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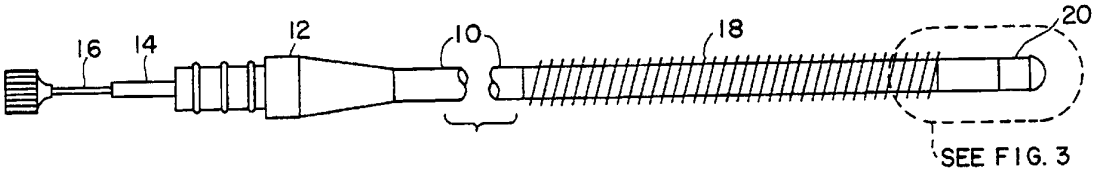

(57) Abstract

Apparatus for affixing implantable catheters and leads to body tissue. An electrode located on the lead or catheter is coupled to an RF signal generator, of the type employed to perform electrosurgical procedures such as electrocoagulation. The RF signal causes the electrode to adhere to body tissue, thus stabilizing the location of the catheter or lead. The electrode may be a dedicated electrode employed only for affixation. Contact between the electrode and the RF signal generator may be made by a removable conductor.

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RF LEAD FIXATION

Background of the Invention

The present invention relates generally to medical electrical leads and more specifically to electrode leads used in conjunction with implantable pacemakers and implantable defibrillators.

Pacing and defibrillation leads are typically located on or in the human heart. The physician carefully places the leads so that their electrodes are located precisely in desired locations. However, the beating of the human heart tends to dislodge these leads from their desired locations. Therefore, over the years, a wide variety of methods and apparatus designed to retain the leads in their desired locations have been developed.

Lead fixation mechanisms can generally be divided into active fixation and passive fixation. Active fixation devices typically take the form of penetrating barbs, screws, or clamps which actively engage, and typically penetrate heart tissue as part of their retention function. Leads employing active fixation mechanisms include U.S. Patent No. 3,737,579 issued to Bolduc, U.S. Patent No. 3,814,104 issued to Irnich et al, U.S. Patent No. 3,844,292 issued to Bolduc, U.S. Patent No. 3,974,834 issued to Kane and U.S. Patent No. 3,999,555 issued to Person. Passive fixation mechanisms are typically less severe, and tend to engage the heart tissue without penetrating it. Pliant tines, located upon the ends of the electrodes are the most commonly used passive fixation device. Such tines are disclosed in U.S. Patent No. 3,902,501, issued to Citron, et al. Alternative passive fixation mechanisms include leads specifically shaped to brace against cardiac tissue, so that the electrodes will remain in a specific desired location, as well as fixation by means of tissue ingrowth, wedging, and so forth. Leads employing passive fixation mechanisms are also disclosed in U.S. Patent No. 4,154,247 issued to O'Neill, U.S. Patent No. 4,149,542 issued to Thoren and U.S. Patent No. 3,937,225 issued to Schramm.

All of the fixation mechanisms described above have one or more drawbacks. Typically, passive fixation

mechanisms are not as reliable in maintaining the leads in their desired locations as active fixation mechanisms, in the absence of trabeculation at the desired electrode location. Active fixation mechanisms typically require deployment of some sharpened member such as a screw or a barb, which adds substantial mechanical complexity, and in some cases risks unwanted perforation of heart tissue or snagging of the fixation devices on venous or valve tissue, during the implantation procedure. Thus, there is still a demand for improved fixation mechanisms, particularly those which do not significantly add to the mechanical complexity of the lead or to the difficulty of the implant procedure, but nonetheless provide reliable fixation at the time of implant.

Summary of the Invention

The present invention is directed toward a new method of fixing of an implantable lead in place adjacent to body tissue. For purposes of this application, the term "lead" should be interpreted broadly as including any device of the types generally referred to as leads or catheters, so long as at least one electrode is included. While the invention can be employed in a number of different contexts, it is believed most likely to be used in the context of cardiac pacing and defibrillation electrode leads, for affixing the leads to desired locations on or in the heart or in the venous system adjacent the heart.

The present invention accomplishes these objects by coupling an electrode located on the lead body to an RF signal generator, of the type typically employed in conjunction with electrosurgical devices, such as electrocoagulators and the like. The lead is located at its desired implant site, and RF energy is applied to an electrode on the lead, causing the electrode to adhere to adjacent tissue. The inventors have determined that by applying RF energy levels typically used for electrocoagulation, for short periods of time (e.g., a few seconds) a reliable connection to the tissue can be made, with the strength of the connection being controlled by the

duration of the RF signal. In this fashion, a light tack can be accomplished for temporary positioning, following which the lead may be relocated, and more permanent connection between the lead and the tissue made by meads of an RF signal of greater duration.

The electrode coupled to the RF generator may be a dedicated electrode located on the lead, specifically used only for fixation. The electrode may be connected to the RF source by means of an insulated stylet, which is passed through the lead body to couple electrodes to the RF generator, or by means of a conductor permanently mounted in the lead body.

After fixation, the RF source is disconnected and the lead is coupled to a medical device. If the lead carries an electrode which is coupled to an electrical connector, such as in electrical stimulation and monitoring leads, the lead and the electrode thereon will thereafter be coupled to an implantable pacemaker, defibrillator, or other implantable medical pulse generator or medical monitoring device. If the electrode on the lead is only used for fixation, the lead may be coupled to an implantable drug dispenser or other implantable device which employs a permanently implanted lead for therapeutic or monitoring purposes.

Brief Description of the Drawings

Fig. 1 is a plan view of a defibrillation lead employing the present invention.

Fig. 2 is a plan view of a second embodiment of a defibrillation lead employing the present invention.

Fig. 3 is a cut away view through the distal tip of the lead illustrated in Fig. 1.

Fig. 4 is a cut away view of the lead illustrated in Fig. 2, adjacent the proximal end of the defibrillation electrode.

Fig. 5 is a plan view of the distal end of a first alternative embodiment of a lead generally as illustrated in Fig. 1.

Fig. 6 is a plan view of the distal end of a second alternative embodiment of a lead generally is illustrated in Fig. 1.

Fig. 7 is a cut away view through the distal end of the alternative embodiments illustrated in Figs. 5 and 6, illustrating a recessed electrode configuration.

Fig. 8 is a cut away view through the distal end of the alternative embodiments illustrated in Figs. 5 and 6, illustrating a flush mounted electrode configuration.

Fig. 9 is a plan view of the distal end of a subcutaneous or epicardial lead employing the present invention.

Fig 10 is a plan view of the distal end of an endocardial lead employing the present invention.

Fig. 11 is a cut away view of a human heart illustrating the location of a defibrillation lead as in Fig. 1, in the coronary sinus.

Detailed Description of the Preferred Embodiment

Fig. 1 is a side plan view of a defibrillation lead, adapted for use in practicing the present invention. The lead is provided with an elongated insulative lead body 10, enclosing a coiled conductor which runs the length of the lead body. At the proximal end of the lead is a connector assembly 12, including a connector pin 14 coupled to the conductor within the lead body 10. A stylet 16 is shown inserted into connector pin 14. An elongated coil electrode 18 is located In the distal region of the lead, also coupled to the conductor within the lead body 10 and thereby to connector pin 14. This much of the structure of the illustrated lead is typical of prior art endocardial defibrillation leads.

Located adjacent to the distal end of the lead is a ring electrode 20, which is not coupled to the conductor within the lead body 10, but instead is coupled to an RF generator by means of stylet 16. Because electrode 20 is insulated from the connector assembly 12, it may not be employed for sensing or stimulation purposes. Although not visible in this illustration, stylet 16 is insulated over

the majority of its length, being uninsulated only at its proximal and distal extremities, whereby the distal extremity of stylet 16 contacts electrode 20 internally to the lead and an alligator clip or other electrical connector may be coupled to the uninsulated proximal end of the stylet 16.

The general method of implantation of the lead of Fig. 1 comprises inserting the lead in its desired location (e.g., right ventricle, right atrium, superior vena cava or coronary sinus) and, when the lead is properly located, coupling an electrosurgical generator to stylet 16 and to a ground plate electrode mounted to the patient's body, which may be a return electrode of the type typically used in conjunction with the electrosurgical devices. RF energy is applied to the stylet and the return electrode, causing electrode 20 to become affixed to heart tissue. While the energy is employed to accomplish such fixation will vary from design to design, in general, fixation can be accomplished using a prior art RF electrosurgical power source within the range of power levels generally used for electrocoagulation. In addition, in devices so equipped, the impedance meter may be used to control the duration of application of the RF signal, with a change of impedance in the range of about 30% being useful to indicate that fixation has occurred.

Initial fixation or temporary fixation can be accomplished with an RF signal terminated prior to the occurrence of the above-mentioned impedance change, with permanent fixation being accomplished by extending the signal period until the change in measured impedance occurs. After fixation is accomplished, the stylet 16 is disconnected from the RF source and the stylet is removed from the lead. The lead is then coupled to an implantable defibrillator, with electrode 18 being coupled to the high voltage output of the defibrillator by means of connector pin 14.

Fig. 2 discloses an alternate embodiment of the lead generally as illustrated in Fig. 1. Like the lead in Fig. 1, it includes an elongated insulative lead body 110 which

carries a conductor coupled to coil electrode 118 and connector pin 114 which in turn is mounted to a connector assembly 112 on the proximal end of the lead. In this case, the fixation electrode 120 is located proximal to the coil electrode 118. Stylet 116 is an insulated stylet, corresponding to stylet 16 (Fig. 1), but coupled to electrode 120, as illustrated in more detail in Fig. 4.

Fig. 3 is a sectional view through the distal end of the lead illustrated in Fig. 1. As illustrated, electrode 20 is located at the distal end of a sleeve 300 of a flexible insulative material, and is typically bonded adhesively thereto. The proximal end of sleeve 300 surrounds a crimp sleeve 302 to which electrode 18 is welded. The conductor 304 located within crimp sleeve 302 is coupled to the connector pin 14, illustrated in Fig. 1.

Crimping core 306 is provided internal to conductor 304, and conductor 304 is crimped between crimping sleeve 302 and crimping core 306 to couple it electrically and mechanically to electrode 18. Similarly, electrode 20 is provided with a cylindrical extension 308 which acts as a crimping sleeve. A crimping core 312 is provided, with coil 310 crimped between sleeve 308 and core 312. As illustrated, coil 310 serves as an electrical connector for coupling the uninsulated portion 314 of stylet 16 to electrode 20. The interior surface of ring electrode 20 is provided with a conical ramp 316, so that the distal 314 of stylet 16 is properly centered for entry into the proximal end of coil 310. The proximal end of coil 310 has an inner diameter slightly less than the outer diameter of the uninsulated portion 314 of stylet 16, to provide a low impedance electrical connection between stylet 16 and electrode 20. At the distal end of the lead, a rounded, insulative tip member 318 is provided.

Fig. 4 is a cut away view through the area adjacent the proximal end of electrode 118 as illustrated in Fig. 2. The proximal end of coil electrode 118 is welded to a sleeve 402 which in turn is mounted adhesively to lead body 110. An elongated conductor 404 extends within lead body 110 and is coupled to connector pin 114 at the proximal end

of the lead and to electrode 118 at the distal end thereof, by means of a crimp sleeve as illustrated in Fig. 3.

Ring electrode 120 is coupled to a coil 410 which is interwound in between the turns of multifilar coil 404, and insulated therefrom. Coil 410 may be insulated from coil 404 by means of an insulative coating applied to the conductors of coil 404 or by means of an insulative coating applied to all but the interior surface of coil 410. Coil 410 is shown engaging the uninsulated portion 414 of insulated stylet 116, coupling it electrically to electrode 120. The interior diameter of coil 410 is very slightly smaller than the outer diameter of stylet 414 providing a low impedance connection to electrode 120.

Fig. 5 illustrates an alternative version of the distal end of the lead illustrated in Fig. 1. In this case, electrode 20A takes the form of a hemi-cylindrical electrode, rather than a complete cylindrical electrode as in Fig. 1. Fig. 6 correspondingly illustrates a button or point electrode 20B, as substituted for electrode 20 in Fig. 1. Electrodes 20A and 20B of Figs. 5 and 6 are believed particularly valuable in the context of a coronary sinus lead where complete fixation around the entire circumference of the lead may not be desirable, particularly if the distal end of the lead is not intended to completely block the coronary sinus or great cardiac vein in which it is located. Similarly, point, button or other small surface area electrodes may be added to or substituted for electrodes presently existing cardiac pacing and defibrillation leads to provide the capability of fixing the lead body to heart tissue at whatever point is desired.

The electrodes 20A and 20B may be mounted flush to the surface of the lead or may be recessed. Figures 7 and 8 illustrate these two alternative electrode configurations. Numbered elements in Figure 7 correspond to identically numbered elements in Figure 3, with the exception that the insulative tip 318A of the lead extends back to the Crimp sleeve 302 (Figure 3) and that the electrode 20C is recessed within the tip 318A and the exposed portion of the

electrode, as in Figures 5 and 6, does not extend around the full circumference of the lead. Figure 8 illustrates a lead in which the electrode 20D is mounted flush to the surface of tip 318B, but otherwise corresponds exactly to the lead illustrated in Figure 7.

Figure 9 illustrates an epicardial or subcutaneous lead employing the present invention. The lead corresponds generally to the leads disclosed in U.S Patent No 4,817,634 issued to Holleman et al and in U.S Patent No. 5,044,374, issued to Lindemans et al. The distal end of the lead is provided with a large surface area insulative electrode pad 700, carrying three concentric electrode coils 702, 704 and 706 coupled to an insulated conductor within lead body 708.

Two electrodes 710 and 712 are provided for fixation purposes, coupled to insulated conductor 714. Conductor 714 may terminate in the vicinity of the pad 700, with electrical connection to conductor 714 and to electrodes 712 and 710 being made by means of an uninsulated stylet as in the leads of Figures 1 and 2. RF energy applied to electrodes 710 and 712 may be used to affix the electrode pad to tissue in a desired epicardial or subcutaneous location, for use in an implantable defibrillation lead system, in the same manner as described above.

Figure 10 illustrates the distal end of yet another embodiment of an endocardial lead employing the present invention. In this case, the pacing and sensing electrode 802 takes the form of a ring shaped electrode mounted at the distal tip of lead body 800 and is connected to an insulated conductor mounted within lead body 800. A fixation electrode 804 is provided, located centrally within ring electrode 802 and insulated therefrom. As in the leads illustrated above, electrical connection to electrode 804 may be made by an insulated stylet mounted in lead body 800.

Figure 11 illustrates the location of a lead as illustrated in Figures 1 and 2, as located in the coronary sinus. In the context of the present invention, after finding an appropriate location for electrode 20 or 120 in the great cardiac vein or coronary sinus, an

electrosurgical generator may be coupled to stylet 16 or 116 and to a ground plate electrode, as described above in order to affix electrode 20 or 120 to heart tissue.

As such, the present invention provides a new mechanism for fixing cardiac pacing leads and defibrillation leads to body tissue, by means of application of an RF signal to an electrode located on the lead. The electrode may be a dedicated electrode used solely for fixation purposes, may take any of a number of different forms, as illustrated in Figs. 1 - 10, and may be coupled to an RF generator by means of an insulated stylet or other temporary conductor placed in the lead body, solely during the fixation process. The present invention may be employed to locate leads in the coronary sinus, atrium, ventricle or other location within the cardiovascular system or subcutaneously.

While not specifically illustrated in the drawings, the present invention is also applicable to electrode leads located in other portions of the human body, such as nerve or muscle stimulation electrodes. Similarly, the invention may also be practiced in leads that do not employ stimulating electrodes, such as used for localized delivery of drugs in conjunction with implantable drug dispensers. In this context, the invention would be realized by adding an electrode to the drug delivery tube, and employing a conductor or an insulated stylet to deliver RF energy to the electrode in the fashion discussed above in conjunction with the illustrated embodiments. As such, the embodiments illustrated above should be taken as exemplary, rather than limiting, with regard to the scope of the claims which follow:

CLAIMS:

1. A medical lead comprising:
an elongated lead body;
means for coupling said lead to a medical device;
a first electrode, mounted to said lead body and electrically insulated from said coupling means;
a conductive stylet, removably insertable in said lead body; and
means for electrically coupling said stylet to said first electrode.

2. A lead according to claim 1, further comprising
a second electrode, insulated from said first electrode and mounted to said lead body;
an elongated conductor, within said lead body, electrically coupled to said second electrode and insulated from said first electrode;
an electrical connector, mounted to said lead body and electrically coupled to said conductor; and
means for insulating said stylet from said conductor.

3. A lead according to claim 1 wherein said stylet comprises electrical insulation covering said stylet along its length, with a portion of said stylet not covered by said insulation, whereby said portion not covered may be electrically coupled to said first electrode.

4. A lead according to claim 1, wherein said first electrode is recessed within said lead body.

5. A lead according to claim 3, wherein said first electrode extends circumferentially around one half or less of said lead body.

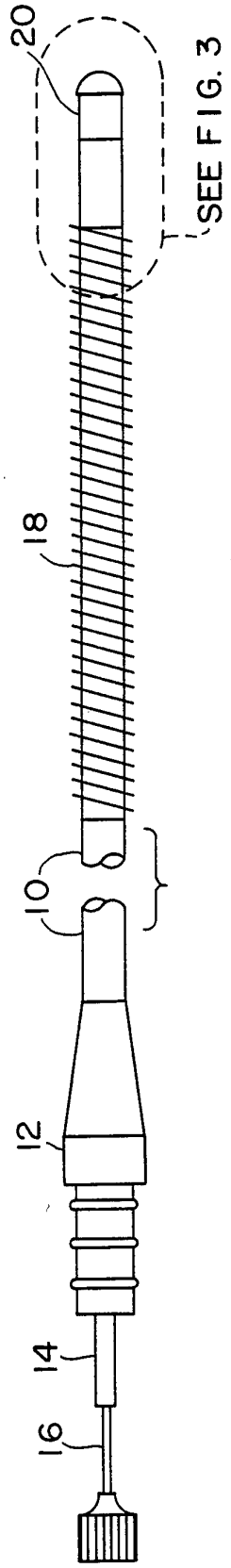

FIG. 1

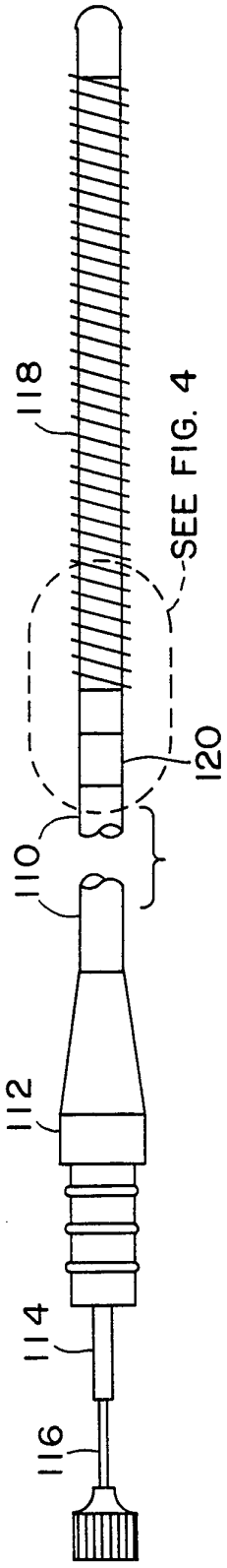

FIG. 2

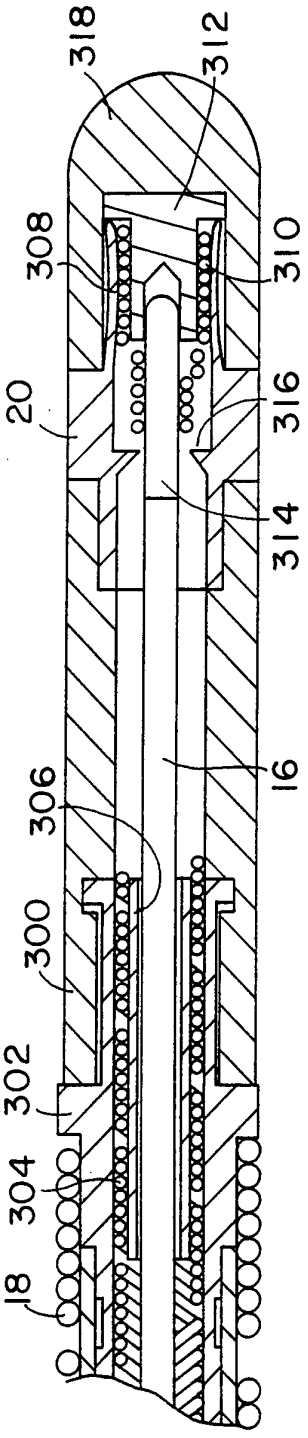
318
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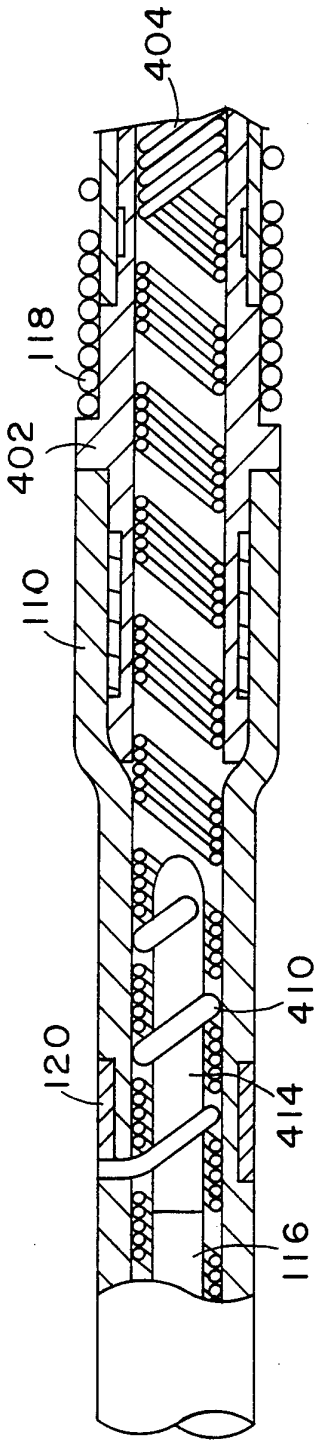
FIG. 3


404
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110
410
120
414
116

FIG. 4

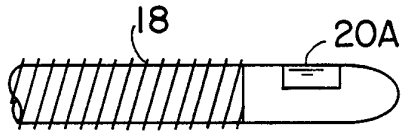

FIG. 5

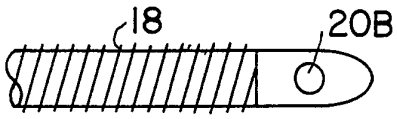

FIG. 6

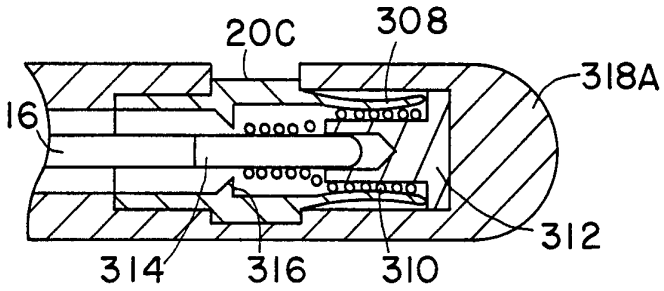

FIG. 7

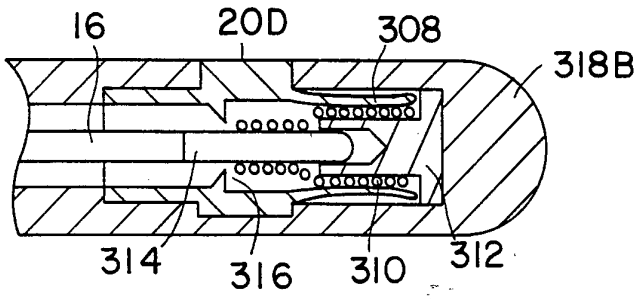

FIG. 8

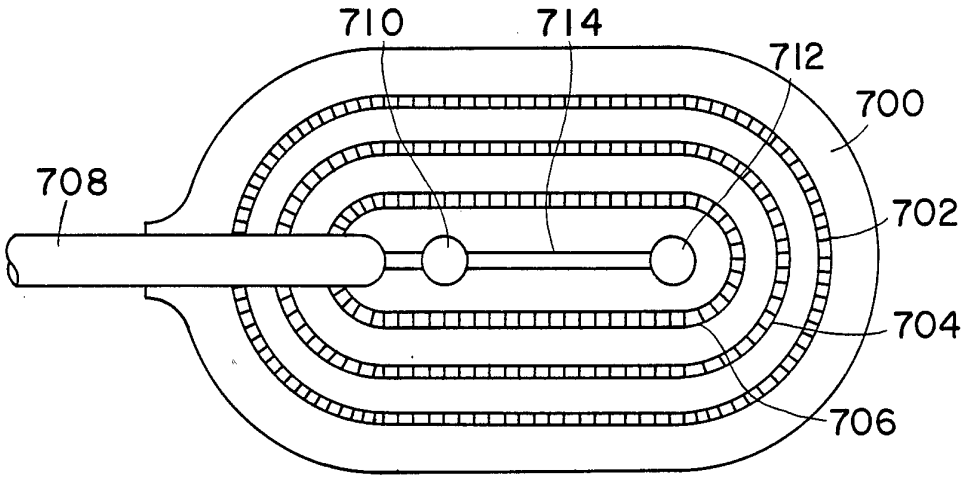

FIG. 9

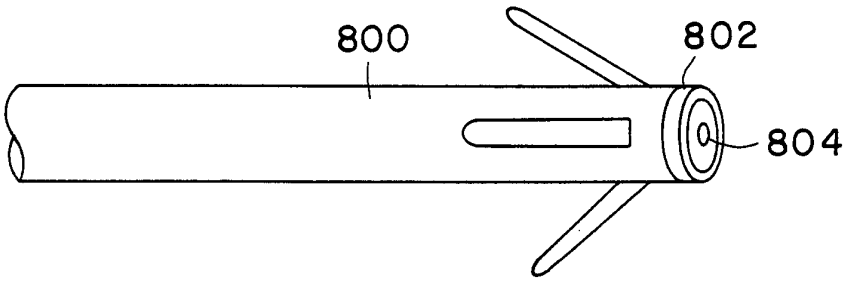

FIG. 10

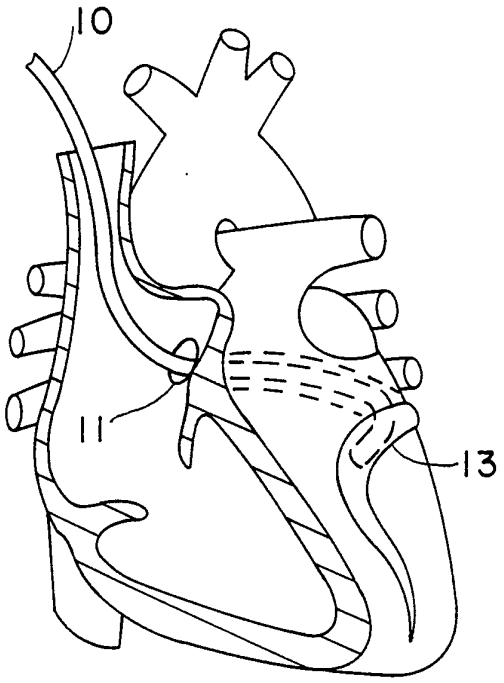

FIG. 11

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 94/00947

A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 A61N1/05

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	EP,A,0 158 397 (PORCELIJN) 16 October 1985 see abstract see page 1, line 34 - page 2, line 3 see page 2, line 12 - line 22 see page 2, line 31 - line 33 see page 3, line 5 - line 18 see page 4, line 13 - line 16 see page 4, line 21 - page 5, line 3; claim 2	1,3 2
X	EP,A,0 102 538 (STERIMED GESELLSCHAFT) 14 March 1984 see page 5, line 15 - line 33 see claim 1	1,3
A	US,A,3 827 428 (HON) 6 August 1974 see abstract	2

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 July 1994	31.08.94

Name and mailing address of the ISA	Authorized officer
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,3 977 411 (HUGHES) 31 August 1976 see abstract see column 2, line 56 - line 61	2
A	US,A,4 995 389 (HARRIS) 26 February 1991 see column 5, line 5 - line 9	2
A	EP,A,0 207 438 (NIVARO-FAR) 7 January 1987 see page 1, line 18 - page 2, line 6	1
A	EP,A,0 517 494 (CARDIAC PACEMAKER) 9 December 1992 see abstract see column 6, line 28 - line 39	1

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter ɔnal Application No
PCT/US 94/00947

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A-0158397	16-10-85	NL-A-	8401181	01-11-85
EP-A-0102538	14-03-84	DE-A-	3229466	09-02-84
		WO-A-	8400692	01-03-84
		JP-B-	3070503	07-11-91
		JP-T-	59501536	30-08-84
		US-A-	4824433	25-04-89
US-A-3827428	06-08-74	US-E-	RE28990	05-10-76
US-A-3977411	31-08-76	NONE		
US-A-4995389	26-02-91	NONE		
EP-A-0207438	07-01-87	FR-A-	2583985	02-01-87
		US-A-	4791939	20-12-88
EP-A-0517494	09-12-92	US-A-	5300106	05-04-94