

Fig. 1

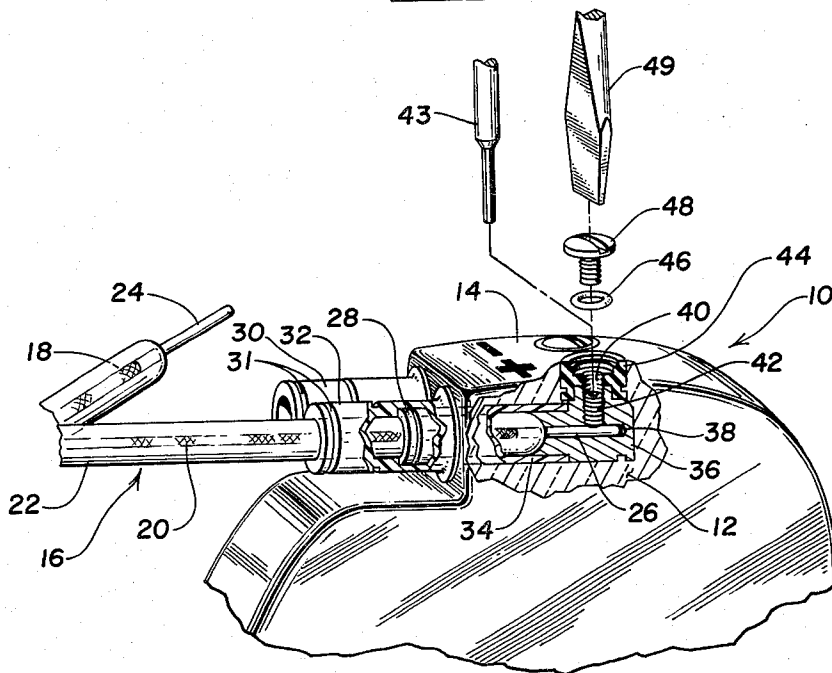


Fig. 2

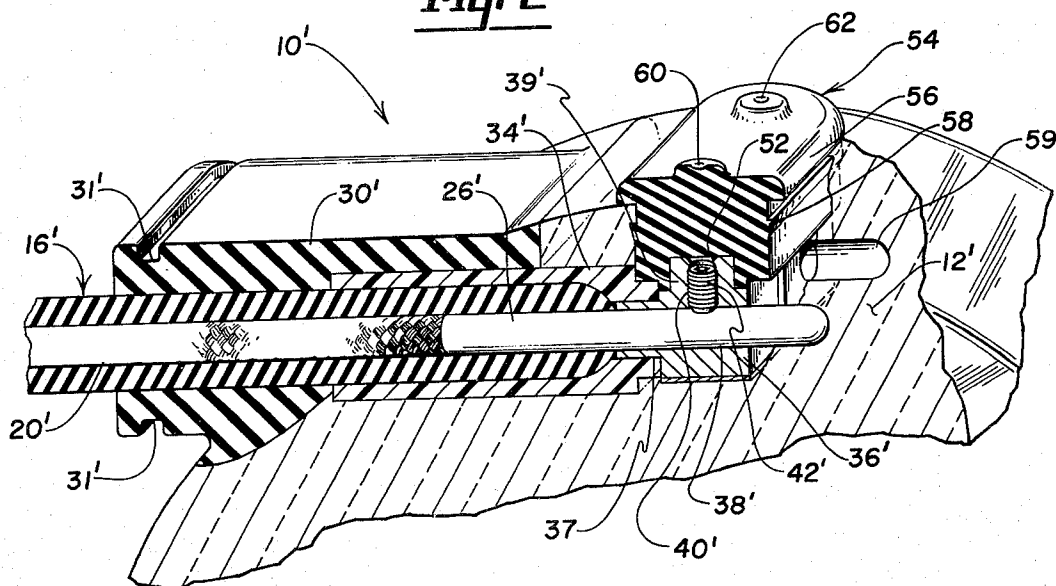
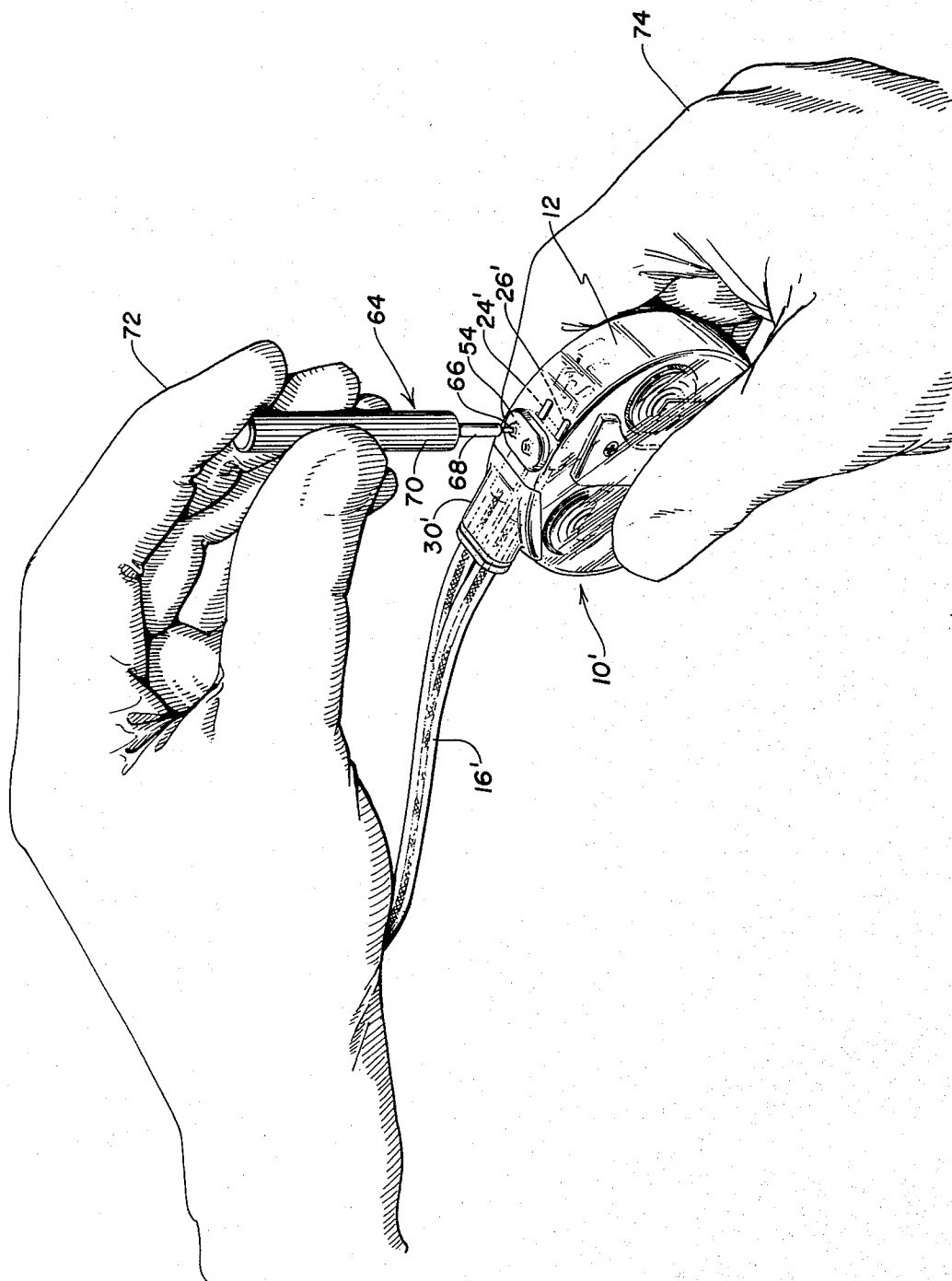


Fig. 3



TISSUE STIMULATOR WITH SEALED LEAD CONNECTOR

This invention relates to electrical tissue stimulating devices, and to an improved method and apparatus for attaching a lead to a pulse generator.

BACKGROUND OF THE INVENTION

Implantable electrical medical tissue stimulating devices are well-known in the art. For example, one of the better-known tissue stimulators is the cardiac pacer, as shown, for example, in U.S. Pat. No. 3,057,356 to Wilson Greatbatch. These devices, such as the cardiac pacer, generally comprise a pulse generator further comprising a power source and associated electrical circuitry embedded in, and encapsulated in, or protected by a substance or substances substantially inert to body fluids and tissue. The electrical circuitry of the pulse generator is adapted to be connected by a lead or leads to one or more electrodes which are adapted to be placed adjacent to a remote, desired spot within the human body, such as adjacent to or within myocardial tissue. The cardiac pacer, for example, supplies electrical stimulating pulses to regulate cardiac function in the absence of naturally occurring cardiac pulses.

In implantation of pulse generator and lead, it is common practice for the surgeon in intravenously position or surgically attach the electrode at the distal end of the lead to the desired spot within the human body, that is, in or adjacent to myocardial tissue, and to thereafter connect the lead to a connector assembly associated with the electrical circuitry of the pulse generator in order to commence electrical stimulation of the heart tissue. Prior to making the electrical connection, the surgeon usually measures the electrical stimulation threshold level sufficient to maintain capture of the heart and the sensing threshold level sufficient to trigger the sense amplifier, if any, in the pulse generator circuitry to inhibit the generation of electrical stimulating pulses in the event the heart is functioning normally.

Thereafter, if the threshold levels are adequate, the surgeon usually creates a subcutaneous pocket to receive the encapsulated pulse generator in connective tissue lying just beneath the skin. After the pulse generator is slipped into the pocket, the incision is closed and precautions are taken to avoid build-up of inert body fluids in the pocket and to guard against infections.

One problem which has been encountered, and is known to those skilled in the art, involves the point in the surgical procedure when the proximal ends of the lead are connected to the lead connector apparatus of the pulse generator. Many leads, such as the Medtronic Model 5818 Bipolar, Endocardial, Transvenous Lead, comprise a flexible insulated conductor having a pair of proximal ends adapted for connection to the pulse generator and a distal end portion comprising a pair of electrodes adapted to be positioned within the left ventricle of the patient's heart in contact with endocardial tissue. The proximal ends comprise a pair of conductive terminal pins each uninsulated for a portion of its length and insulated by an oversized sleeve at the point where the terminal pin is electrically connected to the conductor. Associated pulse generators, such as the Medtronic Model 5842 Implantable, Bipolar Demand Pulse Generator, have a pair of conductive receptacles adapted to receive the terminal pins of the associated

Medtronic Bipolar Leads, through a corresponding pair of silicone rubber boots. The silicone rubber boots have an opening diameter dimensioned with respect to the outside diameter of the sleeve of the lead connector ends to insure a fairly close fit.

Connecting such a lead to a pulse generator of the type noted hereinbefore consists of five steps. The first step is to coat the lead connector ends including the terminal pins and the insulated nylon sleeves with a silicone oil lubricant that is compatible with the silicone rubber portion of the lead and silicone rubber boots and is inert to body fluids and tissue. Thereafter, the lead connector ends are pushed into the terminal until each lead collar snaps into place in the silicone rubber boot and the terminal pin is visible through a set screw hole. A relatively small set screw is then placed on a hex wrench tool and inserted into a threaded set screw bore in the connector block containing the terminal pin receptacle. The set screw is tightened with the hex wrench while making certain that the lead terminal pin does not retract as the set screw is tightened. Thereafter a nylon filler screw with an O-ring in place is inserted in a filler screw hole in line with the socket set screw to seal the set screw and connector block assembly from body fluids and tissue. Finally, each rubber boot is tightened around the insulated portion of the conductor by means of a non-absorbable ligament or suture tied in a groove around the rubber boot. This procedure is repeated for each lead connector end of a bipolar lead.

Among the difficulties that arise at this point in the operation lies with the number of components and separate tools that are required to effect the complete connection of the lead to the pulse generator and to insure that the various components of the connector apparatus are not affected by body fluids and tissue. Normally, the manufacturer supplies with each pulse generator, a separate set screw, an associated hex wrench tool, a nylon filler screw, an O-ring, and a separate common screwdriver. The socket set screw, the nylon filler screw and the O-ring are all rather small in view of the relatively small size of the pulse generator and its components. It is necessary in the practice of the aforementioned procedure to place the socket set screw on the tip of the hex wrench tool, and to thereafter insert the set screw into the threaded bore of the connector block. The risk is great that the set screw will not remain in place on the tip of the tool and may be lost. The fact that a separate screwdriver is necessary to tighten the nylon filler screw adds to the cost of the entire pulse generator package. Also, when the head of the filler screw is wet, it is slippery and difficult to engage with the screwdriver blade.

If, on the other hand, the surgeon prefers to fill the access hole to the connector block with a medical adhesive, it then becomes necessary at the time the pulse generator is to be replaced to dig out the medical adhesive with a tool in order to reach the set screw.

Another problem that occasionally occurs results from the fact that the surgeon may apply too much torque to the hex wrench in engagement with the set screw thereby stripping the threads of the threaded bore of the connector block or the set screw itself. In addition, it may happen that the lead terminal pin retracts out of the receptacle as the set screw is tightened down, and poor electrical contact may result.

The apparatus of this invention and the method set forth herein for connecting a lead to a pulse generator advantageously and economically overcome these problems.

SUMMARY OF THE INVENTION

Briefly described, the apparatus of this invention and its associated method described herein involves lead connector means engageable and operable by tool means for connecting a lead to the pulse generator and sealing means puncturable by the tool means in engagement with the connector means and resealable upon removal of the tool means for providing an inert, electrically insulating seal between the connector means and body fluids and tissue. The sealing means replaces the aforementioned disadvantageous nylon filler screw and associated O-ring or medical adhesive. The lead connector means may further comprise receptacle means for receiving the lead and retaining means associated with the receptacle means and engageable by the tool means for retaining the lead in the receptacle means. Furthermore, the retaining means may further comprise means movable by the tool means into contact with lead means for retaining the lead means in stationary relationship in the receptacle means.

As another aspect of the invention, the receptacle means may comprise means for preventing the release of the movable means from the receptacle means by the tool means.

As a further aspect of the invention, the tool means comprises means for preventing the application of more than a predetermined force to the lead connector means to prevent damage to the lead connector means.

In a preferred embodiment of the invention, the receptacle means comprises a connector block having a receptacle bore for receiving the lead terminal pin, and the retaining means comprises a socket set screw in a threaded bore in operative relationship with the receptacle in the connector block. The components of the connector assembly are encapsulated in epoxy encapsulant, except for the sealing means which is maintained by the epoxy encapsulant in position between the retaining means and the atmosphere. The sealing means further comprises an implantable grade silicone rubber compound that is puncturable by the hex wrench tool means engaging the socket set screw but reseals itself upon withdrawal of the hex wrench tool. In addition, means are provided for preventing withdrawal of the set screw from the threaded bore of the connector block.

To practice the method contemplated by this invention the surgeon simply grasps the encapsulated pulse generator with one hand, pushes the terminal pin into the receptacle and inserts the tool means through the sealing means to engage the retaining means. Threshold measurements may be taken from the tool means. After tightening the lead in the connector means, the tool means may then be simply withdrawn, and the sealing means will reseal to provide electrical insulation between the connector means and body fluids and tissue.

The apparatus and method of this invention advantageously eliminates a number of separate components and steps necessary to connect a lead to a pulse generator.

Further advantages of this invention are elucidated in reference to the drawings. All parts not necessary for

a complete understanding of the apparatus and its operation have been omitted from the drawings for sake of simplicity.

BRIEF DESCRIPTION OF THE DRAWINGS

In the detail description of the preferred embodiment of the invention presented below, reference is made to the accompanying drawings in which:

FIG. 1 is a cutaway pictorial view of a prior art connector apparatus associated with a pulse generator and the associated lead, tools and components necessary to effect a connection of the lead to the pulse generator;

FIG. 2 is a cutaway pictorial view of the connector apparatus and associated tool of the present invention in relation to a lead and pulse generator; and

FIG. 3 is a perspective illustration of a manipulative step in the connection of a lead to a pulse generator in accordance with the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Before describing the invention in detail, it should be noted that in the drawings, all parts not necessary for a complete understanding of the device have been omitted.

Turning now to the drawings and first to FIG. 1, there is shown in partial perspective a section of prior art lead connector assembly associated with a tissue stimulating device. In FIG. 1, the device, for example, comprises a cardiac pacer, e.g. the Medtronic Model 5842 Implantable Bipolar Demand Pulse Generator and the Medtronic Model 5818 Bipolar, Endocardial, Transvenous Lead. The Model 5842 is a bipolar, demand, pulse generator of the ventricular-inhibited type. Programmed from the QRS heart complex, it senses the R-wave and delivers its impulses only when the patient's ventricular rate falls below the pre-set pacing rate of the pulse generator.

The pulse generator 10 may comprise a battery-power source and a miniaturized electrical circuit for sensing the R-wave and for delivering electrical stimulating impulses at a pre-set pacing rate. The electrical components of the pulse generator 10 are encapsulated in a transparent epoxy resin encapsulant 12 that is compatible with and substantially inert to body fluids and tissue. Of course, the Model 5842 Pulse Generator is illustrated as representative of the state of the prior art and other unipolar or bipolar pulse generators could be shown with the prior art lead connector assembly to be described.

Referring to the lead 16, depicted in part, it comprises a pair of electrically conductive, tissue stimulating electrodes (not shown) at its distal end, a corresponding pair of braided electrical conductors 18 and 20 electrically connected to the electrodes and electrically insulated from the surrounding body fluids and tissue by a covering of silicone rubber 22. At the proximal ends of the conductors 18 and 20 are electrically conductive, terminal pins 24 and 26, respectively. Lead collars 28 fabricated of the same silicone rubber covering 22 cover and encircle the electrical connections between the terminal pins 24 and 26 and the conductors 18 and 20.

Turning now to the prior art connector assembly depicted in FIG. 1, it comprises a pair of elongated, silicone rubber boots 30 and 32 with grooves 31 for receiving nonabsorbable sutures, the boots 30 and 32

projecting from the encapsulated pulse generator 10 and adapted to receive the proximal ends of the lead 16 comprising the terminal pins 24 and 26 and their associated lead collars 28. The silicone rubber boots 30 and 32 cooperate with a pair of connector sleeves 34 (only one shown) manufactured from a nonconductive hard plastic material and a pair of electrically conductive connector blocks 36 (only one shown) that are adapted to be electrically connected to the electrical components of the pulse generator 10. Encircling the boots 30 and 32 are grooves 31 to receive nonabsorbable sutures.

The connector block 36 further comprises a first bore or receptacle 38 for receiving the terminal pin of the lead and a second, threaded bore 40 adapted to receive a socket set screw 42. Situated between the connector block 36 and the external surface 14 of the encapsulant 12 is a nylon seat 44 that is to receive a rubber O-ring 46 and a nylon filler screw 48. Of course, each of the aforementioned connector assembly elements are duplicated as shown in the figure for a bipolar pulse generator.

The following prior art method of attaching the lead 16 to the pulse generator 10 is taken in part from the manual provided by Medtronic, Inc. with the sale of each Model 5842 Pulse Generator. The method of attachment comprises the following enumerated steps:

1. After the lead is brought out of the body at the position where the pulse generator is to be implanted, the surgeon cleans the lead connector ends and coats the terminal pins and lead collars with a silicone oil lubricant to facilitate entry into the silicone rubber boots of the pulse generator terminal assembly;

2. After checking the proper polarity of the lead connector end with respect to the positive and negative connector terminals of the pulse generator, the surgeon pushes the correct polarity lead connector ends into the respective silicone rubber boots until each lead collar snaps into place in the silicone rubber boots and both terminal pins are visible through the set screw holes;

3. After placing a socket set screw on a hex wrench (both items provided with the pulse generator by the manufacturer), the surgeon inserts and tightens the respective set screw against the terminal pins with the hex wrench while making certain that the terminal pins do not retract as the set screw is tightened;

4. After the two set screws are tightened down, the surgeon then selects the proper nylon filler screw and rubber O-ring and tightens the filler screw into the seat and the threaded bore of the connector block with a second tool which comprises an ordinary screwdriver (all items provided with the pulse generator by the manufacturer); and

5. Thereafter, the surgeon tightens each silicone rubber boot with respect to the lead by means of nonabsorbable sutures placed in the grooves encircling the silicone rubber boots.

The described prior art method applies to implantable tissue stimulators, such as cardiac pacers, manufactured by many different organizations. Some manufacturers, however, alter step 4 by eliminating the nylon filler screw 48 and instead recommending that the physician seal the holes to the set screws with a medical adhesive. This medical adhesive must be cut away when it becomes necessary to replace the pulse generator. In any event, the prior art methods require

a number of components, such as the set screws 42 and the filler screws 48, that must be separately attached to the connector assembly by separate tools, such as the hex wrench 42, and the common screwdriver 49, respectively. Since the attachment procedure takes place at the incision, there is danger that the lead connector ends or the set screw holes may become contaminated by body fluids before the connection is completed. Also, the physician may find it difficult to place the relatively tiny set screw in the set screw hole under surgical operating conditions. Finally, either the set screws 42 or the filler screws 48, or the tools 43 and 49 used to connect either item may be lost during the procedure.

In addition, when the patient's heart is being paced during the operation by an external pulse generator attached to the lead connector pins, it is necessary to switch from the external pulse generator to the implantable pulse generator without losing capture of the heart. In this case, additional steps are involved to provide electrical connections between the pulse generators during the switch-over from the external pulse generator and the internal pulse generator. This procedure is usually accomplished by sequentially screwing a rather long, machine screw (not shown) into the threaded bores 40 of the pulse generator 10 to allow for electrical connection by means of alligator clips attached to the protruding portion of the machine screws. The use of the machine screw involves an additional item that must be accounted for during the operation and adds further complicating steps to the aforementioned prior art method.

Turning now to FIGS. 2 and 3, the improved connector assembly and the improved method of connecting the pulse generator to the lead are shown in cutaway pictorial and perspective views, respectively. The connector assembly depicted in FIG. 2 is partially sectioned to show elements of one of the two bipolar connector, and the lead 16' is shown in place in the sectioned connector assembly. The lead 16' is identical in all respects with the lead 16 shown in FIG. 1; the other elements of the connector assembly that correspond to elements of the prior art connector shown in FIG. 1 will be indicated by hyphenated numerals.

The pulse generator 10' as shown in FIG. 2 similarly comprises a power source and electrical circuitry that are encapsulated in a transparent epoxy encapsulant 12'. The bipolar boot 30' is manufactured from an implantable grade silicone rubber, but in this FIG. 2 has a slightly different outline than the boots 30 and 32 disclosed in FIG. 1. It will be understood that the bipolar boot 30' has a pair of longitudinal bores adapted to accept the proximal connector ends of the bipolar lead 16'. The single suture groove 31' is shown encircling the entire bipolar boot 30'. It will be understood that the bipolar boot 30' could take the same shape as the prior art bipolar boots 30 and 32. Associated with the bipolar boot 30' is a respective bipolar connector sleeve 34' that may also be constructed of a nonconductive plastic material.

The electrically conductive connector block 36' also has an elongated receptacle 38' adapted to receive the connector pin 26, and a threaded bore 40' in which a movable, socket set screw 42' is permanently situated. An extension 37' of the connector block 36' encasing the receptacle 42' is wedged into a corresponding cavity of the connector sleeve 34'. It will be understood

that a second connector block 36' and set screw 42' are similarly engaged by a similar connector sleeve 34'. Also, the pair of connector sleeves 34' may be unitary in structure.

As mentioned earlier, the threaded bore 40' and the set screw 42' are so dimensioned with respect to the diameter of the receptacle 38' that the length of the set screw 42' is greater than the diameter of the receptacle 38'. Consequently, the set screw 42' may be screwed down in the absence of a connector pin in the receptacle 38' without danger of its being released by the threaded bore 40' into the elongated receptacle 38'.

The top surface 52 of the connector block 36' is staked or deformed over the upper-most portion of the threaded bore 40' to reduce its actual diameter after the set screw 42' is screwed into the threaded bore 40' during manufacture, so that the set screw 42' may not be retracted out of the threaded bore 40'. The deformation should be sufficient in area to prevent removal of the set screw 42' but should not be so large as to impede the application of a hex wrench tool to the set screw 42'. The deformation or staking should withstand at least 24 inch-ounces of torque applied to the set screw 42' in an attempt to remove it.

Situated above the set screw 42' and surrounding a portion of the connector block 36' is a bipolar, self-sealing grommet 54 which may be manufactured from implantable grade silicone rubber and, in reference to FIG. 1, replaces the seat 44, the O-ring 46 and the filler screw 48. The grommet 54 may be of one piece sufficiently long to cover and mate with both connector blocks 36' and set screws 42' of the depicted bipolar connector assembly. The grommet 54 consists of an external portion 56 contacting and protruding from the external surface 14' of the encapsulent 12' and an internal portion 58. The internal portion 58 is slipped over the upward projection 39' of the connector block 36'. The grommet 54 provides a sterilizeable, electrically insulating, inert seal between the components comprising the socket set screw 42' and the connector block 36', and body fluids and tissue.

During manufacture of the connector assembly of FIG. 2, the boot 30', the connector sleeve or sleeves 34', the connector block 36' and a plastic pre-form (not shown) are assembled substantially as shown in a device (not shown) that also positions the pulse generator circuit (not shown), and the power source (not shown), and all electrical connections are then completed. Thereafter, the entire assembly is encapsulated in a mold by the transparent epoxy encapsulent 12' to achieve the general dimensions shown. A removable mold (not shown) extending from receptacles 42' creates cavities 59 in the encapsulent. The pre-form is extracted from the encapsulated pulse generator 10 and the grommet 54 is cemented in place with medical adhesive forming a thin layer (not shown) between the epoxy encapsulent 12 and the grommet 54. In this manner, the entire connector assembly is permanently and securely assembled. The various depicted ribs of the internal portion 58 of the grommet 54 help to maintain it in position during and after encapsulation.

The grommet 54 also comprises a pair of protrusions 60 and 62 which are molded into the grommet 54 at respective positions directly in line with the set screws 42'. Due to the self-sealing nature of the silicone rubber of which the grommet 54 is manufactured, the grommet 54 may be pierced down through the protrusions

60 and 62 by a tool 64 (FIG. 3) in order to reach the socket of the set screw 42'. After the tool 64 is removed or withdrawn from the grommet 54, the silicone rubber operates to close the puncture that the tool 64 makes through the silicone rubber. The protrusions 60 and 62 of the silicone rubber provide guides allowing the surgeon to press the working end of the tool 64 through the protrusion 60 or 62 and down to the mating end of the set screw 42'.

Turning now to FIG. 3, there is shown in partial perspective the step of puncturing the self-sealing silicone rubber grommet 54 with the tool 64. At this point in the procedure, both of the lead connector ends have been positioned in the connector assembly in the manner described hereinbefore. Accurate placement of the lead connector ends is visually verified by observation of the terminal pins 24' and 26' protruding through the connector blocks 36' and extending into pre-formed cavities 59 in the transparent epoxy encapsulent 12'.

The tool 64 comprises an electrically conductive driver portion 66, such as a hex wrench, adapted to mate with the socket set screw 42', an enlarged extension 68 of the conductive hex wrench 66, and a non-conductive handle 70 that is ribbed to provide a gripping surface so that the tool 64 may be readily rotated.

The tool 64 may also be designed to prevent the surgeon from stripping the threads of the set screw 42' or the threaded bore 40' in an attempt to tighten the set screw 42' with too much torque. This may be accomplished, in the preferred embodiment of this invention, by manufacturing the set screw 42' and the connector block 36' of a relatively hard, corrosion resistant metal, such as a titanium alloy and pure titanium, respectively, and manufacturing the hex end 66 of the tool 64 of a relatively harder metal. The composition and dimensions of the metal of the hex wrench 66 may be selected so that any attempt to apply excessive torque to the set screw 42' will not result in breaking off the hex end 66 while it is in the socket set screw 42'.

However, means are provided for preventing the surgeon from exerting a destructive torque on the threaded bore 40' or the set screw 42' which means comprise the handle 70 of the tool 64. The handle 70 is comprised of a plastic material engaging a knurled end of the portion 68 which has an outside diameter of about 1/4 inch. The plastic handle 70 is longitudinally ribbed to provide a frictional surface for the surgeon to grip. However, as shown in FIG. 3, the handle 70 of the tool 64 is relatively small with respect to the surgeon's fingers and, consequently, the inch-ounces of torque that can be applied by a strong hand will be less than that torque necessary to either strip the threads of the set screw 42' or the threaded bore 40' or to break the hex end 66 of the tool 64.

Normally, a pair of tools 64 will be supplied with each pulse generator 10' embodying the connector assembly of this invention. The pair of tools 64 may be used by the surgeon during the procedure of switching from the external pulse generator to the implantable pulse generator 10' and also may be used to take threshold measurements. To this end, both of the tools 64 may be inserted into the set screws 42' in the manner shown in FIG. 3 to provide electrically conductive paths through the insulating grommet 54 external to the pulse generator 10'. Alligator clips (not shown) may be attached to the enlarged, metal portion 68 of each tool 64 to provide the requisite electrical paths.

The enlarged portion 68 preferably is about 1/8 inch in diameter and 1/2 inch long.

Turning now to the simplified and improved method of attaching lead 16' to the pulse generator 10' equipped with the connector assembly of this invention, the operative steps comprise the following:

1. After the lead is brought through the skin at the position where the pocket for the pulse generator is to be made, the surgeon cleans the first lead connector end to be attached and coats it, and lead collars of that lead connector end with lubricant to facilitate entry of the lead connector ends into the silicone rubber boot of the pulse generator terminal assembly;

2. After ascertaining the polarity of the lead connector terminal pins with respect to the polarity of the pulse generator output terminals, the surgeon pushes the first lead connector end into the respective boot until it is visible in the cavity of the transparent epoxy encapsulant;

3. As shown in FIG. 3, the surgeon then grasps the pulse generator body with one hand and inserts the tool through the rubber grommet until the wrench engages the set screw and then (after measuring acceptable threshold levels) rotates the set screws clockwise with the tool until resistance is felt while making certain that the lead terminal pins do not retract as the set screw is tightened; and

4. Following connection of the second terminal pin in the manner set forth in steps 1 to 3, the silicone rubber boot is tightened about the two connector ends with a nonabsorbable ligature placed in the groove provided in the boot.

As can be seen from the description provided above, the operative procedure is considerably simplified and the chances of losing the various components in the incision are eliminated. Since the step of filling the prior art access hole to the connector assembly is eliminated, at least one operative step in the method of attachment of the lead to the pulse generator is eliminated, thus saving both time and materials. Also, the electrical transfer from an external pulse generator to the implantable pulse generator does not require additional components and can be accomplished more quickly.

Although the invention has been described with respect to a bipolar pulse generator and a bipolar lead, it will be apparent that the novel connector assembly described may be applied as well to the unipolar pulse generators and leads. Furthermore, although the invention has been described in particular with respect to an implantable cardiac pacer, it will be apparent to those skilled in the art that the invention has application in other tissue stimulators, both implantable and external.

The invention has been described in detail with particular reference to preferred embodiments thereof, but it will be understood that variations and modifications can be affected within the spirit and scope of the invention.

What I claim is:

1. In combination with a tissue stimulator having pulse generator means for producing tissue stimulation pulses, housing means of a surface material compatible with the human body as an environment enclosing said pulse generator means, lead means adapted to conduct the stimulation pulses to body tissue remote from said pulse generator means upon connection of said lead means to said pulse generator means and lead connector means coupled with said pulse generator means and

situated at a predetermined position within said housing means engageable by tool means in the operation of connecting said lead means to said pulse generator means; the improvement comprising:

sealing means of a homogeneous material compatible with the human body as an environment puncturable by said tool means to engage said connector means and resealable upon removal of said tool means for providing an inert, electrically insulating seal between said connector means and body fluids and tissues, said sealing means being conformed to extend from the surface of said housing means through a gap in said housing means to said predetermined position of said connector means and in contact therewith; and

means associated with said housing means for maintaining said sealing means in fixed contact with said housing means and said connector means.

2. The tissue stimulator of claim 1 wherein said lead connector means further comprises:

a. receptacle means for receiving said lead means; and

b. retaining means associated with said receptacle means and engageable by said tool means for retaining said lead means in said receptacle means.

3. The tissue stimulator of claim 2 wherein said retaining means further comprises means movable by said tool means into contact with said lead means for retaining said lead means in stationary relationship in said receptacle means; and said receptacle means further comprises means for preventing the release of said movable means by said tool means from said receptacle means.

4. The tissue stimulator of claim 1 wherein said sealing means comprises an implantable grade silicone rubber compound.

5. In combination with a tissue stimulator having pulse generator means for producing stimulation pulses, housing means of a surface material substantially inert to body fluids and tissue enclosing said pulse generator means, lead means adapted to conduct the stimulation pulses to remote body tissue upon connection of the lead means to the pulse generator means, said lead means having an electrically conductive connector pin at its proximal end to be electrically connected to said pulse generator means, and lead connector apparatus coupled with said pulse generator means and situated at a predetermined position within said housing means engageable by tool means in the operation of connecting said lead means to said pulse generator means, said lead connector means further comprising electrically conductive, receptacle means for receiving said connector pin, and retaining means associated with said receptacle means engageable by said tool means for retaining said connector pin in electrically conductive, stationary relationship in said receptacle means; the improvement comprising:

sealing means of a homogeneous material compatible with the human body as an environment puncturable by said tool means to engage said retaining means and resealable upon removal of said tool means for providing an inert, electrically insulating seal between said receptacle means and said retaining means and body fluids and tissues, said sealing means being conformed to extend from the surface of said housing means through a gap in said housing

means to said predetermined position of said connector means and in contact therewith; and means associated with said housing means for maintaining said sealing means in fixed contact with said housing means and said receptacle means.

6. The tissue stimulator of claim 5 wherein said lead means further comprises an electrically insulated conductor having a conductive stimulating electrode at its distal end and said electrically conductive connector pin at its proximal end.

7. The tissue stimulator of claim 6 wherein said pulse generator means further comprises a source of electrical energy and electrical circuit means connected to said source of electrical energy for producing periodic, electrical stimulation pulses, and said housing means comprises encapsulating means substantially inert to body fluids and tissue for enclosing and covering said source of electrical energy and said electrical circuit means; and wherein said lead connector means further comprises resilient boot means substantially inert to body fluids and tissue and associated with said receptacle means for guiding said connector pin to said receptacle means and engageable with the electrical insulated conductor at its distal end for inhibiting the entrance of body fluids and tissue into said receptacle means.

8. The tissue stimulator of claim 5 wherein said sealing means comprises a layer of an implantable grade silicone rubber compound.

9. The tissue stimulator of claim 5 wherein said retaining means further comprises movable means engageable by said tool means and responsive to rotation of said tool means in a first direction to move into contact with and retain said connector pin in said receptacle means.

10. The tissue stimulator of claim 9 wherein said retaining means further comprises means associated with said retaining means for preventing said movable means from being released from said retaining means upon engagement by said tool means and by turning said movable means in the second direction.

11. In combination with a tissue stimulator having pulse generator means for producing periodic, stimulation pulses, housing means of a surface material substantially inert to body fluids and tissue enclosing said pulse generator means, lead means adapted to conduct the stimulation pulses to remote body tissue upon connection of the lead means to said pulse generator means, said lead means comprising an electrically insulated conductor having a conductive stimulating electrode at its distal end and an electrically conductive, elongated connector pin at its proximal end adapted to be electrically connected to said pulse generator means and lead connector means coupled with said pulse generator means and situated at a predetermined position within said housing means engageable by driving tool

means in the operation of connecting said lead means to said pulse generator means, said lead connector means further comprising electrically conductive, connector block means having an elongated receptacle for receiving said connector pin and a threaded bore extending perpendicular to and from said receptacle through said connector block means and screw means threaded in said threaded bore and engageable by said tool means for turning said screw means in a first direction to make electrical contact with and tighten said connector pin in said receptacle; the improvement comprising:

sealing means of a homogeneous material compatible with the human body as an environment puncturable by said tool means to engage said connector block means and resealable upon removal of said tool means for providing an inert, electrically insulating seal between said connector block means and body fluids and tissue,

said sealing means being conformed to extend from the surface of said housing means through a gap in said housing means to said predetermined position of said connector means and in contact therewith; and

means associated with said housing means for maintaining said sealing means in fixed contact with said housing means and said connector means.

12. The tissue stimulator of claim 11 wherein said connector block means further comprises means in contact with said threaded bore for preventing the removal of said screw means from said threaded bore when said screw means is turned in a second direction upon engagement by said tool means.

13. The tissue stimulator of claim 11 wherein said pulse generator means further comprises a source of electrical energy and electrical circuit means connected to said source of electrical energy for producing the periodic, electrical stimulation pulses, and said housing means comprises encapsulating means substantially inert to body fluids and tissue for enclosing and covering said source of electrical energy and said electrical circuit means; and wherein said lead connector means further comprises resilient boot means substantially inert to body fluids and tissue and associated with said receptacle means for guiding said connector pin to said receptacle and engageable with the electrical insulated conductor at its distal end for preventing the entrance of body fluids and tissue into said receptacle.

14. The tissue stimulator of claim 11 wherein said sealing means comprises a layer of an implantable grade silicone rubber compound.

15. The tissue stimulator of claim 11 wherein said screw means and said connector block means are composed of a relatively hard, corrosion resistant metal.

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