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Chin(10) **Pub. No.: US 2006/0116746 A1**(43) **Pub. Date: Jun. 1, 2006**(54) **CARDIAC ELECTRODE ATTACHMENT
PROCEDURE****Publication Classification**(76) Inventor: **Albert K. Chin, (US)**(51) **Int. Cl.****A61N 1/05** (2006.01)(52) **U.S. Cl.** **607/119**

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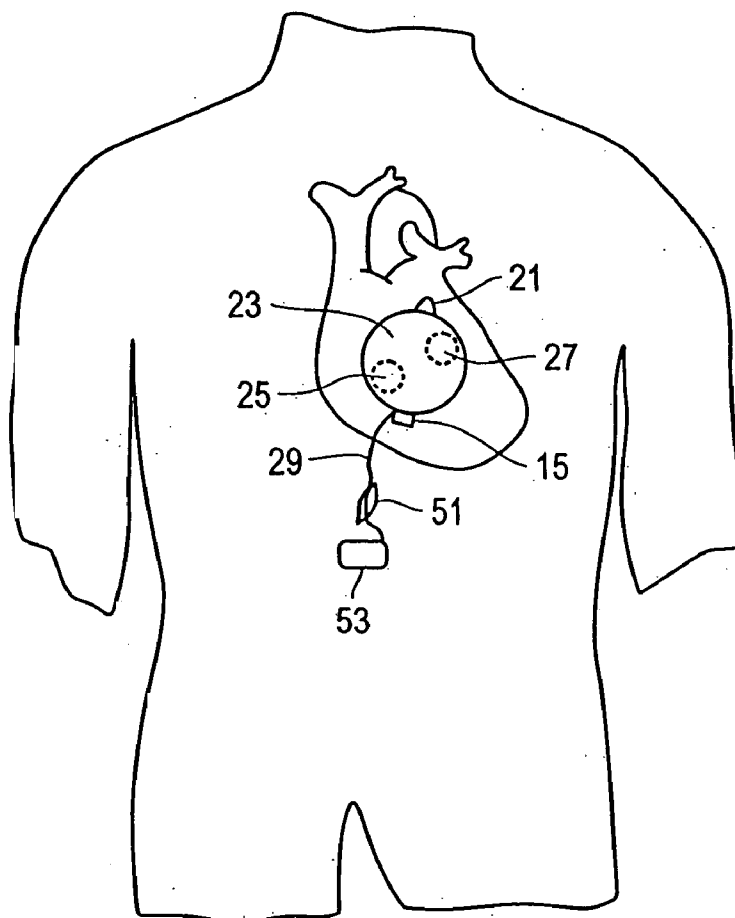
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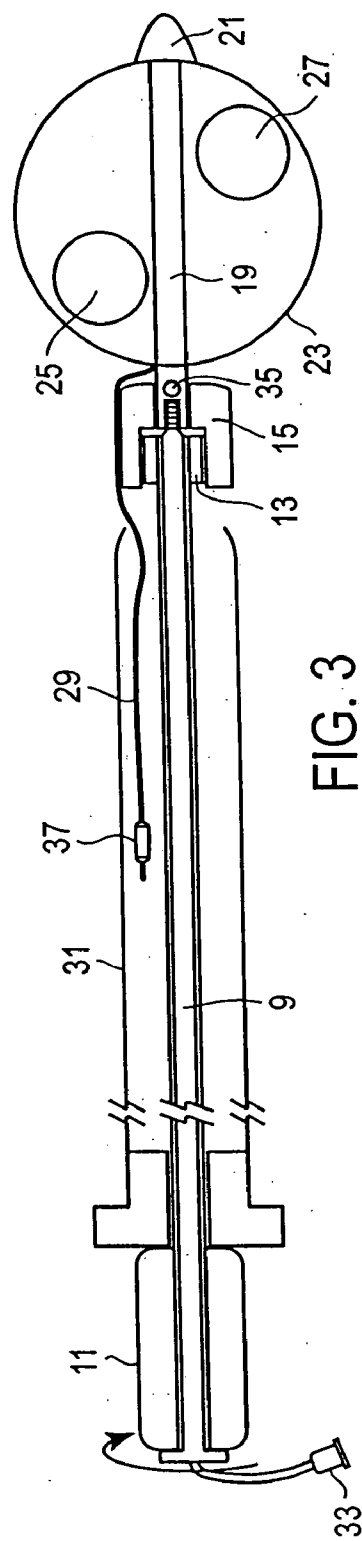
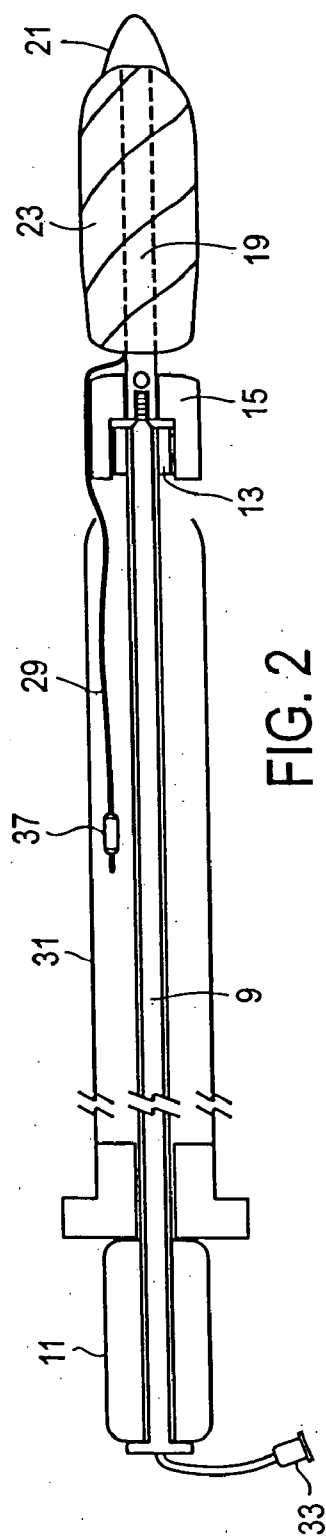
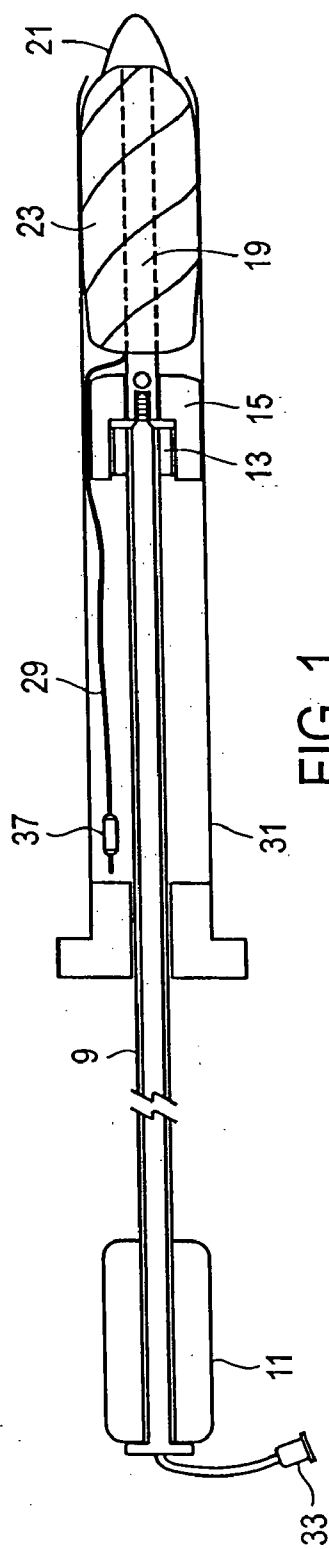
ABSTRACT

Surgical procedure and surgical instruments include an electrode structure for insertion through tissue superiorly of a subxiphoid incision to a position posterior of an aspect of the sternum and anterior of the pericardium. The electrode structure may be expanded, for example, including an inflatable member to position a number of electrodes of the electrode structure in contact with the pericardium. Alternatively, an electrode structure on an insertion cannula may be retained in contact with the pericardium by the cannula positioned within the dissected tissue. Electrical conductors from the contacting electrodes are routed through the tract of dissected tissue toward the subxiphoid incision for attachment to a generator that is implanted in a subcutaneous pocket near the subxiphoid incision.

(21) Appl. No.: **11/326,933**(22) Filed: **Jan. 5, 2006****Related U.S. Application Data**

(63) Continuation of application No. 10/369,980, filed on Feb. 18, 2003, which is a continuation-in-part of application No. 10/346,663, filed on Jan. 17, 2003, and which is a continuation-in-part of application No. 10/347,212, filed on Jan. 17, 2003.





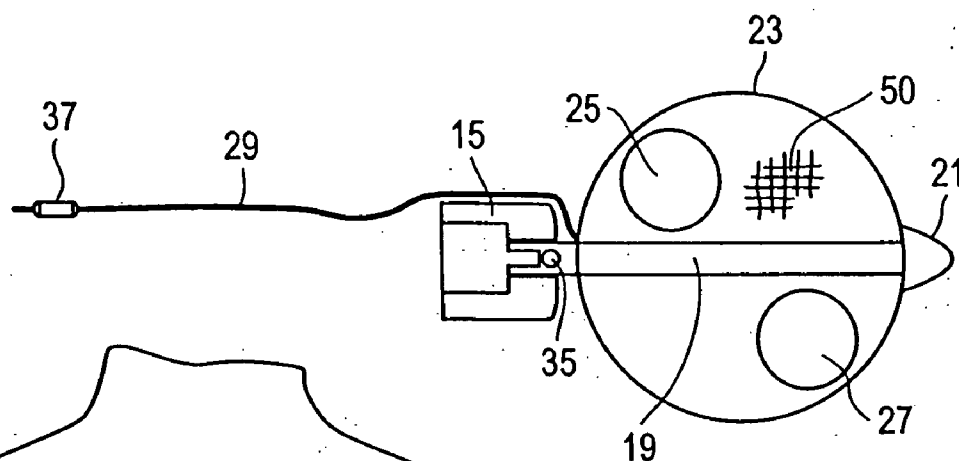


FIG. 4

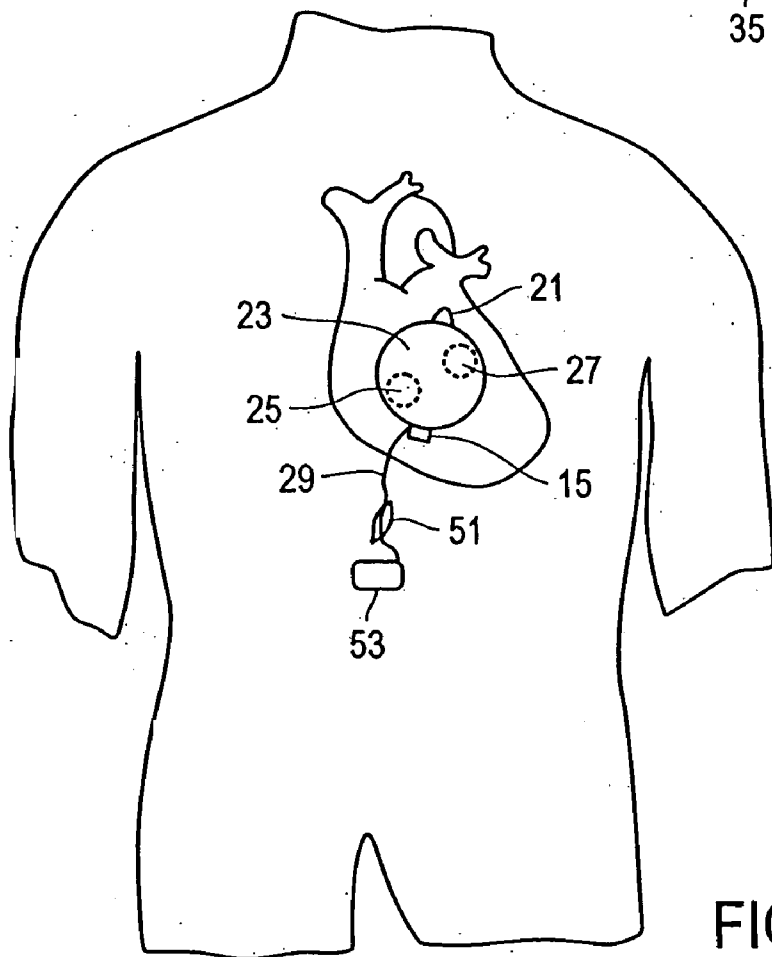


FIG. 9

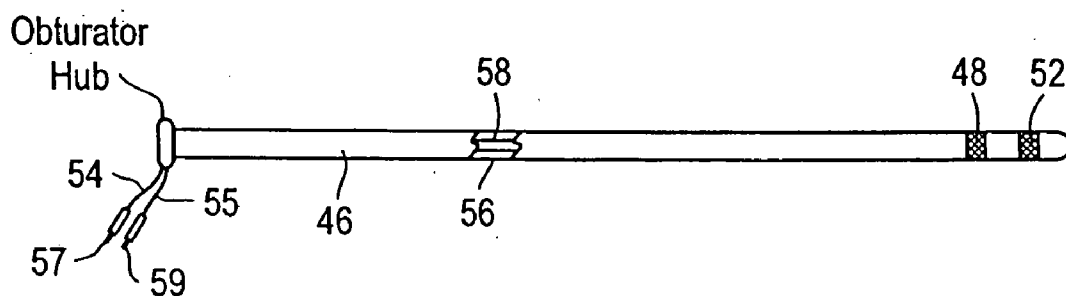


FIG. 10

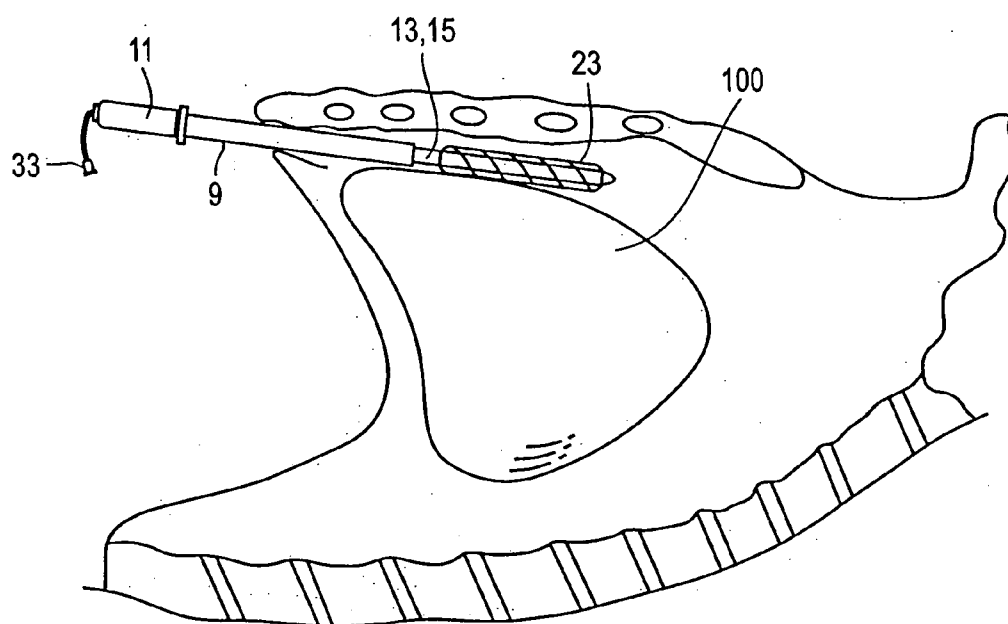


FIG. 5

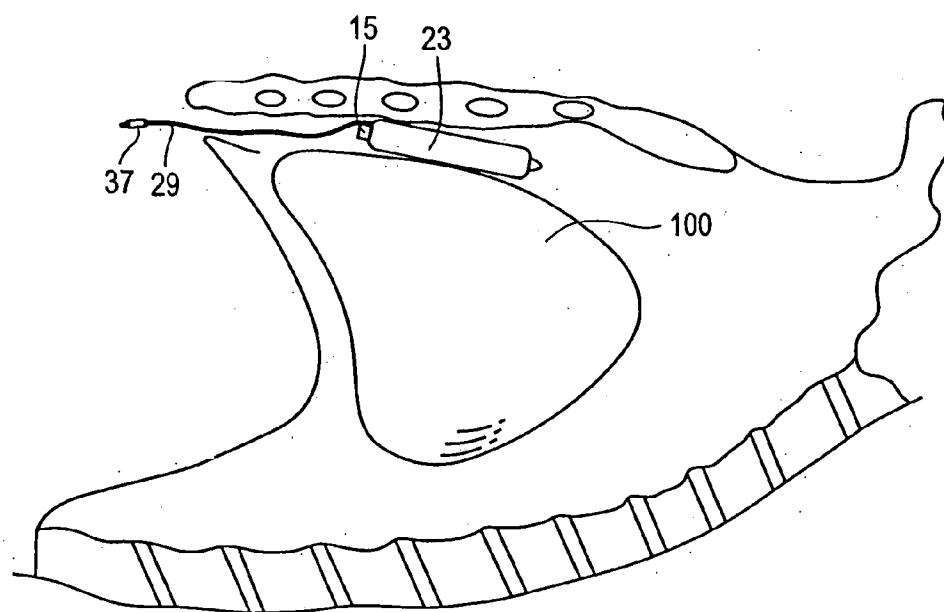
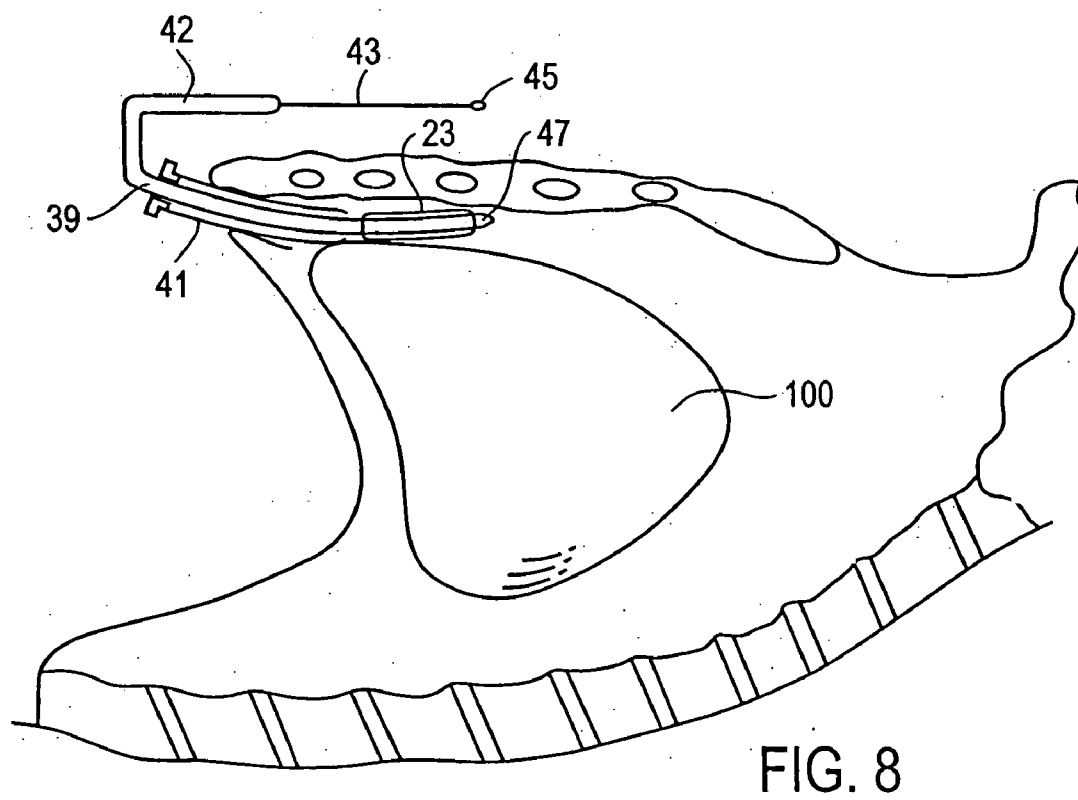
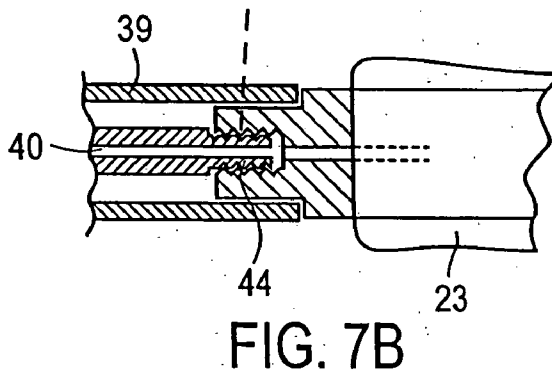
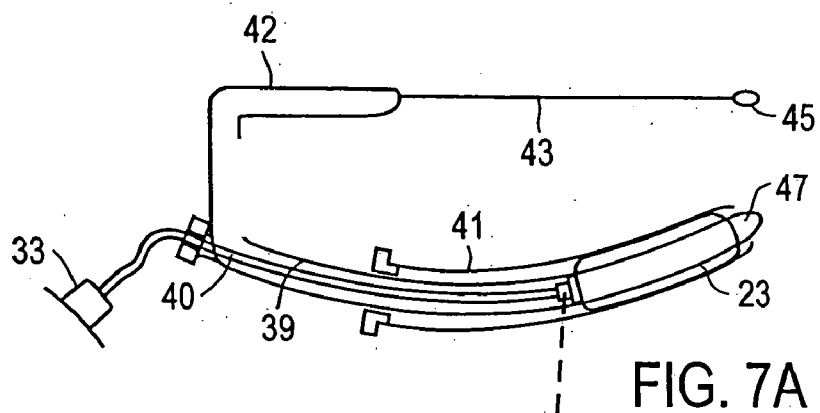


FIG. 6



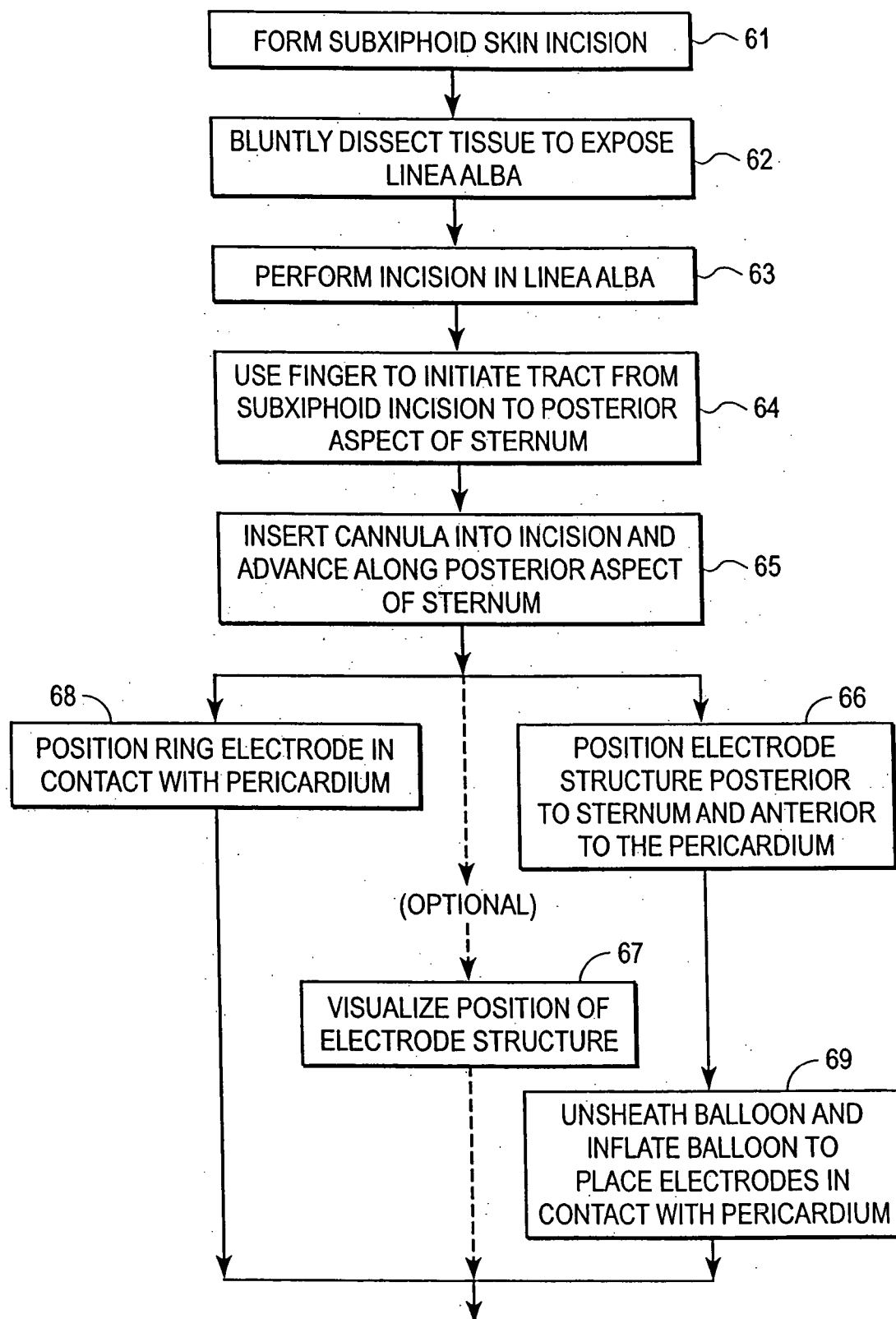


FIG. 11A

To FIG. 11B

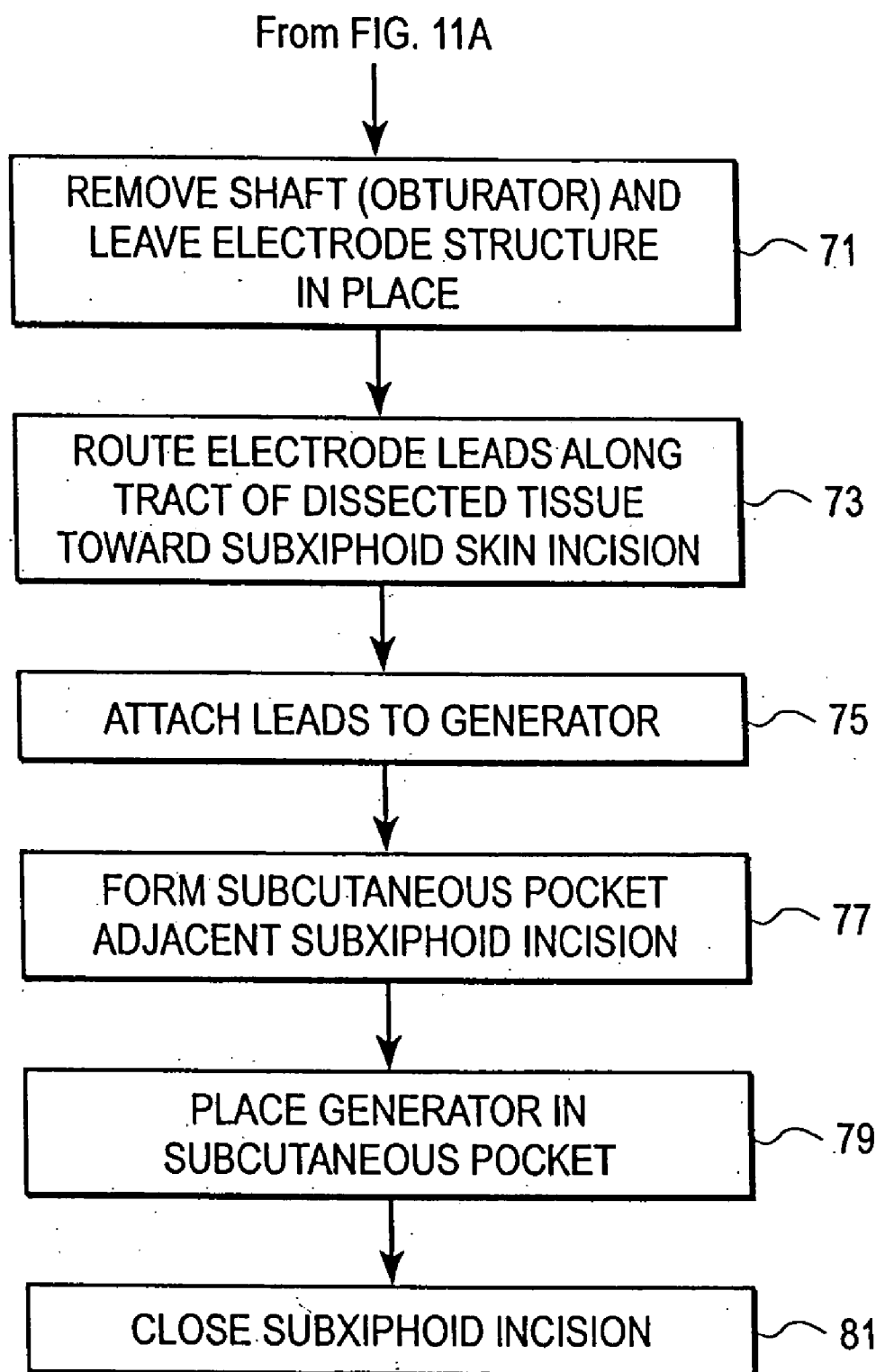


FIG. 11B

CARDIAC ELECTRODE ATTACHMENT PROCEDURE

RELATED CASES

[0001] This application claims benefit under 35 U.S.C. § 120 as a continuation of application Ser. No. 10/369,980 filed on Feb. 18, 2003 by Albert K. Chin, which is a continuation-in-part of application Ser. No. 10/346,663 entitled "Endoscopic Subxiphoid Surgical Procedures," filed on Jan. 17, 2003 by Albert K. Chin, and is a continuation-in-part of application Ser. No. 10/347,212, entitled "Apparatus and Methods for Endoscopic Surgical Procedures," filed on Jan. 17, 2003 by Albert K. Chin, which applications are incorporated in their entireties herein by this reference thereto.

FIELD OF THE INVENTION

[0002] This invention relates to surgical instruments and procedures for placement of cardiac pacer or defibrillator electrodes, particularly via subxiphoid incision and insertion of an electrode structure in an extrapericardial position with a connected generator disposed in a subcutaneous pocket adjacent the subxiphoid incision.

BACKGROUND OF THE INVENTION

[0003] Contemporary surgical techniques for installing electrodes on the heart of a patient that is at risk for ventricular fibrillation or bradycardia arrhythmias commonly involves insertion of a wire electrode through the patient's venous system into the heart, and connection of the electrode to an implanted defibrillator or pacemaker. These procedures are commonly performed in a cardiac catheterization lab, under fluoroscopic x-ray guidance. It is desirable to place defibrillator or pacing electrodes in contact with the pericardium of the heart with minimal trauma and simple surgical techniques that can be rapidly implemented, with or without the need for fluoroscopic guidance.

SUMMARY OF THE INVENTION

[0004] In accordance with one embodiment of the present invention, an electrode structure includes an inflatable balloon having surface-oriented electrode patches for positioning extrapericardially at a posterior aspect of the sternum. The electrode structure is positioned via a subxiphoid incision and entry along a tract of dissected tissue to the posterior aspect of the sternum. Orientation of the electrode patches is gauged via radiological or mechanical techniques, and the balloon is inflated to engage the electrode patches on a surface thereof with selected regions of the pericardium. Surgical instruments for inserting and placing the electrode structure within the posterior aspect of the sternum are specifically configured to facilitate the placement via the subxiphoid entry. Associated electrical conductors are disposed substantially along the dissected tract to an implantable pacer or defibrillator that is inserted into a subcutaneous pocket formed adjacent the subxiphoid entry incision.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] **FIG. 1** is a pictorial view of the instrument in accordance with one embodiment of the present invention;

[0006] **FIG. 2** is a pictorial view of the instrument of **FIG. 1** with the outer sheath retracted;

[0007] **FIG. 3** is a bottom pictorial view of the instrument of **FIG. 2** with the balloon-electrode structure inflated;

[0008] **FIG. 4** is a bottom pictorial view of the electrode structure detached from the instrument;

[0009] **FIG. 5** is a side sectional view of the instrument of **FIG. 2** in position within a patient;

[0010] **FIG. 6** is a side sectional view of the electrode structure of the instrument of **FIG. 5** positioned within the patient;

[0011] **FIGS. 7A and 7B** comprise a pictorial view of another embodiment of the instrument according to the present invention illustrating the curved configuration of the instrument;

[0012] **FIG. 8** is a side sectional view of the instrument of **FIG. 7** positioned within a patient;

[0013] **FIG. 9** is an illustration of the electrode structure according to the present invention positioned within a patient's body;

[0014] **FIG. 10** is a partially cut away pictorial view of another embodiment of the present invention including a cannula-based electrode structure; and

[0015] **FIGS. 11A and 11B** comprise a flow chart illustrating one method embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0016] Referring now to **FIG. 1**, there is shown a pictorial sectional view of one embodiment of the instrument in accordance with the present invention. Specifically, a central elongated hollow shaft **9** includes a handle **11** attached to the proximal end of the shaft **9**, and includes a fitting or connector **13** on the distal end of the shaft **9**. A mating connector **15** is detachably engaged with the connector **13**, and is attached to the proximal end of a hollow support shaft **19** that includes a tissue-dissecting tapered tip **21** on the distal end. An inflatable member **23**, preferably inelastic, as later described herein, is also supported on the shaft **19**, and is shown furled or rolled around shaft **19** in an undeployed configuration. Electrically conductive patches **25**, **27**, as illustrated in the bottom views of **FIGS. 3 and 4**, include electrical conductors **29** that extend from the member **23** toward the proximal end of the shaft **9**. An outer hollow sheath **31** is slidably mounted on the central shaft **9** and extends distally over the mating connectors **13**, **15**, and over the balloon or inflatable member **23** in undeployed configuration substantially to the base of the tapered tip **21**. The cable of electrical conductors **29** is also confined within the outer sheath. A port **33** communicates with the hollow central shaft **9** for supplying fluid under pressure through the shaft **9** to the inflatable member **23** supported on shaft **19**. The instrument illustrated in **FIG. 1** is thus configured for insertion into a patient in a manner as later described herein, with the tapered tip **21** aiding advancement of the instrument through a tissue-dissected channel from the subxiphoid incision toward the anterior pericardium.

[0017] The proximal end of the support tube **19** may be internally threaded, and mating threads on the distal end of the central shaft **9** screw into the support tube to fix the balloon **23** onto the central shaft. The hub **15** attached to the

proximal end of the support tube **19** includes a non-round cavity that mates with the corresponding connector **13** on the distal end of the central shaft. Thus, when the support shaft **19** and the central shaft **9** are screwed together, or are otherwise detachably connected, the assembly may be rotated, and torque may be transmitted to the tip **21** of the instrument for bluntly dissecting tissue. Keying of the connectors **13**, **15** in this manner also preserves the orientation of the balloon **23** so that the patch electrodes **25**, **27** can be properly oriented on the inferior surface of the balloon during placement thereof on the anterior pericardium. In one embodiment, the balloon **23** deflates upon detachment of the central shaft **9** from the support shaft **19**. However, the balloon **23** stays in position on the anterior pericardium due to the conformance of the balloon **23** to the extra-pericardial cavity formed during balloon inflation. Similarly, frictional members or small protrusions can be disposed on the balloon **23** to maintain the position of the electrodes.

[0018] In another embodiment of the invention, a sealing valve may be added to the connector **15**, such as a check-ball valve **35**, to ensure that the balloon does not deflate upon detachment of the central shaft **9**. The balloon retained in inflated configuration is less likely to migrate out of position after insertion. After several days to several weeks, the balloon may be deflated via percutaneous needle puncture in the intercostal space. Additionally, the balloon surface may be coated or covered with fabric or coarse-mesh material or other suitable material **50** that promotes fibrous adhesions to hold the balloon in place. Such coating or covering may be applied to the side opposite the patch electrodes **25**, **27**, or may be on both sides of the balloon except at the locations of the electrodes.

[0019] Referring now to **FIG. 2**, there is shown a pictorial sectional diagram of the instrument in **FIG. 1** re-configured with the outer sheath **31** drawn back proximally to the handle **11** to expose the inflatable member **23** and the mating connectors **13**, **15** between central shaft **9** and support shaft **19**. In this configuration, the inflatable member **23** can be inflated with fluid (e.g., air or saline solution) under pressure to deploy the inflatable member **23**, as illustrated in **FIG. 3**.

[0020] The inflatable member **23** includes two substantially circular membranes of flexible but substantially inelastic material such as mylar or polyurethane that are bonded together substantially only around the periphery thereof (and to the support shaft **19**) to form a disk-like balloon having an interior between the membranes that is disposed in fluid communication with the hollow support shaft **19**. One disk-like surface of the member **23** supports one or more electrode patches **25**, **27** that are spaced apart to form pericardium-engaging contact electrodes. The patch electrodes **25**, **27** may include surface pads of sputtered metal or organic conductive compounds or mesh or spiral grids that are affixed to the outer surface of the posterior membrane, as shown in the bottom view of **FIGS. 3 and 4**. The space between the membranes may thus be pressurized to expand the thickness of the member **23**. The mating connectors **13**, **15** may include a check valve such as a spring-biased ball **35** against a valve seat in connector **15** for retaining fluid pressure within the member **23** once pressurized through the central shaft **9** and support shaft **19**. Thereafter, the mating connectors **13**, **15** are detached or disconnected, leaving in place the inflated member **23** with attached shaft **19**, connector **15** and tip **21**, as shown in **FIG. 4**. The cable **29** of

electrical conductors connected to the electrode patches **25**, **27** may be suitably routed, as discussed later herein, for connection via connector **37** to an implantable defibrillator or pacer unit **53**.

[0021] Referring now to **FIG. 5** there is shown a pictorial side view of the instrument of **FIG. 1** being positioned within a patient. To place the instrument as shown, an incision of about 2 cm length is formed in the subxiphoid region, and blunt dissection is conducted to expose the linea alba, which is also incised a length of about 2 cm. A surgeon's gloved index finger is inserted in the incision in a superior direction, and a tract is bluntly dissected to the posterior aspect of the sternum. The finger is withdrawn, and the instrument in the configuration of **FIG. 1** is inserted through the incision and advanced to dissect tissue along a path toward the posterior aspect of the sternum. The distal balloon **23** is constrained within the outer sheath **31** as the tapered tip **21** dissects tissue along the path. The maximal diameter of the portion of the instrument that is inserted into the body is approximately 10-12 mm, in the area of the sheathed balloon **23**. The instrument is inserted without a sweeping motion, keeping the dissected tissue tract limited to about the 12 mm diameter of the instrument. Torsion about the long axis of the instrument may be employed to advance the instrument through tissue substantially in contact with the posterior aspect of the sternum. This allows the instrument to form a tract anterior to the anterior surface of the pericardium without poking the heart. The instrument is advanced until the balloon member **23** is centered on the anterior surface of the heart **100**. Advancement of the instrument may be performed under fluoroscopic visualization oriented in a lateral direction to visualize the tip **21** in contact with the posterior aspect of the sternum and directed away from the heart **100**. The instrument may be straight and rigid, as shown in **FIG. 1**. Once properly positioned, the outer sheath **31** of the instrument may be slid back along the central shaft proximally toward the handle **11** to expose the balloon member **23**, as shown. The balloon member **23** is inflated to occupy the region between the posterior aspect of the sternum and the anterior pericardium, with the patch electrodes **25**, **27** held resiliently in contact with the pericardium at selected locations, for example, adjacent the right atrium and the left ventricle. The central shaft **9** may then be detached from the support shaft **19** at the connectors **13**, **15**, leaving the member **23** pressurized in place (if connector **15** includes a check valve, as previously described), as illustrated in **FIG. 6**, or depressurized in place (if connector **15** does not include a check valve).

[0022] Another embodiment of the present invention, as illustrated in **FIG. 7**, facilitates placement of the inflatable member **23** without fluoroscopic guidance. Specifically, this configuration of the instrument includes a curved central shaft **39** and an outer sheath **41** of mating curve slidably mounted on the shaft **39** that is formed in a generally U-shape with the handle **42** extending up and forward ending generally parallel to the long axis of the shaft **39**. An indicator **43** may extend from the handle (or the shaft **39** and handle **42** may extend) to position the tip **45** of the indicator, when in use, outside the body corresponding to the position of the tip **47** inside the body. The portion of the instrument for positioning inside the body is curved concave upwardly so that, as the instrument is advanced, the tip **47** is directed into contact with the posterior sternal surface, as shown in **FIG. 8**. A standard chest X-ray of the patient in an AP

(anterior-posterior) orientation may be used initially to determine a desired position of the tip 47 of the instrument. The heart shadow in an AP chest X-ray and its position with respect to the rib cage and sternum can be noted with reference to a correct placement of the tip 47 of the instrument in order to position the balloon 23 and electrode pads 25, 27 on the heart. The patient's chest is palpated to count the ribs and delineate the sternal edge, and the desired spot for location of the tip 47 may be marked on the patient's skin. When the instrument is inserted through the subxiphoid incision and advanced superiorly, the external indicator 43, 45 aligns with the patient's skin marking, and the internal portion of the instrument including the balloon 23 is correctly placed.

[0023] Once the instrument is advanced to the desired position, the sheath 41 is retracted to expose the balloon 23. The balloon is inflated to create a cavity anterior to the anterior portion of the pericardium. The balloon 23 contains two or more patch electrodes 25, 27, as previously described herein, that are oriented on the inferior side of the balloon. The balloon is substantially flat with an outer diameter of approximately 7-8 cm. Balloon inflation creates a cavity in adjacent tissue that conforms to the dimensions of the balloon 23 to hold the balloon 23 in the correct position against the heart 100, as shown in FIG. 9. Following balloon placement, the shaft 39 and handle 42 are detached from the balloon 23 by unscrewing the flexible mounting shaft 40 from the mating threaded connector 44 on the electrode structure to remove the central shaft 39 and sheath 41 and handle assembly 40, 42, 43 from the patient, leaving the balloon-oriented electrode structure 23 in place. Detachment of the mounting shaft 40 may facilitate deflation of the balloon 23 (in the absence of a check valve, as previously described herein), or may leave the balloon 23 inflated (with a check valve installed). The cable 29 of insulated conductive leads connected to the patch electrodes 25, 27 is routed through the tract of dissected tissue back to the subxiphoid incision 51, and is connected to the implantable generator 53 (pacer or defibrillator). The generator 53 is inserted into a subcutaneous pocket formed adjacent the subxiphoid incision 51.

[0024] Referring now to FIG. 10, there is shown a partially cutaway pictorial view of another embodiment of the present invention in which a linear defibrillation or pacing cannula 46 of suitable flexibility may be advanced from a subxiphoid incision into position on the anterior pericardium. The cannula 46 may have two or more ring electrodes 48, 52 near its distal end, allowing conduction through the pericardium to the heart when the cannula 46 is positioned and the conductive leads 54, 55 from the ring electrodes 48, 52 are connected to the implantable generator 53. The circumferential ring electrodes 48, 52 ensure that electrical contact occurs with the anterior pericardium regardless of the angular orientation of the cannula 46 about its axis of elongation. The cannula 46 includes a central lumen 56 to accommodate a rigid obturator 58 that increases the stiffness of the cannula 46 and facilitates its advancement through tissue. Alternatively, the obturator may be disposed about the cannula as an outer sheath or tube. Conductive wires 54, 55 from the electrodes 48, 52 to the proximal end of the cannula 46 and connectors 57, 59 on the proximal end of the conductive wires 54, 55 interface with the generator unit 53 that is implanted near the subxiphoid incision, as previously described herein. Cannula insertion is performed by advancement in a straight line from the subxiphoid incision, without sweeping the cannula 46 back and forth. Torsion or

twisting of the cannula 46 may be performed during insertion to facilitate advancement through tissue. Following insertion of the cannula 46 into position of the ring electrodes 48, 52 contacting the anterior pericardium, for example, in regions near the right atrium and left ventricle, the obturator 58 may be withdrawn from within the central lumen 56. Placement of the linear cannula 46 is simpler, as it does not require retraction of an overlying sheath or balloon inflation, and straight line insertion of the cannula 46 through tissue may adequately anchor the ring electrodes 48, 52 in contact with the anterior pericardium.

[0025] Referring now to the flow chart of FIGS. 11A and 11B, the procedure for placing an electrode structure in contact with the heart of a patient proceeds from initial formation of a subxiphoid entry incision 61. Blunt tissue dissection is performed to expose the linea alba 62 which is incised 63. The surgeon uses a gloved finger to dissect an initial tract 64 from the subxiphoid incision to the posterior aspect of the sternum. The instrument supporting the electrode structure, in a configuration as illustrated in FIG. 1 or 7 or 10, is inserted 65 into the initial tract and is advanced through tissue to a position posterior the sternum and anterior the anterior pericardium. The proper positioning of the instrument in an embodiment as illustrated in FIG. 1 or FIG. 10 can be verified 67 using such radiological visualization as fluoroscopy or x-ray imaging. Alternatively, proper positioning of the electrode structure may be accomplished without requiring radiological visualization and guidance of the instrument using the embodiment of the present invention in a configuration as illustrated in FIG. 7A. A standard chest x-ray of a patient in an AP orientation may be used initially to determine a desired position of the distal tip of the instrument. The heart shadow in such an x-ray image and its position relative to the rib cage and sternum can be designated for correct positioning of the distal tip and the associated electrodes for proper contact with the pericardium. The patient's skin may be marked to designate the correct positioning of the alignment tip 45 of the instrument in the configuration illustrated in FIG. 7A. Then, the instrument in this configuration is inserted through the subxiphoid entry incision, and is advanced superiorly until the external indicator 45 aligns with markings on the patient's skin to designate proper positioning of the electrode structure relative to the heart.

[0026] After the instrument in an embodiment of FIG. 1 or 7 is properly positioned posterior of the sternum and anterior of the anterior pericardium 66, the overlying sheath is slid back along the central shaft to expose 69 the electrode structure including the balloon 23 that supports the electrode pads 25, 27. The balloon is then inflated through the gas port 33 to expand the thickness of the electrode structure sufficiently to contact 69 the electrode pads 25, 27 with the anterior pericardium. Alternatively, the instrument in an embodiment of FIG. 7A is positioned 68 with the electrodes in contact with the pericardium. The proper position of the instrument can be verified, as previously described herein. Thereafter, the central shaft may be detached 71 from the electrode structure, leaving the balloon 23 and electrode pads 25, 27 in position, for removal of the central shaft and the overlying sheath from within the tract of dissected tissue. The removal of the sheath and central shaft of the positioning instrument also releases and positions 73 the cable of electrical conductors that are attached to the electrode pads within the tract of dissected tissue to extend toward the subxiphoid entry incision. These conductors are then attached to a generator 75. A subcutaneous pocket is formed

77 near the subxiphoid entry incision and the generator is implanted 79 in the subcutaneous pocket. The subxiphoid entry incision is then closed.

[0027] After the instrument in an embodiment of FIG. 10 is properly positioned posterior of the sternum and anterior of the anterior pericardium 68, the obturator 58 is withdrawn 71 from within the central lumen 56, leaving the ring electrode 48, 52 of the insertion cannula 46 in contact with the anterior pericardium. The conductive leads 54, 55 extend from the proximal end of the insertion cannula 46. These leads are positioned within the tract of dissected tissue 73 for attachment 75 to a generator, as previously described herein. A subcutaneous pocket is formed 77 adjacent the subxiphoid incision, and the generator with attached leads is placed within the pocket 79, and the subxiphoid incision is closed 81.

[0028] Therefore, the surgical instruments and surgical procedures for placing an electrode structure in contact with the heart advances an electrode structure through a subxiphoid access tract to a posterior aspect of the sternum and the anterior pericardium. The simplified surgical procedure using an embodiment of the present invention facilitates proper placement of the electrode structure with fluoroscopic visualization or x-ray positioning for minimal trauma to the patient. Conductive leads from contact electrodes of the electrode structure are routed along the access tract to the subxiphoid incision for connection to a pulse generator or defibrillator that is implanted within a subcutaneous pocket near the subxiphoid incision.

What is claimed is:

1. A surgical procedure for contacting electrodes supported on an electrode structure to the heart of a patient, the procedure comprising the steps for:

forming a subxiphoid incision on the patient;

dissecting tissue along a tract superiorly from the subxiphoid incision to a posterior aspect of the patient's sternum near the patient's heart for advancing the electrode structure through the subxiphoid incision and along the tract of dissected tissue to the posterior aspect of the patient's sternum; and

positioning the electrode structure within the region posterior to the posterior aspect of the patient's sternum and anterior to the patient's heart to form contact therewith of a number of the electrodes of the electrode structure.

2. The surgical procedure according to claim 1 including:

expanding the electrode structure within said region to form the contact with the pericardium outside the patient's heart by each of the number of electrodes.

3. The surgical procedure according to claim 1 in which the electrode structure includes an inflatable member and conductors extending from each of the number of electrodes, and further comprises the steps for:

inflating the member to contact the number of electrodes with the patient's heart; and

routing the conductors along the tract of dissected tissue toward the subxiphoid incision.

4. The surgical procedure according to claim 1 including a generator for supplying signals to the number of electrodes, and further comprising the steps for:

connecting a conductor for each of the number of electrodes to receive signals from the generator; and

implanting the generator subcutaneously in the patient near the subxiphoid incision.

5. The surgical procedure according to claim 3 performed using an insertion instrument and further comprising the steps for:

confining the inflatable member within the insertion instrument in one configuration thereof;

inserting the insertion instrument in the one configuration through the subxiphoid incision and along the tract of dissected tissue to the posterior aspect of the patient's sternum;

re-configuring the insertion instrument in another configuration to expose the inflatable member; and

disengaging the insertion instrument from the inflated member for removal of the insertion instrument through the subxiphoid incision.

6. The surgical procedure according to claim 1 including radiologically visualizing placement of the electrode structure advanced to the posterior aspect of the patient's sternum through the subxiphoid incision and along the tract of dissected tissue.

7. The surgical procedure according to claim 5 in which the insertion instrument is generally U-shaped with one portion for insertion through the subxiphoid incision, and with another portion in substantial alignment with the one portion and spaced therefrom, and further comprising the steps for:

inserting the one portion through the subxiphoid incision to position the electrode structure at the posterior aspect of the patient's sternum with said another portion extending outside the patient's body superiorly from the subxiphoid incision substantially coextensively with the one portion inside the patient's body.

8. The surgical procedure according to claim 7 further comprising the step for:

determining positioning indicia for said another portion of the insertion instrument on the outside of the patient's body superiorly of the subxiphoid incision for selectively positioning the one portion of the insertion instrument within the patient's body with reference to the positioning indicia.

9. The surgical procedure according to claim 1 performed with an electrode structure disposed near the distal end of an elongated flexible body, the procedure including the steps for:

selectively stiffening the elongated body for positioning the electrode structure; and

removing stiffening of the elongated body following positioning of the electrodes in contact with the patient's heart.

10. The surgical procedure according to claim 9 in which the elongated body slidably carries a substantially rigid obturator; and

removing stiffening includes removing the obturator carried by the elongated body.