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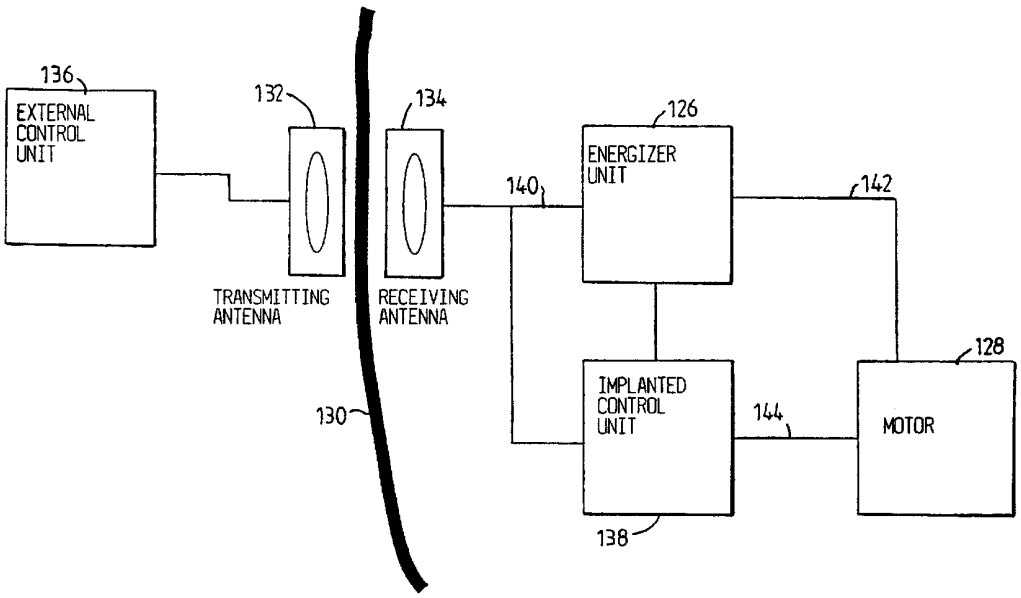

(57) Abstract: A medical implant apparatus comprises an operable medical device implanted in a patient and engaging the tissue, skeleton or an organ of the patient, or replacing an organ of the patient. A control device is provided for controlling a source of energy, which may or may not be implanted, from outside the patient's body, to release energy for use in connection with the operation of the medical device, i.e. to power the operation device.

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MEDICAL IMPLANT APPARATUS WITH CONTROLLED WIRELESS ENERGY SUPPLY

The present invention relates to a medical implant apparatus. More specifically, the invention relates to a medical implant apparatus to be implanted in a human or animal body. A medical implant medical apparatus comprising an operable medical device implanted in a patient and engaging the tissue, skeleton or an organ of the patient, or replacing an organ or function of the patient.

A control device is provided for controlling a source of energy, which may or may not be implanted, from outside the patient's body, to release energy for use in connection with the operation of the medical device, i.e. to power the operation device. If the source of energy is not implanted the control device will release wireless energy.

This energy will be released to power for example a motor or a pump, which will be able to perform a reversible function. A servo system and a gearing may also play an important part of such an implant.

One example of such a product is an apparatus for treating reflux and heartburn disease. Chronic heartburn and reflux disease is a widespread medical problem. This is often due to hiatal hernia, i.e. a portion of the stomach immediately below the gastric fundus slides upwardly through the esophageal hiatus. In consequence, stomach acids and foods are regurgitated into the esophagus.

Characteristic for these patients is the variation of their problems over the course of a day. For example, many patients have difficulties during the night when they lie down because of stomach acid leaking up into the esophagus.

To prevent this is disclosed a controlled restriction device with wireless energy supply.

The object of the present invention to provide a new convenient medical implant apparatus, the performance of which may be affected by the patient at any time after operation, in particular when various needs arise over time, so that the patient substantially always is satisfied or comfortable.

Accordingly, there is provided a medical implant apparatus, comprising an operable medical device implanted in a patient and engaging the organ and/or tissue, and/ or adapted to control bodily functions, a source of energy external to the patient's body, and a control device for releasing wireless energy from the external source of energy, wherein the released wireless energy is used in connection with the operation of the medical device.

As a result, the advantage is achieved that the implanted medical device can be non-invasively adjusted by the control device. Furthermore, the apparatus of the invention provides simple and effective control of the energy supplied to implanted components of the apparatus which ensures an extended and reliable functionality of the apparatus, possibly for the rest of the patient's natural life, and at lest many years.

The medical device preferably controls a device or a bodily function, which gives the advantage that the patient is enabled to adjust the medical or function whenever he likes. The control device may also control the medical device. The control device may comprise an internal control unit, preferably including a microprocessor, implantable in the patient for controlling the medical device. The control device may further comprise an external control unit outside the patient's body, wherein the internal control unit is programmable by the external control

unit, for example for controlling the medical device over time. Alternatively, the internal control unit may control the medical device over time in accordance with an activity schedule program, which may be adapted to the patient's needs.

A great advantage is that the patient is enabled to adjust the medical by using the control device whenever he likes during the day.

Conveniently, the external control unit may load the internal control unit with data in accordance with a loading mode only authorized for a doctor. For specialized controls of the medical device, the external control unit may control the internal control unit in accordance with a doctor mode only authorized for the doctor. For simple controls of the medical device, the external control unit may control the internal control unit in accordance with a patient mode permitted for the patient. Thus, by using the external control unit in accordance with different modes it is possible to have certains functions of the medical device controlled by the patient and other more advanced functions controlled by the doctor, which enables a flexible post-operation treatment of the patient.

The control device may be adapted to control the source of energy to release energy, for instance to intermittently release energy in the form of a train of energy pulses, for direct use in connection with the operation of the medical device. In accordance with a suitable embodiment the control device controls the source of energy to release electric energy, and the apparatus further comprises an implantable capacitor for producing the train of energy pulses from the released energy. In this case the term "direct" is used to mean, on one hand, that the released energy is used while it is being released by the control device, on the other hand, that the released energy may

be somewhat delayed, in the order of seconds, by for instance an energy stabilizer before being used in connection with the operation of the medical device.

It should be understood that the energy consuming parts of the apparatus for example a motor or pump may be or may not be energised with the unchanged wirelessly transmitted energy as this being transmitted as well as being or not being energised with energy different than the transmitted energy for example transformed into electrical energy but still directly used for energising the energy consuming parts of the apparatus as the transmitted energy is transmitted. Alternatively the energy consuming parts of the apparatus may be energised from a implanted source of energy or storage device, which still may be loaded with wireless energy. In all these aspects it is preferable to be able to wirelessly control the release of energy and get an feedback of the result of the performed function of the device. Direct use of transmitted energy may be unrelaible without a feedback what has happened, has the energy reached it's goal?

The medical device may be operable in non-manual, a non-magnetic or non-mechanical manner by use of the released energy.

In accordance with a preferred embodiment of the invention, the apparatus comprises implantable electrical components including at least one, or only one single voltage level guard and a capacitor or accumulator, wherein the charge and discharge of the capacitor or accumulator is controlled by use of the voltage level guard. As a result, there is no need for any implanted current detector and/or charge level detector for the control of the capacitor, which makes the apparatus simple and reliable.

Generally, the apparatus further comprises an operation device implantable in the patient for operating the medical

device, wherein the control device controls the operation device to operate the medical device. The control device may directly power the operation device with energy released from the source of energy and/or power other implantable energy consuming components of the apparatus. In this case the term "directly" is used to mean, on one hand, that the operation device is powered with released energy while the latter is being released by the control device, on the other hand, that the released energy may be somewhat delayed, in the order of seconds, by for instance an energy stabilizer before powering the operation device. The advantage of directly using energy as it is released is that the apparatus can be of a very simple design and the few components involved makes the apparatus reliable.

The medical device may be non-inflatable, i.e. with no hydraulic fluid involved for the adjustments of the medical device. This eliminates problems with fluid leaking from the medical device.

The operation device may comprise hydraulic means and at least one valve for controlling a fluid flow in the hydraulic means. The control device may suitably comprise a wireless remote control for controlling the valve. The medical device may comprise hydraulic means and the operation device may comprise a reservoir forming a fluid chamber with a variable volume connected to the hydraulic means. The operation device may distribute fluid from the chamber to the hydraulic means by reduction of the volume of the chamber and withdraw fluid from the hydraulic means to the chamber by expansion of the volume of the chamber.

In accordance with a first main aspect of the invention, the source of energy is external to the patient's body and the control device controls the source of energy to release wireless energy. The external source of energy may be of any conceivable

kind, such as a nuclear source of energy or a chemical source of energy.

An energy storage device, preferably an electric accumulator, may be implantable in the patient for storing the wireless energy released from the external source of energy. The electric accumulator may comprise at least one capacitor or at least one rechargeable battery, or a combination of at least one capacitor and at least one rechargeable battery. Alternatively, a battery may be implantable in the patient for supplying electric energy to implanted electric energy consuming components of the apparatus, in addition to the supply of wireless energy. Where the control device comprises an implantable control unit the electronic circuit thereof and the medical device may be directly powered with transformed wireless energy, or energy from either the implantable energy storage device or battery.

In accordance with a second main aspect of the invention, the wireless energy is directly used for operation of the medical device, i.e. the medical device is operated as the wireless energy is released from the external source of energy by the control device. In this case the term "directly" is used to mean, on one hand, that the medical device is promptly operated by using the released energy whithout first storing the latter, on the other hand, that the released energy may be somewhat delayed, in the order of seconds, by for instance an energy stabilizer before being used for the operation of the medical device. As a result, a very simple control of the medical device is achieved and there are only a few implanted components of the apparatus. For example, there is no implanted source of energy, such as a battery, nor any implanted complicated signal control system. This gives the advantage that the apparatus will be extremely reliable.

Generally, the control device controls and directly or indirectly powers the operation device with wireless energy released from the source of energy and/or powers other implanted energy consuming components of the apparatus.

In a first particular embodiment in accordance with the first and second main aspects of the invention, the operation device comprises a motor, preferably an electric motor which may have electrically conductive parts made of plastics. The motor may include a rotary motor, wherein the control device is adapted to control the rotary motor to rotate a desired number of revolutions. Alternatively, the motor may include a linear motor, or a hydraulic or pneumatic fluid motor, wherein the control device is adapted to control the fluid flow through the fluid motor. Motors currently available on the market are getting smaller and smaller. Furthermore, there is a great variety of control methods and miniaturized control equipment available. For example, a number of revolutions of a rotary motor may be analyzed by a Hall-element just a few mm in size.

In a second particular embodiment in accordance with the first and second main aspects of the invention, the control device is adapted to shift polarity of the released energy to reverse the operation device. The operation device may suitably comprise an electric motor and the released energy may comprise electric energy.

In a third particular embodiment in accordance with the first and second main aspects of the invention, the medical device is operable to perform a reversible function and there is a reversing device implantable in the patient for reversing the function performed by the medical device. Such a reversing function preferably involves enlarging and restricting a stoma opening by the medical device, suitably in a stepless manner. In this connection, the control device suitably controls the

reversing device, which may include a switch, to reverse the function performed by the medical device. The reversing device may comprise hydraulic means including a valve for shifting the flow direction of a fluid in the hydraulic means. Alternatively, the reversing device may comprise a mechanical reversing device, such as a switch or a gearbox.

Where the reversing device comprises a switch the control device suitably controls the operation of the switch by shifting polarity of released energy supplied to the switch. The switch may comprise an electric switch and the source of energy may supply electric energy for the operation of the switch. The switch mentioned above may comprise an electronic switch or, where applicable, a mechanical switch.

In accordance with the third particular embodiment, the operation device preferably comprises a motor, wherein the reversing device reverses the motor.

In a fourth particular embodiment in accordance with the first and second main aspects of the invention, the medical device comprises hydraulic means, for example including an expansible/contractible cavity for hydraulic fluid. Preferably, the operation device is adapted to conduct hydraulic fluid in the hydraulic means, and comprises a motor, a valveless fluid conduit connected to the hydraulic means of the medical device, and a reservoir for fluid, wherein the reservoir forms part of the conduit. The operation device suitably comprises a pump operated by the motor. All of the hydraulic components involved are preferably deviod of any non-return valve. This is of great advantage, because with valves involved there is always a risk of malfunction due to inproperly working valves, especially when long time periods passes between valve operations. The reservoir may form a fluid chamber with a variable volume, and the pump may distribute fluid from the chamber to the hydraulic means of the

medical device by reduction of the volume of the chamber and withdraw fluid from the hydraulic means to the chamber by expansion of the volume of the chamber.

Preferable the present invention provides an a treatment medical, which is able to perform a reversible function to adjust said adjustment device.

Alternatively, or in combination with a powered operation device, the servo means may be used, which enables manual manipulation without need for strong manipulation forces. The servo means may comprise hydraulic means, electric control means, magnetic means, or mechanical means, which may be activated by manual manipulating means. Using a servo system will save the use of force when adjusting the adjustment device, which may be of importance in many applications.

The term "servo means" encompasses the normal definition of a servo mechanism, i.e. an automatic device that controls large amounts of power by means of very small amounts of power, but may alternatively or additionally encompass the definition of a mechanism that transfers a weak force acting on a moving element having a long stroke into a strong force acting on another moving element having a short stroke. The servo means may comprise a motor, preferably an electric motor, which may be reversible and/or include a gearing.

Another alternative is a pump pumping in only one direction and an adjustable valve to change the direction of fluid to either increase or decrease the amount of fluid in the reservoir. This valve may be manipulated either manually, mechanically, magnetically, or hydraulically.

The main embodiment of the invention described above including the reservoir may alternatively be equipped with a servo means comprising a reverse servo. The term "reverse servo" is to be understood as a mechanism that transfers a strong force

acting on a moving element having a short stroke into a weak force acting on another moving element having a long stroke; i.e. the reverse function of the above-defined alternative mechanism of a normal servo mechanism. A first closed hydraulic system that controls another closed hydraulic system in which hydraulic means of the adjustment device is incorporated may be used. Minor changes in the amount of fluid in a smaller reservoir of the first system could then be transferred by the reverse servo into major changes in the amount of fluid in a larger reservoir in the second system. In consequence, the change of volume in the larger reservoir of the second system affects the hydraulic means of the adjustment device. For example, a short stroke that decreases the volume of the smaller reservoir will cause the larger reservoir to supply the adjustment device with a large amount of hydraulic fluid, which in turn results in a long mechanical adjustment stroke on the restriction device.

The great advantage of using such a reverse servo is that the larger volume system could be placed inside the abdomen or retroperitoneum where there is more space and still it would be possible to use manual manipulation means of the smaller system subcutaneously. The smaller reservoir could be controlled directly or indirectly by a fluid supply means. The fluid supply means may include another small reservoir, which may be placed subcutaneously and may be activated by manual manipulation means. Both the normal servo means and the specific reverse servo may be used in connection with all of the various components and solutions described in the present specification.

Thus, the reverse servo may be adapted to provide relative displacement between the first and second wall portions of the reservoir, suitably in response to the pressure in the reservoir, in order to change the volume of the chamber of the reservoir.

Generally, the servo means, including the reverse servo,

comprises a pressure controlled servo means. The alarm mentioned above may alternatively be adapted to generate an alarm signal in response to the lapse of a predetermined time period during which the pressure controlling the servo means exceeds a predetermined high value.

The reverse servo may comprise magnetic means, electric means or manual manipulation means or a combination thereof. Preferably, however, the reverse servo comprises hydraulic means.

In accordance with a particular embodiment of the invention, the reverse servo further comprises a servo reservoir defining a chamber containing servo fluid, and the operation device comprise first and second wall portions of the servo reservoir, which are displaceable relative to each other to change the volume of the chamber of the servo reservoir. The first and second wall portions of the servo reservoir may be displaceable relative to each other by magnetic means, hydraulic means, or electric control means.

Where the reverse servo comprises hydraulic means it may further comprise a fluid supply reservoir connected to the servo reservoir in a closed system and containing a further predetermined amount of fluid. The fluid supply reservoir defines a chamber for the further predetermined amount of fluid and the operation device is adapted to change the volume of the chamber and thereby control the amount of fluid in the servo reservoir. The fluid supply reservoir comprises first and second wall portions, which are displaceable relative to each other to change the volume of the chamber of the fluid supply reservoir. Suitable, the fluid supply reservoir increases the amount of fluid in the servo reservoir in response to a predetermined first displacement of the first wall portion of the fluid supply reservoir relative to the second wall portion of the fluid supply reservoir and decreases the amount of fluid in the servo

reservoir in response to a predetermined second displacement of the first wall portion of the fluid supply reservoir relative to the second wall portion of the fluid supply reservoir.

In accordance with a third main aspect of the invention, the source of energy is implantable in the patient. Thus, when the source of energy is implanted in a patient the control device controls it from outside the patient's body to release energy. This solution is advantageous for embodiments of the apparatus that have a relatively high consumption of energy which cannot be satisfied by direct supply of wireless energy.

The implantable source of energy may comprise an accumulator, preferably an electric source of energy, such as a battery having a lifetime of at least 10 years.

In accordance with a fourth main aspect of the invention, the apparatus comprises a switch implanted in the patient for directly or indirectly switching the operation of the medical device and an internal source of energy, such as a battery, implanted in the patient for supplying energy for the operation of the medical device, wherein the switch directly or indirectly affects the supply of energy from the internal source of energy. This solution is advantageous for embodiments of the apparatus that have a relatively high energy consumption which cannot be met by direct supply of wireless energy.

In a first particular embodiment in accordance with the fourth main aspect of the invention, the switch switches between an off mode, in which the internal source of energy is not in use, and an on mode, in which the internal source of energy supplies energy for the operation of the medical device. In this case, the switch is conveniently operated by the wireless energy released from the external source of energy to switch between the on and off modes. The control device, preferably comprising a wireless remote control, may control the external source of

energy to release the wireless energy. The advantage of this embodiment is that the lifetime of the implanted source of energy, such as a battery, can be significantly prolonged, since the implanted source of energy does not supply energy when the switch is in its off mode.

In a second particular embodiment in accordance with the fourth main aspect of the invention, the control device comprises a wireless remote control for controlling the internal source of energy. In this case, the switch is operable by the wireless energy from the external source of energy to switch between an off mode, in which the internal source of energy and remote control are not in use, and a standby mode, in which the remote control is permitted to control the internal source of energy to supply energy for the operation of the medical device.

In a third particular embodiment in accordance with the fourth main aspect of the invention, the apparatus further comprises an energy transforming device implanted in the patient for transforming the wireless energy into storable energy, wherein the internal source of energy is capable of storing the storable energy. The internal source of energy preferably comprises an electric accumulator, at least one capacitor or at least one rechargeable battery, or a combination of at least one capacitor and at least one rechargeable battery. In this case, the switch switches from an off mode, in which the internal source of energy is not in use, to an on mode, in which the internal source of energy supplies energy for the operation of the medical device.

The control device, preferably comprising a wireless remote control, may control the switch to switch between the on and off modes.

Alternatively, in this third particular embodiment an energy storage device may be implanted in the patient for storing the

storable energy instead of the internal source of energy, wherein the switch is operable by energy from the implanted energy storage device to switch between an off mode, in which the internal source of energy is not in use, and an on mode, in which the internal source of energy supplies energy for the operation of the medical device. In this case, the control device (the wireless remote control) controls the energy storage device to operate the switch.

The internal source of energy preferably comprises an electric source of energy, such as an accumulator or a battery having a lifetime of at least 10 years. However, other kinds of sources are also conceivable, such as a nuclear source of energy or a chemical source of energy.

The above first, second, third and fourth particular embodiments described in connection with the first and second main aspects of the invention are also applicable in accordance with the third main aspect of the invention, i.e. where the source of energy is implantable, and in accordance with the fourth main aspect of the invention, i.e. where the apparatus comprises an implantable switch.

All of the above embodiments may be combined with at least one implantable sensor for sensing at least one physical parameter of the patient, wherein the control device may control the medical device in response to signals from the sensor. For example, the sensor may comprise a pressure sensor for directly or indirectly sensing the pressure in the stomach or esophagus. The expression "indirectly sensing the pressure in the tissue or organ" should be understood to encompass the cases where the sensor senses the pressure against the medical device or human tissue of the patient. Where the control device comprises an internal control unit to be implanted in the patient, the internal control unit may suitably directly control the medical

device in response to signals from the sensor. In response to signals from the sensor, for example pressure, the patient's position or any other important physical parameter, the internal control unit may send information thereon to outside the patient's body. The control unit may also automatically control the medical device in response to signals from the sensor. For example, the control unit may control the medical device to further restrict a stoma opening in the patient in response to the sensor sensing that the patient is lying, or enlarge the stoma opening in response to the sensor sensing an abnormally high pressure against the medical device.

Where the control device comprises an external control unit outside the patient's body, the external control unit may, suitably directly, control the medical device in response to signals from the sensor. The external control unit may store information on the physical parameter sensed by the sensor and may be manually operated to control the medical device based on the stored information. In addition, there may be at least one implantable sender for sending information on the physical parameter sensed by the sensor.

An external data communicator may be provided outside the patient's body and an internal data communicator to be implanted in the patient may be provided for communicating with the external data communicator. The internal data communicator may feed data related to the patient, or related to the medical device, back to the external data communicator. Alternatively or in combination, the external data communicator may feed data to the internal data communicator. The internal data communicator may suitably feed data related to at least one physical signal of the patient.

Generally, the apparatus of the invention may comprise a switch implantable in the patient for directly or indirectly

switching the energy released from the source of energy. For example, the medical device may be operable to open and close a stoma opening or may steplessly control the size of the stoma opening. A pressure sensor may be provided for directly or indirectly sensing the pressure in the tissue or organ. The control device may control the medical device in response to signals from the pressure sensor.

The apparatus may comprise an implantable energy transforming device, wherein the control device releases electric energy and the energy transforming device transforms the electric energy into kinetic energy for, preferably direct, operation of the medical device. Suitably, an implantable stabilizer, such as a capacitor or a rechargeable accumulator, or the like, may be provided for stabilizing the electric energy released by the control device. In addition, the control device may control the source of energy to release energy for a determined time period or in a determined number of energy pulses. Finally, the medical device may be non-inflatable.

All of the above embodiments are preferably remote controlled. Thus, the control device advantageously comprises a wireless remote control transmitting at least one wireless control signal for controlling the medical device. With such a remote control it will be possible to adapt the function of the apparatus to the patient's need in a daily basis, which is beneficial with respect to the treatment of the patient.

The wireless remote control may be capable of obtaining information on the condition of the medical device and of controlling the medical device in response to the information. Also, The remote control may be capable of sending information related to the medical device from inside the patient's body to the outside thereof.

In a particular embodiment of the invention, the wireless

remote control comprises at least one external signal transmitter or transceiver and at least one internal signal receiver or transceiver implantable in the patient. In another particular embodiment of the invention, the wireless remote control comprises at least one external signal reciever or transceiver and at least one internal signal transmitter or transceiver implantable in the patient.

The remote control may transmit a carrier signal for carrying the control signal, wherein the carrier signal is frequency, amplitude or frequency and amplitude modulated and is digital, analog or digital and analog. Also the control signal used with the carrier signal may be frequency, amplitude or frequency and amplitude modulated.

The control signal may comprise a wave signal, for example, a sound wave signal, such as an ultrasound wave signal, an electromagnetic wave signal, such as an infrared light signal, a visible light signal, an ultra violet light signal, a laser signal, a micro wave signal, a radio wave signal, an x-ray radiation signal, or a gamma radiation signal. Where applicable, two or more of the above signals may be combined.

The control signal may be digital or analog, and may comprise an electric or magnetic field. Suitably, the wireless remote control may transmit an electromagnetic carrier wave signal for carrying the digital or analog control signal. For example, use of an analog carrier wave signal carrying a digital control signal would give safe communication. The control signal may be transmitted in pulses by the wireless remote control.

In all of the above solutions, the control device advantageously releases energy from the source of energy in a non-invasive, magnetic, non-magnetic, mechanical or non-mechanical manner.

The control device may release magnetic, electromagnetic,

kinetic, sonic or thermal energy, or non-magnetic, non-sonic, non-thermal, non-electromagnetic or non-kinetic energy.

The control device may be activated in a manual or non-manual manner to control the source of energy to release energy.

The operation device may be powered by magnetic energy, non-magnetic energy, electromagnetic energy, non-electromagnetic energy, kinetic energy, non-kinetic energy, thermal energy or non-thermal energy. However, preferably the operation device comprises an electrical operation device.

Typically the apparatus of the invention comprises an adjustment device for adjusting the medical device to change the size of a stoma opening. The adjustment device may be adapted to mechanically adjust the medical device. Alternatively, the adjustment device may be adapted to hydraulically adjust the medical device by using hydraulic means which is devoid of hydraulic fluid of the kind having a viscosity that substantially increases when exposed to heat or a magnetic field, i.e. the hydraulic fluid would not become more viscous when exposed to heat or influenced by magnetic forces.

The above-presented embodiments of the invention may be modified in accordance with the following suggestions. The released energy may comprise electric energy and an implantable capacitor having a capacity less than 0,1 μF may be provided for producing the above-mentioned train of energy pulses.

An implantable motor or pump may be provided for operating the medical device, wherein the control device is adapted to control the source of energy to directly power the motor or pump with the released energy. Specifically, the control device may be adapted to release wireless energy in the form of a magnetic field or electromagnetic waves (excluding radio waves) for direct power of the motor or pump, as the wireless energy is being released. Where a pump is used it preferably is not a plunger

type of pump.

Generally, the wireless energy comprises a signal.

The apparatus may further comprise implantable energy transforming device for transforming wireless energy directly or indirectly into energy different than the wireless energy, for operation of the medical device. For example, the motor or pump may be powered by the transformed energy.

The energy transforming device may transform the wireless energy in the form of sound waves, preferably directly, into electric energy for operation of the medical device. The energy transforming device may comprise a capacitor adapted to produce electric pulses from the transformed electric energy.

Generally, the medical device advantageously is embedded in a soft or gel-like material, such as a silicone material having hardness less than 20 Shore.

Of course, the medical device preferably is adjustable in a non-manual manner.

All the above described various components, such as the motor, pump and capacitor, may be combined in the different embodiments where applicable. Also the various functions described in connection with the above embodiments of the invention may be used in different applications, where applicable.

All the various ways of transferring energy and controlling the energy presented in the present specification may be practised by using all of the various components and solutions described.

The present invention also provides methods for treating obese patients.

According to yet another aspect of the present invention there is provided a method of treating a human or animal having a disease, comprising surgically implanting in the human or

animal an operable medical device, providing a source of energy external to the human's or animal's body, controlling the external source of energy from outside the the human's or animal's body to release wireless energy, and using the released wireless energy in connection with the operation of the medical device. The method may further comprise implanting in the human or animal an operation device which can adjust the medical device in response to supplied energy, and using the released wireless energy to activate the implanted operation device to operate the medical device.

In accordance with another alternative method, there is provided a method of treating a human or animal having a disease, comprising the steps of placing at least two laparascopical trocars in the human's or animal's body , inserting a dissecting tool through the trocars and dissecting a region of the patient, implanting an operable medical device in the dissected area by using the trocars, providing a source of energy outside the human's or animal's body, controlling the external source of energy from outside the human's or animal's body to release wireless energy, and using the released wireless energy in connection with the operation of the medical device.

It is the primary object of the present invention to provide a simple yet effective method and apparatus for treating diseases in humans or animals. This and other objects of the invention will become clear from an inspection of the detailed description of the invention and from the appended claims.

FIGURES 1 to 6 are schematic block diagrams illustrating six embodiments, respectively, of the invention, in which wireless energy is released from an external source of energy;

FIGURES 7 to 10 are schematic block diagrams illustrating

four embodiments, respectively, of the invention, in which energy is released from an implanted source of energy;

FIGURES 11 to 15 are schematic block diagrams illustrating five embodiments, respectively, of the invention, in which a switch is implanted in the patient for directly or indirectly switching the operation of the restriction device;

FIGURE 16 is a schematic block diagram illustrating conceivable combinations of implantable components for achieving various communication options;

FIGURE 17 illustrates the apparatus in accordance with the invention implanted in a patient;

FIGURE 18 is a block diagram illustrating remote control components of an embodiment of the invention; and

FIGURE 19 is a schematic view of exemplary circuitry used for the components of the block diagram of FIGURE 18.

Referring to the drawing figures, like reference numerals designate identical or corresponding elements throughout the several figures.

FIGURE 1 schematically shows an exemplary embodiment of the medical implant apparatus of the invention having some parts implanted in a patient and other parts located outside the patient's body. In this example the apparatus comprises a heartburn and reflux disease apparatus in which the medical device comprises a restriction device 4. Thus, in FIGURE 1 all parts placed to the right of the patient's skin 2 are implanted and all parts placed to the left of the skin 2 are located outside the patient's body. The restriction device 4 engages the patient's stomach close to the cardia (or alternatively engages the esophagus) to form a restricted food passageway in the stomach. The restriction device 4 is capable of performing a reversible function, *i.e.* to enlarge and reduce the cross-

sectional area of the food passageway, whereby the restriction device works as an artificial sphincter. An implanted control unit 6 controls the restriction device 4 via a control line 8 to form an adequate size of the cross-sectional area of the restricted food passageway. An external control unit 10 includes an external source of energy and a wireless remote control transmitting a control signal generated by the external source of energy. The control signal is received by a signal receiver incorporated in the implanted control unit 6, whereby the control unit 6 controls the implanted restriction device 4 in response to the control signal. The implanted control unit 6 also uses energy from the control signal for operating the restriction device 4 via a power supply line 12.

FIGURE 2 shows an embodiment of the invention identical to that of FIGURE 1, except that a reversing device in the form of a switch 14 operable by energy also is implanted in the patient for reversing the restriction device 4. The control unit 6 uses the switch 14 to reverse the function performed by the restriction device 4. More precisely, the external control unit 10 releases energy carried by a wireless signal and the implanted control unit 6 transforms the wireless energy into a current for operating the switch 14. When the control unit 6 shifts the polarity of the current the switch 14 reverses the function performed by the restriction device 4.

FIGURE 3 shows an embodiment of the invention identical to that of FIGURE 1, except that an operation device in the form of a motor 16 also is implanted in the patient. The implanted control unit 6 powers the motor 16 with wireless energy released from the external source of energy of the external control unit 10. The implanted control unit 6 controls the operation of the motor 16 in response to a control signal from the remote control of the external control unit 10.

FIGURE 4 shows an embodiment of the invention identical to that of FIGURE 1, except that an assembly 16 including a motor/pump unit 18 and a fluid reservoir 20 also is implanted in the patient. In this case the restriction device 4 is hydraulically operated, *i.e.* hydraulic fluid is pumped by the motor/pump unit 18 from the reservoir 20 through a conduit 22 to the restriction device 4 to reduce the cross-sectional area of the food passageway, and hydraulic fluid is pumped by the motor/pump unit 18 back from the restriction device 4 to the reservoir 20 to enlarge the cross-sectional area. The external control unit 10 releases energy carried by a wireless signal and the implanted control unit 6 transforms the wireless energy into a current, for example a current, for powering the motor/pump unit 18 via an electric power supply line 24. The implanted control unit 6 controls the motor/pump unit 16 and the restriction device 4 via control lines 26 and 27.

FIGURE 5 shows an embodiment of the invention comprising the restriction device 4, hydraulically operated, and the implanted control unit 6, and further comprising a hydraulic fluid reservoir 230, a motor/pump unit 232 and a reversing device in the form of a hydraulic valve shifting device 234, all of which are implanted in the patient. The motor of the motor/pump unit 232 is an electric motor.

FIGURE 6 shows an embodiment of the invention identical to that of FIGURE 1, except that an accumulator 28 also is implanted in the patient. The control unit 6 stores energy received from the external control unit 10 in the accumulator 28. In response to a control signal from the external control unit 10 the implanted control unit 6 releases energy from the accumulator 28 via a power line 30 for the operation of the restriction device 4.

FIGURE 7 shows an embodiment of the invention comprising the

restriction device 4, hydraulically operated, and the implanted control unit 6, and further comprising a source of energy in the form of a battery 32, a hydraulic fluid reservoir 34, a motor/pump unit 36 and a reversing device in the form of a hydraulic valve shifting device 38, all of which are implanted in the patient. The motor of the motor/pump unit 36 is an electric motor. An external control unit 40 includes a wireless remote control transmitting a control signal which is received by the signal receiver incorporated in the implanted control unit 6.

In response to a control signal from the external control unit 40 the implanted control unit 6 powers the motor/pump unit 36 with energy from the battery 32, whereby the motor/pump unit 36 distributes hydraulic fluid between the reservoir 34 and the restriction device 4. The control unit 6 controls the shifting device 38 to shift the hydraulic fluid flow direction between one direction in which the fluid is pumped by the motor/pump unit 36 from the reservoir 34 to the restriction device 4 to reduce the cross-sectional area of the food passageway, and another opposite direction in which the fluid is pumped by the motor/pump unit 36 back from the restriction device 4 to the reservoir 34 to enlarge the cross-sectional area.

FIGURE 8 shows an embodiment of the invention identical to that of FIGURE 6, except that a battery 42 is substituted for the accumulator 28, the external control unit 40 of the embodiment of FIGURE 5 is substituted for the external control unit 10 and an electric motor 44 is implanted in the patient for operating the restriction device 4. In response to a control signal from the external control unit 40 the implanted control unit 6 powers the motor 44 with energy from the battery 42, whereby the motor 44 operates the restriction device 4.

FIGURE 9 shows an embodiment of the invention identical to

that of FIGURE 8, except that the motor/pump unit 36 of the embodiment of FIGURE 7 is substituted for the motor 44 and a fluid reservoir 46 also is implanted in the patient. The reservoir 46 is via fluid conduits 48 and 50 connected to the motor/pump unit 36 and restriction device 4, which in this case is hydraulically operated. In response to a control signal from the external control unit 40, the implanted control unit 6 powers the electric motor of the motor/pump unit 36 with energy from the battery 42, whereby the motor/pump unit 36 distributes hydraulic fluid between the fluid reservoir 46 and the restriction device 4.

FIGURE 10 shows an embodiment of the invention identical to that of FIGURE 8, except that a mechanical reversing device in the form of a gearbox 52 also is implanted in the patient. The implanted control unit 6 controls the gearbox 52 to reverse the function performed by the restriction device 4 (mechanically operated).

FIGURE 11 shows an embodiment of the invention comprising the restriction device 4, the external control unit 10, an implanted source of energy 236 and an implanted switch 238. The switch 238 is operated by wireless energy released from the external source of energy of the external control unit 6 to switch between an off mode, in which the implanted source of energy 236 is not in use, and an on mode, in which the implanted source of energy 236 supplies energy for the operation of the restriction device 4.

FIGURE 12 shows an embodiment of the invention identical to that of FIGURE 11, except that also the control unit 6 is implanted, in order to receive a control signal from the wireless remote control of the external control unit 10. The switch 238 is operated by the wireless energy from the external source of energy 10 to switch between an off mode, in which the implanted

source of energy 236 and the wireless remote control of the external control unit 10 are not in use, *i.e.* the control unit 6 is not capable of receiving the control signal, and a standby mode, in which the wireless remote control is permitted to control the internal source of energy 236, via the implanted control unit 6, to supply energy for the operation of the restriction device 4.

FIGURE 13 shows an embodiment of the invention identical to that of FIGURE 12, except that an energy transforming device for transforming the wireless energy into storable energy is incorporated in the implanted control unit 6 and that the implanted source of energy 236 is of a type that is capable of storing the storable energy. In this case, in response to a control signal from the external control unit 10, the implanted control unit 6 controls the switch 238 to switch from an off mode, in which the implanted source of energy 236 is not in use, to an on mode, in which the source of energy 36 supplies energy for the operation of the restriction device 4.

FIGURE 14 shows an embodiment of the invention identical to that of FIGURE 13, except that an energy storage device 240 also is implanted in the patient for storing the storable energy transformed from the wireless energy by the transforming device of the control unit 6. In this case, the implanted ontrol unit 6 controls the energy storage device 240 to operate the switch 238 to switch between an off mode, in which the implanted source of energy 236 is not in use, and an on mode, in which the implanted source of energy 236 supplies energy for the operation of the restriction device 4.

FIGURE 15 shows an embodiment of the invention identical to that of FIGURE 13, except that a motor 242 and a mechanical reversing device in the form of a gearbox 244 also are implanted in the patient. The implanted control unit 6 controls the gearbox

244 to reverse the function performed by the restriction device 4 (mechanically operated), i.e. enlarging and restricting the food passageway.

FIGURE 16 schematically shows conceivable combinations of implanted components of the apparatus for achieving various communication possibilities. Basically, there are the implanted restriction device 4, the implanted control unit 6 and the external control unit 10 including the external source of energy and the wireless remote control. As already described above the remote control transmits a control signal generated by the external source of energy, and the control signal is received by a signal receiver incorporated in the implanted control unit 6, whereby the control unit 6 controls the implanted restriction device 4 in response to the control signal.

A sensor 54 may be implanted in the patient for sensing a physical parameter of the patient, such as the pressure in the food passageway. The control unit 6, or alternatively the external control unit 10, may control the restriction device 4 in response to signals from the sensor 54. A transceiver may be combined with the sensor 54 for sending information on the sensed physical parameter to the external control unit 10. The wireless remote control of the external control unit 10 may comprise a signal transmitter or transceiver and the implanted control unit 6 may comprise a signal receiver or transceiver. Alternatively, the wireless remote control of the external control unit 10 may comprise a signal receiver or transceiver and the implanted control unit 6 may comprise a signal transmitter or transceiver. The above transceivers, transmitters and receivers may be used for sending information or data related to the restriction device from inside the patient's body to the outside thereof.

The motor 44 may be implanted for operating the restriction device 4 and also the battery 32 may be implanted for powering

the motor 44. The battery 32 may be equipped with a transceiver for sending information on the charge condition of the battery.

Those skilled in the art will realize that the above various embodiments according to FIGURES 1-15 could be combined in many different ways. For example, the energy operated switch 14 could be incorporated in any of the embodiments of FIGURES 4,6,8-10. The hydraulic shifting device 38 could be incorporated in any of the embodiments of FIGURES 4 and 9. The gearbox 52 could be incorporated in any of the embodiments of FIGURES 1,6 and 8.

FIGURE 17 illustrates how any of the above-described embodiments of the heartburn and reflux disease treatment apparatus of the invention may be implanted in a patient. Thus, an assembly of the apparatus implanted in the patient comprises a restriction device 56 engaging the esophagus 58 close to the cardia, and an operation device 60 for operating the restriction device 56 and an internal control unit 62, which includes a signal receiver, for controlling the operation device 60. An external control unit 64 includes a signal transmitter for transmitting a control signal to the signal receiver of the implanted control unit 62. The implanted control unit 62 is capable of transforming signal energy from the control signal into electric energy for powering the operation device 60 and for energizing energy consuming implanted components of the apparatus.

FIGURE 18 shows the basic parts of a wireless remote control of the apparatus of the invention including an electric motor 128 for operating a restriction member, for example of the type illustrated in FIGURE 17. In this case, the remote control is based on the transmission of electromagnetic wave signals, often of high frequencies in the order of 100 kHz - 1 gHz, through the skin 130 of the patient. In FIGURE 18, all parts placed to the left of the skin 130 are located outside the patient's body and

all parts placed to the right of the skin 130 are implanted . Any suitable remote control system may be used.

An external signal transmitting antenna 132 is to be positioned close to a signal receiving antenna 134 implanted close to the skin 130. As an alternative, the receiving antenna 134 may be placed for example inside the abdomen of the patient. The receiving antenna 134 comprises a coil, approximately 1-100 mm, preferably 25 mm in diameter, wound with a very thin wire and tuned with a capacitor to a specific high frequency. A small coil is chosen if it is to be implanted under the skin of the patient and a large coil is chosen if it is to be implanted in the abdomen of the patient. The transmitting antenna 132 comprises a coil having about the same size as the coil of the receiving antenna 134 but wound with a thick wire that can handle the larger currents that is necessary. The coil of the transmitting antenna 132 is tuned to the same specific high frequency as the coil of the receiving antenna 134.

An external control unit 136 comprises a microprocessor, a high frequency electromagnetic wave signal generator and a power amplifier. The microprocessor of the control unit 136 is adapted to switch the generator on/off and to modulate signals generated by the generator to send digital information via the power amplifier and the antennas 132,134 to an implanted control unit 138. To avoid that accidental random high frequency fields trigger control commands, digital signal codes are used. A conventional keypad placed on the external control unit 136 is connected to the microprocessor thereof. The keypad is used to order the microprocessor to send digital signals to either contract or enlarge the restriction device. The microprocessor starts a command by applying a high frequency signal on the antenna 132. After a short time, when the signal has energized the implanted parts of the control system, commands are sent to

contract or enlarge the restriction device in predefined steps. The commands are sent as digital packets in the form illustrated below.

Start pattern, 8 bits	Command, 8 bits	Count, 8 bits	Checksum, 8 bits

The commands are sent continuously during a rather long time period (*e.g.* about 30 seconds or more). When a new contract or enlarge step is desired the Count byte is increased by one to allow the implanted control unit 138 to decode and understand that another step is demanded by the external control unit 136. If any part of the digital packet is erroneous, its content is simply ignored.

Through a line 140, an implanted energizer unit 126 draws energy from the high frequency electromagnetic wave signals received by the receiving antenna 134. The energizer unit 126 stores the energy in a power supply, such as a large capacitor, powers the control unit 138 and powers the electric motor 128 via a line 142.

The control unit 138 comprises a demodulator and a microprocessor. The demodulator demodulates digital signals sent from the external control unit 136. The microprocessor of the control unit 138 receives the digital packet, decodes it and, provided that the power supply of the energizer unit 126 has sufficient energy stored, sends a signal via a signal line 144 to the motor 128 to either contract or enlarge the restriction device depending on the received command code.

Alternatively, the energy stored in the power supply of the energizer unit may only be used for powering a switch, and the energy for powering the motor 128 may be obtained from another

implanted power source of relatively high capacity, for example a battery. In this case the switch is adapted to connect said battery to the control unit 138 in an on mode when said switch is powered by said power supply and to keep said battery disconnected from the control unit in a standby mode when said switch is unpowered.

With reference to FIGURE 19, the remote control schematically described above will now be described in accordance with a more detailed embodiment. The external control unit 136 comprises a microprocessor 146, a signal generator 148 and a power amplifier 150 connected thereto. The microprocessor 146 is adapted to switch the signal generator 148 on/off and to modulate signals generated by the signal generator 148 with digital commands that are sent to implanted components of the apparatus. The power amplifier 150 amplifies the signals and sends them to the external signal transmitting antenna 132. The antenna 132 is connected in parallel with a capacitor 152 to form a resonant circuit tuned to the frequency generated by the signal generator 148.

The implanted signal receiving antenna coil 134 forms together with a capacitor 154 a resonant circuit that is tuned to the same frequency as the transmitting antenna 132. The signal receiving antenna coil 134 induces a current from the received high frequency electromagnetic waves and a rectifying diode 160 rectifies the induced current, which charges a storage capacitor 158. A coil 156 connected between the antenna coil 134 and the diode 160 prevents the capacitor 158 and the diode 160 from loading the circuit of the signal receiving antenna 134 at higher frequencies. Thus, the coil 156 makes it possible to charge the capacitor 158 and to transmit digital information using amplitude modulation.

A capacitor 162 and a resistor 164 connected in parallel and

a diode 166 forms a detector used to detect amplitude modulated digital information. A filter circuit is formed by a resistor 168 connected in series with a resistor 170 connected in series with a capacitor 172 connected in series with the resistor 168 via ground, and a capacitor 174, one terminal of which is connected between the resistors 168,170 and the other terminal of which is connected between the diode 166 and the circuit formed by the capacitor 162 and resistor 164. The filter circuit is used to filter out undesired low and high frequencies. The detected and filtered signals are fed to an implanted microprocessor 176 that decodes the digital information and controls the motor 128 via an H-bridge 178 comprising transistors 180,182,184 and 186. The motor 128 can be driven in two opposite directions by the H-bridge 178.

The microprocessor 176 also monitors the amount of stored energy in the storage capacitor 158. Before sending signals to activate the motor 128, the microprocessor 176 checks whether the energy stored in the storage capacitor 158 is enough. If the stored energy is not enough to perform the requested operation, the microprocessor 176 waits for the received signals to charge the storage capacitor 158 before activating the motor 128.

CLAIMS.

1. A medical implant apparatus comprising: an operable medical device implanted in a patient and engaging the tissue, skeleton or an organ of the patient, or replacing an organ of the patient, a source of energy, and a control device operable from outside the patient's body for controlling the source of energy to release energy for use in connection with the operation of the medical device, when the medical device is implanted.

2. An apparatus according to claim 1, wherein the source of energy is intended to be external to the patient's body when the medical device is implanted therein, and the control device is adapted to control the external source of energy to release wireless energy for use in connection with the operation of the medical device.

3. An apparatus according to claim 1 or 2, wherein the control device controls the medical device.

4. An apparatus according to claim 3, wherein the control device comprises an internal control unit implantable in the patient for controlling the medical device.

5. An apparatus according to claim 4, wherein the internal control unit is programmable.

6. An apparatus according to claim 5, wherein the control device comprises an external control unit intended to be outside the patient's body, the internal control unit being programmable by the external control unit.

7. An apparatus according to claim 5, wherein the internal control unit is programmable for controlling the medical device over time.

8. An apparatus according to claim 7, wherein the internal control unit controls the medical device over time in accordance with an activity schedule program.

9. An apparatus according to claim 7, wherein the internal control unit comprises a microprocessor.

10. An apparatus according to claim 6, wherein the external control unit loads the internal control unit with data in accordance with a loading mode only authorized for a doctor.

11. An apparatus according to claim 6, wherein the external control unit controls the internal control unit in accordance with a doctor mode only authorized for a doctor.

12. An apparatus according to claim 6, wherein the external control unit controls the internal control unit in accordance with a patient mode permitted for the patient.

13. An apparatus according to claim 1, wherein the source of energy is implantable in the patient.

14. An apparatus according to claim 13, wherein the implantable source of energy comprises at least one accumulator, at least one capacitor or at least one rechargeable battery, or a combination of at least one capacitor and at least one rechargeable battery.

15. An apparatus according to claim 14, wherein the implantable source of energy comprises an electric source of energy.

16. An apparatus according to claim 15, wherein the electric source of energy comprises an accumulator, or a battery having a lifetime of at least 10 years.

17. An apparatus according to claim 13, wherein the control device controls the medical device.

18. An apparatus according to claim 2, further comprising an energy storage device implantable in the patient for storing the wireless energy released from the external source of energy.

19. An apparatus according to claim 18, wherein the energy storage device comprises an accumulator.

20. An apparatus according to claim 19, wherein the accumulator comprises an electric accumulator.

21. An apparatus according to claim 20, wherein the electric accumulator comprises at least one capacitor or at least one rechargeable battery, or a combination of at least one capacitor and at least one rechargeable battery.

22. An apparatus according to claim 2, further comprising a battery implantable in the patient for supplying electric energy to implantable electric energy consuming components of the apparatus.

23. The apparatus according to claim 2, wherein the control device is adapted to control the external source of energy to release wireless energy for direct use in connection with the operation of the medical device.

24. The apparatus according to claim 23, wherein the control device is adapted to control the external source of energy to intermittently release wireless energy in the form of a train of energy pulses for direct use in connection with the operation of the medical device.

25. The apparatus according to claim 23 or 24, wherein the medical device is operable in a non-magnetic, non-thermal or non-mechanical manner by use of said released wireless energy.

26. The apparatus according to claim 2, further comprising a switch implantable in the patient for directly or indirectly switching the operation of the medical device.

27. The apparatus according to claim 26, further comprising an internal source of energy implantable in the patient for supplying energy for the operation of the medical device, wherein the switch directly or indirectly affects the supply of energy from the internal source of energy.

28. The apparatus according to claim 27, wherein the switch switches between an "off" mode, in which the internal source of energy is not in use, and an "on" mode, in which the internal source of energy supplies energy for the operation of the medical device.

29. The apparatus according to claim 28, wherein the switch

is operable by the wireless energy released from the external source of energy.

30. The apparatus according to claim 29, wherein the control device controls the external source of energy to release the wireless energy.

31. The apparatus according to claim 30, wherein the control device comprises a wireless remote control.

32. The apparatus according to claim 27, wherein the control device comprises a wireless remote control for controlling the internal source of energy.

33. The apparatus according to claim 32, wherein the switch is operable by the wireless energy from the external source of energy to switch between an "off" mode, in which the internal source of energy and remote control are not in use, and a "standby" mode, in which the remote control is permitted to control the internal source of energy to supply energy for the operation of the medical device.

34. The apparatus according to claim 27, further comprising an energy transforming device implantable in the patient for transforming the wireless energy into storable energy and an energy storage device implantable in the patient for storing the storable energy.

35. The apparatus according to claim 34, wherein the switch is operable by energy from the implantable energy storage device to switch between an "off" mode, in which the internal source of energy is not in use, and an "on" mode, in which the internal

source of energy supplies energy for the operation of the medical device.

36. The apparatus according to claim 35, wherein the control device controls the energy storage device to operate the switch.

37. The apparatus according to claim 36, wherein the control device comprises a wireless remote control.

38. The apparatus according to claim 27, further comprising an energy transforming device implantable in the patient for transforming the wireless energy into storable energy, wherein the internal source of energy is capable of storing the storable energy.

39. The apparatus according to claim 38, wherein the switch switches from an "off" mode, in which the internal source of energy is not in use, to an "on" mode, in which the source of energy supplies energy for the operation of the medical device.

40. The apparatus according to claim 39, wherein the control device controls the switch to switch between the "on" and "off" modes.

41. The apparatus according to claim 40, wherein the control device comprises a wireless remote control.

42. The apparatus according to claim 27, wherein the internal source of energy comprises an electric source of energy.

43. The apparatus according to claim 42, wherein the electric source of energy comprises at least one accumulator, at

least one capacitor or at least one rechargeable battery, or a combination of at least one capacitor and at least one rechargeable battery.

44. The apparatus according to claim 42, wherein the electric source of energy comprises an accumulator or a battery having a lifetime of at least 10 years.

45. The apparatus according to claim 1, wherein the source of energy comprises a nuclear source of energy.

46. The apparatus according to claim 1, wherein the source of energy comprises a chemical source of energy.

47. An apparatus according to any one of claims 1,2,13 or 26, further comprising an operation device implantable in the patient for operating the medical device.

48. An apparatus according to claim 23, further comprising an operation device implantable in the patient for operating the medical device, wherein the wireless energy directly or indirectly powers the operation device.

49. An apparatus according to claim 47 or 48, wherein the control device controls the operation device to operate the medical device.

50. An apparatus according to claim 49, wherein the operation device comprises hydraulic means and at least one valve for controlling a fluid flow in the hydraulic means.

51. An apparatus according to claim 50, wherein the control

device comprises a wireless remote control for controlling the valve.

52. An apparatus according to claim 49, wherein the medical device comprises hydraulic means and the operation device comprises a reservoir forming a fluid chamber with a variable volume connected to the hydraulic means, and the operation device is adapted to distribute fluid from the chamber to the hydraulic means by reduction of the volume of the chamber and to withdraw fluid from the hydraulic means to the chamber by expansion of the volume of the chamber.

53. An apparatus according to claim 49, wherein the operation device comprises a motor.

54. An apparatus according to claim 53, wherein the motor comprises a rotary motor, and the control device controls the rotary motor to rotate a desired number of revolutions.

55. An apparatus according to claim 53, wherein the motor comprises a linear motor.

56. An apparatus according to claim 53, wherein the motor comprises a hydraulic or pneumatic fluid motor, and the control device controls the fluid motor.

57. An apparatus according to claim 53, wherein the motor comprises an electric motor having electrically conductive parts made of plastics.

58. An apparatus according to any one of claims 1,47-49, wherein the control device releases polarized energy from the

source of energy.

59. An apparatus according to any one of claims 47-49, wherein the control device shifts polarity of the released energy to reverse the operation device.

60. An apparatus according to any one of claims 47-49, wherein the operation device comprises an electric motor and the released energy comprises electric energy.

61. An apparatus according to any one of claims 1,47-49, wherein the medical device is operable to perform a reversible function.

62. An apparatus according to claim 61, further comprising a reversing device implantable in the patient for reversing the function performed by the medical device.

63. An apparatus according to claim 62, wherein the control device controls the reversing device to reverse the function performed by the medical device.

64. An apparatus according to claim 62, wherein the reversing device comprises hydraulic means including a valve for shifting the flow direction of a fluid in the hydraulic means.

65. An apparatus according to claim 62, wherein the reversing device comprises a mechanical reversing device.

66. An apparatus according to claim 65, wherein the mechanical reversing device comprises a switch.

67. An apparatus according to claim 65, wherein the reversing device comprises a gearbox.

68. An apparatus according to claim 62, wherein the reversing device comprises a switch.

69. An apparatus according to claim 68, wherein the switch of the reversing device is operable by the released energy.

70. An apparatus according to claim 69, wherein the control device controls the operation of the switch of the reversing device by shifting polarity of the released energy supplied to the switch.

71. An apparatus according to claim 68, wherein the switch comprises an electric switch and the source of energy supplies electric energy for the operation of the switch.

72. An apparatus according to claim 68, wherein the operation device comprises a motor, and the reversing device reverses the motor.

73. An apparatus according to any of claims 47-49, wherein the medical device comprises hydraulic means and the operation device is adapted to conduct a hydraulic fluid in the hydraulic means.

74. An apparatus according to claim 73, wherein the operation device comprises a motor.

75. An apparatus according to claim 73 or 74, wherein the operation device comprises a fluid conduit connected to the

hydraulic means of the medical device, and a reservoir for fluid, the reservoir forming part of the conduit.

76. An apparatus according to claim 75, wherein the hydraulic means and conduit are devoid of any non-return valve.

77. An apparatus according to claim 76, wherein the reservoir forms a fluid chamber with a variable volume, and the operation device is adapted to distribute fluid from the chamber to the hydraulic means of the medical device by reduction of the volume of the chamber and to withdraw fluid from the hydraulic means to the chamber by expansion of the volume of the chamber.

78. An apparatus according to any of the preceding claims, further comprising at least one implantable sensor for sensing at least one physical parameter of the patient.

79. An apparatus according to claim 78, wherein the sensor comprises a pressure sensor for directly or indirectly sensing a physical parameter of the patients body.

80. An apparatus according to claim 78 or 79, wherein the control device controls the medical device in response to signals from the sensor.

81. An apparatus according to claim 80, wherein the control device comprises an internal control unit implantable in the patient, the internal control unit controlling the medical device in response to signals from the sensor.

82. An apparatus according to claim 81, wherein the control device comprises an external control unit outside the patient's

body, the external control unit controlling the medical device in response to signals from the sensor.

83. An apparatus according to claim 83, wherein the external control unit stores information on the physical parameter sensed by the sensor and is manually operated to control the medical device based on the stored information.

84. An apparatus according to any of claims 78-83, further comprising at least one implantable sender for sending information on the physical parameter sensed by the sensor.

85. An apparatus according to any of the preceding claims, further comprising an external data communicator intended to be outside the patient's body and an internal data communicator implantable in the patient for communicating with the external communicator, wherein the internal data communicator feeds data related to the patient back to the external data communicator or the external data communicator feeds data to the internal data communicator.

86. An apparatus according to claim 85, wherein the internal data communicator feeds data related to the medical device.

87. An apparatus according to claim 85 or 86, wherein the implantable communicator feeds data related to at least one physical signal of the patient.

88. An apparatus according to any of the preceding claims, wherein the medical device comprises a performed function in the human body, wherein the medical device is adapted to control the performed function.

89. An apparatus according to claim 88, wherein the medical device is operable to perform the performed function when implanted in the patient.

90. An apparatus according to claim 88 or 89, wherein the medical device is adapted to steplessly control the performed function when implanted in the patient.

91. An apparatus according to any of the preceding claims, further comprising an implantable energy transforming device, wherein the control device is adapted to control the source of energy to release wireless electric energy and the energy transforming device is adapted to transform the electric energy into kinetic energy for operation of the medical device.

92. An apparatus according to claim 91, wherein the medical device is directly operated with the kinetic energy, as the energy transforming device transforms the electric energy into the kinetic energy.

93. An apparatus according to any of the preceding claims, wherein the control device controls the source of energy to release magnetic energy, non-magnetic energy, electromagnetic energy, non-electromagnetic energy, kinetic energy, non-kinetic energy, sonic energy, non-sonic energy, thermal energy or non-thermal energy.

94. An apparatus according to any of the preceding claims, wherein the medical device is non-inflatable.

95. An apparatus according to any of the preceding claims,

wherein the control device controls the source of energy to release energy for a determined time period.

96. An apparatus according to any of claims 1-94, wherein the control device controls the source of energy to release energy in a determined number of energy pulses.

97. An apparatus according to any of the preceding claims, wherein the control device is adapted to control the source of energy to release energy in a non-invasive manner.

98. An apparatus according to any of the preceding claims, wherein the control device comprises a wireless remote control for transmitting at least one wireless control signal for controlling the medical device.

99. An apparatus according to claim 98, wherein the remote control is capable of obtaining information on the condition of the medical device when the medical device is implantable and to control the medical device in response to the information.

100. An apparatus according to claim 98 or 99, wherein the wireless remote control comprises at least one external signal transmitter or transceiver and at least one internal signal receiver or transceiver implantable in the patient.

101. An apparatus according to claim 98 or 99, wherein the wireless remote control comprises at least one external signal receiver or transceiver and at least one internal signal transmitter or transceiver implantable in the patient.

102. An apparatus according to any of claims 98-101, wherein

the remote control is capable of sending information related to the medical device from inside the patient's body to the outside thereof.

103. An apparatus according to claim 102, wherein the remote control controls the medical device in response to the information.

104. An apparatus according to any of claims 98-103, wherein the remote control transmits a carrier signal for carrying the control signal.

105. An apparatus according to claim 104, wherein the carrier signal is frequency, amplitude or frequency and amplitude modulated.

106. An apparatus according to claim 104 or 105, wherein the carrier signal is digital, analog or digital and analog.

107. An apparatus according to any of claims 104-106, wherein the control signal used with the carrier signal is frequency, amplitude or frequency and amplitude modulated.

108. An apparatus according to any of claims 98-107, wherein the control signal comprises a wave signal comprising one of a sound wave signal including an ultrasound wave signal, an electromagnetic wave signal including an infrared light signal, a visible light signal, an ultra violet light signal and a laser light signal, a micro wave signal, a radio wave signal, an x-ray radiation signal, and a gamma radiation signal.

109. An apparatus according to claim 98-107, wherein the

control signal comprises an electric, magnetic or electric and magnetic field.

110. An apparatus according to any of claims 98-108, wherein the control signal is digital, analog or digital and analog.

111. An apparatus according to claim 110, wherein the remote control transmits an electromagnetic carrier wave signal for carrying the digital or analog control signal.

112. An apparatus according to any of claims 98-111, wherein the control signal is transmitted in pulses by the wireless remote control.

113. An apparatus according to any of claims 23-25,89-90, further comprising an implantable stabilizer for stabilizing the energy released by the control device.

114. An apparatus according to claim 113, wherein the energy released by the control device comprises electric energy and the stabilizer comprises at least one capacitor.

115. An apparatus according to claim 1, wherein the medical device is operable by the released energy in a manual, mechanical, thermal or magnetic manner.

116. An apparatus according to claim 1, wherein the medical device is operable by the released energy in a non-manual, non-mechanical, non-thermal or non-magnetic manner.

117. An apparatus according to claim 1, wherein the control device is adapted to control the source of energy to release

energy for direct use in connection with the operation of the medical device.

118. An apparatus according to claim 1, wherein the control device is adapted to control the source of energy to intermittently release energy in the form of a train of energy pulses for direct use in connection with the operation of the medical device.

119. An apparatus according to claim 24 or 118, wherein the control device is adapted to control the source of energy to release electric energy, and further comprising an implantable capacitor for producing the train of energy pulses from the released energy.

120. An apparatus according to claim 1, wherein the medical device comprises a performed function in the human body , further comprising an adjustment device for adjusting the medical device, wherein the adjustment device is adapted to mechanically adjust the medical device, or adapted to hydraulically adjust the medical device by using hydraulic means which is devoid of hydraulic fluid of the kind having a viscosity that substantially increases when exposed to heat or a magnetic field.

121. An apparatus according to claim 47, wherein the operation device comprises an electrical operation device.

122. An apparatus according to claim 47, wherein the operation device is powered by magnetic energy, non-magnetic energy, electromagnetic energy, non-electromagnetic energy, kinetic energy, non-kinetic energy, thermal energy or non-thermal energy.

123. An apparatus according to claim 1, wherein the control device is activated in a manual or non-manual manner to control the source of energy to release energy.

124. An apparatus according to claim 1, further comprising implantable electrical components including at least one voltage level guard.

125. An apparatus according to claim 1, further comprising implantable electrical components including a single voltage level guard.

126. An apparatus according to claim 124 or 125, wherein the electrical components are devoid of any current detector and/or charge level detector.

127. An apparatus according to any of claims 123-126, further comprising an implantable capacitor or accumulator, wherein the charge or discharge of the capacitor or accumulator is controlled by use of the voltage level guard.

128. An apparatus according to claim 117, wherein the released energy comprises electric energy and further comprising an implantable capacitor for producing the train of energy pulses.

129. An apparatus according to claim 117 or 127, wherein the capacitor has a capacity less than 0,1 μF.

130. An apparatus according to claim 117, further comprising an implantable motor or pump for operating the medical device,

wherein the control device is adapted to control the source of energy to directly power the motor or pump with the released energy.

131. An apparatus according to claim 23, wherein the wireless energy comprises electromagnetic waves excluding radio waves.

132. An apparatus according to claim 117, further comprising an implantable motor or pump for operating the medical device, wherein the control device is adapted to release wireless energy in the form of a magnetic field or electromagnetic waves for direct power of the motor or pump, as the wireless energy is being released.

133. An apparatus according to claim 132, wherein the pump is not a plunger type of pump.

134. An apparatus according to claim 23 or 24, wherein the wireless energy comprises a signal.

135. An apparatus according to claim 1, further comprising an implantable energy transforming device for transforming wireless energy directly or indirectly into energy different than the wireless energy for operation of the medical device.

136. An apparatus according to claim 135, wherein the energy transforming device transforms the wireless energy in the form of sound waves into electric energy for operation of the medical device.

137. An apparatus according to claim 136, wherein the energy

transforming device transforms the wireless energy in the form of sound waves directly into electric energy.

138. An apparatus according to any of claims 136 or 137, wherein the energy transforming device comprises a capacitor.

139. An apparatus according to claim 138, wherein the capacitor is adapted to produce electric pulses from the transformed electric energy.

140. An apparatus according to any of claims 135-139, further comprising an implantable motor or pump for oprating the medical device, wherein the motor or pump is powered by the transformed energy.

141. An apparatus according to claim 1, wherein the medical device is adjustable in a non-manual manner.

142. An apparatus according to any of the preceding claims, wherein the medical device is embedded in a soft or gel-like material.

143. An apparatus according to any of the preceding claims, wherein the medical device is embedded in a silicone material having hardness less than 20 Shore.

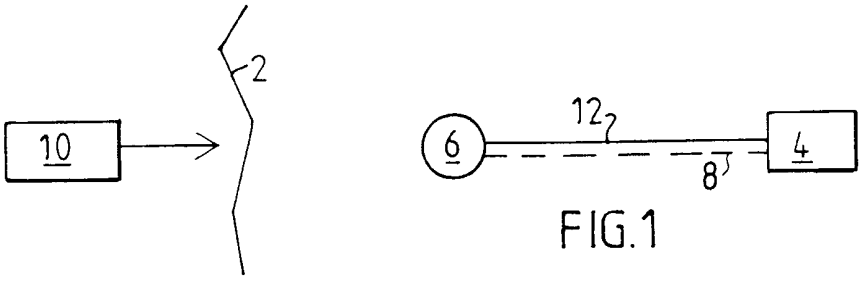

FIG.1

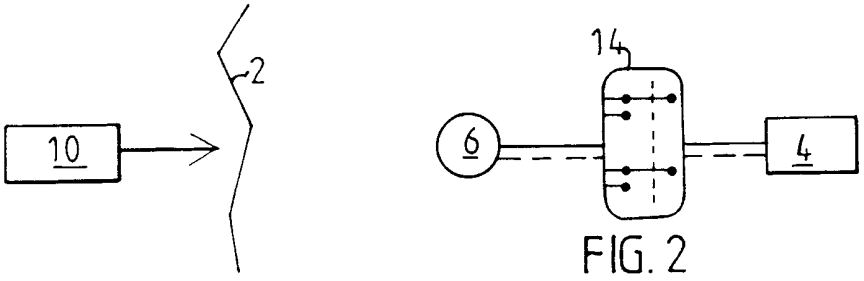

FIG. 2

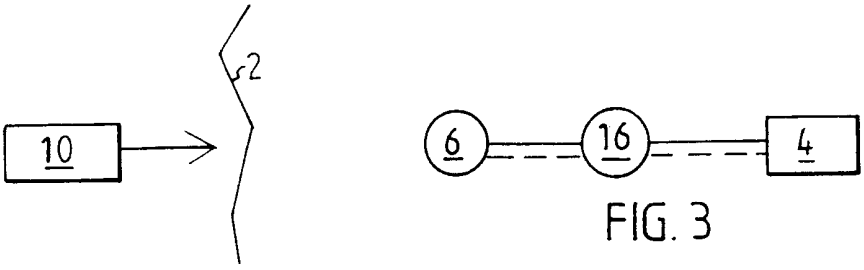

FIG. 3

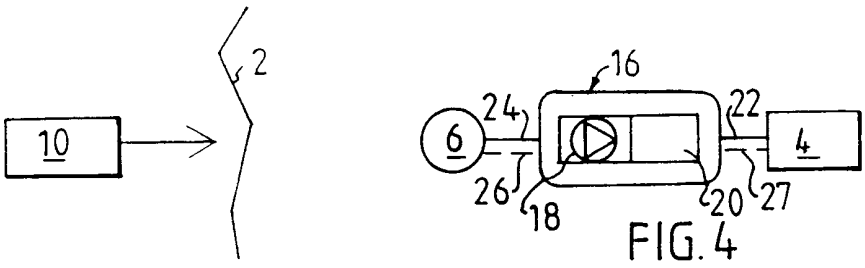

FIG. 4

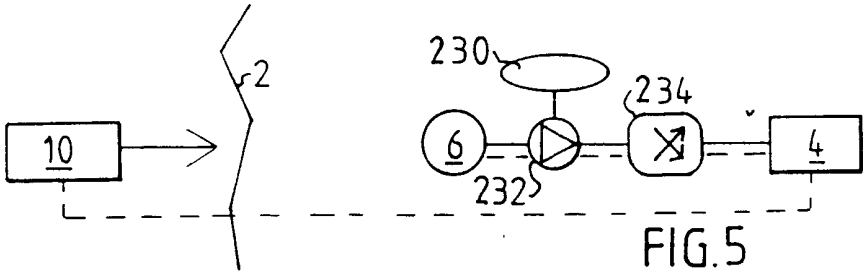

FIG.5

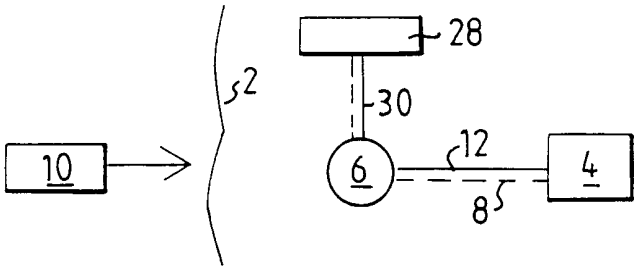

FIG.6

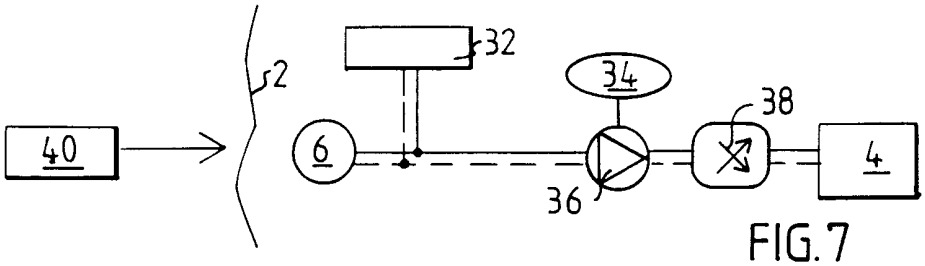

FIG.7

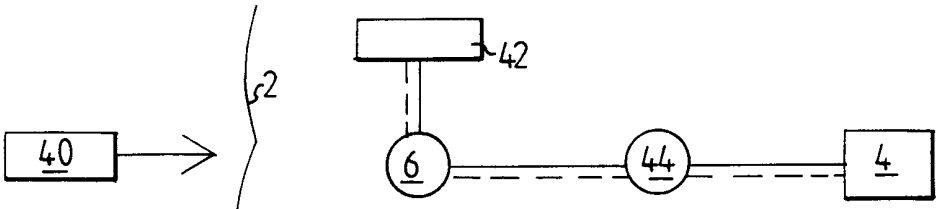

FIG. 8

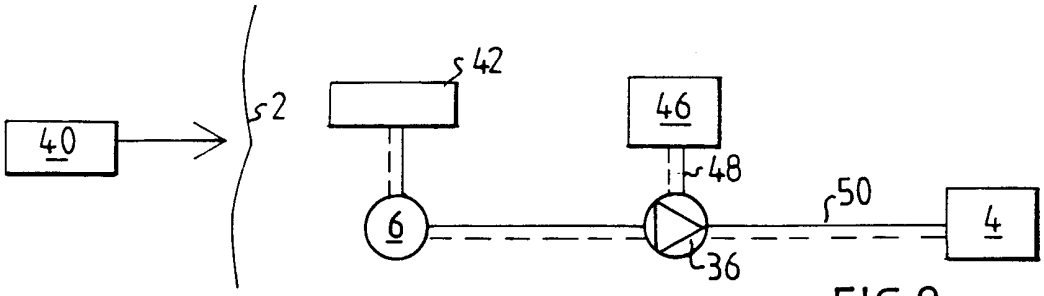

FIG.9

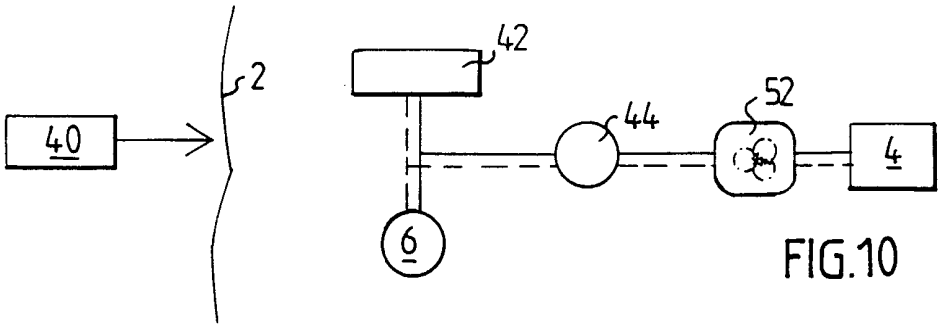

FIG.10

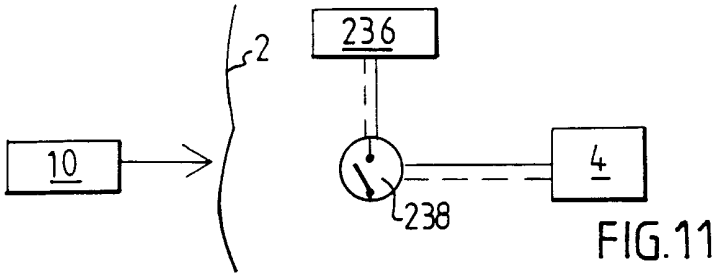

FIG.11

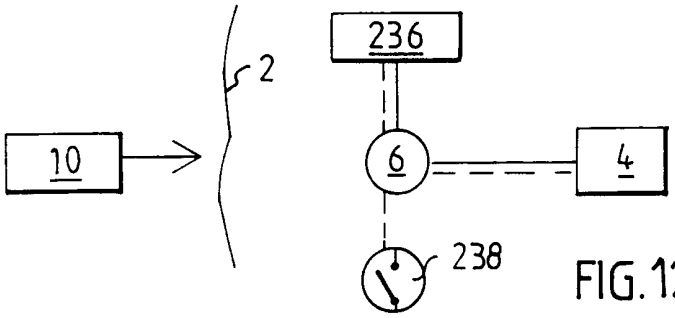

FIG.12

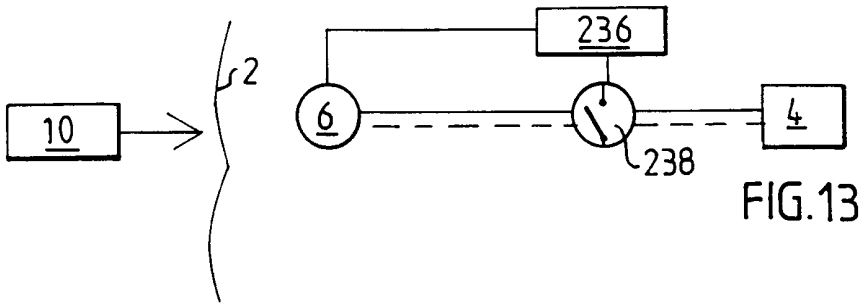

FIG.13

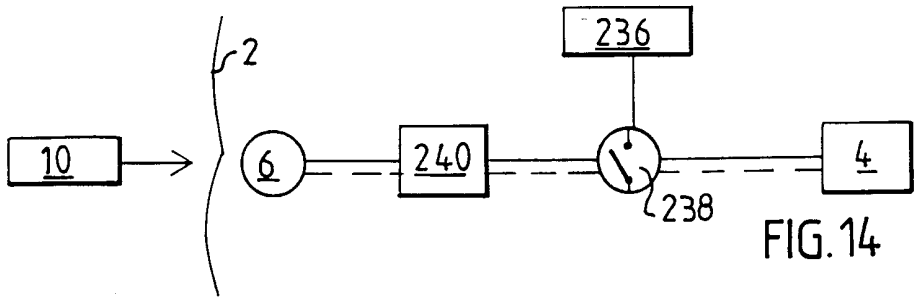

FIG.14

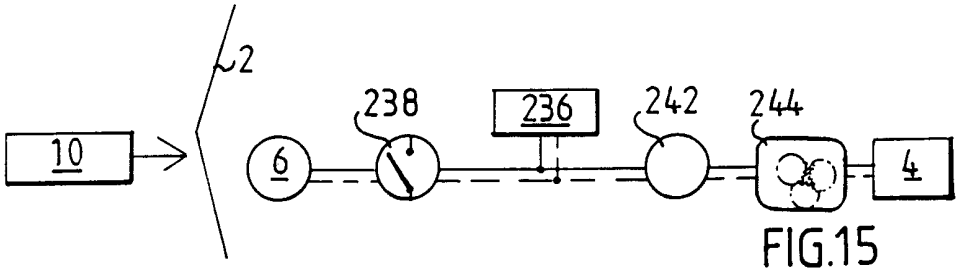

FIG.15

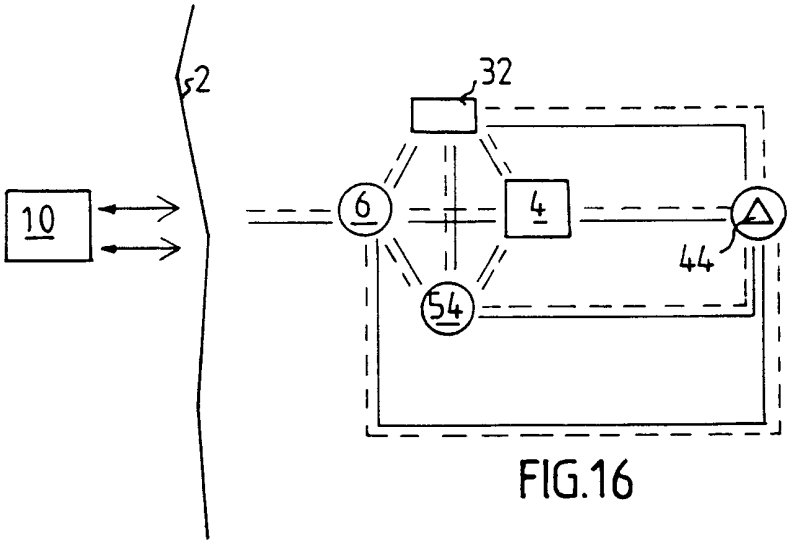

FIG.16

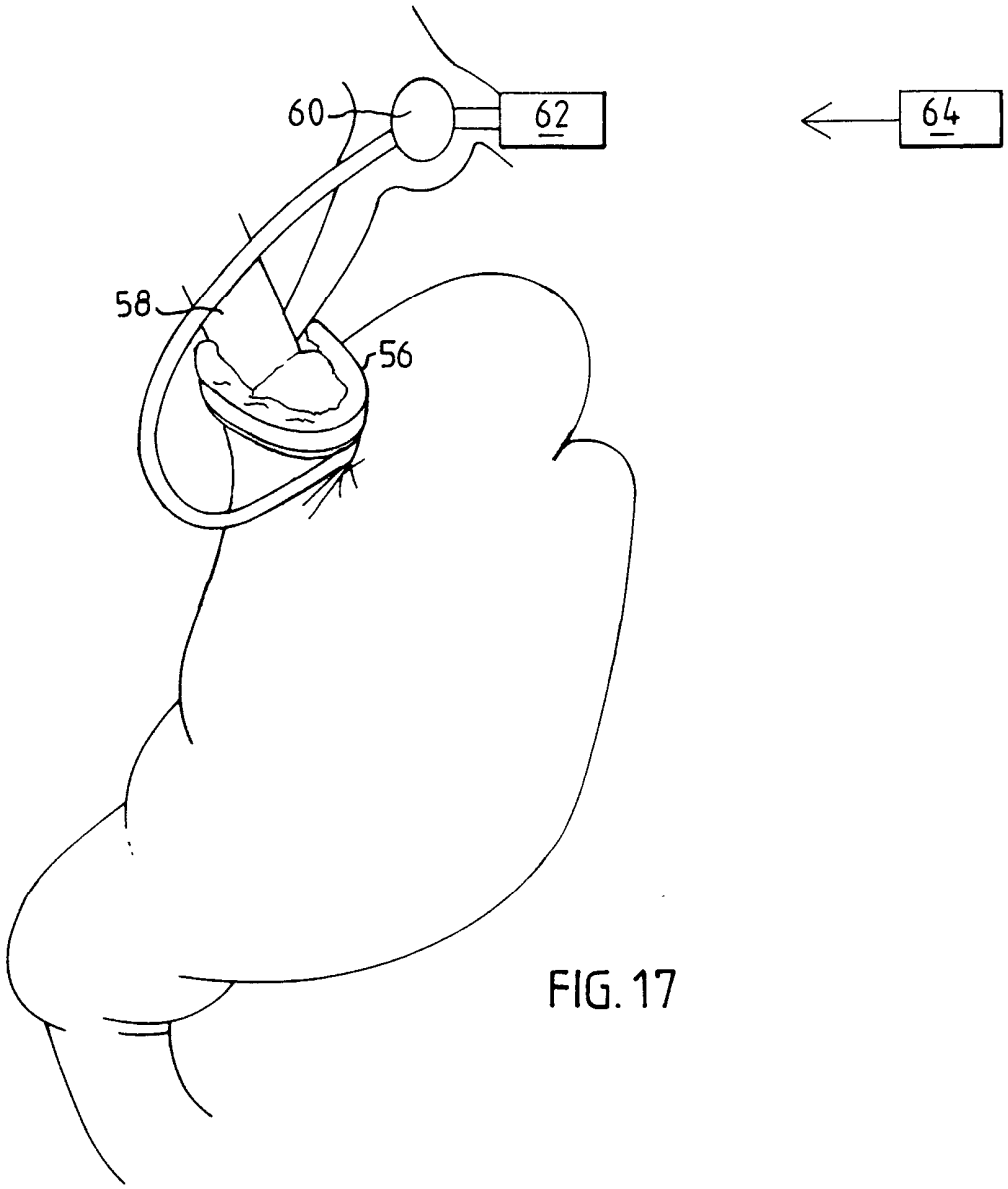

FIG. 17

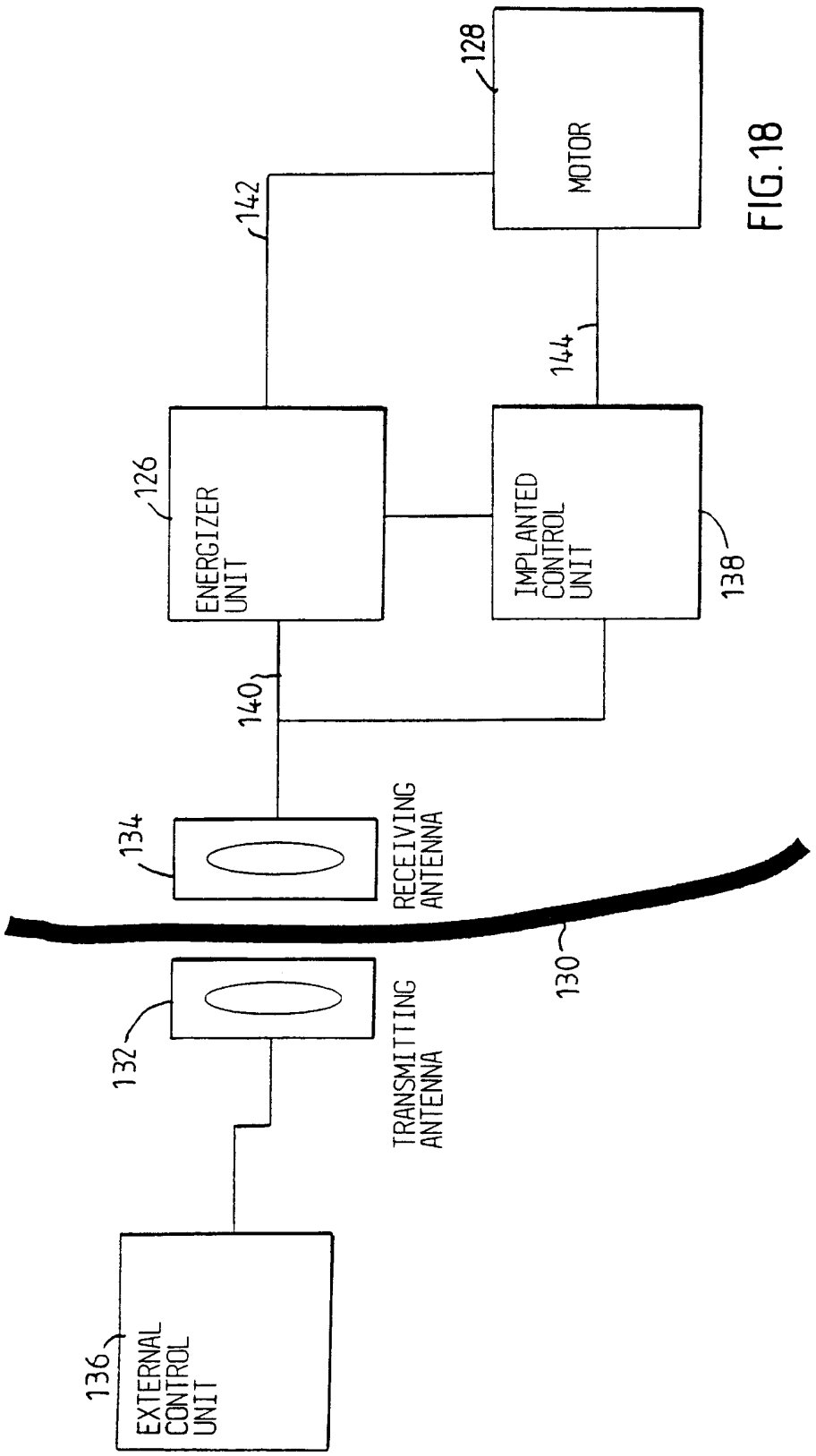
128
MOTOR
142
144
126
ENERGIZER UNIT
IMPLANTED CONTROL UNIT
138
140
134
RECEIVING ANTENNA
130
132
TRANSMITTING ANTENNA
136
EXTERNAL CONTROL UNIT

FIG.18

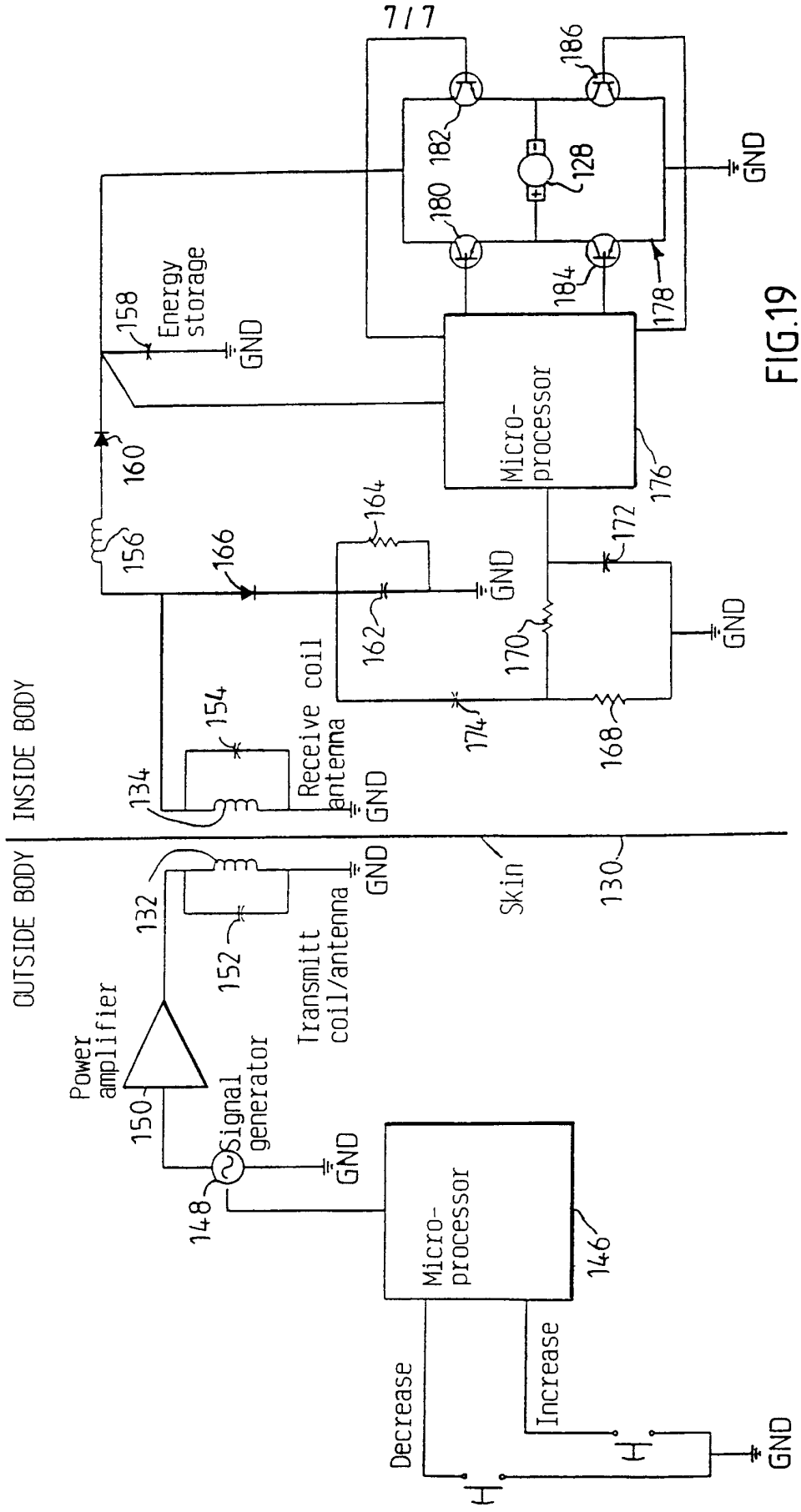
OUTSIDE BODY
INSIDE BODY
Skin
130
Power amplifier
150
Signal generator
148
GND
Micro-processor
146
Decrease
Increase
GND
132
152
Transmitt coil/antenna
GND
134
154
Receive coil antenna
GND
156
158
Energy storage
GND
160
166
164
GND
162
170
172
GND
174
168
Micro-processor
176
178
180
182
128
184
186
GND

FIG.19

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 01/00307

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61F 2/48 // A61F 5/00
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)

IPC7: A61F

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)

EPODOC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0626154 A1 (HELMY, ALI M.), 30 November 1994 (30.11.94)	1-4,23-25, 47-53,55-66, 73-75,88-93, 95-98,
X		100,108-110, 115,117-118, 121-123, 130-132,
X		135,140
	--	

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 June 2001	20 07 2001
Name and mailing address of the International Searching Authority European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel(+31-70)340-2040, Tx 31 651 epo nl, Fax(+31-70)340-3016	Authorized officer Leif Brander/MP Telephone No.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 01/00307

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2797181 A1 (CANCEL RICHARD ET AL), 9 February 2001 (09.02.01)	1,3-4,13-17, 22,26,47,49, 53-54,60-63,
X		65-72,88-90, 93-95,98, 100,108-110, 115,
X		121-123
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X	US 4941461 A (ROBERT E. FISCHELL), 17 July 1990 (17.07.90)	1-4,23-25, 47-53,55-64, 73-75,88-93, 95-98,
X		108,115,117, 130-132,140
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X	US 5938669 A (CHRISTIAN KLAIBER ET AL), 17 August 1999 (17.08.99)	1,3-17,22, 26,47,49-54, 60-75,88-90, 93,
X		98,100, 108-110,115, 121-123
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INTERNATIONAL SEARCH REPORT

Information on patent family members

28/05/01

International application No.
PCT/SE 01/00307

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		US 5437605 A	01/08/95
FR 2797181 A1	09/02/01	WO 0110359 A	15/02/01
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US 5938669 A	17/08/99	EP 0876808 A	11/11/98