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Urbanski et al.

(54) **APPARATUS AND METHODS FOR PUNCTURING TISSUE**

(71) Applicant: **Baylis Medical Company Inc.**, Montreal (CA)

(72) Inventors: **John Paul Urbanski**, Toronto (CA); **Brock Miller**, Toronto (CA); **Matthew Gravett**, Milton (CA); **Rund Abou-Marie**, Mississauga (CA); **Maria Luk**, Kleinburg (CA); **Ahmad Kamal**, Milton (CA)

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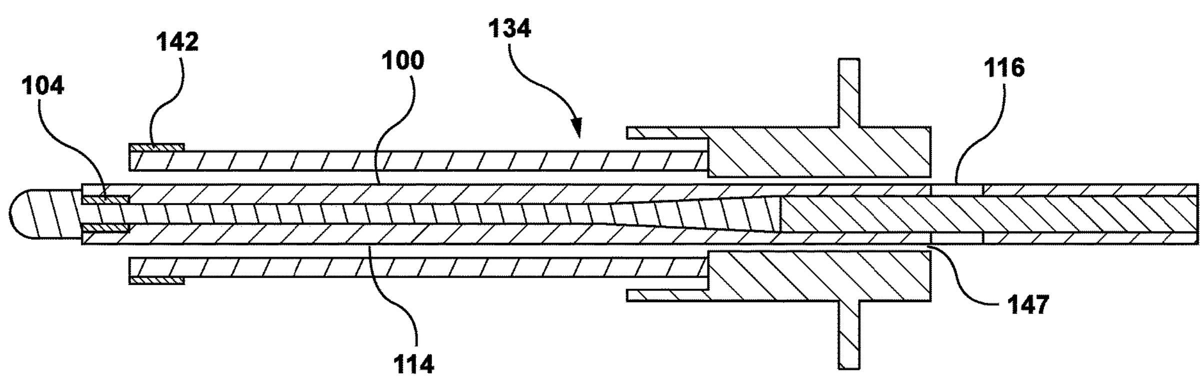
(57) **ABSTRACT**

A method and apparatus are disclosed for puncturing a target tissue. Apparatus includes an elongate puncture device having a tip electrode that is configured for collecting EGMs and for delivering energy for puncturing the target tissue. The method comprising collecting EGMs to indirectly measure and monitor a pressure applied against the target tissue by the elongate puncture device, thereby confirming a position of the tip electrode of the elongate puncture device relative to the target tissue.



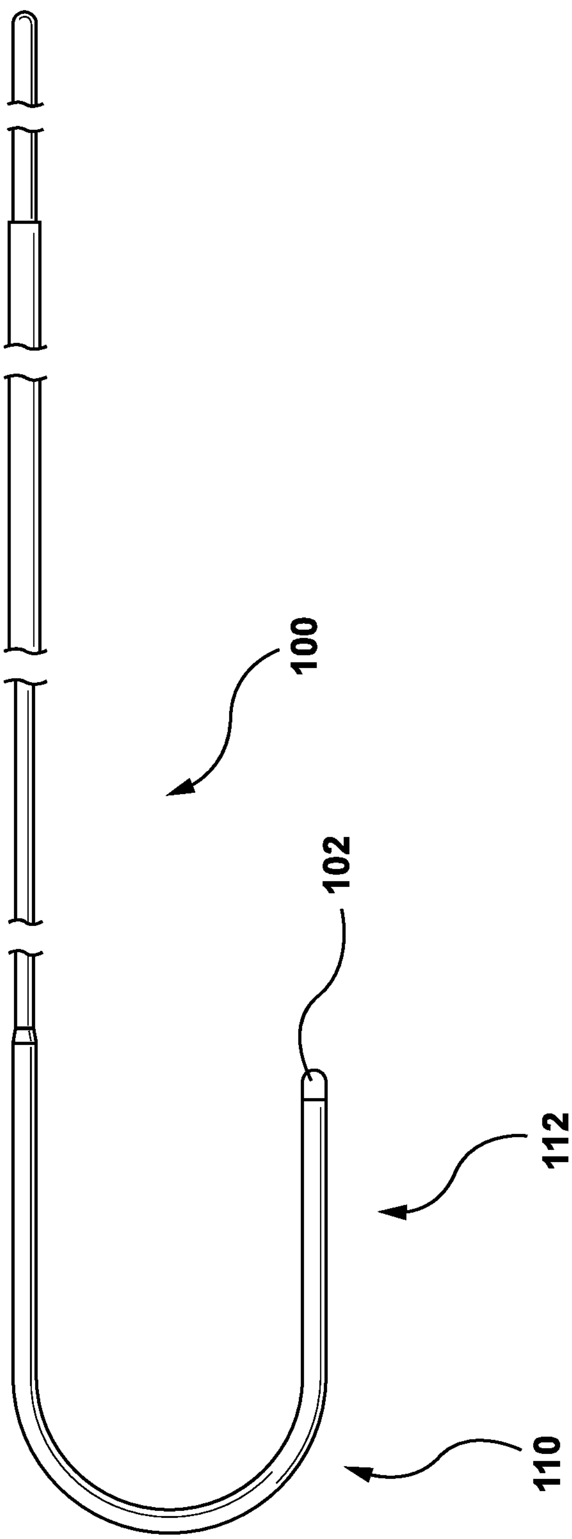


FIG. 1

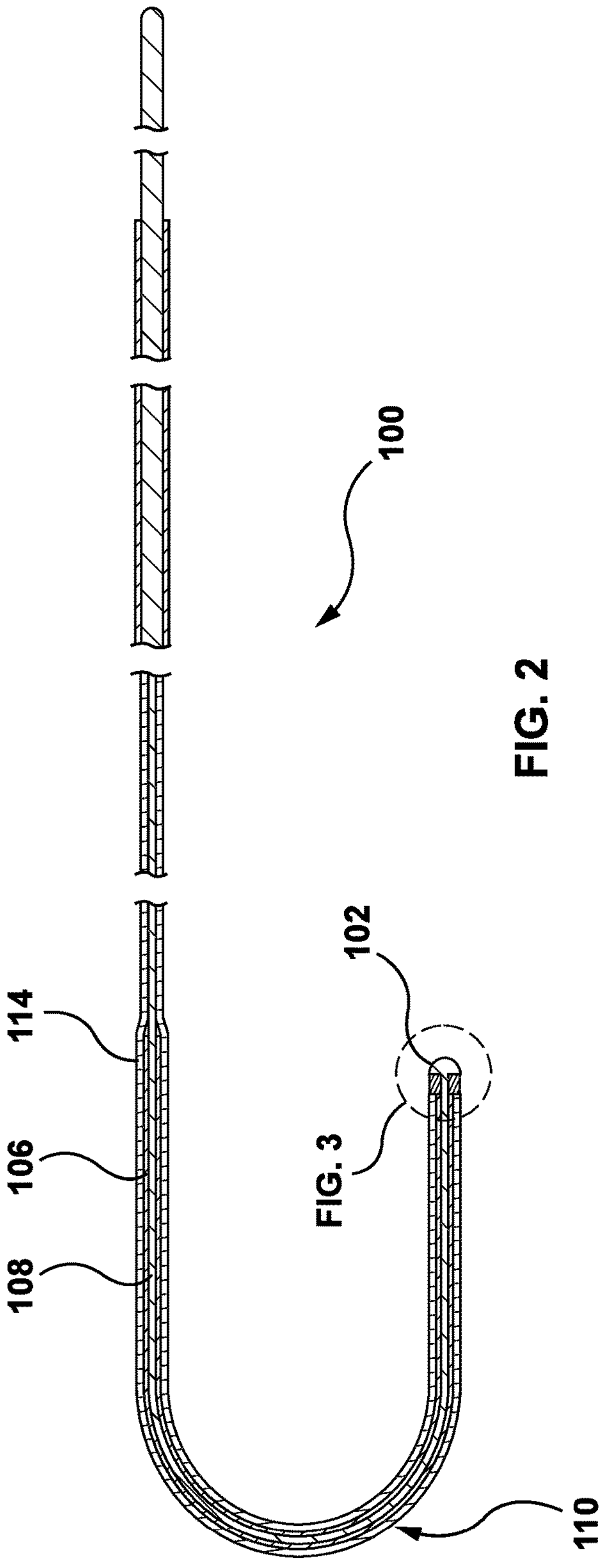


FIG. 2

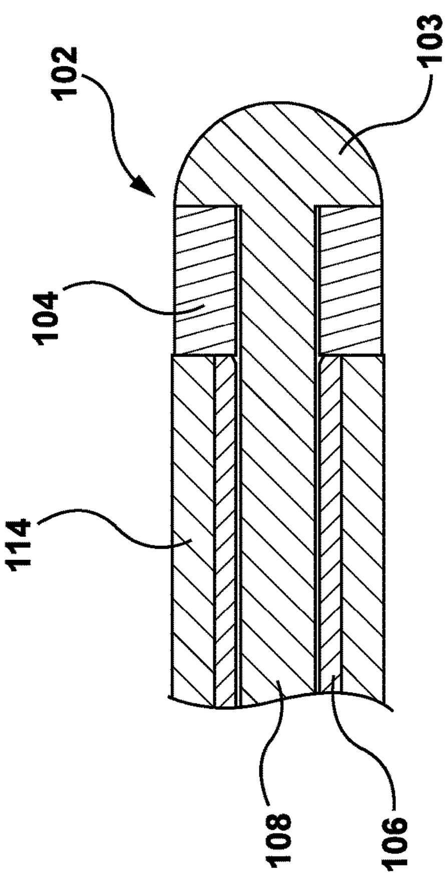


FIG. 3

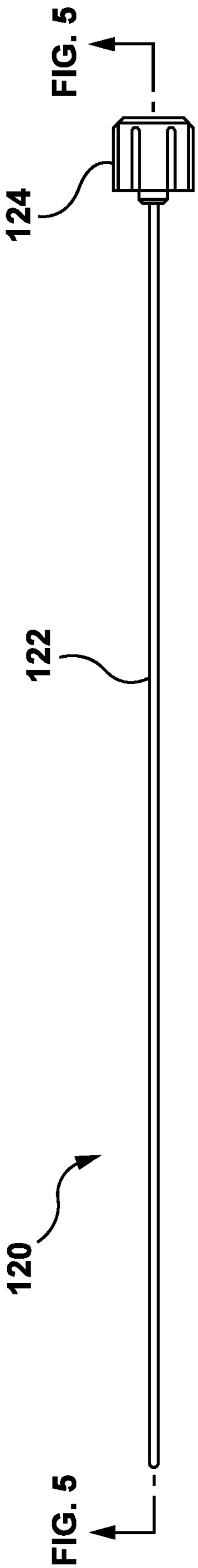


FIG. 4

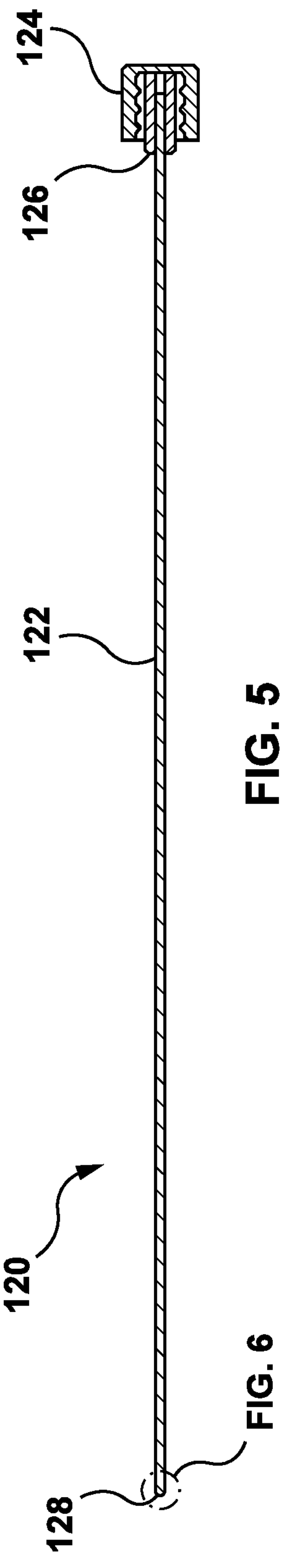


FIG. 5

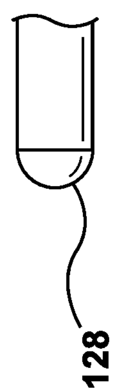


FIG. 6

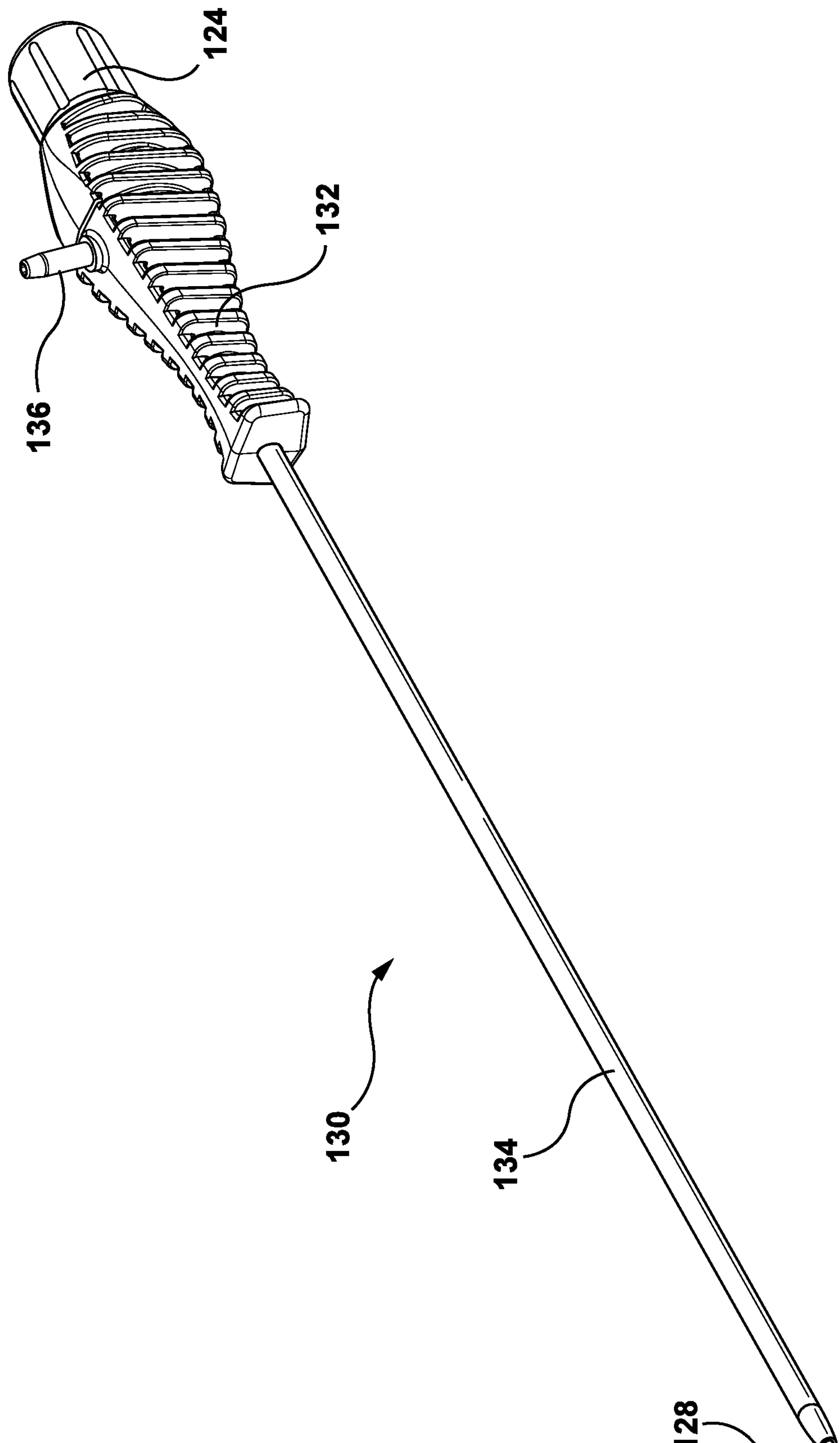


FIG. 7

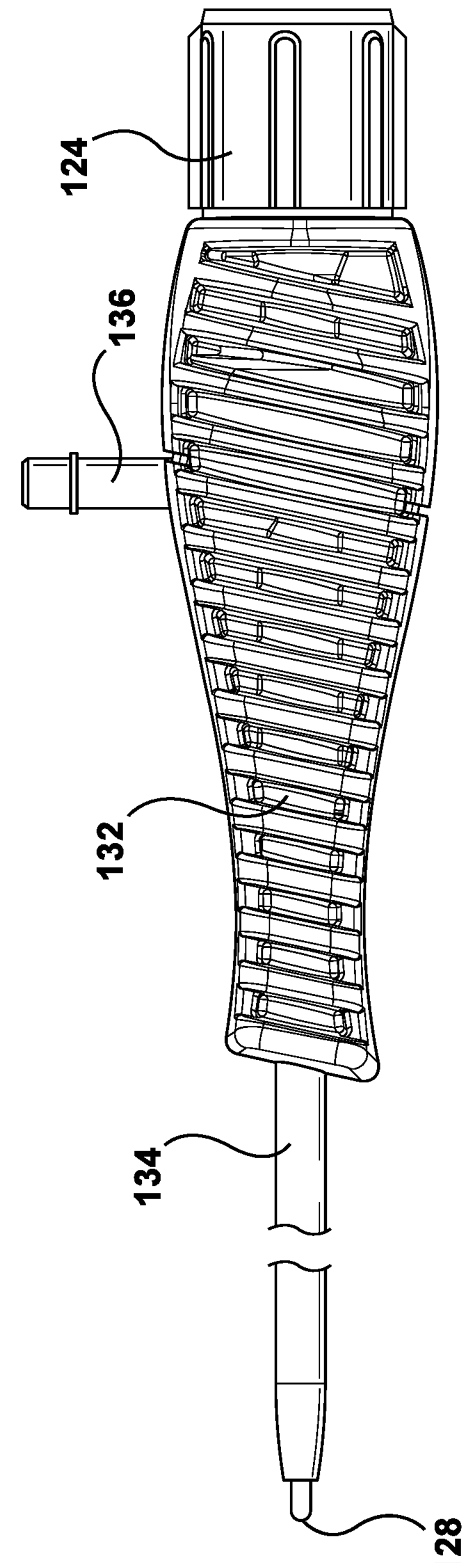


FIG. 8

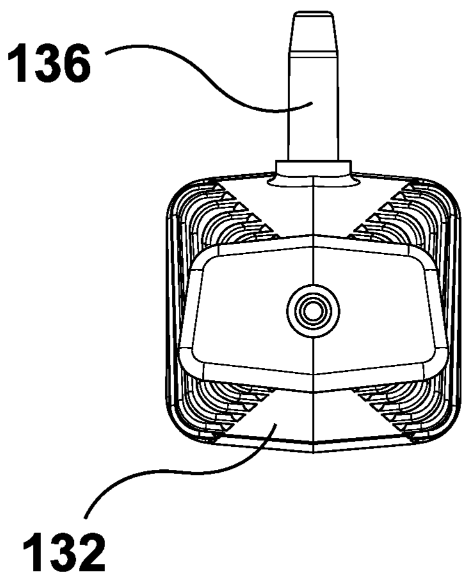


FIG. 9

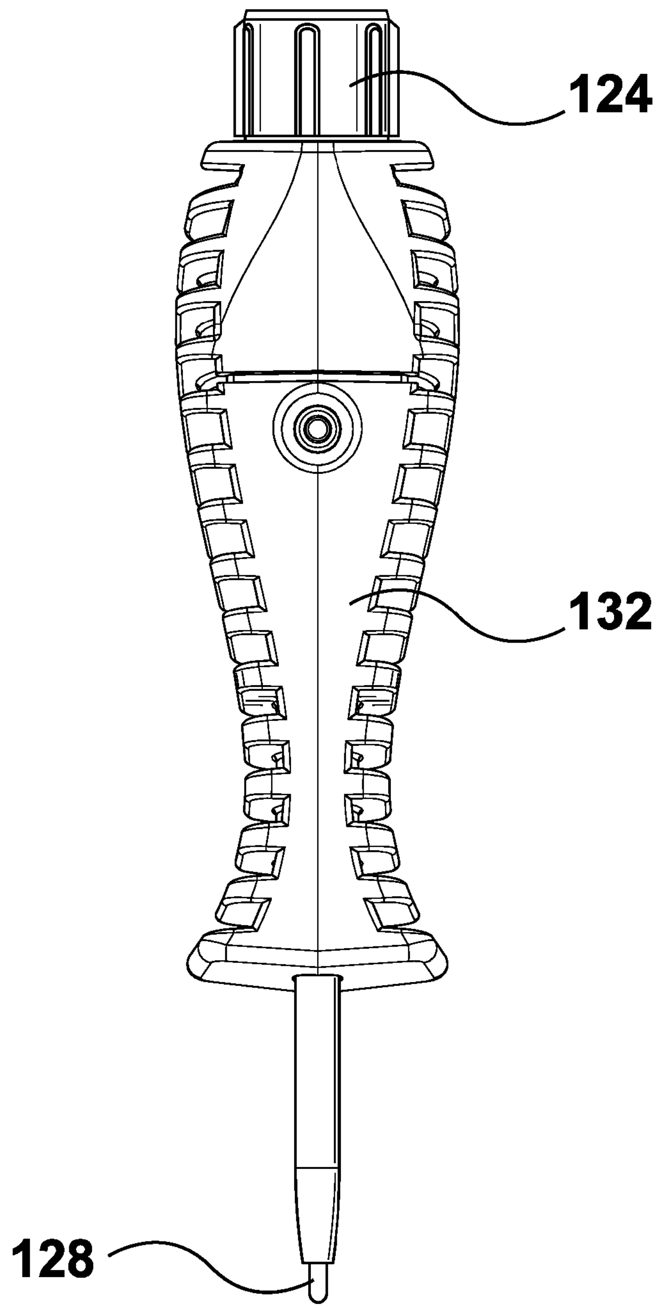


FIG. 10

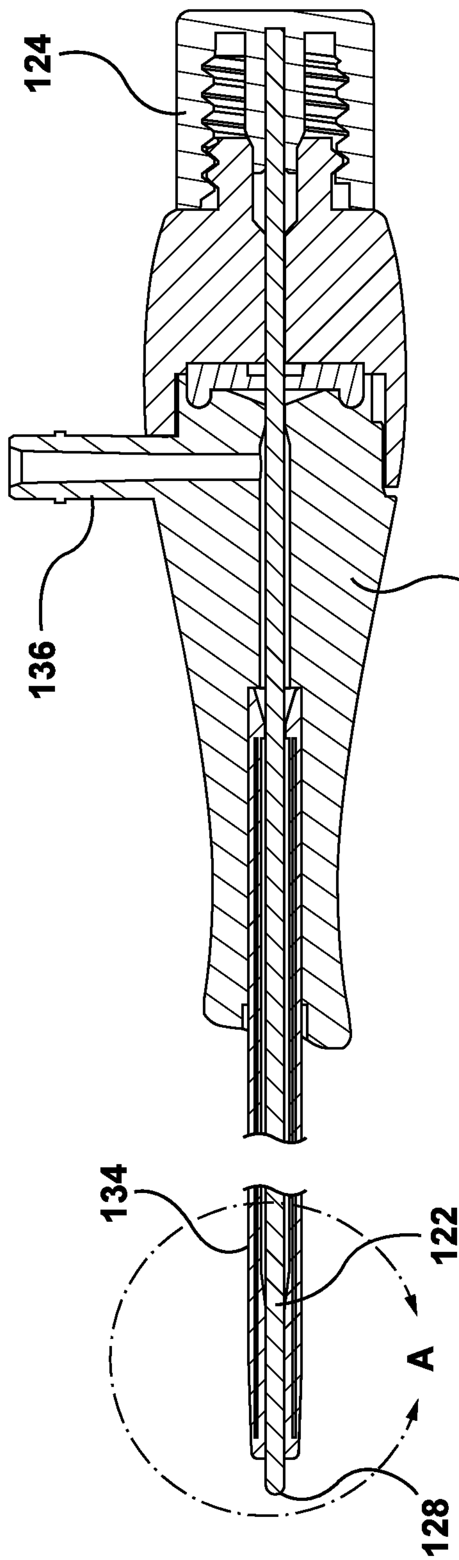
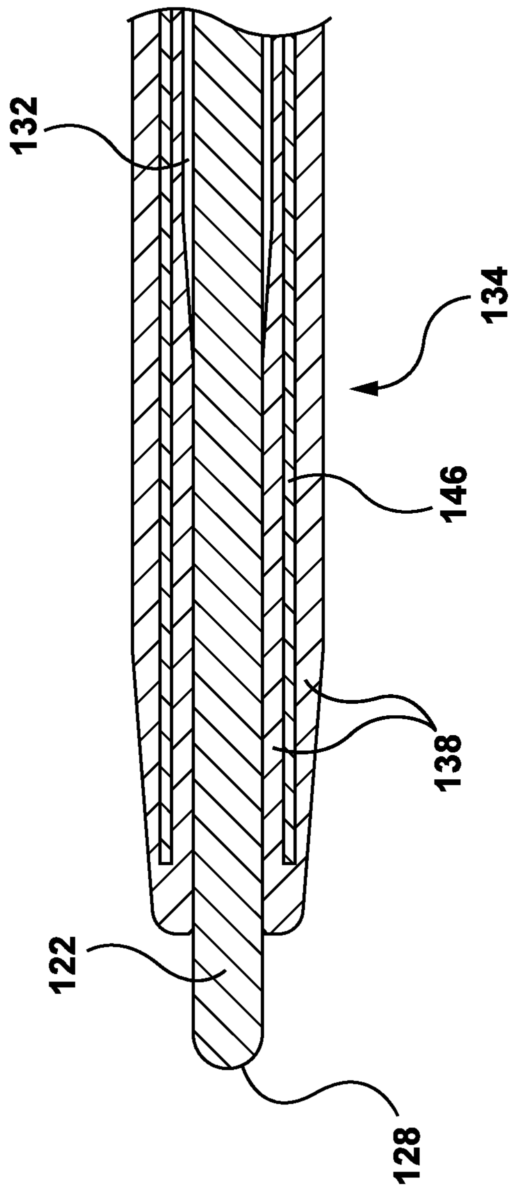


FIG. 11



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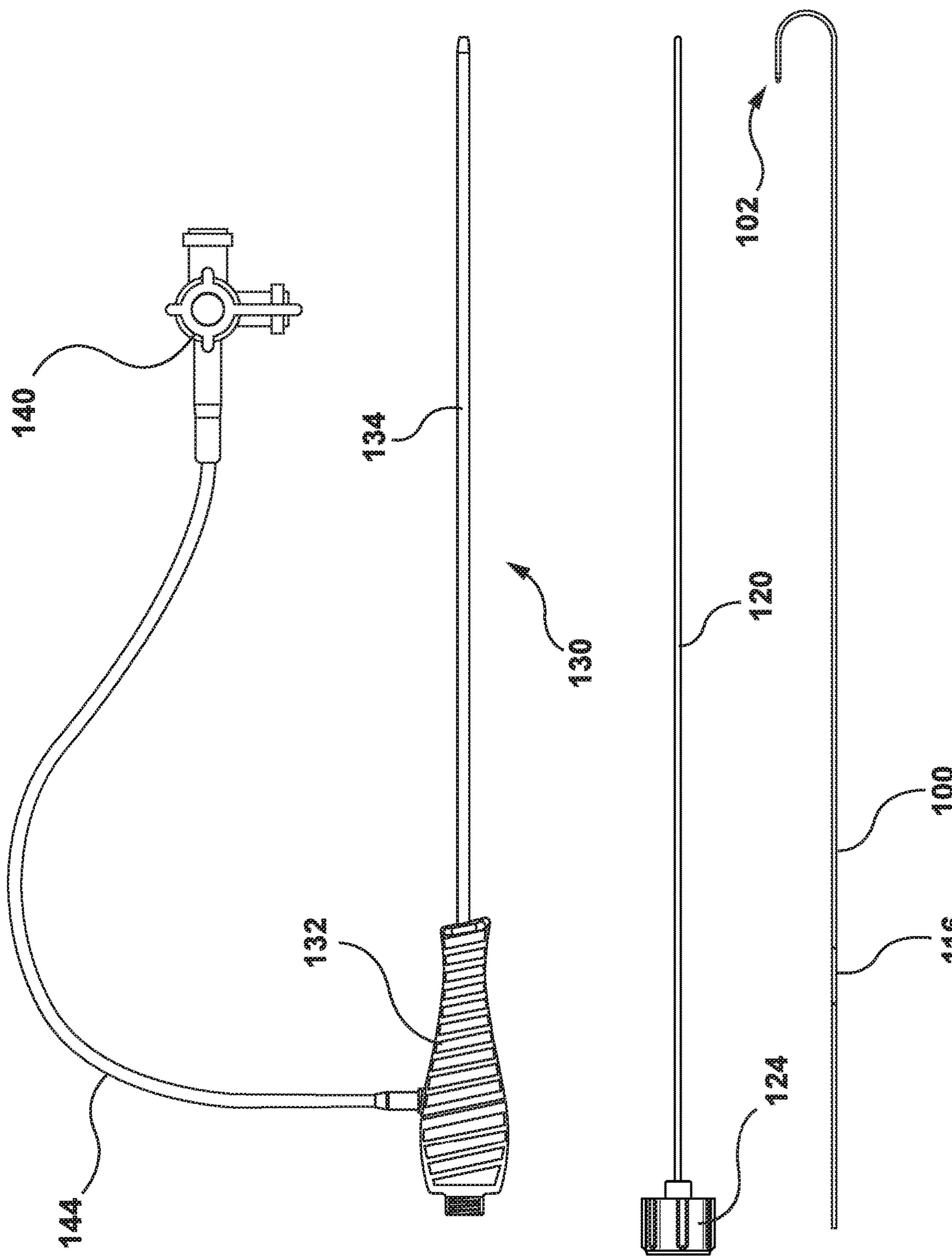


FIG. 13

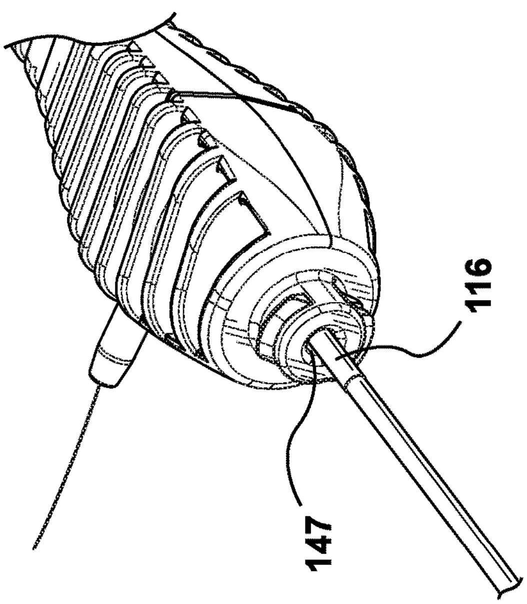
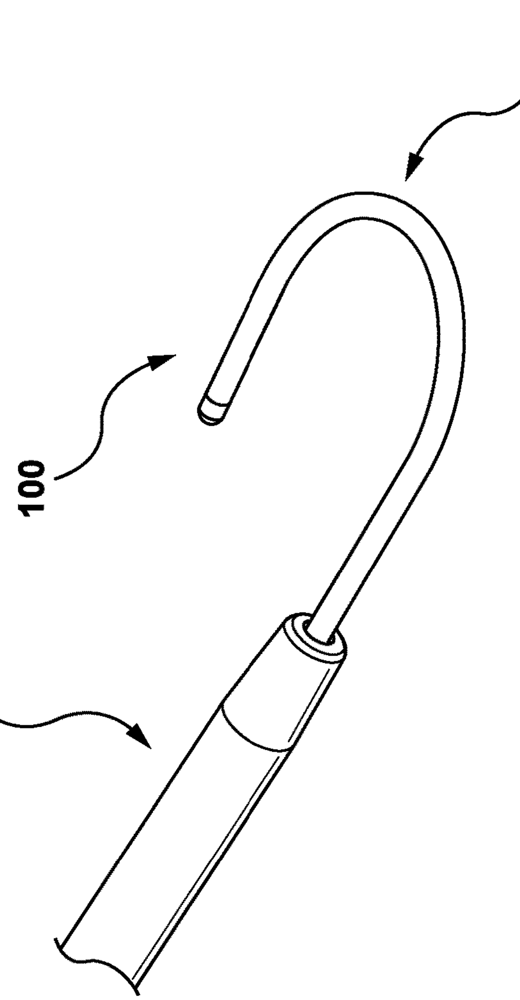


FIG. 16



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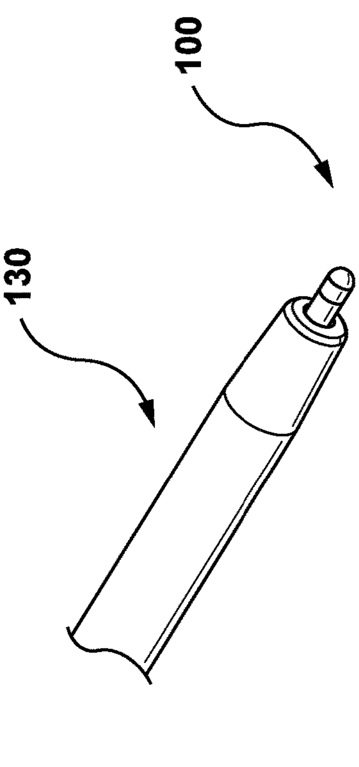
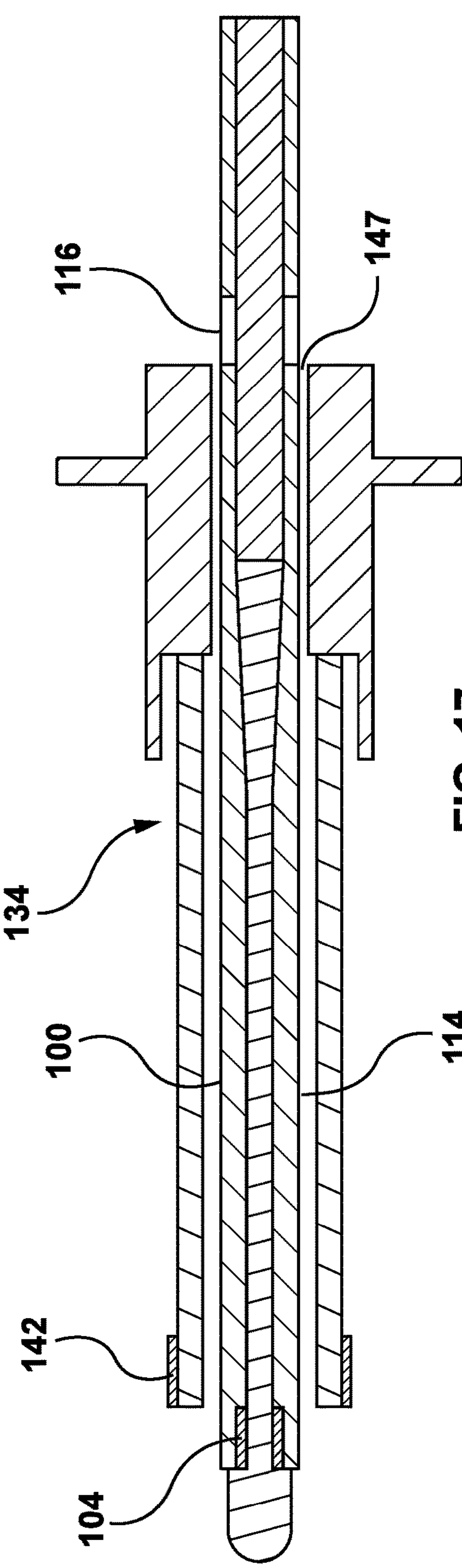


FIG. 14



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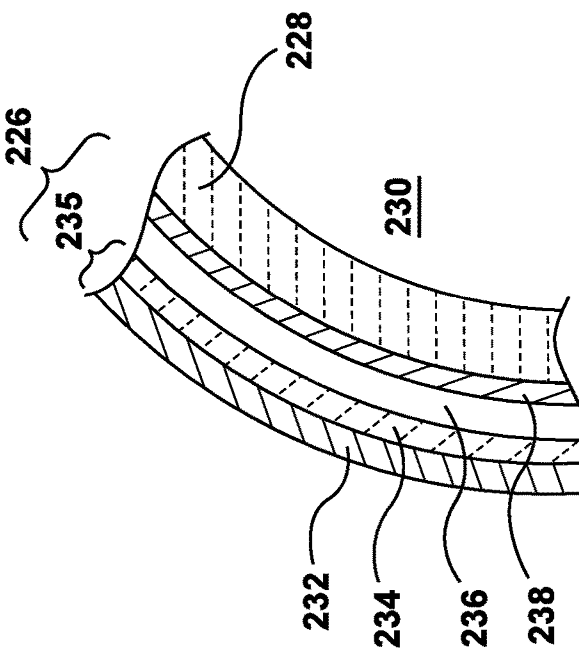

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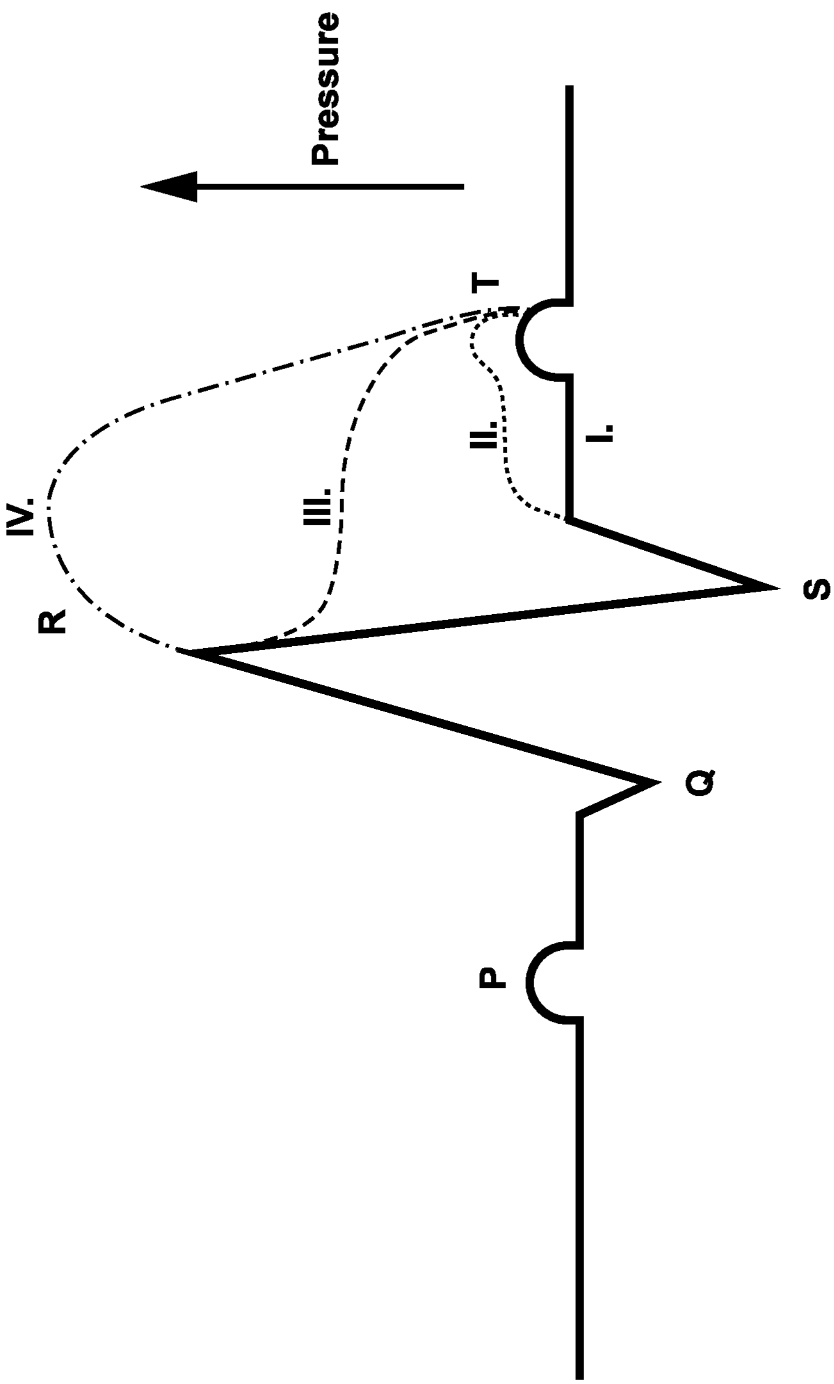

FIG. 19

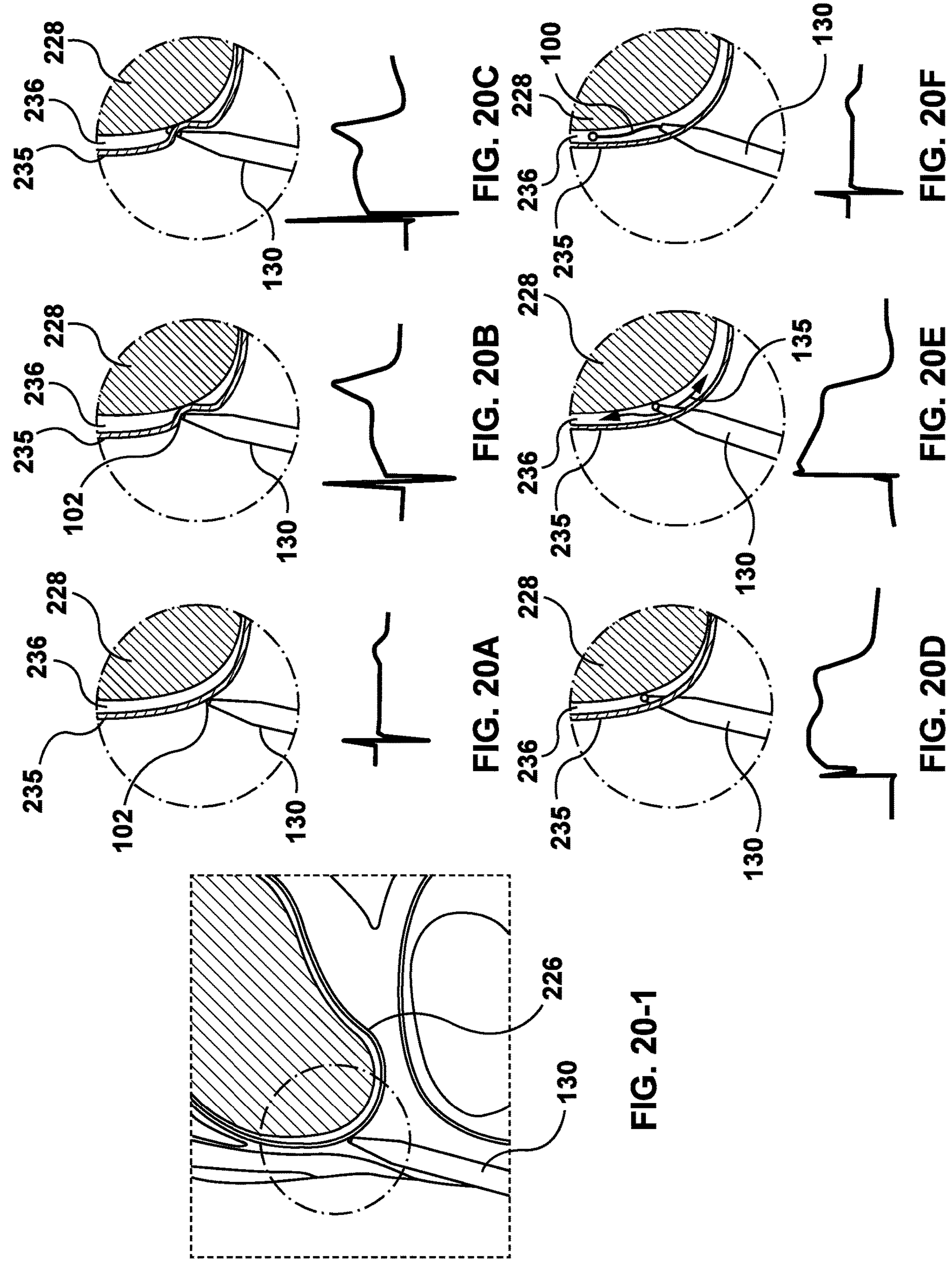

FIG. 20A

FIG. 20B

FIG. 20C

FIG. 20D

FIG. 20E

FIG. 20F

FIG. 20-1

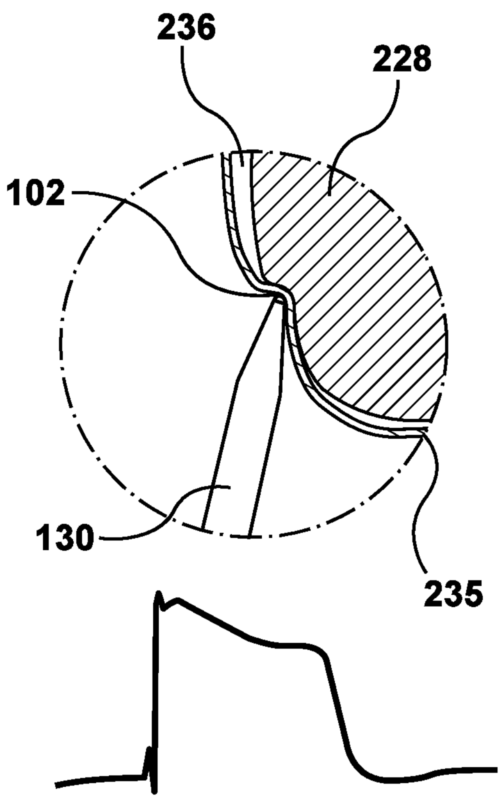

FIG. 21A

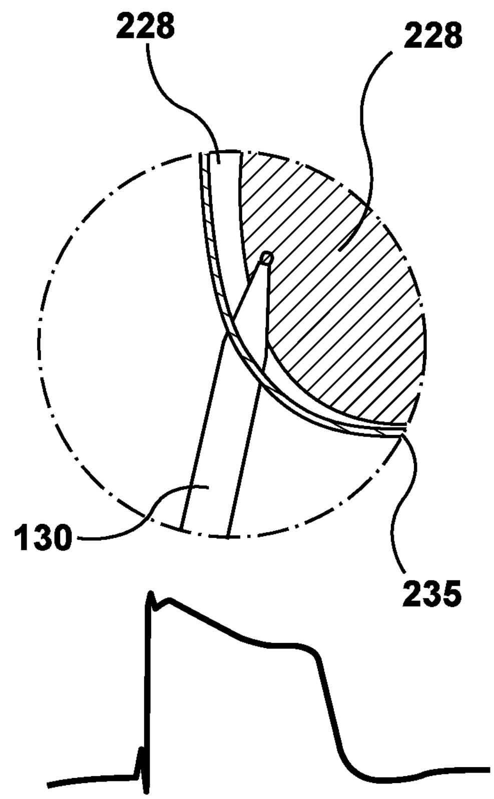

FIG. 21B

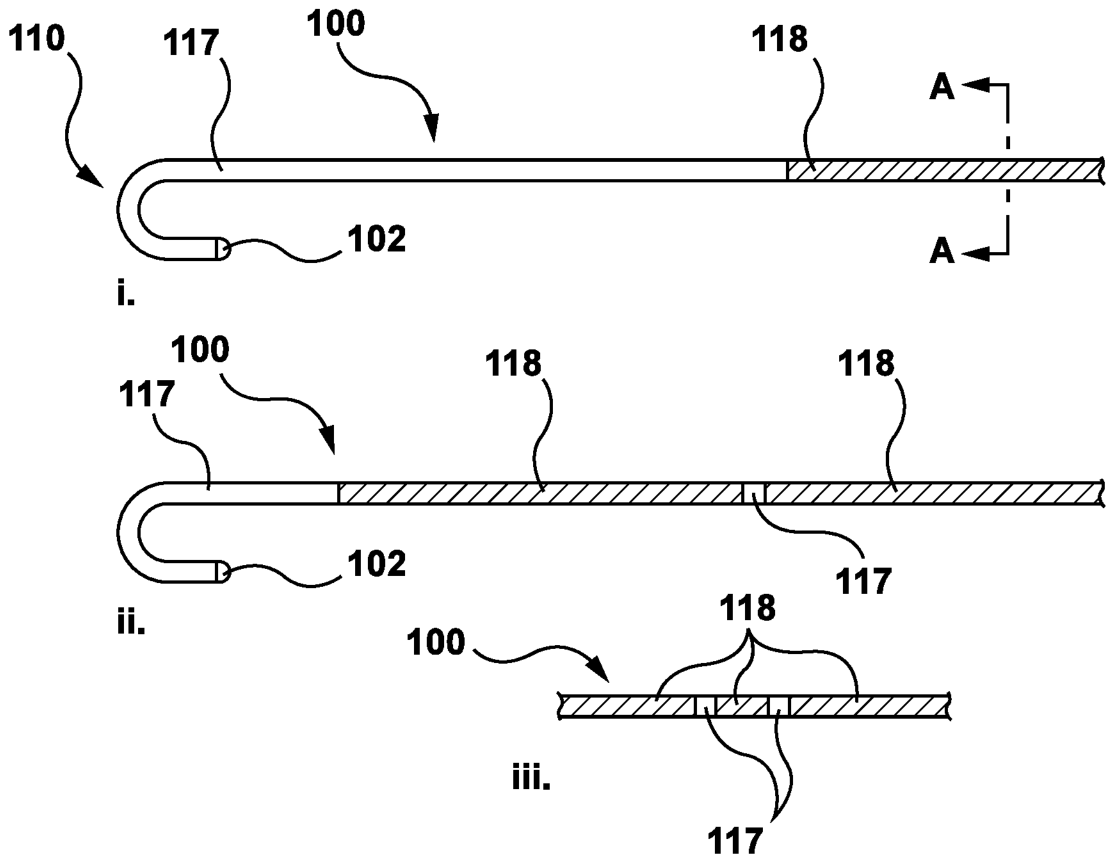

FIG. 22A

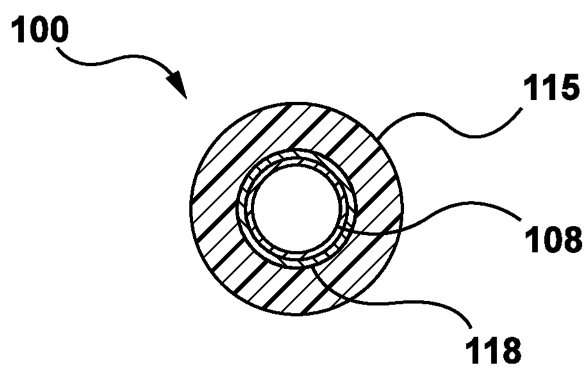

FIG. 22B

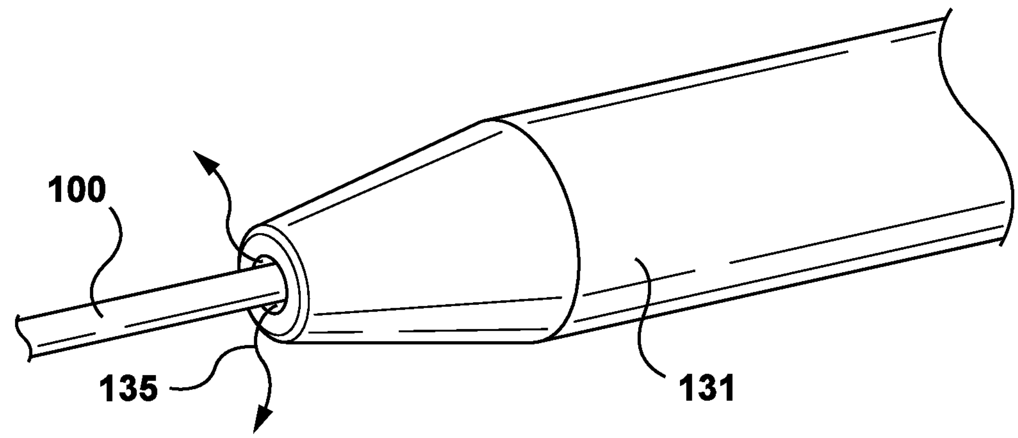

FIG. 23A

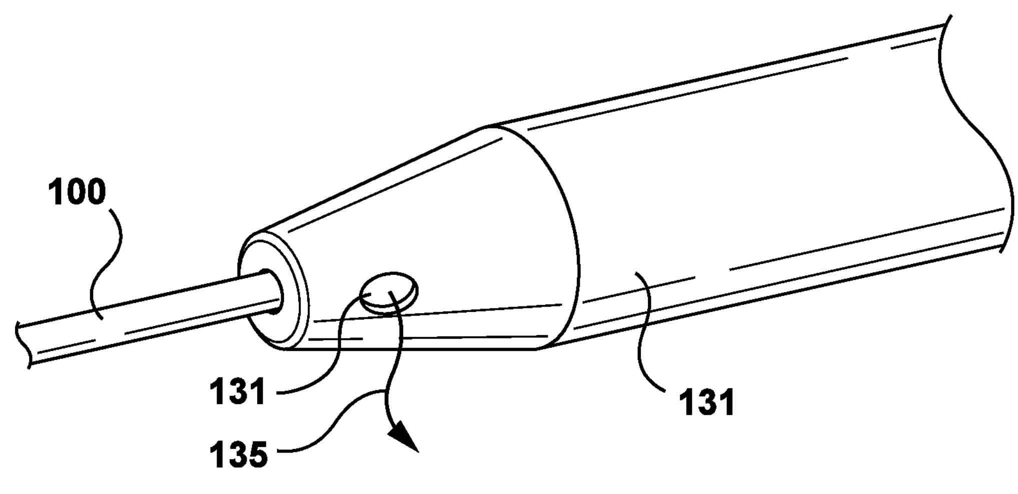

FIG. 23B

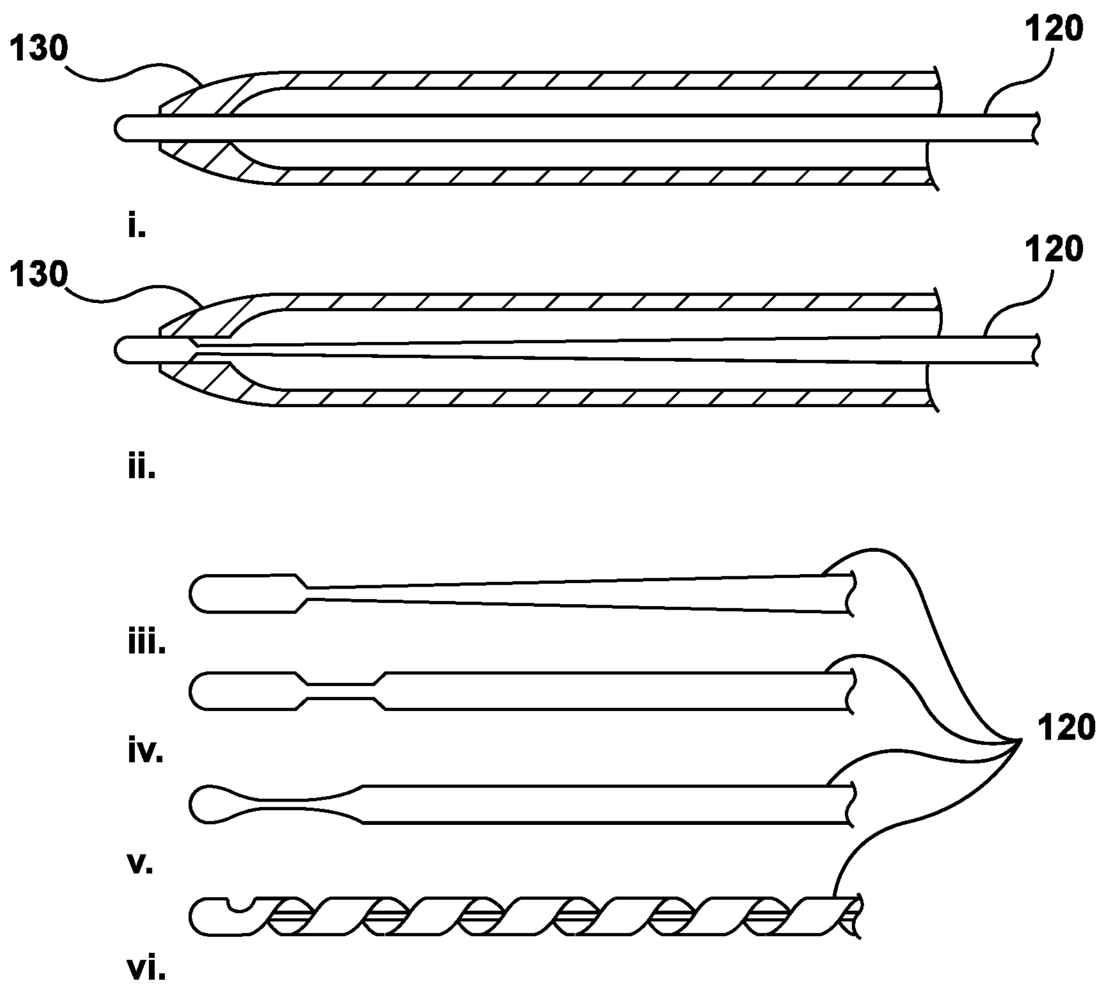

FIG. 24

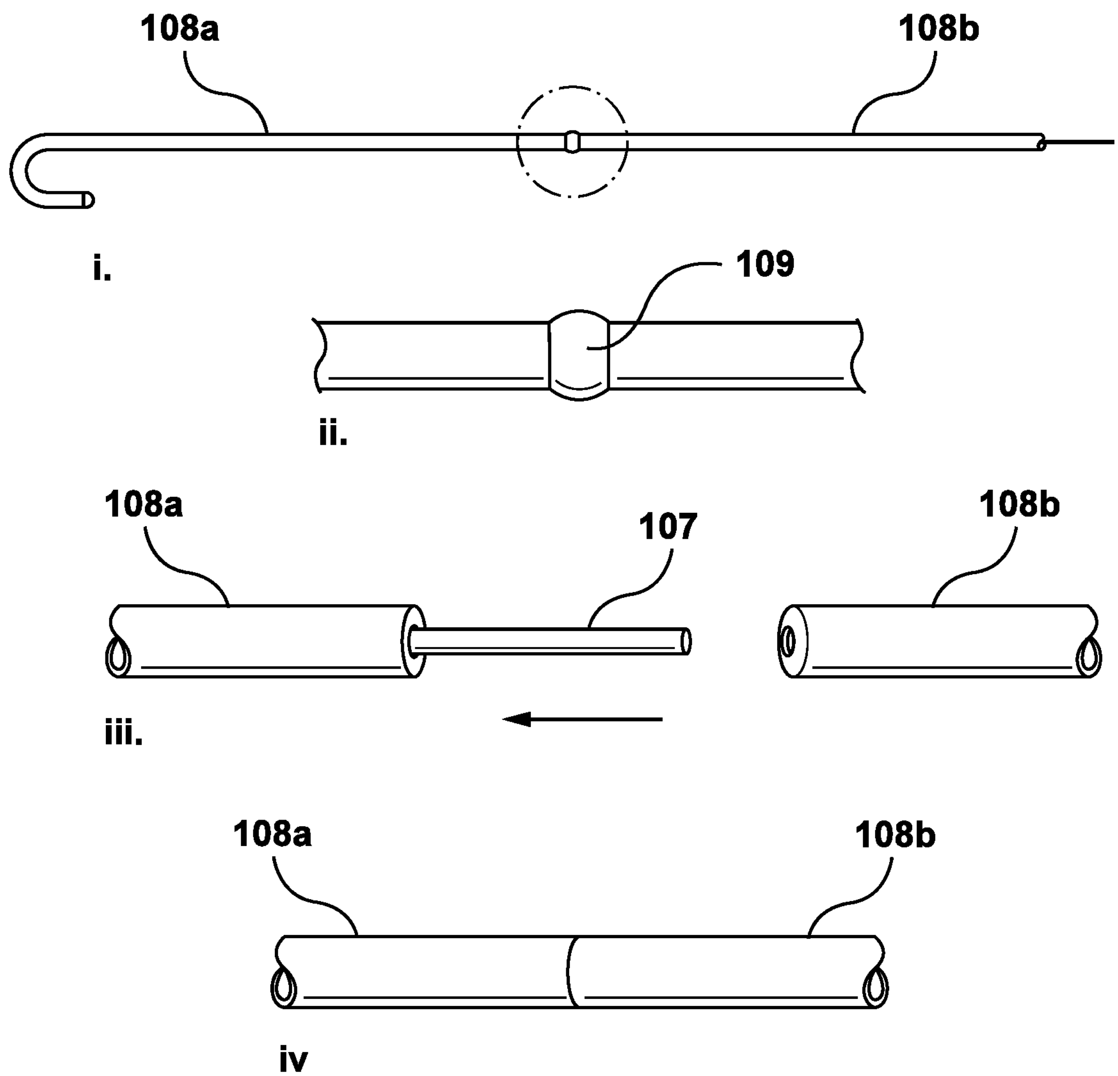

FIG. 25

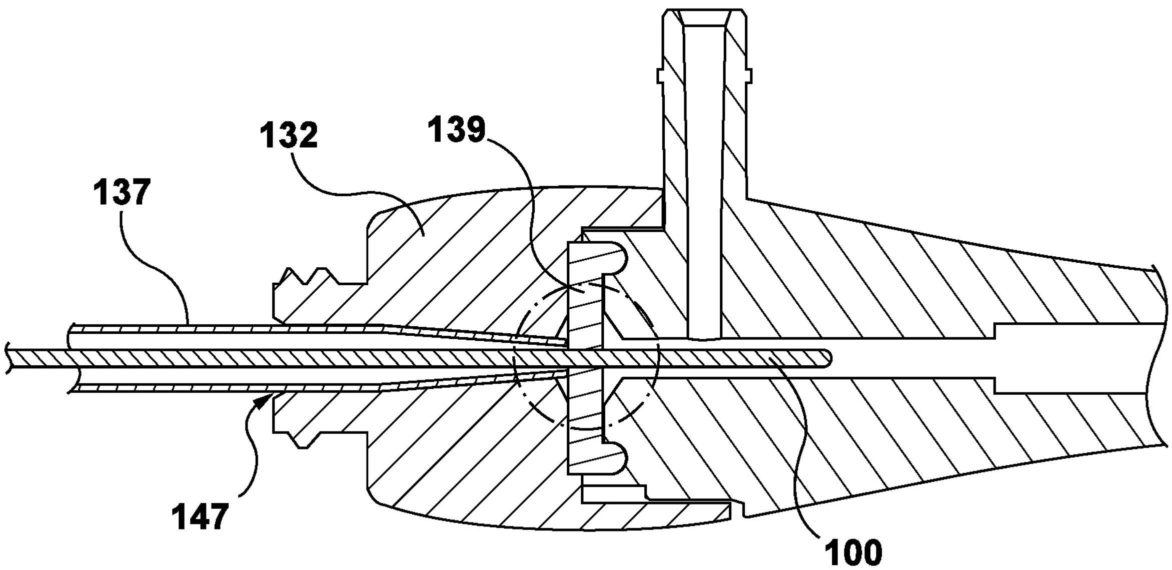

FIG. 26

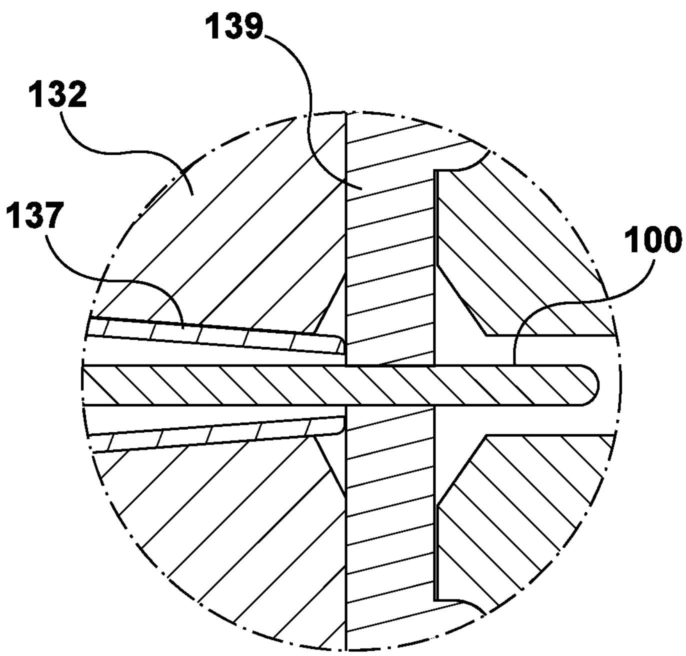

FIG. 27

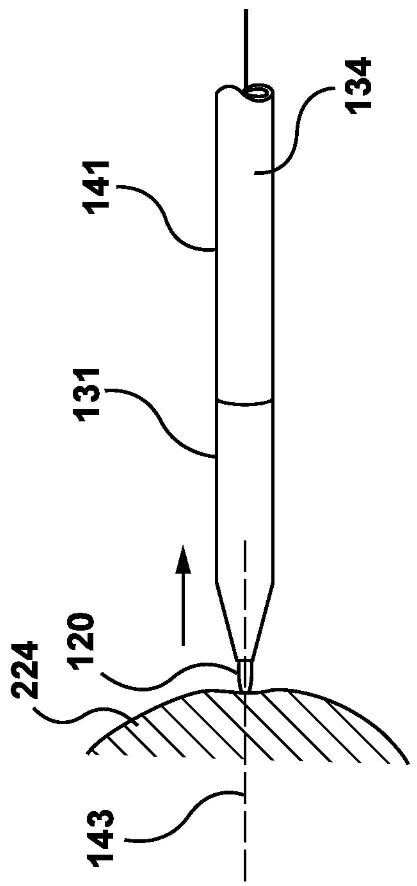

FIG. 29A

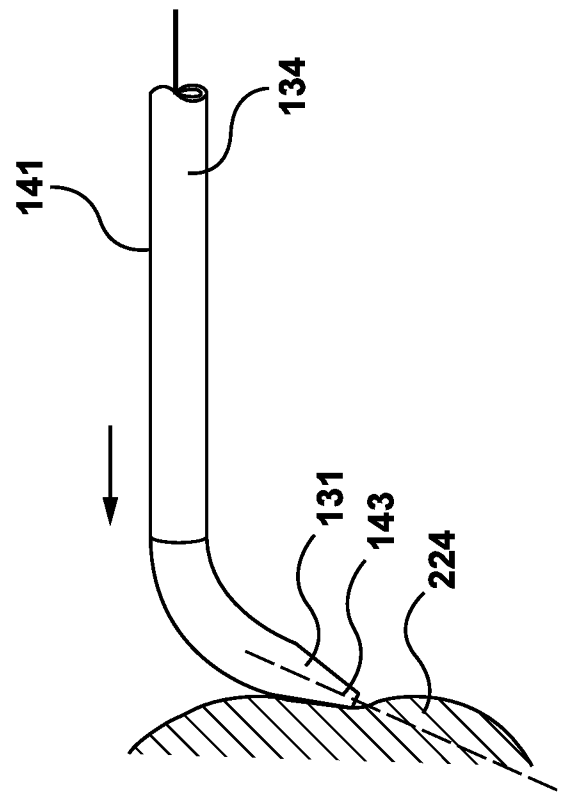

FIG. 29B

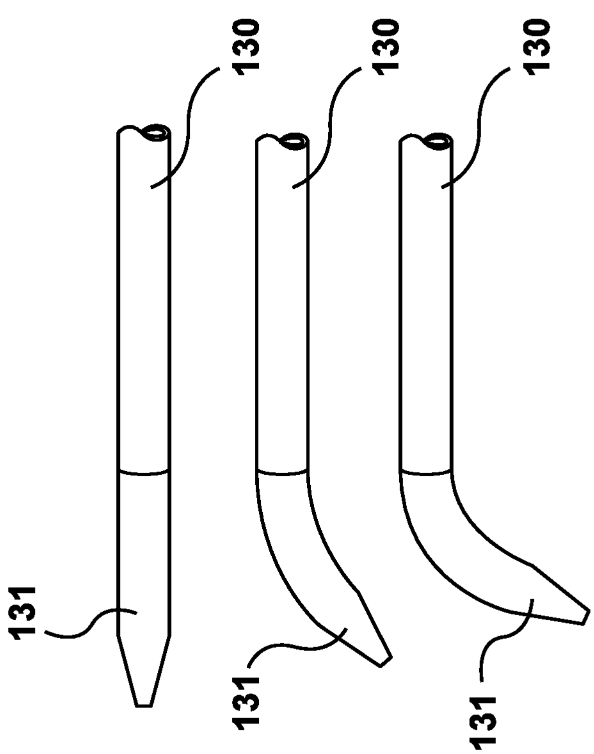

FIG. 28

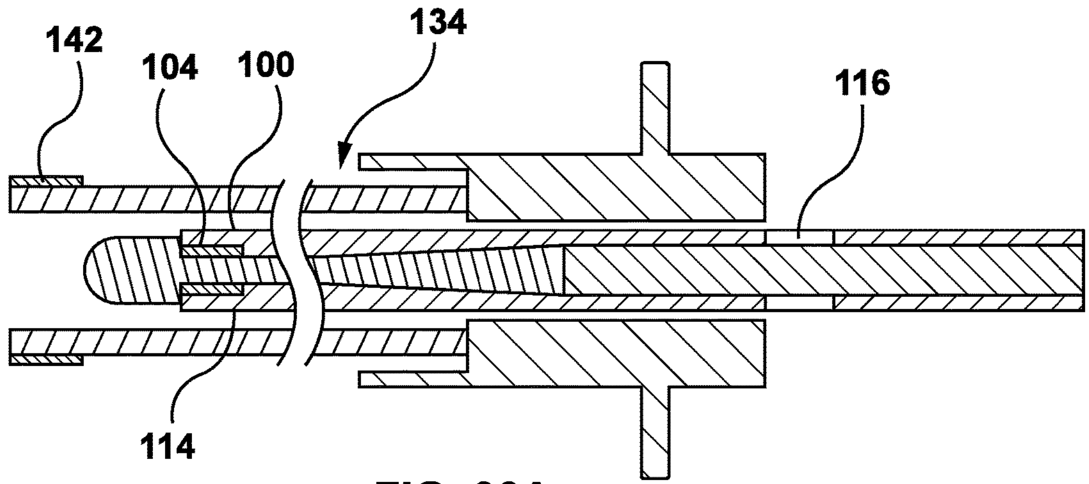

FIG. 30A

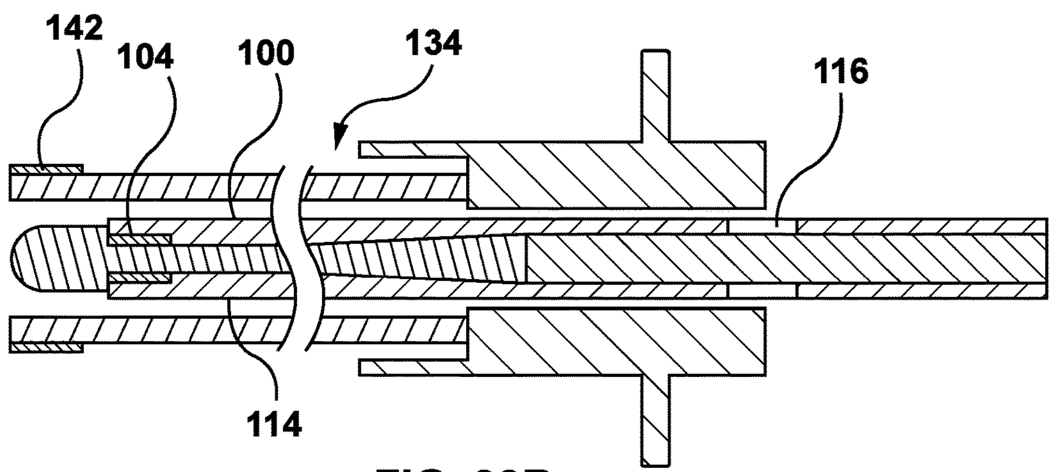

FIG. 30B

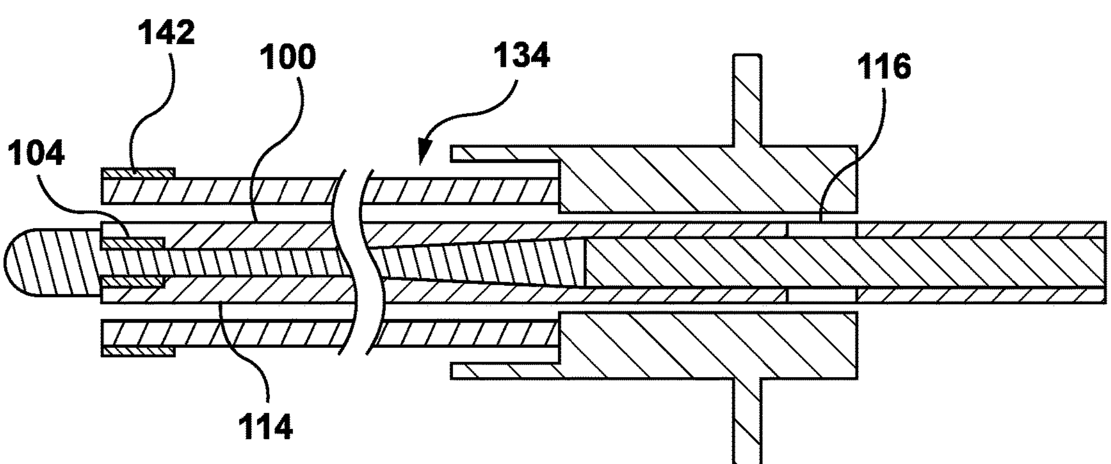

FIG. 30C

APPARATUS AND METHODS FOR PUNCTURING TISSUE

TECHNICAL FIELD

[0001] The disclosure relates to systems and methods of delivering energy to tissue. More specifically, it relates to delivering energy using electrosurgical devices to puncture tissue.

SUMMARY

[0002] The safety of a procedure for puncturing a target tissue with a puncture device can be increased using a method of confirming the position of the tip of the puncture device relative to the target tissue. The method uses an elongate device (e.g. a radiofrequency (RF) guidewire) having a tip electrode, which is configured for collecting electrograms (EGMs) and for delivering electrical energy for puncturing the tissue, and the method including collecting EGMs to indirectly measure and monitor the pressure applied against the target tissue by the elongate device to thereby indicate tip location with respect to the target tissue. In some embodiments the target tissue is on a pericardium and the method includes collecting epicardial electrograms (EGMs) to measure and monitor the pressure applied against the pericardial target tissue site. In other embodiments, the tissue is some part of a body other than a pericardium, for example, a septum of a heart.

[0003] In a first broad aspect, embodiments of the present invention comprise a method of confirming a position of a tip of a puncture device relative to a target tissue which includes using an elongate puncture device having a tip electrode that is configured for collecting EGMs and for delivering energy for puncturing tissue. The method comprises a step of collecting EGMs with the tip electrode to measure and monitor a pressure applied against the target tissue by the tip electrode of the elongate puncture device.

[0004] In some embodiments of the first broad aspect, the target tissue is a pericardium. In some other embodiments, the target tissue is a septum of a heart, and in some such embodiments, the target tissue is an atrial septum. In some examples of the first broad embodiment, the elongate puncture device delivers radiofrequency energy, and in some such examples the elongate puncture device is a radiofrequency guidewire, or a radiofrequency stylet, or a radiofrequency trocar. In some examples, the EGMs are collected from a pericardium, and in some other examples, the EGMs are collected from a septum of a heart. In some embodiments, the elongate puncture device applies pressure against pericardial tissue, and in other embodiments, the elongate puncture device applies pressure against a septum of a heart.

[0005] In a second broad aspect, embodiments of the present invention comprise a method of puncturing a target tissue which includes using an elongate puncture device having a tip electrode that is configured for collecting EGMs and for delivering energy for puncturing the target tissue, the method comprising collecting EGMs to measure and monitor a pressure applied against the target tissue by the elongate puncture device, thereby confirming a position of the tip electrode of the elongate puncture device relative to the target tissue.

[0006] In some embodiments of the second broad aspect, the target tissue is a pericardium. In other embodiments, the target tissue is a septum of a heart, and in some such embodiments, the target tissue is an atrial septum. In some examples of the second broad embodiment, the elongate puncture device delivers radiofrequency energy, and in some such examples, the elongate puncture device is a radiofrequency guidewire. In some examples of the second broad aspect, EGMs are collected from a pericardium, and in some other examples, EGMs are collected from a septum of a heart. In some embodiments of the second broad aspect, the elongate puncture device applies pressure against pericardial tissue, and in other embodiments, the elongate puncture device applies pressure against a septum of a heart.

[0007] In a third broad aspect, embodiments of the present invention comprise a method of gaining access to a pericardial cavity comprising the steps of: (a) introducing a blunt tipped stylet into an introducer; (b) advancing the blunt tipped stylet and the introducer, in combination, through adipose tissue towards a tissue of the pericardium; (c) removing the stylet from the introducer; (d) installing an elongate puncture device, which is flexible, in the introducer; (e) advancing the tip of the elongate puncture device to be distal of the introducer under fluoroscopy whereby an electrode of the elongate puncture device is in contact with a pericardium without any significant force being exerted; (f) monitoring an EGM based on the electrode of the elongate puncture device which is in contact with the pericardium to confirm there is a low ST segment; (g) exerting force with the introducer and the electrode of the guidewire to tent the pericardium; (h) monitoring the EGM to confirm the wave is higher than the wave of step (f); (i) delivering energy through the electrode to the tissue of the pericardium; and (j) monitoring the EGM to confirm the ST segment is higher than the waves of steps (f) and (h).

[0008] In typical embodiments of the third broad aspect, step (i) includes delivering a short pulse of high voltage AC. In some such embodiments, the short pulse is ⅓ second. Typical embodiments further comprise a step (k) of advancing the distal portion of the introducer into the pericardial cavity and monitoring the EGM.

[0009] In some embodiments of the third broad aspect, steps (e) and (f) are performed simultaneously. In some embodiments, steps (g) and (h) are performed simultaneously. In some embodiments, steps (i) and (j) are performed simultaneously.

[0010] Some embodiments of the third broad aspect further comprise a step (l) of delivering a contrast media. Some embodiments further comprise a step (m) of withdrawing fluid from the pericardial space. Some embodiments further comprise a step (n) of advancing the elongate puncture device into the pericardial cavity. Some embodiments further comprise a step (o) of confirming access by wrapping the guidewire around the heart at least once and visualizing under fluoroscopy.

[0011] In a fourth broad aspect, embodiments of the present invention comprise a method of puncturing a target tissue to gain access to the pericardial cavity comprises the steps of: (1) connecting an electrically insulated wire having one distal pole to a recording system that has an electrocardiographic reference to the patient; (2) puncturing the patient's skin via the subxiphoid, parasternal intercostal or apical approach with a rigid introducer and an engaged stylet; (3) advancing the rigid introducer and the stylet through various dermal layers and toward the pericardial sac of the heart under the guidance of fluoroscopy and tactile feedback to position the tip of the introducer near the pericardial sac; (4) removing the stylet while a blunt radial tip of the introducer is docking with the pericardial sac, and installing the elongate puncture device in the introducer; (5) advancing the elongate puncture device while the introducer is contacting the outside of the pericardial sac; and (6) delivering energy to the pericardial sac through the electrode at the tip of Elongate puncture device.

[0012] In typical embodiments of the fourth broad aspect, step (5) includes recording local epicardial EGMs from the electrode tip of the elongate puncture device. In some such embodiments, step (5) further comprises monitoring the EGM to confirm the amplitude of the waveforms increases with higher mechanical force against the heart.

[0013] In some embodiments of the fourth broad aspect, step (6) comprises the energy being delivered as at least one pulse. In some other embodiments of the fourth broad aspect, step (6) comprises the energy being delivered as a series of pulses, starting with a low pressure level against the pericardial sac in the first iteration to avoid overshoot, and the amount of pressure exerted on the pericardial sac is increased with each iteration while maintaining the same pulse time and energy level. In some embodiments step (6) comprises checking if the pericardial sac has been punctured and access to the pericardial cavity has been gained.

[0014] Typical embodiments of the fourth broad aspect further comprise a step (7) of monitoring the electrical activity of the epicardial surface using the electrode on the distal tip of the elongate puncture device (after RF puncture of the pericardial sac provides access to the pericardial cavity). Some embodiments further comprise a step (8) of deploying the elongate puncture device further into the pericardial space to relax pressure at the tip and cause a change in the EGM trace. Some embodiments further comprise a step (9) of deploying the guidewire for tracking along the epicardial surface of the heart while collecting local epicardial EGM. Some embodiments further comprise a step of advancing a sheath and dilator over the elongate puncture device.

[0015] In a fifth broad aspect, embodiments of the present invention comprise a method of confirming a position of a tip of an elongate puncture device relative to an introducer wherein the elongate puncture device has a proximal marker which is visible to a naked eye and a distal tip marker which is visible under an imaging system, and the introducer has distal end marker which is visible under the imaging system. The method includes the steps of: (1) positioning the elongate puncture device relative to a proximal end of the introducer using the proximal marker without an imaging system in a macro-positioning step; (2) turning on the imaging system; and (3) positioning a distal tip of the elongate puncture device relative to an end of introducer by viewing the distal tip marker and distal end marker using the imaging system in a micro-positioning step. In some such embodiments, the imaging system is a fluoroscopy system and the distal tip marker and distal end marker are visible under fluoroscopy.

[0016] In some embodiments of the first, second, third, fourth and fifth broad aspects, the elongate puncture device comprises a radiofrequency guidewire.

[0017] In a sixth broad aspect, embodiments of the present invention include an elongate puncture device comprising a mandrel which is electrically conductive and covered by a clear layer of insulation, the clear layer stopping short of a distal end of the mandrel such that such that the distal end of the mandrel is electrically exposed to define a distal tip electrode, a portion of the mandrel being surrounded by a visible marker, the visible marker being covered by the clear layer, wherein the portions of the elongate puncture device at and adjacent the visible marker have a constant outer diameter.

[0018] In typical embodiments of the sixth broad aspect, the mandrel is surrounded by an oxide coating which is covered by the clear layer of insulation, wherein for at least one portion of the mandrel the oxide coating has been removed such that said at least one portion defines at least one visible marker.

[0019] In some embodiments of the sixth broad aspect, the at least one visible marker comprises at least one portion of the mandrel wherein the oxide coating is in contact with the mandrel. In some such embodiments, the oxide coating is comprised of a layer of titanium dioxide. Embodiments include the visible marker may be a proximal marker, an intermediate marker, or a distal marker. In typical embodiments, the clear layer comprises a heat-shrink layer, wherein in some such embodiments the heat-shrink layer comprises a polytetrafluoroethylene material.

[0020] In some embodiments of the sixth broad aspect, the mandrel is comprised of a nitinol. In some other embodiments, the mandrel is comprised of a stainless steel. In typical embodiments, the elongate puncture device is flexible.

[0021] In typical embodiments of the sixth broad aspect, the mandrel is electrically conductive, and a proximal end portion of the mandrel is uninsulated and operable for connecting to a power supply such that the distal tip electrode is in electrical communication with the power supply, and energy can be delivered through the distal tip electrode to tissue, and the distal tip electrode enables recording epicardial EGM. Such embodiments typically include a shaft of the elongate puncture device being electrically insulated to reduce noise from any collected local EGM. In some embodiments, the distal tip electrode has a hemispherical dome with an outer diameter >0.027" (0.686 mm) and a surface area of about 1.8 to about 2.4 mm^2.

[0022] Typical embodiments of the sixth broad aspect further comprise a distal end portion which has a J-profile. Such embodiments typically further comprise a radiopaque coil which extends around a curve of the distal end portion which has a J-profile. In such embodiments, an end of the radiopaque coil can be used as a distal tip marker. In some examples, the radiopaque coil has echogenic properties when using ultrasound to enable visualization of the guidewire tip.

[0023] In some embodiments of the sixth broad, the elongate puncture device comprises a radiofrequency guidewire.

[0024] In a seventh broad aspect, embodiments of the present invention include an introducer for use with an elongate puncture device, the introducer comprising an introducer shaft connected to a hub, the introducer shaft comprising an internal metal tube which is interposed between two layers of insulation with both ends of the two layers being joined together to bond the layers. In typical examples, the two layers of insulation are comprised of high-density polyethylene. In some examples, the hub further comprise a male side port for connecting to tubing and a receiving opening for receiving a stylet or a wire whereby the hub is operable to be simultaneously attached to source of fluid while a stylet or a wire is inserted into the hub.

[0025] In an eighth broad aspect, embodiments of the present invention include a kit comprising an introducer and an elongate puncture device, the elongate puncture device including a distal tip electrode which enables recording epicardial EGM and a shaft of the elongate puncture device is electrically insulated to reduce noise in any collected local EGM; and the introducer comprising an introducer shaft which connected to a hub, the introducer shaft comprising an internal metal tube which is interposed between two layers of electrical insulation with both ends of the two layers being joined together to bond the layers to reduce noise in any EGM collected by the elongate puncture device. In typical embodiments of the eighth broad aspect, the introducer and the elongate puncture device are configured such that the introducer has the ability to deliver and withdraw fluid while the elongate puncture device is inserted therethrough. In some examples, the radial gap between an inner diameter of a tip of the introducer and outer diameter of the elongate puncture device is >0.025 mm (0.001"). In some such examples, the kit is operable to provide contrast flow >15 ml/min at 69 Kilo Pascal (10 PSI). In some examples, the inner diameter of a tip of the introducer is 0.978 mm (0.0385 inches)+/−0.013 mm (0.0005 inches), and the maximum outer diameter of the elongate puncture device is 0.889 mm (0.0350 inches)+/−0.013 mm (0.0005 inches), whereby the minimum gap with this geometry is 0.032 mm (0.00125").

[0026] Some embodiments of the eighth broad aspect further comprise a stylet wherein a cross section of the stylet varies along the length of the stylet, tapering down towards a distal tip of the stylet to allow a flow of a fluid through a tip of the introducer when the stylet is installed.

[0027] Some embodiments further comprise a stylet wherein the stylet is electrically insulated and operable to be connected to a recording system to facilitate collecting EGM information to help in positioning a tip of the introducer when approaching the heart.

[0028] Some embodiments of the eighth broad aspect further comprise markers for positioning the elongate puncture device relative to the introducer wherein the elongate puncture device has a proximal marker which is visible to a naked eye and a distal tip marker which is visible under an imaging system, and the introducer has distal end marker which is visible under the imaging system. In typical embodiments, the distal tip marker and distal end marker are visible under fluoroscopy.

[0029] In some embodiments of the eighth broad aspect, a tip of the elongate puncture device extends distal of a shaft of the introducer shaft when the proximal marker of the elongate puncture device is positioned at a proximal end of a hub of the introducer. In some other embodiments of the eighth broad aspect, a tip of the elongate puncture device lines up with a distal end of a shaft of the introducer shaft when the proximal marker of the elongate puncture device is positioned at a proximal end of a hub of the introducer.

[0030] In some embodiments of the eighth broad aspect, the elongate puncture device comprises a radiofrequency guidewire.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] In order that the invention may be readily understood, embodiments of the invention are illustrated by way of examples in the accompanying drawings, in which:

[0032] FIG. **1** is an illustration of a radiofrequency (RF) guidewire in accordance with an embodiment of the present invention;

[0033] FIG. **2** is a cross sectional view of the embodiment of FIG. **1**;

[0034] FIG. **3** is an illustration of a detail of FIG. **2**;

[0035] FIG. **4** is an illustration of a stylet in accordance with an embodiment of the present invention;

[0036] FIG. **5** is a cross sectional view of the embodiment of FIG. **4**;

[0037] FIG. **6** is an illustration of detail A of FIG. **4**;

[0038] FIG. **7** is an perspective view of an introducer with a stylet contained therein in accordance with an embodiment of the present invention;

[0039] FIG. **8** is a side view of the embodiment of FIG. **7**;

[0040] FIG. **9** is an end view of the embodiment of FIG. **7**;

[0041] FIG. **10** is a top view of the embodiment of FIG. **7**;

[0042] FIG. **11** is a cross sectional view of the embodiment of FIG. **8**;

[0043] FIG. **12** is an illustration of detail A of FIG. **11**;

[0044] FIG. **13** is an illustration of apparatus in accordance with an embodiment of the present invention;

[0045] FIG. **14** is an illustration of the distal end of an introducer with a with an elongate puncture device contained therein in accordance with an embodiment of the present invention;

[0046] FIG. **15** is an illustration of the embodiment of FIG. **14** with the elongate puncture device extended to form a J-tip;

[0047] FIG. **16** is an illustration of the proximal end of the hub of FIG. **13** with the elongate puncture device inserted therein;

[0048] FIG. **17** is a diagrammatic cross sectional view of an introducer with an elongate puncture device installed therein in accordance with an embodiment of the present invention;

[0049] FIG. **18** is an illustration of the layers surrounding a heart;

[0050] FIG. **19** is an illustration of EGM waves showing a sequence of raised ST segments;

[0051] FIG. **20-1**, and FIG. **20**A to FIG. **20**F illustrate a method in accordance with an embodiment of the present invention;

[0052] FIGS. **21**A and **21**B illustrate possible problem scenarios;

[0053] FIG. **22**A is an illustration of different maker configurations of an elongate puncture device;

[0054] FIG. **22**B is a cross section of FIG. **22**A;

[0055] FIG. **23**A is an illustration of fluid flow from a radial gap at a distal end if an introducer;

[0056] FIG. **23**B is an illustration of an introducer with a side port for fluid flow;

[0057] FIG. **24** is an illustration different stylet embodiments;

[0058] FIG. **25** is an illustration of an alternative embodiment of a mandrel;

[0059] FIG. **26** is an illustration of an introducer hub with a tip straightener;

[0060] FIG. **27** is an enlarged view of a portion of FIG. **26**;

[0061] FIG. **28** is an illustration of alternative embodiments of the introducer distal tip;

[0062] FIG. **29**A is an illustration of an introducer with a flexible tip and an inserted stylet;

[0063] FIG. **29**B is an illustration of the introducer of FIG. **29**A with the stylet removed; and

[0064] FIGS. **30**A to **30**C illustrate the steps of a method of advancing an elongate puncture device through an introducer shaft.

DETAILED DESCRIPTION

[0065] Minimally invasive catheterization of the pericardial space is required for diagnostic and treatment of a variety of arrhythmias. Although epicardial ablation is a preferred route in many situations (for ventricular tachycardias, for instance), physicians may resort to common endocardial ablation due to uncertainties involved in access and high clinical complication rate. The current standard procedure for epicardial access is facilitated by using a 17 Ga Tuohy needle that percutaneously punctures the pericardial sac via the subxiphoid or parasternal intercostal or apical approach. This puncture is typically performed under fluoroscopic guidance using a combination of anterior-posterior and lateral views. Radiopaque contrast agents are periodically injected to provide positive feedback to the user on tip position, and whether or not the needle tip has successfully broached the pericardial sack. With this approach there is the possibility of lacerating the epicardium, cardiac vessels or surrounding soft tissue structures. There is also the risk of inadvertent entry into the ventricle that can lead to an effusion and perhaps tamponade. Any new devices or methods to improve the safety and predictability to confirm targeted tissue site and reduce chance of complications would be beneficial.

[0066] The inventors have come up with a unique and heretofore undiscovered solution of improving the safety of a procedure for puncturing a target tissue with a puncture device, which includes using a method of confirming the position of the tip of the puncture device relative to the target tissue. The method uses an elongate device (e.g. a radiofrequency (RF) guidewire) having a tip electrode which is configured for collecting local electrograms (EGMs) and for delivering energy for puncturing the tissue, with the method including collecting EGMs to indicate tip location with respect to the target tissue. The elongate device doesn't specifically measure the EGM, but passes on the signal to EGM signal processing equipment. In some embodiments the target tissue is on a pericardium and the method includes collecting local epicardial electrograms (EGMs) to indirectly measure and monitor the pressure applied against the pericardial target tissue site. In other embodiments, the tissue is a septum of a heart and the method includes collecting intracardiac electrograms (EGMs) to indirectly measure and monitor the pressure applied against the septum. Typical embodiments include collecting an EGM signal during tenting of the target tissue.

[0067] One embodiment is for a guidewire that is operable to provide tip information back to the user on confirming location of the tip of the device in reference to the targeted tissue. The invention uses local epicardial electrograms (EGM) to aid in confirming location of the guidewire tip when approaching the heart, docking with the targeted tissue before and after puncturing the sac.

[0068] With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of certain embodiments of the present invention only. Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

[0069] An example a system (or a kit) of apparatus suitable for performing the methods disclosed herein is shown in FIG. **13**. The apparatus includes elongate puncture device **100**, stylet **120**, and introducer **130**. While this disclosure uses the term "elongate puncture device" with regards to elongate puncture device **100** for explanatory purposes, elongate puncture device **100** is, in general, an elongate member capable of delivering energy to tissue through a distal end electrode. Elongate puncture device **100** is flexible in some embodiments and stiff in other embodiments. Examples of flexible embodiments include wires capable of delivering electrical energy, such as RF guidewires. Examples of stiff embodiments include needles operable for gaining access to pericardial cavities (some of which have a form and feel which resembles a 17 Ga-20 Ga Tuohy needle) or for gaining transseptal access (some of which have a form and feel which resembles a Brockenbrough needle). Also, typical embodiments of elongate puncture device **100** are operable to deliver electrical energy at frequencies other than radiofrequency. The energy frequency used in a given procedure is typically determined by the user selecting a frequency from the range of frequencies available with the generator being used in the procedure.

[0070] Introducer **130** of FIG. **13** is connected to valve **140** by tubing **144**. In the illustrated embodiment, valve **140** is a 3-way stopcock valve. Alternative embodiments have other valve configurations that are operable to deliver and withdraw fluid. The apparatus of FIG. **13** may be used for a variety of tissue puncture procedures, for example, pericardial puncture procedures or transseptal puncture procedures. The main components of the apparatus shown in FIG. **13** are described in greater detail below.

[0071] Referring to FIG. **1**, an embodiment of elongate puncture device **100** comprises a distal end portion **110** which has a J-profile and a straight portion **112** at the distal end thereof. The elongate puncture device assumes the J-shape when not constrained. The J-profile of the distal end portion **110** helps minimize tissue trauma when tracking the distal tip across the heart's surface. The distal end portion **110** could also be a 'P' or a straight profile. Some embodiments have a distal tip angle from 0 to 35 degrees from the longitudinal axis of the main shaft. The idea is to keep the distal tip's straight portion **112** tucked in as it tracks around the heart to prevent it from swinging out and impinging adjacent soft tissue structures. The distal curve should also be in-plane with the wire body for predictable advancement of the device. One embodiment has a J-profile with an outside diameter of 10-12 mm. The straight portion **112** of the distal tip allows for alignment and orientation of the elongate puncture device tip to the introducer to facilitate RF puncture. One embodiment has a length of straight active tip which is between 6-9 mm in length. This length is required to allow the user to control alignment of the elongate puncture device by hand. Distal tip straight portion **112** has adequate body length to allow for alignment, positioning of the tip with respect to the introducer.

[0072] Electrode **102** is at the end of straight portion **112**. The guidewire has a blunt electrode at the tip to safely dock with tissue and thereby facilitate directly delivering RF energy to the targeted tissue which the electrode is in contact with. Typically the electrode **102** has a dome profile which minimizes the opportunity for premature mechanical puncture, and allows the elongate puncture device to dock with the target tissue at various angles. Embodiments of electrode dome **103** may have a shape which is hemispherical, ellipsoid, or a paraboloid. In some embodiments, electrode dome **103** retains radiopaque marker **104**. In alternative embodiments, other orientations and materials are used to secure radiopaque material to the distal end of elongate puncture device **100**. Referring to FIG. **2**, the proximal end portion of elongate puncture device **100** (I.e. the end which is at the end opposite to the end of the wire having electrode **102**) is uninsulated and is operable for connecting to a power supply or generator. In some embodiments, the proximal end electrically exposed mandrel **108** is about 7.5+/−2.5 mm in length. In typical embodiments, the mandrel **108** is electrically conductive, and a proximal end portion of the mandrel **108** is uninsulated and operable for connecting to a power supply such that the distal tip electrode **102** is in electrical communication with the power supply, whereby energy can be delivered through the distal tip electrode **102** to tissue and the distal tip electrode enables recording epicardial EGM.

[0073] Elongate puncture device **100** of FIG. **13** includes a proximal marker **116**. Laser etching can be used to form proximal marker **116** so that it cannot be removed during use or sterilization. The use of proximal marker **116** is described below.

[0074] Some embodiments of elongate puncture device **100** comprises a mandrel **108** which is electrically conductive and covered by a clear layer of insulation **114** (clear heat-shrink **115**), the clear layer stopping short of a distal end of the mandrel **108** such that such that the distal end of the mandrel **108** is electrically exposed (i.e. not covered) to define a distal tip electrode **102**. A portion of mandrel **108** is surrounded by a visible marker **117**, with the visible marker being covered by the clear layer, wherein the portions of the elongate puncture device at and adjacent the visible marker **117** have a constant outer diameter.

[0075] Some embodiments of elongate puncture device **100** include one or more marker **117** formed by mechanical grinding of an oxide coating of the wire created during heat treatment of the wire to fine-tune transformation temperatures. Marker **117** can be a proximal marker, an intermediate marker, or a distal marker. The formation of said markers is described making reference to FIGS. **22**A and **22**B. FIG. **22***b* shows a cross-section of wire at point "A" of FIG. **22**A after the wire is heat treated. FIG. **22**B illustrates elongate puncture device **100** comprising a solid mandrel **100** surrounded by oxide coating **118** which is covered by clear heat-shrink **115** (a clear layer). In typical embodiments mandrel **108** is comprised of nitinol while in some alternative embodiments it is stainless steel. The typical oxide coating **118** on the wire is a titanium dioxide (TiO(2)) oxide layer. This coating is typically stable and acts as a barrier against ion exchange. After the heat treatment, oxide coating **118** extends the full length of the wire. Typically a portion of the coating at the proximal end is removed to allow electrical connection with the over wire cable connectors and at least one other portion of the coating is removed to form a marker visible without imaging i.e. visible to an unaided eye. The oxide coating **118** can be removed by grinding the surface of the wire to the desired profile to thereby form a marker **117**. Clear heat-shrink **115** typically comprises a Clear PTFE formed from an extruded tube that that is heat shrunk onto the wire. The configuration of the markers of elongate puncture device **100** maintain a smaller consistent outer diameter (i.e. do not increase the outer diameter) while maintaining electrical integrity by including the markers under clear heat shrink **115**. Alternative embodiments of heat-shrink **115** are comprised of a clear layer formed from alternative materials known to those skilled in the art. The elongate puncture device **100** is electrically insulated by the clear heat-shrink which allows a marker **117** to be visible. In some examples, the clear layer has a thickness ranging from about 0.086 mm to 0.118 mm.

[0076] FIG. **22**A shows different examples of marker **17**. FIG. **22**A-i shows a distal end marker **117**. FIG. **22**A-ii shows a distal end marker **117** and an intermediate marker **117**. FIG. **22**A-iii shows two intermediate markers **117**. Proximal marker **116** of FIG. **17** could be formed by removing an oxide as described above and covering the wire with a clear layer. In some such embodiments, visible marker **117** comprises at least one portion of the mandrel wherein the oxide coating is applied directly to the mandrel i.e. in direct contact with the mandrel.

[0077] FIG. **3** illustrates detail C of FIG. **2**. The embodiment of FIG. **3** includes a mandrel **108** (outer diameter 0.011 inches or 0.28 mm) with a radiopaque coil **106** (outer diameter 0.017 inches or 0.43 mm) covering a portion thereof. Insulation **114** (outer diameter 0.028 inches or 0.71 mm) covers the mandrel **108** and the radiopaque coil proximal of electrode **102** to enable delivery of electrical energy through electrode **102** (outer diameter 0.0275 inches or 0.70 mm, radius 0.01375 inches or 0.35 mm). In some embodiments the electrical insulation is comprised of heat shrink (e.g. polytetrafluoroethylene (PTFE)). Radiopaque coil **106** extends around the curve of distal end portion **110** (FIG. **2**). A radiopaque coil aids the physician in determining location of the distal tip of the elongate puncture device while using fluoroscopy. Physicians may reduce fluoroscopy intensity for long procedures reducing visibility of the guidewire. The coil can also improve echogenic properties when using ultrasound to visualize the guidewire tip. The coil can be 3 cm or longer. The coil also aids in visualizing the guidewire track around the cardiac silhouette. The coil aids to better visualize the distal tip's T profile and how it interacts within the space. It can aid physicians in helping determine evidence of adhesions or anatomical abnormalities. The RO coil may be longer or shorter than 3 cm and may be constructed of various materials such as platinum, titanium, gold and tungsten. Some embodiments comprise a radiopaque coating around the mandrel. In some such embodiments, the wire is coated with a thin precious metal. Distal to radiopaque coil **106**, electrode **102** includes a radiopaque marker **104** (outer diameter 0.0275 inches or 0.70 mm, inner diameter 0.011 inches or 0.28 mm, length 0.020 inches or 0.51 mm) which surrounds mandrel **108**. Radiopaque marker **104** can also be referred to as a radiopaque (RO) band or a puck. A Radiopaque marker **104** helps visualize location of the tip under fluoroscopy. The RO band can help confirm if the tip of the elongate puncture device is protruding from the tip of the introducer **130**. Embodiments of the RO band may be of varying lengths and constructed of various materials such as platinum, titanium, gold and tungsten. Elongate puncture device **100** is also visible using ultrasound imaging systems, radiopaque coil **106** being particularly echogenic.

[0078] Electrode **102** also includes an electrode dome **103** which may be formed by laser welding. In typical embodiments the mandrel of the wire, mandrel **108**, is comprised of a shape memory material (e.g. nitinol) allowing it the ability to be kink resistant. The guidewire, when introduced into the pericardial space, may undergo sharp deflections. The flexible mandrel prevents any kinking, mitigating the possibility of getting the guidewire trapped in the body. In some alternative embodiments, mandrel **108** is constructed of stainless steel, which is less kink resistant. In other alternative embodiments, the mandrel is made of other super elastic materials with varying dimensions and cross-sections. In some embodiments, radiopaque coil **106** is comprised of tungsten. Some typical embodiments include radiopaque marker **104** being comprised of a mixture of platinum and iridium (e.g. 10% iridium), and electrode dome **103** being comprised of nitinol which has been dome welded. The distal tip region is floppy (i.e. not rigid) to minimize tissue trauma when tracking across the hearts surface. To achieve this, the mandrel at the distal end portion reduces in diameter necks from 0.025" (0.64 mm) down to 0.006" (0.15 mm) over a length of 25 cm. The tip will deflect creating a secondary bumper to that of the 'J' tip profile.

[0079] Elongate puncture device **100** has a length of about 150 to about 180 cm to ensure the guidewire can be deployed into the pericardial space and wrap around 1 to 2 times around the heart to define the cardiac silhouette under fluoroscopy. Alternative embodiments of the wire have a smaller or larger length to accommodate varying patient sizes and BMIs e.g. lengths of 120 to about 180 cm. The elongate puncture device **100** typically has lubricous coating to ensure the guidewire tracks smoothly around the heart within the pericardial space.

[0080] In some embodiments, the shaft of elongate puncture device **100**, radiopaque marker **104**, and proximal marker **116** have outer diameters <=0.035" (0.89 mm). Radiopaque marker **104** is comprised of platinum and iridium (Pt/Ir) and has an inner diameter >=0.01" (0.25 mm). Mandrel **108** of the guidewire is made of Nitinol designed to be kink resistant. An alternative embodiment (FIG. **25**) is a composite of super elastic material such as Nitinol to provide a flexible kink resistant distal tip portion **108***a* and a proximal wire portion **108***b* of a stiffer alloy such as stainless steel. These materials can be welded (e.g. weld **109**), press fit or glued together using an inner mandrel section **107** which extends from distal tip portion **108***a* in the example of FIG. **25**. In further alternative embodiments, inner mandrel section **107** extends from proximal wire portion **108***b*.

[0081] The body of the guidewire (elongate puncture device **100**) is insulated with polytetrafluoroethylene (PTFE). While typical embodiments of elongate puncture device **100** have an outer diameter of <=0.035" (0.89 mm), any size outer diameter of the guidewire is acceptable as long as it fits within the dilator used for an epicardial procedure. Alternative embodiments of radiopaque marker **104**, which are components of smaller diameter elongate puncture devices, have an inner diameter smaller than 0.01" (0.25 mm). While a typical embodiment of introducer **130** has an inner diameter of >=0.035" (0.89 mm), other inner diameter sizes of the introducer are possible so long as the elongate puncture device **100** used in a procedure can pass through.

[0082] FIG. **4** is an illustration of an embodiment of stylet **120** which includes stylet mandrel **122**, stylet cap **124**, adhesive **126**, and rounded end **128**. In alternative embodiments, the tip is sharp. Some alternative embodiments do not include adhesive **126**.

[0083] FIG. **5** is a cross sectional view of the embodiment of FIG. **4** which internal details of stylet cap **124**. FIG. **6** is an illustration of detail A of FIG. **4** showing rounded end **128**. In alternative embodiments (FIG. **24**, ii to v) the cross section varies along the length of the stylet **120** necking down (or tapering) towards the distal tip to allow better flow of contrast or fluids through the tip of the introducer when the stylet is installed. FIG. **24***i* illustrates a non-tapered stylet **120** inside of an introducer **130**. FIG. **24***vi* illustrates a spiral embodiment of stylet **120**.

[0084] FIG. **7** shows an embodiment of an introducer **130** with a stylet contained therein. Introducer **130** includes an introducer shaft **134** connected to hub **132**. Hub **132** has a male side port **136** for connecting to tubing **144** (FIG. **13**) and a receiving opening (FIG. **16**) for receiving a stylet or wire. Alternative embodiments have other side port configurations that are operable to deliver and withdraw fluid. Stylet cap **124** of the installed stylet is proximal of hub **132** and rounded end **128** of the stylet is distal of introducer shaft **134**. In some embodiments introducer shaft is a reinforced 8Fr shaft covered with high-density polyethylene (HDPE) comprised of 20% $BaSO_4$. The introducer **130** is operable to accommodate the a flexible elongate puncture device allowing the introducer **130** (with a elongate puncture device inserted therein): traverse through adipose tissue to reach the target tissue; facilitate the delivery of RF energy by supporting the proper alignment, orientation and position of the distal tip of a elongate puncture device; and allow the guidewire to be deployed into the pericardial space.

[0085] Alternative embodiments of the introducer distal tip **131** may be straight, curved or bent between 15-45 degrees, such as in the examples of FIG. **28**. A curved or bent tip would allow the ability to align, orientate and position the distal tip of the elongate puncture device more tangential to the cardiac silhouette.

[0086] The introducer is design to allow 'front loading', the insertion of the guidewire through the proximal hub and/or 'back loading', through the distal tip of the introducer. Alternative embodiments allow only certain compatible guidewires to limit use. Referring to FIG. **26** and FIG. **27**, a tip straightener **137** with a distal tip radius of less than 0.057" (1.45 mm) allows for insertion of elongate puncture device **100** through receiving opening **147** and valve **139** and into the introducer proximal hub **132** inside diameter. This allows the distal tip of the introducer to gain close approximation to the valve to facilitate seamless guidewire insertion.

[0087] Alternative embodiments of the introducer is the ability to accommodate and introduce multiple guidewires for ease of downstream work flow. Introducer can accommodate multiple guidewires up to 0.014 inches or 0.018" in diameter, for example, if the inner diameter of the introducer is 0.035 inches (0.89 mm).

[0088] The introducer **130** and elongate puncture device **100** are configured such that introducer **130**, even with an inserted elongate puncture device, has the ability to deliver and withdraw fluid while cannulating the elongate puncture device. Introducer shaft **134** is typically >=5" (12.7 cm). In one embodiment (FIG. **23**A), the radial gap between introducer tip **131** ID and the elongate puncture device **100** OD is >0.001" (0.025 mm) to provide adequate contrast flow **135** (>15 ml/min at 10 PSI (or 69 Kilo Pascal)) wherein contrast flow **135** is measured by delivering fluid by hand into a beaker for a minute at a constant 10 psi (69 Kilo Pascal) and then measuring the volume of fluid at the end of that minute. In one such embodiment, the introducer tip lumen ID is 0.0385 (0.978 mm)+/−0.0005 inches (0.013 mm), and the maximum elongate puncture device OD is 0.0350 (0.889 mm)+/−0.0005 inches (0.013 mm), whereby the minimum gap with this geometry is 0.00125" (0.032) mm. Another embodiment (FIG. **23**B) of the introducer has side ports **131** located at the introducer tip **131** to allow contrast flow **135**. The introducer shaft **134** has a length that is operable to provide adequate stiffness and control to the physician, and to reach the pericardial sac while providing a handle outside of the patient's chest wall. In alternative embodiments, Introducer shaft **134** is less than 5" (12.7 cm). To provide adequate reach and controlled linear trajectory, one embodiment of introducer **130** has a shaft of about 15 cm and a stiffness >0.04 Nm2 and for a shaft 12 cm a stiffness >0.03 Nm2. Another alternative length is from 4 to 6 cm to accommodate younger children, and is from 7 to 10 cm for older children.

[0089] Alternative embodiments (FIG. **29**A and FIG. **29**B) of the distal tip **131** of the introducer **130** include a flexible tip 2-3 cm in length. The tip is supported by the rigid distal tip of the assembled stylet **120** (FIG. **29**A) to facilitate the ability to traverse through adipose tissue. However, once the stylet is removed, the distal tip of the introducer becomes flexible. A flexible tip allows alignment, orientation and positioning of the elongate puncture device to be more tangential to the cardiac silhouette (FIG. **29**B), instead of a perpendicular approach.

[0090] An alternative embodiment is a manually reshapeable introducer shaft. This allows the physician to create the desired curve on the shaft of the introducer to facilitate a more curve device insertion trajectory to get underneath the sternum to reach the pericardial sac. This ability reduces the required length of the device in patients with large abdomens or with patients with a more inferior intercostal margin (rib cage).

[0091] FIG. **8** is a side view of the embodiment of FIG. **7** showing introducer shaft **134**, hub **132**, and male side port **136** of the introducer, and stylet cap **124** and rounded end **128** of the stylet. When a blunt tipped stylet **120** is introduced into introducer **130**, the stylet-introducer combination is operable to be advanced through adipose tissue in order to reach the target tissue. FIG. **9** is an end view of the embodiment of FIG. **7** illustrating hub **132** and male side port **136**. FIG. **10** is a top view of the embodiment of FIG. **7** which shows stylet cap **124**, hub **132**, and rounded end **128** of the stylet distal of introducer.

[0092] FIG. **11** is a cross sectional view of the embodiment of FIG. **8**. FIG. **11** shows stylet mandrel extending from rounded end **128** to inside of stylet cap **124**. To provide for advancing through tissue, rounded end **128** of stylet **120** has a diameter of 0.0375 inches or less, while still being less sharp than a Tuohy needle. FIG. **12** is an illustration of detail A of FIG. **11** which illustrates insulation **138** is on the inside of the lumen defines by introducer shaft **134** as well as on the outside surface of introducer shaft **134**. In some embodiments, introducer **130** has an inner diameter >=0.035" (0.89 mm). The shaft of introducer comprises internal metal tube **146** which is sandwiched (or interposed) between two layers of HDPE (insulation **138**) with both ends of the layers of insulation being tipped (i.e. joined together to form a tip) to bond the layers. An introducer **130** with such a configuration can be combined with an elongate puncture device **100** which is a wire is insulated most of its length with the exceptions of the electrode tip and proximal connector to provide apparatus which is effective collecting local EGM. An example is a kit comprising an introducer **130** and an elongate puncture device **100**, the elongate puncture device including a distal tip electrode **102** which enables recording epicardial EGM and a shaft of the elongate puncture device is electrically insulated to reduce noise in any collected local EGM, with the introducer comprising an introducer shaft **134** which connected to a hub **132**, the introducer shaft comprising an internal metal tube **146** which is interposed between two layers of electrical insulation **138** with both ends of the two layers being joined together to bond the layers to reduce noise in any EGM collected by the elongate puncture device.

[0093] The insulation at distal end of introducer **130** is shaped to form a tip which enables transition through tissue when the intruder is advanced. The length of the introducer shaft **134** is >=5" (12.7 cm). Hub **132** is comprised of plastic and includes a silicone seated valve. FIG. **12** also illustrates the space between stylet mandrel **122** and introducer shaft **134** decreases toward the distal end of introducer shaft **134** i.e. there is a tighter fit between stylet mandrel **122** and introducer shaft **134** at the distal end of introducer shaft **134**.

[0094] FIG. **13** is an illustration of apparatus of an embodiment which shows the size of the components relative to each other. FIG. **14** illustrates an elongate puncture device **100** extending from introducer **130**. Only part of straight portion **112** of the guidewire (FIG. **1**) is protruding from the introducer. In some embodiments, the tip of the elongate puncture device **100** is only protruding out 2 mm from the blunt tip of the introducer. This can act as a depth stop in limiting how deep the tip of the elongate puncture device can penetrate into the targeted tissue. The tip protrusion length could change depending on support of the tip by the introducer and electrode size. FIG. **15** illustrates a situation in which a distal end portion **110**, which has a J-profile, is extended from an introducer **130**.

[0095] FIG. **16** shows the proximal end of an introducer hub wherein an elongate puncture device has been inserted such that proximal marker **116** of the guidewire is lined up with the proximal edge of the hub. Proximal marker **116** is visible to a user without the use of an imaging system i.e. it is visible by the naked eye. While typical embodiments of proximal marker **116** are visual markers, in some alternative embodiments, the proximal marker **116** is a tactile marker. In typical embodiments of the apparatus, this positioning of proximal marker **116** indicates the electrode **102** (FIG. **1**) is outside the introducer close to the distal end of the introducer i.e. electrode **102** is deployed by positioning it slightly extended out of the distal end of the introducer.

[0096] FIG. **17** is a diagrammatic cross sectional view of an introducer **130** with an elongate puncture device **100** installed therein. In typical embodiments, both the introducer **130** and elongate puncture device **100** include markers for positioning the elongate puncture device **100** relative to introducer **130**. In the embodiment of FIG. **17**, introducer shaft **134** has a distal marker **142** at its distal end for indicating the position of the distal end of introducer shaft **134** under imaging, and the elongate puncture device has a radiopaque marker **104** at its distal end for indicating the position of the distal end of elongate puncture device under imaging. The position of the distal ends relative to each other can also be determined under imaging. FIG. **17** also shows the elongate puncture device having proximal marker **116** at the proximal end of the introducer hub. In this illustrated embodiment, the tip of the elongate puncture device is extending out of the introducer shaft when proximal marker **116** is positioned at the proximal end of the introducer hub e.g. the line marker on the elongate puncture device helps to inform when the tip is deployed. In alternative embodiments, the tip of the elongate puncture device is line up with the distal tip of the introducer shaft when the proximal marker **116** is positioned at the proximal end of the introducer hub.

[0097] In the embodiment of FIGS. **30**A to **30**C, introducer shaft **134** has a distal marker **142** at its distal end for indicating the position of the distal end of introducer shaft **134** under imaging, and the elongate puncture device has a radiopaque marker **104** at its distal end for indicating the position of the distal end of elongate puncture device **100** under imaging. FIGS. **30**A to **30**C show the steps of a method of advancing an elongate puncture device **100** through the introducer shaft **134**. FIG. **30**A shows the elongate puncture device **100** is positioned to have the distal end of proximal marker **116** at the proximal end of the introducer hub while the tip of the tip of the elongate puncture device still inside of the lumen of the introducer shaft. The elongate puncture device is advanced to the configuration of FIG. **30**B wherein the middle of proximal marker **116** at the proximal end of the introducer hub and the tip of the tip of the elongate puncture device lines up with the tip of the introducer shaft **134**. The elongate puncture device is further advanced to the configuration of FIG. **30**C wherein the proximal end of proximal marker **116** is at the proximal end of the introducer hub and the tip of the elongate puncture device extends beyond the tip of the introducer shaft **134**. The configuration on FIG. **30**C further includes distal marker **142** of introducer shaft **134** lining up with radiopaque marker **104** at of the distal end of introducer shaft **134**, which under imaging, would confirm the relative positioning of the elongate puncture device and introducer.

[0098] In some embodiments of the method, the user positions the elongate puncture device relative to the introducer using the proximal marker **116** without using an imaging system such a fluoroscopy in a step that can be called, 'macro-positioning'. Subsequent to the 'macro-positioning', the user turns on an imaging system (e.g. fluoroscopy) for more precise positioning of the elongate puncture device relative to the introducer and the target tissue in a step that can be called micro-positioning. By using the proximal and distal markers, a user can perform the early part of positioning the apparatus without fluoroscopy to thereby reduce the amount of X-rays the user and patient are exposed to when compared to performing the entire procedure under fluoroscopy. In some alternative embodiments of the method, the part of the procedure involved with positioning the elongate puncture device relative to the introducer is performed without any fluoroscopy.

[0099] FIG. **18** is an illustration of the layers surrounding a heart. Ventricle **230** is surrounded by the muscular tissue of the heart, myocardium **228**. Pericardium **226** surrounds the myocardium **228** and is comprised of fibrous pericardium **232**, parietal layer **234**, pericardial cavity **236**, and epicardium **238**. The pericardial cavity is often referred to as the pericardial space or the space.

[0100] FIG. **19** is an illustration of epicardial EGM waves showing elevated ST segments in response to tenting the pericardium resulting in an ischemic response of the tissue affecting the local epicardial EGM. Such waves can be collected using electrode **102** of an elongate puncture device **100** when the elongate puncture device is advanced and pushed against the pericardium. Line (I) of FIG. **19** is the wave for no tenting (or insignificant pressure) being applied on the pericardium and line (IV) is the wave for very significant tenting of the pericardium. Lines (II) and (III) are for between the amounts of tenting resulting in lines (I) and (IV).

[0101] FIG. **20-1**, and FIG. **20**A to FIG. **20**F illustrate a method of an embodiment. The following described method can be performed using the different embodiments of the apparatus previously described. FIG. **20-1** illustrates the sub-xiphoid approach of introducer **130** relative to pericardium **226** and the surrounding anatomy. When a blunt tipped stylet **120** is introduced into introducer **130**, the stylet-introducer combination is operable to be advanced through adipose tissue in order to reach the target tissue. Typically, stylet **120** is fastened to the proximal end of the hub **132** of introducer **130**. A physician makes a small nick in the patient's skin to allow the introducer **130** with the protruding stylet tip to pass through the dermal and adipose layers. The blunt tip of stylet **120** provides the necessary cutting action to separate tissue to reach the target. Using a stylet with a blunt tip is advantageous over using stylet with a sharp bevelled tip that will lacerate the tissue as the device traverses through tissue. A blunt tip is also more forgiving if inadvertently advanced too close to the target tissue. It is less likely to puncture the epicardial surface of the heart. Furthermore, other factors being equal, a stylet with a blunt tip provides more tactile feedback than a stylet with a sharp tip. Note that the procedure is done under fluoroscopy.

[0102] After the stylet **120** is removed from introducer **130**, introducer **130** has a rigid shaft that can support the deployment of an elongate puncture device **100** which is flexible and has a soft tip. The guidewire has a dome tip (electrode dome **103**) that can dock with the tissue preventing premature puncture. The physician is able to optimize their position of the tip of the wire. The introducer has an internal metal tube **146** with a lip that is typically within 0.5 to 2 mm from the tip. The internal metal tube **146** functions as a radiopaque marker to indicate where the tip of introducer **130** is located. The physician places the tip of the elongate puncture device **100** outside the introducer **130** to ensure proper delivery of RF electrical energy. The physician can advance and retract the tip of the wire under fluoroscopy to gauge how far the wire is sticking out from the tip of the introducer. FIG. **20**A illustrates electrode **102** of the elongate puncture device being in contact with the pericardium without any significant force being exerted. The associated EGM, with a low ST segment, is shown below (in the lower part of the figure). FIG. **20**B shows the introducer **130** and electrode **102** of the guidewire exerting some force to cause tenting of the pericardium. The wave associated with FIG. **20**B is higher than the wave associated with FIG. **20**A. In this method, the EGM can be measured while moving devices, or before or after devices are moved.

[0103] FIG. **20**C illustrates energy being delivered through the electrode to the tissue of the pericardium. The ST segment of the EGM wave shows higher elevation than that of the previous waves. The guidewire has a blunt electrode at the tip to safely dock with tissue and thereby facilitate directly delivering RF energy to the targeted tissue, which the electrode **102** is in contact with. A short pulse (e.g. ⅓ second) of high voltage AC is delivered by the electrode to create a hole in the pericardial sac **235**, after which the sac will prolapse over the guidewire tip. The delivery of a short pulse (e.g. ⅓ second) of RF energy aids in limiting depth of puncture. A physician could use a longer pulse but risk the chance of penetrating deep into the myocardial tissue. In alternative embodiments the pulse is shorter or longer depending on power settings and required tissue penetration.

[0104] FIG. **20**D shows the distal portion of introducer after being advanced into the pericardial cavity **236** and the associated wave, which has an elevated ST segment. Introducer **130** has valve **140** (e.g. a stopcock) attached to it by tubing **144** (FIG. **13**) and a valve built into hub **132** (a handle) to allow concurrent delivery of contrast media. This will allow the physician to confirm the tip location of introducer **130** with or without the guidewire in place. The inner diameter of the introducer **130** is large enough to accommodate contrast media flow with a cannulated wire. This configuration of the devices allows the physician to withdraw fluid from the pericardial space. For example, if there is excess fluid or blood, it can be aspirated. The arrows in FIG. **20**E represent imaging fluid being injected into pericardial cavity **236**. If the imaging of the fluid indicates the fluid is in the pericardial cavity **236**, then access to the cavity has been achieved.

[0105] FIG. **20**F shows a tip the elongate puncture device **100** being advanced into the pericardial cavity **236**. The guidewire (elongate puncture device **100**) can then be advanced more fully into the space. If the tip of the elongate puncture device continues to move freely after accessing the pericardial space, a physician can confirm access by wrapping the guidewire around the heart at least once (i.e. advancing around the cardiac silhouette) and visualizing under fluoroscopy that the guidewire outlines the cardiac silhouette. The distal 3 cm of the elongate puncture device **100** has a radiopaque coil **106** which increases visibility of the distal end portion **110** under visualization, thereby helping to confirm access to the pericardial space when advancing the tip of the elongate puncture device.

[0106] The tip of the wire starting to bunch up when the physician is attempting to advance the elongate puncture device can indicate access to the pericardial cavity **236** has not been achieved. FIG. **21**A illustrates the complication scenario in which the epicardium is not punctured and significant tenting occurs. The significant tenting is caused by a significant pressure being applied, resulting in a wave with an elevated ST segment. FIG. **21**B illustrates another complication scenario an elongate puncture device passes through the pericardial cavity **236** and into the myocardium **228**, resulting a in a wave with an elevated ST segment which is similar to the wave of FIG. **21**A.

[0107] Elongate puncture device **100** has features facilitating epicardial EGM collection (and non-epicardial EGM collection e.g. EGM collection at the septum of a heart).

[0108] Typical embodiments of elongate puncture device **100** comprise a single electrode at the tip of the guidewire which enables recording epicardial EGM from distal tip of the elongate puncture device **100** while tenting tissue. Alternative embodiments of elongate puncture device **100** have multiple electrodes at the tip to collect additional information.

[0109] Typical embodiments of elongate puncture device **100** are comprised of material which is electrically conductive to allow for the flow of current.

[0110] The electrode **102** is comprised of material which provides for a stable impedance contact with tissue. Impedance depends on the electrode material, tissue, electrode surface area and the temperature. A lower impedance means it less likely for EGM signal to go silent (a DC offset problem). In typical embodiments the electrode is comprised of a solid material. In alternative embodiments, the electrode has a coating of electrically conductive material.

[0111] If the electrode surface area is too large, EGM recording resolution will be negatively impacted. An electrode surface area which is too small is susceptible to electrical interference. Some embodiments of the electrode have hemispherical electrode tips (electrode dome **103**) with outer diameters between 0.024" (0.62 mm) and 0.035" (0.89 mm). Such embodiments were tested on in vivo porcine study which found that the effects of varying the OD and surface area of the electrode tip (with a CardioLab electrophysiology recording system) showed no observable differences between hemispherical electrode tips with outer diameters between 0.024" (0.62 mm) and 0.035" (0.89 mm). Electrode dome **103** has a dome geometry which ensures uniform contact with tissue at various angles of trajectory. To enable the user to collect epicardial EGM to provide guidewire tip location, on embodiment of the tip electrode has a dome OD>0.027" (0.686 mm) and a wire tip surface area of about 1.8 to about 2.4 mm^2 (wherein the dimensions are accurate to one decimal place) such that the electrode is small enough for puncturing tissue while being large enough for effective EGM collection. Further, to create a puncture smaller than a 17 Ga Tuohy needle (OD<0.058" or 1.5 mm), some embodiments have a distal tip electrode OD of about 0.0275 inches (0.70 mm).

[0112] The shaft of elongate puncture device **100** has features which facilitate collecting an EGM signal. The shaft of elongate puncture device **100** is electrically insulated to reduce noise from the collected local EGM. Also, the inner diameter of introducer **130** and the outer diameter of elongate puncture device **100** enable the introducer and elongate puncture device to fit together with clearance to facilitate delivering contrast agent at the same time as collecting epicardial EGM.

[0113] The following method can be performed using the different embodiments of the apparatus previously described. A method which uses the above described devices to puncture a target tissue to gain access to the pericardial cavity **236** comprises the steps of:

[0114] (1) Connecting an electrically insulated wire, with one distal pole (e.g. an elongate puncture device **100** which is a RF guidewire), to a recording system that has an electrocardiographic reference to the patient (e.g. EKG pads, subcutaneous reference or intracardiac reference catheter).

[0115] (2) Puncturing the patient's skin in a minimally invasive manner via the subxiphoid, parasternal intercostal or apical approach with a rigid introducer and an engaged stylet. A small nick is made in the patient's skin below the xiphoid process to initiate the introduction.

[0116] (3) The rigid introducer **130** and stylet **120** are advanced traversing through various dermal layers and toward the pericardial sac of the heart under the guidance of fluoroscopy and tactile feedback to position the tip of the introducer near the pericardial sac. In some embodiments of the method, the stylet is insulated and connected to a recording system to facilitate collecting electrocardiographic information to help in positioning the tips of the devices when approaching the heart (i.e. in large scale positioning).

[0117] (4) The stylet **120** is removed, with the blunt radial tip of the introducer docking with the pericardial sac, and replaced with the elongate puncture device **100**.

[0118] (5) Elongate puncture device **100** is advanced with the introducer **130** contacting the outside of the pericardial sac.

[0119] (5a) Local epicardial electrograms, EGMs are recorded from the electrode tip of elongate puncture device **100**. As the guidewire travels inside introducer **130** there is little to no signal. Once the tip of elongate puncture device **100** is near or protruding from the tip of introducer **130**, the guidewire will start to collect an EGM signal. Under fluoroscopic guidance, the guidewire is advanced until the tip is protruding 2 mm from the tip of the introducer, thereby making contact with the pericardial sac. The tip of elongate puncture device **100** is blunt to prevent lacerating the hearts surface or prematurely puncturing the pericardial sac or myocardial tissue. The blunt tip allows the physician to optimize the location, orientation and angle of approach of the device.

[0120] (5b) As the tip of the elongate puncture device contacts the pericardial sac, the amplitude of the waveforms will increase with higher mechanical force (tenting) against the heart due to transient ischemic response of the pericardial sac and epicardial tissue. Note: if the device (electrode **102**) is not up against the pericardial sac it will collect far field EGMs or other local EGMs, for example, from the diaphragm.

[0121] (5c) Elongate puncture device **100** is docked with the introducer **130**, and the elongate puncture device and the introducer are advanced or retracted together to increase or decrease force required for a successful puncture. The local EGM acts as an indirect pressure sensor. The recorded EGM trace will show evidence of an elevated ST segment. The physician can monitor the amount of tenting of the tissue indicated by the amplitude of the ST segment. As part of an interactive approach, a set elevated ST segment is selected which the physician believes to provide adequate tenting to avoid overshoot. The physician may also use tactile feedback when grasping the guidewire when docked against the pericardial sac. Contrast medium can also be injected through the introducer exiting at the tip to confirm adequate tenting of the sac.

[0122] (6) Delivering energy to the pericardial sac through the electrode **102** at the tip of elongate puncture device **100**. For safety, energy is typically delivered as a pulse (e.g. ⅓ second). Some embodiments include delivering less energy in the pulse by selecting a lower power level or shorter pulse time if a higher pressure level is selected in step (5c). In such embodiments, there is an inverse proportional relationship between the pressure exerted on the sac and the amount of energy delivered in a pulse. In typical embodiments, the physician starts with a low pressure level in the first iteration to avoid overshoot, and the amount of pressure exerted on the pericardial sac is increased with each iteration (while maintaining the same pulse time and energy level) with the physician looking for higher ST elevation to reattempt access.

[0123] (6a) Checking if the pericardial sac has been punctured and access to the pericardial cavity has been gained (using previously described techniques). Upon puncture, the pericardial sack will then prolapse over the guidewire tip. If access has not been gained the elongate puncture device is retracted and repositioned on the pericardial sac for another attempt, and the physician returns to step (5c).

[0124] (7) Monitoring the electrical activity of the epicardial surface using electrode **102** on the distal tip of elongate puncture device **100** (after RF puncture of the pericardial sac provides access to the pericardial cavity).

[0125] (8) Deploying the elongate puncture device **100** further into the pericardial space. Deploying the elongate puncture device **100** further into the pericardial space will relax pressure at the tip and cause a change in the EGM trace. The physician may deliver contrast medium to further confirm access.

[0126] Some embodiments include the further step (9) of deploying the guidewire for tracking along the epicardial surface of the heart while collecting local epicardial EGM. The recorded signal can be inputted into EP mapping systems for added information.

[0127] Elongate puncture device **100** can support a sheath. Typical embodiments include the further step of advancing a sheath and dilator over elongate puncture device **100**. Once the sheath tip is positioned appropriately within the pericardial space, the dilator and guidewire are removed. Subsequently, the sheath provides an access portal for advancement and placement for devices such as mapping or ablation catheters to facilitate diagnosis or therapy of a variety of arrhythmias. Some such embodiments of the method include the use a steerable sheath.

[0128] Also, some embodiments use a system including an amplifier with the ability to amplify voltages and measure impedance from an electrode across a range of anatomically relevant frequencies (from about 10 kHz to about 80 kHz).

[0129] While not considered as a step in the prescribed method, it is possible for the elongate puncture device to be embedded into the epicardium or ventricle after RF puncture. In these situations, the amplitude of the electrical activity (ST segment) decreases, providing feedback to the user that the guidewire should be retracted and RF puncture could be reattempted. These situations can also be confirmed with fluoroscopy.

[0130] Embodiments of the above described methods can use different embodiments of the above described embodiments of apparatus (i.e. different embodiments of devices).

[0131] In a first broad aspect, embodiments of the present invention comprise a method of confirming a position of a tip of a puncture device relative to a target tissue which includes using an elongate puncture device having a tip electrode that is configured for collecting EGMs and for delivering energy for puncturing tissue. The method comprises a step of collecting EGMs with the tip electrode to indirectly measure and monitor a pressure applied against the target tissue by the tip electrode of the elongate puncture device. In a second broad aspect, embodiments of the present invention comprise a method of puncturing a target tissue which includes using an elongate puncture device having a tip electrode that is configured for collecting EGMs and for delivering energy for puncturing the target tissue, the method comprising collecting EGMs to indirectly measure and monitor a pressure applied against the target tissue by the elongate puncture device, thereby confirming a position of the tip electrode of the elongate puncture device relative to the target tissue.

[0132] The embodiments of the invention described above are intended to be exemplary only. The scope of the invention is therefore intended to be limited solely by the scope of the appended claims.

[0133] It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination.

[0134] Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the broad scope of the appended claims. All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention.

We claim:

1. A method of confirming a position of a tip of a puncture device relative to a target tissue includes using an elongate puncture device having a tip electrode which is configured for collecting EGMs and for delivering energy for puncturing tissue, and comprises a step of collecting EGMs with the tip electrode to indirectly measure and monitor a pressure applied against the target tissue by the tip electrode of the elongate puncture device.

2. The method of claim **1**, wherein the target tissue is a pericardium.

3. The method of claim **1**, wherein the target tissue is a septum of a heart.

4. The method of claim **3**, wherein the target tissue is an atrial septum.

5. The method of any one of claims **1** to **5**, wherein the elongate puncture device delivers radiofrequency energy.

6. The method of claim **5**, wherein the elongate puncture device is a radiofrequency stylet, trocar or guidewire.

7. The method of claim **1**, wherein the EGMs are collected from a pericardium.

8. The method of claim **1**, wherein the EGMs are collected from a septum of a heart.

9. The method of claim **1** or **7**, wherein the elongate puncture device applies pressure against pericardial tissue.

10. The method of claim **1** or **8**, wherein the elongate puncture device applies pressure against a septum of a heart.

11. A method of puncturing a target tissue includes using an elongate puncture device having a tip electrode which is configured for collecting EGMs and for delivering energy for puncturing the target tissue, the method comprising collecting EGMs to indirectly measure and monitor a pressure applied against the target tissue by the elongate puncture device, thereby confirming a position of the tip electrode of the elongate puncture device relative to the target tissue.

12. The method of claim **11**, wherein the target tissue is a pericardium.

13. The method of claim **11**, wherein the target tissue is a septum of a heart.

14. The method of claim **13**, wherein the target tissue is an atrial septum.

15. The method of claim **11**, wherein the elongate puncture device delivers radiofrequency energy.

16. The method of any one of claims **11** to **15**, wherein the elongate puncture device is a radiofrequency guidewire.

17. The method of claim **11**, wherein EGMs are collected from a pericardium.

18. The method of claim **11**, wherein EGMs are collected from a septum of a heart.

19. The method of claim **11** or **17**, wherein the elongate puncture device applies pressure against pericardial tissue.

20. The method of claim **11** or **18**, wherein the elongate puncture device applies pressure against a septum of a heart.

21. A method of gaining access to a pericardial cavity comprising the steps of:

(a) introducing a blunt tipped stylet into an introducer;

(b) advancing the blunt tipped stylet and the introducer, in combination, through adipose tissue towards a tissue of the pericardium;

(c) removing the stylet from the introducer;

(d) installing an elongate puncture device, which is flexible, in the introducer;

(e) advancing the tip of the elongate puncture device to be distal of the introducer under fluoroscopy whereby an electrode of the elongate puncture device is in contact with a pericardium without any significant force being exerted;

(f) monitoring an EGM based on the electrode of the elongate puncture device which is in contact with the pericardium to confirm there is a low ST segment;

(g) exerting force with the introducer and the electrode of the guidewire to tent the pericardium;

(h) monitoring the EGM to confirm the wave is higher than the wave of step (f);

(i) delivered energy through the electrode to the tissue of the pericardium; and

(j) monitoring the EGM the ST segment is higher than the waves of steps (f) and (h).

22. The method of claim **21**, wherein step (i) includes delivering a short pulse of high voltage AC.

23. The method of claim **22**, wherein the short pulse is ⅓ second.

24. The method of claim **21**, further comprising a step (k) of advancing the distal portion of the introducer into the pericardial cavity and monitoring the EGM.

25. The method of claim **21**, wherein steps (e) and (f) are performed simultaneously.

26. The method of claim **21**, wherein steps (g) and (h) are performed simultaneously.

27. The method of claim **21**, wherein steps (i) and (j) are performed simultaneously.

28. The method of claim **24**, further comprising a step (l) of delivering a contrast media.

29. The method of claim **24**, further comprising a step (m) of withdrawing fluid from the pericardial space.

30. The method of claim **24**, further comprising a step (n) of advancing a tip of the elongate puncture device into the pericardial cavity.

31. The method of claim **24**, further comprising a step (n) of advancing the elongate puncture device into the pericardial cavity.

32. The method of claim **31**, further comprising a step (o) of confirming access by wrapping the guidewire around the heart at least once and visualizing under fluoroscopy.

33. A method of puncturing a target tissue to gain access to the pericardial cavity comprises the steps of:

(1) connecting an electrically insulated wire having one distal pole to a recording system that has an electrocardiographic reference to the patient;

(2) puncturing the patient's skin via the subxiphoid, parasternal intercostal or apical approach with a rigid introducer and an engaged stylet;

(3) advancing the rigid introducer and the stylet through various dermal layers and toward the pericardial sac of the heart under the guidance of fluoroscopy and tactile feedback to position the tip of the introducer near the pericardial sac;

(4) removing the stylet while a blunt radial tip of the introducer is docking with the pericardial sac, and installing the elongate puncture device in the introducer;

(5) advancing the elongate puncture device while the introducer is contacting the outside of the pericardial sac; and

(6) delivering energy to the pericardial sac through the electrode at the tip of Elongate puncture device.

34. The method of claim **33**, wherein step (5) includes recording local epicardial EGMs from the electrode tip of the elongate puncture device.

35. The method of claim **34**, wherein step (5) further comprises monitoring the EGM to confirm the amplitude of the waveforms increases with higher mechanical force against the heart.

36. The method of claim **33**, wherein step (6) comprises the energy being delivered as at least one pulse.

37. The method of claim **33**, wherein step (6) comprises the energy being delivered as a series of pulses, starting with a low pressure level against the pericardial sac in the first iteration to avoid overshoot, and the amount of pressure exerted on the pericardial sac is increased with each iteration while maintaining the same pulse time and energy level.

38. The method of claim **33**, wherein step (6) comprises checking if the pericardial sac has been punctured and access to the pericardial cavity has been gained.

39. The method of claim **33**, further comprising a step (7) of monitoring the electrical activity of the epicardial surface using the electrode on the distal tip of the elongate puncture device (after RF puncture of the pericardial sac provides access to the pericardial cavity).

40. The method of claim **39**, further comprising a step (8) of deploying the elongate puncture device further into the pericardial space to relax pressure at the tip and cause a change in the EGM trace.

41. The method of claim **40**, further comprising a step (9) of deploying the guidewire for tracking along the epicardial surface of the heart while collecting local epicardial EGM.

42. The method of claim **40**, further comprising the step of advancing a sheath and dilator over the elongate puncture device.

43. A method of confirming a position of a tip of an elongate puncture device relative to an introducer wherein the elongate puncture device has a proximal marker which is visible to a naked eye and a distal tip marker which is visible under an imaging system, and the introducer has distal end marker which is visible under the imaging system, the method including the steps of: (1) positioning the elongate puncture device relative to a proximal end of the introducer using the proximal marker without an imaging system; (2) turning on the imaging system; and (3) positioning a distal tip of the elongate puncture device relative to an end of introducer by viewing the distal tip marker and distal end marker using the imaging system.

44. The method of claim **43**, wherein the imaging system is a fluoroscopy system and the distal tip marker and distal end marker are visible under fluoroscopy.

45. An elongate puncture device comprising: a mandrel which is electrically conductive and covered by a clear layer of insulation, the clear layer stopping short of a distal end of the mandrel such that the distal end of the mandrel is electrically exposed to define a distal tip electrode, a portion of the mandrel being surrounded by a visible marker, the visible marker being covered by the clear layer, wherein the portions of the elongate puncture device at and adjacent the visible marker have a constant outer diameter.

46. The elongate puncture device of claim **45**, wherein the mandrel is surrounded by an oxide coating which is covered by the clear layer of insulation, wherein for at least one portion of the mandrel the oxide coating has been removed such that said at least one portion defines at least one visible marker.

47. The elongate puncture device of claim **46**, wherein the at least one visible marker comprises at least one portion of the mandrel wherein the oxide coating is in contact with the mandrel.

48. The elongate puncture device of claim **45**, wherein the visible marker may be a proximal marker, an intermediate marker, or a distal marker.

49. The elongate puncture device of claim **45**, wherein the clear layer comprises a heat-shrink layer.

50. The elongate puncture device of claim **47**, wherein the heat-shrink layer comprises a polytetrafluoroethylene material.

51. The elongate puncture device of claim **45**, wherein the mandrel is comprised of a nitinol.

52. The elongate puncture device of claim **45**, wherein the mandrel is comprised of a stainless steel.

53. The elongate puncture device of claim **46**, wherein the oxide coating is comprised of a layer of titanium dioxide.

54. The elongate puncture device of any one of claims **45** to **53**, wherein the elongate puncture device is flexible.

55. The elongate puncture device of any one of claims **45** to **53**, wherein the mandrel is electrically conductive, and a proximal end portion of the mandrel is uninsulated and operable for connecting to a power supply such that the distal tip electrode is in electrical communication with the power supply, and energy can be delivered through the distal tip electrode to tissue, and the distal tip electrode enables recording epicardial EGM.

56. The elongate puncture device of claim **55**, wherein a shaft of the elongate puncture device is electrically insulated to reduce noise from any collected local EGM.

57. The elongate puncture device of any one of claims **45** to **53**, wherein the distal tip electrode has a hemispherical dome with an outer diameter >0.027" (0.686 mm) and a surface area of about 1.8 to about 2.4 mm^2.

58. The elongate puncture device of any one of claims **45** to **53**, further comprising a distal end portion which has a J-profile.

59. The elongate puncture device of claim **58**, further comprising a radiopaque coil which extends around a curve of the distal end portion which has a J-profile.

60. The elongate puncture device of claim **59**, wherein an end of the radiopaque coil can be used as a distal tip marker.

61. The elongate puncture device of claim **59**, wherein the radiopaque coil has echogenic properties when using ultrasound to enable visualization of the guidewire tip.

62. An introducer for use with an elongate puncture device, the introducer comprising an introducer shaft connected to a hub, the introducer shaft comprising an internal metal tube which is interposed between two layers of insulation with both ends of the two layers being joined together to bond the layers.

63. The introducer of claim **62**, wherein the two layers of insulation are comprised of high-density polyethylene.

64. The introducer of claim **62** or **63**, wherein the hub further comprise a male side port for connecting to tubing and a receiving opening for receiving a stylet or a wire whereby the hub is operable to be simultaneously attached to source of fluid while a stylet or a wire is inserted into the hub.

65. A kit comprising an introducer and an elongate puncture device, the elongate puncture device including a distal tip electrode which enables recording epicardial EGM and a shaft of the elongate puncture device is electrically insulated to reduce noise in any collected local EGM; and

the introducer comprising an introducer shaft which connected to a hub, the introducer shaft comprising an internal metal tube which is interposed between two layers of electrical insulation with both ends of the two layers being joined together to bond the layers to reduce noise in any EGM collected by the elongate puncture device.

66. The kit of claim **65**, wherein the introducer and the elongate puncture device are configured such that the introducer has the ability to deliver and withdraw fluid while the elongate puncture device is inserted therethrough.

67. The kit of claim **66**, wherein the radial gap between an inner diameter of a tip of the introducer and outer diameter of the elongate puncture device is >0.025 mm (0.001").

68. The kit of claim **67**, wherein the kit is operable to provide contrast flow >15 ml/min at 69 Kilo Pascal (10 PSI).

69. The kit of claim **67**, wherein the inner diameter of a tip of the introducer is 0.978 mm (0.0385 inches)+/−0.013 mm (0.0005 inches), and the maximum outer diameter of the elongate puncture device is 0.889 mm (0.0350 inches)+/−0.013 mm (0.0005 inches), whereby the minimum gap with this geometry is 0.032 mm (0.00125").

70. The kit of any one of claims **65** to **69**, further comprising a stylet wherein a cross section of the stylet varies along the length of the stylet, tapering down towards a distal tip of the stylet to allow a flow of a fluid through a tip of the introducer when the stylet is installed.

71. The kit of any one of claims **65** to **69**, further comprising a stylet wherein the stylet is electrically insulated and operable to be connected to a recording system to facilitate collecting EGM information to help in positioning a tip of the introducer when approaching the heart.

72. The kit of any one of claims **65** to **69**, further comprising markers for positioning the elongate puncture device relative to the introducer wherein the elongate puncture device has a proximal marker which is visible to a naked eye and a distal tip marker which is visible under an imaging system, and the introducer has distal end marker which is visible under the imaging system.

73. The kit of claim **72**, wherein the distal tip marker and distal end marker are visible under fluoroscopy.

74. The kit of claim **72**, wherein a tip of the elongate puncture device extends distal of a shaft of the introducer shaft when the proximal marker of the elongate puncture device is positioned at a proximal end of a hub of the introducer.

75. The kit of claim **72**, wherein a tip of the elongate puncture device lines up with a distal end of a shaft of the introducer shaft when the proximal marker of the elongate puncture device is positioned at a proximal end of a hub of the introducer.

76. The method of any one of claims **1** to **5**, **11** to **15**, **21**, **33**, and **43**, wherein the elongate puncture device comprises a radiofrequency guidewire.

77. The elongate puncture device of any one of claims **45** to **53**, wherein the elongate puncture device comprises a radiofrequency guidewire.

78. The kit of any one of claims **65** to **69**, wherein the elongate puncture device comprises a radiofrequency guidewire.

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