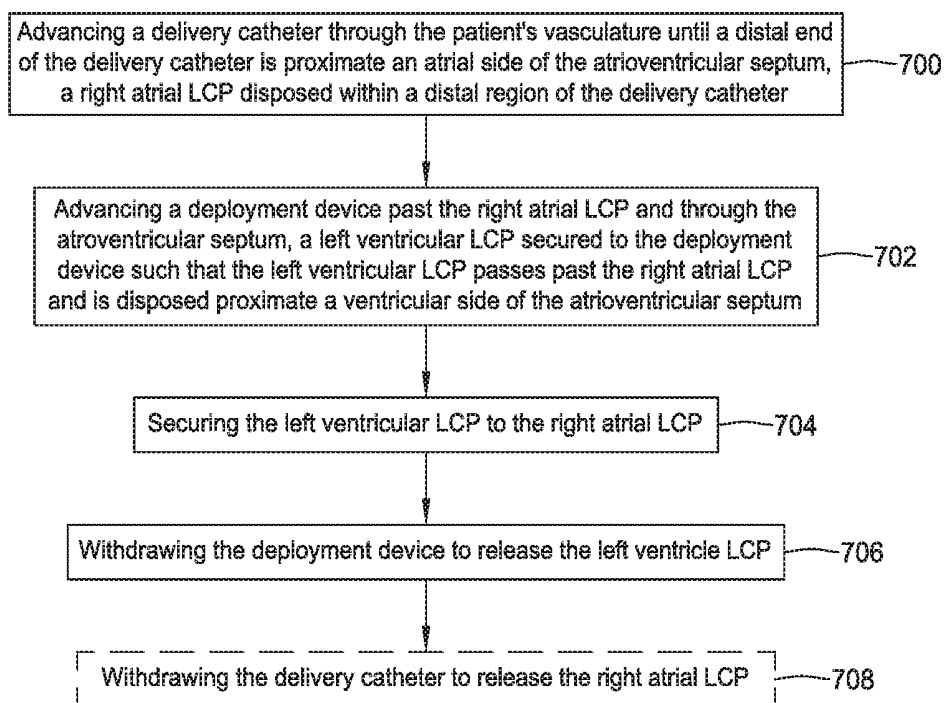


FIG. 15

IMPLANTABLE MEDICAL DEVICE FOR DEPLOYMENT ACROSS THE ATRIOVENTRICULAR SEPTUM

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application Ser. No. 62/271,647 filed on Dec. 28, 2015, the disclosure of which is incorporated herein by reference.

TECHNICAL FIELD

[0002] The present disclosure generally relates to implantable medical devices, and more particularly, to implantable medical devices that are configured to be deployed across the atrioventricular septum.

BACKGROUND

[0003] Implantable medical devices are commonly used today to monitor a patient and/or deliver therapy to a patient. For example, implantable sensors are often used to monitor one or more physiological parameters of a patient, such as heart beats, heart sounds, ECG, respiration, etc. In some instances, pacing devices are used to treat patients suffering from various heart conditions that may result in a reduced ability of the heart to deliver sufficient amounts of blood to a patient's body. Such heart conditions may lead to slow, rapid, irregular, and/or inefficient heart contractions. To help alleviate some of these conditions, various medical devices (e.g., pacemakers, defibrillators, etc.) can be implanted in a patient's body. Such devices may monitor and in some cases provide electrical stimulation to the heart to help the heart operate in a more normal, efficient and/or safe manner. In some instances, it may be beneficial to sense and/or pace two or more chambers of the heart.

SUMMARY

[0004] This disclosure provides design, delivery and deployment method, and clinical usage alternatives for medical devices. An example implantable medical device (IMD) configured for deployment at a patient's atrioventricular septum in order to sense and/or pace a patient's heart is disclosed, the atrioventricular septum of the patient's heart having an atrial facing side defining part of the right atrium of the patient's heart and a ventricle facing side defining part of the left ventricle of the patient's heart. The IMD includes a first component that is configured to be positioned at least in part in the right atrium of the patient's heart proximate the atrioventricular septum once the IMD is implanted and that includes a housing, a power source disposed within the housing and circuitry disposed within the housing and operably coupled to the power source. The IMD includes a second component that is configured to be positioned at least in part in the left ventricle of the patient's heart once the IMD is implanted and that is mechanically coupled to the first component through a passage passing through the atrioventricular septum. The second component includes a housing and two or more electrodes for sensing and/or pacing the left ventricle of the patient's heart.

[0005] Alternatively or additionally to any of the embodiments above, the first component further includes two or more electrodes for sensing and/or pacing the right atrium of the patient's heart.

[0006] Alternatively or additionally to any of the embodiments above, the two or more electrodes of the second component are operably coupled to the circuitry of the first component.

[0007] Alternatively or additionally to any of the embodiments above, at least one of the two or more electrodes of the second component engage the ventricle facing side of the atrioventricular septum of the patient's heart once the IMD is implanted.

[0008] Alternatively or additionally to any of the embodiments above, at least one of the two or more electrodes of the first component engage the atrial facing side of the atrioventricular septum of the patient's heart once the IMD is implanted.

[0009] Alternatively or additionally to any of the embodiments above, the second component is configured to move from a contracted state to an expanded state, wherein during implantation of the IMD, the second component is configured to pass through the passage through the atrioventricular septum in the contracted state and then move to the expanded state once in the left ventricle of the patient's heart.

[0010] Alternatively or additionally to any of the embodiments above, wherein in the expanded state, the second component extends laterally beyond a lateral extent of the passage through the atrioventricular septum and engages the ventricle facing side of the atrioventricular septum of the patient's heart.

[0011] Alternatively or additionally to any of the embodiments above, the first component extends distally beyond a delivery catheter and engages the atrial facing side of the atrioventricular septum of the patient's heart once the IMD is implanted.

[0012] Alternatively or additionally to any of the embodiments above, the second component is configured to cut the passage through the atrioventricular septum while the IMD is implanted.

[0013] Alternatively or additionally to any of the embodiments above, the second component is mechanically coupled to the first component through the passage via a connecting member.

[0014] Alternatively or additionally to any of the embodiments above, the connecting member is part of the second component, and forms an interference fit with the first component.

[0015] Alternatively or additionally to any of the embodiments above, the connecting member is part of the first component, and forms an interference fit with the first component.

[0016] Alternatively or additionally to any of the embodiments above, the first component comprises a fixation element for securing the first component to the atrioventricular septum of the patient's heart.

[0017] Alternatively or additionally to any of the embodiments above, the second component comprises a fixation element for securing the second component to the atrioventricular septum of the patient's heart.

[0018] An implantable medical device (IMD) configured for deployment at a patient's atrioventricular septum is disclosed, the atrioventricular septum of the patient's heart having an atrial facing side defining part of the right atrium of the patient's heart and a ventricle facing side defining part of the left ventricle of the patient's heart. The IMD includes a body having a first end portion, a second end portion and

a connecting portion connecting the first end portion to the second end portion. At least part of the first end portion may be configured to be positioned in the right atrium of the patient's heart proximate the atrioventricular septum once the IMD is implanted and at least part of the second end portion extends into the left ventricle of the patient's heart once the IMD is implanted. The connecting portion extends through a passage that passes through the atrioventricular septum and the second end portion extends laterally beyond a lateral extent of the connecting portion to engage the ventricle facing side of the atrioventricular septum of the patient's heart once the IMD is implanted.

[0019] Alternatively or additionally to any of the embodiments above, the second end portion includes two or more electrodes for sensing and/or pacing the left ventricle of the patient's heart, wherein at least one of the two or more electrodes of the second end portion engages the ventricle facing side of the atrioventricular septum of the patient's heart.

[0020] Alternatively or additionally to any of the embodiments above, the first end portion includes two or more electrodes for sensing and/or pacing the right atrium of the patient's heart, wherein at least one of the two or more electrodes of the first end portion engages the atrial facing side of the atrioventricular septum of the patient's heart.

[0021] Alternatively or additionally to any of the embodiments above, at least part of the second end portion is configured to move from a contracted state to an expanded state.

[0022] A method of deploying a leadless pacing and sensing assembly proximate a patient's atrioventricular septum is disclosed, the leadless pacing and sensing assembly including a right atrial leadless cardiac pacemaker (LCP) and a left ventricular leadless cardiac pacemaker (LCP). The method includes advancing a delivery catheter through the patient's vasculature until a distal end of the delivery catheter is proximate an atrial side of the atrioventricular septum, the right atrial LCP disposed within a distal region of the delivery catheter. A deployment device is advanced past the right atrial LCP and through the atrioventricular septum, the left ventricular LCP secured to the deployment device such that the left ventricular LCP passes past the right atrial LCP and is disposed proximate a ventricular side of the atrioventricular septum. The left ventricular LCP is secured to the right atrial LCP and the deployment device is withdrawn.

[0023] Alternatively or additionally to any of the embodiments above, the method further comprises withdrawing the delivery catheter.

[0024] The above summary is not intended to describe each embodiment or every implementation of the present disclosure. Advantages and attainments, together with a more complete understanding of the disclosure, will become apparent and appreciated by referring to the following description and claims taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] The disclosure may be more completely understood in consideration of the following description of various illustrative embodiments in connection with the accompanying drawings, in which:

[0026] FIG. 1 is a schematic view of an upper portion of a human heart, showing the atrioventricular septum;

[0027] FIG. 2 is a schematic view of a dual chamber leadless cardiac pacemaker (LCP) arrangement shown in a delivery vehicle;

[0028] FIG. 3 is a schematic end view of the right seed of the dual chamber LCP arrangement of FIG. 2;

[0029] FIG. 4 is a schematic view of a human heart, showing the dual chamber LCP arrangement of FIG. 2 during deployment;

[0030] FIG. 5 is a schematic view of another implantable medical device configured for deployment across the atrioventricular septum;

[0031] FIG. 6 is a schematic view of yet another illustrative implantable medical device configured for deployment across the atrioventricular septum;

[0032] FIG. 7 is a schematic view of an illustrative LCP configured for deployment within the right atrium;

[0033] FIG. 8 is a block diagram of another illustrative LCP;

[0034] FIG. 9 is a schematic view of an illustrative two-part LCP, prior to deployment;

[0035] FIG. 10 is a schematic view of the illustrative two-part LCP of FIG. 9, during deployment;

[0036] FIG. 11 is a schematic view of the illustrative two-part LCP, after deployment;

[0037] FIG. 12 is a schematic view of another illustrative two-part LCP;

[0038] FIG. 13 is a schematic view of yet another illustrative two-part LCP;

[0039] FIG. 14 is a schematic view of another illustrative two-part LCP; and

[0040] FIG. 15 is a flow diagram showing an illustrative implantation method.

[0041] While the disclosure is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit aspects of the disclosure to the particular illustrative embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure.

DESCRIPTION

[0042] The following description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The description and the drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the disclosure.

[0043] All numbers are herein assumed to be modified by the term "about", unless the content clearly dictates otherwise. The recitation of numerical ranges by endpoints includes all numbers subsumed within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

[0044] As used in this specification and the appended claims, the singular forms "a", "an", and "the" include the plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

[0045] It is noted that references in the specification to "an embodiment", "some embodiments", "other embodiments", etc., indicate that the embodiment described may include a particular feature, structure, or characteristic, but every

embodiment may not necessarily include the particular feature, structure, or characteristic. Moreover, such phrases are not necessarily referring to the same embodiment. Further, when a particular feature, structure, or characteristic is described in connection with an embodiment, it is contemplated that the feature, structure, or characteristic may be applied to other embodiments whether or not explicitly described unless clearly stated to the contrary.

[0046] The present disclosure generally relates to implantable medical devices, and more particularly, to implantable medical devices that are configured to be deployed across the atrioventricular septum. More particularly, the present disclosure is directed at providing pacing and/or sensing from a position next to or within the atrioventricular septum. In order to call out particular features of the cardiac anatomy, FIG. 1 provides a general illustration of a typical human heart 10. The heart 10 includes a right atrium RA and a left atrium LA. The left atrium LA is fluidly coupled to the pulmonary artery PA. A tricuspid valve TV separates the right atrium RA from a right ventricle RV. A mitral valve MV separates the left atrium LA from a left ventricle LV. Because the tricuspid valve TV is disposed apical (closer to the apex) of the mitral valve MV, an atrioventricular (AV) septum 12 exists. An arrow 14 indicates a portion of the AV septum 12 that may be used to provide access to both the right atrium RA and the left ventricle LV. The AV septum 12 includes an atrial side 16 that faces the right atrium RA as well as a ventricle side 18 that faces the left ventricle LV.

[0047] It will be appreciated that by traversing the AV septum 12 at or near the position indicated by the arrow 14, which is above the tricuspid valve TV and below the mitral valve MV, the left ventricle LV is accessible from the right atrium RA. This area can be reached, for example, via a transvenous catheter passing through either the SVC (superior vena cava) or the IVC (inferior vena cava) and into the right atrium RA. It will be appreciated that by deploying a two-part or multi-part LCP within the AV septum 12, it is possible to reach the left ventricle LV without having to potentially interfere with the mitral valve MV.

[0048] FIG. 2 provides a schematic view of an illustrative LCP assembly 20 that includes, as labeled, a right seed 22 and a left seed 24. In some cases, as illustrated, the right seed 22 may be configured to remain at least partially in the right atrium RA, and the left seed 24 may be configured to extend at least partially into the left ventricle LV. In some cases, the left seed 24 may be configured to pass through the right seed 22 during deployment, but this is not required. In some cases, the left seed 24 may have a diameter that is 3 French (F) or less. The illustrative LCP assembly 20 is shown disposed within a delivery catheter 26 which, as noted, may reach the right atrium RA via the SVC or the IVC. Which route is preferred may be a matter of the cardiologist's preferences, or may be at least in part a function of anatomical idiosyncrasies of a particular patient.

[0049] In some cases, the left seed 24 may be secured to a deployment mechanism 28 that can be used to advance the left seed 24 axially. The left seed 24 and the deployment mechanism 28 may be deployed within a hypotube 30 that may be configured to extend through the atrioventricular septum 12 (FIG. 1). In some cases, the hypotube 30 may have a distal end 32 that is configured to form a passage through the AV septum 12. In some instances, the distal end 32 of the hypotube 30 may be configured to poke a hole through the AV septum 12 without removing tissue from the

AV septum 12. As a result, the left seed 24 may be advanced through the AV septum 12, through the hole made by the distal end 32 of the hypotube 30.

[0050] Once deployed, the left seed 24 may be disposed at least partially on the ventricular side 18 of the AV septum 12, and the right seed 22 may be disposed at least partially on the atrial side 16 of the AV septum 12 (FIG. 1). In some cases, the left seed 24 may be mechanically coupled to the right seed 22 in order to help secure the left seed 24 and the right seed 22 in place on either side of the AV septum 12. In some cases, the left seed 24 and/or the right seed 22 may include an anticoagulant coating. While not illustrated, it will be appreciated that the left seed 24 may include two or more electrodes for pacing and/or sensing within the left ventricle LV. In some cases, the electrodes on the left seed 24 may be electrically coupled with control circuitry within the right seed 22. In some cases, there may be a wired connection between the right seed 22 and the left seed 24. In some instances, there may be a wireless connection between the right seed 22 and the left seed 24.

[0051] FIG. 3 is a schematic end view of the right seed 22 of the dual chamber LCP arrangement of FIG. 2. The illustrative right seed 22 includes a central lumen 34 extending through a body portion 36. While generically illustrated, it will be appreciated that the body portion 36 may include internal components which, for simplicity, are not illustrated here. These internal components, which will be described with respect to subsequent drawings, may include one or more of circuitry and a power supply. The central lumen 34 may be sized to accommodate the left seed 24 extended therethrough. In some cases, as illustrated, the central lumen 34 may include one or more electrodes 38 lining at least a portion of the central lumen 34 for making electrical contact with one or more corresponding electrodes (not shown) on an outer surface of the left seed 24.

[0052] In some cases, the central lumen 34 may also include one or more fixation elements (not explicitly shown) that are configured to engage with the left seed 24 and secure the left seed 24 to the right seed 22 once the left seed 24 has been deployed. The one or more fixation elements may, for example, extend to form a frictional engagement with the left seed 24. In some cases, the one or more fixation elements may be stent-like, and may expand to engage the left seed 24. In some instances, the one or more fixation elements may be formed of a shape memory material that can have a delivery shape that permits the left seed 24 to pass through the central lumen 34 of the right seed 22 and then revert to a "remembered" shape that engages the left seed 24 once the one or more fixation elements reach a particular temperature, for example. The one or more fixation elements could be formed from any of a variety of shape memory polymers or metals. In some cases, the one or more fixation elements may be formed of a nickel-titanium alloy such as Nitinol.

[0053] The right seed 22 includes, as illustrated, a first electrode 40 and a second electrode 42 that may be electrically coupled to internal circuitry within the right seed 22. While two electrodes 40, 42 are illustrated, it will be appreciated that the right seed 22 may include additional electrodes, depending on the desired pacing and/or sensing capabilities. In some cases, the first electrode 40 and the second electrode 42 may be disposed on the distal side of the right seed 22 such that both the first electrode 40 and the

second electrode 42 may be in contact with the atrial side 16 of the AV septum 12 once implanted.

[0054] FIG. 4 provides an illustrative but non-limiting deployment example. As can be seen in FIG. 4, a delivery catheter 26 (FIG. 2) has been passed up through the IVC and into the right atrium RA. In some cases, the delivery catheter 26 may be configured to include a curved distal portion that may help direct the LCP assembly 20 into position proximate the AV septum 12. In some cases, the delivery catheter 26 may be guided into position via an interaction with a chamber wall within the right atrium RA. In some instances, the delivery catheter 26 may be a steerable catheter. While not illustrated, in some cases the delivery catheter 26 and/or the LCP assembly 20 may include radiopaque structures that are visible during imaging processes such as fluoroscopy and/or ultrasound in order to facilitate directing the delivery catheter 26 to an appropriate position proximate the AV septum 12.

[0055] FIG. 5 is a schematic view of another illustrative implantable medical device (IMD) 50 that is configured to be deployed across the AV septum 12 (FIG. 1). The illustrative IMD 50 includes a body 52 having a first end portion 54, a second end portion 56, and a connecting portion 58 that connects the first end portion 54 and the second end portion 56. In some instances, a length of the connection portion 58 may be varied in order to accommodate the cardiac anatomy of a particular patient, in order to provide better electrode contact and to optimize the electrical performance of the IMD 50. In some cases, at least part of the first end portion 54 may be configured to be positioned in the right atrium RA proximate the AV septum 12 once implanted. Likewise, at least part of the second end portion 56 may be configured to extend into the left ventricle LV once implanted. It will be appreciated that the body 52 is shown schematically in FIG. 5, including the first end portion 54 and the second end portion 56.

[0056] Once implanted, it will be appreciated that the connecting portion 58 will extend through a passage that passes across the AV septum 12. In some cases, the passage may be formed directly by the second end portion 56 being forced through the AV septum 12. In some instances, the passage may be formed by a separate needle, hypotube or other suitable device prior to inserting the second end portion 56. The second end portion 56 may extend laterally (e.g. lateral relative to the major axis of the connecting portion 58) beyond a lateral extent of the connecting portion 58 in order to engage the ventricle side 18 (FIG. 1) of the AV septum 12 once the IMD 50 is implanted. In some cases, at least part of the second end portion 56 may be configured to move from a contracted state, such as for delivery to the AV septum 12 and insertion through the AV septum 12, to an expanded state, such as for anchoring the second end portion 56 relative to the ventricle side 18 of the AV septum 12.

[0057] In some cases, as illustrated, the second end portion 56 may include electrodes for sensing and/or pacing the left ventricle LV. In some cases, the second end portion 56 may include a first electrode 60 and a second electrode 62 that are positioned on the second end portion 56 such that the first electrode 60 and the second electrode 62 are able to engage the ventricle side 18 of the AV septum 12. In some instances, the second end portion 56 may also include additional electrodes, but this is not required. In some cases, the first end portion 54 may include electrodes for sensing and/or pacing the right atrium RA. In some cases, the first end

portion 54 may include a first electrode 64 and a second electrode 66 that are positioned on the first end portion 54 such that the first electrode 64 and the second electrode 66 are able to engage the atrial side 16 of the AV septum 12. In some instances, the first end portion 54 may also include additional electrodes, but this is not required.

[0058] FIG. 6 is a schematic view of another illustrative IMD 70 that is configured to be deployed across the AV septum 12 (FIG. 1) in order to sense and/or pace the heart. In some cases, as illustrated, the illustrative IMD 70 may include a first component 72 that is configured to be positioned at least in part in the right atrium RA proximate the AV septum 12 once the IMD 70 is implanted, and a second component 74 that is configured to be positioned at least in part in the left ventricle LV once the IMD 70 is implanted. In some cases, the first component 72 includes a housing 76 and a power supply 78 that is disposed within the housing 76. Circuitry 80 may be disposed within the housing 76 and may be operably coupled to the power source 78. In some cases, the power source 78 may be wirelessly rechargeable.

[0059] The second component 74 may be mechanically coupled to the first component 72 through a passage passing through the AV septum 12. In some cases, the second component 74 is mechanically coupled to the first component 72 via a connecting member 82. In some cases, the connecting member 82 may be part of the second component 74 and may form an interference fit with the first component 72. In some cases, the connecting member 82 may be part of the first component 72 and may form an interference fit with the second component 74. In some cases, the first component 72 includes a fixation element for securing the first component 72 to the AV septum 12. In some instances, the second component 74 includes a fixation element for securing the second component 74 to the AV septum 12. Subsequent drawings will provide examples of such fixation elements, which may include one or more of barbs, spikes, pins, staples, threads, screws, helix, tines, and/or the like.

[0060] In some cases, the second component 74 may include a housing 84. The housing 84 may be a cylindrical body, for example. In some cases, the housing 84 may instead have another shape, or may simply be several insulated wires coupled together and including electrodes that are electrically coupled to the insulated wires, for example. In some instances, the housing 84 could be umbrella-shaped, with electrodes disposed at the tips of wires that may be joined together in a web. A first electrode 86 and a second electrode 88 may be disposed on the housing 84 and may be positioned such that the first electrode 86 and the second electrode 88 may be able to sense and/or pace the left ventricle LV of the heart. In some cases, the first electrode 86 and the second electrode 88 are configured to engage the ventricle side 18 (FIG. 1) of the AV septum 12. In some instances, the second component 74 may also include additional electrodes, but this is not required. In some instances, the first electrode 86 and the second electrode 88 may be operably coupled to the circuitry 80 of the first component 72. In some cases, wiring leads 90 and 92 may lead from the first electrode 86 and the second electrode 88, respectively, to the circuitry 80 and may pass through or over the connecting member 82.

[0061] In some cases, the first component 72 may include electrodes for sensing and/or pacing the right atrium RA. As illustrated, the first component 72 includes a first electrode 94 and a second electrode 96. In some cases, at least one of

the first electrode **94** and the second electrode **96** may be positioned to engage the atrial side **16** (FIG. 1) of the AV septum **12** once implanted. In some instances, the first component **72** may also include additional electrodes, but this is not required. In some cases, wiring leads **98** and **99** may lead from the first electrode **94** and the second electrode **96**, respectively, to the circuitry **80**.

[0062] In some instances, the second component **74** may be configured to move from a contracted state to an expanded state. In some cases, the second component **74** may pass through the passage formed in the AV septum **12** while in its contracted state and then move into its expanded state once the second component **74** has reached the left ventricle LV. In some cases, when in its expanded state, the second component **74** may extend laterally beyond a lateral extent of the passage through the AV septum **12** and may engage the ventricle side **18** (FIG. 1) of the AV septum **12**. In some cases, the first component **72** may extend laterally beyond the lateral extent of the passage through the AV septum **12** and may engage the atrial side **16** of the AV septum **12** once the IMD **70** is implanted. In some cases, the second component **74** may be configured to cut or otherwise form the passage extending through the AV septum **12**. In some instances, a separate device may be used to form the passage through the AV septum **12**.

[0063] FIG. 7 is a schematic view of an illustrative LCP **100** configured for deployment within the right atrium. The LCP may be configured to sense physiological signals and parameters and deliver one or more types of electrical stimulation therapy to the atrial side **16** (FIG. 1) of the AV septum **12**. Example electrical stimulation therapy may include anti-tachycardia pacing (ATP) therapy, cardiac resynchronization therapy (CRT), bradycardia therapy, various types of pacing therapy including rate responsive pacing therapy, and/or the like. The LCP **100** may be considered as an example of the right seed **22** of FIG. 2. The LCP **100** may be a compact device with all components housed within or directly on a housing **120** of the LCP **100**. The illustrative LCP **100** may include a communication module **102**, a pulse generator module **104**, an electrical sensing module **106**, a mechanical sensing module **108**, a processing module **110**, an energy storage module **112**, and electrodes **114**.

[0064] In some cases, as illustrated, the LCP **100** may include a passage **122** that passes through the LCP **100** from a first side **124** of the housing **120** to a second side **126** of the housing **120**. In some cases, the passage **122** is configured to allow the left seed **24** (FIG. 2) to extend through the passage **122** during implantation of the left seed **24**. In some instances, as noted with respect to FIG. 2, the passage **122** may include structure that is configured to enable electrical communication between the left seed **24** and the right seed **22**. In some cases, the passage **122** may include structure to help anchor the left seed **24** to the right seed **22** after deployment. In some cases, the LCP **100** may be configured such that the first side **124** or the second side **126** of the housing **120** may be deployed along the atrial side **16** (FIG. 1) of the AV septum **12**. While the passage **122** is schematically illustrated as extending through the LCP **100** at or near a midpoint of the LCP **100**, it will be appreciated that in some cases the passage **122** may be located at or near one edge of the LCP **100**. In some cases, the passage **122** may be defined by structure that is secured to an outer surface of the housing **120**. For example, depending on the exact size

and configuration of the left seed **24**, the passage **122** may be formed of a cylindrical tube secured to the outside of the housing **120**.

[0065] The electrodes **114** may be secured relative to the housing **120** but may be exposed to the tissue and/or blood surrounding the LCP **100**. The electrodes **114** may generally conduct electrical signals to and from the LCP **100** and the surrounding tissue and/or blood. Such electrical signals can include communication pulses, electrical stimulation pulses, and intrinsic cardiac electrical signals. Intrinsic cardiac electrical signals may include electrical signals generated by the heart and may be represented by an electrocardiogram (ECG). The electrodes **114** can be made up of one or more biocompatible conductive materials such as various metals or alloys that are known to be safe for implantation within a human body. In some instances, the electrodes **114** may be generally disposed on either side of LCP **100** and may be in electrical communication with one or more of modules **102**, **104**, **106**, **108**, and **110**. In examples where the electrodes **114** are secured directly to the housing **120**, the electrodes **114** may have an insulative portion that electrically isolates the electrodes **114** from adjacent electrodes, the housing **120**, and/or other portions of the LCP **100**. Some or all of the electrodes **114** may be spaced from the housing **120** and connected to the housing **120** and/or other components of the LCP **100** through connecting wires or the like.

[0066] The electrodes **114** and/or **114'** may have any of a variety of sizes and/or shapes, and may be spaced at any suitable distance. For example, the electrodes **114** may have a diameter of one to five millimeters (mm). However, in other examples, the electrodes **114** and/or **114'** may have a diameter of one mm, two mm, three mm, or any other suitable diameter, dimension and shape. Example lengths for the electrodes **114** and/or **114'** include a length of one mm, three mm, five mm, or any other suitable length. Additionally, at least some of the electrodes **114** and/or **114'** may be spaced from one another by a distance of five mm, six mm, seven mm, or any other suitable distance. The electrodes **114** and/or **114'** of a single device may have different sizes with respect to each other, and the spacing of the electrodes on the device may or may not be uniform. In some cases, the electrode **114** may be a cathode with a smaller electrode surface area and the electrode **114'** may be an anode electrode with a larger electrode surface.

[0067] The communication module **102** may be electrically coupled to the electrodes **114** and/or **114'** and configured to deliver communication pulses to tissues of the patient for communicating with other devices such as sensors, programmers, other medical devices, and the like. Communication pulses, as used herein, may be any modulated signal that conveys information to another device, either by itself or in conjunction with one or more other modulated signals. In some examples, communication pulses are sub-threshold signals which convey information, but this is not required. Other devices that the communication module **102** may be configured to communicate with may be located either external or internal to the patient's body. The communication module **102** may additionally be configured to sense for communication pulses delivered by the other devices, which are located externally to the LCP **100**. Irrespective of the location, the LCP **100** and the other devices may communicate with each other via the communication module **102** to accomplish one or more desired functions. Some example functions include storing commu-

nicated data, using communicated data for determining occurrences of arrhythmias, coordinating delivery of electrical stimulation therapy, and/or other functions.

[0068] The LCP 100 and the other devices may use the delivered communication pulses to communicate raw information, processed information, messages, and/or other data. Raw information may include information such as sensed electrical signals (e.g. a sensed ECG), signals gathered from coupled sensors, and the like. In some examples, the raw information may include signals that have been filtered using one or more signal processing techniques. Processed information may include any information that has been determined by the LCP 100. For example, processed information may include a determined heart rate, timings of determined heartbeats, timings of other determined events, determinations of threshold crossings, expirations of monitored time periods, and determined parameters such as activity parameters, blood-oxygen parameters, blood pressure parameters, heart sound parameters, and the like. Messages may include instructions directing another device to take action, notifications of imminent actions of the sending device, requests for reading from the receiving device or writing data to the receiving device. In some cases, the LCP 100 may communicate with an S-ICD (subcutaneous implantable cardioverter).

[0069] In at least some examples, the communication module 102 (or the LCP 100) may further include switching circuitry to selectively connect one or more of the electrodes 114 and/or 114' to the communication module 102 in order to select via which electrodes 114 and/or 114' the communication module 102 delivers the communication pulses. Additionally, the communication module 102 may be configured to use one or more methods for communicating with other devices. For example, the communication module 102 may communicate via conducted signals, radiofrequency (RF) signals, optical signals, acoustic signals, inductive coupling, and/or any other signals or methods suitable for communication with an external device such as an S-ICD or a programmer.

[0070] The pulse generator module 104 of the LCP 100 may also be electrically connected to one or more of the electrodes 114 and/or 114'. The pulse generator module 104 may be configured to generate electrical stimulation pulses and deliver the electrical stimulation pulses to tissues of a patient via the electrodes 114 and/or 114' electrodes in order to effectuate one or more electrical stimulation therapies. Electrical stimulation pulses as used herein are meant to encompass any electrical signals that may be delivered to tissue of a patient for purposes of treatment of any type of disease or abnormality. When used to treat heart diseases or abnormalities, the electrical stimulation pulses may generally be configured so as to capture the heart of the patient—cause the heart to contract in response to the delivered electrical stimulation pulse. In at least examples where the pulse generator 104 is configured to generate specific types of electrical stimulation pulses termed defibrillation/cardioversion pulses, the pulse generator module 104 may include one or more capacitor elements.

[0071] The pulse generator module 104 may include capability to modify the electrical stimulation pulses, such as by adjusting a pulse width or amplitude of the electrical stimulation pulses, in order to ensure that the delivered electrical stimulation pulses consistently capture the heart. The pulse generator module 104 may use energy stored in the energy

storage module 112 to generate the electrical stimulation pulses. In at least some examples, the pulse generator module 104 (or the LCP 100) may further include switching circuitry to selectively connect one or more of the electrodes 114 and/or 114' to the pulse generator module 104 in order to select via which electrodes 114 and/or 114' the pulse generator 104 delivers the electrical stimulation pulses.

[0072] In some examples, the LCP 100 may include the electrical sensing module 106 and the mechanical sensing module 108. The electrical sensing module 106 may be configured to sense intrinsic cardiac electrical signals conducted from the electrodes 114 and/or 114' to the electrical sensing module 106. For example, the electrical sensing module 106 may be electrically connected to one or more electrodes 114 and/or 114' and the electrical sensing module 106 may be configured to receive cardiac electrical signals conducted through the electrodes 114 and/or 114'. In some examples, the cardiac electrical signals may represent local information from the chamber in which the LCP 100 is implanted. For instance, if the LCP 100 is implanted within the right atrium RA, cardiac electrical signals sensed by the LCP 100 through the electrodes 114 and/or 114' may represent atrial cardiac electrical signals. The mechanical sensing module 108 may include, or be electrically connected to, various sensors, such as accelerometers, blood pressure sensors, heart sound sensors, blood-oxygen sensors, and/or other sensors which measure one or more physiological parameters of the heart and/or patient. The mechanical sensing module 108 may gather signals from the sensors indicative of the various physiological parameters. Both the electrical sensing module 106 and the mechanical sensing module 108 may be further connected to the processing module 110 and may provide signals representative of the sensed cardiac electrical signals and/or physiological signals to processing the module 110. Although described with respect to FIG. 7 as separate sensing modules, in some examples, the electrical sensing module 106 and the mechanical sensing module 108 may be combined into a single module.

[0073] The processing module 110 may be configured to control the operation of the LCP 100. For example, the processing module 110 may be configured to receive cardiac electrical signals from the electrical sensing module 106 and/or physiological signals from the mechanical sensing module 108. Based on the received signals, the processing module 110 may determine occurrences and types of arrhythmias. The processing module 110 may further receive information from the communication module 102. In some examples, the processing module 110 may additionally use such received information to determine occurrences and types of arrhythmias. However, in other examples, the LCP 100 may use the received information instead of the signals received from the electrical sensing module 106 and/or the mechanical sensing module 108—for instance if the received information is more accurate than the signals received from the electrical sensing module 106 and/or the mechanical sensing module 108 or if the electrical sensing module 106 and/or the mechanical sensing module 108 have been disabled or omitted from the LCP 100.

[0074] Based on any determined arrhythmias, the processing module 110 may then control the pulse generator module 104 to generate electrical stimulation pulses in accordance with one or more electrical stimulation therapies to treat the determined arrhythmias. For example, the processing mod-

ule 110 may control the pulse generator module 104 to generate pacing pulses with varying parameters and in different sequences to effectuate one or more electrical stimulation therapies. In controlling the pulse generator module 104 to deliver bradycardia pacing therapy, the processing module 110 may control the pulse generator module 104 to deliver pacing pulses designed to capture the heart of the patient at a regular interval to prevent the heart of a patient from falling below a predetermined threshold. For ATP therapy, the processing module 110 may control the pulse generator module 104 to deliver pacing pulses at a rate faster than an intrinsic heart rate of a patient in attempt to force the heart to beat in response to the delivered pacing pulses rather than in response to intrinsic cardiac electrical signals. The processing module 110 may then control the pulse generator module 104 to reduce the rate of delivered pacing pulses down to a safe level. In CRT, the processing module 110 may control the pulse generator module 104 to deliver pacing pulses in coordination with another device (e.g. the left seed 24) to cause the heart to contract more efficiently. Additionally, in cases where the pulse generator module 104 is capable of generating defibrillation and/or cardioversion pulses for defibrillation/cardioversion therapy, the processing module 110 may control the pulse generator module 104 to generate such defibrillation and/or cardioversion pulses. In some examples, the LCP 100 may instead communicate with an S-ICD for defibrillation therapy. In other examples, the processing module 110 may control the pulse generator module 104 to generate electrical stimulation pulses to provide electrical stimulation therapies different than those described herein to treat one or more detected cardiac arrhythmias.

[0075] Aside from controlling the pulse generator module 104 to generate different types of electrical stimulation pulses and in different sequences, in some examples, the processing module 110 may also control the pulse generator module 104 to generate the various electrical stimulation pulses with varying pulse parameters. For example, each electrical stimulation pulse may have a pulse width and a pulse amplitude. The processing module 110 may control the pulse generator module 104 to generate the various electrical stimulation pulses with specific pulse widths and pulse amplitudes. For example, the processing module 110 may cause the pulse generator module 104 to adjust the pulse width and/or the pulse amplitude of electrical stimulation pulses if the electrical stimulation pulses are not effectively capturing the heart. Such control of the specific parameters of the various electrical stimulation pulses may ensure that the LCP 100 is able to provide effective delivery of electrical stimulation therapy.

[0076] In some examples, the processing module 110 may further control the communication module 102 to send information to other devices. For example, the processing module 110 may control the communication module 102 to generate one or more communication pulses for communicating with other devices of a system of devices. For instance, the processing module 110 may control the communication module 102 to generate communication pulses in particular sequences, where the specific sequences convey different data to other devices. The communication module 102 may also conduct any received communication signals to the processing module 110 for potential action by the processing module 110.

[0077] In further examples, the processing module 110 may additionally control switching circuitry by which the communication module 102 and the pulse generator module 104 deliver communication pulses and electrical stimulation pulses to tissue of the patient. As described above, both the communication module 102 and the pulse generator module 104 may include circuitry for connecting one or more electrodes 114 and 114' to the communication module 102 and the pulse generator module 104 so those modules may deliver the communication pulses and electrical stimulation pulses to tissue of the patient. The specific combination of one or more electrodes by which the communication module 102 and the pulse generator module 104 deliver communication pulses and electrical stimulation pulses influence the reception of communication pulses and/or the effectiveness of electrical stimulation pulses. Although it was described that each of the communication module 102 and the pulse generator module 104 may include switching circuitry, in some examples the LCP 100 may have a single switching module connected to all of the communication module 102, the pulse generator module 104, and the electrodes 114 and/or 114'. In such examples, the processing module 110 may control the single switching module to connect the modules 102/104 and the electrodes 114/114'.

[0078] In still additional examples, the processing module 110 may control the pulse generator module 104 to generate the communication pulses for communicating with external devices. In such examples, the communication module 102 may not include the capability to generate communication pulses. In some even additional examples, the electrical sensing module 106 may further include the capability to sense communication pulses. In such examples, the electrical sensing module 106 may communicate any received communication pulses to the processing module 110. In such examples, the LCP 100 may not include the communication module 102, as the functions of the communication module 102 are subsumed within the pulse generator module 104 and the electrical sensing module 106. However, in such examples, the LCP 100 may not be able to simultaneously generate both communication pulses and electrical stimulation pulses.

[0079] In some examples, the processing module 110 may include a pre-programmed chip, such as a very-large-scale integration (VLSI) chip or an application specific integrated circuit (ASIC). In such embodiments, the chip may be pre-programmed with control logic in order to control the operation of the LCP 100. By using a pre-programmed chip, the processing module 110 may use less power than other programmable circuits while able to maintain basic functionality, thereby increasing the battery life of the LCP 100. In other examples, the processing module 110 may include a programmable microprocessor or the like. Such a programmable microprocessor may allow a user to adjust the control logic of the LCP 100 after manufacture, thereby allowing for greater flexibility of the LCP 100 than when using a pre-programmed chip.

[0080] The processing module 110, in additional examples, may further include a memory circuit and the processing module 110 may store information on and read information from the memory circuit. In other examples, the LCP 100 may include a separate memory circuit (not shown) that is in communication with the processing module 110, such that the processing module 110 may read and write information to and from the separate memory circuit. The

memory circuit, whether part of the processing module **110** or separate from the processing module **110** may have address lengths of, for example, eight bits. However, in other examples, the memory circuit may have address lengths of sixteen, thirty-two, or sixty-four bits, or any other bit length that is suitable. Additionally, the memory circuit may be volatile memory, non-volatile memory, or a combination of both volatile memory and non-volatile memory.

[0081] The energy storage module **112** may provide a power source to the LCP **100** for its operations. In some examples, the energy storage module **112** may be a non-rechargeable lithium-based battery. In other examples, the non-rechargeable battery may be made from other suitable materials known in the art. Because the LCP **100** is an implantable device, access to the LCP **100** may be limited. In such circumstances, it is necessary to have sufficient energy capacity to deliver therapy over an extended period of treatment such as days, weeks, months, or years. In some examples, the energy storage module **112** may be a rechargeable battery in order to facilitate increasing the useable lifespan of the LCP **100**. In still other examples, the energy storage module **112** may be other types of energy storage devices such as capacitors.

[0082] FIG. 8 is a block diagram of another illustrative LCP **200**. In some cases, the LCP **200** may be considered as being an example of the right seed **22** (FIG. 2). In some cases, the LCP **200** may be considered as being an example of the left seed **24**. In some instances, the components forming the LCP **200** may be split between the right seed **22** and the left seed **24**.

[0083] In some cases, the LCP **200** may include a communication module **202**, a pulse generator module **204**, an electrical sensing module **206**, a mechanical sensing module **208**, a processing module **210**, and a battery **218**. Each of these modules may be similar to the modules **102**, **104**, **106**, **108**, and **110** of the LCP **100**. Additionally, the battery **218** may be similar to the battery **112** of the LCP **100**. In some cases, the LCP **200** may include leads such as leads **212**. The leads **212** may include electrical wires that conduct electrical signals between the electrodes **214** and one or more of the modules located within housing **220**. In some cases, the leads **212** may be connected to and extend away from the housing **220** of the LCP **200** in order to place electrodes **214** adjacent the atrial side **16** and/or the ventricle side **18** of the AV septum **12**.

[0084] The mechanical sensing module **208**, as with the mechanical sensing module **108**, may contain or be electrically connected to one or more sensors, such as accelerometers, blood pressure sensors, heart sound sensors, blood-oxygen sensors, and/or other sensors which are configured to measure one or more mechanical/chemical parameters of the heart and/or patient. In some examples, one or more of the sensors may be located on the leads **212**, but this is not required. In some examples, one or more of the sensors may be located in the housing **220**.

[0085] FIGS. 9 through 11 illustrate deployment of an illustrative but non-limiting example of a two-part LCP **300**. The illustrative LCP assembly **300** includes a right seed **302** that is configured to remain on the atrial side **16** of the AV septum **12**, and a left seed **304** that is configured to extend through a passage **306** formed within the right seed **302**. As illustrated, the left seed **304** includes a cylindrical or other shaped body **308**. A first electrical conduit **310** extends distally from the cylindrical body **308** and includes a first

electrode **312** that is coupled to the first electrical conduit **310**. A second electrical conduit **314** extends distally from the cylindrical body **308** and includes a second electrode **316** that is coupled to the second electrical conduit **314**. As illustrated, the first electrical conduit **310**, the first electrode **312**, the second electrical conduit **314** and the second electrode **316** are captured within a distal tip **318**.

[0086] The distal tip **318** holds the first and second electrical conduits **310**, **314** in the illustrated position for deployment. In some cases, the distal tip **318** is dissolvable upon exposure to blood. In some cases, the distal tip **318** may be formed of a crystallized material such as sugar that is safe for dissolving in the blood stream. Accordingly, the first and second electrical conduits **310**, **314** may be held in a delivery configuration for delivery and subsequently may move into a deployment configuration (as shown for example in FIG. 11) once the distal tip **318** has dissolved. In some instances, the distal tip **318** may be considered as being a sweet tip.

[0087] In FIG. 10, the left seed **304** has been advanced through the passage **306** and through a passage **320** formed within the AV septum **12**. In some instances, the distal tip **318** is configured to push through the AV septum **12** to form the passage **320**. In some cases, a separate device may be extended through the AV septum **12** to form the passage **320** prior to insertion of the left seed **304**. In FIG. 10, the distal tip **318** is still intact. Moving to FIG. 11, it can be seen that the distal tip **318** has dissolved or otherwise disappeared, permitting the first electrical conduit **310** to move into a position in which the first electrode **312** is in contact with the ventricle side **18** of the AV septum **12** and permitting the second electrical conduit **314** to move into a position in which the second electrode **316** is in contact with the ventricle side **18** of the AV septum **12**.

[0088] FIG. 12 is a schematic view of another illustrative two-part LCP **400**. The illustrative two-part LCP **400** includes a right seed **402** that is configured to remain on the atrial side **16** of the AV septum **12**, and a left seed **404** that is configured to extend through a passage **406** formed within the right seed **402**. As illustrated, the left seed **404** includes a cylindrical body **408**. A first electrical conduit **410** extends distally from the cylindrical body **408** and includes a first electrode **412** that is coupled to the first electrical conduit **410**. A second electrical conduit **414** extends distally from the cylindrical body **408** and includes a second electrode **416** that is coupled to the second electrical conduit **414**. As illustrated, the first electrical conduit **410**, the first electrode **412**, the second electrical conduit **414** and the second electrode **416** are captured within a distal tip **418** that in some cases may be a sweet tip as discussed with respect to FIGS. 9 through 11. Once deployed, the distal tip **418** may dissolve or otherwise disappear, and the first electrical conduit **410** and the second electrical conduit **414** may be able to move into a deployed configuration in which the first electrode **412** and the second electrode **416** are positioned against the ventricle side **18** of the AV septum **12**.

[0089] The cylindrical body **408** may include a proximal end **411** that is slidably disposed within a chamber **422** that is formed within the right seed **402**. It will be appreciated that the chamber **422** includes a distal end **424** that is configured to limit axial travel of the proximal end **411** of the left seed **404**. Accordingly, the interaction between the proximal end **411** of the left seed **404** and the distal end **424** of the chamber **422** of the right seed **402** limits how far the left seed **404** can extend into the left ventricle LV. Once the

distal tip **418** has dissolved or otherwise disappeared, the first and second electrical conduits **410** and **414** move into position against the ventricle side **18** of the AV septum **12**, thereby limiting movement of the left seed **404** back towards the right atrium RA. Thus, the left seed **404** is locked in position relative to the right seed **402** and relative to the AV septum **12**. In some embodiments, the left seed **404** may include a membrane **450** that may help to secure between the left seed **404** and the ventricle side **18** of the AV septum **12**. In some cases, the membrane **450** may be formed of a flexible material such as silicone, and may be impregnated with a salt or other material that will cause the membrane **450** to swell upon exposure to blood. In some instances, the membrane **450** may have a folded down configuration for deployment of the left seed **404** and may subsequently revert to the expanded configuration shown in FIG. 12.

[0090] FIG. 13 is a schematic view of yet another illustrative two-part LCP **500**. The illustrative LCP **500** includes a right seed **502** that is configured to remain on the atrial side **16** of the AV septum **12** and a left seed **504** that is configured to extend through a passage **506** formed within the right seed **502**. As illustrated, the left seed **504** includes a cylindrical body **508**. A first electrical conduit **510** extends distally from the cylindrical body **508** and includes a first electrode **512** that is coupled to the first electrical conduit **510**. A second electrical conduit **514** extends distally from the cylindrical body **508** and includes a second electrode **516** that is coupled to the second electrical conduit **514**. As illustrated, the first electrical conduit **510**, the first electrode **512**, the second electrical conduit **514** and the second electrode **516** are captured within a distal tip **518** that in some cases may be a sweet tip as discussed with respect to FIGS. 9 through 11.

[0091] In the example shown, the cylindrical body **508** of the left seed **504** includes a ratchet section **530** that is configured to interact with a corresponding ratchet section **532** disposed within the passage **506** formed within the right seed **502**. In order to implant the LCP **500**, the LCP **500** may be delivered to the right atrium RA with the left seed **504** disposed within the right seed **502** as illustrated, i.e., with the ratchet section **530** positioned outside of the right seed **502**. Alternatively, the left seed **504** may be delivered to the right atrium RA and then the right seed **502** may be advanced over the left seed **504**.

[0092] Once the left seed **504** has been advanced through the AV septum **12**, and the distal tip **518** has dissolved or otherwise disappeared, the electrical conduits **510** and **514** may move the electrodes **512** and **516**, respectively, into position against the ventricle side **18** of the AV septum **12**. The left seed **504** may then be pulled back through the right seed **502** such that the ratchet section **530** engages the ratchet section **532**. The ratchet sections **530** and **532** may be configured to permit the ratchet section **530** to move right to left (in the illustrated orientation), relative to the ratchet section **532** but not permit the ratchet section **530** to move left to right relative to the ratchet section **532**. It will be appreciated that FIG. 13 is not to scale, and that the relative dimensions may vary in order to accommodate a particular patient's cardiac architecture.

[0093] In some embodiments, the left seed **504** may include a membrane **550** that may help to secure between the left seed **504** and the ventricle side **18** of the AV septum **12** and prevent blood from moving towards the right atrium RA after removal of a deployment device. In some cases, the membrane **550** may be formed of a flexible material such as

silicone, and may be impregnated with a salt or other material that will cause the membrane **550** to swell upon exposure to blood. In some instances, the membrane **550** may have a folded down configuration for deployment of the left seed **504** and may subsequently revert to the expanded configuration shown in FIG. 13.

[0094] FIG. 14 is a schematic view of another illustrative two-part LCP **600**. The illustrative LCP **600** includes a right seed **602** that is configured to remain on the atrial side **16** of the AV septum **12**, and a left seed **604** that is configured to extend through a passage **606** formed within the right seed **602**. As illustrated, the left seed **604** includes a cylindrical body **608**. A first electrical conduit **610** extends distally from the cylindrical body **608** and includes a first electrode **612** that is coupled to the first electrical conduit **610**. A second electrical conduit **614** extends distally from the cylindrical body **608** and includes a second electrode **616** that is coupled to the second electrical conduit **614**. As illustrated, the first electrical conduit **610**, the first electrode **612**, the second electrical conduit **614** and the second electrode **616** are captured within a distal tip **618** that in some cases may be a sweet tip.

[0095] In some cases, the cylindrical body **608** of the left seed **604** may include a threaded portion **640** that threadably engages a corresponding threaded portion **642** formed within the passage **606**. Accordingly, advancement of the left seed **604** relative to the right seed **602** may be closely controlled. Once the left seed **604** has been deployed, the distal tip **618** may dissolve or otherwise disappear, and the first electrical conduit **610** and the second electrical conduit **614** may be able to move into a deployed configuration in which the first electrode **612** and the second electrode **616** are positioned against the ventricle side **18** of the AV septum **12**. The left seed **604** may then be moved backward relative to the right seed **602** in order to lock the left seed **604** in place relative to the AV septum **12** and relative to the right seed **602** by rotating the left seed **604** in an opposite direction to that used to advance the left seed **604**. In some cases, the threaded portion **642** may include a vinyl bump or other structure **644** that serves to lock the left seed **604** in position and not permit undesired movement after implantation.

[0096] In some embodiments, the left seed **604** may include a membrane **650** that may help to secure between the left seed **604** and the ventricle side **18** of the AV septum **12**. In some cases, the membrane **650** may be formed of a flexible material such as silicone, and may be impregnated with a salt or other material that will cause the membrane **650** to swell upon exposure to blood. In some instances, the membrane **650** may have a folded down configuration for deployment of the left seed **604** and may subsequently revert to the expanded configuration shown in FIG. 14.

[0097] FIG. 15 is a flow diagram showing an illustrative method of deploying a leadless pacing and sensing assembly proximate a patient's atrioventricular septum. The leadless pacing and sensing assembly may include a right atrial leadless cardiac pacemaker (LCP) and a left ventricular leadless cardiac pacemaker (LCP). A delivery catheter may be advanced through the patient's vasculature until a distal end of the delivery catheter is proximate an atrial side of the atrioventricular septum. The right atrial LCP may be disposed within a distal region of the delivery catheter as generally indicated at block **700**. A deployment device may be advanced past the right atrial LCP and through the

atrioventricular septum. The left ventricular LCP, sometimes secured to the deployment device, may be passed past the right atrial LCP and disposed in the left ventricle and proximate a ventricular side of the atrioventricular septum as generally seen at block 702. In some cases, the relative spacing and/or positioning of the right atrial LCP and the left ventricular LCP may be adjusted to improve pacing and/or sensing performance of the right atrial LCP and/or the left ventricular LCP by, for example, improving contact between one or more electrodes and the atrioventricular septum. The right atrial LCP and/or the left ventricular LCP may, for example, be activated to test performance before their final positions are secured. As indicated at block 704, the left ventricular LCP may be secured to the right atrial LCP. In some instances, the left ventricular LCP may then be released from the deployment device. The deployment device may be withdrawn as seen at block 706. The delivery catheter may be withdrawn as indicated at block 708. In some cases, withdrawing the delivery catheter may release the right atrial LCP.

[0098] Those skilled in the art will recognize that the present disclosure may be manifested in a variety of forms other than the specific examples described and contemplated herein. For instance, as described herein, various examples include one or more modules described as performing various functions. However, other examples may include additional modules that split the described functions up over more modules than that described herein. Additionally, other examples may consolidate the described functions into fewer modules. Accordingly, departure in form and detail may be made without departing from the scope and spirit of the present disclosure as described in the appended claims.

What is claimed is:

1. An implantable medical device (IMD) configured for deployment at a patient's atrioventricular septum in order to sense and/or pace a patient's heart, the atrioventricular septum of the patient's heart having an atrial facing side defining part of the right atrium of the patient's heart and a ventricle facing side defining part of the left ventricle of the patient's heart, the IMD comprising:

a first component configured to be positioned at least in part in the right atrium of the patient's heart proximate the atrioventricular septum once the IMD is implanted, the first component comprising:

a housing;

a power source disposed within the housing; and

circuitry disposed within the housing and operably coupled to the power source;

a second component configured to be positioned at least in part in the left ventricle of the patient's heart once the IMD is implanted, wherein the second component is mechanically coupled to the first component through a passage passing through the atrioventricular septum, the second component comprising:

a housing;

two or more electrodes for sensing and/or pacing the left ventricle of the patient's heart.

2. The IMD of claim 1, wherein the first component further includes two or more electrodes for sensing and/or pacing the right atrium of the patient's heart.

3. The IMD of claim 1, wherein the two or more electrodes of the second component are operably coupled to the circuitry of the first component.

4. The IMD of claim 1, wherein at least one of the two or more electrodes of the second component engage the ventricle facing side of the atrioventricular septum of the patient's heart once the IMD is implanted.

5. The IMD of claim 1, wherein at least one of the two or more electrodes of the first component engage the atrial facing side of the atrioventricular septum of the patient's heart once the IMD is implanted.

6. The IMD of claim 6, wherein the second component is configured to move from a contracted state to an expanded state, wherein during implantation of the IMD, the second component is configured to pass through the passage through the atrioventricular septum in the contracted state and then move to the expanded state once in the left ventricle of the patient's heart.

7. The IMD of claim 7, wherein in the expanded state, the second component extends laterally beyond a lateral extent of the passage through the atrioventricular septum and engages the ventricle facing side of the atrioventricular septum of the patient's heart.

8. The IMD of claim 1, wherein the first component extends laterally beyond a delivery catheter and engages the atrial facing side of the atrioventricular septum of the patient's heart once the IMD is implanted.

9. The IMD of claim 1, wherein the second component is configured to cut the passage through the atrioventricular septum while the IMD is implanted.

10. The IMD of claim 1, wherein the second component is mechanically coupled to the first component through the passage via a connecting member.

11. The IMD of claim 1, wherein the connecting member is part of the second component, and forms an interference fit with the first component.

12. The IMD of claim 16, wherein the connecting member is part of the first component, and forms an interference fit with the first component.

13. The IMD of claim 1, wherein the first component comprises a fixation element for securing the first component to the atrioventricular septum of the patient's heart.

14. The IMD of claim 1, wherein the second component comprises a fixation element for securing the second component to the atrioventricular septum of the patient's heart.

15. An implantable medical device (IMD) configured for deployment at a patient's atrioventricular septum, the atrioventricular septum of the patient's heart having an atrial facing side defining part of the right atrium of the patient's heart and a ventricle facing side defining part of the left ventricle of the patient's heart, the IMD comprising:

a body having a first end portion, a second end portion and a connecting portion connecting the first end portion to the second end portion;

at least part of the first end portion configured to be positioned in the right atrium of the patient's heart proximate the atrioventricular septum once the IMD is implanted;

at least part of the second end portion extending into the left ventricle of the patient's heart once the IMD is implanted;

the connecting portion extending through a passage that passes through the atrioventricular septum; and

the second end portion extending laterally beyond a lateral extent of the connecting portion to engage the ventricle facing side of the atrioventricular septum of the patient's heart once the IMD is implanted.

16. The IMD of claim **15**, wherein the second end portion includes two or more electrodes for sensing and/or pacing the left ventricle of the patient's heart, wherein at least one of the two or more electrodes of the second end portion engages the ventricle facing side of the atrioventricular septum of the patient's heart.

17. The IMD of claim **16**, wherein the first end portion includes two or more electrodes for sensing and/or pacing the right atrium of the patient's heart, wherein at least one of the two or more electrodes of the first end portion engages the atrial facing side of the atrioventricular septum of the patient's heart.

18. The IMD of claim **15**, wherein at least part of the second end portion is configured to move from a contracted state to an expanded state.

19. A method of deploying a leadless pacing and sensing assembly proximate a patient's atrioventricular septum, the leadless pacing and sensing assembly including a right atrial

leadless cardiac pacemaker (LCP) and a left ventricular leadless cardiac pacemaker (LCP), the method comprising:
advancing a delivery catheter through the patient's vasculature until a distal end of the delivery catheter is proximate an atrial side of the atrioventricular septum, the right atrial LCP disposed within a distal region of the delivery catheter;
advancing a deployment device past the right atrial LCP and through the atrioventricular septum, the left ventricular LCP secured to the deployment device such that the left ventricular LCP passes past the right atrial LCP and is disposed proximate a ventricular side of the atrioventricular septum;
securing the left ventricular LCP to the right atrial LCP;
and
withdrawing the deployment device.
20. The method of claim **19**, further comprising withdrawing the delivery catheter.

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专利名称(译)	用于部署穿过房室隔的植入式医疗装置		
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[标]申请(专利权)人(译)	心脏起搏器股份公司		
申请(专利权)人(译)	心脏起搏器，INC.		
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[标]发明人	LIU LILI		
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摘要(译)

可植入医疗设备 (IMD) 可以被配置用于在患者的房室隔中展开，以便感测和/或调节患者的心脏。患者心脏的房室隔可以具有面向心房的侧面，该侧面限定患者心脏的右心房的一部分，并且面向侧面的心室限定患者心脏的左心室的一部分。IMD可以包括第一部件和第二部件，第一部件被配置成至少部分地定位在患者心脏的右心房中靠近房室隔膜，第二部件被配置成至少部分地定位在左心室中。

