United States Patent

Cole

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[45] Aug. 15, 1972

[54] **IMPLANTABLE TISSUE STIMULATOR**

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[73] Assignee: **Adcole Corporation,** Waltham, Mass.

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

[51] **Int. Cl.**.....**A61n 1/36**

[58] **Field of Search**.....128/404, 418, 419 P, 419 R, 128/421, 422

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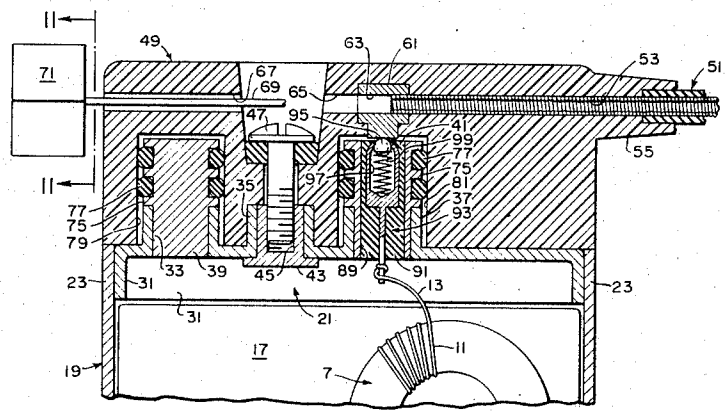
[57] **ABSTRACT**

An implantable tissue stimulator comprising a metal case enclosing a battery and a pulse generating circuit powered thereby, in which the circuit includes a terminal common to the case and a stimulating terminal extending through and insulated from the case, a flexible probe assembly comprising an exposed electrode adapted to be placed in proximity to and in electrical contact with tissue to be stimulated, and an elongated flexible insulated cable connecting the electrode to a connector part adapted to be secured to the stimulating terminal during implantation.

5 Claims, 11 Drawing Figures



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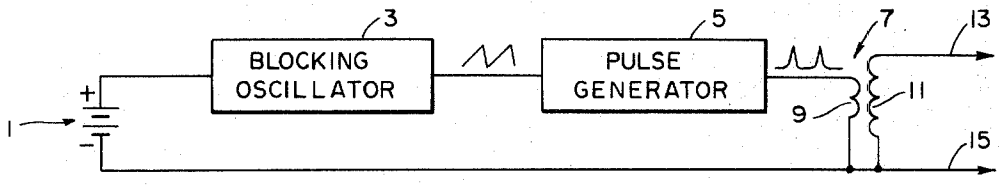

FIG. 1

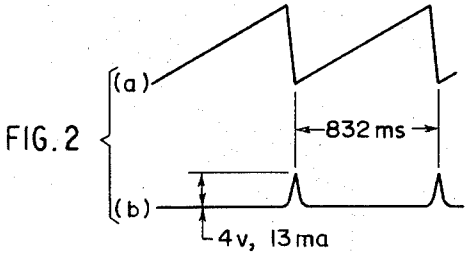

FIG. 2

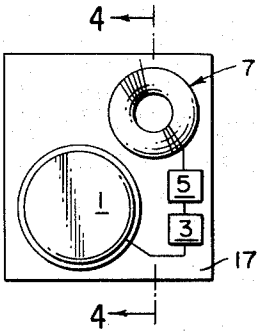

FIG. 3

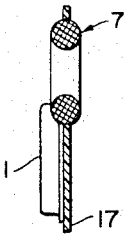

FIG. 4

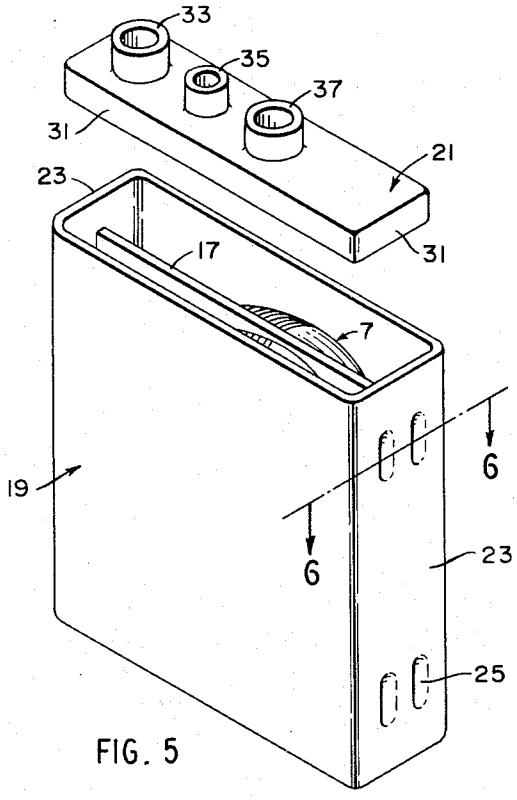

FIG. 5

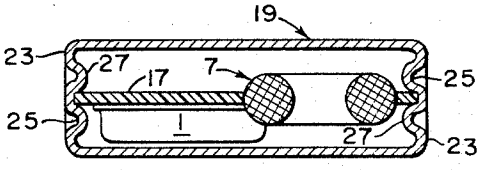

FIG. 6

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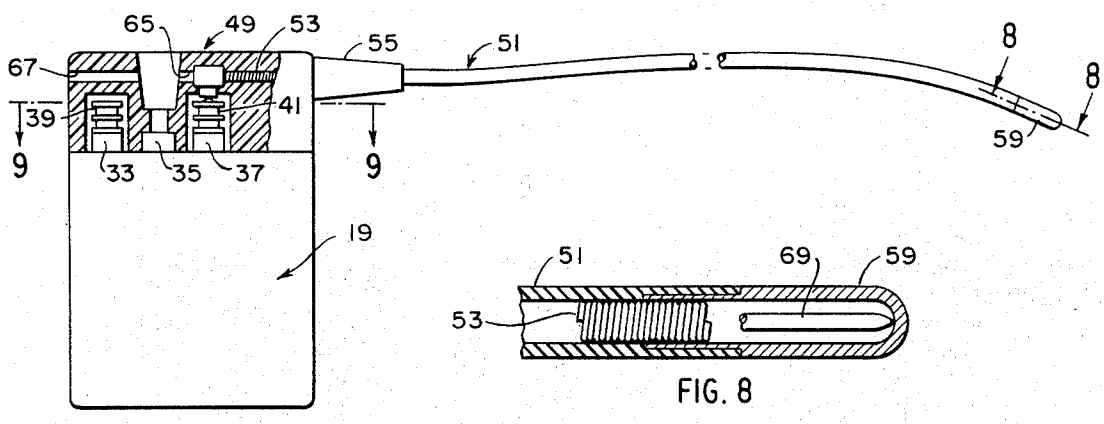


FIG. 7

FIG. 8

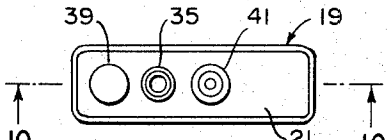
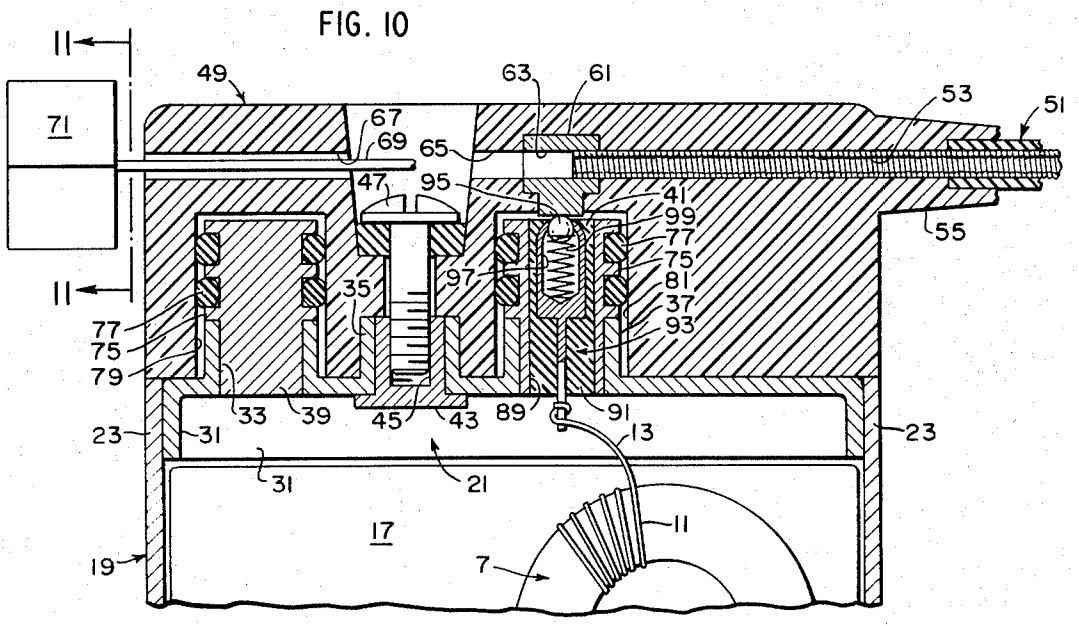


FIG. 9

FIG. 10



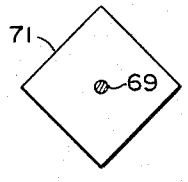


FIG. 11

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IMPLANTABLE TISSUE STIMULATOR

My invention relates to electrical tissue stimulators, and particularly to a novel implantable stimulator.

Great strides have been made in the development of cardiac prosthetic devices for supplanting, supplementing or controlling the action of the heart during periods of malfunction, disease or radical functional disruption, as during surgery or the like. In particular, a demand has arisen for heart pacers that will deliver electrical stimulating pulses in place of natural pulses that fail to occur under various pathological conditions. For many purposes, it is essential that this supplementary stimulating function be performed over relatively long periods of time inconsistent with the use of external circuits and power supplies transcutaneously connected to the stimulated tissue. Thus, a fully implantable, self-contained pacer would be highly desirable.

One of the principal obstacles to the construction of a practical implantable pacer is the physical size of the container for the pulse generating circuit and its power source. There are numerous requirements on such a container that are difficult to meet without excessive size and weight. First, the container must present an exterior that is fluid tight, electrically insulates the contained circuit, and is chemically inert and thermally inactive. Those requirements are generally met by encapsulating the electrical contents of the container in a thermoplastic insulating material, through which insulated electrical connector parts must be passed. In general, the power supply and the electronic pulse generating circuit must be implanted in the body at a distance from the preferred site for stimulation. Thus, the stimulating electrode or electrodes must be connected to the power package by a long, flexible, insulated cable. The necessities of surgery dictate that the assembly be separated before implantation, i. e., by providing a separable electrical connector between the power package and the flexible probe carrying the stimulating electrodes, so that those elements can be separately installed and then connected together after implantation. Since the connectors must maintain a fluid seal between the internal electrical terminals of the pulse generating circuit and the body, a relatively rugged, and therefore massive, connector construction has been employed. The result has been that practical pacers have tended to be limited in design by the maximum size and weight that could be tolerated, rather than by the performance criteria that would govern if space and weight were no object. The objects of my invention are to decrease the size and weight of implantable cardiac pacers while improving their efficiency and service life.

Briefly, the above and other objects of my invention are attained by a novel pacer construction in which the container for the power supply and pulse generating circuits comprises a sealed metal canister that also serves as one electrode of the stimulating circuit. This container is not encapsulated in an insulating plastic material, nor are the electronic components which it surrounds preferably encapsulated. The container preferably comprises a relatively thin, flat rectangular metal package formed with retaining means for holding a circuit board of insulating material inside the container in a fixed position. Mounted on this board are the power supply and pulse generator circuit. The largest single electrical element is the power supply, preferably a single disk shaped mercury-zinc storage battery. Next in size is a pulse transformer forming the output element of the pulse generator. The battery and transformer together determine the basic size of the housing, as other necessary circuit elements may be considerably smaller and thus readily mounted in spaces available adjacent the larger components. Two external mounting posts are preferably connected to the housing. These posts are adapted to cooperate with corresponding recesses in a thermoplastic connector plug. One mounting post contains a central insulated conductor adapted to be connected in circuit with the pulse transformer, and to engage a contact in the connector plug that is in turn connected, through a flexible insulated conductor, to a stimulating electrode. Preferably, a fastener is provided to fix the connector plug to the metallic housing after assembly, to prevent the parts from working loose. Desirably, a passage is provided in the connector and the adjoining flexible probe assembly to admit a stiffening wire to facilitate insertion of the probe into a selected body sinus, such as an artery or the like.

The manner in which the apparatus of my invention is constructed, and its mode of operation, will best be understood in the light of the following detailed description, together with the accompanying drawings, of a preferred embodiment thereof.

In the drawings,

FIG. 1 is a wiring diagram of a conventional cardiac pacer of the type with which my invention is concerned;

FIG. 2 is a composite waveform diagram illustrating the operation of the circuit of FIG. 1;

FIG. 3 is a schematic fragmentary elevational view of a power supply and pulse generating circuit forming a part of the apparatus of my invention;

FIG. 4 is a schematic cross-sectional view of the apparatus of FIG. 3, taken substantially along the lines 4—4 in FIG. 3;

FIG. 5 is a schematic exploded perspective sketch of a pacer housing assembly forming a part of the apparatus of my invention;

FIG. 6 is a schematic cross-sectional view of the apparatus of FIG. 5, taken substantially along the lines 6—6 of FIG. 5 and showing the apparatus of FIGS. 3 and 4 in place;

FIG. 7 is a schematic elevational view, with parts shown in cross section and parts broken away, of a cardiac pacer in accordance with my invention;

FIG. 8 is a detailed cross-sectional view, on an enlarged scale, of a portion of the apparatus of FIG. 7, taken essentially along the lines 8—8 in FIG. 7;

FIG. 9 is a plan view of the apparatus of FIG. 7 with the connector removed, taken essentially along the lines 9—9 in FIG. 7;

FIG. 10 is an enlarged cross-sectional view of a portion of the apparatus of FIG. 7, showing parts in more detail and including a portion of a stiffener assembly; and

FIG. 11 is an end view, taken essentially along the lines 11—11 in FIG. 10, showing a detail of the stiffener assembly.

Referring to FIG. 1, I have shown the essential elements of a fixed-rate cardiac pacer. A primary source

of energy 1 conventionally comprises one or more storage batteries. I prefer to employ a single, disk-like mercury-zinc storage battery for the purpose. The battery 1 energizes a pulse forming network comprising a blocking oscillator 3, a pulse generator 5, and a pulse transformer generally designated 7 and having a primary winding 9 and a secondary winding 11. The secondary winding 11 is adapted to be connected in circuit with the heart by means of electrodes 13 and 15. As will appear, I prefer to make one of the electrodes such as 13 serve to conduct current directly to the site to be stimulated, and to make the second electrode 15 common to one terminal of the battery 1, preferably the negative terminal.

FIG. 2 illustrates the basic mode of operation of the circuit of FIG. 1. The blocking oscillator 3 produces a ramp signal, FIG. 2(*a*), having a period equal to that of the heart beat to be simulated, i.e., typically 832 milliseconds for a normal 72 per minute heartbeat. The trailing edge of the ramp signal causes the pulse generator to produce a stimulating pulse, FIG. 2*b*, of preferably about 4 volts at 13 milliamperes for about ½ millisecond. Average output power dissipation is thus about 31 microwatts.

FIGS. 3 and 4 illustrate the mounting of the principal parts of the circuit of FIG. 1 in accordance with my invention. The largest element is the battery 1, both as to size and weight. The next element in point of size is the pulse transformer 7. These elements are preferably mounted in adjacent, spaced relation on a board 17, of any suitable insulating material such as phenolic resin, glass fiber filled expoxy resin, or the like. Any suitable mounting or adhesive means, such as an epoxy resin or the like, may be employed to secure the parts together. Other electrical components, such as capacitors, resistors, diodes, transistors and the like, being of smaller size, may be disposed about the board 17 in any convenient manner and interconnected by printed circuits mounted on the board 17, by separate insulated conductors, or by other conventional techniques.

FIG. 5 illustrates the manner in which the board 17 and its associated electrical parts is mounted and contained. A two-part housing is formed by a generally rectangular container 19, of stainless steel or the like, having one open end, and an end cap generally designated 21, also of stainless steel or the like. The end cap is adapted to engage the container 19 fairly snugly, and to be sealed in place by welding, as will appear.

The container 19 is arranged to receive the board 17 and its associated electronic parts. As shown in FIGS. 5 and 6, end walls 23 of the container 19 are formed with depressions such as 25, creating ribs 27 to engage the edges of the board 17. A small amount of epoxy resin or other desired adhesive is preferably used to further secure the board 17 within the container 19, and to inhibit vibration.

As best shown in FIGS. 5 and 10, the end cap 21 is formed with downwardly depending side flanges 31 that are adapted to engage the inner sides of the container 19. After assembly and electrical connection of the other parts, in a manner to appear, the flanges 31 of the end plate 21 are welded to the sides of the container 19, with the parts in the position shown in FIG. 10, to form a sealed seam.

Referring to FIGS. 5, 7 and 10, the end cap 21 is formed with three upstanding annular flanges 33, 35 and 37. To the flange 33 is welded an upstanding post 39, of stainless steel or the like. An externally similar conductor post 41 is welded into the flange 37. To the flange 35 is welded a connector 43 that is threaded as indicated at 45 in FIG. 10 to receive a cooperatively threaded bolt 47.

Referring to FIGS. 7 and 10, a separable connector plug 49, of flexible, insulating, physiologically inert material, such as silicone rubber or the like,is provided. The plug 49 serves to establish a physical and insulated electrical connection between the housing 19, its electrical contents, and a flexible elongated probe 51.

The probe 51 essentially comprises a long, flexible electrical conductor 53, of stainless steel or the like. The conductor 53 is preferably wound in the form of a helix, as shown in FIG. 8. While the details of the probe form no part of my invention, in practice it is preferred that the helix 53 be formed of at least two parallel congruent concentric contiguous helices made from two parallel wires, in the manner shown and described in detail in copending U. S. Pat. application Ser. No. 41,980, filed on June 6, 1970 by Jean Bellerose for Flexible Probe Construction and assigned to the assignee of this application.

The probe 51 further comprises an outer insulating coating 55, of silicone rubber or the like, which may be formed integral with the plug 49. At or near the end of the probe 51 remote from the plug 49, there is formed an exposed electrode 59 of stainless steel, platinum or the like. The electrode 59 is bonded to the silicone rubber coating 55 and electrically connected, as by soldering or brazing or the like, to the lead 53.

The flexible lead 53 is soldered or otherwise secured at its other end to a metal contact element 61 located in a suitable recess in the plug 49. For example, the element 61 may be molded into the plug during the manufacture of the latter. As shown, a bore 63 in the element 61 mates with corresponding bores 65 and 67 formed in the plug 49 to form a passage admitting a stiffener 69, such as a stainless steel wire or the like.

As indicated in FIGS. 8 and 10, the stiffener 69 extends through the passage just described and thence through the inside of the helical conductor 53 up into engagement with the electrode 59. A suitable knob 71, FIGS. 10 and 11, is secured to the stiffener 69 to facilitate manipulation of the latter by an operator. In practice, the stiffener is inserted into the plug and up through the flexible probe 51 to stiffen the latter sufficiently to permit it to be inserted into an artery or other body sinus to carry the electrode 59 to the desired operating site. The stiffener is then withdrawn to allow the probe to conform freely to the convolutions of the sinus. Alternatively, it may be desired to omit the stiffener and its function, and to draw the probe assembly into position by means of a forceps.

As best shown in FIGS. 10, the posts 39 and 41 are preferably formed with flanges such as 75, between which sealing washers 77 of flexible insulating material are inserted. These washers 77 serve to cooperate with bores 79 and 81 formed in the plug 49 to seal the posts 39 and 41 and form a firm mechanical connection therewith.

A central passage 89 is formed in the post 41. Supported within the passage 89 by means such as an intermediate insulating glass seal 91 is a contact assembly generally designated 93 and comprising a metal ball 95 within a cage 97 and urged by a spring 99 into engagement with the contact element 61. The conductor from which the cage 97 is formed extends down through the glass seal 91 and is soldered or otherwise secured to the output lead 13 of the pulse transformer 7.

In practice, the plug 49, probe 51 and electrode 59 are installed in the body, and the case 19 and its contents are separately installed. The plug 49 is then engaged with the posts 39 and 41. The plug is then secured to the metal housing by means of the screw 47. Preferably, the screw 47 is made of stainless steel covered with polytetrafluorethylene or the like. The relatively large surface of the housing 19 makes a massive return electrode, so that the principal resistance offered by the body to pulses produced by the pacer circuit occurs at the interface between the electrode 59 and the adjacent tissue.

The apparatus of my invention is suitable for use in any application requiring an implantable tissue stimulator. For example, in addition to its use as a cardiac pacer, it is also useful for stimulating other tissue, such as the carotid sinus nerve.

While I have described my invention with respect to the details of a preferred embodiment thereof, many changes and variations will occur to those skilled in the art upon reading my description. Such changes and variations can obviously be made without departing from the scope of my invention.

Having thus described my invention, what I claim is:

1. In a cardiac pacer, the combination of:
a body stimulating electrode;
an electrical contact element;
an elongated flexible insulated conductor having one end connected to said electrode and a second end connected to said contact element, said contact element being mounted in a surrounding plug member of flexible insulating material;
a pair of spaced parallel cylindrical apertures formed in said plug member, one of said apertures communicating with said contact element;
a metal housing having a first terminal inside said housing and a second terminal outside said housing;
a pair of metal posts mounted on and protruding from said housing, said posts extending into and closing said apertures;
an insulated lead through one of said posts from said first terminal to said second terminal, said second terminal engaging said contact element; and
a pulse generating circuit located in said housing and having an output circuit connected between said housing and said first terminal.

2. The apparatus of claim 1, further comprising
means forming a threaded recess in said housing; and
screw means cooperating with said recess and securing said plug member to said housing.

3. A cardiac pacer, comprising:
a connector plug comprising a body member of flexible insulating material;
a pair of spaced apertures formed in said body and extending from one side thereof along parallel axes from said side to terminations within said body member;
an electrical contact element mounted in said body and communicating with one of said apertures;
an electrode;
an elongated flexible conductor having one end electrically connected to said contact element and a second end connected to said electrode;
insulating means mounted on said flexible conductor;
a metal housing having a first terminal inside said housing and a second terminal outside said housing;
a pair of metal posts mounted on and protruding from said housing extending into and closing said apertures;
an insulated lead extending through one of said posts from said first terminal to said second terminal, said second terminal engaging said contact element; and
a pulse generating circuit located in said housing and having an output circuit connected between said housing and said first terminal.

4. The apparatus of claim 3, in which said flexible conductor comprises
a tubiform metal helix forming a flexible passageway closed at the electrode end by said electrode, and further comprising
means forming a mating passageway through said body member, whereby a stiffener can be passed into said flexible conductor to facilitate insertion of the electrode in a body sinus.

5. A cardiac pacer, comprising:
a conductive metal housing having a generally plane side;
a pulse generating circuit mounted in said housing and having a first output terminal connected to said housing and a second output terminal extending through and insulated from said housing;
a pair of spaced mounting posts formed on said side and projecting from said housing, said second output terminal extending through one of said posts;
a flexible probe assembly comprising an exposed electrode adapted to be placed in proximity to and in electrical contact with cardiac tissue to be stimulated;
a connector plug comprising a body member of flexible insulating material having at least one generally plane side;
a pair of spaced, cylindrical apertures formed in said body for receiving said posts and extending along parallel axes from said plane side to terminations within said body member;
an electrical contact element mounted in said body, communicating with one of said apertures, and connected to said second output terminal; and
an elongated flexible insulated cable connecting said electrode to said electrical contact element.

* * * * *