

[54] **CARDIAC PACER LEAD SYSTEM FOR INTERIM PACING DURING PACER CHANGEOVER**

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[51] **Int. Cl.**²..... **A61N 1/04**

[58] **Field of Search**..... **128/418, 419 P, 419 PS, 128/419 C, 419 E, 404; 339/DIG. 3**

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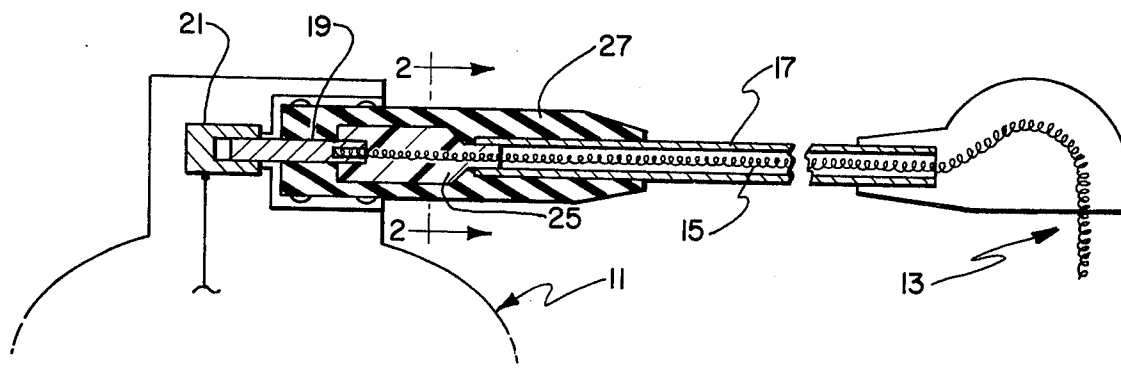
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[57] **ABSTRACT**

In the cardiac pacer lead assembly disclosed herein, a mass of a conductive silastic is cast about the flexible metallic lead, adjacent its connection with the pacer. A jacket of insulating silastic is cast over the conductive silastic and this jacket extends to the usual insulating sheath covering the flexible lead. By inserting a needle-like element through the insulating jacket and into the conductive silastic, a physician can establish a connection for interim pacing, i.e. when the lead is disconnected from a pacer being replaced and the replacement is not yet connected.

5 Claims, 2 Drawing Figures



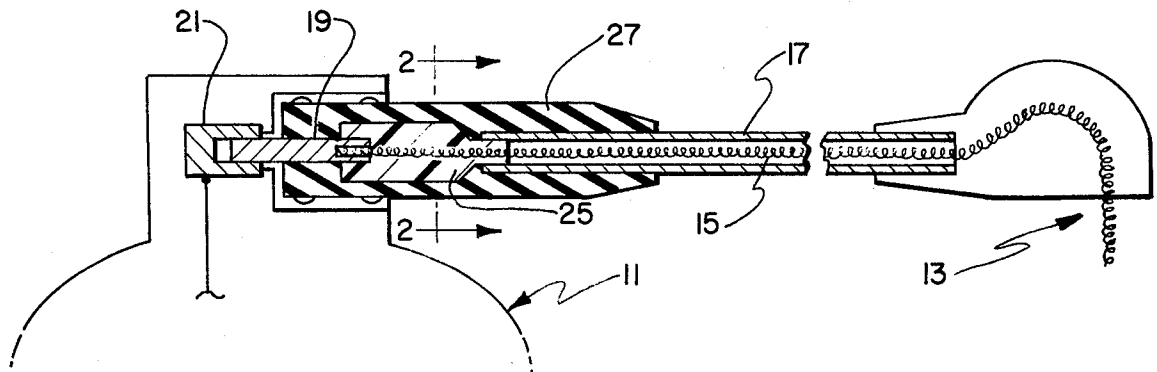


FIG. 1

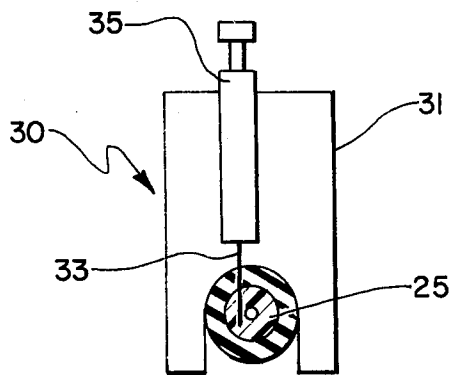


FIG. 2

CARDIAC PACER LEAD SYSTEM FOR INTERIM PACING DURING PACER CHANGEOVER

BACKGROUND OF THE INVENTION

This invention relates to cardiac pacing and more particularly to a cardiac pacer lead system permitting cardiac pacing to be maintained essentially continuously during pacer replacement, especially with unipolar pacers.

While research continues to go forward on developing batteries and other power sources which will provide longer life in a cardiac pacemaker, present practice in most cases is to plan and provide for periodic replacement of the pacemaker unit with its integral batteries. For this reason, among others, the pacer unit itself is typically implanted in a location remote from the patient's heart. The location is selected so that access to the pacer itself can be obtained by means of a relatively simple surgical procedure as compared with that required when the pacer and stimulating electrode are initially installed or placed.

The battery powered pacer unit is typically connected to the lead and electrode assembly by means of some sort of separable connector so that, after a preselected interval or upon the occurrence of some change indicating battery failure, the pacer circuit itself can be replaced while retaining the originally installed electrode and lead assembly. While such an arrangement facilitates the replacement of the pacer unit, some problems have still remained with respect to the patients who require essentially continuous pacing. If pacing is not maintained while the substitute pacer is installed, the attending physician will be under considerable pressure to work quickly. Thus, a danger exists that the connector might not be properly assembled or sealed, due to the haste required. Likewise, the need for the essentially continuous presence of the pacemaker circuit may render it difficult to test stimulation thresholds or pacer sensitivity in the case of standby pacing. In the past, in certain cases a temporary system had to be installed consisting of a pervenous lead and an external pacemaker to provide stimuli to the heart during the replacement of a permanent pacemaker. This method is employed for those patients who are suspected to suffer from standstill of the heart when stimulation is disrupted.

Among the several objects of the present invention may be noted the provision of a cardiac pacer lead system which facilitates pacer replacement by permitting connection to the cardiac electrode of a second pacer or monitor unit before the pacer being replaced is disconnected; the provision of such a lead system which permits threshold and sensitivity testing, either with an implantable pacer unit in place or removed; the provision of such a lead system which does not reduce lead reliability; the provision of such a lead system which is readily and easily used to provide interim pacing; and the provision of such a lead system which is of relatively simple and inexpensive construction. Other objects and features will be in part apparent and in part pointed out hereinafter.

SUMMARY OF THE INVENTION

Briefly, a lead system in accordance with the present invention is adapted for use with an implantable cardiac pacer having a terminal through which signals are coupled for pacing the heart of a patient. A flexible

electrical lead is employed which has an insulating sheath over a majority of its length. At one end of the lead, an electrode is provided which is adapted to contact cardiac tissue for applying stimulating pulses thereto. At the other end of the lead, there is provided a connector adapted to engage the pacer terminal. Typically, at a point close to the juncture of the connector and the lead, there is provided a mass of conductive rubbery material, which material is electrically interconnected with the lead. An insulating jacket of a nonconductive rubbery material extends over the conductive mass from the lead sheath. The jacket is shaped to engage the case of the pacer and form a seal around the contact between the connector and the pacer terminal. As the conductive mass can be electrically contacted by a needle-like element inserted through the insulating jacket, interim pacing is facilitated during replacement of the pacer.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a side view, with parts broken away, of a lead system in accordance with the present invention, showing the connection of the lead system with a cardiac pacemaker; and

FIG. 2 is a view, taken on the line 2—2 of FIG. 1, showing the cross-section of the proximal end of the lead system and showing also the method of connecting to the lead for interim pacing.

Corresponding reference characters indicate corresponding parts throughout the several views of the drawings.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to FIG. 1, there is indicated at 11 generally a conventional cardiac pacemaker. As is understood, such a device incorporates suitable timing circuits and batteries for energizing of those circuits for an appropriate length of time, e.g. several years. In both standby and continuous pacing systems, pacing can be accomplished with a single electrical lead extending to the patient's heart, a metallic portion of the pacemaker case serving as a remote ground or reference potential. However, it should be understood that the invention can also be applied advantageously to bipolar pacing.

Stimulating pulses generated by the pacer 11 are applied to the patient's heart through a suitable electrode 13. In the embodiment illustrated, electrode 13 is of the type which is adapted to be surgically attached to the outside of the patient's heart, i.e. a so-called epicardial electrode. As indicated previously, an alternative method of applying stimulating pulses is through a pervenous electrode, i.e. an electrode which is inserted through a vein and which is caused to be lodged in one of the chambers of the patient's heart. Electrode 13 is coupled with the pacer 11 by means of a flexible insulated electrical lead comprising a coiled wire 15 residing within a tubular insulating sheath 17 of silicone rubber.

A jack 21 constitutes the output terminal of the pacer 11 and at the proximal end of the lead, the helical conductor 15 is attached to a connector pin 19 which is adapted to establish electrical contact with the jack. In accordance with the practice of the present invention, a plug of a conductive silicone rubber is cast around the helical conductor 15 essentially at the point of its juncture with the connector pin 19. Preferably, the conductive silicone rubber is in direct intimate contact with

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the turns of the coiled wire 15 so that good electrical contact is established. Preferably, the end of the plug 25 is shaped so as to receive the end of the tubular lead sheath 17, as illustrated.

Over the conductive closure 25 is case a jacket 27 of an insulating silicone rubber or plastic substance. Preferably, the jacket 27 extends over and is sealed to the tubular sheath 17 and, at the opposite end, extends partially over the connector pin 19. The portion of the jacket 27 around the pin 19 is preferably shaped, as illustrated, so as to contact and effect a seal with the case of the pacer 11.

The lead system described above facilitates interim cardiac pacing during pacer replacement by permitting an alternative connection to be established to the cardiac electrode 13, using a needle-like element to engage the conductive silicone rubber plug 25. Preferably, this is done utilizing a tool 30 which acts as a templet, guiding the needle-like piercing element as illustrated in FIG. 2. Referring now to FIG. 2, the interim contact device comprises a yoke-like member 31, the lower portion of which is bifurcated so as to straddle the connector portion of the lead system. A needle-like element 33 extends from the member 31 into the hollow of the yoke-like portion, so as to pierce the sheath 27 and the plug 25 when the member 31 is placed over the connector portion of the lead assembly. The needle-like member 33 is preferably mounted off center, as illustrated in FIG. 2, so that it does not directly contact the coiled wire 25, thereby avoiding any damage to the wire. However, by passing into the conductive plug 25 as illustrated, the needle-like element 33 establishes an electrical connection to the pacing electrode 13. A terminal 35 extending from the tool 30 is provided for connection to external pacing apparatus, e.g. through a suitable clip or connector (not shown). As will be understood by those skilled in the art, external pacers of various types are known, being commonly used for temporary pacing following cardiac surgery and the like. If the pacer being replaced is a standby type, the external pacer can be operated either in the standby mode or at a fixed rate higher than the natural heart-beat or rhythm of the patient. In the standby mode, both pacers can operate simultaneously, either pacer responding to naturally occurring heartbeats. In the absence of a natural heartbeat, the first to generate a stimulating pulse will be detected by the other and control its operation. In the case of a pacer which operates continuously, the external pacer is appropriately left turned off until the connector is separated, at which time the external pacer can be turned on without delay since the connection to the stimulating electrode can be pre-established. It can thus be seen that, in either case, substitution of pacemakers is greatly facilitated since a connection for interim pacing can be established before disconnecting the original pacer and interim pacing can be provided by an external device while the installation of the replacement pacer proceeds on a deliberate and un-hurried basis.

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While interim pacing of standby and continuous pacers has been described by way of example, since each of these types of pacing can be effected with a single lead, it can be seen by those skilled in the art that the present invention can also be adapted to other pacemakers in which a pair of leads are employed, i.e. by providing respective plugs of conductive silastic adjacent around the respective leads adjacent their connection to the pacer circuitry. Thus, connections can be established for interim pacing while the original pacemaker unit itself is still in place.

In view of the foregoing, it may be seen that several objects of the present invention are achieved and other advantageous results have been attained.

As various changes could be made in the above constructions without departing from the scope of the invention, it should be understood that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

What is claimed is:

1. A pacer interconnection and lead system for use with an implantable cardiac pacer, which system facilitates interim pacing of a patient's heart during pacer replacement, the pacer having a connector terminal through which signals are coupled for pacing the heart of a patient, said pacer interconnection and lead system comprising:
 - a flexible, electrical lead;
 - over said lead, for a majority of its length, an insulating sheath;
 - at one end of said lead, an electrode adapted to contact cardiac tissue for applying stimulating pulses thereto;
 - at the other end of said lead, a connector adapted to engage said pacer terminal for coupling stimulating signals generated by said pacer to said electrode;
 - in the region of the juncture of said lead and said connector, a mass of conductive, rubbery material electrically interconnected with said lead;
 - an insulating rubbery jacket extending over said conductive mass from said insulating sheath;
 - auxiliary connection means including a needle-like conductive element insertable through said jacket to establish electrical contact with said conductive rubbery mass to permit interim pacing of a patient's heart during replacement of a pacer; and
 - guide means for directing said needle-like element into said conductive rubbery mass without directly contacting said lead.
2. A lead system as set forth in claim 1 wherein the lead is helically coiled.
3. A lead system as set forth in claim 2 wherein said sheath is tubular and loosely encloses said helically coiled lead.
4. A lead system as set forth in claim 1 wherein said conductive material is a conductive silicone rubber.
5. A lead system as set forth in claim 4 wherein said jacket is an insulating silicone rubber.

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