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(71) Applicant *(for all designated States except US)*: **UNIVERSITY OF VIRGINIA PATENT FOUNDATION** [US/US]; 250 West Main Street, Suite 300, Charlottesville, Virginia 22902 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **MAHAPATRA, Srijoy** [US/US]; 1857 Rhett Court, Charlottesville, Virginia 22903 (US). **GILLIES, George T.** [US/US]; 202 Colthurst Drive, Charlottesville, Virginia 22901 (US).

(74) Agent: **DECKER, Robert, J.**; 250 West Main Street, Suite 300, Charlottesville, Virginia 22902 (US).

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(54) Title: STEERABLE EPICARDIAL PACING CATHETER SYSTEM PLACED VIA THE SUBXIPHOID PROCESS

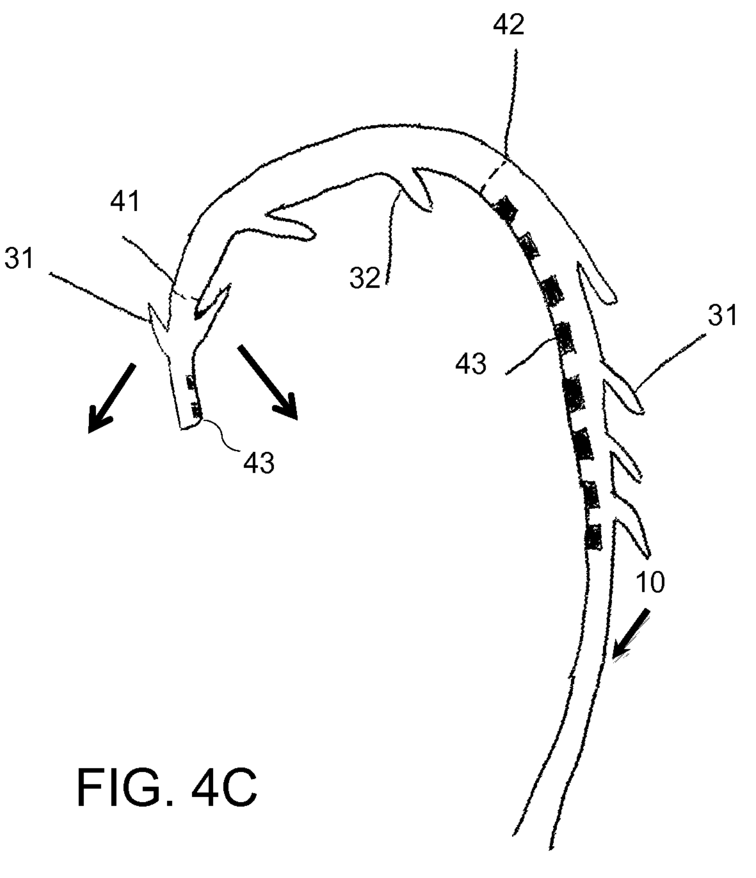

FIG. 4C

(57) Abstract: The epicardial pacing system and related method includes an epicardial catheter configured to be disposed in the middle mediastinum of the thorax of a subject for use in electrical pacing of the heart at one or more locations on the epicardial surface. The epicardial pacing catheter may include at least one electrode whereby the electrode is insulated on at least one side to allow pacing of the heart without damage to adjacent anatomical structures.

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Steerable Epicardial Pacing Catheter System Placed via the Subxiphoid Process

RELATED APPLICATIONS

The present invention claims priority from U.S. Provisional Application Serial No. 60/986,786, filed November, 09, 2007, entitled "Passive Fixation, Steerable Epicardial Lead to be Placed via the Subxiphoid Process for Pacing Left Ventricle, Right Ventricle, Right Atrium and Left Atrium and Cardiac Defibrillation," and U.S. Provisional Application Serial No. 61/023,727, filed January, 25, 2008, entitled "Steerable Epicardial Lead to be Placed via the Subxiphoid Process for Left Ventricular Pacing and Related Method;" the disclosures of which are hereby incorporated by reference herein in their entirety.

This application is related to PCT International Application No. Serial No. PCT/US2008/056643, filed March 12, 2008, entitled, "Access Needle Pressure Sensor Device and Method of Use," the disclosure of which is hereby incorporated by reference herein in its entirety.

This application is related to PCT International Application No. Serial No. PCT/US2008/056816, filed March 13, 2008, entitled, "Epicardial Ablation Catheter and Method of Use," the disclosure of which is hereby incorporated by reference herein in its entirety.

This application is related to PCT International Application No. Serial No. PCT/US2008/057626, filed March 20, 2008, entitled, "Electrode Catheter for Ablation Purposes and Related Method Thereof," the disclosure of which is hereby incorporated by reference herein in its entirety.

FIELD OF THE INVENTION

The present technology relates generally to the field of medical devices to be used for cardiological procedures. More specifically, the technology is in the subfield of catheterization devices to be used for epicardial pacing.

BACKGROUND OF THE INVENTION

Congestive heart failure effects between 4 and 5 million people in the United States and accounts for about $15 billion per year in hospitalization costs alone. While medical therapy, such as prescription drugs, may benefit a number of patients, side effects prevent some patients from completing therapy. Moreover, few patients are completely cured of their symptoms.

In recent years simultaneous pacing of both ventricles (via a biventricular pacemaker) has been shown in multiple studies to improve the quality of life and extend survival of such patients. The American College of Cardiology and American Heart Association has, therefore, recommended that all patients having class II, III or IV heart failure with a wide QRS complex (electrocardiograph deflections of the Q, R and S waves) receive a biventricular pacemaker. This recommendation alone encompasses up to one million people per year in the US, and uses for this type of device are expanding.

Unfortunately, due to inherent difficulties in placing left ventricular (LV) leads, less than 15% of eligible patients are able to receive this device. Unlike the RV, the electrical lead can not be placed directly into the LV due to the unacceptably high risk of stroke. The lead must, therefore, be placed on the surface of the LV. In order to accomplish this placement, a lead is threaded through the right atrium (RA) using a venous system, and passed through the coronary sinus (CS) to any of a number of small veins in communication with the surface of the LV.

Quantitative clinical results, especially those reporting the statistics of negative outcomes, are seldom published. However, in procedures conducted at the inventors' high volume university hospital, 20% of patients have been found to have a very difficult access to the CS, resulting in an abandonment of the procedure. In an additional 20% of patients, a vein in communication with an optimal location on the LV can not be found within the CS. As an example, if one is trying to place a lead on the lateral aspect of the LV (an ideal location), but there is no vein extending from within the CS to the lateral aspect of the LV, a lead can not be placed here. Worse still, many of these patients have multiple areas of dead heart tissue, so even if a lead can be placed within a vein, it might not pace the heart. Even moving the lead slightly would help, but the vein acts like a railroad track to limit placement. All of these limitations result in an unpredictable procedure time, making it difficult for hospitals and doctors to plan the operation.

At present, the most effective option to pace the LV is through invasive surgery requiring cardiac surgeons. The newest techniques allow surgeons to either open a patient's chest or cut between the ribs to place the lead anywhere on the LV. Even the most "minimally invasive" leads currently available require a lateral thoracotomy necessitating a surgeon. Both the Ncontact® and Heartlander® tools, which are not designed to pace, require surgical incisions.

There are two significant barriers to widespread application of these surgical techniques. First, surgical procedures are generally more invasive and require longer recovery times. Second, most cardiologists consider it the standard of care to attempt an initial placement of a lead via CS access; only after that fails is surgery considered. To avoid the need for additional surgical intervention, a cardiologist may choose a sub-optimal location for lead placement. This is typically in keeping with the wishes of most patients; minimally invasive techniques are preferred whenever possible.

There is therefore a need in the art whereby one would be able to place a lead for pacing on any optimal site of the LV based solely on what is clinically efficient for the patient and not the heart's anatomy. Moreover, if this could be accomplished by a cardiologist (non-surgeon) without the need for invasive surgery, the procedure would be used more often. Thus, instead of only 15% of patients receiving biventricular pacing, close to 100% of patients could receive it.

The following U.S. patent documents discuss catheterization tools for cardiology: U.S. Patent Numbers: 7,142,919 to Hine et al.; 7,130,699 to Huff et al.; 7,120,504 to Osypka; 7,101,362 to Vinney; 7,090,637 to Danitz et al.; 7,089,063 to Lesh et al.; 7,059,878 to Hendrixson et al.; 7,041,099 to Thomas et al.; 7,027,876 to Casavant et al.; 7,008,418 to Hall et al.; 6,973,352 to Tsutsui et al.; 6,936,040 to Kramm et al.; 6,921,295 to Sommer et al.; 6,876,885 to Swoyer et al.; 6,868,291 to Bonner et al., all of which are incorporated by reference herein in their entirety. No reference discloses the conceptual arrangements for an integrated cardiological device for epicardial pacing.

To overcome these limitations, we have conceived the subject device and method of use, as described in the Summary of the Invention and Detailed Description of the Drawings below.

These and other objects, along with advantages and features of the invention disclosed herein, will be made more apparent from the description, drawings and claims that follow.

SUMMARY OF THE INVETION

An aspect of an embodiment (or partial embodiment thereof) of the present invention includes an apparatus and means for treating congestive heart failure and arrhythmias (both bradycardias and tachycardias) of the heart. For example, the invention provides for a novel means and method of placing an epicardial lead within a patient for the purpose of permanent multi-site, cardiac pacing and defibrillation, including left ventricular pacing.

An aspect of an embodiment (or partial embodiment thereof) of the present invention includes a lead that paces LV, RV, LA and RA at the same time or in sequence. It could even pace two separate points on the same chamber (the LV or the RV) at the same time or at some offset. This has an important advantage, for example, if a region of tissue ever dies in heart attack, the present invention method can still pace from elsewhere.

An aspect of an embodiment (or partial embodiment thereof) of the present invention may include placing a bipolar pacing lead through a subxiphoid incision and then channeling it back to a pacemaker. The procedure may evolve through three distinct stages. In the earliest stage, one would place the lead on the left ventricle and tunnel it underneath the pectoral muscle back to the chest wall where the pacemaker would normally be placed. In the second, one would place the lead back to the subxiphoid process, attach it to a battery that is positioned just on the outside of the xiphoid process and have it wirelessly communicate with the main pacemaker. Lastly one would place a button-like object right on the top of the left ventricle and then communicate wirelessly back to the main pacemaker. Still yet, another embodiment of the means and method of the invention may include having the battery, anode and cathode means all compounded on the end of the lead so that there would not be any need to have another excision to bring any of the components back out of the heart.

An aspect of an embodiment or partial embodiment of the present invention (or combinations of various embodiments in whole or in part of the present invention) comprises an epicardial pacing system. The system may comprise: an epicardial catheter configured to be disposed in the middle mediastinum of the thorax of a subject for use in electrical pacing of the heart at one or more locations on the epicardial surface. The epicardial pacing catheter comprising: a proximal portion, distal portion, and a longitudinal structure there between; and at least one electrode in communication with the distal portion, wherein the at least one electrode is insulated on at least one side to allow pacing of the heart without damage to adjacent anatomical structures.

An aspect of an embodiment or partial embodiment of the present invention (or combinations of various embodiments in whole or in part of the present invention) comprises a method for use with an epicardial pacing catheter. The method may comprise: disposing the epicardial pacing catheter in the middle mediastinum of the thorax of a subject; and pacing the heart at one or more locations with electrical energy from an at least one electrode; and at least partially insulating the electrical energy to allow pacing of the heart without damage to adjacent anatomical structures.

The epicardial pacing system and related method includes an epicardial catheter configured to be disposed in the middle mediastinum of the thorax of a subject for use in electrical pacing (and/or other diagnostic or therapeutic procedure) of the heart at one or more locations on the epicardial surface. The epicardial pacing catheter may include at least one electrode whereby the electrode is insulated on at least one side to allow pacing of the heart without damage to adjacent anatomical structures.

These and other objects, along with advantages and features of the invention disclosed herein, will be made more apparent from the description, drawings and claims that follow.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated into and form a part of the instant specification, illustrate several aspects and embodiments of the present invention and, together with the description herein, serve to explain the principles of the invention. The drawings are provided only for the purpose of illustrating select embodiments of the invention and are not to be construed as limiting the invention.

Figure 1 schematically illustrates the overall configuration of the epicardial pacing catheter system.

Figure 2 schematically illustrates the pericardium and heart alone (**Figure 2(A))** and an example embodiment in position relative to the heart (**Figure 2(B))**.

Figure 3 schematically illustrates an example embodiment passively disposed within the pericardial sack of the heart**.**

Figures 4(A)-(C) schematically illustrate a number of exemplary embodiments of the steering means employed to position the distal portion of an exemplary embodiment of the epicardial pacing catheter in un-tensioned, partial steering, and full steering modes, respectively.

Figures 5(A)-5(D) schematically illustrate a number of exemplary embodiments of the epicardial pacing catheter **10** near the distal portion.

Figures 6(A)-6(F) schematically illustrate cross sectional views of an exemplary embodiment of the technology from the most distal end to a more proximal point.

Figures 7(A) and (B) schematically illustrate cross sectional views of an exemplary embodiment of the most proximal portion of an exemplary embodiment of the epicardial pacing catheter and the most distal portion of an exemplary embodiment of the control means, respectively.

Figures 8(A)-(C) schematically illustrate cross-sectional views of an example embodiment further comprising a stabilization means for stabilizing the example embodiment. The stabilization means illustrated in an un-deployed position, partially deployed position, and deployed position, respectively.

Figure 9 schematically illustrates an example embodiment of the epicardial pacing catheter further comprising deployable electrodes fixed or adjacent to the heart.

Figure 10(A) schematically illustrates a top view of an exemplary embodiment of the epicardial pacing catheter**.**

Figure 10(B) schematically illustrates a bottom view of an exemplary embodiment of the epicardial pacing catheter.

Figure 10(C) schematically illustrates an axial view of an exemplary embodiment of the epicardial pacing catheter looking at the distal tip of the insulating hood.

Figure 10(D) schematically illustrates a perspective view of an exemplary embodiment of the epicardial pacing catheter.

Figure 11(A)-11(E) schematically illustrate cross sectional views of an exemplary embodiment of the epicardial pacing catheter from a point located proximal to the at least one electrode and distal to the distal point of curvature to a point located at the most proximal point of the epicardial pacing catheter. **Figure 11(F)** schematically illustrates a cross sectional view of an exemplary embodiment of the control handle at the most distal point.

Figure 12(A) schematically illustrates a cross section of an exemplary embodiment of the epicardial pacing catheter comprising a deployable anode and cathode in an un-deployed state.

Figure 12(B) schematically illustrates a cross section of an exemplary embodiment of the epicardial pacing catheter comprising a deployable anode and cathode in a fully-deployed state.

Figure 13(A) schematically illustrates a cross section of an exemplary embodiment of the epicardial pacing catheter comprising a deployable screw or the like in an un-deployed state.

Figure 13(B) schematically illustrates a cross section of an exemplary embodiment of the epicardial pacing catheter comprising a deployable screw or the like in a fully-deployed state.

Figure 14(A) schematically illustrates a cross section of an exemplary embodiment of the epicardial pacing catheter comprising a deployable anode and cathode in an un-deployed state.

Figure 14(B) schematically illustrates a cross section of an exemplary embodiment of the epicardial pacing catheter comprising a deployable anode and cathode in a fully-deployed state.

Figure 15(A) schematically illustrates an example embodiment of an external control handle.

Figure 15(B) schematically illustrates an example embodiment of the proximal steering control means or a least part of the steering control means integral to the control handle.

Figure 15(C) schematically illustrates an example embodiment wherein the proximal steering control means or a least part of the steering control means integral to the control handle has been activated.

DETAILED DESCRIPTION OF THE DRAWINGS

The following detailed description is of the best presently contemplated modes of carrying out the invention. This description to be taken in a limiting sense, but is made merely for the purpose of illustrating general principles of embodiments of the invention.

Figure 1 schematically illustrates an overview of an exemplary embodiment of the epicardial pacing system **5** comprising an epicardial pacing catheter **10** in communication with at least one electrode **43**, a control means or control handle **150**, an interface member **162**, a processor **164** or computer, power supply **166** or battery, or voice control instrumentation/system **168**.

The control means **150** may be in communication with the proximal portion of the catheter **10**, wherein the control means **150** is controllably connected to at least one electrode **43**. In one embodiment, the control means may be a control handle or controller as desired or required. In another embodiment, the control handle (or control means) may be removable. The epicardial pacing catheter **10** may further comprises a processor **164** or computer. The processor **164** may be in communication with said epicardial pacing catheter **10** and system. The processor **164** may be located at or near the patient's shoulder, for example. The epicardial pacing catheter **10** further comprises an interface member **162** in communication with said epicardial pacing catheter **10**. The interface member **162** may be in remote and/or local communication with the processor **164**, pacing system **5,** catheter **10,** controller **150,** power supply **166,** and/or voice control instrumentation to provide information to and/or from a patient, physician, technician, or a clinician. Further, any of the components and systems illustrated in **Figure 1** may be in communication with each other, as well as other systems, computers, devices, printers, displays, PDAs, networks, memory storage, and voice control instrumentations as desired or required.

As discussed, the epicardial pacing system **5** may comprise a power supply **166**. The power supply **166** may comprise a small battery located at the subxiphoid area, preferably of a silicone silver-gallium kind designed specifically for use in implantable cardiac defibrillators (ICDs). The power characteristics of the particular battery may be such that it can maintain the same voltage for a long period of time before falling off suddenly.

The epicardial pacing system **5** and epicardial pacing catheter **10** may further comprise a wireless communication system, wherein the processor **164,** power supply **166**, voice control instrumentation **168**, interface member **162** or desired components of the system **5** may be wirelessly connected to one another. In another embodiment, the battery and processor **164** are both located in the subxiphoid area.

It should be appreciated that any of the components or modules referred to with regards to any of the present technology embodiments discussed herein, may be integrally or separately formed with one another. Further, redundant functions or structures of the components or modules may be implemented. Moreover, the various components may be communicated locally and/or remotely with any user/clinician/patient or machine/system/computer/processor. Moreover, the various components may be in communication via wireless and/or hardwire or other desirable and available communication means, systems and hardwares.

Next, as will be illustrated in Figures that follow, the epicardial pacing catheter **10** in accordance with the present technology may comprise a proximal portion, a distal portion, and a longitudinal structure there between. It should be appreciated that the distal portion may be considered at the distal end tip of the epicardial pacing catheter **10**; or a portion or segment at or in the vicinity of the distal end tip of the epicardial pacing catheter **10** or a portion or segment leading up to (or partially up to but not all the way up to) the distal end of the catheter **10** as desired or required. The length and location of the distal portion may vary as desired or required in order to practice the technology according to medical procedures and anatomical considerations.

It should also be appreciated that the proximal portion may be considered the tip of the beginning of the catheter **10**; or a portion or segment at or in the vicinity of the proximal end of the catheter **10** or a portion or segment leading up to (or partially up to but not all the way up to) the proximal end of the catheter **10** as desired or required. The length and location of the proximal portion may vary as desired or required in order to practice the technology according to medical procedures and anatomical considerations.

The proximal portion, distal portion and longitudinal structure there between may be integrally formed from a biocompatible material having requisite strength and flexibility for deployment within a patient. The proximal portion, distal portion, and longitudinal structure there between may have a lubricious outer surface comprising a material having a low coefficient of friction, such as, but not limited to, silicone, polyurethane, or Teflon, or combination thereof. The proximal portion, distal portion, and longitudinal structure there between may further have an outer surface comprising a drug eluting surface and/or a surface impregnated with sirilimus to prevent the production of fibrosis within a patient. The longitudinal structure may be between about 15 cm and about 100 cm in length, and between about 2 mm and about 6 mm in diameter. It should be appreciated that the length of the longitudinal structure may be longer or shorter as may be desired or required according to medical procedures, device/system operations and anatomical considerations. The cross section of the longitudinal structure comprises an oval, circle, ellipse, polygon, or semi-circular shape. The longitudinal structure may be any one of: lumen, conduit, channel, passage, pip, tunnel or bounded tubular surface.

The epicardial pacing catheter **10** further comprises at least one electrode **43** in communication with the distal portion, wherein the at least one electrode **43** is insulated on at least one side to allow pacing of the heart without damage to adjacent structures.

The at least one electrode **43** may be constructed of platinum, gold, silver, iridium, or any alloy thereof, or other conducting materials known in the art. The at least one electrode **43** may comprise a roughened, profiled, or otherwise prepared surface to increase the total surface area for energy transmission. The at least one electrode **43** may be semi-cylindrical or arc-like in shape, and may be contoured to be compatible with proximate anatomical structures. The at least one electrode **43** may be between about 0.3 mm and about 4 mm in length, and may be spaced between about 1 mm and about 25 mm from each other. Further, the at least one electrode **43** may be a pair of electrodes, commonly referred to as an anode and cathode in the art. Finally, the at least one electrode **43** may be deployable. It should be appreciated that the length of the electrodes may be longer or shorter as may be desired or required according to medical procedures, device/system operations and anatomical considerations.

It should be appreciated that the various sheaths, catheters and guidewires, or any related components disclosed herein, may have a circular or oval-shaped cross-section or various combinations thereof. Further, it should be appreciated that various sheaths, catheters and guidewires, or any related components disclosed herein may have any variety of cross sections as desired or required for the medical procedure or anatomy.

Moreover, it should be appreciated that any of the components or modules referred to with regards to any of the present invention embodiments discussed herein, may be a variety of materials and/or composites as necessary or required. Still further, it should be appreciated that any of the components or modules (or combination thereof) may provide shape, size and volume contoured by adjusting its geometry and flexibility/rigidity according to the target location or anatomy (or region, including structure and morphology of any location) being treated.

Figure 2(A) schematically illustrates the pericardium and heart alone. The pericardium **22** is shown in close proximity to the epicardium **23**.

Figure 2(B) schematically illustrates three contiguous sections of an example embodiment implanted around the heart **21**. The epicardial pacing catheter **10** of the epicardial pacing system **5** is positioned in the pericardial space, cavity or sack **24**, or the area between the pericardium **22** and epicardium **23**. All of the electrodes **43** are facing the heart **21**. The epicardial pacing catheter **10** further comprises outward facing bumper tabs **31** and inward facing friction tabs **32** to stabilize the epicardial pacing catheter **10** from moving within the pericardial sack **24**, once it is implanted.

Although not shown, an aspect of an embodiment of the present technology may be implemented with an access needle (introducer needle), conduit or the like. The access needle or conduit is adapted to be inserted into the epicardial region or other body part or body space so as to provide an access or guideway for the epicardial pacing catheter **10**. An example of an access system is disclosed in PCT International Application No. Serial No. PCT/US2008/056643, filed March 12, 2008, entitled, "Access Needle Pressure Sensor Device and Method of Use," of which is hereby incorporated by reference herein in its entirety. See for example, but not limited thereto, **Figures 2** and **5** of the '056643 PCT Application. The access needle sensor device or the like serves as a guideway for introducing other devices into the pericardium **22**, for instance, sheath catheters that might subsequently be employed for procedures within the pericardium **22** or other applicable regions, space or anatomy. Other devices that the access device may accommodate with the practice of this invention include, but are not limited thereto, the following: ablation catheters, guide wires, other catheters, visualization and recording devices, drugs, and drug delivery devices, lumens, steering devices or systems, drug or cell delivery catheters, fiber endoscopes, suctioning devices, irrigation devices, electrode catheters, needles, optical fiber sensors, sources of illumination, vital signs sensors, and the like. These devices may be deployed for procedures in an integral body part or space.

It should be appreciated that any data, feedback, readings, or communication from the system (for example, catheters, access needles, sensors, systems, etc.) may be received by the user, clinician, physician, or technician or the like by visual graphics, audible signals (such as voice or tones, for example) or any combination thereof. Additionally, the data, feedback, or communication may be reduced to hard copy (e.g., paper) or computer storage medium. It should be appreciated that the pressure related readings and data may be transmitted not only locally, but remotely as well.

Moreover, an aspect of the invention may be in the field of voice control over medical systems and devices of use in specialized electrophysiology procedures that employ subxiphoid access for the purpose of navigating an interventional or surgical probe onto the epicardial surface of the heart, via pericardial transit. In its most particular form, the invention may be in the specialized category of voice control over instruments and systems that measure the intrathoracic and intrapericardial pressures during the process of navigating said intrathoracic or surgical probe within the patient following subxiphoid insertion.

An aspect of an embodiment or partial embodiment of the subject invention (or combinations of various embodiments in whole or in part of the present invention) is one of providing the working electrophysiologist with a means and method for controlling the operational parameters (e.g., the display functions) of diagnostic and therapeutic cardiological equipment by voice, thus eliminating either the need to temporarily take their hands off the patient or the need to have an additional EP Lab technician available to perform such tasks. (Such personnel are often needed to insure that the clinician need never touch anything outside the sterile field.). Generally, examples of voice control instrumentation that teach applications in medical applications but not in electrophysiological approaches to cardiological problems include U.S. Patent Numbers 7,286,992; 7,259,906; 7,247,139; 6,968,223; 6,278,975; 5,970,457; 5,812,978; 5,544,654 and 5,335,313, all of which are hereby incorporated by reference in their entirety.

Additionally, present invention system and method may further comprise imaging said the access needle and the epicardial pacing system (and components thereof) with at least one of magnetic resonance imaging, computed tomography, fluoroscopy, or other radiological modalities. In some embodiments, readings are provided from said sensing of pressure for navigating said needle access and the epicardial pacing system (and components thereof).

Although not shown, as mentioned above, the deploying of the epicardial pacing catheter **10** into the pericardial sack **24** may be minimally invasive, non-surgical, and/or interventional. The deploying of the epicardial pacing catheter **10** may be performed by a non-surgeon and/or cardiologist through use of an access needle and subsequent passage of a guidewire. The access needle may first be inserted through the chest and into the pericardium **22**, with the guidewire then put in place. The epicardial pacing catheter **10** may then be coaxially slid over the guidewire to access the pericardial sack **24**.

Although not shown and involving another approach, the insertion of a sheath into the pericardial sack **24** may be aided by the use of an access needle and subsequent passage of a guidewire. The access needle may first be inserted into the epicardium, with the guidewire then put in place. The sheath may then be coaxially slid over the guidewire to access the pericardial sack **24**. After positioning the sheath in the desired location, the epicardial pacing catheter **10** may then be inserted through the sheath to reach the epicardium **23**.

For example, the guideway provides coaxial alignment for the at least one of guide wire, sheath or catheter, which can be inside or outside the needle. The at least one guide wire, sheath, or catheter can also be coaxially aligned with one another. Further, multiple lumens may be implement and configured between the plurality of distal apertures and plurality proximal apertures. It should be appreciated that coaxial alignment does not need to be exact, but rather one conduit, lumen, sheath, or guidewire slid outside or inside of another.

For example, with the present technology, an epicardial access needle-stick may be implemented in the subxiphoid area of the chest and the epicardial pacing catheter **10** only need be advanced a short distance to get to the heart **21**. However, it may immediately be steered though an acute angle to avoid the heart itself. Because of this, aspects of the present invention devices and those used in conventional techniques can be contrasted. For instance, conventional endocardial catheters may typically be up to100 cm in length or longer since they must go from the shoulder to the heart, while an embodiment of the present technology could be, for example, about 20 cm or less since it may only need to go from the chest to the heart. It should be appreciated that the length may be greater than about 20 cm as well. It should be appreciated that the length of the present invention catheter may be longer or shorter as may be desired or required according to medical procedures, device/system operations and anatomical considerations.

It should be appreciated that as discussed herein, a subject may be a human or any animal. It should be appreciated that an animal may be a variety of any applicable type, including, but not limited thereto, mammal, veterinarian animal, livestock animal or pet type animal, etc. As an example, the animal may be a laboratory animal specifically selected to have certain characteristics similar to a human (e.g. rat, dog, pig, monkey), etc. It should be appreciated that the subject may be any applicable human patient.

Figure 3 schematically illustrates an example embodiment of the epicardial pacing catheter **10** of the epicardial pacing system **5** passively disposed within the pericardial sack **24** (shown with hash marks) of the heart **21**. A cross section of the heart is shown, revealing critical internal structures, including various great vessels. The epicardial pacing catheter **10** may be used to pace the left ventricle, right ventricle, right atrium, and left atrium. It should be appreciated that the present technology may be used to pace the left ventricle, left atrium, right atrium, right ventricle and/or any combination thereof. The epicardial pacing catheter **10** may first be inserted into the pericardium **22** at the insertion point **33**, which may be located at an anterior portion (towards the sternum) of the pericardium **22**, adjacent to the left ventricle. The catheter is then advanced posteriorly (towards the spine) within the pericardial sack **24** towards the left atrium, right atrium and transverse sinus. The catheter is further advanced around the posterior of the heart, and pushed anteriorly toward the right ventricle. Once the catheter is in contact with the left ventricle, right ventricle, right atrium and left atrium, a deployable stabilization means may be deployed. Both outward facing bumper tabs **31** and inward facing friction tabs **32** are shown, and prevent the catheter from moving or slipping. The inward facing friction tabs **32** may interact with the outside wall of structures such as, but not limited to, the transverse sinus, superior vena cava, right inferior pulmonary vein, and the right superior pulmonary vein to prevent the catheter from dislodging. The outward facing bumper tabs **31** may push on the pericardium to further secure the catheter **10** against the epicardium (for example, as shown in **Figure 2**).

Figures 4(A)-(C) provide schematic illustrations of some of the operational aspects of an exemplary embodiment of the steering means, system or device associated with the epicardial pacing catheter **10** of the epicardial pacing system. The epicardial pacing catheter **10** further comprises a distal steering means (not shown) and a proximal steering means (not shown) which may have the steering characteristics taught by Mahapatra et al. in PCT International Application No. PCT/US2008/056816, filed March 13, 2008, entitled, "Epicardial Ablation Catheter and Method of Use," hereby incorporated by reference herein in its entirety. The steering means may comprise guidewires, tensioning lines, pull strings, digitating distal tips, magnetic guidance means, wires, rods, chains, bands, chords, ropes, string tubes, filaments, threads, fibers, strands, other extended elements, or any other method known in the art.

For instance, referring to **Figures 4(A)-(C)** of '056816 PCT International Application, there is provided the mechanism of action for obtaining bi-directional steering of the distal tip or portion that may be implemented for the present invention via tensioning or steering means whereby the tip or end is straight, towards the left, and towards the right, respectively.

Moreover, for instance and referring to **Figures 7(A)-7(B)** of '056816 PCT International Application there is provided some details of an exemplary mechanism of action for directional steering of the proximal segment of the device that may be implemented for the present technology.

Steering adjustments are made along the proximal point of curvature **42** and distal point of curvature **41** using the proximal steering means (as shown in **Figure 15(B)**) and distal steering means (not shown) respectively. The proximal point of curvature **42** may be located between about 1 cm and about 25 cm from the proximal end and the distal point of curvature **41** may be located between about 1 cm and about 20 cm from the distal end. It should be appreciated that the proximal and distal points of curvature may be located at other longer or shorter points and may be implemented as may be desired or required according to medical procedures, device/system operations and anatomical considerations. The steering means are used to direct the epicardial pacing catheter **10** through or navigate it within a patient's body. It should be noted that, while two steering means and points of curvature are shown, the epicardial pacing catheter **10** may further comprise a third and fourth steering means for steering the epicardial pacing catheter **10** around a third and fourth point of curvature. Moreover, though a bi-directional distal point of curvature **41** is shown, it should be appreciated that all points of curvature may be uni-directional, bi-direction, tri-direction, quadra-directional, or greater than quadra-directional.

Specifically, **Figure 4(A)** shows an embodiment of the epicardial pacing catheter **10** in the non-deflected state. **Figure 4(B)** shows the epicardial pacing catheter **10** in a partially-deflected state. **Figure 4(C)** shows the epicardial pacing catheter **10** in a fully-deflected state, as would be the case when it has been navigated into the pericardial space of a subject's heart, or other space or structure. In the fully-deflected state, the at least one electrode **43** is held against a patient's heart by the stabilization means, shown as the inward facing friction tabs **32** and outward facing bumper tabs **31**.

The devices, systems, compositions and methods of various embodiments of the invention disclosed herein may utilize aspects disclosed in the following references, applications, publications and patents. Similarly, the steering means, actuator means (as will be discussed below) and navigation means of the various embodiments of the invention disclosed herein may utilize aspects disclosed in the following references, applications, publications and patents, and which are hereby incorporated by reference herein in their entirety:

1. U.S. Patent Application Publication No. 20050251094, November 10, 2005, “System and method for accessing the coronary sinus to facilitate insertion of pacing leads”, Peterson, Eric D.

2. U.S Patent Application Publication No. 20040147826, July 29, 2004, “System and method for accessing the coronary sinus to facilitate insertion of pacing leads”, Peterson, Eric D.

3. U.S. Patent No. 6928313, August 9, 2005, “System and method for accessing the coronary sinus to facilitate insertion of pacing leads”, Peterson, Eric D.

4. U.S. Patent No. 7004937, February 28, 2006, “Wire reinforced articulation segment”, Lentz, David J., et al.

5. U.S. Patent Application Publication No. 20040024413, February 5, 2004, “Wire reinforced articulation segment”, Lentz, David J., et al.

6. U.S. Patent Application Publication No. 20060064056, March 23, 2006, “Guiding catheter assembly for embolic protection by proximal occlusion”, Coyle, James, et al.

7. U.S. Patent Application Publication No. 20030181855, September 25, 2003, “Pre-shaped catheter with proximal articulation and pre-formed distal end”, Simpson, John A., et al.

8. U.S. Patent No. 6869414, March 22, 2005, “Pre-shaped catheter with proximal articulation and pre-formed distal end”, Simpson, John A., et al.

9. U.S. Patent Application Publication No. 20080262432, October 23, 2008, “System and method for manipulating a guidewire through a catheter”, Miller, Sean.

10. U.S. Patent Application Publication No. 20070016068, January 18, 2007, “Ultrasound methods of positioning guided vascular access devices in the venous system”, Grunwald, Sorin, et al.

11. U.S. Patent Application Publication No. 20070016070, January 18, 2007, “Endovascular access and guidance system utilizing divergent beam ultrasound”, Grunwald, Sorin, et al.

12. U.S. Patent Application Publication No. 20070016072, January 18, 2007, “Endovenous access and guidance system utilizing non-image based ultrasound”, Grunwald, Sorin, et al.

13. U.S. Patent No. 5916194, June 29, 1999, “Catheter/guide wire steering apparatus and method”, Jacobsen, Stephen C., et al.

14. U.S. Patent Application Publication No. 20070016069, January 18, 2007, “Ultrasound sensor”, Grunwald, Sorin, et al.

15. U.S. Patent No. 6500130, December 31, 2002, “Steerable guidewire”, Kinsella, Bryan, et al.

16. U.S. Patent Application Publication No. 20020082523, June 27, 2002, Steerable guidewire”, Kinsella, Bryan, et al....

17. U.S. Patent Application Publication No. 20060025705, February 2, 2006, “Method for use of vascular guidewire”, Whittaker, David R., et al.

18. U.S. Patent Application Publication No. 20050020914, January 27, 2005, “Coronary sinus access catheter with forward-imaging”, Amundson, David, et al.

19. U.S. Patent Application Publication No. 20040034365, February 19, 2004, “Catheter having articulation system”, Lentz, David J., et al.

20. U.S. Patent Application Publication No. 20060064058, March 23, 2006, “Guiding catheter with embolic protection by proximal occlusion”, Coyle, James.

21. U.S. Patent Application No. 20080097399, “Catheter with adjustable stiffness, Sachar, Ravish, et al.

22. U.S. Patent Application Publication No. 20080051671, February 28, 2008, “Intravascular filter monitoring”, Broome, Thomas E., et al.

23. U.S. Patent No. 6616676, September 9, 2003, “Devices and methods for removing occlusions in vessels”, Bashiri, Mehran, et al.

24. U.S. Patent Application Publication No. 20020072737, June 13, 2002, “System and method for placing a medical electrical lead”, Belden, Elisabeth L., et al.

25. U.S. Patent No. 7004937, February 28, 2006, “Wire reinforced articulation segment”, Lentz, David J., et al.

26. U.S. Patent Application Publication No. 20040024413, February 5, 2004, “Wire reinforced articulation segment”, Lentz, David J, et al.

27. U.S. Patent Application Publication No. 20060064056, March 23, 2006, “Guiding catheter assembly for embolic protection by proximal occlusion”, Coyle, James, et al.

27. U.S. Patent No. 6869414, March 22, 2005, “Pre-shaped catheter with proximal articulation and pre-formed distal end”, Simpson, John A., et al.

28. U.S. Patent Application Publication No. 20070016068, January 18, 2007, “Ultrasound methods of positioning guided vascular access devices in the venous system”, Grunwald, Sorin, et al.

28. U.S. Patent Application Publication No. 20070016070, “Endovascular access and guidance system utilizing divergent beam ultrasound”, Grunwald, Sorin, et al.

29. U.S. Patent Application Publication No. 20070016072, “Endovenous access and guidance system utilizing non-image based ultrasound”, Grunwald, Sorin, et al

30. U.S. Patent Application Publication No. 20080262432, October 23, 2008, “System and method for manipulating a guidewire through a catheter”, Miller, Sean.

31. U.S. Patent Application Publication No. 20070016069, January 18, 2007, “Ultrasound sensor”, Grunwald, Sorin.

32. U.S. Patent Application Publication No. 20060025705, February 2, 2006, “Method for use of vascular guidewire”, Whittaker, David R., et al.

33. U.S. Patent Application Publication No. 20030181855, September 25, 2003, “Pre-shaped catheter with proximal articulation and pre-formed distal end”, Simpson, John A., et al.

34. U.S. Patent Application Publication No. 20050020914, January 27, 2005, “Coronary sinus access catheter with forward-imaging”, Amundson, David, et al.

35. U.S. Patent No. 5916194, June 29, 1999, “Catheter/guide wire steering apparatus and method”, Jacobsen, Stephen C., et al.

36. U.S. Patent Application Publication No. 20060064058, March 23, 2006, “Guiding catheter with embolic protection by proximal occlusion”, Coyle, James.

37. U.S. Patent Application Publication No. 20040186507, September 23, 2004, “Stent delivery system and method of use”, Hall, Todd A., et al.

38. U.S. Patent Application Publication No. 20050027243, February 3, 2005, “Steerable catheter”, Gibson, Charles A.

39. U.S. Patent No. 7232422, June 19, 2007, “Steerable catheter”, Gibson, Charles A., et al.

40. U.S. Patent Application Publication No. 20060247522, November 2, 2006, “Magnetic navigation systems with dynamic mechanically manipulatable catheters”, McGee, David L.

41. U.S. Patent No. 6783510, August 31, 2004, “Steerable catheter”, Gibson, Charles A., et al.

42. U.S. Patent Application Publication No. 20080015625, January 17, 2008, “Shapeable for steerable guide sheaths and methods for making and using them”, Ventura, Christine P., et al.

Figures 5(A)-5(D) schematically illustrate a number of embodiments of the epicardial pacing catheter **10** of the epicardial pacing system near the distal portion.

Figure 5(A) schematically illustrates an exemplary embodiment wherein the epicardial pacing catheter **10** may be used to pace the left ventricle (LV) of a patient’s heart. A number of electrodes **43** are adapted to transmit electrical energy to the left ventricle, and are shown facing the left ventricle. The number of electrodes **43** may vary depending on the number of locations required or desired to be paced. The electrodes **43** may be insulated on at least one side away from the heart, as to prevent electrical energy from being transmitted to proximate anatomical structures. The insulation may be about 2 mm thick, and may extend longitudinally through the epicardial pacing catheter **10.** It should be appreciated that the thickness may be wider or narrower as desired or required according to medical procedures, device/system operations and anatomical considerations. Further, the insulation may comprise Teflon, silicone, polyurethane, and/or any combination thereof or any other non-conductive material known in the art.

Outward facing bumper tabs **31** are deployable, and are used to stabilize the epicardial pacing catheter **10** by pushing against the pericardium. As shown, the outward facing bumper tabs **31** are in the non-deployed state as to allow the epicardial pacing catheter **10** to move within the pericardium. Although not shown, the epicardial pacing catheter may further comprise inward facing friction tabs **32** or other stabilization means.

The epicardial pacing catheter **10** further comprises a distal tip **51** in communication with the epicardial pacing catheter **10**. The distal tip **51** extends from the body of the catheter **10** and may further insulate the electrodes **43** from proximate anatomical structures and/or be used to push through harder anatomical structures and adhesions as desired or required.

Figure 5(B) schematically illustrates an exemplary embodiment wherein the epicardial pacing catheter **10** may be used to pace the left ventricle (LV) and left atrium (LA) of a patient's heart. Additional electrodes **43** near the distal point of curvature **41** are shown. These electrodes **43** may be in communication with the outside wall of the left atrium in order to pace said structure. Additional outward facing bumper tabs **31** are present to press against the pericardium in more distal locations. Inward facing friction tabs **32** are now shown. The inward facing friction tabs **32** may be deployed to catch, drag, stick to, or pull on adjacent anatomical structures to keep the epicardial pacing catheter **10** from moving. **Figure 5(B)** shows an example embodiment wherein both the inward facing friction tabs **32** and outward facing bumper tabs **33** are in the non-deployed state to allow movement of the catheter **10**.

Figure 5(C) schematically illustrates an exemplary embodiment wherein the epicardial pacing catheter **10** may be used to pace the left ventricle (LV), left atrium (LA), and right atrium (RA). Additional electrodes **43** are located near the distal point of curvature **41**. These electrodes **43** may be in communication with the outside wall of the right atrium in order to pace said structure. Further, additional outward facing bumper tabs **31** are present to press against the pericardium in more distal locations.

Figure 5(D) shows an example embodiment wherein the epicardial pacing catheter **10** may be used to pace multiple points on the left ventricle (LV), left atrium (LA), right atrium (RA), and right ventricle (RV). Additional electrodes **43** are shown in a more distal location in order to transmit electrical energy to the right ventricle. Further, additional inward facing bumper tabs **32** are present to catch, drag, stick to, or pull on adjacent anatomical structures to keep the epicardial pacing catheter **10** from moving.

It should be appreciated that in **Figures 5(A)-5(D)** both the number of inward facing friction tabs **32** and outward facing bumper tabs **31** may vary as desired or required to stabilize the epicardial pacing catheter **10**. Moreover, inward facing friction tabs **32** may be located proximal or distal to any outward facing bumper tab **31**. Further, outward facing bumper tabs **31** may be located proximal or distal to any inward facing friction tab **32**. Further, outward facing bumper tabs **31** and inward facing friction tabs **32** may be positioned at the same location on the epicardial pacing catheter **10** as desired or required.

It should be appreciated that in **Figures 5(A)-5(D)** any number of electrodes **43** may be present as desired or required to pace a number of locations on the heart of a patient. Moreover, each electrode **43** could be turned on separately in a unipolar or bipolar fashion, allowing for pacing of different chambers and different parts of the same chamber at different times. This has an important advantage: if a region of tissue ever dies in heart attack, pacing can be accomplished from a different location.

It should be appreciated that the inward facing friction tabs and outward facing bumper tabs may be alternated with one another, be staggered with one another, or grouped in numbers among each other as desired or required according to medical procedures, device/system operations and anatomical considerations.

Figures 6(A)-6(F) schematically illustrate cross sectional views of an exemplary embodiment of the epicardial pacing catheter **10** of the epicardial pacing system from the most distal end to a more proximal point.

Figure 6(A) schematically illustrates a cross sectional view of an exemplary embodiment of the most distal portion of the epicardial pacing catheter **10** of the epicardial pacing system. The epicardial pacing catheter **10** further comprises a fluid lumen **61**. The fluid lumen occupies internal cross-sectional area of the epicardial pacing catheter **10**. The fluid lumen **61** may extend from an aperture (not shown) in the proximal end of the catheter **10** to a distal fluid aperture **55.** Both the distal fluid aperture **55** and a proximal fluid aperture (not shown) are adapted for the emitting and extracting of a fluid, drug, or agent. The fluid, drug, or agent may be used, but is not necessarily used, to cool the electrodes **43**, regulate heart activity, or distend proximal anatomical structures. The proximal fluid aperture (not shown) is connected to an external fluid, drug, or agent source (not shown). The emitting and extracting of a fluid, drug, or agent may be controlled by an external control handle **150** (as shown, for example, in **Figure 15**) in communication with the proximal end and fluid, drug, or agent source. It should be appreciated that the fluid, drug, or agent to flow through the epicardial pacing catheter **10** may be at least one of the following: agent, substance, material, saline solutions, thrombolytic agents, clot lysis agents, chemotherapies, cell slurries, gene therapy vectors, growth factors, contrast agents, angiogenesis factors, radionuclide slurries, anti-infection agents, anti-tumor compounds, receptor-bound agents and/or other types of drugs, therapeutic agent and/or diagnostic agent or any combination thereof.

Figure 6(B) schematically illustrates a more proximal cross section of an example embodiment of the epicardial pacing catheter **10** of the epicardial pacing system located proximal to the distal point of curvature **41**. Both the first distal steering pull-wire **68** and second distal steering pull-wire **69** occupy internal cross-sectional area of the epicardial pacing catheter **10** and extend longitudinally to the most proximal portion of said catheter **10**. The first distal steering pull-wire **68** and second distal steering pull-wire **69** may be controllably connected to a control means (as shown, for example, in **Figure 15)** in communication with the proximal portion of the epicardial pacing catheter **10.**

The epicardial pacing catheter **10** may further comprise a stabilization means. The stabilization means may be deployable and may comprise an inward facing friction tab **32,** an outward facing bumper tab **31**, a non-deployable protrusion, a screw, a hook, or other means known in the art.

In an example embodiment, a tab deployment rod **64** extends longitudinally from the most proximal portion of the epicardial pacing lead **10** to the most distal inward facing friction tab **32** or outward facing bumper tab **31**. The tab deployment rod **64** may be a longitudinal structure, such as, but not limited to, a push-rod, pull-rod, wire, string, or rope. The tab deployment rod **64** made be made of a non-conductive material having high tensile strength as is known in the art. The tab deployment rod **64** may further be controllably connected to a control means (as shown, for example, in **Figure 15**) in communication with the epicardial pacing catheter **10**, said control means used to control the deployment of the stabilization means. Further, the tab deployment rod **64** is in communication with a number of tab deployment arms **65,** wherein each tab deployment arm **65** can be actuated to deploy the inward facing friction tab **32** or outward facing bumper tab **31**.

Figure 6(C) schematically illustrates a more proximal cross section of an exemplary embodiment of the epicardial pacing catheter **10** of the epicardial pacing system. The anode wire **62** extends longitudinally from the most proximal portion of the epicardial pacing catheter **10** to the most distal anode **63**. The anode wire **62** may be in communication with one or more anodes **63** located throughout the epicardial pacing catheter **10.** Further, the anode wire **62** is adapted for transmitting and receiving electrical energy. The anode wire **62** may be controllably connected to a control means (as shown, for example, in **Figure 15**) in communication with the proximal portion of the epicardial pacing catheter **10.**

An outward facing bumper tab **31** is shown in communication with the epicardial pacing catheter **10**. The outward facing bumper tab **31** may be deployed by a tab deployment arm **65** in communication with the tab deployment rod **64**.

Figure 6(D) schematically illustrates a more proximal cross section of an exemplary embodiment of the epicardial pacing catheter **10** of the epicardial pacing system located proximal to the proximal point of curvature **42**. The epicardial pacing catheter **10** further comprises a second steering means. The second steering means comprises a first proximal steering pull-wire **70** and a second proximal steering pull-wire **71**. Both the first proximal steering pull-wire **70** and second proximal steering pull-wire **71** occupy internal cross-sectional area of the epicardial pacing catheter **10** and extend longitudinally to the most proximal portion of said catheter **10**. The first proximal steering pull-wire **70** and second proximal steering pull-wire **71** may be controllably connected to a control means (as shown, for example, in **Figure 15)** in communication the proximal portion of the epicardial pacing catheter **10.**

Figure 6(E) schematically illustrates a more proximal cross section of an example embodiment of the epicardial pacing catheter **10** of the epicardial pacing system. A cathode wire **66** extends longitudinally from the most proximal portion of the epicardial pacing catheter **10** to the most distal cathode **67**. The cathode wire **66** may be in communication with one or more cathodes **67** located throughout the epicardial pacing catheter **10.** Further, the cathode wire **66** is adapted for transmitting and receiving electrical energy. The cathode wire **66** may be controllably connected to a control means (as shown, for example, in **Figure 15)** in communication with the proximal portion of the epicardial pacing catheter **10.**

Figure 6(F) schematically illustrates a more proximal cross section of an example embodiment of the epicardial pacing catheter **10** of the epicardial pacing system**.** An outward facing bumper tab **31** is shown in communication with the epicardial pacing catheter **10**. The outward facing bumper tab **31** may be deployed by a tab deployment arm **65** in communication with a tab deployment rod **64**. It should be appreciated that the number of port holes, lumens, wires or rods may vary as may be desired or required according to medical procedures, device/system operations and anatomical considerations.

Figures 7(A) and 7(B) schematically illustrate a cross sectional view of an exemplary embodiment of the proximal end **73** of the epicardial pacing catheter **10** of the epicardial pacing system and the most distal end **74** of the control means **150** respectively. In **Figure 7(A)**, twelve electrode wires, including six anode wires **62** and six cathode wires **66**, occupy internal cross-sectional area of the epicardial pacing catheter **10**. Each anode wire **62** and cathode wire **66** extends longitudinally through the epicardial pacing catheter **10** towards the distal portion. The cathode wire **66** may be in communication with one or more cathodes **67** located throughout the epicardial pacing catheter **10.** The anode wire **62** may be in communication with one or more anodes **63** located throughout the epicardial pacing catheter **10**.

It should be appreciated that any number of electrodes **43**, otherwise known as anodes **63** and cathodes **67**, may be present as desired or required to pace a number of locations on the heart of a patient. A single anode wire **62** may be used to provide electrical energy to a multitude of anodes **63**, or each anode wire **62** can provide electrical energy to a single anode **63**. A single cathode wire **66** may be used to provide electrical energy to a multitude of cathodes **67**, or each cathode wire **66** can provide electrical energy to a single cathode **67**. Moreover, electrical energy can be transmitted to each electrode **43** separately in a unipolar or bipolar fashion, allowing for pacing of different chambers and different parts of the same chamber at different times.

Further, a first proximal steering pull-wire **70**, first distal steering pull-wire **68**, second proximal steering pull-wire **71**, and second distal steering pull-wire **69** occupy internal cross-sectional area of the epicardial pacing catheter **10.** Each first proximal steering pull-wire **70**, first distal steering pull-wire **68**, second proximal steering pull-wire **71,** and second distal steering pull-wire **69** extends longitudinally through the epicardial pacing catheter **10** towards the distal portion. Each first proximal steering pull-wire **70**, first distal steering pull-wire **68**, second proximal steering pull-wire **71,** and second distal steering pull-wire **69** may comprise guidewires, tensioning lines, pull strings, digitating distal tips, magnetic guidance means, wires, rods, chains, bands, chords, ropes, string tubes, filaments, threads, fibers, strands, other extended elements, or any other method known in the art.

Further, a first tab deployment rod **64** and second tab deployment rod **72** occupy internal cross-sectional area of the epicardial pacing catheter **10**. Each first tab deployment rod **64** and second tab deployment rod **72** extends longitudinally from the most proximal portion **73** of the epicardial pacing lead **10** to the most distal inward facing friction tab **32** or outward facing bumper tab **31**. The first tab deployment rod **64** and second tab deployment rod **72** may comprise a longitudinal structure, such as, but not limited to, a push-rod, pull-rod, wire, string, magnetic guidance means, chains, bands, chords, or rope. The first tab deployment rod **64** and second tab deployment rod **72** may comprise a non-conductive material having high tensile strength as is known in the art. The first tab deployment rod **64** and second tab deployment rod **72** may further be controllably connected to the distal end **74** of a control means **150** in communication with the proximal end **73** of the epicardial pacing catheter **10**, said control means used to control the deployment of the tabs.

It should be noted that, while a first tab deployment rod **64** and second tab deployment rod **72** are shown, any number of tab deployment rods may be present as desired or required, up to an including the sum of inward facing friction tabs **32** and outward facing bumper tabs **31** (See **Figures 6(A)-(E)**).

Although not shown, in an example embodiment, a biocompatible cover may be in communication with the most proximal end **73** of the epicardial pacing catheter **10**. The biocompatible cover may prevent fibrosis from occurring around the exposed structures of the epicardial pacing catheter **10.**

Although not shown, in an example embodiment, the proximal end **73** of the epicardial pacing catheter **10** may be located just under the skin of a patient. The proximal end **73** can be reached by a non-surgical, minimally-invasive incision of the skin, carried out by a clinician or cardiologist.

Although not shown, in an example embodiment, all structures beginning at the proximal end **73** may protrude from said proximal end **73** of the epicardial pacing catheter **10**. In this way, the proximal end **73** could act as a male connector in a male-female connection. It should be appreciated that the corresponding male-female connection may be reversed as well.

Figure 7(B) shows a cross sectional view of an example embodiment of the most distal portion **74** of a control handle **150**. In this particular embodiment, the control handle **150** can be controllably connected to the most proximal portion **73** of the epicardial pacing catheter **10**. Wire grippers **75** around each of the internal structures facilitate a secure connection between structures integral the control handle **150** and structures integral the epicardial pacing catheter **10**.

Although not shown, in an example embodiment, all structures within the control handle **150** may end before the distal end **74.** In this way, the distal end **74** can act as a female connector in a male-female connection.

It should be appreciated that the number of lumens, wires, rods or elements discussed with regards to **Figure 7** may vary as may be desired or required according to medical procedures, device/system operations and anatomical considerations.

Figures 8(A)-(C) schematically illustrate cross-sectional views of an example embodiment wherein the epicardial pacing catheter **10** further comprises a stabilization means for stabilizing the epicardial pacing catheter **10**. The stabilization means may comprise at least one deployable member. The stabilization means allows the rotational orientation of the distal portion of the epicardial pacing catheter **10** to remain fixed in place relative to the surface of the heart. If the distal portion of the epicardial pacing catheter **10** were allowed to rotate so that the electrodes **43** faced away from the heart, pacing could not be achieved and adjacent anatomical structures would receive harmful electronic energy.

Figures 8(A)-(C) illustrate an exemplary embodiment wherein the stabilization means is an inward facing friction tab **32**. The inward facing friction tab **32** comprises a catheter-side surface **82** and an anatomical-side surface **83**. The anatomical-side surface **83** comprises a lubricious surface that may be navigated through anatomical structures without sticking or catching. The catheter-side surface **82** comprises a rough surface having a larger coefficient of friction than the anatomical-side surface. The catheter-side surface may further comprise a textured surface to increase friction. Both the catheter-side surface **82** and anatomical-side surface **83** comprise a non-conductive material, such as, but not limited to polyurethane, Teflon, silicone, a radio-opaque material, or similarly lubricious material, or other materials known in the art.

Figure 8(A) illustrates an exemplary embodiment wherein the stabilization means further comprises a stabilizer actuator, wherein said stabilizer actuator deploys the inward facing friction tab **32**. Though the stabilizer actuator is illustrated as a tab deployment rod **64** in communication with a tab joint **84**, tab hinge **81**, and tab deployment arm **65**, the stabilizer actuator may comprise any longitudinal member in communication with at least one of the following: gear, hinge, joint, rack and pinion, pulley, linear actuator, or linear-rotational actuator, or any combination thereof. Further, the longitudinal member may be, for example, a push-rod, pull-wire, wire, string, rope, pole, thread, filament, cord, strand or other means known in the art. The stabilizer actuator may further comprise a micro electrical mechanical system (MEMS).

In an embodiment, a tab deployment rod **64** extends longitudinally from the most proximal portion of the epicardial pacing lead **10** to the most distal inward facing friction tab **32**. The tab deployment rod **64** may be a longitudinal structure, such as, but not limited to, a push-rod, pull-rod, wire, string, pole, thread, filament, cord, strand or rope. The tab deployment rod **64** made be made of a non-conductive material having high tensile strength as is known in the art. The tab deployment rod may further be controllably connected to a control means or control handle (as shown, for example, in **Figure 15)** in communication with the epicardial pacing catheter **10** of the epicardial pacing system **5**, and the control means may be used to control the deployment of the tabs.

The tab deployment rod **64** is in communication with a tab joint **84**, the tab joint **84** in connection with a tab deployment arm **65** having its endpoint within the inward facing friction tab **32**. The tab deployment arm is in further communication with a tab hinge **81.**

When the inward facing friction tab **32** is in the non-deployed state, the epicardial pacing catheter **10** may be moved, navigated, or slid within the middle mediastinum. In this way, the epicardial pacing catheter **10** can be inserted, placed, navigated or removed from the pericardial sack.

Figure 8(B) illustrates an embodiment wherein the stabilization means is an inward facing friction tab **32** in the partially-deployed state. When the tab deployment rod **64** is pushed toward the distal end of the epicardial pacing catheter **10**, the tab deployment arm **65** is pulled or tensioned. This causes the inward facing friction tab **32** to separate from the catheter body, exposing the rough catheter-side **82** to proximate anatomical structures.

Figure 8(C) illustrates an embodiment wherein the stabilization means is an inward facing friction tab **32** in the fully-deployed state.

Although not shown, the outward facing bumper tabs **31** may be deployed using the same means and methods as described above.

Although not shown, the stabilization means may comprise one or more protrusions for engaging proximal anatomical structures such as the pericardium and/or the epicardium. The protrusions may be non-deployable. Further, the protrusions may comprise a non-conductive material, such as, but not limited to, silicone, polyurethane, Teflon, a radio-opaque material, or other materials known in the art.

It should be appreciated that the hinge devices and joint devices may be a number of elements such as, but not limited thereto, a fulcrum, swivel, gear, elbow, pivot, thrust or the like.

It should be appreciated that the tab devices may be a number of elements such as, but not limited thereto, finger, stud, post, tongue, spring, projection, pin, pedestal, extension, offset, knob, protuberance or the like.

Figure 9 schematically illustrates an example embodiment of the epicardial pacing catheter **10** of the epicardial pacing system in relation to the heart **21** and further comprising at least one deployable member. The epicardial pacing catheter **10** has been steered around its distal point of curvature **41**, and is positioned in the pericardial space, cavity or sack **24**, or the area between the pericardium **22** and epicardium **23**. In an embodiment, the deployable member comprises at least one electrode **43**, and each electrode **43** is facing the heart **21**. The electrodes **43** may be deployed from the epicardial pacing catheter **10** and are fixed to the epicardium **23** when in the fully-deployed state. The epicardial pacing catheter **10** may further comprises an insulating hood **101** in communication with the epicardial pacing catheter **10**.

Figure 10(A) schematically illustrates a top view of an example embodiment of the epicardial pacing catheter **10** of the epicardial pacing system. The epicardial pacing catheter further comprises a insulating hood **101** extending from beyond the distal point of curvature **41** to a distal tip **51**. The hood may serve as a cushioning and/or alignment means for the distal tip **51** relative to adjacent anatomical structures. It should be appreciated that some portion of the distal tip shall have insulation to protect from adjacent anatomical structures. The shape of the distal tip and hood may vary according to medical procedures, device/system operations and anatomical considerations.

Figure 10(B) schematically illustrates a bottom view of an exemplary embodiment of the epicardial pacing catheter **10** of the epicardial pacing system. An anode **63** and cathode **67** are shown in communication with the epicardial pacing catheter **10**. In an embodiment, the contact zones containing the anode **63** and cathode **67** electrodes are about 2 mm in length and about 1 mm in width, and are located centrally within the underside surface of the insulating hood **101**. It should be appreciated that the width of the electrodes may be longer or shorter as may be desired or required according to medical procedures, device/system operations and anatomical considerations. The insulating hood extends from a distal location beyond the distal point of curvature **41** to a distal tip **51**.

Figure 10(C) schematically illustrates an axial view of an exemplary embodiment of the epicardial pacing catheter **10** of the epicardial pacing system looking at the distal tip **51** of the insulating hood **101**. A single electrode **43** can be seen on the underside of the epicardial pacing catheter **10**.

Figure 10(D) schematically illustrates a side view of an exemplary embodiment of the epicardial pacing catheter **10** comprising an insulating hood **101**, distal tip **51**, and two electrodes **43**. The insulating hood **101** extends over the side of the epicardial pacing catheter **10**.

It should be appreciated that in **Figures 10(A)-(D)** any number of electrodes **43** may be present as desired or required to pace any number of locations on the heart of a patient. Moreover, each electrode **43** could be powered separately in a unipolar or bipolar fashion, allowing for pacing of different parts of the same chamber at different times.

Figure 11(A)-11(E) schematically illustrate cross sectional views of an exemplary embodiment of the epicardial pacing catheter **10** of the epicardial pacing system from a point located proximal to the most distal anode **62** or cathode **67** and distal to the distal point of curvature **41** to a point located at the most proximal point **73** of the epicardial pacing catheter **10**. **Figure 11(F)** schematically illustrates a cross sectional view of an exemplary embodiment of the external control handle **150** at the most distal point **74**.

Figure 11(A) schematically illustrates a cross section of an example embodiment of the epicardial pacing catheter **10** located more distal than the distal point of curvature **41** and proximal to the most distal anode **62** or cathode **67**. An anode wire **62,** cathode wire **66**, electrode pull-wire **112**, and second-electrode pull-wire **113** occupy internal cross-sectional area of the epicardial pacing catheter **10** and extend longitudinally to the most proximal portion **73** of said catheter **10**. The anode wire **62,** cathode wire **66**, electrode pull-wire **112**, and second-electrode pull-wire **113** may comprise longitudinal structures, such as, but not limited to, push-rods, pull-rods, wires, strings, or ropes. Further, the anode wire **62,** cathode wire **66**, electrode pull-wire **112**, and second-electrode pull-wire **113** may be controllably connected to a control handle **150** in electrical communication with the most proximal point **73** of the epicardial pacing catheter **10**.

The anode wire **62** and electrode pull-wire **112** extend longitudinally from the most proximal portion **73** of the epicardial pacing catheter **10** to the most distal anode **63**. The cathode wire **66** and second electrode pull-wire **113** extend longitudinally from the most proximal portion **73** of the epicardial pacing catheter **10** to the most distal cathode **67.**

Figure 11(B) schematically illustrates a more proximal cross section of an example embodiment of the epicardial pacing catheter **10** located at the distal point of curvature **41**. The epicardial pacing catheter **10** further comprises a first distal steering pull-wire **68** and a second distal steering pull-wire **69** fixed to distal steering anchors **110** in communication with the epicardial pacing catheter **10**. The distal steering anchors **110** comprise a material with requisite strength to hold the first distal steering pull-wire **68** and second distal steering pull-wire **69** in place. The first distal steering pull-wire **68** and second distal steering pull-wire **69** occupy internal cross-sectional area of the epicardial pacing catheter **10** and extend longitudinally to the most proximal point **73** of said catheter **10**. The first proximal steering pull-wire **68** and second proximal steering pull-wire **69** may be controllably connected to a control handle **150** in communication with the most proximal point **73** of the epicardial pacing catheter **10.**

Figure 11(C) schematically illustrates a more proximal cross section of an example embodiment of the epicardial pacing catheter **10** located between the distal point of curvature **41** and proximal point of curvature **42**.

Figure 11(D) schematically illustrates a more proximal cross section of an example embodiment of the epicardial pacing catheter **10** located at the proximal point of curvature **42**. The epicardial pacing catheter **10** further comprises a proximal steering pull-wire **70** fixed to a proximal steering anchor **111** in communication with the epicardial pacing catheter **10**. The proximal steering anchor **111** comprises a material with requisite strength to hold the proximal steering pull-wire **70**. The proximal steering pull-wire **70** occupies internal cross-sectional area of the epicardial pacing catheter **10** and extends longitudinally to the most proximal point **73** of said catheter **10**. The proximal steering pull-wire **70** can be controllably connected to a control handle **150** or control means in communication with the most proximal point **73** of the epicardial pacing catheter **10.**

Figure 11(E) schematically illustrates a more proximal cross section of an example embodiment of the epicardial pacing catheter **10** located at the most proximal point **73**.

It should be noted that, while a single anode wire **62**, electrode pull-wire **112**, cathode wire **66**, and second electrode pull-wire **113** are shown, any number of anode wires **62**, electrode pull-wires **112**, cathode wires **66**, and second electrode pull-wires **113** may be present as desired or required, up to and including, for example, the total number of electrodes **43** (or the sum of the anodes **63** and cathodes **67**).

Although not shown, in an example embodiment, a biocompatible cover may be in communication with the most proximal end **73** of the epicardial pacing catheter **10**. The biocompatible cover can prevent fibrosis from occurring around the exposed wires of the epicardial pacing catheter **10.**

Although not shown, in an example embodiment, the proximal end **73** of the epicardial pacing catheter **10** is located just under the skin of a patient (or location(s) as desired or required). The proximal end **73** can be reached by a non-surgical, minimally-invasive incision of the skin, carried out by a clinician or cardiologist.

Although not shown, in an example embodiment, all structures beginning at the proximal end **73** may protrude from said proximal end **73** of the epicardial pacing catheter **10**. In this way, the proximal end **73** could act as a male connector in a male-female connection. The male-female arrangement may be reversed if desired or required.

Figure 11(F) schematically illustrates a cross sectional view of an example embodiment of the most distal portion **74** of a control handle **150**. In this particular embodiment, the control handle **150** can be controllably connected to the most proximal portion **73** of the epicardial pacing catheter **10**. Wire grippers **75** (or other retention means or devices) around each of the internal structures facilitate a secure connection between structures integral the control handle **150** and structures integral the epicardial pacing catheter **10**.

Although not shown, in an example embodiment, all structures within the control handle or control means may end before the distal end **74.** In this way, the distal end **74** can act as a female connector in a male-female connection (or female-male connection).

Figure 12(A) schematically illustrates a cross section of an exemplary embodiment of the epicardial pacing catheter **10** of the epicardial pacing system comprising a deployable stabilization means in an un-deployed state. The deployable stabilization means comprises an anode **63** and cathode **67** in communication with a hook **124.** The hook **124**, anode **63**, and cathode **67** comprise conductive materials, such as, but not limited to, copper, platinum, gold, silver or iridium, and/or alloys thereof.

The stabilization means further comprises a stabilizer actuator, wherein said stabilizer actuator deploys the anode **63** and cathode **67** in communication with the hooks **124**. Though the stabilizer actuator is illustrated as an electrode pull-wire **112** in communication with a joint **121**, and hinge **122**, the stabilizer actuator may comprise any longitudinal member in communication with at least one of the following: gear, hinge, joint, rack and pinion, pulley, linear actuator, or linear-rotational actuator, or any combination thereof. Further, the longitudinal member may be, for example, a push-rod, pull-wire, wire, string, rope, pole, thread, filament, cord, strand or other means known in the art. The stabilizer actuator may further comprise a micro electrical mechanical system (MEMS).

It should be appreciated that the hook devices may be a number of elements such as, but not limited thereto, pin, claw, latch, finger, stud, spring, post, tongue, projection, pin, pedestal, extension, offset, knob, protuberance or the like.

In an embodiment, an electrode pull-wire **112** extends longitudinally from the most proximal portion of the epicardial pacing lead **10** to the most distal electrode **43**, which may comprise an anode **63** or cathode **67**. The electrode pull-wire **112** is in communication with a joint **121**, the joint **121** in further communication with a hinge **122.**

In an embodiment, the electrode pull-wire **112** may comprise a conductive material having high tensile strength as is known in the art. The electrode-pull wire **112** may further be controllably connected to a control means (for example, as shown in **Figure 15)** in communication with the epicardial pacing catheter **10** and epicardial pacing system. The control means may be used to control the deployment of the anode **63** and cathode **67** in communication with hooks **124**, and any of the devices, systems, subsystems, elements, and devices discussed throughout this disclosure.

In an embodiment, the epicardial pacing catheter **10** further comprises an insulating distal tip **51** in communication with the epicardial pacing catheter. The epicardial pacing catheter **10** further comprises a number of bumpers **120** in communication with the bottom of the epicardial pacing catheter **10**. In an approach, the bumpers enable the epicardial pacing catheter **10** to sit on the surface of the heart in a non-deployed state without allowing the anode **63** or cathode **67** to be in communication with the epicardium.

When the deployable anode **63** and cathode **67** are in the non-deployed state, the epicardial pacing catheter **10** may be moved or navigated within the middle mediastinum. In this way, the epicardial pacing catheter **10** can be inserted, placed, navigated or removed from the pericardial sack.

Figure 12(B) schematically illustrates a cross section of an exemplary embodiment of the epicardial pacing catheter **10** comprising a deployable anode **63** and cathode **67** in a fully-deployed state. When the electrode pull-wire **112** is pushed toward the distal end of the epicardial pacing catheter **10**, the anode **63** and cathode **67** are splayed outward to a 90 degree angle, or an angel(s) as desired or required. This causes the anode **63** and cathode **67** to separate from the catheter body, allowing the hooks **124** to engage proximate anatomical structures, such as the epicardial wall. When the deployable anode **63** and cathode **67** are in the fully-deployed state, the rotational orientation of the distal portion of the epicardial pacing catheter **10** remains fixed in place relative to the surface of the heart. If the distal portion of the epicardial pacing catheter **10** were allowed to rotate so that the electrodes **43** faced away from the heart, pacing could not be achieved and adjacent anatomical structures would receive harmful electronic energy.

It should be appreciated that in **Figures 12(A)** and **(B)** any number of deployable electrodes **43** may be present as desired or required to pace any number of locations on the heart of a patient.

It should be appreciated that when the electrode pull-wire **112** is pulled toward the proximal end of the epicardial pacing catheter **10**, the anode **63** and cathode **67** are drawn back into place within the catheter **10**.

Figure 13(A) schematically illustrates a cross section of an exemplary embodiment of the epicardial pacing catheter **10** of the epicardial pacing system comprising a deployable stabilization means in an un-deployed state. The deployable stabilization means comprises a number of screws **130** in communication with an anode **63** and cathode **67.** The screws **130**, anode **63**, and cathode **67** comprise conductive materials, such as, but not limited to, copper, platinum, gold, silver and/or iridium, and/or alloys thereof.

The stabilization means further comprises a stabilizer actuator, wherein said stabilizer actuator deploys the screws **130** in communication with the anode **63** and cathode **67**. Though the stabilizer actuator is illustrated as an electrode pull-wire **112** in communication with a gear **131**, the stabilizer actuator may comprise any longitudinal member in communication with at least one of the following: gear, hinge, joint, rack and pinion, pulley, linear actuator, or linear-rotational actuator, or any combination thereof. Further, the longitudinal member may be, for example, a push-rod, pull-wire, wire, string, rope, pole, thread, filament, cord, strand, or other means known in the art. The stabilizer actuator may further comprise a micro electrical mechanical system (MEMS).

It should be appreciated that the screw devices may comprise a number of elements such as, but not limited thereto, any translatable protrusion or extension for instance. Some non-limiting examples may include: toggle, press, slide, spring, stud, post, tongue, projection, pedestal, protuberance, contact, or the like.

In an embodiment, an electrode pull-wire **112** extends longitudinally from the most proximal portion of the epicardial pacing lead **10** to the most distal electrode **43**, which may be an anode **63** or cathode **67**. The electrode pull-wire **112** may be a longitudinal structure, such as, but not limited to, a push-rod, pull-rod, wire, string, or rope. The electrode pull-wire **112** may be made of a conductive material having high tensile strength as is known in the art. The electrode-pull wire **112** may further be controllably connected to a control means (as shown, for example, in **Figure 15)** in communication with the epicardial pacing catheter **10** and epicardial pacing system. The control means may be used to control the deployment of the screws **130** in communication with the anode **63** and cathode **67**.

The epicardial pacing catheter **10** further comprises an insulating distal tip **51** in communication with the epicardial pacing catheter.

When the screws **130** are in the non-deployed state, the epicardial pacing catheter **10** may be moved or navigated within the middle mediastinum. In this way, the epicardial pacing catheter **10** can be inserted, placed, navigated, translated, rotated or removed from the pericardial sack.

Figure 13(B) schematically illustrates a cross section of an exemplary embodiment of the epicardial pacing catheter **10** comprising fully-deployed screws **130** in communication with the anode **63** and cathode **67**. When the electrode pull-wire **112** is pushed toward the distal end of the epicardial pacing catheter **10**, the gears **131** are activated and the screws **130** are rotationally-actuated. This causes the screws **130** to engage proximate anatomical structures, such as the epicardial wall. When the screws **130** are in the fully-deployed state, the rotational orientation of the distal portion of the epicardial pacing catheter **10** remains fixed in place relative to the surface of the heart. The electrical energy is transmitted from the anode **63** and cathode **67** through the screws **130** and into the heart.

It should be appreciated that in **Figures 13(A)** and **(B)** any number of deployable screws **130** may be present as desired or required to pace any number of locations on the heart of a patient.

Figure 14(A) schematically illustrates a cross section of an exemplary embodiment of the epicardial pacing catheter **10** epicardial pacing system comprising a deployable stabilization means in an un-deployed state. The deployable stabilization means comprises an anode **63** and cathode **67** in communication with a hook **124.** The hooks **124**, anode **63**, and cathode **67** comprise conductive materials, such as, but not limited to, copper, platinum, gold, silver and/or iridium, or alloys thereof.

The deployable stabilization means further comprises a stabilizer actuator, wherein said stabilizer actuator deploys the anode **63** and cathode **67** in communication with the hooks **124**. Though the stabilizer actuator is illustrated as an electrode pull-wire **112** and second electrode pull-wire **113** in communication with a number of joints **121**, and hinges **122**, the stabilizer actuator may comprise any longitudinal member in communication with at least one of the following: gear, hinge, joint, rack and pinion, pulley, linear actuator, or linear-rotational actuator, or any combination thereof. Further, the longitudinal member may be, for example, a push-rod, pull-wire, wire, string, thread, filament, cord, strand, rope, pole, or other means known in the art. The stabilizer actuator may further comprise a micro electrical mechanical system (MEMS).

In an embodiment, an electrode pull-wire **112** and second electrode pull-wire **113** extend longitudinally from the most proximal portion of the epicardial pacing lead **10** to the most distal anode **63** and cathode **67** respectively. The electrode pull-wire and second electrode pull-wire **113** are in communication with a number of joints **121**, the joints **121** in further communication with a number of hinges **122**. The electrode pull-wire **112** and second electrode pull-wire **113** may comprise longitudinal structures, such as, but not limited to, push-rods, pull-rods, wires, thread, filament, cord, strand, strings, or ropes. The electrode pull-wire **112** and second electrode pull-wire **113** may be made of a conductive material having high tensile strength as is known in the art. The electrode-pull wire **112** and second electrode pull-wire **113** may further be controllably connected to a control means (for example, as shown in **Figure 15**) in communication with the epicardial pacing catheter **10** and epicardial pacing system. The control means may used to control the deployment of the anode **63** and cathode **67** in communication with hooks **124.**

The epicardial pacing catheter **10** further comprises an insulating distal tip **51** in communication with the epicardial pacing catheter. The epicardial pacing catheter **10** may further comprise a number of bumpers **120** in communication with the epicardial pacing catheter **10**. The bumpers **120** enable the epicardial pacing catheter **10** to sit on the surface of the heart in a non-deployed state without allowing the anode **63** or cathode **67** to communicate with the heart.

When the deployable anode **63** and cathode **67** are in the non-deployed state, the epicardial pacing catheter **10** may be moved or navigated within the middle mediastinum. In this way, the epicardial pacing catheter **10** can be inserted, placed, navigated, translated, rotated or removed from the pericardial sack.

Figure 14(B) schematically illustrates a cross section of an exemplary embodiment of the epicardial pacing catheter **10** comprising a deployable anode **63** and cathode **67** in a fully-deployed state. When the electrode pull-wire **112** and second electrode pull-wire **113** are pulled toward the proximal end of the epicardial pacing catheter **10**, the anode **63** and cathode **67** are splayed outward to a 90 degree angle. This causes the anode **63** and cathode **67** to separate from the catheter body, allowing the hooks **124** to engage proximate anatomical structures, such as the epicardial wall. When the deployable anode **63** and cathode **67** are in the fully-deployed state, the rotational orientation of the distal portion of the epicardial pacing catheter **10** remains fixed in place relative to the surface of the heart. The electrical energy is transmitted from the anode **63** and cathode **67** through the hooks **124** and into the heart.

It should be appreciated that in **Figures 14(A)** and **(B)** any number of deployable anodes **63** and cathodes **67** may be present as desired or required to pace any number of locations on the heart of a patient.

It should be appreciated that when the electrode pull-wire **112** and second electrode pull-wire are pushed toward the distal end of the epicardial pacing catheter **10**, the anode **63** and cathode **67** are drawn back into place within the catheter **10**.

It should be appreciated that regarding deployment discussed throughout, varying degrees of deployment may be achieved or implemented as desired or required.

Figure 15(A) schematically illustrates an example embodiment of an external control handle **150** (that may be associated with, although not shown, the epicardial pacing catheter of the system). The epicardial pacing catheter and system further comprises a control means, wherein said control means is an external control handle **150**. The external control handle **150** may be in communication with the most proximal point **73** of the epicardial pacing catheter **10**. The external control handle **150** may have integral to it the distal steering control means **154**, the proximal control means **154**, the irrigation control means (not shown) and the control means for the stabilization means **151**. The stabilization control means **154** may be used to regulate the degree of extension of said stabilization means via a pull-wire or pushrod arrangement or some other suitable tensioning or actuating means know in the art. The external control handle **150** may further comprise a pull-rod control aperture **152**, wherein a tab deployment rod **64** and second tab deployment rod (not shown) may be inserted.

The external control handle **150** is preferably sized to be grasped, held and operated by a user. It should be appreciated that other control and operating interface members, devices, or means may be utilized for the handle. Attached to the proximal end of the control handle **150** is the handle proximal port (not shown) from which anode wires **62** and cathode wires **67** extend in order to make electrical connections to diagnostic or electrical devices (not shown). Electrical wires (for example, shown in **Figures 6, 7,** and **11)** may extend through the proximal portion to each of the electrodes **43** of the epicardial pacing catheter **10**.

Figure 15(B) schematically illustrates an example embodiment of the proximal steering control means **153** integral to the control handle **150**. The proximal steering control means **153** is controllably connected to the first proximal steering pull-wire **70** and second proximal steering pull-wire **71**.

Figure 15(C) schematically illustrates an example embodiment wherein the proximal steering control means **153** integral to the control handle **150** has been activated. As the proximal steering control means **153** is activated by a user, the first proximal steering pull-wire **70** becomes taught, and the second proximal steering pull-wire **71** loosens, creating slack **155**. Both the first proximal steering pull-wire **70** and second proximal steering pull-wire **71** extend longitudinally through the control handle **150,** into the epicardial pacing catheter **10**, and are anchored at the proximal point of curvature **42**. As the first steering pull-wire **70** becomes taught, the epicardial pacing catheter bends toward the proximal steering anchor and around the proximal point of curvature **42**.

For example, the control handle may have channels for the steering pull wires and thumb wheel knobs for tightening or loosening the pull wires.

One skilled in the art can see that many other embodiments of means and methods for using the epicardial pacing catheter **10** of the epicardial pacing system according to the technique of the technology, and other details of construction and use thereof, constitute non-inventive variations of the novel and insightful conceptual means, system and technique which underlie the present invention.

The devices, systems, compositions, computer program products, and methods of various embodiments of the invention disclosed herein may utilize aspects disclosed in the following references, applications, publications and patents and which are hereby incorporated by reference herein in their entirety:

1. U.S. Patent No. 6,973,352 B1 to Tsutsui, D., et. al., entitled "Steerable Cardiac Pacing and Sensing Catheter and Guidewire for Implanting Leads", December 6, 2005.

2. U.S. Patent No. 7,264,587 B2 to Chin, A., entitled "Endoscopic Subxiphoid Surgical Procedures", September 4, 2007.

3. U.S. Patent No. 7,226,458 to Kaplan, et al., issued May 2007.
4. U.S. Patent No. 7,226,448 to Bertolero, et. al., issued May 2007.
5. U.S. Patent No.7,142,919 to Hine, et al., issued May 2006.
6. U.S. Patent No. 7,130,699 to Huff, et al., issued October 2006.
7. U.S. Patent No. 7,120,504 to Osypka, issued October 2006.
8. U.S. Patent No. 7,101,362 to Vinne, issued September 2006.
9. U.S. Patent No. 7,090,637 to Danitz, et al., issued August 2006.
10. U.S. Patent No. 7,089,063 to Lesh, et al., issued August 2006.
11. U.S. Patent No.7,059,878 to Hendrixson, issued August 2006.
12. U.S. Patent No. 7,041,099 to Thomas, et al., issued May 2006.
13. U.S. Patent No. 7,027,876 to Casavant, et al., issued April 2006.
14. U.S. Patent No. 7,008,418 to Hall, et al., issued March 2006.
15. U.S. Patent No. 6,973,352 to Tsutsui, et al., issued December 2005.
16. U.S. Patent No. 6,936,040 to Kramm, et al., issued August 2005.
17. U.S. Patent No. 6,921,295 to Sommer, et al., issued July 2005.
18. U.S. Patent No. 6,918,908 to Bonner, et al., issued August 2005.
19. U.S. Patent No. 6,899,710 to Hooven, issued May 2005.
20. U.S. Patent No. 6,876,885 to Swoyer, et al., issued May 2005.
21. U.S. Patent No. 6,868,291 to Bonner, et al., issued March 2005.
22. U.S. Patent No. 6,837,886 to Collins, et al., issued January 2005.
23. U.S. Patent No. 6,835,193 to Epstein, et al., issued December 2004.
24. U.S. Patent No. 6,527,767 to Wang, et al., issued March 2003.
25. U.S. Patent No. 6,314,963 to Vaska, et al., issued November 2001.

26. U.S. Patent No. 6,270,476 to Santoianni, et al., issued August 2001.

27. U.S. Patent No. 6,263,241 to Rosborough, et al., issued July 2001.

28. U.S. Patent No. 6,237,605 to Vaska, et al., issued May 2001.

29. U.S. Patent No. 6,123,084 to Jandak, et al., issued September 2000.

30. U.S. Patent No. 6,036,685 to Mueller, et al., issued March 2000.

31. U.S. Patent No. 5,733,280 to Avitall, issued March 1998.

32. U.S. Patent No. 5,213,570 to Van Deripe, et al., issued May 1993.

33. U.S. Patent Application Publication No. 2007/0038052 to Swoyer, et al., issued February 2007.

34. U.S. Patent Application Publication No. 2006/0270900 to Chin, et al., issued November 2006.

35. U.S. Patent Application Publication No. 2006/0122591 to Keidar, issued June 2006.

36. U.S. Patent Application Publication No. 2006/0025762 to Mohan, et al., February 2006.

37. U.S. Patent Application Publication No. 20040267326 to Ocel, et al., issued December 2004.

38. U.S. Patent Application Publication No. 2004/0138526 to Guenst, issued July 2004.

39. U.S. Patent Application Publication No. 2004/0087831 to Michels, et al., issued May 2004.

40. U.S. Patent Application Publication No. 2003/0069572 to Wellman, et al., issued April 2003.

41. U.S. Patent Application Publication No. 2003/0065318 to Pendekanti, issued April 2003.

42. U.S. Patent Application Publication No. 2003/0028187 to Vaska, et al., issued February 2003.

43. International Patent Application Publication No. WO97/33526, issued September 1997.

44. International Patent Application Publication No. WO95/15115, issued June 1995.

45. International Patent Application Publication No. WO93/20878, issued October 1993.

46. International Patent Application Publication No. WO87/04081, issued July 1987. 47. M. Tomaske et al., "Do Daily Threshold Trend Fluctuations of Epicardial Leads Correlate with Pacing and Sensing Characteristics in Paediatric Patients," Europace, doi:10.1093/europace/eum100, (2007).

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52.E. Sosa et al., "Nonsurgical Transthoracic Epicardial Approach in Patients with Ventricular Tachycardia and Previous Cardiac Surgery," Journal of Interventional Cardiac Electrophysiology, Vol. 10, pp. 281-288, (2004).

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56. A.V. Sarabanda, et al., "Efficacy and Safety of Circumferential Pulmonary Vein Isolation Using a Novel Cryothermal Balloon Ablation System" Journal of the American College of Cardiology, Vol. 46, pp. 1902-1912 (2005).

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It should be appreciated that various sizes, dimensions, contours, rigidity, shapes, flexibility and materials of any of the embodiments discussed throughout may be varied and utilized as desired or required.

It should be appreciated that the catheter device and epicardial system and their related components discussed herein may can take on all shapes along the entire continual geometric spectrum of manipulation of x, y and z planes to provide and meet the anatomical and structural demands and requirements.

EXAMPLES AND EXPERIMENTAL RESULTS

Practice of the invention will be still more fully understood from the following examples and experimental results, which are presented herein for illustration only and should not be construed as limiting the invention in any way.

Example No. 1

Step 1—Access and place a guidewire in the pericardial space using our EpiNeedle Access system.

Step 2 – Use a sheath, preferably our EpiSheath, or a general long 8 Fr sheath to place over the guidewire and maintain access.

Step 3—Place the lead of the subject invention with handle though the sheath.

Step 4—Guide the lead in the epicardial space using the two steering points and the sheath under fluoroscopic guidance (although this lead may be guided via one or more other imaging methods to include ICE, CT, MRI, Visual Endoscopy, or Echo Methods). The lead should be advanced along the border of the heart apically to base along the LV. Once it crosses the AV groove to the LA it should be deflected downward and advanced through the transverse sinus. Once across the transverse sinus it will need to be deflected up to the SVC and then down to the RA and finally the RV.

Step 5—Slide the sheath back to the inferior portion of the RV.

Step 6—At this point the handle should be hooked up to an EP analyzer. The lead should be clocked for a more anterior position or counter-clocked for a more posterior position until the largest LV signals are found. If multi-chamber pacing is sought one should pick a point when at least two poles of the LV, and of each other chamber, has an amplitude of at least 1mV in the atrium and 5 mV in the ventricle. Note there is no need for all points to have high amplitudes. Next, the tabs should be deployed. This should push the lead more tightly against the heart and actually increase the voltage. Then, pacing should be attempted in the LV. If threshold is less than 2.5 V it is a good site on any pole. The same should then be done with the other points. If no point is good the tab should be let down and then the lead repositioned.

Step 7—Once a good position is found the handle should be removed and the sheath withdrawn completely outside of the patient.

Step 8—The lead should be plugged into either a custom ICD/BiV or attached to our wire interface for a standard ICD. The poles that are not used to pace should be plugged in this case. In the custom ICD, all poles would be active and the user (or an automated system) may decide when to pace.

Step 9—The lead extender to the ICD would then either be tunneled back to the ICD in the shoulder (or elsewhere), placed by the nearby abdominal ICD. Or a battery-powered wireless box will be used to communicate with the main ICD in the shoulder. At this point the patient should be recovered. No stitch is needed for the lead access.

In summary, while the present invention has been described with respect to specific embodiments, many modifications, variations, alterations, substitutions, and equivalents will be apparent to those skilled in the art. The present invention is not to be limited in scope by the specific embodiment described herein. Indeed, various modifications of the present invention, in addition to those described herein, will be apparent to those of skill in the art from the foregoing description and accompanying drawings. Accordingly, the invention is to be considered as limited only by the spirit and scope of the following claims, including all modifications and equivalents.

Still other embodiments will become readily apparent to those skilled in this art from reading the above-recited detailed description and drawings of certain exemplary embodiments. It should be understood that numerous variations, modifications, and additional embodiments are possible, and accordingly, all such variations, modifications, and embodiments are to be regarded as being within the spirit and scope of this application. For example, regardless of the content of any portion (e.g., title, field, background, summary, abstract, drawing figure, etc.) of this application, unless clearly specified to the contrary, there is no requirement for the inclusion in any claim herein or of any application claiming priority hereto of any particular described or illustrated activity or element, any particular sequence of such activities, or any particular interrelationship of such elements. Moreover, any activity can be repeated, any activity can be performed by multiple entities, and/or any element can be duplicated. Further, any activity or element can be excluded, the sequence of activities can vary, and/or the interrelationship of elements can vary. Unless clearly specified to the contrary, there is no requirement for any particular described or illustrated activity or element, any particular sequence or such activities, any particular size, speed, material, dimension or frequency, or any particularly interrelationship of such elements. Accordingly, the descriptions and drawings are to be regarded as illustrative in nature, and not as restrictive. Moreover, when any number or range is described herein, unless clearly stated otherwise, that number or range is approximate. When any range is described herein, unless clearly stated otherwise, that range includes all values therein and all sub ranges therein. Any information in any material (e.g., a United States/foreign patent, United States/foreign patent application, book, article, etc.) that has been incorporated by reference herein, is only incorporated by reference to the extent that no conflict exists between such information and the other statements and drawings set forth herein. In the event of such conflict, including a conflict that would render invalid any claim herein or seeking priority hereto, then any such conflicting information in such incorporated by reference material is specifically not incorporated by reference herein.

CLAIMS

We claim:

1. An epicardial pacing system, said system comprising:

an epicardial catheter configured to be disposed in the middle mediastinum of the thorax of a subject for use in electrical pacing of the heart at one or more locations on the epicardial surface, said epicardial pacing catheter comprising:

a proximal portion, distal portion, and a longitudinal structure there between; and

at least one electrode in communication with the distal portion, wherein the at least one electrode is insulated on at least one side to allow pacing of the heart without damage to adjacent anatomical structures.

2. The system of claim 1, wherein said disposing comprises a minimally invasive procedure.

3. The system of claim 1, wherein said disposing comprises a non-surgical procedure.

4. The system of claim 1, wherein said disposing comprises an interventional procedure.

5. The system of claim 1, wherein the middle mediastinum includes the pericardial space.

6. The system of claim 1, wherein said epicardial pacing catheter is a lead.

7. The system of claim 1, further comprising at least one electrical wire in communication with said at least one electrodes, said electrical wire extending longitudinally through said longitudinal structure toward the proximal end, wherein said at least one electrical wire is adapted for transmitting and receiving electrical energy.

8. The system of claim 7, further comprising a control means in communication with the proximal portion, wherein said control means is controllably connected to said at least one electrical wire.

9. The system of claim 8, wherein said control means is removable.

10. The system of claim9, wherein said control means is a control handle.

11. The system of claim 1, wherein said at least one electrode comprises a conducting material.

12. The system of claim 11, wherein said conducting material comprises at least one of the following: copper, platinum, gold, silver, iridium and/or alloys thereof.

13. The system of claim 1, said catheter further comprising an insulating material, said insulating material in communication with said at least one electrode and a portion of said catheter located opposite the heart.

14. The system of claim 13, wherein said insulating material is non-conductive .

15. The system of claim 13, wherein said insulating material mitigates the transmission of electrical energy away from the heart.

16. The system of claim 1, said catheter further comprising a distal tip, wherein said distal tip comprises a non-conducting material.

17. The system of claim 1, wherein said at least one electrode is semi-cylindrical or arc-like in shape.

18. The system of claim 1, wherein the surface of said at least one electrode is roughened, profiled, or otherwise prepared so as to maximize surface area.

19. The system of claim 1, wherein said at least one electrode comprises at least one electrode pair.

20. The system of claim 19, wherein said at least one electrode pair comprises an anode and cathode.

21. The system of claim 1, wherein said at least one electrode is deployable.

22. The system of claim 1, wherein the cross section of said longitudinal structure comprises an oval, circle, ellipse, or semi-circular shape.

23. The system of claim 1, wherein at least a portion of said longitudinal structure comprises a biocompatible material.

24. The system of claim 1, wherein at least a portion of said longitudinal structure comprises a lubricious material having a low coefficient of friction.

25. The system of claim 1, wherein at least a portion of said longitudinal structure comprises at least one of the following: silicone, polyurethane, or Teflon, any combination thereof, or similarly lubricious material.

26. The system of claim 1, wherein at least a portion of said longitudinal structure is impregnated with sirilimus.

27. The system of claim 1, wherein at least a portion of said longitudinal structure comprises a drug eluting surface.

28. The system of claim 1, wherein said longitudinal structure is between about 15 and about 100 centimeters in length.

29. The system of claim 1, wherein said longitudinal structure is between about 2 and about 6 millimeters in diameter.

30. The system of claim 1, further comprising at least one distal fluid aperture located at the distal tip of said distal portion, said at least one distal fluid aperture in communication with a fluid lumen extending longitudinally through said longitudinal structure toward said proximal portion, wherein said at least one distal fluid aperture is adapted for passage of fluid.

31. The system of claim 30, wherein said passage comprises emitting fluid.

32. The system of claim 30, wherein said passage comprises extracting fluid.

33. The system of claim 30, wherein said passage comprises emitting and extracting fluid.

34. The system of claim 30, wherein said passage comprises emitting a drug or agent.

35. The system of claim 30, further comprising at least one proximal fluid aperture at said proximal portion, wherein the at least one proximal fluid aperture is in communication with said fluid lumen, and wherein the at least one proximal fluid aperture is adapted for passage of fluid.

36. The system of claim 35, wherein said passage comprises emitting fluid.

37. The system of claim 35, wherein said passage comprises extracting fluid.

38. The system of claim 35, wherein said passage comprises emitting and extracting fluid.

39. The system of claim 35, wherein said passage comprises emitting a drug or agent.

40. The system of claim 35, further comprising a fluid control means for controlling said fluid passage.

41. The system of claim 40, wherein said control means comprises a control handle in communication with said epicardial pacing catheter.

42. The system of claim 40, wherein said control means is in communication with an external fluid source.

43. The system of claim 40, wherein said control means is in communication with an external drug or agent source.

44. The system of claim 1, wherein said catheter further comprising a stabilization means for stabilizing said epicardial pacing catheter.

45. The system of claim 44, wherein said stabilization means comprises at least one deployable member.

46. The system of claim 45, wherein said deployable member comprises a screw, hook, or tab.

47. The system of claim 45, wherein said deployable member is in communication with said at least one electrode.

48 The system of claim 45, wherein said deployable member comprises a conductive material.

49. The system of claim 48, wherein said conducting material comprises at least one of the following: copper, platinum, gold, silver, or iridium, and/or alloys thereof.

50. The system of claim 45, further comprising a stabilizer actuator, wherein said stabilizer actuator deploys said at least one deployable member.

51. The system of claim 50, wherein said stabilizer actuator comprises:

at least one longitudinal member in communication with at least one of the following: gear, hinge, joint, rack and pinion, pulley, linear actuator, or linear-rotational actuator, or any combination thereof.

52. The system of claim 51, wherein said at least one longitudinal member comprises at least one of the following: push-rod, pull-rod, wire, string, pole, thread, filament, cord, strand or rope.

53. The system of claim 50, wherein said stabilizer actuator comprises a micro electrical mechanical system (MEMS).

54. The system of claim 44, further comprising a control means for controlling said stabilization.

55. The system of claim 54, wherein said control means comprises a control handle.

56. The system of claim 45, wherein said at least one deployable member comprises a catheter-side surface and anatomical-side surface.

57. The system of claim 56, wherein said catheter-side surface comprises a rough surface and said anatomical-side surface comprises a lubricious surface.

58. The system of claim 56, wherein said at least one deployable member is adapted to engage proximate anatomical structures.

59. The system of claim 56, wherein said catheter-side and anatomical-side surfaces comprise non-conductive materials.

60. The system of claim 56, wherein said catheter-side surface comprises a material having a larger coefficient of friction than said anatomical-side surface.

61. The system of claim 56, wherein said at least one deployable member in a deployed state prevents or impedes said distal portion from slipping or moving.

62. The system of claim 56, wherein said distal portion can be moved around within the middle mediastinum when said stabilization means is in a non-deployed state.

63. The system of claim 56, wherein said anatomical-side surface comprises at least one of the following: silicone, polyurethane, or Teflon, combination thereof, or similarly lubricious material.

64. The system of claim 56, wherein said catheter-side surface comprises a textured surface to increase friction.

65. The system of claim 56, wherein said at least one deployable member comprises a radio-opaque material.

66. The system of claim 44, wherein said stabilization means comprises one or more protrusions for engaging proximal anatomical structures.

67. The system of claim 66, wherein at least one of said one or more protrusions is non-deployable.

68. The system of claim 66, wherein said one or more protrusions comprise a non-conducting material.

69. The system of claim 68, wherein said non-conducting material comprises at least one of the following: silicone, polyurethane, or Teflon, combination thereof, or similarly lubricious material.

70. The system of claim 68, wherein the non-conducting material comprises a radio-opaque material.

71. The system of claim 1, further comprising a steering means for positioning the epicardial pacing catheter.

72. The system of claim 71, further comprising a second steering means for steering said epicardial pacing catheter.

73. The system of claim 71, further comprising a third and fourth steering means for steering said epicardial pacing catheter.

74. The system of claim 71, wherein said steering means allows orientation of said epicardial pacing catheter about one point of curvature.

75. The system of claim 71, wherein said steering means allows orientation of said epicardial pacing lead about two or more points of curvature.

76. The system of claim 75, wherein the most proximal point of curvature is located about 15 cm from the proximal end.

77. The system of claim 75, wherein the most distal point of curvature is located between about 1 and about 20 cm from the distal end.

78. The system of claim 75, wherein the most distal point of curvature is a bidirectional center of curvature.

79. The system of claim 75, wherein the most distal point of curvature is greater than tri-directional.

80. The system of claim 71, wherein said steering means comprises at least one of the following: guide wire, pull string, digitating member or tensioning line.

81. The system of claim 71, wherein said steering means comprises a non-conductive material.

82. The system of claim 71, wherein said steering means comprises a material of high-tensile strength.

83. The system of claim 71, further comprising a control means for controlling said steering means.

84. The system of claim 83, wherein said control means comprises a removable handle in communication with the proximal portion.

85. The system of claim 1, wherein said epicardial pacing catheter is adapted to be in communication with a power supply.

86. The system of claim 85, wherein said epicardial pacing catheter is adapted to be in communication with a processor.

87. The system of claim 86, wherein said epicardial pacing catheter is adapted to be in communication with said power supply and said processor by hardwire, wireless, or a combination thereof.

88. The system of claim 87, wherein said wireless comprises BlueTooth, Infrared, other optical, photo-optical, or radio-based type of telemetry or communication.

89. The system of claim 85, further comprising an interface member in communication with said power supply and processor.

90. The system of claim 89, wherein said interface member is used by a patient, a physician, a technician, or a clinician.

91. The system of claim 90, wherein said interface member may be in remote or local communication with a control means.

.92. The system of claim 91, wherein said control means comprises an external control handle.

93. The system of claim 1, wherein navigation of said epicardial pacing catheter is carried out through a puncture of the thorax.

94. The system of claim 93, wherein said puncture comprises a sub-xiphoid puncture.

95. The system of claim 93, wherein a pressure probe needle is used in navigating the epicardial pacing catheter.

96. The system of claim 95, wherein said pressure probe needle comprises an access needle.

97. The system of claim 95, wherein said pressure probe needle comprises a sensor for sensing pressure in the thorax.

98 The system of claim 1, further comprising an access needle, the access needle adapted to be inserted into the thorax.

99. The system of claim 98, further comprising a guidewire, wherein the guidewire is adapted to be inserted into said access needle.

100. The system of claim 98, wherein said guidewire and said access needle are navigated into the pericardial sack.

101. The system of claim 100, wherein said epicardial pacing catheter is adapted to be inserted into or around said guidewire.

102. The system of claim 1, wherein said epicardial pacing catheter is configured to be used with a sheath, said sheath comprising a distal portion, proximal portion, and a longitudinal structure there between, wherein said sheath is adapted for receiving said epicardial pacing catheter therein.

103. A method for use with an epicardial pacing catheter, said method comprising:

disposing said epicardial pacing catheter in the middle mediastinum of the thorax of a subject;

pacing the heart at one or more locations with electrical energy from an at least one electrode; and

at least partially insulating the electrical energy to allow pacing of the heart without damage to adjacent anatomical structures.

104 The method of claim 103, wherein said disposing comprises a minimally invasive procedure.

105 The method of claim 103, wherein said disposing comprises a non-surgical procedure.

106. The device of claim 103, wherein said disposing comprises an interventional procedure.

107. The method of claim 103, wherein said middle mediastinum includes the pericardial space.

108. The method of claim 103, wherein said at least one electrode may be used to stabilize said epicardial pacing catheter.

.109 The method of claim 103, wherein said at least one electrode is deployed.

110. The method of claim 103, further comprising irrigating said middle mediastinum.

111. The method of claim 110, wherein said irrigating comprises emitting a fluid, drug, or agent.

112. The method of claim 110, wherein said irrigating comprises extracting a fluid, drug, or agent.

113. The method of claim 110, wherein said irrigating comprises both emitting and extracting a fluid, drug, or agent.

114. The method of claim 103, further comprising stabilizing said epicardial pacing catheter.

115. The method of claim 114, further comprising a at least one deployable member, wherein said deployable member is used for stabilizing.

116 The method of claim 115, wherein said at least one deployable member comprises a screw, hook, or tab.

117 The method of claim 115, wherein said at least one deployable member comprises a non-conductive material.

118. The method of claim 115, wherein said at least one deployable member comprises a conductive material.

119 The method of claim 118, wherein said at least one deployable member is in electrical communication with said at least one electrode.

120 The method of claim 103, further comprising steering said epicardial pacing catheter.

121 The method of claim 120, wherein said steering is about at least one point of curvature.

122 The method of claim 103, further comprising supplying power to said epicardial pacing catheter.

123. The method of claim 103, further comprising processing data received from said epicardial pacing catheter.

124. The method of claim 103, further comprising controlling said at least one electrode.

125. The method of claim 124, wherein said controlling comprises controllably connecting a control handle to said epicardial pacing catheter.

126 The method of claim 103, wherein said disposing is carried out through a puncture of the thorax.

127 The method of claim 126, wherein said puncture comprises a sub-xiphoid puncture.

128 The method of claim 126, wherein said disposing is carried out through a pressure probe needle.

129. The method of 128, wherein said pressure probe needle comprises an access needle.

130. The method of 128, wherein said pressure probe needle comprises a sensor for sensing pressure in the thorax.

131. The method of claim 103, further comprising inserting an access needle into the thorax of said subject.

132. The method of claim 131, further comprising inserting a guidewire into said access needle.

133. The method of claim 132, further comprising inserting a sheath over said guidewire.

134. The method of claim 133, further comprising inserting said epicardial pacing catheter into said sheath.

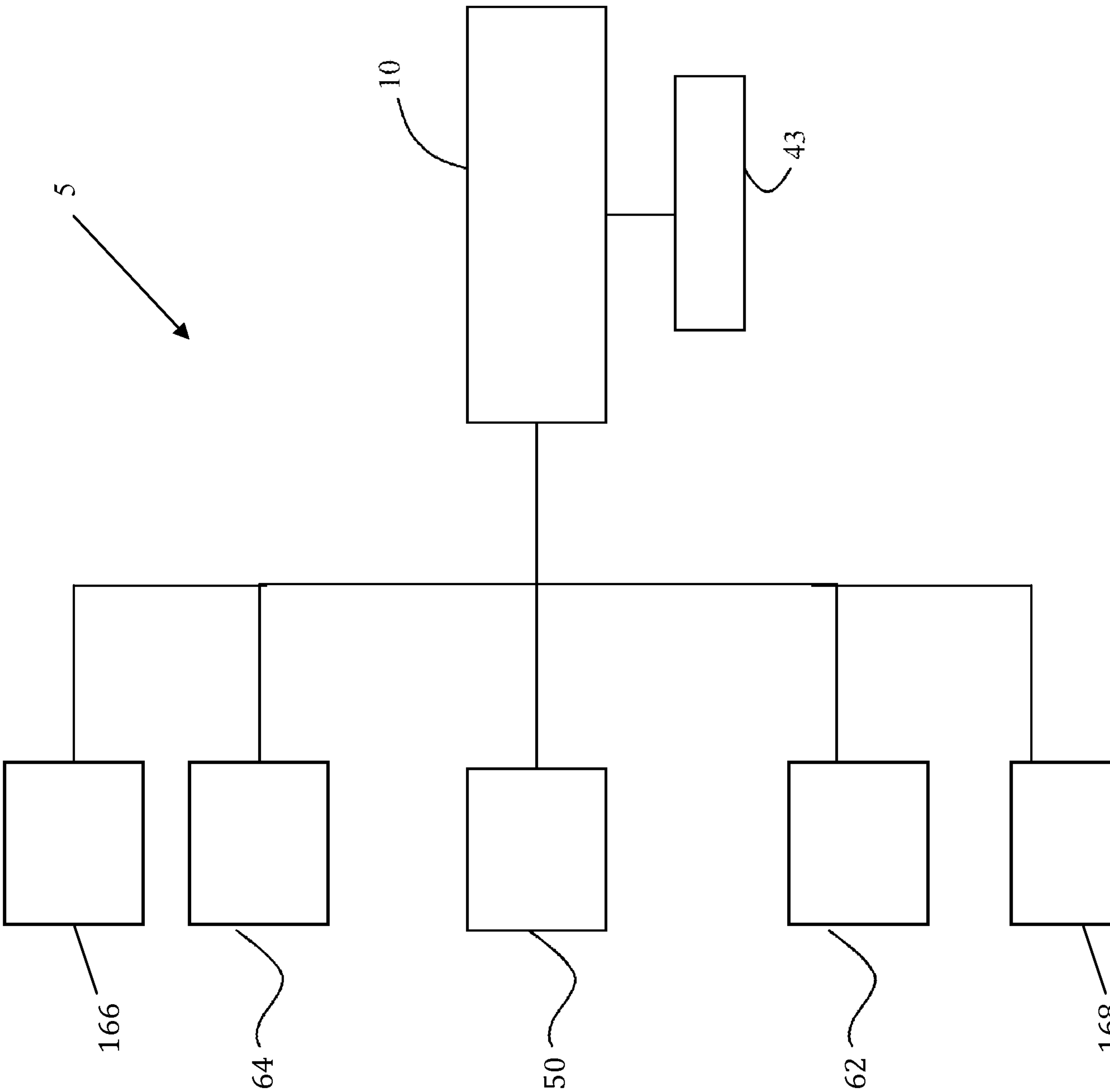


FIG. 1

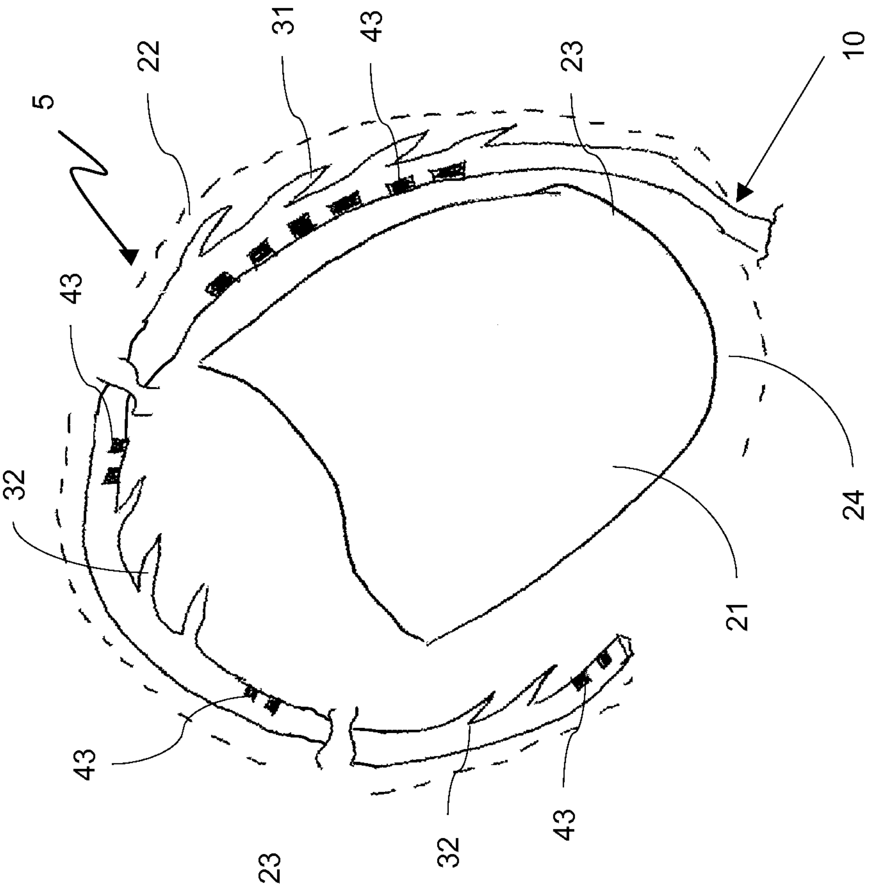


FIG. 2B

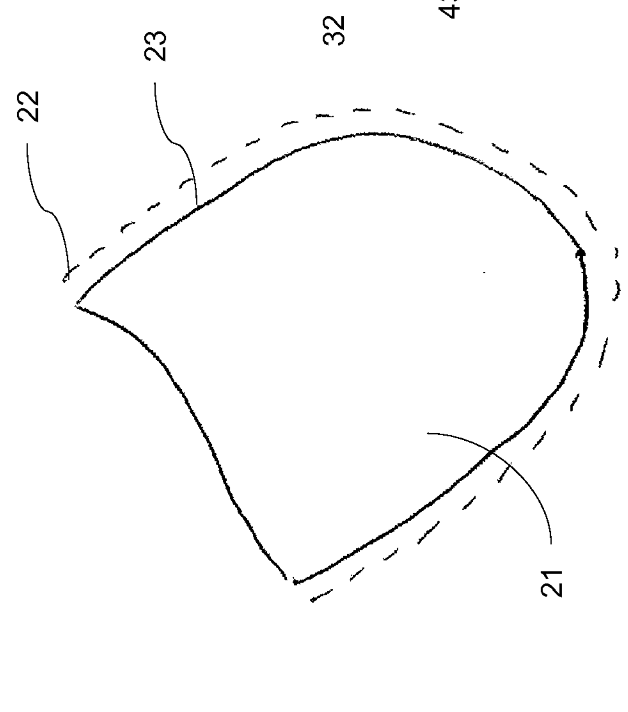
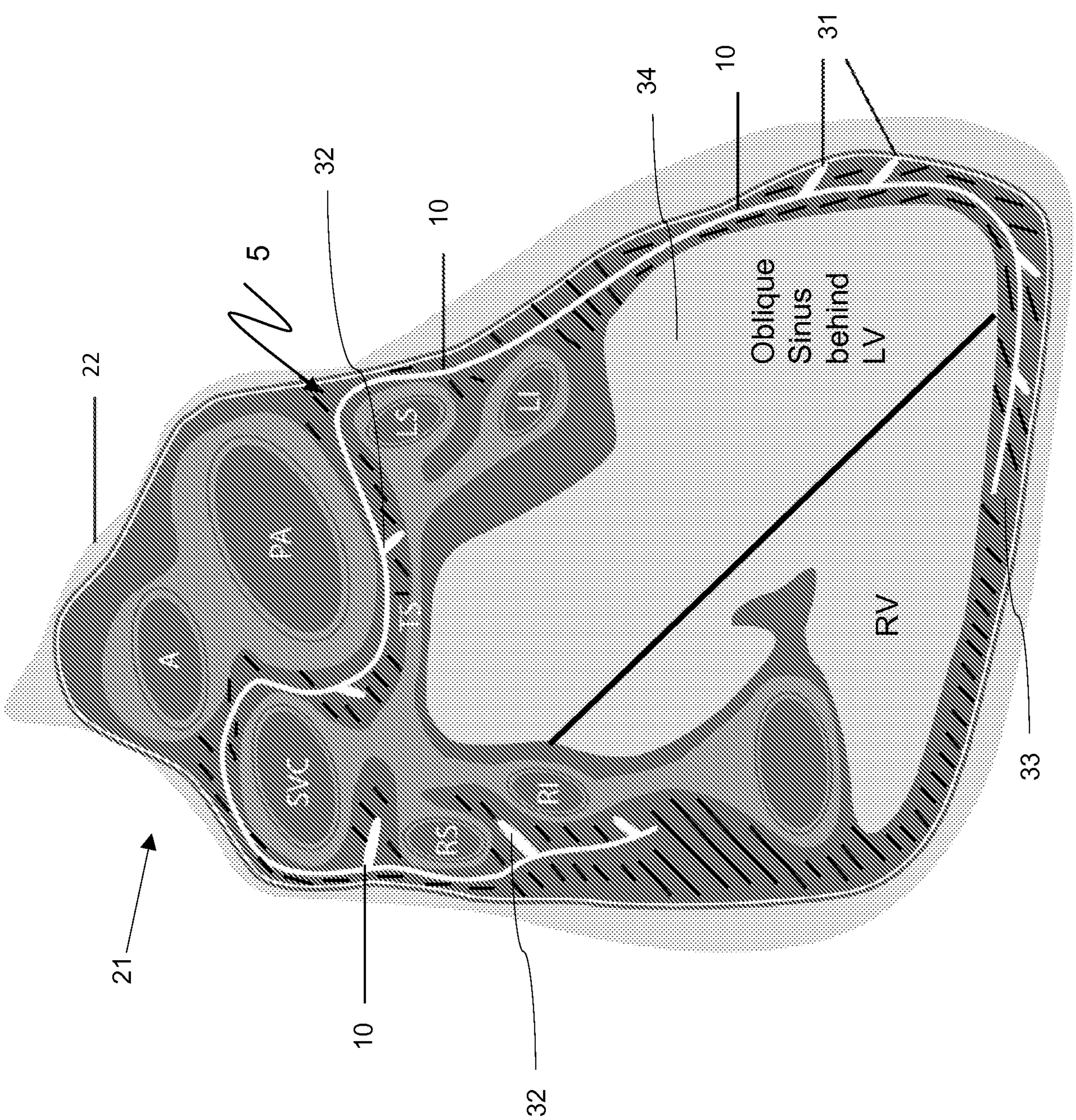


FIG. 2A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Oblique Sinus behind LV
RV

FIG. 3

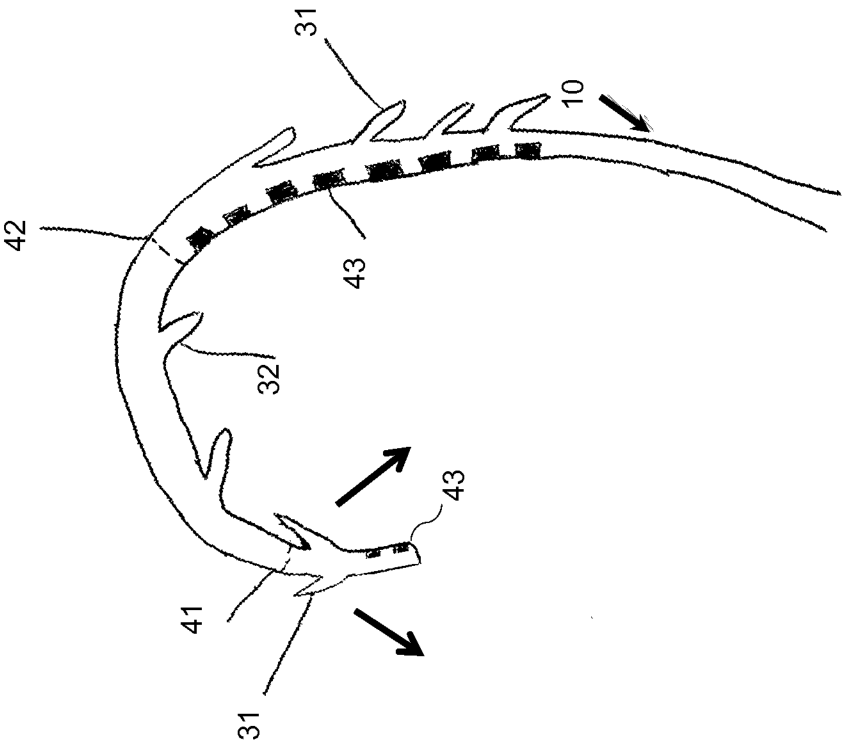

FIG. 4C

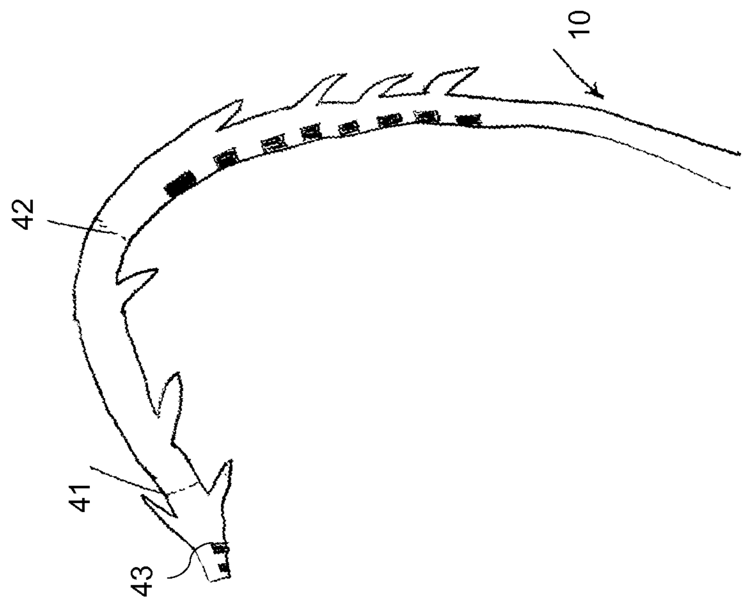

FIG. 4B

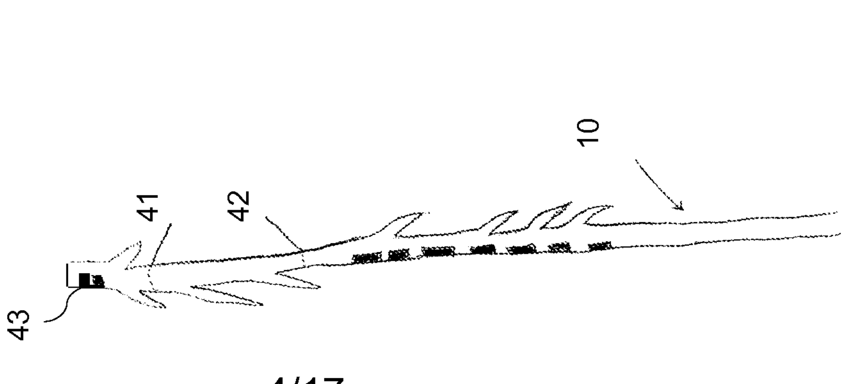

FIG. 4A

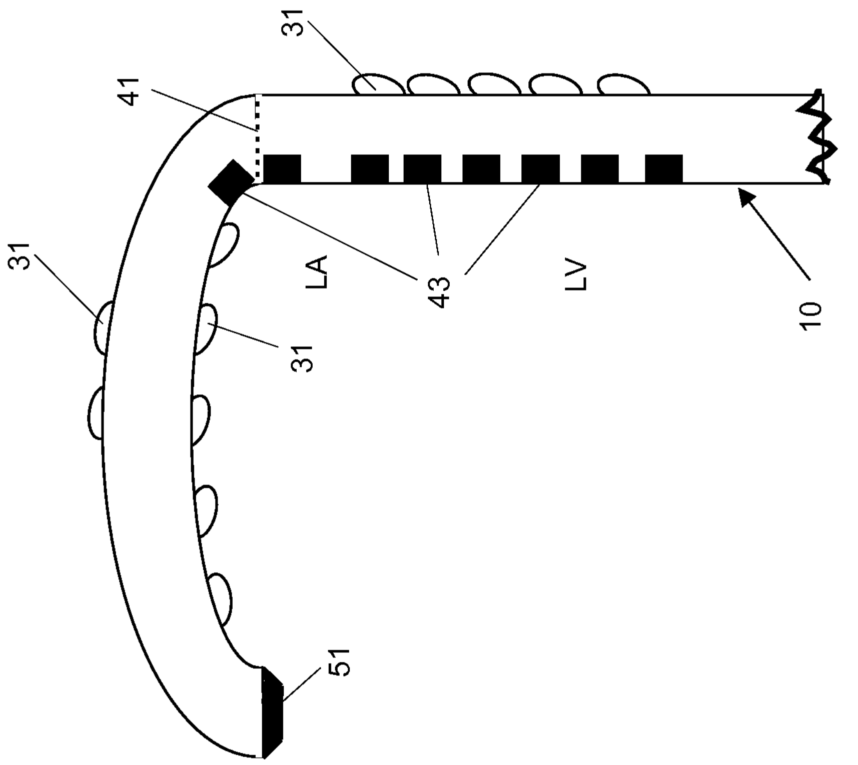

FIG. 5B

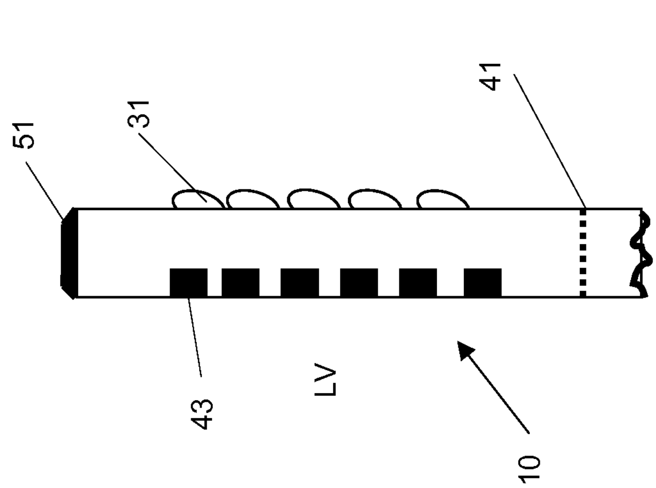

FIG. 5A

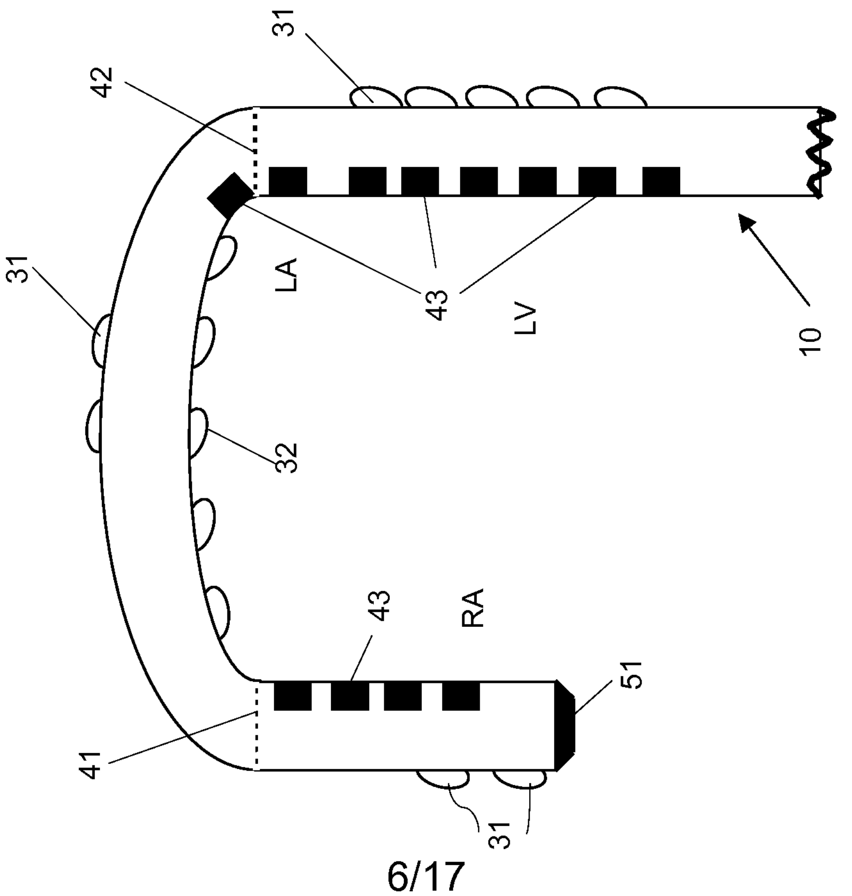

FIG. 5C

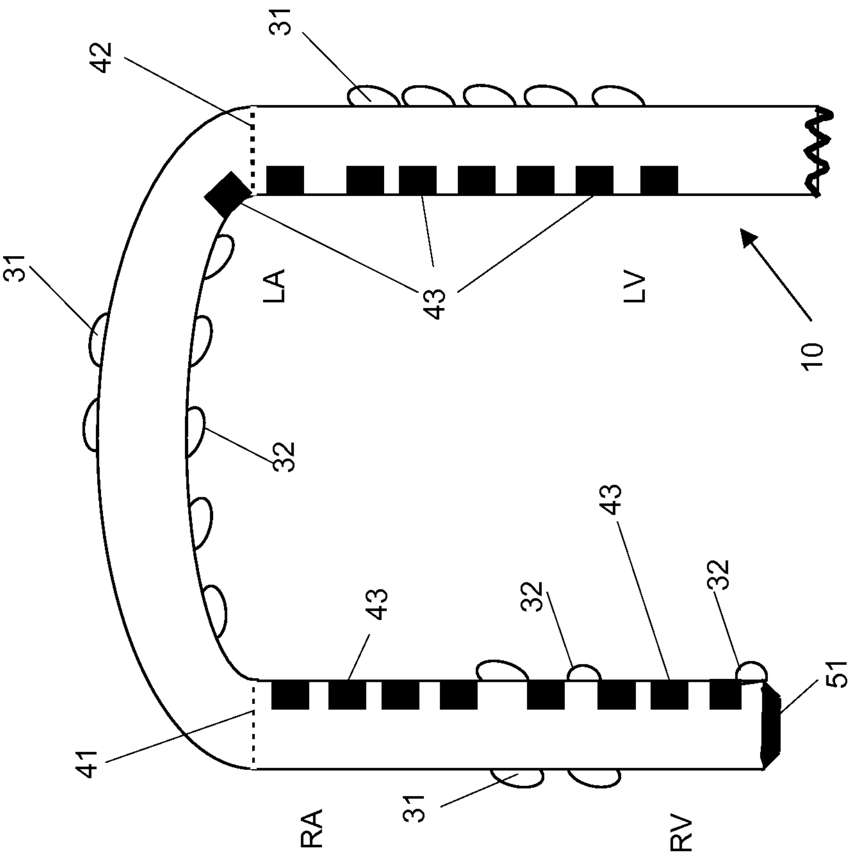

FIG. 5D

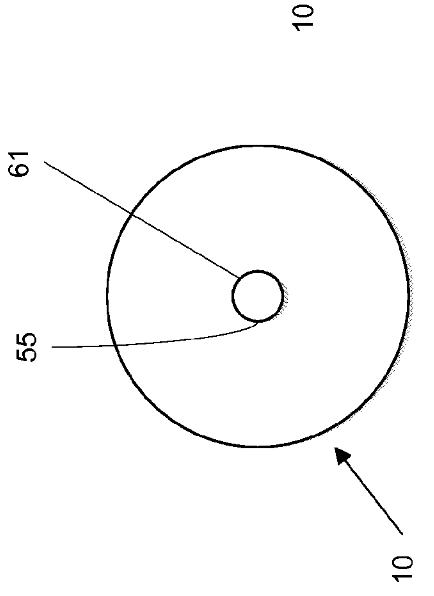

FIG. 6A

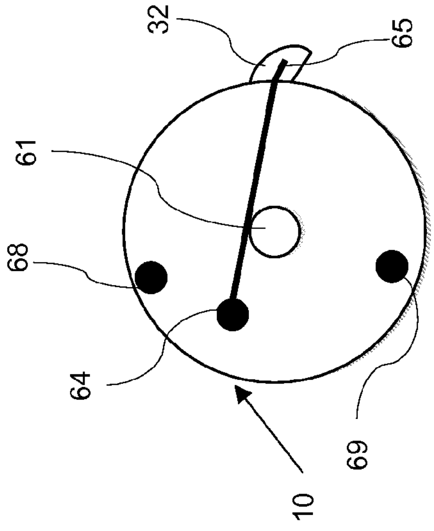

FIG. 6B

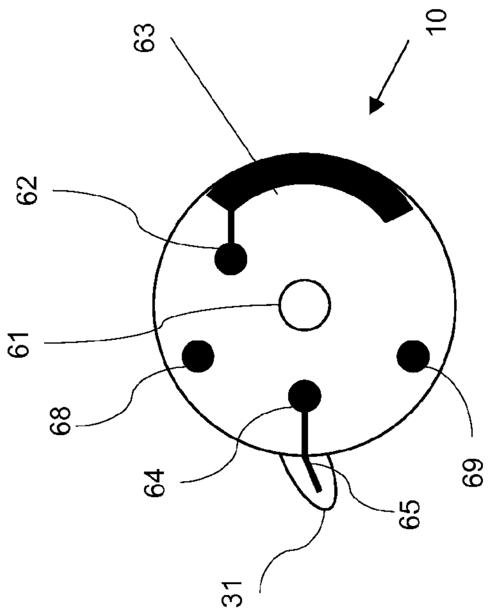

FIG. 6C

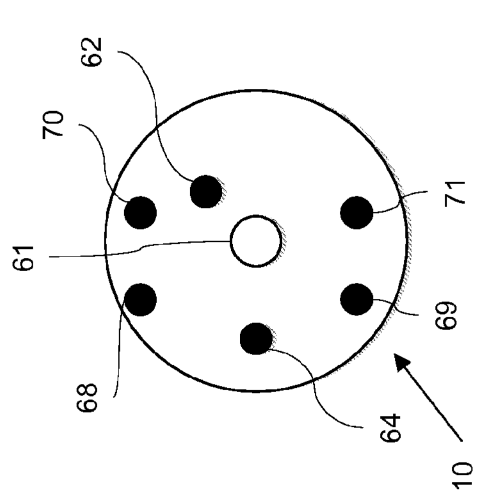

FIG. 6D

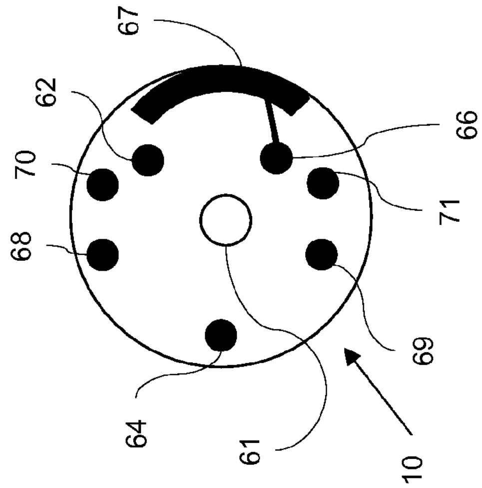

FIG. 6E

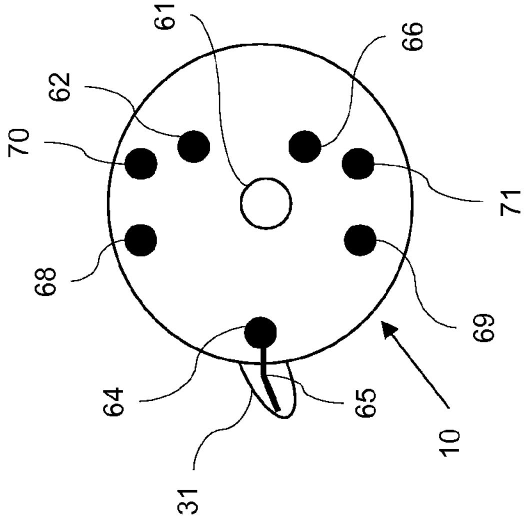

FIG. 6F

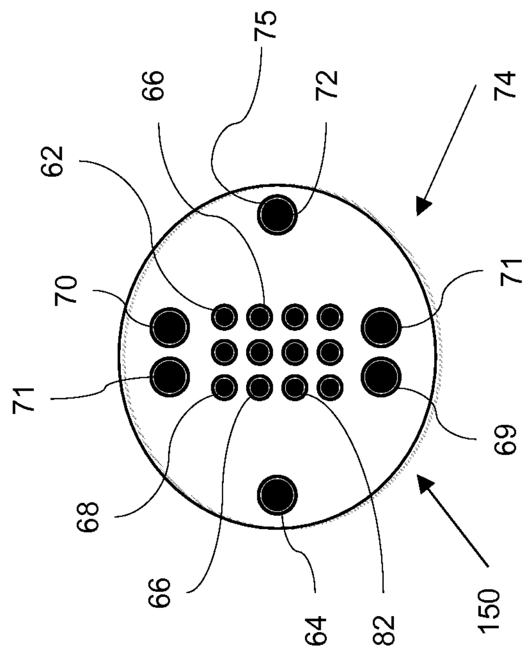
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FIG. 7B

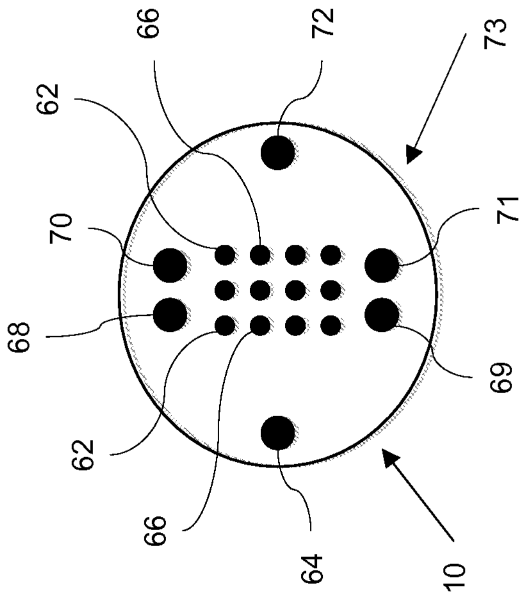
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FIG. 7A

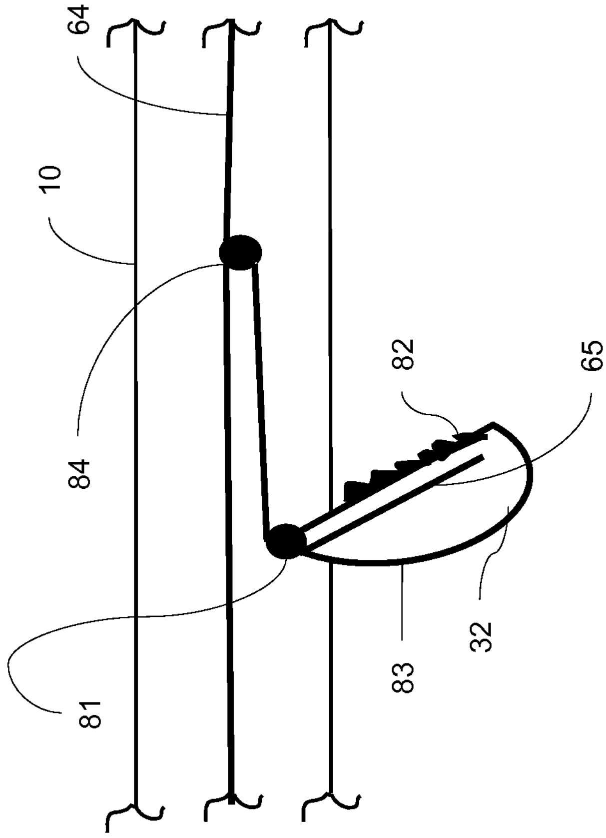

FIG. 8C

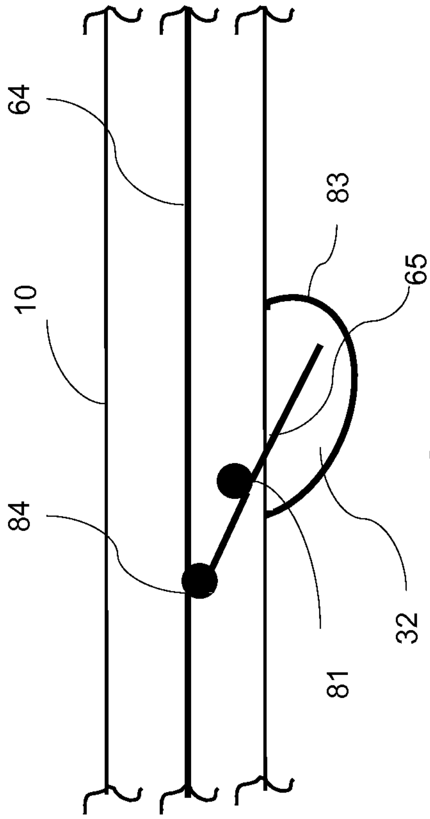

FIG. 8A

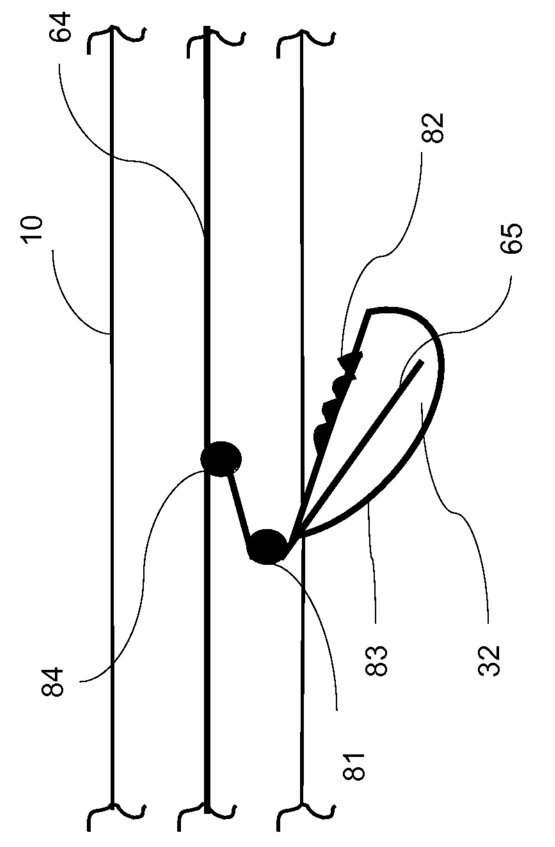

FIG. 8B

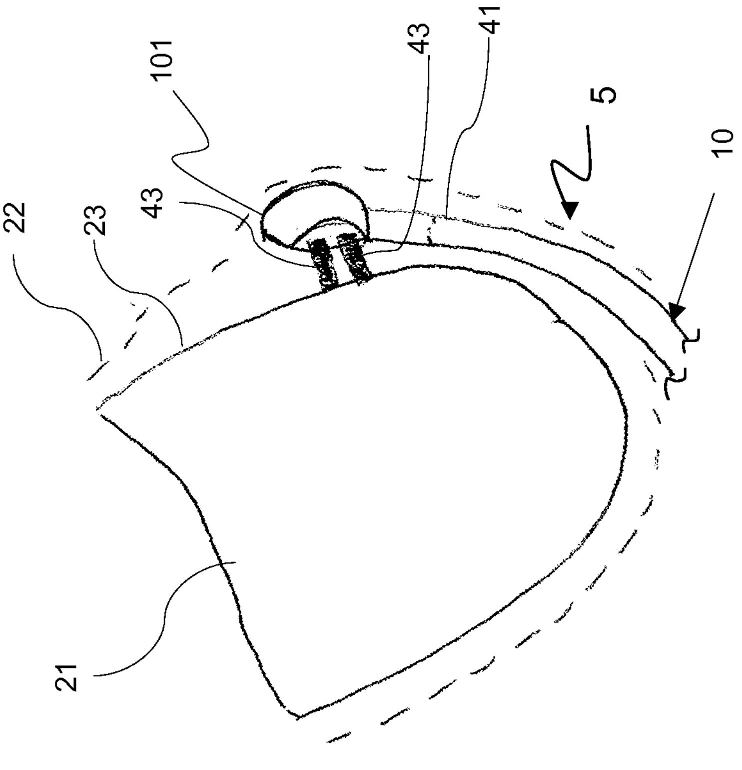

FIG. 9

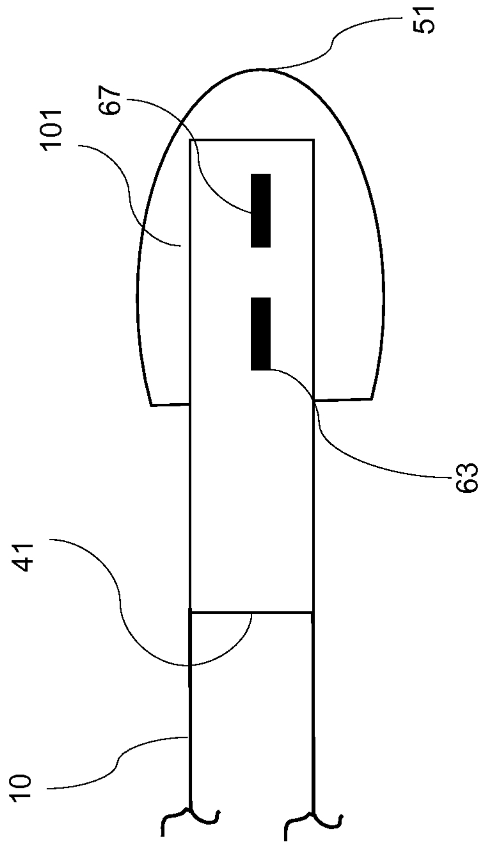

FIG. 10B

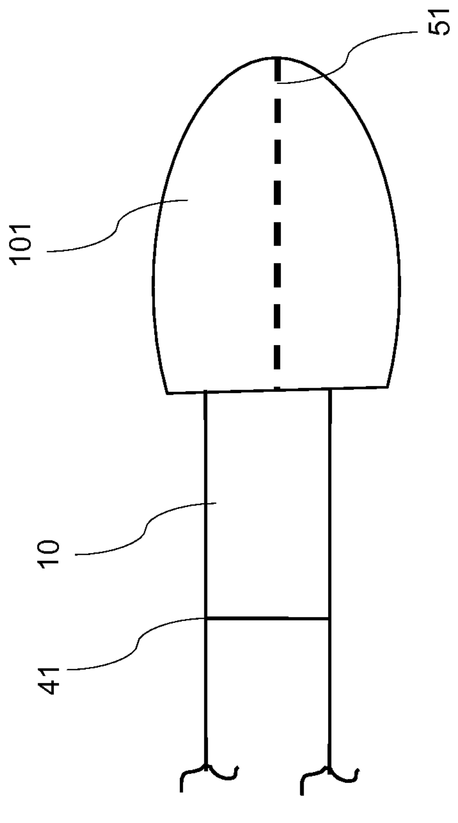

FIG. 10A

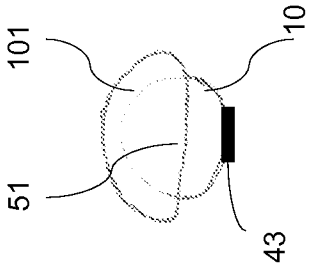

FIG. 10C

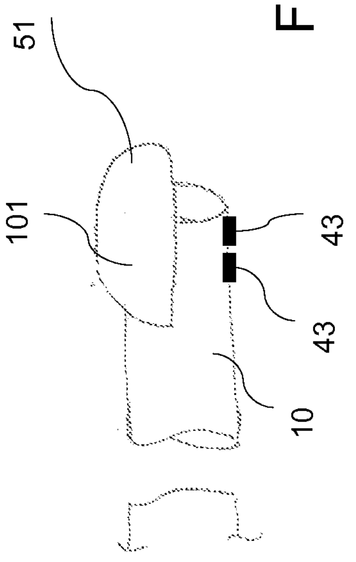

FIG. 10D

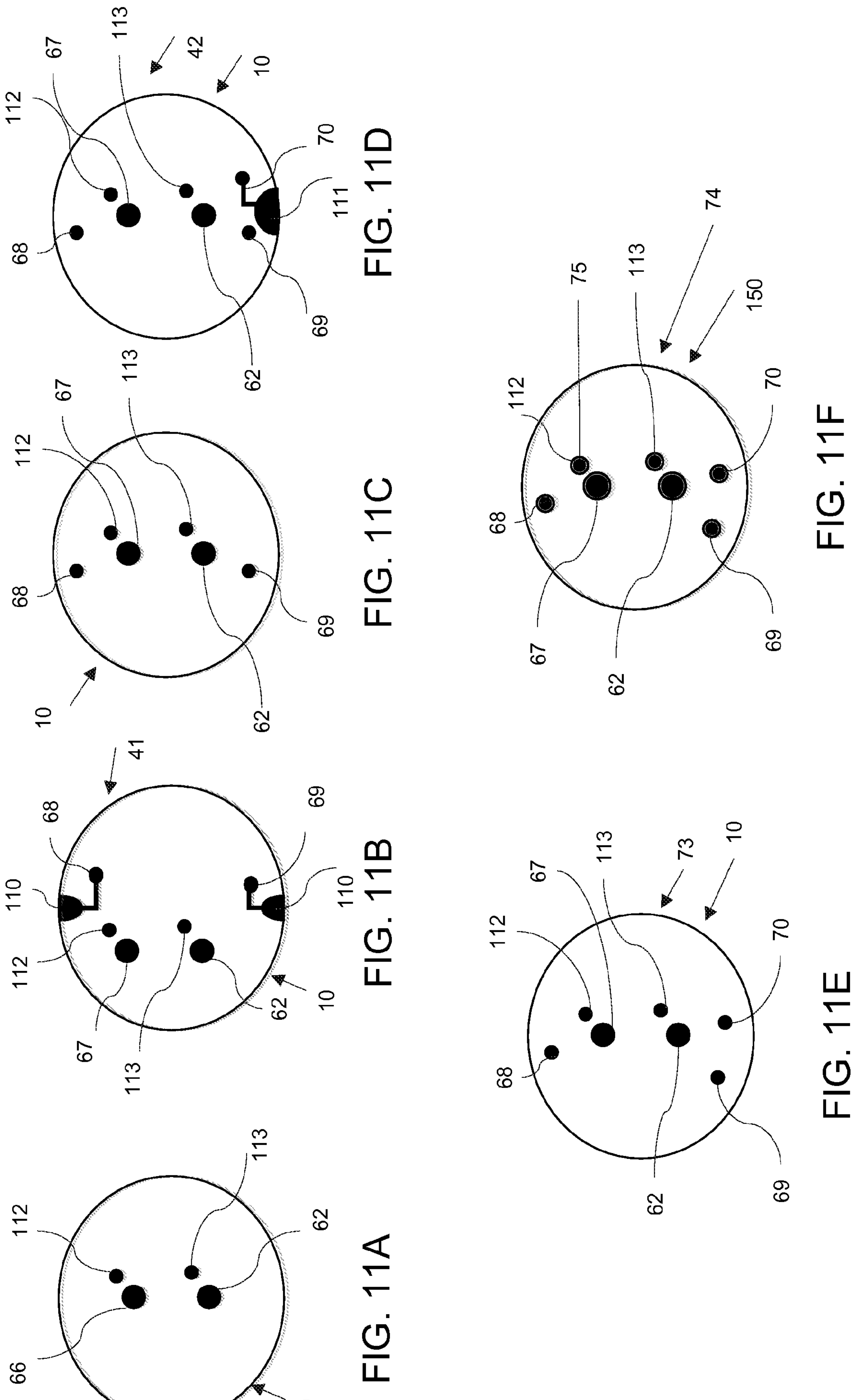

FIG. 11A

FIG. 11B

FIG. 11C

FIG. 11D

FIG. 11E

FIG. 11F

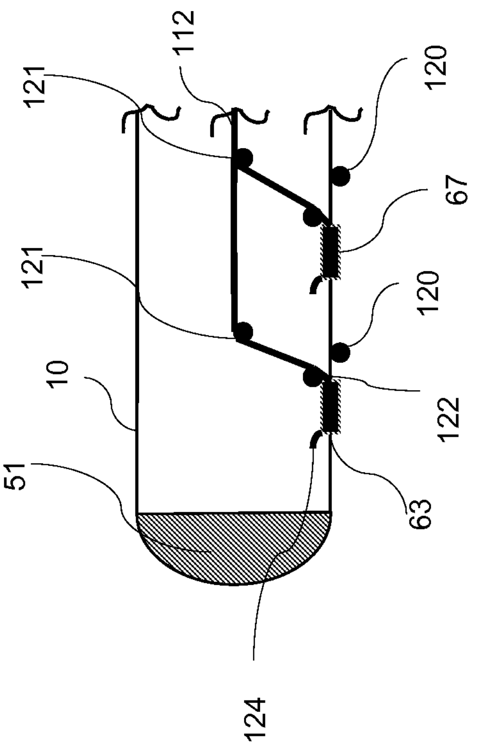

FIG. 12A

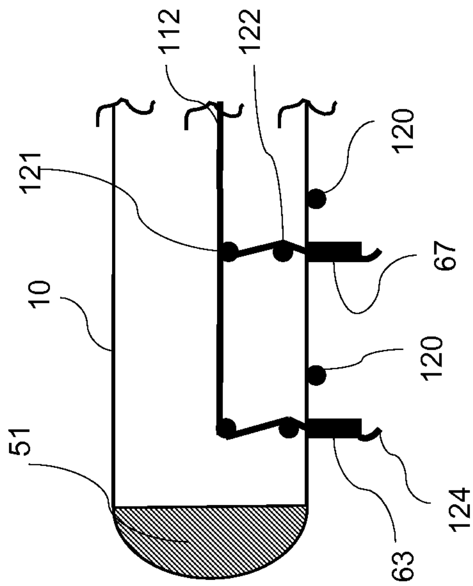

FIG. 12B

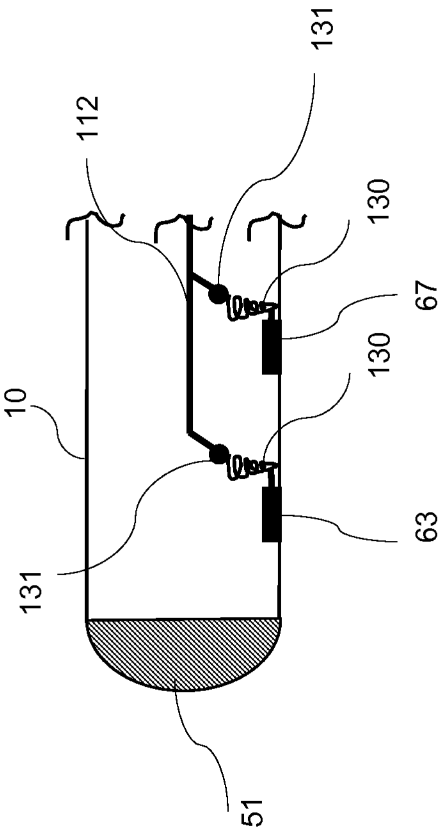

FIG. 13A

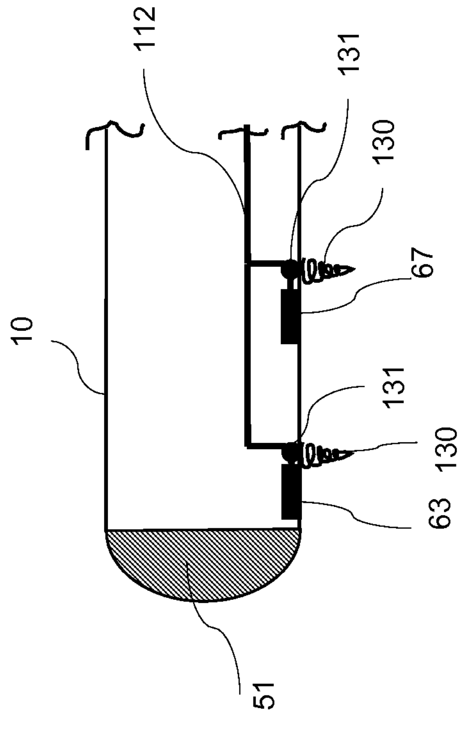

FIG. 13B

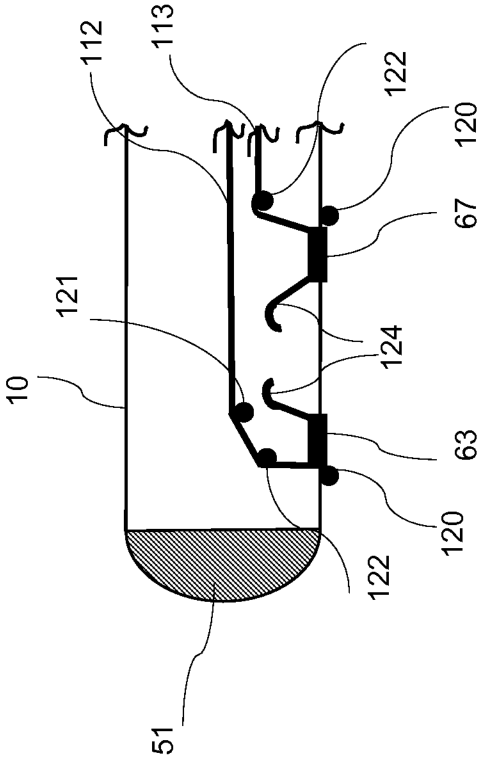

FIG. 14A

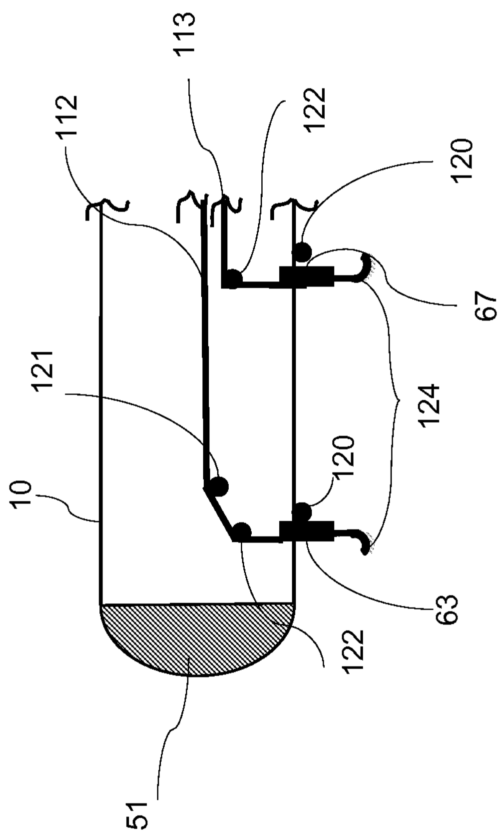

FIG. 14B

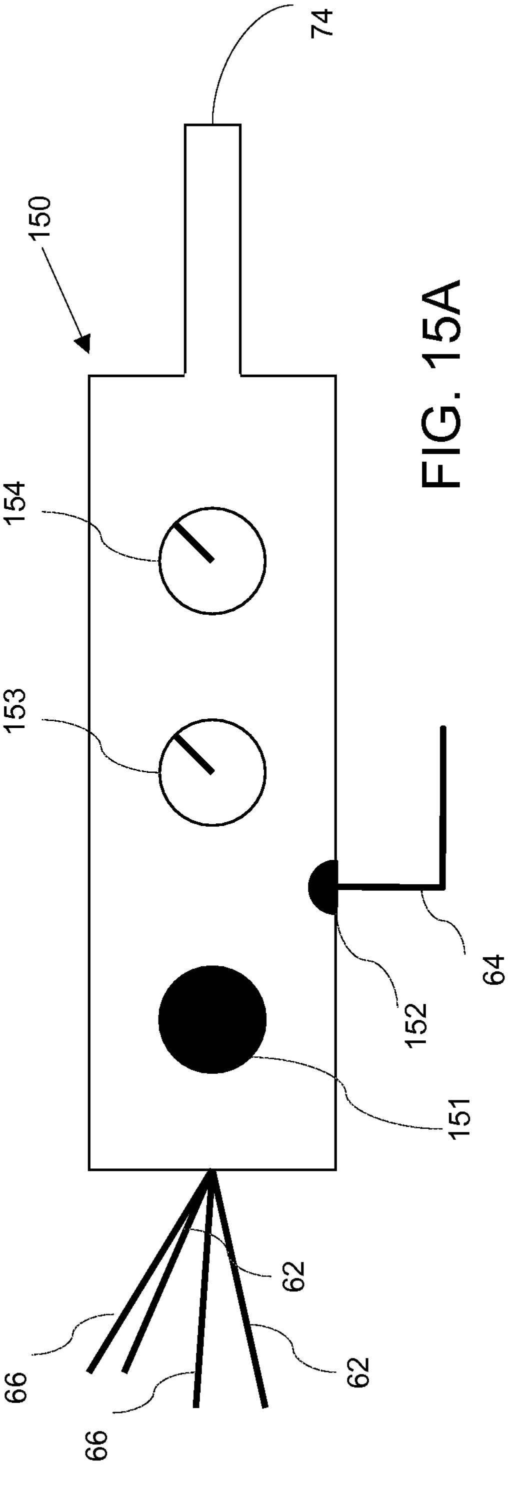

FIG. 15A

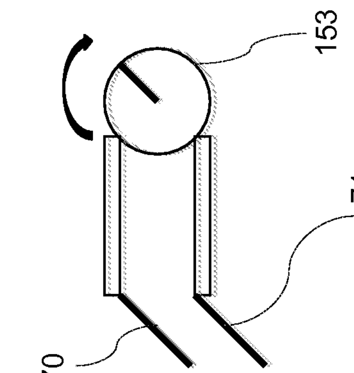

FIG. 15B

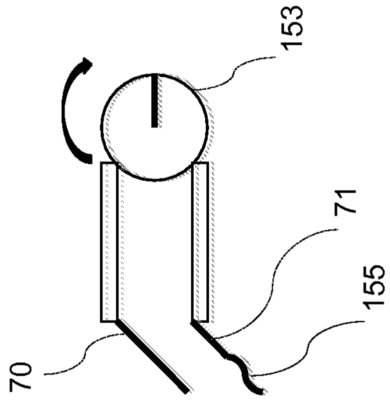

FIG. 15C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/82835

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61N 1/362 (2008.04)
USPC - 607/4
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC: 607/4

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 607/9,11-18,2730,33

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST(USPT,PGPB,EPAB,JPAB), Google patent, Google Scholar
Search Terms: epicardial, pacing system, catheter, mediastinum, thorax,proximal, distal, electrode, communication, insulated,minimal,interventional, procedure,pericardial, lead, wire, longitudinally, transmitting, receiving, electrical energy,control, removable, con

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2006/0041243 A1 (NAYAK et al) 23 February 2006 (23.02.2006) entire document, especially para[0005],[0045],[0046],[0054],[0055],[0141],[0142],[0144],[0148],[0149],[0153],[0155],[0156],[0159],[0160],[0164],[0168],[0170],[0172],[0176],[0185],[0192],[0193],[0195],[0196],[0199],[0200],[0209],[0210],[0214],[0223],[0228],[0231],[0235],[0242],[0245]-[0247],[0255]-[0257],[0259],[0260],[0273]-[0276],[0278]-[0281],[0292],[0320],[0330],[0341],[0351],[0356],[0359],[0361]-[0365], [0368],[0369],[0371]-[0373], FIG. 3B	1-2,5-13,15,18-23,25,30-43,71-74,80-104,107-113,120-134 --- 3-4,14,16-17,24,26-29,44-70,75-79,105-106,114-119
Y	US 2002/0055714 A1 (ROTHSCHILD) 09 May 2002 (09.05.2002)para[0012]	3,105
Y	US 6,711,436 B1 (DUHAYLONGSOD) 23 March 2004 (23.03.2004) col 7, ln 35-40; col 7, ln 45-49; col 26, ln 61-65	4, 28-29, 64, 75-79, 106
Y	US 5,846,239 A (SWANSON et al.) 08 December 1998 (08.12.1998), col 20, ln 35-38	14
Y	US 2007/0043397 A1 (OCEL et al.) 22 February 2007 (22.02.2007)	16
Y	US 6,811,544 B2 (SCHAER) 02 November 2002 (02.11.2002) col 17, ln 15-19	17
Y	US 2006/0106442 A1 (RICHARDSON et al.) 18 May 2006(18.05.2006) para[0026]	24
Y	"Sirilimus eluting stents versus standard stents in patients with stenosis of the coronary artery" (MOSES et al)New England Journal of Medicine, page 1315-1323 Oct. 2, 2003 Vol. 349, No. 14. Abstract	26-27
Y	US 6,051,008 A (SAADAT et al.) 18 April 2000 (18.04.2000),col 4, ln 25-28;	44-70, 75-79, 114-119

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 Dcember 2008 (19.12.2008)	15 JAN 2009
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774