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.
STEERABLE EPICARDIAL PACING 
CATHETER SYSTEM PLACED VIA THE 
SUBXIPHOID PROCESS 

RELATED APPLICATIONS

[0001] The present invention claims priority from U.S. Provisional Application Ser. 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 Ser. No. 61/023,727, filed Jan. 25, 2008, entitled “Steerable Epicardial Lead to be Placed via the Subxiphoid Process for Left Ventricle Pacing and Related Method,” the disclosures of which are hereby incorporated by reference herein in their entirety.


FIELD OF THE INVENTION

[0005] 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

[0006] 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.

[0007] 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.

[0008] 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.

[0009] 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.

[0010] 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 Nucor® and Heartlander® tools, which are not designed to pace, require surgical incisions.

[0011] 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.

[0012] 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.

[0013] The following U.S. patent documents discuss catheterization tools for cardiology: U.S. Pat. Nos. 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 Kraman 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.

[0014] 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 INVENTION

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 position 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.

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.

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.

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

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

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

Figs. 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.

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

Figs. 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.

Figs. 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.

Figs. 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.

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

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

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

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

FIG. 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. FIG. 11(F) schematically illustrates a cross sectional view of an exemplary embodiment of the control handle at the most distal point.

FIG. 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.

FIG. 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.

FIG. 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.

FIG. 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.

FIG. 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.

FIG. 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.

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

FIG. 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.

FIG. 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.

FIG. 1 schematically illustrates an overview of an exemplary embodiment of the epicardial pacing system 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 FIG. 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 silicon silver-gallium krad 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 comprises 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 hardware 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; 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; 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.

[0055] 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 sirolimus 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, pipe, tunnel or bounded tubular surface.

[0056] 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.

[0057] 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, 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.

[0058] 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.

[0059] 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.

[0060] FIG. 2(A) schematically illustrates the pericardium and heart alone. The pericardium 22 is shown in close proximity to the epicardium 23.

[0061] FIG. 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.

[0062] 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 Mar. 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, FIGS. 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.

[0063] 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.

[0064] 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 sub-xiphoid 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 sub-xiphoid insertion.

[0065] 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 cardiac equipment by voice, thus eliminating 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 ensure 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. Pat. Nos. 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 guidewire 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 implemented 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 slide 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 to 100 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, veterinary 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.

FIG. 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, right atrium, right ventricle and/or any combination thereof. The epicardial pacing catheter 10 may be first 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 FIG. 2).

FIGS. 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 Mar. 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 example, referring to FIGS. 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 FIGS. 7(A)-7(B) of '0568166 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 FIG. 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 epipadiac 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 epipadiac pacing catheter 10 may further comprise a third and fourth steering means for steering the epipadiac 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, FIG. 4(A) shows an embodiment of the epipadiac pacing catheter 10 in the non-deflected state. FIG. 4(B) shows the epipadiac pacing catheter 10 in a partially-deflected state. FIG. 4(C) shows the epipadiac 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:


3. U.S. Pat. No. 6,928,313, Aug. 9, 2005, “System and method for accessing the coronary sinus to facilitate insertion of pacing leads”, Peterson, Eric D.


These electrodes 43 may be in communication with the outside wall of the right 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 catech, drag, stick to, or pull on adjacent anatomical structures to keep the epicardial pacing catheter 10 from moving. FIG. 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.

FIG. 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.
order to pace said structure. Further, additional outward facing bumper tabs 31 are present to press against the pericardium in more distal locations.

[0129] FIG. 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.

[0130] It should be appreciated that in FIGS. 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.

[0131] It should be appreciated that in FIGS. 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.

[0132] 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.

[0133] FIGS. 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.

[0134] FIG. 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 FIG. 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, chemotherapy, 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.

[0135] FIG. 6(B) 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 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 FIG. 15) in communication with the proximal portion of the epicardial pacing catheter 10.

[0136] 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.

[0137] 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 need not 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 FIG. 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.

[0138] FIG. 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 FIG. 15) in communication with the proximal portion of the epicardial pacing catheter 10.

[0139] 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.

[0140] FIG. 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 FIG. 15) in communication with the proximal portion of the epicardial pacing catheter 10.

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 tabs 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, 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 FIGS. 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.

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 may comprise guidewires, tensioning lines, pull strings, digitizing 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.
distal end 74. In this way, the distal end 74 can act as a female connector in a male-female connection.

[0153] It should be appreciated that the number of lumens, wires, rods or elements discussed with regards to FIG. 7 may vary as may be desired or required according to medical procedures, device/system operations and anatomical considerations.

[0154] FIGS. 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.

[0155] FIGS. 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 luminous 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.

[0156] FIG. 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 a microelectrical mechanical system (MEMS).

[0157] 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, strap 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 FIG. 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.

[0158] 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.

[0159] 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.

[0160] FIG. 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.

[0161] FIG. 8(C) illustrates an embodiment wherein the stabilization means is an inward facing friction tab 32 in the fully-deployed state.

[0162] Although not shown, the outward facing bumper tabs 31 may be deployed using the same means and methods as described above.

[0163] 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.

[0164] 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.

[0165] 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, protrusion or the like.

[0166] FIG. 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.

[0167] FIG. 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 an 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.
FIG. 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.

FIG. 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.

FIG. 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 FIGS. 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.

FIG. 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. FIG. 11(F) schematically illustrates a cross sectional view of an exemplary embodiment of the external control handle 150 at the most distal point 74.

FIG. 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, 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.

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.

FIG. 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).

FIG. 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, protrusion and 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 FIG. 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.

FIG. 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 angell(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 FIGS. 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.

FIG. 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, protrusion, 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-wire, 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 FIG. 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.

[0199] The epicardial pacing catheter 10 further comprises an insulating distal tip 51 in communication with the epicardial pacing catheter.

[0200] 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.

[0201] FIG. 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.

[0202] It should be appreciated that in FIGS. 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.

[0203] FIG. 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.

[0204] 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).

[0205] 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 FIG. 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.

[0206] 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.

[0207] 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.

[0208] FIG. 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.

[0209] It should be appreciated that in FIGS. 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.

[0210] 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.

[0211] It should be appreciated that regarding deployment discussed throughout, varying degrees of deployment may be achieved or implemented as desired or required.

[0212] FIG. 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 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.

[0213] 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 FIGS. 6, 7, and 11) may extend through the proximal portion to each of the electrodes 43 of the epicardial pacing catheter 10.

[0214] FIG. 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.

[0215] FIG. 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.

[0216] For example, the control handle may have channels for the steering pull wires and thumb wheel knobs for tightening or loosening the pull wires.

[0217] 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.

[0218] 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:


EXAMPLES AND EXPERIMENTAL RESULTS

[0277] It should be appreciated that the catheter device and epicardial system and their related components discussed herein may 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.

[0278] 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 through 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 counterclocked 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 1 mV 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/ATV 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, any number or range of 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.

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 therebetween; 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 claim 9, 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 electrode.

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 silicon.

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 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, digitizing 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.