A transcutaneous energy transfer system (TETS) is disclosed for use with an implantable medical device (IMD), such as a heart assist device or rotary blood pump. The system comprises an implantable controller in a controller housing, a first implantable coil electrically connected to the controller and a second implantable coil in or on the controller housing and electrically connected to the controller. The first and second coils are selectively electrically transcutaneously connectable to a third coil across a skin layer of the patient to provide an electrical path to the controller from a power source in communication with the third coil and external to the patient. The second coil may be encapsulated in or on the controller housing.
TRANSCUTANEOUS ENERGY TRANSFER SYSTEM

TECHNICAL FIELD

The present invention relates to transcutaneous energy transfer systems (TETS) and to devices and systems associated therewith.

BACKGROUND ART

TETS have been previously described in many disclosures including US-A-5,350,413, WO-A-2004/048037 and WO-A-2001/85250. These earlier disclosures all relate to a TETS comprising two coils positioned on opposite sides of the patient's skin layer allowing for receipt and transmission of electrical signals and current without the need for a percutaneous lead. Generally, the first coil is positioned externally relative to the patient and second implanted coil positioned on the opposed side of the skin layer and mounted in parallel to the first coil.

The main disadvantage with these types of systems is that the coils are generally fragile and prone to breakage during normal use. If the internal coil breaks the implantable medical device (IMD) which the TETS is powering will fail to receive power and stop. In situations where the IMD aids a critical bodily function, for example where blood pumps assist the heart in pumping blood through the body, this may cause a serious adverse event for the patient.

It is an object of the present invention to overcome or at least to ameliorate one or more of the disadvantages associated with the above mentioned prior art.

SUMMARY OF THE INVENTION

According to an aspect of the present invention there is provided a transcutaneous energy transfer system (TETS) for use with an implantable medical device (DvID), the system comprising:

an implantable controller in a controller housing;
a first implantable coil electrically connected to the controller; and
a second implantable coil in or on the controller housing and electrically
connected to the controller; wherein
the first and second coils are selectively electrically transcutaneously
connectable to a third coil across a skin layer of the patient to provide an electrical
path to the controller from a power source in communication with the third coil and
external to the patient.

In this way, the external power source may be used to provide power to the
implantable controller. Advantageously, by having the second coil on or in the
controller housing, there is a resultant reduction of necessary implanted material
within the patient's body compared to a system using two internal coils which are
separate to and electrically connected to the controller. This reduces the number of
implantation sites within the patient's body, thus reducing inconvenience, patient lack
of comfort, post operative infection risk, etc.

The second coil may be encapsulated in or on the controller housing.

Optionally, the system may comprise a rechargeable power source electrically
connected to the controller and located within the controller housing. The external
power source may therefore be able to recharge the rechargeable power source.

The housing may comprise a substantially planar surface to which the second
coil is mounted. Optionally, the first and/or the second coils are configured for
implantation immediately beneath the skin layer of the patient. The first coil may also
be configured for implantation between the skin layer and one or more ribs of the
patient.

Optionally, at least one said coil is encapsulated in a relatively flexible
biocompatible shielding material. The biocompatible shielding material may be
silicone or polyurethane. At least one coil may be formed from Litz wire.

Optionally, the IMD is a blood pump. The controller may be configured to
control the DVID.

The system may comprise the third coil. Optionally, the system comprises a
second controller associated with the third coil and adapted for communication with
the first mentioned controller via the electrical connection between either the third coil
and the first coil or the third coil and the second coil. The first and/or the second controller may be configured to detect a fault in the first coil and/or the electrical connection between the first coil and the first controller.

According to another aspect, there is provided a transcutaneous energy transfer system (TETS) for use with an implantable medical device (IMD), the system comprising:

- an implantable controller in a controller housing;
- a first implantable coil electrically connected to the controller;
- a second implantable coil in or on the controller housing and electrically connected to the controller; and
- a third coil which is selectively electrically transcutaneously connectable to the first coil or the second coil across a skin layer of a patient to provide an electrical path from a power source external to the patient to the controller.

The second coil may be encapsulated in or on the controller housing.

Optionally, the system comprises a rechargeable power source electrically connected to the controller and located within the controller housing. The housing may comprise a substantially planar surface to which the second coil is mounted.

Optionally, at least one coil is formed from Litz wire.

The IMD may be a blood pump. The controller may be configured to control the IMD.

The system may comprise a second controller associated with the third coil and adapted for communication with the first mentioned controller via the electrical connection between either the third coil and the first coil or the third coil and the second coil.

Optionally, the first and/or the second controller are configured to detect a fault in the first coil and/or the electrical connection between the first coil and the first controller.

According to another aspect there is provided an implantable medical device comprising the transcutaneous energy transfer system of any of the above described aspects. The device may comprise a blood pump in fluid communication with the patient's heart, the pump being controllable by the controller.
Other aspects of the invention may comprise methods of using the TETS of any one of the above described aspects or optional features thereof.

According to an embodiment, there is provided a transcutaneous energy transfer device for use with an implantable medical device (IMD) wherein said device includes: first coil mounted externally relative to the skin layer of a patient; second coil mounted below the skin layer of the patient and is electrically connected to an implanted controller of the IMD; third coil encapsulated within an implanted controller housing and implanted within the patient; and wherein the second coil or third coil are electrically coupled to the first coil and when the first coil is energised with a first current, a second current is induced in either the coupled second or third coil to communicate electrical current to the implanted controller.

The third coil may be activated when a fault is detected with the second coil. The second and third coils may be implanted parallel to the skin layer of patient. The third coil may be implanted in the abdomen of the patient. The second coil may be implanted between the ribs and skin layer of a patient generally proximal to a clavicle bone.

At least one coil may be encapsulated in a relatively flexible biocompatible shielding material. The biocompatible shielding material may be silicone, or polyurethane.

At least one coil may be constructed of Litz wire. The IMD may be a rotary blood pump.

According to another arrangement there may be provided a transcutaneous energy transfer device for use with a rotary blood pump implanted within a patient said device comprising an external coil and two spaced apart internal coils, wherein said external coil can selectively be electrically coupled to either of said internal coils. One of said internal coils may be implanted between the skin layer and ribs of the patient and the other implanted within the abdomen. The internal coil implanted within the abdomen may be mounted on the housing of a controller electrically connected to said pump.
BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Figure 1 is a schematic view of a preferred embodiment of a TETS; and

Figure 2 is a transparent view of a patient implanted with the embodiment of the TETS and IMD illustrated in Figure 1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Figures 1 and 2, a first preferred embodiment comprises an implantable medical device (IMD) which includes a transcutaneous energy transfer system (TETS) 10. The IMD in this embodiment is a Left Ventricular Assist Device (LVAD) 11, however in alternative embodiments may be another type of heart assist device or other IMD such as a pacemaker. The LVAD 11 comprises a blood pump 12 which is connected to the circulatory system of a patient P and fully implanted in the body B of the patient P. This connection of the pump 12 to the patient P is made between a cored hole in the apex A of the left ventricle LV of the patient's heart H and a portion of the ascending aorta AA. An inflow cannula 14 connects the left ventricle LV to the blood pump 12. An outflow cannula 16 connects the ascending aorta AA to the blood pump 12. The outflow cannula 16 is preferably made of a woven Dacron™ mesh or velour and the inflow cannula 14 is preferably constructed of injection moulded silicone.

The pump 12 is connected to and controlled by an implantable controller 18 by way of cabling 20. The controller 18 is encapsulated within a housing 21, which is constructed of a biocompatible and fluid impermeable material such as moulded silicone, polyurethane (PU), polyetheretherketone (PEEK), titanium alloy, or a combination of these materials. In this embodiment, the implanted controller 18 includes an electronic control system for the pump 12 and a rechargeable battery 24 which is charged by the TETS and which provides power to the controller 18 and to the pump 12.
The TETS comprises first and second internal coils 26, 28 configured for electrical transcutaneous connection to a third external coil 30. In this embodiment, the first coil 26 is electrically connected to the controller 18 by way of cabling 32. Also in this embodiment, as illustrated in Figure 2, the first coil 26 is implanted on the anterior side of the patient P proximal to a clavicle bone. The first coil 26 is preferably implanted on the ribs of the patient P between the skin layer SL and ribs. Mounting the first coil 26 on the ribs of the patient P assists in stabilising the implantation of the coil 26 and preventing lateral movement or dislodgement of the first coil 26. It is believed that this location of the first coil 26 is convenient for patients when connecting to the external coil 30, the connection of which will be described in more detail below. The first coil 26 is implanted to be generally parallel with the skin layer SL of the patient P. The first coil 26 may be made capable of flexing, if, for example, no Electromagnetic Force (EMF) backing plate is included within the design of the first coil 26.

In this embodiment, the second coil 28 is on a substantially planar surface 36 of the controller housing 21. The second coil 28 is fixed to the controller surface 36 by coating of silicone over the second coil 28 on the controller surface 36. An EMF backing plate 38 is located between the second coil 28 and the housing 21. The EMF backing plate increases and better directs the EMF flux generated by the coils and thereby greatly increases the transfer efficiency of the TETS. As illustrated in Figure 2, in use, the controller 18 is implanted such that the second implanted coil 28 is adjacent the inner abdominal wall in the gut.

In an alternative arrangement, the first coil 26 may also be backed with an EMF backing plate. However the inclusion of an EMF backing plate may reduce the overall flexibility of the first coil as EMF backing plates generally comprise ferrites, which can be rigid.

The combined effect of the first and second coils 26, 28 are to allow the pump 12 to be powered without the need for a permanent exit wound or a percutaneous lead, which is commonly used to power blood pumps, such as rotary blood pumps.

In use, the first and second inner coils 26, 28 of the TETS are configured for transcutaneous electrical communication with the external third coil 30. The third coil
30 is selectively electrically transcutaneously connectable to either of the first and second coils 26,28 and in this embodiment is itself connected to a second controller and power source 40 (eg battery or mains power) to provide power to the first mentioned controller 18 and/or power to recharge the internal battery 24 when in electrical transcutaneous communication with the first or second coil 26,28. In an alternative embodiment, the third coil 30 may be connected only to a power source, such as a battery and/or mains power supply, and not to a controller. In practice, a patient P will likely have available to them several external devices which include an external TETS coil 30 and power supply (either battery or mains power connection), or a TETS coil 30, power supply and controller. For example, where the power supply is a battery, typically with a charge which may last 2-3 hours, the user may have several such external coil and battery combinations to allow for battery exchange when a battery in use runs out of charge. Alternatively, a user who is using an external coil with battery may exchange their coil and battery for a coil and mains power supply combination when in an environment where they are unlikely to need to move far from the mains power supply.

Given that the implanted controller 18 includes an internal battery 24 in communication therewith, it is possible for the patient to use the TETS without connection to the external coil 30 for short periods of time determined by the amount of charge of the internal battery 24. For example, the internal battery 24 may have enough charge to power the pump 12 for periods of thirty minutes to two or more hours.

The TETS may also carry encrypted data signals to relay information to and from the controller and the external controller 40. The information can be relayed via the electrical transcutaneous connection between the first or second internal coil 26,28 and the external coil 30.

In this embodiment, the external controller 40 is selectively connectable by cable or wirelessly to a personal computer or laptop 42 running software such as graphical user interface (GUI) software. The software is capable of one or more of updating the controllers’ software, reprogramming the controllers, reading and archiving patient data, and graphically displaying patient and pump data.
The second coil 28 is generally a backup TETS coil for use in situations where the first coil 26 ceases to function. For example, the wire connection between the first coil 26 and the controller may fail due to unusual fatigue or patient injury. In such cases, the patient using the blood pump 12 can use the second implanted coil 28 instead of using the first coil 26. In this manner, patient safety is not compromised during TETS failure and patients are not endangered. In one embodiment, the external controller 40 attached to the external coil 30 has an alarm 44 which indicates to the user that they need to switch their transcutaneous connection with the external coil 40 from the first coil 26 to the second coil 28. The alarm indication may include a visual and/or an aural cue.

Furthermore, the TETS can be arranged such that patients can select to use either the first 26 or second coil 28 depending on their individual preference. For example, if the patient experiences localised pain proximal to the implantation site of one of the coils, the patient can alleviate the problem by switching his transcutaneous connection with the external coil 30 to the other of the coils.

Either, the second coil 28 and/or the implanted controller housing 21 may be at least partially coated with a material to induce tissue in-growth and fixation within the patient's body. Materials for such a coating may include: textured silicone, Dacron™ or velour.

In the preferred embodiments, the coils include centring magnets 46 to hold the first and external coils 26, 30 or the second and externals coils 28,30 in a close facing yet transcutaneous relationship. The centring magnets 46 help the patient P to easily and properly align the coils by feel. The centring magnets 46 in this embodiment are permanent rare earth magnets.

The coils 26,28,30 of the aforementioned embodiments are constructed of specialised copper wire called Litz wire. Litz wire is a special type of wire generally used in electronics. It consists of many thin wires, individually coated with an insulating film and braided, or woven together thus increasing the surface area of the conductor and thereby reducing the so-called and well known electrical conductor "skin effect" and associated power losses when used with high-frequency applications. The ratio of impedance to resistance is increased relative to a solid
conductor, resulting in a higher so-called "Q factor" at these frequencies. The word originated from "Litzendraht", German for braidwire.

Litz wire is generally used to make inductors and transformers, especially for high frequency applications where the skin effect is more pronounced. Litz wire is often prone to material fatigue, if the wire is repeatedly flexed beyond its limits.

To prevent corrosion or accidental breakage of the wire, the wire may be encapsulated within a relatively flexible and fluid impermeable polymer which acts as a barrier or shield for the coils. Examples of the material that may be suitable for this shielding include: perfluoroalkoxy polymer resin ('PFA'), polyurethane ('PU'), polyetheretherketone (PEEK), silicone, and/or Parylene C.

Further embodiments of the present invention may include multiple backup coils to replace the third coil 30 thereby increasing safety and reliability of the system.

In this embodiment, the second coil 28 is fixed to the outer planar surface 36 of the controller housing 21. In an alternative embodiment, the second coil 28 is located within the controller housing 21. It may be magnetically shielded from the controller electrical components.

In an alternative arrangement, the second coil 28 may be in electrical communication with the implantable controller 18, but separate thereto.

As will be understood, unless the context requires or suggests otherwise, features of any one of the above described embodiments may be used in conjunction with another one or more of the above described embodiments.

While the invention has been described in reference to its preferred embodiments, it is to be understood that the words which have been used are words of description rather than limitation and that changes may be made to the invention without departing from its scope as defined by the appended claims.

In the claims which follow and in the preceding description of the invention, except where the context requires otherwise due to express language or necessary implication, the word "comprise" or variations such as "comprises" or "comprising" is used in an inclusive sense, i.e. to specify the presence of the stated features but not to preclude the presence or addition of further features in various embodiments of the invention.
A reference herein to a prior art document is not an admission that the document forms part of the common general knowledge in the art in Australia.
WHAT IS CLAIMED IS:-

1. A transcutaneous energy transfer system (TETS) for use with an implantable medical device (IMD), the system comprising:
   an implantable controller in a controller housing;
   a first implantable coil electrically connected to the controller; and
   a second implantable coil in or on the controller housing and electrically connected to the controller; wherein
   the first and second coils are selectively electrically transcutaneously connectable to a third coil across a skin layer of the patient to provide an electrical path to the controller from a power source in communication with the third coil and external to the patient.

2. The system of claim 1 wherein the second coil is encapsulated in or on the controller housing.

3. The system of claim 1 or 2 comprising a rechargeable power source electrically connected to the controller and located within the controller housing.

4. The system of any one of the preceding claims wherein the housing comprises a substantially planar surface and the second coil is mounted thereto.

5. The system of any one of the preceding claims wherein the first and/or the second coils are configured for implantation immediately beneath the skin layer of the patient.

6. The system of any one of the preceding claims wherein the first coil is configured for implantation between the skin layer and one or more ribs of the patient.

7. The system of any one of the preceding claims wherein at least one said coil is encapsulated in a relatively flexible biocompatible shielding material.
8. The system of claim 7 wherein the biocompatible shielding material is silicone or polyurethane.

9. The system of any one of the preceding claims wherein at least one coil is formed from Litz wire.

10. The system of any one of the preceding claims wherein the IMD is a blood pump.

11. The system of any one of the preceding claims wherein the controller is configured to control the IMD.

12. The system of any one of the preceding claims comprising the third coil.

13. The system of claim 12 comprising a second controller associated with the third coil and adapted for communication with the first mentioned controller via the electrical connection between either the third coil and the first coil or the third coil and the second coil.

14. The system of claim 13 wherein the first and/or the second controller are configured to detect a fault in the first coil and/or the electrical connection between the first coil and the first controller.

15. A transcutaneous energy transfer system (TETS) for use with an implantable medical device (IMD), the system comprising:
   an implantable controller in a controller housing;
   a first implantable coil electrically connected to the controller;
   a second implantable coil in or on the controller housing and electrically connected to the controller; and
a third coil which is selectively electrically transcutaneously connectable to the first coil or the second coil across a skin layer of a patient to provide an electrical path from a power source external to the patient to the controller.

16. The system of claim 15 wherein the second coil is encapsulated in or on the controller housing.

17. The system of claim 15 or 16 comprising a rechargeable power source electrically connected to the controller and located within the controller housing.

18. The system of any one of claims 15 to 17 wherein the housing comprises a substantially planar surface and the second coil is mounted thereto.

19. The system of any one of claims 15 to 18 wherein at least one coil is formed from Litz wire.

20. The system of any one of claims 15 to 19 wherein the DVID is a blood pump.

21. The system of any one of claims 15 to 20 wherein the controller is configured to control the IMD.

22. The system of any one of preceding claims 15 to 21 comprising a second controller associated with the third coil and adapted for communication with the first mentioned controller via the electrical connection between either the third coil and the first coil or the third coil and the second coil.

23. The system of claim 22 wherein the first and/or the second controller are configured to detect a fault in the first coil and/or the electrical connection between the first coil and the first controller.
24. An implantable medical device comprising the transcutaneous energy transfer system of any one of the preceding claims.

25. The device of claim 24 comprising a blood pump in fluid communication with the patient's heart, the pump being controllable by the controller.

26. A transcutaneous energy transfer system or an implantable medical device substantially as herein described with reference to the accompanying drawings.

27. A transcutaneous energy transfer system or an implantable medical device substantially as herein described with reference to the accompanying drawings.
A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.
A61M 1/10 (2006.01) A61N 1/378 (2006.01) H04B 5/00 (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI. Keywords: transcutaneous energy transfer, TETS, two, backup, redundant, auxiliary, coil, safety, spare and similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>US 6058330 A (BORZA) 2 May 2000 See whole document. Especially column 9 lines 17–41. Figures 4-7</td>
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<td>EP 1614445 A1 (ETHICON ENDO-SURGERY, INC) 11 January 2006 See whole document.</td>
<td>1, 2, 4, 5, 7, 8, 11, 12, 15, 16, 18, 21, 26, 27</td>
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Date of the actual completion of the international search

07 April 2008

Date of mailing of the international search report

16 APR 2008

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