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Bolduc

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[54] **INTRAVASCULAR LEAD ASSEMBLY**

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[52] **U.S. Cl.** .... **128/418,** 128/419 P

[51] **Int. Cl.** **A61n 1/04**

[58] **Field of Search** .... 128/418, 419 P, 419, 404, 128/405, 2.06 E, 2.1 E, 348, 349, 214.4, 2 R, 2.1 R, DIG. 4

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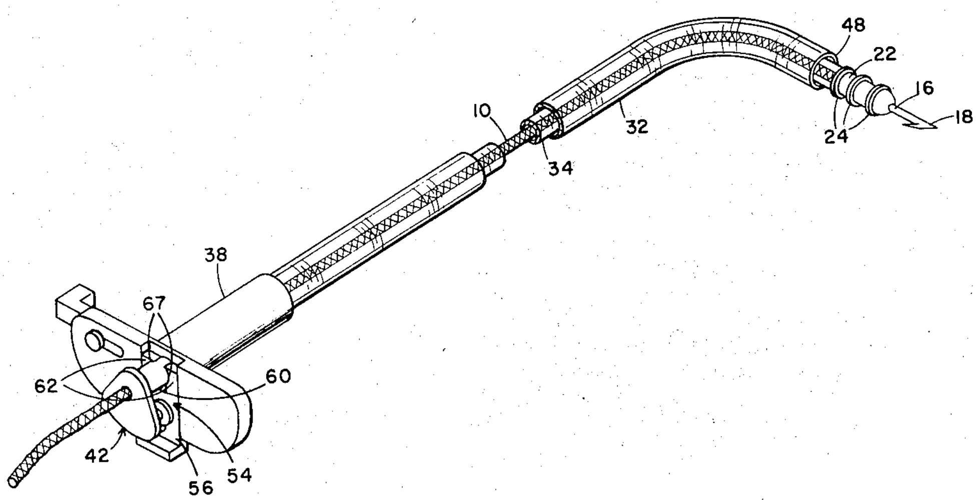
[57] **ABSTRACT**

A body-implantable, intravascular lead assembly which is adapted to be connected to a source of electrical energy at its proximal end. At the distal end of the lead is affixed an electrically conductive barb. Means are provided for inserting the lead in and guiding it through a body vessel to a desired location inside the body. Further means are provided for lodging and permanently securing the barb to body tissue at the desired location. Part of the assembly is withdrawn from the vessel after the barb is lodged and secured in the tissue. The lead and a portion of the barb are sealed from body fluids and tissue by a material substantially inert to body fluids and tissue.

17 Claims, 6 Drawing Figures



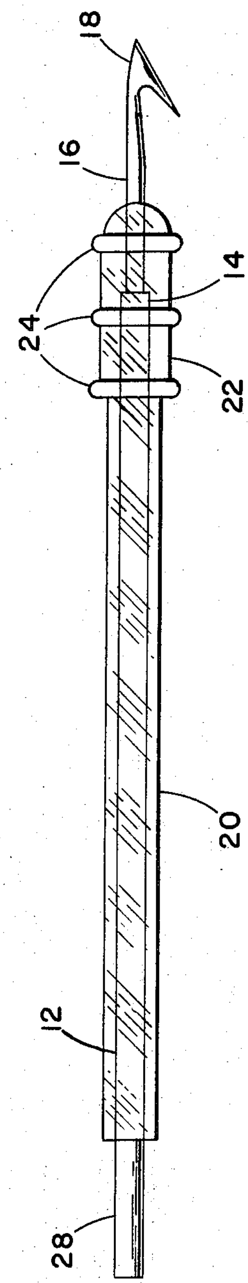


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FIG. 1

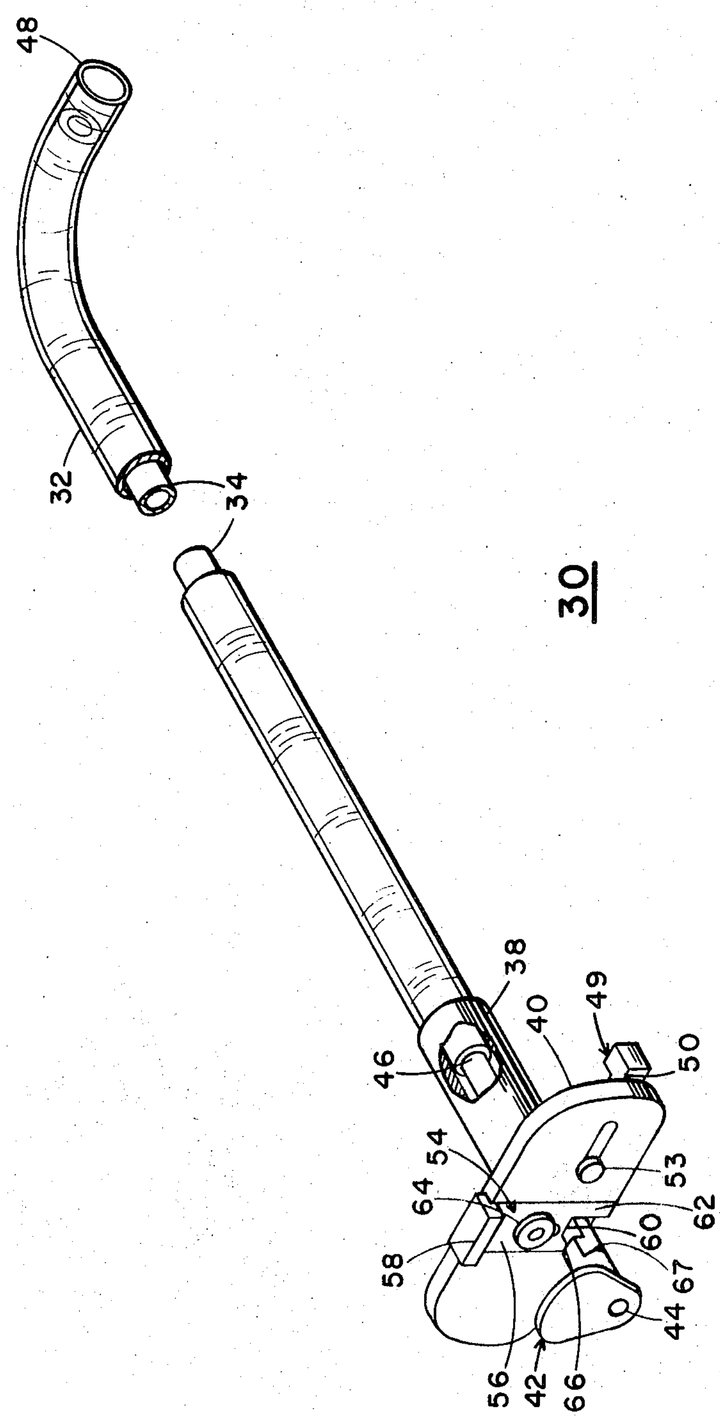

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FIG. 2

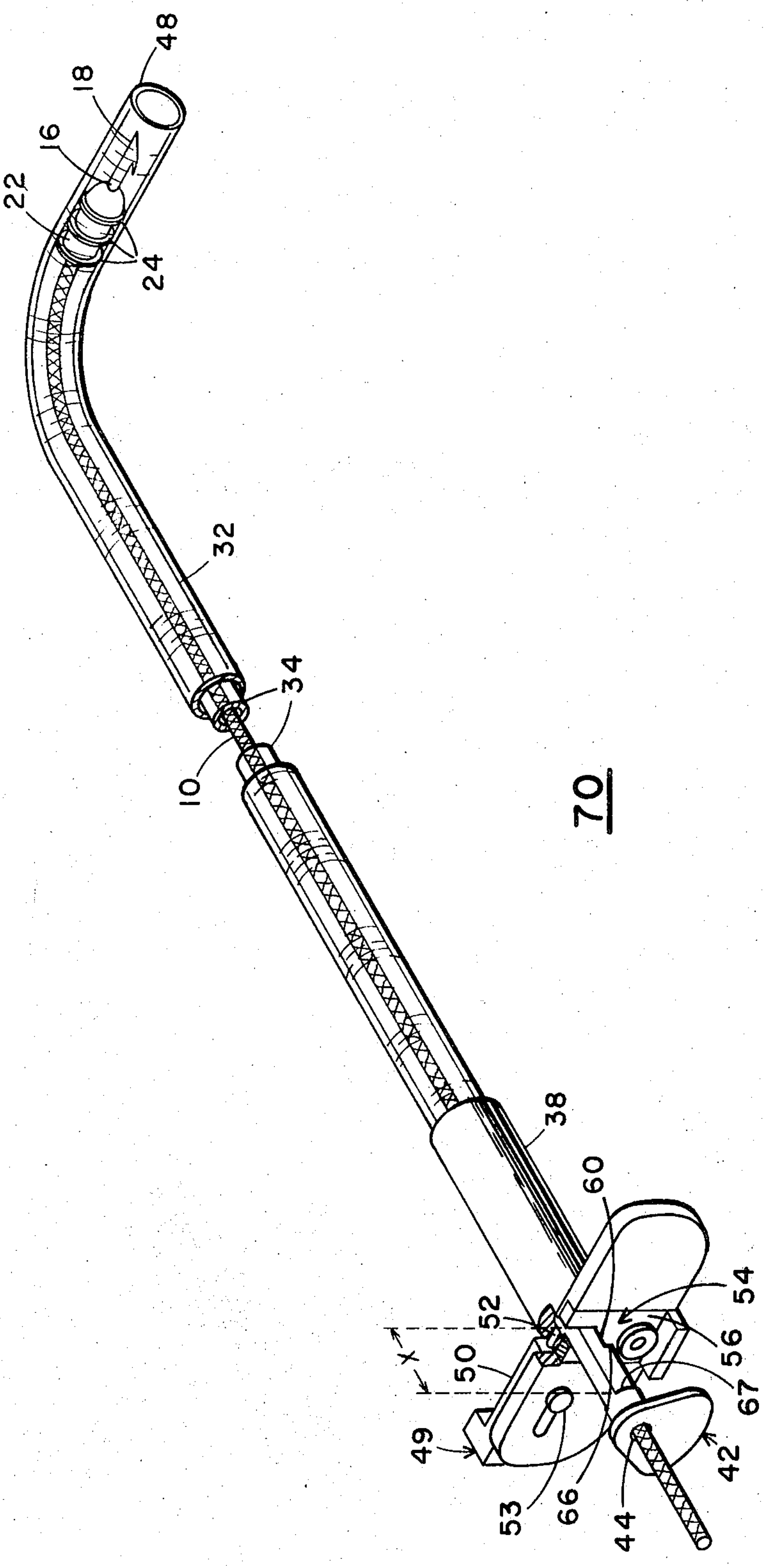

FIG. 3

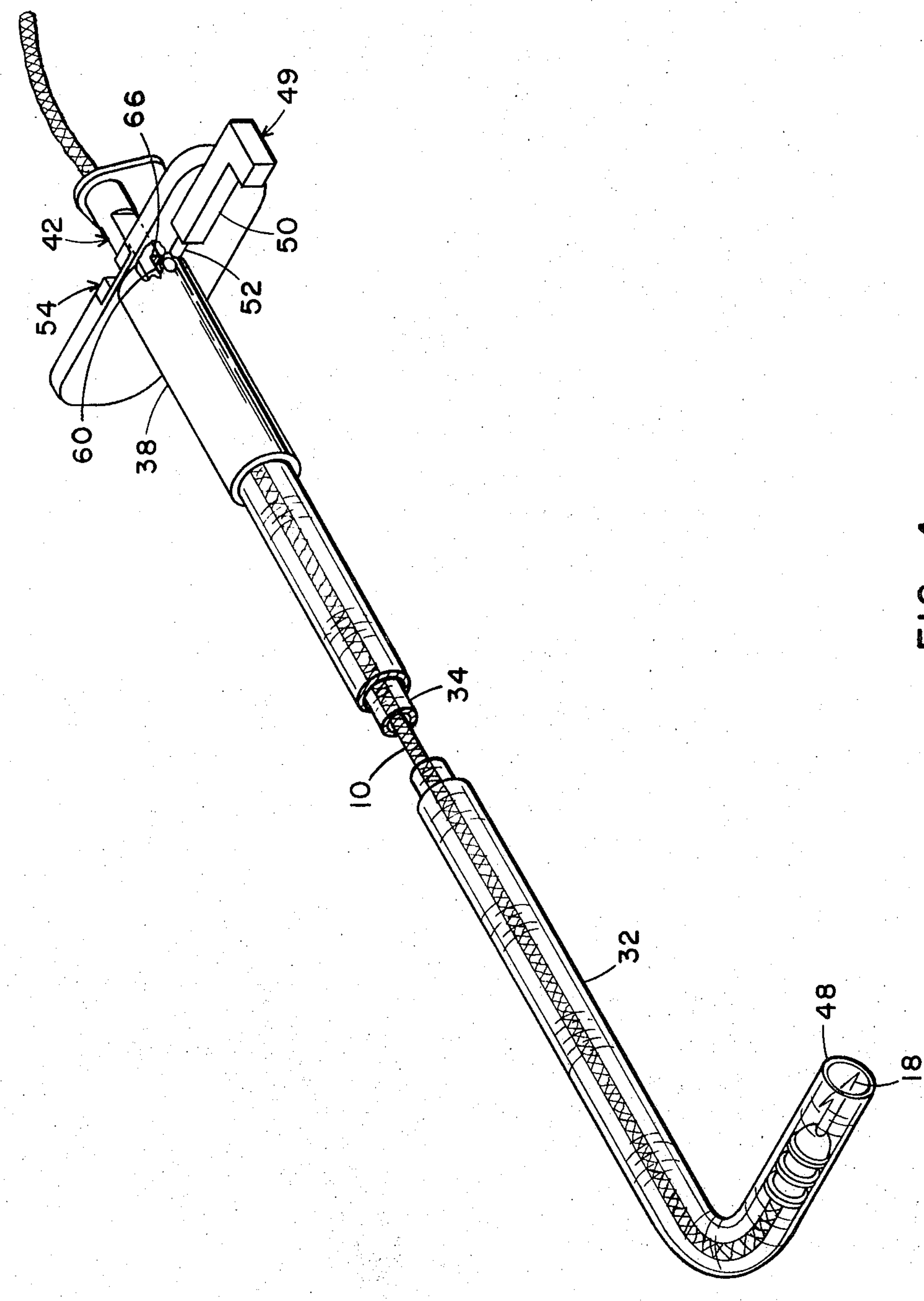

FIG. 4

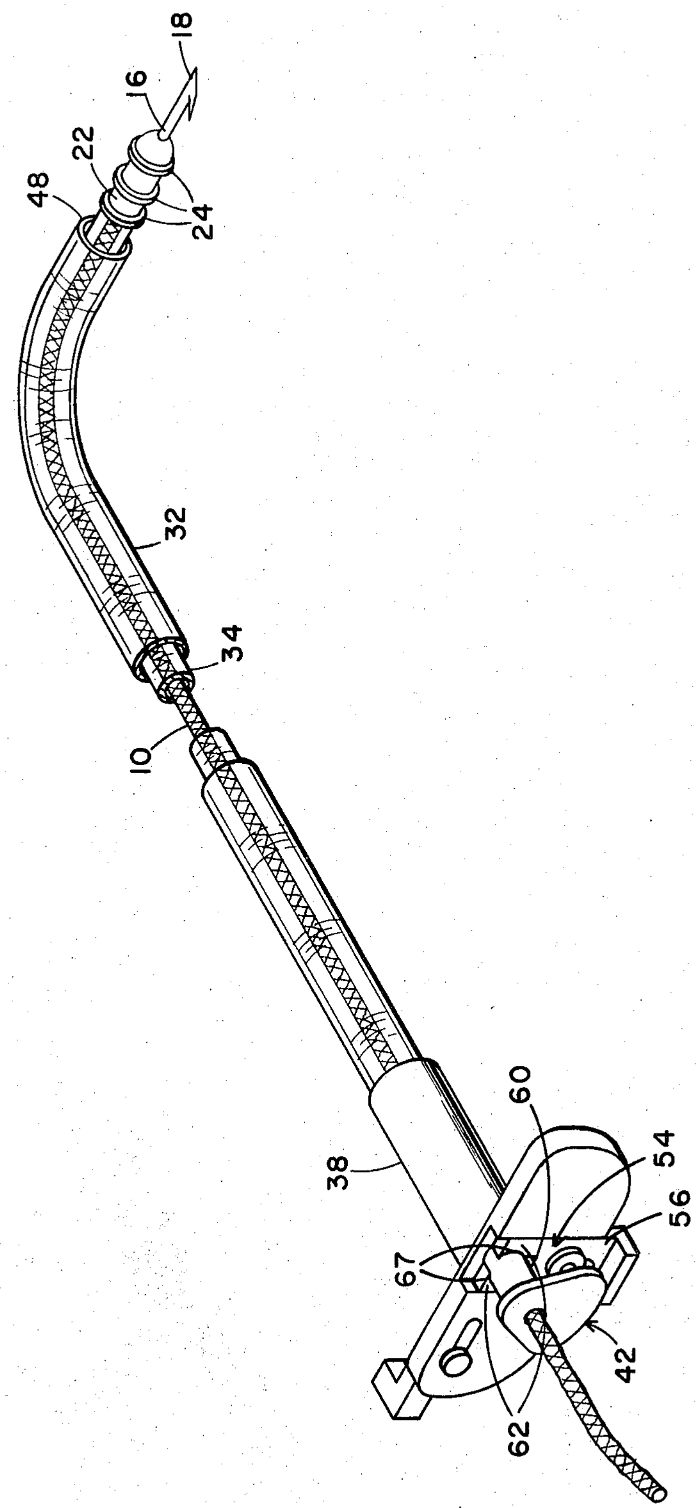

FIG. 5

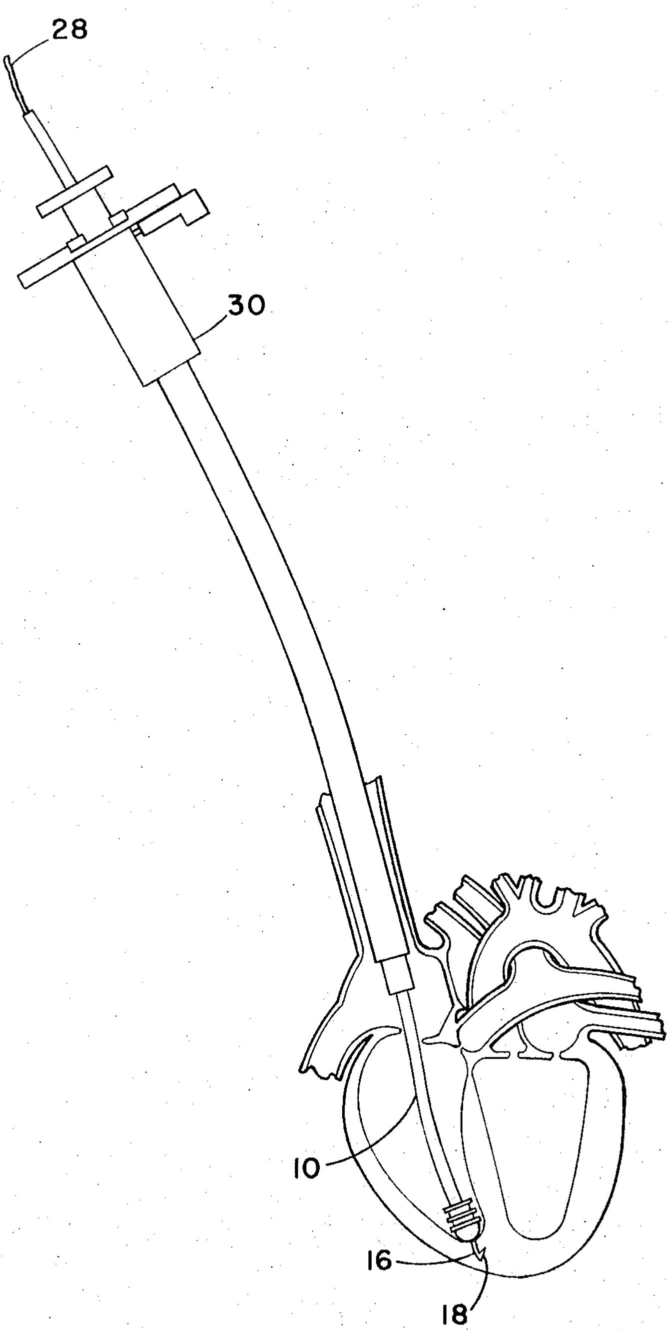

FIG. 6

INTRAVASCULAR LEAD ASSEMBLY

BACKGROUND OF THE INVENTION

There are generally two types of body-implantable leads—one which requires surgery to expose that portion of the body to which the electrode is to be affixed and the other which is inserted in and guided to the desired location through a body vessel. In the cardiovascular field, in particular, there are myocardial and endocardial type leads. Use of a standard myocardial lead generally provides an excellent electrical contact but requires a thoracotomy in order to affix the electrodes in the outer wall of the heart. This type of surgery is quite strenuous on the patient, particularly an elderly one. Use of a standard endocardial lead does not involve serious surgery since the lead is inserted in and guided through a selected vein. However, endocardial leads currently in use are difficult to place and to maintain in proper position and do not insure the best electrical contact since the electrode merely rests against the inner wall of the heart at the apex of the right ventricle. As a result, the electrodes of such prior art leads tend to become dislodged from their proper position, often resulting in loss of heart capture and thus loss of stimulation of the patient's heart. Also, since the electrodes of an endocardial lead are not secured in the cardiac tissue, the lead tends to move with each contraction of the heart muscle, thereby forming an undesirable callous or fibrotic growth on the inner wall of the right ventricle. Another problem is that with the contraction of the heart, the tip or distal electrode may occasionally puncture the heart wall, resulting in serious injury to the heart and a loss of heart capture.

The body-implantable lead of the present invention combines all the advantages of both the myocardial and endocardial leads with none of the attendant disadvantages of each of these leads as currently found in the prior art. One of the features of the present invention is the provision of a body-implantable intravascular lead which can be lodged in and permanently secured to the body tissue which it is desired to stimulate. Another feature of the present invention is an extremely thin, durable, very flexible lead with excellent electrical and mechanical properties. An advantage of the present invention is the fact that the electrode is lodged in and permanently secured to the tissue so that puncturing of the surrounding tissue and formation of a callous or fibrotic growth cannot occur. Still another feature of the present invention is the provision of a very simple, easily operable means for inserting the lead into and guiding it through a body vessel to the desired location. An advantage is realized from the fact that the insertion and guidance means imparts sufficient rigidity to the lead to facilitate its placement, thereby eliminating the need for a stylette and thus allowing the lead to be made thinner and more flexible than would otherwise be possible. Yet another feature is the means for lodging and permanently securing the electrode to the selected body tissue once the lead is in proper position. An advantage is realized from the fact that the insertion and guiding means and the lodging and securing means may be made as an integral, disposable unit which is very simple to manufacture, and extremely easy to operate. Once the electrode is secured in the tissue at the desired location, this unit is easily removed and can be disposed.

SUMMARY OF THE INVENTION

The above features and advantages of the present invention, as well as others, are accomplished by providing a body-implantable, intravascular lead comprising electrically conductive lead means adapted to be connected at one end to a source of electrical energy and electrode means affixed to the opposite end of the lead means and adapted to be firmly lodged in and permanently secured to tissue inside the body at a desired location. The lead means and the portion of the electrode means affixed to the lead means are sealed from living animal body fluids and tissue by a material substantially inert to body fluids and tissue. Further means are provided for permitting the lead means and electrode means to be inserted into and guided through a body vessel to a desired location and position inside the body. Means are also provided for permitting the electrode means to be firmly lodged in and permanently secured to body tissue at the desired location.

Other features, advantages and objects of the present invention will hereinafter become more fully apparent from the following description of the drawings, which illustrate a preferred embodiment.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a view of the body-implantable, intravascular lead of the present invention;

FIG. 2 shows a view of the device used for positioning the lead of FIG. 1 inside the body;

FIG. 3 shows the lead assembly comprising the lead of FIG. 1 and the device of FIG. 2 with the lead in the position for insertion in and guidance through a body vessel to a desired location and position inside the body;

FIG. 4 shows the lead assembly of FIG. 3 in the position for taking threshold measurements with the barb of the lead of FIG. 1 just barely extending beyond the device of FIG. 2;

FIG. 5 shows the lead assembly of FIG. 3 in another position for the lodging and securing of the electrode of the lead into the body tissue at the desired location inside the body; and

FIG. 6 shows the lead assembly of FIGS. 3 and 4 with the electrode of the lead lodged in and permanently secured in the tissue forming the apex of the right ventricle of a heart.

DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 shows a lead **10** having an electrical conductor **12** which may, for example, be of a configuration and construction as the lead described in U.S. Pat. No. 3,572,344. Affixed to the distal end **14** of conductor **12** is an electrically conductive electrode **16** having a sharply-pointed electrically conductive barb **18** formed on the end thereof, both of which may be metallic. Electrode **16** and barb **18** are made of a metal which is substantially inert to body fluids and tissue, such as platinum or a platinum-iridium alloy. Conductor **12** has a covering **20** which is made of a material substantially inert to body fluids and tissue such as, for example, silicone rubber. Surrounding the distal end **14** of conductor **12** and a portion of electrode **16** is a substantially cylindrical sleeve **22** having three spaced ridges **24** formed integrally therewith along its length. Sleeve **22** and ridges **24** are formed as an integral sleeve and may be made of a material substantially inert to body fluids and tissue, such as silicone rubber. Proximal end **28** of conductor **12** may be fitted with a connector pin (not shown) or in any other manner adapted for connection to a source of electrical energy such as a pulse generator.

FIG. **2** shows a cross sectional view of a device **30** which may be used for positioning the lead **10** of FIG. **1** at the desired location within the body as will be described hereinafter. Device **30** has a pair of concentric, substantially cylindrical hollow tubes **32** and **34**. Tubes **32** and **34** are made of a pliant material, such as, for example, teflon. Outer tube **32** is maintained in a fixed position by a substantially cylindrical, hollow sleeve **38** having a flat plate **40** formed integrally therewith. Sleeve **38** and plate **40** may be made of a machineable polymer such as Delrin or Nylon. Inner tube **34** is axially movable within outer tube **32** and sleeve **38**. Projecting through an opening in plate **40** is a plunger **42**, also made of a machineable polymer such as Delrin or Nylon. Plunger **42** has an opening **44** passing therethrough. Plunger **42** has an end **46** to which is affixed inner tube **34**. Tube **34** and opening **44** define a passageway in which lead **10** is placed as will be described later. As plunger **42** is pushed toward plate **40**, when the appropriate locking mechanisms are unlocked, tube **34** moves axially within and toward the distal end **48** of tube **32**.

Device **30** has a first locking mechanism **49**. With reference to FIG. **4**, locking mechanism **49** comprises a slide **50** having a pin **52** projecting from one end thereof. Sleeve **38** and plunger **42** have aligning openings in one side thereof through which pin **52** passes for providing this first locking mechanism. With pin **52** in the aligned openings, plunger **42** cannot be moved in either direction. A screw **53** shown in FIG. **2** passes through an elongated opening through plate **40** and into slide **50** and allows slide **50** to move so that pin **52** may be engaged with, or disengaged from, the openings in the sides of sleeve **38** and plunger **42**.

Device **30** has a second locking mechanism **54** comprising a second slide **56** having a lip **58** which may be grasped for engaging and disengaging an edge **60** of slide **56** with the opposing face of plunger **42**. Slide **56** has a pair of legs **62** between which plunger **42** is located. Slide **56** has an elongated opening. A screw **64** passes through plate **40** and slide **56** and together with legs **62** allows slide **56** to have edge **60** engage with and disengage from a groove **66** located in the opposing face of plunger **42**. Plunger **42** also has a pair of shoulders **67** on opposite sides thereof which are designed to engage legs **62** when locking mechanism **54** is unlocked and plunger **42** is fully depressed.

The operative relationship between device **30** and lead **10** will now be described in conjunction with FIGS. **3–5**. Lead assembly **70** will be described in the application of using lead **10** as a lead positioned intravenously into the heart for use as a cardiac pacemaker lead. When the lead assembly **70** shown in FIG. **3** is removed from its sterile package, lead **10** is positioned in the opening defined by tube **34** and opening **44** in plunger **42**. Pin **52** of slide **50** is positioned in the aligned openings in sleeve **38** and plunger **42** and slide **56** is in the locked position whereby edge **60** abuts against groove **66** in the opposing face of plunger **42**. With locking mechanisms **49** and **54** in their locked positions as shown in FIG. **3**, electrode **16** and barb **18** are located well inside outer tube **32** with the sleeve **22** abutting against the distal end of tube **34**. Ridges **24** of sleeve **22** engage the inner wall of tube **32** thereby forming a seal to prevent the back-up of blood into tubes **32** and **34** when device **30** with lead **10** carried thereby is inserted into a body vessel. With the locking mechanisms **49** and **54** in their locked positions, as shown in FIG. **3**, the distal end **48** of tube **32** is inserted, for example, into the right jugular vein. Device **30** serves as a means for inserting lead **10** into the vein and guiding it to the desired position in the heart. When the tube **32** is believed to be in the proper position in the heart, locking mechanism **49** is unlocked as shown in FIG. **4** by pulling slide **50** so that pin **52** is disengaged from the aligned openings in sleeve **38** and plunger **42**. Plunger **42** may then be depressed to move inner tube **34** and lead **10** to a position, shown in FIG. **4**, where the edge defined by groove **66** in plunger **42** is stopped by edge **60** of locking mechanism **54**. In this position barb **18** just barely extends beyond the end **48** of tube **32** so that the necessary threshold measurements may be taken. The threshold measurements are used to determine whether the electrode position in relation to the heart tissue is adequate or not. Good electrode positioning is important, as only with good positioning can the patient's heart be maintained in capture at low voltages. When these measurements have been completed and a satisfactory electrode position found, locking mechanism **54** is unlocked, as shown in FIG. **5**, by moving slide **56** in a direction away from plunger **42**. Movement of slide **56** disengages edge **60** of slide **56** from plunger **42**. This disengagement allows plunger **42** to be further depressed until shoulders **67** of plunger **42** engage legs **62** of slide **56**, thereby moving electrode **16** a predetermined distance out of tube **32** and driving barb **18** a predetermined distance into the tissue of the heart. These predetermined distances are such that barb **18** is driven sufficiently into myocardial tissue to be permanently secured therein but without puncturing through the heart's wall. The total distance through which barb **18** moves is determined by the distance X from shoulders **67** to the surface of slide **56** when both locking mechanisms **49** and **54** are in their locked positions as shown in FIG. **3**. Device **30** may then be completely withdrawn from the vein by pulling device **30** past lead **10**, leaving barb **18** lodged in and permanently secured to heart tissue.

FIG. **5** shows plunger **42** in its fully depressed position with shoulders **67** abutting legs **62** and with electrode **16** extended beyond end **48** of tube **32**. FIG. **6** shows barb **18** lodged in and permanently secured in heart tissue and with device **30** partially withdrawn. After device **30** is fully withdrawn from the vein, the proximal end **28** of lead **10** is ready to be connected to the pulse generator for applying stimulating pulses through lead **10** and electrode **16** to the heart.

A single lead **10** would be used in a monopolar pacing system. Use of a pair of leads **10** would permit use of a bipolar system. It should be understood that although the use of lead **10** and device **30** together in lead assembly **70** have been described for use in a cardiac pacing system, lead assembly **70** could be used in other types of body stimulating applications.

It should be understood, of course, that the foregoing disclosure relates to only a preferred embodiment of the present invention and that numerous modifications may be made therein without departing from the spirit and scope of the invention as set forth in the appended claims.

What is claimed is:

1. A body-implantable, intravascular lead adapted to be connected at its proximal end to a source of electrical energy and permanently secured at its distal end through the endothelial tissue of a living animal body for electrical stimulation thereof comprising:

electrically conductive lead means for insertion in and guidance through a body vessel to a desired location and position inside an organ of a living animal body the lead means having a cross-section which will fit within a body vessel;

electrode means affixed to the distal end of said lead means and adapted to supply electrical impulses to tissue at a desired location inside the living animal body, said electrode means including a tissue piercing portion and further including separate tissue engaging means for allowing said electrode means to be firmly lodged in and permanently secured through the endothelial tissue at the desired location; and

material means substantially inert to body fluids and tissue encasing said lead means and a portion of said electrode means for sealing them from living animal body fluids and tissue.

2. The lead of claim 1 wherein the means for allowing the electrode means to be firmly lodged in and permanently secured through endothelial tissue comprises means for allowing the electrode means to be firmly lodged in and permanently secured through endocardial tissue.

3. A body-implantable, intravascular lead assembly for use in conjunction with an electromedical device, said lead assembly comprising:

electrically conductive lead means of a cross-section which will fit within a body vessel having electrode means affixed to its distal end and adapted to be electrically connected at its proximal end to a source of electrical power, said electrode means including a tissue piercing portion and further including separate tissue engaging means for allowing said electrode means to be firmly lodged in and permanently secured through the endothelial tissue of selected organs of living animal bodies;

means for inserting and guiding said lead means in and through a body vessel to a desired location and position inside the living animal body organ;

means for allowing said electrode to be moved a predetermined distance for firmly lodging and permanently securing said electrode through the endothelial tissue of the selected organ at the desired location; and

means substantially inert to body fluids and tissues for encasing and sealing all of the lead means for the living animal body fluids and tissue except the distal end of the electrode means.

4. A lead assembly as set forth in claim 3 wherein said electrode means includes an electrically conductive barb means for insertion into the tissue.

5. A lead assembly according to claim 4 wherein said insertion and guide means encases the lead means, said insertion and guide means comprises two separate concentric tubes fitted one within the other, the inner tube being connected to a means adapted for moving it within the outer tube.

6. A lead assembly according to claim 5 wherein said tubes are substantially cylindrical and the lead means is constructed such that it has a substantially cylindrical sleeve means having a cross-sectional diameter greater than the cross-sectional diameter of the inner tube but less than the cross-sectional diameter of the outer tube, said sleeve means being positionable within the outer tube and into abuttment with the distal end of the inner tube so as to provide movement of the lead means when the inner tube is moved within the outer tube.

7. A lead assembly as set forth in claim 6 wherein said sleeve means has at least one ridge formed on the outer surface thereof the diameter of said ridge being substantially equal to the inside diameter of said outer tube and forming a seal with the inside wall of said outer tube to prevent the back flow of body fluids into said tubes when said sleeve is within said outer tube.

8. A lead assembly as set forth in claim 6 wherein said means for lodging and securing includes plunger means connected to said inner tube, said plunger means being adapted to forceably move the inner tube and lead means a predetermined distance so that the electrode means of said lead means moves from a position within the outer tube to a position outside the outer tube, said plunger forceable movement being used to firmly lodge and permanently secure the electrode means through the endothelial tissue of the selected body organ.

9. A lead assembly as set forth in claim 8 wherein said plunger means includes engageable first locking means which when in locked position insures that the barb cannot be inadvertently moved from its position within the outer tube, engageable second locking means which when locked prevents the plunger means from moving the barb further from the outer tube than a position in which it just protrudes from the outer tube, and means for preventing the plunger means from moving the barb more than a predetermined distance when lodging and securing the barb thereby preventing overly deep and injurious barb lodgings.

10. A lead assembly as set forth in claim 3 wherein said insertion and guide means encases the lead means, said insertion and guide means being constructed and adapted to impart sufficient rigidity to facilitate placement of the lead means.

11. The lead assembly of claim 3 wherein the means for firmly lodging and permanently securing the electrode means through the endothelial tissue of a selected body organ comprises means for firmly lodging and permanently securing the electrode through endocardial tissue.

12. A device for inserting a body-implantable intravascular lead with an electrode at one end thereof into a body vessel and for guiding said lead into a desired location and position within a selected organ of the body, said electrode including a tissue piercing portion and further including separate tissue engaging means for allowing said electrode to be firmly lodged in and permanently secured through endothelial tissue at said selected body organ, said device comprising:

means surrounding said lead means for inserting and guiding said lead into and through a body vessel to a desired location and position inside the selected body organ;

locking means for preventing movement of said electrode beyond a position where it just protrudes from said inserting and guiding means; and plunger means for allowing said electrode to be moved a distance, greater than said locking means for firmly lodging and permanently securing said electrode through the endothelial tissue of the selected organ at the desired location.

13. A device as set forth in claim **12** wherein said insertion and guide means comprises inner and outer concentric, flexible tubes, said inner and outer tubes encasing a substantial portion of said lead, said outer tube being constructed and adapted to encase said electrode.

14. A device as set forth in claim **13** wherein said plunger means is operatively connected to said inner tube for allowing said inner tube and lead to move a predetermined distance so that the electrode moves from its position within said outer tube so as to be lodged in and permanently secured to said body tissue.

15. A device as set forth in claim **14** further including additional locking means for insuring that said electrode cannot be inadvertently lodged in and secured to body tissue; and said plunger means including means for allowing said electrode to move only a predetermined distance from said outer tube when lodging and securing the electrode in the tissue so as to prevent injury to the tissue.

16. The device of claim **12** wherein the means for allowing the electrode to be moved a predetermined distance for firmly lodging and permanently securing the electrode through endothelial tissue comprises means for allowing the electrode to be moved a predetermined distance for firmly lodging and permanently securing the electrode through endocardial tissue.

17. A body-implantable, intravascular lead assembly for use in conjunction with an electro-medical device, said lead assembly comprising:

electrically conductive lead means of a cross-section which will fit within a body vessel having electrode means affixed to its distal end and adapted to be electrically connected at its proximal end to a source of electrical power, said electrode means including a tissue piercing portion and further including separate tissue engaging means for allowing said electrode means to be firmly lodged in and permanently secured through the endothelial tissue of selected organs of living animal bodies;

means for inserting and guiding said lead means in and through a body vessel to a desired location and position inside the living animal body organ;

means for allowing said electrode to be moved a predetermined distance for firmly lodging and permanently securing said electrode through the endothelial tissue of the selected organ at the desired location;

means for allowing a threshold measurement with said electrode means while preventing a firm lodging and permanent securement of said electrode means during said threshold measurement; and

means substantially inert to body fluids and tissues for encasing and sealing all of the lead means from living animal body fluids and tissue except the distal end of the electrode means.

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