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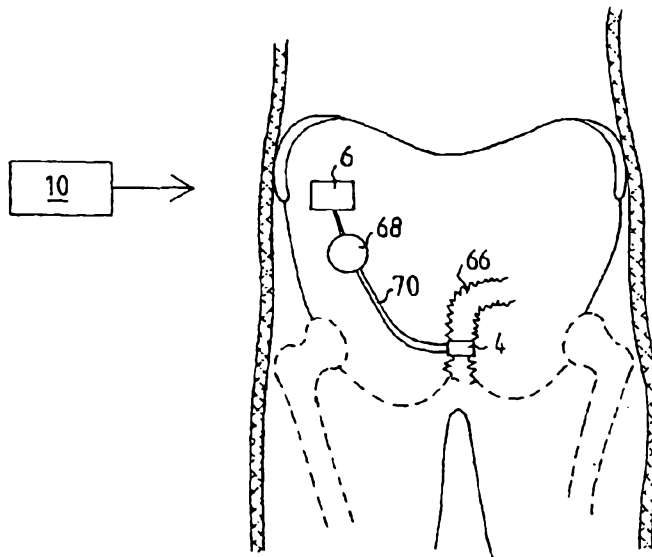
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(54) Title: ANAL INCONTINENCE TREATMENT APPARATUS WITH ENERGY TRANSFORMING MEANS



(57) Abstract: An anal incontinence treatment apparatus includes or uses an operable restriction device implanted in a patient and engaging the colon or rectum to form a restricted fecal passageway. An energy transmission means for wireless transmission of energy of a first form from outside the patient's body is provided. An implanted energy transforming means transforms the energy of the first form wirelessly transmitted by the energy transmission means into energy of a second form, which is used to control and operate the restriction device to vary the size of the restricted fecal passageway.



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ANAL INCONTINENCE TREATMENT APPARATUS WITH ENERGY TRANSFORMINGMEANS

The present invention relates to an anal incontinence treatment apparatus for surgical application in the abdomen of a patient for forming a restricted fecal passageway in the colon or rectum. The term "patient" includes an animal or a human being.

Anal incontinence is a wide-spread disease. Several kinds of sphincter plastic surgery are used today to remedy anal incontinence. There is a prior manually operated sphincter system in an initial clinical trial phase where a hydraulic sphincter system connected to an elastic reservoir (balloon) placed in the scrotum is developed. A disadvantage of this system is that thick, hard fibrosis is created around the reservoir by pump movements making the system useless sooner or later.

U.S. Pat. No. 5 593 443 discloses a hydraulic anal sphincter under both reflex and voluntary control. A pressure controlled inflatable artificial sphincter is disclosed in U.S. Pat. No. 4 222 377.

The object of the present invention is to provide a new convenient and reliable anal incontinence treatment apparatus, having a long lifetime. In particular, the patient should be able to control the apparatus at any time after the operation when various needs arise over the course of a day, so that the patient substantially always is satisfied or comfortable.

Accordingly, the present invention provides an anal incontinence treatment apparatus which comprises: An energy transmission means for wireless transmission of energy of a first form from outside a patient's body. An operable

restriction device implantable in the patient for engaging the
the rectum or colon to form a restricted fecal passageway in the
rectum or colon, the device operable in response to energy of a
second form different than the energy of the first form to vary
5 the restricted passageway. And, an energy transforming means
implantable in the patient for transforming energy of the first
form wirelessly transmitted by the energy transmission means
into energy of the second form.

As a result, the advantage is achieved that the anal
10 incontinence treatment apparatus of the invention provides
simple and effective energy transmission which ensures an
extended and reliable functionality of the apparatus, possibly
for the rest of the patient's natural life, and at least many
years.

15 Preferably, the energy transforming means comprises at
least one element having a positive region and a negative
region, and adapted to create an energy field between the
positive and negative regions when exposed to the energy of the
first form transmitted by the energy transmission means, so that
20 the energy field produces the energy of the second form.

Alternatively, at least one semiconductor circuitry,
transistor circuitry or microchip may be substituted for the
element having a positive and a negative region. Such a
semiconductor circuitry, transistor circuitry or microchip is
25 adapted to create an energy field when exposed to the energy of
the first form wirelessly transmitted by the energy transmission
means, whereby the energy field provides the energy of the
second form.

The restriction device preferably controls the cross-
30 sectional area of the fecal passageway in the rectum or colon,
which gives the advantage that the patient is enabled to adjust
the cross-sectional area of the fecal passageway whenever he

likes during the day. This advantage should not be underestimated.

Advantageously, the restriction device is directly operated with the energy of the second form, preferably in a non-magnetic and/or non-mechanical manner, as the energy transmission means transmits the energy of the first form. The restriction device may be directly operated with the energy of the second form without externally touching subcutaneously implanted components of the apparatus. The advantage of directly using energy as it is transmitted is that the apparatus can be of a very simple design and the few components involved makes the apparatus extremely reliable.

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

In accordance with a preferred embodiment of the invention, the element comprises an electrical junction element capable of inducing an electric field between the positive and negative regions when exposed to the energy of the first form transmitted by the energy transmission means, whereby the energy of the second form comprises electric energy.

Consequently, the restriction device suitably is electrically operated, whereby the positive and negative regions of the electrical junction element supply electric energy for the operation of the restriction device. The apparatus suitably comprises implantable electric conductors connected to the positive and negative regions of the electrical junction element, whereby the electrical junction element is capable of supplying an electric current, such as a direct current, a pulsating direct current, a combination of a direct and pulsating direct current, an alternating current or a

combination of a direct and alternating current, via the conductors. Furthermore, the electrical junction element may be capable of supplying a frequency, amplitude, or frequency and amplitude modulated analog, digital, or a combination of analog and digital signal, which is used in connection with control of the restriction device.

The element, preferably in the form of an electrical semiconductor junction element, suitably forms a flat and thin sheet and has a volume of less than 2000 cm³ to be suited for subcutaneous implantation, so that the electrical junction element can be located just behind the skin of the patient. The electrical junction element should be designed to generate an output current exceeding 1 μ A when exposed to the energy of the first form transmitted by the energy transmission means. Of course, all the components of the energy transforming means including the electrical junction element in contact with the patient's body should be of a biocompatible material. Alternatively, it would be possible to implant the energy transforming means in the thorax or cephal region of the patient, or in an orifice of the patient's body and under the mucosa or intraluminal outside the mucosa of the orifice.

For *in vitro* appliances, a particular type of an electrical semiconductor junction element has been commonly used, namely a so called p-n (positive/negative) junction element, typically in the form of solar cells. A solar cell transfers solar energy in the form of visible light into electric energy in the form of direct current. For example, a p-n junction element may comprise two layers of semiconductor, one p-type (positive) and the other n-type (negative), sandwiched together to form a "p-n junction". This p-n junction induces an electric field across the element when absorbing quanta of light (photons).

To be more precise, the quanta of light transfer their energy to some of the semiconductor's electrons, which are then able to move about through the material. For each such negatively charged electron, a corresponding positive charge - a "hole" - is created. In an ordinary semiconductor, these electrons and holes recombine after a short time and their energy is wasted as heat. However, when the electrons and holes are swept across the p-n junction in opposite directions by the action of the electric field, the separation of charge induces a voltage across the p-n junction element. By connecting the p-n junction element to an external circuit, the electrons are able to flow thereby creating a current.

Surprisingly, it has been proved that although both the skin and subcutis absorb energy from an external light beam directed against the skin portion behind which a properly designed p-n junction element is located, the light energy transmitted through the skin can induce a current from the p-n junction element strong enough (minimum 1 μ A) to enable the operation of the electrically operated restriction device. Thus, such a p-n junction element is now for the first time used for *in vivo* applications.

However, the apparatus of the present invention is not limited to the use of visible light for the wireless transmission of energy. Thus, in accordance with a broad aspect of the invention, the energy transmission means transmits energy by at least one wireless signal, preferably containing radiant energy.

The wireless signal may comprise a wave signal, for example 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, and a gamma radiation signal. Where

applicable, one or more of the above signals may be combined. Alternatively, the wave signal may comprise a sound wave signal, such as an ultrasonic signal. Generally, the wireless signal may comprise a digital, analog or a digital and analog signal.

5 The energy of the first form transmitted by the energy transmission means may comprise an electric or magnetic field transmitted in pulses, for example digital pulses. Furthermore, the energy transforming means may transfer the energy of the first form, which may comprise polarized energy, into a direct
10 current, pulsating direct current, a combination of a direct and pulsating direct current, an alternating current or a combination of a direct and alternating current. Alternatively, the energy of the first form may comprise kinetic energy.

The energy of the second form may comprise a frequency,
15 amplitude or frequency and amplitude modulated analog, digital or combined analog and digital signal.

The apparatus may further comprise an implantable pulse generator for generating electrical pulses from the energy of the second form rendered by the energy field created by the
20 element having positive and negative regions.

In accordance with another embodiment of the invention, the apparatus comprises an implantable operation device for operating the restriction device and a control device for controlling the operation device, wherein the element powers the operation
25 device with the energy of the second form. The operation device preferably comprises a motor, for example an electric linear motor or an electric rotary motor which is controlled by the control device to rotate a desired number of revolutions. The electric motor may have electrically conductive parts made of
30 plastics. Alternatively, the motor may comprise a hydraulic or pneumatic fluid motor, wherein the control device controls 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
5 just a few mm in size.

In accordance with another embodiment of the invention, the
restriction device comprises hydraulic means and the operation
device comprises a pump for pumping a fluid in the hydraulic
means, a motor for driving the pump, a valveless fluid conduit
10 between the pump and the hydraulic means of the restriction
device, and a reservoir for fluid, wherein the reservoir forms
part of the conduit. All of the hydraulic components involved
are preferably devoid of any non-return valve. This is of great
advantage, because with valves involved there is always a risk
15 of malfunction due to improperly 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 restriction device by reduction of the volume of the chamber
20 and withdraws fluid from the hydraulic means to the chamber by
expansion of the volume of the chamber.

The control device may reverse the operation device by
shifting polarity of the energy of the second form. Where the
operation device comprises an electric motor the energy of the
25 second form suitably comprises electric energy.

In accordance with yet another embodiment of the invention,
the restriction device is operable to perform a reversible
function, such as enlarging and restricting the fecal
passageway, and there is a reversing device implantable in the
30 patient for reversing the function performed by the restriction
device. Such a reversing function preferably involves enlarging
and restricting the fecal passageway by the restriction 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 restriction device. The reversing device may comprise hydraulic means
5 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 gear box.

Where the reversing device comprises a switch the control
10 device suitably controls the operation of the switch by shifting polarity of 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.

In accordance with a advantageous embodiment of the
15 invention, the apparatus further comprises an energy storage device implantable in the patient for storing the energy of the second form and for supplying energy in connection with the operation of the restriction device. The energy storage device preferably comprises an electric source of energy, such as an
20 accumulator, a rechargeable battery or a combination of an accumulator and rechargeable battery.

The apparatus may further comprise a switch implantable in the patient for switching the operation of the restriction device and a source of energy implantable in the patient. This
25 embodiment is particularly suited for applications where the energy transmission efficiency of the apparatus is insufficient, i.e. where the restriction device is to perform more advanced operations. Such a source of energy preferably is a battery. Alternatively, the source of energy is an accumulator which also
30 may store the energy of the second form.

In accordance with a first alternative, the switch is operated by the energy of the second form supplied by the energy

storage device to switch from an off mode, in which the source of energy is not in use, to an on mode, in which the source of energy supplies energy for the operation of the restriction device. In this case, the source of energy may comprise a
5 battery, preferably having a life-time of at least 10 years, or an accumulator. However, other kinds of sources are also conceivable, such as a nuclear source of energy or a chemical source of energy.

In accordance with a second alternative, the apparatus
10 further comprises a remote control for controlling the supply of energy of the source of energy, wherein the switch is operated by the energy of the second form supplied by the energy storage device to switch from an off mode, in which the remote control is prevented from controlling the source of energy and the
15 source of energy is not in use, to a standby mode, in which the remote control is permitted to control the source of energy to supply energy for the operation of the restriction device.

In accordance with a third alternative, the energy storage device is omitted, wherein the switch is operated by the energy
20 of the second form supplied by the energy transforming means to switch from an off mode, in which the remote control is prevented from controlling the source of energy and the source of energy is not in use, to a standby mode, in which the remote control is permitted to control the source of energy to supply
25 energy for the operation of the restriction device.

In accordance with a fourth alternative, also the remote control is omitted, wherein the switch is operated by the energy of the second form supplied by the energy transforming means to switch from an off mode, in which the source of energy is not in
30 use, to an on mode, in which the source of energy supplies energy for the operation of the restriction device. Where applicable, in the described embodiments the switch may switch

when the energy transmission means is transmitting wireless energy, preferably while the transferred energy of the second form is stabilized by an implanted capacitor, which may temporarily (for a few seconds) store the energy of the second form.

The switch mentioned above may comprise an electronic switch or, where applicable, a mechanical switch.

The advantage of using a switch above all is increased control safety, i.e. interfering signals in the patient's surroundings cannot affect the implanted restriction device. Furthermore, the lifetime of the source of energy will be significantly prolonged, since the energy consumption of the apparatus will be reduced to a minimum. During the above mentioned standby mode, the remote control uses energy from the implanted source of energy. By means of the energy transmission means energy may be transmitted to activate the switch to connect the source of energy only when energy is required in connection with the operation of the restriction device.

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 restriction device in response to signals from the sensor. For example, the sensor may comprise a pressure sensor for directly or indirectly sensing the pressure against the restriction device, human tissue or in the fecal passageway. The pressure sensor may be any suitable known or conventional pressure sensor such as shown in U.S. patents 5 540,731, 4 846 181, 4 738 267, 4 571 749, 4 407 296 or 3 939 823; or an NPC-102 Medical Angioplasty Sensor. The control device may comprise an internal control unit implantable in the patient for, preferably directly, controlling the restriction 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 restriction
5 device in response to signals from the sensor. For example, the control unit may control the restriction device to further restrict the fecal passageway in the colon in response to the sensor sensing that the patient is lying, or enlarge the fecal passageway in response to the sensor sensing an abnormally high
10 pressure against the restriction device.

Alternatively, the control device may comprise an external control unit outside the patient's body for, suitably directly, controlling the restriction device in response to signals from the sensor. The external control unit may store information on
15 the physical parameter sensed by the sensor and may be manually operated to control the restriction 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.

20 An external data communicator may be provided outside the patient's body and an internal data communicator may be implanted in the patient for communicating with the external data communicator. The internal data communicator may feed data related to the patient, or related to the restriction device,
25 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. The arrangement of external and internal data
30 communicators gives the advantage, among other things, that a longterm control of activities related to the restriction device is provided.

The apparatus may further comprise an implantable programmable control unit for controlling the restriction device, preferably over time in accordance with an activity schedule program. This will advance the apparatus and make possible an adaptation of the apparatus to the individual patients.

All of the above embodiments are preferably remote controlled. Thus, the apparatus advantageously comprises a wireless remote control transmitting at least one wireless control signal for controlling the restriction 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 restriction device and of controlling the restriction device in response to the information. Also, The remote control may be capable of sending information related to the restriction 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 receiver or transceiver and at least one internal signal transmitter or transceiver implantable in the patient.

The wireless 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
5 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.

10 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
15 control signal would give safe communication. The control signal may be transmitted in pulses by the wireless remote control.

The energy transforming means may be placed in the retroperitoneal space, abdomen, scrotum or labia majora, or implanted subcutaneously.

20 The invention also provides an implanting method, comprising the steps of providing an anal incontinence treatment apparatus as described above, cutting an opening in a patient's mucosa in an orifice of the patient's body, and implanting the energy transforming means in the patient's body through the
25 opening. Alternatively, the cutting step may comprise cutting an opening in the patient's skin and the implanting step may comprise implanting the energy transforming means in the patient's body through the opening.

30 There is also provided a laparoscopic implanting method, in accordance with a first alternative, comprising the steps of providing an anal incontinence treatment apparatus as described above, placing at least two laparoscopic cannula within a

patient's body, and implanting the energy transforming means in the patient's body by using the at least two laparoscopic cannula.

In accordance with another alternative there is provided a laparoscopic surgical method of implanting an anal incontinence treatment apparatus, comprising the steps of a) placing at least two laparoscopic trocars within the patient's body, b) using at least one dissecting tool inserted through the laparoscopic trocar, dissecting the region of the colon or rectum, c) introducing a restriction device of the apparatus through the trocars, d) placing the restriction device in engagement with the colon or the rectum to create a restricted stoma, and e) implanting an energy transforming means of the apparatus.

The energy transforming means of the apparatus may be implanted, for example subcutaneously, in the abdomen, thorax or cephal region, or other locations in the patient's body.

The invention also provides a method of treating a human or animal having chronic anal incontinence comprising: (a) Surgically implanting in the human or animal a restriction device engaging the human's or animal's colon or rectum, to form a restricted passageway in the colon or rectum. (b) Surgically implanting in the human or animal an operation device which can adjust the restricted passageway in response to supplied energy. And, (c) in a non-invasive post-operative procedure, from time to time, supplying energy to the operation device so as (i) to enlarge the restricted passageway to allow feces to readily pass.

The invention is described in more detail in the following with reference to the accompanying drawings, in which

FIGURES 1 to 12 are schematic block diagrams illustrating twelve embodiments, respectively, of the anal incontinence

treatment apparatus of the invention, in which wireless energy is transmitted from outside a patient's body to energy consuming components of the apparatus implanted in the patient;

FIGURE 13 is a schematic block diagram illustrating conceivable combinations of implanted components for achieving various communication options;

FIGURE 14 illustrates an electrical junction element for use in the apparatus of the present invention; and

FIGURE 15 illustrates the apparatus in accordance with the invention implanted in a patient.

FIGURE 1 schematically shows a very simple embodiment of the anal incontinence apparatus of the invention having some parts implanted in a patient and other parts located outside the patient's body. 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 apparatus of FIGURE 1 comprises an implanted operable restriction device 4, which engages the patient's colon (or alternatively engages the rectum) to form a restricted fecal passageway in the colon. The restriction device 4 is capable of performing a reversible function, i.e. to enlarge and reduce the cross-sectional area of the fecal passageway, so that the restriction device 4 works as an artificial sphincter. An implanted energy transforming means 6 is adapted to supply energy consuming components of the restriction device 4 with energy via a power supply line 12. An external energy transmission means 10 includes a wireless remote control transmitting a wireless signal which is received by a signal receiver incorporated in the implanted energy transforming means 6. The implanted energy transforming means 6 transforms energy

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from the wireless signal into electric energy which is supplied via the power supply line 12 to the restriction device 4, which energy causes portions of the device 4 to move and thus adjust the fecal passageway.

5 FIGURE 2 shows an embodiment of the invention identical to that of FIGURE 1, except that a reversing device in the form of an electric switch 14 also is implanted in the patient for reversing the restriction device 4. The wireless remote control of the external energy transmission means 10 transmits a
10 wireless signal that carries energy and the implanted energy transforming means 6 transforms the wireless energy into a current for operating the switch 14. When the polarity of the current is shifted by the energy transforming means 6 the switch 14 reverses the function performed by the restriction device 4.

15 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 15 for operating the restriction device 4 also is implanted in the patient. The motor 15 is powered with energy from the energy transforming means 6, as the remote control of
20 the external energy transmission means 10 transmits a wireless signal to the receiver of the energy transforming means 6.

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
25 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 fecal passageway, and hydraulic fluid is pumped by the
30 motor/pump unit 18 back from the restriction device 4 to the reservoir 20 to enlarge the cross-sectional area. The implanted energy transforming means unit 6 transforms wireless energy into

a current, for example a polarized current, for powering the motor/pump unit 18 via an electric power supply line 24.

FIGURE 5 shows an embodiment of the invention comprising the external energy transmission means 10 with its wireless remote control, the restriction device 4, in this case hydraulically operated, and the implanted energy transforming means 6, and further comprising an implanted hydraulic fluid reservoir 30, an implanted motor/pump unit 32 and an implanted reversing device in the form of a hydraulic valve shifting device 34. The motor of the motor/pump unit 32 is an electric motor. In response to a control signal from the wireless remote control of the external energy transmission means 10, the implanted energy transforming means 6 powers the motor/pump unit 32 with energy from the energy carried by the control signal, whereby the motor/pump unit 32 distributes hydraulic fluid between the reservoir 30 and the restriction device 4. The remote control of the energy transmission means 10 controls the shifting device 34 to shift the hydraulic fluid flow direction between one direction in which the fluid is pumped by the motor/pump unit 32 from the reservoir 30 to the restriction device 4 to reduce the cross-sectional area of the fecal passageway, and another opposite direction in which the fluid is pumped by the motor/pump unit 32 back from the restriction device 4 to the reservoir 30 to enlarge the cross-sectional area.

FIGURE 6 shows an embodiment of the invention identical to that of FIGURE 1, except that a control unit 36 controlled by the wireless remote control of the external energy transmission means 10, an accumulator 38 and a capacitor 40 also are implanted in the patient. The control unit 36 stores electric energy received from the energy transforming means 6 in the accumulator 38, which supplies energy to the restriction device 4. In response to a control signal from the wireless remote

control of the energy transmission means 10, the control unit 6 either releases electric energy from the accumulator 38 and transfers the released energy via power lines 42 and 44, or directly transfers electric energy from the energy transforming means 6 via a power line 46, the capacitor 40, which stabilizes the electric current, a power line 48 and the power line 44, for the operation of the restriction device 4.

In accordance with one alternative, the capacitor 40 in the embodiment of FIGURE 6 may be omitted. In accordance with another alternative, the accumulator 38 in this embodiment may be omitted.

FIGURE 7 shows an embodiment of the invention identical to that of FIGURE 1, except that a battery 50 for supplying energy for the operation of the restriction device 4 and an electric switch 52 for switching the operation of the restriction device 4 also are implanted in the patient. The switch 52 is operated by the energy supplied by the energy transforming means 6 to switch from an off mode, in which the battery 50 is not in use, to an on mode, in which the battery 50 supplies energy for the operation of the restriction device 4.

FIGURE 8 shows an embodiment of the invention identical to that of FIGURE 7, except that a control unit 36 controllable by the wireless remote control of the external energy transmission means 10 also is implanted in the patient. In this case, the switch 52 is operated by the energy supplied by the energy transforming means 6 to switch from an off mode, in which the wireless remote control is prevented from controlling the control unit 36 and the battery is not in use, to a standby mode, in which the remote control is permitted to control the control unit 36 to release electric energy from the battery 50 for the operation of the restriction device 4.

FIGURE 9 shows an embodiment of the invention identical to that of FIGURE 8, except that an accumulator 38 is substituted for the battery 50 and the implanted components are interconnected differently. In this case, the accumulator 38 stores energy from the energy transforming means 6. In response to a control signal from the wireless remote control of the external energy transmission means 10, the implanted control unit 36 controls the switch 52 to switch from an off mode, in which the accumulator 38 is not in use, to an on mode, in which the accumulator 38 supplies energy for the operation of the restriction device 4.

FIGURE 10 shows an embodiment of the invention identical to that of FIGURE 9, except that a battery 50 also is implanted in the patient and the implanted components are interconnected differently. In response to a control signal from the wireless remote control of the external energy transmission means 10, the implanted control unit 36 controls the accumulator 38 to deliver energy for operating the switch 52 to switch from an off mode, in which the battery 50 is not in use, to an on mode, in which the battery 50 supplies electric energy for the operation of the restriction device 4.

Alternatively, the switch 52 may be operated by energy supplied by the accumulator 38 to switch from an off mode, in which the wireless remote control is prevented from controlling the battery 50 to supply electric energy and is not in use, to a standby mode, in which the wireless remote control is permitted to control the battery 50 to supply electric energy for the operation of the restriction device 4.

FIGURE 11 shows an embodiment of the invention identical to that of FIGURE 7, except that a motor 15, a mechanical reversing device in the form of a gearbox 54 and a control unit 36 for controlling the gearbox 54 also are implanted in the patient.

The implanted control unit 36 controls the gearbox 54 to reverse the function performed by the restriction device 4 (mechanically operated).

FIGURE 12 shows an embodiment of the invention identical to that of FIGURE 10 except that the implanted components are interconnected differently. Thus, in this case the control unit 36 is powered by the battery 50 when the accumulator 38, suitably a capacitor, activates the switch 52 to switch to an on mode. When the switch 52 is in its on mode the control unit 36 is permitted to control the battery 50 to supply, or not supply, energy for the operation of the restriction device 4.

FIGURE 13 schematically shows conceivable combinations of implanted components of the apparatus for achieving various communication options. Basically, there are the implanted restriction device 4, control unit 36 and motor/pump unit 18, and the external energy transmission means 10 including the external wireless remote control. As already described above the wireless remote control transmits a control signal which is received by the implanted control unit 36, which in turn controls the various implanted components of the apparatus.

A sensor 56 may be implanted in the patient for sensing a physical parameter of the patient, such as the pressure in the fecal passageway. The implanted control unit 36, or alternatively the external wireless remote control of the energy transmission means 10, may control the restriction device 4 in response to signals from the sensor 56. A transceiver may be combined with the sensor 56 for sending information on the sensed physical parameter to the external wireless remote control. The wireless remote control may comprise a signal transmitter or transceiver and the implanted control unit 36 may comprise a signal receiver or transceiver. Alternatively, the wireless remote control may comprise a signal receiver or

transceiver and the implanted control unit 36 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 4 from inside the patient's body to the outside thereof.

Where the motor/pump unit 18 and battery 50 for powering the motor/pump unit 18 are implanted, the battery 50 may be equipped with a transceiver for sending information on the condition of the battery 50.

Those skilled in the art will realize that the above various embodiments according to FIGURES 1-13 could be combined in many different ways. For example, the energy operated switch 14 could be incorporated in any of the embodiments of FIGURES 3,6-12, the hydraulic shifting device 34 could be incorporated in the embodiment of FIGURE 4, and the gearbox 54 could be incorporated in the embodiment of FIGURE 3.

FIGURE 14 shows an energy transforming means in the form of an electrical junction element 58 for use in any of the above embodiments according to FIGURES 1-13. The element 58 is a flat p-n junction element comprising a p-type semiconductor layer 60 and an n-type semiconductor layer 62 sandwiched together. A light bulb 64 is electrically connected to opposite sides of the element 58 to illustrate how the generated current is obtained. The output of current from such a p-n junction element 58 is correlated to the temperature. See the formula below.

$$I = I_0 (\exp(qV/kT) - 1)$$

where

I is the external current flow,

I_0 is the reverse saturation current,

q is the fundamental electronic charge of 1.602×10^{-19} coulombs,

V is the applied voltage,

22

k is the Boltzmann constant, and

T is the absolute temperature.

Under large negative applied voltage (reverse bias), the exponential term becomes negligible compared to 1.0, and I is approximately $-I_0$. I_0 is strongly dependent on the temperature of the junction and hence on the intrinsic-carrier concentration. I_0 is larger for materials with smaller bandgaps than for those with larger bandgaps. The rectifier action of the diode -- that is, its restriction of current flow to only one direction -- is in this particular embodiment the key to the operation of the p-n junction element 58.

An alternative way to design a p-n junction element is to deposit a thin layer of semiconductor onto a supporting material which does not absorb the kind of energy utilized in the respective embodiments. For use with wirelessly transmitted energy in terms of light waves, glass could be a suitable material. Various materials may be used in the semiconductor layers such as but not limited to cadmium telluride, copper-indium-diselenide and silicon. It is also possible to use a multilayer structure with several layers of p and n-type materials to improve efficiency.

The electric energy generated by the p-n junction element 58 could be of the same type as generated by solar cells, in which the negative and positive fields create a direct current. Alternatively, the negative and positive semiconductor layers may change polarity following the transmitted waves, thereby generating an alternating current.

The p-n junction element 58 is designed to make it suited for implantation. Thus, all the external surfaces of the element 58 in contact with the human body are made of a biocompatible material. The p-n junction semiconductors are designed to operate optimally at a body temperature of 37°C because the

current output, which should be more than 1 μA , is significantly depending on temperature as shown above. Since both the skin and subcutis absorb energy, the relation between the sensitivity or working area of the element 58 and the intensity or strength of the wireless energy transmission is considered. The p-n junction element 58 preferably is designed flat and small. Alternatively, if the element 58 is made in larger sizes it should be flexible, in order to adapt to the patient's body movements. The volume of the element 58 should be kept less than 2000 cm^3 .

FIGURE 15 generally illustrates how any of the above-described embodiments of the anal incontinence treatment apparatus of the invention may be implanted in a patient. Thus, a restriction device 4 implanted in a patient engages the colon 66 to form an artificial sphincter around the fecal passageway in the colon. An implanted operation device 68, which may also be referred to as an adjustment device, such as an electric motor or a motor/pump assembly, operates the restriction device 4 through a transmission member 70, such as a mechanical transmission cord or a fluid tube. An energy transforming means in the form of an element 6 having a positive region and a negative region, as described above in more detail, is placed underneath the skin of the patient.

Wireless energy carried by a signal transmitted by a wireless remote control of an external energy transmission means at least partly penetrates the patient's skin and hits the element 6. The energy thus hitting the element 6 is transformed into energy of a different form that is suited for powering the operation device 68. For example, where the operation device 68 is an electric motor the element 6 comprises an electric p-n junction element that transforms the wireless energy into an electric current for powering the electric motor. Where the operation device 68 comprises a pump, the element 6 may

transform the wireless energy into kinetic energy for powering the pump.


The transformed energy may be utilized for directly operating the restriction device 4 or, where the restriction device 4 is electrically operated, for storage in a capacitor and/or an accumulator for later or parallel use. Preferably (but not necessarily) the element 6 is controlled by a microprocessor. The wireless remote control of the external energy transmission means 10 is used to control the utilization of the transmitted energy and any function or command to/from the implanted restriction device 4.

With reference to the use of the word(s) "comprise" or "comprises" or "comprising" in the foregoing description and/or in the following claims, unless the context requires otherwise, those words are used on the basis and clear understanding that they are to be interpreted inclusively, rather than exclusively, and that each of those words is to be so interpreted in construing the foregoing description and/or the following claims.



The claims defining the invention are as follows:

1. An anal incontinence treatment apparatus, comprising:
an energy transmission means for wireless transmission of energy of a first form from outside a patient's body;
an operable restriction device implantable in a patient for engaging the colon or rectum to form a restricted passageway in the colon or rectum, the device operable in response to energy of a second form different than the energy of the first form to vary the restricted passageway; and
an energy transforming means implantable in the patient for transforming energy of the first form wirelessly transmitted by the energy transmission means into energy of the second form, which is used for the operation of the restriction device,
wherein the energy transforming means comprises at least one element having a positive region and a negative region, and adapted to create an energy field between the positive and negative regions when exposed to the energy of the first form transmitted by the energy transmission means, so that the energy field produces the energy of the second form.



2. An apparatus according to claim 1, wherein the element comprises an electrical junction element, and the electrical junction element is capable of inducing an electric field between the positive and negative regions when exposed to the energy of the first form transmitted by the energy transmission means, whereby the energy of the second form comprises electric energy.

3. An apparatus according to claim 2, wherein the restriction device is electrically operated, and the positive and negative regions of the electrical junction element supply electric energy for the operation of the restriction device.

4. An apparatus according to claim 3, further comprising electric conductors connected to the positive and negative regions of the electrical junction element, whereby the electrical junction element is capable of supplying an electric current via the conductors.

5. An apparatus according to claim 4, wherein the electrical junction element is capable of supplying a direct current or pulsating direct current via the conductors.

6. An apparatus according to claim 4, wherein the electrical junction element is capable of supplying an alternating current or a combination of a direct and alternating current via the conductors.

7. An apparatus according to claim 3, wherein the electrical junction element is capable of supplying a frequency or amplitude modulated signal.

8. An apparatus according to claim 3, wherein the electrical junction element is capable of supplying an analog or digital signal.

9. An apparatus according to claim 1, further comprising an implantable operation device for operating the restriction device, wherein the element powers the operation device with the energy of the second form.

10. An apparatus according to claim 9, wherein the operation device comprises a motor.

11. An apparatus according to claim 10, further comprising a control device, wherein the motor comprises a rotary motor, and the control device controls the rotary motor to rotate a desired number of revolutions.

12. An apparatus according to claim 10, wherein the motor comprises a linear motor.

13. An apparatus according to claim 10, further comprising a control device, wherein the motor comprises a hydraulic or pneumatic fluid motor, and the control device controls the fluid motor.

14. An apparatus according to claim 10, wherein the motor comprises an electric motor having electrically conductive parts made of plastics.

15. An apparatus according to claim 9, wherein the restriction device comprises hydraulic means and the operation device comprises a pump for pumping a fluid in the hydraulic means.

16. An apparatus according to claim 15, wherein the operation device comprises a motor for driving the pump.

17. An apparatus according to claim 15, wherein the operation device comprises a fluid conduit between the pump and the hydraulic means of the restriction device, and a reservoir for fluid, the reservoir forming part of the conduit.

18. An apparatus according to claim 17, wherein the hydraulic means, pump and conduit are devoid of any non-return valve.

19. An apparatus according to claim 18, wherein the reservoir forms a fluid chamber with a variable volume, and the pump is adapted to distribute fluid from the chamber to the hydraulic means of the restriction 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.

20. An apparatus according to claim 9, further comprising a control device for controlling the operation device.

21. An apparatus according to claim 20, wherein the control device is adapted to shift polarity of the energy of the second form to reverse the operation device.

22. An apparatus according to claim 21, wherein the operation device comprises an electric motor and the energy of the second form comprises electric energy.

23. An apparatus according to claim 20, wherein the restriction device is operable to perform a reversible function.

24. An apparatus according to claim 23, further comprising a reversing device implantable in the patient for reversing the function performed by the restriction device.

25. An apparatus according to claim 24, wherein the control device controls the reversing device to reverse the function performed by the restriction device.

26. An apparatus according to claim 24, wherein the reversing device comprises hydraulic means including a valve for shifting the flow direction of a fluid flow in the hydraulic means.

27. An apparatus according to claim 24, wherein the reversing device comprises a mechanical reversing device.

28. An apparatus according to claim 27, wherein the reversing device comprises a gearbox.

29. An apparatus according to claim 24, wherein the reversing device comprises a switch.

30. An apparatus according to claim 29, wherein the switch is operable by the energy of the second form.

31. An apparatus according to claim 30, wherein the control device controls the operation of the switch by shifting polarity of the energy of the second form.

32. An apparatus according to claim 30, wherein the switch comprises an electric switch and the energy of the second form comprises electric energy.

33. An apparatus according to claim 1, wherein the element forms a flat and thin sheet, and has a volume of less than 2000 cm³.

34. An apparatus according to claim 2, wherein the electrical junction element comprises at least one semiconductor.

35. An apparatus according to claim 2, wherein the electrical junction element generates an output current exceeding 1 μ A when exposed to the energy of the first form transmitted by the energy transmission means.

36. An apparatus according to claim 1, further comprising an energy storage device implantable in the patient for storing the energy of the second form and for supplying energy in connection with the operation of the restriction device.

37. An apparatus according to claim 36, wherein the energy storage device comprises an accumulator.

38. An apparatus according to claim 37, wherein the energy of the second form comprises electric energy and the energy storage device comprises an electric accumulator.

39. An apparatus according to claim 38, 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.

40. An apparatus according to claim 36, further comprising a switch implantable in the patient for directly or indirectly switching the operation of the restriction device.

41. An apparatus according to claim 40, further comprising a source of energy implantable in the patient, wherein the switch is operated by the energy of the second form supplied by the energy storage device to switch from an off mode, in which the source of energy is not in use, to an on mode, in which the source of energy supplies energy for the operation of the restriction device.

42. An apparatus according to claim 40, further comprising a source of energy implantable in the patient, and a remote control for controlling the supply of energy of the source of energy, wherein the switch is operated by the energy of the second form supplied by the energy storage device to switch from an off mode, in which the remote control is prevented from controlling the source of energy and the source of energy is not in use, to a standby mode, in which the remote control is

permitted to control the source of energy to supply energy for the operation of the restriction device.

43. An apparatus according to claim 1, further comprising a switch implantable in the patient for switching the operation of the restriction device.

44. An apparatus according to claim 43, further comprising a source of energy implantable in the patient for supplying energy for the operation of the restriction device, wherein the switch is operated by the energy of the second form supplied by the energy transforming means to switch from an off mode, in which the source of energy is not in use, to an on mode, in which the source of energy supplies energy for the operation of the restriction device.

45. An apparatus according to claim 43, further comprising a source of energy implantable in the patient for supplying energy for the operation of the restriction device, and a remote control for controlling the supply of energy of the source of energy, wherein the switch is operated by the energy of the second form supplied by the energy transforming means to switch from an off mode, in which the remote control is prevented from controlling the source of energy and the source of energy is not in use, to a standby mode, in which the remote control is permitted to control the source of energy to supply energy for the operation of the restriction device.

46. An apparatus according to claim 1, wherein the energy transmission means transmits the energy of the first form by at least one wireless signal.

47. An apparatus according to claim 46, wherein the signal comprises a wave signal.

48. An apparatus according to claim 46, wherein the signal contains radiant energy.

49. An apparatus according to claim 47, wherein the wave signal comprises an electromagnetic wave signal including one of 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, and a gamma radiation signal.

50. An apparatus according to claim 47, wherein the wave signal comprises a sound wave signal.

51. An apparatus according to claim 46, wherein the signal comprises a digital or analog signal, or a combination of a digital and analog signal.

52. An apparatus according to claim 1, wherein the energy of the first form transmitted by the energy transmission means comprises an electric field.

53. An apparatus according to claim 52, wherein the electric field is transmitted in pulses or digital pulses by the energy transmission means.

54. An apparatus according to claim 1, wherein the energy of the first form transmitted by the energy transmission means comprises a magnetic field.

55. An apparatus according to claim 54, wherein the magnetic field is transmitted in pulses or digital pulses by the energy transmission means.

56. An apparatus according to claim 1, wherein the energy of the first form comprises polarized energy.

57. An apparatus according to claim 1, wherein the energy transforming means transforms the energy of the first form into a direct current or pulsating direct current, or a combination of a direct current and a pulsating direct current.

58. An apparatus according to claim 1, wherein the energy transforming means transforms the energy of the first form into an alternating current or a combination of a direct and alternating current.

59. An apparatus according to claim 1, wherein the energy of the second form comprises a frequency or amplitude modulated signal, or a combination of a frequency and amplitude modulated signal.

60. An apparatus according to claim 1, wherein the energy of the second form comprises an analog or a digital signal, or a combination of an analog and digital signal.

61. An apparatus according to claim 1, further comprising an implantable pulse generator for generating electrical pulses from the energy of the second form produced by the energy field.

62. An apparatus according to claim 1, further comprising at least one implantable sensor for sensing at least one physical parameter of the patient.

63. An apparatus according to claim 62, wherein the sensor comprises a pressure sensor for directly or indirectly sensing the pressure in the fecal passageway.

64. An apparatus according to claim 62, further comprising a control device for controlling the restriction device in response to signals from the sensor.

65. An apparatus according to claim 64, wherein the control device comprises an internal control unit implantable in the patient for controlling the restriction device in response to signals from the sensor.

66. An apparatus according to claim 64, wherein the internal control unit directly controls the restriction device in response to signals from the sensor.

67. An apparatus according to claim 64, wherein the control device comprises an external control unit outside the patient's body for controlling the restriction device in response to signals from the sensor.

68. An apparatus according to claim 67, wherein the external control unit stores information on the physical parameter sensed by the sensor and is manually operated to control the restriction device based on the stored information.

69. An apparatus according to claim 62, further comprising at least one implantable sender for sending information on the physical parameter sensed by the sensor.

70. An apparatus according to claim 9, wherein the operation device comprises hydraulic means and at least one valve for controlling a fluid flow in the hydraulic means.

71. An apparatus according to claim 70, further comprising a wireless remote control for controlling the valve.

72. An apparatus according to claim 1, further comprising a wireless remote control transmitting at least one wireless control signal for controlling the restriction device.

73. An apparatus according to claim 72, wherein the remote control is capable of obtaining information on the condition of the restriction device and to control the restriction device in response to the information.

74. An apparatus according to claim 72, wherein the remote control comprises an implantable control unit for controlling the restriction device.

75. An apparatus according to claim 74, wherein the control unit comprises a microprocessor.

76. An apparatus according to claim 72, 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.

77. An apparatus according to claim 72, 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.

78. An apparatus according to claim 72, wherein the remote control is capable of sending information related to the restriction device from inside the patient's body to the outside thereof.

79. An apparatus according to claim 78, wherein the remote control controls the restriction device in response to the information.

80. An apparatus according to claim 72, wherein the remote control comprises a control signal transmitter for transmitting the control signal, and the energy transmission means comprises the control signal transmitter, whereby the energy of the first form is transmitted by the control signal.

81. An apparatus according to claim 72, wherein the energy transmission means transmits the energy of the first form by at least one signal separate from the control signal.

82. An apparatus according to claim 72, wherein the remote control transmits a carrier signal for carrying the control signal.

83. An apparatus according to claim 72, wherein the energy transmission means transmits the energy of the first form by at least one signal, which is used as a carrier signal for the control signal transmitted by the remote control.

84. An apparatus according to claim 83, wherein the carrier signal is frequency or amplitude modulated, or frequency and amplitude modulated.

85. An apparatus according to claim 83, wherein the carrier signal comprises digital or analog waves, or a combination of digital and analog waves.

86. An apparatus according to claim 83, wherein the control signal used with the carrier signal is frequency or amplitude modulated, or frequency and amplitude modulated.

87. An apparatus according to claim 83, wherein the control signal used with the carrier signal is digital or analog, or digital and analog.

88. An apparatus according to claim 72, 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.

89. An apparatus according to claim 72, wherein the control signal comprises an electric or magnetic field, or an electric and magnetic field.

90. An apparatus according to claim 72, wherein the control signal comprises a digital or analog control signal, or a digital and analog control signal.

91. An apparatus according to claim 90, wherein the remote control transmits an electromagnetic carrier wave signal for carrying the digital or analog control signal.

92. An apparatus according to claim 1, wherein the energy of the second form used for operating the restriction device is wirelessly transmitted by the energy transforming means.

93. An apparatus according to claim 1, further comprising an implantable control unit for controlling the restriction device.

94. An apparatus according to claim 93, wherein the control unit is programmable for controlling the restriction device in accordance with a program.

95. An apparatus according to claim 94, wherein the control unit controls the restriction device over time in accordance with an activity schedule program

96. An apparatus according to claim 94, further comprising an external wireless remote control for programming the implantable control unit.

97. An apparatus according to claim 1, further comprising an external data communicator and an implantable internal data communicator communicating with the external data communicator, wherein the internal data communicator feeds data related to the restriction device back to the external data communicator or the external data communicator feeds data to the internal data communicator.

98. An apparatus according to claim 97, wherein the internal data communicator feeds data related to at least one physical signal of the patient.

99. An apparatus according to claim 1, wherein the restriction device controls the cross-sectional area of the restricted fecal passageway.

100. An apparatus according to claim 1, wherein the restriction device is non-inflatable.

101. An apparatus according to claim 1, wherein the restriction device is directly operated with the energy of the

second form, as the energy transmission means transmits the energy of the first form.

102. An apparatus according to claim 101, wherein the restriction device is directly operated with the energy of the second form in a non-magnetic manner.

103. An apparatus according to claim 101, wherein the restriction device is directly operated with the energy of the second form without externally touching subcutaneously implantable components of the apparatus.

104. An apparatus according to claim 1, wherein the energy of the first form comprises kinetic energy.

105. An apparatus according to claim 1, wherein the energy transforming means is implantable subcutaneously or in the abdomen of the patient.

106. An apparatus according to claim 1, wherein the energy transforming means is implantable in the retroperitoneal space, abdomen, scrotum or labia majora, or implantable subcutaneously.

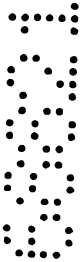
107. An apparatus according to claim 1, wherein the energy transforming means is implantable in an orifice of the patient's body and under the mucosa or intraluminal outside the mucosa of the orifice.

108. An apparatus according to claim 1, wherein the element of the energy transforming means comprises at least one semiconductor circuitry.

109. An apparatus according to claim 1, wherein the element of the energy transforming means comprises at least one transistor circuitry.

110. An apparatus according to claim 1, wherein the element of the energy transforming means comprises at least one microchip.

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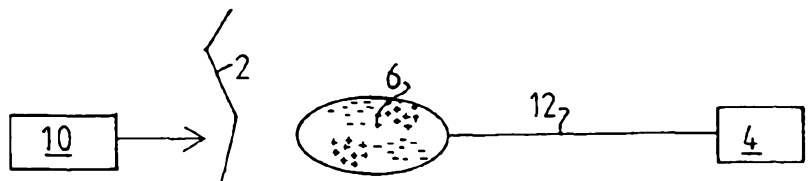


FIG. 1

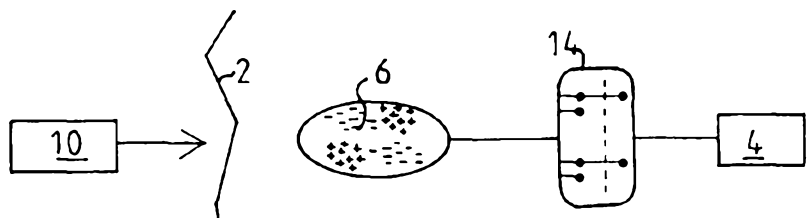


FIG. 2

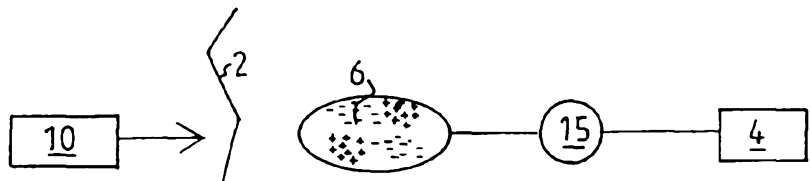


FIG. 3

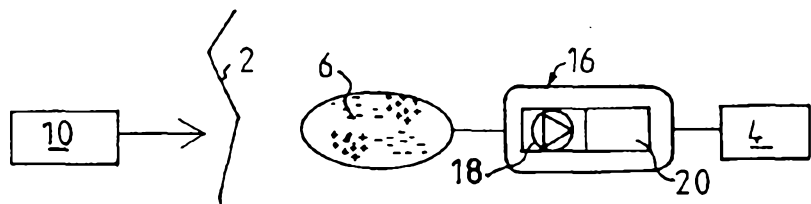


FIG. 4

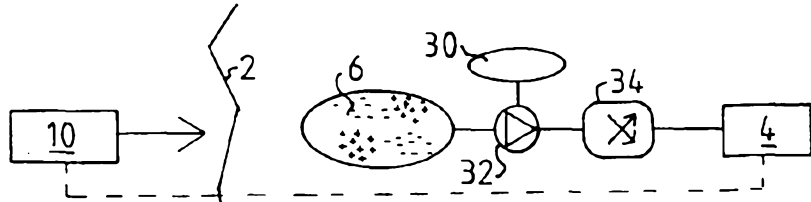


FIG. 5

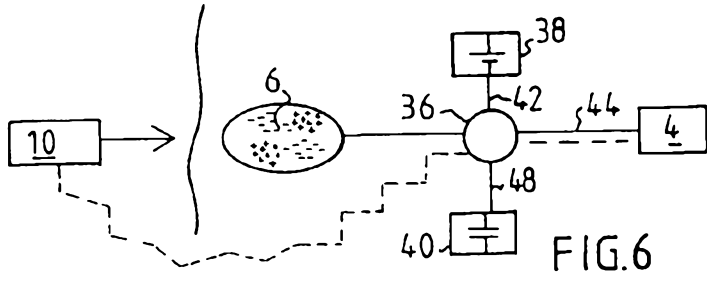


FIG. 6

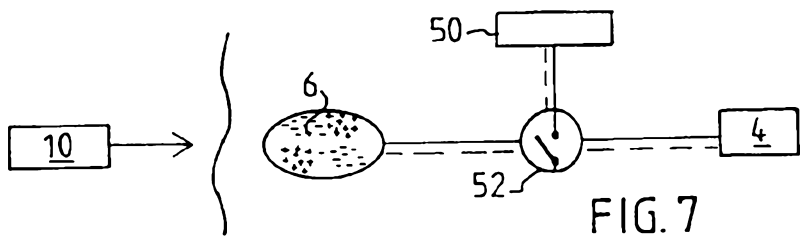


FIG. 7

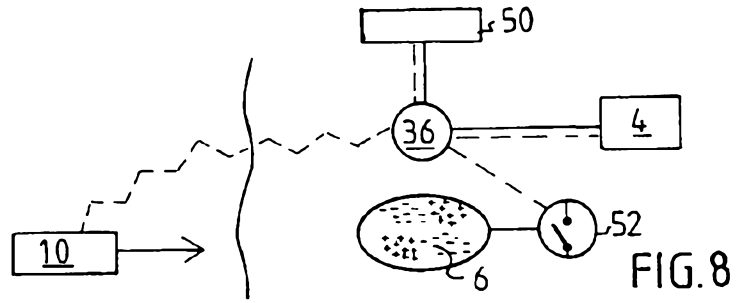


FIG. 8

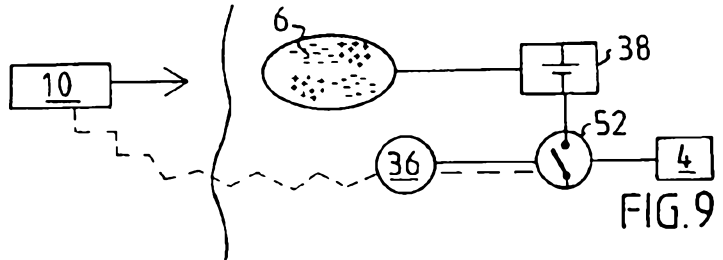


FIG. 9

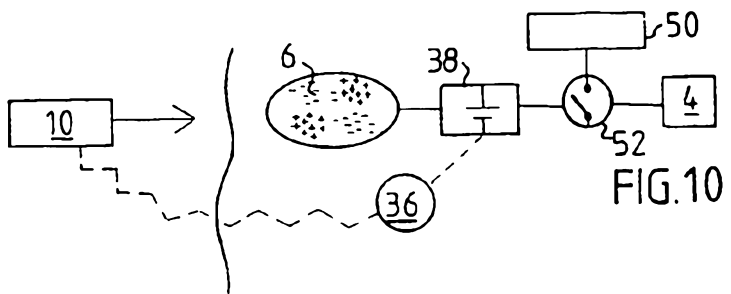
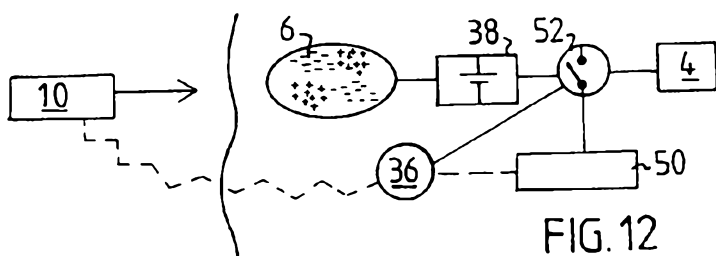
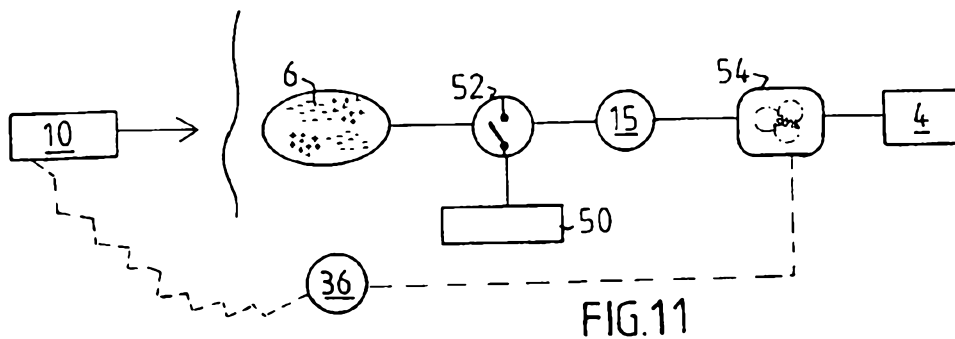
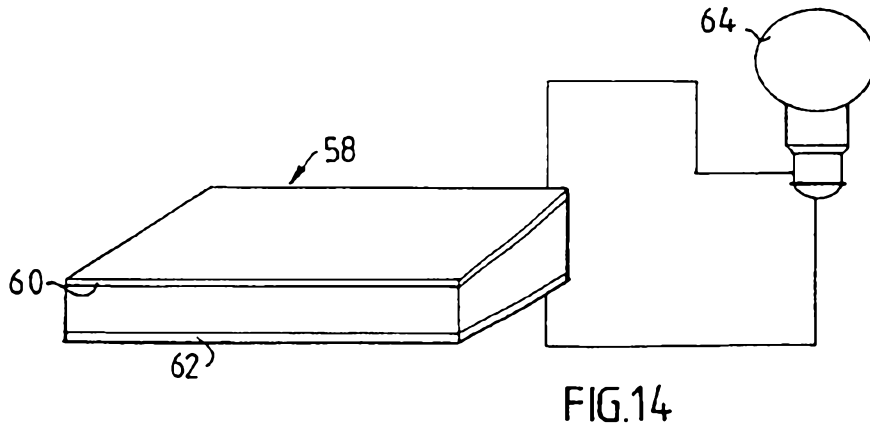
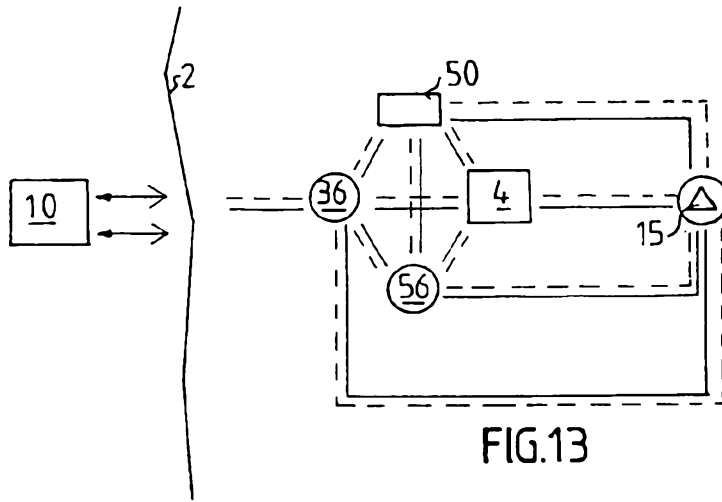


FIG. 10



4/5



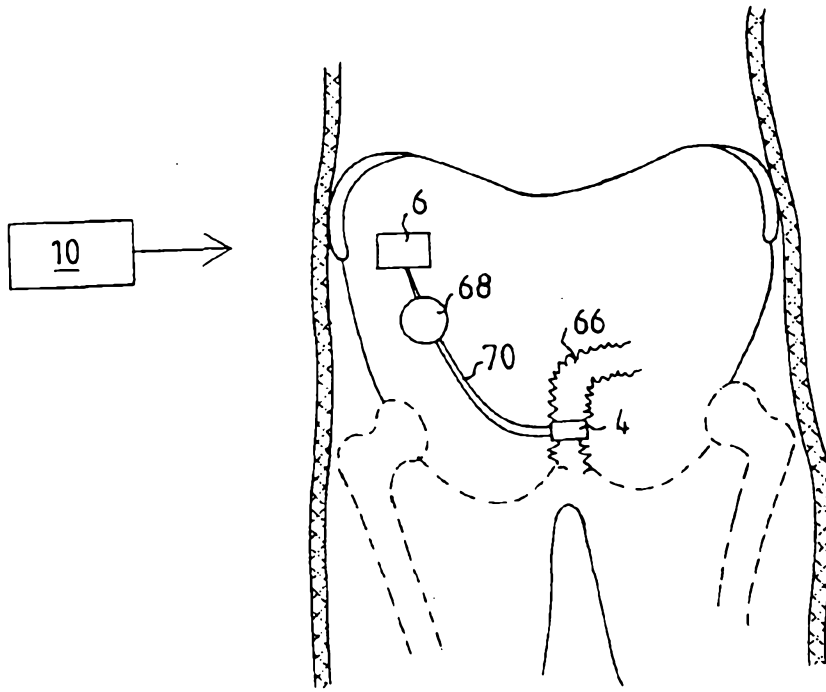


FIG. 15