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(54) MYOCARDIAL LEAD ATTACHMENT SYSTEM

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Related U.S. Application Data

(60) Provisional application No. 60/514,037, filed on Oct. 24, 2003. Provisional application No. 60/514,665, filed on Oct. 27, 2003. Provisional application No. 60/514,042, filed on Oct. 24, 2003. Provisional application No. 60/514,714, filed on Oct. 27, 2003. Provisional application No. 60/514,039, filed on Oct. 24, 2003. Provisional application No. 60/514,146, filed on Oct. 24, 2003. Provisional application No. 60/514,038, filed on Oct. 24, 2003. Provisional application No. 60/514,713, filed on Oct. 27, 2003.

Publication Classification

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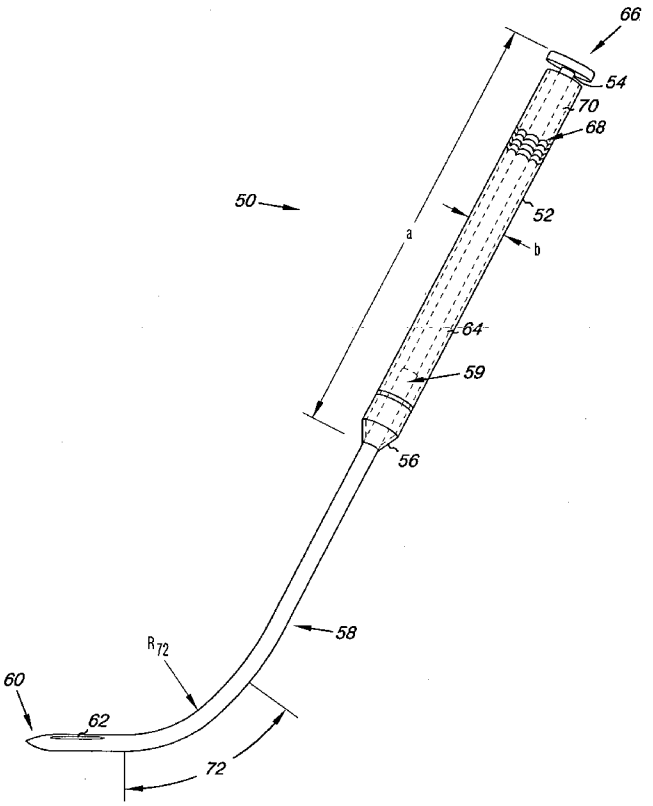
(52) **U.S. Cl.** **607/130**

(57) ABSTRACT

The present invention is a myocardial lead attachment system for securing a distal end of a lead within a myocardium of a patient's heart. The system includes an anchor, a tether coupled to the anchor, and a delivery instrument for receiving and advancing the anchor through a tract in the heart from a proximal entrance site to a distal exit site in such a manner that the tether extends proximally from the anchor through the tract. The delivery instrument includes a needle having a distal tip and a nest. The nest is positioned proximal to the distal tip and is sized to receive the anchor. The delivery instrument further includes an ejection mechanism for ejecting the anchor from the nest.



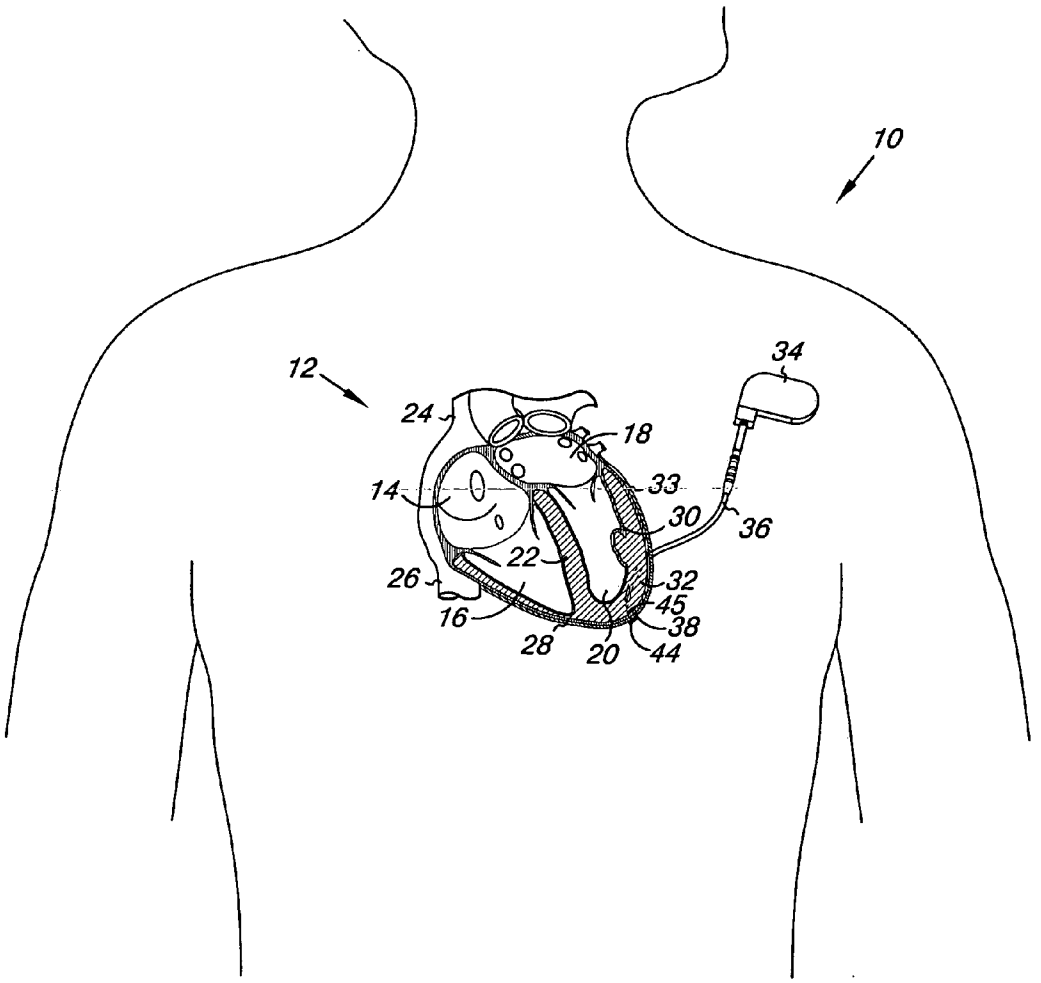


Fig. 1

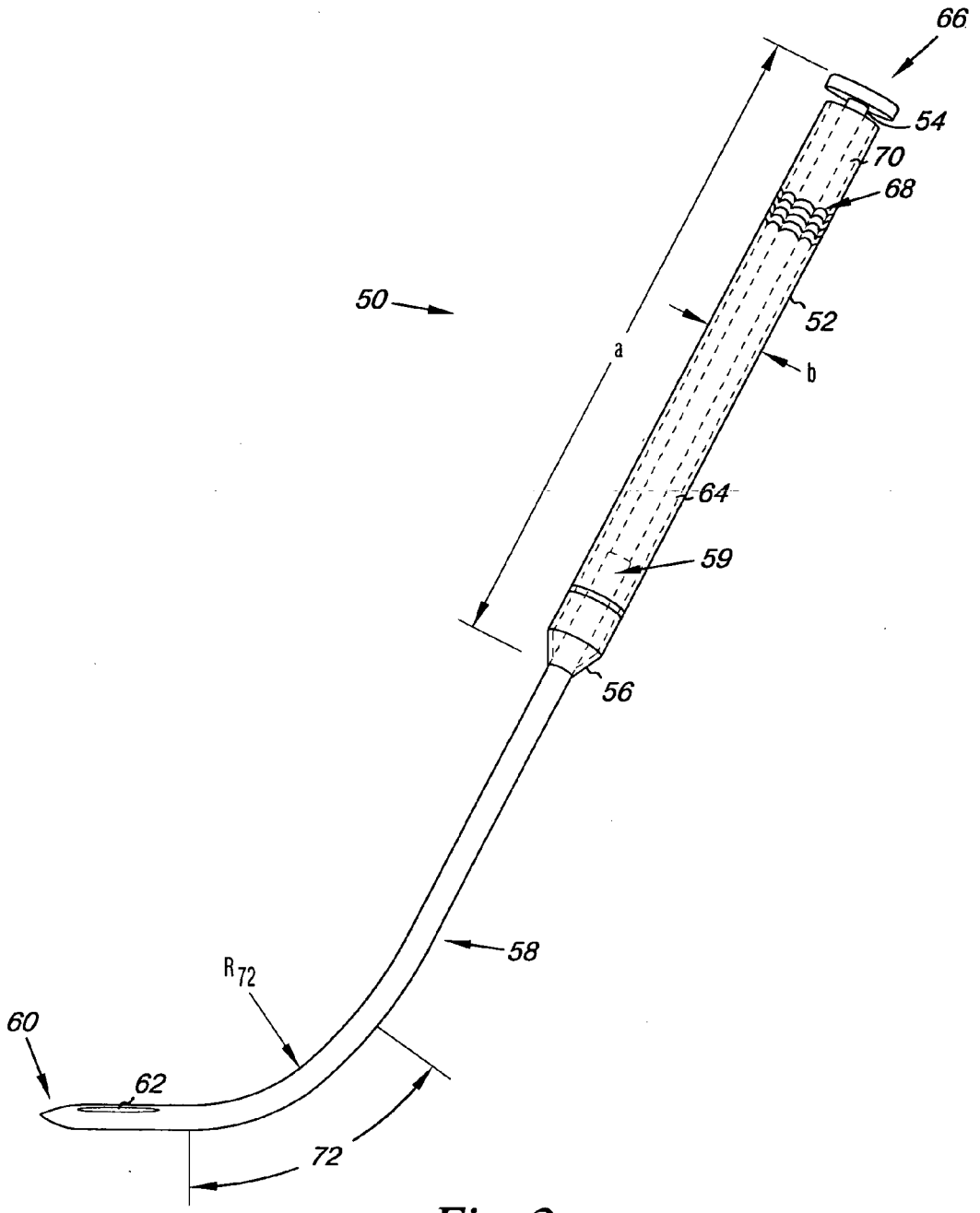


Fig. 2

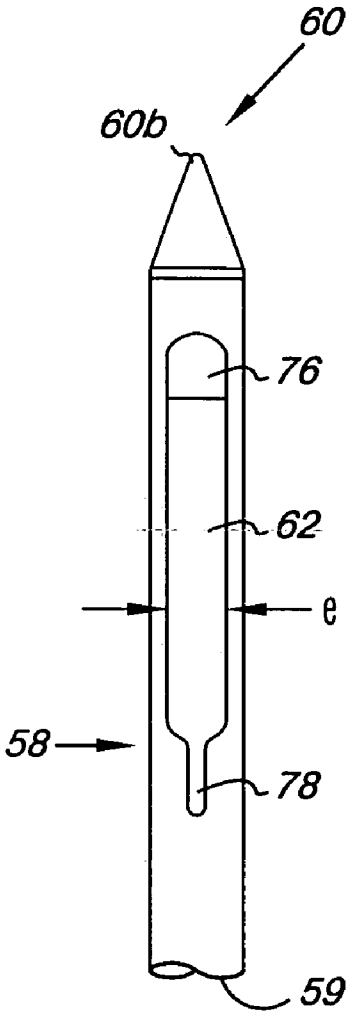


Fig. 3A

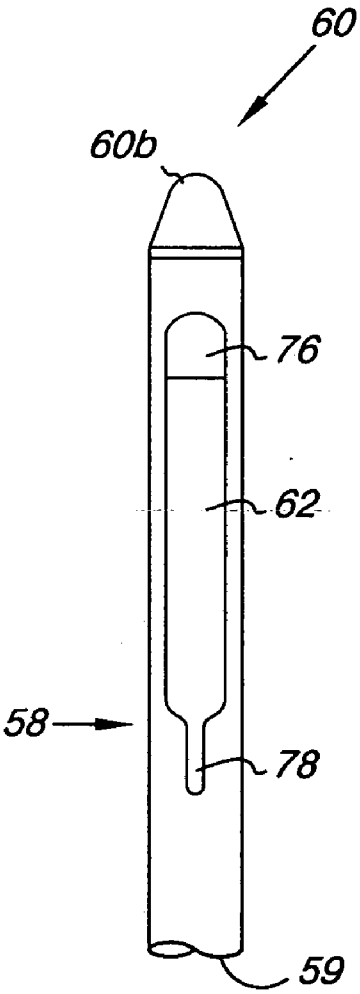


Fig. 3B

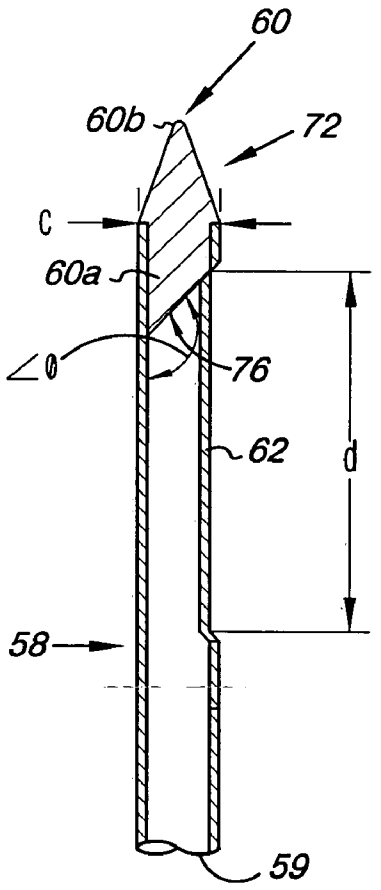


Fig. 3C

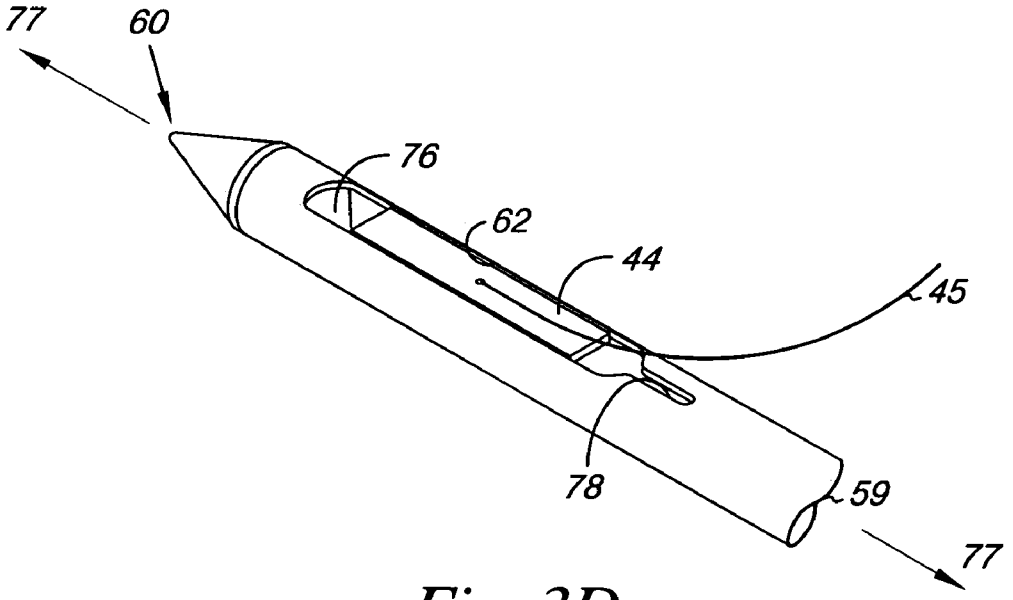


Fig. 3D

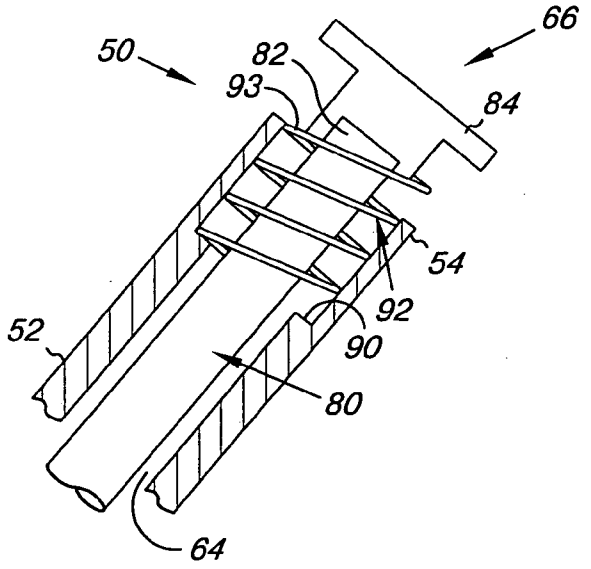


Fig. 4A

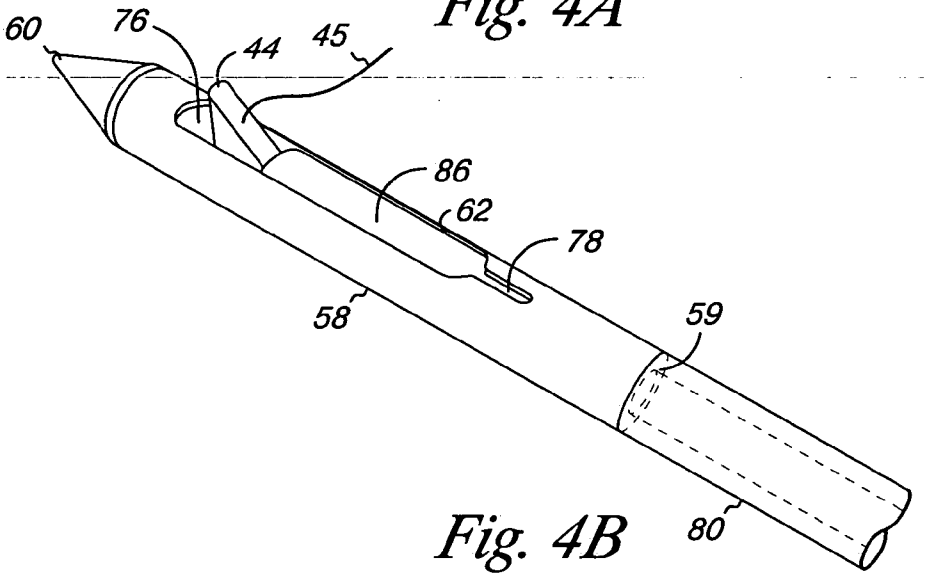


Fig. 4B

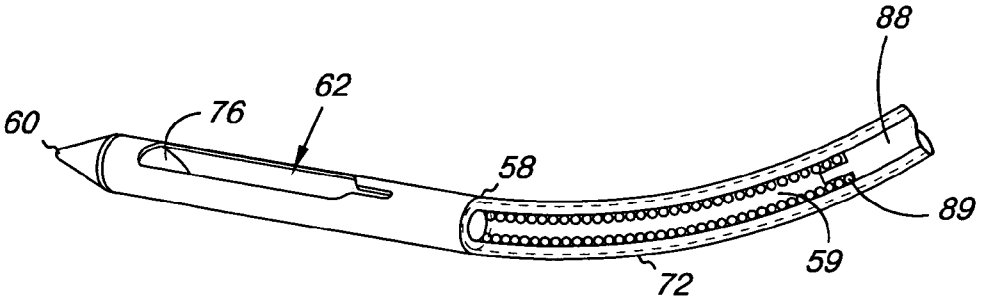


Fig. 4C

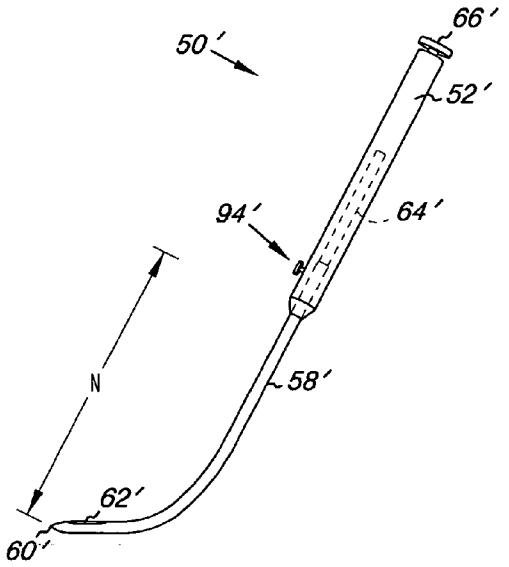


Fig. 5A

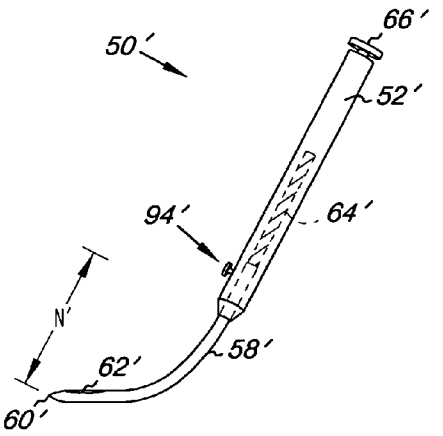


Fig. 5B

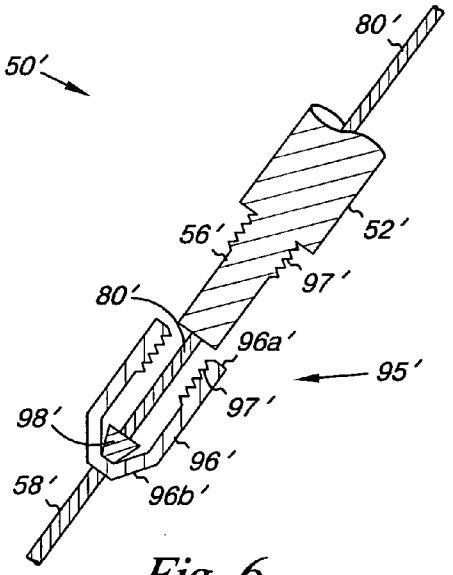


Fig. 6

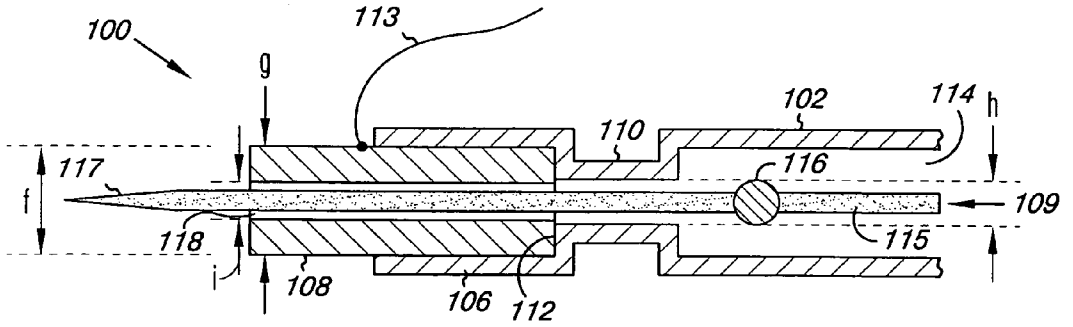


Fig. 7

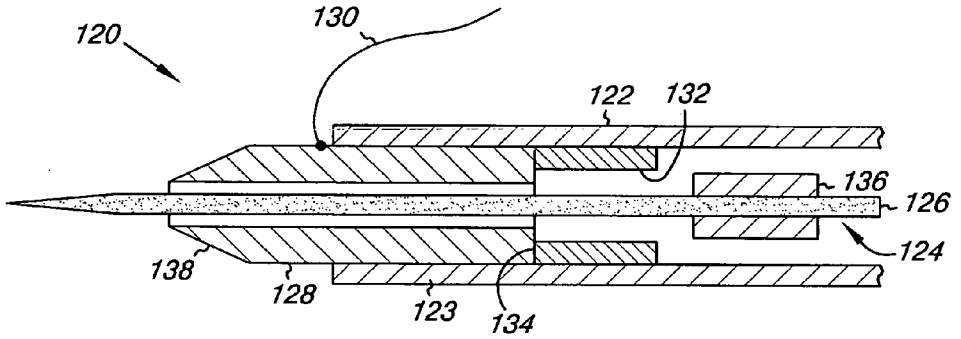


Fig. 8

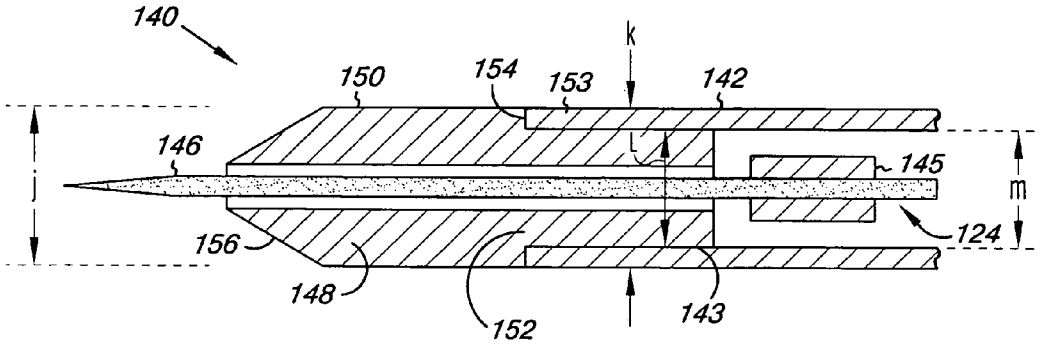


Fig. 9

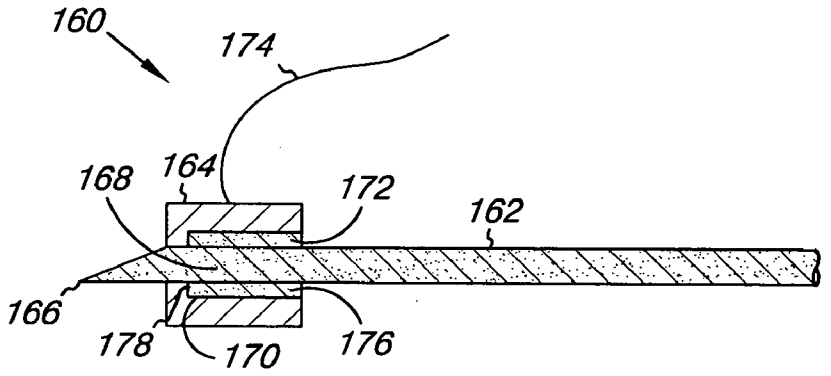


Fig. 10

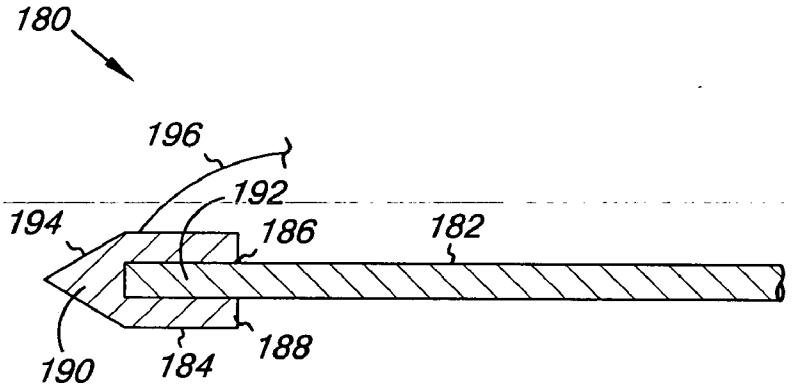


Fig. 11

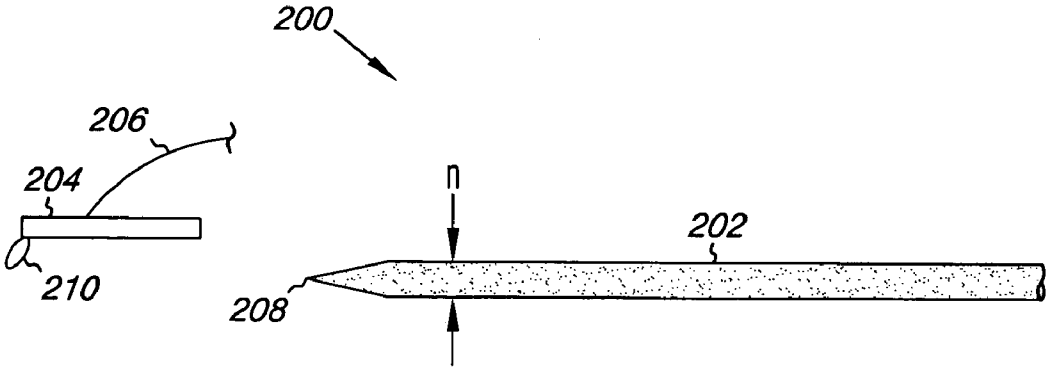


Fig. 12

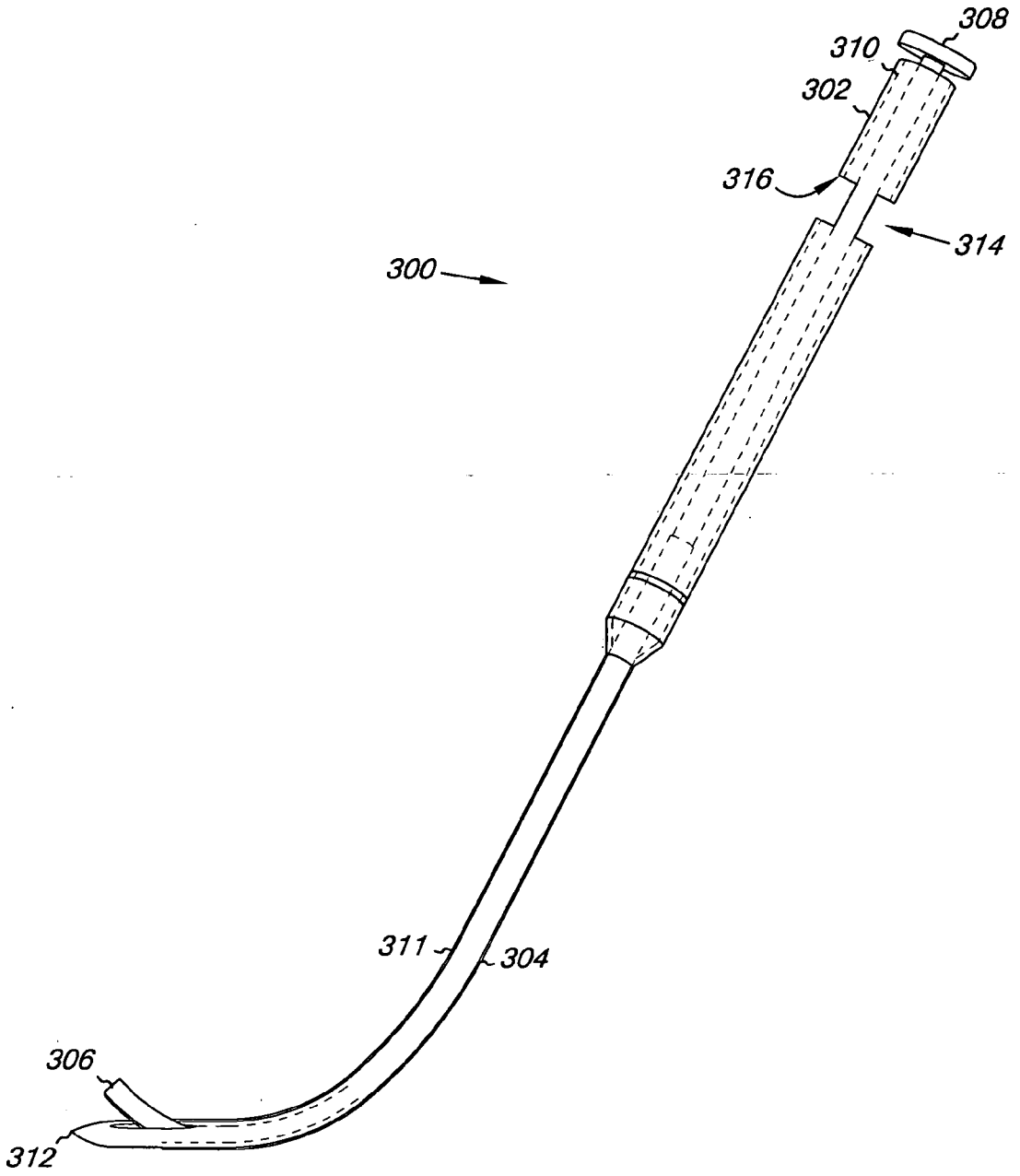


Fig. 13

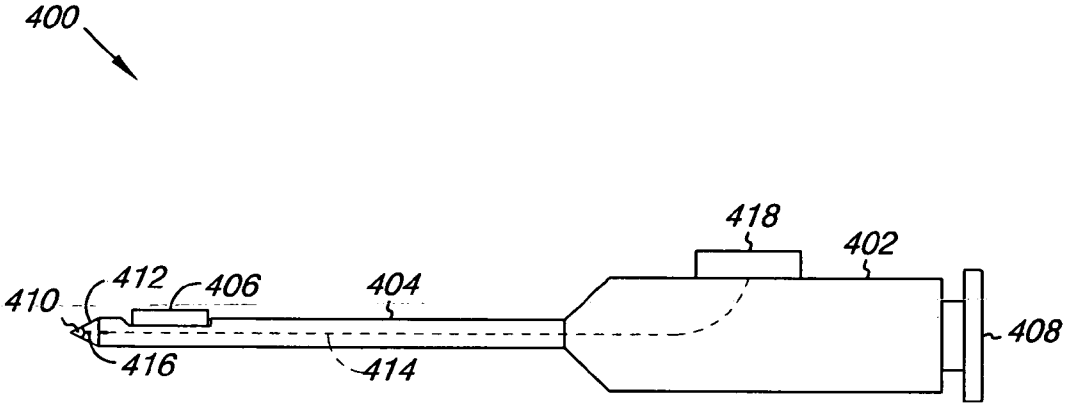


Fig. 14

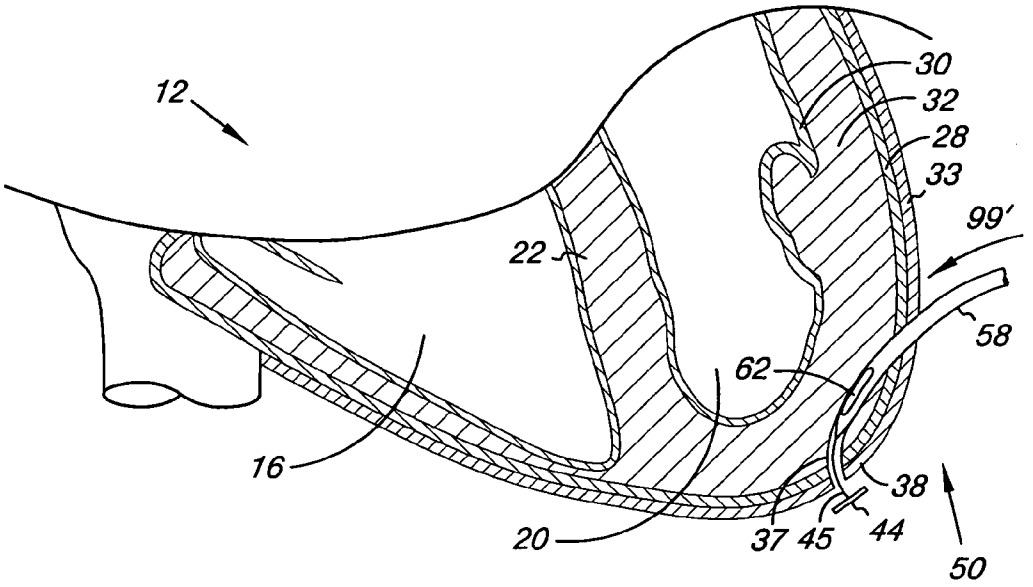


Fig. 15A

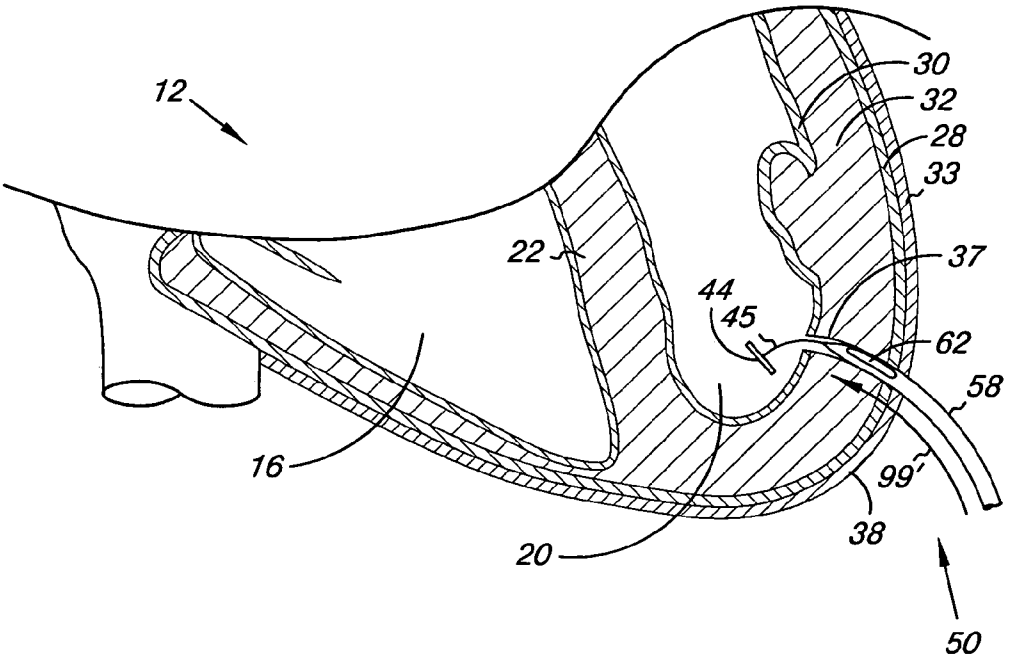


Fig. 15B

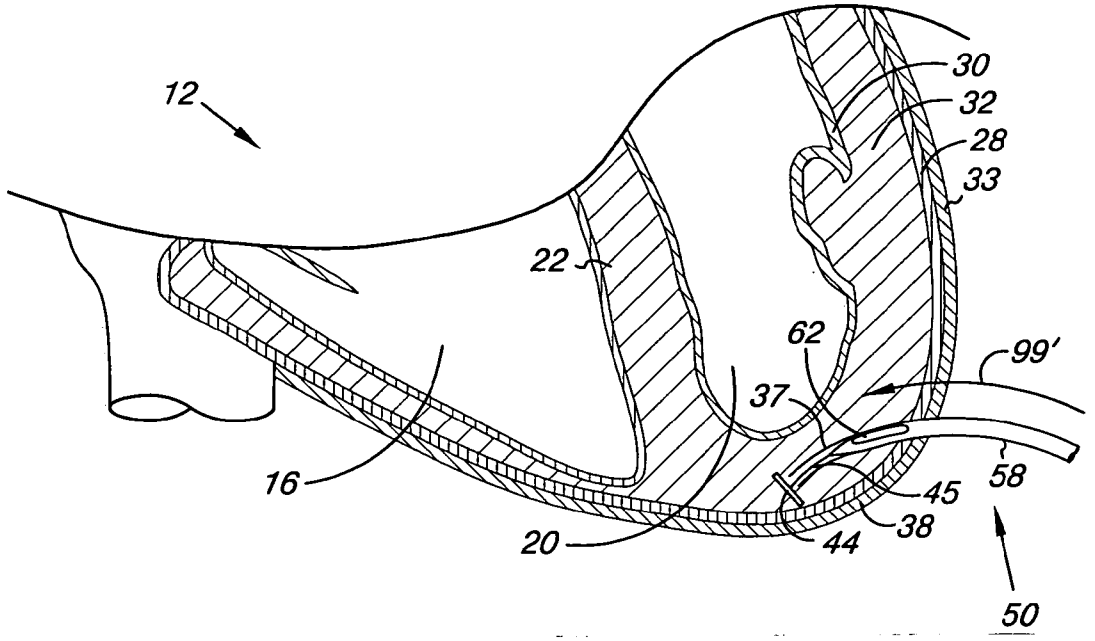


Fig. 15C

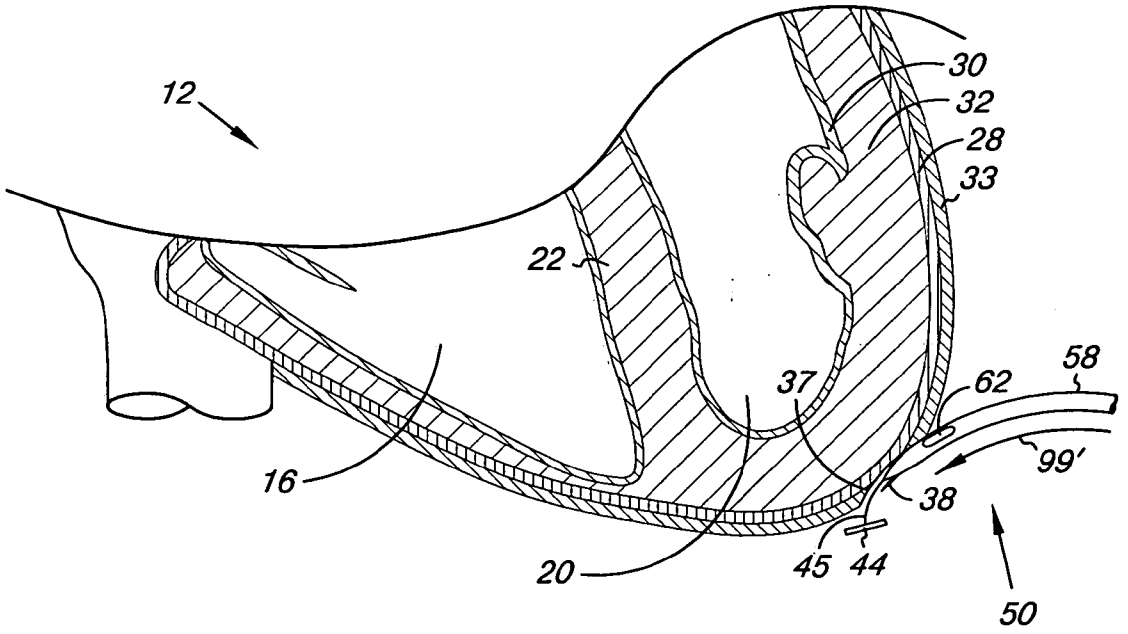


Fig. 15D

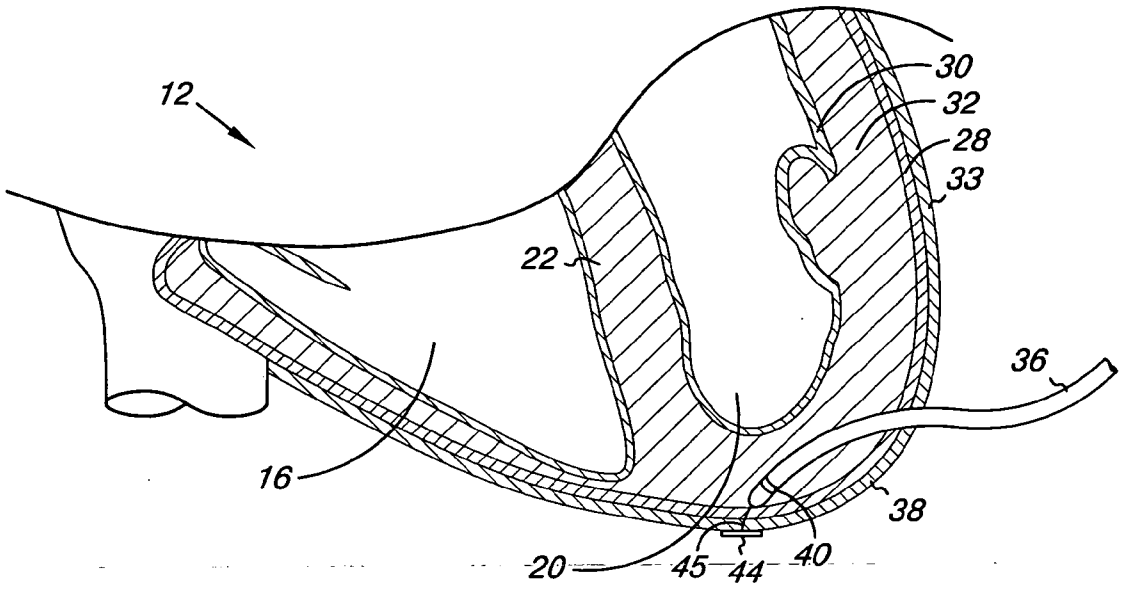


Fig. 16A

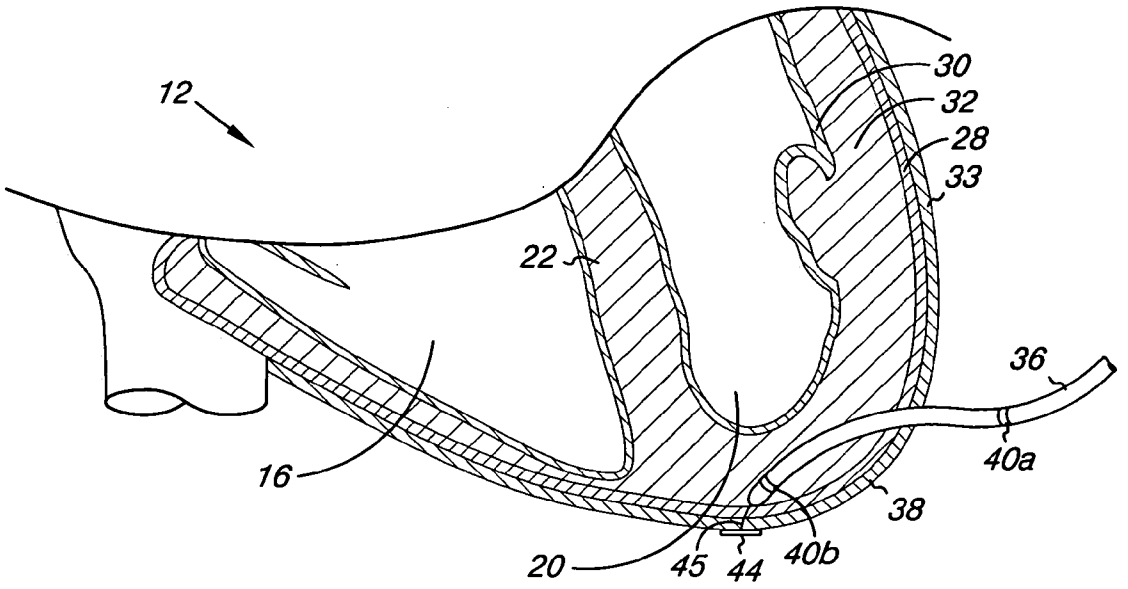


Fig. 16B

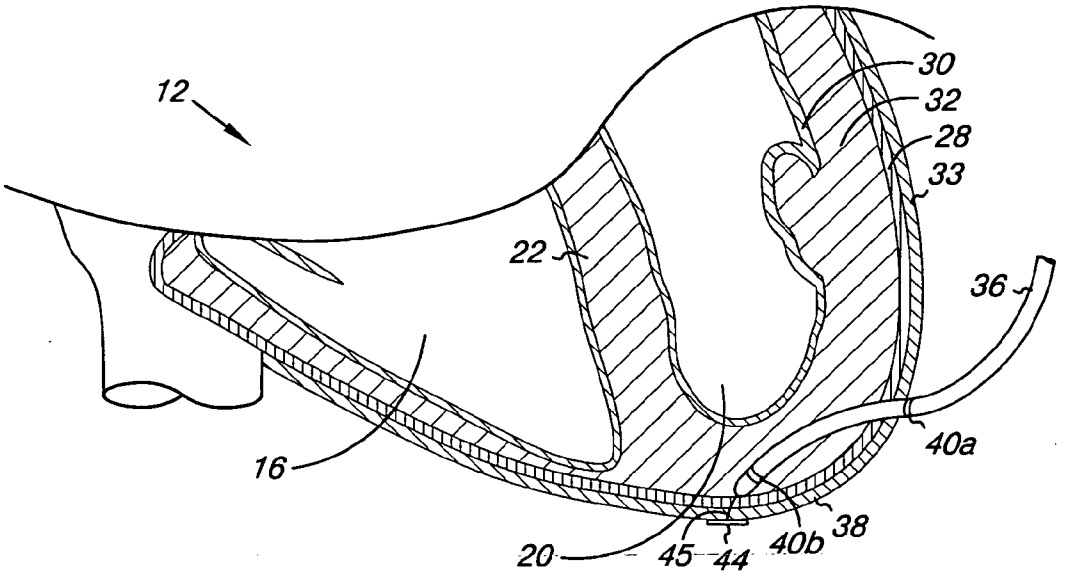


Fig. 16C

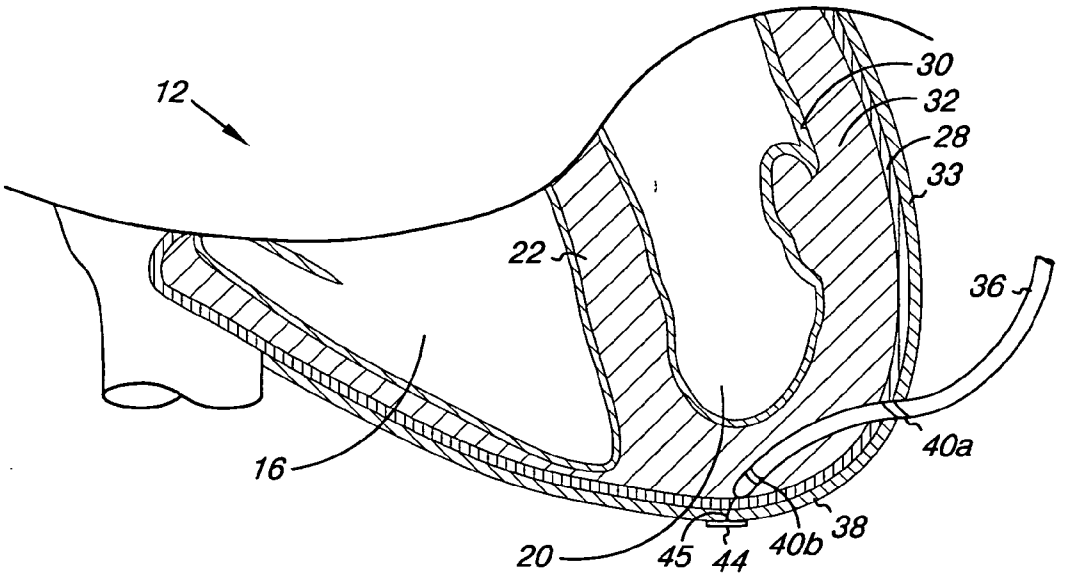


Fig. 16D

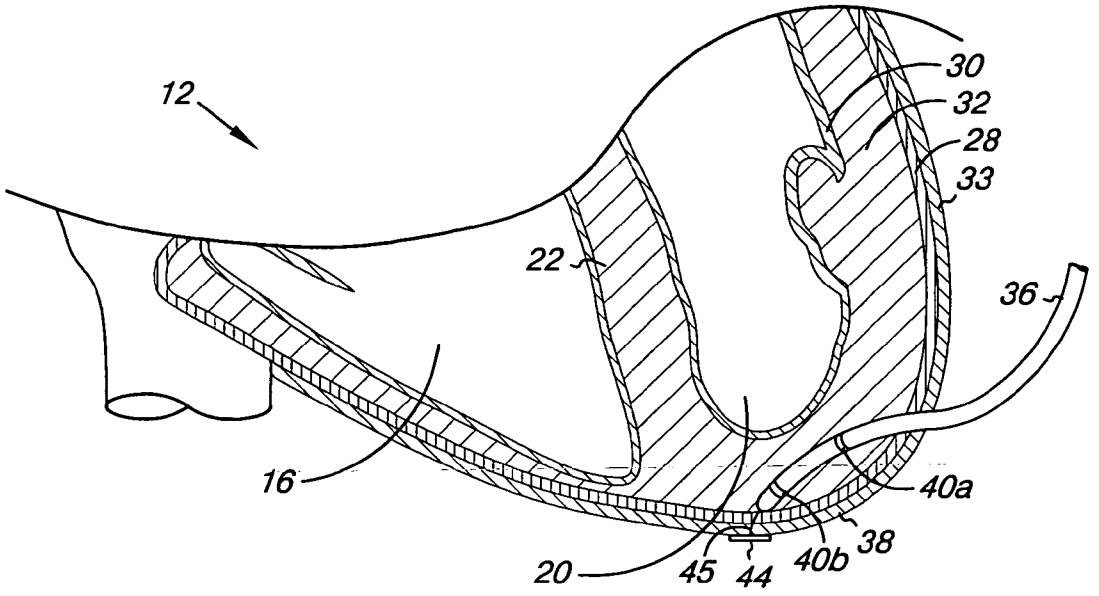


Fig. 16E

MYOCARDIAL LEAD ATTACHMENT SYSTEM

CROSS REFERENCES

[0001] The present application claims the benefit of the following U.S. Provisional Applications: application Ser. No. 60/514,037 filed Oct. 24, 2003, entitled "Absorbable Myocardial Lead Fixation System", application Ser. No. 60/514,665 filed Oct. 27, 2003, entitled "Lead Electrode Arrangement for Myocardial Leads", application Ser. No. 60/514,042 filed Oct. 24, 2003, entitled "Tapered Tip for Myocardial Lead", application Ser. No. 60/514,714 filed Oct. 27, 2003, entitled "Minimally-Invasive Fixation Systems for Over-the-Tether Myocardial Leads", application Ser. No. 60/514,039 filed Oct. 24, 2003, entitled "Distal or Proximal Fixation of Over-the-Suture Myocardial Leads", application Ser. No. 60/514,146 filed Oct. 24, 2003, entitled "Myocardial Lead with Fixation Mechanism", application Ser. No. 60/514,038 filed Oct. 24, 2003 entitled "Delivery Instrument for Myocardial Lead Placement" and application Ser. No. 60/514,713 filed Oct. 27, 2003, entitled "Drug-Eluting Myocardial Leads", all of which are incorporated herein by reference.

[0002] Reference is hereby made to the following commonly assigned U.S. patent application Ser. No. 10/821,421, filed Apr. 9, 2004, entitled "Cardiac Electrode Anchoring System" and the following commonly assigned U.S. Patent applications filed on an even date herewith, all of which are incorporated herein by reference: application Ser. No. _____, entitled "Myocardial Lead", application Ser. No. _____ entitled "Distal or Proximal Fixation of Over-the-Tether Myocardial Leads", application Ser. No. _____, entitled "Myocardial Lead with Fixation Mechanism" and application Ser. No. _____, entitled "Absorbable Myocardial Lead Fixation System."

FIELD OF THE INVENTION

[0003] This invention relates generally to implantable lead assemblies for stimulating and/or sensing electrical signals in muscle tissue. More particularly, it relates to myocardially implanted leads for cardiac stimulation and systems for anchoring the leads.

BACKGROUND OF THE INVENTION

[0004] Cardiac rhythm management systems are used to treat heart arrhythmias. Pacemaker systems are commonly implanted in patients to treat bradycardia (i.e., abnormally slow heart rate). A pacemaker system includes an implantable pulse generator and leads, which form the electrical connection between the implantable pulse generator and the heart. An implantable cardioverter defibrillator ("ICD") is used to treat tachycardia (i.e., abnormally rapid heart rate). An ICD also includes a pulse generator and leads that deliver electrical energy to the heart.

[0005] The leads coupling the pulse generator to the cardiac muscle are commonly used for delivering an electrical pulse to the cardiac muscle, for sensing electrical signals produced in the cardiac muscle, or for both delivering and sensing. The leads are susceptible to categorization according to the type of connection they form with the heart. An endocardial lead includes at least one electrode at or near its distal tip adapted to contact the endocardium (i.e., the tissue lining the inside of the heart). An epicardial lead includes at least one electrode at or near its distal tip adapted to contact the epicardium (i.e., the tissue lining the outside of the heart). Finally, a myocardial lead includes at least one electrode at or near its distal tip inserted into the heart muscle or myocardium (i.e., the muscle sandwiched between the endocardium and epicardium). Some leads have multiple spaced apart distal electrodes at differing polarities and are known as bipolar type leads. The spacing between the electrodes can affect lead performance and the quality of the electrical signal transmitted or sensed through the heart tissue.

[0006] The lead typically consists of a flexible conductor surrounded by an insulating tube or sheath that extends from the electrode at the distal end to a connector pin at the proximal end. Endocardial leads are typically delivered transvenously to the right atrium or ventricle and commonly employ tines at a distal end for engaging the trabeculae.

[0007] The treatment of congestive heart failure ("CHF"), however, often requires left ventricular stimulation either alone or in conjunction with right ventricular stimulation. For example, cardiac resynchronization therapy ("CRT") (also commonly referred to as biventricular pacing) is an emerging treatment for heart failure, which requires stimulation of both the right and the left ventricle to increase cardiac output. Left ventricular stimulation requires placement of a lead in or on the left ventricle near the apex of the heart. One technique for left ventricular lead placement is to expose the heart by way of a thoracotomy. The lead is then positioned so that one or more electrodes contact the epicardium or are embedded in the myocardium. Another method is to advance an epicardial lead endovenously into the coronary sinus and then advance the lead through a lateral vein of the left ventricle. The electrodes are positioned to contact the epicardial surface of the left ventricle.

[0008] The left ventricle beats forcefully as it pumps oxygenated blood throughout the body. Repetitive beating of the heart, in combination with patient movement, can sometimes dislodge the lead from the myocardium. The electrodes may lose contact with the heart muscle, or spacing between electrodes may alter over time.

[0009] There is a need for an improved myocardial pacing lead suitable for chronic implantation and a minimally invasive delivery system and method for implanting such a lead.

SUMMARY OF THE INVENTION

[0010] The present invention, according to one embodiment, is a myocardial lead attachment system for securing a distal end of a lead within a myocardium of a patient's heart. The system includes an anchor, a tether coupled to the anchor and a delivery instrument for receiving the anchor and advancing the anchor through a tract in the heart from a proximal entrance site to a distal exit site in such a manner that the tether extends proximally from the anchor through the tract. The delivery instrument includes a needle having a distal tip and a nest positioned proximal to the distal tip that is sized to receive the anchor and an ejection mechanism for ejecting the anchor from the nest.

[0011] The present invention, according to another embodiment, is a myocardial lead attachment system for securing a distal end of a lead within a myocardium of a

patient's heart. The system includes an anchor having a longitudinal bore extending therethrough, a tether coupled to the anchor and a delivery instrument for receiving the anchor and advancing the anchor through a tract in the heart from a proximal entrance site to a distal exit site in such a manner that the tether extends proximally from the anchor through the tract. The delivery instrument includes a needle having a proximal end, a distal end formed with a nest for receiving the anchor and a central lumen extending therethrough. The delivery instrument further includes a stylet slidably received in the needle lumen and the anchor bore and an ejector plug formed on the stylet for engaging the anchor.

[0012] The present invention, according to another embodiment, is a method for using a delivery instrument to implant a myocardial lead having at least a first electrode with a delivery instrument into a heart. A myocardial anchor coupled to a tether. is mated to a distal end of the delivery instrument. The distal end of the delivery instrument is advanced through a tract in the heart. The anchor is deployed into the heart. The delivery instrument is withdrawn through the tract in such a manner that the tether extends through the tract. A myocardial lead is threaded onto the tether. The lead is advanced over the tether into the heart.

[0013] This summary is not intended to describe each embodiment or every implementation of the present invention. Advantages and a more complete understanding of the invention will become apparent upon review of the detailed description and claims in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] **FIG. 1** is a schematic view of a portion of the vasculature and a myocardial lead attachment system according to one embodiment of the present invention.

[0015] **FIG. 2** is a side view of a delivery instrument for use in conjunction with the myocardial lead attachment system of **FIG. 1** according to one embodiment of the present invention.

[0016] **FIG. 3A** is a side view of a distal portion of the delivery instrument of **FIG. 2** according to one embodiment of the present invention.

[0017] **FIG. 3B** is a side view of the distal portion of the delivery instrument of **FIG. 2** according to another embodiment of the present invention.

[0018] **FIG. 3C** shows a side sectional view of the distal portion of the delivery instrument shown in **FIG. 3A**.

[0019] **FIG. 3D** is a perspective view of the distal portion of the delivery instrument shown in **FIG. 3A**.

[0020] **FIG. 4A** is a sectional view of a proximal portion of the delivery instrument of **FIG. 2** according to one embodiment of the present invention.

[0021] **FIG. 4B** is a perspective view of a distal portion of the delivery instrument of **FIG. 2** according to one embodiment of the present invention.

[0022] **FIG. 4C** is a partial sectional view of a distal portion of the delivery instrument of **FIG. 2** according to another embodiment of the present invention.

[0023] **FIG. 5A** is a side view of an adjustable length delivery instrument in an extended position according to one embodiment of the present invention.

[0024] **FIG. 5B** is a side view of the delivery instrument of **FIG. 5A** in a retracted position.

[0025] **FIG. 6** is a sectional side view of a portion of an adjustable length delivery instrument according to another embodiment of the present invention.

[0026] **FIG. 7** is a sectional view of a distal portion of a delivery instrument for use in conjunction with the myocardial lead attachment system of **FIG. 1** according to one embodiment of the present invention.

[0027] **FIG. 8** is a sectional view of a distal portion of a delivery instrument for use in conjunction with the myocardial lead attachment system of **FIG. 1** according to another embodiment of the present invention.

[0028] **FIG. 9** is a sectional view of a distal portion of a delivery instrument for use in conjunction with the myocardial lead attachment system of **FIG. 1** according to still another embodiment of the present invention.

[0029] **FIG. 10** is a sectional side view of a distal portion of a delivery instrument for use in conjunction with the myocardial lead attachment system of **FIG. 1** according to yet another embodiment of the present invention.

[0030] **FIG. 11** is a sectional side view of a distal portion of a delivery instrument for use in conjunction with the myocardial lead attachment system of **FIG. 1** according to another embodiment of the present invention.

[0031] **FIG. 12** is a side view of a distal portion of a delivery instrument for use in conjunction with the myocardial lead attachment system of **FIG. 1** according to still another embodiment of the present invention.

[0032] **FIG. 13** is a side view of a delivery instrument for use in conjunction with the myocardial lead attachment system of **FIG. 1** according to another embodiment of the present invention.

[0033] **FIG. 14** is a side view of a delivery instrument for use in conjunction with the myocardial lead attachment system of **FIG. 1** according to another embodiment of the present invention.

[0034] **FIG. 15A** is a sectional view of the heart schematically illustrating the use of a delivery instrument in conjunction with a myocardial lead attachment system in an epicardial-epicardial procedure according to one embodiment of the present invention.

[0035] **FIG. 15B** is a sectional view of the heart schematically illustrating the use of a delivery instrument in conjunction with a myocardial lead attachment system in an epicardial-endocardial configuration according to one embodiment of the present invention.

[0036] **FIG. 15C** is a sectional view of a portion of the heart schematically illustrating the use of a delivery instrument in conjunction with a myocardial lead attachment system in an intra-myocardial procedure according to another embodiment of the present invention.

[0037] **FIG. 15D** is a sectional view of a portion of the heart schematically illustrating the use of a delivery instru-

ment in conjunction with a myocardial lead attachment system in a pericardial-pericardial procedure according to yet another embodiment of the present invention.

[0038] **FIG. 16A** is a sectional view of a portion of the heart and a schematically illustrated distal portion of a myocardial lead attachment system having a unipolar electrode arrangement according to one embodiment of the present invention.

[0039] **FIG. 16B** is a sectional view of a portion of the heart and a schematically illustrated distal portion of a myocardial lead attachment system having a pseudo-unipolar electrode arrangement according to one embodiment of the present invention.

[0040] **FIG. 16C** is a sectional view of a portion of the heart and a schematically illustrated distal portion of a myocardial lead attachment system having a pseudo-unipolar electrode arrangement according to yet another embodiment of the present invention.

[0041] **FIG. 16D** is a sectional view of a portion of the heart and a schematically illustrated distal portion of a myocardial lead attachment system having a pseudo-unipolar electrode arrangement according to still another embodiment of the present invention.

[0042] **FIG. 16E** is a sectional view of a portion of the heart and a schematically illustrated distal portion of a myocardial lead attachment system having a bipolar electrode arrangement according to another embodiment of the present invention.

[0043] While the invention is amenable to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and are described in detail below. The intention, however, is not to limit the invention to the particular embodiments described. On the contrary, the invention is intended to cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION

[0044] **FIG. 1** shows a myocardial lead attachment system **10** deployed in a human heart **12** according to one embodiment of the present invention. The heart **12** includes a right atrium **14** and a right ventricle **16** separated from a left atrium **18** and a left ventricle **20** by a septum **22**. During normal operation of the heart **12**, deoxygenated blood is fed into the right atrium **14** through the superior vena cava **24** and the inferior vena cava **26**. The deoxygenated blood flows from the right atrium **14** into the right ventricle **16**. The deoxygenated blood is pumped from the right ventricle **16** into the lungs, where the blood is re-oxygenated. From the lungs the oxygenated blood flows into the left atrium **18**, then into the left ventricle **20**. The left ventricle **20** beats forcefully to pump the oxygenated blood throughout the body.

[0045] The outer walls of the heart **12** are lined with a tissue known as the epicardium **28**. The inner walls of the heart are lined with a tissue known as the endocardium **30**. The heart muscle, or myocardium **32**, is sandwiched between the endocardium **30** and the epicardium **28**. A tough outer pericardial sac **33** surrounds the heart **12**.

[0046] The myocardial lead attachment system **10** includes a pulse generator **34** coupled to a myocardial lead **36**. The pulse generator **34** is typically implanted in a pocket formed, underneath the skin of the patient's chest or abdominal region. The lead **36** extends from the pulse generator **34** to the heart **12** and is implanted in the myocardium **32** near an apex **38** of the heart **12**. The lead **36** delivers electrical signals from the pulse generator **34** to an electrode located at or near a distal tip to accomplish pacing of the heart **12** (not shown in **FIG. 1**). An anchor mechanism **44** is coupled to the lead **36** via a tether **45** to secure the lead **36** to the heart **12** and to retain the electrode in a chosen location.

[0047] According to one embodiment, and generally shown in the following figures, the anchor mechanism **44** is an elongated T-bar, in which the tether **45** is coupled to the anchor mechanism **44** between its opposite ends and preferably at a mid-point to form the "T". According to other embodiments, the anchor mechanism **44** has any other shape suitable for forming an anchor against the heart **12** to retain the lead **36** in the desired location. An important feature of the anchor mechanism **44** is that its shape is configured to engage the heart tissue following implantation through a tract (not visible in **FIG. 1**) in the heart **12** to reduce the likelihood of re-entry of the anchor mechanism **44** into the tract. According to one embodiment, the length of the anchor mechanism **44** is greater than the diameter of the tract. The "T" configuration is such that tension exerted on the mid-point of the anchor mechanism **44** via the tether **45** tends to position the anchor mechanism **44** cross-wise over the tract, preventing the anchor mechanism from siding proximally through the tract. The lead **36** is then advanced over the tether **45** into the myocardium **32**. The anchor mechanism **44** resists the tensioning force exerted on the tether **45** such that the lead **36** may be easily advanced through the tract.

[0048] Placement of the lead **36** and anchor mechanism **44** of **FIG. 1** may be accomplished by exposing a portion of the heart **12**, for example by way of a sternotomy, thoracotomy or mini-thoracotomy. According to other embodiments, the heart **12** may be accessed via an endoscopic procedure according to known methods. Although shown implanted near the apex **38**, the lead **36** may be implanted in the heart **12** anywhere pacing therapy is needed. The anchor mechanism **44** is delivered to the heart **12** with a delivery instrument according to any of the following embodiments.

[0049] **FIG. 2** shows a delivery instrument **50** according to one embodiment of the present invention. The delivery instrument **50** includes a needle portion **58** having a distal tip **60** and a nest **62**. The nest **62** is sized to receive at least a portion of the anchor mechanism **44** (not visible in **FIG. 2**). The delivery instrument **50** further includes an ejection mechanism **66** coupled to an actuator (not visible in **FIG. 2**) for ejecting the anchor mechanism **44** from the nest **62**.

[0050] The delivery instrument **50** includes a handle **52** having a proximal end **54** and a distal end **56**. The needle portion **58** is coupled to the handle **52** and extends from the distal end **56**. The needle portion **58** is of a hypotube construction with an internal lumen **59**. The handle **52** has an internal lumen **64** continuous with the needle lumen **59**. The ejection mechanism **66** is located on the handle **52** and is operable within the internal lumen **64**. According to other embodiments, the ejection mechanism **66** is located elsewhere on the handle **52**.

[0051] The handle **52** is sized with a length a and diameter b for easy grasping and manipulation. According to one embodiment of the present invention, a diameter b of about 5 mm provides a mechanical advantage allowing stable control over the direction of the distal needle tip **60**. Further, a diameter b of about 5 mm can be used within a standard 7 mm or larger thoracic port, which is commonly used in minimally-invasive thoracoscopic procedures to access the heart **12**.

[0052] An outer surface **70** of the handle **52** includes a surface feature **68**. Surface feature **68** may include bumps, ribs, or bulging features on the outer surface **70** chosen to enhance the friction between the handle **58** and the surgeon's hand. Surface feature **68** advantageously reduces slippage between the surgeon's hand and the handle **52** while in wet, slippery environments. The handle **52** can be made of any sterilizable metal or polymeric material, including stainless steel, polypropylene, and polyurethane.

[0053] The shape of the distal needle portion **58** is configured to facilitate access to the heart **12** via thoracotomy or other procedures, such as those mentioned above. According to one embodiment of the present invention, the needle portion **58** is shaped with a curved portion **72**. The shape of the curved portion **72** will be dictated in part by patient anatomy (e.g., overall heart size, peculiarities in geometry due to dilation, epicardial fat, infarct, and vessels), location of the thoracotomy (posterior or anterior to an imaginary mid-axillary line bisecting the heart **12**), and size of the incision into the heart tissue. According to one embodiment, the curved portion **72** has a radius of curvature R_{72} of about 22 mm, a shape intended to be approximately what the physician would need for implanting the lead **36** via a thoracotomy. According to other embodiments, the radius of curvature R_{72} of curved portion **72** is from about 10 to about 35 mm (not shown). According to other embodiments, the curved portion **72** is constructed of multiple curved segments, or is straight (not shown).

[0054] According to one embodiment, the needle portion **58** is constructed of stainless steel. The curved portion **72** may be formed according to a variety of methods. The curved portion **72** may be formed by mechanically bending the needle portion **58**. Alternately, the needle portion **58** is heat-set so that the needle portion **58**, or a smaller portion thereof, is malleable. A chosen curvature can be imparted to the needle portion **58** contemporaneous with the implantation procedure according to the surgeon's needs.

[0055] **FIG. 3A** shows a portion of the needle portion **58** according to one embodiment of the present invention. The tip **60** and nest **62** are shown as previously described. A distal end **60***b* of the tip **60** is configured to minimize trauma to the myocardium **32** during insertion. This is accomplished by dissecting the myocardium **32** as opposed to cutting the myocardium **32**. According to one embodiment, the tip **60** is generally conical in shape, terminating at a slightly rounded point.

[0056] **FIG. 3B** shows another embodiment in which the distal end **60***b* of the tip **60** is more rounded or blunt than the embodiment shown in **FIG. 3A**. A rounded or blunted tip **60** is understood to be less traumatic and less likely to damage coronary vessels when passing through the myocardium **32**. According to one embodiment, the tip **60** is generally isodiametric. An isodiametric configuration generally exerts force equally on the myocardial tissue **32** about the tip **60** when passing through tissue. A uniform force distribution reduces excessive force on the myocardial tissue **32** in directions other than along the axis of dissection. According to other embodiments, the tip **60** is provided with a sharp cutting edge.

[0057] The nest **62** is sized with a length d and a width e chosen such that the nest **62** retains the anchor mechanism **44** when the needle portion **58** is advanced through the myocardium **32** (anchor mechanism **44** not visible in FIGS. **3**A and **3**B—see **FIG. 3D**). According to one embodiment, the nest **62** is an elongated slot in the needle portion **58** opening to the needle lumen **59**. The nest **62** further includes a tether slot **78** located near its proximal end. The tether slot **78** is adapted to accept the tether **45** when the needle portion **58** is advanced through the myocardium **32** (See **FIG. 3D**).

[0058] **FIG. 3C** shows the needle portion **58** of **FIG. 3A**. A proximal end **60***a* of the tip **60** is sized with a diameter c chosen to mate with the needle lumen **59**. The nest **62** includes a distal angled face or ramp **76** facing the interior of the nest **62**. The. ramp **76** is disposed at an angle θ relative to a longitudinal axis **77** of the needle **58**.

[0059] **FIG. 3D** shows the anchor mechanism **44** received in the nest **62**. The anchor mechanism **44** is placed in the slot **62** and slid proximally into the needle lumen **59**. The tether **45** is received in the tether slot **78**, permitting the anchor mechanism **44** to be slid further into the lumen **59**. The ramp **76** is inclined away from the anchor mechanism **44** at the angle θ at distal sliding of the anchor mechanism **44** along the axis **77** causes the anchor mechanism **44** to ride up the ramp **76** and out of the nest **62**.

[0060] **FIG. 4A** shows a proximal portion of the handle **52** and **FIG. 4B** shows a distal portion of the needle portion **58**, both detailing the ejection mechanism **66**. The ejection mechanism **66** includes an elongated member **80** extending from the proximal end **54** of the handle **52**, through the handle lumen **64** and needle lumen **59**, and terminating proximal to the nest **62**. A proximal end **82** of the elongated member **80** is operationally coupled to an actuator **84**. According to one embodiment, the actuator **84** is a depressible button operable to slide the elongated member **80** distally from a neutral or retracted position to an advanced position. **FIG. 4B** shows the elongated member **80** in an advanced position such that a distal end **86** of the elongated member **80** has engaged the anchor mechanism **44** and is pushing the anchor mechanism **44** distally within the nest **62**. Doing so forces the anchor mechanism **44** to slide distally along the ramp **76** and out of the nest **62**.

[0061] According to one embodiment, shown in **FIGS. 4A and 4B**, the elongated member **80** is a solid tubular member sufficiently flexible to navigate the curved portion **72** (see **FIG. 2**) of the needle portion **58**. According to another embodiment, as shown in **FIG. 4C**, the elongated member **80** is constructed of a combination of a solid member **88** and a helically-wound member **89**. The solid member **88** extends through the needle lumen **59** to the curved portion **72** and transfers axial force to the distally positioned helical member **89**, which extends through the needle lumen **59** at the curved portion **72**. The helical member **89** is sufficiently flexible to navigate the curved portion **72**, while the solid member **88** may be rigid. According to other embodiments, the elongated member **80** is a rigid member. Elongated member **80** may be constructed of a polymer or metal.

[0062] Returning to **FIG. 4A**, the handle lumen **64** is formed with a ledge **90** forming a mechanical stop. The ledge **90** blocks actuation of the actuator **84** (i.e. further depression of the button), and prevents over-advancement of the elongated member **80**. A biasing mechanism **92**, including a resilient member **93**, such as a spring, is interposed between the actuator **84** and the handle **52**. The biasing mechanism **92** biases the actuator **84** to a neutral position in which the elongated member **80** is retracted.

[0063] According to one embodiment, the ejection mechanism **66** and actuator **84** are operable to advance the elongated member **80** to one of a plurality of pre-set positions. According to another embodiment, the present invention is an automatic or semi-automatic delivery instrument. In this embodiment a lever mechanism, or trigger and spring mechanism, drives the needle portion **58** from a retracted position into the myocardium **32** in a prescribed path, ejects the anchor mechanism **44** and retracts the needle portion **58** to its original position.

[0064] **FIGS. 5A and 5B** show a delivery instrument **50'** which is generally similar to the delivery instrument **50** shown **FIG. 2**. The length of the needle portion **58'** of the instrument **50'** extending from the handle **52'** is adjustable by sliding portions of the needle portion **58'** into the handle lumen **64'**. In one embodiment, needle portion **58'** is retained in a chosen position within the handle lumen **64'** via a keeper mechanism, such as a set screw **94'**, extending through the handle **52'**. If the physician desires more needle length, N, as shown in **FIG. 5A**, either for patients with thick thoracic walls requiring a deeper reach to the epicardium **28** or for thoracoscopic procedures, he may adjust accordingly. If he requires less length N', as shown in **FIG. 5B**, the needle portion **58'** may be retracted into the lumen **64'**.

[0065] **FIG. 6** shows another embodiment of the adjustable length delivery instrument **50'** in which the needle portion **58'** is adjustably coupled to the handle **52'** via a collet mechanism **95'**. According to one embodiment, the needle portion **58'** is provided with a sleeve **96'** having an open end **96***a'* facing proximally and a distal end **96***b'* coupled to the needle portion **58'** via guide member **98'**. The sleeve **96'** is sized to receive the distal end **56'** of the handle **52'**. The sleeve **96'** and the distal end **56'** of the needle **52'** are provided with complementary threads **97'**. Rotation of the sleeve **96'** about the handle threads **98'** advances the sleeve **96'** onto the handle **52'**, shortening the effective length of the needle portion **58'**. Reverse rotation advances the needle portion **58'** distally from the handle **52'**, increasing the effective length of the needle **58'**. According to other embodiments, the needle **58'** and handle **52'** may be provided with complementary teeth or other means for providing an adjustable length coupling.

[0066] **FIG. 7** shows a delivery instrument **100** for use in conjunction with the myocardial lead attachment system **10** of **FIG. 1** according to another embodiment of the present invention. The instrument **100** includes a tube or needle **102** having a nest **106** for receiving an anchor mechanism **108**, and an ejection mechanism **109** for ejecting the anchor mechanism **108** from the nest **106**. A proximal portion of the needle **102** may be attached to a handle to facilitate manipulation (not shown).

[0067] According to the present embodiment, the nest **106** is an open sleeve at a distal end of the needle **102**. The anchor mechanism **108** is received in the nest **106** and protrudes outwardly from the nest **106**. The needle **102** includes a crimp or detent **110** near to and proximal to the nest **106** for contacting a proximal or trailing edge **112** of the anchor mechanism **108**. An inside diameter f of the nest **106** is slightly greater than an outside diameter g of the anchor mechanism **108**, such that the anchor mechanism **108** can readily release from the nest **106** upon application of a relatively small force on the anchor mechanism **108** directed distally from the needle **102**. The anchor mechanism **108** is coupled to a tether **113** as previously described. The needle **102** is further provided with a central lumen **114** extending therethrough.

[0068] The ejection mechanism **109** is a stylet **115** coupled to an ejection plug **116**. The stylet **115** has a sharpened distal tip **117** shaped to effectively dissect the tissue of the myocardium **32**. According to other embodiments, the tip **117** is blunt or rounded to reduce trauma to the myocardium **32**. The stylet **115** extends through the needle lumen **114** and through a bore **118** extending longitudinally through the anchor mechanism **108**. The ejector plug **116** is spherical and is sized and shaped smaller than an inside diameter h of the needle **102** at the crimp **110** so as to pass through the crimp **110** but larger than an inside diameter I of the bore **118** in the anchor mechanism **108** so as to contact the trailing edge **112** of the anchor mechanism **108**. According to other embodiments, the ejector plug **116** has a cylindrical or other shape. According to still other embodiments, the ejector plug **116** is not formed integrally with the stylet **115** but rather is a separate member such as a clip that is affixed to the stylet **115**.

[0069] During implantation, the anchor mechanism **108** is received in the nest **106**. The tip **117** of the stylet **115** extends through the bore **118** in the anchor mechanism **108** and protrudes from the bore **118**. The tube **102** and the stylet **115** are used to guide the anchor mechanism **108** through the myocardium **32**. The crimp **110** contacts the trailing edge **112** of the anchor mechanism **108** to force the anchor mechanism **108** through the myocardium **32**. Once the anchor mechanism **108** emerges from the myocardium **32**, the ejection mechanism **109** is actuated by advancing the stylet **115** distally with respect to the tube **102**, such that the ejection plug **116** contacts the trailing end **112** of the anchor mechanism **108** and ejects the anchor mechanism **108** from the nest **106**. This deploys the anchor mechanism **108** on the surface of the heart **12**. The needle **102** and stylet **115** are then withdrawn.

[0070] According to one embodiment, the ejection mechanism **109** is coupled to an actuator as described with respect to the embodiment shown generally in **FIGS. 2-6** to distally advance the stylet **106** (not shown). According to other embodiments, the ejection mechanism **109** is actuated by manually advancing the stylet **115** with respect to the needle **102**.

[0071] **FIG. 8** shows a distal portion of delivery instrument **120** according to another embodiment of the present invention. As shown in **FIG. 8**, the instrument **120** includes many of the same components as the delivery instrument **100** of **FIG. 7**. The instrument **120** includes a tube or needle **122** having a nest **123**, an ejection mechanism **124** including a stylet or guide wire **126** and an anchor mechanism **128** coupled to a tether **130**. The instrument **120** does not include

a crimp or detent **110** as described with respect to instrument **100** of **FIG. 7**, but instead includes a ledge **132** forming an internal stop in the needle **122** proximal to the nest **123**. The ledge **132** contacts a trailing edge **134** of the anchor mechanism **128** to drive the anchor **128** forward during implantation. The outer profile of the needle **102** is smooth and continuous.

[**0072**] The stylet **126** is provided with an ejector plug **136** as described previously. According to the present embodiment, however, the ejector plug **136** is cylindrical in shape. According to the embodiment shown, the anchor mechanism **128** includes an angled or tapered leading edge **138**. Tapered edge **138** facilitates dissection of the myocardium **32** during implantation. The leading edge **138** of the anchor mechanism **128** may have a blunt or rounded profile similar to the profile of the needle tip **60** described with reference to the embodiment shown in **FIGS. 3A and 3B**. The instrument **120** is used in a similar manner as described above with reference to the embodiment shown in **FIG. 7**.

[**0073**] **FIG. 9** shows a sectional view of a distal portion of a stylet delivery instrument **140** according to another embodiment of the present invention. The instrument **140** includes many of the same components as the delivery instruments **100** and **120** of **FIGS. 7 and 8**. The instrument **140** includes a tube or needle **142** having a nest **143** and an ejection mechanism **144**. The ejection mechanism **144** is a stylet or guide wire **146** having an ejector plug **145** as described previously. An anchor mechanism **148** having a stepped outside diameter is received in the nest **143**. A distal portion **150** of the anchor mechanism **148** has a diameter j that is roughly equal to an outside diameter k of the needle **142**. A proximal portion **152** of the anchor mechanism **148** has a diameter l slightly smaller than an inside diameter m of the needle **142**, such that the anchor mechanism **148** can be inserted into the nest **143**. In this embodiment, a leading edge **154** of the tube **142** serves to contact the anchor mechanism **148** and transmit axial force during implantation. In this embodiment, the anchor **148** may include either a blunt or a tapered leading edge **156** as described previously. The instrument **140** is used in the manner described above with reference to **FIG. 7**.

[**0074**] **FIG. 10** shows a sectional view of a distal portion of a delivery instrument **160** according to another embodiment of the present invention. The instrument **160** includes a stylet **162** and an anchor mechanism **164**. The stylet **162** includes a distal tip **166**, which is shaped for efficient dissection of the myocardium **32**. A distal end **168** of the stylet **162** is provided with a raised region **170** forming a mechanical stop. According to one embodiment, a tubular sleeve **172** is positioned about the stylet **162** to form the raised region **170**. According to other embodiments the raised region **170** is integrally formed with the stylet **162**. The anchor mechanism **164**, which is coupled to a tether **174**, has an inner bore **176** extending therethrough. An inner surface of the bore **176** includes a ledge **178**. A distal end **168** of the stylet **162** is received in the bore **176**, such that the tip **166** protrudes from the bore **176**. The ledge **178** is adapted to mate with and contact the raised region **170** of the stylet **162** such that upon application of an axial force on the stylet **162**, the raised region **170** contacts the ledge **178** and forces the anchor mechanism **164** to advance distally.

[**0075**] The instrument **160** is advanced through the heart **12**, and the stylet **162** is manipulated into the heart **12** and position the anchor mechanism **164**. When the anchor mechanism **164** has been properly positioned, the stylet **162** is withdrawn.

[**0076**] **FIG. 11** shows a sectional view of a distal portion of a stylet delivery instrument **180** according to another embodiment of the present invention. The instrument **180** includes a stylet **182** and an anchor mechanism **184**. The anchor mechanism **184** includes a blind bore **186** extending from a proximal end **188** of the anchor mechanism **184** but not all the way through to a distal end **190**. The inner surface of the blind bore **186** has a diameter sized to receive a distal end **192** of the stylet **182**. As shown, the anchor **184** has a tapered leading edge **194** to facilitate dissection of the myocardium **32**. A tether **196** is attached to the anchor **184**. The stylet **182** is used to advance the anchor mechanism **184** through the myocardium **32**. When the anchor mechanism **184** is located in a chosen position, for example, on the endocardial surface **30**, the stylet **182** is withdrawn.

[**0077**] **FIG. 12** shows a side view of a stylet delivery instrument **200** according to another embodiment of the present invention. The instrument **200** includes a guide wire or stylet **202** and an anchor mechanism **204** coupled to a tether **206**. The stylet **202** includes a tapered tip **208** shaped for efficient dissection of the myocardium **32**. The anchor mechanism **204** is coupled to a catch mechanism **210** for receiving the stylet **202**. The catch mechanism **210** is a ring-shaped member and may be formed from a looped region of the tether **206** or formed separately and attached to the anchor mechanism **204**. According to one embodiment, the catch mechanism **210** is generally flexible. According to another embodiment, the catch mechanism **210** is rigid.

[**0078**] The catch mechanism **210** has an inner diameter smaller than an outside diameter n of the stylet **202**, such that the stylet tip **208** can be inserted partially into the catch mechanism **210**, but the stylet **202** cannot fully pass through the catch mechanism **210**. The stylet tip **202** is inserted into the catch mechanism .**210** so that the anchor **204** lies adjacent the length of the stylet **202**. According to other embodiments, the stylet **202** is provided with a circumferential groove for receiving the catch mechanism **210** (not shown). The stylet **202** is inserted into the myocardium **32**, drawing the anchor mechanism **204** along via the catch mechanism **210**. Once the stylet tip **208** and the anchor mechanism **204** emerge from the myocardium **32**, the stylet **202** is withdrawn, disengaging from the catch mechanism **210**. Following implantation, the catch mechanism **210** may be removed or may be left in place.

[**0079**] **FIG. 13** shows a delivery instrument **300** in accordance with another embodiment of the present invention. The delivery instrument **300** includes many of the features of the delivery instrument **50** shown in **FIGS. 2-6**. In addition, the delivery instrument **300** may be used for identifying an appropriate or desired implant site. The delivery instrument **300** includes a handle **302**, a needle **304**, an anchor mechanism **306** and an ejection mechanism **308** as previously described. According to the present embodiment, the needle **304** is electrically conductive and extends nearly to a proximal end **310** of the handle **302**. The needle **304** is electrically isolated or masked via a non-conductive insulating or dielectric material polymer sleeve **311** extending the length of the needle **304**. According to one embodiment, the sleeve **311** is formed of a heat shrinkable polyimide.

According to other embodiments, the sleeve **311** is formed of a conformal polymer such as parylene or ethylene-tetrafluoro ethylene. According to another embodiment, the needle **304** is coated with a layer of non-conductive polymer material.

[**0080**] The needle **304** is electrically exposed at a distal tip **312** and at a proximal region **314**. The proximal exposed region **314** is accessible via a cut-out or window **316** formed in the handle **302**. The needle **304** acts as an electrical conductor between the exposed proximal region **314** and the exposed distal tip **312**. Alligator clips or other electrical connectors may be coupled to the needle **304** through the window **316** to electrically couple the exposed distal tip **312** to a pacing and sensing analyzer for performing sensing and pacing functions (not shown).

[**0081**] The exposed area at tip **312** is brought into contact with the epicardium **28** or myocardium **32** to perform sensing and pacing functions prior to ejection of the myocardial anchor **306**. Additionally, acute therapeutic benefit at a particular site may be assessed using said embodiment. If acute benefit is unacceptable, the implant site may be changed prior to implanting the lead **36**.

[**0082**] **FIG. 14** shows a delivery instrument **400** according to another embodiment of the present invention. The delivery instrument **400** includes a handle **402** coupled to a needle **404**, an anchor mechanism **406** and an ejection mechanism **408** as previously described with respect to various embodiments. In addition, the delivery instrument **400** may be used for identifying an appropriate or desired implant site. According to one embodiment, this is accomplished by electrically isolating the needle region **404** except for a small exposed or electrically active area **410** on the conical tip **412**. The needle region **404** may be electrically isolated according to the techniques described with respect to the previously described embodiment shown in **FIG. 13**. A conductive wire **414** with a terminal end **416** in electrical communication with the electrically active area **410** is located in the handle **402**. The wire **414** is connected to a pacing and sensing analyzer **418**. The electrically active area **410** is brought into contact with the epicardium **28** or myocardium **32** to perform sensing and pacing as previously described.

[**0083**] The systems shown in **FIGS. 2-14** are amenable to minimally-invasive introduction into the heart **12**, such as by known thoracoscopic, mini-thoracoscopic or endoscopic techniques. In one embodiment employing an endoscopic technique, a small subxiphoid incision is made to gain visualization of the apex **38** of the heart **12**. The pericardium **33** is perforated to gain access to the epicardial surface **28**. An endoscopic probe having an open working channel is then introduced into the chest. The endoscopic probe includes common features such as a light tube, fiber optic visualization, and means to accomplish distal deflections of the tube or needle when formed of a malleable material as described above.

[**0084**] A target region of the heart **12** is approached and advanced sensing probes may be used to assess the suitability of the location. This assessment may include typical measurements such as pacing thresholds, sensing amplitudes, and tissue impedance. These functions may be accomplished with a delivery instrument in accordance with the embodiments shown in **FIGS. 13 and 14**. The working channel may also be used to assess the physiological suitability of the heart tissue. Temporary pacing of the heart **12** may also be performed at the location through the working channel.

[**0085**] After a determination that the location is suitable for lead implantation, an anchor mechanism **44** as is shown in **FIG. 1** is advanced through the working channel with a delivery instrument **50** as is shown in **FIGS. 2-6** in accordance with one embodiment of the present invention. A separate channel for fiber optic visualization may be used to assist the operator in guiding the delivery instrument **50** through the myocardial tissue **32**. In one embodiment, the visualization channel is further used to avoid tissue structures, such as vessels, fat pads, nervous system tissue, and infarcts.

[**0086**] **FIGS. 15A -15D** illustrate the use of the delivery instrument **50**. The needle portion **58** of the delivery instrument **50** is used to create a channel or tract **37** through the tissue of a patient's heart **12**. **FIG. 15A** shows an epicardial-epicardial procedure, in which the needle portion **58** is inserted in the direction shown by the arrow **99'**, such that it both enters and exits the myocardium **32** through the epicardium **28**. According to one embodiment, the needle tip **60** is rounded or blunt, as previously described to reduce trauma to the myocardial tissue **32** during advancement. During insertion through the myocardium **32**, the anchor mechanism **44** is located within the nest **62**. A tether **45** is attached to the anchor **44** and extends along the outside of the needle portion **58** and the handle **52**.

[**0087**] **FIG. 15B** shows an epicardial-endocardial procedure, in which the needle portion **58** travels in the path indicated by the arrow **99'**, such that it enters the myocardium **32** through the epicardium **28** and exits through the endocardium **30**. Again, the anchor mechanism **44** is located within the nest **62** and a tether **45** travels along the outside of the needle portion **58** and handle **52**.

[**0088**] **FIG. 15C** shows an intra-myocardial procedure, in which the needle portion **58** travels in the path indicated by arrow **99'**, such that it enters the myocardium **32** through the epicardium **28**. The anchor mechanism **44** is ejected into the myocardium **32** and the delivery instrument **50** is withdrawn. The anchor mechanism **44** remains positioned within the myocardium **32**.

[**0089**] **FIG. 15D** shows a pericardial-pericardial procedure, in which the needle portion **58** travels in the path indicated by arrow **99'** such that it enters and exits through the pericardium **33** without traversing the myocardium **32**.

[**0090**] Once the delivery instrument **50** emerges through the epicardium **28** (or the endocardium **30**, pericardium **33**, or myocardium **32**), the ejection mechanism **66** is activated to dislodge the anchor mechanism **44** from the nest **62**. The delivery instrument **50** is then withdrawn back through the tract **37** and removed. The tether **45** is then tensioned to cause the anchor **44** to engage against the epicardium **28** (or endocardium **30**, pericardium **33** or myocardium **32**).

[**0091**] According to other embodiments (see **FIGS. 7-10C**, but referring generally to **FIG. 7**), a stylet or guide wire **106** in combination with a needle **102** and an anchor mechanism **108** is used to create the tract **37** through the myocardium **32** for delivery of the anchor mechanism **108**. Once the distal end of the needle **104** and anchor mechanism

108 have emerged through the epicardium **28** (or endocardium **30**, the myocardium **32** or pericardium **33**), the stylet **106** is advanced. The ejector plug **116** engages the trailing edge **112** of the anchor mechanism **108** to eject the anchor mechanism **108** from the needle lumen **104**. The needle **102** and stylet **106** are then withdrawn through the tract **37**.

[**0092**] According to still other embodiments (see **FIGS. 11 and 12**, but referring generally to **FIG. 11**), a stylet or guide wire **182** in combination with an anchor mechanism **184** is used to create the tract **37** through the myocardium **32** for delivery of the anchor mechanism **184**. Once the distal end **192** of the stylet or guide wire **182** and anchor mechanism **184** have emerged through the epicardium **28** (or endocardium **30**, myocardium **32** or pericardium **33**) the stylet **182** is withdrawn. The anchor mechanism **184** remains in place. The tether **196** is tensioned and the lead **36** advanced as described above. According to other embodiments, the stylet **182** and anchor mechanism **184** are advanced through the working channel rather than creating a separate tract **37**.

[**0093**] Following delivery of the anchor mechanism **44** to the epicardial surface **28** (or the myocardium **32**, the endocardial surface **30** or the pericardial surface **33**) according to any of the aforementioned embodiments, the tether **45** is tensioned and the lead **36** advanced as described above. Following implantation of the myocardial lead **36**, the tether **45** is tensioned and secured to the myocardial lead **36** to secure the myocardial lead **36** within the myocardium **32**. According to other embodiments, the myocardial lead **36** is provided with additional means to secure the myocardial lead **36** within the myocardium **32** following delivery.

[**0094**] The lead **36** is positioned in the heart **12** and anchored, as described above, to position the lead electrode **40** in chosen locations in the heart **12**. Although generally shown in implanted near the apex **38**, the lead **36** may be implanted anywhere in the heart pacing therapy is needed. For example, the lead **36** may be implanted in the free wall of the left ventricle **20**. According to one embodiment, shown in **FIG. 16A**, the lead **36** is configured as a unipolar lead. The electrode **40** is inserted into the heart tissue and is an active "can." The electrode **40** may be positioned in the myocardium **32**, as shown, or may contact the epicardium **30** or the pericardium **33**.

[**0095**] **FIG. 16B** shows another embodiment in which the lead **36** has two electrodes, a proximal anode **40***a* and a distal cathode **40***b*. According to one embodiment, the lead **36** is implanted in a pseudo-unipolar arrangement, such that the cathode **40***b* is positioned within the myocardial tissue **32** and the anode **40***a* is positioned on the lead body **36**, but not in contact with the heart tissue.

[**0096**] **FIG. 16C** shows another embodiment, in which the lead electrode arrangement is pseudo-unipolar, such that the cathode **40***b* is positioned in the heart and the anode **40***a* partially contacts the exterior epicardial tissue **28** of the heart **12**.

[**0097**] **FIG. 16D** shows yet another pseudo-unipolar embodiment in which the cathode **40***b* is positioned in the myocardium **32** and the anode **40***a* is positioned in alignment with the outer layers of the epicardial tissue **28** of the heart **12**. The anode **40***a* may, for example, straddle the epicardium **28** such that a portion anode **40***a* is within the heart tissue and another portion is exposed to a space outside of the heart **12**.

[**0098**] **FIG. 16E** shows another embodiment in which the lead **36** has a bipolar arrangement wherein the cathode **40***b* and anode **40***a* are completely within the myocardial tissue **32**.

[**0099**] In one embodiment, the cathode **40***b* has an active electrode surface area of about 1 square mm. The cathode **40***b* is located near the distal tip **35** of the lead body **36**. An electrode spacing between the cathode **40***b* and anode **40***a* of more than about 2 cm would generate a unipolar lead, as defined above. An electrode spacing of between about 1 and about 2 cm would generate a pseudo-unipolar lead, as defined above. An electrode spacing of less than about 1 cm would generate a bipolar lead, as defined above.

[**0100**] In the epicardium to epicardium configuration, the epicardium to endocardium configuration and the intramyocardial configuration, once implanted, the lead body **36** will serve to block the tract in the myocardium **32** created by the delivery instrument **50** and prevent further loss of blood from the heart **12**. If it becomes necessary to reposition the lead **36** and create a second tract, a porous, clot-promoting "plug" material can be fed over the tether **45** into the tract **37** to serve as a seal. Following implantation of the myocardial lead **36**, the tether **45** is tensioned and secured to the myocardial lead **36** to secure the myocardial lead **36** within the myocardium **32**.

[**0101**] Various modifications and additions can be made to the exemplary embodiments discussed without departing from the scope of the present invention. Accordingly, the scope of the present invention is intended to embrace all such alternative, modifications, and variations as fall within the scope of the claims, together with all equivalents thereof.

We claim:

1. A myocardial lead attachment system for securing a distal end of a lead within a myocardium of a patient's heart, the system comprising:

an anchor;

a tether coupled to the anchor; and

a delivery instrument for receiving and advancing the anchor through a tract in the heart from a proximal entrance site to a distal exit site in such a manner that the tether extends proximally from the anchor through the tract, said delivery instrument comprising:

a needle having a distal tip and a nest positioned proximal to the distal tip and sized to receive the anchor, and

an ejection mechanism for ejecting the anchor from the nest.

2. The lead attachment system of claim 1 wherein the ejection mechanism further comprises an actuator for ejecting the anchor from the nest.

3. The lead attachment system of claim 1 wherein a distal portion of the needle is formed with a radial curvature.

4. The lead attachment system of claim 2 wherein the ejection mechanism further comprises an elongated member slidable from a retracted position to an extended position in response to actuation of the actuator to engage the anchor mechanism.

5. The lead attachment system of claim 4 further comprising:

a mechanical stop for limiting extension of the elongated member; and

a resilient member biasing the actuator to retract the elongated member.

6. The lead attachment system of claim 1 wherein the delivery instrument further comprises:

a distal electrically active area on the needle; and

a conductive member for connecting the electrically active area to an external electrical device.

7. The lead attachment system of claim 1 wherein the nest further includes a slot for receiving the tether.

8. The lead attachment system of claim 1 wherein the nest includes a ramp adapted to assist in ejection of the anchor.

9. The lead attachment system of claim 1 further comprising a lead body having a proximal end, a distal end, and at least a first electrode near the distal end, said lead body adapted to advance over the tether through the tract.

10. The lead attachment system of claim 9 wherein the lead body is a unipolar lead.

11. The lead attachment system of claim 10 wherein the lead body includes a second electrode spaced apart the first electrode apart by about at least 2 cm.

12. The lead attachment system of claim 9 wherein the lead body is a pseudo-unipolar lead.

13. The lead attachment system of claim 9 wherein the lead body is a bipolar lead.

14. A myocardial lead attachment system for securing a distal end of a lead within a myocardium of a patient's heart, the system comprising:

an anchor having a longitudinal bore extending therethrough;

a tether coupled to the anchor; and

a delivery instrument for receiving and advancing the anchor through a tract in the heart from a proximal entrance site to a distal exit site in such a manner that the tether extends proximally from the anchor through the tract, said delivery instrument comprising:

a needle having a proximal end, a distal end formed with a nest for receiving the anchor and a central lumen extending therethrough;

a stylet slidably received in the needle lumen and the anchor bore, and

an ejector plug formed on the stylet for engaging the anchor.

15. The lead attachment system of claim 14 wherein the nest is an open sleeve at the distal end of the needle.

16. The lead attachment system of claim 15 wherein the nest has an internal stop for transmitting an axial force to the anchor.

17. The lead attachment system of claim 15 wherein the anchor has a proximal region sized to be received in the nest and a distal region sized to be retained outside of the nest.

18. The lead attachment system of claim 15 wherein the anchor has a tapered distal face shaped to dissect the tissue of the myocardium.

19. The lead attachment system of claim 14 wherein the stylet has a pointed distal end shaped to dissect the tissue of the myocardium.

20. A method for using a delivery instrument to implant a myocardial lead into the heart, said lead having at least a first electrode, the method comprising:

mating a myocardial anchor coupled to a tether to a distal end of the delivery instrument;

advancing the distal end of the delivery instrument through a tract in the heart;

deploying the anchor into the heart;

withdrawing the delivery instrument through the tract in such a manner that the tether extends through the tract;

threading a myocardial lead onto the tether; and

advancing the lead over the tether into the heart.

21. The method of claim 20 further comprising:

advancing the anchor through the epicardium, into the myocardium, and back through the epicardium; and

deploying the anchor mechanism on the epicardial surface.

22. The method of claim 20 further comprising:

advancing the anchor through the epicardium, into the myocardium and through the endocardium; and

deploying the anchor on the endocardial surface.

23. The method of claim 20 further comprising:

advancing the anchor through the epicardium and into the myocardium; and

deploying the anchor into the myocardium.

24. The method of claim 20 further comprising:

advancing the anchor into the pericardium and out of the pericardium without traversing the epicardium; and

deploying the anchor on the pericardial surface.

25. The method of claim 20 further comprising advancing the lead body until the first electrode is in contact with the heart.

26. The method of claim 20 further comprising advancing the lead body until the first electrode is in contact with the myocardium.

27. The method of claim 26 wherein the lead body includes a second electrode proximal to the first electrode and further comprising advancing the lead body until the second electrode is at least partially in contact with the heart.

28. The method of claim 27 further comprising advancing the lead body until the second electrode straddles the epicardium.

29. The method of claim 27 further comprising advancing the lead body until the second electrode is in contact with the myocardium.

30. The method of claim 20 further comprising:

forming a working channel and a visual channel to the heart with an endoscopic probe; and

advancing the anchor and delivery instrument to the heart through the working channel.

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