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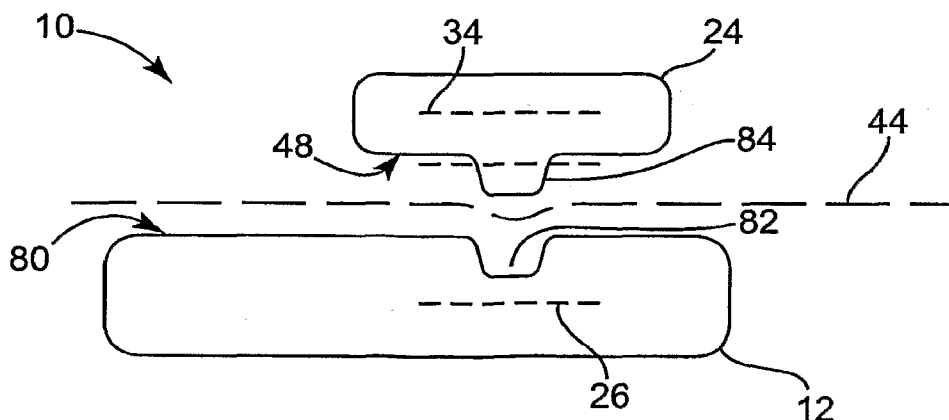
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MATING ELEMENTS



(57) Abstract: System for transcutaneous energy transfer to an implantable medical device adapted to be implanted under a cutaneous boundary having a housing having a first surface adapted to face the cutaneous boundary, the first surface of the housing of the implantable medical device having a first mating element, therapeutic componentry and a secondary coil operatively coupled to the therapeutic componentry. An external power source has housing having a first surface adapted to be placed closest to the cutaneous boundary, the first surface of the housing of the external power source having a second mating element and a primary coil capable of inductively energizing the secondary coil when externally placed in proximity of the secondary coil. The first mating element and the second mating element are configured to tactilely align the external power source with the implantable medical device.

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System for Transcutaneous Energy Transfer to an Implantable Medical Device with Mating Elements

FIELD

- [1] The present invention relates generally to transcutaneous energy transfer and, more particularly, to a system for transcutaneous energy transfer to an implantable medical device.

BACKGROUND

- [2] Implantable medical devices for producing a therapeutic result in a patient are well known. Examples of such implantable medical devices include implantable drug infusion pumps, implantable neurostimulators, implantable cardioverters, implantable cardiac pacemakers, implantable defibrillators and cochlear implants. Of course, it is recognized that other implantable medical devices are envisioned which utilize energy delivered or transferred from an external device.
- [3] A common element in all of these implantable medical devices is the need for electrical power in the implanted medical device. The implanted medical device requires electrical power to perform its therapeutic function whether it is driving an electrical infusion pump, providing an electrical neurostimulation pulse or providing an electrical cardiac stimulation pulse. This electrical power is derived from a power source.
- [4] Typically, a power source for an implantable medical device can take one of two forms. The first form utilizes an external power source that transcutaneously delivers energy via wires or radio frequency energy. Having electrical wires which perforate the skin is disadvantageous due, in part, to the risk of infection. Further, continuously coupling patients to an external power for therapy is, at least, a large inconvenience. The second form utilizes single cell batteries as the source of energy of the implantable medical device. This can be effective for low power applications, such as pacing devices. However, such single cell batteries usually do not supply the lasting power required to perform new therapies in newer implantable medical devices. In some cases, such as an implantable artificial heart, a single cell battery might last the

patient only a few hours. In other, less extreme cases, a single cell unit might expel all or nearly all of its energy in less than a year. This is not desirable due to the need to explant and re-implant the implantable medical device or a portion of the device. One solution is for electrical power to be transcutaneously transferred through the use of inductive coupling. Such electrical power or energy can optionally be stored in a rechargeable battery. In this form, an internal power source, such as a battery, can be used for direct electrical power to the implanted medical device. When the battery has expended, or nearly expended, its capacity, the battery can be recharged transcutaneously, via inductive coupling from an external power source temporarily positioned on the surface of the skin.

- [5] Several systems and methods have been used for transcutaneously inductively recharging a rechargeable used in an implantable medical device. Some examples of systems and method used for transcutaneously inductively charging or recharging an implantable medical device include U.S. Patent No. 5,411,537, Munshi et al, Rechargeable Biomedical Battery Powered Devices With Recharging and Control System Therefor, (Intermedics, Inc.); U.S. Patent No. 5,690,693, Wang et al, Transcutaneous Energy Transmission Circuit For Implantable Medical Device, (Sulzer Intermedics Inc.); U.S. Patent No. 5,733,313, Barreras, Sr., FR Coupled Implantable Medical Device With Rechargeable Back-Up Power Source, (Exonix Corporation); U.S. Patent No. 6,308,101, Faltys et al, Fully Implantable Cochlear Implant System, (Advanced Bionics Corporation); U.S. Patent No. 6,324,430, Zarinetchi et al, Magnetic Shield For Primary Coil of Transcutaneous Energy Transfer Device, (Abiomed, Inc.); U.S. Patent No. 6,516,227, Meadows et al, Rechargeable Spinal Cord Stimulator System, (Advanced Bionics Corporation); U.S. Patent No. 6,505,077, Kast et al, Implantable Medical Device With External Recharging Coil Electrical Connection, (Medtronic, Inc.); European Patent Application 1,048,324, Schallhorn, Medical Li+ Rechargeable Powered Implantable Stimulator, (Medtronic, Inc.); PCT Patent Application No. WO 01/83029 A1, Torgerson et al, Battery Recharge Management For an Implantable Medical Device, (Medtronic, Inc.); and PCT Patent Application No. WO 01/97908 A2, Jimenez et al, An Implantable Medical Device With Recharging Coil Magnetic Shield, (Medtronic, Inc.).

- [6] U.S. Patent Application Publication US 2005/0075700A1 (U.S. Patent Application Serial No. 10/837,506, Schommer et al, External Power Source For An Implantable Medical Device Having An Adjustable Magnetic core and System and Method Related Therefore, filed April 30, 2004), discloses an external power source, and system and method using such external power source, for an implantable medical device having therapeutic componentry and a secondary coil operatively coupled to the therapeutic componentry. A primary coil is capable of inductively energizing the secondary coil when externally placed in proximity of the secondary coil. A repositionable magnetic core associated with the primary coil is capable of being repositioned by a user of the external power source. An indicator is capable of providing the user with information relative to coupling between the primary coil and the secondary coil as a function of repositioning of the repositionable magnetic core.
- [7] Transcutaneous energy transfer through the use of inductive coupling involves the placement of two coils positioned in close proximity to each other on opposite sides of the cutaneous boundary. The internal coil, or secondary coil, is part of or otherwise electrically associated with the implanted medical device. The external coil, or primary coil, is associated with the external power source or external charger, or recharger. The primary coil is driven with an alternating current. A current is induced in the secondary coil through inductive coupling. This current can then be used to power the implanted medical device or to charge, or recharge, an internal power source, or a combination of the two.
- [8] For implanted medical devices, the efficiency at which energy is transcutaneously transferred is crucial. First, the inductive coupling, while inductively inducing a current in the secondary coil, also has a tendency to heat surrounding components and tissue. The amount of heating of surrounding tissue, if excessive, can be deleterious. Since heating of surrounding tissue is limited, so also is the amount of energy transfer which can be accomplished per unit time. The higher the efficiency of energy transfer, the more energy can be transferred while at the same time limiting the heating of surrounding components and tissue. Second, it is desirable to limit the amount of time required to achieve a desired charge, or recharge, of an internal power source. While charging, or recharging, is occurring the patient necessarily has an

external encumbrance attached to their body. This attachment may impair the patient's mobility and limit the patient's comfort. The higher the efficiency of the energy transfer system, the faster the desired charging, or recharging, can be accomplished limiting the inconvenience to the patient. Third, amount of charging, or recharging, can be limited by the amount of time required for charging, or recharging. Since the patient is typically inconvenienced during such charging, or recharging, there is a practical limit on the amount of time during which charging, or recharging, should occur. Hence, the size of the internal power source can be effectively limited by the amount of energy which can be transferred within the amount of charging time. The higher the efficiency of the energy transfer system, the greater amount of energy which can be transferred and, hence, the greater the practical size of the internal power source. This allows the use of implantable medical devices having higher power use requirements and providing greater therapeutic advantage to the patient and/or extends the time between charging effectively increasing patient comfort.

- [9] The efficiency of transcutaneous inductive energy transfer is directly related to the accuracy of positioning of the external, primary coil, to the internal, secondary coil. The two coils should be as close to each other as possible. Of course, since the position of the secondary coil is fixed following implantation, the closer that the primary coil can be positioned to the skin surface the better. The two coils should also be laterally aligned as close as possible. This alignment is typically accomplished by the patient by the attachment of the external power source/charger at the commencement of the charging process or when otherwise transferring power. It is often cumbersome and difficult for the patient, who typically is not a medical professional, to most accurately position the primary coil in the proper location. The lateral alignment is typically done tactilely by the patient. A typical implanted medical device is implanted close enough to the skin that the skin of the patient has a small protuberance at the site of implantation. This can be felt by the patient and can be used as a guide to position the external coil. However, this problem can be exacerbated because the lateral position of the secondary coil is not always laterally centered with the external protuberance providing the patient with tactile lateral location information.

- [10] Even if the primary coil is properly placed at the initiation of energy transfer or of the charging process, energy transfer and/or charging can continue over a significant period of time. During this time, it is usually impracticable for the patient to remain absolutely immobile. Charging can typically occur over several, perhaps many, hours. It is desirable for the patient to be able to continue with as many normal activities as possible. For example, since charging often is accomplished at night, it is desirable that the primary coil not move during normal sleep activities of the patient. As the patient may move during energy transfer or during charging, motions and activities of the patient may cause the primary coil to move with respect to the secondary coil. If this should happen, the efficiency of energy transfer is not optimum which limits the rate at which energy can be transferred and resulting in an increase in charging time, if the system utilizes charging, or a decrease in the amount of energy available to the implanted medical device, if direct energy transfer is utilized.
- [11] It also can be important to secure the primary coil in the proper location once the proper has been located by the patient. Without properly locating the external antenna with respect to the implantable medical device, efficient energy transfer may not be fully achieved.
- [12] Prior art implantable medical devices, external power sources, systems and methods have not always provided the best possible benefit leading to efficiency of energy transfer and patient comfort.

SUMMARY

- [13] It can be especially difficult to properly coaxially locate the primary coil of an external antenna with the secondary coil of an implantable medical device because it can be difficult to tactilely determine the location of the implantable medical device. Exacerbating the problem is that the secondary coil of the implantable medical device may not be centered on a face of the implantable medical device. In this case, even if the implantable medical device is properly located, the primary and secondary coils may still not be properly aligned.
- [14] In an embodiment, the present invention provides a system for transcutaneous energy transfer. An implantable medical device adapted to be implanted under a cutaneous

boundary has a housing having a first surface adapted to face the cutaneous boundary, the first surface of the housing of the implantable medical device having a first mating element, therapeutic componentry and a secondary coil operatively coupled to the therapeutic componentry. An external power source has housing having a first surface adapted to be placed closest to the cutaneous boundary, the first surface of the housing of the external power source having a second mating element and a primary coil capable of inductively energizing the secondary coil when externally placed in proximity of the secondary coil. The first mating element and the second mating element are configured to tactilely align the external power source with the implantable medical device.

- [15] In an embodiment, the first mating element and the second mating element are configured to tactilely align the primary coil with the secondary coil.
- [16] In an embodiment, the first mating element is configured to be off-center of the first surface of the implantable medical device.
- [17] In an embodiment, a depression on the first surface of the external power source constitutes the second mating element and the first mating element of the implantable medical device is a projection.
- [18] In an embodiment, a depression on the first surface of the implantable medical device constitutes the first mating element and the second mating element of the external power surface is a projection.
- [19] In an embodiment, the first surface of the implantable medical device has a plurality of first mating elements and wherein the first surface of the external power source has a plurality of second mating elements and the plurality of first mating elements mate with respective ones of the plurality of second mating elements are collectively configured to tactilely coaxially align the primary coil with the secondary coil.
- [20] In an embodiment, the plurality of first mating elements and the plurality of second mating are asymmetrically arranged enabling tactile orientation of the external power source with respect to the implantable medical device.

- [21] In an embodiment, the first mating element is a ring and the second mating element is a ring mating with the ring of the first mating element.
- [22] In an embodiment, the ring of the first mating element and the ring of the second mating element are circular.
- [23] In an embodiment, the ring of the first mating element and the ring of the second mating element are oval.
- [24] In an embodiment, the present invention provides a method of transcutaneous energy transfer to a medical device implanted in a patient having a secondary charging coil using an external power source having a housing containing a primary coil, the housing having a first surface adapted to face the cutaneous boundary, the first surface of the housing of the implantable medical device having a first mating element; and having an external power source having a housing having a first surface adapted to be placed closest to the cutaneous boundary, the first surface of the housing of the external power source having a second mating element. The primary coil is positioned externally of the patient with respect to the secondary coil. The primary coil of the external power source is tactilely aligned with the secondary coil of the implantable medical device by moving the external power source with respect to the implantable medical device by aligning the second mating element of the external power source with the first mating element of the implantable medical device. Energy is transcutaneously transferred from the primary coil to the secondary coil.
- [25] In an embodiment, the tactilely aligning step uses a depression on the first surface of the external power source constituting the second mating element and the first mating element of the implantable medical device comprising a projection.
- [26] In an embodiment, the tactilely aligning step uses a depression on the first surface of the implantable medical device constituting the first mating element and the second mating element of the external power source comprising a projection.
- [27] In an embodiment, the tactilely aligning step utilizes a plurality of first mating elements and a plurality of second mating elements.

- [28] In an embodiment, the tactilely aligning step further orients the external power source with respect to the implantable medical device utilizing an asymmetrical arrangement of the plurality of first mating elements and the plurality of second mating elements.
- [29] In an embodiment, the first mating element is a ring mating with a ring of the first mating element.
- [30] In an embodiment, the rings are circular.
- [31] In an embodiment, the rings are oval.

DRAWINGS

- [32] **Figure 1** is a block diagram of a charging system utilizing transcutaneous energy transfer;
- [33] **Figure 2** is a cross-sectional illustration of a close-up view of a variation of a portion of a charging system;
- [34] **Figure 3** is a cross-sectional illustration of an embodiment of an external antenna having a central protrusion contacting the cutaneous boundary of the patient;
- [35] **Figure 4** is a cross-sectional illustration of an embodiment of an external antenna having a central protrusion being pressed against the cutaneous boundary of the patient;
- [36] **Figure 5** is a cross-sectional illustration of an embodiment of the external antenna having peripheral protrusions and of an implantable medical device having an mating indent with a central protrusion of the external antenna;
- [37] **Figure 6** is a bottom perspective view of the external antenna of **Figure 5**;
- [38] **Figure 7** is a cross-sectional illustration of an embodiment of an external antenna having an adjustable central protrusion;
- [39] **Figure 8** is a cross-sectional illustration of an embodiment of an external antenna having a rachetable central protrusion;
- [40] **Figure 9** is a cross-sectional illustration of an embodiment of an external antenna having a magnetic core of non-uniform cross-section;

- [41] **Figure 10** is a top view of an embodiment of an implantable medical device portion of a transcutaneous energy transfer system;
- [42] **Figure 11** is a cross-sectional side view of an embodiment of a transcutaneous energy transfer system;
- [43] **Figure 12** is a cross-sectional side view of another embodiment of a transcutaneous energy transfer system;
- [44] **Figure 13a** is a top view of an implantable medical device portion of an embodiment of a transcutaneous energy transfer system utilizing multiple mating elements;
- [45] **Figure 13b** is a bottom view of an external power source of the embodiment of the transcutaneous energy transfer system mating with the implantable medical device portion illustrated in **Figure 13a**;
- [46] **Figure 14a** is a top view of an implantable medical device portion of an embodiment of a transcutaneous energy transfer system utilizing asymmetric mating elements;
- [47] **Figure 14b** is a bottom view of an external power source of the embodiment of the transcutaneous energy transfer system mating with the implantable medical device portion illustrated in **Figure 14a**;
- [48] **Figure 15a** is a top view of an implantable medical device portion of an embodiment of a transcutaneous energy transfer system utilizing ring mating elements;
- [49] **Figure 15b** is a bottom view of an external power source of the embodiment of the transcutaneous energy transfer system mating with the implantable medical device portion illustrated in **Figure 15a**;
- [50] **Figure 15c** is a cross-sectional side view of the implantable medical device of **Figure 15a**;
- [51] **Figure 15d** is a cross-sectional side view of the implantable medical device of **Figure 15b**;
- [52] **Figure 16** illustrates a profile view of an embodiment of mating elements having a rounded bum profile and used with an external power source or an implantable medical device of the invention;

- [53] **Figure 17** illustrates a profile view of an embodiment of mating elements having a planar top and used with an external power source or an implantable medical device of the invention;
- [54] **Figure 18** illustrates a profile view of an embodiment of mating elements having a conical profile and used with an external power source or an implantable medical device of the invention; and
- [55] **Figure 19** illustrates a profile view of an embodiment of mating elements having a truncated cone and used with an external power source or an implantable medical device of the invention.

DETAILED DESCRIPTION

- [56] **Figure 1** illustrates a system 10 into which an improved external antenna 32 may be utilized. System 10 consists of implantable medical device 12 and external power supply 14.
- [57] Implantable medical device 12 is situated under cutaneous boundary 16. Implantable medical device 12 includes charging regulation module 14, electronics module 16 and therapy module 18. Charging regulation and therapy control is conventional. Implantable medical device 12 also has internal telemetry coil 20 configured in conventional manner to communicate through external telemetry coil 22 to an external programming device (not shown), charging unit 24 or other device in a conventional manner in order to both program and control implantable medical device and to externally obtain information from implantable medical device 12 once implantable medical device has been implanted. Internal telemetry coil 20, rectangular in shape with dimensions of 1.85 inches (4.7 centimeters) by 1.89 inches (4.8 centimeters) constructed from 150 turns of 43 AWG wire, is sized to be larger than the diameter of secondary charging coil 26.
- [58] Internal antenna 25 contains secondary coil 26, constructed with 182 turns of 30 AWG wire with an inside diameter of 0.72 inches (1.83 centimeters) and an outside diameter of 1.43 inches (3.63 centimeters) with a height of 0.075 inches (0.19

centimeters). Magnetic shield 28 is positioned between secondary charging coil 26 and housing 30 and sized to cover the footprint of secondary charging coil 26.

- [59] Internal telemetry coil 20, having a larger diameter than secondary coil 26, is not completely covered by magnetic shield 28 allowing implantable medical device 12 to communicate with the external programming device with internal telemetry coil 20 in spite of the presence of magnetic shield 28.
- [60] Rechargeable power source 24 can be charged while implantable medical device 12 is in place in a patient through the use of charging regulation module 14. In a preferred embodiment, charging regulation module 14 consists of charging unit 24 and external antenna 32. Charging unit 24 contains the electronics necessary to drive primary coil 34 with an oscillating current in order to induce current in secondary coil 26 when primary coil 34 is placed in the proximity of secondary coil 26. Charging unit 24 is operatively coupled to primary coil 34 by cable 36. In an alternative embodiment, charging unit 24 and antenna 32 may be combined into a single unit. Antenna 32 may also optionally contain external telemetry coil 22 which may be operatively coupled to charging unit 24 if it is desired to communicate to or from implantable medical device 12 with charging regulation module 14. Alternatively, antenna 32 may optionally contain external telemetry coil 22 which can be operatively coupled to an external programming device, either individually or together with external charging unit 14.
- [61] As will be explained in more detail below, repositionable magnetic core 38 can help to focus electromagnetic energy from primary coil 34 to be more closely aligned with secondary coil 26. Also as will be explained in more detail below, energy absorptive material 40 can help to absorb heat build-up in external antenna 32 which will also help allow for a lower temperature in implantable medical device 12 and/or help lower recharge times. Also as will be explained in more detail below, thermally conductive material 42 is positioned covering at least a portion of the surface of external antenna 32 which contacts cutaneous boundary 44 of the patient.
- [62] Figure 2 is a cross-sectional illustration of a close-up view of a variation of a portion of charging system 10. Internal antenna 25 is shown having been implanted below

cutaneous boundary 44. Secondary coil 26 is positioned within internal antenna 25 above magnetic shield 28.

- [63] External antenna 38 contains primary coil 34 and is positioned in transcutaneous superposition with respect to internal antenna 25. Primary coil 34 is aligned with secondary coil 26 in order to facilitate transcutaneous energy transfer using electromagnetic coupling. Magnetic core 38 helps to focus electromagnetic energy generated by primary coil 34 transcutaneously toward secondary coil 26. In this embodiment, magnetic core 38 extends between windings of primary coil 34. External antenna 32 has a generally planar surface 48 intended to contact cutaneous boundary 44. An edge of magnetic core 38 is coplanar with surface 48 to help promote electromagnetic fields to extend from primary coil 34 and be captured more readily by secondary coil 26. Insulation 46 between magnetic core 38 and primary coil 34, particularly on the side of external antenna 32 facing surface 48, protects magnetic core 38 from collecting heat produced by primary coil 34 and increasing the surface of cutaneous boundary 44.
- [64] **Figure 3** illustrates an alternative embodiment of external antenna 32 used in charging system 10. Again, external antenna 38 contains primary coil 34 and is positioned in transcutaneous superposition with respect to internal antenna 25. Primary coil 34 is aligned with secondary coil 26 in order to facilitate transcutaneous energy transfer using electromagnetic coupling. Magnetic core 38 helps to focus electromagnetic energy generated by primary coil 34 transcutaneously toward secondary coil 26. Central protrusion may be aligned with the axis of primary coil 34.
- [65] However, external antenna 32 illustrated in **Figure 3** extends magnetic core 38 further toward cutaneous boundary 44 and past surface 48 creating protrusion 50. Central protrusion 50 extends beyond surface 48 creating a noticeable bump on surface 48 contacting cutaneous boundary 44. In an embodiment, central protrusion 50 is circular in cross-section and has a conically shaped end intended to contact cutaneous boundary 44. In an embodiment, central protrusion 50 is approximately 0.5 centimeters in diameter and extends approximately 0.5 centimeters beyond surface 48. The outer diameter of central protrusion 50 may be not greater than, and perhaps less than, the inner diameter of primary coil 34.

- [66] External antenna 32 may be pressed by the user against cutaneous boundary 44 as illustrated in **Figure 4**. Central protrusion 50 pushes a portion of cutaneous boundary 44 away from its point of impact allowing external antenna 32, in general, and magnetic core 38, in particular, to come closer to secondary coil 26.
- [67] Central protrusion 50 allows primary coil 34 to more efficiently electromagnetically couple with secondary coil 26 by allowing magnetic core 38 to be closer to internal antenna 25 and secondary coil 26. Commonly, an external antenna 32 having a planar surface 48 may be able to come within 1 centimeter of secondary coil 26 of internal antenna 25. However, central protrusion 50 is able to indent cutaneous boundary 44 and reduce the distance, commonly referred as the “air gap distance” between primary coil 34 and secondary coil 26.
- [68] An alternative embodiment of external antenna 32 of charging system 10 can be seen by referring to **Figure 5** and **Figure 6**. **Figure 5** is a cross-sectional view of external antenna 32 placed in the proximity of implantable medical device 12 and secondary coil 26. **Figure 6** is an underside perspective view of external antenna 32 unencumbered by implantable medical device 12.
- [69] As in **Figure 3** and **Figure 4**, external antenna 32 of **Figure 5** and **Figure 6** has central protrusion 50 enhancing electromagnetic coupling between primary coil 34 and secondary coil 26 as discussed above. In addition, external antenna 32 contains a plurality of peripheral protrusions 52 extending beyond surface 48 in a similar fashion to central protrusion 50. Peripheral protrusions 52 may be sized and positioned to “fit” around the periphery of internal antenna 25 of implantable medical device 12 to further reduce the gap between primary coil 34 and secondary coil 26. One or more peripheral protrusions 52 may be used. Peripheral protrusions may be circular in cross-section, conically shaped, square, rectangular or arcuate. Typically, peripheral protrusions 52 extend a similar distance beyond surface 48 as central protrusion 50, however, peripheral protrusions 52 may extend farther or less far from surface 48 than central protrusion 50. Peripheral protrusions 52 may extend approximately one-half of the distance that central protrusion 50 extends from surface 48.

- [70] Peripheral protrusions 52 may be spaced from one another as illustrated in **Figure 6** or may be more or less continuous around a periphery of external antenna 32 forming, to a large extent or entirely, a peripheral ring around external antenna 32 extending below surface 48.
- [71] In an embodiment illustrated in **Figure 5**, implantable medical device 12, and, in particular, internal antenna 25, has an indent 54 on the surface facing cutaneous boundary 44 aligned with central protrusion 50. So configured, indent 54 of internal antenna 25 provides a locating feature allowing the user to tactilely determine the optimum positioning of external antenna 32 and will help hold external antenna 32 in proper position for electromagnetic energy transfer and will help ensure efficient energy transfer. Further, indent 54 may allow magnetic core 38 in protrusion 50 to get even closer to secondary coil 26 making energy transfer even more efficient.
- [72] In an embodiment illustrated in **Figure 5** and **Figure 6**, peripheral protrusions 52 may be sized and positioned to have a pattern, perhaps a circular pattern, slightly larger in diameter than internal antenna 25 allowing peripheral protrusions 52 to “fit” over the edge of internal antenna 25 enabling ease of tactile positioning of external antenna 32 with respect to internal antenna 25. Further, peripheral protrusions 52 positioned in this manner may tend to push away skin of cutaneous boundary 44 and stretch cutaneous boundary 44 to be more thin over internal antenna 25 allowing external antenna 32 and, hence, primary coil 34, to be closer to secondary coil 26 and increasing the efficiency of energy transfer.
- [73] **Figure 7** illustrates an embodiment of external antenna 32 having screw 56 facilitating implementation of central protrusion 50. Screw 56 may be turned clockwise or counter-clockwise to either increase the amount of protrusion or decrease the amount of protrusion of central protrusion 50 from surface 48. Screw 56 may be turned by hand or by using a tool such as a screwdriver in a slot of the top surface of screw 56. Screw 56 may extend through external antenna 32 as shown, facilitating tool manipulation, or may extend only partly through external antenna 32 allowing manipulation, for example, by hand turning central protrusion 50. Screw 56 may be adjusted to create a greater or lesser extension of central protrusion 50 to

account for patient comfort, varying implant locations and implant depths and type of skin or amount of fat tissue surrounding implantable medical device 12.

- [74] **Figure 8** illustrates an embodiment of external antenna 32 similar to the embodiment illustrated in **Figure 7**. However, in the embodiment illustrated in **Figure 8**, adjustable central protrusion 50 is designed to an adjustable plunger that ratchets within the body of external antenna 32. The ratchet mechanism can allow central protrusion 50 to be adjusted relative to surface 48.
- [75] **Figure 9** illustrates an embodiment of external antenna 32 in which magnetic core 38 has a non-uniform cross-sectional area. Screw 56 is constructed of magnetic core 38 having a larger cross-section nearer the tip of central protrusion 50 and a smaller cross-section farther away from the tip of central protrusion 50. The greater amount of magnetic core 38 nearer the tip of central protrusion 50 increases the focusing effect of magnetic core 38 and increases the efficiency of energy transfer by keeping electromagnetic flux within magnetic core 38 farther toward secondary coil 26. The remainder of screw 56 may be comprised of a non-magnetic protective material 60 such as an injection molded thermoplastic such as nylon 12, nylon PPA, polycarbonate or ABS. While the embodiment of **Figure 8** is illustrated with magnetic core 38 contained within screw 56, it is to be recognized and understood that magnetic core 38 could also be contained within external antenna 32 and within central protrusion 50 without an adjustable screw 56. That is, central protrusion 50 could be fixed and still contain magnetic core 38 on non-uniform cross-section.
- [76] While various embodiments of central protrusion 50 have been described, it is to be recognized and understood such embodiments and techniques could be used for one or more of peripheral protrusions 52, either in addition to be used with central protrusion 50 or alternative to being used with central protrusion 50.
- [77] While peripheral protrusions 52 have been illustrated and described as being used with central protrusion 50, it is to be recognized and understood that peripheral protrusions 52 could be used to benefit in external antenna 32 without central protrusion 50.

- [78] In an embodiment, a portion of insulating material 46 facing surface 48 could be formed of a low permeable material, such as bismuth graphite, to assist in forcing the electromagnetic field generated by primary coil 34 toward secondary coil 26.
- [79] Figure 10 is a simplified view of the top surface 80, i.e., the surface facing cutaneous boundary 44, of implantable medical device 12. Surface 80 of implantable medical device 12 contains mating element 82. Mating element 82 provides a tactile element to surface 80 of implantable medical device 12 so that the location of secondary coil 26 may be tactilely located transcutaneously after implantable medical device 12 has been implanted into a patient. Mating element 82 provides a protrusion from or a depression in surface 80 of implantable medical device 12. Although, the location of implantable medical device 12 typically may be identified following implantation due to the general shallowness of the implant location, determining the location of implantable medical device 12 does not necessarily translate to knowing the location of secondary coil 26. As can be seen in Figure 10, secondary coil 26 may be located off-center, i.e., not centered on surface 80 of implantable medical device.
- [80] Figure 11 provides a cross-sectional side view of implantable medical device 12 implanted under cutaneous boundary 44. Mating element 82, in this embodiment illustrated as a depression, is positioned in a predetermined relationship with secondary coil 26. In this embodiment, mating element 82 is co-aligned with the axis of secondary coil 26. External power source 24 has a complementary mating element 84, in this embodiment illustrated as a projection, positioned in a predetermined relationship with primary coil 34. In this embodiment, mating element 84 is co-aligned with the axis of primary coil 34.
- [81] When transcutaneous energy transfer is desired to be initiated, such as for charging a rechargeable power source in implantable medical device 12, external power source 24, or typically an antenna associated with external power source 24 containing mating element 84 is placed on or near transcutaneous boundary 44 near the location of implantable medical device 12. Such location can be generally determined by tactilely sensing a protrusion or bump that implantable medical device 12 makes in cutaneous boundary 44 due to the shallowness of the implant location.

- [82] However, merely placing external power source 24 in the vicinity of implantable medical device 12 does not necessarily mean that primary coil 34 and secondary coil 26 are aligned. Proper alignment of primary coil 34 and secondary coil 26 provides increased efficiency of energy transfer. As shown in Figure 11, secondary coil 26 may not be centered on surface 80 of implantable medical device. If primary coil 34 is centered on external power source 24 or if the corresponding off-centeredness does not match, the alignment of external power source 24 with implantable medical device 12 may actually lead to misalignment of primary coil 34 and secondary coil 26.
- [83] The bump of mating element 84 on external power source 24, however, may easily find the corresponding depression of mating element 82 on implantable medical device 12 automatically properly aligning primary coil 34 and secondary coil 26 due to the known predetermined relationship, e.g., co-axial relationship, of mating element 84 with primary coil 34 and the known, e.g., co-axial relationship, of mating element 82 with secondary coil 26. An operator using external power source 24, or an antenna of external power source 24, may easily tactilely feel mating element 84 transcutaneously mate with mating element 82 of implantable medical device 12. Once aligned, energy transfer may begin.
- [84] Figure 12 illustrates an alternative embodiment of mating elements 82 and 84. In this embodiment, mating element 82 of implantable medical device 12 is a bump or projection and mating element 84 of external power source 24 is a depression. Nevertheless, mating elements 82 and 84 are complementary and operate in the same way to easily ensure proper alignment of primary coil 34 and secondary coil 26 as in Figure 11.
- [85] Figures 13a and 13b illustrate an embodiment of transcutaneous energy transfer system 10 in which a plurality of mating elements 82 with implantable medical device 12 and a corresponding plurality of mating elements 84 with external power source 24. In this embodiment, four (4) mating elements 82 and four (4) mating elements 84 are shown although other numbers of mating elements work as well. As in Figures 11 and 12, mating elements 82 may be either projections or depressions and, likewise, mating elements 84 may be either depressions or projections. Corresponding mating

elements on each of implantable medical device 12 and external power source 24 should correspond, i.e., one could be a projection and the other a depression. Of course, not all mating elements 82 of implantable medical device need be all projections or depressions. Some of each could be utilized with corresponding mating elements 84 of external power source being complementary thereto. It is also to be recognized and understood that while, generally, mating elements (82 and 84) have been referred to as either projections or depressions, that combinations or more complex shapes could be utilized as well that may not strictly be either purely a projection or a depression. At least some of mating elements 82 should be complementary to and mate with corresponding ones of mating elements 84 of external power source 24.

- [86] Figure 14a and 14b illustrate another embodiment of transcutaneous energy transfer system 10 having a plurality of mating elements. In this embodiment, two mating elements 82 and two mating elements 84 similar to those illustrated with respect to Figures 13a and 13B and an additional mating element 86 in the form of an elongated depression and an additional mating element 88 in the form of a complementary elongated projection, or bar, are utilized. This asymmetrical arrangement, or dissimilar shapes of mating elements, allows external power source 24 to be tactilely placed with respect to implantable medical device in a particular orientation, if that is desired.
- [87] Figures 15a, 15b, 15c and 15d illustrate another embodiment of transcutaneous energy transfer system 10 having mating elements that form mating rings. Mating element 90 of implantable medical device 12 is an indented ring. Mating element 92 of external power source 24 is a complementary projecting ring. Although circular rings are illustrated, it is to be recognized and understood that other shapes, such as ovals, or even dual rings or incomplete rings could be utilized.
- [88] Figure 16 illustrates a side view of an alternative embodiment of the profile shape of a mating element, such as mating element 80 or mating element 82. In this embodiment, mating elements 94 have a rounded, bump-like profile enabling easy engagement between corresponding complementary mating elements.

- [89] Figure 17 illustrates a side view of an alternative embodiment of the profile shape of a mating element, such as mating element 80 or mating element 82. In this embodiment, mating elements 96 have a squared-off profile with a generally planar top. Such a shape may allow secure positioning of corresponding complementary mating elements.
- [90] Figure 18 illustrates a side view of an alternative embodiment of the profile shape of a mating element, such as mating element 80 or mating element 82. In this embodiment, mating elements 98 a conical profile with a generally pointed end. Such a shape may allow precise positioning of corresponding complementary mating elements.
- [91] Figure 19 illustrates a side view of an alternative embodiment of the profile shape of a mating element, such as mating element 80 or mating element 82. In this embodiment, mating elements 96 have truncated conical profile with a generally flat end. Such a shape may allow generally precise positioning of corresponding complementary mating elements perhaps with improved comfort.

Claims:

1. A system for transcutaneous energy transfer, comprising:
an implantable medical device adapted to be implanted under a cutaneous boundary, comprising:
a housing having a first surface adapted to face said cutaneous boundary, said first surface of said housing of said implantable medical device having a first mating element;
a therapeutic componentry; and
a secondary coil operatively coupled to said therapeutic componentry;
and
an external power source, comprising:
a housing having a first surface adapted to be placed closest to said cutaneous boundary, said first surface of said housing of said external power source having a second mating element; and
a primary coil capable of inductively energizing said secondary coil when externally placed in proximity of said secondary coil;
said first mating element and said second mating element being configured to tactilely align said external power source with said implantable medical device.
2. A system as in claim 1 wherein said first mating element and said second mating element are configured to tactilely align said primary coil with said secondary coil.
3. A system as in claim 2 wherein said first mating element is configured to be off-center of said first surface of said implantable medical device.
4. A system as in claim 2 wherein a depression on said first surface of said external power source constitutes said second mating element and wherein said first mating element of said implantable medical device comprises a projection.

5. A system as in claim 2 wherein a depression on said first surface of said implantable medical device constitutes said first mating element and wherein said second mating element of said external power surface comprises a projection.
6. A system as in claim 2 wherein said first surface of said implantable medical device has a plurality of first mating elements and wherein said first surface of said external power source has a plurality of second mating elements and wherein said plurality of first mating elements mate with respective ones of said plurality of second mating elements are collectively configured to tactilely coaxially align said primary coil with said secondary coil.
7. A system as in claim 6 wherein said plurality of first mating elements and said plurality of second mating are asymmetrically arranged enabling tactile orientation of said external power source with respect to said implantable medical device.
8. A system as in claim 2 wherein said first mating element comprises a ring and wherein said second mating element comprises a ring mating with said ring of said first mating element.
9. A method of transcutaneous energy transfer to a medical device implanted in a patient and an external power source, both as in claim 1, comprising the steps of:

positioning said primary coil externally of said patient with respect to said secondary coil;

tactilely aligning said primary coil of said external power source with said secondary coil of said implantable medical device by moving said external power source with respect to said implantable medical device by aligning said second mating element of said external power source with said first mating element of said implantable medical device; and

transferring energy transcutaneously from said primary coil to said secondary coil.

10. A method as in claim 9 wherein said tactilely aligning step further comprises aligning said primary coil with respect to said secondary coil using a depression on said first surface of said external power source constituting said second mating element and said first mating element of said implantable medical device comprising a projection.
11. A method as in claim 9 wherein said tactilely aligning step further comprises aligning said primary coil with respect to said secondary coil using a depression on said first surface of said implantable medical device constituting said first mating element and said second mating element of said external power source comprising a projection.
12. A method as in claim 9 wherein said tactilely aligning step utilizes a plurality of first mating elements and a plurality of second mating elements.
13. A method as in claim 12 wherein said tactilely aligning step further comprises orienting said external power source with respect to said implantable medical device utilizing an asymmetrical arrangement of said plurality of first mating elements and said plurality of second mating elements.
14. A method as in claim 9 wherein said first mating element comprises a ring and wherein said second mating element a ring mating with said ring of said first mating element.

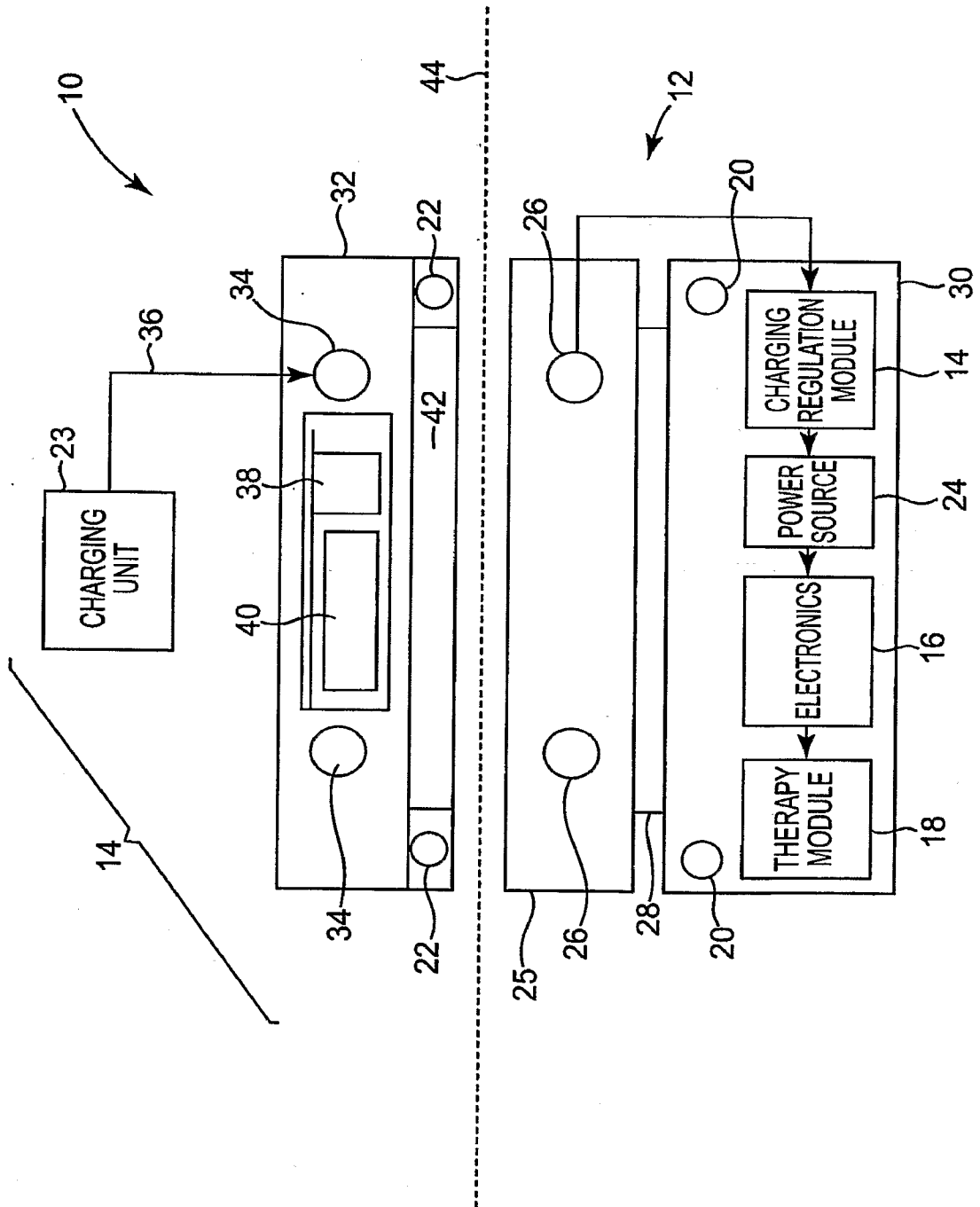


Fig. 1

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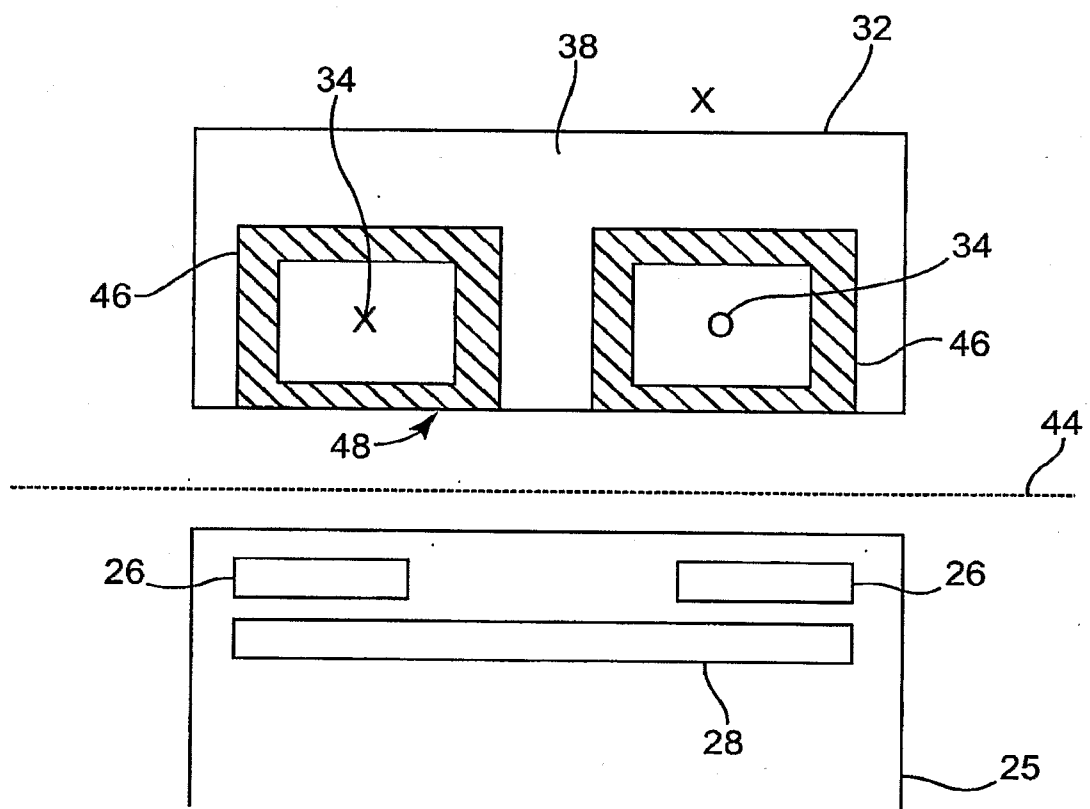


Fig. 2

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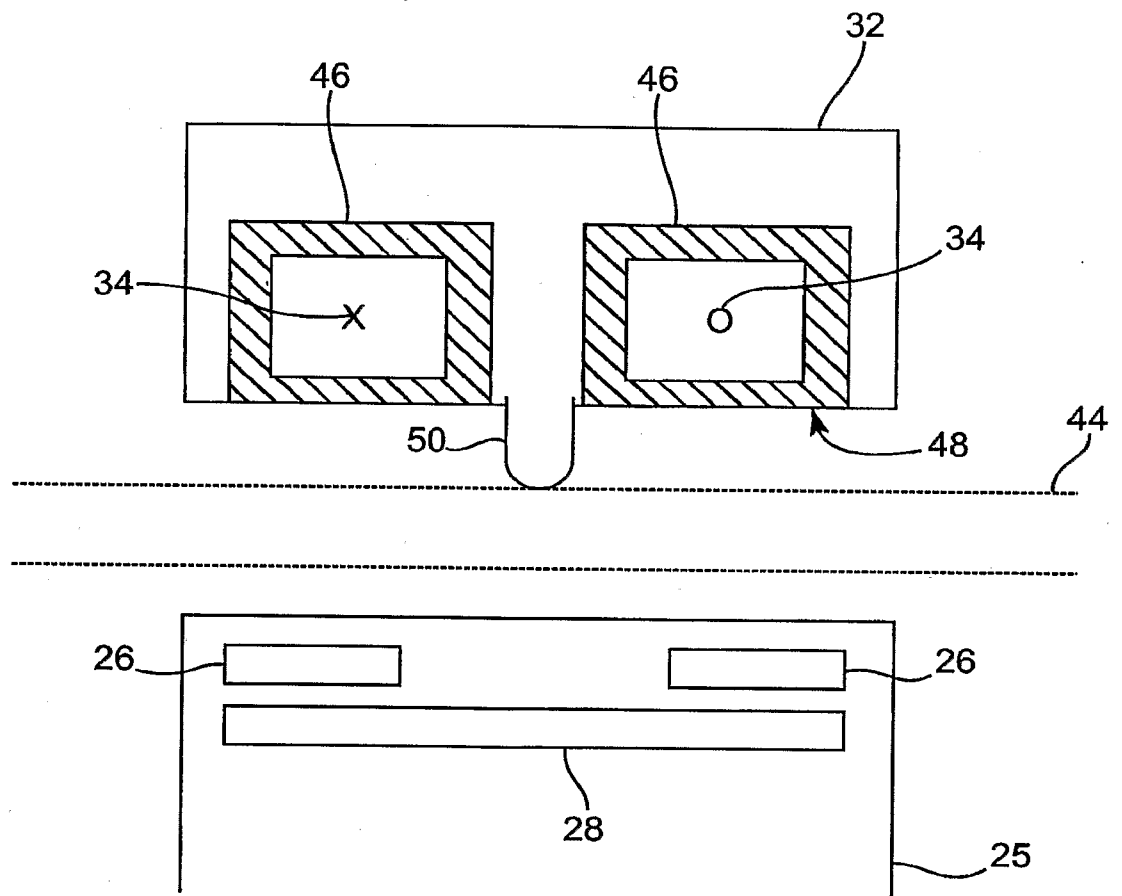


Fig. 3

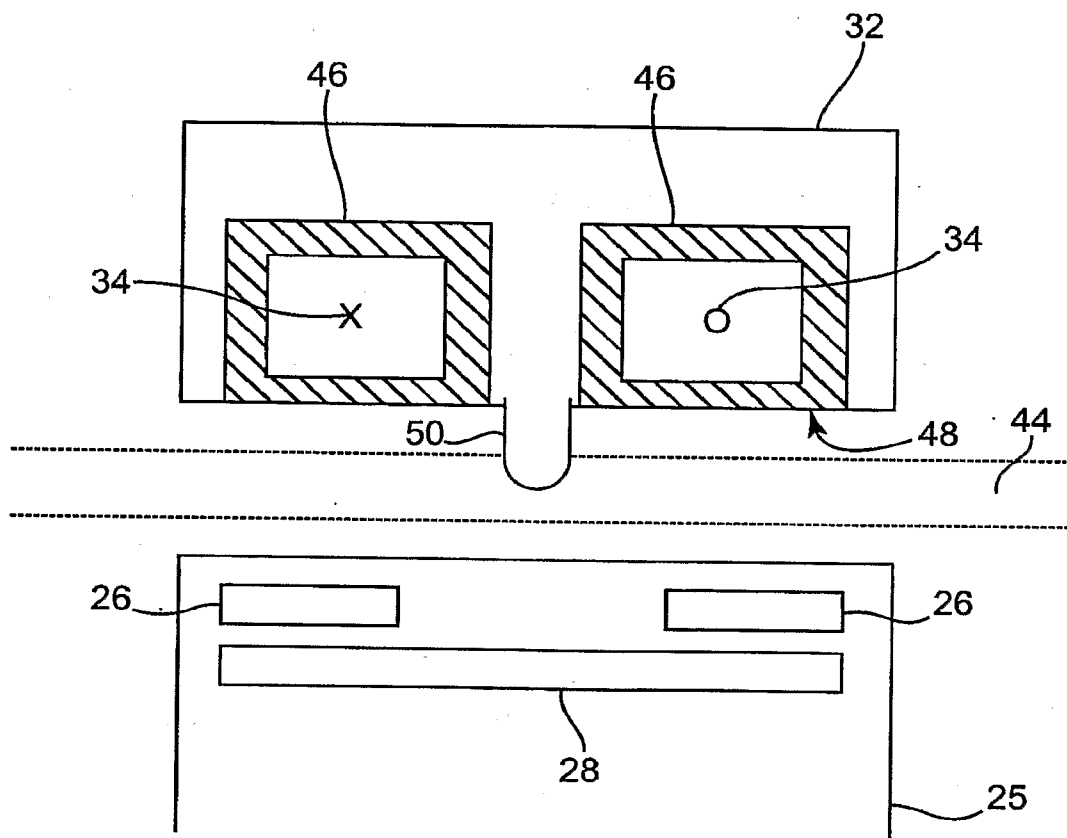


Fig. 4

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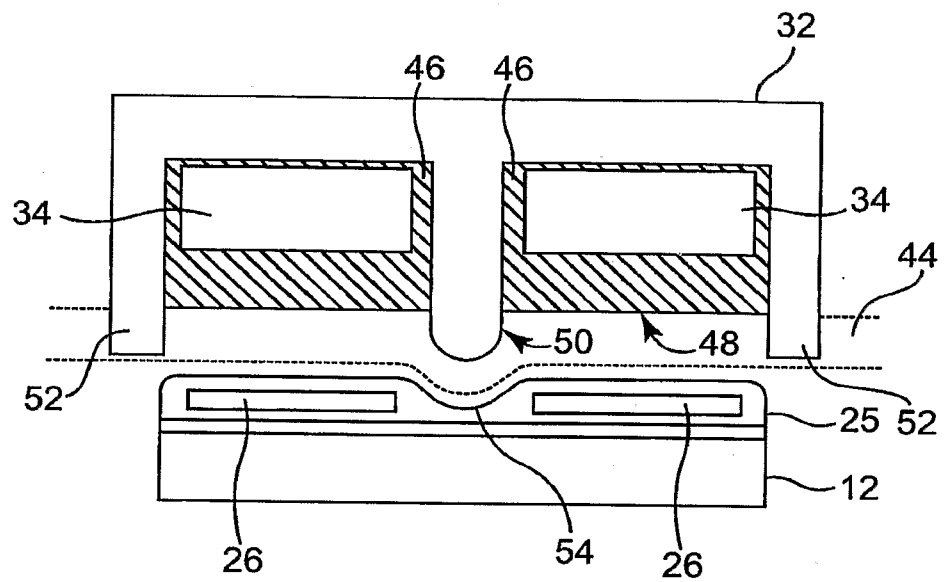


Fig. 5

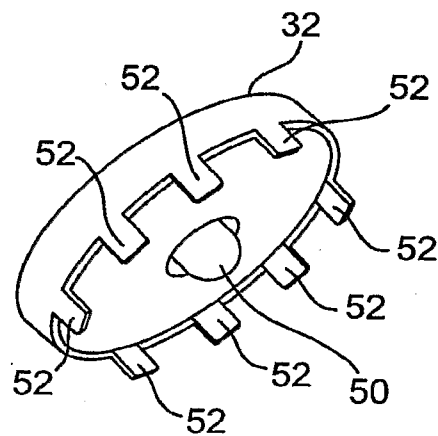


Fig. 6

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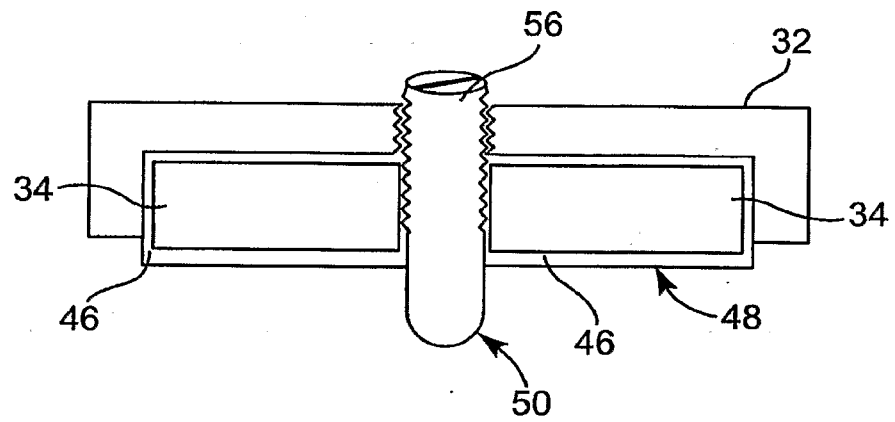


Fig. 7

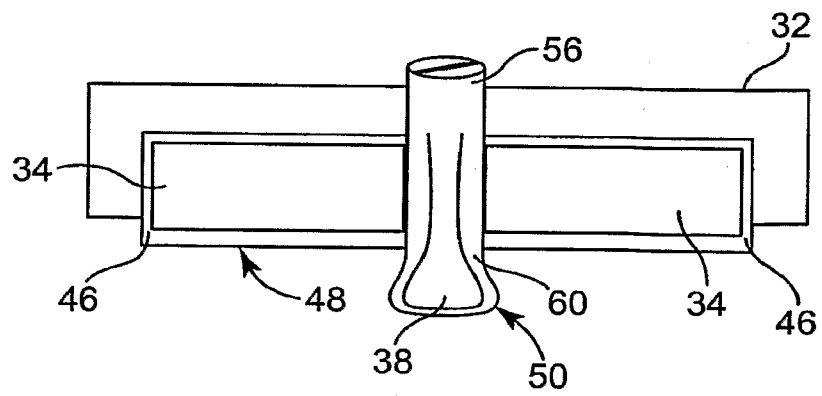


Fig. 9

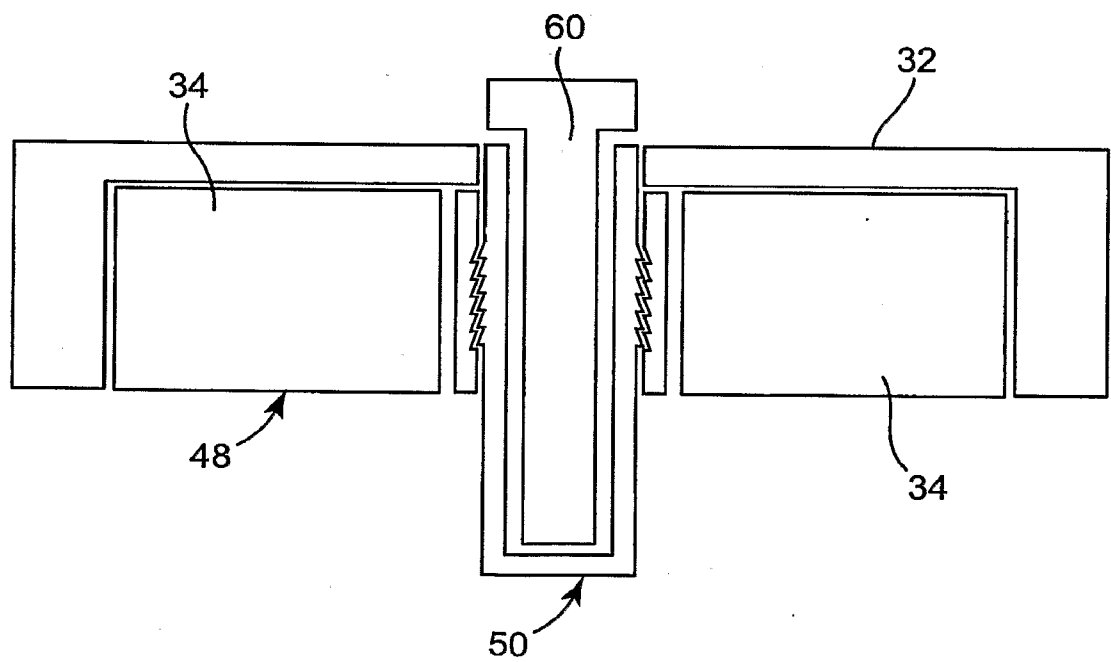


Fig. 8

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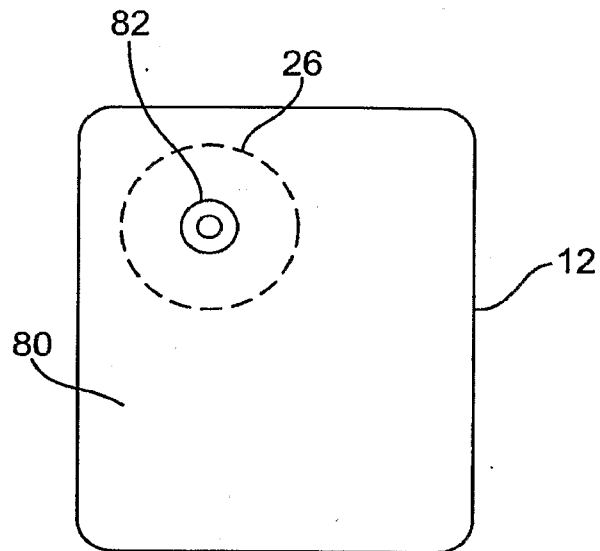


Fig. 10

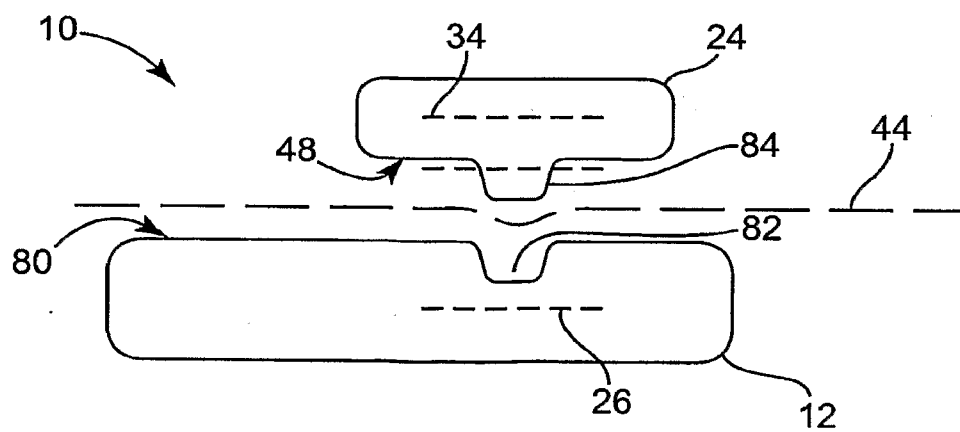


Fig. 11

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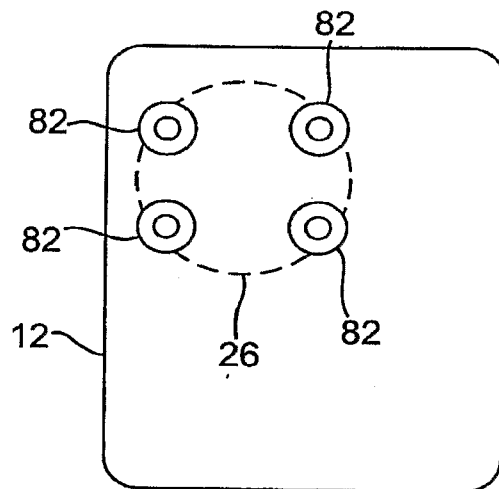


Fig. 13a

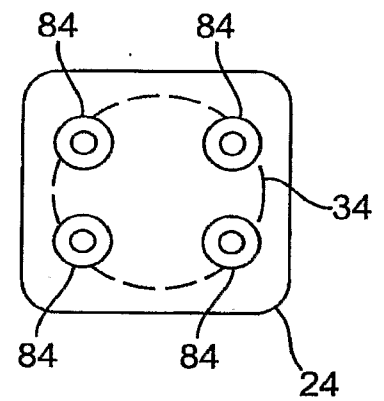


Fig. 13b

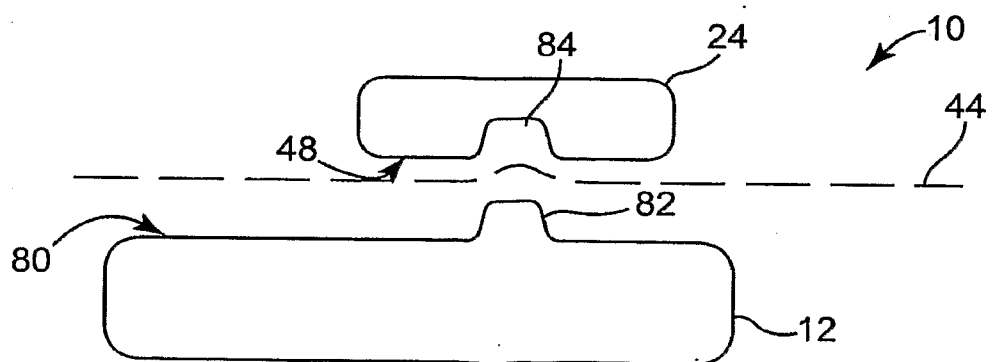


Fig. 12

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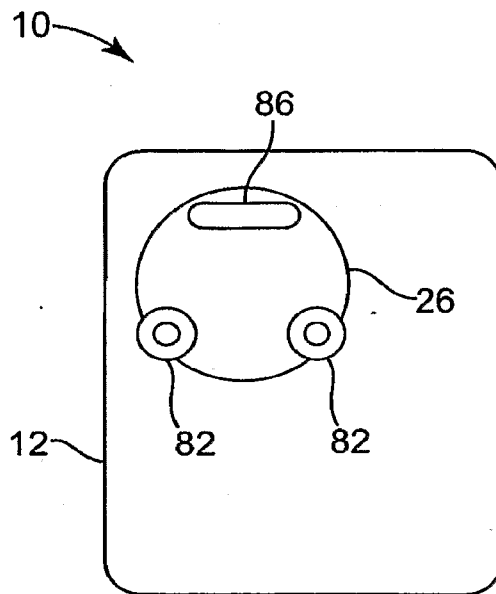


Fig. 14a

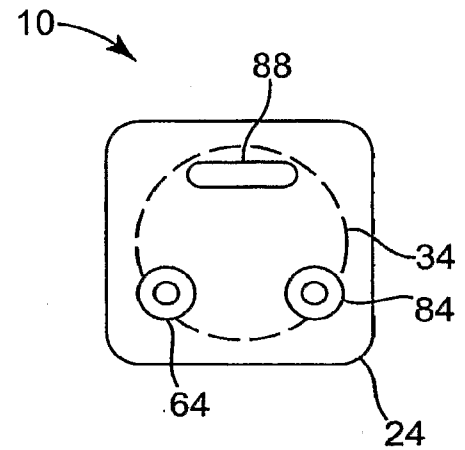


Fig. 14b

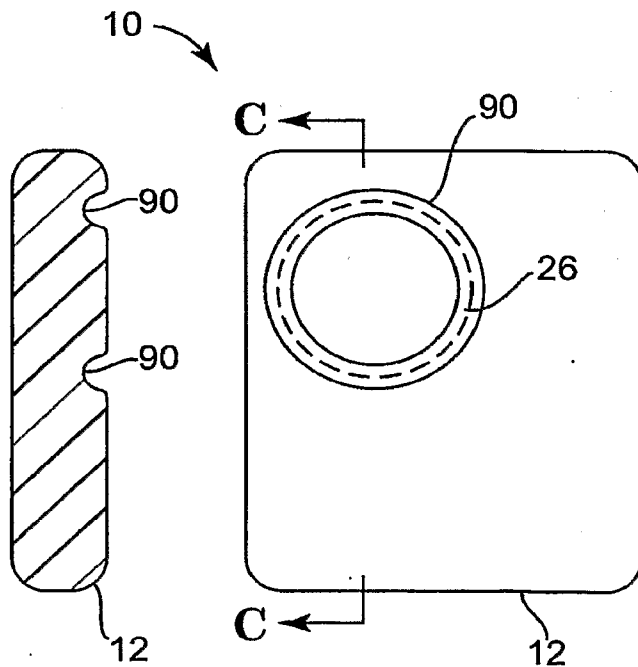


Fig. 15c **Fig. 15a**

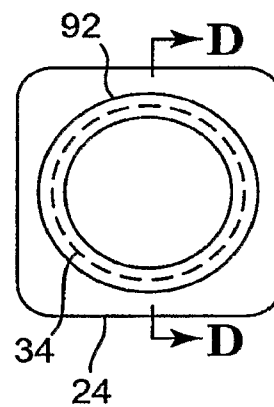


Fig. 15b

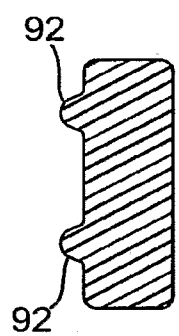


Fig. 15d

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Fig. 16



Fig. 17



Fig. 18



Fig. 19