United States Patent [19]

Cannon

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[54] **LIQUID LEAK STOP FOR AN IMPLANTABLE HEART PACER**

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[73] Assignee: **American Optical Corporation,** Southbridge, Mass.

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[52] **U.S. Cl.** ..... **128/419 P;** 174/52 PE

[51] **Int. Cl.²** **A61N 1/36**

[58] **Field of Search** ..... 128/419 C, 419 E, 419 P, 128/419 R, 1 R; 174/22 R, 23 R, 52 PE, 65 R; 339/214 R; 3/1

[56] **References Cited**

UNITED STATES PATENTS

3,478,746	11/1969	Greatbatch	128/419 P
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FOREIGN PATENTS OR APPLICATIONS

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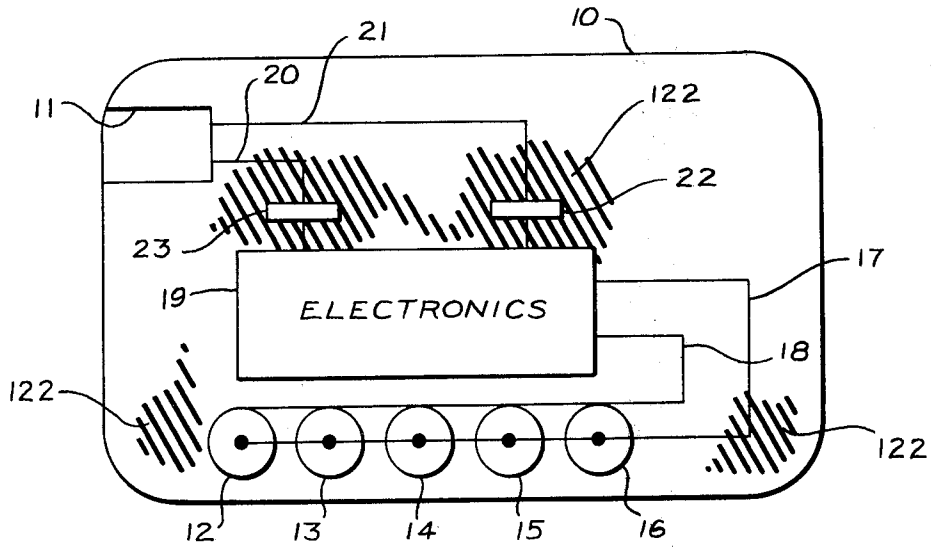
[57] **ABSTRACT**

A liquid leak stop for an implantable heart pacer. There is disclosed an implantable heart pacer for providing stimulation to the heart of a patient. The pacer includes a heartbeat detector, a pulse generator, batteries for powering or energizing the electronics, and electrodes or terminals for connection to the heart. Human body fluids tend to leak into the electrode throat or connector receptacle of the implantable pacer. This leakage can cause pacer malfunction. There are disclosed means for halting this leakage along conductors connecting the pacer-external electrodes and the pacer-internal electronics.

3 Claims, 4 Drawing Figures



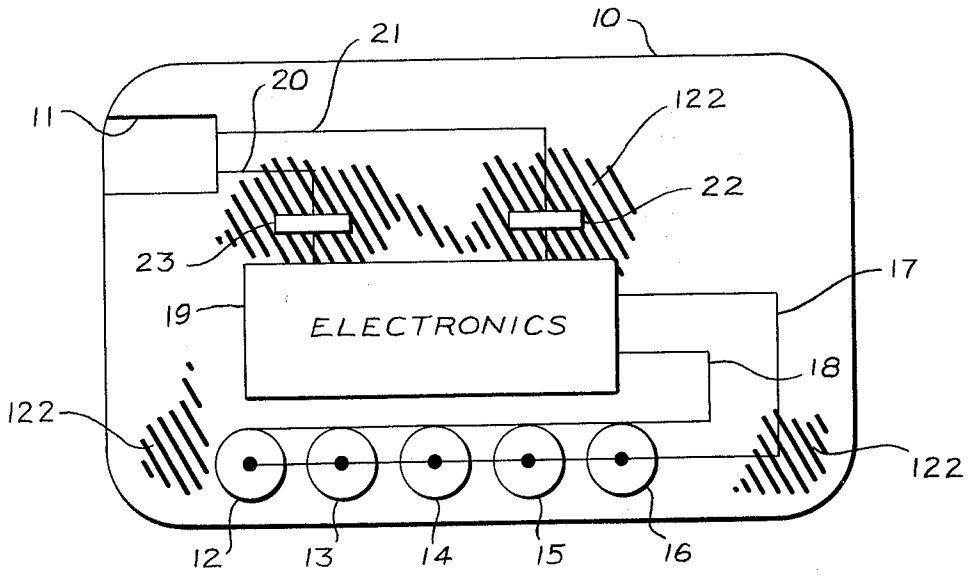


FIG. 1

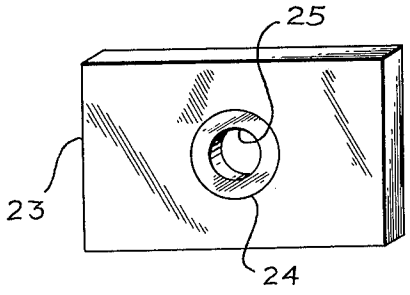


FIG. 2

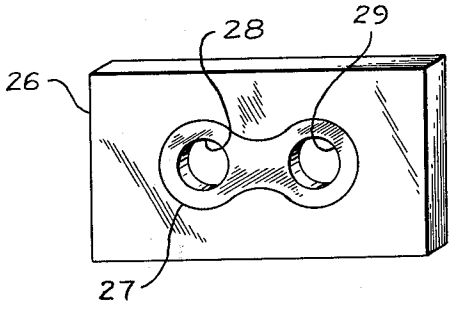


FIG. 3

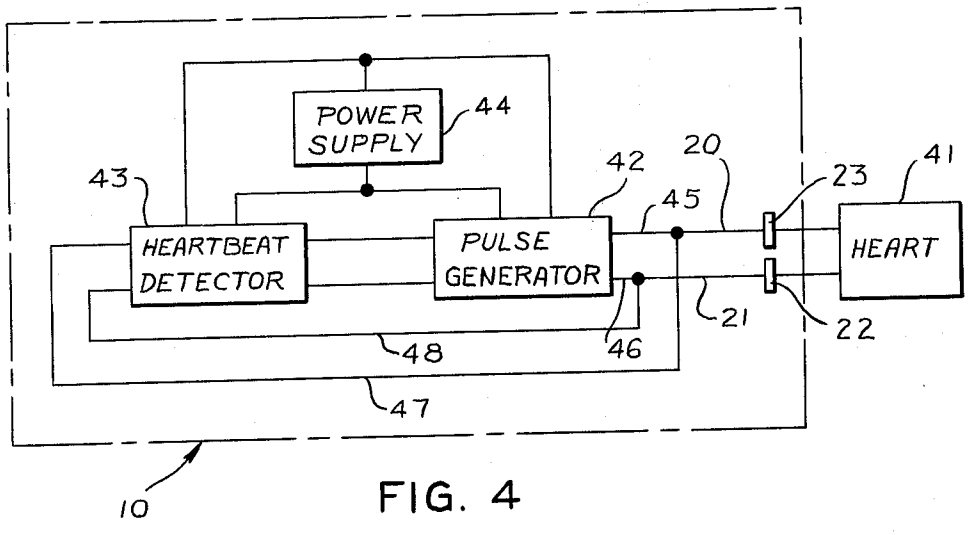


FIG. 4

LIQUID LEAK STOP FOR AN IMPLANTABLE HEART PACER

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to implantable heart pacers, and more specifically relates to means for preventing bodily fluids from leaking into the pacer's electronic circuitry.

2. Description of Prior Art

Heart stimulating devices have been known for some time. Several years ago, heart stimulating devices which provide stimulation at a fixed or constant rate were developed. They had disadvantages since they created competitive problems with a patient's natural spontaneous heartbeat. More recently, heart stimulating devices which supply stimulation to the heart only when required have been developed, and these pacers solved the competition problem. And even more recently, heart pacers that supply stimulation only when required and in proper sequence to two chambers of the heart, the atrium and the ventricle, have been developed. The present invention is adaptable for use with all of these pacers and others.

An implanted pacer provides stimulation to the heart of a patient through electrical conductors contained within a catheter, the conductors connecting the pacer pulse generator output to electrodes in electrical contact with the heart. Because the size and shape of the human body varies from person to person, and for other medical and commercial reasons, catheters are not permanently sealed to the pacer. Thus, there exists a mechanical connection or fitting between the catheter assembly and the pacer itself and this connection is subject to hostile body environment. It is through this connection that fluid leakage may occur. These unwanted fluids can cause a pacer's electronic circuitry to short-circuit, and can cause other metal parts within a pacer to corrode. This situation leads to reduced pacer performance, if not complete failure and is a severe problem.

A malfunctioning pacer is usually removed by surgical procedure and replaced. It is unfortunate that a pacer which would otherwise have additional years of operational life must be removed because of a liquid leak. The unfortunate patient is subjected to surgical procedures which he may otherwise not have to endure so frequently. This has been a shortcoming of prior art pacers over the years.

Applicant's present invention provides a solution to this problem of bodily fluid pacer leakage. The solution is commercially embodied in the Mark II pacer of the American Optical Corporation, which has proven to be capable of virtually completely eliminating this leakage problem.

SUMMARY OF THE INVENTION

In an implantable heart pacer which is constructed in a manner to segregate the electronics portion from the remaining portions of the pacer, and where all pacer components and conductors are "potted" in an epoxy insulation, there are two extending conductors connecting this electronics portion or package to the electrode throat or connector. The electrode throat is adapted to be connected to a catheter for conductive connection to the patient's heart. Leakage from the body of the patient into the throat and along the extending conductors is halted by separate shields or partitions through which each conductor passes, to which each conductor is soldered, and with which the epoxy insulation is bonded. It is the bonding of the epoxy insulation to the shields (which may likewise be constructed from materials related to the epoxy family of materials or from printed circuit board material) that creates the leak stop. Thus, any external bodily fluids leaking into the pacer on these extending conductors are blocked by the shields. Accordingly, advantages of the present invention include elimination of frequent surgical procedures to replace inoperative pacers due to leakage failure.

It is thus an object of the present invention to provide an improved heart stimulating device.

It is another object of the present invention to provide an improved implantable heart pacer.

It is yet another object of the present invention to extend usable life of an implanted pacer beyond that which it would have had if a fluid leak developed.

It is a still further object of the present invention to provide a liquid leak stop or shield to prevent external bodily fluids from causing premature implantable pacer failure.

Other objects and advantages will become apparent to those skilled in the art after referral to a detailed description of the appended drawings wherein:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 depicts an illustrative embodiment of the present invention;

FIG. 2 depicts certain details of the illustrative embodiment of FIG. 1;

FIG. 3 depicts an alternative embodiment of the detail of FIG. 2; and

FIG. 4 depicts an interconnection of the functional blocks of the illustrative embodiment of FIG. 1 and their connection to the heart of a patient.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. **1**, implantable pacer **10** contains batteries **12, 13, 14, 15,** and **16** connected in a manner to provide appropriate supply voltage on conductors **17** and **18** to electronics **19.** The batteries are depicted as being connected in parallel, but a series connection is likewise suitable and generally used. Reference numeral **19** depicts an enclosure for the electronics portion of pacer **10.** Semi-conductors and other components interconnected thereto are contained within enclosure **19** which is intended to act as an RF shield and as a protective device against other harmful physical effects. (U.S. Pat. Nos. 3,528,428 and 3,595,242 describe electronic circuitry which may be employed within enclosure **19.** This subject matter is incorporated herein by reference.) Conductors **20** and **21** are connected between electronics **19** and catheter-throat or electrode-connector-receptacle **11.** The catheter leading to the heart is not shown in FIG. **1.** Conductors **20** and **21** extend input signals from the patient's heart to the electronics and likewise provide output stimulation from the electronics to the patient's heart. Connector aperture **11** is designed to receive electrodes for connection to the patient's heart. Shields or partitions **22** and **23** encompass conductors **21** and **20** respectively. Epoxy insulation **122** is shown in proximity with shields **23** and **22** only, for purposes of clarity of illus-

tration; but it is understood that the insulation extends throughout the interior of pacer **10.**

Referring to FIG. **2,** shield **23** is shown in an elevational view in more detail. Shield **23** contains hole **25** which is plated-through. Reference numeral **24** represents metallic deposition on both sides of shield **23** as well as on the inside surface of hole **25.** Conductor **20** is inserted through hole **25** and is soldered to metallic deposition **24.** Composition of shield **23** is selected to have certain properties including high and substantial adhesion or bonding with insulation **122.** Usually insulation **122** is constructed from epoxy, and material for shield **23** can be selected from the same generic class of synthetics. In a preferred embodiment it is constructed from materials from which ordinary printed circuit boards are constructed, e.g., glass epoxy laminate.

FIG. **1** and FIG. **2,** shows that bodily fluids (not shown) which may tend to leak into aperture **11** and which are transported along conductors **20** and **21** are abruptly halted in their movement by shields **23** and **22.** The extremely tight bonding between surrounding epoxy insulation **122** and the shields prevents the bodily fluids from moving beyond the placement or location of the shields themselves.

FIG. **3** depicts an alternative embodiment of the present invention. Reference numeral **26** depicts a shield having two apertures **28** and **29.** These apertures are conductively connected together by metallic deposit **27** which likewise is plated through each of the apertures. In actual use, two shields are needed as before. One shield **26** is needed for conductor **20** and the other shield **26** is needed for conductor **21.** This alternative embodiment facilitates manufacturing assembly since each conductor need not be inserted through a hole and soldered thereto but merely has to be brought up to the hole and soldered to the metallic deposit. Other separate conductors are extended from the remaining apertures by soldering to the metallic deposits on the remaining apertures.

Finally, FIG. **4** depicts pacer **10** and functional blocks included therein. Power supply or batteries **44** supplies power to heartbeat detector **43** and pulse generator **42.** Conductors **20** and **21** are extended to heart **41** as described earlier. Pulse generator **42** supplies stimulation impulses on conductors **45** and **46** which are connected to conductors **20** and **21** respectively. Likewise, conductors **47** and **48,** which are connected to conductors **45** and **46** respectively, are extended back to the input of heartbeat detector **43** thereby providing means for sensing beating action of heart **41.** Output of heartbeat detector **43** feeds input of pulse generator **42** and thus heartbeat detector **43** controls operation of pulse generator **42.** Shields **23** and **22** are shown in connection with conductors **20** and **21** as noted earlier.

The invention may be embodied in yet other specific forms without departing from the spirit or essential characteristics thereof. Thus, the present embodiments are to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

What is claimed is:

1. An implantable heart pacer for providing stimulation to the heart of a patient, said pacer comprising terminal means for connection to said patient's heart, pulse generator means for providing stimulation impulses, means comprising two conductor leads for extending said impulses to said terminal means, means for detecting the beating action of said patient's heart, means responsive to operation of said detecting means for controlling said pulse generator means, battery means for energizing said pulse generator means and said detecting means, epoxy insulation encapsulating said extending means, said battery means, said detecting means, said controlling means, and said pulse generator means, and incompressible liquid leak stop means constructed from at least glass-epoxy laminate adheringly connected to said extending means and bonded with said insulation for preventing flow of liquid from said terminal means towards said pulse generator means along said extending means, and wherein said incompressible liquid leak stop means is formed as two separate shields with an aperture through each of said shields, the inside shield surface and adjacent shield periphery of each of said apertures having deposited thereon a conductive metal, each of said apertures being adapted to receive one of said leads, and means for sealing said conductive metal around each of said leads in a manner to prevent said flow of liquid through each of said apertures, the remaining surface of each of said shields being bonded to said insulation whereby said flow of liquid is prevented from flowing around each of said shields.

2. An implantable heart pacer for providing stimulation to the heart of a patient, said pacer comprising terminal means for connection to said patient's heart, pulse generator means for providing stimulation impulses, means comprising at least one conductor lead for extending said impulses to said terminal means, means for detecting the beating action of said patient's heart, means responsive to operation of said detecting means for controlling said pulse generator means, battery means for energizing said pulse generator means and said detecting means, epoxy insulation encapsulating said extending means, said battery means, said detecting means, said controlling means, and said pulse generator means, and incompressible liquid leak stop means comprising at least one incompressible shield with an aperture therethrough, conductive metal, the inside shield surface and adjacent shield periphery of said aperture having adheringly deposited thereon said conductive metal, said aperture being adapted to receive said lead, and means for sealing said conductive metal around said lead in a manner to prevent flow of liquid from said terminal means towards said pulse generator means through said aperture, the remaining surface of said shield being bonded to said insulation whereby said flow of liquid is prevented from flowing around said shield.

3. A pacer as recited in claim **2** and wherein said incompressible shield means is constructed from at least glass-epoxy laminate.

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