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GB 1558618
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GB 0581031
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(71) Applicant
Mieczyslaw Mirowski,
2405 Velvet Valley Way,
Owings Mills,
Maryland 21117,
United States of America
(72) Inventors
Mir Imran,
Vernon Leroy Speicher
(74) Agent and/or address for service
J. A. Kemp & Co.,
14 South Square,
Gray's Inn,
London,
WC18 5EU

(54) **Implantable medical device with sealed electrical coupling**

(57) An implantable medical device comprises a casing 10 containing electrical circuitry for stimulating the heart of a recipient, a header 7 integral with the casing having a sealing face 29 provided with seals 81, 83 and terminals 11 (e.g. sockets 31) connected by feedthroughs to the circuitry in the casing, and one or more plugs 17 having a sealing face 21 provided with terminals 19 for insertion into terminals 11. Each plug is secured to the header by a screw 23 having a head 67 which is large enough to overlie at least part of each of the terminals to provide a compressive force aligned therewith.

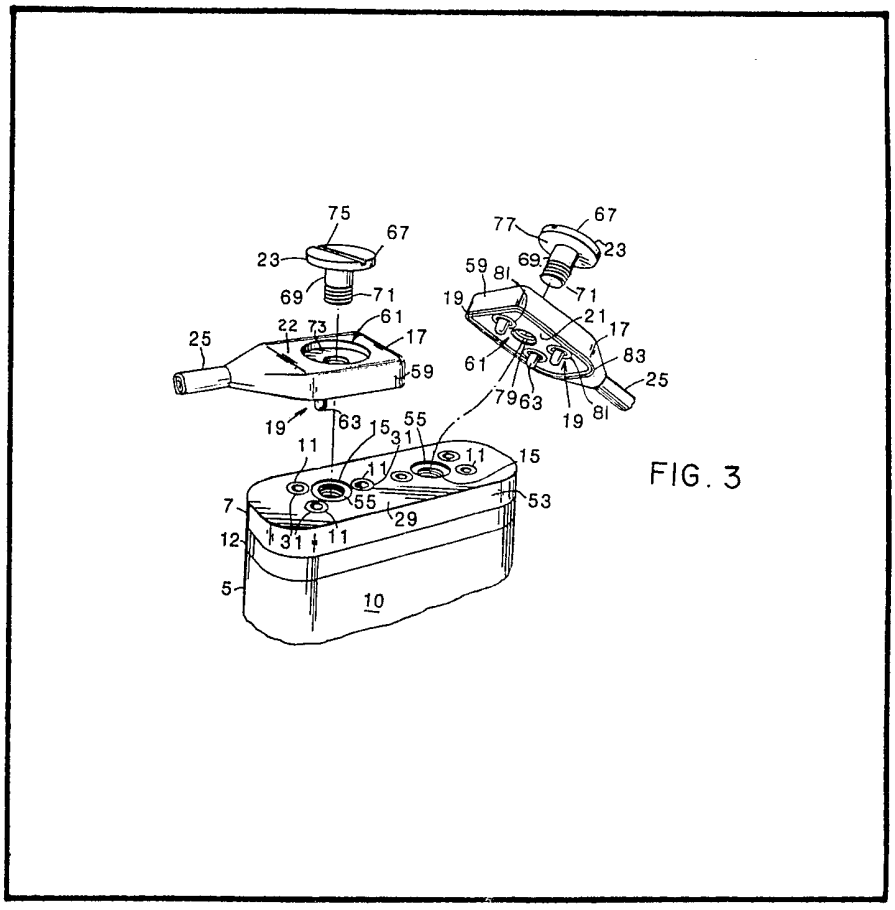

FIG. 3

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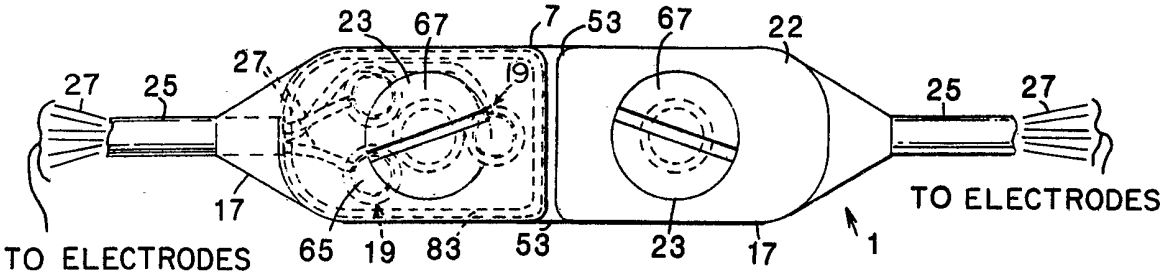
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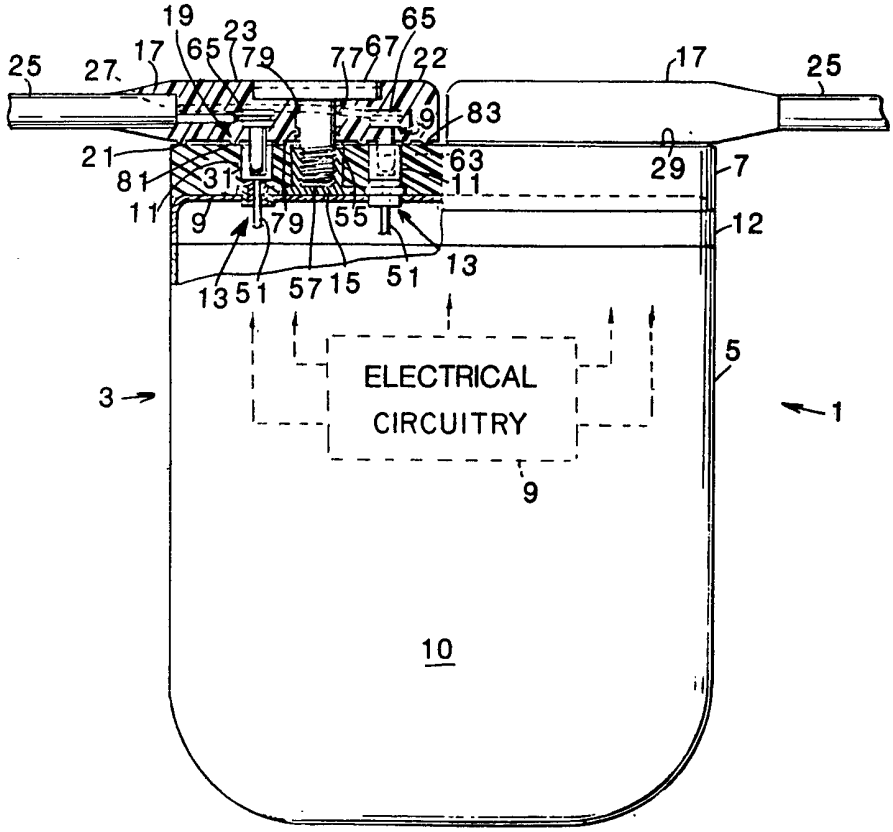
FIG. 1

FIG. 2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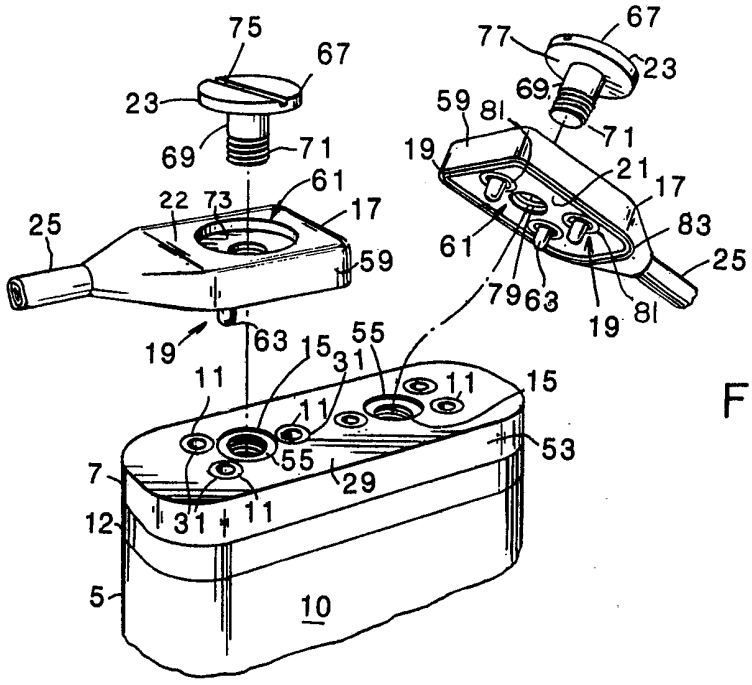


FIG. 3

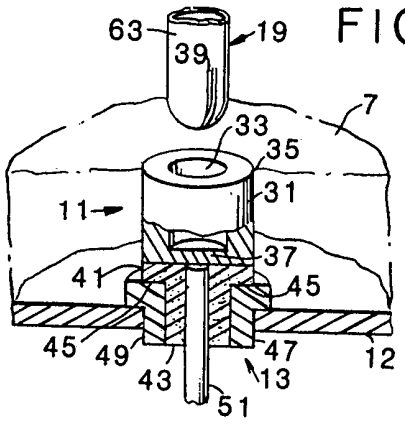
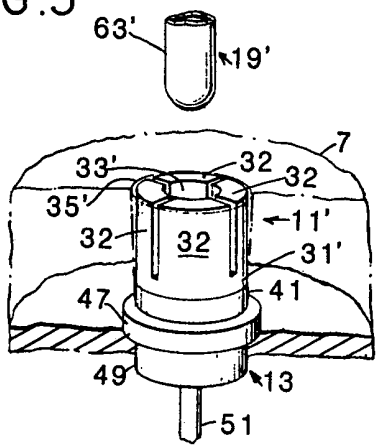


FIG. 4

FIG. 5



SPECIFICATION

Fluid tight plug and header coupling for implantable medical device

Technical field

This invention relates to the coupling of electrode leads to the housing of an implantable medical device, such as a pacer, defibrillator, and/or cardioverter.

Background art

In recent years, implantable medical devices have been developed for providing effective medical response to various heart disorders or arrhythmias. Such devices include means for electrically stimulating the heart in response to such disorder or arrhythmia. Such commonly known devices include pacers, defibrillators, cardioverters, etc. The devices are characterized by one or more implantable electrodes in contact with the heart, electrical circuitry within a housing, and electrode leads interconnecting the electrodes with the housing circuitry. Since the entire electrode, electrode leads, and housing are all implantable, it is important that the coupling of the electrode leads with the housing be properly sealed against seepage of body fluids, including gases, interfering with the integrity of the electrical connections and the electrical circuitry within the housing.

Typical electrical coupling arrangements for implantable heart stimulators, such as automatic defibrillators, are shown in UK patent application No. 80 21 699, filed July 2, 1980, and United States Patent No. 4,262,673, assigned to the present applicant. These coupling arrangements include a coupler, or header, made of biologically inert, nonconductive material integral with the lid of a heart stimulator casing and including terminal openings within the header for receiving terminal plugs of electrode leads. The terminal plugs of the electrode leads are insertable into conducting receptacles within the header and secured thereto by screws.

Various cardiac paper electrode coupling arrangements may be observed from U.S. Patents Nos. 3,253,595, 3,760,332 and 4,027,678.

Recent advances in heart stimulation devices have resulted in the development of implantable devices capable of sensing a condition of the heart and stimulating the heart in various modes of operation. Such modes include a pacing mode, a cardioversion mode, and an automatic defibrillation mode. One such multi-mode heart stimulator is shown in applicant's UK patent specification No. 82 28,372, filed February 18, 1982. Such multi-mode device will generally require multiple electrodes with multiple electrode leads. For example, the heart stimulators discussed in the abovementioned application may require the use of an atrial pacing electrode, a ventricular pacing electrode, a pair of defibrillator electrodes, and a pair of heart rate sensing electrodes. Thus, six electrodes of six electrode leads are required to be interconnected with the housing that houses the electrical circuitry of such multimode device.

Disclosure of invention

The subject invention relates to a fluid tight plug and header coupling for implantable medical devices. The subject invention has particular utility for implantable heart stimulation devices of the multi-mode type wherein several electrode leads must interconnect with electrical circuitry within a housing for implantation in the body of a recipient. As will be apparent, the number of electrode leads may vary depending upon the various modes of operation of the implantable medical device.

The subject invention includes a housing having a casing in which the electrical circuitry for sensing and operating on the heart of the patient is positioned. Integral with the casing, preferably molded to the casing lid, is a header of electrically nonconductive material, inert to body fluids. The header includes electrical terminals, such as female terminal receptacles, which are interconnected with the housing circuitry by feedthroughs. The electrode leads are connected with plugs having electrical terminals, such as male terminal members, which are coupled to the female terminals of the header. In one preferred embodiment of the present invention, two plugs, each connected with three electrode leads, are provided to be coupled to the header. As should be apparent, more or less plugs could be used, depending upon the electrode lead requirements, the space requirements, and, of course, the number of modes of operation of the implantable device.

The plug and header have complementary sealing faces, with O-ring seals disposed about the terminal connections, to seal the terminal connections, and the interior of the casing, from the surrounding body fluids.

To provide a secure connection between the plug and header, a screw connection is employed. A screw, having its shank extending through the plug, is threadingly connected with a screw socket disposed in the header. The screw head is dimensioned of sufficient diameter so that at least a portion of the screw head substantially overlies the connection between the plug and header terminals. This results in a compressive force vectored in substantial alignment with the male and female terminal connections. This aligned force vector ensures a secure, yet releasable, coupling between the plug and the header.

It is an object of the present invention to provide a secure interconnection of the electrode leads to the casing using a minimum number of steps. Generally, the electrodes are first implanted in the body of the recipient and the proximal ends of the electrode leads are secured to the casing during the surgical procedure. As a result, the interconnection between the electrode leads and the casing must quickly be made without elaborate connection procedures, particularly when multiple electrode leads are present.

It is a further object of the present invention to provide a secure interconnection of the electrode leads and casing using a minimum number of parts. The present invention provides for a single attachment member for each plug. This simple attachment member provides a secure mechanical connection of the multiple electrode leads to the casing.

It is a further object of the present invention to provide an electrical coupling device such that the interconnection between the electrode leads and the circuitry within the casing is isolated from the outside environment. A secure coupling avoids fluid seepage, which may impair the conductivity of the connection, and avoids corrosion, thus ensuring easy removability of the plug from the casing should repair ever become necessary.

Still further, it is an object of the present invention to provide an interconnection between a plurality of electrode leads with a casing in a relatively compact space. As the number of electrode leads increases, it is necessary that the leads be connectable with the casing without appreciably increasing the size of the casing. The present invention maximizes the available space requirements to enable a plurality of electrode leads, such as six or more, to be coupled to a casing without increasing the size of the casing in any appreciable manner.

Other objects and advantages of this invention will be further apparent when reference is made to the following description and to the accompanying drawings.

Brief description of drawings

Figure 1 is a top view of a pair of electrode plugs secured to the header of an implantable medical device.

Figure 2 is a front view of the plug and header coupling arrangement.

Figure 3 is an exploded perspective view of the plug and header coupling.

Figure 4 is a detail of the male and female electrical terminals according to one embodiment of the invention.

Figure 5 is a detail of the male and female electrical terminals according to a second embodiment of the invention.

Best mode for carrying out the invention

The present invention comprises an implantable medical device 1 for stimulating the heart of the recipient. The implantable medical device includes a housing 3, comprising a casing 5 and a header 7. Electrical circuitry 9 for operating on the heart of a recipient in one or more modes of operation is disposed within the casing. The header 7 is formed of electrically nonconductive, biologically inert material, preferably molded integral with the lid 12 of the casing 5. The header 7 includes electrical terminals 11, shown as female terminals, extending from the header face into the header, which terminals are coupled by electrical feedthroughs 13 for interconnection with the electrical circuitry 9 within the casing 5. The header 7 further includes a plug attachment socket 15 for connecting each plug 17 to the header 7. A pair of plugs 17 are shown having male terminal pins 19 extending from a plug sealing face 21 for mating engagement with the female terminals 11 of the header 7. Each plug 17 includes a screw 23 for screwing the plug 17 to the header 7 in a secure, yet releasable, manner. A pair of cables 25, having electrode leads 27 disposed therein, is coupled with the plugs 17. The electrode leads 27 are affixed to the male terminals.

The casing 5 includes a bottom portion 10 and a lid portion 12. The casing 5 houses electrical circuitry 9 suitable for operating upon the heart of a patient in accordance with one or more modes of operation. The electrical circuitry 9 disposed within the casing may be pacing, cardioversion, and/or defibrillation circuitry. For example, the electrical circuitry 9 to be housed within the casing could be that described in applicant's UK patent application No. 82 28,372, referred to *supra*, or the automatic defibrillation circuitry as described in UK patent application No. 80 21,699, *supra*, and U.S. Patent No. 4,262,673. As is described in such patent application and patent, the casing may include an inner casing (not shown) which is hermetically sealed from the ouside environment. The casing lid 12 is joined to the casing body 10 to form a hermetically sealed chamber. The casing 5 is preferably made of titanium to assure adequate inertness to body fluids and gases at the implantation site.

Mounted on the casing 5 is a header 7, preferably of molded plastic such as epoxy, polyurethane, and/or any other material that is electrically nonconductive and generally inert to body fluids. The header 7 is preferably molded directly to, and integral with, the casing, preferably to the casing lid 12.

The header 7 is dimensioned to substantially conform with the dimensions of the casing lid 12. The header 7 includes a sealing face 29, which is substantially planar, and is adapted to mate with the plug sealing faces 21, in a manner to be described. The header face 29 and plug faces 21 provide a seal, to be described, against the ingress of bodily fluids which could damage the terminal connections and the circuitry within the casing.

Disposed within the header 7, and molded therewithin, are a plurality of electrical terminals 11 such as electrically conducting female sockets 31. (Two socket embodiments are shown in Figures 4 and 5.) The socket material is preferably titanium. The female sockets 31 are substantially cylindrical in cross-section and define a female socket bore 33 which is adapted to securely receive male terminal pins 19 of the plugs 17. Each female socket bore 33 opens to the exterior of the header 7, through a bore 35 in the header. The socket bore 33 does not extend through the entire female terminal block, but ends to define a base portion 37. The base portion 37 is supported

by an electrical feedthrough 13 in a manner to be described.

The female sockets within the header may be of generally two types. The first type (Figure 4) is a socket 31 having an annular cylindrical portion substantially continuous about the circumference. With such a socket, the male terminal prong 19 of the plug 17 is bifurcated or forked, at 39, and slightly larger in cross-sectional diameter than the socket 31 so that the two forked portions of the male prong 19 are biased toward each other to provide a secure connection when the male prong is inserted into the female socket.

A second embodiment (Figure 5) for the socket provides for the cylindrical portion of the socket 31′ to be segmented to form leaves 32. With such an embodiment, the male terminal prong 19′ is slightly larger in cross-sectional diameter than the bore 33′ defined by the segmented leaves 32 so that the segmented leaves 32 provide a spring bias when the male terminal plug 19′ is inserted therein. As should be apparent with this embodiment, the leaves 32 must be spaced slightly from the bore 35′ defined by the header 7 to permit the leaves 32 of the socket 31′ to move slightly radially outward when the male terminal prong 19′ is inserted therein. It should be further appreciated that the segmented leaves 32 of the female socket 11′ of this embodiment may have an annular lip or ridge (not shown) at the open end thereof to provide a camming surface against the prong 19′.

The electrical feedthroughs 13 interconnect the terminals 11 within the header 7 to the electrical circuitry 9 within the casing. The feedthroughs 13 comprise a plug 41 having a central opening therewithin. The plug 41 is of electrically insulating material such as a ceramic material. The plug 41 includes a cylindrical shank portion 43 that extends through the lid 12 of the casing into the casing interior. The ceramic plug 41 is stepped to provide a support surface 45 for a flange 47 which is molded within the header 7. The flange 47 includes a shank portion 49 extending into the casing. The electrically conductive flange 47 is preferably titanium. Disposed centrally through the ceramic plug 41 and supporting flange 47 is an electrical wire or pin 51, which is affixed to, or may be integral with, the base 37 of the female socket 31. The ceramic plug 41 provides a hermetic seal to prevent fluids from passing into the casing interior.

It should be apparent that the electrically conducting wire or pin 51 may be coupled directly to the electrical circuitry 9 within the casing 5 or, alternatively, may be connected to an additional electrical feedthrough that is disposed within an inner casing (not shown). Such electrical feedthrough within the inner casing is described in applicant's patents and patent applications referred to above.

Disposed substantially equidistantly between opposite sides 53 of the header 7, and substantially centrally of the three female sockets 31, is an attachment socket 15 for receiving an attachment screw 23. The socket 25 includes a metal cylindrical member 55, internally threaded, and integral with a base 57 which is secured to the lid 9 of the casing. The threaded socket 15 communicates with the exterior of the header through the header sealing face 29. The threaded cylindrical socket 15 is operable to receive a threaded screw 23 in a manner to be described. As an alternative, instead of a threaded cylindrical metallic socket 55, the molded plastic header 7 may itself define a threaded socket adapted to receive the screw 23.

As shown in Figures 1 and 3, the header 7 includes six electrical terminals 11 and two threaded attachment sockets 15. Such a header assembly is designed for coupling with a pair of plugs 17, each plug 17 having three male terminals 19 and a single screw attachment 23. The electrical terminals 11 and the threaded attachment sockets 15 are positioned so as to be aligned with the pair of plugs 17 in a manner to be described. It should be apparent that instead of a single molded header 7 disposed substantially across the entire upper surface of the casing lid 12, two separate headers could be employed. Further, the pair of plugs 17 could be integral to form a single elongated plug.

The plugs 17 include a plug housing 59 of molded plastic material similar to the material of the header. That is, the plug housing 59 may be epoxy, polyurethane or any other biologically inert, electrically nonconductive, material. As shown in Figures 1 and 3, each plug 17 is substantially rectangular in shape with stylized ends coupled with the cable 25 in a manner to be described. Each plug 17 includes two substantially parallel planar faces, a sealing face 21, and an exposed face 22. The exposed face 22 is counterbored, at 61, for accommodating the head of an attachment screw 23. The sealing face 21 is of complementary geometry to the header sealing face 29 disposed immediately thereunder.

Imbedded within each plug 17 are a plurality of plug terminals 19. As shown, the plug terminals 19 are male terminal plugs, which define a pin, or prong 63, which extends substantailly perpendicularly from the plug sealing face 21. The male pins 63 are adapted to fit within the female sockets 31 of the header terminals 11. (As should be apparent, the terminals may be reversed so that header terminals 11 may include male pins and the plug terminals 19 may include female sockets.)

The geometry of the male terminal prongs will differ depending upon the particular socket embodiment, as was discussed above. With a substantially continuous female socket 31, as shown in Figure 4, the male prong 63 may include a slot 39 extending axially from the free end of the prong to define a pair of prong forks. The diameter of the male prong is slightly greater than the diameter of the female socket so that when the male prong 63 is inserted into the socket 31, the prong forks will be biased inwardly to provide a

secure connection with the female sockets. Alternatively, as shown in Figure 5, the male prongs 63′ may be substantially solid, but adapted to engage a segmented female socket 31′ so as to expand the leaves 32 of the socket to provide a firm spring bias connection.

The plug terminals 19 embedded within the plugs 17 are connected to wires 27 of the electrode leads. The connection between the electrode lead wires 27 and the plug terminals 19 may be of any conventionally-known means. For example, as shown in Figure 2, the plug terminals 19 include an attachment head 65, substantially circular in cross-section, with a radial opening to receive the wires 27 of the electrode lead. The wires may be resistance welded to the head 65 of the plug terminals. Alternatively, the wires 27 may be wrapped around the plug terminal or the plug terminal may have a crimping structure for crimping the electrode lead wires 27 to the plug terminals 11. Any suitable and secure connection may be used.

It should be apparent that the plug terminals 11 are connected with the electrode lead wires 27 prior to molding of the plug 17.

The electrode lead wires 27 are insulated and are disposed within an electrical cable 25 whose distal end, not shown, is coupled to suitable implantable electrodes. The sheath of the cable 25 is secured to, preferably molded with, the plug 17. As mentioned above, the present invention is particularly useful for a multi-mode type of heart stimulator as disclosed in UK patent application No. 82 28,372, *supra*, wherein six electrode leads would be particularly useful. Of course, the number of electrode leads will depend upon the particular operating requirements of the implantable device.

Substantially centrally disposed within each plug 17 is an attachment device for attaching the plug 17 to the header 7. The attachment device comprises a screw 23, preferably metallic, having a screw head 67 and a screw shank 69 which is threaded at the bottom portion 71 of the shank. The screw 23 fits within a central bore 61, having a counterbored surface 73 in the plug exposed face 22. The screw head 67 has a screw head slot 75 for driving the screw 23 into the threaded socket 15 of the header 7.

The diameter of the screw head 23 is such that the screw head 23 overlies each of the terminal interconnections between the plug and the header. (See Figure 1). This maximizes the compressive force between the plug and header when the screw 23 is tightened into the header socket 15. By sizing the diameter of the screw head 23 to overlie the terminal connections between the header and the plug, a compressive force vector, substantially aligned between the plug terminals 19 and the female socket terminals 11, is provided. By providing such a relatively large diameter screw head, only a single screw connection is necessary to provide a secure fit between each plug and header. The screw head 23 has a substantially planar head surface 77 to provide a flush engagement within the substantially planar exposed face of the plug. As shown, the planar exposed face 23 of the plug has a counterbore portion 73. The substantially planar head surface 77 of the screw 23 engages the exposed face of the counterbored portion 73.

The screw shank 69 is sealed with the plug bore 61 through which the shank passes. This prevents fluid communication from the exterior of the device, around the screw head 23 and through the plug bore 61 for possible fluid communication with the terminal connections or the interior of the casing. The sealing between the screw shank 69 and the plug bore 61 is provided by a plurality of O-ring seals 79 disposed circumferentially about the screw shank. Preferably, the O-ring seals 79 are formed integral with the plug 17, and are molded as part of the plug. Alternatively, the plug bore 61 could define circumferential slots into which O-ring seals could be positioned.

Seals are also provided between the confronting sealing faces 21, 29 of the plug and header, respectively. Disposed circumferentially about each male/female terminal connection is a separate O-ring 81 which prevents fluid communication from the exterior of the device into the terminal connection. As shown in the drawings, the O-ring seals are integral with the plug and extend from the plug sealing face 21 to the header sealing face 29 to provide a tight seal. Alternatively, the O-ring seals could be formed integral with the header. Still further, separate O-rings could be positioned in circumferential slots disposed in either of the plug sealing faces or header sealing faces.

In addition to the O-ring seals about each terminal connection, a separate O-ring seal 83 is disposed about the periphery of the plug sealing face 21, preferably integral with the plug sealing face. This provides an additional seal and provides additional assurance against leakage of bodily fluids into the terminal connections and the interior of the casing. The O-ring 83 disposed about the periphery of the plug sealing face could similarly be disposed in the header sealing face. Still further, a separate O-ring could be disposed in a slot that is defined by either the plug or header sealing faces.

Above, specific embodiments of the present invention have been described. It should be appreciated, however, that these embodiments were described for purposes of illustration only, without any intention of limiting the scope of the present invention. Rather, it is the intention of the present invention that it be limited not by the above, but only as is defined in the appended claims.

Claims

1. A medical device implantable in the body of a recipient for electrically stimulating the heart of a recipient comprising:

a casing having electrical circuit means housed therein for stimulating the heart of a recipient;

a header of electrically insulating material integral with said casing and defining a substantially planar header sealing face, said header including,

a plurality of electrically conducting header terminals disposed within said header and extending from said header sealing face,

means for electrically connecting said header terminals with the electrical circuit means within said casing, and

screw socket means for threadingly engaging an attachment screw, said screw socket means extending from said header sealing face;

a plug of electrically insulating material and defining a substantially planar plug sealing face, and a substantially planar exposed face, including

a plurality of electrically conducting plug terminals extending from said plug sealing face, said plug terminals positioned in complementary relationship with said header terminals for mating engagement therewith,

means for electrically connecting said plug terminals with electrode leads,

a plug bore defined substantially centrally within said plug and extending between said plug sealing face and said exposed face,

an attachment screw having a threaded shank positionable through said plug bore and threadingly engageable with said screw socket means of said header, and having a screw head engaging said planar exposed face, said screw head dimensioned to at least partially overlie each of said plug terminals to provide a force vector in substantial alignment with each said plug terminal and said complementary header terminal when said screw shank is securely threaded into said screw socket means of said header;

a plurality of electrode leads connectable, at one end, with implantable electrodes associated with the heart of a recipient, said electrode leads extending within said plug and connected with said plug terminals; and

sealing means disposed between said header sealing face and said plug sealing face for preventing fluid communication from the exterior of the device of the mated header terminals and plug terminals.

2. The device of claim 1, wherein said sealing means comprises a plurality of O-ring seals, each O-ring seal disposed about a mated header and plug terminal and extending between the header and plug sealing faces.

3. The device of claim 2, wherein said sealing means further comprises a single O-ring seal disposed about all of the mated header and plug terminals, disposed adjacent the periphery of the plug sealing face, and extending between the header and plug sealing faces.

4. The device of claim 2 or 3, wherein said O-ring seals are integral with said plug sealing face and engage said header sealing face.

5. The device of claim 1, wherein each of said header terminals comprises an electrically conducting female socket having a socket bore extending from said header sealing face for receiving the plug terminals through said header sealing face.

6. The device of claim 5, wherein said means of electrically connecting said header terminals with the electrical circuit means comprises a plurality of feedthroughs, each feedthrough associated with a female socket, each feedthrough comprising an insulator member supporting said female socket extending through said header into the casing interior, and a conducting wire connected to said female socket and extending through said insulating member into the casing interior for interconnection with said electrical circuit means.

7. The device of claim 6, wherein each said feedthrough further includes an electrically conducting flange for supporting said insulator member, said flange affixed to said casing.

8. The device of claim 5, wherein each of said plug terminals comprises an electrically conductive male pin extending from said plug sealing face for insertion into a complementary female socket in said header.

9. The device of claim 8, wherein said female socket bore is defined by segmented spring socket leaves, the diameter of said socket bore being less than the diameter of said male pin to provide a secure gripping of said male pin within said female socket.

10. The device of claim 8, wherein said male pin includes a slot extending along the pin axis to define a forked male pin, the diameter of said forked male pin being greater than the diameter of said female socket bore to provide a secure gripping of said male pin within said female socket.

11. The device of claim 5, wherein said means for electrically connecting said plug terminals with said electrode leads comprises an electrode lead opening within each said male pin, at a pin end with said plug, said electrode lead inserted into said lead opening and affixed to said pin.

12. The device of claim 5, wherein said means for electrically connecting said plug terminals with said electrode leads comprises a crimping receptacle connected with said male pin and wherein said electrode lead is mechanically crimped to said crimping receptacle.

13. The device of claim 1, further comprising shank sealing means for preventing fluid communication from the exterior of the device through the plug bore.

14. The device of claim 13, wherein said shank sealing means comprises an O-ring seal circumferentially disposed between said attachment screw shank and the wall of the plug bore.

15. The device of claim 14, wherein said O-ring seal is integral with the wall of the plug bore and extends radially inwardly in sealing engagment with said attachment screw shank.

16. The device of claim 1, wherein said screw socket means comprises an internally threaded screw receptacle embedded within said header for threadingly receiving said attachment screws, said attachment screw externally threaded.

17. The device of claim 16, wherein said screw receptacle is supported on an electrically conductive receptacle base, said receptable base affixed to said casing.

18. The device of claim 1, wherein said attachment screw head has a substantially planar head surface for flush engagement with the substantially planar exposed face of said plug.

19. The device of claim 18, wherein said substantially planar exposed face of said plug is counterbored to provide a planar seat for receiving the planar head surface of said screw head.

20. A medical device implantable in the body of a recipient for electrically stimulating the heart of a recipient comprising:

a housing having electrical circuit means housed therein for stimulating the heart of a recipient, said housing including a housing sealing face having electrical terminals extending therefrom;

a plug interconnected with an electrode lead for implantation in the body of the recipient, said plug having a plug sealing face of complementary geometry with a portion of said housing sealing face for mating and sealing engement therewith, said plug including electrical terminals extending therefrom for engagement with said housing electrical terminals;

sealing means for fluid-tight sealing between said housing sealing face and said plug sealing face; and

attachment means for securely and releasably attaching said housing with each said plug.

21. The device of claim 20, wherein said attachment means comprises a screw.

22. The device of claim 21, wherein said screw includes a screw head, at least a portion of said screw head substantially overlying the mated electrical terminals of said plug and housing to provide a compressive force between said terminals of said plug and housing.

23. The device of claim 20, wherein said sealing means comprises an O-ring seal between said housing sealing face and said plug sealing face.

24. The device of claim 20, wherein said sealing means comprises separate O-ring seals disposed about each plug and housing electrical terminal connection.

25. A medical device implantable in the body of a recipient for electrically stimulating the heart of the recipient, such device being constructed and arranged to operate substantially as hereinbefore described with reference to and as illustrated in the accompanying drawings.

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