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Bowers et al.

[11] 3,735,766

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[54] OPTIONAL UNIPOLAR-BIPOLAR BODY ORGAN STIMULATOR

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[52] **U.S. Cl.** .....**128/419 P**, 128/405

[51] **Int. Cl.** **A61m 1/36**

[58] **Field of Search** .....128/404, 405, 419 E, 128/419 P, 419 R, 421, 422, 2.06 G, 2.1 E, 417, 418, DIG. 4

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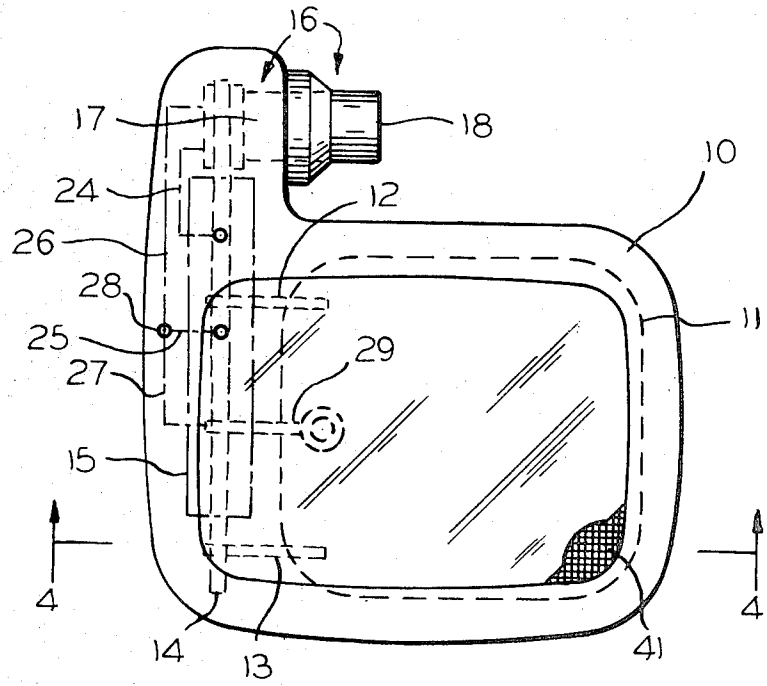
[57] **ABSTRACT**

A body organ stimulator such as an electronic cardiac stimulator has the customary connector for attaching intra-cardiac catheter leads or myocardial leads to operate the stimulator in a bipolar mode. Set in the resin encapsulation of the stimulator or in an adapter is an indifferent electrode plate which connects internally of the device with one of the connector terminals. The plate in the stimulator or the adapter is dipped in medical grade silicone sealant. An insulating label or strip is then superposed over the sealant coated plate and it is dipped and cured again. At the time of implantation, the physician has the option of stripping the label to expose the plate so the stimulator may be operated in the unipolar mode or leave the strip in place for operation in the bipolar mode.

14 Claims, 8 Drawing Figures



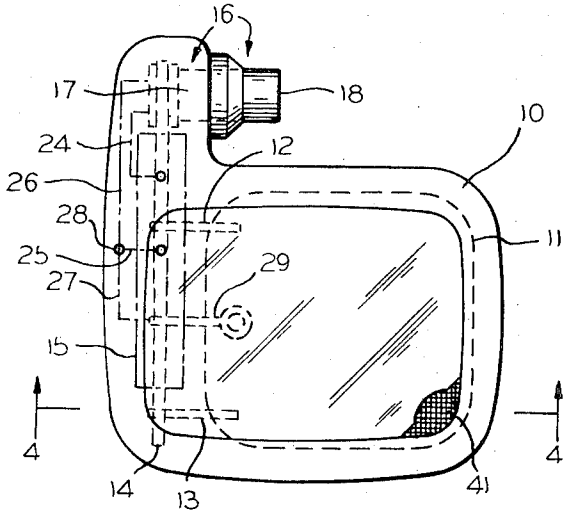


FIG.1

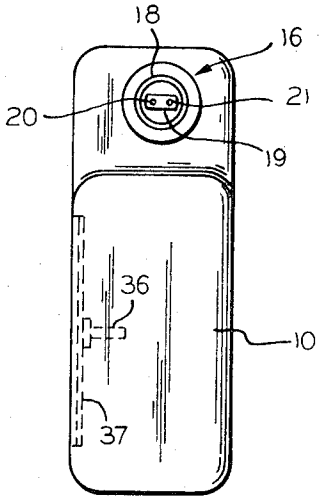


FIG.2

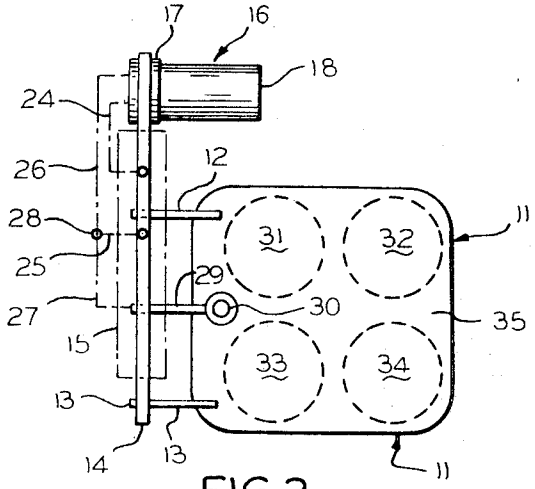


FIG.3

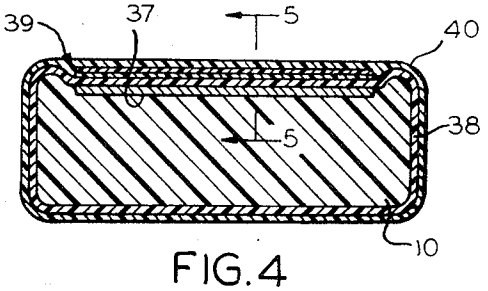


FIG.4

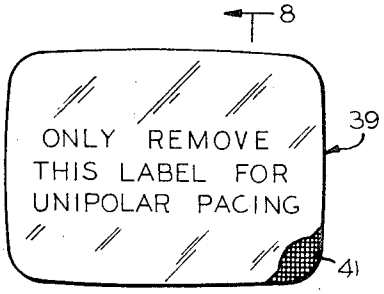


FIG.7

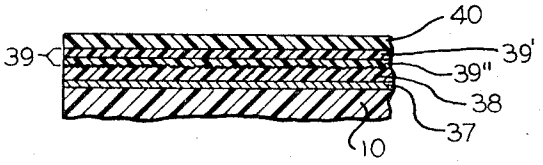


FIG.5

FIG.8

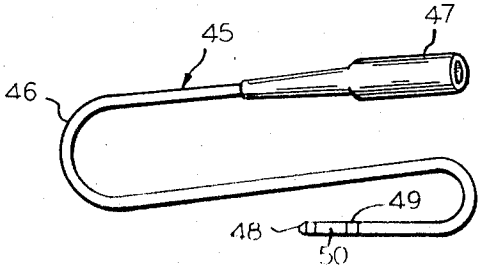


FIG.6

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OPTIONAL UNIPOLAR-BIPOLAR BODY ORGAN STIMULATOR

BACKGROUND OF THE INVENTION

Although the invention is pertinent to various types of body-implantable electric organ stimulators, it will be discussed primarily in connection with an electronic cardiac stimulator which shall hereafter be called a stimulator for brevity.

The pulse or stimulus signal generating circuitry in a stimulator is usually encapsulated in resin along with batteries. A suitable connector extends from the encapsulation. The connector usually has two terminals although certain prior stimulators which have a built-in indifferent electrode employ a one-terminal connector. At the time of implantation, suitable flexible conductive leads are attached to the organ which is to be stimulated and to the stimulator connector. Various types of leads are used. One type has two conductor elements and a connector on one end that couples with the stimulator connector. The other end of the conductors are bared and adapted for suturing directly into the myocardium in which case stimulating pulse current from the stimulator flows through active tissue between the bared ends. The leads just described are commonly called myocardial leads.

Intra-cardiac catheter leads are another type. This type usually has two flexible concentric conductors which are insulated from each other and terminate at one end in a stimulator connector and at the other end in a pair of metal terminals which are spaced apart and insulated from each other. Leads of this type extend from the stimulator through a blood vessel to the interior of the heart. Current pulses which flow between the exposed terminals stimulate the heart.

When leads of the types described above are used, the operating mode is characterized as bipolar because both poles or terminals of the stimulus signal generator are connected directly on or near the heart. Sometimes, however, unipolar stimulation is physiologically indicated or preferred by the physician. Unipolar stimulation implies connecting only one of the output terminals from the stimulus signal generator directly to the heart and using as the other terminal a large area metal plate, called an indifferent electrode, which is implanted at some distance from the heart, usually in subcutaneous tissue, providing a return conductive path from the heart to the stimulator by way of the indifferent electrode.

Some presently available stimulators have an indifferent electrode plate embedded in the insulating encapsulation so that the plate will contact body tissue when the stimulator is implanted. With this arrangement the stimulator will operate in the unipolar mode if it is used in conjunction with an appropriate single conductor lead. If bipolar stimulation is indicated for a particular patient, however, the unipolar type of stimulator just described cannot be used since the indifferent electrode would be exposed and active. Thus, it is evident that up to this time manufacturers have had to provide one type of stimulator having no exposed electrode plate and another with such a plate in order to fulfill the physician's requirements and needs in all cases.

Commercially available stimulators which do not have an integral indifferent electrode plate may be converted to the unipolar mode with a suitable adapter.

Available adapters customarily comprise two conductive leads each of which terminates at a corresponding end in a connector which mates with the connector on the stimulator. The distal tip of one lead is attached to or in contact with the interior of the heart. The other lead terminates in an exposed metal plate constituting an indifferent electrode which is usually implanted in body tissue in proximity with the stimulator. Thus, stimulating current flows from the distal tip of the lead and returns through body tissue to the indifferent electrode and the stimulator.

It should be evident from the foregoing discussion that manufacturers must make and inventory a variety of stimulators, adapters and other accessories to fulfill the diverse needs of the physician and patient. It is also necessary for hospitals to keep the various types of these devices on hand lest a patient remain untreated while a specialized device is awaiting delivery.

SUMMARY OF THE INVENTION

An object of the present invention is to overcome the above-noted disadvantages by providing a body organ stimulator which is adapted for optional use in either the bipolar or unipolar operating modes without employing any adapter or other special accessories.

Another object of the invention is to enable a manufacturer to reduce the number of types of body organ stimulators and adapters that are in production by making types of stimulators and adapters that are originally adapted for bipolar stimulation and which can be readily converted by the user for unipolar stimulation.

A more specific object of this invention is to equip stimulators and adapters with an indifferent electrode, for unipolar stimulation, which may be maintained in an inactive state if desired so that immediately before implantation, or even after, the stimulator may be converted from bipolar to unipolar or from unipolar to bipolar operation.

A more specific object of this invention is to incorporate in or at a remote location from the stimulator an indifferent electrode which is covered and insulated by an adhesive but removable strip or insulating membrane which may remain in place for bipolar stimulation but can be removed for unipolar stimulation.

In general terms, one concept involves embedding an indifferent electrode in the form of a metal plate in the surface of the resinous material in which the electronic components of the stimulator are encapsulated. An insulating adhesive membrane sealant coating is applied to the plate and to give added strength to the membrane an insulating strip is applied to the adhesive membrane sealant. Then another coating of sealant is applied to help retain the protective strip. To convert the stimulator to unipolar operation, the user merely peels off the strip or rubs off the membrane coating covering the plate, thereby exposing the indifferent electrode plate and rendering it active. Another concept is to have the indifferent electrode at a remote location in the body to apply an insulating membrane or strip to the electrode.

How the foregoing and other more specific objects of the invention are achieved will appear from time to time throughout the course of the ensuing more detailed description of a preferred embodiment of the invention taken in conjunction with the drawings.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a plan view of a body organ stimulator incorporating the invention;

FIG. 2 is a view of the right side of FIG. 1;

FIG. 3 is a plan view of the internal components of the stimulator shown in the preceding figures before the components are encapsulated, some of the components being represented schematically;

FIG. 4 is a vertical cross section taken on a line corresponding with 4—4 in FIG. 1;

FIG. 5 is a magnified view of a partial cross section of the stimulator taken on a line corresponding with 5—5 in FIG. 4;

FIG. 6 is a plan view of an intra-cardiac catheter electrode which exemplifies electrodes with which the new stimulator may be used;

FIG. 7 is an isolated plan view of the insulating element or removable strip which is used to maintain the indifferent electrode in an inactive state; and

FIG. 8 is a magnified cross section of the insulating element shown in the preceding figure.

DESCRIPTION OF A PREFERRED EMBODIMENT

The configuration shown in FIG. 1 is that of a cardiac stimulator which typifies stimulators in which the invention may be incorporated. The internal components of the stimulator are in a resinous encapsulation **10** which is conventional. The encapsulation **10** serves as electrical insulation and as a body fluid impervious barrier. The battery pack subassembly for furnishing electric power to the encapsulated electronic components of the stimulator is represented by the broken line marked **11.** The battery pack is also in an encapsulation. There will be a further discussion of the battery pack **11** later in reference to FIG. **3.**

Extending from the battery pack through the encapsulation are a pair of battery terminal extensions **12** and **13** which also serve as supporting post for a printed circuit board **14.** The electronic components of the stimulus signal generating means are not shown in detail but it will be understood that they are mounted on printed circuit board **14** and are encompassed in the space which is defined by the dash-dot rectangle **15.**

Secured to printed circuit board **14** is an electric connector assembly which is generally designated by the reference numeral **16.** One part **17** of connector assembly **16** is embedded in resinous encapsulating material **10** and another tubular part **18** extends therefrom. As can be seen in FIG. **2,** inside of exposed tubular extension **18** is an insulating block **19** in which there are two small connector pin sockets **20** and **21.** These connector pin sockets are optionally available for connecting either single or double conductor organ attachment leads to the stimulator as will be described shortly hereinafter in reference to FIG. **6.**

The electrical conductors for delivering electric stimulus signals from the printed circuit board mounted stimulus signal generator **15** to the output terminals comprising connector pin sockets **20** and **21** may be seen most clearly in FIG. **3** where these conductors are represented schematically by dashed lines. In this figure, the battery pack **11,** printed circuit board **14,** conducting supporting posts **12** and **13** and connector assembly **16** are shown in solid outline. The rectangle **15** in which the electronic components are encompassed is shown in dash-dot lines. A conductor **24,** shown in dashed lines, makes one of the connections between printed circuit board **14** and a connector pin socket **20** within connector assembly **16.** A conductor comprising sections **25** and **26** makes another connection from printed circuit board **14** to the other pin **21** in connector assembly **16.** Thus, one may see that stimulating signals may be delivered from signal generator **15** to each of the connected output terminal sockets **20** and **21.** When two conductor attachment leads are coupled between the connector **16** and the organ, the stimulator will function in the bipolar mode as it is called with both active conductor ends terminated in the organ which is to be stimulated.

Involved with unipolar pacing is another conductor **27** which junctions at **28** with conductor **26** and also connects with a conductive supporting post **29.** Post **29** connects with a contact element **30** which is represented by two concentric circles in FIG. **3.** Contact element **30** connects with an indifferent electrode constituting a metal plate **37,** see FIG. **2,** as will be discussed in detail a little later. The battery pack **11** shown in FIG. **3** comprises four batteries **31, 32, 33** and **34** whose electrical connections are omitted for the sake of clarity. The batteries are in a resin encapsulation **35** from which conductors **12, 13** and **29** extend. After battery pack **11** is attached to printed circuit board **14** and after electronic components **15** and the connector assembly **16** are in place, the unit shown in FIG. **3** is placed in a mold, not shown, and molded into encapsulating material **10** so that the final product has the configuration shown in FIGS. **1** and **2.**

An indifferent electrode comprising a thin stainless steel plate **37** is also embedded in the surface of encapsulation **10** shown in FIG. **2.** As will be described, indifferent electrode plate **37** is only active when the unipolar stimulating mode is desired. For the present, it is sufficient to observe that on the inside of plate **37** there is a contact pin assembly **36** which inserts into cylindrical contact element **30** and makes a sound electrical connection therewith. Other suitable means for making a connection between plate **37** and printed circuit board **14** and its associated signal generating circuitry **15** may also be employed as long as the plate is electrically connected with an output terminal of the stimulus signal generator and to one of the terminals or pin sockets in connector assembly **16.**

Refer now to FIG. **4** which shows in cross section the stainless steel indifferent electrode plate **37** embedded in a surface of encapsulating material **10.** In accordance with a preferred embodiment of the invention, when construction of the stimulator has been advanced to this pint, it is dipped in a silicone rubber compound which is characterized by curing or vulcanizing in air. The ordinary medical grade room temperature vulcanizing silicone compound which is now commonly used in connection with making implantable stimulators is a suitable material for dipping as just described. A coating of silicone material **38** about ten to twenty mils thick remains on the object. This coating does not feel tacky when touched but any thin lightweight object can be made to adhere to it, at least temporarily, by merely pressing the object against coating **38.** Note that silicone rubber coating layer **38** covers plate **37** without any discontinuities. This coating **38** is sufficient to insulate the plate **37** but does not have the strength to resist tearing when sharp objects come in contact such as medical instruments.

After the first coating of silicone rubber 38 is deposited as described above and while it is still viscous and uncured, an insulating element in the form of a laminated plastic label 39, which is used as a protective shield against tearing, is pressed against that part of coating 38 which overlays plate 37 and the assembly is dipped again in the self-curing silicone rubber compound. This forms an outer layer or coating 40 for holding the label in position and covering the entire stimulator except tubular extension 38 of connector 16 which is not coated by the first or second dips.

A plan view of insulating element or label 39, which is comprised of two thin plastic lamina, is shown in FIG. 7 and a cross section thereof is shown in FIGS. 4, 5, 7 and 8. Insulating element 39 should have substantially the same shape and size as indifferent electrode plate 37 in which case element 39 will be substantially congruent with plate 37 when the insulating element is properly placed on the first silicone coating 38. The margins of insulating element 39 may, however, extend beyond the margins of plate 37 if desired. It should be evident from inspection of FIG. 4 that the inner and outer silicone coatings 30 and 40 plus the intervening laminated plastic insulating element 39 will prevent conduction between plate 37 and body tissue in the event the unit is implanted in the body in this condition. When the coatings 38 and 40 and insulating element 39 are intact as shown in FIG. 4, electric stimulating energy can only be delivered from the stimulator through one or the other or both of the output terminals 20 and 21 within connector assembly 16. Of course, any one of the elements 38, 39 or 40 alone could insulate plate 37. Indifferent electrode plate 37 would remain inactive in any case.

As indicated by the legend on the insulating element or the label 39, in FIG. 7, the label is only intended to be removed when unipolar pacing is desired. To direct the user's attention to this capability, a corner 41 of the element is shaded as shown. To remove the label 39, the user may insert the tip of a scalpel at the edge of the shaded area to raise the element 39 insufficiently to allow gripping its corner with the fingers or other suitable instruments and tearing it off. As will be explained, the properties of the insulating element or label 39 are such that the layer of silicone rubber 38 which intervenes between the label and plate 37 peels off with the label as does that area of the outer coating 40 which is congruent with the label. The resin provides a good bonding surface for the silicone coating and makes a clean parting line between the plate and resin during removal. In other words, when the label 39 is removed, the two silicone coatings 38 and 40 will remain with the label 39 and the electrode plate 37 will be exposed and substantially clear of any silicone coating or insulating material. If any residual fragments of coating remain, they can be rubbed off or picked off easily with a knife blade, spatula, or the like. When indifferent electrode plate 37 is exposed in this manner, of course, the stimulator is adapted for operation in the unipolar mode when it comes in contact with body tissue.

FIG. 5 shows a magnified cross section taken through indifferent electrode plate 37 and the various insulating layers which are disposed upon it at completion of the manufacturing process. This general construction has already been described. However, it is important to note that the plastic laminate label 39 which is shown alone in cross section in FIG. 8 is comprised of two individual plastic film layers 39' and 39''. The bottom of layer 39'', it should be noted, is roughened to improve its adhesive properties with respect to silicone layer 38 on which it is adhered. The degree of roughening is not particularly important but it should be sufficient to remove any signs of glossiness from the surface which interfaces with the silicone coating 38 that is on metal plate 37. The metal plate 37 is smooth and free of surface marks which could cause adhering of the silicone rubber. Because the lower surface of lamina 39'' is roughened, its adhesion to silicone coating 38 is better than the adhesion between the silicone coating 38 and plate 37 in which case the coating 38 will remain with the laminated insulating element or label 39 rather than stick to the plate when the label is peeled off. Moreover, if the physician has reason for wanting to replace the label 39 for reinsulating indifferent electrode 37 he may do so by pressing the label back into position over the plate 37 and the silicone rubber coating 38 which adheres to the label will again effect adhesion and a seal between the label and plate 37.

The lamina 39' and 39'' comprising the label 39 have been made of polyester film each about three mils thick in a commercial embodiment. Dupont's Mylar is a suitable material although any non-toxic flexible inert material with good moisture and electrical insulating properties may be used. The top lamina 39' has been made of clear Mylar and the legend which appears in FIG. 7 has been printed directly on the backside of lamina 39' or on its interface 42 with lamina 39''. After the legend is printed on the bottom side of lamina 39', that side is coated with adhesive and the lower lamina 39'' is pressed onto it. By constructing the insulating label 39 in this manner, the legend is made easy to read and there is further assurance that if either the ink or the adhesive between the lamina is even slightly toxic there will be no danger of toxic material ever coming into contact with body tissue. Of course, the ink and adhesives used in the label 39 are chosen from materials which are non-toxic in the light of present knowledge and experimental testing.

It is not imperative to the function of the new stimulator that the label for insulating the indifferent electrode be laminated. It could just as well be a single layer of flexible or relatively inflexible impervious insulating material and it could be opaque if desired. The illustration of the invention will suggest to those skilled in the stimulator art that various means may be used for concealing or electrically isolating the indifferent electrode with an insulating element that is held in place with a rupturable adhesive membrane sealant. It will be evident to those skilled in the art that an indifferent electrode in an adapter may also be provided with removable insulation similarly to the manner just discussed in respect to an electrode in the stimulator.

A lead assembly that will serve as a basis for describing how the new stimulator may be used is shown in FIG. 6 and is indicated generally by the numeral 45. The leads here depicted comprise an elongated flexible conductor assembly 46 which may take many forms but in this case comprises two electrically isolated coaxial conductors, not shown, which are electrically insulated from each other and surrounded by insulation in a well-known manner. The proximal end of the conductor assembly terminates in a self-sealing connector 47 which may be plugged into the connector assembly 16 of the stimulator. The distal end of the conductor assembly

terminates in a metal tip **48** which is spaced from a metal ferrule **49.** The metal tip and ferrule are separated by an insulating section **50.** The distal end of the conductor assembly having the tip and ferrule may terminate in one of the chambers of the heart in connection with cardiac stimulation. Current delivered by the stimulator flows between the tip **48** and ferrule **49** and any tissue or blood that intervenes between them for the purpose of conducting current through the organ and stimulating it. The lead assembly of FIG. **6** may be joined with connector assembly **16** of the stimulator for operation in the bipolar stimulating mode if insulating element or label **39** is intact with indifferent electrode plate **37.** A suitable converter, not shown, may also be used to facilitate connecting a single conductor organ lead to a two-terminal connector such as **16.**

Lead assemblies very similar to that shown in FIG. **6** are also provided with a single conductor terminating in a single conductive tip such as tip **48.** Usually, single conductor lead assemblies are adapted for use as a cathode; in other words, they must be connected to the negative terminal of the stimulator since the leads of some manufacturers are made of materials that will be seriously eroded by electrolytic action if they are used as an anode. The single conductor type of lead must cooperate with an indifferent electrode which is made available either through being built into the stimulator or as part of an adapter as mentioned when discussing the background of the invention. In the present example, only the negative of the connector pins **20** or **21** in stimulator connector assembly **16** is electrically connected with the single conductor in the lead assembly shown in FIG. **6** and the indifferent electrode **37** is activated by removing the label **39** from over it as described above. Hence, after implantation, the indifferent electrode **37** will be in conductive contact with body tissue and in an active state for unipolar stimulation. As mentioned earlier, the ability to convert the stimulator from bipolar to unipolar operation enables the manufacturer to produce only one style of stimulator for making these operating modes available and the user is required to stock only the one style without sacrificing the ability to provide either or both modes of stimulation on short notice, such as during stimulator implantation.

Those versed in the art will appreciate that types of organ stimulating leads other than that in FIG. **6** may also be used with the new stimulator design. In addition, those skilled in the art will appreciate that in certain cases the bipolar electrodes and the indifferent electrode may be used at the same time and that in other cases, particularly in experimental or precautionary implants the stimulator may be implanted with the indifferent electrode concealed and in readiness for activation on a propitious occasion by gaining access for peeling off the insulating element or label by way of minor surgery under local anesthesia. The indifferent electrode may also have forms other than a plate. For instance, it could be one or more pins, a ring, a sleeve, or a metallic casing that houses the electronics and batteries. Rupturable adhesive sealants other than self-curing single component silicone systems can also be used as long as they approximate the properties of medical grade silicones such as body compatibility, fluid impermeability, good electrical insulation, pliability, adhesiveness without permanent bonding and rupturability within limits. The invention is applicable to any type of indifferent electrode whether it is associated directly with or located remotely from the stimulator.

Although a preferred embodiment of the invention has been described in considerable detail, it should be understood that such description is illustrative rather than exclusive, for the invention may be variously embodied and is to be limited in scope only by interpretation of the claims which follow.

We claim:

1. A body-implantable organ stimulator comprising:
a. stimulus signal generating means having at least one output terminal which is adapted to be connected to a body organ and having another output terminal,
b. indifferent electrode means and an insulating support therefor and including means for connecting said electrode means to said other output terminal for receiving a signal therefrom, and
c. insulating means adapted to adhere over said indifferent electrode means sealingly with said insulating support and to jointly cover the entire conductive area thereof, said insulating means being optionally removable to activate said indifferent electrode means and to expose the same to a conductive medium.

2. The invention set forth in claim **1** wherein:
a. said insulating support for said indifferent electrode means comprises a material encapsulating said generating means, said indifferent electrode means being set in said material,
b. said insulating means being a membrane means which covers the said indifferent electrode means.

3. The invention set forth in claim **2** wherein said insulating means comprises:
a. a first layer of rupturable membrane material on said indifferent electrode,
b. flexible strip means adhered as a protective means to said first membrane layer substantially in congruence with said indifferent electrode means, and
c. a second layer of rupturable membrane material on said strip means.

4. The invention set forth in claim **3** wherein:
a. said first and second layers are comprised of silicone rubber.

5. The invention set forth in claim **3** wherein:
a. said flexible strip means is comprised of polyester film which is roughened on at least the one side thereof which interfaces with said first membrane layer.

6. The invention set forth in claim **1** wherein:
a. said indifferent electrode means comprises a conductive stainless steel plate.

7. A body-implantable organ stimulator comprising:
a. stimulus signal generating means having at least two output terminals,
b. a connector means having at least two terminals which are supplied from the aforesaid output terminals, said connector means being adapted to connect with insulated leads that supply an organ,
c. insulating material encapsulating said generating means and a part of said connector means,
d. an indifferent electrode means set in the external surface of said encapsulating material and connected with at least one of said output terminals inside of said encapsulating material, and
e. insulating means adapted to separably adhere to said indifferent electrode means and to cover said

electrode means, said insulating element being optionally removable to activate said indifferent electrode means.

8. The invention set forth in claim **7** wherein:

a. said insulating means comprises a rupturable membrane.

9. The invention set forth in claim **7** wherein:

a. said insulating means comprises at least two flexible films laminated together, and

b. a silicone rubber membrane is on said indifferent electrode to which membrane said laminated insulating films adhere.

10. The invention set forth in claim **7** wherein said insulating means comprises:

a. a first thin layer of rupturable sealant deposited on said encapsulating material and said indifferent electrode means,

b. an insulating strip means adhered to said indifferent electrode means through the agency of said first layer of sealant, and

c. a second thin layer of rupturable sealant deposited over said first layer and said insulating strip means.

11. The invention set forth in claim **7** wherein:

a. said indifferent electrode means comprises a conductive stainless steel plate.

12. An implantable electric body organ stimulator that is characterized by being operable in either bipolar or unipolar modes, comprising:

a. a stimulus signal generator and an insulating encapsulation enclosing said generator,

b. connector means accessible from the exterior of said encapsulation and having at least two terminals which are connected with said generator to receive stimulus signals therefrom and which are adapted to connect with leads for stimulating an organ in the bipolar mode,

c. an indifferent electrode set in said encapsulation at least a part of said indifferent electrode being subject to exposure for contacting body tissue and said indifferent electrode being connected with at least one of said terminals, and

d. an insulating element adhesively engaged with said indifferent electrode to insulate and inactivate said electrode when operation in the bipolar mode is desired, said element being removable when operation in the unipolar mode is desired.

13. An implantable body organ stimulator comprising:

a. a stimulus pulse generator having first and second output terminals and first and second connector means connected respectively with said terminals,

b. an insulating enclosure for said pulse generator, said connector means being exposed through said enclosure to enable connecting organ connectable lead means thereto,

c. lead means including a third connector means for coupling with said output terminal connector means, said lead means including at least one conductor extending from said third connector means and connecting with said first connector means when coupled and an organ engaging conductive electrode element attached to said conductor, said conductor having insulation thereon,

d. another indifferent electrode element connected with said second connector means,

e. insulation means covering the entire conductive area of said indifferent electrode element, a portion of said insulation means being optionally separable from the remainder thereof to expose said indifferent electrode element for enabling contact with body tissue.

14. The invention set forth in claim **13** wherein:

a. said separable portion of said insulation means comprises rupturable membrane means.

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