United States Patent

Mansfield

[15] 3,683,933

[45] Aug. 15, 1972

[54] **IMPLANTABLE TISSUE STIMULATOR WITH A POROUS ANCHORING ENCLOSURE**

[72] Inventor: **Peter B. Mansfield,** 159 Washington Ave., Needham, Mass. 02192

[22] Filed: **June 22, 1970**

[21] Appl. No.: **48,379**

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

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

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

[56] **References Cited**

UNITED STATES PATENTS

3,474,791	10/1969	Bentov	128/419 P
3,253,595	5/1969	Murphy, Jr. et al.	128/419 P
3,486,506	12/1969	Avphan	128/419 P
3,244,174	4/1966	Wesly et al.	128/418
3,572,345	3/1971	Auphan	128/419 P

OTHER PUBLICATIONS

Cammilli et al. " Surgical Forum," 1966, pp. 165–168

Morris et al. " Annals of the New York Academy of Sciences," Vol. 167, Art. 2, Oct. 30, 1969, pp. 987–994

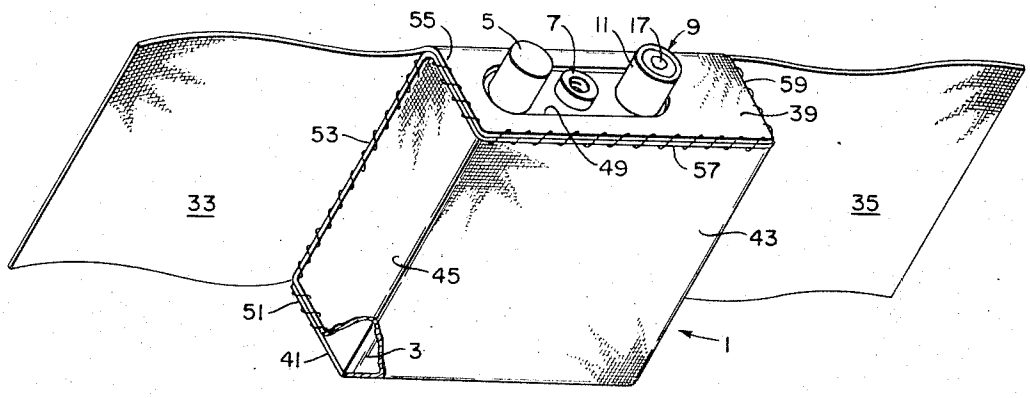
Primary Examiner—William E. Kamm

Attorney—Rich & Ericson

[57] **ABSTRACT**

An implantable cardiac pacer housing comprising a fabric panel having suture flaps extending from a central compartment receiving the power supply and circuit container of a plug connected pacer, a port being provided in said compartment to pass connectors on the container for mating with the plug of a flexible probe and a flap enabling removal and replacement of the container.

4 Claims, 5 Drawing Figures



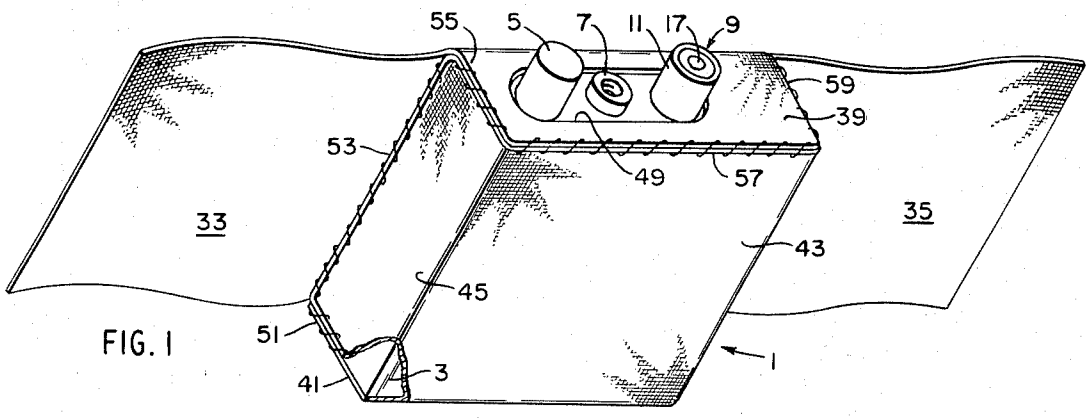


FIG. 1

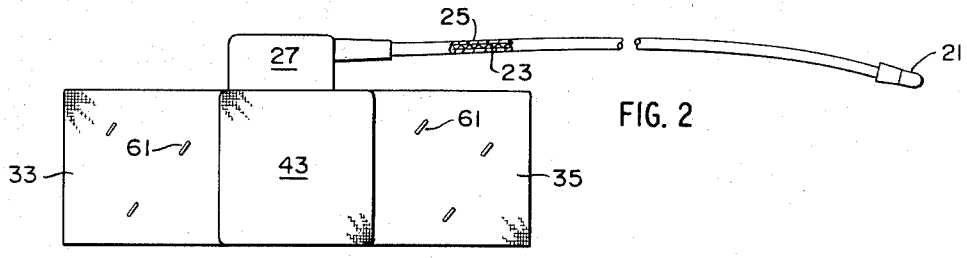


FIG. 2

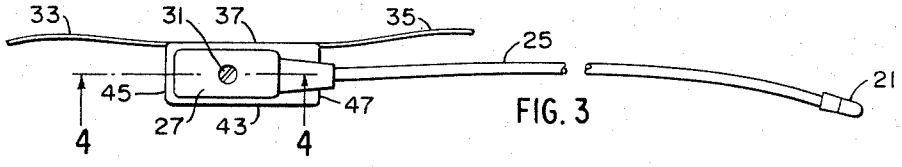


FIG. 3

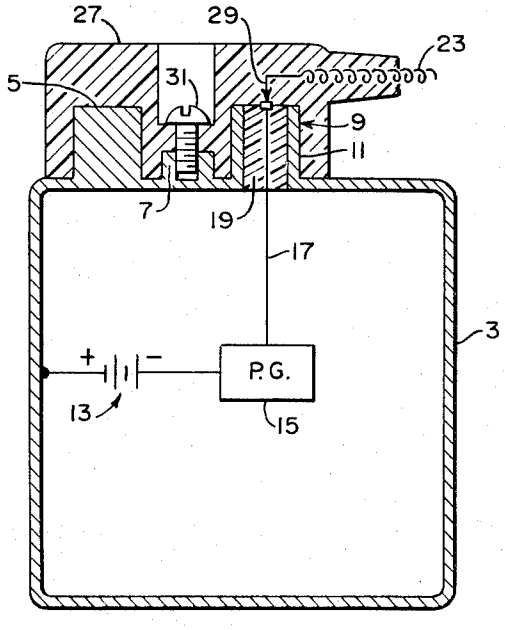


FIG. 4

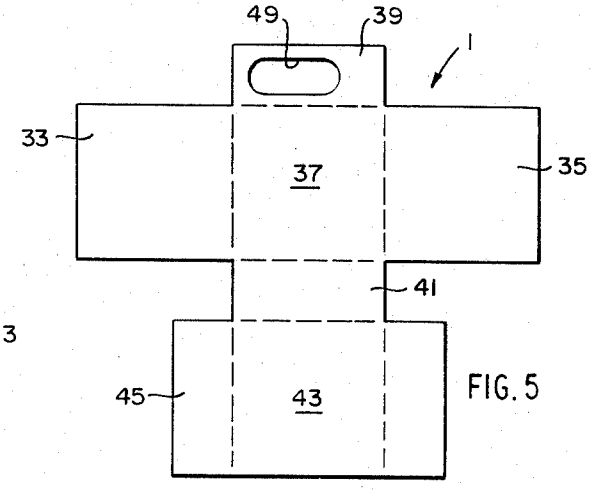


FIG. 5

INVENTOR
PETER B. MANSFIELD
BY Rich & Ericson
ATTORNEYS

IMPLANTABLE TISSUE STIMULATOR WITH A POROUS ANCHORING ENCLOSURE

My invention relates to cardiac pacers, and particularly to a novel implantable housing for the same.

Considerable progress has been made in the development of cardiac pacers for use in supplying electrical stimulating pulses to regulate the mammalian cardiac function in the absence of naturally occurring pulses. For optimum prosthetic efficiency, it is desirable that such devices be entirely implanted in the body of the host. It is usually desired to apply the stimulating pulses directly to the heart, and for example, to the myocardium. On the other hand, the size of the basic elements used for producing the stimulating pulses, namely, the power supply and the pulse generating circuit energized thereby, require a natural or incised body cavity larger than is available directly adjacent the heart. Thus, it is the practice to implant the power package, containing the power supply and pulse generating circuit for the pacer, in the nearest convenient location, and to connect it to a stimulating electrode or electrodes at the heart by means of a flexible insulated cable. The power package is allowed to rest in the selected body cavity. Since the power package is of significant size and weight, trauma may result from movements of the host, or simply from friction incidental to slight shiftings about incident to normal respiration and cardiac function. The object of my invention is to facilitate the anchoring of the power package of a cardiac pacer without interfering with its electrical function.

Briefly, the above and other objects of my invention are attained by a novel pacer support comprising a fabric body formed to provide suture panels for attachment to tissue at the wall of the cavity in which the pacer is to be implanted. The fabric body is further formed with a receptacle for receiving and holding the pacer power package while permitting the exterior of the package to serve as a return electrode for the pulse generating circuit, and admitting electrical and mechanical connections to a flexible probe for connecting a remote stimulating electrode to the power package. In practice, the power package, in its support, is implanted in the selected cavity, and the electrode probe assembly is electrically and mechanically connected to the power package. The suture panels of the support are then sewn to the tissue wall of the cavity, and the surgical entry is closed. Thereafter, scar tissue growth occurring in and about the fabric support anchors the package to the wall of the cavity, supplanting the sutures as they are absorbed by the body. This tissue growth process does not interfere with the electrical return path provided by the metal housing of the pacer power package.

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 schematic orthogonal sketch of a pacer power package provided with a support in accordance with my invention;

FIG. 2 is a schematic elevational sketch of a complete pacer, together with the support of my invention, with parts shown in cross-section and parts broken away;

FIG. 3 is a schematic plan view of the apparatus of FIG. 2, with parts broken away;

FIG. 4 is a schematic cross-sectional elevational sketch of a portion of the apparatus of FIGS. 2 and 3, taken substantially along the lines 4—4 in FIG. 3, with parts omitted and parts broken away; and

FIG. 5 is a schematic plan view of a fabric panel adapted to form a support in accordance with my invention.

Referring to FIG. 1, I have shown the power package of a pacer enclosed in a fabric support and container generally designated 1. The power package may be of any conventional construction, in accordance with my invention in its broader aspects, but preferably comprises a relatively thin, flat generally rectangular metal case 3, of stainless steel or the like, forming a sealed conductive enclosure about a pulse generating circuit, to be described briefly below. Protruding from and electrically continuous with the case 3 are a support post 5, a flange 7 tapped and threaded to receive a connecting screw, and an insulated connector post 9. The post 5, flange 7 and the exterior portion 11 of the connector post 9 may be of stainless steel or the like, welded to or otherwise formed integral with the case 3.

As best shown in FIG. 4, the metal case 3 encloses a battery 13 connected between the case and a conventional pulse generating circuit 15. The pulse output circuit extends between the case 3 and an active output lead 17. The lead 17 extends through the post 11, and is spaced, sealed to and insulated from the post 11 by means of an intermediate glass-to-metal seal 19.

With reference to FIGS. 2, 3 and 4, the active output lead 17 is connected to an exposed body contacting stimulating electrode 21, of stainless steel or the like, over a flexible conductor 23. The conductor 23 preferably comprises a helical coil of wire, and most preferably a construction comprising two parallel wires wound into parallel congruent concentric contiguous helices in the manner shown and described in copending U.S. Pat., application Ser. No. 41,980 filed by Jean E. Bellerose on June 1, 1970 for Flexible Electrical Probe and assigned to the assignee of this application.

The conductor 23 is covered and insulated by a layer 25 of silicone rubber or the like, and extends from the electrode 21 to a termination within the body of an insulating plug 27, also of silicone rubber or the like. The plug 27 may be bonded to or otherwise formed integral with the insulating layer 25.

As schematically indicated in FIG. 4, the lead 23 is electrically and mechanically secured within the plug 27 to a contact 29 adapted to engage the lead 17 when the plug is engaged with the housing 3. As shown, the plug 27 is formed with recesses cooperatively receiving the posts 5 and 11 to seal the latter and form a firm mechanical connection. The plug is secured to the housing by means of a screw 31 engaging the threaded flange 7 and received in suitable recesses formed in the plug 27 as shown in FIG. 4.

The pacer support 1 may be made from a fabric panel of the general configuration shown in FIG. 5. Preferably, the panel is made from relatively open machine knitted mesh, such as MERSILENE polyester fiber mesh made and sold by Ethicon, Inc. of Somer-

ville, New Jersey, and manufactured from DACRON polyester fiber. Comparing FIGS. 1, 2, 3 and 5, the pacer support comprises a pair of suture panels 33 and 35 at the sides of a box-like container formed by a back panel 37, a top panel 39, a bottom panel 41, a front panel 43, and two side panels 45 and 47. The top panel 39 is provided with one or more apertures such as 49 to pass the connector posts 5 and 9 and the flange 7.

The side panels 45 and 47 are each secured to the front panel 37, bottom panel 41 and top panel 39 by suitable means, as by sewing with DACRON thread, in the same manner illustrated in detail for the panel 45. As shown, the panel 45 is secured to the bottom panel 41 by a seam 51, to the back panel 37 (at its juncture with the suture panel 33) by a seam 53, and to the top panel 39 by a seam 55. The seam 55 is sewn after insertion of the case 3. The front panel 43 is then sewn to the top panel 39 to form a seam 57, and a seam 59 corresponding to the seam 55 is sewn to secure the side panel 47 to the top panel 39.

The case 3 is preferably encased in the support 1 before implantation. In general, the flexible probe comprising the cable 23, its insulating cover 25, the electrode 21 and the plug 27 are implanted as one unit, and the case 3 and its support 1 are then implanted. Connection of the plug 27 to the case 3 is then made, and secured by installation of the screw 31. The suture panels 33 and 35 are then sutured to the wall of the selected cavity, as by stitches 61, FIG. 2. As a result, the electrode 21 is precluded from leaving the desired site for stimulation, as might occur if the case 3 were free to move in its assigned cavity. Tissue ingrowth occurring between the tissue wall to which the suture panels are secured and the anchoring network provided by the strands of the fabric support assembly then proceeds, whereupon the support becomes firmly secured to the body.

While designed for maximum operating life, the power supply for a pacer will ultimately be exhausted, requiring replacement. The support apparatus of my invention is especially well adapted to facilitate the process of replacement. Following a suitable surgical entry, the screw 31 is removed, and the plug 27 disconnected from the case 3. An incision is next made in the top panel 39 sufficient to permit the withdrawal of the case 3. A replacement case is inserted in the support 1, and the top panel refastened with a few stitches. The plug 27 is then replaced, and the screw 31 is installed. The support 1 remains anchored in the body, and thus serves as a permanent repository for the power supply package.

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, and such can obviously be made without departing from the scope of my invention.

Having thus described my invention, what I claim is:

1. An implantable body tissue stimulator adapted to be anchored and stored in a selected body cavity, comprising:

a housing;

means within said housing for generating electrical tissue stimulating signals; and

porous means substantially totally enclosing said housing for securing it to living tissue and adapted to anchor it in place in said selected cavity by enabling body processes to interact with said enclosing means, said means including flap means enabling later removal and replacement of said housing without interfering with the anchoring in place of said enclosing means.

2. The stimulator of claim 1 wherein:

said stimulator is a cardiac pacer.

3. The pacer of claim 2, wherein:

said housing is conductive and effectively provides a terminal for an electric circuit; and

said enclosing means is formed from a mesh and includes a gauze suture panel for securing said enclosed pacer to living tissue.

4. The pacer of claim 3, wherein:

said enclosing means includes a set of flaps sewn together to form a bag for receiving and retaining said housing; and

said suture panel includes a pair of flaps sewn to opposite sides of said bag for suturing to living tissue.

* * * * *